

# Implants placed in combination with an internal sinus lift without graft material: an analysis of short-term failure

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Gabbert O, Koob A, Schmitter M, Rammelsberg P. Implants placed in combination with internal sinus lift without graft material: an analysis of short-term failure. *J Clin Periodontol* 2009; 36: 177–183. doi: 10.1111/j.1600-051X.2008.01357.x.

## Abstract

**Aim:** Investigation of the short-term survival of implants placed in combination with an internal sinus lift (ISL) without graft material.

**Material and Methods:** Thirty-six patients received 92 screw-shaped dental implants in combination with an ISL. No bone grafts or bone substitutes were used. Forty-four patients with 77 implants in the native posterior maxilla served as controls. X-rays taken after implant placement and 6 months later were evaluated for the presence of bone gain at the apical aspect of the implants. Kaplan–Meier survival curves and Cox regression analysis were used to estimate survival curves and to isolate risk factors for implant failures.

**Results:** Within a mean observation period of 1.2 years (minimum 9 months; maximum 3.7 years), four failures were recorded in the experimental group and two in the controls. The probability of survival was above 94% for both groups. Six–nine months after surgery, bone gain was observed in 29 out of 92 implants. Comparison of the experimental group and controls revealed no effect of ISL and membrane perforation on the probability of survival.

**Conclusions:** Promising short-term outcomes were observed for implants with ISL without graft material; for a substantial proportion of implants, apical bone gain was observed in the first 6–9 months.

Key words: dental implants; graft; internal sinus lift; osteotome; sinus floor elevation

Accepted for publication 6 November 2008

Elevation of the maxillary sinus floor, using a lateral window, in combination with sinus grafting, has been performed for nearly 20 years (Boyne & James 1980, Tatum 1986). The conventional technique is based on elevation of the Schneiderian membrane from the floor of the sinus, followed by introduction of a bone graft or a bone substitute to

preserve space for the implant. The procedure is technically demanding and invasive, with additional morbidity and cost. Factors such as the surgical technique and the type of graft material or implant can affect implant survival (Jensen et al. 1998, Fugazzotto 2003, Wallace & Froum 2003, Del Fabbro et al. 2004).

The internal sinus lift (ISL) was introduced by Summers as a less invasive procedure with a crestal approach for sinus floor elevation without osteotomy. Following a pilot drill up to the sinus floor, the bony floor and the membrane are elevated with a hand osteo-

tome by pushing the graft material forward. The primary stability of the implant can be increased by compression of the spongiosa. The ISL technique is an option for predictable implant installation in maxillary bone only 5–7 mm in height (Summers 1994a,b, Rosen et al. 1999).

Various graft materials, including autografts, allografts, and synthetic bone grafts, have been used to augment the volume between the sinus floor and the elevated Schneiderian membrane (Rosen et al. 1999, Deporter et al. 2000, Ferrigno et al. 2006, Maiorana et al. 2006). Previous studies reported

## Conflict of interest and source of funding statement

The authors declare they have no conflict of interests. This study was self-funded by the authors and their institution.



an implant survival rate between 75% and 100% after 4–5 years for both augmented and non-augmented sinuses (Graziani et al. 2004).

No clear recommendation was given about which material is superior, however. Autogenous bone grafts are still the gold standard, but shrinkage and a remodelling process associated with loss of graft height are observed for all types of grafts during the first 1–3 years after augmentation (Hallman et al. 2002, Braegger et al. 2004, Maiorana et al. 2006). In recent years, the sinus floor elevation technique has also been performed using a modified approach, differing from other procedures, in which no graft material is placed in the newly created space underneath the Schneiderian membrane (Bruschi et al. 1998, Lundgren et al. 2004, Leblebicioglu et al. 2005, Li 2005, Ellegaard et al. 2006, Ferrigno et al. 2006, Nedir et al. 2006). Although there is ample evidence to support the lateral-wall approach and the use of graft materials, even in conjunction with the ISL, there is a lack of studies evaluating the efficacy of the osteotome technique and the related risk factors that might affect the success of the implant.

In this case series, therefore, the authors attempted to verify the hypothesis that the survival of implants placed in the ungrafted atrophic posterior maxilla is similar to that of implants in the native posterior maxilla.

The objectives of this clinical study were:

1. to investigate the short-term performance of maxillary implants placed in combination with an ISL without a graft and to compare it with that of implants placed in the native maxilla;
2. to evaluate intra-operative complications and implant survival after a minimum observation period of 9 months; and
3. to clarify whether the osseo-inductive nature of the local bone chips of the perforated sinus floor covered by the sinus mucosa like a membrane will lead to the growth of new bone.

## Materials and Methods

### Patients

The prospective clinical study was conducted in accordance with the World Medical Association Declaration of Helsinki and was approved by the regional

ethics committee (ethical registration number 229/2005). All participants gave their informed consent. Implant placement and prosthetic treatment were exclusively performed at the department of Prosthodontics of the University of Heidelberg.

Depending on their residual bone height (RBH), all patients of the department of Prosthodontics of the University of Heidelberg who fulfilled the inclusion criteria were included in either the test or the control group in a parallel group design without any matching procedure or randomization. The study group comprised 36 patients, 16 men and 20 women, mean age  $57.72 \pm 12.4$  years (range 20–76 years), with a lack of sufficient bone height in the posterior maxilla. The patients were in good general health. All patients were non-smokers and none of them displayed signs and symptoms of sinus disease, as was confirmed by clinical and radiographic assessments before surgery. Forty-four patients (26 men, 18 women; mean age  $59.77 \pm 11.7$ ; range 32–85 years) who received 77 implants in the posterior maxilla without sinus floor elevation served as controls.

### Surgical procedure

All patients underwent a radiographic examination before surgery, to calculate the RBH, immediately after implant placement and 6–9 months later. The radiographic evaluations were conducted with non-standardized panoramic and periapical radiographs. A bone height of at least 3 mm was required for an implant in the sinus region. After local anaesthesia and mid-crestal incision, buccal and palatal full-thickness flaps were reflected. A surgical splint was used to mark the implant position with a round bur and for a pilot drill to define the angle of the implant. The pilot drill ended approximately 1 mm below the sinus floor calculated from the pre-surgical X-ray. Preparation of the recipient sites was either performed stepwise with appropriate spiral drills or by use of osteotomes of increasing diameter, compressing the surrounding bone. Finally, a hand osteotome was used under a gentle malleting force to cause initial fracture of the sinus floor. The sinus floor was then elevated using the ITI depth gauge to displace the Schneiderian membrane apically. The depth gauge has a rounded, smooth tip that enables safe apical displacement of

the sinus membrane. This step was performed manually with special attention to avoid perforation of the membrane.

Two methods were used to ascertain the integrity of the Schneiderian membrane. The elasticity of the membrane should be felt while manually inserting the  $\varnothing = 2.8$  mm depth gauge and the Valsalva manoeuvre should be negative. Perforation was indicated when air bubbles were found. All implant insertions were conducted with a hand ratchet, and the insertion torque for implants was  $\geq 15$  Ncm. Even if perforation of the Schneiderian membrane was detected, the entire implant insertion procedure was accomplished without further treatment.

A total of 92 implants were inserted, including 89 ITI solid-screw implants (Institute Straumann, Waldenburg, Switzerland) with a sandblasted, large grit, acid-etched (SLA) surface and three NobelReplace tapered implants (Nobel-Biocare, Göteborg, Sweden). No grafting material was used and primary stability was achieved in all cases except one. The implant sizes were one 10-mm-long full-screw ( $\varnothing 3.5$  mm), 49 10-mm-long full-screws ( $\varnothing 4.1$  mm), seven 12-mm-long full-screws ( $\varnothing 4.1$  mm), one 8-mm-long full-screw ( $\varnothing 4.1$  mm), one 8-mm-long full-screw ( $\varnothing 4.8$  mm), 24 10-mm-long full-screws ( $\varnothing 4.8$  mm), two 11.5-mm (5.0 mm), and seven 12-mm-long full-screws ( $\varnothing 4.8$  mm). Forty-one implants were inserted into the premolar region and 51 into the molar region. Implant length was between 3 and 6 mm above the RBH. Details of the RBH and the distribution of the inserted implants in the ISL and control groups are listed in Tables 1 and 2.

In the control group, a bone height of at least 8 mm below the sinus floor was available. These implants were placed according to the manufacturer's instructions. The surgical procedure was identical to that for the experimental group, except for the ISL procedure. Seventy-seven implants (exclusively ITI solid screws) were inserted into the posterior maxilla, and primary stability was achieved in all cases. Implants from the control group included one 8-mm full-screw ( $\varnothing 4.1$  mm), 38 10-mm full-screws ( $\varnothing 4.1$  mm), 34 12-mm full-screws ( $\varnothing 4.1$  mm), three 10-mm full-screws ( $\varnothing 4.8$  mm), and one 14-mm full-screw ( $\varnothing 4.8$  mm).

As a prophylactic measure, all patients received  $3 \times 1000$  mg Amoxicillin for



6–7 days and analgesics as required. Oral hygiene was performed as normal, except for tooth-brushing around the implants for 7 days. Sutures were removed 6–10 days after surgery.

Surgery and follow-up were performed by two surgeons. One of the surgeons and another dentist who was not involved in the study evaluated the radiographs taken 6–9 months after surgery for the presence or absence of bone gain at the apical aspect of the implants. Any disagreement was resolved by choosing the less favourable result. Implant survival was defined as being symptom free and stable without mobility or radiographic evidence of severe bone loss; it was calculated from the time of implant surgery. Signs of peri-implantitis (probing pocket depth  $\geq 5$  mm and bleeding on probing) were also recorded.

#### Statistics

Statistical analysis was performed using SPSS (Version 14.01S; SPSS Incorporation (Inc.), Chicago, IL, USA). Descriptive data were expressed as means  $\pm$  SD. Kaplan–Meier survival curves and Cox regression analysis were used to estimate survival curves for the implants and to isolate the risk factors for implant failures. The primary outcome variable was implant failure, defined as implant removal, when the criterion for implant removal was implant mobility. Implant survival was calculated by measuring the time elapsed from implant placement to the date of the last follow-up visit or removal of the implant. For putative risk factors, logistic regression analysis with stepwise acceptance of variables ( $P_{in} = 0.05$ ,  $P_{out} = 0.10$ ) was performed.

#### Results

Eighty-seven out of 92 implants in the test group and 76 out of 77 implants in the control group were available for follow-up examinations. Implant failures were recorded after a minimum observation time of 9 months (mean: 1.2 years; SD: 0.69; maximum: 3.76 years). Six implant failures occurred: four in the test group and two in the control group. Five failures were characterized by lack of osseous integration. One failure involved removal of an implant during surgery because of the absence of primary stability. All failures

Table 1. Distribution of inserted implants in the ISL group according to residual native bone

Residual bone height (mm)	Number of sites	Percentage	Length of implants (mm)			
			8.0	10.0	11.5	12.0
3–3.9	13	14.1	1	10	0	2
4–4.9	15	16.3	0	14	0	1
5–5.9	18	19.6	0	15	1	2
6–6.9	20	21.7	0	17	0	3
7–7.9	26	28.3	1	18	1	6
Sum	92	100	2	74	2	14

ISL, internal sinus lift.

Table 2. Distribution of inserted implants in the control group according to residual native bone

Residual bone height (mm)	Number of sites	Percentage	Length of implants (mm)			
			8.0	10.0	12.0	14.0
8–8.9	1	1.3	1	0	0	0
9–9.9	0	0	0	0	0	0
10–10.9	10	13.0	0	10	0	0
11–11.9	5	6.5	0	5	0	0
12–12.9	12	15.6	0	6	6	0
13–13.9	4	5.2	0	4	0	0
> 14	45	58.4	0	16	28	1
Sum	77	100	1	41	34	1

Table 3. Cox regression analysis of the effect of internal sinus lift and perforation on implant survival

	B	Degrees of freedom	Significance	Odds ratio Exp(B)	95.0% confidence interval Exp(B)	
					lower	upper
Internal sinus lift	0.844	1	0.491	2.327	0.211	25.660
Perforation	0.488	1	0.690	1.630	0.148	17.975

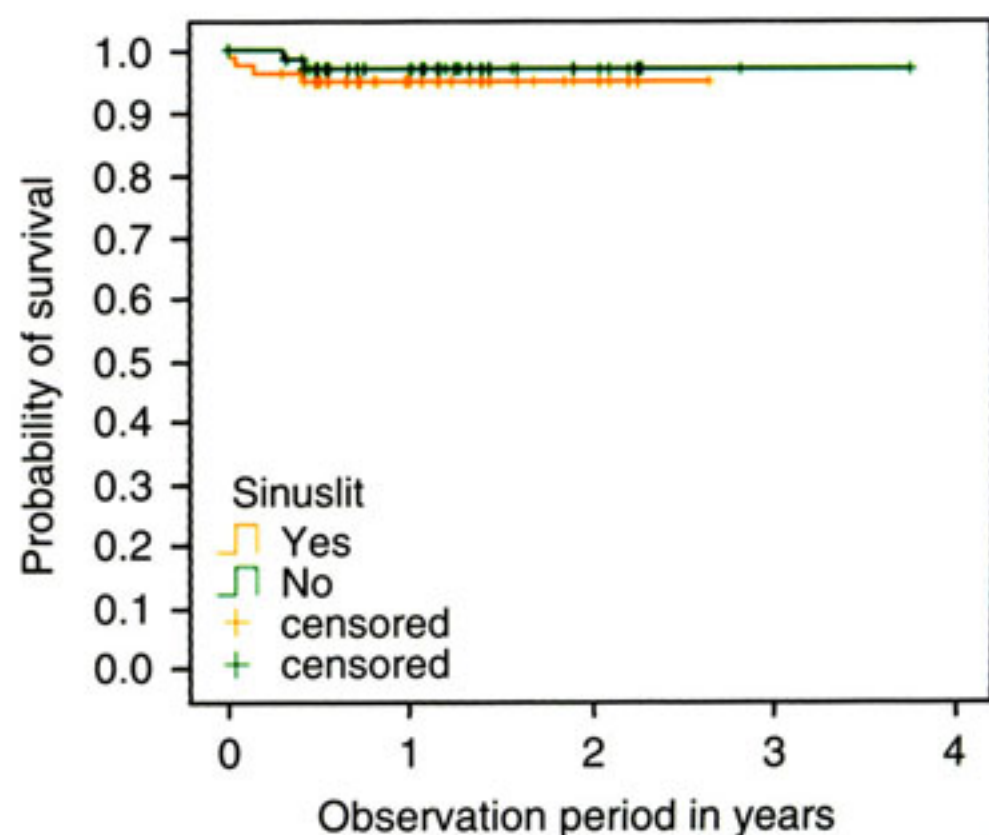


Fig. 1. Kaplan–Meier survival curves for implants placed in combination with an internal sinus lift and for controls.

occurred within the first 6 months after surgery and without functional loading

(Fig. 1). The probability of survival was above 94% for both groups.



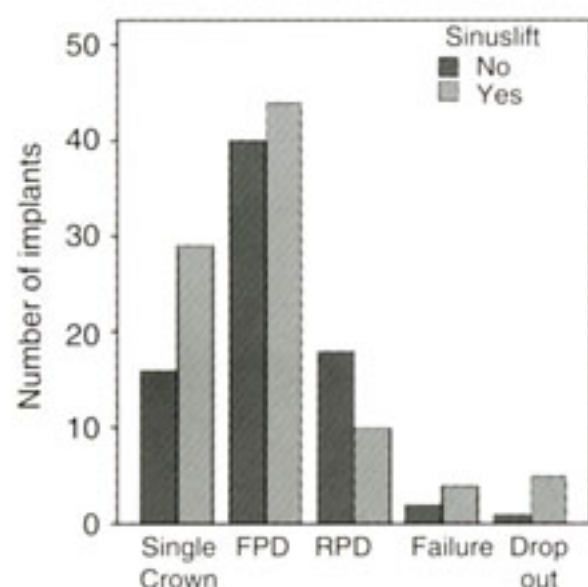


Fig. 2. Prosthetic restoration of the implants in the experimental and control groups.

For 24 of the 92 implants (26%), the Schneiderian membrane was obviously disrupted, as tested by nose blowing. Cox regression analysis, however, revealed no significant effect of perforation and ISL on implant survival (Table 3).

All implants except failures and drop-outs were restored, including 83 of the 92 implants in the test group (29 crowns, 44 fixed partial dentures (fpds), 10 telescopic crown-retained removable partial dentures) and 74 of the 77 implants in the control group (16 crowns, 40 fpds, 18 telescopic crown-retained removable partial dentures) (Fig. 2). No signs of peri-implantitis (probing pocket depth  $\geq 5$  mm and bleeding on probing) were found during the follow-up examinations.

Five patients receiving implants in the test group dropped out: two because of financial problems and three for unknown reasons. In the control group, one patient did not reappear, for unknown reasons. All data for the drop-outs obtained before the last recall were included in the statistical analysis.

Six–nine months after implant placement, bone gain at the apical aspect of the implants was observed for approximately 30% of the implants (29 of 92 implants) (Figs 3 and 4). Several X-rays taken after more than 1 year indicated formation of additional bone.

## Discussion

The results of this study confirm the hypothesis that the survival of implants placed in the ungrafted atrophic posterior maxilla equals that of implants in the native posterior maxilla.

Of a total of 77 implants in the control group without a sinus lift, 75

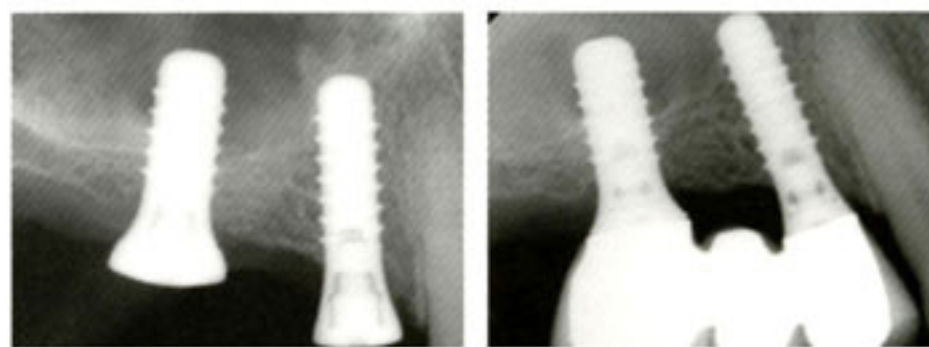


Fig. 3. Implants without bone gain after 7 months.

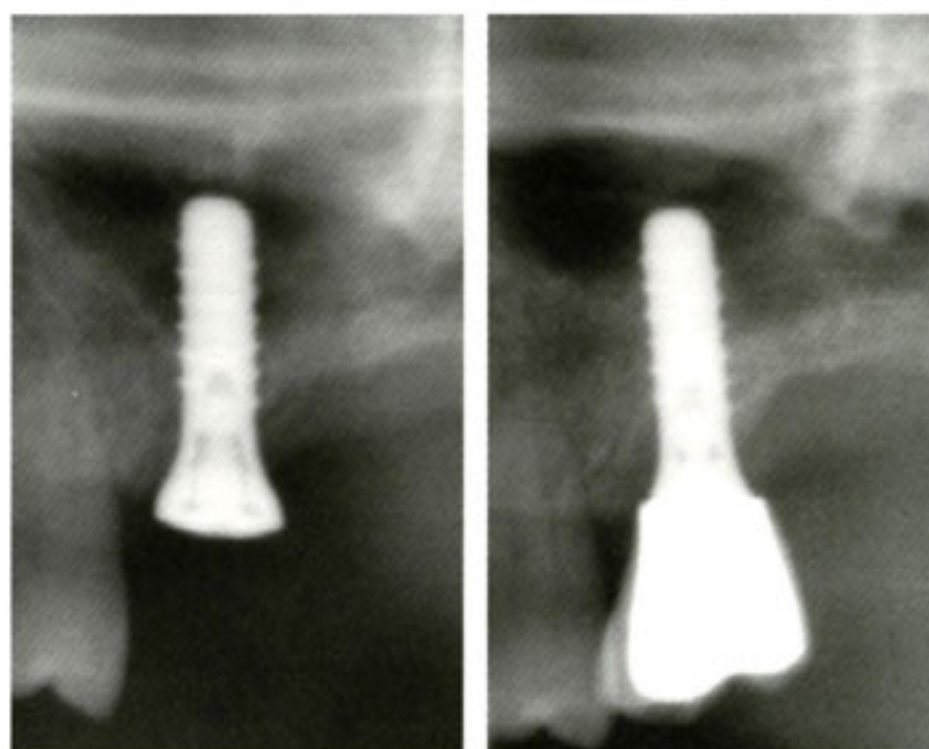


Fig. 4. Implant with bone gain after 8 months.

(97.4%) were osseointegrated compared with 95.6% in the experimental group. This short-term survival is in accordance with survival reported for implants placed in combination with sinus augmentation (Graziani et al. 2004, Zijdeveld et al. 2005, McDermott et al. 2006). In contrast, Olson et al. (2000) reported significantly greater implant success in grafted posterior maxilla sites than in non-grafted sites and traced this to the fact that longer implants could be used in the grafted cases. It must be emphasized that the survival data presented are the result of an implant-based analysis, as in several comparable studies (Winter et al. 2002, Ferrigno et al. 2006, Nedir et al. 2006). This involves a risk of overestimating the success rates compared with patient-based analysis (Fransson et al. 2005, Roos-Jansaker et al. 2006a,b,c). Because no patient had more than one failure, the implant level in this study could be justified. With regard to the result of this study that there was no statistically significant difference between survival of maxillary implants placed with or without ISL, low power must be considered, which was impaired by the relatively high drop-out in the

experimental group (five out of 92 implants). On the basis of data from the literature (Wallace & Froum 2003), a desired power of 80% results in a minimum sample size of 1852 implants, equally distributed among experimental and control groups.

Although it has been stated that implant loss occurs more often when less bone is present (Jensen et al. 1998), in this study the pre-treatment bone height of 3–8 mm in the study group did not result in significantly lower survival than in the control group with more than 8 mm bone height. These findings may be explained by the primary stability, which could be achieved by use of osteotomes and by compression of the surrounding bone. In addition, all implants of the test group were anchored bicortically, resulting in increased stability, in accordance with a previous study by Ellegaard et al. (1997), who achieved primary stability even for 3 mm vertical bone height. Rosen reported a comparable survival of at least 96% for implants in the grafted maxilla when pretreatment bone height was 5 mm or more, but survival declined to 85.7% when the bone height was 4 mm or less (Rosen



et al. 1999). Bruschi et al. (1998) reported on 499 single-stage implants placed in an RBH of 5–7 mm without using membranes or grafts; the success rate was 97.5% after 2–5 years of loading.

Compared with the more invasive treatment options for the atrophic posterior maxilla, the ISL has many advantages. No allografts, xenografts, or membranes are used and, therefore, no secondary surgical site, with an additional risk of infection and surgical trauma, is needed to harvest autogenous bone. The risk of overfilling the maxillary sinus, which may cause necrosis of the membrane, loss of the graft into the sinus, and finally sinusitis (Tidwell et al. 1992, Raghoobar et al. 1997, Timmenga et al. 1997), is also avoided. Even use of particulate graft material during an ISL may have its advantages. The material eliminates direct contact between the membrane and the metallic osteotomes, which, in theory, protects the membrane from perforation and leads to a larger grafted volume around the tip of the implant. Although the grafted area undergoes shrinkage and remodelling (Braegger et al. 2004), the combination of osteotome sinus elevation and graft material has been shown to be successful (Braegger et al. 2004, Toffler 2004, Ferrigno et al. 2006). In a systematic review including 19 studies Tan et al. (2008) reported an estimated survival rate of 92.8% for implants placed in transalveolarly augmented sinuses, after 3 years in function.

The most commonly described intraoperative complication of sinus floor elevation is perforation of the Schneiderian membrane (Jensen et al. 1998, van den Bergh et al. 2000, Tonetti & Hammerle 2008), which sometimes results in abandoning of the sinus lift procedure (Ferrigno et al. 2006). A problem of the described sinus lift technique is that membrane perforations occurring during surgery cannot be detected with sufficient reliability. Because the membrane was not observable through the access hole during surgery, it was just sounded – in this study with the depth gauge used as a probe. Because the statement ‘‘the elasticity of the membrane should be felt’’ can be broadly interpreted, the authors attempted to ensure the validity of their sounding results by using a gently performed Valsalva manoeuvre. A perforation was indicated when air bubbles were found. This manoeuvre is a well-

accepted means of ascertaining the integrity of the Schneiderian membrane. The perforation, furthermore, can neither be sized nor repaired. In this study, the size of the perforations occurring during careful displacement of the sinus membrane with the depth gauge can be assumed to be small compared with impairments during the Caldwell–Luc approach. Because minor perforations do not usually need treatment, because the membrane folds on itself during the elevation in this study, implant treatment was completed in all 24 sites where membrane perforation was detected (26%). The occurrence of perforation in this study is consistent with that in other published reports on sinus elevation (Raghoobar et al. 1997, Shlomi et al. 2004, Barone et al. 2006). The results revealed that perforation during the ISL procedure was not a risk factor for implant survival. Several clinical studies also reported no complications for implants penetrating the maxillary sinus or the nasal cavity (Branemark et al. 1984, Jensen et al. 1994, Raghoobar et al. 1999, Cavicchia et al. 2001, Jung et al. 2006).

A limitation of this study is the two-dimensional radiographic evaluation of bone height with panoramic and periapical radiographs, because distortion can be a major problem when the patient is not correctly positioned (Frei et al. 2004).

Despite this limitation, panoramic radiographs are commonly used for diagnostic purposes in implantology, because they enable a quantitative assessment of the heights of the mandibular and maxillary bones (Xie et al. 1997, Frei et al. 2004). Both panoramic and intraoral radiographs have been shown to be reliable instruments when used to assess the point of bone attachment to implant threads (Kullman et al. 2007). However, even perfect measurements of the mesial and distal bone heights are unable to display the real bony situation around the implants, because the bone support on the vestibule and palate cannot be detected on a two-dimensional radiograph (Nedir et al. 2006).

Some authors therefore recommend cross-sectional imaging techniques, for example computed tomography (CT) or digital volume tomography, because of their diagnostic advantages (Reddy et al. 1994, Bolin & Eliasson 1995, Mengel et al. 2006). These enable three-dimensional imaging true to scale and, com-

pared with panoramic and periapical radiography, without overlay or distortion (Mengel et al. 2006). Besides the accuracy of the three-dimensional imaging technique, they have the disadvantage of exposing the patient to a high level of radiation. Dula calculated the biological risk for different radiographic assessments in the molar region. He demonstrated that the risk from a periapical radiograph is 20% of that from a panoramic radiograph, and that a panoramic radiograph and a series of four conventional tomographs carry 5% and 13% of the risk of a CT examination (Dula et al. 2001a). The routine use of a three-dimensional imaging technique in this study would not, therefore, have been approved by the regional ethics committee.

Implant therapy is, today, a routinely used treatment option, frequently used even for young individuals. The implants must, therefore, ideally, function for decades. Because biological complications of implants have been shown to occur after several years, several authors have demanded an observation period exceeding 5 years for evaluation of clinical outcome (Fransson et al. 2005, Roos-Jansaker et al. 2006a,b,c, Hultin et al. 2007). Because the ISL, especially without graft materials, is a relatively new procedure, the mean follow-up period of 1.2 years in this study was a necessary compromise that enabled evaluation of early implant losses. Additional clinical research is in progress to investigate the long-term success of the technique presented.

This article reports the short-term results of prospective clinical study indicating that ISL and perforation of the membrane were not significant risk factors for implant survival. However, the observation time and the number of failures are limited and the scientific relevance is limited by the nature of the study (no randomisation). Future work must be based on long-term observations of a greater sample size with a significant number of failures to enable reliable analysis of possible risk factors.

## Conclusions

Promising clinical short-term outcomes were observed for implants placed in combination with internal sinus floor elevation without graft material.



Apical bone gain within the first 6 months was observed for a substantial proportion of the implants.

Long-term survival and changes of the bony situation must be evaluated, however.

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## Clinical Relevance

**Scientific rationale for the study:** Use of minimally invasive treatment alternatives for the atrophic posterior maxilla has recently increased.

**Principal findings:** The short-term survival of dental implants placed

in combination with an ISL without graft materials in the atrophic posterior maxilla does not differ significantly from that of implants in the native posterior maxilla.

**Practical implications:** The technique described may help to increase

the number of options in the edentulous atrophic posterior maxilla without any need for an additional invasive treatment.