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Errors, Deficiencies, Complications, Problems, and Developments

Zahnmedizin-Report 6/2007 had an article about some recent statements by Professor Wichmann.

Interestingly – and rather unusually – he seized this opportunity to point out that changes to the masticatory system requiring treatment will inevitably occur in patients with dental restorations over time. While this is a trivial fact, it tends to be conveniently forgotten by the current crop of publications and "patient information" leaflets that tend to be strongest on marketing and lifestyle issues. Whatever measures are required by the most recent schools of thought will invariably be praised – and sold – as a solution sure to last a lifetime, well worth its certainly exorbitant price.

Of course, patients who appear for their regular recall appointments will at most meet the prophylactic nurse– corrections, adjustments and replacements are lowly tasks not worthy to speak of in the presence of an exalted high-end solution. Unfortunately, history has shown that this approach is not exactly new. No one can tell how many state-of-the-art, non-plus-ultra final solutions humankind has had to endure, "solutions" that never stand up to closer scrutiny, so that their erstwhile prophets and former apologists simply jump on the next bandwagon, never looking back for a moment. A rational approach and sound information may be marketing's prime adversaries, but they will certainly constitute better advice in the long term. After all, the "material" we have to deal with in medicine is only human.

One hundred per cent success are a worthy goal, but one that is nearly impossible to achieve in actual practice, regardless of whether we are dealing with the patient's heart, or just her wrinkles – or her teeth. Signs of "wear and tear," degeneration, habits are not just caused by disease but also by physiological processes. So withholding the truth about the inevitability of developments that require further treatment would appear at best highly problematic and at worst singularly inappropriate.

The duration and severity of these inevitable developments, as well as potential remedial treatments, are elements of the overall risk assessment and patient information. The risks of the individual treatment steps are additive. For example, in a seemingly straight forward procedure such as the restoration of edentulous areas with implant-supported dental restorations, the risk inherent in various bone augmentation and destruction measures may already be 10–45%. Add to this the risk of the implant placement itself, which also comes to 5–10%, to say nothing about the prosthodontic or functional risks, for which unfortunately we have next to no statistics. In all fairness, then, we would have

to let every patient know right at the beginning of his or her treatment that complications should be expected, sooner or later; we just do not know when or what kind – if we did we would try to avoid them from the outset.

This is where Professor Wichmann's train of thought takes off: if complications are unavoidable; we need tried and tested methods to meet and confront them. Wichmann's emphasis is on easy removability of prosthetic superstructures, which he would much prefer to see screw-retained, the lot of them. In itself, this is a probate means of countering problems. Unfortunately, Wichmann fails to demonstrate the equivocal approach that behoves the scientist. He unfortunately falls for the temptation to state that cemented superstructures are tantamount to malpractice. The background of his statment as reported by the above article is the high number of unfavorable treatment outcomes regarding implant superstructures, frequent defects of which he blames primarily on excessive masticatory forces.

While it is true that the masticatory forces increase in implant patients following successful treatment, it must be questioned whether these forces are really higher than those occurring with natural teeth. Certainly, the tactile control of masticatory forces in the area of a single dental unit will be less pronounced or even missing. On the other hand, bone morphology will also change over time. Addressing all these problems simply by introducing mandatory transversal screw connections may be just a bit shortsighted, as the only thing the screws truly facilitate is the removal of the superstructure. That long-standing chipped ceramic veneers cannot simply be repaired but must be redone completely should also be mentioned, just like the fact that, unfortunately, screw retentions may also happen to loosen, which all by itself may well lead to a series of sequelae ranging from the simple necessity to reconnect the restoration all the way to a need for a completely new superstructure or even structural damage to and around the implant themselves.

So if there is no single best solution for all problems, serious scientists and practitioners should try to refrain from stigmatizing any other train of thought but their own favored thought of the day. Not only would this show the speaker's own performance in a dubious light, but it might even have legal consequences. Errors and deficiencies have their causes, which may not be too far away from being describable as deliberate. There is a good reason why a professional expert or second opinion will try to avoid the terms "deficiency," let alone "error." It cannot be that a decision in favor of or against a cemented superstructure is classified as an a priori error. None of the treatment methods named is per se wrong or per se right: Received academic opinion may at different times amble in one or the other direction, and there has certainly never been one standard, uniform, generally accepted (German, European or global) academic view of this topic. As we all

know, science is always in the flux, and clinical practice will adopt any functional, practical development in the long term.

If cementing superstructures was really a mistake, then any case of ceramic chipping would have to be classified as "sequelae," with every insurance company potentially getting ideas about not reimbursing the patient for the cost of his or her cemented bridge, a posteriori, i.e. when that bridge has long been inserted and it is time to pay the bill.

It is nevertheless true that the stomatognathic system keeps changing due to the morphological activity of the bone, mandating frequent adaptations of the dental restoration – unless we leave the necessary adaptation work to the patient's temporomandibular joints, with the result of creeping, but later rampant, malocclusion. So in all fairness, we need to inform our patients that the restorations we have provided them must ultimately be considered transitory, something that will also have economic consequences.

But the changes that occur during the maintenance phase may themselves give rise to errors, for which the dentist may or may not be responsible: If a patient neglects his or her routine checkups and, consequently, any adjustment of the occlusal surfaces that may be required, a considerable part of the fault in case of problems lies with the patient, regardless of whether the restoration is screw-retained or cemented. If the patient does appear, and changes in the masticatory system are not appropriately diagnosed and treated, the fault may lie with the dentist: in that an undesirable, though unavoidable, development was not recognized and not treated.

There will always be sequelae to those changes within the stomatognathic system whose occurrence – but not the details or the temporal sequence – must be anticipated in principle. These sequelae cannot be considered complications, simply because they must be expected, because they almost always occur, because they should not really surprise and confuse us, and because they require rational, learnable, trainable action (a priori if possible).

So we should not take the word "error" lightly. Not all complications are culpable. Not everything that is not functional is not functional because of an error. We should learn to discriminate between expected developments, complications, typical problems on one hand and to errors and deficiencies on the other.

Best regards

Dr. Sigmar Kopp
(Managing editor)

Typical contents in ID

Evidence Reports summarize the latest «Hot Topics» from relevant journals putting similar studies «side-by-side». This unique presentation of studies allows you to compare and contrast the patient populations, the treatment interventions, and the quality of the scientific methods. The «evidence-based bottom line» is presented with an overall summary statement at the beginning. Clinical notes by implantologists with special expertise on the topic complete the Evidence Report by providing their expert clinical opinion. ID is an implantology publication that provides attention to detail in balancing science with clinical opinion in such a clear, concise, and visually-friendly presentation.

- 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. In addition to the summary, the study's methods and clinical conclusions are critically reviewed in an effort to challenge the implantology community into not accepting everything that is published, while fostering alternative explanations and ideas.
- Case reports give implantologists the opportunity to publish on unique patients using innovative or alternative methods for treating challenging patient conditions.
- 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 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.

Evidence Report

Comparing Povidone-Iodine Solution to Saline Solution in Osseous Surgery

Evidence Report Purpose

Little is known about the efficacy of using Betadine (trademark over-the-counter name for povidone-iodone solution) in dental implant surgery. No randomized controlled trials or cohort studies exist comparing it to other methods of treatment. With this in mind, we sought to determine if there was evidence in the literature evaluating its use in other osseous surgical methods. Few studies were identified; however, two spine studies and one tooth extraction study were deemed suitable to examine its efficacy.

Summary

Overall and deep infection rates were significantly less for osseous surgical procedures which were irrigated with povidone-iodine compared to normal saline solution. There was no statistically significant difference in the incidence of superficial infection between the two groups. There were no statistically significant differences for postoperative pain, bleeding, union, or function and ambulatory capacity when comparing irrigation with povidone-iodine versus normal saline after osseous surgery. Additional methodologically rigorous comparative studies are needed to better evaluate the effects of povidone-iodine solution with osseous surgery; however, it appears to be a suitable treatment option.

Sampling

After finding no comparison studies in dental implantology, an additional MEDLINE search was performed to identify recent studies published between January 2000 and April 2007 examining the effect of povidone-iodine with osseous surgery upon treatment outcomes. Company websites for all those known to manufacture povidone-iodone were also searched and no clinical studies were provided by the manufacturers. From a list of 12 articles, three compared povidone-iodine solution to a control group – the minimum criteria for producing an Evidence Report. This included two spine surgical studies and one tooth extraction study.

Objective

To critically summarize the recently published literature examining surgical outcomes in studies that compare povidone-iodine antiseptic with no antimicrobial solution during osseous surgery.

Study Interventions and Common Outcome Measures

- Spine studies (N=2): Patients who underwent spinal surgery were randomly assigned to irrigation with 0.35% povidone-iodine solution followed by normal saline during surgery or irrigation with normal saline only. Groups were evaluated for:
  - spinal union
  - post-operative pain
  - post-operative infection
  - post-operative function using the Japanese Orthopedic Association function score
  - post-operative ambulatory capacity
- Tooth extraction studies (N=1): In a randomized controlled trial, the alveolar sockets of 25 patients were irrigated with 1% povidone-iodine plus saline following dental extractions, while the alveolar sockets in the 25 control group patients were irrigated with saline only. Groups were evaluated for spontaneous stoppage of bleeding from the socket following irrigation (significant haemostasis).

Table 1. Comparative studies evaluating povidone-iodine antiseptic solution versus no antimicrobial solution with osseous surgery.

Author (year)	Study Design	Population	Diagnostic Characteristics	Treatment		Follow-up (%)	LoE†
				Povidone-iodine solution	No antimicrobial solution		
Kumar (2006)	Randomized controlled trial	N = 50 female: 46% age: NR	Periodontitis or abscess excluded as indication for dental extractions	n=25	n=25	NR	High
Chang (2006)	Randomized controlled trial	N = 244 female: 49.6% age: 66.5 (20-89) years	Degenerative spinal disorder with lumbar or lumbosacral segmental instability	n=120	n=124	19 months: NR*	High
Cheng (2006)	Randomized controlled trial	N = 414 female: NR* age: 62.5 years	Indication for spinal surgery	n=208	n=206	Mean 15.5 months: NR*	High

*NR (not rated) = for follow-up rate either not reported or precise follow-up rate could not be determined since the initial number of eligible patients or number lost to follow-up were not provided.
†Level of Evidence (LoE) is based on study design and methods (Very high, High, Moderate, and Poor)

Table 2. Evaluation of articles examining povidone-iodine antiseptic solution versus no antimicrobial solution with osseous surgery.

Study design and methods	Kumar (2006)	Chang (2006)	Cheng (2005)
1. What type of study design?	RCT	RCT	RCT
2. Statement of concealed allocation?*	NO	YES	YES
3. Intention to treat?*	YES	NO	NO
4. Independent or blind assessment?	NO	YES	NO
5. Complete follow-up of >85%?	NO	NO	NO
6. Adequate sample size?	YES	YES	YES
7. Controlling for possible confounding?	YES	YES	YES
LEVEL OF EVIDENCE	High	High	High

* Applies to randomized controlled trials only

Results

1. Spine Studies

Infection (Figures 1 and 2)

- A statistically significant smaller number of subjects experienced post-operative wound infection when comparing irrigation with povidone-iodine vs. normal saline after spinal surgery (0% vs. 4.8%, p=0.029 [Chang] and 0% vs. 3.4%, p=.007 [Cheng]).
- A statistically significant smaller number of subjects experienced post-operative deep wound infections when comparing irrigation with povidone-iodine vs. normal saline after spinal surgery (0% vs. 2.9%, p=0.015 [Cheng]), though there was no statistically significant difference in the incidence of superficial infection between the two groups (0% vs. 0.5%, p>.05 [Cheng]).
- 86% of patients had postoperative infection attributable to a single pathogen and 14% to two pathogens [Cheng].
- Fixation for traumatic spinal fracture was associated with a higher chance of infection compared to decompression and fixation for degenerative scoliosis or stenosis (OR 7.09, 95% CI: 1.12, 14.73) [Cheng].

Pain

- There were no statistically significant differences in the degree of improvement in back or leg pain when comparing irrigation with povidone-iodine vs. normal saline after spinal fusion surgery ($p>0.05$) [Chang].

Union

- No statistically significant differences were found for union (spinal fusion) when comparing irrigation with povidone-iodine vs. normal saline after spinal fusion surgery (89.1% vs. 87.9%, $p>0.05$) [Chang].

Function and Ambulatory Capacity

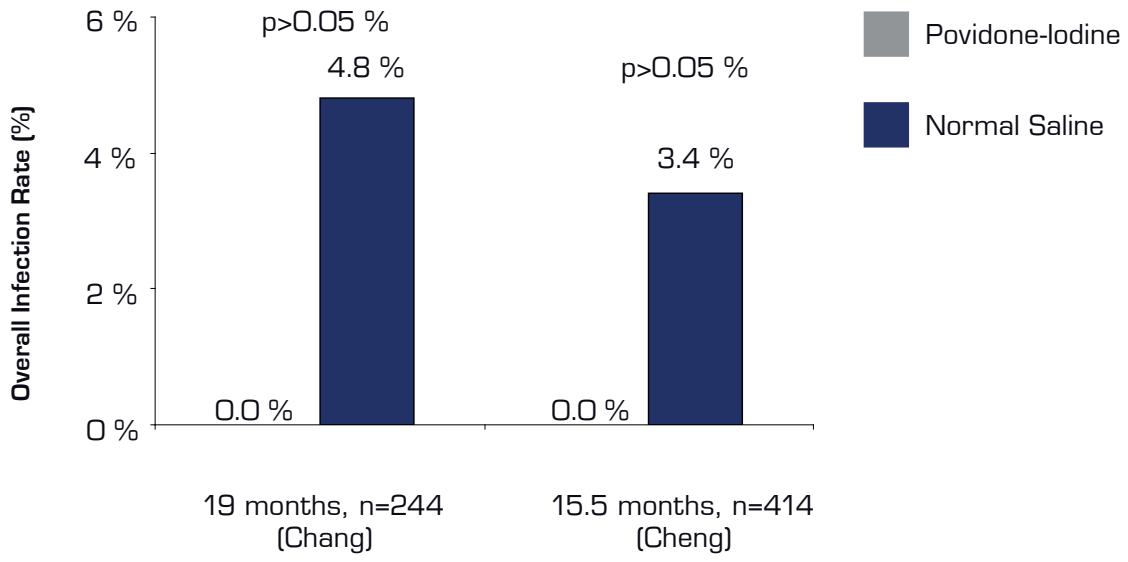
- There were no statistically significant differences in the degree of improvement in the Japanese Orthopedic Association function, score or ambulatory capacity when comparing irrigation with povidone-iodine vs. normal saline after spinal fusion surgery ($p>0.05$) [Chang].

2. Tooth Extraction Studies

Bleeding

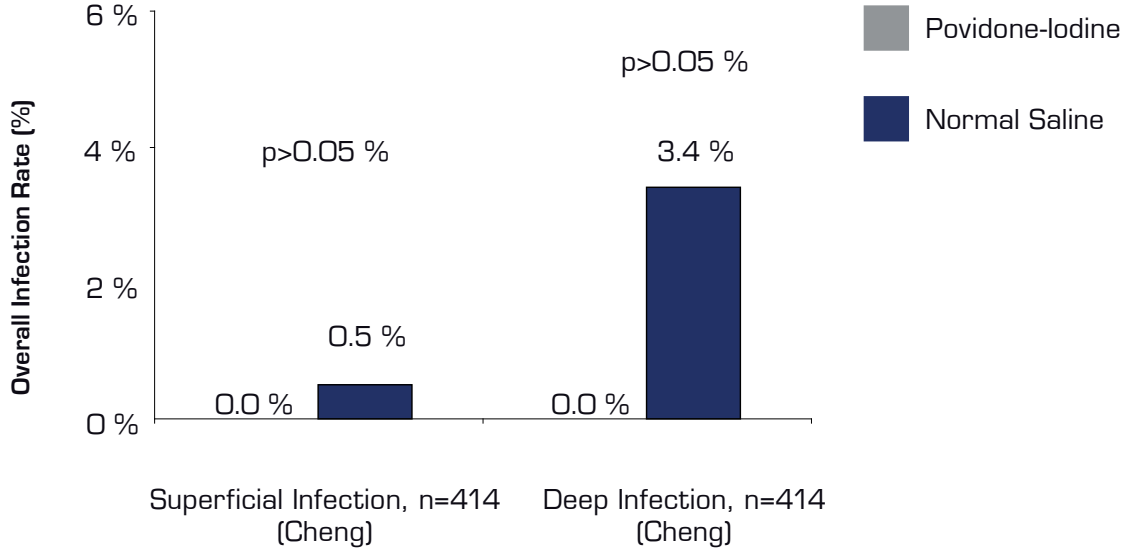
A statistically significant greater number of subjects experienced spontaneous cessation of fresh bleeding after extraction following irrigation with the povidone-iodine solution compared to a saline solution (76% vs. 20%, $p<0.01$) [Kumar].

Figure 1. Overall post-operative infection rate comparing irrigation with povidone-iodine solution vs. normal saline after spinal surgery *



* **Statistical significance noted on graphs if provided by author**

Figure 2. Superficial and deep infection rates comparing irrigation with povidone-iodine solution vs. normal saline after spinal surgery *



* **Statistical significance noted on graphs if provided by author**

Methodological considerations

- All studies were randomized controlled trials with a rating of high level of evidence. No very high quality randomized trials were identified in the literature. Two studies (Kumar and Cheng) did not describe a method of blind assessment of outcomes. In studies like this, it is feasible and critical that the person evaluating the outcome not be aware of the treatment to avoid assessment bias.
- None of the studies reported a follow-up rate or provided data adequate enough to calculate the follow-up rate. A follow-up rate of ≥85% is necessary to ensure valid study results.
- The literature is limited on this topic. Few randomized controlled trials or good quality cohort studies are available evaluating Betadine and none exist in the dental implant literature.

References

Studies

Study 1

Kumar BPR, Maddi A, Ramesh KV, Baliga MJ, Rao SN, Meenakshi (2006)
Is povidone-iodine a hemostyptic?
A clinical study.
Int J Oral Maxillofac Surg 35:765-6.

Study 2

Chang F-Y, Chang M-C, Wang S-T, Yu W-K, Liu C-L, Chen T-H (2006)
Can povidone-iodine solution be used safely in a spinal surgery?
Eur Spine J 15:1005-14.

Study 3

Cheng M-T, Chang M-C, Wang S-T, Yu W-K, Liu C-L, Chen T-H (2005)
Efficacy of dilute betadine solution irrigation in the prevention of postoperative infection of spinal surgery.
Spine 30(15):1689-93.

Literature Analysis «Poor Bone» Part II

Introduction

Overall success rates of dental implants, generally defined as lack of mobility, pain, pathologic problems or crestal bone loss[1], appears to be high, with implant failure rates reported as low as 7.7% over one 20-year review period.[2] This figure does not mean that the "successful" implants are without any problems, it only means that those implants were not taken out and that most of them remain in function. However, there are subgroups of patients that are at an increase risk of implant failure. In particular, patients with poor quantity or quality of bone present a significant challenge to the dental implantologist. Patients who present for dental implant procedures with "poor" or "compromised" bone present a significant challenge to the dental implantologist. Disease, trauma, smoking, periodontal disease or atrophy due to the aging process, medication or radiation therapy leads to low quality or quantity of bone. Such changes in bone require careful attention and appropriate implants to achieve acceptable success rates.

Aging and decreased estrogen levels have a negative influence on both tooth retention and residual alveolar crest preservation[3]. Osteoporotic effects are more pronounced in the maxilla than the mandible, with implant failure rates reported at three times higher in the maxilla than the mandible. 4-6 Even in the healthy jaw, maxillary bone consists of more trabecular, fat containing, softer bone than the mandible, with a significantly thinner or absent cortical plate that may be less able to support an implant.[6] However, cortical bone is more susceptible to the effects of osteoporosis, compounding problems of bone quality in the mandible under osteoporotic-like conditions.[5]

The presence of poor bone requires alternative approaches to conventional implant placement. Bone augmentation, as one possible answer to quantitatively poor bone, may be necessary through procedures such as grafting or more novel therapies including bone morphogenetic proteins.[7] We discussed the limitations of bone augmentation in previous issues of CMF Implant Directions®. Zygomatic implants are an alternative to bone augmentation inside the maxillary sinus, but several conventional implants in the anterior maxilla are still necessary to support the prosthesis.[8] Conclusions regarding the best choice of implant are difficult to make as relatively few studies have been carried out comparing different types of implants within the same study. Studies of low density bone using different generations of the mandible and maxilla have shown failure rates of 2-15%.[5] An implant of >10mm length appears to be the most successful if using root-form implants, requiring sufficient bone to support the length of the implant. Therefore, most conventional methods for treating patients with "poor" bone require additional procedures, delayed loading and increased patient costs.

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

- Define the following bone related conditions as they relate to dental implantology
  - Poor bone quantity
  - Poor bone quality
  - Osteoporosis
  - Bone density
- Report the types of implant "failure" associated with patients with poor bone
- Describe the current methods available for treating patients with poor bone
- Evaluate the association between poor bone and dental implant failure
- Determine whether certain anatomical areas are at greater risk of failure

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 the efficacy of various dental implant methods for treating patients with poor bone
- Review studies evaluating Basal Osseointegrated (BOI®) implants
- Provide justification for BOI® implants as a solution for treating patients with poor bone while allowing immediate loading
- Discuss future research with BOI®
- Summarize the findings on "poor bone" from both Part I and Part II of this Literature Analysis

Search Strategy

MEDLINE was searched to identify studies reporting data on patients with and without poor bone who receive dental implants (Table 1). There was no restriction on year published. An attempt was made to identify studies of high methodological quality (systematic reviews, RCTs and cohort studies) comparing poor bone to good bone in patients receiving dental implants. The following strategies were employed to identify literature to meet the objectives:

First strategy: Identify review articles discussing challenges treating patients with poor bone using dental implants.

Second strategy: Identify review articles describing the current methods of management and their outcomes in treating patients with poor bone using dental implants.

Third strategy: Identify studies or meta-analyses specifically designed to evaluate the association between poor bone and dental implant failure.

Fourth strategy: Identify studies or meta-analyses specifically designed to evaluate the efficacy of specific dental implantology methods used to treat patients with poor bone.

Table 1. Medline Search Summary

Terms	Hits	Reviewed
Dental Implants [MESH] OR Dental Implantation [MESH] OR Dental Restoration, Temporary[MESH] OR Dental Restoration, Permanent [MESH] OR Dental Restoration Failure [MESH] OR Dental Prosthesis, Implant-Supported [MESH]	41.765	0
AND bone AND (quality OR quantity)	558	9
AND osteoporosis	8	3
Studies summarized	12	

Results of the first half of this search strategy are reported in Part I of this Literature Analysis.

Results

Efficacy of various dental implantology methods for treating patients with poor bone

Several case series were identified in the literature evaluating different dental implant systems in poor bone; however, only a few were identified comparing methods to establish superiority of one method over another (i.e., RCT or cohort study). We identified four studies comparing different conventional implant systems in poor bone that may be construed as "efficacy" studies.

TiUnite vs. Machine surfaced implants (Table 2)

In an RCT performed by Rocco et al evaluating different methods of treatment in all qualities of bone, rates of implant failure were significantly higher in machined implants (45.5%) compared to TiUnite implants (8.3%) in patients with LZ-4 quality bone (RR = 5.5, 95% CI 1.0, 39.7; p = 0.04) [9]. Such differences were not observed in the better quality bone levels.

Hydroxyappatite-coated (HA) vs. Non-HA coated implants (Table 2)

In the RCT by Truhlar et al [10], HA-coated (Ti-6Al4V-Grade 23, acid etched collar withHF/NO3 both cylinder and grooved) root-form endosseous implants had an overall failure rate of 3.9% over a 36 month period in all bone qualities combined compared to a 13.4% failure rate in non-coated implants (RR = 3.5, 95% CI 2.6, 4.5; p < 0.001). Implants removed at any stage were recorded as failures as reported by the authors. The highest failure rates and subsequent relative risks were in bone qualities 3 and 4 (19.1% and 25.5%, respectively). Non-coated implants were 4-5 times more likely to fail then coated implants in bone qualities 3 and 4 (RR = 4.6, 95% CI 3.1, 7.0; p <0.001 and 5.3, 95% CI 2.4, 11.4; p <0.001, respectively).

Dual-acid etched versus machine surfaced implants

Khang[11] et al performed an RCT comparing machined-surface (MS) implants to dual acid-etched (DAE) implants. Approximately 50% were placed in normal bone, 40% in soft bone, and 10% in dense bone. The greatest difference between implant types was observed when analyzing bone quality by implant type. The cumulative success rate at 48 months for DAE and MS implants in good quality bone was 93.8% and 87.8%, respectively. The cumulative success rates in poor quality bone were 96.8% and 84.8%, respectively. An interaction between bone quality and implant type, however, was not statistically significant as reported by the authors.

Meaning, one implant was not statistically different than another with respect to failure rates. However, when we calculated using the authors raw numbers we found that machined-surface implants were almost three times more likely to fail than dual acid-etched implants in patients with poor bone with failure rates of 13% and 4.9%, respectively (RR = 2.7, 95% CI 1.4, 5.2; p = 0.003). This was statistically significant.

Basal Implants

Placement procedure

Unlike the two-stage surgical technique used to place vertical implants (i.e., screw implants), basal implants allow for a single surgical procedure with immediate implant loading, even in patients with limited vertical bone supply.[12-15] With the emphasis on lateral rather than vertical placement, pre-implantological bone augmentation is rarely necessary, thus eliminating another costly, invasive and time-consuming procedure.[12] Estimated decrease in cost treatment is ~ 50%.[14]

Previous studies

Diskimplants are similar in form and function to BOI® implants and have reported rates of successful osseointegration of ≥ 97% with relatively long follow-up periods. Scortecci performed a prospective case series of 783 implants (627 laterally inserted Diskimplant®s with similar design to BOI®), placed in 72 patients with completely edentulous maxillae using an immediate load protocol. Follow-up ranged from 6 – 48 months. At 6 months, 98% of implants were osseointegrated, with all fixed prostheses remaining functional during the study period.[15]

Ihde and Mutter performed a retrospective case series of 275 BOI® implants implanted in 228 patients over a period of five years. Molars were replaced with BOI® implants in combination with natural abutments. Osseointegration was achieved in 97.3% (n=254) of implants at final follow-up. Fifteen implants were lost to follow-up.[16]

Donsimoni et al performed a retrospective case series evaluating 1352 consecutive basal implants placed over a 10 year period17. These implants were placed in 234 complete upper and lower bridges. Osseointegration was achieved in 97% of

implants. Of the 41 implants that failed, 25 implants had to be replaced. Of the 234 full bridges placed on basal implants, only one full upper bridge had to be permanently removed rendering a clinical success rate of 99.9%.

The authors report that the success rate increased with the number of implants inserted per jaw (4.3 implants per jaw during the treatment period 1994-1997, 5.2 implants per jaw during the treatment period 1998-1999, 6.4 implants per jaw during the treatment period 2000 – 2004). Constructions that combined natural teeth with basal implants were less successful than those with basal implants alone. Interestingly, smokers and non-smokers experienced similar rates of implant losses. This may indicate that smokers, reported as having a higher risk of implant loss in conventional implants[18], may benefit from BOI® implant treatment as an alternative to axial (i.e. screw) systems.

Basal implants as a solution for treating patients with poor bone

Conventional Implants

Current treatment methods for placement of oral implants in poor bone have clear limitations, including minimum requirements of bone quality and quantity, a minimum of two invasive procedures, high cost, and delayed loading. Standard procedure for placing basal implants requires one surgery followed by immediate loading, thus reducing both time and cost, and not least, stress to the patient. So despite some signs of superiority for some axial implants over others (in poor bone), none overcome these challenges like basal implants.

Root-form endosseous (axial) implants generally require > 10mm of vertical height for safe placement of the implants. Basal implants do not have this requirement.

Indications for basal implants

- Patients with poor bone could benefit from the lateral nature of basal implant as an alternative to bone augmentation, especially in the maxilla region.
- Patients with poor bone in need or desire of immediate loading currently have no alternatives. With evidence that occlusal force is beneficial to bone formation and retention, the basal approach is an obvious choice to slow or reverse the development of poor bone.
- Transsinusal implant placement could eliminate the need for bone augmentation in the distal maxilla completely

Cancer patients in need of maxillary reconstruction after maxillectomy could also benefit from the lateral placement of BOI®, potentially minimizing the amount of reconstructive surgery required to restore them to a functional masticatory state.

Osteoporotic patients may profit form the dual integration process which this type of implants uses. BOI® implants profit from primary stability in the cortical bone areas. Void bone spaces, which are created by the insertion technique offer plenty of space for woven bone generation. It is well known that patients showing osteo-

porosis, still have an unimpaired process of woven bone generation. The nature of their disease affects only the "old" cortical bone regions. In this regard, many patients may profit tremendously from BOI® implant treatments.

Plans for future research

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 BOI® outcomes from different implantologists.
- Finite element analyses of functional stresses in different bone areas comparing BOI® to conventional implants.

Overall Summary of Findings

The methodological qualities of the studies that we identified for this Literature Analysis were moderate at best. To our knowledge, this review is the first attempt to systematically review and summarize the disparate risk of implant failure in patients with and without poor bone. Such a summary is useful both clinically and for research purposes. Patients with acceptable and poor bone should be educated on their differential prognoses. This review provides a tool for such purposes, despite the lack of high quality studies. The following represent a summary of findings from both Part I and Part II of this Literature Analysis on dental implants in poor bone:

- Failures can occur early or late. Causes of early failure are often related to poor bone conditions or surgeon experience. Late failures often occur due to peri-implantitis, "regular" (i.e., typical for axial implants) bone loss around the implants, or overloading.
- There is an increased risk of implant failure in poor bone compared to healthy bone. This risk is up to seven times greater. The studies making this comparison are of moderate quality only; hence, these findings should be taken with caution.
- This effect is observed only in the maxilla. Failure rates between poor and good bone are similar in the mandible.
- The current methods routinely reported in the literature for managing patients with poor bone include bone augmentation procedures, enamel matrix derivatives (EMDs), long-term systemic drug therapies, bone morphogenic proteins (BMPs), combinations of these therapies, and various other alternatives.
- Studies comparing the failure rates of different implants are limited; however, a few good quality studies have been performed demonstrating that dual acid-etched implants are less likely to fail than machine-surfaced implants in patients with poor bone.
- Rates of implant failure are greater in machined implants compared to TiUnite implants and non-coated root-form implants compared to HA-coated root-form implants.

- Despite certain implants performing better than others, these conventional methods for managing patients with poor bone have a number of limitations including prohibitive costs, an accumulation of surgical risk in two-stage treatment approaches, and delayed time to loading, all of which add to the physical and emotional challenges of the patient.
- BOI® implants are a viable alternative for treating patients with poor bone. Published studies show promising results.
- BOI® allows for a single surgical procedure with immediate implant loading, even in patients with limited vertical bone supply [12-15] or after extractions.[19] The estimated decrease in cost is ~ 50% [14] compared to treatment protocols requiring augmentations. The decrease in total treatment time can reach up to 98%, when cases are compared, which would require augmentation and a waiting time for the installation of axial implants.

Table 2. Comparison of Implant Failure Rates by Bone Quality Level or Location Using Various Dental Implant Methods.

Author	Region	Bone Quality (LZ)	n/N (implants)	%	n/N (implants)	%	RR (95% CI)	p-value
			TiUnite		**Machined**			
Rocci (2003)	Maxilla/Mandible (combined)	1	NA	NA	NA	NA		
		2	0/7	0	0/3	0	Not calculable	NA
		3	2/47	4.3	3/41	7.3	1.7 (0.30, 9.8)	0.54
		4	1/12	8.3	5/11	45.5	5.5 (1.0, 39.7)	0.04
			HA-Coated		Non-HA			
Truhlar (2000)		1	3/111	2.7	13/147	8.8	3.3 (1.0, 11.2)	0.04
		2	28/778	3.6	65/609	10.7	3.0 (1.9, 4.6)	<0.001
		3	32/780	4.1	61/320	19.1	4.6 (3.1, 7.0)	<0.001
		4	10/206	4.9	12/47	25.5	5.3 (2.4, 11.4)	<0.001
			Modified		Standard			
Friberg (2003)		Maxilla	3/39	7.7	5/39	12.8	1.3 (0.70, 2.3)	0.48
		Mandible	0/5	0	0/5	0	Not calculable	NA

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Critical Appraisal

Reference

Cornelini R, Cangini F, Covani U, Barone A, Buser D.
Immediate restoration of single-tooth implants in mandibular molar sites: a 12-month preliminary report. Int J Oral Maxillofac Implants. 2004 Nov-Dec;19(6):855-60.

Performing Clinic: University of Genoa, Italy.

Abstract

PURPOSE: The aim of this prospective clinical study was to evaluate the survival rates at 12 months of transmucosal implants placed in the posterior mandible and immediately restored with single crowns. MATERIALS AND METHODS: Thirty ITI dental implants with sandblasted, acid-etched surfaces were placed in 30 patients missing at least 1 mandibular molar and immediately restored if acceptable primary stability was attained. Primary stability was measured with resonance frequency analysis (RFA) using the Osstell device, and only implants with a stability quotient greater than 62 were included in the study. RFA measurement and radiographic assessment were made at baseline and 6 months after implant placement. Plaque Index, Bleeding Index, probing depth, attachment level, and width of keratinized tissue were measured at the 12 month follow-up examination. RESULTS: At 12 months, only 1 implant had been lost; it was removed because of acute infection. Radiographic as well as clinical examination confirmed osseointegration of all implants, with a survival rate of 96.7%. DISCUSSION: Interestingly, implant stability as measured using RFA did not increase significantly from baseline to 12 months (P > .05). CONCLUSION: The present study showed that immediate restoration of transmucosal implants placed in the mandibular area with good primary stability can be a safe and successful procedure. However, larger, long-term clinical trials are needed to confirm the present results.

Article Summary

Author's Summary

- The present study showed that immediate restoration of transmucosal implants placed in the mandibular area with good primary stability can be a safe and successful procedure. However, larger, long-term clinical trials are needed to confirm the present results.

Objectives/Aims

- To evaluate the survival rates at 12 months of transmucosal implants placed in the posterior mandible and immediately restored with single crowns.

Methods

Study Design

- Prospective case series.

Sampling

- 30 patients with single missing molars were treated with a single implant.
- Only patients with an implant stability quotient (ISQ) that exceeded 62 using

the Osstell device were included.
- 12 females and 18 males were included.
- Mean age was 47.5 years (range 27-59).

Inclusion Criteria reported by author
- Need for the restoration of a single mandibular molar
- Natural teeth next to the edentulous space with an intact occlusal surface and free of infection
- Sufficient bone quantity for implant placement (absence of any atrophy)
- An occlusal pattern that allowed for bilateral stability
- Willingness to follow the study protocol
- Provision of informed consent

Exclusion Criteria reported by author
- Compromised general health conditions that would jeopardize the bone healing process
- Severe maxillomandibular space discrepancies
- Severe parafunctional habits
- Drug or alcohol abuse
- Poor oral hygiene
- The need for tissue augmentation procedures

Surgical Protocol
- ITI solid implants with a sandblasted, acid-etched surface were inserted to replace a missing mandibular molar.
- Sterile surgical procedures were followed as described previously by the authors.
- All implants were clinically stable at the time of placement confirmed by resonance frequency analysis
- Sutures were removed 7-10 days after surgery

Prosthetic Protocol
- Restorative treatment was started immediately after implant placement
- Within 24 hours after implant placement, a temporary screw-retained resin restoration was fabricated and connected to the implant
- The occlusal contacts were restored with the provisional crowns

Outcomes measurements
- Resonance frequency measurements for implant stability quotient (ISQ) using the Osstell machine
- Radiographic assessment
- Modified plaque index (mPLI)
- Modified sulcus bleeding index (mSBI)
- Presence or absence of suppuration
- Probing depth (PD, in mm)
- Distance between the implant shoulder and the mucosal margin (DIM, in mm)
- Clinical attachment level (AL, in mm)
- Width of keratinized mucosa
- Distance between the implant shoulder and the first visible bone-implant contact (radiologic assessment; “DIB”, in mm)

Follow-up
- Patients were examined at baseline and 6 months. The authors report a final follow-up at 12 months but there are conflicting statements in the paper regarding 6 month or 12 months as the final follow-up. Mean follow-up times and ranges are not reported. Follow-up rate was implied to be 100%.

Results
- At 12 months, one implant was lost (n=1/30) due to acute infection.

- Twenty nine of 30 implants survived (survival rate = 96.7%).
- The mean ISQ value was 70.6 ± 5.8 at baseline and 76.6 ± 7.0 at 12 months.
- No mechanical complications were reported in the 12-month period.
- All patients considered their restorations to be esthetically acceptable.
- Clinical measurements at the 12 month visit are reported in the following table:

Clinical Parameters	Mean	SD	Range
DIM (mm)	0.8	0.4	0.6-1.4
Probing depth (mm)	1.6	0.8	0.2-2.7
Attachment level (mm)	0.8	0.3	0.2-1.1
mPI	0.5	0.4	0-2
mBI	0.4	0.5	0-2

REVIEWER'S EVALUATION

Table. Evaluation of methodological principles.

Methodological Principle	
Statement of concealed allocation*	NA*
Intent to treat principle*	NA*
Independent blind assessment	NO
Patient reported outcomes	NO
Complete follow-up of > 80%	YES
Consistent follow-up times	NO**
Adequate sample size	NA†
Appropriate analysis and use of effect measures	NA†
Controlling for possible confounding	NA
Inclusion and exclusion criteria clearly defined	YES

*Apply to randomized trials only.
**This cannot be assessed without summary data on follow-up times (i.e., means and ranges)
†Not applicable. These apply to cohort studies where two groups are being compared.

1. What were the study's methodological strengths?
   - High clinical 12-month follow-up rate.
   - Several clinical outcomes were measured at least at one point during the study

2. What were the study's methodological limitations?
   - The authors reported that only patients that achieved an ISQ 62 qualified for the study. It is unclear why the authors excluded the other patients and how many patients during this period of time did not qualify. This creates at least two potential problems:
   - The study conclusion as it is currently written is not valid. We can only apply these findings clinically to patients with a minimum baseline score. It's unclear what percentage of the total population this may represent.
   - We have no way of knowing how patients who had a baseline score lower than this performed. It would be more useful to see a survival rate using this treatment method reported on a "consecutive" series of patients with a score above and below this threshold.
   - It is unclear who performed the outcomes evaluations. In a prospective study, it is advisable to identify an independent observer to make these assessments to avoid unintended bias in the results.
   - The authors report in their statistical section and in their discussion, "the present study confirmed that, at least

at 6 months, the immediate restoration of transmucosal dental implants… can be a safe and successful procedure". Yet they also report conclusions with respect to 12 months so it is unclear if this is a "typo" or if there really was a 12 month follow-up.

3. How might the findings from this Critical Appraisal be applied to patient care?

Clinical Reviewer 1:
I think that the authors should have listed the values of the single placements and of course they should have justified the ISQ value of 62. Further, I wonder why the mean value in the included implants is so high, while the inclusion critieria threshold is low. How can one give a patient an adequate prognosis in an immediate load setting when the values or percentages are not available before the operation. If one can place a 4.8 mm implant with 10 or 12 mm of available bone, then any implant will perform successfully. This population did not possess any horizonzal or vertical atrophy which makes them an unrealistic patient population. The results can not be transferred to edentulous patients with mild or severe atrophy.

Clinical Reviewer 2:
It is important to mention the implant sizes to make a clinical application (i.e., diameter and length). I strongly doubt that a 3.2 x 10 mm is adequate to receive the same immediate load as a 4.1 or 4.8 x 12 mm. Frank Renouard once said regarding the root replacement concept, "when you are replacing a lower molar, it is always safer to place two 3.6 x 11 than a single implant, to avoid the cantilever forces on a single implant in that area, or you might loose your implant in subsequent years, because of continuing crestal resorption".

From a biomechanical point of view, most problems with a single lateral implant appear later than 6 or 12 months, when the implant receives a porcelain crown harder than composite. It is not a problem to achieve nice initial results with a „soft" temporary composite. Moreover, we all know, that we can exclude it from occlusion during the first weeks. In my opinion it would act as a „shock absorber", reducing the load on the implant. The problem is, can they achieve the same results with a definitive restoration in an unprotected load environment?

In summary: the short term results are clinically irrelevant. Single implants in wide gaps may impose a clinical problem in the long term. Further, the conclusion does not clearly inform the reader that the strict exclusion criteria severely limits the generalizeability of these findings - an extremely rare group of selected patients was included, and even within this group, a small sample of cases was reported on.

4. Were all clinically important outcomes for this treatment intervention considered? If not, what additional outcomes should be considered?

Clinical Reviewer 1:
The authors did not note the time after extraction for each case or summary data

for all cases. Survival rates are higher if implants are placed immediately after extraction, but Ostell-values may initially be lower. The samples size and the number of failures appear too small to show that above a certain value immediate load is predictable.

Furthermore, it is unclear why the authors didn't use the modified SLActive surface for this study; there have been experiments by Buser et al, demonstrating the "superiority" of the new surface. Assuming this surface is significantly more beneficial clinically, then it would not appear ethical to use the old surface especially in immediate load cases, as patients may be at greater risk of failure.

The authors should have taken x-rays and compared the horizontal bone levels to other studies. At a minimum they should have reported these findings after 12 months in their own data. It is unclear what the authors mean by "the DIB difference was statitically not significant". Bony remodelling ceases no earlier than 12 months after the surgical intervention. At this time, relative stability within the bone is to be expected but not earlier. It is unclear why they show DIB after 6 months and DIM after 12 months.

5. Are the likely treatment benefits worth the potential harm and costs?

Clinical Reviewer 1

Because large triangular crestal resorbtion or some bone detachment from the vertical implant axis may occur after 1 or 1.5 years in immediate load cases, this should have been described. There was no description of crestal bone loss- was it present? If so, how much loss? How harmful might this be? Interestingly the radiographic assessment of bone level (DIB) ends after 6 months, although the clinical assessment of mucosal level (DIM) shows a wide range between 0.6 and 1.4 mm, indicating that up to 14% of the vertical bone may have been lost. In the 21st century it is definitely not enough to say „We placed 30 implants and 1 year after surgery, they`re OK". One must also define the crestal bone loss (if present) to determine if the benefits of such treatment outweigh the potential harm and costs. There was no description of bone quantity or quality such as classifications described by Leckholm & Zarb. For this reason, the study does not meet adequate scientific standards for clinical application. Were all patients bone type I, or was there a greater variation in bone quality and quantity?

Finally, from the abstract or the paper it is unclear when the provisional was replaced with definite restoration. Was it replaced at all? Further, it is unclear if all implant crowns had antagonists. The authors even fail to admit openly, that all occlusal contacts may have been protected by the surrounding teeth. For this reason the results of this study cannot be transferred to cases where no such protection exists (i.e., where implants are not only restored but loaded immediately).

Case Report

"All on four" - basal implants as solid base for circular bridges in high periodontal risk patients

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Abstract
Immediate loaded fixed bridges and crowns are the standard protocol on basal implants. High survival rates are reported. We have found that another domain of basal implants is the treatment immediately after extraction, even in massive periodontal involved cases. We report exemplarily on the treatment and outcome of a 76 year female patient with progressive periodontal disease. In one single surgical treatment 12 teeth were removed, four implants placed and a temporary circular bridge fixed and immediately fully loaded. Fortynine days later the permanent bridge was cemented. The periodontal involvement did not lead to any problems during the healing phase or during the follow up period of already 32 month. The immediate implant procedure with BOI® implants followed by full immediate loading meets the demands of the patients: it is a minimal invasive, bone preventive, removable denture avoiding, fast and safe method for treating patients providing even severe periodontal involvement.

Keywords
Basal implants, periodontal involvement, immediate loading

Introduction
From the prosthodontists view circular bridges on 4 strong anchors in perfect places would give maximum treatment freedom. But mostly surgeons assign the prosthodontic options.[1] Because distal jaw areas are challenges, implants are often placed interforaminally only, as the base for removable dentures. But solely here fixed bridges lead to anterior chewing pattern, causing overload, TMJ problems and CMD may result.[2,3]

Periodontal diseases are generally considered to be a contraindication for implantations, even if relativised.[4] The presence of germs and a history of ineffective treatments give a difficult prognosis for crestal implants.[5] The advantage of basal implants is the disjunction of the infection risk area of gum perforation and the load transmitting areas in the aseptic deep basal cortical bone.[6-10] Even in cases as here presented, where BOI®s (brand: Dr. Ihde Dental AG Switzerland) are immediately inserted into the infected alveoli the healing can't be disturbed by infection or functional load. The 1st reason are the horizontal osteotomy cuts in the deepest area where a wound drain is not hindered as typical with screw type implants sealing bone hermetically.[6,9,10] Second, the geometry of BOI® is infection preventive. The thin, smooth vertical shaft (diameter <2mm) is not directly load transmitting to the crestal bone. So plaque and calculus adherence is rare and

far away from force-fit implant-bone interaction. Mucositis linked with BOI® is reported rarely (< 1%).[6-10] Third, the primary stable trans osseous anchorage of BOI® in the vestibular and lingual (palatine) cortical bone is the basis for the fully loadable immediate function.[6,8-10] This article reports exemplarily on the treatment modalities and use of basal implants for the one-step procedure of a patient showing severe periodontal involvement.

Subjects

A 76 year old female professor emeritus of dentistry was referred to our clinic to obtain an implant treatment in her lower jaw. The general dentist had saved her teeth as long as possible, using repeated periodontal techniques and applying a fixed splint. A panoramic X-ray was taken prior to the surgery, *Figure 1*. Under terminal anesthesia two full thickness flaps were prepared, 12 teeth were removed, and 4 BOI® inserted in strategic positions. Two different implant shapes were used to match the native bone morphology: Anterior we found an extremely resorbed, thin, but high bone ridge. This morphology was mastered by using triple BOI®. In the distal lower jaw, the bone is generally broad but vertically reduced- ideal conditions for BOI®s with single baseplates. A temporary bridge was fixed immediately after the surgery. The whole treatment in the lower jaw was completed within 4 hours. 49 days later the metal ceramic bridge was cemented, *Figure 2*. During the surgery, all periodontal involved tissues were removed; the extraction sockets were cleaned mechanically and by rinsing. The patient is in regular control for 32 months since surgery. The x-ray shows good bone conditions with no indications for future problems, *Figure 3*. No mobility, pain or periodontal disease were reported or observed. The oral hygiene was always good, but the absence of large gingival perforations as usual with teeth or screw type implants seems to be periodontal preventive.

Conclusion

By using of BOI®, just one session is needed for teeth extraction, implant placement and immediate loadable bridge insertion. Separate surgeries, bone augmentation, functionless healing period and reopening can be avoided. BOI® implants show a strong design, that allows – in a functionally balanced situation – the installation of circular bridges on 4 implants. The thin vertical shaft is smooth and has no direct load transmitting function to the bone, giving no retention to plaque or calculus. So BOI® is periodontal preventive designed and practical proved.

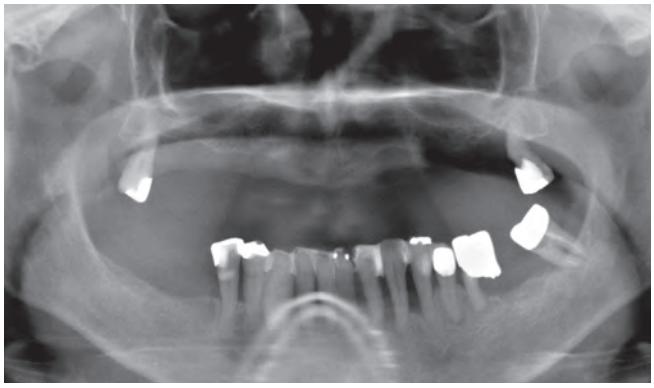

Figure 1. X-ray showing the extreme bone loss at 12 teeth in the lower jaw, to be extracted in the same session with the implantation. The upper jaw treatment was not desired at all. (published with the patient`s consent)

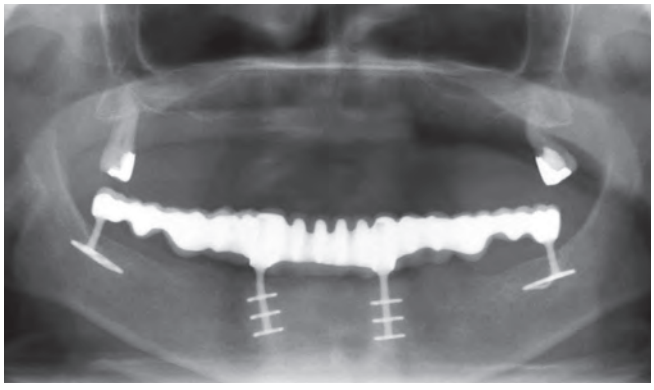

Figure 2. Clinical view of the cemented bridge with no periodontal problems

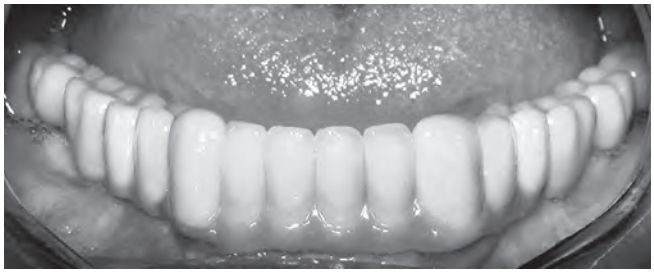

Figure 3. Last control X-ray (24 month past surgery) with no vertical bone lost and good bone adaptation of the BOI® implant. No vertical bone loss or defects are present.

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Research in Context

Learn How to Read the Implantology Literature Critically

Learning how to identify and apply GOOD Clinical Research is the foundation of Evidence Based Implantology. In the next few issues of Implant Directions, we will be discovering the steps that one must take to efficiently identify those articles that are important to an implantology practice. In today's issue, we will discuss two significant steps that will help you to efficiently identify literature important to your clinical practice. These steps include asking the right question and performing a literature search.

Asking the right question

When looking through the piles of literature to find an article that will help you in your practice, you must first clearly define the clinical question of interest. Consider the following when formulating a clinical question:

- The patient population (what is the characteristics of the population under study?)
- The intervention (what is the treatment of interest?)
- The comparison group (to what is the treatment of interest compared?)
- The outcomes (what clinical outcome measures are important?)

A simple way to help you frame a clinical question is to use the acronym PICO (Patients, Intervention, Comparison, and Outcome).

Let's imagine that you typically have your patients load their implants immediately; however, the new implantologist in the office does not feel that is safe and prescribes to delayed loading protocols. You want to be able to justify your practice. Before you begin to look for an answer you might frame the question in terms of PICO.

Patients	• Male or female patients needing several dental implants
Intervention	• Immediate loading
Comparison	• Delayed loading
Outcomes	• Blood loss, infection, time to functional mastication, implant survival, patient satisfaction

<u>The formulated clinical question thus becomes:</u>

Does immediate loading lead to better outcomes (reduced blood loss, fewer infections, faster time functional mastication, higher survival rates and patient satisfaction) than the standard delayed loading protocol?

Performing a literature search

The most efficient and up-to-date method of searching the literature involves electronic searching. Conducting electronic searches of the medical literature has become

a necessary skill for not only performing research, but also for practicing modern evidence-based medicine. There are many databases available, each with their own strengths and limitations.

- A good place to start any electronic search is in MEDLINE, the US National Library of Medicine's bibliographic database containing abstracts of articles and citations from more than 4,000 biomedical journals published worldwide. This database is free and can be searched through PubMed at: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi. Many individual articles identified through the search can be purchased from the publisher through links provided by PubMed.
- Another place to look is in the Cochrane Collaboration Library. The Cochrane Collaboration is an international organization that prepares, maintains, and disseminates systematic reviews of health care interventions. It can be found at: http://www.cochrane.org/index.htm

Using PubMed to search for the answer to our clinical question above identified five citations, all comparing outcomes in immediate versus delayed loading protocols. There were several case series published recently; however, the latest report making a direct comparison is a prospective cohort study published in 2003. The citation is:

> Lorenzoni M, Pertl C, Zhang K, and Wegscheider WA. (2003)
> In-patient comparison of immediately loaded and non-loaded implants within 6 months.
> Clin Oral Impl Res 14:273-79.

We will discuss this article in upcoming issues of Implant Directions. The title of the next Research in Context article will be:

Study Types and Bias –
who shows favoritism?

Full Length Article

Basal implants: A safe and effective treatment option in dental implantology

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Abstract

The purpose of this four years study was to report on the outcomes after using a basal implant design for treating patients especially with poor quality and quantity of bone under immediate load conditions. From May 2003 to end of April 2007, 88 consecutive patients receiving 302 BOI®-implants were enrolled in this study. No patients seeking implant treatment were turned away for any reason nor got screw type implants. The mean age at implant surgery was 50.1 years. All 88 patients and their implants were accounted for at the end of the follow-up period. All but one implant underwent immediate loading. Even in cases of severe bone atrophy, no augmentations were performed. We found a 95.7% implant survival rate among this consecutive group of patients with varying degrees of bone quality and quantity. All patients received a fixed temporary or permanent bridge within 24 hours after the implant procedure. All patients continued to possess fixed dentures, so the prosthetic outcome is 100%. Basal implants used for single tooth replacement showed the lowest survival rate (90.9%), but this was result of specific overload. No other patient or implant related characteristics were found to be associated with a failure rate over 7%. The clinical application of basal implants is safe and effective and useful in a broad range of indications with immediate loading protocols and without the need for invasive, costly, and time consuming bone augmentation procedures.

Keywords

Basal implants, implant survival, immediate loading, poor bone, BOI, basal implants

Introduction

Survival rates for conventional dental implant systems are relatively high in normal healthy bone.1 However, there are subgroups of patients that are at an increase risk of implant or treatment failure. In particular, patients with reduced quantity or quality of bone present a significant challenge to the dental implantologist and have higher rates of implant failure (2-6). Disease, congenital anodontia, trauma, or atrophy due to the aging process leads to this poor quality or quantity of bone.

A lack of physiological forces in fully- or partially edentulous patients often leads to a decrease in the residual alveolar ridge. Dental implants may help to preserve bone due to their positive load-related effects on the jawbone surrounding the implant; hence, appropriate solutions should be explored and discovered to facilitate this process in these challenging patients (7,8).

The management of poor bone with root-form dental implants typically requires additional or augmentative procedures to en-

sure sufficient stability, even if there are newer developments like Osseopore®, a short conical implant design with sintered surface. Most of these short vertical integrated implants require a long functionless healing period. Bone augmentation may be necessary through procedures such as grafting, transplanting, or more novel therapies including augmentation of bone combined with substitutes and/or morphogenetic proteins (9) So all these methods typically add treatment steps to the procedure, delay loading, and increase the total risks and costs.

With basal implants (BOI®-brand of Dr. Ihde Dental AG, Switzerland) we avoid augmentation and reopening, have immediate function and generally do implantation simultaneously with the extraction, so these advantages make a study expedient.

Methods

Subjects

From May 2003 to April 2007, 88 consecutive patients (55.7% female) receiving 302 basal implants (mean = 3.4 per person; SD=2.8; median = 2.0; range, 1 – 16) and 129 prosthetic constructions thereon were enrolled in this study. All patients seeking implant treatment have been treated by BOI® only and included in the study. The surgical and prosthetic treatments were all performed by same clinician. The mean age at implant surgery was 50.1 years (SD=14.1; range: 16 to 80 years).

Implants

Titanium basal implants consist of a cylindrical part and a larger, cortically anchored base plate. Unlike the traditional root-form implants (i.e., screw and blade implants), which are inserted vertically and primarily designed to be supported by trabecular bone, these implants are inserted from the lateral aspect of the host bone providing multicortical support. Hence, are commonly called “disk” or “lateral” or “basal” implants. BOI® implants possess one to three very pronounced „threads“ or “base-plates”, which are securely anchored in the cortical bone, a bone area which is more stable during the remodeling/resorption process and which can respond successfully to immediate loading protocols, Figures 1, 2, 3. BOI® implants allow for the favorable distribution of masticatory loads to the cortical regions. The site of force transmission is far away from the site of bacterial invasion allowing for early loading and resistance to infection. This, as well as the thin smooth shaft, may be a reason for their observed and reported equal success in smokers as in non smokers.

While we used 11 different implant types in this series of patients with varying shaft lengths, they can be basically categorized in two major groups: BOI® with single base plates and more than one base plate (up to three). The majority of the patients who received a single disk were those with poor available vertical bone especially in the distal jaws. But the atrophic bone in this area is frequently broad, which is ideal indication for basal implants due to their lateral placement, Figures 2-5. In a few cases (N=12;

4%), the residual cavities after teeth or implant displacement were so large, that it seemed appropriate to fill them with synthetic material (Nanobone® - brand of Artoss® GmbH, Germany).

Data Analysis

Descriptive statistics were calculated for baseline variables. The primary outcome of interest was implant failure defined as any reason for having to remove an implant. Survival was based on the period from implant placement to final follow-up. Because BOI® implants are immediate load implants, it was not possible to distinguish between a "healing" phase and a "loading" phase and especially in circular restorations all implants were loaded under full masticatory loads. All failures were counted immediately if they were observed. The log-rank test was used to test statistical significance comparing survival rates among risk factors.

Results

Patients were followed for a mean of 637 days (Median=540; SD=427; range: 27 - 1472 days). Because we found the highest loss rate in the first days (~4.4% when including the first month and up) and to show the tendency in survival rates, we included the youngest cases with short follow up time. The survival rate increases by time in situ up to 100% for three years and more. None of the patients disappeared or dropped out of the series reported here for any reason. Of the 302 implants, 162 (53.6%) were placed in the upper jaw and 140 (46.4%) in the lower jaw. Subantral, the distal lower jaw and often subnasal are regions with poor bone. Here were 189 (62.6%) implants inserted. 157 implants (52%) were inserted into fresh alveoli of extracted teeth or crestal and basal implants (N=20; 6.6%). Of all implants 156 (51.7%) were single disks and 146 (48.3%) were multiple disks (> 1 disk). Shaft height used was primarily 8mm (58.6%). Due to our broad inclusion criteria, we placed between 1 and 16 per patient (Mean= 3.4; Median=2), but no more than 8 each jaw. Prosthetic classes included single crowns, linear bridges on teeth and implants, or on implants only, as well as circular bridges on mostly four implants. With the exception of one implant which underwent closed healing, remaining implants (99.7%) were loaded immediately or within the first 24 hours after the implantation. Fixation of the permanent prosthetic construction followed after surgery (Mean=47; SD=30.6; Median=44; range 0-156 days). Thirteen implants failed (Mean=391; Median=432; SD=273; range 41- 841 days) during the follow-up period giving an overall survival rate of nearly 96%.

The survival curve for the entire series of implants is shown in Figure 6. Survival rates stratified by different factors are shown in Table 1. The number of base plates induced a significant ($p<0.05$) difference in survival rates of 1.7%. Only in the single crown group a higher but non-significant failure rate was observed (9.1%). There were no implant failures in the implant groups longer than three years in situ set sub nasal used in combination with Nanobone®, or when fixed horizontally by bone screws, Table 1.

All patients in this series continue to maintain healthy fixed crowns or bridges giving a prosthetic success rate of 100%.

Discussion

We found a nearly 96% implant survival rate among a consecutive series of 88 patients receiving 302 BOI® implants and fixed dentures with varying degrees of bone quality and quantity. The only statistically significant factor on success we found, is implant design ($p<0.05$). The survival rate in multiple disk implants (96.6%) is 1.7% higher than in those with single disk (94.9%). This confirms clinical observations, because multiple disks will be used in higher but narrow bone ridges, single disk implants when vertical bone loss is extreme, so leverage differences are obvious. Patients who received a single crown had the lowest survival rate (90.9%; $p>0.05$). Here were two failures among 22 implants, but these suffered from non-physiological, uncompensated forces. No other patient or implant related characteristics were found to be associated with a failure rate over 7%. The non-significant difference in bone status results brings a strong evidence for immediate placing of basal implants. So even post extraction healing periods can be avoided.

There are limitations to the present study. While we were all inclusive and did not turn any patients away who desired implants, we did not quantify bone quantity and quality. Had we done this, we feel we would make an even stronger case for the use of BOI® implants in patients with poor bone, Figures 3-5. However, we did report a similar rate of survival among patients who received single-disk implants (94.9%) versus multi-disk implants (96.6%). Patients who received single-disks generally had very little vertical bone available and therefore this group may serve as a surrogate for patients with poor vertical bone, as well as the difficult regions (95.2%), Table 1. We have only placed basal implants in our practice during the observation period and therefore a direct comparison to traditional root-form implant is not possible. This is a case series and can only be compared to historical publications; however, our survival rates are very similar to those found in the literature.

The strengths of this study are many. Since we did not exclude any patients who presented to our clinic, even those send away by colleagues, we feel that our findings are generalizeable. Even patients who typically may be turned down due to poor bone quality or recommended to receive bone augmentation procedures, are smoking or show periodontal involvement are, according to our findings, good candidates for basal implants. This is a consecutive series of patients and hence does not represent a convenience sample or select group.

Diskimplants® are similar in form and function to BOI® implants and have reported rates of successful osseointegration of $\geq$ 97% with relatively long follow-up periods. Scortecci performed a prospective case series of 783 implants (627 Diskimplants®), placed in 72 patients with completely edentulous maxillae using an immediate load protocol. Follow-up ranged from 6 – 48 months. At 6 months, 98% of im-

plants were osseointegrated, with all fixed prostheses remaining functional during the study period.10 Scortecci combined crestal and basal implants, which makes it difficult to distinguish between the merits of basal and crestal implant designs. Our study shows that basal implants by themselves are safe and effective.

Ihde and Mutter performed a retrospective case series of 275 BOI® implants in 228 patients over a period of five years. Molars were replaced with BOI® implants in combination with natural abutments. Osseointegration was achieved in 254 implants at final follow-up. Fifteen implants were lost (11). This study shows that basal implants work well in combination with natural abutments.

Donsimoni et al performed a retrospective case series evaluating 1352 consecutive basal implants placed over a 10 year period in 234 circular bridges (12). Osseointegration was achieved in 97%. Of the 41 implants that failed, 25 had to be replaced. Only one full upper bridge had to be permanently removed rendering a clinical success of 99.9%. Interestingly, smokers and non-smokers experienced similar rates of implant losses. This may indicate that smokers, reported as having a higher risk of implant loss in conventional implants (14), may benefit from BOI® implant treatment. Donsimoni et al used only basal implants in their study, however they inserted a greater number of basal implants per jaw (up to 12) compared to us (<= 8). Nevertheless the results presented in this article match well with our findings.

The found missed influence of patient's age, sex, and the time of placement of the implant after tooth extraction correlated with Haas et al (18).

The better survival rate in implants longer in situ comes from their survival of initial threats as possible infections, malocclusions and surgical and prosthodontic mistakes. A similar result is found in literature, where the secondary bone loss like crater in crestal implants begins about eight years after implantation (19). Checkup of this cohort about ten years after implantation may bring significant findings regarding the implant loss after functional use.

Conclusion

The standard procedure for placing basal implants includes one surgery followed by immediate loading, thus reducing time, cost, and stress to the patient (10,14-17). With the emphasis on lateral rather than vertical placement, pre-implantological bone augmentation was never necessary. Estimated decrease in cost treatment time is ~ 50%16. There is no hospital residence needed, no time period without proper masticatory function, no second surgery. Complications associated with basal implants are rare and have proven to be easy to handle. The clinical application of BOI® implants is safe and effective and useful in a broad range of indications.

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Implants	Implanted	%	Survival N	%	Sig.* p-value
Over all	**302**	**100**	**289**	**95.7**	
Time in situ					
30 days and more	297	98.3	284	95.6	
60 days and more	266	88.1	255	95.9	
90 days and more	253	83.8	143	96	
180 days and more	252	83.4	242	96	
1 year and more	197	65.2	190	96.4	
2 year and more	103	34.1	101	98.1	
3 year and more	49	16.2	49	100	
Bonestatus (placed into)					**.671**
Healed bone	145	48	138	95.2	
Fresh alveoli: of teeth/implants	157	52	151	96.2	
of implants only	20	6.6	20	100	
Gender					**.139**
Female patients	156	51.7	151	96.8	
Male patients	146	48.3	138	94.5	
Jaw					**.519**
Upper jaw	162	53.6	154	95.1	
Lower jaw	140	46.4	135	96.4	
Localization					**.576**
Sub nasal	29	9.6	29	100	
Sub antral	76	25.2	71	93.4	
Distal lower jaw	84	27.8	80	95.2	
Summation difficult bone areas	**189**	**62.6**	**180**	**95.2**	
Upper canine & 1st premolar	57	18.9	54	94.7	
Between foramina in lower jaw	56	18.5	55	98.2	
Summation difficult bone areas	**113**	**37.4**	**109**	**96.5**	
Implant design					**.043**
Single disks	156	51.7	148	94.9	
Multiple disks	146	48.3	141	96.6	
Shaft height in mm (range 3-11)					**.567**
< 8	82	27.2	78	95.1	
= 8	177	58.6	169	95.5	
> 8	43	14.2	42	97.7	
Prosthetic class					**.350**
Crown on implant	22	7.3	20	90.9	
Segmental bridge on implants only	58	19.2	54	93.1	
Bridge on implants with teeth	56	18.5	54	96.8	
Circular bridge on implants only	166	55	161	97	
Added by Nanobone®	**12**	**4**	**12**	**100**	
Initially fixed by osseous fixation screw	**6**	**2**	**6**	**100**	
Loaded immediately (within 24h)	**301**	**99.7**	**289**	**95.7**	

*Log-rank test (Mantel-Cox)

Figure 1. Typical BOI® shapes representing single, double and triple base-plate designs as well as three different supra structure connectors as external thread connection, integrated abutment and external octagon connector with internal screw (ITI-compatible).

Figure 2. Schematic drawing showing a typical basal implant after trans-osseous insertion in the distal mandible. This implant was inserted from the right side, achieving a bi-cortical support.

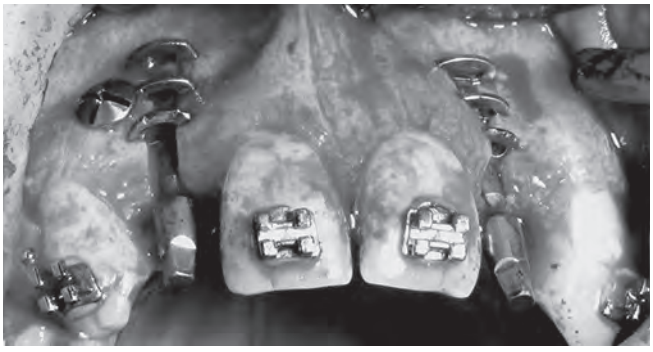

Figure 3. A typical patient with congenital anodontia and therefore a thin bone ridge is treated with BOI® in an immediate loading protocol. The right 2nd incisor implant was primarily fixed by a osseous fixation screw. (Published with the patient's consent)

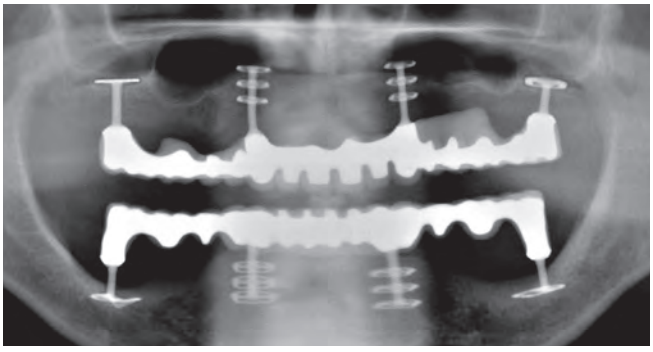

Figure 4. This X-ray shows an exemplary male patient nine months post surgery, where five residual teeth and removable dentures were replaced with two bridges on eight BOI® in strategic position. The atrophic distal jaws are excellent regions for BOI®. (Published with the patient's consent)

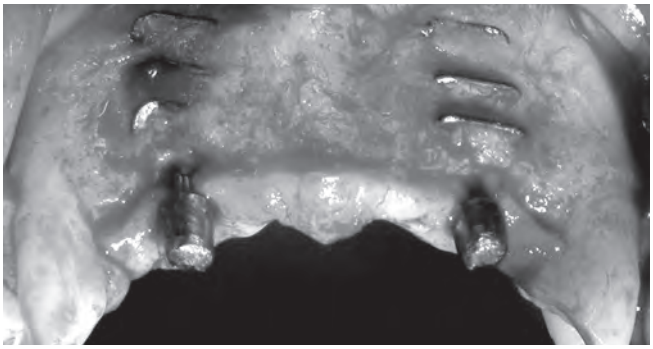

Figure 5. Open implant region nearly one year after Implantation. The reopening was necessary, because the implants were bent forward by artificial forces by this male patient, the osseointegration did not suffer any harm. Two BOI®s were added between the existent ones and a new bridge was fixed. (Published with the patient's consent)

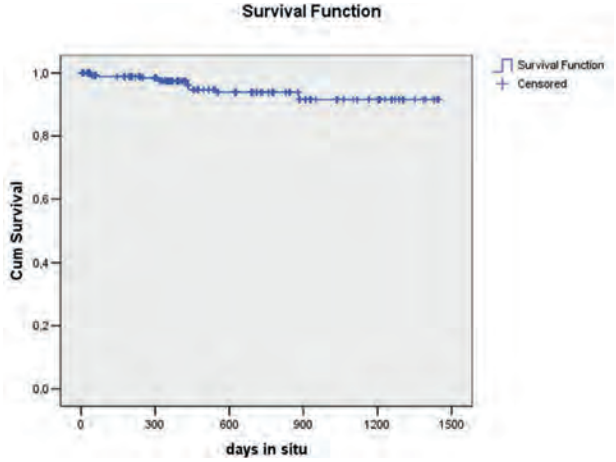

Figure 6. Kaplan-Meier survival curve for all implants in this consecutive case series.

Review:

Principles of BOI – Clinical, Scientific and Practical Guidelines to 4D-Dental Implantology

Author/Editor
Dr. Stefan Ihde

Publisher
Springer, Heidelberg, 2005

Introduction
At a time when all the world thought that things had been long invented in dental implantology, completely unexepected, a scientific textbook appears which provides a completely different view on things, and which has the potential to turn the world of dental implants upside down.

The author, Dr. Stefan Ihde, is a German dentist, who was brought up in the south of Germany and studied in Würzburg at a time when dental implantology had not yet reached Europe. During his postgraduate studies and research the author was in close contact to a group of leading French implantologist, including Frank-Peter Spahn, Jean-Claude Donsimoni and Gerard Scortecci. He was also in an exchange of views with Prof. L. Linkow (USA) around the year 1997, and all these meetings have influenced his work and thinking and the direction of his research.

It takes however the precision and the persistence of a German to compile this book with its 400 pages of text and illustrations and 20 pages of to the point literature citations in different languages.

The book was supported by seven co-authors and their contribution is declared in some chapters. This way it becomes clear that about 95% of the content was contributed by the main author and editor, Dr. Stefan Ihde.

As this technology was unknown and developed to a large extend solely by the author, the whole concept, the history of immediate loading and lateral basal implantology as well as a completely new and objective view on of bone physiology had to be given, in order to understand the matter.

The clinical cases and long term observations show, that the author has a vast and long term experience with his technology. Nevertheless he undertook the task to go back to a well done animal study, with the aim to describe in detail by histology what happens in the jaw bone during the process of immediate loading and healing under those conditions. The study design was a split-mouth, with conventional dental implants on one side of the animal and the other side being equipped with lateral basal implants ("BOI"). The results of this study are explained with the terms of modern bone physiology. The histological slides and bone considerations cover about 100 pages. In such detail this type of investigation was never performed earlier.

Content

In chapters 1 and 2 the author reports about the medical and "political" environment in which this book was written, and he outlines the history of basal implantology by reviewing the patents, - the only reliable source of information about the real developers.

Chapters 3, 4 and 5 describe the tools for surgery and prosthetics as well as various designs of implants. Since the idea of lateral-basal implantology is to utilize in every situation the exactly correct implant for the given anatomy, the number of designs is larger compared to conventional implantology, where the bones of the patients are operated towards the design of the implant. This requires larger stock in the implantologist's office, but it avoids bone augmentations.

Chapter 6 and 7 deal with diagnostics and the plans for the therapy.

In chapter 8 Ihde outlines clearly the massive differences between conventional dental implants and the BOI-designs, when he explains that his designs can be used directly in cases with severe periodontal involvement. This is proven by statistics, which show that the results in periodontally involved cases is even better than in cases where the bone has healed and teeth are absent from the beginning. It will take time until our profession will be ready to accept his results.

In chapters 9 and 23 (Histology) Ihde outlines a new understanding of bone physiology and how it should be applied on oral implants. The animal study was done in cooperation with the University of Belgrade/ Serbia. In this chapter it becomes clear what the author means with the term "4d-Implantology": the 4th dimension is the time, and it reminds the users of the technology to exclusively utilize bone which will be (in any case) present after long time periods, and to avoid anchorage in resorption-probe bone like the alveolar bone. This chapter, as well as chapter 21 "Mechanics meet biomechanics" (which reports on the work covered in cooperation with the Department of Biomechanics of Prague University, Czech Republic), make clear, that mechanistic thinking about bone & implants is the wrong (i.a. not long-term non-successful) approach to dental implantology.

Chapter 10 and 11 explains in detail, how the chewing function will impact the results, and that lateral and anterior patterns of chewing must be avoided. Ihde adds a comprehensive CD to his book where all these masticatory details are shown in very instructive and realistic morphs. This part of the work alone must have cost a fortune to produce. It will help practitioners to understand the importance of exact and correct prosthetic work (done in a way as it is not taught presently for implant borne bridges in our universities).

Several chapters deal with specific indications and treatment approaches, treatments along and within the maxillary sinus, as well as with the treatment-approach for Angle Class II and Class III cases.

Chapters 15 reports about treatment of the atrophied mandible in a way it was never shown before. The demonstration of placing implants below (!) the inferior alveolar nerve is just one of the highlights of this chapter.

The German lawyer Michael Zach contributed two chapters about counselling and case acceptance and about financial aspects and regarding the reimbursement of German private health insurers (as a benchmark for the acceptance of a technology).

Summary

The book "Principles of BOI" is a landmark and a milestone in dental implantology. It paves the way to immediate functional loading, by showing that there is a proven rationale for it form the side of the bone and from the prosthetic side. The book has scientifically proven answers to all relevant questions of immediate functional loading and to the process of "dual healing" which the bone around lateral basal implants is undergoing.

Considering the slow speed in medical science it must be expected however that it will take at least 10-15 years, until this book and the intellectual content in it will have impact on broad clinical work of practitioners and on university teaching. And a lot more work will be necessary to achieve this goal which the author has clearly in mind.

The technology has the potential to make bone augmentation and transplants for the regular implant case unnecessary. This will bring dental implantology back into the hands of dentists, it will make implantology (finally) affordable for all patients, but it will also lead to resistances from within the profession.

09/10/2006

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