Maxillary sinus floor augmentation using a nano-crystalline hydroxyapatite silica gel

A prospective study—Histological results after 3 months of healing

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_**Clinically, posterior maxilla** often represents a hardly suitable zone for implant placement due to insufficient available bone. Sinus floor elevation was developed to increase needed vertical height to overcome this problem (Wallace & Froum 2003, Del Fabbro et al 2004). Variable augmentation materials and techniques using various bone grafts and bone substitutes were frequently used to enable placement of posterior maxillary dental implants (Maiorana et al.2000, Karabuda et al. 2001, Cammack et al. 2005).

A newly developed bone grafting substitute consisted of nanocrystalline hydroxyapatite (HA) and nanostructured silica (SiO_2) (Nanobone, Artoss, Rostock, Germany) is now available for clinical application. It was described to be osteoconductive and biodegradable in a comparable manner to natural bone remodeling process (Henkel et al. 2004). Furthermore, clinical investigation demonstrated that Nanobone has osteoconductive and biomimetic properties and is integrated into the host physiological bone turnover at a very early stage (Gotz et al 2008). Canullo & Dellavia (2009), in a recent clinical trial, showed that grafting of maxillary sinus floor using a nano-structured hydroxyapatite silica gel as bone filler is a reliable procedure in critical anatomical conditions after early healing period.

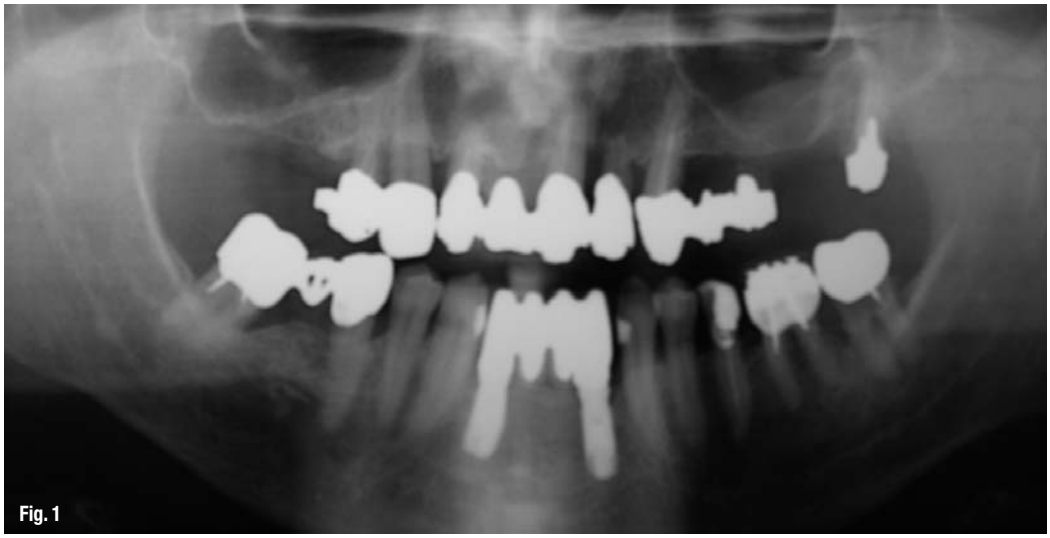
The aim of this prospective study was to evaluate tissue composition of augmented maxillary sinus floor 3 months after using of a nano-crystalline hydroxyapatite bone substitute. Histological analysis and bone-to-implant contact (BIC) assessment between the grafting material and inserted mini-implant were achieved.

_Materials and methods

Patient selection

All procedures and materials in the present prospective study were approved by the local ethical committee, and all patients provided informed consent. Five patients (2 men and 3 women) in need for fixed implant-supported prosthesis in the posterior maxillae were consecutively recruited for the present study. The patients were in good general

Fig. 1_ Preoperative panoramic exam.



health and had a median age of 54 years that ranged from 43 to 72 years. All patients underwent comprehensive dental care and were instructed to maintain a high level of oral hygiene. In the present study, inclusion criteria that had to be fulfilled by all patients are listed in Table 1. Preoperatively, computerized tomography and digital panoramic examinations were acquired for antral anatomy evaluation (Fig. 1).

Surgical procedure

Patients received 875 mg of amoxicillin/clavulanic acid (1 capsule/12h) one day before the surgery and for six days. After local anesthesia, crestal incision was made at the implant site and sulcular at the adjacent teeth if present. Subsequently, a vertical releasing incision was done at the distally and the muco-periosteal flap was raised. A rectangular or oval-shaped osteotomy was then prepared on the lateral aspect of the alveolar ridge under copious normal saline irrigation. The resulted detached "window" was elevated medially and apically while simultaneously reflecting the sinus membrane.

After adequate reflection, the sinus membrane was inspected for tears and Nanobone mixed with antibiotic solution (Lincocin 600 mg, Pharmacia Italia S.p.a., Milano, Italy) was placed incrementally at the superior aspect of the sinus and against the medial aspect of the grafted compartment created in the sinus cavity, according to Donath & Breuner (1982). The graft material was meticulously condensed at each stage (Fig. 2). A mini screw for osteosynthesis of 1.2 mm diameter and 13 mm in length (Sweden & Martina, Padua, Italy) was then positioned to maintain the space opened. This implant in fact kept the internally rotated sinus bone door con-

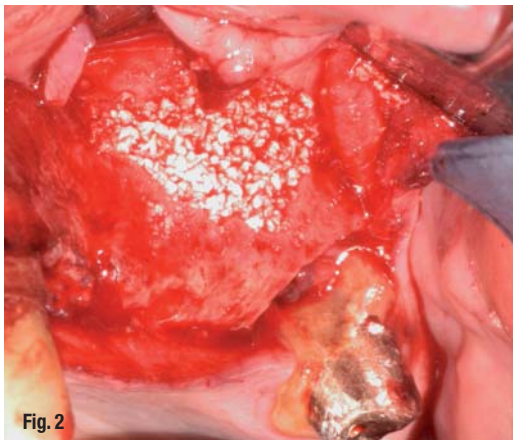


Fig. 2

Fig. 2_ Sinus lift grafted using nano-cristallyne hydroxyapatite silica gel (Nanobone®): buccal view.

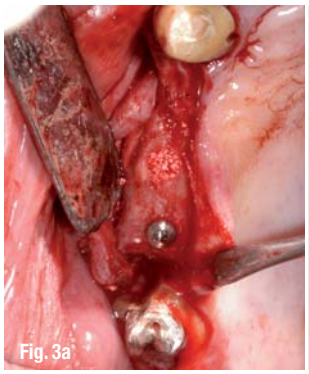


Fig. 3a

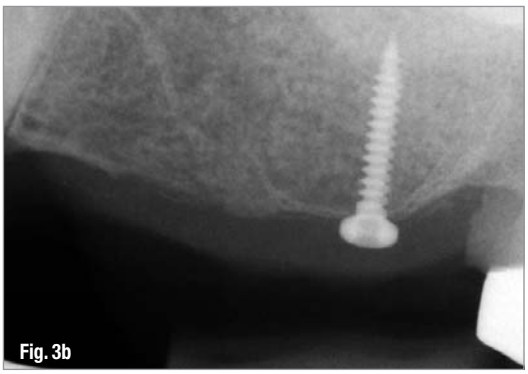


Fig. 3b

Fig. 3a_ Micro-screw inserted at the end of sinus lifting procedure (clinical occlusal view).
Fig. 3b_ Micro-screw kept the internally rotated sinus bone door constantly apart from sinus floor, contrasting eventual increased pressure in the operated sinus.

stantly apart from sinus floor, contrasting eventual increased pressure in the operated sinus (Fig. 3a and 3b). Single interrupted sutures were finally used for flap adaptation. Surgical procedure was applied unilaterally for each patient of this study.

The surface of used mini screw was treated first by cleaning process that was carried out using a solution of isopropylic alcohol and metilbutil-ethers. Then, sandblasting was performed with zirconium microspheres that sized 120 microns at 5 atms while applying a rotation impulse of 120° each 5 seconds. Sand was constantly set with a patented fluid vibrating process to control humidity (ZirTi Surface, Sweden & Martina).

Second surgery and prosthetic restoration

After a 3 month healing period (Fig 4a and 4b), a bioptical core containing the mini-implant was retrieved using a 3 mm trephine bur. In the same surgical step, implants were inserted. After 3 months of submerged healing, implants were restored.

Histological assessments

Samples were immediately immersed in buffered 4%-paraformaldehyde fixative solution with a pH of 7.7 for 5 days. The bone specimens were processed and undecalcified for histological analysis according to previous protocol.[11] Sliced longitudinal sections were then stained with toluidine blue/pyronine G and observed using a light microscope (Nikon Eclipse E600, Nikon, Tokyo, Japan) equipped with a calibrated digital camera (DXM1200, Nikon). At 40x microscopic magnification, using a standard point-counting technique with a 100 test points grid, histomorphometric measurements of the tissue fractions occupied by, Nanobone, regenerated bone, and bone marrow were performed. Additionally, BIC was computed as the percentage ratio between the implant length distances in direct contact with newly mineralized bone and the implant total length.

_Results

After 3 months of healing, varying amounts of newly formed bone were found through the specimens (Fig. 5). From the histomorphometric analysis, Nanobone residuals accounted for 47.35 % ± 5.20 % of the extracted bone volume, marrow spaces presented 19.30 % ± 3.20 % and bone occupied 33.35 % ± 4.1 % (new bone: 22.23 % ± 4.10 %, and native bone: 11.12 % ± 4.20 %). Well-mineralized regenerated bone with lamellar parallel-fibred structure and Haversian systems surrounded the residual Nanobone particles. Mean BIC was 17.75 % ± 2.9 %. No connective tissue was observed at the implant boundary surface (Fig. 6).

_Discussion

The result of this study indicated that Nanobone could be suitable for maxillary sinus floor augmentation as it proved osteogenic behavior, i.e. bone regeneration, at very early healing stage in critical vertical bone height conditions. This was demonstrated by histological and histomorphometric analyses carried out in the present study, in addition to immunohistochemical, SEM, and energy-dispersive X-ray analyses performed in other basic studies.[4, 10, 11]

According to Wallace Froum (2003) and Del Fabbro et al. (2004), 6 to 9 months were considered the optimal period for bone graft healing as the osteogenetic process was considered completed thereafter. However, the present investigation results showed that Nanobone presented a fast turnover compared to other biomaterials (Valentini et al. 2000, Tarnow et al. 2000). This might be correlated to the SiO_2 gel matrix of the material that is degraded and substituted by an or-

Fig. 4a_ Panoramic X-ray of the patient in Figure 1 after 3 months of augmentation.
Fig. 4b_ Clinically, buccal window appears filled of bone-like material.

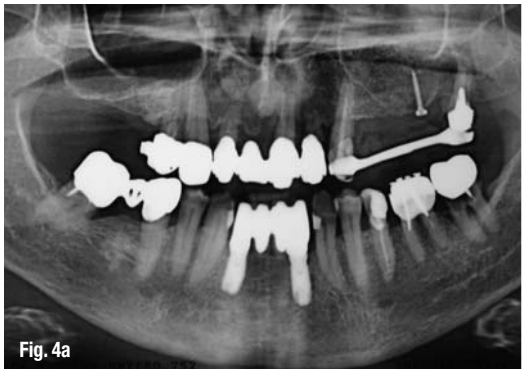


Fig. 4a

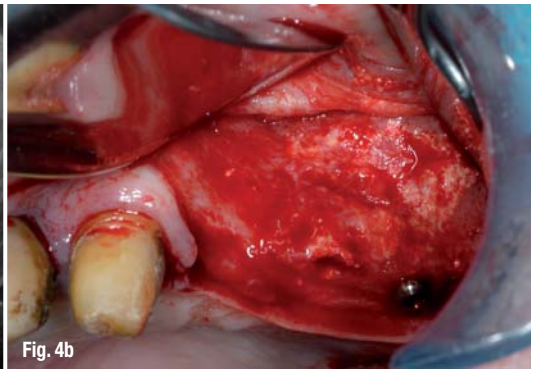


Fig. 4b

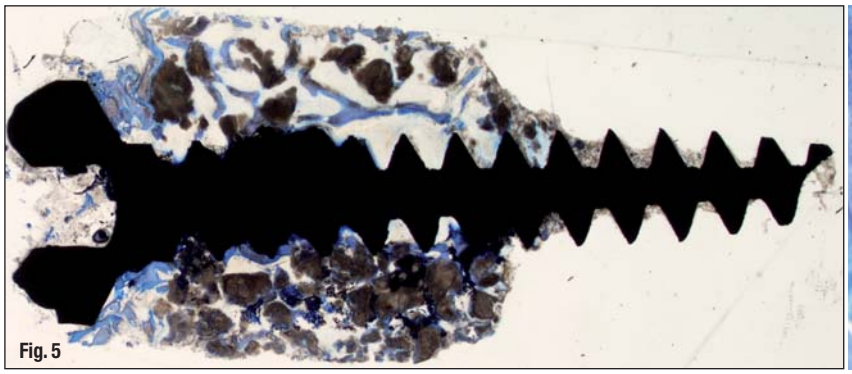


Fig. 5

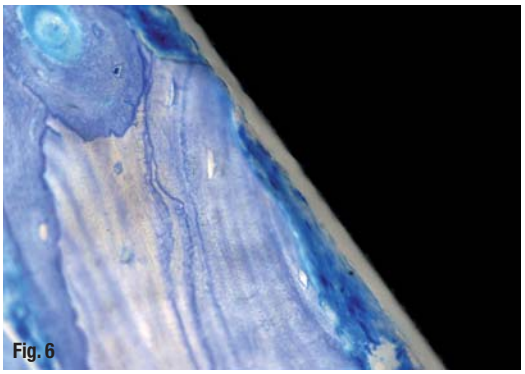


Fig. 6

ganic matrix and to the hydroxyapatite nanoporosity which would allow bone matrix proteins to adhere and promote differentiation of osteoblast precursor cells.[4, 10, 11]

As Literature[6, 8, 18] indicates that in case of severely resorbed maxilla required healing time should be between 6 to 12 months, demonstrated early healing and bone regeneration using Nanobone should encourage longer follow-up and further animal and clinical investigations concerning early implant loading.

Regarding the used mini-implant surface (ZirTi Surface, Sweden & Martina) used in this study, the resulted mean BIC of 17.75 % was comparable to those in a canine model by Conner et al. In that study, mean BIC values were reported as16.24 % for acid etched surfaces and 25.08 % for TPS after a 4-month healing period. Another animal study (Palma et al. 2006) reported mean BIC values of 14.3 to 17.6 % for turned implants and 37.3 to 44.7 % for oxidized implants after a 6-month healing period. Although it is hard to compare animal to clinical studies, the BIC values reported in the present and the quantity of new bone found at 3 months of healing could clinically assess the potential of this grafting biomaterial even in very early stages of bone maturation.

According to Literature (Becker et al. 1995, Buser et al. 1996, Tarnow et al. 2000, Wallace & Froum 2003), the use of collagen barrier membrane to enhance bone regeneration in maxillary sinus augmentation to prevent soft tissues invasion was highly recommended. However in the present investigation, the absence of barrier membrane application to occlude buccal bone wall did not influence healing as histological outcomes of bone formation and absence of connective tissue were observed at the mini-implant boundaries (Fig. 6).

Finally, presented preliminary results encourage further research on this biomaterial in augmenting critical vertical bone conditions and immediate or early implant loading for a longer follow-up period and wider patient size.

_Conclusion

Within the limits of this clinical prospective study, it can be concluded that nano-crystalline hydroxyapatite bone substitute showed good histological outcomes for augmenting maxillary sinus floor in critical bone volume conditions. Furthermore, the absence of covering membrane and 3-month healing period could clinically demonstrate the potential of this grafting biomaterial. In such a critical condition the use of a rough-surfaced mini-implant showed BIC values supposed to be effective also in case of functional loading._

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A literature list can be requested from the editorial office.

Fig. 5_ Specimen stained with toluidine blue/pyronine G. Overview of the mini-implant positioned in sinus lift grafted with Nanobone. Total Magnification: 10x.

Fig. 6_ Specimen stained with toluidine blue/pyronine G. Regenerated bone (B) incorporating a Nanobone fragment (N) and a newly formed osteon in contact with the implant surface (I). Total Magnification: 200x.

Table 1 Subject and study site inclusion and exclusion criteria

Subject inclusion criteria:
_ Need for fixed implant-supported prosthesis in the posterior maxillae
_ Age > 18 years
_ No relevant Medical conditions
_ Non-smoking or smoking⩽10 cigarettes/day (all pipe or cigar smokers were excluded)
_ Full Mouth Plaque Score and Full Mouth Bleeding Score ⩽ 25 %

Study site inclusion criteria
_ Presence of native bone height of 1–3 mm in the sinus zone

Specific subject and site exclusion criteria:
_ Schneiderian membrane acute infections or chronic sinusitis
_ Allergies involving respiratory system
_ Patients with a history of Bisphophonate therap

_contact implants

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