Bone Formation at the Maxillary Sinus Floor Following Simultaneous Elevation of the Mucosal Lining and Implant Installation Without Graft Material: An Evaluation of 20 Patients Treated With 44 Astra Tech Implants

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Purpose: Restoration of lost dentition in the severely atrophic posterior maxilla has for the last 2 decades been successfully treated with various sinus augmentation techniques and installation of dental implants. The use of graft material is anticipated to be necessary; however, recent studies have demonstrated that the mere lifting of the sinus mucosal lining and simultaneous placement of implants result in bone formation. This study was conducted in order to evaluate simultaneous sinus mucosal lining elevation and installation of dental implants without any graft material.

Patients and Methods: Twenty patients were consecutively included from November 2001 to June 2004. Forty-four Astra ST dental implants (Astra Tech AB, Mölndal, Sweden) with a diameter of 4.5 mm or 5 mm were installed in 27 sinuses. A sinus lift was performed where a cortical window was removed from the maxillary anterior sinus wall. The sinus mucosal lining was elevated and implants installed in the residual subantral bone. The cortical window was thereafter replaced and the incision closed. The remaining bone height was recorded during surgery as well as perforations of the sinus mucosal lining. After 6 months of healing, abutments were connected (the series included 5 1-stage procedures). Clinical and radiological follow-up after loading was performed up to 4 years after implant installation.

Results: Patients tolerated the procedure well as few complications were observed. Firm primary stability was achieved for all implants at installation with bone levels in residual bone of 2 to 9 mm. Perforations of the maxillary sinus mucosal lining occurred in 11 of the 27 operated sinuses (41%). One implant was lost during a mean follow-up of 27.5 months (range, 14 to 45 months) giving an implant survival rate of 97.7%. The average gain of bone at the sinus floor was 6.51 mm (SD = 2.49, 44 implants) including all measured implants after a minimum of 1 year follow-up. Marked bone formation was observed around long implants and also when the residual bone below the sinus was diminutive.

Conclusions: The present study including 20 patients showed consistent bone formation at the maxillary sinus floor following simultaneous mucosal lining elevation and installation of implants. It is suggested that the use of this technique can reduce the risk for morbidity related to harvesting of bone grafts and eliminate costs for grafting materials.

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Sufficient bone volume and quality have been regarded as the major predictors in rehabilitation with osseointegrated dental implants. The posterior region of the maxilla has attracted specific interest because of the frequent problem of insufficient bone volume to guarantee a predictable long-term result. Many studies have addressed the problem of bone deficiency in this region and numerous techniques for maxillary sinus floor augmentation have been presented.\(^1\)

Lundgren et al\(^2\) recently evaluated a surgical technique in 10 patients where an open controlled sinus membrane lift procedure with simultaneous installation of 19 dental implants (Brånemark System, TiUnite; Nobel Biocare AB, Gothenburgh, Sweden) was performed.\(^2\) A bony window was cut out at the lateral maxillary sinus wall and repositioned after placement of implants in the remaining subantral crestal bone, thus allowing for a blood clot and subsequently for bone to form in an undisturbed compartment around the implants. The available height of bone at the time of surgery was 4 to 10 mm. Acceptable primary stability of implants was achieved. Patients were followed for 1 year after installation or 6 months post loading of the implants and evidence of bone formation around all installed implants was registered. The authors’ conclusion was that this technique results in bone formation around dental implants.

The present study describes and evaluates a modification of the surgical protocol for sinus mucosal lining elevation and simultaneous installation of osseointegrated implants with a conical design, marginal microthreads, and TiO\(_2\)-grit blasted surface (Astra Tech AB, Mölndal, Sweden) in 20 patients.

**Materials and Methods**

Twenty patients (11 women, 9 men) with a mean age of 59 years (range, 19 to 78 years) were consecutively included from November 2001 to June 2004 with the latest follow-up in October 2005. The patients had been referred to the Department of Oral and Maxillofacial Surgery, University Hospital, Uppsala, Sweden, for dental implant treatment in the posterior maxilla. All patients were healthy. Two patients were smokers. Presurgical and radiologic examinations (panorex and computed tomography scans) revealed healthy conditions of the maxillary sinuses in all study subjects.

A sinus lift procedure was considered when the subantral bone was \(\leq 5\) mm (mean residual bone height, 4.6 mm; range, 2 to 9 mm; 44 implant sites) as measured on panoramic radiographs.

**Surgery**

All patients were operated on under local anesthesia (2% Xylocaine Dental with epinephrine 1:50,000; Dentsply Pharmaceutical, York, PA) and with preoperative oral sedation with midazolam (5 to 12.5 mg Dormicum; Roche AB, Stockholm, Sweden) when required. Preoperative antibiotics were orally administered 45 minutes before surgery; patients routinely received 2 g of phenoxymethylpenicillin or 600 mg of clindamycin (when allergic to phenoxymethylpenicillin).

**Surgical Technique and Modification of the Protocol**

The posterior maxillary edentulous area and the maxillary sinus wall were exposed via a crestal incision and a buccal mucoperiosteal flap was raised. Osteotomy in a rectangular fashion was made with a sagittal saw (KaVo Dental GmbH, Biberach, Germany) with a 5 mm wide rectangular blade (Aesculap AG & Co, Tuttingen, Germany) in the anterior wall of the sinus, 5 to 6 mm cranial to the intended implant site (Fig 1). In denser bone, an angulation of the bone cut was performed in the sinus wall to simplify the repositioning of the bony window at the end of the procedure. With small sharp elevators the cortical bony window was dissected free and gently removed from the underlying sinus mucosal lining of the anterior sinus wall. The cut out bone piece was put aside and stored in a sterile saline compress.

Perforations of various sizes of the sinus mucosal lining were encountered in 11 of the 27 sinus lifts, and attempts were made to repair them in 3 patients. In 2 of these cases, small holes were drilled in the bone above the cortical window to elevate and suture the mucosal lining to that level (Fig 2) using a set of nerve repair instruments and absorbable sutures (Vicryl 6-0; Ethicon Inc, Somerville, NJ). The third patient

**FIGURE 1.** The maxillary sinus wall exposed and a bone window has been cut out. Sinus elevation and “tenting” of the sinus mucosal lining is achieved by the simultaneous installation of the implant.

had a small piece of periosteum (taken from the buccal flap) placed as a lid over a perforation (2 × 3 mm) of the sinus mucosal lining. With angulated elevators of various dimensions, the sinus lifts were accomplished in all directions from the entrance of the cortical window. In cases of perforations of the mucosal lining, the elevation was more extensive, especially in the posterior direction of the sinus cavity, to facilitate the repair and suturing. In the other 8 patients, the perforations were so small that further dissection of the mucosal lining and “tenting” by the implants were considered satisfactory for a blood clot to form around the implants. Two patients had blood retrieved from a peripheral vein to fill the sinus compartment around the implants to create the blood clot because of minimal bleeding at the site upon closure.

After the elevation, implants were installed in the residual subantral bone. The remaining bone height was recorded with a depth gauge (Depth Gauge Fixture; Astra Tech AB) during surgery. Primary implant stability was noted manually at installation, where none of the implants showed rotational or lateral instability. A stabilizing wrench was used when removing the implant carrier in all cases. Cooling with saline during the placement of the implants was not used to prevent the irrigation from removing bone fragments from the drilling procedure and blood needed for the formation of a coagulum in the sinus cavity and around the implants (Fig 3).

To achieve implant stability in the cases of small remaining levels of vertical subantral bone, the protocol of installing the Astra Tech Fixture Microthread ST dental implant was modified in its last preparation step. The final conical burr was leveled into the bone 1 to 2 mm less than the recommended standard protocol in cases with only 2 to 3 mm residual bone. Thus, a slightly smaller hole for the implant was prepared and the implant could be placed with better primary stability, utilizing the effect of the conical design and the retention of the microthreads in the superior part, adding an extra effect to the placement and thereby achieving sufficient primary stability. The compartment around the implants under the sinus mucosal lining in the sinus floor was filled with blood from surrounding bleeding (Fig 3) and the cortical window was thereafter repositioned (Fig 4) and the
incision closed with nonresorbable sutures (Ethibond Excel; Ethicon Inc).

Postoperative Care

Analgesics were prescribed with paracetamol and codeine or with a nonsteroidal anti-inflammatory drug for 1 to 2 weeks following the surgery. Antibiotic treatment was continued for 5 days postoperatively with phenoxymethylpenicillin 1 g (or clindamycin, 300 mg) 3 times daily. Patients were instructed not to blow their nose and to use nasal spray saline for 14 days after surgery. Dentures were not allowed for 7 to 10 days following the surgery. Patients were reviewed and sutures taken out after 7 to 10 days. Postoperative recovery was uneventful. Uneventful healing was encountered in all patients; no infections were recorded.

After 6 months of healing, abutments were connected in all but 5 cases, who had abutments placed in conjunction with the implant fixtures.

Implants

A total of 44 dental implants with a diameter of 4.5 mm or 5 mm (n = 40) (Fixture Microthread ST; Astra Tech), or a diameter of 3.5 mm (n = 4) Fixture Microthread (Astra Tech) were installed.

The Astra Tech Fixture Microthread implant is provided with a TiO<sub>2</sub>grit blasted surface and has a cervical area with threads of a smaller dimension than the major threaded part of the implant. The Fixture Microthread ST is additionally conical in its most cervical part, which also has microthreads (Fig 5).<sup>3</sup>

Firm primary stability was achieved at all implant sites. See Table 1 for length of implants in remaining bone. Five of the 20 patients had implants and abutments placed at the same time but without provisional prosthesis fitted. In these patients, there was no need for a temporary prosthesis because the implants were placed outside the esthetic zone.

In a majority of cases, long implants (13 and 15 mm) were used in relation to the amount of bone of the site of installation (Table 1). The point of doing so was to achieve a considerable height of elevation of the sinus mucosal lining, allowing for a blood clot to form below the membrane and between and along the implants where more than 1 implant was used.

CLINICAL AND RADIOLOGIC FOLLOW-UP

The referring dentists carried out the prosthetic rehabilitation after 6 months, mostly as single crown restorations in metal-ceramics (Fig 6). Five patients had study implants connected to full arch restorations, with additional implants installed in the intercanine region.

Clinical and radiologic follow-up was performed 1) at baseline after surgery, 2) at abutment connection, and 3) annually up to 4 years following implant installation.

Periapical radiographs and orthopantomograms were used for measurements of 1) the height of the residual alveolar bone at each implant site, and 2) the height of newly formed bone in the maxillary sinus in relation to each implant. Measurements were made manually with a millimeter scale on the radiographs with assistance of digital orthopantomograms because axial projections of implants in the maxillary

<table>
<thead>
<tr>
<th>Bone Baseline</th>
<th>Fixture Length</th>
<th>Mean Bone Gain</th>
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<tbody>
<tr>
<td>2.0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>2.5</td>
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<td>4.0</td>
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<td>1</td>
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<td>6</td>
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Mean bone gain 3.50 5.58 6.76 6.94 (std = 2.492)

*Based on only 1 value since bone gained is missing for the combination bone baseline = 2.5 and fixture. Length = 15.

sinus region are difficult to obtain because of the loss of alveolar crest and the nearby obstructing hard palate. The cervical microthreaded area of the implant represents 5.5 mm and this was used as a reference point during measurement.

STATISTICS

Descriptive statistics was used and the correlation of results was confirmed with linear regression analysis.

Results

CLINICAL FOLLOW-UP

The procedure was well tolerated by the patients under local anesthesia, most without any preoperative sedation.

The average healing time of the implants before connecting abutments (15 patients) was in the range of 3 months, 11 days to 8 months, 29 days (mean; 6 months, 15 days).

In 2 of the 5 patients, where a 1-stage implant installation was performed, the healing abutments came loose and had to be replaced during the healing period. In those patients undergoing 1-stage surgery, no temporary prosthesis was allowed during healing. Patients with submerged implants were allowed to wear their dentures after 7 to 10 days, which in some cases were relined with a soft material.

One female patient lost 1 of 2 implants shortly after placing abutments and before loading. The remaining bone in that fixture site was 2 to 3 mm. It was noted during surgery that the entry window to the sinus came only 2 to 3 mm from the prepared implant site.

Follow-up was closed in October 2005. The length of follow-up was then between 14 and 45 months (mean, 27.5 months). At this time, restorations were not removed (as pointed out earlier). In general, good function of the implants and restorations was achieved. No further implants were recorded as lost at last follow-up. No pathologic conditions in the marginal area of the implants were found. However, in 2 patients, 2 implants seemed to have elongated from the original marginal bone level, as seen on radiologic follow-up. One patient had encountered loosening of a crown twice and another patient had a problem with 2 implants placed too close, causing problems with hygiene.

RADIOLOGIC FINDINGS

A mean bone height of 6.5 mm (SD = 2.49; 44 implants) was gained (Table 1). The bone gain was more pronounced in sites with 2 to 5.5 mm of residual alveolar bone (mean, 7.09; SD = 2.48; 33 implants; Table 2) compared with all included sites (Table 1).

The linear regression analysis showed that in the sites where bone was minimal at installation, more bone was gained after 6 months of healing. Also, if a long implant was placed, the newly formed bone was greater ($P = .0008$ for the bone baseline factor and $P = .0142$ for the fixture length factor).

In 2 patients, 2 implants seemed to have elevated from the original marginal bone level after a healing time of 6 months had passed. An elevation of 2 mm was observed on radiographs. These 2 implants were 4.5 in diameter, and placed in 2 and 3 mm of bone. Follow-up was over 2 years in both patients and this marginal “push-out” phenomenon was observed as early as 3 months and remained stable (Fig 7). All other implants showed a stable marginal situation on radiographs; however, no marginal registration is presented here (Fig 8).

<table>
<thead>
<tr>
<th>Bone Baseline</th>
<th>Fixture Length</th>
<th>Mean Bone Gain</th>
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<tbody>
<tr>
<td>2.0</td>
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<td>7.00</td>
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<tr>
<td>2.5</td>
<td>0 0 1 1 2</td>
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<td>4.5</td>
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<tr>
<td>5.0</td>
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</tr>
<tr>
<td>5.5</td>
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<td>9.50</td>
</tr>
<tr>
<td>Total</td>
<td>1 6 12 14 33</td>
<td>7.09</td>
</tr>
</tbody>
</table>

Mean bone gain 5.00 5.58 7.96 7.15 (std = 2.480)

*Based on only one value since bone gained is missing for the combination bone baseline = 2.5 and fixture. Length = 15.

Discussion

This study showed that the described modified technique can be taken further, including even more severely resorbed implant sites. At this diminutive level of bone, as little as 2 mm, the implant design used in this study plays an important role in giving the needed stability for healing and new bone formation. Furthermore, it also confirms the results previously reported by Lundgren et al with stable implants and new bone formation in the sinus floor. In cases where the remaining bone at baseline, in which the implants were placed, was minute, the gain of bone was larger. Additionally, the longer the implant, the larger amount of bone was formed (Tables 1-3), as confirmed with linear regression analysis.

With this technique, new bone is formed without the use of any graft material directly on and around the implants; as was also recently demonstrated in an experimental study in primates by Palma et al. The positive effects of this are obvious. Instead of using autogenous bone (remodeling time up to 6 months) or allografts (remodeling time of 9 to 12 months) for augmenting the sinus floor and later placing the implants, implants are placed simultaneously and left to osseointegrate for 3 to 6 months depending on the amount of bone in the sites. A 1-stage procedure may also be performed in some cases where suitable; even further simplifying the sequence of implant treatment. Because no grafted bone is needed, morbidity is decreased. The health economic consequences are vast as bone grafts for these patients are not needed; in addition, treatment time is shortened significantly. Worldwide, grafting of the sinus floor is performed extensively. As a consequence, of the new data presented here, sinus lift with grafting has decreased substantially over the last 5 years in our clinic.

In 1984, Brånemark et al. used the technique of elevating nasal and sinus mucosa through the preparation of the implant site to gain height and newly formed bone when installing implants. Ten years later, Summers, with elevation of the sinus mucosal lining through the preparation site, also presented a further simplification technique in the vertically compromised implant site of the subantral maxillary area.

Table 3. PEARSON CORRELATION COEFFICIENT

<table>
<thead>
<tr>
<th>Fixture Length</th>
<th>Bone Gain</th>
</tr>
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<tbody>
<tr>
<td>Bone baseline</td>
<td>0.0982 (P = .5260)</td>
</tr>
<tr>
<td>Fixture length</td>
<td>0.2802 (P = .0142)</td>
</tr>
</tbody>
</table>

NOTE. Linear regression: bone gain = 2.32 - 0.56 × bone baseline + 0.51 × fixture length (P = .0008 for the bone baseline factor and P = .0142 for the fixture length factor).

Ellegaard et al\textsuperscript{10} described the technique of sinus implants, but did not replace the bone window after sinus membrane elevation and installation of implants. By maintaining an open bone window, it can be speculated that an important factor for the blood clot to heal into bone is that an undisturbed compartment is lost, as soft tissue healing may be a fact instead of bone formation in the area. Recruitment of endothelial and mesenchymal cells is dependent on hypoxia in the maturing clot.\textsuperscript{11} The amount of newly formed bone in the compartment may then be less of an effect of a local condition with an altered level of oxygen supply when the bone window is not replaced. On the other hand, in a follow-up study, Ellegaard et al\textsuperscript{12} recently concluded that sinus implants had similar long-term results as conventional implants in periodontally compromised patients after 10 years of follow-up.

In a rabbit study, Xu et al\textsuperscript{13} elevated the sinus floor of the maxilla. The shrinkage of the blood clot and the instability of the newly formed bone were evident when only the clot was used as a space holder. Significant decrease of bone height and area was evident as early as between weeks 2 and 6. In 2 of the sites of 2 patients in the present study, a marginal “push-out” of the implant was seen from the original marginal bone level after the healing time of 6 months. This phenomenon may be caused by shrinking of the clot which is reducing in size (and the unstable newly formed bone allowing this) and thereby pushing the implants.\textsuperscript{15} Therefore, the “tent pole” effect of an implant seems vital for keeping a stable situation. The final result of the implants much resembles the original relation between roots elevating up in the sinus floor and the often very thin bone in this area. The present study indicates that the idea of “longer” implants (eg, 13 or 15 mm) are valuable for the result concerning new bone formation.

The advantage of the technique is that bone is formed simultaneously with the healing process of the implants. In bone grafting block or particulated bone, Johansson et al\textsuperscript{14} showed that the results of sinus lift procedures with autogenous bone were highly unpredictable. After 6 months of healing, 49.5% of the initial bone volume was reduced in a volumetric study on computed tomography scans. Hallman et al\textsuperscript{7} showed that the results became more predictable with the combination of bovine hydroxyapatite and autogenous bone at a ratio of 80:20. Only 10% of the volume had decreased after 2 years of follow-up. However, a drawback of that procedure is the time factor, as the bone was seen to be in an immature state after 6 months. The amount of bone in the sinus floor to retain the implants should not be exaggerated because the important factor is the marginal situation of bone along the implant that gives the primary stability.\textsuperscript{15}

The titanium surface of a dental implant has been shown to be markedly thrombogenic when studied in vitro. The superior osseointegration property of titanium compared with other biomaterials has been discussed by Hong et al\textsuperscript{16} as being the result of this fact. Activation of the coagulation system and of platelets is said to have many effects on cell and bone growth.\textsuperscript{11} Platelets contain a number of important growth factors, such as platelet-derived growth factors (PDGF), insulin-like growth factors, transforming growth factors-β, vascular endothelial growth factors, and fibroblast growth factors, which are known to support revascularization and osseointegration.\textsuperscript{17} The local conditions in the sinus with a blood clot being formed on the implants may serve as a model where the generated thrombin cleaves fibrinogen but also contributes to activation of osteoblasts via the protease activated receptors.\textsuperscript{18,19} Thrombin generation on the surfaces of titanium implants may also both stimulate proliferation and inhibit apoptosis of osteoblasts.\textsuperscript{18,20} Thrombin generation on a TiO\textsubscript{2} grit blasted surface in vitro is shown to be significantly larger than on a machined surface.\textsuperscript{21} The TiO\textsubscript{2} grit blasted surface induced an increased release of platelet granule content, reflected as β-thromboglobulin, in whole blood (which correlates well with PDGF). In this study, whole blood was compared with other plasma fractions as platelet-rich plasma and platelet-poor plasma in a slide chamber model.\textsuperscript{22} This initial release of PDGF may be important for the mineralization process. It has been shown that a short initial exposure of PDGF to osteoblastic cells increases the mineralization significantly, while continuous treatment is inhibitory.\textsuperscript{23}

Generation of thrombin on the implant surface is important. Bluteau et al\textsuperscript{24} have shown that thrombin modulates gene expression in osteoblasts resulted in increased expression of angiogenic factors. Furthermore, a thrombin peptide (TP 508) was shown by Wang et al\textsuperscript{25} to promote fracture repair via up-regulation of growth factors and angiogenesis. The implants used in this study differ from those used by Lundgren et al,\textsuperscript{2} but the fact that a micro-roughened surface has superior properties concerning red blood cell distribution and aggregation of platelets on the implant surface makes studies of the initial responses of coagulation and on cell reactions important. The release of growth factors after degranulation of platelets as a consequence of activation by the titanium surface in contact with whole blood is therefore believed to be an important issue in designing implant surfaces now and in future research.\textsuperscript{26} There are several reports supporting that platelet-derived products enhance bone formation.\textsuperscript{27,28} Antiapoptotic effect of transforming growth factor-β on osteoblastic cells has
been reported by Jilka et al. Rompen et al showed in an animal model that blood clotting enhances new bone formation, which may serve as further evidence for this hypothesis.

This study resulted in a high survival rate of the implants at follow-up at 14 months up to nearly 4 years. Only 1 implant was lost before loading. A small local vascular necrosis of the thin bridge of bone between the bone window and implant preparation site may have accounted for the problem with this implant and the loss.

The minimum amount of bone needed vertically to retain an implant is not known, but studies with resonance frequency analysis tell us that the marginal part of bone of an implant is the most important. The good result of significant bone formation in the sites with as low as 2 to 5 mm is promising. Presently, cases with very pronounced anterior protrusion of the maxillary sinus is being treated with the described technique and followed-up. It is not concluded from this study what minimum amount of bone is required to perform a nonsubmerged procedure. However, of the 5 patients in this study, where abutments were placed at installation of implants (9 implants placed), bone range was between 3 and 10 mm. A 1-stage implant procedure is beneficial to the patient, and can be performed in cases where the posterior part of the maxilla is not included in the esthetic zone.

As a result of the follow-up of these initial 20 patients, we must stress the importance not to place the osteotomy of the bony window too close to the implant site. The critical width should preferably be ≥5 mm, so that the stability and the vitality of the small bridge of bone is kept intact. In preventing loss of circulation of the bone, excessive dissection of the palatal mucosa must be prevented.

In a study by Shlomi et al., sinus membrane perforations were discussed in performing sinus lift surgery for augmentation. In that and other studies, perforations were said to occur in 10% to 35% of the procedures. The repair of perforations was made with freeze-dried human lamellar bone sheets. No complications were reported with perforations of the membrane. In this study, 41% of the sinus mucosal lining elevations resulted in perforations of various sizes. To achieve a very thin osteotomy for later replacing the bone window, a sagittal saw was used. This procedure with a saw blade, instead of a round bur often used in sinus lift procedures, and the dissection to free the bone window from the mucosal lining may be an explanation of the high incidence of perforations of the mucosal lining. In 1 patient, a periosteal graft was harvested to cover the perforation, exemplifying another way of solving the problem. Other ways of doing this are with sutures, collagen, or fibrin glue. Two patients were treated with suturing of the membrane to the top of the bone window, as later was recommended by Lundgren et al. In another study by Watzak et al., intraoral bone grafts were used to repair oro-antral fistulas (together with a Rehrman flap) after tooth or implant removal in the molar areas of the maxilla. The bone grafts were press fitted into the defects. In many ways the pressed fit bone grafts from that study resembled the situation of this described technique, where a small osteotomy resulted in an exact repositioning of the bony window. As in our study, Watzak et al. were surprised by the lack of sinus problems after surgery with healthy conditions. It is of interest to discuss the effect a perforation may have on the blood clot and new bone formation, but this question must be addressed in further studies.

Radiologic follow-up of bone levels in these resorbed implant sites is best performed with an orthopantomograph. Dental films will interfere with the palate and are hard to place because the alveolar crest is often no longer present. An orthoradial radiologic view of the implant and the superior bone level (of newly formed bone) will be hard to accomplish without a panorex. Computed tomography scans will of course be valuable (as in the study by Lundgren et al.), but will result in a high dose of radiation.

A 97.7% survival of implants must be considered as a satisfactory long term result of implant treatment using the maxillary sinus mucosal lining elevation technique. Morbidity and costs can be lowered considerably, as well as the total period of treatment.

References