Membrane perforation rate in lateral maxillary sinus floor augmentation using conventional rotating instruments and piezoelectric device—a meta-analysis

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Abstract

Objectives: Maxillary sinus augmentation (MSA) is a successful and predictable intervention with low complication rates. Perforations of the Schneiderian membrane may occur impairing the general success. The aim of this study was to compare the incidence of membrane perforations between conventional rotating instruments and piezoelectric devices in a meta-analysis.

Material and methods: An electronic research on MEDLINE and PubMed database was performed evaluating the literature from 1980 till 2016. Meta-analysis was performed with the studies matching the inclusion criteria. The incidence of perforations between conventional and piezo during the lateral maxillary sinus floor elevation was determined, and forest plots and a t test for significance analysis were performed.

Results: The search provided 377 articles of which 69 could be included. Selected non-randomised and non-controlled prospective and retrospective studies were incorporated. Conventional rotary instruments were associated with a perforation rate of 24%, the piezoelectric devices with 8% with statistically significant difference between both modalities (p < 0.05).

Conclusion: Membrane perforations in MSA may be significantly reduced applying piezoelectric devices for MSA.

Keywords: Membrane perforations in MSA, Conventional, Piezosurgery, Schneiderian membrane, Perforation, Ultrasound

Review

Background

Maxillary sinus augmentation (MSA) is a successful and predictable procedure to rehabilitate the atrophic edentulous posterior maxilla after postextractional pneumatization of the sinus and bone loss with dental implants. Different approaches to elevate the maxillary sinus floor have been described and were originally introduced by Tatum [1, 2]. The lateral approach provides drilling a window in the lateral sinus wall for access to the Schneiderian membrane. This may be performed in terms of a total osteotomy or by drilling a trap door. Then, the Schneiderian membrane is carefully separated and elevated from the bony sinus floor and bone or bone grafting materials are applied to fill the new space between the membrane and bony sinus floor. This approach, however, is limited by the occurrence of Schneiderian membrane perforation while drilling the bony window in the sinus wall or separating the Schneiderian membrane from the bony floor. Schneiderian membrane perforation is the most frequent complication in MSA with an incidence of 7–44% [3, 4]. Two principal different techniques acceding and elevating the Schneiderian membrane are described. The conventional approach is performed applying rotary instruments in osteotomy which represents a risk for membrane perforation [5, 6], followed by the manual elevation of the membrane with hand instruments (special sinus lift kits). Alternatively, piezoelectric devices as proposed by Torella [7] and Vercelotti [8] may be applied for
osteotomy and membrane preparation. Piezoelectric devices are specially designed for osseous surgery and use low-frequency ultrasonic vibrations. The amplitude of the micro vibrations allows a precise cut of bony structures without damaging the soft tissue [9]. Piezosurgery is being increasingly used in implant surgery, and the question rises whether the incidence of membrane perforations may be reduced using piezoelectric devices for MSA. Several cases are described, and many studies report on the occurrence of membrane perforation during MSA. However, only a few meta-analysis compare the incidence of membrane perforations associated to conventional (rotational) instruments and piezoelectric devices so far. There exist two reviews with a similar objective as ours (conventional versus piezosurgery device), one review which compared conventional sinus lift with four alternative techniques including piezосurgery and at least the review of Esposito analysing the study of Rickert et al. [10].

Atieh et al. [11] examined the intra- and postoperative events associated with the use of piezoelectric devices and conventional rotary instruments for lateral MSA in a systematic review. They included four studies with 178 lateral MSA in 120 participants. The meta-analysis did not show any significant difference between the two surgical techniques. Stacchi et al. [12] analysed the occurrence of intraoperative complications during sinus floor elevation with lateral approach and their correlations with the technique adopted by surgeons. They included 21 RCTs and 11 prospective CCTs. Rotary instruments, piezoelectric osteotomes, and manual bone scrapers were used to perform the lateral antrostomy. They found that ultrasonic devices and bone scrapers had a lower incidence (10.9 and 6.0%) of membrane perforation compared with that of rotating instruments (20.1%). They concluded that the thinning of the lateral wall of the sinus by using ultrasonic instruments or bone scrapers seemed to reduce the incidence of accidental sinus membrane perforations.

Geminiani et al. [13] assessed the difference in the incidence of intraoperative and postoperative complications between the conventional and alternative surgical techniques, during sinus floor augmentation surgery. This meta-analysis included 11 articles, while all compared the incidence of complications in conventional lateral window sinus augmentation surgery versus alternative techniques (osteotome: five articles, piezosurgery: four articles, sonic surgery: one article, trephine: one article). They found no statistically significant difference and concluded that the use of alternative techniques does not significantly reduce the incidence of intraoperative perforation of sinus membrane. Esposito et al. [14] researched in their review the beneficial or harmful effects of bone augmentation compared to no augmentation when undertaking a sinus lift procedure. They referred to the trial of Rickert, who undertook the comparison of rotary instruments versus piezosurgery to open a lateral window in the maxillary sinus, and found no evidence for the superiority of piezosurgery. This manuscript is a potential update exclusively on membrane perforation rate in lateral sinus augmentation procedures using conventional rotary or piezoelectric devices.

Material and methods
The database PubMed and the US National Library of Medicine were screened from January 8, 2012, to January 6, 2016, for potential studies reporting on membrane perforations during MSA from 1980 till 2015. The search was conducted independently and in duplicate by two authors (MK and JC). The following search terms were used:

MeSH Terms:
1. Piezo-surgery
2. Ultrasound
3. Ultrasonic Osteotomy
4. Maxillary Schneiderian Membrane Perforation
5. Sinus Perforation
6. Maxillary Sinus Augmentation Complications
7. Lateral Sinus Osteotomy

Cross-references:
1. Piezo-surgery AND Sinus Floor Elevation
2. Piezo-surgery AND Sinus Lift
3. Piezo-surgery AND Maxillary Sinus Grafting
4. Piezo AND Maxillary Sinus Lift
5. Piezoelectric Bone Surgery AND Sinus
6. Piezo-surgery AND Maxillary Sinus Augmentation Complications
7. Piezo-surgery AND Schneiderian Membrane Perforation
8. Ultrasound AND Sinus Augmentation
9. Ultrasound AND Sinus Lift
10. Ultrasonic AND Sinus Lift
11. Ultrasonic Osteotomy AND Sinus
12. Ultrasonic AND Schneiderian Membrane Perforation
13. Sinus Elevation AND Conventional

Included were all studies reporting on the amount of membrane perforations during MSA by the lateral approach. Prospective and retrospective cohort studies and case series were also included. Both studies with split-mouth design and also studies without control group were also included. Excluded were studies describing any other procedure than the lateral approach for MSA, missing information on the occurrence of membrane perforation and in vitro studies. Titles and abstracts of the searches were initially screened for possible inclusion. After analysis of the abstracts, full-text evaluation
was performed. Any disagreement was resolved by discussion between the authors (Fig. 1).

The following data were extracted:

1. Study characteristics: title, authors’ name, year of publication, study design, number of sinus floor elevations (SFE)
2. Interventions: the use of piezoelectric devices or rotary instruments for SFE
3. Outcomes: number and percentage of membrane perforation

**Data synthesis**

For each study, the sample size was determined and the event rate (e.g. perforation or not) was noted in an Excel sheet. Then, a meta-analysis was performed using the Comprehensive Meta-Analysis (Version 3) (Biostat, Englewood, USA) applying the sample size of each study and the event rate (e.g. perforation of the membrane or not). The software calculates the suggested effect of the operation technique (piezo or conventional) on the specific event (perforation of the membrane). This way, the raw data were weighted on the sample size for significance analysis. Applying the weighted data forest plots were calculated, indicating the weight and the 95% confidence interval. Additionally, the random effect was calculated representing the average of all studies in the respective groups (piezo and conventional).

Finally, a significance analysis was performed between both groups in terms of a t test. The significance level was set at $p < 0.05$ (Figs. 2 and 3).

**Results**

**Description of studies**

Abstracts of 377 articles were screened. Of these, 69 studies matched the inclusion criteria and were consecutively analysed (Tables 1 and 2). Nine of these are randomised controlled, 22 retrospective and 32 prospective studies. Comparing both groups, in 46 studies, conventional instruments were used, and in 27 studies, piezoelectric devices were used to perform the MSA (Tables 1 and 2).

The forest plots generally show a higher perforation rate for conventional sinus lift when compared to piezosurgery (Tables 1 and 2, Figs. 2 and 3). It is obvious that studies with smaller sample size reveal higher 95% confidence intervals. The random effect for conventional sinus lift was 0.24 and for the piezo 0.08. This difference between piezo and conventional sinus lift was statistically highly significant with $p < 0.001$. (Figs. 2 and 3).

**Discussion**

The current data show that there is a statistically significant less occurrence of perforation of the Schneiderian membrane when piezosurgery is used compared to conventional approach. The reason for this difference may be explained by the technical skills of piezoelectrical surgery. Piezoelectric devices are able to cut highly mineralized bone due to its surgical power which is three times higher than normal ultrasound and the variable modulations of the powerful piezoelectric handpiece with its functional frequency of 25 to 29 kHz. Specifically designed osteotomy and osteoplasty inserts move with linear microvibrations (60 to 210 μm), which are ideal for
the preservation of the Schneiderian membrane. Low frequency of ultrasonics and the sharp instruments cut mineralized tissue easier than soft tissue. Furthermore, it should be noted that near soft tissue, the cutting process is safer, while not using the intrinsic cutting and using a diamond-coated instrument [8].

This aspect may be especially crucial in MSA since the facial bone is mainly compact and the Schneiderian membrane rather thin and fragile. It could be shown...
Table 1 Overview on the event rate (with lower and upper limits, z value), weight and significance (p values) for conventional approach and random effect

| Event rate | Lower limit | Upper limit | z value | p value | Weight |
|------------|-------------|-------------|---------|---------|--------|
| Conventional | | | | | |
| Galindo-Moreno et al. 2007 [15] | 0.005 | 0.000 | 0.076 | -3.726 | 0.000 | 0.445 |
| Marchetti et al. 2007 [16] | 0.010 | 0.001 | 0.143 | -3.218 | 0.001 | 0.443 |
| Delibasi et al. 2013 [67] | 0.043 | 0.006 | 0.252 | -3.023 | 0.003 | 0.753 |
| van den Bergh et al. 1998 [5] | 0.048 | 0.016 | 0.140 | -5.033 | 0.000 | 1.507 |
| Krekmanov et al. 1995 [17] | 0.071 | 0.030 | 0.160 | -5.527 | 0.000 | 1.870 |
| Watzek et al. 1998 [18] | 0.100 | 0.038 | 0.238 | -4.169 | 0.000 | 1.683 |
| Zijderveld et al. 2008 [19] | 0.102 | 0.059 | 0.171 | -7.153 | 0.000 | 2.394 |
| Papa et al. 2005 [20] | 0.105 | 0.054 | 0.197 | -5.726 | 0.000 | 2.162 |
| Rickert et al. 2011 [73] | 0.111 | 0.042 | 0.261 | -3.921 | 0.000 | 1.673 |
| Rickert et al. 2013 [10] | 0.111 | 0.042 | 0.261 | -3.921 | 0.000 | 1.673 |
| Lindenmüller and Lambrecht 2006 [21] | 0.112 | 0.091 | 0.191 | -6.462 | 0.000 | 2.343 |
| Penarrocha-Diago et al. 2012 [22] | 0.125 | 0.048 | 0.289 | -3.640 | 0.000 | 1.661 |
| Kaptein et al. 1998 [23] | 0.159 | 0.097 | 0.251 | -5.713 | 0.000 | 2.438 |
| Cha et al. 2014 [24] | 0.161 | 0.118 | 0.216 | -8.932 | 0.000 | 2.765 |
| Tawil et al. 2001 [25] | 0.167 | 0.071 | 0.343 | -3.285 | 0.001 | 1.791 |
| Yilmaz et al. 2012 [26] | 0.172 | 0.098 | 0.284 | -4.746 | 0.000 | 2.305 |
| Cho et al. 2001 [27] | 0.184 | 0.098 | 0.317 | -4.043 | 0.000 | 2.178 |
| van den Bergh et al. 2000 [28] | 0.200 | 0.093 | 0.379 | -3.037 | 0.002 | 1.894 |
| Becker et al. 2008 [68] | 0.204 | 0.154 | 0.265 | -7.779 | 0.000 | 2.791 |
| Ewers et al. 2005 [29] | 0.206 | 0.156 | 0.266 | -7.894 | 0.000 | 2.801 |
| Aimetti et al. 2001 [30] | 0.214 | 0.100 | 0.402 | -2.821 | 0.005 | 1.881 |
| Hernández-Alfaro et al. 2008 [69] | 0.219 | 0.184 | 0.259 | -11.435 | 0.000 | 2.934 |
| Barone et al. 2008 [31] | 0.231 | 0.076 | 0.522 | -1.829 | 0.067 | 1.346 |
| Khoury et al. 1999 [3] | 0.241 | 0.188 | 0.302 | -7.217 | 0.000 | 2.831 |
| Barone et al. 2006 [32] | 0.250 | 0.182 | 0.334 | -5.297 | 0.000 | 2.701 |
| Raghoebart et al. 2001 [33] | 0.258 | 0.200 | 0.327 | -6.230 | 0.000 | 2.805 |
| Kim et al. 2011 [34] | 0.259 | 0.129 | 0.453 | -2.391 | 0.017 | 1.948 |
| Shlomi et al. 2004 [35] | 0.274 | 0.184 | 0.387 | -3.714 | 0.000 | 2.533 |
| Wannfors et al. 2000 [36] | 0.275 | 0.159 | 0.432 | -2.738 | 0.006 | 2.228 |
| Hallman et al. 2004 [37] | 0.300 | 0.164 | 0.483 | -2.127 | 0.033 | 2.080 |
| Bornstein et al. 2008 [38] | 0.305 | 0.201 | 0.433 | -2.911 | 0.004 | 2.466 |
| Ardekian et al. 2006 [39] | 0.318 | 0.238 | 0.411 | -3.723 | 0.000 | 2.709 |
| Kazancioglu et al. 2013 | 0.320 | 0.169 | 0.522 | -1.758 | 0.079 | 1.982 |
| Raghoebart et al. 1999 | 0.321 | 0.249 | 0.403 | -4.129 | 0.000 | 2.775 |
| Philippart et al. 2003 | 0.333 | 0.158 | 0.571 | -1.386 | 0.166 | 1.761 |
| Scarano et al. 2015 | 0.333 | 0.131 | 0.624 | -1.132 | 0.258 | 1.455 |
| Oh et al. 2011 | 0.343 | 0.276 | 0.416 | -4.085 | 0.000 | 2.830 |
| Raghoebart et al. 1997 | 0.346 | 0.250 | 0.455 | -2.731 | 0.006 | 2.623 |
| Jensen et al. 1994 | 0.352 | 0.274 | 0.438 | -3.307 | 0.001 | 2.764 |
| From et al. 2013 | 0.375 | 0.240 | 0.532 | -1.564 | 0.118 | 2.320 |
| Stricker et al. 2003 | 0.379 | 0.271 | 0.501 | -1.950 | 0.051 | 2.560 |
| Levin et al. 2004 | 0.468 | 0.362 | 0.578 | -0.562 | 0.574 | 2.648 |
that the mean Schneiderian membrane thickness is 1.13 mm [66]. Therefore, piezosurgery, with its gentle cutting process, is perfectly qualified for the maxillary sinus membrane elevation. Though both techniques exist more than 20 years, only single studies could be found in which the incidence of membrane perforation was focused comparing both operative techniques. This was the rationale for our meta-analysis. Principally, there is a controversy in the literature concerning the use of piezosurgical devices for MSA. Torrella et al. showed a reduced risk for perforations of the sinus membrane while using ultrasound for lateral approach. They additionally mentioned the improved visibility and hygiene in the operating area and

### Table 1 Overview on the event rate (with lower and upper limits, z value, weight and significance (p values) for conventional approach and random effect (Continued)

| Event rate | Lower limit | Upper limit | z value | p value | Weight |
|------------|-------------|-------------|---------|---------|--------|
| Schwartz-Arad et al. 2004 [4] | 0.469 | 0.364 | 0.578 | -0.555 | 0.579 | 2.657 |
| Papa et al. 2009 [50] | 0.511 | 0.371 | 0.649 | 0.146 | 0.884 | 2.437 |
| Kasabah et al. 2003 [6] | 0.562 | 0.480 | 0.640 | 1.486 | 0.137 | 2.812 |
| Krennmair et al. 2007 [51] | 0.575 | 0.420 | 0.717 | 0.945 | 0.345 | 2.343 |
| Random | 0.240 | 0.205 | 0.278 | -11.262 | 0.000 |  

### Table 2 Overview on the event rate (with lower and upper limits, z value, weight and significance (p values) for piezosurgical approach and random effect

| Event rate | Lower limit | Upper limit | z value | p value | Weight |
|------------|-------------|-------------|---------|---------|--------|
| Wallace et al. 2007 [52] | 0.005 | 0.000 | 0.074 | -3.741 | 0.000 | 1.660 |
| Sohn et al. 2010 [53] | 0.008 | 0.001 | 0.054 | -4.817 | 0.000 | 2.712 |
| Toscano et al. 2010 [54] | 0.009 | 0.001 | 0.125 | -3.328 | 0.001 | 1.655 |
| He et al. 2013 [55] | 0.010 | 0.001 | 0.143 | -3.218 | 0.001 | 1.653 |
| Stübinger et al. 2008 [56] | 0.019 | 0.001 | 0.244 | -2.753 | 0.006 | 1.642 |
| Kim et al. 2012 [57] | 0.028 | 0.015 | 0.052 | -11.010 | 0.000 | 6.342 |
| Blus et al. 2008 [58] | 0.038 | 0.009 | 0.139 | -4.493 | 0.000 | 3.924 |
| Scarano et al. 2015 [43] | 0.038 | 0.002 | 0.403 | -2.232 | 0.026 | 1.616 |
| Penarrocha-Diago et al. 2012 [22] | 0.040 | 0.006 | 0.235 | -3.114 | 0.002 | 2.656 |
| Delibasi et al. 2013 [67] | 0.043 | 0.006 | 0.252 | -3.023 | 0.003 | 2.649 |
| Moon et al. 1 (Moon et al. 2015) [74] | 0.045 | 0.003 | 0.448 | -2.103 | 0.035 | 1.607 |
| Moon et al. 2 (Moon et al. 2015) [70] | 0.045 | 0.003 | 0.448 | -2.103 | 0.035 | 1.607 |
| Vercellotti et al. 2001 [8] | 0.048 | 0.007 | 0.271 | -2.924 | 0.003 | 2.642 |
| Cortes et al. 2012 [59] | 0.050 | 0.013 | 0.179 | -4.059 | 0.000 | 3.900 |
| Stacchi et al. 2013 [60] | 0.056 | 0.021 | 0.139 | -5.507 | 0.000 | 5.118 |
| Stübinger et al. 2009 [61] | 0.063 | 0.009 | 0.335 | -2.622 | 0.009 | 2.615 |
| Germiani et al. 2015 [76] | 0.093 | 0.047 | 0.175 | -6.134 | 0.000 | 6.030 |
| Felice et al. 2013 [71] | 0.100 | 0.025 | 0.324 | -2.948 | 0.003 | 3.799 |
| Rickert et al. 2011 [73] | 0.111 | 0.042 | 0.261 | -3.921 | 0.000 | 5.018 |
| Rickert et al. 2013 [10] | 0.111 | 0.042 | 0.261 | -3.921 | 0.000 | 5.018 |
| Sánchez-Recio et al. 2010 [62] | 0.154 | 0.059 | 0.345 | -3.136 | 0.002 | 4.936 |
| Sohn et al. 2011 [72] | 0.164 | 0.091 | 0.279 | -4.711 | 0.000 | 6.189 |
| Barone et al. 2013 [63] | 0.167 | 0.055 | 0.409 | -2.545 | 0.011 | 4.406 |
| Cassetta et al. 2012 [75] | 0.175 | 0.086 | 0.324 | -3.726 | 0.000 | 5.745 |
| Weitz et al. 2014 [64] | 0.175 | 0.086 | 0.324 | -3.726 | 0.000 | 5.745 |
| Barone et al. 2008 [31] | 0.308 | 0.120 | 0.591 | -1.349 | 0.177 | 4.900 |
| Corinaldesi et al. 2013 [65] | 0.333 | 0.131 | 0.624 | -1.132 | 0.258 | 4.522 |
| Random | 0.080 | 0.055 | 0.115 | -11.815 | 0.000 |  

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the controlled osseous incision [7]. Wallace et al. recorded a reduced membrane perforation rate, improved intraoperative visibility, reduced intraoperative bleeding and reduced surgical trauma. No perforation occurred during the antrostomy and the initial membrane elevation with piezoelectric inserts. However, using conventional hand instruments, seven membrane perforations occurred in the same study [52]. Stübing et al. and Toscano et al. also reported on complications during the elevation with hand instruments, especially in delicate situations with underwood septa which have shown to be an additional risk for membrane perforation [54, 61]. In contrast to these studies, Barone et al. observed four membrane perforations in the group treated with piezosurgery and only three perforations in the group treated with conventional instruments. In this randomised controlled clinical trial comparing rotary instruments with a piezoelectric device during maxillary sinus floor elevation, no significant difference was observed between the two groups. The authors concluded that the major limitation of piezosurgery was the time factor. Cutting procedures were substantially longer compared with conventional osteotomy devices [31]. Rickert et al. assessed also in a randomised controlled trial the same issue. In their study, they found no differences in the occurrence of perforations of the sinus membrane during surgery between piezo and conventional approach. They concluded that piezosurgery showed no advantages over conventional rotating instruments. Furthermore, they mentioned that the result is strongly depending on the experience of the respective surgeon with one of the respective techniques [10]. Another randomised controlled trial of Scarano et al. found a statistically significant difference between the incidences of sinus membrane perforation in the two groups. Group 1 used a round oral surgery bur, and the elevation was completed with sinus lift instruments. Group 2 using an ultrasonic surgery created a lateral bony window with nasal suction technique and elevation by using standard sinus lift instruments. Group 1 presented four perforations of the membrane, and no perforation occurred in group 2 [43].

Atieh [11] found no significant difference in perforation risk. In these studies, occurred in the two groups of the RCTs are almost identical perforations. Maybe due to the fact that they included only one RS, while our study included 22, they see no deviation.

The review of Stacchi [12] also described a lower incidence of membrane perforation during piezosurgery (10.9%) than during conventional surgery (20.1%). These results are comparable with ours.

Geminiani [13] found a significantly lower incidence of membrane perforations by the meta-analysis of the retrospective studies. Such a difference was not detected during meta-analysis of the data collected from the randomised clinical trials. They describe that the differences are most likely due to the inherent limitations of retrospective studies that include biases in selection of control and exposure to risk variables. They say that RCTs should be considered the main, because these trials have the preferred design for assessing differences in the outcome of a systematic review.

While incorporating selected non-randomised and non-controlled prospective and retrospective studies, our current data show that there is less perforation of the Schneiderian membrane when using piezosurgery. This might be a weakness resulting from the inclusion of the non-controlled studies.

**Conclusions**

The aim of the present study was to resume in a review the literature evaluating the incidence of sinus membrane perforation comparing conventional rotating instruments with piezoelectric devices. Since only scarce studies exist comparing both techniques directly, we decided to additionally include any study on MSA in which information on the applied technique, e.g. conventional or piezosurgery, was retrievable and additionally reporting on the incidence of membrane perforations. This procedure leads to heterogeneity of the collected data and accordingly included study designs. Obviously, a lot more studies with conventional approach than piezosurgery were included determining the incidence of membrane perforations. In order to reduce the resulting bias, forest plots were calculated and the weight was adjusted on the raw data, resulting in determination of the random effect. Another bias may affect the use of both conventional drilling for antrostomy and additionally piezosurgery for initial membrane elevation. The data were inconsistent in detailed information if combinations were used. Therefore, we decided to determine the piezosurgery group for both: single use for osteotomy and membrane elevation as well as for initial membrane elevation alone.

The present study may have a weakness, because membrane tear detection was not the primary focus and endpoint of many of our included studies. Many perforations might have been overlooked or not paid attention to this specific problem. The impact of different piezo tips on membrane perforation risk needs to be evaluated in further studies. With regard to our results, the present study showed that the weighted average incidence of perforation during MSA is 24% for rotating instruments and 8% for piezosurgery. These differences were statistically highly significant \( p < 0.005 \). With regard to the presented results, piezosurgery can be recommended reducing the risk of membrane perforation during MSA. However, though this seems to be a
reliable statement, it is not clear, whether combinations, e.g. osteotomy with rotating instruments and preparation of the membrane with piezosurgery, may be an alternative approach combining time efficiency with safety. The results suggest that piezosurgery was associated with a lower perforation rate. However, this statement is not reliable because of the inclusion of non-randomised and non-controlled studies as well as retrospective data. More RCTs focusing on membrane perforation are needed for a final conclusion.

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Authors’ contributions
The first two authors share the authorship. CJ and KM contributed to the data acquisition. SK, CJ and KM analysed and interpreted the data and wrote the manuscript. SK was supervising the study. JTL revised it critically and helped in finalising the manuscript and giving important intellectual content. All authors read and approved the final manuscript.

Competing interests
The authors Jordi Corinne, Mukaddam Khaled, Lambrecht Jörg Thomas and Kühl Sebastian state that they have no competing interests.

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