Cranio-maxillofacial

Implant Directions

No.1 December 2006

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IMMEDIATE LOADING

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BONE AUGMENTATION - PART 1

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BUSER ET AL: IMPLANTS IN "AUGMENTED" BONE

ISSN 1864-1199 / e-ISSN 1864-1237

Published by IF Publishing, Germany

Single Issue Price
Euro 30
Annual Subscription
Euro 120

Contact
publishing@implantfoundation.org

CMF.Impl.dir.
ISSN 1864-1199
e-ISSN 1864-1237

Welcome to the inaugural issue of Implant Directions!

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

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

As you know, it becomes increasingly difficult as clinicians to keep up with the scientific literature. You may also be aware that many aspects of implantology, dentistry and medicine are beginning to focus more and more on "best-evidence" for clinical decision making. In addition, government agencies, payers and others are looking at "best-evidence" for making policy decisions to a larger extent.

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

Hot topics!

What do colleagues feel are the hottest topics in implantology? An international team of expert implantologists and epidemiologists collaborate in discovering the important topics of our day.

Evidence!

What really is the "Evidence" to support or refute the latest methods for treating implant patients? While clinical opinion and expertise is important, it MUST be balanced with clinical research. More and more evidence is becoming available in the literature. The challenge is finding it, evaluating it, and summarizing it.
"Implant directions" does that for you!

"Implant Directions" is proactively leading the way for implantologists to keep up to date with the "best evidence". This unique publication will allow implantologists to critically look at the scientific evidence. This benefits our patients by incorporating best evidence into our clinical decision making. As a discipline, we benefit from a better understanding of the strengths and limitations of research in our area. This in turn assists us in designing better research that will ultimately advance our field.

The purpose of ID is to present to you in each issue an array of articles designed to present you the "best evidence" on specific treatment topics, to critically evaluate previously published papers in our field, and to stimulate your thinking with respect to new and innovative ways of managing future implant patients. In each issue, you can look forward to the following types of articles and features: Evidence Reports (ERs), Literature Analyses, Critical Appraisals, Research in Context, Case Reports, and Clinical Notes:

1. **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 the only implantology publication that provides such attention to detail in balancing science with clinical opinion in such a clear, concise, and visually-friendly presentation.

2. **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.

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

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

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

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

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

Best regards,
The ID team

Evidence Report

Effect of immediate versus non-immediate loading of dental implants on implant survival and complications

Summary

Cumulative survival rates were similar comparing immediate to non-immediate loaded dental implants in all studies. One study found better survival rates in the immediate load group within the maxilla only. There are conflicting findings with respect to periotest values and bone loss comparing the two groups. There appear to be no clinically significant differences. Further, immediate loading is not associated with increased peri-implant soft tissue parameters or post-operative complications. Additional methodologically rigorous comparative studies, and studies evaluating other implants and other treatment protocols, are needed to better evaluate advantages, chances, risks, disadvantages and problems of immediate loading in dental implantology.

Sampling

A MEDLINE search was performed to identify recent studies published between January 2000 and October 2006 examining the effect of immediate versus non-immediate loading of dental implants on treatment outcomes. From a list of 32 articles, five evaluated the treatment comparison of interest. We included studies where late loading protocols were used, loading the implants not earlier than three months after implant placement. Four articles which included outcomes on implant survival met our criteria and are included in this report.

Studies

Study 1

Schwartz-Arad D, Gulayev N, and Chaushu G. (2000)

Immediate versus non-immediate implantation for full-arch fixed reconstruction following extraction of all residual teeth: a restrospective comparative study.

J Periodontol 17:923-8.

Study 2

Chiapasco M, Abati S, Romeo E, and Vogel G. (2001)

Implant-retained mandibular overdentures with branemark system MKII implants: a prospective comparative study between delayed and immediate loading.

Int J Oral Maxillofac Implants 16:537-46.

Study 3

Cannizzaro G and Leone M. (2003)

Restoration of partially edentulous patients using dental implants with a microtextured surface: a prospective comparison of delayed and immediate full occlusal loading.

Int J Oral Maxillofac Implants 18:512-22.

Study 4

Lorenzoni M, Pertl C, Zhang K, and Wegscheider WA. (2003)

In-patient comparison of immediately loaded and non-loaded implants within 6 months.

Clin Oral Impl Res 14:273-79.

Objective

To critically summarize the recently published literature examining implant survival and other outcomes in studies that compare immediate with non-immediate dental implant placement in the same patient populations.

Common Outcome Measures

- Implant survival
- Periotest values
- Peri-implant bone resorption
- Soft-tissue parameters
- Post-operative complications

Interventions

Dental implants were placed and were loaded at the time of implant placement (or within 3 days) (immediate) or at least three months after implant placement (non-immediate) and were described as follows:

- HA coated implants placed immediately in edentulous jaws with hopeless teeth received immediate & non-immediate implants [Schwartz-Arad]
- Branemark MK II implants placed, four per patient, in mandible. Dolder bar connected implants and implant-retained overdentures [Chiapasco]
- 92 Spline Twist MTX implants (self-tapping screw with microtextured surface) placed with full-occlusal loading prostheses [Cannizzaro]
- 6 Frialit-2 stepped-screw implants placed in mandibles of 7 patients. There were two implants per patient immediately loaded with dolder-bar retained overdenture. Remaining implants loaded at 6 months. [Lorenzoni]

Table 1: Comparative studies evaluating the effect of immediate versus non-immediate loading of dental implants.

Author (year)	Study Design	Population	Diagnostic Characteristics	Treatment		Follow-up (%)	CoE
				Immediate	Non-immediate		
Schwartz-Arad (2000)	Retrospective cohort	N = 43 pts female: 51.2% age: 55 years (35-72)	Patients with endentulous jaws or hopeless teeth maxilla (n=253) or mandible (n=117);	n=117 implants day of placement	n=263 implants maxilla: 5-9 mos mandible 3-5 mos	NR*	III
Chiapasco (2001)	Prospective cohort	N =20 female: 75% age: 58.4 years (44-73)	Endentulous mandibles	n=10 within 3 days	n=10 4-8 months	2 years: 100%	III
Cannizzaro (2003)	Prospective cohort	N =28 female: 50% age: 36.6 years (20-62)	Partially endentulous jaws; Implants placed in maxilla or mandible	n=14 day of placement	n=14, loaded after 3.5 months in mandible and 4.5 months in maxilla	2 years: NR*	III
Lorenzoni (2003)	Prospective cohort	N = 7 female NR% age: 60.2 ± 9.4 years (50-72)	Endentulous mandibles	N=14 day of placement	N=28 Six months	6 months: 100%	III

*NR= follow-up rate 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

Table 2. Evaluation of articles on immediate vs. non-immediate loading of dental implants

Methodological Principle	Schwartz-Arad (2000)	Chiapasco (2001)	Cannizzaro (2003)	Lorenzoni (2003)
Study Design				
Randomized controlled trial				
Cohort study	✓	✓	✓	✓
Case-series				
Statement of concealed allocation*				
Intention to treat*				
Independent or blind assessment				
Complete follow-up of ≥85%		✓		✓
Adequate sample size	✓			✓
Controlling for possible confounding		✓		✓
Evidence Class	**III**	**III**	**III**	**III**

* Applies to randomized controlled trials only

Table 3. Definition of the different classes of evidence for articles on therapy.

Class	Study type	Criteria
I	Good quality RCT	• Concealment • Blind or independent assessment for important outcomes • F/U rate of 85%+ • Adequate sample size • Intent-to-treat
II	Moderate or poor quality RCT	• Violation of one or more of the criteria for a good quality RCT
	Good quality Cohort	• Blind or independent assessment in a prospective study, or use of reliable data* in a retrospective study • F/U rate of 85%+ • Adequate sample size • Controlling for possible confounding**
III	Moderate or poor quality Cohort	• Violation of any of the criteria for good quality cohort
	Case Control	
IV	Case Series	

* Reliable data are data such as mortality or re-operation

** Authors must provide a description of robust baseline characteristics, and control for those that are unequally distributed between treatment groups.

Results

Implant survival (Figure 1)

- Cumulative survival rates were similar comparing immediate to non-immediate loaded implants in all studies reviewed [Chiapasco, Cannizzaro, Lorenzoni]; however, one study reported higher survival rates in the immediate load group among implants placed in the maxilla after 5 years (96% versus 89%, $p<0.05$). No significant difference was noted in the mandible (97% versus 96%, $p>0.05$) [Schwartz-Arad].

Periotest values (Figure 2)

There are conflicting findings when comparing periotest values in immediate and non-immediate loaded implants and may be dependent on the timing of the periotest.

- One study reported median values which were significantly higher for the immediately loaded group at 6 months ($p<0.05$). [Lorenzoni]
- Two other studies found median values which were not significantly different between the immediate and non-immediate loaded implant groups at 2 years [Chiapasco, Cannizaro].
- No statistically significant differences were found for periotest values between the immediate and non-immediate implant groups at 2 years in the maxilla (median -4.6 versus -4.8; $p>.05$) or the mandible (median -4.1 vs. -4.2; $p>0.05$) [Cannizaro].

Peri-implant bone resorption

There are also conflicting findings when comparing peri-implant bone resorption in immediate and non-immediate loaded implants.

- One study reported clinical peri-implant bone resorption which was significantly higher for the immediately loaded group at 6 months, $p <0.05$. [Lorenzoni]
- One other study found radiographic peri-implant bone resorption which was not significantly different between the immediate and non-immediate loaded implant groups at 2 years [Chiapasco].
- Cumulative radiographic marginal bone loss was 0 to 1 mm for 95.7% of the immediate implant group and 93.3% of the non-immediate group, while 1 to 2 mm of bone loss was exhibited by 4.3% of the immediate group and 6.7% of the non-immediate group. These differences were not statistically significant ($p>0.05$) [Cannizaro].

Soft tissue parameters

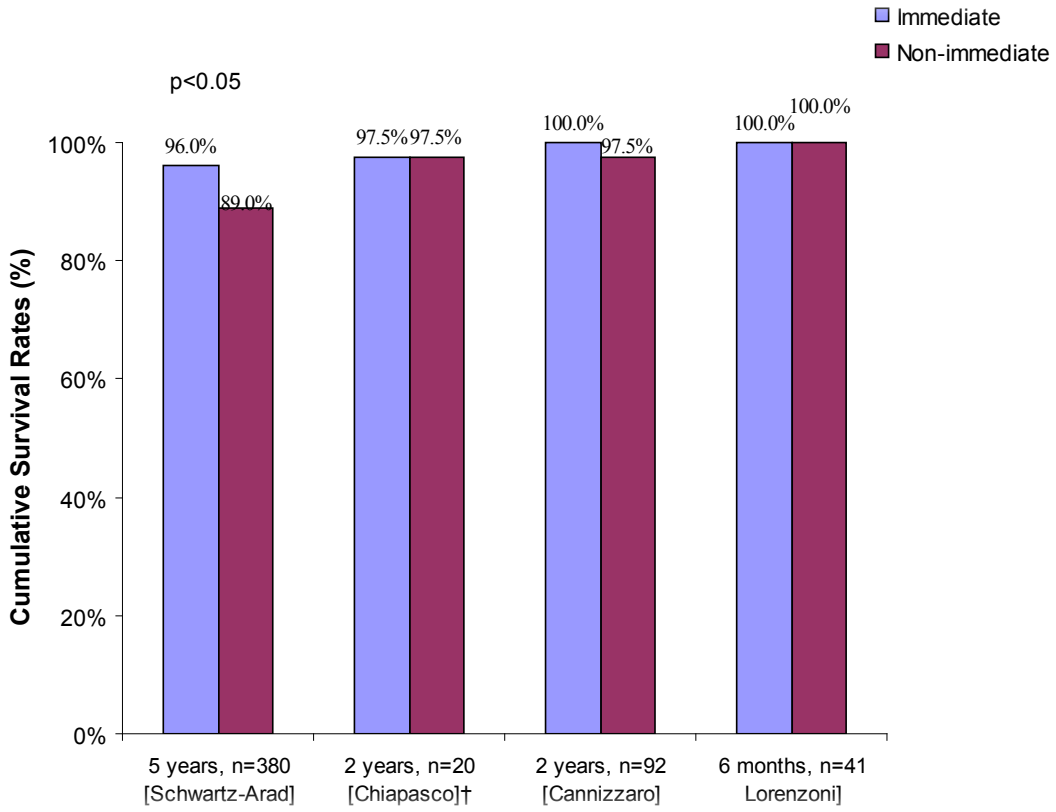
- No statistically significant differences were found for peri-implant soft-tissue parameters (modified plaque index, modified bleeding index, probing depths) between the immediate and non-immediate implant groups at 24 months ($p>0.05$) [Chiapasco, Cannizaro].

Post-operative complications

There were no differences between immediately and non-immediately loaded implant groups for either minor or major complications

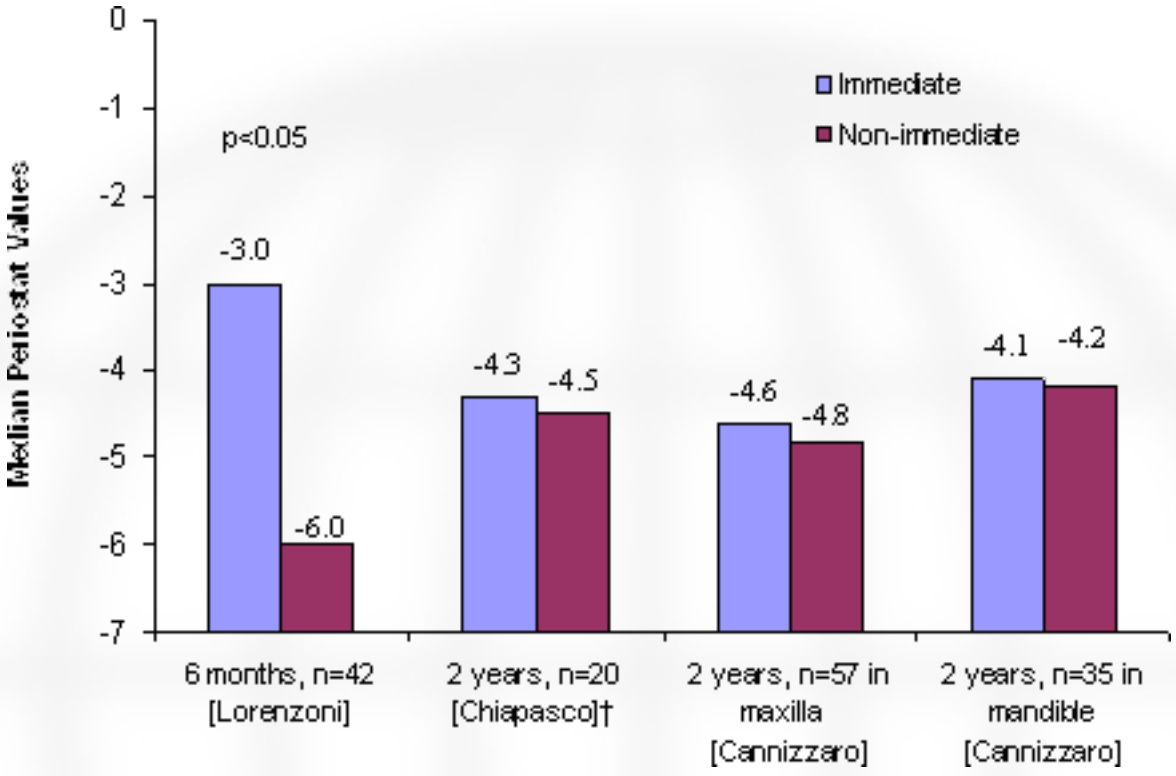
- Minor complications, defined as premature implant exposures which did not require surgical intervention, occurred in 8.5% of patients in the immediate group and 9.1% of patients in the non-immediate group.
- Major complications were implant exposures which required surgical intervention. Such complications occurred in 1.7% of patients in the immediate group and 2.7% of patients in the non-immediate group. These results were not statistically significant ($p>.05$) [Schwartz-Arad].

Figure 1.
Cumulative survival rates for immediately loaded versus non-immediately loaded implants*



* n=number of implants except where noted;
† Authors reported median per patient, thus obtaining a sample size of 20
* Statistical significance noted on graphs if provided by author

Figure 2.
Median periotest values comparing immediately loaded versus non-immediately loaded implants*



* n=number of implants except where noted;
† Authors reported median per patient, thus obtaining a sample size of 20
* Statistical significance noted on graphs if provided by author

Periotest values: A technique used to evaluate osseointegration of dental implants. Implants are considered osseointegrated when periotest values range from -7 to 0, non-integrated when periotest values are over +6, and borderline when periotest values range from 0 to +5.

Methodological considerations

- All studies reviewed were class of evidence (CoE) III studies. No high quality randomized trials (CoE I) or good quality cohort studies (CoE II) were identified in the literature.
- 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.
- Only one study attempted to appropriately account for statistical independence by choosing subject medians and ranges for the analysis, thus obtaining an effective sample size of 10 subjects in the immediate and non-immediate loading groups [Chiapasco].

Facts about: Osteonal bone

Activation time for the osteonal remodelling:	**3 days**
(Resorption speed: 40 µm/day)	
Lag time:	**30 days**
Refilling period:	**100 days**
Primary mineralization (60%):	**10 days**
Seconday mineralization (100%):	**180 days**
Total: approximately	**323 days**
Time of primary mineralization (months):	**130 days (5 months)**

Conclusion:
The decrease in mineralization as a result of osteonal remodelling begins three days after the intervention. 60% of the initial mineralization within the osteons may be reached approximately. 180 days after the surgical intervention. Full mineralization can be expected not earlier than after 12 months. In many cases (depending on the hormonal situation, the mechanical stress, etc.) the time to reach full remineralisation may add up to 24 months.

Note that these facts refer to osteonal bone and not to woven bone or callus and they are valid for human bone.

Clinical application:
All prosthetical manipulations on implants should be finished on day three after the surgical intervention, to avoid the considerable decrease in bone resistance expected during the remodelling phase. Manipulating individual implants during this remodelling phase may cause loosening of the implants.

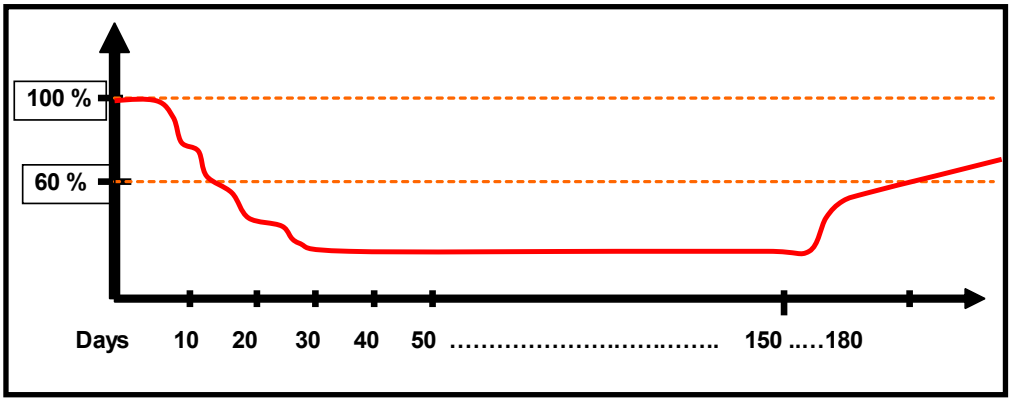


Fig. 1:
Development of the average mineralisation within osteonal bone after surgical interventions. (The relative degree of mineralisation on day 1 equals 100%)

Literature Analysis: Bone Augmentation Procedures - How effective are they and what are the alternatives? Part 1

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.

Clarity and conciseness are the foundation of a Literature Analysis. The majority of the information is presented in bullet format under headings that represent the objectives of the analysis. Only the highest level of evidence is obtained from the literature (the criteria used to judge each article´s "Class of Evidence" (COE) can be found in the Appendix). Hence, out of hundreds of articles, a Literature Analysis will utilize only a small percentage of these in an effort to be efficient and to provide the highest evidence for a particular topic yet be broad enough to answer several important questions.

Similar to a meta-analysis, a "Literature Analysis" uses data presented in published papers, pools it where appropriate, and attempts to quantify treatment or risk factor comparisons, with respect to survival or failure.
Unlike a meta-analysis, a "Literature Analysis" is not nearly as comprehensive in depth, scope, and does not use statistical procedures used to manage multiple papers with heterogenous patient populations. The following are "effect measures" that we use to quantify important comparisons in an attempt to provide a more practical summary of the topics objectives:

- 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). Statistical significance is reached if the 95% confidence intervals do not cross the value of one.
- The number needed to treat (NNT) represents the number of patients one would need to treat in order to prevent a negative outcome (or allow a positive outcome, depending on which outcome is being evaluated). It is calculated as 1/RD, where RD (risk difference) is the proportion of patients with the outcome in the treatment group (A) minus the proportion of patients with the outcome the control group (B). NNTs were calculated only when there was a statistically significant difference in number of outcomes between the two treatment groups.

Introduction

Implantologists are challenged with high patient expectations for optimal function and esthetics. Many patients have insufficient bone volume making the placement of standard root-form implants nearly impossible. When tooth loss is caused by chronic destructive periodontitis, osseous ridge deficiencies or poor bone conditions are the norm rather than the exception all of which hinders implant placement. How are implantologists to manage these patients successfully? Squeezing short or narrow implants into deficient ridges is a poor technique that often fails to properly replace ridge anatomy or provide stable restorations and may result in dehiscence or fenestration of screw implant heads[1]. The minimum required alveolar ridge width must be five to six millimeters upon evaluation for the placement of root-form implants[2].

There are two primary approaches to bone augmentation. In a one-stage procedure, the implants are placed simultaneously to the bone augmentation procedure. Two-stage procedure means that the

augmentation procedure is done first and implants are placed a few months after, with an additional surgical procedure, to allow for bone healing, and the graft to catch.

Several methods have been suggested to improve bone contour which will be discussed in this Literature Analysis. This analysis will be done in two parts. Part I will be presented in this issue of Implant Directions and will address the following objectives:

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

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

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

Data Sources and Search Strategy

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

First strategy:
Identify systematic review articles describing bone augmentation procedures for dental implants. Topics such as criteria, techniques, survival rates, complications, and alternative procedures were included.

Second strategy:
Identify comparative studies reporting bone augmentation procedures for dental implants since October 1, 2005 (last search date for Cochrane Collaboration systematic review).

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

Table 1. Medline Search Summary

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

Results

Results of the various search strategies

First strategy:
We identified six systematic reviews on bone augmentation procedures prior to implant placement. Three of these reviews highlighted studies which were of poor quality, so they were excluded. The remaining three systematic reviews provided background information, techniques, survival rates, complications, and alternative procedures. No studies were found which compared augmentation procedures for different areas of the mouth.

Second strategy:
We identified one comparative study which evaluated bone augmentation procedures for dental implants published after October 1, 2005.

Third strategy:
We identified three articles describing alternatives to bone augmentation for dental implants.

Materials used for bone augmentation[3]

1. Autogenous bone grafts
- bone grafts taken from an adjacent or remote site in the same patient
- considered to be the "gold standard" treatment for bone augmentation
- sites within the mouth may be used for relatively small graft requirements
- sites such as the hip bone (iliac crest) are used for larger bone volumes
- it may be possible to recycle bone taken from the site of implant placement when preparing the hole by using a special filter to collect bone particles that would otherwise be lost and use this to build-up a deficient area

2. Allografts
- bone grafts harvested from cadavers and processed by methods such as freezing or demineralizing and freezing
- grafts are supplied by specially licensed tissue banks in several convenient ways such as bone particles or large blocks
- they are resorbable
- there may be some concern regarding their infectivity

3. Xenografts
- Graft materials are derived from animals such as cow or coral
  - Bio-Oss (Geistlich Pharmaceutical, Wolhusen, Switzerland) is bovine bone that is processed to completely remove the organic component

- Coral has been advocated because of a pore size suitable for permitting bone ingrowth
- There has been concern regarding the infectivity of bovine-derived materials although this has been disputed

4. Alloplastic graft materials

- These are synthetic bone substitutes that provide a physical framework for bone ingrowth. Examples are calcium phosphates and bioactive glasses
- Some implantologists use these materials in combination with autogenous bone grafts
- These materials may resorb completely or to some degree or not at all

5. Barrier membranes for guided bone regeneration (GBR)

- This technique uses barrier membranes to protect defects from the ingrowth of soft tissue cells so that bone progenitor cells may develop bone uninhibited, such that bone is "guided" into the desired position
- Membranes can be resorbable or non-resorbable

6. Bone promoting proteins (BMPs) and platelet rich plasma (PRP)

- BMPs are a family of proteins naturally present in bone and responsible for activation of bone development. They may encourage bone formation and may be incorporated into any of the above graft types
- Growth factors and PRP are also being investigated for their use in bone regeneration. PRP obtained from autologous blood is used to deliver growth factors in high concentrations to the site of the bone defect or a region requiring augmentation. Many growth factors stimulate bone formation

Surgical techniques used for bone augmentation[3]

1. Onlay grafting

- The graft material is laid over the defective area to increase width or height or both of the alveolar jawbone
- The host bed is usually perforated with a small bur to encourage the formation of a blood clot between the graft and recipient bed.
- The graft is immobilized with screws or plates or with dental implants

2. Inlay grafting

- Graft material is inserted to increase bone volume
- One type is a sinus lift or sinus elevation procedure in which graft material is inserted inside the floor of the maxillary sinus to increase bone volume
- The floor of the nose may be grafted
- In a Le Fort I osteotomy with interpositional bone graft, a section of jawbone is surgically separated and graft material sandwiched between two sections

3. Ridge expansion

- The alveolar ridge is split longitudinally and parted to widen it and allow placement of an implant or graft material or both in the void

4. Distraction osteogenesis

- Gradual, controlled displacement of a surgically prepared fracture is used to increase bone volume
- This technique has recently been introduced into implant surgery
- The gap created during the displacement of the bone segment fills with immature non-calcified bone that matures during a subsequent fixation period. The associated soft tissues are also expanded as the bone segment is transported

Compare bone augmentation to no bone augmentation procedures

- Two randomized controlled trials were identified which compared bone augmentation procedures to no augmentation prior to placing dental implants. The studies are summarized in Table 2.
- In one study, subjects who underwent an autogenous bone graft were less likely to have stabilized implants at two years compared to those without augmentation (RR 0.7, 95% CI 0.6, 1.0; NNT 4, 95% CI 2-15) [4].
- This study also found a greater than 3 times improvement in facial esthetics for implants placed in augmented sites or via transmandibular implant (TMI) compared to placement in areas of no augmentation (RR 3.5, 95% CI 1.4, 8.8; NNT 2, 95% CI 1-4) [4].
- There were no statistically significant differences in prosthesis success when comparing augmentation procedures to no augmentation [4,5].
- Patients with bone augmentation were more than 4 times more likely to have pain compared to the non-augmented group (RR 4.3, 95% CI 1.7, 10.4) [4].
- Significant complications of sublingual edema (5%) and necrosis of the osteoma (5%) were reported by the autogenous bone graft group in one study [4].
- Other reported complications were paresthesia (10% bone graft group vs. 5% no augmentation group)[4], infection (7% bone graft group only) [5], and wound dehiscence (7-10% bone graft group only) [4,5].

Compare different materials and techniques used for bone augmentation

- Nine randomized controlled trials were identified which evaluated materials and techniques used for bone augmentation prior to placing dental implants.The studies are summarized in Tables 3 and 4.
- No studies found a statistically significant difference in regards to implant stabilization or prosthesis success between the bone augmentation materials and techniques which were evaluated.
- However, in subjects who underwent sinus lift procedures, implant stabilization at one year was reported as follows:
  - bovine bone augmentation—100% success
  - 80% bovine bone/20% autogenous bone augmentation—82% success
  - autogenous bone only—55% success [6].

- For horizontal/vertical augmentation techniques, complications included:
  - bone graft resorption (18% autogenous bone graft vs. 0% 80 bovine/20 autogenous bone graft vs. 0% bovine bone) [6],
  - abscess (RR 2.0, 95% CI 0.2, 18.7 using GBR with resorbable compared to nonresorbable barriers) [7],
  - minor infections (RR 0.3, 95% CI 0.1, 2.7 using GBR with resorbable compared to nonresorbable barriers) [7],
  - barrier exposures (18% GBR with autogenous graft vs. 0% distraction osteogenesis) [8].
- When bone augmentation occurred in a fresh extraction site, complications reported were:
  - abscess (10% bovine bone+collagen vs 0% bovine bone) [9],
  - chronic inflammation (10% bovine bone+collagen vs 0% bovine bone) [9],
  - minor infection (0% resorbable barrier vs. 8% nonresorbable barrier vs. 8% resorbable barrier+autogenous bone) [5],
  - wound dehiscence (18% resorbable barrier vs. 0% nonresorbable barrier vs. 0% resorbable barrier+autogenous bone)[5].

Compare time to loading for bone augmentation procedures

- One randomized controlled trial evaluated time to implant loading after bone augmentation procedures. The study is summarized in Table 5.
- This study compared a one-stage sinus lift procedure to a two-stage sinus lift procedure for augmentation of the severely atrophied posterior maxilla [10].
- No statistically significant differences were found for implant stabilization or prosthesis success for these procedures.
- Several sinus perforations were reported by both groups (45% one-stage, 50% two-stage), though there were no significant differences between the two groups.

Summarize survival rates of bone augmentation procedures

- A systematic review [11] attempted to report survival rates for implants placed in grafted maxillary sinuses.
  - Implant survival was 90% (95% CI: 87-93) for autogenous bone (484 implants placed in 130 patients followed for 6 to 60 months),
  - 94% (95% CI: 90-97) for the combination of hydroxyapatite (HA) and autogenous bone (363 implants in 104 patients followed for 18 months),
  - 98% (95% CI: 96-100) for the combination of demineralized freezedried bone and HA (215 implants in 50 patients followed for 7 to 60 months),
  - 87% (95% CI 68-95) for HA alone (30 implants in[11]patients followed for 18 months).

- In a longitudinal study 12, 588 ITI implants were placed and followed for a mean of 59.7 months (range 12-144 months).
  - The cumulative survival rate of the implants was 94.8% at 12 years with a cumulative success rate of 90.8%.
  - Survival was defined as retaining an implant, while success was defined as absence of: subjective complaints, peri implant infection, mobility,and radiolucency around the implant.

- In a study which compared guided bone regeneration (GBR) to distraction osteogenesis for bone augmentation [8],
  - the cumulative survival at 3 years was 100%, and the success rate was 68% due to peri-implant bone resorption.
  - For the distraction osteogenesis group, the cumulative survival was 100% while the success rate was 94.1%.

- The individual risk for implant failure in grafted areas among one-stage sinus lift patients was about twice the risk in two-stage patients (OR 2.3, CI: 0.6, 8.5). The risk for implant failure in non-grafted areas was significantly lower ($p < .05$) than in grafted areas, regardless of the technique used [10].

Future Directions

In part I of this Literature Analysis on bone augmentation procedures we made the following important observations:

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

bone augmentation compared to bovine bone/autogenous bone (80/20) augmentation and autogenous bone only.

- No statistically significant differences were found for implant stabilization when comparing one stage sinus lift procedures to two stage sinus lift procedures in severely atrophied maxillae. Approximately 50% of all these procedures led to sinus perforations.

In part II which will be published in the 2nd edition of Implant Directions, we will look at the following objectives:

- Evaluate costs associated with bone augmentation procedures
- Discuss alternatives to bone augmentation procedures
- Report upon BOI as a potential alternative to bone augmentation procedures
- Discuss future research recommendations

References

1. Myoung H, Kim YY, Heo MS, Lee SS, Choi SC and Kim MJ: Comparative radiologic study of bone density and cortical thickness of donor bone used in mandibular reconstruction. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 92: 23-9, 2001.
2. Chavrier C: [Bone grafts from the chin in the treatment of thin alveolar crests]. Rev Stomatol Chir Maxillofac. 1: 8-9, 1997.
3. Esposito M, Grusovin MG, Worthington HV and Coulthard P: Interventions for replacing missing teeth: bone augmentation techniques for dental implant treatment. Cochrane Database Syst Rev: CD003607, 2006.
4. Stellingsma K, Slagter AP, Stegenga B, Raghoebar GM and Meijer HJ: Masticatory function in patients with an extremely resorbed mandible restored with mandibular implant-retained overdentures: comparison of three types of treatment protocols. J Oral Rehabil. 32: 403-10, 2005.
5. Chen ST, Darby IB, Adams GG and Reynolds EC: A prospective clinical study of bone augmentation techniques at immediate implants. Clin Oral Implants Res. 16: 176-84, 2005.
6. Hallman M, Sennerby L and Lundgren S: A clinical and histologic evaluation of implant integration in the posterior maxilla after sinus floor augmentation with autogenous bone, bovine hydroxyapatite, or a 20:80 mixture. Int J Oral Maxillofac Implants. 17: 635-43, 2002.
7. Merli M, Migani M and Esposito M: Vertical ridge augmentation with autogenous bone grafts: resorbable barriers supported by osteosynthesis plates versus titanium reinforced barriers. An interim report of a triple-blind, randomized controlled clinical trial., Submitted.
8. Chiapasco M, Consolo U, Bianchi A and Ronchi P: Alveolar distraction osteogenesis for the correction of vertically deficient edentulous ridges: a multicenter prospective study on humans. Int J Oral Maxillofac Implants. 19: 399-407, 2004.
9. Chen ST and Darby IB: A randomized controlled clinical trial of nonsubmerged immediate implants: clinical outcomes and esthetic results. In manuscript.
10. Wannfors K, Johansson B, Hallman M and Strandkvist T: A prospective randomized study of 1- and 2-stage sinus inlay bone grafts: 1-year follow-up. Int J Oral Maxillofac Implants. 15: 625-32, 2000.
11. Tong DC, Rioux K, Drangsholt M and Beirne OR: A review of survival rates for implants placed in grafted maxillary sinuses using meta-analysis. Int J Oral Maxillofac Implants. 13: 175-82, 1998.
12. Ferrigno N, Laureti M and Fanali S: Dental implants placement in conjunction with osteotome sinus floor elevation: a 12-year life-table analysis from a prospective study on 588 ITI implants. Clin Oral Implants Res. 17: 194-205, 2006.

APPENDIX. Class of Evidence Categories

Definition of the different classes of evidence (CoE) for articles

Class	Study type	Criteria
I	Good quality RCT	• Concealment • Blind or independent assessment for important outcomes • F/U rate of 85%+ • Adequate sample size • Intent-to-treat
II	Moderate or poor quality RCT	• Violation of one or more of the criteria for a good quality RCT
	Good quality Cohort	• Blind or independent assessment in a prospective study, or use of reliable data* in a retrospective study • F/U rate of 85%+ • Adequate sample size • Controlling for possible confounding**
III	Moderate or poor quality Cohort	• Violation of any of the criteria for good quality cohort
	Case-Control	
IV	Case Series	

* Reliable data are data such as mortality or re-operation

** Authors must provide a description of robust baseline characteristics, and control for those that are unequally distributed between treatment groups.

APPENDIX I

Table 2. Summary of studies comparing augmentation procedures to no augmentation before placement of dental implants

	CoE	Outcome	No. of Studies	Patient Characteristics	No Augmentation (n=20)	Autogenous bone graft (n=20)	Trans-mandibular Implant (TMI) (n=20)	Effect Size- bone graft/no augmentation RR (95% CI)	Effect Size- TMI/ no augmentation RR (95% CI)	Favors
Comparison of no augmentation vs. autogenous bone graft vs. TMI: horizontal/ vertical augment	II	**Implant stabilization (2 yr)**	1 3	N = 60; Male: 17%; Mean age: 59 ± 11 years; Median F/U*: 2 years; F/U %: 97	100% (n= 19/19)	7 4 % (n=14/19)	9 5 % (n=19/20)	**0.7 (0.6, 1.0) NNT=4 (2-15)**	1.0 (0.9, 1.1)	**No Augment**
		Prosthetic success (2 yr)			100% (n= 19/19)	9 5 % (n=18/19)	9 5 % (n=19/20)	1.0 (0.9, 1.1)	1.0 (0.9, 1.1)	Neither
		Improvement of facial appearance			20% (n=4/20)	7 0 % (n=14/20)	7 0 % (n=14/20)	**3.5 (1.4, 8.8) NNT= 2 (1-4)**	**3.5 (1.4, 8.8) NNT= 2 (1-4)**	**Auto, TMI**
		Major complication at augmented site			0% (n=0/20)	10% (n=2/20)		Incalculable		Neither
		Pain			20% (n=4/20)	8 5 % (n=17/20)		4.3 (1.7, 10.4) NNT=2 (1-3)		**No Augment**
		Wound dehisence			0% (n=0/20)	10% (n=2/20)		Incalculable		Neither
		Ana-/dysthesia			5% (n =1/20)	10% (n=2/20)		2.0 (0.2, 20.3)		Neither
	CoE	**Outcome**	**No. of Studies**	**Patient Characteristics**	**No Augmentation (n=12)**	**Autogenous bone graft (n=14)**	**No Augmentation: Mean ± SD (n=12)**	**Autogenous bone graft: Mean ± SD (n=14)**	**Effect Size- RR (95% CI)**	**Favors**
Comparison of no augmentation vs. autogenous graft: ext. socket	II	**Implant stabilization (2 yr)**	1 3	N=26; Male: 62%; Median age: 42 years; Median F/U*: 2 years; F/U %: NR	100% (n= 12/12)	8 6 % (n=12/14)			0.9 (0.7, 1.1)	Neither
		Prosthesis success (2 yr)			100% (n= 12/12)	8 6 % (n=12/14)			0.9 (0.7, 1.1)	Neither
		Infection			0% (n=0/12)	7% (n=1/14)			Incalculable	Neither
		Wound dehiscence			0% (n=0/12)	7% (n=1/14)			Incalculable	Neither
		Vertical bone gain					73.6 ± 24.2 %	75.3 ± 20.9 %		Neither
		Horizontal bone gain					69.2 ± 12.8 %	75.6 ± 26.0 %		Neither

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

NNT= number needed to treat – NNT represents the number of patients one would need to treat in order to prevent a negative outcome

Patient characteristics include sample size (N), 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: Comparison of different methods of horizontal/vertical bone augmentation

	CoE	Outcome	No. of Studies	Patient Characteristics	100% Autogenous bone graft (n=20)	80% bovine bone/20% autogenous graft (n=20)	100% bovine bone (n=10)	Effect Size- 80-20 graft/no augmentation *	Effect Size- bovine bone/no	Favors
Comparison of auto vs. 80 bovine/20		**Implant stabilization (1 yr)**	1 [3]	N=21; Male: NR%; Median age: NR; Median F/U*: 3 years; F/U %: NR	55% (n= 6/11)	82% (n=9/11)	100%	p>0.05	p>0.05	Neither
	II	**Bone graft resorption**			18% (n= 2/11)	0% (n=0/11)	0% (n=0/10)	Incalculable	Incalculable	Neither
	CoE	**Outcome**	No. of Studies	Patient Characteristics	Sinus lift: autogenous bone graft (n=20)	Sinus lift: betatricalcium phosphate (n=20)		Effect Size- bone graft/no augmentation RR (95% CI) *		Favors
Comparison of autogenous graft vs.	II	**Implant stabilization at loading**	1 [3]	N=20; Male: NR%; Median age: NR; Median F/U*: 6 months; F/U %: 100	95% (n= 19/20)	95% (n= 19/20)		p>0.05		Neither
	CoE	**Outcome**	**No. of Studies**	**Patient Characteristics**	**GBR with ePTFE barriers and autogenous graft (n=20)**	**Distraction osteogenesis (n=10)**		**Effect Size- GBR/ distraction osteogenesis RR (95% CI)**		**Favors**
Comparison of GBR vs. distraction osteogenesis		**Implant stabilization (3 yrs)**	1 [3]	N=21; Male: 43%; Mean age: 39.8 (range 18-59) years; Median F/U*: 3 years post-loading; F/U %: 100	100% (n= 11/11)	100% (n= 10/10)		1.0 (1.0, 1.0)		Neither
		Prosthesis success (3 yrs)			100% (n= 11/11)	100% (n= 10/10)		1.0 (1.0, 1.0)		Neither
		Complication at augmentation site			27% (n= 3/11)	20% (n= 2/10)		0.7 (0.2, 3.5)		Neither
	II	**Barrier exposure**			18% (n=2/11)	0% (n=0/10)		Incalculable		Neither

	CoE	Outcome	Noof Studies	Patient	GBR with nonresorbable barriers (n=10)	GBR with resorbable barriers (n=10)	GBR with nonresorbable barriers: Mean ± SD (n=10)	GBR with resorbable barriers: Mean ± SD (n=10)	Effect Size-nonresorb/ resorb barriers RR (95% CI)	Favors
Comparison of GBR with nonresorbable barriers vs. GBR with resorbable barriers	II	**Implant stabilization**	1 3	N=20; Male: NR%; Median age: NR; Median F/U*: 5 months; F/U %: 100	100% (n=10/10)	100% (n=10/10)			1.0 (1.0, 1.0)	Neither
		Prosthesis success			100% (n=10/10)	100% (n=10/10)			1.0 (1.0, 1.0)	Neither
		Abscess (augmentation failure)			10% (n= 1/10)	20% (n=2/10)			2.0 (0.2, 18.7)	Neither
		Minor infection			30% (n= 3/10)	10% (n= 1/10)			0.3 (0.1, 2.7)	Neither
		Barrier exposure			0% (n= 0/10)	10% (n= 1/10)			Incalculable	Neither
		Vertical bone gain					1.95 ± 1.42 mm	2.30 ± 1.01 mm	p>.05	Neither

Table 3 continues here

* McNemar's Test used to determine statistical significance due to study design

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), 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 4: Comparison of different methods of bone augmentation in fresh extraction sites

	CoE	Outcome	No. of Studies	Patient Characteristics	Collagen barrier (n=10)	Barrier + bovine bone (n=10)		Effect Size- Barrier+bovine bone/collagen barrier RR (95% CI)		Favors
Comparison of barrier vs. barrier + bovine	II	**Implant stabilization (6 mos)**	1 3	N = 20; Male: NR%; Median age: NR; Median F/U*: 6 months; F/U %: 100	100% (n= 10/10)	100% (n= 10/10)		1.0 (1.0, 1.0)		Neither
		Prosthesis success (6 mos)			100% (n= 10/10)	100% (n= 10/10)		1.0 (1.0, 1.0)		Neither

Table 5: Comparison of time to implant loading following bone augmentation

	CoE	Outcome	No. of Studies	Patient Characteristics	Two-Stage Sinus Lift (n=20)	One-Stage Sinus Lift (n=20)	Effect Size- 2-stage/1-stage sinus lift RR (95% CI)	Favors
Comparison of two-stage vs. one-stage sinus lift	II	**Implant stabilization (1 yr)**	1 3	N = 40; Male: NR%; Median age: NR; Median F/U*: 3 years; F/U %: 100	70% (n= 14/20)	60% (n=12/20)	0.9 (0.5, 1.4)	Neither
		Prosthesis success (1 yr)			95% (n=19/20)	95% (n=19/20)	1.0 (0.9, 1.2)	Neither
		Sinus membrane perforation			50% (n=10/20)	45% (n=9/20)	0.9 (0.5, 1.7)	Neither

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), proportion male, and mean age or range or standard deviation (SD), and mean follow-up (F/U) and range if available; NR = Not reported

	CoE	Outcome	No. of Studies	Patient Characteristics	Nonresorbable barrier (n=12)	Resorbable barrier (n=11)	Resorbable barrier + autogenous bone (n=13)	Effect Size- resorbable/non resorbable barrier RR (95% CI)	Effect Size- resorb+bone/ non resorbable barrier RR (95% CI)	Favors
Comparison of nonresorb barrier vs. resorb barrier vs. resorb barrier+autogenous bone		**Implant stabilization (2 yrs)**		N=36; Male: 36%; Median age: 42 years; Median F/U*: 2 years post-loading; F/U %: 100	100% (n= 12/12)	100% (n= 11/11)	100% (n= 13/13)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	Neither
		Prosthesis success (2 yrs)			100% (n= 12/12)	100% (n= 11/11)	100% (n= 13/13)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	Neither
		Wound dehiscence			0% (n= 0/12)	18% (n=2/11)	0% (n= 0/11)	Incalculable	Incalculable	Neither
	II	**Infection**	1 3		0% (n= 0/12)	8% (n=1/13)	8% (n=1/13)	Incalculable	Incalculable	Neither
	CoE	**Outcome**	**No. of Studies**	**Patient Characteristics**	**Bovine bone (n=10)**	**Bovine bone + collagen barrier (n=10)**		**Effect Size- GBR/ distraction osteogenesis RR (95% CI)**		**Favors**
Comparison of bovine bone vs. bovine bone + collagen barrier		**Implant stabilization (3 yrs)**		N=20; Male: NR%; Median age: NR; Median F/U*: 3 years post-loading; F/U %: 60%	100% (n= 7/7)	100% (n= 5/5)		1.0 (1.0, 1.0)		Neither
		Prosthesis success (3 yrs)			100% (n= 7/7)	100% (n= 5/5)		1.0 (1.0, 1.0)		Neither
		Abscess (augmentation failure)			0% (n= 0/10)	10% (n= 1/10)		Incalculable		Neither
	II	**Chronic inflammation**	1 3		0% (n= 0/10)	10% (n= 1/10)		Incalculable		Neither

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), proportion male, and mean age or range or standard deviation (SD), and mean follow-up (F/U) and range if available; NR = Not reported

Critical Appraisal on two connected publications regarding implant placement in "augmented" jaw bone areas.

The reason(s) this article was choosen (x):

	Strong study design
X	Interesting or important topic

	Strong study methodology
	Work contributes to future research

References:

Article 1: Buser D, Ingimarsson S, Dula K, Lussi A, Hirt HP, Belser UC. (2002) Long-term stability of osseointegrated implants in augmented bone: a 5-year prospective study in partially edentulous patients. Int J Periodontics Restorative Dent.; 2002 Apr;22(2): 109-17.

With reference to and including data from a previously published article:

Article 2: Buser D, Dula K. , Hirt H.-P., Schenk R.K. (1996) Lateral ridge augmentation using autografts and barrier membranes (J. Oral Maxillofac. Surg; 420-432).

Performing Clinic: Department of Oral Surgery and Stomatology, School of Dental Medicine, University of Berne, Switzerland.

Abstract: This prospective clinical study evaluated the 5-year survival and success rates of 66 titanium implants placed in bone that had been previously augmented with autografts and nonresorbable barrier membranes. During the observation period, three patients with five implants dropped out of the study. None of the remaining 61 implants were lost during the follow-up period (implant survival rate of 100%). One implant exhibited a periimplant infection, whereas 60 implants were considered clinically successful at the 5-year examination, resulting in a 5-year success rate of 98.3%. It was concluded that the clinical results of implants in regenerated bone are comparable to those of implants in nonregenerated bone.

ARTICLE SUMMARY

Author's Summary

- There seems to be increasing evidence that bone regenerated underneath non-resorbable barrier membranes has a similar load-bearing capacity as pristine non-regenerated bone and that good long-term results can be expected with osseointegrated implants placed in augmented bone using a staged approach.

Objectives/Aims

- To evaluate the 5-year survival and success rates of 66 titanium implants placed in bone that had been previously augmented with autografts and non-resorbable barrier membranes.

Methods

Study Design

- Prospective case series with historical control.

Sampling

- Between 1992 and 1999, 40 partially edentulous patients (N=26 women and N=14 men) were treated with horizontal ridge augmentation followed by ITI implants (N=60 implants).
- 60 implants were placed in 40 patients.
- Authors of article (1) refer to a previous article (2) describing this patient population reporting a mean age of 40 years (range, 16 to 73).
- The most frequent indications (n=14) was an extended edentulous space (gap) in the maxilla, followed by a single tooth gap in the maxilla (n=12), and a distal extension in the mandible (n=10).

Inclusion

- Partially edentulous patients with successful horizontal ridge augmentation.
- No further inclusion criteria were described.

Exclusion Criteria

- No exclusion criteria were reported.

Intervention

- A total of 66 ITI implants were inserted 6-9 months following horizontal ridge augmentation.
- Surgical procedures were not described.
- Implant locations were not described.
- 39 patients underwent three surgical interventions until the final prosthesis was placed (1.)augmentation under large flap conditions, 2.)implant placement under large flap conditions including the removal of Memfix-screws and the membranes, 3.) uncovery of implants), one patient underwent four surgical interventions (1.) augmentation under large flap conditions, 2.) partial membrane removal, 3.) implant placement (with a full thickness flap), 4.) uncovery of the implants).

Outcome Measures

- Modified plaque index (mPLI): an average of four values obtained from four aspects around the implants.
- Modified sulcus bleeding index (mSBI): an average of four values obtained from four aspects around the implants.
- Probing depth (PD, in mm); an average of four values obtained from four aspects around the implants.
- Distance between the implant shoulder and the mucosal margin (DIM, in mm).
- Clinical attachment level (AL, in mm) at four aspects around the implants (AL=PD + DIM).
- Distance between the implant shoulder and the first visible bone-implant contact (DIB): measured at the mesial and distal aspect of each implant by periapical radiographs with the long-cone technique.
- Implant success/survival defined as: 1) absence of persistent subjective complaints, such as pain, foreign body sensation and/or dysesthesia; 2) absence of per-implant infection with suppuration; 3) absence of mobility; 4) absence of continuous radiolucency around the implant.

Follow-up

- Author reported "Over a 5-year period, they were recalled and examined at annual intervals using a standard protocol."
- Mean follow-up times and ranges or standard deviations were not reported.
- Three patients with five implants dropped out of the study (dropout rate = 7.6%).

Results

- Three patients with five implants dropped out of the study (reasons not given).
- One of the remaining 61 implants developed a periimplant infection.
- All 61 implants survived the 5-year study period (survival rate = 100%).
- 60 implants were considered clinically successful at the 5-year point (success rate=98.3%).
- The clinical parameters at the 1- and 5-year examinations are summarized in Table 1 reproduced from article.
- One implant showed a bone gain exceeding 0.8mm whereas five implants lost more than 0.8mm of bone.

Table 1. Clinical parameters (mean ± standard deviation) of 61 examined implants.

Exam	mPLI	mSBI
1 year	0.27 ± 0.38	0.42 ± 0.44
5 year	0.25 ± 0.29	0.25 ± 0.43

Exam	PD (mm)	DIM (mm)	AL (mm)
1 year	3.64 ± 1.04	-1.14 ± 1.34	2.49 ± 0.99
5 year	4.43 ± 1.24	-1.11 ± 1.27	3.29 ± 0.37

REVIEWER'S EVALUATION

Table 2. Evaluation of methodological principles.

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

* Apply to randomized trials only.

** Not applicable. These apply to cohort studies where two groups are being compared.

1. What were the study's methodological strengths?

- High 5-year follow-up rate
- Long follow-up period reported (though mean follow-up and ranges were not reported).
- Several outcomes were measured.

2. What were the study's methodological limitations?

- A clear description of inclusion and exclusion criteria was not provided. Further it is unclear if these were consecutive patients or a "convenience sample". Such information would make it easier to generalize these findings to other populations. Without such information, the external validity of these data is weakened.
- Patient age ranges, mean ages, and gender distributions were not reported in this paper but in a previous paper published in 1996. Though these data can be searched for and reviewed from a previous study, it is important that a single manuscript can stand alone for the reader and hence these demographic data should have been reported in this paper being reviewed.
- Success rates were compared with historical data from the literature. These patients from the literature are not part of the same population.
- It is unclear who performed the outcomes evaluations (e.g., judgment of implant survival). Was this person an independent disinterested party or one of the authors? In a prospective study, it is advisable to identify an independent observer to make these assessments if at all possible to avoid even unintended bias in the results.
- No patient reported outcomes were assessed. In addition to clinical measures such as implant survival and radiographic findings, it is highly advisable to measure outcomes from the patient's perspective since published rates of survival in the literature are universally high.
- The authors reported in their methods that the data would be analyzed using the "paired t test"; however, no such analyses were performed. Its unclear if this analysis was omitted purposefully or accidentally and further how the manuscript reviewer's did not identify this.
- It is quite interesting that the literature summary in the discussion (page 115) reported several studies on this topic. Only the first author of this paper reported a 100% survival rate in both of his studies. The others reported rates more consistent with the dental implant literature.

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

There are several aspects of this study that make the results impossible to apply to patient care. First, the implants used during the treatment time (1992 - 1999) were removed from the market long before the article was published. "ITI" implants, used at the time the study was performed, were manufactured with a titanium plasma spray (TPS) surface. The manufacturer had switched to the first type of "SLA" surface by this time. Hence, all data from this investigation are not applicable to today's patient care.

Second, noting pictures B and J from "Article 2",

these pictures convey that some of the implants were not inserted into augmented bone at all. Instead, the augmentation was performed in jaw regions nearby the implants presumably to widen the ridge prophylactically. For this reason, the title of the "Article 1" is misleading. The patients only underwent lateral ridge augmentation and not vertical augmentation. Further, based on the pictures presented, we are led to believe that in many of the cases, especially in single or double tooth gaps, an augmentation was performed. However the implants were not inserted in the augmented bone but in the native bone nearby the augmentation. Some of the implants may have been in contact with augmented bone areas in a small section of their endosseous surface.

Interestingly, none of the patients reported in this study received implants in the region of the first and second upper molars (i.e. the really difficult areas). Only four out of 40 implants were placed in the area of the second premolar in the upper jaw. Seven implants were placed in the area of the first premolar. Therefore, the results should not be generalized to the distal maxillary bone, a region providing most of the troubles and failures in conventional dental implantology. Since a considerable number of the implants are usually to be placed in the region of the 1st and 2nd upper molars (e.g. 3 out of 15 implants (20%) placed in the maxilla, in the article of Bornstein et al, Clin Oral Impl.Res. 16, 2005: 631-638), at least a few cases would have been expected in these areas. It's unclear why none of the implants reviewed in this study population were placed in this region.It could mean that, although no selection criteria has been mentioned in both articles, those cases have been excluded completely and deliberately. Without knowledge of clear inclusion and exclusion criteria, we cannot be sure. The placement of 61 implants over the period of 5 years may indicate, that the observation does not cover a continuous series of cases, but rather a series of carefully selected cases, i.e. a "convenience sample".

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

Patients with poor bone needing dental implants are becoming more and more of a challenge in implantology. These patients are challenging yet have several years of life remaining where their quality of life is of utmost importance. The implantologist is faced with the decision of whether to perform bone augmentation or not. Bone augmentation, though some feel will allow for the placement of certain screw implants that would otherwise not be possible, is very expensive and requires a considerable amount of rehabilitation time compared to alternative implants placed without augmentation.

These bone augmentation procedures, require 3 - 4 surgical interventions, which can pose additional potential harm to the patient in the way of donor site morbidity and surgical morbidity as a result of the additional surgeries. One clinically important question must be raised: did these patients really need augmentation at all, which would justify the increase in costs and potential harm and the number of interventions?

In "Article 2", the authors report on two cases with unfavorable augmentation results who still received implants. This makes one wonder if the augmentation was necessary in the first place. The augmentation appears to have been done only for the sake of inserting large-diameter (4.1 and 4.8 mm) ITI®-screw implants. There would have been other implants available (e.g. KOS® compression screw implants) whose use would have avoided the first operation (and the operational risks and the waiting time) and even the uncovery intervention.

None of the patients received vertical bone augmentation; therefore, the vertical bone height must have been sufficient for dental implants in most of these patients and the results of this study may not be transferred to cases with vertical augmentations, e.g. in the maxillary sinus.

There is no data available in the dental literature demonstrating that wider implants have a higher or lower survival rate, so the 1st operation in many of the reported cases can assume to have been superfluous. Hence, these procedures likely could have been done without augmentation and the added cost and risk.

It is the duty of the surgeon to obtain a patients informed consent before starting the intervention.
Fully informed patients presumably would not agree to three to four interventions in cases, where the desired clinical result (fixed teeth on implants with acceptable aesthetics) may be achieved in one single surgical intervention, e.g. by using small diameter compression screws or basal implants. Those implants and treatment alternatives had been available at the time, the study was performed.

The authors may have obtained the participating patients consent by withholding important information on fast, safe and affordable treatment alternatives.

Guide for Authors

ID publishes articles, which contain information, that will improve the quality of life, the treatment outcome, and the affordability of treatments.

The following types of papers are published in the journal:
Full length articles (maximum length abstract 250 words, total 2000 words, references 25, no limit on tables and figures).
Short communications including all case reports (maximum length abstract 150 words, total 600 words, references 10, figures or tables 3).
Technical notes (no abstract, no introduction or discussion, 500 words, references 5, figures or tables 3).
Interesting cases/lessons learnt (2 figures or tables, legend 100 words, maximum 2 references).

Literature Research and Review articles are usually commissioned.
Critical appraisals on existing literature are welcome.

Direct submissions to:
dijana.nukic@implantfoundation.org.

The text body (headline, abstract, keywords, article, conclusion), tables and figures should be submitted as separate ducuments. Each submission has to be be accompanied by a cover letter. The cover letter must mention the names, adresses, e-mails of all authors and explain, why and how the content of the article will contribute to the improvement of the quality of life of patients.