All information provided by the manufacturer.

Application of a Nano-Crystalline Hydroxy Apatite Used for Bone Replacement

Local defects of the alveolar bone after tooth loss make the prosthetic and implant/prosthetic reconstruction difficult because of unfavorable conditions due to reduced width and height of the alveolar bone for a conventional prosthetic reconstruction, and because of not having an adequate implant bed for an endosseous implant.

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Augmentation procedures are firmly established in modern implantology. To use the patient's own bone has turned out to be the most favorable. The bone is harvested from an intra- or extraoral area, depending on the amount that is needed, and then transplanted and fixated in the desired site. Besides autogenous bone whose intraoral availability is limited and because of potential increased morbidity of the intra- or extraoral donor site[1–4], there is a growing use of xenogenous[5,6] or in rarer cases homologous bone replacement materials, as well as algae based or synthetic materials based on hydroxy apatite (HA) or tricalcium phosphate (TCP)[7] during the procedure of membrane guided bone regeneration (GBR). Until now the application of an alternative material for bone replacement made of nano-crystalline HA was documented in cases of traumatology and filling of bone defects after cyst surgery.[8,9]
Nano-crystalline HA is made synthetically. For clinical use it is available as a paste and is therefore easily applied. The size of the crystallite (18 nm) is very small in comparison to the micro-crystalloid HA. In clinical application in traumatology and filling of bone defects after cyst surgery the process of transformation by osteoclasts, macrophages, and giant cells was noted to be comparably fast. The incorporation into vital bone structure occurs after a period of approximately 3 to 6 months[8,9].
In a case presentation the use of nano-crystalline HA is demonstrated during a sinus lift and augmentation procedure.

Case Presentation

Clinical History

A 42-year-old patient presented with a missing tooth 15 (upper right 2nd bicuspid). The adjacent teeth[14,16] were crowned and part of a 3 unit bridge to replace the missing 15. The tooth 14 (UR 1st bic.) showed advanced periodontal breakdown and was not saved. The tooth 13 (UR cuspid) was principally healthy. The alveolar bone in the area of the missing 15 showed vertical atrophy. The distance between the sinus floor and the alveolar ridge was 5 mm. The plan was to extract 14 and to place an immediate implant. At the same session of placing the implant for tooth 15 a simultaneous sinus lift and augmentation was to be made. The general health history showed no obvious problems. In the diagnosis there was no evidence of previously occurring sinus infections. The patient was a non-smoker. The diagnosis was made using a panoramic X ray (Fig.1) as well as transverse tomograms of the area 14 and 15 (Fig. 2). There was no evidence of anything pathological in the right maxillary sinus.

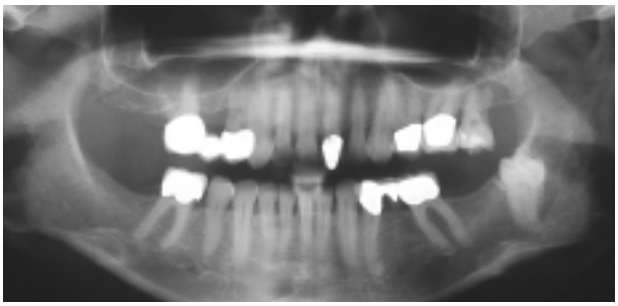

FIGURE 1 *Panoramic tomogram before planning of implantation 14 and 15 and after extraction of 14.*

After cutting the bridge, removing the pontic of 15 and extracting 14 the empty alveolus was cleaned with a curette. Then the surgery site was exposed by making a supracrestal incision and creating a full thickness flap. Using the modified Tatum procedure (Fig. 3) the window to the sinus was created. After freeing the Schneiderian membrane the recipient site for the implant in the area of 14 and 15 was prepared step by step up to a diameter of 3.8 mm to hold 2 Camlog cylindrical screw shaped (external hex) implants of 11 mm length (Camlog®, Altatec, Wurmberg, Germany). After the augmentation of the medial part of the maxillary sinus below the Schneiderian membrane with a paste formed of nano-crystalline HA (Ostim, Heraeus Kulzer, Hanau, Germany) the 2 implants were placed (Fig. 4) and sealing screw caps were put in place. Then autogenous bone (BoneTrap, AstraTech, Mölndal, Sweden) was placed over the implant surfaces and the vestibular surfaces of the defect were filled up with Ostim (Figs. 5 and 6).
It was necessary to mobilize the full thickness flap because of the lateral augmentation. The augmented area was then covered on the vestibular side using a collagen membrane (Bio-Gide, Geistlich Biomaterials, Wolhusen, Switzerland) and then the flap was sutured tension-free.
Pre-op the patient was taking antibiotics (Clindamycin, initially 600 mg orally pre-op, then 300 mg every 8 hrs. for a period of 5 days). The x-ray taken 5 days post-op (Fig. 7) shows a slightly radio-opaque material around the implants on the sinus floor. The next day, the patient presented

with a definite extraoral swelling and a hematoma. The general condition was excellent. 9 days later the sutures were removed. The swelling and the hematoma were completely gone.
6 months later, the 2nd surgery took place with local anesthesia to expose the implants. During that time no problems or symptoms had occurred. Clinically there were no signs of a maxillary sinusitis. On the x-ray the bone replacement material on the sinus floor showed a distinct increase of opaqueness (Fig. 8), it showed structures similar to cancellous bone. After a crestal incision on top of the implant screw caps the mucosa was spread apart . The implants were firmly anchored in the bone up to the implant shoulders. There was no dull thud on a percussion test. The patient accepted to have a tissue sample taken from the vestibular area of the facial wall of the maxillary sinus that was augmented with Ostim paracrestally during the same surgery session. So a sample of 3mm diameter and 4 mm depth was taken and prepared histologically. During the surgery to expose the implants a gingiva former was used. The surgery site healed without any complications and 14 days later the prosthetics was done.

Histology

The tissue sample was stored for 3 days in 4 % buffered formalin, then dehydrated and then embedded in Technovit 9100 (Heraeus Kulzer, Bensheim, Germany) and cut into slices of 60–80 nm thickness with a diamond saw (Leitz 1600, Leitz-Leica, Wetzlar, Germany) under permanent water cooling and stained with a surface stain (Giemsa).
The histomorphological examination was done on a light microscope, magnification 4 x to 20 x , Leitz Orthoplan (Leitz Leica, Wetzlar, Germany).
Figures 9 and 10 show cut out details from the center of the drill core. Osteoblasts adjacent to the bone can be seen clearly next to bone replacement material, which is surrounded by small forming lamellas of undifferentiated bone that is only slightly structured. There are no signs of inflammation on the samples.

Discussion

Implantations in the posterior areas of the maxilla often demand an augmentation of the alveolar bone because usually there is very little bone underneath the the maxillary sinus. The procedure of a sinus lift with augmentation with the use of autogenous bone and even bone replacement materials has been proven to be reliable. This technique is clinically acknowledged and well confirmed by scientific research.[11–17]
In this case presentation the successful implantation and simultaneous sinus lift and augmentation was documented together with the use of autogenous bone in combination with nano-crystalline HA. 6 months after the implantation the x-ray showed osseointegration of the implants as well as a successful augmentation of the sinus floor. At the second surgery when the implants were exposed they clinically presented as stable osseointegrated implants. There was a solid osseous implant bed after lateral augmentation and a stable condition of the soft tissue around the implants. A histological sample was taken from the lateral augmentation area. 6 months after the application of nano-crystalline HA in combination with autogenous bone the histological results indicated an increasing incorporation of the augmentation material into the patient's own bone. There were also areas with augmentation material that were not yet remodeled and that were separated from the bone-structured material. Along the areas with lamella-shaped bone they found conglomerates of osteoblasts and osteoid that were right next to the bone replacement material, so an assumption could be made that

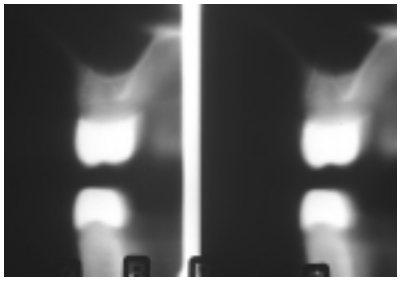
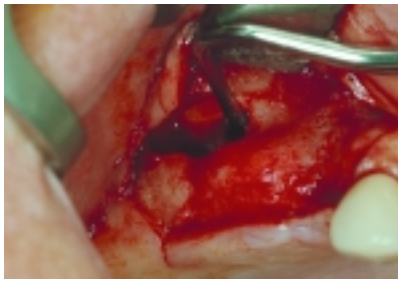
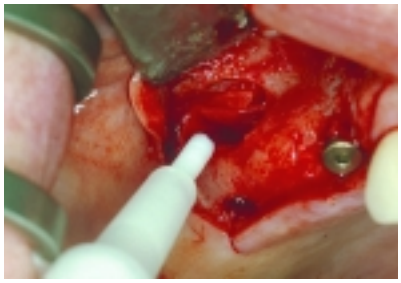

FIGURE 2 *Transverse tomogram of area 14 and 15 and view of alveolar bone.* – **FIGURE 3** *Condition after extraction of 14. Incision and view of surgical site. The upper osseous cover was positioned cranially.* – **FIGURE 4** *Preparation is finished, there is an implant in situ (14). Application of the Ostim bone replacement material in paste form using a syringe to fill up the medial part of the sinus floor that is to be augmented.*

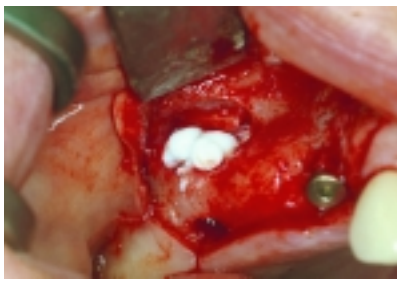
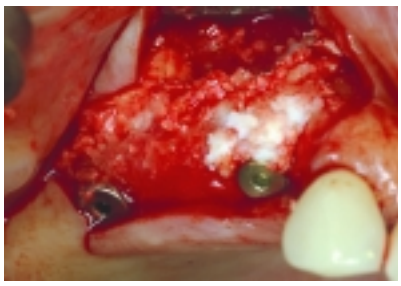
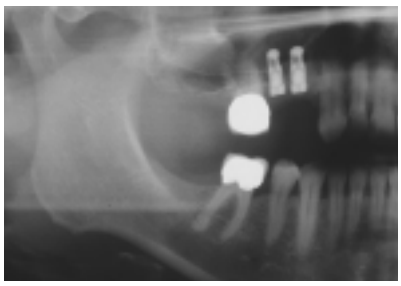

FIGURE 5 *Both implants in situ. The vestibular part of the bone defect is augmented with Ostim.* – **FIGURE 6** *Situation after termination of positioning the augmentation material during the SBEA procedure and after the lateral augmentation.* – **FIGURE 7** *Panoramic tomogram immediately post-op (detail).*

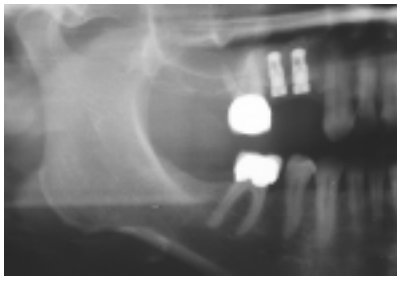
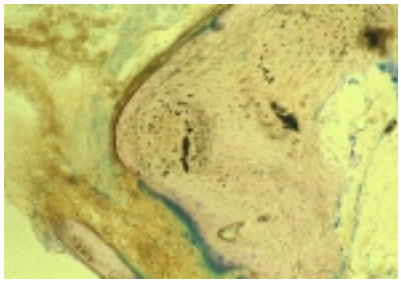
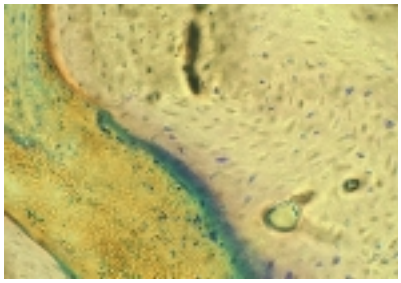

FIGURE 8 *Panoramic tomogram before the second surgery (exposure).* – **FIGURE 9** *Magnified detail from the center of the drill core (Giemsa, magnification 20 x). Still little differentiated bone tissue, in between augmentation material. No evidence of granulocytes or macrophages being present.* – **FIGURE 10** *Magnified detail from Fig. 9. Front of osteoblasts adjacent to bone replacement material, in which some scattered osteoblasts and fibroblasts can be seen.*

a process of bone development was taking place. The bone replacement material seems to have an osteoconductive effect. There were no histological signs of any inflammations. It seems obvious that after 6 months the nano-crystalline HA had not yet been fully resorbed and the bone was not yet fully replaced. Similar results were found with xenogenous HA in a form of deproteinized bovine cancellous bone with different particle sizes. Yet here you could still find some bone replacement material after 4 years.[18]
The stability of the augmentation material height on the sinus floor is yet to be determined. After the combined application of autogenous bone and HA there were no significant changes documented in any dimension after a period of 1 year.[19] Even after 3 years the combination of autogenous and alloplastic bone replacement material proved to be relatively stable (reduction of 0.8 mm in augmentation height) in comparison with total alloplastic material (reduction of 0.9 mm). Yet the difference was not very significant. Since the percentage of autogenous bone was rather small, it can be assumed that there is only a very slight reduction in augmentation height.
It could be demonstrated that the Ostim bone replacement material can be easily applied and is integrated into the bone during a sinus lift and augmentation procedure and lateral augmentations. It has been proven reliable in these techniques.

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