Maxillary Sinus Augmentation with a Porous Synthetic Hydroxyapatite and Bovine-Derived Hydroxyapatite: A Comparative Clinical and Histologic Study

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Purpose: The aim of this study was to determine the clinical and histologic results of a porous synthetic hydroxyapatite (HA) compared with bovine-derived HA used in maxillary sinus augmentation. **Materials and Methods:** A total of 100 titanium implants were placed in 40 patients. Patients in need of maxillary sinus augmentation were divided into 2 groups. Group 1 received bovine-derived HA (20 patients with 50 implants), while group 2 received a porous synthetic HA (20 patients with 50 implants). After a healing period of 6 months, second-stage surgery was carried out. In 50 cases (25 from group 1 and 25 from group 2), bone cores were harvested from grafted areas and processed for histologic examination. **Results:** Four implants that failed to osseointegrate were removed at the second-stage surgery (2 from a patient from group 1, and 2 from a patient from group 2). All patients were followed for at least 1 year after loading. Histologically, most of the HA particles from both groups were surrounded by newly formed bone. No statistically significant differences were found with respect to percentage of newly formed bone between the 2 groups (P = .031); however, the groups did differ significantly with respect to the percentage of residual graft material observed (P = .001). **Conclusion:** This study demonstrates that both bovine-derived and porous synthetic HA can be used successfully as graft materials for maxillary sinus augmentation. The clinical performance of the 2 materials was similar. (Clinical Trial) INT J ORAL MAXILLOFAC IMPLANTS 2007;22:980–986

Key words: anorganic bovine bone, hydroxyapatite, sinus augmentation

Rehabilitation of the edentulous posterior maxilla with dental implants is often complicated by lack of bone volume for the mechanical support and integration of implants.[1]

Maxillary sinus augmentation was first presented by Tatum in 1976.[2] Later long-term results showed that this technique can be an effective treatment option.[2–4] A number of materials have been used for sinus augmentation: autologous bone, mineralized and demineralized freeze-dried bone allografts, bioglass, polylactide-polyglicolide materials, synthetic polymers, calcium sulfate, and hydroxyapatite (HA).[5–10]

Autologous bone grafts are considered the gold-standard graft material in terms of osteogenic potential, but they have some disadvantages. A limited amount of material is available at the intraoral donor site, and the use of an extraoral donor site requires general anesthesia and is often associated with morbidity at the donor site.[7,11]

Bovine-derived HA is a xenogenic material from which all organic components have been removed.[12–21] This material is similar to human cancellous bone,[22] with 75% to 80% porosity and a crystal size of approximately 10 μm in the form of cortical granules. The large interconnecting pore system of bovine-derived HA facilitates angiogenesis and

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migration of osteoblasts.[22,23] Bovine-derived HA has been demonstrated to possess a high biocompatibility and osteoconductivity when used in sinus augmentation procedures.[24] Opinions differ about the resorption rate of bovine-derived HA. Most investigators believe that this material is slowly degraded over time.[1,23,25] If true, this could have negative consequences on the mechanical properties of the regenerated bone and its capacity to support implants. The augmented bone would be a composite rather than a homogenous bone structure.[26]

A porous synthetic HA made in granules with a diameter ranging from 250 to 600 μm has recently been introduced in clinical practice.[27] It is characterized by a very low density and crystallinity. Moreover, it has a high degree of bimodal porosity, ranging from nanodimensions to 10 μm and from 10 to 60 μm.[28] The physical and morphological characteristics of this HA have been determined by x-ray diffraction (XRD) and scanning electron microscopy (SEM).[29] This HA was sterilized by gamma irradiation (25 kGy). HA has already been used as a bone substitute for bone augmentation with good results.[30,31] It may play a role in attracting circulating biocomponents (bone sialoprotein and osteopontin) at sites of tissue repair and thus in promoting bone regeneration.[27]

Because of the limited amount of data on the outcome of sinus elevation using various grafting materials, no definitive conclusions can be drawn regarding the performance of the different materials.

The purpose of the present study was to compare histologically the use of a bovine-derived HA and a porous synthetic HA in maxillary sinus augmentation procedures in humans.

MATERIALS AND METHODS

Patients and Implants

Forty patients were enrolled on the basis of the following criteria: *(1)* maxillary partial (unilateral or bilateral) edentulism involving the premolar/molar areas and *(2)* presence of 3 to 5 mm of crestal bone between the sinus floor and the alveolar ridge, as evidenced at baseline by preoperative radiographic examination. Exclusion criteria were smoking, systemic diseases, maxillary sinus pathology, recent extractions (less than 1 year) in the involved area, or failure to establish primary stability.

At the initial visit all patients underwent a clinical and occlusal examination, including periapical and panoramic radiography. Informed consent was obtained from all patients.

A total of 100 titanium screw-type implants (Leader Implantology, Milan, Italy) were placed simul-taneously with sinus augmentation in 40 patients (18 men and 22 women ranging in age from 42 to 67 years, with a mean age of 52 years). Patients were randomly assigned to 1 of 2 groups: group 1 (20 patients with 50 implants) received bovine-derived HA (Bio-Oss; Geistlich, Wohlhusen, Switzerland) and group 2 (20 patients with 50 implants) received a porous synthetic HA (Fingranule; Finceramica, Faenza, Italy). The implants ranged in diameter from 3.75 to 4.75 mm and in length from 10 to 16 mm. The crestal bone height varied from 3.5 to 5 mm; the average bone thickness of the subantral bone was 4.5 mm.

Surgical Protocol

Prior to surgery, the patients' mouths were rinsed with a chlorhexidine digluconate solution 0.2% for 2 minutes. Local anesthesia (Xilestesin; Espe Dental, Seefeld, Germany) with 2% adrenaline was administered. Mesial and distal buccal releasing incisions were made palatally. Full-thickness flaps were elevated to expose the alveolar crest and the lateral wall of the maxillary sinus. Using a round bur under cold (4 to 5°C) sterile saline irrigation, a "trap door" was made in the lateral sinus wall. The bone segment was totally removed; after graft and implant placement, it was replaced in situ.

The sinus membrane was elevated with curettes of different shapes until it became completely detached from the lateral and inferior walls of the sinus. Preparation of the implant sites was then undertaken. The bone was perforated with sets of twist drills under cold (4 to 5°C) sterile saline irrigation. A minimum of 5 cm^2 of the graft materials (bovine-derived HA or porous synthetic HA) was mixed with sterile saline solution and carefully packed into the sinus cavity, especially posteriorly and anteriorly. The implants were then placed. The remaining sinus space around the implants was completely packed with graft material. Care was taken to pack the graft around the apices of the implants. All surgical wounds were closed with a tension-free adaptation of the flap using Gore-Tex sutures (W. L. Gore & Associates, Flagstaff, AZ). Antibiotic prophylaxis (1 g Zimox; Pharmacia & Upjohn, Milan, Italy) was administered 1 hour before surgery and for 3 days afterward; the patients were given inflammatory and analgesic medication as well (Synflex 550 mg; Recordati, Milano, Italy). Sutures were removed 2 weeks after surgery. Postsurgical visits were scheduled at monthly intervals to check the course of healing. After a healing period of 6 months, second-stage surgery was carried out (ie, the surgical screws were removed, and the healing abutments were connected to the implants). All patients underwent radiographic examination of the treated areas. All implants were followed for at least 1 year after loading.

Histologic Examination

After a healing period of 6 months, in 50 cases (25 from group 1 and 25 from group 2) bone cores were harvested from the lateral wall using a 4 × 10-mm diameter trephine under a cold (4 to 5°C) sterile saline irrigation. The biopsy specimens were retrieved from areas located between the implants at about 10 mm from the alveolar ridge, at a mean depth of 8 mm, and processed for histology.

The specimens were washed in saline solution and immediately fixed in 4% para-formaldehyde and 0.1% glutaraldehyde in 0.15 mol/L cacodylate buffer (4°C and pH 7.4) to be processed for histology. The specimens were processed to obtain thin ground sections with the Precise 1 Automated System (Assing, Rome, Italy). They were dehydrated in an ascending series of alcohol rinses and embedded in a glycolmethacrylate resin (Technovit 7200 VLC, Kulzer, Wehrheim, Germany). After polymerization the specimens were sectioned along their longitudinal axes with a high-precision diamond disk into slices about at 150 μm thick and ground down to about 30 μm with a specially designed grinding machine. Three slides were obtained for each specimen. The slides were stained with acid fuchsin and toluidine blue. The slides were observed in normal transmitted light under a Leitz Laborlux microscope (Leitz, Wetzlar, Germany). Histomorphometry of newly formed bone, marrow spaces, and residual graft particles was carried out using a light microscope (Laborlux S; Leitz, Wetzlar, Germany) connected to a high-resolution video camera (3CCD, JVC KY-F55B, JVC, Santa Clara, CA) and interfaced with a monitor and PC (Intel Pentium III 1200 MMX; Intel, Yokohama, Japan). This optical system was associated with a digitizing pad (Matrix Vision, Oppenweiler, Germany) and a histometry software package with image-capturing capabilities (Image-Pro Plus 4.5; Media Cybernetics, Immagini & Computer, Milan, Italy).

Statistical Analysis

Analysis of variance (ANOVA) was used to test the statistical significance of the differences between newly formed bone, marrow spaces, and residual graft particles between the 2 groups. The Bonferroni-corrected Student t test for unpaired samples was employed as a post-hoc test. Values of $P < .05$ were accepted as statistically significant.

RESULTS

Clinical Observations

None of the 40 patients had complications, except for physiologic swelling at the surgical site; only 4 implants (2 implants and 2 patients from each group) were clinically mobile the time of second-stage surgery; these clinically mobile implants were removed. The remaining implants were stable. After abutment connection, the patients received a provisional fixed acrylic resin prosthesis. After 3 months definitive methyl ceramic fixed prostheses were delivered. Radiographic examination demonstrated the presence of dense bone around and apical to the implants in maxillary sinus. All patients were followed for 1 year after prosthesis placement; no complications were observed.

Histologic Results

Group 1. Most particles were surrounded by newly formed bone (Fig 1). This bone was mature and compact and presented a structure with well-organized osteons. In some fields, osteoblasts were observed in the process of apposing bone directly on the particle surface. No gaps were present at the bone-particle interface, and the bone was always in close contact with the particles (Fig 2). No inflammatory cells and/or multinucleated giant cells were present around the particles or at the interface with bone. At higher magnification wide lacunae were observed. In almost all particles the haversian canals appeared to be colonized by capillaries and cells. In some of the haversian canals, there was no mineralized material lining the inner surface. The most peripheral lacunae present in the bovine-derived HA appeared to be filled by osteocytes (Fig 3), while the most central areas appeared to be filled by small cells with a different morphology. Empty lacunae were infrequently observed. The graft particles had a lower affinity for stains. Histomorphometry showed that newly formed bone represented a mean of 36.2% ± 1.4% of each sample; marrow spaces, 25.2% ± 2.3%; and residual graft material, 39.0% ± 2.9%.

Group 2. Newly formed bone with the large osteocytic lacunae was observed around the HA particles, which appeared to have been partially resorbed and replaced by new bone. A few multinucleated cells were found at the surface of some graft particles of porous synthetic HA (Fig 4). The large osteocytic lacunae were typical of recently mineralized tissues. Lamellar bone and haversian systems were present. No inflammatory cell infiltrate was present around the particles or at the bone-biomaterial interface (Fig 5). Osteoblasts were occasionally observed near the HA particles actively secreting osteoid matrix (Fig 6). No gaps were seen at the bone-particle interface, and the bone was always in close contact with the particles. Histomorphometry showed that newly formed bone represented a mean of 34.7% ± 3.1% of each sample; marrow spaces, 38.1% ± 2.2%; and residual graft material, 35.9% ± 4.2% (Fig 7).
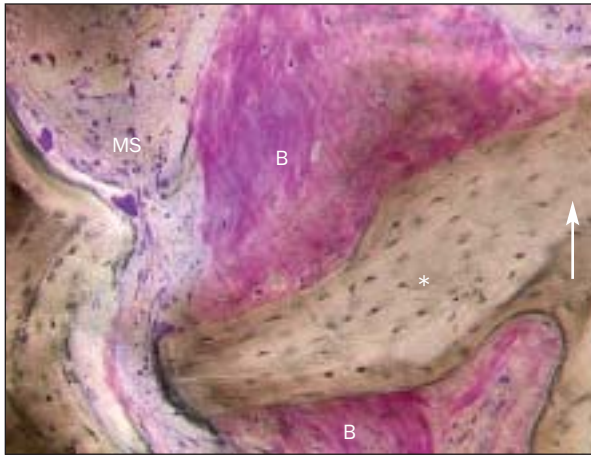
Fig 1 Bovine-derived HA (*) surrounded by newly formed bone (B) and marrow spaces (MS). No osteoclasts or macrophages were present. Implant surface orientation is perpendicular to the arrow (toluidine blue and acid fuchsin; original magnification ×100).
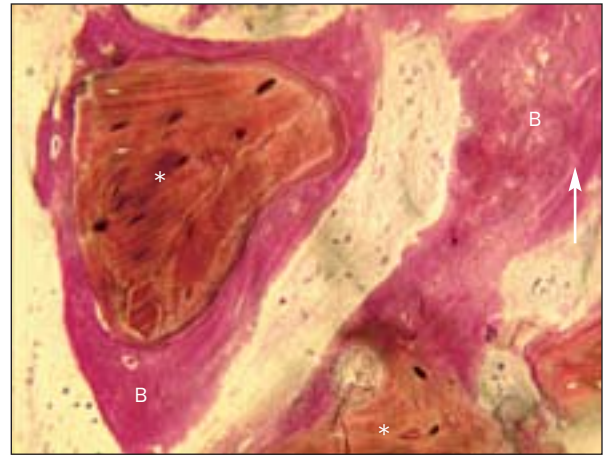
Fig 2 Newly formed bone (B) in close contact with the surface of a bovine HA particle (*). No gaps were present at the interface. No acute or chronic cell infiltrate was present. Implant surface orientation is perpendicular to the arrow (toluidine blue and acid fuchsin; original magnification ×100).
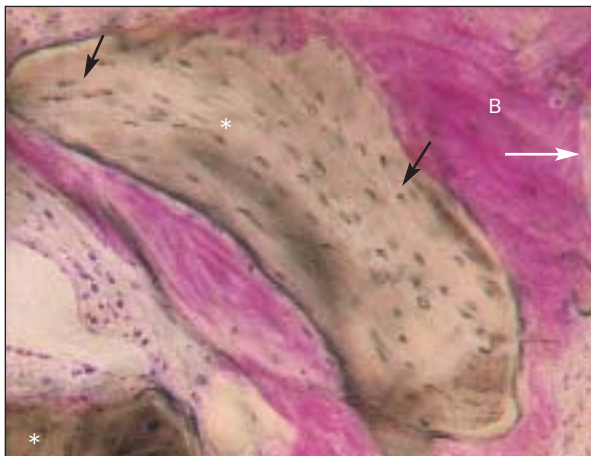
Fig 3 The most peripheral lacunae (arrow) in the bovine HA (*) appeared to be filled by osteocytes. The implant surface orientation is perpendicular to the white arrow (toluidine blue and acid fuchsin; original magnification ×100).
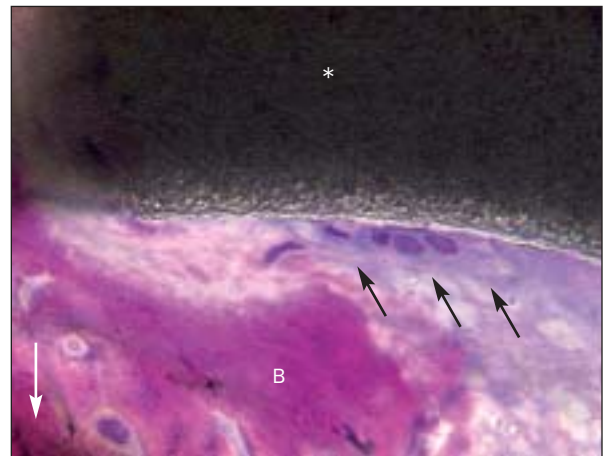
Fig 4 A multinucleated giant cell (multiple arrows) at the surface of some graft particles of porous synthetic HA (*). Osteoid matrix and newly formed bone (B) near the graft particle (*). Implant surface orientation is perpendicular to the white arrow (toluidine blue and acid fuchsin; original magnification ×100).

Statistical Analysis

No statistically significant differences between the 2 groups with respect to percentage of newly formed bone (P = .031). However, statistically significant differences between the 2 groups were found with respect to the percentages of marrow space (P < .001) and residual graft material (P < .001).

DISCUSSION

In the Sinus Consensus Conference of 1996,[10] it was agreed that sinus grafting can be successfully used for implant-supported restorations in the posterior atrophic maxilla when the residual bone is equal to or less than 5 mm. Data from the literature show that grafting in this area is not contraindicated; the procedure is associated with low morbidity.[10] When complications arise during or after the procedure, such as tearing of the sinus membrane, infection of the graft, or implant loss, it is rare that any long-term sinus complications occur.[32] The sinus lining rapidly returns to a normal state after graft wound healing.[32]

The current study is consistent with other studies in that both tested materials showed bone formation without the presence of inflammatory cell infil-
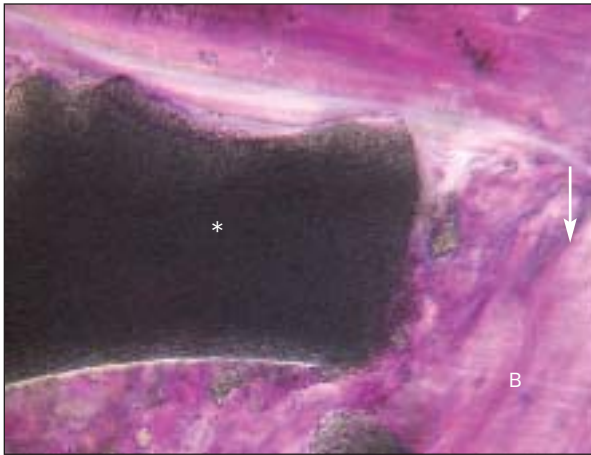
Fig 5 Newly formed bone (B) around the particle (*) or at the bone-biomaterial interface. Some small fragments were detached from the surfaces of the grafted particles. These fragments were surrounded by newly formed bone (B). No acute or chronic inflammatory cell infiltrate was present. The implant surface orientation is perpendicular to the arrow (toluidine blue and acid fuchsin; original magnification ×100).
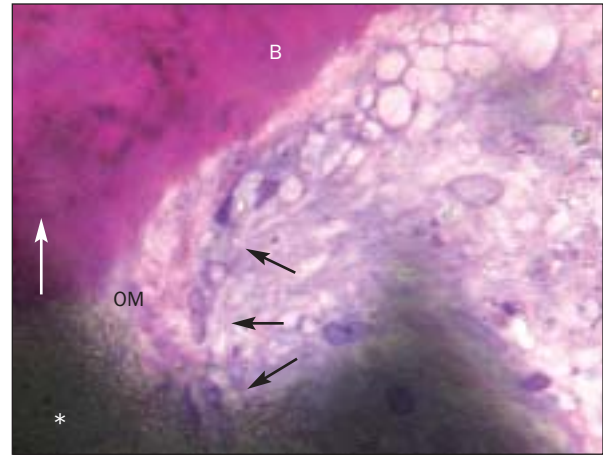
Fig 6 Osteoblasts near the graft particles (*) actively secreting osteoid matrix (OM) and undergoing mineralization (B). The implant surface orientation is perpendicular to the white arrow (toluidine blue and acid fuchsin; original magnification ×100).
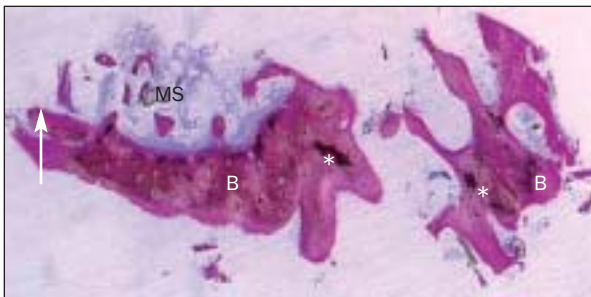
Fig 7 Histologic appearance of a bone core harvested from a site grafted with synthetic porous HA (*). Newly formed bone (B) and marrow spaces (MS) were present near the graft particles. Most of the graft particles had undergone resorption. The implant surface orientation is perpendicular to the arrow (toluidine blue and acid fuchsin; original magnification ×6).

trate.[33–41] Close contact between most of the materials and the newly formed osseous tissue was observed. Osteoblasts were observed apposing osteoid matrix directly on the surfaces of particles from both groups. The 2 groups did not differ significantly with respect to bone formation, but a significantly greater percentage of residual graft material was observed with bovine HA. This could mean that synthetic HA is associated with a higher resorption rate, which would probably be related to higher solubility or to the higher number of multinucleated cells observed around synthetic HA particles.

In some cases, it can be advantageous to use a material that shows very little degradation, such as bovine-derived HA.[42] When this graft material is used, bone grows upward from the pre-existing bone at the sinus floor into the grafted area, maintaining the space, which helps prevent unwanted early resorption without an inflammatory reaction. The success of this graft material for maxillary sinus augmentation has been confirmed in a long-term study.[43]

Close contact between the HA and the newly formed lamellar bone was present in the group 2 specimens. Newly formed lamellar bone developing within and onto the surfaces of HA particles and newly formed vessels were the most prominent features; sometimes osteoblasts were present between the HA particles. Recently, a study has demonstrated that this material can have a possible osteogenetic role by attracting circulating biocomponents (bone sialoprotein and osteopontin) at sites of tissue repair, thus promoting bone regeneration.[28] Long-term studies are needed to evaluate this porous synthetic HA.

CONCLUSION

In the present study, the clinical application of porous synthetic HA was similar to that of bovine-derived HA.

ACKNOWLEDGMENTS

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