Membrane Perforation in Sinus Floor Elevation – Piezoelectric Device versus Conventional Rotary Instruments for Osteotomy: An Experimental Study

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ABSTRACT

Purpose: Sinus membrane perforation is the most common intraoperative complication of maxillary sinus floor elevation (MSFE) procedures and frequently causes postoperative problems. Piezoelectric devices have been claimed to reduce the frequency of membrane perforations although no clear evidence supports this view.

Materials and Methods: Ten surgeons with different expertise levels performed 80 MSFEs in selected lamb heads, with rotary and piezoelectric instruments following standard protocols. After the procedures, specimens were coded and perforations or tears determined through a microscope.

Results: No significant differences in terms of thickness either of the sinus lateral wall (x_i-x_j = 73.2; 95% confidence interval [CI] = 45.3–191.8) or the membrane (x_i-x_j = 24.2; 95% CI = −29.4 to 77.9) were identified between the specimens allocated to each group. Nine membrane perforations (11.2%) occurred during the study, all within the lower expertise group. Membrane elevation by hand instruments caused five perforations (40%) in the rotary instrument group and one in the piezoelectric group. Expert surgeons produced no membrane perforations, the size of the antrostomy that was smaller in the piezoelectric group being the only significant difference between the rotary and piezoelectric groups.

Conclusions: The use of piezoelectric material for MSFE reduces the frequency of membrane perforation among surgeons with a limited experience.

KEY WORDS: bone augmentation, dental implants, maxillary sinus floor elevation, membrane perforation, piezoelectric surgery

INTRODUCTION

Maxillary sinus floor elevation (MSFE) by lateral window approach is a predictable technique for bone augmentation[1] that elicits its best results when combined with rough surface implants and membrane coverage of the lateral window.[2] However, the quest for the optimal MSFE protocol to achieve high implant success rates, shorten treatment periods, and minimize morbidity is permanent and continuous.

Several reports describe perforation of the sinus membrane as the most common intraoperative complication of MSFE with an average frequency of 19.5%,[2] ranging from 0[3,4] to 58.3% in short case series.[5] This event may occur while opening the lateral bony window, either by the heat or the actual drill action, or by

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DOI 10.1111/j.1708-8208.2012.00447.x

handling errors during membrane elevation with manual dissectors.[6]

Membrane perforation endangers the MSFE procedure and frequently causes postoperative complications such as sinus infection, loss of the grafting material, and disruption of the sinus physiologic function,[7] although its impact on vital bone formation and/or on the success rate of the implants placed within the augmented sinus is controversial.[7–9]

Piezoelectric surgery was first introduced by Torrella and colleagues in 1998[10] to perform the maxillary osteotomy during MSFE in order to minimize membrane perforation. From then on, this device was assessed by many noncomparative studies describing low perforation frequencies (0–4.8%).[11–13] Conversely, the only randomized-controlled clinical trial comparing the performance of ultrasonic devices versus conventional rotary instruments was unable to demonstrate any advantage in terms of frequency of membrane perforation.[14] Despite this lack of evidence, many authors support the use of piezoelectric devices for MSFE osteotomies instead of rotary instruments because their ultrasonic vibrations of relatively low frequencies for opening the bony window seem to reduce the risk for Schneiderian membrane perforation.[10]

In the current study, we tested the hypothesis that piezoelectric surgery for osteotomy in MSFE would reduce the rate of sinus membrane perforation.

METHODS AND MATERIALS

An experimental study was designed to test the research hypothesis (Figure 1), with an experimental sample size determined to disclose differences between groups in terms of sinus membrane perforation frequency, presupposing that 34% is a relevant difference (bilateral hypothesis) in the proportions of membrane perforation (2% in the piezoelectric group and 36% within the conventional group) with a confidence level of 95% and a statistical power of 80%. The required sample size was 40 maxillary sinuses (20 for each technique). Bearing in mind that the study also considered two expertise levels, a total of 80 maxillary sinuses (40 treated by expert surgeons and 40 by initiates) were needed to ensure disclosing differences under the stated conditions.

Thus, 40 fresh heads obtained from sheep younger than 12 months (range 6–12 months) were used as a model for this ex vivo study. These materials were disease-free and transported from the slaughterhouse within 8 hour postmortem.

The surgeons participating in the trial were selected according to the expertise classification of Hoffman and colleagues.[15] As “initiate surgeon” (a novice who has began instruction), 10 general practitioners were randomly selected (simple random sampling [SRS]) by means of a computer-generated table of random numbers from a pool of 30 postgraduate students of the University of Santiago de Compostela Oral

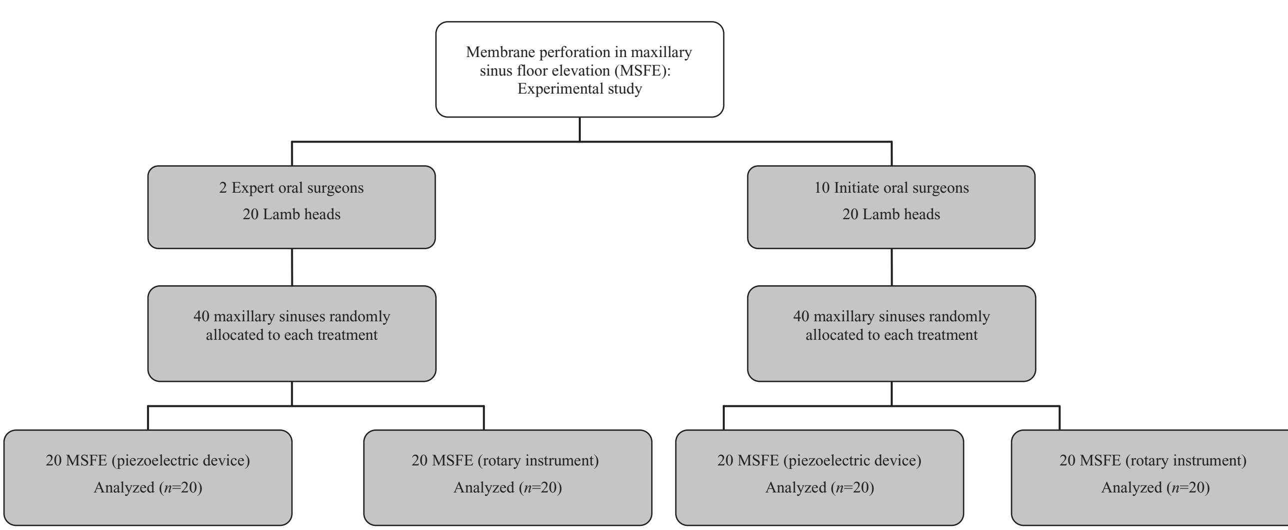

Figure 1 Study design.

Implantology Specialization Course with clinical experience in oral implantology and preclinical exposure to MSFE (five MSFEs in the surgical abilities laboratory in 6 months). As "expert surgeons," two senior lecturers in oral surgery with more than 10 years of experience with piezoelectric devices for MSFE also entered the study.[15,16]

Twenty fresh lamb heads were randomly selected (SRS) from the original pool of 40 and allocated to the initiate surgeon group. Each individual performed four MSFEs, two by each technique, randomly allocating the right or left sinus to each device (rotary vs ultrasonic). The two-surgeon group followed the same protocol (see Figure 1) to perform 40 MSFEs (20 each). To standardize the procedure, every participant received a seminar and a guide with information on the techniques and methods.

Conventional (rotary) MSFE technique included trepanation with a round diamond bur (o23, Komet, Lengo, Germany) mounted on a handpiece and sinus membrane lifting with and ad hoc surgical kit (Mozo-Grau, Valladolid, Spain) according to a previously described surgical protocol (trap door)[2] using the third premolar as a landmark.[17] The piezoelectric osteotomy was undertaken as described by Wallace for maxillary sinuses with lateral walls ≤1 mm in thickness[11] by means of the VarioSurg Se (Set mod VSRG 230V1, Nakanishi Inc., Kanuma-shi, Tochigi, Japan) using a diamond ball (SGD6), and the initial membrane elevation was performed by means of a dull noncutting elevator (SG11) (Figure 2) and continued with conventional hand instruments. All interventions were performed at the Dental School's abilities lab and the partakers were informed about the conditions of its use and safety regulations that were basically identical to those of a real surgical environment.

After MSFE procedures, the specimens were coded and perforations or tears were determined by inspection under a microscope (M525 F40; Leica, Heerbrugg, Switzerland) at 10 magnifications. Samples of the lateral bony wall of the maxillary sinus were then obtained, fixed in 10% neutral buffered formalin for 24 hours, decalcified in Decalc (Histolab Products AB, Göteborg, Sweden) for 1 hour, and embedded in paraffin routinely. The samples of the maxillary sinus membranes were adhered to a thin cardboard to guarantee a correct orientation and fixed and paraffin embedded as for the bony samples.

Figure 2 Initial membrane elevation performed with the VarioSurg dull noncutting elevator insert.

Sections of 4 μm thick were obtained from each specimen. The sections were mounted on microslides and stained with hematoxylin eosin. Each specimen was coded and blindly studied by two pathologists. Only specimens with strict perpendicular orientation were selected for maxillary sinus wall thickness evaluation. Measurements were performed using an optical micrometer (Graticules Ltd, Tonbridge, Kent, UK) at ×100 (×10 objective). Microphotographs were obtained in an Olympus PROVIS AX70 (Olympus, Tokyo, Japan) microscope equipped with an Olympus DP70 camera (Olympus).

The study design was accepted by the Comité de Bioética de la Universidade de Santiago de Compostela (USC ethics committee) and the investigation was undertaken according to European Union ethical protocols.

Statistical Analysis

Data were entered in a statistical package (SPSS + 11.0 statistical package, Chicago, IL, USA), and the sample was characterized by the variables of interest. Data distribution was defined by the mean as central trend statistic, and the standard deviation and the range as spread indicators. Quantitative variables were assessed by means of the Wilcoxon test for related samples (nonparametric) and the Mann-Whitney *U* for independent samples. Qualitative variables were analyzed using the

TABLE 1 Clinical Features of the Experimental Model (Baseline Data)

Clinical Variables. Lamb Maxillary Sinus	Thickness of the Sinus Lateral Bony Wall (μm) X ± SD (Min–Max)	Thickness of the Schneiderian Membrane (μm) X ± SD (Min–Max)
Right sinus ($n = 40$)	903.7 ± 279.6 (500–2,000)	532.0 ± 118.6 (320–800)
Left sinus ($n = 40$)	871.0 ± 256.0 (450.0–1,630)	530.2 ± 123.8 (350–810)
Total, both sinuses ($n = 80$)	887.3 ± 267.2 (450.0–2,000)	531.1 ± 120.5 (320–810)

Fisher's exact test. The significance level chosen for all test was 5% ($p < .05$).

RESULTS

The specimens showed no inflammatory infiltrate in their sinus membranes.

Surgeons at two levels of expertise (10 initiate and 2 experts) undertook 80 MSFEs in 40 specimens (lamb heads), whose characteristics are described in Table 1.

No significant differences in terms of thickness either of the sinus lateral wall (x_i-x_j = 73.2; 95% confidence interval [CI] = 45.3–191.8) or the sinus membrane (x_i-x_j = 24.2; 95% CI = −29.4 to 77.9) could be identified between the specimens allocated to each group of surgeons (Figure 3).

A total of nine membrane perforations (11.2%) occurred during the MSFE procedures, all of them within the group of initiate surgeons, mostly during membrane separation with manual elevators.

Antrostomy with piezoelectric devices caused no perforations in any group, although the use of rotary instruments by initiate surgeons resulted in three membrane perforations. The membrane elevation procedure by initiate surgeons using hand instruments caused five perforations in the control group (rotary instrument) and one in the test group (Table 2). The use of piezoelectric material for MSFE surgery by initiate surgeons significantly diminishes the frequency of membrane perforations no matter the anatomic features of the model (Table 3). Expert surgeons did not produce any membrane perforation, the size of the antrostomy that was smaller in the piezoelectric group being the only significant difference between the experimental and control groups (Table 4).

DISCUSSION

Membrane perforations have been put down to certain anatomic features, namely, thin sinus mucosa, irregularities of the bony sinus floor,[5,18] or to an inadequate surgical technique.[19] Surprisingly, factors such as the thickness of the sinus membrane have not been considered in previous reports assessing iatrogenic damage

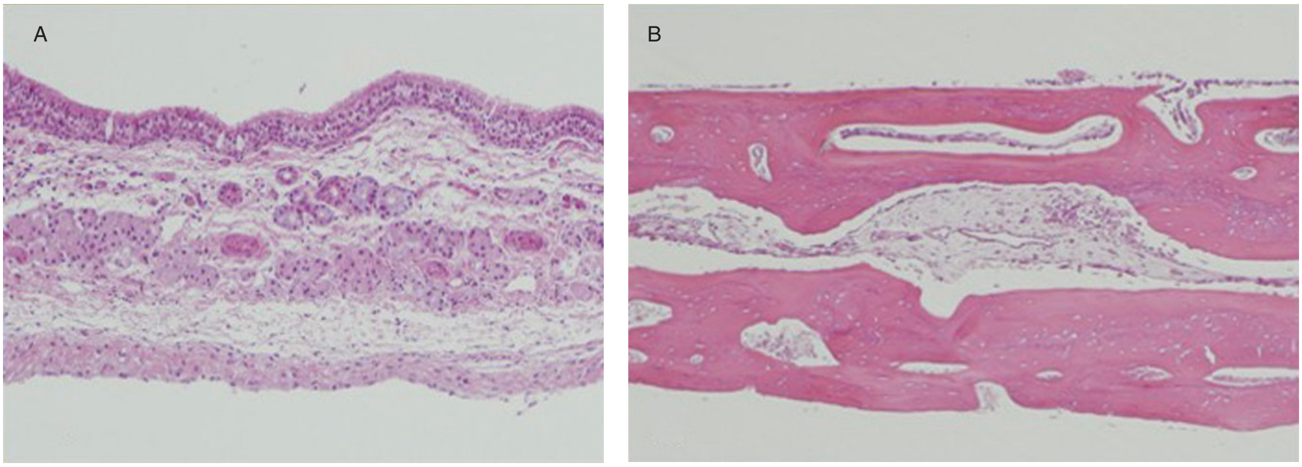

Figure 3 (A) Maxillary sinus membrane (Schneiderian membrane) is recovered by a respiratory epithelium that lies on a wide lamina propria with numerous blood vessels and serous glands. The deep layer corresponds to the periosteum (Hematoxylin & Eosin [HE], ×10). (B) The wall of the maxillary sinus is made up of compact bone with Haversian systems that surrounds the cancellous bone containing inactive yellow marrow (HE, ×6).

TABLE 2 Distribution of Membrane Perforations during Antrostomy or Membrane Elevation according to Surgeons' Expertise and Instruments Employed

	Initiate Surgeons ($n = 40$)		Expert Surgeons ($n = 40$)	
Group	Antrostomy	Membrane Elevation	Antrostomy	Membrane Elevation
Control group (rotary instruments)	3 (15%)	5 (25%)	—	—
Test group (piezoelectric device)		1 (5%)	—	—

Percentages calculated for each subgroup ($n = 20$).

during MSFE.[14] This circumstance is particularly important as the sinus mucosal thickness shows a wide variability which would seem to influence interindividual variations on the risk for perforations.[20] Our results have not shown significant differences in terms of sinus membrane thickness among the models allocated to each group, which would prevent this potential bias.

The prevalence of intrasinusal septa ranges from 13 to 35% in humans[21] and has also been identified as a risk factor for membrane perforation during MSFE procedures. Thus, the presence of septa at the surgical site has been used as exclusion criteria in this kind of studies in order to control for this risk factor.[22] The specimens included in our study did not present any intrasinusal septa, which guarantee homogeneous data on the association between the osteotomy materials and the frequency of membrane perforations.

TABLE 3 Clinical Parameters during Osteotomy and Sinus Membrane Elevation by Initiate Surgeons (Piezoelectric vs Rotary Instruments)

Parameter	Control Group (Rotary Instruments) X ± SD (Min–Max)	Test Group (Piezoelectric Device) X ± SD (Min–Max)	*p*
Window height (mm)	11.2 ± 2.1 (7.0–17.0)	10.7 ± 2.8 (6.5–17.0)	.26
Window length (mm)	16.3 ± 2.5 (10–21)	15.5 ± 3.6 (8.5–21.0)	.27
Lateral bony wall thickness (μm)	855.0 ± 251.6 (500.0–1,630.0)	993.0 ± 365.8 (500.0–2,000.0)	.33
Schneiderian membrane thickness (μm)	564.5 ± 116.7 (350–810)	522.0 ± 97.7 (400.0–780.0)	.21
Perforations during antrostomy (*n* %)	3 (15%)	0 (0%)	.24
Total perforations (*n* %)	8 (40%)	1 (5%)	.02

TABLE 4 Clinical Parameters during Osteotomy and Sinus Membrane Elevation by Expert Surgeons (Piezoelectric vs Rotary Instruments)

Parameters	Control Group (Rotary Instruments) X ± SD (Min–Max)	Test Group (Piezoelectric Device) X ± SD (Min–Max)	*p*
Window height (mm)	8.9 ± 1.4 (7.0–14.0)	8.2 ± 1.1 (7.0–12.0)	.05*
Window length (mm)	14.0 ± 1.6 (10.0–16.0)	12.5 ± 1.7 (7.0–15.0)	.01*
Lateral bony wall thickness (μm)	503.5 ± 125.1 (350–720)	867.0 ± 159.4 (550.0–1,140.0)	.33
Schneiderian membrane thickness (μm)	834.5 ± 241.1 (450–1,250)	534.5 ± 139.4 (320.0–800.0)	.22
Perforations during antrostomy (*n* %)	0 (0%)	0 (0%)	NS
Total perforations (*n* %)	0 (0%)	0 (0%)	NS

*Statistically significant.
NS = not significant.

The participants cannot be blinded about the osteotomy materials used in the study, so a limited risk for performance bias should be assumed. Moreover, bone drilling performance is an important part of surgical expertise as has been previously proved when comparing the occurrence of plunging events (injury to the underlying soft tissue structures) cased by experts and novices.[23] This finding points at the possibility that some effects attributed to different osteotomy materials may well be due to differences in the expertise level of the operators.[24] To avoid this bias, the design of the present study includes two groups of clinicians with different skill levels, according to the criteria of Hoffman and colleagues.[15]

Generalization of the results can be compromised by the use of an animal model, but the lamb maxillary sinus has previously demonstrated close similarities with humans.[17] Our sample elicited values for the thickness of the bony wall of the sinus similar to those described by Barone and colleagues determined by computed tomography[14] and Neiva and colleagues by direct morphometric analysis in Caucasian skulls.[25] Moreover, the experimental model allowed histological measurement of the bony wall and the Schneider membrane, which were both previously linked to perforation events.[11] Bearing in mind that the interventions have been undertaken by surgeons with a wide range of surgical experience, it seems reasonable to assume the generalizability of the results obtained from this trial.

Avoiding potential injury to the Schneiderian membrane is critical, as its integrity ensures stability and vascularization of the graft and thus easing its maturation, whereas tear or perforation of the membrane may induce local postoperative complications and an increased risk of implant failure.[26] Expert surgeons – no matter of the device employed – did not cause any membrane perforation even in maxillary sinuses with thin membranes (≤1 mm). The results obtained by experts during the drilling task are better than the ones achieved by the novice group,[16,23] as happened in our series.

Piezoelectric devices have proved to significantly reduce the frequency of membrane perforations among initiate surgeons probably because these instruments operate at a modulated frequency designed to cut bone without damaging adjacent soft tissues. Moreover, the initial release of the membrane from the antrostomy edges is performed with a dull, rounded, noncutting elevator insert, which may explain the lower percentage of perforations in the experimental (piezoelectric) group, as it eases the use of hand instruments to complete membrane elevation.

Our study's main contribution is to perform an analysis on the MSFE surgical instruments controlling for anatomic variables known to influence membrane perforation (thicknesses of the maxillary sinus lateral bony wall and Schneider's membrane) and also for the expertise of the surgeons who undertake the task.

It is concluded that the use of piezoelectric material for MSFE reduces the frequency of sinus membrane perforations, among surgeons with a limited experience. The use of a round, noncutting elevator insert for the initial release of the membrane seems to be particularly relevant.

Additional controlled and randomized clinical trials in human subjects considering both surgeons' expertise and anatomic variables known to condition sinus membrane perforations would be desirable to disclose the influence of the type of instrument used during the procedure.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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