

Risk Factor Analysis Following Maxillary Sinus Augmentation: A Retrospective Multicenter Study

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Purpose: Implant-supported rehabilitation of the atrophic posterior maxilla often necessitates maxillary sinus surgery to augment existing bone volumes. Recent systematic reviews have reported implant survival rates above 90% following sinus elevation. However, statistical assessment of the effect of anatomic factors, implant design and surface, individual risk factors, and complications related to sinus floor elevation procedures on implant survival through analyzing patient data has not yet been performed. The aim of this study is to identify risk factors that might affect implant survival following sinus elevation. **Materials and Methods:** Three centers were involved in this retrospective multicenter study; 106 patients were treated with 144 sinus elevation procedures and received 328 implants. The mean follow-up was 48.4 months, and the longest follow-up period was 72 months. The analysis considered patient age, gender, health status, and smoking habit; implant size, shape, and surface; residual ridge height; timing of implant placement with respect to grafting; graft material; and the occurrence of surgical complications. For quantitative variables, the Pearson correlation was used. The chi-square test and Fisher exact test (for samples smaller than five units) were used for qualitative variables. **Results:** The cumulative implant survival rate was 93.0% up to 5 years. Complications occurred in 41 patients. Intraoperative sinus membrane perforation occurred in 40 sinuses (28%) and was not a significant risk factor for implant survival. Six patients experienced postoperative infection leading to graft failure, and two patients had considerable intraoperative bleeding. Smoking more than 15 cigarettes/day and a residual ridge height < 4 mm were significantly associated with reduced implant survival. **Conclusions:** Smoking habits and residual ridge height should be evaluated carefully prior to sinus elevation procedures. *Int J Oral Maxillofac Implants* 2012;27:1170–1176

Key words: atrophic maxilla, maxillary sinus elevation, residual ridge, sinus membrane perforation, smoking

Implant-supported rehabilitation of the atrophic maxilla can be a clinical challenge. The loss of posterior teeth and the subsequent progressive maxillary sinus pneumatization result in alveolar bone atrophy and may affect the ability to place implants of adequate size and length. Following tooth extraction or loss, an initial buccopalatal reduction of bone volume occurs because of the interruption of blood supply to the bone plate and to the absence of occlusal loads.^{1,2} Re-

sorption takes place in an apical direction and occurs together with an increase in sinus pneumatization^{3,4} as a consequence of intrasinus positive pressure.⁵ As a result, the sinus floor is closer to the alveolar ridge.

Maxillary sinus floor elevation allows the rehabilitation of the atrophic maxillary ridges. This surgical procedure, initially developed by Tatum⁶ at the end of the 1970s, was first published in a clinical study in 1980 by Boyne and James.⁷ According to the original technique, the antrostomy is performed on the buccal wall of the maxillary sinus, the sinus membrane is elevated, and the graft (autogenous bone harvested from the iliac crest) is placed.⁷

The surgical protocol has evolved through the years regarding harvesting site, grafting materials, implant characteristics, and timing of implant placement. Autogenous bone has long been considered the “gold standard” for atrophic ridge regeneration because of its unique osteogenic, osteoinductive, and osteoconductive properties. The development of biomaterials with osteoconductive properties can represent a valid alternative to autogenous bone. Bone substitutes can provide a scaffold for bone regeneration, eliminating

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the need to harvest autogenous bone. Recent literature reviews have reported no differences in implant survival rates in patients treated with autogenous bone or bone substitutes as a sinus grafting material,⁸⁻¹⁰ with overall implant survival rates well above 90% in both cases.⁸⁻¹¹ The use of implants with a textured surface and the placement of a nonresorbable or resorbable membrane over the antrostomy are associated with increased implant survival rates.¹⁰⁻¹²

Surgical procedures for maxillary sinus surgery are widely documented; however, consistent data regarding the effect of various factors (anatomic factors, implant design and surface, individual risk factors, and complications) on clinical outcomes are still lacking. Systematic reviews, although conducted on large patient samples, use mean data from individual studies rather than individual patient data, which are needed if the effect of individual factors is to be evaluated. To the authors' knowledge, for sinus elevation there is a lack of studies with an adequate sample size reporting individual patient data.

The aim of this study was to use multivariate analysis to identify risk factors affecting implant survival rates in patients who have undergone maxillary sinus surgery.

MATERIALS AND METHODS

Three centers were involved in this retrospective multicenter study (the Dental Clinic at the Galeazzi Institute in Milan and two private practices). These centers have long collaborated and have been using standardized charts to record preoperative and postoperative data.

Charts of sinus elevation patients treated during a 9-year period, from November 2004 to February 2009, were reviewed and data were collected via specific forms. The study population was selected based on the following inclusion criteria: (1) good health (American Society of Anesthesiologists [ASA] status 1 or 2), (2) missing maxillary posterior teeth either unilaterally or bilaterally, and (3) a residual ridge height ≤ 6 mm in the posterior maxilla.

Patients for whom data relating to the prosthetic rehabilitation were unavailable were excluded from the analysis.

Lateral Window Surgical Technique

One hour prior to surgery, patients received preoperative medication (2 g amoxicillin + clavulanic acid, Augmentin, Roche). If the patient was allergic to penicillin, macrolides were used. Sites were anesthetized (articaine 4% with adrenaline 1:100,000) via slow subperiosteal infiltration, with a flow of 1 mL/min maintained. A full-thickness flap was elevated. The releasing incision

was made parallel to the vascular supply and was dependent on the anteroposterior extension of the sinus and the position of the planned antrostomy.

The antrostomy, oval in shape when possible, was free of sharp edges that could cause perforations of the sinus membrane. A few anatomic factors determined the morphology of the antrostomy, eg, Underwood septa, which were detected preoperatively on computed tomographic scans. Another anatomic factor considered was the position and the course of the vascular anastomosis between the posterior superior alveolar artery and the intraorbital artery inside the buccal wall of the sinus. The medial extent of the antrostomy allowed access to the anterior recess, while the distal extent depended on the planned number of implants.

The subsequent sinus membrane elevation was extended to the medial sinus wall. In case of membrane perforation, a resorbable collagen membrane was used to protect the sinus membrane during site preparation and grafting procedures.

The graft material was first placed in the anterior and posterior recesses and was not compacted too densely to ensure the vascular neogenesis that was necessary for bone formation. The flap was closed without tension; if necessary, periosteal releasing incisions were made to help achieve passive closure.

When the residual ridge condition allowed primary stability of the implants, the implants were inserted during the same surgical session as the sinus elevation (simultaneous procedure). Otherwise, the implants were placed in a subsequent surgical phase, after 6 to 9 months (delayed procedure). In the latter case, implant placement could follow either a submerged or a non-submerged technique. The following postoperative medications were prescribed: amoxicillin and clavulanic acid (1,000 mg three times a day), naproxen (500 mg two times daily), and chlorhexidine oral rinse (two times daily for 1 minute). Macrolides were prescribed for patients who were allergic to penicillin.

Variables

The following variables were analyzed and correlated to implant survival:

1. Age, gender, and health status
2. Smoking habit (number of cigarettes per day)
3. Implant macrogeometry (shape, diameter, and length)
4. Implant microgeometry (type of surface)
5. Height of the residual ridge at the intended implant site in the posterior maxilla
6. Type of grafting material
7. Timing of implant placement with respect to grafting (simultaneous or delayed)
8. Single-stage or two-stage implant placement

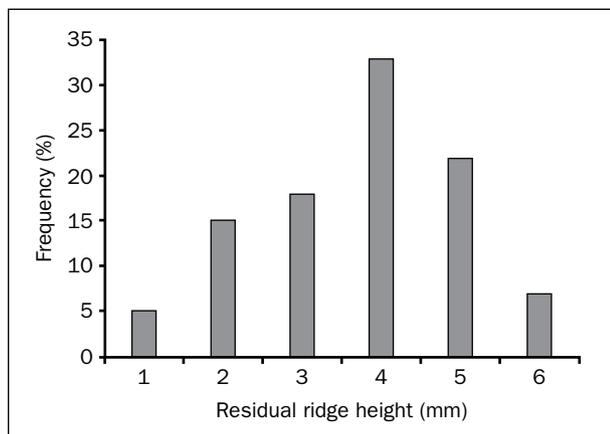


Fig 1 Distribution of residual ridge height.

In addition, intraoperative and postoperative complications were described and analyzed.

Statistical Analysis

The statistical analysis of the data was carried out using SAS 9.1 (SAS Institute) and SPSS version 17.0 (SPSS, IBM). Statistical analysis of the quantitative and continuous variables (age, height of the residual ridge, number of cigarettes smoked per day, implant diameter and length) was performed using the Pearson correlation. Significance was defined using the Pearson coefficient sample distribution with n – 2 degrees of freedom. The Pearson coefficient *r* was calculated by means of dichotomous variables coded 0 and 1. The significance threshold for this test was set at 5%.

The chi-square test was used to analyze the qualitative variables (gender, smoking habit, implant design). When the sample size was smaller than five, the Fisher exact test was used. Odds ratios and 95% confidence intervals were also calculated.

RESULTS

The initial population included 140 consecutively treated patients, who received a total of 404 implants. All implants had a rough surface. After the inclusion and exclusion criteria were applied, the resulting final population included 106 patients. They received 328 implants, and 144 sinuses were elevated. Sixty-eight unilateral (36 right and 32 left maxillary sinus) and 38 bilateral sinus elevation procedures were performed. Surgeries were carried out over a 60-month period, from November 2004 to February 2009. The observation period continued to November 2010, resulting in a mean follow-up period of 48.4 months after implant insertion. The ages of the patients at surgery ranged

Table 1 Characteristics Associated with Failed Implants

Patient	Gender	Center	Age (y)	Smoking (/day)	Residual height (mm)
1	F	1	65	No	4 4
2	F	3	57	No	4 4 4
3	M	1	52	No	2
4	F	2	58	No	3
5	F	3	51	> 30	3 3
6	M	1	52	> 30	2 2 2 2 2
7	F	1	53	11–30	1.8 1.5 1.5 2
8	F	1	46	No	2.5
9	M	1	54	No	3.5
10	M	3	44	11–30	2
11	F	3	66	No	5.6
12	F	1	51	No	3.5

*FDI tooth-numbering system used.
 ABG = autogenous bone graft; Beta-TCP = beta-tricalcium phosphate;
 BMP-7 = bone morphogenetic protein-7 and collagen sponge;
 Con = conical; Cyl = cylindrical; DBB = deproteinized bovine bone;
 Del = delayed; L = large granules; NR = not reported; S = small granules;
 Sim = simultaneous.

between 28 and 77 years (mean age, 55). Fifty-four percent of the patients were female and 46% were male; 93.7% were classified as ASA 1 and 6.3% as ASA 2. Smokers made up 23.15% of the population; 84.3% of them smoked fewer than 15 cigarettes/day and 15.7% smoked more than 15 cigarettes per day.

The residual ridge height ranged between 1 and 6 mm. The mean residual ridge was 3.9 mm high (Fig 1). Xenograft (deproteinized bovine bone [DBB], Bio-Oss, Geistlich Pharma) was the most frequently used grafting material (75.5% of cases). It was used in large granules (46.8% of cases), small granules (17.5%), or a combination of both large and small granules (11.2%). Autogenous bone alone and in combination with DBB was used in 13.5% and 7.0% of cases, respectively. Other bone substitutes alone (2.2%) or in combination with autogenous bone (1.8%) were also used in a few patients.

Failure time (mo)	Implant size (mm)	Implant shape	Graft material	Implant site*	Time of implant placement	Abutment placed	Complications
0	4 × 15	Con	DBB-L	16	Sim	Two-stage	Perforation
0	4 × 15	Con	BMP-7	26			Perforation
0	4 × 13	Con	ABG	15	Sim	Single-stage	None
0	4 × 13	Con		13			
0	4 × 13	Con		16			
0	5 × 13	Con	DBB-L	26	Sim	Two-stage	None
6	4 × 13	Con	DBB-L	15	Del	Single-stage	Perforation
0	4 × 13	Cyl	DBB-L	25	Sim	Single-stage	Graft failure
0	4 × 13	Cyl		26			
0	4 × 15	Cyl	ABG+DBB	16	Sim	Two-stage	
0	5 × 10	Con	ABG+DBB	23			
0	4 × 13	Con		24			Perforation
0	4 × 15	Con		25			
0	4 × 13	Con		26			
6	4 × 13	Con	DBB-S	16	Del	Single-stage	Perforation
6	4 × 13	Con	DBB-S	15			
6	4 × 13	Con	DBB-S	25			Perforation
6	5 × 13	Con	DBB-S	26			
0	4 × 13	Con	Beta-TCP	16	Sim	Single-stage	Infection
0	5 × 13	Cy	NR	24	Sim	Two-stage	None
9	5 × 13	Cyl	DBB-L	26	Del	Single-stage	Perforation
0	4 × 11.5	Cyl	No graft	26	Sim	Single-stage	None
9	4 × 13	Con	DBB-L	16	Sim	Two-stage	None

Complications occurred in 41 patients. Forty intraoperative sinus membrane perforations occurred in 33 patients. Of these, seven perforations in five patients were associated with the failure of 12 implants. Six patients experienced postoperative infection leading to graft failure, and two patients had considerable intraoperative bleeding.

With respect to implant design, 60.9% were conical and 39.1% were cylindrical. Implants placed during the sinus elevation procedure accounted for 58.2% of those placed. Of these, 25.0% were placed in a single-stage procedure (nonsubmerged) and 75.0% were placed in a two-stage procedure (submerged). Of the 52 implants inserted according to the simultaneous, single-stage procedure, 37 (71.2%) were placed in sites with a residual bone height of > 4 mm. Implants placed after graft consolidation accounted for 41.8% of the total. Of these, 17.0% were placed in a single-

stage procedure and 83.0% were placed in a two-stage procedure.

A total of 23 implants (7% of total implants placed) failed during the observation period. Table 1 shows the main characteristics associated with failed implants. Sixteen failures (69.6%) occurred during the healing period, and the remaining seven failures occurred within 1 year of loading. Sixteen (69.6%) of the failed implants were clustered in five patients who experienced multiple failures. In three of these patients, an intraoperative perforation occurred (in two patients, it was bilateral). Implant failures occurred in 15 sinuses (10.4% of total sinuses treated) belonging to 12 patients (11.3% of total patients treated). The overall implant survival rate was 93% over a mean follow-up period of 48.4 months. The health status of the patients did not seem to affect implant survival.

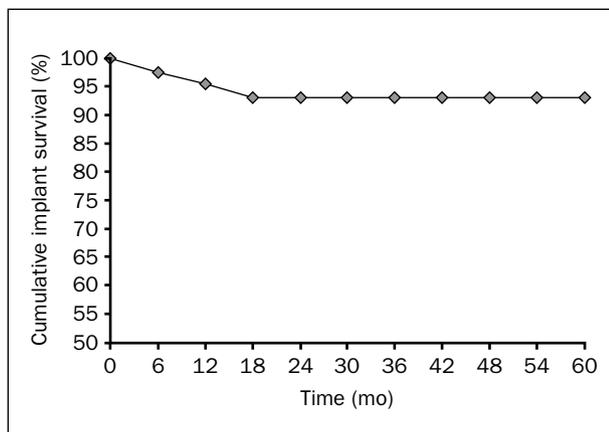


Fig 2 Cumulative implant survival after placement. No failures occurred after the first 18 months.

Implant Survival

Cumulative survival analysis was carried out using the nonparametric Kaplan-Meier method. Failure of implants associated with sinus augmentation occurred mainly within the first 18 months following surgery (Fig 2).

Effects of Risk Factors

Quantitative variables (patient age, height of the residual ridge, number of cigarettes smoked per day, number of surgeries, implant diameter and length) were analyzed according to the Pearson correlation test to evaluate their specific effects on implant survival. Patient age, number of surgical procedures, and implant diameter and length did not affect implant survival in a significant way. In contrast, smoking more than 15 cigarettes per day was significantly correlated to implant failure (chi-square test, $P < .001$). Residual ridge height < 4 mm was also correlated to an increased risk of implant failure (negative Pearson coefficient, $r = -0.17$).

The correlations between the time lapse between grafting procedures and implant placement for delayed implants and the residual ridge height for each implant site were also analyzed. The time lapse between maxillary sinus surgery and implant placement varied from 4 to 9 months for delayed procedures. The analysis of the time lapse in relation to implant failure produced a negative Pearson correlation coefficient ($r = -0.004$), suggesting that an increase in the healing time should reduce implant failures. However, this finding was not statistically significant ($P = .43$).

The chi-square test or Fisher test (as appropriate) was used to analyze qualitative variables (gender, smoking habit, implant shape, and intraoperative and postoperative complications). Implant shape (cylindric

versus conical) did not significantly affect the implant failure rate ($P = .21$). Gender and intraoperative and postoperative complications also did not affect implant survival.

On a per-patient basis, sinus membrane perforation did not represent a significant risk factor for implant survival ($P = .040$). However, on a per-implant basis, sinus membrane perforation was significantly associated with implant failure ($P = .01$).

Analysis of smoking habit as a qualitative variable confirmed the data obtained from the quantitative analysis, with failure rates of 18.57% in smokers and 4.70% in nonsmokers; this was a highly significant difference (odds ratio 9.48, 95% confidence interval 3.90 to 23.02; $P < .0001$).

It was not possible to assess the influence of graft type on implant survival, since DBB was by far the most frequently used material (75.5% of the augmentation procedures).

DISCUSSION

The overall implant survival rate of 93% after a mean of 48.4 months is in agreement with the results published in most recent literature reviews.⁹⁻¹¹ The following variables were analyzed: patient age, gender, and health status; smoking habit; implant size, shape, and surface; residual ridge height; timing of implant placement with respect to grafting; graft material; and the occurrence of surgical complications.

In this study, the mean residual bone height was 4 mm. Statistical analysis showed that a residual bone height of < 4 mm was associated with an increase in implant failures, confirming data available in the literature.^{13,14} Similar findings were reported by a recent prospective study that specifically addressed this issue.¹⁵ A recent review of the available literature on maxillary sinus augmentation, based on a meta-regression analysis, produced similar results; these showed that there is a significant correlation between a residual ridge height of less than 4 mm and increased implant failure, independent of other confounding variables.¹⁶

The number of surgeries (simultaneous or delayed implant placement) did not affect implant survival, although a longer healing period between bone grafting and implant placement resulted in a moderate increase in implant survival, as was also suggested by recent literature reviews.⁹⁻¹¹ Recent studies have shown that implants placed according to a simultaneous procedure (in the same session as sinus grafting) achieve a significantly higher survival rate versus implants placed in a second surgical session after the graft has healed.^{10,12} It can be hypothesized that a more favorable condition of the maxilla is present in

sites that allow simultaneous implant placement, and this can represent an important factor that is beneficial to the outcome of the treatment. Most of the procedures evaluated in this study used a more conservative approach (ie, a two-stage procedure). In the simultaneous, single-stage procedures, most patients had a residual bone height of more than 4 mm, and fewer patients had a reduced bone height. Although the literature describes cases in which a single-stage procedure has been performed in an arch with a residual alveolar bone height between 1 and 2 mm,^{17,18} the number of analogous cases in the present study is quite limited and a conclusion cannot be drawn regarding this specific issue.

Sinus membrane perforation did not affect implant survival on a per-patient basis, whereas when the implant was considered as the unit of analysis, sinus membrane perforations were significantly related to failure. This might indicate that, in some instances, a perforation could interfere with the healing process, perhaps impairing the regeneration potential associated with the sinus membrane itself. Another consideration deriving from this finding is that the choice of the unit of analysis (patient, sinus, implant) is critical for determining the significance of a given factor on the outcome. According to modern evidence-based medicine, the patient should be used, whenever possible, as the unit of analysis. If the effect of perforations on implant failure is analyzed with the implant as the unit of analysis, it might be concluded that whenever a perforation occurs there is a high risk that one or more implants will fail. However, in 28 patients in the present study (84.8% of total perforations), this event did not lead to graft or implant failure.

Several studies of the use of short implants (≤ 8.5 mm) showed survival rates that are similar to those reported for longer implants.¹⁹ In the present study, implant macrogeometry (shape and size) did not significantly influence implant survival.

Patient age is a seldom-investigated variable. In a retrospective cohort study of 1,140 patients treated between 1982 and 2003, a stepwise logistic regression was used to analyze implant failure rates to determine associated risk factors.²⁰ When the results were divided according to age groups, a 91.2% success rate was achieved in patients younger than 40 years, while for patients between 40 and 59 years and between 60 and 79 years, the corresponding success rates were 86.7% (relative risk [RR] = 1.66) and 82.1% (RR = 2.24; $P < .05$), respectively.²⁰ Therefore, increased age was strongly associated with the risk of implant failure. The same study also found a significant effect of smoking behavior. The implant success rate in patients who smoked (15% of total patients) was 79.77% (RR = 1.56), which was significantly lower than the success rate in

nonsmokers ($P = .03$). Most of the failures in smokers occurred within the first year.²⁰ However, the cited study did not take into account the number of cigarettes smoked per day. In the present study, smokers accounted for 23.15% of the patients; 84.3% of these consumed up to 15 cigarettes/day, while the remaining 15.7% smoked more than 15 cigarettes/day. The cutoff point of 15 cigarettes/day was obtained from the median number of cigarettes smoked daily and was preferred to the mean value, because it was influenced less by the extreme values. Implant survival was lower in patients smoking more than 15 cigarettes/day, showing that the number of cigarettes smoked is also important in assessing implant failure risk.

Of the 12 patients in whom implant failures occurred, five experienced more than one failure, accounting for 70% of the total failures recorded and suggesting a clustering behavior. Three of these patients experienced an intraoperative sinus membrane perforation, suggesting that such an event might have interfered with the osseointegration process. Clusters of implant failures in some patients have been previously reported in several studies^{21,22} and analytic models have attempted to describe this occurrence.²³ The same failure pattern was also seen in a recent clinical study that compared survival rates of implants placed in grafted sinuses to those of implants placed in native bone.²⁴

CONCLUSIONS

Implants placed in combination with maxillary sinus elevation in the atrophic posterior maxilla were associated with two main risk factors: a smoking habit of > 15 cigarettes/day and a residual ridge height of < 4 mm. These variables affected implant survival rates in a significant way and should be evaluated during the diagnostic phase. Sinus floor elevation is a predictable procedure with low morbidity and an expected implant survival rate well above 90% in the midterm to long term. Sinus infection with graft failure occurred in 5.6% of patients, which is in agreement with the current literature. Intraoperative sinus membrane perforation did not represent a significant risk factor for implant survival.

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