A Retrospective 5-Year Follow-Up Study of Two Different Titanium Implant Surfaces Used after Interpositional Bone Grafting for Reconstruction of the Atrophic Edentulous Maxilla

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ABSTRACT

Background: Long-term comparative follow-up studies of dental implants placed in augmented bone are rare. Variations in design and surface roughness have been found to be important for bone integration of implants. However, there is no clinical evidence that such variations lead to an improved clinical outcome.

Purpose: To compare two different implant systems used after interpositional bone grafting of the severely resorbed maxilla with a modified augmentation technique using fibrin glue.

Materials and Methods: Twenty-two consecutive patients presenting with severe maxillary atrophy underwent reconstruction with Le Fort I osteotomies and interpositional bone grafting. Before placement of bone blocks, the floors of the maxillary sinuses were packed with bone chips mixed with a fibrin glue, to stabilize the graft. After 6 months of graft healing, the first 11 consecutive patients received Brånemark System® implants with a turned surface (Nobel Biocare AB, Göteborg, Sweden). The following 11 consecutive patients were treated with Astra Tech implants with a blasted titanium surface (Astra Tech AB, Mölndal, Sweden). All patients received fixed prostheses. Marginal bone resorption and donor and recipient site morbidity were evaluated. All patients were clinically and radiographically observed throughout 5 years of functional loading.

Results: In the Brånemark group, 11 (13%) of 84 placed implants were lost, compared to 4 (5.5%) of 72 placed implants in the Astra Tech group. The difference was not significant. All patients retained fixed constructions after 5 years of loading. The mean marginal bone loss was 2.3 $\pm$ 0.8 mm (range, 0–5.0 mm) in the Brånemark group and 2.4 $\pm$ 1.4 mm (range, 0–7.0 mm) in the Astra Tech group, although again no statistical difference was found. A larger number of implants in the Astra Tech group had a marginal bone resorption of $\geq$ 3 mm, and implant success in that group was lower than in the Brånemark group (52% vs 70%).

Conclusion: In this study, reconstruction of the severely resorbed maxilla with Le Fort I osteotomy, interpositional bone grafting, and delayed placement of dental implants was found to be a predictable long-term procedure. Although more implants with a turned surface were lost during the follow-up period, there were no statistically significant differences between turned and titanium blasted implants.

KEY WORDS: comparative study, dental implant surface, fibrin glue, interpositional bone grafting, Le Fort I osteotomy

Severe atrophy of the edentulous maxilla complicates the patient's possibility of using dentures. Moreover when no more than 3 to 5 mm of maxillary bone are left, prosthetic rehabilitation with implant-supported prostheses is complicated. Farell and colleagues[1] and Bell[2] were the first investigators to describe a method for interpositional bone grafting of the maxilla in combination with Le Fort I osteotomy in order to increase the volume of bone in the maxilla. Keller and Triplett[3] described a method for total reconstruction of the maxilla that enabled the patient to receive dentures fixed on dental implants. This involved interpositional bone

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grafting combined with Le Fort I osteotomy, without entry to the maxillary sinus, and either simultaneous or delayed placement of dental implants. The method was modified by Sailer,[4] who grafted the floor of the maxillary sinus and placed dental implants during the same procedure. Other authors have also used this method.[5–8] A two-stage method including an intermediate healing period before implant placement was later described.[9,10] Long-term comparative studies evaluating the use of different implant systems following Le Fort I osteotomy and interpositional bone grafting are rare.

The aim of this study was to retrospectively evaluate the use of two different implant systems with different surface textures in patients who had undergone Le Fort I osteotomy and interpositional bone grafting.

Figure 1 A titanium blasted Astra Tech implant (*left*) and a Brånemark implant with a turned surface (*right*).

MATERIALS AND METHODS

Patients

During a period of 4 years, 22 consecutive patients were treated with Le Fort I osteotomy and interpositional bone grafting. During the first 2 years (1993–1995), patients were treated with Brånemark System® implants with a turned surface (Nobel Biocare AB, Göteborg, Sweden) (Figure 1). In the following 2 years (1995–1997), patients were treated with Astra Tech implants with a titanium blasted surface (TiOblast®, Astra Tech AB, Mölndal, Sweden) (see Figure 1). The mean age of the patients was 57 years (range, 45–65 years) in the first group and 63 years (range, 41–77 years) in the Astra Tech group. Preoperative clinical examination and radiography (including panoramic radiography, tomography, and cephalometry) revealed severe atrophy classified as level VI[2] in the classification of Cawood and Howell.[11]

Bone Grafting Procedures

Surgery was performed with the patient under general anesthesia. Local anesthesia with a vasoconstrictor (lidocaine 2% with epinephrine, 1:80,000 [Xylocaine® with adrenalin, AstraZeneca AB, Södertälje, Sweden]) was used for hemostasis both at the donor site and at the recipient site.

The grafting materials used in both groups were autogenous particulated bone chips and bone blocks harvested from the iliac crest, mixed with fibrin glue (Tisseel®, also called Thrombin® Duo Quick, Immuno AG, Vienna, Austria) that was added to the particulated graft packed in the floor of the maxillary sinuses before placement of the bone blocks. The harvesting of the bone graft and the Le Fort I osteotomy were performed simultaneously.

A skin incision from the anterior to the posterior part of the midcrest of the iliac crest was made. The ilium was exposed through blunt and sharp dissection. A midcrest incision through the periosteum was made 3 cm posterior to the anterior part of the superior iliac spine. Muscular tissue and periosteum were reflected both medially and laterally when the crest was too thin for a medial harvesting. In cases in which the crest was wide enough, the periosteum was reflected only medially. The ileum was exposed to allow the bone graft to be harvested. The surgeon measured and predicted the needed bone volume inside the down-fractured maxilla. The size (length, height, and depth) of the bone graft was approximately 6 × 2 × 2 cm. Bone wax and ligatures were used for hemostasis. Conditions beneficial for healing were created by adapting the medial and lateral muscle and tensor flaps with sutures and by closing the wound in layers. A drain was used for at least 24 hours. Maxillary surgery was performed simultaneously, starting with a circumvestibular incision in the vestibule of the maxilla from the molar to molar regions. A mucoperiosteal flap was raised, and the mucosa in the floor of the nose was dissected. Osteotomies were made according to the method described by Sailer.[4] The maxilla was

down-fractured and mobilized. The floor of the sinus was released from its mucosa. Autogenous bone chips mixed with Tisseel were packed into the floor of the sinus, activated layer by layer with Thrombin to catalyze the setting of the graft. One corticocancellous bone block was then fitted on each side, from the midline to the region of the first molar to the previous floor of the nose and sinus, as described by Sailer.[4] The maxilla was then stabilized with one miniplate on each side, in the planned position. The wound was closed with absorbable 4-0 Vicryl® sutures (Ethicon, Inc., Somerville, NJ, USA).

Implant Placement

After 6 months of graft healing, dental implants were placed. Brånemark implants were used in the first 11 patients, and Astra Tech implants were used in the next 11 patients. Abutment connection was performed after an implant healing period of 6 months. Implant placement was performed with the patients under local anesthesia (lidocaine with epinephrine, 1:80.000 [Xylocaine with adrenalin]), in accordance with the manufacturers' manuals for Brånemark and Astra Tech implants. All patients were orally sedated with midazolam (Dormicum®, Roche AB, Stockholm, Sweden). All patients received 2 g of phenoxymethyl penicillin (Kåvepenin, AstraZeneca) preoperatively and twice a day for 10 days. The miniplates were removed before implant placement. After 6 months of implant healing, abutment connection was performed with the patients under local anesthesia.

Follow-Up

The patients were treated with screw-retained metal-ceramic fixed prostheses, and all patients were observed through 5 years of loading. All prostheses were removed after 1 year of loading, to check the stability of each individual implant and to tighten the abutment and bridge screws.

Intraoral radiography was performed after 5 years of functional loading. The mesial and distal marginal bone levels were measured for each implant. All radiographs were evaluated by one clinician. Measurements were made with a Peak Scale Loupe™ (Peak Optics, Tokyo, Japan) with a magnifying factor of 7× and a scale in tenths of millimeters.

An implant was considered to be successful if the following four criteria were met: (1) the implant was clinically stable as determined after removal of the fixed prosthesis and tightening of the abutments; (2) there was no sign of pathologic reaction, pain, or infection in the hard or soft periimplant tissues; (3) there was no periimplant radiolucency; and (4) there was no marginal bone loss exceeding 3 mm after 5 years of functional loading. An implant was considered a failed implant if it was removed for any reason. Implants that were not removed or that met the success criteria were regarded as survivals.

Evaluation of Aesthetics, Phonetics, and Morbidity. At the time of the 5-year follow-up, the prostheses' aesthetic results and phonetics were evaluated and classified on a 10-grade visual analog scale (VAS). Subjective and objective evaluations of donor site and recipient site morbidity were also performed with a VAS.

Statistical Analysis. The statistical variables (ie, the responses) were observed at the time of implant placement and at 5 years after loading. The SPSS® statistical package (SPSS Inc., Chicago, IL, USA) was used for analysis. A chi-square test using Yates's correction factor was used for the statistical analysis, comparing the survival rates of the two different implant systems with the implant as the unit. The relative risk of implant failure was also calculated. Changes in marginal bone level were calculated with the Mann-Whitney *U* test, with the implant as the unit. A difference was considered to be statistically significant when p was $< .05$.

Each patient had multiple implants, and computations were based on the patient as the unit. The effect of multiple implants is generally positive correlation of implant-specific response variables; clusters are built in the data set. In the case of a continuous response, it is necessary to ensure that the assumption of normal distribution cannot be rejected. For each patient a graphic representation of the implant distribution was carefully examined with an emphasis on symmetry, outliers, and skew. Although good results in these areas cannot prove normal distribution, they did not disprove it; thus the use of the applied models as one method of data analysis was justified.

RESULTS

In the Brånemark group six to eight implants were placed in each patient. Of 84 implants in 5 patients, 11 were lost (8 implants before functional loading,

TABLE 1 Number of Group 1 (Brånemark) and Group 2 (Astra Tech) Implant Failures after 5 Years of Functional Loading

	Group 1		Group 2	
Patient No.	Implants Placed	Implant Failures	Implants Placed	Implant Failures
1	8	0	7	0
2	7	0	8	0
3	8	0	8	1
4	6	1	8	0
5	8	1	7	1
6	8	1	6	2
7	8	0	5	0
8	8	4	6	0
9	8	0	5	0
10	8	4	6	0
11	7	0	6	0
Total	84	11	72	4
Failure Rate	—	13%	—	5.5%

1 implant after 1 year, and 2 implants after 3 years), resulting in a cumulative survival rate (CSR) of 87%. In the Astra Tech group five to eight implants were placed in each patient. Of 72 implants in 3 patients, 4 were lost (94.5% CSR); all but one of these were lost before loading (Table 1). One implant was lost after 4 years of loading. No statistical difference in implant survival was found between the two groups although the relative risk of losing an implant was 2.36 times higher in patients who received Brånemark implants.

The mean marginal bone loss was 2.3 mm (standard deviation [SD], 0.8 mm; range, 0–5.0 mm) in the Brånemark group and 2.4 mm (SD, 1.4 mm; range, 0–7.0 mm) in the Astra Tech group. No statistical difference between the groups was found. If implants with a marginal bone resorption of less than 3 mm were classified as successes, the implant success rate was 70% in the Brånemark group and 52% in the Astra Tech group, although no statistical difference was found.

TABLE 2 Implant Lengths and Failures in the Brånemark Group

Length (mm)	Implants Placed	Implant Failures
7	1	0 (0%)
10	6	0 (0%)
13	17	1 (5.8%)
15	60	10 (16%)

TABLE 3 Implant Lengths and Failures in the Astra Tech Group

Length (mm)	Implants Placed	Implant Failures
8	9	0 (0%)
9	3	2 (55%)
11	21	1 (5%)
13	26	1 (4%)
15	11	0 (0%)

The lengths of the placed implants differed between the two groups (Tables 2 and 3).

Four patients in the Brånemark group were smokers, and three patients in the Astra Tech group were smokers. No correlation was found between smoking habits and implant failure.

The subjective aesthetic result was classified on a VAS by a mean of 8.5 in the Brånemark group (score range, 5–10). Small phonetic disturbances related to pronunciation of the letter "s" were found (range, 2–3) in five patients. Two patients had moderate problems at the donor site, scored (by the patients) as "2" and "3" on a VAS. In this group there were no problems related to the recipient site.

In the Astra Tech group, subjective aesthetics were also classified on a 10-grade VAS as a mean of 8 (range, 5–10). Small phonetic disturbances related to pronunciation of the letter "s" were found in three patients (VAS score, 2–3). One patient expressed a moderate problem at the donor site, which was classed as "2" on a VAS.

Two patients in the Astra Tech group developed fistulae (from the maxillary sinus) at the recipient site; the fistulae had to be surgically closed, twice in one patient and three times in the other, before they finally healed.

Despite the implant failures the rehabilitation of all patients was successful. All fixed prostheses were still functioning after 5 years of functional loading.

DISCUSSION

In a clinical histologic study by Ivanoff and colleagues,[12] implant integration was evaluated after mean healing periods of 6.3 months in the maxilla and 3.9 months in the mandible. A significantly higher degree of bone-implant contact was found for titanium dioxide (TiO_2) blasted implants than was found for implants with a turned surface. These findings indicate that the

bone-implant response is greater if implants with a rougher surface are used; however, the long-term clinical advantages of such implant systems are still unknown.

The aim of the present study was to clinically compare two different implant systems that had different surface textures and that were placed in patients with reconstructions done by interpositional bone grafting and Le Fort I osteotomy. Brånemark implants with turned surfaces were placed in the first 11 patients, and Astra Tech implants with TiO_2 blasted surfaces were placed in the following 11 patients; survival rates were 87% and 94%, respectively. No statistical differences were found between the groups. Considering the reduction of the marginal bone level, the implant success rate was higher for the Brånemark implants (70% vs 52%). There was a trend (although not significant) toward a greater risk of marginal bone resorption over time for implants with rougher surfaces, and there was probably a higher risk of future implant losses in patients with those implants. However, a 10-year follow-up is needed to evaluate whether the levels of marginal bone loss have been at a steady state or have been continuous. Although there are no available published reports of long-term comparative bone grafting studies that evaluate marginal bone level, in a 5-year comparative study of Astra Tech and Brånemark implants placed in the maxilla without bone grafting, no differences in marginal bone resorption were found.[13] Mean marginal bone level changes were minimal for both implant systems, which was not in line with the result of the present study of implants placed in grafted bone. In the study by Åstrand and colleagues,[13] no statistical difference in implant success was found, which indicates that implant surface roughness is not of importance in the long run.

In a study by Nyström and colleagues,[9] 10 consecutive patients were treated with interpositional bone grafts and delayed placement of a total of 60 Brånemark implants with turned surfaces. After a follow-up period ranging from 15 to 39 months, 3 (5%) of the implants had failed, all before loading. Kahnberg and colleagues[10] also reported a two-stage procedure similar to that used in the present study and also using Brånemark implants with turned surfaces. In their study there were two groups of patients: (1) the development group (5 patients), which had a 5-year implant survival rate of 60%, and (2) the treatment group (with a further 20 patients), for which the CSR was 85.6%. Twenty-two patients received fixed prostheses, 2 patients received overdentures, and 1 patient (who lost all but one implant) was rehabilitated with a prong denture. In the studies by Nyström and colleagues and by Kahnberg and colleagues, marginal bone reduction and implant success were not evaluated.[9,10] The study by Kahnberg and colleagues indicated a learning curve owing to extensive losses in the first patients treated.[10] This result was also found in another study by Nyström and colleagues, which evaluated maxillary implant failures in patients treated with onlay bone grafts.[14]

In the present study implants with a turned surface were used in the first 11 patients, which could be one possible reason for the lower survival rate in comparison with the Astra Tech group. However, in one of the aforementioned studies by Nyström and colleagues,[9] in which turned-surfaced implants were used, implant survival was as high as 95%, which is similar to the results of the Astra Tech group in the present study. Although the bone response to different implant surface textures is important for shortening implant healing time, the surgeon's experience is probably more important for implant success.

In the present study 75% of implant losses occurred prior to abutment connection, compared to one-third of the implants lost in the study by Kahnberg and colleagues.[10] One cause of the high early implant failure rate might be loading forces or misfit prostheses during the time of implant healing.

The Le Fort I surgical procedure makes it possible to correct the sagittal relation between the jaws. However, in the present study it was found to be difficult to move the maxilla anteriorly more than 7 mm. In most cases the maxilla could be advanced by 4 to 5 mm. This is in line with the findings of Nyström and colleagues, who found a mean average maxillary advancement of 5 mm.[9] They also found a relapse rate of 10 to 28% during the healing period. One of the reasons for this is that the maxilla is often very thin and has a high risk of fracture during mobilization, which may inhibit further advancement.

Only a few complications were found during the 5 years after bone grafting. Three patients had slight muscular problems at the donor site. None of the patients required analgesia for pain. Two patients experienced repeated problems with fistulization at the recipient site in the first 3 years. Phonetic problems, mostly related to the production of the "s" sound, were

found in patients from both groups. The patients marked this no higher than ''2'' to ''3'' on a VAS.

The use of Tisseel and Thrombin in combination with Le Fort I surgery and bone grafting facilitated the procedure. The particulated graft was easily stabilized and secured in position to the floor of the maxillary sinus. However, thrombin has been associated with adverse immune responses in some patients (although not in the present study), and it is valid to question its use. Platelet-rich plasma could be an acceptable alternative.

In the present study 84 Brånemark implants and 72 Astra Tech implants were placed after the Le Fort I procedure and interpositional bone grafting. No evidence was found that either implant system is preferable. However, a power analysis showed that for a power of 90%, the number of implants inserted would need to be four times greater than the number used in the present study in order to identify a statistical difference of 7.5%. The fact that more implants with a marginal bone resorption of > 3 mm were found in the Astra Tech group than in the other group may be of importance when the survival rates in both groups are evaluated in the future. Today there is an increased focus on implant surface modification. However, the present long-term follow-up study did not show any statistical differences between implants with a turned surface and implants with a titanium blasted surface, which is in line with the results of previous studies of the same implant types (but in patients without grafts).[13]

CONCLUSION

The present long-term study shows that the combination of Le Fort I surgery and interpositional bone grafting with delayed implant placement is a predictable treatment modality resulting in high implant survival rates when used with either implants with a turned surface or implants with a titanium blasted surface.

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