Graft shrinkage and survival rate of implants after sinus floor elevation using a nanocrystalline hydroxyapatite embedded in silica gel matrix: a 1-year prospective study

EL HAGE, Marc, et al.

Abstract
The aims of this study were (1) to evaluate the vertical shrinkage percentage of nanocrystalline hydroxyapatite embedded in silica gel used for maxillary sinus floor elevation (SFE) and (2) to determine the survival rate of the implants 1 year after placement in the healed grafted sinuses.

Reference

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Graft Shrinkage and Survival Rate of Implants After Sinus Floor Elevation Using a Nanocrystalline Hydroxyapatite Embedded in Silica Gel Matrix: A 1-Year Prospective Study

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In the posterior maxilla, insufficient bone volume is frequently encountered due to the pneumatization of the maxillary sinus together with crestal bone (CB) resorption after tooth loss.¹ This can hinder dental implant placement in this region. Maxillary sinus floor elevation (SFE) is a widely used surgical procedure for regaining adequate bone height before implant placement. Commonly, the sinus floor is augmented with autogenous bone or biomaterials or a combination of both.²

Autogenous bone has long been considered the gold standard grafting material because of its osteoinductive and osteoconductive properties. In general, bone substitutes have no osteoinductive potential but are considered to provide a scaffold for optimal bone growth.³ In a recent literature review, different materials used in SFE procedures were examined.² It was noted that intraoral donor sites are convenient but yield limited volume. Extraoral donor sites increase surgical complexity and are associated with significant (and underreported) morbidity and scarring.¹,²,⁴ Therefore, alternative grafting materials have been developed.

Objectives: The aims of this study were (1) to evaluate the vertical shrinkage percentage of nanocrystalline hydroxyapatite embedded in silica gel used for maxillary sinus floor elevation (SFE) and (2) to determine the survival rate of the implants 1 year after placement in the healed grafted sinuses.

Materials and Methods: Eleven maxillary sinuses were augmented in eight patients with NanoBone. After a healing period averaging 14.42 months, 19 implants were placed and followed up with clinical and radiographic evaluation. Panoramic radiographs were taken immediately after SFE and at 12 months after grafting. Measurements of changes in height were made by a computerized measuring technique using an image editing software.

Results: The mean graft height shrinkage percentage at 12 months after surgery was 8.84% (±5.32). One implant was lost before loading. All the 18 remaining osseointegrated implants received the prosthetic rehabilitation and were controlled after 3 months of functional loading. The implant survival rate at the 1-year interval was 94.74%.

Conclusions: A 100% NanoBone alloplastic graft used in lateral SFE procedures presented limited height shrinkage. Implants placed in these grafted sinuses showed survival rates similar to those found in published data. These results should be interpreted cautiously considering the study’s reduced sample size. (Implant Dent 2012;21:213–219)

Key Words: alloplast, dental implant, bone height

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of allografts and xenografts, alloplasts are alternatively used. Of those alloplasts, calcium phosphate bioceramics, for example, hydroxyapatite (HA) or beta-tricalcium phosphate (beta-TCP), or a combination of both, are frequently used. Because of high-temperature processing, these materials present increased density and less porosity. This could negatively influence their potential osteoconductivity.

A nanocrystalline HA embedded in silica gel matrix (NanoBone; Artoss, Rostock, Germany) was developed. This material presents a large internal surface (~84 m²/g) due to the interconnecting pores between 10 and 20 nm of the silica gel. In addition, the HA granules show a rough surface leading to a porous structure ranging from micrometer to millimeter in dimension. An animal study showed a significantly better biological behavior of the new high-porous bone replacement material (NanoBone) in comparison with the conventionally sintered ceramics. Furthermore, the authors noted that bone formation and resorption rates after implantation of the nanocrystalline HA were higher compared with other commercial available HAs, TCPs, or gelatine sponges (control group). Other studies revealed signs of osteoconduction and osteoinduction in the histological and immunohistochemical investigations of human and animal biopsies. Additionally, high levels of biocompatibility and angiogenic response were reported. In recent histological investigations of human biopsies from sinus augmentations using the nanocrystalline HA, newly formed bone although in limited quantities was already found at 3 months of healing, and new trabecular bone was found at 6 months of healing. Well-mineralized regenerated bone with lamellar parallel-fibered structure and Haversian systems surrounded the residual NanoBone particles. Moreover, it was observed that NanoBone has osteoconductive and biomimetic properties and is integrated into the host’s physiological bone turnover at a very early stage.

Clinical and radiographic outcomes of sinus grafts have been studied. Of particular interest is whether graft height and volume are maintained over the long term. A clinical study was conducted to evaluate the factors affecting changes in sinus graft height between and above implants. It concluded that the type of the grafting material is the main factor affecting changes in height.

Therefore, the first aim of this prospective study was to evaluate the vertical shrinkage percentage of nanocrystalline HA embedded in silica gel (NanoBone), 12 months after maxillary SFE and before implant placement. The second aim of the study was to determine the survival rate of the implants at 1 year after placement in the healed grafted sinuses.

**Materials and Methods**

**Patient Selection**

Between July 2006 and July 2009, eight partially edentulous patients scheduled for a two-stage SFE procedure were admitted to the study. Patients were referred to the Department of Oral Surgery and Oral Medicine by their private dentist or by another Department at the University of Geneva. Patient selection included candidates presenting bone defects requiring SFE, and only excluded patients with severe health problems. All included patients had a remaining alveolar bone height of ≥3 mm determined by panoramic radiographs. All patients signed an informed consent and were treated according to the guidelines of the World Medical Association in the declaration of Helsinki (2008). The group comprised five women and three men with a mean age of 53 years (range, 37–65 years).

**Surgical Procedures**

The surgical procedures were carried out under local anesthesia (Ubistesin, 3M ESPE AG, Germany) by either one of three experienced surgeons. All patients received perioperative antibiotic prophylaxis with clindamycin (Dalacin C; Pfizer SA, Zürich, Switzerland) 300 mg three times a day for 5 days, starting with 600 mg 1 hour before surgery.

**Maxillary SFE**

A mucoperiosteal flap was elevated after a crestal incision and two vertical releasing incisions were performed to expose the lateral wall of the sinus. A lateral bony window was outlined and completely removed with a 3-mm diameter round diamond bur. The Schneiderian membrane was carefully reflected, a bioresorbable porcine collagen membrane (Bio-Gide, Geistlich Pharma AG, Switzerland) was placed along it, and the space was filled with 0.6 to 2.4 mL of 0.6 mm granules of NanoBone. Blood was previously collected from the surgical site and mixed with the grafting material. The grafted area was then covered with a Bio-Gide membrane. Tension-free closure was accomplished with interrupted polyamide 5.0 sutures (Suturamid, B. Braun Aesculap, Sempach, Switzerland).

**Implant Insertion**

After an average healing period of 14.42 months (±3.69), rough-surfaced implants with a sandblasted, large-grit, acid-etched surface (SLA or SLActive) transmucosal Straumann implants (Institute Straumann AG, Basel, Switzerland) were placed. Implant bed preparations and biopsies were realized in the grafted area using a trephine drill with an external diameter of 3.5 mm (Straumann Trephine Drill, Institute Straumann AG, Basel, Switzerland). The results from the histological analysis of the biopsies are the subject of a separate study.

**Prosthetic Treatment**

Eight weeks after placement, implant stability was measured with an electromechanical Periotest device (Periotest Classic, Medizintechnik Gulden, Bernsheim, Germany), according to the manufacturer’s working instructions. The device measuring values ranging from –8 (solid osseointegration) to +50 (poor osseointegration). Subsequently, prosthetic rehabilitation was initiated.

**Survival Criteria**

Implant survival was assessed at the 1-year control following the criteria proposed by Buser et al and Cochran et al. These criteria included the following: (1) absence of clinically detectable implant mobility, (2) absence of pain or any subjective sensation, (3) absence of recurrent periimplant
infection, and (4) absence of continuous radiolucency around the implant.

Radiographic Analysis

The aim of the radiographic analysis was to evaluate the postaugmentation graft shrinkage percentage. During the follow-up period, at least four radiographic examinations were made in each patient. For the grafted volume evaluation, panoramic radiographs were taken immediately after surgery (T₀ₒ) and 12 months (range, 11.3–13.3 months) after surgery (T₁ₒ). All the panoramic radiographs were taken using a Scanora unit (Soredex, Orion Corporation Ltd., Helsinki, Finland). For implant control, either panoramic or periapical radiographs with the paralleling technique were taken at the time of implant placement (T₀ᵢ) and 1 year after placement (T₁ᵢ). All radiographs were scanned in a digital format by a flatbed scanner (Epson Expression 1680 Pro, Wadenswil, Switzerland) at a resolution of 600 dpi and were saved as tiff format files. They were then analyzed by a computerized measuring technique with an image editing software (Adobe Photoshop CS4 Extended, Adobe Systems Inc., Seattle, WA). “Adobe product screenshot(s) reprinted with permission from Adobe Systems Incorporated.”

Image Processing

The following digital procedures were applied to all examined radiographs. Image mode was set to grayscale and 8 Bits/Channel. Both the T₀ₒ and T₁ₒ panoramic radiographs were copied on a single .psd file and separated as two layers. The region of interest was then outlined on each radiograph using the crop tool. It was defined as follows: mesially, two neighboring teeth to the grafted sinus; distally, a vertical line passing 2 mm beyond the maxillary tuberosity; crestally, the occlusal plane of the neighboring teeth; apically, a horizontal line passing 1 cm above the grafted sinus floor (Fig. 1). The two layers were only then superposed and equalized to discard grayscale variation outside the region of interest. The superposition was done following the anterior and posterior sinus walls, the neighboring teeth, and the maxillary tuberosity (Fig. 2, a).

Measurements

Three horizontal lines were set on the T₀ₒ and T₁ₒ layers. The first two lines were set on layer T₀ₒ, one passing through the highest point of the CB and the other passing through the highest point of the augmented floor (AF₀) (Fig. 2, b). The third line was set on layer T₁ₒ, passing through the highest point of the actual augmented floor (AF₁) (Fig. 2, c). The T₀ₒ and T₁ₒ layers being superposed, measurement of the distance in pixels between CB and AF₀ (AF₀d) and CB and AF₁ (AF₁d) were taken with the ruler tool (Fig. 2, d). The ratio AF₁d/AF₀d was then calculated for each SFE case. A ratio value less than 1.0 indicates that the grafted sinus floor is more cervically positioned at T₁ₒ than at T₀ₒ, and that the graft

Fig. 1. Region of interest (ROI) definition.

Fig. 2. (A) T₀ₒ and T₁ₒ layers superimposed. (B) Crestal bone (CB) and AF₀ set on layer T₀ₒ. (C) AF₁ set on layer T₁ₒ. (D) Measurements (in pixels) of AF₀d and AF₁d with the ruler tool. AF, augmented floor.
shrank during this period. The graft shrinkage percentage was obtained by multiplying the ratio by 100.

**RESULTS**

Eleven SFE procedures were conducted in eight patients. A total of 19 rough-surfaced implants (17 with a SLA surface and 2 with a SLActive surface) were placed in 10 sinuses. Of those 19 implants, 17 implants were placed in distally shortened arches, and 2 implants in single tooth gaps. Four implants were rehabilitated with single crowns, 13 implants were rehabilitated with splinted crowns, and 1 implant was rehabilitated with a tooth-to-implant fixed partial denture. Implant length was 10 mm in all the cases (Table 1).

**Complications and Morbidity**

During the SFE procedures, no macroscopic perforation of the sinus membrane was noted in any of the cases. Two postoperative wound infections occurred after the augmentation procedures. In the first case, painful swelling of the posterior maxillary area appeared 7 weeks after augmentation and was treated with Clindamycin (Dalacin C; Pfizer SA) at 300 mg three times a day for 5 days and local irrigation with 3% hydrogen peroxide (\( \text{H}_2\text{O}_2 \)). Nonetheless, residual swelling remained for 6 months with no painful symptomatology. During surgical reentry, a macroscopic perforation surrounded by granulation tissue was noted and reaugmentation was conducted. Implant insertion took place 8 months later. Consequently, this case was excluded from the study. In the second case, the patient also complained of painful swelling at the surgical area 3 weeks after sinus augmentation. The infectious incident was treated with clindamycin (Dalacin C; Pfizer SA) at 300 mg three times a day for 5 days and local irrigation with 3% hydrogen peroxide (\( \text{H}_2\text{O}_2 \)). The infection being successfully treated, two implants were placed 10 months later. Radiographic control 4 months after implant placement revealed that one of the implants (site 26) had migrated apically. Reentry was conducted for the removal of the failed implant. No implant replacement was scheduled, and a tooth-to-implant fixed partial denture was made.

**DISCUSSION**

Various radiographic methods were used to assess the position of the maxillary sinus floor. Most authors used panoramic radiographs,\textsuperscript{15,18,19,21–26} Tomographic Scanora,\textsuperscript{18} magnetic resonance imaging,\textsuperscript{29,30} and computed tomography (CT) scanning\textsuperscript{17,19,20,22} were also used. Studying graft sinus height in three dimensions can be carried out with a CT scan or cone beam CT.\textsuperscript{1,24} However, some authors state that this is a more expensive radiographic technique that considerably increases the level of radiation for the patient.\textsuperscript{24}

**Table 1. Patient/Implant Characteristics and Type of Received FPDs**

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Teeth numbering according to the World Health Organization (WHO) site classification.

FPDs indicates fixed partial dentures; i, single crown; i-i, splinted crowns; i-t, implant-to-tooth supported fixed partial denture; RN, regular neck; RC, Regular CrossFit; WN, wide neck.

Radiographic Analysis

The mean graft height shrinkage percentage at 12 months (range, 11.3–13.3 months) after surgery was 8.84% (±5.32) (Table 2).
The dose given to patients with a CT scan is evaluated as approximately 150 to 300 times that of a panoramic radiograph.28,29 On the other hand, panoramic radiographs can be used for bone height measurements but do not allow for volume measurements.23 Consequently, bone height measurement with panoramic radiographs has been conducted in this study to evaluate graft height shrinkage. This technique seemed sufficient because no three-dimensional volume evaluation was sought.

In a study,25 the authors reviewed different published data27–29 and calculated the corresponding shrinkage percentages of several graft types. A shrinkage percentage of 48% was noted during the first 6 months when autogenous bone was used for maxillary SFE.17 Other authors evaluated autogenous bone graft shrinkage and noted a value of 28.95% (27.8% near implant and 30.1% between implants)23 and 18.2% (13% above and 23.4% between implants).25 Another study noted a 7% initial vertical shrinkage during the first year after grafting and before implant placement.30 Bone substitutes shrinkage percentages were also the subject of some studies.1,19,23,25 A radiographic and histomorphometric study was conducted to evaluate various SFE procedures and grafting.19 Results showed that bone substitutes (bovine hydroxyapatite, HA, and beta-TCP) presented shrinkage percentages of 6.19% (range, 4.6%–7.7%). Other authors estimated a graft height reduction of 3.25% for bovine xenograft (6.5% between and 0% above implants).25 A study evaluated the shrinkage of an allograft over a period of 6 months and noted a percentage of 8.49% ± 6.77%.1 Another study noted a shrinkage percentage of 39.55% for bone substitutes (38.9% near implant and 40.2% between implants).25 In two different studies aiming at evaluating the radiographic dimensional changes of the bone graft in maxillary sinuses augmented with autogenous bone and bovine HA in a 20:80 mixture, the authors estimated the shrinkage percentage as less than 10%18 and of 9.4 (6.1% above and 12.7% between the implants).25 In this study, our main objective was to determine the height shrinkage percentage of 100% NanoBone alloplastic graft used for maxillary SFE. Our results show that the estimated mean graft height shrinkage percentage (8.84% ± 5.32) corresponds to the values cited in the literature. Thus, the material seems to maintain its volume in the first critical year of bone remodeling.

Implant survival rates similar to the results in this study have been reported in the literature when rough-surfaced implants are placed after staged SFE procedures.3,4,32–34 A review aimed to evaluate implant survival rates in the grafted sinus versus survival rates of implants placed in the nongrafted posterior maxilla.32 Results showed that the survival rate of implants placed in sinuses augmented with the lateral window technique varied between 61.7% and 100%, with an average survival rate of 91.8%. Rough-surfaced implants showed a higher survival rate than machine-surfaced implants when placed in grafted sinuses. In another review,33 the authors evaluated implant survival rates in the grafted sinus taking into account the influence of the implant surface, graft material, and implant placement timing. Results showed that machine-surfaced implants placed in the grafted maxillary sinus displayed a mean survival rate of 85.64% and rough-surfaced implants exhibited a mean survival rate of 95.98%.34 Another review stated that, independently of the graft material used for lateral SFE, a mean survival rate of 86.3% was noted for machine-surfaced implants compared with 96.7% for rough-surfaced implants.3 One of the reasons for apical implant migration is perforation of the Schneiderian membrane during implant bed preparation.24 Thus, in this study, implant apical migration and its subsequent failure

### Table 2. Radiographic Measurements and Graft Shrinkage Percentages

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<th>Patient</th>
<th>Sinus</th>
<th>$T_{00}$–$T_{15}$ (Months)</th>
<th>$AF_{00}$ (Pixels)</th>
<th>$AF_{15}$ (Pixels)</th>
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Mean ± SD: 11.94 ± 0.57

*Refer to the text.
AF indicates augmented floor; GH, graft height.

### Table 3. Life-Table of Implant Survival Rates and Cumulative Survival Rates

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<th>Time</th>
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<th>CSR (%)</th>
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<td>100</td>
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SR indicates survival rate; CSR, cumulative survival rate.
could be explained by an extended implant bed preparation beyond the augmented sinus floor. Consequently, the implant survival rate (94.74%) obtained in this study is consistent with published results reported for rough-surfaced implants placed in grafted sinuses. Furthermore, it can be concluded that NanoBone in a 100% ratio could provide a viable augmented bone volume for implant placement with a short-term survival rate in accordance with published data.

CONCLUSIONS

This 1-year prospective study indicates that a 100% NanoBone alloplastic graft used in lateral SFE procedures presented limited height shrinkage. Transmucosal Straumann implants with a SLA or SLActive surface placed in these grafted sinuses showed survival rates similar to those found in published data. These results should be interpreted cautiously considering the study’s reduced sample size.

DISCLOSURE

The authors claim to have no financial interests, either directly or indirectly, in the products or information listed in the article.

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REFERENCES


