Impact of Implant Surface and Grafting Protocol on Clinical Outcomes of Endosseous Implants

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Purpose: *The objectives of this study were to* (1) *evaluate the survival of implants placed in maxillary sinuses augmented with a 70:30 mixture of autogenous bone and anorganic bovine hydroxyapatite (Bio-Oss) at 1 and 5 years,* (2) *observe the difference in survival rate between 1-stage and 2-stage procedures, and* (3) *compare the survival rate of rough-surfaced implants with that of machined implants.* ***Materials and Methods:*** *A total of 30 consecutively patients (48 sinuses) with Cawood and Howell Class V and VI atrophy were evaluated. Lateral osteotomy techniques were used in all cases. Implants were placed either simultaneous with grafting (1-stage procedure) or after a delay (2-stage procedure), depending on the amount of residual bone. A 70:30 mixture of autogenous bone and anorganic bovine hydroxyapatite was used as the graft material. All patients were followed up at 1 year after prosthetic loading, while a limited group of these patients was followed up to 5 years.* ***Results:*** *In 8 patients where the residual crestal bone under the sinus floor assessed by computed tomography was at least 4.5 mm (mean, 5.3 mm), the 1-stage procedure was used for 11 sinus elevations and 32 implants. In 22 patients where the residual crestal bone was less than 4.5 mm (mean, 2.5 mm), the 2-stage procedure was used for 37 sinus elevations and 108 implants. For the 140 implants placed, the overall survival rate was 95.7% at the healing abutment surgery, and the cumulative survival rate was 94.9% at 1 and 5 years. The type of surgical technique was significantly associated with implant failure (*$P < .05$*); implants placed using the 1-stage procedure showed a failure rate of 12.5%, while implants placed with the 2-stage procedure had a failure rate of 2.8%. No significant difference in survival rate was observed with respect to implant surface.* ***Conclusions:*** *A high survival rate was achieved when sinus elevation was performed with a combination of autogenous bone and anorganic bovine hydroxyapatite, even where a minimal amount of residual crestal bone was present. The survival rate was improved when implants were placed after a healing period.* Int J Oral Maxillofac Implants 2007;22:399–407

Key words: *autogenous bone graft, bovine hydroxyapatite, dental implants, maxillary sinus augmentation*

Maxillary sinus elevation is a surgical procedure designed to increase bone volume in the posterior maxilla where insufficient residual alveolar bone is available.[1] The aim of this technique is to elevate the maxillary sinus mucosa and place the graft material between the mucosa and the sinus floor to increase the bone volume available for implant placement in the appropriate prosthetic position. A number of graft materials have been used in conjunction with the lateral approach to the sinus elevation technique, with various degrees of clinical success. These include autogenous bone harvested from intra-[2] and extraoral[3] sites and various bone substitutes, such as demineralized freeze-dried bone allograft,[4] bovine hydroxyapatite,[5] bioactive glass granules,[6] calcium sulfate,[7] and growth factors employed either on a stand-alone basis or in conjunction with a bone matrix.[8]

To achieve bone volume augmentation in the posterior maxilla using bilateral sinus elevation, large amounts of bone grafting material are needed. Such quantities are generally not available from intraoral sites. In this case, grafts are harvested from extraoral sites (eg, corticocancellous blocks taken from the internal aspect of the iliac crest).[9] General anesthesia, an additional surgical site, and postoperative mor-

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bidity at the donor site for patients are inevitable.[10] Where only a unilateral sinus augmentation procedure is performed, and the amount of bone graft needed is limited, the lateral ramus and the retromolar region of the mandible or the chin can be used as the donor site. However, this technique also requires an additional surgical site, with varying degrees of postoperative morbidity, especially following chin bone harvesting.[11,12] Bone substitutes can reduce postsurgery discomfort for patients, as bone harvesting becomes unnecessary, but bone regeneration may be limited in patients having extensive bone defects because of the general lack of osteoinductive properties of bone substitutes. At present, surgeons tend to utilize composite grafts (ie, a mixture of autogenous bone and osteoconductive material). Composite grafts retain the osteoinductive properties of the former and the osteoconductive properties of the latter, while requiring only modest amounts of bone taken from the patient.[13]

A major variable to take into consideration in the maxillary sinus augmentation technique is the decision to place implants immediately at the time of sinus augmentation or after graft consolidation and healing.[14] In the immediate technique,[2,6,15–18] a residual bone height of at least 4 mm for primary implant stabilization generally needs to be present to enable implant placement. As outlined by many authors,[4,5,19–23] the delayed or 2-stage approach is used when primary stabilization cannot be predictably achieved because of the lack of bone height below the sinus floor. The disadvantages of this procedure are a longer healing period and the need for additional surgical procedures. However, histologic analysis from experimental research in monkeys[24] has revealed that delayed implant placement at 4 months following sinus augmentation appears to result in higher rates of direct mineralized bone-to-implant (BIC) contact. However, a comparison between the 2 surgical techniques and their clinical outcomes has been evaluated in few controlled reports to date.[10,15,19–23]

Maxillary sinus augmentation has been applied with implants with different surfaces. Roughened implants have been associated with higher survival rates than machined implants in grafted sinuses.[25] In addition, some experimental evaluations have demonstrated that rough-surfaced implants show more BIC than machined implants.[26,27] Although clinical data in literature show that implants placed in augmented sinuses with autologous bone and osteoconductive material may have high survival rates,[14,25] only a few controlled longitudinal studies have assessed the impact of rough surfaces versus machined surfaces on long-term implant success in conjunction with the sinus augmentation technique.[28,29]

The aim of this study was to evaluate the success of implants at 1 and 5 years after prosthetic loading in sites where a lateral-approach sinus augmentation procedure was undertaken using a mixture of autologous bone and anorganic bovine hydroxyapatite (70:30) as the grafting material. Several parameters were taken into account to evaluate the success of implant osseointegration: implant placement protocol (immediate vs 2-stage surgical technique), type of implant surface (rough or machined), implant length, and the presence or absence of a smoking habit.

MATERIALS AND METHODS

Selection of Patients

Thirty patients (21 women and 9 men) with a mean age of 48.8 years (range, 23 to 67 years) were consecutively treated in this study. The patients were referred to the Department of Oral and Maxillofacial Surgery of the University of Bologna, Italy, for maxillary sinus augmentation because of insufficient alveolar bone volume to allow dental implant placement. Crestal bone of 6 mm or less, as determined by preoperative panoramic and computerized tomography (CT) (Fig 1), between the sinus floor and the alveolar ridge was a prerequisite for inclusion in this study. According to the Cawood and Howell classification,[30] all 30 patients examined had class V or VI atrophy in the posterior maxilla. None of the patients had systemic pathologies affecting the immune system functioning, non–insulin-dependent diabetes mellitus, was undergoing chemotherapy and/or radiotherapy of 5,000 rad or higher, or had a previous history of drug abuse. Eight of the 30 patients were smokers, and 5 had a previous history of smoking. Smokers were advised to reduce or refrain from smoking (less than 10 cigarettes/d). After being informed about the study, all the patients gave their informed written consent.

Maxillary Sinus Augmentation Technique

For all sinus augmentation procedures, the same surgical approach was utilized. A full-thickness flap was raised, and the lateral wall of the maxillary sinus was exposed following 2 vertical releasing incisions and a crestal incision slightly displaced toward the palate. A mean 20 × 10-mm bony trap door was outlined using a round bar in a straight handpiece at 1,500 rpm under copious saline solution irrigation, taking care not to tear the sinus membrane. Once mobility of the trap door was obtained, the sinus membrane was elevated starting from the inferior border of the osteotomy site. The sinus mucosa was carefully elevated using blunt sinus curettes to create sufficient volume to accommodate the bone graft.

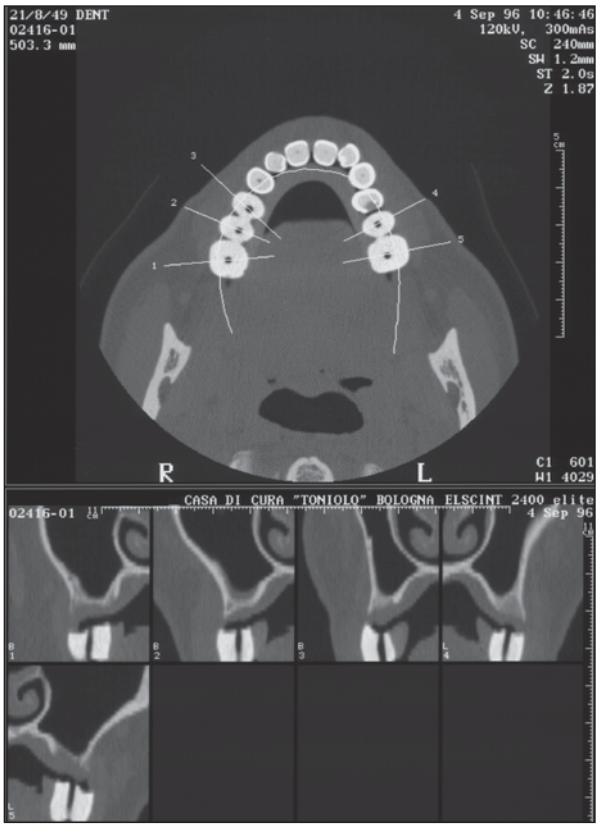

Fig 1 *(Above)* Preoperative CT scan with a radio-opaque diagnostic template showing 5 possible implant sites.

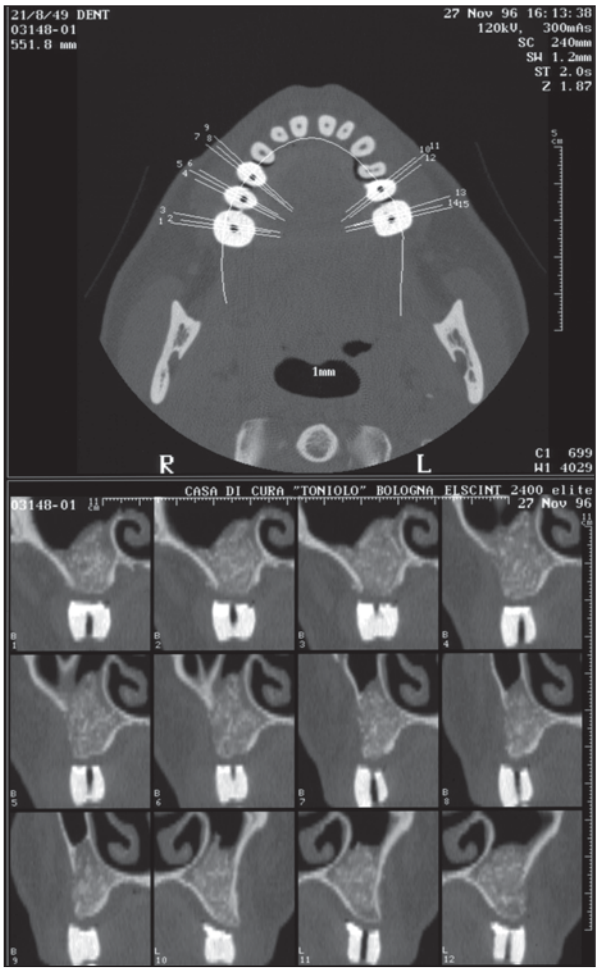

Fig 2 *(Right)* Postoperative CT scan with the same radio-opaque diagnostic template after sinus elevation surgery, with optimal bone filling of implant sites highlighted.

For the patients requiring unilateral sinus augmentation, bone was harvested from the mandibular ramus and performed under local anesthesia (2% lidocaine with epinephrine 1:100,000, Xylocaine/Adrenalin; Astra, Södertälje, Sweden). The mandibular ramus was exposed following a mucoperiosteal incision from the first molar to the lateral area of the ramus. A monocortical osteotomy was performed using a fissure bur. The buccal cortical plate was then infractured laterally with osteotomes. For the patients requiring bilateral sinus augmentation, bone was harvested from the medial wall of the iliac crest under general anesthesia and nasotracheal intubation. The harvesting of bone was performed using a reciprocating saw and bone chisels. With either procedure the harvested bone was then particulated with a bone mill (Quetin Bonemill; Hu-Friedy, Chicago, IL) and mixed with bovine hydroxyapatite (Bio-Oss; Geistlich Pharmaceutical, Wolhusen, Switzerland) in a 70:30 ratio. The mixture of autogenous bone and bovine hydroxyapatite was used to fill the sinus floor prior to implant placement (Fig 2). The mucoperiosteal flap was then replaced; 4-0 vertical interrupted mattress sutures were used to cover the grafts. The implants were placed immediately at the time of grafting when there was adequate height of the residual crestal bone (4.5 mm or more) as determined preoperatively using CT scans. For patients in whom less alveolar bone was present, implant placement was delayed until 5 months after the augmentation procedure. Implant placement was carried out by the 2 clinicians who referred the patients. One operator used sandblasted, acid-etched Frios implants (Frialit-2 System; Friadent, Mannheim, Germany), and 1 operator was trained ad modum Brånemark using machined-surface MK II implants (Nobel Biocare, Göteborg, Sweden). Both operators were in the operating room during surgery when 1-stage implant placement was planned. In the 1-stage procedure, the minimum torque applied was 25 N. Torque was measured at rotation stop with a contra-angle handpiece (20:1 rpm). The implants were prosthetically loaded after a

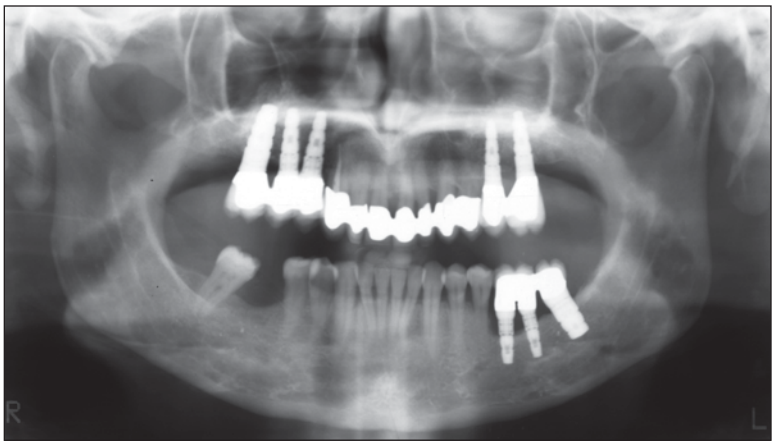

Fig 3 Postoperative panoramic radiograph showing implants at 1 year postloading.

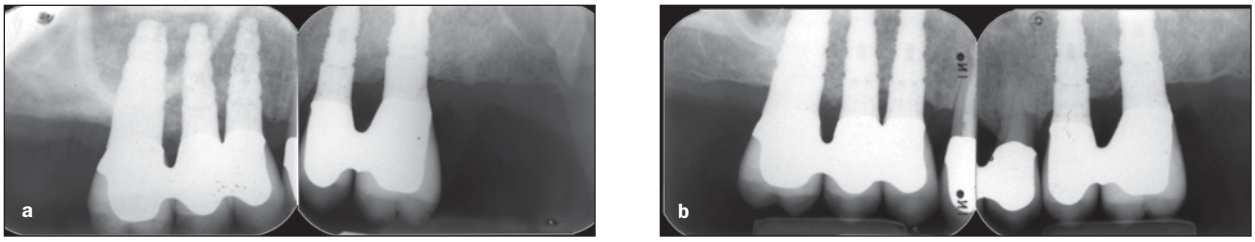

Fig 4 Postoperative intraoral radiographs *(a)* 1 and *(b)* 5 years postloading.

healing period of 5 months. Twenty-seven patients were rehabilitated with fixed partial dentures (Fig 3) and 3 patients with bar-supported constructions.

Medication and Postoperative Care

For both surgical procedures, sinus augmentation and implant placement, the patient received antibiotic therapy (amoxicillin 1 g twice per day, starting 1 day prior to surgery and continued for 7 days postsurgery). For pain, an analgesic agent (ketoprofen [Orudis], Aventis Pharmaceuticals, Bridgewater, NJ) was prescribed. Postoperative oral hygiene was performed with chlorhexidine gluconate 0.2% oral rinsing solution (Corsodyl; GlaxoSmithKline, Research Triangle Park, NC) during the first 15 days. For 2 weeks postsurgery, patients were requested not to wear provisional removable prostheses. Subsequently, provisional removable prostheses were relined using soft lining material (Softliner; GC Corporation, Tokyo, Japan), which was changed every 3 weeks during the treatment period. The patients were then urged to remove temporary prostheses at meals for 2 further weeks. Five weeks after surgery patients were no longer subject to restrictions in the use of temporary prostheses and were allowed to wear them until completion of the definitive prosthetic restoration.

Clinical and Radiographic Examinations

All the implants were screened for complications by the surgeon and the hygienist during implant maintenance care. Clinical assessment of implant stability was performed at the time of healing abutment connection as well as every year from the time of prosthetic loading.

Preoperative radiographic examinations were based on panoramic radiographs, lateral cephalograms, and CT scans. The postoperative examinations at 5 months after grafting included panoramic radiography and CT. Radiographic examination of peri-implant bone resorption was performed through periapical radiographs made using the long-cone paralleling technique, with the central beam on the alveolar crest.[31] Radiographic examination was carried out at the time of abutment connection and at 1 and 5 years from occlusal loading. Measurements were made mesial and distal to each implant using a transparent millimeter ruler. The distance between bone and implant shoulder at the magnification of 7×. The known distance between implant threads was used for purpose of calibration and determination of the exact magnification of the images. The measurements were recorded to the nearest 0.5 mm (Fig 4).

Implant survival rate was evaluated according to the following criteria at the latest clinical and radiographic examination: absence of implant mobility; absence of peri-implant infection with suppuration; absence of persistent peri-implant radiolucency; absence of intolerable pain or paresthesia, anesthesia, or dysesthesia; and radiographic marginal bone loss less than 1.5 mm after the first year and less than 2.5 mm after 5 years.

Statistical Analysis

A total of 140 implants were included in the study, and each implant was considered an experimental unit. The outcome of interest was the occurrence of implant failure. The Kaplan-Meier method was used to assess the implant failure rate at different times. Univariate logistic regression was performed to evaluate the relationship between baseline characteristics and the occurrence of implant failure. Relative risks and odds ratios were calculated. The different occurrence of failures were compared by chi-square test. All the analyses were performed using SAS System version 8.02 (SAS Institute, Cary, NC). All calculated *P* values less than .05 were considered statistically significant.

Table 1 Life Table Analysis of Implant Survival at 1 and 5 years After Prosthetic Loading-Kaplan-Meier Method

Time	No. of implants still at risk for failure	No. of implants failed in the interval	Survival rate for period (%)	Cumulative survival rate (%)
Placement to healing abutment surgery	140	6	95.7	95.7
Healing abutment surgery to 1 year of prosthetic loading	134	1	99.2	94.9
From 1 to 5 years postloading	47	0	100.0	94.9

RESULTS

Forty-eight maxillary sinuses in 30 consecutive patients affected by Cawood and Howell class V and VI atrophy were augmented with a mixture of autogenous bone and Bio-Oss using a lateral osteotomy technique. A 1-stage procedure (implant placement with graft) was used for 11 sinus elevations and 32 implants in 8 patients where the residual crest bone under the sinus floor assessed by tomography was at least 4.5 mm (mean, 5.3 mm). The 2-stage procedure (graft placement, 5 months healing, then implant placement) was used for 37 sinus elevations and 108 implants in 22 patients where the residual crestal bone was less than 4.5 mm (mean, 2.5 mm).

Macroscopic perforations of the sinus membrane were not observed during the sinus grafting procedure. In 3 patients wound dehiscence was reported at the incision site. This complication did not affect the clinical bone graft healing process. In another patient local inflammation of the grafted area was seen 2 weeks postoperatively, and the infection was successfully treated with additional antibiotics (clindamycin twice a day for 1 week). No other patient reported complications.

All 22 patients undergoing bone harvest from the iliac crest reported donor site morbidity in the first 2 weeks postoperatively, particularly during walking. All patients were discharged from the hospital within 5 days after surgery. At 2 months after surgery, pain in the iliac crest was reported by 1 patient and walking difficulties by another patient. No hematomas, serum sickness, or fractures of the iliac crest were observed. Of the 8 patients who underwent bone harvest from the mandibular ramus, 1 reported an infection. That patient was treated with additional amoxicillin for 1 week.

Forty-eight sinus augmentation procedures were performed: 11 augmented sinuses received implants in a 1-stage procedure, the remaining 37 had a bone-graft healing period of 5 months. Of the 140 consecutively placed implants in 30 patients, 62 were sand-blasted, acid-etched Frios implants (Frialit-2 System, Friadent, Mannheim, Germany) and 78 were machined-surface MKII implants (Brånemark System; Nobel Biocare, Göteborg, Sweden). At the time of abutment connection surgery, 6 of the 140 implants placed had failed, representing a 4.3% failure rate. During the first year of prosthetic loading, 1 more implant failed to integrate, raising the failure rate to 5.1%. No subsequent failures were reported within the study period for the 48 implants followed for 5 years after prosthetic loading. At 5 years, the cumulative implant failure rate based on the Kaplan-Meier method was 5.1% (Table 1).

Type of surgical technique was significantly associated with implant failure during the period from implant placement until the 5-year follow-up ($P = .04$; Table 2). Implants placed with a 1-stage surgical technique were 5.0 (95% CI, 1.057 to 23.650) times more likely to fail in this interval than implants placed with a 2-stage surgical technique. Implants placed with a 1-stage technique incurred a higher failure rate (12.5%, or 4 of 32 implants) compared with the implants placed with a 2-stage technique (2.8%, or 3 of 108 implants).

The implant failure rate was analyzed in relation to the type of implant surface. Implants with a machined surface were 2.055 (95% CI, 0.385 to 10.970) times more likely to fail than implants with rough surfaces, but this difference was not statistically significant ($P = .40$, Table 2).

Table 2 Distribution of Placed and Failed Implants

	No. of implants	Failures		Survival rate (%)	OR	95% CI
		n	%			
Surgical technique						
1-stage	32	4	12.5	87.5	5.000	1.057 to 23.650*
2-stage	108	3	2.8	97.2		
Surface						
Machined	78	5	8.6	91.4	2.055	0.385 to 10.97
Rough	62	2	3.7	96.3		

Univariate logistic regression. OR = odds ratio. *The difference was statistically significant ($P < .05$).

Table 3 Distribution of Placed and Failed Implants with Regard to Surface, Diameter, and Length

	No. placed	Failures	
		No.	%
Diameter			
Machined			
3.75 mm	37	4	10.8
4 mm	20	0	0
5 mm	21	1	4.7
Total	78	5	6.4
Rough			
3.8 mm	19	0	0
4.5 mm	25	2	8
5.5 mm	11	0	0
6.5 mm	7	0	0
Total	62	2	3.2
Length			
Machined			
10 mm	3	0	0
13 mm	42	4	9.5
15 mm	31	1	3.2
18 mm	2	0	0
Total	78	5	6.4
Rough			
10 mm	1	0	0
13 mm	37	2	5.4
15 mm	24	0	0
Total	62	2	3.2

The number and distribution of implant failures with their related lengths and diameters are shown in Table 3. The majority of implants (n = 37) were 3.75 in diameter. The most commonly used diameter was 3.75 for machined implants. Four (10.8%) of 37 implants with a diameter of 3.75 mm failed. No implant failures occurred in the 4 patients who had 10-mm implants placed. Six failures were reported among the 13-mm implants (6 of 79, or 7.6%), 1 among 15-mm implants (1 of 55, or 1.8%), and none for the two 18-mm implants. There were too few failures to statistically analyze the difference in failure rate by length.

As for the impact of smoking on implant integration, 111 of 140 implants (79.3%) were placed in nonsmokers (22 patients); 63 were machined and 48 were rough-surfaced. Five failures (3.6%) were recorded, and all involved machined implants. In addition, 29 implants, 14 machined and 15 rough-surfaced, were placed in smokers. Two failures (1.4%) were reported; both involved rough-surfaced implants.

DISCUSSION

The results of this investigation demonstrate success predictability for both roughened and machined implants loaded in maxillary sinuses augmented with a 70:30 mixture of autogenous bone and anorganic bovine hydroxyapatite. A higher survival rate was associated with the 2-stage procedure.

Only patients who presented with Cawood and Howell class V or VI atrophy were included in this study; patients requiring augmentation of an existing alveolar crest were not included in the study group. Patients were examined radiographically with CT with multiplanar reformation. Preoperative tomography allowed precise measurement of the existing alveolar bone, which cannot be evaluated with the normal radiographic techniques unable to take into consideration the alveolar crest slope and smaller bone volumes at the center of the crest, buccally and palatally. Instead, CT enabled the surgeons to determine the exact amount of bone beneath the maxillary sinus floor. The cutoff for the use of the 1-stage procedure was set at 4.5 mm for all implant sites. If 1 measurement was below this threshold, all implant placements were delayed. The mean residual bone height found with CT for patients undergoing the 2-stage procedure was 2.5 mm. All delayed implants were placed at 5 months after sinus augmentation, following subsequent bone evaluation with CT. The same consolidation period of 5 months was adopted when implants were placed in a 1-stage procedure. Healing periods were kept short due to the amount of autolo-

gous bone used. The mean period for revascularization of the bone graft was demonstrated to be 3 to 4 months; consequently, to avoid more graft resorption, implants were placed at 5 months. The use of autogenous bone in combination with bovine hydroxyapatite may be advantageous for enhancing the resistance to resorption and grant better bone graft conservation over time.[32] The clinical results of this study are compatible with the observations of other authors concerning the use of Bio-Oss together with autogenous bone,[13,32–34] although the amount of residual bone in the present study was greater than in other studies. A study in which a composite graft of autologous bone and particulate alloplastic graft material were used in the same proportions as in this study reported a 94% survival rate using HA-coated endosseous implants.[34]

A significantly higher failure rate was associated with the immediate procedure in comparison to the delayed procedure at 1 year (12.5% vs 2.8%, respectively). All implants placed immediately at the time of grafting showed primary stability (25 N). The difference in survival rates might be caused by the fact that implant placement immediately at the time of sinus elevation does not allow maximum revascularization of the graft, which reduces the quantity and mineralization of new bone formed as well as the BIC.[35] At the Sinus Graft Consensus Conference of 1996,[36] it was reported that the outcome of the delayed technique was better only in implants placed in augmented sinuses with autologous bone. Where other materials and/or a composite grafts were used, no statistically significant difference was found between the 2 procedures. The present results contract these findings as well as results reported by Jensen.[37]

When the present clinical study was begun in 1997, the choice of implant surface (rough or machined) rested with the clinicians referring each patient rather than on clinical or radiographic examinations. These examinations were carried out later. The 2 failures of roughened implants of 62 placed and the 5 machined implants of 78 placed represented failure rates of 3.7% and 8.6%, respectively, but these results are not statistically significant. The small number of failures found in this study are probably the reason the difference in failure rate between the 2 surfaces did not reach statistical significance, although histologic and histomorphometric evidence shows that roughened implants placed in human augmented maxillary sinuses have more BIC.[38] In previous studies, a higher success rate was found for rough-surface implants versus machined-surface implants especially when placed in poor quality bone[39] and in autogenous maxillary grafted bone.[40] A recent literature review[25] reported that rough-surface implants show a significantly higher survival rate compared to machined-surface ones in augmented sinuses, while other systematic reviews demonstrated no significant differences in survival among implant surfaces.[40–42] The clinical impact of different surfaces on the success rate of implants placed in maxillary sinuses is not completely clear. In fact, a recent report has shown a 100% success rate with machined-surface screw-type implants.[43]

Six 13-mm implants and one 15-mm implant failed. The majority of implants placed were either 13 or 15 mm long; the statistical analysis demonstrated, however, that implant length was not to be regarded as a variable affecting their survival. Implant length ranged from 10 to 18 mm, with over 95% implants being 13 or 15 mm long, and the implant length might actually be a factor contributing to the high success rate of this study. Implant length, especially where 10 mm or shorter, has been reported as a significant parameter related to implant failure in augmented maxillary sinuses.[44–46]

The composite graft used in the sinus augmentation procedures in the present study was associated with a low failure rate but also with donor site morbidity, especially within the first few weeks postoperatively. Recent clinical studies show very promising short- and medium-term results[47,48] with alloplastic material, which suggests that the future of this technique rests upon further long-term studies using only bone substitute.

CONCLUSIONS

This study demonstrates that maxillary sinus augmentation with a 70:30 mixture of autologous bone and anorganic bovine hydroxyapatite is a reliable procedure with an elevated final success rate. The 2-stage technique has proven to be significantly more successful compared to the immediate technique. Failures occurred at surgical exposure or within 1 year of prosthetic loading.

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