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Maxillary osteotomy complications in piezoelectric surgery compared to conventional surgical techniques: a systematic review

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Abstract. A systematic review was conducted to investigate the available evidence on maxillary complications related to piezoelectric and conventional surgery. Seven databases were searched. A total of 996 maxillary osteotomies were analysed, 864 performed with conventional tools and 132 with a piezoelectric device. One hundred and fifty-six complication events were reported. The complications, in descending order of overall prevalence, were as follows: neurosensory disturbance (64.7%), haemorrhage (8.3%), oroantral communication (7.7%), soft tissue injury (7.7%), tooth injury (5.1%), infection (3.2%), osteonecrosis (1.9%), and permanent nerve injury (1.3%). Among the complications, the results showed the highest prevalence for neurosensory disturbance, and haemorrhage was the most reported complication and the second most prevalent complication. A three-fold meta-analysis was performed. Using GRADEpro, the level of evidence was determined for each complication. The current low level of evidence suggests that piezoelectric bone surgery reduces critical and important complications during maxillary osteotomy procedures, such as neurosensory disturbance, haemorrhage, oroantral communication, tooth injury, and permanent nerve injury. However, an effective comparison between the two techniques was difficult to perform with the current available literature. Due to the small sample sizes in the piezoelectric surgery studies, caution should be exercised when considering almost non-existent reported complications.

Key words: orthognathic surgery; complications; maxillary osteotomy; systematic review.

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Piezoelectric surgical devices are surgical tools based on ultrasonic microvibrations that are utilized for bone cutting[1,2]. The development of piezoelectric surgical devices was based on the piezoelectric effect, in which ceramics and crystals deform under an electric current. The associated amplification of the vibrations is transferred to an instrument tip, which results in a mechanical cutting effect that acts exclusively on mineralized tissue[1]. This technique has shown similar histological and histomorphometric evidence of new bone formation and wound healing when compared to conventional bone-cutting techniques; hence it has become regarded as clinically effective for use in osseous surgery[3]. In addition, it has been suggested that piezoelectric surgical devices are safe for the soft tissues, even in the case of accidental contact[4]. Thus, the use of these devices has become widespread in a variety of oral surgeries, such as implant surgery[5], third molar surgery[6], temporomandibular joint surgery[7], surgery for the treatment of pathologies[8], minor orthodontic surgeries[9], and orthognathic surgical procedures[10].

The use of piezoelectric surgery in orthognathic surgery has increased due to the ergonomic hand piece that requires only slight pressure to promote complete section of the maxilla[11,12]. It also promotes a precise cut between the teeth without a significant risk of compromising tooth vitality[1], reduces thermal damage to the bone, teeth, and surrounding structures[11], and allows nerve regeneration with an intact perineural sheath[13]. The latter is considered the main advantage in bilateral sagittal split osteotomy of the mandible[1]. All types of orthognathic surgery using piezoelectric devices have been described, such as surgically assisted rapid maxillary expansion (SARME)/surgically assisted rapid palatal expansion (SARPE), Le Fort I with or without multi-segmentation, Le Fort II, Le Fort III, unilateral sagittal split osteotomy, and mentoplasty–genioplasty[14].

A previous systematic review explored the complications related to orthognathic surgery in general[15]. The most prevalent complication reported for the mandible was nerve injury or altered sensitivity, followed by temporomandibular joint disorders, while haemorrhage was the most common complication reported for the maxilla, followed by pterygomaxillary separation. Another previous systematic review on segmental Le Fort I stability and complications found infection, followed by oral communication and damage to the adjacent teeth, to be the most common complications[16]. Although these authors explored postoperative complications, they only investigated these complications for conventional surgical techniques.

Regarding the use of piezoelectric devices in orthognathic surgery, Pagotto et al.[17] showed that piezoelectric surgery improved complication rates in terms of intraoperative blood loss and severe nerve disturbance when compared to conventional techniques. They investigated the frequencies of complications regardless of whether the surgery was performed on the maxilla or on the mandible. Silva et al.[18] compared piezoelectric surgery and a conventional saw and showed a statistically significant benefit regarding neurosensory disturbance after 6 months of follow-up in favour of the piezoelectric device. However, they limited their analysis to mandibular sagittal split osteotomies. As the maxillomandibular complex has a different anatomy and bone density, the complications with this surgical approach are likely different. Therefore, we recognized a knowledge gap on the complications with the use of piezoelectric devices in maxillary surgeries.

The aim of this study was to investigate the frequency of complications among patients undergoing maxillary surgery performed with piezoelectric devices when compared to conventional surgical techniques. Additionally, as a secondary aim, the incidence of complications in maxillary osteotomies, regardless of the surgical approach, as reported in papers published between 2005 and 2017, was investigated and reviewed.

Methods

This systematic review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting checklist for the transparent reporting of systematic reviews and meta-analyses[19]. The review protocol was registered in the PROSPERO database[20], the International Prospective Register of Systematic Reviews (Centre for Reviews and Dissemination, University of York, York, UK; registration number CRD42017069152).

Eligibility criteria

The inclusion criteria for this systematic review included retrospective and prospective studies, cohort studies, case series, non-randomized clinical trials (NRCT), and randomized clinical trials (RCT) concerning orthognathic surgery in which a maxillary osteotomy was performed, for example Le Fort I (one or multiple segment approach) and/or a SARPE/SARME.

The following were considered exclusion criteria: animal studies; articles that used a similar sample that was reported by the same authors more than once; articles that did not present relevance (not related to maxillary osteotomy and/or measured a different outcome) or individualized data to answer the study research question. Studies that reported solely the surgical technique, case reports, technical notes, and review articles, as well as papers that were published and/or the surgeries were performed before 2005, were also excluded. The latter were excluded because ultrasonic orthognathic surgery had not been introduced into clinical practice before this time point[10].

Information sources and search

The PubMed, MEDLINE, Embase, LILACS, Web of Science, Cochrane Library, and Google Scholar databases were searched systematically following the PICO strategy[21]: P = patients undergoing maxillary osteotomy surgeries; I = piezoelectric/ultrasonic bone surgery; C = conventional surgical technique (pneumatic saw, conventional drilling, electric saw, conventional saw); O = complications such as tooth injury, necrosis, haemorrhage, nerve injury, infection, and oroantral communication.

Search strategy

The search approach was developed through consultation with researchers with previous experience in systematic review designs and a health sciences research librarian (LC) specialized in database searches. Using appropriate key words, truncation; and word combinations; unique strategies were adapted for each database (**Supplementary Material**, Appendix 1). The references were managed and duplicate titles removed using appropriate software (EndNote X8.1). No language restriction was applied. In the main search; the seven databases were searched up to December 18; 2017. In addition; a manual search of the reference lists of the articles included in a previously published systematic review was also conducted[16].

Study selection and eligibility

Phase I selection began when two reviewers independently screened titles and abstracts to determine eligibility. Af-

ter screening the titles and abstracts, the investigators independently retrieved the full-text articles. Any disagreements in the retrieval of the full-text articles among the reviewers were resolved by discussion and consensus. During phase II, the same two investigators independently evaluated the full texts of the selected papers for eligibility.

Strategy for data extraction and selection

The first reviewer (CTB) collected the key features from the eligible papers (demographic data, methodological data, and data on outcomes and/or complications) and the second author (JGG) crosschecked the collected data.

Strategy for data synthesis

In the analysis of surgical complications, surgical techniques such as Le Fort I (segmented or not) and SARPE/SARME were explored with regard to the following surgical complications: infection, osteonecrosis, haemorrhage, tooth injury, permanent nerve injury, oroantral fistula/communication, soft tissue injury, and neurosensory disturbance. The incidence of each complication was assessed.

Risk of bias between studies

The methodological quality of the studies was assessed using two validated tools, depending on the study design: the National Heart, Lung, and Blood Institute (NHLBI) quality assessment tool[22] and the Cochrane Collaboration risk of bias tool[23]. The NHLBI tool was used to appraise case series, cohort studies, and NRCTs, and the Cochrane risk of bias tool was used to appraise RCTs. According to the risk of bias classification, the studies were considered good (low risk of bias), fair (moderate risk of bias), or poor (high risk of bias) in accordance with the Agency for Healthcare Research and Quality[24].

Risk of bias across studies and level of evidence

The risk of bias across studies was assessed using the GRADEpro tool[25]. The strength of evidence was classified based on areas such as study design, consistency, directness, heterogeneity, precision, publication bias, and other aspects, in order to assess the evidence of the studies in the quantitative analysis.

Synthesis of studies

The included studies were subjected to qualitative and quantitative analyses. For epidemiological purposes, a three-fold meta-analysis was performed. In the first, the prevalence of the complications in the maxilla was synthesized regardless of the technique; in the second, the prevalence of complications in the maxilla was synthesized for each technique; in the third, the prevalence of complications in the maxilla was synthesized by type of procedure (Le Fort I and/or SARME/SARPE). MedCalc for Windows (MedCalc Software, Ostend, Belgium) was used to analyse the results. The random-effects model was selected in all cases[26]. To calculate the heterogeneity, the inconsistency (I^2) index was used. A value of 0% indicated no heterogeneity, and upper limits of 25%, 50%, and 75% were used to categorize the heterogeneity as low, moderate, and high, respectively[27].

Results

Study selection

A total of 5236 articles were initially retrieved from the seven databases (MEDLINE, PubMed, Cochrane Library, Embase, LILACS, Web of Science, and Google Scholar). Following a manual search of the previously published systematic review[16], one additional study was added[28]. After searching the databases and eliminating the duplicate articles, 1741 papers were screened by title and abstract against the inclusion criteria. Of these, 49 were fully assessed for eligibility. After applying the inclusion and exclusion criteria, 10 studies remained for the qualitative and quantitative synthesis. A flow diagram representing the selection process is given in Fig. 1. A list of the excluded articles is given in the **Supplementary Material** (Appendix 2).

Study characteristics

Among the 10 eligible papers, four reported retrospective studies[29–32] and six reported prospective studies[28,33–37]. One was a cohort study[37], six were case series[29–32,35,36], one was a cross-sectional study[34], one was an NRCT[33], and one was an RCT[28]. The study sample size ranged from 12 to 1000 patients. Two studies applied only a piezoelectric surgery technique[34,36], five used only a conventional technique[29–32,35], and three compared the two techniques[28,33,37]. The studies that only performed a conventional technique were included in order to determine the overall prevalence of complications in maxillary surgeries regardless of the technique.

Regarding the type of maxillary osteotomy procedure, six performed exclusively Le Fort I osteotomies[29,30,32–34,37], two performed exclusively SARME/SARPE[28,31], one performed both Le Fort I and SARME/SARPE[36], and one performed Le Fort I and segmented Le Fort I[35].

A total of 996 patients underwent maxillary osteotomy, with a follow-up period ranging from intraoperative up to 3 years. A total of 996 maxillary osteotomies were analysed, 864 performed with conventional tools and 132 with piezoelectric surgery. One hundred and fifty-six complication events were reported in total. The complications, in descending order of overall prevalence, were as follows: neurosensory disturbance (64.7%), haemorrhage (8.3%), oroantral communication (7.7%), soft tissue injury (7.7%), tooth injury (5.1%), infection (3.2%), osteonecrosis (1.9%), and permanent nerve injury (1.3%). A summary of the studies and their key features is presented in Table 1.

Risk of bias within studies

Nine studies were analysed using the NHLBI tool[29–37]; five of them presented a low risk of bias[29,30,33,35,37] and four a high risk of bias[31,32,34,36]. One study was critically appraised with the Cochrane risk of bias tool for RCTs and presented a moderate risk of bias[28]. Thus, overall five studies were appraised as good quality, one as fair quality, and four as poor quality (Table 2).

One NRCT was critically appraised as a case series study because only the data from the piezoelectric surgery group were used, as the data from the conventional group were not individualized for the maxilla[33]. The same criteria were applied to a cohort study using the piezoelectric surgery group raw data[37]; the data from the conventional group were not used because these surgeries were performed before 2005.

Results of individual studies

The analysis of complications was grouped to facilitate both qualitative analysis and quantitative analysis (meta-analysis). Tables containing the results of the meta-analysis are given in the **Supplementary Material** (Appendix 3, tables a–d).

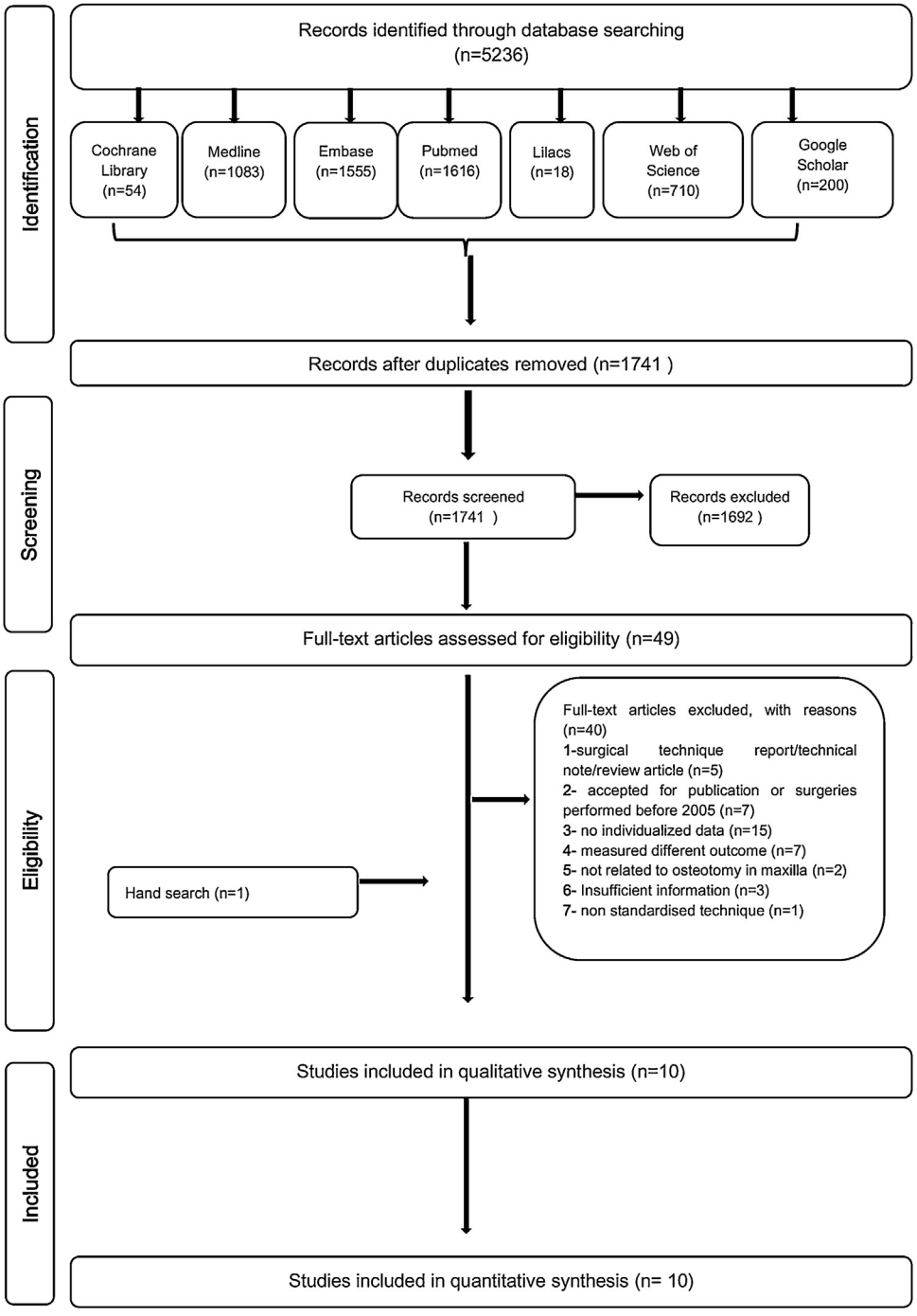

Fig. 1. PRISMA flowchart of the article selection process.

Infection

Three studies analysed infection as a complication of interest[30,32,37], and all of them performed a Le Fort I as the surgical procedure. Out of these studies, one compared piezoelectric surgery and conventional surgery[37], and the other two reported only the conventional technique[30,32]. A total of 724 osteotomies were analysed, 18 performed by piezoelectric surgery and 706 by conventional technique. Of the patients in the conventional surgery group, 0.7% (range 0.6–2.3%) presented infections; none of the patients in the piezoelectric surgery group presented infections. Unfortunately, the smoking habits and the systemic condition based on the American Society of Anesthesiologists (ASA) classification of the patients who had this complication were not mentioned in any of the three studies included in this analysis[30,32,37].

Haemorrhage

Six studies assessed haemorrhage records[29–33,36]. Four performed exclusively Le Fort I as the surgical procedure[29,30,32,33], one performed exclusively

Table 1. Summary of included studies ($N = 10$).

Author, country, year	Maxillary sample (n)	Age (years), mean ± SD (range)	Sex	Type of surgery	Tool	Assessment time	Complications
Dergin et al., Turkey, 2015[31]	60	(17–26)	M = 61.67% F = 38.33%	SARPE	Conv	IO, 8–10 days, 3 months	Haemorrhage = 3.3% Neurosensory disturbance = 18.3%
Friscia et al., Italy, 2017[30]	43	37.5	M = 48% F = 52%	Le Fort I	Conv	IO, 1, 2, 4, 6 weeks, 3, 6, 12 months	Infection = 2.3% Haemorrhage = 9.3% Permanent nerve injury = 2.3% Tooth injury = 7.0%
Gilles et al., Denmark, 2013[36]	68	29 (13–65)	M = 48% F = 52%	Le Fort I SARME	Piezo	IO, 15 days, 2 months to 3 years	Haemorrhage = 0% Neurosensory disturbance = 0% Oroantral communication = 0% Soft tissue injury = 0% Tooth injury = 0%
Landes et al., Germany, 2008[37]	18	21 ± 3 (16–46)	M = 48% F = 52%	Le Fort I	Piezo	IO, 3 months	Infection = 0% Permanent nerve injury = 0% Soft tissue injury = 0%
Olate et al., Chile, 2014[34]	19	(17–34)	NR	Le Fort I	Piezo	IO	Osteonecrosis = 0% Soft tissue injury = 0% Tooth injury = 0%
Robl et al., USA, 2014[32]	663	NR	NR	Le Fort I	Conv	IO, 1–7 days, 1–8 weeks, 3, 6 months	Infection = 0.6% Haemorrhage = 0.6% Neurosensory disturbance = 11.3% Oroantral communication = 1.8% Osteonecrosis = 0.5% Tooth injury = 0.8% Soft tissue injury = 1.8%
Rana et al., Germany, 2013[28]	30	27.4 (Conv) 29.8 (Piezo)	M = 40% F = 60%	SARME	Conv (15) Piezo (15)	4 days, 6 months	Neurosensory disturbance = 0%
Salma et al., Saudi Arabia, 2017[29]	58	24.13 ± 4.51 (17–49)	M = 27% F = 73%	Le Fort I	Conv	IO	Haemorrhage = 5.2%
Spinelli et al., Italy, 2014[33]	12	26.08	M = 41.67% F = 58.33%	Le Fort I	Piezo	IO, 1, 3, 6 months	Haemorrhage = 0%
Thygesen et al., Denmark, 2009[35]	25	25 ± 10 (15–35)	M = 48% F = 52%	Le Fort I Seg Le Fort I	Conv	3, 6, 12 months	Neurosensory disturbance = 60% Permanent nerve injury = 4%

Conv, conventional (saw, bur); F, female; IO, intraoperative; M, male; NR, not reported; Piezo, ultrasonic device; SARME, surgically assisted rapid maxillary expansion; SARPE, surgically assisted rapid palatal expansion; SD, standard deviation; Seg, segmented.

Table 2. Quality assessment of individual studies.

A. National Heart, Lung, and Blood Institute quality assessment tool for case series studies	Dergin et al., Turkey, 2015[31]	Friscia et al., Italy, 2017[30]	Gilles et al., Denmark, 2013[36]	Landes et al., Germany, 2008[37]	Olate et al., Chile, 2014[34]	Robl et al., USA, 2014[32]	Salma et al., Saudi Arabia, 2017[29]	Spinelli et al., Italy, 2014[33]	Thygesen et al., Denmark, 2009[35]
1. Was the study question or objective clearly stated?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Was the study population clearly and fully described, including a case definition?	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
3. Were the cases consecutive?	NR	Yes	NR	NR	Yes	Yes	Yes	NR	No
4. Were the subjects comparable?	Yes	Yes	Yes	Yes	Yes	NR	Yes	Yes	Yes
5. Was the intervention clearly described?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6. Were the outcome measures clearly defined, valid, reliable, and implemented correctly?	No	Yes	No	Yes	No	No	Yes	Yes	Yes
7. Was the length of follow-up adequate?	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
8. Were the statistical methods well described?	No	Yes	NA	NA	No	No	Yes	NA	Yes
9. Were the results well described?	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes
Quality rating (good, fair, or poor)	Poor	Good	Poor	Good	Poor	Poor	Good	Good	Good

Criteria: yes, no, other (NR, not reported; NA, not applicable).

B. Cochrane Collaboration risk of bias tool for RCTs	Rana et al., Germany, 2013[28]
1. Random sequence generation	Low
2. Allocation concealment	Low
3. Blinding of participants and personnel	Low
4. Blinding of outcome assessment	Low
5. Incomplete outcome data	High
6. Selective reporting	Low
7. Other bias	Unclear
Quality rating (good, fair, or poor)	Fair

Criteria: low, high, unclear.

SARPE as the surgical procedure[31], and one performed both SARME and Le Fort I procedures[36]. Two used piezoelectric surgery devices[33,36] and four used saws[29–32]. A total of 904 osteotomies were analysed: 80 performed by piezoelectric surgery and 824 with the conventional technique. In the conventional surgery groups, an average 4.0% of the cases (range 0.6–9.3%) experienced haemorrhage. The piezoelectric surgery groups presented no cases of haemorrhage. Seventy-eight percent of the haemorrhage complications occurred during Le Fort I procedures and 22% during SARME/SARPE; zero haemorrhage was observed in the SARME/Le Fort I study. Two studies included only ASA I patients[29,31], two studies included ASA I and ASA II patients[33,36], and two studies did not mention the health condition of the patients[30,32].

Neurosensory disturbance

Methods for testing neurosensory disturbance included qualitative and quantitative approaches. Touch sensation, sharp/blunt tests, and hot/cold sensation are described as qualitative tests. The two-point static test, dynamic tests, and localization tests are types of quantitative test[15]. In maxillary osteotomies, the infraorbital nerve is the most common cranial nerve exposed to injury. Superior gingiva and palatal mucosa numbness are also associated with maxillary osteotomies. Five studies reported this complication[28,31,32,35,36], among which one performed Le Fort I and segmented Le Fort I as the surgical procedure[35], two performed SARME/SARPE as the surgical procedure[28,31], one performed both Le Fort I and SARME[36], and one performed exclusively Le Fort I[32]. Seventy-four percent of the neurosensory disturbance occurred in the exclusively Le Fort I study, 15% in the Le Fort I and segmented Le Fort I study, 11% in the SARME/SARPE studies, and none in the Le Fort I and SARME/SARPE study. One of the studies compared the two techniques[28], one performed only piezoelectric surgery[36], and three reported the complication in conventional technique cases[31,32,35]. Regarding the type of test, three studies analysed the data both qualitatively and quantitatively[28,32,35], and two analysed the data only qualitatively[31,36]. A total of 846 osteotomies were analysed: 83 performed with piezoelectric surgery and 763 with the conventional technique. Among all complications, this complication presented the highest incidence and affected 13.2% (range 0.0–60%) of the convention-

al technique patients, but none of the piezoelectric surgery group patients. Three studies included only ASA I patients[28,31,35], one study included ASA I and ASA II patients[36], and one did not mention the health condition of the patients[32].

Oroantral fistula/communication/ perforation

Two studies observed oroantral communication as a complication[32,36]; one performed solely Le Fort I with a saw[32], and the other performed both Le Fort I and SARME with piezoelectric surgery[36]. All cases of oroantral communication occurred in the Le Fort I study. A total of 731 osteotomies were analysed: 68 using the piezoelectric device and 663 using the conventional technique. Among the articles included in this assessment, there was an oroantral communication complication rate of 1.8% with the conventional technique; however no cases of oroantral communication were observed in the piezoelectric surgery group. No information on the patients' ASA classification or smoking status was reported by the authors.

Osteonecrosis

Osteonecrosis was a complication observed in two studies, one related to the conventional technique[32] and one to piezoelectric surgery[34]. A total of 682 osteotomies were analysed, and osteonecrosis presented in 0.5% of the cases in the conventional group. The surgery performed in both studies was Le Fort I. Unfortunately, no information regarding the patients' smoking habits or systemic health condition (ASA classification) was reported. Hence it is unknown whether this complication could have been related to any patient habit or comorbidity.

Permanent nerve injury

Three studies observed macroscopic damage to the nerve during the surgery[30,35,37]. Le Fort I was the exclusive surgical procedure in two of them[30,37], and a segmented Le Fort I was also performed in the other one[35]. The procedures rated for 50% of the complications each. Two studies performed the surgeries exclusively with conventional saws[30,35], and one compared the two techniques[37]. A total of 86 osteotomies were analysed: 18 under piezoelectric surgery and 68 using the conventional technique. This complication occurred in 2.9% of the conventional procedures. No case of permanent nerve injury was seen in the piezoelectric surgery subgroup in the study comparing the two techniques.

Soft tissue injury

This complication was assessed in four studies[32,34,36,37]. In three of them, the surgeons performed exclusively Le Fort I as the surgical procedure[32,34,37], and in one they performed both Le Fort I and SARME[36]. A study in which Le Fort I was performed accounted for 100% of this complication[32]. Surgeons observed laceration or damage to the soft tissue adjacent to the osteotomy during the surgery. A total of 768 osteotomies were analysed, 105 under piezoelectric surgery and 663 using the conventional technique. The conventional technique group presented a rate of 1.8% for this complication. No injury was observed in the piezoelectric surgery studies[34,36,37].

Tooth injury

Four studies provided information about damage to the teeth[30,32,34,36]. In three of them, the surgeons performed exclusively Le Fort I as the surgical procedure[30,32,34], and in one they performed both Le Fort I and SARME[36]. The two studies in which a Le Fort I was performed accounted for 100% of this complication[30,32]. A total of 793 osteotomies were analysed, 87 performed by piezoelectric surgery and 706 with the conventional technique. The conventional technique presented 1.1% of cases (eight teeth) of this complication, and no tooth injury was observed in the piezoelectric surgery groups.

Synthesis of results

All studies were included in the meta-analysis, but not all complications were included in all types of meta-analysis. Three types of meta-analysis were performed. In the first, the studies were grouped by complication (adverse effect) regardless of the technique. In the second meta-analysis, the studies were grouped by complication and by technique (subgroup analysis). In the third meta-analysis, the studies were grouped by complication and by procedure (Le Fort I and/or SARME/SARPE). Ultimately, the purpose of the meta-analysis was to determine the prevalence of adverse effects in the maxilla region for each of the different techniques.

In the infection group, the results from studies that analysed this complication were pooled and a prevalence of 0.80% (random-effects, 95% CI 0.28–1.57%; $n = 724$) was calculated; no statistically significant heterogeneity was found between the studies ($P = 0.42$). There was no meaningful heterogeneity between studies in this group and an inconsistency of $I^2 = 0\%$ was found. When the studies were grouped by technique, a meta-analysis could only be performed for the conventional group; a proportion of 1.13% (random-effects, 95% CI 0.05–3.59%; $n = 706$) was found, with a moderate inconsistency of $I^2 = 40.38\%$ ($P = 0.19$).

Haemorrhage in the maxilla showed a frequency of 2.79% (random-effects, 95% CI 0.64–6.38%; $n = 904$), and significant heterogeneity was found between studies ($P < 0.005$). The studies presenting this complication showed a moderate heterogeneity of $I^2 = 71.15\%$. The results of the meta-analysis regarding the prevalence of haemorrhage related to the technique showed a rate of 4.02% (random-effects, 95% CI 0.66–10.06%; $n = 824$) for the conventional group, and a high heterogeneity of $I^2 = 81.82\%$ ($P < 0.001$). For the piezoelectric surgery group, a rate of 0.53% was found (random-effects, 95% CI 0.12–3.25%; $n = 80$); there was no significant heterogeneity between studies.

The results of the meta-analysis considering neurosensory disturbance in maxillary surgeries showed a prevalence of 10.81% (random-effects, 95% CI 2.38–24.29%; $n = 846$). High heterogeneity was found ($I^2 = 91.79\%$); there was a statistically significant pooled heterogeneity between the studies ($P < 0.0001$). The meta-analysis results regarding the prevalence of neurosensory disturbance related to the technique showed a frequency of 17.08% (random-effects, 95% CI 5.94–32.44%; $n = 763$) for the conventional surgery group, associated with a significant heterogeneity ($P < 0.0001$). The meta-analysis results for the piezoelectric surgery group showed a frequency of neurosensory disturbance of 0.53% (random-effects, 95% CI 0.11–3.17%; $n = 83$), and no significant heterogeneity was found ($P = 0.63$).

Oroantral communication in maxillary surgeries showed a prevalence of 1.43% (random-effects, 95% CI 0.32–3.33%; $n = 731$). A moderate inconsistency of $I^2 = 33.02\%$ was found and there was no significant heterogeneity between studies ($P = 0.22$). Meta-analysis of the results regarding the prevalence of oroantral communication related to either the technique or the type of procedure could not be performed as there were insufficient studies.

Osteonecrosis showed a prevalence of 0.54% (random-effects, 95% CI 0.13–

1.23%; $n = 682$). No inconsistency was found ($I^2 = 0.00\%$) and there was no significant heterogeneity between studies ($P = 0.72$). A meta-analysis of the results regarding the prevalence of osteonecrosis related to the technique could not be performed, as there was only one study for each technique.

The prevalence of permanent nerve injury was found to be 3.39% (random-effects, 95% CI 0.65–8.12%; $n = 86$). No heterogeneity was found ($I^2 = 0.00\%$), and no statistical heterogeneity was found between studies ($P = 0.71$). The results of the meta-analysis regarding the prevalence of permanent nerve injury in the maxilla using the conventional technique showed a rate of 4.10% (random-effects, 95% CI 0.75–9.96%; $n = 68$) and no significant heterogeneity ($P = 0.65$). A meta-analysis could not be performed for the piezoelectric surgery groups due to insufficient studies.

The meta-analysis of soft tissue injury in maxillary surgeries showed a prevalence of 1.66% (random-effects, 95% CI 0.88–2.69%; $n = 768$). No statistically significant heterogeneity ($P = 0.67$) and no heterogeneity was found ($I^2 = 0.00\%$). A meta-analysis regarding the prevalence of soft tissue injury related to conventional surgery could not be performed due to insufficient studies. Meta-analysis for the piezoelectric surgery groups showed a frequency of 0.63% (random-effects, 95% CI 0.02–3.00%; $n = 105$), and no significant heterogeneity was found ($P = 0.87$).

Results from the meta-analysis for tooth injury in the maxilla showed a prevalence of 1.53% (random-effects, 95% CI 0.15–4.31%; $n = 793$). High heterogeneity was found with $I^2 = 55.21\%$, and no statistically significant heterogeneity between the studies was found ($P = 0.08$). The results of the meta-analysis regarding the prevalence of tooth injury related to the technique showed a rate of 3.01% (random-effects, 95% CI 0.02–12.60%; $n = 706$) for the conventional surgery group, with significant heterogeneity ($P = 0.01$). The meta-analysis for the piezoelectric surgery group showed a rate of tooth injury of 0.52% (random-effects, 95% CI 0.10–3.07%; $n = 87$), and no significant heterogeneity was found ($P = 0.68$). Forest plots from the meta-analysis are shown in Fig. 2.

Risk of bias across studies

Overall, a low heterogeneity was found in the meta-analysis. This is probably due to all but one study (the RCT[28]) having the same design.

Level of evidence

Using GRADEpro software, the level of evidence was classified by complication. A low level of evidence was consistently observed. The observational design of the majority of the included studies was the principal concern accounting for the low level of evidence found for most complications (Table 3).

Discussion

In this study, a systematic review of the available evidence on maxillary complications related to piezoelectric and conventional surgery was performed. Surgical techniques including Le Fort I and/or SARME/SARPE were included, as the intention was to assess complications related to the surgical anatomical site – the maxilla – and the surgical device. Among the complications, the results showed the highest prevalence for neurosensory disturbance (10.81%); haemorrhage was the most frequently reported complication[29–33,36] and the second most prevalent complication. It appears that this systematic review is novel in comparing and analysing the prevalence of complications in the maxilla with the use of piezoelectric and conventional surgery techniques.

With regard to the operative technique for maxillary osteotomies, standardized techniques recommend the use of a chisel or osteotome to assist in the separation of fragments in close proximity to the noble anatomical structures. Usually, the surgeon uses an osteotome or chisel to separate the nasal septum from the maxilla and to make the pterygomaxillary junction separation from the pterygopalatine plates. During this review, it was noted that one study used the piezoelectric device to perform the nasal septum separation[36], and one study on piezoelectric surgery made use of a chisel to perform this procedure[34]. For the posterior approach, it was found that three studies on piezoelectric surgery made the pterygomaxillary junction separation exclusively with the piezoelectric surgery device[28,33,37], one mentioned the use of an osteotome only after separation of the pterygopalatine plates using the piezoelectric device[36], and one used an osteotome to perform the separation[34]. Overall, three out of five studies exclusively used the piezoelectric surgery device to perform the osteotomies.

Infection has been reported previously as the most prevalent complication in maxillary surgeries[16]. In contrast, this review and the statistical analysis found that this complication was in fact one of the least prevalent in the maxilla surgeries. A possible reason for this difference is that the previous review considered studies published since 1991[16], and included studies published before 2005 among the eligible studies[38,39]. Improvements in infection control have been made over the years. This is a potential explanation for the current finding of infection as one of the least prevalent concerns regarding orthognathic maxillary surgery.

Haemorrhage in maxillary osteotomies may occur as a consequence of pterygomaxillary junction separation, with injury to the descending palatine artery, greater palatine artery, or maxillary artery and its branches[15]. Ueki et al.[40] used a piezoelectric device in 14 cases to clean up small bones around the palatine artery and the device did not damage the vascular structure. Gilles et al.[36] separated the pterygopalatine plates in 49 Le Fort I cases only using piezoelectric surgery and did not have any case of haemorrhage complication. In this review, haemorrhage could not be associated with the ultrasonic device in one of the eligible studies, because the pterygomaxillary junction separation was made with a chisel instead of the ultrasonic device[34]. Furthermore, in another study, although a piezoelectric device was used to start the osteotomy, a chisel was used for the pterygomaxillary separation in 27.7% of cases (five out of 18), and the separation was performed only with the piezoelectric device in 72.3% of cases[37]. One study used the piezoelectric device to perform the separation all the way through the Plates[33]. The data related to haemorrhage in the study by Rana et al.[28] were not included because their methodology was subjective and flawed. To increase the evidence found in the present review, more studies are needed to clarify the real impact of the piezoelectric device in the pterygoid plate separation in terms of the prevention of haemorrhage.

In this review, the rate of neurosensory complications was higher in the conventional surgery group than in the piezoelectric surgery group, even though a formal statistical comparison of the methods was not performed. Although the one RCT study comparing the two techniques showed no statistically significant difference between them[28], it is believed that additional RCTs should be conducted in order to better clarify the real prevalence.

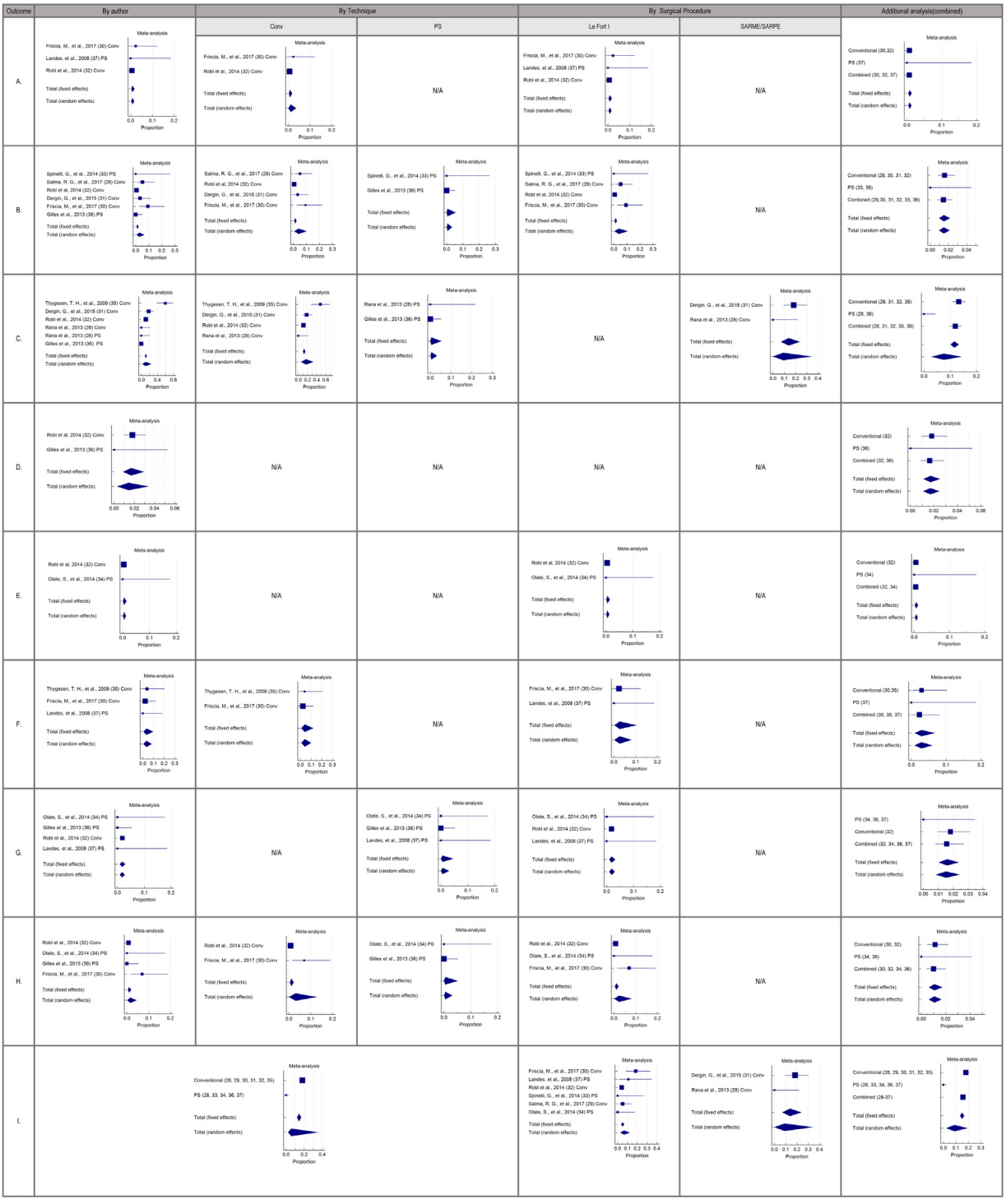

Fig. 2. Forest plots for the meta-analyses. Prevalence of complications in maxillary orthognathic osteotomies: (A) infection, (B) haemorrhage, (C) neurosensory disturbance, (D) oroantral communication, (E) osteonecrosis, (F) permanent nerve injury, (G) soft tissue injury, (H) tooth injury, (I) overall complications. Conv, conventional technique (saw); PS, piezoelectric surgery; N/A, not applicable (studies performed different surgical procedures or used different surgical techniques).

Some of the studies included in the review had neurosensory disturbance as a complication of interest but could not be included in the analysis of this complication. One such study only analysed neurosensory disturbances for the mandible[33], and two studies analysed neurosensory disturbances for the maxilla[30,37], but this information was not useful because they only performed the analysis of neurosensory disturbance for patients who had undergone mandible surgeries and the data were not individualized. All of the included studies conducting this assessment segmented the maxilla[28,31,35,36], and a correlation has been made between segmented maxillary osteotomies and an increase in neurosensory disturbances[35].

Table 3. Piezoelectric surgery compared to the conventional technique in maxillary osteotomy[a].

Outcomes	Number of participants (Studies)	Certainty of the evidence GRADE[b]	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with conventional technique	Risk difference with piezoelectric surgery
Infection	724	++	RR 0.79	1 per 100	0 fewer per 100
Follow-up: range 1 day to 12 months	(3 observational studies)	Low	(0.28–1.57)		(1 fewer to 0 fewer)
Haemorrhage	904	++	RR 2.80	2 per 100	3 more per 100
Assessed: intraoperative to 8 days	(6 observational studies)	Low	(1.04–7.25)		(0 fewer to 10 more)
Neurosensory disturbance	30	++++	RR 1.58	0 per 100	0 fewer per 100
Follow-up: range 1 day to 6 months	(1 RCT)	High	(0.22–8.71)		(0 fewer to 0 fewer)
Neurosensory disturbance	816	++	RR 16.66	14 per 100	211 more per 100
Follow-up: range 1 day to 12 months	(4 observational studies)	Low	(3.81–36.08)		(38 more to 474 more)
Oroantral communication	731	++	RR 1.43	2 per 100	1 more per 100
Follow-up: range 1 day to 12 months	(2 observational studies)	Low	(0.32–3.33)		(1 fewer to 4 more)
Osteonecrosis	682	++	RR 0.54	0 per 100	0 fewer per 100
Follow-up: range 1 day to 6 months	(2 observational studies)	Low	(0.13–1.20)		(0 fewer to 0 fewer)
Permanent nerve injury	86	++	RR 3.38	3 per 100	7 more per 100
Follow-up: range 1 day to 12 months	(3 observational studies)	Low	(0.66–8.12)		(1 fewer to 21 more)
Soft tissue injury	768	++	RR 1.66	2 per 100	1 more per 100
Follow-up: range 1 day to 12 months	(4 observational studies)	Low	(0.88–2.69)		(0 fewer to 3 more)
Tooth injury	793	++	RR 1.53	1 per 100	1 more per 100
Follow-up: range 1 week to 12 months	(4 observational studies)	Low	(0.15–4.31)		(1 fewer to 4 more)

CI, confidence interval; RR, risk ratio.

[a] The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[b] GRADE Working Group grades of evidence: high certainty = we are very confident that the true effect lies close to that of the estimate of the effect; moderate certainty = we are moderately confident in the effect estimate (the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different); low certainty = our confidence in the effect estimate is limited (the true effect may be substantially different from the estimate of the effect); very low certainty = we have very little confidence in the effect estimate (the true effect is likely to be substantially different from the estimate of effect).

Oroantral communication is a complication related to maxillary osteotomy due to the proximity of the osteotomies to the soft tissues (either palatal or gingival between the teeth), lacerations of which can lead to an oroantral fistula. This complication was the least investigated in the present study – only two studies[32,36] – although with a high occurrence of 12 events in a single study[32]. Soft tissue was spared from trauma in the piezoelectric surgery group[36], thus the piezoelectric device minimized this complication. Unfortunately, since all studies assessing oroantral communication were retrospective, prospective studies are needed to better support the evidence regarding this important complication.

Tooth injury, periodontal disease, pulp necrosis, and discolouration may occur when the osteotomy is performed directly to the tooth, near the root apex, and/or when a loss of vascularization occurs due to an injury to the descending palatine artery. Some injuries can heal without an additional intervention, while others require endodontic treatment. Tooth injury is one of the most common complications during maxillary osteotomies[16]. In this review, the number of teeth with damage could be an underestimate due to the unclear reporting. According to our calculations, there could be an increase of 275% if some of the reporting was clearer. In one study, data for tooth injury were not individualized clearly enough, and although they reported a lack of vitality in 21 teeth, only three were considered cases[30]. In another study, four teeth in three patients were considered not clearly associated with the surgical procedure[32].

Resection of the nerve can occur during osteotomies, although with recent technological advances this complication should occur less frequently. This assessment was only reported in the conventional surgery studies[30,35]. A palatal nerve injury is more difficult to avoid in segmental Le Fort I or SARME/SARPE. Due to the advancements made in pre-surgical planning, the occurrence of infraorbital injury should be unusual nowadays; however, the occurrence of this complication was still reported for the conventional technique[30]. In this regard, the use of piezoelectric surgery should be encouraged. Since the piezoelectric surgery studies demonstrated no occurrence of this complication, this technique appears to be safer than conventional surgery regarding permanent nerve injury.

The distinction between case series and cohort studies is confusing in the litera-

ture. It has been reported that the misclassification of studies will lead to a potential impact on the body of evidence[41], and because of this, the inclusion of case series in systematic reviews of surgical and medical devices is now advised for new and emerging techniques[42]. Thus, it was decided to include the case series studies in the present review in order to prevent a potential impact on the evidence as a result of omitted studies that were simply misclassified.

The use of meta-analysis to summarize and synthesize research results from observational studies has increased over the last four decades[43]. Although meta-analysis of RCTs is preferred, meta-analysis of observational studies is nevertheless useful to quantify and understand the variability in results across studies as well as to reveal areas demanding further research. Thus, this meta-analysis including observational studies and an RCT synthesizes the current prevalence of adverse effects in maxillary osteotomy. Nevertheless, strong evidence in relation to the comparison of the two techniques could not be provided.

As piezoelectric surgery is a relatively new technique, the number of RCT studies with a reasonable sample size is a limited. The majority of studies included in this review were case series. As the level of evidence is low, and even though the prevalence of complications is relatively low, it is believed that every effort to reduce the chances of complications should be taken. Better evidence will give clinicians a better understanding of the actual levels of complications. It is probable that the numbers reported herein are lower than they are in real life. Underreporting is to be expected.

In conclusion, the current low level of evidence suggests that piezoelectric surgery reduces critical and important complications during maxillary osteotomy procedures, such as neurosensory disturbance, haemorrhage, oroantral communication, tooth injury, and permanent nerve injury. However, an effective comparison between the two techniques was difficult to perform with the current available literature. Due to the small sample sizes in the piezoelectric surgery studies, caution should be exercised when considering almost non-existent reported complications.

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Competing interests

None.

Ethical approval

Not applicable. This was not a research study.

Patient consent

Not required.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.ijom.2019.01.001.

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