Porous Titanium Granules Used as Osteoconductive Material for Sinus Floor Augmentation: A Clinical Pilot Study

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ABSTRACT

Background: Resorption of grafting material may lead to unpredictable long-term results when rehabilitating the resorbed posterior maxilla. Nonresorbable, osteoconductive bone substitutes may therefore be an advantage over autogenous bone grafts.

Purpose: The aim of the present pilot study was to test titanium granules as bone substitute in patients planned for augmentation of the sinus floor prior to or in conjunction with placement of dental implants.

Materials and Methods: Sixteen patients with uni- or bilateral edentulism and need for augmentation of the sinus floor were included in the study. Residual bone height was 2 to 5 mm. Grafting and installation of the dental implants (18 fixtures) was carried out in the same session if primary stability of the implants could be achieved (12 patients). A staged protocol with implant placement 3 to 7 months after the augmentation procedure was used when primary implant stability was impossible to achieve (four patients). In all, 23 TiOblast™ (Astra Tech AB, Mölndal, Sweden) implants were installed.

Results: The patients have been followed 12 to 36 months after prosthetic loading. Three implants were found mobile and were removed (13.0%). Two of these were in patients where grafting and implant installation were carried out in separate procedures. The implants were found mobile at abutment connection and were removed. One patient in the single-stage group had a postoperative sinus infection, which was successfully treated with antibiotics. However, one out of two implants in this patient was found mobile and was removed after 1 year in function.

Conclusions: In the present study, titanium granules seem to function as augmentation material in the sinus floor. It is, however, not clear if the material can be safely used for two-stage procedures. Further investigations with longer healing time before implant installation are required. Also, the possible risk of granule displacement during preparation of the fixture site should be further investigated. Additionally, biopsies from patients are requested to confirm any bone ingrowth between the granules.

KEY WORDS: clinical study, dental implant, maxillary sinus floor augmentation

Insufficient bone volume in the posterior maxilla has been a challenge for the implant team ever since dental implantology has become a routine clinical method. A correlation between increased failure rate and short implants has recently been shown in an article on 588 ITI implants installed in the posterior maxilla. An implant length of 12 mm showed a survival rate of 93.4%, while a length of 8 mm showed a survival rate of 88.9%.[1] Loss of teeth and the subsequent resorption of the alveolar crest is a well-known problem, and augmentation of the sinus floor in conjunction with implant placement is nowadays a standard procedure when dealing with atrophy of the alveolar process in the posterior parts of the maxilla.[2] The procedure can be carried out as a one- or two-stage procedure.

In the two-stage procedure, the augmentation is usually carried out 4 to 9 months before the fixture

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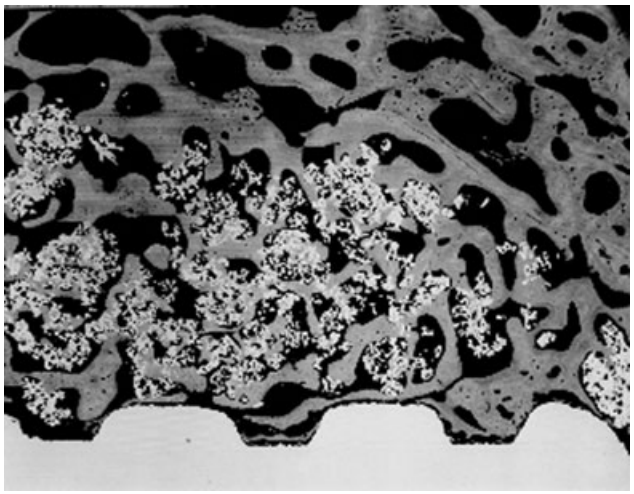

Figure 1 Bone formation in and around titanium granules. Scanning electron micrograph of cross section showing new bone in direct contact with the prostheses.[3]

installation, and in one-stage procedures, the fixture installation is made in the same operation as the augmentation.

Grafting with autogenous bone has been a gold standard due to lack of immunological rejection mechanisms and its osteoinductive and osteoconductive properties. One drawback using autogenous bone is that the harvesting procedure requires additional surgery at the donor site, which may lead to postoperative morbidity.

Therefore, bone substitutes have been used to avoid the graft-harvesting operation. Most of the bone substitutes used today are based on hydroxyapatite (HA), such as bovine HA or synthetically produced HA. They are all more or less resorbable material, although resorbing very slowly. A material that is absolutely resistant to resorption and also has good clotting properties has been awaited, especially for reconstruction of moderately large and large defects. Titanium granules (Natix™, Tigran Technologies AB, Malmö, Sweden) are materials that consist of irregular and porous granules of commercially pure titanium. When implanted, the granules theoretically could interlock with each other, creating an uninterrupted structure. The porous properties may lead to ingrowth of newly formed bone. The granules have been tested in orthopedic surgery for fixation of femoral stems, and the results have been very promising. Histology from both clinical and experimental studies have shown bone formation in and around the granules (Figure 1).[3,4]

The aim of the present pilot study was to assess the feasibility of Natix used as bone substitute together with a commercially available implant system in the resorbed posterior maxilla by evaluating implant survival rate and adverse events.

MATERIALS AND METHODS

Sixteen consecutive patients (11 women and 5 men), mean age 66 years (range 55–83 years), with atrophy of the maxillary alveolar process, diagnosed by panoramic and intraoral radiographs, were included in the study. The dental implants used were, in all cases, TiOblast™ (Astra Tech AB, Mölndal, Sweden). A total of 23 implants were installed. All sinuses had less than 6 mm (2–5 mm) subantral alveolar bone vertically. The augmentation material used was Natix c.p. titanium granules. These granules were 500–1,000 μm in diameter and were partly porous to permit ingrowth of newly formed bone (Figure 2). The amount of granules applied was 1 to 2 mL in each sinus, mixed with blood and saline (Figure 3). Four patients were treated in two separate operations, and 12 patients were treated in a one-stage procedure. The reason for choosing a two-stage procedure was, in all five cases, lack of initial implant stability. In the two-stage procedure, the augmentation was performed 3 to 7 months before implant installation.

The sinus area was prepared under local anesthesia (Xylocain Dental Adrenalin 20 mg/mL + 12.5 μg/mL, Dentsply Pharmaceutical, York, PA, USA). An incision was made on top of the alveolar crest with vertical releasing incisions. A mucoperiosteal flap was then reflected laterally to expose the lateral wall of the maxillary sinus, and a bony window was outlined with a round bur. The window was left attached to the sinus

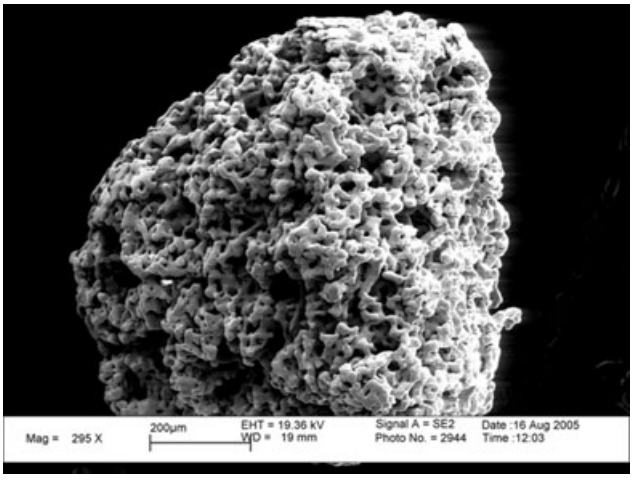

Figure 2 Natix titanium granule.

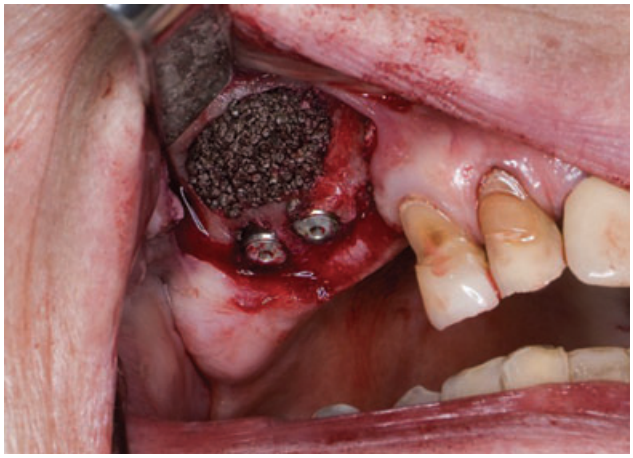

Figure 3 Natix packed around implants in the sinus (one-stage procedure).

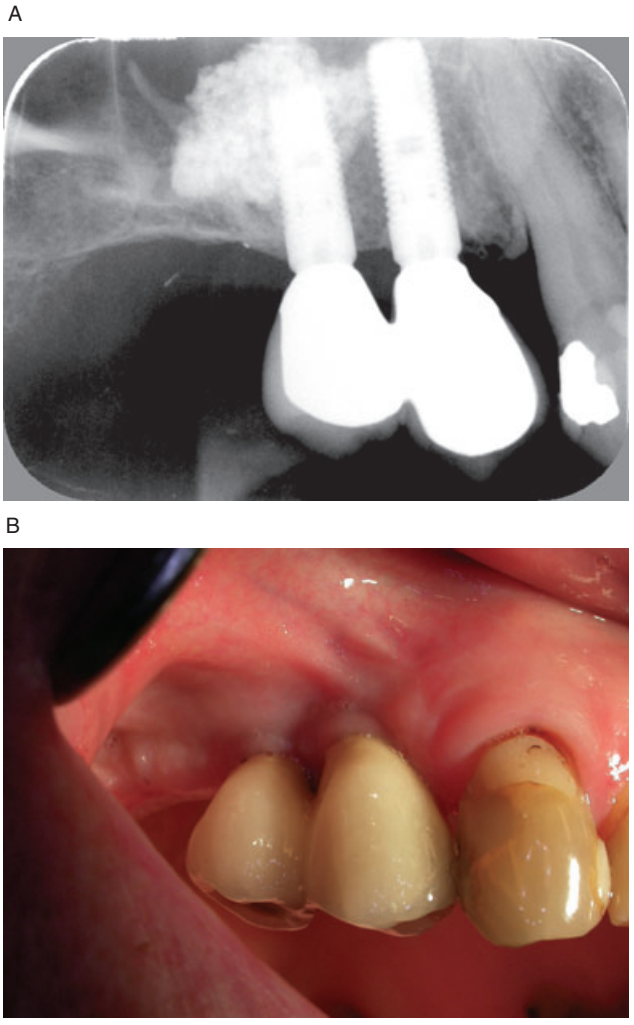

Figure 4 *A*, Radiograph of a case at baseline. *B*, Clinical photograph of the same case.

mucosa, which was carefully elevated from the floor of the sinus. Titanium granules were mixed with blood and physiological saline solution. The granules were then packed at the floor of the sinus using a standard angled elevator instrument. When the implant fixtures were installed in the same procedure, the granules were packed into the sinus before the fixtures were installed. The reason for this was to avoid the risk of destabilizing the fixtures during packing of the granules.

The patients were given 1 g V-penicillin (Kåvepenin, Astra, Södertälje, Sweden) 1 hour before the operation and then 1 g, three times per day for 7 days. The abutment operation was performed 6 months after implant installation.

The local ethic committee accepted the study (Dnr M141-04).

RESULTS

The 16 patients had in total 23 implants installed. Five of these, in four patients, were installed at a second surgery. The patients had their suprastructures in place and were loaded from 12 to 36 months when this evaluation was performed. Radiographs showed a radio opaque area around the implants. However, the expected dark coloring of the soft tissues was not seen (Figure 4, A and B). The postoperative radiographs showed no signs of migration of the granules.

Three implant fixtures out of 23 were lost, 13.0%. Two failures were in the two-stage group (Table 1). One postoperative infection (patient 15) occurred after the augmentation procedure. The infection was probably caused by a communication between the oral cavity and the maxillary sinus. The infection was successfully treated with metronidazol (Flagyl, Sanofi-Aventis AB, Bromma, Sweden) 400 mg × 3 for 10 days. No granules were found migrating out of the wound. However, one out of two implants in this patient was found mobile after 1 year in function.

DISCUSSION

This pilot study has shown that titanium granules seem to work well as bone graft substitute in the sinus lift procedure, also when the augmentation and fixture installation are made in the same procedure. The patients in this study had quite a severe atrophy of the residual bone in the posterior maxilla. It is known that the resorbed maxillary premolar and molar regions are the most difficult to rehabilitate with dental implants.

TABLE 1 Showing Disposition and Follow-Up of the 16 Cases

Patient	Residual Bone Height at Inclusion (mm)	Time of Operations I–II (months)	Operation II Loading (months)	Follow-Up after Loading (months)	No. of Fixtures	Lost Fixtures
1	3	3	7	36	2	
2	4		6	36	1	
3	3		5	35	2	
4	2	5	5		1	1
5	2	7	7	22	1	
6	3	5	9		1	1
7	4		6	24	1	
8	4		6	24	2	
9	3		5	25	1	
10	4		6	20	1	
11	5		4	22	1	
12	3		9	12	3	
13	5		5	18	2	
14	4		6	16	1	
15	2		7	12	2	1
16	3		6	12	1	
Total					23	3

Three implants were lost up to 36 months.

Therefore, the implant survival rate in this pilot study (87.0%) is low but acceptable. However, the material is small and the follow-up period short. Two lost implant fixtures were in the two-stage group, and one reason for the failures could be a too short healing period between the augmentation operation and the fixture installation. It has previously been shown that after 6 months, there are signs of new bone formation around bovine HA (BHA) particles. However, most of the newly formed bone was woven bone, and there were also loose connective tissues filling the space between the particles.[5] It is reasonable to believe that formation of new bone around the titanium granules used in this study takes at least as long as around BHA particles. Therefore, 6 months is probably too short a time period before fixture installation. Bone formation within and around the granules was seen in the study by Turner and colleagues,[4] but the granules were used in the femur in a dog model and were not comparable with the granules in the human sinus. In studies where autogenous bone grafts have been used for sinus augmentation, resorption rate of up to 55% during the first 6 months has been reported.[6,7] Extensive resorption of the grafting material makes the treatment results difficult to predict. However, findings in the literature indicate that autogenous bone grafts are superior to allogenic and alloplastic materials,[8] but then the problems with resorption of the graft have not been taken into consideration. It can therefore be an advantage to have a material such as Natix that is resistant to resorption and therefore would be able to maintain the graft volume. On the other hand, the fact that titanium granules do not resorb might be a negative mechanical factor because granules may prevent new bone from reaching the surface of the dental implant.

The study by Turner and colleagues[4] shows, however, that this does not seem to be the case. The titanium granules were very easy to handle during the grafting procedure, since they stuck together when mixed with blood or saline solution. The packing around the installed implants in the simultaneous cases was simple and predictable. A possible drawback with titanium granules could be anticipated in the two-stage approach since no preparation of the granules is likely to occur during the drilling procedure. One could instead expect that the granules will be displaced laterally/medially and superiorly if the bone healing around them is insufficient. There is consequently also a risk for high temperatures during the site preparation if the drills are not sufficiently cooled. Another drawback with the titanium granules if used for augmentation in the anterior

part of the mouth is the dark color which may give a dark shadow in the soft tissues. However, this was not seen in the present study when the granules were used for sinus augmentation.

The present study showed that titanium granules seem to function as augmentation material in the sinus floor. It is not clear if the material can be safely used for two-stage procedures, and the possible risk of displacement of the granules during preparation of the fixture site should be further investigated in, for example, animal models. Also, additional studies in humans are required. Biopsies from the grafted area would be beneficial to histologically verify expected bone growth in and around the granules at different healing periods.

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