ORIGINAL ARTICLE

Efficacy of demineralized bone matrix for maxillary sinus lift with implant-retained prosthetic rehabilitation: A prospective evaluation

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ABSTRACT

Context: Several materials have been used for maxillary sinus augmentation for subsequent implant-supported prosthetic rehabilitation. No perfect material has been identified for the purpose.

Aims: The aim of the study is to clinically and radiographically evaluate the use of Sterile Demineralized bone matrix (Osseograft™) for maxillary sinus augmentation and subsequent implant-supported prosthetic rehabilitation.

Subject and Methods: Sinus augmentation and implant placement were carried out in twenty patients with Osseograft™. Using intraoral periapical radiographs, radiographic implant length (rIL), residual bone height at the mesial (mRBH) and residual bone height at the distal (dRBH) aspects of the implant, and height of the graft apically (aGH) were measured. Residual bone height (RBH) = Mean of mRBH and dRBH, implant penetration (IP) =difference between rIL and RBH, Extent of the sinus lift (SL) = sum of IP and aGH were calculated and a qualitative assessment of maturation was performed using the Sinus Grafting Remodeling Index (SGRI).

Statistical Analysis Used: Descriptive statistics.

Results: The mean residual bone height immediately after surgery was 6.81 mm. The mean IP length was 5.45 mm. The mean aGH was 3.21 mm. The mean extent of the SL was 8.89 mm. At 3 months and 6 months, the mean aGH was 2.68 mm and 2.57 mm. The mean SL at 3 months and 6 months was 7.84 mm and 7.73 mm. The SGRI was 1 in all cases immediately postsurgery; between 1 and 2 at the end of 3 months; 2 in 15 cases and 1 in 4 cases at the end of 6 months.

Conclusion: Osseograft™ can be used as an effective material for sinus augmentation with minimal complications and morbidity to the patient.

KEY WORDS: Demineralized bone matrix, maxillary sinus augmentation, Osseograft™, sinus grafting remodeling index

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INTRODUCTION

The use of osseointegrated Dental implants has greatly facilitated the placement of a permanent fixture needed to support the abutment prosthesis.[1] Due to the poor

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bone quality and the tendency for progressive resorption following tooth loss, the posterior maxilla has been a high-risk area for rehabilitation with implant-supported fixed prostheses. Therefore, it is of utmost importance to increase the quantity of bone in the posterior-lateral areas of the maxilla, by means of a maxillary sinus floor elevation. In recent years there, has been a growing diffusion of maxillary sinus elevation procedures associated with implantology. The first documented experiences of bone grafts in the maxillary sinus, date back to the late 1960s, attributed to Boyne.[2] Tatum was one of the main proponents of the maxillary sinus elevation technique for implant purposes using autogenous bone grafts taken from the iliac crest.[3]

Variety of materials such as autogenous, allogenic, and alloplastic grafts has been used for sinus augmentation.[4] Although autogenous bone grafts have been described as the gold standard for sinus augmentation, it requires patient compliance, a second surgical site, and increased morbidity.[5] Alloplastic materials though in common use, lack osteoinductive properties, and show increase rate of resorption. Demineralized bone matrix is an allogenic material with osteoconductive and osteoinductive properties due to the inherent bone morphogenetic protein that remains behind which stimulates the adjacent undifferentiated cells to form bone.[6] Numerous studies have been reported in the literature regarding the use of demineralized bone matrix for maxillary sinus augmentation. However, many of these studies have been primarily with Bio-oss, a demineralized bovine bone mineral[7,8] and one of the most widely used bone substitutes, used both alone and in mixtures for sinus augmentation.[9-11]

Osseograft™ is a sterile bioresorbable bovine bone composed of type I collagen. It is prepared from bovine cortical bone with particles size of approximately 250 µm that are completely replaced by host bone in 5–6 months. This aim of the study is to clinically and radiographically evaluate the use of Sterile Demineralized bone matrix (Osseograft™) for maxillary sinus augmentation and subsequent implant-supported prosthetic rehabilitation.

SUBJECT AND METHODS

Over a period of 3 years, twenty patients were randomly selected in the study who reported with complaints with missing maxillary posterior teeth and required prosthetic rehabilitation of the missing dentition. The study was approved by the Hospital Ethics Committee. The inclusion criteria framed for the study were patients in age group between 20 and 50 years, Residual Posterior Maxillary Alveolar residual bone height <10 mm, more than 4 mm of residual bone width, no localized pathology or anatomic limitations of oral cavity, or scarring after previous surgery, no significant history of sinus disease, no history of systemic diseases that may impede wound healing, Nonsmokers and no systemic contraindication to surgery. Patients with residual bone height of <5 mm residual alveolar bone received a two-stage approach, while patients with residual bone height of 5–10 mm received a single-stage approach. Patients with poor oral hygiene advanced periodontal disease, systemic diseases such as uncontrolled diabetes and/or drug therapy known to interfere with soft tissue and bone healing, smokers, and patient with parafunctional habits were excluded from the study. Clinical evaluation was undertaken to assess the surrounding dentition, occlusion, residual alveolar width, interocclusal clearance, and occlusal interferences. Assessment of the buccopalatal width was determined using diagnostic casts. The width of the residual alveolar bone was calculated by the formula: mean width of residual alveolar ridge on the diagnostic cast − (mean width of corresponding buccal + palatal gingiva).

Intraoral periapical radiographs were taken preoperatively to assess the residual alveolar bone height, the relation and direction of sinus floor, and the presence of sinus septae following a standardized technique.

Residual alveolar ridge height was measured as the distance from alveolar crest to the most inferior point on the floor of the sinus [Figure 1].

Radiographic measurements are illustrated [Figure 2] were performed on the periapical radiographs taken immediately after surgery and at 3- and 6-month following surgery.

1. Radiographic implant length (rIL): distance (in mm) between the implant shoulder and the implant apex as assessed at the mid portion of the implant

Figure 1: Assessment of the preoperative height of residual alveolar ridge

2. Residual bone height at the mesial (mRBH) and residual bone height at the distal (dRBH) aspects of the implant: distance (in mm) between the mesial and distal aspect of the implant shoulder, respectively, and the sinus floor
3. Height of the graft apically (aGH): distance (in mm) occupied by a radiopaque area between the implant apex and the sinus floor as assessed at the mid portion of the implant.

   To account for radiographic distortion, radiographic measurements (i.e., mRBH, dRBH, and aGH) on each radiograph were adjusted for a coefficient derived from the ratio: true length of the implant/rIL.

For each patient, the following derived radiographic parameters were obtained:

1. Residual bone height (RBH) calculated as the mean value of mRBH and dRBH
2. Implant penetration (IP) calculated as the difference between rIL and RBH
3. Extent of the sinus lift (SL) calculated as the sum of IP and aGH
4. A qualitative assessment of the maturation of the grafted area was also performed using the Sinus Grafting Remodeling Index (SGRI).[12]

Preoperatively, ENT evaluation was done to rule out any maxillary sinus pathology or anatomic alterations in the outflow of maxillary sinus. After achieving adequate anesthesia, a paracrestal incision with vertical releasing incisions was placed, and a trapezoidal mucoperiosteal flap was raised to expose the lateral bony wall of the sinus. A rectangular window is marked with the lower end of the rectangle just above the floor of the sinus as measured radiographically. A bur hole marking is made on the lateral wall with a No: 4 round bur and joined with a No: 701 bur to refine the osteotomy taking care not to perforate the sinus membrane [Figure 3]. In the presence of septa, a kidney shaped antrostomy or two separate osteotomies were created on either side of the septae to expose the sinus membrane. The average size of the rectangular osteotomy is 20 mm × 15 mm. The membrane is carefully dissected out from the surrounding bony walls using sinus curettes starting at the sinus floor, the lateral wall, medial wall, and the posterior wall of the maxillary sinus. The membrane elevation is continued until complete length of the posterior wall of the maxillary sinus is exposed to prevent tenting of the sinus membrane.

After adapting the prepared surgical stent, a series of sequential osteotomy drills are used to prepare the implant osteotomy. The implant is threaded into the prepared site, using the Ratchet Wrench with a preadjusted torque of 20–50 Ncm.

The demineralized bovine bone, Osseogaft™ mixed with saline to form a paste was carried into the space created by the elevated membrane, and densely packed into the space using a graft condenser [Figure 4]. On an average, 1.5 cc of graft material was packed in to the space created in the sinus cavity. The lateral window was finally covered with

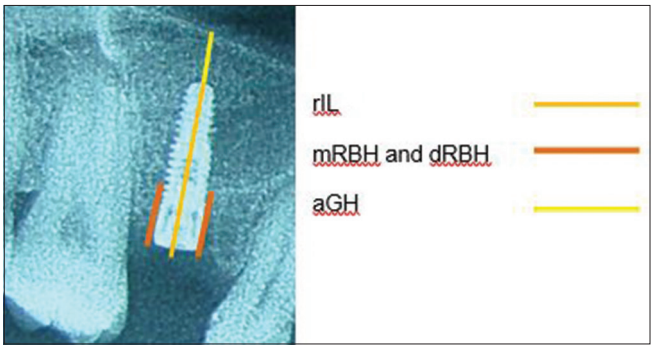

Figure 2: Radiographic measurements to measure the implant penetration, sinus lift, and height of the graft apically

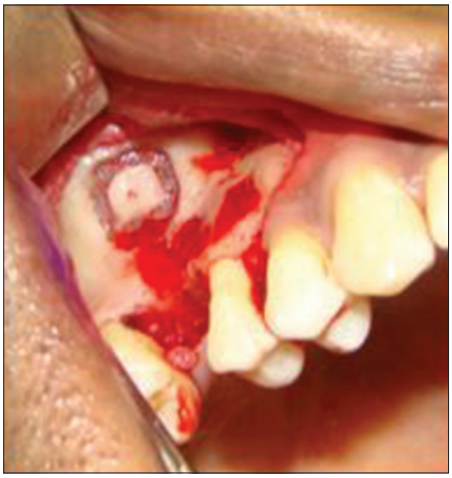

Figure 3: Rectangular-shaped Window created to expose the sinus membrane

Figure 4: The Osseogaft™ is densely packed into the space created after lifting the sinus membrane

a Bioresorbable Collagen membrane [Figure 5], and the soft-tissue flap was then repositioned at the original level and closed with interrupted direct loop sutures using 3-0 silk sutures with care taken to achieve a tension-free primary closure of the flap.

After consolidation of the graft for 6–8 months, the implants exposure was performed using a minimal crestal incision. The cover screw is removed, and a healing abutment in the form of a gingival former is placed for a period of 15 days to form the gingival contour and emergence profile around the implant [Figure 6]. The gingival former was removed after a period of 15 days and replaced with final solid abutment. An abutment level impression was made using a closed tray impression technique using a combination of light and putty silicone impression material [Figure 7]. A bite was registered using a bite registration paste, and treatment casts were poured. A Porcelain fused to metal (PFM) restoration was prepared [Figure 8] and cemented on the abutment using luting GI cement.

Figure 5: The lateral window covered with a Bioresorbable Collagen membrane

Figure 7: Abutment level Impression for PFM preparation

RESULTS

All the patients received maxillary SL with subsequent implant-supported prosthetic rehabilitation for the missing maxillary posterior teeth. The study comprised 12 male and 8 female patients. The residual alveolar height of the patients ranged from 2 to 10 mm. There were 4 patients with <5 mm residual height and 16 patients with >5 mm of residual alveolar height. The mean residual alveolar width was 7 mm (range: 4–12 mm).

The presence of septea was assessed on an orthopantomogram in seven of the 20 cases with multiple septate in three cases. The presence of septae necessitated preparing either a dumbbell-shaped osteotomies or two separate osteotomies for SL. Membrane perforation is a common complication in maxillary SL procedure.[13] Small perforations <5 mm (25% cases), perforations of 5–10 mm in size (10% cases), and perforation >10 mm occurred in one patient. All the membrane perforations >5 mm were sealed with collagen membrane before insertion of the graft into the sinus. All perforations <5 mm were sealed by infolding of the membrane after the sinus membrane elevation.

Variety of other complications was encountered such as postoperative infection (one case), postoperative

Figure 6: The final abutments *in situ*

Figure 8: PFM restoration prepared and cemented on the abutment

sinusitis (one case), implant exposure (two cases), oroantral fistula with graft loss (one case), buccal wall perforation, and incorrect implant angulation occurred in placement of two implants. Partial buccal wall perforation occurred in three cases at the time of implant osteotomy. These perforations were covered with Osseograft™ and secured with a collagen membrane. Stability of the implant was checked manually and by the use of an abutment screw driver when the permanent prosthetic rehabilitation was initiated.

The mean residual bone height immediately after surgery was 6.81 mm (2–9 mm). The mean IP length was 5.45 mm (range 3–11 mm). The mean aGH was 3.21 mm (range: 2–4 mm). The mean extent of the SL was 8.89 mm (range: 6–13 mm). At 3 months and 6 months, the mean aGH was 2.68 mm and 2.57 mm (range of 1–4 mm). The mean extent of the SL was with a range of 5–12 mm. The mean extent of the SL at 3 months and 6 months was 7.84 mm and 7.73 mm (range: 5–12 mm). There was a statistically significant difference in the apical height of the graft and SL immediately postoperatively compared to that at 3 and 6 months. No significant differences were noticed between the aGH and SL values at 3 and 6 months.

The sinus graft maturation was evaluated using SGR Index immediately after surgery and at 3 and 06 months. The score was 1 in all cases immediately postsurgery. The score ranged from 1 to 2 in all cases at 3 months. The score was 2 in 15 cases and 1 in 4 cases at the end of 6 months. Radiographic maturation score of 2 indicates maturation of the graft at the end of 9 months.

DISCUSSION

Implant-retained prosthodontic rehabilitation of the posterior maxilla poses a unique challenge characterized by progressive and irreversible resorption of the alveolus that results in a massive loss of bone substance, both vertically and horizontally. Vertical bone loss occurs at the maxillary alveolar process at a rate of approximately 0.1 mm per year and can vary greatly between individuals.[14]

Frequently, the availability of local host bone may be so compromised that <10 mm of bone remains between the alveolar ridge crest and the floor of the maxillary sinus in the edentulous posterior maxilla. All our cases had a paucity of host bone in the posterior maxillary alveolus demonstrating <10 mm warranting a sinus augmentation procedure for insertion of implants.

Lateral window technique of sinus augmentation and grafting has become a very popular and predictable procedure over the past few decades.[15] Variety of bovine bone substitutes such as Bio-Oss, Dyna blast, Puros, and Dem bone have been successfully used for such procedures.[9,16] However, Bio-Oss appears to undergo slow or even no resorption for up to 6 years, as confirmed by clinical biopsies.[7,17]

The use of demineralized bone matrix as a bone graft was first described in 1889. The first application of demineralized bone matrix in oral and maxillofacial surgery was described in 1975. Osseograft™ is a relatively inexpensive high purity Type I Collagen prepared from bovine cortical bone samples consisting particles of 250 μm size. The current study evaluated the clinical application of a xenogenic demineralized bone matrix (Osseograft™) for maxillary sinus augmentation. The manufacturer of Osseograft™ claims that it has both osteoconductive and osteoinductive properties. Sampath and Reddi[18] reported that subcutaneous implantation of coarse powders (74–420 μm) of DBBM results in local differentiation of bone. Particle size influences the ability of this graft to conduct or induce bone formation. Particles of size 100–300 μm produce osteoinduction while larger particles favor osteoconduction.

On grafting with Osseograft™, a sequential differentiation in four stages takes place to form cartilage and bone. In Stage 1, there is mesenchymal–cell migration into the vascular spaces of matrix within 2 days. In Stage 2, mesenchymal cells differentiate into giant cells and chondrocytes (Days 2–18). In Stage 3, the poorly vascularized areas of matrix show cartilage formation (Days 8–20) and woven bone develops in the vascularized areas of matrix (Days 10–20). During Stage 4, bone formation occurs (Days 20–30).[19]

Histological analysis of freshly purchased DBBM revealed that 10% of particles still retained some amount minerals. Based on this fact, three types of mineralization have been documented in response to demineralized bone grafts. First, formation and biomineralization of new bone, both woven and lamellar were seen in maxillary host bone and the adjacent graft site. The other two types involve physicochemical remineralization of DBBM. One started from the center of the particle and was independent of the presence of vital bone tissue. The other involves remineralization starting from the interface between DBBM particle and newly deposited bone tissue.

Radiographic bone gain of at the end of 6 months was observed in all patients, except in one case in which there was premature graft loss. All sites showed a radiopaque area interposed between the sinus membrane and the implant apex (i.e., aGH) of at least 1 mm. These results are better than some studies where two out of twelve implants were radiographically determined to be

beyond the cranial end of the graft.[20] The mean aGH postoperatively was 3.21 mm with a range of 2–4 mm. At 3 and 6 months, the mean aGH was 2.68 mm (range: 1–4 mm) and 2.57 mm (range: 1–4 mm), respectively. There was a statistically significant difference in the apical height of the graft and SL immediately postoperatively compared to that at 3 ($P = 0.0003$) and 6 months ($P = 0.0002$). No statically significant differences were noticed between the aGH and SL values at 3 and 6 months ($P = 0.3306$). The initial reduction in the height of the graft may be due to volumetric reduction in the graft due to initial graft consolidation and bone maturation from the surrounding areas. However, the presence of stable apical radiodensity (aGH) which was maintained at 3 and 6 months indicates the maturation of the graft. The presence of a radiopaque area apical to the implant apex may be of critical relevance for the long-term stability of the regenerative procedure and prevention of sinus pathologies.

According to histological studies, greater amounts of bone are formed in the region comprised between the implant and the new location of the sinus membrane than with the lateral-external regions due to a larger blood supply from the sinus membrane in the former than in the latter where the nourishment is temporarily reduced during the lateral fractured bony wall technique.[21]

The presence of a radio-opaque structure apical to the implant apex at 6 months with DBBM was found to be dependent on the extent of graft height immediately after surgery.[20] The 6-month stability of aGH 2.57 mm (range: 1–4 mm), respectively, may be explained, at least in part, by the high prevalence of sites with a substantial postsurgery aGH.

The extent of the SL decreased at 6 months compared to immediately postoperatively (mean: 8.89 mm) though there were no statistically significant differences in the SL between 3 (mean: 7.84 mm) and 6 months (mean: 7.73 mm). This could be attributed to volumetric decrease in the grafted area due to the initial graft maturation and crestal bone loss that has occurred following placement of implants. The maintenance of SL at 6 months is consistent with data indicating a slow resorption/degradation rate for DBBM.[22-24]

In our material, the maturation of the grafted area, as assessed by the SGRI on periapical radiographs, appeared incomplete after 6 months (SGR Index score of 1–2 in all cases). In particular, all sites showed the presence of a radiopaque structure with or without the persistence of the lamina dura of the original sinus floor, but in none of the cases, a new maxillary sinus floor outline was observed. Our data are similar to those by Pjetursson *et al*.,[24] who showed that the great majority of sites undergone transcrestal SL with DBBM showed a SGRI comprised between 1 and 2 at 1-year postsurgery. Cross tabulation of the scores at baseline and 6 months showed a significant increase in the graft maturation (Score: 1%–21.1%, score 2%–78.9% at 6 months).

Although measurement of radiological parameters provides an objective assessment of the efficacy of DBBM, the long-term clinical performance of implants placed in these regions is of paramount importance. In none of the cases, we encountered any implant mobility at the end of 6 months either in the single stage or the two-stage technique, leading to a 100% implant success rates that are in conjunction with several studies with the use of 100% DBBM for sinus augmentation.[20]

Membrane perforation (35%) was a common complication encountered in the study and consistent with other studies.[25] Small perforations <5 mm occurred in majority (25%) of the cases. Inferomedial location (Class III)[26] was the most common site of perforation. Large perforations occurred generally due to the presence of sepate and in an effort to circumvent it. All the membrane perforations >5 mm were sealed with collagen membrane before grafting and <5 mm were sealed by in folding of the membrane after the sinus membrane elevation.

CONCLUSION

The study was a modest attempt to assess the efficacy of Osseograft™ as a sinus augmentation material before implant placement, in maxillary posterior areas with deficient alveolar height. Radiographic maturation of the grafted area was noted at 6 months after surgery. Although the study had a short span of follow-up with a small sample size, no major complications were encountered with the material during the follow-up.

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Conflicts of interest

There are no conflicts of interest.

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