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Abstract
To evaluate the long-term survival rate of rough-surfaced implants placed in maxillary sinuses augmented with deproteinized bovine bone (Bio-Oss; Geistlich Pharma AG, Wolhusen, Switzerland).


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Rehabilitation of the Edentulous Posterior Maxilla After Sinus Floor Elevation Using Deproteinized Bovine Bone: A 9-Year Clinical Study

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The use of dental implants to rehabilitate edentulous patients has become a common treatment modality with a high success rate. However, in the posterior maxilla, insufficient residual alveolar bone height is a common restriction to the placement of dental implants. This is the result of crestal bone resorption after tooth loss in combination with pneumatization of the maxillary sinus.

In the 1970s, a surgical procedure for maxillary sinus floor elevation (SFE) was developed and then first published by Boyne and James. The goal of the SFE procedure is the creation of vital bone in the posterior maxilla to allow implant placement. Many variables may influence the outcome of the SFE procedure in combination with implant treatment, such as the grafting material and the implant surface type.

At first, SFE was performed using an autogenous graft. This procedure requires 2 surgical sites, and it is conducted under general anesthesia in cases of extra oral harvesting. This increases the length, risk, morbidity, postoperative pain, and cost of the surgery.

The use of bone substitutes can overcome this problem by eliminating the need for harvesting autogenous bone from secondary sites. Many materials have been used for sinus grafts, including allografts, alloplasts, and xenografts.

Bone grafting materials may induce bone formation by osteogenesis, osteoinduction, or osteoconduction. The first mechanism, osteogenesis, is obtained by providing osteogenic cells and matrix directly in the graft (eg, by grafting autogenous bone or bone marrow). The second mechanism, osteoinduction, implies that the grafted material is chemotactic to undifferentiated osteoprogenitor cells in the host, attracting them to the site of the graft and inducing them to differentiate eventually into osteoblasts. The third mechanism, osteoconduction, is a process allowing the outgrowth of osteogenic cells from existing bone surfaces into adjacent graft material that acts as an inert scaffold.
Bio-Oss (Geistlich Pharma AG, Wolhusen, Switzerland) is a deproteinized bovine bone material, which is chemically and structurally comparable to mineralized human bone. A wide interconnecting pore system encourages bone ingrowth with no associated adverse tissue reaction being reported. In addition, the physical properties of Bio-Oss are similar to those of human bone tissue. Several experimental and clinical studies have demonstrated the osteoconductive potential of this material.

Implant surface texture is another factor that may qualitatively influence the process of bone formation around implants. There is histological and clinical evidence that a more favorable implant-bone interface is established on rough-surfaced implants than on machine-surfaced implants.

The purpose of this study was to estimate the long-term survival rate of rough-surfaced implants placed in sinuses grafted with Bio-Oss as unique grafting material.

**Material and Methods**

**Patient Selection**

Between June 1999 and July 2001, 10 patients (7 women and 3 men) with a mean age of 52.1 years (range, 35–62 years) were included in the study. All patients presented a severe atrophy of the alveolar process in the posterior maxilla, with <4 mm of residual bone below to the maxillary sinus measured on panoramic radiographs. Patients were included in the study provided that no systemic or local contraindications were encountered. All patients were treated according to the guidelines of the World Medical Association in the Declaration of Helsinki (1996).

**Surgical Procedures**

The following pre- and postoperative regimens were applied on each patient: prescription of 300 mg of clindamycin (Pfizer SA, Zurich, Switzerland) (beginning with 2 tablets 1 hour before the surgery and 1 tablet 3 times a day), Locabiotal (Servier SA, Satigny, Switzerland) nasal spray 4 times a day (both for a total of 10 days), and Ibuprofen 400 mg (Abbott AG, Baar, Switzerland) to reduce pain and swelling. Postoperative instructions included rinsing 3 times a day for 2 weeks with 0.12% chlorhexidine gluconate (KerrHawe SA, Bioggio, Switzerland). Patients were instructed not to try to blow their noses during 1 week at least after the surgery and to cough or sneeze with an open mouth to avoid creating pressure within the sinus cavity.

**Maxillary SFE**

All surgical procedures were performed under local anesthesia by the same surgeon. The SFE procedures were realized after the classical method, as described by Boyne and James and Tatum. A crestal incision with 2 vertical releasing incisions to the depth of the vestibule was made, and a full-thickness flap was reflected to allow access to the lateral antral wall. Once the flap has been raised to a desired level, an antrostomy was performed with a no. 8 round diamond bur to create an oval trap door on the lateral buttress of the maxilla. This bone was removed to create a window for better visualization and access. At this point, the underlying sinus membrane was exposed. Specially designed curettes were then used to carefully elevate the sinus membrane. Special care was taken to ensure that all of the sinus membrane has been reflected of the sinus floor so that the bone graft is not lying on the epithelium but rather on raw bone. A space was created after the sinus membrane has been elevated, and all sinuses were grafted with 100% Bio-Oss with a particle size ranging from 0.25 to 1.0 mm along with fresh blood from the wound. The defect of the lateral sinus wall was covered using a resorbable, collagenous membrane (Bio-Gide; Geistlich Pharma AG) before the mucoperiosteal flap was repositioned and sutured.

**Implant Insertion**

Following an average 13.8 months (range, 7–18 months) of healing time, the bone height between the residual crestal ridge and the newly created sinus floor was radio graphically assessed with panoramic x-rays. Rough-surfaced (sandblasted, large-grit, acid-etched [SLA]) titanium fixtures (Straumann AG, Waldenburg, Switzerland) were placed in the regenerated bone. In 4 cases, biopsies were taken using a trephine burr at the sites where the dental implants were placed. The implants were allowed a healing phase of 4 to 16 months (mean, 8.7 months) before the patients were rehabilitated with fixed prosthesis.

**Specimen Processing**

The bone biopsies were immersed in a solution of 10% neutral buffered formalin, decalcified, dehydrated in ethanol/xylene, and embedded in paraffin wax. Sections of 5 μm thick were cut along the longitudinal plane using a microtome and were stained by hematoxylin and eosin (HE).

**Survival Criteria**

Implant survival was evaluated according to the following criteria proposed by Buser et al and Cochran et al. These criteria included the following: (1) absence of clinically detectable implant mobility, (2) absence of pain or any subjective sensation, (3) absence of recurrent periimplant infection, and (4) absence of continuous radiolucency around the implant.

**Radiographic Control**

Four panoramic radiographs were taken in each patient using a Scanora unit (Soredex, Orion Corporation, Ltd, Helsinki, Finland): A preoperative radiograph showing the residual bone height (Fig. 1, A), a postoperative radiograph after SFE (Fig. 1, B), a radiograph after implant placement (Fig. 1, C), and finally a radiograph 9 years after the implant placement (Fig. 1, D). The radiographs were later scanned in a digital format by a flatbed scanner (Epson Expression 1680 Pro, Wadenswil, Switzerland) at a resolution of 600 DPI (dots per inch) and were saved as TIFF format files.

**Results**

The SFE procedure was performed on both sides in 3 cases and on 1 side in 7 cases; thus, a total of 13 SFE procedures were performed. A total of 24 rough-surfaced 4.1 mm in diameter and 12-mm long (except one 10 mm long implant) implants were placed in the regenerated bone. No macroscopic perforation of the Schneiderian membrane was noted, and no additional
clinical complication occurred during this study.

**Implant Survival**

All the implants were osseointegrated and successfully restored with single crowns or fixed partial dentures. Clinical and radiographic control was carried out in all the cases. The 9-year implant survival rate was 100%, with a minimum functional loading time of 8 years for all the implants.

**Histologic Results**

Histological findings showed that Bio-Oss particles are homogeneously distributed and interconnected by bone bridges (Fig. 2). Clear identification of Bio-Oss in the histological preparations remained possible even after a healing phase of up to 18 months. Bio-Oss particles were closely surrounded by mineralized new bone bridges. The newly formed bone consisted mainly of woven bone, whereas mature bone showed a lamellar structure. The spaces between the bridges were occupied by marrow spaces. The intertrabecular marrow consisted of a well-vascularized fibrous tissue. In some places, there were osteoblasts in contact with the bone lamellae; occasionally, osteoclasts or empty osteoclastic resorption lacunae were visible. The bone marrow contained a chronic lymphoplasmacytic inflammatory infiltrate together with some mast cells. Jointly with the newly formed bone, the Bio-Oss particles presented a dense scaffold. These findings confirm the osteoconductive properties of Bio-Oss.

**DISCUSSION**

The present study supports the long-term clinical predictability of dental implants placed in grafted maxillary sinuses for the rehabilitation of the edentulous posterior maxilla. All of the 24 implants placed into augmented sinuses achieved osseointegration and demonstrated an implant survival rate of 100% for an observation period of 9 years.

Many materials have been proposed for SFE procedures: autogenous bone grafts, allografts, alloplasts, and xenografts. The limitations associated to the harvesting of autogenous bone may be overcome by using bone substitutes. Grafts using bone substitutes are at least as effective as autogenous bone, both when used alone or in combination with autogenous bone. The bone graft used in this study was proved to be biocompatible and osteoconductive. The osteoconductive properties of Bio-Oss have been proven in several others studies, showing that Bio-Oss leads to the development of
new bone formation both at the surface of the substitute material and as trabeculae between the Bio-Oss particles.19 A review assessing the value of anorganic bone substitutes in SFE procedures reported that autogenous bone resulted in a higher amount of vital bone after a healing period of 4 to 6 months than any of the bone substitutes.20 However, several histological studies showed that similar percentages of vital bone can be achieved in bone replacement grafts provided those are allowed a longer maturation period.19,21 A longer healing period is needed for maxillary sinus grafted with Bio-Oss alone because new bone proliferation occurs only from the peripheral bone walls, whereas the addition of autogenous bone to Bio-Oss facilitates the proliferation of vessels and tissues; thus, new bone formation and the incorporation of the grafts takes less time to heal.21 According to the aforementioned, in this study, the average healing phase before placing the implants in the grafted sinuses was of 13.8 months.

Considering that a good vascular supply is of utmost importance to the graft site,22 it is furthermore of interest to note that the amount of new regenerated tissue does not only depend on time19,23 but also on the augmentation depth.17 Because bone formation initiates from the sinus walls and floor,4 the lifting and displacement of the maxillary sinus membrane exposes the vascular supply along with the surrounding perivascular osteoblasts to the placed grafting material, allowing angiogenesis and then osteogenesis.18

In this study, a resorbable membrane was used to cover the lateral wall of the graft. The use of a barrier membrane over the lateral window has a positive effect due to the fact that it seals the defect from the outside environment, preventing soft tissue ingrowth and resulting in an important increase in vital bone formation.24

The slightly increased air pressure in the maxillary sinus cavity associated with breathing can cause bone resorption and antrum repneumatization after an augmentation procedure.25 In a study comparing the behavior of autogenous bone and Bio-Oss for maxillary sinus graft, Schlegel et al16 demonstrated that 180 days after the surgery, the autogenous graft lost 39.8% of its original volume compared to 16.5% in the Bio-Oss graft. Grafts in sinuses augmented with Bio-Oss were more stable than those with Bio-Oss mixed with autogenous bone or autogenous bone alone.27

Different resorption rates of Bio-Oss have been reported in the literature. Some experimental studies reported on slight resorption19 or no signs of resorption.19 Long-term clinical results have shown that Bio-Oss particles remained many years after the graft was performed.11 This characteristic avoids premature resorption of the graft by maintaining the initial dimensions of the augmented area with time and confers high stability in the augmented region through integration of Bio-Oss into the new bone formations.16,26 In addition, multiple studies have shown that implants placed in sinuses grafted with Bio-Oss were not in direct contact with the grafting material, thereby leaving the implant surface free to interface with newly formed bone. This demonstrates that the persistence of Bio-Oss, while providing support and density, does not interfere with osseointegration.11,19,21

The presence of Bio-Oss may provide additional structural stability to the matured graft.11 It seems that this may have a positive influence on the high implant survival rates achieved with the utilization of Bio-Oss as a grafting material.19,21,27,28 Because implant failures seem to occur more often in a bone with a low density.29 Some authors reported higher implant survival rates when Bio-Oss was used as sole grafting material than when it was used mixed with autogenous bone30 or than when autogenous bone was used alone.21 In fact, SFE using Bio-Oss resulted in a better bond between implant and bone,10 and the implants placed in sinuses grafted with Bio-Oss required a significantly higher pullout force than control implants placed in nonaugmented sheep maxillary sinuses.30

The type of implant surface has been recognized to be also an important variable in the bone graft setting.32 Implant surface influences osteoblast proliferation, differentiation, matrix synthesis, and growth factor production.32 Apart from the chemistry of the implant, numerous studies have demonstrated the importance of the surface physical properties and microstructure on which cells adhere and grow around.33

Rough surfaces have shown greater rate of the interfacial bone-implant contact.12 In the bone regeneration process, machined surfaces lead to a bone formation close to, but not in direct contact with, the implant surface due to retraction of the blood clot away from the implant surface. Whereas roughened surfaces retain the blood clot in direct contact, allowing the bone apposition to start from the implant surface and leading to a more favorable bone-to-implant contact compared to machined surfaces.34 This may explain the important difference noticed in the implant survival rates when comparing rough-surfaced to machine-surfaced implants.35 In the present study, implants with a rough surface (SLA) were used. The survival rate observed in this study is comparable to literature data concerning rough-surfaced implants.

Appropriate patient selection, careful evaluation of presurgical anatomy and oral health, sound surgical technique, and proper postoperative care represent key factors for the success of the procedure. The choice of the type of graft material and the implant micro morphology may significantly influence the positive outcome of the treatment.5

CONCLUSIONS

This article reports on the clinical and radiographic findings of SFE surgery with subsequent rough-surfaced implant placement using Bio-Oss as a unique grafting material. Within the limits of this study, we can conclude that Bio-Oss is an acceptable substitute to the autogenous bone, and it can be used as a unique material for SFE. Rough-surfaced implants placed in 100% Bio-Oss grafts showed a high survival rate (100%) on the long term. Other clinical trials in a larger patient sample are necessary to confirm our results.

DISCLOSURE

The authors claim to have no financial interests, either directly or
indirectly, in the products or information listed in the article.

References


