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Piezoelectric bone surgery for impacted lower third molar extraction compared with conventional rotary instruments: a systematic review, meta-analysis, and trial sequential analysis

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Abstract. The aim of this study was to evaluate whether piezoelectric bone surgery (PBS) for impacted lower third molar extraction reduces the surgical time and risk of intra- and postoperative complications in comparison with conventional rotary instruments. This meta-analysis followed the PRISMA guidelines and was registered in the PROSPERO database. The PubMed, Embase, Scopus, and OpenGrey databases were screened for articles published from January 1, 1990 to December 31, 2018. Selection criteria included randomized controlled trials (RCTs) comparing PBS with conventional rotary instruments for impacted lower third molar extraction and reporting any of the clinical outcomes (intra- and postoperative complications and duration of surgery) for both groups. A risk of bias assessment was performed using the Cochrane Collaboration tool. A meta-analysis was performed, and the power of the meta-analytic findings was assessed by trial sequential analysis (TSA). Strong evidence suggests that PBS prolongs the duration of surgery and low evidence suggests that PBS reduces postoperative morbidity (pain and trismus) in comparison with rotary instruments. Data were insufficient to determine whether PBS reduces neurological complications and postoperative swelling in comparison with burs.

Key words: piezoelectric surgery; Piezosurgery; lower third molar extraction; trial sequential analysis; morbidity.

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^a Marco Cicciù and Claudio Stacchi contributed equally.

Introduction

New surgical techniques and innovative technologies have greatly improved the predictability and reduced the invasiveness of oral surgery procedures. Piezoelectric bone surgery (PBS) was introduced into clinical practice almost 20 years ago¹. Its technological characteristics allow selective cutting of mineralized tissue and, in the case of accidental contact, preservation of the integrity of soft tissues, such as nerves, vessels, and mucosa². This technology uses ultrasonic wave modulation to produce a micrometric vibration of the active tip of the device, allowing extremely precise cutting and enhanced intraoperative control³. Two additional features of PBS, microstreaming and the cavitation effect, also improve surgical field conditions during ultrasonic osteotomy. Microstreaming, generated by active tip vibration, is a continuous whirling movement of fluids, favouring the mechanical action of debris removal. The cavitation effect, a physical phenomenon caused by the implosion of gas bubbles inside terminal blood vessels during osteotomy, produces a haemostatic effect enhancing intraoperative visibility⁴. These features have paved the way for the rapid spread of PBS in oral surgery^{5,6}, implantology^{7,8}, maxillofacial surgery^{9,10}, otolaryngology¹¹, and spinal surgery¹².

Impacted lower third molar extraction is a common procedure in oral surgery. The conventional technique involves using manual and/or rotary instruments to perform osteotomy and odontectomy, allowing dental extraction with a shorter intervention time and reduced patient discomfort¹³. Osteotomy and odontectomy are usually performed using rotating diamond or carbide burs mounted on turbines or hand-pieces, which are potentially harmful for the surrounding soft tissues. A recent systematic review reported that the risk of injury to the inferior alveolar nerve in lower third molar extraction with rotary instruments varies from 0.35% to 8.4%¹⁴.

The use of PBS to improve the safety and predictability of impacted lower third molar extraction was first described in 2008¹⁵. Since then, numerous clinical studies have compared PBS with rotary instruments for this specific application. Their outcomes, summarized in five recent systematic reviews conducted on this topic^{16–20}, suggest that PBS leads to lower patient morbidity (fewer intraoperative complications and an improved postoperative course), but is also associated with a longer duration of surgery. However,

these data must be interpreted with extreme caution, as the trials included have been widely judged to be medium–low quality studies, with serious limitations related to a high risk of bias, inconsistency of results, and imprecision¹⁸.

The aim of this systematic review, meta-analysis, and trial sequential analysis (TSA) was to analyse the clinical outcomes of impacted lower third molar extraction (duration of surgery, postoperative pain, trismus, and swelling, and incidence of neurological complications), comparing PBS to conventional rotary instruments. The meta-analysis was conducted with strict inclusion/exclusion criteria for study selection (only prospective studies with a control group), and the statistical reliability of the data in the meta-analysis was quantified by means of TSA (taking into consideration type 1 and 2 errors).

Materials and methods

Protocol and search strategy

This systematic review was performed in accordance with the PRISMA guidelines (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)²¹, and has been registered in PROSPERO, an international database of prospectively registered systematic reviews in health and social care (www.crd.york.ac.uk/PROSPERO; registration number CRD42019121960).

Focused question

This review aimed to answer the following PICO (population, intervention, comparator, and outcomes) question: Does PBS for lower third molar extraction reduce the surgical time and risk of intra- and postoperative complications in comparison with conventional rotary instruments?

The population (P) comprised patients requiring impacted lower third molar extraction. The intervention (I) was PBS for impacted lower third molar extraction. The comparator group (C) was conventional rotary instruments for impacted lower third molar extraction. The outcomes (O) assessed were intra- and postoperative complications and the duration of surgery.

Information sources

An extensive electronic search was conducted by two authors independently (G. C. and L.F.), who screened the PubMed, Embase, Scopus, and OpenGrey databases

in duplicate, from January 1, 1990 up to the latest entry on December 31, 2018. No language restriction was applied in order to limit selection bias.

Search

The search of the selected electronic databases was performed using the following algorithms: (1) PubMed, (piezosurgery OR piezo* OR ultrasonic* OR rotary instrument* OR conventional bur*) AND (third molar* OR wisdom); (2) Embase, ((piezosurgery:ti OR piezo\$:ti OR ultrasonic\$:ti OR 'rotary instrument\$':ti OR 'conventional bur\$':ti) AND 'third molar\$ extraction':ti OR 'wisdom tooth':ti OR 'wisdom teeth':ti) AND [1990-2018]/py; (3) Scopus, (piezosurgery OR piezo\$ OR ultrasonic\$ OR rotary OR bur\$ AND third AND molar\$ OR wisdom); (4) OpenGrey, (piezosurgery OR piezoelectric surgery OR ultrasonic surgery OR rotary instruments OR surgical bur OR third molar OR wisdom tooth OR wisdom teeth).

Furthermore, the references lists in all selected papers and in previously published systematic reviews on this topic^{16–20} were checked for additional studies. Pertinent dental journals published in the last 5 years (2014–2018) were hand-searched to identify any potentially relevant paper (*International Journal of Oral and Maxillofacial Surgery*, *Journal of Oral and Maxillofacial Surgery*, *Journal of Craniofacial Surgery*, *British Journal of Oral and Maxillofacial Surgery*, *Journal of Craniomaxillofacial Surgery*).

Selection of studies

Two blinded independent reviewers (M.C. and C.S.) performed an assessment of study eligibility in duplicate. Intra-examiner reliability of the study selection process was assessed using the Cohen κ test, assuming a threshold value of 0.61²². Conflicts were resolved by discussion of each article, and by consulting a third investigator (R.D.L.) when consensus could not be reached.

Types of studies

This systematic review included only randomized controlled trials (RCTs) conducted on human subjects. Reviews and studies of lower quality within the hierarchy of scientific evidence (such as expert opinions, letters, case reports, case series, and retrospective and case–control studies) were excluded.

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Studies were evaluated for selection according to the following eligibility criteria: (1) inclusion criteria: RCT comparing PBS with conventional rotary instruments for impacted lower third molar extraction and reporting any of the clinical outcomes (intra- and postoperative complications and duration of surgery) for both groups. (2) Exclusion criteria: meta-analyses, systematic and narrative reviews, case-control studies, prospective studies with no control group, retrospective studies, case series, case reports, and ex vivo, in vitro, and animal studies, as well as studies providing insufficient data.

Sequential search strategy

Following the initial literature search, all article titles were screened to eliminate irrelevant publications, review articles, case-control studies, retrospective studies, case series, case reports, and in vitro and animal studies. Next, studies were excluded based on data obtained from screening the abstracts. The final stage of screening involved reading the full texts to confirm each study's eligibility based on the inclusion and exclusion criteria.

Data extraction

Two authors (G.C. and L.F.) independently used pre-defined forms to extract the following information from the selected studies: (1) study characteristics: title, author names, corresponding author nationality, language of publication, year of publication, journal name and impact factor in the year of publication, source of study funding, study design, ethics committee/institutional review board approval number, method of randomization, duration of follow-up, allocation concealment, and blinding (participants, investigators, outcome examiners); (2) participants: demographic characteristics, health condition of participants, smoking status, numbers of participants in the test and control groups, and numbers and reasons for dropouts; (3) intervention (PBS for impacted lower third molar extraction): type of piezoelectric device, methods of osteotomy and odontectomy, and pharmacological co-intervention; (4) comparator (conventional rotary instruments for impacted lower third molar extraction): methods of osteotomy and odontectomy and pharmacological co-intervention; (5) outcomes: duration of surgery and postoperative pain, trismus, swelling, and neurological complications.

Attempts were made to contact the corresponding authors of included studies to retrieve any missing information or to clarify specific items.

Assessment of risk of bias in individual studies and across studies

Two reviewers (C.S. and G.T.) independently assessed the risk of bias in the selected RCTs using the Cochrane Collaboration tool for risk of bias assessment²³. The analysis was based on the evaluation of six items: random sequence generation, allocation concealment, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias. The studies were then classified into (1) studies with a low risk of bias, when all criteria were met, (2) studies with an unclear risk of bias, when one or more criteria were partially met, or (3) studies with a high risk of bias, when one or more criteria were not met.

If the Cochrane Collaboration tool scores differed between the two examiners, they were discussed to obtain a consensus. If consensus could not be reached, a third independent examiner (C.S.) evaluated the articles for final quality control, and consensus was obtained.

Heterogeneity was assessed using the χ^2 -based Q -statistic method, with a significant P -value of <0.05 . However, due to the relative insensitivity of the Q -statistic²⁴, the I^2 index was also reported, with values $\geq 50\%$ considered to be associated with substantial heterogeneity of the studies²⁵. The I^2 index describes the percentage of total variation across studies due to heterogeneity rather than chance.

Data synthesis

Meta-analyses were performed for the duration of surgery, postoperative pain, and postoperative trismus, computing the mean difference (MD) between the test and control groups, while for the dichotomous outcome 'neurological complications', the data were pooled and the risk ratio (RR) was computed; 95% confidence intervals (CI) were also calculated. A fixed- or a random-effects model was used based on the presence of heterogeneity (calculated as mentioned above). In the meta-analysis, the split-mouth and parallel studies were pooled, assuming the absence of a carry-over effect between the different interventions performed on the same patient. Overall effects were compared using the inverse variance test, with $P < 0.05$ as the threshold for statistical significance. The pooled analysis and heterogeneity were calculated using Review Manager version 5.2.6 (Cochrane Collaboration).

Additionally, TSA (Trial Sequential Analysis v0.9 β ; Copenhagen Trial Unit, Copenhagen, Denmark) was performed to

adjust the results for the presence of type 1 and type 2 statistical errors and to analyse the power of the available evidence²⁶. Specifically, a type 1 error of 5% and a power of 80% (type 2 error = 80%) were set to calculate trial sequential monitoring boundaries, futility boundaries, and the required information size (RIS). A 'model variance-based' approach was performed for heterogeneity correction, whilst data for MD, RR, and their variance were extracted from the meta-analysis results. A graphical evaluation was performed to analyse whether the Z -curve (showing the treatment effect) crossed either the monitoring or futility boundaries and to obtain the RIS threshold, which measures the statistical power of the results obtained in the meta-analysis.

Results

Description of studies

A total of 929 articles (published in English, Chinese, Dutch, French, German, Greek, Hungarian, Italian, Polish, Spanish, and Russian) were identified in the initial search (123 PubMed, 277 Embase, 464 Scopus, 65 OpenGrey, 0 other sources). After removing duplicates, 807 titles remained and were examined; 785 were excluded after reviewing the abstracts (Cohen κ test for inter-reviewer agreement = 0.81). Twenty-two full-text articles were downloaded^{15,27-47}, of which nine matched the inclusion and exclusion criteria and were included in the final analysis^{27,34,37,38,41-44,47} (Cohen κ test for inter-reviewer agreement = 1). The results of the electronic and manual searches are summarized in Fig. 1. The list of excluded studies and the reasons for exclusion are provided in the **Supplementary Material** (Table S1)^{15,28-33,35,36,39,40,43,46}.

Of the nine included studies, seven were RCTs with a split-mouth design^{34,37,38,41,42,44,47} and two were RCTs with parallel groups^{27,43}. Three studies were self-funded^{41,43,44}; no information about funding was present in the remaining six articles^{27,34,37,38,42,47}. Five studies reported ethics committee/institutional review board approval^{37,38,42,44,47}; no information on this topic was present in four articles^{27,34,41,43}. The characteristics of the included studies are reported in Table 1.

Patient characteristics

The sample size in the individual studies ranged from a minimum of 10 patients³⁷ to

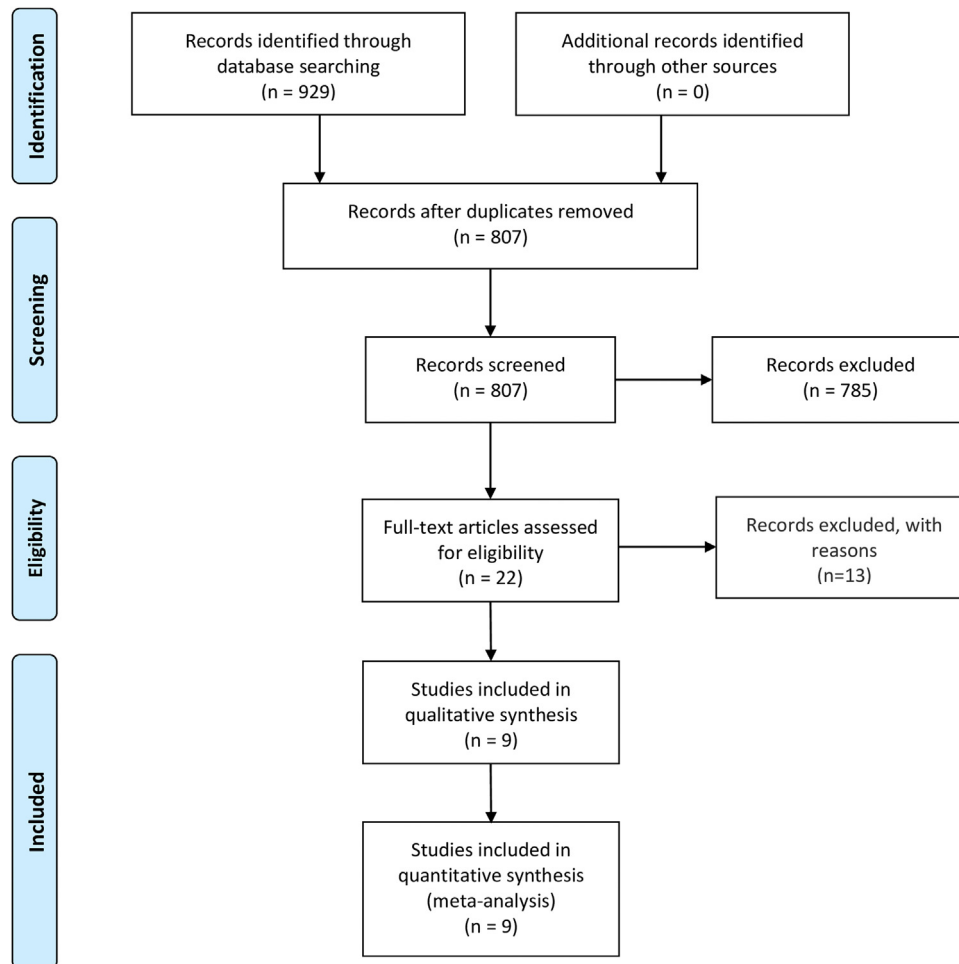


Fig. 1. Flowchart of the search process.

a maximum of 100 patients³⁸. The total number of patients treated was 319 (149 female, 140 male; sex not specified for 30). One study did not report the sex distribution in the test and control groups⁴³. The age range varied from 18 years^{34,37,41} to 54 years³⁴.

Patients were enrolled into the individual studies according to the eligibility criteria outlined below.

Inclusion criteria: healthy patients^{27,34,43,47}; male patients⁴²; age >18 years³⁴; age >20 years⁴³; age between 18 and 35 years⁴²; age between 18 and 25 years³⁷; indications for lower third molar extraction²⁷; indications for bilateral impacted lower third molar extraction^{34,37,38,41,42,44,47}; bilateral molars had to have the same angulation and entail the same surgical difficulty^{34,37,38,41,42,47}; acceptance and signing of a consent form^{27,34,37,38,41-44,47}.

Exclusion criteria: uncontrolled systemic conditions^{38,42,44}; history of systemic disease contraindicating surgical treat-

ment²⁷; systemic disease or use of medication potentially impairing surgery and bone healing dynamics^{38,43}; uncontrolled diabetes⁴⁴; blood dyscrasias⁴⁴; oral sub-mucous fibrosis^{37,41,44}; recent use of antibiotics^{41,43}; recent anti-inflammatory treatment³⁸; allergy to penicillin and/or non-steroidal anti-inflammatory drugs (NSAIDs)^{34,47}; smokers^{34,41,47}; heavy smokers^{27,38,42,44}; no need to raise a mucoperiosteal flap to remove the third molar^{27,34,37}; pregnant or lactating women^{27,34,38}; substance abusers, those with psychiatric problems, or unrealistic expectations^{44,47}; sites with acute infection^{34,37,41-44,47}; active periodontitis and/or poor oral hygiene and motivation³⁴; patients undergoing orthodontic therapy³⁸.

Clinical procedures

Patients in the included studies were similar in terms of age and general health status, but heterogeneous in terms

of level of impaction of the lower third molars. Six split-mouth studies selected bilateral impacted teeth presenting similar angulation and spatial relationships with the ascending ramus of the mandible and the occlusal plane^{34,37,38,41,42,47}. In all included studies, osteotomy and bone guttering around the impacted tooth were performed with rotary instruments in the control group and PBS in the test group. Five studies performed odontectomy with rotary instruments in both groups^{34,37,41,42,44}. One study used rotary instruments in the control group and a mixed technique with burs and PBS in the test group²⁷. Two studies did not report the odontectomy technique^{38,43}. One trial did not section teeth before extraction⁴⁷. Five different brands of PBS device were used in the included studies. Medications were prescribed in all studies (antibiotics and NSAIDs), with different treatment regimens used, potentially influencing some of the outcomes measured.

Table 1. Characteristics of the included studies.

Study Year	Country	Journal (IF)	Design	Number of patients in each group (M/F)		Age range (years)	Mean age (SD) (years)	Medication	Odontectomy method	Ultrasonic device brand
				Control	Test					
Kirli Topcu et al. ⁴⁷ 2019	Turkey	<i>Journal of Oral and Maxillofacial Surgery</i> (1.781)	RCT Split-mouth	21 (7/14)	21 (7/14)	NR	22.4 (NR)	NSAID	No odontectomy was performed	W&H
Bhati et al. ⁴⁴ 2017	India	<i>Annals of Maxillofacial Surgery</i> (-)	RCT Split-mouth	30 (18/12)	30 (18/12)	NR	27.4 (5.27)	AB 5 days NSAID 3 days	Both groups: rotary	Mectron
Basheer et al. ⁴³ 2017	India	<i>Journal of Contemporary Dental Practice</i> (-)	RCT Parallel	15 (NR)	15 (NR)	NR	Control: 30.1 (3.15) Test: 28.4 (2.69)	AB 3 days NSAID 3 days	NR	Mectron
Arajji et al. ⁴² 2016	Lebanon	<i>International Journal of Dentistry</i> (-)	RCT Split-mouth	20 (20/0)	20 (20/0)	19–32	NR	AB 5 days NSAID 3 days	Both groups: rotary	Mectron
Mistry et al. ⁴¹ 2016	India	<i>Annals of Maxillofacial Surgery</i> (-)	RCT Split-mouth	30 (16/14)	30 (16/14)	18–43	25.2 (6.53)	AB 5 days NSAID 5 days	Both groups: rotary	Satelec
Mantovani et al. ³⁸ 2014	Italy	<i>Journal of Oral and Maxillofacial Surgery</i> (1.425)	RCT Split-mouth	100 (41/59)	100 (41/59)	NR	24.0 (4.2)	Prophylactic AB AB 5 days NSAID if needed	NR	Mectron
Piersanti et al. ³⁷ 2014	Italy	<i>Journal of Oral and Maxillofacial Surgery</i> (1.425)	RCT Split-mouth	10 (4/6)	10 (4/6)	18–25	22.4 (2.3)	Prophylactic AB AB 4 days NSAID 4 days	Both groups: rotary	Mectron
Rullo et al. ³⁴ 2013	Italy	<i>Journal of Cranio-Maxillo-Facial Surgery</i> (2.597)	RCT Split-mouth	52 (20/32)	52 (20/32)	18–54	26.2 (NR)	AB 7 days NSAID 4 days	Both groups: rotary	Esacrom
Barone et al. ²⁷ 2010	Italy	<i>Journal of Oral and Maxillofacial Surgery</i> (1.500)	RCT Parallel	13 (7/6)	13 (7/6)	24–45	Test: 32.2 (6.7) Control: 30.3 (5.8)	Prophylactic AB AB 5 days NSAID if needed	Control: rotary Test: mixed (PBS and rotary)	Resista

AB, antibiotic; F, female; IF, impact factor; M, male; NR, not reported; NSAID, non-steroidal anti-inflammatory drug; PBS, piezoelectric bone surgery; RCT, randomized clinical trial; SD, standard deviation.

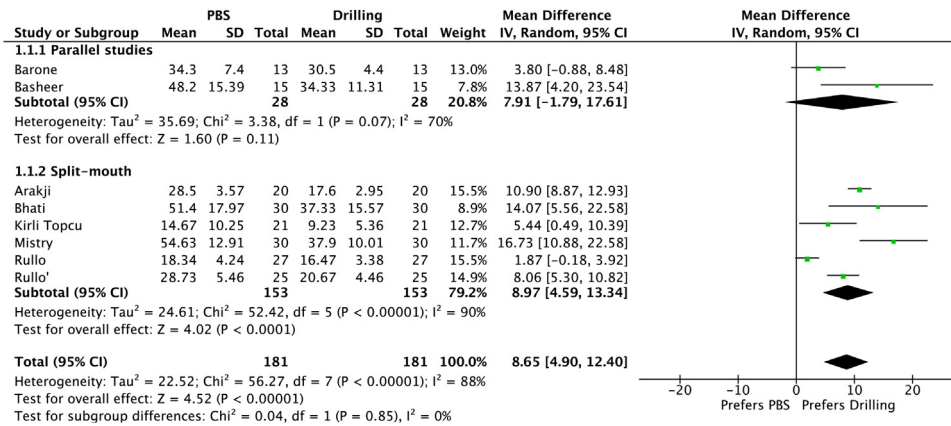


Fig. 2. Forest plot (random-effects model) for the outcome 'duration of surgery', expressed in minutes.

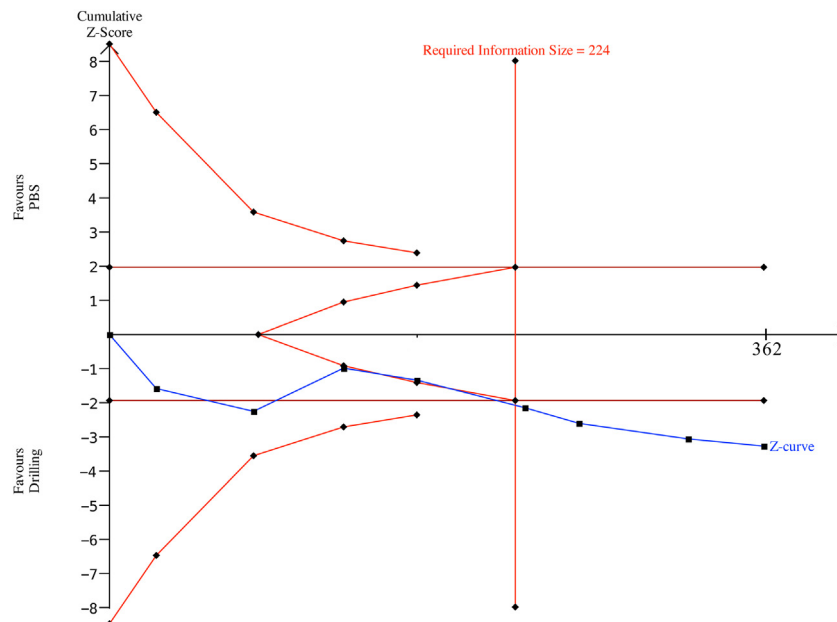


Fig. 3. Trial sequential analysis for the outcome 'duration of surgery'. The cumulative Z-curve crosses both alpha-spending boundaries, revealing the presence of a significant effect. Additionally, the Z-curve surpassed the required information size threshold, revealing strong power of evidence.

Risk of bias in the individual studies

Based on the Cochrane Collaboration tool for risk of bias assessment, one RCT was judged to have an unclear risk of bias³⁸. The remaining eight RCTs were judged to be at high risk of bias (**Supplementary Material**, Table S2).

Surgical time

All included studies recorded the operative time necessary for impacted lower third molar extraction. Most studies defined the duration of surgery as the time elapsed from the start of flap incision to the termination of suturing. One trial defined the operative time as the time

elapsed from the start of incision to the beginning of suturing⁴⁷, and one trial from the start of bone guttering to tooth elevation from its socket⁴³. One study did not report a definition of the duration of surgery and was excluded from the meta-analysis for this specific outcome³⁷. Furthermore, one article did not report the standard deviation and was therefore excluded from the meta-analysis for this specific outcome³⁸.

The mean difference between the two procedures was 8.65 minutes, significantly favouring the control group (95% CI 4.90–12.40 minutes; $P < 0.00001$) (Fig. 2). Heterogeneity was present among the seven included studies ($I^2 = 88\%$; $df = 7$; $P < 0.00001$; $\chi^2 = 56.27$), thus a

random-effects model was used. TSA confirmed these findings, as shown by the Z-curve crossing the lower trial sequential monitoring boundary. Additionally, the number of interventions exceeded the RIS threshold (224 interventions being the required sample for a power of 80% versus 362 interventions included in the present meta-analysis), showing a strong power of evidence (Fig. 3).

Pain

All included studies reported the intensity of pain as a continuous variable using a visual analogue scale (VAS 1–10 or 1–100) at different time intervals ranging from 1 to 15 days. One article reported

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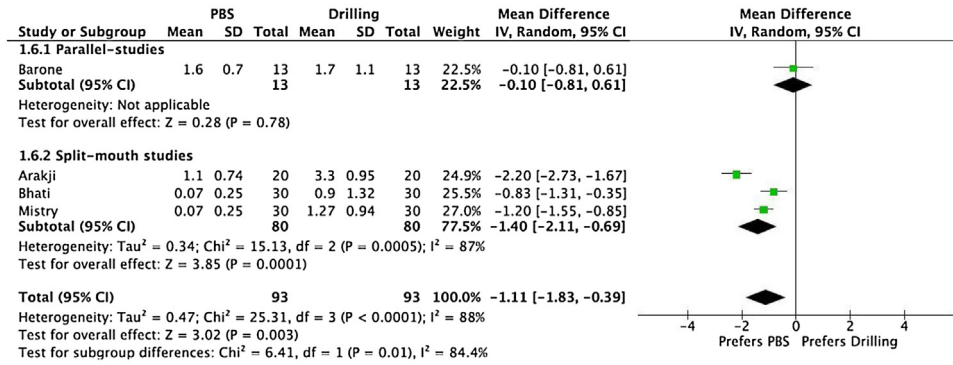


Fig. 4. Forest plot (random-effects model) for the outcome ‘visual analogue pain scale score at 7 days after surgery’. The visual analogue pain scale ranged from 1 to 10.

only graphical and not numerical data and was therefore excluded from the meta-analysis for this specific outcome³⁷. Another article did not report the standard deviation and was therefore excluded from the meta-analysis for this specific outcome⁴³. Two further studies did not report intensity of pain at the time points selected for the present analysis.^{38,47}

One day after surgery, the mean difference between the test and control groups was -1.66 points, significantly favouring the test group (95% CI - 2.72 to -0.59; P = 0.002) (**Supplementary Material**, Fig. S1). Heterogeneity was present among the five studies included at this time point (I² = 85%; df = 5; P < 0.00001; χ² = 32.92), thus a random-effects model was used. TSA highlighted that a more powered information size would be necessary to allow conclusions to be drawn for this outcome (836 interventions being the required sample for a power of 80% versus 290 interventions included in the present meta-analysis), showing a low power of evidence (**Supplementary Material**, Fig. S2).

Similar results were found when analysing VAS data recorded 3 days after surgery. The mean difference between the test and control groups was -1.37 points, significantly favouring the test group (95% CI - 2.58 to -0.16; P = 0.03) (**Supplementary Material**, Fig. S3). Heterogeneity was also present among the four studies included at this time point (I² = 87%; df = 4; P < 0.00001; χ² = 29.77), thus a random-effects model was used. TSA highlighted that a more powered information size would be necessary to draw conclusions for this outcome (700 interventions being the required sample for a power of 80% versus 250 interventions included in the present meta-analysis), showing a low power of evidence (**Supplementary Material**, Fig. S4).

Finally, VAS data recorded 7 days after surgery showed a mean difference between the test and control groups of -1.11 points, significantly favouring the test group (95% CI - 1.83 to -0.39; P = 0.003 (Fig. 4). Heterogeneity was also present among the four studies included at this time point (I² = 88%; df = 3; P < 0.0001; χ² = 25.31), thus a random-effects model was used. TSA confirmed that the cumulative Z-curve crossed both alpha-spending boundaries, revealing the presence of a significant effect. However, the Z-curve did not reach the RIS threshold (318 interventions being the required sample for a power of 80% versus 186 interventions included in the present meta-analysis), revealing moderate power of evidence for this outcome (Fig. 5).

Trismus

Six studies assessed maximum mouth opening at various time points^{27,37,41-44}. One of these reported only graphical and not numerical data³⁷, and was therefore excluded from the meta-analysis for this specific outcome. Differences in maximum mouth opening between baseline and the 1- and 7-day follow-ups were analysed.

The mean difference between the test and control groups measured 1 day after surgery was -5.37 mm, significantly favouring the test group (95% CI - 8.56 to -2.19 mm; P = 0.0009) (Fig. 6). Heterogeneity was present among the four studies included at this time point (I² = 72%; df = 3; P = 0.01; χ² = 10.57), thus a random-effects model was used. TSA confirmed that a more powered information size would be necessary to allow conclusions to be drawn for this outcome (1015 interventions being the required sample for a power of 80% versus 186 interventions included in the present meta-analysis), showing a low power of evidence (Fig. 7).

Seven days after surgery, maximum mouth opening was still reduced in the control group when compared to the test group, although not significantly. The mean difference was -3.32 mm, favouring the test group (95% CI - 7.06 to -0.43 mm; P = 0.08) (**Supplementary Material**, Fig. S5). Heterogeneity was present among the five studies included at this time point (I² = 91%; df = 4; P < 0.00001; χ² = 44.10), thus a random-effects model was used. TSA highlighted that a more powered information size would be necessary to draw conclusions for this outcome (1670 interventions being the required sample for a power of 80% versus 216 interventions included in the present meta-analysis), showing a low power of evidence (**Supplementary Material**, Fig. S6).

Swelling

Swelling was reported in six studies^{27,37,38,41,42,44}. Five of these reported significantly less swelling in the PBS group during the first week after surgery^{27,37,38,41,42}. One study reported no statistically significant difference between the two groups⁴⁴. A quantitative analysis for this specific outcome was not performed due to the significant differences in methods used to evaluate swelling across the studies.

Neurological complications

Three studies reported neurological complications^{38,44,47}. One study described this outcome as paresthesia of the inferior alveolar nerve⁴⁴. Two studies defined this outcome simply as paresthesia, without reference to specific nerves^{38,47}. The meta-analysis revealed no significant differences in terms of neurological complications between the test and control groups (RR 1.07, 95% CI 0.16-7.05;

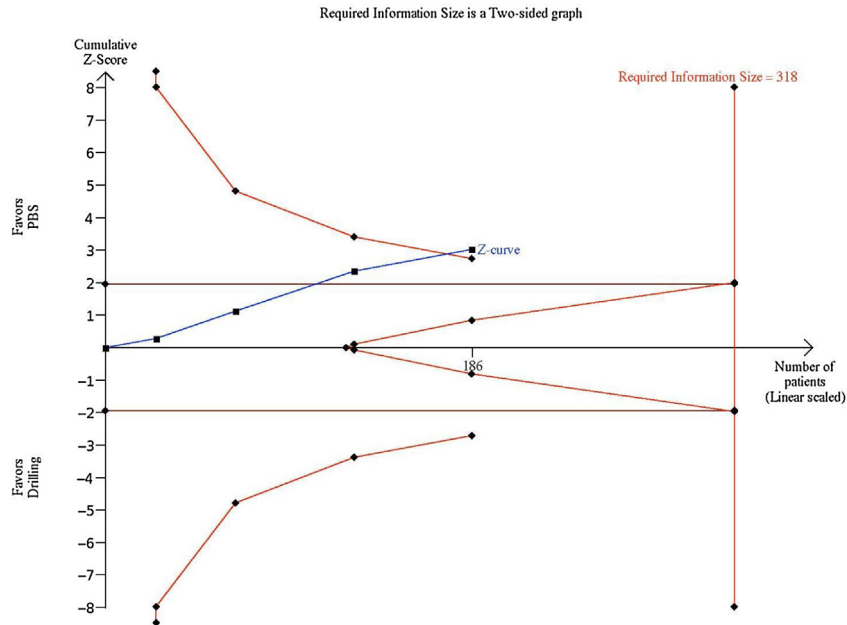


Fig. 5. Trial sequential analysis for the outcome ‘visual analogue pain scale score at 7 days after surgery’. The cumulative Z-curve crosses both alpha-spending boundaries, revealing the presence of a significant effect. However, the Z-curve does not reach the required information size threshold, revealing moderate power of evidence.

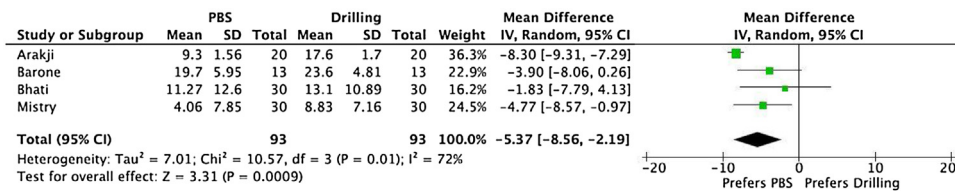


Fig. 6. Forest plot (random-effects model) for the outcome ‘trismus 1 day after surgery’. Differences in maximum mouth opening in comparison with baseline, expressed in millimetres.

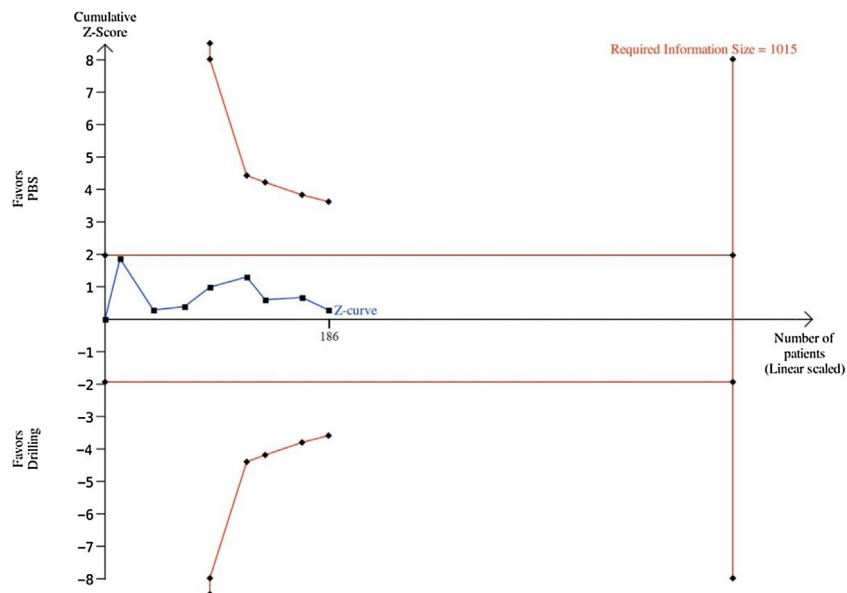


Fig. 7. Trial sequential analysis for the outcome ‘trismus 1 day after surgery’. The cumulative Z-curve does not cross both alpha-spending boundaries and does not reach the required information size threshold, revealing a low power for current evidence.

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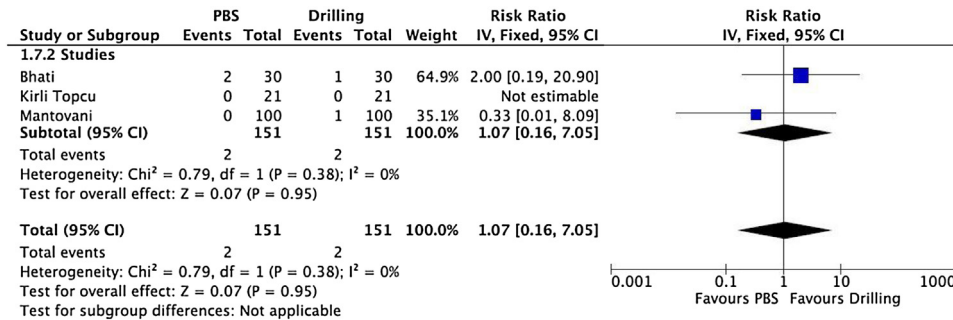


Fig. 8. Forest plot (fixed-effects model) for the outcome 'neurological complications'.

$P = 0.95$) (Fig. 8). No heterogeneity was noted ($I^2 = 0\%$; $df = 1$; $P = 0.38$; $\chi^2 = 0.79$) and therefore a fixed-effects model was used. No TSA analysis was performed for this specific outcome as the number of included studies was too low.

Discussion

Clinical findings

PBS has been proposed as a viable alternative to rotary instruments in impacted lower third molar surgery. The main advantages of PBS are the precision of cutting, enhanced surgical control, selective action on hard tissue, and improved visibility in the surgical field. Moreover, biomolecular studies have shown that PBS is more effective than conventional rotary instruments in reducing postoperative inflammation^{48–50} and oxidative stress after osteotomy⁵¹. The combined effect of these factors contributes to lower postoperative morbidity, a faster recovery time, and less interference with impacted third molar extraction patient quality of life.

This systematic review, meta-analysis, and TSA evaluated the available evidence comparing PBS and conventional rotary instruments in impacted lower third molar extraction with respect to the duration of surgery, postoperative pain, trismus, and swelling, and neurological complications.

In accordance with all recent meta-analyses^{16–20}, the duration of surgery was found to be significantly shorter in the control group. All included studies performed osteotomy and bone guttering with PBS in the test group and with rotary instruments in the control group. Five trials used rotary instruments for odontectomy in both the test and control groups^{34,37,41,42,44}. One study used a mixed technique (PBS/rotary) in the test group²⁷. Two studies did not report how odontectomy was performed^{38,43}, and one study did not perform odontectomy before extraction⁴⁷. The use of rotary instruments

for initial tooth sectioning in areas far from delicate structures could be reasonable to shorten the duration of surgery. Additionally, ultrasonic inserts wear down very rapidly when working on enamel, resulting in a significant increase in cost.

Numerous studies have directly associated a prolonged duration of surgery with increased postoperative morbidity after impacted third molar extraction^{52–54}. In the present study, despite the longer duration of surgery, postoperative morbidity parameters (pain and trismus) were significantly lower in the PBS group at almost all time points considered (except trismus on day 7, where statistical significance was not reached). This finding can be explained by the physical characteristics of ultrasonic bone cutting together with the PBS-induced biomolecular modifications described above, leading to less traumatic surgery and a faster healing response. This outcome is in agreement with all previous meta-analyses conducted on this topic^{16–20}. Postoperative swelling, as with the other morbidity parameters, was significantly lower in the test group than in the control group in five out of the six studies reporting this outcome. Nevertheless, a meta-analysis for swelling was not conducted, due to the differences in methodologies used across the studies. Standardized measurement protocols are strongly recommended for future studies in order to be able to perform reliable comparisons between different investigations.

Neurological complications were uncommon in the present study. Out of 151 interventions, two cases of paresthesia were recorded in both the test group and the control group (1.3%). Meta-analysis showed that there was no significant difference between the two groups, in contrast with the outcomes of a recent systematic review¹⁸, which also included case-control studies. Further high quality trials on a broader population are necessary to draw definitive conclusions on this topic.

Quality of evidence

Eight of the nine RCTs included in this meta-analysis were judged to be at high risk of bias^{27,34,37,41–44,47}. One trial was judged to have an unclear risk of bias³⁸.

TSA of the difference in duration of surgery between the two techniques showed a strong power of evidence, although high heterogeneity was present across the studies. For this specific outcome, the power of the present meta-analysis exceeded the RIS threshold (224 interventions being the required sample for a power of 80% versus 362 interventions included in the present meta-analysis).

TSA on postoperative pain at 1, 3, and 7 days after surgery showed that the power of evidence of this meta-analysis was moderate/low, with high heterogeneity present across the studies. At these time points, the number of interventions included in the present meta-analysis was lower than the RIS needed to evaluate the magnitude of the treatment effect with a statistical power of 80%.

TSA on postoperative trismus at 1 and 7 days after surgery demonstrated low power of evidence of the present study, with high heterogeneity across the studies. At these time points, the number of interventions included in the present meta-analysis was lower than the RIS needed to evaluate the magnitude of the treatment effect with a statistical power of 80%.

No meta-analysis was performed for postoperative swelling, as the methods of measurement in the included studies were too heterogeneous to enable a reliable comparison.

TSA on the rate of neurological complications between PBS and conventional rotary instruments for impacted lower third molar extraction was not performed, as the number of included studies was too low.

Limitations

Despite the strict inclusion/exclusion criteria adopted in this meta-analysis, high

heterogeneity was noted among the included studies. It should also be highlighted that the great majority of the included studies presented a high risk of bias. Furthermore, the use of antibiotics and/or NSAIDs with different regimens in all of the included studies may potentially have influenced some of the investigated outcomes.

The methodological approach used in this meta-analysis and the TSA help to explain the real available evidence on PBS used in impacted lower third molar extraction and could motivate researchers to design appropriate clinical trials on unclear topics in the future.

In conclusion, based on the results of this meta-analysis and TSA to examine whether PBS for impacted lower third molar extraction prolongs the duration of surgery, reduces postoperative pain, trismus, and swelling, and reduces the risk of neurological complications in comparison with conventional rotary instruments, the following conclusions can be drawn: (1) there is strong evidence suggesting that PBS prolongs the duration of surgery in comparison with conventional rotary instruments; (2) there is moderate/low evidence suggesting that PBS reduces postoperative pain and trismus in comparison with conventional rotary instruments; (3) there are insufficient data to determine whether PBS reduces postoperative swelling in comparison with conventional rotary instruments; (4) there are insufficient data to determine whether PBS reduces neurological complications in comparison with conventional rotary instruments. Hence, the results reported in this meta-analysis should be interpreted with caution.

Further high quality, adequately powered RCTs are necessary to confirm these findings and to improve the level of evidence on unclear topics.

Declarations

The following additional information is required for submission. Please note that failure to respond to these questions/statements will mean your submission will be returned to you. If you have nothing to declare in any of these categories then this should be stated.

Competing interests

Dr Tomaso Vercellotti is a scientific consultant for Mectron S.p.A., manufacturer of piezoelectric devices for bone surgery. The other authors report no conflicts of interest related to this study.

Ethical approval

Not required.

Patient consent

Not required.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.ijom.2020.03.008>.

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