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Welcome to the second issue of ID!

Information is paramount .....your time is valuable and limited!

Implant Directions is a valuable publication with a unique balance of scientific methodology and expert clinical ideas and opinion presented in a concise, easy to read manner.

In this edition, you will discover the following important topics in implant dentistry:

The Literature Analysis an impotant clinical topic in implant dentistry: of scientific implant related topics „Bone Augmentation Procedures. How effective are they and what are the alternatives?" Part II. You will find the results of this Analysis surprising!

Furthermore, we adress a **Research in Context** question: "What is a p-value?".
Answering this question will help you to distinguish if the obtained results from statistical tests are real or due to chance! The „p-value" is often misinterpreted or relied on innapropriately in clinical decision making.

In addition we offer you two case study describing the "Complete immediate maxillary denture with rehabilitation following insertion of two BOI®-Implants" and "Complete oral rehabilitation including BOI® Implants" This method can satisfy all the patient's needs much better than in contrast the insertion of a removable denture with a cast framework or risky and costly bone build ups!

"Implant directions" challenges you to not trust everything! Critical appraisals on existing literature are badly needed in the implant profession. Published information available today, is prone to bias as many authors receive third party funding.

We encourage readers who are trying to critically interpret a specific paper to submit that paper for a thorough evaluation through the IF Research and Evidence Department. Feel free, to join our efforts and in promoting the publication of sound methods and quality „evidence".

Implant Directions is your chance to find out what world-class epidemiologists and implantologists have to say about "hot topics" and "evidence" in implantology.

We are excited to be offering ID! We look forward to your constructive comments and recommendations.

Best regards,
The ID team

Typical contents in ID

- **Literature Analyses** provide you with an in-depth look at the research on a given topic. A "Literature Analysis" is a critical review of the literature on the epidemiology, treatment methods, and prognosis for implant-related topics or conditions. Literature Analyses are broader than "Evidence Reports" and are written to serve as a reference tool for implantologists to help them make decisions regarding how to manage patients, to assist them in evaluating needs for future research, and to use the material for future presentations.

- **Critical Appraisals** summarize the findings from important papers used for clinical decision making or marketing by implant companies. However, in addition to the summary, we take a critical look at both the study's methods and clinical conclusions in an effort to challenge the implantology community to not accepting everything that is published while fostering alternatives explanations and ideas.

- **Case reports** give implantologists the opportunity to publish on unique patients using innovative or alternative methods for treating challenging patient conditions.

- **Clinical notes** provide clinical perspectives from renowned experts on topics presented in the ID. Evidence-based practice balances the "evidence" with clinical insight. Clinical notes provide this portion, helping the reader put the "evidence" into clinical context.

- **Research in Context** is a helpful "what is" section to consult if you've ever read a study and asked "what is a p-value" or any other research method question. It assists us as clinicians with the critical evaluation of the literature by briefly describing relevant aspects of research methods and statistical analysis that may bias results and lead to erroneous conclusions.

Literature Analysis

Bone Augmentation Procedures. How effective are they and what are the alternatives? Part II.

Introduction

Implantologists are challenged with high patient expectations for optimal function and esthetics. Many patients have insufficient bone volume making the placement of standard root-form implants nearly impossible. When tooth loss is caused by chronic destructive periodontitis, osseous ridge deficiencies or poor bone conditions are the norm rather than the exception all of which hinders implant placement. How are implantologists to manage these patients successfully? Squeezing short or narrow implants into deficient ridges is an alternative which allows to place implants, but of course fails to replace ridge anatomy. From the patients point of view this technique is desireable however. Because patients usually demand teeth rather than soft or hard tissues, as long as the aesthetic result is acceptable. Slim compression srew implants, e.c. KOS® are becoming more and more popular and they provide in many cases even the option of immediate loading. Short implants like the Osseopore® brand provide grounds for stable restorations even if the vertical bone supply is severely reduced, however they require a healing time. Squeezing conventional screw implants into reduced ridges may result in dehiscence or fenestration of screw implant heads[1]. The minimum required alveolar ridge width must be five to six millimeters upon evaluation for the placement of those conventional root-form implants[2].

There are two primary approaches to bone augmentation. In a one-stage procedure, the implants are placed simultaneously to the bone augmentation procedure. Two-stage procedure means that the augmentation procedure is done first and implants are placed a few months after, with an additional surgical procedure, to allow for bone healing.

Part I of this Literature Analysis was published in the last issue of Implant Directions and addressed the following objectives:

- Review different materials used for bone augmentation
- Discuss different surgical techniques used for bone augmentation
- Compare bone augmentation to no bone augmentation
- Compare different materials and techniques used for bone augmentation
- Compare time to loading for bone augmentation procedures
- Summarize survival rates of bone augmentation procedures

A summary of these objectives can be found at the end of this Literature Analysis in the overall summary of findings.

Part II will be presented in this issue of Implant Directions and will address the following objectives:

- Evaluate costs associated with bone aug-

mentation procedures
- Discuss alternatives to bone augmentation procedures
- Report upon BOI® as a potential alternative to bone augmentation procedures
- Future research recommendations
- Summarize the Literature Analysis findings on bone augmentation procedures from both Part I and Part II

Data Sources and Search Strategy

MEDLINE was searched to identify studies reporting data on bone augmentation procedures prior to placement of dental implants (Table 1). There was no restriction on year published. An attempt was made to identify studies of high methodological quality (systematic reviews, RCT and cohort studies) comparing bone augmentation procedures. From the search strategy, we identified 1 Cochrane Collaboration systematic review evaluating 10 randomized controlled trials. Studies evaluating a series of patients (i.e. case-series) and studies of < 10 subjects were excluded from the primary review but may have been used to support some of the background information. The following strategies were employed to identify literature to meet the objectives:

- *First strategy:* Identify systematic review articles describing bone augmentation procedures for dental implants. Topics such as criteria, techniques, survival rates, complications, and alternative procedures were included.
- *Second strategy.* Identify comparative studies reporting bone augmentation procedures for dental implants since October 1, 2006 (last search date for Cochrane Collaboration systematic review).

- *Third strategy.* Identify articles describing alternatives to bone augmentation for dental implants.

Table 1. Medline Search Summary

Terms	Hits	Reviewed
Search ("alveolar ridge augmentation" (MeSH) OR "bone transplantation" OR "oral surgical procedures, preprosthetic" (MeSH) AND "dental implantation, endosseous"	9857	
Search ("alveolar ridge augmentation" (MeSH) OR "bone transplantation" (MeSH) AND "dental implantation, endosseous" (MeSH) AND systematic review NOT case report, Limits ENGLISH, Literature containing Abstracts	116	10
Search ("alveolar ridge augmentation" (MeSH) OR "bone transplantation" (MeSH) OR "oral surgical procedures, preprosthetic" (MeSH) AND "dental implantation, endosseous" (MeSH), Limits ENGLISH, Literature containing Abstracts, Publication date from 10/1/05	140	0
Bibliographies from existing literature		3
Total Reviewed	**13**	

Results

Costs associated with bone augmentation procedures

No formal cost effectiveness analyses were identified in the literature comparing augmentation to no augmentation; however, two systematic reviews did report on the additional costs and hospitalization time associated with bone augmentations procedures. These increased costs should be considered when deciding whether augmentation is necessary.
In a systematic review, Episito found the augmentation of resorbed mandibles of 6 to 12 millimeters height with iliac crest graft resulted in more surgical and prosthetic complications, and statistically significant more implant failures, severe pain, days of hospitalization, costs, and longer treatment time than using short implants[3]. With respect to cost and treatment time, while short implants were placed under local anesthesia, the graft procedures required general anesthesia, a mean of 5.9 days of hospitalization (range, 3 to 9 days) and patients could not wear the lower denture for 6 months. He concluded that current evidence may not justify major bone grafting procedures for resorbed mandibles.

Major bone grafting operations are often done under general anesthesia requiring patients to be hospitalized for several days. Some degree of morbidity related to the donor site should be expected and two to three surgical interventions may be needed before the implants become functional. Sometimes patients have to wait more than one year before a denture can be fixed to the implants and the total cost of the treatment is high[4].

Given the costs of general anesthesia, lengthy hospital stays, the potential for additional morbidity, and prolonged healing periods before functional loading, one must weigh this against the potential benefits compared to not providing fixed implants or other potential alternatives that may not require bone augmentation.

Alternatives to bone augmentation procedures

Various bone augmentation procedures were summarized in Part I of this Literature Analysis. Bone grafting is the most traditional approach used by implantologists. Several bone grafting materials are currently in use, including the following: Autogenous bone from the iliac crest, calvarian bone, tibia, fibula, the mandibular angle or maxillary tuberosities, allogenic bone, bone graft substitutes (e.g., xenografts), or a combination [5]. Success rates of dental implants when combined with bone grafting have been reported at 75-90% [6].

One must weigh the costs and benefits of these bone augmentation procedures. Though they allow for patients to receive fixed dental implants, they also have a number of limitations including high costs, increased surgical risk, and delayed time to loading, all of which add to the physical and emotional challenges of the patient.

There are alternative methods for treating

patients with poor bone which may be less costly, incur less surgical risk, and allow for early loading in lieu of prolonged healing periods because they generally do not require bone augmentation procedures. The dental implantologist should be aware of these options especially when these challenges are an important consideration.

Zygomatic implants are in some cases an alternative to bone augmentation in the severely atrophic maxilla or following maxillectomy in cancer patients [4,6]. One to three zygomatic implants can be placed in the body of the zygomatic bone, with a couple of conventional dental implants in the frontal region of the maxilla to stabilize the prosthesis. These implants are placed transsinusally without augmentation. Eliminating the need for bone grafting allows for earlier implant loading. A Cochrane review article[7] highlighted studies which evaluated dental implants in zygomatic bone as a partial or complete alternative to bone augmentation procedures for the severely atrophic maxilla.

No randomized clinical trials or controlled clinical trials were identified; however, observational studies were reviewed. Details of these studies are reported in Table 2. The authors report that it is not possible to give reliable evidence-based advice to potential users with respect to the efficacy of zygomatic implants as an alternative to various augmentation procedures for severely deficient maxillae. These studies demonstrate that zygomatic implants yield high survival rates; however, complications are common and may increase over time. The authors could not encourage the routine use of zygomatic implants until convincing evidence is available.

Other alternatives for treating poor bone prior to implantation include Enamel Matrix Derivative (EMD), systemic treatments, and Bone Morphogenic Proteins (BMPs). Treatment using bone grafting and these other alternatives are summarized in Table 3.

Report upon BOI® as a potential alternative to bone augmentation procedures

Another alternative to treating patients with poor bone without the need for augmentation procedures are trans-osseous, lateral implants (e.g. BOI® brand, Diskimplant® brand). These implants are inserted from the lateral aspect of the jaw bone and are anchored bicortically. These implants utilize the horizontal supply of the bone, rather than the vertical. In those cases, where the augmentation is only performed in order to provide bone for conventional screw-type implants (and not for aesthetical reasons), usage of BOI®-implants can usually avoid bone augmentation procedures; however, in aesthetical zones, augmentations may still be necessary.

The vestibular struts of BOI® implants may project out of the bone and support the augmentation material. In this technique, augmentation may be performed simultaneously with the implant placements, and even the extraction of the tooth. Root-form endosseous implants generally require > 10mm of vertical bone height for safe placement to achieve primary stability and subsequent osseointegration. BOI® implants require

far less vertical bone and cases have been done with as little as 2-3 mm of vertical bone.

Unlike the two-stage surgical technique used to place root-form implants, BOI® implants allow for a single surgical procedure with immediate implant loading, even in patients with limited vertical bone supply [8-11]. The estimated decrease in cost is ~ 50% [10] compared to treatment protocols requiring augmentations. The decrease in total treatment time can reach up to 98%. Lateral implants are placed in both patients with acceptable and poor bone; however, they may have a unique indication in patients with poor quality or quantity bone who may need augmentation. These and other alternative methods to standard bone augmentation procedures need further evaluation to establish their safety and efficacy.

BOI® implants are currently under rigorous evaluation. The following three primary methods of evaluation are being conducted, analyzed, and will be reported in manuscripts in the near future:

- Preclinical animal study in rabbit tibiae comparing both conventional and BOI® implants in normal and irradiated bone evaluating histological, histomorphometric, and biomechanical outcomes.
- Clinical data evaluating several years of outcomes comparing BOI® to screw implants from different implantologists in all bone qualities.
- Finite element analyses of functional stresses in different bone areas comparing BOI® to conventional implants

Overall Summary of Findings

The following represent a summary of findings from both Part I and Part I of this Literature Analysis on bone augmentation procedures in dental implantology:

MEDLINE was searched to identify studies reporting data on bone augmentation procedures prior to placement of dental implants. An attempt was made to identify studies of high methodological quality (systematic reviews, RCT and cohort studies) comparing bone augmentation procedures. We identified one Cochrane Collaboration systematic review which evaluated 10 randomized clinical trials. Three additional comparative studies were identified, providing a total of 13 studies which were reviewed.

Based on this search, we conclude the following:

- When comparing bone augmentation to no bone augmentation, two studies demonstrated no statistically significant differences in prosthesis success.
- Subjects who underwent an autogenous bone graft were less likely to have stabilized implants at two years compared to those without augmentation.
- Patients with bone augmentation were more than 4 times more likely to have pain compared to the non-augmented group.
- When comparing different augmentation techniques, implant stabilization at one year was greater in subjects who underwent sinus lift procedures with bovine bone

augmentation compared to bovine bone/autogenous bone (80/20) augmentation and autogenous bone only.
- No statistically significant differences were found for implant stabilization comparing one stage sinus lift procedures to two stage sinus lift procedures in severely atrophied maxillae. Approximately 50% of all these procedures led to sinus perforations.
- No studies were found which performed a cost-benefit analysis of bone augmentation procedures. Cost-benefit analyses comparing augmentation to no augmentation procedures should be performed.
- Alternatives to bone augmentation reported in the literature include the placing of dental implants in zygomatic bone, placing short implants or wearing removable dentures rather than fixed prostheses, EMD, systemic treatments, BMPs and BOI®.

The following findings from this literature overview make BOI® a potential alternative to bone augmentation procedures:

- Patients may undergo invasive and multiple procedures with long wait times before loading implants.
- There are a limited number of alternatives reported in the literature including placement of short implants or wearing removable dentures. BOI® is a superior alternative.
- No bone augmentation techniques or materials have been found to be superior in augmenting bone in the mandible or maxilla.
- Bone augmentation procedures are very costly and may be associated with complications.
- BOI® has been found effective in the treatment of patients with poor bone without bone augmentation procedures. These findings are pending publication in peer-reviewed journals.
- Clinical trials comparing BOI® to other implant procedures would be an addition to the current literature. In addition, it may be advantageous to compare BOI® to implant procedures which require bone augmentation.

Table 2. Detailed information on studies comparing dental implants in zygomatic bone (zygomatic implants) [7]

Author (Year)	Study Design	CoE	Population	Diagnosis	Treatment Group(s)	Results (outcomes)	Complications
Branemark (2004) [12]	Cohort	III	N = 28; Male: NR%; Median age: NR; F/U range*: 5-10 years; F/U %: 89%	28 consecutive patients treated with zygomatic and conventional implants	Group 1: Conventional implants placed (n=28) Group 2: Zygomatic implants placed (n=28)	Implant stabilization Group 1: 54% (n=15/28) Group 2: 89% (n=25/28)	Recurrent sinusitis 14% (n=4/28) Recurrent sinusitis with recurrent infection 7% (n=2/28)
Malevez (2005) [13]	Cohort	III	N=55; Male: 26%; Median age: men=62 (range 40-76) years, women=57 (range 22-79) years; F/U*: 6 to 48 months; F/U %: NR	Partially or totally edentulous patients consecutively received zygomatic and conventional implants	Group 1: Conventional implants placed (n=55) Group 2: Zygomatic implants placed (n=55)	Implant stabilization Group 1: 87% (n=48/55) Group 2: 100% (n=55/55) Prosthesis success Group Group 1: 95% (n=52/55) Group 2: 100% (n=55/55)	Severe sinus infection 2% (n=1/55)
Hirsch (2004) [14]	Case series, multi-center	IV	N=76; Male: 25%; Mean age: 58 (35-77) years; Median F/U*: 1year in f(x) F/U %: 87%	Patients consecutively treated with zygomatic implants	N/A	Implant stabilization at 1 year 97% (n=64/66)	Excessive intraoperative bleeding 4% (n=3/76) Persistent pain 8% (n=6/76) Chronic infection 7% (n=5/76)

Table 3. Limitations of the current treatments for poor bone

Method	Description	Limitations
Bone Grafting[5]	• Augmentation by means of autogenous, allogeneic or bone substitute grafting.	• Delayed loading due to bone healing time. • Additional surgery (e.g. bone harvesting) • Complications (e.g., pain, infection) • Cost • Potential lack of harvestable bone
Zygomatic implants[4,6]	• A partial or complete alternative to bone augmentation in the severely atrophic maxilla or following maxillectomy in cancer patients.[4,6]	• A few conventional implants in the frontal maxilla are still required to stabilize the prosthesis.
Enamel Matrix Derivative (EMD) [15]	• An extract derived from developing pig teeth used to help regenerate lost tissue following severe periodontitis.	• Delayed loading • Authors suggest that overall treatment effect may be overestimated. • Cost
Long-term high-dose glucocorticosteroids, estrogen replacement therapy, calcium plus vitamin D_3, bisphosphonate therapy.[6]	• Systemic treatments used to treat osteoporosis symptoms.	• Study results are conflicting regarding effects of these therapies. • Loss of Osseointegrated implants after bisphosphonate therapy has been reported. • Cost
Bone Morphogenetic Proteins (BMPs) [5]	• A family of osteoinductive proteins used to reduce the resorptive effects of osteonal remodeling • Increases bone density	• Long treatment course (4-months bone induction before implant placement in Phase II clinical trial)- • Delayed loading during augmentation response • In clinical trial stage • Cost

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Critical Appraisal of a citation on early loading of titanium implants.

Reference

Bornstein MM, Schmid B, Belser UC, Lussi A, Buser D. (2005).
Early loading of non-submerged titanium implants with a sandblasted and acid-etched surface.
Clin Oral Implants Res; 2005 Dec; 16(6):631-8.

Introduction

Early loading has become a hot topic in implant dentistry. It shortens the treatment time and makes it possible to provide the patient with an aesthetic reconstruction in a relatively short period of time. Historically, dental implantologists have followed the well-established Branemark protocol(1). This protocol requires two surgical procedures separated by a 3- to 6- month healing period(2). Success rates with conventional implant methods are relatively high(3); however, clinically, many patients express a strong desire to receive fixed provisional bridgework as soon as possible or even immediately. Early loading is not immediate loading which allows for loading even during the healing phase, immediately after implant placement.

Given the desire to produce implants that can be safely administered in early or immediate loading protocols, manufacturers are eager to achieve this goal by modifying the implant or implant surface to promote faster healing. There is not any scientific proof for the feasibility of this attempt or this direction of investigation yet. On the other hand some designs of implants and the implant-prosthetical system have proved to be successful in immediate loading protocols (5). Considering the tremendous importance of this endeavor, and the potential for overly optimistic claims, we thought it would be important to look at this topic more critically. With the majority of published articles reporting high rates of survival almost universally, our objective is to critically look at recently published articles and appraise them of their methodological and clinical quality. Our aim for this critical appraisal was to take a recently published clinical article reporting a very high survival rate after an early loading protocol using non-submerged titanium implants with sandblasted and acid-etched surfaces.

Article summary

The purpose of this study by Bornstein et al was to evaluate the success rate of titanium screw-type implants with the sandblasted and acid-etched (SLA) surface loaded early, after 6 weeks of healing(4). This was reported as a prospective cohort study; however, only one treatment group was followed and results were compared to previous findings in the literature. Hence, this is more appropriately classified as a case series. The authors reported a series of 51 partially edentulous, selected patients receiving 104 implants were placed between May 1997 and June 1999. No patient demographics were provided in the text or a table. Patients were included if they were partially edentulous and judged to have a bone density of class I-III. Patients were excluded if they had severe systemic health problems, local bone defects requiring

bone augmentation, *or heavy smokers.*
SLA titanium implants of varying lengths and diameters were inserted into posterior sites carried out under local anesthesia using a standardized surgical procedure, with the border of the SLA surface approximating the alveolar bone rest, leaving the machined neck portion in the transmucosal area. Fifteen implants were placed in the maxilla. Of these, four implants (four patients) were inserted into single-tooth gaps and 11 implants (five patients) were inserted into extended edentulous gaps. Eighty-nine implants were placed in the mandible. Of these, 44 implants (19 patients) were placed in distal-extension situations, 21 implants (17 patients) in single-tooth gaps, and 24 implants (9 patients) in extended edentulous gaps. After a healing period of 6 weeks, all implants were functionally loaded with cemented crowns or fixed partial dentures.

Implant success/survival defined as: 1) absence of persistent subjective complaints, such as pain, foreign body sensation and/or dysesthesia; 2) absence of per-implant infection with suppuration; 3) absence of mobility; 4) absence of continuous radiolucency around the implant. The following additional outcomes measures were assessed:

- Modified plaque index (mPLI): an average of four values obtained from four aspects around the implants.
- Modified sulcus bleeding index (mSBI): an average of four values obtained from four aspects around the implants.
- Probing depth (PD, in mm); an average of four values obtained from four aspects around the implants.
- Distance between the implant shoulder and the mucosal margin (DIM, in mm).
- Clinical attachment level (AL, in mm) at four aspects around the implants (AL=PD + DIM).
- Mobility: evaluated by the Periotest procedure
- Distance between the implant shoulder and the first visible bone-implant contact (DIB): measured at the mesial and distal aspect of each implant by periapical radiographs with the long-cone technique.

The day of abutment connection was set as day zero and patients were recalled at 3, 12, 24, 36, 48 and 60 months for clinical and radiographic examination. Three implants were lost to follow-up and were considered dropouts (n=3/104, 2.9%, or 97% follow-up rate). Mean follow-up and ranges were not reported.

The authors reported the following results: One implant (n=1/104, 0.96%) failed during the healing phase. No other failures were reported resulting in a 5-year survival rate of 99%. Two implants developed local peri-implant infections caused by failure to remove cement. These were treated successfully. The peri-implant soft tissues were reportedly stable over time. Mean probing depths and mean attachment levels did not change during the follow-up period. None of the radiographs exhibited signs of continuous peri-implant radiolucency, which the authors reported confirmed ankylotic stability for all 100 remaining implants. The authors reported the measurement of the bone crest levels (DIB val-

ues) confirmed stability as well.

The authors compared their 99% survival rate to a recent systematic review which reported that implant loss prior to functional loading after 5-years of follow-up is expected to occur in about 2.5% of all implants placed.

Further, they report that implant loss during function occurs in about 2-3% of implants supporting fixed reconstructions. They contrast this with a less than 1% implant loss during the healing period in their study and no additional implant losses during functional loading. The authors conclude that under defined conditions (i.e., low-risk patients without complicating health factors), early loading of SLA titanium implants after 6 weeks of healing offers successful tissue integration with high predictability for at least 5 years and can be considered standard care.

What were the study's methodological strengths?

This study reported a follow-up rate of 97%. Though mean follow-ups and ranges were not reported, high loss to follow-up rates is a common problem in clinical studies can render study results invalid in certain cases. This study showed an acceptable rate of patients that seemed to have remained under control during the follow-up period.

The authors reported several clinical outcomes measures giving the reader an opportunity to judge success based on several acceptable methods. Data on study results were reported nicely in tables and life table analyses were performed which made it very useful to follow the progression of the enrolled patients.

What were the study's methodological limitations?

The study was not a cohort study as mislabeled by the authors. Success rates were compared with historical data from the literature. These patients from the literature are not part of the same population or data collection period. Even for this reason, superiority claims of SLA over other methods or devices should not be made. The authors may be applying superiority on page 636 when comparing their failure rate (1%) to healing implant failure rates from a systematic review (2.5%) and reported implant failure rates during loading of 2-3%. This comparison should be interpreted with caution.

Summary demographic data in text or table form were not reported. Patient age ranges, mean ages, and gender distributions were not reported in this paper. This is quite remarkable given the long term follow-up of this study and calls in to question the integrity of this data set. Most journals will not accept manuscripts without these data reported.

The authors restricted their patient population to non-smokers with acceptable bone quality. However, the authors who made the judgment regarding bone quality performed these procedures in patients with grade IV bone (5 implants, page 632) but only reported the results of patients with grade I-III bone. It is unclear why the

authors would do this and unclear when these patients were excluded. Were they excluded *apriori* as part of the study design or after their outcomes were assessed? This limits the generalizeability of these findings to patients with less than favorable oral conditions and calls into question again the integrity of the data. Hence, these findings should not be applied to the upper jaw where poor bone commonly exists.

It is unclear who performed the outcomes evaluations (e.g., judgment of implant survival). Was this person an independent disinterested party or one of the authors? In a prospective study, it is advisable to identify an independent observer to make these assessments if at all possible to avoid even unintended bias in the results. The location of the lost implant was not reported. Further, no patient reported outcomes were assessed. In addition to clinical measures such as implant survival and radiographic findings, it is highly advisable to measure outcomes from the patient's perspective since published rates of survival in the literature are universally high.

How might the findings from this publication be applied to patient care?

It is difficult to confidently apply these findings to patient care. Several methodological limitations or oversights call into question the findings from this study. If one were to practically apply these findings in the clinical setting, it is unclear from table 1 or 2 which lengths of screws were placed in the corresponding areas of the jaw.
In patients with poorer bone where little vertical bone is available in areas 16 and 26 (upper first molars). More vertical and horizontal bone is typically available compared to distal extension sites between teeth (gaps). So we must assume the authors evaluated patients with relatively good bone in the areas of 16 and 26 and excluded five implants that may have been placed in relatively poor bone (presumably from these areas). Poor bone (grade IV) is found only in the distal maxilla and never in the mandible. Since only 15 implants were placed in the maxilla (table 1, upper line), and another 5 were excluded, the results of this study do not address success of implants placed in the upper jaw in general. For example, reduced bone height and quality was present in only 5 implants in the maxilla (e.g., 8 mm), Table 2. Eighty-nine implants were placed in the lower jaw - an area which is known for good bone density.

Implant placement in the lower jaw with implant lengths of 10 mm and more is not a difficult task, especially if there is enough horizontal bone available for implants with a diameter of 4.1 or 4.8 mm. The authors used implant diameters in the following distribution: 4.8 mm (21.2%), 4.1 mm (78.8%) and *no* implants of 3.3 mm. Hence cases of even mild atrophy (horizontal) or poor bone have obviously not treated in this series of patients and in neither jaw. Without demographic data presented, this leads to the assumption that the patients recruited or included in this study were very young. Cases where atrophy was unlikely or the implants were placed soon after the extraction of the natural teeth. Hence, the results may not be generalizeable to older patients (i.e. those who are typically candidates for implant treatment), especially since patients

aged 40 and over suffer from a higher percentage of degenerative diseases. These patients are not so sick that they would present with "medical conditions" the authors would have excluded; however, would present a challenge nonetheless and therefore ought to be considered in clinical studies.

Measurements on the vertical bone level can not be generalized: in this study all implants have placed between teeth, most of them in single tooth gaps. It is well known that in these clinical situations (especially given a slightly deeper insertion of the implant as shown in the radiographs of this article) it is not difficult to maintain the bone level stable. This situation will work with all implants and is not a special benefit of the SLA surface. The results of bone level measurements should not be transferred to situations where no teeth are left in a jaw or where the implants are the only distal support on one or both sides of the jaws.

Were all clinically important treatment interventions or outcomes evaluated? If not, what additional parameters should be considered?

These patients were followed during the period between 1997 and 1999. To our knowledge, by then immediate or even early loading was not under discussion. It was after 1999 that the discussion regarding immediate and early loading began. It was at this outset, that the way implants were loaded was also initiated. The authors do not mention anything about the kind of prosthetical work that was instituted. Early loading could mean progressive loading (that type was fashionable at that time), meaning that very little masticatory function was imposed early; or that no masticatory function was present (i.e., the crowns did not engage each other).

Branemark reported that remodeling of the bones after implant placements takes place in conjunction with an absolute bone loss. In cases where marginal bone does not shrink, overall bone volume must shrink which would cause the implants to move into infra-occlusion. In this scenario, the crowns on the implants are protected from the forces caused by natural dentition or implant based antagonists (5), (see fig 26.4 page 364). However, this situation is not a recommended result of the treatment. Teeth are often overloaded and implants under loaded over time which may lead to detrimental results. In cases where a unilateral distal-extension has been treated, the patient has teeth on the opposite side, which means that most of the load may have been placed on these teeth. Certainly the temporomandibular joint will be able to compensate with quite a bit of compression, but in general, the replacement of molars and premolars should support the bite.
Given this complex interplay of adaptation during the functional phase, without remarks about prosthetical strategies and corrections or checks one must question if adequate function was achieved for these patients. Further, without a patient reported outcome to assess such parameters as patient-perceived appearance, pain, physical function, work disability, social disability, psychological disability, and overall patient satisfaction, we will never know if such implants are really "successful".

Conclusion

The authors limit their results to cases with bone quality I-III in otherwise healthy non-smoking patients with no active periodontal disease. Without knowledge of summary demographic data, it appears this population may also have been limited to lower jaw implants in young patients with no horizontal bone atrophy. Their findings are not generalizeable to the upper jaw patients or in patients with less than ideal overall and oral health conditions, especially on smokers. Taking this into consideration, the authors unfortunately only show that SLA implants may be suitable for early loading only in those cases, in cases where most other implants on the market are known to be successful. Clinical cases like these are rare and present no challenge to the practicing implantologist. Scientific investigations should rather focus on innovative implantological solutions for patients with poor bone (quantitatively, qualitatively), patients with medically compromised conditions, smokers and patients showing periodontal involvement.

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Complete Immediate Maxillary Rehabilitation Following Insertion of two BOI® Implants

KEY WORDS:
Immediate loading, basal implants, transosseous implant placement, maxillary rehabilitation

BOI® implants consist of a vertical shaft with a threaded pin and one or three baseplates horizontally attached to the shaft. Following a T-shaped osteotomy, BOI® implants are inserted transosseously, i.e., they are inserted into the jaw from the labial cortical bone to the palatal cortical bone. Osseointegration is obtained in the area of the baseplates.

The shaft is not overly elastic, comparable to the teeth's micromovements. This is why BOI® implants can be combined with natural teeth. BOI® implants must be loaded immediately, i.e within a few days after implantation, in order to achieve a functionally determined level of healing.

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Case report

A 42-year-old woman presented at our office with a fractured maxillary bridge. She was unable to chew because of the mobility of her bridge and because of pain involving tooth 13. This tooth exhibited a fistula in the apical region. Preparatory measures included an OPG of the jaws, a thorough clinical examination, and an evaluation of the patient's medical history to exclude potential contraindications. The patient was given comprehensive information about the imminent procedure, implant choices, and the surgical risks. Bone height and width were measured, and BOI® implants of the appropriate sizes were procured.

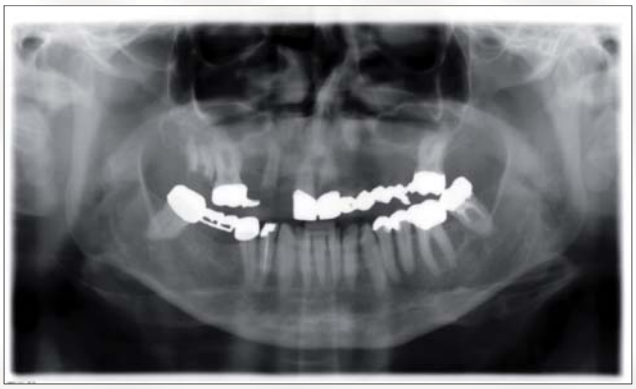


Fig.1 Baseline situation. Insufficient maxillary bridge

Procedure

One appointment was made for the surgical and prosthetical procedure. In this single appointment, the old maxillary bridge was removed, using local anesthesia, and teeth 16, 11, and 27 were prepared. Tooth 23 was endodontically treated and received an intraradicular post, followed by apical tip resection. Carious lesions on teeth 16 and 21 were removed, and the cavities were restored. This was followed by the insertion of the BOI® implants. An incision was made in the gingiva, and the bone between teeth 21 and 27 were exposed using a bone rasp. Both vertical cuts for the implants were made with a Lindemann cutter to provide orientation for parallelizing the abutments. The horizontal cut for the implant was made exactly at the canine position using a double cutter with 3 mm inter-

disc-distance. The implant was carefully tapped into its place inside the jaw bone. The next implant bed between the regions of the second premolar and first molar was prepared using a 7-mm combination-cutter, followed by a 9 mm- and finally a 10-mm lateral cutter, making sure to extend the final cut all the way through to the palatal cortical bone. This was checked visually by flapping the mucosa in the palatal region cranially . Finally, the mucosal flaps were carefully sutured back into place. It is possible to puncture the flap in the area of the vertical implant part, in order to be able to slip it over the threaded pins. In this way, sutures directly adjacent to the emergence site of the implant are avoided, while at the same time the correct position of the mucosal flap is ensured. During a short break between treatment steps, a panoramic x-ray was taken to visualize the relative position of the implants within the jaw. Impressions were taken of both jaws immediately after this procedure, and the bite was registered using red bite wax.

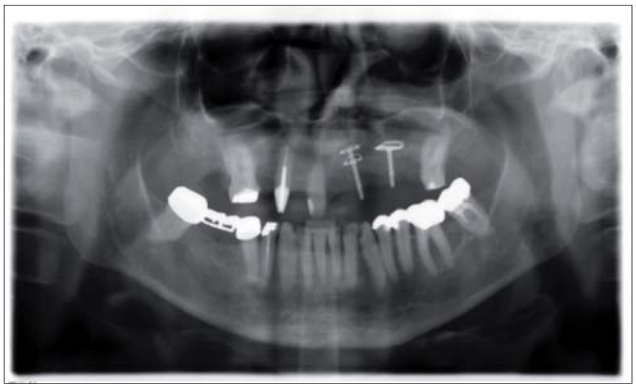
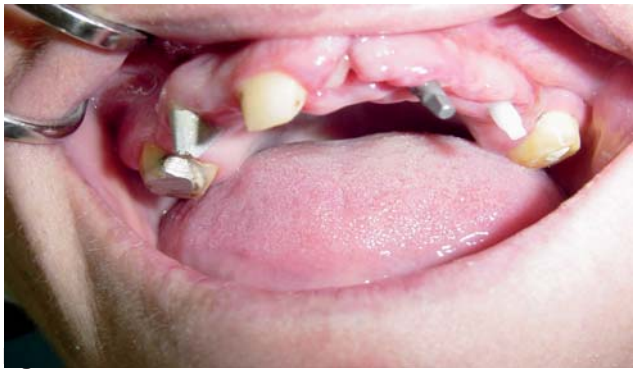


Fig. 2 Control radiograph following the implantation



Based on the impressions, models were made by the dental technician and a resin bridge with a continuous metal core was fabricated within two days. At the second appointment, two days after the surgical intervention, the sutures were removed, and the temporary bridge was inserted. This restored the patient's function to the point where she was able to eat and speak. After six months, the provisional restoration was removed and replaced by a metal to ceramic bridge. The provisional provided the level of reference for vertical height. This maxillary restoration has been functioning to the patient's satisfaction for over one year now.

Discussion

The use of BOI® implants to increase the number of available abutments opens up new possibilities for immediate prosthetic rehabilitation. If it had not been for the implants, the only alternative would have been a removable denture with a cast framework, which the patient rejected. The definitive restoration could not have been designed in the same way had crestal screw implants been used. Other factors to consider were the inadequate amount of bone and the extensive dimensions of the maxillary sinus, some-

thing that would have necessitated at least a course of sinus bone augmentation. Thanks to the availability of BOI® implants, immediate loading and a fixed prosthetical solution were possible. The patient regained her masticatory function almost immediately, and the esthetic appearance of the resin provisional was reasonably acceptable.

One general problem remained unsolved: the unequal length of the two upper dental arches on the left and the right side may cause a unilateral pattern of chewing. In order to avoid this, regular check-ups and considerable corrections over the years must be taken into consideration. It would have been possible to place one additional implant in the right distal edentulous area. According to FDI guidelines, however, distal support ranging from the left first molar to the right first molar is sufficient for the prevention of detrimental loads on the temporomandibular joint and for the restoration of physiological masticatory function. This guideline however, does not take the tendency of the unilateral use of the masticatory apparatus into consideration, which may develop in a case like this with unequal arch lengths.

The rehabilitation of the maxilla as presented here constituted an economical and fast solution for the patient. Being able to have all surgical steps (tooth extraction, apical resection, implant insertion) performed during a single appointment is greatly appreciated by the patients.

Reviewed by:
Dr. Richard Musicer, USA

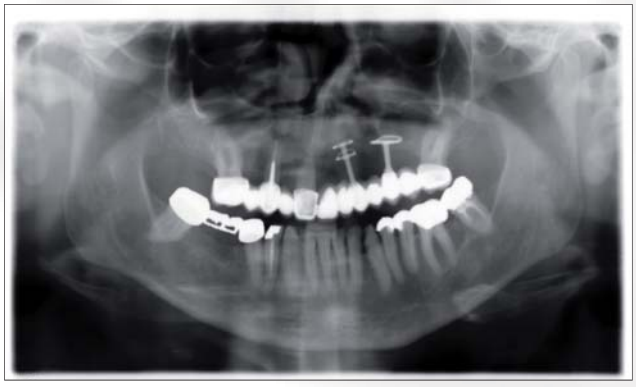


Fig. 4 **Final control radiograph.**

Fig.5 **A satisfied patient**

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Complete Oral Rehabilitation Including BOI® Implants

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KEYWORDS
Immediate loading, basal implants, transosseous implant placement, maxillary rehabilitation

More and more, patients who consult our office express an interest in comprehensive and definitive long-term oral rehabilitation. In many cases, several previous care providers would have treated them from time to time, based on acute clinical findings, but not offering an overall solution. Teeth may have been extracted, some of them replaced by bridges or removable dentures; crowns may have been inserted; all in the absence of a convincing overall treatment concept. In many cases, malocclusion or non-occlusion, unilateral patterns of chewing, and the consequent migration of teeth and unequal dysfunction of muscles may have resulted in compound damage to the dentition and the temporomandibular joint. Missing lower molars will frequently and quickly result in the elongation of their maxillary antagonists, resulting in plane of bites that are disfunctional because of their misalignment relative to Camper's plane. Additional problems such as abrasion, muscular strain, migraine, or tension headache may be the result. It is therefore important to sit down with the patient and to develop a complete treatment concept based on x-rays and diagnostic casts, contrasting the various treatment options.

In our dental practice, providing the patient with fixed restorations has top priority, because this result is desired by the vast majority of the patients. The wearers comfort, esthetics, functional loads and, consequently, an optimized transmission of masticatory forces and the protection of the natural tooth structures are the advantages of this approach compared to any removable therapy. All viable natural teeth are integrated into the design. Edentulous distal spaces or large edentulous spaces delimited by natural teeth are usually treated with the help of implants, using mainly basal osseointegrated (BOI®) implants, often in combination with conventional screw implants, for the restoration of harmonious, bilateral mastication. Temporal and economic constraints often also have to be acknowledged and discussed. However, the main objective of the treatment will always be to ensure a durable long-term solution. This article presents two case reports to illustrate this treatment philosophy.

Case 1

Based on the diagnostic findings, it was decided that the maxilla should be restored with a fixed complete denture and that two posterior bridges were indicated for the mandible.

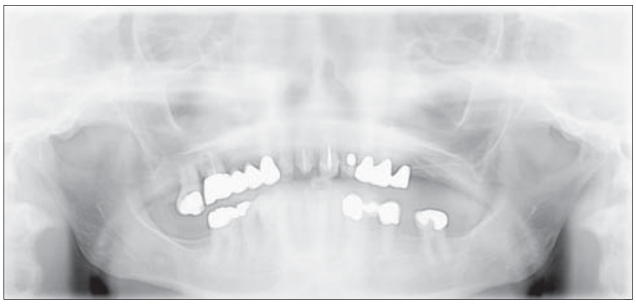

Fig.1 **Patient, female, 52 years, baseline situation. Insufficient restorations, missing and elongated teeth.**

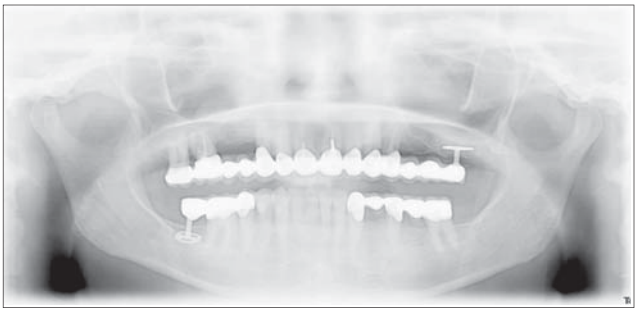

Fig.2 **Final OPG of the patient. The bridges are in harmo nious occlusion, and the implants integrate seamlessly into the ovrall design**

The bite was to be opened by 2 mm, with the occlusion adjusted to coincide with Camper's plane. The treatment proper was preceded by splint therapy to allow the temporomandibular joint and the muscles to adapt. The patient's elongated tooth 17 had to be considerably shortened, while teeth 27 and 47 were replaced by BOI® implants integrated into the overall restorative design. The minimal bone height of approximately 3 mm relative to the maxillary sinus that was present in the region of tooth 27 is not a problem with a BOI® implant; the implant is inserted naturally, giving it bicortical anchorage without invading the maxillary sinus or inserting any bone replacement materials. The implant can be loaded immediately thanks to its special shape. In our case, the maxilla was restored first, with a dental technician designing the bridge to conform to the ideal occlusion (Camper's plane). Only a single session was needed to insert the upper bridge, to prepare the mandibular teeth and to insert the BOI® implant in the region of tooth 47. This allowed the dental technician to adapt the regular bridges to the maxillary restoration.

Once the mandibular bridges had been inserted, no further splint therapy was required. The patient rapidly grew accustomed to the new situation and was happy not to have to wear a removable denture

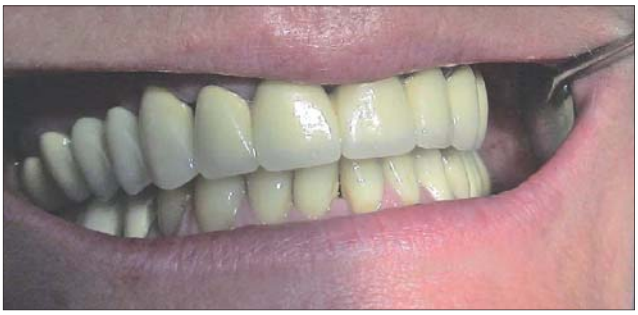

Fig.3 **Clinical situation following complete rehabilitation.**

Case 2

The 64-year-old patient complained about his teeth getting shorter. In the presence of a maxillary restoration that had become insufficient and residual anterior mandibular teeth, massive abrasion had damaged the remaining teeth to the point where the patient was inconvenienced by hypersensitivity to heat and to cold, as well

as by sharp edges. The impacted lower third molars presented no irritation, so the patient wanted to retain them to avoid the trauma their surgical removal would cause.

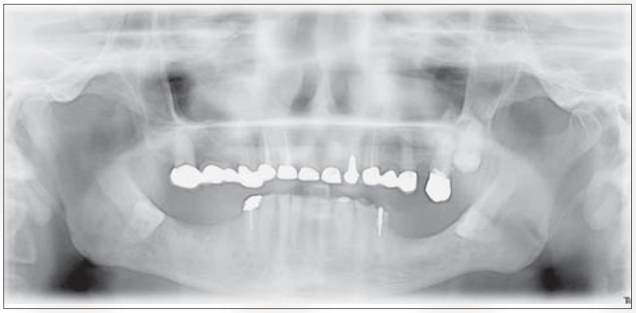

Fig.4 **Patient, male, 64 years, baseline radiograph showing abraded dentition.**

Nevertheless we informed the patient that impacted molars may deviate the optimum strain distribution in the mandible, which may lead to minor unwanted changes of the mandibles morphology over the years.

The treatment plan fur this restoration included the use of existing teeth. The elongation of the tooth in area 27 provided a special problem, because without shortening the Camper´s plane it could never be restored properly on this side. The upper right 3rd molar had to be extracted, and the teeth to be extended in length by approximately 4 mm overall to render them visible again. Implants were to be inserted in the edentulous distal spaces in the mandible, at the same time increasing the bite by 3 to 4 mm in order to distribute the enormous masticatory forces evenly. The definitive treatment was preceded by splint therapy to allow the temporomandibular joint and the muscles to adapt. Here, too, the maxilla was restored first, with the bridge supported by the nine existing teeth, even though some of the abutments teeth were relatively short clinically, providing only reduced retention

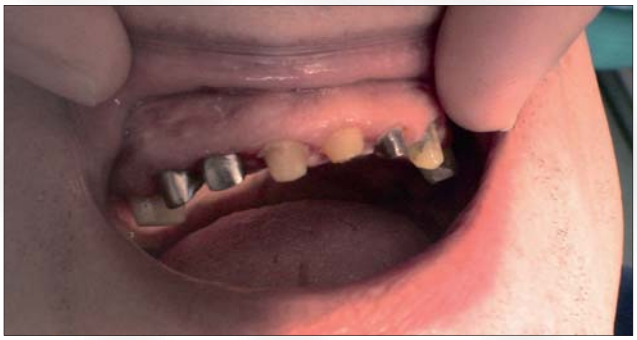

Fig.5 **Clinical situation following preparation of the maxillary teeth**

An ideal occlusion was created, i.e., regardless of the clinical length and relative position of the teeth in the lower jaw.

Fig.6 **Clinical situation following insertion of the maxillary bridge.**

In a case like this it is important to align the occlusion along Camper's plane, since this is the only way to balance and compensate large masticatory forces and allow for undisturbed, physiological movements of the mandible in relation to the maxilla . Following the insertion of the maxillary restoration, the mandible was treated immediately.

The teeth were prepared, BOI® implants were inserted in the areas 37 and 47, and one KOS® screw implant (compression-screw-implant) was inserted in the area 45.

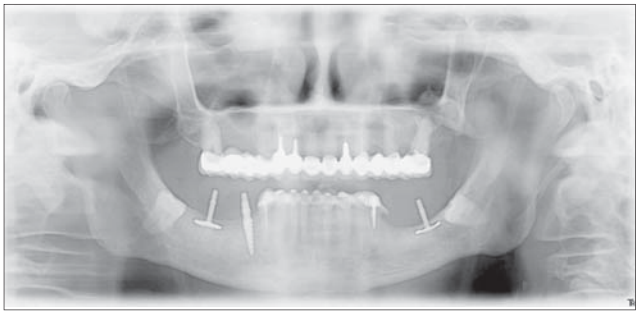

Fig.7 **Control OPG after implant insertion.**

BOI® implants are well suited for distributing the masticatory forces to a large surface inside the jawbone and to cortical, resorption-resistant areas. Their shape allows them to keep an appropriate distance from the inferior alveolar nerve even in a situation with reduced vertical height. They can be loaded immediately, as can the KOS® screw implant. Once the mandibular bridge had been inserted, no further splint therapy was required.

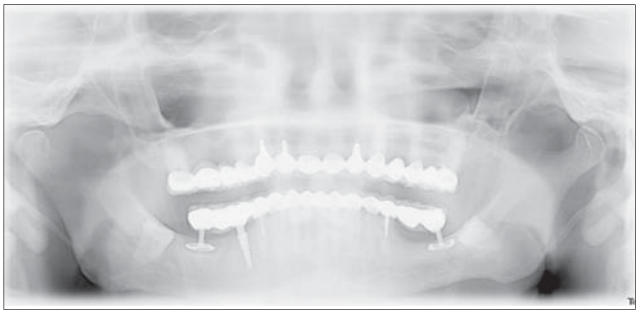

Fig.8 **Control OPG at one year.**

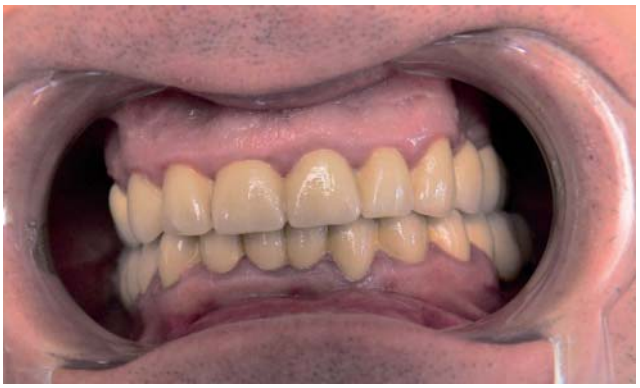

Fig.9 **Clinical situation at one year.**

The patient rapidly adjusted to his elevated bite. He is happy with his dental work, and his improved esthetic appearance

Discussion

Complete rehabilitation usually requires considerable effort on the part of the treatment provider. Esthetic, functional, temporal, surgical, and economic requirements need to be discussed with the patient, since he or she will expect long-term results that can only be achieved by using a high-precision approach. Only physiological mastication with an appropriately positioned and in-

clined plane of bite allows safe management of the masticatory forces. Since this often requires enormous modifications of the entire stomatognathic system, preliminary splint therapy is in many cases indispensable. All teeth should be examined for their preservation potential. Non-viable teeth have to be endodontically treated or extracted. In the case of large edentulous spaces, including distal spaces, basal implants are easy to insert, to manage and to integrate in the overall treatment concept and yielded good results in our hands.

Such results can be attained with KOS® and BOI® implants. Their small, compatible and standardized abutments are easily and esthetically integrated into the bridge, facilitating good oral hygiene. Due to their special shape, BOI® implants can be inserted in the maxilla and in the mandible even in reduced bone height situations without encroaching upon sensitive structures and without having to resort to the use of bone replacement materials. In some cases, BOI®implants are the only way to directly reach the result of a fixed restoration. The rapid progression of the treatment facilitated by immediate loading is usually greatly appreciated by patients. A stringent recall schedule including a full dental checkup, professional teeth cleaning and a full occlusal and masticatory reassessment will help safeguard the treatment result for many years.

Providing the patient with fixed restorations should be the aim of the restorative work, because this result is desired by the patients. We have never experienced a patient that offered a fixed restoration at an affordable price who chooses a removable (even implant based) denture.

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Clinical Note

Prophylactic use of botulinum toxin in dental implantology

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The clinical role of botulinum toxin as a therapeutic agent is expanding. Our group has found a new role for its use in dental implantology. Its safe and effective use with bruxism and oral mandibular dystonia prompted its use with dental implants in immediate load protocols where temporarily reducing masticatory forces can be of prophylactic benefit to protecting the osseointegration process.

Immediate loading has become a hot topic in implant dentistry. It shortens the treatment time and makes it possible to provide the patient with an aesthetic reconstruction during the whole treatment period. Controlling functional forces has been suggested as one of the ingredients for obtaining success with immediate implant loading [1].

Furthermore, whether one prescribes to immediate or delayed loading, osseointegration rates for conventional dental implant systems are relatively high (>93%) under normal bone conditions.

Jaw volume, bone quality, and overload are the three major determinants for late implant failures [2]. Since osseointegration represents a dynamic process both during its establishment and its maintenance, implants initially well integrated may occasionally show unexpected mobility when the bone/implant/restoration system is in actual function. This mobility can be the result of increasing muscular forces or a changing occlusal situation after an unexpected repositioning of the temporomandibular joints. If the mobility is not the result of infection, the implant may be treated and protected without an invasive removal procedure. *Prophylactic* administration of botulinum toxin close to the time of implantation for immediately loaded implants has been reported to control functional forces.

Therapeutic administration of botulinum toxin in patients exhibiting instability after implant placement for the purpose of preserving an implant/restoration system unrelated to infection has also been reported

The use of Botulinum Toxin has become routine practice both *prophylactically* and *therapeutically* when basal (lateral) implants are used. Basal implants consist of a thin cylindrical part and a larger, cortically anchored base plate. They are inserted from the lateral aspect of the jaw bone through a T-shaped slot. The slot may be closed by means of bone augmentation or through self healing (Figure 1). When cases with extreme bone atrophy are treated with this implant therapy, long prosthetical cantilevers are often required to establish correct restoration of the vertical dimension (Figure 1). These cantilevers may in addition increase the risk of overload.

Comprehensive insertion of implants and immediately loaded restorations can change all parameters of masticatory function; the newly created occlusal surfaces will be included in the masticatory process and the vertical dimension is often changed.

This results in considerable changes in the patterns of muscular function, which in turn influences the morphology of the jawbone and thus the relative position of the dental arches. Most patients are able to position and move their dental arches congruently during the day. During phases in which voluntary control is absent (i.e., during the night), the jaws may approximate in positions that greatly deviate from their daytime positions. If this happens, balance is lost. Muscular dynamics during the patient's sleep are unique and differ from those during voluntary clenching exerting a greater mechanical load on the temporomandibular joint on the balancing side [5].

The *prophylactic* administration of botulinum toxin may reduce the risk of damage being exerted to the bony interface by gradual or sudden changes in mandibular position on the interface of immediately loaded implants before they are detected at the scheduled follow-up appointments. Especially in early phases of the implant therapy, such forces may mobilize the implants.

If implants are placed in bone areas where tensile forces dominate [6], these forces may enhance bone resorption by creating unfavorable conditions for implant integration, especially if the implant it not yet firmly integrated (e.g., immediate load conditions). To avoid detachment of the bony interface from the implant and overload in areas that have been subject to minor loads preoperatively, the *prophylactic* reduction of masticatory forces through the use of botulinum toxin therapy appears to be a sensible therapeutic adjunct.

Whether one prescribes to early or delayed loading, the phase of functional use of dental implant systems is often characterized by extensive changes in the relative positions of the dental arches, segments or individual teeth.

The extent and sequence of these changes cannot be predicted, which is why the inserted restorations must be monitored and adjusted at regular intervals. Even more unpredictable are the morphological changes which can have a variety of effects in the implanted jawbone. Changes in the integrated implants and thus the functional surfaces of the restorations will passively follow [7]. In addition to masticatory force and masticatory function, age, hormonal status and genetic dispositions as well as habits and other factors will play a role in determining the nature and extent of these changes [8-11]. Collectively, these changes often exceed the extent of what dentists know and expect from their daily experience with tooth-supported restorations.

One might be concerned that though the therapeutic approach using botulinum toxin will inhibit masticatory function temporarily, the masticatory forces will eventually return to previous levels once the effect of the drug has subsided, once again exercising their potential deleterious

functions. However, a permanent reduction of masticatory forces is not the therapeutic objective. Rather, the objective is to create a more favorable load situation during a phase of higher elasticity in the region of the bony interface for a limited time to allow the bone to remineralize and the implant to reintegrate in the bony interface region. Hence, it is necessary to address premature contacts and unilateral loading at the outset of botulinum toxin therapy to ensure the stabilization of the bone/implant system will be a lasting success.

The authors commonly prescribe to the *prophylactic* administration of botulinum toxin in full arch implant cases with advanced atrophy of the maxilla in immediate load protocols using basal (discussed earlier) implants. If sufficient bone is available in the upper jaw to allow the placement of eight or more implants (with a diameter of 10 mm or more), the need for botulinum toxin therapy is less imminent; however, we often apply it in all cases because we find the benefits outweigh the risks of failed osseointegration in immediate loading protocols. In our clinical experience, witnessing the benefits of this treatment, we no longer can deprive patients in immediate load protocols from this treatment, especially in cases with reduced bone supply. Since the bone in the mandible is usually of better quality, botulinum toxin is not indicated. The authors believe that bilateral medication of the masseter muscles (without treating the temporalis muscles) will generally suffice to achieve satisfactory results both *prophylactically* and *therapeutically;* however, no studies have been conducted to support this clinical anecdote.

In cases of severe preoperative atrophy, the surgeon may want to medicate both muscles. We administer a full dose of 200 -250 U for each masseter muscle in order to provide an adequate reduction of chewing forces for up to eight weeks, (Figures 3-5). Our rationale is based on the 50-60 day time period for primary mineralization of woven bone (callus). These recommendations are based on the principles of bone physiology and healing, clinical experience and its application in other maxillofacial conditions.

There are alternative treatment strategies to decrease the loads on the bony interface, such as the use of interceptors, splint therapies, and TENS devices. Interceptors and splints tend to change the location and the time pattern of increased masticatory forces, whereas TENS devices provide relaxation for a very limited time period. We find that that these strategies do not provide enough protection against deleterious involuntary nocturnal mandibular excursions or nocturnal changes in the mandibular position. No clinical studies exist comparing these methods to botulinum toxin therapy.

Botulinum toxin therapy is not indicated in cases where the heavily remodelled intrabony overload areas have become infected. To our knowledge and clinical experience, reintegration of implant surfaces cannot occur in the presence of granulomatous changes at the bony interface, especially if the interface of the implant is roughened which promotes retention of the infection.

Our experience with botulinum toxin has been applied with lateral implants [12-15].

However, it is conceivable, in principle, that this medication can be used as an adjunct in treatment concepts including either root-form implants or a combination of root-form and lateral implants. To establish the scientific safety and efficacy of botulinum toxin use in dental implantology, more studies need to be published on this topic. Based on its safety and efficacy in other craniomaxillofacial conditions, and in our 10-year clinical experience with lateral implants, we consider it safe to use, however, encourage research in its application.

This research could compare patients with poor bone who do or do not receive botulinum toxin therapy or compare botulinum toxin therapy to other methods of controlling masticatory forces. A focus on discovering the appropriate doses for therapeutic and prophylactic indications while considering the bone physiology for increasing the chances of successful integration in immediate load protocols for root-form dental implants would also be useful.

In particular, patients with reduced bone supply as well as patients suspected of delivering high masticatory forces present special challenges to the implantologist. Prophylactic administration of botulinum toxin may facilitate a reduction of the strength of the masseter and temporalis muscles after implantation, especially with immediate load.

Bone/implant/restoration systems can become mobile due to overload on the peri-implant bone during the treatment phase. Botulinum toxin can reduce the indirect influence of the masticatory load on the bone/implant interface which may in turn protect the osseointegration process.

Figures

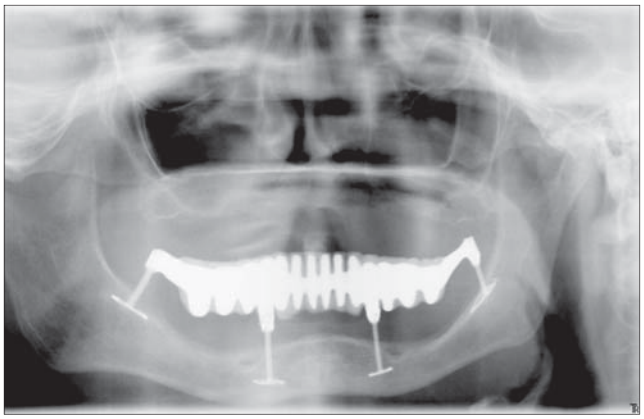

Figure 1. Fixed restoration of the extremely atrophied mandible with a metal-to-ceramic bridge and basal implants (6 years postoperative panoramic view).

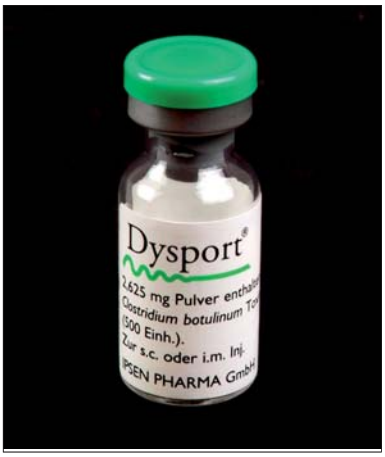

Figure 2. One vial of Dysport contains 500 U of dry substance which should be diluted with sodium chloride. The molecule is very sensitive; therefore, should not be shaken.

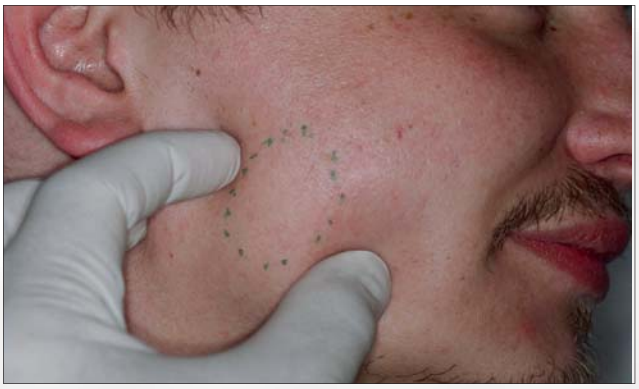

Figure 3. The prominent areas of the masseter muscle are easy to palpate. Before injecting the drug, markings may be made on the skin to allow orientation for the injection.

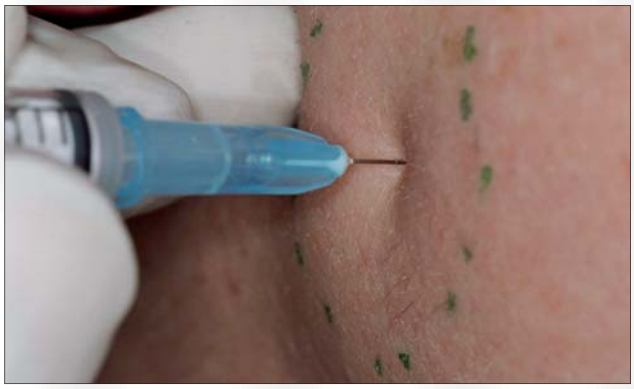

Figure 4. Injection of one half of the dose for one masseter muscle from outside the mouth into the center of the marked area. The 200-250 Units of Botulinum toxin are divided between two areas of the masseter muscle.

Figure 5. The superior and anterior part of the masseter muscle may be easily identified and accessed from inside the mouth.

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Research in Context
What is...a p-value?

Learning how to use research is the foundation for applying "best evidence" to clinical practice. Evidence-based implantology uses concepts of epidemiology, study design and biostatistics. The goal of this section is to help clinicians use these concepts to find the best evidence and critically appraise the literature. These two key activities allow the successful integration of science with clinical judgment.

In this issue, we'll explore "what is a p-value?" and aspects of "statistical significance" since these are common threads in research studies. The majority of research studies use statistical methods to compare groups, or to compare treatments, or to compare results before and after an intervention. The statistical comparison usually results in the generation of a "p-value" and determination of whether the results are "statistically significant". Statistical analysis plays an important role in research studies primarily to assess the "chance" component. Misuse, misinterpretation and over-interpretation of statistics is not, however uncommon in the research literature. Thus, it is worth discussing some of the issues.

At some point during a study, the investigators face the question of "How important are these results?" or "What do these results really mean?" Just because a statistical test declares the results "significant", it does not mean that the differences are meaningful. Why not? Simply stated,

- Statistical significance relates to how likely the observed effect is due to chance (i.e. random error due to sampling) instead of a "true" difference between treatments or groups.

- Clinical significance relates to the magnitude of the observed effect and whether the magnitude or "effect size" is big enough to consider changes to clinical care.

In order to begin to answer these questions, statistical tests are done. The purpose of analytical statistics is to assess the effects of treatment and risk factors on specific outcomes. This evaluation/assessment relies on the testing of statistical hypotheses. The testing of statistical hypotheses (sometimes called testing of statistical significance) is an important application when evaluating treatment safety or superiority. The primary hypothesis that is tested, termed the null hypothesis, is that there is "no effect" or "no difference" other than that which may be expected by chance.

Statistical significance depends on three parameters:

- Sample size (the larger the sample size, the easier to demonstrate statistical significance)
- Variability in patient response or characteristics, either by chance or by non-random factors (the smaller the variability, the easier to demonstrate statistical significance)

- Effect size, or the magnitude of the observed effect between groups (the greater the size of the effect, the easier to demonstrate statistical significance).

Formal hypothesis testing generally involves examining the observed value for some factor compared with an expected value in a manner which includes consideration of the standard error (i.e. the inherent variability) of the estimate. The process generates a "test statistic" value which is then used to determine the probability of having obtained the result by chance (often sampling error) alone. The probability, or p-value, is the probability that the observed difference would happen if the null hypothesis of no association were true. As all research is performed on samples of subjects, there is always a possibility, at least in theory, that the results observed are due to chance only and that no true differences exist between the compared treatment groups. Statistical tests help sort out how likely it is that the observed difference is due to chance only.

The smaller the p-value, the less likely that the result obtained could be due to chance if the null hypothesis were true. The p-value is usually compared to an arbitrary value to evaluate "statistical significance". By convention, this level of "statistical significance" is usually 0.05 and corresponds to the probability of rejecting the null hypothesis when no association really exits (called the alpha or Type I error).

While evaluation of the p-value against this arbitrary number of 0.05 may provide some guidance with respect to the role of sampling variability and random error, **it should not be the sole criterion on which the value of a study or set of decisions is based**. There are many caveats and assumptions which are an integral part of statistical testing. Not all investigators understand these and may not use the appropriate statistical methods or may use and interpret the appropriate test inappropriately. Choosing the correct statistical test to compare outcomes depends on the study design (discussed in future editions) and on the types of outcome variables collected.

Failure to reject the null hypothesis doesn't necessarily mean that no association is present and, likewise, rejection of the null hypothesis doesn't necessarily "prove" that the association exists, nor does it mean that the relationship is causal. First of all, at the 0.05 level, our sampling will be off 5% of the time and by chance we may/may not observe a difference. In other words, we'll be wrong 1/20 times. There are also times when we support the null hypothesis when it is false (called the type II or Beta error). In this case we don't find a statically significant finding when there really is a difference.

As outlined previously, the sample size and power may not be sufficient to identify a difference that is "statistically significant". There is also the dilemma of how to consider p-values that are close to the cut off: Should 0.046 be rounded to 0.05 and the null hypothesis rejected? Is a value of 0.06 really "insignificant"? One should remember that the 0.05 is an arbitrary cut-off, not a magic number on which to base important decisions. One should also remember that the

sample size and variation in the population sampled contribute to the size of the p-value. All the information contained in the study must be considered, including sources of potential bias and confounding in the study, topics to be covered in future **ID** issues.

There are some additional caveats regarding statistical testing which require consideration. Studies which attempt to evaluate numerous associations will eventually find something that is "statistically significant", but it may not be of importance in practice. One also must be cautious not to equate "statistical significance" and clinical significance. For example, if the difference in blood pressure in one group of patients was "statistically significant" but the difference in terms of real numbers was 1 mmHg, does it represent a clinically (or biologically) significant difference given the limitations and variability inherent in blood pressure determination? No!

Given the above, many epidemiologists and biostatisticians advocate reporting relative risks or odds ratios and the associated confidence interval, which describes the range of variation around the relative risk. Such an estimate provides the magnitude or relative difference between two different treatments or risk factors – something more clinically useful than whether the p-value is greater or less than 0.05 (or other significance level). These concepts will be described in future issues of Implant Directions.

In summary...

Statistical tests aim to distinguish true differences (associations) from chance and result in a "p-value" as an estimation of probability due to chance. Commonly, an arbitrary test threshold value (e.g., alpha=.05) is used to distinguish results that are assumed to be due to chance from the results that are due to other factors.

- If the probability that the results are due to chance is less than the threshold value ($p<.05$), it is assumed the differences are due to these other factors (e.g., true differences in treatment effects).
- Significance testing in it self does not take into account factors which may bias study results.
- Sample size and random variation play an important role in whether a result is statistically significant or not
- A statistically significant result does not "prove" anything and does not establish a causal relationship.
- Although a result may be statistically significant, the effect size (i.e. magnitude of the effect) may not be clinically or biologically important.

In further issues, we'll describe some "effect size" measures that are commonly used in clinical research and how they are important in determining *clinical significance* versus *statistical significance.*

In upcoming issues we'll use the concepts in greater depth and begin laying the foundations of Evidence-base Practice (EBP)
.....so stay tuned!

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