

Sinus lift surgery in severely resorbed maxillae: One-year follow-up

Abstract

Objective

The aim of this prospective study was to clinically analyze the behavior of implants inserted into severely resorbed maxillae after sinus grafting.

Materials and methods

Twenty-six wide-diameter implants with a rough surface over their entire length were inserted during 13 consecutive sinus lifts. Radiographic analysis was preoperatively requested for each patient. After Schneiderian membrane elevation, a magnesium-enriched hydroxyapatite (Mg-e HA) and collagen-based scaffold with a porous 3-D structure was used to prevent perforation during implant placement. Sinus grafting was performed using a biomimetic Mg-e HA. No membrane was used to cover the buccal window. The preoperative residual bone height ranged between 1 and 4 mm (mean value: 2.5 mm; SD: 1.0 mm).

After 6 months of healing, uncovering was carried out and the definitive restoration was seated after 2 weeks. In order to monitor the stability changes, resonance frequency analysis was performed and ISQ (Implant Stability Quotient) values were collected at the first surgery (baseline, T_0), at the abutment connection (T_1) and at the 1-year follow-up (T_2).

In order to measure bone changes, the patients underwent panoramic radiographs after 2-year follow-up. Image analysis software calculated the grafted bone height changes at the level of the implant site, comparing preoperative and follow-up panoramic radiographs.

Results

No postoperative complications were observed. The mean ISQ value was 42.5 (SD: 2.7) at T_0 , 75.3 (SD: 8.2) at T_1 and 81.5 (SD: 2.6) at T_2 . Statistically significant differences ($P \leq 0.005$) regarding mean ISQ values were found between T_1 and T_0 , as well as between T_1 and T_2 . After 12 months of functional loading, only 1 implant was lost (cumulative survival rate: 96.15%). During the same observation period, the mean radiographic vertical height of the grafted sinus floor was 11.05 mm (SD: 2.10 mm), with a mean gain of 8.50 mm.

Conclusion

Within the limitations of this study, despite preoperative critical residual bone height, maxillary sinus lift restoration using a biomimetic Mg-e HA and an Mg-e HA/collagen-based scaffold with a porous 3-D structure seems to be a reliable procedure.

Keywords

Sinus lift, magnesium enriched hydroxyapatite, x-ray analysis, ISQ.

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Introduction

Sinus floor augmentation has recently become a widely accepted surgical procedure to improve the amount of bone volume before implant placement. Although the use of autogenous bone appears to be the gold standard,^{1,2} much attention has been paid to the use of bone substitutes. After the harvesting procedure, donor site morbidity has to be taken into consideration.³ Additional disadvantages for autografts are the limited availability and the tendency to resorb.⁴ In order to overcome these limitations, several biomaterials have been evaluated in experimental and clinical studies, such as demineralized freeze-dried bone allograft,⁵ bovine bone matrix,⁴ composite bone graft including platelet-rich plasma,⁶ resorbable and nonresorbable hydroxyapatite^{7,8} and beta-tricalcium phosphate.⁹ In particular, bioceramics based on calcium phosphate are widely used owing to their biocompatibility, absence of immunogenic factors and osteoconductivity; although, the high temperature during the sintering process could negatively influence osteoconductivity and resorption time.¹⁰ New hydroxyapatites enriched with magnesium (Mg-e HAs) have recently been introduced on the market. Mg-e HA has been demonstrated to allow complete healing of the tissue around a graft and undergoes almost complete resorption already after 1 year.¹¹ Despite its high predictability, the more recent literature has highlighted possible complications after this procedure.¹² The main complication is membrane perforation, mostly during implant insertion. Mg-e HA/collagen-based scaffolds have been successfully used for sinus augmentation procedures, demonstrating bone formation after 6 months already.¹³ Owing to its properties, this material might be suitable to protect the sinus membrane from eventual perforation during implant insertion.

The present preliminary prospective study was designed to evaluate clinically and radiologically implant restorations 12 months after prosthetic loading in severely resorbed maxillae requiring 1-stage sinus lift surgery. The graft used was an Mg-e HA and Mg-e HA/collagen-based scaffold with a porous 3-D structure and was used to prevent Schneiderian membrane perforation.

Materials and methods

Study design and patient selection

One dental center consecutively recruited 13 patients scheduled for implant-supported

restoration in the posterior maxilla with a sinus augmentation procedure. A total of 26 wide-diameter implants with a rough surface over their entire length were inserted in extremely resorbed posterior maxillae. The present study was performed following the principles outlined in the Declaration of Helsinki of 1975, as revised in 2013, on experimentation involving human subjects. All of the patients were in general good health. They were informed about the procedure and required to sign a consent form. They were followed for a period of 12 months after prosthetic rehabilitation. The principal inclusion criterion was a residual bone crest (distance between the sinus floor and bone crest) ranging between 1 and 3 mm in height and allowing wide-diameter implant insertion. Additional inclusion and exclusion criteria are summarized below:

Subject inclusion criteria:

- Need for fixed implant-supported prosthesis in the posterior maxilla.
- Aged > 18 years.
- No relevant medical conditions.
- Nonsmoker or smoked ≤ 10 cigarettes/day (pipe or cigar smokers were excluded).
- Full-mouth plaque score and full-mouth bleeding score of ≤ 25%.

Study site inclusion criteria:

- Native bone height of 1–3 mm in the sinus zone.

Subject and site exclusion criteria:

- Acute infection of the Schneiderian membrane or chronic sinusitis.
- Allergies involving the respiratory system.
- A history of bisphosphonate therapy.
- Uncontrolled diabetes (glycated hemoglobin A_{1c} > 6%, glycemic level > 110 mg/dL).

Preoperative and postoperative medication

The patients underwent a preoperative digital panoramic radiograph, subsequently used as baseline. A cone beam computed tomography scan was also required to investigate antral anatomy (**Fig. 1**). One week before the surgical procedure, full-mouth professional prophylaxis was performed. The patients were instructed to use 1 g of penicillin clavulanate 1 day prior to surgery and continue with 2 g per day for 6 days. Just before surgery, the patients underwent a 5-min mouth rinse with 0.2% chlorhexidine gluconate.

Figs. 1A & B

Preoperative digital panoramic radiograph with preoperative computed tomography scans.

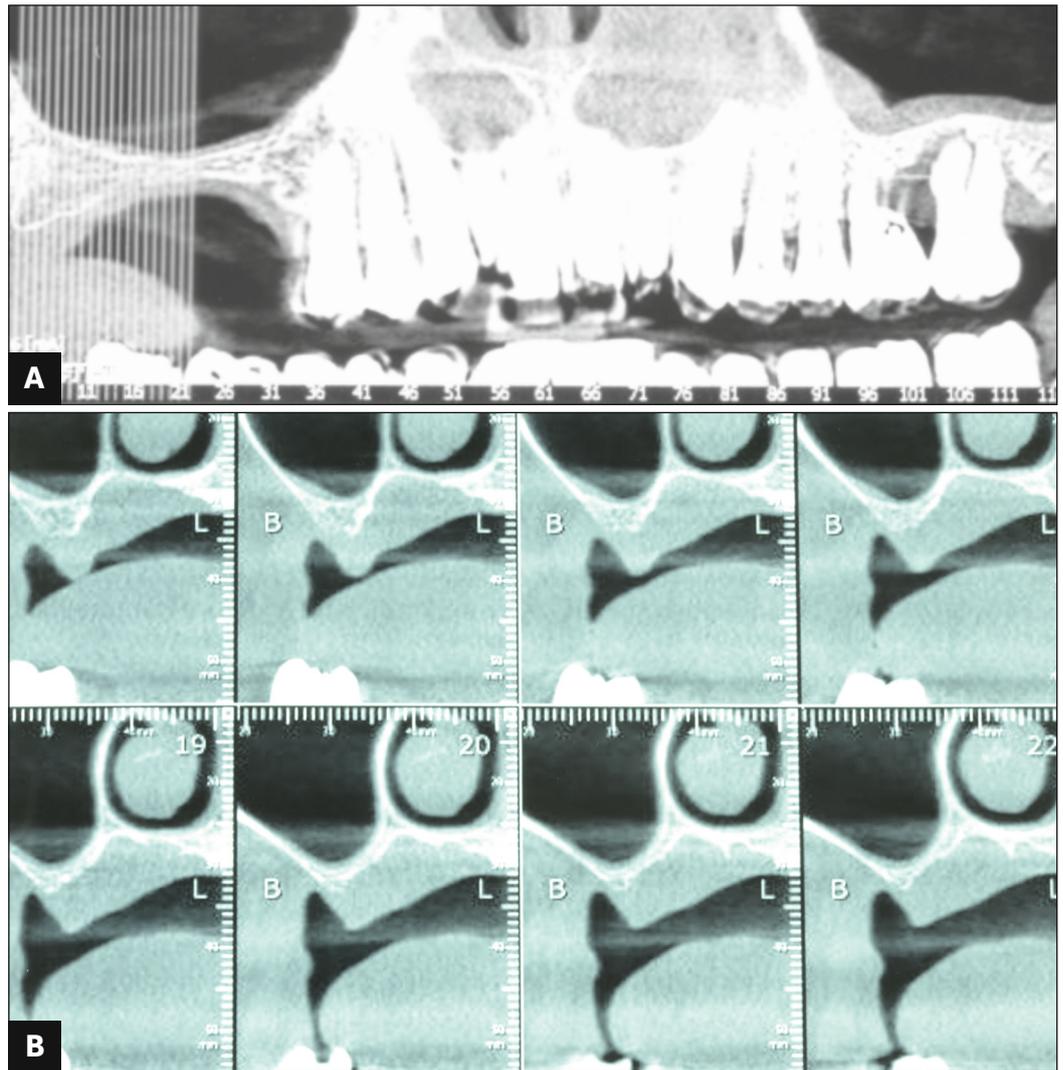


Fig. 1A

Fig. 1B

Surgical technique

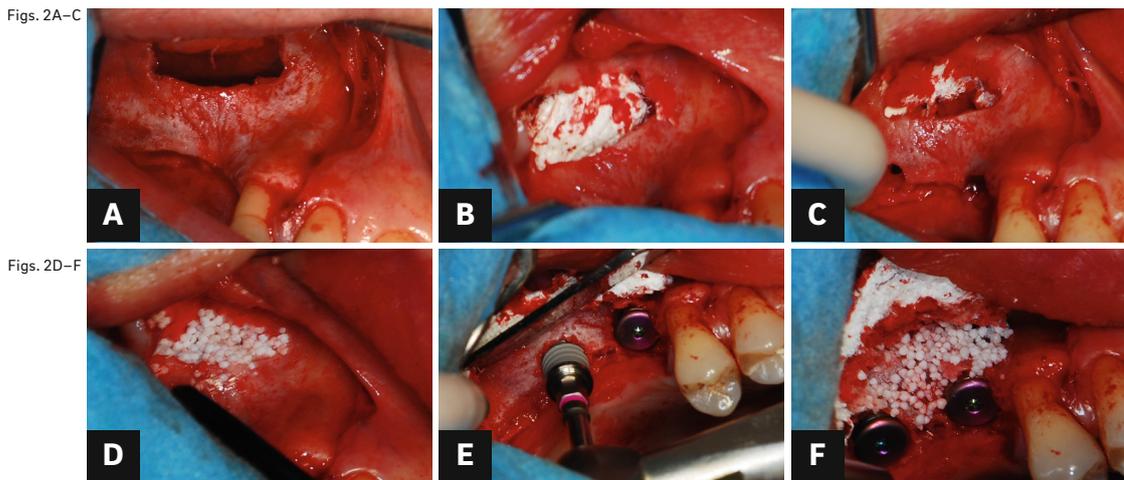
The sinus area was prepared under local anesthesia, as described by Boyne and James.¹ The bony window was left attached to the Schneiderian membrane. The sinus mucosa was elevated, taking care to avoid laceration. In all cases, an Mg-e HA/collagen-based scaffold with a porous 3-D structure (RegenOss, Finceramica, Faenza, Italy) was used to protect the Schneiderian membrane and prevent any mechanical complication during grafting and implant insertion.

Implant sites were marked using a surgical template. In order to increase primary stability, osteotomies were performed using the narrowest drill able to allow implant insertion, to avoid buccal bone fracture. Residual bone height was assessed using a modified probe with a small hood. Then, the graft material (HA granules, 600–900 μ , SINTlife, Finceramica) was placed

at the superior aspect of the sinus and against the medial aspect of the grafted compartment created in the sinus cavity. The graft material was meticulously condensed at each stage. Then, 2 implants (5 mm in diameter, 10–13 mm in length, Premium SP, Sweden & Martina, Due Carrare, Italy) were placed at a torque value of > 10 Ncm. The root-shaped implant used in this study had a sandblasted and acid-etched surface over its entire length. No membrane was used to cover the buccal window (**Fig. 2**). The oral mucosa was then sutured with 5-0 resorbable interrupted sutures (Vicryl, Ethicon, New Brunswick, N.J., U.S.).

Postoperative treatment

The patients were instructed to avoid blowing their noses for at least 7 days after surgery and to cough or sneeze with an open mouth to prevent



increased pressure in the operated sinus. They underwent a new digital panoramic radiograph for postoperative evaluation. Clinical and surgical postoperative complications were measured.

Second-stage procedure and follow-up evaluation

Second-stage surgery to expose the implants was performed 6 months after implant placement. After performing a minimal crestal incision just over the area corresponding to the implant, the cover screws were exposed and removed. Attached keratinized mucosa was left on both the palatal and buccal aspects around all of the implants, and healing abutments were screwed in at a torque of 10 Ncm.

Clinical evaluation criteria at the time of implant exposure included stability in all directions, eventual crestal bone resorption, and any reported pain or discomfort. One week later, after impression taking using pickup coping transfers, titanium abutments were screwed in at a torque of 32 Ncm. In the same procedure, an additional impression of the screwed-in abutment was taken using the metallic structure. The provisional restoration was seated. In order to allow better distribution of the occlusal forces, splinted crowns were used. Implants inserted in residual neighboring bone without augmentation were not splinted to the ones inserted in augmented bone. One week later, definitive crowns were cemented using a provisional cement (Temp-Bond, Kerr, Orange, Calif., U.S.) Twelve months after prosthetic loading, a digital panoramic radiograph was obtained to assess the newly formed bone and its interface with the implant (**Fig. 3**).

Implant stability measurements

Immediately after implant insertion (baseline, T_0), resonance frequency analysis (RFA; Osstell Mentor, Osstell, Gothenburg, Sweden) for each implant was carried out and the values were used as baseline. The transducer was hand-screwed into the implant body as recommended by manufacturer. The RFA value is represented by a quantitative parameter called ISQ (Implant Stability Quotient). The ISQ ranges between 1 and 100. The measurements were repeated for each implant after 6 (T_1) and 12 months after prosthetic loading (T_2). Each measurement was taken twice buccolingually and the mean value was used. Because each transducer had a unique fundamental RF, the measurements were calibrated using a calibration block. All stable implants were considered successful.

Complications

Any technical (implant fracture, screw loosening, etc.) and/or biological (pain, swelling, suppuration, etc.) complications were considered.

Radiographic evaluation

The grafted area was evaluated with a computerized measuring technique applied to the digital panoramic radiographs (preoperative and 12-month follow-up). In each case, the surface of grafted sinus was marked with a virtual marking instrument. An image analysis software program (AutoCAD 2006, Version Z 54.10, Autodesk) calculated the total (native + grafted) bone height changes at the level of the implant site, comparing preoperative and follow-up

Figs. 2A–F

(A) Following the limits of the sinus, a bone window was outlined along the sinus edge with a round diamond bur (2,000 rpm) under copious irrigation. (B) The sinus mucosa was elevated, taking care to avoid laceration, and RegenOss was inserted to protect the membrane during insertion of the graft material. (C) An Mg-e HA collagen-based scaffold was elevated to allow particulate graft material to fill the sinus cavity. (D) SINTlife graft material was compacted in the sinus cavity. (E) Implants were inserted. Final step of the surgery: No membrane was used. Implant insertion. (F) Final filling of the sinus cavity.

Fig. 3

Digital panoramic radiograph
12 months after prosthetic
loading.



Fig. 3

panoramic radiographs, with the ability to compensate for eventual radiographic distortion.^{14,15} All measurements were conducted and recorded by the same trained independent examiner, without input from the implant surgeon.

Statistical analysis

Descriptive statistics, including mean values and standard deviation, were used to describe changes in implant stability over the time and bone area. Student's *t*-test for paired data was performed to test the significant difference between ISQ values at T_0 , T_1 and T_2 . Student's *t*-test was used to perform bone area comparison. Significance was set at $P > 0.05$.

Results

A total of 13 consecutive patients (8 females and 5 males) were treated. The mean age was 62.1 years (SD: 11.05 years). No patient dropped out during the study. The preoperative mean residual bone level was 2.5 mm (SD: 1.0 mm). Minimal perforation of the sinus membrane occurred in 4 cases. The healing period after sinus augmentation was without complication for all of the patients. Minor nosebleeds occurred in 1 case. No clinical symptoms of maxillary sinusitis occurred in any patient. Only 1 implant was mobilized during the uncovering procedure, in a light smoker. For the failed implant, the preoperative height was 2 mm, the ISQ value was 39 at T_0 and 42 at T_1 . The patient did not report any symptoms during the healing period. After surgical debridement, the implant

was substituted with an implant 6 mm in diameter at the same surgical stage and restored after an additional 3 months of healing. All of the other implants were osseointegrated after 12 months of prosthetic loading (cumulative survival rate: 96.15%).

The mean ISQ value was 42.5 (SD: 2.7) at T_0 , 75.3 (SD: 8.2) at T_1 and 81.5 (SD: 2.6) at T_2 . Statistically significant differences ($P \leq 0.0005$) regarding mean ISQ values were found between T_1 and T_0 , as well as between T_1 and T_2 . The mean radiographic vertical height of the grafted sinus floor was 13.75 mm (SD: 1.30 mm) after 12 months of prosthetic loading ($P \leq 0.0005$).

Discussion

This prospective study demonstrated that, even in critical conditions, osseointegration and longitudinal stability of implants with a rough surface over their entire length could be a reliable clinical outcome when placed in maxillary sinuses grafted with a biomimetic Mg-e HA. Additionally, the use of an Mg-e HA/collagen-based scaffold with a porous 3-D structure seems to prevent surgical complications due to microperforation of the Schneiderian membrane.

The main limitations of the present study were the short-term follow-up (1 year) and small sample size (13 patients). However, this study is a preliminary report proving the feasibility of the combination of an Mg-e HA/collagen-based scaffold with a biomimetic HA. Additionally, the absence of a control group does not allow for demonstration of any additional benefit compared with the gold standard in sinus lift surgery.

The graft material investigated in this study was a new generation of HA, biomimetic scaffolds, and was studied as an alternative to overcome the disadvantages of conventional graft material, simulating bone structure not only from a chemical point of view, but also microscopically, reproducing micropores and their interconnections. Within this graft material category, Mg-e HAs have chemical and morphological properties close to that of natural bone and have showed comparable results to autologous bone in regenerative procedures. This configuration seems to be able to induce migration, adhesion and proliferation of osteoblasts inside the pore network and to promote angiogenesis inside.¹¹

A recent literature review showed the residual bone crestal height to be one of the most critical factor influencing implant survival rate. At the same time, a minimum bone height of 4–5 mm is recommended for a 1-stage implant insertion.¹⁶ However, according to Peleg et al., despite severely resorbed maxillae, a 1-stage surgical technique was adopted in the present study.¹⁷

This approach finally reported only 1 implant failure, according to the results obtained by Fugazzotto and Vlassis¹⁸ in their retrospective report and according to Wallace and Froum¹⁹ and Del Fabbro et al.¹⁶ in their reviews. Furthermore, in their systematic review, Wallace and Froum indicated membrane placement over the lateral window to be an important factor to improve the quality of regenerated bone.¹⁹ An absorbable collagen membrane placed on the buccal sinus wall, in fact, seemed to protect the graft from soft-tissue invasion, which would reduce the amount and the quality of the *de novo*-formed mineralized tissue.^{20,21} This finding was also confirmed by a published systematic review.²² In this study, Pjetursson et al. showed an annual implant failure rate significantly higher (4.0% vs. 0.7%) when no membrane was used to cover the lateral window after the grafting procedure.²²

Results from the present study showed that a membrane may not be a critical factor for the implant survival rate. An additional result to be noted is the absence of any postsurgical complication in the case of microperforation of the membrane. In fact, sinus membrane perforation is a typical surgical complication. This event could occur during membrane elevation before graft insertion or after graft insertion at the time of implant positioning. According to the literature, the second possibility is often clinically

unknown, and it is probably due to membrane compression from the graft shifting subsequent to the implant insertion.¹²

In order to prevent this complication, an Mg-e HA/collagen-based scaffold with a porous 3-D matrix was placed between the sinus membrane and the graft. The clinically relevant peculiarity of this scaffold is its appearance, which is similar to that of a collagen membrane, and therefore its similar elasticity. The scaffold was advantageous, preventing perforation of the sinus mucosa by the graft material particles. At the same time, the scaffold acted as not only a membrane but, as demonstrated by the literature,¹³ also a graft material itself. From a surgical point of view, despite very resorbed maxillae, no postoperative problems or complications were observed when implants were inserted simultaneously with the graft material. Although the literature describes problems during the surgical phase in sinus augmentation in patients with 1–4 mm residual bone height,²³ the use of wide-diameter implants allows a sufficient primary stability.²⁴

Although the mean value of ISQ at T_0 was very low, the data reported at T_1 are in line with that of previously reported findings. In fact, Lai et al. reported the same findings for rough-surfaced implants installed after minor sinus floor elevation.²⁵

The statistically significant increase of ISQ values between T_0 and T_1 could be evidence of fast maturation of the graft, after just 3 months. An additional increase between T_1 and T_2 could indicate a further maturation of the material after 12 months of prosthetic loading. Despite some clinical studies suggesting positive results with the use of RegenOss alone in sinus lift procedures after 6 months,¹² controversial outcomes with the use of a soft matrix were reached in the literature.²⁶ In fact, Caneva et al. suggested the use of rigid materials to counteract negative pressure during respiration.²⁶

Conclusion

The present study, within its limitations, demonstrated that the use of a soft matrix in association with a graft material allows bone regeneration without postoperative complications. However, further studies should aim to measure discrepancies between preoperative and long-term postoperative increments using the promising matrix used in the present study.

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