

MAXILLARY SINUS AUGMENTATION WITH DEPROTEINIZED BOVINE BONE (BIO-OSS®) AND IMPLADENT® DENTAL IMPLANT SYSTEM

PART II. EVALUATION OF DEPROTEINIZED BOVINE BONE (BIO-OSS®) AND IMPLANT SURFACE

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Summary: The objective of this clinical study was to determine the predictability of endosseous implant placed in a maxillary sinus augmented with deproteinized bovine bone (Bio-Oss®). A total of 185 implants (109 titanium and 76 hydroxyapatite-coated) were placed in 77 patients representing 92 sinuses either a one- or two-stage surgical technique. A mixture of venous patient's blood and Bio-Oss® was used alone within 20 sinuses (Group 1), or in combination with autogenous bone within 72 sinuses (Group 2). Thirty-nine implants were placed in Group 1 and 147 implants were inserted in Group 2. The grafted sinuses were evaluated clinically and radiographically at second stage surgery. According to certain criteria, of the implants placed, only two titanium implants (1.08 %) failed with 98.91 % implant survival. There was no statistically variable difference for the use of hydroxyapatite-coated or titanium implants. The two failed implants were from Group 2. No clinical benefit has been achieved from the combination with autogenous bone ($P < 0.05$). All the grafted sinuses were sufficient to place dental implants of at least 12 mm length (100 % graft success). The results of this short-term study support the hypothesis that Bio-Oss® can be a suitable material for sinus augmentation.

Key words: Endosteal implant; Maxillary sinus; Augmentation materials; Xenograft; Sinus lift; Bio-Oss®

Introduction

The use of dental implants in oral rehabilitation has become a standard of dental care. Unfortunately, replacement of missing teeth with implants in the posterior maxilla often associates with challenging problems. In most instances, the poor bone density of this region is compromised by sinus pneumatization and bone resorption, causing a lack of height for endosseous implants of adequate length to support occlusal loads. Successful implantation in this area calls special surgical techniques and procedures such as a maxillary sinus floor elevation (sinus lift operation). Sinus lifting is a type of inlay augmentation of the maxillary sinus in order to create more bone height in the edentulous lateral maxilla for the placement of dental implants of sufficient length. In-fracture of the lateral wall of the maxillary sinus provides access for sinus mucosa elevation and augmentation material placement (10,19). However, it has not been definitely determined: what is the best grafting material, the best implant surface (hydroxyapatite-coated versus titanium), and whether immediate or delayed implant placement is desirable.

A wide variety of grafting materials have been used to augment bone volume within the sinus including both block and particulate autografts, demineralized lyophilized human bone, xenografts, and resorbable and nonresorbable alloplast grafts. These materials have been used alone or in combination. Xenograft has witnessed a rebirth in popularity over the past decade. Its use was popular in the 1960s but fell into disfavor because of reports of patients developing autoimmune diseases after bovine-derived bone transplants. The re-introduction of these products to the marketplace in the 1990s comes after years of careful scientific evaluation and the development of methods to further deproteinize bone particles (6). The processing reduces the antigenicity, thus resulting in almost complete removal of the organic component of the bone, making it more acceptable to the host tissues. Bio-Oss® (Geistlich, Wolhusen, Switzerland) is a particular inorganic bovine bone matrix of calcium-deficient carbonate apatite. The biocompatibility of this bone graft was demonstrated by Dennissen et al (2). This material has excellent osteoconductive properties (7) and it has been investigated in several studies of guided bone regeneration and augmentation (23). Moreover, it has

been used for sinus floor augmentation both clinically (11,17) and experimentally (13). It is deproteinized by being heat-processed at 300°C for more than 15 hours so that all organic and possibly antigenic components are eliminated. After alkaline treatment, the material, consisting of hydroxyapatite (HA) and carbonate, is sterilized at 160°C; this leaves the crystalline structure (crystal size = 10 to 60 nm), with its high porosity, intact. The material is commercially available in three particle sizes (250 to 1,000 µm, 500 to 1,000 µm, and 1,000 to 2,000 µm) as well as in two different bone types (cortical or cancellous bone) (22). This material is similar to human cancellous bone both in its crystalline and morphological structure. In addition, the physical properties of Bio-Oss® granulate also approximate to the values for human bone tissue and the modulus of elasticity is similar to that of natural bone (21). The large-mesh, interconnecting pore system (75 % pores) of xenogenic bone substitute material facilitates angiogenesis and the migration of osteoblasts. Simultaneously, the inner surface becomes greatly enlarged (Bio-Oss®: 100 m²/g, HA: 1–10 m²/g), which is intended to influence positively the formation and inward growth of new bone, and thus the bonding between transplant material and bone (12).

The aim of the present investigation was to evaluate:

1. The clinical and radiographic results of sinus augmentation procedure performed with Bio-Oss®.
2. The clinical benefit of using hydroxyapatite (HA)-coated implants in this procedure.

Materials and Methods

Patient selection. The present study comprised 77 patients (36 men and 41 women) with severe atrophy of the maxillary alveolar process, as diagnosed by panoramic radiographs, who underwent sinus lift operation with Bio-Oss® in our center from January-1998 to March-2000 (Tab. 1).

Surgical technique. It was performed as reported in the first part of this publication (Fig. 1 a,b,c).

Augmentation material. We used a mixture of Bio-Oss® and venous patient's blood, with/without autogenous bone har-

vested from the maxillary tuberosity. The use of autogenous bone was only considered depending on the possibility to harvest that bone. The sinuses that were augmented only with Bio-Oss® mixed with venous patient's blood were classified as group 1 (20 sinus, 38 implants); while the other sinuses were considered as group 2 (72 sinuses, 147 implants).

Implant type. A total of 185 implants (Impladent®, Lasak, Czech Republic) were placed in these sinuses. They were two types either 109 titanium (109 implants) or HA-coated implants (76 implants). These implants were placed into the grafted sinus in one- or two-stage surgical procedure in the same protocol that was described in the first part of this publication. The types of the surgical procedure and the augmentation material are presented in Table 2.

Follow-up. All patients were given appropriate antibiotic treatment for 1 week beginning 1 hour before the surgery. Clinical evaluations were noted and radiographs were taken prior to sinus augmentation, 9 months after implantation and at yearly intervals thereafter. Implant mobility, at second stage procedure, was determined with the aid of a Periotest® (Siemens, Bensheim, Germany). The following were investigated and subjected to statistical analysis:

Tab. 1: Number of patients and sinus floor elevations.

	Number of patients	Number of sinus grafts
Unilateral sinus lift	62	62
Bilateral sinus lift	15	30
Total	77	92

Tab. 2: The type of the surgical procedure and the augmentation material.

	One-stage procedure	Two-stage procedure	Total
Venous patient's blood and Bio-Oss®	3	17	20
Venous patient's blood, Bio-Oss®, and autogenous bone	32	40	72



Fig. 1: (a) Inward and upward rotated trap-door of the right lateral maxillary sinus wall. (b) Space underneath lifted maxillary sinus mucosa and trap-door is filled with Bio-Oss® graft material. (c) Illustration demonstrates the surgical procedure- frontal section.

1. What was the healing time of the Bio-Oss®?
2. What was the failure rate of the implants?
3. What was the type of implant surface?
4. Was the graft height sufficient to place an implant of at least 12 mm?

Success criteria. At second stage procedure, the criteria for implant success were taken from the O’Roark and Wayne study published in the International Journal of Oral Implantology in 1991, in which success was defined as, “Survival: Any implant removed or one that will be removed because of any reason by experienced implantologist is a failure. The remainders are reported as percent survival” (21). A sinus augmentation was deemed successful if sufficient bone was generated to allow placement entirely in bone of an implant of at least 12 mm in length, such regeneration was assessed with panoramic radiographs.

Statistical study. Fisher’s exact test was used statistically to compare our results ($P < 0.05$).

Results

Postoperative complications. The most common complication during operation was sinus mucosa perforation (51.08 %). Postoperatively wound dehiscence occurred in 15.21 %, however, it healed spontaneously within a period of 3 weeks and did not influence the ultimate healing process in a negative fashion.

Surgical observations. When implants were placed 6 months after grafting, few particles of Bio-Oss® were present within the implant osteotomy.

Implant failure. Two titanium implants (1.08 %) were removed during the second stage surgery from the same sinus that was augmented in combination with autogenous bone. There was no clinical evidence of crestal bone loss around the survival implants (98.91 %) (Tab. 3). However, no statistically variable result for the use of HA-coated or titanium implants ($P = 0.513$), and no clinically benefits have been achieved from the combination of Bio-Oss® with auto-

genous bone ($P = 1.00$). At abutment connecting stage all of these implants appeared well integrated and they tolerated the torque force (35 N cm) applying to stretch the abutment’s screws without pain feeling. Clinical evaluation of their stability using the Periotest® instrument (Siemens, Bensheim, Germany) showed positive results. All implants were loaded prosthetically at the time of the investigation.

Graft success. Radiological examination of the orthopantomogram at the evaluation period revealed no distinct changes in vertical graft height. In one sinus contained three implants, one of them was 10 mm implant because of insufficient bone height to place longer; however, because in the same sinus other two implants were placed 12 mm length so this augmented sinus was considered successful. The other grafted sinuses were sufficient in height to place implants of at least 12 mm length (100 % graft success) (Fig. 2 a,b).

Tab. 3: Implant clinical results.

	Successful implants	Failed implants	Survival percentage
Titanium implants	76	2	97,36 %
HA-coated implants	109	0	100,00 %
Total	185	2	98,91 %

Discussion and Conclusions

Bio-Oss® is chemically deorganified and undergoes a physiologic remodeling characterized by three phases. First, the particles are incorporated and surrounded by host bone. Second, the particles are resorbed by osteoclastic activity. Third, new bone is formed by osteoblasts and replaces the Bio-Oss® particles with dense lamella bone. The rate of conversion of dense lamellar bone is dependent on the cellularity, as well as local and systemic factors. However, in the literature, the resorption of this material has been the subject of controversy; it has been demonstrated in animal experiments where the material was placed in

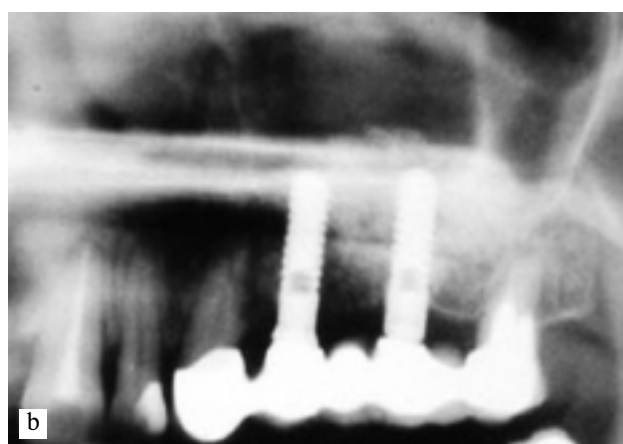
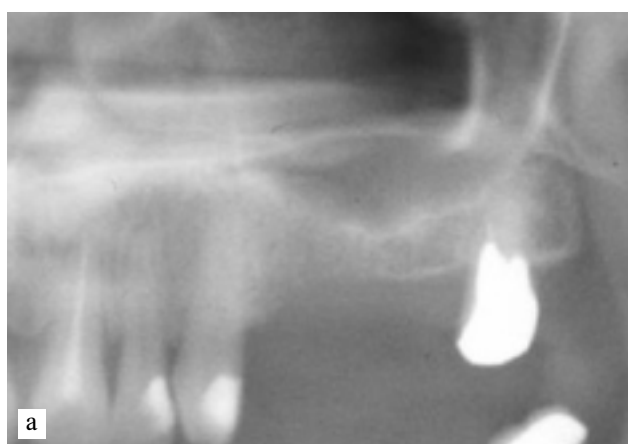


Fig. 2: (a) Radiograph before the operation demonstrates insufficient bone height to place proper implant length. (b) Sufficient bone height to place 14 mm implant length after sinus lift operation.

skull bone defects in rabbits (9). In human studies, Smiler et al (17) in clinical evaluations demonstrated that the formation of new bone by osteoconduction is a slow process taking several months, which can be expected to become established in humans after a time lapse of 1–5 years. On the other side, no overt signs of resorption of the Bio-Oss® particles were visible in Valentini et al's study (20). In Hallman et al's (5) study there were no signs of resorption or degradation of the Bio-Oss® particles. In other radiographic examination has been able to identify the presence of Bio-Oss® granulate even after a resting time of up to 7 years (15).

The primary method of long-term evaluation of sinus grafts has been implant survival in these regions (8,14). Hypothetically, if the graft is composing of good quality bone, the endosteal implant should be maintained in health. Of course, proper implant and prosthetic procedures are required for these implants (3). The results obtained in this study represent better results than other have been published at least for short-term study. Yildirim et al (21) used Bio-Oss® and placed simultaneously 38 Brånemark® implants. When the implants were uncovered, after an average healing phase of 6.8 months, 4 of the 28 implants had become loose. Thus, the resulting clinical survival rate, prior to prosthetic loading, was 89.5 %. In Sinus Graft Consensus Conference (1), implant survival was 80 % after 3 years in augmented sinus by autogenous bone and xenograft. It is noticeable that frequently a failed implant was observed early at the time of uncovering, within the first 3 weeks following uncovering, at abutment placement stage, before loading, or during the first year of loading. Thus, specific reasons for the lack of osseointegration were speculative (4). Moreover, our experiences with the sinus lift procedure with Bio-Oss® calls into question the current gold standard of exclusive use of autogenous bone in this procedure. The survival rate of 98.91 % that we achieved over the period of observation with Bio-Oss® is comparable to that was achieved with autogenous bone or some time better. In the Sinus Consensus Conference (1), implant survival after 3 years using autogenous bone graft was 94 %.

Bio-Oss® mixed with autogenous bone will be converted faster than Bio-Oss® alone. That is because the combination of Bio-Oss® with autogenous bone allows the achieving of the autogenous bone osteoinductive properties. However, no clinical benefits have been obtained from this combination in our study. The addition of patient's intravenous blood to the mixture of augmentation material improves the material degradation by increasing the growth factors concentration. Moreover, the blood will infuse into the pores of the augmentation material, discouraging particle extravasations and making the graft mixture a more solidified mass.

Positive clinical results have been reported with the use of HA-coated implants in association with maxillary sinus augmentation (8,16). In the present study, HA-coated implants did not offer better results as titanium implants that

can be interpreted to the high success of titanium implants too.

As conclusion, from this short-term study, it can be deduced, a positive features of Bio-Oss® as a material for sinus augmentation. For clinical use, both titanium and HA-coated implants can be considered predictable in this surgical procedure. Clinically, it is not important to add autogenous bone to the augmentation mixture especially if that will complicate the surgical technique. However, further follow-up of these patients is important to determine the long-term stability of both material and technique; and more number of patients is necessary to explain if there is relation between the surgical technique and the surgical procedure that we could not demonstrate.

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