# A 5-Year Prospective Follow-Up Study of Implant-Supported Fixed Prostheses in Patients Subjected to Maxillary Sinus Floor Augmentation with an 80:20 Mixture of Bovine Hydroxyapatite and Autogenous Bone

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## ABSTRACT

*Background:* Prospective long-term follow-up studies evaluating the use of bone substitutes to enable dental implant placement and integration are rare.

*Purpose:* This study was undertaken to evaluate the survival rate of dental implants placed 6 months after maxillary sinus floor augmentation using a mixture of 80% bovine hydroxyapatite (BH) and 20% autogenous bone (AB).

*Material and Methods:* Twenty patients subjected to 30 maxillary sinus floor grafting procedures using fibrin glue and an 80:20 mixture of BH and AB to enable placement of dental implants 6 months later were followed for 5 years of functional loading. Clinical and radiographic examinations of the grafts and implants were performed.

*Results:* After 5 years of functional loading with fixed bridges, 15 of 108 implants had been lost, giving a cumulative survival rate of 86%. The mean marginal bone loss after 5 years was 1.3 $\pm$ 1.1 mm.

*Conclusion:* Grafting of the maxillary sinus with a mixture of BH and AB and later placements of turned implants could be performed with predictable long-term results. All but one of the patients who were observed had functional fixed bridges after 5 years of functional loading.

KEY WORDS: autogenous bone graft, bovine hydroxyapatite, clinical study, dental implants, fibrin glue, maxillary sinus floor augmentation, prospective

Maxillary sinus floor augmentation is a technique that is widely used to enable the placement of dental implants in the severely resorbed posterior maxilla. Although the use of autogenous bone (AB) is regarded as the first choice of grafting material, other bone substitutes are frequently used, partly to minimize morbidity and the risk of complications. One bone substitute that has been evaluated in animal and clinical trials is anorganic bovine bone hydroxyapatite (BH) with a structure similar to that of human bone. Histologic studies have demonstrated this material to have bone-conductive properties because it becomes bone encapsulated in osteogenic environments.[1–5] This material was introduced as a resorbable material; however, results from clinical studies have shown that the material is nonresorbable.[2–7] Some authors have suggested that the stability, in terms of resistance to resorption, of BH is favorable since the volume of the grafted area is better maintained with time.[6,7] The reinforcement effect of BH particles in newly formed bone may also result in a positive influence on the biomechanical properties and ability of the bone to support an implant.[8] Even though BH is widely used together with different brands of dental implants, there are no studies that include long-term follow-ups.

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The purpose of the present longitudinal study was to evaluate the clinical outcome of implants placed in patients subjected to a maxillary sinus floor augmentation procedure using an 80:20 mixture of BH and AB and observed for 5 years.

## MATERIAL AND METHODS

### Patients

Twenty consecutive healthy patients, 14 women and 6 men, with a mean age of 62 years (range, 48–69 years) were included in the study. All patients had severe atrophy of the alveolar process in the posterior maxilla as diagnosed by panoramic radiography and Scanora® imaging (Soredex, Orion Corporation, Helsinki, Finland). Eighteen of the patients had unilateral or bilateral loss of molars and premolars while two patients were fully edentulous. The former patients were class IV-V in the posterior regions of the maxilla, and the two edentulous patients were class III-IV in the anterior maxilla and class ÍV and class V in the posterior regions, all according to the classification of Cawood and Howell.[9] Patients were included in the study if no systemic or local contraindications were encountered. Smokers were not excluded but were instructed to refrain from or to reduce their smoking.

Patients included in the study had less than 5 mm of subantral alveolar bone in the vertical direction. Thirty maxillary sinuses met this inclusion. The average residual bone height was 1.6 mm at the lowest part (range, 1–3 mm) and 3.8 mm at the highest part (range, 2–5 mm). Nine of the 20 patients were smokers, and 7 patients had an earlier history of smoking. All patients gave their informed consent, and the study was approved by the regional ethics committee.

### Mandibular Bone Graft Harvesting

Harvesting of the corticocancellous chin grafts was performed with patients under local anesthesia and sedation with 10 to 25 mg of oral diazepam (Apozepam®, Dumex-Alpharma, Stockholm, Sweden) or 5 to 10 mg of oral midazolam (Dormicum®, Roche AB, Stockholm, Sweden). As a prophylactic measure, all patients received 2 g of penicillin V (Kåvepenin®, Astra, Södertälje, Sweden) and 500 mg of metronidazole (Fasigyn®, Pfizer, Stockholm, Sweden) preoperatively. Anesthesia of the inferior alveolar nerve and mandibular symphysis region was induced with lidocaine 2% with epinephrine (1:80,000) (Xylocaine®/Adrenaline; Astra, Södertälje, Sweden). The mandibular symphysis was exposed through a mucoperiosteal incision from canine to canine in the deepest part of the vestibule, and a unicortical labial osteotomy was performed with a thin-fissure bur. The osteotomies were made at least 5 mm inferior to the root tips and 4 mm superior to the mandibular inferior border. The bone graft was divided in the midline and harvested with a thin osteotome. The harvested bone was kept in blood until put into particulate form with a surgical bone mill (Tessier Osseous Microtome®, Stryker Leibinger GmbH, Freiburg, Germany). The wound was carefully sutured in layers with resorbable sutures.

### Maxillary Sinus Augmentation

The sinus area was prepared with the patient under local anesthesia, as described elsewhere.[2,10,11]

Following a crestal incision and a vertical releasing incision, a mucoperiosteal flap was elevated and reflected laterally to expose the lateral wall of the sinus. An approximately 20 mm wide and 10 mm high window was outlined with a round bur. The bone in the center of the window was left attached to the schneiderian membrane. Care was taken not to lacerate the membrane during the elevation procedure.

The autogenous bone particles were mixed with bovine hydroxyapatite (Bio-Oss® spongiosa 0.25–1.0 mm granules, Geistlich Pharma AG, Wolhusen, Switzerland) in a 20:80 mixture by weight (mean, 18:82), along with fresh blood from the wound. To make the graft material easier to handle and to hinder the particles from penetrating perforations of the schneiderian membrane, 0.5 mm of fibrin glue (Tisseel® Duo Quick, Immuno AG, Vienna, Austria) was added. The graft mixture was packed layer by layer, and thrombin (Thrombin®, Immuno AG) was added to catalyze setting of the fibrin glue. The oral mucosa was then sutured with resorbable sutures.

### Implant Insertion

After a graft healing time of 6 months, 108 pure titanium implants with a machined surface (Brånemark System®, Nobel Biocare AB, Gothenburg, Sweden), 7 to 18 mm in length, were inserted (Table 1), 79 in augmented bone and 29 in residual bone. Two of the implants were 5.5 mm wide, and three were 4 mm wide; the rest were 3.75 mm wide and of a self-tapping

**TABLE 1 Lengths of Inserted Implants**

| Length (mm) | Number ($n$ = 108) |
|---|---|
| 7 | 2 |
| 10 | 8 |
| 11 | 1 |
| 13 | 30 |
| 15 | 61 |
| 18 | 6 |

type. After a healing period of 6 to 8 months (mean, 6.7 months), the implants were exposed and healing abutments were connected.

### Prosthetic Procedures

The first 10 days after each surgical procedure, the patients did not wear any removable dentures. Thereafter the dentures were adjusted and relined with a soft material (Viscogel®, Dentsply, York, PA, USA) that was changed monthly during the healing period.

Two weeks after surgery for abutment connection, the healing abutments were changed to permanent abutments, and all patients were rehabilitated with fixed bridges using either titanium or gold frameworks and either porcelain or acrylic teeth.

### Clinical Follow-Up

Clinical checking of the stability of each individual implant was carried out with a screwdriver at the time of abutment connection and bridge connection as well as after 1 and 3 years of functional loading. A rotation-mobile implant and/or a painful implant was classified as a failure and was removed.

Implant survival was evaluated according to the criteria of Albrektsson and colleagues[12] and calculated with a life table.

### Radiographic Examination

Preoperative radiographic examinations were based on panoramic radiography, lateral cephalography, and tomography with the Scanora imaging system using screens of speed group 2.5 (Lanex™, Eastman Kodak Co., Rochester, NY, USA) and T-MAT™ L films (Kodak Industrie). In addition, intraoral radiography using Kodak Ektaspeed Plus™ dental film (Eastman Kodak) was performed with a Philips Oralix 65 apparatus (Philips, Milano, Italy).

The cross-sectional tomography was done perpendicular to the hard palate and the buccal cortical plate and included the base of the maxillary sinus.[13] The maxillary bone was examined with respect to shape and volume of the residual alveolar process.

The postoperative examinations at 3 and 12 months post grafting, after 1 and 3 years of loading, included panoramic radiography and cross-sectional tomography of the jaws, with use of the Scanora technique for both. In addition, scanography (narrow beam radiography) was used for detailed examination of the marginal bone in relation to the implants.[13–15] After 5 years of functional loading, panoramic and intraoral radiographs were obtained for detailed information on the marginal bone around the implants.

The marginal bone level was measured on the left and right sides of each implant on radiographs made at baseline (at the time of abutment connection), after 1, 3, and 5 years of loading. The mean (plus or minus standard deviation) was calculated for implants in grafted bone and for implants in residual alveolar bone. All measurements were made twice (with 6 months between the measurements).

### Statistical Analysis

The *t*-test was used to analyze changes in marginal bone loss with time and to compare implant stability in augmented and residual bone. The Fisher exact test was used to calculate statistical differences between dental implants placed in residual and grafted bone.

## RESULTS

### Clinical Findings

Sixteen of the 20 patients were observed throughout the study period. One patient developed disease, and two patients had moved and could not attend the 3-year follow-up examination. One more patient developed disease after 4 years and could not attend the 5-year examination.

*Healing.* Two postoperative wound infections occurred 3 weeks after the augmentation procedure. Both were successfully treated with clindamycin (Dalacin®, Pharmacia and Upjohn, Stockholm, Sweden), 300 mg × 3 for 10 days, and local irrigation with saline. In both cases granules of Bio-Oss exfoliated from the incision. After 5 years of healing, 4 (25%) of 16 patients who were

**TABLE 2 Life Table**

| Time | Implants Entering Interval | Failed Implants in Interval | Dropouts | CSR (%) |
|---|---|---|---|---|
| Placement to loading | 108 | 9 | 0 | 91.7 |
| Loading to 1 yr | 99 | 1 | 0 | 90.7 |
| 1–2 yr | 98 | 5 | 0 | 86.2 |
| 2–3 yr | 93 | 0 | 20 | 86.2 |
| > 5 yr | 73 | 0 | 1 | 86.2 |

CSR = cumulative survival rate.

examined complained of numbness in the chin region and sensory disturbances in the lower incisors. No destructions were found apically around the teeth at the donor site. The sensory disturbances in the buccal gingiva were classified as paresthesia in all four patients; however, the disturbances in the skin area were classified as uncomfortable sensations.

*Implant Failure.* At abutment surgery nine implants were classified as failures and were removed, giving an early failure rate of 8.3%. Two implants were not used and were left "sleeping." After 1 year of functional loading, one additional implant was lost, giving a failure rate of 9.3%. Five more implants were lost during the following (second) year of loading. No further implants were lost. The cumulative survival rate (CSR) calculated with a life table based on 15 failures in 6 of the patients was 86% after 5 years of bridge loading (Table 2). Of the failed implants, 6 implants were placed in residual bone and 9 were placed in

**TABLE 3 Number of Placed and Lost Implants in Residual and Grafted Bone**

| Patient | Placed in Residual Bone | Lost in Residual Bone | Placed in Grafted Bone | Lost in Grafted Bone | Total Failures |
|---|---|---|---|---|---|
| 1 | 4 | 2 | 5 | 2 | 4 |
| 2 | 1 | 0 | 3 | 1 | 1 |
| 3 | 2 | 0 | 2 | 0 | 0 |
| 4 | 0 | 0 | 2 | 1 | 1 |
| 5 | 3 | 0 | 8 | 0 | 0 |
| 6 | 1 | 0 | 3 | 0 | 0 |
| 7 | 1 | 0 | 6 | 0 | 0 |
| 8 | 2 | 0 | 4 | 0 | 0 |
| 9 | 2 | 0 | 4 | 0 | 0 |
| 10 | 1 | 0 | 3 | 0 | 0 |
| 11 | 2 | 0 | 4 | 0 | 0 |
| 12 | 1 | 0 | 3 | 0 | 0 |
| 13 | 0 | 0 | 4 | 2 | 2 |
| 14 | 0 | 0 | 3 | 0 | 0 |
| 15 | 1 | 0 | 6 | 0 | 0 |
| 16 | 0 | 0 | 4 | 0 | 0 |
| 17 | 0 | 0 | 3 | 0 | 0 |
| 18 | 1 | 0 | 6 | 1 | 1 |
| 19 | 3 | 0 | 4 | 0 | 0 |
| 20 | 4 | 4 | 2 | 2 | 6 |
| All Patients | 29 (26.9%) | 6 (20.7%)* | 79 (73.1%) | 9 (11.4%)† | 15 (13.9%) |

*Failure rate of implants in residual bone.
†Failure rate of implants in grafted bone.

augmented bone (Table 3). No statistical difference was found between implant failures in grafted or nongrafted bone.

One partially edentulous patient who was a smoker (15 cigarettes per day for more than 30 years) lost four of his nine implants prior to loading. A totally edentulous patient who also was a smoker (more than 20 cigarettes per day for more than 30 years) and who bruxed lost two implants at the time of abutment connection surgery. After wearing a fixed prosthesis on four implants for 2 years, he also lost the remaining implants. Three other patients, two smokers and one with a history of smoking, each lost one implant. The four patients with no history of smoking did not lose any implants.

*Prosthetic Results.* The 20 patients initially received two full and 26 partial fixed bridges. After 5 years of loading, all but one of 16 examined patients had a fixed prosthesis in function. One partial bridge in one patient was transformed into a single crown owing to a loss of implants. Although not examined, the two patients that did not attend the 5-year examination reported good function of their bridges.

### Radiographic Findings

The marginal bone levels from the reference point of all implants were 0.4 ± 0.8 mm (range, 0–6 mm), 0.8 ± 1.3 mm (range, 0–7 mm), 1.2 ± 1.1 mm (range, 0–7 mm), and 1.3 ± 1.0 mm (range, 0–7 mm) at baseline and after 1, 3, and 5 years, respectively (Figure 1).

When implants placed in augmented bone were evaluated, the corresponding values at baseline and after 1, 3, and 5 years were 0.4 ± 0.9 mm, 0.8 ± 1.5 mm, 1.1 ± 1.1 mm, and 1.3 ± 1.07 mm, respectively; for implants placed in residual bone, the respective values were 0.2 ± 0.5 mm, 0.9 ± 1.0 mm, 0.7 ± 1.0 mm, and 0.8 ± 1.0 mm. There were no statistically significant differences between implants in BH and implants in residual bone.

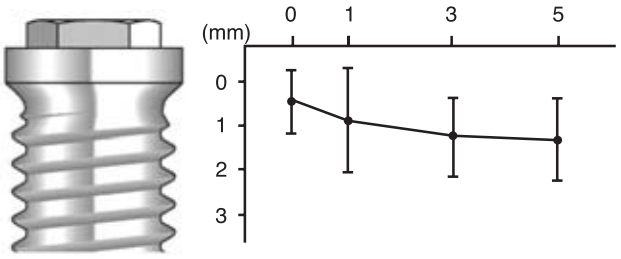


**Figure 1** Marginal bone levels at the time of abutment connection (baseline) and after 1, 3, and 5 years of functional loading.

## DISCUSSION

Prospective long-term studies evaluating the outcome of dental implants placed in grafted maxillary sinuses using bone substitutes are rare. In this study 30 sinuses were grafted with an 80:20 mixture of BH and AB mixed with fibrin glue. The survival rate after 5 years of loading was 86% for all implants and 89% for implants placed in grafted bone. Only a few complications were noted. After the augmentation two early infections were curable with antibiotics, and no other complications related to the sinus surgery were recorded in the present study. In spite of the lack of clinical symptoms, CT performed after 3 years of healing revealed that 7 (29%) of 24 augmented sinuses showed mucosal changes. Other authors have reported transient sinusitis in 5 to 27% of cases.[15–18] It is unclear whether these findings were related to the grafting procedure or if they reflected normal sinus conditions in a population of 20 patients.

The use of the mandibular symphysis as a donor site for harvesting bone in reconstructive jaw surgery is a well known method. However, some recent reports have focused on the morbidity that occurs after the harvesting of bone from this region.[19,20] These studies showed that the morbidity incurred when harvesting bone from the mandibular symphysis is not negligible and that the surgical technique and the amount of bone might be factors of importance. In our study the morbidity has been high as 4 of 16 examined patients experienced sensory disturbances and discomfort in the chin after 5 years. It seems that this area is sensitive and should be avoided and that other areas, such as the mandibular ramus, should be preferred. Because morbidity after bone harvesting is not negligible, one obvious advantage of using a biomaterial in combination with or instead of AB is that a minor or nondonor site is needed.

In the present study 15 of 108 implants were lost. Nine were recorded before prosthesis connection, and 6 were recorded during loading. No implant was lost after 2 years. Previously reported histologic findings[2,3] showed that BH has bone conduction properties but that mainly immature bone was found after 6 months of healing (from the time of implant placement). Perhaps the woven-bone/BH complex resulted in poor

primary stability of the implants, which may have impaired the integration process, and perhaps a prolonging of the healing time by 3 months might have improved the results. One intriguing observation was that proportionally more failures (however nonsignificant) occurred in residual bone, which contradicts this theory. It can be speculated that the relatively smooth surface of the implants was a negative factor for the integration process and that a rough surface would have been more favorable in the present study. However, other authors have reported survival rates of 100% for turned implants in augmented maxillary sinuses.[20]

Another factor that possibly contributed to failure is cigarette smoking.[21,22] In this study two patients lost 10 of the total 15 failed implants, and both patients smoked more than 15 cigarettes per day. This corresponds with the observations of other authors using BH and other graft materials for maxillary sinus floor augmentation.[23,24] However, 45% of the treated patients were smokers; still, all but one of the patients had their fixed constructions in function after 5 years of healing.

Bone grafting in conjunction with implant treatment has been extensively documented, and several reviews including meta-analyses of the data have been presented.[25–27] With regard to maxillary sinus floor augmentation, most authors recognize that the documentation is too heterogeneous to make comparisons and to draw conclusions about which technique and what grafting material are preferable. Moreover, follow-up parameters vary, which makes it difficult to compare different studies. In a recently published review by Merkx and colleagues,[27] assessments of the value of anorganic bone additives in sinus floor augmentation were examined. They concluded that only 12 studies fulfilled the stated criteria. In the cases of at least two treated patients at the minimum 3 months' follow-up, available histomorphometric data indicated that composite grafts may have a place in sinus floor augmentation procedures. However, attempts have been made to find outcome determinants by meta-analyses of pooled data. Jensen and colleagues[25] analyzed the outcomes of more than 3,500 implants, and according to their analyses, all graft materials performed well, with survival rates of greater than 80%, the allograft being the least successful. However, their material on xenografts and BH was too small for analysis. Tong and colleagues[26] reviewed the literature on maxillary sinus floor augmentation and found 28 studies. Owing to specified inclusion criteria, 18 studies could be used for a meta-analysis, including studies on various implant designs in AB (intra- and extraoral), hydroxyapatite (HA) alone, and HA mixed with AB or demineralized freeze-dried bone (DFDB). Implants had been placed simultaneously with the graft or after initial healing. Follow-up varied from 6 to 60 months. Based on their analysis the authors concluded that similar results (around 90% survival) could be achieved for the various grafting materials although no detailed statistical analyses could be done. However, no conclusions about the use of BH were drawn in the articles by Jensen and colleagues and Tong and colleagues, since few reports were available at that time.

Increasing interest in using BH in conjunction with implant therapy has resulted in several published assessments since then. Froum and Abensur[1] evaluated BH in different combinations with autogenous bone and DFDB, and both simultaneous and delayed implant placements were used. They lost 2 (1.8% of 215) implants after a follow-up of 2 to 3 years. Valentini and colleagues[28] placed 57 implants 6 months after sinus floor augmentation with BH and lost only one (1.8%) of the implants during 4 to 5 years of loading. In a clinical study Mayfield and colleagues[24] placed implants in BH used alone or in combination with AB for augmentation of the jaws or maxillary sinus floor; they lost 2 (14.2%) of 14 implants placed in augmented maxillary sinuses during a follow-up of 4 to 6 years. Hising and colleagues[15] used a blend of BH and AB for bone augmentation procedures to enable implant placement; 104 implants had been placed in previously augmented maxillary sinuses, and 18 (17.3%) were lost during the observation time of 12 to 113 months. Tawil and Mawla[29] reported on the outcome of 61 implants placed simultaneously with or after maxillary sinus floor augmentation procedures with BH and a mean follow-up of 22 months. They also studied the influence of using a bioresorbable membrane to cover the bone window. They lost 9 implants (14.8%) and found that a staged approach gave better results than simultaneous placement if a healing period of 9 months or longer was allowed before implant placement. It was observed that membrane coverage of the bone window gave better results when a simultaneous implant placement approach was used. The heterogeneity of the studies above does not allow comparisons, but the results (including our own experiences) indicate that

acceptable results can be obtained with BH. For the same reason, it is difficult to directly compare the present data with those of previously published studies that used AB for maxillary sinus augmentation. For instance, Lundgren and colleagues[30] reported a 100% survival rate after a mean follow-up of 26 months whereas Kahnberg and colleagues[31] found a survival rate of 61.2% after 3 to 5 years. The difference may be related to the fact that a two-stage approach and chin bone were used by Lundgren and colleagues whereas a simultaneous approach and iliac crest bone were used by Kahnberg and colleagues.

## CONCLUSION

A mixture of 80% bovine hydroxyapatite and 20% autogenous bone can be used as a grafting material for maxillary sinus floor augmentation prior to implant surgery, with few complications and with acceptable long-term results.

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