Marginal Bone Loss in Implants Placed in the Maxillary Sinus Grafted With Anorganic Bovine Bone: A Prospective Clinical and Radiographic Study

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Background: Sinus elevation is a reliable and often-used technique. Success of implants placed in such situations, even with bone substitutes alone, prompted the authors of this study to strive for bone loss close to zero and research variables that cause higher or lower rates of resorption. The objective of this study is to evaluate survival rates and marginal bone loss (MBL) around implants placed in sites treated with maxillary sinus augmentation using anorganic bovine bone (ABB), and identify surgical and prosthetic prognostic variables.

Methods: Fifty-five implants were placed in 30 grafted maxillary sinuses in 24 patients. Periapical radiographs were evaluated immediately after implant placement (baseline), 6 months, and at the most recent follow-up. MBL was calculated from the difference between initial and final measurements, taking into account a distortion rate for each radiograph compared with original implant measurements.

Results: Survival rate was 98.2%, with only one implant lost (100% survival rate after loading) over a mean follow-up time of 2.0 \pm 0.9 years. MBL ranged from 0 to 2.85 mm: 75.9% of mesial sites and 83.4% of distal sites showed <1 mm of MBL, whereas 35.2% of mesial sites and 37% of distal sites exhibited no bone loss. MBL was significantly (P < 0.05) greater in openflap compared with flapless surgery.

Conclusions: Within the limitations of the present study, it was concluded that maxillary sinus elevation with 100% ABB gives predictable results, and that flapless surgery results in less MBL compared with traditional open-flap surgery. J Periodontol 2016;87:880-887.

KEY WORDS

Alveolar bone loss; bone substitutes; bone translpantation; dental implants; sinus floor augmentation.

he challenge of placing implants in the posterior area of the maxilla is a common situation faced by dentists. The subsinus edentulous ridge in the posterior maxilla often presents with limited bone volume due to both lack of alveolar bone after ridge remodeling and maxillary sinus pneumatization.^{1,2} Bone grafting in the maxillary sinus floor is a well-accepted surgical procedure to increase bone volume in the posterior maxilla and has been studied for decades.³

To the best of the authors' knowledge, the grafting maxillary sinus procedure was first studied using autogenous bone from the iliac crest, as presented by Tatum⁴ to the Alabama Implant Study Group in 1977 and published in 1986 in a report on the necessity of a 6-month healing period prior to loading and restorative treatment with fixed bridges. In 1980, Boyne and James⁵ were first to report on the sinus lift technique. In a preliminary report, Smiler and Holmes⁶ discussed the sinus lift procedure using porous hydroxyapatite in 1987, and in 1988 Wood and Moore⁷ described grafting of the maxillary sinus with autogenous bone harvested from other intraoral sites in an attempt to reduce morbidity in the placement of 20 implants in eight patients. Studies have supported use of autogenous bone in conjunction with bone substitutes, or even bone substitutes alone, with good survival rates and

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histologic results.⁸⁻¹⁰ For this reason, anorganic bovine bone (ABB) has demonstrated excellent results as a graft material, mainly due its good osteoconductive proprieties.^{7,9}

With the success of implants placed in the grafted maxillary sinus, focus shifted to marginal bone loss (MBL) around these implants. Previously, an initial MBL of 1 mm after the first year and progressive annual bone loss of 0.2 mm after 5 years was considered to be successful.^{3,8-11} However, with current advancements and new technologies in implant dentistry, in the authors' opinion there should be a drive both for bone loss close to zero and research of variables that cause higher or lower rates of resorption. Galindo-Moreno et al.¹² reported that: 1) bone substratum; 2) type of connection; and 3) heavy smoking can affect implant MBL. Additionally, MBL rates >0.44 mm/year are an indication of progression of peri-implant bone loss. In a study evaluating implants in the grafted sinus, Galindo-Moreno et al.¹² also concluded that MBL in implants at those sites are related to modifiable clinical variables, such as: 1) implantation time; 2) type of connection; 3) length of prosthetic abutment; and 4) smoking habit of the patient.¹³

This retrospective study aims to: 1) evaluate survival rates for implants after maxillary sinus augmentation using ABB by means of clinical and radiographic evaluation; 2) evaluate MBL around implants placed in grafted areas; and 3) compare MBL of implants with assessed clinical variables. Considered hypotheses were: 1) high survival rates for implants with little MBL; 2) higher MBL in implants placed after raising a flap; and 3) no difference in MBL in implants with lower prosthetic abutment, according to restoration type.

MATERIALS AND METHODS

Population, Research Design, Inclusion/ Exclusion Criteria, and Masking

For the present study, 18- to 85-year-old patients seeking implant placement in the posterior maxilla with bone availability ≤ 7 mm were selected in a private clinic (JCD) in Porto Alegre, Brazil. Twenty-four patients were selected (eight males and 16 females, aged 41 to 81 years; mean age: 59.3 years) between 2010 and 2013. Patients with: 1) blood disorders; 2) uncontrolled diabetes; 3) were current smokers; 4) history of previous surgery; and 5) presence of any pathology in the sinus were excluded. After clinical and radiographic evaluation, patients provided written informed consent after reading about advantages and disadvantages of the surgical procedure. The implant specialist (JCD), who performed all sinus grafts, did not participate in data analysis. Study protocol was reviewed and approved by the Research Ethics Committee of the São Lucas Hospital (CEP/HSL, No #0033/14), Porto Alegre, Brazil.

Clinical Variables

The following data were gathered for each patient: 1) age; 2) sex; 3) ABB quantity per sinus; 4) implant features; 5) height of prosthetic abutment; 6) teeth replaced; 7) timing of implant placement; 8) flap elevation; and 9) type of restoration. Implant features included length (11.5 and 13 mm) and diameter (3.5, 4.3, and 5 mm). Height variation of the transmucosal portion of the abutment used to support the crown on the implant body was 1.5 to 3.5 mm, as indicated for each clinical situation. The sinus graft and implant placement was performed simultaneously when native bone was >3 mm. When native bone was \leq 3 mm, treatment was performed in two stages: graft first, followed by implants. Implants performed in two stages were placed either after raising a conventional mucoperiosteal flap or using a freehand flapless technique. All implants were installed using a precision guide for determining their position and depth (i.e., 1 mm subcrestal). Restoration type was defined as one of: 1) full-arch rehabilitation; 2) fixed partial denture; or 3) single crown.

Sinus Augmentation Procedure

The need for sinus augmentation (i.e., native bone \leq 7 mm) was determined after a clinical evaluation with computed tomography (CT). Before the surgical procedure for sinus augmentation, patients were given 2 g amoxicillin.[§] After use of a mouthrinse with an aqueous solution of 0.12% chlorhexidine, the area intended for surgery was carefully anesthetized using a local anesthetic. $\ensuremath{^{\parallel}}$ To raise a mucoperiosteal flap, the paracrestal technique was used, placing the line of incision toward the palatal aspect of the ridge in the maxilla. Oblique releasing incisions were used to allow for both a wide flap basis and sufficient access to the lateral bone wall of the sinus. Flaps were carefully raised using tissue elevators. The bone ridge was examined, and any soft tissue remaining on the crest was meticulously removed with a surgical curet. The lateral window was established in an oval shape using a #3 round diamond bur. The sinus membrane was reflected, and the space created was filled with small (0.25- to 1-mm) ABB particles, $\ensuremath{\P}$ which have been shown in the literature to have higher osteoconduction compared with larger particles.¹⁴ If the membrane was perforated or torn, a collagen membrane was used to repair the damage.[#] The aim was to increase bone height to sufficient size for 10-mm or greater implant placement. Graft particles were positioned into the sinus cavity, and no membrane was placed to cover the area. Releasing incisions were made through the periosteum at base of the flap to allow for tension-free

[§] Amoxil 500 mg, GlaxoSmithKline, Brentford, U.K.

Articaína 4%, Nova DFL, Rio de Janeiro, Brazil.

[¶] Bio-Oss, Geistlich Pharma, Wolhusen, Switzerland.

[#] Bio-Gide, Geistlich Pharma.

adaptation of wound margins. Single interrupted or continuous sutures were placed to achieve healing by primary intention. Patients received prescriptions for: analgesic (500 mg acetaminophen daily); antiinflammatory (200 mg of nimesulide daily for 5 days); and antibiotic (1,500 mg amoxicillin daily, for 7 days) therapies. Patients were instructed to rinse with a 0.12% solution of chlorhexidine twice daily for 2 weeks, starting on the day after surgery. Provisional dentures were not used for at least 2 weeks. Ten days after augmentation surgery, interrupted sutures were removed. Follow-up visits were scheduled every 4 to 6 weeks until reentry surgery with clinical and radiographic evaluation was performed.

Six to 8 months after augmentation surgery, clinical evaluation with CT was performed to analyze bone availability, and reentry and implantation surgery were carried out. Patients who only had graft placed in the first surgery (i.e., two stages) were scheduled for implant placement. Patients who had graft and implant placed simultaneously (i.e., one stage) were scheduled for reentry. All implants were used with a Morse-taper connection and were placed 1 mm subcrestally in the previously planned position (i.e., corresponding to the future crown center).** All implants used in this study had a full sandblasted and acid-etched surface treatment.

Follow-Up

After final prosthodontic treatment, patients were included in a maintenance program with recall appointments every 6 months. Standardized periapical radiographs were taken using the paralleling technique. Clinical evaluation examined: 1) mobility; 2) pain; or 3) infection associated with implants. Cases were considered successful in the absence of pain or mobility upon reentry and at recall appointments.

Measurement Technique

Standardized digital periapical x-rays^{††} were obtained at: 1) baseline (i.e., from 0 to 6 months after implant placement); 2) time of final restoration; and 3) the last assessment after functional loading. Data were analyzed using appropriate computer software for further analysis.^{‡‡} For each patient grafted with ABB, two periapical radiographs were analyzed: 1) one taken at baseline (i.e., from 0 to 6 months after implant placement, or t1); and 2) one at the most recent follow-up examination (i.e., at 2, 3, or 4 years postoperatively, or t2). All x-rays were taken using the same equipment with 70 kVp, 8 mA, 0.2 s, and with a focal distance of \approx 30 cm. Universal positioners were used to take the periapical x-rays, and mensuration was rounded to 0.05 mm. Using software,^{§§} MBL measurements were performed independently by two examiners (TD and FS) and repeated three times for each reference point on the periapical radiograph, from the most mesial and distal point of the implant platform to the crestal bone (Figure 1). Mean values were considered in the evaluation. All implants were analyzed, regardless of the number of implants placed. To standardize measurements and reduce the influence of anatomic variables, distortion was calculated for each implant. This was carried out by comparing radiographic values to true values of each implant using a digital caliper.

Statistical Analyses

Data analysis was carried out using a statistical software package.^[]] The Kolmogorov–Smirnov normality test and Levene homogeneity of variance test were used. For bivariate analysis, Mann–Whitney U and Student t tests were used. Repeated-measures analysis of variance was used to analyze reduction in MBL.

RESULTS

In the 24 selected patients, 55 implants were placed. Among these patients, six required bilateral sinus augmentation, and 18 required unilateral sinus augmentation, totaling 30 sinus augmentation surgeries. MBL ranged from 0 to 2.85 mm and when compared with other variables, the most important finding was the statistically significant difference between surgeries performed with and without a flap; MBL was lower in flapless surgery.

Implant survival rate was 98.2% with only one implant lost (3.5 mm in diameter and 13 mm in length), which occurred 5 months after placement. The implant was replaced 3 months after its removal, and no implants were lost after loading (100% survival rate after loading). Thirteen implants were placed simultaneously with the sinus lift (23.6%), and 42 were placed in two stages (76.4%). Twenty-two implants were inserted during a flapless surgery (40%), and the other 60% were inserted after raising a flap.

An average of 1.9 g of ABB per sinus was used, varying from 0.5 to 5 g. Only one case had membrane perforation (1.8%), which was covered by collagen membrane, and it was possible to perform sinus graft. First molars were the most restored teeth (43.7%) followed by second premolars (25.5%). Exactly 50% of cases had a follow-up within 1.5 years (combining 1 and 1.5 years), and mean follow-up time was 2 years.

Forty-two implants (76.4%) had a 4.3-mm diameter, and 49 (89.1%) were 13 mm long. Multiple abutments were used in 43 implants (78.2%), and single abutments were used in 12 implants (21.8%). Multiple abutments were used for full-arch (40%) and

‡‡ DBSWIN, Dürr Dental.

SPSS v.17, IBM, Chicago, IL.

^{**} Drive implant, Neodent, Curitiba, Brazil.

^{††} VistaScan Perio Plus, Dürr Dental, Bietigheim-Bissingen, Germany.

^{§§} ImageJ software v.1.44, National Institutes of Health, Bethesda, MD.

partial (38.2%) rehabilitations. Abutment height varied from 1.5 to 4.5 mm. Twenty-seven cases (49.1%) were rehabilitated with 2.5-mm abutments, and 20 cases (36.4%) involved placement of 3.5-mm abutments.

Of the 42 implants placed in two stages, one was lost. In the remaining 41, bone substratum was divided as follows: 1) >0 mm \leq 1 mm (13 implants); 2) >1 mm \leq 2 mm (12 implants); and 3) >2 mm \leq 3 mm (16 implants). Mean MBL in the group >0 mm \leq 1 mm was 0.76 mm. In the >1 mm \leq 2 mm group, MBL was 0.41 mm, and in the >2 mm \leq 3 mm group it was 0.48 mm.

Tables 1 and 2 show the comparison between mesial versus distal MBL for different variables. Mean mesial and distal MBL was 0.6 ± 0.7 mm and 0.4 ± 0.5 mm, respectively. Mesial MBL in flapless surgery was 0.2 ± 0.3 mm versus 0.8 ± 0.8 mm in flap surgery (*P*<0.001). In the distal aspect, MBL in flapless

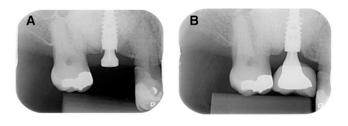


Figure 1. Radiographic measurements at baseline (A) and 2 years after implant was loaded (B).

surgery was 0.2 ± 0.4 mm versus 0.5 ± 0.6 mm in flap surgery (*P* <0.05). This difference between flapless and open-flap surgery might have been due to disruption of vascularization after raising the mucoperiosteal flap. Comparison of MBL among: 1) timing of implant placement; 2) type of abutment; 3) sex of patient; 4) abutment size; and 5) type of rehabilitation resulted in non-statistically significant differences. Figure 2 shows frequency of bone loss as a function of interproximal site (mesial or distal).

DISCUSSION

Graft Material

Graft was performed only with ABB, which is a proven evidence-based method of treatment according to Wallace et al.¹⁰ Bone-substitute materials are as effective as autogenous bone when used alone or in combination with autogenous bone.⁸ One study has demonstrated that after 10 to 12 months, histologic specimens revealed new bone formation adjacent to particles of ABB in all samples.⁹ Long-term maintenance of these results has been shown after 9 years by Mordenfeld et al.¹⁵ and after 11 years by Traini et al.¹⁶ In addition to autogenous bone, xenografts, and the mixture of both, successful outcomes have been shown with allografts and alloplasts; however, these studies are fewer in number.^{17,18} Therefore, in respect to particle size used in the present study, studies that compare small and large particle sizes have demonstrated a higher osteoconduction of the former compared with the latter.¹⁴

Table I.

Comparison of Mesial Versus Distal MBL Among Different Variables

			P Value	
Independent Variables	MBL (mm)	MBL (mm)	Mann–Whitney U test	Student <i>t</i> test (two-tailed)
Mesial versus distal	0.6 (± 0.7) n = 54	0.4 (± 0.5) n = 54	NS	NA
Flapless versus flap surgery Mesial Distal		0.8 (± 0.8) n = 32 0.5 (± 0.6) n = 32	NA <0.05	<0.001 NA
One-stage versus two-stage surgery Mesial Distal	0.5 (± 0.5) n = 13 0.3 (± 0.4) n = 13		NA NS	NS NA
Multiple versus single abutment Mesial Distal	· /	0.8 (± 0.7) n = 12 0.4 (± 0.7) n = 12	NS NS	NA NA
Women versus men Mesial Distal	0.6 (± 0.7) n = 31 0.3 (± 0.5) n = 31	· · · · ·	NA NS	NS NA

MBL values are shown as mean (\pm SD).

NS = not significant; NA = not applicable.

Table 2.

Comparison of Mesial and Distal MBL (in mm) Among Different Variables

Independent Variables	Mesial MBL	Distal MBL
Abutment I.5 mm (n = 6)	0.7 (± 1.0)	0.6 (± 0.9)
Abutment 2.5 mm (n = 27)	0.6 (± 0.8)	0.4 (± 0.5)
Abutment 3.5 mm (n = 19)	0.5 (± 0.5)	0.4 (± 0.5)
Single crown (n = 12)	0.8 (± 0.7)	0.4 (± 0.7)
Fixed partial denture $(n = 21)$	0.6 (± 0.8)	0.3 (± 0.4)
Full-arch rehabilitation $(n = 21)$	0.4 (± 0.6)	0.5 (± 0.6)

Values are shown as mean (\pm SD).

No significant differences among variables were found.

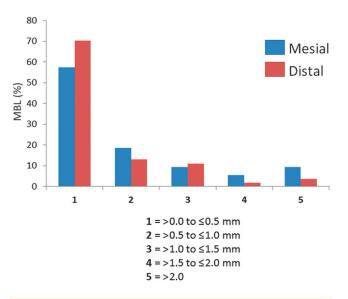


Figure 2.

Frequency of bone loss as a function of interproximal site (mesial or distal).

Barrier Membrane

No collagen membranes were used to cover the lateral window, as possible ingrowth of connective tissue into the sinus was reported in an animal study.¹⁹ In spite of these results, Wallace et al.¹⁰ and Tarnow et al.²⁰ have shown that membranes tend to enhance vital bone formation and result in increased implant survival rate. In the present study, implant survival rate was 98.2%, with only one implant lost out of 55 rough-surfaced and Morse-tapered implants; these results are in agreement with similar studies.⁸⁻¹⁰

Smoking

In a study with 52 maxillary sinus lifts, Galindo-Moreno et al. 21 concluded that: 1) history of peri-

 of bone after elevation of the maxillary sinus floor. Additionally, in multivariate analysis of 1,320 implants, Vervaeke et al.²² reported that smoking is a predictor of implant failure and peri-implant bone loss. Exposure to smoking had a harmful effect on peri-implant bone loss in a systematic review and meta-analysis, and to reduce the confounding effect of this variable, smokers were excluded.²³
Bone Substratum

In the present study, mean MBL was 0.6 ± 0.7 mm and 0.4 ± 0.5 mm in the mesial and distal aspects, respectively. These values were slightly higher than those of Cecchinato et al.,²⁴ who showed a mean MBL of 0.2 ± 1.2 mm. However, this work considered the 1-year postloading radiograph as baseline, which can underestimate these values because there is a greater rate of MBL during the first 6 months postloading.²⁵ Moreover, regardless if implants were placed either in the maxilla or mandible, and without specifying supporting tissue (i.e., grafts or native bone), implants still presented good results because only 20% of individuals and 11% of sites lost >1 mm, whereas 8% of individuals and 4% of sites lost >2 mm of marginal bone.²⁴ Galindo-Moreno et al.^{25,26} compared MBL between native bone and grafted sinus, resulting in statistically significant differences in MBL between implants placed in grafted (1.09 mm) versus pristine (0.71 mm) bone at the 12-month follow-up. However, there were no differences in subsequent progression rate, which is in agreement with a previous study.¹³ Difference in MBL between grafted bone or pristine bone was not found in the present study when comparing preoperative crestal bone height below the sinus, perhaps because of the small sample size. The group with >0 mm \leq 1 mm presented a slightly higher MBL (0.76 mm) compared with groups with >1 mm \leq 2 mm (0.41 mm) and >2 mm ≤3 mm (0.48 mm).

odontitis; 2) type of edentulism; and 3) smoking/ drinking habits play an important role in maturation

Implant-Abutment Connection

Galindo-Moreno et al.²⁶ also presented significantly higher MBL around implants with external connections (1.30 mm) than those with internal connections (0.50 mm) after the 3-year follow-up period. Annibali et al.²⁷ compared differences between platformswitched and conventionally restored implants, concluding that a smaller amount of MBL was noted around platform-switched implants despite no statistically significant difference in success rate. Dursun et al.²⁸ showed similar findings, but Wang et al.²⁹ suggested that when a conical implant–abutment connection is present, similar peri-implant tissue responses can be achieved with platform-switched and non-platformswitched abutments.

Surgical Technique

Mesial MBL for implants placed in one stage (0.5 \pm 0.5 mm) was no different from those placed in two stages (0.6 \pm 0.7 mm), and distal MBL for implants placed in one stage (0.3 \pm 0.4 mm) also did not differ from those placed in two stages (0.4 \pm 0.6 mm). These results are in agreement with those found by Siadat et al.³⁰ in a randomized clinical trial with 1 year of functional loading of 34 implants. Del Fabbro et al.⁸ also reported similar survival rates between simultaneous or delayed procedures.

Prosthetic Abutment

For Galindo-Moreno et al.,²⁵ abutment height is a key factor in MBL, and they reported higher MBL for abutments <2 mm compared with those \geq 2 mm. In their study, 315 implants placed in the posterior maxilla in 131 patients with follow-up of 18 months were included. However, the present study did not find any statistically significant MBL difference in different abutment heights, perhaps due to the small sample size. In the present study, all implants were placed 1 mm subcrestally, but Galindo-Moreno et al.²⁵ placed all implants at bone level, and they were then splinted to another implant. Galindo-Moreno et al.²⁵ found significantly greater MBL in shorter prosthetic abutments, in agreement with the finding by Vervaeke et al. 31 of greater bone level changes in implants with short abutments.

Flap Manipulation

Interestingly, MBL was statistically significantly different between flapless and traditional open-flap surgery, with 0.2 ± 0.3 mm and 0.8 ± 0.8 mm, respectively, in the mesial crest, and 0.2 ± 0.4 mm and 0.5 ± 0.6 mm, respectively, in the distal crest. Doan et al.³² stated that the posterior maxilla is the most applicable area for performing flapless surgery in the mouth, with high survival rates and an average rate of intraoperative complications of 6.55%. Conversely, in a systematic review, Voulgarakis et al.³³ compared flapless surgery in freehand or guided surgery (with or without three-dimensional navigation), and concluded that none of the methods demonstrated advantages over others, even though the freehand technique presented the best survival rates (98.3% to 100%) and less MBL (0.09 to 1.40 mm). In a systematic review and meta-analysis, Lin et al.³⁴ evaluated the effect of flapless surgery on both implant survival and marginal bone level. Twelve studies were included, and survival rate was comparable between flapless surgery (97%) and open-flap procedures (98.6%). However, MBL was similar and did not exhibit statistical significance as it presented considerable heterogeneity among studies.

In a randomized controlled clinical trial with 30 implants, Tsoukaki et al.³⁵ showed that implants placed with a flapless approach present decreased peri-implant sulcus depth values, a milder post-surgical inflammatory reaction, and no peri-implant bone resorption compared with implants placed with conventional flap surgery. Elevated numbers of specific periodontal pathogens detected around flapless implants possibly indicated earlier formation and maturation of the peri-implant sulcus in that group. These statements can explain the difference between flapless and flapped MBL around implants placed in grafted sinuses.

The present study differs in some aspects from other similar studies on MBL around implants in grafted sinuses. Distortion rate of the periapical radiograph was calculated for each implant, taking the implant or abutment as the standard value. Identical implants were studied with platform switching (Morse taper) and rough surfaces, all placed in maxillary sinuses lifted with ABB. Additionally, MBL was calculated in flapless and flap surgeries; MBL was greater around implants placed with flap surgery.

CONCLUSIONS

Within the limitations of this retrospective study, the following was concluded: 1) maxillary sinus elevation with 100% ABB had predictable results; 2) the 98.2% implant survival rate found here encourages placement of implants in grafted sinus; 3) placement of Morse-tapered implants after sinus lift seems to result in little MBL; 4) flapless surgery results in less MBL compared with traditional openflap surgery, and must be taken into consideration to ensure maintenance of bone level; 5) there might be a slightly lower risk for MBL when using higher prosthetic abutments and when placing implants in higher preoperative height of crestal bone below the sinus; and 6) no significant differences were found between MBL and surgeries performed in one or two stages.

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