Sinus Augmentation Utilizing Anorganic Bovine Bone (Bio-Oss) with Absorbable and Nonabsorbable Membranes Placed over the Lateral Window: Histomorphometric and Clinical Analyses

Stephen S. Wallace, DDS¹ / Stuart J. Froum, DDS²  
Sang-Choon Cho, DDS³ / Nicholas Elian, DDS⁴  
Diogo Monteiro⁵ / Byung Soo Kim⁵  
Dennis P. Tamow, DDS⁶

The purpose of the present study, which used anorganic bovine bone (Bio-Oss) with and without autogenous bone as the augmentation material, was to compare the results of sinus elevation performed without a membrane (control) with the results of sinus elevation performed with either a short-term bioabsorbable membrane (Bio-Gide) or a nonabsorbable membrane (Gore-Tex) with regard to both vital bone formation and implant survival. Sinus lifts were performed on 51 patients (38 unilateral, 13 bilateral) with the delayed placement of 135 implants. Histomorphometric data were obtained at the time of implant placement, 6 to 10 months following the grafting procedure. Vital bone formation was 17.6%, 16.9%, and 12.1%, respectively, for the Bio-Gide, Gore-Tex, and no membrane groups. Of the 135 implants placed there were 3 failures (2 Bio-Gide, 1 Gore-Tex). There was no significant difference between the membrane groups as to vital bone formation and implant survival. (Int J Periodontics Restorative Dent 2005;25:551–559.)

¹Associate Professor, Ashman Department of Implant Dentistry, New York University, New York, New York.  
²Clinical Professor, Department of Surgical Services (Periodontics), Clinical Professor and Director of Clinical Research, Ashman Department of Implant Dentistry, New York University, New York, New York.  
³Associate Research Scientist, Ashman Department of Implant Dentistry, New York University, New York, New York.  
⁴Director, Advanced Program for International Dentists, Ashman Department of Implant Dentistry, New York University, New York, New York.  
⁵Implant Resident, Advanced Program for International Dentists, Ashman Department of Implant Dentistry, New York University, New York, New York.  
⁶Professor and Chairman, Ashman Department of Implant Dentistry, New York University, New York, New York.

Correspondence to: Stephen S. Wallace, 140 Grandview Avenue, Waterbury, CT 06708; fax: 203-573-0773; e-mail: sswwdds.sinus@sbcglobal.net.

Insufficient residual alveolar bone height is a common deterrent to the placement of dental implants in the posterior maxilla. This can be the result of alveolar bone resorption following tooth loss, bone loss resulting from periodontal disease, pneumatization of the maxillary sinus, or a combination of the above. A technique for grafting the floor of the maxillary sinus was first presented in 1977 by Tatum¹ and first published in 1980 by Boyne and James.² Since that time, the sinus grafting surgical technique has been modified by many clinicians, and lateral window techniques today involve the use of at least three distinct entry procedures,³ various bone graft substitutes, and a barrier membrane over the lateral window.

Systematic reviews of periodontal guided tissue regeneration,⁴,⁵ preprosthetic guided bone regeneration⁶ (GBR), and sinus augmentation surgery⁷ reveal that barrier membranes have been used with proven efficacy. While many investigators have reported a positive result with barrier membrane placement in sinus augmentation.
surgery.\textsuperscript{8,9} Fewer studies have compared the results achieved with and without barrier membranes,\textsuperscript{13–16} and, to date, no study has attempted to compare the results achieved with different types of barrier membranes.

Nonabsorbable barrier membranes require stabilization via fixation to best perform their barrier function. This may be a result of membrane stiffness and a subsequent inability to conform to the bone surface and thereby stabilize the graft and exclude connective tissue. Further, these membranes must be removed with a flap procedure as significant as the one used to place them, with an increase in morbidity for the patient. Some, but not all, bioabsorbable membranes lack this stiffness and conform well to the bony walls of the lateral sinus wall. The lack of stiffness would not be considered a liability, because the sinus graft is internal. Most bioabsorbable membranes possess a limited barrier function time in comparison to nonabsorbable membranes. These times vary from 1 to 6 months and may not be long enough to produce the desired effect.

The purpose of the present study, which used anorganic bovine bone (Bio-Oss, Osteohealth) with and without autogenous bone as the augmentation material, was to compare the results of sinus elevation performed without a membrane (control) to the results of sinus elevation performed with either a short-term bioabsorbable membrane (Bio-Gide, Osteohealth) or nonabsorbable membrane (Gore-Tex, W. L. Gore) with regard to both vital bone formation and implant survival.

\textbf{Method and materials}

This study is part of an ongoing sinus elevation study begun in 1993 at the New York University (NYU) Department of Implant Dentistry. All patients in this histologic, histomorphometric, and clinical study chose sinus elevation surgery with implant placement as opposed to alternative treatment plans that were presented. Patients with absolute contraindications (e.g., uncontrolled diabetes, long-term steroid use, blood disorders) were excluded from both implant treatment and from this study, while those patients with relative contraindications (controlled diabetes, smoking) were included. All study participants received informed consent and signed the appropriate consent forms. All participants had the right to withdraw from the study at any time. The research protocol for this study was approved by the NYU Institutional Review Board (H11302-01B).

The data for this study were obtained from 64 sinus augmentation procedures performed on 51 patients (13 bilateral augmentations and 38 unilateral augmentations). The grafting material used in these cases was either Bio-Oss alone or a composite graft consisting of Bio-Oss with less than 20% intraorally harvested autogenous bone. The lateral window was left uncovered, covered with a nonabsorbable expanded polytetrafluoroethylene.
(e-PTFE) membrane (Gore-Tex), or covered with a bioabsorbable collagen membrane (Bio-Gide).

Surgical procedure

The surgical protocol for the lateral window procedure used in this study was reported previously in detail. The only procedural differences between the 64 augmentation procedures in the present study involved either the lack of a membrane over the window or the use of either a bioabsorbable or a nonabsorbable membrane over the lateral window osteotomy. All sinuses were grafted with either a 100% bone replacement graft (Bio-Oss) or a composite graft consisting of Bio-Oss plus a maximum of 20% introral autogenous bone harvested from the maxillary tuberosity or the mandibular ramus. The nonabsorbable membrane used was e-PTFE (Gore-Tex), and the bioabsorbable membrane was collagen (Bio-Gide). All surgical and prosthetic procedures were performed by implant fellows under the supervision of the implant faculty.

Histologic and histomorphometric analyses

Histomorphometric data were obtained from bone core biopsies retrieved from the area of the lateral window at the time of implant placement, ie, 6 to 10 months after graft placement. The cores were numerically coded and sent to the Hard Tissue Research Laboratory at the University of Minnesota, where they were subjected to a blinded histomorphometric analysis for a determination of the vital bone content.

Implant survival data

Data on implant survival were included only for those implants that were loaded for a minimum of 1 year.

Results

The bone biopsies were evaluated for percentage of vital bone, percentage of residual graft material, and percentage of connective tissue/marrow. The results for the three groups are presented in Table 1. Data on 1-year implant survival rates are provided in Table 2.

Histologic specimens revealed vital bone formation adjacent to par-
Fig 1  (a) Uncovered graft, with 14% vital bone, 43% Bio-Oss, and 43% connective tissue. Foci of vital bone formation (red) can be seen between the residual Bio-Oss particles (yellow) (Stevenel blue and van Gieson stain; original magnification ×10). (b and c) Higher-magnification view (Stevenel blue and van Gieson stain; original magnification ×20).

Fig 2  (a) Graft covered with membrane (Gore-Tex), composed of 30% vital bone, 29% Bio-Oss, and 41% connective tissue. Vital bone formation (red) is apparent between the residual Bio-Oss particles (yellow) (Stevenel blue and van Gieson stain; original magnification ×10). (b) Higher-magnification view (Stevenel blue and van Gieson stain; original magnification ×20).

ticles of Bio-Oss in all specimens. Figures 1 to 3 are representative samples from the no-membrane, Gore-Tex, and Bio-Gide groups, with vital bone formation of 14%, 30%, and 30%, respectively. All undecalcified specimens were stained with Stevenel blue and van Gieson stain and are shown at original magnification of 10× or 20×.

Figure 4 illustrates the osteoconductive properties of the Bio-Oss grafting material. Bio-Oss particles (yellow) were evident everywhere in contact with newly formed bone (red), which was, in turn, covered by a layer of osteoid (green) and numerous osteoblasts (black). Interparticular bridging appeared to connect and solidify the matured graft.

Discussion

As surgical techniques have evolved, so have the use of various grafting materials, barrier membranes over the lateral window, implants with varying macro- and micromorphologies, and new technologies. One hopes that this evolution will result in ever-higher survival rates for implants placed in grafted maxillary sinuses. Successful outcomes have been documented in systematic literature reviews for both guided tissue regeneration around teeth⁴,⁵ and for preprosthetic GBR prior to implant placement.⁷,¹⁷

There is sufficient evidence today to justify the placement of a barrier membrane over the lateral window. A systematic review has now been published that discusses membrane
placement as a co-variable in sinus augmentation surgery. This review cited three controlled studies that showed more favorable bone formation and higher implant survival rates when a membrane was used over the sinus graft and window. A randomized controlled trial by Tarnow et al. using a bilateral sinus model showed that vital bone formation in the membrane-covered sinus was, on average, twice that of sinuses not covered by membranes. The present study, as well as controlled trials by Tawil and Mawla and Froum et al., showed higher implant survival rates on the membrane side than on the control side (Table 3). A systematic review by Wallace and Froum further showed that, in 20 additional studies (15 without membrane placement, 5 with membrane placement), implant survival rates for sinuses grafted with particulate grafts were higher when a barrier membrane was placed over the lateral window (93.6% versus 88.7%).

As in a GBR procedure, the membrane appears to exclude nonosteogenic connective tissue from the grafted sinus, with a resultant increase in vital bone formation and an increased rate of implant survival. Clinically, the ingrowth of connective tissue into sinus grafts not protected by a membrane (encleftation) has been reported by McAllister et al.

We tend not to think of a sinus graft as a form of GBR; yet in reality, it may be considered as a GBR pro-

<table>
<thead>
<tr>
<th>Table 3 Controlled studies: Membrane versus no membrane</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Membrane</strong></td>
</tr>
<tr>
<td><strong>Study</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Tarnow et al (2000)</td>
</tr>
<tr>
<td>Tawil and Mawla (2001)</td>
</tr>
<tr>
<td>Froum et al (1998)</td>
</tr>
</tbody>
</table>
procedure that occurs within a cavity. Murray et al. demonstrated a phenomenon called the “caging effect” in an animal model. When a membrane was placed over a grafted bone defect, completely sealing the defect from the outside environment, corticalization of the wound surface, contiguity of the graft particles, and increased vascularity of the graft were noted. Bone formation in sinus grafts has been evaluated by Boyne and Kruger, Boyne and James, Misch and Dietsch, Margolin et al., Smiler et al., Boyne et al., and Nevins and Fiorellini. These histologic wound healing studies all show that bone formation initiates from the walls and floor of the sinus after the Schneiderian membrane has been lifted and displaced. This displacement would expose the vascular supply in the lateral wall, along with the surrounding perivascular osteoblasts, to the placed graft material, allowing for the “angiogenesis that must precede osteogenesis.”

Bone formation in the grafted sinus is certainly aided by the displacement of the Schneiderian membrane, which was shown by Haas et al. to be avascular and by Hürzeler et al. to offer minimal osteogenic potential in sinus grafts in an animal model. Bone formation also appears to be aided by the exclusion of the periosteum from the regenerating sinus graft. Once lifted and replaced, the periosteum loses its osteogenic potential and becomes fibrogenic, which would explain the soft tissue enucleation that is seen when a membrane is not used over the window. This is quite similar to the soft tissue ingrowth that occurs into unprotected (no membrane coverage) periodontal and ridge augmentation sites.

As demonstrated in Table 1, this study showed that vital bone formation in sinus grafts was greater when either a nonabsorbable membrane or a bioabsorbable membrane was used (16.9% and 17.6%, respectively), in comparison to sinuses grafted without a membrane (12.1%). There was no statistical difference between the membrane groups. Both were higher than the no-membrane group, but the small sample size for this group did not allow for statistical comparison.

Further, as demonstrated in Table 2, there was no significant difference in implant survival between the nonabsorbable and bioabsorbable membrane groups (97.8% and 97.6%, respectively). This compares with the results of a 5-year prospective study on GBR by Zitzmann et al. This study showed no statistical difference in implant survival rates following GBR procedures with either Bio-Oss/Gore-Tex or Bio-Oss/Bio-Gide.

The efficacy of xenografts as a sinus bone replacement graft may be the result of a combination of factors. Foremost would be the osteoconductive capacity of the cancellous xenograft, a feature that may be dependent on pore size. In addition, the xenografts supply minerals that are necessary for bone formation; their density provides stiffness to the graft and the implants placed in them; and this density persists long-term because these grafts do not completely resorb.

The Bio-Oss grafting material used in this study appears to be a highly effective osteoconductor, with its performance enhanced by the placement of a barrier membrane over the window. The histologic example shown in Fig 4 demonstrates this quite well, with vital bone formed on a majority of the surfaces. Further, significant residual Bio-Oss particles were present in all specimens, with these particles surrounded by vital bone. When implants are placed in these matured bone grafts, the placement procedure creates a secondary wound, with subsequent bleeding. Implant surfaces, particularly those that are textured, retain the blood clot for the eventual bone-implant contact (BIC) that we call osseointegration.

Histologic reports of explants taken from the maxillary sinus by Rosenlicht and Tarnow, Valentini et al., and Scarano et al. do not show xenograft material in direct contact with the implant surface. This would mean that the residual xenograft in effect increases the mineral content of the resulting matured graft while not interfering with the possibility for BIC. This may help to explain the excellent implant survival rates achieved by Valentini et al., Hising et al., Hallman et al., Yildirim et al., and John and Wenz following the use of this grafting material. These histomorphometric studies, listed in Table 4 with additional data from New York University sinus research studies, all showed percentages of vital bone.
connective tissue, and residual xenograft to be in the order of 25%, 50%, and 25%, respectively, at a time interval of 6 to 12 months after grafting. Because of the residual 25% xenograft volume, a mature graft that is classified as type 3 or 4 by nature of its vital bone content may, in fact, function like bone of type 2 density. These observed histologic and wound healing phenomena may explain why mineralized particulate bone replacement grafts used for sinus augmentation surgery have been shown to perform as well or better than grafts of 100% autogenous bone.7,17

Conclusions

This paper reports on the histologic, histomorphometric, and clinical findings of sinus augmentation surgery with subsequent implant placement using Bio-Oss as a grafting material without membrane placement or with the placement of either a nonabsorbable membrane (Gore-Tex) or a short-term bioabsorbable membrane (Bio-Gide) over the lateral window.

Within the limits of this histomorphometric and clinical study, the following conclusions may be drawn:

1. Vital bone formation in sinus grafts is improved when a membrane is placed over the window.
2. Vital bone formation is similar with nonabsorbable Gore-Tex and bioabsorbable Bio-Gide membranes.
3. Implant survival is similar with Gore-Tex and Bio-Gide membranes.
4. Bio-Oss demonstrates excellent osteoconductive properties in the grafted sinus.
5. Bio-Oss alone, or as a composite graft with minimal amounts of autogenous bone, results in an extremely high implant survival rate in the grafted sinus (97.8%).

Acknowledgments

We offer our thanks to Michael D. Rohrer and Hari S. Prasad, of the Hard Tissue Research Laboratory at the University of Minnesota, who performed the histomorphometric analyses.
References


