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In this clinical study, a 1:1 mix of particulate cancellous bone and marrow (PCBM) and bovine deproteinized bone (Bio-Oss) was used to fill cavities after elevating the sinus mucosa for major sinus dehiscences. Ten patients with edentulous posterior maxillae were treated with 12 sinus augmentation procedures according to a 2-stage technique, and 30 Frialit-2 endosseous implants were used to complete the implant-prosthetic rehabilitation. Bone cylinders were removed at second-stage surgery immediately prior to implant placement (5 to 7 months after grafting), and histologic evaluation was performed. The results showed that Bio-Oss is a reliable osteoconductive material and its association with PCBM leads to the formation of new bone with an increased overall density. (INT J ORAL MAXILLOFAC IMPLANTS 2000;15:873–878)

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The maxillary sinus augmentation procedure is an internationally accepted method for rehabilitation with endosseous implants in atrophic posterior areas of the maxilla. With minor sinus involvement (at least 4 mm of residual ridge height and in a non-extensive area), the procedure can be carried out under local anesthesia using the fenestration osteotomy as reported by Tatum.¹ Whenever major sinus intervention is necessary (less than 4 mm of residual ridge height and 2 to 3 cm mesiodistal extension), the bony support for implants will require a 1- or 2-stage procedure and autogenous bone graft. If a 1-stage procedure is chosen, an inlay graft from the iliac crest will likely be necessary, using a monocortical block fixed by titanium implants according to Sailer.² If the option is a 2-stage surgical technique, a cancellous bone graft from the hip will probably be needed.³⁻⁹ Currently, particulate cancellous bone and marrow (PCBM) is mixed with an osteoconductive material to maintain graft volume during the remodeling process and to increase bone density. This approach encourages better quality new bone when implants are placed 5 to 6 months later. The authors describe clinical and histologic evaluations obtained with a 2-stage procedure employing cancellous bone graft and bovine deproteinized bone (Bio-Oss, Geistlich, Wolhusen, Switzerland) and Frialit-2 titanium implants (Friatec AB, Mannheim, Germany).

MATERIALS AND METHODS

Ten consecutive patients, aged 34 to 56 years and with a mean age of 46.5 years, were included in the investigation. All patients were in good health, and standard examinations demonstrated no local or
systemic contraindication to surgical treatment. Initially, each patient was given a description of the treatment and informed that a histologic evaluation would be done at the time of implant placement. Every patient signed a surgical consent form. All the operations were performed by the same surgeon. Over the course of the study, 30 Frialit-2 stepped screw-type implants were placed, and gold-ceramic or titanium-ceramic crowns were fabricated for the prosthetic rehabilitation.

**Surgical Procedure**

Surgery was performed under general anesthesia using controlled hypotension. The cancellous bone harvesting source was the iliac crest, which provided enough bone for extensive sinus involvement. The initial 5-cm incision was made 1 cm posterior to the anterior-superior iliac spine and 1 cm inferior to the crest of the ridge. After the fascia lata was dissected up to the bone, the medial aspect of the hip was exposed and cancellous bone was reached by means of a window osteotomy. The desired amount of cancellous bone and marrow was taken and placed in the defect prior to closure of the muscles and the aponeurosis. Muscular and facial closure were performed with a 3-0 non-chromic gut suture, and skin closure was obtained with 2-0 nylon suture. Depending on defect bleeding at the time of suturing, a drain was placed up to 48 hours postoperative; suture removal was performed 5 days postsurgery.

The sinus augmentation was done in a 2-stage procedure, and the implants were placed 6 months later (Fig 1). In the first stage, the lateral wall of the sinus was exposed by a midcrestal incision and 2 vertical release incisions forward and backward from the area to be treated. A rectangular bone window (2 cm long and 1 cm high) was created with a round bur until the Schneiderian membrane was exposed (Fig 2a). The bone plate was then carefully pushed inward and upward from below, making certain the integrity of the membrane was maintained. After the membrane was separated from the floor, a cavity was created into which the cancellous bone and Bio-Oss were placed (Fig 2b). The mucoperiosteal flap was replaced and sutured with 4-0 nylon gut.

In the second-stage operation, performed 5 to 7 months after the grafting procedure, a new flap was raised to expose the alveolar ridge, and Frialit-2 implants were placed (Figs 3a and 3b). In the area corresponding to each implant, bony cylinders were removed with a trephine bur for histologic examination. At the conclusion of surgery, the mucosa was sutured with 4-0 nylon gut. Five months elapsed before the implants were exposed and healing caps were placed.

**Biomaterials**

The aim of using Bio-Oss together with cancellous bone and marrow was to increase the bone density in areas of regenerated bone, particularly around the implants. Bio-Oss is a bovine deproteinized bone consisting of tiny crystals similar to those found in human bone. The bone density increase is the result of the unique micro- and macroporous structure and intercrystalline spaces of this material, which assure an overall porosity of 75%. When Bio-Oss is placed inside the sinus cavity, 75% of its structure is available for the regeneration of new bone tissue. In addition, the 6- to 8-month reabsorption process of Bio-Oss helps to maintain the volume of the graft during the faster remodeling and reabsorption processes of the cancellous bone. The absence of proteins in Bio-Oss is fundamental to circumventing the immunologic or allergic reactions that can occur after placing the bovine material in humans. Bio-Oss is available as either cancellous or cortical granules, sized 0.25 to 2 mm. For sinus augmentation, the 1- to 2-mm cancellous particles are recommended since they can be easily placed in larger areas.10-12

**Histology**

Each biopsy specimen from the retrieved bone cylinders was fixed in a 4% formaldehyde solution, then dehydrated in ethanol, embedded in methylmethacrylate resin, cut with a diamond blade saw, and ground to 80 µm. The slides were stained with toluidine blue and basic fuchsin.

**RESULTS**

**Clinical Findings**

At the re-entry surgery for implant placement, the clinical aspect of the cortical window prepared for the sinus approach was evaluated. When this was done at 5 months post-augmentation, several particles of Bio-Oss on the surface were found to be absolutely stable and incorporated with PCBM particles to reconstitute the maxillary buccal cortical plate. When implants were placed 7 months after grafting, few particles of the osteoconductive material were present, and normal cortical buccal plate was seen. All 30 Frialit-2 implants placed in the grafted bone achieved osseointegration within 5 months after placement. This was assessed by means of radiographic examination and clinical evaluation of their stability using the Periotest instrument (Siemens, Bensheim, Germany). No signs of bone loss, dehiscence around the implants, or infection were seen.
**Fig 1** Panoramic radiograph showing alveolar atrophy in the posterior areas of the maxilla and the bilateral sinus situation.

**Fig 2a** (Left) The bony window has been created and the sinus lift has been performed.

**Fig 2b** (Below) A mixture of PCBM and Bio-Oss has been placed in the cavity to provide the bone augmentation.

**Fig 3a** Detail of the ridge at re-entry surgery after placing the Frialit-2 4.5 × 13-mm implants.

**Fig 3b** Postoperative radiograph.
Histologic Findings

The slides prepared from biopsies done 5 months after grafting showed areas filled with connective fibrous tissue surrounding the Bio-Oss (Fig 4), probably the result of either fibrous transformation of the marrow or an invasion of the soft tissue that covered the grafted site. The core of the specimens usually demonstrated a rather dense package of Bio-Oss particles and bony ingrowth (Figs 5a and 5b); Bio-Oss was seen to be partially or completely surrounded by bone. In graft segments represented mostly by autograft, the grafted bone appeared to be almost totally covered by new lamellar bone (Fig 6) partially substituted by small osteons. Large vascular spaces and initial remodeling by means of reabsorption coupled with formation could also be seen (Fig 7).

Biopsies obtained 7 months after grafting revealed different situations. Occasionally, most of the trabecular surface was lined by new living bone and the bone marrow was well vascularized. Remodeling appeared to be active in the autograft, but the Bio-Oss remained almost untouched (Fig 8). On the other hand, vigorous trabeculae were found, remnants of the autograft were recognized (Fig 9a), and the Bio-Oss particles were surrounded and interconnected by newly formed bone that indicated remodeling and ongoing apposition of lamellar packets (Fig 9b).

DISCUSSION

The treatment of severe maxillary residual ridge resorption by sinus augmentation, to include endosseous implant placement, involves sinus surgical elevation and grafting of the residual cavity by means of autogenous bone or bone substitutes that can be reabsorbed in a short or medium time period (6 to 8 months). Autogenous cancellous bone and marrow still represent the best grafting material, but a certain amount of reabsorption must be taken into consideration because of the physiologic remodeling process. Bone substitutes such as alloplastic or xenogenic materials cannot completely replace autogenous bone, since they do not have osteoinductive and osteoproliferative properties. However, they are usually reabsorbed in 6 to 8 months, more slowly than cancellous bone. Thus, a combination of PCBM and osteoconductive materials may have all of the advantages associated with autograft properties and provide good maintenance of the graft volume because of the slow osteoconductor reabsorption. In the present clinical investigation, the behavior of a graft consisting of PCBM and Bio-Oss in a 1:1 ratio for large maxillary sinus augmentation
**Fig 6** Biopsy taken 5 months after grafting. A nice autograft particle is located at the right end of this cylinder (faint staining). It is almost completely covered by new lamellar bone (dark red) and partially substituted by 2 small osteons in the upper part (arrows) (toludine blue and basic fuchsin; ×25).

**Fig 7** This fragment (5 months after grafting) of cortical bone shows filling in of new bone in larger vascular spaces (arrows) (toludine blue and basic fuchsir; ×12.5).

**Fig 8** In this image (7 months after grafting) the diameter of the trabecular profiles is smaller, except for those including Bio-Oss particles (arrows) (toludine blue and basic fuchsin; ×12.5).

**Figs 9a and 9b** Vigorous bony trabeculae comprised remnants of the autograft (arrowheads) (biopsy obtained 7 months after grafting). Newly formed bone (dark staining) indicates remodeling and apposition of lamellar packets (arrows) (toludine blue and basic fuchsin; ×25).
was evaluated, as was the osseointegration of titanium implants placed in the augmented area. Twelve large sinuses were augmented using a 2-stage procedure, and Frialit-2 implants were placed 5 to 7 months after the grafting. Histologic results showed that Bio-Oss generally acts as a scaffold for new bone formation, and its substitution requires at least 8 months for completion. All sections prepared 5 months after sinus augmentation showed Bio-Oss embedded in fibrous tissue, with slight new lamellar bone apposition around the particles. The situation was different when the biopsy was done 7 months later. At the time of implant placement, the new bone appeared to have increased in density when compared to autografts alone or alloplasts. This clinical situation, probably related to the morphologic structure of Bio-Oss, creates an enhanced environment for an effective bone response to functional modifications after occlusal loading. None of the 30 Frialit-2 implants placed in the regenerated bone failed before or after functional loading by means of titanium-ceramic or gold-ceramic restorations.

CONCLUSION

The histologic examination of specimens from sinus augmentations with Bio-Oss and cancellous bone confirmed the desirable osteoconductive properties of bovine deproteinized bone, as shown by the osteoblastic activity around the Bio-Oss particles; these results concur with those from other studies. The clinical findings revealed a higher bone density than that achieved with autogenous cancellous grafts alone. No negative effects have been found with the use of Bio-Oss for sinus augmentation in association with dental implants. The use of this material in advanced osseointegration procedures can bring benefits to bone regeneration without significant risk of infection or disease transmission.

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REFERENCES