

Comparison between Conventional and Piezoelectric Surgical Tools for Maxillary Sinus Floor Elevation. A Randomized Controlled Clinical Trial

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ABSTRACT

Aim: The aim of this study was to assess the performance of conventional rotative instruments and a piezoelectric device for maxillary sinus floor elevation surgery, and to assess whether application of a resorbable membrane reduces resorption of an augmented site in a randomized clinical trial.

Materials and Methods: Thirty-six consecutive patients (59.2 ± 10.7 years, range 38–76 years) needing bilateral sinus floor elevation surgery agreed to participate in this study. In a parallel split mouth design randomized clinical trial, in which the allocation of the surgical technique to be used on the determined sites was randomly assigned, one site was always treated with conventional rotative instruments (control group) and the other site with piezosurgery (test group). In addition, in a random order, the grafted sites were covered with a collagen membrane or no membrane. After a healing period of 3–4 months implants were placed.

Results: Comparison of clinical features of the test and control sites revealed no differences with regard to wound healing and complications (perforations of the sinus membrane) during or postsurgery ($p = .458$, $p = 1.0$, respectively). A clinically insignificant, but statistically shorter operation time was observed when using conventional rotative instruments (11.1 ± 2.4 minutes) than using piezosurgery (15.1 ± 2.9 minutes; $p < .001$). In both groups, application of a resorbable membrane did not result in less horizontal bone resorption (membrane: 1.43 mm, no membrane: 1.06 mm; $p = .062$); All 193 implants could be placed with primary stability. One year after functional loading, survival rate was 100%.

Conclusion: It can be concluded that, for maxillary sinus floor elevation surgery, a piezoelectric device shows no advantages over rotative instruments as well as that placement of a barrier membrane did not reduce resorption of the augmented site.

KEY WORDS: conventional rotative instruments, maxillary sinus floor elevation, piezosurgery

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INTRODUCTION

The application of implant-based prosthodontics has evolved into a viable alternative to conventional prosthetic procedures. However, implant procedures in the posterior maxilla often pose a problem because of an insufficient preexistent bone volume.¹ This restriction is not reserved to edentulous patients, but is also often observed in partially dentate patients needing an implant-based prosthodontic reconstruction in this region. An insufficient volume of bone to allow for reliable primary placement of implants can be solved by a maxillary sinus floor elevation procedure using

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autogenous bone and/or bone substitutes.^{2,3} Such approaches are in need of access to the maxillary sinus.

Many surgical techniques have been used to get access to the maxillary sinus via the lateral wall allowing for elevation of the sinus membrane. The most common intraoperative complication of the various surgical approaches is perforation of the Schneiderian membrane, with perforation rates of 7% up to 56% reported in the literature.^{4,5} In most instances, perforation occurs either while using rotative instruments to make the window or when using hand instruments to gain initial access to begin the elevation of the membrane from the sinus walls.

More recently, in line with the tendency toward minimally invasive surgery, the use of ultrasonic waves for bone cutting has been introduced in oral and maxillofacial surgery. An important achievement of this approach, using a piezoelectric device, is the much lower risk on causing visible injury to the adjacent soft tissues. The piezoelectric device has been reported to decrease the risk of damage to surrounding soft tissues and many other critical structures (nerves, vessels).⁶⁻⁸ Wallace and colleagues⁸ have shown in a series of 100 consecutive cases using the piezoelectric technique, that when using a piezoelectric device instead of rotative instrumentation, the risk of perforations of the Schneiderian membrane dropped from 30% to 7%. Furthermore, in their study, all perforations with the piezoelectric technique occurred during the hand instrumentation phase and not with the piezoelectric inserts. However, their study is limited because it lacked a control group. In the current study we tested the hypothesis that a piezoelectric device during maxillary sinus floor elevation, was noninferior to conventional rotative instruments with respect to bone healing, operation time, and complications per and postsurgery. In addition, we tested whether application of a resorbable membrane reduces resorption of an augmented site.

MATERIALS AND METHODS

Patients

Thirty-six consecutive patients (age 59.2 ± 10.7 years, range 38–76 years, 21 female, 15 male), fulfilling the inclusion criteria mentioned below, agreed to participate in this study. The patients had been referred to the Department of Oral and Maxillofacial Surgery of the

University Medical Center Groningen because of insufficient retention of their upper denture related to a severely resorbed maxilla. The patients had been edentulous in the maxilla. Patients were selected using the following inclusion criteria:

- severely resorbed maxilla (class V-VI, Cawood and Howell⁹) with reduced stability and retention of the upper denture;
- edentulous period of at least 1 year;
- no history of radiotherapy in the head and neck region;
- no history of reconstructive pre-prosthetic surgery or previous implant surgery; and
- no pathology in maxillary sinus.

In all patients, maxillary overdentures were planned supported by 4–6 implants. Informed written consent to participate in this study was obtained from all patients.

Orthopantomograms, lateral cephalometric analysis, and postero-anterior oblique radiographs were made to assess the height of the maxillary alveolar bone, the dimensions of the maxillary sinus, and the anterior-posterior relationship of the maxilla to the mandible. The radiographs were also screened for sinus pathology. The mean vertical height of the alveolar bone on the orthopantomogram between the top of the alveolar crest and the sinus floor was 3 ± 2 mm (range 1–5 mm), indicating that there was a need for preimplant reconstructive surgery in all cases.

Study Design

All 36 patients were treated with a bilateral sinus floor elevation procedure with conventional rotative instruments and piezosurgery. Randomly, by envelopes, one side was treated with conventional rotative instruments (control group) and the other side with piezosurgery (test group; Piezosurgery, Mectron Medical Technology Spa, Carasco, Genoa, Italy).^{6,7,10} Furthermore, to assess whether there was a need to apply a resorbable collagen membrane to reduce bone resorption in a horizontal direction related to either the conventional or piezo approach, in a random order either or not a resorbable membrane (Bio-Gide®, Geistlich Pharma AG, Wolhusen, Switzerland) was used to cover the grafted area.

The following variables were analyzed per patient:

- operation time;
- width of alveolar crest, after mucoperiosteal flap, measured with a caliper on six points per jaw (three right, three left) before and 3–4 months after sinus floor elevation;
- application of a resorbable membrane (at random);
- complications pre-/postsurgery; and
- dehiscences

Surgical Protocol

The maxilla of the patients was reconstructed with autogenous anterior iliac crest bone grafts under general anesthesia. In all cases, a two-stage bilateral procedure (first stage: bone grafting; second stage: placement of implants) had to be performed because the height of the maxillary bone and/or the width of the alveolar crest were less than 5 mm. A bone height of 5 mm or more is thought to be prerequisite for implant placement with sufficient primary stability.^{11,12} In addition to elevation of the floor of the maxillary sinus the width of the alveolar crest was reconstructed.

All the surgeries were carried out by two surgeons (one harvesting the iliac crest bone graft, one performing the sinus elevation surgery). Using the surgical procedure described by Raghoobar and colleagues,¹¹ an osteotomy was made in the lateral wall of the maxillary sinus after a pedicled mucoperiosteal flap was raised to expose the lateral wall of the maxillary sinus with or a conventional rotative bur or piezosurgery. All bone grafts were harvested from the anterior iliac crest. Subsequently, the monocorticocancellous iliac crest bone grafts were placed buccally of the cortex of the alveolar defect in order to increase the width of the superior alveolar process. The “remaining” graft was ground in a bone mill (Stryker Leibinger, Freiburg, Germany). The cancellous side of the bone graft was in contact with the maxillary bone and again cancellous bone particles were used to fill the small gaps between the bone graft and the alveolar crest. The bone blocks were fixed to the alveolar bone with six titanium screws (Martin Medizin Technik, Germany) (diameter 1.5 mm, length 10 mm). After the bone blocks were placed, the horizontally bone width was measured at the spot of the screws with a calliper to the nearest 0.5 mm (pre-augmentation width) as described by von Arx and Buser.¹³ Per patient six measurements per jaw (three on each site) were done. Randomly, per envelopes, at one treated site, a collagen

membrane (Bio-Gide®, Geistlich Pharma AG, Wolhusen, Switzerland) was used to cover the facial sinus wall defect on the surface of grafted sites, the other side was left uncovered. The mucoperiosteal flap was replaced and wound closure was performed by using resorbable suture material Vicryl 4.0 (Ethicon, Norderstedt, Germany).

Before harvesting the bone grafts, the patients received broad-spectrum antibiotics, starting one hour preoperatively (intravenously) and continued orally for 2 days after surgery. Postoperatively, the patients received an aqueous 0.2% chlorhexidine mouth rinse (1 minute, three times daily) for 2 weeks. One month postoperatively, the edentulous patients were allowed to wear their dentures, after relining them in the operated areas with a soft liner.

After a healing period of 3–4 months, second stage surgery was done under general anesthesia in the day clinic. After reflecting the mucoperiosteal flap, the width of the reconstructed alveolar crest was measured again at the spot of the screws with a calliper.

Thereafter the titanium screws were removed and implants were inserted. In all cases the bone volume was sufficient and a total of 193 nonsubmerged one-piece implants (Straumann (ITI)®, Dental Implant System, Institut Straumann, Waldenburg, Switzerland) with adequate primary stability could be placed. Three months after insertion the prosthetic construction was fabricated.

Clinical Evaluation

Clinically, all patients were evaluated according to a standardized protocol 1, 3, 6, and 12 weeks after surgery by a clinical research not knowing which procedure had been performed at a particular site. The clinical protocol included assessment of complications during surgery and postoperative healing (inflammation, redness of the mucosa, wound dehiscence, sequestration, and loss of bone particles). Furthermore, patients were followed up to 1 year after functional loading.

Statistical Analysis

For statistical analysis a *t*-test and for analysis of time a linear regression analysis were used. All 36 patients were included for analysis. A *p*-value of <.05 was considered as a significant result.

RESULTS

Clinical Results

In all 36 patients, healing was uneventful and all patients could be supplied with an adequately implant placement and functioning implant-supported maxillary overdenture. In all cases, there was adequate bone and all 193 implants were placed with primary stability. Loss of bone particles through the nose was not observed.

Surgery

Operation time was significantly shorter when using conventional rotative instruments (11.1 ± 2.4 minutes) than when using piezosurgery (15.1 ± 2.9 minutes) ($p < .001$; linear regression analysis).

Width of the Alveolar Bone

In all cases, bone healing was uneventful and no problems were seen. Therapy (conventional rotative bur versus piezosurgery) had not significantly influenced horizontal bone width 3 months after sinus floor elevation. The average bone (mean \pm SD) width after the augmentation was 7.5 ± 0.2 mm in the conventional treated group and 7.6 ± 0.4 mm in the piezogroup. Three to 4 months after sinus lift surgery the bone the average bone width had reduced to 6.2 ± 0.2 mm in the conventional group and 6.3 ± 0.3 mm in the test group ($p = .523$, t -test). All measurements were performed in the 3–4-month post-sinus augmentation surgery period (14.6 ± 2.6 weeks; range 12–17 weeks).

Application of a Resorbable Membrane

Application of a resorbable membrane had not reduced horizontal bone resorption 3 months after sinus floor elevation, both within and between groups ($p = .062$; t -test). During the healing period, the width of the sites covered with a membrane reduced from 7.4 ± 0.3 mm to 6.0 ± 0.2 mm and at the sites not covered with a membrane from 7.6 ± 0.2 mm to 6.6 ± 0.3 mm.

Perforation of the Sinus Membrane

In total, eight sinus membrane perforations occurred, four in each group ($p = 1.0$; t -test).

Dehiscences after Implantation Procedure

In total, eight dehiscences (in eight patients) occurred were observed during implant placement on the buccal side. All dehiscences were covered with autogenous bone

and bovine bone mineral (BioOss®, Geistlich Biomaterials, Wolhusen, Switzerland). A collagen membrane (Bio-Gide®, Geistlich Pharma AG, Wolhusen, Switzerland) was used to cover the defects. Wound healing was uneventful. The occurrence of a dehiscence of the implant was not related to the type of surgery applied during the sinus floor elevation surgery ($p = 1.0$; t -test).

Implants

In all augmented regions, all 193 implants could be installed with primary stability. On average the implants had been placed 14.6 weeks (range 12–17 weeks) post-augmentation. Healing was uneventful and all patients could be supplied with an adequately implant placement and functioning implant-supported maxillary overdenture. One year implant survival rate (1 year after functional loading) was 100%.

DISCUSSION

The present randomized controlled clinical trial assessed the performance of conventional rotative instruments and a piezoelectric device during maxillary sinus floor elevation, with respect to bone healing, application of a membrane, operation time, and complications per and postsurgery. It was shown that piezoelectric bone surgery is a reliable alternative to the use of conventional rotative instruments as the results of both techniques were comparable. This observation is in agreement with the clinical results reported by Barone and colleagues.¹⁴ The only limitation of piezosurgery observed in this study was the time factor as the operation time was significantly shorter when using conventional rotative instruments. This observation is in agreement with the studies of Kotrikova and colleagues, Barone and colleagues, and Landes and colleagues,^{14–16} but the difference in operation time between both operative procedures for maxillary bone is, from a clinical perspective, negligible. However, in areas with a higher bone structure or thickness, the extra time needed for making an osteotomy by piezoelectric surgery can be much higher, up to fivefold and even more.¹⁵

The perforation of the Schneiderian membrane represents the most frequent complication in standard sinus lift surgery using rotative instruments. Torella and colleagues¹⁷ reported a reduced risk of perforating the Schneiderian membrane using normal ultrasound instruments for the opening of the bony window. They posed that inadvertent perforations of the sinus

membrane are unlikely when piezosurgical techniques are appropriately applied. In addition, in a series of 21 bony window and membrane elevations performed with piezoelectric surgery, only one perforation was reported, which resulted in a 95% success rate.¹⁰ In our study comparison of the clinical features at the test (piezosurgery) and control (conventional rotative instruments) revealed no differences with regard to perforations of the sinus membrane during surgery. Barone and colleagues¹⁵ showed a higher number of membrane perforations noted with piezosurgery than we observed in our trial, but the differences in their study also did not reach the level of significance. Therefore, it may be concluded that risk on sinus membrane perforation is comparable between the use of piezosurgery or a conventional rotative bur, at least from a clinical perspective. Probably, it is the experience of the surgeon in using conventional rotative instruments instead of piezoelectric surgery that is leading whether perforations will occur and what the consequences of such perforations will be. That also means that piezoelectric surgery only is reliable if the surgeon does have sufficient experience in using piezoelectric surgery and reverse for rotative instruments.

In previous reports, there are no differences found in implant survival with respect to membrane perforations.^{4,18} Also, our study showed a 1-year implant survival rate of 100% in both groups.

Application of a resorbable membrane did not significantly reduce post augmentation loss of bone width, which is in agreement with the observations of Gielkens and colleagues.¹⁹ The latter authors studied the effect of membrane coverage on resorption and incorporation of autogenous onlay bone grafts in rats. In that study, it was concluded that application of a membrane barrier is not necessary to prevent bone resorption. Furthermore, the present study showed that application of a membrane does not have any significant influence on the operation time in addition applying a membrane increase the cost of treatment.

From this randomized-controlled clinical trial comparing the performance of conventional rotative instruments and a piezoelectric device during maxillary sinus floor elevation, with respect to bone healing, operation time, and complications per-/postsurgery, it can be concluded that piezoelectric bone surgery showed no advantages over conventional rotative instruments. Furthermore, placement of a barrier membrane did not result in less resorption of the augmented site.

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