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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

Effect of machined-surfaced versus chemically conditioned surfaced dental implants upon implant survival and complications

Evidence Report Purpose

Increased surface roughness may enhance mechanical interlocking between the implant surface and the bone, which may result in increased resistance to compression, tension, and shear stress. Surface roughness may also stimulate faster and stronger osseointegration because host tissue biomolecules adapt more firmly to the implant surface. By chemically altering the surface morphology of dental implants, bone-to-implant contact may be enhanced, thereby influencing the rate and extent of osseointegration of titanium implants.

Objective

To critically summarize the recently published literature examining implant survival and other outcomes in studies comparing machined-surfaced with chemically conditioned surfaced (i.e. dual acid-etched, titanium-oxide, anodized surface) dental implants.

Summary

Cumulative survival rates were similar comparing machined-surfaced to chemically conditioned surfaced dental implants in all studies. One study found lower success rates in machined-surfaced compared to chemically conditioned implants. There are conflicting findings with respect to peri-implant bone resorption comparing the two groups. Further, there were no statistically significant differences for implant stability or peri-implant bone resorption between machined-surfaced and chemically conditioned surfaced implants. Additional methodologically rigorous comparative studies, and studies evaluating other implants, are needed to better evaluate advantages and disadvantages of implant surface conditioning.

Sampling

A MEDLINE search was performed to identify recent studies published between January 2000 and September 2007 examining the effect of machined-surfaced versus chemically conditioned surfaced dental implants upon treatment outcomes. Twelve articles evaluated the treatment comparison of interest. Five articles which included outcomes on implant survival met our criteria and are included in this report.

Common Outcome Measures

- Implant survival
- Implant success
- Peri-implant bone resorption
- Implant stability
- Soft-tissue parameters

Table 1. Medline Search Summary

Terms	Hits	Reviewed
Search dental implants OR dental implantation, endosseous [MeSH]	13,872	
Search (dental implants OR dental implantation, endosseous [MeSH]) AND surface properties AND comparative study, Limits ENGLISH, Human, Literature containing Abstracts	232	5
Bibliographies from existing literature	0	0
Total Reviewed	**5**	

Interventions

Dental implants were placed and were described with respect to surface conditioning as follows:

Stach (2003)

- In a multicenter study, screw-type, 2093 patients received self-tapping machined-surface (n=1162) or dual acid-etched Osseotite® implants (n=931), which were placed in a two-stage surgical protocol.

Khang (2001)

- Dual acid-etched (n=247) and machined-surface implants (n=185) were randomly assigned to 97 patients, each of whom received at least one of both implant types. Overdentures were fabricated following a two-stage surgical protocol.

Al-Nawas (2007)

- Patients received a Nobel Biocare AB MK II™ (n=78) or 3i™ Osseotite® implant (n=39) with a diameter of 3.75mm and length ≥ 10 mm.

Watzak (2006)

- Thirty-one patients with edentulous mandibles received four screw-type titanium implants 3.75mm in diameter and at least 10mm long. Fifteen patients received machined-surface implants, while 16 patients received anodized-surface implants.

Schincaglia (2007)

- Ten patients received machined-surfaced implants on one mandibular edentulous ridge and titanium-oxide surfaced implants on the other mandibular edentulous ridge. Implant types for the edentulous ridges were randomly assigned, and implants were immediately loaded within 24 hours of the procedure.

Table 2. Comparative studies evaluating machined-surfaced versus chemically conditioned surfaced dental implants.

				Treatment			
Author (year)	**Study Design**	**Population**	**Diagnostic Characteristics**	**Machined-Surfaced (Group A)**	**Chemically Conditioned Surfaced (Group B)**	**Follow-up (%)**	**LoE†**
Stach (2003)	Randomized controlled trial	N = 2093 female: 58% age: MS= 51.6±11.1 years; DAE= 54.3±8.3 years	Indication for dental implant placement	N=1162; Ni=2585	N=931; Ni=2236	5 years: 98%	High
Khang (2001)	Randomized controlled trial	N = 97; Ni=432 female: 62% age: 60±12 years	Indication for placement of >1 dental implant in the same restoration	N=NR; Ni=185	N=NR; Ni=247	3 years: NR*	High
Al-Nawas (2007)	Retrospective cohort	N = 118; Ni=264 female: 60% age: 51±17 yrs	Indication for dental implant placement	N=78	N=39	43-51 months: 74%	Moderate
Watzak (2006)	Retrospective cohort	N = 31 female: 58% age: 67.6 (52-86) years	Edentulous mandible, treated with implant-supported fixed bridges	N=15	N=16	30-48 months: 62%	Moderate
Schincaglia (2007)	Randomized controlled trial	N=10; Ni=42 female: 40% age: 61.3 (37-74) years	Bilateral edentulous posterior mandible requiring a fixed partial denture of at least 2 teeth per side, same type of opposing occlusion bilaterally	N=10; Ni=20	N=10; Ni=22	12 months: 100%	Moderate

N=number of subjects; Ni=number of implants; MS=machined-surfaced; DAE=dual acid-etched
*NR (not reported) = 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 3. Evaluation of articles comparing machined-surfaced versus chemically conditioned surfaced dental implants

Study design and methods	Stach (2003)	Khang (2001)	Al-Nawas (2007)	Watzak (2006)	Schincaglia (2007)
1. What type of study design?	RCT	RCT	Retrospective Cohort	Retrospective Cohort	RCT
2. Statement of concealed allocation?*	NO	NO	N/A	N/A	YES
3. Intention to treat?*	NO	NO	N/A	N/A	NO
4. Independent or blind assessment?	NO	NO	NO	NO	NO
5. Complete follow-up of >85%?	YES	NO	NO	NO	NO
6. Adequate sample size?	YES	YES	YES	NO	YES
7. Controlling for possible confounding?	NO	YES	YES	YES	YES
LEVEL OF EVIDENCE	High	High	Moderate	Moderate	High

* Applies to randomized controlled trials only

Results

Implant survival (Figure 1)

There are conflicting findings when comparing survival rates in machined-surfaced and chemically conditioned surfaced implants; however, differences were not statistically significant:

- At 5 years, there were no statically significant differences in survival rates between machined-surface and anodized-surface implants (92.7% vs. 98.3%, p>.05) [Stach].
- At a mean functional loading time of 33 months, there were no statistically significant differences in survival rates between machined-surface and anodized-surface implants (100% vs. 98.4%, p>.05) [Watzak].
- At one year, there was a higher survival rate for machined-surfaced compared to titanium-oxide surfaced implants, but the difference was not statistically significant (100% vs. 90.5%, p>.05) [Schincaglia].

Implant success

Overall success was defined as pocket probing depth ≤ 5mm, negative bleeding on probing, and bone loss < 0.2mm annually.

- Significantly lower implant success rates were found for machined-surface implants compared to dual acid-etched implants at 36 months (86.7% and 95.0%, respectively; p<.01). In good quality bone, the cumulative success rates at 48 months for machined-surface and dual acid-etched implants were 87.8% and 93.8%, respectively; the 48-month cumulative success rates in poor quality bone were 84.8% and 96.8%, respectively (p<.01) [Khang].
- Mean implant success rates did not reveal any statistically significant differences between machined-surface and dual acid-etched implants (49 vs. 46 months, respectively; HR=0.7, 95% CI 0.3-1.5) [Al-Nawas].

Peri-implant bone resorption (Figure 2)

There is a trend towards increased peri-implant bone resorption associated with machined-surfaced implants compared to chemically conditioned surfaced implants.

- One study reported a significantly greater mean marginal bone loss around machined-surface implants compared to anodized surface implants (-1.4 ± 0.1mm vs. -1.2 ± 0.1mm, p=.03) [Watzak].
- Another study found no statistically significant differences for radiographic bone loss between machined-surfaced and titanium-oxide surfaced implants at one year (-1.1 ± 0.6mm vs. -0.9 ± 0.7mm, p=.224). Although these differences are not statistically significant, these findings may be due to the small number of subjects in this study. [Schincaglia]

Implant stability

- No statistically significant differences were found for Periotest® or resonance frequency analysis values between machined-surfaced and dual acid-etched dental implants at 2 years (p>0.05) [Al-Nawas].
- No statistically significant differences were found for resonance frequency analysis values between machined-surfaced and titanium-oxide surfaced dental implants at 1 year (p>0.05) [Schincaglia].

Soft tissue parameters

- No statistically significant differences were found for peri-implant soft-tissue parameters (probing depths, bleeding on probing) between machined-surface and dual acid-etched dental implants at 2 years (p>0.05) [Al-Nawas].
- No statistically significant differences were found for peri-implant soft-tissue parameters (marginal plaque index, probing depths, bleeding on probing) between machined-surface and anodized surface dental implants at a mean functional loading time of 33 months (p>0.05) [Watzak].

Methodological considerations

- All studies reviewed were randomized controlled trials with a rating of high (low quality RCT) or cohort studies with a rating of moderate (low quality cohort) level of evidence. No very high quality randomized controlled trials or high quality cohort studies were identified in the literature.
- One of the studies [Schincaglia] had a sample size that was likely inadequate to show a difference between the study groups.
- Since multiple implants in the same subject are not statistically independent, either one implant should be chosen per patient or statistical analysis should account for multiple implants per patient. None of the studies reviewed accounted for multiple implants in the same subject.
- Only two 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.

References

Studies

Study 1
Stach RM and Kohles SS (2003)
A meta-analysis examining the clinical survivability of machined-surfaced and osseotite implants in poor-quality bone
Implant Dentistry 12(1):87-93.

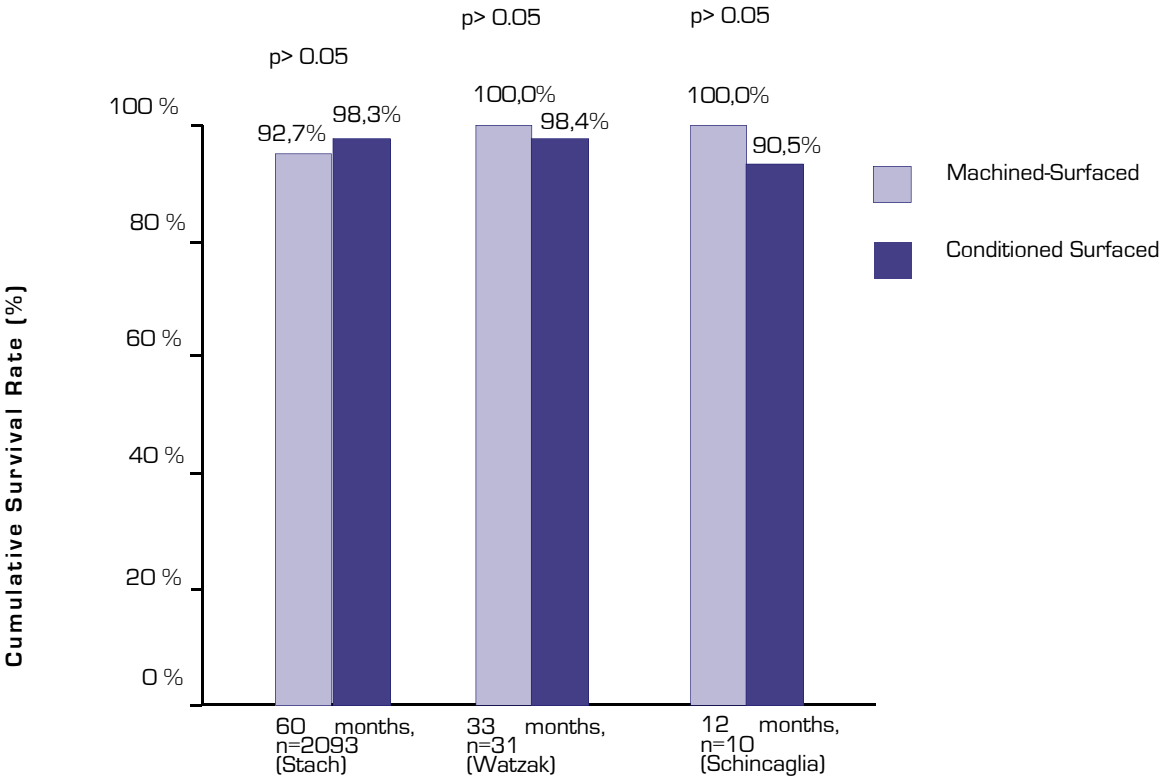
Study 2
Khang W, Feldman S, Hawley CE, Gunsolley J
A multi-center study comparing dual acid-etched and machined-surfaced implants in various bone qualities
J Periodontol 72(10):1384-90.

Study 3
Al-Nawas B, Hangen U, Duschner H, Krummenauer F, Wagner W (2007)
Turned, machined versus double-etched dental implants in vivo
Clin Implant Dent Relat Res 9(2):71-78.

Study 4
Watzak G, Zechner W, Busenlechner D, Arnhart C, Gruber R, Watzak G (2006)
Radiological and clinical follow-up of machined- and anodized-surface implants after mean functional loading for 33 months
Clin Oral Impl Res 17:651-7.

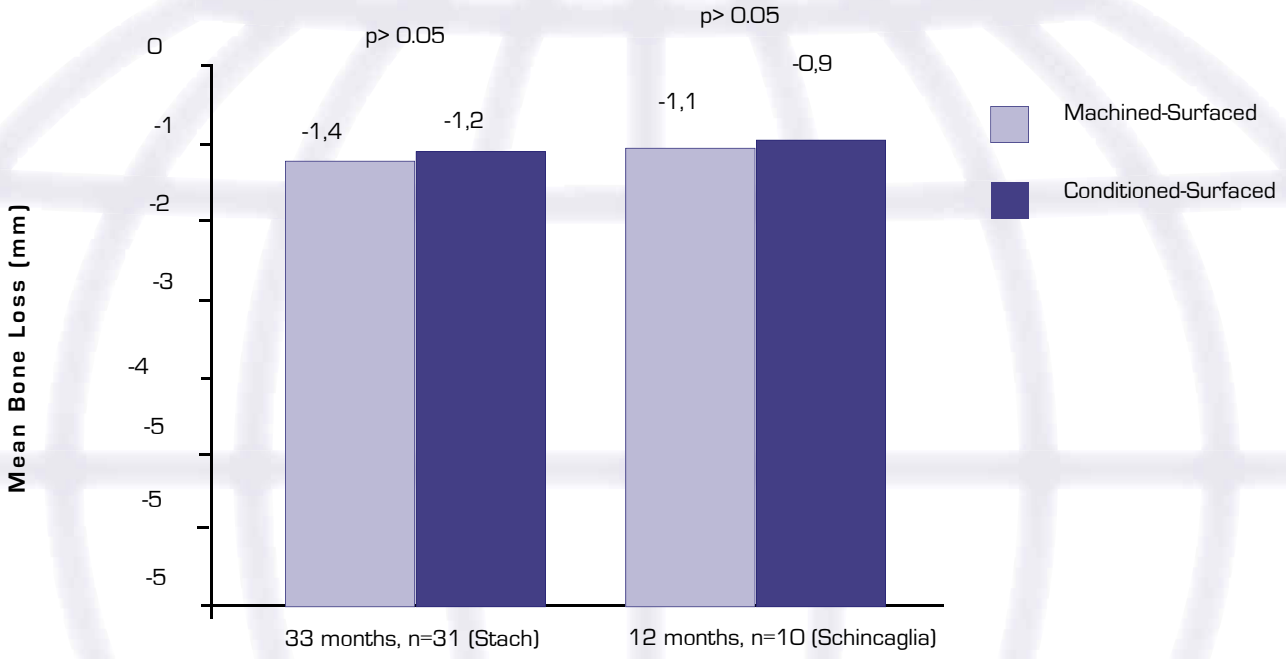
Study 5
Schincaglia GP, Marzola R, Scapoli C, Scotti R (2007)
Immediate loading of dental implants supporting fixed partial dentures in the posterior mandible: a randomized controlled split-mouth study—machinged versus titanium oxide implant surface
Int J Oral Maxillofac Implants 22:35-46.

Figure 1. Cumulative survival rates for machined-surfaced vs. chemically conditioned surfaced dental implants*



Statistical significance noted on graphs if provided by author

Figure 2. Mean peri-implant bone loss for machined-surfaced vs. chemically conditioned surfaced dental implants*



Statistical significance noted on graphs if provided by author

Literature Analysis

Smoking and Dental Implants
Are patients who smoke at greater risk of implant failure?

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" (also published in each issue of Implant Directions) which focus on one specific treatment intervention by comparing and contrasting only 3 to 5 high quality articles in greater depth.

Literature Analyses 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;
- To use the material for future presentations.

Purpose

The purpose of this Literature Analysis was to systematically search the literature to identify key articles in an effort to better understand the risk of implant failure in patients who are smokers. We were interested in how smoking may contribute to implant failure and other complications. Moreover, we wanted to compare survival rates of dental implants in smokers versus nonsmokers. This literature analysis will address the following objectives:

1. **Report** definition(s) of implant failure
2. **Summarize** how smoking may contribute to implant failure
3. **Examine** the effect of smoking upon implant failure
4. **Examine** the effect of smoking upon implant complications
5. **Summarize** survival rates of dental implants in smokers versus nonsmokers
6. **Compare** survival rates of one and two-stage procedures in smoker and nonsmokers
7. **Report** upon BOI as a potential alternative to dental implantation in smokers

Data Sources and Search Strategy

MEDLINE was searched to identify studies reporting data on smoking as a risk factor for dental implant failure (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 dental implant failure in smokers and nonsmokers. 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 evaluating smoking as a risk factor for dental implant failure. Topics such as criteria for implant failure, dental implant survival rates, and risk factors for failure were included.

Second strategy: Identify comparative studies evaluating smoking as a risk factor for dental implant failure.

Third strategy: Identify comparative studies evaluating smoking as a risk factor for dental implant complications.

Table 1. Medline Search Summary

Terms	Hits	Reviewed
Search („dental implantation, endosseous“ [MeSH] OR “dental implants” [MeSH]) AND “smoking” [MeSH]	160	8
Search („dental implantation, endosseous“ [MeSH] OR “dental implants” [MeSH]) AND “smoking” [MeSH] AND systematic review NOT case report, Limits ENGLISH, Literature containing Abstracts	22	0
Bibliographies from existing literature		2
Total Reviewed	10	

The following are results of the various search strategies:

First strategy: We identified three systematic reviews on risk factors contributing to dental implant failure. One of these reviews did not evaluate smoking as a risk factor due to poor data, and two of these reviews highlighted studies which were of poor quality, so they were excluded.

Second strategy: We identified six comparative studies which evaluated evaluating smoking as a risk factor for dental implant failure.

Third strategy: We identified four comparative studies which evaluated evaluating smoking as a risk factor for dental implant complications.

Background

Dental Implant Failure

Definition:

Implant failures can be categorized into biological failure, mechanical failure, iatrogenic failure, and inadequate patient adaptation1. A radiographic finding of implant failure is progressive bone loss. Clinically, implant failures may present with mobility, pain and/or infection.

Smoking as an Etiology for Dental Implant Failure

Mechanism for smoking causing implant failure:The negative effect of tobacco use on implant success may be related to the deleterious effect of smoking on wound healing, including a diminished proliferation of red blood cells, fibroblasts, and macrophages.[2]

Nicotine has also been associated with increased platelet adhesiveness, which causes microclots and decreases microperfusion[3] and may lead to tissue ischemia. In addition, nicotine causes vasoconstriction, resulting from the release of adrenal and peripheral catecholamines.[4] Studies have shown that catecholamines released in this fashion undermine wound healing by retarding and decreasing the rate of epithelialization.[5] Furthermore, the intake of carbon monoxide decreases the levels of oxygen available for tissue perfusion and leads to cellular hypoxia and diminished wound healing.

Methodological Definitions

The relative risk (RR) is a relative comparison of outcomes between two groups that have different exposures; it is the proportion of patients with the outcome in the treatment group (A) divided by the proportion of patients with the outcome in the control group (B). In survival analysis, the hazard ratio (HR) is reported and can be interpreted similarly. Statistical significance is reached if the 95% confidence intervals do not cross the value of one. The cumulative hazard is the probability of the endpoint of interest (e.g. dental implant failure), taking into account the effect of several risk factors upon this probability. The odds ratio (OR) is an estimate of the strength of the association between the risk factor and the disease outcome. The adjusted odds ratio is an odds ratio that takes into account the effect of several risk factors upon the association.

Studies evaluating smoking as a risk factor for dental implant failure

Six comparative studies were identified which evaluated the effect of smoking upon dental implant failure. The studies are summarized in Table 2. Five studies found a significant increased risk of implant failure associated with smoking[6-10], while one study found an increased number of implant failures in smokers compared to nonsmokers, but the difference was not statistically significant.[11]

One prospective cohort study followed patients who received implants for 2 years. They found the increased risk of implant failure associated with smoking was 14.4 ($p<.0001$)[6]. Another prospective cohort study followed patients for 10 years after having received hollow screw implants of the ITI Dental Implant System. 35.7% of smokers experienced implant failure, while 22.6% of nonsmokers had failed implants, though this difference was not statistically significant in a multivariate logistic regression[11]. A third prospective cohort study evaluated 3 - 5 year follow-up data of patients who received implants in a multicenter clinical study.

They found an increased risk of implant failure associated with smoking (p=.02).[7] The same study also found an increased rate of implant failure in the maxilla (10.9% smokers, 6.4% nonsmokers) as well as in the mandible (6.9% smokers, 5.6% nonsmokers) for smokers compared to nonsmokers.[7] One retrospective cohort study evaluated charts from patients who received Bicon implants in place for 3-5 years. They found smokers had four times the increased risk of implant failure compared to nonsmokers (HRadj 4.3, 95% CI 1.9-9.7).[8]

Another study evaluated the same population of patients but only evaluated implants placed in the posterior maxilla. Patients were followed for a mean of 22.5 months (range 0-90 months). They found three times an increased risk of implant failure in smokers compared to nonsmokers (HRadj 3.5, 95% CI 1.7-7.2).[10] A third retrospective cohort study evaluated patients who had crystal sapphire implants (Bioceram, Kyocera) placed to support mandibular overdentures. The median follow-up was 9 years (range 1-14 years), and the increased risk of implant failure associated with smoking was 4.2 (HRadj, 95% CI 1.7-10.4)[9].

Studies evaluating smoking as a risk factor for dental implant complications

Four comparative studies were identified which evaluated the effect of smoking upon dental implant complications. The studies are summarized in Table 3. Three studies found a significant increased risk of implant complications associated with smoking[12-14], while one study found an increased number of implant complications in smokers compared to nonsmokers, but the difference was not statistically significant[15]. One prospective cohort study followed patients who received titanium implants for 9-14 years after placement. They found nearly three times the increased risk of mucositis, defined as probing depths ≥4 mm and bleeding upon probing, for current smokers compared to nonsmokers (ORadj 2.8, 95% CI 1.2-6.2), though the increased risk was not significant for former smokers compared to nonsmokers (ORadj 1.0, 95% CI 0.5-2.1).[12]

Another prospective cohort study followed 39 patients in whom implants were placed for marginal bone loss, defined as more than 0.5mm of marginal bone loss in one implant or more. They found a nonsignificant risk of marginal bone loss in smokers compared to nonsmokers (ORadj 1.1, 95% CI 0.2-7.0).[15]

However, the sample size was very small, and additionally, the study did not account for violating the statistical principle of independent observations. A retrospective cohort study evaluated charts from patients who received Bicon implants, with a mean follow-up of 13.1 months (range 0-85.6 months).

They found more than three times the increased risk of implant complications, such as mobility, pain, infection, radiographic peri-implant bone loss, impaired wound healing, and gingival recession, in smokers compared to nonsmokers (HRadj 3.3, 95% CI 1.7-6.1).[13] Another retrospective cohort study evaluated consecutive

patients who underwent placement of implants plus guided bone regeneration. They found an adjusted odds ratio of exposed surface area of the implant (bone fill <87%) to be 2.9 (95% CI 1.0-7.9).[14] This study did not account for violating the statistical principle of independent observations.

Survival rates of one and two-stage procedures in smokers and nonsmokers

One study estimated implant survival rates while taking into account potential confounders which may contribute to implant failure. In a retrospective cohort study[8], 553 patients who received Bicon implants and in whom smoking status was known were followed for 3-5 years.

Implant survival rates were estimated using a multivariate model. The highest survival rates were associated with nonsmokers who had implants placed in 2 stages. The 1- and 5- year survival rates, estimated from the multivariate model, were 97.1% (95% CI: 95.4-96.7) and 92.9% (95% CI: 88.9-97.1), respectively. Survival rates for nonsmokers who had 1- stage implants were 91.1% (95% CI: 85.4-97.2) 1-year survival and 79.5% (95% CI: 65.0-97.3) 5-year survival. Smokers who have implants placed in 2-stages had a 1- year survival rate of 88.2% (95% CI: 80.6-96.5) and a 5-year survival rate of 73.5% (95% CI: 57.4-94.0). The poorest outcome was expected from smokers who underwent a single-stage implant placement procedure. For this group, the estimated 1- and 5- year survival rates were 67.6% (95% CI: 47.6-96.0) and 38.3% (95% CI: 13.5-100), respectively.

BOI® as a potential alternative to conventional implants among smokers

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

1. **There** appears to be an increased risk of implant failure in smokers compared to nonsmokers.
2. **A** proposed mechanism for implant failure is poor wound healing following the invasive procedure of implant placement.
3. **Since** BOI® can be an effective implant in poor bone by distributing the loads laterally and capitalizing on cortical support, it may be superior dental implant in smokers when compared to root-form implants.

Future research recommendations

MEDLINE was searched to identify studies reporting data on smoking as a risk factor for dental implant failure. An attempt was made to identify studies of high methodological quality (systematic reviews, RCT and cohort studies) comparing dental implant failure in smokers and nonsmokers.

- Although there is substantial literature on smoking as a risk factor for dental implant failure, the majority of these studies have significant methodological flaws.
- Few studies took into account any possible confounders which may also contribute to implant failure and/or obtaining poor follow-up of subjects.

- Nevertheless, the included trials did provide limited but useful clinical information on the association between smoking and dental implant failure.
- Future studies on this topic should be clinical trials, concentrating research efforts on few important clinical questions, increasing the sample size, and decreasing the number of treatment variables in the trials. Collaborative efforts among various research groups are also encouraged.
- Clinical trials comparing BOI® to other implant procedures in smokers compared to nonsmokers would be an addition to the current literature.
- Longitudinal studies are needed to determine long-term survival rates of dental implants in smokers compared to nonsmokers.

Executive Summary

- We identified three systematic reviews on risk factors contributing to dental implant failure, though they were eliminated because they did not address smoking as a risk factor or highlighted studies which were of poor quality. Ten additional comparative studies were identified, six of which evaluated the association between smoking and dental implant failure, and four studies analyzed the association between smoking and dental implant complications.
- Five studies found a significant increased risk of implant failure associated with smoking[6-10], while one study found an increased number of implant failures in smokers compared to nonsmokers, but the difference was not statistically significant.[11]
- Three studies found a significant increased risk of implant complications associated with smoking[12-14], while one study found an increased number of implant complications in smokers compared to nonsmokers, but the difference was not statistically significant.[15]
- Implant survival rates were highest in nonsmokers who had implants placed in two stages. The 1- and 5-year survival rates, estimated from the multivariate model, were 97.1% (95% CI: 95.4-96.7) and 92.9% (95% CI: 88.9-97.1), respectively. The poorest outcome occurred smokers who underwent a single-stage implant placement procedure. For this group, the estimated 1- and 5-year survival rates were 67.6% (95% CI: 47.6-96.0) and 38.3% (95% CI: 13.5-100), respectively.
- In the literature, it has been recommended that smokers refrain from smoking 1 week prior to and 8 week after implant placement.[16]
- Since BOI® can be an effective implant in poor bone by distributing the loads laterally and capitalizing on cortical support, it may be superior dental implant in smokers when compared to root-form implants.

Table 2. Detailed information on studies evaluating the effect of smoking upon dental implant failure

Author (year)	Study Design	Population	Diagnosis of Implant failure	Treatment Group (s)	Results (outcomes)	Favors
Moheng (2005)	Prospective cohort, 2 year follow-up	N = 93, Ni = 266; Male: 61.3%; Mean age: 60.3, range 18-85 yrs; Median F/U*: 2 years; F/U %: NA	Removal of implant due to probing depths ≥3 mm or radiographic bone loss	Group 1: Current smoker, at least 1 cigarette/day (n=15) Group 2: Not a current smoker (n=78)	Implant failure • Group 1: 26.7% (n=4/15) • Group 2: 3.8% (n=3/78) • Adjusted RR = 14.4 (p<.0001) [multivariate logistic regression, statistically accounted for clustering]	**Nonsmokers**
Karoussis (2003)	Prospective cohort	N = 53, Ni = 112; Male: 40.2%; Mean age: NR; Median F/U*: NR (up to 10 years); F/U %: NR	Clinical signs of implant pain or mobility, probing depths >5mm or =5mm+bleeding upon probing, or radiographic bone loss or vertical bone loss >2mm	Group 1: Current smoker (n=12, number implants=28) Group 2: Not a current smoker (n=41, number implants=84)	Implant failure • Group 1: 35.7% (n=10/28) • Group 2: 22.6% (n=65/84) • Statistical analysis: p>.05 [multivariate logistic regression, did not statistically account for clustering]	Nonsmokers
Lambert (2000)	Prospective cohort	N = NR, Ni = 2887; Male: NR; Mean age: NR; Median F/U*: NR (range 3-5 yrs); F/U %: 90	Implant removal	Group 1: Current smoker (n=959 implants) Group 2: Not a current smoker (n=1928 implants)	Implant failure • Group 1: 10.8% (±0.68) • Group 2: 6.9% (±1.48) • Statistical analysis: ln logistic regression, p=.02 Implant failure in maxilla • Group 1: 10.9% (n=52/478) • Group 2: 6.4% (n=51/793) Implant failure in mandible • Group 1: 6.9% (n=33/481) • Group 2: 5.6% (n=64/1135) [multivariate logistic regression, did statistically account for clustering]	Implant failure **Nonsmokers** Implant failure in maxilla Nonsmokers Implant failure in mandible Nonsmokers

Author (year)	Study Design	Population	Diagnosis of Implant failure	Treatment Group (s)	Results (outcomes)	Favors
Vehemente (2005)	Retrospective cohort	N = 553, Ni = 553; Male: 49.9%; Mean age: 53.3 ± 13.9 yrs; Median F/U*: NR (range 3-5 yrs); F/U %: 96.4	Implant removal	Group 1: Current smoker (n=57) Group 2: Not a current smoker (n=496)	Implant failure • Adjusted HR = 4.3 (1.9-9.7) [1 implant randomly selected from each patient]	**Nonsmokers**
Berge (2000)	Retrospective cohort, sapphire implants placed to support mandibular overdentures	N = 30, Ni = 116; Male: 30.0%; Mean age: 63.8 yrs (range 47-77 yrs); Median F/U*: 9 yrs (range 1-14 yrs); F/U %: 50	Clinical signs of implant infection, pain, mobility or radiographic marginal bone loss >4mm	Group 1: Current smoker (n=16, n=61 implants) Group 2: Not a current smoker (n=14, n=55 implants)	Implant failure • Group 1: Mean implant survival = 10.19 yrs (8.85-11.54) • Group 2: Mean implant survival = 11.74 yrs (10.89-12.59) • Crude HR = 3.26 (1.38-7.72) • Adjusted HR = 4.21 (1.71-10.43) [multivariate logistic regression, did not statistically account for clustering]	**Nonsmokers**
McDermott (2006)	Retrospective cohort, implants placed in posterior maxilla	N = 269; Male: 50%; Mean age: 56.1±12.4; Mean F/U*: 22.5 mo (range 0-90.0 mos); F/U %: NR	Implant renoval, secondary to mobility	Group 1: Current smoker (n=28) Group 2: Not a current smoker (n=241)	Implant failure • Unadjusted HR: 3.9 (2.1-7.5) • Adjusted HR: 3.5 (1.7-7.2) [multivariate logistic regression, did statistically account for clustering]	**Nonsmokers**

Bolded findings are statistically significant, p <0.05, while those that are not bolded are NOT statistically significant but tended to favor one treatment
Patient characteristics include sample size (N), number of implants (Ni), proportion male, and mean age or range or standard deviation (SD), and mean follow-up (F/U) and range if available; NR = Not reported

Table 3. Detailed information on studies evaluating the effect of smoking upon dental implant

Author (year)	Study Design	Population	Diagnosis of Implant complications	Treatment Group (s)	Results (outcomes)	Favors
Roos-Jansaker (2006)	Prospective cohort	N=218, Ni = 999; Male: 50.9%; Mean age: NR; Median F/U*: NR (range 9-14 yrs); F/U %: 74.1	Mucositis: Probing depth ≥4mm and bleeding upon probing	Group 1: Current smoker (n=307) Group 2: Former smoker (n=382) Group 3: Never smoker (n=309)	Mucositis • Group 1: 59.0% (n=181/307) • Group 2: 42.9% (n=164/382) • Group 3: 42.7% (n=132/309) • Crude OR, former = 1.1 (0.6-2.3) • Crude OR, current = 2.9 (1.4-6.0) • Adj OR, former = 1.0 (0.5-2.1) • Adj OR, current = 2.8 (1.2-6.2) [multivariate logistic regression, statistically account for clustering]	**Nonsmokers**
Shimpuku (2003)	Prospective cohort	N = 39, Ni = 251; Male: 38.5%; Mean age: 55.1±9.4 yrs (range 29-74 yrs); Median F/U*: NR; F/U %: NR	Marginal bone loss: More than 0.5mm of marginal bone loss in one implant or more	Group 1: Current smoker (n=14) Group 2: Not a current smoker (n=25)	Marginal bone loss • Group 1: 35.7% (n=5/14) • Group 2: 48.0% (n=12/25) • Adjusted OR: 1.09 (0.17-6.97) [multivariate logistic regression, did not statistically account for clustering]	**Nonsmokers**
McDermott (2003)	Prospective cohort	N=553; Ni = 553; Male: 49.9%; Mean age: 53.5±13.9; Median F/U*: 13.1 mos (range 0-85.6 mos); F/U %: NR	*Implant complication:* mobiity, pain, infection, radiographic peri-implant bone loss, impaired wound healing, gingival recession	Group 1: Current smoker (n=57) Group 2: Not a current smoker (n=496)	Implant failure • Adjusted HR = 3.26 (1.74-6.10) [1 implant randomly selected from each patient]	**Nonsmokers**
Zitzmann (1999)	Retrospective cohort, subjects underwent placement of implants + guided bone regeneration	N = 75, Ni = 112; Male: 25.3%; Mean age: NR; Median F/U*: NR; F/U %: NR	exposed surface area of implant at baseline compared to re-entry (4 months for mandible, 6 months for maxilla) < 87%	Group 1: Current smoker (n=22) Group 2: Not a current smoker (n=53)	Increase in bony defect • Group 1: 18% of implants • Group 2: 11.9% of implants • Crude OR = 1.96 (0.78-4.76) • Adjusted OR = 2.86 (1.01-7.94) [multivariate logistic regression, did not statistically account for clustering]	**Nonsmokers**

Bolded findings are statistically significant, p <0.05, while those that are not bolded are NOT statistically significant but tended to favor one treatment

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Critical Appraisal

Reference
Buser D., Broggini N., Wieland M., et al (2001)
Enhanced Bone Apposition to a Chemically Modified SLA Titanium Surface.
J Dent Res;83(7):529-533

Summary

- This article concludes that the modified SLA surface promotes enhanced bone apposition during early stages of bone regeneration. However, this animal study has many methodological weaknesses and significant bias cannot be ruled out. Furthermore, even if the results are valid, the authors acknowledge that these findings do not suggest superior bone anchoring at earlier time points. As a result, claims of this magnitude by manufacturers or other clinicians are not warranted.

Objectives/Aims

- To examine bone apposition to a modified SLA (modSLA) surface in the maxillae of miniature pigs as compared with a standard SLA surface. The authors hypothesized that the mod SLA surface would promote a faster bone apposition in comparison with the standard SLA surface.

Methods
Study Design

- Prospective matched-cohort animal study.

Sampling
Six adult miniature pigs.

Implant design and surface characterization

- Test implants = modSLA surface rinsed under N2 protection and continuously stored in an isotonic NaCl solution
- Control implants = Standard SLA surface
- All were cylindrical titanium with two circular bone chambers with a depth of 0.75 mm and a height of 1.8 mm (Institut Straumann AG, Waldenburg, Switzerland)
- Both implants underwent the same sandblasting and acid-etching procedure

Intervention
Two surgical procedures per pig were performed:

- First surgery = Anterior teeth in maxilla were removed by means of a flap elevation, careful osteotomy, and tooth separation. After wound closure, the sites were allowed to heal for at least 6 months.
- Second surgery = Titanium implants were inserted according to a low-trauma surgical technique. The implants were placed, with good primary stability provided by the press-fit of the implants with the bone walls of the prepared implant beds.
- Three or four implants were inserted on ei-

ther side of the maxilla, in a split-mouth design.
- Following irrigation, primary wound closure was achieved with interrupted sutures, and implants were left to heal in a submerged position.

Surface analysis

Four different methods were employed:

- Surface topography – 10 images examined under scanning electron microscopy (SEM).
- Quantitative 3-D topographical analysis – calculated dimensional roughness parameters of 10 images under a white-light confocal microscope.
- Surface wettability – Dynamic contact angle (DCA) measurements of 10 surfaces.
- Chemical composition – Six samples were examined for oxygen, titanium, and carbon by x-ray photoelectron spectroscopy (XPS)

Histological preparation and analysis

- Two miniature pigs were killed after 2, 4, and 8 weeks of healing respectively.
- In each animal, two bone blocks were removed and immersed in a solution of formaldehyde (4%) combined with CaCl2 (1%).
- The specimens were dehydrated and embedded in methylmethacrylate. ~500 µm thickness sections were prepared and stained superficially with toluidine blue followed by basic fuchsin.
- Assessment of bony ingrowth
- Assessment of bone density

Histomorphometric analysis

- Bone to implant contact (BIC; %)

Timing of assessments

- Surface analysis timing unknown
- Histological and histomorphometric analyses performed at 2, 4, and 8 weeks

Results

Surface analysis

- Surface topography – No qualitative differences observed.
- Quantitative 3-D topographical analysis – No statistically significant differences in surface roughness parameters.
- Surface wettability – DCA measurements indicated that SLA was hydrophobic (DCA = 138.3o ± 4.2) and modSLA was hydrophilic (DCA = 0 o; $p<0.05$).
- Chemical composition – modSLA had increased oxygen and titanium concentrations (O, 55.0% ± 2.0; Ti, 26.5% ± 0.9) compared with SLA surface (O, 44.2% ± 1.9; Ti, 18.4% ± 1.6). Conversely, modSLA surface demonstrated reduced carbon concentration (C, 18.4% ± 1.6) compared with the standard SLA surface (C, 37.3% ± 3.4). No statistical tests reported.

Histological analysis

For both implants:

- At 2 weeks, bony ingrowth into the bone chambers and direct bone-to-implant contact were evident. A scaffold of woven bone formation was observed.
- At 4 weeks, bone density increased, as indicated by the reinforcement of woven bone trabeculae.
- At 8 weeks, bone density in the bone chambers had increased further and early signs of bone remodeling were apparent.

Histomorphometric analysis (Figure)

- At 2 and 4 weeks, significant differences in percentage of BIC between test and control implants were observed.
- At 8 weeks, no significant differences were observed.

Methodological Principle	
Randomized design	NO
Independent or blind assessment	NO
Adequate sample size	YES
Controlling for possible confounding	YES*
Appropriate measures	
Histological analysis	YES
Histomorphometric analysis	YES
Biomechanical analysis	NO

Reviewers Comment

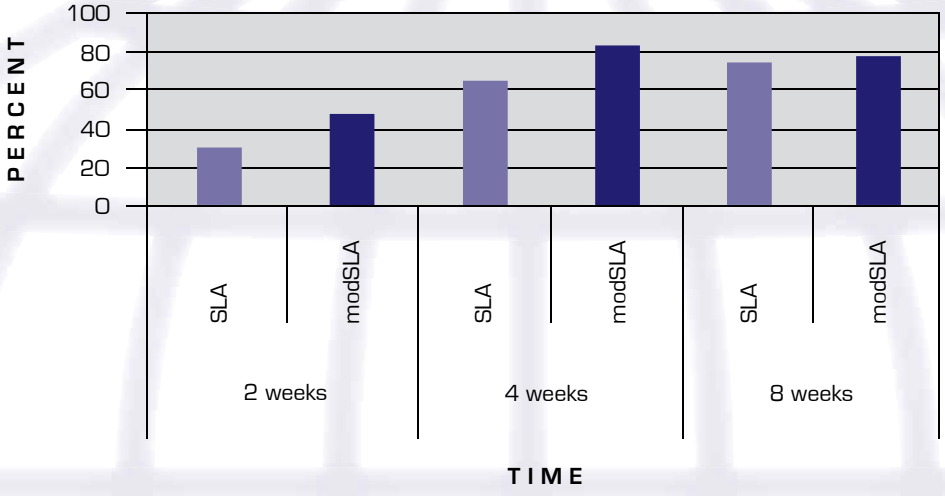
1. **What** were the study`s methodological strengths?

- Matched pair design – comparisons were made within the same pig and within the same region of the mouth.
- Some quantitative methods were used at different time points.

2. **What** were the study`s methodological limitations?

- Side of mouth was not randomized. We cannot be sure that all factors that might influence outcome were equal. One cannot prevent bias that may exist by pre-inspecting animals prior to placement of one implant or another.
- The most critical methodological principle violated was blinding of assessors. If the assessor was not blind (or at least independent) to the implant, we cannot be sure that knowledge of the implant did not have a direct or indirect effect on the interpretation of the analyses.
- There were no biomechanical tests performed. This makes the inference that increased bone apposition during the 2 and 4 week period leads to increased initial stability rather tenuous. The authors acknowledge this weakness. Hence claims of this magnitude by manufacturers or other clinicians are not warranted.

Figure. Bone-to-implant contact (BIC) in two implant surfaces.



Clinical note

Was the preparation of the implant sites relevant to the clinical setting?

To improve the chances for the successful integration of an implant, a direct bone-to-implant contact must be achieved by the surgeon. This means that there should be no gap between the drilled out cavity of bone and the implant. In this experiment, the authors show large cavities with no direct bone contact.

The soft tissue development inside these cavities as well as the later ingrowth of secondary osteons is described. The tissue observed initially is pre-bone converting to woven bone (i.e., a type of endosseous callus which requires a blood clot and space to develop). Space, however, is not present under normal placement conditions in crestal (i.e., screw) implantology.

The implants used do not appear to have threads in the pictures presented. Clinically, threads influence the load distribution of the implanted bone and interfere with the direction of osteonal repair. If threads are not present, bony ingrowth into the cavities for this experiment are not under "normal conditions".

The authors do not explain their "low trauma insertion technique". If no flap was raised during the surgical procedure, this experiment will not be relevant for many dental implant cases. Raising a full thickness flap will create a "regional acceleratory phenomenon" (RAP) [1], thus reducing the amount of spongious bone between

the cortical bone. This reduction of old (mature, mineralized) spongious bone may have a significant influence on the implant stability in the first 4-6 months and may be one of the reasons why crestal implants inserted after raising full thickness flaps in the upper jaw are more safely loaded after 4-6 months.

What is the clinical relevance of the chemical composition?

Increasing the amount of oxygen on the titanium surface of implants is not difficult to do. However, ion exchanges (in-diffusion of oxygen, out-diffusion of titanium) may lead to an overall increase of solubility of the outer area of the titanium body and to a decrease of the integrity thereby increasing the risk of fracture for the whole implant body.[2]

In particular, with 3.3 mm implants, the fracture resistance is critically reduced, because the thickness of the wall of the implants is thin. The standard implants described in this experiment were designed to be used as additional implants in non load bearing areas. The modified implants (modSLA) are potentially even weaker since ion exchanges of this magnitude do not only affect the actual surface, but create a considerable layer of defect areas in the depth of the surface .[2] This may lead to cracks, which ultimately lead to the failure of the Titanium structure as the supporting bone retracts over time from the collar of the implant.

Fillies et al[3] evaluated SLA-surfaces and showed that the type and roughness of the surface determines the behavior and development of cells with a potential to differentiate. On smooth and microstructured surfaces of pure titanium, bone forming cells are found predominantly whereas the proportion of fibrous tissue cells is lower, whereas fibroblasts (instead of the desired osteoblasts) are increased on SLA-surfaces. This may have a negative influence on the integration of the implants. It may be considered that the changes in surface composition from pure titanium to a titanium alloy (Ti55018C) caused by the SLA-preparation are one of the major reasons for this observation.

Were all important assessments performed?

The degree of mineralization of the newly formed tissues was not determined in this experiment. This however should be a standard procedure for bone quality assessments.[4] If this experiment would have shown a considerable amount of mineralization, statements about "increased bone apposition" would be justified. However, if no mineralization (or an increase in mineralization compared to SLA) was examined, we would have expected a statement about a histologically visible, blood-derived, granulation with later resorption and replacement by osteonal bone. One must be careful when describing this tissue as "bone". Standard staining methods, such as tetracycline labeling would have helped to enlighten the histological findings. Furthermore, the authors used the term "increased bone density" inappropriately. An increase in the volume of non-mineralized tissue was observed and should not be confused with bone density.

Are there alternative explanations for the findings observed in this study?

The implants described (modSLA) are supplied in vials containing liquid; therefore, the implants are wet when they are inserted into the bone. Remnants of this wet storage might enhance the liquid quantity available on the surface of the implant after the implant is enveloped into the bone. In order to distinguish between the effects of this NaCl-coating, the modSLA should have been compared to pre-wetted SLA-Implants (using sterile water). One must be careful in assuming the surface made the difference when the wet supply condition may have contributed to an alternate behavior of the tissue. We cannot be sure without a comparable control.

How might the findings of this animal study be applied to patient care?

The average implantologist might consider using modSLA implants for immediate or early loading protocols. This should be considered with caution given the findings presented above. There does not appear to be "bone" available in the vicinity of the implant at this stage of healing; hence, the load bearing capability of the peri-implant bone (being under heavy remodeling) is likely low.

Furthermore, without biomechanical testing, a statement of stability cannot be made. However, if prosthetic work pieces are to be inserted at this stage, abutments must be screwed in and tightened (e.g., with 25-30 Ncm) which may impose extremely high forces on the surfaces of bone. Especially in the maxilla, implants may show immediate loosening under these conditions. The bone in the anterior mandible is more resistant and less fragile and may tolerate this approach more successfully. Finally, the authors of this paper acknowledge that these findings do not suggest superior bone anchoring at earlier time points so careful consideration of early loading is highly recommended.

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Corrective Intervention

Immediate restoration after failure and replacement of basal implants

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ABSTRACT

Corrective interventions in basal implantology may be managed in one surgical intervention by qualified dentists. The failing implant is removed and the new implant is inserted. Given appropriate amounts of bone and a suitable state of dentition in the opposite jaw, the treatment may be finished by an immediate load procedure.

A corrective intervention using axial implants to replace failed basal implants immediately is usually not the method of first choice when the initial treatment was performed because vertical bone was missing. However basal implants are the devices of first choice, when failed implants of any design have to be replaced. An appropriate surgical technique and tools are mandatory.

KEYWORDS:

Basal implants, corrective intervention, implant failure, immediate implant replacement

INTRODUCTION

Although dental implantology is assumed to be a relatively safe procedure, failures may occur. A large body of literature on complications in axial implants is available. Qualified reports and analyses about problematic treatments outcomes with basal implants are rare. Our clinic has reported earlier on a case of failed basal implants and the methods to solve the problem [7].

This article reports on the occurrence of a complete failure and the treatment steps until the case was recovered.

Case Report

A 47 year old woman was treated in 1997 in our office with basal implants (Diskimplant®, Victory SA, Nice, France). A total of 7 implants had been inserted: 5 single-disk-implants and two double-disk-implants. A circular bridge was cemented after 12 days on the screw-on abutments. After this, the patient did not appear for occlusal and masticatory adjustments until the middle of 2000. During this period, several of the implants had become mobility inside the bone and decementations had occured. This could be diagnosed clinically and with x-ray (Fig. 1). Due to her absence from the mandatory follow-up appointments, the masticatory conditions had slipped into a very unfavorable situation, with heavy overloading having occurred in the distal mandible. We immediately corrected the bite situation by means of grinding and building up and recommended the necessary follow-up interval of at least 6 months. The patient was

informed that a problematic situation had developed. She refused to undergo the proposed corrective surgical intervention, since she was able to function without any limitation and no pain at all.

After this we had the chance to monitor the gradual deterioration of the situation for another six years, because the patient appeard for follow-ups and x-rays, but refused any corrective intervention during this long time period.

In 2006, the patient had a new full upper denture fabricated alio loco. The dentist did not adjust the occlusion and mastication properly, but he created severe early contacts on the left distal side, inducing partial and punctual overloadings. This drastic change of resulting forces coupled with the unbalanced bite situation quickly led to severe deterioration in the implant-equipped opposite jaw (Fig. 2, 6/2006). Formerly separate defects in the lower left mandible became confluent and mobility severely increased. The bridge was only supported by two implants in area 43 and 42. The cementation on the implant in area 33 had been lost. Only when chewing became painful, the patient agreed to a corrective surgical intervention. This intervention was performed in late 2006. One of the existing implants was still fixed (area 33), so the implant in area 33 was left in place while all others were removed. Immediately, three new basal implants were inserted in strategic positions 43, 47, 37, to create a basis for an "all on four" circular mandibular bridge (Fig. 3, 12/2006). The resoration was well balanced until the last follow up in July 2007 and the actual panoramic picture shows a complete recovery of the bony defects, formation of new cortical bone, the well integrated implants and the new bridge. (Fig.4, 7/2007).

Failure analysis

1. Implant design related problems

When the initial treatment was performed, basal implants with round, rotation-symmetrical base-plates were all that were available. Achieving primary fixation was not easy and the possibility of initial basal implant rotation in the cavity was not hindered by implant design. As long as the fixation and splinting of the implants with the bridge is given, failures should not occur. As we understand today, the dual mechanism of integration involves callus formation in the void spaces of the cavity which forms and mineralizes quite fast. If the treatment protocol is delayed or infections occur, callus can not form and the integration gained from it will not be realized. In many cases, osteonal remodeling alone will be enough to secure integration.

Further, at the time when initial treatment was performed, no rotation-symmetrical abutments were available. The manufacturer had made only abutments with one flat vertical face but since the external connection of the implants was not designed to provide congruent design hindering rotation, the abutments were not screwed tightly onto the threads, but "positioned" in the correct direction to fit the bridge. This way the bridge was more or less "swimming" on the implants and it was thus impossible to intentionally distribute masticatory forces between all implants; In fact, the implants were not splinted at all due to this problem of implant and abutment design.

In addition at the time of treatment, the surfaces of the disk-plates and the vertical shaft were roughened by sandblasting. The intention

of this surface treatment was to enable better bony integration. Roughened implants do provide a better chance for the blood cloth to stabilize near/at the implant. On the other hand, the hose surfaces provide a lower chance for re-integration. They irritate the matrix of the bone during the movement. Modern basal implants are not sandblasted any more, their surface is machined & blanc.

2. Problems relating to the treatment protocol & the treatment itself

It is understood today, that "immediate loading" means loading within no more than 3 days postoperatively. At the time of the treatment this was not known as a general rule. Implantologists working in immediate load protocols tried to place prosthetics within 2-3 weeks, depending on the capacity and willingness of their dental laboratories [1]. With today`s experience and knowledge, loading around day 12 must be considered to be of high failure risk. Implants should be loaded immediately or considerably later.

We also have to face the fact, that especially the distal implants in this case have been placed within the alveolar bone and not in the basal bone. As we know today, basal implants have to be placed in the resorption resistant basal bone (i.e. below the white linea oblique), a bone region which resists the masticatory forces better. At the time of the initial treatment, the term "basal implantology" had not been "invented" yet.

3. Problems stemming from missing follow-ups during the first post-treatment

phase. When the patient reappeared in our office three years post surgery the first time, several crowns had become unfixed in the abutments. This caused additional overload on the remaining fixed implants, resulting in increasing mobility in these implants. This envirunment may cause mobility to spread and reach additional implants during functional time, until all implants became mobile. Since "dropping out" is not an easy option for implants at all, the situation will deteriorate gradually, if no intervention takes place.

4. Tertiary problems during the last phase of usage.

If basal implants are ailing, a recovery may be attempted, as long as the interface with bone does not develop infections and stability can be guaranteed by any means, thus allowing the unstable implant to re-integrate[2].

Well trained and experienced basal implantologists manage early implant mobilities by means of prosthetic adjustments and the reduction of load by different means [6]. However this has to be repeated regularly and early, as soon as mobility is discovered. Since we were able to evaluate and treat the patient after 2002 regularly, we adjusted the occlusal surface extremely carefully and managed to keep the situation more or less stable. The dentist, who inserted the new upper denture in 2006, likely did not have adequate experience and the insight into the necessity of precise adjustments. His careless intervention without any contact to our clinic quickly ruined the unfavorable, but balanced situation.

Discussion

We are reporting about this case in such detail, because a number of basal implant specifics can be learned from this case.

First of all, it is interesting that it is was possible to maintain the implants in situ for such a long time, despite in the year 2000, the necessary surgical revision was obvious. The indication for removal of the implants in area 35, 36, 45, 46 was recommended as early as 2000[3], because sharp black zones of osteolytic were visible around the implants circularly.

Recently in the german literature, two articles were published [4, 5], stating that after the loss or (unqualified) removal of basal implants large bony defects are to be expected and that those defects can only be treated by means of major bone transplants (e.g. from the hip, parietal bone, etc) in order to allow the placement of another set of axial implants. The case shown here, clearly demonstrates, that this is not true. As a matter of fact, the authors of the above mentioned citations are maxillofacial surgeons who have at their disposal the ability to perform such autologous bone transplantations and a large financial incentive to do so.

It would have been the duty of those surgeons instead, to clearly inform the patient, that the maximally-invasive intervention is not necessary at all- that bone transplants are not necessary. Hospitalization is avoidable and no waiting time is required replacing the failed basal implants with new ones.

Had they revealed this truth frankly to the patient, the patient would probably never have agreed to their ambiguous "treatment" plan. It must be stated at this point that the treatments of Tetsch and Neukam were probably not based on a truly informed consent, which leads to a situation where their "treatment" must be categorized as an intentional damage of the patient`s health. Both groups of authors can not excuse themselves, because they must have known details of the existing scientific literature, namely the works of Scortecci [10-22] and Donsimoni et al. [23-28], Bocklage [8,9] (just to name a few).

Conclusion

Basal implants are the devices of first choice, when it comes to replacing implants. This is especially true, when basal implants have to be replaced. The patients have chosen this therapy for good reasons: they wanted an affordable, straight forward therapy and they wanted to avoid risky bone augmentations. For corrective interventions, there is no reason to change the therapy plan towards crestal implant designs and bone augmentations.

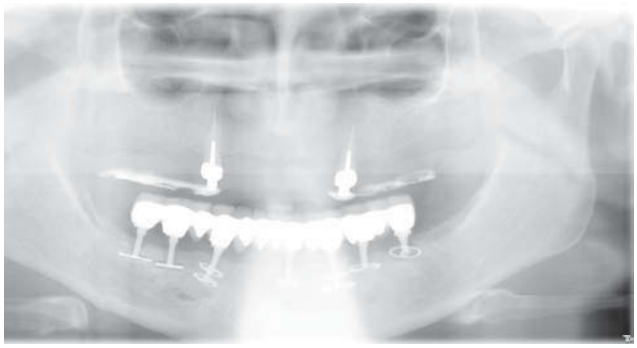

Fig.1 The first rediagraphic picture after the patient had been out of controll for more than 3 years after the placement of the prosthetical workpiece (2000)

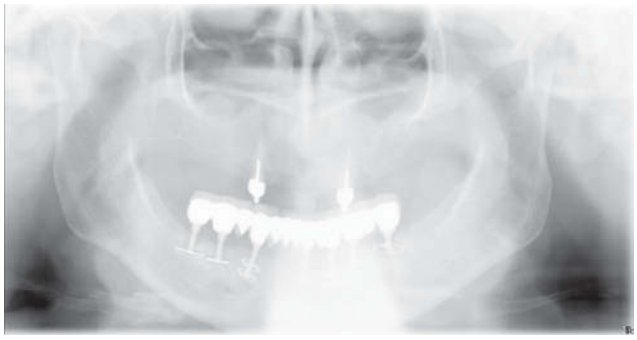

Fig.2 A further radiological picture as taken in April 2001; the black zones around the imlpants present almost unchanged compared to Fig. 1

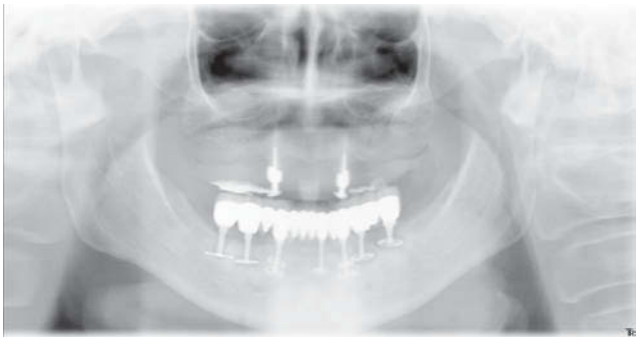

Fig.3 The radiological control in February 2002.

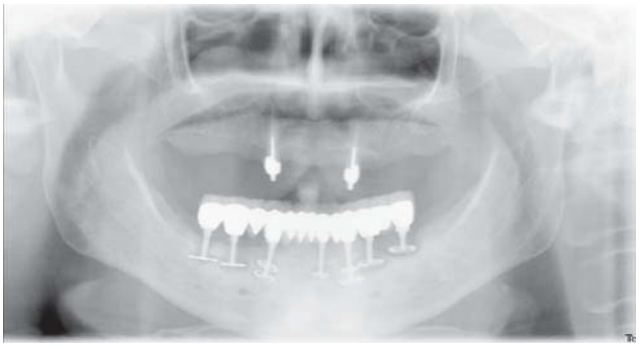

Fig.4 In 2005 confluent black zones in the left lower mandible are visible. However the patient did not agree to a corrective intervention at that time.

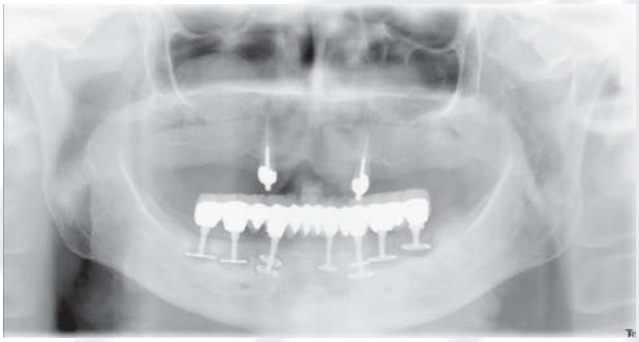

Fig.5 After the upper jaw had received a new denture with out adequate adjustment of the mastication, the integration of the basla imlpants was reduced rapidly. Only now the patient agreed to a corrective intervention.

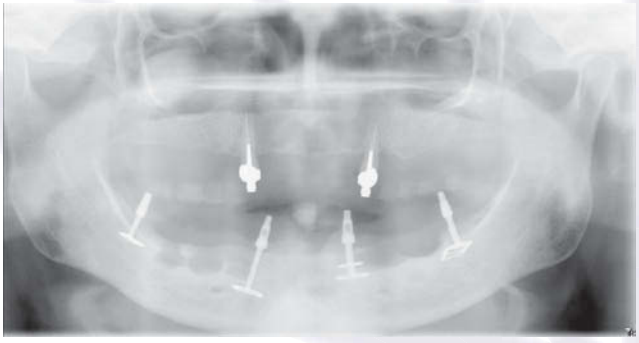

Fig.6 Immediately after the removal of six (out of seven) basal implants, thre new basal implants were placed. The implant in area 33 remained in function.

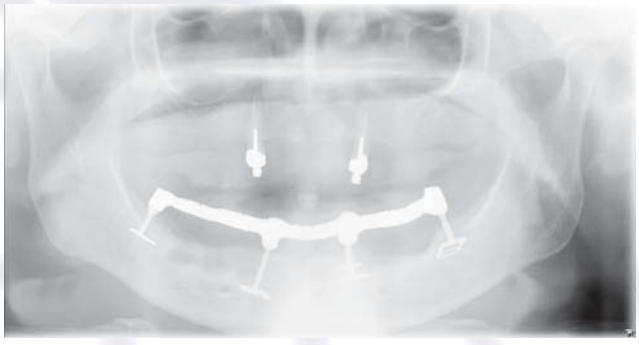

Fig.7 Six months after the corrective intervention the bony defects have healed without any augmentation. The implants and the bridge are stable.

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Short Communication

A novel osteoinductive bone grafting substitute?

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ABSTRACT

Hydroxyapatite (HA) is the main component of bone. The bone grafting substitute described here consists of nanocrystalline HA embedded in a highly porous matrix of silica (SiO_2) gel. This HA-silica-matrix is fully biodegradable and at the same time extremely osteoconductive. Ectopic bone formation was induced even when implanting the HA silica matrix subcutaneously into porcine fatty tissue thus proving osteoinductive properties.

KEYWORDS:

Bone grafting substitute, osteoinductivity, hydroxyapatite, silica, sol-gel-technique

Introduction

Hydroxyapatite (HA) - on the basis of alcoxides - was distributed homogeneously in a SiO_2 sol (24% by weight), which formed a granular material during the transformation to a gel [1]. While drying the gel at a temperature of < 700 °C, the solvent evaporated and prompted a slight shrinking of the material. The production of the highly porous compound finally resulted in granules (density of 0.5 g/cm^3). Evaporation also led to the formation of small pores ("micropores", Ø 5-100µm), which allow the immigration of osteoblasts and connective tissue fibrils. These are the starting points of bone formation within the HA silica matrix in multiple locations simultaneously. The loosely packed HA crystallites are held together by SiO_2 leading to nanopores (Ø 10-20 nm). The extremely enlarged outer and inner surfaces of the HA-silica-matrix (84 m2/g) allow the fast invasion of endogenous proteins, particularly the growth factors. The favourable biological behaviour of the new HA silica matrix is due to the natural nanocrystalline structure of HA (Ø 90 nm) and the highly interconnecting porosity of the granules (61% of volume) [1]. In vivo studies demonstrate that the HA silica matrix is extremely osteoconductive and at the same time fully biodegradable [2, 3].

Materials and methods

Osteoinductivity means that a material induces bone formation outside the skeleton. 0.3 ml of HA silica matrix granules (0.6 x 2 mm) were

applied into the subcutaneous fatty tissue and the adjacent musculature in the neck region of 12 adult Goettingen minipigs. The surrounding tissue was excised 2.5 (group 1, 3 animals), 4 (group 2, 3 animals) and 8 months (group 3, 6 animals) postoperatively. The tissue samples were studied macroscopically, radiologically, histologically (cutting and grinding technique, Giemsa - toluidine blue, Masson-Goldner and von Kossa stains) and histomorphometrically (ITEM®, Soft-Imaging-Systems, Münster, Germany).

Results and discussion

Biodegradation of the HA silica matrix was considerably slower in soft tissues than in bone [3]. Residues of the material were found, but could not be clearly differentiated from foci of ossification macroscopically. In radiographs it was also not possible to differentiate safely between HA particles of the material and foci of ossification, since both were similarly radioopaque. Computer tomography (CT) produced better information: e. g. in one animal two clearly separated foci of ossification were visible 8 months after implantation (Fig. A). These findings were confirmed histologically in five out of the six minipigs (group 3). Multiple foci were visible even macroscopically in three animals. The largest one measured 2.5 mm by 12.5 mm (Fig. B). Foci of ossification were found in all animals of groups 1 and 2: micro foci (Ø < 1mm) after 2.5 months and larger foci (Ø 1mm - 3.5 mm) after 4 months. The foci of ossification were located almost exclusively in the subcutaneous fatty tissue (Fig. C). No ossification took place in the muscular tissue probably due to the permanent movement of the myofibrils. The close contact between partially biodegraded HA particles and newly formed bone spoke in favour of the osteoinductive properties of this material (Fig. D)

Fig. A-D: Findings 8 months following implantation of HA-silca-matrix into subcutaneously fatty tissue (minipig, neck region)..

Fig. A. High power computer tomography: two separate large calcified areas

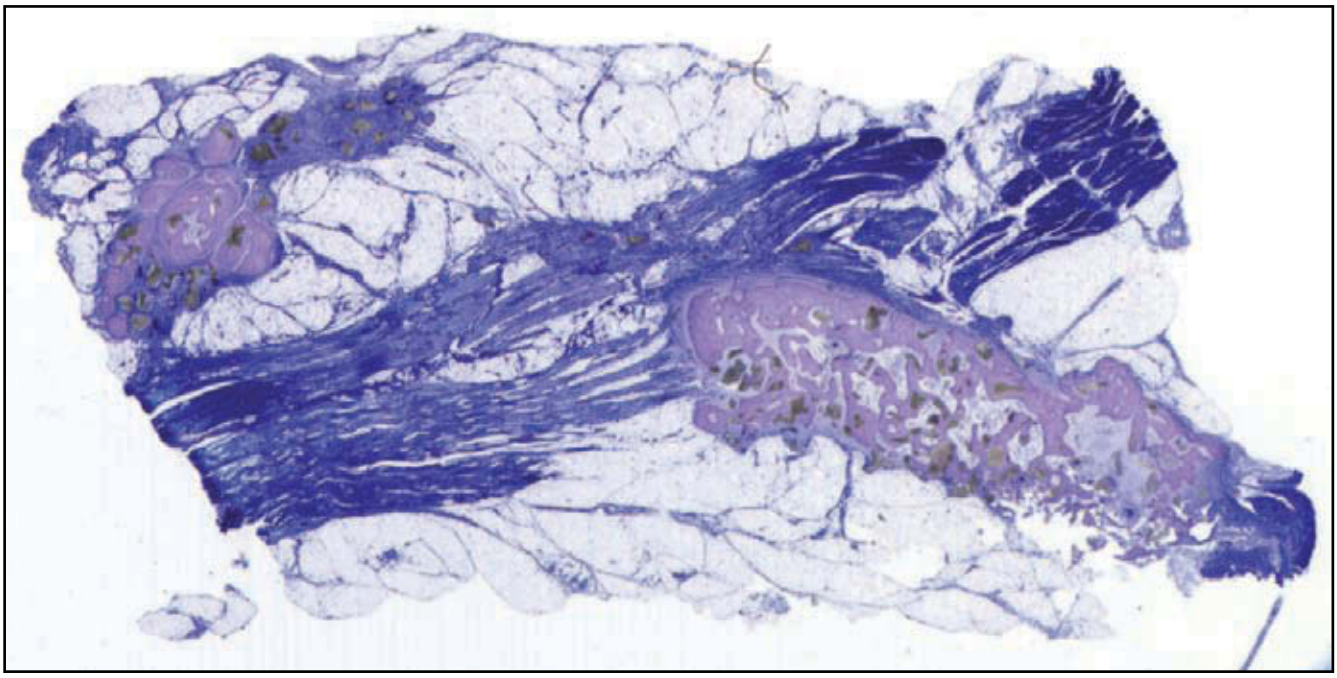

Fig. B. Histological findings (cutting and grinding technique) Two large foci of ossification (same as in Fig. 1a), adjacent to muscula ture in subcutaneous fatty tissue
(Giemsa-toluidine blue, original magnif. 4 x)

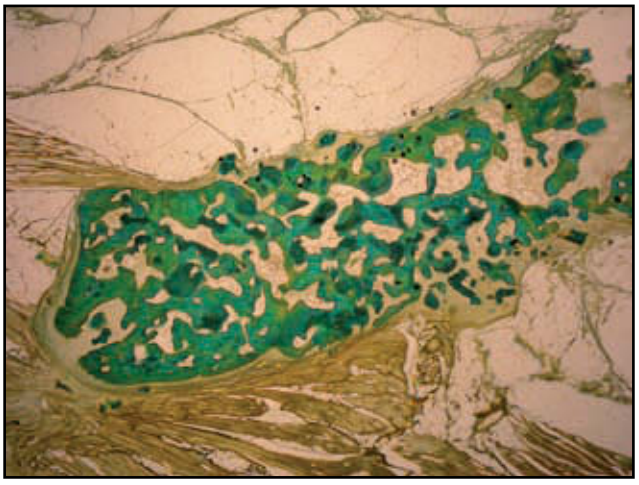

Fig. C. Histological findings (cutting and grinding technique) Ossified material (bright green) in subcutaneous tissue with subtotally biodegraded HA particles enclosed
(dark green, Masson-Goldner, original magnif. 12,5 x)

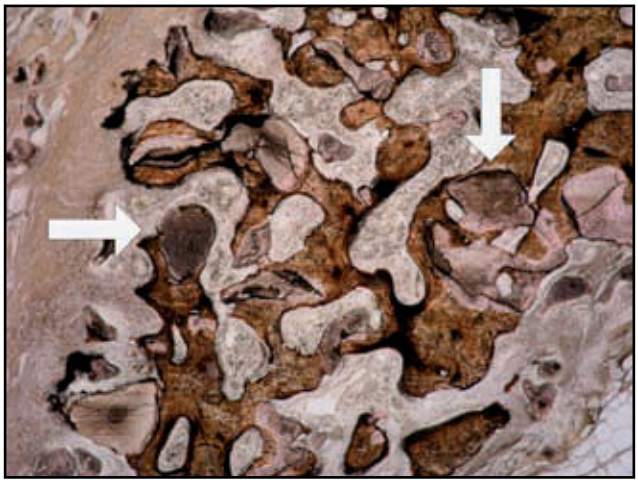

Fig. D. Histological findings (cutting and grinding technique) Osteoid and of newly formed cancellous bone (dark brown/black) with subtotally biodegraded HA particles enclosed
(arrows, von Kossa, original magnif. 40x)

Conclusion

These studies led to the conclusion that differentiation of adipocytes (or other adult stem cells) into osteoblasts can be induced in vivo by highly porous bone grafting substitutes with natural nanocrystalline structure. Further in vivo studies will be required to understand those processes.

The HA- silica- matrix tested is available in the form of granules for application in medicine (Nano Bone® / CE 0483, Artoss GmbH, Rostock / Germany). First, positive results in oral and maxillofacial surgery , i.e. in treating bone defects with the new HA-silica matrix, have been published [4]. At the same time the HA-silica matrix is a favourable carrier for osteoinductive material like bone morphogenic proteins, and stem cells. This is of particular clinical importance in recipient tissues with poor regenerative properties.

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Full length article

BOI® implants as the therapy of choice in dental offices

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SUMMARY

BOI® implants allow cantilever situations in the mandible to be definitively restored in a prompt and cost-effective fashion. They can be used alone or in combination with natural tooth abutments and/or crestal implants. A number of case studies are presented to illustrate treatments of this type. They can be planned and conducted in any well-equipped dental office without deviating from routine treatment approaches. In her own dental office, the author relies on BOI® implants as the alternative of choice to removable restorations.

KEYWORDS

BOI® implants, cantilever situation in mandible, fast and cost-effective restoration

INTRODUCTION

Dental offices offer prosthetic restorations to replace any teeth that have been lost. Most patients wish to have fixed restorations installed. Very often, this expectation can be met by delivering bridges. However, if any gaps along the arch can no longer be reasonably closed with a bridge, removable partial dentures are indicated [1]. Given the very low acceptance of removable dentures, patients are today increasingly opting for implants. BOI® implants are capable of assuming the function of missing abutment teeth, allowing the masticatory function to be restored in a timely fashion. With this strategy, functional problems can be avoided that would otherwise sooner or later affect the masticatory pattern in its entirety [2]. BOI® implants offer stable bicortical support due to their shape and transosseous insertion path. As a result, they can be immediately loaded. The amount of vertical bone is irrelevant with these designs, since the horizontal rather than the vertical structures of the jawbone are utilized for the transmission of forces. BOI® implants come in a large variety of shapes enabling dentists to select appropriate designs in accordance with individual bone conditions. Different implant sizes should be kept in stock at all times, allowing clinicians to select the most suitable implant type even in the midst of the surgical procedure and to immediately place implants should a need for extractions arise unexpectedly. The available bone volume should be optimally utilized. Since the jawbone is safe from resorption in its basal segment, this area is typically the one that is most suitable[3].

First contact with patients

With patients who present at our office for the first time, our policy is to find out about their desires and treatment expectations. What should the outcome look like?
Some patients may only ask to have a lost tooth restored because they were able to use it for mastication until recently, when the tooth was eventually lost.
However, a new and broader perspective has emerged in modern dentistry, based on the notion that focusing on overall function is more productive. The stomatognathic system is comprised of the maxilla and mandible including their dental arches and periodontal structures but also includes the temporomandibular joints, the masticatory muscles with adjoining muscle system, the salivary glands, and the vessels and nerves supplying the various tissue structures [4]. It must be made completely clear to the patient that appropriate dental treatment is mainly about restoring the functional unit as a whole. The objective is to ensure that the masticatory organ can meet its primary tasks of breaking down food and ensuring mutual stabilization of both jaws during swallowing. Good esthetics with teeth of pleasant size, color and shape are of secondary importance – but nevertheless still very important. Patients must be willing to maintain their new teeth (e.g. by brushing them twice daily, rinsing, and complying with scheduled recall visits).
The first conversation with the patient includes the medical history. Any problems that may have contributed to the present oral status need to be discussed and understood. The patient`s systemic health must be discussed as well. There is a need to define which teeth should be preserved and what steps should be taken for them to become healthy and stable (including measures such as caries treatment, root canal therapy, apical resection, periodontal treatment, or vitality testing).

Orthopantomographs

An orthopantomograph will normally suffice for prosthetic treatment planning. The image will reveal the state of the residual dentition, the vertical bone height, the position of the condyles, the bone structure, and the trabecular pattern. The location of the implant site can be determined as well. Both the maxillary sinus and the course of the mandibular nerve will be visible.

Clinical examination

The inspection of the oral cavity is followed by palpating the muscles, determining the jaw width, and exploring the mylohyoid line. Any systemic diseases need to be identified and, if necessary, controlled by the physician in charge or general practitioner. Examples would include diseases such as diabetes, HIV, cardiovascular disorders, hypertension, or curare patients.
The author`s personal list of contraindications also includes excessive alcohol consumption, depression, poor general hygiene, indecisiveness or lack of reliability, skeptical attitude toward the clinician or the treatment modality, and insistence on being informed about every tiny detail of treatment.
Surgery is postponed if infections of the re-

spiratory tract, herpes sores, or aphthae are present. Establishing a harmonious relationship with the patient is essential for success. Implant therapy continues to be a service that involves special requirements. This treatment should only be performed by highly competent and responsible clinicians selecting only patients with adequate levels of intelligence, demands on life, cooperation, compliance, and the ability to pay for the treatment. Implant treatment is elective in nature, to be conducted only on patients truly willing to receive them.

Treatment planning

First, a decision must be made which jaw to treat first. This should generally be the opposing jaw or the jaw requiring fewer implants. The occlusal level is determined and the vertical dimension defined by bite registration. It must be checked whether suitable implant types and sizes are available and at hand. Occlusal splints may be helpful in raising the occlusal plane. It is important to follow Camper`s plane. All conservative treatment procedures need to be planned as well.

Preparation for surgery

We use Ringer solution as a cooling agent and store it in the refrigerator prior to surgery. The solution is applied by connecting special flasks to the dental unit. All instruments, the turbine including the angled handpiece and the surgical towels are autoclaved. Special caps are worn by the clinician, but also by the assistants and the patient, to cover their hair. An oxygen bottle is kept at hand to mitigate any panic attacks and to avoid hyperventilation.

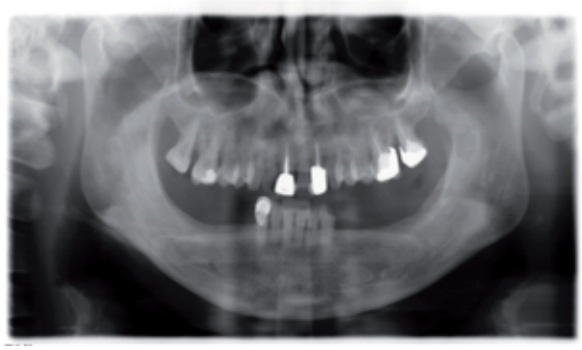
Medication

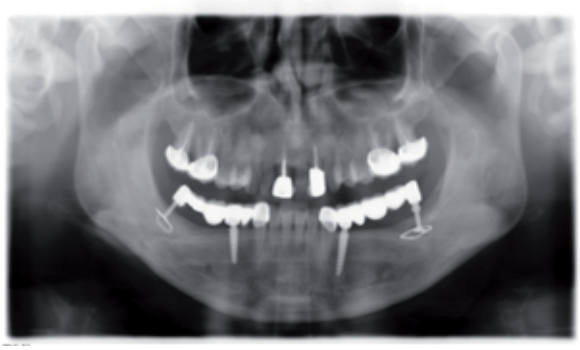
Patients without systemic diseases are given lexotanil, xanax (Alprazolam) 0.25 mg as anxiolytic medication if they become psychologically tense or experience fear. The patient should have had breakfast as usual. Men should shave to avoid contamination of suture material by facial hair. Women susceptible to menstrual symptoms such as blood loss or psychological instability should have the day of surgery scheduled accordingly. Our patients are advised to arrive at the office in company and to avoid driving after the procedure. Lukewarm sweetened tea is always on hand for drinking with a straw. Communication with the patient (eye contact, conversation) is continuously maintained. Treatment is started with preparatory procedures of operative dentistry (abrasive instruments, caries treatment, root-canal treatment, or root-tip resection). The patient`s oral cavity is disinfected with betadine and the face with rubbing alcohol.
Antibiotics are administered only to patients who required intraoperative coverage because of a concomitant disease. They are not routinely administered, however, since antibiotics do not per se improve treatment outcomes in any significant way [5]. Analgesics are offered in the form of preparations containing acetaminophen or mefenamic acid 500 mg, administered 3 or 4 times daily. Patients are advised to use chlorhexidine mouthwash solutions.

Surgical approach

The clinician aims to create a congruent implant bed by raising and reflecting a mucoperiosteal flap using specialized burs and cutters. The BOI® implant is laterally advanced into the implant with the help of gentle knocking movements. Finally, the flap is repositioned and sutured.

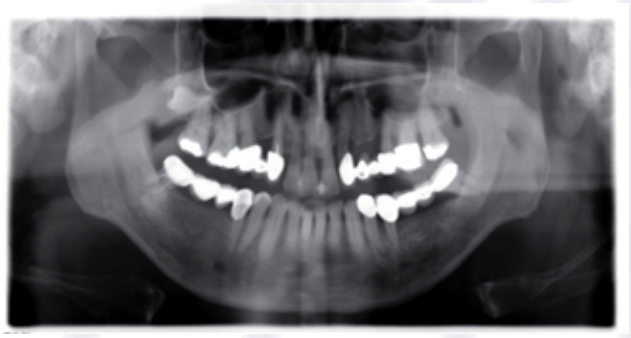
Case report 1

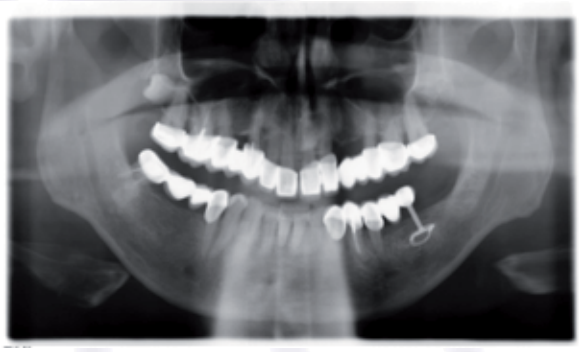




A woman born in 1963 presented at my office after a "cosmetic crown" restoration in her maxilla had fractured. After conducting a post-and-core buildup, the crown could be reinserted. However, it was pointed out to the patient that mastication was confined to her anterior teeth. The crown was likely to fracture again, and other teeth might be damaged. The upper molars were significantly elongated because their lower antagonists had been missing for several years. A removable denture was refused by the patient out of hand. Two years later, debonding of the restoration on tooth 21 occurred. Recementation was possible but did not address the underlying problem. The patient requested that her lower anterior teeth should not be prepared to serve as abutments. After obtaining an orthopantomograph, the case was thoroughly examined and a treatment plan established. Four ceramic crowns were delivered in the maxilla to guide the occlusal plane. The molars were reduced in length and the teeth treated endodontically, because encroachment on the pulp proved unavoidable. In this way, the occlusal plane could be aligned with Camper`s plane. The new shape of the dental arch is readily discernible in Figure 2. Rehabilitation of the mandible was planned as follows: One distal BOI® implant was selected for each posterior segment, and compression screws for both premolar sites. The canines were to be included in the structure as well. Treatment began by preparing the canines under local anesthesia. The BOI® implants were inserted, followed by placement of the KOS® screws. The threaded pin of the left implant was too deep (or the number of threads too small). An elongated polished abutment was therefore selected to compensate for this deficit. The ceramic bridge could be inserted after 7 days on November 20, 2006. The patient continues to be happy with her new teeth after one year of clinical service.

Case report 2



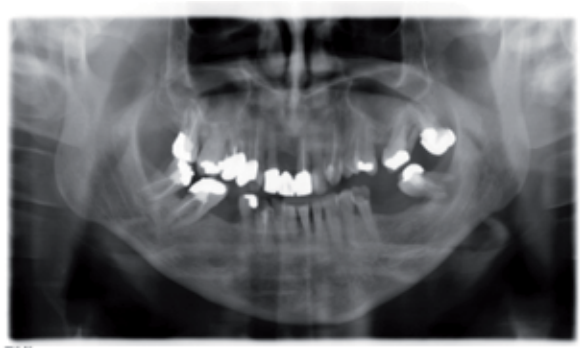


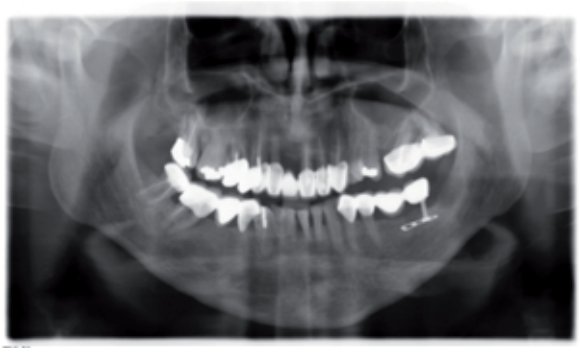
This male patient, born in 1951, had worn ceramic crowns in the posterior segment over many years. At the time of presentation, the teeth were periodontally compromised and involved crown margins located 2 to 3 mm above the gingival level.

A treatment plan was developed after conducting an extensive conversation and examination. The roadmap was to remove the maxillary bridges, treat the existing periodontitis, and fabricate new ceramic bridges including all existing teeth. Molar 18 was fully intact and was therefore preserved, which was unusual. This was followed by restoring the right half of the mandible, thus determining the occlusal plane and paving the way toward restoring the contralateral cantilever situation. Teeth 33, 34, and 35 were prepared and subjected to vitality testing in a single session. This was followed by placing a BOI® implant and taking an impression. The final ceramic bridge could be inserted 8 days later on May 25, 2006.

At almost two years, the patient has complied with periodic recall visits and improved his oral hygiene status. He continues to be happy with his fixed restoration and about the fact that it had been implemented rapidly and at reasonable cost.

Case report 3

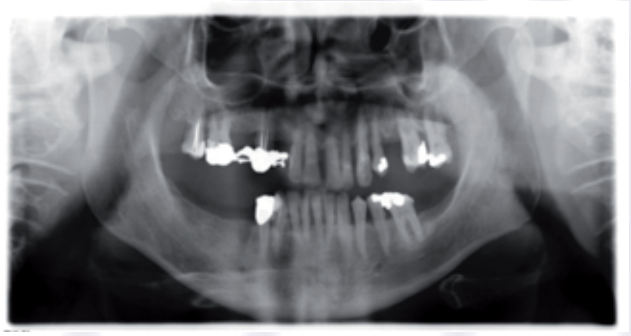


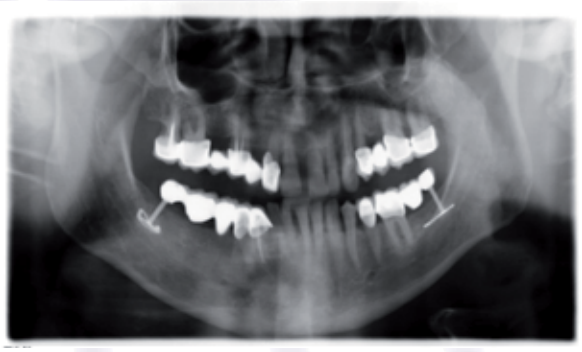


This woman, born in 1958, was in good general health. Mastication was confined to the anterior segment. This situation was compounded by increasing mobility of the lower incisors. Dental treatment was therefore mandated. A treatment plan was developed after duly completing the required discussions with the patient. Two bridges were planned in the upper anterior and lower right posterior segments. Molars 27 and 28 were to be preserved. Considerable abrasive reductions were required because a considerable divergence was present between the teeth. All teeth were treated for periodontitis. Upon completion of these steps, the left posterior segment of the mandible was addressed. After taking an impression of the maxilla, teeth 34 and 35 were prepared with abrasive instruments and tested for vitality. Tooth 38 was hopeless and had to be extracted. In the same session, the jawbone was thoroughly cleared of granulation tissue, followed by inserting the BOII® implant infero-anteriorly to the socket of the extracted third molar. The load-transmitting segments of the implant were located in the linea obliqua region, which is safe from resorption. This jawbone region offers an enhanced regenerative tendency compared to other regions due to the local stresses involved[6]. The baseplate of the BOI® implant was located in the basal segment of the mandibular jawbone.

This was followed by taking an impression of the mandible. The final ceramic bridge could be inserted 7 days later on February 5, 2008.

Case report 4





This male patient was 57 years old. The maxillary rehabilitation had just been completed. The next step was to treat the mandible. Cantilever situations were present bilaterally. The patient was offered two options: he could make do with a denture or opt for an implant-supported rehabilitation. All abutment teeth (43, 44, 35, 36) were prepared with abrasive instruments in a single session. BOI® implants were then placed bilaterally in distal positions of the mandible. After impression-taking, the bridges were fabricated in the laboratory and could be delivered as final restorations within 7 days of implant placement. Both BOI® - supported bridges have now been in situ for over three years. The patient has complied with his periodic recall visits.

DISCUSSION

BOI implants are used to transfer masticatory forces to the jawbone *instead of lost teeth*. The force-transmitting disks are designed to offer bicortical support by transosseous positioning. Cortical bone is dense and stable, offering an ideal level of load-bearing capacity. It is superior to cancellous bone (where conventional implants are inserted in the traditional way) in all respects. The basal jawbone area is safe from resorption. Achieving bicortical support in that region is essential to the success of implant therapy, whereas the amount of vertical bone present above the level of the basic disk becomes largely irrelevant. This bone-anchored disk connects to the prosthetic structure via the shaft of the BOI® implant. The length of this shaft may vary depending on the desired level of the occlusal plane along the bridge. We do not replace bone but rely entirely on available bone to anchor implants. This strategy eliminates the need for any adjunctive measures involving bone grafting or osseodistraction, reducing the overall risk of treatment and avoiding waiting periods. This makes the procedure easier to handle and more benign on patients.

Bicortical support allows blood to be supplied to implants that have been freshly inserted in posterior regions of the mandible through three different arteries: the mandibular artery inside the jawbone and the lingual/facial arteries in the periosteum on both sides of the mandible. This blood supply will improve wound healing and implant integration as well as implant function.

Short crestal implants with large diameters have not turned out to yield good results in clinical practice[6]. The blood supply is confined to the mandibular artery in treatment strategies of this type and is further restricted by the compact volume of these implants.

Also, the surface area for transmucosal bacterial colonization is increased due to the large diameter of these implants. BOI® implants feature shafts that are both very thin and highly polished. The surface for bacterial colonization is much smaller. Consequently, the condition of "peri-implantatis" commonly observed with crestal implants does not occur in basal implantology.

CONCLUSION

BOI® implants are a method of first choice whenever the function of the entire stomatognathic system needs to be restored by prosthetic rehabilitation of the mandible, even (and precisely) if little bone is available.

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Clinical Research

Outcomes of immediately loaded full arch reconstructions on basal implants and teeth in the mandible: retrospective report on 115 consecutive cases during a period of up to 134 months.

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ABSTRACT

We report on a retrospective review of outcomes after the insertion and usage of basal implants alone or in combination with natural abutments for treating patients with full arch bridges in the mandible. From June 1996 to August 2007, 115 consecutive patients seeking implant treatment in the lower jaw received 457 basal implants and a total of 130 bridges thereon. Only cases where basal implants were used alone or in combination with teeth were included. During the observation period no patient seeking treatment was turned away for any reason. Teeth were included into the constructions whenever available and in an appropriate location and condition. The mean age at implant surgery was 60.7 years. Even in cases of severe bone atrophy, no augmentations were performed. All patients received fully loaded fixed bridges between 3 to 12 days postoperatively. Whenever implants had to be replaced after extractions, this was done in one surgical step without waiting or healing time. An overall success rate of 93.4 % was observed. Basal implants alone or in combination with stable teeth can securely be placed and used in immediate load protocols to form a base for full arch bridges in the edentulous or partly dentate mandible.

KEYWORDS

Basal implants, BOI®, Diskos®, immediate load, immediate implant placement, full arch mandibular reconstructions.

INTRODUCTION

Placement of circular bridges on basal implants in immediate load conditions is a frequently performed procedure and there are various reports on this procedure in the literarture[1, 8, 11]. Other than in axial (crestal) implantology, the restoration of basal implants is in most cases done by a fixed bridge: telescopes are contraindicated and bar-based restorations are rarely delivered. Due to the straight forward treatment protocol and the possibility to avoid intermediate prosthetical constructions, the overall treatment costs are low. All these aspects reflect the desire and expectations of the overwhelming majority of the patients [13].

Atrophy is the result of a lack of bony stimulation and nutrition. Generalized diseases may

aggravate the disease and promote the bone loss.[3,4]

The management of quantitative and/or qualitative poor bone with root-form dental implants typically requires additional procedures to ensure sufficient stability[5], with augmentations, bone transplants or distractions being the most "popular" procedures. The management of the atrophied distal mandible with axial implants imposes special problems, since the nerve canal forbids in many cases the usage of the full amount of vertical bone in the zone bearing most of the chewing forces. Augmentations and distractions in this region are difficult and associated with considerable patient discomfort. If teeth are to be extracted, additional waiting time before equipping the mandible with axial implants has to be considered. Additional treatment steps such as augmentations and distractions add risks to the procedure, delay loading, and increase costs.

Basal implants are placed transosseously and at least one base-plate is bicortically anchored in the basal, cortical bone. Basal implants utilize the horizontal bone supply as well as the cortical bone walls; therefore, they are well suited for placement immediately after extractions. It is understood today, that basal implants undergo a dual mechanism of integration: ring areas in direct, primary contact with the native bone show primary integration though osteonal remodeling also occurs. Empty slot areas (the void space left after osteotomy and insertion) fill with callus, which later undergo osteonal remodeling[13]. This dual integration also allows placement of basal implants right into extraction sockets of teeth or implants and other cavities, e.g. empty spaces left after cystektomies or granulation removals, or may even be applicated trans-sinusally.

There is a long tradition in combining basal implants with stable teeth. As a matter of fact, professional who use basal implants continue to discuss whether to do so or not which should be validated by such data analyses as reported in this manuscript.

METHODS

SUBJECTS

From June 1996 to August 2007, 115 consecutive patients (60% female) receiving 457 basal implants and 130 full arch prosthetic constructions in the mandible thereon were enrolled in this study. All patients seeking implant treatment during this period have been treated using basal implants alone or in combination with natural abutments. Patients receiving at least one screw type implant were excluded from this study, because their inclusion would make distinction between the benefits of these two implant types difficult and would not allow reporting on the independent performance of basal implants. The surgical and prosthetic treatments were all performed by the same group of clinicians. The mean age at implant surgery was 60.7 years (SD=9.8; median=61; range: 33 to 80 years, Fig. 6). The average number of implants used per circular bridge was 3.9 and on average 3.5 teeth were included into the constructions. Sixty-seven constructions on 330 implants were erected only

on basal implants, without teeth -, with three implants being the minimum and eight implants being the maximum number of implants used for the fixation of these mandibular bridges (Average number of implants in this subgroup: 4.9 basal implants per mandible), thirty edentulous mandibles received four strategically placed basal implants only. A typical treatment plan with teeth includes the six front teeth and two basal implants placed in the area of the 2nd molar (Fig. 3), typical treatment plans without teeth would include basal implants at least in the strategic positions of the canines and second molars (Fig. 2, 4).

IMPLANTS

Basal implants consist of a thin vertical shaft (1.9 – 2.3 mmd) and one to three horizontal base plates, designed for cortical load transmission. (Fig.1) Unlike the traditional axial ("root-form") implants, which are inserted vertically and primarily designed to be supported by trabecular bone, these implants are inserted from the lateral aspect of the jaw bone into a T-shaped slot created by high-speed precision instruments, providing bi- or multi-cortical support and immediate fixation even if placed in extraction sites right away. Hence, they are commonly called "disk" or "lateral" or "basal" implants [10].

BOI® implants transmit the masticatory forces into cortical bone areas and they are placed to utilize resorption free bone areas, such as the interforaminal region and the bone below the linea oblique in the distal mandible. The site of force transmission is far away from the area of bacterial invasion; hence base plates never develop infections as long as they are well integrated. The vertical implant shafts are not meant to transfer masticatory loads directly to the bone, hence they are relatively thin and allowed to be machined or even polished. As a result peri-implant infections are never seen in basal implants. Basal implants have proven to be well suitable for smokers.[12]

During the treatment- and observation period, the manufacturer has made a number of small changes in the implant design and this study does not distinguish between the different types available at their times, since treatment protocols and indications did not change. As a principle, the fixed bridge on basal implants (Brands: BOI®, Diskos®) serves as an immediate external fixation for the implants. The bridge also distributes the masticatory loads between the implants and it allows masticatory function at the same time.

SURGICAL TECHNIQUE

Under local anaesthesia, an appropriate full thickness flap is raised. Using high-speed precision cutters, the implant bed is prepared which provides the appropriate number of vertical and horizontal slots for the chosen implant. Basal implants must always be inserted bicortically and trans-osseously. The implants are inserted (depending on the anatomical condition and the desired position) from the lateral,

medial or palatinal aspect of the jaw bone with careful tapping action until full bi- or multicortical support is achieved. The presence of sufficient support is verified visually or manually by testing with the fingers. The implants may also be fixed horizontally by use of bone screws (Brand: SSF), when primary stability cannot be achieved right away, e.g. when the implant bed is not exactly congruent to the implant or parts of the implant cannot reach cortical walls, or if these walls are missing after the extraction of teeth or soft tissue.
A flapless, trans-mucosal insertion is not possible for basal implants.

OUTCOME EVALUATION

Implants were counted as successful, if they are in situ at the point of observation, connected to a bridge in function, if they allow mastication without pain or visible infection, and if no indication for their removal according to the "Consensus on BOI®" was given [14].

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 basal implants are designed for immediate loading (meaning that immediate loading is the method of choice and late or delayed loading is a rather poor, even

RESULTS

Patients were followed for a mean of 67.1 months (Median=69.5; SD=28.8; range: 3- 134 months, Fig. 7) in this study. Six patients (5.2%) with 16 implants (3.5%) were lost to follow-up for different reasons. Patients refraining from follow-up for more than12 months were excluded from the study and counted as drop out. Another seven patients (6.1 %) died during the observation period with all of their implants (n= 30; 6.6% of all implants) in full function. Those cases and implants were kept in the study but the implants were censored at the point of death. All implants were loaded immediately or within the first 24 hours after the implantation with a fixed temporary or permanent bridge. Fixation of the second, more permanent, prosthetic construction followed in subsequent days after surgery in most cases. In extraction cases, "final" bridges were delivered after 6-18 months if requested by the patient. We found an overall survival rate of 93.4% of the implants during the follow-up period.

If was reported after the healing period mobility of the implant causing an internal irritation of the periosteum was the most common cause. In cases where the implant could be left in place [14], this was addressed by a occlusal reorganization, i.e. grinding or building up chewing surfaces, thus relieving the interface region between the endosseous implant part and the bone from overload and allowing the peri-implant bone to recover and to remineralize. In the distal mandible, vertical bone growth even along the implant was observed regularly

[12]. Two implants had to be removed, because the vertical bone growth did not allow cleaning of the site any more and recurrent infections occurred. The replacement implants were situated more anteriorly. At the time of the first intervention, a more anterior placement of the implant had not been possible, because the available bone crestally of the alveolar bundle of vessels was less than 1 mm. Only at the time of the second intervention, enough bone whose growth had been induced by functional stimulation and/or the remodeling following the first intervention, had been available. (Fig. 10a, 10b). For the replacement of the implant, the bridges were shortened and the new implant parts were connected to the existing bridge by means of over-cementation. Those two implants were not counted as a failure since they did not meet the criteria of failure. Fifteen (13%). bridges had to be renewed completely, following implant and/or tooth loss. The majority of the renewals were caused by tooth associated problems (decay, decementation of bridge, loosening of posts inside root canals followed by loosening of the bridges), often followed by implant loss due to overload (and subsequent mobility) or even implant fracture.
Implant losses (n = 30) occurred mainly during the first four years after implant placement (Fig.8), with the mean time of lost implants in function being 783 days (Std.-Dev. 530 days).

DISCUSSION

We report a 93.4% implant survival rate among a consecutive series of 115 patients receiving 457 basal implants and a total of 130 fixed circular bridges in the mandible.
This result is great, that even cases of severe atrophy were treated in one surgical intervention with basal implants, thus avoiding augmentations and bone transplants. Combined with the early external fixation via the bridges, this implant system responds well to early load analogous with physiological forces observed orthopedic surgery with early partial weight bearing. Living healthy bone will be remodeled and grows with daily use. It may be possible to minimize the antagonistic contacts in subtotal constructions to reduce the initial forces, but in circular bridges on implants this is impossible. So the application of a real immediate loading protocol is necessary. All patients were treated under local anaesthesia in a regular dental office. The average absence from work was 1.9 days for the initial treatment phase. No one stopped working for more than one week. Most of the patients went back to work on the day after implant placement. None of the patients including those showing severe atrophy, had to be hospitalized.

There are limitations to the present study. The design of the basal implants used during the years has been improved by the manufacturer and we do not distinguish between the different designs. One major change in design which occurred approximately 1999 was that no surface enlargening (i.e sandblasting) was

administered to the vertical implant surface. This change eradicated the crater-like bone losses found earlier in some of the basal implants of the sandblasted shaft type. Later, no sand-blasting was not performed at all, i.e. basal implants are completely machined today (Fig.1). Another change in double-disk designs occurred approximately in the year 2000. From this point, the crestal base-plate was manufactured with more elasticity than the basal plate. Subsequently translucencies around the crestal plate, occurring in about 10-15% of those implants, were not observed any more. A slight increase in the thickness of the baseplate (0,1 - 0.2 mm) may have contributed to the fact that no fractures were seen in implants placed after 2002. Triple-base-plate designs with strong primary stability were introduced about the same time period. Those small changes and developments have combined with our learning curve and have made the treatment even more predictable in the last years of observation (Fig.9); it must be taken into account also that at the time when we started using and exploring the basal approach in implantology, no teaching and no textbooks were available and the author and his group as well as associated colleagues interested in this technique have learned the handling and possibilities auto-didactically. Losses of implants during the period 1997 – 2002 were unavoidable.

As progress in axial implantology occurs, many cases classified "untreatable" earlier, are treated today with screw type implants with considerable success, although for many patients, the installation of fixed teeth on those (axial) implants remains impractical. We feel that the patient cases which reached our office in the last years have become more difficult to treat and atrophies treated in our center became increasingly severe, because patients with more available bone at the start of treatment find a capable screw- implantologist easier today and they are not referred so easily. A new group of patients is seaking this treatment because of the possibility of immediate loading and avoiding risky, time consuming and expensive bone augmentations. This group is increasing.

Furthermore we have not treated a control group with bone augmentations or distractions, since this was not the desire of our patients. For patient cases presenting with severe bone atrophy (as shown in Figure 2 as an example), no realistic alternative treatment plan could be developed, carried out, or used as a comparison. The primary reason that none of our patients expressed the wish to have "more bone", was their desire for "fixed teeth" and they knew that our clinic offers straight forward treatments without augmentations or waiting times. So the "alternatives" simply wouldn`t sell in the same dentists office. We have asked several other centers from whom we knew that they provided heavy maxillofacial surgery, distractions and bone augmentations during the same period of time, to contribute their retrospective data for comparism with our result. None of the centers receiving our inquiry was willing to release data or to cooperate. However one of those centers, after seeing our results and how we solved the cases, changed the way of

treatment drastically. Bone augmentations are not performed any more in this center and the system of basal implantology was impemented and is used more and more today. And finally, some patients seeking additional implants after screw implants have been placed in the anterior mandible were treated during the observation period. We have placed BOI® in the distal mandible to allow placement of a fixed bridge. These cases of "upgrading" are not included in this report because it could be argued that the outcome of this treatment could be mainly due to the integrated screw implants alone. Inclusion of those cases would not make the this report stronger.

This is a case series and can be compared to historical publications. Our survival rates are very similar to those found in the literature.[6-8,10-12] Diskimplants® are similar in design and function to BOI® implants and have reported rates of successful osseointegration of up to 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 implants were osseointegrated, with all fixed prostheses remaining functional during the study period.[6] However Scortecci combined crestal and basal implants, which makes it difficult to distinguish between the merits of these designs on their own. This study shows that BOI® 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 anterior natural abutments. Osseointegration was achieved in 97.3% (n=254) of implants at final follow-up. Fifteen implants were lost.[7] The results are similar to our findings.

Donsimoni et al performed a retrospective case series evaluating 1352 consecutive basal implants placed over a 10 year period in 234 circular bridges.[8] 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, whereas reports from axial implants indicate opposite results[9]. 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 (4.9 per jaw). The results presented in this article are consistent with our findings. Neither Scortecci, Ihde & Mutter or Donsimoni distinguished between placements into fresh extraction sockets and placements into healed bone.

The strengths of this study are many. Since we did not exclude any patients who presented to our clinic, even those sent away by colleagues, we feel that our findings are without any exception generalizeable. this includes patients who typically may be turned down due to poor bone quality or recommended to receive bone augmentation procedures, or simply are otherwise "untreatable" (Fig. 2). According to our findings,

these patients are good candidates for basal implants. This is a consecutive series of patients and hence does not represent a convenience sample or a select group.

CONCLUSION

The standard procedure for placing basal implants includes one surgery followed by immediate loading, thus reducing time, cost, and stress to the patient.[9-13] With the emphasis on horizontal rather than vertical placement, pre-implantological bone augmentation was never necessary. Estimated decrease in cost compared to augmentation-cases is ~ 50%. Compared to cases where augmentations and two-stage implant protocols are the chosen alternative, up to 95% of treatment time is saved[11]. There is no hospitalization required, no time period without proper masticatory function, no second surgery, no bone transplants, no bone distractions. We have observed for basal implants a success rate of 93.4 % during an observation period of up to 134 months. All lost implants were replaced in one single surgery where necessary. All patients reached and maintained the treatment aim of a fixed mandibular prosthesis. This indicates that the immediate placement and loading of basal implants for treating the mandible with fixed bridges, with or without inclusion of available teeth, is a safe and effective way of treatment.

Figure 1.

Typical one-piece basal implant (BOI®) with a broad, cortically anchored load transmission area, a thin and polished vertical part, bending zones, and abutment for cementation.

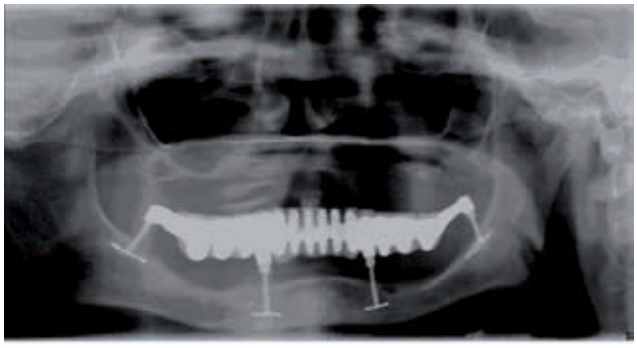

Figure 2.

Atrophied mandible after treatment with 4 BOI®-implants in strategic positions, 6 years post-operatively.

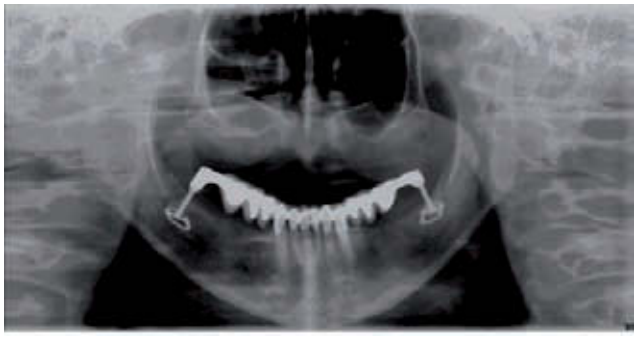

Figure 3.

Two BOI® implants used in combination with 6 anterior teeth, 7 years postoperatively.

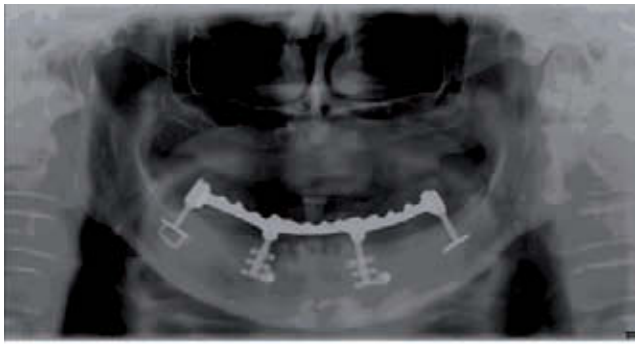

Figure 4.

Four BOI® implants are serving as a base for a full arch bridge in the mandible. The anterior implants are secured by horizontally inserted bone screws to enhance the primary stability (48 hours postoperatively).

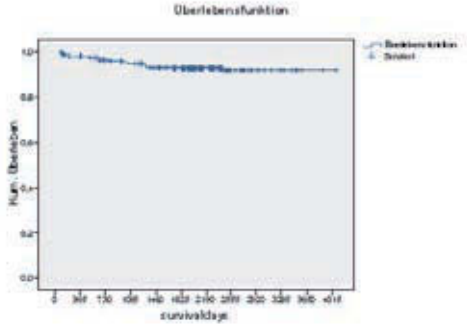

Figure 5.

Survival function for all implants during the observation period.

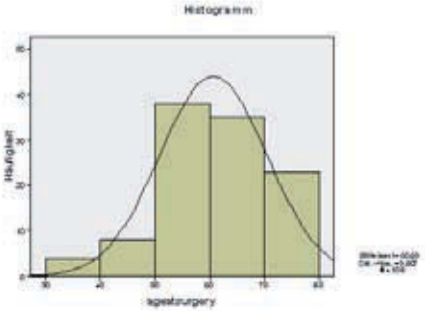

Figure 6.

Age distribution of patients treated during the observation period.

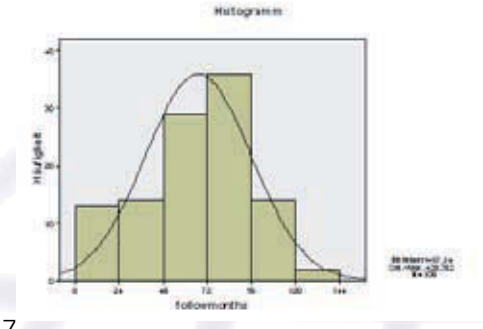

Figure 7.
Distribution of follow up times in this case series.

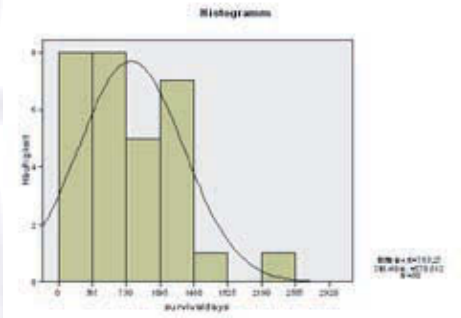

Figure 8.
Distribution of follow up times in this case series.

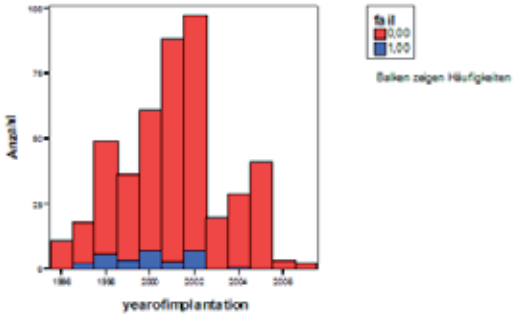

Figure 9.
Implant losses (blue) related implant placements (red) in the year of implant placement. The majority of the losses occurred in implants placed 1997 – 2002.

Fig. 10a, b:
Replacement of this BOI® implant in area 37 became necessary after vertical bone growth has made cleaning of the site impossible. The new implant was placed anteriorly, using the bone which had newly developed as a result of functional stimulus.

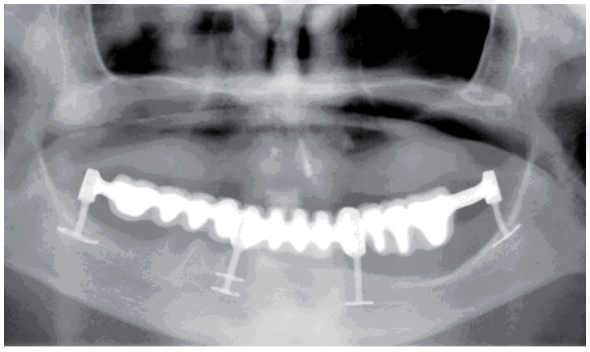

Figure 10 a.
Postoperative X-ray

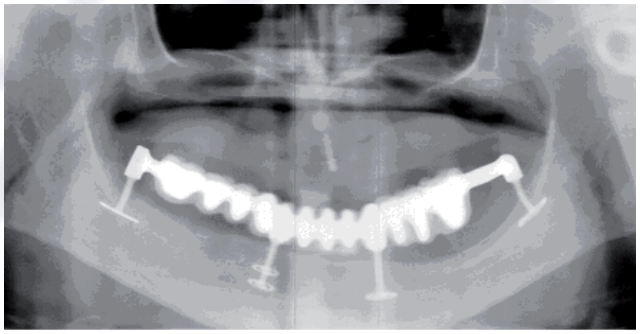

Figure 10b.
Control radiograph 18 month later.

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Case Report

Immediate loading of a maxillary full-arch rehabilitation supported by basal and crestal implants

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ABSTRACT

The present article discusses an approach of implant treatment taken in a patient with pronounced maxillary atrophy. Immediate loading with a fixed restoration could be offered and successfully implemented with the help of BOI® implants and tuberopterygoid screws despite an inadequate bone volume in the vertical and horizontal planes.

KEYWORDS

Basal implants, immediate loading, jaw atrophy, tuberopterygoid implants

INTRODUCTION

The present article discusses the case of a 54-year-old female patient who was referred to our office for treatment with dental implants. The initial examination revealed that her dentition was in a desolate state, including hopeless residual teeth and a mobile existing bridge. Even though the patient had been highly skeptical, her previous dentist treated the case with a complete denture. This solution fell short of adequately meeting the patient`s needs. She failed to adapt to the removable restoration and struggled with a gag reflex.

Severe bone atrophy was observed distal to sites 14 and 24. The resorption was progressing from a cranial and a caudal direction. This was compounded by the presence of an extremely narrow alveolar ridge along sites 13 to 23, which was not going to allow for any screw-type implants to be used unless extensive bone grafting was performed. The patient was adamant that an additional surgical procedure for bone augmentation was out of the question. This attitude was based on negative experience reported by some friends. Rather than undergoing bone augmentation, she would have abandoned her plan of having implants inserted, carrying on with her denture instead despite all the problems involved, had we not offered a treatment plan without bone augmentation.

PROCEDURE

After the first information and counseling session, the patient immediately asked to have appointments scheduled for implant placement. All treatment and follow-up appointments were immediately scheduled.

The existing denture was used both for bite registration and to take a silicone impression, which provided the basis for implementing a temporary fixed restoration immediately after implant placement. Vestibular and palatal anesthesia was applied. A mild sedative was administered. Betadine was used for local disinfection. Generous incisions (18–11 and 21–28) were performed and flaps reflected in palatal and vestibular directions, with exposure of the palatal artery. This approach also enabled the clinician to visualize precisely the morphology of the tuberopterygoid region. The following implants were placed: one TPG screw (4.1 19 mm) at site 28, one EDDS 9/7 h4 implant at site 24, and one EDDDS 7 h6 implant at site 23. Due to their narrow transmucosal profile (approximately 2 mm), basal implants of the BOI type can frequently be placed in areas that would otherwise require bone splitting or augmentation. For wound closure, we use 3.0 silk or other non-resorbable materials. The threads are used during the first two postoperative days. We therefore like to use silk sutures, as they are durable and amenable to knotting.

Subsequently, the jaw segment 11 to 18 was prepared, including palatal and vestibular reflection of a large flap. A TPG screw like the one at site 28 (4.1 19 mm) could also be placed at site 18. The same implants could be used on the contralateral side as well. All maxillary implants were placed in a single surgical procedure lasting around 90 minutes. Immediately after the surgical phase of treatment, an anesthetic was once again injected on the vestibular and palatal aspects for optimal relief of cellular stress. In addition, Celeston Chronodose 2 ml was injected intramuscularly into the vestibulum to mitigate pain and swelling.

Impression copings were inserted for the impression in a slightly viscous material (Impregnum). Good results have been obtained with this material due to its high dimensional stability and optimal consistency (will not flow into wounds). Then the tuberosity screws were covered with healing caps. Note that these must not be tightened firmly. A facebow was used for recording to allow mounting the casts in an adjustable articulator.

The second appointment took place 2 days after the procedure, including suture removal and a framework try-in. Another bite record was obtained with the framework in place, and an orthopantomograph was taken. Radiographs of this type, however, are not mandatory, because the transosseous implant positions can be readily verified by visual inspection during surgery.

A temporary resin bridge was used for initial restoration. Four days after the intervention, the ceramic bridge was inserted in a temporary fashion. Temp Bond was used on the cementable abutments and screw retention on the tuberosity screws.

DISCUSSION

The patient presented in this case report had been rejected as untreatable elsewhere. Nevertheless, we were able to deliver a fixed ceramic bridge to her in a matter of days. It remains to be seen whether gingival recession will occurs that might require a new bridge. Our policy is to make financial concessions, should a need for refabrication arise, by charging only the additional laboratory costs while accepting a greatly reduced treatment fee. Adaptations to the gingival margin are unavoidable after immediate loading of implants. For this reason, immediate loading of implants can only be performed in sporadic cases. These are almost exclusively confined to the mandible and cannot include situations with implants immediately placed in fresh extraction sockets.

The case presented could not have been resolved with crestal implants alone. The available bone volume was minimal both vertically and horizontally. Since the patient insisted that bone grafting was not to be performed, treatment without basal implants would have been both impossible and a source of frustration for the patient and our office team alike.

One should be concerned about the fact that numerous "implantologists" had failed to offer an acceptable treatment plan. It took a long journey for the patient to find out about basal implant treatment as routinely performed in our office.

We have been discussing this case in great detail to inform general dental practitioners and "family dentists" about the excellent possibilities of combining basal with crestal implants. Based on this implant combination concept, treatment can be offered not only in the presence of inadequate bone volume but also if a bone graft procedure is not accepted by a patient. This may well be the case because augmentation procedures will almost invariably involve a waiting period during which the patient is left without teeth.

References available from the author.

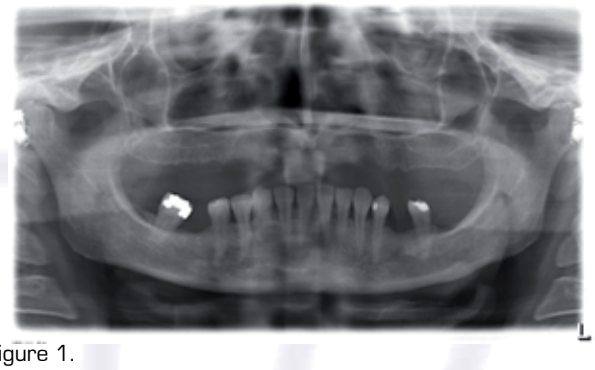

Figure 1.

Panoramic view of the upper and the lower jaw before the implant placement

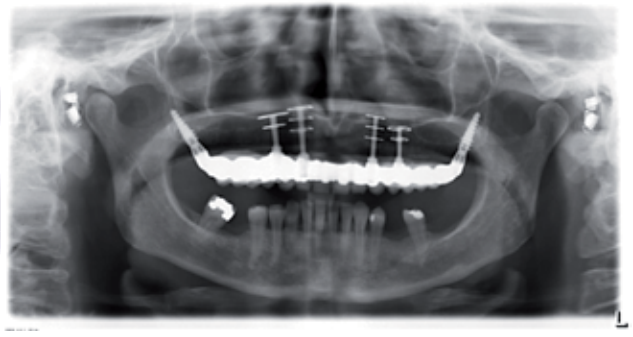

Figure 2.

Panoramic view 6 months postoprative, showing well integrated and functinally loaded basal and crestal implants. The lower jaw remains to be reconstructed

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Research in Context – Part III

Random Assignment: Let chance be your friend.

Teaser

Not all study designs are created equal. Randomized controlled trials are the best study designs for minimizing bias. In this issue of Implant Directions, learn the characteristics (random allocation, concealment, and intent to treat) of a randomized controlled trial and why these are important in minimizing the potential bias that may occur in the other study designs described in the last edition of Implant Directions.

Text

The goal of a clinical trial assessing treatment is to obtain the most accurate and unbiased effect of the treatment. One important way to help minimize bias is to select the best study design to accomplish your purpose. The randomized controlled trial, though often difficult and sometimes unethical to perform, is the most effective way to minimize bias when comparing two treatment techniques.

Random allocation

- Patients who are recruited to participate in studies should represent a relatively broad sample from the potential target population.
- It is important for the authors to describe the study population to ensure that conclusions made are not only valid, but also apply to the patient population to which one is interested in making inference.
- Ideally, comparison groups are comprised of participants who are similar in all respects, with the exception of the particular intervention(s) that is being studied. The best method to achieve this similarity between groups is that of random allocation or random assignment.
- The study design utilizing random allocation is the randomized controlled trial (RCT).

Ideally, comparison groups are comprised of participants who are similar in all respects, with the exception of the particular intervention(s) that one is studying. The best method to achieve this similarity between groups is that of random allocation.

Random allocation is a method of dividing subjects into groups in such a way that the characteristics of the subject do not affect the group to which they are allocated. To achieve this, we allow chance to decide to which group each subject is allocated. Thus, each subject is equally likely to be allocated to any of the available groups, and any differences between these groups happen by chance.

Concealment

It is important for investigators to keep treatment group assignments unpredictable over the course of a study. In other words, a participant`s treatment allocation should not be revealed until they have been officially enrolled. This helps to prevent the bias that can arise when either caregivers or patients delay enrollment until they think chances are better of receiving a desired intervention. The most popular methods for allocation concealment include:

- Having a central study office that performs the randomization and is telephoned upon participant enrollment.
- Using sequentially numbered, sealed, opaque envelopes that contain treatment group assignments.

RCTs that use non-concealed randomization are otherwise known as Quasi-RCTs. These are studies that allocate participants to different forms of care that is not truly random; for example, allocation by date of birth, day of the week, medical record number, month of the year, or the order in which participants are included in the study (e.g. alternation). This type of allocation is more prone to selection bias.

Intent-to-treat

Sometimes patients in a clinical trial are assigned to one treatment group, but for a variety of reasons, receive the other treatment. When this occurs, subjects should be analyzed as if they had completed the study in their treatment groups, which were formed by randomization. This is called intent-to-treat. If the composition of each treatment group is altered in the analysis, one negates the intention of the randomized trial design – to have a random distribution of unmeasured characteristics that may affect outcome.

What Methods are Concealed?	
Use of Hospital Chart Numbers to Randomize Patients	NO
Alternate Patients Sequentially to Treatment and Control Groups	NO
Assign by Patient Date of Birth	NO
Assign by Day of Week or Month of Year	NO
Place Patient Treatment Allocation into Sequentially Numbered, Sealed and Opaque Envelopes	YES
Use Central Telephone Randomization System	YES

When this happens, the randomized trial in effect is converted to an observational trial (e.g. cohort study). For example, consider a trial omparing machine surfaced versus chemically conditioned surfaced dental implants, where 50 patients are randomly assigned to receive either machine surfaced (n=25) or chemically conditioned (n=25) implants. Let us imagine that 5 of the patients randomly assigned to the chemically conditioned group actually required machine surfaced due to a contraindication for the chemical being used. The investigator is now faced with three possible ways to analyze the data in this situation. If she chooses to discard the 5 who were suppose to get chemically conditioned implants but actually received the

machine surfaced implants, or if she adds them to group randomly assigned to receive the machine surfaced implants, the beneficial effects of random assignment are diminished. The correct analysis is the intent-to-treat analysis as demonstrated below.

Figure. Illustration of Intent-to-treat Analysis.

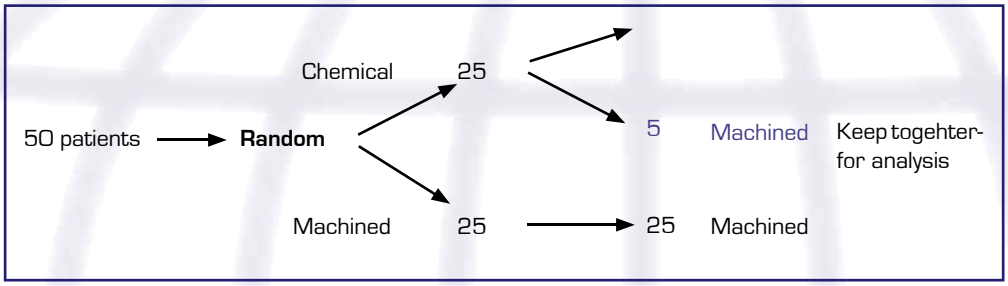

Table 3. Evaluation of articles examining implant placement in patients with and without a history of periodontal disease

Type of Analysis	Comparisons made
"Intent-to-treat" Correct analysis	Compare the 25 machined implant patients with the 25 randomized to the chemically conditioned implant group (20 chemical plus 5 machined)
"Per protocol" Biases results	Compare the 25 machined implant patients with 20 who received the chemically conditioned implants; discard the 5 machined implant patients who were randomized into the chemically conditioned implant group
"Treatment administered" Biased results	Compare 30 machined patients (5 machined implant patients who were randomized to the chemically conditioned implant group but who actually received the machined implants plus the 25 randomized to the machined implant group) with 20 chemically conditioned implant patients

Intent-to-treat analyses are the best way to assure bias due to an unequal distribution of certain risk factors (i.e., confounding) will not play a role here. The price paid, however, is typically a reduction of any observed associations between treatment and outcome – any treatment effect found in an intent-to-treat analysis is likely to be a conservative estimate of efficacy.

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