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Patient centered management and optimal number of implants in the treatment of edentulism

A consensus conference University of Mainz, Germany 27th and 28th March 2014





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Editorial

This supplemental issue of *EJOI* is dedicated to the Foundation for Oral Rehabilitation (FOR) consensus conference, 'Patient centered management and optimal number of implants in the treatment of edentulism', which was held on the 27th and 28th March, 2014. Scientific associations and other organisations using *EJOI* as their official publication are welcome to publish the outcome of their consensus conferences or working groups in the journal.

It is the policy of *EJOI* that these publications will not be peer reviewed as they are normally. Consequently, readers are encouraged to critically evaluate the findings presented, as they would with all scientific publications. Guidance on how to develop critical skills for research, analysis and the evaluation of scientific publications (an important mission of *EJOI*) can be found in the 'educational articles'¹⁻⁴ and on the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) website (http://www.equatornetwork.org/). The EQUATOR Network is aimed at helping authors properly report their health research studies. After selecting the 'Resource Centre', please click on the 'Library for health research

reporting' and you will access a comprehensive list of reporting guidelines, organised by study type. More specifically, to evaluate systematic reviews please go to the PRISMA transparency guidelines (http://www.prisma-statement.org/).

The results of consensus conferences or working groups can be interpreted differently, depending on people's perspectives and circumstances. Please consider the conclusions presented carefully. They are the opinions of the review authors, and are not necessarily shared by *EJOI* editors.

We would like to thank all contributors to the present supplement for their efforts.

Marco Esposito and Michele Nieri

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Guest editorial



Wilfried Wagner, Prof Dr Dr University Medical Center of the Johannes Gutenberg University Mainz, Mainz,

Oral rehabilitation of complete edentulism by means of implants is, and has been for decades, a predictable treatment option. It provides an improved quality of life, clearly superior to what can be achieved by mucosally retained dentures. But when the question is raised of how many implants one needs to properly deal with the rehabilitation of edentulous patients, opinions are sometimes country-specific, while science should be borderless.

The Foundation for Oral Rehabilitation (F O R) took up the challenge. Being a global network of experts and clinicians it always refers to scientifically sound and well-proven data, which are universally accepted. A number of reputed researchers and clinicians were selected to tackle the question of the number of implants needed, in a thoroughly scientific manner. Their selection was based on expertise, number of publications and their citation index related to this theme. Each one received a specific subject to critically review in the literature, and if data were sufficiently available to provide a metaanalysis. After exchanging their manuscripts, the experts met during 2 days at the University of Mainz. Travel and hotel expenses were taken care of by F O R, but no other compensation was provided.

For any elective surgery, the patient should be involved in opting among the wide range of treatment alternatives. All participants chose the patient-centred viewpoint as a starting point. For a removable overdenture, one can choose whether to have it on 2 or 4 implants in the mandible and 4 or more implants in the maxilla. Fixed prostheses are generally placed on 5 or 6 implants and sometimes even more in the maxilla.

When only a limited jawbone volume remains, it can be necessary to consider bone augmentation procedures to (optimally) place a sufficient number

of implants to support a fixed dental prosthesis with a long-term predictable outcome. The key question is whether a more limited number of implants, than the classical 5 to 6 and more, suffice. A more limited number of implants could avoid the invasiveness of bone augmentation/grafting procedures. A review of the literature (Nkenke and Neukam) underlined that, as an intraoral donor site for autologous bone grafting, the mandibular ascending ramus is preferable. The symphyseal area leads to the highest (incidence of) morbidities. The posterior iliac crest is a good alternative but implies mostly general anaesthesia.

Another meta-analysis (Al-Nawas and Schiegnitz) proved that the survival rate of oral implants placed in conjunction with augmentation procedures is as good with bone substitute material as with autologous bone grafts. Nevertheless, the bone augmentation procedure by itself is more invasive and more prone to postoperative pain and discomfort than the straightforward (flapless) placement of implants. Thus, if the treatment is patient-centred, avoiding bone augmentation should be considered. Patient satisfaction with graftless solutions is indeed very high and patients' preference to minimally invasive implant surgery well established (Pommer and Watzek).

The key question then becomes what should be the minimal/optimal number of implants to insure a reliable long-term outcome for the (fixed) prosthetic rehabilitation. Two decades ago (Brånemark et al¹), it was shown in a large-scale retrospective study that the 10-year survival in edentulous patients of fixed dental prostheses on either 4 or on 6 implants was not significantly different. The tradition to insert at least 5 to 6 implants in edentulous jaws thus became questionable. Since very high survival rates are pres-



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The group of experts from left to right: Drs Gerry Raghoebar, Bernhard Pommer, Claudia Dellavia, John Brunski, Wilfried Wagner, Daniel van Steenberghe, Emeka Nkenke, Massimo Del Fabbro, Bilal Al-Nawas, Regina Mericske-Stern, Georg Watzek.

ently reached by implants with moderately rough surfaces, the concept of inserting supplementary implants just to avoid a revision surgery should one implant fail became more or less obsolete.

Furthermore, biomechanical calculations prove that with 4 implants to support a complete crossarch fixed reconstruction, strains in the bone or at the bone-implant interface remain within the safe range (Brunski). Tilted implants, to insure a proper anterior-posterior spread, can even be subject to lower forces than axial ones (Del Fabbro and Ceresoli). Furthermore, the marginal bone level around tilted implants does not significantly differ from that around axial implants. The latter offers the possibility to achieve a good anterior-posterior spread with few implants.

Functional aspects of implant-supported rehabilitations have been investigated by different methodologies. The number of implants supporting the prostheses does not appear as a relevant factor in the functional qualities (Dellavia et al).

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framework is necessary, more than 4 implants are needed (Mericske-Stern and Worni), which raises the treatment cost and can render a bone augmentation procedure indispensable. One may wonder why CAD-CAM technologies, which do reach the necessary precision of fit, are not used in these instances to keep the treatment less invasive.

When segmentation of the fixed cross-arch

We both feel privileged to coordinate this first F O R consensus conference. The multidisciplinary interactions favoured cross-fertilisation but nevertheless led to an iteratively written consensus document, which was unanimously approved.

The conclusions of this workshop should lead clinicians to also consider, for the benefit of their edentulous patients, less invasive procedures. Established scientific data, which should always prevail on traditions, do indeed prove that for complete edentulism, unless specific aesthetic and/or functional demands are pressing, 4 implants only can already provide a predictable anchorage for fixed prostheses.

Daniel van Steenberghe
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Moderators of the Consensus meeting

1. Brånemark PI, Svensson B, van Steenberghe D. Ten-year survival rates of fixed prostheses on four or six implants ad modum Brånemark in full edentulism. Clin Oral Implants Ress1995;6:227–231.

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ISSN 1756-2406 (Print) ISSN 1756-2414 (Online) Bernhard Pommer, Georg Mailath-Pokorny, Robert Haas, Dieter Busenlechner, Rudolf Fürhauser, Georg Watzek

Patients' preferences towards minimally invasive treatment alternatives for implant rehabilitation of edentulous jaws

Key words dental implants, implant-supported dental prosthesis, quality of life, patient preference, patient satisfaction

Purpose: To evaluate patient satisfaction, oral health-related quality of life, and patients' preferences towards minimally invasive treatment options for graftless rehabilitation of complete edentulism by means of dental implants.

Material and methods: A MEDLINE search of literature in the English language up to the year 2013 was performed to summarise current evidence from the patient's perspective. The final selection included 37 studies reporting on minimally invasive implant treatment of 648 edentulous maxillae and 791 edentulous mandibles in 1328 patients, via a total of 5766 implants.

Results: Patient satisfaction averaged 91% with flapless implant placement (range: 77 to 100%), 89% with short implants, 87% with narrow-diameter implants (range: 80 to 93%), 90% with a reduced number of implants (range: 77 to 100%), 94% with tilted implant placement (range: 58 to 100%), and 83% with zygomatic fixtures (range: 50 to 97%). Indirect comparison yielded patient preference towards tilted implant placement compared to a reduced number of implants (P = 0.036), as well as to zygomatic implants (P = 0.001).

Conclusions: While little evidence on patients' preferences towards minimally invasive treatment alternatives vs. bone augmentation surgery could be identified from within-study comparison, it may be concluded that patient satisfaction with graftless solutions for implant rehabilitation of completely edentulous jaws is generally high. Comparative effectiveness research is needed to substantiate their positive appeal to potential implant patients and possible reduction of the indication span for invasive bone graft surgery.

Conflict-of-interest notification: The authors declare that they have no conflict of interest.

Introduction

During the past decade, there has been an obvious trend in oral health care towards techniques attempting to provide optimum service for patients with the minimal amount of treatment¹. Interest for minimally invasive procedures as standard treatment is notably growing in the field of oral implantology².

While modification of the patient's jaw anatomy by bone augmentation surgery to allow placement of longer and wider implants has been generally considered the best treatment strategy in the past, adaptation of implant dimensions and positions to the existing anatomy may represent a more appropriate solution in cases of severe atrophy of the residual alveolar bone³. The option of a minimally invasive



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Table 1 Outcome measures to evaluate oral implant treatment.

| Implant-related outcome measure | | | | | | | |
|--|--|--|--|--|--|--|--|
| implant survival rate | percentage of implants in situ | | | | | | |
| implant success rate | percentage of implants fulfilling certain criteria of success | | | | | | |
| marginal bone remodelling | radiologic peri-implant crestal bone position (marginal bone level) or alterations (marginal bone resorption) | | | | | | |
| peri-implant mucosal health | pocket probing depth, bleeding on probing, sulcus bleeding index, and presence of keratinised mucosa | | | | | | |
| peri-implant mucosal aesthetics | professional rating of "pink" aesthetics, e.g. via the Pink Esthetic Score ²³ | | | | | | |
| Denture-related outcome measur | es | | | | | | |
| denture survival rate | percentage of dentures in situ (in spite of potential implant loss in cases of sustained usability) | | | | | | |
| technical complications | frequency of mechanical damage of the implant components and suprastructures or maintenance work | | | | | | |
| objective masticatory function | masticatory performance in terms of bite force, food break-down, mastication time or electromyographic jaw muscle activity ²⁴ | | | | | | |
| objective phonetic function | speech intelligibility, articulation and oromyofunctional behaviour ²⁵ | | | | | | |
| Patient-related outcome measure | s | | | | | | |
| oral health-related quality of life (OHRQoL) | hierarchy of functional, psychological and social parameters assessed, e.g. via the Oral Health Impact Profile (OHIP) | | | | | | |
| patient satisfaction | subjective visual analogue scale (VAS) ratings regarding stability, chewing efficiency, phonetics, aesthetics, or ease of cleaning | | | | | | |
| patient preference | patients' choice of preferred treatment | | | | | | |

technique - per definition - appeals to a greater number of potential implant patients and is frequently associated with economic benefits⁴. Implant surgery may be termed 'minimally invasive' referring to avoidance of bone grafts⁵, and/or prevention of intra- and postoperative patient morbidity in terms of pain⁶, swelling⁷, bleeding⁸, or expended operating time⁹. Transmucosal healing modality¹⁰ or immediate implant placement¹¹, by contrast, may reduce the number of surgical interventions, however, circumvent only insignificant trauma and do not strictly reflect the concept of minimal invasion. The same is true for prosthetic concepts, such as immediate provisionalisation or early loading¹² in spite of their inherent advantages of reduced treatment duration relevant to patients. Reduction of surgical invasion may thus be achieved by either:

- reduction in the extent of mucosal flap elevation: flapless implant placement frequently combined with CAD/CAM surgical templates¹³ or intraoperative navigation¹⁴
- reduction of the size of implants used: short implants less than 10 mm in length¹⁵, or narrowdiameter implants less than 3.75 mm in width¹⁶

- reduction of the number of implants placed¹⁷, or
- maximum use of anatomical buttresses: tilted¹⁸ or zygomatic implants¹⁹.

Patient satisfaction represents one of the most fundamental goals to achieve in oral rehabilitation²⁰. Treatment evaluation in evidence-based medicine and dentistry should thus embrace the opinion and attitude of patients as a variable of therapeutic success²¹. Outcomes of oral implant therapy have traditionally been described in terms of survival rates, clinical and radiological surrogate parameters and durability of implant superstructures²², however, patient-based outcome measures are considered essential to complement the clinical component for more comprehensive assessment of health status and the impact on the recipient (Table 1)²³⁻²⁵. Complete edentulism can substantially affect oral and general health, as well as overall quality of life²⁶. Patients may suffer pain in the denture-bearing area, impaired chewing efficiency and nutrition due to limited retention and stability of conventional prostheses²⁷. As Professor Per-Ingvar Brånemark famously put it28: "The edentulous patient is an amputee, an oral invalid, to whom we should pay total respect and rehabilitation ambitions." The aim of the present systematic review was to evaluate patient satisfaction, oral health-related quality of life, and patients' preferences towards minimally invasive treatment options for graftless rehabilitation of complete edentulism.

for each treatment strategy after conversion of individual study results to per cent scale (i.e. a rating of 4 in a 5-point Lickert scale was expressed as 80%). Likewise, Oral Health Impact Profile (OHIP) ratings were divided by the maximum total value (i.e. 196 for the full version OHIP-49 using a 0-4 Lickert scale) to achieve normalisation of OHIP versions and enable outcome comparison⁷³.

Materials and methods

The authors searched for clinical scientific literature in the English language via the US National Institutes of Health free digital archive of biomedical and life sciences journal literature (Pubmed MEDLINE). The last search was performed on 23 December 2013. The search term 'dental implant' was combined with 'patient satisfaction', 'patient perspective', 'patient preference', 'minimally invasive', 'flapless', 'short', 'reduced diameter', 'narrow diameter', 'tilted' and 'zygomatic'. After exclusion of 65 duplicates, a total of 424 abstracts were screened. Studies were considered if they met the following eligibility criteria: 1) clinical investigations; 2) reporting on patient-based outcome measures (patient satisfaction, oral healthrelated quality of life, or patient preference); 3) of minimally invasive 4) graftless implant treatment 5) in completely edentulous patients.

A total of 81 papers were screened in full text, of which 33 did not fulfil eligibility criterion 2, 14 did not fulfil eligibility criterion 3, and 18 did not fulfil eligibility criterion 5 (listed in the APPENDIX; available online). After exclusion of 1 duplicate publication reporting on a patient cohort already included, 15 studies were selected as preliminary candidates. Moreover, the references of all eligible original publications as well as those of relevant review articles and meta-analyses²⁹⁻⁷² were screened, resulting in an additional 22 included studies. Study selection was performed in duplicate (BP and GW) and disagreements were resolved by consensus.

Descriptive analysis of study characteristics included: study design; number of patients and jaws treated; number of implants placed per jaw and in total; length of follow-up; scale used for outcome assessment; and performance of within-patient comparison (pre-vs. post-implantation). Weighted mean rates of patient satisfaction were calculated

Results

The final selection included 37 studies reporting on minimally invasive graftless implant treatment of 648 edentulous maxillae and 791 edentulous mandibles in 1328 patients via a total of 5766 implants. Patientbased outcome measures constituted of treatment satisfaction (34 studies), oral health-related quality of life (4 studies) or patient preferences (2 studies). The following minimally invasive treatment options were investigated: flapless implant placement (5 studies, 90 patients, 427 implants); short implants (1 study, 19 patients, 76 implants); narrow-diameter implants (7 studies, 152 patients, 523 implants); reduced number of implants (7 studies, 320 patients, 992 implants); tilted implant placement (11 studies, 660 patients, 3266 implants); and zygomatic fixtures (6 studies, 87 patients, 482 implants).

Flapless implant placement

Hof and co-workers (2014)⁷⁴ investigated 22 patients (16 women, 6 men, mean age: 61 years) with 20 edentulous maxillae and 11 edentulous mandibles in a cross-sectional questionnaire-based interview survey. Inclusion criteria involved patients seeking implant treatment without history of previous implant surgery. Patient preferences were assessed by polar questions regarding their disposition to receive flapless guided implant placement. A total of 77% were keen to avoid open flap surgery, while the remainder did not favour one treatment strategy over the other (Table 2).

Nkenke and co-workers (2007)⁷⁵ investigated 10 patients (2 women, 8 men, mean age: 65 years) all with edentulous maxillae in a prospective comparative study with a follow-up of 1 year. Inclusion criteria involved the placement of 6 implants into

Table 2 Studies on patient satisfaction with flapless implant placement in edentulous jaws (mx = maxilla, md = mandible): study design (cross = cross-sectional study, pro = prospective study), number of patients (Patient no.), implants placed per patient (Impl/pat), length of follow-up (in years), assessment scale (+/- = polar questions), and within-patient comparison pre- vs. post-implantation.

| | Study design | Jaw | Patient no. | Impl/ pat | Follow- up | Scale | Within patient |
|---|-----------------|----------------|-------------|--------------|------------|-------|----------------|
| Hof et al, 2014 ⁷⁴ | cross | 20 mx 11 md | 22 | | | +/- | no |
| Nkenke et al, 2007 ⁷⁵ | pro | mx | 5 | 6 | 1 a | 100-0 | no |
| Papaspyridakos & Lal, 2013 ⁷⁶ | pro | 6 mx 10 md | 14 | 5-8 | 3 a | +/- | no |
| van Steenberghe et al, 2005 ⁷⁷ | pro | mx | 24 | 6-8 | 1 a | 0-10 | no |
| Wittwer et al, 2007 ⁷⁸ | pro | md | 20 | 4 | | +/- | no |

native anterior maxillary bone and matched patients' demographics (equal gender, maximum age difference: 5 years, maximum weight difference: 10 kg) between the two treatment groups: 5 patients were subjected to flapless implant placement using CAD/ CAM surgical templates after virtual treatment planning in a computed tomographic scan (Procera; Nobel Biocare, Zurich, Switzerland), while in the remaining 5 patients mucoperiosteal flaps were elevated. Patient satisfaction was assessed on a visual analogue scale (VAS) regarding the following questions: 1) Would you have this procedure done again?; 2) Did you recognise bleeding during surgery?; 3) Was the duration of surgery acceptable?; and 4) Would you recommend this procedure to a friend? (0 = maximal agreement to 10 = maximal disagreement). VAS-ratings regarding pain and discomfort differed significantly (P < 0.01) between open (57.2, 61.2, and 23.6) and flapless implant placement (11.6, 9.6, and 4.6), 6 h, 1 day and 7 days after surgery, respectively. Patients subjected to flap elevation were less likely to repeat the procedure, recognise intraoperative bleeding, accept the duration of surgery, and recommend the procedure to a friend.

Papaspyridakos and Lal (2013)⁷⁶ investigated 14 patients (10 women, 4 men, mean age: 58) with 6 edentulous maxillae and 10 edentulous mandibles in a prospective study with a mean follow-up of 3 years. Inclusion criteria involved mouth opening of at least 50 mm to accommodate for the surgical instrumentation. Flapless placement of 103 implants was performed using virtual planning software (NobelGuide, Nobel Biocare) and stereolithographic

surgical templates. The patients received 14 full arch and 2 segmented porcelain fused to zirconia implant fixed prostheses (Procera, Nobel Biocare). Patient satisfaction was assessed by polar questions regarding aesthetic outcome and occlusal function. Great patient satisfaction with function and aesthetics was recorded for all these patients that had undergone flapless surgery.

van Steenberghe and co-workers (2005)⁷⁷ investigated 27 patients (mean age: 63 years) with edentulous maxillae in a prospective multicentre study, of which 24 patients completed the 1-year follow-up. Inclusion criteria involved sufficient bone volume to harbour at least 6 implants of at least 10 mm in length. A total of 184 implants (Brånemark MK III TiU, Nobel Biocare) were placed according to the Teeth-in-an-Hour concept using double-scan spiral computed tomography, 3D treatment planning software (NobelGuide, Nobel Biocare) and stereolithographic surgical templates to allow for guided flapless implant placement. Immediate provisional restoration was performed using prefabricated customised fibre-reinforced acrylic full-arch fixed prostheses. Patient satisfaction was assessed at 3 months and after 1 year of loading (0 = poor to 10 = excellent outcome) regarding speech, oral function, aesthetics and tactile sensation. While after 3 months half of the patients were not completely satisfied with their speech, at the 1-year follow-up, 88% judged aesthetics as either excellent or good. Function and tactile sense was perceived as excellent or good by all patients after 1 year.

Wittwer and co-workers (2007)⁷⁸ investigated 20 patients (6 women, 14 men, mean age: 64 years) with edentulous mandibles in a prospective

Table 3 Studies on patient satisfaction with short implants in the edentulous mandible (md): study design (pro = prospective study), number of patients (Patient no.), implants placed per patient (Impl/pat), length of follow-up (in years), assessment scale (+/- = polar questions), and within-patient comparison pre- vs. post-implantation.

| | Study design | Jaw | Patient no. | Impl /pat | Follow-up | Scale | Within patient | Catio |
|---------------------------------------|-----------------|-----|-------------|--------------|-----------|-------------|----------------|------------------|
| Stellingsma et al, 2003 ⁷⁹ | pro | md | 19 | 4 | 1 a | 0-10 +/- | yes es | sen ² |

pilot study. Inclusion criteria involved residual bone height of more than 15 mm in the anterior mandible and complete edentulism for at least 1 year prior to surgery. Flapless placement of 4 implants (Ankylos, Dentsply Friadent, Mannheim, Germany) in the interforaminal region was performed using the VISIT implant planning and navigation software (University of Vienna), allowing for real-time navigation after matching the patient's computed tomographic scans with a point-to-point registration. All patients received bar-retained overdentures. Patient satisfaction was assessed by a dichotomous variable: the procedure was claimed to be well tolerated by all 20 patients (100%).

Short implants

Stellingsma and co-workers (2003)⁷⁹ investigated 60 patients (50 women, 10 men, mean age: 59 years) with edentulous mandibles in a prospective comparative study with a follow-up of 1 year. Inclusion criteria involved long-term edentulism (patients wearing their third complete lower denture on average). While the other 2 groups in the study were subjected to bone augmentation (19 patients) or transmandibular implants (20 patients), the remaining 19 patients received 4 short implants (IMZ, Friatec) in the anterior mandible. However, implant lengths were 8 or 11 mm, thus not all met the generally accepted definition of short implants of less than 10 mm in length¹⁵. Patient satisfaction was assessed on a 10-point rating scale (0 = completely dissatisfied to 10 = completely satisfied). In addition, denture satisfaction was assessed using a validated questionnaire⁸⁰ consisting of eight items focusing on the function of upper and lower dentures, and on specific features such as aesthetics, retention and functional comfort (5-point rating scale). Patients' experiences in the surgical phase were more negative than expected for 25% of short

implant patients vs. 50% of augmentation patients. Postoperative pain lasting longer than 1 week also differed significantly (20% vs. 85%). Overall satisfaction with short implant therapy increased significantly from 4.4 before treatment to 8.9 after implant placement (+45%), but however, did not differ significantly (increase from 4.3 to 7.9) compared to the augmentation group (Table 3).

Narrow-diameter implants

Brandt and co-workers (2012)81 investigated 24 patients (age range: 35 to 75 years) with edentulous mandibles in a 2-year follow-up study. Inclusion criteria involved presence at the followup examinations. A total of 96 narrow-diameter implants (MDL, Intra-Lock) with a diameter of 2.0 mm and an O-ball attachment were placed in the anterior mandible and loaded immediately. Patient satisfaction was assessed on a scale from 1 = extremely poorer than before, 2 = considerably poorer than before, 3 = slightly poorer than before, 4 = the same as before, 5 = slightly better than before, 6 = considerably better than before, to 7 = extremely better than before: 1) How well can you bite with your present dentures after occlusal adjustments as compared with before implant placement?; 2) Rate your satisfaction from your present dentures after implant placement as compared with before implant placement?; 3) How secure do you feel with your present dentures after implant placement compared with your present dentures before implant placement?; and 4) How much have your present dentures, after implant placement, affected your speech compared with your present denture before occlusal adjustements? Mean patient satisfaction was 3.8 (54%) prior to implant placement was 6.5 (93%) after 2 years of loading (Table 4).

Table 4 Studies on patient satisfaction with narrow-diameter implants in edentulous jaws (mx = maxilla, md = mandible): study design (RCT = randomised controlled trial, pro = prospective study, retro = retrospective study), number of patients (Patient no.), implants placed per patient (Impl/pat), length of follow-up (in years), assessment scale (OHP = Oral Health Impact Profile, +/- = polar questions), and within-patient comparison pre- vs. post-implantation (*both ratings assessed after implant treatment).

| | Study design | Jaw | Patient no. | Impl /pat | Follow- up | Scale | Within patient |
|--|-----------------|-----|----------------|--------------|---------------|--------------|----------------|
| Brandt et al, 2012 ⁸¹ | retro | md | 24 | 4 | 2 a | 1–7 | yes* |
| Cho et al, 2007 ⁸² | retro | md | 10 | 2–4 | 0.2 a | 0–10 | yes* |
| Griffitts et al, 200583 | pro | md | 24 | 4 | 0.5 a | 1–10 | yes* |
| Jofre et al, 2013 ⁸⁴ | RCT | md | 15 | 2 | 1 a | OHIP | yes |
| Morneburg & Pröschel, 2008 ⁸⁶ | pro | md | 37 | 2 | 6 a | 0–10 | yes |
| Šćepanović et al, 2012 ⁸⁷ | pro | md | 30 | 4 | 1 a | OHIP 0–10 | yes |
| Veltri et al, 2008 ⁸⁹ | pro | mx | 12 | 5-8 | 1 a | +/- | no |

Cho and co-workers (2007)82 investigated 10 patients (7 women, 3 men, mean age: 58 years) with edentulous mandibles in a retrospective study with a mean follow-up of 22.8 months (range: 14 to 36 months). Inclusion criteria involved dissatisfaction with conventional prostheses due to lack of stability. A total of 34 one-piece narrow-diameter implants (Atlas; Dentatus, New York, NY, USA) with a diameter of 2.4 mm were placed in the interforaminal region. Existing mandibular dentures were relined to establish adequate retention and allow immediate function. Patient satisfaction with complete as well as implant-retained prostheses was assessed 2 months after surgery using the following patient satisfaction questionnaire: 1) Does your lower denture stay in place during function?; 2) Are you comfortable with your lower denture?; 3) How well does your lower denture fit?; 4) Do your upper and lower dentures fit well together?; 5) Are you satisfied with your lower denture?; 6) How well do you speak with your lower denture?; 7) How well do people understand you when you speak?; 8) How happy are you with your facial appearance with your dentures in place?; and 9) Do you feel comfortable with your social life with your dentures? (0 = very dissatisfied to 10 = very satisfied). Patients rated implantretained dentures better than their previously worn conventional dentures in all categories: 7.8 vs. 3.0 for question 1 (+48%), 8.1 vs. 3.4 for question 2 (+47%), 8.6 vs. 2.2 for question 3 (+54%), 9.0 vs. 4.0 for question 4 (+50%), 8.2 vs. 1.6 for question 5 (+66%), 9.3 vs. 5.4 for question 6 (+39%), 9.4 vs.

7.6 for question 7 (+18%), 8.4 vs. 7.2 for question 8 (+12%), and 8.4 vs. 5.6 for question 9 (+28%), however, no statistical comparison was attempted.

Griffitts and co-workers (2005)83 investigated 24 patients (mean age: 67 years) with edentulous mandibles in a prospective questionnaire study with a mean follow-up of 0.5 years. No further inclusion criteria were stated. In each patient 4 narrow-diameter implants 10 to 18 mm in length and 1.8 mm in diameter (Sendax MDI, IMTEC; 3M ESPE, Seefeld, Germany) were placed between the mental foramina. The complete dentures were retrofitted with the MDI housings and the implants were immediately loaded. Patient satisfaction regarding comfort, retention, chewing ability and speaking ability was assessed on a scale of 1 = poor to 10 = excellent. The patients rated satisfaction before as well as after surgery when receiving the questionnaire 6 months after surgery. Significant improvement was noted in all 4 categories: pre- vs. postoperative scores were 2.2 vs. 9.4 for comfort (+71%), 1.7 vs. 9.6 for retention (+79%), 2.3 vs. 9.3 for chewing ability (+73%) and 5.3 vs. 8.5 for speaking ability (+32%).

Jofre and co-workers (2013)⁸⁴ investigated 15 patients (10 women, 5 men, mean age: 75 years) with edentulous mandibles in a randomised controlled trial with a follow-up of 1 year. Inclusion criteria involved being aged between 45 and 90 years, experience with instability of conventional prostheses and absence of temporomandibular disorders. The test group received a total of 30 narrow-diameter implants, 1.8 x 15 mm (Sendax MDI,

IMTEC) using surgical guides and immediate loading with a pre-fabricated bar attachment, while the control group comprised 15 patients with complete mandibular dentures. Oral health-related quality of life was assessed using a version of the Oral Health Impact Profile (OHIP-EDENT) with 19 items⁸⁵ prior to intervention as well as 1 year after surgery. While no differences in the baseline OHIP scores could be seen between test (37) and control (37) group, a significant effect of implant treatment could be observed. Treatment with narrow-diameter implants significantly reduced OHIP-scores by 26 points, i.e. 34.2%, to an average score of 11.

Morneburg and Pröschel (2008)86 investigated 37 patients (mean age: 69 years) with edentulous mandibles in a prospective study with a mean follow-up of 6 years. Inclusion criteria involved severe ridge resorption (either completely level or only slightly raised). In a two-stage procedure, a total of 74 implants with a diameter of 2.5 mm (MicroPlant, Komet Brasseler Group, Lemgo, Germany) were placed in the mandibular canine/lateral incisor region. All patients received overdentures with either magnetic or O-ring attachments. Patient satisfaction was assessed prior to implant surgery as well as 6 weeks after overdenture connection, ranging from 0 = totally dissatisfied to 10 = excellent with respect to denture retention and chewing ability. Pre- and postoperative ratings were 2.0 vs. 8.4 regarding denture retention (+64%), and 2.1 vs. 9.1 regarding chewing ability (+70%), both showing highly significant increase.

Šćepanović and co-workers (2012)87 investigated 30 patients (16 women, 14 men, age range: 45 to 63) with edentulous mandibles in a prospective observational study with a follow-up of 1 year after implant placement and immediate loading. Inclusion criteria involved patients edentulous in both jaws, mandibular bone height of at least 15 mm and minimum residual bone width of 5 mm. In each patient 4 one-piece mini-implants, 1.8 mm in diameter and 13 mm in length (MDI, 3M ESPE) were placed and the O-ball heads were connected to the metal housings in the mandibular overdentures within 24 h after surgery. Patient satisfaction was assessed on a VAS (labelled as 'completely dissatisfied' to 'completely satisfied') with regards to comfort, stability, speaking ability, ability to maintain hygiene, aesthetics and

general chewing ability, as suggested by Awad and Feine⁸⁸. In addition, subjective chewing efficiency was also assessed on a VAS (labelled 'impossible to chew' to 'not hard to chew at all') regarding six types of food: carrots; apples; cheese; bread; sausages and lettuce. Oral health-related quality of end life was assessed using a version of the Oral Health Impact Profile (OHIP-EDENT) with 19 items85 using a six-point Lickert scale (1 = never to 6 = always) 15 weeks after they received conventional prostheses as well as 15 weeks after implant placement (while blinded to their baseline scores). Patient satisfaction increased significantly before vs. after implant treatment regarding comfort (5.4 vs. 7.5, +21%), stability (5.3 vs. 8.3, +30%), speaking ability (7.0 vs. 8.6, +16%), and chewing ability (5.5 vs. 7.6, +21%), while no difference regarding hygiene (7.2 vs. 7.5, +3%) and aesthetics (8.4 vs. 8.7, +3%) could be noted. Subjective ability to chew carrots (5.4 vs. 7.0, +16%), apples (5.9 vs. 8.1, +22%), cheese (7.1 vs. 8.6, +15%), bread (5.9 vs. 8.4, +25%), sausages (5.4 vs. 8.4, +30%), as well as lettuce (6.2 vs. 8.1, +19%) improved significantly. Mean OHIP-scores improved from 74.1 pre- to 50.6 post-implantation (mean paired difference: 23.5).

Veltri and co-workers (2008)89 investigated 12 patients (8 women, 4 men, mean age: 58 years) with edentulous maxillae in a prospective study with a follow-up of 1 year after loading. Inclusion criteria involved knife-edged resorption with maxillary bone width below 4 mm, however, sufficient residual bone height. A total of 73 implants of 3.5 mm diameter (MicroThread, Astra Tech; Dentsply, York, PA, USA) were placed according to a two-stage surgical protocol. Implant lengths between 9 and 17 mm were used. After 6 months of healing, all patients were rehabilitated with fixed metal acrylic prostheses. Patient satisfaction was assessed by occurrence of imperfect pronunciation (polar question). One year after rehabilitation, 10 patients (83%) were satisfied with the phonetic outcome.

Reduced number of implants

Burns and co-workers (2011)⁹⁰ investigated 30 patients (11 women, 19 men, mean age: 59 years) with edentulous mandibles in a prospective randomised clinical trial. Inclusion criteria involved

Table 5 Studies on patient satisfaction with a reduced number of implants in edentulous jav/s (mx = maxilla, md = mandible): study design (RCT = randomised controlled trial, pro = prospective study, co = cross-over design), number of patients (Patient no.), implants placed per patient (Impl/pat), length of follow-up (in years), assessment scale (OHIP = Oral Health Impact Profile, +/- = polar questions), and within-patient comparison pre- vs. post-implantation.

| | Study design | Jaw | Patient no. | Impl /pat | Follow- up | Scale | Within patient |
|---|-----------------|-----|-------------|--------------|------------|---------------|----------------|
| Burns et al, 2011 ⁹⁰ | RCT (co) | md | 30 | 2 | 1 a | 3-0 | yes |
| De Bruyn et al, 2001 ⁹¹ | pro | md | 20 | 3 | 1 a | 1–6 | yes |
| De Kok et al, 2011 ⁹² | RCT | md | 10 10 | 2 | 1 a | OHIP 0–100 | yes |
| Slot et al, 2013 ⁹⁴ | RCT | mx | 25 25 | 4 | 1 a | 1–10 | yes |
| Visser et al, 2005 ⁹⁵ = Meijer et al, 2009 ⁹⁶ | RCT | md | 29 29 | 2 4 | 5 a | 3–0 | yes |
| Walton et al, 2009 ⁹⁷ | RCT | md | 38 37 | 1 2 | 1 a | 0–100 | yes |
| Weinländer et al, 2010 ⁹⁸ | pro | md | 21 46 | 2 4 | 5 a | 1–5 | no |

adequate bone quantity to minimally accommodate 4 implants of 3.75 mm diameter and at least 1 year of previous conventional complete denture treatment history. Four implants (Brånemark, Nobel Biocare) were placed in the anterior mandible and subjected to submucosal healing for 4 to 6 months. Following a crossover study design, 3 different overdenture attachment types were delivered to each patient for 1 year, each in randomised treatment sequences: 4-implant bar attachment; 2-implant bar attachment; and 2-implant O-ring attachments (Ball Attachment, Nobel Biocare). Patient satisfaction was assessed via a 40-item denture complaint questionnaire (0 = not at all, 1 = a little, 2 = quite alot, 3 = extremely) that did not demonstrate equivalence of treatment modalities. Treatment preference was assessed in the following categories: overall best satisfied (64% vs. 32%); selected treatment (68% vs. 32%); easiest to get used to (56% vs. 20%); best denture retention (52% vs. 32%); best able to chew (56% vs. 24%); best able to speak (40% vs. 20%); greatest movement (64% vs. 8%); and easiest to clean (56% vs. 1%), revealing significantly higher patient acceptance with prostheses supported by 2 vs. 4 implants (Table 5).

De Bruyn and co-workers (2001)⁹¹ investigated 20 patients (12 women, 8 men, mean age: 64 years) with edentulous mandibles rehabilitated by fixed

prostheses on 3 implants only in a prospective multicentre study with a follow-up of 1 year. Inclusion criteria involved enough bone volume for the insertion of implants 13 to 15 mm in length and edentulism in the mandible for at least 6 months. The 3 implants (1 in the symphysis area and 2 anterior to the mental foramina) with a regular platform of 3.75 or 4 mm and 13 to 15 mm length (Nobel Biocare) were placed in each patient to support titanium milled frameworks mounted with acrylic teeth after a mean healing period of 1 month (range: 4 to 53 days). Patient satisfaction was assessed on a 6-grade scale ranging from 'negative' to 'positive' or 'never' to 'always' regarding general satisfaction, phonetic problems and comfort problems related to eating. Satisfaction was 77% in general, 85% with phonetics and 85% with eating (compared to 7%, 10% and 25% prior to surgery wearing complete prostheses, respectively). No statistical comparison was attempted.

De Kok and co-workers (2011)⁹² investigated 20 patients (11 women, 9 men, mean age: 63 years) with edentulous mandibles in a randomised controlled pilot trial with a follow-up of 1 year. Inclusion criteria involved mandibular bone height of at least 10 mm in the parasymphysis area and complete edentulism for at least 3 months. Two-implant-supported overdentures were compared to three-implant-supported dentures. A total of 50 implants (OsseoSpeed, Astra

Tech; Dentsply) were placed. Patient satisfaction was assessed on a visual analogue scale (complete dissatisfaction to complete satisfaction) regarding general satisfaction, denture satisfaction, ease of cleaning, stability, retention, comfort, ease of chewing, ease of speaking and aesthetics. Oral health-related quality of life was assessed using the full version of the Oral Health Impact Profile (OHIP) with 49 items⁹³. In both groups, all VAS-ratings as well as the OHIP-scores improved significantly compared to baseline. No difference between 3-implant and 2-implant groups were found regarding general satisfaction (95% vs. 94%), denture satisfaction (96% vs. 96%), stability (96% vs. 94%), retention (97% vs. 95%), comfort (98% vs. 95%), ease of chewing (94% vs. 92%), ease of speaking (89% vs. 91%), aesthetics (98% vs. 95%), as well as oral health-related quality of life (18.9 vs. 20.2). However, ease of cleaning was significantly worse with 3 vs. 2 implants (89% vs. 97%).

Slot and co-workers (2013)94 investigated 50 patients (27 women, 23 men, mean age: 59 years) with edentulous maxillae in a randomised controlled study on bar-retained overdentures, of which 49 completed the 1-year follow-up. Inclusion criteria involved lack of retention and stability of the upper complete denture and sufficient bone volume in the anterior maxilla (at least 12 mm in height and 5 mm in width). Half of the patients received 4 implants (OsseoSpeed, Astra Tech, Dentsply), in the remainder 25 patients 6 implants were placed. After 3 months of submucosal healing both groups received milled bar-retained overdentures without palatal coverage. Patient satisfaction was assessed by a questionnaire consisting of 54 items (each rated between 0 = no complaints and 3 = severe complaints) divided into 6 subscales: 9 items concerning functional problems of the lower denture; 9 items concerning functional problems of the upper denture; 18 items concerning functional problems/complaints in general; 3 items concerning facial aesthetics; 3 items concerning accidental lip, cheek and tongue biting (neutral space); and 12 items concerning denture aesthetics. In addition, a Chewing Ability Questionnaire rating 9 different kinds of food (0 = good to 2 = bad) was filled out. Patients' overall denture satisfaction was expressed on a 10-point rating scale (1 = very bad to 10 = excellent). There was significant improvement after vs. before implant placement in all scales, both

in the 4-implant group (8.9 vs. 4.0) and the 6-implant group (8.9 vs. 4.1). However, there were no significant differences between the groups.

Visser and co-workers (2005)95 investigated 60 patients (39 women, 21 men, mean age: 55 years) with edentulous mandibles in a randomised con-Sentrolled trial, of which 56 patients completed the 5-year follow-up. Inclusion criteria involved residual bone height of 12 to 18 mm in the anterior mandible and an edentulous period of at least 2 years prior to surgery. Half of the patients received 2 implants (IMZ, Friedrichsfeld, Mannheim, Germany); in the other 30 patients, 4 implants were placed. After 3 months of submucosal healing, bar-retained mandibular overdentures and new maxillary complete dentures were delivered. Patient satisfaction was assessed by the same 54-item questionnaire used by Slot and coworkers (2013)94. Significant improvement of patient satisfaction after 5 years of loading could be observed only in the first subscale concerning overdenture function: mean pre-treatment scores were 2.2 in both groups and improved to 0.3 in both groups without any differences between the 2-implant vs. the 4-implant group. Meijer and co-workers (2009)⁹⁶ published 10-year results of the same patient group, again without revealing differences between the groups (score 0.4 vs. 0.5, 3 patients with 4 implants and 7 patients with 6 implants lost to follow-up).

Walton and co-workers (2009)97 investigated 86 patients (43 women, 43 men, mean age: 67 years) with edentulous mandibles in a randomised controlled trial, of which 74 patients completed the 1-year follow-up. Inclusion criteria involved a residual bone height of at least 6 mm in the anterior mandible and at least 6 month's experience with conventional complete dentures that were aesthetically satisfactory to the patient and technically acceptable in the judgement of the study prosthodontists. Thirty-eight patients were randomised to the singleimplant group, while 37 patients received 2 implants (ITI Solid Screw SLA, Straumann, Waldenburg, Switzerland) to retain overdenture via ball attachments (ITI spherical stud, Straumann) after a healing period of 6 weeks. Patient satisfaction was assessed by VAS-ratings in 8 denture-related issues, both prior to as well as 1 year after rehabilitation: pain; comfort; appearance; function; stability; speech; hygiene and overall satisfaction. While baseline satisfaction scores

Table 6 Studies on patient satisfaction with tilted implant placement in edentulous jaws (mx = maxilla, md = mandible). study design (pro = prospective study, retro = retrospective study), number of patients (Patient no.), implants placed per patient (Impl/pat), length of follow-up (in years), assessment scale (+/- = polar questions) and within-patient comparison pre- vs. post-implantation.

| | Study design | Jaw | Patient no. | Impl /pat | Follow-up | Scale | Within 7 patient |
|---------------------------------------|-----------------|------------------|-------------|--------------|-----------|-------|---------------------|
| Agliardi et al, 2009 ¹⁰⁰ | pro | mx | 20 | 6 | 1 a | 1-5 | no |
| Antoun et al, 2012 ¹⁰¹ | retro | 13 mx 31 md | 44 | 4–5 | 1.5 a | 0–10 | yes |
| Babbush, 2012 ¹⁰² | retro | 167 mx 113 md | 250 | 4 | - | 1–5 | no |
| Capelli et al, 2007 ¹⁰³ | pro | 41 mx 24 md | 65 | 4–6 | 2.0 a | +/- | no |
| Fortin et al, 2002 ¹⁰⁴ | retro | mx | 45 | 3–7 | 5 a | +/- | no |
| Maló et al, 2012 ¹⁰⁵ | pro | 79 mx 133 md | 142 | 4 | 2.2 a | +/- | no |
| Mattsson et al, 1999 ¹⁰⁶ | pro | mx | 15 | 4–6 | 3.8 a | +/- | no |
| Peñarrocha et al, 2010 ¹⁰⁷ | retro | mx | 12 | 4 | 1 a | 1–10 | no |
| Rosén & Gynther, 2007 ¹⁰⁸ | retro | mx | 19 | 4–6 | 8–12 a | +/- | no |
| Testori et al, 2008 ¹⁰⁹ | pro | mx | 28 | 6 | 1 a | 1–5 | no |
| Weinstein et al, 2012 ¹¹⁰ | pro | md | 20 | 4 | 0.5 a | 1–5 | no |

differed between the single-implant (VAS = 29%) and double-implant group (VAS = 51%), however not significantly; no difference in patient satisfaction after 1 year of loading could be found (93% vs. 94%). Improvement in overall satisfaction was highly significant in both groups; however, differences between the groups may be related to differences in the baseline values.

Weinländer and co-workers (2010)98 investigated 76 consecutive patients (42 women, 34 men, mean age: 60 years) with edentulous mandibles in a prospective comparative study with a minimum follow-up of 5 years. Inclusion criteria involved atrophic mandibles (Cawood and Howell⁹⁹-class III to V). Twenty-one patients received 2 interforaminal implants (IMZ, Frialoc or Camlog) with an ovoid bar; 22 patients received 4 implants with multiple ovoid bars (implant-retained overdenture); and 24 patients received 4 implants with a milled bar (implant-supported prosthesis). Patient satisfaction was assessed as not satisfactory, adequate, satisfactory, good, or excellent (score ranging from 1 to 5) regarding general satisfaction, chewing ability, denture stability, speech, and aesthetics. Mean ratings did not differ between the groups (5.0 for general satisfaction, 5.0 for chewing ability, 5.0 for denture stability, 4.6 for speech, and 4.5 for aesthetics).

Tilted implant placement

Agliardi and co-workers (2009)100 investigated 20 consecutive patients (9 women, 11 men, mean age: 57 years) with edentulous maxillae rehabilitated by fixed prostheses on 4 implants in a prospective study with a mean follow up of 27.2 months (range: 18 to 42 months). Inclusion criteria involved sufficient bone for the placement of implants at least 10 mm long and 4 mm in diameter. A total of 120 implants were placed (30 Brånemark MK IV and 90 NobelSpeedy Groovy, Nobel Biocare), the posterior implants were tilted between 30 and 45 degrees. Acrylic resin provisional prostheses were delivered within 4 h after surgery. Patient satisfaction was rated as excellent, very good, good, sufficient, or poor, regarding aesthetics, phonetics and masticatory function at baseline at 6 months (all patients) and 1 year after surgery (8 patients lost to follow-up). Excellent or very good ratings were given in 85%, 85%, and 83% regarding aesthetics, in 80%, 70%, and 92% regarding phonetics, and in 75%, 65%, and 75% regarding mastication, respectively (Table 6).

Antoun and co-workers (2012)¹⁰¹ investigated 44 patients (32 women, 12 men, mean age: 70 years) with 13 edentulous maxillae and 31 edentu-

lous mandibles in a retrospective study with a mean follow-up of 17.6 months (range: 3 to 56 months). Inclusion criteria involved favourable occlusal context (restriction to Angle Class I and II). A total of 78 implants (Brånemark TiUnite, Nobel Biocare) were placed in the maxilla (All-on-Six concept) and 124 in the mandible (All-on-Four concept). All patients received screw-retained full-arch acrylic resin provisional prostheses within 24 h after surgery. Patient satisfaction was assessed (0 to 10) before intervention and at the last follow-up visit. Overall, patients were satisfied or very satisfied with the procedure. Aesthetics, mastication, and comfort increased from 3.6 to 8.5 (+49%), from 3.0 to 8.3 (+53%) and from 2.8 to 8.8 (+60%), respectively. Pain, swelling, and haematoma was unpleasant for 20%, 33%, and 53%, respectively. However 98% declared they would recommend this treatment to others.

Babbush (2012)¹⁰² investigated 250 patients (143 women, 107 men) with 167 edentulous maxillae and 113 edentulous mandibles in a retrospective study. Patients received immediate provisional fixed prostheses on 4 implants (NobelActive, Nobel Biocare) according to the All-on-Four concept in one or both jaws with the 2 posterior implants tilted distally. After treatment they completed the 20-question Edentulous Patient Impact Questionnaire (EPIQ). Patient satisfaction was 95% (74% extremely satisfied, 21% satisfied) and 98% would recommend similar treatment to a friend or colleague. Some 75% rated their postsurgical discomfort as being less than expected and 70% reported less swelling than expected. And 60% reported better chewing and 32% better speaking capabilities with the temporary prosthesis then they experienced preoperatively.

Capelli and co-workers (2007)¹⁰³ investigated 65 consecutive patients (43 women, 22 men, mean age: 59 years) with 41 edentulous maxillae and 24 edentulous mandibles in a prospective multicentre study with a mean follow-up of 24.3 months. Inclusion criteria involved severe atrophy of posterior jaw regions that would have necessitated bone augmentation surgery. A total of 246 implants were placed in the maxilla (6 per jaw) and 96 implants in the mandible (4 per jaw), while posterior implants were tilted between 25 and 35 degrees (Osseotite NT, Biomet 3i, Palm Beach Gardens, FI, USA). Temporary fixed prostheses were delivered within 48 h. Patient

satisfaction was assessed by polar questions regarding aesthetics, phonetics, ease of maintenance and functional efficiency. All patients were totally satisfied with all aspects of treatment.

Fortin and co-workers (2002)104 investigated 45 consecutive patients (30 women, 15 men, 96% CONT between 31 and 70 years of age) with edentulous maxillae in a retrospective study with a follow-up of 5 years. The inclusion criteria involved sufficient bone for implants with a minimum diameter of 3.75 mm and necessity of lip support or position of the lip when smiling requiring a flange extension to the prosthesis. A total of 245 implants (Brånemark system, Nobel Biocare) were placed, of which 90 posteriorly placed implants were tilted to avoid the maxillary sinus. All patients received full-arch, double-structure Marius implant prostheses. Patient satisfaction regarding phonetics, aesthetics and psychological and functional aspects was assessed by polar questions. All patients were satisfied with each of the four aspects.

Maló and co-workers (2012)¹⁰⁵ investigated 142 patients (86 women, 56 men, mean age: 54 years) with 79 edentulous maxillae and 133 edentulous mandibles in a prospective cohort study with a mean follow-up of 2.2 years. Inclusion criteria involved the possibility of placing implants at least 10 mm length. According to the All-on-Four concept (30 to 45 degrees tilting of the posterior implants) 4 implants per jaw were placed (Brånemark MK III, Brånemark MK IV, or NobelSpeedy, Nobel Biocare). Full-arch acrylic resin prostheses were delivered on the day of surgery. Patient satisfaction was assessed by polar questions regarding aesthetic complaints, phonetic complaints, comfort complaints and hygienic complaints. No complications were registered during the study period.

Mattsson and co-workers (1999)¹⁰⁶ investigated 15 patients (11 women, 4 men, mean age: 59 years) with edentulous maxillae rehabilitated by fixed prostheses on 4 implants in a prospective study with a mean follow-up of 3.8 years. Inclusion criteria involved maxillary bone dimension not more than 10 mm in the vertical aspect and more than 4 mm thickness (Cawood and Howell⁹⁹-class V or VI). A total of 86 implants (Brånemark, Nobel Biocare) were placed, the two posterior of 4 to 6 implants per patient were angulated according to the

anatomy of the anterior-medial wall and floor of the maxillary sinus. After a submerged healing period of at least 6 months fixed superstructures were made of cobalt-chromium (6 patients), silver-palladium (6 patients) or titanium (3 patients). Patient satisfaction was assessed by polar questions regarding aesthetics and phonetics. The aesthetic outcome was considered to be satisfactory for all patients (100%). Phonetic problems were initially reported by 4 patients (27%), but no longer perceived as socially limiting at the 1-year recall.

Peñarrocha and co-workers (2010)107 investigated 12 patients (10 women, 2 men, mean age: 61 years) with edentulous maxillae in a retrospective case series with 1-year follow-up. Inclusion criteria involved severe maxillary resorption (Cawood and Howell⁹⁹-class V). A total of 48 implants (Impladent or Straumann) were placed in tilted, palatal positions in the anterior maxillary buttress. Overdentures were fabricated 3 to 4 months after implant surgery. Patient satisfaction was assessed on a 10-cm visual VAS using the anchor words 1 = totally dissatisfied to 10 = completely satisfied in the following categories: general satisfaction with the implant-retained prosthesis; comfort and stability; ability to speak; ability to perform oral hygiene; aesthetics; self-esteem; and function. The mean general level of satisfaction was 8.5, comfort and stability 8.0, ability to speak 9.0, ease of cleaning 8.5, aesthetics 8.5 and function 8.5 after 1 year of loading.

Rosén and Gynther (2007)108 investigated 19 patients (13 women, 6 men, mean age: 60 years) with edentulous maxillae in a retrospective longterm follow-up study (8- to 12-year follow-up). Inclusion criteria involved severe resorption (Cawood and Howell⁹⁹-class V or VI) and posterior implants tilted in an angle of more than 30 degrees. In total, 103 implants (Brånemark MK II, Nobel Biocare) were placed in the anterior maxilla, 4 to 6 in each patient. Second-stage surgery was performed after 6 months and all patients received metal-acrylic fixed full-arch prostheses. Patient satisfaction was assessed by polar questions regarding pre- or postoperative disorders or problems, including paraesthesia, infection of the maxillary sinus, oral hygiene difficulties, temporomandibular joint disorders, problems with biting or chewing, and phonetic or aesthetic problems. One patient had problems with biting (5%), 8 patients reported speaking differently (42%) and 7 patients reported aesthetic problems (37%).

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Testori and co-workers (2008)¹⁰⁹ investigated 41 patients (26 women, 15 men, mean age: 59 years) with edentulous maxillae in a prospective multicentre study, of which 28 patients (68%) completed the 1-year follow-up. Inclusion criteria involved severely resorbed maxillae with at least 4 mm height and 6 mm width in the first premolar region that would have needed bone augmentation for placing implants in a more posterior location. In each patient 6 implants were placed (Osseotite NT, Biomet 3i), with the 2 posterior implants tilted between 30 and 35 degrees. Provisional screw-retained full-arch prostheses were delivered within 48 h after surgery. Patient satisfaction was assessed by rating aesthetics, phonetics, ease of maintenance and functional efficiency as either excellent, very good, good, sufficient or poor. Patients were satisfied with aesthetics, phonetics, maintenance, and function (ratings excellent or very good) in 75%, 86%, 36%, and 69%, respectively. All patients affirmed that their quality of life had improved after the treatment.

Weinstein and co-workers (2012)¹¹⁰ investigated 20 patients (12 women, 8 men, mean age: 61 years) with edentulous mandibles in a prospective observational study (mean follow-up: 31 months, range: 20 to 48 months) on the effect of fixed prostheses on 4 implants. Inclusion criteria involved residual bone height of at least 10 mm and bone width of at least 4 mm and patients who manifested a clear preference for fixed implant-supported rehabilitation, but refused any kind of bone augmentation procedure. Two anterior implants were placed axially and 2 posterior implants were tilted (Brånemark System MK IV or NobelSpeedy Groovy, Nobel Biocare) with an insertion torque of at least 30 Ncm. All patients received immediately loaded full-arch fixed prostheses. Patient satisfaction was assessed on a 5-point Lickert-type scale (1 = poor to 5 = excellent) by means of a questionnaire delivered at the 6-, 12-, and 24-month visit. All patients completed the 6-month follow-up and 18 patients (90%) responded after 1 year. The mean ratings regarding function, aesthetics and phonetics were 3.9, 3.4, and 3.7 after 6 months and 4.0, 3.7, and 3.8 after 1 year, respectively. No significant differences were noted between the 6-months and 1-year evaluation.

Table 7 Studies on patient satisfaction with zygomatic fixtures (zyg) in combination with regular implants (reg) in edentulous maxillae (mx): study design (pro = prospective study, retro = retrospective study), number of patients (Patient no.), implants placed per patient (Impl/pat), length of follow-up (in years), assessment scale (OHIP = Oral Health Impact Profile, +/- = polar questions), and within-patient comparison pre- vs. post-implantation (*both ratings assessed after implant treatment).

| | Study design | Jaw | Patient no. | Impl /pat | Follow- up | Scale | Within patient |
|--|-----------------|-----|-------------|--------------------|------------|-------|----------------|
| Bothur & Garsten, 2010 ¹¹¹ | retro | mx | 7 | 2–5 zyg 0–3 reg | 0.3 a | 0–10 | yes |
| Davó & Pons, 2013,112 | pro | mx | 17 | 4 zyg | 3 a | OHIP | no |
| Farzad et al, 2006 ¹¹⁴ | retro | mx | 11 | 2 zyg 2–4 reg | 1.5-3.8 a | 0–10 | yes* |
| Peñarrocha et al, 2007 ¹¹⁵ | retro | mx | 23 | 1–2 zyg 3–6 reg | 1 a | 0–10 | no |
| Peñarrocha et al, 2009116 = 2013 ¹¹⁷ | retro | mx | 13 | 0–2 zyg 2–7 reg | 5.8 a | 0–10 | no |
| Sartori et al, 2012 ¹¹⁸ | pro | mx | 16 | 5.9 | 1 a | +/- | no |

Zygomatic fixtures

Bothur and Garsten (2010)¹¹¹ investigated 7 patients (5 women, 2 men, mean age: 64 years) with edentulous maxillae in a retrospective case series with a follow-up of 4 months. Inclusion criteria involved severe atrophy of the maxilla (Cawood and Howell⁹⁹-class VI) with extensive resorption into the basal bone. The patients received a total of 28 zygomatic fixtures and 5 conventional implants (Brånemark System, Nobel Biocare) to support fixed prostheses after a mean healing period of 6.5 months. Patients judged their speaking ability prior to implant treatment as well as 4 months after surgery on a scale of 0 to 10. Mean subjective ratings were 6.9 before surgery, 5.9 after one week and 7.1 after 4 months of loading (Table 7).

Davó and Pons (2013)¹¹² investigated 17 consecutive patients (10 women, 7 mean, mean age: 58 years) with edentulous maxillae in a prospective study with a follow-up of 3 years. Inclusion criteria involved severe maxillary atrophy (Cawood and Howell⁹⁹-class IV or V). In each patient 4 zygomatic fixtures (Brånemark System, Nobel Biocare) of 30 to 52.5 mm length were placed and subjected to immediate loading (15 fixed screw-retained prostheses and 2 overdentures). Oral health-related quality of life was assessed using a short version of the Oral Health Impact Profile (OHIP) with 14 items¹¹³. The average OHIP-score was 2.7 after 3 years of loading (no baseline value was available for comparison).

Farzad and co-workers (2006)¹¹⁴ investigated 11 patients (10 women, 1 man, mean age: 58 years) with edentulous maxillae in a retrospective study with a follow up of 18 to 46 months. Inclusion criteria involved insufficient bone volume for routine implant placement in the posterior maxilla. A total of 22 zygomatic fixtures and 42 conventional implants (Nobel Biocare) were placed. After a healing period of 6 to 11 months all patients were provided with fixed prostheses (Procera Implant Bridge titanium framework, Nobel Biocare). Patient satisfaction was assessed on a 10-cm VAS regarding the following questions: 1) How is your chewing ability today?; 2) How was your chewing ability before treatment?; 3) How do you experience the aesthetic results of the treatment?; 4) How did you feel about the overall appearance of your teeth before treatment?; 5) How is your speech today?; 6) How was your speech before treatment? (endpoints of the scale were defined as 'best possible' and 'worst possible'). Significant improvement was seen with regards to chewing and aesthetics, however not for speech with mean differences before vs. after treatment of 4.3, 4.0 and 1.0, respectively.

Peñarrocha and co-workers (2007)¹¹⁵ investigated 23 patients (12 women, 11 men, mean age: 53 years) with edentulous maxillae in a retrospective clinical study with a follow-up of 1 year. No further inclusion criteria were stated. Patients received 1 to 2 zygomatic fixtures (Nobel Biocare) and 3 to 6 additional implants (Defcon; Impladent, Barcelona, Spain) in the anterior maxilla – in total

144 implants. All patients received fixed prostheses. Patient satisfaction was assessed on a 10-cm visual analogue scale ranging from 0 = totally dissatisfied to 10 = completely satisfied with regards to general satisfaction with the implant-retained prosthesis, comfort and stability, ability to speak, ease of cleaning, aesthetics, self-esteem and functionality. Mean patients' ratings were 9.7 for general satisfaction, 9.8 for comfort and stability, 9.8 for aesthetics, 9.8 for ease of cleaning, 9.8 for ability to speak, 9.8 for self-esteem and 9.7 for functionality. Ratings regarding aesthetics were significantly better than in the control group without zygomatic implants (8.9).

Peñarrocha and co-workers (2009)116 investigated 13 patients (8 women, 5 men, mean age: 55 years) with edentulous maxillae in a retrospective study and reported the results after a mean followup of 70 months (range: 24 to 132 months) in a subsequent article in 2013¹¹⁷. Inclusion criteria involved severe maxillary atrophy (Cawood and Howell⁹⁹class IV or V) and implants placed in the nasopalatine canal. A total of 6 zygomatic fixtures and 72 conventional implants (Impladent or Straumann). All patients received fixed screw-retained full-arch prostheses after 12 weeks of submerged healing. Patient satisfaction was assessed on a 10-cm visual analogue scale regarding general satisfaction with the implant-retained prosthesis, comfort and stability, ability to speak, ease of cleaning, aesthetics, self-esteem, and function (anchor words: 'totally dissatisfied' and 'completely satisfied'). Average patient ratings were 9.0 for general satisfaction, 9.7 for comfort and stability, 9.5 for ability to speak, 8.5 for function, aesthetics and self-esteem, and 9.0 for ease of cleaning.

Sartori and co-workers (2012)¹¹⁸ investigated 16 patients (10 women, 6 men, age range: 38 to 77 years) with edentulous maxillae in a prospective clinical study with a follow-up of 1 year. No further inclusion criteria were stated. Patients received either zygomatic fixtures alone or combined with conventional implants. In total 37 zygomatic fixtures and 58 conventional implants (Alvim Cone Morse, Neodent) were placed. All patients were rehabilitated with fixed prostheses on titanium cylinders and acrylic teeth within 48 h after surgery. Patient satisfaction was assessed by a self-designed ques-

tionnaire: 1) Satisfaction with treatment (a = completely satisfied, b = satisfied but with some complaints, c = had different expectation of treatment. d = unsatisfied); 2) If unsatisfied, the reason is as follows (a = aesthetics, b = discomfort when chewing, c = pain, d = phonetics, e = hygiene), 3) Number of clinical sessions required to solve problems after insertion of prosthesis in addition to scheduled follow-up visits (a = 0 sessions, b = <3 sessions, c = >3 sessions); 4) The complication was related to the following (a = prosthesis, b = implants). Half of the patients were completely satisfied, the other half were satisfied but with some complaints. Dissatisfaction was related to aesthetics, chewing, phonetics and hygiene in 4 (25%), 1 (6%), 4 (25%) and 4 cases (25%), respectively. Eight patients required no sessions to solve problems (50%), 6 patients fewer than 3 sessions (38%) and 2 patients more than 3 sessions (13%). Complications were related to the prosthesis in 5 patients (31%) and to the implants in 3 patients (19%).

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Discussion

The present systematic review summarises current evidence in the literature regarding minimally invasive treatment options for edentulism from the patient's perspective. Patient satisfaction averaged 91% with flapless implant placement (range: 77 to 100%), 89% with short implants, 87% with narrowdiameter implants (range: 80 to 93%), 90% with a reduced number of implants (range: 77 to 100%), 94% with tilted implant placement (range: 58 to 100%), and 83% with zygomatic fixtures (range: 50 to 97%). Indirect comparison yielded patient preference towards tilted implant placement compared to a reduced number of implants (P = 0.036) as well as to zygomatic implants (P = 0.001) while no differences could be seen between other treatment options. It may be concluded that patient satisfaction with graftless solutions for implant rehabilitation of completely edentulous jaws is generally high and compares well with implant survival of 97 to 99% reported in reviews of literature (Table 8).

However, no studies comparing patient satisfaction with minimally invasive treatment alternatives vs. bone augmentation surgery could be identified in

Table 8 Patient satisfaction (results from the present review) and implant survival rates (results from literature eviews) with minimally invasive treatment alternatives for graftless rehabilitation of edentulous jaws (n.d. = no data).'

| Minimally invasive treatment option | Mean patient satisfaction rate (range) | Mean implant survival rate (range) ¹¹⁹⁻¹²¹ |
|-------------------------------------|--|--|
| flapless implant placement | 91% (77–100) | 97% (92–100) |
| short implants | 89% | 97% (74–100) |
| narrow-diameter implants | 87% (80–93) | 99% (89–100) |
| reduced number of implants | 90% (77–100) | n.d. |
| tilted implant placement | 94% (58–100) | 98% (89–100) |
| zygomatic implants | 83% (50–97) | 98% (82–100) |

the current literature. It thus remains unexplored to what extent graftless therapeutic options are actually preferred by patients or whether they offer significant advantages from the patients' point of view at all. The inherent difficulty of this comparison is certainly due to the fact that it is not possible to perform two - or even more - alternative implant procedures in the same patient (with the possible exception of splitmouth trials that are not easy to conduct as the left and right patient side rarely present with truly comparable baseline situations with regards to residual alveolar bone volume and anatomy), particularly when investigating rehabilitation of complete edentulism. Comparative effectiveness research, i.e. within-study comparison in randomised controlled clinical trials, is needed to substantiate the positive appeal of graftless options to potential implant patients and their possible reduction of the indication span for invasive bone augmentation surgery.

Clinical heterogeneity within the studies included in the present literature review arises from a variety of sources involving patient demographics, diverging inclusion criteria (Cawood and Howell⁹⁹ - classes of atrophy, residual bone volume, period of edentulism, satisfaction with as well as stability of previous removable prostheses), use of virtual treatment planning software and surgical templates, implant treatment protocols as well as timing of surgical and prosthodontic interventions. Multiple confounding factors (such as the type of implant superstructure) may carry the potential to significantly influence patient opinion while not being directly related to the question under focus, that is amount of surgical invasion. Due to the lack of consensus guidelines regarding the absolute necessity of bone augmentation in defined clinical situations, it remains hard to judge whether

minimally invasive procedures actually represent an alternative to bone graft surgery or merely options associated with reduced patient morbidity.

The major challenge in trying to compare literature results on patient-related outcomes in the present review was the diversity of outcome assessment throughout the included studies. While the majority of investigations evaluated subjective treatment satisfaction (92%), only a few examined oral health-related quality of life (11%) or actual patient preferences towards therapeutic options (5%). Methodology and outcome definitions varied extensively with regards to questions asked, scale items and endpoint definitions, anchor words of visual analogue scales, and performance of withinpatient comparison. In fact, only a single study87 utilised a validated instrument88 for assessment of patient-centred treatment satisfaction. Conversion of outcome formats to a uniform per cent scale was thus necessary to facilitate outcome comparison, however, must be suspected to have introduced bias to some extent. Future research may pay special attention to uniform and standardised use of validated instruments (such as the Oral Health Impact Profile⁷³) for the assessment of patient opinion as a variable of treatment preference.

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Biomechanical aspects of the optimal number of implants to carry a cross-arch full restoration

Key words all-on-4, biomechanics, cantilever, design, finite element (FE) analysis, forces, implants, loading, moments, optimal, prosthesis, Skalak model, strain, stress, tilting

A proper definition of the 'optimal' number of implants to support a full arch prosthesis should go beyond solely a listing of the number of implants used in a treatment plan; it should be based upon a biomechanical analysis that takes into account several factors: the locations of the implants in the jaw; the quality and quantity of bone into which they are placed; the loads (forces and moments) that develop on the implants; the magnitudes of stress and strain that develop in the interfacial bone as well as in the implants and prosthesis; and the relationship of the stresses and strains to limits for the materials involved. Overall, determining an 'optimal' number of implants to use in a patient is a biomechanical design problem. This paper discusses some of the approaches that are already available to aid biomechanically focused clinical treatment planning. A number of examples are presented to illustrate how relatively simple biomechanical analyses - e.g. the Skalak model - as well as more complex analyses (e.g. finite element modelling) can be used to assess the pros and cons of various arrangements of implants to support fullarch prostheses. Some of the examples considered include the use of 4 rather than 6 implants to span the same arc-length in a jaw, and the pros and cons of using tilted implants as in the 'all-on-4' approach. In evaluating the accuracy of the various biomechanical analyses, it is clear that our current prediction methods are not always perfectly accurate in vivo, although they can provide a reasonably approximate analysis of a treatment plan in many situations. In the current era of cone beam computerised tomography (CT) scans of patients in the dental office, there is significant promise for finite element analyses (FEA) based on anatomically-accurate input data. However, at the same time it has to be recognised that effective use of FEA software requires a reasonable engineering background, especially insofar as interpretations of the clinical significance of stresses and strains in bone and prosthetic materials.

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Introduction

This article presents basic biomechanical analyses to guide the optimal use of oral implants in full-arch prosthetic restorations. However, at the outset, the adjective 'optimal' requires some explanation. Definitions of 'optimal' include the following:

- "Most favourable or desirable" (Anonymous, 2009)¹.
- "In mathematics, an optimal solution is one that is determined to be the best solution from all feasible solutions. In business, it is a solution that best fits a situation by employing organizational resources in the most effective and efficient manner" (Anonymous, 2014)².



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Mob: 518.229.6963 Email: brunsj6@stanford.edu "[Optimal] describes a solution to a problem which minimizes some cost function" (Howe, 2010)³.

But what are the criteria for determining what is 'favourable' or 'best'? In searching for an 'optimal' solution to a problem – such as the problem of selecting how many implants are 'best' in treating a full-arch reconstruction of an edentulous jaw – it is important to have some criteria for defining 'optimality'.

In this regard, the last definition above is helpful because it explains that an 'optimal' solution is one that "...minimises some cost function". For instance, 'cost function' can be used in the context of economics: a 'cost function' is an equation (function) whose value depends on several variables ('inputs'), each of which have 'prices' or 'costs'; ultimately this cost function explains how the cost to produce a certain 'output' depends on the prices of the 'inputs'⁴. At least in this economics example, it would be considered 'optimal' to minimise (as opposed to maximise) the 'cost function', since typically when producing goods in a business, it is desirable to reduce the costs of production.

In analogy with the above idea, one way to apply a 'cost function' in patient treatment would be to recognise that a non-economic 'cost' to a patient includes pain and discomfort, limited function, and time of disablement. And while choosing the 'optimal' number of implants to treat an edentulous jaw is not (solely) an economics problem, nevertheless it is instructive to consider how a 'cost function' might be developed to help guide optimal treatment planning with implants. For example, first it would be possible to define a 'risk function' where this function would depend on key 'inputs' (variables) in the problem, including: the number of implants; location of implants in the arch; shape/size/biomaterial of the implants; quality of bone at the implant sites; expected masticatory loading; prosthesis design; loading paradigm (i.e. immediate vs. delayed loading); patient pain and discomfort; patient inconvenience, etc. Second, one could then develop an 'optimal' solution by minimising the defined risk function. This could be done by assigning a 'risk value' to each variable or 'input' in the 'risk function' (analogous to assigning a 'price' to each input in the cost function noted earlier), and then minimising the total risk function with respect to the inputs. Alternatively, it would be possible to take a different approach and develop a 'probability of success function (PSF), which would also depend on the same variables noted earlier in the risk function, except that here with the PSF, one would seek to maximise this PSF.

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In any case, whether dealing with a 'risk function' (or its inverse, a 'probability of success function') defining an optimal therapy with implants involves many inputs (variables, factors) that influence the outcome. Therefore, with intraoral implants, any attempt to define 'optimality' only in terms of the number of implants is incomplete and risks missing the main point - which is that optimality of the treatment depends on more than just the number of implants. While certainly the number of implants is a key factor, so are the length and diameter of the implant(s), how and where the implants are placed in the bone, what the bone properties are, what the prosthesis is made of, how the prosthesis is designed and loaded, whether one is planning for immediate loading or delayed loading, and many non-biomechanical factors such as patient discomfort and related issues, etc.

So in this context, this article answers three main questions that can help define optimality in a biomechanical sense:

- 1. How does one predict the forces and moments on implants supporting a cross-arch prosthesis in vivo?
- 2. How do certain variables influence the forces and moments on implants, namely, variables including: number of implants; location of implants; length and diameter of implants; length of a cantilever; 'upright' vs. 'tilted' implants; stiffness of the implant in the bone; type of prosthesis, etc.
- 3. How accurate are our existing methods for predicting the loadings on implants *in vivo*?

This paper will not delve into the clinical evidence about how many implants can or should be used to support full-arch reconstructions; such clinical information is covered in other papers in this issue of the journal. Instead, this article summarises the biomechanical background that can be used to quantitatively evaluate the pros and cons of various ways that clinicians may place implants in full-arch

treatments. For more in-depth biomechanical background, it may be useful for readers to consult previous articles related to this topic^{5,6}.

Biomechanical approach to treatment planning

Before considering detailed calculations and numerical analyses about numbers of implants etc., it is important to consider the over-arching design perspective surrounding treatment planning with oral implants. When designing any load-bearing structure, a primary goal is to design against mechanical failure, in all of the ways in which mechanical failure might manifest itself. Depending on the nature of the structure being considered and how it will be loaded, mechanical failure is possible by a number of mechanisms, such as single-cycle overload, fatigue under cyclic loading condition, yielding, etc. In the specific instance of treatment planning with oral implants, a flowchart (Fig 1) helps to illustrate a step-by-step design paradigm by which biomechanical case planning can unfold. It's easy to imagine that the steps in this flowchart could be applicable to many common mechanical design problems, including, for example, deciding how best – from architectural and structural viewpoints - to build a small wooden deck behind a house, or how best to design a large skyscraper. The mention of architectural and structural design is apt because it suggests the importance of defining and adhering to certain well-accepted quantitative 'building codes' to assure a safe and effective construction. Indeed, building codes in the construction industry have - or should have - analogues when it comes to design and construction of any full-arch implant-supported prosthesis to restore a mandible or maxilla.

So, consider Step 1 of the treatment planning algorithm (Fig 1): a clinician starts to consider factors such as the patent's oral health history, bone of the dental arches, what the prosthesis might look like, how many implants might be used, where those implants might be placed to support the prosthesis, what sorts of implants might be used, and what sorts of functional loading are likely in this patient.

Then Step 2 is to analyse the biomechanics in more detail, based on the initial plans conceived in

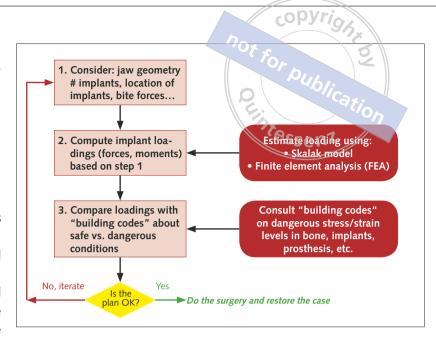


Fig 1 Schematic biomechanical paradigm for treatment planning.

Step 1. For example, if 6 implants are initially contemplated to support a full-arch mandibular denture in a delayed loading scenario, then the clinician would start to estimate what loadings (forces and moments) are anticipated on the implants, and how such loadings would factor into whether the implant performance will be optimal. (This can be done by several methods to be discussed shortly.) Among the numerous factors influencing this analysis is how the 6 implants are situated relative to one another in the jaw, the arc-length over which they are spread, the size/material of the prosthesis, and how the prosthesis will be loaded. For example, in one tentative plan, 6 implants might be equally spaced between the mental foramina in the mandible, whereas in another possible treatment plan, 4 implants might be spaced over that same arc-length. And perhaps in each plan the distal cantilever lengths are, say, 20 mm, and the largest biting forces on the proposed prosthesis occur at those distal locations. A clinician might want to consider several possible plans, but in any event, each plan would be examined further using calculations about the loadings on the implants. Finally, at the end of this Step 2, the main outcome would consist of quantitative results about the anticipated forces and moments on each implant in each of the possible treatment plans that have been considered.

In Step 3, the clinician would take the results from Step 2 and make more detailed analyses about the significance of the loadings on each implant.

For example, for various reasons besides just the biomechanics at this stage - perhaps economic considerations, or issues of bone quantity in certain locations in a patient's maxilla - the clinician might decide to more closely examine a treatment plan involving just 4 implants to avoid the 'cost' of bone augmentation procedures. Then one key analysis that needs to occur involves answering the following question: Suppose the analysis in Step 2 reveals that a 3.75 mm diameter × 10 mm long implant in the plan with 4 implants will experience an axial compressive force of 250 N and a mesiodistal bending moment of 20 N-cm: is this loading going to create improper levels of stress and strain in the bone around this implant? (Actually, this question has to be answered for each implant, since the loading of each implant in a distribution is not going to be the same, as will be clear from some examples to be considered shortly.)

In principle, an answer to this stress-analysis question may seem straightforward. Look up the stress-strain limits for interfacial bone and compare them to the predicted stress-strain levels found in our analysis in Step 3; then, if the predicted stressstrain levels exceed certain limits, reconsider the original plan so as to reduce to proper levels the loadings on implant(s) in question. Unfortunately, at this stage of our understanding of implants and interfacial bone, getting a satisfactory answer to this central stress-analysis question remains problematic. (Indeed, Step 3 is not practiced by clinicians, although as research continues, this step will likely become more practical, if not routine.) The reason for Step 3's difficulty is that the ability to make accurate predictions of the stress-strain levels in bone around oral implants – for instance using finite element (FE) computational models – requires accurate input data that is not always available, e.g. 1) the quantity and spatial location of interfacial bone; 2) the exact mechanical properties of that interfacial bone (e.g. its elastic modulus, stress-strain limits in terms of ultimate, yield, and fatigue strengths); and quantitative rules describing bone's long-term modelling/remodelling response to interfacial stress-strain conditions. While the technical capability of modern commercial finite element (FE) software is outstanding, a relevant programmer's adage still applies: 'GIGO, Garbage In, Garbage Out'. So while progress is being made in these types of interfacial stress analyses - and certainly a rudimentary level of stress analysis is possible - the unfortunate fact is that the oral implant field currently lacks a robust set of 'building codes' for making fully accurate, clinically and biologically reliable assessments of interfacial stresses and strains around oral implants. To make a comparison, if the predictive success of stress analysis were to be ranked on a 1 to 10 scale, with 10 being excellent and 1 being poor, the predictive success of analyses used in designing common engineering structures such as modern buildings and jet engines would be at a 9 or 10, while the validity of analyses used in assessing bone around oral implants would be at a 6 or 7.

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After Step 3, the treatment planning process reaches a cautionary decision box (Fig 1) asking, 'Is the plan OK?' If the answer is 'No', the algorithm reverts back to Step 1, for a redesign effort that could involve the use of more implants or different implant locations, or perhaps wider or longer implants, or perhaps a different prosthesis design, etc. On the other hand, if after Step 3 the treatment plan looks 'OK', then the clinician continues with the rest of the planning, with a focus on the remaining steps, e.g. details of the surgery, prosthetics, etc.

Two additional points are useful in the context of Step 3 and the associated stress-strain analysis alluded to in the oval to the right in Fig 1. First, if stresses or strains become too large in a material in a structure, the material will fail, compromising the integrity of the structure. Obviously materials can fail mechanically in a number of ways, such as by yielding, fracture, or fatigue. (A summary of the basics of mechanical failure appears in other references7.) Second, the stresses and strains in materials in a structure depend on the external loads that act on the structure. So in deciding on how many implants will properly support a prosthesis, the designer must also know as much as possible about the external loadings on the prosthesis, implant, and interfacial bone. As will be seen especially in the example of using 'upright' versus 'tilted' implants to support a prosthesis in an 'all-on-4' system, this issue of loading (as well as stresses and strains in the implants, prosthesis, and interfacial bone) becomes decisive.

Methods to predict loading on oral implants

Methods for analysing the forces and moments on oral implants have been discussed in several previous publications and textbook chapters^{5,8,9}. When implants support a prosthesis, each implant must act - in the language of basic mechanics - as a 'fixed connection'. This means that each implant should be able to carry forces' moments (torques) in all directions. Hence when trying to predict the 'loadings' on implants, this means, in general, trying to predict the forces and moments on each implant. What makes this problem difficult to solve is the fact that each implant is connected to both the bone and the prosthesis; computing the loads (and stresses and strains) in each part of the structure is a problem that is not solvable by statics alone, but also requires data on the material properties of the implants, bone and prosthesis as well as their stressstrain behaviours.

The main methods for predicting loadings on oral implants consist of two types of analyses.

The first type of analysis is the so-called analytical approach, which is based on using equations taken from conventional engineering textbooks and applied to the case of oral implants supporting a prosthesis. Examples of this approach include the so-called 'see-saw' analysis of loading on two implants by Rangert¹⁰ as well as a more involved analysis first presented in the pioneering 1983 publication of Skalak⁸. The so-called 'Skalak model' idealised the distribution of implants, bone and prosthesis as a special case of a mechanical engineering model used to compute the vertical and horizontal load-sharing among bolts used to fasten together two rigid plates. Skalak, Brunski and Mendelson⁹ and Brunski and Hurley¹¹ then extended this original Skalak model to take account of different axial and bending stiffness values for the various implants in the distribution. Morgan and James¹² did work along the same lines. It is beyond the scope of this paper to present the details of these analytical approaches, but calculations with the Skalak model can be readily done with a spreadsheet such as Excel; indeed, all of the calculations of implant loading per the Skalak model in this paper have been done in this manner.

The second main way to predict loadings on implants is via more sophisticated computational methods, such as finite element analysis (FEA). There are many examples of analyses of implant loading using FEA, e.g. Elias and Brunski, 199113; Ujigawa et al 2007¹⁴; Naini et al, 2011¹⁵. The input data in these analyses include the geometry of the bone, implants and prosthesis; the known or estimated material properties of all materials; the boundary conditions between materials; the known or assumed loadings on the prosthesis; and the stress-strain laws for all materials involved. Such models can be relatively straightforward to develop using any number of FEA software packages running on a common laptop, although if the geometry is more complicated - for example when attempting to create a FE model from extensive input datasets derived from computerised tomography (CT) scans - then the computational problem can become large enough to require a more powerful computational platform.

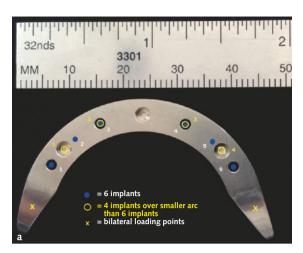
Calculations of implant loading in various situations

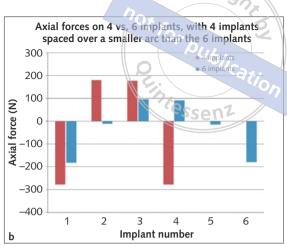
Example 1: Is it better to use 4 or 6 implants to support a prosthesis when the 4 implants are spread out over a smaller arc-length than the 6 implants?

Using the Skalak-type analytical model described previously, it is possible to answer this question as follows. Fig 2a shows the labelled undersurface of a prosthetic bar illustrating possible placements of 4 or 6 implants to support a prosthesis; the legend in the image shows where the 4 or 6 implants have been placed, and the yellow X's indicate the locations of the two distal loading points where test forces of 100 N were bilaterally applied. (The anterior of the jaw is toward the top of the figure.) When the 4 implants span a smaller arc than the 6 implants, the 4-implant construction has longer cantilevers than the 6-implant structure – a parameter that definitely influences the loading on the implants.

The results of the axial load calculations with the Skalak-type model (Fig 2b) show clearly that the magnitudes of the axial forces on the 4 implants arranged over the smaller arc is larger than for 6 implants. (By convention in this modelling, a posi-

Fig 2 (a) Image of the undersurface of a titanium prosthetic bar with locations marked for 4 implants spanning a smaller arc-length than 6 implants. (b) Bar graph showing the axial forces on the 4 or 6 implants as computed using the Skalak model.





tive axial force on an implant is tensile, tending to extract it from the bone, while a negative axial force indicates a compressive force on the implant, tending to push it into the bone.) For example, a comparison of axial forces on the distal-most implants 1 and 4 in the 4-implant option (with smaller arc) vs. the distal-most implants 1 and 6 in the 6-implant option shows that the forces are about twice as large for the 4 implant solution. Similarly, for the anterior implants, the force levels are much greater – for example more than twice as large – in the 4-implant solution. It follows from this example that if one's goal is to have smaller axial forces on the implants, then the 6-implant case is 'optimal'.

Example 2: Is it better to use 4 or 6 implants to support a bar when the 4 implants are spread out over the same arc-length as the 6 implants?

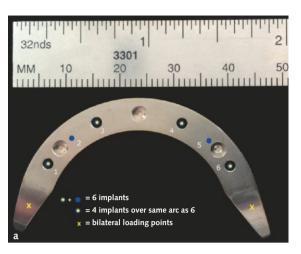
This is a similar case to Example 1, except now the 4 implants cover the same arc as the 6 implants. Again the numbered circles in Fig 3a indicate the positions of the 4 or 6 implants, and the distal Xs represent two loading points where test forces of 100 N were applied bilaterally in the comparisons; the legend in the image shows where the 4 vs. 6 implants are placed. When the 4 implants span the same arc as the 6 implants, implants 1 and 4 are at the same distal locations as implants 1 and 6 in the 6-implant distribution. This also means that the 4-implant case has the same distal cantilever lengths as the 6-implant prosthesis.

The results of the axial load calculations with the Skalak-type model (Fig 3b) show that when the 4 implants span the same arc as the 6 implants, the compressive axial loads on the most distal implants 1 and 4 in the 4-implant option are loaded to virtually the same axial force values as the implants 1 and 6 with 6 implants. Likewise, the forces on the anterior implants are similar, with 4 and 6 implants. Notably, two finite element models of essentially this same example – 4 vs. 6 implants spread out over the same arc length - predict the same results as this analysis with the Skalak model¹⁶⁻¹⁸. From these results it follows that if the goal is to have smaller axial loads on the implants, then there is no significant benefit in selecting 6 rather than 4 implants, as long as the 4 implants span the same arc length as the 6.

Regarding the 4- and 6-implant options discussed in Examples 1 and 2, it is also possible to use the concept of the 'anteroposterior spread (AP spread)' to obtain insight into the pros and cons of various arrangements of implants, although this concept does not provide quantitative information about actual implant loadings; instead it is more of a general guideline for determining a maximum cantilever length. The AP spread has been defined as¹⁹:

"Distance from a line drawn between the posterior edges of the two most distal implants in an arch and the midpoint of the most anterior implant in the arch. This measurement is used to calculate the maximum posterior cantilever length of the prosthesis, which is usually 1.5 times the AP spread."

Applying the idea of the AP spread to Examples 1 and 2, it is possible to re-examine the merits of



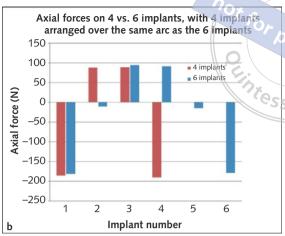


Fig 3 (a) Image of the undersurface of a titanium prosthetic bar with locations marked for 4 implants spanning the same arc length as with 6 implants (b) Bar graph showing the axial forces on the 4 or 6 implants as computed using the Skalak model.

4 implants spread over a smaller arc or the same arc as 6 implants. (See also McAlarney and Stavropoulos, 1996²⁰.) In the former case, the AP spread rule would suggest about 7 mm for the maximum cantilever length, while in the latter case it suggests about 12 mm. Comparing these suggestions to the Skalak calculations in Examples 1 and 2, the Skalak calculations used cantilever lengths of 12.2 mm for the 4 implants over a smaller arc, and 8.6 mm for the 4 implants spanning a larger arc. Comparing these values to what is suggested by the AP spread guideline, this means therefore the cantilever length of 12.2 mm for the 4 implants over a smaller arc is not optimal because 12.2 mm >7 mm. Alternatively, a cantilever length of 8.6 mm for the 4 implants spanning the larger arc (i.e. the same arc as the 6 implants) would be deemed suitable in terms of AP spread, because the cantilever length of 8.6 mm used in the Skalak modelling is less than the maximum cantilever length of 12 mm suggested by the AP spread. So in these examples, the guideline of the AP spread is consistent with the more detailed findings from the Skalak model.

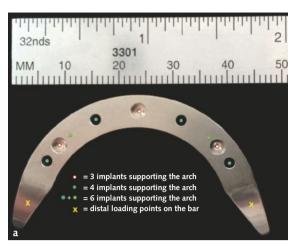
However, it is important to remember that neither the AP spread nor the Skalak model alone is conclusive in defining the optimality of implant loading; ultimately, as discussed later, that issue must also consider the stresses and strains in the interfacial bone, implants and prosthesis, as well as the relationship of those stresses and strains to failure limits for the materials involved.

Example 3: If one uses 3, 4, or 6 implants to support a prosthesis, what differences exist in the loadings per implant, and what is 'optimal'?

A biomechanical comparison of using 3, 4 or 6 implants to support a bar loaded bilaterally by 100 N in the distal locations provides an instructive comparison. As shown in Fig 4a, the legend for labels on the undersurface of the titanium bar describes the placements of 3, 4 or 6 implants. In this example, the positions of the 3 implants are marked and correspond to their locations in the Novum design of Brånemark²¹. The 3 implants span an arc slightly smaller than the 4 and 6 implants in this example, e.g. the cantilever length of the 4- and 6-implant prostheses is a few mm shorter than the cantilever length of the 3-implant prosthesis. The results from the Skalak-type calculations (Fig 4b) show that the axial loads on the implants in the 3-implant distribution are larger than they are for the 4- and 6-implant distribution. In particular, the tensile axial force on anterior implant 2 in the 3-implant treatment option is nearly 300 N, while the maximum tensile force on anterior implants for the 4- and 6-implant options reaches 100 N - a 3-fold difference. The values of the compressive axial forces on the distal implants in the 3-, 4- and 6-implant prostheses are similar, although slightly larger with 3 implants.

However, the above results about forces alone do not tell the whole story vis a vis an evaluation of 'optimality' of 3, 4 or 6 implants; there is more to the analysis. The implants within the 3-implant system

Fig 4 (a) Image of the undersurface of a titanium prosthetic bar with locations marked for 3, 4 or 6 implants; in this example the 3 implants are located as originally planned in the 2001 Novum system of Brånemark, while the 4 and 6 implant arrangements span a slightly larger arc-length than the 3 implants; (b) bar graph showing the axial forces on the 3, 4 or 6 implants as computed using the Skalak model.



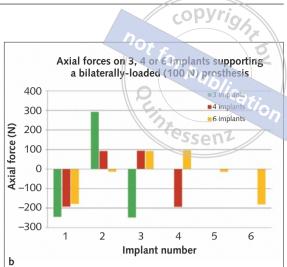
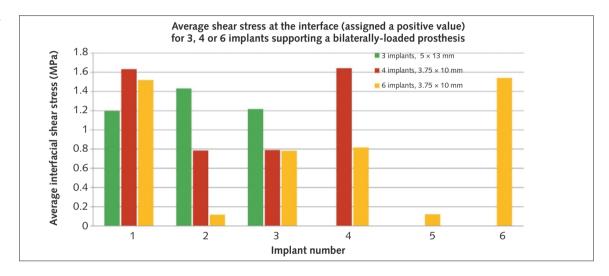


Fig 5 Bar graph showing the average interfacial shear stresses on the 3, 4 or 6 implants analysed in Fig 4. The implants in the 3-implant distribution have larger diameters (and therefore larger interfacial surface area) than the 3.75 mm-diameter implants in the 4- or 6-implant distributions, which explains why the interfacial stresses in the 3-implant case are sometimes smaller than in the 4- and 6-implant situations.



here correspond to the 3 implants used in the original Brånemark Novum system and those implants had a larger diameter (5 mm) than the diameter of 3.75 mm for typical implants used in typical 4 and 6 implant arrangements. As pointed out earlier in this paper, while the axial forces on implants are relevant, so are the resulting stresses in the interfacial bone, and these stresses depend on the implant diameter as well as other factors. So, a critical question is how the stresses in interfacial bone compare in the 3-, 4- and 6-implant options.

An initial answer to this question comes from Fig 5. First consider the average interfacial shear stress for the implants in the 3-, 4- and 6-implant options; these average shear stresses can be estimated by taking the absolute value of the axial force on each implant from the Skalak model and dividing that axial force by the available surface area of each implant. (For the stress calculations, it is not as relevant to be concerned with

sign of the axial load on the implants - negative for compression, positive for tension; the key value is the magnitude of the resulting average shear stress.) The approximate surface area of each 5 mm × 13 mm implant is larger than the approximate surface area of each 3.75 × 10 mm implant in the 4- and 6-implant options. So the difference in the data in Figs 4 and 5 is that the forces in Fig 4 have been divided by boneimplant area in order to produce Fig 5. From these stress calculations it is clear that the shear stresses in bone around the two distal implants (1 and 3) in the 3-implant option are actually less than they are in the bone around the two distal implants of the 4- and 6-implant options. At the same time, the average shear stress in bone around the anterior implant of the 3-implant Novum system is about 1.4 MPa, larger than the average shear stress on the anterior implants in the 4- and 6-implant options, although the absolute value of this average shear stress is actually less than the average shear stress on the distal implants in the 4- and 6-implant options. Therefore, if a discussion of 'optimality' of treatment with implants starts to consider the magnitude of the interfacial stresses in the bone (as was recommended earlier in this paper, in Step 3 of the treatment planning analysis), then it becomes clear that there are some benefits of the 3-implant situation with large diameter implants, because the interfacial shear stresses are somewhat lower in the 3-implant option than in the 4- and 6-implant options. This analysis is approximate, because it does not account for details such as screw threads on the implants, amount of bone coverage, properties of the bone, etc., but the gist of the argument remains clear.

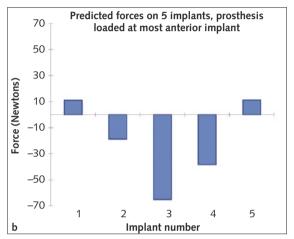
Example 4: Is a fixed prosthesis with 5-implants suitable in a maxilla where more than 5 implants were originally planned?

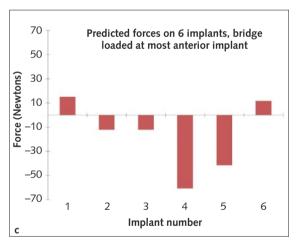
This is an analysis of an actual patient (courtesy of Dr Kenji W. Higuchi, Spokane, WA, USA) where problems in the healing of 2 of the originally-installed 7 implants raised the question of whether the 5 remaining integrated implants would be adequate to support the intended prosthesis in the maxilla (Fig 6). From a biomechanical viewpoint, the question is whether the 5 remaining implants would adequately support loading of the prosthesis, or whether it would make a significant difference if the clinician were to perform a revision surgery to install a 6th implant at a position in the right anterior side (marked by an 'X' in Fig 6), followed by substantial additional healing time (e.g. 5 to 6 months) before a final prosthesis could be considered.

A Skalak model was set up to allow comparison of possible 5- and 6-implant prostheses (Fig 6), for a test load of 100 N being applied over the location of the implant 3 in the images. An inspection of the bar graphs in the two treatment options reveals that there is hardly any difference in the axial forces per implant. Certainly the axial forces are a bit larger with 5 implants, but not significantly larger. Because of this result and additional simulations about the loading (not shown here), the decision was made to go ahead and use the remaining 5 implants to support a Marius denture. The patient had no problems after this stage of treatment.



Fig 6 (a) Image of the maxilla of a patient in which 7 implants had been planned, but only 5 implants were properly integrated. (b and c) Calculations of the axial loading per implant (using the Skalak model) revealed little difference in using 5 (b) vs. 6 (c) implants.

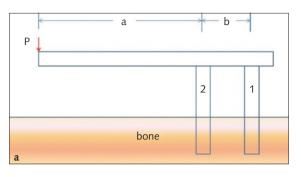


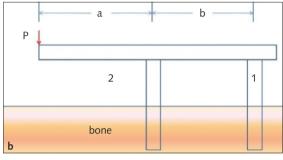


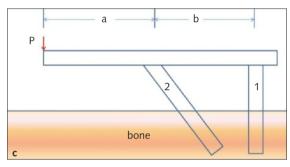
Example 5: The biomechanical rationale for tilting an implant: a prelude to the rationale for the 'all-on-4' approach in a full arch

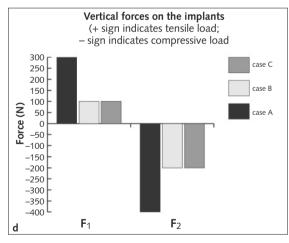
The basic biomechanical aspects related to tilting of oral implants in situations such as the 'all-on-4' approach have been discussed by this author²² as well as by others¹⁸. However, before discussing the biomechanical details of tilting in full arch cases and how this relates to 'optimal' numbers of implants, it

Fig 7 Two-dimensional illustration of the rationale for tilting an implant. The diagrams in (a) to (c) - plus the vertical forces predicted by the Skalak model in (d) - show that if the cantilever distance 'a' is reduced by increasing the implant spacing 'b', the vertical force on each implant can be decreased. The vertical loading on the implants in (b) and (c) are the same because tilting implant no. 2 as shown in (c) produces the same point of connection of the top of that implant to the prosthesis - and the same inter-implant spacing 'b' - as with the upright implant no. 2









is first worth analysing the simplest example of the pros and cons of tilting, which can be seen in a 2-implant structure (Fig 7).

For example, in Fig 7a upright implants no. 1 and no. 2 are spaced at inter-implant distance 'b' while supporting a prosthesis loaded by downward vertical force P acting at the end of a cantilever, which is at

a distance 'a from implant no. 2. Assuming the prosthesis is attached to the implants by ball-and-socket joints (which means that no moments are supported by the denture-implant junctions), this problem can be analysed using simple 2D statics yielding the following result: the vertical force on implant no. 1, F1, will be tensile (acting vertically upward) with a magnitude equal to (a/b)P; and the vertical force on implant no. 2, F2, will be compressive (acting vertically downward) with a magnitude of (1+a/b) P. Inserting some numerical values into these equations, if a = 30 mm, b = 10 mm, and P = 100 N, then F1 = +300 N and F2 = -400 N (with the + sign indicating a tensile force and the - sign indicating a compressive force). These results are plotted in the bar graph of Fig 7d, along with the results from analysing cases B and C, as follows.

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Now if it were possible in a given clinical case to achieve a larger inter-implant spacing (distance 'b' – from, say, 10 mm to 20 mm – the cantilever distance 'a' would then be decreased from 30 mm to 20 mm, which in turn means that the recomputed values of F1 and F2 (using the formulae above) are F1 = +100 N and F2 = -200 N (again with a + sign indicating a tensile force and a – sign indicating a compressive force). The interesting result is that these two vertical forces in case B now are substantially decreased by the increased implant spacing and shorter cantilever, compared to the forces in the situation of Fig 7a.

Given these results, it would be preferable, or 'optimal' – all other things being equal – to arrange two upright implants as in Case B, with the larger spacing 'b' of 20 mm and the smaller cantilever 'a' of 20 mm, because that would give lower forces on the two implants compared to the situation of two implants spaced closer at 10 mm (Case A). However, the key point is that sometimes anatomical factors – such as lack of enough available bone – prevent placing the upright implant no. 2 at the desired larger inter-implant spacing; indeed, this is the anatomical problem originally explained by Krekmanov and coworkers²³.

A benefit of tilting is that it is a way around the problem of lacking enough available bone for an implant where one wants it. The idea is to place the apex of implant no. 2 in available bone stock (perhaps about 10 mm away from implant no. 1, as in Fig 7a) while tilting the top of implant no. 2 so its

top now can connect to the prosthesis at the larger, more desirable, inter-implant spacing of b=20 mm. The see-saw (and Skalak) analysis predicts that this approach will be effective, because the distances 'a' and 'b' in the equations for F1 and F2 are measured at the locations where implants connect to the prosthesis, not the locations where the implants' apices reside in bone. So, for example in Case C (Fig 7c) the tilting of implant no. 2 produces the same downward forces on the two implants as in the upright, 20 mm-spaced implants in Fig 7b, i.e. F1 = +100 N and F2 = -200 N (with the + sign again indicating a tensile force and the – sign indicating a compressive force).

It is also important to realise that although there are identical vertical forces on the implants at the locations where they connect to the prosthesis, there is a major difference between the two situations in Figs 7b and 7c: while calculations predict that the same force F2 acts in a vertically-downward direction at the top of implant no. 2 in Figs 7b and 7c, implant no. 2 is tilted in Fig 7c but upright in Fig 7b. This last fact begs the obvious question: In Figs 7b and 7c, doesn't the tilting of an implant make a major difference in terms of the stresses and strains in the prosthesis, implant and bone? The answer is: "Yes, if the same vertically directed force is acting on the upright and tilted implants, but no if the same force does not act on the upright and tilted implants".

The foregoing can be illustrated with a convenient series of examples in Fig 8 (developed using FE simulations). These simulations illustrate in a simple example that, yes, all things being equal, tilting will cause larger stress and strain in the surrounding bone, and on that basis, tilting might appear detrimental. However, the point about tilting implants is that, in a sense, we are not considering a situation of 'all things being equal'. If we do the tilting effectively, it is possible to decrease the vertical force on the tilted (and other) implants, e.g. compare the forces on the implants in Figs 7a and 7c in the example just discussed. So for instance in Fig 8, when 50 N acts on a tilted implant instead of, say 150 N, then there are smaller tensile and compressive strains in the interfacial bone compared to when 150 N of vertical force acts on either the upright or tilted implant.

The aforementioned is another example of the need to define 'optimality', not just in terms of the

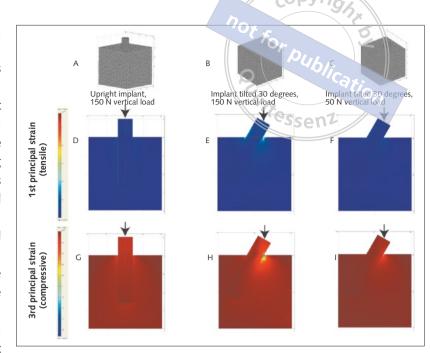


Fig 8 Results from FE simulations of simplified upright (A, D, G) and tilted (B, E, H) cylindrical implants integrated in bone and loaded by the same 150 N vertical force; comparing these two situations, the interfacial principal strains in the bone are larger for the tilted implant. Alternatively if the tilted implant is loaded with a smaller vertical force of 50 N (C, F, I), the interfacial principal strains are not very different from what they were in the case of the upright implant loaded with 150 N. In the images D, E, and F, light blue indicates a higher tensile strain, while in images G, H and I, light-red to greenish-yellow indicates higher compressive strain. (Reproduced with permission from: Brunski JB. "Biomechanical aspects of tilted regular and zygoma implants." Chapter 4, pp. 24–45 in Zygomatic Implants: The Anatomy Guided Approach (Ed. C. Aparicio), Quintessence, 2012²²)

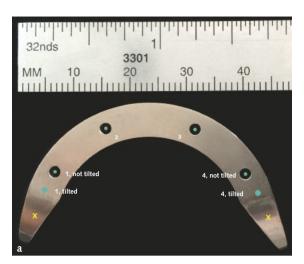
number of implants but also in terms of the stress-strain criteria noted in connection with Step 3 of our treatment planning paradigm (Fig 1). That is, tilting can be safe and effective as long as the overall design of the treatment keeps the implant loading – and the stress-strain magnitudes in the bone – in a permissible range.

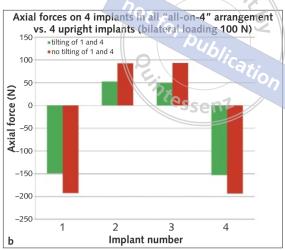
Example 6: What is the rationale for an 'all-on-4' approach in a full arch?

It is only a small step from the analysis in Example 5 to the biomechanical rationale of the 'all-on-4' approach, which is that tilting can be a means to effectively increase the inter-implant spacing and decrease the length of cantilevers. This in turn can significantly decrease the vertical forces on the implants as well as the interfacial stresses and strains. This idea is now illustrated with some additional examples of full-arch patient rehabilitations.

For instance, Fig 9a considers two treatment options. The first option shows a bar (the under-

Fig 9 (a) Image of the undersurface of a titanium prosthetic bar showing the locations of 4 upright implants vs. 4 implants, in which the two distal-most implants are tilted. (b) Bar graph showing the vertical forces on the upright vs. tilted implants as computed using the Skalak model.





surface of a Brånemark Novum bar, used in earlier examples) supported by 4 upright implants. The second option shows the same bar supported by the same two anterior upright implants (implants 2 and 3) but now two distally-tilted implants (1 and 4), where the tops of the distal implants 1 and 4 are tilted distally by about 4 mm. (Assuming an abutment height of about 5 mm, this corresponds to a tilting angle of about 38 degrees). The example calculations of implant loading are done with the Skalak model assuming bilateral downward loading of the bar by 100 N at the distal Xs.

The bar graph in Fig 9b shows that in the no-tilting option, the vertical loads on the implants approach -200 N (compression) on distal implants 1 and 4, and about +100 N (tension) on anterior implants 2 and 3. Alternatively, for an 'all-on-4' approach with tilting, this has the effect of decreasing the vertical forces on not only the distal implants 1 and 4, so they are now about -150 N (compression) – but also on the anterior implants 2 and 3 – to about +50 N. Therefore, tilting has substantially lowered the forces on all the implants relative to the non-tilting option, e.g. about a 50% decrease for the anterior implants and a 25% decrease for the distal implants.

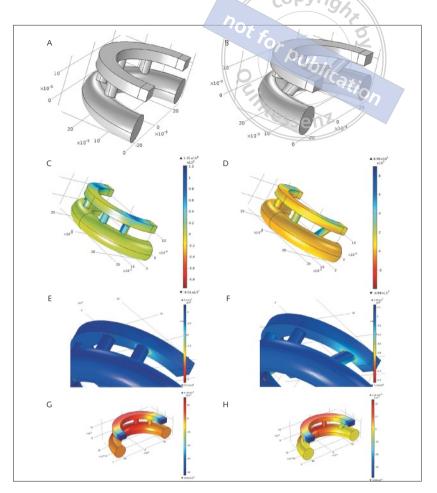
Taking this result a step farther, and considering it in terms of the stresses and strains in the interfacial bone (as suggested, again, in Step 3 of our treatment planning algorithm in Fig 1), note in the above example that the tilted implants are not as heavily loaded as their upright counterparts. Now while it is true that a tilted implant exposed to the same vertical loading as an upright implant would typically have

larger (possibly less-than-optimal) interfacial stresses and strains, the point is that the tilted implants in the 'all-on-4' structure have less vertical loading than the upright implants located more mesially in our example. Hence, the lower forces diminish concerns about the stress-strain levels in the interfacial bone, the titanium of the tilted implants, and the material of the prosthesis.

To provide a more detailed stress analysis of specific situations involving upright vs. 'all-on-4' treatments, the following examples discuss results from 3-D FE stress analyses of the same prosthesis supported by a) 4 upright implants, or b) 4 identical implants arranged in an 'all-on-4' configuration, in which the two distal implants are tilted (Figs 10a and 10b). The 'upright' and 'all-on-4' options in the FE models are based on the same U-shaped, commercial purity titanium framework (6 mm wide, 4 mm thick) and the same simplified semi-circular idealisation of a mandible of solid bone. In all models, commercial-purity titanium implants (4×13 mm cylinders) are assumed to be anchored (bonded) in bone via osseointegration. The distal end of each mandible is constrained from moving in all of the FE models. The distal end of each cantilever of the prosthesis is loaded by a downward force of 100 N. The distal two implants in the 'upright' and 'all-on-4' options have their apices in exactly the same locations; however, in the 'all-on-4' configuration, the top of each distal implant is tilted 30 degrees distally and 10 degrees buccally. The elastic properties of the bone and pure titanium are E = 20 GPa, nu = 0.33and E = 105 GPa, nu = 0.33, respectively. Also, as a separate exercise, Skalak calculations were used to compute the vertical forces on the upright and 'allon-4' implants in the two options.

The results from the FE analyses (using Comsol 4.4) of the upright vs. 'all-on-4' options – as well as the results from the Skalak calculations – can be summarised by focusing on 10 selected evaluation criteria that serve as convenient metrics by which to compare the two prosthetic options. As explained in more detail shortly, these 10 criteria include 4 factors characterising stress levels in the prosthesis and implants; 4 factors characterising strain magnitudes in interfacial bone; 1 criterion describing the maximum vertical force on any one implant; and 1 criterion describing the maximum downward deflection of the distal ends of the cantilever sections of the U-shaped prosthetic bar.

The results show that application of the bilateral 100 N loading at the end of the cantilevers elastically bends the prosthesis in each option, creating tensile stresses along the mesiodistal length of each prosthesis; however, these tensile bending stresses were about twice as large in the case of the upright implant configuration, e.g. 79 vs. 44 MPa, respectively (Figs 10c and 10d). Likewise, larger tensile bending stresses occurred on the anterior aspects of the abutment regions of all 4 implants in the upright option compared to implants in the 'all-on-4' option (Figs 10c and 10d). There were also larger compressive stresses in the upright vs. 'all-on-4' option at the locations where the abutment regions of the two distal implants joined the undersurface of the prosthesis (Figs 10e and 10f). Finally, there was a larger downward bending deflection of the cantilever regions of the prosthesis when supported by the upright vs. the 'all-on-4' implants, i.e. 85 vs. 38 microns, respectively; no doubt this result was because of the longer length of the cantilever regions in the upright implant configuration (Figs 10g and 10h). In terms of stress magnitudes that could cause concern about fatigue fracture in titanium, the 107 endurance limit for commercial purity titanium is about 300 MPa depending on the exact grade and degree of cold-work of the titanium²⁴. Therefore, none of the stress levels developing in the prostheses or implants in the current FE analyses would cause undue concern, although stresses were indeed higher in the upright-implant situation. If loads greater than 100 N were used in the



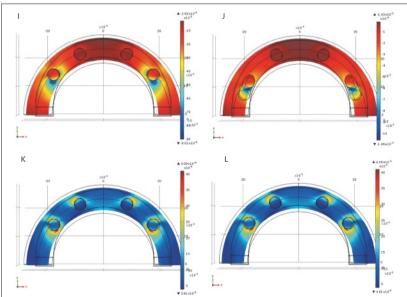


Fig 10 Results from three-dimensional FE analyses of 4 upright implants supporting a bilaterally-loaded bar vs. 'all-on-4' implants supporting the same loaded bar. (a and b) Geometry of the situations. (c and d) 1st principal (tensile) stresses in the upright vs. 'all-on-4' cases. (e and f) 3rd principal (compressive) stresses in the two cases; note junction between abutment and undersurface of bar. (g and h) Vertical (occluso-apical) displacements of the bars in each case; note displacement at the ends of the bars. (I and j) 3rd principal (compressive) strains in bone in a plane of section taken approximately 1 mm below the crest of the mandible. (k and l) 1st principal (tensile) strains in bone in the same section plane as in (i) and (j).

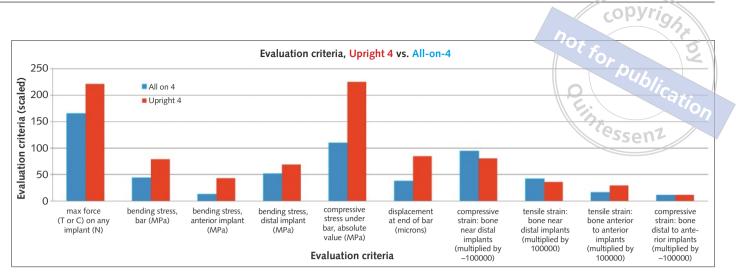


Fig 11 Bar graph collecting 10 criteria for comparing biomechanical conditions found in the 'upright 4' vs. 'all-on-4' simulations discussed in Fig 10 (see text for discussion).

FE simulations, stresses would increase proportionally in both models, so that stresses in the upright-implant option would reach the fatigue endurance limit before the 'all-on-4' option.

Concerning compressive strains in interfacial bone in upright vs. 'all-on-4' options (Figs 10i and 10j, the strain magnitude in regions of crestal bone located distal to the most distal implants was only slightly larger for the 'all-on-4' configuration compared with the upright option, i.e. -0.0945% vs. -0.0805%, respectively, and there was virtually no difference in the compressive strain magnitude at the distal crestal locations around the anterior implants of both the upright and 'all-on-4' configurations. For the tensile strain magnitudes on the distal aspects of the two distal implants in each configuration (Figs 10k and 10l), the strains were somewhat larger for the 'allon-4' option, i.e. 0.0421% vs. 0.0358% respectively. Also, the tensile strains at crestal locations anterior to the anterior implants were larger for the upright as opposed to the 'all-on-4' option, i.e. 0.0293% vs. 0.0164%, respectively (Figs 10k and 10l). Notably, these magnitudes of strain in bone - peaking at about -0.09% in compression and 0.03% in tension – are below a danger limit of 0.4%, which has been cited as an approximate threshold for fatigue failure in compact bone after about 1000 cycles in tension or 10000 in compression²⁵. Therefore, as in the discussion of stresses, none of the strain levels in the bone would cause undue concern in either option - at least for 100 N bilateral loading. (Note that these simplified FE analyses do not account for threads on the implants,

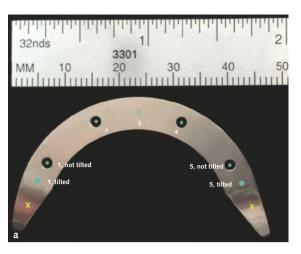
which are known to concentrate stress and strain in the bone.) If loads greater than 100 N were used in the FE simulations, strains would increase proportionally in both FE models, and could eventually reach magnitudes that could cause concern.

One last metric of comparison between the upright and 'all-on-4' option is the maximum force occurring on any one implant in the distribution; this maximum force was larger in the upright option than in the 'all-on-4' option, i.e. 221 vs. 165 N.

In reviewing the 10 criteria just discussed, there was a 'tie' in one criterion (compressive strain distal to the anterior implants), but in 8 of the remaining 9 criteria, the 'all-on-4' option had smaller stress magnitudes in the bar and implants, as well as smaller strain magnitudes in the bone (Fig 11). Hence, judging from these biomechanical metrics, the 'all-on-4' configuration ranked better than the 'upright 4 implant option', and could in that sense be considered optimal. These results are also consistent with conclusions from an excellent comparative analysis 18 of 3-, 4- and 5-implant options including an 'all-on-4' option; these authors concluded that: "...the 'All-on-Four' configuration...resulted in a favorable reduction of stresses in the bone, framework, and implants."

Example 7: Is there any benefit in using 'all-on-5' instead of 'all-on-4'?

An answer to this question is evident from Fig 12a, which shows two implant arrangements, the first having the same 'all-on-4' arrangement studied in



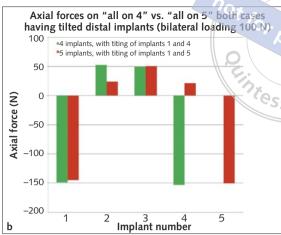


Fig 12 (a) image of the undersurface of a titanium prosthetic bar showing the locations of 5 upright implants vs. 5 implants in which the two distal-most implants are tilted. (b) Bar graph showing the vertical forces on the upright vs. tilted implants as computed using the Skalak model.

Example 6 (with the two distal implants 1 and 4 tilted) and the second having 5 implants with one 'extra' implant in the middle anterior position – implant 3 – and tilted implants in the 1 and 5 positions that are the same as for implants 1 and 4 in the 'all-on-4' option.

Results from the Skalak analysis of these two situations (Fig 12b) shows that there is little difference between the two cases, i.e. the vertical compressive forces on the distal-most implants are virtually the same in the 4- and 5-implant cases, and so are the tensile loads on the more anterior implants in the two cases. As seen previously, when trying to define the 'optimal' number of implants to use in supporting a full arch prosthesis, biomechanical analyses can help, and in this instance 5 implants in an 'all-on-5' arrangement would be over-designed and inefficient compared to the 'all-on-4'.

Example 8: How accurate are the predictive biomechanical analyses used in this paper? Part 1, in vitro tests

The term accuracy means "...closeness of a measured or computed value to its true value", according to Sokal and Rohlf²⁶. Here it is useful to ask whether the vertical forces on implants as predicted by the methods employed in this paper – namely the Skalak model and FE models – are close to the 'true' or actual forces on the implants.

One assessment of accuracy of the Skalak modelling comes from the test results shown in Fig 13⁹.

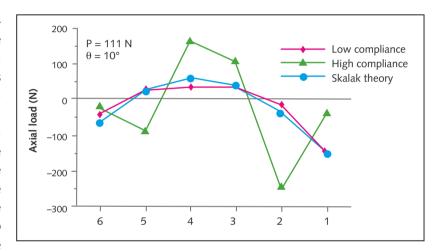
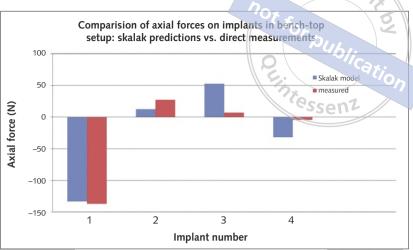


Fig 13 Results from tests of a system consisting of a loaded rigid steel plate ('prosthesis') supported by load-sensing bolts ('implants') whose axial stiffness values could be adjusted. The plate is loaded by 111 N at a cantilever position distal to implant no. 1. Results from Skalak calculations are not shown for the 'High compliance' case; see reference 9 for this detail.

In this testing, a laboratory setup was devised so that the experimental conditions were as close as practical to the assumptions inherent in the Skalak model, i.e. spring-like bolts connecting infinitely rigid plates. To that end the experimental model consisted of strain-gauged load-sensing steel bolts joining two rigid steel plates. (The bolts were analogous to implants while the plates were analogous to the jaw and the prosthesis. The strain-gauged bolts were also known to provide accurate experimental measurements of the axial loading.) The top plate was loaded with vertical forces in different locations, while the vertical forces were then measured using the strain-gauged bolts. The aim of the test was to compare the Skalak model predictions to accurate







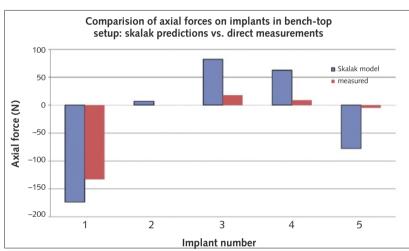


Fig 14 Comparison of experimentally-measured vs. predicted vertical forces on 4 (a) or 5 (b) implants supporting titanium bars loaded at the location of the 'X' in each figure. Predicted forces came from the Skalak model (Bench-top loading system designed and built by Mr Steve Hurson, Nobel Biocare USA).

measurements of the axial loads on each bolt (implant). Fig 13 illustrates that the agreement between the Skalak predictions and measurements was excellent – both when all bolts (implants) had the same axial stiffness and also when the stiffness values of two of the bolts (implants) were decreased. So in this experimental system, it was evident that the Skalak model had reasonably high accuracy in predicting axial loading on multiple bolts (implants) supporting a rigid plate.

In a similar manner, experiments were then conducted to make comparisons of Skalak model predictions vs. measurements of implant loading using a bench-top system designed by Mr Steve Hurson of Nobel Biocare in Yorba Linda, CA, USA (Fig 14). This system consisted of titanium prostheses supported by either 4 or 5 implants connected to 4 or

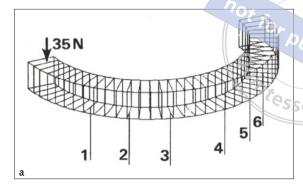
5 separate force transducers mounted beneath the implants; the force transducers were able to measure the vertical forces on each implant when the prosthesis was loaded at any point using a loading device (not shown). For analysis of the 4 and 5 implant cases with the Skalak model, we measured the (x, y) spatial coordinates of implant locations and points on the prostheses where vertically-downward test loads were applied near the end of the left-hand side cantilever (red X in Fig 14).

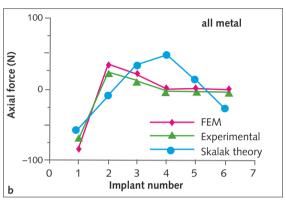
The force analysis (Fig 14) allowed comparisons of the measured vertical (axial) force on each implant (red bars) with the forces predicted on each implant via the Skalak model (blue bars). In both the 4- and 5-implant cases, the Skalak model reasonably accurately predicted the vertical force on the implant nearest to the applied loading (implant 1),

both in sign (compressive) and in magnitude. For the vertical forces on the rest of the implants, the Skalak model was reasonably accurate in predicting the signs of the forces – including the tensile forces on the anterior implants (2, 3 and 4 in the 5-implant case, plus 2 and 3 in the 4-implant case) as well as the compressive forces (on implant 5 in the 5-implant case and implant 4 in the 4-implant case) – but was not accurate in predicting the true values of the vertical forces on these other implants.

In these bench-top laboratory experiments, the likely reason for the imperfect agreement between the Skalak modelling and the measured forces has to do with the deformability of the prosthesis¹³. That is, the underlying theory of the Skalak model assumes that the prosthesis and jaw are idealised, rigid structures that do not deform under loading, but of course it is known that real materials and structures, including typical full-arch dental prostheses, are deformable, e.g. prostheses do deform even if they are made of metallic or acrylic materials that appear to be 'rigid' to the naked eye. Experiments and FE modelling of metal-backed and all-acrylic prostheses (Fig 15) confirm that as the prosthesis becomes more deformable (less rigid), the implants nearest the loading point on the prosthesis take a larger share of the applied load - which, in turn, causes less sharing of loads among all the implants in the distribution. For example, in Fig 15, when the prosthesis is loaded at the cantilever near implant 1, the Skalak model (which assumes an infinitely-rigid prosthesis) under-predicts the forces on implants 1 and 2 and over-predicts the force magnitudes on implants 3, 4, 5, and 6. However, a more accurate FE simulation of the implants and prostheses – which takes into account prosthesis deformability – shows closer agreement between predicted and measured forces.

The role of deformability of the prosthesis in load-sharing among implants was also evident in the results of FE models of 4 vs. 6 implants supporting a titanium prosthesis 16,17. These workers developed a FE model in which 4 or 6 implants were evenly spaced along the 47 mm of arc between the mental foramina. The implants were attached to a titanium prosthesis loaded with a 100 N vertically-downward force plus a 10 N lingually-directed horizontal force that were both applied along the cantilever region





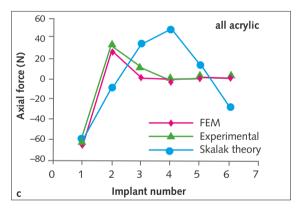
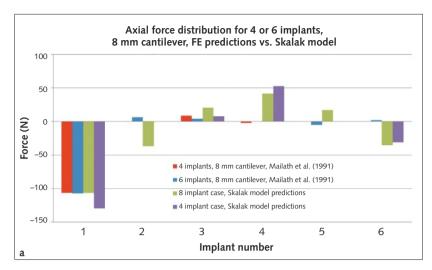


Fig 15 Comparison of experimentally-measured vs. predicted vertical forces on 6 implants supporting an all-acrylic or all-metal U-shaped prosthesis. Here forces were measured using strain-gauged abutments, while forces were predicted using FE modelling and the Skalak model, as indicated in the lower two plots. Clearly the structural rigidity of the prosthesis, which depends on modulus and cross-sectional dimensions, affected load-sharing among the 6 implants. (For more details see Elias and Brunski, 1991¹³.)

– which was 8 mm or 16 mm long – on the left side of the mandible. Data on the axial forces on each implant in the 4 vs. 6 arrangement – for both 8 mm vs. 16 mm cantilever lengths – are shown in Figs 16a and 16b (which are based on the present author's plotting of tabulated data in the 1991 paper of Mailath et al¹⁶). Also plotted in Figs 16a and 16b are results from Skalak modelling of the same cases. Two interesting findings from these data are: a) the 4 and 6 implant arrangements over the same arc show virtually the same axial forces on the 4 or 6 implants – as has already been discussed in earlier examples in this article – and this is true for both the FE and Skalak modelling; b) the values of the axial loads on the implants as predicted by the FE modelling



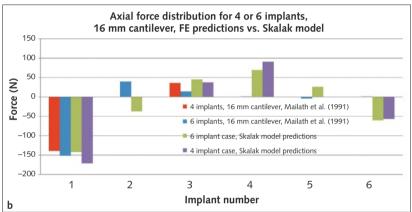


Fig 16 Vertical forces on 4 or 6 implants supporting a deformable prosthesis with a 8 mm (a) vs. 16 mm (b) cantilever, as predicted using FE methods¹⁶ and the Skalak model. The same trend as seen in Fig 15 is seen here: a more deformable prosthesis does not allow as much load sharing among implants as would be predicted by the Skalak model, which assumes an infinitely rigid prosthesis.

do not agree, quantitatively, with predictions from the Skalak modelling, although there is reasonable qualitative agreement between the FE and Skalak modelling. On the last point, the FE model of Mailath et al¹⁶ accounts for deformability of the prosthesis, whereas the Skalak model does not – the same finding that was discussed in the preceding paragraph.

Example 9: How accurate are the predictive biomechanical analyses used in this paper? Part 2, in vivo tests

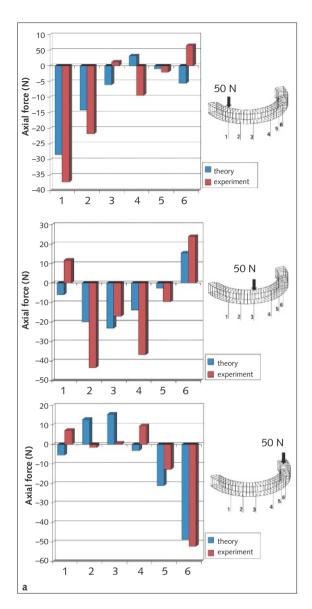
To assess the accuracy of force predictions in actual *in vivo* studies with implants, one approach is to compare the accurately-measured vertical forces on oral implants in humans with predictions of the vertical forces on implants as computed using the Skalak

model. To this end, data were available from two male patients (based on data gathered using loadsensing abutments²⁷. Each patient had 6 implants supporting a full-arch prosthesis. In the two patients to be discussed below, Case 'H' involved implantsupported prostheses in both jaws, with force data taken only from the mandible, while Case 'C' involved maxillary implants opposed by a natural dentition. Special metal prostheses were used in the patients when measuring the forces on the implants, because these prostheses had special markings allowing the patient to bite down on a special bite fork placed at specific, known locations around the arc of the prosthesis. Before the metal prosthesis was placed, the original Brånemark-style abutments were removed and replaced by special load-sensing (strain-gauged) abutments of 5.5 mm height, which also fit passively with the denture. After the denture was installed over the load-sensing abutments, the patient was asked to bite on a bite fork to measure the biting force exerted at specific locations on the prosthesis, e.g. two distal locations and one anterior location, while the data on the vertical forces on all six implants was collected following the methods outlined in Duyck et al²⁷.

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Meanwhile, to predict the vertical forces on the same set of implants at each loading event, the (x, y) coordinates of each abutment as well as the locations of the applied biting force (50 N) on the prosthesis were input into the Skalak model²⁸. In the results presented here, data are discussed for the case of a 50 N bite force exerted at three locations on the prosthesis.

Results from Cases H and C (Fig 17) reveal trends resembling those seen in the in vitro tests discussed previously in Example 8. That is, the Skalak model under-estimated the vertical forces on the implants for each of the three loading points with the 50 N force on the prosthesis. For instance, in vivo, when the 50 N applied load acted on the prosthesis near implant 1, implants 1 and 2 sustained more vertical force than predicted by the Skalak model. Likewise, the Skalak model under-predicted the loading in vivo for the anterior implants when the biting force acted on the prosthesis in the anterior region. The reason for this discrepancy is most likely the same as in the in vitro trials of Example 8, i.e. the actual deformability of the prosthesis vs. the assumed infinite rigidity of the prosthesis in the Skalak model. Evidently,



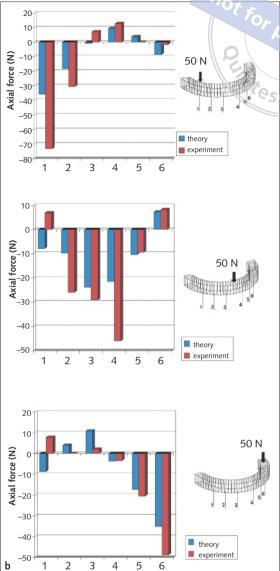


Fig 17 Comparison of measured vs. predicted (Skalak model) vertical forces on implants in vivo, based on data taken from work of Duyck et al. 2000²⁷. Cases 'C' (a) and 'H' (b) are results from two different patients.

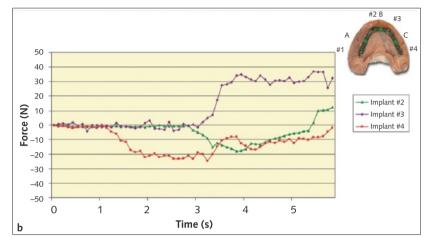
the Skalak model's numerical predictions are not of high accuracy when compared to actual *in vivo* data, although if one considers the model's qualitative ability to predict trends in implant loading, then the overall accuracy is sufficient to allow this model to serve as an approximate guideline in treatment planning.

Besides prosthesis rigidity, two other factors can significantly influence the accuracy of predictions with the Skalak model. The first factor relates to bone-implant stiffness, which is assumed to be the same for all implants in the simplest version of the Skalak model, but which can be varied in the more sophisticated version of the Skalak model⁹. For example, if one had data on the stiffness of each implant in the human trials performed by Duyck et al²⁷ (Fig 17), then it would have been possible to

incorporate that data in the Skalak model to see if there would have been better agreement between experimental and predicted values of forces.

The second source of mismatch between the measured forces and forces predicted by the Skalak model is deformability of the mandible^{29,30}. It is known from previous work in human patients³¹ that when a patient simply opens the mouth wide while wearing a metal prosthesis attached to loadsensing abutments (Fig 18a), forces and bending moments develop on the abutments (Figs 18b and 18c). In this instance, the magnitudes of the forces and moments are at the low end of the range of typical forces and moments measured during chewing or biting, e.g. a few N and perhaps 10 N-cm, respectively⁶. Notably, such loadings occur simply as





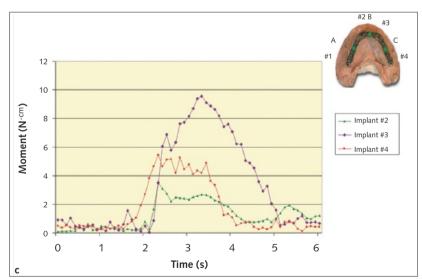


Fig 18 Example of *in vivo* forces and moments on implant abutments supporting a metal prosthesis in a patient who is asked to open his jaw at about the 1-s mark in the plots; vertical force components occur (tensile and compressive, depending on the implant) as well as bending moments^{31,34}.

a consequence of jaw opening, without any biting or chewing directly on the prosthesis. The explanation for this finding is likely due to human mandibular deformability plus the metal prosthesis rather rigidly attached to the mandible via the implants. It is likely that the intraoral situation becomes analogous to a standard bone plate screwed to bone to prevent or limit motion at a healing fracture site. In other words, when a bone plate is attached to a bone to stabilise a fracture site, the plate carries some of the loading that occurs on the bone; this is accomplished by making sure that the structural stiffness of the plate (and its firm attachment to the bone using screws) produces a stiff system that can support greater or lesser degrees of the loading of the bone, depending on the relative stiffness of the healing fracture vs. plate^{32,33}. However, when using the Skalak model to predict implant loading, there is no allowance in the model for jaw flexion; the model assumes that both the prosthesis and jaw are infinitely rigid (undeformable). Therefore, the Skalak model will not predict implant loading from simply opening the jaw - a likely source of the numerical disagreement between the Skalak model predictions and actual measurements taken in the study by Duyck et al²⁷.

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Conclusions

The optimal number of implants to support a full arch prosthesis is predicated on a biomechanical definition of this term; 'optimal' must be broad enough to go beyond just describing the number of implants, and also needs to consider where the implants are placed in the jaw, what sort of bone they are anchored in, what magnitudes of stress and strain develop in the bone, implants and prosthesis; and the relationship of the stresses and strains to thresholds for damage to bone and prosthetic parts. In general, a complete biomechanical treatment-planning regimen should include attention to all of these subjects.

In order to integrate more biomechanical approaches with clinical treatment planning, there are existing aids that can help a clinician predict implant loading. Examples of methods include the Skalak model as well as more involved finite element modelling. While the Skalak model is not always perfectly accurate when used to predict *in vivo* loadings, it can nevertheless provide a reasonable initial analysis of the biomechanical circumstances surrounding a proposed treatment. Increasingly, user-friendly finite element methods can also assist treatment planning, although using such software does require an engineering background in order to use it effectively.

Acknowledgements

The author would like to thank Dr Daniel van Steenberghe for help with editing; Dr Kenji W. Higuchi for many helpful discussions about the clinical use of treatment-planning software in connection with the 5 implant case in one of his patients (Example 4); Dr Joke Duyck for sharing data on *in vivo* loading of implants, as discussed in Example 9; and Drs Thomas Balshi and Glenn Wolfinger for the opportunity to make *in vivo* measurements of implant loading in some of their patients (Example 9).

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Optimal number of oral implants for fixed reconstructions: A review of the literature

Key words dental implants, edentulous jaw, fixed prosthesis

Background and aim: So far there is little evidence from randomised clinical trials (RCT) or systematic reviews on the preferred or best number of implants to be used for the support of a fixed prosthesis in the edentulous maxilla or mandible, and no consensus has been reached. Therefore, we reviewed articles published in the past 30 years that reported on treatment outcomes for implant-supported fixed prostheses, including survival of implants and survival of prostheses after a minimum observation period of 1 year.

Material and methods: MEDLINE and EMBASE were searched to identify eligible studies. Short and long-term clinical studies were included with prospective and retrospective study designs to see if relevant information could be obtained on the number of implants related to the prosthetic technique. Articles reporting on implant placement combined with advanced surgical techniques such as sinus floor elevation (SFE) or extensive grafting were excluded. Two reviewers extracted the data independently. Results: A primary search was broken down to 222 articles. Out of these, 29 studies comprising 26 datasets fulfilled the inclusion criteria. From all studies, the number of planned and placed implants was available. With two exceptions, no RCTs were found, and these two studies did not compare different numbers of implants per prosthesis. Eight studies were retrospective; all the others were prospective. Fourteen studies calculated cumulative survival rates for 5 and more years. From these data, the average survival rate was between 90% and 100%. The analysis of the selected articles revealed a clear tendency to plan 4 to 6 implants per prosthesis. For supporting a cross-arch fixed prosthesis in the maxilla, the variation is slightly greater.

Conclusions: In spite of a dispersion of results, similar outcomes are reported with regard to survival and number of implants per jaw. Since the 1990s, it was proven that there is no need to install as many implants as possible in the available jawbone. The overwhelming majority of articles dealing with standard surgical procedures to rehabilitate edentulous jaws uses 4 to 6 implants.

Conflict of interest statement: The authors declare that they have no conflict of interest.

■ Introduction

Implants have changed prosthodontics more than any other innovation. Brånemark and co-workers' seminal work had one primary goal: to restore the edentulous jaw by means of fixed prostheses supported by 'titanium fixtures'. This aimed at 'restitutio ad integrum', while replacement of teeth with a removable prosthesis in the edentulous jaw is a 'restitutio ad similem'. While worldwide still many patients do not benefit from oral implants and remain with complete dentures (if any), implant retained and supported prostheses

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Correspondence to: Regina Mericske-Stern, Prof Dr med dent Department of Prosthodontics, University of Bern, Tel: ++41 31 632 25 39 Email: regina.mericske@zmk. unibe.ch became a well accepted treatment modality for edentulism since the 1980s. Complaints about instability of complete dentures, impaired function and discomfort are associated with progressive atrophy of the jawbone and changes in the tissue structures after becoming completely edentulous¹.

Developments in prosthetic concepts and technology occurred in the 1980s². Since then a rapid and broad evolution in implant-supported rehabilitation has occurred with an exponential increase in publications.

Clinicians tend to select the prosthetic type and design based on the number of implants that can be placed, meaning that more implants are needed for fixed than for removable prostheses. Such planning is prevalently bone driven. It appears that the better the bone is maintained, the more implants can be placed and the less replacement of tissues is necessary.

Yet even today, the scientific evidence for the required/optimal number of implants is weak. The literature often deals with implant survival rates as the main focus, e.g. in relation to different loading protocols or comparing between fixed and removable prostheses. Suggestions for the optimal number of implants and the related prosthetic designs are rather to be found in textbooks or reviews on treatment methods, technical aspects and biomechanical considerations²⁻⁴.

While restoring the mandible often offers a broad range of options – fixed prostheses with different designs, removable prostheses with different attachment and retention systems – the maxilla is more restrictive. It requires more planning steps and offers even less options. The mandibular overdenture on two implants is well documented, is even suggested to be the gold standard of care and is also the outcome of consensus conferences^{2,6,7}. Even one single implant may stabilise a mandibular overdenture, while up to 10 implants have been used for a fixed prosthesis in the edentulous maxilla⁸. Anecdotal patient reports with the replacement of each tooth by one implant have even been published.

The placement of multiple implants requires good bone conditions or comprises elective surgical procedures in patients with advanced jawbone resorption. This can require invasive surgery like sinus floor elevation (SFE) and grafting procedures or guided bone regeneration (GBR). In the

posterior mandibular jaw nerve repositioning and augmentation are suggested, but this is invasive and it is preferred to use the interforantial region. Procedures like sinus floor augmentation are well documented^{9,10} but eventually accompanied by biological complications and risks. Moreover, when restoring the maxilla, the following criteria play a predominant role and must be considered: aesthetic appearance; facial morphology; the replacement of lost hard and soft tissues.

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As a consequence, when discussing the number of implants to be placed in the edentulous jaw, various, sometimes controversial aspects must be outlined:

- different soft and hard tissue conditions with regard to the edentulous mandible vs. edentulous maxilla
- option of fixed or removable prosthesis
- distribution of implants, anatomic risks and surgical aspects
- aesthetics and facial appearance
- choice of material and design of prostheses
- type of retention and fixation of the prostheses
- type and timing of occlusal loading.

For the rehabilitation of the edentulous jaw, in particular the maxilla, decision-making for the prosthesis design and the choice between fixed and removable prostheses, morphological and functional criteria must be considered. They often play a greater role than the number of implants^{3,11-13}.

Prosthetic options related to implants are mostly not evidence-based but a result of (recent) clinical experience, anatomical conditions, patients' preferences and costs.

The aim of the present review was to identify reliable data on the fixed dental prostheses on oral implants in the edentulous jaw. The focus was placed on the number of implants that were used to support the prostheses.

Material and methods

This overview is based on an electronic search (Pubmed, Embase) of publications in the English language from the past 30 years. The search terms were: edentulous jaw; edentulous maxilla; edentulous mandi-

ble; dental/oral implants; number of implants; fixed prostheses; cross-arch; All-on-4; tilted implants. These terms were used in various combinations. Titles and abstracts were screened and for relevant studies a full-text analysis was performed. Besides the Medline search, a manual search was conducted in journals easily accessible within Bern University.

The search included the following journals: Journal of Prosthetic Dentistry; International Journal of Prosthodontics; Journal of Implantology; The International Journal of Oral and Maxillofacial Implants; Clinical Oral Implants Research; Implant Dentistry; European Journal of Oral Implantology; Clinical Implant Dentistry and Related Research; International Journal of Oral and Maxillofacial Surgery; Journal of Periodontology; and The International Journal of Periodontics and Restorative Dentistry. The search was limited to clinical studies on patients who were edentulous in one or both jaws.

Inclusion criteria

Short and long-term clinical studies were included with prospective and retrospective study designs and even case series, if relevant information could be obtained on the number of implants related to the prosthetic technique.

- The implant system should still be on the market (2013).
- The studies must be published in peer-reviewed journals.
- The studies on completely edentulous patients must report data for the maxilla and mandible separately.
- From the study data, the number of implants placed per edentulous jaw is reported or can be calculated.
- The study should include a minimum of 10 patients (preferably more) rehabilitated with a full fixed prosthesis in one or both jaws supported by implants.
- The follow-up time is ≥ 3.5 years. However, when particularly relevant, some 1-year reports were also considered.
- The prosthesis is (provisionally) cemented or screw retained, but only detachable by a dentist.
- The studies report on implant survival rates, or survival of the prosthesis.

Exclusion criteria:

- The main study goal was advanced surgical techniques such as SFE, extensive grafting, etc.
- The number of patients and implants was not clearly defined.
- The study material reported on patients but the endintent of the study was to demonstrate technical procedures.
- The study reported on patients with interfering systemic/local factors: trauma; tumour resection; radiotherapy; chemotherapy; Sjögren syndrome; Parkinsons disease; cleft palate; and other specific rare diseases.

Data extraction

The two reviewers extracted the data independently. If differences in the interpretation existed, agreement was sought by joint evaluation.

The main objective of the present data collection was to identify the number of implants used to support the fixed prostheses. Therefore the studies reported on various endpoints: survival of implants; survival of prostheses; crestal bone level; biological and technical complications; patient satisfaction; and quality of life were collected. If the implant sites (anterior/posterior) were not specified, it did not lead to exclusion of the studies. Such studies were also included if they accounted for the number of implants.

A few more recent studies that presented specific topics such as tilted implants, immediate loading, implants in extraction sockets or zygoma implants were also included when information about the number of implants could be obtained. This allowed for comparisons with the 'standard' procedures and for general considerations regarding the number of implants to be used.

From the identified papers, the following variables were used for the analysis:

- number of patients
- number of edentulous jaws
- number of implants
- number of implants per prosthesis
- · implant diameter
- · implant length
- implant location
- survival rate of implants
- number of prostheses

- survival rate of prostheses
- prosthetic complications
- segmentation of prosthesis
- · cantilever (length)
- study type
- study duration
- smoking.

Statistical analysis

Since this is a critical but not a systematic review, a meta-analysis could not be performed. The calculation of implant survival and of drop-outs, along with the criteria for survival and success often varied. The goal of this extensive review was to relate the number of implants used to support the fixed prostheses and their outcome, and to formulate conclusions and suggestions regarding the number of implants. Thus, only descriptive statistics are reported.

Results

Description of the studies

The last electronic search for the screening process was performed in December 2013. The first hit from a MEDLINE search delivered over 4830 titles. A narrower search led to 1021, which was broken down to 222 articles, including some obtained by hand search. After the screening of these titles and abstracts for full analysis, 36 studies were included. Seven of these were excluded for final data extraction since they reported on the same patient groups at various time points or provided insufficient numbers. Thus the final analysis was based on 29 papers (see Table 1: 14-42). These publications cover a period of 30 years from 1981 onwards.

All but three articles¹⁴⁻¹⁶ included the Brånemark system; respectively the Nobel Biocare implant system. Among the selected 29 publications, three¹⁷⁻¹⁹ and two papers respectively^{20,21} each included the same patient groups. Thus, the basic pool on patients, implants and prostheses covered in the present review is provided by 26 datasets.

The study endpoint of these publications was not the number of implants. The outcomes did not focus on the optimal number of implants to support the prostheses. Only one study compared 4 vs. 6 implants to support the prostheses in the edentulous jaw²². The latter paper analysed patients treated by Brånemark himself in the early days. Depending on the available bone volume in between the mental foramina and in between the maxillary sinuses, either 4 or 6 implants were placed. All patients had a 10-year follow-up. There was no statistical difference for the implant survival rates whether 4 or 6 implants were placed.

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With two exceptions, no randomised clinical trials were found, and these two studies did not compare different numbers of implants supporting the prosthesis^{23,24}. Five multi-centre (MC) studies^{15,25-28} were found.

Eight studies were retrospective, while eighteen were prospective. Three of them had only a 1 to 2 years observation time²⁹⁻³¹. Four of the 18 prospective studies and one retrospective study claimed follow-up times up to 10, 15 or 20 years. However the average observation time was much less^{22,26,32-34}. Nevertheless, 14 studies calculated cumulative survival rates for 5 and more years (with censored data) and provided documentation on withdrawn patients and implants respectively. Only 216,35 out of the 26 datasets reported on less than 40 study patients, while 19 had >50 or >100 up to >800 patients included. Thirteen studies reported on both jaws, while 6 and 7 studies respectively each comprised either the maxilla or the mandible. More female patients and more mandibular jaws were identified in the 26 datasets.

Apart of the 26 datasets, 17 articles on immediate loading, fourteen papers on tilted implants, respectively – the so-called All-on-4 concept, and 7 articles on zygoma implants were also considered for the present review. They were selected from the final search on 222 abstracts and titles.

Number of patients, jaws and implants (Table 1)

It appears that the concept of placing the implants in the interforaminal area and within the bicuspid maxillary zone to support a cross-arch one-piece fixed prosthesis is represented by all but one report¹⁵. However, information on the prosthetic design is often not available. The analysis of the selected arti-

 Table 1
 An overview of the literature.

| Author | No. of patients | Jaw, | No. of impl. / | Study | Impl. | Other information |
|--|-----------------------------------|--|---|---------|-------|---|
| Author | female / male | max / mand | prosthesis | type | type | Other Chromitation |
| Adell et al, 1981 ²⁵ | 371 230 / 141 age 53, 20–77 | Total 410 max mand 191 / 219 | Total 2768 max: 6 / mand: 6 (few 5 or 7) | MC P | Br | ressen2 |
| Albrektsson et al, 1988 ²⁷ | ca. 1000 age 28–63 | Total 1641 max mand 918 / 723 | Total 7996 , max: 4.2 mand: 5.3 | MC R | Br | |
| Zarb and Schmidt, 1990a,b,c ^{17,81,91} | 46 36 / 10 age 49.9 (28–63) | Total 49 max mand 6 / 43 | Total 274 max: 6 mand: 6 (4–7) | Р | Br | yrs of previous edentulousness loss of impl. = OD |
| Adell et al, 1990 ²⁶ | 700 399 / 301 age 55.3 | Total 700 max mand 272 / 428 | Total 4636 max: 6 mand: 6 | MC P | Br | many drop-outs |
| Ahlqvist et al, 1990 ²⁹ | 48 30 / 18 age | Total 50 max mand 17 / 33 | Total 269 max: 4.8 (4–6) mand: 5.3 (5–6) | Р | Br | jaw classification |
| Friberg et al, 1991 ³⁰ | 780 ?? age 31->70 | Total 780 max mand 289 / 491 | Total 4641 max: 5.3, mand: 5.3 | Р | Br | |
| Jemt, 1991 ³¹ | 384 215 / 169 age 32–84 | Total 391 max mand 99 / 292 | Total 2199 max: 5.9., (4–6) mand: 5.5 (5–6) | Р | Br | jaw classification |
| Naert et al, 1992 a,b / Quirynen et al, 1992 ^{20,21} | 90 56 / 34 age 53.7 (15–88) | Total 99 max mand 42 / 57 | Total 599 (6) max: 5.8, mand: 5.7 | Р | Br | jaw classification years of edentulism (loss of implants = OD) |
| Brånemark et al, 1995 ²² | 156 100 / 56 age 20–80 | Total 156 max: 84 (14, 70) mand: 72 (13, 59) | Total 782 4 little (108), 6 normal (674) | Р | Br | jaw classification, yrs of edent, short impl. 7 / 10 mm, anat- gonistic teeth |
| Jemt, 1994 ³⁹ | 76 28 / 48 age | 76 max | Total 449 6 (few 5) | R impl. | Br | jaw classification |
| Ericsson et al, 1997 ³⁵ | 11 | 11 mand | Total 63 6 (few 5) | R | Br | |
| Friberg et al,1997 ⁴⁰ | 103 54 / 49 age 59 (33–83) | Total 102 max: 33 mand: 69 | Total 563 5–6 | MC P | Br | jaw classification |
| Arvidson et al, 1998 ¹⁴ | 107 64 / 43 age | 107 mand | Total 618 6 (few 5) | Р | Astra | |
| Friberg et al, 2000 ³² | 49 45 / 4 age 63 (38–93) | 49 mand | Total 247 4–6 average: 5 | Р | Br | |
| Eliasson et al, 2000 ³⁸ | 119 71 / 48 age 21->80 | 119 mand | Total 476 mand: 4 | Р | Br | 2 different prosthesis framework |
| Jemt et al, 2002 ²³ | 58 25 / 33 age 60 (38–74) | 58 max | Total 349 6 | RCT | Br | 2 different prosthesis framework |
| Ferrigno et al, 2002 ¹⁵ | 85 ?? age 59 (35–79) | 55 max, 40 mand | Total 760 8 | MC P | ITI | some with SFE, segmented bridgework (4 per jaw) |
| Ekelund et al, 2003 ³³ | 47 33 / 14 age 53 (34–67) | 47 mand | Total 273 6 (few 5) | Р | Br | |

Table 1 (cont.) An overview of the literature.

| Author | No. of patients female / male | Jaw, max / mand | No. of impl. / prosthesis | Study type | Impl. type | Other information |
|---|--|--|--------------------------------|---------------|-----------------------------|---|
| Engfors et al, 2004 ⁴¹ | 133 79 / 54 age 83 (80–93) | 44 max, 95 mand | Total 761 max: 6 mand: 5 | R | Br | patients aged >80 yrs |
| Astrand et al, 2004 ²⁴ | 33 / 33 38 / 28 age 61.5 (35–74) | 35 max 104A, 107 B 31 mand 80 A,80 Br | Total 371 6 (few 5) | RCT | Astra Br | comparison Astra / Br |
| Jemt and Johansson, 2006 ⁴² | 76 28 / 48 age 60.1 (32–75) | 76 max | Total 456 6 | PR | Br | |
| Friberg and Jemt, 2008 ³⁶ | 75 36 / 39 age 62.5 (20–80) | max wide jaw 33 narrow jaw 42 | Total 505 6 or 7 | R | Br | jaw classification location of implants |
| Örtrop and Jemt, 2009 ³⁴ | 155 age 67 (39–86) | 155 mand | Total 821 4–6 mean 5.3 | R | Br | different framework fabrica- tion compared |
| Gallucci et al, 2009 ²⁸ | 45 26 / 19 age 59.5 (34–78) | 45 mand | Total 237 5 (4-6) | MC P | ITI | |
| Mertens and Steveling, 2011 ¹⁶ | 17 12 / 5 age 55.6 (41–69) | 17 max | Total 106 6 | Р | Astra | no implant in jawbone = 4 |
| Hjalmarsson et al, 2011 ³⁷ | 80 age 43 / 37 | max: 40 test 40 control | Total 513 mostly 6 | R | Br / ITI Astra Biomet | external / internal connection 4 implant systems abutment / implant level compared 3 different frameworks |

cles revealed a clear tendency to plan 6 implants per prosthesis. Nevertheless, the number of implants installed was sometimes limited by the limitation of available bone and/or the arch size, resulting in 4 or 5 implants. Vice versa, although rarely, 7 or 8 implants per prosthesis were reported within the same study groups. The 26 data sets listed in Table 1 represent a total of 4833 patients, who received a total of 31353 implants in 5586 jaws. This accounts for an average number of 5.6 implants per jaw.

The average number per jaw related to the maxilla and mandible is not different, but a greater variation is observed for the maxilla. One study made a clear differentiation between limited bone volume = 4 implants and sufficient bone volume = 6 implants²². Some other comparisons within the study groups were made by some authors such as narrow and wide crest³⁶, submerged vs. nonsubmerged³⁵ or internal vs. external connection³⁷. These comparisons were not related to the number of number of supporting implants and were thus not further considered in this review.

For the mandibular interforaminal region, 4 to 6 implants were reported with a high prevalence for 5. One study exclusively installed 4 implants in the mandible³⁸, while only one study reported on 8 implants per jaw (both maxilla and mandible)¹⁵. This concept includes the installation of implants in the molar areas, which eventually required a sinus floor elevation. All other studies limited themselves to standard surgical procedures with placement of the implants in the interforaminal area of the mandible and in areas ventral to the sinuses in the maxilla.

Survival of implants and prostheses (Tables 2 and 3)

Many investigators observed some early implant losses, i.e. at abutment connection or during the first year of loading 19,25,30,21,31,39,40. Thus critical implants were lost early during follow-up. Studies dealing with success need to apply strict, clearly defined and generally accepted success criteria to allow comparisons to be made. A few reports

Table 2 Survival rates.

| Author | No. | No. of impl. / | Study | Impl. | Survival (%) | Survival (%) |
|--|-------------|--|--|-------|--|---|
| | of patients | prosthesis | duration | type | implants | prosthesis |
| Adell et al, 1981 ²⁵ | 371 | Total 2768 max: 6 / mand: 6 (few 5-7) | MC prosp., 1–9 yrs | Br | >5 yrs max: 81–88% / mand: 91–97% development and routine groups most implant loss in first year | max: 89–96% mand: 100% development group 79–100% |
| Albrektsson et al, 1988 ²⁷ | ca. 1000 | Total 7996, max: 4.2 mand 5.3 | MC, retro. data at 3,5, 7–8 yrs | Br | after 5 yrs in situ max: 89% poor bone maxilla mand: 98% | |
| Zarb and Schmidt, 1990a,b,c ¹⁷⁻¹⁹ | 46 | Total 274 max: 6 mand: 6 (4–7) | prosp 4–9 yrs | Br | after 4 to 9 yrs in situ, average survival: max: 96.3% mand: 83.7% | loss = conversion to OD |
| Adell et al, 1990 ²⁶ | 700 | Total 4636 max: 6 mand: 6 | MC prosp. 1–20 yrs | Br | after 5,10,15 yrs still in situ 92–78% 98–86% development and routine groups | prosthesis stability at 15 yrs: max: 95% / 92% mand: 99–100% |
| Ahlqvist et al, 1990 ²⁹ | 48 | Total 269 max: 4.8 (4–6) mand: 5.3 (5–6) | prosp. 2 yrs survival | Br | at 2 yrs in situ: max: 89% mand: 97% without early loss, cluster effect | prosthesis stability: 98% (96%); one prosthesis remade on 3 implants |
| Friberg et al, 1991 ³⁰ | 780 | Total 4641 max: 5.3 mand: 5.3 | prosp. first year | Br | at 1 yr in situ: 1.5% did not inte- grate max: 97 mand: 99.4 | |
| Jemt, 1991 ³¹ | 384 | Total 2199 4–6 max: 5.9 mand: 5.5 | prosp. 1 year | Br | in situ after 1 yr: 98.1 | survival: 99.5% |
| Naert et al, 1992a,b, Quirynen et al, 1992 ^{20,21} | 90 | Total 599 6 max: 5.8, mand: 5.7 | prosp. follow-up 1–7yrs | Br | CSR at 7 yrs 92.6 max: 91.6% mand: 95% most losses early, in 18% of jaws impl. lost | CSR: 93% 98.3% cantilever length |
| Brånemark et al, 1995 ²² | 156 | Total 782 4 little 6 normal max/ mand | prosp. up to 10 yrs: all patients 10 yrs examined | Br | CSR at 10 yrs max: (4) 78.3%, (6) 81.3% mand: (4) 88.4% (6) 93.3% | CSR: max: 93.2% mand.: 78.3% |
| Jemt, 1994 ³⁹ | 76 | Total 449 max: 6 (few 5) | retro 5 yrs at 5 yrs: still 62 patients, 350 impl. | Br | at 5 yrs 92.1 in situ cluster effect of impl. loss in 2 patients more short impl. (7 mm) failed | |
| Ericsson et al, 1997 ³⁵ | 11 | Total 63 mand: 6 (few 5) | retro 5 yrs at 5 yrs: 61 impl. exam- ined | Br | CSR after 5 yrs 96.8 submerged vs. non submerged no diff | |
| Friberg et al, 1997 ⁴⁰ | 103 | Total 563 5–6 max / mand | 3 centres, prosp. 5 yrs follow-up at 5 yrs: 86 patients examined | Br | CSR at 5 yrs, more lost in maxilla max: 87 mand: 99.7 clustering effect | CSR: 97% |
| Arvidson et al, 1998 ¹⁴ | 107 | Total 618 mand: 6 (few 5) | prosp. 5 yrs follow-up at 5 yrs: 91 patients examined | Astra | CSR at 5 yrs = 98.7 | CSR: 100% |
| Friberg et al, 2000 ³² | 49 | Total 247 mand: 4–6 average: 5 | prosp. 1–10 yrs follow-up at 5 yrs: 37 pat / 193 impl. at 10 yrs: 25 pat / 125 impl. | Br | CSR at 5 yrs 95.5 CSR at 10 yrs 92.3 short impl. 7 mm and 6 mm 1.9% early failure (7 mm, thin diameter) | after failure = conversion to OD |

 Table 2
 (cont.)
 Survival rates.

| A 11 | | | er I | | 6 1 1/0/2 | a De la casi |
|---|-----------------------|---|--|----------------------------|--|---|
| Author | No. of patients | No. of impl. / prosthesis | Study duration | Impl. type | Survival (%) implants | prosthesis/Cations |
| Eliasson et al, 2000 ³⁸ | 119 | Total 476 mand: 4 | prosp. 3 yrs and 5 yrs at 3 yrs: 105 pat at 5 yrs: 53 pat | Br | 97.1 successful 2.9% implants lost in the study | essen2 |
| Jemt et al, 2002 ²³ | 58 | Total 349 max 6 | RCT 5 yrs examined at 5 yrs: 50 | Br | CSR at 5 yrs = 91.4 / 94.4 2 different prosthesis frameworks clustering effect (all impl. lost in 2 patients) | |
| Ferrigno et al, 2002 ¹⁵ | 85 | Total 760 max: 8 | MC prosp. up to 10 yrs, 5 yrs data of 288 implants | ITI | CSR success at 5 yrs max: 92.1% mand: 96.25%, no heavy smokers | |
| Ekelund et al, 2003 ³³ | 47 | Total 273 mand: 6 (few 5) | prosp. follow-up to 20 yrs 30 pat / 179 implants examined at 20 yrs | Br | CSR 98.9% at 20 yrs more bone loss at mesial implants | survival: 100% at 20 yrs (2 prostheses remade) |
| Engfors et al, 2004 ⁴¹ | 133 | Total 761 max: 6 mand: 5 | retro 5 yrs at 5 yrs 76 patients examined 162 / 240 impl. | Br | CSR at 5 yrs: mand: 99.5 max: 93 | CSR: max: 92.2 mand: 100% |
| Astrand et al, 2004 ²⁴ | 33 / 33 | Total 371 max / mand 6 (few 5) | RCT prosp. 5 yrs observation time at 5 yrs: 170 A 176 Br | Astra Br | At 5 yrs: CSR 98.4% A CSR 94.6% Br bone slightly more stable at Astra | |
| Jemt and Johansson, 2006 ⁴² | 76 | Total 456 max: 6 | retro follow-up to 15 yrs, 25 patients. | Br | CSR 97.2 at 5 yrs / 90.9 at 15 yrs early implant losses | CSR: at 5 yrs: 97.2% at 10 yrs: 95.4% at 15 yrs: 90.6% |
| Friberg and Jemt, 2008 ³⁶ | 75 | Total 505 wide: 226 narrow: 279 6 or 7 max | retro 7 yrs at 7 yrs still 181 / 209 implants | Br | CSR at 7 yrs wide bone crest: 94.5 / narrow bone crest: 93.6 smokers | |
| Örtrop Jemt, 2009 ³⁴ | 155 | Total 821 4–6, mand mean 5.3 | retro 15 yrs at 15 yrs 65 patients examined | Br | CSR 98.7 at 15 yrs different frameworks | CSR: 91.7% Ti: 89.2 Gold 100% |
| Gallucci et al, 2009 ²⁸ | 45 | Total 237 mand: 5 (4–6) | MC prosp. 5 yrs follow-up all examined at 5 yrs | ITI | at 5 yrs implant survival: 100%, cross arch successful patients: 86.7 | CSR: 95.5% cantilever length |
| Mertens and Steveling, 2011 ¹⁶ | 17 | Total 106 max: 6 | prosp. at 5 yrs, at 8 yrs 16 patients examined | Astra | survival at 8 yrs: 99% bone loss: 0.3 mm +-0.7 success: 96% smokers included | CSR: 100% |
| Hjalmarsson et al, 2011 ³⁷ | 80 | Total 513 max mostly: 6 | retro 5 yrs patients available at 5 yrs recruited | Br, ITI Astra Biomet | survival at 5 yrs 98.6 / 97.6 loaded 100% / 99% external / internal connection | |

described in detail the criteria of success. They differentiate between survival and success sometimes by involving crestal bone measurements¹⁴⁻¹⁶. But such criteria varied among the studies and did not allow for comparison of success rates. Thus it is adequate to use the term survival in the present review.

In early reports^{25,26} a distinction was made between development groups – representing the learning curve with the implant-supported fixed prostheses concept – and the routine groups. For the development groups, often a lower survival rate is reported with more complications (including technical aspects of the prosthesis).

Table 3 Prospective studies with 5 years' CSR.

| Fable 3 Prospective studies with the studies with the studies of the studies with the studies with the studies of the studies with the studies of the studies of the studies with the studies of the studies o | | | ı / Worni Nur | mber of implant | s supporti | ng fixed prosthesis | pyrigh, 5 | ■ S1 |
|--|-----------------|---------------------|---------------------------|-----------------------|-------------|--------------------------------|------------------|------|
| Author | No. of patients | Jaw, max / mand | No. of impl. / prosthesis | Number examined | Impl. | Survival (%) implants | Ublica | |
| Friberg et al, 1997 ⁴⁰ | 103 | max: 33 mand: 69 | Total 563 5–6 | 86 patients examined | Br | CSR: max: 87 mand: 99.7 | ation | 7 |
| Arvidson et al, 1998 ¹⁴ | 107 | 107 mand | Total 618 6 (few 5) | 91 patients examined | Astra | CSR: 98.7 | sen ² | |
| Friberg et al, 2000 ³² | 49 | 49 mand | Total 247 4–6 | 37 patients examined | Br | CSR: 95.5 | | |
| Eliasson et al, 2000 ³⁸ | 119 | 119 mand | Total 476 4 | 53 patients examined | Br | CSR: 97.1 | | |
| Jemt et al, 2002 ²³ | 58 | 58 max | Total 349 6 | 50 patients examined | Br | CSR: 91.4 / 94.4 | | |
| Ferrigno et al, 2002 ¹⁵ | 85 | 55 max, 40 mand | Total 760 8 | 288 implants examined | ITI | CSR: max: 92,1%, mand: 96.25% | | |
| Astrand et al, 2004 ²⁴ | 33 / 33 | 35 max 31 mand | Total 371 6 | 246 implants examined | Astra Br | CSR: 98.4% A, CSR: 94.6% Br | | |
| Gallucci et al, 2009 ²⁸ | 45 | 45 mand | Total 237 5 (4–6) | 45 patients examined | ITI | CSR: 100% | | |

In early studies and up to the 1990s, the implant surfaces were mostly machined. For machined surfaces, a slightly lower survival rate is observed as compared to the slightly rough surfaces used today with most available implant systems.

Overall, the survival varies between 78% (the minimum observed for the maxilla in the development group) and 100% (maximum for mandible). Life table analysis and censored data were used and 14 articles reported on the cumulative survival rates at 5, 10 or more years. From these data, the average survival rate was between 90% and 100%. The Cumulative Survival Rate (CSR) at 5 years exclusively obtained from prospective studies is summarised separately in Table 3. It ranged from 87% to 92.1% for the maxilla and from >95 up to 100% for the mandible. A 'clustering' effect was sometimes observed^{23,29,39,40}, meaning that the majority of implant failures occurred within one or a few patients. This effect was more typical for maxillary implants and in the early phase. Some studies found that the trend for failures was more obvious in the severely atrophied maxilla, with poor bone quality and short implants^{20,22,25-27,29,30,32,38,41}. This led some investigators to hypothesise that a minimum number of ≥ 4 of ≥ 10 mm length might be necessary.

If implants failed within a study group, then no distinction was made whether these implants were

integrated in a prosthesis with a 4, 5 or 6 implant support.

Crestal bone measurements (Table 4)

especially prospective Seventeen studies, ones14,16,20,23-25,29,32-34,36-42 included some outcomes on crestal bone measurements. Annual radiographic measurements were not systematically taken and some studies only performed those in selected patient groups²⁵. A distinction between the healing phase and first year of loading versus the follow-up periods was often made, meaning that more bone loss was observed in the first period (i.e. from implant placement to abutment connection and first year of loading) with up to 1.5 mm loss, than in the follow-up period with little changes (e.g. ≤ 0.2 mm per year) for successful implants.

This way of considering crestal bone alterations is based on articles from the early to mid-1980s. More crestal bone loss was observed in the maxilla. Some authors mentioned above-average bone loss in a few patients^{20,34,36,37,40,42}. Two papers mentioned that more crestal bone loss was found around mesial implants^{29,33}.

The reasons for increased bone loss were unclear, but smoking was occasionally addressed as a negative factor.

 Table 4
 Crestal bone alterations.

| Authors | No. of impl. / | Study | Impl. | Crestal bone level alterations |
|---|--|---|-------------------|---|
| Adellet al, 1981 ²⁵ | rosthesis Total 2768 max: 6 / mand: 6 (few 5–7) | MC prosp., 1–9 yrs | type Br | after first year, mean 1.2, then 0.1 mm only selected groups impl. fracture with accelerated bone loss more prominent in maxilla |
| Ahlqvist et al, 1990 ²⁹ | Total 269 max: 4.8 (4–6) mand: 5.3 (5–6) | prosp. 2 yr survival after 2 yrs | Br | average loss after 2 yrs: max 1.7, mand 1.1, more loss in max more loss at mesial implants: 1.9 m / 1.3 mm |
| Naert et al, 1992 a,b Quirynen et al, 1992 ^{20, 21} | Total 599 max: 5.8, mand: 5.7 | prosp. follow-up 1–7 yrs | Br | jaw classification, healing: max 1.2 mm, mand. 0.86 mm, then 0.1 to 0.2 per yr max: 20.9%, mand: 5.4% more loss than average |
| Jemt, 1994 ³⁹ | Total 449 max: 6 (few 5) | retro 5 yrs at 5 yrs still 62 patients, 350 impl. | Br | jaw classification at 5 yrs average: 1.2 +-0.58 |
| Friberg et al,1997 ⁴⁰ | Total 563 5–6 max / mand | 3 centres, prosp. at 5 yrs 86 pat. examined | Br | bone los first year: 0.3–0.4 mm, thereafter 0.1 mm per yr some sites with ≥ 2 mm |
| Arvidson et al, 1998 ¹⁴ | Total 618 mand: 6 (few 5) | prosp. at 5 yrs 91 pat. examined | Astra | minimal bone loss = success radiographs at 1, 3 and 5 yrs average <1 mm after 5 years |
| Friberg et al, 2000 ³² | Total 247 mand: 4–6 average: 5 | prosp. 1–10 yrs follow-up at 5 yrs: 37 pat / 193 impl. at 10 yrs 25 pat / 125 impl. | Br | short implants (6 or 7 mm), 2 different diameters first yr; 0.5+-0.6 at 5 yrs: 0.7+-0.8 at 10 yrs: 0.9+-0.6 |
| Eliasson et al, 2000 ³⁸ | Total 476 mand: 4 | prosp. 3 yrs and 5 yrs at 3 yrs: 105 pat at 5 yrs 53 pat | Br | no average values frequency analysis of changes of 0, 1 mm, >1 mm loss per site, 10% short implants |
| Jemt et al, 2002 ²³ | Total 349 max: 6 | RCT 5 yrs examined at 5 yrs: 50 | Br | average 0.59 +-0.97 at 5 yrs no diff. in bone loss between 2 frameworks |
| Ekelund et al, 2003 ³³ | Total 273 mand: 6 (few 5) | prosp. follow-up to 20 yrs 30 patients / 179 implants examined at 20 yrs | Br | at 20 yrs: little bone loss: 1.6 +-9 mm 24% more loss than average up to 5.9 mm more loss at mesial implants |
| Engfors et al, 2004 ⁴¹ | Total 761 max: 6 mand: 5 | retro 5 yrs at 5 yrs 76 pat examined 162 / 240 impl. | Br | bone loss average: max: 0.7, mand. 0.6 mm slightly more loss in >80 years old |
| Astrand et al, 2004 ²⁴ | Total 371 max / mand 6 (few 5) | RCT prosp. 5 yrs observation time at 5 yrs: 170 A 176 Br | Astra Br | at 5 years Astra vs Br max: 1.74+-+-0.45 / 1.98 +-0.21 mand: 1.06 0.19 / 1.38 +- 0.17 stat. not significant |
| Jemt and Johansson, 2006 ⁴² | Total 456 max: 6 | retro follow-up to 15 yrs, 25 patients | Br | bone loss at 5, 10, 15 yrs: 0.5 +-0.47/ 0.6+-0.6 / 0.5 +-0.6 15.% / 23.6% /18% up to >3 mm loss |
| Friberg and Jemt, 2008 ³⁶ | Total 505 wide / narrow 6 or 7 max | retro 7 yrs at 7 yrs still 181 / 209 implants | Br | bone loss at 5 yrs: 0.64 to 0.74 +-0.65 some with >1.5 mm loss, more loss in smokers |
| Örtrop and Jemt, 2009 ³⁴ | Total 821 4–6, mand mean 5.3 | retro 15 yrs at 15 yrs 65 patients examined | Br | at 15 yrs Ti vs. Gold framework: 0.59+- 0.56 / 0.98+-0.64 13.7% >1.2 up to 5.9 mm 28% >1.2 up to 5.9 mm |
| Mertens and Steveling, 2011 ¹⁶ | Total 106 max: 6 | prosp. at 5 yrs , at 8 yrs 16 patients examined | Astra | regular Rx: average loss: 0.3 +-0.72 after 8 yrs 0 up to 4.56 mm longer impls. slightly more loss |
| Hjalmarsson et al, 2011 ³⁷ | Total 513 max: mostly 6 | retro 5 yrs patients available at 5 yrs recruited | Br, ITI Astra | bone loss at 5 yts: 1-1.2 mm (3 diff groups) 16%-27% of implants >1.9 mm lost |

Table 5 Complications.

| Author | No. of impl. / prosthesis | Resin / teeth fracture | Veneering fracture | Frame- work fracture | Abutment screw | Gold screw | Phonetics diction | Lip/cheek biting | Others |
|---|--|------------------------------|--------------------|----------------------------|----------------|---------------|-------------------|---------------------|---|
| Adell et al, 1981 ²⁵ | max: 6 mand: 6 | | | yes | yes | yes | 131 | essen? | ill fitting denture |
| Albrektsson et al, 1988 ²⁷ | max: 4.2 mand: 5.3 | | | | | | yes | | |
| Zarb and Schmidt, 1990a,b,c ^{17,18,19} | max: 6 mand: 6 (4–7) | | | yes | | yes | yes | | food trapping |
| Jemt, 1991 Jaw classification | max: 5. 9., mand: 5.5 | yes | yes | | | yes | yes | yes | air escape |
| Naert et al, 1992 a,b Quirynen et al, 1992 ^{20,21} | max: 5.8, mand: 5.7 | | yes | yes | yes | yes | yes | | fractures: impl. cantilever |
| Brånemark et al, 1995 ²² | Total 782 4 little (108), 6 normal (674) | | | | | | | | more risk of compl. max. 4 implants |
| Jemt, 1994 ³⁹ | 6 (few 5) | yes | | yes | yes | yes | yes | yes | change design |
| Ericsson et al, 1997 ³⁵ | 6 (few 5) | | | | | yes | | | |
| Friberg et al, 2000 ³² | 4–6 average 5 | | | | yes | | | | |
| Eliasson et al, 2000 ³⁸ | mand: 4 | yes | | yes | | | | | (gold / titan framework) |
| Jemt et al, 2002 ²³ | 6 | yes | | | | yes | | | gold / titan soft tissue affection |
| Engfors et al, 2004 ⁴¹ | max: 6 mand: 5 | yes | | yes | yes | yes | yes | yes | |
| Astrand et al, 2004 ²⁴ | 6 (few 5) | | yes | yes | | yes | yes | | |
| Jemt and Johansson, 2006 ⁴² | 6 | yes | yes | yes | | | yes | | hyperplasia, fistula |
| Örtrop Jemt, 2009 ³⁴ | 4–6 mean 5.3 | yes | yes | yes | yes | yes | | yes | laser welded vs. gold alloy |
| Gallucci et al, 2009 ²⁸ | Total 237 5 (4–6) | yes | | | | yes | | yes | length of canti- levers |
| Hjalmarsson et al, 2011 ³⁷ | mostly 6 | | yes | | | | yes | yes | wear, new design, occl adjustment |

Prosthesis related complications (Table 5)

Data of prosthetic/technical complications that could be extracted from the studies^{17-25,27,28,31,32,34,35,37-39,41,42} are given in Table 5. Seventeen articles listed in Table 5 reported occasionally, or in detail, on prosthesis survival/stability. Nine calculated a prosthesis based survival rate^{14,16,21,22,28,34,40-42}, see Table 2). It appears that in all but one¹⁵ of the selected articles for the present review, the basic prosthetic concept is cross-arch, screw-retained. The choice of the num-

ber of implants was adopted from the early publications^{17-19,25,26}. This prosthetic concept was described together with technical procedures in Brånemark et al's standard book on osseointegration, published in 1985². The prosthesis was designed around a metal framework and the prevalent veneering material was resin; or resin teeth were mounted and resin denture material added. This type of prosthesis was either described or was visible from the illustrations in the selected papers. A distinction was clearly made between the crown design and the hybrid design

by one study²¹. Ceramic veneering was occasionally mentioned in a few studies. Four studies reported on specific technologies and compared different fabrications of frameworks^{23,34,37,38}.

According to the prevalently utilised prosthetic technology, fracture of veneering material, resin tooth or resin denture base fractures, loosening of screws (gold screw, abutment screw) and some fractures of frameworks were typical and frequently listed as technical, prosthesis related complications. Fracture of an opposing complete denture was occasionally mentioned. Additionally biological complications such as soft tissue hyperplasia, fistulae, TMJ problems, occlusal wear, plaque accumulation or the fracture of an opposing complete denture were also occasionally mentioned. Patient-related problems and complaints were food trapping and phonation with air escape. Specific attention to the length of distal cantilevers was given in two papers^{21,28}. Cementation or screw retention on the other hand was not an issue in the papers, which were also considered. Only one study¹⁵ reported cemented prostheses. The prosthesis design and technical complications identified in the study groups were not specified according to the number of supporting implants per prosthesis (4, 5 or \geq 6 implants).

Immediate loading/tilted implants (All-on-4) and zygoma implants (Tables 6, 7 and 8)

The articles related to these topics are listed in Tables 6 to 8. They will not be discussed in detail, but reviewing these articles adds further information and considerations to the question of the number of implants to be used for fixed prostheses.

Since they report more recent treatment concepts with special surgical techniques, the observation periods are shorter, as shown in Table 1.

Immediate loading: This has been defined as loading within 24 to 48 h after implant insertion, but some studies report even 13 days from implant placement to the prosthesis connection. The number of implants placed per prosthesis varied from 4 to $10^{8,43-58}$. For the maxilla, four papers reported the use of 7 to 10 implants^{8,45,46,56}, while only one study⁵² reported on 4 to 5 implants. With regard to the mandible, 4 to 5 implants were placed in two studies^{50,53} and

only 3 implants in two others^{49,57}. On average, the patients received 5.8 implants per jaw and the idea was to place 6 implants.

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The transition from the failing dentition to complete edentulism by means of immediate installation of implant-supported fixed prostheses is discussed in various publications. Immediate implant placement into fresh extraction sockets is reported in three studies^{53,54,58}. Such procedures were combined with immediate provisional prostheses, providing crossarch fixation. Problems with provisionals, such as fractures, are mentioned. In one study, representing only three patients, the simultaneous completion of immediate loading in both jaws was described⁴⁵. The distribution of utilised implants was similar to previous publications^{4,15}.

Tilted implants: The reports on tilted implants⁵⁹⁻⁷² also comprised immediate loading and/or flapless procedures. The prevalent number of implants was 4 as in the All-on-4 concept, i.e. two tilted, two axial implants^{65,66}. Four studies^{59,60,62,64} on tilted implants reported 5 or 6 implants in the maxilla, meaning that 3 or 4 implants were axially placed. Only 4 implants were systematically installed in the mandible in all studies. One RCT⁷² compared 2 vs. 4 implants to support a fixed prosthesis.

Zygoma implants: Extra-maxillary anchorage in the zygomatic bone is used to deal with the atrophic maxilla. It avoids extensive grafting procedures⁷³⁻⁷⁹. The prevalent number per prosthesis was 4 or 5 implants and the average number of implants per jaw was 4.5. Some studies report exclusively on 4 zygoma implants per prosthesis⁷⁵ or a combination of 2 zygoma and 2 or more axial maxillary implants.

Discussion

Publications on osseointegration in oral rehabilitation from the 1980s and 1990s include a number of long-term observations on large patient populations. The attitude of today has somewhat changed, with shorter observation periods and smaller patient groups.

One recent systematic review on fixed prostheses in complete edentulism⁸⁰ identified only two reports on fixed prostheses in the maxilla and nine (including both jaws) for the mandible with a minimum of 50

Table 6 Immediate loading.

| Author | Jaw | No. of patients | No. of implants | Study type duration | Impl. type | Survival % | Comments Publicani |
|--|-------------|-------------------|---------------------------|------------------------------|------------------------|------------------|--|
| Schnitmann et al, 1997 ⁴³ | mand | 10 | (60) 6 | retro 10 yrs | Br | 100, 84.7 | some submerged, some immediate loading |
| Olsson et al, 2003 ⁴⁴ | mand | 10 | (61) 6 | prosp. 1 yr | Br | 93.4 | immediate (2 to 9 days) impl. loss due to infection, stable bone |
| Degidi et al, 2005 ⁸ | max | 43 | (388) 8–10, Ø 9 | retro 5 yrs | | 98 | impl. failures in first 6 months, large diameter more often failed |
| Gallucci et al, 2005 ⁴⁵ | max mand | 3 / 3 | (42) max: 8 mand: 6 | <1 yr | ITI | 100 | immediate max / mand in one patient, good stability of bone, prosthesis segmented, cemented |
| Collaert De Bruyn, 2008 ⁴⁶ | max | 25 | (195) 7–9 | prosp. 3 yrs | Astra | 100 | within 24 hours, very little bone loss, more in smokers |
| Fischer, 2008 ⁴⁷ | max | 24 | (142) 6 (2 only 5) | prosp. 5 yrs | ITI | 95 | good bone stability, RFA same as for late loading |
| Bergkvist et al, 2009 ⁴⁸ | max | 28 | (168) 6 | prosp. 32 months | ITI | 98.2 | within 24 hours, bone loss like standard healing, most lost after healing when loading started |
| Hatano et al, 2011 ⁴⁹ | mand | 132 | (396) | retro Ø 5 yrs 1 to 10 yrs | Br | 96.7 | implants mostly 13 mm, failures in first 6 months, all replaced, prosthesis survival 92.4% |
| Friberg et al, 2005 ⁵⁰ | mand | 152 | 750 5 (few 4) | retro 1 yr | Br | CSR 97.5 | loading after 13 days, good crestal bone stability |
| Erkarpers et al 2011 ⁵¹ | max | 51 | (306) 6 | MC prosp. | ?? | | loading within 24 h, satisfaction measured (OHIP-49) 3 times, very good scores |
| Malo et al, 2011 ⁵² | max | 221 | (995) 4–5 mostly 5 | retro 5 yrs | Nobel | 78.5 to 92.4% | implants in different position, posterior more failure, biolog. compl., smokers more problems |
| Gillot et al, 2011 ⁵³ | mand | 105 | (448) Ø 4 few 5–6 | pros. 4 months | Nobel | 98.2 | 40% of impl. in fresh extraction socket, no diff. to healed bone |
| Gillot et al, 2012 ⁵⁴ | max | 113 | (675) 6 (3 pat. 5) | retro 6 months | Nobel | 99.1 | impl. in fresh extraction socket, more immediate impl. failed, fractures of provisionals |
| Komjoama et al, 2012 ⁵⁵ | max mand | 19 max 10 mand | (165) 6 few 7 / 4 | prosp. ≥ 1 yr | Br | 100 | teeth in a hour, some increased BoP, ulcera crestal bone loss >1.5 mm bone loss frequent |
| Covani et al, 2012 ⁵⁶ | max mand | 19 | (184) 8 max 6 mand | retro 4 yrs | Osse- an Intra-L | CSR 95 | immediate implants, immediate loading |
| Rivaldo et al, 2012 ⁵⁷ | mand | 33 | (99) 3 | retro 18 months | Nobel | 100 | crestal bone loss similar at mesial and distal impl. |
| Barbier et al, 2012 ⁵⁸ | max | 20 | (120) 6 | 18 months | Astra | 100 | immediate impl. and loading combined (24 h) CAD/CAM prosthesis, stable bone |

patients for a minimum of 5 years. Thus the majority of studies in the present review were excluded in the latter report. The authors concluded that the evidence on the optimal number of implants to be used to carry fixed prostheses was not available. Although from a statistical and systematic review point of view this conclusion is correct, the omission of so much pertinent

information about therapeutic concepts and clinical procedures obliterates the issue. Another review paper on the same subject also complained about the weak study designs and consequently the weak evidence⁸¹. By including more clinical data, the present review tries to come to some conclusions regarding the number of implants needed in the edentulous jaws.

Table 7 Tilted implants / All-on-4.

| Author | Jaw | No. of patients | No. of implants | Study type duration | Impl. type | Survival % | Comments PUblicar. |
|---|-------------|-----------------|------------------------------|------------------------------|------------------------|-----------------------------|--|
| Capelli et al, 2007 ⁵⁹ | max mand | 65 | (342) max 6 mand 4 | prosp. 33–85 Ø 55 months | Osseotite Biomet 3i | mand: 100%, max: 98% | immediate implants |
| Tealdo et al, 2008 ⁶⁰ | max | 21 | (111) average 5 (few 6) | prosp. 13–28 Ø 22 months | Osseotite Biomet 3i | 92.8% | immediate, few implants in extraction sockets prosth. survival 100% |
| Agliardi et al, 2010 ⁶¹ | max | 20 | (120) 6 | prosp. 18–42 Ø 27 | Nobel | max: 98.3% mand: 99.7 | immediate |
| Pomares, 2010 ⁶² | max mand | 30 | (218) max 6 mand 4 | retro 1 yr | Nobel | 98% | immediate immediate, CAD CAM Nobelguide, some technical compl., template fracture, crestal bone |
| Francetti et al, 2010 ⁶³ | max mand | 47 | (196) 4 | prosp. 30–60 22–40 months | Nobel | 100% | immediate, crestal bone: no diff., tilted vs. axial |
| Degidi et al, 2010 ⁶⁴ | max | 30 | (210), 5 3 axial 2 tilted | prosp. 3 yrs | Dentsply | 97.8% axial 99.2% tilted | immediate, welded frameworks, bone level similar |
| Malo et al, 2011 ⁶⁵ | mand | 245 | (980) 4 | prosp. up to 10 yrs | Nobel | 98% (5 yrs) 93% (10 yrs) | All-on-4 concept, immediate |
| Malo et al, 2012 ⁶⁶ | max | 242 | (968) 4 | retro Ø 3.5 yrs | Nobel | 98% | All on-4 concept, immediate |
| Weinstein et al, 2012 ⁶⁷ | mand | 20 | (80) 4 | prosp. 20–48 Ø 30.1 | Nobel | 100% | extremely atrophied jaw |
| Grandi et al, 2012 ⁶⁸ | mand | 47 | (148) 4 | MC prosp. 12–84 | J Dental Care | 100% | post extraction, immediate impl. immediate loading |
| Francetti et al, 2012 ⁶⁹ | max mand | 47 | (198) 4 | prosp. 36–66 months | Nobel | 10% | immediate, regular bone level measurements, no sig. diff,. between max / mand |
| Malo et al, 2013 ⁷⁰ | max | 70 | (280) | retro Ø 36 months | Nobel | 96.4% (drop-outs) | all tilted implants, 83 trans sinus, many complications and bone loss, immediate |
| Krennmair et al, 2013 ⁷¹ | max | 38 | (152) 4 | retro 5–7 yrs Ø 66.5 | Nobel | 100, axial 98.6 tilted | degree of tilting, length of canti- levers, no influence on bone loss, resin and tooth fractures |
| Cannizzaro et al, 2013 ⁷² | mand | 60 | (180) 2 or 4 | RCT 1 yr | Osseotite Biomet 3i | 100% | immediate, some technical comp. fixed prosth. on 2 or 4 impl. No diff. of bone level |

The rehabilitation of edentulism by means of fixed prostheses has always been a priority goal in prosthodontics. The first long-term results were reported in Sweden²⁵ and by the Toronto study¹⁷⁻¹⁹. Overdentures were not considered a viable solution at this time. In these early days, restorations for the edentulous mandible predominated. The prostheses were designed around a metal-framework from metal-alloys with acrylic veneering. The so-called 'wrap-around' technique with prefabricated acrylic denture teeth and denture base material to compensate for lost hard and soft tissues was also applied with a hybrid design (where the prosthesis material was not in contact with the alveolar mucosa). This type of prosthesis

was often labelled the 'Toronto bridge'. All these early fixed prostheses were supported preferably by more than 4 implants, mostly by 5 or 6. One reason for the selection of this number of implants was the perceived risk of early implant failures. Thus, in spite of the lack of osseointegration that might be detected at abutment connection, or in spite of failures in the first year of loading, a sufficient number (4) of remaining implants, hopefully located on both sides of the jaw, would still be available to support the prosthesis. The implants were placed in the interforaminal/anterior regions, avoiding surgical risks such as the vicinity of the mental nerve or sinus and therefore shortened dental arches became necessary. In these early days,

Table 8 Zygoma implants.

| | | | | | - | |
|---|-----------------|---|--------------------------|---------------|---------------------------------|---|
| Author | No. of patients | No. of implants | Study duration | Impl. type | Survival % | Comments PU6/iCax |
| Malevez et al, 2004 ⁷³ | 55 | 103 zyg 2–6-axial | 6–48 months | Nobel | 100% for zygoma | all zygoma impl. with osseointegration 52 fix prost., 3 removable |
| Becktor et al, 2005 ⁷⁴ | 16 | 31 zyg 74 axial | retro 9–69 months | Nobel | 90.3% for zygoma | zygoma and standard impl. lost,, poor hygiene, sinusits, local infection |
| Stiévenart and Malevez, 2010 ⁷⁵ | 20 | (80) 4 zyg | prosp. 6–40 months | Nobel | CSR: 96 | 10 pat. 2-stage , 10 pat. immediate, severe atrophy, 3 impl. lost in 1 pat., Procera bridge |
| Bedrossian, 2010 ⁷⁶ | 36 | (172) 2 zyg 2–4 axial | prosp. up to 7 yrs | Nobel | 100% (after loading) | sinus infection, 2 zyg. mobile during healing, replaced |
| Malo et al, 2013 ⁷⁷ | 350 | (1542) 4 (few 5) 747 zyg, 795 axial | pros 1–5 yrs | Nobel | CSR: 98.2 zyg 5 yrs 94.4% | immediate, prosthesis survival 99%, biological compl., technical compl. bruxism |
| Degidi et al, 2012 ⁷⁸ | 10 | (40) 4 2zyg, 2 axial | prosp. 12 months | Nobel | 100% | immediate, welded framework intraorally |
| Testori et al, 2013 ⁷⁹ | 32 | (190) 5 4–5 | retro 1 yr | Nobel | 98.4% | mucositis, screw loosening, chipping, bone level no diff. |

the implants had a 'smooth' (machined) surface and the probability of lack of osseointegration after the healing phase was greater than nowadays with slightly rough surfaces.

Fixed full arch prostheses with the implants located in the anterior zone exhibit a possible risk of cantilever fracture. One could also speculate that cantilevers are longer in prostheses supported by only 4 implants as compared to 6, but this also depends on the anterior-posterior spread. Framework fractures were reported, but the fracture location was not specified and the cantilevers' length varied and mostly was not measured. From the available data it could not be extracted whether the prostheses were designed according to the shortened dental arch concept. In a systematic review, which included partial and complete fixed prostheses, frequent technical complications were veneer chipping and fracture, screw loosening and de-cementation⁸². Another study confirmed these observations83. Loading patterns of fixed cantilever prostheses were investigated and demonstrated maximum loading forces on the distal implants adjacent to the cantilevers84,85. Although higher stress in the cortical bone around the implants was registered, in single cases it was shown that with this treatment concept bone apposition could be

observed underneath the cantilevers in the posterior zone of the mandibular jaw⁸⁶. In spite of these increased stresses around distal implants, two studies reported on more crestal bone loss, with some bone loss at mesial implants^{29,33}.

A more recent concept introduced a titled position for the posterior implants. It was mostly combined with immediate loading. A reduced number of implants was proposed, namely 4. A recent systematic review⁸⁷ reported good short-term outcomes for this concept that mostly utilised only 4, sometimes 5 (2 axial and 2 to 3 tilted) implants. The prosthesis design comprised distal cantilevers. This arrangement of the implants should reduce the number of implants to a minimum and increase the arch of extension and support of cross-arch fixed prostheses. As a consequence, the cantilever length will decrease. A meta-analysis found stable marginal bone levels with no difference between axial and tilted implants88. Another study, although reporting a 100% survival rate, observed ongoing bone loss around immediately loaded implants that were installed during a flapless procedure following the All-on-4 concept⁸⁹.

Comparisons of implant survival or success data among authors are not meaningful since methodologies and criteria vary considerably. The most stringent success criteria should rely on annual crestal bone measurements with standardised radiographs. For many reasons, this annual follow-up documentation was not provided in most of the selected studies for the present review. Some single implants exhibited more marginal bone loss than the expected 0.1 to 0.2 mm per year⁹⁰. A meta-analysis comparing three implant systems found bone loss below or much below such cut-off values for defining success⁹¹. The implants exhibited different neck configurations and abutment connections and nowadays much attention is paid to the implant shoulder design with or without platform switching⁹². This aspect was not considered in the studies of the present data set.

In the present review, the maxilla is less represented and leads to lower survival rates as compared to the mandible. A review on immediate implant placement confirms that more information is available for the mandible⁹³. One review on exclusively maxillary implants⁹⁴ comprised studies with various grafting procedures and immediate implant placement. One relevant outcome of the review was that placement of >6 implants results in a higher survival rate as compared to <6 implants that were installed within the bicuspid area and not having a support in the molar zone. One could argue that due to the atrophied maxilla, only 4 or 5 implants were placed, and thus this would confirm the observation that maxillary implants may more frequently fail in poor bone. The review identified different survival rates for machined and slightly rough surfaces, particularly with regard to grafted and native bone.

Some studies reported that only a small number of implants could be placed in the maxilla due to insufficient bone volume, and associated with this condition an increased failure rate was reported. In the 1990s, a surprisingly high failure (>20%) rate for maxillary overdentures was reported^{31,95-97}. A critical analysis revealed that the indication for overdentures was often given in an emergency situation⁹⁸, meaning that overdentures were a substitute for failing fixed prostheses. When properly planned, overdentures led to excellent survival rates99-102. The marginal bone surrounding the implants was maintained at the same level as with fixed prostheses^{98,103}, also in ridges with advanced atrophy. Three studies of the present review reported on the transition from fixed prosthesis to overdentures due to implant losses 19,20,32.

Some studies tried to classify complications of implant-prostheses by means of categories that could be generally be applied to prosthetic reconstructions^{101,104}. Still today clear criteria to report on technical complications, repair and maintenance service are not binding and not applied in the same way. Therefore, survival includes minor or major complications that required repair and adjustments that may be within the range of normal maintenance service or exceed it. The distinction between maintenance to support long-term function and complications may be based on the frequency of events that occur within a given observation time.

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Beside the experiences with cross-arch fixed prostheses that often had a hybrid design, efforts were made to fabricate porcelain fused to metal fixed prostheses with a crown design, with the aim of improving aesthetics and prosthesis quality. Such frameworks are large, of heavy weight and misfit could not be avoided. Based on laboratory measurements it was concluded that passive fit cannot be reached by conventional techniques¹⁰⁵. Thus segmentation was preferred, with the consequence that a symmetrical anterior/posterior distribution of the implants was suggested. However, limited clinical research was conducted on the concept of placing 8 implants, with segmentation into 4 prosthetic units^{4,15,45}. One study exhibits this approach to locate the implant position for fixed prosthesis in the mandible and maxilla¹⁵. Thus, giving up the concept of cross-arch splinting, the authors suggest segmenting the fixed prosthesis into three parts as follows: 6×4 , 3×3 , 4×6 for the mandible and 6×4 , 3×1 , 1×3 , 4×6 for the maxilla. This way of restoring the edentulous jaw with fixed prosthesis is a treatment concept, which is described but not frequently present in clinical research. It is concluded that cross-arch fixed prostheses require a smaller number of implants than when segmentation of the frameworks is planned.

Survival of a prosthesis means that the same prosthesis, or at least the same type of prosthesis, is still in function at the end of the reported study period. It does not mean that complication did not occur or that repairs and adaptation were not necessary. Some studies observed temporary functional problems with phonation, diction, cheek and lip biting with fixed prosthesis. These were observed

already in the 1980s¹⁰⁶, and now again reported with the recent All-on-4 technique¹⁰⁷.

The prostheses-related complications that were encountered also reflect the techniques typically used to fabricate the prostheses. Screw loosening was frequently reported, as well as chipping of resin denture base material or of resin denture teeth, and some fractures of frameworks occurred. Cantilever fracture, as could be expected, was not specifically reported and the percentage of framework fractures was low among all complications, but is accompanied by higher investment and costs for repair. Fracture and technical complications of provisional prostheses that were regularly utilised when doing immediate loading were often observed. Thus immediate loading may be a comfortable and quick solution, as expressed by measurements with the OHIP questionnaire⁵¹ but accompanied by higher costs. A systematic review found a high complication rate with fixed prostheses. Although these events may not lead to complete failures, they require a considerable amount of repair and maintenance, which means time and cost¹⁰⁸.

By means of modern CAD CAM technologies with titanium and high strength ceramics, the crossarch fixed prostheses supported by 4 to 6 implants is taken up again with a titanium or zirconia framework and optimised design, mostly exhibiting cantilevers. Such frameworks are processed in one piece, are of high precision and are lightweight as compared with metal-alloys. This evolution of technologies will translate into a better predictability of treatment outcomes and will simultaneously enhance more uniform material quality. Laboratory studies that were based on real patient cases confirmed high precision of fit and accuracy with titanium and zirconia using different CAD CAM technologies¹⁰⁹.

These days, computer assisted planning has shown that the feasibility of implant-supported prostheses becomes more predictable with regard to the available bone, the need of tissue replacement, the number of implants to be optimally placed and aesthetics when using these methods^{13,110-112}. Modern technologies will set future directions in planning and fabrication prostheses for the edentulous jaw.

Conclusions

Long-term results and RCTs comparing different numbers of implants and designs for fixed prostheses in the edentulous jaws are not available. The selected articles of the present review exhibit a great heterogeneity and differences in methodology to report on survival of implants, prostheses, crestal bone loss and complications. In spite of a dispersion of results, similar outcomes are reported with regard to survival, bone stability and with a different number of implants per jaw. The fact that such data do not show up indicates that the number of implants is not a major issue.

The review cannot show which other parameters influenced the treatment concepts and subsequently the selection of the number of implants. The size of the jaw, inter-jaw relation (sagittal class) opposing dentition, minimum or maximum distance between adjacent implants etc. were not reported to be used as diagnostic research criteria. However, the overwhelming majority of articles dealing with standard surgical procedures to rehabilitate edentulous jaws report on 4 to 6 implants. The latter number appeared more frequently in studies on immediate loading, while the All-on-4 concept brings another reduction to 4 or rarely 5 implants.

Since the 1990s, it was proven that there is no need to install as much implants as possible in the available jawbone²². Even 4 implants can suffice to support cross-arch prostheses if implants are $\geq 10 \text{ mm long}^{22,38}$.

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Functional jaw muscle assessment in patients with a full fixed prosthesis on a limited number of implants: A review of the literature

Key words functional evaluation, implant-supported fixed rehabilitation, masticatory muscles

Background: Full fixed prosthesis on a limited number of implants (FFP) are a viable treatment option for edentulous patients with a reduced amount of residual bone. Jaw muscular function in FFP patients has been evaluated in several studies, however heterogeneous data emerge from literature. **Purpose:** The aim of this review of the literature was to assess the function of jaw muscles in edentulous patients restored with full fixed prostheses on a limited number (\leq 6) of implants, as compared to dentate subjects and edentulous subjects wearing dentures, implant-supported overdentures or full fixed prostheses supported by more than six implants.

Materials and methods: An electronic search of databases up to December 2013 was performed. The articles were selected using specific inclusion criteria, independent of the study design.

Results: A total of 1598 records were identified. After removing the duplicates and excluding records based on title and abstract, only 37 eligible records were identified. After full-text review, seventeen studies were selected for analysis according to the inclusion criteria. From the included studies, only one evaluated masseter muscle thickness in a cross sectional study by means of ultrasound, while the 16 remaining papers evaluated muscular function by using electromyography (EMG). Those studies analysed several heterogeneous parameters throughout the execution of five functional tests and were therefore described and pooled according to the following task categories: clenching; swallowing; reflex and fatigue for statics; and chewing for dynamics.

Conclusions: The results of selected studies seem to indicate that, compared to dentate controls, FFP patients display a global satisfactory neuromuscular equilibrium in static activities, but still have some impairment during chewing.

Conflict-of-interest statement: The authors declare that they have no conflict of interest.

Introduction

After tooth extraction, the alveolar process undergoes an extended resorption¹. In completely edentulous subjects, the reduced bone height in posterior mandibular and maxillary areas confines implant placement to the median regions, thus limiting the prosthetic treatment options. As reported in several

studies for edentulism, full fixed implant-supported restorations significantly increase patient satisfaction and masticatory function compared to implant-retained prostheses or dentures^{2,3}. However, when severe jaw atrophy occurs, important bone augmentation/regenerative surgeries are needed to allow implant placement in posterior areas that support distal prosthesis extensions. Augmentation proce-



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Prof Claudia Dellavia Academic Researcher and Assistant Professor of Human Anatomy, Via Mangiagalli, 31, 20133 Milano, Italy Tel: +39 02 503 15405 Email: claudia.dellavia@unimi.it dures are operator-dependent, invasive, expensive, and with a high risk of complication. Longer time intervals are also imposed to complete the rehabilitation⁴.

The placement of distally tilted implants^{5,6} or distal short implants was proposed to improve bone anchorage and prosthetic support on a limited number of implants in the frontal areas, thus avoiding regenerative surgeries. Studies report promising results at short and long-term evaluations for the All-on-four and All-on-six treatment approaches ^{7,8}. From a masticatory point of view, direct and indirect methods have been used to assess the function of jaw muscles in edentulous patients wearing prostheses on implants⁹. Direct methods use instruments (electromyography, ultrasounds) to measure muscular tasks in both static (clenching, interarch stability) and dynamic (chewing, neuromuscular coordination) situations^{10,11}. Otherwise indirect methods deduce the efficiency of mastication by measuring the bite force, the effects of chewing on food crumbling/breaking down and mixing, and the mastication time, until all of the food bolus is swallowed^{12,13}. However, these techniques have different and specific outcomes, thus heterogeneous data on masticatory function emerge from the literature.

The aim of the present review was to assess the function of jaw muscles in edentulous patients restored with full fixed prosthesis on a limited number (\leq 6) of implants (full fixed prosthesis or FFP), compared to dentate subjects and edentulous subjects wearing dentures, implant-supported overdentures or FFP on a higher number (>6) of implants.

Methods

Eligibility criteria

Types of studies

The inclusion criteria for studies were: clinical trials and randomised controlled clinical trials published in English (no publication date or publication status was imposed); no unpublished studies were included.

Types of participants

Patients of any age and gender treated for complete maxillary and/or mandibular edentulism were considered.

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Types of interventions and criteria for inclusion/exclusion

Trials that assessed by using direct methods (electromyography or EMG, ultrasonography) jaw muscle function in edentulous patients restored with full fixed prosthesis on up to six implants, compared with patients restored with dentures, removable implant retained prostheses, or full fixed prostheses on more than six implants, or dentate patients, were included.

Studies evaluating jaw muscle function by indirect methods (i.e. food mixing, food crumbling/breaking down, mastication time until the entire food bolus is swallowed, bite force, pattern of movement), were excluded.

Studies evaluating patients treated with mandibulectomy for oncologic reasons, or patients that underwent bone augmentation/regenerative procedure prior to implant placement were also excluded.

Types of outcomes

The primary outcome was the assessment of neuromuscular function of jaw muscles in edentulous patients restored with full fixed prosthesis on up to six implants.

Search strategy

Studies were identified by the Medline (Pub Med) electronic databases and the last search was performed on 30 December, 2013.

Hand search by scanning reference lists of included articles and reviews, as well as consultation with experts in the field were performed. Authors were contacted in order to acquire missing information.

The search terms were: 'EMG'; 'Electromyography'; 'Temporal'; 'Fixed dental prosthesis'; 'All-onfour'; 'All-on-six'; 'Dental implant'; 'Oral implant'; 'Full fixed prosthesis'; 'Limited number of dental implants'; 'Masseter'; 'Reduced number of den-

tal implants'; 'Jaw muscle assessment'; 'Masticatory muscle assessment'; 'Jaw muscle'; 'Masticatory muscle'; and 'Chewing'. They were used alone or in combination using Boolean operators OR and AND.

Study selection

Two independent reviewers (GP and RR) first excluded irrelevant records by their title and abstract. In order for them to be included in the review, the full texts of the remaining papers were evaluated by two independent reviewers (CD and GP); disagreements between reviewers were solved by consensus.

Data extraction and management

To perform a statistical comparison between articles, studies that used similar protocols were selected and the data of comparable outcome variables were extracted. The data extracted from studies reporting comparable outcomes were imported in the software RevMan (Review Manager [RevMan] Version 5.2, 2012, The Nordic Cochrane Center, The Cochrane Collaboration, Copenhagen, Denmark) and submitted to meta-analysis. A random effect model was chosen. The estimates of the various parameters were expressed as mean difference together with 95% confidence intervals (CI). The statistical evaluation was conducted considering the patient as the analysis unit. The outcomes were presented as forest plots.

Results

Search

A total of 1598 records were identified from all databases and by hand search. After removing the duplicates and excluding records (based on title and abstract) because they were non-relevant, only 37 records were selected. Full-texts of the selected records were carefully read and 20 articles were excluded because they did not meet the inclusion criteria. Papers excluded at this second step and reasons for exclusion were reported in Table 1¹²⁻³¹. Fig 1 depicts the screening process. At the end, a total of 17 articles were included in this review (Table 2).

Table 1 Excluded studies and reasons for exclusion

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|---|---|
| Study | Reason for exclusion |
| Akeel et al, 1993 ¹⁴ | Masticatory efficiency evaluated by chewing Optosil tablets |
| Berretin-Felix et al, 2009 ¹⁵ | Masticatory function evaluated with tactile sensitivity of the face and observation of food intake, masticatory type, formations of bolus and pain during mastication. Swallowing evaluated by observation of clinical signs related to the oral and pharyngeal stages of swallowing, as well as the presence of food residue |
| Book et al, 1992 ¹⁶ | Masticatory function evaluated by registrations of mandibular movement characteristics and maximal bite force |
| Carlsson & Lindquist, 1994 ¹⁷ | Evaluated maximal occlusal force or mastication efficiency index |
| Albuquerque et al, 2000 ¹⁸ | Masticatory function evaluated by mastication tests and psychometric evaluations using visual analog scales and categorical scales |
| Dellavia et al, 2007 ¹⁹ | Enrollment of hemimandibulectomy-reconstructed patients |
| Haraldson & Zarb, 1988 ²⁰ | Jaw muscle function evaluated by assessment of bite force |
| Jemt et al, 1985 ²¹ | Chewing pattern evaluated by assessment of mandibular movement |
| Jemt & Lindqvist, 1985 ²² | Chewing pattern evaluated by assessment of mandibular movement |
| Jemt, 1986 ²³ | Chewing pattern evaluated by assessment of mandibular movement |
| Jemt & Carlsson, 1986 ²⁴ | Masticatory function assessed by chewing effi- ciency index and bite force |
| Karlsson & Jemt, 1991 ²⁵ | Masticatory rhythmical pattern assessed by registration of masticatory cycle duration, mandibular velocity and displacement |
| Lindquist & Carlsson, 1985 ²⁶ | Masticatory function evaluated by means of a questionnaire, a comminution test for chewing efficiency and bite measurements |
| Lundqvist & Haraldson, 1990 ²⁷ | Evaluation of occlusal relationship, chewing force, chewing efficiency and interocclusal threshold |
| Lundqvist & Haraldson, 1992 ²⁸ | Evaluation of occlusal relationship, chewing force, chewing efficiency and interocclusal threshold |
| Luraschi et al, 2012 ¹³ | Evaluation of active tactile sensitivity and bite force |
| Matsui et al, 1996 ¹² | Enrollment of patients with tumours of the oral cavity and mandibulectomy. Chewing performance evaluated by a low-adhesive, colourdeveloping, chewing-gum system |
| Mericske-Stern et al, 2000 ²⁹ | Measurements of bite force |
| Roumanas et al, 2006 ³⁰ | Masticatory and swallowing threshold performance assessed by test food |
| Yan et al, 2008 ³¹ | Full-fixed prosthesis sustained by a large number of implants |

 Table 2
 Characteristics of the included studies.

| Study | Patients group (n) | Mean age in years (range) | Maxillary prosthetic rehabilitation | Mandibular prosthetic rehabilitation | Number of implants in FFP | Period of edentulism (months) | Follow-up (months) |
|--|---------------------------------------|---|--|---|----------------------------------|-------------------------------|-----------------------|
| Haraldson et al, 1979 ³⁷ | A) 13, B) 10 | A) 56 (42–59), B) 55 (42–64) | A) FFP or PFP, B) Dentate | A) FFP or PFP, B) Dentate | 3–8 (maxilla), 4–6 (mandible) | 6-66 Ssen | 2 |
| Haraldson & Ingervall, 1979 ³⁸ | A) 13, B) 10 | A) 56 (42–59), B) 55 (42–64) | A) FFP or PFP, B) Dentate | A) FFP or PFP, B) Dentate | 3-8 (maxilla), 4-6 (mandible) | 6–66 | 30 |
| Haraldson, 1983 ³⁹ | A) 13, B) 10 | A) 56 (42–59), B) 55 (42-64) | A) FFP or PFP, B) Dentate | A) FFP or PFP, B) Dentate | 3–8 (maxilla), 4–6 (mandible) | 6–66 | 30 |
| Bonte & van Steenberghe, 1991 ⁴³ | A) 5, B) 2, C), 6, D) 2, E) 2 | \ | A) FFP, B) FFP, C) FFP, D) Partially dentate, E) Dentate | A) FFP, B) PFP, C) Partially dentate, D) Partially dentate, E) Dentate | \ | \ | \ |
| Feine et al, 1994 ³⁴ | A) 8, B) 8 | 30–62 | A) Denture, B) Denture | A) FFP then Overdenture, B) Overdenture then FFP | 4–5 | 120 | 2 |
| Duncan et al, 1992 ⁴⁶ | A) 10, B) 10, C) 10 | 57.7 | A) Denture, B) Denture, C) Dentate | A) Denture, B) FFP, C) Dentate | 4–5 | \ | \ |
| Jacobs & van Steenberghe, 1995 ⁴⁵ | A) 8, B) 2, C) 10, D) 10, E) 10 | 56 (24–72) | A) FFP, B) PFP, C) PFP, D) Denture, E) Dentate | A) FFP, B) FFP, C) Dentate, D) Overdenture, E) Dentate | 4–6 | \ | \ |
| Jacobs et al, 1995 ³² | A) 10, B) 7 | A) 56 (40–68), B) 50 (34–62) | A) Denture / Dentate, B) FFP/ Denture/Dentate | A) Overdenture, B) FFP/Denture/Dentate | 4–7 | A) 168 B) 156 | up to 24 |
| Jacobs & van Steenberghe, 1993 ⁴⁴ | A) 16, B) 20, C) 9, D) 8 | A) 50 (33–67), B) 60 (46–82), C) 65 (52–64), D) 45 (26–64) | A) Denture, B) Denture, C) FFP/Denture, D) Dentate | A) Denture, B) Overdenture, C) FFP/Denture, D) Dentate | 5–6 | A) 180, B) 80, C) 48 | 12 |
| Ferrario et al, 2004 ³⁶ | A) 7, B) 7, C) 5 | A) 58 (45–75), B) 65 (45–79, C) 53 (45–57) | A) FFP, B) Denture, C) Dentate | A) FFP, B) Overdenture, C) Dentate | 6 (maxilla), 6 (mandible) | \ | A) 6, B) 3 to 6 |
| Berretin-Felix et al, 2008 ³³ | 15 | 66 (60–76) | Denture | Denture (FFP after surgery) | 5 | 60 | 18 |
| Tartaglia et al, 2008 ¹⁰ | A) 5, B) 5, C) 7, D) 8 | A) 61 (50–71), B) 60 (52–66), C) 64 (54–80), D) 51 (40–69) | A) FFP, B) Denture, C) FFP/Dentate or teeth-supported fixed prosthesis, D) Dentate | A) FFP, B) FFP, C) FFP/Dentate or teeth-supported fixed prosthesis, D) Dentate | 6 (maxilla), 6 (mandible) | \ | 6 |
| Bersani et al, 2011 ⁴¹ | A) 28, B) 28 | A) 46–85, B) 45–82 | A) Denture, B) Dentate | A) FFP, B) Dentate | 5 | \ | \ |
| Grigoriadis et al, 2011 ⁴⁰ | A) 13, B) 13 | A) 71 (58-82), B) 66 (59-79) | A) FFP, B) Dentate | A) FFP, B) Dentate | 6 (maxilla), 4–5 (mandible) | \ | 12 |
| Dellavia et al, 2012 ³⁵ | A) 10, B) 8, C) 8 | A) 61 (50–74), B) 62 (53–73), C) 60 (56-69) | A) Denture, B) FFP, C) Dentate | A) FFP, B) FFP, C) Dentate | 4 (maxilla), 4 (mandible) | \ | 12 |
| Muller et al, 2012 ¹¹ | A) 20, B) 20, C) 20, D) 20 | A) 68, B) 61, C) 68, D) 66 | A) Denture, B) FFP C) Denture, D) Dentate | A) Overdenture, B) FFP, C) Denture, D) Dentate | 6-8 for arch | 84–108 | 12 |
| De Rossi et al, 2013 ⁴² | A) 21, B) 21, C) 21 | 58 (32–75) | A) FFP, B) Denture, C) Dentate | A) FFP, B) Denture, C) Dentate | 4 (maxilla), 4 (mandible) | \ | 6 |
| | | | | | | | |

 $PFP = implant - supported \ partial \ fixed \ prosthesis \ we are rs; \ FFP = implant - supported \ full \ fixed \ prosthesis \ we are rs.$

Between selected studies (17), only one evaluated muscle thickness in a cross sectional study, and was reported separately¹¹. Müller et al¹¹ observed by means of ultrasound scanners the masseter muscle thickness of dentate subjects and edentulous patients restored with: (i) maxillary dentures and mandibular implant-supported overdentures (C/OD); (ii) upper and lower implant-supported fixed prosthesis (FFP/FFP); or (iii) conventional upper and lower complete dentures (C/C). The authors reported the thickest muscle in dentate patients and the thinnest in the C/C group (P <0.0001), and a lower but not significantly different value in FFP/FFP and C/OD groups than dentate.

All of the 16 remaining papers (Tables 3 to 7) evaluated muscular function by means of EMG and analysed several parameters throughout the execution of functional tests (i.e. clenching, maximum voluntary contraction). For this reason the articles were described and pooled in the following task categories: (i) fatigue; (ii) swallowing; (iii) muscle reflex; (iv) clenching; (v) chewing.

All studies were cross-sectional, except two that were longitudinal^{32,33}, and one within-subject crossover trial³⁴. No randomised clinical trials were performed. Of the 17 included studies, 3 have been performed in Italy^{10,35,36}, 4 in Sweden³⁷⁻⁴⁰, 3 in Brazil^{33,41,42}, 4 in Belgium^{32,43-45}, 1 in Canada³⁴, 1 in the US⁴⁶ and 1 in Switzerland¹¹. All the studies were conducted at universities.

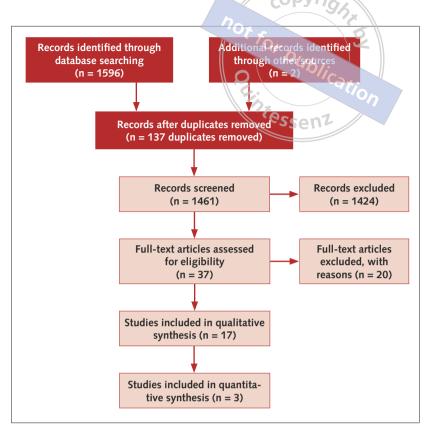


Fig 1 Flowchart of the study selection process.

Fatigue

The monitoring of muscle performance by assessing the fatigue task was done in two of the selected studies^{32,44}. The resistance to fatigue and shifts in the power spectrum of the masseter muscle during a submaximal (50%) clenching effort was investigated. The authors observed that the EMG signal significantly

Table 3 Main outcomes of the included studies evaluating muscular fatigue.

| Study | Group (n) | Measured parameter | Results | | | |
|-------------------------------------|---------------------|---|--|--|--|--|
| Jacobs et al, 1995 ³² | A) Overdenture (10) | 1) EMG amplitude range (μV) with and without fatigue | FFP increase EMG amplitude after 2 years | | | |
| | B) FFP (7) | 2) MPF (Hz) with and without fatigue | Only Overdenture wearers maintain a significant MPF downshift during sustained clench after rehabilitation | | | |
| | | 3) Endurance time (s) | No differences in endurance time are measured | | | |
| Jacobs & van Steenberghe, | A) Denture (16) | 1) EMG amplitude range (μV) with and without fatigue | Dentate and Overdenture patients show a significant EMG amplitude decrease after fatigue effect | | | |
| 1993 ⁴⁴ | B) Overdenture (20) | 2) MPF (Hz) with and without fatigue | Only FFP patients do not show a significant reduction in MPF after fatigue | | | |
| | C) FFP (9) | 3) Endurance time (s) | No differences in endurance time are measured | | | |
| | D) Dentate (8) | | | | | |

FFP = implant-supported full fixed prosthesis wearers; MPF = EMG mean power frequency.

Table 4 Main outcomes of the included studies evaluating swallowing activity.

| Study | Group (n) | Measured parameter | Results PUb/; |
|---|--------------------------------|---|---|
| Haraldson & Ingervall, 1979 ³⁸ | A) FFP (13) B) Dentate (10) | Amplitude EMG (μV) of AT, PT, M | No differences between groups |
| Berretin- Felix et al, 2008 ³³ | FFP (15) | Amplitude EMG (µV RMS) of M, submental muscle, superior orbicularis | With FFP significant reduction of EMG amplitude only for M at 6 and 18 months |

FFP = implant-supported full fixed prosthesis wearers; AT = anterior temporalis muscle; PT = posterior temporalis muscle; M = masseter muscle; RMS = root mean square.

Table 5 Main outcomes of the included studies evaluating muscular reflexes.

| Study | Group (n) | Measured parameter | Results | | | | |
|------------------------------------|---|---|--|--|--|--|--|
| Bonte & van | A) Dentate (2) | Post stimulus EMG com- | A) PSEC detected in both subjects (QR wave) | | | | |
| Steenberghe, 1991 ⁴³ | B) FFP (5) | plex (PSEC) after mechan- ical tooth stimulus (P, Q, | B) no PSEC | | | | |
| 1551 | C) FFP/PFP (2) | R, S, T waves) | C) no PSEC | | | | |
| | D) FFP/partially edentulous (6) | | D) PSEC in 5 patients (QR wave) | | | | |
| | E) Partially edentulous (2) | | E) no PSEC | | | | |
| Duncan et al, | A) Dentate (10) | SPUR (silent period of | The time of onset for the unloading reflexes was not signifi- | | | | |
| 1992 ⁴⁶ | B) Denture (10) | the unloading reflexes) latency (ms) | cantly different among the three groups | | | | |
| | C) Denture/FFP | latericy (ms) | | | | | |
| Jacobs & van | A) FFP (8) | Post stimulus EMG com- | FFP have no reflexes in 7 of 8 patients. 1 patient has QR wave | | | | |
| Steenberghe, 1995 ⁴⁵ | B) FFP with only one natural tooth in the maxilla (2) | plex (PSEC) after mechan- ical tooth stimulus | Both FFP patients with natural teeth have a reflex response | | | | |
| | C) PFP (10) | | 7 of 10 patients with PFP have reflex responses | | | | |
| | D) Denture/PFP (10) | | Only 5 patients with denture have reflexes with QR morphology | | | | |
| | E) Dentate (10) | Latencies Q-R-S-T wave (ms) | T wave only appears in the Dentate subjects | | | | |

FFP = implant-supported full fixed prosthesis wearers; PFP = implant-supported partial fixed prosthesis wearers.

increased after fixing a prosthesis on implants and that it reached the levels of dentate control patients, thus indicating an improvement in masticatory muscle performance after FFP. Otherwise, patients restored with complete dentures or overdentures on implants had significantly lower EMG amplitudes than dentate controls. A significant downward indication of the mean power frequency was also observed for all patients (dentate, restored with dentures or overdentures), apart from those with FFP.

Swallowing

The amplitude of the muscle activity was recorded to assess muscular function during swallowing^{33,38}. In a longitudinal interventional study³³, the authors observed a decrease of masseter muscular activity

after the rehabilitation of patients wearing removable dentures in both jaws with implant-supported prostheses. A further cross-sectional study failed to find differences in EMG amplitude of masseter and anterior/posterior temporal muscles between dentate and patients with FFP³⁸.

Reflex

Studies evaluated the presence/absence and onset of a periodontal-masseteric reflex elicited by the application of a mechanical stimulus on a tooth. In particular, a standardised tap was delivered to an osseointegrated implant and the subsequent variations in the mean EMG activity during clenching were recorded as the 'post-stimulus complex' (PSEC), characterised by downward- and upward-

Table 6 Main outcomes of the included studies evaluating teeth clenching.

| Study | Group (n) | Measured parameter | Results P46/: | | | |
|------------------------------------|---------------------|---|--|--|--|--|
| Haraldson et | | Mean EMG voltage (μV) during: | No group differences | | | |
| al, 1979 ³⁷ | A) FFP (13) | 1) postural position | William Non | | | |
| | | 2) maximal biting | intessen2 | | | |
| | B) Dentate (10) | 3) biting with gentle force | | | | |
| | | 4) biting with force equivalent to that used during mastication | | | | |
| Jacobs & van | A) Denture (16) | EMG amplitude range (µV) during clench- | Dentate subjects have greater EMG activity than denture | | | |
| Steenberghe, 1993 ⁴⁴ | B) Overdenture (20) | ing | and Overdenture wearers. Overdenture patients have greater EMG activity than denture wearers | | | |
| 1555 | C) FFP (9) | | greater Livio activity than dentare wearers | | | |
| | D) Dentate (8) | | | | | |
| Ferrario et al, | A) Denture (7) | Standardised EMG indexes (µV/µV%) | Dentate and FFP patients show greater AT symmetry | | | |
| 2004 ³⁶ | B) FFP (7) | during clenching | during clenching. Maximal EMG activity result greater i Dentate than FFP and denture wearers | | | |
| | C) Dentate (5) | | Defitate than 111 and defitate wearers | | | |
| Tartaglia et | A) FFP (5) | Standardised EMG indexes (µV/µV%) | FFP show a significantly smaller AT to M ratio than other | | | |
| al, 2008 ¹⁰ | B) Denture/FFP (5) | during clenching. | subjects. No other differences are measured | | | |
| | C) FFP/Dentate (7) | | | | | |
| | D) Dentate (8) | | | | | |
| Bersani et al, | | EMG amplitude (μV) during: | | | | |
| 201141 | A) Denture/FFP (28) | 1) maximal voluntary clench | Great EMG values in R AT at rest in Dentate subjects Smaller EMG values in R M in Dentate subjects Great L AT activity in FFP during R and L laterality; smaller R and L M in Dentate subjects during right laterality | | | |
| | | 2) protrusion | | | | |
| | B) Dentate (28) | 3) left and right laterality | | | | |
| | | 4) rest | Smaller R M and L AT in Dentate subjects at rest | | | |
| Dellavia et | A) Denture/FFP (10) | Standardised EMG indexes (µV/µV%) | Rehabilitated subjects show a significantly greater lateral | | | |
| al, 2012 ³⁵ | B) FFP (8) | during maximal clenching. | displacement effect (torque coefficient). No other differences during maximal clenching are measured | | | |
| | C) Dentate (8) | | erices during maximal ciencing are measured | | | |
| De Rossi et | A) FFP (21) | Standardised EMG indexes (µV/µV%) | During clenching, denture wearers show a lower R M | | | |
| al, 2013 ⁴² | B) Denture (21) | during maximal clenching and rest pos- ition. | activity than Dentate and FFP. At rest, denture wearers showed greater AT activity than other subjects. The L AT resulted in being more active in FFP than Dentate | | | |
| | C) Dentate (21) | tuon. | | | | |
| D : 1 1 1 1 | (, 550 ; , , , , , | 16 116 1 11 1 | tamparalis muselo M – massatar muselo | | | |

R = right, L = left; FFP = implant-supported full fixed prosthesis wearers; AT = anterior temporalis muscle; M = masseter muscle.

going waves. Latencies, peak latencies and surfaces of those waves can be quantified on the basis of a confidence interval computed from the full-wave rectified and averaged EMG physiologic fluctuations recorded during the pre-stimulus period^{43,45}.

In edentulous subjects with FFP in both jaws, the absence of a reflex response after application of a mechanical stimulus was observed^{43,45}. However, when patients were partially edentulous or when the FFP was occluding with a denture, a reflex could be

observed in some patients without differences in the onset of the jaw-unloading reflex^{43,45,46}.

Clenching

This task was analysed in seven of the selected reports^{10,35-37,41,42,44}. No homogenous data arose from these studies evaluating EMG activity on patients restored with FFP, compared to dentate or patients wearing dentures. In two studies, muscular activity was significantly higher in dentate

 Table 7
 Main outcomes of the included studies evaluating a chewing task

| Study | Group (n) | Measured parameter | Results | | | | | |
|---|--|--|---|--|--|--|--|--|
| • | - | | 3461 | | | | | |
| Haraldson & Ingervall, | A) FFP (13) | Chewing duration (s) Chewing cycles (n) | Duration significantly longer in FFP than in Dentate subjects for all muscles No differences in chewing rate between FFP and Dentate patients and | | | | | |
| 1979 ³⁸ | | | between different foods | | | | | |
| | B) Dentate (10) | Maximal mean amplitude (μV) and duration of the closing phase of each cycle (ms) | No differences in amplitude, but longer duration in FFP than in Dentate subjects | | | | | |
| | | 4) Onset of activity – peak per muscle in the closing phase | Onset of activity in M earlier in FFP than in Dentate subjects | | | | | |
| Haraldson, 1983 ³⁹ | A) FFP (13) | 1) Maximal mean amplitude (µV) in the closing phase of first 3 and last 3 cycles | No differences between FFP and Dentate patients | | | | | |
| | B) Dentate (10) | 2) Duration of the closing phase of first 3 and last 3 cycles (ms) | No differences in chewing rate between FFP and Dentate subjects and between different foods | | | | | |
| | | 3) Onset of activity – peak per muscle in the closing phase | Onset of activity in M earlier in FFP than in Dentate subjects in the first 3 cycles chewing peanuts | | | | | |
| Feine et al, | A) FFP (8) | 1) Chewing duration (s) | Duration shorter in patients with Overdenture | | | | | |
| 1994 ³⁴ | B) Overdenture (8) | 2) Maximal mean amplitude (μV) | Tendency to less activity in Overdenture patients (significant only R M for bread) | | | | | |
| Ferrario et al, | A) FFP (7) | 1) Frequency (Hz) per side | No differences between groups | | | | | |
| 2004 ³⁶ | B) Overdenture (7) | 2) Confidence ellipse (%) per side | Tendency (but not significant) to smaller areas in Dentate than in FFP and Overdenture subjects | | | | | |
| | C) Dentate (5) | 3) Symmetry Masticatory Index (SMI) | Larger in FFP and Overdenture than in Dentate subjects | | | | | |
| Berretin-Felix et al, 2008 ³³ | FFP (15) 1) Median amplitude (μV) No significant differences pre- and post-surgery at any follow | | | | | | | |
| Tartaglia et | A) FFP (5) 1) Frequency (Hz) per side | | No differences between groups | | | | | |
| al, 2008 ¹⁰ | B) FFP/Denture (5) | 2) Total activity (µV) per side | Higher activity in FFP and FFP/Denture than in the other groups in both sides | | | | | |
| | C) FFP/Dentate (7) | 3) Total standardised activity (μνV/ μV%) per side | Higher activity in FFP and FFP/Denture than in the other groups in both sides | | | | | |
| | D) Dentate (8) | 4) Confidence ellipse (%) per side | Larger areas in implant patients than in Dentate (difference significant only on the left side) | | | | | |
| | | 5) SMI | No significant differences between groups | | | | | |
| Grigoriadis et al, 2011 ⁴⁰ | A) FFP (13) | 1) Normalised amplitude | Weaker increase with hard food and less reduction of signals over time in FFP than in Dentate subjects | | | | | |
| | B) Dentate (13) | 2) Chewing duration (s) | No differences between FFP and Dentate, but always increase with hard foods | | | | | |
| | | 3) Chewing cycles (n) | No differences between FFP and Dentate, but always increase with hard foods | | | | | |
| De Rossi et al, 2013 ⁴² | A) FFP (21) | Maximal mean amplitude (µV) during chewing, in habitual and non habitual chewing | During chewing and non habitual chewing FFP and Dentate were similar, R M was less active during chewing and L AT higher during non habitual chewing in Denture than in FFP and Dentate | | | | | |
| | B) Denture (21) | | | | | | | |
| | C) Dentate (21) | | | | | | | |
| Dellavia et al, 2012 ³⁵ | A) FFP/Denture (10) | 1) Frequency (Hz) per side | No differences between groups | | | | | |
| | B) FFP (8) | 2) Total standardised activity (µvV/µV%) per side | Higher activity in patients with FFP and Denture than in Dentate in both sides | | | | | |
| | C) Dentate (8) | 3) Total standardised activity (µvV/µV%) per cycle and side | Higher activity in patients with FFP and Denture than in Dentate in both sides | | | | | |
| | | 4) Total standardised activity (μνV/μV%) on the working side per side | No significant differences between groups | | | | | |
| | | 5) Confidence ellipse (%) per side | Tendency to larger areas in implant patients than in Dentate (no significance) | | | | | |
| | | 6) SMI | Lower in implant patients but significant differences only between FFP/ Denture and Dentate subjects | | | | | |

R = right, L = left; FFP = implant-supported full fixed prosthesis wearers; AT = anterior temporalis muscle; M = masseter muscle.

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| | | | | | | | | | h |
|-------------------------------------|-------------|------------------------|-------|-------|---------|-------|--------|----------------------|-----------------------------------|
| Study or Subgroup | | all fixed | | | Control | | | Mean Difference | Mean Difference |
| | Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% CI | IV, Fixed, 95% CI |
| Dellavia et al, 2012 | 83.9 | 2.4 | 8 | 85.3 | 3.3 | 8 | 22.4% | -1.40 [-4.23, 1.43] | |
| Ferrario et al, 2004 | 86.9 | 1.3 | 7 | 87.5 | 2.3 | 5 | 35.9% | -0.70 [-2.93, 1.53] | |
| Tartaglia et al, 2008 | 84.89 | 1.85 | 5 | 86.96 | 1.87 | 8 | 41.6% | -2.07 [-4.15, 0.01] | |
| | | | | | | | | | |
| Total (95% CI) | | | 20 | | | 21 | 100.0% | -1.43 [-2.77, -0.09] | |
| Heterogeneity: Chi2 = 0.78, df = | = 2 (P = 0) | .68); 1 ² = | 0% | | | | | | |
| Test for overall effect: $Z = 2.09$ | (P = 0.04) |) | | | | | | | -10 -5 0 5 10 |
| | | | | | | | | | Favours all fixed Favours control |

Fig 2 Forest plot of the mean differences in anterior temporalis index of symmetry (POC TA) during maximal voluntary clenching between patients with FFP in both jaws and dentate subjects computed in the three comparable studies 10,35,36 . A significant effect (P = 0.04) is visible: FFP patients have a lower symmetry than reference individuals.

patients than in patients with FFP36,41, while the remaining papers failed to find significant differences^{10,35,37,42,44}. Only three reports compared data from patients treated with FFP, or with overdentures or dentures^{36,42,44}. These studies found an overall decrease of muscular activity in subjects with removable prostheses, however only De Rossi et al⁴² reported a significant value. The symmetrical pattern of muscular contraction and potential lateral displacing components (i.e. the tendency of the mandible to move toward one side during a symmetric bilateral clenching, caused by unbalanced contractile activity of contralateral masseter and temporalis muscles) were analysed by three trials^{10,35,36}. Ferrario et al³⁶ observed a significantly higher symmetry in muscular activity of dentate and FFP than for overdentures. Tartaglia et al¹⁰ reported an increment of temporalis activity in patients with FFP in both jaws than in dentate subjects, while Dellavia et al³⁵ did not report any difference.

Chewing

The jaw muscle function during chewing has been analysed in seven cross-sectional studies^{10,35,36,38-40,42}, one within-subject crossover trial³⁴ and one longitudinal study³³.

Two studies compared the EMG amplitude of edentulous patients wearing dentures in both jaws or FFP and reported contrasting data^{33,42}. Berretin-Felix et al³³ did not find any difference between groups, while De Rossi et al⁴² observed a different muscle contraction pattern between groups (higher temporalis than masseter contraction in the denture group, the opposite in FFP group).

Two studies compared data from patients with FFP and with overdentures^{34,36}, and both reported no significant differences on muscular activity and

symmetry between the two prostheses. When patients with FFP were compared with dentate patients, it appeared that:

- neuromuscular coordination is higher in dentate patients than in FFP group^{10,35,36}
- two studies reported that the global muscular activity was higher in FFP than in dentate^{10,35}, while a further two studies did not find differences in EMG amplitude between groups^{39,40}
- unlike the FFP group, dentate patients modulate the muscular activity on food hardness (stronger EMG activity with hard food) and during the whole chewing sequence (decreased activity at the end of chewing act)^{39,40}
- two studies reported that duration of activity before swallowing was higher in the FFP group than in the dentate group^{38,39}, while Grigoriadis et al⁴⁰ failed to find any difference.

Data analysis

At in-depth evaluation of the parameters reported by the included studies, only three had comparable data that allowed a statistical analysis 10,35,36. These studies evaluated static and dynamic tasks in edentulous patients restored with FFP in both jaws or with FFP only in the mandible and denture in the maxilla and in a dentate control. For all the comparable parameters, the effect estimates and confidence intervals were computed by forest plot. The following parameters had significant results (Figs 2 to 14):

- Anterior temporal symmetry in maximal voluntary clenching (POC = percentage overlapping coefficient) was lower only in patients with FFP in both arches, compared to dentate.
- Chewing frequency in FFP patients (with FFP in both jaws or only in mandible) was always larger than in dentate.

| Study or Subgroup | | all fixed | | | Control | | | Mean Difference | Mean Difference |
|--|-----------------|------------------------|-------|------|---------|-------|--------|--------------------|-----------------------------------|
| | Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% CI | IV, Fixed, 95% Cl |
| Dellavia et al, 2012 | 1.5 | 0.1 | 8 | 1.3 | 0.1 | 8 | 69.0% | 0.20 [0.10, 0.30] | |
| Ferrario et al, 2004 | 1.4 | 0.2 | 7 | 1.2 | 0.2 | 5 | 12.6% | 0.20 [-0.03, 0.43] | 100 |
| Tartaglia et al, 2008 | 1.32 | 0.17 | 5 | 1.25 | 0.17 | 8 | 18.4% | 0.07 [-0.12, 0.26] | |
| | | | | | | | | | 1.94 |
| Total (95% CI) | | | 20 | | | 21 | 100.0% | 0.18 [0.09, 0.26] | 200 |
| Heterogeneity: Chi ² = 1.47 | df = 2 (P = 0) | .48); 1 ² = | 0% | | | | | | |
| Test for overall effect: $Z = 4$ | 4.24 (P < 0.00) | 01) | | | | | | | -0.5 -0.25 0 0.25 0. |
| | | | | | | | | | Favours all fixed Favours control |
| | | | | | | | | | -30111 |

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Fig 3 Forest plot of the mean differences in the right side chewing frequency between patients with FFP in both jaws and dentate subjects computed in the three comparable studies 10,35,36 . A significant effect (P < 0.0001) in favour of the dentate subjects is visible.

| | all fixed | | | Control | | | Mean Difference | Mean Difference |
|-------------|------------------------|---------------------------------|---|--|---|--|---|---|
| Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% CI | IV, Fixed, 95% CI |
| 1.4 | 0.2 | 8 | 1.3 | 0.1 | 8 | 62.9% | 0.10 [-0.05, 0.25] | |
| 1.4 | 0.1 | 7 | 1.2 | 0.3 | 5 | 20.2% | 0.20 [-0.07, 0.47] | |
| 1.48 | 0.22 | 5 | 1.24 | 0.33 | 8 | 16.9% | 0.24 [-0.06, 0.54] | |
| | | | | | | | | |
| | | 20 | | | 21 | 100.0% | 0.14 [0.02, 0.27] | |
| = 2 (P = 0) | .65); 1 ² = | 0% | | | | | | |
| (P = 0.02) | | | | | | | | -0.5 -0.25 0 0.25 0.5 |
| | | | | | | | | Favours all fixed Favours control |
| | Mean 1.4 1.4 1.48 1.48 | 1.4 0.2 1.4 0.1 1.48 0.22 | Mean SD Total 1.4 0.2 8 1.4 0.1 7 1.48 0.22 5 20 20 | Mean SD Total Mean 1.4 0.2 8 1.3 1.4 0.1 7 1.2 1.48 0.22 5 1.24 20 | Mean SD Total Mean SD 1.4 0.2 8 1.3 0.1 1.4 0.1 7 1.2 0.3 1.48 0.22 5 1.24 0.33 20 20 20 20 | Mean SD Total Mean SD Total 1.4 0.2 8 1.3 0.1 8 1.4 0.1 7 1.2 0.3 5 1.48 0.22 5 1.24 0.33 8 2 20 21 21 | Mean SD Total Mean SD Total Weight 1.4 0.2 8 1.3 0.1 8 62.9% 1.4 0.1 7 1.2 0.3 5 20.2% 1.48 0.22 5 1.24 0.33 8 16.9% 20 21 100.0% | Mean SD Total Mean SD Total Weight IV, Fixed, 95% CI 1.4 0.2 8 1.3 0.1 8 62.9% 0.10 [-0.05, 0.25] 1.4 0.1 7 1.2 0.3 5 20.2% 0.20 [-0.07, 0.47] 1.48 0.22 5 1.24 0.33 8 16.9% 0.24 [-0.06, 0.54] 2 (P = 0.65); 12 = 0% 21 100.0% 0.14 [0.02, 0.27] |

Fig 4 Forest plot of the mean differences in the left side chewing frequency between patients with FFP in both jaws and dentate subjects computed in the three comparable studies 10,35,36 . A significant effect (P = 0.02) in favour of the dentate subjects is visible.

| Study or Subgroup | fix | ked/mobi | le | | Control | | | Mean Difference | Mean Difference | |
|--|---|----------|-------|------|---------|-------|--------|---------------------|-----------------------------------|--|
| | Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% CI | IV, Fixed, 95% Cl | |
| Dellavia et al, 2012 | 1.5 | 0.1 | 10 | 1.3 | 0.1 | 8 | 80.7% | 0.20 [0.11, 0.29] | | |
| Tartaglia et al, 2008 | 1.24 | 0.17 | 5 | 1.25 | 0.17 | 8 | 19.3% | -0.01 [-0.20, 0.18] | | |
| | | | | | | | | | | |
| Total (95% CI) | | | 15 | | | 16 | 100.0% | 0.16 [0.08, 0.24] | | |
| Heterogeneity: Chi ² = 3.79, df = | Heterogeneity: $Chi^2 = 3.79$, $df = 1$ ($P = 0.05$); $1^2 = 74\%$ | | | | | | | | | |
| Test for overall effect: $Z = 3.74$ ($P = 0.0002$) | | | | | | | | | -0.2 -0.1 0 0.1 0.2 | |
| | | | | | | | | Fav | ours fixed/mobile Favours control | |

Fig 5 Forest plot of the mean differences in the right side chewing frequency between patients with mandibular FFP and maxillary denture and dentate subjects computed in the three comparable studies 10,35,36 . A significant effect (P = 0.0002) in favour of the dentate subjects is visible.

| Study or Subgroup | fix | ked/mobi | le | Control | | Control | | | Mean Difference | Mean Difference |
|---|--|----------|-------|---------|------|---------|--------|--------------------|---------------------------------|-----------------|
| | Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% CI | IV, Fixed, 95% Cl | |
| Dellavia et al, 2012 | 1.5 | 0.1 | 10 | 1.3 | 0.1 | 8 | 87.4% | 0.20 [0.11, 0.29] | | |
| Tartaglia et al, 2008 | 1.3 | 0.1 | 5 | 1.24 | 0.33 | 8 | 12.6% | 0.06 [-0.18, 0.30] | | |
| _ | | | | | | | | | | |
| Total (95% CI) | | | 15 | | | 16 | 100.0% | 0.18 [0.10, 0.27] | | |
| Heterogeneity: Chi ² = 1.1 0, df | Heterogeneity: $Chi^2 = 1.1 O$, $df = 1 (P = 0.29)$; $1^2 = 9\%$ | | | | | | | | | |
| Test for overall effect: Z = 4.11 | (P < 0.000) | 01) | | | | | | -Ó.5 | -0.25 0 0.25 0.5 | |
| | | | | | | | | Favou | rs fixed/mobile Favours control | |

Fig 6 Forest plot of the mean differences in the left side chewing frequency between patients with mandibular FFP and maxillary denture and dentate subjects computed in the three comparable studies 10,35,36 . A significant effect (P < 0.0001) in favour of the dentate subjects is visible.

| all fixed | | | Control | | | | Mean Difference | Mean Difference |
|-------------|-----------------------------|---|--|--|--|--|---|---|
| Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% Cl | IV, Fixed, 95% Cl |
| 53.7 | 11.9 | 8 | 69.5 | 9.5 | 8 | 83.4% | -15.80 [-26.35, -5.25] | |
| 28 | 32.1 | 7 | 67.9 | 16.7 | 5 | 11.9% | -39.90 [-67.82, -11.98] |] |
| 59.25 | 42.38 | 5 | 55.29 | 34.97 | 8 | 4.7% | 3.96 [-40.39, 48.31] | |
| | | | | | | | | |
| | | 20 | | | 21 | 100.0% | -17.74 [-27.37, -8.10] | • |
| = 2 (P = 0) |).18); 1 ² | = 42% | | | | | | |
| (P = 0.00) | 03) | | | | | | | -50 -25 0 25 50 |
| | | | | | | | | Favours all fixed Favours control |
| | Mean 53.7 28 59.25 | Mean SD 53.7 11.9 28 32.1 59.25 42.38 | Mean SD Total 53.7 11.9 8 28 32.1 7 59.25 42.38 5 = 2 (P = 0.18); 12 = 42% | Mean SD Total Mean 53.7 11.9 8 69.5 28 32.1 7 67.9 59.25 42.38 5 55.29 20 = 2 (P = 0.18); 1 ² = 42% | Mean SD Total Mean SD 53.7 11.9 8 69.5 9.5 28 32.1 7 67.9 16.7 59.25 42.38 5 55.29 34.97 20 2 (P = 0.18); 12 = 42% | Mean SD Total Mean SD Total 53.7 11.9 8 69.5 9.5 8 28 32.1 7 67.9 16.7 5 59.25 42.38 5 55.29 34.97 8 | Mean SD Total Mean SD Total Weight 53.7 11.9 8 69.5 9.5 8 83.4% 28 32.1 7 67.9 16.7 5 11.9% 59.25 42.38 5 55.29 34.97 8 4.7% 20 21 100.0% = 2 (P = 0.18); 12 = 42% 24% 100.0% | Mean SD Total Mean SD Total Weight IV, Fixed, 95% CI 53.7 11.9 8 69.5 9.5 8 83.4% -15.80 [-26.35, -5.25] 28 32.1 7 67.9 16.7 5 11.9% -39.90 [-67.82, -11.98] 59.25 42.38 5 55.29 34.97 8 4.7% 3.96 [-40.39, 48.31] 20 21 100.0% -17.74 [-27.37, -8.10] 2 (P = 0.18); 12 = 42% |

Fig 7 Forest plot of the mean differences in the symmetry masticatory index (SMI) between patients with FFP in both jaws and dentate subjects computed in the three comparable studies 10,35,36 . A significant effect (P = 0.0003) is visible: FFP patients have a lower symmetry than reference individuals during chewing.

| Study or Subgroup | fi | xed/mob | ile | | all fixed | | | Mean Difference | Mean Difference |
|--|------------|-----------|--------|-------|-----------|-------|--------|------------------------|---------------------------------|
| | Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% Cl | IV, Fixed, 95% Cl |
| Dellavia et al, 2012 | 31.3 | 22.2 | 10 | 53.7 | 11.9 | 8 | 89.4% | -22.40 [-38.44, -6.36] | |
| Tartaglia et al, 2008 | 33.76 | 31.93 | 5 | 59.25 | 42.38 | 5 | 10.6% | -25.49 [-72.00, 21.02] | 1 - 7 |
| | | | | | | | | | |
| Total (95% CI) | | | 15 | | | 13 | 100.0% | -22.73 [-37.89, -7.56] | |
| Heterogeneity: Chi ² = 0.02, df | = 1 (P = | 0.90); 12 | 9 = 0% | | | | | <u> </u> | 00 50 100 |
| Test for overall effect: Z = 2.94 | (P = 0.00) | 03) | | | | | | | 00 –50 0 50 100 |
| Test for overall effect: $Z = 2.94$ | (P = 0.00) | 03) | | | | | | | ours fixed/mobile Favours all f |

Fig 8 Forest plot of the mean differences in the symmetry masticatory index (SMI) between patients with FFP in both jaws and with mandibular FFP and maxillary denture computed in the three comparable studies 10,35,36 . A significant effect (P = 0.003) is visible: patients with FFP combined with a maxillary denture have a lower symmetry than patients with both FFP during chewing.

| Study or Subgroup | fi | ked/mobi | le | | Control | | | Mean Difference | Mean Difference |
|-------------------------------------|-------------|-----------------------|-------|-------|---------|-------|--------|-------------------------|---|
| | Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% CI | IV, Fixed, 95% CI |
| Dellavia et al, 2012 | 31.3 | 22.2 | 10 | 69.5 | 9.5 | 8 | 85.5% | -38.20 [-53.45, -22.95] | |
| Tartaglia et al, 2008 | 33.76 | 31.93 | 5 | 55.29 | 34.97 | 8 | 14.5% | -21.53 [-58.55, 15.49] | l ——— |
| | | | | | | | | | |
| Total (95% CI) | | | 15 | | | 16 | 100.0% | -35.78 [-49.88, -21.68] | |
| Heterogeneity: Chi2 = 0.67, df : | = 1 (P = 0) |).41); 1 ² | = 0% | | | | | _ | |
| Test for overall effect: $Z = 4.97$ | (P < 0.00) | 0001) | | | | | | Favo | -50 -25 0 25 50 urs fixed/mobile Favours control |

Fig 9 Forest plot of the mean differences in the symmetry masticatory index (SMI) between patients with mandibular FFP and maxillary denture and dentate reference subjects computed in the three comparable studies 10,35,36 . A significant effect (P < 0.0001) is visible: patients with FFP combined with a maxillary denture have a lower symmetry than dentate subjects during chewing.

| Study or Subgroup | | all fixed | | | Control | | | Mean Difference | Mean Difference |
|---|---|-----------|-------|-------|---------|-------|--------|--------------------|-----------------------------------|
| | Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% Cl | IV, Fixed, 95% Cl |
| Dellavia et al, 2012 | 1.721 | 1.211 | 8 | 1.04 | 0.733 | 8 | 60.6% | 0.68 [-0.30, 1.66] | + |
| Ferrario et al, 2004 | 3.792 | 2.4 | 7 | 0.784 | 0.363 | 5 | 17.9% | 3.01 [1.20, 4.81] | l |
| Tartaglia et al, 2008 | 2.55 | 1.82 | 5 | 1.144 | 0.567 | 8 | 21.6% | 1.41 [-0.24, 3.05] | l — |
| | | | | | | | | | |
| Total (95% CI) | | | 20 | | | 21 | 100.0% | 1.25 [0.49, 2.02] | |
| Heterogeneity: Chi2 = 4.97, df : | = 60% | | | | | | | | |
| Test for overall effect: $Z = 3.22$ ($P = 0.001$) | | | | | | | | | -4 -2 0 2 4 |
| | 1651 101 Overall effect. 2 = 3.22 (r = 0.001) | | | | | | | | Favours all fixed Favours control |

Fig 10 Forest plot of the mean differences in the variability of pattern contraction (confidence ellipse area) during right side chewing between patients with FFP in both jaws and dentate subjects computed in the three comparable studies^{10,35,36}. A significant effect (P = 0.001) in favour of the control group is visible.

| Study or Subgroup | fix | ked/mobi | le | | Control | | | Mean Difference | | Mea | n Diff | erence | |
|-----------------------------------|-------------|-----------|-------|-------|---------|-------|--------|-------------------|---------|---------|--------|----------|--------|
| | Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% Cl | | IV, Fi | xed, 9 | 5% CI | |
| Dellavia et al, 2012 | 3.732 | 2.335 | 10 | 1.04 | 0.733 | 8 | 34.9% | 2.69 [1.16, 4.23] | | | | | |
| Tartaglia et al, 2008 | 2.679 | 1.199 | 5 | 1.144 | 0.567 | 8 | 65.1% | 1.53 [0.41, 2.66] | | | - | | |
| | | | | | | | | | | | | | |
| Total (95% CI) | | | 15 | | | 16 | 100.0% | 1.94 [1.03, 2.84] | | | | | |
| Heterogeneity: Chi2 = 1.42, df = | = 1 (P = 0) | 0.23); 12 | = 30% | | | | | - | - | | _ | -i- | - |
| Test for overall effect: Z = 4.20 | (P < 0.00) | 001) | | | | | | | -4 | -2 | 0 | 2 | 4 |
| | | | | | | | | Fa | vours f | ixed/mo | bile F | avours c | ontrol |

Fig 11 Forest plot of the mean differences in the variability of pattern contraction (confidence ellipse area) during right side chewing between patients with mandibular FFP and maxillary denture and dentate subjects computed in the three comparable studies 10,35,36 . A significant effect (P < 0.0001) in favour of the control group is visible.

| Study or Subgroup | | all fixed | | | Control | | | Mean Difference | Mean Difference |
|--|-------------|-----------------------|-------|-------|---------|-------|--------|--------------------|-----------------------------------|
| | Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% Cl | IV, Fixed, 95% Cl |
| Dellavia et al 2012 | 1.481 | 0.51 | 8 | 0.933 | 0.395 | 8 | 82.4% | 0.55 [0.10, 1.00] | |
| Ferrario et al 2004 | 2.576 | 1.437 | 7 | 1.372 | 1.084 | 5 | 8.1% | 1.20 [-0.22, 2.63] | - |
| Tartaglia et al 2008 | 2.998 | 1.423 | 5 | 1.077 | 0.607 | 8 | 9.5% | 1.92 [0.60, 3.24] | |
| | | | | | | | | | |
| Total (95% CI) | | | 20 | | | 21 | 100.0% | 0.73 [0.33, 1.14] | |
| Heterogeneity: Chi ² = 4.21, df : | = 2 (P = 0) |).12); 1 ² | = 52% | | | | | | |
| Test for overall effect: Z = 3.53 | (P = 0.00) | 04) | | | | | | | -4 -2 0 2 4 |
| | | | | | | | | | Favours all fixed Favours control |

Fig 12 Forest plot of the mean differences in the variability of pattern contraction (confidence ellipse area) during left side chewing between patients with FFP in both jaws and dentate subjects computed in the three comparable studies 10,35,36 . A significant effect (P = 0.0004) in favour of the control group is visible.

| Study or Subgroup | fix | ked/mobi | le | | Control | | | Mean Difference | Mean Difference |
|--|-------------|-----------------------|-------|-------|---------|-------|--------|-------------------|------------------------------------|
| | Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% Cl | IV, Fixed, 95% CI |
| Dellavia et al, 2012 | 3.307 | 1.73 | 10 | 0.933 | 0.395 | 8 | 76.0% | 2.37 [1.27, 3.48] | |
| Tartaglia et al, 2008 | 3.144 | 2.192 | 5 | 1.077 | 0.607 | 8 | 24.0% | 2.07 [0.10, 4.03] | |
| | | | | | | | | | |
| Total (95% CI) | | | 15 | | | 16 | 100.0% | 2.30 [1.34, 3.26] | |
| Heterogeneity: Chi ² = 0.07, df | = 1 (P = 0) |).79); 1 ² | = 0% | | | | | // < | |
| Test for overall effect: Z = 4.67 | (P < 0.00) | 01) | | | | | | | -4 -2 0 2 4 |
| | | | | | | | | Fa | vours fixed/mobile Favours control |
| | | | | | | | | // | 1000007 |

Fig 13 Forest plot of the mean differences in the variability of pattern contraction (confidence ellipse area) during left side chewing between patients with mandibular FFP and maxillary denture and dentate subjects computed in the three comparable studies 10,35,36 . A significant effect (P < 0.00001) in favour of the control group is visible.

| Study or Subgroup | fix | ked/mobi | le | | Control | | | Mean Difference | | Mear | Differ | ence | |
|-------------------------------------|-------------|-----------------------|-------|-------|---------|-------|--------|--------------------|---------|----------|---------|----------|-------|
| | Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% Cl | | IV, Fix | ed, 95 | % Cl | |
| Dellavia et al, 2012 | 3.307 | 1.73 | 10 | 1.481 | 0.51 | 8 | 80.5% | 1.83 [0.70,2.95] | | | | _ | |
| Tartaglia et al, 2008 | 3.144 | 2.192 | 5 | 2.998 | 1.423 | 5 | 19.5% | 0.15 [-2.14, 2.44] | | | | | |
| | | | | | | | | | | | | | |
| Total (95% CI) | | | 15 | | | 13 | 100.0% | 1.50 [0.48, 2.51] | | | | | |
| Heterogeneity: Chi2 = 1.66, df = | = 1 (P = 0) |).20); 1 ² | = 40% | | | | | | - | - | | <u> </u> | - |
| Test for overall effect: $Z = 2.90$ | (P = 0.00) | 14) | | | | | | | -4 | -2 | 0 | 2 | 4 |
| | | | | | | | | Fa | vours f | ixed/mob | ile Fav | ours co | ntrol |

Fig 14 Forest plot of the mean differences in the variability of pattern contraction (confidence ellipse area) during left side chewing between patients with mandibular FFP and maxillary denture and patients with FFP in both jaws computed in the three comparable studies 10,35,36 . A significant effect (P = 0.004) in favour of the FFP/FFP group is visible.

- Masticatory symmetry during chewing (SMI = symmetry masticatory index) in subjects with FFP in both jaws was smaller than in dentate and larger than in subjects with FFP only in the mandible.
- Variability of contraction pattern during chewing (confidence ellipse area) in subjects with FFP in both jaws was larger than in dentate and smaller than in subjects with FFP only in the mandible except for right side mastication (P = 0.06).

The following parameters resulted in not being deemed significant:

- Masseter symmetry in maximal voluntary clenching (POC = percentage overlapping coefficient) between all groups.
- Activity standardised in maximal voluntary clenching between all groups. Even if the remaining 13 trials analysed the same tasks, differences in the parameters, study population and study design, did not allow to perform any statistical comparison. In particular, the following variables were found:
 - study population: different age, control patients with different dental situations (dentate, dentate with partial bridges...)
 - prosthetic treatment performed (i.e. different antagonist, number of implants supporting the full-fixed prosthesis, materials used to realise the prosthesis), and surgical protocols (i.e. tilted or axial implants)

- follow-up
- electromyographic parameters evaluated
- experimental protocols (i.e. different force used to induce reflex)
- analysed muscles
- recording of standardised or non-standardised signals.

Discussion

The aim of the present review was to evaluate the function of jaw muscle in response to occlusal rehabilitation performed with a full fixed prostheses on a limited number of implants.

To investigate this topic, the authors mostly designed cross-sectional observational studies, and all but one paper used electromyography to directly measure muscular activity. Furthermore, muscular function was analysed following specific tasks for statics (clenching, swallowing, reflex and fatigue) and dynamics (chewing). In the present review, the selected records were pooled and reported following these tasks; furthermore a statistical analysis was performed for the resulting data that were comparable between studies.

Briefly, fatigue was analysed in two studies^{32,44}. Results indicate a similar behaviour in dentate and FFP patients, except for a significant downward trend

of the mean power frequency that was observed in dentate but not in FFP patients. Patients with FFP expressed a fear of biting too hard and fracturing the prosthesis, thus modifying the real maximal clenching output performed by subjects and the related MPF signal.

The reflex is a protective masticatory function resulting in a decreased EMG activity that suddenly arrests jaw-closing movements before tooth contact when a hard object occurs between teeth, thus preventing large forces exerting on teeth^{47,48}. Results reported by studies evaluating reflexes seem to support the idea that reflex generation is mainly due to periodontal mechanoreceptors, and also mucosal receptors participate at this function^{43,45,46}. In contrast, inner ear receptors may be excluded for this physiological activity^{43,45}.

From studies evaluating the swallowing task, it may be concluded that stabilisation of occlusion by anchoring prostheses on implants reduces the muscular activity required during swallowing, thus making the masticatory system more efficient^{33,38}.

The maximum voluntary clenching force is largely used to measure the isometric muscle activity, symmetry, the balanced and standardised contractile activity. It was evaluated in seven studies^{10,35-37,41,42,44}. Even if some conflicting data emerge from studies on clenching, all authors agree that subjects with FFP have a global neuromuscular equilibrium and that the EMG contraction patterns are similar to those observed in dentate subjects.

The jaw muscle function during chewing has been analysed in nine studies^{10,33-36,38-40,42}. From the studies that tested chewing activity by means of foods with different textures, it emerges that masticatory function is adjusted and EMG pattern is typical for each food^{33,34,40}. Even if some conflicting data exist between trials, studies converge on the substantial conclusion that muscular function in subjects with FFP still has some impairment during chewing when compared to dentate patients.

The main fact that arises from this review is the considerable heterogeneity on evaluated parameters for each task and the different study populations among the studies.

The interval time elapsing between prosthetic rehabilitation and data collection also varied considerably among studies. However, this is an essential

variable that should be standardised, since studies reported that in patients rehabilitated by oral implants. neuromuscular adaptation takes few months to recover^{49,50}. Haraldson and Ingervall³⁸ also found that the number of years of wearing maxillary FFP was positively correlated to the number of chewing cycles. Sen 7 Furthermore, the age of control patients should be similar to that of treated patients, since the muscular function may be impaired in old patients⁵¹. Considering the high variability among the included studies, it was not possible to statistically compare data from most trials, with the exception of three studies performed by the same research group 10,35,36. Data reported from De Rossi et al⁴² seemed to be comparable. However, at deeper evaluation of the presented data, non-standardised values were reported; therefore it was not included in this comparison.

A further important element that needs to be considered is that several studies were designed and conducted some decades ago (in the 1970s to 1990s)^{32,34,37-39,43-46}; surgical protocols as well as prosthetic design and materials have changed much over the years.

Studies on mechanical signal transduction report that periodontal ligament mechanoreceptors are mostly sensitive to force direction⁵² and have the highest sensitivity to change during the appliance of static forces at a very low level (1 N). In particular, anterior teeth seem to be much more sensitive to low forces than posterior teeth⁵³. During chewing, periodontal receptors provide information to the sensorimotor cortex on the contact state between food and teeth, on direction of tooth loading and on food texture. After tooth extraction, these mechanoreceptors are lost thus inducing significant changes in jaw or tongue motor representation in the facial sensorimotor cortex (for review see Trulsson et al⁵⁴ and Lobbezoo et al⁵⁵). Furthermore, subjects without periodontal receptors loose the ability to perceive force changes; they apply high hold forces and are disturbed in the control of precisely directed and low biting forces. In edentulous patients restored with complete denture or overdenture, the mucosal receptors are activated by the contact with the prosthesis and generate a sort of mechanical signal that provides information about movements and pressure⁴⁵. In edentulous patients restored with full fixed prosthesis on implants, the mucosal receptors are not activated by the prosthesis; however a sensory awareness, called osseoperception, intervenes. The osseoperception is the perception of mechanical stimuli that are transmitted from the prosthesis throughout the implants to the mechanical receptors within the bone, the periosteum, the mucosa, or to the spindle of muscles and capsular receptors of the joint⁵⁵. The papers selected in the present review reveal that edentulous subjects rehabilitated with FFP have in statics a muscular function resembling that observed in dentate controls. On the other hand, in dynamic tasks the neuromuscular system seems to be less efficient, coordinated and equilibrated. Osseoperception seems to be more efficient on the perception of forces loading the structures, while it may be less sensitive to force direction thus resulting in uncoordinated movements, higher muscular activity and expenditure of energy with higher fatigue than in dentate patients.

As result of our research, we only found trials testing muscular function of patients with complete dentures, overdentures and FFP on a limited number of implants compared to dentate. No articles comparing patients with FFP supported by a limited number of implants and patients with FFP supported by a large number of implants were found.

Since the implant loading seems to increase the density of nerve fibres in peri-implant tissues⁵⁶, it could be interesting to assess if a large number of implants may stimulate the post-loading re-innervation, thus improving the osseoperception and muscular function.

In conclusion, the presently available literature indicates that prostheses supported by a limited number of implants offers a satisfying jaw function. This should be seen against the surgical risk/biological cost of a surgical intervention for bone augmentation/regeneration.

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The fate of marginal bone around axial vs. tilted implants: A systematic review

Key words dental implants, mandible, marginal bone loss, maxilla, systematic review, tilted implants

Aims: The use of tilted implants has recently gained popularity as a feasible option for the treatment of edentulous jaws by means of implant-supported rehabilitations without recurring to grafting procedures. The aim of this review was to compare the crestal bone level change around axially placed vs. tilted implants supporting fixed prosthetic reconstructions for the rehabilitation of partially and fully edentulous jaws, after at least 1 year of function.

Materials and methods: An electronic search of databases plus a hand search on the most relevant journals up to January 2014 was performed. The articles were selected using specific inclusion criteria, independent of the study design. Data on marginal bone loss and implant survival were extracted from included articles and statistically analysed to investigate the effect of implant tilting, location, prosthesis type, loading mode and study design. The difference in crestal bone level change around axial vs. tilted implants was analysed using meta-analysis.

Results: The literature search yielded 758 articles. A first screening based on titles and abstracts identified 62 eligible studies. After a full-text review, 19 articles (14 prospective and five retrospective studies) were selected for analysis. A total of 670 patients have been rehabilitated with 716 prostheses (415 in the maxilla, 301 in the mandible), supported by a total of 1494 axial and 1338 tilted implants. Perimplant crestal bone loss after 1 year of function ranged from 0.43 to 1.13 mm for axial implants and from 0.34 to 1.14 mm for tilted implants. In spite of a trend for a lower bone loss around axial implants with respect to tilted ones at 12 months, as well as after 3 or more years of function, no significant difference could be found (P = 0.09 and P = 0.30, respectively). The location (maxilla vs. mandible), the loading mode (immediate vs. delayed), the restoration type (full vs. partial prosthesis) and the study design (prospective vs. retrospective) had no significant effect on marginal bone loss. Forty-six implants (18 axial and 28 tilted) failed in 38 patients within the first year of function. All failures except five occurred in the maxilla. After 12 months of loading, the survival rate of implants placed in the maxilla (97.4%) was significantly lower as compared to the mandible (99.6%). No prosthesis failure was reported.

Conclusions: Tilting of the implants does not induce significant alteration in crestal bone level change as compared to conventional axial placement after 1 year of function. The trend seems to be unchanged over time even though the amount of long-term data is still scarce. The use of tilted implants to support fixed partial and full-arch prostheses for the rehabilitation of edentulous jaws can be considered a predictable technique, with an excellent prognosis in the short and mid-term. Further long-term trials, possibly randomised, are needed to determine the efficacy of this surgical approach and the remodelling pattern of marginal bone in the long term.

Conflict-of-interest statement: The authors declare that they have no conflict of interest.

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Introduction

After tooth loss the alveolar ridge undergoes progressive atrophy, which may become severe over time, especially for totally edentulous jaws. A number of prosthetic treatment alternatives are available to address this situation, such as complete dentures, implant-retained removable reconstructions, fixed implant-supported prostheses¹. The latter represent today a common and well-accepted treatment for the rehabilitation of partial and completely edentulous jaws. They offer an established long-term predictability as well as a higher level of satisfaction for the patient in terms of aesthetics, phonetics and functionality, as compared to removable prostheses²⁻⁴.

Most patients wearing complete dentures complain about progressive loss of stability during phonetics and mastication, and request a fixed rehabilitation. However, the rehabilitation of severely atrophic jaws using implant-supported prosthesis is often challenging because of the poor quality and quantity of residual jawbone, especially in patients with long term edentulism.

For example, progressive bone loss in the posterior mandible may lead to superficialisation of the alveolar nerve, which may cause pain to denture wearers during mastication. Bone augmentation procedures might represent a solution for facilitating implant placement in the posterior mandible, but these types of intervention are poorly accepted by patients. With regard to the maxilla, its rehabilitation with osseointegrated implants is often associated with several problems. In many cases, sufficient alveolar crest volume is found in the anterior region, while in the premolar and molar region, severe bone resorption can occur as a consequence of tooth loss.

The presence of the maxillary sinus and a limited ridge dimension must also be considered when placing implants in this region⁵⁻⁶. During past decades, various alternative surgical procedures have been adopted to place implants in the posterior atrophic maxilla; one of them is the maxillary sinus augmentation procedure, with either lateral or transcrestal approach. In spite of the excellent outcomes of this procedure, it is associated with several possible complications like morbidity at the donor site, sinusitis, fistulae, loss of the graft or the implants, and

osteomyelitis⁷⁻¹¹. Grafting procedures are generally demanding for both clinicians and patients and are often associated with increased surgical risks and financial cost as well. Another therapeutic option in case of limited available bone is represented by the use of implants of reduced length¹²⁻¹³. However, in the posterior maxilla, a minimum ridge height of 6 to 7 mm should be present for a safe placement of implants shorter than 8 mm. On the other hand, in the case of extremely atrophic posterior mandible, the use of short implants is to be carefully considered because of the risk of violating the alveolar nerve.

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The combined use of axially placed and tilted implants represents another possible alternative for the treatment of edentulous jaws, which has been extensively documented in the recent years¹⁴⁻¹⁹. Implant inclination may be carefully planned by the surgeon in order to avoid damage to important anatomical structures. At the same time, the adoption of longer implants and a proper insertion axis may allow engagement of as much cortical bone as possible, favouring the achievement of adequate primary stability of the implants²⁰. This may allow for immediate rehabilitation in many cases. Furthermore, increasing the inter-implant distance and reducing cantilever length, an optimal load distribution may be achieved. Several computational studies suggested possible biomechanical advantages of implant tilting in full-arch restorations²¹⁻²³. On the other hand, unfavourable loading direction could in theory induce greater bone resorption around tilted implants as compared to axially placed ones, as suggested by other in vitro studies that reported accentuated stresses around non-axially placed implant necks²⁴⁻²⁵.

Excellent clinical results of rehabilitations supported by a combination of axial and tilted implants have been reported, with high implant survival and prosthesis success rates, and a high level of satisfaction for the patients, in spite of a relatively high incidence of biomechanical complications (from 15.6%²⁶ to 27%¹⁵ of cases). The latter could be generally managed at chairside¹⁶⁻¹⁹.

What still remains to be studied is the stability of the peri-implant hard and soft tissues around tilted and axially placed implants over time. According to previous systematic reviews, while excellent implant survival rates were always emphasised by most studies, the crestal bone level change around tilted implants has not been systematically reported¹⁶⁻¹⁸.

The primary aim of this systematic review was to evaluate the fate of marginal bone around tilted versus axial implants supporting partial and complete rehabilitations, after at least 1 year of function. Further aims were to investigate if a relationship exists between marginal bone change and the survival rate of axial and tilted implants over time and if factors like the arch (maxilla vs. mandible) the type of prosthesis (partial vs. complete) or the loading timing (immediate vs. delayed) could affect marginal bone changes.

Materials and methods

Search methods

An electronic search was performed on the following databases: MEDLINE; Embase; and the Cochrane Central Register of Controlled Trials (CENTRAL). The last search was performed on 15 January, 2014. The search terms used were: 'dental implant*'; 'oral implant*'; 'tilted implant*'; 'angled implant*'; 'angulated implant*'; 'offset implant*'; 'upright implant*'; 'straight implant*'; 'axial implant*'; 'edentulous patient*'; 'edentulous mandible'; 'edentulous maxilla'; 'All-on-four'; 'All-on-4', 'All-on-six'; and 'All-on-6'. They were used alone or in combination using Boolean operators OR and AND. Furthermore, a hand search of issues from 2000 up to the last issue available on 15 January, 2014, including the 'Early view' (or equivalent) section was undertaken on the following journals: Clinical Implant Dentistry and Related Research; Clinical Oral Implants Research; Implant Dentistry; European Journal of Oral Implantology; International Journal of Oral and Maxillofacial Surgery; International Journal of Prosthodontics; Journal of Implantology; Journal of Oral and Maxillofacial Surgery; Journal of Periodontology; Journal of Prosthetic Dentistry; The International Journal of Oral and Maxillofacial Implants; and The International Journal of Periodontics and Restorative Dentistry. The reference list of the retrieved reviews and of the included studies was also searched for possible additional eligible studies not identified by the electronic search.

Inclusion criteria

The search was limited to clinical studies involving human subjects. Restrictions were not placed regarding the language. Both prospective and retrospective studies were included. Further inclusion criteria were: a minimum of 10 partially edentulous or completely edentulous patients rehabilitated with partial or complete fixed prosthesis supported by both axially placed and tilted implants; a minimum follow-up duration of 1 year; bone loss around tilted and axial implants clearly reported; survival rate for tilted and axial implants clearly indicated or calculable from data provided; and implants placed in a pristine jaw-bone without additional grafting.

Publications that did not meet the above inclusion criteria and those that were not dealing with original clinical cases (e.g. reviews, technical reports) were excluded. Multiple publications of the same pool of patients were also excluded from the database. When papers from the same group of authors, with very similar databases of patients, materials, methods and outcomes were identified, the authors were contacted for clarifying if the pool of patients was indeed the same. In case of multiple publications relative to consecutive phases of the same study, only the most recent data (those with the longer follow-up) were considered.

Selection of the studies

Two reviewers (MDF and VC) independently screened the titles and the abstracts of the articles initially retrieved through the electronic search. The reviewers were previously calibrated by assessing a sample of 20 articles. The concordance between reviewers was assessed by means of the Cohen's Kappa coefficient. In case of disagreement, a joint decision was taken by discussion. The full texts of all studies of possible relevance were independently assessed by the same two reviewers to check if they met all inclusion criteria. For articles excluded at this stage, the reason for exclusion was noted.

Data extraction

Data were extracted by two reviewers independently (MDF and VC). Cases of disagreement were subject

to joint evaluation until an agreement was reached. The following variables were extracted from each included study: study design; sample size; patient gender and age; proportion of smokers; total number of implants; number, type and location of the prostheses; follow-up duration; number of tilted and upright implants; degree of tilting; number of failed implants and details (time after loading, location; reason for failure); number of patients experiencing implant failure; prosthesis success rate; marginal bone level change around tilted and upright implants; occurrence and type of complications.

The following methodological parameters were also recorded: for randomised studies (if any), the random sequence generation method and allocation concealment; for all studies: clear definition of inclusion and exclusion criteria; clear definition of outcomes assessment and success criteria; number of surgeons involved; completeness of the outcome data reported; recall rate (it was assumed adequate if dropout <20%); explanation for dropouts/ withdrawal (when applicable); sample size (it was assumed adequate if >20 patients were treated); and length of follow-up period (it was assumed adequate if the mean duration was ≥3 years). Details on the methods adopted for crestal bone level change evaluation were also noted, such as: type of radiographs and standardisation (periapical radiographs (PA) with an individual holder; PA without individual holder, panoramic radiographs); blinding or independency of evaluators. The methodological quality of the selected studies was evaluated independently and in duplicate by two reviewers (MDF and VC) according to the above methodological parameters. All the criteria were assessed as adequate, unclear, or inadequate. The authors of the included studies were contacted for providing clarifications or missing information as needed. Studies were considered at low risk of bias if more than 2/3 of the nine parameters were judged as adequate.

Statistical analysis

In order to make comparisons between studies with different follow-up duration, the statistics were made considering the 1-year data for all studies. Studies reporting longer follow-ups were considered separately. The data extracted from each included study

were imported in the software RevMan (Review Manager [RevMan] Version 5.2, 2012; The Nordic Cochrane Center, The Cochrane Collaboration, Copenhagen, Denmark) for meta-analysis. For marginal bone loss evaluation the mean value and standard deviation of crestal bone level change and the number of tilted and axial implants available for analysis in each study were used. A random effect model was chosen. The estimates of the bone level change around axial and tilted implants were expressed as mean difference (mm) together with 95% confidence intervals (CI). The statistical evaluation was conducted considering the implant as the analysis unit. The contribution of each article to the primary outcome was weighted based on the sample size and standard deviation. Subgroup analysis was performed taking into account location (maxilla or mandible), angulation (tilted or axial), loading timing (immediate or delayed), study design (prospective or retrospective) and restoration type (partial or complete prosthesis).

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Regarding implant survival, the estimates of the effects of an intervention were expressed as odds ratio (OR) together with 95% confidence intervals. The statistical evaluation was conducted considering both the implant and the patient as the analysis unit. Comparison among studies was performed by meta-analysis. ORs were combined using a fixed-effects model (Mantel-Haenszel method). Pearson's chi-square analysis was used to investigate the effect of implant location, angulation, loading timing, study design and restoration type on implant survival at 1-year follow-up. P = 0.05 was considered as the significance level.

Results

The flowchart summarising the screening process is presented in Fig 1. The last electronic search was performed on 15 January, 2014. The electronic search yielded a total of 758 articles. No additional article was found by the hand search. After a first screening of the titles and abstracts, 62 articles were selected, which reported results of clinical studies in which edentulous patients have been rehabilitated using prostheses supported by axial and tilted implants 14,15,20,26-84. The Cohen's kappa coefficient was 0.92, indicating excellent agreement between reviewers.

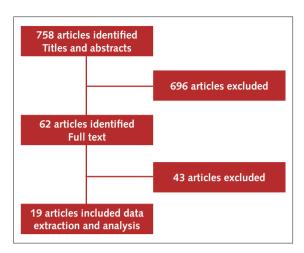


Fig 1 Flowchart of the study selection process.

After examining the full text of the 62 articles, 43 of them were excluded from the review (Table 1). Of the 19 remaining articles, 14 reported the results of prospective studies^{27,29,37,38,40,43,44,56,59,60,63,69,71,76} and five of retrospective studies^{20,31,32,42,72}. No randomised clinical study was identified. Table 2 reports the most relevant characteristics of the included studies. The main outcomes of these studies are described in Table 3. Of the 19 included studies, 11 have been performed in Italy^{37,38,40,43,44,56,59,63,69,71,76}, two in Spain^{20,42}, and one each in Austria³¹, Belgium²⁷, China²⁹, Germany⁶⁰, Portugal³², and Sweden⁷². All studies were conducted at universities or specialist dental clinics.

A total number of 2993 implants, of which 112 (3.74%) had a machined surface, were originally inserted in 670 patients rehabilitated with 91 partial and 625 complete fixed prostheses (415 in the maxilla, 301 in the mandible). Of the placed implants, 1494 were axial and 1338 tilted. These 2832 implants were submitted to statistical analysis regarding implant survival. Other implants were not considered because they were inserted in unusual regions and/or could not be regarded as axial nor as tilted (e.g. in the study by Peñarrocha et al⁴² in the same patients in which axial and tilted implants were placed, 55 implants were pterigomaxillary or zygomatic or placed in the frontomaxillary region, and in the study by Malò et al32 there were 83 trans-sinus implants). A total of 1576 maxillary (904 axial, 742 tilted) and 1171 mandibular implants (590 axial, 581 tilted) was considered for the analysis on marginal bone level change.

Table 1 Excluded studies and reasons for exclusion

| | 10, 2 |
|---------------------------------------|--|
| Excluded studies | Reason for exclusion PUb. |
| Balshi et al, 2013 ²⁸ | No details on marginal bone loss No details on marginal bone loss |
| Francetti et al, 2013 ³⁰ | No details on marginal bone loss |
| Tabrizi et al, 2013 ³³ | No axial implants, only tilted ones |
| Testori et al, 2013 ³⁴ | No details on marginal bone loss; grafting |
| Agnini et al, 2012 ³⁵ | No details on bone loss; inadequate report of failures |
| Cavalli et al, 2012 ³⁶ | Inadequate report of bone loss |
| Galindo et al, 2012 ³⁹ | Inadequate report of bone loss |
| Malò et al, 2012 ⁴¹ | Inadequate report of bone loss |
| Acocella et al, 2011 ⁴⁵ | Inadequate report of bone loss |
| Butura et al, 2011 ⁴⁶ | Inadequate report of bone loss |
| Butura et al, 2011 ⁴⁷ | No details on marginal bone loss |
| Butura et al, 2011 ⁴⁸ | Redundant publication (Butura et al, 2011 ⁴⁷) |
| De Vico et al, 2011 ⁵⁰ | Redundant publication (Pozzi et al, 2012 ⁴³) |
| Franchini et al, 2011 ⁵¹ | Too few tilted implants (not in all patients) |
| Graves et al, 2011 ⁵² | Technical article; no details on marginal bone loss |
| Graves et al, 2011 ⁵³ | Redundant publication (Graves et al, 2011 ⁵²) |
| Kawasaki et al, 2011 ⁵⁴ | Inadequate report of failures and bone loss |
| Parel et al, 201155 | Inadequate report of failures and bone loss |
| Agliardi et al, 2010 ²⁶ | Redundant publication (Agliardi et al, 2010 ⁵⁶) |
| Alves et al, 2010 ⁵⁷ | No details on marginal bone loss |
| Balleri et al, 2010 ⁵⁸ | Peculiar clinical procedure; no details on marginal |
| Corbella et al, 2011 ⁴⁹ | No details of implants and failures, no bone loss report |
| Peñarrocha et al, 2010 ⁶¹ | Redundant publication (Peñarrocha et al, 2012 ⁴²) |
| Pomares et al, 2010 ⁶² | Inadequate report of bone loss |
| Fortin et al, 2009 ⁶⁴ | No bone loss report |
| Pancko et al, 2009 ⁶⁵ | No axial implants, no bone loss report |
| Agliardi et al, 2008 ⁶⁶ | Redundant publication |
| Bilhan et al, 2008 ⁶⁷ | Case report (1 patient) |
| Francetti et al, 2008 ⁶⁸ | Redundant publication (Francetti et al, 2012 ³⁸) |
| Testori et al, 2008 ⁷⁰ | Redundant publication (Capelli, 2007 ⁷¹) |
| Malò et al, 2007 ⁷³ | Inadequate report of bone loss |
| Rosén and Gynther, 2007 ⁷⁴ | Inadequate report of bone loss |
| Malò et al, 2006 ⁷⁸ | Inadequate report of bone loss |
| Krennmair et al, 2005 ⁷⁷ | Inadequate report of bone loss |
| Malò et al, 2005 ⁷⁸ | Inadequate report, few hollow cylinder tilted implants |
| Karoussis et al, 2004 ⁷⁹ | Inadequate report of bone loss |
| Malò et al, 2003 ¹⁵ | Inadequate report on patients & bone loss |
| Aparicio et al, 200280 | Inadequate report of bone loss |
| Fortin et al, 2002 ⁸¹ | Inadequate report of bone loss |
| Krekmanov et al, 2000 ¹⁴ | Inadequate report of bone loss |
| Krekmanov et al, 2000 ⁸² | Inadequate report and partially redundant (Krekmanov et al, 2000 ¹⁴) |
| Mattsson et al, 2000 ⁸³ | Inadequate report of bone loss |
| | ' |

| Articles | Study | Setting | No. of | % Men/ | Mean age | Smokers | Total | No. maxillary | No. mandiblu- | Type of res- | Follow-up dura- |
|--|-----------|------------------------------|---------------|------------------|----------------|------------------------------|-------------|-----------------|-------------------|-----------------------|------------------|
| | ıype | | patients | | (Idlige) | | implants | (implants) | (implants) | tolation | (range) |
| Browaeys et al, 2014 ²⁷ | ۵ | University | 20 | 30% / 20% | 55 (35–74) | NR | 80 | 9 (36) | 11 (44) | Full-arch | 36 |
| Di et al, 2013 ²⁹ | ۵ | University | 69 | 54% / 46% | 56.7 (37–74) | NR | 344 | 38 (152) | 48 (192) | Full-arch | 33.7 (12–56) |
| Krennmair et al, 201331 | œ | University | 38 | 39% / 61% | 67.1 (NR) | 18% | 152 | 1 | 38 (152) | Full-arch | 66.5 (5–7 yrs) |
| Malò et al, 2013 ³² | ~ | Private Centre | 70 | 41% / 59% | 54 (35–81) | 27% | 280 | 70 (280) | ı | Full-arch | 36 |
| Crespi et al, 2012 ³⁷ | ۵ | University | 36 | 39% / 61% | 54.6 (41–81) | 39% | 176 | 24 (96) | 20 (80) | Full-arch | 36 |
| Francetti et al, 2012 ³⁸ | ۵ | University | 47 | 53% / 47% | 53 (44–63) | 32% | 196 | 16 (64) | 33 (132) | Full-arch | 36 max. 60 mand. |
| Grandi et al, 2012 ⁴⁰ | А | 1 Private 2 Univ. centres | 47 | 47% / 53% | 62 (52–78) | 23 % | 188 | - | 47 (188) | Full-arch | 18 |
| Peñarrocha et al, 2012 ⁴² | ~ | University | 18 | 33% / 67% | NR (35–69) | 39% | 117 | 18 (62)* | - | Full-arch | 39.2 (12–84) |
| Pozzi et al, 2012 ⁴³ | Ь | University | 27 | 56% / 44% | 54 (38–77) | NR | 81 | 37(81) | - | FPD | 43.3 (36–54) |
| Weinstein et al, 2012 ⁴⁴ | А | University | 20 | 40% / 60% | 60.8 (44–77) | 20% | 80 | - | 20 (80) | Full-arch | 30.1 (20–48) |
| | | | | | | | | | | | |
| Agliardi et al, 2010 ⁵⁶ | Д | Private Centre | 24 | 42% / 58% | 56.4 (42–73) | 25% | 96 | | 24 (96) | Full-arch | 26.8 (14–42) |
| | | | | | | | | | | | |
| Degidi et al, 2010 ⁵⁹ | Ь | Private Centre | 30 | 53% / 47% | 58.1 (NR) | NR | 210 | 30 (210) | 1 | Full-arch** | 36 |
| | | | | | | | | | | | |
| Hinze et al, 2010 ⁶⁰ | ۵ | Private Centre | 37 | 49% / 51% | 64.6 (39–84) | 30% | 148 | 19 (76) | 18 (72) | Full-arch | 12 |
| Agliardi et al, 2009 ⁶³ | Ь | University | 20 | 55% / 45% | 57 (44–68) | 35% | 120 | 20 (120) | ı | Full-arch | 27.2 (18–42) |
| Tealdo et al, 2008 ⁶⁹ | Ь | University | 21 | 52% / 48% | 58 (NR) | NR | 111 | 21 (111) | 1 | Full-arch | 20 (13–28) |
| Capelli et al, 2007 ⁷¹ | Д | University | 65 | 34% / 66% | 59.2 (28–83) | 15% | 342 | 41 (246) | 24 (96) | Full-arch | 55 (33–82) |
| Koutouzis and Wennstrom, 2007 ⁷² | ~ | University | 38 | 53% / 47% | 59.5 (NR) | %97 | 111 | 24 (40) | 18 (39) | FPD | 09 |
| Calandriello and Tomatis, 2005 ⁷⁶ | ۵ | Private Centre | 81 | 39% / 61% | 64 (51–76) | heavy smokers excluded | 09 | 19 (60) | 1 | 12 FPD 7 full-arch | 12 |
| Aparicio et al, 2001 ²⁰ | ~ | University | 25 | 40% / 60% | 59 (M) 49 (F) | 24% | 101 | 29 (101) | 1 | 29 FPD | 37 (21-87) |
| P = prospective; R = retrospective; NR = not reported; * only tilted (n = 30) and conventionally placed axial implants (n = 32) were considered; **the implants were all splinted by welded bar. | ospective | s; NR = not report | th (luo * ;be | ilted (n = 30) a | nd conventiona | illy placed ax | ial implant | s (n = 32) were | considered; **the | e implants were | a D |

 Table 3
 Main outcomes of the included studies.

| | | | | | | | Teson Bone 1 | oss around th | соруг | 96 | 31// |
|---------------------------------------|--------|---------------------------------------|--|---|---|--|---|--|---|---|---|
| Complications reported | | | 3 abutment screw loosened, 5 artificial teeth separated from the acrylic resin base. Fracture near the implant metal coping in 3 provisional restorations. | 256 in total (described in details in a table). | Mechanical complications in 36 patients (28 prosthetic screw loosening, 8 prosthesis fracture); Biological complications in 26 patients/30 implants: bone resorption and BoP (11), fistulae (2), excessive bone loss (2). | 1 case of mucositis around 1 axial implant. | | Light hypoaesthesia on the left side of the lower lip after surgery, resolved after 6 months (1 patient); fracture of the acrylic prosthesis (7 patients); 3 axial implants showed peri-implantitis after 3 y (3 mm bone | Ot for publi | Three patients had a fracture of the provisional restoration, but all of the definitive prostheses remained stable throughout the study period without any complications. | NR |
| mm (no. of | tilted | 1.67 ± 1.22 (n = 32) | | 1.24 ± 0.32 (n = 76) | 1.06±0.71 (n = 40/50) | Maxilla: 1.07 ± 0.46 (n = 47, 24 m) 1.11 ± 0.32 (n = 47, 36 m) | Mandible: 1.09 ± 0.29 (n = 38; 24 m) 1.12 ± 0.35 (n = 38; 36 m) | Maxilla: 0.63 ± 0.38 (n = 32; 24 m) 0.85 ± 0.34 (n = 14; 36 m) | Mandible: 0.67 ± 0.38 (n = 64, 24 m) 0.69 ± 0.52 (n = 54, 36 m) 0.39 ± 0.18 (n = 24, 60 m) | 0.68 ± 0.14 (n = 94; 18 m) | I |
| >12 m bone loss, mm (no. of implants) | axial | 1.55 ± 0.73 (n = 32) | | 1.17 ± 0.26 (n = 76) | 1.15 ± 0.51 (n = 88/123) | Maxilla: 1.08 ± 0.4 (n = 48; 24m) 1.10 ± 0.45 (n = 48; 36m) | Mandible: 1.04 ± 0.35 (n = 40; 24 m) 1.06 ± 0.41 (n = 40; 36 m) | Maxilla: 0.44 ± 0.37 (n = 32; 24 m) 0.85 ± 0.74 (n = 14; 36 m) | Mandible: 0.90 ± 0.49 (n = 64; 24 m) 0.92 ± 0.43 (n = 54; 36 m) 0.51 ± 0.17 (n = 24; 60 m) | 0.68 ± 0.14 (n = 94; 18 m) | I |
| mm (no. of | tilted | $1.14 \pm 1.,14$ (n = 32) | 0.8 ± 0.4 (n = 148) | ı | 0.89 ± 0.54 (n = 47/55) | Maxilla: 1.05 ± 0.29 (n = 47) | Mandible: 1.05 ± 0.32 (n = 38) | Maxilla: 0.32 ± 0.28 (n = 32) | Mandible: 0.48 ± 0.23 (n = 66) | 0.60 ± 0.16 (n = 94) | 0,76 ± 0.06 (n = 30) |
| 12 m bone loss, mm (no. of implants) | axial | 1.13 ± 0.71 (n = 32) | 0.7 ± 0.2 (n = 148) | I | 0.62 ± 0.35 (n = 114/135) | Maxilla: 1.02 ± 0.35 (n = 48) | Mandible: 1.04 ± 0.30 (n = 40) | Maxilla: 0.40 ± 0.27 (n = 32) | Mandible: 0.57 ± 0.42 (n = 66) | 0.57 ± 0.13 (n = 94) | 0.52 ± 0.10 (n = 32) |
| Location of failed implants | | I | 11 maxilla (1 ax, 10 tilt), 2 mandible (1 ax 1 tilted) | 1 | Maxilla | 1 maxilla 2 mandible | | I | | 1 | 3 maxilla |
| PSR | | 100% | 100% | 100% | 100% | 100% | | 100% | | 100% | 100% |
| nplants | tilted | 40 | 172 | 92 | 57(1)* | 88 (3) | | 86 | | 94 | 30 (1) |
| Inserted implants (failures) | axial | 40 | 172 | 92 | 140(1) | 88 | | 86 | | 94 | 32 (2) |
| Articles | | Browaeys et al, 2014 ²⁷ | Di et al, 2013 ²⁹ | Krennmair et al, 2013 ³¹ | Malò et al, 2013 ³² | Crespi et al, 2012 ³⁷ | | Francetti et al, 2012 ³⁸ | | Grandi et al, 2012 ⁴⁰ | Peñarrocha et al, 2012 ⁴² |

 Table 3
 (cont.) Main outcomes of the included studies.

| | | Del Fab | 0010 / | Cereso |)II D U | ne loss around | tiitea | impiants | | | | |
|---------------------------------------|--------|--|--|--|--|--|--|---|--|---|---|---|
| | | | | | | | | | | ha | col | oyrigh, |
| Complications reported | | No biological or mechanical complications occurred during the entire follow-up period. | NR | No complication during surgical and prosthetic procedures. | Three implants had serious biologic complication (peri-implantitis). | 4 fractures of provisional prostheses. One fracture of definitive prosthesis. Loss of the screw access hole restoration in 9.5% of the cases. Occlusal screw loosening in 6% of cases. Extensive bruising in 2 patients. | No complications occurred during surgical and prosthetic procedures. | No loose abutment screws nor reported fractures of prosthesis frameworks. | Two more implants failures (1 axial and 1 tilted in maxilla) were recorded during the second year of function. | Three implant fractures, three cases with crown-screw loosening and three cases with minor porcelain fractures. | One fracture of the acrylic bridge that probably lead to implant failure. | 28 mechanical incidents in 16 prostheses (55.2%). 18 retightening of the abutment screw in 14 prostheses, gold screw retightening in five prostheses. Fracture of the abutment screws and of the occlusal material was in two prostheses. |
| mm (no. of | tilted | Ant: 0.7 ± 0.38 (n = 14; 36 m) Post: 0.7 ± 0.2 (n = 26; 36 m) | I | I | 1.03 ± 0.87 (n = 120; 36 m) | 1 | I | I | 1 | 0.5 ± 0.95 (n = 33; 60 m) | I | 1.21 ± 0.68 (n = 12; 60 m) |
| >12 m bone loss, mm (no. of implants) | axial | 0.5 ± 0.3 (n = 38.36m) | I | 1 | 0.92 ± 0.89 (n = 89; 36 m) | I | I | 1 | 1 | 0.4 ± 0.94 (n = 36; 60 m) | I | 0.92 ± 0.55 (n = 12; 60 m) |
| bone loss, mm (no. of nts) | tilted | Ant: 0.6 ± 0.38 (n = 14) Post: 0.62 ± 0.37 (n = 26) | 0.7 ± 0.4 (n = 36) | 0.8 ± 0.5 (n = 42) | 0.63 ± 0.24 (n = 120) | 0.76 ± 0.49 (n = 70) | 0.9 ± 0.5 (n = 60) | Mesial 0.92 (n = 42); Distal 1.04 (n = 42) | Maxilla: 0.88 ± 0.59 (n = 42); Mandible: 0.75 ± 0.55 (n = 32) | I | 0.34 ± 0.76 (n = 26) | 0.57 ± 0.50 (n = 40) |
| 12 m bone loss, implants) | axial | 0.48 ± 0.3 (n = 38) | 0.6 ± 0.3 (n = 36) | 0.9 ± 0.4 (n = 42) | 0.60 ± 0.11 (n = 89) | 0.82 ± 0.31 (n = 71) | 0.8 ± 0.4 (n = 30) | Mesial: 0.62 (n = 61); Distal 0.86 (n = 61) | Maxilla: 0.95 ± 0.44 (n = 84); Mandible: 0.82 ± 0.64 (n = 32) | I | 0.82 ± 0.86 (n = 32) | 0.43 ± 0.45 (n = 53) |
| Location of failed implants | | 3 maxilla (1 patient) | 1 | I | maxilla | Tilted: 3 maxilla 1 mandible Axial: 3 maxilla | I | maxilla | maxilla | ı | maxilla | maxilla |
| PSR | | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| ıplants | tilted | 42 (2) | 40 | 48 | 120 | 74 (4) | 80 | 47 (5) | 117 (1) | 33 | 27 (1) | 42 |
| Inserted implants (failures) | axial | 39 (1) | 40 | 48 | 90 (1) | 74 (3) | 40 | 64 (3) | 189 (2) | 36 | 33 (1) | 59 (2) |
| Articles | | Pozzi et al, 2012 ⁴³ | Weinstein et al, 2012 ⁴⁴ | Agliardi et al, 2010 ⁵⁶ | Degidi et al, 2010 ⁵⁹ | Hinze et al, 2010 ⁶⁰ | Agliardi et al, 2009 ⁶³ | Tealdo et al, 2008 ⁶⁹ | Capelli et al, 2007 ⁷¹ | Kout- ouzis and Wennstrom, 2007 ⁷² | Calandriello and Tomatis, 2005 ⁷⁶ | Aparicio et al, 2001 ²⁰ |

* in adjunct, 83 trans-sinus tilted implants were placed; NR = not reported.

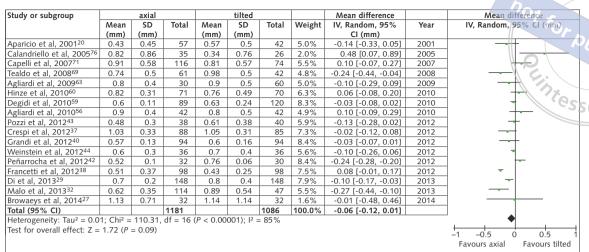


Fig 2 Forest plot of the mean differences in marginal bone level change between axial and tilted implants in the included studies at 12-months follow-up.

| Study or subgroup | axial | | | tilted | | | Mean difference | | | Mean difference | |
|-------------------------------------|----------|----------|------------|------------------------|------|-------|-----------------|----------------------|---------|-----------------------------|--|
| | Mean | SD | Total | Mean | SD | Total | Weight | IV, Random, 95% | Year | IV, Random, 95% CI (mm) | |
| | (mm) | (mm) | | (mm) | (mm) | | _ | CI (mm) | | | |
| Aparicio et al, 2001 ²⁰ | 0.92 | 0.55 | 13 | 1.21 | 0.68 | 12 | 3.5% | -0.29 [-0.78, 0.20] | 2001 | | |
| Koutouzis & Wennstrom, 200772 | 0.4 | 0.94 | 36 | 0.5 | 0.95 | 33 | 4.0% | -0.10 [-0.55, 0.35] | 2007 | | |
| Degidi et al, 2010 ⁵⁹ | 0.92 | 0.89 | 89 | 1.03 | 0.87 | 120 | 9.6% | -0.11 [-0.35, 0.13] | 2010 | | |
| Crespi et al, 2012 ³⁷ | 1.08 | 0.43 | 88 | 1.115 | 0.33 | 85 | 17.5% | -0.03 [-0.15, 0.08] | 2012 | | |
| Pozzi et al, 2012 ⁴³ | 0.5 | 0.3 | 94 | 0.7 | 0.3 | 94 | 19.5% | -0.20 [-0.29, -0.11] | 2012 | - - - | |
| Francetti et al, 2012 ³⁸ | 0.91 | 0.49 | 68 | 0.72 | 0.48 | 68 | 14.0% | 0.19 [0.03, 0.35] | 2012 | _ - | |
| Malo et al, 2013 ³² | 1.15 | 0.51 | 88 | 1.06 | 0.71 | 40 | 9.5% | 0.09 [-0.15, 0.33] | 2013 | - | |
| Krennmair et al, 2013 ³¹ | 1.17 | 0.26 | 76 | 1.24 | 0.32 | 76 | 19.0% | -0.07 [-0.16, 0.02] | 2013 | - | |
| Browaeys et al, 2014 ²⁷ | 1.55 | 0.73 | 32 | 1.67 | 1.22 | 32 | 3.4% | -0.12 [-0.61, 0.37] | 2014 | - | |
| Total (95% CI) | | | 1181 | | | 1086 | 100.0% | -0.06 [-0.12, 0.01] | | | |
| Heterogeneity: Tau2 = 0.01; Chi2 | = 21.36 | , df = 8 | (P < 0.00) | 6); I ² = 6 | 3% | | | | | . T | |
| Test for overall effect: Z = 1.04 (| P = 0.30 |) | | | | | | | + -1 | -0.5 0 0.5 1 | |
| | | | | | | | | | F | avours axial Favours tilted | |

Fig 3 Forest plot of the mean differences in marginal bone level change between axial and tilted implants in the six included studies reporting data of at least 36-months followup.

Crestal bone level change

One-year follow-up (seventeen studies)

The results of the random effects meta-analysis for marginal bone level change around axial vs. tilted implants at 12 months are presented in Fig 2. Two studies provided results at 5 years only31,72, therefore they were not included in this meta-analysis. The comparison between axial and tilted implants across the 17 studies (Fig 2) showed considerable statistical heterogeneity ($I^2 = 0.85\%$, P < 0.001). No significant difference was found (P = 0.09), with a slight discrepancy in favour of the axially placed implants (mean difference in bone loss -0.06 mm (95% C.I.: -0.12, 0.01)). Only one study reported significantly lower bone loss for tilted implants as compared to axial ones⁷⁶. A sensitivity analysis was also performed by excluding such a study, but the result did not substantially change, though slight significance was achieved (P = 0.04, mean difference in bone loss -0.07 mm (95% C.I.: -0.13, 0.00)), confirming the robustness of the analysis.

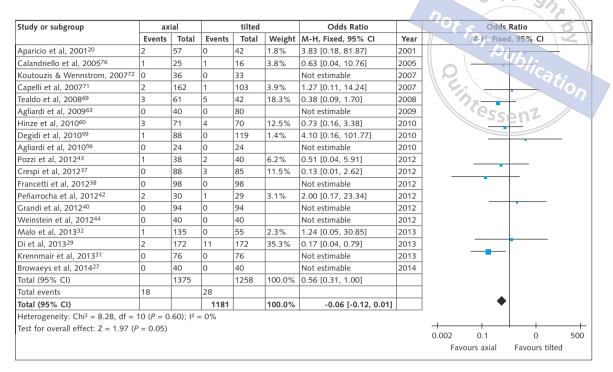
At least 36-months follow-up (nine studies)

Nine studies evaluated marginal bone level change around axial and tilted implants after at least 36 months of loading^{20,27,31,32,37,38,43,59,72}. The meta-analysis relative to these studies is shown in Fig 3. Again, a trend for lower marginal bone level change in favour of the axial implants was found (-0.05 mm, 95% C.I.: -0.15, 0.05) but did not achieve significance (P = 0.30).

Prosthesis type (sixteen studies)

When separating the data according to the prosthesis type, a significant difference in marginal bone loss in favour of axial implants was found for fixed partial prostheses (P = 0.03, mean difference -0.13 mm, 95% C.I.: -0.25, -0.02) but not for full-arch fixed prostheses (P = 0.09, mean difference -0.06 mm, 95% C.I.: -0.13, 0.01). The study by Calandriello and Tomatis⁷⁶ was not considered because the bone loss data for full-arch and partial prostheses

Fig 4 Forest plot of the differences in implant survival between axial and tilted implants in the included studies at 12-months follow-up.



were not reported separately. The study by Krennmair et al³¹ and Koutouzis et al⁷² provided bone loss data on fixed partial dentures relative only to 5-year follow-up, so they were excluded from this subgroup analysis.

Implant location (fifteen studies)

When considering the data from the maxilla and from the mandible separately, no significant difference was found in marginal bone loss between axial and tilted implants at 12-months follow-up in both jaws. For maxillary implants the mean difference in bone loss was -0.08 mm, 95% C.I.: -0.17, 0.01 (P = 0.09) and for the mandibular implants it was 0.00 mm, 95% C.I.: -0.06, 0.05 (P = 0.96). The studies by Hinze et al⁶⁰, Di et al²⁹ and Browaeys et al²⁷ were not considered because the bone loss data of axial and tilted implants relative to maxilla and mandible were not reported separately. Conversely, the study by Koutouzis et al⁷² reported separately the bone loss data for maxilla and mandible, but only 5-year data were provided.

Study design (eighteen studies)

When separating the studies according to the study design, no significant difference in bone

loss around axial and tilted implants was found at 12-months follow-up in 14 prospective studies^{27,29,37,38,40,43,44,56,59,60,63,69,71,76}

 $(P=0.32, \text{ mean difference } -0.02 \text{ mm}, 95\% \text{ C.I.:} -0.07, 0.02), while significant difference in favour of axial implants was found in three retrospective studies <math>^{20,32,42}$ (P < 0.001, mean difference -0.24 mm, 95% C.I.: -0.28, -0.20). Again, the retrospective studies by Krennmair et al³¹ and Koutouzis et al⁷² were not considered because they only reported 5-year data.

Loading timing (eighteen studies)

A similar result was found when considering the studies separately according to loading timing. In fact, 14 of the 15 immediate loading studies were the same prospective studies considered above. Only one study adopting immediate loading protocol had a retrospective design³². Two studies in which conventional delayed loading procedure was adopted^{20,42} showed significant difference in bone loss in favour of axial implants (P <0.001, mean difference -0.24 mm, 95% C.I.: -0.28, -0.19). The overall sample size of implants rehabilitated according to a delayed loading protocol was consistently lower than immediately loaded implants (n = 161 and 2106, respectively).

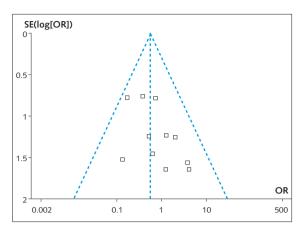


Fig 5 Funnel plot of the studies reporting implant survival for axial and tilted implants at 12-months follow-up, showing homogeneity among studies.

Implant survival

A total number of 46 implants (1.54%) failed in 38 patients (6.58%) during the first year of function. The reasons for failure were: mobility/lack of osseointegration (n = 31); mobility and pain (n = 2); pain (n = 3); while for 10 implants (22%) no reason was reported. Two maxillary implants (one axial and one tilted) failed in two patients later than 1 year, after 15 and 18 months of function⁷¹ and another maxillary tilted implant failed after 23 months in another patient³². Of the implants that failed within 12 months, 18 were axial and 28 tilted and all but five implants (one axial and four tilted) were placed in the maxilla. Two of the failed implants (one axial and one tilted, both in maxilla) had a machined surface⁷⁶. One-year implant survival was 97.4% and 99.6% for the maxilla and the mandible, respectively. No prosthesis failure was reported in any of the evaluated studies. Consequently, no further analysis was performed at prosthesis level.

The results of the fixed effects meta-analysis for implant survival at 1 year is presented in Fig 4. Considering the outcome of tilted versus axial implants in both jaws, slightly statistically significant difference in favour of axial implants (OR = 0.56, 95% CI: 0.31, 1.00, P = 0.05) and no heterogeneity was found (Fig 5). In this analysis, a single recent study had a consistent influence on such result, as its weight was more than one-third (35.3%) of the overall studies²⁹. Sensitivity analysis performed excluding this study showed no significant difference in implant survival between axial and tilted implants (P = 0.43).

Table 4 Results of the comparisons of implant survival at 12-months follow-up for axial and tilted implants according to loading time and location.

| | | | | O/: | | | | |
|--------------------|--------------|----------------------|------------------|------------------|-------------------|--|--|--|
| | P value | Tilted vs. axial | | | | | | |
| | (chi square) | Tilted ISR% | Axial ISR% | Tilted N. | Axial N. | | | |
| Total | 0.481 | 97.9% | 98.8% | 1338 | 1494 | | | |
| Delayed | 0.849 | 99.4% | 98.1% | 181 | 213 | | | |
| Immediate | 0.225 | 97.7% | 98.9% | 1157 | 1281 | | | |
| Maxilla total | 0.545 | 96.8% | 98.1% | 742 | 904 | | | |
| Maxilla delayed | 0.860 | 98.9% 96.5% | | 90 | 113 | | | |
| Maxilla immediate | 0.266 | 96.5% | 98.4% | 652 | 791 | | | |
| Mandible total | 0.763 | 99.3% | 99.8% | 581 | 590 | | | |
| Mandible delayed | 1.000 | 100.0% | 100.0% | 91 | 100 | | | |
| Mandible immediate | 0.771 | 99.2% | 99.8% | 490 | 490 | | | |
| | P value | Maxilla vs. mandible | | | | | | |
| | (chi square) | Maxilla ISR% | Mandible ISR% | Maxilla total | Mandible total | | | |
| Total | <0.001* | 97.4% | 99.6% | 1576 | 1171 | | | |
| Tilted | 0.037* | 96.8% | 99.3% | 742 | 581 | | | |
| Axial | 0.003* | 98.1% | 99.8% | 904 | 590 | | | |

^{* =} significant difference.

Table 4 reports the results of the comparisons of implant survival between axial and tilted implants according to the arch and the loading mode, as well as comparisons between survival rates of maxillary and mandibular implants. Implants placed in the mandible (independent of the inclination) displayed a significantly better survival rate after 12 months as compared to maxillary ones (P < 0.001). This trend was confirmed when the analysis was performed separately for tilted (P = 0.037) and axial implants (P = 0.003). When performing the analysis at patient level, no significant difference in implant survival rate was found according to the loading mode (P = 1.00), while a significant difference was found according to the arch, with patients rehabilitated in the mandible experiencing significantly fewer implant failures than patients treated with maxillary prostheses (P = 0.01).

As most of the failed implants were located in the maxilla, a further meta-analysis was conducted on 14 studies that reported 1-year treatment out-



Fig 6 Risk of bias summary: review authors' judgements about each risk of bias item for each included study (H = high risk of bias; L = low risk of bias).

comes for the maxilla (in total 870 axial and 716 tilted implants). Again, significant difference favouring axial implants (OR = 0.45, 95% CI: 0.24, 0.83, P = 0.01) and no heterogeneity was found.

The 1-year implant survival rate was at 97.2% and 97.8% for maxillary complete rehabilitations

supported by 4 implants according to the all-on-four concept (total n. implants = 704) or supported by 5 to 7 implants (n = 777 implants), respectively. The difference was not significant (P = 0.96).

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Complications

The most common complications described in the included studies were fracture of the temporary acrylic prosthesis and screw loosening (Table 3). No significant relationship with the arch was found for such mechanical complications. A few authors reported wear patterns in the opposing dentition⁴¹. Most of patients that experienced fracture of the prosthetic reconstruction orloosening of the prosthetic screw displayed parafunctions like bruxism^{41,43} or had a short face morphotype with powerful mastication muscles^{46,48}.

Other outcome variables

In studies that assessed parameters related to oral hygiene level, plaque and bleeding scores progressively decreased over the first year of function^{38,44,56,59,60,63}. Two studies with longer follow-up reported substantial maintenance of plaque and bleeding scores up to 5 years^{31,38}. Finally, all studies that evaluated patient satisfaction by means of questionnaires or interviews reported extremely positive feedback of patients regarding function, phonetics and aesthetics after 1 year of loading^{32,38,44,56,63}.

Quality assessment/risk of bias of the included studies

According to the criteria established in this review, eleven studies^{20,29,31,32,37,42,56,60,69,71,76} were considered to have a high potential risk of bias and eight^{27,38,40,43,44,59,63,72} having a low risk (Fig 6). Of the five retrospective studies, only the study by Koutouzis et al⁷² was considered at low risk of bias. The most critical parameter was the number of surgeons involved, which was not declared in five studies^{31,32,37,43,69} and was greater than one in another seven studies^{20,29,38,40,60,71,76}. One of them declared that surgeries have been performed by a "surgical team" ⁶⁹. The bone loss assessment method in six studies was based on non standard-

ised periapical radiographs ^{20,27,31,32,40,76}, and in three studies it was performed using only panoramic radiographs^{29,37,60}. Finally, eight studies reported a mean follow-up shorter than 3 years (see Table 2).

Discussion

The aim of this review was to determine the trend of marginal bone loss around axial and tilted implants supporting partial and full-arch rehabilitations, after at least 1 year of function. For this reason, some studies with a large sample size and/or long term follow-up that reported details on the survival/success of axial and tilted implants, but not on crestal bone level changes around axial and tilted implants have been excluded from the present review. A different situation was represented by the study by Agnini et al, which correctly reported the results of bone loss evaluation separately for tilted and axially placed implants for the maxilla and mandible, up to 5 years of function³⁵. However, it had to be excluded, because not all patients received tilted implants and the bone loss data of those patients treated with both tilted and axial implants could not be separated from the overall data.

The level of evidence of the included studies was rather poor because no randomised clinical trials neither comparative prospective trials were found. The included studies were mostly prospective single cohort or multicentre studies. The study quality assessment showed that more than half of the studies were at high risk of bias. Among the parameters that were considered to potentially affect the reliability of the study outcomes was the procedure for radiographically evaluating the peri-implant bone loss. Since the main aim of the present review was to assess changes in peri-implant bone level around tilted and axial implants, particular emphasis was dedicated to parameters related to such outcome. In fact, the quality of the radiographic method adopted might potentially affect the accuracy of the measurements. Of the 19 included studies only eight (42%) adopted a standardised paralleling technique based on periapical radiographs taken with an individual film holder, while others used non standardised periapical radiographs (five studies) or panoramic radiographs (three studies). Two studies used panoramic radiographs and, when possible, periapical films, but did not specify the relative proportion of both techniques^{44,63}. Standardised periapical radiographs should be adopted whenever possible because they have a better accuracy than panoramic radiographs, estimated within a range en of 0.2 mm from actual values85. In adjunct to a low resolution, panoramic radiographs may cause image distortion rate averaging up to 25%86. However, it has to be acknowledged that in cases of extremely atrophic jaws in patients with a shallow vestibule, it might be practically very difficult to take periapical radiographs. Furthermore, in nine studies the radiographic evaluation was reported to be performed by a non-independent/not blinded evaluator or was not specified^{20,29,31,32,37,42,56,59,60}. Therefore, the non systematic use of a standardised technique aiming at obtaining a precise and reproducible bone loss measurement poses an experimental limitation and suggests that the results of the present review should be cautiously interpreted.

The meta-analyses comparing axial versus tilted implants were performed at implant level. In fact, since all patients received both axial and tilted implants and no individual data was provided, it was not feasible to present results at patient level. The analysis took into account different factors. Considering the overall studies, peri-implant bone loss at 1 year of function did not show significant difference between axial and tilted implants, although there was a trend in favour of the axially placed implants. Only the study of Calandriello and Tomatis, which also included partial prostheses, was discordant with such a trend⁷⁶. In that study, lower bone loss values for tilted implants were recorded, as compared to axial ones. The authors suggested that this could be related to the position of the implant neck relative to the bone crest: mesially, the neck was in a supracrestal position, while distally it was positioned subcrestally, resulting in a favourable soft tissue seal⁷⁶. It should be considered that in the study by Calandriello and Tomatis⁷⁶, partial and complete restorations were analysed together, even though a different performance could be expected, given the biomechanical differences between complete and partial prosthetic rehabilitations. However, after performing a sensitivity analysis by excluding this specific study, the result did not substantially change, suggesting that the weight of this study was negligible, and highlighting the robustness of the meta-analysis.

In all the included studies, limited peri-implant bone loss was observed over a follow-up period of 1 year, the greatest value reported averaging 1.13 mm and 1.14 mm around axial and tilted implants, respectively²⁷. In the nine studies reporting peri-implant bone loss after 3 or more years of function, a similar trend was observed, that is an overall limited bone loss around axial and tilted implants, with the latter presenting slightly higher (but not significant) bone loss values (Fig 3). The subgroup analysis showed that such a trend was unaffected by the arch and the prosthesis type, and a significant difference was achieved in the delayed loading studies but not in the immediate loading ones. However, one should consider that the sample size of delayed loading studies is very small respect to the immediate loading cases, preventing any comparison.

The results of the present review are slightly discordant with another recent meta-analysis on a similar topic¹⁸. That review found that marginal bone loss was lower (though not significantly) around tilted as compared to axial implants at 12 months, while the trend reversed in favour of the axial implants in studies with follow-up greater than 1 year. Our review adopted similar inclusion criteria but since we could count upon a more extended database of studies, a greater number of patients could be included. In fact most of the recent studies report a slight difference in bone loss in favour of axial implants at 12 months^{29,31,40,42-44}. This trend is maintained in studies with a longer follow-up, this result being similar to that found in the review by Monje et al¹⁸. However, it must be acknowledged that, significant or not, the order of magnitude of the mean difference in marginal bone loss between axial and tilted implants (0.05 mm in the Monje et al review¹⁸ and 0.06 mm in the present one at 12-months followup) can be considered clinically irrelevant.

In theory, the stress received by tilted implants under functional loading is higher than axially placed implants, which should result in greater marginal bone loss. Studies based on finite element analysis showed higher stress around a tilted implant neck^{24,25}. The compressive stress can be up to five times higher around tilted implants when the load

is applied vertically²⁴. Furthermore, tensile stresses were shown to peak on the opposite side of the inclination⁸⁷, posing tilted implants in a situation of nonhomogeneous stress pattern⁸⁸. *In vivo* animal studies showed that both cortical and trabecular bone remodelling is greater around non-axially placed implants under loading⁸⁹⁻⁹⁰. Nevertheless the present meta-analysis, like the previously published ones, did not support the hypothesis of greater bone loss around tilted implants.

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The use of posterior tilting of the implants presents some biomechanical advantages as compared to the configuration based fairly axial position for all implants²²⁻²³. This could be due to several reasons. For example, tilting of the implants may allow using longer implants that may engage greater quantity of residual bone, which is beneficial to implant stability. In the majority of studies on tilted implants, length ranged from at least 10 mm up to 20 mm²⁰. When increasing implant length, a more even distribution of stress around implants is achieved as shown by a number of computer-simulated studies⁹¹⁻⁹⁴. Further important means for reducing stress around tilted implant necks are splinting into a fixed suprastructure and shortening of the distal cantilever, both producing favourable biomechanical situations^{21,95-96}. These features were observed in most of the prosthetic configurations of the included studies. In all studies, tilted implants were splinted in both partial and full-arch reconstructions. The distalisation of the implant platform reduces the moments of force, improving the load distribution^{22-23,78,97}. Recent finite element studies support the hypothesis that reduction of the cantilever length in a full-arch prosthesis, achieved by tilting of the distal implants, allows for a more widespread distribution of the occlusal forces under loading and consequently for a reduction of the stresses at the implant neck^{23,95-96,98}. The findings of such computer-simulated studies may partially explain the favourable crestal bone level changes observed around tilted implants.

One limitation to the widespread use of tilted implants is the relative difficulty in the placement of the fixtures that must be inserted with a precise angulation, so as to engage as much cortical bone as possible. The latter is essential for achieving adequate primary implant stability, which is a

prerequisite in case an immediate implant loading protocol is adopted, as in the majority of the studies included in the present review. However, in recent years, the placement of tilted implants has become easier due to the introduction of computer-guided implant planning and the widespread use of customised surgical mask.

The survival of tilted vs. axial implants was not the primary aim of the present review. Therefore the failure analysis performed on the studies included according to the specific criteria of this review is under-representative of the published evidence regarding tilted vs. axial implant survival. Nevertheless, the results of the present analysis are in line with those of other recent reviews that addressed this topic in a more comprehensive way¹⁶⁻¹⁹.

In this review, slight statistically significant difference in implant survival at 12-months follow-up was observed, favouring axial over tilted implants (Fig 4), although, similar to what was discussed for marginal bone loss, such difference cannot be considered clinically relevant, being less than 1%. Regarding implant survival, a fair homogeneity was found among studies, as shown by the funnel plot in Fig 5. Due to the absence of randomised clinical studies, definitive conclusions cannot be drawn on the efficacy of rehabilitations supported by a combination of axial and tilted implants. However, based on the available included studies, the present review suggests that the prognosis of such a therapeutic approach is excellent, as only 1.54% of the implants was lost during the first year of loading, and only three failures were recorded thereafter.

From the implant failure analysis, some trends can be observed. Regarding the comparison between axial and tilted implants, the meta-analysis performed on the overall studies provided borderline significance (P = 0.05, Fig 4) in favour of the axial implants. However, such meta-analysis was strongly affected by a single study²⁹ in which 2 axial and 11 tilted implants failed (that is 40% of the overall failed tilted implants). Since the author of that study attributed most failures to the early cases in which there was scarce acquaintance with the allon-four technique, we repeated the meta-analysis after excluding that study. Such sensitivity analysis displayed no significant difference in survival rate between axial and tilted implants (P = 0.43). The

latter more closely reflects the standard clinical outcomes of most clinical studies included in the review as well as the results of all the subgroup analyses. In fact, when considering subgroups, no effect could be attributed to loading temporisation, to the arch or to a combination or both. In other words, as shown in Table 4, there was no significant difference in failure rate between axial and tilted implants when the immediate and the delayed loading cases were evaluated separately, though the latter was not significantly different between implants placed in the maxilla and those placed in the mandible.

The technical difficulty of placing angulated implants in the maxilla for surgeons not accustomed to such a technique has been claimed by some authors as a factor contributing to implant failure²⁹. As a consequence, for achieving optimal outcomes when dealing with tilted implants, a learning curve is recommended and guided surgery might help in the early approaches.

The improvement in oral hygiene parameters frequently reported in some studies on tilted implants might reflect the easy maintenance of this type of rehabilitations, in which there is a relatively wide distance between fixtures. Another factor that might be accounted for such a good compliance is the high level of satisfaction correlated with this treatment, as reported by patients^{45-46,49} in a few studies.

The most frequent complication reported by the included studies was the fracture of the acrylic prosthesis. One of the reasons addressed for such inconvenience was the progressive shift from a soft diet to a diet including hard food, as well as the wear of the resin due to repeated cycles of deglutition and mastication^{38,44,63}. Furthermore, some authors pointed out that most fractures of the prosthesis occurred close to the temporary abutments of the anterior implants, which can be considered a relatively weak point^{26,38,68}. In the study by Tealdo and co-workers, the provisional and definitive prostheses were made of cast metal (palladium-alloy) frameworks⁶⁹. Metal reinforced frameworks, as suggested by these authors, are significantly stronger than allacrylic resin frameworks since they provide increased rigidity, and could represent a solution for reducing the incidence of such complication.

The current review presents some limitations, which deserve to be discussed. First of all, the follow-

up duration for most studies is in the short-medium range (Table 2). As a matter of fact, the introduction of tilted implants for supporting prosthetic rehabilitations is a relatively recent technique, which started to spread among clinicians during the past 10 years with the advent of the so-called "All-on-four" technique¹⁵. Studies evaluating the performance of tilted implants with a follow-up longer than 5 years are quite scarce^{30,32,38,98}. Only one study on the all-onfour technique with a follow-up range of 10 years has been published to date but did not provide specific information about marginal bone loss around axial and tilted implants⁹⁸. Besides, different implantsupported prosthetic designs, which differ regarding the total number of implants as well as the number and angulation of tilted implants were considered all together, thus neglecting any possible different performance. It should also be taken into account that the minimum angulation required to define an implant as tilted has not yet been established. Some studies arbitrarily defined a threshold of 15 degrees of inclination respect to the occlusa plane^{20,80}. In the included studies, the inclination of the distal fixtures in the full-arch rehabilitations ranged from about 25 to 35 degrees for the mandible and from 25 to 45 degrees for the maxilla, respective to the occlusal plane. Only in the study by Calandriello and Tomatis was a higher inclination reported (45 to 75 degrees relative to the occlusal plane)⁷⁶. In some studies, the angulation was standardised, while in most cases of extreme atrophy it was individually chosen according to the available bone^{44,63,76}. Most of the studies were performed in private practice settings by experienced surgeons, and some report that multiple operators performed the surgeries. Though the latter might introduce a source of variability undermining the internal validity of the single studies, the relative homogeneity in outcomes suggests that the external validity of the results of this review is rather high, provided that the surgical operators are adequately skilled. The most consistent limitation, however, is represented by the low level of evidence for publications on this topic to date. This review, in fact, was based only on retrospective and single-cohort prospective studies (except for Capelli et al⁷¹ and Grandi et al⁴⁰ that were multicentric prospective studies), which provided indications on the prognosis of the technique mostly in the short-medium term.

Conclusion

This review demonstrated that the tilting of implants does not induce significant alteration in crestal bone level change as compared to conventional axial placement after 1 year of function, and this trend apparently maintains up to 5 years of function. Due to the lack of evidence, no conclusion can be drawn regarding the fate of marginal bone around axial vs. tilted implants in the long term.

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In rehabilitations supported by tilted and axial implants, there is a higher risk of implant failure in the maxilla as compared to the mandible, although no significant difference in bone loss was found around implants placed in the maxillary as compared to the mandible, independent of implant inclination. In the maxilla, the all-on-four concept is as successful as rehabilitations supported by five or more implants.

In order to determine the efficacy of tilted implants as an alternative to grafting techniques or to the use of short implants or other treatment options for the rehabilitation of edentulous atrophic jaws, randomised clinical trials with large sample size and long-term follow-up are urgently needed. The impact on the quality of life for the patients of these two alternative techniques cannot be ignored.

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A systematic review of implant-supported overdentures in the edentulous maxilla, compared to the mandible: How many implants?

Key words dental implants, edentulous mandible, edentulous maxilla, overdentures, systematic review

Background and aim: There is now overwhelming evidence from systematic reviews that a two-implant overdenture is the first choice of treatment for the edentulous mandible. Conversely, consensus is lacking for implant-supported maxillary overdentures. Therefore, we systematically reviewed the treatment outcome of concepts used for implant-supported maxillary overdentures, focusing on the survival of implants, survival of maxillary overdentures and condition of the implant surrounding hard and soft tissues after a mean observation period of at least 1 year.

Material and methods: MEDLINE (1950 to December 2013), EMBASE (1966 to December 2013) and CENTRAL (1800 to December 2013) were searched to identify eligible studies. Two reviewers independently assessed the articles using specific study design-related quality assessment forms.

Results: Out of 195 primarily selected articles, 24 studies fulfilled the inclusion criteria. A meta-analysis showed an implant survival rate of 98.1% and overdenture survival of 99.5% per year in the case of \geq 6 implants and a splinted (bar) anchorage. In the case of \leq 4 implants and a splinted (bar) anchorage, implant survival rate and overdenture survival were 97.0% and 96.9% per year, respectively. In the case of \leq 4 implants and a non-splinted anchorage (ball, locator, telescopic crown), implant survival rate and overdenture survival were 88.9% and 98.8% per year, respectively. The condition of the peri-implant tissues was not reported in most studies.

Conclusions: An implant-supported maxillary overdenture (all studies \geq 4 implants) provided with a splinted anchorage is accompanied with a high implant and overdenture survival rate (both >95% per year), while there is an increased risk of implant loss when \leq 4 implants with a non-splinted anchorage are used.

Conflict-of-interest statement: *None declared.*

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Introduction

Edentulous patients often experience serious functional and psychosocial problems related to their conventional dentures because of an impaired load-bearing capacity^{1,2}. These problems include pain

during mastication, and insufficient stability and retention of the denture. Resolving such problems, particularly before the advent of implants, has been a challenge for both the prosthodontist and surgeon.

More than 20 years ago, van Steenberghe et al³ first reported on the possibility of using man-



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Table 1 Search strategy.

| #1 Search | "Denture, Overlay" [MeSH] | | | |
|--|--|--|--|--|
| #2 Search [MeSH] | "Dental Prosthesis, Implant supported" | | | |
| #3 Search | "Dental Implants" [MeSH] | | | |
| #4 Search | "Dental Implantation, Endosseous" [MeSH] | | | |
| #5 Search | "Mouth, Edentulous" [MeSH] | | | |
| #6 Search | "Jaw, Edentulous" [MeSH] | | | |
| #7 Search | "Maxilla" [MeSH] | | | |
| #8 Search | #2 OR #3 OR #4 | | | |
| #9 Search | #5 OR #6 | | | |
| #10 Search | #1 AND #7 AND #8 AND #9 | | | |
| Last run of data search: 31 December, 2013 | | | | |
| | | | | |

dibular overdentures supported by two implants to treat problems where usually conventional mandibular dentures would be used. Since then, mandibular overdentures have been extensively studied with respect to a number of implants, a variety of clinical items (including implant survival, health of peri-implant soft tissues and peri-implant bone loss) and patients' satisfaction⁴⁻¹⁰. For the vast majority of patients, an overdenture on two implants in the mandible is the first choice of treatment when complaining about the lack of stability in their mandibular denture¹¹⁻¹³. Underlining the McGill and York consensus statements, Thomason et al14 concluded that there is now overwhelming evidence to support the proposal that a two-implant overdenture should become the first choice of treatment for the edentulous mandible. The number of implants in the edentulous mandible for support of an overdenture are well studied^{15,16}.

Regarding implant-supported maxillary overdentures, consensus is lacking, but implant-supported maxillary overdentures have been shown as a favourable treatment option for patients with persistent complaints of retention and stability of their conventional maxillary denture¹. Next to sufficient retention and stability, proper phonetics, aesthetics and hygiene access can be achieved with implant-supported maxillary overdentures.

While two endosseous implants are generally considered to provide sufficient support to a mandibular overdenture, the number of implants needed to support a maxillary overdenture is still not set.

Currently, a variety of numbers of implants is applied to support the maxillary overdenture, as well as a variety of anchorage systems 17. Sadowsky 18 evaluated maxillary implant-supported overdentures with emphasis on the number of implants and anchorage design. He concluded that a number of 4 implants was the minimum to support a maxillary overdenture and recommended 6 implants in case of compromised bone. He could not detect a difference between the treatment outcome of splinted and non-splinted implants in the literature he assessed. Three years later, Slot et al¹⁹ showed in a metaanalysis that the survival of implants used to support a maxillary overdenture is high if concepts were used with at least 4 implants supplied with either a bar or ball anchorage. Finally, from the systematic review of Roccuzzo et al16, it can be concluded that the question of how many implants should support a maxillary overdenture is still open. Therefore, the aim of this systematic review was to assess the treatment outcome of concepts used for implant-supported maxillary overdentures focusing on survival of implants, survival of maxillary overdentures and the condition of surrounding hard and soft tissues after a mean observation period of at least 1 year.

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Material and methods

Design of the study and search strategy

Although randomised controlled trials (RCTs) provide the highest evidence in comparing effectiveness of different therapies, relevant information is not exclusively provided by RCTs. Well-designed clinical trials and case series may also provide valuable information.

A search of the literature was conducted in the databases of MEDLINE (1950 to 31 December, 2013) (via PUBMED) and EMBASE (1966 to 31 December, 2013). The search was supplemented with a systematic search in the Cochrane Central Register of Controlled Trials' (CENTRAL) (1800–31 December, 2013). No language restriction was applied. The search strategy was a combination of MeSH terms (Table 1). The search was completed by checking the references of the relevant review articles and eligible studies.

Full-text documents were obtained for all articles meeting the inclusion criteria. Full text analysis was performed independently by two reviewers (GR, HM). Methodological quality was assessed independently by the reviewers using specific study design-related modified forms designed by the Dutch Cochrane Collaboration²⁰. In case of disagreement, a consensus was reached by discussion, if necessary in consultation with a third reviewer (AV). To ensure that datasets were unique, of the studies in which the same patients were analysed at different times, leading to different publications, the study with the longest follow-up was selected for definitive analysis.

The criteria for a paper to be included in the study selection were:

- detailed information on maxillary overdentures supported by root-form endosseous implants; in case of combined data for implant-supported maxillary and mandibular removable overdentures, extraction of data for the maxillary overdenture must be possible
- the treatment of the patients has to be initially planned for a maxillary overdenture
- at least five patients should be described in a paper
- the follow-up period for implants in maxilla should be at least 1 year
- study design: RCTs, clinical trials or case series; retrospective studies were excluded.

Outcome measures

The following outcome measures were assessed:

- survival of implants
- survival of overdentures
- condition of peri-implant hard and soft tissues.

Statistical analysis

For the meta-analysis, the statistical software package 'Meta-analysis' was used (Comprehensive Meta-analysis Version 2.2, Biostat, Englewood, NJ 2005). For the calculation of the overall effects for the included studies, weighted rates together with random effect models were used.

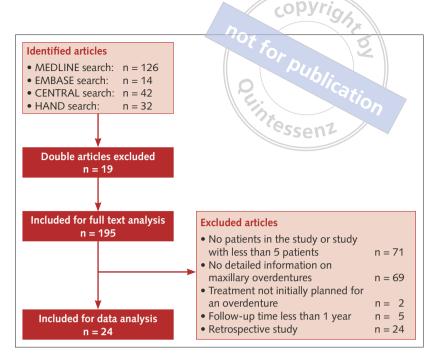


Fig 1 Algorithm of study selection procedure.

Results

Description of the studies

The MEDLINE search provided 126 hits, the EMBASE search 14 hits and the CENTRAL search 42 hits. Nineteen articles appeared to be duplicated. After scanning titles and abstracts, it was decided to select them all for evaluation as the full text article, because the abstracts did not always give a clear insight in the method of the study and the number of hits was reasonable to assess. This way no article was excluded beforehand. Reference-checking of relevant reviews and included studies revealed 32 additional articles to be screened. This approach resulted in 195 articles to be evaluated by full text analysis. Seventy-one articles were excluded because no patients at all or less than 5 patients were described. Another 69 articles were excluded because there was no detailed information available on maxillary overdentures as a separate treatment. Two articles were excluded because the treatment with implants was not initially planned for an overdenture. Five articles were excluded because the follow-up was less than 1 year. Finally, 24 articles were excluded because they were retrospective studies. The remaining 24 articles were scored (Fig 1).

Table 2 General characteristics of included studies.

| Study | Year of publication | Study design | Follow-up in months | No./of patients in study |
|--------------------------------------|---------------------|---|---------------------|-----------------------------|
| Zou et al ⁴⁴ | 2013 | Prospective | 36 | 30 |
| Slot et al ⁴¹ | 2014 | Prospective (Straumann group) | 12 | 25 |
| | | Prospective (Astra Tech group) | 12 | 25 |
| Slot et al ⁴³ | 2014 | Randomised Controlled Trial | 12 | 66 |
| Slot et al ⁴² | 2013 | Randomised Controlled Trial | 12 | 50 |
| El-Ghareeb et al ⁴⁰ | 2012 | Prospective | 14 | 6 |
| Van Assche et al ³⁹ | 2012 | Prospective | 24 | 12 |
| Katsoulis et al ³⁸ | 2011 | Prospective | 24 | 28 |
| Mangano et al ³⁷ | 2011 | Prospective | 60 | 38 |
| Akça et al ³⁶ | 2010 | Prospective | 59 | 11 |
| Pieri et al ³⁵ | 2009 | Prospective | 12 | 22 |
| Raghoebar et al ³⁴ | 2006 | Prospective | 22 | 8 |
| Raghoebar et al ³³ | 2005 | Prospective | 20 | 5 |
| Payne et al ³² | 2004 | Randomised Controlled Trial (Brånemark group) | 12 | 20 |
| | | Randomised Controlled Trial (Southern group) | 12 | 19 |
| Raghoebar et al ³¹ | 2003 | Prospective | 12 | 10 |
| Ferrigno et al ³⁰ | 2002 | Prospective | 120 | 35 |
| Zitzmann and Marinello ²⁹ | 2000 | Prospective | 12 | 10 |
| Zitzmann and Marinello ²⁸ | 2000 | Prospective | 27 | 10 |
| Bergendal and Engquist ²⁷ | 1998 | Randomised Controlled Trial (bar group) | 60 | 10 |
| | | Randomised Controlled Trial (ball group) | 50 | 8 |
| Naert et al ²⁶ | 1998 | Prospective | 48 | 13 |
| Watson et al ²² | 1997 | Prospective | 60 | 30 |
| Jemt et a ^{l21} | 1996 | Prospective | 60 | 30 |
| Hutton et al ²⁵ | 1995 | Prospective | 36 | 30 |
| Jemt et al ²⁴ | 1994 | Prospective | 12 | 6 |
| Johns et al ²³ | 1992 | Prospective | 12 | 30 |

Two studies were suspected to present the same study population^{21,22}. Whether the same study population was used was not clearly stated in the manuscript and for this reason, it was doubtful. As these two studies deliver the same data for the meta-analysis, the data from the most recent manuscript was used for the meta-analysis²². Both studies were saved for the tables, however, as regards survival, the focus was on different evaluation items. The two disagreements that occurred were easily resolved in a consensus meeting.

General characteristics of the 24 included studies are depicted in Table 2²¹⁻⁴⁴. Authors of two articles^{35,38} responded to an email concerning queries regarding the different groups they mentioned in their article. In the latter study, patients with 5

implants were excluded³⁸. Four studies were randomised controlled trials (RCTs)27,32,42,43. In the study of Payne et al³² two different implant systems were analysed and in the study of Bergendal and Engquist²⁷, the difference between a bar and a ball anchorage design was studied. In both studies, the patients that were included received 3 or less implants and a ball anchorage. Only one study was included regarding <4 implants provided with a bar suprastructure²². Slot et al^{42,43} reported on the 1-year treatment outcome of 4 and 6 bar-connected implants placed with or without pre-implant bone augmentation to support an overdenture in edentulous patients. There was no difference in implant loss between these groups. In a 3-year prospective study, Zou et al⁴⁴ evaluated the use of telescopic crown, bar and locator attachments to support a removable 4 implant-supported maxillary overdenture. No significant differences were observed in the implant survival and success rates. Furthermore, they showed that the locator attachment system was accompanied with the best peri-implant hygiene, frequency of prosthodontic maintenance measures, costs and ease of denture preparation when compared to the telescopic crown and bar attachment systems. Slot et al⁴¹ also reported the results of a 1-year prospective case series in two groups of 25 patients on the treatment outcome of maxillary overdentures supported by 6 implants opposed by natural antagonistic teeth in the mandible. In the 25 patients in whom the implants were placed after augmentation, one implant was lost and in the 25 patients not needing pre-implant augmentation, three implants. The remaining 19 studies described prospectively analysed case series. The number of patients in the studies varied from five patients to 66 patients. The follow-up period varied from 12 to 120 months (Table 2).

Table 3 summarises the treatment procedures of the included studies. The number of implants placed to support the overdenture varied from 2 to 8 implants. Onlay block graft procedures and elevation of the floor of the maxillary sinus were carried out in some studies before insertion of the implants or together with the placement of the implants. Also, the placement of implants without bone graft procedures was described. The position of the implants, in relation to the availability of a bone volume sufficient to reliably insert endosseous implants, was often not well described. Furthermore, different implant systems were used (the majority were Brånemark and Straumann implants) as well as various anchorage systems. As regards anchorage systems, both splinted (bar) and non-splinted (ball, locator and telescopic crown) designs were used. With ≥ 6 implants, the anchorage design was splinted in all cases. With ≤ 4 implants both designs were used. In the majority of the studies, the kind of opposing dentition was not described; other studies described that there were all kinds of opposing dentition. Only in three RCTs^{32,42,43} was it mentioned that all patients had a 2-implant or 4-implant overdenture in the mandible.

Table 4 gives the outcomes of the studies included in this review. For the survival rates of implants and

overdentures, see the meta-analysis paragraph. The condition of the surrounding hard and soft tissues was mentioned in nine out of the 24 studies. In 13 studies, a change in mean marginal bone level was mentioned. When reported, a variety of outcome parameters were used, as measurements were done en on either non-standardised rotational panoramic radiographs and intraoral radiographs, or on standardised intraoral radiographs. Loss of marginal bone varied from 0.22 mm in 12 months to 1.25 mm in 60 months. In 7 studies, the condition of the periimplant mucosa was mentioned, but unfortunately a variety of indices was used to score this condition. In 8 studies, bleeding on probing was noted. Finally, in 7 studies probing depth was mentioned, varying from 3.2 mm to 4.8 mm.

Meta-analysis

Due to the methodological diversity of the studies, only the number of implants, anchorage design, survival of implants and survival of the overdenture could be meaningfully combined in a meta-analysis. It was chosen to include ≥ 6 implants and ≤ 4 implants in the meta-analysis to have a clear distinction between these two groups.

Figs 2, 3 and 4 depict the results of the weighted meta-analysis, expressed as event rates per year. Event rates were used to describe failures and were calculated by the ratio of the number of failures or complications (e.g. events) to the total exposure time of the construction. The exposure time was the time the implants or the overdenture was followed. Distinct event rates were calculated for both implants and dentures. In case of an implant failure or dentures that were lost during the observation time, the time to the event was used for the analysis. The survival rate (SR) is the complement of the event rate (ER), and was calculated as SR = 1-ER.

Survival of implants

Implant survival was defined as the percentage of implants initially placed that was still present at follow-up. A total of 1876 implants in 406 patients was analysed. The survival rates of the implants varied from 100% to 72.4% (Table 4). The event rate for implant loss in the case of \geq 6 implants and a splinted

 Table 3
 Treatment procedures in the included studies.

| Study Year of Implants Pre-implant bone | | | | | 101 | |
|---|---------------------|----------------------------|--|---|---------------------------------|---------------------------------|
| Study | Year of publication | Implants per patient | Pre-implant bone augmentation | Implant system | Anchorage design | Opposing dentifien |
| Zou et al ⁴⁴ | 2013 | 4 | No | Straumann Standard SLA | Bar | # 7/2 |
| | | 4 | No | Straumann Standard SLA | Locator | # CSsenz |
| | | 4 | No | Straumann Standard SLA | Telescopic crown | # |
| Slot et al ⁴¹ | 2014 | 6 | No | Astra Tech AB | Bar | Natural teeth |
| | | 6 | Maxillary sinus floor augmentation | Straumann Standard SLA | Bar | Natural teeth |
| Slot et al ⁴³ | 2014 | 4 | Maxillary sinus floor augmentation | Straumann Standard SLA | Bar | Implant overdenture |
| | | 6 | Maxillary sinus floor augmentation | Straumann Standard SLA | Bar | Implant overdenture |
| Slot et al ⁴² | 2013 | 4 | No | Astra Tech AB | Bar | Implant overdenture |
| | | 6 | No | Astra Tech AB | Bar | Implant overdenture |
| El-Ghareeb et al ⁴⁰ | 2012 | 4 | Nasal floor augmentation | Brånemark MK III(20 implants) and Straumann Bone Level (4 implants) | Bar | All kinds of opposing dentition |
| Van Assche et al ³⁹ | 2012 | 6 | No | SLActive Standard Plus | Bar | All kinds of opposing dentition |
| Katsoulis et al ³⁸ | 2011 | 4 | No | Replace Select tapered | Bar | All kinds of opposing dentition |
| | | 5 | No | Replace Select tapered | Bar | All kinds of opposing dentition |
| | | 6 | No | Replace Select tapered | Bar | All kinds of opposing dentition |
| Mangano et al ³⁷ 2011 4 No | | No | Leone implant system | Bar | # | |
| Akça et al ³⁶ 2010 4 No | | No | Straumann | Bar | All kinds of opposing dentition | |
| Pieri et al ³⁵ 2009 4 No | | No | PrimaConnex | Bar | All kinds of opposing dentition | |
| | | 5 | No | PrimaConnex | Bar | All kinds of opposing dentition |
| Raghoebar et a ^{l34} 2006 | | 6–8 | Sinus floor augmentation and onlay block | Brånemark | Bar | # |
| Raghoebar et al ³³ | 2005 | 6 | Sinus floor augmentation | Brånemark | Bar | # |
| Payne et al ³² | 2004 | 3 | No | Brånemark | Ball | Two implant overdenture |
| | | 3 | No | Southern implant system | Ball | Two implant overdenture |
| Raghoebar et al ³¹ 2003 | | 6–8 | Sinus floor augmentation | Osseotite (3i) | Bar | All kinds of opposing dentition |
| Ferrigno et al ³⁰ | 2002 | 4–6 | Some | ITI | Bar | # |
| Zitzmann and Marinello ²⁸ | 2000 | 6–8 | # | # | Bar | # |
| Zitzmann and Marinello ²⁹ | 2000 | 6–8 | No graft procedures | Brånemark | Bar | # |
| Bergendal and Engquist ²⁷ | 1998 | 2–5 | No | Brånemark | rånemark Bar All kinds of o | |
| 2–3 No | | Brånemark | Ball | All kinds of opposing dentition | | |
| Naert et al ²⁶ | 1998 | 4 | No | Brånemark | Bar | All kinds of opposing dentition |
| Watson et al ²² 1997 3–4 # Brá | | Brånemark | Bar | Natural teeth or implant supported prosthesis | | |
| Jemt et al ²¹ | 1996 | 3–4 | # | | | All kinds of opposing dentition |
| Hutton et al ²⁵ | 1995 | # | No | Brånemark | Bar | All kinds of opposing dentition |
| Jemt et al ²⁴ | 1994 | 4–6 | # | Brånemark | Bar | # |
| | | | 1 " | | J | I " |

^{# =} no (detailed) information provided

 Table 4
 Outcomes in the included studies.

| Of Description Of Imparts Cathon Imparts I | | | | | | | | | | Or . | 12 | <u> </u> |
|--|---|--------------|------------------|----------------|------------------|---------------------------|------------------|------------------------|--------------------------------|------------------|------------------|------------------|
| Side et al | Study | of publi- | of im- plants | of lost im- | lost patients | (No. implants, mesostruc- | rate implants | rate over- dentures | marginal bone level (mean ± | index (mean ± | index (mean ± | depth (mean ± |
| Side et al | Zou et al ⁴⁴ | 2013 | 40 | 0 | 0 | 4, bar | 100 | 100 | 1.0 (0.6) | 0.25501 | 0.22 | 3.3 (0.7) |
| Side tet als 150 1 150 3 0 6, bar 98 100 0.22 0.2 0.3 4.3 | | | 40 | 0 | 0 | 4, locator | 100 | 100 | 0.9 (0.4) | | 0.16 | 3.4 (0.5) |
| Signet et al ¹⁴³ | | | 40 | 0 | 0 | | 100 | 100 | 0.9 (0.3) | 0.19 | 0.20 | 3.2 (0.8) |
| Siot et al ⁸³ 2014 132 0 0 0 4, bar 100 100 0.35 0 0 1 4.8 es 15 | Slot et al ⁴¹ | 2014 | 150 | 3 | 0 | 6, bar | 98 | 100 | 0.22 | 0.2 | 0.3 | 4.3 |
| Slot et al ¹⁴² 2013 100 0 1 4, bar 100 100 0.24 0.2 0.4 4.6 150 1 0 0 6, bar 99.5 100 0.24 0.2 0.4 4.6 150 1 0 0 6, bar 99.3 100 0.25 0.3 0.4 3.6 16.6 16.6 14.6 150 1 0 0 6, bar 99.3 100 0.25 0.3 0.4 3.6 16.6 16.6 14.6 150 1 0 0 6, bar 99.3 100 0.25 0.3 0.4 3.6 16.6 16.6 14.6 150 1 0 0 0 4, bar 100 100 # # # # # # # # # # # # # # # # | | | 150 | 1 | 0 | 6, bar | 99.3 | 100 | 0.5 | 0.1 | 0.6 | 4.3 |
| Siot et al ⁶² 2013 100 0 1 4, bar 100 100 0.24 0.2 0.4 4.6 6.6 et al ⁶² 150 1 0 0 6, bar 99.3 100 0.25 0.3 0.4 3.6 et al ⁶² 2012 24 0 0 0 4, bar 100 100 # # # # # # # # # # # # # # # # | Slot et al ⁴³ | 2014 | 132 | 0 | 0 | 4, bar | 100 | 100 | 0.35 | 0 | 0 | 4.8 |
| El-Ghareeb et al ⁴⁰ 2012 24 0 0 0 4, bar 99.3 100 0.25 0.3 0.4 3.6 et al ⁴⁰ 2012 72 1 0 0 6, bar 98.6 100 1.3 # # # # 0.28 3.4 exatsoulis et al ⁸⁸ 2011 88 1 0 0 4, bar 98.6 100 1.3 # # 0.28 3.4 exatsoulis et al ⁸⁸ 2011 88 1 0 0 4, bar 98.9 100 # # # # # # # # # # # # # # # # # # | | | 198 | 1 | 0 | 6, bar | 99.5 | 100 | 0.46 | 0 | 1 | 4.4 |
| El-Ghareeb et al ⁴⁰ 2012 24 0 0 0 4, bar 100 100 # # # # # # # # # # # # # # # # | Slot et al ⁴² | 2013 | 100 | 0 | 1 | 4, bar | 100 | 100 | 0.24 | 0.2 | 0.4 | 4.6 |
| Van Assche et al ³⁸ 2012 72 1 0 6, bar 98.6 100 1.3 # 0.28 3.4 Katsoulis et al ³⁸ 2011 88 1 0 4, bar 98.9 100 # # # # # Mangano et al ³⁷ 2011 152 4 0 0, bar 100 100 # # # # # Akça et al ³⁶ 2010 44 1 # 4, bar 97.7 88 1.15 0.8 0.2 # Pieri et al ³⁵ 2009 28 1 0 4, bar 97.4 100 # # # # # Raghoebar et al ³⁴ 2006 56 0 0 6. bar 97.3 100 # # # # # Raghoebar et al ³³ 2005 30 1 0 6. bar 97.7 100 # # # # # Raghoebar et al ³⁴ 2006 56 0 0 6. bar 97.3 100 # # # # # Raghoebar et al ³³ 2005 30 1 0 6. bar 96.7 100 # # # # # Raghoebar et al ³⁴ 2006 56 0 3, ball 92 # # # # # # Raghoebar et al ³⁴ 2006 57 10 1 3, ball 82 # # # # # # Ferrigno et al ³⁰ 2002 114 3 # 6., bar 95.6 100 0.3 (0.7) 0.5 (0.7) 0.7 (0.9) 3.4 (1.3) Ferrigno et al ³⁰ 2002 114 3 # 4., bar 86.9 (Older bar) bar) 2004 4 4 6 # 4., bar 86.9 (Older bar) bar) 2004 4 4 6 # 4., bar 86.9 (Older bar) bar) 2004 4 4 4 4 4 4 4 4 4 | | | 150 | 1 | 0 | 6, bar | 99.3 | 100 | 0.25 | 0.3 | 0.4 | 3.6 |
| Katsoulis et al ³⁸ 2011 88 1 0 0 4, bar 98.9 100 # # # # # # # # # # # # # # # # # # | El-Ghareeb et al ⁴⁰ | 2012 | 24 | 0 | 0 | 4, bar | 100 | 100 | # | # | # | # |
| Segregation | Van Assche et al ³⁹ | 2012 | 72 | 1 | 0 | 6, bar | 98.6 | 100 | 1.3 | # | 0.28 | 3.4 |
| Mangano et al ³⁷ 2011 152 4 0 0 4, bar 97.4 100 # # # # # # # # # # # # # # # # # # | Katsoulis et al ³⁸ | 2011 | 88 | 1 | 0 | 4, bar | 98.9 | 100 | # | # | # | # |
| Mangano et al ³⁷ 2011 152 4 0 4, bar 97.4 100 # # # # # # # # # # # # # # # # # # | | | 25 | 0 | 0 | 5, bar | 100 | 100 | # | # | # | # |
| Akça et al ³⁶ 2010 44 1 # 4, bar 97.7 88 1.15 0.8 0.2 # Pieri et al ³⁵ 2009 28 1 0 0 4, bar 96.4 100 # # # # # # # Raghoebar et al ³⁴ 2006 56 0 0 5, bar 97.3 100 # # # # # # # # # Raghoebar et al ³³ 2005 30 1 0 6, bar 96.7 100 # # # # # # # # # Payne et al ³² 2004 60 5 0 3, ball 92 # # # # # # # # # # # # # Raghoebar et al ³⁴ 2003 68 3 0 0 6-8, bar 96.7 100 # # # # # # # # # # # # # # # # # # | | | 6 | 0 | 0 | 6, bar | 100 | 100 | # | # | # | # |
| Pieri et al 35 | Mangano et al ³⁷ | 2011 | 152 | 4 | 0 | 4, bar | 97.4 | 100 | # | # | # | # |
| Raghoebar et al ³⁴ 2006 56 0 0 0 6-8, bar 100 ## # # # # # # # # # # # # # # # # | Akça et al ³⁶ | 2010 | 44 | 1 | # | 4, bar | 97.7 | 88 | 1.15 | 0.8 | 0.2 | # |
| Raghoebar et al ³⁴ 2006 56 0 0 0 6-8, bar 100 100 # # # # # # # # # # # # # # # # | Pieri et al ³⁵ | 2009 | 28 | 1 | 0 | 4, bar | 96.4 | 100 | # | # | # | # |
| Raghoebar et al ³³ 2005 30 1 0 6, bar 96.7 100 # # # # # # # # # # Raghoebar et al ³² 2004 60 5 0 3, ball 92 # # # # # # # # # # # # # Raghoebar et al ³¹ 2003 68 3 0 6-8, bar 95.6 100 0.3 (0.7) 0.5 (0.7) 0.7 (0.9) 3.4 (1.3) | | | 75 | 2 | 0 | 5, bar | 97.3 | 100 | # | # | # | # |
| Payne et al ³² 2004 60 5 0 3, ball 92 # # # # # # # # # # # Raghoebar et al ³¹ 2003 68 3 0 6-8, bar 95.6 100 0.3 (0.7) 0.5 (0.7) 0.7 (0.9) 3.4 (1.3) Ferrigno et al ³⁰ 2002 114 3 # 6, bar 92.2 (Milled bar) # # # # # # # # # # # # # # # # # # # | Raghoebar et al ³⁴ | 2006 | 56 | 0 | 0 | 6-8, bar | 100 | 100 | # | # | # | # |
| ST 10 1 3, ball 82 # # # # # # # # # | Raghoebar et al ³³ | 2005 | 30 | 1 | 0 | 6, bar | 96.7 | 100 | # | # | # | # |
| Raghoebar et al ³¹ 2003 68 3 0 6-8, bar 95.6 100 0.3 (0.7) 0.5 (0.7) 0.7 (0.9) 3.4 (1.3) Ferrigno et al ³⁰ 2002 114 3 # 6, bar 92.2 (Milled bar) 64 6 # 4, bar 86.9 (Dolder bar) 71 4 0 6-8, bar 94.4 100 0.92 54% (SD 26%) # # # # # # # # # # # # # # # # # # # | Payne et al ³² | 2004 | 60 | 5 | 0 | 3, ball | 92 | # | # | # | # | # |
| Ferrigno et al ³⁰ 2002 114 3 # 6, bar 92.2 (Milled bar) 64 6 # 4, bar 86.9 (Dolder bar) [Colder bar) 87.5 (Dolder bar) # # # # # # # # # # # # # # # # # # # | | | 57 | 10 | 1 | 3, ball | 82 | # | # | # | # | # |
| Company | Raghoebar et al ³¹ | 2003 | 68 | 3 | 0 | 6–8, bar | 95.6 | 100 | 0.3 (0.7) | 0.5 (0.7) | 0.7 (0.9) | 3.4 (1.3) |
| Colder bar Col | Ferrigno et al ³⁰ | 2002 | 114 | 3 | # | 6, bar | (Milled | (Milled | # | # | # | # |
| Marinello ²⁸ Zitzmann and Marinello ²⁹ Bergendal and Engquist ²⁷ Naert et al ²⁶ 1998 53 6 6 4, bar 72.4 75.9 76.9 77.9 78.9 79.90 1.25 ################################### | | | 64 | 6 | # | 4, bar | (Dolder | (Dolder | # | # | # | # |
| Marinello ²⁹ Bergendal and Engquist ²⁷ Bergendal and Engquist ²⁷ 1998 29 6 # 2-5, bar 79 90 1.25 # # # # ** Naert et al ²⁶ 1998 53 6 6 4, bar 88.6 85 0.5 # # # # # # Watson et al ²² 1997 117 30 14 3-4, bar 72.4 77.9 # # # # # # # # # # # # # | Zitzmann and Marinello ²⁸ | 2000 | # | # | 0 | 6-8, bar | # | # | # | # | # | # |
| The image of the | Zitzmann and Marinello ²⁹ | 2000 | 71 | 4 | 0 | 6-8, bar | 94.4 | 100 | 0.92 | | # | # |
| Naert et al ²⁶ 1998 53 6 6 4, bar 88.6 85 0.5 # 0.2 (0.7) 3.6 (0.9) Watson et al ²² 1997 117 30 14 3–4, bar 72.4 77.9 # # # # Hutton et al ²⁵ 1995 117 29 # #, bar 72.4 72.4 # # # # Jemt et al ²⁴ 1994 32 0 0 0 4–6, bar 100 100 Mesial side 0.30 (0.25) Distal side 0.34 (0.11) | Bergendal and | 1998 | 29 | 6 | # | 2-5, bar | 79 | 90 | 1.25 | # | # | # |
| Watson et al ²² 1997 117 30 14 3-4, bar 72.4 77.9 # # # # # # # # # # # # # # # # # # # | Engquist ²⁷ | | 18 | 7 | # | 2-3, ball | 61 | 88 | 1.0 | # | # | # |
| Jemt et al ²¹ 1996 117 30 14 3-4, bar 72.4 77.9 0.8 (0.8) # # # Hutton et al ²⁵ 1995 117 29 # #, bar 72.4 72.4 # # # # Jemt et al ²⁴ 1994 32 0 0 4-6, bar 100 100 Mesial side 0.30 (0.25) Distal side 0.34 (0.11) # # # | Naert et al ²⁶ | 1998 | 53 | 6 | 6 | 4, bar | 88.6 | 85 | 0.5 | # | 0.2 (0.7) | 3.6 (0.9) |
| Hutton et al ²⁵ 1995 117 29 # #, bar 72.4 72.4 # # # # # Jemt et al ²⁴ 1994 32 0 0 4-6, bar 100 100 Mesial side 0.30 (0.25) Distal side 0.34 (0.11) | Watson et al ²² | 1997 | 117 | 30 | 14 | 3-4, bar | 72.4 | 77.9 | # | # | # | # |
| Jemt et al ²⁴ 1994 32 0 0 4–6, bar 100 100 Mesial side 0.30 (0.25) Distal side 0.34 (0.11) | Jemt et al ²¹ | 1996 | 117 | 30 | 14 | 3–4, bar | 72.4 | 77.9 | 0.8 (0.8) | # | # | # |
| 0.30 (0.25) Distal side 0.34 (0.11) | Hutton et al ²⁵ | 1995 | 117 | 29 | # | #, bar | 72.4 | 72.4 | # | # | # | # |
| Johns et al ²³ 1992 117 21 5 #, bar 82.2 86.3 0.5 # # # | Jemt et al ²⁴ | 1994 | 32 | 0 | 0 | 4–6, bar | 100 | 100 | 0.30 (0.25) Distal side | # | # | # |
| | Johns et al ²³ | 1992 | 117 | 21 | 5 | #, bar | 82.2 | 86.3 | 0.5 | # | # | # |

^{#=} no (detailed) information provided

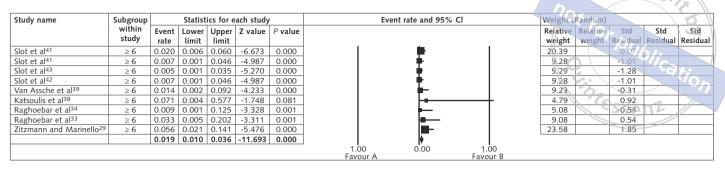


Fig 2 Meta-analysis of implant loss in case of \geq 6 implants and a splinted superstructure. (When a study is mentioned twice, more than one implant system was analysed in that study. For details see Table 2.)

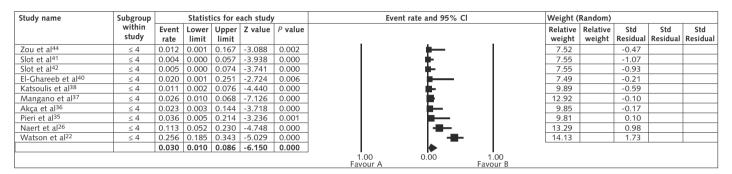


Fig 3 Meta-analysis of implant loss in case of \leq 4 implants and a splinted superstructure.

| Study name | Subgroup | | Statist | ics for e | ach study | , | Event rate and 95% Cl | Neight (I | Random) | | | |
|--------------------------------------|-----------------|------------|----------------|----------------|-----------|---------|-------------------------------------|--------------------|--------------------|-----------------|-----------------|-----------------|
| | within study | Event rate | Lower limit | Upper limit | Z value | P value | | Relative weight | Relative weight | Std Residual | Std Residual | Std Residual |
| Zou et al ⁴⁴ | ≤ 4 | 0.012 | 0.001 | 0.167 | -3.088 | 0.002 | | 10.41 | | -1.40 | | |
| Zou et al ⁴⁴ | ≤ 4 | 0.012 | 0.001 | 0.167 | -3.088 | 0.002 | - •- □ | 10.41 | | -1.40 | | |
| Payne et al ³² | ≤ 4 | 0.175 | 0.097 | 0.296 | -4.444 | 0.000 | | 27.97 | | 0.59 | | |
| Payne et al ³² | ≤ 4 | 0.083 | 0.035 | 0.185 | -5.134 | 0.000 | | 25.76 | | -0.33 | | |
| Bergendal and Engquist ²⁷ | ≤ 4 | 0.389 | 0.198 | 0.621 | -0.935 | 0.350 | | 25.44 | | 1.69 | | |
| | | 0.111 | 0.040 | 0.273 | -3.703 | 0.000 | | | | | | |
| | | | | | | | 1.00 0.00 1.00 Favour A Favour B | | | | | |

Fig 4 Meta-analysis of implant loss in case of ≤ 4 implants and a non-splinted superstructure. (When a study is mentioned twice more than one implant system was analysed in that study. For details see Table 2.)

anchorage was 0.019, which can be expressed as a survival rate of 98.1% per year (Fig 2). The event rate for implant loss in the case of \leq 4 implants and a splinted anchorage was 0.030, which can be expressed as a survival rate of 97.0% per year (Fig 3). The event rate for implant loss in the case of \leq 4 implants and a non-splinted anchorage was 0.111, which can be expressed as a survival rate of 88.9% per year (Fig 4).

Survival of maxillary overdentures

The survival of maxillary overdentures was defined as the percentage of overdentures initially placed that was still present at follow-up. Survival rates of the overdentures varied from 100% to 77.9% (Table 4). The weighted meta-analysis (for person-years and for study size) for overdenture loss, expressed as event rates, in case of \geq 6 implants and a splinted anchorage was 0.005 (95% CI [0.002 – 0.012]), which can be expressed as a survival rate of 99.5% per year. The event rate for overdenture loss in the case of \leq 4 implants and a splinted anchorage was 0.031 (95% CI [0.013 – 0.076]), which can be expressed as a survival rate of 96.9% per year. The event rate for overdenture loss in the case of \leq 4 implants and a non-splinted anchorage was 0.012 (95% CI [0.002 – 0.086]), which can be expressed as a survival rate of 98.8% per year²⁷.

Discussion

In contrast to the edentulous mandible, prospective studies with clinical and radiological baseline data reflecting the number of implants needed to support a maxillary overdenture, with an appropriate sampling frame, adequate sample size and sampling method are currently scarce. In addition, there is a shortage of RCTs to compare the outcome of specific questions related to the number of implants and design of the superstructure. In only two RCTs, the treatment outcome of 4 and 6 implants to support a maxillary denture was compared^{42,43}. In these RCTs no difference was noted between these treatment concepts after 1-year follow-up. All the other included publications provided data from convenience samples. Notwithstanding this drawback, on the basis of the available data we conclude that an implant-supported maxillary denture on at least 4 implants and provided with a bar anchorage is a proper treatment option for the edentulous maxilla, mainly because implant loss is considerably higher when the implant-denture is supported by < 4 implants.

By contrast and as mentioned before, there is a large body of evidence on which treatment concept is most suitable for the edentulous mandible. A 2-implant supported mandibular overdenture should be the minimum offered to edentulous patients as a first choice of treatment. The implant survival rate of mandibular overdentures is high, regardless of the number of implants¹⁵. Furthermore, there is evidence from systematic reviews and a large number of RCTs applying patient-based outcome assessments such as patients' satisfaction, oral-health related quality of life and in-depth qualitative interviews with patients that implant-supported mandibular overdentures have considerable benefits over conventional complete dentures¹⁴. It has to be mentioned, however, that the aforementioned recommended 2-implant supported mandibular overdenture treatment was based mainly on the results of studies that described implants placed in edentulous mandibles with a mandibular height in the symphysis region of at least 12 mm, and not in extremely atrophied jaws (mandibular height <12 mm). For the extremely resorbed mandible, there might be a need to modify this treatment concept. A treatment proposal for these very

atrophied mandibles based on the best evidence currently available in the literature is made². According to this proposal, in the extremely resorbed mandible (bone height and width ≥ 6 mm), 4 short implants could be placed if the soft tissues are in a good condition. Only in cases with a bone height of <6 mm, or when the soft tissue not in a good-enough condition to support an implant-supported mandibular denture, a bone augmentation procedure is advised.

In contrast to the excellent long-term implant and prosthodontic survival and success rates for implant-supported mandibular overdentures^{10,45,46}, several studies have described a higher number of implant failures and prosthodontic complications for implant-supported maxillary overdentures^{1,19,21,45}. Poor bone quality, low bone quantity, short implant length with reduced diameter and poor initial stability are problems observed in edentulous maxillae cases and may adhere to the higher risk of implant loss and loss of maxillary overdentures^{21,47}.

As reported, the 1-year implant survival rate in the case of ≥ 4 implants supplied with a bar anchorage is >95%, which is very promising and comparable to the concepts using 4 or 6 implants and a bar anchorage to support the maxillary denture⁴¹⁻⁴⁴. Reliable long-term data are not yet available. When losing an implant as part of 6-implant concept, a new surgical treatment procedure is usually not needed, as the overdenture can be adjusted. This is often not the case for the 4-implant approach, as with many of these patients a new implant has to be placed and a new suprastructure has to be made before the overdenture can be adjusted.

Progressive marginal bone loss is a predictor for future implant loss. Therefore, it is very important to analyse marginal bone loss in a standardised and reliable way. However, most studies used panoramic radiographs on which small changes in marginal bone loss are often not easy or not possible to assess. In the few studies that used standardised intraoral radiographs, marginal bone loss was less than 1.3 mm after 1 year, which is promising 35,36,39,41-44. Further studies are needed to truly rate the long-term marginal bone loss around maxillary implants.

Mucosa indices, bleeding indices and pocket probing depth provide insight into the health of the peri-implant soft tissues. In the studies covering this aspect, the soft tissues appeared relatively healthy, although mucositis and gingival hyperplasia may occur around the implants and below the bar^{21,22}. Mucositis and gingival hyperplasia are usually reserved to conditions where the space between the bar and the oral mucosa or the space between the implants is limited. These conditions make proper oral hygiene difficult.

Future research concerning implant treatment of the edentulous maxilla should focus on long-term prospective clinical trials with detailed follow-up, in which clinical and radiographic aspects are analysed, restoration of function is assessed and patient satisfaction is scored. The current RCTs still only report on the 1-year follow-up data. Besides trials with overdentures, long-term RCTs comparing maxillary implant overdentures and fixed implant prostheses (e.g. costs, success rate, patient preference, and patient quality of life) are needed. Such comparisons are currently lacking. Only when all these factors are properly assessed will an evidence-based treatment concept for implant-supported maxillary dentures be found, thereby contributing to a higher level of care in this field.

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Autogenous bone harvesting and grafting in advanced jaw resorption: Morbidity, resorption and implant survival

Key words autogenous bone graft, complication, donor site morbidity, resorption

Aim: To analyse the morbidity arising from autogenous bone graft harvesting, graft resorption and implant survival in grafted sites.

Materials and methods: Only comparative clinical trials on the harvest of autogenous bone grafts were selected. Studies were excluded if they compared autogenous bone grafts to bone substitutes or vascularised free bone grafts.

Results: A total of 24 studies were included in the review. Six intraoral or distant donor sites were identified. The highest level of evidence was reached by a randomised controlled trial. The mandibular ramus was the source of bone that was preferred by the patients. From this intraoral donor site bone was harvested under local anaesthesia on an outpatient basis. Patients' acceptance of chin bone harvesting was low. It led to a considerable morbidity that included pain, superficial skin sensitivity disorders and wound healing problems at the donor site. Patients even preferred iliac crest bone harvesting over bone harvesting from the chin, although this distant donor site required general anaesthesia and a hospital stay. The harvest of posterior iliac crest block led to less morbidity than the harvest of anterior iliac crest block grafts. When only cancellous bone was needed, percutaneous bone harvesting from the iliac crest led to less morbidity than an open approach to the iliac crest.

Conclusions: Dependent on the required graft structure and amount of bone needed, ramus grafts, block bone grafts from the posterior iliac crest and cancellous bone grafts harvested with a trephine from the anterior iliac crest should be chosen.

Conflict-of-interest statement: The authors declare that they have no conflict of interest.

Introduction

Edentulism profound marginal periodontitis, trauma, malformation, neoplasia and insufficient dentures can lead to atrophy of the alveolar crest¹. Advanced jaw resorption can cause problems when the placement of dental implants is intended. Limited residual alveolar bone volume potentially results in aesthetic and functional compromise. Therefore, an adequate quantity and quality of bone can be considered a

prerequisite for a successful oral rehabilitation with dental implants².

Augmentation procedures allow the re-establishing of bone volume that is adequate for implant placement. Autogenous bone, allografts, xenografts, alloplastic materials, and mixtures of the various materials have been used for this purpose³. Among the different available materials, only autogenous bone combines osteoconductive, osteo-inductive, and osteogenic properties⁴. Autogenous



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Tel: +493455575244 Fax: +493455575292 Email: emeka@nkenke.de bone is believed to be the most effective grafting material⁵. Consequently, it is not surprising that the use of autogenous grafts is still considered to be the method of choice when augmentation procedures have to be performed on patients with advanced jaw resorption⁶. The high predictability of these procedures has been stressed. Success rates exceeding 95% have been achieved, even when major augmentation procedures with autogenous bone had to be carried out for severely resorbed jaws⁷.

A number of different donor sites are available for the harvest of bone grafts. The grafts differ considerably as far as embryology, histology, mechanical properties and the volume that can be harvested are concerned. Membranous as well as endochondral bone grafts from regional or distant sites are available. The choice of a specific donor site often is based on a number of different aspects like resorption rate of the graft or the donor site morbidity².

The present review aimed at comparing different donor sites for autogenous bone based on comparative studies. The focused question was: Does a donor site exist that is superior to alternative sites, in terms of the extent of donor site morbidity, the quantity of available bone, the extent of bone graft resorption and the survival or success rate of dental implants placed in the augmented sites?

Materials and methods

Search strategy

A systematic search strategy was used. In the initial phase of the review, a computerised literature search for human studies was performed (Medline and Embase databases, 1 January 1966 to 31 December 2013). There was no language restriction.

In addition, a hand search was carried out in: Annals of Periodontology; British Journal of Oral and Maxillofacial Surgery; Clinical Implant Dentistry & Related Research; Clinical Oral Implants Research; Dental Clinics of North America; European Journal of Oral Implantology; European Spine Journal; Implant Dentistry; The International Journal of Oral and Maxillofacial Surgery; International Journal of Periodontics and Restorative Dentistry; International Journal of Prosthodontics; Journal of Clinical Periodontology;

Journal of Cranio-Maxillofacial Surgery; Journal of Oral Implantology; Journal of Oral and Maxillofacial Surgery; Journal of Periodontology; Journal of Prosthetic Dentistry; Journal of the American Dental Association; Medicina Oral Patologia Oral y Cirugia Bucal; Mund-, Kiefer- und Gesichtschirurgie, Oral and Maxillofacial Surgery; Oral and Maxillofacial Surgery Clinics of North America; Oral Surgery Oral Medicine Oral Pathology; Periodontology 2000; Scandinavian Journal of Plastic and Reconstructive Surgery; The International Journal of Oral and Maxillofacial Implants; The Journal of Bone and Joint Surgery; and The Knee.

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Moreover, the Cochrane Controlled Trials Register and The Cochrane Health Group Specialized Register were checked for publications on harvesting of autogenous bone grafts.

The full texts of publications with potential relevance were obtained. Additional articles were identified from the reference lists of the retrieved papers.

Search terms

Keywords were 'bone graft' OR 'autogenous bone graft' OR 'autologous bone graft' OR 'autogenous bone harvesting' OR 'autologous bone harvesting'. The search was limited to 'human trial' (what the Medical Subject Headings (or MeSH) term clinical studies). Additionally, the MeSH terms 'clinical trial', 'comparative study', 'controlled clinical trial', 'randomised controlled trial', 'meta-analysis', and 'review' were also used.

Inclusion criteria

The inclusion criteria for study selection were: (i) comparative clinical studies; (ii) exclusive use of autogenous bone grafts for the augmentation procedure; and (iii) a number of at least 10 patients.

Exclusion criteria

Publications dealing with *in vitro* studies, preclinical (animal) studies, cadaver studies, case reports and reviews were excluded. Human studies not meeting all the inclusion criteria were also excluded from the review. In addition, studies were excluded if: (i) additional augmentation procedures were performed with materials other than autogenous bone (e.g.

xenografts, allografts, barrier membranes, growth factors, stem cells, etc.); (ii) vascularised free bone grafts were used; (iii) distraction osteogenesis was used; (iv) augmentation procedures were compared to short implants; (v) data presentation that did not allow distinguishing results for the different types of grafts used; (vi) bone grafts were harvested from patients suffering from malformations; (vii) augmentation procedures were carried out following the removal of benign or malignant tumours; (viii) the included patients had received radiation therapy or chemotherapy; and (ix) the studies reported on a patient cohort that had been the basis for a previous publication by the same authors.

Selection of studies

Titles derived from the broad search were screened based on the inclusion criteria. Subsequently, abstracts of all titles considered relevant were obtained and again screened for meeting the inclusion criteria. If an abstract was not available in the database, the abstract of the printed article was used. Again, a selection was made based on the inclusion criteria, and relevant full texts were obtained. The final selection of the publications to be included in the review was based on an analysis of the 'Materials and methods' and 'Results' sections of the full-text articles concerning the fulfilment of the inclusion and exclusion criteria.

Data extraction

From the selected papers, data were extracted on the following: author(s); year of publication; study design; follow-up period; number of patients; donor site; kind of anaesthesia; graft volume; grafting procedure; complications and donor site morbidity; graft resorption; implant survival; and implant success.

Results

Initial electronic search

By the electronic search, a total of 798 titles were identified. Out of these, 316 abstracts were obtained. Screening of the abstracts led to the selection of 136 full texts. Based on a hand search, an additional 43

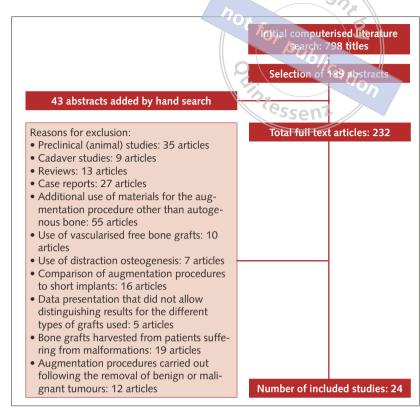


Fig 1 Search strategy for identification of relevant articles.

relevant abstracts were included and the respective full texts were obtained. Further selection of studies was based on a total of 232 full texts. A total of 24 original articles fulfilled the inclusion criteria and did not meet any exclusion criteria. The study with the highest level of evidence was a randomised controlled one⁸.

Exclusion of studies

Reasons for excluding studies after the full text was obtained were: preclinical (animal) studies (35 articles); cadaver studies (9 articles); reviews (13 articles); case reports (27 articles); additional use of materials for the augmentation procedure other than autogenous bone (55 articles); use of vascularised free bone grafts (10 articles); use of distraction osteogenesis (7 articles); comparison of augmentation procedures to short implants (16 articles); data presentation that did not allow distinguishing results for the different types of grafts used (5 articles); bone grafts harvested from patients suffering from malformations (19 articles); or augmentation procedures carried out following the removal of benign or malignant tumours (12 articles, Fig 1).

Included studies

A total of 24 articles were selected for inclusion in a narrative style review. They are presented in Table 1. In the selected comparative studies, six donor sites for bone harvesting were identified. They comprised the calvarium, the mandibular ramus, the chin, the anterior iliac crest, the posterior iliac crest and the proximal tibia.

Patients' acceptance of bone harvesting

A questionnaire-based interview survey shows that harvesting bone grafts for preprosthetic procedures is widely accepted by potential patients¹⁸. Some 61% of the interviewees were willing to undergo bone grafting if this procedure would facilitate implant placement. However, 23% of the patients were willing to accept bone harvesting from the iliac crest, but 15% of the patients indicated that they would prefer bone harvesting from the chin. The majority of the patients (85%) answered that they would prefer bone harvesting from the retromolar region¹⁸.

When the harvesting of chin bone grafts was proposed to patients who would benefit from an augmentation procedure, again the limited acceptance of this donor site became obvious²¹. Patients had cosmetic concerns and feared changes of the chin contour. Conversely, cosmetic concerns did not arise when bone harvesting from the ramus was proposed²¹.

In one study, patients were asked to compare the postoperative strain put on them by the bone harvesting procedure with their preoperative expectations¹⁶. The two patient cohorts that were compared received bone harvesting from the anterior iliac crest either with an anteromedial or a superolateral approach. Both procedures were well accepted. For the anteromedial and the superolateral approach, the postoperative course was considered better than expected by 26 out of 30 patients and 34 out of 40 patients, respectively¹⁶.

The acceptability of bone harvesting from intraoral sites did not statistically significantly differ between chin and ramus grafts²⁵. However, the acceptability of ramus bone harvesting increased significantly when it was combined with the removal of the third molar.

Following chin bone harvesting, patients sometimes complain about an altered chin contour. In one study, 10 out of 29 patients noted changes of their chin contour when bone was harvested from this site¹⁴. Comparable complaints were not described for a cohort of 24 patients who underwent ramus bone harvesting¹⁴. On clinical examination, contour changes following chin bone harvesting could not be verified.

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Characteristics of bone graft harvesting procedures

Bone harvesting from the mandibular ramus and the chin was performed, preferably under local anaesthesia and was sometimes combined with intravenous sedation (Table 1). Instead, for all other donor sites bone harvesting under general anaesthesia was preferred (Table 1). The surgical access to the ramus has been described as being more difficult than the access to the chin²¹. As far as the duration of surgery was concerned, bone harvesting from the proximal tibia with a trephine took a mean time of 15 mins, while trephine bone harvesting from the iliac crest took 21 mins¹⁹. As far as the duration of surgery for other donor sites and harvesting techniques is concerned, there are no data available from comparative studies. The same is true for the assessment of the duration of the inpatient period following bone graft harvesting. The comparison of bone harvest from the iliac crest with a trephine compared to an open approach showed that the length of the hospital stay was significantly shorter for the trephine procedure (4.1±0.9 days and 2.2 \pm 0.4 days, respectively, $P < 0.05)^{26}$.

Bone graft volume and density

Bone from the ramus was preferred for vertical and horizontal onlay augmentation procedures compared to chin bone. A greater volume of chin bone could be harvested, compared to retromolar bone¹⁵. A mean volume of 1.74 cm³ has been found for chin bone grafts, while the mean volume for ramus bone grafts was 0.9 cm³ ²¹. Therefore, bone from the chin was preferred when a bilateral sinus floor augmentation had to be performed¹⁵.

The percutaneous harvesting of iliac crest bone with a trephine was limited to 10 cm³, while

larger volumes could be harvested using an open approach²⁰.

When the available bone volume at the anterior iliac crest was compared to the proximal tibia, it was significantly less $(17.63 \text{ cm}^3 \text{ and } 38.60 \text{ cm}^3, \text{ respectively}, P < 0.001)^{22}$.

When the bone density of grafts from the anterior iliac crest, the posterior iliac crest and the chin were compared at the time of the grafting procedure, the density of the anterior iliac crest bone $(35.1 \pm 7.6\%)$ at the time of grafting, $36.1 \pm 7.6\%$ 6 months after grafting) and the density of the posterior iliac crest bone grafts (30.7 \pm 9.5% at the time of grafting, $34.5 \pm 6.5\%$ 6 months after grafting) did not change significantly²⁷. The density of chin bone grafts reduced significantly during that time interval $(74.6 \pm 8.6\% \text{ at the time of grafting}; 54.0 \pm 8.6\%$ 6 months after grafting, $P = 0.003)^{27}$. When bone density was measured in Hounsfield Units (HU), the density of particulated grafts (chin and iliac crest) increased significantly over a time interval of 5 years $(704 \pm 213 \text{ HU at time of grafting}, 868 \pm 169 \text{ HU})$ after 5 years, $P = 0.0313)^{30}$. During the same time interval, block bone grafts (chin and iliac crest) did not change statistically significantly, as far as HU were concerned $(P = 0.3750)^{30}$.

Donor site morbidity

It has been shown that the patient perception of the morbidity of harvesting of bone grafts from the chin or the mandibular ramus did not lead to statistically significant differences when the morbidity was rated on a visual analogue scale. For both procedures, the morbidity was low¹⁵. However, an altered sensation in the mandibular incisors has been identified as a source of morbidity on a frequent basis following chin bone harvesting. This problem was described by 29% of the patients who underwent this procedure²¹. Root canal treatment became necessary in 2 out of 282 teeth following chin bone harvesting¹⁵. It has been stressed that altered sensations did not occur in patients who underwent ramus bone harvesting²¹.

The occurrence of superficial skin sensitivity disorders has been identified as an issue with intraoral bone harvesting. Superficial skin sensory disturbances were found significantly more often after

chin bone harvesting, compared to bone harvesting from retromolar sites¹³⁻¹⁵. A percentage of 9.6% for superficial skin sensitivity impairment has been described following chin bone harvesting, while sensitivity disorders were not found following ramus bone harvesting²¹. However, postoperative pain during chewing and bleeding were only reported after retromolar bone harvesting¹⁵. The problem did not occur following ramus bone harvesting. Conversely, incision-line dehiscence was exclusively found following chin bone harvesting in 10.7% of the cases²¹. A comparable problem did not occur following ramus bone harvesting.

It has been described in the current literature that besides harvesting bone from the ramus, bone harvesting from the calvarium as well as the iliac crest can be performed without significant patient morbidity as far as pain and discomfort are concerned^{12,13}. However, it has to be stressed that comparative studies that evaluate the morbidity of calvarial bone harvesting are scarce.

On the other hand, a number of comparative studies have been dedicated to the assessment of donor site morbidity arising from bone harvesting from the iliac crest.

After bone harvesting from the anterior iliac crest by an open approach, patients complained about significantly more pain in the initial postoperative phase compared to the harvesting from the posterior iliac crest (P = 0.004)²³. Pain sensations even seemed to last for a longer period of time when the anterior iliac crest is used as a donor site (P = 0.0017)⁹. Bone harvesting from the posterior iliac crest led to significantly less minor complications (e.g. haematomas) compared to bone harvesting from the anterior iliac crest (P = 0.006).⁹ As far as superficial skin sensitivity disorders were concerned, they were also significantly more pronounced following open bone harvesting from the anterior iliac crest, compared to the posterior iliac crest (P = 0.023)²³.

When an anterolateral approach to the anterior iliac crest was compared to a superolateral approach to the anterior iliac crest, there was no statistically significant difference in persistent postoperative pain (17% and 34%, respectively), gait disturbance (17% and 25%, respectively), and the need for the use of crutches (37% and 50%, respectively)¹⁶. Neither of the two different approaches was able to reduce the

Table 1 Compilation of the studies included in the review (/ = no data available).

| Authors | Design of study | Follow-up period | No. of patients | Patient age (years) | Donor site | Kind of anaesthesia |
|--|---------------------------------------|----------------------|-----------------|---------------------------------|---|--|
| Ahlmann et al, 2002 ²⁹ | Retrospective | ≥ 2 years | 66 | Range 12–77 | Anterior iliac crest Posterior iliac crest | General 10/1 |
| | | | 42 | | Posterior iliac crest | General |
| Carinci et al, 2005 ¹⁰ | Prospective | 16.5 ± 7.7 months | 21 47 | 48.2 ± 8.4 (both cohorts) | Iliac crest Calvarium | / |
| Chiapasco et al, | Prospective | 19 months on | 7 | 49.1 (both | Calvarium | General |
| 2012 ¹¹ | · | average | 11 | cohorts) | Ramus | Local (combined with sedation) |
| Chiapasco et al, | Prospective | 23.9 months | 15 | 50.2 ± 16.1 | Calvarium | Local or general (all |
| 2013 ¹² | | on average | 19 | 53.5 ± 10.5 | Calvarium (with pericranium) | cohorts) |
| | | | 6 | 44.3 ± 18.3 | Ramus | |
| | | | 4 | 40.5 ± 15.3 | Ramus (with pericranium) | |
| Chiapasco et al, 2014 ¹³ | Prospective | 33 months on | 9 | 53.8 ± 13.0 | Calvarium (tissue level implant) | Local or general (all |
| 201413 | | average | 10 | 40.9 ± 17.0 | Ramus (tissue level implant) | cohorts) |
| | | | 6 | 59.3 ± 4.4 | Iliac crest (tissue level implant) | |
| | | | 7 | 55.9 ± 13.2 | Calvarium (bone level implant) | |
| | | | 11 | 44.8 ± 12.1 | Ramus (bone level implant) | |
| | | | 7 | 49.2 ± 14.9 | Iliac crest (bone level implant) | |
| Clavero et al, 2003 ¹⁴ | Prospective | 18 months | 29 | Mean of 48 years (both cohorts) | Chin | Local (combined with sedation, both |
| 2003 | | | 24 | (Sour conorts) | Ramus | cohorts) |
| Cordaro et al, 2011 ¹⁵ | Cross sectional | 29 months on average | 41 | Range 18–68 (both cohorts) | Ramus | Local (combined with sedation, both cohorts) |
| | | | 37 | | Chin | |
| Cricchio and Lund- gren, 2003 ¹⁶ | Retrospective | 2 years | 30 | 56 on average (both cohorts) | Anteromedial iliac crest | General |
| gren, 2005.° | | | 40 | (DOLIT COHOITS) | Superolateral iliac crest | General |
| Eufinger and Lep- pänen, 2000 ¹⁷ | Retrospective | Range 1–6 years | 26 | 12.2 on average | Anterior iliac crest (trephine) | General |
| parieri, 2000 | | years | 26 | | Anterior iliac crest (open approach) | General |
| Felice et al, 2009 ⁸ | Randomised controlled | 18 months on average | 10 | 55.2 ± 13.6 | Anterior iliac crest (both groups) | General |
| | | | 10 | 52.7 ± 7.6 | | General |
| Hof et al, 2014 ¹⁸ | Cross sectional (Questionnaire-based | / | 150 | Range 18–84 | Chin | Local |
| | assessment of patients' perspectives) | | | | Ramus | Local |
| | ,p 3.700/ | | | | Iliac crest | General |
| Ilankovan et al, 1998 ¹⁹ | Prospective | 7 days | 15 | Range 14–66 | Proximal tibia (trephine) | / |
| 133013 | | | 15 | (both cohorts) | Anterior iliac crest (trephine) | |

| | Ĭ. | | | 10, | 2 |
|---|---|---|------------------|------------------|---|
| Graft volume | Grafting procedure | Complications | Graft resorption | Implant survival | Implant success |
| 54.53 cm ³ on average | / | Haematoma, sensory disturbance, pain Sensory disturbance | / | / Einzessen | Lion |
| 55.12 cm³ on average | | | | | |
| / | Onlay/inlay (both cohorts) | None | 39% | / | / |
| | | None | 17% | | |
| / | Onlay/sinus floor augmentation (both | Dehiscence at recipient site None | 0.41 ± 0.67 mm | 100% | 90.3% |
| | cohorts) | | 0.52 ± 0.45 mm | 100% | 93.1% |
| / | Onlay (all cohorts) | Dehiscence at recipient site | 0.64 ± 2.35 mm | 100% | 91.03% |
| | | Dehiscence at recipient site | 0.23 ± 0.50 mm | 98.97% | 94.18% |
| | | Dehiscence at recipient site | 1.86 ± 3.76 mm | 100% | 100% |
| | | None | 0 | 100% | 100% |
| / | Onlay (all cohorts) | None | 0.21± 0.37 mm | 100% | 100% |
| | | None | 0.23 ± 0.30 mm | 100% | 100% |
| | | None | 0.36 ± 0.39 mm | 100% | 100% |
| | | Dehiscence | 0.35 ± 0.52 mm | 100% | 90.3% |
| | | None | 0.48 ± 0.42 mm | 100% | 93.5% |
| | | Dehiscence | 1.34 ± 1.33 mm | 100% | 76.4% |
| / | Onlay/inlay (both cohorts) | Pain, bleeding, swelling, bruising, neuro- sensory disturbance, functional limita- tions in eating, chewing, limited drinking, and speaking, reduced mouth opening (both cohorts) | / | / | / |
| / | Onlay/sinus floor augmentation (both cohorts) | Swelling, bleeding, pain, sensory disturbance, prolonged healing Swelling, pain, sensory disturbance (lip, teeth), prolonged healing | / | / | No difference between the two cohorts |
| / | / | Persistent pain, gait disturbance | / | / | / |
| | | Persistent pain, gait disturbance | | | |
| / | Onlay (both | Pain, wound infection | / | / | / |
| | cohorts) | Pain | | | |
| / | Interpositional graft | Dehiscence at recipient site | 13.6 ± 14.4% | 100% | 90% |
| | Onlay | Dehiscence and infection at recipient site | 44.5 ± 15.7% | 100% | 86.9% |
| / | / | / | / | / | / |
| 17 cm ³ on average, range 5 to 26 cm ³ (both cohorts) | Inlay/onlay Inlay/onlay | Pain, gait disturbance Pain, gait disturbance | / | / | / |

Table 1 (cont.) Compilation of the studies included in the review (/ = no data available).

| Authors | Design of study | Follow-up period | No. of patients | Patient age (years) | Donor site | Kind of anaesthesia |
|---|------------------|---------------------------|--------------------------|-------------------------------|--|--|
| Kreibich et al, 1994 ²⁰ | Cross sectional | / | 58 (both groups) | / | Anterior iliac crest (percuraneous) Anterior iliac crest (open approach) | enz enz |
| Misch, 1997 ²¹ | Prospective | 6 months | 19 31 | / | Ramus | Local (combined with sedation, both cohorts) |
| Nikolopoulos et al, 2008 ²² | Cross sectionall | / | 15 15 | Range 24–96 (both cohorts) | Anterior iliac crest Proximal tibia | / |
| Nkenke et al, 2004 ²³ | Prospective | 1 month | 25 25 | 52.0 ± 9.6 52.9 ± 9.1 | Anterior iliac crest Posterior iliac crest | General (both cohorts) |
| Pollock et al, 2008 ²⁴ | Prospective | 19.8 months on average | 52 | 46.1 on average | Anterior iliac crest (trephine) | General (both cohorts) |
| Raghoebar et al, 2007 ²⁵ | Prospective | 12 months | 15 | 45.6 on average 29 ± 7 | Anterior iliac crest (open approach) Chin | Local (all cohorts) |
| | | | 15 15 | | Ramus Ramus (simultaneous third molar removal) | |
| Sandor et al, 2003 ²⁶ | Prospective | 3 days | 54 22 | 22.6 ± 9.6 24.2 ± 9.6 | Anterior iliac crest (trephine) Anterior iliac crest (open approach) | / |
| Schlegel et al, 2006 ²⁷ | Prospective | 6 months | 18 15 28 | | Chin Anterior iliac crest Posterior iliac crest | Local General General |
| Sbordone et al, 2009 ²⁸ | Retrospective | 3 years | 40 (both cohorts) | 46.8 ± 12.1 (both cohorts) | Chin Anterior iliac crest | General (both cohorts) |
| Sbordone et al, 2012 ²⁹ | Retrospective | 6 years | 16 (both cohorts) | 55.4 ± 8.2 (both cohorts) | Anterior iliac crest (both cohorts) | General (both cohorts) |
| Sbordone et al, 2013 ³⁰ | Retrospective | 6 years | 10 7 | Range 24–96 (both cohorts) | Chin/anterior iliac crest block not specified (cohorts) Chin/anterior iliac crest particulate | |
| Wiltfang et al, 2005 ³¹ | Retrospective | 5 years | 100 (both cohorts) | 56.3 (both cohorts) | Anterior iliac crest Posterior iliac crest | General General |

| | | | | 10% | |
|---|--|--|---|--------------------------------|-----------------|
| Graft volume | Grafting procedure | Complications | Graft resorption | Implant survival | Implant success |
| ≤ 10 cm ³ | / | Postoperative pain, abnormal neurology, wound tenderness | / | 1 Sinterna | idion |
| Not specified | | Postoperative pain, pain on walking, abnormal neurology, wound tenderness | | cssen | |
| 0.9 cm³ on average | Onlay (both cohorts) | Pain | Up to 25% | / | / |
| 1.74 cm ³ on average | Constant and the consta | Pain, dehiscence, neurosensory disturbance of teeth and soft tissue | Up to 25% | | |
| 17.63 cm ³ | / | / | / | / | / |
| 38.60 cm ³ | | | | | |
| 10 cm ³ | Onlay/sinus floor augmentation (both cohorts) | Pain, gait disturbance, neurosensory impairment | / | / | / |
| 14 cm ³ | CONOTES | Pain, gait disturbance, neurosensory impairment | | | |
| / | / | Haematoma, meralgia paraesthetica, superficial infection | / | 1 | / |
| | | Haematoma, meralgia paraesthetica, chronic pain | | | |
| Range 1 to 3 cm ³ | Onlay (all cohorts) | Prolonged postoperative pain, altered sensations in lower incisors, transient hypoesthesia of labial gingiva, paraesthesia, meteorotropism | / | 100% | / |
| Not specified | | Prolonged postoperative pain | | 1 implant loss | |
| Not specified | | Prolonged postoperative pain, delayed socket healing | | 100% | |
| ≤ 30 cm ³ (both cohorts) | / | Pain, gait disturbance (both cohorts) | / | / | / |
| / | Sinus floor augmentation (all cohorts) | / | / | / | / |
| / | Onlay (both cohorts) | / | Maxilla 4.6 ± 0.9 mm Mandible / | Maxilla 100% Mandible / | / |
| | | | Maxilla 2.6 ± 1.4 mm Mandible 4.0 ± 1.6 mm | Maxilla 100% Mandible 98.1% | |
| 1.25 cm ³ | Onlay (both cohorts) | / | Maxilla 105.5% | Maxilla 100% | / |
| 1.25 cm ³ | · | | Mandible 87% | Mandible 100% | |
| >0.5 cm ³ | Sinus floor augmentation (both cohorts) | 1 | 21.5% | 100% | |
| >0.5 cm ³ | Onlaw/sings flags | | 39.2% | 86.6% | / |
| / | Onlay/sinus floor augmentation (both cohorts) | / | Anterior less than posterior | 92.4% | / |

donor site morbidity of iliac crest bone harvesting by an open approach, significantly¹⁶.

The donor site morbidity of anterior iliac crest bone harvesting is significantly reduced when a percutaneous approach is used instead of an open approach²⁰. Lower postoperative pain (P < 0.02), pain on walking (P < 0.05), superficial skin sensitivity impairment (P < 0.01) and wound tenderness (P < 0.05) were documented²⁰. Significantly reduced postoperative pain with trephine hip bone harvesting has been confirmed by other authors $(P < 0.05)^{26}$. Unassisted ambulation also could be reached earlier when a trephine was used, compared to an open approach (2.8 days and 4.1 days, respectively)²⁶. Harvesting of bone from the iliac crest with a trephine reduced the analgesic consumption significantly compared to an open approach $(P < 0.008)^{17}$. Although there is one study in the current literature that found comparable results as far as donor site morbidity was concerned when a trephine and an open method were used for bone harvesting from the iliac crest, it has never been described that the trephine technique increases donor site morbidity²⁴. Moreover, the length of the scar that resulted from the surgical approach was significantly shorter when the incision was made for trephine harvesting compared to an open approach (24.2 mm and 60.3 mm, respectively, $P < 0.0001)^{17}$.

When bone harvesting with a trephine from the proximal tibia and the anterior iliac crest were compared, pain and difficulty in walking were lower for the tibia group¹⁹.

Complications at recipient site

After onlay augmentation with ramus, iliac crest or calvarial bone grafts, the rate of dehiscences were comparable for the different types of bone grafts¹¹⁻¹³. There was a tendency towards a lower rate of dehiscences with ramus bone grafts. However, statistically significant results were not found.

When the rate of complications (e.g. mucosal dehiscence or infection) was compared between sites augmented by inlay grafts or onlay grafts, the rate was comparable for both techniques (30% for each technique)⁸.

The small amount of data on complications following bone grafting at the recipient site seems to show that the kind of bone graft chosen only has a minor influence on the complication rate.

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Graft resorption

Resorption of bone grafts is a major issue following augmentation procedures. It has been stated that the volume of block bone grafts (chin and iliac crest) did not change significantly over a 6-year period $(P=0.2754)^{30}$. The same result was found for particulated grafts $(P=0.0781)^{30}$. During a 5-year follow-up period, resorption of bone grafts from the anterior iliac crest did not differ statistically significantly from the resorption of bone grafts from the posterior iliac crest³¹. Block bone grafts from the iliac crest as well as the chin used for sinus floor augmentation tended to show less resorption during a 6-year follow-up interval compared with particulated bone grafts from the same donor sites (21.5% and 39.2% resorption, respectively)³⁰.

When the resorption of iliac crest bone grafts used for vertical or horizontal onlay augmentation was compared between maxilla and mandible, the resorption in the maxilla was significantly more pronounced after 2 years²⁹. After 6 years, 87% of resorption was found in the mandible, while the grafts were completely resorbed in the maxilla²⁹.

It has been shown that the resorption of onlay grafts was significantly more pronounced for chin grafts, compared to iliac crest bone grafts²⁸. Block bone grafts from the chin and the ramus did not differ as far as resorption was concerned when they were used for onlay augmentation procedures²¹.

The results for graft resorption are conflicting when calvarial bone is involved in comparative studies. It has been described that graft resorption was more pronounced for calvarial grafts compared to ramus bone grafts after a mean interval of 23.9 months¹². On the other hand, the same working group described that calvarial bone showed less resorption than mandibular ramus bone, while graft resorption was the most pronounced for iliac crest bone grafts¹³. At the time of implant placement, ramus bone grafts showed a resorption of 0.42 ± 0.39 mm, while calvarial bone grafts showed a resorption of 0.18 ± 0.33 mm¹¹. After a mean of 19 months of prosthetic loading, graft resorption was 0.52 ± 0.45 mm with mandibular ramus bone and 0.41 ± 0.67 mm with calvarial bone¹¹.

Results with the same tendency were also found by other authors. Graft resorption was significantly less for calvarial bone after 10 months of follow-up compared to iliac crest bone grafts (P = 0.004)¹⁰. However, after 30 months, the difference in resorption was no longer statistically significant¹⁰. Age and gender of the patients, the site to be augmented, and the type of augmentation surgery did not influence graft resorption significantly¹⁰.

When onlay bone grafting was compared to inlay bone grafting, the initial height gain of the alveolar crest was significantly larger for the onlay procedure⁸. However, the loss in vertical dimension was significantly lower for inlay bone grafting compared to onlay bone grafting (0.5 mm and 2.75 mm, respectively, P < .001)⁸.

Implant survival and success

Implant survival and success rate are important parameters that are at least in part dependent on the preceding augmentation procedures. When implant sites grafted with chin bone or bone from the ramus no differences in implant success could be found¹⁵. After a mean follow-up period of 23.3 months, an implant success rate of 95.5% was found¹⁵. During an average follow-up interval of 23.9 months, the survival and success rate for implants placed in ramus bone grafts was 100%. For implants placed in calvarial grafts, a survival rate of 99% and a success rate of 91% were reached¹².

After a mean prosthetic loading period of 19 months, the implant survival rate was 100% for implant sites grafted with mandibular ramus bone, as well as for implant sites grafted with calvarial bone ¹¹. The success rate was 90.3% for implants placed in calvarial bone and 93.1% for implants placed in mandibular ramus bone ¹¹. All failures were attributed to peri-implant disease.

After a mean follow-up period of 33 months, the implant success rate was 93.5% for implant sites grafted with mandibular ramus bone, 90.3% for sites grafted with calvarial bone, and 76.4% for sites grafted with iliac crest bone. Irrespective of the graft origin, an influence of the implant design on the success rate was found¹³.

A 3-year cumulative implant survival rate of 100% following onlay grafting regardless of source

(either chin or iliac crest bone) could be identified for the maxilla²⁸. With the mandible grafted with iliac crest onlay grafts, the 3-year cumulative implant survival rate was 98.1%.

After a follow-up period of 5 years, the implant survival rate was 92.4%, when the implant sites had been grafted with bone from the anterior iliac crest, and 93.9% when the grafting procedure had been carried out with bone from the posterior iliac crest³¹. The difference did not show a statistical significance.

When implant survival is compared for sites augmented by inlay grafts or onlay grafts, the survival rate is 100% for both techniques⁸. With 90.0% and 86.9%, respectively, implant success is also comparable for both techniques⁸.

Discussion

Although a number of alternatives exist, autogenous bone is still considered one of the most popular materials for preprosthetic augmentation procedures³². A wide variety of donor sites are available for the harvest of autogenous bone. Grafts that are harvested by an intraoral approach (e.g. coronoid process, tuber, zygomatic buttress) as well as grafts that are harvested from distant sites (e.g. rib, radius, femur) have been described³³⁻³⁶. Quality, quantity and high predictability of uneventful healing at the recipient sites are major reasons to opt for autogenous bone. However, harvesting of bone potentially causes donor site morbidity. Morbidity is a major issue for the patients. They appreciate procedures that reduce morbidity associated with implant-based oral rehabilitation³⁷. Bone substitutes avoid donor site morbidity. However, although excellent clinical and histological outcomes have been reported for smaller defects, the predictability of the repair of larger defects is still limited³⁸. Therefore, in cases where large amounts of bone are required, autogenous bone is considered the first choice³⁸. Nevertheless, preprosthetic augmentation procedures have to be considered elective surgery.

Therefore, besides a successful reconstruction of the alveolar crest, patient acceptance of the procedure should be high, while the morbidity of the procedure should be minimal¹. The present review aimed at comparing different donor sites for autogenous bone based on comparative studies. The focused question was: Does a donor site exist that is superior to alternative sites in terms of the extent of donor site morbidity, the quantity of available bone, the extent of bone graft resorption, and the survival or success rate of dental implants placed in the augmented sites?

Patients' acceptance of bone harvesting

The analysed literature reveals that bone harvesting is accepted by patients if this procedure is necessary to allow placing implants¹⁸. The least popular donor site was the chin, while a majority of the participants of the study would prefer bone harvesting from the mandibular ramus. Even more participants opted for iliac crest bone harvesting than for chin bone harvesting. It seems that these patient decisions are based on major aesthetic concerns that arise when chin bone harvesting is planned²¹. Surprisingly, approximately one third of the patients who undergo chin bone harvesting complain about an altered chin contour that cannot be verified on clinical examination¹⁴. Again, this finding hints at the limited acceptance of chin bone harvesting by the patients.

During the postoperative course, the patients tend to consider the reconstructive procedures performed with anterior iliac crest bone better than expected¹⁶. This finding reflects the good acceptance of this bone harvesting procedure that usually even has to be carried out under general anaesthesia (Table 1).

As far as patients' acceptance of calvarial or tibial bone harvesting is concerned, no relevant data could be identified in the present review.

Characteristics of bone graft harvesting

Bone harvesting from intraoral sites is preferably performed under local anaesthesia (Table 1). Consequently, this kind of bone harvesting can be performed with fewer risks than bone harvesting from distant sites, where general anaesthesia is preferred. The access to the chin bone has been described as being easier than that to the mandibular ramus (Misch, 1997)²¹. Both techniques are performed on an outpatient basis, while harvesting of bone from

distant sites is associated with a hospital stay and again increases costs²⁶. Only limited data are available on the duration of bone harvesting surgery. It has been documented that bone harvesting from the proximal tibia with a trephine can be performed faster than bone harvesting from the iliac crest with the same technique¹⁹. This fact seems to be a reason to prefer tibial bone grafts over iliac crest bone grafts. In this context, it has to be noted that the use of trephines instead of open harvesting techniques reduces the inpatient period significantly²⁶.

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Based on the harvesting characteristics, it seems that bone harvesting from the mandibular ramus should be preferred by experienced surgeons. Bone harvesting from a distant site seems to increase costs and should be performed with a trephine in order to reduce the inpatient period. However, one has to keep in mind that bone harvesting is limited to non-structural, cancellous grafts, when trephines are used.

Bone graft volume and density

Chin grafts have the highest bone density. Their density is even considerably higher after the completion of the healing time compared to iliac crest bone grafts²⁷. However, the available bone volume is small compared to distant sites where volumes over 50 cm³ can be collected⁹. Therefore, it can be assumed that distant donor sites will be preferred when major augmentation procedures have to be performed on extremely resorbed jaws.

Donor site morbidity

Morbidity is one of the most important criteria for the selection of a specific donor site in elective preprosthetic surgery. The chin seems to fall behind the ramus bone graft, because of the relatively high percentage of superficial skin sensitivity disorders and altered sensations in the mandibular incisors, compared to ramus bone grafts^{14,15,21}.

When distant donor sites have to be adopted, it can be assumed that the morbidity arising from tibial bone harvesting is low¹⁹. Unfortunately, this site has not been an intensive focus of clinical trials in the past. The same is true for calvarial bone grafts. But the availability of bone relevant data on morbidity is missing. In contrast, the morbidity of iliac crest

bone harvesting has attracted a lot of interest in the past. It has been shown that bone grafts from the posterior iliac crest lead to lower postoperative pain, less superficial skin sensitivity disorders and less gait disturbances compared to the anterior iliac crest^{9,23}. A further reduction in morbidity can be achieved by the use of trephines, which allow accessing the iliac crest through small incisions¹⁷.

Graft resorption

Graft resorption is a major issue following augmentation procedures. It has been stated that membranous bone is superior to enchondral bone in maintaining volume in the initial phase following the augmentation procedure. There seemed to be a higher tendency to resorption of the iliac crest onlay grafts compared with calvarial onlay grafts¹⁰. However, this tendency seems to decrease with an increasing follow-up interval¹⁰. Some authors have even reported resorption rates of calvarial bone grafts that exceeded that of other bone grafts¹².

It seems that interpositional bone grafts lead to more predictable results compared to onlay bone grafts. However, the interpositional bone graft technique requires an experienced surgeon, while performing an onlay bone graft requires a shorter learning curve. Because of the more pronounced resorption, it has been recommended to oversize onlay bone grafts. Once implants have been placed in the augmented sites, the outcomes are similar for interpositional and onlay grafts⁸. Due to a reduced tendency towards resorption, it has been recommended to prefer block bone grafts over particulated autogenous bone grafts for sinus floor augmentation³⁰.

Especially as far as bone resorption around dental implants is concerned, it seems that there is a clear dependence on the types of implants used¹³. It seems that graft resorption is present with every grafted site to a variable extent. Based on the knowledge derived from the review, interpositional grafting should be used wherever possible. An alternative is overcorrection during onlay grafting. Moreover, types of implants should be chosen that only lead to minimal resorption of peri-implant bone.

Implant survival and success

Implant survival was high in the selected studies independent from the source of bone chosen for the augmentation procedure (Table 1). The lowest survival rate was found with particulated grafts for the chin, as well as anterior iliac crest bone after 6 years (86.6%)³⁰. Even when extensive graft resorption was described, it was possible to reach an implant survival rate of 100% after 6 years²⁹. Also for implant success, high values were found throughout the different selected studies (Table 1). Only two studies reported on success rates below 90%8,13. A specific kind of implant combined with iliac crest only grafts led to an implant success rate of 76.4% after 33 months¹³. When a different implant type was used, the success rate increased up to 100% after the same time interval. These data again demonstrate the influence of the selected implant types on the implant success rate.

The data on implant survival and success do not allow the identification of a bone graft that is associated with a significant improvement of these parameters. Even with complete resorption of the grafted bone, an implant survival rate of 100% can be reached¹¹. It seems that the type of bone graft has only a limited influence on implant survival and success. Instead, confounders like the type of implant installed seem to have a major influence on implant survival and success.

When the aim of the treatment concept is to reduce patient morbidity to a minimum, bone should be harvested from the mandibular ramus. However, even bone harvesting from this donor site can lead to relevant impairments of the patient^{15,25}. Therefore, it has to be kept in mind that alternatives to autogenous bone exist for some indications of bone grafting. For example, as far as sinus floor augmentation is concerned, it seems that the use of bone substitutes finally leads to implant survival rates that are comparable to those that can be achieved with implants placed in sites grafted with autogenous bone³². For these grafting indications, autogenous bone should no longer be considered the 'golden standard'. In the future, there is a perspective to reduce the morbidity of autogenous bone harvesting by the adoption of tissue engineering approaches^{39,40}.

Conclusions

The mandibular ramus is the source of bone that is preferred by the patients. From this intraoral donor site, bone is harvested under local anaesthesia on an outpatient basis. In contrast, patients' acceptance of chin bone harvesting is low. Harvesting of chin grafts leads to a considerable morbidity that includes pain, superficial skin sensitivity disorders and wound healing problems at the donor site. Patients even prefer iliac crest bone harvesting over bone harvesting from the chin, although this distant donor site requires general anaesthesia and a hospital stay. The analysis of the comparative studies reveals that the posterior iliac crest should be preferred over the anterior iliac crest when large amounts of block bone grafts are needed. Conversely, when only non-structural cancellous grafts are needed, percutaneous bone harvesting from the iliac crest with a trephine should be preferred.

The data provided by the included studies did not allow evaluation of the relevance of tibial and calvarial bone harvesting. It seems that the type of bone graft does not have a major influence on implant survival and success.

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Bilal Al-Nawas, Eik Schiegnitz

Augmentation procedures using bone substitute materials or autogenous bone – a systematic review and meta-analysis

Key words bone augmentation procedures, bone substitute materials, dental implants, metaanalysis, oral implants, survival rate

Aims: Bone substitute materials (BSM) are described as a reasonable alternative to autologous bone (AB) to simplify the grafting procedure. In a systematic review and meta-analysis, the influence of BSM compared to AB on treatment success in augmentation procedures of the edentulous jaw was analysed.

Material and methods: Literature analysis resulted in only two studies addressing reconstruction of the totally edentulous jaw using BSM. Therefore the literature analysis was extended to partially and totally edentulous jaws. The following augmentation procedures were analysed: maxillary sinus floor augmentation (MSFA) and vertical and/or lateral alveolar ridge augmentation; guided bone regeneration (minor and contained defects) were excluded. Meta-analysis was implemented using the literature from the years 2000 to early 2014 and only studies with a mean follow-up of at least 10 months were included.

Results: After screening 843 abstracts from the electronic database, 52 studies in qualitative and 14 in quantitative synthesis were included. In studies examining MSFA, the mean implant survival rate was $98.6\% \pm 2.6$ for BSM, $88.6 \pm 4.1\%$ for BSM mixed with AB and $97.4 \pm 2.2\%$ for AB alone. For MSFA, meta-analysis showed a trend towards a higher implant survival when using BSM compared to AB, however the difference was not statistically significant ([OR], 0.59; [CI], 0.33-1.03). No statistically significant difference in implant survival for MSFA between BSM mixed with AB and AB was seen ([OR], 0.84; [CI], 0.5-1.42). Concerning ridge augmentation, the mean implant survival rate was $97.4 \pm 2.5\%$ for BSM, $100 \pm 0\%$ for BSM mixed with AB and $100 \pm 0\%$ for AB alone. Meta-analysis revealed no statistically significant difference in implant survival for ridge augmentation using BSM or AB ([OR], 1.85; [CI], 0.38 to 8.94). For BSM mixed with AB versus AB alone, a meta-analysis was not possible due to missing data.

Conclusions: Within the limitation of the meta-analytical approach taken, implant survival seems to be independent of the biomaterial used in MSFA and alveolar ridge augmentation. Therefore, based on the current literature, there is no evidence that AB is superior to BSM. The conclusions are limited by the fact that influence of defect size, augmented volume and regenerative capacity of the defects is not well described in the respective literature.

Conflict of interest statement: There are no commercial or other associations that might create a duality of interests in connection with the article.



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Introduction

Management of partially or totally edentulous patients with implants has been a routine treatment modality for decades, with reliable long-term successes¹⁻⁶. The predictability of the implant survival and the maintenance of long-term stability of implants in function are directly associated with the quality and quantity of the available bone for implant placement⁷. In the case of alveolar ridges with insufficient bone volume or unfavourable vertical, horizontal or sagittal intermaxillary relationships, additional surgical procedures can be necessary to reconstruct and augment the deficiency.

The physiological properties of bone grafts and bone substitute materials (BSM) are often described by the terms osteoinductivity, osteoconductivity and osteogenicity. Osteoinductivity is the capability of a graft to actively promote bone formation^{8,9}. Osteoconductivity is a characteristic of the scaffold that facilitates the colonisation and ingrowth of new bone cells and sprouting capillaries by reason of its three-dimensional structure. Osteoconduction is by definition a passive process and primarily destined by the porosity properties of the scaffold and in a lower degree by its chemical and physical properties that stimulate adhesion and cell growth¹⁰. Osteogenicity is referred to the presence of bone-forming cells within the bone graft¹¹.

Autogenous bone (AB), with its osteogenic, osteoinductive and osteoconductive characteristics, is often considered as the gold standard in bone regeneration procedures^{2,12}. It contains osteoblasts, osteoclast precursor cells, undifferentiated mesenchymal cells and monocytes, which promote the remodelling and formation of new bone^{13,14}. However, donor site morbidity, limited quantities available, unpredictable graft resorption and the need to include additional surgical sites are unavoidable disadvantages that have encouraged the search for BSM as convenient alternatives^{15,16}.

There are a variety of BSM available with different biological and mechanical properties. They can be categorised in the following three groups: (1) allogenic, from another individual within the same species; (2) xenogenic, from another species; and (3) alloplastic, synthetically produced (Jensen, 2009). Chemical compositions range from biological

apatites, monophasic calcium phosphates (tricalcium phosphates, hydroxyapatites [HAs]) and silicates to bi- and more-phasic mixed ceramics¹³. To date, there is no BSM commercially available that is equal to AB regarding its osteoinductive characteristics. In fact, BSM primarily serves as filling and scaffold building substances, mostly providing osteoconduction for the bone healing process^{12,17,18}. However, there is strong clinical evidence that BSM can still be used successfully in augmentation procedures^{2,12,19}.

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A multiplicity of augmentation procedures, depending on location and size of defect, are used to provide the osseous support necessary to allow placement of implants. In continuation of the study of Klein et al¹², the following classification of augmentation procedures was applied in the present review: (1) maxillary sinus floor augmentation (MSFA), including the lateral window technique and the transalveolar approach ('external' or 'internal' sinus lift); and (2) vertical and/or lateral alveolar ridge augmentation of different dimensions, including peri-implant defects in the form of dehiscence-type defects and fenestration-type defects.

The aim of the present systematic review and meta-analysis was to assess the clinical outcome of different graft materials used in augmentation procedures of the edentulous jaw.

Material and methods

Protocol development

The study protocol was designed according to the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analyses) statement as described before²⁰⁻²². In the context of the consensus conference 'Patient centered rehabilitation of edentulism with an optimal number of implants' (Foundation for Oral Rehabilitation (F O R) at the University of Mainz, 2014), the original objective of this study was to evaluate the clinical outcome of augmentation procedures using bone substitute materials or autogenous bone in totally edentulous patients. The initial search for primary literature showed that only very few studies have been published on this specific topic^{23,24}. Therefore, the literature search was expanded on augmentation procedures in partially

edentulous patients. With reference to the PICO format (Patient, Intervention, Comparison and Outcome), the following focused question was developed²⁵: 'In partially and totally edentulous patients treated with dental implants and augmentation procedures, are there any differences in terms of implant survival between BSM compared to AB?' Bone augmentation procedures were classified into MSFA and vertical and/or lateral alveolar ridge augmentation as described before¹². Minor augmentation procedures of contained defects ('guided bone regeneration') were excluded.

Literature research and meta-analysis

The current review was based on a study by Klein et al¹² that had already revised the literature on the present topic for the years from 2000 to 2010. This study was built upon by performing an extensive electronic search in the electronic databases of the National Library of Medicine for articles published between January 2010 and January 2014 to identify literature presenting implant survival data in augmentation procedures using BSM or AB. In addition, the reference lists of related review articles and publications were systematically screened. The search was completed with an additional hand search of selected journals and reviews. However, to improve the quality of this study, a meta-analysis was performed using the literature of the years 2000 to 2014. For the meta-analysis, only studies with a mean follow-up of at least 10 months were included.

Search terms

The search strategy included the following key words: 'bone substitute materials'; 'dental/oral implants'; 'augmentation'; 'implant survival', 'sinus floor elevation'; 'vertical ridge augmentation'; 'horizontal ridge augmentation'. The literature research was completed using the following MeSH Terms (Medical Subject Heading): ('dental implants' [Mesh] OR 'dental implantation' [Mesh] OR 'oral implants' [Mesh]) AND ('augmentation' [Mesh] OR 'vertical ridge augmentation' [Mesh] OR 'sinus floor elevation' [Mesh]) AND ('clinical outcome' [Mesh]) OR 'implant survival' [Mesh]).

Inclusion criteria

All studies retrieved from the above search were screened on the basis of titles and abstracts. Screening and selection of studies for inclusion were carried out according to the following inclusion criteria:

- Randomised controlled clinical trials (RCT), controlled clinical trials (CCT), prospective studies
 (PS) and retrospective studies (RS) on the topic
 of extended augmentation procedures with BSM
 or autogenous bone in partially and totally edentulous patients.
- 2. Use of a BSM or AB.
- 3. Inclusion of \geq 10 subjects.
- 4. Published in English.
- 5. Documentation of the implant survival rate after a defined period of time.

Only solid, granular BSM of alloplastic, xenogenic or phycogenic origin were included. As growth factors and platelet rich plasma were not part of the objectives of this study, all studies including those substances were excluded.

Study selection

The abstracts derived from this extensive search were independently screened by the two authors based on the inclusion criteria. For all abstracts meeting the inclusion criteria, full texts were requested for in-depth evaluation and further data extraction. Any disagreement on study selection was resolved by discussion. Data was extracted using structured data extraction forms. The PRISMA flow diagram shows the flow of information through the different phases of the literature research (Fig 1). Concerning the quality of the selected studies, no prospective randomised studies were found on the defined PICO question. Therefore, in the present study the best available external evidence was collected as described above in the inclusion criteria. The authors are aware that the risk of bias is higher compared with other reviews that include only randomised studies.

Quality assessment

According to the study of Proskin et al²⁶, six quality categories were used to analyse the quality of

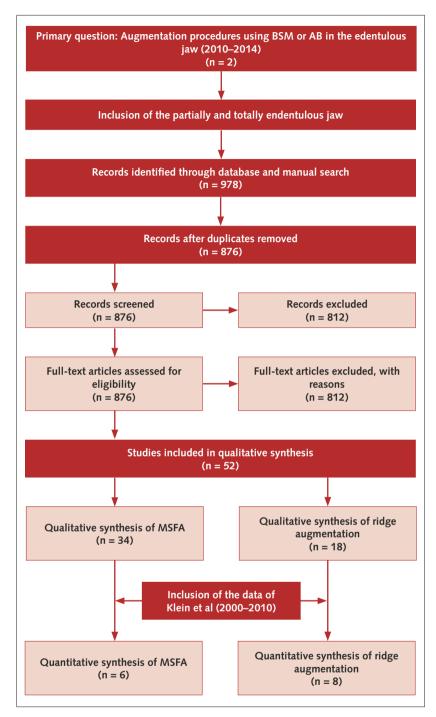


Fig 1 PRISMA flow diagram.

each selected study according to its design: 'fair' for a retrospective study; 'average' for a prospective case study; 'good' for a prospective study with historical controls; 'better' for a prospective study with concurrent controls; 'best' for a double-blind randomised controlled trial (RCT); and 'unknown' when the study design could not be ascertained or fit none of the definitions.

Statistical analysis

The overall estimated effect was considered significant if P was <0.05. Meta-analysis was conducted using the statistical software package RevMan (Review Manager (RevMan) [Computer program]. Version 5.2. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2012) to collect the data, calculate the overall estimated effects and to produce the forest plots.

Results

Study selection

The electronic search of the databases and the manual search resulted in the identification of 978 abstracts (Fig 1). Sixty-four of these 978 abstracts were considered potentially relevant and complete texts of these studies were sampled and reviewed. Further reference cross-checks generated four additional publications for a full text analysis. Finally, 52 methodologically acceptable publications with relevant data on implant survival in augmentation procedures were selected to be included for interpretation and statistical analysis. These articles were further subdivided into two categories according to the augmentation procedures: 34 articles reporting on MSFA (category I) and 18 articles reporting on vertical and/or lateral alveolar ridge augmentation (category II) were provided. Hereof, six studies were used for meta-analysis on implant survival in MSFA and eight studies used for meta-analysis on implant survival in ridge augmentation procedures.

Quality assessment of selected studies

Fifteen of the included studies were RCTs and were rated as 'best'. Three studies were classified as 'better'. Seventeen studies were categorised as 'average', as they were prospective case studies without historical or concurrent controls. The remaining 17 studies were retrospective and were classified as 'fair'. In general, both quality and level of evidence of the investigated articles were limited. Most of the studies were categorised as 'average' and 'fair'. However, this review includes 15 RCTs with best

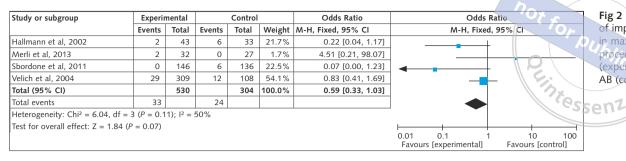


Fig 2 Forest plot of implant survival in maxillary sinus lift procedures using BSM (experimental) versus AB (control)

quality level. Allocation concealment at a high risk of bias, lack of reporting characteristics of drop-out, missing blind examiners to assess clinical outcomes and lack of CONSORT adherence suggests being cautious with data interpretation and drawing general conclusions derived from these studies.

Results for MSFA using BSM or AB

A summary of all studies examining the implant survival rate in patients receiving MSFA is shown in Table 1. Altogether, in the investigated studies 1816 patients received a total of 4687 implants. The numbers of patients ranged between 10 and 461 and the age of patients between 21 and 83 years. Sinus membrane perforation occurred in $19.2 \pm 10.8\%$ of the cases. Sinusitis was reported in four studies. Mean healing periods were 5.5 ± 1.9 months for BSM, 5.4 ± 1.3 for BSM mixed with AB and 4.33 ± 0.57 for AB.

The mean follow-up was 39.7 ± 34.6 months (a range of 4 to 170 months). The mean implant survival rate of all examined studies (2010 to January 2014) was $98.6\% \pm 2.6$ for BSM, $88.6 \pm 4.1\%$ for BSM mixed with AB and $97.4 \pm 2.2\%$ for AB alone. Implant success was described in eight studies and ranged from 91.7% to 100%.

This study aimed at performing a meta-analysis on the implant survival of augmentation procedures using BSM or AB. In the literature of the past 14 years (2000 to 2014), four studies comparing implant survival after MSFA using BSM or AB were found (Table 2). Meta-analysis showed a trend towards a higher implant survival when using BSM compared to AB, however the difference was not statistically significant (odds ratio [OR], 0.59; confidence interval [CI], 0.33–1.03; Fig 2). Begg and Mazumdar's funnel plot indicated a low risk for publication bias for this meta-analysis (Fig 3). In addition, four stud-

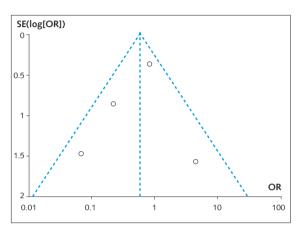


Fig 3 Funnel plot calculated for selected studies reporting on implant survival in maxillary sinus lift procedures using BSM versus AB.

ies comparing implant survival after MSFA using BSM mixed with AB or using AB alone were found. Meta-analysis of these studies revealed no statistically significant difference in implant survival between the two groups ([OR], 0.84; [CI], 0.5–1.42; Fig 4). Begg and Mazumdar's funnel plot for this meta-analysis is shown in Fig 5.

Vertical and/or lateral alveolar ridge augmentation using BSM or AB

Concerning vertical and/or lateral alveolar ridge augmentation, Table 3 shows a summary of all studies found in the electronic search. In these studies, 417 patients received a total of 1216 implants. The number of patients varied between 11 and 50 and the age of patients between 17 and 84 years. Mean healing periods were 4.7 ± 1.1 months for BSM, 5.25 ± 1.9 months for BSM mixed with AB and 5.1 ± 1.4 months for AB alone. The mean follow-up was 30.6 ± 27.1 months (a range of 4 to 120 months). A mean implant survival rate of $97.4 \pm 2.5\%$ for BSM, $100 \pm 0\%$ for BSM mixed with AB and $98.6 \pm 2.9\%$ for AB alone was seen. Implant success was indicated in five studies and ranged from 90.3% to 100% (from 2010 to Jan 2014).

 Table 1
 Summary of studies on implant survival in sinus lift with BSM or AB.

| Study | Study type | Indica- tion | No. of patients | No. of implants | BSM | Healing period | Complications | Mean follow-up (months) | ISR BSM | Success BSM | |
|--|---------------|--------------------|--------------------------------|---------------------------|--|------------------------------|--|-------------------------------|---|--------------------|--------------|
| Bae et al, 2010 ⁴⁰ | PS | SL | 16 (52.3; 36–68) | 32 | 70% HA + 30% 5-TCP | Simultan and 4 months | 6 perforations of sinus membrane (37.5%), 2 cases of sinusitis | 15 (12–30) | 96.9% (1 of 32) | 96.9% (1 of 32) | |
| Calvo-Guirado et al, 2010 ⁶⁰ | PS | Transal- veolar | 30 (53.6; 36–63) | 09 | Porcine HA | Simultan | QZ | 36 | 96.6% (2 of 60) | 96.6% (2 of 60) | |
| Cho-Lee et al, 2010³ ⁶ | RS | SL | 119 (50.02; | 272 1) 123 2) 149 | 1) AB + DBBM 2) AB | Simul- tan and delayed | 17 perforations of sinus membrane (9.6%), 6 cases of sinusitis (3.7%) | 60.7 ± 36.5 | 1) 93.5% 2) 94% | QN | Al-Nawa |
| Covani et al, 2011 ⁶¹ | PS | SL | 15 (61.5 ± 8.9) | 40 | HA + b-TCP | 6 months | QN | 14.9 ± 3.1 | 92.5% (3 of 40) | ND | |
| Esposito et al, 2010 ⁶² | RCT | SL | 10 (50; 35–60) | 24 | DBBM | 6 months | 1 perforation of sinus mem- brane | 12 | 100% (0 of 24) | ND | |
| Garlini et al, 2010 ⁶³ | RS | SL | 26 (58) | 47 | НА | Simultan | QN | 72 | 100% (0 of 47) | ND | |
| Lambert et al, 2010 ⁶⁴ | RS | SL | 40 (56.5; 38–79) | 120 | DBBM | Simultan | 9 perforations of sinus membrane (18%), 2 subantral artery lesion (4%) | 45 (32–74) | 98% (2 of 102) | ND | |
| Scarano et al, 2010 ⁶⁵ | RS | SL | 121 (54; 51–63) | 279 | Porcine HA | 4–6 months | 20 perforations of sinus membrane | 09 | 92% (21 of 279) | ND | <u> </u> |
| Tetsch et al, 2010 ⁶⁶ | RS | 1) SL 2) SL | 1) 461 (65.1) | 1207 1) 1085 2) 131 | 1) DBBM 2) b-TCP | QN | 148 perforations of sinus membrane (13.4%) | 1) 170 months 2) 91 months | 1) 95.5% 2) 94.1% | ND | |
| Uckan et al, 2010 ⁴¹ | RS | SL | 62 | 121 | b-TCP | Simultan | QN | 29.8 | 99.17% (10f 121) | ND | |
| Urban et al, 2010 ⁶⁷ | PS | SL | 79 (52.4; 30–80) | 245 | DBBM + AB | 7 months | 10 perforations of sinus membrane (10 %) | 60 months | 99.6% (1 of 245) | % 5.96 | |
| Viscioni et al, 2011 ⁶⁸ | RS | SL | 12 (50.4; 40–61) | 84 | Homologous fresh frozen bones, cryo- preserved homo- logue grafts | Simultan | ND | 14 months | 96.4% (3 | ND | e substitute |
| Sbordone et al, 2011 ²⁹ | RS | SL | 93 (51.9; 37–83) | 282 1) 146 2) 136 | 1) DBBM 2) AB (iliac, chin) | 3–5 months | ON . | 24 | 1) 100% (0 of 146) 2) 95.6% (6 of 136) | QN | |
| Sakka and Krenkel, 2011 ⁶⁹ | RS | SL | 17 (62) | 77 | AB (parietal) | Simultan | QN | 12 | 94.8% (4 of 77) | OY / | |
| Lee et al, 2011 ⁷⁰ | PS | SL | 12 (61.2; 41–86) | 12 | DBBM | 9 months | | 37.2 | 100% | 100%00 | col |
| Kim et al, 2011 ⁷¹ | PS | SL | 27 (54.09 ± 11.25) | 61 | Allogenic + xeno- genic | Simultan | 22 perforations of sinus membrane (36%) | 12.56 ± 5.95 | 98.4% (1 of 61) | Ub/ | pyr |
| Hansen et al, 2011 ⁷² | RS | SL | ND (14 aug- mented regions) | 58 | AB, DBBM | 6.5 months (3–14) | 1 sinusitis | 12 | 91% (5 of 58) | QNO. | 19/1/2 |
| Barone et al, 2011 ¹⁶ | PS | SL | 41 (53.6) | 201 | AB + porcine HA | 6 months | QN | 55.5 | 86.1% (28 of 204 | QM | _ |

| | | AI-Nawas / Schiegh | 112 A | ugmentatio | in proced | iuies i | asilig | DOILE S | ubstii | ute m | aterra | is or autogen | Jus De | on | /ri- |
|--|--|--|------------------------------------|---------------------------------------|---|--------------------------------------|--------------------------------------|--------------------------------------|---------------------------------------|------------------------------|---------------------------------------|--|--|---|---|
| | | | | | | | | | | | | no. | | ,OP. | Vrigh, |
| ND | 93.3% (2 of 31) | 1) 94.7% (8 of 150) 2) 94% (3 of 50) | ND | 1) 91.7% (2 of 25) 2) 95.7% (1 of 23) | 96.54% (16 of 462) | | | | | | | | Fo | PU | blicati |
| 96.9% (2 of 65) | 100% (0 of 31) | 1) 95.7% (7 of 163) 2) 94.9% (3 of 59) | 97.7% (2 of 90) | 1) 95.8% (1 of 25) 2) 95.7% (1 of 23) | 98.91% (5 of 462) | 97% (2 of 67) | (0 of 31) | 95.45% (1 of 22) | 100% (0 of 44) | 95.2% (1 of 21) | 93.3% (2 of 30) | 1) (2 of 32) 2) (0 of 27) | 5 of 44 | 1 of 38 | 1) (3 of 66) (2) (1 of 69) |
| 09 | 43.2 (11.4– 41.6) | 12 | 12 | 36 | 57.1 ± 15.6 (36–98) | 24 | 4 months post- loading | 120 months | 5 months post- loading | 36 | 09 | 15 | 09 | 09 | 4 months post- loading |
| 9 perforations of sinus membrane (22.5%) | 3 cases of mucosal laceration | Minor perforations of sinus membrane | ND | ND | 35 perforations of sinus membrane (16.13%) | 4 perforations of sinus membrane | 5 perforations of sinus membrane | ND | 4 perforations of sinus membrane | ND | ND | 1) 1 complication 2) 2 complications | 2 perforations of sinus membrane, 1 sinusitis, 1 abscess | None | 3 complications |
| 4 months | simultan | 6 months | 4–5 months | 8 months | Simultan | Simultan | 4 months | 4 months | 3 months | Simultan | 5 months | Simultan | Simultan | Simultan | 1) Simul- 3 complications tan 2) 4 months |
| AB + DBBM | DBBM | 1) Biphasic micro- and macroporous calcium phosphate combined with fibrin sealant (MBCP-FS) 2) DBBM + AB | DBBM + AB | 1) HA + b-TCP 2) DBBM | DBBM | НА | Porcine HA | AB | Porcine HA | DBBM + AB | AB | 1) DBBM 2) AB | AB + DBBM | AB | DBBM |
| 99 | 31 | 1) 172 2) 66 | 06 | 48 1) 25 2) 23 | 462 | 29 | 37 | 127 | 44 | 21 | 30 | 59 1) 32 2) 27 | 44 | 38 | 135 1) 66 one-stage approach 2) 69 two-stage approach |
| 34 (53; 35–74) | 14 (53.7; 34–67) | 98 (52.5; 22.7–82.6) | 20 (54.6; 47–69) | 11 (67; 50–79) | 161 | 30 (58.3) | 20 (58.5; 45–75) | 25 (64.4; 35-84) | 20 (57.6; 45–80) | 21 | 27 (50.3; 35–64) | 40 1) 20 (49.8; 38–62) 2) 20 (51.5; 38–66) | 20 (53.3; 30 – 72) | 20 (47.5; 21–70) | 60 (ND) |
| SL | SL | SL | SL | SL | SL | SL | SL | SL | SL | Transal- veolar | SL | SL | SL | Transal- veolar | SL |
| RS | RS | RCT | PS | RCT | PS | PS | RCT | RS | RCT | RCT | RS | RCT | RCT | RCT | RCT |
| Caubet et al, 2011 ⁷³ | Sivolella et al, 2011 ⁷⁴ | Wagner et al, 2011 ⁷⁵ | Pieri et al, 2012 ²³ | Lindgren et al, 2012 ⁷⁶ | Cha et al, 2012 ⁷⁷ | Canullo et al, 2012 ⁷⁸ | Felice et al, 2012 ¹⁰¹ | Schmitt et al, 2012 ⁷⁹ | Espostio et al, 2012 ⁸⁰ | Si et al, 2013 ⁸¹ | Sbordone et al, 2013 ⁸² | Merli et al, 2013 ⁹⁴ | Cannizzaro et al, 2013 ⁸³ | Cannizzaro et al, 2013 ⁸³ | Felice et al, 2013 ⁸⁴ |

Max = maxilla; Man = mandible; ND = no data available or data cannot be separated; PS = prospective study; RS = retrospective study; RCT = randomised controlled trial, CSS = cross sectional study; ISR = implant survival rate; BSM = bone substitute material; AB = autogenous bone; DBBM = deproteinised bovine bone mineral; DFDBA = demineralised freeze-dried bone allograft; HA = hydroxyapatite; b-TCP = b-tricalcium phosphate; CM = collagen barrier membranes; ACS = absorbable collagen sponge carrier (ACS)

Table 2 Summary of studies on sinus lift for meta-analysis.

| Study | Study type | No. of patients | No. of implants | BSM | Preopera- tive alveolar crest height | Mean follow-up (months) | Implant survival rate BSM | Implant survival rate BSM + AB | Implant survival rate AB |
|--------------------------------------|---------------|-----------------|-----------------|--|--|-------------------------------|---|---|--------------------------------|
| Hallman et al, 2002 ²⁷ | RCT | 21 | 36 | DBBM | ND | 12 | 96% (2 of 43) | 94.4% (2 of 35) | 82.4% (6 of 33) |
| Velich et al, 2004 ³⁰ | | 624 | 1482 | HTR Polymer, Algipore, Biocoral Gel, Cerasorb | 2–6 mm | >12 | HTR Polymer: 89.9% (19 of 188) Algipore: 88.5% (2 of 16) Biocoral Ge 93.4% (1 of 15) Cerasorb 92.2% (7 of 90) Total: 29 of 309 | HTR Polymer: 87.7% (29 of 235) Algipore: 97.3% (1 of 37) Biocoral Ge 83.3% (2 of 12) Cerasorb 92.6% (6 of 81) Total: 38 of 365 | 88% (12 of 108) |
| Diserens et al, 2005 ³⁵ | RS | 33 | 44 | DBBM | 5.78 ± 1.4 | 15 | ND | 100% | 100% |
| Cho-Lee et al, 2010 ³⁶ | RS | 119 | 272 | DBBM | 6.59 ± 2.11 | 60.7 ± 36.5 | ND | 93.5% (8 of 123) | 94% (9 of 149) |
| Sbordone et al, 2011 ²⁹ | RS | 119 | 282 | DBBM | ND | 24 | 100% (0 of 146) | ND | 95.6% (6 of 136) |
| Merli et al, 2013 ²⁸ | RCT | 40 | 59 | DBBM | 1) 2.0 ± 0.8 2) 2.3 ± 0.9 | 15 | (2 of 32) | ND | (0 of 27) |

Max = maxilla; Man = mandible; ND = no data available or data cannot be separated; PS = prospective study; RS = retrospective study; CSS = cross sectional study; ISR = implant survival rate; BSM = bone substitute material; AB = autogenous bone.

Fig 4 Forest plot of implant survival in maxillary sinus lift procedures using BSM mixed with AB versus AB alone.

| Study or subgroup | Experir | nental | | Control | | Odds Ratio | Odds Ratio |
|--|---------|----------------------|--------|---------|--------|--------------------|--|
| | Events | Total | Events | Total | Weight | M-H, Fixed, 95% CI | M-H, Fixed, 95% CI |
| Cho-Lee et al 2010 | 8 | 123 | 9 | 149 | 25.3% | 1.08 [0.40, 2.89] | |
| Diserens et al 2005 | 0 | 22 | 0 | 22 | | Not estimable | Γ |
| Hallmann et al 2002 | 2 | 35 | 6 | 33 | 19.4% | 0.27 [0.05, 1.46] | |
| Velich et al 2004 | 38 | 365 | 12 | 108 | 55.3% | 0.93 [0.47, 1.85] | |
| Total (95% CI) | | 545 | | 312 | 100.0% | 0.84 [0.50, 1.42] | 7 |
| Total events | 48 | | 27 | | | | |
| Heterogeneity: Chi ² = 6.04, df = 3 | P = 0.1 | 1); I ² = | 50% | | | | |
| Test for overall effect: Z = 1.84 (P | = 0.07) | | | | | | |
| | | | | | | | 0.01 0.1 1 10 100 Favours [experimental] Favours [control] |

Five studies compared the clinical outcome of ridge augmentation procedures using BSM or AB (from 2000 to Jan 2014; Table 4). Meta-analysis of these studies showed no statistically significant difference between BSM and AB ([OR], 1.85; [CI], 0.38 to 8.94; Fig 6).

Fig 5 Funnel plot calculated for selected studies reporting on implant survival in maxillary sinus lift procedures using BSM mixed with AB versus AB alone.

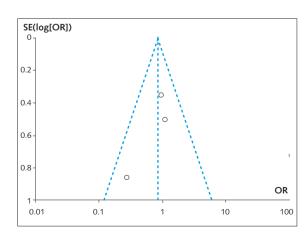


Fig 7 shows Begg and Mazumdar's funnel plot for this meta-analysis. Three studies comparing implant survival after ridge augmentation using BSM mixed with AB or AB alone were identified. As all of these studies showed in both the experimental as well as in the control group, with an implant survival of 100%, a meta-analysis of these data was not possible (Fig 8).

Discussion

The wide range of graft materials available has provided numerous alternatives to AB. Therefore, it was the aim of this study to analyse the literature of the years 2000 to 2014 to identify graft materials that provide the best reconstructed osseous ridge for successful implant placement and long-term function.

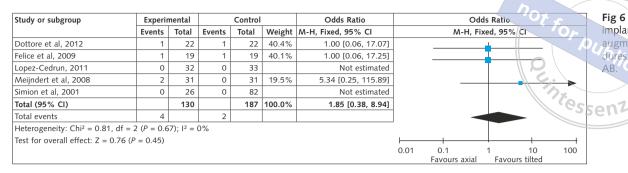


Fig 6 Forest plot of implant survival in ridge augmentation procedures using BSM versus AB.

Maxillary sinus floor augmentation (MSFA)

In the examined period, four studies regarding implant survival after MSFA using BSM or AB were published²⁷⁻³⁰. All of them showed no significant difference in implant survival between BSM and AB. Our meta-analysis of these combined studies confirmed the individual findings, as no significant difference in implant survival was seen. In a systematic review examining animal studies on this subject, the initial osseointegration of implants seemed independent of the biomaterial used in grafting procedures³¹. For human histomorphometric data, Klein et al showed a sufficient formation of at least 20% to 30% new vital bony tissue both for BSM and AB12. In addition, several current literature reviews indicated that the success of MSFA is independent of the used graft material^{2,3,12,32,33}. For example, Jensen et al in their review observed the same implant survival rate in sinuses augmented with BSM alone (96.1%) versus augmentation protocols including AB (95.8%)³². In contrast, one review by Pjetursson et al³⁴ showed significantly lower annual failure rates for AB, compared to BSM in MSFA. However, all types of grafting materials had high survival rates ranging from between 96.3% and 99.8% after 3 years in this review. Further, it must be noted that a constant annual event rate was assumed throughout the followup time after placement of the reconstruction, which limits the validity of this review.

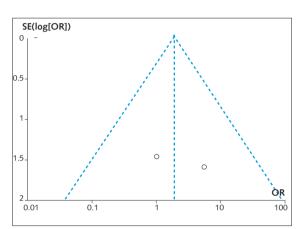


Fig 7 Funnel plot calculated for selected studies reporting on implant survival ridge augmentation procedures using BSM versus AB.

Regarding the origin of the BSM, the use of deproteinised bovine bone mineral (DBBM) for MSFA is particularly well documented in the literature^{27-29,35-39}. Besides DBBM, there are several studies with a favourable clinical outcome for synthetic porous beta-tricalcium phosphate (beta-TCP)40-42. From a biological aspect, it might be advantageous to mix BSM with AB due to the osteoinductive properties of AB³⁸. However, two recently published systematic reviews concluded that the amount of new bone formation was comparable when DBBM or DBBM mixed with AB were used as graft material for MSFA⁴³. The hypothesis that there are no differences between DBBM or DBBM mixed with AB as graft for MSFA could neither be confirmed nor rejected³⁸. Moreover, four clinical studies showed no

| Study or subgroup | Experimental Control Odds Ratio | | | | | | Odds Ra | atio | | | |
|-------------------------------------|---------------------------------|-------|--------|-------|--------|--------------------|---------|--------------------|--------|--------------|--------|
| | Events | Total | Events | Total | Weight | M-H, Fixed, 95% CI | | M-H, Fixed, 95% CI | | | |
| Cordaro et al 2010 | 0 | 12 | 0 | 37 | | Not estimable | | | | | |
| Cordaro et al 2011 | 0 | 28 | 0 | 27 | | Not estimable | | | | | |
| Urban et al 2011 | 0 | 43 | 0 | 15 | | Not estimable | | | | | |
| Total (95% CI) | | 83 | | 79 | | Not estimable | | | | | |
| Total events | 0 | | 0 | | | | | | | | |
| Heterogeneity: Not applicable | | | | | | | _ | | | | |
| Test for overall effect: Not applic | cable | | | | | | | | | | |
| | | | | | | | 0.01 | 0.1 | 1 | 10 | 100 |
| | | | | | | | Favour | s [experim | ental] | Favours [cor | ntrol] |

Fig 8 Forest plot of implant survival in ridge augmentation procedures using BSM with AB versus AB alone.

 Table 3
 Summary of studies on implant survival in vertical or/and horizontal ridge augmentation with BSM or AB.

| No. of No. of Jaw patients implants region | | | | Mean follow- up (months) | Bone gain | Implant survival rate | Implant success rate |
|--|---|---|---|--------------------------------|---|--|----------------------------|
| Vertical and 50 106 Max, or horizontal 1) 27 Man ridge deficien- 2) 23 cies | 1) FDBA 2) FDPA + AB | .A 4–6 .A months | Membrane expo- sure: 24% | 5–7 months | 1) 3.47 ± 1.25 vertical and 5 ± 1.25 horizontal 2) 3.5 ± 1.2 vertical and 3.6 ± 1.72 horizontal | 1) 100% 2) 100% | Q Z |
| Vertical ridge20 (59;42Max,augmentation30–72)Man | H | 3 months | Membrane expo- sure: 2% | 24 months | 5.6 ± 1.4 | 100% | ND |
| Vertical ridge 15 (50.06; 32 Max, augmentation 22–69) | Allograft | uft 4–5 months | 2-stage graft- ing n = 5; partial wound dehiscence n = 2, screw head exposure n = 3 | 16.8 months (4–38) | ND | 100% | ND |
| Vertical ridge 22 77 Man augmentation | AB | Simultan | None | 36 | ND | 100% | QN |
| Vertical ridge 37 (48.9; 73 Max, augmentation 25–68) bone Man grafts: 39 | AB (chin, retromo- lar area, maxillary tuberosity | in, Simultan o- a, ary sity | Graft failure: 5.1% (2 of 39) | 12 | ND | ND | 95.9% (3 of 73) |
| Inlay—onlay 16 (51) 49 Max 1 2 | 1) AB + DBBM 2) AB | + 4 months | 1 case of wound dehiscence | 40 (32–48) | 2.1 ± 0.3 mm vertical and 4.3 ± 1.1 mm horizontal | 1) 100% 2) 100% | 1) 100% 2) 100% |
| Two-step 19 (58.8; 141 Man osteotomy 48–68) 1) 73 (| 1) AB (symphy- seal area) 2) AB (molar area) | 4 months ea) | 3 cases with small sequestrum | 48 | | 1) 96% (3 of 73) 2) 91% (6 of 68) | Q |
| Sandwich 23 65 Man osteotomy 1) 24 segments 2) 6 segments constants | 1) DFDBA 2) AB (iliac crest) | JBA 5–6 (iliac months | 4 cases of minor dehiscence | (12–93) | 5.3 mm (2–10) | 1) 100% | not for A |
| Horizontal 22 (50) 58 Max, 1) AB ridge aug- 2) 15 AB Man DBBM mentation 2) 15 2 AB | 1) AB + DBBM | + 8.12 ± 2.32 | None | 45.88 ± 12.43 | 5.56 ± 1.45 | 1) 100% 2) 100% | Publi |

| T Horizontal 17 (42; 55 Man ridge aug- 19–66) 1) 28 mentation 2) 27 | 17 (42; 55 Man 19–66) 1) 28 2) 27 | Man | - u n | 1) AB + DBBM 2) AB | 4 months | Partial dehiscence (n = 3) Partial dehiscence (n = 1) | | 1) 4.18 ± 1.17 2) 4.56 ± 1.38 | | 1) 100% |
|---|---|-------------|---------|-------------------------------------|---------------|--|--------------------------------|---|--|--|
| PS 31 (32; 63 Max A 17–70) | 63 Max | Max | 4 | Allograft | 6 months | Soft tissue break- down and graft exposure n = 13 (28%) | 34 (6–59) | 5 ± 0.5 mm horizontally, and 2 ± 0.5 mm vertically | 98% (1 of 19) | ΩN |
| PS Vertical ridge 21 (55; 85 Man augmentation 40–65) | 21 (55; 85 Man 40–65) | Man | | Allograft | 6 months | Graft failure: 6 | 37 (6–60) | Mean horizon- tal and vertical bone gains were 5.6 and 4.3 mm | 95.2% | ND |
| RCT Vertical ridge 30 (55; 61 Man E augmentation 43–67) | 30 (55; 61 Man 43–67) | Man | | DBBM | 5 months | Graft failure: 2 of 28; other compli- cations: 22 of 61 | 36 months | ND | 95.1% (3 of 61) | ND |
| PS Vertical ridge 18 60 Max, AB augmentation 1) (| 18 60 Max, Man | Max, Man | ₹ Ç ï % | AB 1) Calva- rium 2) Ramus | 4–7 months | | 19 months (12–36 months) | NΩ | 1) 100% 2) 100% | 1) 90.3% 2) 93.1% |
| RCT Vertical ridge 20 (54.1; 47 Man Ec augmentation 42–70) cii | 20 (54.1; 47 Man 42–70) | Man | G T i | Equine HA, por- cine HA | 3 months | Graft failure: 15% 7 temporary lower lip paraesthesia | 5 months post- loading | ND | 93.6% (3 of 47) | Q N |
| RS Onlay aug- 25 (64.4; 127 Max Al mentation 35–84) | 25 (64.4; 127 Max 35–84) | Max | Z V | AB (iliac crest) | 4 months | ND | 120 months | ND | 95% (2 of 40) | ND |
| PS Sandwich 11 (54.2) 44 Man 1) osteotomy 2) 22 | 11 (54.2) 44 Man 1) 22 2) 22 | Man | 7 2 3 | 1) HA 2) AB | 6 months | None | 12 | 1) 7.0 ± 2.6 vertical 2) 6.5 ± 1.6 vertical | 1) 95.5% (1 of 22) 2) 95.5% (1 of 22) | 1) 90.9% (2 of 22) 2) 90.9% (2 of 22) |
| RCT Vertical ridge 20 (52.8; 31 Man b augmentation 42–70) | 20 (52.8; 31 Man 42–70) | Man | 9 | bovine HA | 4 months | Transient paraes- thesia n = 14 | 4 months post- loading | ND | 96.8% (1 of 31) | ND |

Max = maxilla; Man = mandible; ND = no data available or data cannot be separated; PS = prospective study; RS = retrospective study; RCT = randomised controlled trial; CSS = cross sectional study; ISR = implant survival rate; BSM = bone substitute material; AB = autogenous bone; DBBM = deproteinised bovine bone mineral; DFDBA = demineralised freeze-dried bone allograft; HA = hydroxyapatite; b-TCP = b-tricalcium phosphate; CM = collagen barrier membranes; ACS = absorbable collagen sponge carrier (ACS).

Table 4 Summary of studies on ridge augmentation for meta-analysis.

| | ĺ | | | | | | | | |
|--|---------------|-----------------|-----------------|----------------------|-------------------------|---------------------------------|--------------------------------------|--------------------------------|---|
| Study | Study type | No. of patients | No. of implants | BSM | Mean follow-up (months) | Implant survival rate BSM | Implant survival rate BSM + AB | Implant survival rate AB | Bone gain (mm) |
| Simion et al, 2001 ⁸⁷ | RS | 49 | 108 | DFDBA (allograft) | AL: 39.3; AU: 30.4 | 100% (0 of 26) | ND | 100% (0 of 82) | ND |
| Felice et al, 2009 ⁵² | RCT | 10 | 38 | DBBM | 12 | 1 of 19 | ND | 1 of 19 | ND |
| Meijndert et al, 2008 ⁵⁰ | RCT | 49 | 93 | DBBM | ND | 93.5% (2 of 31) | ND | 100% (0 of 31) | ND |
| Cordaro et al, 2010 ⁸⁸ | PS | 16 | 49 | DBBM | 40 | ND | 100% (0 of 12) | 100% (0 of 37) | lateral: 4.3 ± 1.1 vertical: 2.1 ± 0.3 |
| Lopez-Cedrun, 2011 ⁸⁵ | RS | 23 | 65 | DFDBA | 12–93 | 100% | ND | 100% | 5.3 |
| Urban et al, 2011 ⁹⁰ | PS | 22 | 58 | DBBM | 45.88 | ND | 100% (0 of 43) | 100% (0 of 15) | 5.56 ± 1.45 |
| Cordaro et al, 2011 ⁸⁹ | RCT | 17 | 55 | DBBM, CM | 24 | ND | 100% (0 of 28) | 100% (0 of 27) | 1) 4.18 ± 1.17 2) 4.56 ± 1.38 |
| Dottore et al, 2012 ⁵⁴ | PS | 11 | 44 | ncHA | 4 | 95.5% (1 of 22) | ND | 95.5% (1 of 22) | 1) 6.5 ± 1.6 2) 7.0 ± 2.6 |

Max = maxilla; Man = mandible; ND = no data available or data cannot be separated; PS = prospective study; RS = retrospective study; CSS = cross sectional study; ISR = implant survival rate; BSM = bone substitute material; AB = autogenous bone.

significant difference in the clinical outcome for BSM in combination with AB or AB alone^{27,30,35,36}. The results of meta-analysis affirmed these conclusions, as no significant differences in implant survival after MSFA using BSM mixed with AB or using AB alone were found. Potentially, if the ideal mix of AB and BSM will be found in the future, those results might change as currently there is no common understanding on the best makeup of this combination.

A common technical challenge in MSFA is the sinus membrane perforation. The results showed that in $19.2 \pm 10.8\%$ of the cases a perforation occurred. This is in accordance with the study of Pjetursson et al, which indicated a value of 19.5% (a range of 0% to 58.3%)34. Karabuda et al stated that sinus membrane perforation does not compromise the osseointegration process or the survival rate⁴⁴. Additionally, a relation between sinus membrane perforation and extended postoperative sinusitis or implant loss could not be described⁴⁵. Nkenke et al demonstrated in their review that the event of sinusitis, partial, or total graft loss is independent of the used graft material². Consequently, applying AB instead of BSM in MSFA will not protect patients from developing sinusitis or graft loss.

Vertical and horizontal ridge augmentation

For ridge augmentation, there are techniques available to effectively and predictably increase the width

(horizontal) and the height (vertical) of the alveolar ridge^{12,46,47}. Generally, survival rates of implants placed in ridge augmentation are high⁴⁶⁻⁴⁸. Long-term analysis by van Steenberghe et al over 10 years for simultaneous placement of autogenous bone grafts and implants showed high success rates of 95%⁴⁹. Five studies comparing implant survival after ridge augmentation using BSM or AB were published between 2000 and 2014⁵⁰ ⁵⁴. None showed any significant difference in implant survival. Our meta-analysis of these studies confirmed these results, indicating no statistically significant difference in implant survival for ridge augmentation using BSM or AB. In a Cochrane systematic review on this topic, three randomised controlled clinical trials (RCC) comparing BSM and AB were described⁴⁶. These studies showed heterogeneous results. Felice et al⁵² investigated whether DBBM could replace AB harvested from the iliac crest for vertical augmentation of atrophic posterior mandibles. No statistical differences for clinical outcomes were described in this study, however, statistically significant more patients preferred the augmentation procedure with the BSM. The split-mouth pilot study by Fontana et al55, including only five patients, showed significantly more vertically augmented bone for the BSM compared to AB. In contrast, the study of Meijndert et al⁵⁶ indicated that implants placed in bone augmented with DBBM showed increased healing time and failure rates, although all failed implants could be successfully replaced without the need for additional augmentation.

All of these results should be interpreted with caution, because they are mostly related to small initial defects and these conclusions might not be applicable to large defects. Furthermore, patient numbers in these studies were relatively small. Altogether, the use of BSM or AB in ridge augmentation procedures indicated similar clinical outcomes. However, as the quantity of initially available bone before the augmentation procedure was seldom specified, it is difficult to determine whether the clinical outcome of implants relied on the augmented tissue or on the residual native bone. Consequently, there is insufficient evidence to suggest if applying BSM or AB in ridge augmentation is preferable.

The ability to shorten treatment length with AB in augmentation procedures is another matter of scientific discussion. With the transplantation of AB, osteoinductive factors are applied to the augmented site^{8,9}. For BSM, this is not the case. Therefore, it may be assumed that the ingrowth of newly formed bone is delayed with BSM compared to AB, and that implant insertion and loading in two-stage procedures will have to be postponed. A recently published review analysing the total bone volume after MSFA based on histomorphometric analysis demonstrated a significantly higher portion of mineralised bone during the early healing phase for AB, compared to various BSM⁴³. Interestingly, the different total bone volumes equalled out over time, and after 9 months no statistically significant difference was detected between the various grafting materials. Our review showed contradictory results for healing periods. In MSFA studies, healing periods were shorter, and in ridge augmentation procedures longer for BSM, compared to AB. The review of Jensen et al described almost identical healing periods in MSFA for BSM and AB³². Hence, a clear conclusion cannot be drawn on this topic. When using graft materials, the aspect of cost cannot be ignored. A data analysis on this topic was unfortunately not possible due to missing information in the examined studies. For AB, the harvesting procedure lengthens operating time, which is especially problematic in the case of extraoral donor sites surgery, as it is often performed under general anaesthesia^{57,58}. Consequently, higher costs for a longer operating time and general anaesthesia could surpass the expenses for BSM². In this context, cost-effectiveness analyses are required to clarify this aspect.

In general, literature-based systematic reviews of implant prognosis and survival pose a multitude of problems⁵⁹, which were also apparent in this study. Many of the included studies failed to report the original residual bone height at the site of presumptive implant placement. There was also a lack of RCTs with COLD sufficient statistical information for the comparison of various grafting materials. In addition, comparisons were complicated due to relevant differences in number of patients, number of implants and the type of implant surface. Furthermore, the publication bias has to be kept in mind. This means that some authors reported mainly from good results and bad or unwanted results were neglected and not published. Therefore, even the results of this meta-analysis, although representing the highest grade of evidence, indicate presumably slightly too optimistic survival rates.

Conclusions

A large but heterogeneous body of literature was available regarding BSM in augmentation procedures, including all levels of clinical evidence. Within the limits of this meta-analytic approach to the literature, we showed a comparable implant survival in MSFA and ridge augmentation between BSM, BSM mixed with AB and AB. Therefore, depending on the size of the defect, BSM might be as effective as AB for augmentation procedures. Considering the side-effects accompanying AB procedures, BSM should be seen as a valuable alternative. However, in order to improve decision-making on the type of bone graft to be used for treating large defects properly, more standardised studies are required to better understand the clinical efficacy and limitations of these grafts. Future studies should define defect size, augmented volume and regenerative capacity of the defects.

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Patient-centred rehabilitation of edentulism with an optimal number of implants

A Foundation for Oral Rehabilitation (F O R) consensus conference

UNIVERSITY OF MAINZ, GERMANY, 27 & 28 MARCH, 2014. CONSENSUS TEXT

Edentulism

Complete edentulism is a common problem in many countries and can be a serious disability. It concerns about one-fifth of the adult world population, in some countries reaching 50% at the age of 50. The decline in the prevalence of edentulism is offset by the increase of the elderly population. This leads to an increasing demand for implant-based treatments by the potential population of the 150 million who are completely edentulous.

The members of the consensus conference agreed that, when surgery is considered as a treatment option for edentulism, it should be seen as elective surgery.

■ Elective surgery

Elective surgery can be planned, or eventually postponed, since there is no (vital) medical emergency. The impact of eventual complications and patient discomfort will thus be perceived differently than for acute surgery. In elective surgery, decision-making must be shared with the patient, and based upon robust clinical evidence. This kind of surgery carries a greater risk for litigation. Therefore, clinicians must have well-defined guidelines available to be able to provide an informed consent – not to be confused with a consent form – to the patient.

Explaining the invasiveness of treatment alternatives, the optimal number and size of implants needed, and the prognosis and the cost of treat-

ment, are important parts of the treatment plan information. Optimal can be defined as most effective, favourable or desirable. While choosing among clinical alternatives, the clinician should also consider the concept of risk-benefit function. The latter does involve the financial costs, the 'cost' of pain, of the time spent on the treatment, and of the patient's unavailability to normal social/professional life. The financial cost of different implant-based treatments has not been analysed by the working group. However, a recent publication on two patient cohorts, one with a mean of 8 implants in the maxilla and 5 in the mandible, vs. a fixed prosthesis on 4 implants only (Babbush et al, Impl Dent 2014;23:218-224) confirmed that the latter treatment option is, on average, several thousand Euros cheaper and less time-consuming than the historical treatment with \geq 5 or 8 implants.

Optimal number of implants needed

In the 1980s, Brånemark and co-workers proposed, for the rehabilitation of complete edentulism, the installation in an arch-wise mode of 6 implants as the gold standard of care. Completely edentulous patients sometimes lack a sufficient volume of bone of adequate quality to allow the installation of 6 implants with good primary stability. Various bone augmentation procedures have thus been performed to be able to reach that goal when the bone available was too limited.

The main focus of the present consensus meeting, which was based on a series of 8 individual critical reviews of the literature¹⁻⁸ and prepared by the members of the consensus group, addressed different aspects of patient-centred rehabilitation of edentulism. They analysed different treatment options and how many implants are really needed to carry/retain complete cross-arch prostheses, either removable or fixed. The impact of the number of oral implants, supporting/retaining the dental prosthesis, was assessed from different aspects: quality of life and functional aspects; biomechanics; survival rates; and marginal bone level changes. Furthermore, the side-effects of bone graft harvesting from different donor sites was analysed and the potential of bone substitute material in bone augmentation scrutinised. The latter two reviews, dealing with bone grafting and bone substitute materials, identify the assets and liabilities of eventual bone augmentation procedures in the rehabilitation of completely edentulous patients by means of implants.

Discomfort related to bone augmentation

While pain experience and/or consumption of painkillers following implant placement is low and limited to a few days (and even less when a flapless technique is used), for bone grafting procedures, the pain level seems generally higher. The morbidity is especially pronounced after horizontal and vertical crestal bone augmentation procedures, compared to the less invasive sinus inlay grafts.

Much depends on the graft donor site. For cortico-cancellous grafts of the iliac crest, pain can be moderate to high for several days. A disturbed gait is observed in rare instances. Unassisted ambulation can take a few days. For trephined bone samples from the iliac bone, or from other extraoral donor sites, this side-effect is more limited. Ambulatory intraoral graft harvesting is much less uncomfortable, with moderate pain experience for a few days only. The mandibular ramus area seems to be the preferred donor site. The symphyseal donor site leads to the most pain and other side-effects like (permanent) sensory disturbances.

Reliable placement of implants sometimes necessitates simultaneous or staged bone augmentation procedures. If such discomfort and even the remote possibility of more side-effects can be avoided one should consider graftless treatment options. For example, different implant locations and inclinations, a reduced number and/or size of implants, etc., can offer a long-term predictable outcome. Bone augmentation in the anterior areas of patients with extreme maxillary resorption can lead to soft tissue dehiscence and other complications. Bilateral sinus lifting procedures, either with or without bone addition, with 2 to 3 implants on each side, seems a predictable approach to avoid anterior bone augmentation procedures.

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The pros and cons of both approaches, invasive and less invasive, should be discussed with the patient before choosing the best individual adapted approach.

Data from literature

The available literature on the rehabilitation of edentulism remains generally below the highest levels of evidence. Randomised controlled trials are rare or the randomisation does not concern different treatment modalities. For the present analysis, such studies should then be referred as prospective.

Another problem when referring to the literature is that nearly all papers originate from centres of excellence. Since implant treatment, both surgical and prosthetic, is technique sensitive, the published results may have low external validity and may not reflect the daily practice outcome. The group advocates to encourage multicentre studies and to conduct, in cooperation with implant manufacturers, post-market surveillance studies.

Biomechanical considerations

The optimal number of implants must be chosen on the basis of patient cost and perceived patient benefit, besides local factors such as bone and soft tissue quantity and quality, primary implant stability and anterior-posterior spread of the implants. Limiting loading forces on implants and superstructures

are relevant, but the calculation of stresses in the surrounding bone is even more important. Managing loading and stresses so they are in a safe and effective range is a design goal.

Tilted implants show high survival rates, are not subject to more marginal bone loss than axial ones after 1 year and beyond, and help achieve a sufficient anterior-posterior distance when only 4 implants can be placed. Biomechanical model calculations in such 4-implant configurations indicate the merit of tilted implants. For example, the forces in the tilted configurations can be lower than for axial ones due to a greater anterior-posterior spread and more limited cantilever spans. Tilting also allows the use of longer implants and to avoid important anatomical structures such as the mental nerve.

The positioning of tilted implants is technique sensitive. Guided surgery may be an option to improve the precision of angulation and position.

Prosthetic aspects

It seems technically demanding if not impossible, if CAD-CAM technologies are not used, to achieve a perfect passive fit of the cross-arch prosthesis in cases where 6 implants are being deployed. In the lower jaw, additionally the mandible's flexion may encourage segmentation of the prosthesis. When segmentation of the fixed metallic framework is considered, the consequence is that more than 4 implants are needed.

■ Functional aspects

Besides biomechanical aspects, functional parameters on the different prosthetic treatment options to rehabilitate complete edentulism indicate that with the fixed prosthesis, one comes closer to the function of dentate patients than with removable (implant-supported) prostheses during clenching. However these improvements were not so relevant during chewing.

In the mandible, overdentures also enhance the jaw function and quality of life. Edentulous patients with implant-supported prostheses do not seem to adapt to the hardness of food. The number of

implants supporting the fixed prosthesis has never emerged as a relevant factor in the literature on jaw function.

Optimal number of implants in mandible/maxilla for removable/ fixed prostheses

In the mandible, 2 implants to retain an overdenture seems highly reliable and satisfactory. One can opt for 4 implants if a tilting prosthesis is not the best option (e.g. with young patients, considering the slow resorption of distal parts of the mandible). Some studies report that even one central implant can stabilise an overdenture in the mandible.

In the maxilla, 4 implants to retain an overdenture leads to high survival rates and very good patient satisfaction. To support fixed cross-arch prostheses, a wealth of clinical reports reveal that 4 and even, for the mandible, 3 implants can suffice. In the maxilla, the placement of two frontal axial implants and two distal tilted implants leads to high survival rates. The placement of supplementary implants, just to avoid revision surgery should a failure occur, does not seem reasonable anymore. Local anatomical factors such as poor/limited bone, aesthetic or phonetic arguments, or different prosthetic concepts may lead to ≥ 5 implants in the maxilla.

As a conclusion, if a fixed prosthesis is the best treatment option for a patient, in the maxilla 4 to 6 implants are appropriate numbers if their placement does not necessitate major bone grafting procedures. If bone grafting is being contemplated to allow 6 implants, it should be recalled that 4 implants of standard dimensions, with the two distal ones tilted, is a well-documented and reliable alternative treatment option.

An argument against using as many implants as possible in edentulous jaws is the fact that a minimal distance is necessary for soft tissue healing around each implant and to allow cleaning. Thus, the 1 implant per tooth treatment option has become questionable.

The reduced size of endosseous implants sometimes allows for the circumvention of the need for grafting procedures. The consensus group reemphasises that, while previously short implants

meant <10 mm, more recently 'short' refers to ≤ 8 mm. Narrow implants are those of ≤ 3.5 mm.

Another technique to avoid the more invasive bone augmentation procedures is the use of extramaxillary anchorage places, such as the zygoma. The use of 2 to 4 zygomatic implants, with or without anterior implants, seems a reliable option to carry a complete fixed prosthesis.

■ General conclusions

Treatment options should be evaluated from the perspective of anatomical features and patient preferences, taking into account all risk-benefit aspects and especially the evidence from the scientific literature. Therefore a need for randomised controlled trials and comparative multicentre studies with good external validity clearly exists.

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