Sinus Floor Augmentation with Bovine Hydroxyapatite Mixed with Fibrin Glue and Later Placement of Nonsubmerged Implants: A Retrospective Study in 50 Patients

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Purpose: *The aim of the present study was to evaluate retrospectively both the results of using a mixture of bovine hydroxyapatite (BHA) and fibrin glue as the only grafting material in the floor of the maxillary sinus and the outcome of nonsubmerged implants placed later.* ***Materials and Methods:*** *A total of 50 consecutive patients (71 maxillary sinuses) were augmented with a mixture of BHA and fibrin glue. The grafts were allowed to heal for a mean of 8 months prior to implant placement. A total of 218 solid titanium screw-type implants were placed in a nonsubmerged fashion and allowed to heal for a mean of 10 weeks before loading (range, 10 days to 10 months). The outcome of the placed dental implants was evaluated retrospectively.* ***Results:*** *Twelve implants were lost, giving a cumulative survival rate of 94.5% after a mean loading time of 20 months (range, 6 to 42 months).* ***Discussion:*** *This study shows that augmentation of the maxillary sinus with a BHA/fibrin glue mixture and later placement of nonsubmerged implants with short healing times preceding functional loading can be a predictable concept. However, the use of autogenous bone and placement of submerged implants in the grafts with long healing times is routine in many clinics. This article discusses the evidence on which this protocol is based.* ***Conclusion:*** *The short-term results from this retrospective clinical study indicated that BHA/fibrin glue can be used as a grafting material without autogenous bone in the maxillary sinus to produce a high survival rate for later placement of nonsubmerged implants.* INT J ORAL MAXILLOFAC IMPLANTS 2004;19:222–227

Key words: *bovine hydroxyapatite, dental implants, endosseous dental implantation, fibrin glue, maxillary sinus*

Bone resorption in the posterior maxilla can limit the possibility of placing implants that are long enough for stability to be ensured under loading forces. In some cases, bone augmentation procedures are a necessary prelude to implant placement. During the last decade, bovine hydroxyapatite (BHA) has been used as a grafting material in the maxillary sinus and has been evaluated in several clinical studies.[1–6] In most of the studies, various mixtures with other grafting materials, varying healing times, and various brands of implants have been used. Although the results have been impressive and predictable, often the numbers of placed implants and treatment are insufficient for statistical analyses. To date, no study of grafting of the maxillary sinus has been reported in which the same protocol, grafting materials, and brands of implants have been used in a patient sample as large as 50 individuals. In addition, there have been no studies using 100% BHA as a grafting material with later placement of nonsubmerged implants and short healing times before functional loading. Only a few studies using 100% BHA have been presented.[3,6,7] Moreover, the results from studies of different bone grafting techniques using machined screw-type implants have

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generally shown that the implant failure rate was higher[8–12] than that observed with standard treatment procedures.[13–15]

There is evidence from animal research that rougher implant surfaces result in more bone-implant contact than smoother surfaces.[16–18] A higher resistance to removal torque forces has also been demonstrated for rough implant surfaces, suggesting stronger fixation between rough implants and the bone tissue.[17,18] However, comparative clinical studies have demonstrated no statistically significant differences between titanium oxide grit–blasted and machined screw-type implants.[19] A number of follow-up studies of titanium plasma-sprayed (TPS) implants, both hollow-screw and solid-screw, have demonstrated survival rates that are similar to those for machined-surface, screw-type implants.[20–24] TPS cylinders have shown lower short-term failure rates but similarly high long-term failure rates as compared with the machined-surface implants.[21] The present lack of evidence for the clinical superiority of rough-surfaced implants, in spite of the data from animal studies, may be related to the fact that surface roughness is not as important in patients with high-quality bone. If there are other benefits to be gained from rough-surfaced implants, besides a reduction in healing time, this should be evident in clinically compromised bone situations; for instance, in situations where limited bone volume requires bone augmentation.

The use of BHA as a grafting material can be beneficial for patients because no donor site is needed. Also, the use of nonsubmerged implants will spare the patient an extra operation (abutment connection surgery). This study was designed to evaluate the clinical efficacy of BHA and fibrin glue as grafting materials in the maxillary sinus for later placement of nonsubmerged implants.

MATERIALS AND METHODS

Patients

The study sample comprised 50 consecutive patients (28 women and 22 men) with a mean age of 61 years (range 23 to 82 years) referred to the Department of Oral Surgery, Sophiahemmet Private Hospital, Stockholm, Sweden, for implant treatment. All patients were candidates for augmentation in the posterior maxilla prior to implant surgery. Two surgeons performed all the surgical procedures.

Forty-one of the patients were partially edentulous (4 were missing a single tooth) and 9 were totally edentulous. All patients were scheduled to receive fixed prostheses or crown restorations.

The inclusion criterion was insufficient bone volume in the floor of the maxillary sinus (less than 5 mm residual bone) to allow placement of standard-size implants, as judged from panoramic radiography and, if required, tomography of the proposed implant placement area. The exclusion criteria were severe illness, a history of head and neck radiation, chemotherapy, uncontrolled diabetes, uncontrolled periodontal disease, and physiologic problems that could prevent long-term treatment. Smoking was not regarded as an exclusion criterion, but smokers were advised to refrain from smoking or to reduce their smoking.

Surgical Procedure

Seventy-one maxillary sinuses were augmented according to the technique of Boyne and James.[25] Twenty-seven were unilateral, 10 were bilateral, 4 involved a single missing tooth, and 9 involved totally edentulous maxillae bilaterally. All patients were treated under local anesthesia; approximately 10 mL (2%) lidocaine with epinephrine (1:80,000) (Xylocaine-Adrenalin; Astra, Södertälje, Sweden) was used in each patient. The patients were also periorally sedated with benzodiazepam (Triazolam; Gerard Laboratories, Dublin, Ireland). All patients were also given prophylactic antibiotics (penicillin [Kåvepenin], 2 g, twice daily; Astra) and metronidazole (Flagyl, 400 mg, 3 times daily; Rhône-Poulenc Rorer, London, United Kingdom) for 10 days.

The grafting materials used were BHA (Bio-Oss; Geistlich Pharma, Wolhusen, Switzerland) with a particle size of 0.25 to 1 mm (spongiosa) mixed with a biologic glue (Tisseel Duo Quick; Immuno, Vienna, Austria). Two grams BHA were mixed with blood from the wound and 0.5 mL Tisseel (0.5 to 4 g BHA per sinus). The graft was then packed layer by layer and activated with thrombin (Immuno) to catalyze setting of the graft (0.5 mL/2 g), a process described earlier by Hallman and coworkers.[26] The graft was allowed to heal for a mean of 8 months (range, 6 to 11 months) before implant placement.

All implants used in this study were solid titanium screws. The implants had a sandblasted, large-grit, acid-etched (SLA) surface (Straumann, Waldenburg, Switzerland). The planning of the treatment and the surgical procedures were performed according to the manufacturer's instructions.

All 218 implants were placed in a nonsubmerged fashion. One hundred ninety-six of the implants were placed in grafted bone, and the remaining 22 were placed in nongrafted areas. The lengths and the diameters of the placed implants are shown in Tables 1 and 2.

Table 1 Dimensions of Implants Placed in Grafted Bone (n = 196)

Diameter/length	No. placed	No. lost (%)
3.3 mm		
14 mm	6	3 (50)
12 mm	5	0 (0)
4.1 mm		
14 mm	118	3 (2.5)
12 mm	44	2 (4.5)
10 mm	5	0 (0)
12 mm*	3	0 (0)
10 mm*	2	0 (0)
4.8 mm		
10 mm	9	0 (0)
12 mm	4	0 (0)
Total	196	8 (4)

*Esthetic Plus Implants (Straumann) (the polished neck was 1 mm shorter).

Table 2 Dimensions of Implants Placed in Residual Bone (n = 22)

Diameter/length	No. placed	No. lost (%)
3.3 mm		
14 mm	4	1 (25)
4.1 mm		
14 mm	5	0 (0)
12 mm	5	1 (20)
10 mm	1	1 (100)
6 mm	1	0 (0)
4.8 mm		
10 mm	3	0 (0)
8 mm	3	1 (33)
Total	22	4 (18)

Postsurgical Care

The sutures were removed after 7 to 10 days. During this period, no brushing was allowed at the operation sites. After surgery, the patients' existing prostheses were adjusted and lined with a resilient liner (Viskogel; Dentsply, York, PA). After implant placement all patients rinsed with surface antiseptic antimicrobial (0.1% chlorhexidine) twice daily for 10 days. The patients were prescribed a soft diet.

Prosthetic Procedure

The resilient liner was replaced every fourth week until the definitive prostheses were seated. The mean healing time prior to loading was 10 weeks (range, 10 days to 10 months). The prosthodontic treatment was performed according to the manufacturer's protocol, except that in most of the patients shorter healing times were used. In the contralateral arch, the patients had removable mandibular prostheses, fixed prostheses, crown restorations, or natural dentition. In all patients, the fixed prostheses, including the cantilevers or crowns in the maxilla, had an opposing tooth contact.

Follow-up

All patients, except for 10 who had not yet had passed the 1-year loading examination, were followed yearly after functional loading. All patients were monitored according to a research protocol, and no dropouts were experienced. Clinical recordings of implant stability were carried out at baseline (the time at which the patient received a fixed restoration) and at the 1-, 2-, and 3-year follow-up examinations. All screw-retained prostheses were removed at 1 year to facilitate examination of the implants for stability.

Implant survival and success were evaluated according to Roos and associates,[27] using the following definitions:

- Survival = implant still in function
- Failure = mobile or removed implant
- Success = stable implant individually tested with the suprastructure removed and continuously supporting a prosthesis
- Unaccounted for = implant that was not checked

RESULTS

Of the 71 grafted maxillary sinuses, 2 encountered postoperative infections; these were treated with antbiotics. All other grafted sinuses healed without any complications. The sinus membrane was accidentally perforated in 15% of the cases. However, this did not seeem to complicate the healing. If the perforation was smaller than 1 cm, it was repaired with Tisseel and thrombin. Five larger perforations were repaired with autogenous bone or a resorbable membrane (Bio-Gide; Geistlich Pharma). The mean graft healing time was 8 months (range 6 to 11 months).

The mean healing time for the 218 placed implants before functional loading was 10 weeks (range, 10 days to 10 months). Eight of the 196 implants placed in grafted bone were lost (4%) and 4 of 22 placed in residual bone (18%) were lost (Tables 1 and 2).

Twelve implants were lost in 6 patients; 6 were lost before functional loading and the other 6 were lost in a single patient who lost 6 of 8 implants after

1 year and 3 months of loading. This patient was a heavy smoker and had her 8 implants loaded 10 days after placement. In 16 patients, 18 fixed prostheses and 2 single crowns were functionally loaded within 6 weeks. The overall survival rate after a mean loading time of 20 months was calculated to be 94.5%. Peri-implantitis was not found at any implant site.

DISCUSSION

The patients treated in this study were all candidates for bone grafting procedures in the posterior maxilla. A standard protocol for sinus lifting using BHA and fibrin glue as the only grafting materials and delayed placement of nonsubmerged implants implants was used. In spite of the short implant healing time and composition of the graft (no autogenous bone), the cumulative survival rate was 94.5%. Only a few complications were observed, such as perforation of the sinus membrane and 2 postoperative infections that did not jeopardazie the treatment. When the perforation was small, it was repaired with Tisseel/thrombin, and in cases where larger perforations were found, a piece of bone or a resorbable membrane was also used. Tisseel/thrombin was also used to make the graft easier to handle.[4–6] In other studies, the grafting procedure has been done without a biologic glue with equivalent results.[2,3,7] Since thrombin has been associated with an immune response in some patients, although not in the present study, its use can be a valid consideration.

One patient lost 6 implants after more than a year of loading. This patient was a heavy smoker and her 8 implants were loaded 10 days after placement. Furthermore, this patient was treated for osteoporosis, which might have been an additional factor contributing to the implant failures. Perhaps smokers should be treated with a submerged surgical placement and with a longer implant healing time. However, the overall results confirm that sinus lifting using BHA and nonsubmerged implants can be predictable and used in completely edentulous patients. Nine completely edentulous patients were included in the study. In many clinics these patients would be treated with iliac crest bone grafts and reconstructed using methods such as Le Fort I osteotomies and buccal onlays. However, the sinus lift technique has limitations; for instance, the sagittal and vertical relationships will not be reconstructed and a good esthetic result may not be possible in such cases. These are possible factors of interest for younger patients. However, 11 of the patients included in this study were over 70 years old and not interested in major reconstructive surgery.

Several grafting techniques have been described involving implant treatment for severely resorbed maxillae. The efficacy of bone grafting procedures is difficult to assess, since no studies have been performed with ungrafted controls. Moreover, the limited number of placed implants in most studies reduces the possibility of achieving high statistical power. Therefore retrospective studies with larger samples can be of great value.

The implant survival rates for machined implants in conjunction with various bone grafting techniques are generally lower[28–30] than when standard protocols are used.[13–15] In the present study, the survival rate based on defined criteria was 94.5%. Valentini and coworkers[7] also used 100% BHA as a grafting material. Fifty-seven TPS-coated implants were placed after 6 months of healing, and after a mean follow-up of 3 years only 1 implant was lost (1.8%). The results indicated that rough-surfaced implants may perform better than smoother, machined-surface implants in restoration of grafted maxillae, probably because of a better bone response. In a study by Stricker and associates,[31] autogenous bone was used as a grafting material in the sinus. One hundred eighty-three nonsubmerged ITI, screw-type SLA implants (Straumann) were placed, and after a follow-up of between 15 and 40 months the survival rate was amazingly high (99.5%). In similar studies using machined implants, the failure rates were found to be much higher (10% to 20%),[30] indicating higher failure rates with machined implants.

Usually most surgeons employ a submerged technique to place implants in grafts. One of the reasons for this is protection of the implants during the healing period. Secondly, longer healing times for implants placed in grafted tissue have been used to secure osseointegration before loading. However, this approach is not evidence-based. The results from the present study and from that of Stricker and associates[31] indicate that implants can be placed nonsubmerged in grafts with relatively short healing times before functional loading.

It has been suggested that the use of rough-surfaced implants can increase the risk of peri-implantitis. This has been confirmed in some studies involving the use of TPS implants.[20,32,33] However, in the short perspective of this study, the risk of peri-implantitis has not been confirmed. One explanation might be that the TPS surface is rougher than the SLA surface. In the present study, 1 patient who lost 6 implants was a heavy smoker, which also was a frequent cause of implant losses in a study by

Åstrand and coworkers.[32] There may be a correlation between smoking habits, peri-implantitis, and implant loss in the treatment of the maxilla.

Autogenous bone is considered the "gold standard" grafting material, and it has been found that adding as little as 20% autogenous bone to a graft consisting of BHA will improve bone formation and shorten the graft healing time by 3 months prior to implant placement.[6] This might be one reason for adding autogenous bone to an osteoconductive graft.[3,6] In the study by Valentini and coworkers,[7] the grafts were allowed to heal for only 6 months before implant placement. In the present study, an average of 8 months was used according to earlier histologic experiences using BHA and autogenous bone.[26] Other authors have advocated longer healing times.[4] Histologic results from biopsies harvested after 6 months using 100% BHA[7] or a mixture with autogenous bone (80:20)[26] have shown equal results. Twenty-one percent and 24%, respectively, of the bone specimen area consisted of new bone. In another study by Hallman and associates,[6] equivalent histologic results were found using an 80:20 mixture or 100% BHA; however, the healing time for the latter was prolonged by 3 months. Since equivalent clinical results have been found for both shorter and longer graft healing times, it cannot be concluded which healing time is preferable.

The short-term results of this study imply that the use of BHA and fibrin glue as the only grafting materials and the later placement of nonsubmerged implants could be considered as an alternative treatment to bone grafting with autogenous bone in patients with severe atrophy in the posterior maxilla. Nine of the 50 patients were completely edentulous, with severe vertical resorption in the posterior maxillae (Class V or VI according to Cawood and Howell[33]), and with 1 exception these patients were all treated successfully.

CONCLUSION

The short-term results of the present study indicate that sinus lifting using BHA and fibrin glue with later placement of nonsubmerged implants may be considered as an option in treatment planning and an alternative to bone grafting with autogenous bone and submerged implants. This treatment demonstrated lower morbidity in this patient population.

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