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# The International Journal of ORAL & MAXILLOFACIAL IMPLANTS

# PROCEEDINGS OF THE FIFTH ITI CONSENSUS CONFERENCE

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# <u>Proceedings of the</u> <u>Fifth ITI Consensus</u> <u>Conference</u>

April 23–25, 2013 • Bern, Switzerland

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International Team for Implantology



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## INTRODUCTION

Once every 5 years, the International Team for Implantology (ITI) organizes a consensus conference to review the dental literature on a topical area in Implantology. In 2013, the Fifth ITI Consensus Conference was held in Bern, Switzerland, April 23–25. In the preceding year, the organizing committee identified five main topics for review. The working group leaders for each principal topic, as well as the authors commissioned to prepare review papers, met in Zürich in May 2012 for a workshop conducted by Prof Ian Needleman, Unit of Periodontology and International Centre for Evidence-Based Healthcare, UCL Eastman Dental Institute, London. The aim of this workshop was to streamline and standardize the process of undertaking systematic reviews of the literature based on comprehensive search strategies.

The following is a summary of the materials and methods employed by the authors in preparing the systematic reviews. Details of the search strategies are tabulated within each review paper.

**Focus question.** Framing of the research question was undertaken using the PICO strategy.<sup>1,2</sup> Based on the four PICO elements (Population, Intervention, Comparison, and Outcome), the focus question was constructed by the authors and subsequently accepted and confirmed by the authors within each working group.

**Search strategy.** A systematic and comprehensive search of the literature was conducted. Electronic databases were searched using key terms. Relevant journals were hand searched to identify additional articles. Additionally, the bibliographies of selected papers and published review articles on the topic were also scanned for relevant publications. The details of the key words used for electronic searches are provided in each paper.

**Selection criteria.** All levels of evidence except for expert opinion were considered in order to provide a comprehensive search of the literature. Screening of the records was performed independently by the authors of each review paper. Any disagreement between the reviewers was resolved by discussion.

**Quality assessment.** A quality assessment of each included publication was undertaken. For randomized controlled trials and controlled clinical trials, the Cochrane Collaboration's tool for assessing risk of bias was utilized.<sup>3</sup> Nonrandomized controlled studies were assessed for quality using the Newcastle-Ottawa Quality Assessment Scale for Observational Studies.<sup>4</sup>

**Results and conclusions.** From the included studies, the relevant data were extracted and tabulated. Metaanalyses were performed when relevant. The results were then presented and conclusions drawn.

**Peer review.** Prior to the consensus conference, the manuscripts were submitted to *The International Journal* of Oral and Maxillofacial Implants for peer review. Cor-

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rections, amendments, and revisions were then completed. Once accepted for publication by the editor of the journal, the review papers provided the basis for the formulation of consensus statements and treatment recommendations within each working group.

The five topics and groups leaders were as follows:

#### Group 1: Contemporary Surgical and Radiographic Techniques in Implant Dentistry Group Leader: Michael M. Bornstein

Group Leader: Michael M. Bornstein

Group 2: Restorative Materials and Techniques for Implant Dentistry Group Leader: Daniel Wismeijer

Group 3: Optimizing Esthetic Outcomes in Implant Dentistry

Group Leader: Dean Morton

**Group 4: Implant Loading Protocols** Group Leader: German O. Gallucci

**Group 5: Prevention and Management of Biologic and Technical Implant Complications** Group Leader: Lisa J. A. Heitz-Mayfield

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### Stephen Chen

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## **GROUP** 1

### Contemporary Surgical and Radiographic Techniques in Implant Dentistry

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#### **Review Papers Submitted for Discussion:**

Horizontal Ridge Augmentation in Conjunction with or Prior to Implant Placement in the Anterior Maxilla: A Systematic Review Ulrike Kuchler/Thomas von Arx

**Computer Technology Applications in Surgical Implant Dentistry: A Systematic Review** Ali Tahmaseb/Daniel Wismeijer/Wim Coucke/Wiebe Derksen

**Systematic Review on Success of Narrow-Diameter Dental Implants** Marc O. Klein/Eik Schiegnitz/Bilal Al-Nawas

#### Cone Beam Computed Tomography in Implant Dentistry: A Systematic Review Focusing on Guidelines, Indications, and Radiation Dose Risks

Michael M. Bornstein/William C. Scarfe/Vida M. Vaughn/Reinhilde Jacobs

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## Horizontal Ridge Augmentation in Conjunction with or Prior to Implant Placement in the Anterior Maxilla: A Systematic Review

Ulrike Kuchler, MD, DMD<sup>1</sup>/Thomas von Arx, DMD<sup>1</sup>

Purpose: To systematically review clinical studies examining the survival and success rates of implants in horizontal ridge augmentation, either prior to or in conjunction with implant placement in the anterior maxilla. Materials and Methods: A literature search was undertaken up to September 2012 including clinical studies in English with  $\geq$  10 consecutively treated patients and a mean follow-up of at least 12 months. Two reviewers screened the pertinent articles and extracted the data. Key words focused on the outcome parameters (implant success, implant survival, horizontal bone gain, and intra- and postoperative complications) in studies utilizing either a simultaneous approach (ridge augmentation performed at the time of implant placement) or a staged approach (ridge augmentation performed prior to implant placement) were analyzed. Results: A total of 13 studies met the inclusion criteria, with 2 studies in the simultaneous group and 11 studies in the staged group. In the simultaneous group, survival rates of implants were 100% in both studies, with one study also reporting a 100% implant success rate. No data on horizontal bone gain were available. In the staged group, success rates of implants placed in horizontally augmented ridges ranged from 96.8% to 100% (two studies), and survival rates ranged from 93.5% to 100% (five studies). However, follow-up periods differed widely (up to 4.1 years). Mean horizontal bone gain determined at reentry (implant placement) ranged from 3.4 to 5.0 mm with large overall variations (0 to 9.8 mm, five studies). Intraoperative complications were not reported. Postsurgical complications included mainly mucosal dehiscences (five studies), and, occasionally, complete failures of block grafts were described in one study. Conclusions: Staged and simultaneous augmentation procedures in the anterior maxilla are both associated with high implant success and survival rates. The level of evidence, however, is better for the staged approach than for the simultaneous one. INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):14-24. doi: 10.11607/ jomi.2014suppl.g1.1

**Key words:** anterior maxilla, bone gain, esthetic zone, horizontal ridge augmentation, implant success, implant survival, surgical complications

mplant therapy has become an integral part of clinical dentistry, with ever-increasing numbers of patients seeking such treatment. In conjunction with this development, patient awareness, particularly regarding time and esthetics has risen. Many patients have expectations of a short treatment time and perfect results, posing a significant challenge to the clinician and dental technician alike.

Whether a low or high smile line is present, many patients consider their maxillary anterior teeth to be one of their most important esthetic facial features.<sup>1,2</sup> In addition, many patients present with tissue deficiencies in the anterior maxilla, either following traumatic tooth loss or periodontal or endodontic disease. Malformation and tumors are less frequently the cause of tissue loss in the anterior maxilla. Tissue deficiencies may include deficits of soft tissue (alveolar mucosa) and/or hard tissue (alveolar bone). Bone deficiencies of the alveolar process may be categorized as vertical or horizontal deficits, or combinations thereof. Hard and/or soft tissue defects may lead to functional, structural, or esthetic compromises in the final prosthesis.<sup>3</sup> Various classifications of bone resorption or alveolar ridge configurations have been proposed in relation to treatment planning in dental and maxillofacial implantology.<sup>3–6</sup>

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A plethora of surgical techniques have been described in the last four decades regarding reconstruction of deficient alveolar bone for supporting dental implants, eg, particulate graft augmentation, block graft augmentation, ridge splitting or ridge expansion, and distraction osteogenesis.<sup>7</sup> Materials used for the reconstruction of alveolar bone include autogenous bone, allogeneic bone, xenografts, alloplasts, bone promoting proteins, barrier membranes, titanium meshes and foils, fixation screws, pins and plates, and bone transportation devices.<sup>7</sup>

Alveolar ridge rebuilding can be undertaken at different time points during treatment, and is generally categorized as simultaneous or staged. In the staged approach, the alveolar bone is first reconstructed in an initial surgery, and implant placement is then carried out 2 to 6 months later.<sup>8</sup> In contrast, in the simultaneous approach, implant placement and alveolar ridge reestablishment are undertaken in the same surgery.<sup>9</sup> The simultaneous approach is obviously the preferred technique by the patient and clinician alike, since it reduces treatment time and cost. However, if the residual bone volume precludes primary implant stability, or results in inadequate prosthodontic implant positioning, the staged approach is recommended. In the anterior maxilla (esthetic zone), a third component must be considered in the treatment decision process: the esthetic expectations of the patient and his/her esthetic profile (level of smile line, gingival biotype, soft tissue deficit, size of edentulous gap, and bone level at adiacent teeth).

Treatment planning and precise scheduling of tooth extraction and implant placement are important issues to reduce healing periods, morbidity of the patient, and to create the fewest number of surgical interventions. The risk of inadvertent bone loss is particularly high in the anterior maxilla which is commonly known to exhibit a thin (or even partially absent) labial bone plate.<sup>10</sup> Since this bone plate mainly consists of the socalled bundle bone, associated with the presence of a non-ankylotic tooth together with a viable periodontal ligament, removal of the root or post-traumatic root ankylosis will disturb this functional unit, resulting in considerable resorption of the labial bone plate. As a consequence, many cases referred for implant treatment in the anterior maxilla present with horizontal bone deficiencies that requires horizontal bone augmentation.

While previous systematic reviews of clinical studies on alveolar ridge reconstruction have pooled data from different jaw locations (maxilla, mandible, anterior sites, posterior sites)<sup>11–17</sup> the present systematic review will focus on the anterior maxilla, ie, the esthetic zone. The review aims to report success and survival rates of implants placed in conjunction with simultaneous or staged horizontal bone augmentation in patients with single or multiple gaps in the anterior maxilla. In addition, data about gain of horizontal bone width and intra- and postsurgical complications are collected and presented.

#### MATERIALS AND METHODS

Inclusion and exclusion criteria were defined before beginning the study by the authors. Criteria included study type, number of treated patients, type and area of intervention, outcome parameters and follow-up period.

#### Study Type

Only clinical studies in humans and published in English were accepted for this systematic review. Experimental studies, case reports, review articles, technical notes, and expert opinion articles were excluded. The clinical study had to be performed in a minimum of 10 patients, irrespective of the number of treated patients for a given therapeutic option.

#### Type and Area of Intervention

Horizontal bone augmentation had to be carried out in the anterior maxilla (esthetic zone), defined as the area from the right first premolar to the left first premolar. Studies reporting vertical ridge augmentation, distraction osteogenesis, ridge expansion or splitting techniques, and alveolar socket preservation were excluded for this review. Clinical studies on horizontal bone augmentation in patients with congenital malformations, after tumor resection, or following osteoradionecrosis were also excluded, since treatment and outcome in these cases are not comparable.

#### **Outcome Parameters and Follow-Up Period**

Studies were included provided they reported data about implant success (with specified success criteria) and/or survival rates of implants that were inserted either in conjunction with horizontal bone augmentation (simultaneous approach) or after horizontal bone augmentation (staged approach), and that the implants had been loaded for a minimum period of one year. Additionally, studies describing the horizontal bone gain at reentry time or reporting intra- and postoperative complications were also included, irrespective of the follow-up period or loading period of implants (Table 1).

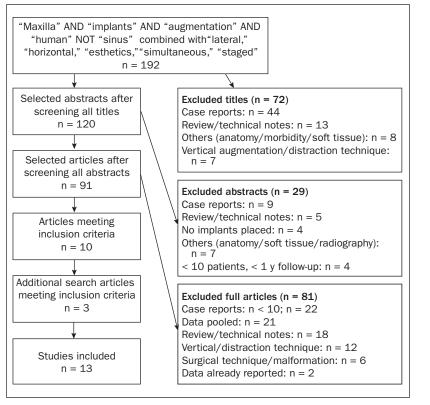
#### Search Strategy

PubMed using Endnote X4 served as the source for searching studies up to September 2012. Articles were selected using the following search terms: "maxilla"

#### Table 1 Systematic Search Strategy

Focus question: Does horizontal ridge augmentation in conjunction with or prior to implant placement in the anterior maxilla influence the implant outcome?

Search strategy	
Population	Patients presenting with single/multiple gaps in the anterior maxilla with deficiency of ridge width
Intervention or exposure	Horizontal ridge augmentation in the anterior maxilla
Comparison	Simultaneous versus staged approach
Outcome	<ol> <li>Success (parameters) ≥ 1 year</li> <li>Survival ≥ 1 year</li> <li>Complications: intraoperative/postoperative (up to abutment connection)/late complications</li> <li>Gain of bone width</li> </ol>
Search combination	"maxilla" AND "implants" AND "augmentation" AND "human" NOT "sinus". This search was com- bined with: "lateral", "horizontal", "esthetics", "simultaneous," and "staged"
Database search	
Electronic	PubMed (English)
Selection criteria	
Inclusion criteria	Horizontal ridge augmentation and implant placement Clinical studies Anterior maxilla (first premolar–first premolar)
Exclusion criteria	Animal studies Case reports Reviews Patients with congenital malformations Studies < 10 patients < 1 year of follow-up (success and survival) Pooled data (extraction of detailed information is impossible)



AND "implants" AND "augmentation" AND "human" NOT "sinus". This search was combined with the following search terms: "lateral", "horizontal", "esthetics", "simultaneous," and "staged". Duplicates were removed from the search. The authors UK and TvA individually screened the titles of articles based on the inclusion criteria. Following this, the remaining abstracts were selected and disagreement was solved by discussion. If title or abstract did not allow a clear decision about the inclusion criteria, the full article was obtained. In addition, related articles in PubMed and in the private library of TvA were screened and led to another three publications which met the inclusion criteria. Based on the pre-selection, the full text articles were then analyzed as to whether they met the inclusion criteria and mutual agreement on the final selection of studies was obtained (Fig 1).

**Fig 1** Search strategy.

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#### **Data Extraction**

The two reviewers independently extracted the data of the publications included. In studies reporting pooled data of various jaw areas but providing detailed information for sites in the anterior maxilla, data were extracted and recalculated for those sites.

The following information was collected from the publications:

- Number of treated patients
- Material/technique used for horizontal ridge augmentation
- Width of alveolar bone before and after augmentation
- Intra- and postoperative complications
- Interval between augmentation and reentry
- Width of alveolar bone at reentry
- · Number of inserted implants
- Follow-up period of loaded implants
- Success rate of loaded implants (with success criteria) in the augmented ridge
- Survival rate of loaded implants in the augmented ridge

#### RESULTS

The literature search yielded a total of 192 publications within the specified search terms. Seventy-two studies were excluded after screening the titles, and 29 did not meet the inclusion criteria after reading the abstracts. Overall, 91 full articles were analyzed but only 10 articles fulfilled the inclusion criteria for data extraction (Fig 1). Based on an additional search, three articles were included in this review. The results are presented separately for the simultaneous and the staged approaches (Tables 2 and 3).

#### Simultaneous Approach

Two prospective cohort studies<sup>18,19</sup> met the inclusion criteria for this review, reporting on a total of 35 patients, investigating implant placement in conjunction with simultaneous horizontal ridge augmentation in the anterior maxilla (Table 2). In one study, periimplant horizontal ridge augmentation was performed with locally harvested bone chips, deproteinized bovine bone mineral (DBBM) particles, and collagen membrane coverage.<sup>18</sup> In the other study, DBBM particles and a titanium-reinforced expanded polytetrafluoroethylene (ePTFE) membrane with non-resorbable pins were utilized for the same purpose.<sup>19</sup> Buser et al<sup>18</sup> reported an implant success rate of 100% (follow-up period three years), and both studies described a survival rate of 100% for the follow-up period (Table 2). No data were reported on horizontal bone gain in these two studies. Neither intraoperative nor postoperative complications occurred in one study,<sup>19</sup> whereas the other study provided no information about complications (Table 2, Fig 2a).<sup>18</sup>

#### **Staged Approach**

A total of 11 studies (3 cohort prospectives,<sup>20–22</sup> 6 cohort retrospectives,<sup>23–28</sup> 1 prospective comparative,<sup>29</sup> and 1 randomized clinical trial<sup>30</sup>) were identified, with a total of 353 patients in whom horizontal bone augmentation was performed prior to implant placement. Various augmentation techniques were reported including the use of autogenous, allogeneic, or xenogenic bone with or without membrane coverage (Table 3, Fig 2b). The majority of studies utilized autogenous bone blocks from either the symphysis or retromolar area.

With regard to success rates of implants placed into horizontally augmented ridges in the anterior maxilla, two studies with a total of 91 implants reported a success rate of 100% in one study with a mean followup period of 1 and 4.1 years<sup>25,26</sup> and a success rate of 96.8% in the other study with a mean follow-up of 37 months.<sup>23</sup> The latter study described marginal bone loss in 3 out of 31 implants in the first year (Table 3).

Five studies reported the survival rates of implants placed into horizontally augmented ridges in the anterior maxilla.<sup>23,25,26,28,29</sup> Three studies reported a survival rate of 100%.<sup>23,25,26</sup> In the comparative study by Meijndert et al,<sup>29</sup> survival rates differed for the three treatment options: While implants placed into sites augmented with chin bone presented a survival rate of 100%, implants placed into sites augmented with DBBM had a survival rate of 93.5% within a follow-up period of 1 year. In the study by Nissan et al (2012),<sup>28</sup> the survival rate was 96.8% after a mean follow-up period of 4 years (Table 3).

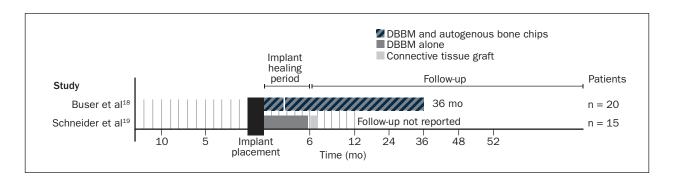
Five studies reported on horizontal bone gain assessed at the time of reentry (implant placement).<sup>20-22,27,30</sup> Mean intervals between augmentation and reentry ranged from 5 to 13 months (Fig 2). The actual horizontal bone gain varied between 0 and 9.8 mm in those five studies with mean values of 3.4 mm, 3.6 mm, 4.5 mm, 4.6 mm/2.15 mm (study comparing allogeneic bone blocks with and without autogenous bone marrow aspirate), and 5 mm, respectively. Two additional studies evaluated graft resorption between augmentation and reentry with intervals ranging from 3 to 8 months.<sup>23,24</sup> One study reported a mean loss of 6% (range 0% to 20%), with greater resorption observed in grafts from the tuberosity.<sup>23</sup> In the other study,<sup>24</sup> mean graft resorption was 0.79 mm (range 0 to 2 mm). Cases with 3 to 4 months of graft healing presented less resorption (0.33 mm) than cases with 5 to 8 months of graft healing (1.22 mm).<sup>24</sup>

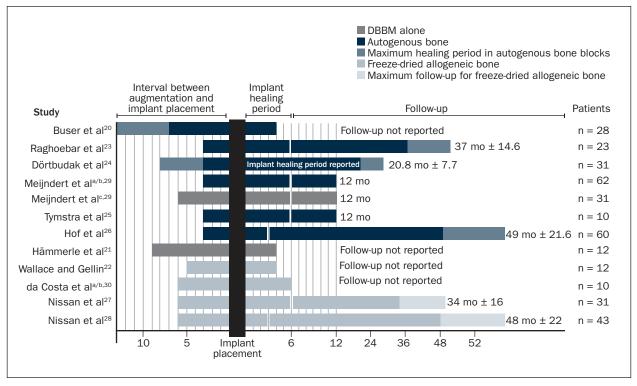
#### Table 2 Results of Studies Using Simultaneous Approach

Author	Study type	Patients	Techniques	Implant healing period	Width before grafting (mm)	Width after grafting*	
Buser et al <sup>18</sup>	Cohort, prospective	20	Locally harvested autogenous bone chips, DBBM and collagen membrane	8–12 wk	< 6	N/A	
Schneider et al <sup>19</sup>	Cohort, prospective	16	DBBM and titanium-reinforced ePTFE mem- brane (secured with 1–2 nonresorbable pins), connective tissue graft after 6 months	6 mo	< 3	N/A*	

\*Authors reported combined soft and hard tissue width, data extraction not possible.

N/A: not reported or unable to be extracted; PES: Pink Esthetic Score, WES: White Esthetic Score; mPI: modified Plaque Index; mSBI: modified Sulcus Bleeding Index; PD: probing depth; KM: keratinized mucosa; DIM: distance of mucosal margin to implant shoulder; DIB: distance of bone to implant contact.





Figs 2a and 2b Characteristics of studies on (a) simultaneous and (b) staged approaches.

Regarding surgical complications, two studies reported that no intraoperative complications occurred (Table 3).<sup>23,24</sup> All other studies did not provide such information. With respect to postoperative complications, five studies described such incidents.<sup>20,23,24,27,28</sup>

Most frequently, postsurgical complications included soft tissue dehiscences with exposure of grafts. Complete failure of two block grafts was reported by Nissan et al.<sup>27</sup> Dörtbudak et al<sup>24</sup> described spontaneous healing of a fistula after removal of necrotic bone.

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Width at follow-up*	Bone width gain*	Intraoperative complications	Postoperative complications	Follow-up after loading	Implants at follow-up	Implant success	Implant survival
N/A	N/A	N/A	N/A	З у	20	100% (clinical examination: mPl, mSBI, PD, KM DIM, DIB, PES, WES)	100%
N/A*	N/A*	None	None	1 yr	15	N/A	100%

The same authors<sup>24</sup> also reported wound dehiscences of donor sites as well as transient and permanent tooth sensitivity changes in the anterior mandible in two patients. No postoperative complications occurred in three studies,<sup>21,22,29</sup> but no gain of bone at all was reported for one case<sup>21</sup> and significant allogeneic block resorption was observed also in one case.<sup>22</sup> No information regarding postoperative complications was found in the remaining studies.<sup>25,26,30</sup>

#### DISCUSSION

Bone deficiency in the anterior maxilla prevents primary implant stability or results in an inadequate implant position with compromised esthetics or function.<sup>1</sup> Therefore, horizontal ridge augmentation is a prerequisite before or during implant placement. The present systematic review evaluated clinical studies reporting data about implant success, implant survival, gain of bone width, and intra- and postoperative complications, in conjunction with horizontal bone augmentation limited to the anterior maxilla. The decision to focus the systematic review on the esthetic zone was based on three facts:

The anterior maxilla is the most challenging area regarding esthetics in implant dentistry.

Many, if not most, cases in the anterior maxilla require horizontal ridge augmentation due to partial or complete loss of the facial bone plate following tooth extraction or tooth loss.

To the knowledge of the authors, no such systematic review has been carried out before.

However, limiting the search to the anterior maxilla resulted in a low number of relevant clinical studies fulfilling the inclusion criteria. Additionally, in order to attain some homogeneity of included articles, the surgical approach used to improve alveolar ridge width was narrowed down to horizontal bone augmentation, thus excluding other surgical techniques like immediate implant placement with socket grafting or implant placement after ridge expansion, ridge splitting, or distraction osteogenesis. Also, the majority of excluded clinical studies could not be taken into consideration because they either report single cases, describe technical notes of alveolar ridge reconstruction, or the study material comprised maxillary and mandibular anterior and posterior cases with pooled data, thus not allowing for data extraction.

Since timing, surgical technique, and geometry of defects differ in simultaneous versus staged horizontal bone augmentation, studies were grouped accordingly and will be discussed separately.

#### **Simultaneous Approach**

The fact that only two studies could be analyzed in this group calls for further clinical research focusing on simultaneous peri-implant horizontal ridge augmentation in the anterior maxilla. While many studies evaluate the vertical coverage of exposed implant surfaces using bone augmentation, they lack information about the horizontal bone dimension on the facial aspect. Various authors have highlighted the importance of the thickness of the facial bone showing that a minimum of 2 mm of facial bone is required to avoid vertical buccal bone resorption.<sup>31–33</sup> Although both studies included in this review<sup>18,19</sup> reported an implant survival rate of 100%, no firm conclusions can be drawn, with a total of only 35 implants. The same refers to the success rate, which was only evaluated in one study with 20 implants, all of them categorized as successful.<sup>18</sup>

#### **Staged Approach**

For this review, 11 studies with a total of 353 patients investigated outcome parameters after staged bone augmentation, in a time period of 15 years of research. The overall success rates range between 96.8% and 100%, and survival rates range from 93.5% to 100%. The data reported by Meijndert et al<sup>29</sup> are rather interesting since the authors performed a prospective comparative study on staged horizontal ridge augmentation in the anterior maxilla. While implants placed into sites augmented with chin bone blocks presented a success rate of 100%, those inserted into sites augmented with DBBM particles had a success rate of 93.5%.

#### Table 3 Results of Studies Using Staged Approach

Author	Study type	Patients	Techniques	Interval augmentation and implant placement	Width before grafting (mm)	Width after grafting (mm)
Buser et al <sup>20</sup>	Cohort, prospective	28 (total = 40 pa- tients; data extracted from 28 patients with 40 anterior maxillary sites)	Autogenous bone block graft from chin or retromolar area, fixation with bone screw. Surrounding spaces filled with autogenous bone chips. Coverage with ePTFE-membrane.	7–13 mo	3.6 (2–4.5)	N/A
Raghoebar et al <sup>23</sup>	Cohort retrospective	23 (+4)	Group A, Monocortical autogenous grafts (12× symphysis, 7× retro- molar, 4× tuberosity), fixation with titanium plates or screws. Group B, 4 cases, alveolus filled with bone from tuberosity	3 mo	< 2	7.3 (range, 7–8) (results com- bined groups A and B)
Dörtbudak et al <sup>24</sup>	Cohort, retrospective	31	Autogenous block grafts from chin fixated with titanium miniscrew	3–8 mo	< 4	N/A

Meijndert et al <sup>29</sup>	Prospective comparative	93	Group A, chin bone/titanium screw (n = 31) Group B, chin bone/titanium screw + collagen membrane (n = 31) Group C, DBBM + collagen mem- brane (n = 31)	Groups A and B, 3 mo; Group C, 6 mo	N/A	N/A
Tymstra et al <sup>25</sup>	Cohort, retrospective	10	Autogenous chin bone blocks	3 mo	N/A	N/A
Hof et al <sup>26</sup>	Cohort, retrospective	60	Autogenous bone block grafts with screw fixation	Minimum 3 mo	< 6	N/A
Hämmerle et al <sup>21</sup>	Cohort, prospective	12	Blocks or granules of DBBM + collagen membrane (fixed with resorbable pins)	9–10 mo	$3.2 \pm 0.9$ (1.5-4.5)	N/A
Wallace and Gellin <sup>22</sup>	Cohort, prospective	12	Cancellous freeze-dried allograft bone blocks fixed with 2 bone screws; spaces filled with particu- lated mineralized cortical allograft bone mixed with rhPDGF-BB; Ossix Plus resorbable membrane covered augmentation site.	5 mo	3.9 (17 sites: 1 x max molar, 1 x max pre- molar, 15 x max anterior)	N/A (123%)
da Costa et al <sup>30</sup>	Randomized clinical trial	10	Group A, allogeneic corticocancel- lous bone blocks embedded with an autogenous bone marrow aspirate; fixed with titanium screw ( $n = 5$ ) Group B, allogeneic corticocancel- lous bone blocks fixed with titanium screw ( $n = 5$ )	6 mo	Group A, 4.3 Group B, 4.8	N/A

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Width at follow-up (mm)	Bone width gain (mm)	Intra- operative compli- cations	Postoperative complications	Interval between implant place- ment and loading	Follow-up after loading	Implants at follow-up	Implant success (criteria)	Implant survival
7.0 (5–9.75)	3.4 (1-6)	N/A	Soft tissue dehiscence - required partial removal of ePTFE (n = 1) Soft tissue encapsulation (n = 2)	3–4 mo	N/A	N/A	N/A	N/A
N/A	Group A, Mean loss 6% of graft (range, 0%–20%; resorption more pronounced in tuberosity) Group B, no resorption	None	Mucosal dehiscence over graft requiring osteoplasty (n = 3)	6 mo	37 ± 14.6 mo (24-68 mo)	31	96.8% (radiographic examination, no radiolucency; vertical bone loss < 1/5th of implant length [n = 3])	100%
N/A	Mean graft resorption, $0.79 \pm 0.6 (0-2);$ 0.33 for 3-4 mo healing; 1.22 for 5-8 mo healing (P < .001)	None	Fistula above the bone graft, healed spontane- ously after removal of necrotic bone $(n = 1)$ Wound dehiscence in donor sites $(n = 4)$ Sensitivity loss remaining in 2 out of 10 patients 12 mo postop	N/A	20.8 ± 7.7 mo	42	N/A	N/A
N/A	N/A	N/A	None	6 mo	12 mo	91	N/A (All groups, peri-implant hard and soft tissue stable after 12 months; radiographic ex- amination; clinical examination; MBL; PS; BI; PD; MGL)	Group A, 100% Group B, 100% Group C, 93.5% (implant loss, n = 2) All groups, 97.8%
N/A	N/A	N/A	N/A	6 mo	Minimum 1 y	20	N/A (All groups, peri-implant hard and soft tissue stable after 12 months; radiograph- ic examination; clinical examination; MBL; PI; BI; PD)	
N/A	N/A	N/A	N/A	Minimum 3 mo	4.1 ± 1.9 y (1.2-8.1 y)	60	100% (success criteria by Smith and Zarb); clinical examina- tion; KM (buccal); mPI; PD	100%
6.9 ± 1.4 (3-9)	3.6 ± 1.5 (0-6)	N/A	None (n = 1, no gain of bone volume)	4 mo	N/A	N/A	N/A	N/A
8.4	4.5 (1.5–9.8)	N/A	None (n = 1, significant resorption at reentry)	4 mo	N/A	N/A	N/A	N/A
Group A, 8.9 Group B, 6.9	Group A, $4.6 \pm 1.43$ Group B, $2.15 \pm 0.47$ ( <i>P</i> = .005)	N/A	N/A	N/A	N/A	40	N/A	N/A

Author	Study type	Patients	Techniques	Interval augmentation and implant placement	Width before grafting (mm)	Width after grafting (mm)
Nissan et al <sup>27</sup>	Cohort, retrospective	31	Freeze-dried cancellous block allograft, fixed with bone screws; particulated bone, mineralized freeze-dried bone allograft, or DBBM were used to fill any deficiencies; collagen membranes used.	6 mo	< 3	N/A
Nissan et al <sup>28</sup>	Cohort, retrospective	43	Freeze-dried cancellous block allograft; fixed with bone screws; particulated bone, mineralized freeze-dried bone allograft, or DBBM were used to fill any deficiencies; collagen membranes used.	6 mo	< 3	N/A

#### Table 3 continued Results of Studies Using Staged Approach

MBL: marginal bone level, clinical examination; PI: Plaque Index; BI: Bleeding Index; PD: Probing depth; MGL: marginal gingiva level; KM: keratinized mucosa buccal; mPI: modified Plaque Index.

Two implants were lost during the healing phase in the DBBM group although sites augmented with DBBM particles were left to heal for 6 months before implant placement (compared to 3 months for chin-bone augmented sites). Since the study was terminated after 1 year of implant loading, the long-term success rates remain unknown. Hämmerle and coworkers<sup>21</sup> also used granules or blocks of DBBM for staged ridge augmentation, but waited 9 to 10 months before implant placement. In one out of 12 sites, no gain of bone volume was observed at reentry. The tissue was inflamed and the DBBM granules were encapsulated into connective tissue. Long-term follow-up information regarding implant success and survival rates are not available yet. Both studies<sup>21,29</sup> indicate that a particulate graft may not have the same potential for staged ridge augmentation compared to a block graft, as has been documented previously in other clinical studies.<sup>34–38</sup> This has been attributed mainly to the instability of graft particles due to mucosal pressure or mechanical load (provisional, mastication). Therefore, caution must be exercised when using a particulate graft for staged horizontal ridge augmentation in large bone deficiencies. The quantity of horizontal bone gain in the anterior maxilla documented in this review is similar to the figures reported in previous studies about horizontal ridge augmentation.34-41 Mean values of bone gain in this systematic review ranged from 2.15 to 5 mm, whereas previous reports not restricted to the anterior maxilla have described gain of bone width between 1.1 to 2.7 mm for particulate grafts<sup>34–38</sup> and 2.9 to 5 mm for block grafts.<sup>8,39–41</sup> In the present systematic review, the actual bone or bone substitute material and surgical technique utilized for horizontal ridge augmentation varied considerably among the

studies (Fig 2). All materials led to the gain of bone width: autogenous block grafts with ePTFE-membrane coverage (gain of width, 3.4 mm),<sup>20</sup> DBBM blocks or granules with collagen membrane coverage (gain of width, 3.6 mm<sup>21</sup>), freeze-dried allograft bone block with platelet-rich plasma and recombinant platelet derivative growth factor (rhPDGF-BB) and chemically modified collagen membrane (gain of width, 4.5 mm<sup>22</sup>), allogeneic corticocancellous bone block with (gain of width, 4.6 mm) or without (gain of width, 2.15 mm<sup>30</sup>) autogenous bone marrow aspirate, freezedried allograft bone block with particulate bone or allograft, or DBBM with collagen membrane (gain of width, 5 mm<sup>27</sup>). To further complicate the drawing of any conclusions, the interval between ridge augmentation and reentry varied considerably among the studies (5 to 13 months). Two other studies did not report bone gain but rather the amount of graft resorption.<sup>23,24</sup> An interesting phenomenon was documented by Dörtbudak et al<sup>24</sup> when chin bone blocks for horizontal ridge augmentation were used. Significantly less surface resorption of grafts in sites reentered 3 to 4 months after augmentation (0.33 mm) were found compared to sites reentered 5 to 8 months after augmentation (1.22 mm). Whether this difference was clinically relevant is unknown since the authors did not mention the initial width of the bone blocks. The benefit of barrier membranes to avoid surface resorption of autogenous bone blocks remains unclear. Although several clinical studies have documented a positive effect,<sup>8,20,39</sup> a systematic review on that topic found that the available evidence is too weak to support a protective effect of a barrier membrane.<sup>13</sup>

With regard to complications in staged horizontal bone augmentation, such information has been divided

(4-6)down and graft expo- sure with complete(6-59 mo) with im- mediate(n = 19 immediate nonfunctional loading; 98% for immediate nonfunctional loading. (Not all implants)									
(4-6)down and graft expo- sure with complete(6-59 mo) with im- mediate(n = 19 immediate nonfunctional loading; 98% for immediate nonfunctional loading. (Not all implants)	follow-up		operative compli-	Postoperative	between implant place- ment and	· · · · · ·	at	success	Implant survival
	N/A		N/A	down and graft expo- sure with complete	6 mo		(n = 19 with im-	N/A	100% implant survival in delayed loading; 98% for immediate nonfunctional loading. (Not all implants had minimum 1 y loading.)
N/A N/A N/A Soft tissue dehiscen- ces in 16 sites in 27 (14–82 mo) block allografts with vertical alone or in combination with hori- zontal augmentation	N/A	N/A	N/A	ces in 16 sites in 27 block allografts with vertical alone or in combination with hori-	3 mo		83	N/A	98.8%

into intra- and postoperative complications. Studies included in this systematic review either did not mention if intraoperative complications had occurred, or they reported that no such intraoperative complications were observed. In contrast, postoperative complications were reported in five studies.<sup>20,23,24,27,28</sup> All of these studies reported soft tissue complications relating to block graft augmentation, such as mucosal dehiscences, soft tissue breakdown, or sinus tract formation (fistula). As reported by Nissan et al,<sup>27</sup> soft tissue dehiscence may lead to complete failure of block grafts and must be taken seriously. Interestingly, cohorts of both studies by Nissan et al<sup>27,28</sup> had relatively large frequencies of soft tissue complications, although augmented sites were covered with collagen membranes. The authors used different types of collagen membranes, but they did not specify if mucosal dehiscences occurred more frequently in one membrane versus another. Furthermore, it cannot be ruled out that a vertical component of horizontal ridge augmentation caused the soft tissue breakdown with subsequent graft exposure. In those studies using autogenous bone blocks, only one study provided data about donor site morbidity.<sup>24</sup> The authors describe two patients with persistent sensitivity loss of anterior mandibular teeth 12 months postsurgically. Many studies have reported sensitivity changes of perioral soft tissues or of adjacent teeth, particularly following bone block harvesting in the symphysis.<sup>42–45</sup> As a consequence, grafts and bone substitutes other than the autogenous type of block grafts are also used increasingly for staged horizontal ridge augmentation, as shown with this systematic review. The last four studies included in this review all utilized nonautogenous grafts for reconstruction of deficient alveolar processes.

#### CONCLUSIONS

The number of articles meeting the outcome parameters in simultaneous versus staged horizontal augmentation procedures in the anterior maxilla is limited. Most of the excluded publications describing augmentation procedures in the anterior maxilla are case reports with a high risk of bias. Within the 13 articles meeting the inclusion criteria, only one randomized clinical trial was found. Therefore no conclusions can be drawn for the best performing material for augmentation in the anterior maxilla. In summary, the authors found that bone augmentation and implant placement is associated with high implant success and survival rates in both treatment modalities with different bone substitutes.

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### Computer Technology Applications in Surgical Implant Dentistry: A Systematic Review

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Purpose: To assess the literature on the accuracy and clinical performance of static computer-assisted implant surgery in implant dentistry. Materials and Methods: Electronic and manual literature searches were applied to collect information about (1) the accuracy and (2) clinical performance of static computerassisted implant systems. Meta-regression analysis was performed to summarize the accuracy studies. Failure/complication rates were investigated using a generalized linear mixed model for binary outcomes and a logit link to model implant failure rate. Results: From 2,359 articles, 14 survival and 24 accuracy studies were included in this systematic review. Nine different static image guidance systems were involved. The meta-analysis of the accuracy (24 clinical and preclinical studies) revealed a total mean error of 1.12 mm (maximum of 4.5 mm) at the entry point measured in 1,530 implants and 1.39 mm at the apex (maximum of 7.1 mm) measured in 1,465 implants. For the 14 included survival studies (total of 1,941 implants) using static computer-assisted implant dentistry, the mean failure rate was 2.7% (0% to 10%) after an observation period of at least 12 months. In 36.4% of the treated cases, intraoperative or prosthetic complications were reported, which included: template fractures during the surgery, change of plan because of factors such as limited primary implant stability, need for additional grafting procedures, prosthetic screw loosening, prosthetic misfit, and prosthesis fracture. Conclusion: Different levels of quantity and quality of evidence were available for static computer-assisted implant placement, with tight-fitting high implant survival rates after only 12 months of observation in different indications achieving a variable level of accuracy. Future long-term clinical data are necessary to identify clinical indications; detect accuracy; assess risk; and justify additional radiation doses, effort, and costs associated with computer-assisted implant surgery. INT J ORAL MAXILLOFAC IMPLANTS 2014;29 (SUPPL):25-42. doi: 10.11607/jomi.2014suppl.g1.2

Key words: guided surgery, dental implants, computer planning

Prosthetically driven implant surgery in reference to surrounding anatomical structures has been a subject of interest to dental clinicians for a number of

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years. Correct implant positioning has a number of advantages such as a favorable esthetic and prosthetic outcome and the potential to ensure optimal occlusion and implant loading. Moreover, the consideration of correct implant positioning may enable design optimization of the final prostheses, allowing for adequate dental hygiene. Consequently, all of these factors may contribute to the long-term success of dental implants.

The introduction of cone-beam computed tomography (CBCT) scanning to implant dentistry as a threedimensional (3D) imaging tool has led to a breakthrough in this field, particularly because these scanning devices result in lower radiation dosages than conventional computed tomography (CT) scanners.<sup>1–3</sup> In combination with implant planning software, the use of CBCT images has made it possible to virtually plan the optimal implant position regarding surrounding vital anatomical structures and future prosthetic needs. The resulting planning information is then used to fabricate so-called drill guides, and this process ultimately results in the transfer of the planned implant position from the computer to the patient, with the

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drill guide directing the implant osteotomy and implant insertion. Importantly, this entire process can be performed in such a way that the predicted ideal implant position can be achieved without damaging the surrounding anatomical structures.<sup>4</sup>

The various so-called guided systems incorporate the planning of the implant positions, using a variety of software tools. The resulting planned implant positions are then converted into surgical guides or loaded into positioning software following a variety of methods. Jung and coworkers<sup>5</sup> have categorized many of these into static and dynamic systems. Static systems are those that communicate predetermined sites using surgical templates or implant guides in the operating field. Meanwhile, dynamic systems communicate the selected implant positions to the operative field with visual imaging tools on a computer monitor, instead of rigid intraoral guides. The dynamic systems include surgical navigation and computer-aided navigation technologies, and allow the surgeon to alter the surgical procedure and implant position in real time using the anatomical information available from the preoperative plan and a CT or CBCT scan. Since the surgeon can see an avatar of the drill in a 3D relationship to the patient's previously scanned anatomy during surgery, modifications can be accomplished with significantly more information. In essence, the navigation approach provides a virtual surgical guidance that may be altered according to the conditions encountered during surgery.

In their systematic review, Jung et al<sup>5</sup> stated that the static systems have the tendency to be more accurate than the dynamic approaches. However, most of the publications on navigation have been clinical studies, whereas the majority on static protocols has been preclinical (models or cadaver, etc), where more accurate measurements are possible. The greater accuracy of these latter studies can be explained by the better access, the greater visual control of the axis of the osteotomy, the lack of movement in the cadaver, and the absence of saliva or blood in the preclinical models. In the dynamic approach, the osteotomy and implant insertion can be altered during the surgery. Thus the osteotomy has then no other guidance than the surgeon's vision in the virtual model, giving the surgeon the ability to choose the implant position based on the visual real-time anatomy. Hence, no true comparison is possible between the planned and placed implant position. Due to this fact, in this systematic review, only the studies conducting computer-guided (static) surgery were considered for inclusion.

For computer-guided (static) surgery, one can distinguish different modalities regarding the procedure for fabricating the drill guides such as stereolithography (rapid prototyping) or the use of mechanical positioning devices that convert the radiographic template to a surgical one by executing computer transformation algorithms.<sup>5</sup> The different computer guided systems can also be differentiated in terms of their respective design for the drill guidance through the template. For example, some systems use surgical templates with sleeves of an increasing diameter, while others design different drills with stops to achieve depth control. Some systems allow a guided implant placement<sup>6-8</sup> whereas in other systems the implants are inserted without using a guided device9-11 or after removal of the template. Some systems use pre-installed reference points such as mini-implants<sup>8,12</sup> while others use different reference markers (eg, gutta percha markers on the CT imaging) or no references for performing the procedures. These variations make it extremely difficult to draw a clear line in comparing the different systems. For this reason, a clear description on every system and their variation in use and precision can be beneficial to clinicians who are interested in these techniques.

Moreover, different accuracy measurement techniques and terms have been introduced in the literature in the comparison of planned implant positions to actual inserted implants. Some use baseline criteria such as entry or apical point while others use 3D coordinates (eg, x-, y-, and z-axes), making it more challenging to conduct a unified comparison.

The aim of this systematic review is to systematically assess the literature regarding the accuracy and the clinical performance, limitations, and complications of different static techniques based on computer assisted technique applications in guided surgical implant dentistry.

#### MATERIALS AND METHODS

An electronic search on dental literature was performed with the purpose of collecting relevant data on (1) the accuracy and (2) the clinical performance (survival) of computer-aided dental implant placement. A MEDLINE and EMBASE systematic search was completed using the following terms: dental AND (implant OR implants OR implantation OR implantology) AND (guide\* OR computer\*) (Table 1).

The results were limited to studies published between January 1, 2008, and January 9, 2012, and written in English, German, Italian, or French. These results were complemented by the data extracted in a previous ITI consensus paper accessing the literature from 1966 through 2008.<sup>5</sup> Two independent reviewers performed the article selection. In addition, hand searches were performed using the reference lists of the selected full-text articles and were also conducted in the following pertinent implant-related journals; *Clinical Implant Dentistry and Related Research, Clinical Oral Implants Research, The International Journal of Oral* 

Table 1 Systemat	ic Search Strategy
	does static computer-guided surgery perform in terms of implant survival and accuracy of placement treating (partially) edentulous patients?
Search strategy	
Population	Edentulous or partially edentulous patients treated with dental implants
Intervention or exposu	re Implant placement using static computer-guided surgery
Comparison	Nonguided/conventional methods
Outcome	(1) Accuracy of placement, (2) Implant survival
Search combination	dental AND (implant OR implants OR implantation OR implantology) AND (guid* OR compute*)
Database search	
Electronic	PubMed (MEDLINE) & EMBASE
Journals	Hand search: Clin Implant Dent Relat Res, Clin Oral Implants Res, Int J Oral Maxillofac Implants, J Oral Maxillofac Surg, J Periodontal, J Prosthet Dent
Selection criteria	
Inclusion criteria	G <i>eneral:</i> Reporting on static-guided implant placement through digital planning based on CBCT imaging Clinical studies with at least 5 patients
	Accuracy studies: Primary outcome of the studies was the accuracy of computer-guided implant placement Clinical, model, or cadaver studies
	Survival studies: Follow-up period in clinical studies at least 12 months Data on complications incorporated if available
Exclusion criteria	G <i>eneral:</i> Zygoma, pterygoid, and orthodontic implants Multiple publications on the same patient population
	Accuracy studies: Studies reporting just on position or shape of osteotomies Studies reporting freehand final drilling
	Survival studies: Insufficient information on survival rates or lost implants

& Maxillofacial implants, Journal of Oral and Maxillofacial Surgery, Journal of Periodontology, Journal of Prosthetic Dentistry, Implant Dentistry, and The International Journal of Periodontics and Restorative Dentistry. Only articles that reached consensus between the reviewers were selected for data extraction. Figure 1 illustrates the search strategy.

#### **Inclusion and Exclusion Criteria**

This review includes only computer-guided (static) surgery in which a CT/CBCT scan was conducted for computerized planning prior to the actual implant insertion. Therefore, articles regarding dynamic computer-navigated surgery and 2D radiographic stents were excluded. Meanwhile, for the accuracy and clinical performance studies, different inclusion criteria were considered.

Accuracy studies:

- Studies with zygomatic, pterygoid, and orthodontic implants were excluded.
- Clinical, model, and cadaver studies were included.
- The primary outcome of the studies had to be the accuracy of computer-guided implant surgery.

- The measurement of distances between the planned and actual position of the implants and/ or implant angle deviations had to be clearly described.
- Only the data on the position of actual inserted implants were included, whereas data were excluded if the position of the osteotomy following computer-guided surgery was provided but no actual insertion of the implants was performed.

#### Clinical studies:

- Clinical studies were included when based on at least 5 patients.
- The follow-up period had to be at least 12 months. The reported data had to include implant survival based on at least one of the following parameters: clinical, radiographic, or patient-centered outcomes of computer-assisted implant dentistry in humans.
- Other factors such as prosthetic survival, complications, or bone-level changes were incorporated if available.

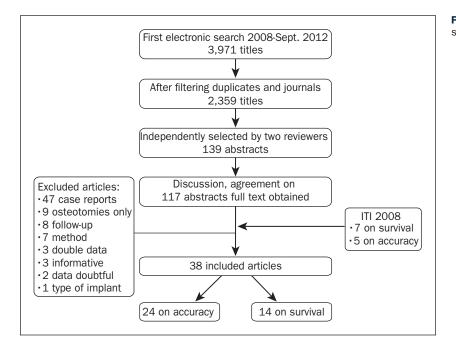


Table 2 Contacted	Table 2 Contacted Authors										
Authors	Year	Response	Action								
Behneke et al <sup>13</sup>	2012	Y	Data added (SDs)								
Komiyama et al <sup>14</sup>	2008	Y	Explanation/clarification								
Nickenig et al <sup>15</sup>	2010	Ν	Included (missing information not crucial)								
Kuhl et al <sup>16</sup>	2013	Y	Data added (SDs)								
Ozan et al <sup>17</sup>	2011	Υ	Explanation/clarification								
Ozan et al <sup>18</sup>	2009	Y	Explanation/clarification								
Ersoy et al <sup>9</sup>	2008	Y	Explanation/clarification								
Pettersson et al <sup>19</sup>	2012	Y	Data changed (means and SDs)								
van Steenberghe et al <sup>20</sup>	2002	Y	Missing info not crucial								

#### **Data Extraction**

Two data sheets (accuracy and clinical performance) were created in consultation between the two reviewers. The reviewers independently from each other extracted the data of the included studies using these data sheets. Any disagreements were resolved by discussion. Studies were only definitively included in the analysis if consensus was reached between the reviewers. Further, in cases of incomplete or unclear data, the respective authors were contacted to complete or clarify their data. Table 2 shows the contacted authors and their valuable contribution.

As well as a general analysis of the extracted data, the reviewers agreed to create different subgroups in the accuracy assessment to evaluate the different data correctly and to perform a clear comparison between the various techniques and protocols and their possible statistical significance. Subgroups were created according to the following criteria:

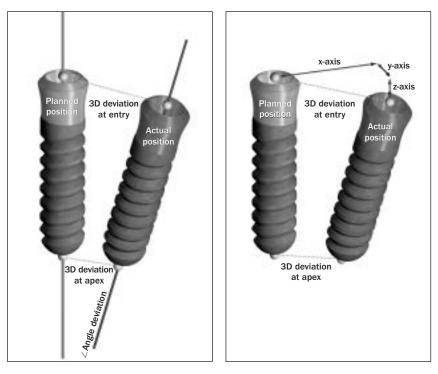
- State of the implanted jaw: (1) fully edentulous or (2) partially edentulous
- Implanted jaw: (1) maxilla or (2) mandible
- Flapless surgery: (1) yes or (2) no
- Guide support: (1) mucosa, (2) mucosa with pins or screws, (3) bone, (4) tooth, or (5) reference mini-implants
- Methods of implant insertion: (1) freehand implant placement (guide removed) or (2) fully guided implant placement (using guide)
- Guide production: (1) produced in a laboratory, (2) fabricated with rapid prototyping/ stereolithography (SLA)
- Study design: (1) clinical, (2) cadaver, or (3) model

### Fig 1 Schematic illustration of search strategy.

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**Fig 2** (*left*) Different variables for describing the deviations per implant illustrated.

**Fig 3** (*right*) Illustration of the distinction between the deviation measured in the x, y, and z-axis.



#### Analysis

For analyzing the accuracy, the planned position of the implant was compared with the actual position of the implant after insertion. Several measuring points were used in the studies for the comparison of these positions:

- Error at the entry point, measured at the center of the implant
- Error at the apex, measured at the center of the implant apex
- Angular deviation
- Error in implant height

Actual comparison between the different studies is only possible if the measurement mode is the same. Error at the entry and the apex and the error in the height were measured in mm or µm, while the angular deviation was measured in degrees. For angular deviation, the comparison was less complicated, since every study used degrees of deviation. The error or deviation of the other aforementioned points was 3D, though several methods were used to describe the distance between the given points. The most common method was to measure the actual distance between the planned and actual point in 3D. Other authors made a distinction between the deviation measured in the x, y, and z-axis, where x = buccolingual, y = mesiodistal, and z = apicocoronal deviation. The apicocoronal deviation was frequently expressed as a negative number if the implant was not inserted as deeply as planned (too coronal). Furthermore in some studies the deviation in a horizontal plane was measured and referred to as the x-, y-error. Figure 2 illustrates the different variables for describing the deviations.

The main purpose of this study was to compare the results of different study designs. To accomplish this goal, if data was missing, the respective authors were contacted to assist the reviewers in completing the data.

In addition, it was attempted to convert the data as uniformly as possible. Therefore, in cases where axiomatic (x, y, z) measurements were used, the values were converted to 3D deviations using the Pythagorean Theorem. Figure 3 illustrates these variables before conversion.

$$3Ddev = \sqrt{x^2 + y^2 + z^2}$$

For recalculating the combined standard deviations of the 3D deviations the following formula was used:

$$SDcomb = \sqrt{\frac{(Nx(SDx^2 = (x - 3Ddev)^2) + Ny(SDy^2 + y^2) + Nz(SDz^2 + (z - 3Ddev)^2))}{(Nx + Ny + Nz)}}$$

Note that in some of the included studies, there was insufficient data to perform a Pythagorean calculation. In these instances the data were included, but for this part not incorporated in the metaregression analysis.

#### **Statistical Analysis**

R version 2.14 for Windows, Metatest, and Meta-Library software were used for statistical analysis.

#### Table 3 Studies on Accuracy of Guided Implant Placement

Authors	Year	Study design	Comparison	System	State of dentition	Jaw	Guide support	Implant placement	Guide type	
van Steenberghe et al <sup>20</sup> Di Giacomo et al <sup>11</sup>		Cadaver Clinical	Postop CBCT Postop CBCT		Edentulous Partially	Maxilla Both	Bone Bone/tooth	FG FHP	dig dig	
van Assche et al <sup>21</sup>	2007	Cadaver	Postop CBCT	Nobel Guide	edentulous Partially edentulous	Both	Tooth + 2x anchor pins	FG	dig	
Ersoy et al <sup>9</sup>	2008	Clinical	Postop CBCT	StentCad	Both	Both	Mixed (mucosa/tooth/bone)	FHP	dig	
					Edentulous Partially	Both Both	Mixed (mucosa/tooth/bone) Mixed (mucosa/tooth/bone)	FHP FHP	dig	
					edentulous				dig	
					Single tooth Both	Both Both	Mixed (mucosa/tooth/bone) Mucosa	FHP FHP	dig dig	
					Both	Both	Tooth	FHP	dig	
					Both	Maxilla	Mixed (mucosa/tooth/bone)	FHP	dig	
					Both	Mandible	Mixed (mucosa/tooth/bone)	FHP	dig	
					Both	Both	Bone	FHP	dig	
					Both Both	Both Both	Mixed (mucosa/tooth) Mixed (mucosa/tooth/bone)	FHP FHP	dig dig	
Ruppin et al <sup>22</sup>	2008	Cadaver	Postop CBCT	SimPlant	Both	Mandible	Bone	FHP	dig	
Dreiseidler et al <sup>23</sup>		Model	Postop CBCT	Nobel Guide	Partially edentulous	Both	Tooth	FG	dig	
Dzan et al <sup>18</sup>	2009	Clinical	Postop CBCT	StentCad	Both	Both	Mixed (mucosa/tooth/bone)	FHP	dig	
						Maxilla	Mixed (mucosa/tooth/bone)	FHP	dig	
						Mandible	Mixed (mucosa/tooth/bone)	FHP	dig	
						Both Both	Bone Mucosa	FHP FHP	dig dig	
						Both	Tooth	FHP	dig	
Arisan et al <sup>24</sup>	2010	Clinical	Postop CBCT	SimPlant	Both	Both	Mucosa + pin	FG	dig	
				Simplant	Both	Both	Tooth	FG	dig	
				SimPlant	Both	Both	Bone	FHP	dig	
				StentCad	Both	Both	Mucosa + pin	FHP	dig	
				StentCad StentCad	Both Both	Both Both	Tooth Bone	FHP FHP	dig dig	
Nickenig et al <sup>15</sup>	2010	Clinical	Postop CBCT	coDiagnostiX	Partially edentulous	Mandible	Tooth	FHP	lab	
Pettersson et al <sup>19</sup>	2012	Clinical	Postop CBCT	Nobel Guide	Edentulous	Both	Mucosa + pin	FG	mix	
	2012	omnour	100000000001		Edonitalouo	Maxilla	Mucosa + pin	FG	mix	
						Mandible	Mucosa + pin	FG	mix	
Pettersson et al <sup>6</sup>	2010	Cadaver	Postop CBCT	Nobel Guide	Edentulous	Both	Mucosa + pin	FG	dig	
						Maxilla	Mucosa + pin	FG FG	dig	
Fahmaseb et al <sup>7</sup>	2010	Model	Strain Gauges	Exe-plan	Edentulous	Mandible Mandible	Mucosa + pin Mini–implant	FG	dig dig	
Viegas et al <sup>25</sup>	2010	Model	Postop CBCT	•	Edentulous	Mandible L		FG	dig	
-						Mandible R		FG	dig	
Cassetta et al <sup>26</sup>	2013	Clinical	Postop CBCT	SimPlant	Both	Both	Mixed (mucosa/bone/tooth)	FHP	dig	
							Mixed + pin (mucosa/bone) Mixed (mucosa/bone/tooth)	FG FG	dig	
Dzan et al <sup>17</sup>	2011	Clinical	Postop CBCT	StentCad	Both	Maxilla	Mucosa (mucosa/bone/tooth)	FG	dig dig	
		5		StentCad	Both	Mandible	Mucosa	FHP	dig	
				StentCad	Both	Maxilla	Mucosa + pin	FG	dig	
				Beyond StentCad	Both	Mandible	Mucosa + pin	FG	dig	
				Beyond					-	
Platzer et al <sup>27</sup>	2011	Clinical	Pick–up Impression	SimPlant	Partially edentulous	Mandible	Tooth	FG	dig	
Tahmaseb et al <sup>8</sup>	2011	Model	Strain Gauges	Exe-plan	Partially edentulous	Maxilla	Mini–implant	FG	dig	
Vasak et al <sup>28</sup>	2011	Clinical	Postop CBCT	Nobel Guide	Both	Both	Mixed + pin (mucosa/tooth)	FG	dig	
Arisan et al <sup>29</sup>	2012	Clinical	Postop CBCT	SimPlant & CBCT	Edentulous	Both	Mucosa + pin	FG	dig	
<b>D</b> 1 1 1 1 2				SimPlant & CT	Edentulous	Both	Mucosa + pin	FG	dig	
Behneke et al <sup>13</sup>	2012	Clinical	Postop CBCT	Implant 3D	Partially	Both	Tooth	FG	lab	
D'Haese et al <sup>30</sup>	2012	Clinical	Poston CPCT	Facilitato	edentulous	Maxillo	Mucosa + nin	FHP FG	lab	
D Haese et al <sup>55</sup> Di Giacomo et al <sup>10</sup>		Clinical Clinical	Postop CBCT Postop CBCT	Facilitate Implant Viewer	Edentulous Edentulous	Maxilla Both	Mucosa + pin Mucosa + pin	FG	dig dig	
	2012	5				Maxilla	Mucosa + pin	FHP	dig	
						Mandible	Mucosa + pin	FHP	dig	
Kuhl et al <sup>16</sup>	2012	Cadaver	Postop CBCT	coDiagnostiX	Both	Mandible	Mixed (mucosa/tooth)	FHP	lab	
Coorco ot al <sup>31</sup>	2010	Cadaver	Dooton ODOT	Necourida	Edontulous	Mondilla	Muccoo L min	FG	lab	
Soares et al <sup>31</sup>	2012	Model	Postop CBCT	NeoGuide	Edentulous	wanuble	Mucosa + pin	FG	dig	

FHP = freehand placement; FG = fully guided implant insertion; lab = templates produced in laboratory;

dig = digitally produced templates (stereolithographic or milled); \*at entry; †at apex

Implants	Flap-		Error entry (mm)		Error apex (mm)			Error angle (°)			Error height (mm)			
(n)	less	x,y,z	Mean	SD	Max	Mean	SD	Max	Mean	SD	Max	Mean	SD	Max
10 21	Y N	3D 3D	0.8 1.45	0.3 1.42	- 4.5	0.9 2.99	0.3 1.77	- 7.1	1.8 7.25	1 2.67	_ 12.2	_	-	1.1
21	IN	30	1.45	1.42	4.5	2.99	1.77	1.1	1.25	2.07	12.2	-	-	-
12	Y	3D	1.1	0.7	2.3	1.2	0.7	2.4	1.8	0.8	4	-	-	-
94	44%	3D	1.22	0.85	-	1.51	1	-	4.9	2.36	-	-	-	-
65	mix	3D	1.28	0.92	-	1.6	1.08	-	5.1	2.59	-	-	-	-
20	mix	3D	1.23	0.67	-	1.59	0.74	-	4.78	1.86	-	-	-	-
9	mix	ЗD	0.74	0.4	_	0.66	0.28	_	3.71	0.93	_	-	-	-
23	mix	3D	1.1	0.7	-	1.7	1	-	4.9	2.2	-	-	-	-
26	mix	3D 3D	1.1	0.6 0.56	_	1.3	0.7	_	4.4	1.6	-	_	_	_
48 46	mix mix	3D 3D	1.04 1.42	1.05	_	1.57 1.44	0.97 1.03	_	5.31 4.4	0.36 0.31	_	_	_	_
40	N	3D 3D	1.42	1.05	_	1.44	1.5	_	4.4 5.1	2.7	_	-	_	_
53	N	3D	1.4	1	_	1.4	1.7	_	5	2.6	_	-	-	-
41	Y	ЗD	1.1	0.6	-	1.4	1	-	4.7	2	-	-	-	-
40	N	х, у	1.5	0.8	_	-	-	_	7.9	5	-	0.6	0.4	0.0
24	N	х, у	0.22	0.099	0.38	0.34	0.15	0.62	1.09	0.51	2	0.25	0.20	0.8
110	55%	3D	1.11	0.7	-	1.41	0.9	-	4.1	2.3	-	-	-	-
58 52	mix	3D 3D	0.95 1.28	0.5 0.9	_	1.41 1.4	1 0.9	_	4.85 3.32	2.4 1.9	_	_	_	_
52 50	mix N	3D 3D	1.28	0.9 0.9	_	1.4 1.57	0.9	_	3.32 4.63	1.9 2.6	_	_	_	_
30	Y	3D	1.06	0.6	_	1.6	1	_	4.51	2.0	_	_	_	_
30	Y	ЗD	0.87	0.4	-	0.96	0.6	-	2.91	1.3	-	-	-	-
54	Y	3D	0.7	0.13	0.83	0.76	0.15	0.99	2.9	0.39	3.5	-	-	-
50	Y	3D	0.81	0.33	1.6	1.01	0.4	1.72	3.39	0.84	4.6	-	-	-
43 43	N Y	3D 3D	1.56 1.24	0.25 0.51	3.48 2.7	1.86 1.4	0.4 0.47	2.6 2.83	4.73 4.23	1.28 0.72	6.9 6	_	_	_
43 45	Y	3D 3D	1.24	0.51	2.7	1.4	0.47	2.85 3.4	4.23 3.5	1.38	5.9	_	_	_
44	N	3D	1.7	0.52	3.48	1.99	0.64	3.8	5	1.66	8.2	-	_	-
23	Y	х	0.9	1.06	-	0.6	0.57	-	4.2	3.04	-	-	-	-
100		У	0.9	1.22	-	0.9	0.94	-	4.2	3.04	-	-	-	-
139 89	Y Y	3D 3D	0.95 0.95	0.55 0.53	2.68 2.68	1.22 1.15	0.63 0.51	3.62 2.63	2.76 2.71	1.76 1.41	11.74 6.96	-0.15 -0.06	0.76 0.7	-2.33 2.05
89 50	ř Y	3D 3D	0.95	0.53	2.68 2.45	1.15	0.51	2.63	2.71	2.27	0.96 11.74	-0.06 -0.29	0.7	-2.33
145	Y	3D	1.06	0.58	3.13	1.25	0.68	3.63	2.64	1.42	7.44	0.28	0.59	1.61
78	Y	ЗD	0.83	0.57	2.78	0.96	0.5	2.43	2.02	0.66	5.38	0.1	0.6	1.61
67	Y	3D	1.05	0.47	3.13	1.24	0.58	3.63	2.46	0.67	7.44	0.48	0.52	1.46
6	Model	3D	0.055	0.032	-	-	-	-	-	-	-	-	-	-
11 11	Model Model	3D 3D	0.37 0.3	0.2 0.17	_	0.41 0.36	0.22 0.25	_	0.7 1.45	0.3 0.89	_	_	_	_
116	81%	3D 3D	1.47	0.17	3.88	1.83	1.03	6.41	5.09	3.7	21.16	0.98	0.71	3.53
57	84%	3D	1.49	0.63	3	1.9	0.83	3.98	3.93	2.34	14.34	0.85	0.63	2.29
54	83%	ЗD	1.55	0.59	2.79	2.05	0.89	4.23	5.46	3.38	15.25	0.63	0.43	1.58
80	Y	0	-	-	-	-	-	-	6.29	2.12	-	-	-	-
44 49	Y Y	0 0	_	-	-	-	_	-	4.35	1.8	-	-	-	-
49	ſ	-	-	-	-	-	-	-	3.91	1.21	-	-	-	-
43	Υ	0	-	-	-	-	-	-	3.55	1.08	-	-	-	-
15	V	Y	0.07	0.10	0.6			_				0.20	0.10	0 50
15	Y	Х	0.27	0.19	0.6	-	-	-	-	-	-	0.28	0.19	0.59
		У	0.15	0.13	0.34	_	-	_	_	_	_	-	-	-
4	Model	х	0.027	0.015	0.046	-	-	-	-	-	-	0.0104	0.057	0.01
		У	0.025	0.022	0.061	-	-	-	-	-	-	-	-	-
86	Y	х	0.46	0.35	1.42	0.7	0.49	1.84	3.53	1.77	8.1	0.53*	0.38	1.85
52	Y	y 3D	0.43 0.81	0.32 0.32	1.5 1.31	0.59 0.81	0.44 0.32	1.89 1.33	- 3.47	- 1,144	- 5.12	0.52 <sup>†</sup> -	0.42	2.02
52	1	50	0.01	0.02	1.01	0.01	0.02	1.55	5.47	±,±++	0.12			-
50	Y	ЗD	0.75	0.32	1.26	0.8	0.35	1.34	3.3	1,085	4.98	-	-	-
24	Mix	x,y	0.21	0.19	0.6	0.28	0.2	0.77	1.49	1.1	4.53	-	-	-
86	Mix	x,y	0.3	0.21	0.78	0.47	0.27	1.3	2.06	1.19	6.26	-	-	-
78	Y	3D	0.91	0.44	2.45	1.13	0.52	3.01	2.6	1.61	8.86	-	-	-
60	Y	3D	1.35	0.65	2.69	1.79	1.01	4	6.53	4.31	18.64	-	-	-
22 38	Y Y	3D 3D	1.51 1.26	0.62	_	1.86 1.75	1.07 0.99	_	8.54 5.37	4.2 3.98	_	_	_	_
38 19	Y Y	3D 3D	1.26 1.56	0.66 0.53	- 3.43	1.75	0.99	- 3.22	5.37 4.3	3.98 3.12	- 11.09	-	-	_
19	Y	3D 3D	1.50	0.81	3.54	1.55	0.41	3.64	4.3 3.6	2.68	8.75	_	_	_

Table 4         Guided Systems Used in           Selected Studies								
System	No. of studies using system							
Nobel Guide	15							
SimPlant	9							
StentCad Classic/Beyond	4/1							
coDiagnostiX	3							
Exe-plan	3							
Dental Slice/NeoGuide	2							
Implant Viewer 1.9	2							
Facilitate (AstraTech)	1							
Implant 3D	1							

Differences in accuracy between each group were assessed by means of metaregression. A separate analysis was performed for each of the three types of deviation (eg, error at the entry point and apex, error in the angle).

In addition, forest plots were prepared to visualize the difference between groups. Since evidence of heterogeneity was observed between the publications, the totals were calculated using random effects metaanalysis for continuous variables.

For survival, a generalized linear mixed model for binary outcomes and a logit link was used to model implant failure rate.

#### RESULTS

After the initial search, a total of 3,971 titles were found. Because multiple search engines were used (PubMed & EMBASE) the duplicates needed to be filtered out, which reduced the number of articles to 2,359 titles. Subsequently, 139 abstracts of relevant studies were then selected by two reviewers. After reviewers examined and discussed the abstracts, 117 publications were selected, in consensus, for full-text evaluation. In addition, 12 full-text articles that were selected from the 2008 consensus statement<sup>5</sup> were analyzed and added to selected publications. The final selection as based upon full-text analysis and the inclusion and exclusion criteria resulted in 24 accuracy studies and 14 survival studies that could be used for data extraction (Fig 1).

#### Accuracy Studies

Twenty-four articles provided useful information on the accuracy of computer-guided (static) implant surgery (Table 3). Fourteen of these articles were clinical studies, while ten were in vitro (model, cadaver) studies. The sample size of the groups varied considerably with 15 to 279 implants in the clinical studies and 4 to 145 in vitro studies. Nine computer-guided systems were used (Table 4). Fifteen of all selected studies (and therefore the majority of the studies) used NobelGuide.

The deviation at the implant entry point was reported in 23 of the 24 studies while the angle and apex deviations were mentioned in 21 and 19 studies, respectively. For comparing the data as accurately as possible, the data were converted to 3D deviation when possible. This conversion resulted in suitability of 21 studies on entry point error and 17 on implant apex error for comparison. The deviations in implant height were only rarely reported and were converted to 3D deviation when available. Because of the limited reporting on this parameter, the implant height deviations were solely reported in the results (Table 3).

The overall average deviation at the implant entry point was 1.12 mm as measured in 1,530 implants, and the maximum reported deviation was 4.5 mm. As determined for 1,465 implants, the average deviation reported at the apex was 1.39 mm, with a maximum reported deviation of 7.1 mm. The largest number of measurements (1,854 implants) was performed on the implant angle; the average angular deviation was 3.89 degrees with a maximum reported deviation of 21.16 degrees.

Statistically significant differences were observed when the following parameters were compared:

- Study design
- Flapless versus flap approach
- Freehand versus guided implant placement
- Guide support

No statistically significant differences were found in the testing of modalities in maxilla vs mandible, fully edentulous vs partially edentulous, or the guide production. Table 5 shows the *P* values of the differences per compared parameter.

#### Study Design

**Cadaver Studies.** As measured in 390 implants, the lowest and highest mean deviations at the entry point in the cadaver studies were 0.8 and 1.5 mm, respectively. The minimum and maximum measured values were 0.07 and 3.54 mm, respectively. The lowest and highest mean errors at the apex were 0.9 and 1.84 mm, respectively, where as the lowest and highest values were 0.12 and 3.64 mm, respectively. The lowest and highest mean angular deviations were 1.8 and 7.9 degrees with the minimum and maximum values of 0.08 and 11.9 degrees, respectively.

**Model Studies.** As determined in only 74 implants, the lowest and the highest mean deviations at the entry point were 0.025 and 1.38 mm, respectively. The maximum and minimum deviations at the entry

	Gr	oup 1		Group 2				P-value	
Grouping	Method	n mean		Method	n	mean	Error	difference	
Implant insertion	Freehand placement	868	1.38 mm	Fully guided	1,011	0.78 mm	Entry	.002	
	Freehand placement	868	1.74 mm	Fully guided	1,011	1.08 mm	Apex	0	
	Freehand placement	868	4.35 Degree	Fully guided	1,011	2.57 Degree	Angle	0	
Flap	Flap raised	306	1.34 mm	Flapless	1,225	1.01 mm	Entry	.012	
	Flap raised	306	5.13 Degree	Flapless	1,225	3.42 Degree	Angle	.02	
Guide support	Bone	275	1.19 mm	Mini-implant	10	0.05 mm	Entry	.026	
	Bone (Clinical)	203	1.43 mm	Mucosa + pin (Clinical)	568	0.98 mm	Entry	.01	
	Bone (Clinical)	203	1.87 mm	Mucosa + pin (Clinical)	568	1.20 mm	Apex	.022	
	Bone (Clinical)	203	5.32 Degree	Mucosa + pin (Clinical)	568	3.57 Degree	Angle	.02	
	Bone (Clinical)	203	1.43 mm	Mucosa (Clinical)	177	1.07 mm	Entry	.015	
	Bone (Clinical)	203	1.87 mm	Tooth (Clinical)	299	1.15 mm	Apex	.007	
	Bone (Clinical)	203	5.32 Degree	Tooth (Clinical)	299	3.28 Degree	Angle	.006	
	Bone (Clinical)	203	1.43 mm	Tooth (Clinical)	299	0.84 mm	Entry	.001	
	Mucosa	177	4.73 Degree	Mucosa + pin	731	3.25 Degree	Angle	.041	
	Mucosa	177	4.73 Degree	Tooth	335	2.76 Degree	Angle	.024	
	Mucosa (Clinical)	177	1.64 mm	Tooth (Clinical)	299	1.15 mm	Apex	0	
	Mucosa (Clinical)	177	4.73 mm	Tooth (Clinical)	299	3.28 Degree	Angle	.034	
	Mucosa + pin	731	1.05 mm	Tooth	335	0.78 mm	Entry	.023	
	Mucosa + pin	731	1.05 mm	Mini-implant	10	0.05 mm	Entry	0	
	Tooth	335	0.78 mm	Mini-implant	10	0.05 mm	Entry	.016	
Study design	Cadaver	245	1.22 mm	Model	74	0.36 mm	Entry	.015	
	Clinical	1,560	0.78 mm	Model	74	0.36 mm	Entry	.002	
	Clinical	1,560	4.06 Degree	Model	74	1.44 Degree	Angle	.003	
	Clinical	1,560	1.45 mm	Model	74	0.73 mm	Apex	.017	

point were not often reported. The lowest reported value was 0 whereas the maximum measured value was 2.25 mm. The lowest and highest mean error at the apex was 0.34 and 1.39 mm, whereas the minimum and maximum reported values were 0.12 and 2.25 mm, respectively. The lowest mean angular deviation was 0.7 degrees, while the highest observed mean was 2.16 degrees. The minimum and maximum values were 0.3 and 2.16 degrees, respectively.

**Clinical Studies.** The majority of accepted studies were clinical studies, which assessed a total of 2,355 implants. The lowest and highest mean error at the entry point was 0.15 and 1.7 mm with minimum and maximum values of 0 and 4.5 mm, respectively. The mean apical deviation varied from 0.28 to 2.99 mm with a minimum and maximum of 0.3 and 7.1 mm respectively. The mean angular deviation ranged from 1.49 to 8.54 degrees with a minimum and maximum of 0 and 21.16 degrees, respectively.

A forest plot (Fig 4) shows the data for the deviation at the point of entry, the apex, and for the angulation based on the study design. Statistically significant differences were observed for all three parameters in the clinical trials versus the model studies. Model studies showed a significantly better accuracy. However, the number of implants (n = 245) tested in these studies was much lower than that (n = 1,560) used in the clinical assessments.

#### **Flapless versus Flap Approach**

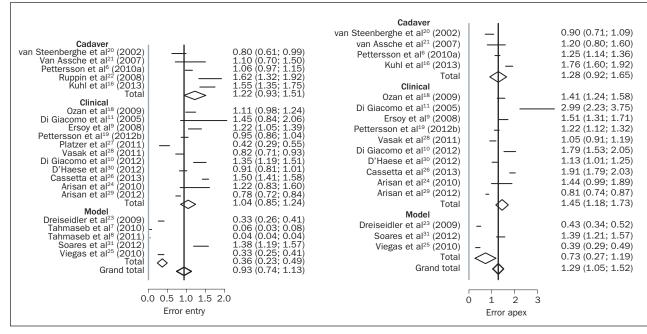
Figure 5 illustrates a forest plot presenting significant differences (P < .05) between cases treated with a flapless protocol compared to those in which a flap was raised. The flapless procedures seemed to show a significantly better accuracy.

#### **Freehand versus Guided Implant Placement**

Guided implant placement showed a statistically superior accuracy when they are compared with freehand placement after guided osteotomy (Fig 6).

#### **Guide Support**

When all study types (clinical, in vitro) were concerned, the accuracy of mini-implant–supported guides was significantly higher than all other types of support, except mucosa. Bone-supported guides showed significantly larger deviations than other types of guide support. Tooth-supported guides tended to be slightly more accurate than mucosa or mucosa and pin– supported guides; however, these differences were only found in some of the compared parameters. When only clinical studies were assessed, the accuracy of bonesupported guides were significantly lower in almost every compared parameter (Table 5). There were no clinical studies available that investigate accuracy when using mini-implants.





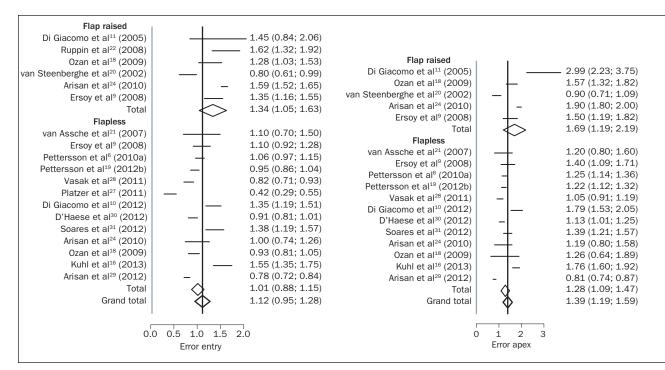
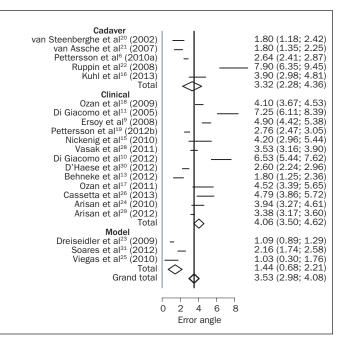
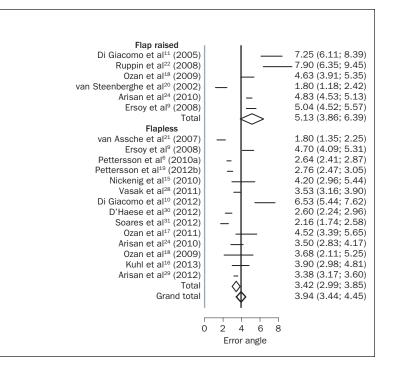


Fig 5 Forest plot illustrating mean deviation at all parameters, stratified by principle of the surgery (flap raised vs flapless).

Although no overall statistically significant differences were found in the remaining comparisons for guided implant placement, it may be of interest to state them briefly:

Maxilla versus mandible: No overall significant difference was found for any of these parameters between the two groups. However, some studies found significantly better accuracy in one arch compared to the other. Ozan et al<sup>17</sup> reported significantly better accuracy in the mandible when compared to the maxilla within the same study, whereas Pettersson et al<sup>6</sup> observed a statistically significant higher deviation





in the mandible. Of note, these studies used different supports for the surgical guides (eg, mucosa, mucosa and pin, tooth support).

Guide production: No overall significant differences were noted between different guide production types.

#### **Survival Studies**

Fifteen clinical studies reporting on implant survival for at least 12 months were selected (Table 6). Seven of these studies reported on bone loss. The average survival rate of the 1,941 implants included in this review was 97.3%. Several studies showed longer follow-up periods, while others had large dropouts at 12 months. Nevertheless, when only studies reporting on survival at 12 months were examined and further corrected for dropouts, the survival percentage was the same: 97.3%.

In 12 out of the 14 selected studies the implants were immediately loaded. Three studies even reported on immediate definitive prostheses. Sanna et al<sup>32</sup> and Johansson et al<sup>34</sup> used adjustable abutments while Tahmaseb et al<sup>12</sup> achieved sufficient accuracy to install the final prosthesis without adjusting abutments.

Eight studies reported on prosthetic survival. The average prosthetic survival rate based on these 211 prostheses was 95.5%.

There were no statistically significant differences between the various groups (immediate loading versus delayed loading, guide support). However, a slight difference in survival was observed between the maxilla and mandible in favor of the maxilla (*P* value difference of .14). Table 7 demonstrates the *P* value differences per reported parameter.

#### Complications

Within the 2,355 implants inserted in 343 treated cases, a total of 125 cases reported complications. Although the numbers should be interpreted with caution (not every study reports on all possible complications), a cumulative complication rate of 36.4% per case was calculated.

Eight studies recorded template fractures occurring during surgery. The incidence was 3.6% (7 out of 192 templates). All the fractures occurred in three of eight studies.

Ten studies reported surgical plan changes per implant. The overall incidence was 2.0% (23 out of 1,133 implants).

Five studies reported on implants lost during placement because of the lack of primary stability. This complication was recorded as occurring two times in one study and three times in another study.<sup>10,16</sup> The overall incidence was 1.3% (5 out of 383 planned implants). These implants were not counted in the implant survival since they were not successfully inserted in the first place.

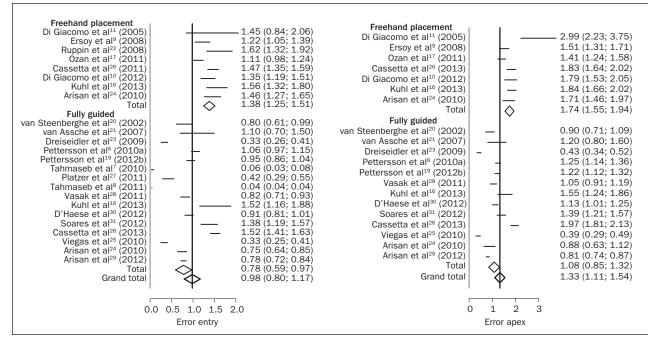
Ten studies recorded the occurrence of prosthesis fracture. The incidence was 10.19% (26 out of 238 prostheses).

Five studies registered the occurrence of screw loosening. The incidence was 2.9% (23 out of 798).

#### Table 6 Data of Clinical Studies on Implant Survival

Author	Year	Study design	System	Implant	Prosthetic appliance	Jaw	Guide support
Sanna et al <sup>32</sup>	2007	Prospective	NobelGuide	Nobel	FB	Maxilla	Mucosa + pin
Balshi et al <sup>33</sup>	2008	Retrospective	Nobel Guide	Nobel	FB	Both	Mucosa + pin
Johansson et al <sup>34</sup>	2009	Prospective	Nobel Guide	Nobel	FB	Maxilla	Mucosa + pin
Komiyama et al <sup>14</sup>	2008	Retrospective	Nobel Guide	Nobel	FB	Both	Mucosa + pin
Barter <sup>35</sup>	2010	Case series	CoDiagnostiX	Straumann	4 FPDs + 2 IOD	Maxilla	Mucosa + pin
Gillot et al <sup>36</sup>	2010	Retrospective	Nobel Guide	Nobel	FB	Maxilla	Mucosa + pin
Meloni et al <sup>37</sup>	2010	Retrospective	Nobel Guide	Nobel	FB	Maxilla	Mucosa + pin
Nikzad et al <sup>38</sup>	2010	Prospective	SimPlant	div.	FPDs	Mandible	Tooth
Pomares <sup>39</sup>	2010	Retrospective	Nobel Guide	Nobel	FB	Both Maxilla Mandible	Mucosa + pin
Van de Velde et al <sup>40</sup>	2010	RCT	SimPlant	Straumann	FB	Maxilla	Tooth
Landázuri-Del Barrio et al <sup>41</sup>	2013	Prospective	Nobel Guide	Nobel	FB	Mandible	Mucosa + pin
Abboud et al <sup>42</sup>	2012	Retrospective	NobelGuide	Nobel	3 FPDs + 3 FB	Both	Tooth or Mucosa + pin
			SimPlant	Ankylos	4 FPDs + 4 FB	Both	Tooth, bone, or mucosa
Di Giacomo et al <sup>10</sup>	2012	Prospective	Implant Viewer 1.9	E-fix	FB	Both	Mucosa + pin
Tahmaseb et al <sup>12</sup>	2012		Exe-plan	Straumann	FB	Both Maxilla Mandible	Mini-implants

FB = fixed full-arch bridge; FPDs = fixed partial dentures; IOD = implant-supported overdentures; NR = not reported; div = diverse; \*cumulative survival rate.



**Fig 6** Forest plot illustrating mean deviation of all parameters, stratified by principle of the implant insertion (freehand placement vs guide implant placement).

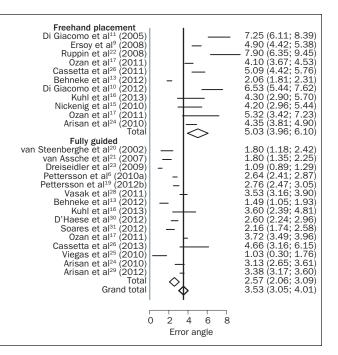
Seven studies reported on the occurrence of misfit at the time of the superstructure connection. The incidence was 18.0% (34 out of 189 prostheses).

Five studies reported on the need for extensive occlusal adjustment after placement of the superstructures. The incidence was 4.6% (7 out of 153 prostheses).

#### DISCUSSION

This review systematically evaluated the literature regarding accuracy and clinical outcome of static computer-assisted (static) implant dentistry. The main differences between this systematic review and the

Immediate loading	Mean age (y)	Age range	Patients (prosthesis)	Implants	Implants placed with flapless surgery	Lost to follow-up at 12 mo	Implant survival (mo)	Implants lost (n)	Implant survival (%)	Prosthesis survival (%)
Y	56	38–74	30	212	212	NI = 13	12 12–66	0 9	100 91.5*	NR NR
Y	NR	NR	23	168	168	NI = 122	12	4	97.6*	100
Y	72	37–85	52	312	312	NP = 4	12	2	99.4*	96.2
Y	71.5	42-90	29 (31)	176	176	NI = 45	12	19	91.5*	83.9*
Ν	63	54–71	6	43	43	0	60	1	97.7	NR
Y	61.2	46-80	33	211	211	NP = 1	12	2	99.1*	100
			1–32	8–204	204		12–51	4	98.1*	100
Y	52	40–70	15	90	90	0	18	2	97.8	NR
N	51.9	42–66	16	57	57	0	12	2	96.5	NR
Y	53	35–84	30 (42)	195	191	0	12	4	98.0	NR
			25	128	NR	0	12	2	98.5	NR
			17	67	NR	0	12	2	97.5	NR
Y	55.7	39–75	13	36	36	NP = 1	12	1	97.3*	NR
							18	1	97.3*	NR
Y	59	49–73	16	64	64	0	12	6	90.0	93.8
Y	60.1	56–66	6	41	41	0	12	1	97.6	100
Y	59.2	51-77	8	34	0	0	12	0	100	100
Y	60.3	41-71	12	62	60	0	30	1	98.3	91.7
Y	NR	NR	35 (40)	240	234	0	12	11	95.4	97.5
			(25)	150	144	0	12	10	93.6	96.0
			(15)	90	90	0	12	1	98.8	100



recent publication by Van Assche et al <sup>43</sup> can be sum-
marized in the fact that in this review only the mea-
surements based on actual implant placement were
included, whereas in the European Association for
Osseointegration consensus publication, the osteoto-
mies without implant placement were also analyzed.

Table 7         P Values by Survival Parameter	rs
Effect	P value
Differences in survival rate per jaw	
Mandible-maxilla	.1459
Differences in survival rate per guide support	
Mini-implants–mucosa + pin	.6717
Mini-implants-tooth	.9787
Mucosa + pin-tooth	.9142
Differences in survival rate per time of loading	
Not immediate-immediate	.7207

In addition, in this systematic review, both accuracy and survival studies were analyzed and there were slightly more accuracy studies included.

Nine different static image guidance systems were reported in the literature. Based on 14 included clinical studies with a total of 1,941 implants using static computer-assisted guided implant surgery, it was demonstrated that the mean failure rate was 2.7% (0% to 10%) after an observation period of at least 12 months. Twenty-four clinical and preclinical studies that assessed the accuracy of static implant density demonstrated the accuracy at the entry point to have a mean error of 1.12 mm, with a maximum of 4.5 mm, while at the apex the mean error was 1.39 mm, with a maximum of 7.1 mm.

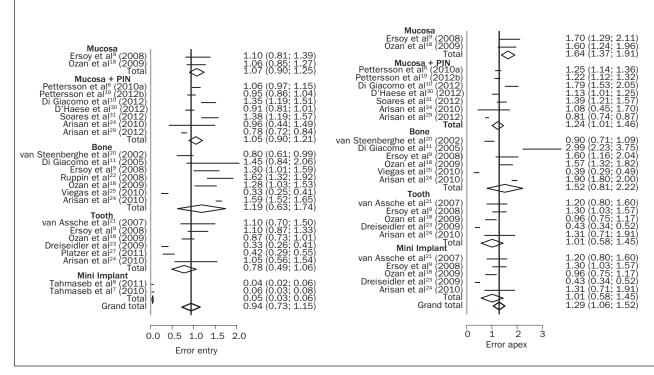


Fig 7 Forest plot illustrating statistical evaluation based on the guide support (tooth, bone, mucosa, and mucosa + pin support).

#### **Survival Studies**

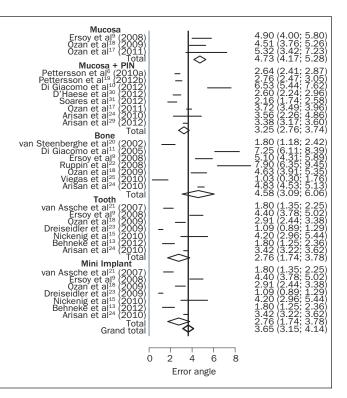
This review systematically demonstrated with the limitation of the executed studies that the overall success rates of implants inserted using computer-guided surgery are comparable to implants placed following a non-guided protocol.<sup>44,45</sup>

However, several issues need to be considered before any significant conclusions can be drawn. For example, considerable inconsistency was observed between implants placed in the maxilla and those placed in the mandible. Pomares<sup>39</sup> reported more failures in the lower jaw whereas Tahmaseb et al<sup>12</sup> reported a higher failure rate in the upper jaw. However, different external factors, such as sinus augmentation procedures, could have influenced the results. In addition, some selected studies<sup>14,33</sup> suffered a substantial number of dropouts, which could have affected the survival rate considerably, as well as the different approaches used to restore the patients. Furthermore, most of the studies reported on the superstructures involving only provisional prostheses where the existing dentures were post-surgically adapted to the inserted implants postsurgical.<sup>36,39,40</sup> Tahmaseb et al<sup>12</sup> used a system in which provisional mini-implants were inserted prior to actual surgery, thus achieving a level of accuracy that allowed the fabrication of the final prosthesis.

An overall, surgical and prosthetic, complication rate of 36.4% was found for the selected studies. The incidence of surgical complications was significantly lower (35) than the prosthetic complication rate (90). However these numbers (ie, 125 complications in 343 treated cases) have to be interpreted with caution, since even minor complications, such as a loose screw in a single implant, were considered as a prosthetic complication.

#### Accuracy Studies

Computer-guided implant procedures have often been recommended for flapless surgery for situations with a limited bone quantity, or in critical anatomical situations (eg, an implant to be placed adjacent to mandibular nerve). Therefore, knowledge of the potential maximal implant deviations of these systems are highly relevant to daily clinical practice. The analyzed data showed an inaccuracy at the implant entry point of 1.12 mm with maximum of 4.5 mm and an inaccuracy of 1.39 mm at the apex of implants with maximum of 7.1 mm. However, the maximal measured deviations occurred in two studies<sup>11,26</sup> and were far from the acceptable range. The outliers might be related to external factors. For example, Di Giacomo et al<sup>11</sup> proposed that the differences in the deviation



might be caused by movements of the surgical guide during implant preparation. This group suggested further improvements that could provide better stability of the template during surgery when unilateral bonesupported and non-tooth-supported templates are used. Moreover, SLA (computer-assisted manufacture [CAM]) guides had slightly better accuracy than the lab guides (non-CAM), although the number of cases was significantly lower for the non-CAM group (171 vs 1,569 implants). Furthermore, the support of guides has a significant impact on accuracy (Fig 7). Tahmaseb et al<sup>7</sup> showed that guides supported by mini-implants provided better accuracy than all the other types of support. This might be the result of the reproducibility of the template position during the acquisition of radiographic data and during implantation, especially in edentulous patients. This group also used a system with a vertical control device and adjustable osteotomy drills, which might have improved the precision. Moreover, for the clinical studies (Fig 8), a statistically significant lower accuracy was observed in the bonesupported guides. These results could also explain why the flapped approaches had a much lower accuracy than the flapless ones (Fig 4), as the majority of treatments where a flap was raised conducted bonesupported surgical guides.

The authors intentionally decided not to include studies that analyzed the accuracy of computerguided surgery if they only reported the position of the osteotomy, but the actual implant was not inserted.<sup>15,18–20,22–26,29</sup> The reason for this exclusion is that guided drill holes after osteotomy are only an indication of the position and cannot be compared with the actual implant positions, since implants can be inserted in a deviant position. This exclusion would lead to a more meaningful comparison. Nonetheless, Table 8 shows a list of the studies assessing the accuracy based only on osteotomies.

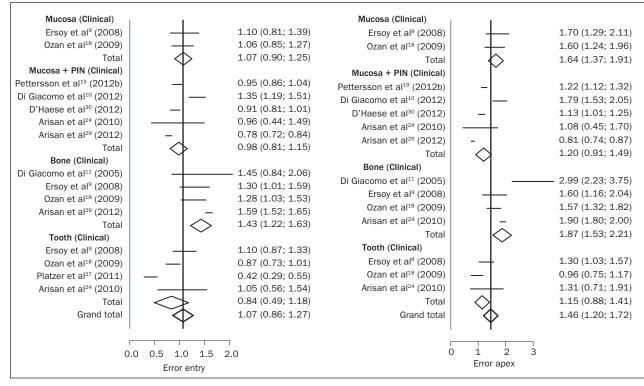
When comparing the data for the maxilla and mandible, some publications reported no differences.<sup>9,29</sup> Ozan et al<sup>17</sup> reported significantly better accuracy in the mandible compared to the maxilla within the same study, while others<sup>10</sup> reported profoundly higher deviations in the maxilla as well. However, Pettersson et al<sup>6</sup> observed a statistically significant higher deviation in the mandible. RCTs looking to these factors individually might shed light on their impact on overall precision.

Even though implant placement with a flapless approach seems to show significantly more accuracy, one has to interpret these numbers with care. All six studies where a flap was raised reported the use of bonesupported drill guides. The inaccuracy might thus be related to the guide design rather than to the raising of a flap as such.

As demonstrated in the studies selected in this systematic review as well as recent EAO consensus publication on the same topic,43 different factors (teeth- versus mucosa- versus implant-supported; type of guidance, etc) can play a crucial role in the overall success of these advanced techniques. Therefore, it would be of high importance to perform randomized clinical trials, analyzing the importance of one specific factor separately and the impact of their mutual interactions. Generally it can be assumed that an accumulation of series of different types of errors can occur during the entire diagnostic and operative procedure leading to larger implant deviations. Finally, because of different study designs (human versus cadaver or model, drill holes versus implants, or different evaluation methods), it is not possible to identify one system as superior or inferior to others.

## CONCLUSIONS

As observed in this systematic review, nine different computer-assisted (static) guided implant systems are described in the literature. The clinical performance of these systems reveals a high implant survival rate of 97.3% after 12 months of observation in different



**Fig 8** Forest plot illustrating statistical evaluation based on the guide support in clinical studies only (tooth, bone, mucosa, and mucosa + pin support).

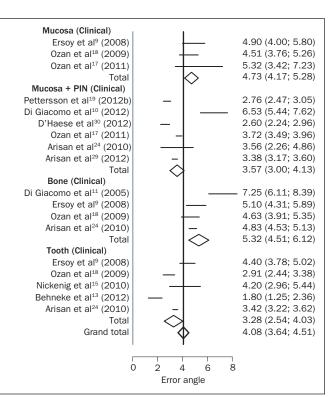
Table 8         Studies Excluded Reporting Only Osteotomy Position										
Author	Year	Study design	Method							
Sarment et al	2003	Model	CBCT scanning of drill holes							
Widmann et al	2007	Model	Distance between drill holes measured on CBCT							
Widmann et al	2009	Model	CBCT scanning of drill holes							
Kero et al	2010	Cadaver	Just virtual implantation; but part 1 was included <sup>6</sup>							
Abboud et al	2011	Model	Distance between two drill holes measured on CBCT							
Chan et al	2011	Model/clinical	Angular deviations of several systems compared with CBCT scans of inserted wooden sticks							
Murat et al	2011	Cadaver	CBCT of cadaver with guided inserted drills							
Nokar et al	2011	Model	Optical scanning of drill holes							
Paris et al	2011	Cadaver	Not implants but fit of special tubes was compared							

clinical situations. Furthermore, a high overall rate of surgical and prosthetic complications and unexpected events of 36.4% occurred at different levels of complexity.

The accuracy of these systems depends on all the cumulative and interactive errors involved, from dataset acquisition to the surgical procedure. The metaanalysis of the in vitro and in vivo studies revealed a total mean error of 1.12 mm at the entry point and 1.39 mm at the apex.

Furthermore, it can be stated that the tooth- and mucosa-supported guides seem to have a better ac-

curacy compared to the bone-supported guides. A different level of evidence was stated although longterm RCTs were lacking. Long-term clinical data and randomized clinical trials are necessary to detect and understand the different factors individually and their mutual interaction influencing the accuracy of these techniques. Additionally, as it was concluded in the ITI systematic review in 2008,<sup>5</sup> no evidence yet suggest that computer-assisted surgery is superior to conventional procedures in terms of safety, outcomes, morbidity, or efficiency.



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## Systematic Review on Success of Narrow-Diameter Dental Implants

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Purpose: The aim of this systematic review was to determine the survival and success rates of narrowdiameter implants (NDI) in different clinical indications compared to standard diameter implants. Materials and Methods: Implant diameters were categorized into categories 1 (< 3.0 mm), 2 (3.00 to 3.25 mm), and 3 (3.30 to 3.50 mm). Retro- and prospective studies with more than 10 patients and a follow-up time of 1 year or more were included. Results: A literature search from 1995 to 2012 revealed 10 articles reporting on implant diameters < 3 mm (Category 1), 12 articles reporting on implant diameters 3 to 3.25 mm (Category 2), and 16 articles reporting on implant diameters 3.3 to 3.5 mm (Category 3). The quality of the studies was mostly low with a high risk of bias. Dental implants < 3.0 mm (mini-implants) were one-piece in the edentulous arch and non-loaded frontal region with survival rates between 90.9% and 100%. For dental implants with a diameter between 3.0 and 3.25 mm, most were two-piece implants inserted into narrow tooth gaps without loading and in the frontal region. Survival rates for these implants ranged between 93.8% and 100%. Implants of 3.3 to 3.5 mm were two-piece and were also used in the load-bearing posterior region. Survival rates were between 88.9% and 100%, and success rates ranged between 91.4% and 97.6%. A meta-analysis was conducted for NDI (3.3 to 3.5 mm), which showed no statistically significant difference in implant survival compared to conventional implants with an odds ratio of 1.16 (0.7 to 1.69). Conclusions: Narrow-diameter implants of 3.3 to 3.5 mm are well documented in all indications including load-bearing posterior regions. Smaller implants of 3.0 to 3.25 mm in diameter are well documented only for single-tooth non-load-bearing regions. Mini-implants < 3.0 mm in diameter are only documented for the edentulous arch and single-tooth non-load-bearing regions, and success rates are not available. Long-term follow-up times > 1 year and information on patient specific risk factors (bruxism, restoration type) are also missing. INT J ORAL MAXILLOFAC IMPLANTS 2014;29 (SUPPL):43-54. doi: 10.11607/jomi.2014suppl.g1.3

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H istorically, implants have been used and documented mainly with diameters between 3.75 mm and 4.1 mm. Employing these diameters for numerous indications, scientifically substantiated treatment protocols with excellent long-term results have been established.<sup>1,2</sup> These types of implants are widely regarded as standard-diameter implants. Fracture of the abutment or implant body of a standard-diameter implant is an extremely rare condition, even after long term use. In a recent review from Sánchez-Pérez et al, the authors estimated a risk of approximately two fractures per 1,000 implants in the mouth.<sup>3</sup> One disadvantage of a standard-diameter implant is the fact that, in clinical use, the available horizontal crestal dimensions of the alveolar ridge as well as the spaces between adjacent teeth and dental implants are sometimes too small. Although there is some discussion on the amount of bone (buccal and oral) necessary for a successful dental implant, most authors advise at least 1 mm residual bone present adjacent to the implant surface, which consequently requires a horizontal crestal alveolar width of 6 mm for a standard implant. However, the exact threshold for the residual buccal bone thickness has yet not been scientifically clarified and is still under discussion. Furthermore, based on available studies, a 3-mm interimplant distance seems to be beneficial for adequate papillary fill.<sup>4,5</sup> As implant diameters have been established historically, the

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question has been raised whether optimal implant diameters might be smaller than the "standard diameter" for many indications.

Narrow-diameter implants (NDI) would be beneficial to decrease the rate of augmentations necessary for implant insertion. This might help especially elderly patients or patients with general medical risk factors who would benefit from implant therapy with reduced surgical invasiveness. Epidemic studies showed that especially elderly edentulous patients are not able or willing to undergo expensive surgical procedures.<sup>6,7</sup> Furthermore, there are concerns and restrictions against time-consuming treatments associated with complications and pain.<sup>8,9</sup> The other important indication, for which NDI would be beneficial, are small interdental or interimplant gaps, which are often found in the premolar or incisor region. Therefore, the employment of NDI ( $\leq$  3.5 mm) might broaden the treatment spectrum and also help to reduce or avoid augmentation procedures.

However, several potential biomechanical risk factors have been identified for NDI. In vitro studies and finite element analyses have illustrated that stress values affecting the crestal cortical bone are reciprocal to the dental implant diameter, which means that especially small diameters result in disadvantageous stress peaks at the implant-bone interface.<sup>10</sup> Ding et al showed that the stress values at the implant-bone interface rise more significantly by reducing the diameter from 4.1 mm to 3.3 mm, compared to reducing the diameter from 4.8 mm to 4.1 mm.<sup>11</sup> As a biological implication, inadequate overloading of NDI might possibly lead to disadvantageous peri-implant crestal bone resorption resulting in clinical complications. The implant itself is also more prone to fatigue fracture as a result of a reduced implant diameter.<sup>12</sup> One way of increasing the implant fracture resistance is to use an alloy instead of commercially pure titanium (cpTi). Most available NDIs are made of Ti-Al-V. However, this alloy is lesser biocompatible than cpTi in cell cultures and animal experiments.<sup>13</sup> The clinical relevance of this finding is critically discussed. Recently, a titaniumzirconium (TiZr) alloy is commercially available with increased fatigue resistance and unimpaired biocompatibility compared to cpTi.<sup>14,15</sup>

Until now, the use of NDI has been restricted to certain defined indications with comparable low occlusive loading like incisors or as retaining elements for overdentures. Before NDI can be recommended in a broader clinical setting, the analysis of available external evidence is necessary. The aim of the present systematic review was to determine the survival and success rates of NDI in different clinical indications compared to standard-diameter implants.

### **MATERIALS AND METHODS**

Evaluation criteria were defined in accordance to the PICO(S) (Patient or Population, Intervention, Control or Comparison, Outcome and Study types) criteria.

### **Patient Selection**

The present review includes studies with patients scheduled for insertion of at least one dental implant into the maxilla and/or mandible with insufficient bone volume (eg, narrow alveolar ridge) and/or limited interdental space requiring diameter-reduced endosseous dental implants. The mandatory time interval after tooth removal was defined as  $\geq$  6 weeks. No simultaneous bone augmentation procedure was allowed. Only healthy patients with no systemic illness affecting bone metabolism and no signs of local infection were included in the studies. There were no restrictions to sex and age.

#### Intervention: Narrow-Diameter Dental Implants

Only studies involving dental implants  $\leq$  3.5 mm in diameter were included with no restrictions to implant length. Looking at the different NDI, it becomes obvious that not all implants with a diameter  $\leq$  3.5 mm are comparable with each other. Following the manufacturers' indications for use, the implant diameters were categorized as follows:

- Category 1: < 3.0 mm (mini-implants)</li>
- Category 2: 3.00 to 3.25 mm (single-tooth indications)
- Category 3: 3.30 to 3.50 mm (broader indications)

Implant type, manufacturer, and implant characteristics were documented.

Implant indications were categorized as follows:

- Edentulous arch (maxilla and/or mandible),
- Single-tooth gap without loading of the prosthesis (eg, second incisor),
- Prosthetic loadbearing in the frontal region,
- Prosthetic loadbearing distal to the canine tooth.

Furthermore, the type of surgery (raising of a fullthickness flap vs transmucosal implant insertion), healing mode (subgingival vs transgingival), and restoration type (fixed vs overdentures) was described.

#### **Control Groups**

Within each included study, groups with conventionalsized dental implants (> 3.5 to 4.5 mm) were accepted as control groups.

### Table 1 Systematic Search Strategy

#### Focus question: How do the survival and success rates and bone level development of narrow-diameter dental implants compare to standard-diameter implants?

#### Search strategy

Search strategy	
Population	Edentulous OR partially edentulous
Intervention or exposure	Dental implantation with NDI
Comparison	Other diameters than NDI
Outcome	Implant survival, implant success, marginal bone level under functional loading
Search combination	"small diameter dental implants": 107 hits "narrow diameter dental implants": 68 hits "narrow dental implants": 225 hits "small dental implants": 720 hits "diameter dental implants": 1,107 hits "mini-implants": 767 hits
Database search	
Electronic	PubMed
Journals	-
Selection criteria	
Inclusion criteria	Clinical studies of at least 10 treated patients, published in English prospective: randomized-controlled, non-randomized-controlled, cohort studies retrospective: controlled, case control, "single cohort"
Exclusion criteria	Studies in languages other than English Studies with < 10 patients, case reports, animal models or experimental in vitro studies Reviews Mini-implants for orthodontic anchorage Studies dealing with simultaneous bone augmentation procedures Studies with mean follow-up time < 1 year

## Outcome

Outcome parameters were defined with respect to existing reviews and the main outcome parameters of the included studies:

 Dental implant survival under a follow-up of at least 12 months. Survival was defined as in situ or not planned for removal at the time of clinical control.

Implant success:

- Clinical success (implants in function, no signs of peri-implantitis, etc). There was no unique definition of implant success within the various investigated studies.
- Development of the marginal peri-implant bone level under functional loading.

### **Study Types**

Clinical studies on dental implant survival under functional loading, as well as radiographic analysis of the marginal bone level including at least 10 treated patients and published in English journals were evaluated. The following study designs were included:

- Prospective: randomized-controlled, nonrandomized-controlled, cohort studies
- Retrospective: controlled, case control, single cohort

## **Exclusion Criteria**

The following studies were excluded:

- Studies composed of languages other than English
- Studies with < 10 patients, case reports, animal models, or experimental in vitro studies
- Reviews
- Mini-implants for orthodontic anchorage
- Studies dealing with simultaneous bone augmentation procedures
- Studies with mean follow-up time < 12 months

### Search Strategy for Identification of Studies

A systematic PubMed literature search was performed between 1995 and 2012, including the following terms (Table 1):

- "Small diameter dental implants": 107 hits
- "Narrow diameter dental implants": 68 hits
- "Narrow dental implants": 225 hits

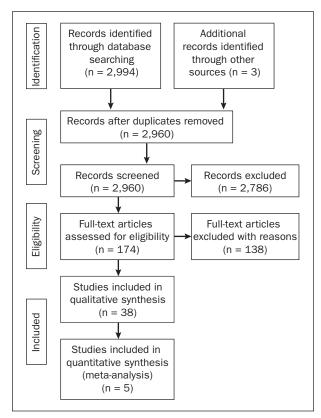


Fig 1 PRISMA Flow Diagram.

- "Small dental implants": 720 hits
- "Diameter dental implants": 1,107 hits
- "Mini-implants": 767 hits

Reference lists of the included articles (including selected reviews) were checked for additional publications of relevance. The last search was performed on November 24, 2012. After reviewing all abstracts, relevant full-text articles were obtained. Outcome parameters, descriptive summaries of the relevant study characteristics, and influence parameters (study design, number of patients, number of inserted dental implants, implant characteristics, indications, surgical technique, healing modus, etc) of the respective included studies were tabulated.

## Study Selection, Data Extraction, and Quality Assessment

Two independent observers independently scanned the abstracts and later the pre-selected full-text articles. For studies meeting the inclusion criteria, full-text manuscripts were obtained and evaluated further.

All studies meeting the inclusion criteria were subject to further data extraction. Data were extracted

using structured data extraction forms. Any disagreement was discussed and an additional review author was consulted when necessary. Kappa value as a measure of concordance was documented. The PRISMA flow diagram depicts the flow of information through the different phases of a systematic review (Fig 1). It maps out the number of records identified, included and excluded, and the reasons for exclusions.

After a first search, it was clear that no prospective randomized studies could be found for the defined PICO question. Thus, in the present review, the best available external evidence was collected. The authors are aware that the risk of bias is higher compared with other reviews that include only randomized studies. To reduce the risk of bias, the tangible and objective main outcome criterion of implant survival and the objective secondary outcome criterion of marginal bone level changes were chosen.

## RESULTS

The electronic search in the database PubMed provided a total of 2,994 abstracts that were considered potentially relevant (Fig 1). In the second phase of study selection, complete texts of 174 articles were sampled and reviewed. Throughout this procedure, 38 articles were selected. These articles were further subdivided into three categories according to the diameter of the investigated implants: 10 articles reporting on implant diameters < 3 mm (category 1), 12 articles reporting on implant diameters 3 to 3.25 mm (category 2), and 16 articles reporting on implant diameters 3.3 to 3.5 mm (category 3) were provided. Altogether in the investigated studies, 3,151 patients received a total of 7,742 NDI. Data on the implant material were only rarely available and could not be interpreted systematically. It should be noted that to the authors' knowledge, < 3 mm implants were all made of Ti-Al-V. In category 3, TiZr alloys were described in three studies.<sup>16–18</sup> Table 2 provides an overview of the different dental implant diameters employed.

## **Results of Quality Assessment of Selected Studies**

The overall proportion of inter-reviewer agreement was 93.4%, indicating an 'excellent' level of agreement.<sup>19</sup> In general, quality and level of evidence of the investigated articles were low. Most of the studies were retrospective analyses. The allocation concealment was at high risk of bias, the lack of reporting characteristics of drop-out, missing blind examiners to assess clinical outcomes, and the lack of CONSORT adherence suggests caution with data interpretation and drawing general conclusions out of these studies.

## Implant Survival, Implant Success, and Marginal Bone Level Under Functional Loading

Diameter Category 1. The mean functional follow-up of the investigated dental implants < 3.0 mm (miniimplants) ranged between 12 and 96 months (Table 3). Most of the implants used were one-piece implants and had a diameter of 1.8, 2.4, or 2.5 mm. The only defined indications were the edentulous arch and the nonloaded frontal region. In five out of seven studies in which the type of flap was described, an open procedure was performed. In most of the studies, the implants were loaded immediately with an overdenture. Survival rates of the dental implants < 3.0 mm were described to be between 90.9% and 100%. Only one study provided an implant success rate (92.9%). In radiological assessments, 24 months after dental implant insertion, the average peri-implant bone loss was 0.98 ± 0.36 mm.

**Diameter Category 2.** For the investigated dental implants with a diameter between 3.0 and 3.25 mm, mean follow-up was between 12 and 63 months (Table 4). The predominant study design was a single arm prospective or retrospective study. Most of the implants used were two-piece implants with a diameter of 3.0 mm. The leading indication for these implants was the narrow tooth gap without loading and frontal region. The shortest implant length was 10 mm. In every study a flap was raised for implant insertion. Implants were either loaded directly or after a healing time of 6 to 24 weeks. Survival rates for these implants ranged between 93.8% and 100%, and the implant success rate was only described in one study. Average peri-implant bone loss after 12 months was  $0.78 \pm 0.48$  mm.

**Diameter Category 3.** The literature research showed a follow-up of dental implants in category 3 (3.3 to 3.5 mm) between 12 and 144 months (Table 5). All implants used were two-piece with a shortest length of 8 mm. The indications were not well defined in every case, but also included the load-bearing posterior region. A flap was raised for implant insertion in every study. Healing was either sub- or transgingival. Healing time ranged from 6 to 24 weeks. Survival rates were between 88.9% and 100% and success rates between 91.4% and 97.6%. Radiological assessments indicated an average peri-implant bone loss of 0.31  $\pm$  0.03 mm after 12 months.

### Meta-analysis of Survival of NDI Versus Conventional Implants

For category 1, only one study with a control group,<sup>20</sup> and for category 2, only two studies with a control group<sup>20,31</sup> were found in the database. Therefore, a meta-analysis regarding the survival rate could not be conducted for these categories. For category 3, five studies with a control group were found. Begg and

Table 2	Dental Implants by Diameter Category									
Category	Diameter	Implants								
1	< 3.0 mm	3,656								
2	3.0–3.25 mm	672								
3	3.3–3.5 mm	3,414								

Mazumdar's funnel plot, as shown in Fig 2, illustrates a low risk for publication bias for this meta-analysis. Since all studies had quite similar follow-up times, a meta-analysis of the event rate (implant failure) in the test groups (3.3 to 3.5 mm) versus control (standard diameter) was performed. Data are given as odds ratio with 95% confidence interval (CI) and a forest plot was created using RevMan Version 5 (Cochrane IMS). No statistically significant difference in implant survival was demonstrated between NDI (3.3 to 3.5 mm) and conventional implants (odds ratio: 1.16 [0.7 to 1.69]) (Table 6).

## DISCUSSION

Up to date, only few comparative prospective clinical studies, especially randomized ones, are available to document survival or success rates of NDI. Therefore, the authors decided to also include observational studies into this review. It should be pointed out that many of these studies did not clearly report a follow-up rate as suggested by the STROBE criteria on reporting observational data.<sup>54</sup> The data from these trials, particularly the retrospective ones, should be interpreted with caution.

Survival rates of NDI appear to be similar compared to those of regular diameter implants (> 3.5 mm). In the current review, the majority of investigated studies reported survival rates > 95% and no study reported survival rates below 88%. This might suggest a reliable therapy option, but evaluation of the success of the employment of small diameter dental implants should not be carried out exclusively by determination of implant survival. The reported indications, implant success, and changes of the marginal bone level should also be considered.<sup>55</sup> There exist various intrinsic and extrinsic factors which may impact peri-implant marginal bone stability. Important intrinsic factors are quantity and quality of surrounding hard and soft tissue. As already stated in the introduction, certain crestal alveolar dimensions as well as distances between adjacent teeth and dental implants are of crucial importance for the establishment and maintenance of a stable biological width. Extrinsic, implant-related factors affecting the marginal bone level are implant design (dimensions,

Table 3 Summary of	Studi	es on Im	plants wit	h < 3 mm	Diameter (C	Category 1)		
Study	Study type	No. of patients	Mean age (range)	Implant design	Diameter (mm)	Length (mm)	Implants	Indication (jaw region)
Anitua et al <sup>20</sup>	RS	ND	ND	Two-piece	2.5 3.75 (C)	10–15 7.5–18	38 1,654	ND (MAN + MAX)
Anitua et al <sup>21</sup>	RS	51	55 (19–90)	One-piece	2.5	10–15	31	ND (MAN + MAX)
Balaji et al <sup>22</sup>	RS	11	29 (20–52)	One-piece	2.4	13	11	III (MAN + MAX)
Elsyad et al <sup>23</sup>	PS	28	63 (49–75)	One-piece	1.8	12, 14, 16, 18	112	I (MAN)
Froum et al <sup>24</sup>	RS	27		Two-piece	1.8, 2.2, 2.4	7, 10, 14	48	III (MAN + MAX)
Jofre et al <sup>25,26</sup>	RCT	45	(45–90)	One-piece	1.8	15	90	I (MAN)
LaBarre et al <sup>27</sup>	RS	ND	ND	ND	1.8-2.4	ND	626	ND
Morneburg and Proschel <sup>28</sup>	PS	67	69 (53–83)	One-piece	2.5	9, 12, 15	134	I (MAN)
Shatkin et al <sup>29</sup>	RS	531		ND	1.8-2.4	ND	2,514	ND (MAN + MAX)
Vigolo and Givani <sup>30</sup>	RS	44	35 (18–74)	Two-piece	2.9	8.5, 10, 13, 15	52	II (MAX + MAN)

C = control; MAN = mandible; ND = no data available or data cannot be separated; OV = overdenture; PLS = plasma sprayed; PRGF = preparation rich in growth factors; PS = prospective study; RS = retrospective study; RCT = randomized controlled trial; SG = subgingival;

TG = transgingival; Ti = titanium; TiZr = titanium-zirconium. Indications: I: edentulous jaw; II: narrow tooth gap without loading;

III: loading of the frontal region; IV: loading distal of the canine.

#### Table 4 Summary of Included Studies on Implants with 3.0 to 3.25 mm Diameter (Category 2)

Study	Study type	No. of patients	Mean age (range)	Implant design	Diameter (mm)	Length (mm)	Implants	Indication (jaw region)
Andersen et al <sup>31</sup>	PS	55	23 (17–54)	Two-piece	3.25 3.75 (C)	13, 15	60 32 28	II, III (MAX)
Anitua et al <sup>20</sup>	RS	ND		Two-piece	3.0 3.75 (C)	10–15	69	ND (MAN + MAX)
Anitua et al <sup>21</sup>	RS	51	55 (19–90)	Two-piece	3.0	10–15	58	ND (MAN + MAX)
Degidi et al <sup>32</sup>	PS	40	(55 ± 17)	Two-piece	3.0	11, 13, 15	93 48 45	IV IV (MAX) IV (MAN)
Degidi et al <sup>33</sup>	RCT	60	32 (18–55)	Two-piece	3.0	13, 15	60 30 30	III (MAX)
Galindo-Moreno et al <sup>34</sup>	PS	69	$(32 \pm 17)$	Two-piece	3.0	11, 13, 15	97	II (MAN + MAX)
Mazor et al <sup>35</sup>	RS	33	49.2 (23–76)	Two-piece	3.0	13	66	II (MAN + MAX)
Oyama et al <sup>36</sup>	PS	13	32.9 (18-84)	Two-piece	3.0	ND	17	II (MAN + MAX)
Polizzi et al <sup>37</sup>	RS	21	30 (13–58)	Two-piece	3.0	10, 13, 15	30	II (MAN + MAX)
Reddy et al <sup>38</sup>	RS	17	(19–74)	One-piece	3.0	ND	31	II (MAN + MAX)
Sohn et al <sup>39</sup>	RS	36	53 (42–72)	One-piece	3.0	12, 15	62	II (MAN + MAX)
Zembic et al <sup>40</sup>	RS	47	31 (17–76)	One-piece	3.0	13, 15	57	II (MAN + MAX)

C = control; MAN = mandible; ND = no data available or data cannot be separated; OV = overdenture; PLS = plasma sprayed;

PRGF = preparation rich in growth factors; PS = prospective study; RS = retrospective study; RCT = randomized controlled trial;

SG = subgingival; TG = transgingival; Ti = titanium; TiZr = titanium-zirconium. Indications: I: edentulous jaw; II: narrow tooth gap without loading; III: loading of the frontal region; IV: loading distal of the canine.

implant-abutment interface), insertion depth, implant angulation, and the overall number of inserted implants. Additionally, the overall treatment plan has to deal, in some cases, with parafunctional activities like bruxism. The categorization of the implants into three groups according to their diameter was a hypothesis that seems to be supported by the indications in which the respective implants were used:

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Flap elevation	Healing	Healing period (wk)	Restoration type	Follow-up (mo; mean, range)	Implant failures (survival rate)	Implant success rate	Mean bone level (mm)
Yes	ND	ND	OV, fixed	29	1 (97.4%) 9 (99.5%)	ND ND	ND ND
Yes	ND	ND	OV, fixed	48	1 (98.9%)	ND	-1.26 ± 0.5 (24 mo)
Yes	TG	0	Fixed	24	1 (90.9%)	ND	-0.6 (24 mo)
No	TG	0	OV	36	4 (96.4%)	92.9%	-1.26 ± 0.6 (36 mo)
Yes	TG	16-24	Fixed	12-64	0 (100%)	ND	ND
No	TG	0	OV	15–24	0 (100%)	ND	$-1.43 \pm 1.26$ (24 mo, ball-retained) $-0.92 \pm 0.75$ (24 mo, bar-retained)
ND	ND	ND	ND	72	46 (92.6%)	ND	ND
ND	SG	12–16	ND	72	6 (95.5%)	ND	0.7 ± 0.4 (2 y)
ND	ND	ND	OV, fixed	35	145 (94.2%)		
Yes	SG	ND	Fixed	60	3 (94.2%)	ND	0.8 (0.5-1.1) (5 y)

Flap elevation	Healing	Healing period (wk)	Restoration type	Follow-up (mo; mean, range)	Implant failures (survival rate)	Implant success rate	Mean bone level (mm)
Yes	SG	24	Fixed	36	2 (93.8%) 0 (100%)	ND ND	-0.5 ± 0.0 (36 mo) -0.4 ± 0.2 (36 mo)
Yes	ND	ND	OV, fixed	29	0 (100%) 9 (99.5%)	ND	ND
Yes	ND	ND	OV, fixed	48	1 (96.8%)	ND	$-1.26 \pm 0.5$ (24 mo)
Yes	TG	24	Fixed	48	0 (100%) 0 (100%) 0 (100%)	ND	-1.16 ± 0.9 (48 mo)
Yes	TG	0 24	Fixed	36	0 (100%) 0 (100%) 0 (100%)	ND	-0.85 ± 0.7 (36 mo) -0.75 ± 0.6 (36 mo)
Yes	TG	6–10	Fixed	12	4 (95.9%)	ND	$-0.7 \pm 1.0 (12 \text{ mo})$
ND	TG	ND	Fixed	$12 \pm 1.9$	0 (100%)	ND	
Yes	TG	12	Fixed	12	0 (100%)	ND	0.38 ± 0.36 (1 y)
Yes	TG	ND	Fixed	63	1 (96.7%)		Minimal marginal bone loss after 1 y
Yes	TG	16–24	Fixed	12	1 (96.7%)		0.7 (1 y)
Yes	TG	12–20	Fixed	$23 \pm 4.3$	0 (100%)	100%	0.53 ± 0.37 (1 y)
Yes	TG	0	Fixed	13 (9.8–20.8)	1 (98%)		1.6 ± 1.2 (1 y)

Category 1: (< 3.0 mm, mini-implants) These were only described for single non-load-bearing teeth or the edentulous arch in combination with an overdenture. For the latter, no systematic data are available on implant distribution or implant number per arch. Due to the one-piece design, immediate restoration/ loading was predominantly performed. It should be noted that despite the fact that more than 3,000 implants were documented, nearly nothing is known about success rates or long-term success.

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Table 5 Summa	ry of In	cluded S	Studies on Im	plants wi	th 3.3 to 3	.5 mm Diamete	er (Categ	gory 3)
Study	Study type	No. of patients	Mean age (range)	Implant design	Diameter (mm)	Length (mm)	Implants	Indication (jaw region)
Al-Nawas et al <sup>16</sup>	RCT	89	66 (49–86)	Two-piece	3.3	8, 10,12, 14	178 89 89	I (MAN)
Anitua et al <sup>20</sup>	RS	ND		Two-piece	3.3 3.75 (C)	8.5 - 18 7.5 - 18	804 1,654	ND ND
Arisan et al <sup>41</sup>	RS	139	55 (21–80)	Two-piece	3.3 3.4	8 - 14 9.5 - 15	316 235 81	ND
Barter et al <sup>17</sup>	PS	22	54 (22–73)	Two-piece	3.3	ND	22	III, IV (MAN + MAX)
Cordaro et al <sup>42</sup>	RS	31	43 (13–84)	Two-piece	3.5	10, 12	44	II, III (MAN)
Haas et al <sup>43</sup>	RS	607	52 (22–86)	Two-piece	3.3 4.0 (C)	10, 13, 15	1,920 198 1,722	ND (MAN + MAX)
Hallman <sup>44</sup>	PS	40	57 (19-86)	Two-piece	3.3	8, 10, 12	160	ND (MAN + MAX)
Lazzara et al <sup>45</sup>	RS	ND		Two-piece	3.3 3.3 4.0 (C) 4.0 (C)	ND	82 120 147 279	ND (MAN) ND (MAX) ND (MAN) ND (MAX)
Lee et al <sup>46</sup>	RS	338	52.5 (20-85)	Two-piece	3.3–3.5	10, 11.5, 12, 13	541	ND (MAN + MAX)
Malo and de Araujo Nobre <sup>47</sup>	RS	147	47.5 (26–77)	Two-piece	3.3	10, 11.5, 13, 15	247	IV (MAN + MAX)
Romeo et al <sup>48</sup>	RS	188	55.8 (21–74)	Two-piece	3.3	10, 12	122	ND (MAN + MAX)
					4.1 (C)		208	ND (MAN + MAX)
Spiekermann et al <sup>49</sup>	RS	136	60 (24.5–87.4)	Two-piece	3.3 4.0 (C) 4.0 (C)	ND	127 99 38	ND
Veltri et al <sup>50</sup>	RS	12	58 (42–74)	Two-piece	3.5	9, 13, 15, 17	73	I (MAX)
Yaltirik et al <sup>51</sup>	RS	28	(18–65)	Two-piece	3.3	10, 12, 14	48	II, III, IV (MAX + MAN)
Zarone et al <sup>52</sup>	PS	30	(21-45)	Two-piece	3.3	10, 12, 14	34	II (MAX)
Zinsli et al <sup>53</sup>	PS	149	62 (19-87)	Two-piece	3.3	8, 10, 12	298	I, II, III, IV (MAX + MAN)

C = control; MAN = mandible; ND = no data available or data cannot be separated; OV = overdenture; PLS = plasma sprayed;

PRGF = preparation rich in growth factors; PS = prospective study; RS = retrospective study; RCT = randomized controlled trial; SG = subgingival;

TG = transgingival; Ti = titanium; TiZr = titanium-zirconium. Indications: I: edentulous jaw; II: narrow tooth gap without loading;

III: loading of the frontal region; IV: loading distal of the canine.

Category 2: (3.0 to 3.25 mm) In contrast to miniimplants, these were mostly two-piece implants with a shape similar to standard implants. They were predominantly documented in non-load-bearing single-tooth gaps. No load-bearing areas were described. Despite the fact that more than 600 implants are documented, only a few studies reported on success rates. Longterm data were also rare in this group.

Category 3: (3.3 to 3.5 mm) In this group all indications were described, including the load-bearing posterior region. The documentation of success rates was rather promising. Some long-term studies are available.

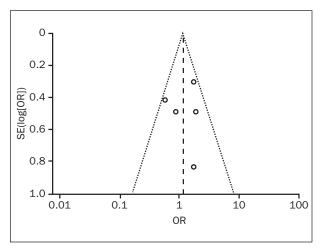
In the present analysis, we found no differences in the implants' survival rate between studies using the flap reflection of flapless surgery. Interestingly, only implants with a diameter < 3.0 mm were used in a flapless procedure. In general, very narrow one-piece screws with a diameter below 2.5 mm are placed in a flapless procedure with a transgingival healing mode and immediate loading. In contrast, the "classical"

Flap elevation	Healing	Healing period (wk)	Restoration type	Follow-up (mo; mean, range)	Implant failures (survival rate)	Implant success rate	Mean bone level (mm)
Yes	TG	6–8	OV	12	3 (98.3%) 1 (98.9%) 2 (97.8%)	96.6% 94.4%	$-0.3 \pm 0.5$ (12 mo) $-0.3 \pm 0.6$ (12 mo)
Yes	ND	ND	OV, fixed	29	8 (99%) 9 (99.5%)	ND ND	ND ND
Yes	TG SG	12–24	OV, fixed	60–124	14 (92.3%) 5 (97.9%) 9 (88.9%)	91.4%	-1.3 ± 0.1 (10 y)
Yes	TG	10–14	Fixed	24	1 (95.2%)	ND	-0.33 ± 0.54 (24 mo)
ND	ND	ND	Fixed	18–42, 23	0 (100%)	94%	ND
Yes	SG	12–24	ND	27	86 (95.5%) 14 (92.9%) 72 (95.8%)	ND	ND
Yes	TG	12–24	OV + fixed	12	1 (99.4%)	96.3%	$-0.35 \pm 1.05$ (12 mo)
ND	ND	ND	ND	60	9 (96%) 11 (95.5%) 8 (95%) 12 (92%)	ND	ND
Yes	ND	ND	Fixed	144, 58.8	9 (98.1%)	91.8%	$0.07 \pm 0.20$ (annual change)
Yes	TG, SG	16–24	Fixed	132	12 (95.1%)	ND	1.74 ± 0.9 (10 y)
Yes	TG	12–24	OV, fixed	84	MAX: 1 (98.1%) MAN: 2 (96.9%)	3.3 mm diameter: MAX: 96.1% MAN: 92% 4.1 mm diameter: MAX: 97.6% MAN: 93.8%	3.3 mm diameter: $1.5 \pm 1.5$ 4.1 mm diameter: $1.4 \pm 1.1$ (7 y)
ND	SG	ND	OV	60	8 (91%) 7 (95%) 3 (97%)	ND	$\begin{array}{l} 0.34 \pm 0.52 \text{ mesial}, \ 0.36 \pm 0.49 \text{ distal} \\ 0.26 \pm 0.35 \text{ mesial}, \ 0.29 \pm 0.34 \text{ distal} \\ 0.53 \pm 0.53 \text{ mesial}, \ 0.54 \pm 0.619 \text{ distal} \end{array}$
Yes	SG	24	Fixed	12	0 (100%)	ND	0.30 ± 0.13 (1 y)
Yes	TG	12–24	Fixed	60	3 (93.75%)	ND	ND
Yes	SG	16	Fixed	39	0 (97.06%)	94.12%	$1.2 \pm 0.6 (2 \text{ y})$
ND	TG	12–24	OV, fixed	60	9 (98.7%)		

two-piece dental implants are inserted with flap elevation procedure and a certain healing period (regardless of sub- or transgingival mode). Comparative data on this aspect are missing. The lengths of the implants used in the analyzed studies of this review were all in a high to normal range, meaning that a combination of short and diameter-reduced implant was not used.

The idea of avoiding augmentations or invasive surgery by using NDI is intriguing but has not been tested by any of the studies. For short implants, randomized studies comparing short implants with augmentation and standard implants are available.<sup>56–58</sup> It would be desirable to have similar studies for diameter-reduced implants in the future. A clear definition of the indications and reporting of success and follow-up rates is mandatory.

For implant-retained overdentures, the number, distance, and distribution (geometry of loaded area) of the employed NDIs (eg, two versus four versus six) might be of significance for implant success and development



**Fig 2** Funnel plot calculated for selected studies (n = 5) reporting on narrow diameter (3.3 to 3.5 mm; category 3) versus conventional implants. Each study is represented by a dot. The x-axis quantifies the treatment effect, the y-axis the study size.

## Table 6 Forest plot of survival of narrow diameter (3.3 to 3.5 mm; category 3) versus conventional implants

	Narrow		Standard		Odds ratio			
Study or subgroup	Events	Total	Events	Total	Weight (%)	M-H Fixed	95% CI	Year
Spiekermann et al49	8	127	10	137	18.5	0.85	0.33, 2.24	1995
Lazzara et al <sup>45</sup>	8	202	29	426	36.8	0.56	0.25, 1.26	1996
Haas et al <sup>43</sup>	14	198	72	1,722	28.3	1.74	0.96, 3.15	1996
Romeo et al <sup>48</sup>	3	122	3	208	4.4	1.72	0.34, 8.67	2006
Anitua et al <sup>20</sup>	8	804	9	1,654	12.0	1.84	0.71, 4.78	2008
Total (95% CI)		1,453		4,147	100.0	1.16	0.79, 1.69	
Total events	41		123					
Heterogeneity: $Chi^2 = 6.44$ , $df = 4$ , $P = .17$ , $l^2 = 38\%$ .								

Test for overall effect: Z = 0.75, P = .45.

0.01 0.1 1 10 100 Favors (experimental) Favors (control)

of the marginal bone level. Unfortunately, no respective studies could be identified.

Another very important, but not yet scientifically adequate investigated aspect is whether adjacent NDIs are splinted or blocked against each other. Only one study dealt with splinted NDIs.<sup>26</sup> According to Jofre et al, splinted mini-implants (1.8 mm in diameter) with a rigid superstructure decreased the bone stress level in comparison with single mini-implants. Consequently, splinted mini-implants supporting a mandibular overdenture showed less marginal bone loss compared with nonsplinted mini-implants.<sup>26</sup>

#### CONCLUSIONS

Dental implants with narrow diameters of 3.3 to 3.5 mm are well documented in all indications including load-bearing posterior regions for a follow-up time of 1 year. Smaller implants with diameters 3.0 to 3.25 mm are well documented only for single-tooth non-load-bearing regions. Mini-implants < 3.0 mm in diameter are only documented for the edentulous jaw and single-tooth non-load-bearing regions. Long-term data and success rates for the latter are not available. Due to missing comparative studies, no conclusion can be drawn about the possibility of reducing the burden of care by using NDI. As suggested by the concept of internal evidence and patient preferences, the individual decision for NDI or augmentations and regular diameter implants should take into account patient-specific risk factors, which are often not reported in the available studies.

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## Cone Beam Computed Tomography in Implant Dentistry: A Systematic Review Focusing on Guidelines, Indications, and Radiation Dose Risks

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Purpose: The aim of the paper is to identify, review, analyze, and summarize available evidence in three areas on the use of cross-sectional imaging, specifically maxillofacial cone beam computed tomography (CBCT) in pre- and postoperative dental implant therapy: (1) Available clinical use guidelines, (2) indications and contraindications for use, and (3) assessment of associated radiation dose risk. Materials and Methods: Three focused questions were developed to address the aims. A systematic literature review was performed using a PICO-based search strategy based on MeSH key words specific to each focused question of English-language publications indexed in the MEDLINE database retrospectively from October 31, 2012. These results were supplemented by a hand search and gray literature search. Results: Twelve publications were identified providing guidelines for the use of cross-sectional radiography, particularly CBCT imaging, for the pre- and/or postoperative assessment of potential dental implant sites. The publications discovered by the PICO strategy (43 articles), hand (12), and gray literature searches (1) for the second focus question regarding indications and contraindications for CBCT use in implant dentistry were either cohort or case-controlled studies. For the third question on the assessment of associated radiation dose risk, a total of 22 articles were included. Publication characteristics and themes were summarized in tabular format. Conclusions: The reported indications for CBCT use in implant dentistry vary from preoperative analysis regarding specific anatomic considerations, site development using grafts, and computer-assisted treatment planning to postoperative evaluation focusing on complications due to damage of neurovascular structures. Effective doses for different CBCT devices exhibit a wide range with the lowest dose being almost 100 times less than the highest dose. Significant dose reduction can be achieved by adjusting operating parameters, including exposure factors and reducing the field of view (FOV) to the actual region of interest. INT J ORAL MAXILLOFAC IMPLANTS 2014;29 (SUPPL):55-77. doi: 10.11607/jomi.2014suppl.g1.4

**Key words:** cone beam computed tomography, contraindications, dental implants, effective dose, guidelines, indications, radiation dose.

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**S**uccessful dental implant rehabilitation requires accurate preoperative surgical planning. The use of specific imaging to assist planning is based on the patient's need as determined by clinical presentation and professional judgment, which is defined by the individual clinician's need for information supplemental to that already obtained from clinical examination to formulate a diagnosis.<sup>1,2</sup> Specific considerations should include clinical complexity, regional anatomic considerations, potential risk of complications and esthetic considerations in the location of implants. The use of imaging modalities for presurgical dental implant planning should be adequate to provide information supporting the following three goals:

- 1. Establish the morphologic characteristics of the residual alveolar ridge. The morphology of the residual alveolar ridge (RAR) includes considerations of bone volume and quality. Vertical bone height, horizontal width, and edentulous saddle length determine the amount of bone volume available for implant placement. This information is necessary to correlate the available bone dimensions with the selection of the number and physical dimensions of the dental implant.
- 2. Determine the orientation of the residual alveolar ridge. The orientation and residual topography of the alveolar-basal bone complex should be assessed to determine deviations of the RAR that compromise alignment of the implant fixture with respect to the prosthetic plan.
- 3. Identify local anatomic or pathologic boundaries within the RAR limiting implant placement. Numerous internal anatomic features of the jaws (eg, nasopalatine fossa and canal, nasal fossa, mental foramen, submandibular gland fossa, inferior alveolar [or mandibular] canal) compromise and limit implant fixture placement or risk involvement of adjacent structures. Anatomic anomalies and local pathologies (eg, retained root tips, sinus disease, or adjacent inflammatory processes) may also prevent or restrict implant placement.

For many years, the information required to satisfy these goals has been obtained from clinical examination and, most commonly, two-dimensional (2D) imaging such as intraoral periapical, lateral cephalometric, and panoramic radiography. Using these imaging modalities, implants have been used predictably and with high success rates in clinical practice for more than 30 years. Because of the additional financial cost and higher patient radiation dose, the decision to use cross-sectional imaging such as tomography, multidetector computed tomography (MDCT), or, most recently, maxillofacial cone beam computed tomography (CBCT) should be based on clear clinical benefits. Since its first description in 1998 by Mozzo and coworkers,<sup>3</sup> CBCT has already become an established diagnostic tool for various dental indications, such as endodontics,<sup>4–6</sup> orthodontics,<sup>7</sup> dental traumatology,<sup>8</sup> apical surgery,<sup>9-12</sup> challenging periodontal bone defects,<sup>13,14</sup> preoperative planning of periodontal surgery,<sup>15,16</sup> forensic odontology,<sup>17,18</sup> and dental implant surgery including bone quality assessment.<sup>1,2,19–22</sup> Even for visualization of the paranasal sinuses, for which conventional computed tomography (CT) is considered to be the diagnostic method of choice,<sup>23</sup> CBCT imaging is becoming increasingly popular.<sup>24,25</sup>

While the selection of an imaging protocol is principally based on the assessment of the surgical and restorative difficulty of the clinical situation and the individual practitioners' preferred pattern of practice, choice should also be influenced by an understanding of the evidence supported by additional clinical benefits and recommendations of representative organizations. It is highly desirable to identify situations where cross-sectional imaging may provide crucial treatment planning information that may not be readily appreciated by clinical examination, dental study model analysis, and conventional imaging alone. This includes the potential need for site preparation and the appropriate selection of implant type and size.

The aim of the present paper is to identify, review, analyze, and summarize available evidence on the use of cross-sectional imaging, specifically CBCT imaging, in pre- and postoperative dental implant therapy in regards to (1) currently available use guidelines, (2) specific indications and contraindications for use, and (3) the associated relative radiation dose risk.

## **MATERIALS AND METHODS**

### **Overall Search Strategy**

A systematic literature review was performed using a PICO (Patient or Population, Intervention, Control or Comparison, Outcome and study types) search strategy<sup>26,27</sup> using the MeSH keywords specific to each focus question (Tables 1 to 3) of English-language publications indexed in the MEDLINE database retrospectively from October 31, 2012. This strategy was further augmented by reference to the bibliographies (or citation lists) of all reports identified by the databases (reference harvesting), hand-searching of journals, as well as publications identified after consultation with the Working Group. In addition, grey literature was identified by group consensus and included for consideration. Grey literature is written material (such as reports, technical reports, working papers, or white papers) from government agencies, professional, business and university bodies, and scientific research groups that is difficult to find via conventional online methods such as PubMed because it is not published commercially or is not generally accessible.

### Focus Question 1 and Study Parameters

Do guidelines currently exist for the use of cross-sectional radiography, particularly CBCT imaging, in the pre- and/or postoperative assessment of potential dental implant sites?

Guidelines proposed by recognized international associations, government agencies, professional, business and university bodies, and scientific research groups in the field of implant dentistry were selected as the primary study parameter.

Focus question:	Do guidelines currently exist for the use of cross-sectional radiography, particularly CBCT imaging for the pre- and/or postoperative assessment of potential dental implant sites?
Search strategy	
Population	<ul> <li>#1 (position paper[Text Word]) AND (radiology[Text Word]) AND (maxillofacial[Text Word]) OR (oral[Text Word])</li> <li>AND (implant dent*[Text Word])</li> <li>#2 (guideline) OR (consensus statement) AND (implant dent*[Text Word]) AND (diagnostic imaging[Text Word])</li> </ul>
Intervention or exposure	#3 (cone beam computed tomography) AND (position paper) #4 (patient care planning) AND ("Cone-Beam Computed Tomography/methods"[MeSH]) AND ("Dental Implantation/methods"[MeSH])
Comparison	#5 (position paper) AND (radiology[Text Word]) AND (maxillofacial[Text Word]) AND ("Radiography, Dental/methods"[MeSH]) OR "(Radiography, Dental/utilization"[MeSH]) #6 (position paper) AND (radiology[Text Word]) AND (maxillofacial[Text Word]) AND ("Radiography, Dental/methods"[MeSH]) OR ("Radiography, Dental/utilization"[MeSH])
Outcome	#7 (cone beam computed tomography) AND ("Dental Implantation/methods"[MeSH]) AND (patient care planning
Search combination	<ul> <li>(#1) OR (#2) OR (#3) OR (#4) OR (#5) OR (#6) OR (#7)</li> <li>(position paper[Text Word]) AND (radiology[Text Word]) AND (maxillofacial[Text Word]) OR (oral[Text Word])</li> <li>AND (implant dent*[Text Word]) OR (guideline) OR (consensus statement) AND (implant dent*[Text Word]) AND (diagnostic imaging[Text Word]) OR (cone beam computed tomography) AND (position paper) OR</li> <li>(patient care planning) AND ("Cone-Beam Computed Tomography/methods"[MeSH]) AND ("Dental Implantation/methods"[MeSH]) OR (position paper) AND (radiology[Text Word]) AND (maxillofacial[Text Word])</li> <li>AND ("Radiography, Dental/methods"[MeSH]) OR ("Radiography, Dental/utilization"[MeSH]) OR (position paper) AND ("Radiography, Dental/methods"[MeSH])</li> <li>OR ("Radiography, Dental/utilization"[MeSH]) OR (cone beam computed tomography) AND ("Radiography, Dental/methods"[MeSH])</li> <li>OR ("Radiography, Dental/utilization"[MeSH]) OR (cone beam computed tomography) AND ("Radiography, Dental/methods"[MeSH])</li> <li>OR ("Radiography, Dental/utilization"[MeSH]) OR (cone beam computed tomography) AND ("Cone beam computed tomography) AND ("Radiography, Dental/methods"[MeSH])</li> </ul>
Database searc	h
Electronic	MEDLINE, Organizational websites (http://ec.europa.eu/index_en.htm, http://www.eadmfr.eu/, http://www. sedentexct.eu/content/national-guidance-cbct, http://www.dgzmk.de/, http://www.health.belgium.be/eportal/ index.htm)
Journals	Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology; Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontics; Clinical Oral Implants Research; Implant Dentistry; The International Journal of Oral & Maxillofacial Implants; Clinical Implant Dentistry and Related Research; Journal of Oral Implantology; European Journal of Oral Implantology
Selection criter	ia
Inclusion criteria	Manuscripts published by government agencies, professional, business and university bodies, and scientific research groups only Consensus development conference Guideline Practice guideline Clinical conference
Exclusion criteria	Reviews Engineering, medical (eg, otolaryngologic), dental clinical applications Clinical trials Case reports

### **Search Strategy**

Table 1 provides details of the PICO search strategy, inclusional and exclusional selection criteria, and final electronic and journal database from which the articles were identified. This search strategy was designed for high recall rather than high precision in the first instance. There were no language restrictions.

## Study Selection and Quality Assessment Procedures

Since the included publications were all non-interventional (neither randomized or non-randomized controlled trials nor controlled clinical trials) and comprised statements from government agencies or professional organizations, subjective quality assessment according to PRISMA<sup>28</sup> was not performed.

### **Data Extraction Strategy**

Clinical practice guidelines have been defined as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" (http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx).<sup>29</sup> Guidelines help clinicians translate best evidence into best practice. The hallmark of a clinical practice guideline is methodological rigor. Currently accepted guideline statement standards<sup>29–34</sup> present the following key components<sup>35</sup>:

Background and development: This should include specific descriptions on the scope, overall purpose, and specific objectives, the population to whom the guidelines apply, and features of the development group including potential for bias.

Evidence synthesis and analysis methodology: This includes a description of the methodology used to identify and report the best available research evidence through systematic review, the rigor of the literature review including when applicable the search strategy, grading the quality and strength of the synthesized evidence, and external review.

Key specific action statements: These should be supported with a specific action statement profile clearly summarizing the decision-making process, specific clinical scenario use recommendations, modifications due to patient presentation, risk-benefit assessment, reasons for intentional vagueness, and the role of patient preference.

Applicability: Statements should be included on implementation issues such as when, how, and by whom the recommendations can be put into practice, identifying barriers to implementation including resource and financial constraints, update mechanisms, as well as disclosure of the potential for conflict of interest.

To address focus question 1 in this context, each publication was characterized in regard to type of sponsoring body, type of organization, constituents represented, modalities considered, and method of identification for inclusion. A thorough review and assessment of each paper was performed by the working group members and the structure of each publication analyzed and characterized non-empirically and qualitatively according to compliance to the key elements of accepted guideline statement standards identified above. In addition, three broad categories were identified with respect to level of compliance with these standards and categorized each publication accordingly:

*Clinical practice guideline:* These publications provide specific evidence-based action statements developed from a rigorous systematic review and grading of the available literature, producing clinically specific action statements.

*Clinical guidance statements:* These publications provide recommendations that are consensus-based or derived from a limited methodological approach with partial retrieval and/or analysis of the literature.

*Clinical practice advice statements:* These publications provide relatively ill-defined, generalized, or non-case-specific statements using an ill-defined methodological approach to literature retrieval and/or analysis representing considered professional and/or expert opinion.

#### Focus Question 2 and Study

Are there specific indications or contraindications for the use of cross-sectional radiography, specifically CBCT imaging for the pre- and/or postoperative assessment of potential dental implant sites?

Clearly specified selection criteria for the use of CBCT imaging in the field of dental implantology were selected as the study parameter, and further grouped into diagnostic indications and contraindications for planning of dental implant insertion and postoperative assessment.

#### Search Strategy

Table 2 provides details of the PICO search strategy, inclusional and exclusional selection criteria, and final electronic and journal databases from which the articles were identified. In addition, all the relevant clinical guideline publications from the search strategy related to focus question 1 were included for consideration.

## Study Selection and Quality Assessment Procedures

All publications identified in focus question 1 were also included. Since these publications were all noninterventional (neither randomized or nonrandomized controlled trails nor controlled clinical trials) and comprised statements from government agencies or professional organizations, subjective quality assessment according to PRISMA<sup>28</sup> was not performed.

#### Data Extraction Strategy

The specific indications and contraindications of crosssectional imaging for implant dentistry from the previously identified guideline documents identified in focus question 1 were reviewed and analyzed. In addition, publications identified from the specific search strategy addressing focus question 2 providing direct or indirect support of the statements were extensively reviewed.

#### **Focus Question 3 and Study Parameters**

What additional radiation dose risks are associated with the use of cross-sectional radiography, specifically CBCT imaging, for the pre- and/or postoperative assessment of potential dental implant sites compared to other radiographic modalities?

Table 2 Sys	stematic Search Strategy for Focus Question 2
Focus question	Are there specific indications or contraindications for the use of cross-sectional radiography, specifically CBCT imaging for the pre- and/or postoperative assessment of potential dental implant sites?
Search strategy	1
Population	#1 ("Dental Implantation, Endosseous"[MeSH]) OR ("Dental Implantation"[MeSH]) OR ("Dental Implantation"[MeSH]) OR ("Dental Implantation, Endosseous"[MeSH]) OR ("dental implants"[MeSH Terms]) OR ("dental"[All Fields] AND "implants"[All Fields]) OR ("dental implants"[All Fields])
Intervention or exposure	<ul> <li>#2 ("radiography, dental"[MeSH Terms]) OR ("radiography"[All Fields]) AND ("dental"[All Fields]) OR</li> <li>("dental radiography"[All Fields]) OR ("dental"[All Fields]) AND ("radiography"[All Fields]) OR ("Radiography, Dental, Digital"[MeSH]) OR (cone beam computed tomography[Text Word]) OR (cone beam computed tomography[Text Word]) OR ("radiography, dental"[MeSH Terms]) OR ("radiography"[All Fields]</li> <li>("radiography"[All Fields]</li> <li>#3 "dental"[All Fields]) OR ("dental radiography"[All Fields]) OR ("radiography"[All Fields])</li> <li>("radiography"[All Fields]</li> <li>#3 "dental"[All Fields]) OR ("dental radiography"[All Fields]) OR ("dental"[All Fields]) AND ("radiography"[All Fields])</li> </ul>
Comparison	#4 "Patient Care Planning"[MeSH]
Outcome	#5 (pre-surgical[All Fields]) OR (post-surgical[All Fields]) OR (post-surgical[Title/Abstract]) OR (post-surgical [All Fields]) OR (pre-surgical[All Fields]) OR ("postoperative period"[MeSH Terms] OR ("postoperative"[All Fields]] AND "period"[All Fields]) OR ("postoperative period"[All Fields]) OR ("post"[All Fields]) AND ("operative" [All Fields]) OR ("post operative"[All Fields]) OR (pre-operative[All Fields])
Search combination	#1 AND (#2 OR #3) AND #4 AND #5 ("Dental Implantation, Endosseous"[MeSH]) OR ("Dental Implantation"[MeSH]) AND ("radiography, dental"[MeSH Terms]) OR ("radiography"[All Fields]) AND ("dental"[All Fields]) OR ("dental radiography" [All Fields]) OR ("dental"[All Fields]) AND ("radiography"[All Fields]) OR ("Radiography, Dental, Digital"[MeSH]) OR (cone beam computed tomography[Text Word]) AND ("Patient Care Planning"[MeSH]) OR ("Dental Implantation"[MeSH]) OR ("Dental Implantation, Endosseous"[MeSH]) OR ("dental implants"[MeSH Terms]) OR ("dental"[All Fields]) AND "implants"[All Fields]) OR ("dental implants"[All Fields]) OR ("dental implants"[All Fields]) OR ("dental implants"[All Fields]) OR ("dental implants"[All Fields]) AND (cone beam computed tomography[Text Word]) OR ("Radiography, Dental, Digital"[MeSH]) OR ("radiography, dental"[MeSH Terms]) OR ("radiography[Text Word]) OR ("Radiography, Dental, Digital"[MeSH]) OR ("radiography, dental"[MeSH Terms]) OR ("radiography"[All Fields]) AND ("dental"[All Fields]) OR ("dental radiography, dental"[MeSH Terms]) OR ("radiography"[All Fields]) AND ("dental"[All Fields]) OR ("dental" [All Fields]) OR ("dental radiography"[All Fields]) OR ("dental" [All Fields] AND ("radiography"[All Fields]) OR ("dental radiography"[All Fields]) OR ("dental" [All Fields] OR post-surgical[All Fields]) OR (post-surgical[Title/Abstract]) OR (post-surgical[All Fields]) OR (pre-surgical[All Fields]) OR (post-surgical[All Fields]) OR ("postoperative period"[MeSH Terms]) OR ("postoperative"[All Fields]) AND ("period"[All Fields]) OR ("postoperative period"[MeSH Terms]) OR ("postoperative"[All Fields]) AND ("period"[All Fields]) OR ("postoperative period"[All Fields]) OR ("post"[All Fields] AND "operative"[All Fields]) OR ("post operative"[All Fields]) OR pre-operative[All Fields]) AND ("Patient Care Planning"[MeSH])
Database searc	h
Electronic	MEDLINE, Hand search of publication references
Journals	Dentomaxillofacial Radiology; Journal of Periodontal & Implant Science; The International Journal of Oral & Maxillofacial Implants; Clinical Implant Dentistry and Related Research; Implant Dentistry; European Journal of Oral Implantology; British Dental Journal; Journal of Orofacial Pain; Clinical Oral Implants Research; Implant Dentistry; Indian Journal of Dental Research; International Journal of Prosthodontics; Journal of Periodontology; Journal of Oral Implantology; Journal of Oral and Maxillofacial Surgery; Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology; Journal of Prosthetic Dentistry; Swedish Dental Journal; Fortschritte auf dem Gebiet der Röntgenstrahlen und der bildgebenden Verfahren
Selection criter	ia
Inclusion criteria	Manuscripts included for focus question 1 Studies related to implant dentistry Clinical trials including case series
Exclusion criteria	Studies describing non-implant associated (eg, third molar) use of CBCT Reviews (other than included in focus question 1) Case reports

The specific radiation dose risks associated with the use of cross-sectional imaging, specifically CBCT, as compared to the radiation dose risks of conventional radiographic methods in the field of dental implantology, were selected as the study parameter.

### **Search Strategy**

Table 3 provides details of the PICO search strategy, inclusional and exclusional selection criteria, and final electronic and journal database searches from which the articles were identified.

#### Table 3 Systematic Search Strategy for Focus Question 3

Focus question: What additional radiation dose risks are associated with the use of cross-sectional radiography, specifically CBCT imaging, for the pre-and/or postoperative assessment of potential dental implant sites compared to other radiographic modalities?

Search strategy	
Population	#1 (Dental Implants[Text Word]) OR ("Dental Implantation, Endosseous"[MeSH]) #2 (dent*)
Intervention or exposure	#3 (Imaging, Three-Dimensional/methods"[MeSH]) OR (cone beam computed tomography[Text Word]) OR ("Cone-Beam Computed Tomography/standards"[MeSH]) OR ("Cone-Beam Computed Tomography/ methods"[MeSH]) #4 (CBCT[Title/Abstract]) OR (cone beam computed tomography[Title/Abstract])
Comparison	
Outcome	#5 (radiation dosage) OR ("Radiation Dosage"[MeSH]) #6 (dosimetry[Title/Abstract]) OR (dose[Title/Abstract])
Search combination	(#1 AND #3 AND [#5 Or #6]) OR (#2 AND #4) ("Imaging, Three-Dimensional/methods"[MeSH]) OR (cone beam computed tomography[Text Word]) OR ("Cone-Beam Computed Tomography/standards"[MeSH]) OR ("Cone-Beam Computed Tomography/ methods"[MeSH]) AND (Dental Implants[Text Word]) OR ("Dental Implantation, Endosseous"[MeSH]) AND ("Radiation Dosage/standards"[MeSH]) OR (radiation dosage) OR ("Radiation Dosage"[MeSH]) OR (dosimetry[Title/Abstract]) OR (dose[Title/Abstract]) AND (CBCT[Title/Abstract]) OR (cone beam computed tomography[Title/Abstract]) AND (dent*)
Database searc	h
Electronic	PubMed
Journals	Dentomaxillofacial Radiology; Journal of Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology; American Journal of Orthodontics and Dentofacial Orthopedics; British Journal of Radiology; European Journal of Radiology; La Radiologia medica; Journal of Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology;Imaging Science in Dentistry
Selection criteri	a
Inclusion criteria	Maxillofacial Effective dose reported (ICRP <sub>2007</sub> )
Exclusion criteria	Reviews Case reports

## Study Selection and Quality Assessment Procedures

The Working Group considered only studies that reported effective dose (E), using the most recent published organ weighting factors, referred to as ICRP<sub>2007</sub>, or mean absorbed dose for specific head and neck organs.<sup>36</sup> In ICRP<sub>2007</sub>, the estimated risk weighting factors for specific tissues have been revised, and a number of additional tissues found in the head and neck region are included (most importantly the salivary glands, lymphatic nodes, muscle, and oral mucosa). These modifications have resulted in substantial increases in radiation effective doses for specific maxillofacial radiographic procedures as compared to pre-2007 publications ranging from 32% to 422%<sup>37,38</sup> and there-fore the inclusion criteria included only dose literature specifying ICRP<sub>2007</sub> calculations.

#### **Data Extraction Strategy**

Publications reporting ICRP<sub>2007</sub> effective doses were reviewed, analyzed and specific results summarized in tables.

## **RESULTS AND DISCUSSION**

#### Focus Question 1

The initial PICO search strategy resulted in identifying 266 published articles dating back to 1967. By applying the inclusional and exclusional criteria, six publications were initially identified. A hand search of relevant references within the bibliographies of the publications identified one additional publication, not revealed by the PICO search. Based on discussions between the working group members, websites of professional dental organizations (specialty, general dental, or multidisciplinary) and government organizations, both national and international, were also searched and a further five "grey literature" publications were found. Thus, twelve publications were identified, providing guidelines for the use of cross-sectional radiography, particularly CBCT imaging, for the pre- and/or postoperative assessment of potential dental implant sites (Table 4).<sup>1,2,39–48</sup>

#### 

				Modalities considered				
Study	Organization	Representing	Туре	СВСТ	CST	10/E0	Source	Comment
Tyndall et al <sup>48</sup>	AAOMR	OMFR, US	P0 (S)	+	+	+	PICO	Update of White et al <sup>40</sup>
Harris et al <sup>2</sup>	EAO	Europe	PO (MD)	+	+	+	PICO	Update of Harris et al <sup>1</sup>
DGZMK <sup>47</sup>	DGZMK	German Dent. Association/ German Assoc. for Implantology	PO (MD)	+	+	_	GL	In German
Benavides et al <sup>46</sup>	ICOI	International	PO (MD)	+	+	+	PICO	
SHC <sup>45</sup>	SHC	Belgium Govt.	GA (N)	+	-	_	GL	
EC <sup>44</sup>	EC	EU	GA (I)	+	-	-	GL	SEDENTEXCT guidelines <sup>43</sup> adopted by the EC
SEDENTEXCT <sup>43</sup>	SEDENTEXCT	EADMFR / EU	PO (MD)	+	-	-	GL	Collaboration in response to EU Directives
A0 <sup>42</sup>	AO	International	PO (MD)	+	_	-	PICO	Adopted Harris et al <sup>1</sup>
ARö <sup>41</sup>	DGZMK	German Dental Association	PO (G)	+	-	-	GL	In German
Harris et al <sup>1</sup>	EAO	Europe	PO (MD)	-	+	+	PICO	
White et al <sup>40</sup>	AAOMR	OMFR, US	P0 (S)	-	+	+	HS	
Tyndall and Brooks <sup>39</sup>	AAOMR	OMFR, US	PO (S)	-	+	+	PICO	

SHC: Superior Health Council; EC: European Commission; SEDENTEXCT: Safety and Efficacy of a New and Emerging Dental X-ray Modality Computer Tomography; AO: Academy of Osseointegration; ARö: Association for Radiology; AAOMR: American Association of Oral and Maxillofacial Radiology; EAO: European Academy of Osseointegration; ICOI: International Congress of Oral Implantologists; DGZMK: German Society of Dental Sciences; OMFR: Oral and Maxillofacial Radiology; EADMFR: European Academy of Dentomaxillofacial Radiology; PO (S): dental professional organization, specialty; PO (G): dental professional organization, general; PO (MD): dental professional organization, multi discipline; GA (I): government agency, international; GA (N): government agency, national; CBCT: maxillofacial cone beam computed tomography; CST: cross-sectional tomography including tomography and multi-detector computed tomography; IO/EO: includes intraoral (eg, periapical, occlusal) and extraoral (eg, panoramic, lateral cephalometric) radiographic techniques; +: included in publication; -: excluded in publication; PICO: PICO search result; HS: hand search; GL: grey literature search result.

Publication dates ranged from 2000 to 2012, with most (9) being published within the last 3 years. The most recent publications presented updates to initial statements made by respective organizations specifically addressing CBCT use for implant dentistry.<sup>2,48</sup> One publication developed by a professional organization<sup>43</sup> was adopted almost in toto by an international government agency.<sup>44</sup> Most reports were from professional organizations (10) with only two publications from government agencies, both of which were European—one being national and the other representing the European Union. Only three publications, all published in 2012, provide CBCT use guidelines in the context of all dental imaging modalities (eg, cross-sectional tomography including tomography and multidetector computed tomography, intraoral [periapical, occlusal], and extraoral [panoramic, lateral cephalometric] radiography).

The authors analyzed each of the identified publications according to the key elements of clinical practice guideline development described above (Table 5). Only three publications satisfy the requirements for the highest level of compliance with currently accepted guideline statement criteria, as clinical practice guidelines. Two of these publications<sup>42,44</sup> adopt the same evidence synthesis methodology and provide the same action statements as the parent publication by the SEDENTEXCT Project.<sup>43</sup> Evidence synthesis in all other publications is poor. However, there appears to be a trend towards reporting more specific action statements in the most recent publications from discipline specific (ie, American Academy of Oral and Maxillofacial Radiology [AAOMR])<sup>48</sup> and multi-discipline (ie, Academy of Osseointegration<sup>42</sup> and European Academy of Osseointegration<sup>2</sup>) dental professional organizations.

Considering the results of the analysis of focus question 1, the authors report that there are currently twelve publications which provide guidelines for the use of cross-sectional radiography, particularly CBCT imaging, in the pre- and/or postoperative assessment of potential dental implant sites. However, in the context of validity, only one publication, the guidelines of the SEDENTEXCT project reprinted by two other

			-9				
Guidelin	e component			Reference			
Component	Specific element	Tyndall et al <sup>48</sup>	Harris et al <sup>2</sup>	Benavides et al <sup>46</sup>	SHC <sup>45</sup>	<b>EC</b> <sup>44</sup>	
Background/ development	Purpose	+++	+++	++	++	Same as reference 43	
	Population	+++	+++	++	++	Same as reference 43	
	Group features	++	++	+	++	Same as reference 43	
Evidence synthesis	Rigor of literature review	+	-	+	Same as reference 43	Same as reference 43	
	Methodology	-	-	+	Same as reference 43	Same as reference 43	
	Evidence grading	-	-	+	Same as reference 43	Same as reference 43	
Action statements	Prescription	+++	++	++	+	Same as reference 43	
	Modification	+++	++	++	+	Same as reference 43	
	Risk/benefit	++	++	++	Same as reference 43	Same as reference 43	
Applicability	Implementation	+	-	-	-	Same as reference 43	
	COI	-	_	-	Same as reference 43	Same as reference 43	
Publication Cla	ssification	CGS	CPA	CGS	CPA	CPG	

## Table 5Comparison, Analysis, and Classification of Strength of Publications Reporting the<br/>Use of Cross-Sectional Radiography

CPG: clinical practice guideline; CGS: clinical guidance statement; CPA: clinical practice advice

-: the element is not reported, +, ++, and +++: weak, moderate, or strong scientific rigor, with +++ being the highest score.

organizations, complies with standards for evidence synthesis.<sup>43</sup> However, the publication which provides the strongest action statements is the publication by the AAOMR.<sup>48</sup> There is a clear need for guidelines that provide strong action statements based on a rigorous methodologic review of the evidence.

#### **Focus Question 2**

The initial PICO search strategy identified 694 published articles dating back to 1969. By applying the inclusion and exclusion criteria, the authors initially identified 43 publications.<sup>49–92</sup> A hand search of relevant references within the bibliographies of the publications identified 12 additional publications, not revealed by the PICO search.<sup>93–104</sup> One additional "grey literature" publication was found.<sup>105</sup>

Publications identified by the PICO strategy (43), hand (12), and "grey literature" searches (1) were either cohort or case-controlled studies. Table 6 provides a summary of recommended imaging modalities with emphasis on cross-sectional and CBCT imaging according to stage of implant therapy and clinical situation.

Before the advent of CBCT use for implant dentistry, the AAOMR was the first professional dental organization to provide specific recommendations for cross-sectional imaging in implant dentistry.<sup>39</sup> Simply stated, they indicated that "...any potential implant site includes cross-sectional imaging orthogonal to the site of interest." Choice of imaging modality was determined by the potential number of implant sites, if bone grafts were considered, or if complex trauma was present. Tomography was recommended for patients presenting with less than eight sites, whereas multidetector computed tomography (MDCT) was recommended for patients with greater than eight to ten sites. However, they acknowledged that, "...currently there is no published evidence to support the position that some form of cross-sectional imaging should be a part of implant site assessment..."

A second report from the AAOMR by White and coworkers addressed imaging for a variety of clinical situations including implant placement.<sup>40</sup> The authors reaffirmed the position of the AAOMR proposing cross-sectional imaging for all potential implant sites by indicating that "cross-sectional information con-

			Reference			
SEDENTEXCT43	A0 <sup>42</sup>	ARö <sup>41</sup>	Harris et al <sup>1</sup>	White et al <sup>40</sup>	Tyndall and Brooks <sup>39</sup>	DGZMK <sup>47</sup>
+++	Same as reference 43	+	++	++	++	++
+++	Same as reference 43	+	++	+	-	++
+++	Same as reference 43	++	++	+	+	++
+++	Same as reference 43	-	-	-	+	++
+++	Same as reference 43	+	-	+	-	++
+++	Same as reference 43	-	-	-	-	-
++	Same as reference 43	_	+	+	+	++
++	Same as reference 43	-	++	+	++	+
++	Same as reference 43	_	++	+	++	+
++	Same as reference 43	-	+	+	+	+
-	Same as reference 43	-	-	-	-	—
CPG	CPG	CPA	CGS	CPA	CPA	

cerning a qualitative and quantitative assessment of preoperative implant site bone is now readily achievable and needed. Such information is essential for optimum implant selection..." Furthermore, they stated "panoramic imaging alone is not sufficient to provide all of the necessary information described earlier for optimum implant selection and should be augmented with tomography." In addition, they provided specific indications for MDCT.

The European Association for Osseointegration (EAO) held a consensus workshop to provide recommendations for imaging in various clinical situations published in 2002.<sup>1</sup> They presented their findings as answers to a series of focus questions. While the EAO made no specific mention of CBCT, they made a number of key points in relation to the use of cross-sectional imaging (at that time, spiral tomography and MDCT): (1) Clinicians should decide if a patient requires cross-sectional imaging on the basis of the clinical examination, the treatment requirements, and information obtained from standard imaging modalities (ie, combinations of conventional dental images); (2) the technique chosen should provide the required

diagnostic information with the least radiation exposure to the patient; and (3) cross-sectional imaging be used in situations where more information is required after appropriate clinical examination and standard radiographic techniques. The specific clinical situations that could potentially benefit from cross-sectional imaging were subjective in nature. Essentially, they were defined as when there was a possibility of implant intrusion on anatomic structures (eq, incisive canal, maxillary sinus, mandibular canal) or doubt (based on clinical or interpretation of standard radiographic procedures) in the amount of adequate bone volume or shape of alveolar ridge. In addition, the authors of this publication were the first to suggest that cross-sectional imaging not be part of a "routine protocol" for postoperative examinations "unless there is a need for assessments in situations where some kind of complications have occurred, such as nerve damage or postoperative infections in relation to nasal and/or sinus cavities close to implants".

The Working Group for Radiology of Germany (ARö) convened an expert group to provide the dental profession in Germany with general guidelines for the use

Table 6Analysis of Publications Reporting Guidelines and Specific Indications and/or Contraindicationsfor the Use of Cross-Sectional Radiography for the Assessment of Potential Dental Implant Sites								
Clinical situation	Specific indication(s)							
Initial examination								
Preoperative								
All sites								
Clinical doubt of alveolar bone height, width and/or shape								
Bone density evaluation								
Specific anatomic sites	<ul> <li>Anterior maxilla (nasal floor, naso-palatine canal, anterior superior alveolar canal)</li> <li>Posterior maxilla (maxillary sinus and related structures, posterior superior alveolar canal, maxillary tuberosity, pterygoid plates</li> <li>Anterior mandible (lingual foramen, incisive canal, genial tubercles)</li> <li>Posterior mandible (inferior alveolar nerve canal, mental foramina, anterior loop, retromolar foramen, sublingual fossa [lingual</li> </ul>							
	undercut], mylohyoid undercut, lingula of ascending ramus) Zygomatic region (orbital floor, infraorbital foramen, zygomatic bone)							
Anterior aesthetic zone								
Site development	Sinus augmentation Block or particulate bone grafting Ramus or symphysis grafting Pathology/impacted teeth in field of interest Prior traumatic injury							
Computer-assisted treatment planning, treatment options, optimal implant position								
Postoperative								
Integration	Marginal peri-implant bone height Bone-implant interface Postaugmentation assessment (eg, sinus, particulate/block)							
Postoperative complications	Altered sensation Infection/postoperative integration failure Implant mobility Rhino-sinusitis							

Pa: intraoral periapical radiograph; Pan: panoramic radiography.

\*Papers included from Focus Question 1.

\*\*Papers included from Pico strategy, hand search, and grey literature search (Focus Question 2).

of CBCT in various clinical situations.<sup>41</sup> In a small section on implant dentistry, the authors provided only two recommendations: (1) that "a computer-aided planning on the basis of three-dimensional radiograph procedure should be performed with the help of CBCT," and (2) "that because of beam hardening artifacts, the assessment of bone in the immediate periimplant region as well as the region between adjacent implants is limited." As a follow-up publication, the proceedings of different dental associations of Germany from a consensus meeting in 2010 were published by the Deutsche Gesellschaft für Zahn-, Mund- und Kieferheikunde (DGZMK)<sup>47</sup> focusing on indications for three-dimensional diagnosis and treatment planning for dental implants and guided surgery. The group based their recommendations on a systematic literature search, although the selected papers were not presented or discussed.

The Academy of Osseointegration (AO) provided an update on general clinical guidelines on the provision of dental implants<sup>42</sup> initially published in 2008<sup>106</sup> based on a 2006 consensus conference.<sup>107</sup> For implant dentistry, the AO adopted the indications for the use of CT imaging proposed by the EAO<sup>1</sup> and recommended that for CBCT use members review the provisional specific guidelines promulgated by the SEDENTEXCT

	Modali	ty Recommendations According to	Reference*
Ра	Pan	Cross-sectional (inc. MDCT)	СВСТ
1*, 2*, 39*, 40*, 47*, 48*	1*, 2*, 39*, 40*, 47*, 48*		
		39*, 40*, 48*	39*, 45*, 48*
		1*, 2*, 47*, 50**, 52**	2*, 41*, 42*, 43*, 44*, 46*, 47*
1*	1*		42*, 43*, 44*, 46*, 77**
		1*, 2* 1*, 2*, 47* 1*, 2*	2*, 42*, 43*, 44*, 46*, 61**, 79**, 87**, 95**, 96**, 100**, 103** 2*, 42*, 43*, 44*, 46*, 47*, 97**, 101**, 105** 2*, 42*, 43*, 44*, 46*, 84**, 93**, 94**, 98**
	49**, 67**, 104**	1*, 2*, 47*, 55**, 56**, 57**, 62**,64** 1*, 2*, 76**	
		1*	46*, 90**
		1*, 2*, 47*, 48* 1*, 2*, 39*, 40*, 48* 1*, 2*, 48* 47* 39*, 40*	1*, 41*, 46*, 47*, 48*, 82** 2*, 41*, 46*, 48* 2*, 48* 46*, 47*, 48* 46*, 48*
		47*, 51**, 53**, 54**, 58**, 59**, 60**, 63**, 65**	2*, 36, 41*, 42*, 43*, 44*, 46*, 47*, 48*, 69**, 72**, 73**, 80**, 88**, 90**
48* 48*			
			46*, 48*, 82**, 83**
		1*, 2*, 47*, 48*, 66** 1*, 2*, 48*	2*, 46*, 47*, 48*, 75**, 78**, 86**, 91** 2*, 46*, 48* 48*
		1*	46*

group at that time—a document that has been revised and accepted<sup>43</sup> and subsequently adopted by the European Commission (EC).<sup>44</sup> In addition, they indicated that large field of view images should not be routinely used.

The SEDENTEXCT Project was a funded collaborative European Atomic Energy Community (EURATOM) project of dentists, dento-maxillofacial radiologists, imaging technologists, medical physicists, and equipment manufacturers from within Europe under directives from the European Commission.<sup>43</sup> It is the only funded group that has developed CBCT use guidelines. The report includes all aspects of CBCT use with a specific section on implant dentistry. The analysis of the literature was performed with moderate methodologic rigor; however, as the literature available for formal review was limited in quantity, the Guideline Development Panel (GDP) also reviewed case reports/series and non-systematic reviews. The GDP did not develop new clinically-based use criteria, however, and accepted the EAO guidelines for cross-sectional imaging<sup>1</sup> as equivalent for CBCT imaging. This group made two specific recommendations: "that CBCT could be considered as an alternate to existing cross-sectional techniques when the radiation dose was lower" and that "CBCT provides advantages to MDCT because of adjustable

fields of view reduce radiation dose detriment." In addition they were the first to report uncertainty on the validity and reliability of CBCT bone density measurements as an index of bone quality. These findings were corroborated by a recent study that was evaluating the variability of intensity values in CBCT imaging compared with multislice computed tomography (MSCT) HU units in order to assess the reliability of density assessments in jawbone phantoms.<sup>21</sup> The authors concluded that the use of intensity values in CBCT images is not reliable, because these values are influenced by device, imaging parameters, and positioning.

The publication by the Superior Health Authority (SHA) of Belgium is the only national government professional organization to provide specific guidelines and indications for the use of CBCT with a specific reference to implant dentistry.45 The working group comprised experts in dentistry, oral and maxillofacial surgery, radiology, medical physics, and radiation protection. This group acknowledged basing their guideline on expert consensus as well as the scientific literature identified by the SEDENTEXCT Project.<sup>43</sup> The SHA provide only one statement regarding the use of CBCT for dental implants "... if 2D images do not provide sufficient information, a dental CBCT image can be made of the dental and maxillofacial region by experienced operators for diagnostic purposes and/or preoperative surgical planning in the event of ... preoperative planning for ... and the placing of implants". The working group did apply the caveat that use was predicated on compliance with the principles of radiation protection "... especially by adjusting the size of the field to the indication, selecting the mA(s) settings according to individual cases and potentially adapting other optimization means ..."

Benavides et al<sup>46</sup> reported the consensus findings from a multi-disciplinary international professional organization concerned with dental implantology. They stated that based on their literature review and expert opinion, "... it is virtually impossible to predict which treatment cases would not benefit from having this (CBCT) additional information before obtaining it" and suggested that CBCT should be considered as an imaging alternative: (1) "in cases where the projected implant receptor or bone augmentation site(s) are suspect", and (2) when "conventional radiography may not be able to assess the true regional three-dimensional anatomical presentation." In regards to situations in which CBCT was considered as superior to conventional radiography, the group cited five specific indications including computer-aided implant planning cases, anterior esthetic zone or regions of suspicious anatomy (eg, concavities, ridge inclination, inadequate bone volume), pre- and post-bone graft evaluation, history of suspected trauma to the jaws, and evaluation of postimplant complications (postoperative neurosensory impairment, osteomyelitis, acute rhino-sinusitis). They indicated that future research was needed in the areas of CBCT-derived bone density measurements (as first identified by the SEDENTEXCT Project),<sup>43</sup> CBCT-aided surgical navigation, and post-implant CBCT artifacts.

Harris and coworkers in 2012 reported on a follow up EAO consensus workshop 10 years after the original workshop in 2002.<sup>2</sup> The workshop was closed and included European experts in both clinical practice and radiology on the basis of their established scientific contributions to the field, specialist knowledge, significant clinical experience, and relevant activities in their academic institutions. The consensus group stated that cross-sectional imaging is not indicated for situations, "if the clinical assessment of implant sites indicates that there is sufficient bone width and the conventional radiographic examination reveals the relevant anatomical boundaries and adequate bone height and space". The group made general and specific recommendations for cross-sectional imaging (including CBCT) for implant site assessment and treatment planning. Generally, cross-sectional imaging was recommended when clinical examination and conventional radiography have failed to adequately demonstrate relevant anatomical boundaries or the location of important anatomical structures. More specifically, imaging was deemed appropriate in cases where extensive bone augmentation is anticipated, for all sinus augmentation and guided surgery cases, in some instances for autogenous bone donor sites and special techniques (eg, zygomatic implants and osteogenic distraction) and possibly in some cases presenting with postoperative complications (eq, nerve damage or infection).

In 2012, the AAOMR produced literature based, consensus-derived, clinical guidance recommendations for overall imaging approaches in implant dentistry with emphasis on CBCT technology<sup>48</sup> as an update to their report twelve years earlier.<sup>39</sup> Eleven specific action statements are provided within each phase of implant therapy including initial assessment (three statements), preoperative site specific imaging (four statements), and postoperative imaging (four statements). Recommendation 4 and 5 together form the basis of the report and state that "... radiographic examination of any potential implant site should include cross-sectional imaging ..." and "CBCT should be considered as the imaging modality of choice for preoperative cross-sectional imaging ..." They also provide specific action statements in that initial imaging should comprise panoramic and intra-oral radiography only (recommendations 1, 2, and 3), CBCT should be considered prior to and after clinical conditions indicating a need for bone augmentation or site development (recommendations 6 and 7), and CBCT postoperative use be restricted to situations where implant retrieval is anticipated or if the patient presents with implant mobility or altered sensation.

The literature results from the PICO, hand, and grey literature searches provide specific evidence in support of many of the recommendations described above: numerous authors have described the importance of various anatomic structures identified on cross-sectional imaging<sup>71</sup> including the inferior alveolar (mandibular) canal,<sup>55,57,68,70,102</sup> anterior loop and mandibular incisive canal,<sup>89,93</sup> mental foramen,<sup>56,64,92,99</sup> lingual canal,<sup>84,98</sup> submandibular gland fossa/lingual undercut,74,94,100 maxillary incisive/nasopalatine canal,<sup>61,79,87,95</sup> and maxillary sinus,<sup>62,81,82,97,101,105</sup> and highlight the variability of imaging identification and characteristics of these structures in relation to implant placement. In addition, the value of cross-sectional imaging in treatment planning of sinus augmentation procedures has been reported.85

Many authors have reported on the improved clinical efficacy of cross-sectional imaging and, more recently CBCT, as compared with standard radiographic techniques to facilitate the evaluation of implant sites,<sup>50,52</sup> in achieving an ideal position of dental implants as compared to conventional techniques<sup>88,90</sup> particularly in the mandible<sup>53,59</sup> or influencing treatment options such as choice and placement of implants in edentulous regions of the jaws<sup>51,54,58,60,63,65,69</sup> <sup>,72,73,80</sup> as well as the zygomatic arch.<sup>76</sup> However, some authors have demonstrated that clinical examination and panoramic radiography alone may provide sufficient imaging for posterior mandibular implant placement,<sup>49,104</sup> especially when there is a 2-mm margin of safety above the inferior alveolar canal.<sup>67</sup>

Placement of dental implants is an important cause of iatrogenic inferior alveolar nerve injuries.<sup>66,86</sup> Overall, implant cases only account for 3% of all reported postsurgical neurosensory disturbances.<sup>108</sup> But when focusing on permanent neurosensory disturbances, the contribution of implant placement is four-fold (12% of injuries).<sup>108</sup> Overall, the incidence of neuropathic orofacial pain following implant placement varies from 0% to 24% for transient and 0% to 11% for permanent damage, depending on the anatomical area, the presurgical planning, the surgical act, and the postoperative neurosensory evaluation method.<sup>109</sup> Recently some authors have correlated post-implant mandibular nerve neuropathy with preoperative imaging. Renton and coworkers reported that of 30 patients with implant placement related permanent neuropathy of the inferior alveolar nerve (IAN),<sup>91</sup> CBCT preoperative imaging was associated with only 10%, whereas the remaining patients had only intraoral images (30%), panoramic radiography (50%), and long

cone periapical radiography (48%). CBCT imaging has been reported to be of value in assessment of IAN risk injury in regard to immediate implant placement at premolar and first molar sites in the posterior mandible<sup>78</sup> and, together with surgical guides, in reducing immediate postoperative complications.<sup>75</sup>

Besides neurosensory disturbances, neurovascular complications due to implant surgery can also result in severe intraoral hemorrhage. Significant hemorrhages are mostly described after anterior mandibular implant placement, and sinus augmentation prior to or with implant placement. For mandibular implant placement, there are 19 case reports related to hemorrhage in the floor of the mouth and potentially life-threatening upper airway obstruction (see Jacobs et al).<sup>109</sup> Significant bleeding may also occur during sinus augmentation procedures. Because of its location in the lateral sinus wall, the intraosseous artery has the potential to cause bleeding complications in lateral window osteotomies.<sup>110</sup> Nevertheless, it has to be stated that it will be difficult to prove a clear benefit of CBCT over conventional two-dimensional imaging such as panoramic radiography with respect to damage of the IAN or other vital neurovascular structures in prospective studies. Recently, a study calculated patient sample sizes ranging from 39,584 to 245,724, or 140,024 to 869,250 of mandibular third molar removals needed, ideally performed by only one or two surgeons, to prove a potential benefit from presurgical CBCT scans, with respect to the most important outcome parameter of reduced damage to the IAN.<sup>111</sup>

There are limited studies suggesting good correlation in the use of CBCT density values to monitor ossification of sinus augmentation material<sup>83</sup> and cancellous bone.<sup>77</sup>

#### **Focus Question 3**

The PICO search identified 121 publications. After screening of the abstracts (50) and full text articles (28), and hand searching (2), a total of 22 articles were included.<sup>37,38,112-131</sup> Table 7 provides the results of this literature search, providing a summary of the current evidence on effective dose (ICRP<sub>2007</sub>)<sup>36</sup> or mean absorbed dose for specific organs for cross-sectional and conventional imaging classified as to the dose measurement reported; the purpose of the study, whether general dose information or specifically related to implant dentistry; and the type and number of devices examined. Only two articles specifically reported effective doses for the use of CBCT imaging in oral implantology,<sup>117,118</sup> and one reported dose-area products for two CBCT devices in two diagnostic tasks (periapical diagnosis and implant planning).<sup>124</sup> Most articles reported on measured effective doses in the context of general maxillofacial imaging.

## Table 7 Summary of Current Evidence on Effective Dose (ICRP<sub>2007</sub>) or Organ-Specific Mean Absorbed Dose for CBCT

				Applic	ation	Modality examined (No. of devices studied)			
Study	Year	Measurement	Implant	General	Ortho	Other	СВСТ	MSCT	Pan
Ludlow et al*37	2006	E		+			3		
Ludlow and Ivanovic <sup>38</sup>	2008	E		+			8	1	
Silva et al <sup>112</sup>	2008	E			+		3	1	
Hirsch et al <sup>113</sup>	2008	E		+			2		
Palomo et al <sup>114</sup>	2008	E		+			1		
Lofthag-Hansen et al <sup>115</sup>	2008	E		+			2		
Roberts et al <sup>116</sup>	2009	E		+			1		
Loubele et al <sup>117</sup>	2009	E	+				3	2	
Okano et al <sup>118</sup>	2009	E	+				3	1	
Suomalainen et al <sup>†119</sup>	2009	E		+			3	2	
Qu et al <sup>120</sup>	2010	E		+			1		
Carrafiello et al <sup>121</sup>	2010	E		+			1	1	1
Librizzi et al <sup>+122</sup>	2011	E				+	1		
Ludlow <sup>123</sup>	2011	E		+			1		
Lofthag-Hansen et al <sup>124</sup>	2011	DAP	+			+	2		
Theodorakou et al <sup>125</sup>	2012	E		+			5		
Davies et al <sup>126</sup>	2012	E		+			1		
Pauwels et al <sup>127</sup>	2012	E		+			12		
Grünheid et al <sup>128</sup>	2012	E			+		1		1
Qu et al <sup>129</sup>	2012	E		+			1		
Koivisto et al <sup>130</sup>	2012	E		+			1		
Jeong et al <sup>131</sup>	2012	E		+			3	1	

CBCT: cone beam computed tomography; Ortho: orthodontics; MDCT: multi-detector computed tomography; Pan: panoramic radiography; E: effective dose using ICRP<sub>2007</sub> calculations; DAP: dose-area product.

\*Individual organs were summed using 1990 and proposed 2005 ICRP tissue-weighting factors.

<sup>†</sup>One of five studies published and summarized in the academic dissertation: Kiljunen T. Patient dose in CT, dental cone beam CT and projection radiography in Finland, with emphasis on pediatric patients. STUK / Radiation and Nuclear Safety Authority. Helsinki, Finland, 2008.

<sup>†</sup>Application of CBCT in this study for imaging of the temporomandibular joint.

Table 8 provides the radiation effective dose (based on ICRP<sub>2007</sub>)<sup>36</sup> measured in  $\mu$ Sv for specific CBCT equipment and conventional radiographic techniques. CBCT devices were grouped according to their FOV, resulting in three categories: CBCT devices with small (< 40 cm<sup>2</sup>), medium (40 to 100 cm<sup>2</sup>), and large (> 100 cm<sup>2</sup>) FOVs. Reported dose-area products (DAPs) were converted using specific publications.<sup>132,133</sup> When looking at the reported effective dose ranges for all three groups, there is a wide range of doses ranging from 11 to 252  $\mu$ Sv for small, from 28 to 652  $\mu$ Sv for medium, and from 52 to 1,073  $\mu$ Sv for large. Although Table 8 lists a wide variety of doses for a wide variety of indications with many different CBCT machines, it is obvious that dose values reported in various studies are not always comparable in absolute terms, as thermoluminescent dosimeter (TLD) calibration, TLD positioning, number of TLDs (per organ), organs measured, phantom characteristics, and exposure conditions may easily yield differences in organ doses of greater than 80%.<sup>127</sup>

# Table 8Published Effective Doses (μSv) (ICRP2007) for Small, Medium, and Large FOVCBCT in Comparison to MSCT, Panoramic, and Cephalometric Radiography

Study	Publication year	CBCT unit specification	Scanning characteristics (machine dependent)	Adult / adolescent/ child protocol	Effective dose (µSv)
CBCT: Dentoalveolar sn	nall (< 40 cm	2)			
Lofthag-Hansen et al <sup>115</sup>	2008	3D Accuitomo IID	$3  imes 4 \text{ cm}^2 36.5 \text{ mA}$	Adult	11–27*
Suomalainen et al <sup>119</sup>	2009	3D Accuitomo IID	$3 \times 4 \text{ cm}^2$	Adult	27
Loubele et al <sup>117</sup>	2009	3D Accuitomo IID	$3 \times 4 \text{ cm}^2$	Adult	29
Lofthag-Hansen et al <sup>124</sup>	2011	3D Accuitomo IID	$3 \times 4 \text{ cm}^2 46 \text{ mA}$	Adult	29-48†
Lofthag-Hansen et al <sup>124</sup>	2011	3D Accuitomo IID	$3 \times 4 \text{ cm}^2 \text{ IQ sufficient-better}$ for implant planning	Adult	15-81†
Hirsch et al <sup>113</sup>	2008	3D Accuitomo FPD	$4 \times 4 \text{ cm}^2$	Adult	20
Lofthag-Hansen et al <sup>115</sup>	2008	3D Accuitomo FPD	$4 \times 4 \text{ cm}^2 46 \text{ mA}$	Adult	21–31*
Okano et al <sup>118</sup>	2009	3D Accuitomo FPD	$4 \times 4 \ \text{cm}^2$	Adult	102
Lofthag-Hansen et al <sup>124</sup>	2011	3D Accuitomo FPD	$4 \times 4 \text{ cm}^2 46 \text{ mA}$	Adult	41–69†
Lofthag-Hansen et al <sup>124</sup>	2011	3D Accuitomo FPD	$4\times4~\text{cm}^2$ IQ sufficient-better for implant planning	Adult	21-116
Hirsch et al <sup>113</sup>	2008	3D Accuitomo FPD	$6 \times 6 \text{ cm}^2$	Adult	43
Lofthag-Hansen et al <sup>115</sup>	2008	3D Accuitomo FPD	$6  imes 6 \text{ cm}^2 \text{ 4.5-6 mA}$	Adult	52–77*
Suomalainen et al <sup>119</sup>	2009	3D Accuitomo FPD	$6 \times 6 \text{ cm}^2$	Adult	166
Okano et al <sup>118</sup>	2009	3D Accuitomo FPD	$6 \times 6 \text{ cm}^2$	Adult	50
Lofthag-Hansen et al <sup>124</sup>	2011	3D Accuitomo FPD	$6 \times 6 \text{ cm}^2 46 \text{ mA}$	Adult	90–151
Lofthag-Hansen et al <sup>124</sup>	2011	3D Accuitomo FPD	$6 \times 6 \text{ cm}^2 \text{ IQ sufficient-better}$ for implant planning	Adult	46–252
Theodorakou et al <sup>125</sup>	2012	3D Accuitomo 170	$4 \times 4 \ \text{cm}^2$ lower molars	10 y old	28
Theodorakou et al <sup>125</sup>	2012	3D Accuitomo 170	$4 \times 4 \ \text{cm}^2$ lower molars	Adolescent	32
Pauwels et al <sup>127</sup>	2012	3D Accuitomo 170	$4 \times 4 \text{ cm}^2$	Adult	43
Hirsch et al <sup>113</sup>	2008	Veraviewepocs 3D	$4 \times 4 \text{ cm}^2 / 4 \times 4 \text{ cm}^2 + \text{pano}$	Adult	31/30
Hirsch et al <sup>113</sup>	2008	Veraviewepocs 3D	$8 imes 4~{ m cm^2}$ / $6 imes 6~{ m cm^2}$	Adult	40/40
Pauwels et al <sup>127</sup>	2012	Kodak 9000 3D	$5  imes 3.7 \ \mathrm{cm^2}$ lower molars	Adult	40
Theodorakou et al <sup>125</sup>	2012	Kodak 9000 3D	$5 imes 3.7~{ m cm^2}$ upper front	10 y old	16
Theodorakou et al <sup>125</sup>	2012	Kodak 9000 3D	$5 imes 3.7~{ m cm^2}$ lower molars	Adolescent	24
Pauwels et al <sup>127</sup>	2012	Kodak 9000 3D	$5 imes 3.7~\text{cm}^2$ upper front	Adult	19
Pauwels et al <sup>127</sup>	2012	Kodak 9000 3D	$5 imes 3.7~{ m cm^2}$ lower molars	Adult	40
Pauwels et al <sup>127</sup>	2012	Pax-Uni3D	$5  imes 5 \ \mathrm{cm^2} \ \mathrm{upper} \ \mathrm{front}$	Adult	44
Suomalainen et al <sup>119</sup>	2009	Scanora 3D	$6 \times 6 \text{ cm}^2$	Adult	91
Jeong et al <sup>131</sup>	2012	Implagraphy	$8 \times 5 \text{ cm}^2$	Adult	83
BCT: Dentoalveolar me	edium (40–10	00 cm²)			
Jeong et al <sup>131</sup>	2012	3DeXAM	$10  imes 5 \ \mathrm{cm^2} \ \mathrm{LJ}$	Adult	111
Pauwels et al <sup>127</sup>	2012	3D Accuitomo 170	$10 imes 5~{ m cm^2}~{ m UJ}$	Adult	54
Jeong et al <sup>131</sup>	2012	AZ3000CT	$7.9 imes7.1~{ m cm^2}$	Adult	333
Ludlow and Ivanovic <sup>38</sup>	2008	Prexion 3D	$8.1 imes7.6~{ m cm^2}$ standard/HR	Adult	189/388
Ludlow and Ivanovic <sup>38</sup>	2008	Promax 3D	$8 \times 8 \text{ cm}^2$ low/high dose	Adult	488/652

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# Table 8 continuedPublished Effective Doses (µSv) (ICRP2007) for Small, Medium, and Large FOVCBCT in Comparison to MSCT, Panoramic, and Cephalometric Radiography

Study	Publication year	CBCT unit specification	Scanning characteristics (machine dependent)	Adult / adolescent/ child protocol	Effective dose (µSv)
Suomalainen et al <sup>119</sup>	2009	Promax 3D	$8 \times 8 \text{ cm}^2$	Adult	674
Qu et al <sup>129</sup>	2012	Promax 3D	$8  imes 8  { m cm^2}$ low/high dose/standard	Adult	30/306/197
Theodorakou et al <sup>125</sup>	2012	Promax 3D	$8 \times 8 \ \text{cm}^2$ low dose	10 y old	28
Theodorakou et al <sup>125</sup>	2012	Promax 3D	$8 \times 8 \ \text{cm}^2$ low dose	Adolescent	18
Koivisto et al <sup>130</sup>	2012	Promax 3D	$8 \times 8 \text{ cm}^2$	Adult	153
Pauwels et al <sup>127</sup>	2012	Promax 3D	$8  imes 8 \ { m cm^2}$ low/high dose	Adult	28/122
Pauwels et al <sup>127</sup>	2012	Veraviewepocs 3D	$8 \times 8 \text{ cm}^2$	Adult	73
Theodorakou et al <sup>125</sup>	2012	Scanora 3D	$10 imes 7.5~{ m cm^2}$	10 y old	67
Theodorakou et al <sup>125</sup>	2012	Scanora 3D	$10 imes7.5~{ m cm}^2$	Adolescent	52
Pauwels et al <sup>127</sup>	2012	Scanora 3D	$10 imes 7.5~{ m cm^2}~{ m UJ/LJ/UJ+LJ}$	Adult	46/47/45
Ludlow <sup>123</sup>	2011	Kodak 9500	5 imes 15 cm² without/with filtration	Adult	93/76
Ludlow <sup>123</sup>	2011	Kodak 9500	9 imes 15 cm² without/with filtration	Adult	163/98
Pauwels et al <sup>127</sup>	2012	Kodak 9500	$9 imes15~{ m cm^2}$	Adult	92
Pauwels et al <sup>127</sup>	2012	Picasso Trio	$12 imes 7~{ m cm^2}$ low/high dose	Adult	81/123
Pauwels et al <sup>127</sup>	2012	NewTom VGi	$12 imes 8~{ m cm^2}$ high dose	Adult	265
Theodorakou et al <sup>125</sup>	2012	3D Accuitomo 170	$14  imes 5 \ \mathrm{cm^2} \ \mathrm{UJ}$	10 y old	214
Theodorakou et al <sup>125</sup>	2012	3D Accuitomo 170	$14 imes 5~{ m cm^2}~{ m UJ}$	Adolescent	70
Roberts et al <sup>116</sup>	2009	i-CAT classic	$16 imes 6~{ m cm^2}~{ m standard/HR}$	Adult	59/93
Roberts et al <sup>116</sup>	2009	i-CAT classic	$16 imes 6~{ m cm^2}$ standard/HR	Adult	96/189
Theodorakou et al <sup>125</sup>	2012	i-Cat Next Generation	$16 imes 6~{ m cm^2}~{ m LJ/UJ}$	10 y old	63/43
Theodorakou et al <sup>125</sup>	2012	i-Cat Next Generation	$16 imes 6~{ m cm^2}~{ m LJ/UJ}$	Adolescent	49/33
Ludlow and Ivanovic <sup>38</sup>	2008	i-Cat Next Generation	$16  imes 6 \ \mathrm{cm^2}$	Adult	74
Davies et al <sup>126</sup>	2012	i-Cat Next Generation	$16 imes 6~{ m cm^2}{ m LJ}$ low/high dose	Adult	58/113
Davies et al <sup>126</sup>	2012	i-Cat Next Generation	$16 imes 6~{ m cm^2}$ UJ low/high dose	Adult	32/60
Pauwels et al <sup>127</sup>	2012	i-Cat Next Generation	$16 \times 6 \text{ cm}^2 \text{ LJ low dose}$	Adult	45
CBCT: Craniofacial (>	<b>100 cm</b> <sup>2</sup> )				
Ludlow et al <sup>37</sup>	2006	CB Mercuray	$10 imes10~{ m cm^2}$	Adult	283
Ludlow and Ivanovic <sup>38</sup>	2008	CB Mercuray	$10 \times 10 \text{ cm}^2$	Adult	407
Palomo et al <sup>114</sup>	2008	CB Mercuray	$10 \times 10 \text{ cm}^2$	Adult	603
Librizzi et al <sup>122</sup>	2011	CB Mercuray	$10 imes 10~{ m cm^2}{ m TMJ}$ imaging	Adult	283
Theodorakou et al <sup>125</sup>	2012	3D Accuitomo 170	$14 \times 10 \text{ cm}^2$	10 y old	237
Theodorakou et al <sup>125</sup>	2012	3D Accuitomo 170	$14 \times 10 \text{ cm}^2$	Adolescent	188
Theodorakou et al <sup>125</sup>	2012	Scanora 3D	$14.5 \times 13.5 \text{ cm}^2$	10 y old	85
Theodorakou et al <sup>125</sup>	2012	Scanora 3D	$14.5 \times 13.5 \text{ cm}^2$	Adolescent	74
Pauwels et al <sup>127</sup>	2012	Scanora 3D	$14.5 \times 13.5 \text{ cm}^2$	Adult	68
Theodorakou et al <sup>125</sup>	2012	NewTom VG	$15 \times 11 \text{ cm}^2$	10 y old	114
Theodorakou et al <sup>125</sup>	2012	NewTom VG	$15 \times 11 \text{ cm}^2$	Adolescent	81

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# Table 8 continuedPublished Effective Doses ( $\mu$ Sv) (ICRP<br/>2007) for Small, Medium, and Large FOV<br/>CBCT in Comparison to MSCT, Panoramic, and Cephalometric Radiography

Study	Publication year	CBCT unit specification	Scanning characteristics (machine dependent)	Adult / adolescent/ child protocol	Effective dose (µSv)
Pauwels et al <sup>127</sup>	2012	NewTom VG	$15 \times 11 \text{ cm}^2$	Adult	83
Silva et al <sup>112</sup>	2008	NewTom 9000	$15 imes15~{ m cm^2}$	Adult	56
Qu et al <sup>129</sup>	2012	NewTom 9000	15 imes15 cm² with/without thyroid shielding	Adult	79/95
Ludlow et al <sup>37</sup>	2006	NewTom 9000	$15  imes 15 \ \mathrm{cm^2}$	Adult	52 recalculate
Loubele et al <sup>117</sup>	2009	NewTom 3G	$15 imes15~{ m cm^2}$	Adult	57
Pauwels et al <sup>127</sup>	2012	NewTom VGi	$15 imes15~{ m cm^2}$	Adult	194
Ludlow and Ivanovic <sup>38</sup>	2008	Galileos	$15 imes15~{ m cm^2}$ low/high dose	Adult	70/128
Theodorakou et al <sup>125</sup>	2012	Galileos comfort	$15 imes15~{ m cm^2}$	10 y old	70
Theodorakou et al <sup>125</sup>	2012	Galileos comfort	$15 imes15~{ m cm^2}$	Adolescent	71
Pauwels et al <sup>127</sup>	2012	Galileos comfort	$15 imes15~{ m cm^2}$	Adult	84
Ludlow et al <sup>37</sup>	2006	CB Mercuray	$15 imes15~{ m cm^2}$	Adult	436
Ludlow and Ivanovic <sup>38</sup>	2008	CB Mercuray	$15 imes15~{ m cm^2}$	Adult	569
Palomo et al <sup>114</sup>	2008	CB Mercuray	$15 imes15~{ m cm^2}$	Adult	680
Okano et al <sup>118</sup>	2009	CB Mercuray	$15 imes15~{ m cm^2}$	Adult	511
Librizzi et al <sup>122</sup>	2011	CB Mercuray	15 imes15 cm² TMJ imaging	Adult	436
Silva et al <sup>112</sup>	2008	i-CAT Classic	$16 imes13~{ m cm^2}$	Adult	61
Ludlow et al <sup>37</sup>	2006	i-CAT Classic	$16 imes13~{ m cm^2}$	Adult	105
Roberts et al <sup>116</sup>	2009	i-CAT Classic	$16 imes13~{ m cm^2}$	Adult	134
Ludlow and Ivanovic <sup>38</sup>	2008	i-CAT Classic	$16 imes13~{ m cm^2}$	Adult	69
Ludlow and Ivanovic <sup>38</sup>	2008	i-CAT Next Generation	$16 imes13~{ m cm^2}$	Adult	87
Theodorakou et al <sup>125</sup>	2012	i-CAT Next Generation	$16 imes13~{ m cm^2}$	10 y old	134
Theodorakou et al <sup>125</sup>	2012	i-CAT Next Generation	$16 imes13~{ m cm^2}$	Adolescent	82
Pauwels et al <sup>127</sup>	2012	i-CAT Next Generation	$16 imes13~{ m cm^2}$	Adult	83
Davies et al <sup>126</sup>	2012	i-CAT Next Generation	$16 imes13~{ m cm^2}$	Adult	77
Theodorakou et al <sup>125</sup>	2012	3D Accuitomo 170	$17 imes12~{ m cm^2}$	10 y old	282
Theodorakou et al <sup>125</sup>	2012	3D Accuitomo 170	$17 imes 12~{ m cm}^2$	Adolescent	216
Theodorakou et al <sup>125</sup>	2012	Skyview 3D	$17 imes 17~{ m cm^2}$	10 y old	105
Theodorakou et al <sup>125</sup>	2012	Skyview 3D	$17 imes 17~{ m cm^2}$	Adolescent	90
Pauwels et al <sup>127</sup>	2012	Skyview 3D	$17 imes 17~{ m cm^2}$	Adult	87
Ludlow et al <sup>37</sup>	2006	i-CAT Classic	$16  imes 22  ext{ cm}^2$	Adult	193
Loubele et al <sup>117</sup>	2009	i-CAT Classic	$16  imes 22  ext{ cm}^2$	Adult	82
Roberts et al <sup>116</sup>	2009	i-CAT Classic	$16 imes 22~{ m cm}^2$	Adult	206
Carrafiello et al <sup>121</sup>	2010	i-CAT Classic	$16  imes 22  ext{ cm}^2$	Adult	110
Grünheid et al <sup>128</sup>	2012	i-CAT Classic	$16  imes 22  ext{ cm}^2  ext{ LR}$	Adult	65–69
Grünheid et al <sup>128</sup>	2012	i-CAT Classic	$16  imes 22  ext{ cm}^2  ext{ HR}$	Adult	127–131
Ludlow <sup>123</sup>	2011	Kodak 9500	$18  imes 20 \ { m cm^2}$ without/ with filtration	Adult	260/166

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## Table 8 continuedPublished Effective Doses (µSv) (ICRP2007) for Small, Medium, and Large FOVCBCT in Comparison to MSCT, Panoramic, and Cephalometric Radiography

Study	Publication year	CBCT unit specification	Scanning characteristics (machine dependent)	Adult / adolescent/ child protocol	Effective dose (µSv)				
Pauwels et al <sup>127</sup>	2012	Kodak 9500	$18 imes 20~{ m cm^2}$	Adult	136				
Ludlow and Ivanovic <sup>38</sup>	2008	ILUMA	$19 imes19~ ext{cm}^2$ standard/HR	Adult	98/498				
Ludlow et al <sup>37</sup>	2006	CB Mercuray	$20 imes 20~{ m cm^2}~{ m standard/HR}$	Adult	558/1025				
Palomo et al <sup>114</sup>	2008	CB Mercuray	$20  imes 20 \text{ cm}^2$	Adult	761				
Ludlow and Ivanovic <sup>38</sup>	2008	CB Mercuray	$20 imes 20~{ m cm^2}$	Adult	1073				
Librizzi et al <sup>122</sup>	2011	CB Mercuray	$20 imes 20~{ m cm^2}~{ m TMJ}$ imaging	Adult	916				
Ludlow et al <sup>37</sup>	2006	New Tom 3G	$20  imes 20 \ \mathrm{cm^2}$	Adult	59				
Ludlow and Ivanovic <sup>38</sup>	2008	New Tom 3G	$20  imes 20 \ \mathrm{cm^2}$	Adult	68				
Ludlow and Ivanovic <sup>38</sup>	2008	i-CAT Next Generation	23  imes 17 cm <sup>2</sup>	Adult	74				
Davies et al <sup>126</sup>	2012	i-CAT Next Generation	$23 \times 17$ cm <sup>2</sup>	Adult	78				
Pauwels et al <sup>127</sup>	2012	ILUMA Elite	$21 imes$ 14 cm $^2$	Adult	368				
Carrafiello et al <sup>121</sup>	2010	Aquilion 64	$9 imes 4~{ m cm^2}~{ m LJ}$	Adult	990				
Okano et al <sup>118</sup>	2009	HiSpeed QX/I	$15 imes7.7~{ m cm^2}~{ m UJ/LJ}$	Adult	769				
Loubele et al <sup>117</sup>	2009	Philips M $ imes$ 8000IDT	LJ/head	Adult	541/1160				
Suomalainen et al <sup>119</sup>	2009	GE 4 slice CT	$25 imes 34.8~{ m cm^2}$	Adult	685				
Suomalainen et al <sup>119</sup>	2009	GE 64 slice CT	$25 imes 41.25~\mathrm{cm^2}$	Adult	1410				
Loubele et al <sup>117</sup>	2009	Somatom Volume Zoom 4	LJ/head	Adult	494/1110				
Jeong et al <sup>131</sup>	2012	Somatom Emotion 6	LJ low dose	Adult	199				
Jeong et al <sup>131</sup>	2012	Somatom Sensation 10	5 cm <sup>2</sup> LJ	Adult	426				
Loubele et al <sup>117</sup>	2009	Somatom Sensation 16	LJ/head	Adult	474/995				
Silva et al <sup>112</sup>	2008	Somatom Sensation 64	$10  imes 12 \ \mathrm{cm^2}$	Adult	430				
Theodorakou et al <sup>125</sup>	2012	Somatom Sensation 64	20  imes 11.7 cm <sup>2</sup>	10 y old	605				
Theodorakou et al <sup>125</sup>	2012	Somatom Sensation 64	$20  imes 12.8 \ \mathrm{cm^2}$	Adolescent	1047				
Extraoral radiography in 2D (panoramic/cephalometric)									
Theodorakou et al <sup>125</sup>	2012	Veraviewepocs 2D	$15 imes10~{ m cm^2}$ panoramic	Adolescent	6				
Silva et al <sup>112</sup>	2008	Orthophos DS	15 imes 11 cm² panoramic	Adult	10				
Carrafiello et al <sup>121</sup>	2010	Orthophos XG	$15 imes23~{ m cm^2}$ panoramic	Adult	50				
Grünheid et al <sup>128</sup>	2012	OP 100	$15 imes 30~{ m cm^2}$ panoramic	Adult	21.5				
Silva et al <sup>112</sup>	2008	Orthophos DS	$18 imes15~{ m cm^2}$ cephalometric	Adult	10				
Grünheid et al <sup>128</sup>	2012	OP/OC 100	$18 imes24~{ m cm^2}$ cephalometric	Adult	4.5				

UJ: Upper Jaw; LJ: Lower Jaw; LR: Low Resolution; HR: High Resolution; IID: Image Intensifier Detector; FPD: Flat Panel Detector; IQ: Image Quality. Within each of the five categories (small, medium, large CBCT, MSCT, extraoral radiography), ranking is based on chronologically reported data for machine-specific dose ranges, with an increasing field of view (FOV), while ordering from child to adult.

 $20 imes 20 \ \text{cm}^2$  cephalometric

2

Adolescent

Veraviewepocs 2D

\*Effective dose (E) was converted from dose-area-product (DAP measurements using the general formula  $E = DAP \times EDAP$  with  $EDAP = 0.08 \ \mu Sv$  per mGy cm<sup>2</sup> deriving from the conversion factor for panoramic radiography found by Helmrot & Alm Carlsson (2005).<sup>132</sup> This was the conversion factor used in the paper Lofthag-Hansen et al.<sup>115</sup>

<sup>†</sup>The DAP-data in the paper by Lofthag-Hansen et al<sup>124</sup> has been converted to effective dose using the conversion factor EDAP = 0.15 μSv per mGy cm<sup>2</sup>. Reference is personal communication with Ebba Helmrot, PhD, Department of Dentomaxillofacial Radiology, The Institute for Postgraduate Dental Education, Jönköping, Sweden, and the results presented in a poster at the IAEA conference in Bonn, Germany, 3–7 December 2012.<sup>133</sup>

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2012

Patient risk from radiation has been a continuing concern in oral and maxillofacial imaging, due to the frequency of radiographic examinations in dental practice. ALARA is the acronym for As Low As Reasonably Achievable and is a fundamental principle for diagnostic radiology.<sup>134,135</sup> In recent years, epidemiologists have suggested a link between genetics, sex, the immune system, and exposure to radiation with an increased risk of meningioma.<sup>136–138</sup> In particular, the association between self-reported dental radiographic exposure may be associated with an increased risk of intracranial meningioma.<sup>138</sup> With the increased use of CBCT imaging in dental practice, clinicians must be made aware that patient radiation doses associated with CBCT imaging are higher than those of conventional radiographic techniques. Therefore, routine replacement of current radiographic techniques must be considered with great care—especially when treating children. To measure the radiation risk for patients from a radiographic device or technique, the effective dose is considered as the most widely accepted figure.<sup>127,139</sup> Effective dose is measured using an anthropomorphic phantom, representing the shape and attenuation of an average human, most commonly an adult male.<sup>140</sup> However while average effective doses to the children and adolescent phantoms have been reported to be similar to adult doses,<sup>125</sup> specific organs in children (eg, salivary glands, thyroid) may receive up to a fourfold increase in dose relative to that of the adolescent. It is therefore imperative that dental CBCT examinations on children should be fully justified over conventional radiographic imaging, and that dose reduction is always achieved by reducing the field of view (FOV) size of the CBCT examinations to the actual region of interest.<sup>127</sup>

The present results indicate that depending on the CBCT equipment type and operator preferences, alteration of various exposure (milliamperage, kilovoltage), image quality (number of basis images, resolution, arc of trajectory), and radiation beam collimation settings (FOV) can markedly affect radiation dose to the patient. In fact, this review confirmed a recent report that CBCT devices on the market demonstrate a 20-fold range of the effective doses.<sup>127</sup> In addition, currently available CBCT units from different manufacturers vary in dose by as much as 10-fold for an equivalent FOV examination. The present literature review suggests that a single average effective dose is not a concept that should be used for the CBCT technique as a whole, when comparing it to alternative radiographic methods. As most devices exhibited effective doses in the 50-200 µSv range, it can be stated that CBCT imaging results in higher patient doses than standard radiographic methods used in dental practice for dental therapy but remain well below those reported for common MDCT protocols. Strategies which optimize exposure, such as FOV reduction to the region of interest, half-trajectory scanning, and reduction in exposure parameters often provide images of sufficient image quality for most diagnostic tasks associated with dental therapy.

To minimize patient radiation dose, the working group suggests that practitioners adopt CBCT equipment specific protocols to incorporate the imaging goal for the patient's specific presenting circumstances. The protocol should include considerations of exposure (mA and kVp), minimum image-quality parameters (eg, number of basis images, resolution), and restriction of the FOV to visualize adequately the region of interest.

## CONCLUSIONS

On the basis of the data found in the literature, the following can be concluded:

- Most published national and international guidelines on implant dentistry do not offer evidencebased action statements developed from a rigorous systematic review approach.
- Most publications on guidelines for CBCT use in implant dentistry provide recommendations that are consensus-based or derived from a limited methodological approach with only partial retrieval and/ or analysis of the literature or contain even generalized or non-case-specific statements.
- Indications or contraindications reported for CBCT use in implant dentistry are based on nonrandomized clinical trials, either cohort or case-controlled studies.
- The reported indications for CBCT use in implant dentistry vary from preoperative analysis regarding specific anatomic considerations, site development using grafts, and computer-assisted treatment planning to postoperative evaluation focusing on complications due to damage of neurovascular structures.
- It will be difficult to prove a clear and statistically significant benefit of cross-sectional imaging (with special emphasis on CBCT) over conventional twodimensional imaging such as panoramic radiography with respect to damage of the IAN or other vital neurovascular structures in the arches resulting in dysesthesia or pain in comparative prospective studies due to the high number of cases needed for such an evaluation (power).
- Effective doses for different CBCT devices exhibit a wide range, but for all devices, significant dose reduction can be achieved by reducing the FOV to the actual region of interest.

 Practitioners who prescribe or use CBCT units should design specific CBCT equipment protocols that are task specific and incorporate the imaging goal for the patient's specific presenting circumstances. The protocol should include considerations of exposure (mA and kVp), minimum image-quality parameters (eg, number of basis images, resolution), and restriction of the FOV to visualize adequately the region of interest.

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# Consensus Statements and Recommended Clinical Procedures Regarding Contemporary Surgical and Radiographic Techniques in Implant Dentistry

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## INTRODUCTORY REMARKS

Successful dental implant rehabilitation requires accurate preoperative planning of the surgical intervention based on prosthodontic considerations and validated treatment methods. The introduction and widespread use of cross-sectional imaging in implant dentistry using cone beam computed tomography (CBCT) over the last decade has enabled clinicians to diagnose and evaluate the jaws in three dimensions before and after insertion of dental implants, thus replacing computed tomography (CT) as the standard of care. Furthermore, computer-guided implant surgery uses data from cross-sectional imaging derived from CBCT scans on a routine basis. Considering rapid changes in science

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and clinical practice, two systematic reviews in this group, by Bornstein et al and Tahmaseb et al, have centered their focus questions on these topics.

There are two possible surgical interventions for the treatment of the narrow edentulous ridge. The use of narrow-diameter implants has been suggested to avoid augmentation procedures and thus decrease patient morbidity. Nevertheless, this has not been validated in a systematic review of the literature to date. Horizontal augmentation procedures are widely used to increase the bone available for subsequent implant placement. However, knowledge on the efficacy and long-term outcomes of this procedure in the anterior maxilla is still limited. Therefore, the systematic reviews prepared for group 1 by Klein et al and by Kuchler and von Arx evaluated the existing data for these two rather different treatment options.

#### Disclosure

All the group members were asked to reveal any conflicts of interest that could potentially influence the outcomes of the consensus deliberations. No such conflicts were identified.

# CONE BEAM COMPUTED TOMOGRAPHY (CBCT) IN IMPLANT DENTISTRY

#### **General Comments**

The aim of the review by Bornstein et al was to identify, review, analyze, and summarize available evidence on the use of CBCT imaging in pre- and postoperative dental implant therapy with regard to: (1) currently available use guidelines, (2) specific indications and contraindications for use, and (3) the associated relative radiation dose risk.

For all three focused questions, the variablity of the selected papers was considerable, making comparisons of outcomes difficult. Regarding guidelines and specific indications or contraindications for CBCT use, it has been stated that the diagnostic procedures must be justified for each patient to demonstrate that the

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benefits outweigh the risks (http://www.eadmfr.eu/ basic-principles-use-dental-cone-beam-ct). However, it will be difficult to prove a clear and statistically significant benefit of cross-sectional imaging using CBCT over conventional two-dimensional imaging such as panoramic radiography with respect to implant survival/success and damage of the inferior alveolar nerve or other vital neurovascular structures in the jaws in comparative prospective studies due to the high number of cases (power) needed for such an evaluation. With regard to radiation dose risks, there is a trend for dose optimization by applying specific imaging protocols that include considerations of exposure (mA and kVp), image-guality parameters (eg, number of basis images, resolution), and restriction of the field of view to visualize adequately the region of interest.

## **Consensus Statements**

With respect to CBCT imaging in dental implant therapy and respective use guidelines, specific indications and contraindications for use, and the associated relative radiation dose risk, the following statements can be made:

- Current clinical practice guidelines for CBCT use in implant dentistry provide recommendations that are consensus-based or derived from non-standardized methodological approaches.
- Published indications for CBCT use in implant dentistry vary from preoperative analysis to postoperative evaluation, including complications. However, a clinically significant benefit for CBCT imaging over conventional two-dimensional methods resulting in treatment plan alteration, improved implant success, survival rates, and reduced complications has not been reported to date.
- CBCT imaging exhibits a significantly lower radiation dose risk than conventional CT, but higher than that of two-dimensional radiographic imaging. Different CBCT devices deliver a wide range of radiation doses. Substantial dose reduction can be achieved by using appropriate exposure parameters and reducing the field of view (FOV) to the actual region of interest (ROI).

# **Treatment Guidelines**

- The clinician performing or interpreting CBCT scans for implant dentistry should take into consideration current radiologic guidelines.
- The decision to perform CBCT imaging for treatment planning in implant dentistry should be based on individual patient needs following thorough clinical examination.
- When cross-sectional imaging is indicated, CBCT is preferable over CT.

- CBCT imaging is indicated when information supplemental to the clinical examination and conventional radiographic imaging is considered necessary. CBCT may be an appropriate primary imaging modality in specific circumstances (eg, when multiple treatment needs are anticipated or when jawbone or sinus pathology is suspected).
- The use of a radiographic template in CBCT imaging is advisable to maximize surgical and prosthetic information.
- The FOV of the CBCT examination should be restricted to the ROI whenever possible.
- Patient- and equipment-specific dose reduction measures should be used at all times.
- To improve image data transfer, clinicians should request radiographic devices and third-party dental implant software applications that offer fully compliant DICOM data export.

# **Recommendations for Future Research**

- Future research should evaluate the benefits of CBCT over conventional radiographic imaging according to clinician- and patient-centered outcomes, such as selection and/or change of treatment planning, or reduction of costs and morbidity of procedures.
- Future guidelines for CBCT use in implant dentistry should provide evidence-based statements developed from a systematic review of the literature.
- A standardized set of evaluation and measurement criteria for systematic reviews of the literature for oral and maxillofacial radiological imaging procedures needs to be formulated.
- Further primary research (observational and interventional) is required to provide additional evidence that can be used in the formulation of future guidelines for CBCT use in implant dentistry.
- Manufacturers, medical physicists, and researchers should be encouraged to pool data to facilitate dose reduction measures.

# **COMPUTER-GUIDED IMPLANT SURGERY**

# **General Comments**

Computer-guided (static) surgery is defined as the use of a static surgical template that reproduces virtual implant position directly from computerized tomographic data and does not allow intraoperative modification of implant position. Reports on the use of computer-guided implant surgery have increased over the past years. In addition to avoidance of damage to vital anatomic structures and accomplishing full-arch immediate loading, applications now also include partially edentulous situations. Although more data are now available, it is still difficult to compare reported treatment outcomes due to a number of factors, such as insufficiently defined preoperative parameters or the variety of therapeutic approaches. In addition, the impact of computer-guided software programs available on the market in treatment planning remains insufficiently defined.

## **Consensus Statements**

- Implants placed utilizing computer-guided surgery with a follow-up period of at least 12 months demonstrate a mean survival rate of 97.3% (n = 1,941), which is comparable to implants placed following conventional procedures.
- There are significantly more data to support the accuracy of computer-guided implant surgery compared to 2008. Meta-analysis of the accuracy revealed a mean error of 0.9 mm at the entry point (n = 1,530), 1.3 mm at the implant apex (n = 1,465), and a mean angular deviation of 3.5 degrees (n = 1,854) with a wide range in all measurements.
- Mucosa-, tooth-, and mini-implant-supported templates demonstrated accuracy of implant placement superior to that of bone-supported guides.
- After template osteotomy preparation, the accuracy of template implant insertion was superior to freehand implant insertion.

## **Treatment Guidelines**

- Guided surgery should be viewed as an adjunct to, not a replacement for, appropriate diagnosis and treatment planning.
- Guided surgery should always be prosthetically driven. This includes either a radiographic template generated from a wax-up, or appropriate software application to create a digital wax-up.
- Information to be gathered from the combination of high-quality CBCT images and digital planning should include locations of vital structures, desired implant positions and dimensions, the need for augmentation therapy, and the planned prostheses.
- Due to the reported mean deviations, an additional 2 mm should be taken into consideration when planning implant position with relation to vital structures and adjacent implants in all directions. In borderline cases, an intraoperative periapical radiograph should be taken as a safety measure.
- Guided surgery may be utilized with a flapless or raised flap approach.
- Only mucosal- and/or tooth- or implant-supported surgical templates should be utilized.
- For improved accuracy, implants should be inserted in a fully guided manner (versus guided implant bed preparation alone) whenever possible.

- Guided surgery may be used with different loading protocols, in partially and fully edentulous indications.
- Indications for guided surgery include: to aid in treatment planning, when encountering complex anatomy, to perform minimally invasive surgery, and to improve patient understanding of therapeutic needs and treatment options.

## **Recommendations for Future Research**

- Standardization of parameters to assess the accuracy of implant placement through the use of a guided surgery approach
- Identification of factors contributing to the inaccuracy of guided surgery implant placement
- Use of new methods such as digital impressions for studies on accuracy of guided implant placement, not using post-operative CBCT imaging
- Randomized controlled trials (RCTs) comparing the efficacy of guided surgery versus conventional treatments, and focusing on patient-centered outcomes

# NARROW-DIAMETER IMPLANTS

## **General Comments**

Narrow (reduced)-diameter implants (NDI) were categorized as follows for the systematic review by Klein et al:

- Category 1: one-piece, < 3.0 mm (mini-implants)
- Category 2: two-piece, 3.00 to 3.25 mm
- Category 3: two-piece, 3.30 to 3.50 mm

Potential benefits of NDIs may include less invasive surgery and reduced need for bone augmentation. However, these issues have not yet been scientifically assessed. Possible confounding factors of the studies evaluated might be available bone quantity and quality, splinting of the suprastructure, loading forces of the opposing dentition, and the biomechanical role of the implant-abutment connection.

### **Consensus Statements**

 One-piece titanium mini-implants with a diameter of 1.8 to 2.9 mm demonstrated a mean survival rate of 94.3% (91% to 100%) after a mean follow-up time of 3.9 years (1 to 6 years) for the indications of overdenture treatment in the edentulous mandible (four implants) and for an anterior single tooth (maxillary lateral incisor, mandibular incisor).

- Two-piece titanium implants with a diameter of 3.0 to 3.25 mm demonstrated a mean survival rate of 98.5% (94% to 100%) after a mean follow-up time of 2.8 years (1 to 5 years) in only a single-tooth treatment (maxillary lateral incisor, mandibular incisor).
- Two-piece titanium implants with a diameter of 3.3 to 3.5 mm demonstrated a mean survival rate 96.9% (89% to 100%) after a mean follow-up time of 4.1 years (1 to 11 years) for all indications including posterior regions.
- There is insufficient evidence on the success rates for all NDIs. Clinical parameters and treatment protocols are often not sufficiently described and no controlled comparative studies are available, resulting in a high risk of bias.

# **Treatment Guidelines**

- NDIs might be indicated in situations with reduced mesiodistal space or reduced ridge width, provided that the general positioning rules are followed.
- NDIs have several indications. However, the risk of biomechanical problems (eg, fracture) after long-term loading and the limited knowledge of their clinical behavior should be taken into account.
- In this respect, implant diameter should be the widest possible in relation to the emergence profile and ridge configuration.
- NDIs should have a length of 10 mm or more.
- Clinical indications may include:
  - 1. Single-tooth replacements in the anterior zones: categories 1, 2, and 3 (category 1 and 2 only for incisors). One-piece implants often have specific prosthodontic disadvantages.
  - 2. Edentulous jaws to be rehabilitated with overdentures: categories 2 and 3, and category 1 for mandibles only (4 implants).
  - 3. Single posterior, multiple-unit fixed dental prothesis (FDP), and edentulous jaws to be rehabilitated with FDP: only category 3; individual informed consent should include the possibility of more technical complications. Alternative treatment options should also be discussed.

# **Recommendations for Future Research**

- Future study design should include the comparison of narrow- versus larger-diameter implants with or without an augmentation procedure.
- Future studies should compare new materials and implant designs.
- Success rates and long-term documentation (> 5 years) of potential technical and biological complications have to be reported.

 The esthetic effect of a reduced-diameter implant and the resulting emergence profile should be investigated.

# HORIZONTAL RIDGE AUGMENTATION IN THE ANTERIOR MAXILLA

## **General Comments**

There is a paucity of information in the literature regarding stability of the bone and esthetic outcomes following horizontal bone augmentation in the anterior maxilla. Confounding variables include the vertical component of the augmentation, defect morphology, periodontal status of the neighboring teeth, number of missing teeth, position of the site, soft tissue characteristics, time between augmentation and implant placement, implant design and diameter, prosthetic connection type and material, and provisional prostheses. Studies available in the literature were not designed for esthetic outcome assessment and included no decision criteria relating to the choice of a simultaneous or staged approach. Combined vertical and horizontal augmentation procedures should also be evaluated in the esthetic area.

## **Consensus Statements**

- Horizontal bone augmentation in the anterior maxilla is a reliable treatment option to enable the proper placement of implants.
- Mean horizontal bone gain in the staged approach (measured at the time of implant placement) ranged from 2.2 to 5 mm. The included studies do not provide information about the long-term stability of horizontal ridge augmentation.
- There is not enough data available to indicate superiority of one method or material over another.
- Survival and success rates of implants placed in horizontally augmented bone were not different from those reported for implants placed in native bone with adequate width.

# **Treatment Guidelines**

- In sites with inadequate ridge width, horizontal bone augmentation is indicated to enable proper implant placement. Ideally, a bone thickness of 2 mm should be achieved on the facial aspect of the implant.
- The primary aim of horizontal ridge augmentation procedures in the anterior maxilla is to optimize implant positioning in order to improve function and esthetic outcome. The position and the shape of the augmented bone influence the soft tissue profile, which should follow the contour of the neighboring teeth.

- Clinicians performing horizontal ridge augmentation in the anterior maxilla may choose from a wide range of treatment options, including particulate bone grafts for simultaneous and bone blocks for staged approaches with or without placement of resorbable and nonresorbable membranes.
- Soft tissue augmentation may be required as an adjunctive procedure to improve the esthetic outcome.
- Horizontal ridge augmentation with simultaneous implant placement is indicated when adequate soft tissue conditions are present and correct implant positioning with primary implant stability is achievable.
- If defect morphology is such that successful regeneration is unlikely to be achieved using the simultaneous approach, a staged approach should be used.
- In large defects precluding implant primary stability and proper three-dimensional implant positioning, a staged approach is recommended.
- In general, the choice of augmentation materials should assure the long-term stability of the bone volume created and should be based on solid documentation in the literature.

## **Recommendations for Future Research**

- Data related to long-term stability of horizontal augmentations in the anterior maxilla should be reported, including the width and the height of the facial bone plate.
- Studies should be performed focusing on the type of augmentation procedure, implant design, and grafting material in the anterior maxilla.
- Accepted esthetic outcome indices should be applied to make results measurable and individual studies comparable.
- It is essential that baseline defect morphology is reported.
- In either the simultaneous or the staged approach, augmented bone dimension and ongoing volumetric stability should be reported.
- Regenerated hard tissue characteristics should be examined by histology when evaluating new materials.

# **GROUP 2**

# Restorative Materials and Techniques for Implant Dentistry

#### **Group Leader:**

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#### **Review Papers Submitted for Discussion:**

**Clinical Performance of Screw- Versus Cement-Retained Fixed Implant-Supported Reconstructions—A Systematic Review** Julia-Gabriela Wittneben/Christopher Millen/Urs Brägger

Systematic Review of the Survival Rate and Incidence of Biologic, Technical, and Esthetic Complications of Single Implant Abutments Supporting Fixed Prostheses

Anja Zembic/Sunjai Kim/Marcel Zwahlen/J. Robert Kelly

CAD/CAM Technology for Implant Abutments, Crowns, and Superstructures Theodoros Kapos/Christopher Evans

### Consensus Statements and Recommended Clinical Procedures Regarding Restorative Materials and Techniques for Implant Dentistry

Daniel Wismeijer/Urs Brägger/Christopher Evans/Theodoros Kapos/J. Robert Kelly/ Christopher Millen/Julia-Gabriela Wittneben/Anja Zembic/Thomas D. Taylor

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# Clinical Performance of Screw- Versus Cement-Retained Fixed Implant-Supported Reconstructions— A Systematic Review

Julia-Gabriela Wittneben, DMD, Dr Med Dent, MMSc<sup>1</sup>/ Christopher Millen, BDS, MFDS, MClinDent, MPros<sup>2</sup>/Urs Brägger, DMD, Dr Med Dent<sup>3</sup>

Purpose: To assess the survival outcomes and reported complications of screw- and cement-retained fixed reconstructions supported on dental implants. Materials and Methods: A Medline (PubMed), Embase, and Cochrane electronic database search from 2000 to September 2012 using MeSH and free-text terms was conducted. Selected inclusion and exclusion criteria guided the search. All studies were first reviewed by abstract and subsequently by full-text reading by two examiners independently. Data were extracted by two examiners and statistically analyzed using a random effects Poisson regression. Results: From 4,324 abstracts, 321 full-text articles were reviewed. Seventy-three articles were found to qualify for inclusion. Five-year survival rates of 96.03% (95% confidence interval [CI]: 93.85% to 97.43%) and 95.55% (95% CI: 92.96% to 97.19%) were calculated for cemented and screw-retained reconstructions, respectively (P = .69). Comparison of cement and screw retention showed no difference when grouped as single crowns (I-SC) (P = .10) or fixed partial dentures (I-FDP) (P = .49). The 5-year survival rate for screw-retained full-arch reconstructions was 96.71% (95% CI: 93.66% to 98.31). All-ceramic reconstruction material exhibited a significantly higher failure rate than porcelain-fused-to-metal (PFM) in cemented reconstructions (P = .01) but not when comparing screw-retained reconstructions (P = .66). Technical and biologic complications demonstrating a statistically significant difference included loss of retention (P ≤ .01), abutment loosening (P  $\leq$  .01), porcelain fracture and/or chipping (P = .02), presence of fistula/suppuration (P  $\leq$  .001), total technical events (P = .03), and total biologic events (P = .02). Conclusions: Although no statistical difference was found between cement- and screw-retained reconstructions for survival or failure rates, screw-retained reconstructions exhibited fewer technical and biologic complications overall. There were no statistically significant differences between the failure rates of the different reconstruction types (I-SCs, I-FDPs, full-arch I-FDPs) or abutment materials (titanium, gold, ceramic). The failure rate of cemented reconstructions was not influenced by the choice of a specific cement, though cement type did influence loss of retention. INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):84-98. doi: 10.11607/jomi.2014suppl.g2.1

Key words: cement, dental implants, fixed dental prostheses, prosthodontics, screw, single crown

mplant-supported reconstructions are wellestablished treatment options and have evolved to

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a standard of care in dental medicine. The possibilities and expectations of achieving a successful, functional, and stable treatment outcome have increased with the evolution of implant surfaces and designs, prosthetic components, clinical techniques, and dental materials. One of the important decisions in implant prosthodontics is the choice of the connection type of the final restoration to the implant via the screw-retained abutment. The restorative connection can be either screwor cement-retained. With screw-retained restorations, an abutment or a mesostructure may be separate to the restoration (two-piece) or combined as part of the fabrication procedure (one-piece). In general, both retention types have their advantages and limitations.<sup>1–5</sup>

Despite patients showing no preference for either retention system,<sup>6</sup> there are relevant clinical and technical issues. These include ease of fabrication,

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precision, passivity of the framework, retention provided by cement and abutment, occlusion, esthetics, accessibility, retrievability, complications, and cost. These are not easily examined objectively together, and to single out the effect of a specific factor seems to be very demanding. A previous systematic review has focused on implant and prosthesis survival, finding no statistically significant differences between screw and cement retention.<sup>7</sup> In vitro and animal studies have been conducted to more closely examine technical and biologic complications in screw- and cement-retained prostheses.<sup>8–10</sup> While these may give useful information to help design future human trials, this information cannot routinely be related to a clinical situation.

The survival rates of implant-supported reconstructions and the associated technical complication rates have been well established. Implant-supported single crowns (I-SC), fixed partial dentures (I-FDP), and I-FDPs with cantilever extensions demonstrate survival rates of 94.5%, 95.2%, and 94.3% at 5 years, respectively.<sup>11–13</sup> The prevalence of technical complications is higher for implant reconstructions compared to those on teeth,<sup>12</sup> and the most commonly reported technical complications are veneer fracture, screw loosening, and loss of retention.<sup>11–13</sup> With respect to biologic complications, peri-implantitis and bone loss are reported to have the highest prevalence.<sup>11,14</sup> Although these figures are now commonly cited, they have not been attributed to screw or cement retention.

A recent and comprehensive systematic review on this subject was presented at the European Association of Osseointegration Consensus Conference 2012.<sup>15</sup> This review focused on implant and reconstruction survival, reporting estimated rates for 5 and 10 years, as well as technical and biologic complications in studies with a mean follow-up of at least 1 year. The authors grouped the event rate data by cement- or screwretained single crowns, I-FDPs, and full arch I-FDPs. No statistically significant differences were reported for restoration survival. Estimated biologic complication rates (bone loss > 2 mm) were found to be higher in cemented reconstructions, whereas screw-retained reconstructions exhibited more technical complications. Based on their improved retrievability, the screwretained reconstructions were given preference.

The objective of the present review was to retrieve a detailed data pool from published clinical studies on biologic and technical failure and complication rates observed with cement- and screw-retained fixed implant-supported reconstructions. The aim was also to associate the observed differences in the estimated event risks with a list of additional prosthetic characteristics such as type of reconstruction, material of the supra-structure (restorative and abutment material), and cement type.

## MATERIALS AND METHODS

A PICO (population, intervention, comparison, and outcome) question was agreed upon between the authors. This question asked what the clinical performance (including complications and failures) of implant-supported reconstructions was in patients with edentulous sites treated with either screw or cement retention.

#### Systematic Search Design and Strategy

An electronic search of publications from 2000 to September 2012 was established using three electronic databases: EMBASE, Medline (via PubMed), and the Cochrane Library. The search included peer-reviewed publications in the English, German, and French languages. MeSH and free-text terms were used in the search and included the terms listed in Table 1.

The search was then narrowed by exclusion of nondental studies by adding the terms "dental" OR "dentist\*" OR "tooth" OR "teeth." All articles were selected by well-defined inclusion and exclusion criteria (Table 1).

The inclusion criteria included study designs of randomized controlled trials (RCTs), clinical trials, prospective studies, and retrospective cohort studies. Patients in the studies had to have been followed clinically for the observation period. Studies using telephone interviews or patient records were not included.

Other inclusion criteria for study selection were studies with:

- A mean follow-up time of at least 3 years
- A minimum number of 10 patients
- A report of the restoration retention used (screw or cement)
- Implant-supported fixed reconstructions
- English, German, or French language

Case reports, animal studies, in vitro studies, abstracts, and letters were excluded from review. Studies with a mean follow-up of < 3 years; not reporting on retention type; not written in English, German, or French; or examining removable prostheses were also excluded from the review. Data from patient cohorts used for repeated publications were limited to the most recent version.

The selection strategy of the articles is outlined in Fig 1. Following the electronic search, titles and abstracts were screened by two independent reviewers (JW, UB) to assess their suitability for inclusion in the review. Following discussion, a consensus was reached regarding disputed articles. Subsequently, a full-text search was performed by two reviewers (JW, CM). In addition, a manual search (CM) was conducted of the bibliographies of recently published relevant reviews.

Focus question	What is the clinical performance of implant-supported reconstructions (including complications and failures) in patients with edentulous sites treated with either screw or cement retention?
Search strategy	
Population	#1 (implant*) OR (full arch) OR (cross arch) OR (crossarch) OR (abutment) OR (dental abutments [MeSHTerms]) OR (dental arch [MeSH Terms]) OR (dental implants [MeSH Terms])
Intervention or exposure	#2 (implant supported prosthesis) (Dental Prosthesis, Implant supported [MeSH Terms] )OR (insertion) OF (crown [MeSH Terms]) OR (fixed partial dentures) OR (denture, Partial, Fixed [MeSH Terms]) OR (FPD) OR (FDP) OR (bridge) OR (reconstruct*) OR (passive fit) OR (crown margin) OR (marginal adapation[MeSH Terms]) OR (interface*) OR (implant bridge) OR (laborator*) OR (friction[MeSH Terms]) OR (clamping force) OR (fixture) OR (insert lodges) OR (suprastructure)
Comparison	#3 (screw*) OR (cement*) OR (retain*) OR (retention*) OR (fixation) OR (transvers*) OR (retrievab*) OR (torque) OR (transfer) OR (access hole) OR (torque wrench) OR (retrieval) OR (tight*) OR (transocclusal) OR (Bone Screws [MeSH Terms]) OR (dental cements [MeSH Terms]) OR (dental prosthesis retention[MeSH Terms]) OR (denture retention [MeSH Terms]) OR (cementation[MeSH Terms]) OR (torque[MeSH Terms]) OR (seat*)
Outcome	#4 (loss of retention) OR (precision) OR (fit) OR (seal) OR (loosening) OR (fracture) OR (fatigue) OR (leakage) OR (gap) OR (cement rest) OR (deformation) OR (cement dissolution) OR (survival) OR (complicat*) OR (risk) OR (success) OR (rate) OR (failure) OR (prosthesis failure [MeSH Terms]) OR (dental leakage[MeSH Terms]) OR (treatment outcome[MeSH Terms]) OR (dental restoration failure[MeSH Terms])
Search combina	tion #1 AND #2 AND #3 AND #4
Database search	
Language	English, German, and French
Electronic	EMBASE, Medline (via PubMed), and Cochrane Library
Selection criteria	
Inclusion criteria	<ul> <li>RCTs</li> <li>Clinical trials</li> <li>Prospective studies</li> <li>Retrospective studies with patient recall (clinical examination)</li> <li>Written in English, German, or French</li> <li>Minimum follow-up time of 3 y</li> <li>Report of retention type</li> <li>Studies including implant supported fixed reconstructions (single crowns or FDPs)</li> <li>Report of clinical performance (including complications and failure) of fixed implant-supported reconstruction</li> </ul>
Exclusion criteria	<ul> <li>Not written in English, German, or French Minimum follow-up time &lt; 3 y</li> <li>Studies that were based on patients' charts</li> <li>Case reports</li> <li>Animal studies</li> <li>In vitro studies</li> <li>No report on retention type</li> <li>No report on clinical performance of implant-supported reconstructions</li> <li>Studies on removable reconstructions</li> </ul>

The manual search included articles that were published prior to the year 2000.

Data of each individual study were extracted by two authors (CM, JW) and broken down on an Excel (Microsoft) spreadsheet by: author, year, type of study (prospective/retrospective), planned number of patients, actual number of patients, mean age patient, age range patient, study setting (university/private practice), location (anterior/posterior), restoration type, abutment material, restoration material, retention type, cement type, implant brand, implant types, and total implant number. The total exposure time of the reconstructions was calculated, and survival of the restorations was defined as remaining in situ throughout the study period.

Data regarding technical complications were also extracted, including loss of retention, loosening of the occlusal/abutment screws, loss of screw access filling, fracture and/or chipping of the veneer, fracture of the implant/abutment/framework/screw, and any other complications.

The data for biologic complications included bone loss > 2 mm, peri-implantitis, peri-implant mucositis, general soft tissue complications (including fistulaswelling), recession, loss of the implant, any esthetic complication, and any other reported complications.

### **Statistical Analysis**

Failure and complication rates of single studies were calculated by dividing the number of events by the total exposure time of the I-FDPs. Estimated failure rates, event rates, and 95% confidence intervals (CI) were calculated by assuming Poisson distributed number of events. Random effects Poisson regression was used when several studies were summarized.

Five- and 10-year survival rates were calculated through the relationship between event rate and the survival function S by assuming constant event rates as follows:

 $S(T) = exp(-T \times event rate)$ 

All statistical analysis was performed using Stata 11.2. Significance level was set at P = .05.

The estimated event rate per 100 years was calculated using the observation time of the studies together with the number of reconstructions observed (eg, 100 reconstructions observed for 1 year each, with only one failure, would have an event rate of 1 per 100 years).

Comparisons included differences in event rates per 100 reconstruction years between cemented and screw-retained reconstructions in total and when grouped according to reconstruction type, reconstruction material, and abutment material. The compared events were failures, single technical and biologic complications, and combined (total) technical and combined (total) biologic complications.

# RESULTS

The titles and abstracts of 4,324 articles (initial search) were screened independently by two authors (JW, UB) to assess their suitability for inclusion in the review (Fig 1). Following discussion, a consensus was reached regarding disputed articles. There were 302 full-text articles obtained for screening. In addition, a further 19 articles were obtained from a manual search of the bibliographies of review articles identified within the initial search and recently published relevant reviews. Two authors (JW, CM) independently reviewed the 321 articles. Of these full-text articles, 73 were found to qualify for inclusion in the review.

The study designs of these articles were: 52 prospective cohort studies (71.2%), 13 retrospective (17.8%), 2 split-mouth design, and 6 RCT (8.3%) (Table 2). Most studies were carried out in a university setting (63%) (Table 3).

### Failures

A total of 5,858 fixed implant reconstructions were analyzed with a mean exposure time of 5.40 years.

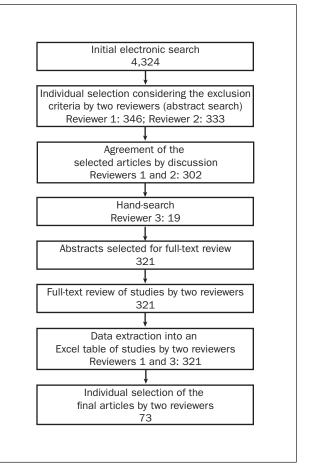


Fig 1 Flow diagram describing the search design and strategy.

Table 2 Study Designs							
	Studies	%					
Prospective cohort	52	71.2					
Retrospective cohort	13	17.8					
Split mouth	2	2.7					
RCT	6	8.3					
Total	73	100					

Table 3 Study Settings								
	Studies	%						
Private practice	13	17.8						
University	46	63.0						
Specialist clinic	6	8.2						
Multicenter	6	8.2						
Not reported	2	2.8						
Total	73	100						

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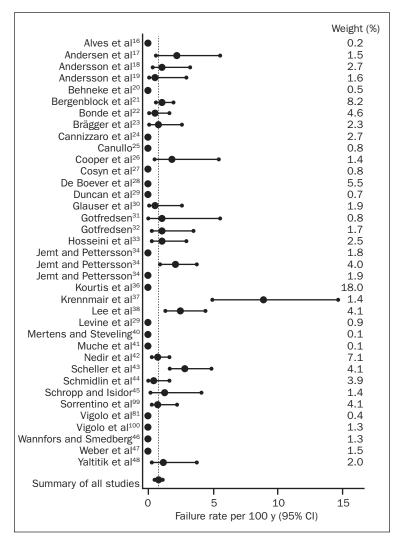


Fig 2 Failure rate and weight of all included studies on cement-retained reconstructions (n = 37).

Of these 3,471 (59%) were screw-retained and 2,387 (41%) were cement-retained. The failure rates and weighting of each study are shown in Figs 2 and 3. Based on a random-effects Poisson regression analysis, overall 5-year survival rates of 96.03% (95% CI: 93.85% to 97.43%) and 95.55% (95% CI: 92.96% to 97.19%) were calculated for cement- and screw-retained reconstructions, respectively. Tenyear survival rates were also estimated and revealed survival rates of 92.22% (95% CI: 88.07% to 94.93%) and 91.30% (95% CI: 86.42% to 94.46%) for cement- and screw-retained reconstructions, respectively. Overall estimated failure rates of 0.81 (95% CI: 0.52 to 1.27) and 0.91 (95% CI: 0.57 to 1.46) per 100 restoration years were calculated for cement- and screw-retained reconstructions, respectively. This difference was not statistically significant (P = .69) (Table 4). However the estimated failure rate of two-piece screw-retained reconstructions (0.45 [95% CI: 0.32 to 0.64]) was significantly different compared to the cemented types (P = .00).

Of the 5,858 reconstructions, 1,720 were I-SC, 979 were I-FDP, 928 were full-arch reconstructions, and 61 were cantilever I-FDPs (Table 5). In some studies, several types of reconstructions were

used and not reported separately in the article. These data have therefore been used for the calculation of the overall reconstruction failure and survival rate of screw versus cement retention but have not been included in the separate reconstruction groups.

### Failures by Reconstruction Type

**Single Crowns (I-SC).** A total of 25 studies reported on cemented and 9 on screw-retained single crowns (I-SC) with a mean follow-up time of 4.92 years. A total of 1,720 SCs were analyzed; 1,316 were cemented and 404 screw-retained. The failure rate of the cemented I-SCs (0.74 [95% CI: 0.44 to 1.24]) was not significantly different from the screw-retained I-SCs (1.85 [95% CI: 0.65 to 5.29]) (P = .10) (Table 6). The 5-year survival rate was 96.37% (95% CI: 93.99 to 97.82) for cement- and 91.16% (95% CI: 76.76 to 96.80) for screw-retained single crowns (Table 7).

Fixed Partial Dentures (I-FDP) and Cantilever I-FDP. A total of 19 studies (5 on cemented and 14 on screw-retained) with a mean follow-up time of 5.73 years reported on a total of 1,040 I-FDPs (including cantilever I-FDPs) showing no significant difference between cement (1.11 [95% CI: 0.40 to 3.07]) and screw retention (1.78 [95% CI: 0.59 to 5.34]) (P = .49) (Table 6). The 5-year survival rate was 94.60% (95% CI: 85.77% to 98.02%) for cemented and 91.48% (95% CI: 76.57% to 97.09%) for screw-retained I-FDPs (Table 7).

**Full-Arch Reconstructions.** A total of 22 studies (1 on cemented and 21 on screw-retained) with a mean follow-up time of 7.46 years (Table 6) were obtained. The failure rate was estimated at 0.67 per 100 reconstruction years and the 5-year survival rate was 96.71% (95% CI: 93.66% to 98.31%) (Table 7). Further analysis was not possible due to the low number of studies with cement-retained full-arch reconstructions.

## Failures by Material Type

**Abutment Material.** There was no significant difference between the failure rates of screw-retained reconstructions on either titanium, gold, or ceramic abutments. Neither cemented nor screw-retained reconstructions exhibited a statistically

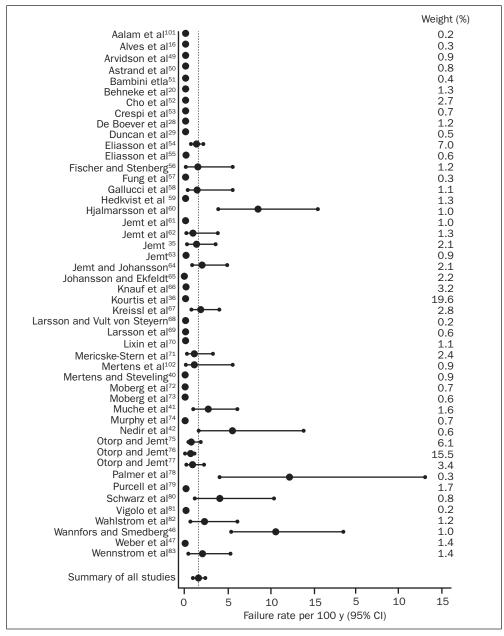




Table 4	Overall Estimated Failure Rates									
Studies	Retention type	Reconstructions	Exposure time (y)	No. of failures	Estimated failure rate per 100 y (95% CI)	P value				
37	Cement	2,387	11861	102	0.81 (0.52 – 1.27)					
48	Screw	3,471	19799	99	0.91 (0.57 - 1.46)	.69				
7	One-piece screw	276	1327	23	2.08 (0.47 - 9.27)	.08*				
14	Two-piece screw	932	7481	34	0.45 (0.32 – 0.64)	.00*				

\*Compared with the estimated event rate of cement reconstructions.

significant difference between material types (P = .09 and P = .06 for cement and screw, respectively). These results are reported in Table 8.

**Prosthetic Material.** The use of all-ceramic material exhibited a significantly higher failure rate (0.88 [95% Cl: 0.58 to 1.33]) than porcelain-fused-to-metal (PFM)

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Table 5         Type of Reconstructions										
Reported restoration	Reconstructions	%								
I-SC	1,720	29.4								
I-FDP	979	16.7								
Full-arch	928	15.8								
I-SC and full-arch	123	2.1								
I-SC and I-FDP	461	7.9								
Cantilever I-FDP	61	1.0								
I-FDP and full-arch	56	1.0								
I-SC, I-FDP, and cantilever	168	2.9								
I-SC, I-FDP, full-arch, cantilever	1,308	22.3								
Not reported	54	0.9								
Total	5,858	100								

(0.37 [95% CI: 0.22 to 0.61]) in cemented reconstructions (P = .01), whereas there was no significant difference in the failure rates when comparing screw-retained reconstructions fabricated with different materials (P = .66) (Table 9).

**Cement Material.** When examining the differences between failure rates for the cement types (phosphates, glass ionomers, resins and eugenol-based cements), no statistically significant difference was found (P = .37) (Table 10).

#### Complications

The data extraction of the included studies only allowed a statistical analysis if the complications were presented in the study. Where the data was not complete, the statistical analysis was not performed. Therefore, the number of studies and reconstructions varies among the complication types, and this information is listed in Table 11.

**Technical Complications.** Complications demonstrating a statistically significant difference between cement- and screw-retained reconstructions include loss of retention, abutment loosening, and porcelain fracture and/or chipping, as well as the total events.

The other complications including fracture of abutment, fracture of framework, fracture of implant, screw fracture, and resin chipping and/or fracture did not demonstrate statistical significance. The complications loss of cover of access hole and loosening of occlusal screw could not be compared, as they were only available for screw-retained reconstructions. Here, event rates of 1.76 per 100 reconstruction years could be calculated for loosening of occlusal screw and 0.81 for loss of cover of access hole. A full summary of the data related to technical complications is given in Table 11.

A comparison between loss of retention and cement type was carried out and showed a statistically significant difference between cement type and loss of retention ( $P \le .01$ ). The estimated event rates per 100 years are outlined in Table 12.

When assessing the overall technical complications between cement- and screw-retained reconstructions, the resin chipping category was removed due to the fact that no further analysis was possible on this category. This comparison of the total events demonstrated a significant difference (P = .03) (Table 11). However comparing one- and two-piece screw-retained reconstructions to the cemented ones demonstrated no significant difference (Table 11).

**Biologic Complications.** When comparing the event rates of biologic complications between screw- and cement-retained reconstructions, only the category for presence of fistula/suppuration demonstrated statistical significance, indicating a higher event rate with cement retention (1.65 [95% CI: 0.55 to 4.96]) ( $P \le .01$ ). Outcomes of the other event rates of bone loss (> 2 mm), peri-implantitis, presence of fistula/suppuration, peri-implant mucositis, and recession were not statistically significant among the two retention systems.

The summary of the total biological complications as shown in Table 13 shows a statistically significant result (P = .02). One- and two-piece screw- retained reconstructions presented no significant difference in comparison to cemented ones (Table 13).

## DISCUSSION

The fabrication of an implant-supported reconstruction includes many clinical and laboratory processes and a series of decisions related to the use of implant components, materials, etc. At some point during the treatment planning stage, the treating clinician and the technician must select the method of retention, screw or cement. Both of these methods have their advantages and limitations, and it is therefore the clinician's responsibility to select the most appropriate method of retention for the individual patient.<sup>5</sup>

Screw-retained implant reconstructions have the advantages of predictable retrievability; require a minimal amount of interocclusal space; and are easier to remove when hygiene maintenance, repairs, or surgical interventions are required. Screw-retained implant reconstructions require precise, prosthetically driven placement of the implant due to the position of the screw access hole. The manufacturing process of screw-retained reconstructions is more technique sensitive and more demanding when compared to cement-retained reconstructions.<sup>4</sup>

The construction of cemented restorations is not as technically demanding as screw-retained restorations and therefore they are less cost-intensive to produce.

Table 6         Characteristics and Estimated Failure Rates of Reconstructions									
Restoration type	Studies	Retention type	Reconstructions	Exposure time (y)	Failures	Estimated failure rate per 100 y (95% Cl)	P value		
I-SC	25 9	Cement Screw	1,316 404	6,695 1,761	65 17	0.74 (0.44–1.24) 1.85 (0.65–5.29)	.10		
I-FDP	5 14	Cement Screw	309 731	1,343 4,618	23 35	1.11 (0.40-3.07) 1.78 (0.59-5.34)	.49		
Full-arch	1 21	Cement Screw	6 922	18 6,905	0 39	0 (—) 0.67 (0.34–1.31)			

Table 7         Estimated Failure and Survival Rates									
Restoration	<b>Retention type</b>	Failure rate	5-year survival	10-year survival					
All	Cement	0.81 (0.52–1.27)	96.03 (93.85–97.43)	92.22 (88.07–94.93)					
	Screw	0.91 (0.57–1.46)	95.55 (92.96–97.19)	91.30 (86.42–94.46)					
I-SC	Cement	0.74 (0.44–1.24)	96.37 (93.99–97.82)	92.87 (88.34–95.70)					
	Screw	1.85 (0.65–5.29)	91.16 (76.76–96.80)	83.11 (58.92–93.71)					
I-FDP	Cement	1.11 (0.40–3.07)	94.60 (85.77–98.02)	89.49 (73.57–96.08)					
	Screw	1.78 (0.59–5.34)	91.48 (76.57–97.09)	83.69 (58.63–94.27)					
Full-arch	Cement	0 (—)							
	Screw	0.67 (0.34–1.31)	96.71 (93.66–98.31)	93.52 (87.72–96.66)					

Table 8	Abutment Material - Exposure Time and Estimated Failure Rate of Reconstructions								
Retention	Studies	Abutment type	Reconstructions	Exposure time (y)	Failures	Estimated failure rate per 100 y (95% Cl)	P value		
Cement	4 6 10	Titanium Gold Ceramic	98 280 617	474 1,213 4,128	3 4 70	0.57 (0.12–2.72) 0.33 (0.04–2.59) 1.97 (0.97–3.99)	.09		
Screw	12 11 4	Titanium Gold Ceramic	560 637 239	3,041 2,804 1,925	13 33 9	0.39 (0.16-0.97) 1.50 (0.66-3.42) 0.38 (0.09-1.57)	.06		

Table 9	Material of Reconstructions								
Retention	Studies	Material	Reconstructions	Exposure time (y)	Failures	Estimated failure rate per 100 y (95% Cl)	P value		
Cement	17 0 6	PFM Acrylic Ceramic	876 — 333	4,058 — 2,513	15 22	0.37 (0.22–0.61)  0.88 (0.58–1.33)	.01		
Screw	17 14 2	PFM Acrylic Ceramic	868 741 35	3,420 6,113 155	23 26 0	0.74 (0.32–1.68) 0.42 (0.17–1.01) 0 (—)	.66		

Table 10	Failure of Reconstructions by Cement Type									
Studies	Cement type	Reconstructions	Exposure time (y)	Failures	Estimated failure rate per 100 y (95% Cl)	P value				
5	Phosphate	414	2,935	29	0.95 (0.33–2.75)					
4	GI	151	1,063	9	0.85 (0.47-1.51)	27				
3	Resin	238	1,241	4	0.32 (0.06-1.65)	.37				
5	ZOE	226	790	15	1.90 (0.30-12.15)					

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Table 11 Technical	Complication	S					
Complication	Retention type	Studies	Reconstructions	Exposure time (y)	Events	Estimated event rate per 100 y (95% CI)	P value
Loss of retention	Cement Screw	30 36	2,015 2,741	10,394 15,402	95 77	5.44 (2.14–13.82) 0.61 (0.30–1.25)	< .01
Loss of cover of access hole	Cement Screw	— 32	2,534	 14,744	 131		
Fracture and/or chipping of ceramic	Cement Screw	31 37	1,958 3,001	10,063 17,428	30 212	1.02 (0.37–2.83) 3.56 (1.95–6.49)	.02
Loosening of occlusal screw	Cement Screw	— 39	3,023	 17,031	 201		
Loosening of abutment	Cement Screw	31 36	1,958 2,786	10,063 15,970	86 85	2.31 (1.09–4.89) 0.62 (0.33–1.17)	< .01
Fracture of abutment	Cement Screw	31 34	1,958 2,611	10,063 14,459	4 20	0.04 (0.01–0.20) 0.07 (0.03–0.18)	.52
Fracture of framework	Cement Screw	2 37	125 2,976	569 16,727	14 59	2.46 (1.63–3.72) 0.28 (0.11–0.71)	.35
Fracture of implant	Cement Screw	31 37	1,958 2,893	10,063 16,291	2 11	0.02 (0.00–0.15) 0.16 (0.03–0.79)	.27
Screw fracture	Cement Screw	31 39	1,958 3,125	10,063 18,051	10 47	0.10 (0.02–0.49) 0.20 (0.09–0.44)	.85
Resin chipping and/or fracture	Cement Screw	1 35	28 2,757	84 15,846	0 539	0 (—) 4.40 (1.50–12.88)	_
Other	Cement Screw	29 39	1,790 2,980	8,903 17,518	33 243	2.29 (0.74–7.11) 1.73 (0.77–3.89)	.52
Summary (all except resin chipping)	Cement Screw	33 42	2,078 3,226	10,778 18,480	274 1,086	9.81 (6.60–14.60) 7.50 (5.37–10.47)	.03
	One-piece screw	6	236	1,127	83	9.47 (4.83–18.59)	.93*
	Two-piece screw	12	857	7,052	394	6.27 (3.35–11.74)	.166*

\*Compared with the estimated event rate of cement reconstructions.

## Table 12 Cement Type and Loss of Retention

Studies	Cement type	Reconstructions	Exposure time (y)	Events	Estimated event rate per 100 y (95% CI)	P value
4	Phosphate	183	2,089	0	0 ( )	
4	GI	151	1,063	8	1.04 (0.22-4.98)	< .01
2	Resin	208	1,141	20	1.75 (0.52-5.95)	10. >
5	ZOE	226	790	5	0.72 (0.15-3.41)	

Other advantages of this retention type include compensation of implant position discrepancies, passivity of fit, improved esthetics, and easier control of occlusion.<sup>2,4,84</sup> A major problem of cement retention is the difficulty of removing excess cement,<sup>85,86</sup> which has been associated with the development of peri-implant diseases such as peri-implant mucositis and periimplantitis.<sup>84,87</sup>

A considerable emphasis can be seen in the dental literature concerning screw versus cement retention. Several conventional and systematic reviews have already been published exploring the advantages and disadvantages of cement- versus screw-retained implant-supported reconstructions,<sup>5,7,15,88–90</sup> leaving the clinician with conflicting information.

There are a large variety of methods to connect a restoration to the implant other than just cement or screw retention. An attempt to address this problem was made in this review by attempting to differentiate between one- and two-piece screw-retained restorations. Unfortunately, however, the number of studies that accurately reported the method of restoration at-

Table 13 Biolo	ogic Complicati	ions Sun	nmary				
Complication	Retention type	Studies	Reconstructions	Exposure time (y)	Events	Estimated event rate per 100 y (95% CI)	P value
Bone loss (> 2 mm)	Cement Screw	27 32	1,780 2,632	9,497 15,415	39 470	0.81 (0.29–2.24) 2.09 (1.11–3.93)	.07
Peri-implantitis	Cement Screw	26 29	1,691 2,549	8,059 15,112	46 48	0.54 (0.22–1.31) 0.36 (0.15–0.86)	.16
Presence of fistula, suppuration	Cement Screw	27 30	1,713 2,567	9,102 15,292	55 36	1.65 (0.55–4.96) 0.22 (0.10–0.52)	< .01
PI mucositis	Cement Screw	24 29	1,612 2,496	7,237 14,881	60 167	1.38 (0.60–3.17) 1.61 (0.71–3.64)	.75
Recession	Cement Screw	24 28	1,527 2,365	7,143 13,737	6 1	0.12 (0.03–0.47) 0.01 (0.00–0.06)	.19
Any esthetic complication	Cement Screw	27 29	1,786 2,613	8,969 16,144	17 24	0.20 (0.08–0.54) 0.24 (0.09–0.63)	.69
Other	Cement Screw	27 31	1,811 2,731	9,429 16,498	45 207	1.44 (0.49–4.28) 1.31 (0.67–2.59)	.87
Summary	Cement Screw	29 33	1,864 2,778	9,749 16,802	268 953	7.01 (4.66–10.55) 4.81 (3.43–6.76)	.02
	One Piece screw	4	114	617	39	4.87 (1.52–15.63)	.54*
	Two Piece screw	11	842	7,028	705	10.51 (5.89-18.74)	.17*

\*Compared with the estimated event rate of cement reconstructions.

tachment was few and thus the results of the one- and two-piece were not further analyzed. The estimated failure rates of one- and two-piece screw-retained reconstructions were calculated and compared to the cemented ones. Studies including restorations that demonstrated a mix of types by being cemented extraorally prior to being screw-retained were excluded from this review. Analysis of further retention types was not possible due to the low numbers reported.

The present systematic review was initiated to compare failure and complication rates not only based on the type of retention but also considering additional prosthetic and material aspects and hopefully to gather new arguments to support one or the other retention type.

#### **Failures**

The estimated failure rates of the pooled cemented and the pooled screw-retained reconstructions were similar to what has been reported in other systematic reviews on implant-supported reconstructions.<sup>11,12,15,91</sup> In a previous systematic review by Weber and Sukotjo,<sup>7</sup> the prosthetic success rates of screw- and cement-retained implant-supported reconstructions were reported at the most recent examination (> 72 months) as 93.2% for cemented and 83.4% for screwretained restorations (P > .05). It should be noted that this study reported on success rates and not survival as in the present review. Failures were more frequently observed with screwretained crowns compared to cemented single crowns. The survival rate at 5 years for screw-retained I-SC was comparably lower than that for cemented I-SCs. However, this comparison lacked statistical significance, which was in agreement with a recent review by Sailer et al.<sup>15</sup>

Cement- or screw-retained I-FDPs (including cantilever I-FDPs) showed no statistical differences in survival rates between the retention systems. Similar survival rates were published by Pjetursson et al<sup>14</sup> in a systematic review evaluating implant-supported I-FDPs (survival rates, 95% [95% CI: 92.2% to 96.8%] after 5 years).<sup>92</sup>

Articles examining full-arch reconstructions reported the longest mean follow-up time (7.46 years) of all reconstruction types. Only one study was included in the present review regarding cemented full-arch reconstructions; therefore, survival rates were not statistically compared to the screw-retained group.

Failures rates for cement- and screw-retained reconstructions in the present study were analyzed not only by reconstruction type (I-SC, I-FDP, and full arch), but also by the materials used (abutment material, prosthetic material, and cement type). The failure rates for cemented reconstructions were influenced by the prosthetic material, with statistically higher rates with ceramic materials.

In the systematic review by Jung et al,<sup>11</sup> the survival rate of PFM single crowns was 95.4% (95% CI: 93.6%

to 96.7%) which was statistically significantly higher compared to the survival rate of all ceramic crowns of 91.2% (95% CI: 86.8% to 94.2%). When the data pool was updated in a follow-up systematic review the failure rates were very similar for PFM crowns (0.85 [95% CI: 0.51 to 1.41]) and ceramic crowns (0.86 [95%CI: 0.38 to 1.95]).<sup>93</sup> This clearly reflects the improvement of the biomechanical characteristics of the newer ceramic materials. In the present review, survival rates of screw-retained crowns were also not influenced by prosthetic material.

Failure rates with cemented reconstructions were not influenced by the abutment material (titanium, gold, ceramic). The screw-retained reconstructions had higher failure rates in combinations with gold abutments (P = .062). However, the use of ceramic abutments did not increase the risk for failure which confirms the results obtained by Sailer et al<sup>94</sup> who reported the 5-year survival of ceramic abutments to be 99.01% (95% CI: 93.8% to 99.9%) and 97.4% (95% CI: 96% to 98.3%) for metal abutments and that the annual failure rates with all ceramic crowns on ceramic abutments were similar to the rates observed with PFM crowns on metal abutments.

The failure rate of cemented reconstructions was not influenced by the choice of a particular cement whereas the event loss of retention depended on the type of cement. This leaves the clinician to select a cement based on the amount of preferred retention.

#### **Technical and Biologic Complications**

The results of the current review indicate a statistically significant (P = .03) higher overall rate of technical complications with cement-retained reconstructions compared to screw-retained reconstructions (Table 11). The recent review by Sailer et al<sup>15</sup> did not assess the overall rate of technical complications, but reported that the estimated cumulative incidence of technical complications at 5 and 10 years was higher with only screw-retained I-SC reconstructions and not I-FDP or full-arch I-FDP. The current review did not evaluate technical complications in terms of individual reconstruction type.

The technical complication fracture/chipping of ceramic was statistically significantly more frequent in screw-retained reconstructions compared to cemented ones (Table 11). Loosening of abutment complications were more frequent with cemented reconstructions. The total rate of technical complications, however, was statistically significantly higher with cemented reconstructions (Table 11).

Chipping of the ceramic veneer may be more likely in the presence of an access opening for an occlusal/abutment screw. In this situation, the integrity of the framework and the veneer layers are interrupted, and tension might be produced while tightening the assembly and manipulations with the screwdriver, provoking stress peaks laterally in the region of the access opening.

Although chipping of the resin veneer could not be compared between retention type, this complication was extremely frequent in screw-retained reconstructions with an event rate of 4.40 (95% CI: 1.50 to 12.88), thus making it the second most common complication for screw-retained reconstructions. These complications were also mainly seen in full-arch reconstructions and this should therefore be taken into account when designing an implant-supported reconstruction for edentulous patients.

The biologic complications and the total event rate for biologic complications were significantly increased with cement- compared to screw-retained reconstructions (Table 13). Presence of fistula/suppuration appeared statistically significantly more often with cemented reconstructions.

In the chain of processes leading to biologic complications, many host factors and biologic interactions with the inserted materials play a role. The type of retention (screw/cement) seemed to have a decisive role in the risk of developing a biologic complication (Table 13).

This is in agreement with other reports that discuss the role of cement in the development of infections and progressive bone loss<sup>87</sup> as well the observed improvement after removal of excess cement.<sup>84</sup> For bacterial colonization, even a micro-gap and a small space between the implant shoulder/abutment and supra-structure may create an anaerobic niche for undisturbed growth of a biofilm,<sup>95–97</sup> independent of retention type.

# Data Extraction, Limitation, and Future Prognosis

Stringent inclusion and exclusion criteria were selected including a minimum mean follow-up time of 3 years for the included studies. This follow-up time is greater than that of previous studies and allows for a more accurate estimation of 5-year survival rates. 8.3% of the included studies were RCT, which is a reassuringly high number compared to that usually reported in dental literature reviews. However, the main limitation of this review is the heterogeneity between the included studies, mainly their definitions of success, survival, failure, and complications, as well as the presentation of the data and design. However with a greater number of included studies compared to previous reviews, it is hoped that the negative effect of heterogeneity can be minimized. Further, If a study did not note the absence of events, it was excluded for a statistical comparison, since it was unclear if events were present.

Another limitation to this study is the lack of a standardized definition of prosthetic failure. While implant failures were well-reported, it was not always possible to distinguish true prosthetic failures from those where the implant failed and resulted in the reporting of a prosthetic failure. As a result, there may be an overestimation of prosthetic failure in these results. Although it is not possible to determine to exactly what degree this overestimation occurs in the various groups, it must be remembered that survival of the restoration and implant together is what is important to the patient.

For the two categories of screw-retention (onepiece and two-piece screw-retained reconstructions), the estimated event rates were calculated and compared to cement-retained reconstructions; however, due to a limitation of studies, further analyses were not performed.

In addition, a further biomechanical aspect that was not separately analyzed was the effect of an external or internal connection. This has previously been shown to have an impact on screw loosening, but little else.<sup>98</sup>

With respect to future prognosis of a reconstruction, the determination of which retention system leads to more failures/complications has to be complemented with the question: Which retention system is more advantageous in the successful management of future failures and complications? Handling of these complications and the cost of doing so represent further questions of importance and are recommended as avenues for future research.

## CONCLUSIONS

The estimated 5-year survival rate of screw-retained reconstructions (based on a random-effects Poisson regression analysis) is similar to that for cemented reconstructions. Estimated failure rates calculated for cemented and screw-retained reconstructions were not statistically significant (P = .63).

There were no statistically significant differences between the failure rates of the different reconstruction types (I-SC, I-FDPs, full-arch I-FDPs).

Failures of cemented reconstructions were not statistically significantly influenced by the abutment material (titanium, gold, ceramic) or the choice of a specific cement.

The total event rate of technical complications was statistically significantly higher with cemented reconstructions. The technical complication fracture/ chipping of ceramic was significantly more frequent in screw-retained reconstructions compared to the cemented ones. The loosening of abutment complication was more frequent with cemented reconstructions. The remaining technical complications such as fracture of abutment, fracture of framework, fracture of implant and screw fracture did not demonstrate statistical significance.

The total event rate for biologic complications was significantly higher with cemented compared to screw-retained reconstructions. Presence of fistula/ suppuration appeared statistically significantly more often with cemented reconstructions. Outcomes of the other event rates of biologic complications such as bone loss (> 2 mm), peri-implantitis, presence of fistula/ suppuration, peri-implant mucositis, recession, and loss of implant were not statistically significantly different between the two retention systems.

Considering the risks with cemented reconstructions and the limited options for interventions after definitive cementation, it seems to be appropriate to recommend a preference towards screw retention of implant-supported reconstructions.

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# Systematic Review of the Survival Rate and Incidence of Biologic, Technical, and Esthetic Complications of Single Implant Abutments Supporting Fixed Prostheses

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Purpose: To assess the 5-year survival rate and number of technical, biologic, and esthetic complications involving implant abutments. Materials and Methods: Electronic (Medline) and hand searches were performed to assess studies on metal and ceramic implant abutments. Relevant data from a previous review were included. Two reviewers independently extracted the data. Failure and complication rates were analyzed, and estimates of 5-year survival proportions were calculated from the relationship between event rate and survival function. Multivariable robust Poisson regression was used to compare abutment characteristics. Results: The search yielded 1,558 titles and 274 abstracts. Twenty-four studies were selected for data analysis. The survival rate for ceramic abutments was 97.5% (95% confidence interval [CI]): 89.6% to 99.4%) and 97.6% (95% CI: 96.2% to 98.5%) for metal abutments. The overall 5-year rate for technical complications was 11.8% (95% Cl: 8.5% to 16.3%), 8.9% (95% Cl: 4.3% to 17.7%) for ceramic and 12.0% (95% Cl: 8.5% to 16.8%) for metal abutments. Biologic complications occurred with an overall rate of 6.4% (95% CI: 3.3% to 12.0%), 10.4% (95% CI: 1.9% to 46.7%) for ceramic, and 6.1% (95% CI: 3.1% to 12.0%) for metal abutments. Conclusions: The present meta-analysis on single-implant prostheses presents high survival rates of single implants, abutments, and prostheses after 5 years of function. No differences were found for the survival and failure rates of ceramic and metal abutments. No significant differences were found for technical, biologic, and esthetic complications of internally and externally connected abutments. INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):99-116. doi: 10.11607/jomi.2014suppl.g2.2

**Key words:** biologic complications, ceramics, complication rates, esthetic complications, failures, implant abutments, implant prostheses, metal, survival, systematic review, technical complications, titanium, zirconia

Today, partially edentulous individuals represent the main group of patients requiring treatment in daily dental practice. Therefore, oral implants are the

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predominant treatment modality for the rehabilitation of these patients.<sup>1</sup> Using implants, fixed partial dentures can be applied in situations where removable dentures would previously have been necessary.<sup>2-4</sup> In addition, more treatment options that preserve the tooth structure are possible by replacing missing single teeth with dental implants.<sup>5</sup> Since most of the patients provided with oral implants are between 40 and 50 years of age, promising long-term survival rates for implants and prostheses are expected both by the clinician and the patient to ensure the longevity of the prosthesis.<sup>6–8</sup> The definition "long-term" has been specified as a follow-up of at least 5 years.<sup>9</sup> Thus, survival rates and the incidence of biologic, technical, and esthetic events should be based on mean observation periods of at least 5 years.<sup>10</sup>

Several years ago, hierarchies of evidence were developed as aid for the interpretation and evaluation of research findings.<sup>11</sup> As evidence, systematic reviews were ranked to be excellent in terms of effectiveness, appropriateness, and feasibility. An evidence level of "excellent" equates with the strongest scientific basis

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for clinical practice along with the least risk of error.<sup>11</sup> Consequently, systematic reviews are an optimal tool for the development of practice guidelines and clinical recommendations.

A recent systematic review confirmed single implants to be a successful treatment method with survival rates of 97.2% at 5 years and 95.2% at 10 years.<sup>12</sup> However, implant survival rates are not the only essential consideration when advising the patient on different treatment options. Prosthetic and implant abutment outcomes need to be considered as well. Different kinds of abutments are available with respect to material (metal and ceramic) and shape (prefabricated and customized, both with various internal designs). At this time, metal abutments are classified as the "gold standard," although high-strength zirconia abutments are being utilized more widely and may be an adequate alternative to metal abutments for the clinical use. The results of a previous systematic review showed similar outcomes for ceramic and metal abutments.<sup>13</sup> However, the results need to be interpreted with caution due to a high variation in the number of analyzed abutments and differing numbers of studies and follow-up times.

Since the use of ceramic abutments has spread within the last few years, an increase in clinical studies might thus be expected. An update of the available most recent clinical data may help the clinician decide upon the most ideal abutment in each individual situation.

The aim was to systematically review the existing dental literature on the survival rates of metal and ceramic abutments supporting single implant crowns with a mean observation period of at least 3 years. In addition, the occurrence of negative biologic, technical, and esthetic events was evaluated for metal and ceramic abutments.

## MATERIALS AND METHODS

The PICO (population, intervention, comparison, outcome) question was stated as follows: For single-tooth implant prostheses in anterior and posterior locations, are there differences in survival/performance based on technical, biologic, and esthetic outcomes as influenced by material and design?

### Search Strategy

The present systematic review was performed as an update of a previously published systematic review with the same objectives.<sup>13</sup>

A Medline (PubMed) search was performed for clinical studies published in dental journals from January 1, 2009 up to April 30, 2012. The search was limited to English, German, French, Dutch, and Korean language publications (Table 1).

#### **Search Terms**

The following search terms were grouped to the three main subjects (implants, abutments, and material) and linked with "and" as follows:

#### Implants

"Dental Implants, Single-Tooth" [MeSH] AND "dental implants" AND "dental implant\* single tooth" AND "single tooth implant\*" AND "single implant" AND "dental implant" AND "single tooth implant" AND "single tooth implants" AND "single implants" AND "Denture, Partial, Fixed" [MeSH] AND "Dental Prosthesis Design" [MeSH] AND "fixed restoration" AND "Denture Design" [MeSH] AND "fixed restoration" AND "Denture Design" [MeSH] AND "fixed restoration" AND "fixed prosthodontic" AND "fixed partial denture" AND "fixed prosthodontics" AND "fixed partial dentures" AND "dental implants" [MeSH] AND "Dental Prosthesis, Implant-Supported" AND "fixed dental prosthesis" AND "fixed dental prostheses".

#### Abutments

"Dental Abutments" [MeSH] AND "implant abutment" AND "implant\* reconstruct\*" AND "implant\* abutment\*" AND "implant abutments" AND "abutment\*" AND "dental abutment\*".

#### Material

"Titanium" [MeSH] AND "Gold" [MeSH] AND "ceramics" [MeSH] AND "aluminum" [MeSH] AND "Zirconium" [MeSH] AND "ceramic\*" AND "titan\*" AND "metal\*" AND "zirconi\*" AND "gold\*" AND "alumin\*" AND "metals" [MeSH].

Thereafter, the search results from the three subject groups were combined with each other using "OR." The electronic search was complemented by manual searching of the bibliographies of the most recent systematic reviews<sup>12,14,15</sup> and of all included publications.

## **Inclusion Criteria**

The criteria for study inclusion were:

- Studies with at least 10 included patients
- Clinical studies only
- Studies with a mean follow-up of at least 3 years (unless there was an immediate negative effect)
- Studies reporting on details and outcomes of implant abutments
- Studies reporting on partially edentulous patients receiving implant-supported single crowns

#### **Exclusion Criteria**

Reports based on patient chart reviews, questionnaires, or interviews were excluded as were case reports and multiple publications on the same patient cohort.

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#### Table 1 Systematic Search Strategy

Focus question For single-tooth implant reconstructions in anterior and posterior locations are there differences in survival/performance based on technical, biologic, and esthetic outcomes as influenced by material, design, and fabrication?

Search strategy	
Population	Patients with single-implant reconstructions
Intervention or exposure	Single implants with a mean follow-up of 3 y
Comparison	Abutment material (metal vs ceramic)
Outcome	Survival rate of implants, abutments, reconstructions
Search combination	Implants: "Dental Implants, Single-Tooth" [MeSH] AND "dental implants" AND "dental implant* single tooth" AND "single tooth implant*" AND "single implant" AND "dental implant" AND "single tooth implant" AND "single tooth implants" AND "single implants" AND "Denture, Partial, Fixed" [MeSH] AND "Dental Prosthesis Design" [MeSH] AND "fixed restoration" AND "Denture Design" [MeSH] AND "im- plant*" AND "fixed prosthodontic" AND "fixed partial denture" AND "fixed prosthodontics" AND "fixed partial dentures" AND "dental implants" [MeSH] AND "Dental Prosthesis, Implant-Supported" AND "fixed dental prosthesis" AND "fixed dental prostheses" <i>Abutments:</i> "Dental Abutments" [MeSH] AND "implant abutment" AND "implant* reconstruct*" AND "implant* abutment*" AND "implant abutments" AND "abutment*" AND "dental abutment*" <i>Material:</i> "Titanium" [MeSH] AND "Gold" [MeSH] AND "ceramics" [MeSH] AND "zirconi*" AND "gold*" AND "alumin*" AND "metals" [MeSH] Thereafter, the search results from the three subject groups were combined with each other using "OR"
Database search	
Electronic	PubMed, Cochrane Central Register of Controlled Trials (CENTRAL)
Journals	Clinical Oral Implants Research, International Journal of Oral Maxillofacial Implants, International Journal of Oral and Maxillofacial Surgery, Clinical Implant Dentistry and Related Research, Implant Dentistry, Jour- nal of Implantology, Journal of Periodontology, Journal of Clinical Periodontology, Clinical Oral Investigation, Dental Materials, International Journal of Prosthodontics, European Journal of Oral Implantology
Selection criteria	
Inclusion criteria	Studies with at least 10 included patients Clinical studies only Studies with a mean follow-up of at least 3 years; studies reporting on details and outcomes of implant abutments Studies reporting on partially edentulous patients receiving implant-supported single crowns
Exclusion criteria	Reports based on patient chart reviews, questionnaires, or interviews Case reports

CT, controlled trial; RCT, randomized controlled trial; NR, not reported.

## **Study Selection**

All obtained titles and abstracts were checked for inclusion by two independent reviewers (SK and AZ). In case the abstract was not available, a full text article was acquired. On the basis of the chosen abstracts, full-text articles were selected for independent assessment by the reviewers. If the information in title and abstract was insufficient for inclusion or exclusion, full-text articles were also obtained. In case of any disagreement regarding inclusion, a decision was made by the three reviewers by consensus. The agreement among the three reviewers for the inclusion of full-text articles was subsequently calculated by Cohen kappa coefficient. In addition, 16 publications on single implant prostheses were included for analysis from the previous review.<sup>13</sup>

#### **Data Extraction**

A data extraction sheet was used by two reviewers (SK, AZ) to extract the relevant data from the included papers. Information on several parameters was recorded including: author(s), study design, year of publication, mean follow-up time, implant system, number of abutments, abutment material, drop-outs, and survival rates, as well as the incidence of biologic, technical, and esthetic complications of abutments. Disagree-

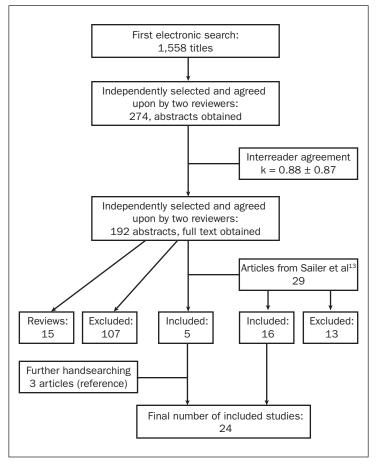


Fig 1 Search strategy.

ment regarding data extraction was resolved by consensus. The number of events and the corresponding total exposure time of the prostheses were calculated. In case the publication did not provide sufficient information, the corresponding authors of the respective publications were contacted via email. Additionally, the data from included studies on single implant crowns from the previous review were extracted.<sup>13</sup>

Survival was defined as the abutment/implant prosthesis remaining in situ for the observation period with or without modifications.

Technical complications included abutment fracture, abutment screw fracture, abutment screw loosening, misfit at the implant-abutment junction (gap), fracture of the implant prosthesis, chipping of the veneering ceramic, and loosening of the implant prosthesis.

The analysis of biologic complications encompassed bone loss of more than 2 mm, soft tissue recession, and general soft tissue complications.

The analysis of the esthetic complications included soft tissue discoloration and other esthetic problems.

### **Statistical Analysis**

Failure and complication rates were calculated by dividing the

number of events (failures or complications) as the numerator by the total time of the prostheses being under observation as the denominator. The numerator could usually be extracted directly from the publication. If all patients/prostheses had a fixed followup time point, this was taken as the observation period for all. Otherwise, the total observation time was calculated by taking the sum of the following: (1) exposure time of prostheses that could be followed for the full observation period; (2) exposure time up to failure of the prostheses that were lost due to failure; and (3) exposure time up to the end of observation time for prostheses that did not complete the observation period for reasons such as death, change of address, refusal to participate, nonresponse, chronic illnesses, missed appointments, and work commitments. If all three components for the calculation of the total exposure time were not available, the total exposure time was estimated by multiplying the mean follow-up time by the number of constructions under observation.

For each study, event rates for the abutments and the prostheses were calculated by dividing the total number of events by the total abutment exposure time in years. For additional analysis, the total number of events was considered to be Poisson distributed for a given sum of abutment exposure years and robust Poisson regression with a logarithmic link-function and total exposure time per study as an offset variable was used.<sup>16</sup> Robust Poisson regression allowed for the calculation of standard errors and 95% confidence intervals (CI), which incorporated heterogeneity among studies.

Five-year survival proportions were calculated via the relationship between event rate and survival function S(T) by assuming constant event rates<sup>17</sup>:

 $S(T) = exp(-T \times event rate)$ 

For the 5-year survival, T was equal to 5.

The 95% CIs for the survival proportions were calculated by using the 95% CIs of the event rates. Multivariable robust Poisson regression was used to formally compare construction subtypes and to assess other study characteristics and to estimate event rate ratios and their 95% CIs. All analyses were performed using Stata, version 12.

Study	Year of publication	Study design	Total no. of included patients	Age range	Mean age	Setting	Mean follow-up (y)	Drop-out (%)
Avivi-Arber and Zarb <sup>18</sup>	1996	Prospective CT	41	14.5–3.9	33.5	University	4	5
Henry et al <sup>19</sup>	1996	Prospective CT	92	NR	NR	Multicenter	5	8
Andersson et al <sup>20</sup>	1998	Prospective CT	57	NR	32	Specialist clinic	5	5
Scheller et al <sup>21</sup>	1998	Multicenter prospective CT	82	14–73	35	Multicenter	5	25
Levine et al <sup>22</sup>	1999	Retrospective	129	NR	NR	Multicenter	3.3	19
Wannfors and Smedberg <sup>23</sup>	1999	Prospective	69	17–72	26	Specialist clinic	3	3
Bianco et al <sup>24</sup>	2000	Retrospective CT	214	16-70	NR	Multicenter	8	9
Andersson et al <sup>25</sup>	2001	RCT	15	17–49	32	Specialist clinic	3	0
Krennmair et al <sup>26</sup>	2002	Retrospective	112	NR	31.3	Private practice and university	3	NR
Muche et al <sup>27</sup>	2003	Retrospective	76	NR	45	University	3	NR
Glauser et al <sup>28</sup>	2004	Prospective CT	27	26-75	44	University	4.1	9
Romeo et al <sup>29</sup>	2004	Prospective CT	250	20-67	NR	University	3.9	NR
Brägger et al <sup>30</sup>	2005	Prospective cohort study	127	19–78	49.3	University	10	NR
Vigolo et al <sup>31</sup>	2006	Prospective RCT	20	NR	NR	University	4	0
Canullo <sup>32</sup>	2007	Prospective cohort study	25	25–70	NR	Private practice	3.3	NR
Cooper et al <sup>33</sup>	2007	Prospective cohort study	48	NR	30.6	University	3	9
MacDonald et al <sup>34</sup>	2009	Prospective	20	NR	43.5	University	8	3
Vigolo and Givani <sup>35</sup>	2009	Prospective	144	25–55	37	Private practice	5	0
Bonde et al <sup>36</sup>	2010	Retrospective	51	19–79	43	University	10	3
Urdaneta et al <sup>37</sup>	2010	Retrospective	81	28-92	58.7	Specialist clinic	5.9	27
Ekfeldt et al <sup>38</sup>	2011	Retrospective	25	NR	NR	Specialist clinic	3–5	NR
Visser et al <sup>39</sup>	2011	Prospective	93	18-63	33	University	5	1
Gotfredsen <sup>40</sup>	2012	Prospective	20	18–59	33	University	10	5
Zembic et al <sup>41</sup>	2013*	Prospective RCT	22	23–59	41.3	University	5.6	4

\*Available ahead of print in 2012.

# RESULTS

The search strategy is presented in Fig 1. The Medline search provided a total of 1,558 titles. After screening of all titles, both reviewers agreed upon 274 abstracts. Finally, 24 full-text articles reporting on the clinical performance of implant abutments were selected (Table 2). Three out of 24 studies were gained through the hand search and 16 articles were retrieved from the previous review. The studies were published from 1996 until 2012. The inter-reviewer agreement for the inclusion of the studies was  $\kappa = 0.88 \pm 0.87$  (Cohen kappa coefficient).

## **Excluded Studies**

One hundred twenty-two studies were excluded due to the following reasons: mean observation period less than 3 years (n = 27), no detailed information on abutments (n = 42), no detailed results on abutments (n = 6), data obtained from patient chart reviews (n = 3), splinted crowns (n = 8), case reports (n = 19), reviews (n = 15), or mixed data on FPDs and single implant crowns (n = 2).

### **Included Studies**

Among the selected full-text articles, three studies<sup>25,31,41</sup> were randomized clinical trials (RCTs) comparing different abutment materials (zirconia vs titanium, alumina vs

Table 3 Characte			nd Prostheses		
Study	Year of publication	Implant system	Implant diam- eter	Location	Total abutments
Avivi-Arber and Zarb <sup>18</sup>	1996	Nobel Biocare	3.75, 4.0	Incisor, canine, premolar, molar	42
Henry et al <sup>19</sup>	1996	Nobel Biocare	NR	NR	96
Andersson et al <sup>20</sup>	1998	Nobel Biocare	NR	51 incisors, 1 canine, 13 premolars	65
Scheller et al <sup>21</sup>	1998	Nobel Biocare	3.75, 4.0	87 maxilla, 12 mandible	65
Levine et al <sup>22</sup>	1999	Straumann	3.5, 4.1	22 anterior, 135 posterior	157
Wannfors and Smed- berg <sup>23</sup>	1999	Nobel Biocare	NR	40% max incisor, 20%–30% max lateral incisor, 15%–20% max canine, 5 implants in mandible	76
Bianco et al <sup>24</sup>	2000	Nobel Biocare	NR	anterior and posterior	229
Andersson et al <sup>25</sup>	2001	Nobel Biocare	3.75, 4.0	17 incisors, 2 canines, 1 premolar	10
Andersson et al <sup>25</sup>	2001		NR	NR	10
Krennmair et al <sup>26</sup>	2002	Frialit 2	NR	NR	146
Muche et al <sup>27</sup>	2003	3i	NR	NR	205
Glauser et al <sup>28</sup>	2004	Nobel Biocare	3.75, 4.0	25 incisors, 14 canines, 15 premolars	36
Romeo et al <sup>29</sup>	2004	Straumann	Narrow, regular wide	, Anterior, posterior	121
Brägger et al <sup>30</sup>	2005	Straumann	NR	NR	69
Vigolo et al <sup>31</sup>	2006	3i	3.75, 4.0	16 maxilla, 4 mandible, 0 anterior, 20 posterior	20
Vigolo et al <sup>31</sup>	2006	3i	3.75, 4.0	16 maxilla, 4 mandible, 0 anterior, 20 posterior	20
Canullo <sup>32</sup>	2007	TSA implants	NR	Anterior and posterior	30
Cooper et al <sup>33</sup>	2007	Astra Tech	NR	Incisor, canine	43
MacDonald et al <sup>34</sup>	2009	Endopore	3.5, 4.1	13 posterior, 7 anterior	17
Vigolo and Givani <sup>35</sup>	2009	3i	wide	Only molars	182
Bonde et al <sup>36</sup>	2010	Nobel Biocare	3.3 (4), 3.75 (51)	42 anterior, 13 premolars, 49 maxilla, 6 mandible	52
Urdaneta et al <sup>37</sup>	2010	Bicon	3.3-6.0	NR	326
Ekfeldt et al <sup>38</sup>	2011	Nobel Biocare	3.3–5.0	NR	40
Visser et al <sup>39</sup>	2011	Straumann	4.1	Anterior maxilla	92
Gotfredsen <sup>40</sup>	2012	Astra Tech	4.5	18 anterior, 2 posterior	19
Zembic et al <sup>41</sup>	2013*	Nobel Biocare	3.75	2 anterior, 16 posterior	18
Zembic et al <sup>41</sup>	2013*	Nobel Biocare	3.75	2 anterior, 8 posterior	10

\*Available ahead of print in 2012. NR, not reported.

titanium, and titanium vs gold). Seventeen studies had a prospective design, seven studies were retrospective.

In total, 12 studies were performed at a university setting, 5 studies in a specialist clinic, 2 in private practice, and 1 both at university and private practice. Four studies were multicenter studies.

Overall, 1,877 patients with 2,999 abutments were involved in the included studies. Out of these, 139 (7.4%) patients and 813 (27%) abutments were dropouts and thus not followed. Six studies did not report the patient dropout rate. The mean age of all patients was 41 years, ranging from 14 to 92 years.

Abutment material	Abutment type	Fixation torque	Abutment connection	Prosthesis material	Cemented implants	Screw-retained implants
Titanium	NR	NR	External hexagon	Metal-ceramic or metal-acrylic, 1 all-ceramic	NR	NR
Titanium	NR	NR	External hexagon	NR	NR	NR
Titanium	NR	NR	External hexagon	62 all-ceramic, 3 metal-ceramic	65	0
Titanium	Prefabricated	32	External hexagon	16 porcelain fused to metal, 81 full ceramic	97	0
Titanium	NR	32	Internal	NR	76	81
Gold	Customized, prefabricated	32	External hexagon	36 gold-resin, 35 gold-ceramic, 9 all-ceramic	36	44
Titanium	NR	NR	External hexagon	Metal, metal-ceramic, all-ceramic	203	31
Alumina	NR	NR	External hexagon	All-ceramic	10	0
Titanium	NR	10-32	External hexagon	All-ceramic	10	0
Titanium	NR	NR	Internal	Metal-ceramic, all-ceramic	93	53
Metal	NR	35	External hexagon	Metal-ceramic	5	200
Zirconia	NR	32	External hexagon	All-ceramic	54	0
Titanium	NR	NR	Internal	Metal-ceramic	NR	NR
Metal (titanium, gold-alloy)	NR	32	Internal	NR	67	2
Titanium	Customized	35	External hexagon	Metal-ceramic	20	0
Gold	Customized	35	External hexagon	Metal-ceramic	20	0
Zirconia	NR	15	Internal	All-ceramic	30	0
Titanium	NR	32	Internal	Metal-ceramic, all-ceramic	54	0
Titanium	Prefabricated	NR	External hexagon	Metal-ceramic	0	20
Titanium	Customized	32	External hexagon	Metal-ceramic	182	0
Titanium	Prefabricated	NR	External hexagon	All-ceramic	55	0
Titanium	NR	NR	Internal	228 gold-resin, 82 metal-ceramic, 16 all-ceramic	326	0
Zirconia	Customized	35	External hexagon	40 all-ceramic (25 one-piece)	15	25
Titanium abutment with gold coping screwed onto it	Customized	15	Internal	All-ceramic	92	0
Titanium	Prefabricated, customized	15	Internal	Metal-ceramic	19	0
Zirconia	Customized	32	External hexagon	All-ceramic	16	2
Titanium	Customized	32	External hexagon	Metal-ceramic	10	0

In the above-mentioned three RCTs, the outcomes were compared for 10 alumina and 10 titanium abutments, 20 gold and 20 titanium abutments, and 18 zirconia and 10 titanium abutments.<sup>25,31,41</sup>

The majority of studies (13) reported on anterior and posterior abutment locations.  $^{18,20,22,24,25,28,29,31,32,34,36,40,41}$ 

Three studies reported on anterior abutment locations only.<sup>23,33,39</sup> One study described posterior abutment locations only.<sup>35</sup> Seven studies did not state the exact location of the abutments with regard to anterior or posterior.<sup>19,21,26,27,30,37,38</sup>

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#### Table 4 Failed Abutments and Prostheses

Study	Year of publication	Total no. of abutments/ prostheses	Mean follow-up	Abutment material	Prosthesis material
Avivi-Arber and Zarb <sup>18</sup>	1996	42	4	Titanium	Metal-ceramic or metal-acrylic, 1 all-ceramic
Henry et al <sup>19</sup>	1996	96	5	Titanium	NR
Andersson et al <sup>20</sup>	1998	55	5	Titanium	62 all-ceramic, 3 metal-ceramic
Scheller et al <sup>21</sup>	1998	65	5	Titanium	16 meta-ceramic, 81 all-ceramic
Levine et al <sup>22</sup>	1999	157	3.3	Titanium	NR
Wannfors and Smedberg <sup>23</sup>	1999	76	3	Gold	36 gold-resin, 35 gold-ceramic, 9 all-ceramic
Bianco et al <sup>24</sup>	2000	229	8	Titanium	Metal, metal-ceramic, all-ceramic
Andersson et al <sup>25</sup>	2001	10	3	Alumina	All-ceramic
Andersson et al <sup>25</sup>	2001	10	3	Titanium	All-ceramic
Krennmair et al <sup>26</sup>	2002	146	3	Titanium	Metal-ceramic, all-ceramic
Muche et al <sup>27</sup>	2003	205	3	Metal	Metal-ceramic
Glauser et al <sup>28</sup>	2004	36	4.1	Zirconia	All-ceramic
Romeo et al <sup>29</sup>	2004	121	3.9	Titanium	Metal-ceramic
Brägger et al <sup>30</sup>	2005	69	10	Metal (titanium, gold-alloy	) NR
Vigolo et al <sup>31</sup>	2006	20	4	Titanium	Metal-ceramic
Vigolo et al <sup>31</sup>	2006	20	4	Gold	Metal-ceramic
Canullo <sup>32</sup>	2007	30	3.3	Zirconia	All-ceramic
Cooper et al <sup>33</sup>	2007	43	3	Titanium	Metal-ceramic, all-ceramic
MacDonald et al <sup>34</sup>	2009	17	8	Titanium	Metal-ceramic
Vigolo and Givani <sup>35</sup>	2009	182	5	Titanium	Metal-ceramic
Bonde et al <sup>36</sup>	2010	52	10	Titanium	All-ceramic
Urdaneta et al <sup>37</sup>	2010	326	5.9	Titanium	228 gold-resin, 82 metal-ceramic, 16 all-ceramic
Ekfeldt et al <sup>38</sup>	2011	40	3-5	Zirconia	40 all-ceramic (25 one-piece)
Visser et al <sup>39</sup>	2011	92	5	Titanium abutment with gold coping	All-ceramic
Gotfredsen <sup>40</sup>	2012	19	10	Titanium	Metal-ceramic
Zembic et al <sup>41</sup>	2013*	18	5.6	Zirconia	All-ceramic
Zembic et al <sup>41</sup>	2013*	10	5.6	Titanium	Metal-ceramic

\*Available ahead of print in 2012. Total summary estimate (95% Cl, random-effects Poisson regression) for total exposure time: 11,089; estimated abutment failure rate per 100 abutment years: 0.48 (0.30–0.77); estimated prosthesis failure rate per 100 prosthesis years: 0.91 (0.62–1.32); estimated 5-year abutment failure rate per 100 abutment years: 2.37% (1.49–3.77); estimated 5-year prosthesis failure rate per 100 prosthesis years: 4.42% (3.06–6.37).

The studies reported on eight commercially available implant systems: Brånemark System (Nobel Biocare), Astra Tech Dental Implants System (Astra Tech), ITI Dental Implants System (Straumann), 3i Implants (Implant Innovations), Endopore Implants (Innova Corporation), TSA Implants (Impladent), Frialit 2 Implants (Friatek), and Bicon Dental Implants (Bicon) (Table 3).

Thus, nine studies evaluated implant systems with internal implant-abutment connections (Astra Tech, Straumann, Bicon, Frialit 2, and TSA Implants), and the remaining 15 studies evaluated implants with external implant-abutment connections (Brånemark System, 3i, and Endopore Implants) (Table 3). In total, 1,003 internally connected abutments (30 zirconia and 973 metal abutments) were evaluated and 1,183 externally connected abutments (94 zirconia, 10 alumina, and 1,079 metal abutments).

#### Abutment Survival

A total of 2,186 abutments were followed with a mean observation period of 5.5 years. Altogether, 134 ceramic abutments and 2,052 metal abutments were evaluated at follow-up in the included studies (Table 4).

Only two studies did not report on abutment failures.<sup>18,22</sup> Out of the 22 studies reporting abutment failures, two ceramic abutments (1.5%) and 45 metal abutments (2.2%) were lost, resulting in an estimated

No. of failures (abutments)	No. of failures (prostheses)	Total abutment/prosthesis exposure time
NR	NR	168
8	8	480
0	4	275
1	8	325
0	4	518
4	7	228
5	NR	1,832
2	NR	30
0	1	438
2	0	615
3	1	468
0	0	690
5	5	80
5	5	80
0	0	129
0	0	136
0	0	910
3	3	520
0	1	1,923
0	0	460
3	3	190
3	16	30
0	0	148
3	11	99
0	2	160
2	2	101
1	1	56

5-year failure rate of 2.5% (95% CI: 0.6% to 10.4%) for ceramic and 2.4% (95% CI: 1.5% to 3.8%) for metal abutments (Table 4). The failure rate of all abutments per 100 abutment years amounted to 0.48% (95% CI: 0.30% to 0.77%) (Table 4 and Fig 2). The overall estimated 5-year abutment survival rate was 97.6% (95% CI: 96.2% to 98.5%) (Table 4 and Fig 2).

Ceramic abutments showed survival of 97.5% (95% CI: 89.6% to 99.4%) at 5 years and did not differ significantly from metal abutments, which showed 97.6% survival (95% CI: 96.2% to 98.5%).

In total, six abutments fractured, two internally connected zirconia abutment (Replace Select, Nobel Biocare), two externally connected alumina abutments (Brånemark, Nobel Biocare), and three titanium abutments that were internally connected to Bicon implants.<sup>25,37,38</sup>

Sixty-eight abutments could not be evaluated due to implant loss as reported in 13 studies (2 ceramic, 66 metal abutments).<sup>19,21,23,24,26,27,29,30,33,36,37,39,41</sup> For the remaining abutments, no reason for loss was mentioned.

There was no difference in the occurrence of abutment failures for implants with internal compared to external implant-abutment connection (rate ratio = 1.0; 95% CI: 0.4 to 2.6).

## **Implant Survival**

Since it is logical to assume that implant survival signals abutment survival, it is reasonable to use implant survival as secondary measure.

All included studies except for two<sup>28,32</sup> reported on the survival rates of implants. Overall, the estimated 5-year implant survival rate for single implants amounted to 96.9% (95% CI: 95.6% to 97.8%). Sixtynine out of 2,186 followed-up implants were lost. The estimated 5-year failure rate for single implants amounted to 3.1% (95% CI: 2.2% to 4.4%).

The 5-year survival rate was similar for implants supporting metal abutments (96.9%; 95% CI: 95.6% to 97.8%) and implants supporting ceramic abutments (95.8%; 95% CI: 83.7% to 99.0%). Implants restored with ceramic abutments failed more often at 5 years (4.2%; 95% CI: 1.0% to 16.3%).

There was no difference in the occurrence of implant failures for implants with internal compared to external implant-abutment connection (rate ratio = 1.0; 95% Cl: 0.5 to 2.0). The estimated implant failure per 100 implant years was 0.64% (95% Cl: 0.5% to 0.9%) (Fig 3).

### **Prosthesis Survival**

All studies reported on the survival rates of the prostheses. The reasons for failure or refabrication, respectively, were mainly major fracture or insufficient esthetics.

The estimated 5-year survival rate of single-implant prostheses was 95.6% (95% Cl: 93.6% to 96.9%) (Fig 4). The failure rate for prostheses on ceramic abutments was less than for prostheses on metal abutments (2.6%; 95% Cl: 0.6% to 11.3% vs 4.5%; 95% Cl: 3.1% to 6.6%). This difference was not significant.

The rate of lost prostheses was similar for internal and external implant-abutment connections (rate ratio = 0.9; 95% CI: 0.4 to 2.1) (Table 4).

### **Technical Complications**

Several technical complications were reported in 21 studies. The overall estimated 5-year rate for technical complications was 11.8% (95% CI: 8.5% to 16.3%) (Table 5; Fig 5).

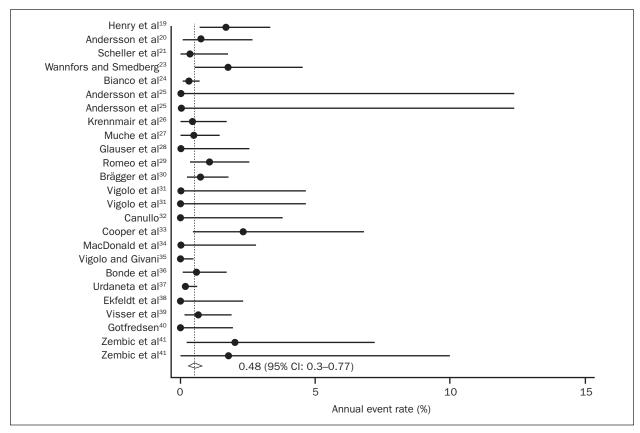


Fig 2 Annual abutment failure rates (per 100 years).

There was no significant difference with respect to the technical complication rate for ceramic and metal abutments. The estimated 5-year technical complication rate for ceramic abutments added up to 8.9% (95% Cl: 4.3% to 17.7%), whereas it was 12.0% (95% Cl: 8.5% to 16.8%) for metal abutments. The rate of technical complications was found to be 1.3 times (rate ratio = 1.3; 95% Cl: 0.7 to 2.4) higher for implants with external implant-abutment connection than with internal implant-abutment connection.

The most common technical complication was abutment screw loosening, which was reported for 4.6% of the abutments. In total, 99 abutment screws were found loose (2 ceramic and 97 metal abutments). One of the studies was an outlier with 29.1% abutment screw loosening.<sup>19</sup> In that study, Brånemark gold abutment screws were used. The second most common technical complication was crown loosening, reported in 13 studies with an incidence of 4.3% (93 loosened crowns out of 2,186 evaluated crowns). In total, 9 loosened crowns were metal-ceramic and 6 were all-ceramic crowns, while 8 studies did not specify the prosthesis material of loose crowns.<sup>18,19,22,24,26,30,33,37</sup> Metal abutments supported all loosened crowns.The third most common complication was chipping of the veneering ceramic, which was evident in 2.7% of the abutments supporting single implant crowns (55 crowns supported by metal abutments and 4 crowns supported by ceramic abutments).

Misfit was reported in seven studies and occurred at 20 out of 2,186 implant-abutment connections (1 ceramic and 19 metal abutments).<sup>20,23,24,32,38,39,41</sup> Abutment fractures were found in 0.2% of abutments reported from two studies.<sup>37,38</sup> In one study, three abutment fractures occurred at internally connected titanium abutments with a narrow neck part connecting to Bicon implants.<sup>37</sup> The other retrospective study described a broken customized CAD/CAM zirconia abutment after 2 months (Procera, Nobel Biocare).<sup>38</sup> This abutment type is externally connected to the implant. The incidence of abutment screw fractures was low at 5 years with 0.2% and was reported at externally connected metal abutments only.<sup>18,19,27</sup>

#### **Biologic Complications**

Biologic complications (from a total of 2,186 abutments) affected both soft and hard tissue (Table 6). Fistulae (n = 5), general peri-implant soft tissue inflammations (n = 5), mucositis (n = 3), and bleeding (n = 2)

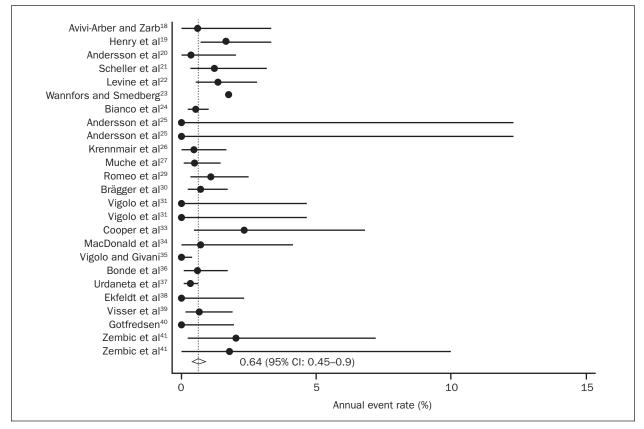


Fig 3 Annual implant failure rates (per 100 years).

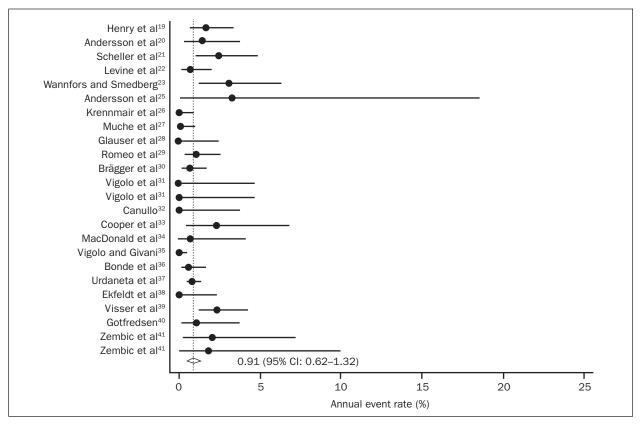


Fig 4 Annual prosthesis failure rates (per 100 years).

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Table 5 Technical Con	nplications (	Occurring in	Abutment	ts and I	Prosthese	s		
Study	Year of publication	Total no. of abutments/ prostheses	Abutment fractures	Misfit	Screw fractures	Abutment screw loosening	Chipping	Crown loosen- ing
Avivi-Arber and Zarb <sup>18</sup>	1996	42	NR	NR	2	NR	5	1
Henry et al <sup>19</sup>	1996	96	0	NR	1	28	NR	13
Andersson et al <sup>20</sup>	1998	55	NR	1	NR	1	NR	NR
Scheller et al <sup>21</sup>	1998	65	NR	NR	NR	4	7	3
Levine et al <sup>22</sup>	1999	157	0	NR	0	4	NR	18
Wannfors and Smedberg <sup>23</sup>	1999	76	NR	8	NR	14	2	NR
Bianco et al <sup>24</sup>	2000	229	NR	9	NR	22	3	13
Andersson et al <sup>25</sup>	2001	10	2	NR	0	0	0	0
Andersson et al <sup>25</sup>	2001	10	0	NR	0	0	0	0
Krennmair et al <sup>26</sup>	2002	146	0	NR	0	5	1	12
Muche et al <sup>27</sup>	2003	205	0	NR	1	8	2	NR
Glauser et al <sup>28</sup>	2004	36	0	NR	NR	2	3	NR
Romeo et al <sup>29</sup>	2004	121	NR	NR	0	0	2	4
Brägger et al <sup>30</sup>	2005	69	0	NR	0	2	3	1
Vigolo et al <sup>31</sup>	2006	20	0	NR	0	0	0	0
Vigolo et al <sup>31</sup>	2006	20	0	NR	0	0	0	0
Canullo <sup>32</sup>	2007	30	0	0	0	0	1	0
Cooper et al <sup>33</sup>	2007	43	0	NR	0	0	3	2
MacDonald et al <sup>34</sup>	2009	17	0	NR	0	3	0	3
Vigolo and Givani <sup>35</sup>	2009	182	NR	NR	0	0	0	0
Bonde et al <sup>36</sup>	2010	52	0	NR	0	3	3	3
Urdaneta et al <sup>37</sup>	2010	326	3	NR	NR	NR	18	18
Ekfeldt et al <sup>38</sup>	2011	40	1	1	0	NR	NR	0
Visser et al <sup>39</sup>	2011	92	NR	1	NR	1	1	NR
Gotfredsen <sup>40</sup>	2012	19	0	NR	0	2	2	2
Zembic et al <sup>41</sup>	2013*	18	0	0	0	0	0	0
Zembic et al <sup>41</sup>	2013*	10	0	0	0	0	3	0

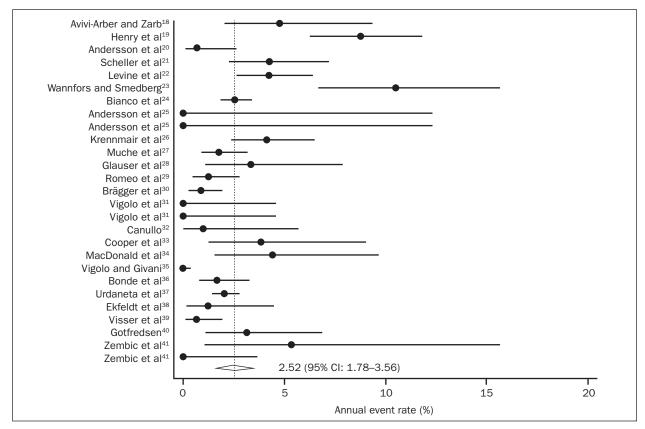
\*Available ahead of print in 2012. Total summary estimate (95% CI, random-effects Poisson regression) for technical complications: 2.5 (1.8–3.6); estimated 5-year failure rate for technical complications: 11.8% (8.5–16.3). NR, not reported.

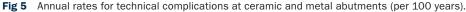
were described with regard to the soft tissue.<sup>19,20,31,36,38</sup> With regard to hard tissue, peri-implantitis (n = 14), pocket probing depths  $\geq$  5 mm (n = 1), and bone loss of more than 2 mm was mentioned in nine studies.<sup>19–21,24,30,34,38–40</sup> A peri-implant abscess was a rare event and found only in one study.<sup>40</sup>

The estimated 5-year rate for biologic complications was 6.4% (95% Cl: 3.3% to 12.0%). The biologic failure rate per 100 abutment years ranged from 0.7% to 2.6% (Fig 6). The incidence of biologic events was almost twice as high for ceramic abutments compared to metal abutments (10.4%; 95% Cl: 1.9% to 46.7% vs. 6.1%; 95% Cl: 3.1% to 12.0%) (Table 6 and Fig 6). Even though, there was no significant difference (P > .05) between metal and ceramic abutments. The rate of biologic complications was found to be two times (rate ratio = 2.0, 95%; CI: 0.4 to 8.9) higher for implants with external implant-abutment connection than with internal implant-abutment connection. This difference did not reach statistical significance (P > .05).

## **Esthetic Complications**

Esthetic outcomes were reported in several studies in a nonstandardized way. Whereas some studies used questionnaires for patients to rate the esthetic outcome, other studies evaluated the esthetic outcome of the crowns by dentists and patients subjective-ly.<sup>20,23,26,38-40</sup> In addition, some studies evaluated the papilla height and/or peri-implant mucosal color.<sup>34,42</sup>





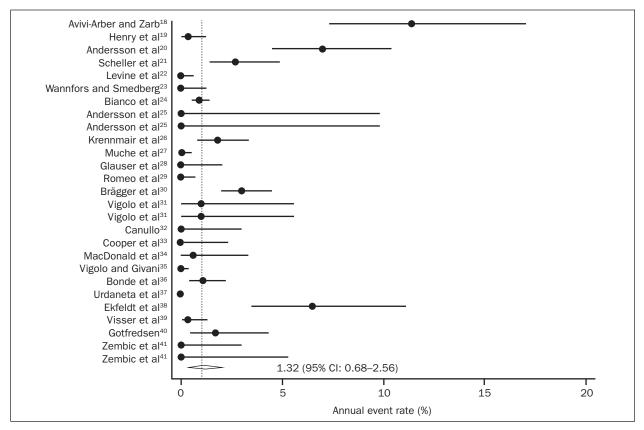


Fig 6 Annual rates for biologic complications at ceramic and metal abutments (per 100 years).

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# Table 6 No. of Biological and Esthetic Complications at Abutments/Prostheses and Estimated5-Year Failure Rrate

Study	Year of publication	Total no. of abutments/ prostheses	Bone loss (> 2 mm)	Soft tissue complication	Recession	Biologic complications	Esthetic complications
Avivi-Arber and Zarb <sup>18</sup>	1996	42	NR	7	5	12	NR
Henry et al <sup>19</sup>	1996	96	1	NR	NR	1	NR
Andersson et al <sup>20</sup>	1998	55	11	1	NR	12	0
Scheller et al <sup>21</sup>	1998	65	4-8	5	NR	0	1
Levine et al <sup>22</sup>	1999	157	4	NR	NR	4	NR
Wannfors and Smedberg <sup>23</sup>	1999	76	0	NR	NR	NR	7
Bianco et al <sup>24</sup>	2000	229	6	2	2	10	5
Andersson et al <sup>25</sup>	2001	10	0	0	0	0	0
Andersson et al <sup>25</sup>	2001	10	0	0	0	0	0
Krennmair et al <sup>26</sup>	2002	146	0	1	4	5	4
Muche et al <sup>27</sup>	2003	205	NR	NR	NR	NR	NR
Glauser et al <sup>28</sup>	2004	36	0	0	NR	0	NR
Romeo et al <sup>29</sup>	2004	121	NR	NR	NR	NR	NR
Brägger et al <sup>30</sup>	2005	69	13	NR	NR	13	NR
Vigolo et al <sup>31</sup>	2006	20	0	0	0	1	NR
Vigolo et al <sup>31</sup>	2006	20	0	0	0	1	NR
Canullo <sup>32</sup>	2007	30	NR	0	NR	0	NR
Cooper et al <sup>33</sup>	2007	43	0	0	0	0	NR
MacDonald et al <sup>34</sup>	2009	17	1	NR	NR	0	NR
Vigolo and Givani <sup>35</sup>	2009	182	0	NR	NR	NR	NR
Bonde et al <sup>36</sup>	2010	52	0	NR	NR	7	NR
Urdaneta et al <sup>37</sup>	2010	326	NR	NR	NR	NR	NR
Ekfeldt et al <sup>38</sup>	2011	40	3	NR	1	9	0
Visser et al <sup>39</sup>	2011	92	NR	NR	1	1	4
Gotfredsen <sup>40</sup>	2012	19	1	1	NR	2	NR
Zembic et al <sup>41</sup>	2013*	18	0	0	0	0	0
Zembic et al <sup>41</sup>	2013*	10	0	0	0	0	0

\*Available ahead of print in 2012. Total summary estimate (95% CI, random-effects Poisson regression) for biologic complications: 1.32 (0.68–2.56); total summary estimate (95% CI, random-effects Poisson regression) for esthetic complications: 0.19 (0.08–0.47); estimated 5-year failure rate for biologic complications: 6.4% (3.3–12.0); estimated 5-year failure rate for esthetic complications: 0.94% (0.38–2.30). NR, not reported.

The overall estimated 5-year esthetic complication rate for single-implant prostheses was 0.9% (95% Cl: 0.4% to 2.3%) (Fig 7). Esthetic problems occurred in 1.0% (95% Cl: 0.4% to 2.5%) of all implant prostheses supported by metal abutments. No esthetic complications were reported in the five studies using ceramic abutments. The instrumented color analysis of mucosal tissues found a tissue color change both for metal and ceramic abutments.<sup>13,41</sup> However, no perceivable difference between titanium and zirconia abutments was visually observed when the thickness of the mucosa exceeded 2 mm.

The rate of negative esthetic events was found to be 1.3 times higher (rate ratio = 1.3; 95% CI: 0.2 to 8.1, P > .05) at prostheses with external implant-abutment connection than with internal. This difference did not reach statistical significance.

# DISCUSSION

The 5-year survival rate of single implant abutments was 98%. Thus, both ceramic and metal abutments survived at a rate of more than 95% at 5 years.

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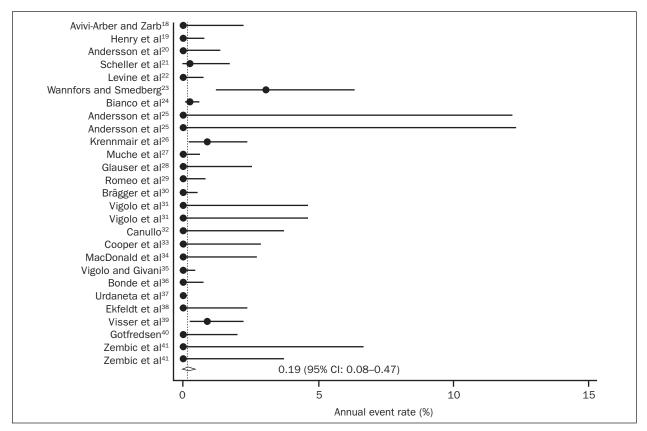


Fig 7 Annual rates for esthetic complications at ceramic and metal abutments (per 100 years).

The most common complications at 5 years were technical complications (11.8%), followed by biologic complications (6.4%). Esthetic complications were fewest and occurred in 0.9% at 5 years.

#### Implant Survival

The overall 5-year implant survival rate of single implants amounted to 96.9% based on this systematic review. This result is in accordance with the results of two systematic reviews on single implants reporting 5-year survival rates of 96.4% and 97.2%, respectively.<sup>12,13</sup> With today's optimized implant surfaces and configurations, most of the implant failures are likely to occur before loading.<sup>12</sup> Thus, not many failures are expected to happen at 5 years of clinical function. This might explain the positive implant survival rates found in the existing studies.

#### **Abutment Survival**

The present results correspond to the results of a previous systematic review on implant abutments, also reporting an estimated 5-year abutment survival rate of 98%.<sup>13</sup> Most of the evaluated abutments were metal abutments (n = 2,052). From the 134 ceramic abutments, mainly zirconia abutments were evaluated (124 zirconia, 10 alumina abutments). In total, six abutments fractured, one externally connected zirconia abutment, two externally connected alumina abutments, and three titanium abutments being internally connected to Bicon implants.<sup>25,37,38</sup>

Alumina abutments were the first generation of ceramic abutments. Previous studies demonstrated a failure rate between 1.9% and 7% after 1 to 5 years of clinical use.<sup>25,43,44</sup> In the above-mentioned RCT alumina abutments were compared with the "gold standard" titanium and showed a lower survival rate of 93% compared to 100% for titanium abutments.<sup>25</sup> This explains the introduction of a stronger substitute material.

The subsequently developed high-strength ceramic zirconia showed superior mechanical properties with much higher bending strength and fracture toughness compared to alumina.<sup>45</sup> Thus, a superior clinical behavior for zirconia might be expected and zirconia might even serve as an alternative to metal in various indications. However, clinical studies on zirconia abutments are scarce (only four studies in this review). When zirconia and titanium abutments were compared in a RCT, the survival rate for both materials was 100% after 5 years of function.<sup>41</sup> Other studies with a shorter follow-up confirm these positive results for zirconia abutments.<sup>28,32,46-48</sup>

Two internally connected zirconia abutments fractured within 2 months in a retrospective study.<sup>38</sup> Among several factors influencing the stability of zirconia abutments, the abutment wall thickness is discussed as being critical.<sup>49</sup> A minimum abutment wall thickness of 0.5 mm was recommended for zirconia abutments, especially when using CAD/CAM techniques.<sup>50</sup> The fractured abutment consisted of an internal insert of titanium to adapt to the implant.<sup>38</sup> The abutment wall thickness might have been insufficient, which might have caused the fractures after a short period of only 2 months.

No clinical long-term data are available for zirconia abutments. Taking the nature of ceramics into account, one might assume fatigue fractures over time.<sup>51</sup> On the other hand, the fatigue performance of zirconia is likely increased through its behavior called "transformation toughening" which causes a resistance to crack growth compared to other polycrystalline ceramics.<sup>52</sup> This might explain the positive clinical results for zirconia abutments thus far.

Metal abutments are still considered the "gold standard" due to high survival rates and excellent physical properties.<sup>20</sup> When gold and titanium abutments were compared in a RCT there were no significant differences with regard to survival and peri-implant bone and soft tissue parameters after 4 years of clinical service.<sup>31</sup>

Three internally connected titanium abutments fractured in one study.<sup>37</sup> These abutments are constructed for specially configured locking-taper implants (Bicon) containing a thin neck part, which might be prone to fracture. Furthermore, the crown-to-implant ratio is increased in this implant-abutment configuration, which might increase the stress at the weakest point, ie, the thin abutment neck part, and thus contribute to its fracture.

Usually, fractures of metal abutment are a rare event and were estimated to occur in only 0.07% at 5 years.<sup>13</sup> The only additional fractures were limited to one specific implant system (Bicon implants).<sup>37</sup>

It has to be taken into account that the number of observed metal abutments (n = 2,052) was much higher than of ceramic abutments (n = 134). On one hand, this might explain why no significant difference between the outcomes of ceramic and metal abutments was calculated. On the other hand, the results have to be interpreted with caution. It may be recommended that the application of ceramic abutments should be selective and not generalized for every situation.

There was no difference in the occurrence of abutment failures for implants with internal compared to external implant-abutment connection. In contrast, a tendency towards less risk for fracture was observed with abutments having an internal implant-abutment connection in the previous review.<sup>13</sup>

#### **Technical Complications**

The most common technical complication found was abutment screw loosening (4.6%), mostly observed with metal abutments. This finding is in agreement with several other studies.<sup>12,13,53,54</sup> The high rate for abutment screw loosening in the present study might partly be explained by one study, which reported 29.1% of screw loosenings and used the first generation of Brånemark gold abutment screws, known for this problem.<sup>19</sup> The majority of the abutment screws loosened in externally connected abutments (n = 85)compared to internally connected ones (n = 14). The tendency of less screw loosening at internal implantabutment connections is supported by other studies.<sup>13,55,56</sup> A recent systematic review on abutment screw loosening for single-implant restorations did not find a difference with internally compared to externally connected implants.<sup>57</sup> The authors concluded that abutments screw loosening is irrespective of the implant-abutment geometry and occurs rarely, provided that a proper antirotational torque is applied.<sup>57</sup>

The second most common technical complication was crown loosening (4.3%). Metal abutments supported all loosened crowns. The cement used was not evaluated. Since in some parts of the world there is a preference for the use of provisional cement for implant prostheses, one might speculate that a high rate of crown loosening is plausible.

The chipping rate of veneering ceramics (2.7%) in the present study was less than reported in previous systematic reviews (4%) at 5 years.<sup>12,13</sup>

#### **Biologic and Esthetic Complications**

There is a lack of classification for the report of biologic complications. Consequently, negative events were reported in a non-standardized way and comparison of the studies was impeded. There was a trend for a higher incidence of biologic complications with ceramic abutments (10.4%) compared to metal abutments (6.1%), but without statistical significance. This finding is rather unusual. Animal studies demonstrated a comparable soft tissue integration of alumina, zirconia, and titanium.<sup>58–60</sup> Other studies found even fewer inflammatory cells in the epithelium around zirconia than titanium and gold, and finally less bacterial adhesion at zirconia clinically.<sup>61–64</sup>

Another systematic review indicated a similar soft tissue complication rate of 7.1% after 5 years.<sup>12</sup> Even though the proportion of biologic complications at externally connected abutments was found to be 1.7 times that of internally connected abutments, the type of connection did not have a significant influence on the estimated rate of biologic complications (P > .05).

In contrast to the results of a previous review, the incidence of recession in the present study was higher

at metal abutments.<sup>13</sup> The reason for this observation remains unclear. The present review indicated no esthetic failures with prostheses on ceramic abutments. This finding is in accordance with a previous review and RCT where less soft tissue discoloration was found for ceramic abutments.<sup>13,54</sup>

There is a large heterogeneity among the studies concerning the evaluation of the esthetics, due to a lack of standardization. The scientific value of the estimated 5-year esthetic complication rate is rather low. Standardized esthetic parameters, such as the pink and white esthetic score<sup>65,66</sup> are thus strongly advisable and should be applied more often in future studies on implant prostheses.

# CONCLUSIONS

The present meta-analysis on single implant prostheses presents high survival rates of single implants, abutments and prostheses after 5 years of function.

There are no performance differences in technical or biologic outcomes for ceramic and metal abutments. The only significant finding pertaining to esthetics was a difference in tissue color with both metal and ceramic abutments, which was greater for metal abutments up to 2 mm mucosal thickness.

Similarly, no differences were found for either external or internal implant-abutment connections. The incidence of technical complications is higher than for either esthetic or biologic complications.

# ACKNOWLEDGMENTS

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# CAD/CAM Technology for Implant Abutments, Crowns, and Superstructures

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**Purpose:** The aim of this systematic review was to compare implant prostheses fabricated by computerassisted design and computer-assisted manufacturing (CAD/CAM) with conventionally fabricated implant prostheses when assessing esthetics, complications (biologic and mechanical), patient satisfaction, and economic factors. Materials and Methods: Electronic searches for clinical studies focusing on long-term follow-up were performed using the PubMed and Ovid search engines. Concentrating on the restorative aspect of the CAD/CAM technology applicable to implant dentistry, pertinent literature was divided into articles related to implant abutments, crowns, and frameworks. Results: A total of 18 articles satisfied the inclusion criteria. Two articles reported on CAD/CAM crowns, six on abutments, and 10 on implantsupported CAD/CAM frameworks. The mean survival rate for CAD/CAM crowns was 98.85% and for CAD/ CAM abutments 100%. The mean survival rate for CAD/CAM frameworks was 95.98%. Conclusion: Based on the current literature, CAD/CAM fabricated crowns, abutments, and frameworks demonstrate survival rates comparable to conventionally fabricated prostheses. Implant survival appears unaffected by fabrication technique. Since this technology encompasses several manufacturing variations, a new definition might be necessary to accurately define the processes under which the CAD/CAM restorations are fabricated. "Complete CAD/CAM product" where no or minimal manual intervention is employed could be a possible term. INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):117-136. doi: 10.11607/jomi.2014suppl.g2.3

**Key words:** abutment, CAD/CAM, crown, dental prosthesis implant-supported, implant-supported framework, implant superstructure

Computer-assisted design (CAD) and computerassisted manufacturing (CAM) have been gaining increased use in implant dentistry over the past 10 years. Continuous improvements to CAD/CAM technology have started to challenge the technique of fabricating implant-supported prostheses and abutments using conventional methods. Fundamental to considering the routine use of these techniques for the fabrication of implant-supported prostheses (ISP) in every clinical situation is the premise that the outcomes are improved when compared to traditional fabrication techniques. The purpose of this systematic review was to answer the focus question: "How do CAD/CAM implantsupported prostheses in patients with missing teeth, who have one or more dental implants, perform compared with conventionally fabricated prostheses, when assessing esthetics, complications (biologic and mechanical), patient satisfaction, and economic factors?"

# **MATERIALS AND METHODS**

#### **Focus Question**

Framing of the research question was undertaken using the PICO strategy.<sup>1,2</sup> The focus question was constructed based on the four PICO elements: Population, Intervention, Comparison, and Outcome. Following development of the focus question by the authors, it was accepted and confirmed by consensus within the working group.

#### Search Strategy

A systematic and comprehensive search of the literature was conducted (Table 1). The search was started in August 2012 and completed in January 2013. Electronic databases (Medline) were searched using the MeSH

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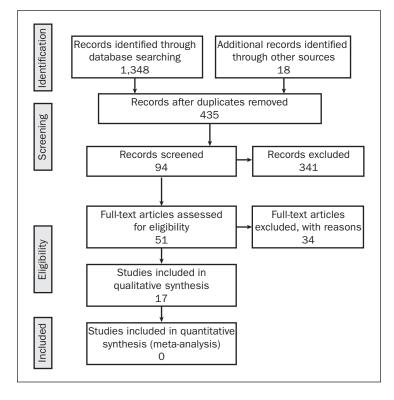
Table 1 Syst	tematic	Search Strategy
Focus question:	implants	CAD/CAM implant prostheses in patients with missing teeth who have one or more dental perform comparable to conventionally fabricated implant prostheses when assessing esthetics, ations (biologic and mechanical), patient satisfaction, and economic factors.
Search strategy		
Population		#1 (partially dentulous) OR (partially edentulous) OR (edentulous)
Intervention or e	exposure	<ul> <li>#2 (Computer-Aided Design [MeSH]) AND (Dental Prosthesis, Implant-Supported) [MeSH]</li> <li>#3 (Computer-Aided Design [MeSH]) AND (Dental Implant-Abutment Design [MeSH])</li> <li>#4 (Computer-Aided Design [MeSH]) AND (Dental Implants [MeSH]) AND crown</li> <li>#5 (Computer-Aided Design [MeSH]) AND (Dental Implants [MeSH]) AND denture</li> <li>#6 (Computer-Aided Design [MeSH]) AND (Dental Implants [MeSH]) AND prosthesis</li> <li>#7 (Computer-Aided Design [MeSH]) AND (Dental Implants [MeSH]) AND prostnesis</li> <li>#7 (Computer-Aided Design [MeSH]) AND (Dental Implants [MeSH]) AND reconstruction</li> <li>#8 (Computer-Aided Design [MeSH]) AND (Dental Implants [MeSH]) AND restoration</li> <li>#9 (Computer-Aided Design [MeSH]) AND (Dental Implants [MeSH]) AND superstructure</li> <li>#10 CAD CAM (keywords and select subject Heading) + Dental Prosthesis, implant supported (keywords and select subject Heading) + Dental Abutment</li> <li>(keywords and select subject Heading)</li> <li>#11 CAD CAM (keywords and select subject Heading) + Dental Abutment</li> <li>(keywords and select subject Heading)</li> <li>#12 CAD CAM + dental implant + crown</li> <li>#13 CAD CAM + dental implant + dentures</li> <li>#14 CAD CAM + dental implant + dentures</li> </ul>
Comparison		#15 ((conventional techniques) OR (cast techniques) OR (stock abutments) OR (prefabricated abutment
Outcome		#16 ((complications) OR (precision) OR (patient satisfaction) OR (esthetics))
Search combina	ation	#1 AND #2 (or #3, #4, #5, #6, #7, #8, #9) AND #15 AND #16 #10 (or #11, #12, #13, #14) AND #15 AND #16
Database search		
Electronic		PubMed, Ovid
Journals		Peer reviewed journal
Selection criteria	1	
Inclusion criteria		All levels of the hierarchy of evidence except for expert opinion and case reports Studies with 10 case series or more Clinical observational or experimental studies reporting a minimum of 12 mo follow-up Studies with CAD/CAM techniques designed for implant use or/as directed by implant manufacturer
Exclusion criteri	a	Case reports and case series Clinical experimental studies with less than 1 y follow-up Laboratory studies Non-prosthetic publications Papers with no abstract available Finite element analyses Studies with non-endosseous root form implants Not dentally related articles and review or commentary articles

terms: "Computer-Aided Design" [MeSH] AND "Dental Prosthesis, Implant-Supported" [MeSH] (201 results) and "Computer-Aided Design" [MeSH] AND "Dental Implant-Abutment Design" [MeSH] (10 results).

The search was expanded using MeSH terms including keyword (prosthesis, crown, denture, reconstruction, restoration, and superstructure): "Computer-Aided Design" [MeSH] AND "Dental Implants" [MeSH] AND "crown" (25 results); "Computer-Aided Design" [MeSH] AND "Dental Implants" [MeSH] AND "denture" (86 results); "Computer-Aided Design" [MeSH] AND "Dental Implants" [MeSH] AND "prosthesis" (220 results); "Computer-Aided Design" [MeSH] AND "Dental Implants" [MeSH] AND "reconstruction" (18 results); "Computer-Aided Design" [MeSH] AND "Dental Implants" [MeSH] AND "restoration" (74 results); "Computer-Aided Design" [MeSH] AND "Dental Implants" [MeSH] AND "superstructure" (6 results).

All results were filtered for human studies and English language, yielding a total of 642 articles.

In addition, an Ovid search was carried out for the headings: "CAD CAM (key words and select subject heading) + Dental Prosthesis, implant supported (key words and select subject heading)" (207 results) and Fig 1 Literature search and selection of articles.



"CAD CAM (key words and select subject heading) + Dental Abutment (key words and select subject heading)" (236 results). The search was further expanded using the key words: "CAD CAM + dental implant + crown" (66 results); "CAD CAM + dental implant + dentures" (96 results); "CAD CAM + dental implant + dental restoration" (101 results).

A total of 706 articles were identified. Relevant journals were hand-searched to identify additional articles. The bibliographies of selected papers and published review articles on the topic were also scanned for relevant publications. All searches resulted in a total of 1,348 articles, which were collected in the reference manager software Endnote X4 (Thomson Reuters). All duplicates were electronically discarded and 435 articles were considered for review.

# **Selection and Exclusion Criteria**

All levels of evidence, except for expert opinion, were considered to provide a comprehensive search of the literature. The articles excluded from full-text analysis were:

- Individual case reports
- Case series with less than 10 cases
- Clinical experimental studies with less than 1 year follow-up
- Laboratory studies
- Non-prosthetic publications

- Papers with no abstract available
- Finite element analyses
- Studies on non-endosseous root-form implants
- Articles not related to dentistry
- Review or commentary articles

In addition, the CAD/CAM technology discussed in the article must have been designed for implant use and carried out in accordance to the implant manufacturer's recommendations. The authors screened all 435 articles independently. They then met to review any disagreement on articles inclusion, which was resolved through discussion. After screening, 51 articles were identified as appropriate for full-text review. However, 7 of these were systematic review articles. A total of 17 articles were then selected for data extraction (Fig 1).

#### **Quality Assessment**

A quality assessment of each included publication was undertaken. For randomized control trials and controlled clinical trials, the Cochrane Collaboration's tool for assessing risk of bias was utilized.<sup>3</sup> Nonrandomized controlled studies were assessed for quality using the Newcastle-Ottawa Scale.<sup>4</sup>

# **Assessment Scale for Observational Studies**

Results and conclusions from the included studies and the relevant data were extracted and tabulated. The results were then presented and conclusions drawn.

Table 2         Selected CAD/CAM Crown Articles									
Study	Year published	No. of patients	No. of crowns	Retention method	Material	Cumulative survival rate	Implant type		
Hosseini et al <sup>5</sup>	2011	36	75	All cement-retained	Ti and Zr abutments; Procera Zirconica core crowns (CAD/CAM)	100%	Astra Tech		
Henriksson and Jemt <sup>6</sup>	2003	20	24	13 cement-retained, 11 screw-retained	Procera Alumina Oxide	100%	Nobel Biocare		

# Table 3 Selected CAD/CAM Abutment Articles

Study	Year published	Patients	Abutments	Material	CAD/CAM system	Cumulative survival rate
Zarone et al <sup>11</sup>	2005	44*	58	Aluminum Oxide <sup>†</sup>	Procera, Nobel Biocare	98.3% (one patient lost to follow-up)
Zembic et al <sup>8</sup>	2009	22	40	20 Zr 20 Ti	Procera, Nobel Biocare	100%
Canullo <sup>10</sup>	2007	25	30	Zr bonded to $\mathrm{Ti}^{\dagger}$	ZirconZahn	100%
Furze et al <sup>12</sup>	2012	10	10	Zr	Straumann Cares	100%
Sailer et al <sup>7</sup>	2009	22	40	20 Zr, 20 Ti	Procera, Nobel Biocare	100%
Zembic et al <sup>9</sup>	2012	22	40	20 Zr, 20 Ti	Procera, Nobel Biocare	88.9% Zr 90% Ti

\*Report included some crowns on natural teeth, but disclosed abutment numbers.

 $^{\dagger}\text{CAD}$  design reported, scanned wax body used.

NR = not reported.

# Table 4 Study and Patient Characteristics of the Reviewed CAD/CAM Crown and CAD/CAM Abutment Studies Abutment Studies

Abaciment	otudios						
Study	Year of publication	Journal	Study design	CAD/CAM system	Restoration type	Patients	
Crowns							
Hosseini et al <sup>5</sup>	2011	EJOI	RCT	Procera	Single crown	36	
Henriksson and Jemt <sup>6</sup>	2003	IJP	Prospective clinical report	Procera	Single crown	20	
Abutments							
Zarone et al <sup>11</sup>	2005	CIDRR	Retrospective review	Procera	Single crown	86	
Zembic et al <sup>8</sup>	2009	COIR	RCT	Procera	Single crown	22	
Canullo <sup>10</sup>	2007	IJP	Prospective	ZirconZahn	Single crown	25	
Furze et al <sup>12</sup>	2012	QUINT	Consecutive case series	Straumann Cares	Single crown	10	
Sailer et al <sup>7</sup>	2009	COIR	RCT	Procera	Single crown	22	
Zembic et al <sup>9</sup>	2012	COIR	RCT	Procera	Single crown	22	

NR = not reported; FDPs = fixed dental prostheses; RCT = randomized-controlled clinical trial; IJP = The International Journal of Prosthodontics; EJOI = European Journal Oral Implantology; CIDRR = Clinical Implant Dentistry & Related Research; COIR = Clinical Oral Implants Research; QUINT = Quintessence International.

#### **Peer Review**

# Prior to the consensus conference, each manuscript in the working group was submitted to the *International Journal of Oral and Maxillofacial Implants* for peer review. Corrections, amendments, and revisions were then completed. Once accepted for publication by the editor of the journal, the review papers provided the basis for the formulation of consensus statements and treatment recommendations within each working group.

# RESULTS

The studies included that reported on crowns are presented in Table 2. The studies included that reported on abutments are presented in Table 3. The patient characteristics of the reviewed studies are presented in Table 4.

Follow-up (mo)	CAD/CAM system	Patients dropped out
Mean 13.5 (11–22)	Procera (Nobel Biocare)	0/30
12	Procera (Nobel Biocare)	1

Implant type	Mean follow-up (mo)	Patients dropped out
Straumann, Brånemark	48	NR
Brånemark RP	36	4
TSA Implantdent	40	NR
Straumann Bone Level	12	0
Brånemark RP	12.6	2
Brånemark RP	67.2	4

Age range (y)	Mean age (y)	Setting	Patients dropped out
19-57	28.1	University	0
18-62	29	Private practice	1
18-62	NR	University	NR
NR	41.3	NR	2
25-70	52.3	Private Practice	NR
26-61	45.1	Private practice	0
NR	41.3	NR	2
NR	41.3	NR	4

#### **CAD/CAM Crowns**

Only two studies were identified: one randomized controlled trial (RCT)<sup>5</sup> and a prospective clinical report.<sup>6</sup> Fifty patients were treated with a total of 99 implants supporting single crowns in patients with an age ranging from 19 to 60.1 years of age. The mean age of the patient population was 28 years of age for the study by Hosseini et al<sup>5</sup> and 45.1 years of age for the study by Henriksson and Jemt.<sup>6</sup> The mean survival rate of the crowns was 98.85%. The implant survival rate was unaffected by the crown fabrication technique. The failure rates and survival of implants supporting CAD/CAM crowns are summarized in Table 5. The failure rates, survival rates, and complications rates for CAD/CAM crowns<sup>7-12</sup> are presented in Tables 6 and 7.

Hosseini et al<sup>5</sup> evaluated the biologic, technical, and esthetic outcomes of implant-supported single crowns (ISSC) treating single tooth agenesis in the premolar region. Thirty-eight zirconia abutments and crowns (test group) were compared to 37 metal abutments and metal ceramic crowns (control group). In the test group, 38 zirconia abutments (ZrDesign, Astra Tech) supported all-ceramic crowns fabricated using CAD/CAM milled zirconia copings and layered with HeraCeram zirconia veneering porcelain. KaVo zirconia copings (Ivoclar Vivadent) were used in 27 of 38 cases, and Procera zirconia copings (Nobel Biocare) were used in 11 of 38 cases. In the control group, 37 metal abutments were used to support metal ceramic crowns. In 35 of these cases, TiDesign (Astra Tech) titanium abutments were used and 2 cases used a gold alloy Cast-to abutment (Astra Tech) modified using conventional fabrication techniques. No implant failures were recorded and no difference in mean marginal bone loss was seen between the test and control groups. Two technical complications (2 of 37) were reported, both from the control group. No technical complications were reported for the test group. The esthetic outcomes were evaluated using both patient-reported VAS scores and professionally reported esthetic outcomes employing the Copenhagen Index Score (CIS). No significant difference in esthetic parameters was reported when comparing the test and control group for patient-reported outcomes. However, the professionally reported color match was significantly better for the all-ceramic crowns (P = .031). No difference was seen in mucosal discoloration between the all-ceramic crown group and the metal-ceramic crown group. Mucosal inflammation was reported in 7 of 10 (16.3%) of all-ceramic crowns, and 3 of 10 (7%) of metal-ceramic crowns.

Henriksson and Jemt<sup>6</sup> evaluated the clinical performance of customized ceramic single-implant Procera abutments in combination with two different crown types. This prospective clinical study evaluated 20 patients consecutively treated for single-unit implant restorations in the maxillary anterior region. Customized Procera alumina oxide abutments were fabricated for the 24 implants. In 13 cases, the crowns were fabricated using Procera techniques and cemented onto the abutment using zinc phosphate cement. In 11 cases, porcelain was fused directly onto the abutment to provide a direct screw-retained restoration with a screw access hole on the palatal surface.

Study	Year of publication	Restoration type	Loading	Implants	Mean follow-up time (mo)	
Crowns						
Hosseini et al <sup>5</sup>	2011	Single crown	Delayed	75	13.5	
Henriksson and Jemt <sup>6</sup>	2003	Single crown	Delayed	24	12	
Abutments						
Zarone et al <sup>11</sup>	2005	Single crown	Delayed	58	48	
Zembic et al <sup>8</sup>	2009	Single crown	Delayed	40	36	
Canullo <sup>10</sup>	2007	Single crown	Delayed	30	40	
Furze et al <sup>12</sup>	2012	Single crown	Delayed	10	12	
Sailer et al <sup>7</sup>	2009	Single crown	Delayed	40	12.6	
Zembic et al <sup>9</sup>	2012	Single crown	Delayed	40	67.2	

ZR = zirconia group; Ti = titanium group.

Table 6 Failure Rat	Table 6         Failure Rates and Survival of CAD/CAM Crowns and Abutments							
Study	Year of publication	Restoration type	Loading	Total restorations	Restorations lost to follow-up			
Crowns								
Hosseini et al <sup>5</sup>	2011	Single crown	Delayed	75 AC = 38 MC = 37	0			
Henriksson and Jemt <sup>6</sup>	2003	Single crown	Delayed	24	1			
Abutments								
Zarone et al <sup>11</sup>	2005	Single crown	Delayed	58	1			
Zembic et al <sup>8</sup>	2009	Single crown	Delayed	40 AC = 20 MC = 20	11 AC = 1 MC = 10			
Canullo <sup>10</sup>	2007	Single crown	Delayed	30	NR			
Furze et al <sup>12</sup>	2012	Single crown	Delayed	10	0			
Sailer et al <sup>7</sup>	2009	Single crown	Delayed	40 AC = 20 MC = 20	9 AC = 1 MC = 8			
Zembic et al <sup>9</sup>	2012	Single crown	Delayed	40 AC = 20 MC = 20	11 AC = 1 MC = 10			

AC = all-ceramic group, MC = metal-ceramic group, NR = not reported.

\*Implant but not restoration failure

Nineteen patients were examined at the 1-year recall, with all implants stable. One ceramic abutment fractured in the laboratory and was remade before clinical placement. All crowns in both groups were stable during the 12-month period. One patient in the cement crown group experienced a buccal fistula (1 of 13) and a further two cement-retained crowns (2 of 13) experienced buccal recession for an estimated annual biologic complication rate of 12.5%.

No studies reported any data regarding CAD/CAM implant prostheses or conventional prostheses in terms of cost effectiveness.

#### **CAD/CAM** Abutments

The six studies that met inclusion criteria for data extraction on CAD/CAM dental implant abutments are shown in Table 3. These comprise three RCTs, which describe the same patient cohort at 12, 36, and 67 months<sup>7–9</sup>; one prospective clinical report<sup>10</sup>; one retrospective case report<sup>11</sup>; and one case series.<sup>12</sup> A further case report by Vafiadis<sup>13</sup> had to be excluded due to lack of detail regarding patient recruitment and treatment details. A total of 101 patients were treated with a total of 138 CAD/CAM implant abutments to support single-crown restorations. The patients' ages

Implant failures	Estimated annual failure rate	Cumulative survival rate
0	0%	100%
0	0%	100%
0	0%	100%
0	0%	100%
0	0%	100%
0	0%	100%
0	0%	100%
3	1.30%	88.9% Zr 90% Ti

Mean follow- up time (mo)		Total restoration exposures	Estimated annual failure rate
13.5	1, MC group, remade	75	MC: 2.6% AC: 0%
12	0	23	0%
48	1	57	0.80%
36	0	29	0%
40	0	30	0%
12	0	10	0%
12	0	31	0%
67.2	3*	28*	0%

ranged from 18 to 70 years with the mean ages of each study group ranging from 41.3 to 52.3 years. Three different CAD/CAM systems were used to fabricate the abutments for the included studies; Procera technique (Nobel Biocare) was used in 4 studies,<sup>7–9,11</sup> Straumann Cares for one study,<sup>12</sup> and Zirconzahn for one study.<sup>10</sup> No abutment complications, including screw loosening or fracture, were reported for any of the publications reviewed. The CAD/CAM abutment survival rate is 100%. The survival rate of the crowns supported by CAD/CAM abutments is 99.8%. The failure rates and survival of implants supporting CAD/CAM abutments are summarized in Table 5. Tables 6 and 7 detail the failure rates, complication rates, and survival rates for CAD/CAM fabricated implant abutments. While no technical complications were reported for the CAD/CAM abutments, most studies reported a low incidence of veneering porcelain chipping (0% to 3% estimated annual chipping rate) from the crown on the abutment.

The papers by Sailer et al and Zembic et al<sup>7-9</sup> evaluated the survival and complication rate of customized zirconia and titanium abutments in a randomized controlled clinical trial. Twenty-two consecutively recruited patients were included in this study that evaluated 40 fixed implant-supported crowns replacing missing canines, premolars, and molars. Patients were randomly assigned to a test or control group. The test group consisted of 20 customized Procera zirconia abutments to support all-ceramic crowns. The control group of 20 single-tooth implant replacements received customized Procera titanium abutments for the support of metal-ceramic crowns. All patients received a regular platform (RP) Nobel Biocare implant installed according to standard surgical protocol. The all-ceramic crowns were fabricated from glass ceramic or two high-strength ceramics, alumina or zirconia. Metal-ceramic crowns were fabricated for the titanium abutments. Clinical examinations were made at baseline, 6, 12, and 36 months with four patients lost to follow-up at the 36-month review. Implants in the test group replaced crowns in 2 canines, 11 premolars, and 5 molars. All implants showed a 100% survival rate for both implant groups. No technical complications were seen in either group for the abutments with the survival rate being 100% for both groups.

Zembic et al<sup>9</sup> reported that between the 3- and 5-year reviews, two patients lost three implants due to loss of integration. These were supporting 2 of 20 zirconia abutments and 1 of 20 titanium abutments. In spite of these three implant failures, biologic complications associated with CAD/CAM abutments were rare. Plague and bleeding scores were low, and bone levels were reported as stable at follow-up. At 12 months' review, Sailer et al<sup>7</sup> reported that the mean bleeding on probing (BOP) was more often observed around the implant crowns than teeth and zirconia abutments had a higher mean BOP than titanium (60% vs 30%). However, at the 3-year review these changes were no longer reported<sup>8</sup> and this remained the same at the 5-year review.<sup>9</sup> Only one case was reported showing facial tissue recession at the CAD/CAM zirconia abutment.<sup>12</sup>

Canullo<sup>10</sup> studied the efficacy of a zirconia abutment cemented to an antirotational titanium component attached to the implant in a prospective clinical report. Twenty-five patients requiring 30 singleimplant-supported crowns were selected for the

Year of Type of Total Mean follow- Estimated annual rate Estimated annual r						
Study	publication	restoration	restorations	up time (mo)	of screw loosening	of abutment fracture
Crowns						
Hosseini et al <sup>5</sup>	2011	Single crown	75 AC = 38 MC = 37	13.5	0	0
Henriksson and Jemt <sup>6</sup>	2003	Single crown	24	12	0	0
Abutments						
Zarone et al <sup>11</sup>	2005	Single crown	58	48	0	0
Zembic et al <sup>8</sup>	2009	Single crown	40 AC = 20 MC = 20	36	0	0
Canullo <sup>10</sup>	2007	Single crown	30	40	0	0
Furze et al <sup>12</sup>	2012	Single crown	10	12	0	0
Sailer et al <sup>7</sup>	2009	Single crown	40 AC = 20 MC = 20	12	0	0
Zembic et al <sup>9</sup>	2012	Single crown	40 AC = 20 MC = 20	67.2	0	0

MC = metal-ceramic crown group; AC = all-ceramic crown group; BOP = bleeding on probing.

study. The abutments were designed such that for one group, zirconia contacted the implant shoulder and in the other group, the titanium structure contacted the implant shoulder. No abutment screws fractured and no screw loosening occurred. The survival rate was 100%. One crown demonstrated marginal porcelain chipping at the 1-year follow-up. Periodontal and gingival indices showed healthy tissue at both natural tooth and implant sites.

In a retrospective evaluation of 86 patients treated with CAD/CAM fabricated restorations, Zarone et al<sup>11</sup> evaluated the performance of Procera all-ceramic maxillary anterior restorations over a period of 48 months. The crowns were fabricated on both natural teeth (28/86) and implant-supported abutments (58/86). Both non-submerged (Institut Straumann, Waldenberg) and submerged (Nobel Biocare) implants were restored. Alumina oxide Procera abutments where fabricated for the submerged implants and titanium abutments for the non-submerged ones. The implants were restored with crowns fabricated using Procera aluminum oxide copings, which were machined and finished with layering porcelain by the dental technician in the laboratory. All restorations were cement retained using a hybrid glass ionomer cement (RelyX, 3M ESPE). One implant-supported restoration failed during the follow-up, but it is not stated which implant type and how the implant failed. One implant crown

exhibited porcelain fracture at the incisal edge of the veneering porcelain. Although marginal adaption was reported to be very good, the other indices evaluated (Plaque, Gingival, BOP, and patient satisfaction) while showing generally very high scores, were not distinguished between implant and natural teeth. No abutment complications were reported.

Furze et al<sup>12</sup> evaluated the clinical and esthetic outcomes of 10 consecutive single-tooth implant restorations in the anterior maxilla. Ten Straumann SLActive bone-level implants were used to replace six central incisors, one lateral incisor, two canines, and one premolar. Implants were restored with provisional prostheses customized to the mucosa before restoration with CAD/CAM zirconia abutments (Straumann Cares) and zirconium-based all-ceramic crowns (Straumann Cares). Pink and white esthetic scores (PES and WES) were made after 12 months of loading. The only reported complication was fracture of the provisional restoration. The mean PES score was 7.9 and mean WES was 7.

No studies reported any data regarding CAD/CAM implant prostheses or conventional prostheses in terms of cost effectiveness.

#### **CAD/CAM** Frameworks

Nine studies were included under the search of clinical trials of CAD/CAM frameworks. These comprised one RCT,<sup>14</sup> six prospective,<sup>15–20</sup> and two retrospective

Total veneer chipping/fracture	Estimated annual rate of veneer chipping/fracture	Total loss retention	Estimated annual loss retention	Biologic complications	Estimated annual rate of biologic complication
1 chip, MC group	2.4% MC 0% AC	1, MC group	2.4% MC 0% AC	7/10 inflamma- tion, AC group; 3/10, MC group	11.80% 16.3% AC 7% MC
0	0%	0	0%	1 fistula, 2 buc- cal recession	12.50%
1 chip, 1 fracture	0.80%	0	0%	0	0%
2 chip, MC group	3% MC 0% AC	0	0%	0, but greater mean BOP at implants	0%
1 chip	1%	0	0%	0	0%
0	0%	0	0%	1, facial reces- sion	10%
2 chip, MC group	3% MC 0% AC	0	0%	0 (BOP similar for teeth and implants)	0%
2 chip, MC group	3% MC 0% AC	0	0%	0, but greater mean BOP at implants and 3 implant failures	1.30%

clinical reports<sup>21,22</sup> published between 2005 and 2012. The study and patient characteristics are summarized in Table 8.

The implant-supported prostheses were fabricated using CAD/CAM technology to mill the framework from either titanium or zirconia. Three different manufacturing companies were involved in the production of the frames: Decim (Denzir), Nobel Biocare (Procera), and Es-Healthcare.

Eight clinical investigations used CAD/CAM technology to restore completely edentulous patients with full-arch fixed partial dentures (FDPs). In six studies, both the maxilla and the mandible received a full-arch rehabilitation.<sup>15,17,18,20-22</sup> The Engquist et al<sup>16</sup> study restored only mandibular arches and the Katsoulis et al<sup>19</sup> restored only maxillary arches. Only one study reported the application of CAD/CAM framework technology in partially edentulous patients.<sup>14</sup> In this study, FDPs were used to restore both maxillary and mandibular edentulous spaces.

The loading time of the prostheses varied significantly in all these investigations. Three studies described immediate loading protocols of CAD/CAM frameworks.<sup>17,18,20</sup> Four reported on conventional loading<sup>14,15,19,21</sup> and one reported on both immediate and conventional loading.<sup>22</sup> Finally, Engquist et al<sup>16</sup> applied immediate, early, and conventional loading protocols. The definitions of the terms relating to timing of restoration used were: immediate loading (less than 1 week), early loading (at 24 days), and conventional loading (12 weeks or later), and they are all based on the 2007 Cochrane Review.<sup>23</sup>

Larsson et al<sup>14</sup> performed a randomized prospective clinical trial during which two different ceramic systems, Denzir (DZ) and In-Ceram Zirconia (InZ), were compared in partially edentulous patients. Eighteen patients were treated with a total of 25 implant-supported reconstructions ranging in size from two to five units. They were reviewed after 60 months (5 years). In the CAD/CAM arm of the study, nine patients received 13 FDPs with frameworks made out of yttria-stabilized tetragonal zirconia polycrystal material (DZ). Seven of the nine patients (69%) in the DZ group showed chipoff fractures, whereas two out of nine patients (17%) in the InZ group showed such fractures. More specifically, 16 units (52%) in the DZ group and 3 units (9%) in the InZ group were affected. Three of the 16 fractures (19%) in the DZ group were judged to be adhesive between the framework and veneering porcelain. None of the fractures in the InZ group were adhesive, all being cohesive in nature within the layering porcelain. Although the CAD/CAM frameworks did not present any complications, the DZ system exhibited an unacceptable amount of veneering porcelain fractures. Since these complications were superficial, the study reported 100% survival rate for the restorations of both

Table 8 Study	and Patie	nt Cha	racteristics of the l	Reviewed CAD/CAM	Framework S	Studies
Study	Year of publication	Journal	Study design	CAD/CAM system	Restoration type	Arch loaded
Larsson et al <sup>14</sup>	2010	IJP	RCT	Denzir, Decim	partial FDPs (2-5 units)	Mandible and maxilla
Engquist et al <sup>16</sup>	2005	CIDRR	Prospective cohort	Procera, Nobel Biocare	Full-arch FDPs	Mandible
Komiyama et al <sup>18</sup>	2008	COIR	Prospective	Procera, Nobel Biocare	Full-arch FDPs	Mandible and maxilla
Ortorp and Jemt <sup>15</sup>	2012	CIDRR	Prospective control	Procera, Nobel Biocare	Full-arch FDPs	Mandible and maxilla
Sanna et al <sup>17</sup>	2007	JPD	Prospective cohort	Procera, Nobel Biocare	Full-arch FDPs	Mandible and maxilla
Tahmaseb et al <sup>20</sup>	2012	IJOMI	Prospective	Es-Healthcare	Full-arch FDPs	Mandible and maxilla
Katsoulis et al <sup>19</sup>	2011	IJOMI	Prospective controlled cohort	Procera, Nobel Biocare	Full-arch FDPs	Maxilla
Papaspyridakos and Lal <sup>22</sup>	2013	COIR	Retrospective	Procera, Nobel Biocare	Full-arch FDPs	Mandible and maxilla
Malo et al (1) <sup>21</sup>	2012	JP	Retrospective	Procera, Nobel Biocare	Full-arch FDPs	Mandible and maxilla
Malo et al (2) <sup>21</sup>	2012	JP	Retrospective	Procera, Nobel Biocare	Full-arch FDPs	Mandible and maxilla

NR = not reported: FDPs = fixed dental prostheses: RTC = randomized-controlled clinical trial: IJP = The International Journal of Prosthodontics: CIDRR = Clinical Implant Dentistry and Related Research; COIR = Clinical Oral Implant Research; JDP = The Journal of Prosthetic Dentistry;

IJOMI = The International Journal of Oral & Maxillofacial Implants; JP = Journal of Prosthodontics.

groups after 5 years. The differences in the success rates from baseline to the 5-year follow-up were statistically significant for the two groups at both the FDP level (31% DZ vs 83% InZ) (P < .05) and the unit level (48% DZ vs 91% InZ) (*P* < .001).

Ortorp et al,<sup>15</sup> in their prospective control study, evaluated and compared the clinical and radiographic performance of implant-supported prostheses during 10 years of function. Patients were randomly assigned to the test or control group. The test frameworks (n = 67) were constructed using a computer numericcontrolled (CNC) titanium technique (All-in-One Procera, Nobel Biocare) while the control group frameworks (n = 62) were cast from gold alloy. Acrylic resin teeth were processed to each metal framework. This university-based study (The Brånemark Clinic, Gotenberg, Sweden) originally included 126 edentulous patients. After 10 years, there were 52 patients lost to follow-up, of which 29 belonged to the test group (36 remaining patients). At the implant level the overall 10-year implant cumulative survival rate (CSR) was 95.0% and 97.9% for the test and control groups, respectively. The titanium framework group had five framework incidents out of which three were recorded as "survival and modified" since the modification shortened the prosthesis span. In the remaining two cases, the first prosthesis was lost due to failure of the supporting six implants after 2 years of function, and the second one fractured after 9 years in function. As a result the 10-year prosthesis CSR was 89.0% for the test group and

94.4% for the control group (P > .05). In addition, there were three incidents of prosthesis loosening in the test group. These were all from the same case. Thirty-five incidents of acrylic chipping in 19 cases were reported from the test group. Eight of these incidents from seven cases were uncomplicated while the remaining 27 incidents from 12 cases required removal and management in the dental laboratory. There were no significant differences in bone loss around the implants between the two groups. The mean marginal bone loss after 10 years was 0.7 mm (SD = 0.77) and 0.6 mm (SD = 0.57) in the test and control groups, respectively (P > .05).

In the Engquist et al<sup>16</sup> prospective cohort study, the results of early loading in the edentulous mandible were evaluated and compared with delayed loading, for both one- and two-stage implant surgery protocols. One hundred and eight patients each received four Brånemark (Nobel Biocare) implants. A total of 432 implants were placed to support 108 prostheses that were followed for up to 36 months. The superstructure used for all patients was a titanium frame (Procera Allin-One, Nobel Biocare) combined with acrylic teeth. The frameworks were milled from a titanium block in a computer-steered three-dimensional milling machine. Due to the vertical placement of the four implants, the bridges were constructed with cantilevers having two teeth on each side. Nine patients were lost to followup and of the 418 remaining implants, 24 failed due to loss of integration. As a result 98 cases were surviving at the 3-year period. Prosthetic outcomes were not

Loading type	Patients	Age range (y)	Mean age (y)	Setting	Drop out (% of patients/ cases lost to follow-up)
Delayed	9	37–70	NR	Malmö University Hospital, Sweden	0%
Delayed + early + Immediate	108	25–75	64.9	University Hospital, Linkoping, Sweden & Vrinnevi Hospital, Norrkoping, Sweden	9.25% (10 patients/cases)
Immediate	26 (excluding 5 carbon frames)	42–90	71.5	University Karolinska Institutet, Huddinge Sweden	NR
Delayed	65	49–85	66.8	Brånemark Clinic, Göteborg, Sweden	44.6% (29 patients/cases)
Immediate	30	38–74	56	University Hospital Leuven, Belgium	13.3% (4 patients/cases)
Immediate	35	NR	NR	University of Amsterdam School of Dentistry, ACTA, Amsterdam, The Netherlands	0%
Delayed	13	52-78	63.3	University of Bern, Switzerland	0%
13 delayed and 3 immediate	14	35-71	58	Columbia University, New York, USA	0%
Delayed	52	38-81	59.5	Private Center: Malo Clinic Lisbon, Portugal	11% (12 patients/cases)
	56	34-82	57.6	Private Center: Malo Clinic Lisbon, Portugal	

reported, and the study concentrated on implant survival and marginal bone loss. The survival rate of the early-loaded implants did not significantly differ from that of implants inserted with the conventional two-stage procedure. Survival rates of the implants showed a tendency toward better results with the two-stage technique, but the differences were not significant. The mean marginal bone loss from fixture insertion to the 3-year examination was significantly lower with early loading than with the conventional two-stage technique (range 1.24 to 1.68 mm). Finally, the survival rates and marginal bone changes of the one-piece implants did not differ from those of the two-piece implants.

Komiyama et al<sup>18</sup> reported on the treatment of 29 edentulous patients, 9 women and 20 men, using the Nobel Guide immediate loading Teeth-in-an-Hour protocol. In this prospective clinical investigation, 176 Brånemark MKIII TiUnite (Nobel Biocare) implants were placed in 31 edentulous jaws. Twenty-six edentulous jaws were restored with prostheses fabricated from machined titanium frameworks supporting acrylic resin teeth and 5 edentulous jaws used carbon fiber reinforced resin prostheses. All cases were followed up to 1 year and thereafter annually for up to 44 months. Upon delivery the authors experienced abutment/prosthesis misfit in five cases, and there was extensive occlusal adjustment in three cases. This resulted in prosthesis disconnection in two cases for retreatment. At the implant level, 157 of 176 implants (89%) survived over 44 months (92% in maxilla and 84% in mandible). Nineteen implants (11%) were removed within 18 months of implant installation, with 10 of 124 from the maxilla and 9/52 from the mandible. At the prosthesis level, 26 of 31 prostheses were surviving at 44 months (84%); 19 of 21 in the maxilla (90%) and 7 of 10 in mandible (70%). Superstructure failure occurred in five patients (17%); two due to fixture loss, two due to prosthesis misfit, and one due to a combination of both complications. These superstructures were removed within the first 6 months.

In a prospective cohort study Sanna et al<sup>17</sup> evaluated 30 consecutive patients, who were treated with a full-arch implant-retained reconstruction, in either the maxillary or mandibular arch. Two hundred and twelve TiUnite Brånemark implants (Nobel Biocare) were placed (Department of Periodontology at the University Hospital in Leuven) and 30 edentulous arches were restored following an immediate loading protocol. All patients received a prefabricated CAD/CAM framework veneered with acrylic resin teeth. Four patients were lost to follow-up (29 implants) although they were contacted to confirm that their prostheses remained in function. Twenty-six patients with 183 implants were followed for a mean time of 2.2 years. Overall 9 out of 183 implants were lost (4.9%), 8 of which were from a smoking group. The CSR after 5 years was 91.5%. Digital panoramic radiographs were taken at annual recalls and were used to evaluate bone loss. The mean bone loss was 2.6 mm  $(\pm 1.6 \text{ mm})$  for the smoker group and 1.2 mm  $(\pm 0.8 \text{ mm})$ for the nonsmoker group. There was no report for any prosthetic complications or prosthetic survival rates.

Tahmaseb et al<sup>20</sup> evaluated the immediate loading of 40 full-arch cases in both the mandibular and maxillary jaw in a prospective study. The definitive fixed full-arch restorations were fabricated prior to surgery using CAD/CAM technology. A total of 35 patients, including 20 edentulous maxillae, 10 edentulous mandibles, and 5 patients with edentulism in both arches were treated with 240 Straumann Standard Tissue level implants (Straumann). A total of 40 superstructures were made out of a prefabricated CAD/CAM framework (Es-Healthcare), which was veneered with resin and connected directly to the implants without using Straumann abutments. All patients were followed for at least 1 year with a range of 12 to 36 months. All metal frameworks (n = 40) showed a clinically passive fit at the time of surgery and no adjustments were needed. Thirty-nine finished superstructures (97.5%) showed satisfactory occlusion and only one case required significant occlusal adjustment. Of the 240 inserted implants, 229 (95.4%) survived after 12 months, with 146 (93.6%) and 83 (98.8%) implants in the maxillary and mandibular arches, respectively. Four implants in one patient failed 6 months post-surgery and as a result the superstructure was lost as well (1 of 40 arches). No other additional prosthetic complications were reported at the 1-year follow-up period.

Katsoulis et al<sup>19</sup> in a prospective controlled cohort study compared the outcomes of three different treatment modalities in the maxilla: overdentures with conventional soldered gold bars (Dolder bars), overdentures with CAM-fabricated titanium bars, and fixed prostheses with CAM-fabricated titanium frameworks. Forty-one patients were treated in the study. Thirteen patients received between four to six implants to support a CAD/CAM implant-supported fixed prosthesis that was conventionally loaded. The titanium frameworks were fabricated using Procera and veneered with acrylic resin denture teeth (Candulor). The frameworks were screw-retained at the implant level and followed for 2 years. At the end of the follow-up period there were no fractures reported (100% survival rate) and there was no need for re-tightening of occlusal screws. There were 14 repair incidents reported (five acrylic resin denture base fractures, eight teeth fractures, one redesign of prosthesis). In addition, there were 11 prosthesis adaptation incidents (one sore spot, three prosthesis relinings, five occlusal corrections, one excessive tooth wear, and one discoloration of acrylic resin teeth). Furthermore, there were no implant failures reported for the fixed CAD/CAM group, yielding a 100% implant survival rate. Finally, the Oral Health Impact Profile (OHIP) was used to investigate the patients' oral health-related quality of life (QoL). The OHIP confirmed high satisfaction, but QoL appeared to be slightly higher with fixed CAD/CAM prostheses.

Malo et al,<sup>21</sup> in a retrospective study with mean follow-up of 5 years (range: 9 months to 10 years), compared milled titanium frameworks, restoring edentulous patients using a delayed loading protocol, with two different all-ceramic crown systems. In the first group (development group), a CAD/CAM fabricated Procera titanium frame had Duceram (Ducera Dental) veneering porcelain used to replicate the gingival tissue replacement. Multiple individual crowns were fabricated and luted to the framework. The crowns were made out of Alumina copings (Nobel Biocare), and Allceram porcelain (Ducera Dental). A total of 66 full arches (both maxilla and mandible) were restored and followed for a mean of 6.5 years (range: 9 to 127 months). In the second group (routine group), similar titanium Procera frameworks and a gingival replacement veneering material of PalaXpress Ultra (Heraeus Kulzer) was used to replicate the gingival tissues. Individual crowns were made out of zirconia copings (Nobel Biocare) and Nobel Rondo Zirconia Ceramic (Nobel Biocare) porcelain. Fifty-nine arches were restored (both maxilla and mandible) and followed for a mean of 3.8 years (range: 12 to 67 months). A total of 634 Nobel Speedy Brånemark (Nobel Biocare) implants were placed. The cumulative survival rates for the implant-supported fixed prostheses were 92.4% for the alumina crown group at 10 years and 100% at 5 years (overall 96%) for the zirconia crown group. The authors reported six lost frameworks (including one that was lost due to the implant failure) for the first group and none for the second. Veneer chipping occurred in 36 and 14 cases, respectively, for the development and routine groups.

Papaspyridakos and Lal<sup>22</sup> in their retrospective cohort study evaluated 14 patients who were restored with screw-retained implant-supported superstructures. Thirteen edentulous arches were treated with conventional loading protocols and three with an immediate loading protocol. Ten cases were in the mandibular jaw and six were in the maxillary jaw. The frameworks were zirconia frameworks made with Procera CAD/CAM. Veneering porcelain was applied to the framework. Out of the 16 edentulous arches, 14 received one-piece restoration and 2 received a segmented two-piece fixed restoration. The mean clinical follow-up period was 36 months (3 years). One hundred and three Tiunite implants were placed, distributed as 57 implants in the mandible and 46 implants in the maxilla. There were five to six implants placed to support mandibular prostheses and six to eight to support the maxillary prostheses. No screw loosening was observed throughout the follow-up period. The prostheses in 11 of 16 arches were structurally sound, whereas porcelain veneer chipping/fracture was observed in five prostheses (four patients), yielding a ceramic chipping rate of 31.25% at the prosthesis level. Great

patient satisfaction with function and esthetics was recorded for all patients both at baseline and recall.

Statistical analysis was thus based on nine studies, with one reporting on partial FDPs with CAD/CAMfabricated zirconia frameworks veneered with porcelain,<sup>14</sup> eight reporting on implant-supported full-arch FDPs with CAD/CAM-fabricated titanium frameworks (seven with acrylic teeth and one with porcelain veneering),<sup>15–21</sup> and one reporting on implant-supported full-arch FDPs with CAD/CAM-fabricated zirconia frameworks veneered with porcelain.<sup>22</sup>

No studies reported any data regarding CAD/CAM implant prostheses or conventional prostheses in terms of cost effectiveness.

# DISCUSSION

This literature search revealed a total of 17 studies which used CAD/CAM techniques to restore implants. The first observation that needs to be made is that in most investigations the primary goal of the authors was not the assessment of the actual CAD/CAM prosthesis. Instead, in several cases there was a focus on the surgical aspect of the treatment. As a result, acquiring the relevant prosthetic data was challenging and in some cases not possible since there was no prosthetic outcome reported.

In addition, the selected studies evaluated a variety of factors such as the fit of the prosthesis, bone loss, and numerous complications using different assessment techniques or parameters. For this reason, the comparison of the presented data would not be accurate or even feasible in certain occasions. Parameters that could be easily reported and compared were the survival rate of the implants that supported the prostheses and the survival rate of the actual prostheses. This data could be easily determined in most of the investigations. Any technical complications could be reported but not included in the analysis.

The purpose of this systematic review was to compare the clinical outcomes of restorations that were fabricated using CAD/CAM technology with the ones that were fabricated conventionally. Two recent systematic reviews<sup>24,25</sup> have assessed and reported the survival and complication rates of implant-supported restorations for both single crowns and FDPs, respectively, for a mean observation period of at least 5 years.

#### Crowns

The use of all-ceramic CAD/CAM restorations in the short term appears to provide acceptable clinical outcomes. The difference in materials used for ceramic core fabrication, choice of ceramic veneering porcelain and crown retention between the studies makes direct comparison between studies difficult. Hosseini et al<sup>5</sup> in their randomized controlled trial restored single missing teeth in the maxillary or mandibular premolar region. All implants survived and no mobility was recorded. No significant differences were seen between all-ceramic (AC) and metal-ceramic (MC) crowns for Plaque or Bleeding Indices. Mean marginal bone loss was not significantly different. Inflammatory reactions were seen at the 1-year examination for seven AC crowns and three MC crowns. The inflammatory reactions were believed to be due to poor marginal adaption with five of seven AC crowns showing poorer marginal adaption than the MC crowns (one of three). No abutment complications were seen and porcelain chipping was seen in one MC crown. Patient-reported VAS score did not report differences in outcomes from the AC versus MC crowns; however, professionally reported color matching was found to be significantly better in the AC crowns. No difference was seen between MC and AC crowns for crown morphology or papilla index, and the frequency of mucosal discoloration was unchanged for both types. None of the studies were able to employ a pure CAD/CAM technique (devoid of human intervention) for the crown fabrication. Currently, to achieve optimal esthetic outcomes, coloration, staining, or layering of a core is needed to appropriately match natural tooth color. The CAD/ CAM technique was used for the core fabrication, onto which layering porcelain was applied. Henriksson and Jemt<sup>6</sup> reported one abutment fracture in the laboratory during crown fabrication in their prospective clinical evaluation; however, all crowns in both groups were stable during the 12-month period. One patient in the cement crown group experienced a buccal fistula and a further two experienced buccal recession. The recession exposed the cement-abutment joint. While comparable outcomes were seen with both techniques, the issue of recession and increased bone loss on two implants in the cement-retained group possibly point toward a trend that the direct screw-retained group may yield better outcomes with less risk of tissuerelated complications.

The studies of Zarone et al<sup>11</sup> and Furze et al<sup>12</sup> also employed high strength ceramic cores, of different material, which appear to have been fabricated using CAD/ CAM processes. Unfortunately, the description of the process for crown fabrication was not detailed enough to be certain of the CAD/CAM process, and thus were excluded from the CAD/CAM crown section. These studies reported overall low complication rates and good esthetics. It was interesting that in the publication by Furze et al<sup>12</sup> the clinician wished to reject the color of one crown but the patient did not feel it necessary. This reduced the mean WES score by 0.2. Newer generation color- and translucency-graded ceramic blocks are becoming available for use in CAD/CAM milling machines, which may reduce the need for routine manual intervention in achieving optimal coloration of the anterior restoration.

# **Abutments**

Very few technical complications were reported with the CAD/CAM abutments from the studies reviewed. This indicates that in the short- to medium-term, CAD/CAM abutments demonstrate acceptable clinical performance with no reported incidence of screw loosening or abutment fracture of either ceramic or metallic materials. Zembic et al<sup>8</sup> reported many of the test group ceramic abutments (16 of 18 cases) were in posterior areas of the mouth subjected to high masticatory load with no technical complications reported. However, the rate of veneering porcelain fracture from the prostheses upon the abutments is still comparable to other reviews. The rate of porcelain chipping for the cohort did reduce dramatically from 16.7% in the metal-ceramic group in the first 12 months<sup>7</sup> to 0% at the 3-year review.<sup>8</sup> The majority of the crowns were cement-retained. A modest number of abutments, totaling 11 at the 3-year review and mostly titanium,<sup>10</sup> were lost to follow-up. The study by Zarone et al<sup>11</sup> had one crown chipping and one fracture, which was in the incisal edge region.

The study by Ekfeldt et al<sup>26</sup> evaluated the clinical outcome of custom-made zirconia abutments for implant-supported single-tooth restorations. Unfortunately, this study was excluded since during the first follow-up (1 year), the implant-supported restorations (185 single-tooth implant restorations placed in 130 patients) were evaluated retrospectively using only patient records. This action could involve a possible bias in the values presented since the evaluation did not include an actual clinical examination. During the second follow-up of this cohort (greater than 3 years), only 37% of the original 130 patients were invited for a clinical examination. Out of these patients, only 25 (40 restorations) could be examined, which means that 105 were lost to follow-up. The paper was thus considered to be highly biased and was therefore not included in the data analysis.

The latest generation CAD/CAM techniques are utilizing newer technologies, which allow the clinician or technician to fully customize the abutment contour to match carefully the clinical situation<sup>12</sup> after tissue customization with provisional restorations. Of further interest is the ability of the abutment material choice to influence the mucosal color and have a negative affect on the final esthetic outcome. Zembic et al<sup>8</sup> reported that both the zirconia and titanium abutments induced a visible color change in the mucosa when compared with natural teeth. No difference in

mean mucosal thickness was seen when comparing abutment type. The average thickness of the mucosa over the abutments  $(1.8 \pm 0.7 \text{ mm})$  was slightly higher than the gingival thickness overlying natural teeth  $(1.5 \pm 0.9 \text{ mm})$ . However, the tissue thickness was reduced over the zirconia abutments from 2.1 to 1.9 mm and the tissue thickness increased from 1.3 to 1.5 mm over teeth in the follow-up period from 12 to 36 months. This may be as a result of the technique used to measure the overlying tissue thickness. This is different than the data published by Bressan et al,<sup>27</sup> who reported less change with zirconia abutments. Unfortunately, the publication of Bressan et al<sup>27</sup> was excluded from the review as the abutments were only installed for a period of 10 minutes prior to color evaluation. The mucosal thickness overlying the abutments in the cases presented by Zembic et al<sup>8</sup> was less than that reported by Bressan et al<sup>27</sup> and this could explain the differences seen, as could the different measurement techniques. However, they did not seek to classify the tissue thickness and measurements were made using different techniques, which may also explain the difference in spectrophotometric evaluation. Only one publication reviewed the esthetic outcome using the objective PES/WES scale.<sup>12</sup> More widespread use of these objective evaluation scales will enable better comparison of the studies.

One of the true advantages of the latest generation CAD/CAM techniques is the ability for the clinician or technician to fully customize the abutment contour without the need for human intervention. The distinction between these generational technology changes should be considered by clinicians when evaluating these techniques. One of the limitations of this technology, which is progressing at a rapid rate, is that direct comparisons of "old" and "new" generation technologies become difficult. For the purposes of this review, the design of the abutment needed to include some computer-aided design process, if not exclusively CAD/ CAM produced. Scanning of a manually-produced wax pattern could be argued to be non-computer-aided design, as the majority of the design is not performed in the digital environment. Vanlioglu et al<sup>28</sup> describes a technique for manually-aided design (MAD) and/ or manually-aided manufacturing technique (MAM) of abutments. Often, similar materials for abutment production as those employed in CAD/CAM strategies are used for this technique. Two papers were excluded from evaluation due to the employment of a MAD/MAM technique used to produce abutments.<sup>28,29</sup> Additionally, any hand modification to the abutment after return from the laboratory where digitally design and production occurs breaks the chain of "purity" of CAD/CAM production. Zafiropoulos et al<sup>30</sup> was also excluded, as this study required multiple manual interventions to achieve the abutment outcome. These manual interventions may cloud the true accuracy of the CAD/CAM systems at precision output of a product for clinical use.

The review conducted by Jung et al<sup>24</sup> reported a total of 46 studies that met the inclusion criteria and a mean follow-up of at least 5 years. This can serve as a comparison for these techniques. Based on the metaanalysis, survival of implants supporting SCs at 5 years amounted to 97.2% (95% CI: 96.3% to 97.9%), and at 10 years to 95.2% (95% CI: 91.8% to 97.2%). While three late implant failures were reported in one publication between the 3- and 5-year review, no other papers reported implant failure for a mean cumulative survival rate of 98.3%. It is unlikely that these failures were a result of the CAD/CAM technology.

The survival of implant-supported SCs was 96.3% (95% CI: 94.2% to 97.6%) after 5 years and 89.4% (95% CI: 82.8% to 93.6%) after 10 years. While only two papers were found which met inclusion for crowns fabricated with a CAD/CAM technique, the mean survival rate of 98.85% for these two studies is comparable. The survival rate of CAD/CAM abutments was 100% indicating good success of this technology, with the crowns supported by CAD/CAM abutments having a mean survival rate of 99.8%.

For biologic complications, a 5-year cumulative soft tissue complication rate of 7.1% (95% CI: 4.4% to 11.3%) and a cumulative complication rate for implants with bone loss > 2 mm of 5.2% (95% CI: 3.1% to 8.6%) were calculated. Technical complications reached a cumulative incidence of 8.8% (95% CI: 5.1% to 15.0%) for screw-loosening, 4.1% (95% CI: 2.2% to 7.5%) for loss of retention, and 3.5% (95% CI: 2.4% to 5.2%) for fracture of the veneering material after 5 years. The cumulative 5-year esthetic complication rate amounted to 7.1% (95% CI: 3.6% to 13.6%). The mean cumulative complication rate for CAD/CAM crowns based on only two studies was 0%. Compared to the control group for Hosseini et al,<sup>5</sup> which had a technical complication rate for metal-ceramic restoration similar to Jung et al's 4.8% compared to 3.8%, no technical complications were observed for abutments fabricated with CAD/ CAM technology. The crowns supported by these appeared to suffer technical complications with similar frequency to that reported by Jung et al.<sup>24</sup> The mean rate of biologic complications for the CAD/CAM techniques was almost twice as high when compared to that reported previously (14.4% vs 7.1%), however, the use of CAD/CAM abutments did not approach this previously reported rate (2.5% vs 7.1%).

#### Frameworks

There were two articles that were initially considered but excluded from statistical calculation. Both of these

studies warrant discussion. Pieri et al<sup>31</sup> reported a 1-year follow-up of 26 patients that received a full-arch CAD/CAM-fabricated FDP. However, patients had a temporary prosthesis for the first few months, and the definitive CAD/CAM composite resin restoration was then delivered 4 to 5 months after surgery. This would imply that the follow-up time would apply only for the implants placed and not the final prosthesis. Since the time followed was less than 1 year, the study was excluded. In the second excluded study, by Yong and Moy,<sup>32</sup> there were 14 arches restored with an immediate loading protocol. Patients received either carbon fiber frameworks with acrylic teeth or acrylic denture teeth on a milled titanium frame (Procera Implant Bridge, Nobel Biocare). The mean follow-up period was 26.6 months. Unfortunately, the exact number of titanium-milled cases was not reported and the complications presented included both treatment modalities. Since it was not possible to distinguish the outcomes of the CAD/CAM prosthesis, the study was excluded.

During the analysis of the CAD/CAM data for frameworks, the terminology needs to be addressed again. It seems that the techniques used to produce CAD/CAM frames vary significantly between the different investigations. A technique that seems to be very prominent is the scanning of a framework, usually fabricated out of resin, composite, or wax. Jemt at al<sup>33</sup> first introduced the concept in 1999 as a CNC milling technique. It was an innovative protocol under which a titanium framework could be fabricated. Following a clinically acceptable tooth try-in, "a resin pattern was made to reproduce the design of the final titanium framework. This resin pattern was then placed in a laser scanner to feed information on the contour of the framework into a computer. Following measurement of the positions of the implant replicas in the master cast, a block of grade 2 titanium was milled in a CNC milling machine with 5 degrees of freedom. An identical copy of the resin pattern was achieved in one piece of titanium". Several authors in their clinical investigations have used this protocol with some minor modifications.<sup>15,16,19,21,22</sup>

Since then, dental technology and adjunctive computer techniques have advanced, and the software and the available materials have also improved significantly. As a result, there is now the option of completely designing the CAD/CAM parts virtually using a computer and not by scanning a prototype. This virtual protocol is encountered in most of the immediate loading cases where the final prosthesis is designed prior to the implant placement. There were three studies that followed this model in the present review.<sup>17,18,20</sup> The existing dental technology allows clinical information to be fed into computer software as digital data by scanning an actual implant master cast or even by taking a digital intra-oral impression of the clinical situation.

Table 9 Failure Rates and Survival of CAD/CAM Frameworks Supporting Implants						
Study	Year of publication	Restoration type	Implant Placement	Implants	Type of implants	
Larsson and Vult von Steyern <sup>14</sup>	2010	Partial FDP (2–5 units)	Delayed	NR	Astra Tech standard or ST	
Engquist et al <sup>16</sup>	2005	Full-arch FDP	Delayed	432	Brånemark (Nobel Biocare)	
Komiyama et al <sup>18</sup>	2008	Full-arch FDP	Delayed	176	Brånemark MKIII, TiUnite	
Ortorp and Jemt <sup>15</sup>	2012	Full-arch FDP	Delayed	367	Brånemark (Nobel Biocare)	
Sanna et al <sup>17</sup>	2007	Full-arch FDP	Delayed	183	Brånemark TiUnite (Nobel Biocare)	
Tahmaseb et al <sup>20</sup>	2012	Full-arch FDP	Delayed	240	Straumann Standard Tissue Level	
Katsoulis et al <sup>19</sup>	2011	Full-arch FDP	Delayed	74	Replace Select tapered (Nobel Biocare)	
Papaspyridakos and Lal <sup>22</sup>	2013	Full-arch FDP	Delayed	103	Brånemark TiUnite (Nobel Biocare)	
Malo et al (1) <sup>21</sup>	2012	Full-arch FDP	Delayed	634	Brånemark system, Nobel Speedy; (Nobel Biocare)	
Malo et al (2) <sup>21</sup>	2012	Full-arch FDP	Delayed	634	Brånemark system, Nobel Speedy; (Nobel Biocare)	

NR = not reported; FDPs = fixed dental prostheses;

\*Mean follow-up time for combined studies: 60 (range, 9 months-10 years).

A digital wax-up is usually evaluated and the abutment or framework can then be designed virtually. This technique seems to follow the designation of CAD, computer-aided design, most closely.

For this reason, the authors feel that a distinction needs to be made between the products that require a pattern to be scanned, and the ones that can be fully designed using only a computer software program. A new definition of the dental CAD/CAM procedures would be beneficial to more accurately define the processes under which these restorations are manufactured. "Complete CAD/CAM product" vs "Partial CAD/ CAM product" (product referring to abutment, mesostructures, frameworks, and prostheses) could be two terms that would provide a classification of the implant-supported prosthesis fabrication technique that more accurately reflects the processes used.

To compare the CAD/CAM literature with the conventional implant-supported frameworks, a scientific systematic review was assessed and analyzed. The search for this clinical investigation was conducted by Pjetursson et al<sup>25</sup> and reported a total 32 studies that met the inclusion criteria. A meta-analysis of these studies indicated an estimated survival of implants supporting fixed dental prostheses (FDPs) of 95.6% after 5 years and 93.1% after 10 years. When machinedsurface implants were excluded from the analysis and only rough-surfaced implants included, the survival rate increased to 97.2% after 5 years. Under the selected CAD/CAM publications, there was a total of 2,209 rough-surfaced implants that were evaluated (excluding the paper by Larsson and Vult von Steyern,<sup>14</sup> which did not report the number of implants related to CAD/CAM prosthesis). The range of the survival rate for those implants varied between 89.2% and 100%. If only the studies that reported on a purely delayed loading protocol<sup>15,16,21</sup> (1,001 implants) were chosen, then the survival rate range becomes 95% to 100%. The failure rates and the survival of CAD/CAM supporting implants are summarized in Table 9.

For the Pjetursson et al<sup>25</sup> review, the survival rate of implant-supported FDPs was 95.4% after 5 years and 80.1% after 10 years of function. When the analysis was done exclusively for metal-ceramic FDPs and excluding gold-acrylic FDPs, the survival rate increased to 96.4% after 5 years and 93.9% after 10 years. Those values can be compared with the ones reported by the CAD/CAM publications. The total number of prostheses evaluated was 438, and the range of the prosthesis survival rate (excluding the Engquist et al<sup>16</sup> study that did not report on survival rates) was between 80.7% and 100% for a follow-up range of 2 to 5 years.<sup>17–19,21</sup> Concentrating on the studies that reported on a delayed loading protocol<sup>14,15,19,21</sup> for a total of 218 prostheses changes the survival rate range to 90.1% to 100% over a followup range of 3.5 from 6 years.<sup>14,21</sup> The failure rates and survival of the CAD/CAM frameworks are summarized in Table 10.

Under the Pjetursson et al<sup>25</sup> report only 66.4% of the patients were free of any complications after 5 years

Mean follow-up time (mo)	No. of implant failures	CSR	Mean marginal bone loss
60	NR	NR	NR
36	24	92.30%	1.24 mm (Group D) – 1.68 mm (Group B)
44	19	89.20%	
120	17 and 161 lost to follow-up	95%	0.7 mm (SD, 0.77)
26.4	9	95%	Smokers, 2.6 mm (± 1.6); nonsmokers, 1.2 mm (± 0.8)
12 months minimum (range: 12–36 mo)	11	95.40%	Radiographic analysis showed bone loss on 2 implants up to second thread, both in posterior augmented maxillae, 15 implants not measurable
24	0	100%	NR
36	0	100%	NR
78 (range: 9–127)*	Implants NR, failures in 2 patients	98.10%	NR
46 (range: 12-67)*	0	100%	NR

(biological and technical complications were present in 33.6% of cases). The most frequent complications over the 5-year observation period were fractures of the veneering material (13.5%), peri-implantitis and soft tissue complications (8.5%), loss of access hole restoration (5.4%), abutment or screw loosening (5.3%), and loss of retention of cemented FDPs (4.7%).

The evaluated CAD/CAM framework investigations presented great variations between them. Studies differed in the number of implants that supported the prostheses, the loading protocols, the presence or absence of cantilevers, the type of restorations present in the opposing arch, and the type of veneering material. These differences as well as the variations in the techniques used for CAD/CAM framework fabrication made direct comparison between studies impossible. Table 11 summarizes the data of the observed CAD/CAM framework complications. Not all authors reported on complications and even when that was done, the methodology of assessment varied significantly. As with conventional fabrication techniques, veneering material fractures were the most common complication to be encountered. A total of 104 incidents were recorded from a total of 221<sup>15,19,21,22</sup> prostheses. On several occasions the fracture took place in the same prosthesis, increasing the overall number of fracture incidents. A total of six screw-loosening incidents were reported out of 221 cases<sup>15,19,21,22</sup> and nine occlusal adjustments out of 79 cases.<sup>18-20</sup> Malo et al<sup>21</sup> was the only study which reported in detail soft tissue complications. Nineteen incidents of peri-implant pathology and 12 of soft tissue inflammation were recorded in total.

In summary, the use of CAD/CAM frameworks for implant-supported restorations appears to provide acceptable clinical outcomes. When a delayed loading protocol was followed, the implant survival values between CAD/CAM restorations and conventional implant-supported frameworks seemed to be similar. In the relatively short-term, (3.5 to 6 years follow-up) the survival of prostheses fabricated by CAD/CAM (delayed loading protocol) and conventional also presented comparable values.

# CONCLUSION

CAD/CAM technology is currently available which can be used to predictably facilitate the restoration of dental implants from single-unit cases to complex full-arch reconstructions. The purpose of this systematic review was to compare the outcomes of CAD/CAM generated restorations and abutments to those generated using conventional techniques. For crowns, abutments, and frameworks, CAD/CAM technology is able to provide results which, based on the current literature, are comparable to that of conventional techniques for implant survival, prosthesis survival, technical, and biologic complications. The authors believe that with the advent of a wide variety of CAD/CAM techniques being

# Table 10 Failure Rates and Survival of CAD/CAM Frameworks

Study	Year of publication	Restoration type	Material
Larsson and Vult von Steyern <sup>14</sup>	2010	partial FDP (2–5 units)	Zr frame (Denzir, Decim) veneered with Esprident Triceram (Dentaurum) porcelain
Engquist et al <sup>16</sup>	2005	Full-arch FDP	Tiframe (Procera All-in-One, Nobel Biocare) combined with acrylic teeth
Komiyama et al <sup>18</sup>	2008	Full-arch FDP	Ti frame (Procera Implant Bridge, Nobel Biocare) combined with acrylic teeth
Ortorp and Jemt <sup>15</sup>	2012	Full-arch FDP	Ti frame (Procera All-in-One, Nobel Biocare) combined with acrylic teeth
Sanna et al <sup>17</sup>	2007	Full-arch FDP	Ti frame (Procera All-in-One, Nobel Biocare) combined with acrylic teeth
Tahmaseb et al <sup>20</sup>	2012	Full-arch FDP	Ti frame (Es-Healthcare) combined with acrylic teeth
Katsoulis et al <sup>19</sup>	2011	Full-arch FDP	Ti frame (Procera, Nobel Biocare) combined with acrylic resin Candulor
Papaspyridakos and Lal <sup>22</sup>	2012	Full-arch FDP	Zr frame (Procera, Nobel Biocare) + veneering porcelain
Malo et al (1) <sup>21</sup>	2012	Full-arch FDP	Ti frame (Procera, Nobel Biocare), Alumina copings (Nobel Biocare), Allceram (Ducera Dental) + Duceram (Ducera Dental) veneering porcelain
Malo et al (2) <sup>21</sup>	2012	Full-arch FDP	Titanium frame (Procera, Nobel Biocare), Zirconia copings (Nobel Biocare), Nobel Rondo Zirconia Ceramic (Nobel Biocare), PalaXpress Ultra (Heraeus Kulzer)

NR = not reported.

\*Mean follow-up time for combined studies: 60 (range, 9 months-10 years).

#### Table 11 Complications of CAD/CAM Frameworks

Study	Year of publication	Restoration type	Mean follow-up time (mo)	Occlusion	Passive fit	
Larsson and Vult von Steyern <sup>14</sup>	2010	Partial FDP (2-5 units)	60	NR		
Engquist et al <sup>16</sup>	2005	Full-arch FDP	36	NR		
Komiyama et al <sup>18</sup>	2008	Full-arch FDP	44	3/31	misfit in 5 cases	
Ortorp and Jemt <sup>15</sup>	2012	Full-arch FDP	120	NR		
Sanna et al <sup>17</sup>	2007	Full-arch FDP	26.4	NR	NR	
Tahmaseb et al <sup>20</sup>	2012	Full-arch FDP	12 months minimum (range: 12–36 mo)	1/40 lab adjustment	100%	
Katsoulis et al <sup>19</sup>	2011	Full-arch FDP	24	5 corrections	NR	
Papaspyridakos and Lal <sup>22</sup>	2013	Full-arch FDP	36			
Malo et al (1) <sup>21</sup>	2012	Full-arch FDP	78 (range: 9–127)	NR	100%	
Malo et al (2) <sup>21</sup>	2012	Full-arch FDP	46 (range: 12-67)	NR	100%	

NR = not reported; FDPs: fixed dental prostheses.

presented in the literature, the following recommendations should be made:

- 1. Authors should carefully consider how to report their processes for future publications so readers are able to easily and accurately compare the true advantages of newer technology.
- 2. Two new definitions are recommended for dental CAD/CAM procedures. These would more accu-

rately define the process under which these restorations are manufactured. "Complete CAD/CAM Product," (product referring to abutment, mesostructures, frameworks, and prostheses) where the entire design and manufacturing process is softwareimplemented and controlled.

3. "Partial CAD/CAM Product," where some design and manufacturing processes involve manual intervention.

Loading	Arch loaded	Restorations	Mean follow-up time (mo)	Restoration failures	CSR
Delayed	Mandible and maxilla	13	60	0	100%
Delayed + early + immediate	Mandible	108	36	NR	NR
Immediate	Mandible and maxilla	26 (5 carbon)	44	5	80.70%
Delayed	Mandible and maxilla	67	120	2 incidents in 2 cases	95.60%
Immediate	Mandible and maxilla	30	26.4	0 (phone contact in 4)	100%
Immediate	Mandible and maxilla	40	12 months minimum (range: 12–36 mo)	1 (due to implant failure)	97.50%
Delayed	Maxilla	13	24	0	100%
13 delayed and 3 immediate	Mandible and maxilla	16	36	0	100%
Delayed	Mandible and maxilla	66	78 (range: 9–127)*	5 + 1 (due to implant failure) = 6	90.10%
Delayed	Mandible and maxilla	59	46 (range: 12–67)*	0	100%

Screw loosening	Total no. of veneering material chipping/fracture	Other
	16 (52%)	NR
NR	NR	NR
NR	NR	NR
3 incidents in 1 prosthesis	35 incidents out of 19 cases	NR
NR	NR	NR
NR	NR	NR
0	14	Sore spots: 1, Relining: 3, Excessive tooth wear: 1, Discoloration of acrylic: 1
0	5 (4 patients), ceramic chipping rate of 31.25%	NR
2	36	
1	14	

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# Consensus Statements and Recommended Clinical Procedures Regarding Restorative Materials and Techniques for Implant Dentistry

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# **INTRODUCTORY REMARKS**

Computer-assisted design (CAD) and computer-assisted machining (CAM) have been increasingly used in implant dentistry over the past 10 years. The continu-

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ous improvement of these newer techniques by their developers has started to challenge traditional techniques of fabricating implant-supported prostheses. The premise that there is an improvement in outcome compared with traditional fabrication techniques is fundamental to the use of CAD/CAM. The systematic review by Kapos and Evans is focused on the performance of CAD/CAM prostheses when compared to conventionally manufactured prostheses.

Since most patients provided with oral implants are between 40 and 50 years of age, long-term survival rates for implants and prostheses are expected both from the clinician and the patient to ensure the longevity of the reconstruction. "Long-term" has been specified as a follow-up of at least 5 years. Thus, survival rates and the incidence of biologic, technical, and esthetic events should be based on mean observation periods of at least 5 years. However, implant survival rates are not the only essential consideration when advising the patient on different treatment options. Prosthetic and implant-abutment outcomes need to be considered as well. Different kinds of abutments are available with respect to material (metal and ceramic) and shape (prefabricated and customized, both with various internal designs). At this time, metal abutments are classified as the gold standard, although high-strength zirconia abutments are being utilized more widely and may be an adequate alternative to metal abutments for the clinical use. The systematic review by Zembic et al focuses on the survival rates of metal and ceramic abutments supporting singleimplant crowns with a mean observation period of at least 3 years, as sufficient 5-year data were not available. In addition, the occurrence of negative biologic, technical, and esthetic events was evaluated for metal and ceramic abutments.

One of the important decisions in implant prosthodontics is the choice of the connection type of the final restoration to the implant via the screw-retained abutment. The restorative connection can be either screw- or cement-retained. With screw-retained restorations, an abutment or mesostructure may be separate

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to the restoration (two-piece) or combined as part of the fabrication procedure (one-piece). In general, both retention types have their advantages and limitations. Clinical and technical issues relevant in making the choice include ease of fabrication, precision, passivity of the framework, retention, occlusion, esthetics, accessibility, retrievability, complications, and costs. The focus of the review by Wittneben et al is on biologic and technical failures and complication rates observed with cement- and screw-retained fixed implant-supported reconstructions.

# Disclosure

All the group members were asked to reveal any conflicts of interest that could potentially influence the outcomes of the consensus deliberations. No such conflicts were identified.

# CAD/CAM TECHNOLOGY FOR IMPLANT ABUTMENTS, CROWNS, AND SUPERSTRUCTURES

# **General Comments**

The aim of the first systematic review was to answer the focus question "How do CAD/CAM implant-supported prostheses in patients with missing teeth and one or more dental implants perform compared to conventionally fabricated implant-supported prostheses when assessing esthetics, complications (biologic and mechanical), patient satisfaction, and economic factors?" CAD/CAM technology that can be used to predictably facilitate the restoration of dental implants from single-unit cases to complex full-arch reconstructions is currently available. The techniques used to produce the CAD/CAM frames vary significantly between the different investigations. The first described techniques were based on resin patterns placed in a laser scanner to feed information on the contour of the framework into a computer. An identical copy of the resin pattern was then milled out of one piece of titanium. Currently, it is possible to design a complete virtual prosthesis using computer-generated CAD/CAM parts without scanning a physical prototype. For crowns, abutments, and frameworks, CAD/CAM technology is able to provide results that, based on the current literature, are comparable to that of conventional techniques when considering implant survival, prosthesis survival, and technical and biologic complications.

# **Consensus Statements**

With respect to CAD/CAM technology for implant abutments, crowns, and superstructures, the following statements can be made:

- CAD/CAM technology has been successfully incorporated into implant dentistry.
- The clinical performance of implant-supported prostheses produced using CAD/CAM and conventional techniques is similar over the short term (mean: crowns, 1 year [1 to 1.1 years]; abutments, 3.5 years [1 to 5 years]; frameworks, 4 years [1 to 10 years]).
- The variability of CAD/CAM software and hardware used in fabricating implant-supported prostheses makes comparison difficult.
- The variability of outcome measures and material choices in investigations of CAD/CAM implantsupported prostheses makes comparison difficult.
- The short-term (mean, 3.5 years [1 to 5 years]) survival rate of individually customized CAD/CAM abutments is similar to that of conventionally fabricated or stock abutments.
- The short-term (mean, 4 years [1 to 10 years]) survival rate of individually customized CAD/CAM frameworks is similar to that of conventionally fabricated frameworks.

# **Treatment Guidelines**

- The implementation of CAD/CAM technologies should lead to acceptable clinical outcomes.
- Continuous training for both the restorative dentist and technician is essential to successfully implement CAD/CAM techniques for the restoration of dental implants.
- There is continuous industry-controlled development in CAD/CAM devices, techniques, and materials. The dentist and technician should be aware that product hardware and software, as well as support, will change with generational advances.
- As the dentist remains responsible for treatment outcomes, it is recommended that he/she play an active role, together with the technician, to carefully control CAD/CAM processes and material selection.
- It is recommended that the dentist approve a virtual final prosthesis (virtual diagnostic wax-up) that dictates abutment/framework design.
- It is recognized that digitally derived prostheses can be remanufactured from stored data sets. It is recommended that digital data sets be stored/protected for this eventuality and that digital technology work platforms maintain programming compatibility/ transparency.

# **Recommendations for Future Research**

- Renew the definitions relating to CAD/CAM techniques:
  - 1. Complete CAD/CAM product (including abutment, mesostructures, frameworks, and prostheses): The entire design and manufacturing process is software implemented and controlled.
  - 2. Partial CAD/CAM product (including abutment, mesostructures, frameworks, and prostheses): Some design and manufacturing process steps involve manual intervention.
- Standardization of measured outcomes and study protocols for clinical investigations are recommended.
- Studies on economic impacts and patient-centered outcome measures for new technologies are recommended.

# SURVIVAL RATE AND INCIDENCE OF COMPLICATIONS OF SINGLE IMPLANT– SUPPORTED FIXED RECONSTRUCTIONS

# **General Comments**

Different kinds of implant abutments are available with respect to material (metal and ceramic) and shape (prefabricated and customized, both with various internal designs). Although metal abutments are classified as the gold standard, high-strength zirconia abutments are being utilized more widely. However, the available data in the literature only covers a limited time span. Therefore, the consensus statements and clinical recommendations are based on a review of the survival rates of metal and ceramic abutments supporting single-implant crowns with a mean observation period of at least 3 years.

# **Consensus Statements**

- No differences were found between ceramic and metal abutments in clinical performance based upon esthetic, technical, or biologic outcomes.
- No differences were found between the clinical performance of metal abutments with external or internal connections, based upon esthetic, technical, or biologic outcomes (mean, 5 years [3 to 10 years]).
- The reported rate of technical complications is higher than either esthetic or biologic complications (mean, 5 years [3 to 10 years]).

# **Treatment Guidelines**

- As many different types of zirconia with differing microstructures and performance are being introduced into implant dentistry, they should be obtained from a reputable/qualified manufacturer.
- For anterior and premolar prostheses, zirconia abutments may be indicated. However, they should not be ground, abraded, or adjusted by the clinician or technician following sintering, unless recommended by the manufacturer.
- Ceramic abutments should not replace metal ones for all indications. Preliminary findings reflect an inherent sensitivity of ceramics to design and processing problems; eg, stress concentration, thin walls, sintering, and residual machining flaws.
- The design of full ceramic abutments should not be based on metal abutment design to avoid stress concentrations or the development of unfavorable stresses.
- Caution is recommended in the clinical use of ceramic abutments in molar sites, as their behavior in these sites has not been sufficiently described.
- The performance of bonded titanium-zirconia implant abutments is not yet established. Thus, caution is recommended in the clinical use of such abutments due to insufficient data.

# **Recommendations for Future Research**

More clinical research is needed for:

- Bonded titanium-zirconia abutments
- Studies on zirconia abutments (both anterior and posterior) longer than 5 years
- Internal versus external implant-abutment connections for both ceramic and metal abutments
- Instrumented and visual esthetic outcomes for ceramic versus metal abutments
- Single- versus multiple-unit prostheses

Minimum standardized data set on outcome measures for future research protocols:

- 1. Abutment material and fabrication methods
- 2. Restoration sites (anterior, posterior)
- 3. Failure type with descriptive information and photographs
- 4. Timing of failure
- 5. Gingival indices
- 6. Soft tissue esthetic outcome(s) with information about tissue thickness
- 7. Radiographic bone level changes
- 8. Screw failure

# CLINICAL PERFORMANCE OF SCREW-VERSUS CEMENT-RETAINED IMPLANT-SUPPORTED FIXED RECONSTRUCTIONS

# **General Comments**

The restorative connection to the implant or abutment can be either screw- or cement-retained. With screwretained restorations, an abutment or a mesostructure may be separate from the restoration (two piece) or combined as part of the fabrication procedure (one piece). In general, both retention types (screw- and cement-retained) have their advantages and limitations. The consensus statements of this review focus on biologic and technical failures and complication rates observed with screw- and cement-retained implantsupported fixed reconstructions.

# **Consensus Statements**

- High survival rates can be achieved with both cemented and screw-retained fixed implant-supported prostheses. Neither failure nor complication can be avoided by selecting a prosthesis retention type.
- Cemented all-ceramic prostheses have a higher failure rate than cemented metal-ceramic prostheses. However, no difference was found with screwretained prostheses.
- Based upon the literature reviewed, the type of cement used does not influence the failure rate of cemented prostheses.
- Technical complications occurred (estimated annual event rate of up to 10%) with both cemented and screw-retained prostheses. In the pooled data, the cemented prostheses exhibited a higher rate of technical complication.
- Screw-retained prostheses exhibited a higher rate of ceramic chipping than cemented prostheses.
- Biological complications can be found (estimated annual event rate of up to 7%) with both cemented and screw-retained prostheses. Cemented prostheses exhibit a higher rate of fistula formation and suppuration.

### **Treatment Guidelines**

Based on the data in this review, a universal recommendation cannot be made for either cementation or screw retention. However, in a clinical situation that offers a choice of prosthesis retention type, the following recommendations may be made: Cement retention may be recommended:

- For short-span prostheses with margins at or above tissue level to simplify fabrication procedures
- To enhance esthetics when the screw access passes transocclusally or in cases of malposition of the implant
- When an intact occlusal surface is desirable
- To reduce initial treatment costs
- It is further recommended that the clinician understand that the procedures involved with cement retention for implant-supported crowns are not simple and should be carried out with great caution.

Screw retention may be recommended:

- In situations of minimal interarch space
- To avoid a cement margin and thus the possibility of cement residue (this may be particularly important if the prosthetic margin is placed submucosally, since it has been shown to be more difficult to completely remove cement residue from margins placed > 1.5 mm submucosally)
- When retrievability is of importance
- In the esthetic zone, to facilitate tissue contouring and conditioning in the transition zone (emergence profile)
- To facilitate screw retention, it is recommended that the implant be placed in a prosthetically driven position.

# RECOMMENDATIONS FOR FUTURE RESEARCH

- Standardization of outcomes for clinical investigations is recommended.
- Improved protocols for chairside cementation should be developed.
- Combined prostheses retention types should be tested (eg, bonding base).
- Ceramic chipping occurs frequently. Reporting of ceramic chipping should include the severity and location of the chipping. This should also be related with patient-centered outcomes.
- Details of the restorative and technical procedures, which may influence prostheses survival, should be reported.
- Prosthetic factors, such as the material of the components used, should be reported in greater detail.

# **GROUP** 3

# **Optimizing Esthetic Outcomes in Implant Dentistry**

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#### **Review Papers Submitted for Discussion:**

The Influence of Restorative Procedures on Esthetic Outcomes in Implant Dentistry: A Systematic Review William C. Martin/Adrien Pollini/Dean Morton

Soft Tissue Augmentation Procedures for Mucogingival Defects in Esthetic Sites Robert A. Levine/Guy Huynh-Ba/David L. Cochran

Esthetic Outcomes Following Immediate and Early Implant Placement in the Anterior Maxilla—A Systematic Review Stephen T. Chen/Daniel Buser

**Consensus Statements and Recommended Clinical Procedures Regarding Optimizing Esthetic Outcomes in Implant Dentistry** Dean Morton/Stephen T. Chen/William C. Martin/Robert A. Levine/Daniel Buser

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# The Influence of Restorative Procedures on Esthetic Outcomes in Implant Dentistry: A Systematic Review

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Purpose: The objectives of this review were to (1) identify if prosthodontic parameters influence the esthetic outcome of implant-supported restorations and (2) make clinically relevant recommendations based upon the findings. Materials and Methods: Electronic and manual searches of dental literature were performed to collect information on esthetic outcomes based on objective criteria. The prosthodontic parameters included optimal three-dimensional implant position, the utilization of provisional restorations, the timing of provisional restoration with regard to implant placement, the choice of prosthodontic platform size and form, the abutment and definitive restoration material, and the mode of prosthesis retention. Regions including maxillary and mandibular anterior teeth and premolars were considered. All levels of evidence, including case studies, were accepted. Results: From 472 titles, 152 full-text articles were evaluated and 58 records included for data extraction (15 randomized controlled trials, 6 cohort studies, and 37 case series studies). Considerable heterogeneity in study design was found. A meta-analysis of controlled studies was not possible. It was consistently reported that facial malpositioning of implants increases the likelihood of mucosal recession. No studies directly compared esthetic outcomes associated with the use or non-use of provisional restorations. The literature contains a greater number of case series studies evaluating esthetic outcomes for protocols including, rather than excluding, provisional restorations. It is not possible to identify any significant variation in esthetic outcomes based on the character of the abutment platform from the current literature. Based on the findings, no significant difference can be established between all-ceramic and metal-ceramic prostheses with regard to esthetic indices over short observation periods. No firm conclusions relating esthetic benefits for cement in comparison to screw retention can be identified. Conclusions: There is a need for RCTs comparing accepted procedures in routine practice. The utilization of provisional restorations remains strongly recommended in order to trial the planned definitive restoration, to facilitate maturation of healing tissues and for patient convenience. Implant positioning according to the planned prosthesis remains a requirement to achieve a long-lasting esthetic outcome. The majority of studies reported on single-tooth replacement, and many of the outcomes may not be relevant or applicable to the large number of esthetic indications involving more than one tooth. INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):142-154. doi: 10.11607/jomi.2014suppl.g3.1

**Key words:** abutment material, final restoration material, implant position, implant restoration mode of retention, implant-supported provisional restoration, restorative implant platform size and form, timing of provisional restoration

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mplant therapy has evolved to routinely include rehabilitation of patients missing teeth of esthetic significance. From the perspective of the restorative dentist or prosthodontist, several procedural options may be identified as capable of influencing both the esthetic quality of the treatment, and the predictability of the esthetic outcome. These procedures include:

- The implant position, as well as the communication of the optimal implant position through the use of templates
- The utilization of implant-supported provisional prostheses

- The timing of provisional prostheses with regard to implant placement
- · The restorative platform size and form
- The abutment material
- The final prosthetic material
- The mode of retention for the final prosthesis

This systematic review examined the existing literature specific to these procedures. Literature was identified via an electronic search and was restricted to partially edentulous adult patients. The literature was confined to articles published in the most recent 10 years, and to randomized controlled trials (RCTs), cohort studies, and case series involving more than five patients. Treatment interventions and cross-sectional comparisons included the presence or absence of the above identified procedures.

The objectives of the review were to both identify procedures confirmed by the literature to influence the esthetic outcome of implant-based therapy, and to make clinically relevant recommendations based upon these procedures.

# MATERIALS AND METHODS

#### Search Strategy

This systematic review was intended to assess restorative procedures that influence the esthetic outcomes of therapy involving dental implants. Keywords were chosen to include restorative treatment interventions, including the use of templates or guides in the placement of implants, the utilization of provisional restorations, the timing of provisional restoration, the nature of the restorative platform on the implant, the abutment material, the restorative material, and the mode of prosthesis retention. The reporting of esthetic outcomes was required for inclusion.

A Medline (PubMed) search was undertaken to identify randomized controlled trials, cohort studies and case series involving a minimum of five patients. A search of The Cochrane Central Register of Controlled Trials (CENTRAL), and a hand search of journals, was additionally undertaken to maximize the likelihood of capturing all relevant publications. The reporting of this review is based upon PRISMA guidelines.

## **Selection of Studies**

Two of the authors independently screened the titles and abstracts obtained from the electronic search for inclusion or exclusion. Disagreements were resolved via direct discussion. Full-text versions of articles were obtained when compliance with the criteria required for the review was positive, or when exclusion could not be confirmed. Two reviewers independently performed a review of the full-text articles and disagreements were again managed via reviewer discussion prior to final inclusion or exclusion. The search protocol is summarized in Table 1.

### **Excluded Studies**

Criteria for exclusion included:

- Failure to identify the inclusion criteria
- Methodology or review article
- Presence of more recent follow-up publication including the same patient pool
- Inability to differentiate procedures in the esthetic zone
- Lack of identifiable information relating to specific prosthodontic procedures
- Patient pool of five or less patients
- Animal, histologic, or nonclinical outcomes
- Non English language
- Failure to report on esthetic outcomes

# **Quality Assessment**

RCTs were assessed for bias according to the Cochrane Collaboration tool. This tool uses domains, including adequacy of sequence generation, allocation concealment, blinding of participants, the handling of incomplete outcome data, and steps to minimize selective outcome reporting to evaluate bias. The quality of cohort studies was assessed using the Newcastle-Ottawa scale. This scale includes eight domains.

#### **Data Extraction**

A standardized descriptive table was utilized to record data for each study, with inclusion and exclusion criteria. Two reviewers evaluated the descriptive tables independently, and any disagreement was resolved via discussion.

#### **Statistical Analysis**

The literature identified in this review does not meet criteria required for quantitative data or meta-analysis. Further, the heterogeneity of the case series prevents the plotting of outcomes to feature results.

# RESULTS

The Medline (PubMed) search identified 305 titles, to which an additional 31 articles were added subsequent to hand searching. Of the 336 titles identified via PubMed and the hand-search, 193 were excluded with author agreement subsequent to title and abstract review. A search of the Cochrane Central Register of Controlled Trials identified 136 citations, of which 127 were excluded with author agreement (Fig 1).

Table 1 Systematic Search Strategy			
Focus question: Wh	at is the influence of restorative or prosthodontic procedures on esthetic outcomes in implant dentistry?		
Search strategy			
Population	1) dental implants [MeSH Terms] OR oral implant OR endosseous implant OR dental implants, single tooth [MeSH Terms]		
Intervention or exposure	2) implant restoration OR implant supported prosthesis OR implant supported fixed dental prosthesis OF implant supported FDP OR implant supported FPD		
Comparison	<ul> <li>3) implant position OR implant positioning</li> <li>4) diameter OR platform OR abutment OR abutment material OR zirconia OR PFM</li> <li>5) immediate provisional OR immediate provisionalization OR immediate temporary OR immediate temporization</li> <li>6) provisional crown OR provisional fdp OR provisional fpd OR temporary crown OR temporary fdp OR temporary fpd OR immediate temporization OR immediate loading</li> </ul>		
Outcome	7) papilla OR papilla index OR keratinized mucosa OR width of keratinized mucosa OR PES/WES OR pink esthetic score OR white esthetic score OR esthetic outcome		
Search combination	1 OR 2 AND (3 or 4 or 5 or 6) AND 7		
Database search			
Language	English		
Electronic	PubMed (Medline), Cochrane Central Register of Controlled Trials (CENTRAL)		
Journals	Clinical Oral Implants Research, International Journal of Oral Maxillofacial Implants, Clinical Implant Dentistry and Related Research, Journal of Prosthetic Dentistry, Journal of Prosthodontics, International Journal of Prosthodontics		
Selection criteria			
Inclusion criteria	Clinical trials Controlled clinical trials Multicenter studies Randomized controlled trials Case reports Published last ten years Humans Adult (19+)		
Exclusion criteria	Failure to identify inclusion criteria Methodology or review article Multiple publications on the same patient population Inability to differentiate procedures in the esthetic zone Lack of identifiable information specific to prosthodontic procedures Patient pool of 5 or less Non-English language Animal studies Histologic or nonclinical outcomes Discussion, technique, or review articles Failure to report esthetic outcomes		

Table 2         Studies Included for Data Extraction			
Туре	Number	Studies	
Randomized controlled studies (RCTs)	15	Lindeboom et al, <sup>1</sup> Oh et al, <sup>2</sup> den Hartog et al, <sup>3</sup> den Hartog et al, <sup>4</sup> De Rouck et al, <sup>5</sup> Hall et al, <sup>6</sup> Canullo et al, <sup>7</sup> Pieri et al, <sup>8</sup> Tymstra et al, <sup>9</sup> Gallucci et al, <sup>10</sup> Gallucci et al, <sup>11</sup> Hosseini et al, <sup>12</sup> Jung et al, <sup>13</sup> Donati et al, <sup>14</sup> Degidi et al <sup>15</sup>	
Cohort studies	6	Sherif et al, <sup>16</sup> Henrikson and Jemt, <sup>17</sup> Lops et al, <sup>18</sup> Santing et al, <sup>19</sup> Cosyn et al, <sup>20</sup> Ottoni et al <sup>21</sup>	
Case series studies	37	Cabello et al, <sup>22</sup> Noelken et al, <sup>23</sup> Cosyn et al, <sup>24</sup> Chang and Wennström, <sup>25</sup> Di Alberti et al, <sup>26</sup> Oyama et al, <sup>27</sup> Lee et al, <sup>28</sup> Furze et al, <sup>29</sup> Malchiodi et al, <sup>30</sup> Hof et al, <sup>31</sup> Cosyn et al, <sup>32</sup> Tsuda et al, <sup>33</sup> Kan et al, <sup>34</sup> Chung et al, <sup>35</sup> Buser et al, <sup>36</sup> Nisapakultorn et al, <sup>37</sup> Tortamano et al, <sup>38</sup> Belser et al, <sup>39</sup> Chen et al, <sup>40</sup> Buser et al, <sup>41</sup> Reddy et al, <sup>42</sup> Kan et al, <sup>43</sup> Canullo and Rasperini, <sup>44</sup> Degidi et al, <sup>45</sup> Cardaropoli et al, <sup>46</sup> Cornelini et al, <sup>47</sup> Jemt and Lekholm, <sup>48</sup> Juodzbalys and Wang, <sup>49</sup> Noelken et al, <sup>50</sup> Brown and Payne, <sup>51</sup> Cooper et al, <sup>52</sup> Gallucci et al, <sup>53</sup> Crespi et al, <sup>54</sup> Botticelli et al, <sup>55</sup> Vandeweghe et al, <sup>56</sup> Zarone et al, <sup>57</sup> Cutrim et al <sup>58</sup>	
Total	58		

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Table 3         Risk of Bias for Randomized Controlled Trials									
Study	Adequate sequence generation?	Allocation concealment?	Blinding of participants?	Incomplete outcome data addressed?	Free of selective outcome reporting?	Other sources of bias?			
Tymstra et al <sup>9</sup>	Yes	No	Yes	Yes	Yes	No			
Pieri et al <sup>8</sup>	Yes	Yes	No	Yes	Yes	No			
Hosseini et al <sup>12</sup>	No	Yes	Yes	No	Yes	No			
De Rouck et al <sup>5</sup>	Yes	Yes	Yes	Yes	Yes	No			
Canullo et al <sup>7</sup>	Yes	Yes	Yes	Yes	Yes	No			
Oh et al <sup>2</sup>	No	No	No	Yes	Yes	No			
Lindeboom et al <sup>1</sup>	Yes	No	No	Yes	Yes	No			
Jung et al <sup>13</sup>	No	No	No	Yes	No	No			
Hall et al <sup>6</sup>	No	Yes	No	Yes	Yes	Yes			
Gallucci et al <sup>10</sup>	Yes	Yes	Yes	Yes	Yes	No			
Gallucci et al <sup>11</sup>	Yes	Yes	Yes	Yes	Yes	No			
den Hartog et al <sup>3</sup>	Yes	Yes	Yes	Yes	Yes	No			
den Hartog et al <sup>4</sup>	Yes	Yes	Yes	Yes	Yes	No			
Donati et al <sup>14</sup>	Yes	No	No	Yes	Yes	No			
Degidi et al <sup>15</sup>	Yes	Yes	No	Yes	Yes	No			

Full-text versions of the 152 identified titles were obtained and evaluated independently by two reviewers. Ninety-four of the full-text articles were excluded based on the established criteria. This process identified 58 articles for inclusion and data extraction, including 15 randomized controlled trials, 6 cohort studies, and 37 case series studies (Table 2).

Of the 15 randomized controlled trials, 11 were considered to be at high risk of bias according to the Cochrane Collaboration tool (Table 3). This was primarily the result of non-concealment or non-blinding. The six cohort studies were assessed using the Newcastle-Ottawa method (Table 4). The outcomes for the 44 case series studies were, as a result of the broad heterogeneity of the data, evaluated for overall trends with regard to papilla scores, pink and white esthetic scores (PES/WES), and midfacial mucosal levels, rather than comparative data. Significant variations exist in the methods of measuring these criteria, and the scales for measurement also vary between articles using the same criteria (eq PES/WES).

### DISCUSSION

### **Implant Positioning**

No studies were identified comparing esthetic outcomes obtained with or without a surgical guide or template designed to facilitate a specific implant position. Therefore, there is no scientific basis for any conclusion, positive or negative, with regard to template use and effect on esthetic outcomes. Several studies,

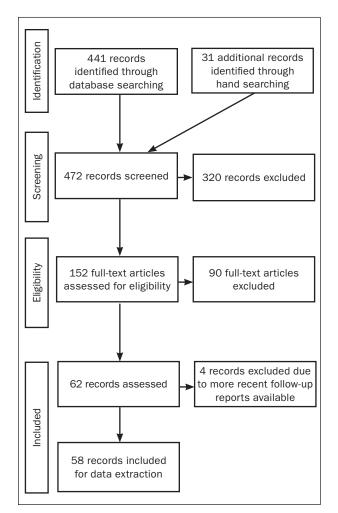


Fig 1 Search strategy.

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	ssessment and					
Study	Representative of the exposed cohort	Selection of the nonexposed cohort	Ascertainment of exposure	Outcome of risk not present at commencement of study	Comparability of cases and controls (maximum 2 stars)	
Cosyn et al <sup>20</sup>	*		*	*		
Santing et al <sup>19</sup>	*	*	*	*		
Sherif et al <sup>16</sup>	*		*	*		
Henriksson and Jemt <sup>17</sup>	*	*	*	*	*	
Lops et al <sup>18</sup>	*		*	*	*	
Ottoni et al <sup>21</sup>	*	*	*	*	*	

### Table 4 Quality Assessment and Risk of Bias for Nonrandomized Trials

however, identified poorly positioned implants (particularly in the orofacial dimension) as a negative influence on esthetic outcomes.

Cosyn et al<sup>20</sup> in a retrospective cohort study, concluded using logistic regression analysis that facial positioning of the implant shoulder increased the likelihood of midfacial mucosal recession. Chen et al,<sup>40</sup> in a retrospective case series study analyzed 85 implants after 7 ( $\pm$  3.4) months. A facial implant shoulder position was significantly associated with recession of the midfacial mucosa.

In a retrospective cross-sectional study, Nisapakultorn et al<sup>37</sup> were not able to identify a correlation between orofacial implant position and recession when using logistic regression analysis. The authors did, however, report that a proclined implant angle was significantly associated with an increased risk of apical mucosal migration.

Only retrospective studies are available evaluating the influence of orofacial implant position on esthetic outcomes. It is, however, consistently reported that facial malpositioning of implants increases the likelihood of mucosal recession.

# Provisional or Temporary Restorations and Timing of Loading

The search identified 43 articles addressing provisional or temporary restorations. None of the identified studies directly compared esthetic outcomes associated with the use or non-use of provisional prostheses as the primarily experimental focus. Therefore, articles reporting esthetic outcomes for treatments utilizing provisional prostheses and outcomes for treatments excluding the use of provisional prostheses are presented.

In a RCT, Degidi et al<sup>15</sup> reported on 60 single-tooth maxillary lateral incisor replacements in healed ridges. Sites were randomly assigned to an immediate restoration protocol (30), or a delayed loading protocol utilizing only a healing abutment (30). All sites were definitively restored after 6 months of healing. Using

the papilla index score (PSI), no statistically significant differences were identified between the groups.

In a randomized controlled trial, Oh et al<sup>2</sup> reported outcomes for 24 patients treated with implant-supported restorations for single missing teeth in healed sites. Twelve patients were randomly assigned to the test group, receiving a provisional prosthesis in an immediate load protocol, and 12 patients served as the control group, receiving no prosthesis as part of a conventional protocol. For the control group a healing abutment was utilized for 4 months prior to restoration. Patients were evaluated 6 months subsequent to final restoration, and no statistically significant variation between test and control groups was established for PSI, recession of midfacial mucosa, or width of keratinized mucosa. This article represents the only RCT identified whereby the comparison treatments include the use versus non-use of provisional prostheses; however, the primary focus of the study was the loading protocol. It is possible, therefore, that outcomes are associated with the loading protocol rather than use of the provisional restoration. Therefore, meaningful conclusions are difficult to determine. Further, this study is limited by a short follow-up period.

The literature contains a greater number of case series studies evaluating esthetic outcomes for protocols including, rather than excluding, provisional restorations. The majority of case series studies describe outcomes for single missing teeth, and the heterogeneity in (1) study design, (2) follow-up period, (3) timing of implant placement, and (4) surgical protocol prevents identification of firm conclusions.

Of the 31 case series studies reporting outcomes of therapy that included use of a provisional restoration, 17 described alterations in mid-facial mucosal levels during follow-up. Of these, eight studies described mucosal stability (Di Alberti et al,<sup>26</sup> Brown and Payne,<sup>51</sup> Buser et al,<sup>36</sup> Chung et al,<sup>35</sup> Tsuda et al,<sup>33</sup> Tortamano et al,<sup>38</sup> Canullo and Rasperini,<sup>44</sup> and Cooper et al<sup>52</sup>). Importantly, nine authors reported recession (Cabello et al,<sup>22</sup> Cosyn et al,<sup>24</sup> Crespi et al,<sup>54</sup> Cosyn et al,<sup>32</sup> Gallucci

Assessment of outcome	Sufficient follow-up time for outcome to occur	Adequacy of follow-up	Total
	*	*	5
*			5
	*	*	5
*	*	*	8
*			5
*			6

et al,<sup>53</sup> Kan et al,<sup>34</sup> Malchiodi et al,<sup>30</sup> Zarone et al,<sup>57</sup> and Cornelini et al<sup>47</sup>). It is important to note that the loss of facial mucosal height reported (recession) may be associated with other treatment variables.

In a retrospective case series study, Buser et al<sup>41</sup> reported outcomes associated with 45 single-tooth replacements, where implants were placed and restored according to early protocols. Follow-up was reported as between 2 and 4 years, at which time all implants had maintained an esthetic subgingival margin according to implant shoulder to mucosal margin measurements.

Degidi et al,<sup>15</sup> in a retrospective case series, reported on 52 single-tooth implants placed in extraction sockets or healed ridges in the anterior region. Implants were restored according to an immediate restoration protocol. Papilla height changes showed no statistically significant variation over the follow-up period (from 6 months to 48 to 72 months after implant placement).

Four case series studies including the use of provisional restorations in the treatment protocol evaluated the esthetic outcome using the PES.<sup>23,31,40,50</sup> Four additional studies<sup>24,29,32,39</sup> assessed esthetic outcomes using both PES and WES. The significance of outcomes measured using PES/WES is difficult to determine for several reasons. The measured parameters vary between citations, and there is no accepted numerical value differentiating favorable versus nonfavorable esthetic outcomes. What constitutes an acceptable esthetic outcome therefore varies at an author's discretion.

Several studies with a primary focus on the timing of implant loading and using a protocol associated with provisional prostheses reported on esthetic outcomes. Lindeboom et al<sup>1</sup> in a RCT reported outcomes associated with placement of 50 implants into healed ridges. Treatment was randomly allocated to either an immediate loading or immediate restoration protocol. Although no statistical analysis was provided, the authors reported mesial and distal papillae regeneration in 70% and 91% of instances, respectively, for the immediate loading group versus 91% for both mesial and distal papillae for the immediate restoration group. The midfacial gingival levels were considered ideal for 100% of the immediate loading group, versus 91% of the immediate restoration group, with two implants demonstrating recession between 1 and 2 mm.

Donati et al,<sup>14</sup> in a multicenter RCT, reported on 159 single-tooth replacements where a provisional restoration was utilized. Fifty-seven sites were randomly assigned to conventional loading (control), 50 sites to immediate loading with conventional implant bed preparation, and 52 sites to immediate loading with osteotome site preparation. No statistical difference was determined throughout the follow-up period (time of restoration and six months subsequent) in papilla height or width of keratinized mucosa, based on the loading protocol assigned.

These two studies do not identify a positive or negative influence of provisional restorations on measureable esthetic outcomes based on immediate loading or immediate restoration protocols for implants placed in healed ridges. Therefore, although the volume of evidence is limited, based on existing evidence the decision to immediately load or restore implants positioned into healed ridges cannot be based on esthetic outcomes.

De Rouck et al,<sup>5</sup> in a RCT of 49 single implants positioned in extraction sockets, compared delayed loading after 3 months of healing (25) with immediate restoration (24). Patients were evaluated 1 year after implant placement, and no significant variation in papilla levels was identified. The authors reported significantly greater midfacial recession for the delayed loading group compared to the immediately restored group, with mean values of -1.16 mm and -0.41 mm, respectively. The mean difference in recession noted between the two groups was 0.75 mm.

Den Hartog et al<sup>3</sup> reported on 62 implants positioned into healed sites, with treatment randomly allocated to immediate restoration (31), and conventional loading (31) after three months of healing. Patients were evaluated 12 months after crown placement, and although papilla gain was observed for both groups, there was no significant difference in gain or PSI. For each group, midfacial mucosal levels remained stable with no significant variation between groups. Further, no significant variation between groups was identified using PES/WES.

Hall et al<sup>6</sup> evaluated 28 single implants positioned into healed ridges, randomly assigned to an immediate restoration (14 patients) or conventional loading protocol (14 patients). Follow-up evaluation was undertaken 10 months subsequent to the placement of the definitive crown and no significant variation was identified with regard to PSI. For the combined patient pool, the papilla was considered unchanged in 28.5% of instances and improved in 63%. No significant variation in midfacial mucosal levels was identified, nor was a significant variation identified in the width of keratinized mucosa.

The heterogeneity in study design, follow-up period, and treatment protocols prevents strong conclusions from being drawn; however, the limited evidence suggests that esthetic outcomes may not be influenced either positively or negatively based on the provisional restoration of implants placed according to different protocols.

In a split mouth, prospective cohort study, Ottoni et al<sup>21</sup> positioned two implants each in 23 patients and restored one immediately and one with a conventional protocol. No detailed information was available with regard to ridge condition at the time of placement, delay of loading for the conventional loading group, or for timing of definitive restoration placement. The soft tissue condition associated with each implant was evaluated 1 and 6 months subsequent to implant placement. For the test group (immediate restoration), the authors reported an improvement in papilla score for 88.2% of mesial sites and 65% of distal. For the control group, the corresponding papilla score improvements were 83.3% and 50%, respectively. For the test group, gingival levels were considered stable in 49.17% of instances, with recession noted in 31.66%. For the control group, these figures were 59.52% and 21.43%, respectively.

Therefore, based on these studies, the literature does not identify strong scientific evidence that esthetic outcomes are influenced positively or negatively by utilization of a provisional prosthesis. The utilization of provisional prostheses remains strongly recommended in order to test the planned final prosthesis, to facilitate maturation of healing tissues, and for patient convenience.

### **Abutments and Implant Platform**

Several articles compare horizontal and vertical offset (platform switching) implant designs. In a RCT involving 22 implants, Canullo et al<sup>7</sup> compared immediately positioned and restored implants cemented onto abutments that were horizontally offset (platform switched) or conventional (abutment diameter fit the implant diameter). The treatment provided was randomly generated, and definitive abutment allocation was similar to that of the provisional restoration. At an average of 25 months subsequent to provisional restoration placement, a significant difference was identified with regard to midfacial mucosal margin levels, with the horizontally offset group showing a mean gain of 0.18 mm, and the conventional abutment design characterized by a mean loss of 0.45 mm. Soft tissue (papilla) levels (with mesial and distal papillae considered as one group) were also significantly different, with the horizontally offset group associated with a mean gain of 0.045 mm, and the conventional group associated with a mean 0.88 mm loss.

Pieri et al<sup>8</sup> evaluated 40 implants positioned immediately into extraction sockets. In this RCT patients were randomly assigned to immediate restoration on a horizontally offset implant abutment or to immediate restoration on an abutment whose diameter matched the implant. The definitive abutments shared the morphology of the provisional abutment in each instance. No significance between groups was identified with regard to papilla height, with loss of height on the mesial and distal papillae being 0.3 mm and 0.25 mm for the horizontally offset design, and 0.36 mm for both the mesial and distal papillae for the conventional design group. Significant recession of the midfacial mucosa was reported for both the horizontally offset and conventional groups (mean 0.61 mm and 0.71 mm, respectively), although the difference between the two was not considered to be significant.

These two RCTs report similar test protocols that compare esthetic outcomes associated with the platform design. It is difficult, however, to draw conclusions due to the variation in outcomes reported.

In a retrospective cross-sectional study, Chang and Wennström<sup>25</sup> reported on 32 single-tooth implants placed in the anterior maxilla and characterized by a horizontal offset. No information about implant placement timing was provided. Provisional restorations were positioned after 6 months of healing and left in place for 4 weeks prior to final cementation of definitive metal ceramic restorations. After an average of 7.5 years of follow-up subsequent to implant placement (range 19 months to 14 years), PSI was recorded. A complete papilla was reported in 21 sites (38%) while 34 sites had what was described as deficient papillae (62%).

In a prospective case series, Oyama et al<sup>27</sup> reported on 17 reduced diameter (3 mm) implants positioned in maxillary and mandibular incisor sites. The implants were positioned into healed sites and immediately restored with provisional prostheses. Definitive metal ceramic prostheses were delivered 3 months subsequent to implant positioning. Papilla index scores were obtained 12 months after implant placement, and a statistically significant increase in both mesial and distal papillae scores was recorded. At the 12-month followup, 11 of 17 mesial papillae (64%) and 10 of 17 distal papillae (59%) were given maximum scores.

Lops et al,<sup>18</sup> in a prospective cohort study, compared a conventional vertical offset platform design with an abutment platform design characterized by horizontal offset. As part of the outcome evaluation, the mesial and distal papillae were evaluated 6 months subsequent to definitive restoration, with no significant difference being revealed.

As a result of the heterogeneity in study design, follow-up period, timing of implant placement, surgical protocols and pretreatment conditions, no firm conclusions can be drawn from the case series studies. Among the case series describing horizontally offset designs, six featured results including the midfacial mucosal levels. Of these, five<sup>33,35,36,44,52</sup> illustrated stability or a slight gain in midfacial mucosal height. One study<sup>24</sup> identified slight recession.

Of the 10 case series studies reporting on findings with conventional abutment connections, 8 identified slight recession, <sup>32,34,46,47,49,54,55,57</sup> and two authors reported stability of the midfacial mucosa.<sup>38,48</sup>

Three case series studies of implant platforms characterized by a horizontal offset,<sup>24,29,36</sup> and four characterized by conventional platforms,<sup>31,32,49,58</sup> reported outcomes using PES or PES/WES. As a result of inconsistency in measured parameters or scales considered esthetically acceptable, comparison of reported findings is not possible.

Two studies described esthetic outcomes from case series studies reporting on abutments inclined from the long axis of the implant.<sup>51,56</sup> Brown identified an overall improvement in height for both the mesial and distal papilla, while Vandeweghe reported improvement only for the mesial papilla. Brown reported midfacial mucosal stability, while Vandeweghe reported slight recession.

Two RCTs evaluated the contour of the implant abutment connection. den Hartog et al<sup>4</sup> reported esthetic outcomes associated with 93 single-tooth replacements. The implant design was randomly assigned as a smooth implant collar (31), a roughened implant collar (31), and a scalloped platform (31). At 18 months after implant placement, no significant variation was identified between groups for papilla height, with each showing a slight gain. PSI improved significantly for all groups; however, there was no significant difference between groups. The midfacial mucosal levels remained stable throughout the follow-up period, with no significant variation identified between groups.

Tymstra et al<sup>9</sup> compared adjacent implants characterized by a conventional (flat) platform to those characterized by a scalloped platform. A total of 80 implants were positioned in 40 patients, with implant type by platform randomly generated. All implants were allowed to heal for four months prior to loading. The sites were evaluated 1 year subsequent to the positioning of the final crowns. No significant difference in recession was noted based on platform design at the proximal surface between the implants and adjacent teeth; however, significantly greater recession was identified between the scalloped platform implants than between the implants with the conventional platform design. The scalloped implant design was also associated with significant midfacial mucosal recession.

Three additional case series studies reported on platform variables. Kan et al<sup>43</sup> reported papilla as being stable throughout follow-up, while the other two studies<sup>23,50</sup> reported PES only with no comparisons. None of these three studies evaluated midfacial mucosal changes. One case series study reported outcomes in papilla score index associated with monolithic implants.<sup>42</sup> For restorations in the anterior maxilla, 93% of sites were highly scored (3).

The volume of identified literature associating platform design and esthetic outcomes is small. It is not possible to identify any significant variation in esthetic outcomes based on the character of the abutment platform from the current literature volume.

### **Definitive Restorative Material**

In a RCT, Gallucci et al<sup>10</sup> reported on 20 single-tooth implant restorations placed according to an early loading protocol. According to a randomized allocation, 10 implants received a screw-retained all-ceramic restoration, while 10 received a screw-retained metal-ceramic restoration. Patients were evaluated 1 and 2 years subsequent to insertion of the definitive restorations, and no significant differences were identified between groups with regard to papilla height. After 1 year both groups recorded a significant increase in both mesial and distal papilla heights (0.23 mm and 0.17 mm, respectively). Between years 1 and 2 of follow-up, a significant increase was observed only in mesial sites (0.36 mm). No significant difference during follow-up was noted between groups with regard to clinical crown length. In both groups the mucosal showed significant recession (0.26 mm). Between groups there was no significant difference noted in the width of keratinized mucosathroughout follow-up, with the dimension being 4.83 mm and 4.67 mm for the all-ceramic and metalceramic restorations, respectively. No significant difference was identified between groups with regard to the combined PES/WES score, with the all-ceramic group and the metal-ceramic group recording 13.2 and 13.89, respectively. Interestingly, with blinded observation, there was no significant variation from random guessing with regard to differentiation of restorative material.

In a second article reporting on the same patient pool, Gallucci et al<sup>11</sup> reported outcomes of different parameters. While no significant differences were identified between the all-ceramic and metal-ceramic groups, in contrast to the outcomes in the previous study (Gallucci et al<sup>10</sup>) where 0.26 mm of recession was noted, the distance recorded from the implant shoulder to peri-implant mucosa was reported as stable over the follow-up period.

Hosseini et al<sup>12</sup> described outcomes of a RCT involving 36 patients and 75 single-tooth premolar restorations. According to randomized assignment, 38 of the implants were restored with an all-ceramic cemented definitive restoration, while 37 implants received a cement retained metal-ceramic option. At an average of 13.5 months subsequent to the positioning of the definitive restoration, each site was evaluated according to the Copenhagen Index Score (CIS). This protocol included crown morphology, crown color, mucosal discoloration, and the levels of the mesial and distal papillae. The only parameter associated with a significant variation between the groups was the crown color match. The all-ceramic groups identified a significantly lower score, associated with a statistically superior esthetic outcome. There was no significant difference in overall CIS between the groups.

Jung et al<sup>13</sup> evaluated 30 single-tooth implant supported replacements positioned in the anterior maxilla or mandible. Fifteen implants were randomly assigned to receive cement- or screw-retained all-ceramic definitive restorations, and 15 were assigned to receive cement- or screw-retained metal-ceramic restorations. Baseline was considered to be immediately prior to placement of the definitive restoration. The color of the peri-implant mucosa was assessed using a standardized reflectance spectrometer at both the implant site and at an adjacent tooth. No significant differences were noted in the color of the gingival tissues between implant and adjacent tooth sites prior to the positioning of the definitive restorations. Gingival thickness was recorded 1 mm apical to the free gingival margin for all sites and no significant difference between groups was identified. Subsequent to the positioning of the definitive restorations, gingival color was considered significantly more favorable (improved match to the adjacent tooth) when associated with the allceramic crowns in comparison to the metal-ceramic crowns, especially in sites characterized by thin tissue. It should be emphasized that the follow-up period was very short (1 to 2 weeks), and the longer-term outcome remains unknown.

Based on the results of the RCTs, no significant difference can be established between all-ceramic and metal-ceramic restorations with regard to esthetic indices (CIS, PES/WES) over short observation periods. There may be a favorable trend towards all-ceramic restorations with regard to color stability of periimplant tissues, and the correlation with thin tissue requires additional investigation.

In a nonrandomized retrospective cohort study, Henriksson and Jemt<sup>17</sup> evaluated 18 patients receiving 18 single-tooth implants in healed sites. A standard (prefabricated) abutment was used in conjunction with a metal-ceramic crown in 9 patients, and a customized ceramic abutment was used with an all-ceramic restoration for the remaining 9 patients. All implants were restored using a delayed loading protocol. While each group was associated with a significant increase in PSI through the 1-year follow up, no statistical variation was identified between the groups. Through the 1-year follow-up, both groups were also reported to have been associated with a significant decrease in buccal marginal soft tissue volume (rather than recession), although again there was no significant variation between groups.

The heterogeneity in study design, follow-up period, timing of implant placement, surgical protocol, and pretreatment conditions prevents firm conclusions being established from the case series studies addressing this topic. Of the 13 case series studies reporting findings associated with metal-ceramic restorations, eight reported midfacial mucosal level changes, with tissue stability being reported by three authors,<sup>35,38,48</sup> and slight recession being reported by five authors.<sup>28,32,34,54,57</sup> Two studies reported PES and WES.<sup>32,39</sup>

Of the seven case series studies describing outcomes associated with all-ceramic restorations, six reported changes in the midfacial mucosal levels. Stability was reported by four authors,<sup>33,36,44,51</sup> and two authors described slight recession.<sup>46,56</sup> PES and WES outcomes were reported by three authors.<sup>29,36,56</sup>

For each of the above combinations metal abutments supported metal-ceramic restorations, while ceramic abutments supported all-ceramic restorations. With regard to materials utilized for abutments and definitive restorations, it is clear that additional RCTs are required in order to identify clear esthetic benefits. There is a need to evaluate these materials in combination with tissue thickness. There are no studies evaluating different metal or ceramic options with esthetic parameters. Lastly, no advantage or disadvantage could be established based on material choice.

### Mode of Restoration Retention

No RCTs were identified comparing cement and screw retention with regard to esthetic outcomes. Twentyfour studies (1 cohort study, 1 retrospective crosssectional study, and 22 case series) were identified where a defined cement or screw retention was defined in the protocol, and esthetic outcomes were reported.

In a prospective, multicenter cohort study, Sherif et al<sup>16</sup> reported outcomes for 214 single or multiple implants positioned in healed ridges. Of the surviving implants, 103 of the implants were restored using a screw-retained restoration, and 90 were restored with a cement-retained restoration. All were restored using a conventional loading protocol. No significant differences in the width of facial keratinized tissue between groups were noted 60 months subsequent to restoration placement. In addition, no significant difference was observed in the distance measured from the top of the implant collar to the midfacial marginal gingiva between the cement- and screw-retained groups.

Santing et al<sup>19</sup> reported findings of their prospective cohort study primarily focused on grafted versus non-grafted sites, although the authors also compared screw and cement retention using WES, and marginal gingival recession. The results relating the mode of restoration retention are therefore reported here as a case series study. Of the 60 implants, 29 were placed in previously grafted sites, and 31 were positioned in sites that had not been grafted. Of the definitive restorations, 27 were cemented and 33 were screw retained. No significant difference was reported with regard to buccal midfacial recession through 5 months of follow-up. No significant difference was reported with regard to WES.

In a cross-sectional, retrospective study comparing PES of screw- and cement-retained single crowns, Cutrim et al<sup>58</sup> concluded after at least 1 year of followup, that no significant differences existed between the groups.

The heterogeneity in study design, follow-up period, timing of implant placement, surgical protocol, and pretreatment conditions prevents the drawing of meaningful conclusions from the case series studies. Seven case series studies reported outcomes associated with definitive screw-retained restorations. Six reported midfacial mucosal level changes, three noting stability<sup>36,38,51</sup> and three reporting slight recession.<sup>28,53,56</sup> One study<sup>36</sup> reported PES and WES, and one study<sup>31</sup> reported only PES. It should be noted that each of these case series studies described single-tooth situations with the exception of Gallucci et al,<sup>53</sup> which reported on full-arch restorations.

Fifteen case series studies described outcomes associated with definitive cement-retained prostheses. Of these, eight reported midfacial mucosal level changes, with two reporting stability<sup>33,44</sup> and six describing slight recession.<sup>30,32,34,49,46,57</sup> Two additional studies reported on PES,<sup>31,49</sup> and two reported PES and WES.<sup>24,29</sup> Meaningful conclusions regarding PES and/ or WES are difficult to identify.

No firm conclusions relating esthetic benefits for cement in comparison to screw retention can be identified from the literature. Further, the heterogeneity of the existing literature prevents meaningful comparisons and conclusions being drawn.

#### **Outcomes and Objective Esthetic Indices**

Two RCTs reported on outcomes based on objective esthetic indices. Den Hartog et al<sup>3</sup> reported on outcomes associated with 62 nonhorizontally offset implants positioned into healed sites. Of this total, 31 implants were allocated to an immediate restoration protocol and 31 implants to a conventional loading protocol. Definitive restorations were all-ceramic screw- or cement-retained. One year subsequent to the placement of the definitive restorations, mean PES for the immediate restoration group and the conventional loading group were respectively 7.1 (1.5) (range 3 to 10) and 6.5 (1.63) (range 4 to 10). Mean WES for immediate restoration group and conventional loading group were respectively 7.8 (1.5) (range 4 to 10) and 7.6 (1.6) (range 4 to 10). The differences between the two groups were not considered statistically significant.

Gallucci et al<sup>10</sup> reported on findings associated with 20 single-tooth implant restorations placed at least 2 months after implant placement. According to a randomized allocation, 10 implants received a screwretained all-ceramic restoration while 10 received a screw-retained metal-ceramic restoration. At 2 years subsequent to insertion of the definitive restorations, no significant difference was identified between groups with regard to the combined modified PES/ WES score. The all-ceramic group and metal-ceramic group recorded 13.12 and 13.89, respectively.

Several non-randomized studies reported outcomes using objective esthetic indices. Four case series studies including the use of provisional restorations in the treatment protocol evaluated the esthetic outcome using the PES. <sup>23,31,40,50</sup> Five additional studies assessed esthetic outcomes using both PES or modified PES and WES.<sup>24,29,32,36,39</sup>

Three case series studies assessed implants with a platform characterized by horizontal off-set<sup>24,29,36</sup> and six studies assessed conventional platforms.<sup>31,32,39,40,49,58</sup> Two case series studies reported on a platform variable in correlation to PES.<sup>23,50</sup>

Two studies reported PES or modified PES combined with WES for metal-ceramic prostheses.<sup>32,39</sup> Three studies reported PES or modified PES combined with WES for all-ceramic restorations.<sup>29,36,56</sup> One study included both all-ceramic and metal-ceramic in its protocol and reported on PES and WES.<sup>24</sup>

Three studies reported on objective esthetic outcomes including both screw- and cement-retained restorations in their protocol; one study described WES,<sup>19</sup> and two studies reported on PES.<sup>31,58</sup> Three studies reported on screw-retained restorations only, one described modified PES/WES,<sup>36</sup> and one reported on PES/WES.<sup>56</sup> Three studies reported on cemented restoration only, one study described only PES,<sup>49</sup> and two studies reported on PES and WES.<sup>29,32</sup>

In a prospective case series, Vandeweghe et al<sup>56</sup> reported on 15 single-tooth implants (nonhorizontally offset) placed in healed ridges and restored according to an immediate loading protocol. The implant platform had a 12-degree angulation to the long axis. All

ceramic screw-retained definitive restorations were delivered 24 hours after implant placement. One year after baseline the authors described a mean PES of 8.53 with a range 6 to 10. At the same follow-up, 80% of sites had at least a score of 8. The mean value for WES was 6.53 with a range of 4 to 9, with 67% of sites exhibiting a score of at least 6.

In a cross-sectional retrospective study, Cutrim et al<sup>58</sup> reported on 40 single-tooth implants (nonhorizontally offset), 23 of which received screw-retained prostheses and 17 cemented prostheses. At least 1 year after definitive crown placement, the mean PES for the screw-retained group was 10.73 with a range 5 to 13, with 74% of restorations exhibiting a score superior to 10. For the cemented group, the mean PES was 10.41 with a range 5 to 14, with 64% of the prostheses exhibiting a score superior to 10. There was no statistically significant difference between groups.

In a cross-sectional retrospective study, Belser et al<sup>39</sup> reported on 45 tissue-level single-tooth implants placed according to an early placement protocol. Implants received provisional prostheses 6 to 12 weeks after surgical placement and were subsequently restored with metal-ceramic definitive prostheses. At 2 to 4 years from baseline, the mean value for modified PES was 7.8 with a range 6 to 9, and mean value for WES was 6.9 with a range of 4 to 10. The combined modified PES/WES was 14.7 with a range 11 to 18. At last follow-up, 22% of sites had an excellent modified PES (9 to 10), 78% had acceptable modified PES (6 to 8), and 0% had a poor modified PES (< 6).

In a prospective case series, Noelken et al<sup>23</sup> reported on 24 scalloped-platform implants restored according to an immediate restoration protocol. At 5 years follow-up, the mean PES was 10.5 with a range of 3 to 13. In 16 patients, preoperative and 5 years postoperative scores were available. Improvement was noticed in 18.75% of sites. Esthetic status was unchanged in 37.5%, and 43.75% showed a slight to moderate decrease on the esthetic rating scale.

In another prospective case series, Noelken et al<sup>50</sup> reported on 18 scalloped platform implants placed in extraction sockets with complete loss of the facial bony lamella. The implants were restored according to an immediate restoration protocol. The mean preoperative PES score was 12.2 with a range 8 to 14. After 13 to 36 months of follow-up (median 22 months), the mean PES score was 12.5 with a range 10 to 14. From preoperative situation to last follow-up, 44% of sites showed improvement, 28% featured unchanged PES, and 28% featured slight to moderate decrease on PES value.

In a prospective case series, Buser et al<sup>36</sup> reported on 20 bone-level implants (horizontal offset) placed according to an early implant protocol. Provisional prostheses were delivered between 8 and 12 weeks after implant placement. Subsequently, all-ceramic screw-retained definitive prostheses were delivered. At the 1-year follow-up, mean modified PES scores were 8.1 and mean WES 8.65. After 3 years of follow-up, mean modified PES were 8.1 and WES 8.65. After 3 years, modified PES was considered excellent (9 to 10) for 45% of sites, acceptable (6 to 8) for 50% of sites, and poor (< 6) for 5% of sites.

In a retrospective case series, Chen et al<sup>40</sup> reported on 85 tissue-level single-tooth implants placed according to type 1 protocol and restored according to a conventional loading protocol. After a mean follow-up period of 26 months, with a range 10.3 to 46.7 months, the mean PES score was 10.95 with a range of 8 to 14. Of the sites, 39% featured an excellent PES score (12 to 14), 52% of sites showed an acceptable PES score (9 to 11), and a poor score (PES 0 to 8) was noticed in 9% of sites.

In a prospective case series, Juodzbalys and Wang<sup>49</sup> reported on 14 single-tooth implants (nonhorizontally offset) placed according to a type 1 protocol. Implants were restored according to a conventional loading protocol and the definitive prostheses were cemented. At the 1-year follow-up, mean PES was 11.1 with a range of 10 to 14. Excellent PES (12 to 14) was recorded in 29% of sites, acceptable PES (9 to 11) was noted in 71% of sites, and poor PES (0 to 8) in 0% of sites.

In a prospective case series, Cosyn et al<sup>24</sup> reported on 22 horizontally offset, single-tooth implants placed according to a type 1 protocol. The provisional prostheses were delivered according to an immediate restoration protocol. Definitive prostheses included both all-ceramic and metal-ceramic crowns. At the 1-year follow-up, the mean PES was 12.15 with a range 10 to 13, and the mean WES was 8.63 with a range 7 to 10. There were no significant differences in WES between all-ceramic and metal-ceramic restorations at the 1-year follow-up.

In another prospective case series, Cosyn et al<sup>32</sup> reported on 25 single-tooth implants (nonhorizontally offset) placed according to a type 1 protocol and restored according to an immediate restoration protocol. The final prostheses were metal-ceramic and cemented. At 3 years follow-up, the mean PES was 10.48 with a range of 5 to 14. Mean WES was 8.17 with a range of 5 to 10. Excellent PES (12 to 14) was recorded in 36% of sites, acceptable PES (9 to 11) was noticed in 56% and poor PES (0 to 8) in 8%. Combined PES/WES was excellent (PES  $\geq$  12, WES  $\geq$  9) in 21% of sites, acceptable (PES 8 to 11, WES 6 to 8) in 58%, and poor (PES < 8, WES < 6) in 21%.

In a retrospective case series, Hof et al<sup>31</sup> reported on 60 single implants (nonhorizontally offset) placed in healed ridges. Provisional prostheses were delivered according to a conventional loading protocol. Of the definitive prostheses, 28% were screw retained and 72% were cemented. After a mean 4.1 years (range 1.2 to 8.1) follow-up period, the median PES was 11. Excellent PES (12 to 14) was described in 35% of sites, acceptable PES (9 to 11) was noticed in 38% and poor PES (0 to 8) was recorded in 27%. There were no statistical significant differences between screw- and cement-retained restorations according to PES scores.

In a prospective case series, Furze et al<sup>29</sup> reported on 10 single-tooth implants (horizontally offset) placed according to early placement protocol. Provisional prostheses were placed 2 to 3 months subsequent to implant positioning. Definitive prostheses were all-ceramic and cemented. After 1 year of follow-up, the mean modified PES score was 7.9 and the mean WES score was 7.0.

Santing et al<sup>19</sup> reported findings of a prospective cohort study primarily focused on grafted versus nongrafted sites, although the authors also compared screw and cement retention using WES. The results relating the mode of retention are therefore reported as a case series study. Of 60 single definitive restorations, 27 were cemented and 33 were screw retained. The mean WES score was 7.5 with a range of 4 to 10. There was no significant difference between screw- and cement-retained prostheses 12 months after definitive crown delivery.

### CONCLUSIONS

The existing literature reporting on the influence of restorative procedures on esthetic outcomes is small in volume and can be considered of generally low quality. There is a need for RCTs comparing accepted procedures in routine practice. There is some standardization for papilla evaluation, with PSI being widely reported. The reporting of midfacial mucosal levels (recession) is varied and a more accepted protocol for reporting is required. PES/WES is a promising method for the reporting of esthetic outcomes; however, at present there is no consistency in reference scale, making comparison between studies difficult at best. In addition, the majority of studies report on single-tooth replacement, and many of the outcomes may not be relevant or applicable to the large number of esthetic indications involving more than one tooth.

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### Soft Tissue Augmentation Procedures for Mucogingival Defects in Esthetic Sites

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Purpose: This systematic review was performed to address the focus question: "In adult patients with soft tissue deficiencies around maxillary anterior implants, what is the effect on esthetic outcomes when a soft tissue procedure is performed?" In addition, this paper reviews the importance of presurgical esthetic risk assessment (ERA) starting with comprehensive team case planning prior to surgical intervention and a restorative-driven approach. Materials and Methods: A thorough Medline database search performed on related MeSH terms yielded 1,532 titles and selected abstracts that were independently screened. Out of the 351 abstracts selected, 123 full-text articles were obtained for further evaluation. At each level, any disagreements were discussed until a consensus was reached. Results: A total of 18 studies were included in this systematic review of esthetic outcomes following soft tissue procedures around implants with soft tissue deficiencies. A preliminary analysis of the included studies showed that the vast majority were case series studies with most not providing objective outcomes of their results. Moreover, only one randomized controlled trial was identified. Therefore, quantitative data analysis and subsequent meta-analysis could not be performed. The included studies were grouped according to the intervention on the peri-implant soft tissue performed and six groups were identified. The periodontal procedures performed around dental implants gave initial good results from the inflammation involved in wound healing, but in virtually all cases significant recession occurred as healing resolved and the tissues matured. Conclusions: Although success of implant therapy is similar in the anterior maxilla and other areas of the mouth, the majority of studies evaluating this therapy in the esthetic zone are lacking literature support, few in number, devoid of long-term follow-up and number of patients, and are subject to inclusion bias. The use of the ERA tool for all esthetic zone cases can benefit both the clinician and the patient to avoid any miscommunication and problems of expectation upon completion. All the available knowledge on this topic, including the approaches described in this paper, is based on a very limited literature support and thus should be addressed with caution. These concerns should encourage long-term good clinical trials for better assessment of those issues. INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):155-185. doi: 10.11607/jomi.2014suppl.g3.2

Key words: keratinized mucosa, mucogingival surgery, peri-implant mucosa, recession

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ong-term clinical studies have shown that functional osseointegration is a predictable outcome when endosseous implants are placed in the treatment of missing teeth.<sup>1-5</sup> However, the success of dental implant therapy is no longer based only on functional osseointegration but positive patient outcomes of creating an illusion that the tooth replacement is in esthetic harmony with the remaining dentition upon smiling. Patients expect not only the ability to function long term with their restored implants but also to have a reasonable esthetic result. The knowledge base has significantly improved over the last two decades when it comes to clinicians' understanding of the biology and healing of the oral hard and soft tissues, with the esthetic zone being studied extensively over this time period. Although the success of dental implants is

Table 1         Implant Esthetic Risk	Profile Assessment		
Esthetic risk factors	Low	Medium	High
Medical status	Healthy patient, intact immune system	-	Reduced immune system
Smoking habit	Nonsmoker	lonsmoker Light smoker (< 10 cigarettes/d)	
Patient esthetic expectations	Low	Medium	High
Lip line	Low	Medium	High
Gingival biotype	Low scalloped, thick	Medium scalloped, medium thickness	High scalloped, thin
Shape of tooth crowns	Rectangular	Slightly triangular	Triangular
Infection at implant site	None	Chronic	Acute
Bone level at adjacent teeth	$\leq$ 5 mm to contact point	5.5 to 6.5 mm to contact point	7 mm to contact point
Restoration status of neighboring teeth	Virgin	_	Restored
Width of edentulous span	1 tooth $\ge$ 7 mm	1 tooth $\leq$ 7 mm	2 or more teeth
Soft tissue anatomy	Intact soft tissue	_	Soft tissue defects
Bone anatomy of alveolar crest	No bone deficiency	Horizontal bone deficiency	Vertical bone deficiency

similar in the anterior maxilla to that of posterior areas, attaining predictable esthetic results are not.

The straightforward, advanced, and complex (SAC) classification was developed to aid in clinical decisionmaking for the benefit of the patient and to help avoid complications based on the experience level of the clinician and the potential difficulty of the treated implant site.<sup>6</sup> The SAC classification system has both restorative and surgical categories that use a normative classification system, which can be influenced by modifying factors based on individual clinical situations. One area that can influence this classificationboth from a surgical and restorative perspective—is found in the International Team for Implantology (ITI) esthetic risk assessment (ERA) analysis (Table 1). The ERA is a pretreatment assessment tool that uses clinical precursors to determine the risk of achieving an esthetic result based on known surgical and restorative approaches in given clinical situations.<sup>7</sup> Esthetic risk factors (Table 1) should be addressed directly with the patient before the initiation of treatment to avoid any posttreatment misunderstandings that may result from unmet high expectations. The clinician can best avoid potential posttreatment complications and an unhappy patient by gathering information chairside with patients during their initial consultation visit and sharing it with them using aids such as the ERA form. This is also an excellent team (surgeon, restorative dentist, and patient) communication tool that can be used in all esthetic cases to help both the clinician and the patient achieve their esthetic goals.<sup>7</sup>

The SAC classification advises that the anterior maxillae is an advanced or complex treatment procedure and requires comprehensive preoperative planning and precise surgical execution based on a restorativedriven approach.<sup>6–10</sup> The goal of risk assessment is to identify patients whose implant therapy carries a high risk for a negative outcome. Avoidance of any potential postsurgical complication or misunderstanding on the patient's part is communicated prior to therapy, and based on the esthetic risk profile of the patient, an appropriate treatment plan is developed.<sup>7,10</sup> The more high-risk categories the patient falls into, the more conservative the surgical and restorative approach should be. This will help avoid any potential esthetic problems later.

The ITI Treatment Guide 19 states, "An esthetic implant prosthesis is defined as one that is in harmony with the perioral facial structures of the patient. The esthetic peri-implant tissues, including health, height, volume, color, and contours, must be in harmony with the surrounding dentition. The restoration should imitate the natural appearance of the missing dental unit(s) in color, form, texture, size, and optical properties."

In some cases of implants placed in esthetic areas of the mouth, conditions develop after implant placement where the implant restoration is no longer pleasing in appearance. In those cases, the important clinical question is whether or not a soft tissue procedure can restore the esthetic outcome of the restoration. The purpose of this paper was therefore to address a PICO (patient or population, intervention, control or comparison, outcome) question aimed at identifying literature that addresses this topic. In addition, this paper will review the literature on the role of keratinized gingiva in regards to maintaining periodontal health, the biologic differences in soft tissues between teeth and dental implants, and the timing and need for soft

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	In adult patients with soft tissue deficiencies around maxillary anterior implants, what is the effect on esthetic outcomes when a soft tissue procedure is performed?
Search strategy	
Population	#1 – jaw, edentulous, partially[MeSH Terms] OR partially edentulous OR partial edentulism
Intervention or exposure	# 2 - soft tissue graft OR connective tissue graft OR subepithelial connective tissue graft OR alloplastic graft OR alloderm OR xenograft OR mucograft OR free gingival graft OR coronally positioned flap OR double papilla flap OR roll technique OR push back OR vestibuloplasty OR apligraf OR living cell construct
Comparison	N.A.
Outcome	#4 - papilla OR papilla index OR keratinized mucosa OR width of keratinized mucosa OR recession coverage OR PES/WES OR pink esthetic score OR white esthetic score OR esthetic outcome
Search combina	tion #1 AND (#2 OR #4)
Database search	
Language	English
Electronic	PubMed
Journals	Clinical Oral Implants Research, International Journal of Oral Maxillofacial Implants, Clinical Oral Implants and Related Research, Implant Dentistry, Journal of Implantology, Journal of Periodontology, Journal of Clinical Periodontology, Periodontology 2000, International Journal of Periodontics and Restorative Dentistry, Compendium of Continuing Education Dentistry, Practical Periodontics and Aesthetic Dentistry, Journal of Esthetic Dentistry as well as bibliographies of articles and recent text books relevant to the topic. In addition, reference lists of recent review papers were searched for additional citations. <sup>11–22</sup>
Selection criteria	
Inclusion criteria	Clinical studies only Studies at all levels of evidence Implant placement in the esthetic zone, defined as the maxillary anterior and premolar region of the dentition
Exclusion criteri	Studies without any soft tissue deficiency around the implant at baseline Studies reporting soft tissue procedure performed previous to and at implant placement Animal studies

tissue augmentation procedures in helping to achieve an improved long-term and stable esthetic result. Furthermore, recommendations will be made on the variables that can predict the need for augmentation procedures and possible ways to clinically avoid their need by proper treatment planning exercises PRIOR to any surgical intervention. Our therapeutic goal is to provide the patient the best evidenced-based therapy with the least risk of patient morbidity.

### **MATERIALS AND METHODS**

### **Focus Question**

The focus (PICO) question to be addressed was: "In adult patients with soft tissue deficiencies around maxillary anterior implants, what is the effect on esthetic outcomes when a soft tissue procedure is performed?"

### Search Strategy

A search in the MEDLINE database was performed on 10/30/2012 using the following search query:

- (dental implants[MeSH Terms] OR oral implant OR endosseous implant) AND papilla OR papilla index OR keratinized mucosa OR width of keratinized mucosa OR recession coverage OR PES/WES OR pink esthetic score OR white esthetic score OR esthetic outcome OR soft tissue graft OR connective tissue graft (CTG)
- OR subepithelial connective tissue graft (SECTG)
   OR alloplastic graft OR alloderm OR xenograft
   OR mucograft OR free gingival graft OR coronally
   positioned flap (CPF) OR double papilla flap OR
   roll technique OR push back OR vestibuloplasty OR
   apligraf OR living cell construct. Further criteria are
   provided in Table 2.

### **Study Selection**

This search yielded 1,532 titles that were independently screened by two reviewers (DLC and GH).

The two reviewers compared their respective selection and the calculated Kappa score for inter-examiner agreement indicated a "fair" agreement ( $\kappa = 0.353, 95\%$ confidence interval [CI]: 0.303 to 0.403). Out of the initial 1,532 titles, 351 abstracts were obtained for further

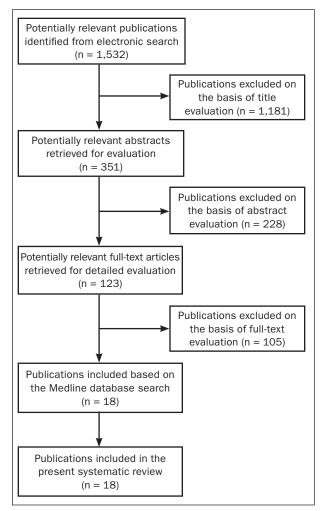


Fig 1 Selection process of the included publications.

evaluation. If article abstracts were not available, the reviewers included those articles to the next level, ie, full-text review.

Selected abstracts were independently screened by the same two reviewers (DLC and GH). The two reviewers compared their respective selection and the calculated Kappa score for inter-examiner agreement indicated a "good" agreement ( $\kappa = 0.743, 95\%$  CI: 0.670 to 0.815).

Out of the 351 abstracts selected, 123 full-text articles were obtained for further evaluation. The same reviewers compared their respective independent selection (on February 5, 2013) and the calculated kappa score for inter-examiner agreement indicated a "very good" agreement ( $\kappa = 0.833, 95\%$  CI: 0.692 to 0.975).

At each level, any disagreements were discussed until a consensus was reached. Finally, 18 full-text articles relevant to answer the PICO question formulated previously were included. The hand search did not yield any further articles to be included (Fig 1).

### **Excluded Studies**

Out of the 123 full-text articles assessed, 105 were excluded from the final analysis due to the following reasons:

- Review article
- Article describing a technique without any case report
- No soft tissue deficiency around the implant present at baseline
- Sites were located in the mandible
- Unable to distinguish data for sites in the anterior maxilla from posterior nonesthetic sites

### **Quality Assessment and Data Extraction**

From the included articles the following characteristics and data were extracted:

- Author
- Year
- Study design
- Number of patients
- Implant site
- Timing of implant placement (Type 1, 2, 3, or 4 according to Hämmerle et al)<sup>23</sup>
- Patient age
- Smoking status
- Soft tissue defect treated
- Intervention
- Follow-up
- Qualitative assessment of outcome
- Quantitative assessment of outcome
- Outcome measurement
- Conclusion of the study as reported by the author(s)

### **Statistical Analysis**

A preliminary analysis of the included studies showed that the vast majority of studies were case series studies. Moreover only one randomized controlled trial was identified. Therefore, quantitative data analysis and subsequent meta-analysis could not be performed.

### RESULTS

A total of 18 studies were included in this systematic review of esthetic outcomes following soft tissue procedure around implants with soft tissue deficiencies. Of these, one study was a randomized controlled trial (RCT) (Basegmez et al<sup>24</sup>). The remaining studies were case series with the vast majority including one to three patients (Hsu et al,<sup>25</sup> Hidaka and Ueno,<sup>26</sup> Cosyn et al,<sup>27</sup> Mareque-Bueno,<sup>28</sup> Lai et al,<sup>29</sup> Shibli and d'Avila,<sup>30</sup> Yan et al,<sup>31</sup> Shibli et al,<sup>32</sup> Matthews,<sup>33</sup> Block,<sup>34</sup> Price and Price,<sup>35</sup> Han et al,<sup>36</sup> Alpert,<sup>37</sup> and Silverstein and Lefkove<sup>38</sup>). The remaining three case series had either 10 (Becker et al<sup>39</sup> and Burkhardt et al<sup>40</sup>) or 20 patients included (Zucchelli et al<sup>41</sup>). Since no meta-analysis was possible, the review of these studies will be descriptive in nature.

The included studies were grouped according to the intervention on the peri-implant soft tissue performed and six groups were identified:

- Connective tissue graft (CTG) with a coronally advanced flap (CAF): Seven studies (Zucchelli et al,<sup>41</sup> Hidaka and Ueno,<sup>26</sup> Lai et al,<sup>29</sup> Burkhardt et al,<sup>40</sup> Shibli and d'Avila 2006,<sup>30</sup> Shibli et al,<sup>32</sup> and Price and Price 1999<sup>35</sup>)
- Connective tissue graft in combination with an envelope flap or pouch: Three studies (Hsu et al,<sup>25</sup> Cosyn et al,<sup>27</sup> and Silverstein and Lefkove<sup>38</sup>)
- Free gingival graft (FGG): Three studies (Basegmez et al,<sup>24</sup> Yan et al,<sup>31</sup> Han et al,<sup>36</sup> and Alpert<sup>37</sup>)
- Acellular dermal matrix (ADM) with a coronally advanced flap (CAF): One study (Mareque-Bueno<sup>28</sup>)
- Pediculated connective tissue graft (PCTG): Two studies (Matthews 2002<sup>33</sup> and Block<sup>34</sup>)
- Injection of hyaluronic acid: One study (Becker et al<sup>39</sup>)

Table 3 summarizes the included studies.

# Connective Tissue Graft (CTG) and Coronally Advanced Flap (CAF)

Two studies,<sup>40,41</sup> used this technique in case series including, respectively, 10 and 20 patients, with each patient having one implant presenting a mean buccal soft tissue recession of approximately 3 mm in both studies.

The technique used by Burkhardt et al<sup>40</sup> included the collection of a subepithelial CTG using a single incision harvesting technique,<sup>42,43</sup> which was secured on the prepared connective tissue bed recipient site and over the implant-abutment junction. The partial thickness flap, which was mobilized beyond the mucosalgingival junction (MGJ), was then coronally advanced and sutured to cover the graft. The mean initial recession depth reported was 3.0  $\pm$  0.8 mm. The final position of the mucosal margin was located up to 1.2 mm more coronally (mean, 0.5 mm) than the margin on the contralateral natural tooth. Therefore, immediately after surgery, all sites presented recession coverage of  $\geq$  100%. Unfortunately, these positive outcomes were not maintained over the 6-month follow-up. One month after surgery, a significant decrease of coverage to 75% (SD, 17%) was observed. Further decreases, although statistically significant, were reported for the 3- and 6-month follow-up visits with, respectively, 70% (SD, 18%) and 66% (SD, 18%) of the initial recession covered. The same trend of healing was observed for all the treated sites. The authors concluded that a CTG in

conjunction with a CAF could improve the condition of the soft tissue recession around dental implants. However, complete coverage was not achieved.

In contrast, Zucchelli et al,<sup>41</sup> with similar amount of soft tissue dehiscence at baseline ( $2.72 \pm 0.68$  mm), reported a mean coverage of 96.3% and complete coverage observed at 75% of the treated sites at the final follow-up visit, one year after final crown delivery. Moreover, the authors reported a significant increase in keratinized tissue height ( $0.57 \pm 0.41$  mm), in tissue thickness ( $1.54 \pm 0.21$ ), and patient satisfaction using a visual analog scale.

The discrepancy observed in the amount of recession coverage between the two studies was discussed by Zucchelli and coworkers.<sup>41</sup> They speculated that the difference in outcome was probably due to the fact that 1 month prior to surgery they removed the implant crown and reshaped and polished the underlying abutment. Moreover, the newly fabricated provisional crown was removed at the time of surgery. As a consequence of these prosthetic procedures, more room was created for the soft tissue graft to be placed over the implant-abutment interface and a better adaptation between the graft and the smoothed abutment surface was obtained. This may have contributed to the better clinical outcomes reported.

The five remaining studies<sup>26,29,30,32,35</sup> using a CTG and CAF to treat mucosal recession around implants included a total of six sites treated. Four studies did not report any objective outcome measurements but only a qualitative assessment of the coverage observed, such as "patient was pleased with the esthetics." Shibli et al<sup>32</sup> reported on one treated site for which a complete 3-mm recession coverage was achieved following surgery and the use of two temporary crowns. The limited amount of cases treated in each of these reports combined with the fact that all but one study (Shibli et al<sup>32</sup>) did not report any objective outcome measurements constitute anecdotal evidence that CTG and CAF may be able to improve soft tissue recession around dental implants.

# Connective Tissue Graft (CTG) and Pouch or Envelope Flap

Hsu et al<sup>25</sup> reported on one case in which an immediately placed implant at the right maxillary central incisor presented with a facial mucosal recession 3 months after surgery. A CTG with an envelope flap was performed at the site in order to correct the level of the soft tissue. Moreover, the provisional crown was modified to sculpt the tissue. A final crown was delivered 2 months after the procedure, and the results at 3.5 years were stated to demonstrate "favorable esthetic outcomes." No quantitative measurements were reported.

Table 3	Detail	s of Incl	uded Studi	ies					
Study	Year	Study design	Patients	Age	Smoking status	Implant site	Details on implant placement	Defect	Intervention
Zucchelli et al <sup>41</sup>	2013	Case series	20 (14 F/6 M)	26–53	< 10 cigarettes/d	Esthetic area	NR	Buccal soft tissue dehiscence	CTG and CAF, abut- ment modification (if needed), new restora- tion
Hsu et al <sup>25</sup>	2012	Case series	1 F	53	NR	Implant #8 (11)	Type 1	Mucosa recession observed 3 mo after place- ment	CTG with envelope flap and modification of provisional prosthesis
Basegmez et al <sup>24</sup>	2012	RCT	64 (36 F/28 M; 32 FGG, 32 VP)	60 ± 11	NR	NR	NR	Inadequate attached mucosa (< 1.5 mm)	FGG or VP
Hidaka and Ueno <sup>26</sup>	2012	Case series	1 F	33	NR	Implant #9 (21)	NR	3 mm abutment exposure on the buccal mucosa (dehiscence)	2× at same site: subepithelial CTG with CAF with 1 y interval and new restoration
Cosyn et al <sup>27</sup>	2012	Case series	2	NR	NR	In the esthetic zone	Type 1 flapless	Midbuccal facial recession 1.5 and 2 mm, 3 mo after placement	CTG
Mareque- Bueno <sup>28</sup>	2011	Case series	1 F	41	Nonsmoker	Implant #7 (12)	Type 1	Midfacial mucosa recession, 3 mm	ADM graft and CAF
Lai et al <sup>29</sup>	2010	Case series	1 F	39	NR	Implant #9 (21)	Type 4 (staged approach)	1 mm gingival recession after 1 y orthodontic treatment with provisional implant- supported crown #9	Removal of provisional crown and abutment. Resubmerged implant with CTG and CAF for 2 mo before uncovering and abutment/provi- sional crown delivery. 6 mo later, final cemented crown delivery
Becker et al <sup>39</sup>	2010	Case series 10 implants in 10 patients	NR	NR	NR	7 cases: Implant #7 (12) 3 cases: Implant #10 (22)	NR	Deficient papillae characterized by dark deficiencies adjacent to implant site	Injection of hyaluronic- acid based gel $2-3$ mm coronal to the tip of the deficient papil- lae at 3 wk interval up to $3\times$
Burkhardt et al <sup>40</sup>	2008	Case series	10	43–59	NR	Maxillary front	were two-stage (sum- erged) and	Soft tissue recession with unfavorable esthetics developed over 1-6 y (3 mm $\pm$ 0.8 SD)	CTG and CAF (covered graft + 2 mm)

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Follow-up	Qualitative measurements	Quantitative measurements	Outcome measurements	Conclusion
1 y after final prosthesis	NR	Difference in clinical parameters between baseline and 1 year	Increase in keratinized tissue height, 0.57 mm $\pm$ 0.41 ( $P < .01$ ); Increase in soft tissue thickness, 1.54 mm $\pm$ 0.21 ( $P < .01$ ); Reduc- tion in dehiscence, 2.62 mm $\pm$ 0.81 ( $P < .01$ ); Patient esthetic satisfaction improvement, VAS 4.2 ( $P < .01$ )	75% complete coverage (defined by comparison to contralateral tooth)
3.5 y after final prosthesis	Favorable esthetic outcome was main- tained for 3.5 years after delivery of the final prosthesis	NR	NR	NA
1, 3, 6, 12 mo after procedure	NR	Width of attached mucosa	FGG vs VP: baseline, $0.75 \pm 0.36$ vs $0.67 \pm 0.32$ ( $P = .37$ ); 1 mo, $5.11 \pm 0.71$ vs $4.89 \pm 0.84$ ( $P = .27$ ); 3 mo, $3.54 \pm 0.61$ vs $2.92 \pm 0.62$ ( $P < .05$ ); 6 mo, $3.26$ $\pm 0.59$ vs $2.06 \pm 0.62$ ( $P < .05$ ); 12 mo, $3.11 \pm 0.58$ vs $1.83 \pm$ 0.73 ( $P < .05$ )	Statistically significant improvement in attached mucosa width in both treatment groups and at all time points compared to baseline. FGG resulted in significantly more attached mucosa at 3, 6, 12 mo after surgery as compared to VP.
9 mo after second graft	Harmonious mucosa observed	NR	NR	Two-step split pouch technique with SCTG could achieve substantial soft tissue dehiscence coverage
6 and 12 mo after CTG	NR	Difference in recession	1 and 1.5 mm reduction of recession	Final recession, 0.5 mm in 2 cases
2, 4, 6 mo	Partial coverage was obtained	NR	NR	
3 y postgrafting	Soft tissue contour in the anterior region was harmonious	NR	NR	If peri-implant soft tissue recession occurs, the implant resubmergence technique with CTG can provide es- thetic result.
6-25 mo after initial injec- tion	At the final examination, none of the patients showed evidence of relapse	Percentage change of black triangle size	3 cases 100% (complete fill); 6 cases: 88%–97%; 1 case: 57% Mean ± SD (calculated): 92.4% ± 13.0%	The use of an injectable hyaluronic get to enhance papillary esthetics after implant treatment should be evalu- ated in a controlled clinical study. The results of this pilot study are promising.
6 mo	After 6 mo, only partial coverage	% coverage, width of keratinized mucosa	1) At surgery: 100% (8 out of 10 cases overcompensated up to 1.2 mm, mean 0.5 mm); 1.3 mm (SD 1 mm), contralateral tooth 2.3 mm (SD 1.6 mm) 2) At 1 mo: 75% (SD 17%) (Decrease is significant $P < .05$ ); 1.3 mm (SD 0.5 mm) 3) At 3 mo: 70% (SD 18%) (decrease not significant); 1.2 mm (SD 0.5 mm) 4) At 6 mo: 66% (SD 18%) (decrease not significant); 1.1 mm (SD 0.5 mm)	All sites clinically significant improvement but none had complete coverage at 6 mo.

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Table 3 co	ontinue	ed Deta	ils of Inclu	ided Stu	idies				
Study	Year	Study design	Patients	Age	Smoking status	Implant site	Details on implant placement	Defect	Intervention
Shibli and d'Avila <sup>30</sup>	2006	Case series	1 M/1 F	26 (M), 25 (F)	NR	Implant #8 (11), #9 (21)	NR	<ul> <li>#8: implant facial margin apical to adjacent natural central incisor</li> <li>#9: dehiscence showing healing abutment and non- keratinized mucosa</li> </ul>	New abutment and crown, SECTG and CAF and antibiotics in both cases
Yan et al <sup>31</sup>	2006	Case series	1 M	35	NR	Implants #7 to #10 (12 to 22)	NR	Insufficient keratinized tissue (≤ 1 mm)	$28 \times 11 \text{ mm FGG and}$ antibiotics
Shibli et al <sup>32</sup>	2004	Case series	1 F	37	NR	Implant #9 (22)	Type 1	3 mm midfacial gingival recession	CTG + CAF with a provisional crown, 6 wk after surgery, 2nd provisional crown, 4 months after surgery
Mathews <sup>33</sup>	2002	Case series	3 F	45, 35, 18	NR	1) Implant #8 (11) 2) Implant #7, 10 (12,22) 3) Implant #10,11 (22,23)	NR	<ol> <li>Soft tissue profile deficient, platform fixture visible, black triangles visible with provisional prosthesis</li> <li>Midfacial reces- sion</li> <li>Gingival disharmo- ny due to soft tissue deficiency</li> </ol>	Pediculated CTG ro- tated over implant and underneath a facial pouch
Block <sup>34</sup>	1999	Case series	1 F	40	NR	Implant #10 (22)	Type 2	Thin gingiva over implant with metal showing. Translucent thin gingiva pre- vented an esthetic restoration.	Palatal roll flap
Price and Price <sup>35</sup>	1999	Case series	1 F	41	NR	Implant #8 (11)	Type 1	Siebert class III defect and hard and soft tissue deficiencies in the apicocoronal and buccolingual direc- tions.	1st surgery: free CTG with a 3-mm epithelial collar to increase soft tissue volume and keratinization 2nd surgery (17 days later): CAF
Han et al <sup>36</sup>	1995	Case series	1 F	50	NR	5 in anterior maxilla	NR	Lack of keratinized mucosa	Strips of FGG covered by foil and periodontal dressing

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Follow-up	Qualitative measurements	Quantitative measurements	Outcome measurements	Conclusion
2 y	Both patient "pleased with final esthetic result; mucosal margins 2-3 mm more coronal and at same level as adjacent central incisor	NR	NR	Modification of the peri-implant margin and repositioning of the abutment with a new abutment closer to adjacent tooth CEJ were important. Authors felt that the position of the implant shoulder in relation to the CEJ, the amount of keratinized tissue, and the implant buccolingual axis are important.
6 mo	Uneventful healing, best color blend 1 mo post-op, complete keratinization and maturation at 3 mo	Width of keratinized tissue	Baseline, mean 0.5 mm; 3 mo, mean 8 mm (net gain 7.5 mm, 30.5% shrinkage); 6 mo, mean 7.8 mm (net gain 7.3 mm, 32.4% shrinkage)	The FGG gave a patchlike appearance, achieved satisfactory result, and increased the width of keratinized tissue.
18 mo recall	Peri-implant soft tissues were stable and patient was pleased with esthetic results.		Mucosal margin was 3 mm more coronal. No recession in com- parison to adjacent contralateral central incisor.	The use of a subepithelial c tissue graft to restore the labial mar onnective gin discrepency of a single implant-supported crown in the anteror maxilla was described. The procedure was successful and demonstrated esthetic improvement and stability of peri-implant tissue over a follow-up period of 18 mo.
after surgery 2) Final resto- ration 11 mo after surgery 3) Final res-	2) Improved tissue con-	NR	NR	The pediculated CTG is an excellent technique that can be used for vertical and labial augmentation of soft tissue. It can be employed to improve unesthetic soft tissue structures around implants and can also be used to augment deficient ridges where pontics are scheduled.
NR	Healthy soft tissue appearance around implant	NR	-	NR
	6 wk after surgery: adequate apicocoronal tissue height and bucco- lingual width; 3 y after: patient very pleased with esthetics, soft tis- sue defect corrected	NR	NR	A subepithelial CTG with an emer- gence-profile provisional crown and final restoration may be used to successfully restore the gingival papil- lae and augment ridge soft tissue adjacent to a dental implant.
2 wk	Increased attached keratinized gingiva and presence of firm keratin- ized tissue provided a tighter seal around implant, resulting in easier maintenance of oral hygiene for patient. Inflammation, bleed- ing on probing, probing depths decreased.	NR	NR	With the strip gingival autograft, extended areas with mucoginigval problems can be treated in one appointment, which makes it a very practical technique. This techique consistenly provides a wider zone of keratinized gingiva and promotes a tight seal of firm tissue around implants for improved health.

Table 3 c	able 3 continued Details of Included Studies								
Study	Year	Study design	Patients	Age	Smoking status	Implant site	Details on implant placement	Defect	Intervention
Alpert <sup>37</sup>	1994	Case series	2 F	64, 17	NR	1st case: Implant #13 (24) 2nd case: Implant #7 (12)	NR	Case 1: Lack of keratinized gingiva, Case 2: Soft tissue concavity and blue appearance	FGG
Silverstein and Lefkove <sup>38</sup>	1994	Case series	1 M	40 y	NR	Implant #10 (22)	NR	Concavity and gum with gray appear- ance	SECTG underneath par- tial thickness flap

FGG = free gingival graft; VP = vestibuloplasty procedure; NR = not reported; CTG = connective tissue graft;

CAF = coronally advanced flap; ADM = acellular dermal matrix; SECTG = subepithelial connective tissue graft.

Cosyn et al<sup>27</sup> reported on the outcomes of 22 immediately placed implants in a 1-year prospective study. At 3 months, two cases demonstrated advanced mid-facial recession of 1.5 and 2 mm, which were corrected by means of a connective tissue graft. The recession measured at the 1-year time point was 0.5 mm for both cases.

Silverstein and Lefkove<sup>38</sup> also presented one case in which a gray peri-implant mucosal appearance and a concavity were observed around an implant at the left maxillary lateral incisor. However, no recession was reported at the baseline. The soft tissue deficiencies were corrected by a subepithelial CTG placed over the dental implant underneath a partial thickness flap. This procedure resulted in a desired soft tissue prominence and masking of the gray color.

### Free Gingival Grafts (FGG)

Four publications<sup>24,31,36,37</sup> have reported on the use of an autogenous free gingival graft (FGG) in mucogingival surgeries to augment implant esthetic soft tissue defects. Most of these procedures were used to increase the amount of keratinized tissue around an implant; however, the need for such tissue remains controversial. Only one of the studies involved more than one or two cases using a FGG. That study<sup>24</sup> described a randomized controlled clinical trial around implants to augment the amount of keratinized tissue using a FGG versus a vestibuloplasty procedure (VP). In this 1-year study 64 patients with less than 1.5 mm of keratinized tissue were randomized between the groups. Study criteria included mobile mucosa but no recession or radiographic bone resorption. Smokers were excluded. Each site demonstrated inflammation with signs of bleeding on probing, hyperemia, or swelling. Measurements (made by an independent examiner) at baseline, 1, 3, 6, and 12 months included Plaque Index (PI), Gingival Index (GI), probing

depth (PD), and the width of attached mucosa (WAM). The FGG procedure was performed following the techniques described by Bjorn<sup>44</sup> and as followed by Sullivan and Atkins.<sup>45</sup> The VP was performed as described by Edlan and Mejchar.<sup>46</sup> Healing was uneventful and no patients experienced any complications. The change in WAM from baseline at all time points was significant for both techniques (P = .000). The 3-, 6-, and 12-month WAM gains were significantly greater (P = .000) in the FGG group compared to the VP group, with the 1-year gain in the FGG group being 2.36 mm compared to the VP group with 1.15 mm.

A critical finding in many of these soft tissue procedures is relapse after healing. In this study, the amount of relapse at one year was significantly less (P = .000) in the FGG group (2.00 mm) compared to the VP group (3.06 mm). It is important to note that both procedures resulted in large amounts of relapse in WAM. In addition, pocket depth values were significantly greater (P = .02, P = .024 and P = .000, respectively) in the VP group at 3, 6, and 12 months in this study. Plaque accumulation and gingival inflammation at all measurement points were not significantly different between test (FGG) and control (VP) groups. Although the patients reported no significant complications, the FGG group participants did complain about the donor site, reporting moderate to severe pain in that area. The examiner in this study could not be blinded due to the clear differences clinically when using a FGG tissue graft compared to a VP. One criticism of this report is that the location and number of each type of tooth treated was not reported. The authors concluded that in spite of the observed relapse that occurred using both procedures, that the use of a FGG to augment the amount of keratinized tissue around implants is more effective than a VP.

Follow-up	Qualitative measurements	Quantitative measurements	Outcome measurements	Conclusion
NR	Case 1: excellent zone of keratinized gingiva. Case 2: improvement of contour and decrease in blue appearance	NR	NR	NR
8 wk	Successful soft tissue root prominence and masked gray color.	NR	NR	NR

In one of the three papers involving a single case report,<sup>31</sup> a patient received an autogenous FGG and an acellular dermal matrix (ADM) allograft in the maxillary and mandibular anterior areas respectively (randomly allocated) to augment keratinized mucosa around multiple implants. The patient was 35 years old and did not smoke. Measurements were made at baseline, 3, and 6 months postsurgery. These measurements (all made by one examiner) included Plaque and Gingival Index, probing depth, and gingival recession on the facial aspect with the implant shoulder as the reference point. At baseline, no more than 1 mm of keratinized tissue was found on the facial aspect of the implants. The ADM allograft was placed with the basement membrane side exposed and the connective tissue facing the periosteal recipient bed and was not covered by the mucosal flap. Antibiotics were prescribed for 2 weeks. Both recipient sites healed uneventfully but postoperative bleeding did occur at the palatal donor site. The FGG was best color-matched 1 month after surgery and at 3 months was reported to be completely keratinized with mature healing. At 6 months there was an increase in keratinized tissue. The authors felt that the ADM allograft took approximately 2 weeks longer to heal than did the FGG with surface necrosis occurring at 2 weeks. Graft shrinkage was noted at 1 month with keratinization occurring by 2 months. Epithelialization and color blend was found at 3 months with maturation and stability of the tissue at 6 months. The width of keratinized tissue increased significantly with both procedures. The FGG graft at baseline had a mean of 0.5 mm and increased to 7.8 mm at 6 months. The ADM allograft had 0.6 mm at baseline and 2.4 mm at 6 months. Shrinkage occurred at both 3 and 6 months, and for the ADM allograft was 78% and 82%, while shrinkage for the FGG was 30.5% and 32.4%, respectively. No significant difference was found between the FGG and the ADM allograft in regards to plague and gingival index or in gingival recession after 3 and 6 months. The authors felt that the FGG had a more "patch-like" appearance than did the ADM allograft with poorer esthetics and more postoperative complications due to the donor site. Another difference in procedures is that the FGG autograft is limited in the amount of tissue availability compared to the unlimited allograft material; however, the ADM allograft had greater shrinkage than did the FGG and the ADM site had much less keratinized tissue after 3 and 6 months. As reported, both grafts achieved satisfactory results; however, the FGG achieved a greater increase in keratinized tissue than did the ADM allograft. Because only one case was reported, the influence of the jaw (maxilla versus mandible) on the outcome is unknown and may have affected the final results in this case report.

A descriptive publication regarding a zone of keratinized tissue around teeth and implants reported on five cases, two of which involved soft tissues that were augmented with a FGG in esthetic areas.<sup>37</sup> In one case, a 64-year-old woman had an implant placed at the maxillary left second premolar site. After 6 months, a FGG from the palate was used to provide an adequate zone of keratinized tissue. The final restoration revealed an "excellent zone of bound-down keratinized gingiva around the implant." In a second case involving an implant in the maxillary right lateral incisor site in a 17-year-old woman, the patient was concerned about a concavity on the facial and a bluish, veiny appearance of the soft tissues. In this case an autogenous FGG was used to eliminate the concavity and change the appearance of the tissue. The surgical technique left a small collar of tissue on the facial to help prevent recession and did not involve the interproximal papillae. A 2.0- to 2.5-mm thick FGG tissue graft was placed in the site and the authors reported a "substantial change" in overall color and contour of the facial tissue. However, the tissues did remain slightly bluish in color and edematous in the marginal tissue surrounding the crown.

The last publication involved a case report using a variation in the gingival autograft technique to augment unattached and nonkeratinized mucosa around an implant.<sup>36</sup> This technique utilized individual strips of palatal tissue in order to minimize patient discomfort from the traditional autogenous palatal FGG. Five implants supporting an overdenture had been in place for approximately 4 years in the maxillary anterior of a 50-year-old healthy Asian woman. She presented with chronic inflammation and pain in the loose, nonkeratinized soft tissues surrounding the implants. This swollen, pinched tissue was a recurrent problem every 2 to 3 months and required denture relief and a soft liner until the inflammation resolved. This technique includes preparation of the recipient site by suturing the elevated flap to the apical border of the prepared site and the harvesting of thin narrow palatal strips approximately 2 mm wide and 0.50 to 0.75 thick leaving intact palatal tissue between the donor strips to facilitate donor site healing. No sutures or dressing is used at the donor area. At the recipient site, dry foil and surgical dressing is used to stabilize the palatal tissue. At one week, superficial sloughing of tissue was observed as well as epithelialization of the wound. The patient experienced minimal discomfort at both donor and recipient sites and there was increased epithelialization in both areas. The patient reported more comfort in the area of the implants after the procedure. The authors suggest that extended areas can be treated since only strips are used, and that at 3 months there is condensing of the healing strips with coronal migration of the mucogingival junction to a width similar to the total width of the donor strips, regardless of the width of the prepared recipient site or the way in which the strips are laid on the periosteal bed.

### Allograft and Coronally Advanced Flap

One case report<sup>28</sup> described the use of an ADM graft as an alternative to an autogenous FGG to augment the facial soft tissues around a single implant placed at the time of tooth extraction in the esthetic zone approximately 2 years prior to presentation. In this case report, a coronally advanced flap was combined with the ADM to cover an exposed implant restoration. A 41-year-old systemically healthy, nonsmoking female presented with a chief complaint that the implant prosthesis at the maxillary right lateral incisor was esthetically unacceptable due to marginal tissue recession and that the recession had been increasing over time. The clinical examination revealed thin tissues with 2 mm of pocket depth, 3 mm of facial recession, and 2 mm of keratinized mucosa and an exposed implant shoulder. The authors used a novel incision design (no vertical incisions) where triangular shaped incisions were made mesially and distally, the depth of which was the dimension desired for flap advancement. The coronal aspect was a butt joint and the rest beveled apically. A partial-thickness flap was created so that the flap could be advanced passively over the ADM allograft. The patient was placed on antibiotics for 7 days. Healing in the first few weeks showed scarring and papilla shrinkage. Six months after treatment, partial coverage of the recession occurred with no bleeding on probing and pocket depths less than or equal to 2 mm. There appeared to be some recession of the tissue between the 2- and 6-month recall visits. The implant shoulder was covered, the scarring had disappeared and the shoulder of the implant was no longer visible. The authors felt that the post-treatment facial tissue was thicker than at pretreatment and the patient was satisfied with the result.

### Pediculated Connective Tissue Graft (PCTG)

Two publications reported on cases where a pediculated connective tissue graft (PCTG) was used to improve unesthetic implant restorations. One paper described three cases using this technique to treat what appeared to be three different causes for unesthetic restorations in the maxillary anterior.<sup>33</sup> One case involved a 45-yearold female patient who had repeated prior surgeries yet presented with deficient tissue at the gingival margin and interproximal areas of an implant in the site of the right maxillary central incisor. The treatment plan involved removal of the crown and abutment, placement of an internal cover screw, and healing time for new tissues to grow over the implant. After 3 months, a palatal approach was used to uncover the implant and labial pouch was created with a split-thickness dissection. Pediculated connective tissue from the palate was dissected from the area of the first molar toward the central incisor with the length and width scribed to bone. After elevation from the bone, the pedicle with its base just lingual to the site to be augmented was flipped over a 2-mm healing abutment and tucked into the pouch and sutured. The graft extended at least 3 mm past the implant platform into the pouch. An orthodontic appliance was used over the teeth to keep pressure off of the soft tissues. After 4 months a punch technique was used to uncover the healing screw and a 4-mm healing abutment was placed. Three weeks later, a provisional prosthesis was fabricated and used for 2 months, after which a final impression was taken.

A second case involved a 35-year-old female with two apically and labially malpositioned implants that had been placed 2 years prior to presentation for con-

genitally missing lateral incisors. The implants were visible and the marginal gingiva was 4 mm apical to their ideal location. Similar to the first case, the prostheses were removed, and in this case, implant level impressions taken and then internal cover screws used. Two months later, a 2-mm healing abutment was placed and a PCTG tucked into a labial pouch as described above. Four months were allowed for healing and then a punch technique used with an ovate provisional partial denture for an additional 3 months. Provisional prostheses were then placed for 3 months prior to definitive all-ceramic restorations were made.

In the last case an 18-year-old female presented who had lost the maxillary left lateral incisor and canine due to trauma. Two implants were placed with significant apical gingival margins. A connective tissue graft had been performed that augmented the labial tissues but did not provide coronal placement so the gingival levels remained unesthetic. The patient was wearing a removable provisional prosthesis over the implants. The treatment plan involved covering the implant in the position of the lateral incisor and placing a cantilevered partial denture on the implant in the left canine position. A PCTG was utilized as described in the cases above and the final prosthesis utilized an ovate partial denture over the covered implant. In this case, some gingivalcovered porcelain was used to enhance the final restoration. The authors felt that using wide, long, and thick PCTGs that vertical soft tissue augmentation can be predictably achieved; however, the depth and thickness of the palate will influence the amount of tissue that can be utilized. A complication of this technique is excessive tissue on the palatal aspect where the tissue was flipped over (a palatal bump) which might need to be carefully thinned. The authors warned that because the tissue is so vascular, prolonged bleeding could occur even with the punch uncovering procedure. Furthermore, deep probing depths may occur around apically placed implants since vertical soft tissues become thick over the implants in some cases. Lastly, the author cautions that the gingival margin in these cases will recede over time in spite of the augmentation procedure and the use of an angulated abutment.

A variation of a pedicle connective tissue graft from the palate has been described in another publication of a single case report.<sup>34</sup> A partial-thickness palatal flap is reflected in this technique, exposing the connective tissue over the palatal bone. This denuded palatal tissue is elevated beginning at the apical extent of the palatal flap coronally over the covered implant and then folded or rolled under the full thickness of the facial aspect of the flap, creating a thicker amount of facial tissue. The author states that this technique is limited in that only about 1 mm of thickness is obtained whereas with a subepithelial connective tissue graft, one generally obtains around 2 mm of augmented tissue. Thus, this de-epithelialized PCTG involving a roll technique is limited to small defects that require small increases in gingival thickness. The advantages claimed are that the papillae are not involved and all scars are located on the palatal side of the tissue and are not visible. Thick palatal rugae make this technique difficult and a subepithelial CTG is recommended in those cases. One case is presented involving a 40-yearold female who dislocated and lost the left lateral incisor and had an implant placed 2 months after this injury. Four months after implant placement, the patient presented with thin tissue and metal showing through the tissue resulting in an unesthetic appearance. The palatal roll technique was performed to increase the thickness of the facial gingiva and hide the metal show-through. Sutures were used to secure the rolled tissue on the labial as well as to secure and align the gingival margins avoiding excessive vertical tension. A temporary or removable prosthesis must be used to relieve pressure on the tissue during healing. After 1 month, a gingivoplasty was performed to create an anatomical sulcus and after gingival healing occurred, the final restoration was fabricated.

#### **Hyaluronic Gel**

Papillary deficiencies around dental implant restorations significantly hamper esthetic results of teeth and implant restorations. One study examined a case series of patients who had deficient papillary tissue around dental implants.<sup>39</sup> Eleven patients with 14 sites, including seven women and four men ranging in age from 25 to 75 years (average 55.8 years) were injected with a commercially available hyaluronic acid gel (less than 0.2 mL) 2 to 3 mm apical to the coronal tip of the deficient papillae after a short-acting local anesthetic was administered. Informed consent included that this use of the gel was not approved and was considered experimental or off-label. The patients were seen every 3 weeks and the treatment repeated up to three times. Follow-up ranged from 6 to 25 months after initial injection. Standardized photographs were not used and a computerized program measured changes in pixels and the percent change in negative space between the initial and final examination was calculated. The results revealed that two sites had 100% improvement, seven sites had 94% to 97% improvement, three sites had from 76% to 88% improvement and one site had 57% improvement. In regard to multiple injections, eight sites required two injections and six sites required three injections. According to the authors, there was no relapse in the therapy and all patients considered the treatment to be painless with six patients feeling that their treatment resulted in a clinically significant improvement.

### DISCUSSION

A systematic review of the PICO question, "in adult patients with soft tissue deficiencies around maxillary anterior implants, what is the effect on esthetic outcomes when a soft tissue procedure is performed?" yielded 1,532 titles that after two independent reviews by two of the authors ended up in 18 reviewable articles. Our extensive literature search has demonstrated that the available knowledge on this topic is based on a very limited literature support and, thus should be addressed with caution. Only one article was randomized and controlled and the rest were either small case series or a case report demonstrating a technique. Furthermore, few of the case reports provided objective outcomes of their results. In most all reports, techniques used around teeth were applied to implant soft tissue dehiscences and to areas of thin soft tissue or minimal amounts of keratinized tissue. It should be pointed out, however, that because the soft tissue relationships around teeth and implants are different, particularly in regards to the soft connective tissue, the outcomes of periodontal procedures may not be applicable to dental implants. In fact, due to the lack of periodontal ligament and transeptal fibers that insert into root cementum, one might speculate that such periodontal procedures might result in less optimal long-term results around dental implants. The findings in the included systematic review articles are noteworthy regarding the fact that the periodontal procedures performed around the implants gave good initial results from the inflammation involved in wound healing, but virtually all cases resulted in some significant recession as healing resolved and the tissues matured.

Most all cases involved autogenous soft tissue grafts, which is not surprising since this tissue is predominantly used in periodontal mucogingival defects. Due to the fact that soft tissue grafting does not always adequately address the esthetic needs around an implant, the logical conclusion is that attempts should be made to prevent an esthetic soft tissue defect from occurring. This can be helped by performing preimplant placement risk analyses and by making certain that adequate bone is present to support the implant, completely encase the endosseous implant, and support the soft tissue, since there is a limit as to how much soft tissue can exist beyond the bone.

### **Presurgical Planning and Consultation**

An important goal in maintaining a long-term esthetic implant result in the anterior maxillae is creating stable hard and soft tissues. Achieving a long-term esthetic result starts with comprehensive team case planning prior to surgical intervention and a restorative-driven approach.<sup>47–56</sup> A patient's presurgical implant evaluation in the esthetic zone should include an initial visit to establish a diagnosis and prognosis based on a comprehensive examination of the patient's medical, dental, and compliance history, including their periodontal and restorative needs. Diagnostic casts and necessary radiographs may include cone beam computerized tomography (CBCT) to evaluate important anatomical landmarks,57,58 skeletal relationships, and bone availability to aid in careful presurgical planning. Skeletal relationships may require an initial orthognathic evaluation with an oral maxillofacial surgeon and orthodontist or an endodontist who may aid in determining a definitive prognosis of the tooth or teeth in question. In addition, in younger patients, the determination of alveolar bone growth cessation is important prior to anterior maxillary implant placement frequently by evaluation of sequential cephalometric radiographs over a 6- to 12-month time frame. The concern is to avoid placing an implant too early in teenagers or young adults who may not have stopped growing, as the alveolar bone will continue to grow adjacent to the implant, leaving an asymmetrical gingival and incisal relationship with an unesthetic result. Intraand extraoral photographs with documentation of the patient's smile at rest and full smile is recommended. These pictures aid in the treatment planning of the case and may influence the surgical approach.<sup>7,9,10,59</sup>

During the presurgical evaluation and consultation, the clinician should also review with the patient their ERA (see Table 1) and establish their overall esthetic risk. This would take into account the patient's smile line and esthetic demands, and establish a comprehensive site analysis of hard and soft tissue thickness and width along with the patient's gingival biotype. If a CBCT is taken, evaluation of the buccal plate presence or lack of along with ridge width will aid the surgeon in preplanning the case and assessing the need for soft and/or hard tissue augmentation<sup>23,60–63</sup> at the time of or prior to implant placement. The CBCT can also guide the surgeon as to the surgical approach to be performed (type 1: immediate placement with extraction, type 2: 6 to 8 weeks postextraction, type 3: 3 months postextraction, type 4: healed ridge).<sup>23,59–63</sup> The dentist can then determine the need for, and if appropriate, the fabrication of an anatomically correct surgical guide to aid in correct three-dimensional placement.<sup>7,8,10,56,64</sup> Diligent presurgical planning and thorough local site evaluation with subsequent patient discussions can frequently help to avoid potential esthetic complications postsurgery. Knowledge of hard and soft tissue dimensions of the existing local site to be treated is helpful in the treatment planning process and in planning for long-term esthetic stability.

### **Considerations for Treatment Options**

There are three important considerations which will influence treatment options of the existing local site:

- The bone: is augmentation needed or not?
- The patient's gingival biotype and its importance in treatment planning decisions.
- The soft tissue: is augmentation needed and what are the surgical options and timing if it is necessary?

Importance of Presurgical Buccal Bone Width. A key determinant of a long-term esthetic implant restoration is the available bone in three dimensions. Without adequate bone, labial recession with vertical bone loss of the buccal plate, loss of the interproximal papillae, and poor implant positioning will result.<sup>56,64–66</sup> Although this paper addresses soft tissue augmentation procedures, there is also a need to evaluate the existing local site and its hard tissue and alveolar bone, as its width may reflect the need for a soft tissue or hard procedure concomitant with implant placement. Bone availability at an edentulous site for a future implant can be measured via bone sounding and mapping under local anesthesia, palpation, or most accurately, with the evaluation of a CBCT. When placing implants it would be of interest to know the anatomical dimensions and width of the ridge or socket walls if immediate placement is anticipated prior to the procedure. A presurgical CBCT can provide invaluable information on the need for bone grafting and anticipated implant width, length, and need for creating or reducing the anticipated implant site with orthodontic therapy or extrusion for implant site development.55,67,68 Based on limited studies and a general consensus, the scientific community seems to agree that ideally a minimum of 2 mm of buccal bone wall (and preferably more than 2 mm) is necessary once the implant osteotomy has been prepared in a healed site to ensure proper soft tissue support and to avoid the resorption of the buccal bone wall following restoration.<sup>8,64,65,69–71</sup> Spray and coworkers<sup>71</sup> evaluated two-stage implant placement in healed sites and measured facial thickness at time of implant placement and after 3 to 6 months at second stage uncovering using calipers. There was significantly greater bone loss seen as the facial bone thickness decreased. Sites with > 3 mm of bone loss showed the lowest mean facial bone thickness at 1.3 mm. Whereas sites with no change in facial bone response had a mean thickness of 1.8 ± 1.10 mm at implant placement. Thus, a critical thickness to help in clinical decision-making to reduce facial bone loss was determined at 2 mm. If this minimal requirement is not met, then a hard tissue ridge augmentation procedure (before or at implant placement) should be performed to obtain this minimum dimension of 2 mm after anticipated implant placement.<sup>72-76</sup>

The loss of a tooth sets in motion a number of biologic phenomena resulting in the horizontal and vertical loss of the buccal and lingual plate. The alveolar process that harbors a tooth is comprised of spongy bone enclosed in an envelope of compact bone. This compact or cortical bone is continuous with the dense bone found at the lateral aspect to the periodontal ligament (PDL) and is referred to as bundle bone. The periodontal ligament provides the blood supply to bundle bone of a tooth when present and can do so for a lifetime without bone loss even in situations of it being less than 1 mm thick.<sup>77</sup> As buccal bundle bone is part of the periodontium, and thus a toothdependent tissue, it develops in conjunction with the eruption of the tooth.<sup>78</sup> The removal of the tooth will render this bone useless, and its resorption is a natural consequence resulting in buccal and lingual wall resorption and alveolar ridge reduction. This canine study<sup>78</sup> showed the importance of the alveolar ridge width in bone architecture maintenance. The buccal bone plate is significantly thinner than the lingual plate, with horizontal resorption most likely also causing vertical height reduction of this thinner buccal bone, with minimal loss of the lingual plate. This marked reduction of the buccal-lingual dimension of the alveolar ridge after tooth removal agrees with other studies.<sup>79–83</sup> In the study by Botticelli and coworkers,<sup>81</sup> when measurements were taken 4 months after the removal of single teeth (maxillary and mandibular canines and premolars) with immediate implant placement, the buccal-lingual dimensions of the marginal bone of the edentulous sites was significantly reduced (approximately 2.8 mm or 40%). In a multicenter prospective, randomized controlled parallel-group study<sup>83</sup> of 104 patients and 111 sites to evaluate bone preservation, Sanz and coworkers studied implants with differing geometries placed in fresh extraction sites in the maxilla, and found that the corresponding ridge reduction at 4 months was much less at 1.6 mm or about 25%. The discrepancy between studies may be related to the larger number of patient sites treated as well as the larger number of implant surgeons who were involved in this latter study.83 This agrees with immediate placement of an implant in a dog model, which also did not prevent the buccal lingual ridge contractions that were seen following extraction alone.84-87 Interestingly, in the Araujo et al<sup>84</sup> and Botticelli et al<sup>85</sup> studies the implants were positioned in the center of the alveolus with the coronal margin of the rough surface flush to the level of the buccal alveolar wall. This aspect of recommended implant positioning will be addressed later.

The socket bone wall dimensions were studied by CBCT in the anterior maxillae of 93 patients<sup>69</sup> in a prospective randomized controlled multicenter clinical study in relation to immediate (type 1) implant placement. Huynh-Ba and coworkers<sup>69</sup> found that 87% of the buccal bone walls were thin ( $\leq 1$  mm) and only 3% of the buccal bone walls were thick (2 mm wide). They also noted that the buccal bony wall was significantly thinner than the palatal bony wall. This agrees with other human clinical studies.<sup>88–90</sup> The authors<sup>69</sup> suggest that in most clinical situations encountered, augmentation procedures are necessary to achieve adequate buccal bony contours around the implant if the minimum buccal bone width of 2 mm is valid to maintain buccal bony wall stability over time. In a follow-up multicenter study at 4-month reentry of these same patients, Tomasi and coworkers<sup>91</sup> used multilevel, multivariate models to further analyze factors that may affect tissue alteration occurring at the buccal and palatal aspects of the bony crest during healing after immediate placement of an implant into an extraction socket. The following variables were evaluated: (1) the distance between the implant surface and the outer bony crest (S-OC), (2) the horizontal residual gap (S-IC), (3) the vertical residual gap (R-D), and (4) the vertical position of the bone crest opposite the implant (R-C). Measurements made at surgical reentry 4 months postimplant placement revealed that (1) the S-OC change was significantly affected by the thickness of the bone crest, (2) the size of the residual gap was dependent on the size of the initial gap and the thickness of the bone crest, and (3) the reduction of the buccal vertical gap was dependent on the age of the subject. In addition, the position of the implant opposite the alveolar crest of the buccal ridge and its buccolingual implant position influenced the amount of buccal crest resorption. The authors stressed that as part of the decision-making process, clinicians need to be aware of the buccal bony wall in the extraction site and the vertical as well as the horizontal positioning of the implant in the socket, as these factors will influence hard (and subsequent esthetic soft) tissue changes during healing.<sup>91</sup> Thus the further to the palatal aspect of the socket that the implant is placed, the less implant exposure was seen at the buccal aspect after 4 months. This also correlated well with the apical placement of the implant. This conclusion was valid irrespective of all other influencing factors included in their model (ie, thickness of remaining bony walls, patient age, smoking habit ,and reason for extraction). In addition, at sites with thick bony walls (> 1 mm), there was more bone fill than at sites with a thin alveolar crest ( $\leq 1$  mm). Bone fill had the same relationship, as its amount on the buccal as well as on the palatal aspects was similar and dependent on the original thickness of the alveolar crest.

Smoking and age as patient-related factors also negatively influenced bone fill. The vertical gap fill (RD) was smaller in older than younger subjects and S-IC change was smaller in smokers than nonsmokers. Others have also found that smoking negatively affects the healing of periodontal intrabony defects<sup>92-94</sup> and maxillary socket healing postextraction.<sup>95</sup>

In a recent CBCT study, Januario and coworkers<sup>89</sup> measured the facial bone wall at 1, 3, and 5 mm from the bone crest in the anterior maxillae in 250 patients and found that in most locations in all tooth sites examined was  $\leq$  1 mm thick and that close to 50% of sites had a bone wall thickness that was  $\leq$  0.5 mm. In addition, the distance from the cementoenamel junction (CEJ) and the facial bone crest varied between 1.6 and 3 mm in this study. To achieve a lasting biological and esthetic outcome an ideal buccal bone width of 2 mm is recommended once the osteotomy site is performed. It can be speculated that immediate implant placement with extraction may require even a greater width to account for the dimensional changes seen following tooth extraction.<sup>69</sup>

In a retrospective review of the esthetic outcomes, Evans and Chen<sup>96</sup> evaluated 42 nonadjacent singleunit implant restorations using an immediate implant surgical placement protocol with a restorative platform of 4.1 (3i implants) or 4.8 mm (Straumann implants). They found a highly significant change in crown margin height due to marginal tissue recession of 0.9  $\pm$  0.78 mm, which was recorded at all sites with no difference seen between implant systems. Implants with a buccal shoulder position showed three times more recession than implants with a lingual shoulder position (1.8  $\pm$  0.83 mm vs 0.6  $\pm$  0.55 mm).

Schropp and coworkers<sup>82</sup> examined tissue changes that occurred at the mesial and distal septa between the adjacent tooth and the extraction site following single tooth removal and found only minor alterations at these interproximal locations at 12 months of healing. They did find a reduction in residual alveolar ridge up to 50% in width during the first 3 months of healing. Studies have also shown that multiple adjacent extraction sites induce greater apicocoronal alterations compared with single-tooth extractions. Thus as a consequence of removal of all adult teeth, the alveolar processes will atrophy.<sup>97–99</sup> Replacing multiple adjacent teeth in the esthetic zone becomes a greater challenge than single-tooth replacement, as the amount of hard and soft tissue requiring replacement to create gingival symmetry of contralateral natural teeth is difficult if not impossible to obtain, especially in a patient with high esthetic demands and a high lip line. The general loss of buccal bone in these multiple extraction cases can therefore have great clinical implications, and attempts should therefore be made to limit ridge alterations that would occur. Pietrokovski and Massler<sup>79</sup> noted that this loss amounted to between 3 and 3.5 mm. The results of a recent study by Januario and coworkers<sup>89</sup> confirmed results seen clinically, that as much as 50% of the facial wall thickness in the maxillary anterior was  $\leq$  0.5 mm. It may be concluded based on these two studies that once a tooth is lost, not only may the entire marginal buccal bone wall be lost, but an additional 2 mm of the original socket dimension may also disappear during the process of healing. For a review of ridge preservation techniques see three excellent reviews.<sup>16,20,74</sup>

In another CBCT study, Miyamoto and Obama<sup>88</sup> measured the thickness of the labial alveolar bone and its corresponding level of vertical resorption in 18 patients in 31 sites who underwent implant placement in the maxillary anterior region, using either a delayed two-stage placement using nonresorbable expanded polytetrafluoroethylene (e-PTFE) guided bone regeneration (GBR) membrane with a mixture of anorganic bovine bone (DBBM) and freeze-dried bone allograft (FDBA) (group 1), delayed placement using a resorbable GBR membrane with the same graft material (group 2), or immediate placement with autogenous bone grafting (group 3). The buccal plate was measured by CBCT at least 6 months later and the relationship between each measurement and gingival recession was analyzed. Group 1 maintained the most sufficient esthetic mucogingival conditions based on minimal gingival recession (less than 0.5 mm) supported by ample alveolar bone (average of  $2.22 \pm 0.81$  mm in the cervical section) with little vertical bone loss ( $0.13 \pm 0.36$  mm). Group 2 had 50% of sites showing measurable gingival recession (0.50  $\pm$  0.53 mm) and corresponding vertical bone loss (0.70  $\pm$  1.02 mm) as well as decreased buccal alveolar bone (average  $1.15 \pm 0.82$  mm in the cervical section). The worst result was in Group 3 where gingival recession was  $0.85 \pm 0.75$  mm, vertical bone loss  $3.25 \pm 4.68$  mm, and buccal alveolar bone  $1.19 \pm 0.60$  mm. There was a negative, but significant, correlation between vertical bone loss and cervical width, as well as middle section width and a similar negative correlation between the cervical and middle width with gingival recession. Vertical bone loss and gingival recession showed a significant positive correlation as expected. The data suggest that gingival recession post-implant placement in the anterior region could be negatively associated with alveolar bone thickness as well as the level of alveolar bone width at the labial aspect. The authors postulated that after implant placement in the anterior region, gingival recession was minimal by a labial bone thickness of more than 1.2 mm at the cervical area of the implant at least 6 months after placement as determined by CBCT. If this 1.2 mm is added to the approximate average bone loss

of 0.7 mm<sup>100</sup> that occurs after raising a flap and disrupting the periosteal vasculature, then the criteria of 2.0 mm appears satisfied (0.7 mm + 1.2 mm = 1.9 mm).<sup>88</sup> This study and others suggest clinical caution as immediate implant placement in the esthetic zone is a technique-sensitive, advanced to complex SAC procedure.<sup>7,8,10,21,23,53,56,63,64,66,96</sup> This study partially agrees with a prospective study on early (type 2) implant placement at 8 weeks postextraction by Buser and coworkers<sup>60</sup> who with the aid of a bioabsorbable collagen membrane in combination with autogenous bone grafts and DBBM (which has a low substitution rate), were able to provide successful contour augmentation on the facial aspect of implants and soft tissue stability for up to 3 years. The esthetic outcomes as measured by the pink esthetic score (PES) and the white esthetic score (WES) were favorable for 19 of 20 cases treated in this manner with the platform-switching concept in implant design. One case out of the series measured less than 1 mm of facial recession at 3 years. The stability of the facial soft tissues can be attributed in part to stable facial bone with the use of DBBM granules that will not be resorbed during the natural bone-remodeling process, which helps in maintaining the dimensions of the facial bone wall. Sanz and coworkers' systematic review on early implant placement in postextraction sockets found that this surgical protocol may offer advantages in terms of soft and hard tissue preservation, when compared to a delayed placement protocol.<sup>22</sup> The type 2 placement protocol is in contrast to various clinical studies using type 1 placement, which is summarized in a recent systematic review by Chen and Buser.<sup>101</sup> Lang and coworkers'<sup>21</sup> recent systematic review on immediately placed implants into fresh extraction sockets noted approximately 20% of patients who underwent immediate implant placement and delayed restorations had suboptimal esthetic outcomes due to facial marginal gingival recession in studies of 3 years or more.<sup>21</sup> These studies on immediate implant placement have documented an alarming high incidence of mucosal recession in the range of 20% to 40%.<sup>96,101–105</sup> The recent 4th ITI Consensus Conference in 2008 on dental implant therapy and on immediate implants in particular recommended that immediate implant placement should be considered in selected healthy patients with a low esthetic risk profile and performed by master clinicians with adequate clinical experience and expertise.75

To further emphasize the advanced to complex SAC classification of implant placement in the anterior maxillae, Kan and coworkers<sup>63</sup> evaluated 100 patient CBCTs retrospectively and classified the relationship of the sagittal root positions of the maxillary anterior teeth (600 samples) to their respective osseous housings. They found that 81.1% were class 1 (the root is

positioned against the labial cortical plate), 6.5% were class 2 (the root is centered in the middle of the alveolar housing without engaging either the labial or palatal cortical plates at the apical third of the root), 0.7% were class 3 (the root is positioned against the palatal plate) and 11.7% were class 4 (at least two thirds of the root is engaging both the labial and palatal cortical plates). The authors believe that this information of the sagittal root position will aid in treatment planning of immediate implant placement with immediate provisionalization (IIPP) with improved interdisciplinary communication. The authors consider class 4 sagittal root position (SRP) as a contraindication for IIPP that requires hard and/or soft tissue augmentation prior to implant placement. This study further supports the importance of a local site CBCT and precise assessment and pre-operative planning as an adjunct to implant treatment planning.<sup>106–109</sup> It allows clinicians to appropriately recognize sites that are favorable for IIPP (class 1 SRP) and sites that are more technique sensitive (class 2 and 3 SRP).

Finally, the horizontal gap buccal to the implant is another important factor to consider in addition to implant placement and its affect on bone remodeling. Ferrus and coworkers<sup>110</sup> found that in reentry (stage 2 surgery) at 4 months of 93 placed implants at sites between the maxillary premolars where the horizontal gap buccal to the implant was large (> 1 mm) and where the buccal bone width was wide (> 1 mm) the greatest bone fill was noted. This horizontal gap bone fill was more pronounced in the maxillary premolar than the incisor-canine region. However, the degree of bone fill as measured by horizontal defect resolution was more pronounced in smaller defects. Thus larger buccal gaps will not predictably be completely resolved following immediate implant placement. The authors suggest that grafting material may improve treatment outcomes.<sup>110</sup> Their findings agreed in most respects with Botticelli and coworkers<sup>81</sup> who also found that the marginal gap could predictably heal with new bone and defect resolution after immediate implant placement in fresh extraction sites.

*Importance of the Patient's Gingival Biotype.* Gingival biotype is a term used to describe the thickness of the gingiva in a buccolingual dimension. There is a clinical impression that patients who exhibit a thin tissue biotype also have a thin buccal plate overlying the roots of the maxillary anterior teeth.<sup>111–115</sup> De Rouck and coworkers<sup>114</sup> also noted two distinct gingival biotypes. In one-third of their patient population and most prominent in women, was the thin gingival biotype classification with a slender tooth form, narrow zone of keratinized tissue, and high gingival scallop. In two-thirds of the study population and seen predominantly in males was a thick gingival biotype with quadratic tooth form, broad zone of keratinized gingiva, and a flat gingival margin.

Cook and coworkers<sup>115</sup> looked at CBCTs, diagnostic impressions and clinical examinations in 60 (26 thin biotype, 34 thick/average biotype) patients in the maxillary canine-to-canine area in cases where no gross tooth malposition were present which can affect the soft and hard tissue thicknesses and position to the alveolar crest. Compared to a thick/average biotype, a thin biotype was associated with a thinner labial plate thickness, a narrower width of keratinized tissue, a greater distance from the CEJ to the initial alveolar crest and probe visibility through the sulcus. This study was the first human evidence to support the clinical impression that a thin biotype is associated with a thin underlying labial plate and a greater distance from the CEJ to the alveolar crest, and a thick or average biotype is associated with a thicker labial plate and a reduced distance from the CEJ to the alveolar crest.<sup>115</sup> Probe visibility through the gingival sulcus was a good clinical indicator to differentiate a thin from a thick/average biotype and can be used as a simple diagnostic tool by the clinician. Since the esthetic outcome of implant and other periodontal surgical therapies can be influenced by many factors, knowledge of a patient's gingival biotype can be helpful in clinical surgical decision-making, since the majority of patients likely have teeth in which the distance from the CEJ to the alveolar crest is between 2.5 and 3.5 mm (71.4%), with less frequent measurements of < 2.5 mm (9.2%) or > 3.5 mm (19.4%).<sup>115</sup> Kan and coworkers<sup>116</sup> defined a thin biotype as one where the outline of the periodontal probe can be seen through the marginal tissue when probing, whereas a thick biotype is one where the probe is camouflaged by the marginal tissue. In their 2- to 8-year follow-up<sup>117</sup> of the same patient population (mean 4 years), all 35 maxillary anterior Nobel Biocare implants that were immediately restored were successful with the mean overall facial gingival level change of -1.13 mm significantly greater than that of -0.55 mm at the 1-year exam. This would indicate that facial gingival recession is a dynamic process and may continue beyond 1-year post-implant placement. The effect of tissue biotype on peri-implant tissue response was limited to facial gingival recession and not the interproximal papilla, which partially rebounded over time. Sites with a thick tissue biotype showed significantly less facial gingival level change than sites with a thin tissue biotype at both the 1-year post-implant placement (-0.25 mm vs -0.75 mm, respectively) and final examination at a mean of 4 years postplacement (-0.56 mm vs -1.50 mm, respectively). The authors speculated that the lack of bone grafting of any of the implant-socket gaps or connective tissue under the buccal margin for biotype conversion in the

original protocol may have contributed to the significant overall facial marginal gingiva changes seen in that study. In studies where bone and soft tissue grafting were done to eliminate the implant-tooth socket gap, the observed recession was significantly smaller.

Evans and Chen<sup>96</sup> also noted that the thin tissue biotype has more of a tendency to recede around dental implants. In their study the thin tissue biotype sites showed greater recession than thick biotype sites (mean 1.0 vs 0.7 mm) although the difference was not statistically significant. They also found that recession was seen at both thin and thick biotype sites and only 14.3% of the sites demonstrated no recession. Thus, presenting with a thick tissue biotype does not make one immune to gingival recession postplacement. Sites with thin tissue biotypes had a greater frequency of gingival recession of 1 mm or greater compared with a thick tissue biotype (45.8% vs 33.3%, respectively) with a mean recession of 1.8  $\pm$  0.82 mm (range, 1 to 3 mm) and 1.3  $\pm$  0.52 mm (range, 1 to 2 mm), respectively. The thin tissue biotype should be looked at as having a higher possible propensity for a greater magnitude of recession in the anterior maxilla than the thick tissue biotype, especially if the implant shoulder is in a more buccal position (as the recommended position is lingual in relation to the center of the alveolus). Similar to thin gingival tissues, thin peri-implant tissues appear more susceptible to recession due to thinner tissues being more friable, less vascularized, and thinner than underlying osseous tissue.113,115,117 A thicker tissue biotype is important in implant dentistry as the peri-implant tissue is lacking a periodontal ligament (PDL) blood supply which aids in healing around teeth.<sup>113</sup> vans and Chen<sup>96</sup> made important points as to variables that are important besides implant position and tissue biotype. These include surgical and restorative techniques and technical skills and patient variables such as the presence and thickness of the buccal plate, soft tissue volume, and thickness. Smoking, compliance, and plaque control also need to be added as potential variables.<sup>118–120</sup>

In contrast, a prospective randomized clinical study by van Kesteren and coworkers<sup>121</sup> measured the soft tissue position following immediate and delayed implant placement and found no significant differences in midbuccal and interproximal soft tissue changes regarding thin vs thick tissue biotypes and implant surgical approaches at 6 months. In this study there was no clear-cut definition for tissue biotype, and additionally, the data may have been affected by the buccal gap bone grafting that was completed in the immediate implant group only.

# Statements on Bone Availability and Tissue Biotype

When considering implant placement in the anterior maxillae, there are a number of factors that will influence hard tissue and subsequently soft tissue and esthetic changes. Recommendations to help in controlling these factors include:

- Use of a CBCT for pre-planning and evaluation of buccal plate thickness along with sagittal root position is helpful in establishing an appropriate treatment plan and in guiding proper 3D placement. An anatomically correct surgical guide is recommended when the interdisciplinary team members deem necessary.
- 2. Thickening thin bone buccal to the implant in an early placement or healed site with a bioabsorbable collagen membrane in combination with autogenous bone and DBBM granules appears to maintain buccal contours and soft tissue margin location in a mid-term study. Clinical experience would recommend at least 2 mm of bone buccal to the implant upon healing. This dimension helps create soft tissue stability long-term.
- 3. Correct 3D placement with the vertical (1 mm deeper than the buccal wall) and horizontal position (lingual in relation to the center of the alveolus) of the implant in the socket in an immediate placement case and a minimum of 1.5 to 2 mm from an adjacent tooth or 3 mm between dental implants. Implants placed in extraction sockets should have a larger safety margin with the implant shoulder positioned at least 2 mm from the internal buccal socket wall.<sup>122</sup>
- 4. Measuring the width of the horizontal gap (horizontal defect dimension [HDD]) in an immediate placement case with consideration for bone grafting at the time of immediate placement to limit bone remodeling of the buccal plate with subsequent significant facial gingival recession.
- 5. Noting the patient's tissue (gingival) biotype, which is a reflection of the bony profile in the anterior maxillae, since the thin tissue biotype may be more prone to extremes of marginal tissue recession. Since a thick tissue biotype is desirable, the decision to convert a thin tissue to a thick tissue needs surgical consideration through soft tissue grafting for more predictable surgical and prosthetic outcomes.
- 6. It should be noted that good plaque control and periodontal health should be established prior to any implant surgical procedure, as this would be a major risk factor for future peri-implant disease.

Good compliance to a future periodontal maintenance program along with smoking reduction with a goal of cessation should be addressed presurgically with the patient.

### Importance of Keratinized Gingiva and Tissue Thickness Around Teeth and Implants

The keratinized gingiva includes the free and the attached gingiva and extends from the gingival margin to the mucogingival junction.<sup>123</sup> Lang and Loe<sup>124</sup> published the first controlled clinical study that examined the relationship between the width of keratinized gingiva and gingival health. They reported that over 80% of tooth sites with at least 2 mm of keratinized gingiva (with at least 1 mm being attached) showed gingival health whereas the sites with less than these parameters had varying amounts of gingival inflammation. The suggested width of 2 mm of keratinized gingiva, with at least 1 mm of it attached, was recommended for maintenance of gingival health around teeth to prevent a movable gingival margin that could help facilitate the entry of bacteria into the gingival crevice, making them difficult to remove by conventional toothbrushing. Kennedy and coworkers<sup>125</sup> found in their study that when plaque control was not optimum in patients lacking attached gingiva, the chances of gingival recession was seen in 20% of the sites, whereas under similar poor plaque control, attachment loss was not noted in subjects with wide zones of attached gingiva. When clinically acceptable subgingival crown margins are placed in humans in areas with narrow  $(\leq 2 \text{ mm})$  or wide zones (> 2 mm) higher Gingival Index scores were recorded in the former.<sup>126</sup> Stetler and Bissada<sup>126</sup> recommended gingival augmentation in patients scheduled to receive subgingival restorations where narrow zones of keratinized gingiva exist, and who cannot maintain optimal plague control levels. A number of studies have alternatively concluded that in the absence of inflammation, gingival health can be maintained and unchanged attachment levels can be maintained in areas lacking keratinized and attached gingiva.126-131

The necessity of the presence of keratinized mucosa around dental implants, like teeth, continues to be controversial. Clinical studies by Adell and coworkers<sup>1</sup> and Albrektsson and coworkers<sup>2</sup> indicated that smooth titanium dental implants placed entirely in alveolar mucosa yielded similar survival rates to those placed within keratinized mucosa. Later studies, however, have documented that the peri-implant and periodontal tissues appear to differ in their resistance to bacterial inflammation.<sup>123–134</sup> Supracrestal collagen fibers around implants are oriented in a parallel "cuff" rather than a perpendicular configuration as in the dentoalveolar complex. These features are independent of the implant being placed in a one- or two-stage procedure.<sup>135</sup> The peri-implant "cuff" has a weaker mechanical attachment as compared to the periodontal attachment apparatus around natural teeth. This weaker attachment can increase the susceptibility of dental implants to infection.<sup>136–138</sup> The need for a zone of keratinized tissue adjacent to dental implants has been suggested since its absence increases the susceptibility of the peri-implant region to plaque-induced tissue destruction in a study using a monkey model.<sup>139</sup> Lindhe and Berglundh<sup>140</sup> have also noted that the peri-implant mucosa's ability to regenerate itself is limited by its compromised number of fibroblasts, lack of inductive potential of the periodontal ligament, and less vascular supply. A study by Bouri and coworkers<sup>141</sup> in both fully and partially edentulous patients found that the mean Gingival Index score, Plague Index score, and radiographic bone loss were significantly higher for those implants with a narrow zone (< 2 mm) of keratinized mucosa and were more likely to bleed upon probing. The authors concluded that increased width of keratinized mucosa  $(\geq 2 \text{ mm})$  around implants is associated with lower mean alveolar bone loss and improved indices of soft tissue health. This study supports the view that narrow zones of keratinized gingiva are less resistant to insult along the implant-mucosa interface. When inflammation is present, its apical proliferation may occur more rapidly than wider zones of keratinized gingiva that have an epithelial seal and are more resistant to the forces of mastication and local trauma that may occur during oral hygiene procedures. As in teeth, more keratinized mucosa means more collagen and less elastic fibers in the lamina propria, which gives the tissue more rigidity and tensile/shearing strength, important factors against mechanical insults.

Warrer and coworkers<sup>139</sup> documented the protective role of keratinized mucosal tissue around implants in a monkey model. It was found that ligated implants without keratinized mucosa demonstrated significantly more recession and slightly more attachment loss than implants with keratinized mucosa. It can be concluded that if an area is lacking keratinized tissue, there is only a weak tissue seal to cope with the local bacterial challenge. In contrast, Chung and coworkers<sup>142</sup> found no correlation between width of keratinized mucosa and alveolar bone loss, but did find an association with higher plaque accumulation and gingival inflammation. Based on animal and human clinical trials, however, it cannot be concluded that all patients are more prone to plaque accumulation and loss of attachment with resulting recession due to lack of keratinized gingiva.<sup>143</sup> Esposito and coworkers<sup>144</sup> concluded in their systematic review that there was insufficient evidence to recommend augmenting keratinized tissue around dental implants to maintain health. However, recent clinical studies indicate additional bone<sup>141,145</sup> or attachment loss<sup>146</sup> was associated with a lack of keratinized gingiva. It does appear that for some patients a lack of keratinized gingiva may be a risk factor for one or more issues: plaque accumulation, tissue soreness while brushing, increased gingival inflammation, recession, bone loss, and esthetics.<sup>37,143</sup> The recommendation of Greenstein and Cavallaro was that when there is a lack of keratinized gingiva, clinicians need to make a decision about whether to augment the zone of keratinized gingiva at a site for that particular patient based on the literature, the patient's dental history, the unique characteristics for the site being treated, and clinical experience.<sup>143</sup> The situations where it would be logical to augment keratinized gingiva would be in the following situations according to these authors:

- Chronically inflamed sites, despite oral hygiene instruction and periodontal therapy (sometimes it is necessary to alter the local gingival topography to make oral hygiene easier for the patient)
- Locations with ongoing loss of clinical attachment, recession and bone loss, regardless of periodontal therapy and good oral hygiene by the patient
- Sites where the patient complains of soreness when brushing, despite the appearance of gingival health
- Dental history suggesting predisposition to periodontitis or recession
- Patients noncompliant with periodic professional maintenance
- To improve esthetics

A combination of keratinized and nonkeratinized peri-implant mucosa gives the prosthetic restoration a more natural look.<sup>37,147</sup> Jung and coworkers<sup>148</sup> studied the color of the peri-implant mucosa in pig maxillae in vitro and found that mucosa thickness is a crucial factor in terms of discoloration and esthetic appearance caused by different restorative materials. They recommend zirconia abutments in patients with thinner mucosa (≤ 2 mm) because it shows the least color change as compared to titanium. In a tissue thickness of 3.0 mm, no change in color could be distinguished by the human eye on any specimen (titanium, titanium veneered with feldspathic ceramic, zirconia, and zirconia veneered with feldspathic ceramic). The authors recommend measuring the thickness of the periimplant mucosa to decide which abutment material is indicated in a given clinical situation. Furhauser and coworkers<sup>149</sup> evaluated soft tissue esthetics around single-tooth implant crowns and found that the color of the peri-implant mucosa matched in no more than a third of the cases. This would agree with Jung and coworkers as to consider the thickness of the tissue prior to determining the final abutment material to be used.

Cochran et al<sup>150</sup> has proposed that a minimum of 3 mm of peri-implant mucosa, referred to as the biologic width, is required for a stable epithelial connective tissue attachment to form and serves as a protective mechanism for the underlying bone.<sup>151</sup> The establishment of the biologic width around teeth also involves crestal bone loss as was observed in a surgical tooth lengthening study by Oakley and coworkers.<sup>152</sup>

Regarding esthetics in the anterior maxilla, Zigdon and Machtei<sup>146</sup> observed in their retrospective study that the keratinized mucosa thickness and width around dental implants affects both the clinical and the immunological parameters at these sites. A negative correlation was found between mucosal thickness and marginal recession. Likewise, keratinized mucosa width showed a negative correlation with marginal recession, periodontal attachment level, and prostaglandin E2 (PgE2) levels. A wider mucosal band (> 1 mm) was associated with less marginal recession compared with a narrow ( $\leq$  1 mm) band (0.27 and 0.9 mm, respectively). A thick mucosa ( $\geq$  1 mm) was associated with lesser recession compared with a thin (< 1 mm) mucosa (0.45 and 0.9 mm, respectively). Their findings are of special importance in the esthetic zone, where narrow and thin buccal keratinized mucosa may lead to marginal tissue recession and a localized esthetic problem. Linkevicius and coworkers<sup>153</sup> also found in a 1-year prospective study in humans that the initial gingival thickness at the alveolar crest might be considered a significant influence on marginal bone stability around implants. If the tissue thickness is 2.5 mm or less, crestal bone loss up to 1.45 mm may occur within the first year of function, despite a supracrestal position of the implant-abutment interface. The authors further recommended that the measurement of gingival thickness should be mandatory in any evaluation of marginal bone loss. They also recommend considering the thickening of thin mucosa before implant placement, in essence converting a thin tissue biotype into a thicker one. The results of the Linkevicius study are consistent with an animal study by Berglundh and coworkers<sup>154</sup> that reported the potential of thin tissues to cause crestal bone loss during the process of biologic width formation. When tissues were thinned at second stage surgery (to 2 mm in thickness), a minimum dimension of the biologic width was not satisfied and bone resorption occurred to allow a sufficient soft tissue attachment to form. The stability of crestal bone remains controversial. Moreover, the influence of mucosal thickness on crestal bone around implants has been discussed only recently and has received little attention in comparison to other factors.<sup>153,155,156</sup> In the Berglundh and Lindhe<sup>157</sup> animal study, they reported

that thin tissues could provoke crestal bone loss during reformation of the biologic width, which creates the peri-implant seal.

Interestingly, Anderegg and coworkers<sup>158</sup> found, in the treatment of facial furcation defects using the principles of guided tissue regeneration (GTR) and an ePTFE membrane, a significant difference at 6 months postoperatively in recession between thin tissues  $(\leq 1 \text{ mm}: \text{ recession } 2.1 \text{ mm}) \text{ vs thick tissues } (> 1 \text{ mm}:$ recession 0.6 mm). Gingival tissue thickness was therefore noted to be an important factor to consider if postoperative recession is to be minimized or avoided in the treatment of GTR cases with ePTFE membranes. The authors further noted that the similarity of this GTR technique to placing a soft tissue graft over an avascular root surface where the failure of thin  $(\leq 1 \text{ mm})$  free gingival autografts to successfully cover wide recession areas is seen compared with thick autografts (1.5 mm to 2 mm). The thicker the connective tissue, the more intact capillary system is seen than thinner tissues<sup>159</sup> and the greater the chance for flap survival. Baldi and coworkers<sup>160</sup> similarly found flap thickness being significantly associated with the percentage of root coverage in shallow gingival recession defects in humans using the coronally advanced flap technique. They found a flap thickness of > 0.8 mm was associated with 100% root coverage, while < 0.8-mm-thick flaps never achieved complete root coverage. The tissue biotype appears to be an important factor in many periodontal plastic surgical procedures including implant placement in the anterior maxillary region. Surgically changing a thin to a thick biotype appears to be important in success of these periodontal plastic surgical procedures.

# Statements on Need for Keratinized Mucosa and Mucosal Thickness around Implants

Evaluation of the site needs to be analyzed on a caseby-case basis for soft tissue augmentation.

The biologic width appears to be critical in its formation around teeth as well as implants. It will form via crestal bone loss when it does not fulfill its appropriate dimensions of 3 mm.

Consideration for thickening tissues either prior to or at the time of implant placement would be recommended when they are thin, especially in the esthetic zone as thick tissues appear to reduce or prevent marginal tissue recession.

Consideration as to the abutment material to be used in the esthetic zone should be made by the tissue thickness and the patient's esthetic demands on a case-by-case basis. When tissue is thinner in an esthetically demanding patient, the use of zirconia is recommended.

### **Soft Tissue Augmentation**

**Surgical Options and Timing.** Periodontal plastic surgery has its origins in mucogingival surgery and addresses soft tissue defects that require functional and esthetics results for the patient. Mucogingival surgery as described by Friedman<sup>161</sup> addressed only three clinical problems and their treatment: a shallow vestibule, an aberrant frenum, and problems associated with lack of attached gingiva. Periodontal plastic surgery today is much broader in scope in therapies and is considered one aspect of regenerative periodontal surgery.<sup>162</sup> It not only addresses the original mucogingival concerns but also addresses the treatment of the following defects according to Miller and Allen<sup>162</sup> that include:

- 1. Marginal gingival recession with soft tissue grafting for coverage of denuded root surfaces.
- 2. Excessive gingival display and treatment of the "gummy smile" which requires crown lengthening through soft and, frequently, hard tissue removal. This procedure is frequently timed prior to or at the same visit of implant placement in patients so as to provide an esthetic symmetrical gingival margin with normal tooth lengths at a normal location in relation to the patient's smile. This form of periodontal plastic surgery is considered excisional or subtractive.
- Treatment of deficient ridges requiring ridge augmentation to allow for an esthetic final result of either a partial prosthesis or prior to or simultaneously with implant placement.
- Loss of interdental papillae and soft tissue reconstruction.
- 5. Surgical exposure of unerupted teeth prior to orthodontic tooth movement.
- Esthetic defects surrounding dental implants requiring frequently both hard and soft tissue reconstruction.

**Soft Tissue Grafting.** Epithelized palatal grafts for root coverage were introduced by Miller<sup>163</sup> and Holbrook and Ochsenbein<sup>164</sup> to provide not only a functional result of increasing the zones of attached keratinized gingiva but also to gain coverage of exposed root surfaces. However, the color match of the tissues is often less than esthetic, as the palatal tissue tends to be lighter and more opaque than the adjacent gingiva.

Subepithelial connective tissue grafts (SECTG) as described by Langer and Langer<sup>165</sup> result generally in a better color match and do not require removal of the frenum. Both the epithelized grafts and SECTG require adequate donor tissue, which may be an issue in large multiple tooth defects or in patients who are hesitant in having a second surgical site. These concerns have

been addressed with the use of acellular dermal matrix (ADM)<sup>31,166–169</sup> for the treatment of recession and keratinized mucosal defects along with a porcine collagen matrix (Mucograft)<sup>170–175</sup> and tissue-engineered bilayered cell therapy.<sup>176,177</sup>

### Soft Tissue Augmentation of the Healed Ridge

Studer and coworkers<sup>178</sup> described a localized defect in the alveolar crest as one involving a limited deficit in the volume of bone and soft tissues within the alveolar process. These deficits are frequently found in partially edentulous patients resulting from many causes including traumatic tooth extractions, extractions in the presence of extensive periodontal bone loss or periapical pathology, developmental disorders or removal of tumors.<sup>179</sup> Abrams and coworkers<sup>180</sup> studied the prevalence of anterior ridge deformities in partially edentulous patients and reported the presence of defects in 91% of the cases studied. The anatomical configuration of the ridge defect often determines the selection and sequence of treatment. Seibert<sup>181,182</sup> categorized ridge defects in three general categories:

- 1. Class 1: Buccolingual loss of tissue with normal ridge height in an apicocoronal dimension.
- 2. Class 2: Apicocoronal loss of tissue with normal ridge width in a buccolingual dimension.
- 3. Class 3: Combined buccolingual and apicocoronal loss of tissue resulting in loss of normal ridge height and ridge width.

Class 1 defects can frequently be treated in a single procedure but class 2 and class 3 defects may require second and third procedures to accomplish the goal of ridge reconstruction with a minimum of two months between procedures. When the prevalence of these defects was evaluated in a partially edentulous population the most prevalent were class 3 defects (55.8%), followed by class 1, (32.8%), and with class 2 defects (2.9%) being the least detected clinically.<sup>180</sup>

Various soft tissue procedures have been proposed for ridge augmentation using soft tissues:

The "roll" technique as described by Abrams and coworkers<sup>180</sup> was an original soft tissue augmentation procedure to correct a class 1 or an early class 2 ridge defect. It involves dissecting a de-epithelialized palatal flap and creating a pedicle toward the vestibular aspect. This connective tissue pedicle is then rolled below the vestibular flap in the area of the ridge thus gaining volume of tissue to the buccal aspect of the deficient ridge. The advantage is a good color match of the surrounding tissues involving a single surgical site; however, the disadvantage is the inability to treat larger defects because of the lack of donor tissue availability.

The use of a palatal subepithelial connective tissue graft implanted into a pouch or tunnel prepared in the mucosa that lines the defect was described by Langer and Calagna<sup>183</sup> and modified by Garber and Rosenberg.<sup>184</sup> This procedure may require multiple surgical procedures to treat large defects of the class 2 and 3 varieties.

Full-thickness free gingival or onlay grafts using the palate as the donor site as described by Seibert<sup>181,182</sup> and Seibert and Salama.<sup>185</sup> The Seibert "onlay" graft technique was described to treat the clinical challenges of both the class 2 and class 3 ridge defects originally for fixed partial denture sites as it is effective in gaining significant tissue volume in three dimensions. The disadvantages of this technique are the need for two surgical sites, potential partial sloughing of the graft due to lack of blood supply, a poor color match to the surrounding tissues, and the possibility of needing multiple surgical procedures thus adding to patient morbidity. Seibert modified the onlay graft with the interpositional (wedge and inlay) graft<sup>186</sup> where a pouch is created but not closed and a pie-shaped free gingival graft is removed from the palate or tuberosity area and inserted like a wedge into the opening of the pouch. This elevates the labial surface of the pouch to eliminate the ridge concavity. The epithelized surface of the wedge is positioned at the level of the surrounding epithelial surfaces and sutured to the surrounding tissues. The percentage of "take" is improved over the onlay graft procedure as more of the surface area of the grafted tissue receives a flow of plasma and ingrowth of capillaries from the connective tissue surrounding it.<sup>185</sup> Since these prior mentioned procedures were developed for crown and partial denture site development there have been many periodontal plastic surgical procedures developed specifically for implant therapy with the procedure to be used being based on different time points for soft tissue augmentation in the maxillary anterior sextant: soft tissue augmentation prior to implant placement, soft tissue augmentation at the time of implant placement, and soft tissue augmentation postimplant placement.<sup>187</sup>

Soft Tissue Augmentation Prior to Implant Placement. In cases of thin tissue biotypes or at the time of extraction and socket preservation, considerations need to be made as to the value or benefit of adding keratinized tissue to augment the future implant site in the maxillary anterior. Based on the biologic width around dental implants, a minimum 3 mm width with a minimum 2 mm thickness of keratinized gingiva is recommended. Surgical procedures to be used prior to implant placement should include using tissues or products that blend well with the surrounding host tissues locally as well as adding the necessary tissue thickness.

The main goals when treating the extraction socket in the esthetic zone is to preserve as much soft and hard tissue volume as possible existing for future implant placement.<sup>187</sup> Landsberg and Bichacho<sup>188</sup> described a modified ridge preservation technique called "socket seal surgery" where flap elevation is not performed and it combines both bone and soft tissue grafting and is performed prior to implant placement. The authors noted the benefits of closing the extraction site from the oral environment without changing the vestibular depth, enabling optimal preservation of the ridge topography immediately after tooth extraction. The thick epithelized palatal graft containing part of the submucosa can also act as a membrane over a bone graft for socket/ridge preservation.

Jung and coworkers<sup>189</sup> in a prospective study evaluated the short-term healing of this approach in 20 humans in the maxillary and mandibular anterior sextants. They used a biopsy tissue punch technique with a diameter corresponding to the socket orifice with a tissue thickness of 2 to 3 mm in conjunction with DBBM (BioOss Collagen, Geistlich). The authors stressed the importance of meticulous close adaptation of the grafts to the soft tissue wound margins with 6 to 10 single interrupted microsurgical sutures. The primary intention in this study for the placement of the DBBM particles was not to enhance bone formation, but to support the buccal contour of the alveolar ridge and stabilize the blood clot. The authors found that the tissue integrated at 3 weeks at 92.3% of the graft surface and 99.7% at 6 weeks with 0.3% of the surface in four grafts showing incomplete wound closure with no fibrin or graft necrosis present. Using a colorimeter comparison of the graft and the adjacent tissues they found excellent color matching of the grafted and host tissues that could not be detected clinically. The authors concluded that using this approach showed high predictability and reliability for a good esthetic result for future type 2 or type 3 implant placement. Studies have documented that the survival rate of the grafted tissue depends on both the nourishment from the organizing blood clot beneath the graft<sup>45,190,191</sup> and its close contact to the host's marginal soft tissues.<sup>181</sup> The advantages of using an epithelized FGG over a connective tissue graft is twofold: the rigidity of the epithelium increases its stability and ease to suture to the surrounding gingival margin preventing tissue collapse and necrosis and secondly, the use of the FGG avoids tissue flap elevation and additional buccal wall resorption which is well documented in animal studies.<sup>78,192</sup>

Stimmelmayr and coworkers<sup>193</sup> described a technique for reliable wound closing using a combined epithelized-subepithelial CTG that leaves the mucogingival line in place while supporting the papillae of the neighboring teeth, and has an added advantage of thickening the buccal soft tissue with the resultant local conversion of a thin marginal gingiva biotype to a thick marginal gingiva biotype. In contrast to Jung and coworkers' punch technique, the authors' primary concern with using the FGG to cover extraction sockets is the high failure rate as noted also by Landsberg and Bichacho,<sup>188</sup> because their blood supply relies on the gingival wall of the socket and the subjacent clot. The FGG/socket seal technique also does not thicken the facial soft tissue. Stimmelmayr and coworkers<sup>193</sup> developed the technique based on the onlay-interpositional graft described by Seibert and Louis<sup>186</sup> for closing extraction sockets. They reported predictable results over the onlay-type grafts due to the improved blood supply by the two inlay components. In their retrospective study of 58 cases, only one patient experienced a soft tissue dehiscence and secondary wound healing.

Other techniques described by Becker and Becker<sup>194</sup> involved coronally advanced flaps for primary closure over extraction sites and ePTFE membranes, which coronally shifts the mucogingival junction and can result in an esthetic deformity in high esthetic areas such as the anterior maxillae. Similarly, the use of rotated palatal connective tissue flaps<sup>195,196</sup> have the disadvantage of also repositioning the buccal mucogingival line coronally to gain coverage of the rotated flap. The advantage is the two-layer coverage of the augmented site with the palatal pedicle connective graft and its overlying coronally positioned flap. This ensures a good blood supply, as the pedicle flap remains vascularized, as does the coronally positioned buccal flap unlike a FGG. This would aid the undisturbed healing of the grafted socket ensuring complete closure of the GBR site during the healing phase.<sup>195</sup> Another disadvantage of the flap techniques is the extensive flap manipulation needed to gain closure which can result in additional volume shrinkage due to surgical trauma and loss of the fragile buccal plate of bone.<sup>78,197</sup> Techniques that can minimize or avoid raising a buccal flap may be more suitable from a healing standpoint reducing the risk of soft and hard tissue shrinkage.<sup>187</sup>

## Statements on Soft Tissue Augmentation Prior to Implant Placement

- 1. Evaluation of the site needs to be analyzed on a case-by-case basis for soft tissue augmentation.
- 2. Consideration for soft tissue augmentation would be based on the quantity and quality of the keratinized gingiva present, which may be reflected as a thin or thick gingival biotype. A minimum of 3 mm of keratinized gingiva in the esthetic zone is recommended to allow for the biologic width to reform with a minimal gingival thickness of 2 mm.
- The main goals when treating the extraction socket in the esthetic zone is to preserve as much as pos-

sible existing soft and hard tissue volume. To effectively limit the loss of the thin friable buccal plate, the avoidance of a buccal gingival flap is recommended for socket preservation procedures. The use of a palatal epithelized free gingival graft as a "socket seal" which is sutured meticulously with microsurgical sutures for tight adaptation of the FGG to the marginal soft tissue walls of the socket has documented success in achieving these goals.

## Soft Tissue Augmentation at the Time of Implant Placement

Kan and coworkers<sup>198</sup> stated that the success of the concept of immediate implant placement and provisionalization (IIP) is influenced by a number of factors defined as extrinsic or intrinsic. Extrinsic factors include proper three-dimensional implant positioning and properly contoured provisional restoration.7,8,64,117,199 In contrast, intrinsic factors are patient dependent and, therefore can be favorable or unfavorable. They include bone level, soft and hard tissue relationship, buccal bone thickness, and gingival biotype. To achieve an esthetic outcome the conversion of unfavorable traits to favorable traits is vital to achieving an esthetic outcome.<sup>200</sup> Kan and coworkers<sup>117</sup> in a follow-up paper of their original study with 1-year data reported significant buccal recession in IIP cases, especially those with a thin gingival tissue biotype. However, in their study of 20 patients and 20 sites in the maxillary anterior they did not address the patient's intrinsic factors such as bone thickness (no bone grafting of the buccal gap was done) or biotype conversion with the use of connective tissue grafts. They found that recession was a dynamic process and continued from 1 year onward and by the final examination on average had doubled from -0.5 to -1.00 mm.

In terms of immediate tooth replacement, buccal recession is a common occurrence in these cases<sup>201,202</sup> especially in the thin gingival biotype when these intrinsic, patient dependent factors are not addressed. In contrast, maintenance of interproximal papillae heights is more predictable in periodontally healthy patients due to predictable tissue rebound over time, which can be anticipated by the interproximal heights of bone on the adjacent tooth surfaces.<sup>203–205</sup> Complete papilla fill has been observed when the distance from the contact point to the bone crest was < 5 mm.

Recent clinical studies have reported on the use of connective tissue grafts at implant placement and at immediate tooth replacement for biotype conversion.<sup>206,207</sup> The study of the subepithelial connective tissue grafting (SCTG) technique in conjunction with bone grafting the implant-socket gap with IIP in the esthetic zone has been recently evaluated in a number of case studies. Redemagni and coworkers<sup>208</sup> in a retrospective study evaluated the dimensional alterations after immediate implants and immediate screw-retained restorations in 28 patients using Dentsply 33XiVE implants with a mean follow-up of 20.4 months. A buccal detachment of the gingiva was completed creating an envelope and a palatal connective tissue graft was inserted and the implant-socket gap was grafted with Bio-Oss collagen. They found buccal soft tissue stability with an average of 0.0 mm (range of -0.5 to 1.0 mm).

Chung and coworkers<sup>209</sup> evaluated the facial gingival stability following immediate cemented restoration, SCTG (full thickness pouch created to accept the SCTG) with Bio-Oss grafting in the implant-socket gap of 10 patients using Biomet 3i implants with a platform shift between the abutment and the implant. At 12 months, 9 out of 10 implants remained osseointegrated with a mean facial gingival soft tissue change of -0.05 mm, mean marginal bone loss of -0.31, and more than 50% papillae fill in 89% of all sites. The authors concluded that SCTG in conjunction with IIP in the esthetic zone may be beneficial in minimizing facial gingival tissue recession when proper 3-dimensional implant position is achieved and bone graft is placed in the implant-socket gap. Similar results were observed at 1 year in another study of 10 patients by Tsuda and coworkers<sup>210</sup> using OsseoSpeed (Astra Tech) implants with a platform switch concept, SCTG, bone grafting, and immediate cemented restoration in the esthetic zone. All implants remained osseointegrated, with an overall mean marginal bone level change of 0.10, mean facial gingival level change of -0.05 mm, and more than 50% papilla fill in 80% of all sites.

Cosyn and colleagues<sup>27</sup> evaluated immediate screwretained restorations in 22 patients who presented with thick gingival biotypes (thin biotype patients were excluded). NobelActive implants were used with the platform switch concept and all implant-socket gaps were grafted with Bio-Oss. At 3 months, five cases demonstrated major alveolar process remodeling and were grafted with a SCTG using the pouch technique while two cases showed advanced midfacial gingival recession and were also grafted with a SCTG. Thus a total of seven cases were grafted at 3 months due to esthetic complications. At 6 months, final impressions were taken with final examination completed at 1 year. One implant failed during the study. The authors found similar pink esthetic scores post-treatment (PES 11.86) as they were pre-surgery (PES 12.15). The authors concluded that preservation of pink esthetics is possible following immediate tooth replacement. However, to achieve that, a SCTG is necessary in about one-third of the patients (who presented with a thick gingival biotype).

Kan and coworkers<sup>201</sup> evaluated the facial gingival tissue stability after IIP and SCTG in the esthetic zone

in 20 consecutive patients (8 thick and 12 thin gingival biotypes) using NobelReplace Tapered Groovy or NobelPerfect Groovy implants and an immediate cemented restoration and grafting of the implant-socket gap with Bio-Oss. The authors noted that at 2.15 years mean follow-up, all implants were functioning and all exhibited a thick gingival biotype. No differences were seen between the initial thick vs thin biotypes in regards to mean marginal bone loss or mean facial soft tissue recession. At the last examination a mean of 0.13 mm facial gingival level was recorded. Over 50% of papilla fill was noted at all sites with  $\geq$  80% having a 100% papillae fill. The authors concluded that regardless of the initial gingival biotype, the thin gingival biotype can be converted to a thick gingival biotype morphologically and behaviorally with this procedure and, at least in the short term, biotype conversion by increasing quality and quantity of the facial gingival tissue with SCTG might be beneficial for facial gingival stability after an immediate tooth replacement procedure. The authors further stress that careful patient selection and treatment planning, as well as immaculate execution by skillful clinicans, are required to achieve successful results.

Based on the above studies noted, all IIP procedures in the esthetic zone are a complex SAC procedure with the suggested clinical usage of the ERA tool (see Table 1) to aid in treatment planning with the patient.

# Statements on Soft Tissue Augmentation at the Time of Implant Placement Using a CTG

Consideration needs to be made on a case-by-case, site-by-site basis using the ERA as a guide as to the need to augment at the time of implant placement with soft and/or hard tissue.

Recent case studies have shown that with IIP there is a benefit in augmenting both the buccal gap and using a CTG to thicken the buccal tissue for biotype conversion to one that is less susceptible to future gingival recession and esthetic deformity. The literature that has been presented in this paper has shown that unpredictable esthetic results are common in the treatment of a dental implant for facial gingival recession.

Immediate implant placement in the esthetic zone is a complex SAC procedure requiring immaculate execution by skillful clinicians as a prerequisite to attempting this procedure.

### CONCLUSIONS

The need for soft tissue augmentation procedures around dental implants in the anterior maxillae remains a controversial and unpredictable topic. Although success of implant therapy is similar in the anterior maxilla and other areas of the mouth, the majority of studies evaluating this therapy in the esthetic zone are lacking literature support, few in number, devoid of long-term follow-up and number of patients, and are subject to inclusion bias and thus should be addressed with caution. Patient-dependent factors are usually not addressed, as a biologic success frequently does not equal an esthetic success to the patient. The use of the ERA tool for all esthetic zone cases can benefit both the clinician and the patient by addressing objective criteria and modifying factors that can affect the final esthetic outcome prior to treatment to avoid any miscommunication and problems of expectation upon completion. All the available knowledge on this topic including the approaches described in this paper is based on very limited literature support and, thus, should be addressed with caution. These concerns should encourage long-term good clinical trials for better assessment of those issues.

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## Esthetic Outcomes Following Immediate and Early Implant Placement in the Anterior Maxilla—A Systematic Review

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**Purpose:** The objectives of this systematic review are (1) to quantitatively estimate the esthetic outcomes of implants placed in postextraction sites, and (2) to evaluate the influence of simultaneous bone augmentation procedures on these outcomes. Materials and Methods: Electronic and manual searches of the dental literature were performed to collect information on esthetic outcomes based on objective criteria with implants placed after extraction of maxillary anterior and premolar teeth. All levels of evidence were accepted (case series studies required a minimum of 5 cases). Results: From 1,686 titles, 114 full-text articles were evaluated and 50 records included for data extraction. The included studies reported on single-tooth implants adjacent to natural teeth, with no studies on multiple missing teeth identified (6 randomized controlled trials, 6 cohort studies, 5 cross-sectional studies, and 33 case series studies). Considerable heterogeneity in study design was found. A meta-analysis of controlled studies was not possible. The available evidence suggests that esthetic outcomes, determined by esthetic indices (predominantly the pink esthetic score) and positional changes of the peri-implant mucosa, may be achieved for single-tooth implants placed after tooth extraction. Immediate (type 1) implant placement, however, is associated with a greater variability in outcomes and a higher frequency of recession of > 1 mm of the midfacial mucosa (eight studies; range 9% to 41% and median 26% of sites, 1 to 3 years after placement) compared to early (type 2 and type 3) implant placement (2 studies; no sites with recession > 1 mm). In two retrospective studies of immediate (type 1) implant placement with bone graft, the facial bone wall was not detectable on cone beam CT in 36% and 57% of sites. These sites had more recession of the midfacial mucosa compared to sites with detectable facial bone. Two studies of early implant placement (types 2 and 3) combined with simultaneous bone augmentation with GBR (contour augmentation) demonstrated a high frequency (above 90%) of facial bone wall visible on CBCT. Recent studies of immediate (type 1) placement imposed specific selection criteria, including thick tissue biotype and an intact facial socket wall, to reduce esthetic risk. There were no specific selection criteria for early (type 2 and type 3) implant placement. Conclusions: Acceptable esthetic outcomes may be achieved with implants placed after extraction of teeth in the maxillary anterior and premolar areas of the dentition. Recession of the midfacial mucosa is a risk with immediate (type 1) placement. Further research is needed to investigate the most suitable biomaterials to reconstruct the facial bone and the relationship between long-term mucosal stability and presence/absence of the facial bone, the thickness of the facial bone, and the position of the facial bone crest. INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):186-215. doi: 10.11607/jomi.2014suppl.g3.3

Key words: bone grafts, CBCT, contour augmentation, early implant placement, esthetics, GBR, immediate implant

mplant therapy is today widely regarded as a reliable treatment option to replace missing teeth, both for function and esthetics, as documented by recent 10-year

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studies conducted with current implant systems.<sup>1–7</sup> The original treatment protocols of the 1970s and 1980s required fully healed alveolar ridges before implants were placed.<sup>8,9</sup> In the 1990s, these protocols were modified to include implant placement in fresh extraction sockets<sup>10,11</sup> or in partially healed alveolar ridges<sup>12</sup> predominantly for implants in the esthetic zone.

At a consensus conference of the International Team for Implantology (ITI) in 2003, Belser et al concluded that although the use of dental implants in the esthetic zone was well documented, there was a lack of well-defined esthetic parameters to evaluate outcomes.<sup>13</sup>

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At the same conference, a classification system for the timing of implant placement after tooth extraction was developed, which was based on morphologic, histologic, and dimensional changes of the alveolar ridge.<sup>14</sup> The systematic review that formed the basis of this classification concluded that the evidence for esthetic outcomes in postextraction sites was insufficient for definitive conclusions to be drawn.<sup>15</sup> Postextraction implant placement in this context refers to immediate placement (type 1), early placement with soft tissue healing (type 2), early placement with partial bone healing (type 3), and late placement (type 4).

In the 10-year period since this consensus conference, there has been an increase in the reporting of esthetic parameters including changes in the position of the peri-implant mucosa<sup>16</sup> and esthetic indices based on ordinal scales.<sup>17</sup> Esthetic indices have provided clinicians and researchers with more objective tools to evaluate hard and soft tissue-related esthetic outcomes with implant-supported prostheses.

During the same period, it was recognized that the resorption and modeling of the alveolar ridge in postextraction sites has the potential to influence esthetic results.<sup>18</sup> The use of bone augmentation procedures using biomaterials with a low substitution rate has been proposed as a means to reduce these postextraction dimensional changes.<sup>19</sup> Technological advances in three-dimensional (3D) radiology have provided researchers with a noninvasive method to evaluate these bone augmentation procedures in relation to postextraction implants.<sup>20,21</sup>

The objectives of this systematic review are (1) to quantitatively estimate the esthetic outcomes of implants placed in postextraction sites, and (2) to evaluate the influence of simultaneous bone augmentation procedures on these outcomes.

### **MATERIALS AND METHODS**

### Search Strategy

The reporting of this systematic review is based on the PRISMA guidelines (http://www.prisma-statement. org). An electronic search of the literature was performed according to the criteria set out in Table 1.

### **Selection of Studies**

Screening of the titles and selection of abstracts for potential inclusion in the review was undertaken independently by the two reviewers. The full texts of the shortlisted abstracts were reviewed independently, and articles for inclusion were selected on the basis of the criteria stipulated in Table 1. Any disagreement was resolved by discussion between the reviewers. The Kappa value for interassessor agreement during screening of title and abstract was 0.92 and 0.88 respectively, indicating excellent agreement.

### **Excluded Studies**

Out of the 117 full-text articles assessed, 67 were excluded from the final analysis due to the following reasons:

- Review papers or papers of methodology
- Data for the same population duplicated in another study
- Insufficient data/lack of esthetic parameters to assess esthetic outcomes
- Unable to separate data for different placement time
- Unable to separate data for sites in the anterior maxilla (esthetic zone defined as the maxillary anterior and maxillary premolar teeth) from posterior and mandibular sites
- Data available only for implant placement in healed sites
- Case reports with less than 5 cases

### **Quality Assessment**

Randomized controlled trials (RCTs) and cohort studies were assessed for bias using the Cochrane Collaboration tool, which consisted of six domains that addressed the adequacy of sequence generation, allocation concealment, blinding of participants, handling of incomplete outcome data, steps to minimize selective outcome reporting, and whether other sources of bias were identified (http://ohg.cochrane. org/sites/ohg.cochrane.org/files/uploads/Risk%20 of%20bias%20assessment%20tool.pdf). According to the Cochrane Collaboration tool, a judgment of "risk of bias" was assigned if one or more key domains had a high risk of bias. Cohort studies were assessed for quality and reporting using the Newcastle-Ottawa scale, which provides for eight key domains (http://www. ohri.ca/programs/clinical\_epidemiology/oxford.asp). One star is awarded for each domain in which the criteria are fulfilled, with the exception of "comparability" which can be awarded two stars. A maximum of nine stars may be assigned to a study.

### **Data Extraction**

From the included articles, data on timing of implant placement postextraction, simultaneous placement of bone grafts, connection of provisional crowns immediately after implant placement, peri-implant soft tissue dimensional changes, and esthetic indices were extracted and recorded on standardized forms. In addition, inclusion and exclusion criteria were recorded. Any disagreement between reviewers was resolved by discussion.

	natic Search Strategy
•	hat is the influence of implant placement timing and augmentation procedures on esthetic outcomes in the terior maxilla?
Search strategy	
Population	1) Jaw, edentulous, partially[MeSH terms] OR partially edentulous OR partial edentulism
Intervention or exposure	2) Dental implantation, endosseous[MeSH terms] OR "dental implants, single tooth"[MeSH terms] OR endosseous implant* OR dental implant*
Comparison	<ul> <li>3) Immediate implant OR immediate-delayed AND implant OR delayed-immediate AND implant OR early implant placement</li> <li>4) Guided bone regeneration OR gbr OR bone substitute* OR bone filler* OR autogenous bone OR autologous bone OR allogenic graft* OR allograft* OR xenogenic graft* OR xenograft* OR freeze dried bone allograft OR fdba OR demineralized freeze dried bone allograft OR dfdba OR Bio-Oss OR Bio-Oss collagen OR tricalcium phosphate OR tricalciumphosphate OR xenogenic graft* OR alloplast</li> <li>5) 3D imaging, computer generated[MeSH terms] OR cone beam ct OR cbct OR ct</li> </ul>
Outcome	6) Esthetics[MeSH terms] OR esthetics OR esthetic indices OR esthetic index OR esthetic outcomes OR mucosal recession OR white esthetic score OR wes OR pink esthetic score OR pes OR implant crown esthetic index OR complex esthetic index OR copenhagen index score OR recession OR mucosal recession OR midfacial recession
Search combinatio	1 AND 2 AND (3 or 4 or 5) AND 6
Database search	
Language	English
Electronic	Medline (PubMed 1985 to August 2012), Cochrane Central Register of Controlled Trials (CENTRAL)
Journals	Clinical Oral Implants Research, International Journal of Oral Maxillofacial Implants, Clinical Implant Dentist and Related Research, Implant Dentistry, Journal of Implantology, Journal of Periodontology, Journal of Clinical Periodontology (from 1985 to November 2012)
Selection criteria	
Inclusion criteria	Clinical studies on adults only Studies at all levels of evidence, except expert opinion Case reports must include at least five patients Implant placement in the esthetic zone defined as the maxillary anterior and premolar region of the dentitio
Exclusion criteria	Insufficient information on timing of implant placement after tooth extraction Studies reporting on multiple placement times in which insufficient information is available to sort the data Absence of objective parameters: esthetic indices, soft tissue measurements Animal studies Multiple publications on the same patient population No author response to inquiry email for data clarification

#### **Statistical Analysis**

A preliminary analysis of the included studies showed that the majority of studies were case series studies. There were insufficient RCTs of similar design to permit a meta-analysis. Of the non-randomized studies (cohort, cross-sectional, and case series), it was noted that there was significant heterogeneity in study design, study population, follow-up times, and esthetic parameters reported. Therefore, descriptive methods were mainly used to present the data.

For non-randomized studies, a trend analysis was undertaken. Studies were included for this analysis if the subjects were consecutively enrolled, there was no deviation in the treatment protocol, and the follow-up period was between 1 and 3 years. Studies were grouped according to methodologic similarities based on timing of implant placement postextraction, use of bone graft, use of connective tissue (CT) graft, and use of immediate provisional crowns. The data were presented in forest plots with weights derived from random-effect analysis (Comprehensive Meta Analysis v2.2.064). Data from randomized studies were not included in this part of the analysis (http://handbook. cochrane.org/chapter\_13/13\_including\_non\_randomized studies.htm). Overall effects were not calculated due to the high risk of bias with case series studies and significant heterogeneity. Statistical homogeneity was determined using Cochran Q and its associated P value, and the I-squared statistic. Clinical implications of data heterogeneity were reviewed when the P value was less than 0.1, and the I-squared statistic became increasingly higher. The random-effects model was used to weight studies on the forest plots. All data are presented in mm as means  $\pm$  standard deviations.

Table 2 Included	Studies	
	Number	Studies
Randomized controlled studies (RCTs)	6	Lindeboom et al, <sup>22</sup> Palattella et al, <sup>23</sup> De Rouck et al, <sup>24</sup> Block et al, <sup>25</sup> Chen et al, <sup>26</sup> Felice et al <sup>27</sup>
Cohort studies	6	Gotfredsen, <sup>28</sup> Cangini and Cornelini, <sup>29</sup> Juodzbalys and Wang, <sup>30</sup> Grunder, <sup>31</sup> Raes et al, <sup>32</sup> De Bruyn et al <sup>33</sup>
Cross-sectional studies	5	Evans and Chen, <sup>34</sup> Buser et al, <sup>35</sup> Belser et al, <sup>36</sup> Miyamoto and Obama, <sup>37</sup> Cosyn et al <sup>38</sup>
Case series studies	33	Grunder, <sup>39</sup> Kan et al, <sup>40</sup> Cornelini et al, <sup>41</sup> Juodzbalys and Wang, <sup>42</sup> Kan et al, <sup>43</sup> Canullo and Rasperini, <sup>44</sup> Noelken et al, <sup>45</sup> De Rouck et al, <sup>46</sup> Buser et al, <sup>47</sup> Kan et al, <sup>48</sup> Pirker and Kocher, <sup>49</sup> Redemagni et al, <sup>50</sup> Tortamano et al, <sup>51</sup> Chen et al <sup>52</sup> Cosyn and De Rouck, <sup>53</sup> Cooper et al, <sup>54</sup> Cosyn et al, <sup>55</sup> Brown and Payne, <sup>56</sup> Tsuda et al, <sup>57</sup> Buser et al, <sup>58</sup> Chung et al, <sup>59</sup> Cosyn et al, <sup>60</sup> Kan et al, <sup>61</sup> Malchiodi et al, <sup>62</sup> Mangano et al, <sup>63</sup> Noelken et al, <sup>64</sup> Benic et al, <sup>20</sup> Cabello et al, <sup>65</sup> Lee et al, <sup>66</sup> Buser et al, <sup>21</sup> Cosyn et al, <sup>67</sup> Furze et al, <sup>68</sup> Noelken et al <sup>69</sup>
Total	50	

### RESULTS

Following the systematic search strategy (Fig 1), a total of 50 studies were included in this systematic review of esthetic outcomes with postextraction implants (Table 2). These 50 studies were comprised of 6 RCTs,<sup>22–27</sup> 6 cohort studies,<sup>28–33</sup> 5 cross-sectional studies,<sup>34–38</sup> and 33 case series studies.<sup>20,21,39–69</sup> There were 7 studies.<sup>21,33,38,58,60,61,69</sup> that were identified as follow-up reports of previous publications.<sup>35,40,45–47,54,55</sup> One paper<sup>36</sup> presented data on esthetic outcomes on the patient pool of a previous paper.<sup>35</sup> Data were extracted from the more recent publications and tabulated. Any missing data were obtained from the earlier publications. The list of excluded studies,<sup>45,70–132</sup> including reasons for exclusion may be found in Table 3.

Of the six included RCTs, four were judged to be at risk of bias mainly due to nonconcealment and nonblinding of the examiners (Table 4).<sup>22,23,25,26</sup> The majority of the included cohort studies were of sufficient quality (Table 5).<sup>28,29,32,33</sup> For the case series studies, the majority were prospective in design with consecutively enrolled subjects. All the included studies assessed outcomes following placement of singletooth implants in postextraction sites adjacent to natural teeth.

**Change in Position of the Peri-implant Mucosa** *Study Characteristics.* There were 5 RCTs,<sup>22–26</sup> 5 cohort studies,<sup>28–31,33</sup> 3 cross-sectional studies,<sup>21,34,37</sup> and 25 case series studies<sup>20,21,30,39–41,44,46,48–53,56–62,65–72,92</sup> that provided data on change in position of the periimplant mucosa following implant placement. The majority of studies were prospectively designed, with only two studies identified as retrospective reports.<sup>20,53</sup> The data are summarized in Table 6 for studies with comparative data (RCT and cohort studies) and Table 7 for cross-sectional and case series studies.

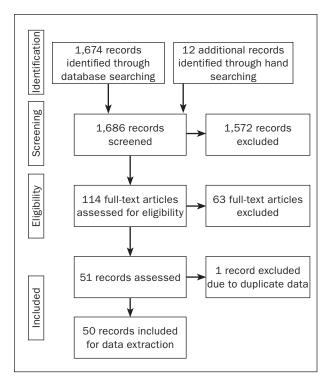


Fig 1 Search results.

**Study Duration.** For studies with comparative data, four studies provided short-term data with observation periods of 6<sup>31</sup> and 12 months.<sup>22,24,29</sup> Three studies reported on 2-year outcomes<sup>23,25,37</sup> and one study provided 3-year data.<sup>26</sup> One study reported on outcomes after a follow-up period of 5 years.<sup>28</sup>

Most of the case series were short-term, with a follow-up period of 12 months reported in 13 studies,  $^{30,39-42,46,47,56,57,59,65,67,92}$  13 to 24 months in 7 studies  $^{34,44,49-51,53,66}$  and 25 to 36 months in 6 studies.  $^{36,48,52,58,60,62}$  There was 1 study with an observation

Table 3         Excluded Studies		
Reason for exclusion	Number	Studies
Review papers or papers of methodology	4	Kan and Rungcharassaeng, $^{71}$ Den Hartog et al, $^{97}$ Grutter and Belser, $^{108}$ Freitas et al $^{111}$
Data for the same population reported in a later study	1	Raes et al <sup>132</sup>
Insufficient data and/or lack of parameters to evaluate esthetic outcomes	31	Handelsman, <sup>70</sup> Hui et al, <sup>72</sup> Proussaefs et al, <sup>73</sup> Saadoun, <sup>74</sup> Kan and Rungcharassaeng, <sup>75</sup> Covani et al, <sup>77</sup> Doring et al, <sup>78</sup> Locante, <sup>79</sup> Norton, <sup>80</sup> Dhanrajani and Al-Rafee, <sup>82</sup> Barone et al, <sup>85</sup> De Kok et al, <sup>86</sup> Steigmann and Wang, <sup>88</sup> Calvo Guirado et al, <sup>89</sup> Covani et al, <sup>90</sup> Kan et al, <sup>92</sup> Sammartino et al, <sup>93</sup> Siepenkothen, <sup>94</sup> Fagan et al, <sup>98</sup> Lops et al, <sup>100</sup> Mankoo, <sup>101</sup> Romeo et al, <sup>103</sup> Avvanzo et al, <sup>105</sup> Del Fabbro et al, <sup>107</sup> Crespi et al, <sup>110</sup> Shibly et al, <sup>115</sup> Balshi et al, <sup>119</sup> Grunder et al, <sup>121</sup> Kehl et al, <sup>123</sup> Lops et al, <sup>126</sup> Fugazzotto <sup>130</sup>
Data for different placement times could not be separated	9	Vanden Bogaerde et al, <sup>84</sup> Noelken et al, <sup>45</sup> Degidi et al, <sup>96</sup> Kollar et al, <sup>99</sup> Stein et al, <sup>109</sup> Juodzbalys and Wang, <sup>113</sup> Siebers et al, <sup>114</sup> Di Alberti et al, <sup>129</sup> Schwarz et al <sup>131</sup>
Data for maxillary anterior sites could not be separated from posterior and mandibular sites	6	Bianchi and Sanfilippo, <sup>76</sup> Cordaro et al, <sup>106</sup> Schropp and Isadore, <sup>104</sup> van Kesteren et al, <sup>117</sup> De Angelis et al, <sup>120</sup> Covani et al <sup>128</sup>
Data available only for implant placement in healed sites or sites that underwent ridge preservation prior to implant placement	11	Van der Zee et al, <sup>81</sup> Hall et al, <sup>91</sup> Lindeboom et al, <sup>87</sup> Cannizzaro et al, <sup>95</sup> Meijndert et al, <sup>102</sup> Aldredge and Nejat, <sup>118</sup> Hof et al, <sup>122</sup> Tymstra et al, <sup>116</sup> Fu et al, <sup>112</sup> Lee et al, <sup>124</sup> Schneider et al <sup>127</sup>
Case reports with less than 5 cases	2	Testori et al, <sup>83</sup> Levin <sup>125</sup>
Total	64	

### Table 4 Quality Assessment and Risk of Bias of Included RCTs

<b>_</b>						
Study	Adequate sequence generation?	Allocation concealment?	Blinding of participants?	Incomplete outcome data addressed?	Free of selective outcome reporting?	Other sources of bias?
Lindeboom et al <sup>22</sup>	Yes	Yes	No	Yes	Yes	No
Chen et al <sup>26</sup>	Yes	No	No	Yes	Yes	No
Palattella et al <sup>23</sup>	Yes	Yes	No	Yes	Yes	No
De Rouck et al <sup>24</sup>	Yes	Yes	Yes	Yes	Yes	No
Block et al <sup>25</sup>	Yes	No	Yes	Yes	Yes	No
Felice et al <sup>27</sup>	Yes	Yes	Yes	Yes	Yes	No

A "no" response in any of the first 5 domains indicates a high risk of bias.

### Table 5 Quality Assessment and Risk of Bias of Included Non-Randomized Studies

Study	Representative of the exposed cohort	Selection of the non- exposed cohort	Ascertainment of exposure	Outcome of risk not present at commencement of study	Comparability of cases and controls (maximum 2 stars)	Assessment of outcome	Sufficient follow-up time for outcomes to occur	Adequacy of follow-up	
Gotfredsen <sup>28</sup>	*	*	*	*	*		*	*	7
Cangini and Cornelini <sup>29</sup>	*	*	*	*	*		*	*	7
Grunder <sup>31</sup>	*	*	*	*				*	5
Juodbalys and Wang <sup>30</sup>	*	*	*	*			*	*	6
Raes et al <sup>32</sup>	*	*	*	*	*	*	*	*	8
De Bruyn et al <sup>33</sup>	*	*	*	*	*		*	*	7

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period of 48 months<sup>61</sup> and 2 long-term studies with 84 month follow-up.<sup>20,21</sup> Four studies<sup>21,58,60,61</sup> were follow-up reports of previous studies.<sup>36,40,46,47</sup>

**Outcomes from Randomized Studies.** Palattella and coworkers compared immediate (type 1) and early (type 2) implant placement in a RCT in which provisional restorations were connected within 48 hours of the implants being placed.<sup>23</sup> Each group comprised eight patients and nine single-tooth implants in the maxillary anterior region. Recession of the midfacial mucosa occurred in both groups without statistically significant difference between the groups after 2 years (type I group,  $-0.8 \pm 0.7$  mm vs type 2 group,  $-0.6 \pm 0.6$  mm; P > .05).

In a RCT that compared type 1 and type 3 implant placement at single-tooth sites with radiographic evidence of chronic periapical lesions, no difference in the level of the midfacial mucosa was observed between the two placement protocols.<sup>22</sup> The frequency of mucosal recession, however, was slightly greater in type 1 placement sites (0 to 1 mm in 7 of 23 sites; 1 to 2 mm in 2 of 23 sites) compared to type 3 placement sites (0 to 1 mm in 4 of 25 sites; 1 to 2 mm in 0 of 25 sites).

Immediate versus delayed restoration of immediately placed implants was compared in a RCT which combined implant placement and grafting of the periimplant defect with DBBM.<sup>24</sup> After 1 year, significantly less recession of the midfacial mucosa (P = .005) was observed in the immediate restoration group (25 implants in 25 patients; 1 early failure;  $-0.41 \pm 0.75$  mm) compared to the delayed restoration group (25 implants in 25 patients;  $-1.16 \pm 0.66$  mm). No differences were observed in recession of the mesial and distal papillae between the immediate restoration group and delayed restoration group (mesial papilla  $-0.41 \pm 0.77$  mm vs  $0.43 \pm 0.42$  mm, respectively; distal papilla  $-0.31 \pm 0.81$  mm vs  $-0.53 \pm 0.55$  mm, respectively).

Three bone augmentation methods with type 1 implant placement were compared in a RCT.<sup>26</sup> A high proportion of sites across all three groups (10 of 30) demonstrated recession of the midfacial mucosa of greater than 1 mm. Implants placed buccally in the extraction sockets were significantly associated with recession.

**Outcomes from Non-randomized Studies.** Four cohort studies provided comparative data on timing of implant placement after extraction.<sup>28,30,33,37</sup> In a prospective cohort study, 25 consecutively enrolled patients received implant placement after extraction according to a decision tree based on the morphology of the extraction socket.<sup>30</sup> Sockets that were considered adequate were treated by flapless type 1 implant placement with a non-submerged approach. Compromised sockets were treated with one of the following techniques: Flapless type 1 implant placement

with a non-submerged approach, type 2 placement 6 weeks after tooth extraction with simultaneous soft and/or hard tissue augmentation, or type 1 implant placement with simultaneous soft and/or hard tissue augmentation. Deficient sockets were reconstructed with GBR and soft tissue grafting procedures prior to implants being placed. After 12 months, all "adequate" sockets achieved satisfactory esthetic outcomes. Compromised sockets treated with type 1 implant placement showed initially adequate esthetic results, but 50% were downgraded to compromised after 1 year. On the other hand, compromised sockets with type 2 placement showed better results, initially 87.5% satisfactory at prosthesis placement and 62.5% after 1 year.

Miyamoto and Obama in a retrospective cohort study reported significantly greater recession at the 2-year follow-up visit with type 1 placement compared to type 2 placement.<sup>37</sup> There were three treatment groups: type 1 placement combined with autogenous bone graft (5 patients and 7 implants), type 2 placement in which guided bone regeneration (GBR) was performed with nonresorbable membranes (8 patients and 16 implants), and type 2 placement combined with GBR using resorbable membranes (3 patients and 8 implants). The implants were conventionally loaded. Recession of the midfacial mucosa of  $0.85 \pm 0.79$  mm,  $0.06 \pm 0.25$  mm, and  $0.50 \pm 0.53$  mm was observed for the three groups, respectively. The differences were significant between the type 1 placement group and the type 2 placement with nonresorbable membrane group (P < .05). Cone beam computed tomography (CBCT) data indicated that vertical resorption of the facial bone occurred, with dimensions of 3.25  $\pm$  4.68 mm, 0.13  $\pm$ 0.36 mm, and  $0.70 \pm 1.02$  mm recorded, respectively.

Gotfredsen compared outcomes between type 2 and type 3 implant placement in a prospective cohort study.<sup>28</sup> Single-tooth implants were placed in 10 patients 4 weeks after extraction (type 2 group) and 10 patients 12 weeks after extraction (type 3 group). After 5 years, the difference in crown length between implants and control teeth was  $0.6 \pm 0.7$  mm in the type 2 placement group and  $0.7 \pm 1.4$  mm in the type 3 placement group (no significant difference; P > .05). Recession of the papillae  $0.3 \pm 0.5$  mm and  $1.0 \pm 0.7$  mm occurred in the type 2 and type 3 placement groups, respectively.

Type 1 and type 4 implant placement were compared in a prospective cohort study.<sup>33</sup> In the type 1 placement group, 55 patients received 55 single-tooth implants. In the type 4 placement group, 58 patients received 58 single-tooth implants. All implants had provisional crowns with no occlusal contacts connected immediately after placement. In the type 1 placement group, two early failures (3.6%) were recorded and one patient was lost to follow-up. In the type 4 placement group, one early failure (1.7%) was noted.

# Table 6Studies with Comparative Data on Different Implant Placement Times that Report on<br/>Dimensional Changes of the Peri-implant Mucosa

Study	Study design	Placement time (n patients/n implants)	Location	Simultaneous bone grafting	Time from surgery to evaluation	Healing protocol (time from surgery to loading in months)
Gotfredsen <sup>28</sup>	Cohort study	Group A: Type 2 at 4 weeks (10/10) Group B: Type 3 at 12 weeks (10/10)	Maxillary anterior and premolar sites	Nonresorbable ePTFE membrane	5 y	Conventional

Cangini and Cornelini <sup>29</sup>	Cohort study	Teeth with periodontal defects requiring extraction Type 1: EMD group (18/18) Membrane group (14/14)	Maxillary anterior and premolar sites	Enamel matrix derivative or resorbable collagen membrane	1 y	Conventional
Lindeboom et al <sup>22</sup>	RCT	Туре 1 (25/25) Туре 3 (25/25)	Maxillary anterior and premolar sites	Milled autogenous bone from the mandibular retromolar or symphyseal region and covered with a resorbable collagen membrane	1 y	Conventional
Chen et al <sup>26</sup>	RCT	Type 1 with 3 augmentation techniques: Control group no and graft no membrane (10/10) BG group DBBM only (10/10) BG+M group DBBM and collagen membrane (10/10)	Maxillary anterior and premolar sites	DBBM	З у	Conventional
Palattella et al <sup>23</sup>	RCT	Type 1 (8/9) Type 2 (8/9) Immediate provisional non-loaded restorations attached within 48 hours of implant placement	Maxillary anterior teeth	No	2 у	Immediate provisional prosthesis (no occlusal contacts)
De Rouck et al <sup>24</sup>	RCT	Type 1: IRG group immediate restoration (24/24) DRG group delayed restoration (25/25)	Maxillary anterior teeth	IRG group DBBM only DRG group DBBM and collagen mem- brane	1 y	IRG group immediate provisional prosthesis (no occlusal contacts) DRG group conventional loading
Block et al <sup>25</sup>	RCT	Type 1 (26/26) Ridge preservation (29/29)	Maxillary anterior and premolar teeth	DFDB	2 у	Immediate provisional prosthesis (no occlusal contacts)
· · · ·	Cohort study	Type 1 (9/9) Type 2 (10/10)	Maxillary anterior and premolar sites	DBBM and collagen membrane	1 y	Immediate provisional prosthesis (no occlusal contacts)
	Cohort study	Type 1 no CT graft (12/12) Type 1 with CT graft (12/12)	Maxillary incisors and canines	No	6 mo	

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Midfacial mucosal margin	Mesial papilla	Distal papilla	
Mean (SD)	Mean (SD)	Mean (SD)	Other findings
Change from baseline to 5 years: Group A: 0.3 (0.5) mm Group B: -0.3 (0.6) mm Difference between implant crown and contralateral control tooth: Group A: 0.6 (1.2) mm Group B: 0.7 (1.4) mm 9/10 Group A and 8/10 Group B implant crowns were longer than the natural control tooth crown No significant difference between groups	Mesial and distal papillae combined Change from baseline to 5 years: Group A: -0.3 (0.5) mm Group B: -1.0 (0.7) mm No significant difference between groups		Patient centered esthetic assessment using a 10 point VAS: Group A: 9.4 (range, 7.1–9.9) Group B: 8.8 (range, 5.1–10.0) Dentist esthetic assessment using a 10 point VAS: Group A: 5.9 (range, 2.9–9.5) Group B: 8.4 (range, 6.1–9.7)
Distance between mucosal margin and submucosally placed implant shoulder: EMD group, 0.90 (1.29) mm Membrane only group, 0.22 (1.47) mm (significant difference between groups; P < .05)	Mesial and distal papillae combined Distance between proximal soft tissue level and submucosally placed implant shoulder: EMD group, 1.30 (2.37) mm Membrane only, group 1.16 (1.0) mm (significant difference between groups; $P < .05$ )		
Compared to the adjacent control tooth: No difference in mucosal level: Type 1, 14/23, Type 3, 21/25 0–1 mm difference: Type 1, 7/23 Type 3, 4/25 1–2 mm difference: Type 1, 2/23 Type 3, 0/25	Jemt Papilla Index mesial and distal papillae combined: Score 2: Type 1 group 5/23 Type 3 group 18/25 Score 3: Type 1 group 18/23 Type 2 group 18/25		All sites had radiographic evidence of chronic periapical lesions Implant failures: 2/25 in Type I group 0/25 in Type 3 group
10/30 sites exhibited recession of 1 to 3 mm (3 in BG group, 3 in control group, 4 in BG+M group)			Implants placed in a buccal in the socket were significantly associated with recession of the mucosa Midfacial mucosal margin and papillae were stable between 1 and 3 years.
Change from baseline Type 1 group: –0.8 (0.7) mm Type 2 group: –0.6 (0.6) mm No significant difference between groups	NR	NR	Jemt Papilla Index (mesial and distal papillae combined) Type 1 group: Score 0, 0; Score 1, 3/18; Score 2, 8/18; Score 3, 7/18; Score 4, 0 Type 2 group: Score 0, 0; Score 1, 2/18; Score 2, 7/18; Score 3, 9/18; Score 4, 0
Baseline to 1 year: IRG group, $-0.41$ (0.75) mm DRG group, $-1.16$ (0.66) mm Significant difference between groups ( $P = .005$ )	Baseline to 1 year: IRG group, -0.41 (0.77) mm DRG group, -0.43 (0.42) mm No significant difference between groups	Baseline to 1 year: IRG group, -0.31 (0.81) mm DRG group, - 0.53 (0.55) mm No significant difference between groups	Excluded patients: 2 with partial loss of facial bone after extraction; 1 in the IRG was excluded because insertion torque was only 20 Ncm Most dimensional change took place in the first 3 months Patient's esthetic satisfaction: IRG, 93% (range, 92%–100%) DRG, 91% (range, 80%–96%)
Length of implant crowns at 2 years Type I group, 7.4 (2.42) mm Ridge preservation group, 8.6 (2.63) mm Groups were significantly different			21/76 patients lost to follow-up
	Nordland and Tarnow classification: Mesial papilla: Adequate: Type 1, 7/9; Type 2, 6/10 Compromised: Type 1, 2/9; Type 2, 4/10	Nordland and Tarnow classification: Distal papilla: Adequate: Type 1, 8/9; Type 2, 8/10 Compromised: Type 1, 1/9; Type 2, 2/10	Type 1: 0% recession ≥ 1 mm Type 2: 20% recession ≥ 1 mm
			Changes in orofacial dimension of the ridge: Type 1 no CT graft, $-1.06$ mm (range $-0.25$ to $-2.0$ ) Type 1 with CT graft, 0.34 mm (range 0 to 1.5)

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## Table 6 continued Studies with Comparative Data on Different Implant Placement Times that Report on Dimensional Changes of the Peri-implant Mucosa

Study	Study design	Placement time (n patients/n implants)	Location	Simultaneous bone grafting	Time from surgery to evaluation	Healing protocol (time from surgery to loading in months)
Miyamoto and Obama <sup>37</sup>		Type 1 with autogenous bone graft (5/7) Type 2 GBR with DBBM and nonresorbable membrane (8/16) Type 2 GBR with DBBM and resorbable membrane (3/8)	Maxillary incisors and canines	Autogenous bone, DBBM, resorbable and non-esorbable membrane	Mean 28 (SD 15.8) mo	Early and conventional
et al <sup>33</sup>	Cohort study	Type 1 (55/55) Type 4 (58/58)	Maxillary anterior and premolar teeth	No	З у	Immediate provisional prosthesis (no occlusal contacts)
Raes et al <sup>32</sup>	Cohort study	Type 1 (16/39) Type 4 (23/39) Failures: 1 in Type 1 group	Single-tooth maxillary anterior and premolar sites	No	1 y	Immediate provisional prosthesis

A slight positive change in the mucosal level was observed from final crown placement to the 3-year recall in both type 1 and type 4 placement groups (0.23  $\pm$ 0.87 mm vs 0.27 ± 1.03 mm). Similarly, a slight gain in papilla height (mesial and distal papillae combined) was observed between final crown insertions to the three-year recall in both groups (0.29 ± 1.08 mm vs  $0.53 \pm .07$  mm, respectively). The difference between groups for midfacial mucosa and papillae were not significant. In a RCT comprising 55 implants and 55 patients, type 1 placement (26 patients) was compared to placement in sites that had undergone ridge preservation (29 patients) using demineralized freeze-dried bone allograft.<sup>25</sup> Implants were immediately restored with provisional crowns. After 2 years, the lengths of the implant crowns were significantly longer in the ridge preservation group (8.6  $\pm$  2.6 mm) compared to the type 1 placement group (7.4  $\pm$  2.4 mm).

In a prospective cohort study, enamel matrix derivative (EMD) was compared to resorbable collagen membrane in conjunction with type 1 implant placement.<sup>29</sup> Significantly less recession of the midfacial mucosa was observed in the EMD-treated sites compared to the membrane-treated sites.

The majority of the case series studies with data on dimensional changes of the peri-implant mucosa were reports on type 1 implant placement. Four studies reported on type 2 implant placement, two of which were follow-up reports on the same patient population.<sup>21,36,47,58</sup> The remaining 24 studies reported on type 1 placement, 18 of which combined immediate implant placement with connection of an immediate

Midfacial mucosal margin Mean (SD)	Mesial papilla Mean (SD)	Distal papilla Mean (SD)	Other findings
Type 1 group 0.85 (0.79) mm * Type 2 group with non-resorbable membrane 0.06 (0.25) mm * Type 2 group with resorbable membrane 0.50 (0.53) mm * P < .05 between these 2 groups			CBCT obtained at least 6 months after abutment connection Vertical bone resorption: Type 1 group 3.25 (4.68) mm * Type 2 group with nonresorbable membrane 0.13 (0.36) mm * Type 2 group with resorbable membrane 0.70 (1.02) mm * P < .05 between these 2 groups Width of labial bone at cervical section: Type 1 group 0.48 (0.67) mm (4/7 implant had no bone visible) Type 2 group with non-esorbable membrane 2.22 (0.81) mm Type 2 group with resorbable membrane 1.15 (0.82) mm (2/8 implants had no bone visible) P < .01 between Type 1 groups and both Type 2 groups
Final crown to 1 year: Type 1 group 0.35 (0.89) mm range -1.0 to 2.5 Type 4 group 0.29 (0.76) mm range -2.0 to 2.0 Final crown to 3 years: Type 1 group 0.23 (0.87) mm range -2.0 to 2.0 Type 4 group 0.27 (1.03) mm range -3.0 to 2.0 No significant differences between groups	Mesial and distal papillae combined: Final crown to 1 year: Type 1 group 0.34 (0.95) mm range -1.8 to 2.3 Type 4 group 0.58 (0.94) mm range -2.8 to 2.5 Final crown to 3 years: Type 1 group 0.29 (1.08) mm range -2.0 to 2.0 Type 4 group 0.53 (1.07) mm range -2.8 to 2.8 No significant differences between groups		Failure rate after 1 year: Type 1 group 3/54 (one patient lost to follow-up) Type 4 group 1/58 (no significant differences between groups) Type 1 cases had intact facial bone or clinically insignificant dehiscences and fenestrations
Type 1 group –0.12 (0.78) mm Type 4 group –1.00 (1.15) mm	Type 1 group 0.07 (0.99) mm Type 4 group 0.30 (1.38) mm	Type 1 group –0.38 (1.21) mm Type 4 group 0.60 (0.87) mm	11/16 implants in the Type 1 group were placed flapless Less recession observed with flapless placement

provisional crown.<sup>30,41,44,46,48–51,56,57,59–62,65,67,92</sup> Type 1 placement using a flapless surgical approach was reported in 13 studies.<sup>44,48–52,56,57,59,61,62,65,92</sup> Various bone and soft tissue augmentation methods were used at the time of implant placement, including autogenous bone graft alone,<sup>62</sup> deproteinized bovine bone mineral (DBBM) alone,<sup>44,46,60,67</sup> resorbable membrane alone,<sup>41</sup> DBBM particles and/or autogenous bone chips covered by a resorbable collagen membrane,<sup>20,21,30,53,58</sup> and DBBM alone combined with a connective tissue (CT) graft.<sup>42,48,50,57,59,92,124</sup>

The predominant finding was that recession of the midfacial mucosa and papillae occurred with postextraction implant placement. In most studies, the mean recession of the midfacial mucosa and tooth-implant papillae was less than 1 mm.<sup>39,41,46,48,49,53,56–59,62,65,67</sup> There were five studies that reported no change<sup>50</sup> or a gain in mucosal height.<sup>44,48,51,66</sup> Four of these studies were of type 1 placement using a flapless approach and immediate provisional prosthesis,<sup>44,51</sup> as well as incorporation of a connective tissue graft at the same time.<sup>48,50</sup> One study combined CT graft and coronal flap advancement to correct preexisting gingival recession at sites in which the extracted teeth were periodontally compromised.<sup>66</sup> A significant mean gain of 2.1 ± 0.7 mm of the midfacial mucosa was reported in this study.

Non-randomized studies that fulfilled the criteria of consecutively enrolled patients, nondeviation of the treatment protocol, and follow-up time of 1 to 3 years were analyzed for trends in outcomes.<sup>34,35,39–41,44,48,51,53,56–60,62,65</sup>

# Table 7Case Series Studies Reporting on Change in Position of the Peri-implant Mucosa at<br/>Postextraction Implants in the Maxillary Esthetic Zone

Study	Study Design	Patients (implants)	Placement time	Healing protocol	Loading protocol	Augmentation technique	Follow-up period
Grunder <sup>39</sup>	Prospective case series	10 (10)	Туре 1	Submerged	Delayed	No augmentation	12 mo
Cornelini et al <sup>41</sup>	Prospective case series	22 (22)	Type 1	Transmucosal	Immediate provisional restoration	Collagen membrane	12 mo
Juodzbalys and Wang <sup>42</sup>	Prospective case series	12 (14)	Type 1	Submerged	Delayed	DBBM and collagen mem- brane; CT graft to correct soft tissue deficiencies	12 mo
Kan et al <sup>43</sup>	Prospective case series	23 (23)	Type 1 flap and flapless	Transmucosal	Immediate provisional restoration	Autogenous bone or DBBM and collagen membrane; CT graft in 11/23 cases in which tissue biotype was thin	12 mo
Canullo and Rasperini <sup>44</sup>	Prospective case series	9 (10)	Type 1 flapless	Transmucosal	Immediate provisional restoration	DBBM if defect > 1 mm in orofacial dimension	Mean 22 mo (range, 18 to 36)
Evans and Chen <sup>34</sup>	Cross-sectional	42 (42)	Туре 1	NR	Conventional	Not stated	Mean 19 mo
De Rouck et al <sup>46</sup>	Prospective case series	29 (29)	Type 1	Transmucosal	Immediate provisional restoration	DBBM	12 mo
Kan et al <sup>48</sup>	Prospective case series	20/20	Type 1 flapless	Transmucosal	Immediate provisional restoration	DBBM and CT graft	Mean 26 mo (range, 12 to 48)
Pirker and Kocher <sup>49</sup>	Prospective case series	12/12	Type 1 flapless	Transmucosal	Immediate provisional restoration	No augmentation	Mean 18 mo (SD 10; range, 6–34)
Redemagni et al <sup>50</sup>	Retrospective case series	28 (33)	Type 1 flapless	Transmucosal	Immediate provisional restoration	DBBM + CT graft	Mean 20.4 mo (range, 6 to 50)
Chen et al <sup>52</sup>	Retrospective case series	85 (85)	Type 1 flapless	Transmucosal	Early	No augmentation	Mean 26 mo
Cosyn and De Rouck <sup>53</sup>	Prospective case series	27 (27)	Type 2	Submerged	Conventional	DBBM + collagen mem- brane	Mean 21 mo
Tortamano et al <sup>51</sup>	Prospective case series	12 (12)	Type 1 flapless	Transmucosal	Immediate provisional restoration	Not stated	18 months

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Change in midf	acial mucosa*		
Frequency	Mean (SD)	Change in papillae height	Additional comments
NR	–0.6 (0.39) mm (median –0.5 mm; range 0 to –1.5 mm)	Mesial –0.5 (0.33) mm Distal –0.25 (0.26) mm Papillae combined –0.375 (0.32) mm (median –0.5 mm; range 0 to –1 mm)	
NR	Mean recession 0.75 mm	Jemt Papilla Index <sup>138</sup> : Score 2, 61% of papillae Score 3, 39% of papillae No scores of 0, 1, and 4	
21.4% with recession of 1 to 2 mm	NR	Jemt Papilla Index <sup>138</sup> : Score 2, 64.3% of papillae Score 3, 35.7% of papillae No scores of 0, 1, and 4	
34.8% - recession ≥ 1.5 mm 8.3% of sites with V-shaped defects of the facial bone 42.8% of sites with U-shaped defects of the facial bone 100% of sites with UU-shaped defects of the facial bone	NR	NR	CT graft was used in 4/8 with gingival recession of $\geq$ 1.5 mm
	0.2 (0.42) mm	Mesial, 0.4 (0.52) mm Distal, 0.1 (0.32) mm	
45.2%, recession 0.5 mm; 21.4%, recession 1.0 mm; 19.1%, recession ≥ 1.5 mm	–0.9 (0.78) mm	Mesial, –0.5 (0.52) mm Distal, –0.5 (1.0) mm	Subjective Esthetic Score (SES) <sup>34</sup> 82% satisfactory (score I and II) 18% unsatisfactory (score III and IV)
	–0.53 (0.76) mm Significantly different from baseline	Mesial, -0.41 (0.71) mm Distal, -0.31 (0.83) mm Mesial was significantly different from baseline	Patient's esthetic evaluation (VAS) Mean 93% (range 82 to 100%) The largest dimensional changes took place i the first 3 mo of implant placement
	+0.13 (0.61) Thick biotype: +0.23 (0.82) Thin biotype: +0.06 (0.45) No significant differences between thin and thick biotype cases	Jemt Papilla Index <sup>138</sup> : Score 2, 20% of papillae Score 3, 80% of papillae	
	–0.5 (0.7) mm Range 0-1.5 mm		58% cases had no discernible mucosal recession
	Mean 0 Range –1 to +0.5 mm	Mesial papilla: –0.21 (range 2 to –0.5) mm Distal papilla: –0.02 (range 1 to –0.5) mm	
At 44 sites with initial gingival margins level with adjacent maxillary central incisor: 20.5% recession 5% to 10%; 18% recession of >10%	-4.6 (6.6)% of length of the reference tooth	Mean change of papillae: Mesial, –6.2 (6.8)% Distal, –7.4 (7.5)% of length of the reference tooth	
	–0.3 (1.2) mm	Mean change of papillae: Mesial: -0.4 (0.9 mm) Distal: -1.0 (1.0) Significant difference between groups	
	+0.03 mm	Mesial, +0.14 mm Distal, +0.03 mm	Only cases with intact facial bone were included

### Table 7 continued Case Series Studies Reporting on Change in Position of the Peri-implant Mucosa at Postextraction Implants in the Maxillary Esthetic Zone

Postextraction Implants in the Maxillary Esthetic Zone							
Study	Study Design	Patients (im- plants)	Placement time	Healing protocol	Loading protocol	Augmentation technique	Follow-up period
Kan et al <sup>61</sup>	Prospective case series	35 (35)	Type 1 flapless	Transmucosal	Immediate provisional restoration	No augmentation	Mean 48 mo (range, 2 to 8.2 y)
Brown and Payne <sup>56</sup>	Prospective case series	27 (28)	Type 1 flapless	Transmucosal	Immediate provisional restoration	Not stated	12 mo
Tsuda et al <sup>57</sup>	Prospective case series	10 (10)	Type 1 flapless	Transmucosal	Immediate restoration	DBBM + CT graft	12 mo
Buser et al <sup>58</sup>	Prospective case series	20 (20)	Туре 2	Submerged	Conventional	Autogenous bone chips + DBBM + collagen mem- brane	36 mo
Chung et al <sup>59</sup>	Prospective case series	10 (10) 1 failure	Type 1 flapless	Transmucosal	Immediate restoration	DBBM and CT graft	12 mo
Malchiodi et al <sup>62</sup>	Prospective case series	58 (64)	Type 1 flapless	Transmucosal	Immediate provisional restoration	Autogenous bone chips	36 mo
Benic et al <sup>20</sup>	Cross-sectional	14 (14)	Type 1	Transmucosal	Conventional	DBBM + collagen mem- brane in 11 cases	Mean 84 mo
Cabello et al <sup>65</sup>	Prospective case series	13 (13)	Type 1 flapless	Transmucosal	Immediate provisional restoration	No augmentation	12 mo
Lee et al <sup>66</sup>	Prospective case series	10 (11)	Type 1	Transmucosal	Conventional	DBBM + CT graft	24 mo
Buser et al <sup>21</sup>	Prospective case series	41 (41)	Type 2	Submerged	Early	Autogenous bone chips + DBBM + collagen mem- brane	Mean 84 mo (range 5–9 y)
Cosyn et al <sup>67</sup>	Prospective case series	22 (22)	Type 1	Transmucosal	Immediate provisional restoration	DBBM Some cases required CT grafts at a later stage to correct soft tissue defi- ciencies	12 mo

\* Negative value indicates recession of the mucosa; DBBM = deproteinized bovine bone mineral; CT = connective tissue.

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Change in mid	facial mucosa*	_	
Frequency	Mean (SD)	Change in papillae height	Additional comments
	All –0.53 (0.23) mm Baseline to last follow-up: Thin biotype –1.50 (0.88) mm	Thin biotype, -0.18 (0.36) mm; Thick biotype, -0.27 (0.30) mm; All, -0.22 (0.34) mm	All cases had intact facial bone 4 patients (11%) required adjunctive treatment including CT graft, autograft or xenograft to treat mucosal recession Patient evaluation of esthetic outcome (Rating 0 to 10; 0 = totally unsatisfied, 10 = totally satisfied): 33/35 patients were totally satisfied with the esthetic outcome (rated 10) 2/35 patients rated the outcome as 9 Mean patient rated esthetic outcome 9.9
	–0.2 (0.99) mm	Jemt Papilla Index <sup>138</sup> : Score 1, 7% of papillae Score 2, 58% of papillae Score 3, 37% of papillae No scores of 0, 1, and 4	
	–0.05 mm	Jemt Papilla Index <sup>138</sup> : Mesial papilla: Score 0, 20%; Score 1, 10% Score 2, 20%; Score 3, 50% Distal papilla: Score 0, 10%; Score 2, 10% Score 3, 80%	Necrosis of the CT graft in 2 patients resulted
Recession < 1 mm in 1/20	Length compared to control tooth (negative value indicates recession) 1 y: -0.18 (0.58) mm 3 y: -0.09 (0.33) mm		
	–0.05 mm	Jemt Papilla Index <sup>138</sup> : Mesial papilla: Score 2, 11%; Score 3, 89% Distal papilla: Score 0, 11%; Score 1, 11% Score 2, 11%; Score 3, 67%	
46.9% sites had no recession 21.9% recession of 0.5 mm 18.8% recession of 1.0 mm 12.5% recession $\ge$ 1.5 mm	–0.5 (0.6) mm	Distance between contact point to tip of papilla: Mesial, 0.6 (0.5) mm; Distal, 0.8 (0.6) mm	Significant relationship between crestal bone levels and papilla volume and midfacial mucosal level
At implants with no detectable facial bone on CBCT (5/14) there was 1 mm more recession of the facial mucosa (4/5 received GBR)	-1.5 mm (extrapolated by authors)		Implant shoulder submucosally positioned (tissue level implants) in 12/14 cases
	–0.45 (0.25) mm	Mesial, -0.38 (0.60); Distal, -0.80 (0.96)	No correlation between tissue biotype and dimensional changes of the mucosa between baseline and 12 months
	+2.1 (0.7) mm	Mesial, –0.1 (0.5) mm; Distal, –0.3 (0.5) mm	All cases had preexisting soft tissue recession
	No sig difference between implant crown and control tooth crown Implant crown length at 2006 9.48 (1.09) mm Implant crown length at 2010 9.47 (1.22) mm		CBCT measurement of facial bone thickness at 2010 examination: In relation to implant shoulder: 2 mm level, 1.58 (1.0) mm; 4 mm level, 2.22 (0.98) mm; 6 mm level, 2.33 (1.14) mm; In 2 implants (4.9%) no facial bone was detected
At 3 months: 9% > 1 mm recession At 12 months: 0% > 1 mm recession	At 3 months: -0.3 (0.8) mm range -2.0 to 1.5 At 12 months: -0.2 (0.4) mm range -1.0 to 0.5)	At 12 mo: Mesial papilla, -0.2 (0.5) mm, range -1.0 to 1.0 Distal papilla, -0.5 (0.5) mm, range -1.5 to 0	1 failure, 1 drop out Severe recession (1.5 mm and 2.0 mm) noted in 2 patients at 3 months. A further 5 patients had noticeable recession. 7 patients required adjunctive CT graft at 3 months to correct recession of the midfacial mucosa

Placement timing	Mean	Lower limit	Upper limit	Mean and 95% Cl	Relative weight
Type 1					
Grunder <sup>39</sup>	-0.60	-0.84	-0.36		7.63
Kan et al <sup>40</sup>	-0.53	-0.61	-0.45	-	8.95
Cornellini et al <sup>41</sup>	-0.75	-0.91	-0.59		8.40
Canullo and Rasperini <sup>44</sup>	0.2	-0.06	0.46		7.43
Evans and Chen <sup>34</sup>	-0.90	-1.14	-0.66		7.69
Tortamano et al <sup>51</sup>	0.03	-0.25	0.31		7.27
Kan et al <sup>48</sup>	0.23	-0.04	0.50		7.36
Malchiodi et al <sup>62</sup>	-0.50	-0.65	-0.35		8.51
Chung et al <sup>59</sup>	-0.05	-0.34	0.24		7.07
Tsuda et al <sup>57</sup>	-0.05	-0.26	0.16		7.97
Brown and Payne <sup>56</sup>	-0.20	-0.57	0.17	<b>_</b> _	6.29
Cosyn et al <sup>60</sup>	-0.34	-0.65	-0.03		6.86
Cabello et al <sup>65</sup>	-0.45	-0.59	-0.31	-	8.59
	<i>I</i> -square	d = 89.783,	P = .000		
Туре 2					
Buser et al <sup>35</sup>	-0.29	-0.36	-0.22		50.66
Cosyn and De Rouck <sup>53</sup>	-0.30	-0.75	0.15		10.42
Buser et al <sup>58</sup>	-0.09	-0.23	0.05		38.92
	I-square	ed = 66.103,		–1.00 0.00 icosal loss Mu (mm)	1.00 ucosal gain (mm)

**Fig 2** Mean change in midfacial mucosal position reported in studies grouped by timing of implant placement. NB weights are from random-effects analysis.

Studies were grouped according to placement timing (Fig 2). A greater variation in results was noted for type 1 placement (13 studies; *l*-squared = 89.783, P = .000) compared to type 2 placement (3 studies; *l*-squared = 66.103, P = .062). These studies varied in surgical protocol (flap vs flapless elevation), hard and soft tissue grafting, and loading protocols. Further stratification of studies on type 1 placement was made according to treatment methodology (use of bone graft, flapless surgery, provisional crown, and CT graft) (Fig 3). From the forest plots, less variation in results was seen for the combination on bone graft, flapless surgery, provisional crown, and CT graft at the time of type 1 implant placement (3 studies; *l*-squared = 33.74, P = .223).

There was one study of type 2 implant placement<sup>53</sup> and eight studies of type 1 implant placement<sup>34,39,40,44,51,53,60,62,65</sup> that provided data on change in position of the mesial and distal papillae (Fig 4). Significant heterogeneity between studies was noted which generally indicated that recession of the papillae occurred with both placement timings. Grouping of type 1 placement studies according to use of provisional crown and surgical approach (flap versus flapless surgery) revealed a homogeneity between two studies<sup>34,39</sup> in which implants were placed with conventional flap surgery and no provisional crowns connected immediately (mesial papilla: *I*-squared = 0.000, P = .999; distal papilla: *I*-squared = 51.089, P = .153) (Fig 5). Examination of the forest plots yielded no distinct trend in change of papilla position based on surgical approach and use of immediate provisional crowns.

**Frequency of Recession.** In addition to reporting mean values, several studies also reported on the frequency of recession of the midfacial mucosa. In a RCT, Lindaboom and coworkers reported a higher frequency of recession at the type 1 placement group (0 to 1 mm in 7 of 25 sites and 1 to 2 mm in 2 of 25 sites) compared to type 3 placement group (0 to 1 mm in 4 of 25 sites and 1 of 2 mm in 0 to 25 sites) when compared to the adjacent control teeth.<sup>22</sup> In another RCT, 10 of 30 sites exhibited recession of the midfacial mucosa of 1 to 3 mm following type 1 implant placement and transmucosal healing.<sup>26</sup> In two studies of type 1 placement using a conventional surgical approach and conventional loading protocol, the frequency of recession of the midfacial mucosa of 1 mm or more was

Study	Bone graft		Provisional crown	CT graft	Mean	Lower limit	Upper limit	Mean and 95% C	Relative V weight
Evans and Chen <sup>34</sup>	No	No	No	No	-0.91	-1.14	-0.66		100
Grunder <sup>39</sup>	Yes	No	No	No	-0.60	-0.84	-0.36	│╶╋┼╴│	100
Kan et al <sup>40</sup>	No	Yes	Yes	No	-0.53	-0.61	-0.45	🚔	32.66
Tortamano et al <sup>51</sup>					0.03	-0.25	0.31		21.18
Brown and Payne56					-0.20	-0.57	0.17	│ ┼╋┼╴│	16.4
Cabello et al <sup>65</sup>					-0.45	-0.59	-0.31	📥	29.76
				l-squ	uared = 8	2.500, F	P = .001		
Cornelini et al <sup>41</sup>	No	No	Yes	No	-0.75	-0.91	-0.59	-■-	100
Canullo and Rasperini <sup>44</sup>	Yes	Yes	Yes	No	0.20	-0.06	0.46		48.77
Malchiodi et al <sup>62</sup>					-0.50	-0.65	-0.35	📥	51.23
				/-squ	uared = 9	5.252, F	<i>p</i> = .000		
Cosyn et al <sup>60</sup>	Yes	No	Yes	No	-0.34	-0.65	-0.03		100
Kan et al <sup>48</sup>	Yes	Yes	Yes	Yes	0.23	-0.04	0.50		30.82
Chung et al <sup>59</sup>					-0.05	-0.34	0.24		26.86 42.32
Tsuda et al <sup>57</sup>					-0.05	-0.26	0.16		42.32
				l-so	quared =	33.74, P		–1.00 0.00 ucosal loss (mm)	1.00 Mucosal gain (mm)

**Fig 3** Mean change in midfacial mucosa reported in studies on immediate (type 1) placement grouped by treatment method. NB weights are from random-effects analysis.

reported to be 21.4%<sup>42</sup> and 40.5%.<sup>34</sup> Two studies of type 1 placement with immediate provisional restoration of the implants reported on the frequency of recession of the midfacial mucosa. In one study, implants were placed in extraction sites with thick tissue biotype using a minimal flap elevation. Recession of the midfacial mucosa of 1 mm or more was noted in 9% of sites within 3 months of the implants being placed.<sup>67</sup> In the other study, implants were placed with a flapless surgical technique. After 3 years, recession of the midfacial mucosa of 1 mm or more was observed in 31.3% of sites.<sup>62</sup> In contrast, one study of type 2 implant placement using conventional flap elevation, GBR with autogenous bone chips and DBBM and a submerged healing protocol reported 1 out of 20 sites with recession (0.5 to 1 mm) after 3 years.<sup>58</sup>

In a study of type 1 placement in the presence of defects in the facial bone of varying size, recession of the midfacial mucosa of 1.5 mm or more was reported in 34.8% of sites.<sup>92</sup> The defects were grafted with autogenous bone chips or DBBM combined with a resorbable collagen membrane. In the presence of thin periodontal tissue biotype, additional grafting with

CT was carried out. The implants were provisionally restored following placement. It was noted that the frequency of recession increased with correspondingly larger defects in the facial bone.

In contrast, one study of type 2 placement reported a relatively low incidence of recession of the midfacial mucosa.<sup>58</sup> Type 2 implant placement was combined with GBR using autogenous bone chips and DBBM and resorbable collagen membrane. After 3 years, 1 of 20 sites (5%) demonstrated recession, which was in the range of 0.5 to 1 mm.

**Outcomes from CBCT.** Three studies provided data on CBCT reconstructed images of the bone on the facial aspect of maxillary anterior implants. In the study of Miyamoto and Obama, type 1 placement sites were grafted with autogenous bone to fill the peri-implant defect. Type 2 placement sites were grafted with DBBM and either a resorbable or non-resorbable barrier membrane.<sup>37</sup> Significantly greater recession of the midfacial mucosa occurred at type 1 placement sites compared to type 2 placement sites after a mean of 28 months (SD, 15.8 months). There was correspondingly greater vertical crestal bone

			Mes	sial papilla	
Study	Mean	Lower limit	Upper limit	Mean and 95% Cl	Relative weight
Type 2					1
Cosyn and De Rouck <sup>53</sup>	-0.400	-0.739	-0.061		100.00
Type 1					
Grunder <sup>39</sup>	-0.500	-0.705	-0.295		12.70
Kan et al <sup>40</sup>	0.220	-0.333	-0.107	-	14.37
Canullo and Rasperini <sup>44</sup>	0.400	0.078	0.722		- 10.18
Evans and Chen54	-0.500	-0.657	-0.343		13.63
Tortamano et al <sup>51</sup>	-0.150	-0.239	-0.061	-	14.69
Malchiodi et al <sup>62</sup>	-0.600	-0.722	-0.478		14.22
Cosyn et al <sup>60</sup>	-0.050	-0.375	0.275		10.11
Cabello et al <sup>65</sup>	-0.380	-0.706	-0.054		10.10
	I-squared	d = 89.454	·	–1.00 0.00 lucosal loss Mu (mm)	1.00 ucosal gain (mm)

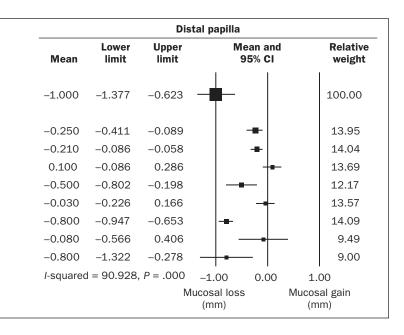
**Fig 4** Mean change in position of the mesial and distal papilla reported in studies grouped by timing of implant placement. NB weights are from random-effects analysis.

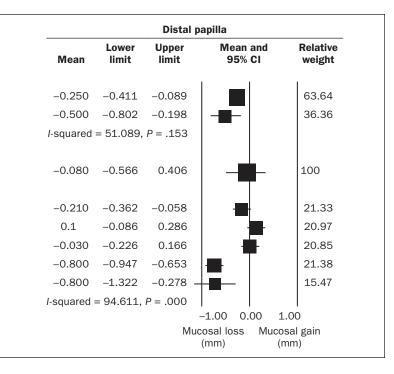
			Mesia	l papilla	
Study	Mean	Lower limit	Upper limit	Mean and 95% Cl	Relative weight
No provisional crown, flap surgery					
Grunder <sup>39</sup>	-0.500	-0.705	-0.295	- ■	37.15
Evans and Chen <sup>34</sup>	-0.500	-0.657	-0.343		62.85
	I-squared	= 0.000,	P = .999		
Provisional crown, flap surgery					
Cosyn et al <sup>60</sup>	-0.050	-0.375	0.275	│ -∰-	100.00
Provisional crown, flapless surgery					
Kan et al <sup>40</sup>	-0.220	-0.333	-0.107		22.32
Canullo and Rasperini <sup>44</sup>	0.4	0.078	0.722		16.48
Tortamano et al <sup>51</sup>	-0.150	-0.239	0.061		22.74
Malchiodi et al <sup>62</sup>	-0.600	-0.722	-0.478		22.12
Cabello et al <sup>65</sup>	-0.380	-0.706	-0.054		16.36
	I-squared =	92.391,	P = .000		
				-1.00 0.00 1.0	0
			Mu	cosal loss Mucosa (mm) (mr	0
				(1111) (1111	

**Fig 5** Mean change in position of the mesial and distal papilla reported in studies of type 1 implant placement grouped by treatment method. NB weights are from random-effects analysis.

resorption at type 1 placement sites  $(3.25 \pm 4.68 \text{ mm})$  compared to type 2 placement sites  $(0.13 \pm 0.36 \text{ mm})$  for nonresorbable membrane and  $0.70 \pm 1.02 \text{ mm}$  for resorbable membrane) which suggests that dimensional change in crestal bone influences the position of the peri-implant mucosa. From reformatted images of the scans, the orofacial thickness of the facial bone

was measured at various points along the implants. At the cervical region of the implants, type 1 placement sites grafted with autogenous bone had a mean bone thickness of  $0.48 \pm 0.67$  mm; 4 of 7 (57.1%) sites had no detectable bone on the facial surface of the implants. Type 2 placement sites grafted with DBBM had bone thickness of  $2.22 \pm 0.81$  mm for the sites treated with





nonresorbable membrane and 1.15  $\pm$  0.82 for sites treated with resorbable membrane. Two of eight (25%) of the type 2 sites treated with resorbable membrane had no detectable facial bone on the scans. The risk of resorption of the facial bone crest in type 1 placement was also identified in a recent retrospective study.<sup>20</sup> In 14 patients with 14 single-tooth type 1 implant placements, CBCT data were obtained 7 years after

implant placement. At 11 sites, the peri-implant defects were grafted with DBBM and collagen membrane. The remaining three sites were not grafted. The authors reported an average of 1.5 mm of recession of the midfacial mucosa. There was no detectable facial bone on the reformatted CBCT images in 5 of 14 sites (35.7%). At sites with no radiographically detectable facial bone, recession of the midfacial mucosa was 1 mm greater than at sites with detectable facial bone.

A recent follow-up study of type 2 implant placement reported stable facial bone conditions.<sup>21</sup> Out of the original 45 patients who received single-tooth implants combined with GBR using autogenous bone chips, DBBM and resorbable collagen membrane and were examined in 2006,<sup>35</sup> 41 were able to be recalled 4 years later in 2010 (5 to 9 years after implant placement).<sup>21</sup> Clinical data were recorded and CBCT scans were obtained. There was no change in the length of the implant crowns between the 2 time points (9.48  $\pm$  1.09 mm at the first examination and 9.47  $\pm$  1.22 mm at the second examination). From reformatted CBCT images, the orofacial thickness of the facial bone wall was measured at three levels. At 2 mm from the implant shoulder, the mean orofacial thickness was 1.58 ± 1.00 mm. The corresponding measurements at 4 mm and 6 mm levels were  $2.2 \pm 0.98$  mm and  $2.33 \pm 1.14$  mm, respectively. In 2 of 41 implants (4.9%), no facial bone wall was detectable radiographically.

**Factors Associated with Risk for Recession.** From the included studies, factors associated with risk for recession of the midfacial mucosa were identified as pre-existing defects of the facial bone, tissue biotype, implant malposition, stability, and thickness of the facial bone and biomaterials used.

The influence of pre-existing defects in the facial bone on recession of the midfacial mucosa was identified in a study of type 1 placement.<sup>43</sup> In this study, all extraction sites presented with varying degrees of damage to the facial socket wall. Following implant placement, the defects were grafted with autogenous bone or DBBM combined with a resorbable collagen membrane. In the presence of thin periodontal tissue biotype, additional grafting with CT was carried out in 11 of 23 (47.8%) sites. The implants were provisionally restored immediately following implant placement. After 1 year, recession of the facial mucosa of 1.5 mm or more was observed in 34.8% of sites. At sites with minor defects in the facial bone, 8.3% of sites developed

Study	Mean	Lower limit	Upper limit	Mean and 95% Cl	Relative weight
Type 1					
Juodzbalys and Wang <sup>42</sup>	11.1	10.39	11.81	-	13.32
Chen et al <sup>113</sup>	10.95	10.59	11.31		15.19
Cosyn et al <sup>60</sup>	10.48	9.51	11.45		11.64
Mangano et al <sup>63</sup>	9.58	8.62	10.54		11.71
Noelken et al <sup>64</sup>	12.5	11.99	13.18		- 14.48
Noelken et al <sup>69</sup>	11.28	10.26	12.29		- 11.33
Cosyn et al <sup>38</sup>	10.88	9.95	11.81	-	11.91
Raes et al <sup>32</sup>	10.33	9.17	11.49		10.42
	<i>I</i> -squar	ed = 83.645	, <i>P</i> = .000		
Туре 2					
Buser et al <sup>58</sup>	11.5	10.72	12.28		<b>-</b> 33.89
Cosyn et al <sup>38</sup>	10.07	9.47	10.67		36.72
Cosyn et al <sup>38</sup> GBR	9.65	8.59	10.71	-=-	29.39
	<i>I</i> -squar	ed = 81.146	, <i>P</i> = .005	0.00 7.00 PES	14.00

Fig 6 Esthetic outcomes based on pink esthetic score (PES) reported in studies grouped by timing of placement. NB weights are from random-effects analysis.

recession. At sites with larger defects, 42.8% of sites demonstrated recession of the mucosa. In extraction sites with a complete loss of the facial bone wall, recession of the mucosa occurred in 100% of sites.

Thin tissue biotype was identified as a risk factor for mucosal recession. In a study of type 1 implant placement using a flapless surgical approach and immediate provisional restoration, thin biotype sites had significantly more recession than thick biotype sites after 1 year (0.75  $\pm$ 0.59 mm vs 0.25  $\pm$  0.33 mm, respectively). In a retrospective study of type 1 placement using a conventional surgical approach and loading protocol, a higher frequency of recession of the midfacial mucosa of 1 mm or more was observed for thin biotype sites (11 of 24 sites) compared to thick biotype sites (6 of 18).<sup>34</sup> Of the sites that developed recession, 6 of the 11 thin biotype sites showed severe recession of more than 2 mm. In contrast to these observations, Kan et al reported no differences between thick and thin tissue biotype sites when CT grafts were incorporated in the surgical protocol of flapless implant placement and immediate restoration.48

Two studies reported that the position of the implant in the extraction socket at type 1 placement sites was an important risk factor for mucosal recession.<sup>26,34</sup> Implants that were malpositioned facially in the extraction sockets were significantly associated with an increased risk for mucosal recession.<sup>2</sup> Recession of the mucosa was three times greater in facially malpositioned implants (1.8 ± 0.83 mm) compared to implants placed more orally in the socket (0.6 ± 0.55 mm); the difference was statistically significant.<sup>34</sup> Based on the studies with CBCT data, type 1 implant placement was associated with significant vertical resorption of the crestal bone and recession of the midfacial mucosa irrespective of the grafting material used (autogenous bone versus DBBM).<sup>20,37</sup> A significant proportion of type 1 placement sites did not have a detectable bone wall on the facial aspect of the implants.<sup>20</sup> In contrast, type 2 placement sites grafted with autogenous bone chips and/or DBBM were associated with less recession of the mucosa<sup>21,37</sup> and a much higher proportion of sites retained detectable bone on the facial aspect of the implants after 7 years.<sup>21</sup>

Mucosal Stability. Several studies of type 1 implant placement reported that the greatest dimensional change took place within the first 3 months of surgery.<sup>24,26,46,65,67</sup> In two studies, mucosal recession was severe enough to require intervention with CT grafts.<sup>26,67</sup> In the study of Chen et al, recession of the midfacial mucosa of 1 to 3 mm occurred in 10 of 30 sites within the first 12 months of surgery. Several sites required corrective treatment using CT grafts.<sup>26</sup> Cosyn and coworkers reported that with type 1 placement combined with immediate provisional restoration and grafting of the peri-implant defect with DBBM, 9% of sites had recession of 1 mm or more within 3 months of implant placement.<sup>67</sup> Severe recession of 1.5 to 2 mm was noted in two patients. Overall, seven patients (seven implants or 31.8% of cases) required adjunctive CT grafts to correct the recession of the midfacial mucosa.

Between 1 to 3 years, the mucosa was reported to be stable in two studies.<sup>26,33</sup> In contrast, Kan and

co-workers reported that after initial recession of the peri-implant mucosa, ongoing changes took place between the first examination at 1 year and the followup of examination that took place 2 to 8.2 years later (mean 4 years).<sup>61</sup> Patients had received type 1 placement implants with connection of immediate provisional restorations. Bone grafts were not placed. At 1 year, mean recession of the midfacial mucosa was 0.53  $\pm$  0.23 mm. Recession at the follow-up examination had increased to  $1.13 \pm 0.87$  mm. There was a corresponding increase in the recession of the tooth-implant papillae. Thin biotype sites receded three times more than thick biotype sites. Four patients (11%) expressed concern about the mucosal recession, and three underwent hard and soft tissue grafting procedures to repair the recession. Studies of type 2 placement showed stable mucosal conditions after 3 years<sup>58</sup> and after an average of 7 years in another study from the same group.<sup>21</sup> In both studies, GBR using autogenous bone chips, DBBM, and resorbable collagen membrane was performed. Gotfredsen and coworkers observed stable peri-implant mucosal conditions following type 2 and type 3 implant placement after 5 years.<sup>28</sup> Non-resorbable e-PTFE membranes were used for bone augmentation in this study.

#### **Outcomes Based on Esthetic Indices**

Study characteristics. One RCT,<sup>27</sup> one cohort study,<sup>32</sup> one cross-sectional study,<sup>38</sup> and 13 case series studies<sup>21,36,42,47,52,55,58,60,63,64,67-69</sup> reported on esthetic outcomes based on esthetic indices (Tables 8 and 9). Three studies<sup>21,38,58</sup> were follow up reports of previous studies.<sup>36,47,55</sup> All papers were recent publications, the majority having been published since 2009. The majority of studies that fulfilled the inclusion criteria for this systematic review reported on outcomes using the Pink Esthetic Score (PES) in which scores of 0,1, and 2 are assigned to seven soft tissue esthetic parameters to reach a maximum score of 14.<sup>21,27,32,36,38,42,47,52,58,60,63,64,67-69</sup> In five of the studies, a modified version of the PES was used, in which scores of 0, 1, and 2 are assigned to five soft tissue esthetic parameters to reach a maximum score of 10.<sup>21,36,58,63,68</sup> The authors of two of the studies, when contacted, provided the full PES.<sup>58,63</sup> The White Esthetic Score (WES), which assigns scores of 0, 1, and 2 to 5 prosthesis-related parameters (to reach a maximum score of 10) was reported in five studies.<sup>21,58,60,67,68</sup> The Subjective Esthetic Score (SES), which ranks soft tissue related outcomes according to the degree of mucosal recession and volume of the soft tissues on a categorical scale of 1 to 4, was reported in two papers.<sup>34,52</sup>

**Outcomes from Randomized Studies.** One RCT reported on outcomes using an esthetic index. In this study, type 1 placement with DBBM graft was com-

pared to implant placement in sites that had been grafted with DBBM 4 months previously (ridge preservation group).<sup>27</sup> Provisional restorations were connected to the implants in both groups immediately following their placement. There were 54 patients in the type 1 placement group and 52 patients in the ridge preservation group. Short-term data at 4 months from the time of provisional prosthesis insertion were reported. The authors reported that 35% and 75% of implants in the type 1 placement and ridge preservation groups respectively did not have the provisional restorations connected immediately due to lack of sufficient implant stability. The PES for the type 1 placement and ridge preservation groups were  $12.75 \pm 0.25$ and 12.62 ± 1.05, respectively, with no significant difference between groups.

**Outcomes from Non-randomized Studies.** In a cohort study that involved single-tooth implants with immediate provisional restorations, type 1 placement was compared to type 4 placement after 1 year. No bone grafts were placed at the time of implant insertion. After 1 year, the PES was  $10.33 \pm 2.04$  for the type 1 placement group and  $10.35 \pm 1.58$  for the type 4 group. The difference was not significantly different. The WES was similar between the type 1 placement (WES  $7.20 \pm 2.04$ ) and type 4 placement (WES  $7.00 \pm 2.37$ ) groups.

In a cross-sectional study in which patients were examined on average 33 months from the time of implant placement, 4 treatment modalities were identified in relation to timing of implant placement.<sup>38</sup> For type 1 placement, DBBM was grafted to the gap between the implant and socket wall (28 patients and 30 implants). There were two treatment modalities for type 2 placements-49 implants in the 44 patients were placed without augmentation procedures and at 19 implants in 18 patients, GBR using DBBM and resorbable collagen membrane was used. A staged bone graft and late placement group was also identified, in which block bone grafts had been placed to augment deficient sites prior to implant insertion (14 implants in 14 patients). At type 1 placement sites, all cases had thick gingival biotype, intact facial bone, and ideal soft tissue levels. For the type 2 without GBR group, a minimum of 1.5 mm of bone thickness was present on the facial aspect of the implants. Both thin and thick tissue biotype cases were treated in this group. For the type 2 group with GBR, less than 1.5 mm of bone thickness was present on the facial aspect of the implant. Both thin and thick biotype cases were treated in this group. There were two early failures in the type 1 placement group, five in the type 2 placement group (three in the nongrafted group, and one in the GBR group) and one failure in the staged block graft group. Esthetic outcomes were assessed using PES. Similar results were achieved

, c	Jucon	les Using Esthetic I				
Study	Study design	Placement time (patients/implants)	Location	Simultaneous bone augmentation	Time from surgery to evaluation	Healing protocol (time from surgery to loading in mo)
Raes et al <sup>32</sup>	Cohort study	Type 1 (16/39) Type 4 (23/39) Failures: 1 in Type 1 group	Single-tooth maxillary anterior and premolar sites	No augmentation	52 weeks from connection of the provisional restoration	Immediate provisional prosthesis
Felice et al <sup>27</sup>	Multi- center RCT	Type 1 (54/54) Type 4 after ridge preservation (52/52) Failures: 2 in the Type 1 group	Single-tooth maxillary anterior and premolar sites	Yes DBBM grafted to the horizontal gap between the facial bone and implant (Type 1) or into the socket (Type 4)	4 months from pro- visional prosthesis insertion	Immediate provisional prosthesis 35% of Type 1 group and 75% of Type 4 ridge preserved group were not immediately loaded due to lack of sufficient insertion torque (at least 35 Ncm)
Cosyn et al <sup>38</sup>	Cohort study	Type 1 (28/30) Type 2 (no GBR) (44/49) Type 2 + GBR (19/18) Type 4 block graft (14/14) Failures: 2 in Type 1 group, 3 in Type 2 (no GBR) group, 1 in Type 2 + GBR group, 1 in staged bone graft group		Type 1 DBBM applied to gap between implant and socket wall Type 2 + GBR grafted with DBBM and collagen membrane Type 4 bone graft group had block grafte placed derived from the chin	Type 1 33 months (SD 8; range $17-41$ ) Type 2 (no GBR) 30 months (SD 8; range $17-41$ ) Type 2 + GBR 30 months (SD 9; range $17-42$ ) S Staged bone graft 31 months (SD 6; range $19-40$ )	Type 1 group immediate provisional; All other groups early or conventional loading

## Table 8 Studies with Comparative Data on Different Implant Placement Times That Report on Outcomes Using Esthetic Indices

PES = pink esthetic score, WES = white esthetic score, DBBM = deproteinized bovine bone mineral, GBR = guided bone regeneration, NR = not reported. NS = not significant (P > .05).

with type 1 and type 2 placements (type 1 group 10.88  $\pm$  2.41, type 2 no GBR group 10.07  $\pm$  1.96, type 2 with GBR group 9.65  $\pm$  2.23). The worst esthetic outcomes were observed in the staged bone graft group (9.00  $\pm$  1.73), the difference with the type 1 placement group approaching statistical significance (*P* = .045).

The overall esthetic outcomes reported in the case series studies were good, with average PES ranging from 10.48 to 12.5 in six studies<sup>42,52,60,64,67,69</sup> and modified PES ranging from 7.0 to 8.1 in four studies.<sup>21,58,63,68</sup> From selected studies, the forest plots showed no clear trend to indicate a difference between placement times (Fig 6). Prosthesis related esthetic outcomes using WES was reported in five studies with mean scores ranging 7.0 to 8.65.<sup>21,58,60,67,68</sup>

**Ranking of Esthetic Outcomes.** Several studies (Table 8) presented data that allowed esthetic outcomes to be ranked according to the criteria proposed by Cosyn et al<sup>60</sup> and Belser et al.<sup>36</sup> There were two studies of type 1 placement that reported excellent soft tissue esthetic outcomes (PES 12 to 14) in 29% to 36% of cases.<sup>30,60</sup> Acceptable outcomes (PES 8 to 11) were achieved in 56% to 71% of sites and poor outcomes (PES 0 to 7) were found in 8% of cases in one study. In two studies of type 2 placement using the modified PES, excellent esthetic outcomes (modPES 9 to 10) were achieved in 22% to 45% of sites, accept

able outcomes (modPES 6 to 8) in 50% to 78% of sites and poor outcomes (modPES < 6) in 1 of 20 cases (5%) in one study.<sup>58</sup> When PES and WES were considered together in determining esthetic outcomes, between 8% to 21% achieved excellent outcomes (PES  $\ge$  12, WES  $\ge$  9), 58% to 68% achieved acceptable outcomes (PES 8 to 11, WES 7 to 8), and 21% to 24% resulted in poor outcomes (PES < 8, WES < 6).<sup>32,60</sup> These results suggest that prosthesis related factors may contribute significantly to poorer outcomes when soft tissue and hard tissue related esthetic parameters are combined.

In two reports of type 1 placement using SES to evaluate esthetic outcomes, about 80% of implants had satisfactory esthetic outcomes, whereas 20% were found to be unsatisfactory.<sup>34,52</sup>

#### Inclusion and Exclusion Criteria

A number of systemic, oral, and site-related factors were listed as inclusion and exclusion criteria in the studies included in this review.

*Systemic Factors.* Medical conditions or medications that could compromise wound healing or osseointegration were common exclusion criteria.<sup>22,24–26,33,35,38,40,47,51,56,60,62,65,67,68</sup> Conditions such as uncontrolled diabetes,<sup>23,25,27,32,33,41,44,69</sup> coagulation disorders,<sup>41</sup> psychological conditions,<sup>26,27,40</sup> immunosuppressive medications,<sup>25,27,64,69</sup> irradiation therapy to the

Mean PES (SD; range)	Mean WES (SD; range)	Ranking of esthetic outcomes	Other findings
Type 1 = 10.33 (2.29; 6-14) Type 4 = 10.35 (1.58; 7-13) ns	Type 1 = 7.20 (2.04; 3-10) Type 4 = 7.00 (2.37; 2-10) ns	8 % were excellent (PES $\geq$ 12, WES $\geq$ 9) 68% were acceptable (PES 8–11, WES 7–8) 24% were poor (PES < 8, WES < 6)	Only cases with intact socket walls and a thick gingival biotype were included in the immediate implant group
Type 1 = 12.75 (1.25) Type 4 = 12.62 (SD 1.05) ns	NR	NR	To be included for immediate implant placement, sites had to have no more than 4 mm loss of buccal bone height (assessed using the highest peak of palatal wall as the reference) Sites with missing facial bone judged to be sufficient to comprise esthetic results were excluded
Type 1 group: 10.88 (2.41; 6–14) Type 2 (no GBR) group: 10.07 (1.96; 6–13) Type 2 + GBR group: 9.65 (2.23; 4–13) Type 4 bone graft group: 9.00 (1.73; 5–11) P = .045 (staged bone graft significant- ly less than Type 1 group)	NR	NR	For Type 1 placement, all cases had thick gingival biotype, intact facial bone and ideal soft tissue levels For Type 2 with GBR < 1.5 mm bone thickness present on facial aspect of implant, thin and thick biotype

head and neck region,<sup>27,56,59,64,69</sup> systemic bone diseases,<sup>64,69</sup> history of intravenous bisphosphonates,<sup>27,56</sup> osteoporosis,<sup>25</sup> and systemic corticosteroid therapy<sup>33</sup> were listed. Some studies specifically excluded pregnant and lactating individuals.<sup>27,33,44,47,68</sup> One study excluded individuals with incomplete skeletal growth.<sup>28</sup> Another study excluded patients with known allergies to the materials used.<sup>41</sup> Patients with alcohol or drug dependence were also excluded in a number of studies.<sup>23,25,27,33,40,41</sup>

The criteria applied to cigarette smoking varied between studies. In some studies, smokers were excluded<sup>22,32,33,40,57,59,67</sup> whereas smokers were not excluded in other studies<sup>35</sup> or only excluded if subjects were heavy smokers.<sup>23</sup> A number of studies provided specific exclusion thresholds for cigarette smoking. A threshold of 10 cigarettes a day was commonly applied.<sup>24,42,44,47,56,60,68</sup> A threshold of 15 cigarettes a day was applied in one study<sup>63</sup> and 20 cigarettes a day was applied in another study.<sup>62</sup>

**Oral Factors.** Untreated or uncontrolled periodontal disease was a common exclusion criteria.<sup>22,24–28,31,32,51,56,60,63,65,67,68</sup> In addition, untreated caries was an exclusion criteria in several studies.<sup>22,25,32,33</sup>

**Site-Related Factors.** For type 1 placement, acute infection at the site was a consistent exclusion criteria across the studies reviewed.<sup>23–27,32,40,41,44,51,56,57,59,60,65,67</sup> A number of studies of Type 1 placement only included

cases that presented with intact bone walls after tooth extraction<sup>23–25,38,40,41,44,51,60,63,65,67,121</sup> or cases with minimal loss of the facial bone wall.<sup>27,41,56</sup> Some studies stipulated a minimum distance from the midfacial gingival margin to crestal bone of 3 mm,<sup>40</sup> 4 mm,<sup>51</sup> and 5 mm<sup>26</sup> or pre-extraction probing pockets of 3 mm or less.<sup>25</sup> A minimum distance from the gingival margin to the proximal bone of 4 to 6 mm was a requirement in one study<sup>40</sup> and 5 mm in another study.<sup>51</sup> One study included cases with varying degrees of damage to the facial bone wall.<sup>48</sup> Another study was designed specifically to include cases with complete loss of the facial bone wall.<sup>64</sup>

There were a number of studies of type 1 placement that specifically excluded sites with thin tissue biotype, accepting cases with normal to thick tissue biotypes.<sup>24,32,60,62,63</sup> Two studies specifically included cases with thick tissue biotype only.<sup>38,67</sup>

In studies reporting on type 1 placement with connection of immediate provisional restorations, a high degree of stability of the implant was a strict requirement.<sup>24,25,32,38,40,44,51,57,59,60,62–65,67,69</sup> The majority of these studies stated that they excluded subjects with bruxism or cases where it was determined that the posterior occlusion lacked stability.<sup>24,25,40,56,57,59,60,62,63</sup> Some studies specified a minimum height of 4 to 5 mm of bone apical to the extraction socket for stability of the implants to be achieved.<sup>24,38,41,56,60,67</sup>

### Table 9 Case Series Studies of Esthetic Outcomes at Postextraction Implants in the Maxillary Esthetic Zone Using Objective Indices

Study	Study Design	Patients (implants)	Placement time	Healing protocol	Loading protocol	Augmentation technique
Juodzbalys and Wang <sup>42</sup>	Prospective case series	12 (14)	Туре 1	Submerged	Conventional	DBBM + collagen mem- brane, CT graft to correct soft tissue deficiencies
Evans and Chen <sup>34</sup>	Retrospective case series	42 (42)	Туре 1	NR	Conventional	NR
Chen et al <sup>52</sup>	Retrospective case series	85 (85)	Type 1 flapless	Transmucosal	Conventional	No augmentation performed
Mangano et al <sup>63</sup>	Retrospective case series	26 (26)	Туре 1	Transmucosal	Immediate provisional restoration	Biphasic calcium phosphate + tetracycline powder
Cosyn et al <sup>60</sup>	Prospective case series	25 (25)	Type 1	Transmucosal	Immediate provisional restoration	DBBM
Noelken et al <sup>64</sup>	Prospective case series	16 (18)	Type 1 flapless	Transmucosal	Immediate provisional restoration	Autogenous bone
Buser et al <sup>58</sup>	Prospective case series	20 (20)	Туре 2		Early	Autogenous bone chips + DBBM + collagen membrane
Buser et al <sup>21</sup>	Prospective case series	41 (41)	Туре 2		Early	Autogenous bone chips + DBBM + collagen membrane
Furze et al <sup>68</sup>	Prospective case series	10 (10)	Type 2	NR	Early	DBBM + collagen membrane
Noelken et al <sup>69</sup>	Prospective case series	9 (15) Data for only maxillary anterior and pre-molar sites de- rived from the paper	Type 1 flapless	Transmucosal	Immediate provisional restoration	Autogenous bone
Cosyn et al <sup>67</sup>	Prospective case series	22 (22)	Type 1	Transmucosal	Immediate provisional	DBBM

PES = pink esthetic score; modPES = modified pink esthetic score; WES = white esthetic score; SES = subjective esthetic score; DBBM = deproteinized bovine bone mineral; GBR = guided bone regeneration.

An additional criterion was identified for flapless type 1 implant placement in conjunction with immediate provisional restoration. In five studies, cases with pre-extraction soft tissue contours that were in harmony with the surrounding teeth were included.<sup>24,32,38,60,67</sup> In contrast, one study of type 1 placement included sites in which the extracted teeth were periodontally involved and had pre-existing gingival recession.<sup>66</sup> In this study, CT grafts were placed in conjunction with coronally advanced flaps to correct the recession. Two studies, both of type 1 placement with immediate restoration, required that at least 2 mm of keratinized gingiva was present facially at the extraction site.<sup>25,62</sup>

Time from surgery to	Esthetic	Index		
evaluation	PES	WES	SES	Other comments
1 y	11.1 (1.35) range 10-14			Excellent (PES 12–14) 29% Acceptable (PES 9–11) 71% Poor (PES 0–8) 0%
Mean 19 mo (range 6–50 months)				Subjective Esthetic Score (SES) 82% satisfactory (score I and II) 18% unsatisfactory (score III and IV)
Mean 26.2 mo (range 10.3–46.7 mo)	10.95 (1.68) range 8–14			Subjective Esthetic Score: 81% satisfactory (score I and II) 19% unsatisfactory (score III and IV) PES outcomes: Excellent (PES 12–14) 39% Acceptable (PES 9–11) 52% Poor (PES 0–8) 9%
2 у	7.30 (1.78) range 4–10			
З у	10.48 (2.47) range 5–14	8.17 (1.52) Range 5–10		Excellent (PES 12–14) 36% Acceptable (PES 9–11) 56% Poor (PES 0–8) 8% Combined PES/WES: Excellent (PES $\geq$ 12, WES $\geq$ 9) 21% Acceptable (PES 8–11, WES 6–8) 58% Poor (PES < 8, WES < 6) 21%
Median 22 mo (range 13 to 36 mo)	Preop PES 12.2 (1.77) range 8–14 Final PES 12.5 (1.10) range 10–14			All sites had loss of facial bone; grafted with autogenous bone derived from the mandibular ramus 5/18 sites showed a slight deterioration in PES from baseline to final examination; 5/18 were unchanged and 8/18 showed improvement
3 years	PES (modified) 8.1 at y 1 8.1 at y 3	8.65 at y 1 8.65 at y 3		Excellent (modPES 9–10) 45% Acceptable (modPES 6–8) 50% Poor (modPES < 6) 5%
Mean 7 years (range 5-9 years)	PES (modified) 7.78 at 2006 7.49 at 2010	6.95 at 2006 6.88 at 2010		Excellent (modPES 9–10) 22% Acceptable (modPES 6–8) 78% Poor (modPES < 6) 0%
1 у	PES (modified) 7.9 (1.7)	7.0 (1.5)		
Mean 65 mo (range 55.4 to 77.6)	Baseline PES 12.14 (1.65) Final PES 11.28 (1.93)			
1 y	At 3 mo: 11.86 (1.61) range 8–14 At 12 mo: 12.15 (0.99) range 10–13	8.63		I failure, 1 drop-out Severe recession (1.5 mm and 2.0 mm) noted on 2 patients at 3 months. A further 5 patients had noticeable recession. 7 patients required adjunctive CT graft at 3 months to correct recession of the midfacial mucosa

For type 2 placement, there were no specific site related criteria imposed in studies in relation to tissue biotype, condition of bone walls, or presence of acute infection at the time of extraction,<sup>35,47,68</sup> except in one study which excluded cases where there was apical pathology at neighboring teeth.<sup>68</sup> Thin and thick biotypes for type 2 placement were specifically mentioned for inclusion in one study.<sup>38</sup>

### DISCUSSION

Implant placement in postextraction sites has been a subject of great interest over the last 15 years and was included as a major topic in the two previous ITI Consensus Conferences of 2003 and 2008. In the first systematic review in 2003, the focus was on survival outcomes and the success of bone augmentation

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procedures.<sup>15</sup> The second systematic review in 2008 centered on clinical and esthetic outcomes.<sup>133</sup> In this third systematic review, the main focus was on esthetic outcomes for the various treatment options in postex-traction implant placement based on objective esthetic criteria. The two esthetic parameters identified were (1) changes in the position of the peri-implant mucosa, and (2) two esthetic indices, predominantly the PES index. The studies included in this systematic review were found to have reported on single-tooth implant replacements adjacent to intact natural teeth. No papers dealing with multiple missing teeth were identified in the search.

In the present systematic review, the search was limited to publications in the English language from two databases. It is possible that relevant articles were missed thereby undermining the internal validity of the systematic review.

The majority of included studies in this review were case series studies. The evidence from the pooled cases series studies should be evaluated with caution, as significant heterogeneity between studies was observed. This was most likely due to differences in study populations, surgical and grafting techniques, and loading protocols used. Grouping of studies according to the different clinical techniques used provides an insight into trends, but should not be regarded as strong evidence.

Concerning positional changes of the midfacial peri-implant mucosa, there were two RCTs and one cohort study, which compared outcomes following different implant placement timings. These studies showed no differences between immediate (type 1) and early implant placement (type 2). The majority of included studies were case series studies, which predominantly reported on type 1 placement.

For changes in the midfacial mucosal position, the studies were heterogeneous and showed a wide variation in results. Although case series studies on type 2 placement appeared more homogenous, the analysis was based on a small number of studies (3) and should be interpreted with care. Stratification of the type 1 placement studies according to similarity in treatment protocols revealed more homogenous results in relation to changes in the midfacial mucosal level when flapless implant placement was combined with bone graft, CT graft, and connection of an immediate provisional crown. It should be noted that this finding is based on only three case series studies and should be interpreted with caution. For change in position of the papillae, the results between studies were highly variable. No trend was observed for differences in outcomes when studies were stratified according to surgical approach (flap vs flapless placement) and use of immediate provisional crowns.

For outcomes based on esthetic indices, most studies used the PES index. One RCT and two cohort studies provided data on different placement timings. The RCT compared type 1 and type 4 placements; however, the follow-up time of 4 months from provisional prosthesis insertion was too short to make any meaningful conclusions. One cohort study provided evidence that PES was significantly higher for type 1 placement compared to sites that had received block bone grafts to correct significant ridge defects. Similar to the available data for change in peri-implant mucosal position, the majority of studies using esthetic indices were case series studies that predominantly reported on type 1 placement. The studies showed a high degree of heterogeneity.

In summary, the evidence to evaluate the esthetic outcomes with postextraction implants are based on a limited number of randomized and cohort studies, with the vast majority of evidence provided by cross-sectional and case series studies. Nevertheless, well-conducted cross-sectional and case series studies can provide meaningful data when interpreted carefully. Currently, the evidence suggests that acceptable esthetic outcomes can be achieved with type 1 and early implant placement (type 2 and type 3). For positional change of the peri-implant mucosa, it may be anticipated that on average, a small degree of recession of the midfacial mucosa of about 0.5 mm will occur following implant placement. When comparing treatment options, the outcomes for type 1 placement showed more variation compared to type 2 and 3 placements. There was also a higher frequency of recession of > 1 mm of the midfacial mucosa for type 1 placement compared to type 2 and 3 placements.

The analysis clearly shows the variability and potential risk for mucosal recession in the range of 20% to 30%, if no inclusion criteria are used for immediate implants (type 1 placement). This is in accordance with the findings of the previous ITI Consensus Conference in which the potential risk factors for recession with type 1 placement were identified as pre-existing defects of the facial bone, thin facial bone, thin soft tissue biotype, and facial malposition of the implant.<sup>134</sup> To reduce the risk of mucosal recession, the majority of studies published after 2008 on type 1 placement have imposed strict case selection criteria by only including sites with intact facial bone and medium to thick tissue biotype. It has also been recognized that ongoing resorption and modeling of the facial bone takes place following implant placement, with changes most notable after type 1 placement. To reduce the risk of recession of the mucosa with type 1 placement, clinicians have applied treatment strategies to counteract these changes, including the concomitant use of CT grafts, low-substitution bone fillers in the peri-implant defects, and flapless surgery.

Table 10a         Ranking of Esthetic Outcomes: PES Score							
Study	Placement time	Excellent PES 12–14 (%)	Acceptable PES 8-11 (%)	Poor PES 0-7(%)			
Juodzbalys and Wang <sup>42</sup>	Type 1	29	71	0			
Cosyn et al <sup>60</sup>	Type 1	36	56	8			

PES = pink esthetic score; modPES = modified pink esthetic score; WES = white esthetic score.

Table 10b	Ranking of Esthetic Outcomes: modPES Score				
	Placement time	Excellent modPES 9–10(%)	Acceptable modPES 6–8 (%)	Poor modPES < 6 (%)	
Buser et al <sup>58</sup>	Type 2	45	50	5	
Buser et al <sup>21</sup>	Type 2	22	78	0	

PES = pink esthetic score; modPES = modified pink esthetic score; WES = white esthetic score.

Table 10c	Ranking of Esthetic Outcomes: Combined Score				
	Placement time	$\begin{array}{l} \textbf{Combined} \\ \textbf{PES} \geq \textbf{12, WES} \geq \textbf{9 (\%)} \end{array}$	Combined PES 9–11, WES 7–8 (%)	Combined PES < 8, WES < 6 (%)	
Raes et al <sup>32</sup>	Type 1 and 4	8	68	24	
Cosyn et al <sup>60</sup>	Type 1	21	58	21	

PES = pink esthetic score; modPES = modified pink esthetic score; WES = white esthetic score.

For papillae, the evidence shows that recession of the tooth-implant papillae of 0.5 to 1 mm may be anticipated following implant surgery irrespective of the timing of placement. Interestingly, there was little evidence to support flapless surgery or connection of an immediate provisional crown as a means to reduce papillary recession with type 1 placement.

The predominant index used to report on esthetic outcomes was the PES index. The esthetic outcomes for type 1 and type 2 placements were similar although significant heterogeneity between studies was noted. Mean scores reported were in a narrow range of 9.5 to 11.5. The strength of the PES is that it has been shown to be consistently reproducible in a number of studies<sup>135–137</sup> and provides a measure of symmetry of the peri-implant mucosa with the adjacent natural teeth. The PES, however, is a summation of seven soft tissuerelated factors assigned scores on an ordinal scale. The weakness of the PES is that each factor is assumed to carry equal weight in contributing to the overall score; however, this has not been demonstrated in the literature. Indeed it may be argued that, for example, midfacial mucosal recession of 1 to 2 mm (assigned a score of 1) has more impact esthetically then the equivalent score of 1 for color or consistency of the peri-implant mucosa. The PES is therefore not sensitive to linear changes in soft tissue levels. A clinically more meaningful application of PES is to rank esthetic outcomes as shown in Table 10. The proportion of excellent, acceptable, and poor outcomes may provide the clinician with greater insight into the esthetic success of the clinical techniques under scrutiny rather than comparing the mean PES. Several studies reported on outcomes relating to the papillae using the Papilla Index of Jemt.<sup>138</sup> This index, however, was originally designed to monitor changes in the degree of soft tissue fill within the tooth-implant embrasure spaces after delivery of the definitive crowns. As it is neither a measure of symmetry nor a record of linear soft tissue changes, it is unsuitable as an esthetic index.

A critical determinant for stable esthetic outcomes long-term is the integrity and stability of the facial bone wall. Recently, 3D radiology predominantly using CBCT has provided a noninvasive method to assess the status of the facial bone. This technology does have limitations, as intact but thin facial bone may not always be detectable on the reformatted images.<sup>139</sup> However the strong correlation between the radiographic presence of the facial bone and a more coronal location of the midfacial mucosa<sup>20</sup> suggests that the thickness of the facial bone is an important outcome variable. The study of Buser and coworkers that reported on the dimensions of the facial peri-implant bone on CBCT images is worthy of particular note.<sup>21,35</sup> The facial bone walls that were reconstructed with a combination of autogenous bone chips and DBBM particles were largely intact at an average of 7 years following implant placement. Of clinical significance was the stability of the position of the peri-implant mucosa throughout the observation period, which, it may be

speculated, could be due to the underlying thick facial bone. A recent follow-up of a previous study<sup>47</sup> by the same group reported that all 20 implant sites had a detectable facial bone wall averaging 1.9 mm in thickness after 6 years. The timing of implant placement may also be an important consideration. The two CBCT studies of type 1 placement reported diminished bone thickness and increased mucosal recession even when the peri-implant defects were grafted with either autogenous bone or DBBM.<sup>20,37</sup> It may be speculated that the thin facial bone at the crestal region continued to resorb even in the presence of a bone graft, a phenomenon previously observed in a RCT with surgical reentry.<sup>36</sup> It is hypothesized that DBBM particles have only low substitution characteristics if the particles are embedded in bone. As shown in a recent preclinical study, DBBM particles embedded in soft tissue showed signs of resorption.<sup>141</sup> More research is needed to better understand these aspects. It also must be noted that the current evidence with CBCT data is limited, since some studies are based on small numbers of patients with rather short observation periods. It is anticipated that future studies using 3D radiologic imaging of the facial bone wall will provide further evidence for the relationship between the presence or absence of the facial bone, the thickness of the facial bone, the position of the bone crest, and the long-term stability of the peri-implant mucosa.

### CONCLUSIONS

Six RCTs and six cohort studies provided high level evidence for the assessment of esthetic outcomes with postextraction implants.

The majority of included studies were cross-sectional and case series studies that allowed trends in esthetic outcomes with various surgical approaches to be explored.

Acceptable esthetic outcomes, determined by esthetic indices and positional changes of the periimplant mucosa, may be achieved for single-tooth implants placed following tooth extraction.

Immediate (type 1) implant placement is associated with a greater variability in outcomes and a higher frequency of recession of > 1 mm of the midfacial mucosa (8 studies; range 9% to 41% and median 26% of sites; 1 to 3 years after placement) compared to early (type 2 and type 3) implant placement (two studies; no sites with recession > 1 mm).

In two retrospective studies of immediate (type 1) implant placement with bone graft, the facial bone wall was not detectable on cone beam CT in 36% and 57% of sites. These sites had more recession of the midfacial mucosa compared to sites with detectable facial bone.

Two studies of early implant placement (type 2 and 3) combined with simultaneous bone augmentation with GBR (contour augmentation) demonstrated a high frequency (above 90%) of facial bone wall visible on CBCT.

Further research is required to determine the effect of different surgical and loading protocols on esthetic outcomes.

Integrity of the facial bone may be an important factor for long-term stability of esthetic outcomes. Further research is needed to investigate the most suitable biomaterials to reconstruct the facial bone and the relationship between mucosal stability long-term and the presence or absence of the facial bone, the thickness of the facial bone, and the position of the facial bone crest.

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## Consensus Statements and Recommended Clinical Procedures Regarding Optimizing Esthetic Outcomes in Implant Dentistry

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### INTRODUCTORY REMARKS

In the anterior maxilla, dental implant-supported prostheses need to replicate the dental hard and soft tissues in order to be esthetically acceptable. Three systematic reviews in Group 3 were prepared to address the topic of optimizing esthetic outcomes.

Following tooth extraction, the clinician has the choice of various time points to place implants. Implant placement postextraction is often accompanied by bone augmentation procedures to manage residual bone defects and enhance esthetic results. Thus, the first systematic review by Chen and Buser analyzed the influence of the timing of implant placement and bone

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augmentation procedures in relation to their effect on esthetic outcomes. Unfortunately, complications with implant treatment can occur. In the esthetic zone, these complications often lead to adverse esthetic results due to recession and deficiencies associated with the peri-implant soft tissues. The second paper by Levine et al therefore reviewed the literature on procedures to treat mucosal defects following the placement and restoration of implants in the esthetic zone. In order to achieve acceptable esthetic outcomes, a number of restorative procedures have been developed with the aim of optimizing esthetic outcomes with implant-supported prostheses. However, these procedures have not been evaluated in a systematic way to determine their efficacy in relation to esthetics. The aim of the third systematic review by Martin et al was therefore to assess the influence of various restorative procedures on esthetic outcomes.

From these three systematic reviews, a general observation was made that the available data on esthetic outcomes were predominantly represented by case series studies. Relatively few randomized controlled trials (RCTs) and cohort studies were identified, and a minority of these was judged to be at low risk of bias. Nevertheless, the case series studies provided invaluable information in establishing the current clinical trends in techniques and materials related to esthetic outcomes. Indeed, well-designed prospective case series studies of consecutively enrolled subjects with clearly defined inclusion and exclusion criteria can provide important information to validate clinical procedures and materials.

The group recognized that RCTs are not always feasible or ethical when clinical conditions that are known to increase the risk of adverse esthetic outcomes are under investigation. Implant treatment in the esthetic zone is a challenging procedure and classified as advanced or complex according to the SAC classification.<sup>1</sup> Most patients present with multiple esthetic risk factors and often have high expectations. If esthetic complications occur, they are usually difficult or im-

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possible to manage. As a consequence, the prevention of esthetic complications should be a primary objective. Therefore, a conservative treatment approach is recommended to facilitate successful outcomes with high predictability and a low risk of complications.

#### Disclosure

All the group members were asked to reveal any conflicts of interest that could potentially influence the outcomes of the consensus deliberations. No such conflicts were identified.

## ESTHETIC OUTCOMES FOLLOWING IMMEDIATE AND EARLY IMPLANT PLACEMENT IN THE ANTERIOR MAXILLA

#### **Consensus Statement**

The included studies reported on single-tooth implants in postextraction sites adjacent to natural teeth. For postextraction implant placement, esthetic outcomes determined by objective indices and positional changes of the peri-implant mucosa can be achieved in the majority of cases. However, adverse esthetic outcomes may occur.

Regarding the position of the soft tissues following immediate implant (type 1) placement, there is considerable variability. Following immediate implant placement, midfacial mucosal recession of 1 mm or more occurs in 9% to 41% (median, 26%) of sites between 1 and 3 years after implant placement.

The factors associated with midfacial recession for immediate implant placement are (1) thin facial bone plate, (2) lack of intact facial bone plate, (3) facial malposition of the implant, and (4) thin soft tissue biotype. Following immediate implant placement, the lack of a facial bone wall associated with increased mucosal recession is a frequent observation, based on two retrospective studies with small sample sizes.

Based on a small number of studies (one RCT and one case series), early implant placement (type 2 or 3) demonstrates no midfacial mucosal recession of 1 mm or more. Two studies of early implant placement (type 2) combined with simultaneous bone augmentation with guided bone regeneration (GBR) (contour augmentation) demonstrate a high frequency (above 90%) of a facial bone wall visible on cone beam computed tomography.

#### **Treatment Guidelines**

Esthetic outcomes can be achieved at postextraction sites irrespective of the timing of implant placement. Different placement times, however, present with specific treatment challenges and variable predictability of esthetic outcomes. With immediate placement, a high level of clinical competence and experience in performing the treatment is needed. Careful case selection is required to achieve satisfactory esthetic outcomes. The following clinical conditions should be satisfied:

- Intact socket walls
- · Facial bone wall at least 1 mm in thickness
- Thick soft tissue
- No acute infection at the site
- Availability of bone apical and palatal to the socket to provide primary stability

For immediate placement, a preoperative threedimensional (3D) radiographic examination may be considered in determining the above-mentioned bony anatomical conditions and to assist in treatment planning.

For predictable esthetic outcomes with immediate placement with or without flap elevation, the following treatment requirements should be met:

- Correct 3D position of the implant platform (according to previous ITI recommendations).
- If that position falls within the extraction socket, a minimum distance of 2 mm between the implant platform and the inner surface of the facial socket wall should be present. A technique should be used to compensate for postextraction resorption, such as bone filler with a low substitution rate.

If these conditions are not met, immediate implant placement is not recommended.

The above-mentioned preconditions for immediate placement are rarely present. Thus, early implant placement (type 2) is the option of choice in most instances. If, however, it is anticipated that primary stability cannot be achieved, the postextraction healing period should be extended. Ridge preservation/ augmentation procedures may be considered when implant placement needs to be delayed for patient- or site-related reasons.

To optimize the esthetic outcomes of early implant placement (type 2 and 3), the implant platform should be placed in the correct restoration-driven 3D position. Implant placement is combined with GBR using a low-substitution bone filler to overcontour the facial aspect of the ridge. This is followed by coverage of the augmentation material with a barrier membrane and submergence of the biomaterials.

### **Recommendations for Future Research**

Further research is required to document the esthetic outcomes of postextraction implants using objective criteria. Studies should report on both positional and volume changes of the peri-implant tissues (midfacial mucosal margin, implant papillae position, and bone volume).

In all study designs (case reports, case series studies, nonrandomized and randomized studies) the following core data should be reported:

- Full characterization of the socket dimensions
- Systemic, oral, and site-specific inclusion and exclusion criteria
- Consecutive enrollment of subjects with reporting of intention to treat and reasons for not treating
- Follow-up period of at least 1 year after the delivery of the final prosthesis
- The following baseline data should be described:
  - For immediate implant placement, the pretreatment position and volume of the marginal gingival tissue at the test site and the relationship to the adjacent/contralateral natural tooth.
  - For early (type 2 and 3) and late placement (type 4), the relationship of the test site(s) to the adjacent/contralateral natural tooth.
  - For reporting on esthetic indices, scores for the individual domains that make up the index should be reported. If the Pink Esthetic Score<sup>2</sup> is used, all seven domains should be evaluated and reported.
  - In addition to the mean, standard deviation, and range of the outcome variables, a frequency distribution analysis should be reported.
  - Patient-centered outcomes should be reported.

Further research is needed to investigate:

- The long-term stability of tissue volume
- The most suitable biomaterials to preserve/reconstruct the facial bone
- The influence of (1) the presence/absence of the facial bone, (2) dimensions of the socket, (3) thickness of the facial bone, and (4) position of the bone crest on esthetic outcomes

## SOFT TISSUE AUGMENTATION PROCEDURES FOR MUCOSAL DEFECTS IN THE ESTHETIC ZONE

## **Consensus Statements**

The included studies consisted predominantly of case reports and case series of small numbers and short duration. The studies did not always identify the etiology and timing of the facial soft tissue recession around single implants. Periodontal soft tissue surgical procedures were applied to treat facial soft tissue recession. There is no consensus on how to treat a facial soft tissue defect in esthetic sites. In some of the papers, the implant restoration was removed and/or facially altered (crown, abutment, and/or implant) in order to facilitate the treatment.

Limited improvement of the soft tissue (including increase in soft tissue thickness, keratinized tissue width, and facial marginal soft tissue level) can be achieved following soft tissue augmentation procedures.

Following soft tissue augmentation procedures, complete resolution of the soft tissue defect ranged from 0% to 75% (3 studies; 32 patients).

#### **Treatment Guidelines**

A team approach and Esthetic Risk Assessment<sup>3</sup> should be utilized to improve predictability of an esthetic outcome and to reduce risk when managing soft tissue defects in the esthetic zone.

When soft tissue recession is found around a singletooth implant, the clinician needs to diagnose the etiology based on evaluation of 3D implant position, restoration, existing hard and soft tissue support, as well as factitious (self-inflicted) injury such as tooth brushing and flossing trauma.

The surgical procedures to correct soft tissue facial recession around a single implant are complex. A systematic assessment and treatment protocol are required. The assessment should include the following:

- Patient's expectations
- Medical status
- Smoking habit
- · Visibility of defect upon smiling
- Width of keratinized tissue remaining at the defect site
- Restoration contour
- · Infection at the implant site
- · Contributing patient-related factors
- 3D implant position
- Proximity of implant to adjacent teeth
- Interproximal radiographic bone loss
- Scarring of soft tissue at implant site

When the above-mentioned factors are favorable, hard and/or soft tissue augmentation procedures can be effective. The patient should be made aware of the high variability of the outcome. When the abovementioned factors are unfavorable, hard and/or soft tissue augmentation procedures are less effective. Restorative modifications (abutment/crown replacement and/or reshaping) combined with a surgical approach may be indicated. Implant removal should also be considered as an option. When an implant needs to be removed, techniques that minimize bone loss are preferred. Specialized implant removal kits are available and preferred to trephines.

#### **Recommendations for Future Research**

Future studies on the correction of soft tissue defects around single-tooth implants in esthetic sites should provide objective, quantitative outcome measurements.

The etiology of soft tissue defects on implants in the esthetic area need to be investigated. Future studies should include randomized trials comparing techniques to correct soft tissue defects on single implants in the esthetic zone. Alternatively, cohort studies involving sufficient numbers of patients, treated prospectively and consecutively, and having at least 12 months of follow-up could be evaluated.

Future research should distinguish if a surgical approach alone, a restorative approach alone, or a combination therapy is necessary. Future research should distinguish the optimal surgical technique, including incision design, and the type and shape of the augmentation material.

New therapeutic approaches and materials need to be investigated for the treatment of soft tissue defects around single and multiple implants in esthetic sites, such as the use of stem cells, growth factors, synthetic materials, etc.

## THE INFLUENCE OF RESTORATIVE PROCEDURES ON ESTHETIC OUTCOMES IN IMPLANT DENTISTRY

#### **Consensus Statements**

The available literature does not demonstrate that esthetic outcomes can be improved by:

- The use of surgical templates (surgical guides)
- The utilization of implant-retained provisional prostheses
- The timing of provisional implant-retained prostheses
- The mode of prosthesis retention (cement- or screw-retained)

There is limited evidence (one study) reporting improved esthetic outcomes (color matching) in implant dentistry associated with ceramic abutment/prosthesis combination.

Esthetic outcomes can be improved (mean, 0.3 mm on the midfacial mucosal margin) by the presence of a horizontal offset, or platform switch (smaller abutment diameter).

#### **Treatment Guidelines**

The use of surgical templates, developed from a restoration-driven approach that communicates the optimal implant position in 3D respecting the comfort zones as reported in previous ITI publications, is recommended.

The use of provisional implant-retained restorations in the esthetic zone is recommended. Provisional restorations enhance communication between all members of the treatment team and the patient. They should be anatomically and functionally correct, and respect the emergence profile of the restoration apical to the planned mucosal margin (highest convexity) to allow for maximum tissue volume. Screw retention of the interim restoration is considered advantageous for multiple reasons (retrievability, tissue shaping, tissue health and maturation, ease of modification).

Immediate loading or restoration of an implant cannot be recommended as a routine procedure because risks are elevated and esthetic outcomes are variable. In agreement with previously published ITI documents, early loading of dental implants in the esthetic zone is recommended.

In sites of elevated esthetic risk, a horizontally offset (platform switched) implant/abutment design is advantageous for single-tooth replacements. Further, an oversized implant platform and prosthetic components must be avoided to respect the interproximal and facial regions of the site.

The abutment and prosthesis material are a patient- and site-specific choice for the clinician. Provided that the material chosen is of high quality and documented, the design of the abutment and/or prosthesis is more critical than the material chosen, for reasons including:

- Controlling emergence profile
- Material properties and strength
- Access to finish lines
- Retrievability

In patients with thin tissues, a tooth-colored abutment and/or final prosthesis emerging through the tissues can offer esthetic advantages. When the implant angulation allows, screw retention of the prosthesis offers clinical advantages.

## **Recommendations for Future Research**

These recommendations may exhibit crossover with other groups in the ITI Consensus Conference due to the similarity of topic. The following are noted with specific reference to achieving esthetic outcomes in implant dentistry:

- In studies that address esthetic outcomes, documentation is needed to report the use and design of templates (ie, based upon a prosthesis-driven plan) utilized.
- Studies are needed that report the characteristics specific to the implant-retained provisional prosthesis (emergence profile and dimension in the tissue, material, mode of manufacture, timing of placement, surface texture, and retention).
- Regarding abutments and crowns, all aspects of the indications and use of materials, combinations, and compatibility of components in diverse treatment indications should be reported. In particular, the mode of manufacture should be detailed.
- The influence of the implant shoulder design in single and extended edentulous situations on esthetic outcomes should be reported.
- When using objective esthetic assessment indices, consistency in reporting should be utilized. A system for weighting the different factors that may contribute to esthetic outcomes should be developed.
- Research into the development of root/toothcolored implant materials that exhibit proven mechanical and biologic properties with success and survival rates comparable to currently accepted implants is recommended.

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## **GROUP** 4

## **Implant Loading Protocols**

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#### **Participants:**

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- Alexander Schrott Murali Srinivasan Charlotte Stilwell Aldo Tumini Paul van Zyl Hans-Peter Weber Thomas Wilson

#### **Review Papers Submitted for Discussion:**

Loading Protocols for Single-Implant Crowns: A Systematic Review and Meta-Analysis Goran I. Benic/Javier Mir-Mari/Christoph H.F. Hämmerle

Implant Loading Protocols for Partially Edentulous Patients with Extended Edentulous Sites—A Systematic Review and Meta-Analysis Alexander Schrott/Martine Riggi-Heiniger/Katsuichiro Maruo/German O. Gallucci

Implant Loading Protocols for Edentulous Patients with Fixed Prostheses: A Systematic Review and Meta-Analysis Panos Papaspyridakos/Chun-Jung Chen/Sung-Kiang Chuang/Hans-Peter Weber

Loading Protocols for Implant-Supported Overdentures in the Edentulous Jaw: A Systematic Review and Meta-Analysis Martin Schimmel/Murali Srinivasan/François R Herrmann/Frauke Müller

Consensus Statements and Clinical Recommendations for Implant Loading Protocols

German O. Gallucci/Goran I. Benic/Steven E. Eckert/Panos Papaspyridakos/ Martin Schimmel/Alexander Schrott/Hans-Peter Weber

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## Loading Protocols for Single-Implant Crowns: A Systematic Review and Meta-Analysis

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Purpose: To test whether or not immediate loading of single-implant crowns renders different results from early and conventional loading with respect to implant survival, marginal bone loss, stability of peri-implant soft tissue, esthetics, and patient satisfaction. Materials and Methods: An electronic search of Medline and Embase databases including studies published prior to August 1, 2012, was performed and complemented by a manual search. Randomized controlled trials (RCTs) comparing different loading protocols of singleimplant crowns with a follow-up after restoration of at least 1 year were included. A meta-analysis yielded odds ratios (OR) and standardized mean differences (SMD) together with the corresponding 95% confidence intervals (95% CI). Results: The search provided 10 RCTs comparing immediate and conventional loading and 1 RCT comparing immediate and early loading. When assessing the implant survival at 1 year of loading, the meta-analysis of 10 studies found no significant differences between immediate and conventional loading (OR = 0.75; 95% CI: 0.32 to 1.76). The total difference of marginal bone loss during the first year of function between immediate and conventional loading protocols in 7 RCTs did not reach statistical significance (SMD = -0.05 mm; 95% Cl: -0.41 to 0.31 mm). There were no significant differences between immediate and conventional loading regarding implant survival and marginal bone loss at 2, 3, and 5 years of loading. Three RCTs comparing the change of papilla level between immediate and conventional loading identified no significant differences. One study investigated the recession of the buccal mucosa after implant placement and found significantly inferior soft tissue loss for immediate loading as compared to conventional loading. Two RCTs investigated the recession of the buccal mucosa after insertion of the definitive crown and found no differences between immediate and conventional loading. The esthetics and the patient satisfaction were assessed in one and two RCTs, respectively. There were no significant differences between immediate and conventional loading. Conclusions: Immediately and conventionally loaded single-implant crowns are equally successful regarding implant survival and marginal bone loss. This conclusion is primarily derived from studies evaluating implants inserted with a torque  $\geq 20$  to 45 Ncm or an implant stability quotient  $(ISQ) \ge 60$  to 65 and with no need for simultaneous bone augmentation. Immediately and conventionally loaded implants do not appear to differently affect the papilla height during the first year of loading. Due to the heterogeneity of the time point of baseline measurements and contradictory findings in the studies, it is difficult to draw clear conclusions regarding the recession of the buccal mucosa. With respect to the assessment of esthetic outcomes and patient satisfaction, the data available remain inconclusive. INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):222-238. doi: 10.11607/jomi.2014suppl.g4.1

**Key words:** bone, crowns, dental implants, early, esthetics, function, immediate, loading, meta-analysis, papilla, restoration, satisfaction, soft tissue, survival, systematic review

Dental implants supporting single crowns represent a well-documented therapy for the restoration of single tooth gaps showing high long-term survival rates.<sup>1</sup> Despite varying rates of technical, biologic, and

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esthetic complications, this treatment modality can be considered a safe and predictable therapeutic option.<sup>1</sup>

Traditional clinical guidelines recommended the placement of implants in healed sites, followed by 3 to 6 months of submucosal healing prior to functional loading.<sup>2</sup> Subsequently, new clinical protocols have been applied, aiming at shortening the overall treatment duration and reducing the number of surgical interventions. These protocols were characterized by decreased time spans between tooth removal, implant placement, and delivery of the implant-supported prosthesis.

Several clinical studies showed similar short-term survival rates of single implants either loaded conventionally, early, or immediately after implant placement.<sup>3–9</sup> These favorable results have been reported for single implants placed in anterior and posterior regions of the jaw.

In addition to implant and crown survival rates, stability of the peri-implant bone and soft tissues are important factors for determining the clinical success of dental implant treatment. Several controlled clinical studies investigating marginal bone loss at single implants did not reveal significant differences among implants that were loaded at different time points following the implant placement.<sup>3,4,10,11</sup>

With respect to the facial soft tissue levels, heterogeneous results were found between studies comparing different loading protocols. One study found immediate loading of implants inserted into fresh extraction sockets, leading to more favorable levels of facial soft tissue compared with delayed loading.<sup>10</sup> On the other hand, studies investigating single tooth implants inserted into healed sites described similar soft tissue levels for conventionally and immediately loaded implants.<sup>3,12</sup>

Besides functional and health-related aspects, the visual appearance of the reconstruction becomes an important factor for clinical success in esthetic sites. It has recently been stated that the scientific literature regarding esthetic outcomes in implant dentistry remains inconclusive.<sup>13,14</sup> This statement was formulated because of the lack of studies using objective and well-defined parameters for the assessment of esthetics.

Furthermore, it is currently widely accepted that clinical measures provide limited understanding regarding patients' perceptions. Therefore, a standardized use of validated patient-reported outcome measures (eg, patient satisfaction) was recommended for clinical research to understand the benefit of a treatment with implants from the patients' perspectives.<sup>15,16</sup>

The highest level of evidence for answering clinical questions derives from systematic reviews analyzing the results of randomized controlled clinical trials (RCTs).<sup>17</sup> The aim of the present systematic review was, therefore,

to test whether or not the immediate loading of singleimplant crowns render different clinical results from early and conventional loading with respect to implant survival rate, marginal bone loss, stability of peri-implant soft tissue, esthetics, and patient satisfaction.

## **MATERIALS AND METHODS**

This systematic review was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines.<sup>18</sup>

#### **Focus Question**

The following focus question was developed according to the PICO (population, intervention, comparison, outcome) format for this review: Does immediate loading of single-implant crowns render different results from early and conventional loading with respect to implant survival rate, marginal bone loss, stability of periimplant soft tissue, esthetics, and patient satisfaction?

#### **Search Strategy**

An electronic search of Medline (PubMed) and Embase databases was performed including studies published prior to August 1 2012. The search was limited to publications with abstract (text options), published in English, French, and German (language). The search strategy is summarized in Table 1.

The electronic search was complemented by a manual search of reference lists of the reviews published from January 1, 2009, to July 31, 2012. Additionally, the bibliographies of the reviews on loading protocols from the 4th ITI Consensus Conference (2008) were screened.

#### **Selection of Studies**

The criteria for inclusion and exclusion of studies are specified in Table 1.

Two investigators independently performed the literature search including selection of titles, abstracts, and full-text publications. Any disagreement regarding inclusion was resolved by a discussion between the two investigators. All titles obtained by the search were screened for meeting the selection criteria. If the title did not contain sufficient information for exclusion, it was selected for the abstract evaluation. Subsequently, the abstracts of all potentially relevant titles were reviewed based on the selection criteria. Cohen's kappa coefficient ( $\kappa$ ) was used as measure of inter-reviewer agreement for the title and the abstract selection.<sup>19</sup> The selected abstracts were obtained as full texts and screened for the final inclusion by reading the Materials and Methods and Results sections. The reason for rejecting studies based on the full-text evaluation was recorded.

Focus question	Does immediate loading of single implant crowns render different results from early and conventional loading with respect to implant survival rate, marginal bone loss, stability of peri-implant soft tissue, esthetics, and patient satisfaction?
Search strategy	
Population	#1 - (dental implantation, endosseous[MeSH] OR dental implants[MeSH] OR implantation*[all fields] OR implant[all fields] OR implants[all fields])
Intervention or exposure	#2 - (crowns[MeSH] OR crown[MeSH] OR dental crowns[MeSH] OR crowns, dental[MeSH] OR crowns[all fields] OR crown[all fields] OR denture, partial, fixed[MeSH] OR dental prosthesis, implant-supported[MeSH] OR fixed partial denture*[all fields] OR FPD[all fields] OR FPDs[all fields] OR fixed dental prosthesis[all fields] OR fixed dental prostheses[all fields] OR FDP[all fields] OR FDPs[all fields] OR FDPs[a
Comparison	#3 - (Immediate Dental Implant Loading[MeSH] OR function[all fields] OR time[all fields] OR immediate [all fields] OR early[all fields] OR load*[all fields])
Outcome	#4 - (Survival[MeSH] OR survival rate[MeSH] OR survival analysis[MeSH] OR intraoperative complications[MeSH] OR postoperative complications[MeSH] OR dental restoration failure[MeSH] OR prosthesis failure[MeSH] OR treatment failure[MeSH] OR complication*[all fields] OR success*[all fields OR failure*[all fields] OR esthetics, dental[MeSH] OR dental esthetics[MeSH] OR esthetics[MeSH] OR esthetic*[all fields] OR aesthetic*[all fields])
Filters	#5 - (English[lang] OR German[lang] OR French[lang]) AND hasabstract[text]
Search combina	ation #1 AND #2 AND #3 AND #4 AND #5
Database search	
Electronic	Pubmed and Embase
Journals	All peer reviewed journals available in PubMed and Embase. No filters were applied for the journals.
Selection criteria	1
Inclusion criteri	<ul> <li>a Single implants supporting single crowns</li> <li>Rough surface solid screw type implants</li> <li>Prospective and retrospective clinical study</li> <li>≥ 10 patients; if number of patients not reported: ≥ 20 implants</li> <li>≥ 1 year of loading</li> <li>Must specify: number of implants placed, time of loading, follow-up duration, number of failures</li> </ul>
Exclusion criter	<ul> <li>In vitro and animal studies; studies based on charts or questionnaires</li> <li>Machined and hydroxyapatite surface implants; ceramic implants</li> <li>Monotype implants; non-solid-screw-type implants; scalloped-platform implants</li> <li>Implants with a diameter &lt; 3 mm; orthodontic or temporary implants</li> <li>Sinus floor elevation</li> <li>Zygomatic or pterygoid implants; bicortically stabilized (transmandibular) implants</li> <li>Implants placed in irradiated bone or bone reconstructed after tumor resection; implants placed in grafted alveolar cleft sites</li> <li>Splinted fixed or removable implant-supported reconstructions</li> <li>In case of multiple publications on the same patient cohort the article with less inclusive data</li> </ul>

## **Data Extraction**

The data were extracted independently by two reviewers using data extraction tables. Disagreement regarding data extraction was resolved by a discussion between the two reviewers.

The implant loading protocols were classified as follows<sup>20</sup>:

- Immediate loading: prosthesis connected to the dental implant within 1 week subsequent to implant placement
- *Early loading:* prosthesis connected to the dental implant between 1 week and 2 months subsequent to implant placement

 Conventional loading: prosthesis connected to the dental implant > 2 months subsequent to implant placement.

The following data were extracted from the full-text publications: author(s), year of publication, loading protocol, time of implant placement following tooth extraction, number of patients included, number of patient drop-outs, number of implants placed, number of implant drop-outs, follow-up period of loading, jaw, intraoral region, implant system, implant length and diameter, implant insertion torque, implant stability quotient (ISQ), simultaneous bone augmentation procedure, and number of implant failures. Mean

and standard deviation values of marginal bone loss were recorded between the implant placement and the annual follow-up examinations. The patient cohorts presenting a gain of marginal bone following implant placement were excluded from the analysis of the marginal bone level. Mean and standard deviation values of recessions of midbuccal mucosa and of interproximal papillae were recorded between the implant placement, the insertion of the final crown, and the 1-year follow-up examination. In addition, results regarding the esthetics of peri-implant mucosa and crowns and the patient's satisfaction were recorded.

#### **Quality Assessment**

Two reviewers independently assessed the methodological quality of the included studies, by using the Cochrane risk of bias tool<sup>21</sup> for RCTs. For this purpose, the Materials and Methods, Results, and Discussion sections of the publications were evaluated. Any disagreement between the reviewers was resolved by a discussion aiming for consensus.

## **Statistical Analysis**

A meta-analysis of binary and continuous outcome variables was computed for RCTs (STATA software version 10.1) if there were at least two studies comparing the same loading protocols and reporting the same outcome measures.

For binary outcomes (eg, implant survival) the estimate of the effect of an intervention was expressed as odds ratio (OR) and 95% confidence interval (CI). For continuous outcomes (eg, marginal bone loss, soft tissue recession) mean differences and standard deviations (SD) were used to calculate standardized mean differences (SMD) and 95% CI.

The outcomes were pooled by using both the fixed effect model (Mantel-Haenzel-Peto test) and the random effect model (Dersimonian-Laird test). The *Q*-test for heterogeneity was performed and the corresponding forest plots were drawn. If a significant heterogeneity was found, the results of the random effect model have been considered valid. In cases with no evidence of heterogeneity the results of the fixed effect model were considered valid. The level of statistical significance was set at  $P \le .05$ .

## RESULTS

#### Literature Search

The search of the electronic databases yielded a total of 2,726 titles (Fig 1). A total of 1,437 potentially relevant titles were selected by the two reviewers for abstract evaluation (inter-rater agreement  $\kappa = 0.81$ ). The screening of the abstracts resulted in the selection

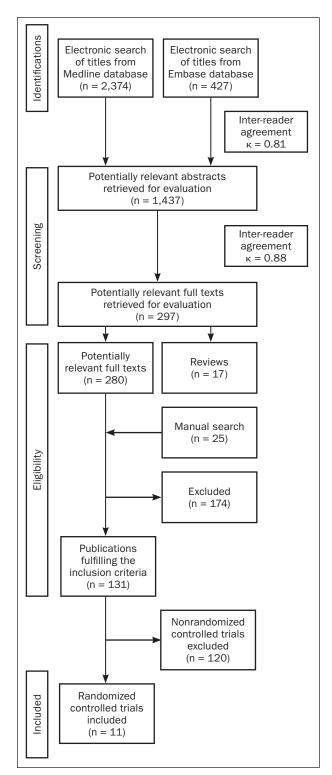


Fig 1 Search flow diagram.

of 297 publications (inter-rater agreement  $\kappa = 0.88$ ). A manual search of the 17 reviews rendered an additional 25 relevant publications (see Appendix 1 in online edition). After the full-text evaluation, 174 publications were excluded (see Appendix 2 in online edition).

Table 2 Chara	acteristics	of the Inclu	ded Stud	lies						
Study	Year of publication	Loading protocol	Occlusal contact	Implant placement (type 1–4)	No. of patients	No. of drop-outs	No. of implants	No. of implant drop-outs	Follow-up period (y)	
Crespi et al⁵	2008	Immediate Conventional	Yes	1 1	20 20	0 0	20 20	0 0	2 2	
De Rouck et al <sup>10</sup>	2009	Immediate Conventional	No	1 1	24 25	0 0	24 25	0 0	1 1	
Degidi et al <sup>4</sup>	2009	Immediate Conventional	No	2,3,4 2,3,4	30 30	0 0	30 30	0 0	3 3	
den Hartog et al <sup>3</sup>	2011	Immediate Conventional	No	3,4 3,4	31 31	0 0	31 31	0 0	1.5 1.5	
Donati et al <sup>22</sup>	2008	Immediate Conventional	Yes	3,4 3,4	NR NR	NR NR	50 57	0 2	1 1	
Güncü et al <sup>23</sup>	2008	Immediate Conventional	Yes	4 4	12 12	0 0	12 12	0 0	1 1	
Hall et al <sup>12</sup>	2007	Immediate Conventional	No	2,3,4 2,3,4	14 14	1 2	14 14	1 2	1 1	
Prosper et al <sup>24</sup>	2010	Immediate Conventional	Yes	1 1	NR NR	0 0	60 60	0 0	5 5	
Schincaglia et al <sup>25</sup>	2008	Immediate Conventional	Yes	3,4 3,4	15 15	0 0	15 15	0 0	1 1	
Shibly et al <sup>6</sup>	2010	Immediate Conventional	NR	1 1	30 30	1 1	30 30	1 1	2 2	
Testori et al <sup>26</sup>	2007	Immediate Early	No No	NR NR	7 10	0 0	7 10	0 0	1 1	

I, incisive; C, canine; PM, premolar; M, molar; NR, not reported.

The reasons for excluding studies based on the full-text evaluation are specified in Table A1 (see online edition). A total of 131 publications fulfilled the inclusion criteria, of which 11 were RCTs comparing different loading protocols. Due to the significant number of RCTs available for analysis, 120 non-RCTs were excluded from the analysis (see Appendix 3 in online edition).

#### **Study Characteristics**

In 11 RCTs, a total number of 597 single implants were placed. The characteristics of the included studies are presented in Table 2.

There were 10 RCTs comparing immediate and conventional loading protocols.<sup>3–6,10,12,22–25</sup> In one study, one out of three groups under investigation (osteotome technique in combination with immediate loading) was excluded from the meta-analysis.<sup>22</sup> In the included studies, 286 implants were immediately loaded and 294 implants were conventionally loaded. The grouping of studies according to the duration of the follow-up period of loading yielded the following results: six studies analyzed a loading period of up to 1 year, two up to 2 years, one up to 3 years, and one up to 5 years. In six studies the need for simultaneous bone augmentation at implant placement was considered as an exclusion criterion. Seven studies included implants inserted with a minimal insertion torque rang-

ing from 20 to 45 Ncm. In four studies, a minimal ISQ ranging from 60 to 65 was considered as an inclusion criterion. There were no studies evaluating implants placed in the maxillary molar region.

One RCT compared immediately and early loaded implants.<sup>26</sup> The follow-up period of these 17 implants amounted to 1 year. This study included implants inserted with a minimum torque of 30 Ncm and presenting no peri-implant bone defects at implant placement.

#### **Parameters and Methods of Measurement**

Eleven RCTs assessed implant survival. In eight trials, the level of interproximal bone level was measured by means of periapical radiographs immediately following the implant placement and at the annual followup examinations. The level of papillae and the level of buccal mucosa were evaluated and expressed in millimeters in three studies each.<sup>3,10,12,22</sup> In one study, the measurements were clinically performed prior to tooth extraction and after 1 year by means of acrylic stents with direction grooves.<sup>10</sup> In another RCT, the assessment was performed 6 months after the implant placement and at the 1-year follow-up. For this purpose, calibrated digital photographs were analyzed and the incisal edge of the implant-supported crown was used as reference for the measurement.<sup>3</sup> One publication reported the results of the examinations at 3 months

Jaw	Region	Implant brand	Implant length (mm)	Implant diameter (mm)	Implant insertion torque (Ncm)	ISQ	Simultaneous bone augmentation
Maxilla	I,C,PM	Sweden & Maritina	13	3.75–5	≥ 25	≥ 60	No
Maxilla	I,C,PM	Sweden & Maritina	13	3.75–5	≥ 25	≥ 60	No
Maxilla	I,C,PM	Nobel	NR	NR	≥ 35	NR	Yes
Maxilla	I,C,PM	Nobel	NR	NR	≥ 35	NR	Yes
Maxilla		Xive	13–15	3	≥ 25	≥ 60	No
Maxilla		Xive	13–15	3	≥ 25	≥ 60	No
Maxilla	I,C,PM	Nobel	13–16	3.5–4.3	≥ 45	NR	Yes
Maxilla	I,C,PM	Nobel	13–16	3.5–4.3	≥ 45	NR	Yes
Mixed	I,C,PM	Astra Tech	8–13	4–4.5	≥ 20	NR	No
Mixed	I,C,PM	Astra Tech	8–13	4–4.5	≥ 20	NR	No
Mandible		Nobel	11.5	4	NR	≥ 65	No
Mandible		Nobel	11.5	4	NR	≥ 65	No
Maxilla	I,C,PM	Southern Implants	10–15	4	NR	≥ 60	Yes
Maxilla	I,C,PM	Southern Implants	10–15	4	NR	≥ 60	Yes
Mandible		Winsix	9–13	6.5–7.5	NR	NR	No
Mandible		Winsix	9–13	6.5–7.5	NR	NR	No
Mandible		Nobel	8.5–11.5	5	≥ 20	NR	No
Mandible		Nobel	8.5–11.5	5	≥ 20	NR	No
NR	NR	Nobel	NR	NR	≥ 35	NR	Yes
NR	NR	Nobel	NR	NR	≥ 35	NR	Yes
NR	NR	3i	8.5–15	4-6	≥ 30	NR	No
NR	NR	3i	8.5–15	4-6	≥ 30	NR	No

after implant placement and at the 1-year follow-up.<sup>22</sup> In this study, the level of the papillae was clinically assessed. The line between the mucosal margin of the implant-supported crown and the gingival margin of the adjacent tooth was used as a reference structure. In one study, the level of facial mucosa was clinically assessed 4 weeks after the insertion of the definitive crown and at the 1-year examination.<sup>12</sup> In the immediate loading group the definitive crowns were inserted 12 weeks after the implant placement, whereas in the conventional loading group this occurred 32 weeks after the implant placement. A circumferential reference line on the surface of the definitive crown was used for the clinical measurements.

#### **Quality Assessment**

The results of the quality assessment of the included RCTs are presented in Table 3. No study fulfilled all the criteria for the control of bias as described in the Cochrane Collaboration's tool for assessing risk of bias (Table 3).

#### **Study Outcomes**

*Implant Survival.* The results regarding implant survival are summarized in Table 4.

In RCTs comparing immediate and conventional loading, 275 of the original 284 immediately loaded

implants (96.8%) survived up to 1 year of function, whereas 283 of the 289 implants assigned to conventional loading (97.9%) survived up to 1 year. The metaanalysis of the 10 trials found no significant differences with OR fixed-effects of 0.75 (95% CI: 0.32 to 1.76) and no evidence of heterogeneity (Fig 2). In the four RCTs evaluating implants at 2 years of loading, 136 of the 139 immediately loaded implants (97.8%) and 135 of the 139 implants assigned to conventional loading (97.1%) were in situ at the follow-up examination.<sup>4–6,24</sup> The meta-analysis did not reveal significant differences between the treatment groups with OR fixed-effects of 1.26 (95% CI: 0.33 to 4.80) and no evidence of heterogeneity (Fig 3). Immediately and conventionally loaded implants were examined at 3 years of loading in two trials.<sup>4,24</sup> Based on the meta-analysis of these studies, there were no differences between the two loading protocols (Fig 4). In one RCT, immediately and conventionally loaded implants were assessed at 5 years of loading.<sup>24</sup> In both treatment groups in this study there were two implant failures rendering an implant survival rate of 96.7% in each group.

In one study comparing immediate and early loading, 17 implants were evaluated at 1 year of function.<sup>26</sup> One out of seven immediately loaded implants failed 2 months after the implant placement. There were no implant failures in the early loading group.

## Table 3 Quality Assessment of RCTs Based on The Cochrane Collaboration's Tool for Assessing Risk of Bias

Study	Year of publication	Adequate sequence generation	Allocation concealment	Blinding	Incomplete outcome data addressed	Free of selective reporting	Free of other sources of bias
Crespi et al <sup>5</sup>	2008	Unclear	Unclear	Unclear	Yes	Yes	Yes
Degidi et al <sup>4</sup>	2009	Yes	Yes	Unclear	Yes	Yes	Yes
De Rouck et al <sup>10</sup>	2009	Yes	No	Yes	Unclear	Yes	Yes
den Hartog et al <sup>3</sup>	2011	Yes	Yes	Yes	Yes	No	Yes
Donati et al <sup>22</sup>	2008	Yes	Unclear	Unclear	Yes	Yes	Yes
Güncü et al <sup>23</sup>	2008	Yes	Yes	Unclear	Yes	Yes	Yes
Hall et al <sup>12</sup>	2007	Yes	Unclear	Unclear	Yes	Yes	Yes
Prosper et al <sup>24</sup>	2010	Unclear	Unclear	Partial	Yes	Yes	Yes
Schincaglia et al <sup>25</sup>	2008	Yes	Unclear	Yes	Yes	Yes	Yes
Shibly et al <sup>6</sup>	2010	Yes	Unclear	Yes	Yes	Yes	Yes
Testori et al <sup>26</sup>	2007	Yes	Yes	Partial	Yes	Yes	Yes

## Table 4 Implant Survival Results

						At	<b>1</b> y	
Study	Year of publication	Loading protocol	No. of implants	No. of implant drop-outs	Mean follow-up (y)	No. of failures	Survival rate	
Crespi et al <sup>5</sup>	2008	Immediate Conventional	20 20	0 0	2 2	0 0	100% 100%	
De Rouck et al <sup>10</sup>	2009	Immediate Conventional	24 25	0 0	1 1	1 2	96% 92%	
Degidi et al <sup>4</sup>	2009	Immediate Conventional	30 30	0 0	3 3	0 0	100% 100%	
den Hartog et al <sup>3</sup>	2011	Immediate Conventional	31 31	0 0	1.5 1.5	1 0	97% 100%	
Donati et al <sup>22</sup>	2008	Immediate Conventional	50 57	0 2	1 1	1 0	98% 100%	
Güncü et al <sup>23</sup>	2008	Immediate Conventional	12 12	0 0	1 1	1 0	92% 100%	
Hall et al <sup>12</sup>	2007	Immediate Conventional	14 14	1 2	1 1	1 0	92% 100%	
Prosper et al <sup>24</sup>	2010	Immediate Conventional	60 60	0 0	5 5	2 2	97% 97%	
Schincaglia et al <sup>25</sup>	2008	Immediate Conventional	15 15	0 0	1 1	1 0	93% 100%	
Shibly et al <sup>6</sup>	2010	Immediate Conventional	30 30	1 1	2 2	1 2	97% 93%	
Testori et al <sup>26</sup>	2007	Immediate Early	7 10	0 0	1 1	1 0	86% 100%	

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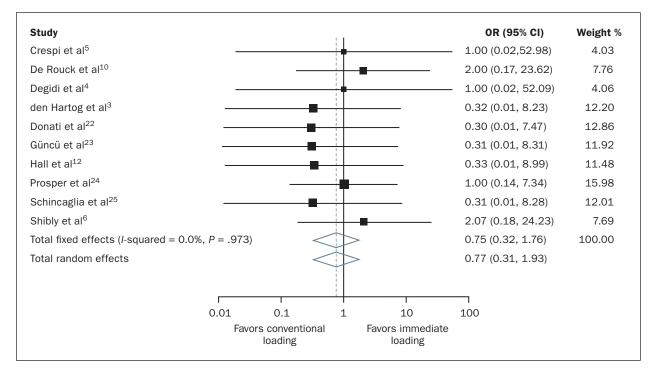


Fig 2 Results of meta-analysis for the comparison of implant survival at 1 year between immediate and conventional loading.

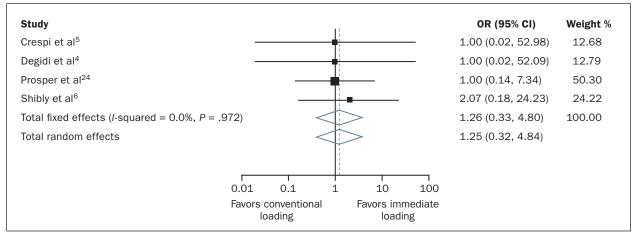
At	2 у	At	З у	At 5 y		
No. of failures	Survival rate	No. of failures	Survival rate	No. of failures	Survival rate	
0 0	100% 100%	0 0				
0 0	100% 100%	0 0	100% 100%			
0	100%	0	10070			
2	97%	2	97%	2	97%	
2	97%	2	97%	2	97%	
1	97%					
2	93%					

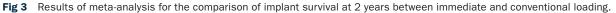
*Marginal Bone Loss.* Table 5 depicts the data for marginal bone loss between the implant placement and the annual follow-up examinations.

Seven RCTs comparing 215 immediately and 224 conventionally loaded implants reported marginal bone level changes at 1 year of loading. The heterogeneity reached statistical significance (P = .003). The meta-analysis found no significant differences with SMD random-effect -0.05 mm (95% CI: -0.41 to 0.31 mm) (Fig 5). In two trials immediate and conventional loadings were compared with regards to bone level change at 2 years of function.<sup>4,5</sup> The SMD fixed-effect amounted to -0.06 mm (95% Cl: -0.45 to 0.34 mm) with no significant difference between the two treatment groups (Fig 6). One RCT compared 30 immediately and 30 conventionally loaded implants and found no differences in marginal bone loss at the 3-year follow-up examination.<sup>4</sup> In one study the outcomes of immediate and conventional loading were assessed 5 years after prosthesis delivery.<sup>24</sup> The mean marginal bone loss for immediately and conventionally loaded implants amounted to 1.31 mm and 1.01 mm, respectively. There was no significant difference between the two groups.

**Papilla Level.** The results of the change in papilla level are presented in Table 6.

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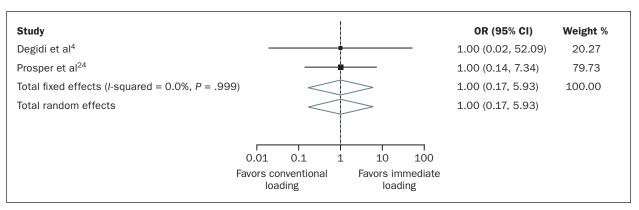


Fig 4 Results of meta-analysis for the comparison of implant survival at 3 years between immediate and conventional loading.

## Table 5 Marginal Bone Loss Results

				Marginal bo	ne loss (mm)	
Study	Year of publication	Loading protocol	At 1 y (mean ± SD)	At 2 y (mean ± SD)	At 3 y (mean ± SD)	At 5 y (mean ± SD)
Crespi et al <sup>5</sup>	2008	Immediate Conventional		$1.02 \pm 0.53$ $1.16 \pm 0.51$		
De Rouck et al <sup>10</sup>	2009	Immediate Conventional	0.86 ± 0.54 0.97 ± 0.35			
Degidi et al <sup>4</sup>	2009	Immediate Conventional	$0.69 \pm 0.38$ $0.58 \pm 0.28$	0.73 ± 0.40 0.70 ± 0.29	0.85 ± 0.71 0.75 ± 0.63	
den Hartog et al <sup>3</sup>	2011	Immediate Conventional	$0.91 \pm 0.61$ $0.90 \pm 0.57$			
Donati et al <sup>22</sup>	2008	Immediate Conventional	$0.32 \pm 0.87$ $0.38 \pm 0.89$			
Güncü et al <sup>23</sup>	2008	Immediate Conventional	$0.45 \pm 0.39$ $0.68 \pm 0.30$			
Prosper et al <sup>24</sup>	2010	Immediate Conventional	$0.24 \pm 0.12$ $0.17 \pm 0.11$			$1.31 \pm 0.44$ $1.01 \pm 0.59$
Schincaglia et al <sup>25</sup>	2008	Immediate Conventional	$0.77 \pm 0.38$ $1.20 \pm 0.55$			

Positive values represent bone loss.

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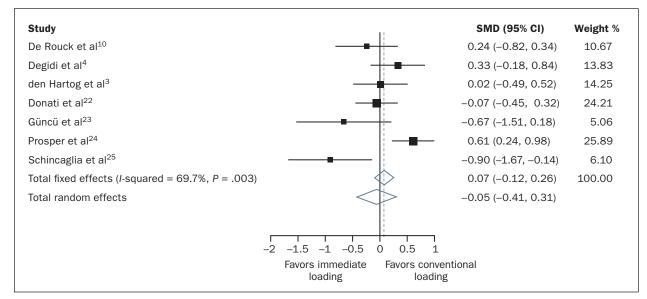


Fig 5 Results of meta-analysis for the comparison of bone loss at 1 year between immediate and conventional loading.

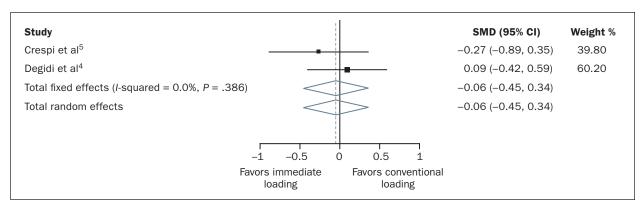




Table 6 Results Regarding Change of Papilla Level										
				plant placement im)		At 1 y after placement of definitive prosthesis (mm)				
Study	Year of publication	Loading protocol	Mesial (mean ± SD)	Distal (mean ± SD)	Mesial (mean ± SD)	Distal (mean ± SD)				
De Rouck et al <sup>10</sup>	2009	Immediate Conventional	$0.44 \pm 0.77$ $0.43 \pm 0.42$	$0.31 \pm 0.81$ $0.53 \pm 0.55$						
den Hartog et al <sup>3</sup>	2011	Immediate Conventional			$-0.41 \pm 0.49$ $-0.19 \pm 0.29$	$-0.27 \pm 0.49$ $-0.35 \pm 0.52$				
Donati et al <sup>22</sup>	2008	Immediate Conventional			$0.43 \pm 1.20$ $0.55 \pm 1.14$	$0.21 \pm 1.27$ $0.50 \pm 0.95$				

Positive values represent papilla recession.

One RCT evaluated the change of papilla height between the implant placement and the 1-year follow-up at conventionally and immediately loaded implants placed into fresh extraction sockets.<sup>10</sup> At 1-year of follow-up, the mean recession of mesial and distal papillae ranged from 0.31 to 0.53 mm with no significant differences between immediate and conventional loading. Two RCTs evaluated the level of the papillae at immediately and conventionally loaded implants between insertion of the definitive crown and the 1-year follow-up.<sup>3,22</sup> In one study, average papilla recession was found in both groups, ranging from 0.21 to 0.55 mm.<sup>22</sup> In the other study, an average gain of papilla height was reported for both groups.<sup>3</sup> The meta-analysis of the

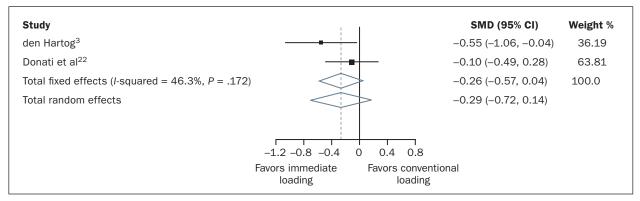


Fig 7 Results of meta-analysis for the comparison regarding change of mesial papilla level at 1 year between immediate and conventional loading.

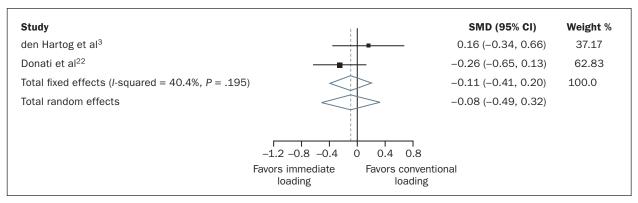


Fig 8 Results of meta-analysis for the comparison regarding change of distal papilla level at 1 year between immediate and conventional loading.

Table 7 Results Regarding Change of Buccal Mucosal Level										
Study	Year of publication	Loading protocol	At 1 y after implant placement (mean ± SD) (mm)	At 1 y after placement of definitive prosthesis (mean ± SD) (mm)						
De Rouck et al <sup>10</sup>	2009	Immediate Conventional	$0.41 \pm 0.75$ 1.16 ± 0.66							
den Hartog et al <sup>3</sup>	2011	Immediate Conventional		-0.06 ± 0.42 0.09 ± 0.34						
Hall et al <sup>12</sup>	2007	Immediate Conventional		$0.67 \pm 0.49$ $0.33 \pm 0.78$						

Positive values represent mucosal recession.

two RCTs did not reveal significant differences between immediate and conventional loading (Figs 7 and 8).

*Midbuccal Mucosa Level.* The results of the midbuccal mucosal recession are summarized in Table 7.

In one RCT comparing immediately and conventionally loaded implants placed into fresh extraction sockets, the level of the midbuccal mucosa was recorded at implant placement and at the 1-year followup.<sup>10</sup> The immediate loading group presented a mean mucosal recession of 0.41 mm, whereas in the conventional loading group the midbuccal mucosa receded by 1.16 mm on average. The difference between the study groups was statistically significant.

Two studies including 42 immediately and 43 conventionally loaded implants recorded the level of the facial soft tissue at definitive crown insertion and at the 1-year follow-up.<sup>3,12</sup> There was no evidence of heterogeneity and the meta-analysis did not reveal significant differences with SMD fixed-effects –0.14 mm (95% Cl: –0.57 to 0.29 mm) (Fig 9).

*Esthetic Outcomes.* Only one RCT included in the present review assessed the overall esthetic out-

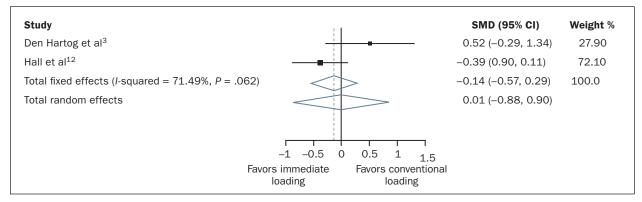


Fig 9 Results of meta-analysis for the comparison regarding change of buccal mucosal level at 1 year between immediate and conventional loading.

comes.<sup>3</sup> In this study, the esthetics of peri-implant mucosa and crowns at immediately and conventionally loaded implant sites were determined using the Pink Esthetic Score-White Esthetic Score (PES-WES)<sup>27</sup> and Implant Crown Esthetic Index (ICEI).<sup>28</sup> The mucosal esthetics were rated with a mean PES of 7.1  $\pm$  1.5 (range: 3 to 10) and 6.5  $\pm$  1.6 (range: 4 to 10) for the immediate and the conventional group, respectively. According to ICEI, the mucosal esthetics were satisfactory in 24 cases (80%) in the immediate loading group and in 19 cases (62%) in the conventional loading group. One case in both groups showed excellent soft tissue esthetics. The esthetics of the crown, expressed as WES, amounted to  $7.8 \pm 1.5$  (range: 4 to 10) in the immediate loading group and to 7.6  $\pm$  1.6 (range: 4 to 10) in the conventional loading group. None of the scores described in these studies showed significant differences between the two groups under investigation.

**Patient Satisfaction.** One RCT analyzed the patient satisfaction after immediate and conventional loading of implants.<sup>3</sup> Satisfaction regarding function, esthetics and treatment procedures was assessed using a form comprised of questions to be answered on a five-point rating scale. In addition, the overall satisfaction was measured using a 100-mm visual analog scale (VAS). Patient satisfaction was generally high and no differences were observed between the groups. However, approximately one-third of the patients in the conventional loading group judged the healing time after implant placement as long.

Another trial comparing immediate and conventional loading of implants placed into fresh extraction sockets evaluated patient satisfaction regarding esthetics by means of a 100 mm VAS.<sup>10</sup> This study reported an average patient satisfaction of 93% (range: 80% to 96%) for the immediate loading. The satisfaction for the conventional loading amounted to 91% (range: 80% to 96%) with no significant difference between the groups.

## DISCUSSION

#### **Implant Survival and Marginal Bone Level**

Ten RCTs comparing immediately and conventionally loaded implants and one RCT comparing immediately and early loaded implants met the inclusion criteria. The meta-analysis of data from the included trials did not reveal differences between immediately and conventionally loaded implants with regards to implant survival and marginal bone loss. The majority of the included studies evaluated implants inserted with a minimal torque in the range of 20 to 45 Ncm or a minimal ISQ in the range of 60 to 65. In addition, approximately half of the included studies considered the presence of peri-implant bone defects at implant insertion as an exclusion criterion.

Two recent systematic reviews did not find a significant effect of the loading protocol on implant survival and marginal bone loss.<sup>29,30</sup> Differently from the present study, however, these reviews included trials evaluating both single and splinted implants. In a previous systematic review comparing immediate, early, and conventional loading of single-implant restorations in the esthetic zone, no significant differences were found regarding the implant survival and marginal bone loss.<sup>31</sup>

It has been stated that a high degree of primary implant stability is one of the prerequisites for successful outcomes of immediate or early loading.<sup>29</sup> From the clinical standpoint, it is important to know what amount of primary stability is required to immediately or early load a single implant. Moreover, there are different methods for the assessment of primary implant stability.

In a previous study, a significant correlation was found between implant insertion torque and early failures of immediately restored single implants.<sup>32</sup> Nine out of 10 immediately loaded implants placed with 20 Ncm failed versus only 1 out of 10 inserted with a torque of 32 Ncm. In this study, step-cylinder type

implants were used. The implant survival rate was independent of implant length, site, bone quality and quantity. It was, therefore, concluded that an insertion torgue of 32 Ncm is necessary to achieve osseointegration of immediately loaded implants. In another study, 50 patients received two single nonadjacent implants, randomly inserted with a torque either ranging from 25 to 35 Ncm or being above 80 Ncm.<sup>33</sup> Nonoccluding provisional crowns were inserted immediately after implant placement. At 6 months of loading, seven implants inserted with a torque ranging from 25 to 35 Ncm failed whereas none of the implants failed inserted with high insertion torque. The difference of the implant survival rate between groups was statistically significant. There were no significant differences with regards to marginal bone loss and complication rates. The investigators concluded that an insertion torque of 35 Ncm was not sufficient to achieve high survival rates for immediately loaded single implants.

In contrast, several clinical studies reported high survival rates for immediately loaded implants inserted with low insertion torques.<sup>34–36</sup> A retrospective clinical study evaluated immediately restored, singletooth implants placed into fresh extraction sockets with a torque of  $\leq$  25 Ncm.<sup>35</sup> Lack of axial stability was an exclusion criterion in this study. At 1.25 to 9.5 years of loading, an implant survival rate of 95.5% and optimal maintenance of marginal bone levels were found.

Another parameter for the assessment of primary implant stability is ISQ as measured by resonance frequency analysis (RFA).<sup>37</sup> Interestingly, several preclinical and clinical studies found a lack of correlation between insertion torque and ISQ.<sup>38–42</sup> These results may be explained by the fact that the ISQ is a measure of axial stiffness between implant and bone. In contrast, the insertion torque corresponds to the degree of rotational friction between an implant and the surrounding bone tissue.

Currently, results remain inconclusive regarding the minimum insertion torque and the minimum ISQ needed to achieve successful osseointegration of immediately or early loaded implants. Hence, more research is needed to make clear clinical recommendations.

#### Level of Interproximal Papillae

The results of the present review indicated that the timing of the restorative procedure does not influence the level of the papillae at single-implant crowns at 1 year of function.

Only one RCT included in this review evaluated the change of papilla height between implant placement and the 1-year follow-up.<sup>10</sup> This study compared conventionally and immediately loaded implants placed into fresh maxillary extraction sockets. The mean papilla

shrinkage at 3 months was about twice as high in the conventional group as in the immediate loading group (0.9 mm vs 0.5 mm). In the following 9 months, papillae at conventionally loaded implants showed a tendency to fill the proximal spaces. At the 1-year follow-up, the mean recession of mesial and distal papillae ranged from 0.3 to 0.5 mm with no significant differences between immediate and conventional loading. Two RCTs included in this systematic review measured the change of the papilla height from the insertion of the definitive crown to the 1-year follow-up at immediately and conventionally loaded implants.<sup>3,22</sup> In both studies, implants were placed into sites with healed soft tissues. In one trial, a mean gain of the papilla height of approximately 0.3 mm was observed in both treatment groups.<sup>3</sup> In contrast, the other RCT recorded a minimal mean recession of the papillae between 3- and 12-month examinations.<sup>22</sup> The meta-analysis of data from the two trials did not reveal significant differences between immediate and conventional loading.

Other clinical studies, not meeting the inclusion criteria of the present systematic review, investigated immediately loaded implants placed into fresh extraction sockets in the anterior maxilla.<sup>43–47</sup> These studies measured the changes of the soft tissue level 12 months following the implant placement in relation to the preoperative status. The average papilla recession ranged from 0.3 to 0.5 mm. The papilla recession at conventionally loaded implants was evaluated in a study, in which 3 months of healing was allowed before restoration.<sup>48</sup> The measurements were taken prior to the implant placement and repeated at the insertion of the provisional, at 3 and 15 months. When compared to the presurgical soft tissue level, approximately 1 mm of papilla recession was recorded at the time of insertion of the provisional restoration, after which little changes took place. Other clinical studies assessed the change of the papilla level from the insertion of the definitive crown to the 1-year examination.49-53 In the majority of the trials a slight gain of the papilla height was found during this time frame for both immediately and conventionally loaded implants.<sup>49–52</sup> In a recent publication, immediately loaded implants placed into fresh extraction sockets were followed up to 2 to 8 years.<sup>54</sup> When compared to the pre-surgical status, mesial and distal papillae had lost 0.53 mm and 0.39 mm of height at the 1-year follow-up. The corresponding values at the last examination amounted to 0.22 mm and 0.21 mm. These results indicate that a recession of the papilla level occurs after implant placement and that the papillae have the capacity of growing following incorporation of the restoration. The papilla growth following the crown insertion, however, does not completely compensate the postoperative papilla recession.

#### Level of Buccal Mucosa

Only one RCT included in the present systematic review assessed the change of the buccal mucosa level from implant placement to the 1-year follow-up.<sup>10</sup> This study compared immediately and conventionally loaded implants placed into fresh extraction sockets. In the conventional loading group, the buccal mucosa receded by 1.2 mm in average, whereas immediate loading of implants led to 0.4 mm of mucosal recession. The difference between the groups was statistically significant. It was, therefore, concluded that immediate restoration of implants placed into fresh extraction sockets help limit the amount of buccal mucosal recession. Two RCTs analyzed in this review recorded the level of the facial soft tissue at the insertion of the definitive crown and at the 1-year followup.<sup>3,12</sup> In both studies implants were placed into sites with healed soft tissues. One study found stable mucosal levels at the 1-year follow-up for both immediate and conventional loading.<sup>3</sup> In the other trial mucosal recession amounting to 0.67 mm and 0.33 mm, respectively, was reported for immediate and conventional loading.<sup>12</sup> This difference did not reach statistical significance. The meta-analysis of the data from the two investigations did not reveal significant differences between immediate and conventional loading.

Other clinical studies, not meeting the inclusion criteria of the present systematic review, investigated immediately loaded maxillary implants. These trials measured the change of the buccal mucosa level 1 year following the implant placement in relation to the preoperative status. The average soft tissue recession ranged from 0.12 mm to 0.67 mm.<sup>45–47,55</sup> A recent systematic review included three trials investigating immediately loaded implants placed into fresh extraction sockets in the anterior maxilla.<sup>56</sup> The calculated average recession of the buccal mucosa from implant placement to the 1-year follow-up was 0.5 mm. Recession of the midbuccal mucosa at conventionally loaded implants was evaluated in a study described above.48 The measurements were taken prior to the implant placement and repeated at the insertion of the provisional and at 3 and 15 months. When compared to the pre-surgical soft tissue level, 0.8 mm of mucosal recession was recorded at the time of insertion of the provisional prosthesis, after which little changes took place. Other studies evaluated the level of the facial mucosa at the insertion of the definitive crown and at the 1-year examination. A trial investigating immediately loaded implants found 0.3 mm of gain of the midbuccal mucosal level.<sup>49</sup> Several clinical studies analyzing conventionally loaded implants reported stable mean buccal mucosal level at 1 year of function.<sup>51–53</sup> In contrast, one trial with 11 conventionally loaded implants found a mean mucosal recession amounting to 0.6 mm.<sup>57</sup>

In a recent publication, immediately loaded implants placed into fresh extraction sockets were followed up to 2 to 8 years.<sup>54</sup> Significantly more recession of the facial mucosa was reported at the last examination (1.13 mm) as compared to the 1-year follow-up (0.55 mm). These results indicate that recession of the buccal mucosa occurs after implant placement and can become more pronounced in the long term.

#### **Esthetic Outcomes**

Only one study included in the present systematic review reported the outcomes regarding esthetics following immediate and conventional implant loading.<sup>3</sup> In this study, the esthetics of peri-implant mucosa and implant crown were determined using the PES-WES<sup>27</sup> and ICEI.<sup>28</sup> There were no differences between the two groups under investigation.

Other clinical studies evaluating the esthetics of single-implant crowns by means of PES-WES and ICEI reported similar results.<sup>27,58–60</sup> In these studies, the mean total PES-WES for conventionally loaded single-implant crowns ranged from 13.5 to 16.8.<sup>27,58,59</sup> In a study including 93 patients with conventionally loaded single-implant crowns in the anterior maxilla, the mean ICEI amounted to 4.8. The overall result was rated as acceptable in 66% of the cases.<sup>60</sup>

#### **Patient Satisfaction**

Two RCTs analyzed in the present review reported patient satisfaction following immediate and conventional implant loading.<sup>3,10</sup> Patient satisfaction was high and no differences were observed between the groups. Other clinical studies evaluating the patient satisfaction after immediate and conventional loading of single-implant crowns by means of a VAS reported similar findings.<sup>44,58,60–62</sup>

It is well documented that patient satisfaction with esthetics can considerably differ from that of professionals, with patients usually showing a higher degree of satisfaction.<sup>60,63–65</sup> This indicates that concerning the esthetics of implant-supported reconstructions and their surrounding tissues, patients may have different views regarding the factors contributing to a satisfying result.

#### **Time Points of Baseline Measurements**

It is obvious that to assess the influence of a given therapeutic intervention on a certain parameter, baseline measurements are ideally performed prior to the intervention under investigation. In other words, to compare the effect of immediate and conventional loading protocols on peri-implant tissues, baseline assessments should be performed at implant placement in both groups.

Regarding marginal bone loss, a reasonable number of RCTs were found reporting bone level changes from

a baseline at the time of implant placement. Hence, a large amount of data were available for analysis.

In contrast, as far as soft tissue changes are concerned, only one RCT was found evaluating changes of the soft tissues with implant placement as the baseline for measurement. Therefore, inclusion was extended to studies reporting changes in soft tissue with insertion of the final crown as the baseline. As a consequence, the comparability of the results from different studies regarding mucosal levels was hampered by the fact that different time points for baseline measurements (implant placement and final crown insertion) were selected.

### **Study Strength and Limitation**

The present systematic review included only the highest level of evidence (data from RCTs) for examining whether or not immediate loading of single-implant crowns rendered different results from early and conventional loading. One previous systematic review investigating the effects of different loading protocols on single-implant crowns included RCTs, controlled clinical trials, cohort studies, and case series.<sup>31</sup> Two other systematic reviews on loading protocols included studies investigating both single and splinted implants.<sup>29,30</sup>

The main limitation of this review is the fact that the majority of the included studies did not provide observations beyond 1 year of implant function. In addition, only a limited number of trials were found evaluating the levels of peri-implant soft tissue, esthetics, and patient satisfaction.

## CONCLUSIONS

Based on the findings of the present systematic review it can be concluded that for single-implant crowns:

- Immediately and conventionally loaded implants are equally successful clinical procedures regarding implant survival and marginal bone loss. This conclusion is primarily derived from studies evaluating implants inserted with a minimal torque in the range of 20 to 45 Ncm or a minimal ISQ in the range of 60 to 65 and with no need for simultaneous bone augmentation. In addition, most studies did not include observation periods beyond 1 year of implant function.
- Immediately and conventionally loaded implants do not appear to differently affect the papilla height during the first year of loading.
- Due to the heterogeneity of the time point of baseline measurements and the contradictory findings in the studies it is difficult to draw clear

conclusions regarding the recession of the buccal mucosa between immediately and conventionally loaded implants.

- With respect to the assessment of esthetic outcomes, the data available remain inconclusive.
- Patient satisfaction was measured in only very few trials rendering insufficient data to draw conclusions.

There is a need for well-designed prospective randomized controlled trials investigating the effectiveness of different loading protocols.

Future investigations should ideally focus on clinically relevant parameters able to assess whether or not the treatment goal of a given therapy has been achieved. A standardized use of patient-reported outcome measures is, therefore, recommended to understand the benefit of a treatment from the patients' perspectives. Moreover, clinical trials should include analyses of the cost-effectiveness of the examined therapy.

To assess the esthetic outcome of an intervention, the use of reproducible methods and validated indices is recommended. More studies are needed comparing different loading protocols regarding their effect on the mucosal level over time. For repeated metric assessments, adequate reference structures should be selected for baseline and follow-up measurements.

Baseline assessments should be performed prior to the intervention under investigation. Therefore, in cases of immediate loading, baseline measurement is ideally performed at implant placement. However, to truly understand the influence of treatment timing on the therapeutic outcomes, future studies should be designed to investigate both the effects of the time point of implant placement and the time point of loading. For studies investigating the timing of implant placement, baseline measurements should be assessed prior to tooth extraction. Finally, there is a need for more long-term observation.

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## Implant Loading Protocols for Partially Edentulous Patients with Extended Edentulous Sites— A Systematic Review and Meta-Analysis

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Purpose: The aim of this study was to systematically review the evidence for immediate implant loading in partially edentulous patients with extended edentulous sites and evaluate potential treatment modifiers. Materials and Methods: An electronic search was performed in Medline, Embase, and Central to identify studies investigating the outcome of implants subjected to immediate loading (IL) (less than 1 week), early loading (EL) (1 week to 2 months), or conventional loading (CL) (more than 2 months) with implant-supported fixed dental prostheses (IFDPs) in partially edentulous patients with extended edentulous sites, ie, at least two adjacent teeth are missing. Only human studies with at least 10 cases and a minimum follow-up time of 12 months, reporting on solid-screw-type implants with rough surfaces and a diameter of at least 3 mm, were included. Weighted means of implant survival rates and risk ratios for implant survival at 1 year using meta-analytic tools were calculated to perform the following comparisons: IL vs EL, IL vs CL, and IL in the maxilla vs mandible. Noncomparative studies reporting on IL and EL protocols were summarized through descriptive methods. Results: The search provided 3,872 titles, 837 abstracts, and 444 full-text articles. A total of 24 publications that comprised six comparative studies (five randomized controlled trials, one nonrandomized controlled trial) and 18 noncomparative studies were included for analysis. The comparison of weighted mean survival rates revealed no statistically significant difference between IL (97.9%) and EL (97.8%, P = .9405), and between IL (100%) and CL (99.3%, P = .3280). Meta-analysis showed no statistically significant difference in implant survival at 1 year between IL and EL (RR 0.90; 95% CI 0.30, 2.70; P = .502). A meta-analysis comparing IL and CL could not be performed due to the low number of failures. No statistically significant difference was found for IL implants placed in the maxilla vs the mandible (RR 1.55; 95% Cl 0.49, 4.84; P > .05). Due to the small number of IL implants placed in the anterior, a comparison between implant survival in anterior vs posterior zones was not performed. Treatment modifiers were bone quality, primary stability, insertion torque, ISQ values, implant length, the need for substantial bone augmentation, the timing of implant placement, and the presence of parafunctional and smoking habits. Conclusions: IL presents similar implant survival rates as EL or CL for partially edentulous patients with extended edentulous sites in the posterior zone, as long as strict inclusion/exclusion criteria are followed. There is a lack of evidence for IL of multiple implants in the anterior zone of partially edentulous patients. Preliminary evidence suggests that IL may be equally successful in either the maxilla or mandible. Further research is needed before IL in partially edentulous patients with extended edentulous sites can be recommended in everyday practice. INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):239–255. doi: 10.11607/jomi.2014suppl.g4.2

**Key words:** conventional loading, dental implants, early loading, fixed dental prostheses, immediate loading, meta-analysis, partial edentulism, systematic review

The literature on dental implants demonstrates that conventional loading (CL) of implant-supported fixed dental prostheses (IFDPs) in partially edentulous patients is associated with predictable long-term outcomes.<sup>1-6</sup> When a reduced healing time is considered, such as in early loading (EL) or immediate loading (IL)

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protocols, several clinical parameters such as bone volume and density, implant placement protocol, implant size, and primary stability have to be considered.<sup>7</sup>

The 2008 ITI Consensus Meeting reviewed the predictability of EL and IL protocols in partially edentulous arches and revealed different results depending on the mandibular or maxillary location of the implant-prosthodontic complex.<sup>8–10</sup> In the mandible of partially edentulous patients, EL (6 to 8 weeks) was supported in the absence of modifying factors and IL appeared to be a treatment alternative in carefully selected clinical situations.<sup>9,10</sup> In the maxilla, however, EL and IL protocols were recommended only in selected patients since they appeared to be technique sensitive.<sup>8,10</sup> The recommendations from these systematic reviews were mainly based on implant survival as the primary outcome.

To determine the viability of a shortened implant healing time, a comparison among different loading protocols for partially edentulous patients seems to be of clinical relevance. However, the evaluation of the clinical relevance and practicality of early and immediate implant loading calls for a comprehensive assessment of criteria used for selecting such loading protocols and an intention-to-treat analysis (ITT) rather than the sole presentation of survival rates.

The objectives of this systematic review are to present, analyze, and summarize scientific and clinical evidence of IL protocols in partially edentulous patients with extended edentulous sites and to identify criteria associated with the selection of such loading protocols.

## **MATERIALS AND METHODS**

This systematic review was conducted consulting the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA),<sup>11</sup> the Standards for Developing Trustworthy Clinical Practice Guidelines published by the Institute of Medicine (IOM),<sup>12</sup> and the Cochrane Handbook for Systematic Reviews of Interventions.<sup>13</sup>

### **Focus Question**

The focus question was developed according to the PICO (population, intervention, comparison, outcome) format<sup>14</sup> with the population being partially edentulous patients with extended edentulous sites, intervention being IL of dental implants with IFDPs, comparison being EL and CL of dental implants with IFDPs, and outcome being implant survival.

The focus question was: In partially edentulous patients with extended edentulous sites, what is the effect of immediate implant loading with implant-supported fixed dental prostheses compared to early or conventional loading on implant survival? Loading protocols were defined as follows<sup>10,15</sup>:

- Conventional loading: Dental implants are allowed a healing period greater than 2 months after implant placement with no connection to the prosthesis.
- *Early loading:* Dental implants are connected to the prosthesis between 1 week and 2 months subsequent to implant placement.
- Immediate loading: Dental implants are connected to the prosthesis within 1 week subsequent to implant placement.

#### Search Strategy

The search strategy was developed in close collaboration with a trials search coordinator, who also serves as the Reference and Education Services Librarian at the Countway Library of Medicine of the Harvard Medical School, Boston, Massachusetts. The electronic search was performed utilizing the databases of PubMed/ Medline, Embase, and the Cochrane Central Register of Controlled Trials (CENTRAL) (Table 1).

A total number of 4,496 publications were identified. This number was reduced to 3,872 publications (2,578 from PubMed, 1,294 from Embase, 0 from CEN-TRAL) after duplicates had been removed. All 3,872 studies were included for title screening (Fig 1). A reference manager software (EndNote X, Version 4.0.2) was utilized to search electronic databases, identify and discard duplicate publications, screen studies, and monitor reviewer agreement.

#### **Selection Criteria**

Inclusion and exclusion criteria are summarized in Table 1. Clinical studies of all levels of the hierarchy of evidence were included as long as the investigators performed a clinical exam on all patients under investigation to collect the data. As CL in partially edentulous patients is a well-documented protocol, noncomparative studies describing the outcome of CL implants were not included. In case of multiple publications on the same study population, only the study with the longest follow-up time was included, while previous studies were consulted only to retrieve information not provided in the most recent publication.

#### **Screening of Studies**

Screening was performed independently by two reviewers, who were calibrated during an ITI calibration meeting (AS and GG). Titles, abstracts, and full-text articles were consecutively excluded at the corresponding stages of screening (Fig 1). Accordingly, 3,872 titles, 837 abstracts, and 444 full text articles were evaluated for inclusion. For title and abstract screenings, articles which were not marked for exclusion by both reviewers,

Table 1 Search	n Strategy and Selection Criteria
	a partially edentulous patients with extended edentulous sites, what is the effect of immediate implant ading with IFDPs compared to early or conventional loading on implant survival?
Search terminology	
PubMed/Medline (NLM) No limits applied 2,579 results	(dental implantation, endosseous[MeSH] OR dental implants[MeSH] OR implantation*[all fields] OR implant[all fields] OR implants[all fields]) AND (Denture, Partial, Fixed[MeSH] OR dental prosthesis, implant-supported[MeSH] OR fixed partial denture*[all fields] OR FPD[all fields] OR FPDs[all fields] OR fixed dental prosthesis[all fields] OR fixed dental prostheses[all fields] OR bridge*[all fields] OR FDP[all fields] OR FDPs[all fields]) AND (Immediate Dental Implant Loading[MeSH] OR function[all fields] OR time[all fields] OR immediate[all fields] OR early[all fields] OR load*[all fields]) AND (English[Iang] OR German[Iang] OR French[Iang])
Embase (Elsevier) 1974 - current 1,869 results	('tooth implantation'/exp OR implantation* OR 'implant' OR 'implants') AND ('denture'/exp OR 'tooth pros- thesis'/exp OR 'fixed partial denture' OR 'fixed partial dentures' OR bridge* OR 'FPD' OR 'FPDs' OR 'fixed dental prosthesis' OR 'fixed dental prostheses' OR 'fdp' OR 'fdps') AND ('function' OR 'time' OR 'immedi- ate' OR 'early' OR load*) AND ('survival'/exp OR 'complication'/exp OR 'treatment failure'/exp OR complica- tion* OR success* OR failure*) AND ([english]/lim OR [french]/lim OR [german]/lim) AND [embase]/lim
Cochrane Central Register of Controlled Trials (CENTRAL) No limits applied 48 results	(implantation* OR implant OR implants) AND ("fixed partial denture" OR "fixed partial dentures" OR bridge* OR FPD OR FPDs OR "fixed dental prosthesis" OR "fixed dental prostheses" OR fdp OR fdps) AND ("function" OR "time" OR "immediate" OR "early" OR load*) AND (complication* OR success* OR failure*)
Selection criteria	
Inclusion criteria	Human studies Partially edentulous patients receiving IFDPs Solid screw-type implants with a rough surface
Exclusion criteria	Animal or in vitro studies Follow-up time less than 12 months Case series with less than 10 cases Noncomparative studies reporting the outcome of conventional implant loading Non–solid-screw-type implants Implants with machined surfaces or hydroxyapatite (HA) coatings Implants with a diameter of less than 3 mm Studies mainly reporting on implants in single-unit gaps Implants supporting full-arch restorations or removable appliances Implants placed in irradiated bone or alveolar clefts Data retrieved from chart reviews or questionnaires Insufficient information provided on loading protocol or type of implant suprastructure Insufficient information provided to determine implant survival rates Results of the same study were published again later with a longer follow-up

were included in the next screening step. At the levels of full-text screening and data extraction, disagreements were resolved by discussion.

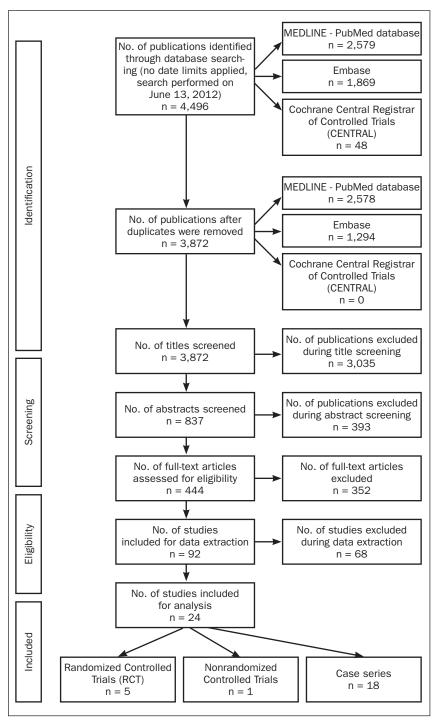
#### **Exclusion of Studies**

A total of 92 articles were included for data extraction. Sixty-eight articles had to be excluded from the final analysis because they did not meet the inclusion criteria (Table 2).

During full-text screening, it became evident that the majority of publications reported on implants placed in single-unit gaps and in extended edentulous sites (at least two adjacent teeth missing) without providing separate data for these two different types of restorations. To avoid the loss of valid information, these studies were included for analysis as long as they met the remaining inclusion criteria. However, studies reporting exclusively or mainly on implants in singleunit gaps were excluded.

#### **Data Collection**

Data extraction was performed on the twenty-four studies included for analysis by two independent reviewers (AS and MR). Disagreement regarding data collection was resolved in personal meetings and by consulting a third senior reviewer (GG). Authors were contacted directly via email as needed for clarification or missing information. If the obtained data were still not sufficient to meet the inclusion criteria of this systematic review, the study was excluded.



**Fig 1** Search strategy and postextraction dimensional changes.

## **Outcome Measures**

The primary outcome measure was implant survival. Secondary outcome measures were location and time of implant failures, number and time of prosthetic failures, and treatment modifiers affecting the choice of loading protocols.

#### **Quality Assessment**

Two independent reviewers (AS and MR) assessed the methodological quality of all included comparative studies. Randomized (RCT) and nonrandomized (NRCT) controlled trials were rated according to their risk of bias by using the Cochrane quality assessment tool for RCTs.<sup>13</sup>

#### Table 2 Studies Excluded During Data Extraction

Case series on conventional loading protocols	Astrand et al 2004, Bahat et al 2012, Balleri et al 2010, Behneke et al 2000, Bilhan et al 2010, Bornstein et al 2008, Boronat et al 2010, Carlson et al 2001, Cecchinato et al 2008, Cecchinato et al 2004, Chaushu et al 2009, Chiapasco et al 2006, Cordaro et al 2002, Cordioli et al 2001, De Bruyn et al 1992, Esposito et al 2011, Esposito et al 2011, Felice et al 2009, Felice et al 2010, Ferrigno et al 2005, Fugazzotto 2008, Halg et al 2008, Jebreen and Khraisat 2007, Johansson et al 2010, Karabuda et al 2011, Karlsson et al 1998, Khayat et al 2001, Krennmair et al 2011, Mannai 2006, Ozkan et al 2011, Pieri et al 2012, Romeo et al 2006, Romeo et al 2009, Sivolella et al 2011, Urban and Lozada 2010, Vigolo and Zaccaria 2010, Wahlstrom et al 2010, Wennstrom et al 2004, Zinsli et al 2004
Insufficient information to separate partially and completely edentulous patients	Boronat et al 2008, Crespi et al 2007, Glauser et al 2003, Glauser et al 2005, Glauser et al 2007, Kielbassa et al 2009, Malo and Nobre 2011, Ostman et al 2010, Ostman et al 2012
Insufficient information to separate the number of maxillary and mandibular implants	Barter et al 2012, Cannizzaro et al 2011, Palmer et al 2012, Siebers et al 2010
Combined data for implants with machined and rough surfaces	Calandriello and Tomatis 2005, Degidi and Piattelli 2003, Malo et al 2007, Rocci et al 2003
Insufficient information to separate data for individual loading protocols	Bornstein et al 2007, Malo et al 2011
Insufficient information to separate data for IFDPs in partially edentulous patients	Akca and Cehreli 2008, Arisan et al 2010
Type of prosthetic restoration does not meet inclusion criteria	Bornstein et al 2010, Ostman et al 2008
Comparative study with insufficient information on the number of implants in test and control groups	Achilli et al 2007
Implants placed in cleft palate	Landes 2006
Follow-up time less than 12 months	Degidi and Piattelli 2005
Insufficient information on patient population	Smith et al 2009
Insufficient information on loading protocol	Bragger et al 2001

IFDPs = Implant-supported fixed dental prostheses.

#### **Statistical Analysis**

Simple kappa statistics were calculated to measure reviewer agreement.<sup>13</sup> The associations between loading protocols were assessed using risk ratios (RR) for implant survival at one year. The scenarios IL vs EL, IL vs CL, and IL implants in the maxilla vs mandible were evaluated utilizing random-effects models accounting for inverse variance weighting, incorporating the estimation of heterogeneity of precisions, and effect sizes of the studies being evaluated. These meta-analyses were performed using the STATA statistical software version 11.2 with the meta-analysis command "metan."

Studies without failures in both test and control groups were not taken into account and were excluded from the meta-analysis. Heterogeneity between studies was assessed using *I*-squared statistics describing the variation in RR, which is attributable to the heterogeneity of the studies.

## RESULTS

A total of 24 publications were included for final analysis, which consisted of six comparative studies (five RCTs, one NRCT) and 18 noncomparative studies (case series). Kappa statistics revealed a score of 0.74 as a measure of reviewer agreement.

#### Meta-analysis of Comparative Studies

**Immediate vs Early Loading.** Three RCTs<sup>16–18</sup> investigated the influence of IL and EL protocols on implant survival (Table 3a). IL implants were loaded within 48 hours, whereas EL implants were loaded between 28 days and 2 months after implant placement. Overall, 6 of 285 IL implants and 6 of 272 EL implants failed. The survival analysis with weighted follow-up time resulted in an overall survival rate of 97.9% for the IL group, compared to 97.8% for the EL group. The difference was not statistically significant (RR: 0.90; 95% CI: 0.30, 2.70; P = .9405).

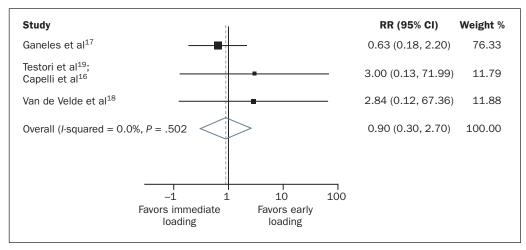


Fig 2 Forest plot for the comparison of IL and EL regarding the 1-year implant survival rates.

The heterogeneity between studies was not statistically significant (*I*-squared = 0.0%, *P* = .502) (Fig 2).

Immediate vs Conventional Loading. One NRCT<sup>20</sup> and two RCTs<sup>21,22</sup> compared the impact of IL or CL on implant survival (Table 3a). IL implants were loaded within 48 hours of implant placement, whereas CL implants were loaded between 3 and 3.5 months after implant placement in the mandible and 4 and 4.5 months in the maxilla. One failure out of a total of 272 implants investigated occurred in the CL group. The survival analysis with weighted follow-up time resulted in a statistically nonsignificant difference in survival rates of 100% for the IL group and 99.3% for the CL group (P = .3280). Meta-analysis could not be performed as there were no failures in both test and control groups of two studies. Heterogeneity between studies could not be evaluated as two out of three studies had to be excluded from the meta-analysis.

#### **Quality Assessment**

A high risk of bias was assigned to three studies (Table 3a). In Capelli et al,<sup>16</sup> allocation was manually generated with a restricted randomization list and not all assessors were blinded. Sequence generation in Cannizzaro and Leone<sup>20</sup> was not randomized and insufficient information was provided to judge if clinical factors influenced the decision to assign patients to test or control groups. Furthermore, there was no allocation concealment and investigators was also found in Cannizzaro et al.<sup>21</sup>

An unclear risk of bias was assessed for three studies. Ganeles et al<sup>17</sup> provided insufficient information on the method of blinding. In Van de Velde et al,<sup>18</sup> it was not clear if allocation concealment was guaranteed and if investigators were blinded besides the radiographic evaluation. Romanos and Nentwig<sup>22</sup> reported insufficient information on sequence generation, allocation concealment, and methods of blinding.

A low risk of bias could not be assigned to any study included in this review.

# Descriptive Analysis of Noncomparative Studies

Of the 18 case series included in this review,<sup>23-40</sup> three studies reported on the same study population than previous reports,<sup>23-25</sup> resulting in a total of 15 independent publications (Table 3b). Twelve of those reported on IL and three on EL. The study population comprised between 10 and 51 patients and 20 to 111 implants, with a mean follow-up time between 12 and 96 months.

*Immediate Loading.* Combining the 12 noncomparative studies on IL included in this review, a total of 685 implants placed in 297 patients were followed for a period of 1 to 8 years. Altogether, 15 failures were reported. The survival rates ranged from 89.8% to 100%, resulting in a mean survival rate of 97.8%. Studies were conducted in academic and private practice settings.

All noncomparative studies that provided sufficient information on the implant placement protocol utilized a type 4 placement approach, ie, implants were placed in fully healed postextraction sites. Several studies did not provide information on the implant placement protocol.

Only five publications included in this systematic review reported on prostheses failures. Two publications did not experience any failures,<sup>26,27</sup> while three investigations revealed one prosthesis failure each.<sup>28–30</sup> All prosthesis failures occurred due to the loss of one of the supporting implants.

**Early Loading.** Three case series describing the outcome of EL met the inclusion criteria of this system-

atic review. Implants were loaded between 14 and 30 days after implant placement. A total of 205 implants were placed in 87 patients and followed up for 1 to 5 years. One implant failure occurred, leading to an overall mean survival rate of 99.5% for EL implants. Only one study provided information on implant placement protocol and prosthesis failure.<sup>31</sup>

#### **Implant and Failure Distribution**

The vast majority of implants reported in the included comparative studies were placed in the posterior region of the jaw (Table 4a). Three out of six comparative studies included posterior implants only<sup>17,18,22</sup> while two studies included 94.2%<sup>16</sup> and 67.6%<sup>21</sup> of posterior implants, respectively. Cannizzaro and Leone<sup>20</sup> did not provide sufficient information on implant location and failures. Implants investigated in comparative studies were placed more frequently in the mandible than in the maxilla. The location of failure was given for 12 out of a total of 13 lost implants. All of those failures occurred in the posterior region. Five implants failed in the maxilla and seven in the mandible. Six of those failed implants were immediately loaded. All IL failures occurred in the posterior, and four out of a total of six IL implants were lost in the maxilla. All implant failures occurred within three months after implant placement.

The majority of IL implants investigated in noncomparative studies were placed in the posterior region of the jaw (80.1%) and the mandible (63.9%) (Table 4b). Twelve studies reported a total of 15 failures. Four of those failures occurred in the anterior (26.7%) and 11 occurred in the posterior (73.3%), which was in accordance with the distribution of implants placed in those regions of the jaw (19.9% vs 80.1%). The exact failure location was provided for nine implants. Six out of those implants were lost in the mandible and three failed in the maxilla. Two studies, which included six failures, did not provide sufficient information to determine which jaw the respective implants failed in.<sup>30,32</sup> All but one implant failure occurred within 6 months of placement. One failure did not occur until 12 months after implant placement.

One noncomparative study on EL reported one implant failure.<sup>31</sup> The failure occurred in the posterior region of the mandible and was not associated with the loading protocol as the implant was lost to a periimplant infection during the healing period.

As several studies did not provide information on the exact time and location of implant drop-outs and failures, a survival analysis with weighted follow-up time comparing IL implants placed in the maxilla vs mandible could not be performed. However, the meta-analysis revealed that the difference in survival of IL implants placed in the maxilla vs mandible was not statistically significant (RR: 1.55; 95% CI, 0.49, 4.84; P > .05). The heterogeneity between studies was not statistically significant (*l*-squared = 0.0%, P = .671) (Fig 3).

Due to the small number of implants placed in the anterior zone, a statistical comparison between anterior and posterior IL implants was not performed.

#### **Criteria for Immediate Loading**

Insertion torque was a frequently applied tool to determine if an implant was suitable for IL (Table 5). It was used in 12 out of a total of 19 studies and ranged between 15 Ncm and 45 Ncm.<sup>16,20,21,25,27,30,34–39</sup> Notably, 9 of those studies required an insertion torque of at least 30 Ncm.<sup>16,20,21,25,27,36–39</sup> However, one of those studies considered an insertion torque of at least 20 Ncm sufficient if the implants were splinted together.<sup>16</sup>

Resonance frequency analysis (RFA) was utilized in six studies.<sup>26,28,29,34,35,39</sup> Minimum Implant Stability Quotient (ISQ) values required for IL ranged between 50 and 62. Three studies relied on ISQ values only to confirm adequate primary stability.<sup>26,28,29</sup> Two publications confirmed primary stability by hand only.<sup>17,18</sup>

Nine publications required a minimum implant length for IL, which ranged between 8 mm and 11 mm.<sup>18,27–29,35–39</sup> A combination of insertion torque, ISQ values, and minimum implant length as criteria for IL was applied by two investigations.<sup>35,39</sup>

Four studies explicitly excluded implants placed immediately into fresh extraction sockets,<sup>17,18,21,34</sup> while three studies included those implants.<sup>16,19,25,39</sup> Implants requiring bone augmentation procedures were excluded by nine studies.<sup>17,18,21,22,26,29,30,34,35</sup> Four publications included implants requiring minimal bone grafting to either cover bone dehiscences<sup>32</sup> or gaps present after type 1 implant placement.<sup>16,25,39</sup> Parafunctional habits were considered exclusion criteria by twelve studies.<sup>16–18,21,25–29,32,34,38</sup> Only one publication included patients with parafunctional habits.<sup>39</sup> Smokers consuming more than 10 cigarettes per day were included by eight studies,<sup>16,20–22,29,32,35,39</sup> while seven studies excluded them.<sup>17,18,26,27,30,34,38</sup>

Immediately placed provisional prostheses were either in full occlusal or light centric contact with no excursive contacts in 13 out of 19 studies.<sup>18,20–22,25,27,29,30,34–37,39</sup> The remaining six studies removed all occlusal contacts before delivering the immediate restorations.<sup>16,17,26,28,32,38</sup>

#### Intention to Treat Analysis (ITT)

Table 6 summarizes how many implants were originally intended for IL and how many of those implants were ultimately not immediately loaded because they did not fulfill certain criteria established by the respective authors. Almost half of the studies analyzed in this systematic review did not provide information on ITT.

Table 3a Compa	arative Stu	dies Inc	luded for A	nalysis				
Study	Study type	Setting	Comparison	Patients	Mean follow- up (mo)	Patient drop-outs	Placement type	Brand
Immediate vs early lo	ading							
Ganeles et al <sup>17</sup>	RCT	U, PP	IL vs EL IL group EL group	266 138 128	12 12 12	8 4 4	Type 4 Type 4 Type 4	Strauman, Standard, Standard Plus
Testori et al <sup>19</sup> ; Capelli et al <sup>16</sup>	RCT	PP	IL vs EL IL group EL group	52 25 27	60 60 60	1 0 1	Type 1, type 4 Type 1, type 4 Type 1, type 4	BIOMET 3i, Full Osseotite Tapered
Van de Velde et al <sup>18</sup>	RCT, split mouth	U	IL vs EL IL group EL group	13 13 13	18 18 18	1 1 1	Type 4 Type 4 Type 4	Straumann, Tapered Effect
Total			IL group EL group	331 176 168				
Immediate vs conven	tional loading	ŝ						
Cannizzaro and Leone <sup>20</sup>	NRCT	PP	IL vs CL IL group CL group	28 14 14	24 24 24	0 0 0	NR	Zimmer Dental, Spline Twist
Cannizzaro et al <sup>21</sup>	RCT	PP	IL vs CL IL group CL group	40 20 20	36 36 36	0 0 0	Туре 4	Zimmer Dental, Tapered SwissPlus
Romanos and Nentwig <sup>22</sup>	RCT, split mouth	U	IL vs CL IL group CL group	12 12 12	25.3 25.3 25.3	0 0 0	NR	Dentsply, Ankylos
Total			IL group CL group	80 46 46				

IL = immediate loading; EL = early loading; CL = conventional loading; RCT = randomized controlled trial; NRCT = nonrandomized controlled trial; PP = private practice; U = university; NR = not reported; SLA = sandblasted, large grit, acid-etched; SLActive = sandblasted, large grit, acid-etched, conditioned in nitrogen and immediately preserved in an isotonic saline solution; MTX = microtextured titanium; Implant placement: type 1 = immediate placement; type 2 = postextraction site with healed soft tissues but without significant bone healing; type 3 = postextraction site with healed soft tissues but without significant bone healing; type 3 = postextraction site with healed soft \*P = .3280.

### Table 3b Noncomparative Studies Included for Analysis

Churche	Cattling	Dettente	Mean follow-	Placement	Durad
Study	Setting	Patients	up (mo)	type	Brand
Immediate loading					
Boronat-Lopez et al <sup>28</sup>	U	12	NR	NR	Impladent, Defcon TSA
Cornelini et al <sup>29</sup>	U, PP	20	12	NR	Straumann
Degidi et al <sup>34</sup>	U, PP	50	36	Type 4	Dentsply-Friadent, XiVE Plus
Luongo et al <sup>30</sup>	PP	40	12	Type 4	Straumann
Machtei et al <sup>32</sup>	U	20	12	Type 4	Biomet 3i, Osseotite
Malo and Nobre <sup>36</sup>	PP	41	12	Type 4	Nobel Biocare, NobelSpeedy Groovy
Nikellis et al <sup>37</sup>	PP	18	12–24	NR	Southern Implants
Payer et al <sup>38</sup>	U	24	60-96	Type 4	Dentsply Friadent, XiVE
Rismanchian et al <sup>26</sup>	U	10	12	Type 4	Astra Tech
Schincaglia et al <sup>24</sup> ; Fung et al <sup>35</sup>	U	10	36	Type 4	Nobel Biocare, Branemark Mk IV
Vanden Bogaerde et al <sup>25,27</sup>	PP	31	18	NR	Nobel Biocare, Branemark Mk III, IV
Vanden Bogaerde et al <sup>39</sup>	U, PP	21	18	NR	Neoss Ltd, Neoss
Total		297			
Early loading					
Bornstein et al <sup>23,33</sup>	U	51	60	NR	Strauman
Fischer et al <sup>40</sup>	PP, U	16	12	NR	Nobel Biocare, Nobel Replace Select
Todisco <sup>31</sup>	PP	20	12	Type 4	Zimmer Spline, Nobel Replace Select
Total		87			

PP = private practice; U = university; NR = not reported; NA = not applicable; RCT = randomized controlled trial; NRCT = non-randomized controlled trial; SLA = sandblasted, large grit, acid-etched; MTX = microtextured titanium; Implant Placement: type 1 = immediate placement; type 2 = postextraction site with healed soft tissues but without significant bone healing; type 3= postextraction site with healed soft tissues and with significant bone healing; type 4 = fully healed postextraction site.

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Surface	Implants placed	Implant failures	Implant survival rate (%)	Prosthetic failures	Prosthetic survival rate (%)	Risk of bias
SLActive	383 197 186	10 4 6	97.4 98.0 96.8	NR NR NR	NR NR NR	Unclear
Full Osseotite	104 52 52	1 1 0	99.0 98.0 100	1 1 0	98.1 96.0 100	High
SLA	70 36 34	1 1 0	98.6 97.2 100	0 0 0	100 100 100	Unclear
	557 285 272	12 6 6	97.9 97.9* 97.8*			
MTX	92 46 46	1 0 1	98.9 100 97.8	NR NR NR	NR NR NR	High
MTX	108 52 56	0 0 0	100 100 100	0 0 0	100 100 100	High
Sandblasted	72 36 36	0 0 0	100 100 100	0 0 0	100 100 100	Unclear
	272 134 138	1 0 1	99.6 100** 99.3**			

Surface	Implants placed	Implant failures	Implant survival rate (%)	Prosthetic failures	Prosthetic survival rate (%)
Avantblast	36	1	97.2	1	91.6
SLA	40	1	97.5	1	95.0
Grit-blasted, acid-etched	100	2	98.0	NR	NR
SLA	82	1	98.8	1	97.5
Osseotite	49	5	89.8	NR	NR
TiUnite	72	1	98.6	NR	NR
Sandblasted, acid-etched	46	0	100	NR	NR
Grit-blasted, etched	40	2	95.0	NR	NR
Osseospeed	20	0	100	0	100
TiUnite	20	0	100	NR	NR
TiUnite	111	1	99.1	0	100
Bimodal	69	1	98.6	NR	NR
	685	15	97.8		
SLA	104	1	99.0	NR	NR
TiUnite	37	0	100	NR	NR
MTX & TiUnite	64	0	100	0	100
	205	1	99.5		

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	Implant distribution				Time from	Failed				
Study	Comparison	Anterior	Posterior	Maxilla	Mandible	Implant failures	placement to failure	implant position		
Immediate vs early loading										
Ganeles et al <sup>17</sup>	IL vs EL	0%	100%	32.1%	67.9%	10				
	IL	0%	100%	36.0%	64.0%	4	7, 19, 28, 56 d	2 post max, 2 post man		
	EL	0%	100%	28.0%	72.0%	6	15, 19, 28, 30, 30, 82 d	1 post max, 5 post man		
Testori et al <sup>19</sup> ;	IL vs EL	5.8%	94.2%	43.3%	56.7%	1				
Capelli et al <sup>16</sup>	IL	5.8%	94.2%	26.9%	73.1%	1	2 mo	Post max		
	EL	5.8%	94.2%	59.6%	40.4%	0				
Van de Velde et al <sup>18</sup>	IL vs EL	0%	100%	100%	0%	1				
	IL	0%	100%	100%	0%	1	3 mo	Post max		
	EL	0%	100%	100%	0%	0				
Total		1.1%	98.9%	42.7%	57.3%	12				
	IL	1.1%	98.9%	42.5%	57.5%	6				
	EL	1.1%	98.9%	43.0%	57.0%	6				
mmediate vs convent	ional loading									
Cannizzaro and	IL vs CL	NR	NR	38.0%	62.0%	1				
Leone <sup>20</sup>	IL	-	-	39.1%	60.9%	0				
	CL	-	-	37.0%	63.0%	1	11 d	NR		
Cannizzaro et al <sup>21</sup>	IL vs CL	32.4%	67.6%	45.4%	54.6%	0				
	IL	25.0%	75.0%	48.1%	51.9%	0				
	CL	39.3%	60.7%	42.9%	57.1%	0				
Romanos and	IL vs CL	0%	100%	0%	100%	0				
Nentwig <sup>22</sup>	IL	0%	100%	0%	100%	0				
	CL	0%	100%	0%	100%	0				
Total		19.4%*	80.6%*	30.9%	69.1%	1				
	IL	14.8%*	85.2%*	32.1%	67.9%	0				
	CL	23.9%*	76.1%*	29.7%	70.3%	1				

L = immediate loading; EL = early loading; CL = conventional loading; NR = not reported; post = posterior; max = maxilla; mand = mandible. \*Percentages do not account for the 92 implants from Cannizzaro and Leone.<sup>20</sup>

#### Table 4b Implant and Failure Distribution from Noncomparative Studies

		Implant di	stribution			Time from	Failed
Study	Anterior Posterior		Maxilla Mandible		Implant failures	placement to failure	implant position
Immediate loading							
Boronat-Lopez et al <sup>28</sup>	77.8%	22.2%	69.4%	30.6%	1	NR	Ant mand
Cornelini et al <sup>29</sup>	0%	100%	0%	100%	1	2 mo	Post mand
Degidi et al <sup>34</sup>	0%	100%	0%	100%	2	5, 7 wk	2 post mand
Luongo et al <sup>30</sup>	0%	100%	12.2%	87.8%	1	5.5 mo	NR
Machtei et al <sup>32</sup>	49.0%	51.0%	67.3%	32.7%	5	During first 6 mo	2 ant, 3 post
Malo and Nobre <sup>36</sup>	30.6%	69.4%	69.4%	30.6%	1	NR	Post max
Nikellis et al <sup>37</sup>	15.2%	84.8%	23.9%	76.1%	0		NA
Payer et al <sup>38</sup>	0%	100%	0%	100%	2	NR	Post mand
Rismanchian et al <sup>26</sup>	0%	100%	40.0%	60.0%	0		NA
Schincaglia et al <sup>24</sup> ; Fung et al <sup>35</sup>	0%	100%	0%	100%	0		NA
Vanden Bogaerde et al <sup>25,27</sup>	26.1%	73.9%	62.2%	37.8%	1	12 mo	Post max
Vanden Bogaerde et al <sup>39</sup>	37.7%	62.3%	59.4%	40.6%	1	4 wk	Ant max
Total	19.9%	80.1%	36.1%	63.9%	15		
Early loading							
Bornstein et al <sup>23,33</sup>	0%	100%	14.4%	85.6%	1	3 wk	Post mand
Fischer et al <sup>40</sup>	37.8%	62.2%	100%	0%	0		NA
Todisco <sup>31</sup>	12.5%	87.5%	1.6%	98.4%	0		NA
Total	10.7%	89.3%	25.9%	74.1%	1		

NR = not reported; NA = not applicable; ant = anterior; post = posterior; max = maxilla; mand = mandible.

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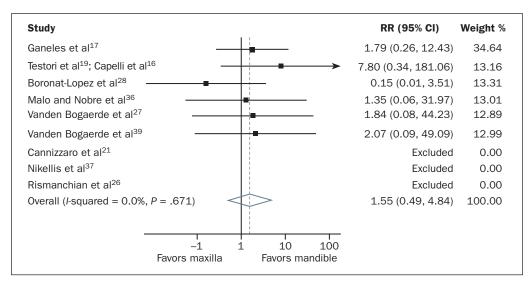
Study	Insertion torque (Ncm)	ISQ value	Implant length (mm)	Immediate implant placement	Bone augmentatior	n Parafunction	Smoking (> 10 cig/d)	Provisional in occlusion
Comparative studies								
Cannizzaro and ${\rm Leone}^{20}$	30*						I	Yes
Cannizzaro et al <sup>21</sup>	≥ 45			Е	Е	Е	I	Yes
Ganeles et al <sup>17</sup>				E	Е	Е	Е	No
Romanos and Nentwig <sup>22</sup>					E		I	Yes
Testori et al <sup>19</sup> ; Capelli et al <sup>16</sup>	$\geq$ 30 Ncm (single implants) $\geq$ 20 Ncm (splinted implants)			I	I	E	I	No
Van de Velde et al <sup>18</sup>			≥ 8	Е	Е	Е	Е	Yes
Noncomparative studies								
Boronat-Lopez et al <sup>28</sup>		> 60	≥ 8.5			E		No
Cornelini et al <sup>29</sup>		> 62	≥ 10		E	E	I	Yes
Degidi et al <sup>34</sup>	≥ 25	≥ 60		Е	Е	Е	Е	Yes
Luongo et al <sup>30</sup>	≥ 15				Е		E	Yes
Machtei et al <sup>32</sup>					l	Е	I	No
Malo and Nobre <sup>36</sup>	≥ 30		≥ 10					Yes
Nikellis et al <sup>37</sup>	≥ 32		≥ 10					Yes
Payer et al <sup>38</sup>	≥ 32		≥ 11			E	E	No
Rismanchian et al <sup>26</sup>		> 60			E	E	Е	No
Schincaglia et al <sup>24</sup> ; Fung et al <sup>35</sup>	≥ 20	≥ 60	≥ 8.5		E		I	Yes
Vanden Bogaerde et al <sup>27</sup>	≥ 40		≥ 8.5			E	Е	Yes
Vanden Bogaerde et al <sup>25</sup>	≥ 30			I	I	E		Yes
Vanden Bogaerde et al <sup>39</sup>	≥ 30	≥ 50	≥ 9	I	I	I	I	Yes
Range	15–45	50-62	8–11					
Frequency	12/19	6/19	9/19	l: 3/19 E: 4/19	l: 4/19 E: 9/19	l: 1/19 E: 12/19	l: 8/19 E: 7/19	Yes: 13/19 No: 6/19

\* = torque at abutment placement; ISQ = implant stability quotient; I = included; E = excluded; Yes = full occlusal contacts or light centric/ no excursive contacts; No = no occlusal contacts; Range = minimal and maximal values of the particular parameter used as loading criteria; Frequency = number of studies applying the particular parameter as a loading criteria out of a total of 19 studies.

Cannizzaro et al<sup>21</sup> excluded two patients with an unknown number of implants because of poor bone quality. As the number of implants placed in these two patients was not provided, the ITT percentage could not be calculated. One implant was not loaded until 4 months after placement because it failed to achieve the minimal insertion torque of 45 Ncm.

Ganeles et al<sup>17</sup> excluded 11 implants allocated to the IL group, because they did not achieve primary stability, were spinning after insertion, or required a sinus elevation or bone augmentation procedure. In Van de Velde et al,<sup>18</sup> one patient with an unknown number of implants had to be excluded per protocol because bone regeneration was necessary at the time of implant placement. Boronat-Lopez et al<sup>28</sup> and Luongo et al<sup>30</sup> reported that one patient with two implants and three patients with six implants, respectively, had to be excluded due to a lack of primary stability. The implants did not reach the required RFA criterion (ISQ > 60) or an insertion torque of 15 Ncm. In Vanden Bogaerde et al,<sup>25</sup> one implant showed slight mobility and pain to pressure after six weeks of loading and hence was taken out of occlusion.

All remaining studies reporting on ITT had an intention to treat percentage of 100%, as all implants fulfilled the respective inclusion criteria and could be immediately loaded.



**Fig 3** Forest plot for the comparison of IL implants placed in the maxilla and IL implants placed in the mandible regarding the 1-year implant survival rates.

Table 6         Intention to Treat (ITT) Analysis									
Study	Implants intended for IL	Intention to treat failures	Intention to treat percentage	Reason					
Comparative studies									
Cannizzaro et al <sup>21</sup>	52 + 2 patients (no. of implants NR)	1 + 2 patients (no. of implants NR)	NA	IT < 45 Ncm + 2 patients with BD type 4					
Ganeles et al <sup>17</sup>	217	11	94.9%	5 lack of PS, 4 spinners at surgery, 2 need for GBR					
Romanos and Nentwig <sup>22</sup>	36	0	100%	NA					
Testori et al <sup>19</sup> ; Capelli et al <sup>16</sup>	52	0	100%	NA					
Van de Velde et al <sup>18</sup>	36 + 1 patient (no. of implants NR)	1 patient (no. of implants NR)	NA	need for GBR					
Noncomparative studies									
Boronat-Lopez et al <sup>28</sup>	43	2	95.3%	$ISQ \le 60$					
Cornelini et al <sup>29</sup>	40	0	100%	NA					
Luongo et al <sup>30</sup>	97	6	93.8%	IT < 15 Ncm					
Nikellis et al <sup>37</sup>	46	0	100%*	NA					
Payer et al <sup>38</sup>	40	0	100%	NA					
Rismanchian et al <sup>26</sup>	20	0	100%	NA					
Schincaglia et al <sup>24</sup> ; Fung et al <sup>35</sup>	20	0	100%	NA					
Vanden Bogaerde et al <sup>27</sup>	111	0	100%	NA					
Vanden Bogaerde et al <sup>25</sup>	50	1	98.0%	Pain and mobility (crown was taken out of occlusion					

IL = immediate loading; NR = not reported; NA = not applicable; BD = bone density; PS = primary stability; GBR = guided bone regeneration;

IT = insertion torque in Ncm; ISQ = implant stability quotient.

\* = 5 implants were replaced by wider diameter implants at the time of surgery because they did not achieve the immediate loading criteria.

## DISCUSSION

# Quality of Included Studies and Validity of Methods

The 24 studies included in this systematic review were of different study designs and reported findings on loading protocols using a diverse range of parameters. From the six comparative studies (five RCTs, one NRCT), three were of unclear and three of high risk of bias according to the Cochrane quality assessment tool.<sup>13</sup> Two comparative studies followed a split-mouth design,<sup>18,22</sup> but did not meet other criteria necessary to qualify for a low risk of bias. No quality assessment was performed for the 18 noncomparative studies, which

were all case series according to the purposes of this systematic review. However, the clinically relevant data were used for a descriptive analysis.

With the exception of Machtei et al,<sup>32</sup> who found a relatively low implant survival rate of 89.8%, all other included noncomparative and comparative studies homogenously showed high survival rates for IL implants that compare well with reported survival rates of CL implants.<sup>1–6</sup>

Evaluations of prosthodontic parameters and details on prosthetic design were scarce and frequently lacking. This seems surprising since the prosthodontic phase plays a central role in the clinical implementation of loading protocols.

Initially, only IFDPs replacing two or more adjacent teeth (extended edentulous sites) in partially edentulous patients were planned for inclusion in this systematic review. During the data extraction process, however, it became evident that the vast majority of studies also included implants supporting single crowns in single-unit gaps, without providing sufficient information to separate the data for implants supporting IFDPs in extended edentulous sites. Hence, the inclusion criteria had to be modified and studies comprising mainly implants in extended edentulous sites but containing some implants in single-unit gaps were included. Studies that mainly examined implants in single-unit gaps and did not separately report data on implants in extended edentulous sites were excluded. Consequently, numerous articles with potentially useful information were not included in this systematic review.

Details on number, timing, and location of implant drop-outs were often poorly reported and only a small number of high-evidence studies were available for analysis. Furthermore, data for the comparison of IL implants placed in the maxilla vs the mandible were partly provided by noncomparative studies, with significant heterogeneity in study design and clinical protocol. Consequently, the results of the meta-analyses performed in this systematic review have to be interpreted with caution.

The insufficient reporting on implant success and the significant heterogeneity in applied success criteria allowed for implant survival only as the primary outcome measure of this systematic review, although stricter success criteria would certainly render clinically more useful information. A summary of surgical and prosthetic complications was not deemed feasible in the context of this review, due to the nonstandardized and often deficient description of complications.

#### Immediate vs Early Loading

In a multicenter investigation comprising 19 clinics in private practice and universities in 10 different countries, Ganeles et al<sup>18</sup> reported on survival rates and bone level

changes of 383 implants randomly assigned to receive either IL or EL. All implants investigated were placed in completely healed sites (type 4 placement) in premolar and molar positions. After 12 months, the implant survival rates were 98% and 96.8%, respectively. The difference in survival rates was not statistically significant.

Capelli et al<sup>16</sup> compared IL and EL of 104 implants over a period of 5 years in a RCT conducted in five private practices. A total of 15 implants, 6 in the IL group and 9 in the EL group, were placed in postextraction sockets (type 1 placement). All other implants were placed in healed alveolar bone (type 4 placement). Of the 52 IL implants loaded within 48 hours and the 52 EL implants loaded at 2 months, one implant failed in the IL group. The respective survival rates of 98% and 100% were not statistically different. Testori et al<sup>19</sup> previously had reported the 1-year results of the same study population.

In a split-mouth RCT following 13 patients over a period of 18 months, Van de Velde et al<sup>18</sup> compared IL implants placed flapless and guided, with EL implants placed with a conventional surgical protocol. All implants were placed in the posterior maxilla. The authors reported survival rates of 97.2% and 100% for the IL and EL groups, respectively, and found that the difference in survival rates was statistically not significant. No prosthesis failure occurred in either group.

All three comparative studies presented similar overall results when comparing IL vs EL in partially edentulous patients (Table 3a), with the weighted means yielding no significant differences between implant survival rates for IL (97.9%) and EL (97.8%) (P = .9405). The similarity in survival rates between IL and EL implants was confirmed by the included non-comparative studies (Table 3b). For noncomparative studies, the average survival rate was 97.8% for IL implants and 99.5% for EL implants. However, these generalized comparisons should be interpreted with caution, since they report on overall implant survival rates without correlating major treatment modifiers.

Surprisingly, a significantly lower number of noncomparative studies investigating EL implants were found compared to the number of publications on the supposedly more experimental IL protocol. One reason for this unexpected finding may be based on the exclusion of numerous articles with potentially useful information on EL implants, for the reason of not reporting separately on IFDPs in extended edentulous sites.

#### Immediate vs Conventional Loading

In a NRCT conducted in a private practice setting comparing 92 implants subjected to IL and CL, Cannizzaro and Leone<sup>20</sup> reported one implant failure in the CL group, which occurred 11 days after implant placement. The survival rates were 97.8% and 100% for CL and IL groups, respectively, after a mean follow-up time of 2 years. The authors did not provide information on prosthesis failures and the time of implant placement related to the time of extraction.

Cannizzaro et al<sup>21</sup> investigated a total of 108 implants randomly assigned to receive either IL or CL in several private practices. All implants were placed into healed alveolar ridges. No implant was lost, and survival rates after a period of 36 months were 100% for both groups. However, two implants in two patients from each group developed peri-implantitis with 3 to 4 mm of peri-implant bone loss and purulent exudate, deeming the implants not successful. No prostheses were lost during the follow-up time.

Romanos and Nentwig<sup>22</sup> compared IL and CL in a RCT with a split-mouth design conducted in a university setting. A total of 72 implants were subjected to IL or CL in either side of the posterior mandible of 12 partially edentulous patients. All implants were placed into healed alveolar bone. No implant or prostheses failure occurred over a mean follow-up time of 25.3 months.

All three comparative studies presented similarly high mean implant survival rates of 100% and 99.3%, respectively, when comparing IL and CL in partially edentulous patients with the difference being statistically not significant (P = .3280) (Table 3a). Due to the lack of implant failures in two out of three studies, a meta-analysis could not be performed.

#### **Time and Distribution of Implant Failures**

Failures of IL implants seem to have a tendency to occur early, as the vast majority of implant failures occurred within the first 3 months after loading. None of the included studies reported any implant failure later than 12 months of loading. Regardless, if an IL implant fails later than 12 months after loading, it can be hypothesized that the reason for failure would most likely be based on factors other than the loading protocol.

The posterior regions of the jaw may be of concern for IL implants due to the poor bone quality often found in these areas, especially in the maxilla. The finding that almost all implant failures occurred in the posterior was in accordance with the fact that the vast majority of implants reported in the included studies were placed in the posterior zone. Because of the small number of anterior implants included, it can be stated that currently there is insufficient clinical data available to support IL of anterior implants in extended edentulous sites of partially edentulous patients.

The meta-analysis performed in this systematic review comparing outcomes of IL implants in the maxilla vs the mandible showed no statistically significant differences in survival (Fig 3). However, due to the significant heterogeneity in study designs and clinical protocols of the included studies, this finding has to be interpreted with caution. Furthermore, it has to be noted that weighted mean survival rates for IL implants according to implant location could not be calculated due to insufficient detail on time and location of implant failures and drop-outs provided by the respective studies.

#### **Immediate Loading Criteria**

Insertion torque measurements were used to confirm primary implant stability in 12 out of 19 studies (Table 5). Required insertion torque values ranged between 15 Ncm and 45 Ncm. Implant stability quotient (ISQ) values from resonance frequency analyses (RFA) were utilized in six studies.<sup>26,28,29,34,35,39</sup> The minimum ISQ value required for IL ranged between 50 and 62. Primary stability seems to be considered of paramount importance for loading protocols with reduced healing times.

Almost all IL implants in both comparative and noncomparative studies were placed in healed sites (type 4 placement), and most of the studies excluded implants requiring substantial bone augmentation procedures.

Implant length was considered another indicator for or against IL by several studies. Based on the data assessed in this systematic review, an implant length of at least 8 to 11 mm was deemed necessary for applying an IL protocol. In cases where anatomical restrictions only allowed for implants shorter than 8 to 11 mm, a tendency towards a delayed loading approach existed. However, as several different implant brands were used in the included studies, it has to be mentioned that aspects of implant design, such as thread design to achieve sufficient primary stability, or the location of the implant-abutment interface to avoid crestal bone loss in the initial healing phase, may play a significant role when determining a minimum implant length required for IL.

Occlusion has often been presented as a treatment modifier for IL. While several occlusal scenarios such as full occlusal contacts, light centric but no excursive contacts, and no occlusal contacts have been presented in this review, it is important to bear in mind that in any case, the provisional prosthesis will be exposed to masticatory forces, pressure from the tongue, and patient habits. Therefore, immediately restored implants are unavoidably subject to a certain amount of load even if all occlusal contacts have been removed.

When parafunctional habits are present, a CL approach should be considered, as the majority of studies excluded patients with parafunction.

Strict inclusion criteria have been followed by all included studies assessing IL or EL protocols. In this context, the application of such loading protocols as a routine practice should be of no exception and any result merely based on overall survival rates may not be reproducible if the required criteria are not present.

#### **Intention to Treat**

An ITT analysis is based on the initial treatment assignment and not on the treatment eventually received. Thus, ITT analysis is intended to avoid misleading information that can arise in interventional research.<sup>41</sup> Table 6 summarizes the number of implants originally intended for IL but not fulfilling certain criteria established by the respective authors, resulting in a change of the treatment rendered. This information is relevant to understand the predictability and practicality of IL in the treatment of partial edentulism, yet almost half of the studies analyzed in this systematic review did not provide any information on ITT. Without clear information on patient selection criteria for IL protocols, the current status of the scientific evidence should be interpreted with caution.

However, from the few studies reporting on the ITT analysis, it can be noted that IL protocols are highly technique sensitive. Common reasons leading to a change of the rendered loading protocol were lack of primary implant stability, failure to achieve the minimal insertion torque, low ISQ values, poor bone quality, and the necessity of substantial bone augmentation procedures. As the frequency of these clinical situations has been scarcely investigated, further studies containing a well-described ITT analysis are necessary to assess the practicality of IL or EL protocols and to present clear clinical recommendations.

#### **Clinical Significance**

To develop clinically significant statements, risks and benefits of a shortened implant healing time have to be considered. Most of the included studies selected IL or EL protocols on implants that had been placed in healed edentulous sites (type 4 implant placement), which means that these patients had already been partially edentulous for at least several months. Hence, the clinical benefit of an immediate delivery of the provisional in those cases may be questioned. Moreover, an IL approach requires the fabrication of an immediate provisional, whereas this is often not necessary when applying an EL or CL approach in posterior sites. One of the clinical advantages of IL would be the delivery of a final prosthesis within the first week after implant placement. However, the inadequate reporting on prosthetic designs associated with IL, as well as the obvious technical and logistical challenges in completing definitive IFDPs in such short periods of time makes this approach a weak indication for IL in partially edentulous patients at this point in time. In addition, most of the failures of IL implants occurred within three months from implant placement. This suggests that a longer observation period with immediate provisional prostheses may be advisable before fabricating the definitive prosthesis. For cases where hopeless teeth have to be replaced by implants, particularly in the esthetic zone, the combination of an implant placement type 1 with IL would provide clear benefits for the patient. However, a scientific validation of this approach does not exist at this time.

#### **Clinical Recommendations**

According to the current literature presented in this systematic review, IL of dental implants placed in healed posterior extended edentulous sites of partially edentulous patients may be a predictable treatment approach if applied with extreme caution. Reasonable doubts can be raised about the clinical benefit of this treatment modality as posterior zones are of minor esthetic concern and patients with healed extraction sites have been partially edentulous for several months.

Due to insufficient documentation, IL for anterior implants in partially edentulous patients with extended edentulous sites is not supported by the literature at this time. Immediate loading of implants in extended edentulous sites immediately placed into extraction sockets, which would clearly provide the biggest clinical benefit to patients, has to be considered experimental at this point, since very limited clinical evidence exists to support such treatment. Further research is needed to investigate this tempting treatment modality.

Until further studies clarify the impact of several treatment modifiers, the following criteria should be considered when selecting a loading protocol: bone quality, primary stability, insertion torque, ISQ values, implant length, need for substantial bone augmentation, timing of implant placement, parafunction, and smoking habit.

#### CONCLUSIONS

Under strict selection criteria, IL presents similar implant survival rates than EL or CL in posterior extended edentulous sites of partially edentulous patients. Insufficient evidence exists to support such treatment in the anterior zone. Despite a tendency favoring mandibular implants, differences in survival rates between the maxilla and the mandible were not statistically significant. Bone quality, primary stability, insertion torque, ISQ values, implant length, the need for substantial bone augmentation, the timing of implant placement, and the presence of parafunctional and smoking habits were common selection criteria in choosing a loading protocol. Further research is needed before IL can be recommended as a standard protocol in partially edentulous patients with extended edentulous sites. Such research should include an ITT analysis and a detailed report on prosthetic parameters.

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# Implant Loading Protocols for Edentulous Patients with Fixed Prostheses: A Systematic Review and Meta-Analysis

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Purpose: To report on the effect of immediate implant loading with fixed prostheses compared to early and conventional loading on implant and prosthesis survival, failure, and complications. Materials and Methods: An electronic and manual search was conducted to identify randomized controlled clinical trials (RCTs) as well as prospective and retrospective studies involving rough surface implants and implant fixed complete dental prostheses for edentulous patients. Results: The 62 studies that fulfilled the inclusion criteria featured 4 RCTs, 2 prospective case-control studies, 34 prospective cohort studies, and 22 retrospective cohort studies. These studies yielded data from 2,695 patients (2,757 edentulous arches) with 13,653 implants. Studies were grouped according to the loading protocol applied; 45 studies reported on immediate loading, 8 on early loading, and 11 on conventional loading. For the immediate loading protocol with flap surgery, the implant and prosthesis survival rates ranged from 90.1% to 100% and 93.75% to 100%, respectively (range of follow-up, 1 to 10 years). When immediate loading was combined with guided flapless implant placement, the implant survival rates ranged from 90% to 99.4%. For the early loading protocol, the implant and prosthesis survival rates ranged from 94.74% to 100% and 93.75% to 100%, respectively (range of follow-up, 1 to 10 years). For the conventional loading protocol, the implant and prosthesis survival rates ranged from 94.95% to 100% and 87.5% to 100%, respectively (range of follow-up, 2 to 15 years). No difference was identified between maxilla and mandible. Conclusions: When selecting cases carefully and using dental implants with a rough surface, immediate loading with fixed prostheses in edentulous patients results in similar implant and prosthesis survival and failure rates as early and conventional loading. For immediate loading, most of the studies recommended a minimal insertion torque of 30 Ncm. The estimated 1-year implant survival was above 99% with all three loading protocols. Caution is necessary when interpreting these results, as there are many confounding factors that affect treatment outcomes with each of the loading protocols. INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):256-270. doi: 10.11607/jomi.2014suppl.g4.3

Key words: dental implants, edentulous patients, fixed prosthesis, immediate loading, loading protocols

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reatment of the edentulous jaw with dental implants represents a scientifically and clinically validated treatment modality.<sup>1,2</sup> Osseointegrated dental implants provide a predictable base for the restoration of function and esthetics in edentulous patients. However, the extended healing time without implant loading associated with the conventional loading protocol is a disadvantage from the patient perspective. Hence, reducing the healing period or time to loading would be of great benefit to the patient. Today, many implant surgical and prosthodontic concepts are used for the treatment of the edentulous jaw.<sup>3</sup> Rough implant surfaces and immediate or early loading protocols have led to faster healing times and immediate or early restoration of function and esthetics in carefully selected cases.<sup>3</sup> Prosthodontic protocols and materials have also significantly evolved since the mandibular hybrid prostheses with acrylic teeth on a cast gold alloy framework, especially due to the introduction of CAD/

CAM technology.<sup>4</sup> Choosing the most appropriate protocol for the rehabilitation of the edentulous jaw may represent a challenge and should rely on evidencebased, thorough information.

The edentulous predicament is directly related to alteration of facial esthetics and decrease in the lower facial height, as well as loss of ability to chew, taste, and smile.<sup>2</sup> A recent study reported that the percentage of patients with complete edentulism varies substantially among the G8 countries (Canada, France, Germany, Italy, Japan, Russia, United Kingdom, and United States of America). It ranged from 16.3% in France to 58% in Canada for patients older than 65 years of age.<sup>5</sup> There were no data available from Russia in the aforementioned study. In the United States of America, the percentage of edentulous patients is 10% of the total population and is expected to increase in future years as the life expectancy increases.<sup>6,7</sup> Although the incidence of complete edentulism in the United States has been steadily declining (approximately 6% between 1988 and 2000), the continuous growth of the population 65 years of age and older indicates that the incidence rate of complete edentulism will remain constant or even increase over the coming decades.<sup>8</sup> As the average life expectancy is constantly increasing, and with that the percentage of the population aged 65 and older, it becomes clear that the need for prosthodontic treatment including dental implants for completely edentulous patients will increase. Besides the continuously growing need for full-arch rehabilitations with dental implants, there is a tendency in the field of oral implantology to reduce treatment time and simplify procedures in order to increase patient acceptance and satisfaction.

Hence, the purpose of this systematic review was to investigate the effect of immediate implant loading with fixed prostheses on implant and prosthesis survival, failure, and complications in edentulous patients compared to early and conventional loading.

### MATERIALS AND METHODS

This systematic review was conducted in accordance with the guidelines of Transparent Reporting of Systematic Reviews and Meta-analyses (PRISMA statement), as reported by Moher et al.<sup>9</sup>

#### **Focus Question**

The following focus question was developed following the PICO (population, intervention, comparison, outcome) format:

In edentulous patients, what is the effect of immediate implant loading with fixed prostheses compared to early and conventional loading on implant and prosthesis survival, failure, and complications?

#### **Definitions of Time to Loading**

The different times for loading dental implants have been somewhat confusing in the past; however, in accordance with recently published reports, the following current definitions were used for the present systematic review.<sup>3,10</sup>

- Immediate loading: A prosthesis is connected to the dental implants within 1 week following implant placement.
- Early loading: A prosthesis is connected to the dental implants between 1 week and 2 months following implant placement.
- Conventional loading: Dental implants are allowed to heal for a period greater than 2 months after implant placement without connection of a prosthesis.

#### Search Strategy

Three internet sources were used to search for eligible articles (published, early view online and accepted) in English and German that satisfied the study purpose. These included Medline-PubMed, Embase, and the Cochrane Central Register of Controlled Trials (CENTRAL). Additionally, the following journals were hand searched for potentially relevant articles: Clinical Oral Implants Research, Clinical Implant Dentistry and Related Research, Journal of Periodontology, Journal of Clinical Periodontology, International Journal of Oral and Maxillofacial Implants, Journal of Prosthetic Dentistry, International Journal of Prosthodontics, Implant Dentistry, and Journal of Oral Implantology. The hand search and the electronic database search extended from January 1, 1980 to August 31, 2012. The inclusion/exclusion criteria and the systematic search strategy are outlined in Table 1.

#### Selection Strategy and Data Collection

Titles and abstracts were initially screened by two calibrated reviewers (C-JC and PP) for potential inclusion. All titles and abstracts selected by the two reviewers were discussed individually for full-text reading inclusion. If title and abstract did not provide sufficient information regarding the inclusion criteria, the full report was obtained as well. The full-text reading of selected publications was carried out independently by the reviewers. Consensus between the reviewers was reached in every step of the review. The electronic search was supplemented by manual search of the bibliographies of all the full-text articles that were selected from the initial search and previous systematic reviews relevant to the topic. Inter-reviewer agreement between the two reviewers was always determined with the use of Cohen's kappa statistics (κ). In cases where information was not clear, the study authors were contacted by email for clarification.

Focus question: In	edentulous patients, what is the effect of immediate implant loading compared to early or conventional
	ding with fixed prostheses on implant survival, failure, and complications?
Search strategy	
Population	#1 - dental implantation, endosseous[MeSH] OR dental implants[MeSH] OR implantation*[all fields] OR implant[all fields] OR implants[all fields]
Intervention or exposure	#2 - denture, complete, fixed[MeSH] OR dental prosthesis, implant-supported[MeSH] OR fixed complete denture*[all fields] OR fixed complete dental prosthesis*[all fields] OR bridge*[all fields] OR FDPs* [all fields] OR fixed rehabilitations*[all fields] OR fixed restorations*[all fields]
Comparison	#3 - immediate dental implant loading[MeSH] OR function[all fields] OR time[all fields] OR immediate [all fields] OR early[all fields] OR load*[all fields]
Outcome	#4 - survival[MeSH] OR survival rate[MeSH] OR survival analysis[MeSH] OR intraoperative complications[MeSH] OR postoperative complications[MeSH] OR dental restoration failure[MeSH] OR prosthesis failure[MeSH] OR treatment failure[MeSH] OR complication*[all fields] OR success*[all fields] OR failure*[all fields]
Filters (language)	#5- English[lang] OR German[lang]
Search combination	#1 AND #2 AND #3 AND #4 AND #5
Database search	
Electronic	PubMed, Embase and the Cochrane Central Register of Controlled Trials (CENTRAL)
Journals	All peer reviewed dental journals available in PubMed, Embase and CENTRAL. No filters were applied for the journals
Selection criteria	
Inclusion criteria	Rough surface solid screw-type implants RCTs, observational, cross-sectional, case report (≥ 10 cases), prospective studies Retrospective studies recalling all patients under investigation Studies reporting outcomes after 12 or more months of function English and German language Human studies only
Exclusion criteria	Smooth (machined) implant surface HA implant surface Non-solid screw-type implants or implant with a diameter less than 3 mm Studies based on charts or questionnaires only, ie, no clinical examination was performed at follow-ups Insufficient information on the time of failures provided to calculate cumulative survival rate Multiple publications on the same patient cohort No author response to inquiry email for data clarification Animal studies

#### **Quality Assessment**

The assessment of study quality was performed for all the included articles. In the case of randomized controlled clinical trials (RCTs), the Cochrane Collaboration's tool for assessing risk of bias was used.<sup>9</sup> In the case of case-control studies and cohort studies, the methodological quality assessment of the studies was based on the Newcastle-Ottawa Quality Assessment Scale.<sup>11</sup> The risk of bias was assessed independently by the two reviewers who scored the methodological quality of the included studies. This assessment is referred to as the overall risk of bias.<sup>11</sup>

#### **Statistical Analysis**

For each study involved, event failure rates for the implants or the prostheses were calculated by dividing the total number of failure events for the implants or the prostheses by the total exposure time (follow-up time) of implants or prostheses in years. For further analysis, the failure event rate estimates were used to calculate their standard errors (standard errors were estimated by the standardized formula of failure rates divided by the square root of the number of failure cases of the implants or prostheses). With each study's estimates and standard errors obtained, the authors further determined the 95% confidence intervals (95% CI) of the summary estimates of the failure event rates. Studies without any failures in the implants or the prostheses group were excluded from the meta-analysis due to zero events. Heterogeneity between studies was assessed using I-squared statistics describing the variation in risk ratio (RR), which is attributable to the heterogeneity of the studies. All statistical analyses were performed using STATA (Stata

Group 4

Statistical Software), and level of statistical significance ( $\alpha$  level) was based at .05. Using the METAN command in the STATA computing environment, we assessed the heterogeneity of the study-specific failure event rates. The estimated 1-year (T = 1) survival rates were calculated via the relationship between failure event rates and the negative exponential survival function S,  $S(T) = \exp(-T * failure event rate)$ , by assuming constant failure event rates. The 95% CI for the survival rates were then calculated by using the 95% confidence limits of the failure event rates. The STATA software computed the  $l^2$  statistic to assess the heterogeneity between studies and the associated P-value. If the heterogeneity (goodness-of-fit) P-value was below .05, indicating heterogeneity, meta-analysis with random effects was used to obtain a summary estimate of the event rates and the estimated 1-year survival rates. If the heterogeneity P-value was above .05, indicating no statistical significant heterogeneity, meta-analysis with fixed effects was used with a weighting scheme based on the study's total exposure time (follow-up time).

### RESULTS

#### **Selection of Included Studies**

The initial search yielded 2,539 hits after discarding duplicate references (Fig 1). The subsequent search at the title level exhibited 826 titles (k-score = 0.80). The subsequent search at the abstract level identified 527 abstracts (k-score = 0.85). The independent abstract investigation revealed 123 articles for full-text reading (k-score = 0.90). Out of the 123 articles selected for full-text reading, 62 studies were finally selected for inclusion (one clinical trial by Fischer et al was reported in two articles as part 1 and 2, but was considered as one study).<sup>12-74</sup> Sixty studies were excluded.

#### **Characteristics of Included Studies**

The 62 included studies featured 4 RCTs, 2 prospective case-control studies, 34 prospective cohort studies, and 22 retrospective cohort studies. Thirty-one studies were conducted in universities, 28 studies in private clinics, and 3 in combination of universities and private clinics. The year of publication ranged from 2001 to 2013. The distribution of studies broken down per loading protocol is shown in Fig 2.

Implant and Prosthesis Survival and Failure with Immediate Loading. The scientific evidence on immediate loading with fixed prostheses for edentulous patients was supported by 45 studies (1 RCT, 28 prospective, and 16 retrospective).<sup>12–55,62</sup> These clinical studies reported data from 2,146 patients (2,206 edentulous arches) with 10,600 implants, with follow-up from 12 months to 120 months.

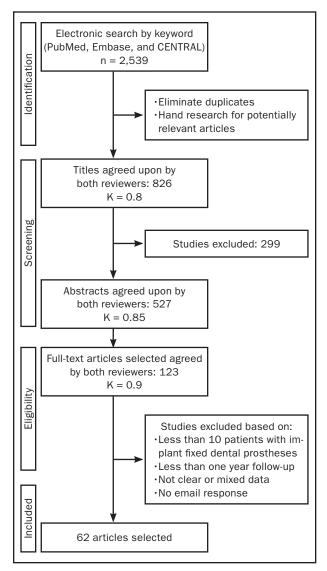
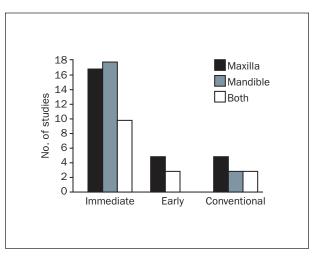


Fig 1 Search flow diagram.



 $\ensuremath{\mbox{Fig}}\xspace 2$   $\ensuremath{\mbox{Distribution}}\xspace$  of studies by loading protocol for maxilla and mandible.

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Study	Study type	Brand	Patients	Implants/ patient	Prosthesis type	Follow-up time (mo)	Implants
Agliardi et al <sup>12</sup>	Prosp	Nobel Biocare	32	6	M-C	55.53	192
Barbier et al <sup>14</sup>	Prosp	Astra Tech	20	6	M-R	18	120
Crespi et al <sup>16</sup>	Prosp	PAD	24	4	M-R and all-acrylic	36	96
Degidi et al <sup>17</sup>	Prosp	Friadent	9	6 to 7	M-R	12	61
Degidi et al <sup>18</sup>	Prosp	Nobel Biocare	5	7 to 9	M-C	120	40
Francetti et al <sup>19</sup>	Prosp	Nobel Biocare	16	4	M-R	33.8	64
Ji et al <sup>28</sup>	Retro	Nobel Biocare and Friadent	17	4 to 8	M-R	36	115
Maló et al <sup>21</sup>	Retro	Nobel Biocare	242	4	M-C and M-R and all-acrylic	60	968
Mozzati et al <sup>22</sup>	Retro	Nobel Biocare	65	4 or 6	M-C	24	334
Pieri et al <sup>24</sup>	Prosp	Astra Tech	20	7 to 8	M-R	12	155
Babbush et al <sup>25</sup>	Retro	Nobel Biocare	109	4	M-R	12	436
Strietzel et al <sup>31</sup>	Retro	Alpha Bio	20	6 to 12	M-C	29	172
Tealdo <sup>62</sup>	Prosp	Biomet 3i	34	4 to 6	M-R	40.5	163
Agliardi et al <sup>32</sup>	Prosp	Nobel Biocare	61	4	M-R	26.9	244
Artzi et al <sup>33</sup>	Retro	DFI/ITO/SPI	32	8.6	M-C and M-R	36	302
Degidi et al <sup>35</sup>	Prosp	Friadent	30	7	M-R	36	210
Gillot et al <sup>39</sup>	Retro	Nobel Biocare	33	4 to 8	M-R	30.4	211
Meloni et al <sup>40</sup>	Retro	Nobel Biocare	15	6	Zirconia-ceramic and M-R	18	90
Bergkvist et al <sup>41</sup>	Prosp	Straumann	28	6	M-C and M-R	32	168
Johansson et al <sup>42</sup>	Prosp	Nobel Biocare	48	6	M-R	12	288
Pieri et al <sup>43</sup>	Prosp	Keystone Dental	9	5 to 8	M-R	19	66
Cannizzaro et al <sup>37</sup>	RCT	Zimmer	15	5 to 8	M-C and M-R	12	90
Collaert and De Bruyn <sup>45</sup>	Prosp	Astra Tech	25	7 to 9	M-C and M-R	36	195
Degidi et al <sup>38</sup>	Prosp	Friadent	20	6 to 8	M-R	12	153
Testori et al <sup>47</sup>	Prosp	Biomet 3i	30	6	M-C and M-R	22.1	180
Jaffin et al <sup>51</sup>	Retro	Straumann	29	6 to 8	M-C and M-R	24	236
Olsson et al <sup>53</sup>	Retro	Nobel Biocare	10	6 to 8	M-R	12	61
Total			998				5410

Retro = retrospective; Prosp = prospective; RCT = randomized controlled trial; M-R = metal-resin; M-C = metal-ceramic.

\*Maximum number of stars that a study can receive is 8, based on the Newcastle-Ottawa assessment scale.

In the maxilla, the implant survival rate ranged from 90.43% to 100% based on 27 studies (range of follow-up, 1 to 10 years).<sup>12,14,16–19,21,22,24,25,28,31,32,35,37–43,45,47,51,53,62</sup> The number of implants placed in the maxilla was between 4 and 12 implants per patient. The prosthesis survival rate ranged from 90% to 100%, based on these 27 studies (Table 2).

In the mandible, the implant survival rate ranged from 90% to 100%, based on 28 studies (range of follow-up, 1 to 10 years).<sup>13,15–20,23,25–34,36,43,44,46,48–50,52,54,55</sup> The number of implants placed in the mandible was between 2 and 10 implants per patient. The prosthesis survival rate ranged from 93.75% to 100%, based on these 28 studies (Table 3).

Based on most of the 45 studies that reported on immediate loading, one of the prerequisites was an insertion torque of at least 30 Ncm (range from 10 to 80 Ncm). Only a study by Degidi et al in 2012 reported insertion torques of less than 25 Ncm. However, in all cases that some implants had insertion torques of equal or less than 20 Ncm they were always splinted with implants that had torque between 25 to 50 Ncm.<sup>17</sup> If resonance frequency analysis was used to assess the primary stability, an ISQ value of more than 60 was chosen as the minimum value for immediate loading.

The prosthodontic design was generally one-piece. Only the studies by Ganeles et al<sup>55</sup> and Jaffin et al<sup>51</sup> reported on a small number of segmented prostheses

Failures	Prostheses	Prosthesis failures	Implant survival rate (%)	Prosthesis survival rates (%)	Weight (%)	Overall risk of bias
2	32	0	98.96	100.00	6.04	6*
0	20	0	100.00	100.00	1.23	6*
1	24	0	98.96	100.00	1.96	6*
1	9	0	98.36	100.00	0.41	6*
0	5	0	100.00	100.00	2.72	6*
0	16	0	100.00	100.00	1.23	6*
11	17	0	90.43	100.00	2.35	6*
19	242	0	98.04	100.00	32.94	6*
7	65	0	97.90	100.00	4.55	6*
2	20	0	98.71	100.00	1.05	6*
3	109	0	99.31	100.00	2.97	5*
1	20	0	99.42	100.00	2.83	6*
10	34	0	93.87	100.00	3.74	8*
4	61	0	98.36	100.00	3.72	6*
6	32	0	93.05	100.00	6.17	5*
1	30	0	99.52	100.00	4.29	6*
4	33	0	98.10	100.00	3.64	6*
2	15	0	97.78	100.00	0.92	6*
3	28	0	98.21	100.00	3.05	6*
2	48	2	99.31	95.83	1.96	6*
2	9	0	96.97	100.00	0.71	6*
1	15	0	98.89	100.00	0.61	low
0	25	0	100.00	100.00	3.98	6*
0	20	0	100.00	100.00	1.04	6*
3	30	0	98.33	100.00	2.26	6*
16	29	0	93.22	100.00	3.21	6*
4	10	1	93.44	90.00	0.42	6*
105	998	3	98.06	99.70	100	

as well. The prosthetic materials for definitive prostheses were metal resin, metal ceramic, or full acrylic, with the latter used only for a small number of "all-onfour" rehabilitations. The materials used for provisional prostheses with immediate loading were acrylic alone, fiber-reinforced acrylic, or metal-reinforced acrylic.

Four studies implemented guided flapless surgery with the Teeth-In-An-Hour protocol (NobelGuide), which involved immediate loading with a prefabricated definitive and/or provisional prostheses, made of titanium and resin or full acrylic.<sup>29,39,40,42</sup> Two more studies reported on flapless surgery without stereo-lithographic guides.<sup>15,37</sup> In total, these six studies yielded data from 207 patients with 903 implants.

When immediate loading was combined with guided flapless implant placement, the implant survival rates ranged from 90% to 99.4% (range of follow-up, 12 to 51 months).

Implant and Prosthesis Survival and Failure with Early Loading. The scientific evidence on early loading with fixed prostheses for edentulous patients was supported by eight studies (three RCTs, two prospective, and three retrospective).<sup>56–59,63–67</sup> These clinical studies reported data from 267 patients with 1,365 implants, with follow-up from 12 months to 120 months.

In the maxilla, the implant survival rate ranged from 94.7% to 100% based on five studies (range of followup, 1 to 3 years).<sup>56–59,64,66</sup> The number of implants

Study	Study type	Brand	Patients	Implants/ patient	Prosthesis type	Follow-up time (mo)	Implants
Acocella et al <sup>13</sup>	Retro	Astra Tech	45	5	M-R	48	225
Cannizzaro et al <sup>15</sup>	Prosp	Biomet 3i	80	2	M-R	12	160
Crespi et al <sup>16</sup>	Prosp	PDA	20	4	M-R and all-acrylic	36	80
Degidi et al <sup>17</sup>	Prosp	Friadent	4	6	M-R	12	21
Degidi et al <sup>18</sup>	Prosp	Nobel Biocare	8	5 to 6	M-C	120	44
Francetti et al <sup>19</sup>	Prosp	Nobel Biocare	33	4	M-R	52.8	132
Galindo and Butura <sup>20</sup>	Retro	Nobel Biocare	183	4	M-R	12	732
Ji et al <sup>28</sup>	Retro	Nobel Biocare and Frident	24	4 to 8	M-R	36	128
Mozzati et al <sup>23</sup>	Retro	Nobel Biocare	50	4	M-C and M-R	24	200
Weinstein et al <sup>50</sup>	Prosp	Nobel Biocare	20	4	M-R	30.1	80
Babbush et al <sup>25</sup>	Retro	Nobel Biocare	68	4	M-R	12	272
Collaert et al <sup>26</sup>	Prosp	Astra Tech	25	5	M-C and M-R	24	125
Hatano et al <sup>27</sup>	Retro	Nobel Biocare	78	3	M-R	60	234
Landázuri-Del Barrio et al <sup>29</sup>	Prosp	Nobel Biocare	16	4	M-R	12	64
Vlaló et al <sup>30</sup>	Retro	Nobel Biocare	91	4	M-C and M-R and all-acrylic	60	364
Strietzel et al <sup>31</sup>	Retro	Alpha Bio	14	6 to 10	M-C	29	111
Agliardi et al <sup>32</sup>	Prosp	Nobel Biocare	93	4	M-R	26.9	372
Artzi et al <sup>33</sup>	Retro	DFI/ITO/SPI	46	8.6	M-C and M-R	36	374
Degidi et al <sup>34</sup>	Prosp	Friadent	20	4	M-R	24	80
Degidi et al <sup>36</sup>	Prosp	Friadent	40	7	M-R	24	160
Pieri et al <sup>43</sup>	Prosp	Keystone Dental	15	5 to 8	M-R	19	78
Arvidson et al <sup>44</sup>	Prosp	Straumann	61	4 to 5	M-R	36	246
De Bruyn et al <sup>46</sup>	Prosp	Astra Tech	25	5	M-C and M-R	36	125
Capelli et al <sup>48</sup>	Prosp	Biomet 3i	23	4	M-R	29.1	92
Drago and Lazzara <sup>49</sup>	Prosp	Biomet 3i	27	5 to 7	M-R	12	151
Testori et al <sup>52</sup>	Prosp	Biomet 3i	62	5 to 6	M-R	12	325
Cooper et al <sup>54</sup>	Prosp	Astra Tech	10	5 to 6	M-R	12	54
Ganeles et al <sup>55</sup>	Retro	Straumann and Astra Tech and Frialit-2	27	5 to 8	M-C	25	161
Total			1,208				5,190

Retro = retrospective; Prosp = prospective; RCT = randomized controlled trial; M-R = metal-resin; M-C = metal-ceramic.

\*Maximum number of stars that a study can receive is 8.

placed in the maxilla was between five to eight per patient. The prosthesis survival rate ranged from 93.75% to 100%, based on these five studies (Table 4).

In the mandible, the implant survival rate ranged from 98.51% to 100%, based on three studies (range of follow-up, 1 to 2 years).<sup>63,65,67</sup> The number of implants placed in the mandible was between four to five per patient. The prosthesis survival rates ranged from 97.78% to 100%, based on these three studies (Table 5).

The prosthodontic design was one-piece for both maxilla and mandible except for the study by Lai et al,

who reported on the use of a segmented design.<sup>64</sup> The prosthetic materials used for the definitive prostheses were metal resin or metal ceramic.

**Implant and Prosthesis Survival and Failure with Conventional Loading.** The scientific evidence on conventional loading with fixed prostheses for edentulous patients was supported by 11 studies (2 RCTs, 6 prospective, and 3 retrospective), while 3 studies reported on both maxilla and mandible.<sup>56,57,60–62,68–74</sup> These clinical studies reported data from 282 patients (284 edentulous arches) with 1,688 implants, with follow-up from 24 months to 180 months.

Failures	Prostheses	Prosthesis failures	Implant survival rates (%)	Prosthesis survival rates (%)	Weight (%)	Overall risk of bias
2	45	1	99.11	97.78	7.10	5*
2	80	2	98.75	97.50	1.26	6*
2	20	0	97.50	100.00	1.90	6*
0	4	0	100.00	100.00	0.17	6*
0	8	0	100.00	100.00	3.47	6*
0	33	0	100.00	100.00	4.59	6*
1	183	2	99.86	98.91	5.78	5*
13	24	0	90	100.00	3.03	6*
0	50	0	100.00	100.00	3.16	6*
0	20	0	100.00	100.00	1.58	6*
0	68	0	100.00	100.00	2.15	5*
0	25	0	100.00	100.00	1.97	6*
3	78	3	98.72	96.15	9.24	5*
6	16	1	90.63	93.75	0.51	6*
5	91	0	98.63	100.00	14.37	6*
0	14	0	100.00	100.00	2.12	6*
1	93	0	99.73	100.00	6.58	6*
15	46	0	94.39	100.00	8.86	5*
0	20	0	100.00	100.00	1.26	6*
0	40	0	100.00	100.00	2.53	6*
0	15	0	100.00	100.00	0.98	6*
3	61	0	98.78	100.00	5.83	6*
0	25	0	100.00	100.00	2.96	6*
0	23	0	100.00	100.00	1.76	6*
3	27	0	98.01	100.00	1.19	6*
2	62	0	99.38	100.00	2.57	6*
0	10	0	100.00	100.00	0.43	6*
1	27	0	99.38	100.00	2.65	6*
59	1,208	9	98.86	99.25	100	

In the maxilla, the implant survival rate ranged from 94.95% to 100%, based on eight studies (range of follow-up from 2 to 15 years).<sup>56–58,61,62,68–70,73,74</sup> The number of implants placed in the maxilla was between four to nine implants per patient. The prosthesis survival rate ranged from 87.5% to 100%, based on these eight studies (Table 6).

In the mandible, the implant survival rate ranged from 96.47% to 100%, based on six studies (range of follow-up from 3 to 15 years).<sup>60,68,69,71–73</sup> The number of implants placed in the mandible was between four to six implants per patient. The prosthesis survival rate

ranged from 95.56% to 100%, based on the aforementioned six studies (Table 7).

The prosthodontic design was one-piece for both maxilla and mandible. Only the study by Papaspyridakos and Lal reported on a small number of segmented prostheses as well.<sup>69</sup> The prosthetic materials used for the definitive prostheses were metal resin, metal ceramic or zirconia ceramic.

The estimated 1-year implant and prosthesis survival rates with 95% CI for each loading protocol are shown in Table 8. No difference was identified between maxilla and mandible.

Table 4 Studies on Early L	oading <b>v</b>	vith Comple	ete Dental	Prostheses	in the Edentulo	us Maxilla		
Study	Study type	Brand	Patients	Implants/ Patient	Prosthesis type	Follow-up time (mo)	Implants	
Fischer and Stenberg (2012) <sup>56</sup> and Fischer and Stenberg (2013) <sup>57</sup>	RCT	Straumann	16	5 to 6	M-R	120	95	
Jokstad et al <sup>58</sup>	RCT	Straumann	36	5 to 6	M-C	36	214	
Cannizzaro et al <sup>59</sup>	RCT	Zimmer	15	5 to 8	M-C and M-R	12	87	
Lai et al <sup>64</sup>	Prosp	Straumann	12	6 to 8	M-C	36	91	
Nordin et al <sup>66</sup>	Retro	Straumann	20	6 to 7	M-R	12	122	
Total			99				609	

Retro = retrospective; Prosp = prospective; RCT = randomized controlled trial; M-R = metal-resin; M-C = metal-ceramic. \*Maximum number of stars that a study can receive is 8.

#### Table 5 Studies on Early Loading with Complete Dental Prostheses in the Edentulous Mandible

Study	Study type	Brand	Patients	Implants/ patient	Prostheses type	Follow-up time (mo)	Implants
Friberg and Jemt <sup>63</sup>	Retro	Nobel Biocare	67	4	M-R	12	268
Friberg and Jemt <sup>65</sup>	Prosp	Nobel Biocare	76	5	M-R	12	380
Collaert and De Bruyn <sup>67</sup>	Retro	Astra Tech	25	4 to 5	M-R	24	108
Total			168				756

Retro = retrospective; Prosp = prospective; RCT = randomized controlled trial; M-R = metal-resin; M-C = metal-ceramic. \*Maximum number of stars that a study can receive is 8.

# Table 6 Studies on Conventional Loading with Complete Dental Prostheses in the Edentulous Maxilla Study Implants/ Follow-up

Study	Study type	Brand	Patients	Implants/ patient	Prostheses type	Follow-up time (mo)	
Mertens et al <sup>70</sup>	Prosp	Astra Tech	15	6 to 8	M-C	135	
Papaspyridakos and Lal <sup>69</sup>	Retro	Nobel Biocare	5	6 to 8	Zirconia-ceramic	3	
Ravald et al <sup>68</sup>	Prosp	Astra Tech	10	6	M-C and M-R	162	
Fischer and Stenberg (2012) <sup>56</sup> and Fischer and Stenberg (2013) <sup>57</sup>	RCT	Straumann	8	5 to 6	M-R	120	
Hjalmarsson et al <sup>61</sup>	Retro	Astra Tech, Biomet 3i, Straumann, Nobel Biocare	53	4 to 8	M-C and M-R	60	
Tealdo et al <sup>62</sup>	Prosp	Biomed 3i	15	6 to 9	M-R	40.5	
Rasmusson et al <sup>73</sup>	Prosp	Astra Tech	16	4 to 6	M-R	120	
Bergkvist et al <sup>74</sup>	Retro	Straumann	25	5 to 7	M-C and M-R	24	
Total			147				

Retro = retrospective; Prosp = prospective; RCT = randomized controlled trial; M-R = metal-resin; M-C = metal-ceramic.

\*Maximum number of stars that a study can receive is 8.

#### Table 7 Studies on Conventional Loading with Complete Dental Prostheses in the Edentulous Mandible

Study	Study type	Brand	Patients	Implants/ patient	Prostheses type	Follow-up time (mo)	Implants
Papaspyridakos and Lal <sup>69</sup>	Retro	Nobel Biocare	8	5 to 6	Zirconia-ceramic	36	47
Ravald et al <sup>68</sup>	Prosp	Astra Tech	15	5	M-C and M-R	162	85
Eliasson et al <sup>71</sup>	Prosp	Paragon	29	4 to 6	M-R	60	168
Gallucci et al <sup>72</sup>	Prosp	Straumann	45	4 to 6	M-C and M-R	60	237
Rasmusson et al <sup>73</sup>	Prosp	Astra Tech	20	4 to 6	M-R	120	108
Moberg et al <sup>60</sup>	RCT	Straumann	20	4 to 6	M-R	36	106
Total			137				751

Retro = retrospective; Prosp = prospective; RCT = randomized controlled trial; M-R = metal-resin; M-C = metal-ceramic.

\*Maximum number of stars that a study can receive is 8.

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Failures	Prostheses	Prosthesis failures	Implant survival rates (%)	Prosthesis survival rates (%)	Weight (%)	Overall risk of bias
5	16	1	94.74	93.75	45.81	Low
0	36	0	100.00	100.00	30.95	Low
3	15	0	96.55	100.00	4.19	Low
1	12	0	98.90	100.00	13.16	6*
1	20	0	99.18	100.00	5.89	6*
10	99	1	98.36	98.99	100	

Failures	Prostheses	Prosthesis failures	Implant survival rates (%)	Prosthesis survival rates (%)	Weight (%)	Overall risk of bias
4	67	1	98.51	98.51	31.02	6*
0	76	2	100.00	97.78	43.98	6*
0	25	0	100.00	100.00	25	6*
4	168	3	99.47	98.21	100	

Implants	Failures	Prostheses	Prosthesis failures	Implant survival rates (%)	Prosthesis survival rates (%)	Weight (%)	Overall risk of bias
94	3	15	1	96.81	93.33	17.25	6*
39	0	5	0	100.00	100.00	1.91	6*
99	5	10	1	94.95	90.00	21.80	6*
47	2	8	1	95.74	87.50	7.67	Low
324	5	53	0	98.46	100.00	26.43	8*
97	4	15	0	95.88	100.00	5.34	8*
91	3	16	0	96.70	100.00	14.84	6*
146	5	25	0	96.58	100.00	4.76	6*
937	27	147	3	97.12	97.96	100	

Failures	Prostheses	Prosthesis failures	Implant survival rates (%)	Prosthesis survival rates (%)	Weight (%)	Overall risk of bias
0	8	0	100.00	100.00	2.99	6*
3	15	0	96.47	100.00	24.36	6*
1	29	0	99.40	100.00	17.83	6*
0	45	2	100.00	95.56	25.15	6*
3	20	0	97.22	100.00	22.92	6*
3	20	0	97.17	100.00	6.75	Unclear
10	137	2	98.67	98.54	100	

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Each Loading Protocol							
Loading protocol	Arch	Estimated implant survival rate (%) and the 95% Cl at one year	Estimated prosthesis survival rate (%) and the 95% CI at one year				
Conventional	Maxilla	99.60 (99.60–99.70)	99.90 (99.80–100.0)				
	Mandible	99.70 (99.50–99.90)	99.80 (99.60–99.90)				
Early	Maxilla	99.30 (98.91-99.70 )	99.90 (99.70–100.0)				
	Mandible	98.51 (97.04-100.0)	99.50 (99.00–100.0)				
Immediate	Maxilla	99.20 (99.10–99.40)	99.10 (98.22-100.0)				
	Mandible	99.30 (99.20–99.50)	99.70 (99.50-99.90)				

# Ectimated Cumulative 1 Vear Survival Pate

CI: Confidence intervals.

# DISCUSSION

There is a tendency in the medical and dental field to reduce the treatment time and simplify treatment procedures in order to increase patient acceptance and satisfaction while maintaining long-term predictability of treatment outcomes.<sup>75</sup> The objective of this systematic review was to investigate the effect of immediate implant loading with fixed prostheses on implant survival, failure, and complications in edentulous patients compared to early and conventional loading in order to provide evidence-based clinical guidelines. Sixtytwo studies, including 2,695 patients (2,757 edentulous arches) with 13,653 implants, were included in the present systematic review. Forty-five studies reported on immediate loading protocols, 8 on early, and 11 on conventional loading protocols.

For the edentulous maxilla, the focus question was answered in regards to survival and failure. Immediate loading with fixed prostheses in the maxilla yielded implant survival rates that ranged from 90.43% to 100%, based on 27 studies (range of follow-up, 1 to 10 years). The estimated cumulative 1-year implant survival rate was 99.2% (95% CI, 99.10 to 99.40) for immediate loading. With early loading in the maxilla, the implant survival rates ranged from 94.7% to 100%, based on 5 studies (range of follow-up, 1 to 3 years). The estimated cumulative 1-year implant survival rate was 99.3% (95% CI, 98.91 to 99.70) for early loading. When conventionally loading the implants in the maxilla, the implant survival rates ranged from 94.95% to 100%, based on eight studies (range of follow-up, 2 to 15 years). The estimated cumulative 1-year implant survival rate was 99.6% (95% Cl, 99.60 to 99.70) for conventional loading. Thus, no difference was identified between immediate loading and early or conventional loading and their effect on implant survival in the edentulous maxilla.

For the edentulous mandible, the focus question was answered in regards to survival and failure. Immediate loading with fixed prostheses in the mandible yielded implant survival rates that ranged from 90% to 100%, based on 28 studies (range of follow-up, 1 to 10 years). The estimated cumulative 1-year implant survival rate was 99.3% (95% CI, 99.20 to 99.50) for immediate loading. Early loading in the mandible yielded implant survival rates that ranged from 98.51% to 100%, based on three studies (range of follow-up from 1 to 2 years). The estimated cumulative 1-year implant survival rate was 98.51% (95% CI, 97.04 to 100.00) for early loading. Finally, with conventional loading in the mandible, the implant survival rates ranged from 96.47% to 100%, based on six studies (range of follow-up from 3 to 15 years). The estimated cumulative 1-year implant survival rate was 99.7% (95% CI, 99.50 to 99.90) for conventional loading. Hence, no difference was identified between immediate loading and early or conventional loading and their effect on implant survival in the edentulous mandible.

Only three studies were identified to directly compare outcomes with different loading protocols within the same study. All three studies involved edentulous maxillary arches. One RCT by Cannizzaro et al compared immediate with early loading, and found implant survival rates of 98.89% in the immediate and 96.55% in the early loading group.<sup>59</sup> One case-control comparative study by Tealdo et al compared immediate with conventional loading. The authors found implant survival rates of 93.87% for the immediate and 95.88% for the conventional loading group.62 One RCT by Fischer et al compared conventional with early loading with implant survival rates of 95.74% for conventional and 94.74% for early loading.<sup>56,57</sup>

The clinical implications of the aforementioned findings are obvious. With careful patient selection and appropriate training, the experienced clinician

can shorten treatment for the edentulous jaw by implementing immediate loading with fixed prostheses. Immediate loading can shorten treatment time, provide immediate restoration of function and esthetics, and mitigate the psychological impact of complete edentulism.<sup>3</sup> Taking into consideration that the majority of completely edentulous patients belong to older age groups, the shortening of treatment time would appear to be an additional advantage in clinical treatment and for patient acceptance.<sup>56,57</sup>

Various prerequisites for applying immediate loading have been reported in the literature. Primary stability has been advocated as one of the most important factors for successful osseointegration. Based on the 45 studies on immediate loading included in this review, one of the prerequisites reported by the majority of authors was the observation of an insertion torque of at least 30 Ncm. If resonance frequency analysis was used to assess the primary stability, an ISQ value of at least 60 was observed for immediate loading. The use of surfacemodified implants has also played an important role in the favorable findings of the present report. Experimental studies have shown a stronger and more rapid bone tissue response to surface-modified implants.

The number of implants per patient varied between the research groups and loading protocols. For the edentulous maxilla it ranged from 4 to 12 implants per arch, and for the edentulous mandible from 2 to 10. One longitudinal retrospective study by Hatano et al reported on an "all-on-three" protocol for the mandible.<sup>27</sup> It was obvious that every implant loss would lead to prosthesis loss. The medium to high risk of bias of that study precluded any solid conclusion or recommendations on this protocol. A short-term prospective study by Cannizzaro et al reported on an "all-on-two" protocol for shortened dental arch rehabilitation in the mandible.<sup>15</sup> The decision was made to include this study in the meta-analysis, since it satisfied the inclusion criteria. However, the short-term follow-up of 1 year and the insufficient evidence coupled with the medium risk of bias of that study also precluded any clinical recommendation for this protocol. Immediate loading of two implants with a fixed prosthesis cannot be recommended since any implant loss will always lead to prosthesis loss as well. A number of prospective and retrospective studies on the "all-on-four" protocol documented favorable outcomes for both maxilla and mandible.<sup>12,16,19–23,29,30</sup> More long-term studies are necessary to assess the predictability of this protocol, since loss of one implant usually requires the refabrication of the prosthesis.

The prosthodontic design most frequently applied in the included studies was that of a one-piece prosthesis. Only a few studies reported on a small number of segmented restorations. For complete arch implant rehabilitation, the segmented design offers easier fabrication and prosthetic maintenance.<sup>75</sup> A recent systematic review showed that technical complications after placement of the definitive prosthesis may not affect the implants negatively but will result in an increased number of repairs and maintenance events.<sup>2</sup> The 10-year cumulative rate reported in this review for prostheses free of complications of 8.6% (95% CI, 7.1 to 10.3) highlights the advantage of segmenting implant fixed dental prostheses if possible. No correlation was identified between loading protocol and encountered complications between maxilla or mandible. It seems that once osseointegration has been achieved, there are many factors other than the loading protocol that may be related to biologic and technical complications.

The findings of the present systematic review are in agreement with the existing knowledge regarding immediate loading of the edentulous maxilla with full-arch fixed dental prostheses. The conclusions of the 2008 ITI Consensus Conference stated that for the edentulous maxilla, both immediate, 6 to 8 weeks post-implant placement, and conventional loading protocols with fixed prostheses were supported by the literature.<sup>1,3</sup> The present study corroborates these statements and is supported by 45 clinical studies (1 RCT, 28 prospective and 16 retrospective).<sup>12–55,62</sup>

As far as the edentulous mandible, the findings of the present review are also in agreement with those of the 2008 ITI Consensus Conference, which concluded that both immediate or early loading (early being 6 to 8 weeks after implant placement, since the definition was different in 2008 than at present) with fixed prostheses were equally as predictable as conventional loading.<sup>1,3</sup> No evidence had been found, however, regarding differences in early loading between the second to the sixth week post-implant placement. In the context of evidence from eight studies included in the present review, early loading (between 1 to 8 weeks post-implant placement) yields similar implant survival rates compared with immediate and conventional loading.

Caution is necessary when interpreting these findings, as there are many confounding factors that affect treatment outcomes with every loading protocol. Most importantly, the favorable outcomes reported in the dental implant literature are the results of treatments performed by clinicians with extended education, training, experience, and skill.

The advances in contemporary oral implantology coupled with patients' high esthetic expectations underscore the necessity for more factors to be included in the assessment of implant prostheses besides implant and prostheses survival.<sup>76</sup> Additionally, patient preference for a specific treatment option relies on the longitudinal efficacy of the option coupled with the associated cost and maintenance. However, in spite of the obvious consequences in the success of dental implant therapy, patient-centered outcomes are frequently not addressed.<sup>77</sup> Most of the included articles did not present data on patient-centered outcomes. Restoration of function, esthetics, and patient satisfaction is the goal when treating the edentulous patient with dental implants, and thus new studies should report on these important parameters of implant treatment. In this context, well-defined success criteria should be established and used for assessing and reporting implant, prosthodontic, and patient-centered outcomes as well as biologic and technical complications.

#### CONCLUSIONS

With careful patient selection and using implants with rough surfaces, immediate loading with fixed prostheses in edentulous patients has the same effect on implant survival, failure, and complications as with early and conventional loading in maxillary and mandibular arches. For immediate loading, a minimal insertion torque of 30 Ncm is recommended. The estimated 1-year implant survival was above 99% with all three loading protocols. Caution is necessary when interpreting these results, as there are many confounding factors that affect treatment outcomes with every loading protocol. More comparative studies directly comparing different loading protocols are necessary. Longitudinal clinical studies should ideally report on complications in order to provide clinicians with reliable and thorough information for evidence-based treatment planning.

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# Loading Protocols for Implant-Supported Overdentures in the Edentulous Jaw: A Systematic Review and Meta-Analysis

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Purpose: High survival rates have frequently been reported for immediately loaded implants. The aim of this systematic review was to compare immediately loaded with early and conventional loaded implants for overdenture treatment with regard to their 1-year survival rates. Materials and Methods: Systematic database (Medline, Embase, CENTRAL) and hand searches were performed to identify prospective studies reporting on loading protocols for two-piece implants with micro-rough surfaces and diameters > 3 mm. Studies were grouped according to loading protocol, jaw, number of implants per jaw, and splinting. Metaanalyses of comparative reports were performed based on the calculated risk difference (RD). Descriptive analyses included the remainder prospective studies. Two investigators extracted the data independently. Kappa statistics served to evaluate the inter-investigator agreement. Results: Of the 3,142 identified articles, 58 were included for data extraction. They comprised 11 studies comparing loading protocols as well as a further 47 prospective reports. Comparative studies were only available for mandibular overdentures. The meta-analysis revealed a statistical tendency to support conventional over immediate loading (RD: -0.03, 95% confidence interval: -0.06, 0.00). The descriptive analysis of studies with lower evidence demonstrated partially contradictory findings. There, reported survival rates for immediately loaded implants lay between 81.6% and 100%, but depended on the number of implants placed. Most investigators preferred verifying an initial high insertion torque ( $\geq$  35 Ncm) or ISQ value ( $\geq$  60) before considering an implant for an immediate or early loading protocol. Conclusions: Although all three loading protocols provide high survival rates, early and conventional loading protocols are still better documented than immediate loading and seem to result in fewer implant failures during the first year. Only a few prospective case series are available to document immediate loading of implants supporting an overdenture in the edentulous maxilla. INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):271-286. doi: 10.11607/jomi.2014suppl.g4.4

Key words: dental implants, edentulism, loading protocol, meta-analysis, overdenture, systematic review

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Edentulism still has a high prevalence in the elderly population and is generally considered a common clinical entity. The treatment modalities for the completely edentulous jaw frequently incorporate conventional removable dentures.<sup>1,2</sup> However, these show functional shortcomings and are often associated with psychosocial limitations.<sup>3,4</sup>

The advent of osseointegrated implants has greatly enhanced the treatment outcomes in edentulous patients and has been advocated as a predictable and successful therapeutic concept for many decades.<sup>5–7</sup> Implant-supported overdentures, especially in the edentulous lower jaw, help restore oral function and may improve psychosocial well-being and oral healthrelated quality of life.<sup>8</sup> Rehabilitations with implantsupported overdentures are documented as reliable and cost-effective.<sup>9,10</sup> Mandibular overdentures with two implants, retained by either splinted or unsplinted attachments are considered a globally accepted treatment option.<sup>11–15</sup> Single, implant–retained overdentures may also demonstrate adequate success in the completely edentulous mandible, yet long-term data are still missing.<sup>16–19</sup>

In the early days of implantology, Brånemark and collaborators empirically advocated an unloaded healing period of 3 months for the mandible and 6 months for the maxilla following implant placement to facilitate an uneventful osseointegration, avoid soft tissue encapsulation, and improve implant survival rates.<sup>20,21</sup> Successful osseointegration has been linked to sound primary stability at the time of surgery and the prevention of subsequent micromovements of the implant during the healing phase.<sup>22</sup> However, researchers have demonstrated that osseointegration can be achieved with early or immediate loading protocols if micromotion is contained within the suggested limits.<sup>23</sup> Most patients perceive the period between tooth loss and definitive rehabilitation as traumatic and uncomfortable because provisional prostheses mostly provide compromised function and esthetics.<sup>24</sup> Substantial benefits may be derived by shortening the provisional prosthetic period as well as reducing treatment duration.24,25

The immediate loading of implants in the edentulous mandible is not a new idea.<sup>26,27</sup> Developments such as improved implant design contributed towards increased primary implant stability,<sup>28,29</sup> and implants with osseoinductive surfaces promised faster osseointegration<sup>30</sup>; hence the concept of immediate and early loading gained popularity. Since then, high survival rates for immediately loaded splinted and unsplinted implants have frequently been reported.<sup>24</sup> The splinting of immediately loaded implants was advocated in order to avoid peak forces on the boneimplant interface during the healing phase and thus improve implant survival rates.<sup>31</sup> However, the literature is not conclusive as survival rates may not only depend on the loading protocol, but also on the number of implants, the attachment system, or the implant surface.<sup>18,32–36</sup>

The purpose of this systematic review and metaanalysis is to test the hypothesis that immediate loading protocols for implant-supported overdentures show 1-year survival rates similar to early or conventional loading protocols.

#### MATERIALS AND METHODS

This systematic review was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines.<sup>37</sup>

The PICO (population, intervention, comparison, outcome) focus question formulated for this review was: "In edentulous jaws with implant-supported overdentures, what is the effect of immediate implant loading versus early or conventional loading on the 1-year implant survival?"

#### Search Strategy and Selection of Studies

The electronic databases CENTRAL, Embase, and PubMed were searched for relevant scientific reports published in English, German, and French between January 1980 and November 30, 2012 (Table 1).

Reference lists from review articles were screened for eligible studies to complete the hand search. Requests were posted on online forums such as the ITI-net, the IADR LinkedIn group, and ResearchGate. Finally, personal contacts were used to identify relevant unpublished studies.

Two investigators (MS and MS) performed the electronic queries based on a search design devised by an expert on database searches (FRH). Since the available research on this topic is limited, it was decided to include randomized clinical trials (RCTs), prospective case series, and prospective cohort and case control studies. Publications reporting on the same patient pool were identified and in such instance, only the most recent publication was considered.

#### Data Extraction

Two investigators (MS and MS) independently screened the titles and abstracts of the identified studies. Eligibility for inclusion of studies was confirmed by mutual agreement; in case of disagreement the senior investigator (FM) was consulted. Full-text analysis and data extraction was performed after agreement on the final list. The following information was extracted: name of author(s) and year of publication, study design, follow-up period in months, number of implants placed, number of implants failed, jaw, time point of failure, number of drop-outs, reported cumulative survival rates (CSR%), time of loading, overdenture attachment type, and number of implants supporting the overdenture. The two investigators performed data extraction independently and were reciprocally blinded. If relevant data could not be extracted from the full-text manuscript, the corresponding author was contacted. Those studies were only included if the relevant information was provided.

#### **Quality Assessment**

The methodological quality of case control and cohort studies was assessed with the Newcastle-Ottawa scale (NOS).<sup>38</sup> The Cochrane collaboration's tool for assessing the risk of bias was employed for the assessment of RCTs.<sup>39</sup>

	edentulous jaws with implant-supported overdentures, what is the effect of immediate implant loading sus early or conventional loading on the 1-year implant survival?
ver Search strategy	sus early or conventional loading on the 1-year implant survival?
Population	# 1 – (Removable dental prostheses* [all fields]) OR (Overdentures [all fields]) OR (Implant supported Overdentures [all fields]) OR (Implant assisted Overdentures [all fields]) OR (Overdentures [MeSH] OR Jaw Edentulous [MeSH]) OR (Mouth, Edentulous [MeSH])
Intervention or exposure	#2 – (dental implantation, endosseous [MeSH]) OR (dental implants [MeSH]) OR (implantation* [all fields OR (implant [all fields]) OR (implants [all fields])
Comparison	#3 – (Immediate Dental Implant Loading [MeSH]) OR (function [all fields]) OR (time [all fields]) OR (immediate [all fields]) OR (early [all fields]) OR (load* [all fields])
Outcome	#4 – (Survival [MeSH]) OR (survival rate [MeSH]) OR (survival analysis [MeSH]) OR (intraoperative complications [MeSH]) OR (postoperative complications [MeSH]) OR (dental restoration failure [MeSH]) OR (prosthesis failure [MeSH]) OR (treatment failure [MeSH]) OR (complication* [all fields]) OR (success* [all fields]) OR (failure* [all fields])
Filters (Language)	# 5 – (English [lang]) OR (German [lang]) OR (French [lang])
Search combination	#1 AND #2 AND #3 AND #4 AND #5
Database search	
Electronic	PubMed, Embase, and the Cochrane Central Register of Controlled Trials (CENTRAL)
Journals	All peer reviewed dental journals available in PubMed, Embase, and CENTRAL. No filters were applied for the journals
Selection criteria	
Inclusion criteria	Dental implants placed in completely edentulous human jaws Implant-supported overdenture prostheses Must specify the study design, number of patients, number of implants placed and failed, time of loading and number of dropouts Implant type: two-piece, rough-surfaced solid screws Patients must have been clinically examined during recall
Exclusion criteria	Retrospective studies Studies with observation periods of less than 12 months post loading Implants were placed in irradiated bone, or augmented bone Reports with sample size of less than 10 cases Implant diameter less than 3 mm

#### **Outcome Measures**

The primary outcome measure in this review was the effect of the loading protocol on the 1-year implant survival. Implant survival or success was defined as the absence of mobility, pain, recurring peri-implant infection and continued radiolucency around the implant.<sup>40</sup> The secondary outcome measure was the time point of implant failure. Furthermore, the clinical criteria for choosing either immediate or early loading of implants were extracted from the manuscripts.

The definitions of loading protocols used in this review are in agreement with the latest Cochrane review from Esposito and coworkers.<sup>24,41</sup> Thus, immediate loading was defined as functional loading within 7 days following implant placement. Functional loading between 7 days and 8 weeks was specified as early loading; implant loading after 8 weeks following placement was considered as conventional loading.

For the purpose of this review a worst-case scenario was employed. Hence, implants in participants lost to follow-up were considered as failures. The failures were scored on the implant level.

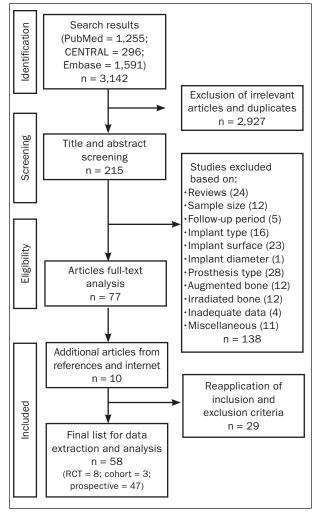
#### **Statistical Analysis**

The agreement of data extraction between the two investigators was assessed by kappa ( $\kappa$ ) statistics.

A meta-analysis was performed for the prospective comparative studies (RCTs and cohort studies for mandibular overdentures) using the STATA command "metan."<sup>42</sup> Therefore, risk differences (RD) and the corresponding 95% confidence intervals (95% CI) for the implant survival at 1 year were calculated for the sets of studies comparing:

- Set 1: Immediate and early loading
- Set 2: Immediate and conventional loading
- Set 3: Early and conventional loading

A weighted average across these studies was provided according to a fixed-effect model; study weight corresponded to 1/study variance.<sup>43</sup> Heterogeneity between studies was assessed with the  $l^2$  statistic. It describes the percentage of variation across studies that is due to heterogeneity, rather than chance.<sup>42</sup> A specialist bio-statistician and physician (FRH) performed



#### Table 2 Studies Comparing Loading Protocols for Implant-Supported Overdentures in Completely Edentulous Mandibles

Study	Year	Study type	Loading protocols compared	Loading time (d)
Romeo et al <sup>31</sup>	2002	RCT	Immediate	2
			Conventional	90
Assad et al <sup>48</sup>	2007	RCT	Immediate	4
			Conventional	120
Stephan et al <sup>35</sup>	2007	Prospective	Immediate	1
		cohort	Conventional	90
Alfadda et al <sup>47</sup>	2009	Prospective	Immediate	0
		cohort	Conventional	120
Enkling et al <sup>50</sup>	2010	RCT	Immediate	0
			Conventional	90
Elsyad et al <sup>49</sup>	2012	RCT	Immediate	0
			Conventional	90
Turkyilmaz et al <sup>51</sup>	2012	RCT	Immediate	7
			Conventional	90
Røynesdal et al <sup>55</sup>	2001	Prospective	Early	21
		cohort	Conventional	90
Ma et al <sup>54</sup>	2010	RCT	Early	14
			Conventional	84
Cannizzaro et al <sup>52</sup>	2008	RCT	Immediate	0
			Early	42
Gadallah et al <sup>53</sup>	2012	RCT	Immediate	7
			Early	42

RCT = randomized controlled trial; NR = not reported.

Fig 1 The search flow diagram for the systematic literature search and selection process.

all statistical tests, using the STATA Statistical Software release 12.1.

#### RESULTS

#### **Data Selection and Identification**

The electronic database searches identified a total of 3,142 articles (CENTRAL = 296, Embase = 1,591, PubMed = 1,255). The flow of information through the different phases of the systematic review process is reported according to the PRISMA guidelines in Fig  $1.^{37}$  From the electronically identified reports (n = 3,142), cross-references (n = 9) and online discussion forums (n = 1), 77 full texts were analyzed. From those, three relevant RCTs assessing immediate loading in implant-supported overdentures were excluded because one had an observation period of only 6 months,<sup>44</sup> while

the other two reported on machined surface implants.<sup>45,46</sup> This process resulted in a final inclusion of 58 studies for data extraction and analysis. The final list included eight RCTs and three prospective cohort studies comparing loading protocols for implant-supported overdentures in the edentulous jaw<sup>31,35,47-55</sup> (Table 2). The remaining 47 prospective studies were case series, RCTs, or cohort studies not comparing loading protocols<sup>16–19,25,33,34,36,56–94</sup> (Tables 3 to 6).

Prospective comparative studies (RCTs, cohort studies) were available only for mandibular implantsupported overdentures (Table 2). Every attempt was made to eliminate publication bias; hence, some studies were excluded because they reported data from the same cohort at different time points. In case of doubt, the corresponding author was contacted. If double publication was confirmed, only the most recent report was included in the analysis.

Arch	Brand	Attachment type	Observation period (mo)	Patients	Implants/ patient	Implants placed	Implants failed (at 1 y)	Total survived (failed)	Reported survival rate (%)
Mandible	Straumann	Bar	24	10	4	40	0	40 (0)	100
				10	4	40	1	39 (1)	97.5
Mandible	Paragon	Bar	24	5	4	20	0	20 (0)	100
				5	4	20	0	20 (0)	100
Mandible	Nobel Biocare	Bar	24	17	3	51	0	51 (0)	100
				9	3	27	0	27 (0)	100
Mandible	Nobel Biocare	Bar	60	35	2	70	2	68 (2)	98.4
				42	2	111	3	108 (3)	98.2
Mandible	SI Cace	Bar	36	16	2	32	0	32 (0)	100
				16	2	32	0	32 (0)	100
Mandible	ImplantDirect	Ball	36	18	2	36	2	30 (6)	NR
				18	2	36	0	30 (6)	NR
Mandible	Nobel Biocare	Ball	84	13	2	26	0	26 (0)	100
				13	2	26	0	26 (0)	100
Mandible	Straumann	Ball	24	11	2	22	0	22 (0)	100
				10	2	20	0	20 (0)	100
Mandible	Straumann	Ball	120	48	2	96	0	96 (0)	100
	Southern			24	2	48	0	48 (0)	100
Mandible	Swiss Plus	Bar	12	30	2	60	0	60 (0)	100
				30	2	60	2	58 (2)	96.7
Mandible	Swiss Plus	Ball	12	6	2	12	0	12 (0)	100
				6	2	12	0	12 (0)	100

The inter-investigator agreement for the data extraction was considered very good ( $0.86 < \kappa < 1.00$ ).

#### **Quality Assessment**

The risk of extracting biased results from the comparative studies was scored as low for four studies, and only one RCT was appraised with a high risk of bias (Tables 7a and 7b).

# Meta-Analysis of High Evidence Comparative Studies

The meta-analysis of the two studies comparing immediate and early loading (set 1) failed to demonstrate a difference between treatment modalities (RD: 0.03; 95% Cl: -0.03, 0.08; Fig 2).<sup>52,53</sup>

The forest plot for the studies comparing immediate and conventional loading (set 2) combined the results of seven studies.<sup>31,35,47–51</sup> The analysis showed a statistical tendency in favor of the conventional loading protocols with regard to the 1-year implant survival (RD: -0.03; 95% CI: -0.06, 0.00; Fig 3).

The two studies in set 3 (early versus conventional loading)<sup>54,55</sup> reported no implant failures in either treatment arm (Table 2), thus a meta-analysis was redundant.

# Descriptive Analysis of Studies Not Comparing Loading Protocols

**Mandibular Overdentures with Splinted Implants.** Seven prospective studies,<sup>36,56,61,65–67,85</sup> including some RCTs not comparing loading protocols, reported survival rates between 94.4% and 100% for immediately loaded and splinted implants in a follow-up period of 12 to 96 months. Those studies evaluated a total of 924 implants of which 7 had failed or the patient had dropped out after 1 year. Lethaus et al<sup>83</sup> were the only authors to report on early loading of four-implant bars

# Table 3 Studies on Loading Protocols for Mandibular Implant-Supported Overdentures with Splinted Attachments

		Loading		Attachment	Observation		
Study	Year	time (d)	Brand	type	period (mo)	Patients	
Immediate							
Gatti et al <sup>56</sup>	2000	0	Straumann	Bar	25-60	21	
Chiapasco and Gatti <sup>61</sup>	2003	1	Straumann, Nobel, Ha-Ti, Frialoc	Bar	36–96	82	
Stricker et al <sup>36</sup>	2004	1	Straumann	Bar	24–36	10	
Degidi and Piattelli65	2005	2	XiVe	Bar	24	14	
Weischer et al <sup>66</sup>	2005	6	Frialoc	Bar	12–29	18	
Martínez-González et al <sup>67</sup>	2006	2	Defcon	Bar	12–24	20	
Stoker and Wismeijer <sup>85</sup>	2011	0	Straumann	Bar	12-40	124	
Total (7)	2000–2011	0-6		Splinted	12-96	289	
Early							
Lethaus et al <sup>83</sup>	2011	42	Straumann	Bar	12-60	14	
Total (1)	2011	42		Splinted	12-60	14	
Conventional							
Gotfredsen and Holm <sup>57</sup>	2000	90	Astra	Bar	12-60	11	
Heydenrijk et al <sup>58</sup>	2002	90	Straumann	Bar	12	20	
Karabuda et al <sup>59</sup>	2002	90	Frialit, PittEasy	Bar	12–72	18	
Meijer et al <sup>64</sup>	2004	90	Straumann	Bar	12-60	30	
Cakarer et al <sup>78</sup>	2011	60	Straumann, Nobel, Frialit, Swiss-Plus, Biohorizons, Bio-Lok	Bar	12-60	9	
Heschl et al <sup>81</sup>	2013	90	XiVe	Bar	12-60	39	
Mangano et al <sup>84</sup>	2011	90	Leone	Bar	12-60	38	
Elsyad <sup>92</sup>	2012	90	ImplantDirect	Bar	36	30	
Guljé et al <sup>87</sup>	2012	90	Astra	Bar	12	12	
Total (9)	2000-2012	90		Splinted	12–72	207	

NR = not reported.

in a study that included 60 implants. Of those, two had failed during the first year; the authors reported a survival rate of 96.7% (12- to 60-month observation period). A further nine studies<sup>57–59,64,78,81,84,87,92</sup> described the results of conventional loading of bars supported by two, three, or four implants. The survival rates were reported to be 96% to 100% (12 to 72 months observation period), for a total of 599 placed implants, of which seven had failed at 1 year (Table 3).

**Mandibular Overdentures with Unsplinted Implants.** Nine studies<sup>17,18,33,34,68,70,74,75,86</sup> with observation periods of 12 to 60 months and with one to four unsplinted implants in the mandible employed immediate loading concepts. Of the 520 implants placed in total, 22 had failed or the patients had dropped out during the first year after loading. Kronstrom and coworkers<sup>17</sup> compared within a RCT immediate loading of a single-implant versus two-implant overdentures, with reported 1-year survival rates of 82.4% and 81.6%, respectively. Thus, immediately loaded single implants for mandibular overdentures show reduced 1-year survival rates when compared to more conservative procedures like the splinting of two or more implants.

Five studies<sup>16,19,73,77,90</sup> evaluated the early loading of mandibular overdentures with reported survival rates of 96.6% to 100% during a 12- to 60-month period. The total number of implants placed in this group was 424, engaging either one or two implants to support Locator- or ball-retained overdentures, and with 14 failing within a 12-month period. In one of these studies, Walton and her colleagues<sup>19</sup> compared one- versus twoimplant overdentures and reported no implant losses for the one-implant group versus 7.9% failures in the two-implant group after 1 year.

Eleven studies<sup>57,59,62,63,71,76,78,79,91,93,94</sup> reported on a total of 661 placed implants, loaded conventionally and supporting one- to four-implant overdentures. Of those, 21 failed within the first year after loading. The reported survival rates ranged from 90.4% to 100% during a 12 to 120 month observation period. The studies comprised of telescopic, ball, and Locator attachments (Table 4).

Implants/ patient	Implants placed	Implants failed (at 1 y)	Total survived (failed)	Reported survival rate (%)
4	84	0	73 (11)	96
4	328	0	. ,	96 96.1
		-	296 (32)	
2	20	0	20 (0)	100
4	92	0	92 (0)	100
4	72	4	68 (4)	94.4
4	80	0	80 (0)	100
2	248	3	245 (3)	98.8
2 or 4	924	7	874 (50)	94.4–100
4	60	2	54	96.7
4	60	2	54 (6)	96.7
2	22	0	22 (0)	100
2	40	0	38 (2)	NR
2 or 4	44	1	43 (1)	NR
2	60	0	58 (2)	100
3 or 4	33	0	32 (1)	NR
4	156	1	128 (26)	99.4
4	136	2	134 (2)	98.6
2	60	1	40 (20)	NR
4	48	2	46 (2)	96
2 or 3 or 4	599	7	543 (56)	96–100

*Maxillary Overdentures with Splinted Implants.* Three studies dealt with the immediate loading of implants placed in the maxilla.<sup>25,65,72</sup> They employed immediate loading with bars on four or five implants. A total of 312 implants were followed over a period of 12 to 24 months; the authors reported survival rates between 97.1% and 98.7%. Of the 312 implants placed, 6 had failed at 1-year postinsertion.

Van Assche et al<sup>89</sup> were the only group that reported prospectively on the early loading in the maxilla. Of 72 placed implants, which supported bar-retained overdentures, one short implant of 6 mm length failed during the first year.

Conventional loading of four-, five-, or six-implant bar-retained overdentures was described in five studies.<sup>60,78,82,84,88</sup> Of a total of 699 placed implants, 12 failed within the first year after loading. Survival rates between 97.4% and 99.3% with observation periods of 12 to 108 months were reported (Table 5). *Maxillary Overdentures with Unsplinted Implants.* Eccellente et al<sup>80</sup> studied the immediate loading of four implants in the maxilla using telescopic attachments. In this study, 180 implants were placed and with 4 failing within the first year after loading. The authors reported a survival rate of 97.8% over a 12to 54-month observation period.

Weng and Richter<sup>69</sup> also used telescopic attachments, but for two-implant maxillary overdentures with an early loading protocol. Of the 28 implants placed none was lost during the first year. However, five implants had failed at the end of a 12- to 48-month observation period.

Two studies<sup>62,78</sup> report in part on the conventional loading of unsplinted implants in the edentulous maxilla with telescopic and ball attachments on two or four implants. After the first year, all 28 placed implants were still in place. However, during the remaining observation periods of 12 to 120 months, four implants had failed (Table 6).

**Clinical Criteria for Applying Specific Loading Protocols.** Few studies adopting conventional loading were specific in assessing abutment torque values (in most cases 15 to 35 Ncm) before loading.<sup>31,35,63,79</sup> Harder and colleagues<sup>94</sup> conventionally loaded singleimplant retained overdentures after verifying the implant mobility with Periotest values of –7 to –4.

Most studies describing immediate or early loading protocols advocated a specific implant insertion torque value of  $\geq$  30 Ncm.<sup>16–18,25,31,34–36,52,66,72,73,75,83,85,86,90</sup> Lower insertion torque values between 15 to 25 Ncm have also been advocated prior to immediate or early loading in a few studies.<sup>17,33,89</sup> Wittwer et al<sup>70</sup> applied Periotest values ranging between –7 to –1 for successfully employing an immediate loading protocol in the mandible (Table 8).

Resonance frequency analysis has been used in few studies for the assessment of implant stability prior to loading.<sup>16,18,65,72</sup> Authors have maintained an ISQ value between 60 to 75.1 prior to immediate or early loading.<sup>16,18,65,72</sup>

# DISCUSSION

#### **Critique of the Method**

In this review, the attempt was made to identify and critically review the highest available evidence for implant loading protocols in implant-supported overdentures for patients with edentulous jaws. Today, a meta-analysis combining the results of RCTs is regarded as the highest evidence level.<sup>95</sup> However, the current systematic literature search provided only eight RCTs and a further three nonrandomized comparative studies for the three possible comparisons of loading protocols.

#### Table 4 Studies on Loading Protocols for Mandibular Implant-Supported Overdentures with Unsplinted Attachments

Study	Year	Loading time (d)	Brand	Attachment type	Observation period (mo)	Patients	
Immediate							
Ormianer et al <sup>68</sup>	2006	0	Zimmer	Ball	12-30	10	
Marzola et al <sup>34</sup>	2007	0	Nobel	Ball	12	17	
Wittwer et al <sup>70</sup>	2007	0	Ankylos	Telescope	12–24	25	
Eccellente et al <sup>74</sup>	2010	0	Ankylos	Telescope	12–60	39	
Kronstrom et al <sup>17</sup>	2010	0	Nobel	Ball	12	17	
Kronstrom et al <sup>17</sup>	2010	0	Nobel	Ball	12	19	
Liao et al <sup>75</sup>	2010	0	Nobel	Ball	12	10	
Liddelow and Henry <sup>18</sup>	2010	0	Nobel	Ball	12–36	35	
Büttel et al <sup>33</sup>	2012	0	Straumann	Ball	24–36	20	
Grandi et al <sup>86</sup>	2012	0	JD Evolution	Ball	12	42	
Total (9)	2006–2012	0		Unsplinted	12-60	234	
Early							
Walton et al <sup>19</sup>	2009	42	Straumann	Ball	12	42	
Walton et al <sup>19</sup>	2009	42	Straumann	Ball	12	44	
Cehreli et al <sup>73</sup>	2010	42	Straumann, Nobel	Ball	60	28	
Al-Nawas et al <sup>77</sup>	2012	42	Straumann	Locator	12	91	
Alsabeeha et al <sup>16</sup>	2011	42	Southern, Neoss	Ball and locator	12	36	
El-Sheikh et al <sup>90</sup>	2012	28	Straumann	Ball	12	20	
Total (5)	2009–2012	28-42		Unsplinted	12-60	261	
Conventional							
Gotfredsen and Holm <sup>57</sup>	2000	90	Astra	Ball	12-60	15	
Karabuda et al <sup>59</sup>	2002	90	Frialit, PittEasy	Ball	12-40	18	
Lambrecht et al <sup>62</sup>	2003	112	Straumann	Ball	120	11	
Lambrecht et al <sup>62</sup>	2003	112	Straumann	Telescope	120	23	
Cune et al <sup>63</sup>	2004	117	Frialoc	Ball	12	18	
Cooper et al <sup>71</sup>	2008	90	Astra	Ball	6	59	
Kleis et al <sup>93</sup>	2010	105	3i-Biomet	Ball, L, O-ring	12	60	
Akoglu et al <sup>76</sup>	2011	56	Straumann, Astra, Zimmer	Ball	60	36	
Cakarer et al <sup>78</sup>	2011	60	Straumann, Nobel, Frialit, Swiss-Plus, Biohorizons, Bio-Lok	Ball	12-60	19	
de Kok et al <sup>79</sup>	2011	56	Astra	Ball	12	10	
Harder et al <sup>94</sup>	2011	60	Camlog	Ball	35–52	11	
El-Sheikh et al <sup>91</sup>	2012	70	Straumann	Locator	24	10	
El-Sheikh et al <sup>91</sup>	2012	70	Straumann	Locator	24	10	
Total (11)	2000-2012	56-117		Unsplinted	12–120	300	

NR = not reported.

These studies were pooled in order to have sufficient data for performing a meta-analysis in accordance with a previous meta-analysis on the same topic.<sup>96</sup> When interpreting the results, it also has to be considered that little evidence is available on the loading protocols for implant-supported overdentures in the treatment of the edentulous maxilla.

Retrospective studies were excluded from this systematic review. One has to distinguish between several types of bias in retrospective reports. Firstly, patient related parameters might only be retrieved from patient records. Especially in university hospitals, record-keeping is difficult because it often involves several persons due to high staff turnover as well as the fact that implant patients are often seen by different specialists. Secondly, investigated parameters are mostly not predefined, thus relevant data may not be documented. Furthermore, handling of missing data is rarely reported and

Implants/ Patient	Implants placed	Implants failed (at 1 y)	Total survived (failed)	Reported survival rate (%)
2	20	1	19 (1)	96.4
2	34	0	34 (0)	100
4	88	5	83 (5)	97.7
4	156	2	154 (2)	98.7
1	17	3	14 (3)	82.4
2	38	7	31 (7)	81.6
2	20	4	16 (4)	94
1	23	0	23 (0)	100
2	40	0	38 (2)	100
2	84	0	84 (0)	100
1 or 2 or 4	520	22	496 (24)	81.6–100
1	42	0	42 (0)	NR
2	88	7	81 (7)	NR
2	56	0	44 (12)	100
2	182	5	177 (5)	96.6
1	36	2	34 (2)	
1	20	0	20 (0)	100
1 or 2	424	14	398 (26)	96.6-100
2	31	1	30 (1)	100
2 or 4	52	1	51 (1)	NR
2	22	0	22 (0)	100
> 2	91	0	85 (6)	NR
2	36	4	32 (4)	93.9
2	118	5	98 (20)	95.9
2	120	8	112 (8)	90.4
2	72	0	72 (0)	100
2	38	0	38 (0)	NR
2	00	Ū	00(0)	
2	20	0	20 (0)	100
1	11	1	10 (1)	NR
2	20	0	20 (0)	100
3	30	1	29 (1)	98
 1/2/3/4	661	21	619 (42)	90.4–100

such patient records might have been entirely excluded. Thirdly, it might be unclear on which basis patients are selected for a retrospective analysis. They might be included for convenience and availability. Patients with the worst outcomes might refuse further cooperation or seek treatment elsewhere and no longer be available for follow-up.<sup>97</sup> Therefore retrospective studies might be subject to an inclusion bias, underestimating implant failures or other adverse events.

#### Interpretation of Findings

The current systematic review found some contradicting evidence between the comparative studies and those prospective studies, which did not compare different loading protocols. Whereas the meta-analysis of studies with matched intervention groups shows a tendency to favor conventional loading protocols for the overdenture treatment of the edentulous mandible, some of the remainder studies reported better survival rates for immediate loading. Although mostly not reported on, patient selection for innovative immediate loading protocols may be biased by pressure for success, leading to selection of patients with few or no risk factors such as smoking, diabetes, or poor bone quality. As there is no independent control group in these studies, the inclusion bias remains unidentified. This may result in excellent success rates, which may not be reproducible in everyday practice where patients with risk factors are encountered frequently. In contrast, the comparative high evidence studies with matched intervention groups statistically tend to favor conventional loading and also found no significant difference between early and conventional loading. This discrepancy highlights the importance of developing well-designed research protocols and carefully conducting clinical studies in order to provide a high level of evidence for conscious clinical decision-making.

To address concerns about statistical versus clinical significance the results were reported as relative risks/ risk differences along with their 95% Cl. They represent a "common measure of combined statistical and clinical significance because it provides a direct assessment of the treatment effect size."<sup>98</sup>

Whereas numerous advantages of immediate loading were mentioned in the introduction, shortcomings have also to be discussed. Astonishingly, few patientcentered benefits of immediate implant loading in overdenture treatment are documented. Most studies aim to demonstrate the equality of the procedure compared to conventional loading with regard to implant survival or peri-implant bone loss. However, patients will benefit earlier from the stabilization of their denture than with conventional loading protocols.<sup>61</sup> There are further clinical considerations for immediate loading protocols which are also poorly investigated, but deserve mentioning. When the superstructure is inserted on the day of surgery or shortly after, the soft tissues are still traumatized from surgery and will in some cases guickly change morphology in the weeks following the intervention.<sup>85</sup> Thus, relines are frequently necessary during this adaptive period with implant-supported overdentures,<sup>52</sup> creating additional cost and multiple clinical visits.<sup>99</sup> Another shortcoming of immediate loading is the necessity to take an impression when the sutures are still in place and the

### Table 5 Studies on Loading Protocols for Maxillary Implant-Supported Overdentures with Splinted Attachments

Study	Year	Loading time (d)	Brand	Attachment type	Observation period (mo)	Patients	
Immediate	Tear	time (u)	Brailu	type	penou (iiio)	Fallents	
Degidi and Piattelli <sup>65</sup>	2005	2	XiVe	Bar	24	20	
Cannizzaro et al <sup>25</sup>	2007	0	Zimmer	Bar	12	12	
Pieri et al <sup>72</sup>	2009	2	Nobel	Bar	12	22	
Total (3)	2005–2009	0–2		Splinted	12–24	54	
Early							
Van Assche et al <sup>89</sup>	2012	42	Straumann	Bar	24	12	
Total (1)	2012	42		Splinted	24	12	
Conventional							
Mericske-Stern et al <sup>60</sup>	2002	120	Straumann	Bar	12-108	41	
Cakarer et al <sup>78</sup>	2011	60	Straumann, Nobel, Frialit, Swiss-Plus, Biohorizons, Bio-Lok	Bar	12-60	1	
Katsoulis et al <sup>82</sup>	2011	90	Nobel	Bar	24	28	
Mangano et al <sup>84</sup>	2011	120	Leone	Bar	12-60	34	
Slot et al <sup>88</sup>	2012	90	Astra	Bar	12	50	
Total (5)	2002–2012	60–120		Splinted	12–108	154	

NR = not reported.

#### Table 6 Studies on Loading Protocols for Maxillary Implant-Supported Overdentures with Unsplinted Attachments

Study	Year	Loading time (d)	Brand	Attachment type	Observation period (mo)	Patients	
Immediate							
Eccellente et al <sup>80</sup>	2011	0	Ankylos	Telescope	12–54	45	
Total (1)	2011	0		Unsplinted	12–54	45	
Early							
Weng and Richter <sup>69</sup>	2007	42	3i-Biomet	Telescope	12–48	14	
Total (1)	2007	42		Unsplinted	12–48	14	
Conventional							
Lambrecht et al <sup>62</sup>	2003	168	Straumann	Telescope	120	1	
Lambrecht et al <sup>62</sup>	2003	168	Straumann	Ball	120	2	
Cakarer et al <sup>78</sup>	2011	60	Straumann, Nobel, Frialit, Swiss-Plus, Biohorizons, Bio-Lok	Ball	12–60	10	
Total (2)	2003–2011	60–168		Unsplinted	12–120	13	
NR - not reported							-

NR = not reported.

# Table 7a Results of Quality Assessment of the Comparative Studies Analyzed (Newcastle – Ottawa Scale for assessment of Cohort Studies)

Study	Year	Design	Selection (max 4*)	Comparability (max 3*)	Outcome (max 3*)
Røynesdal et al <sup>55</sup>	2001	Cohort	* * *	* * *	* *
Stephen et al <sup>35</sup>	2007	Cohort	* *	* *	* *
Alfadda et al <sup>47</sup>	2009	Cohort	* * *	*	* *

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Implants/ patient	Implants placed	Implants failed (at 1 y)	Total survived (failed)	Reported survival rate (%)
4	161	2	159 (2)	98.7
4	48	1	47 (1)	97.9
4 or 5	103	3	100 (3)	97.1
4 or 5	312	6	306 (6)	97.1–98.7
6	72	1	61 (11)	NR
6	72	1	61 (11)	NR
4	173	6	153 (20)	98.3
4	4	0	4 (0)	NR
4 or 5 or 6	120	1	119 (1)	99.2
4	152	2	148 (4)	97.4
4 or 6	250	3	247 (3)	99.3
4 or 5 or 6	699	12	671 (28)	97.4–99.3

Implants/ patient	Implants placed	Implants failed (at 1 y)	Total survived (failed)	Reported survival rate (%)
4	180	4	176 (4)	97.8
4	180	4	176 (4)	97.8
2	28	0	28 (0)	NR
2	28	0	28 (5)	NR
4	4	0	4 (0)	100
2	4	0	4 (0)	100
2	20	0	16 (4)	NR
2 or 4	28	0	24 (4)	Up to 100

surgical site might still be vulnerable. The latter will be contaminated with impression material or, even worse, with methyl-methacrylate resin monomer in case the attachments are engaged by means of direct polymerization. Last but not least, after surgery patients may be exhausted and traumatized and may not wish to extend their clinical appointment beyond the most necessary procedures. This might be especially true for overdenture treatment, because edentulism increasingly occurs in old age when the acceptance of long and invasive treatments is largely diminished<sup>100</sup> and treatment sessions have to be tailored to the patient's compliance, fragility, and general health.<sup>101</sup>

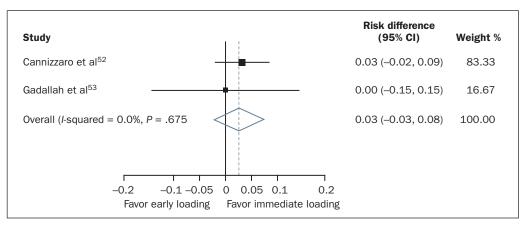
Early loading, on the other hand, eliminates these shortcomings to a great extent without challenging the patient's compliance with several months of compromised function. The patient has recovered from surgery, the sutures are removed, the incision has healed, and the vulnerable interface between implant and peri-implant tissues is no longer at risk from contamination or trauma. However, it remains unclear if early loading avoids the unfavorable necessity of an early reline. Early loading has become more frequently used with the advent of improved implant surfaces and the results of the present review support adopting this protocol.<sup>102</sup> It may be an acceptable compromise, as it alleviates the disadvantages of immediate (lower implant survival rate) and conventional loading protocols (prolonged compromised function).

This review suggests only a tendency for the superiority of one loading protocol with regard to the 1-year implant failure rate, as appropriate clinical studies are too few to reach statistical significance. Nevertheless, all three proposed loading protocols present excellent survival rates which are in the range of or superior to other state-of-the-art treatment options in dentistry. Therefore, other factors like patient-centered benefits and disadvantages or the costs of prosthodontic aftercare may also be considered for clinical decisionmaking with regard to loading protocol for an individual patient.

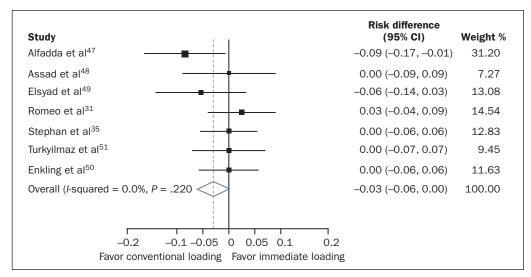
### Table 7b Results of Quality Assessment of the Comparative Studies Analyzed (The Cochrane Collaboration tool for the assessment of the risk of bias for Randomized Controlled Trials)

Study	Year	Design	Risk of Bias
Romeo et al <sup>31</sup>	2002	RCT	Unclear
Assad et al <sup>48</sup>	2007	RCT	Unclear
Canizzarro et al <sup>52</sup>	2008	RCT	Low
Enkling et al <sup>50</sup>	2010	RCT	Low
Ma et al <sup>54</sup>	2010	RCT	Low
Elsyad et al <sup>49</sup>	2012	RCT	Unclear
Gadallah et al <sup>53</sup>	2012	RCT	Low
Turkyilmaz et al <sup>51</sup>	2012	RCT	High

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**Fig 2** Forest plot for the comparison of early versus immediate loading protocols with regard to 1-year implant survival.



**Fig 3** Forest plot for the comparison of conventional versus immediate loading protocols with regard to 1-year implant survival.

# Individual Decision-Making for a Particular Loading Concept

Recommendations for the use of either immediate or early loading concepts were proposed based on clinical parameters like bone quality, primary stability of more than 35 Ncm insertion torque, or resonance frequency analysis (RFA) testing. This review was able to identify that most investigators would prefer to establish an initial high insertion torque ( $\geq$  35 Ncm) or ISQ value ( $\geq$  60) before engaging the implant for an immediate or early loading protocol. These items might be of special interest in immediate loading protocols to avoid overloading of the implant-bone interface early after implant placement. High primary stability is considered to be beneficial when the implant is prone to early instability due to bone remodeling.<sup>103</sup> The empirical evidence of the reviewed literature with regard to those parameters seems to result in high survival rates of the immediately loaded implants.

On the other hand, most studies with conventional loading protocols assessed the implant stability with either a subjective clinical assessment and/or the standard success criteria prior to abutment connection and loading. There, high primary stability seems to be less important because of the prolonged healing time and is based on the experience in implant dentistry from the last four decades.<sup>20</sup>

Table 8 Studies Reporting on Clinical Criteria Applied Prior to Implant Loading				
Study	Year	Loading protocol	Arch	Criteria applied prior to immediate/early loading
Romeo et al <sup>31</sup>	2002	Immediate	Mandible	Insertion torque $\geq$ 35 Ncm
Stricker et al <sup>36</sup>	2004	Immediate	Mandible	Insertion torque $\ge$ 35 Ncm
Degidi and Piattelli65	2005	Immediate	Mandible	RFA ISQ value = 60
Degidi and Piattelli <sup>65</sup>	2005	Immediate	Maxilla	RFA ISQ value = 60
Weischer et al <sup>66</sup>	2005	Immediate	Mandible	Insertion torque $\geq$ 30 Ncm
Cannizzaro et al <sup>25</sup>	2007	Immediate	Maxilla	Insertion torque $\geq$ 45 Ncm
Marzola et al <sup>34</sup>	2007	Immediate	Mandible	Insertion torque between 20–50 Ncm
Stephan et al <sup>35</sup>	2007	Immediate	Mandible	Insertion torque $\geq$ 30 Ncm
Wittwer et al <sup>70</sup>	2007	Immediate	Mandible	Periotest values between -7 to -1
Cannizzaro et al <sup>52</sup>	2008	Immediate	Mandible	Insertion torque $\geq$ 48 Ncm
Pieri et al <sup>72</sup>	2009	Immediate	Maxilla	Insertion torque $\geq$ 30 Ncm; RFA ISQ value $\geq$ 60
Enkling et al <sup>50</sup>	2010	Immediate	Mandible	Insertion torque $\geq$ 35 Ncm
Kronstrom et al <sup>17</sup>	2010	Immediate	Mandible	Insertion torque values between 20-45 Ncm
Liao et al <sup>75</sup>	2010	Immediate	Mandible	Insertion torque $\ge$ 35 Ncm
Liddelow and Henry <sup>18</sup>	2010	Immediate	Mandible	Insertion torque $\geq 45$ Ncm; RFA ISQ value $\geq 60$
Stoker and Wismeijer <sup>85</sup>	2011	Immediate	Mandible	Insertion torque $\ge$ 35 Ncm
Büttel et al <sup>33</sup>	2012	Immediate	Mandible	Insertion torque $\geq$ 25 Ncm
Grandi et al <sup>86</sup>	2012	Immediate	Mandible	Insertion torque $\geq$ 40 Ncm
Cannizzaro et al <sup>52</sup>	2008	Early	Mandible	Insertion torque $\ge$ 48 Ncm
Cehreli et al <sup>73</sup>	2010	Early	Mandible	Abutment torque = 35 Ncm
Alsabeeha et al <sup>16</sup>	2011	Early	Mandible	Insertion torque $\geq$ 45 Ncm; RFA ISQ value 66.6–75.1
Lethaus et al <sup>83</sup>	2011	Early	Mandible	Abutment torque $\geq$ 35 Ncm
El-Sheikh et al <sup>90</sup>	2012	Early	Mandible	Insertion torque $\ge$ 35 Ncm
Van Assche et al <sup>89</sup>	2012	Early	Maxilla	Insertion torque $\geq$ 15 Ncm

RFA = resonance frequency analysis; ISQ = implant stability quotient.

#### CONCLUSIONS

Although all three loading protocols provide high survival rates, early and conventional loading protocols are still better documented than immediate loading and seem to result in fewer early implant failures compared to immediate loading.

Immediate loading of single implants for mandibular overdentures cannot be recommended until further evidence is available.

There are only a few prospective case-series available to document the feasibility of immediate loading of implants in the maxilla, but employing four or more implants seem to provide high survival rates.

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# Consensus Statements and Clinical Recommendations for Implant Loading Protocols

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# **INTRODUCTORY REMARKS**

This report summarizes the statements and clinical recommendations for implant loading protocols as per consensus agreement among the participants at the 5th ITI Consensus Conference.

Group 4 was composed of participants from 13 different countries and of various specialties in dental medicine. Prior to the conference, scientific evidence on conventional, early, and immediate implant loading

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protocols was evaluated by four systematic reviews according to well-differentiated clinical situations: single implant crowns, extended edentulous spaces in partially edentulous patients, edentulous jaws with fixed prostheses, and edentulous jaws with overdenture prostheses. The primary outcome was implant survival. In addition, number of implants, prosthetic design, marginal bone loss, stability of peri-implant soft tissue, prosthetic failures, treatment modifiers, esthetics, and patient satisfaction were considered as secondary outcomes.

Reports from previous consensus conferences<sup>1,2</sup> stated that conventional and early implant loading are well-established protocols and should be considered routine. In particular, several clinical studies<sup>3–5</sup> demonstrated the high predictability of early loading protocols when compared to conventional healing times, showing no differences in regard to implant survival rates. In this context, the design of the systematic reviews presented at the 5th ITI Consensus Conference aimed to assess whether immediate loading showed similar clinical outcomes to early and conventional loading.

At the conference, the authors presented their methodology, results, and conclusions for the four systematic reviews to all participants in the loading protocols group. These manuscripts provided substance for a comprehensive and methodical discussion leading to the unbiased formulation of consensus statements, clinical recommendations, and directions for future research on implant loading protocols. The group's determinations were then presented to the plenum, where additional input was collected for the preparation of this final report.

#### **Definition of Terms**

The definitions of loading protocols presented by Weber et al<sup>2</sup> were used for the calibration of the systematic reviews and endorsed without modifications by the group as follows:

 Conventional loading of dental implants is defined as being greater than 2 months subsequent to implant placement.

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- *Early loading* of dental implants is defined as being between 1 week and 2 months subsequent to implant placement.
- *Immediate loading* of dental implants is defined as being earlier than 1 week subsequent to implant placement.

### Disclosure

All the group members were asked to reveal any conflicts of interest potentially influencing the outcomes of the consensus work. No such conflicts were identified.

# LOADING PROTOCOLS FOR SINGLE IMPLANTS IN PARTIALLY EDENTULOUS PATIENTS

### **Focus Question**

Does immediate loading of single-implant crowns render different results from early and conventional loading with respect to implant survival rate, marginal bone loss, stability of peri-implant soft tissue, esthetics, and patient satisfaction?

#### **Consensus Statements**

- 1. In general, there is a high level of comparative evidence supporting the use of both immediate and conventional loading of single-implant crowns in terms of implant survival and marginal bone level stability.
- 2. A minimal insertion torque in the range of 20 to 45 Ncm, a minimal implant stability quotient (ISQ) in the range of 60 to 65, and the need for simultaneous bone augmentation were the most common inclusion/exclusion criteria.
- 3. There are limited data comparing immediate and conventional loading in terms of stability of the papilla height and of the facial mucosal margin.
- Esthetics and patient satisfaction were measured only in a few trials that compared immediate and conventional loading, rendering insufficient data to draw conclusions.

#### **Treatment Guidelines**

The recommendations for immediate and early loading of single-implant crowns are limited to situations fulfilling the following prerequisites:

- Primary implant stability (insertion torque ≥ 20 to 45 Ncm and/or implant stability quotient (ISQ) ≥ 60 to 65
- Absence of systemic or local contraindications (eg, parafunctional activities, large bone defects, need for sinus floor elevation)
- When the clinical benefits exceed the risks

- For the anterior and premolar regions, immediate and early loading of single-implant crowns are predictable procedures in terms of implant survival and stability of the marginal bone. However, data regarding soft tissue aspects are not conclusive enough to recommend immediate or early loading of single-implant crowns in esthetically demanding sites as a routine procedure. Immediate loading in such sites should be approached with caution and by experienced clinicians.
- 2. For the mandibular molar region, immediate and early loading of single-implant crowns is a predictable procedure and can generally be recommended in cases where clinical benefits are identified.
- 3. The low amount of data on immediate and early loading of single-implant crowns in the maxillary molar region does not allow general recommendation of these loading procedures. In these sites, conventional loading should be the procedure of choice.

# LOADING PROTOCOLS FOR PARTIALLY EDENTULOUS PATIENTS IN EXTENDED EDENTULOUS SITES

#### **Focus Question**

In partially edentulous patients with extended edentulous sites, what is the effect of immediate implant loading with implant-supported fixed dental prostheses compared to early or conventional loading on implant survival?

#### **Consensus Statements**

- Based on limited scientific evidence and under strict selection criteria, immediate implant loading in partially edentulous patients with healed posterior extended edentulous sites presents similar implant survival rates compared to early or conventional loading.
- 2. Insufficient evidence exists to support immediate implant loading in anterior maxillary or mandibular extended edentulous sites.
- 3. Insertion torque, ISQ values, implant length, the need for bone augmentation procedures, the timing of implant placement, smoking, and the presence of parafunctional habits were common criteria in selecting a loading protocol.

#### **Treatment Guidelines**

1. In the absence of modifying factors, early loading of solid-screw-type implants with a microtextured surface after 4 to 8 weeks in extended edentulous sites of partially edentulous patients is a predictable treatment approach.

- 2. Immediate loading of posterior implants in healed extended edentulous sites seems to be predictable. However, in such cases immediate implant loading is of limited clinical benefit.
- 3. Immediate loading of anterior implants in extended edentulous sites of partially edentulous patients should be approached with caution and by experienced clinicians, since insufficient evidence exists to support such treatment.
- 4. When immediate implant loading is intended, the following criteria should be considered: primary implant stability, need for substantial bone augmentation, implant design and dimension, occlusal factors, patient habits, systemic health, and clinician experience.

#### LOADING PROTOCOLS FOR FIXED PROSTHESES IN EDENTULOUS JAWS

#### **Focus Question**

In edentulous patients, what is the effect of immediate implant loading with fixed prostheses compared to early and conventional loading on implant and prosthesis survival?

#### **Consensus Statements**

- 1. The existing literature provides high evidence that immediate loading of microtextured dental implants with one-piece fixed interim prostheses in both the edentulous mandible and maxilla is as predictable as early and conventional loading.
- 2. Inclusion criteria, such as insertion torque  $\geq$  30 Ncm, ISQ  $\geq$  60, and minimal implant length  $\geq$  10 mm, have been used in the majority of the included studies.
- 3. The number of implants used to support a fixed prosthesis varied from 2 to 10 in the mandible and 4 to 12 in the maxilla.

#### **Treatment Guidelines**

- The treatment of edentulism with fixed implantsupported prostheses is complex according to the ITI SAC criteria. Therefore, careful case selection and treatment planning, as well as adequate knowledge, skill, and experience of the clinician(s) performing the procedures are key. Immediate, early, or conventional loading with one-piece fixed interim prostheses have demonstrated high implant and prosthesis survival rates and can be recommended for the mandible and maxilla.
- Patient-centered benefits of immediate loading include the immediate fixed restoration of function, the reduction of postoperative discomfort caused by a removable interim prosthesis, as well as the reduction of overall treatment time.

- The number, size, and distribution of implants for a full-arch fixed prosthesis needs to be based on the implant-prosthodontic plan, arch form, and bone volume, regardless of the loading protocol.
- 4. Primary implant stability is critical for predictable osseointegration regardless of the loading protocol. It is suggested that prior to immediate loading in the edentulous arch, the primary stability of each implant must be confirmed.
- 5. The need for simultaneous procedures such as bone augmentation or sinus floor elevation is considered a relative contraindication for immediate loading.

#### LOADING PROTOCOLS FOR IMPLANT-SUPPORTED OVERDENTURES IN EDENTULOUS JAWS

#### **Focus Question**

In edentulous jaws with implant-supported overdentures, what is the effect of immediate implant loading versus early or conventional loading on implant survival at 1 year?

#### **Consensus Statements**

- Current clinical research supports high survival with the use of threaded, microtextured implants with a minimum diameter of 3 mm for the support of overdenture prostheses when used with immediate, early, or conventional loading protocols. Limited evidence exists for immediate loading of implants supporting overdentures in the maxilla.
- 2. Descriptive material from the review in this group for immediate loading by Schimmel et al lists inclusion criteria of: insertion torque ( $\geq$  30 Ncm), ISQ value ( $\geq$  60), two or more implants in the mandible, or four or more implants in the maxilla.
- 3. Splinting of implants and the type of attachment system had no effect on 1-year survival rate compared to freestanding implants.

#### **Treatment Guidelines**

- 1. The intended loading protocol should be selected considering implant-prosthodontic parameters as well as functional, psychosocial, and financial aspects and patient preference.
- 2. Early loading represents a satisfactory treatment modality in the management of the edentulous jaw, when using implants to support/retain an overdenture prosthesis, and can be recommended as routine in the absence of modifying factors.
- 3. Immediateloadingprotocolsinimplant-supported/ retained overdentures appear predictable. The available research arbitrarily uses an insertion torque of 30 Ncm or greater and/or an ISQ value of 60 or greater. The evidence for immediate implant

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loading in the maxilla is less compelling. However, there is no reliable pretreatment predictor that has determined conclusively that the clinician can perform an immediate loading procedure.

 Given the lack of research, the use of a single implant in an immediately loaded fashion may not be indicated for support/retention of overdenture prostheses.

#### **GENERAL STATEMENTS**

#### General Clinical Recommendations for Loading Protocols

Conventional implant loading is predictable in all clinical situations and is particularly recommended in the presence of treatment modifiers such as poor primary implant stability, substantial bone augmentation, implants of reduced dimensions, and compromised host conditions.

# General Recommendations for Future Research

Future research should ideally evaluate the following aspects of loading protocols in oral implantology:

- 1. Timing of implant placement following tooth extraction and the time of implant loading as associated variables
- Validity of selection criteria as predictors for treatment outcomes, including clinically validated thresholds for resonance frequency analysis and/ or insertion torque
- Clinical research for implant loading protocols, ideally including an Intention-to-Treat (ITT) analysis.
- 4. Surrogates that can be applied presurgically to determine the possibility of immediate implant loading

- Outcome of immediate loading protocols in situations with a clear clinical benefit, such as anterior implants and implants placed into fresh extraction sockets (type 1 placement)
- 6. Patient-centered outcomes (eg, psychosocial, functional) and clinical benefits associated with immediate implant placement and loading
- 7. Esthetic outcome of an intervention using reproducible methods, standardized baseline measurements, and validated indices
- 8. Cost-effectiveness of different implant loading concepts to support/retain overdentures
- 9. Effect on implant survival when implants are loaded between 1 and 4 weeks after implant placement

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### **GROUP 5**

### Prevention and Management of Biologic and Technical Implant Complications

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#### **Review Papers Submitted for Discussion:**

The Effects of Anti-infective Preventive Measures on the Occurrence of Biologic Implant Complications and Implant Loss: A Systematic Review Giovanni E. Salvi/Nicola U. Zitzmann

**Improvements in Implant Dentistry over the Last Decade: Comparison of Survival and Complication Rates in Older and Newer Publications** Bjarni E. Pjetursson/Asgeir G. Asgeirsson/Marcel Zwahlen/Irena Sailer

The Therapy of Peri-implantitis: A Systematic Review Lisa J. A. Heitz-Mayfield/Andrea Mombelli

**Consensus Statements and Clinical Recommendations for Prevention and Management of Biologic and Technical Implant Complications** Lisa J. A. Heitz-Mayfield/Ian Needleman/Giovanni E. Salvi/Bjarni E. Pjetursson

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### The Effects of Anti-infective Preventive Measures on the Occurrence of Biologic Implant Complications and Implant Loss: A Systematic Review

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Purpose: To systematically appraise whether anti-infective protocols are effective in preventing biologic implant complications and implant loss after a mean observation period  $\geq$  10 years after loading. Materials and Methods: An electronic search of Medline via PubMed and Embase via Ovid databases complemented by manual search was conducted up to October 31, 2012. Studies were included provided that they were published in English, German, French, or Italian, and conducted on  $\geq$  20 partially and fully edentulous patients with dental implants and regular ( $\geq 1 \times /y$ ear) supportive periodontal therapy (SPT) over a mean observation period  $\geq$  10 years. Assessment of the identified studies and data extraction were performed independently by two reviewers. Authors were contacted if required. Collected data were reported by descriptive methods. Results: The initial electronic search resulted in the identification of 994 titles from Medline via PubMed and 531 titles from Embase via Ovid databases, respectively. After elimination of duplicate titles and exclusion of 60 full-text articles, 143 articles were analyzed, resulting in 15 studies eligible for qualitative analysis. The implant survival rate ranged from 85.7% to 99.2% after a mean observation period  $\geq$  10 years. One comparative study assessed the effects of regular SPT on the occurrence of biologic complications and implant loss. Overall, regular diagnosis and implementation of anti-infective therapeutic protocols were effective in the management of biological complications and prevention of implant loss. Residual probing depths at the end of active periodontal therapy and development of reinfection during supportive periodontal therapy (SPT) represented a significant risk for the onset of peri-implantitis and implant loss. Comparative studies indicated that implant survival and success rates were lower in periodontally compromised vs noncompromised patients. Conclusions: In order to achieve high long-term survival and success rates of dental implants and their restorations, enrollment in regular SPT including anti-infective preventive measures should be implemented. Therapy of peri-implant mucositis should be considered as a preventive measure for the onset of peri-implantitis. Completion of active periodontal therapy should precede implant placement in periodontally compromised patients.INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):292–307. doi: 10.11607/jomi.2014suppl.g5.1

**Key words:** bone loss, complication, dental implants, implant loss, implant survival, peri-implantitis, prevention, prophylaxis, supportive periodontal therapy

Outcomes from long-term clinical studies demonstrated that supportive periodontal therapy (SPT) after completion of active therapy is an essential component for the prevention of disease recurrence (eg, caries and periodontitis) and tooth loss.<sup>1–5</sup> Patients treated for advanced periodontitis and subsequently enrolled in a regular SPT program experienced a mean incidence of tooth loss ranging between 2% and 5% over an observation period of 10 years.<sup>1,4,6-8</sup> On the other hand, lack of enrollment in or adherence to a regular SPT program was associated with disease progression and higher rates of tooth loss.<sup>5,9,10</sup> In the majority of patients complying with SPT, periodontal disease progression and tooth loss occurred rarely.<sup>10</sup> In patients not adhering to SPT, however, a sevenfold increase in tooth loss due to periodontitis was reported compared with patients adhering to SPT over a mean period of 10 years following active periodontal therapy.<sup>10</sup> Despite the evident benefits of SPT following active periodontal therapy, only a minority of patients comply with the recommended recall intervals.<sup>11–13</sup>

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It should be noted that residual pocket probing depths (PPD)  $\ge$  6 mm, full-mouth bleeding on probing (BoP+)  $\ge$  30%, and heavy smoking (ie,  $\ge$  20 cigarettes per day) after active periodontal therapy represented risks for periodontitis progression and tooth loss over a mean period of 11 years of SPT.<sup>14</sup>

Over the last decades, placement of dental implants with high long-term survival and success rates became a routine procedure in the oral rehabilitation of fully<sup>15–19</sup> and partially edentulous patients,<sup>20–24</sup> respectively. While survival rates describe implants or prostheses still in place and functioning, implant prosthetic success takes any technical and biologic complications into account. The latter comprise peri-implant diseases including peri-implant mucositis and peri-implantitis.<sup>25</sup>

Based on the fact that biologic complications around dental implants are characterized by similar etiologic factors as those involved in the development of periodontal diseases,<sup>26</sup> it may be postulated that long-term survival and success rates of dental implants can be achieved by applying the same principles used during supportive therapy of natural teeth. A cause-effect relationship between bacterial biofilms and the development of an inflammatory response (ie, peri-implant mucositis) was demonstrated in humans when bacterial biofilms were allowed to accumulate around dental implants.<sup>27-29</sup> If left untreated, periimplant mucositis may lead to progressive destruction of peri-implant marginal bone (peri-implantitis) and, eventually, implant loss. Partially edentulous patients with high plague scores before implant placement experienced more implant losses than those with lower plaque levels.<sup>30</sup> Moreover, peri-implant mucositis represented a common finding among patients not adhering to a regular SPT program including implant maintenance.31-33

Periodontitis-susceptible patients treated for their periodontal conditions may experience more biologic complications and implant losses compared with non-periodontitis patients.<sup>34</sup> Outcomes from several studies indicated that in partially edentulous patients treated for periodontitis and adhering to a regular SPT program, the remaining dentition acted as a reservoir for bacterial colonization around implants.<sup>35–40</sup>

Once osseointegration is established, evidence indicates that the use of clinical and radiographic parameters may be used for the long-term evaluation of peri-implant tissue conditions.<sup>41</sup> In 1997, a systematic diagnostic and anti-infective therapeutic approach for the prevention and treatment of peri-implant diseases was proposed.<sup>42</sup> This protocol, referred to as Cumulative Interceptive Supportive Therapy (CIST),<sup>42</sup> includes diagnostic and therapeutic procedures aimed at detecting and interfering at an early stage with the disease process. The diagnostic component includes the assessment of peri-implant bleeding on probing (BoP+), suppuration, peri-implant pocket probing depth (PPD), and radiographic crestal (ie, marginal) bone loss. Furthermore, long-term diagnostic monitoring of tissue conditions around dental implants should be performed at regular intervals. From a therapeutic point of view, infection control by nonsurgical mechanical debridement followed by the adjunctive delivery of antiseptics and in some cases, local or systemic antibiotics, should always precede surgical interventions of peri-implant lesions.<sup>42</sup>

Based on the fact that peri-implant tissue destruction is characterized by a chronic inflammatory process becoming evident after several years of recurrent biofilm exposure,<sup>8,43–45</sup> an observation time exceeding 5 years may be required to detect the onset of biologic implant complications. Outcomes of a multicenter retrospective comparative study indicated that a past history of treated periodontitis may not have a significant impact on implant failures up to 5 years after loading.<sup>46</sup> Moreover, conclusions from systematic reviews on implant therapy in patients with a history of treated periodontitis emphasized the necessity of reporting on long-term data of well-characterized patient samples with an appropriate size.<sup>34,47–49</sup>

Therefore, the aim of the present systematic review was to assess the effects of anti-infective preventive measures on the occurrence of biologic implant complications and implant loss after a mean observation period of at least 10 years.

#### **MATERIALS AND METHODS**

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) were adopted throughout the process of the present systematic review.<sup>50</sup>

#### **Focus Question**

The focus question for this review was developed using the PICO (population, intervention, comparison, outcome) criteria<sup>51</sup>: "In patients with osseointegrated dental implants, what are the effects of adherence to a regular SPT program on the occurrence of biological implant complications and implant loss?"

The PICO criteria used were as follows:

- Population: Patients with osseointegrated dental implants
- Intervention or exposure: Adherence to a regular SPT program
- Comparison: Lack of adherence to a regular SPT program
- Outcomes: Occurrence of biological implant complications and implant loss

#### **Search Strategy**

A comprehensive and systematic electronic search of Medline via PubMed and Embase via Ovid databases was conducted for articles published in the dental literature in English, German, French, and Italian up to October 31, 2012.

The following key words were used:

• Population:

MeSH terms: dental implantation OR dental implant OR dental implants

OR

Text words: oral implant OR oral implants OR dental implant OR dental implants OR implant dentistry OR dental

AND

Intervention:

MeSH terms: dental prophylaxis OR maintenance OR

Text words: prevention OR prophylaxis OR maintenance OR maintenance care OR implant maintenance OR supportive therapy OR supportive care OR supportive periodontal care OR supportive periodontal therapy OR recall AND

• Outcome:

MeSH terms: peri-implantitis OR mucositis OR alveolar bone loss OR bone resorption OR

Text words: periimplantitis OR peri-implantitis OR peri-implant disease OR peri-implant diseases OR mucositis OR peri-implant mucositis OR bone loss OR crestal bone loss OR marginal bone loss OR implant loss OR bone resorption OR implant failure OR implant survival OR implant success OR complication

A manual search of the reference lists of relevant articles published in the Journal of Periodontology, Journal of Oral Rehabilitation, Journal of Clinical Periodontology, Clinical Oral Implants Research, International Journal of Oral & Maxillofacial Implants, Implant Dentistry, Clinical Implant Dentistry and Related Research, International Journal of Periodontics and Restorative Dentistry, and International Journal of Prosthodontics was performed up to October 31, 2012.

#### **Study Selection**

**Inclusion Criteria.** Studies were included provided that they were published in English, German, French, or Italian and conducted in partially and/or fully edentulous patients with the intervention being the enrollment of  $\ge 20$  patients with dental implants adhering to a regular SPT program ( $\ge 1 \times$ /year) over a mean follow-

up of  $\geq$  10 years. In addition, publications reporting on fixed and/or removable implant-supported dental prostheses were considered.

Screening was performed independently by two reviewers (GES and NUZ). Eligibility assessment was performed first through titles and abstract analysis and second through full-text analysis. In order to avoid exclusion of potentially relevant articles, abstracts providing unclear results were included in the full-text analysis. If necessary, authors were contacted for clarifications on frequency and content of SPT. From all studies of potential relevance, full text was obtained for independent assessment by the two reviewers against the stated inclusion criteria. Any disagreement was resolved by discussion between the two reviewers. In the event of multiple publications on the same patient sample, relevant data on the primary and secondary outcome measures were extracted from each publication.

**Outcome Measures.** The primary outcome measure included:

• Implant loss after delivery of the prosthetic restoration

The secondary outcome measures included:

- Radiographic crestal (marginal) bone loss
- Bleeding on probing (BoP+), Gingival Index (GI), modified Sulcus Bleeding Index (mSBI), Plaque Index (PII), suppuration
- Pocket probing depth (PPD), mucosal recession (REC), probing attachment level (PAL)

**Exclusion of Studies.** Studies not reporting on the content and frequency of anti-infective preventive measures during SPT were excluded unless personal communications were available and the inclusion criteria were fulfilled. Furthermore, publications not reporting on the number of patients/implants assessed at the 10-year follow-up were excluded.

Animal studies, abstracts, letters to editors, narrative reviews, case reports, and studies with < 20 patients were excluded.

**Data Collection.** From the selected articles fulfilling the inclusion criteria, data addressing the primary and secondary outcome measures were extracted for analysis.

#### **Quality Assessment**

Quality analysis of nonrandomized studies including case-control and prospective and retrospective cohort studies was performed according to the Newcastle-Ottawa scale (NOS). Based on a system assigning a rank of one to nine stars, the NOS was developed to provide a simple tool for quality assessment of nonrandomized studies included in a systematic review.

#### **Data Synthesis**

Preliminary evaluation of the selected publications revealed considerable heterogeneity between the studies with respect to design, population characteristics, and modalities, content, and frequency of SPT. Consequently, a qualitative report of the data was planned by applying descriptive methods, and a quantitative data synthesis for meta-analysis was discarded.

#### RESULTS

According to the search strategy, a total of 1,525 titles were screened, followed by a full-text screening of 203 articles (Fig 1). Detailed assessment for eligibility was performed in 143 full texts and supplemented by direct author contact via email if required. A total of 15 studies were included in the systematic review (Table 1). Three studies not fulfilling the inclusion criterion of a mean observation period  $\geq$  10 years but adding substantial findings on patient subgroups with and without SPT<sup>64</sup> and with and without residual periodontal disease<sup>21,65</sup> were considered as supplemental information (Table 3). The quality assessment of the 12 cohort and 3 case-control studies was performed according to the Newcastle-Ottawa scale.

# Characteristics and Outcomes of the Included Studies

The oldest study included in this review reported data from 71 patients, who had been restored with 151 hollow-cylinder ITI implants and observed for a mean period of 14.1 years (range: 11.4 to 19.7 years).<sup>52</sup> Patients had been followed regularly in the Department of Prosthodontics at the University of Bern, Switzerland (41 patients) or in four private practices of ITI members in Switzerland (30 patients). According to personal communication, all patients received regular recalls (1 to 2 times per year) including SPT.<sup>52</sup> Plaque was scored at 38% of all implants; 32% showed BoP+ and there was a correlation between increased PPD, radiographic bone loss, and BoP+. Ten implants (6.6%) were affected by peri-implantitis, eight of which had to be removed.

Four studies reported different aspects from the same study cohort<sup>8,44,53,54</sup> with patients receiving implants after comprehensive periodontal treatment and examinations at 1 and 10 years (range: 8 to 12 years). Patients underwent SPT at regular intervals between 3 and 6 months at the university clinic or in private practice. Karoussis et al<sup>44</sup> focused on 53 patients treated with 112 hollow-screw implants, and distinguished between 8 patients being treated for chronic periodontitis (group A) and 45 patients with no history of periodontal disease (group B). The 10-year peri-

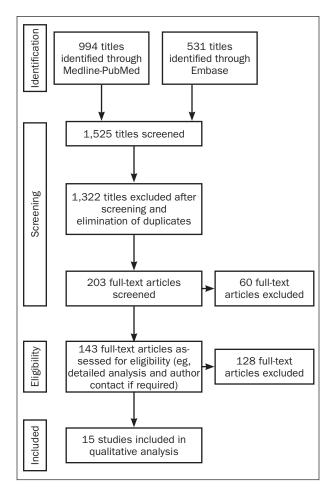


Fig 1 Flow diagram of the systematic review.

implantitis incidence was higher in patients in group A (28.6%) than among those in group B (5.8%). Among patients in group A, there was a tendency for less favorable survival in smokers (80%) versus nonsmokers (100%).<sup>44</sup> In following studies from the same research group,<sup>8,53,54</sup> a total of 89 patients with 179 implants of the ITI Dental Implant System (former Bonefit System, Institut Straumann) were reevaluated at 10 years. In addition to the 112 hollow screws (HS), 49 hollow cylinder (HC) and 18 angulated hollow cylinder implants (AHC) had been placed. Karoussis et al<sup>8</sup> compared the 179 implants with matching contralateral control teeth. While the Plaque Index (PII) was similar at implants and teeth, PPD, BoP+ and radiographic bone loss was higher at implants than teeth.8 Peri-implantitis (defined as PPD  $\geq$  5 mm, BoP+, and presence of radiographic bone loss) was found at 15.4% of all implants with the greatest incidence at HC (29%) compared to HS (10%) and AHC (12%).53 With respect to peri-implantitis incidence among different types of restorations, it was reported that implant-supported single crowns were most frequently affected (29%), compared to implants

Focus question	In patients with osseointegrated dental implants, what are the effects of adherence to a regular supportive periodontal therapy (SPT) program on the occurrence of biological implant complications and implant loss?
Search Strategy	
Population	Patients with osseointegrated dental implants
Intervention or exposure	Adherence to a regular SPT program
Comparison	Lack of adherence to a regular SPT program
Outcome	Occurrence of biological implant complications and implant loss
Search combination	Population:         MeSH terms: dental implantation OR dental implant OR dental implants         OR         Text words: oral implant OR oral implants OR dental implant OR dental implants OR implant dentistry OR dental         AND         Intervention:         MeSH terms: dental prophylaxis OR maintenance         OR         Text words: prevention OR prophylaxis OR maintenance OR maintenance care OR implant maintenance OR supportive therapy OR supportive care OR supportive periodontal care OR supportive periodontal therapy OF recall         AND         Outcome:         MeSH terms: peri-implantitis OR mucositis OR alveolar bone loss OR bone resorption         OR         Text words: peri-implantitis OR peri-implant disease OR peri- implant diseases OR mucositis OR peri-implant disease OR peri- implant diseases OR
Database search	implant loss OR bone resorption OR implant failure OR implant survival OR implant success OR complication
Language	English, German, French, Italian
Electronic	Medline via PubMed, Embase via Ovid
Journals	Journal of Periodontology, Journal of Oral Rehabilitation, Journal of Clinical Periodontology, Clinical Oral Implant Research, International Journal of Oral & Maxillofacial Implants, Implant Dentistry, Clinical Implant Dentistry an Related Research, International Journal of Periodontics and Restorative Dentistry, and International Journal of Prosthodontics
Selection criteria	
Inclusion criteria	Clinical studies only Enrollment of $\ge 20$ partially and/or fully edentulous patients with dental implants in a regular SPT program (ie, $\ge 1 \times /y$ ) Mean follow-up of $\ge 10$ years Publications reporting on fixed and/or removable implant-supported dental prostheses
Exclusion criteria	Animal studies Abstracts Letters to editors Narrative reviews Case reports Studies with < 20 partially and/or fully edentulous patients No author response to inquiry email for data clarification

included in combined implant-tooth–supported fixed dental prostheses (FDPs) (13.6%), and those included in solely implant-supported FDPs (11.6%).<sup>54</sup>

A case-control study investigated periodontally healthy patients (PHP, 28 patients) and periodontally compromised patients (PCP) with moderate (37 patients) or severe disease (36 patients), who had received periodontal therapy before implant placement. Data were reported in two parts focusing on implant loss and bone loss<sup>55</sup> and on the clinical results.<sup>62</sup> After insertion of HC, HS, or solid-screw (S) implants, all patients were placed on an individual SPT program including motivation, reinstruction, instrumentation, and treatment of re-infected sites. Two patients decided not to attend follow-up examinations and were classified as drop-outs. Among the 101 patients followed

for 10 years, their frequency of participation to the proposed SPT program was classified as "adherence" or "nonadherence" to SPT (24/4 in PHP, 26/11 in moderate PCP, and 29/7 in severe PCP). More pronounced radiographic bone loss of  $\geq$  3 mm was more often observed in moderate (11.2%) and severe PCP (15.1%) than in PHP (4.7%). Less plaque and BoP+ were observed in PHP (PII 16.1%, BoP+ 12.3%) compared to moderate (PII 29%, BoP+ 31%) and severe PCP (PII 23.1%, BoP+ 30.9%).<sup>62</sup> The deepest probing pocket depths during SPT were higher in severe PCP, with 5.5 mm, compared to 5.1 mm in moderate PCP and 4.2 mm in PHP. More sites with PPD  $\geq$  6 mm during SPT were found in moderate PCP (29.5%) and severe PCP (45.6%) compared to PHP (6.6%). Treatment of peri-implantitis was required during SPT in 10.7% of PHP, 27% of moderate PCP, and 47.2% of severe PCP. While no differences were found in PHP with or without complete adherence to SPT, patients in both periodontally compromised subgroups who did not adhere ideally to the proposed SPT revealed a higher incidence of implant loss.<sup>55</sup> This correlation was documented for the clinical parameters with higher PII and BoP+ at the 10-year examination and higher values of the deepest PPD in subjects not adhering to SPT.<sup>62</sup> In addition, more implants had  $PPD \ge 6 \text{ mm}$  during SPT, when patients did not regularly adhere to SPT compared to those adhering to SPT (58.1% versus 15.6% in moderate PCP, 88.9% versus 34.7% in severe PCP).

Matarasso et al<sup>56</sup> compared implants with machined (N-implants; Nobel Biocare) and titanium plasmasprayed surfaces (TPS, S-implants; Straumann Dental Implant System) in patients with a history of treated periodontitis (PCP) and a group of periodontally healthy patients (PHP). All patients were nonsmokers and adhered to a regular SPT program. The single-unit implant restorations revealed greater bone loss in PCP (N-implants: 2.78 mm, S-implants: 2.32 mm) than in PHP (N-implants: 1.95 mm, S-implants: 1.43 mm).<sup>56</sup> The same study protocol was applied in tobacco smokers with an uninterrupted consumption of > 10 cigarettes/ day at the beginning and at the 10-year follow-up.<sup>59</sup> Similarly, greater bone loss was observed in PCP (N-implants: 3.47 mm, S-implants: 3.77 mm) than in PHP (N-implants: 2.65 mm, S-implants: 2.51 mm) with a trend to more bone loss in the smoking cohort.<sup>59</sup>

Data from an edentulous cohort provided with implant-retained mandibular overdentures was reported in two separate publications.<sup>57,58</sup> The SPT recall attendance with at least 1 annual visit was 93.4% and comprised an average of 1.5 visits at the dental hygienist and 2.4 dental visits including treatments for prostheses remake.<sup>57</sup> The cumulative implant survival after 24 years amounted to 85.9%, and 31% of the failures were related to peri-implantitis.<sup>58</sup>

Östman et al<sup>60</sup> reported on 52 single, partial, or complete restorations inserted in 46 patients including 121 implants (TiUnite, Brånemark). SPT was adapted according to individual patient needs, with 20 patients recalled annually presenting with good oral hygiene and healthy soft tissue conditions, 24 patients who received professional cleaning twice a year showing acceptable oral hygiene, and 2 smoking patients with poor oral hygiene who received SPT every 3 months. At the 10-year recall appointment, 10.8% of the implants showed BoP+ or suppuration, 11.3% had more than 2 mm radiographic bone loss, and 4.7% had more than 3 mm bone loss. In these sites with pronounced bone loss (ie, > 3 mm), a correlation with BoP+ or suppuration and impaired oral hygiene was observed.<sup>60</sup>

In partially edentulous patients treated at the University of Bern and recalled at the university clinics and in private practice, high survival (98.8%) and success rates (97%) were reported.<sup>22</sup> Failures from periimplantitis with acute infection, suppuration, and progressive bone loss were rare (1.8%), while sites with increased PPD of  $\geq$  5 mm were found in 11.5% and bone levels  $\geq$  4 mm measured from the implant shoulder to the bone-to-implant contact were present in 15.6% of the implants at 10 years. With the standard tissue level implants (Straumann Dental Implant system) used in this study, a 2.8-mm polished neck is intended for the transmucosal portion and a bone level at 4 mm corresponds theoretically to only 1.2-mm bone loss. Similar failure rates (2.4%) from peri-implantitis were also reported with TiUnite implants (Nobel Biocare); however, a total of 10% of the implants were diagnosed for periimplant mucositis and 8% had peri-implantitis requiring surgical treatment.<sup>61</sup> Frisch et al<sup>63</sup> reported on overdenture prostheses retained by telescopic crowns placed on 6 different types of implant systems (Table 2). After a mean observation period of 14 years with an SPT program for peri-implantitis prophylaxis, peri-implant mucositis was found in 21.3% of the implants and 36.4% of the patients. Peri-implantitis was defined as PPD of  $\geq$  5 mm, BOP+, and radiographic bone loss > 3.5 mm. Eight percent of the implants and 9.1% of the patients were diagnosed with peri-implantitis.<sup>63</sup>

Although the study by Costa et al<sup>64</sup> did not fulfill the requirement of a mean observation period  $\geq$  10 years and was therefore not included in the review, some results of this study revealed important aspects related to the effects of SPT (Table 3). A group of 80 partially edentulous patients had been diagnosed for peri-implant mucositis in 2005, when they had implants in place for 6 months up to 5 years.<sup>66</sup> During the following 5 years, patients either adhered to SPT with at least 5 dental visits (GTP group: 39 patients with 156 implants) or remained without SPT (GNTP group: 41 patients with 180 implants).

		the Systematic Review	CDT mand
Study	Study type	Materials and methods	SPT used
Mericske-Stern et al <sup>52</sup>	Retrospective cohort study	71 patients with 151 HC ITI implants (Straumann) SCs, FDPs, or overdentures Mean observation time: 14.1 y (range: 11.4–19.7)	SPT not clearly specified in the text, patients had been followed regularly in the Department of
	Implant therapy at university clinic	Reevaluation of the 71 patients in 1998–1999 (132 implants still in situ)	Prosthodontics, University of Bern (41 patients) or in 4 private practices of early ITI members in Switzerland (30 patients)
Karoussis et al <sup>44</sup>	Prospective cohort study Implant therapy at	53 patients with 112 HS implants (ITI, Straumann) SCs or FDPs Mean observation time: 10 y (range: 8–12)	SPT at intervals between 3 and 6 mo (at university clinic or private practice) with an implant maintenance and CIST treatment
	university clinic	Group A: 8 patients with 21 implants with history of chronic periodontitis Group B: 45 patients with 91 implants, no history of periodontitis Success criteria: PPD $\leq$ 5 mm, BoP–, bone loss < 0.2 mm/y	protocol
Karoussis et al <sup>8</sup>	Prospective cohort study Implant therapy at university clinic	127 patients included: 9 passed away, 29 moved Mean observation time: 10 y (range: 8–12), 10-y reevaluation in 89 partially edentulous patients with 179 implants (ITI, Straumann) after comprehensive periodontal treatment SCs or FDPs	SPT at intervals between 3 and 6 mo
		179 matching control teeth as reference	
Karoussis et al <sup>53</sup>	Prospective cohort study Implant therapy at university clinic	127 patients included: 9 passed away, 29 moved Mean observation time: 10 y (range: 8–12), 10-y reevaluation in 89 partially edentulous patients with 179 implants (ITI, Straumann) after comprehensive periodontal treatment 112 HS implants 49 HC implants 18 AHC implants Success criteria: PPD $\leq$ 5 mm with BoP– (or BoP+ with PPD < 5 mm), bone loss < 0.2 mm/yr	SPT at intervals between 3 and 6 mo During recall all biological complications (peri- implantitis) were recorded and treated according to the CIST protocol
Brägger et al <sup>54</sup>	Prospective cohort study Implant therapy at university clinic	<ul> <li>127 patients included: 9 passed away, 29 moved Mean observation time: 10 y (range: 8–12),</li> <li>10-y exam in 89 partially edentulous patients (comprehensive perio therapy), 179 implants (ITI, Straumann):</li> <li>112 HS, 49 HC, 18 AHC</li> <li>48 patients with 69 SC (69 implants)</li> <li>29 patients with 33 I-I FDP (69 implants)</li> <li>21 patients with 22 mixed I-T FDP (22 implants and 24 tooth abutments)</li> <li>Success criteria: PPD ≤ 5 mm with BoP–</li> </ul>	Supportive periodontal care was provided either at the clinic or by referring dental practices. During recall sessions, all incidences of biological and/or technical complications were noted. In case of a biological complication (defined PPD $\geq$ 5mm and BoP+ or suppuration), the CIST protocol was applied
Roccuzzo et al <sup>55</sup>	Prospective case- control study Private specialist	112 partially endentulous patients (11 patients lost); 246 TPS implants (ITI, Straumann) with HC, HS, S	SPT individualized (motivation, reinstruction, instrumentation, and treatment of reinfected sites)
	practice	10 y follow-up exam with 101 patients: 28 PHPs 37 moderate PCPs 36 severe PCPs	Adhering/not adhering to SPT: 24/4 PHP 26/11 moderate PCP 29/7 severe PCP

Results	Remarks from authors	NOS
Survival: 10 y 91.4%, at mean observation of 14.1 y 84.6% More biologic complications with baskets than with cylinder type F 13 implants lost before 10-y observation, 4 implants lost after 10 y in situ 7 implant fractures, 2 loss of osseointegration, 10 peri-implantitis (with 2 still in situ) 38% of all implants had some plaque, 32% BoP+, correlation between increased PPD and radiographic bone loss and BoP+	Personal communication: all patients had regular $(1-2\times/y)$ recalls with SPT	4
Survival rate: group A 90.5%, group B 96.5% Success rate: group A 52.4%, group B 79.1% 10-y peri-implantitis incidence: group A: 28.6%, group B: 5.8% Among group A: tendency for poorer survival in smokers (80%) vs nonsmokers (100%)		6
PII similar at implants (0.36) and teeth (0.40) PPD (2.78 vs 2.02 mm) and BoP+ (42.2% vs 30.2%), radiographic bone loss (0.68– 0.72 vs 0.59–0.62mm) higher at implants than at teeth Smoking was associated with greater marginal bone loss	Same patient cohort as in Karoussis et al <sup>53</sup>	4
Survival rates at 10 y: 95.4% HS, 85.7% HC, 91.7% AHC Success rates at 10 y: 74% HS, 63% HC, 61% AHC Peri-implantitis (PPD $\geq$ 5 mm with BoP+ and radiographic bone loss): 15.4% of all implants, and 10% HS, 29% HC, 12% AHC	Same study group as in Karoussis et al <sup>8</sup>	4
Success (free of complication): 66.5% SC, 54.5% I-I FDP, 50% I-T FDP Survival: 90% SC, 93.9% I-I FDP, 68.2% I-T FDP Peri-implantitis treatment in: 20% of SCs, 11.6% implants in I-I-FDPs, 13.6% implants in I-T FDPs Suprastructures with implants treated for peri-implantitis had an increased OR of 5.44 to result in a biological failure compared to suprastructures with healthy implants	Same patient cohort as in Karoussis et al <sup>8,53</sup>	4
Survival: 96.6% PHP, 92.8% moderate PCP, 90% severe PCP Mean bone loss: 0.75 mm PHP, 1.14 mm moderate PCP, 0.98 mm severe PCP Bone loss ≥ 3mm: 4.7% PHP, 11.2% moderate PCP, 15.1% severe PCP Lack of adherence to SPT correlated with higher incidence of implant loss in patients with PCP: -moderate PCP: 5/11 patients not attending SPT had lost implants, 1/26 patients attenting SPT lost implant -severe PCP: 4/7 patients not attending SPT lost implants, 3/29 patients attending SPT lost implants	Same patients as in Roccuzzo et al <sup>62</sup>	8

Table 2 continue	ed Publications Ir	ncluded in the Systematic Review	
Study	Study type	Materials and methods	SPT used
Matarasso et al <sup>56</sup>	Retrospective case-control study Private specialist practice and university clinic	80 patients (contributing 1 implant in single-unit gaps, in 1997), SCs Observation time: 10 y -40 PHPs -40 PCPs (generalized chronic perio, treated, but in some cases isolated residual pockets) 20 patients each in PHP and PCP groups with Brånemark N (machined) or Straumann S (TPS screw) implants Baseline exclusion of smokers, FMPS or FMBS > 25%	SPT regular programm with individually tailored maintenance care program
Rentsch-Kollar et al <sup>57</sup>	Prospective cohort study Implant therapy at university clinic 1984–1997	147 edentulous patients with 314 implants (HC and S, Straumann) Observation time 16.5 y (range: 10–24) Mandibular overdentures (gold bar or single abutments) Reevaluation of 101 patients in 2008	Regular maintenance scheduled 2×/y, plaque control by dental hygienist, OH reinstruction SPT attendance defined as ≥ 1 annual visit
Ueda et al <sup>58</sup>	Prospective cohort study Implant therapy at university clinic 1984–1997	147 edentulous patients with 314 implants (HC and S, Straumann) Observation time 16.5 y (range: 10–24) Mandibular overdentures (gold bar or single abutments) Reevaluation of 101 patients in 2008 (46 drop-outs)	Regular maintenance 1–2×/y, plaque control by dental hygienist, OH reinstruction
Aglietta et al <sup>59</sup>	Retrospective case- control study Private specialist practice and university clinic	40 tobacco smokers (>10 cig/day during the 10-y period) Observation time: 10 y -20 PCPs -20 PHPs 10 patients each in PCP and PHP groups with Brånemark N (machined) or Straumann S (TPS screw) Single-unit gaps with SCs (in 1997)	All patients enrolled in a regular, individually tailored maintenance care program
Östman et al <sup>60</sup>	Prospective cohort study Private office	46 completely and partially edentulous patients, 121 implants (Brånemark TiUnite) 22 single, 23 partial, 7 complete restorations Observation time > 10 y, exam at 10 y 24 patients with immediate loading, 97 unloaded healing period	Clinical and radiographic check-ups after 3, 6, 12 mo, and thereafter annually up to 10 y (OH, peri-implant mucosa examined by probing, individual program for hygiene controls and professional cleaning) SPT frequencies: 20 patients with good OH and healthy soft tissue conditions annually, 24 patients with acceptable OH $2 \times /y$ , 2 patients (smokers) with poor OH every 3 mo
Buser et al22	Retrospective cohort study University clinic	Records of 358 patients, 303 patients participated, 511 implants (tissue-level SLA, Straumann) Inserted 1997–2001 Partially edentulous patients Observation time: 10 y with exam	SPT not clearly specified in the text
Degidi et al <sup>61</sup>	Prospective cohort study Private office	<ul> <li>59 patients, 210 implants (Brånemark TiUnite)</li> <li>SCs, partial or complete restorations</li> <li>Observation time: 10 y</li> <li>22.4% of implants not examend due to patient dropout (refused recall), at 10-y exam: 48 patients with 158 implants</li> <li>Immediate loading protocol, healed and extraction sites</li> </ul>	All patients received precise OH instruction and were recalled for professional cleaning by dental hygienists every 6 mo

Results	Remarks from authors	NOS
Survival overall 92.5%: - PCP N group: 95% - PCP S group: 85% - PHP N group: 95% - PHP S group: 95% Mean peri-implant marginal bone loss at N/S implants: PCP 2.78/2.32, PHP 1.95/1.43 Number of implants ≥ 3 mm bone loss: PCP 13/9, PHP 3/2		8
Annual visit rate: 1.5 at dental hygienist, 2.4 at dentist (including restoration remakes) Regular recall attendance 93.4% (with $\ge$ 1 SPT visit/y)	Same patient cohort as in Ueda et al <sup>58</sup>	5
Survival 85.9% after 24 y (13 implants removed in 10 patients, 4 due to peri-implantitis) Mean crestal bone loss 0.54 after 16.5 y	Same patient cohort as in Rentsch-Kollar et al <sup>57</sup>	5
Survival overall 90% (4 implant losses): -PCP N group: 90% -PCP S group: 80% -PHP N group: 90% -PHP S group: 100% 4 implant failures were related to marginal bone loss Mean peri-implant marginal bone loss at N/S implants: PCP 3.47/3.77, PHP 2.65/2.51 Number of implants ≥ 3 mm bone loss: PCP 6/9, PHP 3/1	Same protocol as in Matarasso et al <sup>56</sup>	8
Survival 99.2% after 10 y (1 implant lost) 11 sites (9.2%) with BoP+, 2 sites with pus 12 (11.3%) implants with > 2 mm bone loss, 5 (4.7%, all smokers and poor OH) implants with > 3 mm bone loss; all 5 implants with > 3 mm bone loss were BoP+ and 2 (1.9%) had suppuration		6
Survival 98.8% at 10 y, success 97% Peri-implantitis: 1.8% (acute infection with suppuration and progressive bone loss) PPD $\geq$ 5 mm: 11.5%	Personal communications: SPT according to CIST protocol (at university clinic	6

Distance implant shoulder to bone-to-implant contact  $\geq 4$  mm (corresponds to  $\geq 1.2$  mm bone loss): 15.6% ( $\geq 4.5$  mm: 4.4%)

2.4% implant losses (5/210), all due to recurrent peri-implantitis 29 (18.4%) implants had soft tissue adverse events over the whole follow-up period: 10.1% with peri-implant mucositis, 8.2% with peri-implantitis requiring surgical treatment 5

or private practice), average

of 1.7 visits/y over 10 y

Table 2 continu	Table 2 continued         Publications Included in the Systematic Review					
Study	Study type	Materials and methods	SPT used			
Roccuzzo et al <sup>62</sup>	Prospective case- control study	112 partially endentulous patients (11 patients lost); 246 TPS implants (Straumann) with HC, HS, S	SPT individualized (motivation, reinstruction, instrumentation,			
	Private specialist practice	10 y follow-up exam with 101 patients -28 PHP	and treatment of reinfected sites)			
		-37 moderate PCP -36 severe PCP	Adhering/ not adhering to SPT: -24/4 PHP -26/11 moderate PCP -29/7 severe PCP			
Frisch et al <sup>63</sup>	Retrospective cohort study Private practice	36 nonsmoking edentulous patients (1991–2002), 14 drop-outs, 22 patients included who participated in regular SPT with 89 implants (Ankylos, Brånemark, IMZ, ITI Bonefit, Frialit2) Mean observation: 14.1 y (range: 10.2–18.9) Reevaluation in 2011 Overdentures (9 maxilla, 13 mandible) retained at implant-telescopes	Professional maintenance program with 1–4 appointments per year (evaluating PII, PPD, BoP, with remotivation and professional cleaning) Practice internal aftercare program for peri-implantitis prophylaxis			

NOS = Newcastle-Ottawa Scale (max of 9 stars for cohort or case-control studies); CIST = cumulative interceptive supportive therapy; SPT = supportive periodontal therapy; PPD = probing pocket depth; BoP = bleeding on probing; PII = Plaque Index; OH = oral hygiene; SC = single crown, FDP = fixed dental prosthesis; HS = hollow screw; HC = hollow cylinder; AHC = angulated hollow cylinder; S = solid screw; PHP = periodontally patient; PCP = periodontally compromised patient; I-I = implant-implant supported FDP; I-T = implant-tooth supported FDP; FMPS = full-mouth plaque score; FMBS = full-mouth bleeding score.

# Table 3 Supplemental Publications Providing Comparative Data on Patient Cohorts with/without SPT or Residual Periodontitis

Study	Study type	Materials and methods	SPT used
Costa et al <sup>64</sup>	Prospective cohort study University clinics	Baseline 80 partially edentulous patients after periodontal treatment and with peri-implant mucositis (in 2005) Observation time: 5 y after diagnosing peri-implant mucositis -39 with SPT (GTP, 156 implants) -41 without SPT (GNTP, 180 implants) Implant types: Nobel Biocare, 3i Implant Innovation, Intralock International	With and without preventive maintenance during a 5-y period
Lee et al <sup>65</sup>	Retrospective case-control study Private specialist periodontal practice	30 periodontally healthy patients (PHP) with 61 implants, with observation time 8.2 y $(5.0-13.5)$ 30 treated periodontally compromised patients (PCP) with 56 implants, with observation time 8 y $(5.0-14.4)$ , subgroups RP (residual periodontitis) and NRP (non-residual periodontitis) RP: patients with $\geq$ 1 site with PPD $\geq$ 6 mm at follow-up examination Tissue level implants (Standard and Standard Plus, Straumann)	individually tailored SPT program within the practice, or in conjunction with the referring practitioner
Pjetursson et al <sup>21</sup>	Retrospective cohort study University clinic	70 partially edentulous patients after perio treatment, with 165 implants placed during initial corrective phase plus 12 implants additionally placed during SPT (Straumann Dental Implant system) - 115 S implants - 50 HS and HC implants Mean observation time: 7.9 y (range: 3–23 y) Peri-implantitis definitions: - Level 1: PPD $\geq$ 5 mm and BOP+ - Level 2: PPD $\geq$ 6 mm and BOP+ radiographic bone level $\geq$ 5 mm below implant shoulder (corresponding to $\geq$ 2 mm bone loss with 2.8 mm transmucosal neck)	SPT at university clinic or in private practice

NOS = Newcastle-Ottawa Scale (max of 9 stars for cohort or case-control studies); CIST = cumulative interceptive supportive therapy; SPT = supportive periodontal therapy; PPD = probing pocket depth; BoP = bleeding on probing; PII = Plaque Index; OH = oral hygiene; SC = single crown, FDP = fixed dental prosthesis; HS = hollow screw; HC = hollow cylinder; AHC = angulated hollow cylinder;

S = solid screw; PHP = periodontally healthy patient; PCP = periodontally compromised patient.

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Results	Remarks from authors	NOS
PII: 16.1% PHP, 29% moderate PCP, 23.1% severe PCP BoP+: 12.3% PHP, 31% moderate PCP, 30.9% severe PCP Mean PPD: 3.1 mm PHP, 3.5 mm moderate PCP, 3.9 mm severe PCP Mean deepest PPD during SPT: 4.2 mm PHP, 5.1 mm moderate PCP, 5.5 mm severe PCP Implants with deepest PPD $\geq$ 6 mm during SPT: 6.6% PHP, 29.5% moderate PCP, 45.6% severe PCP	Same patients as in Roccuzzo et al <sup>55</sup>	8
Attendance/no regular attendance of SPT affected only PCP with more pronounced signs of inflammation: PII: 25/38.5% moderate PCP, 20.3/39.6% severe PCP BoP+: 23/50% moderate PCP, 27.2/52.1% severe PCP Mean deepest PPD during SPT: 4.5/6.3 mm moderate PCP, 5.1/7.2 mm severe PCP implants with deepest PPD $\geq$ 6 mm during SPT: 15.6/58.1% moderate PCP, 34.7/88.9% severe PCP		
Survival: 98.9% (1 implant lost due to peri-implantitis) Peri-implant mucositis: 21.3% of implants/ 36.4% of the patients Peri-implantitis (PPD $\ge$ 5 mm, BOP+, radiographic bone loss > 3.5 mm): 8% of implants/ 9.1% of the patients		5
Overall mean marginal bone loss after 14 y: 1.6 mm (65% implants with < 2 mm bone loss, 27% with 2–3.5 mm, 8% with > 3.5 mm)		

Results	Remarks from authors	NOS
Incidence of peri-implantitis: 31.2% -GTP (with SPT) 18% -GNTP (without SPT) 43.9% At final exam: -GTP: 30.5% healed, 51.5% mucositis, 18.0% peri-implantitis (periodontitis in 28.2% of the patients) -GNTP: 0% healed, 56.1% mucositis, 43.9% peri-implantitis (periodontitis in 41.5% of the patients)	At baseline exam all implants had peri- implant mucositits and were already in place for 6 mo to 5 y (details in Ferreira et al <sup>66</sup> )	7
Implants PPD $\geq$ 5 mm and BoP+ (implant level): PHP 13.1%, PCP 26.7% (RP 43.5%, NRP 15.2%) Implants PPD $\geq$ 5 mm and BoP+ (patient level): PHP 16.7%, PCP 6.7% (RP 53.8%, NRP 23.5%) Bone level > 3 mm (implant level): PHP 3.3%, PCP 8.9% (RP 17.4%, NRP 3.0%); overall 6% Bone level > 3 mm (patient level): PHP 6.7%, PCP 16.7% (RP 30.8%, NRP 5.9%); overall 11.7%	Personal communications: 14 patients had follow-up data greater than 10 y (6/30 in PHP and 8/30 in PCP)	7
Cumulative survival rate of 165 implants: 95.8% -S: 99.1% -HS and HC: 89.7% Peri-implantitis (related to 165 plus 12 implants) -Level 1: 22.2% of implants and 38.6% of patients with $\geq$ 1 implants with peri-implantitis -Level 2: 8.8% of implants and 17.1% of patients with $\geq$ 1 implants with peri-implantitis	Personal communication: all patients had regular ( $\ge 1 \times /y$ ) recalls with SPT	6
$\mbox{PPD} \geq 5$ mm at the end of active periodontal therapy was a risk for development of peri-implantitis and implant loss		
Patients developing re-infections during SPT were at greater risk for peri-implantitis and implant loss compared with periodontally stable patients		

After this 5-year period, the incidence of peri-implantitis was 31.2%, with 18% in the subgroup with SPT and 43.9% in the subgroup without SPT. While 30.5% of the mucositis sites had healed in GTP and 51.5% still presented with peri-implant mucositis, no sites in GNTP showed healthy tissues, but 56.1% had mucositis. The incidence of periodontitis among the patients slightly increased after the 5-year period in GTP (from 26.5% to 28.2%) and was almost twice as high in GNTP (from 22%) to 41.5%). Univariate analysis revealed an association of the following variables with peri-implantitis: presence of periodontitis, plaque (PII), BoP+, width of keratinized mucosa at implants  $\geq$  1 mm, and PPD  $\geq$  4 mm. In addition, PAL  $\geq$  3 mm showed an association only in GNTP. Logistic regression analysis showed that in GTP peri-implantitis was associated with > 50% of sites with BoP+ and > 5% of sites with PPD  $\ge$  4 mm, while in GNTP periimplantitis was related to > 5% of sites with PPD  $\ge 4$  mm and the presence of periodontitis.

Another study<sup>56</sup> not included due to the limited mean observation period (8.2 years) compared the peri-implant conditions of 30 partially edentulous patients with a history of treated periodontitis (PCP) with those of 30 patients with healthy periodontal conditions (PHP) (Table 3). The PCP group was subdivided in a residual periodontitis group (RP, 13 patients) when at least one periodontal site with PPD  $\geq$  6 mm was present during the final examination, or in a no residual periodontitis group (NRP, 17 patients). In RP patients, 43.5% of the implants and 53.8% of the subjects were affected by PPD  $\geq$  5 mm and BoP+, while only 15.2% of the implants (23.5% of the patients) in NRP and 13.1% of the implants (16.7% of the patients) in PHP showed these clinical signs of peri-implantitis. Similarly, the prevalence of bone levels > 3 mm was 17.4% of the implants (30.8% of the patients) in RP, while only 3.0% of the implants (5.8% of the patients) in NRP and 3.3% of the implants (6.7% of the patients) in PHP showed progressive bone loss. The authors concluded that absence of residual periodontal pockets and maintenance of periodontal health played a more important role for the increased risk of peri-implantitis than a previous history of treated periodontitis.<sup>65</sup>

The susceptibility to peri-implantitis was assessed in a retrospective cohort study on 70 patients treated for periodontitis and rehabilitated with 165 dental implants<sup>21</sup> (Table 3). All patients were enrolled in a regular SPT program either at the University or in private practice. The follow-up time ranged from 3 to 23 years (mean: 7.9 years). The findings indicated that residual periodontal pockets represented a reservoir for bacterial colonization of dental implants.<sup>21</sup> More specifically, residual PPD  $\geq$  5 mm at the end of active periodontal therapy represented a significant risk for the development of peri-implantitis and implant loss during SPT. Moreover, patients experiencing periodontal disease recurrence during SPT displayed a significantly greater risk for the development of periimplantitis and implant loss compared with control patients with stable periodontal conditions during SPT.<sup>21</sup>

### DISCUSSION

The aim of the present systematic review was to evaluate the effects of anti-infective preventive measures on the occurrence of biologic implant complications and implant loss in edentulous and partially edentulous patients. Out of 15 included studies, only one comparative study assessed the effects of adherence to recommended SPT on the occurrence of biologic complications and implant loss after a mean observation period of at least 10 years. Overall, the results of the present systematic review confirmed that adherence to recommended SPT of fully and partially edentulous patients yielded beneficial effects with respect to the occurrence of biologic complications and implant loss. In order to evaluate the effects of adherence to SPT on the incidence of peri-implant diseases and implant loss, a randomized clinical trial (RCT) with and without SPT would be ideal but cannot be justified for ethical reasons, although RCTs of different maintenance care frequencies would be ethical. Therefore, observational studies including adherence and lack of adherence to recommended SPT were considered valuable in order to estimate the effects of SPT on implant longevity and the occurrence of biologic complications.

So far, findings from one systematic review<sup>67</sup> on a similar topic as the present one had been reported. Hultin et al<sup>67</sup> concluded that "no evidence is available to suggest the frequency of recall intervals or to propose specific hygiene treatments" and that "there is an urgent need for such studies to be initiated."

Owing to the importance of SPT for periodontal disease progression and tooth loss, it was assumed that patients with dental implants could also benefit from regular adherence to SPT with respect to implant success and survival. This assumption was based on the outcomes of a study in patients with dental implants enrolled in a 3-month SPT program.<sup>68</sup> In that study, no significant differences between periodontal and periimplant conditions were recorded up to 5 years.<sup>68</sup>

In all studies included in the present systematic review, SPT was offered to the patients and recall intervals were mostly scheduled on an individual basis. However, the modalities, content, and frequency of SPT varied among the different study protocols. Lack of adherence of partially edentulous patients with dental implants to recommended SPT was associated with a higher incidence of peri-implantitis and implant loss compared with those of patients adhering to recommended SPT.<sup>55,62,64</sup> In addition, recent data indicated

that patients with a history of treated periodontitis who received dental implants as part of their oral rehabilitation displayed a higher rate of adherence to scheduled SPT appointments compared with patients who underwent periodontal surgery without receiving dental implants.<sup>69</sup>

Outcomes of a prospective cohort study with a 5-year follow-up indicated that implants placed in patients with treated periodontal conditions and adhering to a SPT program yielded a 20% prevalence of mucositis.<sup>70</sup> In that study,<sup>70</sup> upon diagnosis of mucositis or periimplantitis, all implants with the exception of one were successfully treated according to a cumulative antiinfective protocol.<sup>42</sup> Findings from a 3-month randomized placebo-controlled clinical trial revealed that mechanical debridement with and without local application of chlorhexidine gel in conjunction with optimal self-performed oral hygiene was effective in reducing soft tissue inflammation and probing depths around implants with mucositis.<sup>71</sup> Among patients not adhering to regular SPT, however, peri-implant mucositis was reported to be a common finding with a prevalence of 48% during an observation period of 9 to 14 years.<sup>31–33</sup> In partially edentulous patients, pre-existing peri-implant mucositis in conjunction with lack of adherence to SPT was associated with a higher incidence of peri-implantitis over a 5-year follow-up period.<sup>64</sup> The characteristics of 212 partially edentulous patients rehabilitated with dental implants reported by Ferreira et al<sup>66</sup> formed the target sample of the study by Costa et al.<sup>64</sup> The outcomes of that study yielded a 5-year incidence of peri-implantitis of 18.0% in the group of patients with SPT and of 43.9% in the group without SPT, respectively.<sup>64</sup> The logistic regression analysis<sup>64</sup> revealed that lack of adherence to SPT within the overall patient sample was significantly associated with peri-implantitis with an odds ratio (OR) of 5.92. Moreover, a diagnosis of periodontitis was significantly associated with the occurrence of peri-implantitis in the overall patient sample (OR = 9.20) and particularly in patients without SPT (OR = 11.43).<sup>64</sup>

Outcomes from long-term comparative studies revealed that patients with a history of treated periodontitis and rehabilitated with dental implants were more prone to develop peri-implantitis compared with nonperiodontitis patients.<sup>44,55,56,62,72,73</sup> Patients with a history of moderate to severe periodontitis and not adhering to regular SPT displayed significantly higher incidences of implant losses and peri-implant bone loss  $\geq$  3 mm compared with patients adhering to SPT after an observation period of 10 years.<sup>55,62</sup> High implant survival rates and low incidence of peri-implant bone loss in patients treated for moderate to advanced chronic periodontitis were reported in a 5-year study.<sup>74</sup> In that study, all patients adhered to a regular SPT program (2 to 3× per year) after implant placement and prosthetic rehabilitation.<sup>74</sup> In this well-maintained patient sample, the 5-year implant survival rate was high (97.3%), the amount of bone level change during the final 4 years was 0.02 mm per year, and only 11% of the implants yielded > 2 mm bone loss during the 5-year observation period.<sup>74</sup>

Although it is clinically meaningful that in partially edentulous patients active periodontal therapy precedes implant placement, the endpoints of periodontal therapy were shown to impact on the survival and success rates of natural teeth and dental implants. Results from long-term studies indicated that periodontally treated teeth could be maintained even though a significantly increased risk for tooth loss was reported for  $PPD \ge 6 \text{ mm and } BoP+ \ge 30\%$ <sup>14</sup> and furcation involvement<sup>75-77</sup> was still present after completion of active periodontal therapy and adherence to SPT. Results from two recent studies confirmed that the presence of these risks for natural teeth (ie, residual PPD and BoP+) after completion of periodontal therapy could also be assessed in periodontally compromised patients with dental implants.<sup>21,65</sup> Residual PPD  $\geq$  5 mm at the end of active periodontal therapy represented a significant risk for the onset of peri-implantitis and implant loss over a mean follow-up period of 7.9 years.<sup>21</sup> Furthermore, patients adhering to regular SPT who had re-infections were at greater risk for peri-implantitis and implant loss compared with periodontally stable patients.<sup>21</sup> In a retrospective case-control study, the effects of periodontal conditions on the outcomes of implant therapy were evaluated in periodontally compromised patients stratified according to the presence of  $\geq$  1 residual PPD  $\geq$  6 mm after a mean follow-up period of 8.2 years.<sup>65</sup> Patients with  $\geq$  1 residual PPD  $\geq$  6 mm displayed a significantly greater mean peri-implant PPD and radiographic bone loss compared with both periodontally healthy and periodontally compromised patients without residual PPD, respectively.<sup>65</sup> Moreover, patients with  $\geq$  1 residual PPD  $\geq$  6 mm had significantly more implants with  $PPD \ge 5 \text{ mm}$  with BoP+ and radiographic bone loss compared with either of the other two groups of patients.<sup>65</sup>

#### **CONCLUSIONS**

The following conclusions and clinical implications were determined based on the reviewed studies:

- High long-term survival and success rates of dental implants can be achieved in partially and fully edentulous patients adhering to regular SPT. Enrollment in an individual SPT program with regular intervals and including anti-infective preventive measures should be implemented.
- Peri-implant mucositis (ie, inflammation without crestal bone loss) represents a common finding

among patients with dental implants. Pre-existing peri-implant mucositis in conjunction with lack of adherence to SPT is associated with a higher incidence of peri-implantitis. Therapy of peri-implant mucositis should be considered as a preventive measure for the onset of peri-implantitis.

 Long-term implant survival and success rates in patients with a history of treated periodontitis are lower compared with those in periodontally healthy patients. Control of periodontal infection should precede implant placement.

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### Improvements in Implant Dentistry over the Last Decade: Comparison of Survival and Complication Rates in Older and Newer Publications

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Purpose: The objective of this systematic review was to assess and compare the survival and complication rates of implant-supported prostheses reported in studies published in the year 2000 and before, to those reported in studies published after the year 2000. Materials and Methods: Three electronic searches complemented by manual searching were conducted to identify 139 prospective and retrospective studies on implant-supported prostheses. The included studies were divided in two groups: a group of 31 older studies published in the year 2000 or before, and a group of 108 newer studies published after the year 2000. Survival and complication rates were calculated using Poisson regression models, and multivariable robust Poisson regression was used to formally compare the outcomes of older and newer studies. Results: The 5-year survival rate of implant-supported prostheses was significantly increased in newer studies compared with older studies. The overall survival rate increased from 93.5% to 97.1%. The survival rate for cemented prostheses increased from 95.2% to 97.9%; for screw-retained reconstruction, from 77.6% to 96.8%; for implant-supported single crowns, from 92.6% to 97.2%; and for implant-supported fixed dental prostheses (FDPs), from 93.5% to 96.4%. The incidence of esthetic complications decreased in more recent studies compared with older ones, but the incidence of biologic complications was similar. The results for technical complications were inconsistent. There was a significant reduction in abutment or screw loosening by implant-supported FDPs. On the other hand, the total number of technical complications and the incidence of fracture of the veneering material was significantly increased in the newer studies. To explain the increased rate of complications, minor complications are probably reported in more detail in the newer publications. **Conclusions:** The results of the present systematic review demonstrated a positive learning curve in implant dentistry, represented in higher survival rates and lower complication rates reported in more recent clinical studies. The incidence of esthetic, biologic, and technical complications, however, is still high. Hence, it is important to identify these complications and their etiology to make implant treatment even more predictable in the future. INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):308–324. doi: 10.11607/jomi.2014suppl.g5.2

**Key words:** biologic complications, dental implants, esthetic complications, failures, fixed dental prosthesis, implant dentistry, marginal bone loss, single crowns, survival, success, systematic review, technical complications

n recent years, a number of systematic reviews on the survival and complication rates of fixed implantsupported prostheses have been published. The reviews focused on implant-supported single crowns (SCs)<sup>1,2</sup> or on multiple-unit implant-supported fixed dental prostheses (FDPs)<sup>3,4,5</sup> and reported high 5- and 10-year survival rates for both types of prostheses. Due to these good results, fixed implant-supported prostheses are fully accepted as a reliable treatment option for the replacement of single or multiple missing teeth today.<sup>1,4</sup>

In the daily clinical practice, however, patient (and clinician) satisfaction is not only influenced by survival rates. Survival rates in general represent prostheses that remained in clinical service for a defined follow-up period. However, those prostheses were not necessarily free of complications. Both implant-supported

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SCs as well as implant-supported FDPs suffer from different kinds of biologic or technical complications as the reviews indicated.<sup>1,5</sup> These complications lead to the need for corrective treatment, increasing the total chairside time and the treatment costs. As a consequence, a reduction of the general satisfaction with the prosthesis may occur.<sup>6</sup>

The etiology of biologic complications is mostly patient-based and can be multifactorial (eg, hereditary susceptibility to peri-implantitis, bad oral hygiene, excess cement).<sup>7</sup> A reduction of risk therefore implies good patient compliance and intensive oral care. Biologic risk can only be minimally influenced by modification of the implants, implant surfaces, and components, according to the current literature.

Technical problems are mostly related to the materials and the design of the components.<sup>8</sup> Studies have shown various types of technical problems, like prosthetic fixation screw or abutment loosening, fractures of components (eg, abutments, screws), fractures of reconstructive materials (eg, chipping of veneering ceramic), and loss of retention of cemented prostheses due to fracture of the luting cement.<sup>1,5</sup> In contrast to the biologic risks, the technical outcome can be improved with technical amendments.

In order to reduce the risk for technical complications, the materials and components used for the implant-supported prostheses are, therefore, constantly being enhanced. Some improvements have already led to better outcomes. As an example, after the introduction of implant-supported SCs, very high numbers of abutment or occlusal screw loosening were reported.<sup>9,10</sup> The change of screw material from titanium to gold and the use of defined screw fixation torques led to significant lowering of the incidence of screw loosening.<sup>9,10</sup> Screw loosening is still one of the most frequently reported complications for implantsupported reconstruction. Therefore, further refinements are desired, and debates about the best materials and techniques for the implant-supported prostheses are continually raised.<sup>1,4</sup>

The introduction of new restorative materials, such as ceramic zirconia for the abutment and framework, can on the one hand improve the outcomes (esthetics), but on the other increase technical problems. It has been shown that the veneering ceramics for zirconia-based prostheses exhibited very high rates for fracture and chipping.<sup>11–13</sup> Thus, not all further developments were really an improvement.

Very little scientific evidence is currently available to help determine whether changes in materials and implant components in the last decades have influenced survival rates of implants and implantsupported prostheses and the incidence of biologic and technical complications. The objective of this systematic review was to assess and compare the survival and complication rates of implant-supported prostheses reported in studies published in the year 2000 and before to those reported in studies published after the year 2000.

#### MATERIALS AND METHODS

#### **Focus Question**

The following focus question was developed using a PICO approach:

Have the survival rate of implant-supported prostheses and the incidence of complications changed over the last decade?

#### Search Strategy and Study Selection

Three Medline (PubMed) searches were performed for articles published in the Dental Literature in English and German. The first one covered the time period 1990 to September 2012 utilizing both MeSH terms and free text words. The following search terms were used: "implant\*", "cement\*" or "screw\*", "fix\*" or "retain\*", "single-crown", "single crowns" "FPD", "FDP", "bridge", "reconstruct\*" and "suprastruct\*". Moreover, the terms "long-term", "long term", "longitud\*", "survival" or "failure", "complicat\*", "technical" or "biological" were utilized. In addition, Cochrane Library and Embase searches were conducted applying the same search terms.<sup>10</sup> The second search was an updated search from a previous systematic review<sup>1</sup> covering the time interval through the end of August 2011. The following MeSH terms were selected for the search: "dental implants" AND ("crowns" OR "survival").<sup>2</sup> The third search was performed for studies published between May 1, 2004, and August 31, 2011,<sup>5</sup> using the following MeSH search terms: "dental implants" AND ("denture, partial, fixed" OR survival). Additionally, the studies from the predecessor systematic review were included, encompassing publications from 1966 through the end of April 2004.<sup>14</sup> All three searches were complemented by manual searches of the bibliographies of all full-text articles and related reviews, selected from the electronic search. Furthermore, manual searching was applied to relevant journals in the field of interest (Table 1).

#### **Inclusion Criteria**

This systematic review was based on randomized controlled clinical trials (RCTs), controlled clinical trials (CCTs), prospective cohort studies, prospective case series, and retrospective studies. The additional inclusion criteria for study selection were:

Table 1 Sea	rch Strategy
Focus question	Have the survival rate of implant-supported reconstructions and the incidence of complications changed over the last decade?
Search strategy	
Population	Partially edentulous patients with single-implant FDPs or multi-unit partial/full FDPs
Intervention or exposure	1 year of clinical follow-up, and after 5 and 10 y of follow-up
Comparison	Different decades/timepoints of intervention and/or publication
Outcome	Survival and complication rates over time
Search combination	<ul> <li>Sailer et al<sup>10</sup>: used ""implant*", "cement*" or "screw*", "fix*" or "retain*", "single-crown", "single crowns "FPD", "FDP", "bridge", "reconstruct*"and "suprastruct*". Moreover, the terms "long-term", "long term", "longitud*", "survival" or "failure", "complicat*", "technical" or "biological"</li> <li>Jung et al<sup>2</sup>: used "dental implants" and ("crowns" OR "survival").</li> <li>Pjetursson et al<sup>5</sup>: used "dental implants" AND ("denture, partial, fixed" OR survival). All these search terms were MeSH terms.</li> </ul>
Database search	
Electronic	Medline (PubMed), Cochrane Library, and Embase
Journals Selection criteria	Clinical Oral Implants Research, International Journal of Oral and Maxillofacial Implants, International Journal of Oral Surgery, Journal of Prosthetic Dentistry, International Journal of Periodontics and Restorative Dentistry International Journal of Prosthodontics, Clin Implant Dent Relat Res, Journal of Clinical Periodontology, Journal of Oral Rehabilitation, British Dental Journal, Journal of Prosthodontics, Implant Dentistry, Journal of Periodontology, International Journal of Epidemiology, European Journal of Oral Sciences, Australian Dental Journal, Clinical Oral Investigations, Dental Materials, Journal of the Canadian Dental Association, Quintessence International, Journal of Oral Implantology, Clinical Implant Dentistry and Related Research
Inclusion criteria	<ul> <li>This systematic review was based on randomized controlled clinical trials (RCTs), controlled clinical trials (CCTs), prospective cohort studies, prospective case series, and retrospective studies. The additional inclusion criteria for study selection were:</li> <li>Human trials with minimum of 10 subjects.</li> <li>Studies reported in English and German language and published in dental journals.</li> <li>Patients were examined clinically at the follow-up visit. Publications based on patient records only, on questionnaires or interviews were excluded.</li> <li>Studies reported details on the characteristics and outcome of the suprastructures.</li> <li>For the short-term data, the studies had to have a mean time of functional loading of at least 1 year.</li> <li>For the longitudinal data, the studies had to have a mean follow-up time of 5 years or more.</li> </ul>
Exclusion criteri	a The main reasons for exclusion were lack of detailed information on the reconstruction design and no detailed information on the outcome of the reconstruction at the follow-up visit, or mean observation period not fulfilling the inclusion criteria and studies with less than 10 subjects. Furthermore, publication based on questionnaires or interviews without clinical examinations, multiple publications on the same patient cohorts, and case descriptions of failures without relevant information on the entire patient cohor were excluded.

- Human trials with a minimum of 10 subjects.
- Studies reported in English and German language and published in dental journals.
- Patients examined clinically at the follow-up visit. Publications based on patient records only, on questionnaires or interviews were excluded.
- Studies reporting details on the characteristics and outcome of the suprastructures.
- For short-term data, the studies had to have a mean time of functional loading of at least 1 year.
- For longitudinal data, the studies had to have a mean follow-up time of 5 years or more.

#### **Selection of Studies**

Titles and abstracts of the searches were always screened by at least two independent reviewers for possible inclusion in the reviews. The full text of all studies of possible relevance was then obtained for independent assessment by the reviewers. Any disagreement was resolved by discussion.

The first search extending through August 2011 identified 59 full-text articles that gave information on the clinical performance of cemented and screw-retained implant-supported prostheses with a functional loading of at least 1 year.<sup>10</sup> The extended search

up to September 2012 identified two additional publications fulfilling the inclusion criteria. In the second search, the original search extending until August 2006 identified 24 studies reporting on implantsupported single crowns (SCs) with a mean follow-up time of 5 years or more.<sup>1</sup> The extended search, through August 2011, added 22 new publications to the included studies.<sup>2</sup> In the third search, identifying implantsupported fixed dental prosthesis (FDPs) with a mean follow-up time of at least 5 years, the original search extending until May 2004 identified 21 studies.<sup>14</sup> The extended search through August 2011 identified an additional 11 studies.<sup>5</sup>

The results of the present systematic review are based on a total of 139 included studies.

#### **Excluded Studies**

The main reasons for exclusion were no detailed information on the prostheses design and no detailed information on the outcome of the prosthesis at the follow-up visit, mean observation period not fulfilling the inclusion criteria, and studies with less than 10 subjects. Furthermore, publications based on questionnaires or interviews without clinical examinations, multiple publications on the same patient cohorts, and case descriptions of failures without relevant information on the entire patient cohort were excluded.

#### **Data Extraction**

From the included studies, information on failures of the supporting implants and the prostheses was extracted. Information on esthetic, biologic, and technical complications was also retrieved. Biologic complications were characterized by a biological process affecting the supporting tissues. Soft tissue complications and peri-implantitis characterized by a substantial (> 2 mm) marginal bone loss were included in this category.

Technical complications were characterized by mechanical damage of implants, abutments, and/or the suprastructures. Among these, fractures of implants, screws, or abutments; fractures of the luting cement (loss of retention); fractures or deformations of the framework or veneers; and screw or abutment loosening were included. From the included studies, the number of events for all of these categories was abstracted and the corresponding total exposure time of the implants, abutments, and prostheses was calculated.

#### **Statistical Analysis**

By definition, failure and complication rates are calculated by dividing the number of events (failures or complications) in the numerator by the total exposure time (implant, abutment, or reconstruction time) in the denominator. The numerator could usually be extracted directly from the publication. The total exposure time was calculated by taking the sum of:

- Exposure time of implants, abutments, or prostheses that could be followed for the entire observation time.
- Exposure time up to a failure of implants, abutments, or prostheses that were lost due to failure during the observation time.
- Exposure time up to the end of observation time for implants, abutments, or prostheses that did not complete the observation period due to reasons such as death, change of address, refusal to participate, non-response, chronic illness, missed appointments, and work commitments.

For each study, event rates for implants, abutments, or prostheses were calculated by dividing the total number of events by the total implant, abutment, or prosthesis exposure time in years. For additional analysis, the total number of events was considered to be Poisson distributed for a given sum of abutment exposure years, and robust Poisson regression with a logarithmic link-function and total exposure time per study as an offset variable was used.<sup>15</sup> Robust Poisson regression allowed calculation of standard errors and 95% confidence intervals, which incorporated heterogeneity among studies.

Five-year survival proportions were calculated via the relationship between event rate and survival function S, S(T) = exp(-T \*event rate), by assuming constant event rates.<sup>16</sup> The 95% confidence intervals for the survival proportions were calculated by using the 95% confidence limits of the event rates. Multivariable robust Poisson regression was used to formally compare publication years and to assess other study characteristics. All analyses were performed using Stata version 12.

#### RESULTS

#### **Study Characteristics**

The 139 included studies were divided into three categories. The first group was a group of 61 studies reporting on the clinical performance of cemented and screw-retained implant-supported prostheses of different types. This group included 37 studies reporting on implant-supported single crowns (SCs), 16 studies that reported on implant-supported partial fixed dental prostheses (FDPs), and 18 studies reporting on implant-supported fixed complete dentures (FCDs), with various mean follow-up periods ranging from 1 to 10 years.<sup>10</sup> The result for this group is referred to as the overall results. The second group was a group of

	Published before 2000		Published		
	Annual failure rate (95% CI)	5-year survival rate (95% CI)	Annual failure rate (95% CI)	5-year survival (95% CI)	P value
Overall results	0.29% (0.15-0.57)	98.6% (97.2–99.3)	0.39% (0.25–0.63)	98.1% (96.9–98.8)	.466
Implant-supported SCs	0.60% (0.39-0.90)	97.1% (95.6–98.1)	0.56% (0.40-0.78)	97.2% (96.2–98.0)	.815
Implant-supported FDPs	1.28% (1.05–1.56)	93.8% (92.5–94.9)	0.81% (0.57-1.14)	96.1% (94.4–97.2)	.021

 Table 3
 Comparison of the Prosthetic Survival Rate in Articles Published Through and After 2000

	Published through 2000		Published after 2000		
	Annual failure rate (95% CI)	5-year survival rate (95% CI)	Annual failure rate (95% CI)	5-year survival rate (95% CI)	P value
Overall results	1.34% (0.65–2.77)	93.5% (87.1–96.8)	0.59% (0.38-0.91)	97.1% (95.6–98.1)	.050
Cemented reconstructions	0.99% (0.58-1.69)	95.2% (91.9–97.2)	0.42% (0.23–0.75)	97.9% (96.3–98.8)	.030
Screw-retained reconstructions	5.07% (1.17–22.07)	77.6% (33.2–94.3)	0.65% (0.39–1.10)	96.8% (94.6-98.1)	.004
Implant-supported FCDs	NR	NR	0.86% (0.45-1.66)	95.8% (92.0–97.8)	NA
Implant-supportzed SCs	1.54% (1.01–2.34)	92.6% (88.9–95.1)	0.58% (0.35–0.95)	97.2% (95.3–98.3)	.002
Implant-supported FDPs	1.34% (0.69–2.62)	93.5% (87.7–96.6)	0.73% (0.55–0.97)	96.4% (95.3–97.3)	.087

NR = not reported; NA = not applicable.

46 studies reporting on 3,199 implant-supported SCs with a mean follow-up time of at least 5 years.<sup>2</sup> The last group was a group of 32 studies reporting on 1,881 implant-supported FDPs with a mean follow-up period of at least 5 years.<sup>5</sup>

The year of publication for the 139 studies (see reference list) included in this systematic review ranged from 1994 to 2012.<sup>2-14,17-141</sup> Thirty-one publications were classified as older studies published in the year 2000 or before and 108 were classified as newer studies published after the year 2000. From the 61 studies reporting on overall results, the year of publication ranged from 1995 to 2012. Twelve of the studies were classified as older studies and 49 as newer studies published in the present millennium. Out of the 46 studies reporting on implant-supported SCs, the publication year ranged from 1995 to 2012. Eight of the studies were considered older studies and 38 newer studies published after the year 2000. For the 32 studies reporting on implant-supported FDPs, the year of publication ranged from 1995 to 2012. Eleven of the included studies were considered older studies, and 21 were considered newer studies published after the year 2000.

#### Survival

Survival was defined as the implants or prostheses remaining in situ with or without modification over the observation period.

*Implant survival.* The annual implant failure rates in the older publications ranged from 0.29% to 1.28%,

translating into 5-year survival rates of 93.8% to 98.6%. The annual failure rates in the newer publications ranged from 0.39% to 0.81%, translating into a 5-year survival rate of 96.1% to 98.1% (Table 2). Comparing the survival rates in the older publications with the survival rates in the newer publications, there was only a minor difference (P = .466, .815) of the overall results and for the implant-supported SCs. However, for the implant-supported FDPs there were significantly (P = .021) less implant failures in the newer studies and the 5-year implant survival rate increased from 93.8% in the older studies to 96.1% (Table 2).

Survival of Prostheses. The annual failure rate of prostheses in the older publications ranged from 0.99% to 5.07% (Figs 1 to 6), translating into a 5-year survival rate of 77.4% to 95.2%. The highest 5-year survival rate in the older studies was seen for cemented prostheses, and the lowest survival rate was reported for screw-retained prostheses (Table 3). The range in annual failure rates of different types of prostheses was significantly reduced in the newer publications. They ranged from 0.42% to 0.86%, translating into a 5-year survival rate of 95.8% to 97.9% (Table 3, Figs 1 to 6). Formally comparing the survival rates of prostheses in the older publications with the survival rates in the newer publications, there was a marked reduction of failures, translating into increased survival rates of implant-supported prostheses in the more recent studies. The difference reached statistical significance (P = .002 to .050) for all types of prostheses analyzed, except for implant-supported FDPs (P = .087)

(Table 3). The most pronounced improvement was seen for screw-retained prostheses, with a 5-year survival rate of 77.6% in the older studies compared with a 5-year survival rate of 96.8% in the newer studies (Table 3).

#### **Esthetic Complications**

For implant-supported SCs, there were 12 studies reporting on the esthetic outcome of the treatment. In the older studies the annual rate of implant-supported SCs with semioptimal or unacceptable esthetic outcomes was 3.47%, translating into a 5-year complication rate of 15.9% (Table 4). In the newer studies, the annual rate of esthetic complications was reduced to 1.12%, translating into a 5-year complication rate of 5.4%. The difference in the incidence of esthetic complications between the older and the newer studies did not, however, reach statistical significance (P = .085) (Table 4).

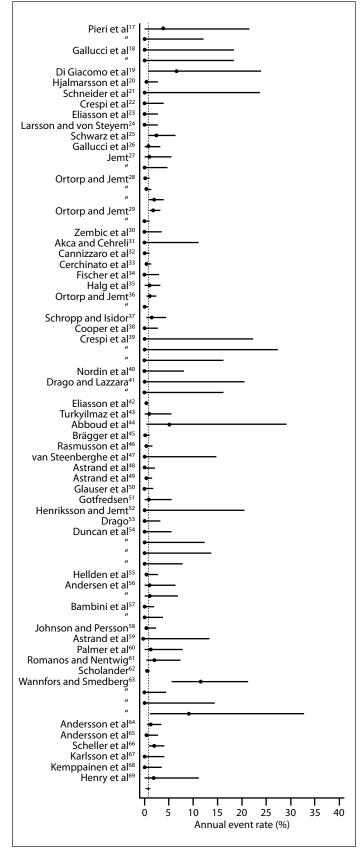
#### **Biologic Complications**

Peri-implant mucosal lesions were reported in various ways by the different authors. Several studies provided information on soft tissue complications, peri-implantitis, and marginal bone loss, while other studies reported signs of inflammation (pain, redness, swelling, and bleeding) or soft tissue complications, defined as fistula, gingivitis, or hyperplasia.

For implant-supported SCs and implantsupported FDPs, information on biologic complications was extracted from the included publications.

For implant-supported SCs, the annual rate of biologic complications was reduced from 2.56% in the older studies to 1.31% in the new studies, translating into a reduction in 5-year complication rate from 12.0% to 6.4% (Table 3). This difference, however, did not reach statistical significance (P = .252). No formal comparison could be made regarding marginal bone levels around implant-supported SCs, because this complication was not reported in the older studies.

For implant-supported FDPs, the incidence of biologic complications increased slightly in the newer studies compared with the older ones. On the other hand, the incidence of substantial bone loss  $\geq 2$  mm decreased slightly. The annual rate of biologic complications by implant-supported FDPs increased from 1.54% to 1.97%, hence the 5-year complication rate increased from 7.4% to 9.4%. The annual rate of marginal bone loss decreased from 0.68% to



**Fig 1** Annual failure rates—overall results. Dots indicate annual failure rates; lines indicate 95% confidence interval.

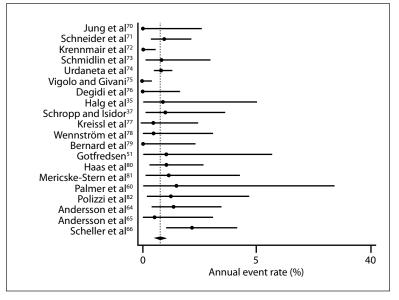


Fig 2 Annual failure rates of implant-supported SCs.

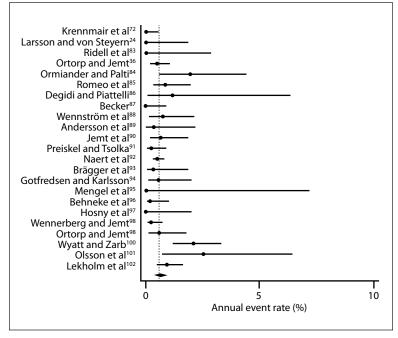


Fig 3 Annual failure rates of implant-supported FPDs.

0.52%, translating into a 5-year complication rate of 3.3% in the older studies compared with 2.5% in the newer studies. The differences regarding biologic complications between the older and the newer studies for implant-supported FDPs at 5 years did not reach statistical significance (P = .540, .543) (Table 4).

#### **Technical Complications**

**Abutment or Screw Loosening.** The annual rate of abutment or screw loosening in the older publications ranged from 0.79% to 6.08%, translating into a 5-year complication rate of 3.9% to 26.2% (Table 5).

The highest incidence of abutment or screw loosening in the older studies was reported for screw-retained prostheses (26.2%) and implant-supported SCs (24.4%), and the lowest complication rate was reported for cemented prostheses (3.9%). In the newer studies, the annual rate of abutment or screw loosening ranged from 0.62% to 2.29%, translating into a 5-year complication rate ranging from 3.1% to 10.8% (Table 5). The highest incidence of abutment or screw loosening in the newer studies was still seen for screw-retained prostheses and the lowest for cemented prostheses. For all types of prostheses, lower incidences of abutment and screw loosening were reported in the newer studies. For screw-retained prostheses and implant-supported SCs, this difference reached statistical significance (P = .002, .045) (Table 5).

Abutment or Screw Fractures. The annual rate of abutment or screw fractures in the older publications ranged from 0.16% to 0.44%, translating into a 5-year complication rate of 0.8% to 2.2% (Table 6). In the older studies, this information was not available for screw-retained prostheses and implantsupported FCDs. In the more recent studies, the annual rate of abutment or screw fractures ranged from 0% to 1.20%, translating into a 5-year complication rate between 0% and 5.8% (Table 6). Comparing the overall results in the older and the newer studies in respect to abutment or screw loosening, there was an increase in annual failure rates from 0.27% to 0.56%, representing a change for the 5-year complication rate from 1.3% to 2.8% (P = .371). It must, however, be kept in mind that among the older studies, no studies on screw-retained prostheses and implant-supported FCDs were available. When the different types of prostheses were analyzed separately, they all showed a decreased rate of abutment or screw loosening when comparing the older studies with the more recent ones. The difference between the older and the newer studies, however, only reached statistical significance for implant-supported SCs (P = .029). The highest 5-year rate of abutment or

screw fractures of 5.8% was reported for implant-supported FCDs. For implantsupported screw-retained prostheses, the 5-year complication rate was 4.1%, compared with a complication rate of 0% for implant-supported cemented prosthesis (Table 6).

Fracture of the Veneering Material. The annual rate of fracture of the veneering material in the older publications ranged from 0.28% to 4.28%, translating into a 5-year complication rate of 1.4% to 19.2% (Table 7). The highest 5-year rate of fracture of the veneering material in the older studies was reported for implant-supported FDPs. In the newer studies, the annual rate of fracture of the veneering material ranged from 0.64% to 5.82%, translating into a 5-year complication rate ranging between 3.2% and 25.5% (Table 7). The lowest 5-year rate of fracture of the veneering material was reported for implant-supported SCs, and the highest rate was reported for implant-supported FCDs. Comparing the older studies with the newer studies, there was a significant increase in the incidence of fracture of the veneering material for the overall results (P < .0001), for the cemented prostheses (P = .004), and for the screw-retained prostheses (P < .0001). It must, however, be kept in mind that among the older studies, there were no studies reporting on implant-supported FCDs that showed the highest incidence of complications in the newer studies. On the other hand, there was a significant decrease in fracture of the veneering material reported for implant-supported SCs (P = .054) and for the implant-supported FDPs (P = .013) (Table 7).

**Implant Fractures.** Implant fractures are a rare complication. For implantsupported SCs, the annual rate of implant fractures was reduced from 0.06% in the older studies to 0.02% in the newer studies, translating into a reduction in the 5-year complication rate from 0.3% to 0.08% (Table 8). This difference did not reach statistical significance (P = .271). For implant-supported FDPs the 5-year rate of implant fractures was the same or 0.5% both on the older and the newer studies (Table 8).

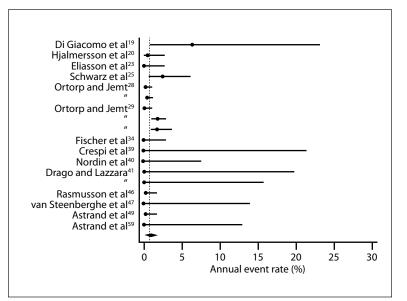


Fig 4 Annual failure rates of implant-supported FCDs.

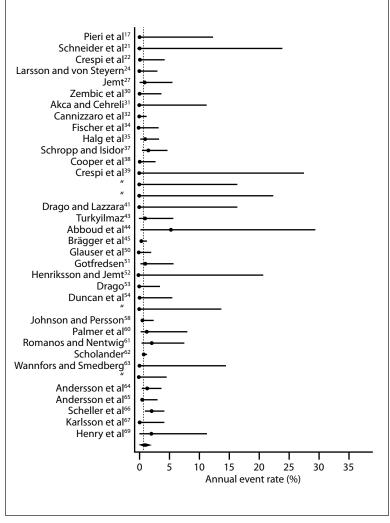


Fig 5 Annual failure rates of implant-supported cemented reconstructions.

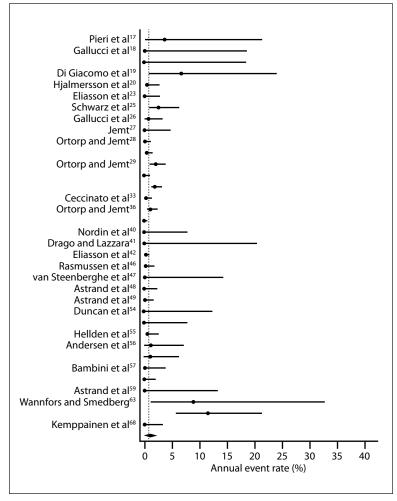


Fig 6 Annual failure rates of implant-supported screw-retained reconstructions.

**Fracture of the Framework.** Fractures of the framework of the prosthesis are also a rare complication. For implant-supported FDPs, the annual rate of framework fractures was reduced from 0.19% in the older studies to 0.04% in the newer studies. This represents a reduction in the 5-year complication rate from 1.0% to 0.2% (Table 8). The difference between the results from the older studies and the newer studies did not reach statistical significance (P = .128).

**Loss of Retention.** The loss of retention for cemented prostheses could only be analyzed for implant-supported SCs. The annual complication rate was reduced from 1.52% in the older studies to 0.63% in the newer studies, translating into a reduction in 5-year rate of loss of retention from 7.3% to 3.1% (Table 8). This difference, however, did not reach statistical significance (P = .118).

**Total Technical Complications.** The annual rate of the total number of reported technical complications in the older publications ranged from 2.32% to 10.46%, translating into a 5-year complication rate ranging from 10.9% to 40.1% (Table 9). The highest 5-year complication rate in the older studies was reported for implant-supported FDPs (40.1%) and for screw-retained prostheses (33.3%), and the lowest

survival rate was reported for cemented prostheses (10.8%). In the newer publications, the annual rate of total number of technical complications ranged from 3.55% to 15.19%, translating into a 5-year complication rate ranging from 16.3% to 53.4%. The highest 5-year complication rate was reported for implant-supported FCDs (Table 9). Comparing the older studies with the more recent studies, there was a significant increase in number of technical complications for the overall results (P = .028). For the cemented prostheses there was also an increased number of technical complications reported (P = .225), but for the screw-retained prostheses the incidence was similar (P = .808) in the older and the newer studies. It should also be considered that among the older studies, there were no publications reporting on implant-supported FCDs that showed the highest incidence of technical complications among the newer studies. This fact might skew the outcome. Furthermore, there was a significant (P = .005) decrease in the total complication rate reported for implantsupported FDPs in the newer studies compared with the older ones (Table 9).

The 41 meta-analyses (Tables 2 to 9) that were included this systematic review were also performed by dividing the year of publication into three time-interval groups: studies published before the year 2000, studies published between 2000 and 2005, and finally studies published after the year 2005. Interestingly, this analysis showed that most of the significant changes happened in the publication periods before 2000, and between 2000 and 2005. In this time period, important improvements in materials and methods were made in implant dentistry. The only complication that demonstrated significant improvement from the studies published between 2000 and 2005 to the studies published after 2005 was screw or abutment loosening at screwretained prostheses.

The results for implant-supported SCs and implant-supported FDPs divided into three publication time intervals are presented in Table 10.

# Table 4Comparison of Esthetic and Biologic Complications in Articles Published Through and<br/>After 2000

	Published through 2000		Published after 2000		
	Annual complication rate (95% CI)	5-year complication rate (95% CI)	Annual complication rate (95% CI)	5-year complication rate (95% CI)	P value
Esthetic complications, SCs	3.47% (0.86–14.08)	15.9% (4.2–50.5)	1.12% (0.68–1.84)	5.4% (3.3-8.8)	.085
Biologic complications, SCs	2.56% (0.82-7.99)	12.0% (4.0-32.9)	1.31% (0.85–2.05)	6.4% (4.2–9.7)	.252
Biologic complications, FPDs	1.54% (0.74-3.20)	7.4% (3.6–14.8)	1.97% (1.31–2.97)	9.4% (6.3–13.8)	.540
Marginal bone loss $\ge 2$ mm, SCs	NR	NR	1.31% (0.66–2.58)	6.3% (3.3–12.1)	NA
Marginal bone loss $\ge 2 \text{ mm}$ , FDPs	0.68% (0.26-1.80)	3.3% (1.3-8.6)	0.52% (0.38–0.70)	2.5% (1.9-3.5)	.543

NR = not reported; NA = not applicable.

#### Table 5 Comparison of Abutment or Screw Loosening in Articles Published Through and After 2000

	Published through 2000		Published after 2000		
	Annual complication rate (95% CI)	5-year complication rate (95% CI)	Annual complication rate (95% CI)	5-year complication rate (95% CI)	P value
Overall results	1.65% (0.75–3.65)	7.9% (3.7–16.7)	1.82% (1.22–2.73)	8.7% (5.9–12.8)	.826
Cemented reconstructions	0.79% (0.57–1.09)	3.9% (2.8–5.3)	0.62% (0.33-1.21)	3.1% (1.6–5.8)	.530
Screw-retained reconstructions	6.08% (3.79-9.74)	26.2% (17.3–38.6)	2.29% (1.47-3.56)	10.8% (7.1–16.3)	.002
Implant-supported FCDs	NR	NR	1.88% (0.63-5.61)	9.0% (3.1-24.4)	NA
Implant-supported SCs	5.58% (1.19–26.11)	24.4% (5.8–72.9)	1.16% (0.66–2.03)	5.6% (3.2–9.6)	.045
Implant-supported FDPs	1.08% (0.78-1.48)	5.2% (3.8–7.1)	0.81% (0.45-1.46)	4.0% (2.2–7.0)	.387

NR = not reported; NA = not applicable.

#### Table 6 Comparison of Abutment or Screw Fracture in Articles Published Through and After 2000

	Published th	Published through 2000		Published after 2000	
	Annual complication rate (95% CI)	5-year complication rate (95% CI)	Annual complication rate (95% CI)	5-year complication rate (95% CI)	P value
Overall results	0.27% (0.05-1.35)	1.3% (0.3–6.5)	0.56% (0.29-1.11)	2.8% (1.4-5.4)	.371
Cemented reconstructions	0.28% (0.05-1.50)	1.4% (0.3–7.2)	0%	0%	NA
Screw-retained reconstructions	NR	NR	0.84% (0.42-1.67)	4.1% (2.1-8.0)	NA
Implant-supported FCDs	NR	NR	1.20% (0.31-4.68)	5.8% (1.5-20.9)	NA
Implant-supported SCs	0.16% (0.05-0.49)	0.8% (0.3–2.4)	0.07% (0.02–0.20)	0.3% (0.1–1.0)	.238
Implant-supported FDPs	0.44% (0.23–0.84)	2.2% (1.1-4.1)	0.16% (0.08-0.32)	0.8% (0.4-1.6)	.029

NR = not reported; NA = not applicable.

#### DISCUSSION

The aim of this systematic review was to investigate the survival and complication rates of implantsupported prostheses in older studies and compare them with survival and complication rates reported in more recent publications.

With the exception of implant-supported FDPs, implant survival rate was similar in the older and in the more recent studies. The overall 5-year implant survival rate and the survival rate for implant-supported SCs was high, ranging between 97.1 and 98.6% in both the older and the newer studies. For implant-supported FDPs, the 5-year survival rate even increased over time.

Considering this, what does it mean for daily clinical practice when the survival rate is increased from 93.8% to 96.1%? A survival rate of 93.8% indicates that 1 implant out of 16 was lost, and 96.1% means that

#### Table 7 Comparison of Fractures of Veneering Material in Articles Published Through and After 2000

	Published through 2000		Published after 2000		
	Annual complication rate (95% CI)	5-year complication rate (95% CI)	Annual complication rate (95% CI)	5-year complication rate (95% CI)	<b>P</b> value
Overall results	0.31% (0.09–1.03)	1.5% (0.5-5.0)	3.65% (2.55–5.23)	16.7% (12.0–23.0)	.0001
Cemented reconstructions	0.28% (0.08-1.01)	1.4% (0.4-4.9)	2.84% (1.04-7.81)	13.3% (5.0–32.3)	.004
Screw-retained reconstructions	0.76% (0.37-1.55)	3.7% (1.8–7.4)	3.95% (2.74-5.69)	17.9% (12.8–24.8)	.0001
Implant-supported FCDs	NR	NR	5.82% (3.77–9.00)	25.3% (17.2–36.2)	NA
Implant-supported SCs	1.27% (0.67–2.41)	6.2% (3.3–11.4)	0.64% (0.43-0.96)	3.2% (2.1–4.7)	.054
Implant-supported FDPs	4.28% (3.10-5.90)	19.2% (14.4–25.5)	1.60% (0.77-3.30)	7.7% (3.8–15.2)	.013

NR = not reported; NA = not applicable.

#### Table 8 Comparison of Implant Fractures, Framework Material Fractures, and Loss of Retention in Articles Published Through and After 2000

	Published through 2000		Published after 2000		
	Annual complication rate (95% CI)	5-year complication rate (95% CI)	Annual complication rate (95% CI)	5-year complication rate (95% CI)	P value
Implant fractures, SCs	0.06% (0.008–0.52)	0.3% (0.04–2.6)	0.02% (0.004-0.07)	0.08% (0.02–0.35)	.271
Implant fractures, FDPs	0.10% (0.03-0.30)	0.5% (0.2–1.5)	0.11% (0.4–0.30)	0.5% (0.2–1.5)	.912
Fractures of the framework, FDPs	0.19% (0.08–0.50)	1.0% (0.4–2.4)	0.04% (0.005–0.27)	0.2% (0.02–1.4)	.128
Loss of retention, SCs	1.52% (0.56-4.17)	7.3% (2.7–18.8)	0.63% (0.30-1.29)	3.1% (1.5-6.3)	.118

NR = not reported; NA = not applicable.

#### Table 9 Comparison of Combined Complication Rates in Articles Published Through and After 2000

	Published through 2000		Published after 2000			
	Annual complication rate (95% CI)	5-year complication rate (95% CI)	Annual complication rate (95% CI)	5-year complication rate (95% CI)	P value	
Overall results	3.21% (1.85-5.56)	14.8% (8.8–24.3)	6.33% (4.78-8.38)	27.1% (21.3–34.2)	.028	
Cemented reconstructions	2.32% (1.50-3.57)	10.9% (7.2–16.3)	3.55% (2.05–6.17)	16.3% (9.7–26.5)	.225	
Screw-retained reconstructions	8.10% (4.02–16.32)	33.3% (18.2–55.8)	7.42% (5.5–10.1)	31.0% (23.9–39.7)	.808	
Implant-supported FCDs	NR	NR	15.19% (9.62–24.0)	53.2% (38.2–69.9)	NA	
Implant-supported FDPs	10.46% (10.20–10.73)	40.1% (39.9-41.5)	6.37% (4.41–9.20)	27.3% (19.8–36.9)	.005	

NR = not reported; NA = not applicable.

1 implant out of 26 was lost. To simplify, for example, 99% survival means loss of 1 implant out of 100, and 90% means loss of 1 implant out of 10. Hence, it has a major influence on the daily practice whether the survival and/or the success rate of an implant-supported prosthesis is 90% or 99%.

For all groups of implant-supported prostheses, there was a substantial to significant improvement in survival rates comparing the older studies with the newer studies. In the older studies, the 5-year survival rates were between 77.6% and 95.2%, compared with survival rates between 95.8% and 97.9% in the newer studies. The most significant improvement was reported for screw-retained implant-supported prostheses.

A positive improvement was also seen regarding esthetic outcomes comparing the older to the newer studies. This might represent a positive learning curve regarding improved understanding of biologic principles that must be respected during implant treatment in areas of esthetic priority. This might also represent a positive influence of new materials like ceramics, most specifically zirconia, that make it possible to improve

the esthetic outcome of the treatment.<sup>1,103</sup> The results regarding biologic complications were not consistent. For implant-supported SCs, the incidence of biologic complications decreased from the older studies compared with the newer studies. For implant-supported FDPs, there was a slight increase in biologic complications and a slight decrease in the number of implants with substantial marginal bone loss. The changes in esthetic outcomes and biologic complications did not reach statistical significance.

For most of the implant-supported prostheses, there were slightly to significantly fewer incidences of screw or abutment loosening and fractures, again displaying an improvement of the materials and methods. For screw-retained prostheses, the rate of screw or abutment loosening was reduced from 26.2% to 10.8%, and for implant-supported SCs the complication rate was reduced from 24.4% to 5.6%. One of the reasons for the significant reduction in screw or abutment loosening was a clear outlier among the older studies, Henry et al,<sup>104</sup> reporting on the first generation of single crowns on Brånemark implants. This group reported on titanium screws replaced with new gold abutment screws and new abutments replaced with older ones, resulting in dramatically reduced screw loosening.

Fracture of the veneering material was the most frequently reported technical complication. Comparing the rate of this complication within the older and the newer studies, the results varied significantly. For implant-supported SCs and implant-supported FDPs with at least 5 years of follow-up time, there was a significant decrease in the incidence of veneering material fractures. One of the reasons for this is probably that several studies reporting on implant-supported prostheses with gold-framework and acrylic veneers are included in the group of older studies. It has been demonstrated in previous systematic reviews<sup>4,14</sup> that implant-supported prostheses with acrylic veneers have a significantly lower survival rate than implantsupported metal-ceramic prostheses. On the other hand, the fracture rate of veneering material reported in studies with shorter follow-up time was significantly increased in the newer studies compared with the older studies. The risk of fracture of the veneering material was increased with the size of the reconstruction. The lowest 5-year complication rate (3.2%) was reported for implant-supported SCs, and the highest complication rate (25.3%) was reported for implant-supported FCDs. It is difficult to speculate what could be the reason for increased rate of fractures of the veneering material. One explanation could be a tendency to evaluate and report complications in more detail in recent publications. A minor ceramic chipping is a typical complication that could go unnoticed if the clinical examiner is not carefully investigating the prostheses. This could

also explain the fact that the total number of technical complications was significantly higher in the newer studies compared with the older studies. Another explanation could be the increased application of more delicate types of prostheses, eg, zirconia- or titaniumbased implant FDPs. The veneering ceramics for these types of framework materials exhibited high rates of chipping in clinical studies.

The high rate of technical complications must be given serious consideration. The 5-year rate of technical complications ranged from 16.3% to 53.2%. The lowest rate was reported for cemented prostheses and the highest rate was reported for implant-supported FCDs, where every second prosthesis had a technical complication of some kind. Since the latter observation is only based on very few studies, it has to be interpreted with caution. Specific clinician- or technician-based factors might be one possible reason for these complications.

The 41 meta-analyses performed are based on 139 clinical studies reporting on 8,193 implant-supported prostheses. Therefore, it can be concluded that the results are based on substantial material size. Another strength of the present systematic review is that the methodology used is well standardized in the way the search strategy was performed, the data extraction, and how the statistical approach was performed. Due to the fact that there was a substantial heterogeneity among the included studies, it was decided to use the robust Poisson regression, which incorporated heterogeneity among the studies.

One limitation of this review is that it was mainly based on studies that were conducted in an institutional environment, such as university or specialized implant clinics. Therefore, the long-term outcomes observed cannot be generalized to dental services provided in private practice. A further limitation is that the published information did not allow estimating annual failure rates separately for different time periods or years after insertion of the prosthesis. Thus, it was not possible to estimate whether annual failure rates increased over time. One of the limitations of the present systematic review was that both prospective and retrospective cohort studies and case series were included. To assess the influence of study design, the results from prospective and retrospective studies have been analyzed separately in a recent systematic review.<sup>5,14</sup> In two of the analyses, no influence of study effect could be seen, but in the third analysis higher survival rates were reported for retrospective studies. Hence, it was difficult to draw any robust conclusions regarding the influence of including retrospective studies in the analysis. In the present systematic review, the study design should not be a problem as long as the distribution of retrospective and prospective studies is similar between the older and the more recent study groups.

# Table 10Comparison of Failure and Complication Rates of Implant-Supported SCs and<br/>FDPs in Articles Published Before 2000, from 2000 to 2005, and After 2005

	Published before 2000		Published 2	2000–2005	
	Annual failure/ complication rate (95% Cl)	5-year survival/ complication rate (95% CI)	Annual failure/ complication rate (95% CI)	5-year survival/ complication rate (95% CI)	
Implant survival, SCs	0.52% (0.35–0.79)	97.4% (96.1–98.3)	0.61% (0.36-1.04)	97.0% (95.0–98.2)	
Implant survival, FDPs	1.35% (1.12–1.62)	93.5% (92.2–94.5)	0.81% (0.53-1.22)	96.0% (94.1–97.4)	
Survival of implant-supported SCs	1.54% (0.97–2.44)	92.6% (88.5–95.3)	0.83% (0.53-1.30)	95.9% (93.7–97.4)	
Survival of implant-supported FDPs	1.57% (0.80-3.07)	92.4% (85.8–96.1)	0.63% (0.49–0.83)	96.9% (95.9–97.6)	
Biologic complications, SCs	2.69% (0.85-8.57)	12.6% (4.1–34.8)	1.44% (0.83–2.51)	6.9% (4.0-11.8)	
Esthetic complications, SCs	3.47% (0.86-14.08)	15.9% (4.2–50.5)	1.17% (0.40-3.41)	5.7% (2.0–15.7)	
Implant fractures, SCs	0.08% (0.009-0.72)	0.4% (0.04–3.54)	0.03% (0.004-0.2)	0.1% (0.02-0.99)	
Implant fractures, FDPs	1.35% (1.12–1.62)	6.5% (5.5–7.8)	0.81% (0.53-1.22)	4.0% (2.6-5.9)	
Abutment or screw loosening, SCs	6.81% (1.43-32.26)	28.8% (6.9-80.1)	0.95% (0.37–2.49)	4.7% (1.8–11.7)	
Fractures of the veneering material, SCs	1.27% (0.67–2.41)	6.2% (3.3–11.4)	0.49% (0.24-1.01)	2.4% (1.2–4.9)	
Fractures of the veneering material, FDPs	4.66% (3.54-6.14)	20.8% (16.2–26.4)	1.29% (0.68–2.43)	6.3% (3.4–11.5)	
Total number of complications, FDPs	10.46%(10.2–10.73)	40.1% (39.9-41.5)	8.10% (3.50–18.74)	33.3% (16.1–60.8)	

\*Published before 2000 vs published 2000–2005.

<sup>†</sup>Published before 2000 vs published after 2005.

#### CONCLUSIONS

Despite of high survival rate of implant-supported prostheses and substantial improvements within implant dentistry over time, esthetic, biologic, and technical complications are still frequent. This, in turn, means that a substantial amount of chair time has to be accepted by the patient and dental services. The present systematic review demonstrated in many aspects a positive learning curve in implant dentistry, represented by lower failure and complication rates reported in more recent clinical studies.

It is, however, of outmost importance that the industry, the scientific community, and clinicians worldwide work together to identify failures, complications, and weaknesses in implant dentistry and develop solutions that make implant treatment an even more predictable and safe therapeutic option.

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Published a	after 2005	
Annual failure/ complication rate 95% Cl)	5-year survival/ complication rate (95% Cl)	P value
0.55% (0.36-0.84)	97.3% (95.9–98.2)	.636*, .839 <sup>†</sup>
0.78% (0.51-1.20)	96.2% (94.2–97.5)	.021, .007
0.53% (0.28-1.03)	97.4% (95.0–98.6)	.040, .006
0.83% (0.40-1.70)	95.9% (91.9–98.0)	.008, .166
1.23% (0.66–2.28)	5.9% (3.2-10.8)	.289, .196
1.09% (0.61–1.94)	5.3% (3.0–9.3)	.166, .083
0.01% (0.001-0.09)	0.05% (0.006-0.5)	.467, .172
0.78% (0.51-1.20)	3.8% (2.5–5.8)	.021, .007
1.19% (0.61–2.35)	5.8% (3.0-11.1)	.020, .026
0.68% (0.44-1.05)	3.3% (2.2–5.1)	.025, .084
2.08% (0.59–7.32)	9.9% (2.9–30.7)	.0001, .170
5.85% (3.90-8.78)	25.4% (17.7–35.5)	.441, .0001

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# The Therapy of Peri-implantitis: A Systematic Review

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Purpose: To evaluate the success of treatments aimed at the resolution of peri-implantitis in patients with osseointegrated implants. Materials and Methods: The potentially relevant literature was assessed independently by two reviewers to identify case series and comparative studies describing the treatment of peri-implantitis with a follow-up of at least 3 months. Medline, Embase, and The Cochrane Library were searched. For the purposes of this review, a composite criterion for successful treatment outcome was used which comprised implant survival with mean probing depth < 5 mm and no further bone loss. Results: A total of 43 publications were included: 4 papers describing 3 nonsurgical case series, 13 papers describing 10 comparative studies of nonsurgical interventions, 15 papers describing 14 surgical case series, and 11 papers describing 6 comparative studies of surgical interventions. No trials comparing nonsurgical with surgical interventions were found. The length of follow-up varied from 3 months to 7.5 years. Due to the heterogeneity of study designs, peri-implantitis case definitions, outcome variables, and reporting, no metaanalysis was performed. Eleven studies could be evaluated according to a composite success criterion. Successful treatment outcomes at 12 months were reported in 0% to 100% of patients treated in 9 studies and in 75% to 93% of implants treated in 2 studies. Commonalities in treatment approaches between studies included (1) a pretreatment phase, (2) cause-related therapy, and (3) a maintenance care phase. Conclusions: While the available evidence does not allow any specific recommendations for the therapy of peri-implantitis, successful treatment outcomes at 12 months were reported in a majority of patients in 7 studies. Although favorable short-term outcomes were reported in many studies, lack of disease resolution as well as progression or recurrence of disease and implant loss despite treatment were also reported. The reported outcomes must be viewed in the context of the varied peri-implantitis case definitions and severity of disease included as well as the heterogeneity in study design, length of follow-up, and exclusion/inclusion criteria. INT J ORAL MAXILLOFAC IMPLANTS 2014;29(SUPPL):325-345. doi: 10.11607/jomi.2014suppl.g5.3

**Key words:** peri-implantitis, systematic review, treatment, therapy

Peri-implantitis—an infectious condition of the tissues around osseointegrated implants with loss of supporting bone and clinical signs of inflammation (bleeding and/or suppuration on probing)—has a prevalence on the order of 10% of implants and 20% of patients 5 to 10 years after implant placement.<sup>1</sup> The numbers of patients with a history of periodontitis and those who are smokers in a cohort, as well as the type and frequency of aftercare, are factors that influence these prevalence data. Furthermore, the prevalence of peri-implantitis will vary depending on the bone loss threshold and/or probing depth threshold used for case definition. Various clinical protocols for prevention and treatment of peri-implantitis have been proposed, including mechanical debridement, the use of antiseptics and local or systemic antibiotics, as well as surgical access and regenerative procedures. Several attempts to combine the data of the available literature in a meta-analysis have failed in the past due to insufficient data.<sup>2-6</sup> In a recent review on a part of this literature,<sup>7</sup> it was noted that almost all reports on the treatment of naturally occurring peri-implantitis in humans do in fact not satisfy the strict criteria for a randomized controlled trial (RCT). The absence of a true control group (no treatment or placebo) was a common limitation. Trials at the highest level of evidence compared test procedures, both of which had an unclear outcome. As it is difficult to recruit sufficient numbers of patients with peri-implantitis to take part in a true randomized trial, some studies may have

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been underpowered. With regard to outcomes, there is inconsistency about primary treatment goals and minimally required observation periods.

A recent Cochrane systematic review included nine randomized controlled trials in an attempt to identify the most effective interventions for treating periimplantitis around osseointegrated oral implants.<sup>8</sup> The authors concluded that there is no reliable evidence suggesting which could be the most effective interventions for treating peri-implantitis.<sup>8</sup>

Due to the above observations, the authors of the present review decided to take a broader approach to evaluate the effect of treatment, feeling that it was currently not suitable to restrict a review on the therapy of peri-implantitis to randomized trials. This report aims to evaluate the results of treatment of peri-implantitis in humans in a broader way than done previously.

An ideal goal of peri-implantitis therapy would be the resolution of disease (ie, no suppuration or bleeding on probing, no further bone loss) and the establishment and maintenance of healthy hard and soft peri-implant tissues. If this goal were not achievable, a reduction in clinical inflammation, ie, a reduction in peri-implant probing depths and bleeding on probing, as well as the establishment of a local environment conducive to biofilm control would be desirable.

The authors of this systematic review considered a composite outcome for successful peri-implantitis therapy would ideally be: implant survival with the absence of peri-implant probing depths (PD)  $\geq$  5 mm, with concomitant bleeding on probing (BoP) with light pressure and no suppuration, in addition to no further bone loss. If these criteria were met, it can be assumed that no further intervention other than nonsurgical maintenance care would be required, and the treatment outcome would therefore be regarded as successful.

Therefore, the focus question for this systematic review was "In patients with osseointegrated implants diagnosed with peri-implantitis, how successful is treatment aimed at resolution of the disease?"

#### MATERIALS AND METHODS

#### Search Strategy

On August 15, 2012, the authors searched the following medical databases to identify the literature on the treatment of peri-implantitis in humans: Medline via OVID, PubMed (NLM), Embase via OVID, The Cochrane Central Register of Controlled Trials (The Cochrane Library). The Boolean search algorithm employed to find the potentially relevant literature was developed on the basis of preliminary scoping searches and the experience of previous reviews conducted by these authors on the same subject<sup>7,9</sup> and included the following terms:

"peri-implant disease" OR "periimplant disease" OR "peri-implant complication" OR periimplant complication OR peri-implant infection OR periimplant infection OR peri-implant" OR "periimplant" OR "peri-implantitis" OR "periimplantitis" OR ("implant" AND "failure" OR "failing" OR "ailing")

together with (AND)

"treatment" OR "therapy" OR "management"

In addition, previous review articles on the subject were searched, as well as the reference lists of the articles already identified for further potentially relevant publications. Although there was no language restriction, the minimum requirement was access to an English version of title and abstract (Table 1).

#### **Study Selection Criteria**

To be eligible for inclusion in this review, reports had to provide treatment outcomes evaluating nonsurgical or surgical interventions to treat peri-implantitis in humans. The study selection criteria were:

- Include patients with at least one dental osseointegrated implant affected by peri-implantitis
- Describe a pathological condition compatible with the definition of "peri-implantitis"
- Describe a clinical intervention aiming at the treatment of the condition
- Include at least five comparable cases treated with the same procedure, followed up for at least 3 months after therapy.

The authors independently screened titles and abstracts of the search results. The full text of all studies of possible relevance was obtained for assessment against the stated inclusion criteria. Any disagreement regarding inclusion was resolved by discussion.

#### Data Extraction

The following information was sought and recorded by the two authors independently on data extraction forms: study design, year of publication, number of patients and implants with peri-implantitis, implant type, disease definition, treatment procedures (pretreatment phase, procedure to gain access, implant surface treatment, antimicrobial agents, regenerative materials, postsurgical care), length of follow-up, and outcomes.

The following treatment outcomes, when reported, were recorded: (1) implant failure leading to loss or removal of the implant; (2) persistence or recurrence of peri-implantitis, ie, suppuration from the peri-implant sulcus, continued bone loss; (3) complications and side

Table 1 Syst	ematic Search Strategy
Focus question	In patients with osseointegrated implants diagnosed with peri-implantitis, how successful is treatment aimed at resolution of the disease?
Search strategy	
Population	Patients diagnosed with peri-implantitis
Intervention or exposure	Treatment
Comparison	Include both nonsurgical and surgical treatment
Outcome	Resolution of disease: implant survival and absence of PD $\geq 5$ mm with suppuration/BoP and no further bone loss
Search combination	"peri-implant disease" OR "periimplant disease" OR "peri-implant complication" OR "periimplant complication" OR "peri-implant infection" OR "periimplant infection" OR "peri-implant" OR "peri-implantitis" OR "peri-implantitis" OR ("implant" AND "failure" OR "failing" OR "ailing") together with (AND) "treatment" OR "therapy" OR "management"
Database search	
Electronic	Medline via OVID, Pubmed (NLM), Embase via OVID, The Cochrane Central Register of Controlled Trials (The Cochrane Library)
Journals	All journals
Selection criteria	
Inclusion criteria	<ul> <li>Include patients with at least one dental osseointegrated implant affected by peri-implantitis</li> <li>Describe a pathological condition compatible with the definition of peri-implantitis</li> <li>Describe a clinical intervention aiming at the treatment of the condition</li> <li>Include at least five comparable cases treated with the same procedure, followed up for at least 3 months after therapy</li> </ul>
Exclusion criteri	a No access to an English version of title and abstract

effects; (4) change in peri-implant probing depth; (5) change in bleeding on probing; (6) change in periimplant mucosal recession; and (7) change in radiographic marginal bone level.

While the ideal composite criterion for successful treatment outcome, as outlined in the introduction, would have included the absence of peri-implant probing depths  $\geq$  5 mm with concomitant BoP, this data could not be extracted from the available studies. Therefore, for the purposes of this review, the following composite criterion for a successful treatment outcome was used: implant survival with mean PD < 5 mm and no further bone loss.

# **Assessment of Case Definition**

The authors of this review classified the case definition of peri-implantitis of each study as follows:

- Clear: (1) A clear threshold of loss of supporting bone (eg, bone loss > 1.8 mm, (2) presence of bleeding on probing and/or suppuration on probing.
- Unclear: (1) Bone loss with no threshold given or where the threshold could indicate peri-implant mucositis rather than peri-implantitis (eg, bone loss < 1.8 mm, or < 30% implant length); (2) presence of bleeding on probing and/or suppuration on probing.

• *Inadequate:* Bone loss without information on bleeding and/or suppuration on probing.

# Quality Assessment and Risk of Bias Assessment

Quality assessment and assessment of risk of bias were undertaken independently, and in duplicate by the two authors as part of the data extraction process. For the included randomized controlled trials, this was conducted using the Cochrane Collaboration's tool for assessing risk of bias.<sup>10</sup>

The following possible sources of bias were addressed: random sequence generation (selection bias); allocation concealment (selection bias); blinding of participants and personnel (performance bias and detection bias); incomplete outcome data (attrition bias); and selective reporting (reporting bias). The authors' judgment for each source of bias item was assigned for each trial in the data extraction table. An overall risk of bias was then assigned to each trial according to Higgins et al.<sup>10</sup>

For the included case series, the quality assessment addressed examiner blinding, examiner calibration, standardized probing force, standardized radiographic assessment, incomplete data outcome, and selective reporting.

#### Table 2 Characteristics of Case Series of Nonsurgical Therapies in Peri-implantitis Patients

Study	Patients	Implants	Implant type	Disease definition	Surface treatment	
Mombelli and Lang <sup>16</sup>	9	9	Straumann: HC	$PD \ge 5 \text{ mm}$ , marked BL, anaerobes	PS, CHX	
Mombelli et al <sup>17</sup>	25	30	Straumann: HC, HS, S	$PD \ge 5 \text{ mm}$ , circumferential BL	PS, CHX	
Salvi et al <sup>18</sup> Persson et al <sup>19</sup>	25	31	NR	$PD \geq 5 \text{ mm, BL} \geq 2 \text{ mm, BoP}$	CFC, CHX	

HC: hollow-cylinder implant; HS: hollow-screw implant; S: screw-shaped implant; NR: not reported; PD: probing depth; BL: bone loss; BoP: bleeding on probing; PS: plastic scaler; CFC: carbon fiber curette; CHX: chlorhexidine; AB: systemic antibiotic; DD: local delivery device: CHDQ: full results also and the scale of the scale of

LDD: local delivery device; FMPS: full-mouth plaque score.

#### Table 3 Characteristics of Comparative Studies of Nonsurgical Therapies in Peri-implantitis Patients

			•		-	
Study	Patients	Implants	Implant type	Disease definition	Pretreatment	Surface treatment
Büchter et al <sup>20</sup>	14	24	Straumann SLA	BL > 50%, implant length	FMD removal	PS, CHX
	14	24		BL > 50%, implant length	of prosthesis	PS, CHX
Renvert et al <sup>21</sup>	16	NR	Brånemark	$PD \ge 4 \text{ mm}, BoP \text{ and/or}$	NR	PS
Renvert et al <sup>22</sup>	16	NR	Diditeritark	SUP, BL $\leq$ 1.8 mm, anaerobes	INIX	PS
Renvert et al <sup>23</sup>	15	38		$PD \ge 4 \text{ mm}$ , BoP and/or		PS
	17	57	Brånemark: machined	SUP, BL $\leq$ 1.8 mm, anaerobes	NR	PS
Karring et al <sup>24</sup>	11	11	Straumann, Astra Tech,		NR	CFC
	ΤT	11	Brånemark: S	$PD \ge 5 \text{ mm}, BL \ge 1.5 \text{ mm}, BoP$	NR	US: Vector
Renvert et al <sup>25</sup>	19	19	Astra Tech, Brånemark: S	$PD \ge 4 \text{ mm}$ , BoP and/or	NR	TC
Persson et al <sup>26</sup>	18	18	Astra Tech, Drahemark. S	SUP, BL < 2.5 mm	NR .	US: Vector
Sahm et al <sup>27</sup>	16	23	S, multiple surfaces	$PD \ge 4 \text{ mm}$ , BoP and/or SUP,	Polishing	APG
	16	20	o, multiple surfaces	$BL \leq 30\%$ implant length		CFC
Schwarz et al <sup>28</sup>	10	16	S, SLA, TPS	PD ≥ 4 mm, BL, BoP and SUP	NR	PS, CHX
	10	16	0, 0EA, 110			Er:YAG laser
Schwarz et al <sup>29</sup>	10	10		Moderate: PD 4–6 mm, BL < 30% implant length, BoP and SUP		PS, CHX
	10		7 brands	Advanced: PD $> 7 \text{ mm}$ , BL $> 30\%$	NR	Er:YAG laser
	10	20		implant length, BoP and SUP		
Renvert et al <sup>30</sup> Persson et al <sup>31</sup>	21	45	Machined, moderately	$PD \ge 5 \text{ mm}$ , BoP and/or SUP,	Removal of	APG
	21	55	rough	BL > 3 mm	prosthesis	Er:YAG laser
Schär et al <sup>32</sup>	20	20	S, Straumann SLA	PD 4–6 mm, BoP, BL = 0.5–2.0 mm	NR	TC, APG, H <sub>2</sub> O <sub>2</sub>
	20	20	,	· · · · · · · · · · · · · · · · · · ·		TC, APG, $H_2O_2$
o			THE REPORT OF THE REPORT		1.	

S: screw-shaped implant; SLA: sandblasted large-grit acid-etched; TPS: titanium plasma sprayed; BL: bone loss; PD: probing depth; BoP: bleeding on probing; SUP: suppuration; FMD: full-mouth debridement; NR: not reported; PS: plastic scaler; CHX: chlorhexidine; CFC: carbon fiber curette; US: Ultrasonic device; TC: titanium curette; APG: air-powder abrasive with glycine powder; LDD: local delivery device; PDT: photodynamic therapy.

#### **Data Synthesis**

# The two reviewers extracted the pertinent information independently, and in duplicate from the selected trials into four spreadsheets, representing either case series or comparative studies, and nonsurgical protocols or surgical protocols. Due to the heterogeneity of study designs, outcome variables, and reporting, no meta-analysis was performed.

# RESULTS

The initial search yielded over 400 potentially relevant publications. A majority of them, however, failed to satisfy all inclusion criteria for this review because they did not concern patients with dental osseointegrated implants; turned out to be reviews, commentaries or editorials without original data; did not address a path-

Antimicrobial	Maintenance	Follow-up
AB: ornidazole	NR	12 mo
LDD: tetracycline fiber	NR	12 mo
LDD: minocycline	Oral hygiene instruction, FMPS $\leq 20\%$	12 mo

Antimicrobial	Maintenance	Follow-up
LDD: doxycycline	Oral hygiene instruction	4.5 mo
CHX LDD: minocycline	Oral hygiene instruction	12 mo
CHX: repeated 3 times LD: minocycline repeated 3 times	Oral hygiene instruction	12 mo
	Retreated at 3 mo	6 mo
	Oral hygiene instruction	6 mo
СНХ	Supramucosal prophylaxis, oral hygiene instruction	6 mo
CHX rinsing	4, 12, 24 wk supragingival/ mucosal polishing	6 mo
CHX rinsing	1, 3, 6, 12 mo supragingival/ mucosal polishing	12 mo
	NR	6 mo
LDD: minocycline PDT	Oral hygiene instruction: wk 1, 2, 4, 8	6 mo

ological condition compatible with the definition of peri-implantitis; and/or did not report the same treatment in at least five cases with a follow-up of at least 3 months. This left 48 papers for which the full text was sought for further evaluation. After further evaluation, an additional 5 papers were excluded due to the following reasons: insufficient information<sup>11–13</sup> and paper unavailable,<sup>14,15</sup> leaving a total of 43 papers. The 43 papers fulfilling all study selection criteria were subdivided into four categories. Table 2 lists the details of 4 papers concerning 3 studies describing a series of at least 5 patients treated with the same nonsurgical protocol. Table 3 lists the characteristics of the 13 papers concerning 10 studies presenting a comparison of nonsurgical treatment groups. Table 4 lists the 15 articles concerning 14 studies describing a series of at least 5 patients treated with the same surgical protocol. Table 5 lists the 11 papers describing the 6 studies presenting a comparison of groups of patients, where one surgical method is applied per group.

#### **Characteristics of the Interventions**

Tables 2 and 3 list the characteristics of studies describing nonsurgical therapies of peri-implantitis. Methods to decontaminate the implant surface included debridement using manual or ultrasonic instruments with carbon fiber or plastic tips, air-powder abrasive devices, laser treatment, and the systemic or local application of antimicrobial agents.

**Case Series of Nonsurgical Interventions.** Three case series evaluating manual debridement (using a plastic scaler or carbon fiber curette) with adjunctive antimicrobials were identified. One study included systemic ornidazole prescribed for 10 days,<sup>16</sup> while the others incorporated adjunctive local antibiotic delivery via fibers containing tetracycline hydrochloride (HCI) (Actisite)<sup>17</sup> and minocycline HCI microspheres (Arestin).<sup>18,19</sup> All patients received adjunctive chlorhexidine application as part of the treatment and were followed for 12 months.

Comparative Studies (RCTs) of Nonsurgical Interventions. Three studies compared manual debridement versus manual debridement with local antimicrobials. Büchter et al<sup>20</sup> compared manual debridement (plastic scaler and submucosal irrigation of chlorhexidine) to the same debridement technique with adjunctive local delivery of 8.5% doxycycline hyclate gel (Atridox). In both treatment groups, the implant-supported prostheses were removed prior to treatment, and full-mouth debridement with subgingival irrigation with chlorhexidine was performed. Renvert et al<sup>21,22</sup> compared manual debridement using a plastic scaler and chlorhexidine gel application to debridement using a plastic scaler and local delivery of minocycline HCl (Arestin). In another trial by the same authors,<sup>23</sup> manual debridement in conjunction with repeated submucosal application of 1% chlorhexidine gel was compared to manual debridement with repeated application of minocycline HCl microspheres (Arestin). Treatment in both groups was repeated at day 30 and day 90.

Two studies compared manual debridement with ultrasonic debridement. Karring et al,<sup>24</sup> in a split-mouth

#### Table 4 Case Series of Surgical Therapies in Peri-implantitis Patients

Study	Patients	Implants	Implant type	Disease definition	Pretreatment	
Augthun et al <sup>33</sup>	12	15	IMZ	$PD \ge 5 mm, BL \ge 5 mm$	NR	
Behneke et al <sup>34</sup>	17	25	Straumann	PD > 5 mm, crater-like BL not observed at > 90% of implant length	lodine irrigation for 4 wk	
Roccuzzo et al <sup>35</sup>	26	26	Straumann: TPS/SLA, S	$PD \ge 6 \text{ mm}$ , crater-like BL	Oral hygiene instruction, FMPS, FMBS < 20%	
Wiltfang et al <sup>36</sup>	22	36	No data	BL > 4 mm	Nonsurgical debridement, rinsing CHX	
Froum et al <sup>37</sup>	38	51	10 brands	$PD \ge 6 mm$ , $BoP$ , $BL \ge 4 mm$	FMD 1 mo prior	
Romanos and Nentwig <sup>38</sup>	15	19	Ankylos, Straumann, IMZ	BL > two-thirds implant length	NR	
Haas et al <sup>39</sup>	17	24	IMZ	PD > 6 mm, progressive BL during 1 y, narrow vertical BD	NR	
Roos-Jansåker et al <sup>40</sup>	12	16	Brånemark	$BL \ge 3$ threads (1.8 mm), BOP and/or SUP	NR	
Schwarz et al <sup>41</sup>	27	27	4 brands: S	PD > 6 mm, BL > 3 mm	Er:YAG laser	
Leonhardt et al <sup>42</sup>	9	26	Brånemark	$BL \ge 3$ threads, BOP/SUP	Removal of prosthesis + abutment	
Heitz-Mayfield et al <sup>43</sup>	24	36	6 brands	$PD \geq 5 \text{ mm, BL} \geq 2 \text{ mm, BoP}$	Nonsurgical debridement	
de Mendonça et al <sup>44</sup>	10	10	S	$PD \ge 5 \text{ mm}$ , BoP and/or SUP, BL at $\ge 3$ threads	Oral hygiene instruction	
Maximo et al <sup>45</sup> Duarte et al <sup>46</sup>	13	20	Brånemark	$PD \geq 5$ mm, BoP/SUP, BL $\geq 3$ threads until half implant length	Supragingival cleaning	
Serino and Turri <sup>47</sup>	31	86	Brånemark, Straumann, Astra Tech: S	$PD \ge 6 mm$ , $BoP/SUP$ , $BL \ge 2 mm$	Supra/subgingival debridement, adjustment prosthesis if required	

TPS: titanium plasma sprayed; SLA: sandblasted large-grit acid-etched; S: Screw-shaped implant; PD: probing depth; BL: bone loss;

BoP: bleeding on probing; SUP: suppuration; NR: not reported; FMPS: full-mouth plaque score; FMBS: full-mouth bleeding scoree; CHX: chlorhexidine; AUG: Augmentin; FMD: full-mouth debridement; APB: air-powder abrasive with sodium bicarbonate powder; PC: plastic curette; EDTA: ethylene diamine tetra-acetate gel; IPP: Implantoplasty with bur; CFC: carbon fiber curette; TC: titanium curette; PDT: photodynamic therapy; TET: tetracycline; MTR: metronidazole; AMX: amoxicillin; CLI: clindamycin; ePTFE: expanded polytetrafluorethylene membrane; ABG: autogenous bone graft;

XBM: xenogenic bone mineral (Bio-Oss); EMD; enamel matrix derivative; PDGF: platelet-derived growth factor; CT: connective tissue;

PCC: phytogenic calcium carbonate (Algipore); RSM: resorbable synthetic membrane; CM: collagen membrane.

study design, compared manual debridement with carbon fiber curettes to an ultrasonic device (Vector system) with a carbon fiber tip combined with aerosol spray of hydroxyapatite particles. The treatment procedures were repeated after 3 months. A second trial with parallel design compared manual debridement (with a titanium instrument) with the same ultrasonic device (Vector system).<sup>25,26</sup>

Sahm et al<sup>27</sup> compared manual debridement (carbon fiber curettes), with adjunctive submucosal chlorhexidine application with debridement using an air-powder abrasive device and glycine powder. Oral hygiene instruction and supramucosal polishing was provided 4 weeks prior to treatment procedures in both groups.

Two trials conducted by the same authors, using a similar protocol, compared manual debridement (plastic scaler) with adjunctive chlorhexidine (submucosal irrigation and gel application followed by chlorhexidine rinsing for 2 weeks) with debridement using an erbium-doped yttrium aluminium garnet (Er:YAG)

laser.<sup>28,29</sup> Oral hygiene instruction and supramucosal polishing was provided in both studies in a pretreatment phase.

Renvert et al<sup>30</sup> and Persson et al<sup>31</sup> compared treatment with an Er:YAG laser to debridement using an air-powder abrasive device and amino acid glycine powder. The implant-supported prostheses were removed prior to treatment.

Schär et al<sup>32</sup> compared debridement and photodynamic therapy (application of phenothiazine chloride and laser irradiation at a wavelength of 660 nm) (HELBO), which was repeated at 1 week with debridement and adjunctive minocycline HCl microspheres (Arestin). The debridement protocol in both treatment groups involved the use of titanium curettes, glycine-based air-powder abrasion, and submucosal pocket irrigation using 3% hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>). Oral hygiene instruction was provided in both groups prior to treatment.

Tables 4 and 5 list the studies reporting information from surgical therapies of peri-implantitis. All protocols included the elevation of a mucoperiosteal flap and the

Surface treatment	Antimicrobial	Materials	Maintenance	Follow-up
APB	TET	ePTFE	NR	6–12 mo
APB	MTR	ABG	Oral hygiene instruction every 3 mos for the first year	6–36 mo
PC, EDTA, CHX, saline	AMX+clavulanic acid, CHX	XBM	Tailored maintenance care	12 mo
IPP, phosphoric acid	Ampicillin or CLI	Xenograft (Coloss) + ABG	3 monthly	12 mo
APB, CFC, TC	AMX or CLI, CHX	EMD, PDGF, XBM, CM, CT graft	6–8 weekly rubber cup polishing	90 mo
TC, CO <sub>2</sub> laser	None	ABG or XBM, CM	NR	18 mo
PDT	AUG	ePTFE, ABG	NR	Mean 9.5 mo
H <sub>2</sub> O <sub>2</sub>	AMX+MTR, CHX	PCC, RSM submerged healing	3 monthly rubber cup polishing	12 mo
CFC + saline	СНХ	XBM + CM	Once a month for 6 mo, then every 3 mo	12 mo
$H_{2}O_{2}$	5 different antibiotics	None	3–6 monthly	5 у
CFC, TC	AMX + MET, CHX	None	3 monthly or as required	12 mo
CFC, APB	СНХ	None	3 monthly supramucosal prophylaxis	12 mo
APB, CFC	СНХ	None	None	3 mo
US, rubber cup + CHX	CLI, CHX	ABG + bone recontouring, apically positioned flap	3 to 6 monthly	24 mo

removal of the peri-implant inflammatory granulation tissue. Methods to decontaminate and condition the implant surface adjacent to the diseased peri-implant soft tissues included cleaning with carbon or plastic curettes, ultrasonic scalers, air-powder abrasive devices using sodium bicarbonate or glycine powder, irradiation with hard or soft laser light, implantoplasty, and/or the application of acids or various antimicrobial agents. A majority of the protocols included the systemic administration of an antibiotic in addition to chlorhexidine rinsing. In many studies, peri-implant bony defects were filled with graft materials including autogenous bone, allogenic decalcified freeze-dried bone, xenogenic bone mineral, phytogenic calcium carbonate, hydroxyapatite or tricalcium phosphate. Nonresorbable membranes of expanded polytetrafluoroethylene (ePTFE) or resorbable collagen or synthetic membranes were used to cover the graft material.

**Case Series of Surgical Interventions.** Augthun et al<sup>33</sup> elevated a flap, cleaned the implant surfaces with an air-polishing device, and covered the peri-implant

defects with an ePTFE membrane. Systemic tetracycline was administered.

Three studies reported on regenerative treatments using grafts without membranes. Behneke et al<sup>34</sup> treated peri-implanitis lesions with autogenous bone grafts. Treatment included flap elevation, removal of granulation tissue, air-powder abrasion of implant surfaces with sodium carbonate powder, placement of grafts, and systemic metronidazole. Roccuzzo et al<sup>35</sup> treated peri-implantitis lesions with bovine-derived xenograft (BioOss). After flap elevation and granulation tissue removal, the implant surfaces were cleaned with a plastic curette and a 24% ethylenediaminetetraacetic acid (EDTA) gel was applied for 2 minutes followed by 1% chlorhexidine gel for an additional 2 minutes. The bone defect was then filled with the xenograft, and the flap was closed around the nonsubmerged implants. Amoxicillin with clavulanic acid was prescribed for 6 days and 0.2% chlorhexidine rinse for 3 weeks. Wiltfang et al<sup>36</sup> treated peri-implantitis defects with a mix of autologous bone and a demineralized xenogenic

Study	Pa- tients	lm- plants	Implant type	Disease definition	Pretreatment	
Deppe et al <sup>48</sup>		17				
	32	22	IMZ, Frialit, Brånemark,	$PD \ge 5 \text{ mm}$ , progressive BL,	Nonsurgical debridement +	
	52	15	Straumann	or BoP	CHX rinsing	
		19				
Schwarz et al <sup>49,50</sup>	19	19	10 branda, na UC	DD - C mm introheny DL - 2 mm	Nonsurgical debridement	
	16	16	10 brands: no HC	PD > 6 mm, intrabony BL > 3 mm	PS, irrigation CHX + CHX gel	
Khoury and	25	12			Removal prostheses + PS	
Buchmann <sup>51</sup>		20	IMZ, Friadent	BL > 50%	+ CHX irrigation + AB 6 mo	
		9			prior to surgery	
Roos-Jansåker	15	27	Astra Tech, Brånemark	$BL \ge 1.8 \text{ mm}, BoP/SUP$	Nonsurgical debridement	
et al <sup>52,53</sup>	17	19	Astra lecil, branemark	$BL \ge 1.0$ mm, $BOF/30F$	Nonsuigical debridement	
Schwarz et al <sup>54–56</sup>	11	11	7 brands: S	PD > 6 mm, intrabony BL > 3 mm	Nonsurgical debridement	
	11	11	r branus. S		PS, irrigation CHX + CHX gel	
Romeo et al <sup>57,58</sup>	10	19		DD > 4 mm BoD/SUD ovident Pl	Socier DS AMY	
	9	18	S, HS; all TPS	PD > 4 mm, BoP/SUP, evident BL	Scaling PS, AMX	

S: screw-shaped implant; HC: hollow-cylinder implant; HS: hollow-screw implant; TPS: titanium plasma sprayed; PD: probing depth; BL: bone loss; BoP: bleeding on probing; SUP: suppuration; CHX: chlorhexidine; PS: plastic scaler; AB: systemic antibiotic; AMX: amoxicillin; APB: air-powder abrasive with sodium bicarbonate powder; IPP: implantoplasty with bur; PS: plastic scaler; CA: citric acid; MTR: metronidazole; TET: tetracycline; TCP: beta-tricalcium phosphate; ABG: autogenous bone graft; ePTFE: expanded polytetrafluorethylene membrane; XBM: xenogenic bone mineral (Bio-Oss); CM, collagen membrane; PCC: phytogenic calcium carbonate (Algipore); RSM: resorbable synthetic membrane; NR: not reported.

bone graft including growth factors (Colloss E). A flap was raised, granulation tissue was removed, the implant surface was decontaminated with a phosphoric acid etching gel, and the defects were filled with the grafting material. Ampicillin (clindamycin in case of allergy) was given perioperatively.

Five studies reported on regenerative treatments with grafts and membranes. Froum et al<sup>37</sup> carried out the following treatment: flap elevation followed by surface decontamination consisting of a six-step protocol including instrumentation with graphite curettes or titanium tips, air-powder abrasion with sodium bicarbonate powder, and application of a tetracycline and a chlorhexidine solution. Following this, enamel matrix derivative and a combination of platelet-derived growth factor (PDGF) with anorganic bovine bone or mineralized freeze-dried bone were applied and covered with a collagen membrane or a subepithelial connective tissue graft. In addition, amoxicillin or clindamycin was prescribed for 10 days. Romanos and Nentwig<sup>38</sup> elevated a flap, mechanically debrided the implant surfaces with titanium curettes, and treated the surfaces using a carbon dioxide (CO<sub>2</sub>) laser. Following this, an autogenous bone graft or a xenogenic bone grafting material (BioOss) was placed and covered with a collagen membrane (Bio-Gide). No systemic antimicrobials were prescribed. Haas et al<sup>39</sup> raised mucoperiosteal flaps and removed the granulation tissue in the bony craters around implants. Implant surfaces were then treated with photodynamic therapy (application of toluidine blue and laser irradiation at a wavelength of 906 nm). The bone defects were filled with autogenous bone and covered with an ePTFE membrane. Systemic penicillin was administered for 5 days. Roos-Jansåker et al<sup>40</sup> raised a mucoperiosteal flap, removed granulomatous tissue, and cleaned the implant surface with  $H_2O_2$ . The defects were filled with a bone substitute (Algipore), covered with a resorbable synthetic membrane (Osseoquest), and submerged healing was allowed for 6 months. Systemic amoxicillin plus metronidazole was prescribed for 10 days.

Schwarz et al<sup>41</sup> raised mucoperiosteal flaps, removed the granulation tissue, and cleaned the implant surfaces with plastic curettes and swabbing with cotton pellets soaked in saline. The bone defects were then filled with a bovine-derived xenograft (BioOss) and covered with a collagen membrane (Bio-Gide). No systemic antimicrobials were prescribed.

Two studies reported on access surgery and decontamination with systemic antibiotics. Leonhardt et al<sup>42</sup> treated peri-implantitis lesions with a combined surgical and antimicrobial protocol. Implants were surgically exposed and cleaned using  $H_2O_2$ . Two patients were given systemic amoxicillin and metronidazole, two patients received tetracycline, two ciprofloxacin, one sulfonamide plus trimethoprim, and one metronidazole alone. Heitz-Mayfield et al<sup>43</sup> raised a mucoperiosteal flap and removed granulation tissue, and the implant surfaces were cleaned using titanium coated curettes and by rubbing

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#### Table 5 Comparative Studies of Surgical Therapies in Peri-implantitis Patients

Surface treatment	Antimicrobial	Materials	Maintenance	Follow-up
APB, $\rm{CO}_2$ laser	None	TCP, ABG, ePTFE None: resective surgery	NR	Up to
APB	None	TCP, ABG, ePTFE None: resective surgery		5 y
IPP, Er:YAG-laser	СНХ	XBM, CM	1, 3, 6 mo supragingival clean-	2 y
IPP, PS + saline	СПХ	XBM, CM	ing, OHI	∠ y
CA, CHX, $H_2O_2$ + saline	Various unspecified antibiotics, CHX	ABG ABG, ePTFE ABG, CM	Every 3 to 6 mo OHI prophylaxis as required	З у
H <sub>2</sub> O <sub>2</sub> H <sub>2</sub> O <sub>2</sub>	AMX+MTR, CHX	PCC, RSM PCC	3 monthly polishing rubber cup oral hygiene instruction	З у
PS + saline rinse	СНХ	Nanocrystalline HA XBM + CM	1–6 monthly	4 y
Resective IPP, MTR gel, TET	AMX, CHX	None	Strict maintenance care	З у
Resective MTR gel, TET	AIVIA, CHA	None	Strict maintenance cale	5 y

with gauze soaked in saline, followed by saline irrigation. Systemic amoxicillin and metronidazole was prescribed for 7 days and chlorhexidine rinsing for 4 weeks.

Two studies reported on access surgery and decontamination without systemic antibiotics. de Mendonça et al<sup>44</sup> gained surgical access, removed granulation tissue, and cleaned the implant surfaces with resin curettes and an air-powder abrasive device using sodium bicarbonate powder. Maximo et al<sup>45</sup> and Duarte et al<sup>46</sup> raised a flap and removed granulation tissue, and implant surfaces were decontaminated with teflon curettes and an air-powder abrasive device using sodium bicarbonate powder.

In the one retrieved study on reconstructive surgery, Serino and Turri<sup>47</sup> raised an access flap and recontoured the bone. The implant surfaces were instrumented using an ultrasonic instrument and rotating rubber cup under chlorhexidine irrigation. Patients received clindamycin for 1 week and rinsed for 2 weeks with chlorhexidine after the intervention.

**Comparative Studies (RCTs) of Surgical Interventions.** Deppe et al<sup>48</sup> treated peri-implantitis lesions using both resective and regenerative procedures with or without  $CO_2$  laser (wavelength 10.6 µm). After flap elevation and granulation tissue removal, all implants were cleaned with an air-powder abrasive. The regenerative procedures included bone augmentation using a combination of autologous bone and beta-tricalcium phosphate covered by an ePTFE membrane. Schwarz et al<sup>49,50</sup> compared two surface decontamination methods in conjunction with regenerative surgical treatment of peri-implantitis. Following access flap, granulation tissue removal, and implantoplasty at buccally and supracrestally exposed implant parts, the intrabony aspects were randomly allocated to surface cleaning with either (1) Er:YAG laser or (2) plastic curettes plus swabbing with cotton pellets soaked in saline and irrigation with saline. In both groups, the intrabony component was augmented with a xenogenic bone mineral (Bio-Oss) and covered with a collagen membrane.

Two studies reported on regenerative treatments using grafts with or without barrier membranes. Khoury and Buchmann<sup>51</sup> evaluated three regenerative protocols. The implants were treated with flap surgery plus autogenous bone grafts alone, graft plus ePTFE barrier membranes, or graft plus bioabsorbable barrier membranes (Bio-Gide). After flap elevation and granulation tissue removal, the surgical sites were rinsed with chlorhexidine and the implant surfaces were treated with citric acid, irrigated with H<sub>2</sub>O<sub>2</sub>, and rinsed with saline. Augmentation procedures were then completed and systemic antimicrobials were administered with the choice of drug based on a microbiological examination. Roos-Jansåker et al<sup>52,53</sup> evaluated regenerative treatment of peri-implantitis comparing a bone substitute with or without a barrier membrane. Following flap elevation, the implant surfaces were mechanically

cleaned, treated with  $3\% H_2O_{2r}$  and rinsed with saline. Peri-implant defects were treated with a phytogenic calcium carbonate bone substitute (Algipore) or with the bone substitute and a resorbable synthetic membrane (Osseoquest). Systemic amoxicillin and metronidazole was prescribed for 10 days, and patients rinsed with chlorhexidine.

Schwarz et al<sup>54–56</sup> elevated a flap, removed granulation tissue, and cleaned the implant surfaces with plastic curettes and rinsed with saline solution. The defects were filled with either a synthetic nanocrystalline hydroxyapatite (Ostim) or a bovine-derived xenogenic bone mineral (BioOss), and covered with a collagen membrane (Bio-Gide). No systemic antimicrobials were prescribed.

Romeo et al<sup>57,58</sup> compared two different surgical approaches. Patients were treated either with resective surgery and implantoplasty (modification of the implant surface topography using a sequence of different burs and polishers) or with resective surgery alone. A pretreatment phase included nonsurgical debridement and systemic antibiotics for 8 days. Following flap elevation and granulation tissue removal, alveolar bone peaks were removed. Metronidazole gel was applied and a tetracycline HCl solution was rubbed on the implant surface for 3 minutes and then rinsed off with saline. The flaps were apically positioned.

**Nonsurgical versus Surgical Interventions.** No trials were found reporting on nonsurgical versus surgical interventions.

# **Case Definitions**

The inclusion criteria for each study are presented in Tables 2 and 3 for nonsurgical interventions and Tables 4 and 5 for surgical interventions. The criteria used varied widely between studies. As outlined in the Materials and Methods section, the authors of this review rated the case definition of each study as clear, unclear, or inadequate.

*Case Series of Nonsurgical Interventions (3 Studies).* One study was assigned as having a clear case definition<sup>18</sup> and two studies with an unclear case definition.<sup>16,17</sup>

**Comparative Studies of Nonsurgical Interventions (10 Studies).** Two studies were assigned as having a clear case definition,<sup>24,30</sup> seven studies with an unclear case definition,<sup>12,21,23,25,27,28,32</sup> and one study with an inadequate case definition.<sup>20</sup>

**Case Series of Surgical Interventions (14 Studies).** Seven studies were assigned as having a clear case definition,  $^{37,40,42-45,47}$  five with an unclear case definition,  $^{33-35,39,41}$  and two studies with an inadequate case definition.  $^{36,38}$ 

**Comparative Studies of Surgical Interventions** (6 Studies). One study was assigned as having a clear case definition,  $^{52}$  four with an unclear case definition,  $^{48-50,54-58}$  and one study with an inadequate case definition.  $^{51}$ 

# Quality Assessment and Risk of Bias Assessment

**Case Series of Nonsurgical Interventions.** Examiner blinding and calibration were not reported in any of the case series.

A standardized probing force and the use of a parallel radiographic technique for standardizing radiographs were reported in one case series.<sup>18</sup>

**Case Series of Surgical Interventions.** Examiner blinding was reported in five studies.<sup>35–37,40,41</sup> Examiner calibration was reported in five studies.<sup>35,37,41,44,45</sup> A standardized probing force was reported in two studies.<sup>40,43</sup> A paralleling technique for standardizing radiographs was reported in seven studies.<sup>34,35,39,40,42–44</sup> One study reported use of a bite block for standardization of radiographs.<sup>40</sup>

**Comparative Studies.** Tables 6 and 7 outline the risk of bias assessment, as judged by the authors of this review, for non-surgical and surgical comparative studies (RCTs) respectively.

The majority of comparative studies were judged to be at unclear risk of bias. Two studies were judged to have a high risk of bias.<sup>28,29</sup>

# Outcome Measures Reported in the Included Studies

The following treatment outcomes were reported in the included studies.

#### **Case Series of Nonsurgical Interventions**

- Implant failure leading to loss or removal of the implant was evaluated in all studies.<sup>16–18</sup>
- Persistence or recurrence of peri-implantitis, ie, suppuration from the peri-implant sulcus, was evaluated in two studies.<sup>17,18</sup>
- Change in peri-implant PD was evaluated in all studies.<sup>16–18</sup>
- Change in BoP was evaluated in all studies.<sup>16–18</sup>
- Change in mucosal recession was evaluated in all studies.<sup>16–18</sup>
- Radiographic marginal bone levels were evaluated in two studies.<sup>17,18</sup>
- Complications and side effects were not reported in any of the studies.

# **Comparative Studies of Nonsurgical Interventions**

- Implant failure leading to loss or removal of the implant was evaluated in all studies.<sup>20,21,23–25,27–30,32</sup>
- Persistence or recurrence of peri-implantitis, ie, suppuration from the peri-implant sulcus, was evaluated in five studies.<sup>24,28–30,32</sup>
- Change in peri-implant PD was evaluated in all studies.<sup>20,21,23–25,27–30,32</sup>

Table 6         Risk of Bias Assessment for Nonsurgical Comparative (RCT) Studies								
	Random sequence generation	Allocation concealment	Blinding	Incomplete outcome data	Selective reporting	Other bias	Summary assessment	
Büchter et al <sup>20</sup>	+	?	+	+	+	+	Unclear	
Karring et al <sup>24</sup>	?	?	+	+	?	+	Unclear	
Renvert et al <sup>30</sup> Persson et al <sup>31</sup>	+	?	+	+	?	+	Unclear	
Renvert et al <sup>25</sup> Persson et al <sup>26</sup>	+	?	+	-	?	+	Unclear	
Renvert et al <sup>21</sup>	+	+	+	-	?	+	Unclear	
Renvert et al <sup>23</sup>	+	?	+	+	?	+	Unclear	
Sahm et al <sup>27</sup>	+	?	?	+	?	+	Unclear	
Schär et al <sup>32</sup>	+	?	+	+	?	+	Unclear	
Schwarz et al <sup>28</sup>	+	?	_	_	_	+	High	
Schwarz et al <sup>29</sup>	+	?	?	-	_	+	High	

+ low risk; ? unclear risk; - high risk.

# Table 7 Risk of Bias Assessment for Surgical Comparative (RCT) Studies

	Random sequence generation	Allocation concealment	Blinding	Incomplete outcome data	Selective reporting	Other bias	Summary assessment
Deppe et al <sup>48</sup>	?	?	?	?	+	+	Unclear
Khoury and Buchmann <sup>51</sup>	?	?	?	+	?	+	Unclear
Romeo et al <sup>57,58</sup>	?	?	?	+	?	+	Unclear
Roos-Jansåker et al <sup>52,53</sup>	?	?	?	-	?	+	Unclear
Schwarz et al <sup>54–56</sup>	+	?	+	_	?	+	Unclear
Schwarz et al <sup>49,50</sup>	-	?	?	?	?	+	Unclear

+ low risk; ? unclear risk; - high risk.

- Change in BoP was evaluated in all studies.<sup>20,21,23–25,27–30,32</sup>
- Change in mucosal recession was evaluated in four studies.<sup>27–29,32</sup>
- Radiographic marginal bone levels were evaluated in four studies.<sup>23,24,29,30</sup>
- Complications and side effects were evaluated in four studies.<sup>25,27–29</sup>

#### **Case Series of Surgical Interventions**

- Implant failure leading to loss or removal of the implant was evaluated in all studies.<sup>33–45,47</sup>
- Persistence or recurrence of peri-implantitis, ie, suppuration from the peri-implant sulcus, was evaluated in seven studies.<sup>36,37,41,44,45,47</sup>
- Change in peri-implant PD was evaluated in all studies except two.<sup>38,42</sup>
- Change in BoP was evaluated in 10 studies.<sup>33,35–37,40–45</sup>
- Change in mucosal recession was evaluated in five studies.<sup>36,40,41,43,44</sup>
- Radiographic marginal bone levels/change were evaluated in 10 studies.<sup>33–40,42,43</sup>
- Complications and side effects were evaluated in 11 studies.<sup>33–41,43,44</sup>

# Comparative Studies of Surgical Interventions

- Implant failure leading to loss or removal of the implant was evaluated in all studies.<sup>48,49,51,52,54,57</sup>
- Persistence or recurrence of peri-implantitis, ie, suppuration from the peri-implant sulcus, was reported in two studies.<sup>49,50,54</sup>
- Change in peri-implant PD was evaluated in all studies.<sup>48,49,51,52,54,57</sup>
- Change in BoP was evaluated in four studies.<sup>49,50,52,54,57,58</sup>
- Change in mucosal recession was evaluated in five studies.<sup>48–50,52,57</sup>
- Radiographic marginal bone levels were evaluated in three studies.<sup>51–53,57</sup>
- Complications and side effects were evaluated in four studies.<sup>49–52,54</sup>

# **Treatment Outcomes**

**Case Series of Nonsurgical Interventions.** Mombelli and Lang<sup>16</sup> evaluated manual debridement with systemic ornidazole in 9 patients with 9 implants. There were no withdrawals, no implant losses and no complications reported. At 12 months there was a reduction

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in mean PD from 5.9 mm to 3.4 mm. The mean BoP reduced from 89% to 43%, and the mean recession increased from 1.1 mm to 2.1 mm. There were no radio-graphic data presented.

Mombelli et al<sup>17</sup> evaluated manual debridement with local delivery of tetracycline fibers in 25 patients with 30 implants. At 6 months, 2 patients (3 implants) were discontinued from the study due to persistent peri-implantitis and suppuration on probing. There were no implant losses and no complications reported. The mean PD was 4.7 mm at baseline and 3.5 mm at 12 months, and the mean BoP reduced from 90% to 40% at the deepest implant site. Mean radiographic bone levels were 5.2 mm at baseline and 4.9 mm at 12 months.

Salvi et al<sup>18</sup> evaluated manual debridement with local delivery of minocycline in 25 patients with 31 implants. Six implants in 6 patients were withdrawn from the study due to persistent peri-implantitis and suppuration on probing. The mean PD was 4.5 mm at baseline and 3.5 mm at 12 months, and the mean % of sites with BoP reduced from 69% to 19% at 12 months. Radiographic analysis, while not possible at all implants, showed no significant change in the marginal bone levels.

Comparative Studies (RCTs) of Nonsurgical Interventions. Three studies compared manual debridement with manual debridement using local antimicrobials. Büchter et al<sup>20</sup> evaluated a local antimicrobial (doxycycline) as an adjunct to manual debridement as well as manual debridement alone. The 28 patients (14 in each group) were followed for 4.5 months with no loss to follow-up. No implant loss and no complications were reported. Both treatment groups showed a reduction in mean probing depths and mean BoP from baseline to 4.5 months, with a greater reduction in the doxycycline group. However, at the completion of the study there was incomplete resolution of disease in both groups, with a mean PD of 5.4 mm and mean BoP of 50% in the manual debridement group compared with a mean PD of 4.5 mm and mean BoP of 27% in the doxycycline group. There were no radiographic data presented and no reporting on presence/absence of suppuration on probing.

Renvert et al<sup>21,22</sup> evaluated a local delivery of minocycline as an adjunct to manual debridement in comparison with manual debridement with submucosal chlorhexidine application. Thirty-two patients were treated (16 in each group) and 2 were lost to followup, leaving 30 patients for reevaluation at 12 months. No implant loss was reported. In the manual debridement group, the mean PD was 3.9 mm at baseline with no change at 12 months, while there was a reduction in the mean BoP from 86% at baseline to 78% at 12 months. In the minocycline group, the mean PD was 3.9 mm at baseline and 3.6 mm at 12 months, and the mean BoP was reduced from 88% at baseline to 71% at 12 months. There were no radiographic data reported and no reporting on presence/absence of suppuration on probing.

In a second trial, Renvert et al<sup>23</sup> evaluated a similar protocol in which the treatments in each group were repeated after day 30 and 90. Fifteen patients were included in the manual debridement group and 17 patients in the minocycline group. There were no withdrawals and no implant losses. In the manual debridement group, the mean PD was 3.9 mm at baseline and 3.7 mm at 12 months, and there was a reduction in mean BoP from 89% at baseline to 64% at 12 months. In the minocycline group, the mean PD was 3.9 mm at baseline and 3.6 mm at 12 months, and the BoP was reduced from 87% at baseline to 48% at 12 months. Radiographic bone levels were reported with minor changes at 12 months. There was no reporting on the presence/absence of suppuration on probing or complications or side effects.

Two studies compared manual debridement with ultrasonic debridement. Karring et al<sup>24</sup> compared manual debridement with the Vector method in a splitmouth design in 11 patients. Both interventions were repeated after 3 months. Six months after treatment, no implants were lost and there were no changes in the marginal bone levels reported in either treatment group. There was also no reduction in the mean PD in either treatment group. In the group treated by the Vector method, 4 patients showed resolution of disease (no BoP), while in the group treated with manual debridement, 1 patient showed resolution of disease (no BoP). In both treatment groups, 2 patients had recurrence of disease according to the authors' criteria of PD > 4 mm with BoP. Despite one of the inclusion criteria in this study being positive BoP, not all patients had implants with positive BoP at baseline.

Renvert et al<sup>25</sup> and Persson et al,<sup>26</sup> in a parallel design study, compared manual debridement with the Vector method. Two of the 19 patients were lost to follow-up in the manual debridement group, while 4 of the 18 patients were lost to follow-up in the Vector group. Six months after treatment, no implants were lost; however, there was no reduction in mean probing depth or mean number of BoP sites in either treatment group. The authors of the study concluded that there were no clinically relevant changes within the groups over a 6-month period. No radiographic data were reported and there were no adverse events reported by the patients participating in the study.

Sahm et al<sup>27</sup> evaluated manual debridement with submucosal chlorhexidine compared to debridement using an air-powder abrasive device. Thirty-two patients were included (16 in each group) and 1 patient in each group was lost to follow-up. At 6 months, there was no implant loss and no complications were reported. In the air-powder abrasive group, the mean PD was

4.0 mm at baseline and 3.5 mm at 6 months, with a reduction in mean BoP from 95% to 51%. In the manual debridement group, the mean PD was 3.8 mm at baseline and 3.2 mm at 6 months, with a reduction in mean BoP from 95% to 84%. No radiographic evaluation or data on suppuration on probing were reported.

Two studies with a similar protocol evaluated the 12-month outcomes of manual debridement and submucosal chlorhexidine compared with Er:YAG laser treatment.<sup>28,29</sup> Schwarz et al<sup>29</sup> evaluated 20 patients (10 patients with 20 implants in each group) 12 months following treatment. Two patients with 4 implants were excluded from the manual debridement group prior to the 12-month follow-up due to persistent periimplantitis with pus formation. One patient in the Er:YAG laser group had a healing complication that resulted in marked mucosal recession. There were no implant losses reported. At 12 months in the manual debridement group, the initial deep peri-implant pockets (mean PD 6.0 mm) had reduced to a mean PD of 5.6 mm. In the Er:YAG laser group, the initial deep periimplant pockets (mean PD 5.9 mm) had reduced to a mean PD of 5.5 mm. The authors reported a greater reduction in BoP in the laser group; however, no numerical data were presented. The authors reported that there were no changes in radiolucency; however, no radiographic measurements were reported. In this study, all patients were discontinued at 12 months and received further treatment (surgical procedures), indicating that none of the patients had resolution of disease.

Schwarz et al<sup>28</sup> reported 6-month treatment outcomes in 20 patients (10 patients with 16 implants in each treatment group). One patient (with 2 implants) in the manual debridement group was excluded from the 6-month evaluation due to persistent peri-implantitis and suppuration. There were no implant losses reported and no adverse effects of treatment. The mean PD was reduced from 5.5 mm to 4.8 mm in the manual debridement group, with a reduction in mean BoP from 80% to 58%. In the Er:YAG laser group, the mean PD was reduced from 5.4 mm to 4.6 mm and there was a reduction in mean BoP from 83% to 31% at 6 months. No radiographic data were reported.

Renvert et al<sup>30</sup> evaluated the 6-month outcomes following treatment with an Er:YAG laser (21 patients with 55 implants) compared with an air-abrasive device (21 patients with 45 implants). There were no patient withdrawals, no implant losses, and no adverse effects of treatment reported. At baseline, 31% of the implants in the laser group and 38% of the implants in the air-powder abrasive group had suppuration on probing. After 6 months, both treatment groups reported 11% of implants with suppuration on probing. At the patient level, 25% of the patients in the laser group had a mean PD reduction  $\geq$  1 mm, whereas 38% of the patients in the air-abrasive group had an average PD reduction  $\geq 1$  mm. The mean BoP was reduced from 100% to 75% in the air-powder abrasive treatment group and from 100% to 70% in the Er:YAG laser treatment group. Radiographic evaluation showed a mean bone loss of 0.1 mm in the air-powder abrasive group and a mean bone loss of 0.3 mm in the Er:YAG laser treatment group. The authors reported that none of the implants in either group had a positive outcome (defined as having PD  $\geq$  5 mm with BoP and suppuration at baseline, but no PD  $\geq$  5 mm and no BoP or suppuration at 6 months).

Schär et al<sup>32</sup> evaluated the 6-month treatment outcome of photodynamic therapy compared to local delivery of minocycline (20 patients with 20 implants in each group). There were no withdrawals and no implant losses. At 6 months, the minocycline group had a mean PD reduction from 4.4 mm to 3.9 mm, with a reduction in mean number of sites with BoP from 4.4 to 2.1 sites. The photodynamic group had a mean PD reduction from 4.2 mm to 3.8 mm, with a reduction in mean number of sites with BoP from 4.0 to 2.3 sites. At 6 months, 15% of the implants in the minocycline group had complete resolution of mucosal inflammation compared to 30% in the photodynamic treatment group. There were no data on radiographic bone levels, suppuration on probing, or complications reported.

**Case Series of Surgical Interventions.** Augthun et al<sup>33</sup> (treated 15 implants in 12 patients by implant surface decontamination with an air-powder abrasive device, placement of an ePTFE membrane, and administration of systemic tetracycline. In 13 of 15 treated implants, premature membrane removal was required due to wound-healing complications. No implant losses were reported. At 12 months there was no change in BoP and a mean bone loss of 0.8 mm. Peri-implant probing depths were reduced by a mean of 1 mm.

Three studies reported on regenerative treatment using grafts without membranes. Behneke et al<sup>34</sup> treated 25 implants in 17 patients with an air-powder abrasive, autogenous bone grafts, and systemic metronidazole. Healing complications were reported in 6 patients. One graft was removed after 40 days because of flap dehiscence and graft mobility. In another patient, healing was uneventful but the graft was resorbed entirely. There were no implant losses reported. At 12 months there was a mean PD reduction from 5.3 mm at baseline to 2.2 mm. A radiographic median marginal bone gain of 4 mm was reported at 12 months. There were no data presented for BoP. Positive outcomes were documented up to 3 years; however, not all implants were followed. Roccuzzo et al<sup>35</sup> reported on 26 patients with 26 implants with two different sufaces (TPS and SLA). Regenerative treatment, using bovinederived xenograft following implant cleaning with a

plastic curette, application of EDTA, and chlorhexidine and antibiotic therapy, resulted in 12-month mean PD reductions of 2.1 mm at implants with a TPS surface and 3.4 mm at implants with a SLA surface. Complete defect fill was not found around TPS implants, while it occurred in 3 out of 12 SLA-surface implants. At 12 months, 4 of the 26 patients had implants with suppuration. Two of these implants were removed after 12 months. Mean BoP decreased from 91% to 57% (TPS) and from 75% to 15% (SLA). Overall, the mean PD reduced from 7.0 mm to 4.2 mm, and the mean BoP reduced from 83% to 36% at 12 months. There was a mean radiographic bone gain of 1.7 mm, with incomplete defect fill in 75% of the implants.

Wiltfang et al<sup>36</sup> evaluated 22 patients with 36 implants. Regenerative treatment was performed following implant-surface decontamination and implantoplasty using a mix of autologous bone and a demineralized xenogenic bone graft including growth factors in combination with systemic antimicrobials. One implant had a local infection 1 week after treatment, resulting in loss of the graft. At 1 year, 1 implant was lost due to mobility. Probing depths were reduced by 4 mm on average and were > 4 mm at 7 of the 36 treated implants. Before surgical intervention, BoP was observed in 61% of the implants and in 25% after 1 year. The corresponding values for suppuration were 80% and 8%. After 12 months, a mean gain in bone height of 3.5 mm was reported (evaluated using panoramic radiographs). Recessions increased from 0.7 mm before surgery to 2 mm 1 year after surgery.

Five studies reported on regenerative treatment using grafts and membranes. Froum et al<sup>37</sup> evaluated a regenerative approach including surface decontamination, use of enamel matrix derivative, a combination of PDGF with anorganic bovine bone or mineralized freeze-dried bone, and coverage with a collagen membrane or a subepithelial connective tissue graft. None of the 51 implants in 38 patients were lost after 3 to 7.5 years of follow-up. At the final evaluation, the mean PD reduction was 5.3 mm (from 8.4 mm pretreatment to 3.1 mm). There was a reduction in BoP from 100% to 18% of implants and mean radiographic bone gain of 3.4 mm. No implant recorded an increase in buccal mucosal recession. Twelve-month results were not provided, and the authors reported that 6 patients required two or three surgical procedures to achieve the desired outcome.

Romanos and Nentwig<sup>38</sup> evaluated regenerative treatment; following mechanical debridement and  $CO_2$  laser irradiation, they placed either an autogenous bone graft (10 implants) or a xenogenic bone graft covered by a collagen membrane (9 implants). In the 15 patients who were treated and followed for 27 ± 18 months, no implants were lost. A mean PD reduction from 6.0 mm

to 2.5 mm postoperatively was reported. Implants treated with xenogenic bone grafting material had complete radiographic bone fill, while partial fill was reported for defects treated with autogenous bone. There were no data on complications or BoP reported.

Haas et al<sup>39</sup> evaluated regenerative treatment in 17 patients (24 implants) using autogenous bone and an ePTFE membrane in conjunction with photodynamic therapy and systemic penicillin. Premature membrane exposure occurred in all patients; however, the membranes were left in situ for 6 weeks in all patients except one. Two implants with severe initial bone loss were removed, one after 10 months and another after 35 months. The mean radiographic peri-implant bone gain amounted to 2 mm at 9.5 months. There were no data on BoP or PD changes reported.

Roos-Jansåker et al<sup>40</sup> evaluated regenerative treatment in 12 patients (16 implants) using a phytogenic bone substitute combined with a resorbable synthetic membrane, systemic antimicrobials, and submerged healing. Two weeks postoperatively, 63% of the implants had inadequate primary healing. One patient reported an allergic reaction to the systemic antimicrobials. There were no implants lost at the 12-month follow-up. At the deepest implant site there was a mean PD reduction from 6.4 mm to 2.2 mm, and a reduction in BoP from 75% to 13% at 12 months. All implants had a defect fill of at least one thread (0.6 mm) with a mean radiographic defect fill of 2.3 mm. Suppuration on probing was recorded at 94% of the implants prior to treatment. The presence/absence of suppuration was not reported at 12 months.

Schwarz et al<sup>41</sup> evaluated regenerative treatment in 27 patients (27 implants) using bovine-derived xenograft covered with a collagen membrane and nonsubmerged healing. The results at 6 and 12 months were presented for three different defect types separately. Circumferential intrabony defects showed higher changes in mean probing depth and clinical attachment level than circumferential or semicircumferential lesions with a buccal dehiscence. All patients were followed, no implants were lost, and there were no postoperative complications reported. Overall, there was a reduction in mean PD from 6.9 mm to 2.0 mm and a reduction in mean BoP from 83% to 41%. There were no radiographic data presented.

Leonhardt et al<sup>42</sup> reported the outcome of access surgery and implant-surface decontamination with  $H_2O_2$  and administration of five different systemic antibiotics in 9 patients (26 implants). Seven implants in 4 patients were lost during a 5-year follow-up period. Despite a significant reduction in the presence of plaque and sulcus bleeding, 4 implants continued to lose bone, 9 had an unchanged bone level, and 6 gained bone. The benefit of administering systemic antibiotics according to a susceptibility test of presumed target bacteria remained unclear. The authors concluded 58% treatment success after 5 years based on implant and radiographic bone loss. There was no peri-implant probing performed.

Heitz-Mayfield et al<sup>43</sup> evaluated access surgery and implant surface cleaning with titanium-coated curettes and by rubbing with gauze soaked in saline, plus prescription of amoxicillin and metronidazole in 24 patients (36 implants). At 12 months, all patients were followed and there were no implant losses. Six patients reported side effects related to mild gastrointestinal disturbance. The mean PD was reduced from 5.3 mm at baseline to 2.9 mm at 12 months. At 12 months, all treated implants had a mean PD < 5 mm and 47% of implants had no BoP. The mean recession of the buccal peri-implant mucosa at 12 months was 1 mm. At 12 months follow-up, 3 implants in 3 patients had radiographic bone loss, 3 implants in 3 patients showed bone gain, while the remaining implants had stable crestal bone levels.

Maximo et al<sup>45</sup> and Duarte et al<sup>46</sup> reported on access surgery and decontamination without systemic antibiotics in the same group of 13 patients (20 implants) with peri-implantitis. Access surgery and mechanical implant cleaning with teflon curettes and an airpowder device was evaluated at 3 months. There were no postoperative complications, no patient withdrawals and no implant losses reported. At 3 months there was a reduction in mean PD from 7.5 mm to 4.4 mm and a reduction in mean BoP from 100% to 53%. The frequency of implants that presented with a mean  $PD \ge 5 \text{ mm}$  and concomitant BoP or suppuration was 100% at baseline and 25% at 3 months. The frequency of implants with suppuration on probing at baseline was 65% at baseline and 5% at 3 months. There were no radiographic data presented.

de Mendonca et al<sup>44</sup> evaluated access surgery and mechanical implant cleaning with resin curettes and air-powder abrasion in 10 patients (10 implants). There were no implant losses, no patient withdrawals, and no postoperative complications reported. Prior to treatment, 7 patients had suppuration on probing, while none had suppuration at 12 months. At 12 months, the mean PD reduced from 6.7 mm to 4.3 mm, and the mean BoP from 100% to 27%. There was a mean increase in recession of 2.0 mm. At 12 months, 40% of the patients had implants with a mean PD  $\geq$  5 mm with concomitant BoP. No radiographic data were reported.

Serino and Turri<sup>47</sup> reported the outcome of a resective surgical procedure that included pocket elimination and bone recontouring at 86 peri-implantitis lesions in 31 patients. At 3 months, 7 of the 18 implants with advanced bone loss ( $\geq$  7 mm) were removed due to persistent peri-implantitis. Two years after therapy, 15 patients displayed no signs of peri-implant disease (no BoP and/or suppuration). At 2 years, 24 patients had no implants with a PD  $\geq$  6 mm with concomitant bleeding and/or suppuration upon probing. Between the 6-month and 2-year evaluation, the number of implants with PD  $\geq$  6 mm and BoP or suppuration increased. Out of 86 implants with an initial diagnosis of peri-implantitis, 36 (42%) still presented peri-implant disease despite treatment. No radiographic data were provided following treatment.

**Comparative Studies (RCTs) of Surgical Interven**tions. Deppe et al<sup>48</sup> evaluated resective and regenerative treatment with and without CO<sub>2</sub> laser for the treatment of peri-implantitis in 32 patients with 73 implants. Four months after therapy, 4 implants were lost in a patient treated with laser and 4 implants in a patient treated without laser. Four months after treatment, the mean PD in the laser group was 3 mm for implants in residual bone and 2.7 mm for implants in augmented bone. In the non-laser group, the mean PD was 3.6 mm for implants in residual bone and 4.7 mm for implants in augmented bone. At 4 months there were no significant differences in the distance from implant shoulder to the first bone contact between implants treated with or without the laser. The followup period varied between 20 and 236 weeks posttreatment. There were no data presented for BoP or radiographic bone levels, and no reporting on the presence or absence of complications.

Two studies reported on regenerative treatments using grafts with or without barrier membranes. Khoury and Buchmann<sup>51</sup> evaluated the outcomes of three regenerative treatment protocols for periimplantitis. In 25 patients, 41 peri-implant defects were treated with either flap surgery plus autogenous bone graft alone (n = 12); autogenous bone graft plus nonresorbable membrane (n = 20); or autogenous bone graft plus bioabsorbable barrier (n = 9) and various systemic antimicrobials. At 12 months, no implants were lost. The treatment groups in which a barrier membrane was used had healing complications: in 60% of cases using ePTFE membrane and in 56% of cases in which a collagen membrane was used. At 12 months, the mean PD at implants treated with autogenous bone graft alone was 5.4 mm, ePTFE membrane 4.8 mm, collagen membrane 3.3 mm. After 3 years, significant changes in mean probing depth from baseline were noted in all three groups. Three-year radiographic evaluation showed a mean bone gain in all treatment groups. The differences between the three surgical treatment protocols were not significant. There were no data presented for BoP.

Roos-Jansåker et al<sup>52,53</sup> evaluated the extent of radiographic bone fill 12 months and 3 years following regenerative surgical treatment of peri-implantitis us-

ing a graft with or without a membrane. Prior to augmentation, the implants were mechanically cleaned, treated with H<sub>2</sub>O<sub>2</sub>, and rinsed with saline. Thirty-eight patients were treated; however, 2 died before the 12- month follow-up, leaving 17 patients with 29 implants in the group treated with bone substitute and resorbable membrane and 19 patients with 36 implants in the group treated with bone substitute alone. Systemic amoxicillin and metronidazole were administered for 10 days, and patients rinsed with chlorhexidine. One patient reported an allergic reaction to the antibiotics and 5 patients reported postoperative healing complications (pain, swelling). When membranes were used, membrane exposure occurred in 44% of the treated implants. In the bone substitute plus membrane group the mean PD was 5.4 mm ay baseline and 2.5 mm at 12 months. The mean percentage of sites with BoP was 79% at baseline and 22% at 12 months. In the bone substitute group, the mean PD was 5.6 mm at baseline and 2.2 mm at 12 months. The mean BoP was 96% at baseline and 25% at 12 months. At 12 months. the mean radiographic defect fill was 1.5 mm in the bone substitute plus membrane group compared to 1.4 mm in the bone substitute group. At 12 months, there were no implant losses; however, 6 implants continued to lose bone (1 implant lost two threads, and 5 implants lost one thread). Information on the number of patients with further bone loss was not provided.

Four patients in the group treated with bone substitute alone were lost to follow-up during the 1- to 3-year period, leaving 15 patients with 27 implants in this group after 3 years. Statistical analysis failed to demonstrate changes in bone fill between 1 and 3 years both between and within procedure groups. There were no PD or BoP data presented at the 3-year follow-up.

Romeo et al<sup>57,58</sup> compared the clinical outcome of resective surgery and modification of surface topography (implantoplasty) with resective surgery alone for the treatment of peri-implantitis in 17 patients. All patients received systemic amoxicillin for 8 days. At 12 months there were no implant losses and no complications reported. The mean PD in the implantoplasty group had reduced from 5.8 mm at baseline to 3.4 mm at 12 months, and the mean number of sites with positive BoP from 2.8 mm at baseline to 0.4 mm at 12 months. The mean recession in the implantoplasty group was increased from 0.5 mm to 2.3 mm. In the group treated with resective surgery alone, the mean PD had reduced from 6.5 mm to 5.9 mm and the mean number of sites with BoP had reduced from 2.9 at baseline to 2.7 at 12 months. The mean recession had increased from 0.2 mm to 1.4 mm.

After 24 months, Romeo et al<sup>58</sup> reported the loss of 2 hollow-screw implants from the resective surgery group due to mobility. After 3 years, 1 patient was lost to follow-up in the implantoplasty group and 2 patients in the resective surgery group. The mean marginal bone level was unchanged 3 years after implantoplasty, while in the resective surgery group there was a mean bone loss of 1.4 mm at the mesial and 1.5 mm at the distal surfaces.

Schwarz et al<sup>55,56</sup> evaluated the 6-month and 1-, 2-, and 4-year results of regenerative treatment of 22 peri-implantitis lesions in 22 patients. The defects were filled with a graft material in combination with a collagen membrane. The graft was either a nanocrystalline hydroxyapatite or a xenogenic bone mineral (11 patients with 11 implants in each group). Two patients treated with nanocrystalline hydroxyapatite experienced severe pus formation at 12 months and were withdrawn from the study. One patient receiving xenogenic bone mineral was withdrawn due to severe pus formation at 3 years. At 12 months, the mean PD was reduced from 6.9 mm to 4.9 mm, with a reduction of BoP from 80% to 36% in the the hydroxyapatite group. In the xenogenic bone mineral group, the mean PD was reduced from 7.1 mm to 4.4 mm, with a reduction in the mean BoP from 78% to 29%. There were no radiographic data reported. Higher mean probing depth reductions and clinical attachment level gains were reported at 4 years in the group treated with xenogenic bone mineral and covered with a collagen membrane. No implant loss or complications were reported.

Schwarz et al<sup>49,50</sup> investigated the impact of two surface debridement/decontamination methods on the clinical outcomes of a combined surgical treatment of peri-implantitis. Thirty-two patients suffering from advanced peri-implantitis were treated with flap surgery, implantoplasty, and xenogenic bone mineral covered with a collagen membrane. The intrabony aspects were randomly allocated to surface cleaning with either (1) Er:YAG laser or (2) plastic curettes, followed by cotton swabbing with pellets soaked in saline. Clinical parameters were recorded at baseline and after 6 and 24 months of nonsubmerged healing. One patient was lost to follow-up at 3 months in the laser group and a further 5 patients between 6 and 24 months. One patient was lost to follow-up at 6 months in the plastic curette debridement group and a further patient between 6 and 24 months. There were no implant losses reported. All barrier membranes became exposed; however, there were no infections reported. At 12 months, the mean PD had reduced from 4.9 mm to 3.2 mm and the mean BoP from 97% to 42% in the laser group. In the plastic curette group, the 12-month mean PD reduced from 5.2 mm to 3.2 mm and the mean BoP reduced from 100% to 40%. The mean recession increased from 1.5 mm to 1.9 mm in the laser group and from 1.3 mm to 1.8 mm in the plastic curette group. The authors reported both groups showed comparable radiographic bone fill at the intrabony defect component at 6 months; however, no radiographic bone level data were reported at 12 months. At 24 months there were 5 implants in both groups with recurrent peri-implantitis, which were retreated. No radiographic data were reported.

#### **Successful Treatment Outcome Criterion**

Table 8 includes 11 studies in which data were presented such that the number of patients (or implants) with successful treatment outcomes at 12 months could be determined according to the proposed success criterion (implant survival with mean PD < 5 mm and no further bone loss).

Six studies evaluating regenerative protocols,<sup>33,35–37,40,52</sup> one study evaluating access surgery,<sup>43</sup> one study evaluating resective surgery,<sup>57,58</sup> and three studies evaluating nonsurgical treatment<sup>17,18,29</sup> were included in Table 8. Successful treatment outcomes at 12 months were reported from between 76% to 100% of the patients treated in seven of the studies. Two studies reported successful treatment outcomes from 75% to 93% of implants treated. The two remaining studies in Table 8 reported none of the patients with a successful outcome according to the success criterion. One evaluated nonsurgical treatment in deep periimplantis lesions where all patients required surgery after 12 months follow-up,<sup>29</sup> while the other used a regenerative protocol using a nonresorbable membrane, where frequent barrier membrane exposure occurred, with no clinical improvement after 12 months.<sup>33</sup>

This does not mean that the other studies included in this review did not achieve successful outcomes; however, the data were not available to evaluate the proposed success criterion.

# DISCUSSION

Given that the field of research into peri-implantitis is relatively new, it is not surprising that there are many different treatment approaches reported in the literature. Until now, no particular treatment protocol has been shown to be definitively effective (ie, a gold standard) so no one specific treatment protocol could be validly considered as a control in an RCT. Therefore, the RCTs included in the present review were analyzed for treatment outcomes for each treatment arm and not comparatively.

The effectiveness of a treatment protocol for the resolution of the disease could be measured in a number of ways. Ideally, resolution of disease would mean absence of clinical inflammation (bleeding on probing). Few studies reported on the number of patients with implants with absence of BoP. While most studies showed a reduction in mean BoP, 19% to 84% of implant

sites still bled on probing following nonsurgical treatment, while 13% to 53% of sites bled on probing following surgical treatment. Few studies provided individual data on the probing depth associated with bleeding sites or the frequency of patients with implants with deep sites (PD > 5 mm) with concomitant BoP.

The authors have proposed a composite criterion designed to provide a threshold or deliniation separating the need for further treatment of disease versus the need for maintenance of health. This would be meaningful for both the patient and clinician. The criterion includes a PD threshold of 5 mm with no concomitant BoP and absence of further bone loss. The difficulty in any attempt to review the diverse treatments described in this review in the context of such a criterion is that the presentation of the outcome data is also quite diverse. Many studies did not provide data in a form that could be used to assess this composite citerion. Therefore, Table 8 includes studies where successful treatment referred to implant survival with a mean PD < 5 mm and with no further bone loss. While it is recognized that there is an inherent high risk of bias in case series studies, the data in the case series were often presented in a form easier to analyze regarding the composite criterion than the comparative trials. This does not decrease the value of any one trial; rather, it varies the confidence with which we can make conclusions about the treatments trialed.

On the basis of the analysis of the studies, commonalities in treatment approaches between studies included (1) a pretreatment phase, (2) cause-related therapy, and (3) a maintenance care phase. A surgical approach with elevation of a mucoperiosteal flap was performed where access to the implant surface was judged as inadequate due to a deep peri-implant pocket. The majority of the surgical protocols included administration of perioperative or postoperative systemic antibiotics and postoperative chlorhexidine rinsing. However, there were no randomized controlled trials found comparing treatment with or without systemic antimicrobials.

An important observation was that the periimplantitis case definition for inclusion varied considerably between studies. In some studies it was not clear from the information provided relating to bone loss whether the patients had peri-implantitis or periimplant mucositis. Furthermore, some studies did not provide information regarding presence of clinical inflammation (bleeding or suppuration on probing) in the inclusion criteria. The severity of disease (initial PD and amount of bone loss) also varied between studies and among patients within studies.

It is also important to realize that most studies had specific exclusion criteria, including exclusion of: patients who smoked<sup>27–29,32</sup> or smoked  $\geq$  10 cigarettes

Table 8 Suco	cessful Treatment Outcomes At 12	Months		
Study	Study type and treatment	Patients	Successful treat- ment outcome (% patients)	12 mo mean % of sites with BoP (*deepest site)
Mombelli et al <sup>17</sup>	Case series, nonsurgical LDD: Actisite	25	84%	NR 41%*
Salvi et al <sup>18</sup>	Case series, nonsurgical LDD: Arestin	25	76%	19% 44%*
Schwarz et al <sup>29</sup>	RCT, nonsurgical manual debridement Laser	8 10	0% 0%	58% (estimated from figure in paper) 65% (estimated from figure in paper)
Augthun et al <sup>33</sup>	Case series, regenerative surgery	12	0%	47% implants
Heitz-Mayfield et al <sup>43</sup>	Case series, access surgery	24	88%	25%
Roccuzzo et al <sup>35</sup>	Case series, regenerative surgery	26	85%	36%
Wiltfang et al <sup>36</sup>	Case series, regenerative surgery	22	75% of implants	25% of implants
Roos-Jansåker et al <sup>40</sup>	Case series, regenerative surgery	12	100%	13%*
Froum et al <sup>37</sup>	Case series, regenerative surgery	38	84% (36–90 mo results)	18%*
Romeo et al <sup>57,58</sup>	Comparative trial, Resective surgery + IPP	10	100%	NR Modified bleeding index 2.7
	Resective surgery	9	0%	NR Modified bleeding index 0.4
Roos-Jånsaker et al <sup>52</sup>	Comparative trial, Bone substitute + membrane	17	93% of implants	22%
	Bone substitute	19	89% of implants	25%

Includes studies that reported on implant loss, mean PD, % of sites or implants with bleeding and/or suppuration on probing,

and radiographic bone levels at 12 mo (or longer) following treatment. Successful treatment outcome defined as:

implant survival with no mean PD  $\geq$  5 mm and no further bone loss 12 mo after treatment.

LDD: local delivery device; IPP: implantoplasty with bur; NR: not reported.

per day<sup>41</sup>; patients with FMPS > 20% or FMBS >  $20\%^{43}$ or a Plaque Index >  $1^{27,29,41,54-56}$ ; patients with periodontal pockets > 5 mm<sup>24</sup>; pregnant or lactating women<sup>18,21,23,32,43</sup>; patients with poorly controlled diabetes<sup>25-27,30,31,41,43</sup>; patients taking bisphosphonate medication<sup>27,41,47,49,50,54–56</sup>; patients who had taken systemic antibiotics in recent months prior to treatment<sup>3,18,21,22,24–26,29–32,42–46</sup>; patients with implants with < 2 mm keratinized mucosa,<sup>27</sup> or no keratinized mucosa.<sup>28,54–56</sup> Therefore, the results reported in individual studies should be interpreted with this in mind and may not apply to all patients.

The length of follow-up in the included studies also varied from 3 months to 7.5 years. Whilst clinical healing could be expected to be complete by 3 months following cause-related therapy (ie, removal of the biofilm),<sup>43,45</sup> detectable changes in radiographic marginal bone levels may not be apparent at this time. Therefore, a 12-month reevaluation period for assessment of successful treatment outcome was chosen for this review. However, it should be recognized that successful outcomes at 12 months might be influenced by the quality of maintenance care.

It is also likely that risk factors for peri-implantitis, including smoking, poor oral hygiene, untreated periodontal disease, and diabetes, 1,9,59,60 may modify both the initial outcome of treatment as well as the long-term outcome. There were 11 studies included in this review with follow-up greater than 12 months. While longer-term studies are desirable, the guestion remains as to whether recurrence of disease after 12 months constitutes failure of initial treatment or rather the institution of a new disease process. Continuous collection of data over 5 years or longer could provide valuable insights into answering this question.

Further questions, which remain unanswered, include the influence of implant surface and topography on treatment outcomes. Most of the studies include a number of implant brands and designs. One study<sup>35</sup> reported differences in outcomes for implants with TPS or SLA surfaces. It is conceivable that protocols for surface decontamination may have different effects depending on macro- and microstructure of the surface and that not all methods may work equally well in all instances. To what extent bacterial and nonbacterial residues have to be removed from an implant surface

12-mo mean PD	Baseline mean PD	12-mo radiographic bone change	Comments
3.5 mm 3.9 mm*	4.7 mm 6 mm*	No significant change	Case definition unclear: BoP and BL threshold not included individual implant data available
3.5 mm 4.2 mm*	4.5 mm 5.9 mm*	No significant change	6 patients (6 implants) with persistent suppuration
5.6 mm 5.5 mm	6.0 mm 5.9 mm	No significant change	Advanced lesions included in this table All patients re-treated after 12 mo
4.1 mm	5.2 mm	0.8 mm mean bone loss	Case definition unclear: BoP not included
2.9 mm	5.3 mm	No change or bone gain	3 patients with further bone loss + suppuration 47% of implants had absence of BoP at 12 mo
4.3 mm	7.0 mm	1.7 mm mean bone gain	4 patients with TPS-surface implants with suppuration
3.5 mm	7.5 mm	3.5 mm mean bone gain	8% of implants had suppuration, 1 patient lost 1 implant
2.2 mm*	6.4 mm*	2.3 mm mean bone gain	6 mo submerged healing
3.0 mm*	8.3 mm*	3.4 mm mean bone gain	6 patients required 2 or 3 surgical procedures, no implants lost bone
3.4 mm	5.8 mm	No change	No BoP data
5.9 mm	6.5 mm	0.5 mm mean bone loss	No BoP data, 2 implants removed at 2 y, 2 implants removed at 3 y
2.5 mm	5.4 mm	2 implants lost, 1 thread bone	
2.2 mm	5.6 mm	1 implant lost 2 threads, 3 implants lost 1 thread	

to obtain a predictable and stable clinical result after treatment remains to be elucidated. The requirements for a clean implant surface may differ depending on the goal of therapy. While a reduction in the bacterial load and suppression of pathogens in the peri-implant pocket may be enough to establish a balance between the peri-implant microbiota and the host defense, the implant surface may not be biocompatible for direct reapposition of bone.

The influence of defect morphology and the initial severity of disease may also influence the treatment outcome for certain interventions. There is evidence that nonsurgical therapy is ineffective in advanced peri-implantitis cases where access to the contaminated implant surface is limited.<sup>29</sup> Introsseous defect configuration may also impact on treatment outcome following a regenerative protocol.<sup>41</sup> Other factors that may play a role in the success of peri-implanitis treatment and warrant further investigation include the proximity of adjacent implants, the position of implants within the arch, and the absence of keratinized peri-implant mucosa.

In a recent Cochrane systematic review of randomized controlled trials, no clinically relevant advantage of one treatment over another was identified.<sup>6</sup> In the included trials in the Cochrane systematic review, and the present review, many different treatments were frequently combined, making it difficult to evaluate the effectiveness of a single procedure. Future RCTs might include single procedures believed to be the most effective as controls, such as some protocols identified in Table 8, rather than combining numerous techniques and materials all at once. In this review, no studies were considered at low risk of bias. In future studies, power calculations should be performed to ensure an adequate sample size and efforts should be made to reduce the risk of bias (adequate randomization and blinding). Reporting should account for patient dropouts, withdrawals and failures. Treatment outcomes, including esthetic parameters, patient preference, and relative cost of treatments, should be considered. It would be useful for studies to document the number of patients with resolution of periimplantitis or successful treatment outcome (defined as implant survival with no  $PD \ge 5$  mm with concomitant BoP or suppuration or further bone loss).

# CONCLUSIONS

This review showed that successful treatment outcomes 12 months following therapy of peri-implantitis could be achieved in a majority of patients in seven studies. While favorable short-term outcomes were reported in many studies, lack of disease resolution as well as progression or recurrence of disease and implant loss despite treatment were also reported. All studies included in this review had either an unclear or high risk of bias, which should be considered when interpreting the results. Furthermore, the reported outcomes must be viewed in the context of the varied peri-implantitis case definitions and severity of disease included, as well as the heterogeneity in study design, length of follow-up, and exclusion/inclusion criteria.

While the currently available evidence does not allow any firm specific recommendations for nonsurgical or surgical therapy of peri-implantitis, the following elements of therapy seem to be beneficial:

A pretreatment phase including

- Oral hygiene instruction and counseling for smoking cessation
- Assessment of the prosthesis for access for plaque control
- · Prosthesis removal and adjustment if required
- Nonsurgical debridement with or without antimicrobials

# Surgical access (when resolution of peri-implantitis is not achieved with nonsurgical treatment)

- Full-thickness mucoperiosteal flap to allow thorough cleaning of the contaminated implant surfaces (numerous techniques, may involve modification of the implant surface topography).
- The stabilization of the intraosseous peri-implant defect with a bone substitute/bone graft/bioactive substance with or without a resorbable barrier membrane

#### Postoperative anti-infective protocol

- Peri-or postoperative systemic antibiotics
- Chlorhexidine rinses during the healing period (several weeks)

#### Maintenance care

 Three- to 6-month maintenance, including oral hygiene instruction and supramucosal biofilm removal

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# Consensus Statements and Clinical Recommendations for Prevention and Management of Biologic and Technical Implant Complications

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# INTRODUCTORY REMARKS

# Disclosure

Implant treatment is highly successful, as documented in a wealth of scientific literature. However, patients and clinicians should expect to see complications within their daily practice. The aim of the papers presented by this group was to address the prevention and management of technical and biologic complications in order to make recommendations both for clinical practice and future research. Three topics were chosen within the field of complications of implant treatment, and these addressed prevention and therapy of peri-implant disease and prevention of technical complications.

Three systematic reviews were conducted and formed the basis for discussion of working group 5. The discussions led to the development of statements and recommendations determined by group consensus based on the findings of the systematic reviews. These were then presented and accepted following modifications as necessary at plenary sessions.

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All the group members were asked to reveal any conflicts of interest that could potentially influence the outcomes of the consensus deliberations. No such conflicts were identified.

# EFFECTS OF ANTI-INFECTIVE PREVENTIVE MEASURES ON BIOLOGIC IMPLANT COMPLICATIONS AND IMPLANT LOSS

# **Consensus Statements**

The aim of the review by Salvi and Zitzmann was to systematically appraise whether anti-infective protocols are effective in preventing biologic implant complications and implant loss after a mean observation period of at least 10 years following delivery of the prosthesis. Out of 15 included studies, only one comparative study assessed the effects of adherence to supportive periodontal therapy (SPT) on the occurrence of biological complications and implant loss. In view of the lack of randomized trials, observational studies including adherence and lack of adherence to SPT were considered valuable in order to estimate the effects of SPT on implant longevity and the occurrence of biological complications.

- Overall, the outcomes of this systematic review indicated that high long-term survival and success rates of dental implants can be achieved in partially and fully edentulous patients adhering to SPT.
- Long-term implant survival and success rates are lower in patients with a history of periodontal disease adhering to SPT compared with those without a history of periodontal disease.
- The findings of this systematic review indicate that pre-existing peri-implant mucositis in conjunction with lack of adherence to SPT was associated with a higher incidence of peri-implantitis.

# **Treatment Guidelines**

# **Preventive Measures Before Implant Placement**

 Residual periodontal pockets are a risk for periimplant disease and implant loss. Therefore, completion of active periodontal therapy aiming for elimination of residual pockets with bleeding on probing

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should precede implant placement in periodontally compromised patients.

- In cases of residual probing depths (PD) ≥ 5 mm with concomitant bleeding on probing, full-mouth plaque scores > 20%, and associated risk factors, retreatment and periodontal reevaluation are recommended before implant placement.
- In subjects diagnosed with aggressive periodontitis, an SPT program with shorter intervals is a prerequisite.
- During implant treatment planning, factors to be considered that may result in biological complications include: insufficient keratinized mucosa and bone volume at the implant recipient site, implant proximity, threedimensional implant position, and design and cleansability of the prosthesis. Alternative restorative solutions should be considered according to a patient's individual circumstances.

#### **Preventive Measures After Implant Placement**

- All oral health care providers, including undergraduate students, should be trained to recognize clinical signs of peri-implant pathology and maintain or reestablish periimplant health.
- After delivery of the definitive implant-supported prosthesis, clinical and radiographic baseline measurements should be established.
- During SPT, an update of medical and dental history and a clinical inspection of the implant-supported prosthesis including the evaluation of iatrogenic factors (eg, cement remnants, misfit of prostheses, implant proximity with insufficient access for interproximal oral hygiene) should constitute the basis of a proper diagnostic process.
- Regular diagnostic monitoring of the peri-implant tissues includes assessment of presence of plaque, PD, bleeding on gentle probing (approx 0.25 N), and/or suppuration.
- Changes in PD from a fixed landmark should be assessed regularly and compared to previous examinations.
- In the presence of clinical signs of disease, an appropriate radiograph is indicated in order to detect radiographic bone-level changes compared to previous examinations.
- A diagnosis of *peri-implant health* is given in the absence of clinical signs of inflammation. A recall frequency of at least once per year is recommended unless systemic and/or local conditions require more frequent intervals. In cases of peri-implant health, professional cleaning including reinforcement of self-performed oral hygiene is recommended as a preventive measure.
- A diagnosis of *peri-implant mucositis* is given in the presence of individual clinical signs of soft tissue inflammation (eg, redness, edema, suppuration) and bleeding on gentle probing. If mucositis is diagnosed, in addition to reinforcement of self-performed oral hygiene, mechanical debridement with or without antiseptics (eg, chlorhexidine) is delivered. The use of systemic

antibiotics for the treatment of peri-implant mucositis is not justified. Therapy of peri-implant mucositis should be considered as a preventive measure for the onset of peri-implantitis.

 A diagnosis of *peri-implantitis* is given in the presence of mucositis in conjunction with progressive crestal bone loss. When peri-implantitis is diagnosed, early implementation of appropriate therapy is recommended to prevent further progression of the disease.

# **Recommendations for Future Research**

Future clinical research on preventive measures should include:

- Establishment of baseline data reflecting healthy periimplant conditions at time of delivery of the definitive prosthesis should constitute the basis for conducting a study on the effects of SPT on the occurrence of biological complications and implant loss.
- Randomized controlled trials (RCTs) comparing SPT protocols with different frequencies should be conducted in patient populations characterized by different risk factors (eg, periodontal health vs history of treated periodontitis, smokers vs nonsmokers, healthy vs systemically compromised patients). These studies may be directed to investigate surrogate measures and risk indicators of peri-implantitis (eg, diagnosis of mucositis, increase in PD, and bone loss on radiographs).
- Studies evaluating the effects of SPT programs in patients with dental implants should assess the occurrence of peri-implant diseases and implant loss as well as the need for interventions. Patient-reported outcomes and health economic aspects of different SPT protocols should be investigated.
- Although RCTs and prospective studies are desirable, well-conducted and reported observational studies are likely to be required in view of the long-term follow-up necessary to detect peri-implantitis.
- All trials should be prospectively registered on an openaccess database to minimize publication bias.

# THERAPY OF PERI-IMPLANTITIS

#### **Consensus Statements**

The focus question for the review by Heitz-Mayfield and Mombelli was: In patients with osseointegrated implants diagnosed with peri-implantitis, how successful is treatment aimed at resolution of the disease?

Currently, there is no standard of care for treating periimplantitis. Various clinical protocols for treating periimplantitis have been proposed, including mechanical debridement, the use of antiseptics and local and systemic antibiotics, as well as surgical and regenerative procedures. In view of the lack of comparable randomized controlled trials (RCTs) this review has taken a broader approach to capture as many relevant studies as possible, including randomized and observational studies, but with consideration to the strengths and limitations of the included research.

The ideal goal of the treatment of peri-implantitis would be the resolution of disease, ie, no suppuration or bleeding on probing, no further bone loss, and the reestablishment and maintenance of healthy peri-implant tissues. A composite outcome to reflect this would include absence of peri-implant PD  $\geq$  5 mm with concomitant bleeding on probing and no suppuration, in addition to no further bone loss. If these criteria are met, it can be assumed that no further intervention other than nonsurgical maintenance care would be required, and the treatment outcome would therefore be regarded as successful. Unfortunately these data were rarely reported in the literature and therefore a compromise composite criterion for successful treatment outcome was employed, ie, implant survival with mean PD < 5 mm and no further bone loss. Although there is no consensus in the literature on whether a 5-mm peri-implant PD alone represents health or disease, this threshold was adopted for the purposes of the review.

This review was based on 33 studies reported in 43 papers including case-series of at least 5 patients treated with the same protocol and comparative studies. No studies were found comparing surgical and nonsurgical protocols. Based on this literature, the following conclusions were drawn:

- 1. The case definition of peri-implantitis remains unclear and varies substantially between studies.
- 2. There is a great variety of treatment protocols for both nonsurgical and surgical treatment.
  - a. Nonsurgical therapy included: debridement with hand and powered instruments, air-powder abrasive devices, laser treatment, and local and systemic antimicrobial agents.
  - b. Surgical therapy included: elevation of a mucoperiosteal flap and removal of granulation tissue to gain access to the implant and defect surfaces, decontamination of the implant surface (various techniques) with or without implant surface modification. Some studies also evaluated resective therapy or a variety of regenerative procedures. The majority of the studies employed systemic antimicrobial administration.
- 3. The following elements are common to most protocols for peri-implantitis therapy:
  - a. Pretreatment phase including establishment of good oral hygiene
  - b. Anti-infective treatment including implant surface cleaning achieved by nonsurgical/surgical access
  - c. Supportive maintenance care
- 4. The available evidence does not allow recommendation of specific treatment options for peri-implantitis. However, improvement of clinical parameters was reported for the majority of patients, although complete resolution according to a composite success criterion

was not usually achieved for all patients. Favorable short-term outcomes were reported in many studies; however, lack of disease resolution as well as progression or recurrence of disease and implant loss, despite treatment, were also reported.

- 5. Interpretation of the results of studies is complicated by unclear or high risk of bias, heterogeneity of study design, and difficulty of generalizing outcomes to practice settings due to frequent exclusion of patients who smoke, those with poorly controlled diabetes, and other conditions that may affect clinical outcomes.
- 6. There are no data investigating patient-reported outcomes and economic analysis of therapy.
- 7. Peri-implantitis therapy was associated with soft-tissue recession, which was most evident following surgical treatment. Postsurgery complications including membrane exposure and infection were also reported.

#### **Treatment Guidelines**

- As peri-implantitis is an infection associated with the presence of a submucosal bacterial biofilm around implants, the primary goal of therapy must be the resolution of the infection, which is achieved by the disruption of the biofilm, the removal of calculus and/or overhanging restoration margins, and the prevention of recurrence of the disease.
- It is important to try to establish if iatrogenic or other factors have contributed to the infection, for example, ill-fitting or noncleansable overcontoured prostheses, malpositioned implants, or foreign bodies such as impression material or excess luting cement. Noniatrogenic factors may include impacted dental floss.
- 3. The following sequence of treatment of periimplantitis is normally recommended.
  - a. Pretreatment phase including:
    - i. Thorough assessment and diagnosis
    - Reduction of risk factors for peri-implantitis; in particular poor oral hygiene, prostheses that prevent adequate access for plaque control, tobacco use, presence of periodontal diseases, and systemic diseases that may predispose to periimplant disease
    - iii. If required, prosthesis removal and adjustment/ replacement
  - b. Nonsurgical debridement focused on maximal removal of biofilm, with or without antimicrobials
  - c. Early reassessment of peri-implant health; normally within 1 to 2 months
  - d. Surgical access if resolution of peri-implantitis has not been achieved. This should include:
    - i. Full-thickness mucoperiosteal flaps and removal of granulation tissue to allow thorough cleaning of the implant surface.
    - ii. Thorough surface decontamination of the implant and restorative components. The following

techniques have been proposed: locally applied chemicals, gauze soaked with saline or antiseptics, hand-powered instruments, air-powder abrasives, Er-YAG lasers, photodynamic therapy, and implant surface modification. There is no evidence for the superiority of any one approach.

- iii. Surgical therapy might also include regenerative or resective approaches
  - Regenerative approaches include filling of the intraosseous peri-implant defect with a bone substitute/graft/bioactive substance with or without a resorbable barrier membrane. Defect morphology for regeneration would normally require a contained defect. Submerged healing might reduce the risk of membrane exposure. Reestablishment of osseointegration following treatment has not been demonstrated in humans.
  - 2. Resective approaches include osseous recontouring with apical positioning of the flap.
- iv. Immediate postoperative anti-infective protocol should include daily chlorhexidine rinsing during the healing period until mechanical oral hygiene can be resumed. In the absence of evidence comparing surgical treatment with or without antibiotics, peri- or postoperative systemic antibiotics are recommended in view of the aggressive nature of disease. Professional support of healing and plaque control will be needed during this phase.
- e. Clinical monitoring should be performed on a regular basis and supplemented by appropriate radiographic evaluation as required. Supportive maintenance therapy including reinforcement of effective oral hygiene and professional biofilm removal should be provided on a frequency determined by oral health and the risk profile, likely to be between every 3 to 6 months.
- 4. Surgical access is likely to be needed for the majority of deep lesions due to the difficulty of accessing the threads and surfaces of the implant.
- 5. The patient should be advised that:
  - a. Recession of the peri-implant mucosa should be expected following peri-implantitis treatment, in particular after surgical therapy.
  - b. Progression or recurrence of disease might require additional therapy or implant removal.
- 6. The clinician should consider implant removal as a treatment option. Factors influencing this decision may include the severity of the peri-implantitis lesion, the position of the implant, the surrounding tissues, or when the treatment outcomes are likely to be unsatisfactory.
- 7. Referral to specialist care for nonresponding periimplantitis should be considered.

- 8. Regular assessment of peri-implant health is recommended during SPT to identify disease at an early stage.
- 9. Training of dental team professionals should include diagnosis and management of peri-implant disease.

# **Recommendations for Future Research**

- 1. Future research should try to simplify experimental interventions with few component aspects. If possible, the most effective single procedures derived from the literature should be used.
- 2. Studies are needed to compare surgical and nonsurgical therapy of peri-implantitis.
- 3. The role of systemic antibiotics in treating periimplantitis needs to be investigated in RCTs.
- 4. Reporting of peri-implantitis research outcomes:
  - a. Clinical evaluation should report the number of patients with resolution of peri-implantitis defined as: implant survival with no PD greater than 5 mm with concomitant bleeding on probing or suppuration, and no further bone loss.
  - b. Patient-reported outcomes (oral health-related quality of life, esthetics, preferences, etc) should be routinely included in research on peri-implantitis therapy.
  - c. Health economic evaluation of treatment options is needed to help inform choice of therapy.
  - d. Adverse events and complications following treatment should be fully reported.
- 5. The relatively small differences in outcomes between experimental groups that are common in the existing literature underline the need for RCTs to be confident of the potential to conclude clinically important differences.
- 6. Critical methodological issues for future research include
  - a. Maximizing protection from bias
  - b. Power calculation for all important outcomes
  - c. Study design to allow and account for drop-outs with full reporting of losses to follow-up
- 7. All trials should be prospectively registered on an openaccess database to minimize publication bias.

# SURVIVAL RATES OF IMPLANT-SUPPORTED FIXED PROSTHESES OVER THE LAST DECADES

# **Consensus Statements**

The systematic review by Pjetursson et al was conducted to compare the survival and complication rates of implantsupported prostheses published up to the year 2000 with those reported in studies published after the year 2000. An association between period of publication and fixed implant-supported prosthesis outcomes were found with higher survival rates and overall lower rates of mechanical and technical complications reported in more recent clinical studies. However, the incidence of reported technical complications is still high. The difference in survival rates was most evident for screw-retained prostheses, where the reported survival rate of 77.6% in the older publications was increased to 96.8% in the more recent ones.

# **Treatment Guidelines**

### Risk of Fracture—Implants

- 1. Implant fracture is a rare complication. To avoid implant fracture it is recommended that clinicians consider the use of appropriately designed and manufactured implants with properly investigated and documented low fracture rates. Similarly, the clinician should use implants manufactured from materials that have been thoroughly investigated.
- 2. The risk of implant fracture can be considered extremely low when:
  - a. The appropriate distribution, number, and diameter of implants are used
  - b. Implants are placed using a restoratively driven protocol
  - c. Implants are combined with an adequately fitting prosthesis

#### *Risk of Fracture and/or Loosening—Prosthetic Screws*

Fracture of manufacturer screws made to specified tolerances can be influenced by three factors: mishandling, misfit, and occlusal forces.

- 1. Mishandling: To reduce the risk of fracture of prosthetic screws, it is recommended that a clinician follow the manufacturer's instructions for use.
- Misfit: An inadequately fitting framework may be a predisposing factor to prosthetic screw fracture or loosening. It is recommended to prioritize evaluation of the accuracy of the interface between the machined head of the screw and its seating surface over the entire area of contact to reduce the risk of loosening and fracture.
- 3. Occlusal forces, usually in the presence of other predisposing factors, misfit, and mishandling, may lead to prosthetic screw fracture or loosening.

#### Risk of Fracture and/or Loosening—Abutments

- It is recommended that the clinician carefully evaluate the differential etiology of screw loosening, as the literature does not differentiate between abutment or prosthetic screw loosening sufficiently to conclude which type of screw is more likely to loosen.
- 2. Metal abutment fracture is a rare complication. Greater caution is advised with ceramic abutments. It is recommended that the specific material-based requirements of ceramics should be respected when choosing, designing, and handling these abutments.

# Risk of Fracture of Framework and/or Veneering Materials

1. Currently framework fracture is a rare complication. The choice of material, appropriate design, and method of

fabrication are all factors in reducing the risk of framework fracture.

- 2. To reduce the risk of fracturing the veneering materials, the framework must provide adequate support for the veneering ceramic or resin in order to avoid excessive thickness of the veneering material.
- 3. When choosing the material and determining framework design, it is recommended that the final contour of the definitive prosthesis be visualized prior to framework fabrication.
- 4. Scheduled regular maintenance appointments should include a careful occlusal review. It is recommended that clinicians undertake any required adjustments to the prosthesis, inclusive of meticulous polishing of worn ceramic surfaces, to reduce the risk of fracturing of the veneer material.

#### **Quality Assurance**

It is recommended that clinicians, technicians, and manufacturers employ a tracking system for implants and restorative components. Clinicians should be aware that not all implant systems have the same level of documentation. The clinician should be aware of the origin of the components used.

#### **Recommendations for Future Research**

In order to deliver relevant information for the understanding and the improvement of technical outcomes, future clinical studies should include the following information:

- The definition of technical complications should be specified as either mechanical, ie, failure of components resulting from standardized production procedures (industrial), or technical, ie, failure of custom components (laboratory-fabricated or modified).
- Mechanical and technical complications should further be divided into (1) major: such as implant fracture, framework fracture, abutment fracture, loss of prosthesis, etc;
   (2) intermediate: such as abutment fracture, abutment screw loosening, veneer or framework fractures, phonetic complications, etc; or (3) minor: such as abutment and screw loosening, loss of retention, debonding, loss of screw hole sealing, chipping of veneering material (to be polished), and occlusal adjustments.
- Patient-based and prosthesis-based rates of mechanical and technical complications as well as time/cost required for the management should be reported. Moreover, detailed information on the components, materials, procedures, and techniques utilized should be given.
- Well-designed RCTs with adequate statistical power should be initiated to address specific issues in restorative dentistry, such as abutment materials and types (ceramics vs metals), customized vs stock components, restorative outcomes of different implant types, and screw-retained vs cemented prostheses.
- All trials should be prospectively registered on an openaccess database to minimize publication bias.



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