Sinus Elevation with Alloplasts or Xenogenic Materials and Implants: An Up-to-4-year Clinical and Radiologic Follow-up

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Purpose: *The clinical and radiologic results of bone substitute application in the sinus elevation procedure were evaluated for up to 4 years after a grafting procedure followed by implant placement.* ***Materials and Methods:*** *Between 1997 and 2001, augmentation of the maxillary sinus floor with alloplastic or xenogenic materials was performed in 34 nonsmoking patients with generally good health. However, only 18 patients attended all of the required annual clinical and radiographic examinations and thus were included in the study. Mean follow-up after implantation was 29 months.* ***Results:*** *At the second-stage surgery all the implants were osseointegrated, except for 1 Frialit-2, which was removed. Following prosthetic rehabilitation no implant was lost after 4 years of function, for a prosthetic success rate of 100%. The cumulative implant survival rate after 48 months was 97% (36 of 37 implants).* ***Discussion:*** *Osseointegrated implants are a reliable treatment option for restoring the posterior maxilla, and final predictability was not influenced by their placement in augmented areas after sinus elevation with bone substitutes.* ***Conclusions:*** *The survival rate obtained with this study is similar to that expected for implants placed in nongrafted areas. This study showed that alloplasts and xenogenic materials are reliable for bone regeneration in the subantral cavities, as they showed very low resorption in the present study.* Int J Oral Maxillofac Implants 2006;21:426–432

Key words: *allografts, dental implants, maxillary sinus elevation, xenografts*

New procedures for the treatment of edentulous areas of the jaws have provided more options for implant-supported restorations. Placement of implants in the posterior area of the maxilla is often challenging, either because of the lack of alveolar bone or because of the structural characteristics of the trabeculae in that region. During recent decades, different surgical procedures have been utilized for the reconstruction of this area, resulting in variable success rates.[1]

Although some consider autogenous bone the gold-standard reconstructive material for bone augmentation, not all patients are able to undergo more complex surgeries including bone harvesting intra- or extraorally.[2–8] Many bone substitutes have been tried in the search for an acceptable alternative to autografts, but even the best among them are only osteoconductive materials (hydroxyapatite, allografts, xenografts, and alloplastic materials). These materials have been applied in sinus augmentation procedures, since they are available in the needed quantity and maintain the original volume during healing.[9–15]

In the present study, the clinical and radiologic results of bone substitute application in the sinus elevation procedure were evaluated 2 to 4 years after grafting and implant placement.

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MATERIALS AND METHODS

Between 1997 and 2001, augmentation of the maxillary sinus floor with alloplastic or xenogenic materials was performed in 34 nonsmoking and generally healthy patients (17 men and 17 women). However, only 18 patients were evaluated (10 men and 8 women; age range, 25 to 66 years; mean, 52 years); the remainder failed to attend the required annual clinical and radiographic examinations. The mean follow-up after implantation was 29 months (range, 12 to 48 months). All patients received oral hygiene instructions before entering the study.

Treatment Planning

Orthopantomographs and computerized tomographic (CT) scans were performed to evaluate the residual height of maxillary alveolar bone. The radiographs were also screened for sinus pathologies. The residual alveolar height was measured on the orthopantomograph. The mean vertical height of the alveolar bone between the most caudal part of the sinus and the oral cavity was on average 7 mm (range, 5 to 9.5 mm). Since all patients were partially edentulous, a diagnostic waxup for each prosthesis was made and converted to a drilling template.

Surgery

Beginning the day before surgery, amoxicillin (1 g/8 h for 6 days; Pharmacia Italia, Milan, Italy) and desketoprofene (50 mg/12 h for 3 days; Desketo; Malesci, Bagno a Ripoli, Italy) were administered. On the day of the surgery, each patient received diazepam (1 drop/2 kg weight; Valium 2; Roche, Basel, Switzerland), an hour before the operation. Local anesthesia was obtained with lidocaine hydrochloride (Ecocain 2%; Molteni Dental, Scandicci, Italy) with 1:50,000 epinephrine.

All surgical procedures were performed by skilled operators in oral and maxillofacial surgery at the Odontoiatric Clinic, Milan, Italy. A 2-stage procedure (bone grafting in stage 1 and, after 8 months of healing, implant placement in stage 2) was performed when the height of the residual alveolar crest was less than 5 mm (4 patients, 4 sinuses, 8 implants). Otherwise, a 1-stage approach, with bone grafting and implant placement at the same appointment, was performed (14 patients, 22 sinuses, 29 implants).

The approach to the sinus surgery was done according to the Tatum technique.[16] A midcrestal incision was made distally from the maxillary first premolar to the maxillary tuberosity, and 2 vertical releasing incisions were made mesially and distally in the buccal mucosa to elevate a mucoperiosteal flap. The lateral wall of the maxillary sinus was fenestrated with a round diamond bur with saline solution irrigation to mark the limits of a rectangular area. Care was taken to preserve the mucosal lining. The sinus membrane was exposed, and an infraction was carried out. The membrane was raised, and the mobilized part of the lateral sinus wall, together with the raised sinus membrane, was rotated medially and upward to create a subsinus cavity into which graft material could be placed. Small perforations of the sinus membrane were not treated, as these defects were closed off by folding of the lifted membrane. In the event of a 1-stage procedure, the implant sites were drilled in the desired positions. A resorbable membrane (Bio-Gide; Geistlich, Wohlusen, Switzerland) was used to cover the lateral wall defect after the bone graft was placed. Postoperatively the patients were instructed to rinse their mouths with 0.2% chlorhexidine for 2 weeks.

Bone Augmentation Materials

Two different grafting materials were used: anorganic bovine bone (ABB) (Bio-Oss; Geistlich) or ABB and hydroxyapatite (HA) + collagen (Biostite; Vebas, Milan, Italy). In 22 of the 26 elevations performed, implants were simultaneously placed; in the remaining 4 cases, a 2-stage procedure was performed, with implant placement after 8 months. Eight months after implant placement surgical uncovering of the implants was performed. A total of 37 implants were placed: 23 Frialit-2 (Friatec, Mannheim, Germany) and 14 Osseotite (3i Implant Innovations, Palm Beach Gardens, FL). The prosthetic restorations were provided by different prosthodontists; 36 fixed partial prostheses were fabricated.

Radiologic Evaluation

According to the protocol adopted, orthopantomographs were obtained before surgery and at implant placement (t1; in the event of a 1-stage procedure, before surgery was considered t1), 6 to 12 months following implant placement, and 24, 36, and 48 months following implant placement.

Measurements were made by 4 operators: a senior dental student, 2 doctors with DDS degrees, and an MD who specialized in both in dentistry and radiology.

For each patient grafted with ABB, 2 panoramic radiographs were taken into account, the one made at implant placement (t1) and the one made at the most recent examination 2, 3, or 4 years postoperatively (t2). For each patient, the distance between the elevated sinus floor and the apex of the implant (A), the distance between the original sinus floor and the elevated sinus floor in the area with implants (B), and (for t1 only) the distance between the crest of the ridge and the original sinus floor in the area with implants (C) (Fig 1) were calculated.

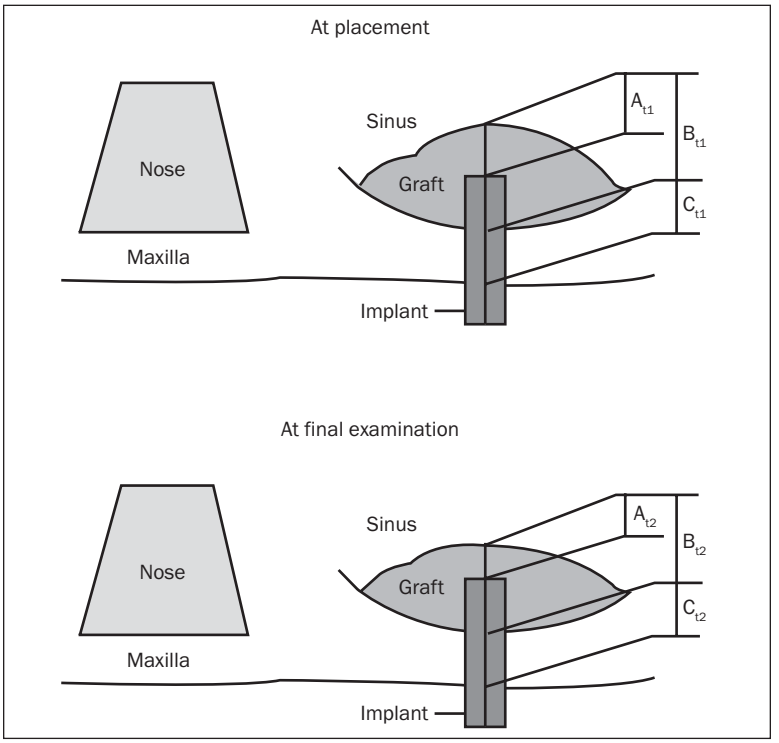


Fig 1 *(a)* Apical bone graft resorption, *(b)* global bone graft resorption, and *(c)* residual bone crest were measured radiographically at placement and at the final examination.

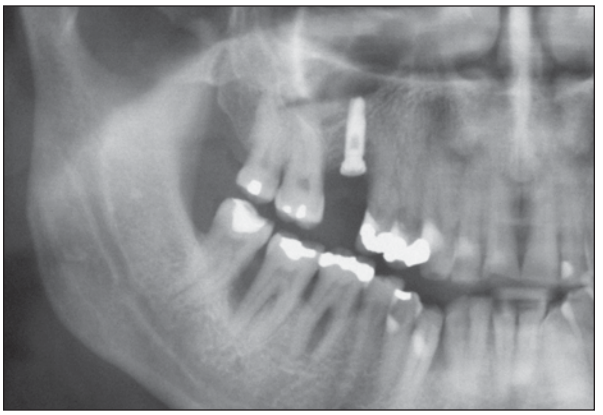


Fig 2 HA + collagen sinus lift after surgery (very low radiopacity).

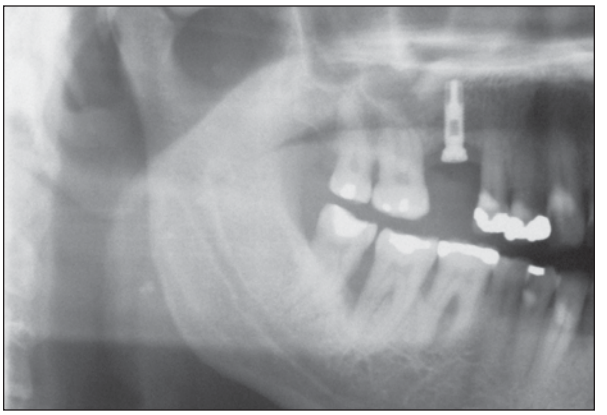


Fig 3 HA + collagen sinus lift after 8 months (good radiopacity and mineralization).

In the cases treated with HA + collagen, a different approach was necessary. Since this material is radiolucent in the first weeks after placement, evaluation of the graft was only possible after the mineralization processes took place (Figs 2 and 3). For this reason, measurements A_{t1} and B_{t1} were not made.

To evaluate ABB volume reduction in the grafted area after 2 and 3 years, A_{t1} and B_{t1} values were compared with A_{t2} and B_{t2} (Figs 4 and 5).

A_{t2} indicated the amount of bone still present apical to the implant, and after considering B_{t2}, the degree of sinus elevation was established. By adding the B_{t2} and C_{t2} values, the total vertical dimension was evaluated in both the cases treated with ABB and those treated with HA + collagen (Fig 1).

Each investigator made the aforementioned measurements for each implant by placing the radiograph on a negatoscope with a millimeter ruler at 4× magnification. Since all the radiographs were made with the same machine, whose magnification degree was 25% of the real, this percentage was deducted from each measurement. All measurements were rounded to the nearest 0.5 mm. To measure A_{t1} and A_{t2}, the ruler was placed along the midline of each implant, and the distance between the implant apex and the elevated sinus floor was measured.

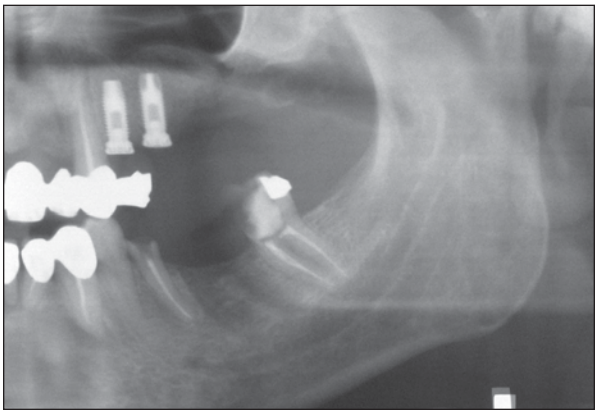


Fig 4 ABB sinus lift after surgery.

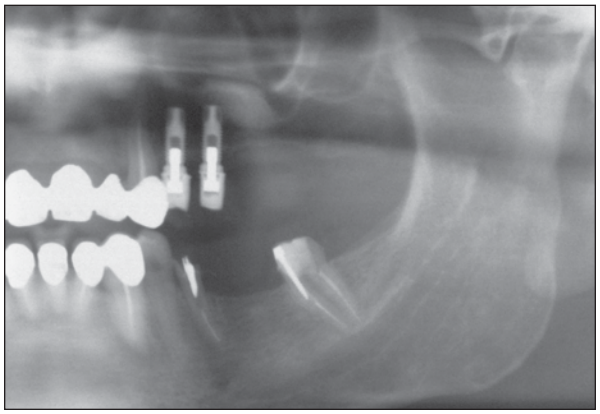


Fig 5 ABB sinus lift after 2 years.

Fig 6 Vertical augmentation with HA + collagen in 1-stage implants.

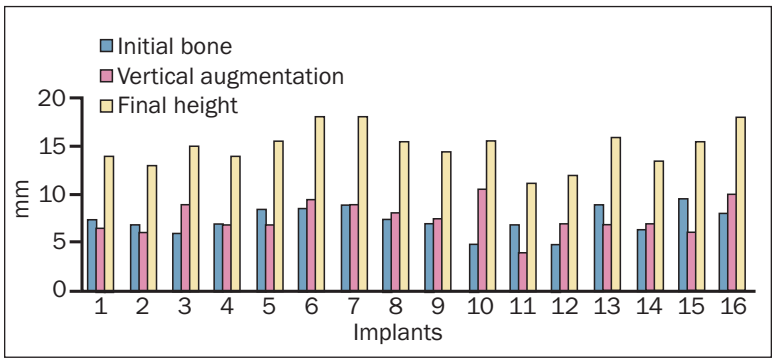
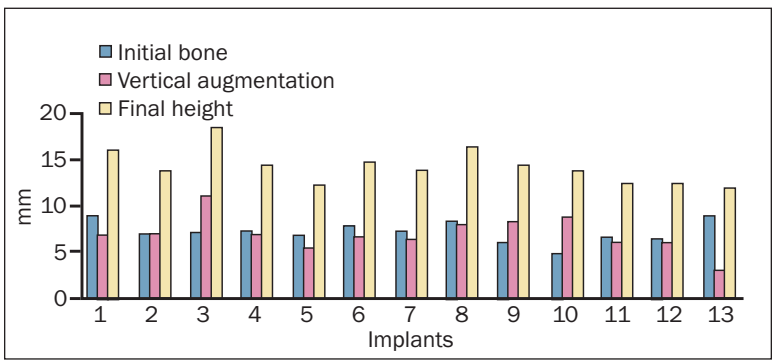


Fig 7 Vertical augmentation with ABB in 1-stage implants.



Regarding B_{t1}, B_{t2}, and C_{t2} surveys, the ruler was placed along the midline of each implant, and the distance between the elevated sinus floor and the original sinus floor was measured. Because of some radiologic artifacts, the upper limit of the graft was impossible to detect for 1 implant, and this case was eliminated from the study, since the A_{t1}, A_{t2}, B_{t1}, and B_{t2} values could not be determined.

All measurements were separately made by each investigator and copied out in a blinded manner (Figs 6 to 9 and Tables 1 and 2).

RESULTS

A total of 26 sinus elevations (13 with ABB and 13 with HA + collagen) were performed in 18 patients. The results involved a total of 37 implants.

No infections were observed. At second-stage surgery all the implants were rigidly anchored, except for 1 Frialit-2 implant, which was removed. No more implants were lost after 4 years of function, and the prosthetic success rate for the remaining 36 implants was 100%. The cumulative implant survival rate after 48 months was 97% (Table 3).

Table 1 Resorption of ABB in mm

Implant	Months followed	No. of surgical stages	Vertical augmentation	Final examination	Difference	% difference
1	24	1	7	7.5	0.5	7
2	24	1	7	6.5	−0.5	−7
3	24	1	11	10	−1	−9
4	24	1	7	5.5	−1.5	−21
5	24	1	5.5	5	−0.5	−9
6	24	1	7	6.5	−0.5	−7
7	24	1	6.5	5.5	−1	−15
8	24	1	9	9	0	0
9	24	1	8	7	−1	−12
10	24	1	8.5	7	−1.5	−18
11	36	1	6	5	−1	−16
13	36	1	3	3.5	0.5	16
Mean			7	6.5	−0.5	−7
13	24	2	5	5	0	0
14	24	2	7.5	7	−1	−13
15	24	2	10	9.5	−0.5	−5
16	24	2	5.5	5	−0.5	−9
17	24	2	6	6.5	0.5	8
Mean			7	6.5	−0.5	−7

Implant 12 failed and was removed at uncovering.

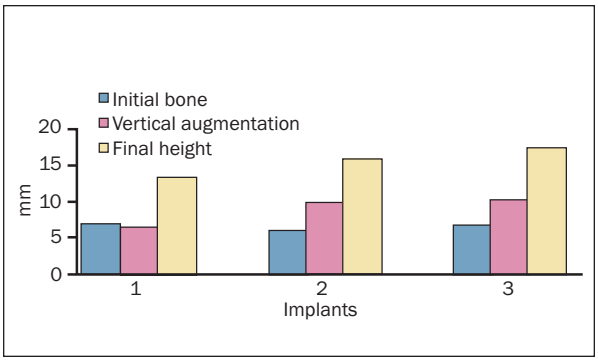


Fig 8 Vertical augmentation with HA + collagen in 2-stage implants.

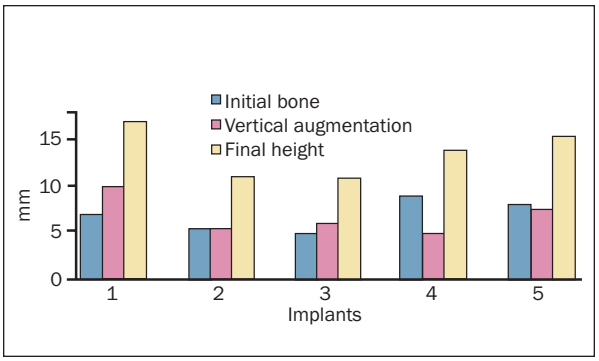


Fig 9 Vertical augmentation with ABB in 2-stage implants.

Mean values for each measurement were calculated. For each implant it was possible to evaluate

- Bone augmentation in a specific area
- Resorption of the ABB graft after 2 and 3 years
- Apical resorption of ABB after 2 and 3 years

To summarize, the following were evaluated:

- Vertical augmentation with ABB (B_{t2})
- Vertical augmentation with HA + collagen (B_{t2})
- Final ridge height (ABB): $B_{t2} + C_{t1}$
- Final ridge height (HA + collagen) :$B_{t2} + C_{t1}$
- Resorption of the graft (ABB): $B_{t2} - B_{t1}$
- Resorption of the graft (ABB): $B_{t2} - B_{t1}$
- Resorption of the apical portion (ABB): $A_{t2} - A_{t1}$

The vertical augmentation obtained with ABB ranged from 3 to 11 mm, with an average value of 7 mm. The vertical augmentation obtained with HA + collagen ranged from 4.0 to 10.5 mm, with an average value of 7.8 mm. The final ridge height obtained with ABB was an average of 14.3 mm (range, 11.0 to 18.5 mm). With HA + collagen, the final ridge height obtained was an average of 15 mm (11 to 18 mm). The resorption of the graft obtained with ABB ranged from 0 to 1.5 mm, with an average value of 0.6 mm. The resorption of the apical portion obtained with ABB was the same (an average of 0.6 mm; range, 0 to 1.5 mm).

Table 2 Resorption of ABB (Apical Portion of the Implant) in mm

Implant	Months followed	No. of surgical stages	Apical augmentation	Final examination	Difference	% difference
1	24	1	5	5	0	0
2	24	1	2.5	2	−0.5	−20
3	24	1	6.5	5.5	−1	−15
4	24	1	3.5	2.5	−1	−28
5	24	1	3	2.5	−0.5	−16
6	24	1	3	2.5	−0.5	−16
7	24	1	5	4	−1	−20
8	24	1	4.5	3	−1.5	−33
9	24	1	6.5	5	−1.5	−23
10	24	1	4	2.5	−1.5	−37
11	36	1	0.5	0	−0.5	−100
13	36	1	1	1	0	0
Mean			4	3	−1	−25
13	24	2	4.5	4	−0.5	−11
14	24	2	4.5	4	−0.5	−11
15	24	2	5.5	5	−0.5	−9
16	24	2	0	0	0	0
17	24	2	0	0	0	0
Mean			3	2.5	−0.5	−16

Table 3 Life Table Anaylsis

Months	No. of implants followed	Failures for period	Survival rate (%) for period	Total no. of failures	Cumulative survival rate (%)
12	37	0	100	0	100
24	36	1	97	1	97
36	11	0	100	1	97
48	6	0	100	1	97

DISCUSSION

The aim of this clinical and radiologic study was to evaluate the efficacy of 2 different bone substitutes for the sinus elevation procedure. Even though this surgical technique has become routine for patients with poor bone support in the posterior regions of the maxilla, the best augmentation material for the purpose has not yet been determined. Although autogenous bone is the gold standard grafting material for the oral cavity because of its osteoinductive and osteoconductive properties,[17] ABB and HA + collagen appear to be useful human bone substitute materials where sinus augmentation procedures are required. ABB in particular resorbs slowly over a long period of time.[18] Yildirim and colleagues reported that 6 months after sinus grafting, histomorphometric analysis of human biopsy specimens showed an average of 14.7% of newly formed bone, with 29.7% of xenogenic bone substitute material (ABB) and 56.0% soft tissue.[18]

The implant survival rate observed in this small patient population is in line with data from patients treated with implants in the posterior maxilla without any bone atrophy.[19] A recent long-term study[19,20] (16 years of follow-up) of implant-supported fixed partial prostheses showed an implant success rate of 96.6%; that approximates the 97.0% reported in the present study of 37 implants.

Concerning bone augmentation and overall vertical dimension obtained after grafting with ABB and HA + collagen, no practical differences were observed between the results for the 2 materials. Vertical augmentation ranged from 3.0 to 10.5 mm; initial ridge height ranged from 5.0 to 9.5 mm. Mean vertical augmentation obtained was 7.0 with ABB and 7.8 with HA + collagen.

Likewise no practical differences were observed between the 2 materials with respect to the overall vertical dimension obtained: the final height values ranged from 11 to 18.5 mm.

The final mean ridge heights obtained with ABB and HA + collagen, respectively, were 14.3 and 15.0 mm. This would allow the placement of implants at least 11 mm in length. Since ABB is a radiopaque material, its resorption over time was evaluated, and an average resorption of 0.5 to 1 mm was calculated after 4 years of function.

CONCLUSIONS

Osseointegrated implants represent a reliable way to restore the posterior maxilla, and their predictability is generally not influenced by their placement in augmented areas after sinus elevation with bone substitutes. The survival rate obtained with this study is similar to that found for implants placed in non-grafted areas.

This study showed that alloplasts and xenogenic materials are reliable for bone regeneration in the subantral cavities, as they demonstrated very low resorption and provided optimal primary stability for the implants in this patient population. No essential differences were found in the results for the 2 implant systems utilized in this study. Although a relatively small number of patients was considered in the present study, both ABB and HA + collagen seemed to be suitable materials for sinus grafting.

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