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A split-mouth randomized clinical trial to evaluate the performance of piezosurgery compared with traditional technique in lower wisdom tooth removal.

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Abstract

Purpose: The surgical removal of mandibular third molars is frequently accompanied by significant post-surgical sequelae, and different protocols have been described to improve such adverse events. The aim of this study was to investigate the performance of piezosurgery compared with traditional rotating instruments during mandibular third molar removal.

Methods: A single-centre, randomized, split-mouth study was performed using a consecutive series of unrelated healthy Caucasian patients, attending the Oral Surgery Unit of the University of Turin, for surgical removal of bilateral mandibular third molar teeth. Each patient was treated, at the same appointment, using bur removal on one side of the mandible and a piezoelectric device on the contralateral side. The primary outcomes reported were post-operative pain, objective orofacial swelling and the duration of surgical time; secondary outcomes were sex, age and possible adverse events. Anova or paired t-test were used as appropriate to test any significant differences at baseline according to each treatment subgroups and categorical variables were analysed by $\chi 2$ test.

Results: The study sample consisted of 100 otherwise healthy patients. The mean pain evaluation reported by patients who underwent surgery with the piezosurgery was significantly lower than that experienced after bur (conventional) removal, reaching a statistical difference after 4 days ($P=0.043$). The clinical value of orofacial swelling at 7th day, normalized to baseline, was lower in the piezosurgery group ($P<0.005$).

The average time of surgery was significantly lower in the bur than piezosurgery group ($P<0.05$).

Three patients having bur removal experienced short-term complications (two dry sockets and one temporary paraesthesia): both totally resolved by 4 weeks.

Conclusions: To date, this prospective investigation is the largest reported split-mouth study on piezosurgery for lower third molar tooth removal, also comparing surgeons with different

degrees of experience. It is evident that using a piezoelectric device can enhance the patient experience and reduce post-operative pain and swelling.

Key words: third molar removal, piezosurgery, randomized clinical trial, oedema, trismus, pain.

The surgical removal of mandibular third molars is one of the most common interventions in oral surgery.[1] This procedure is frequently accompanied by significant post-surgical sequelae, especially pain and swelling, which may have both social and biological impact and can impair quality of life.[2-4] Other important complications may occasionally include dysaesthesia, dry socket, infection, or fracture .[4-6] Protocols evaluated to improve such adverse postoperative sequelae have included different medications,[4,7] different flap designs,[9,10] and the use of rotary rather than hand instruments for bone removal (osteotomy).[11-13]

Piezosurgery is an osteotomy technique utilizing micro-vibrations at ultrasonic frequency to perform efficient bone cutting.[14] The piezoelectric device has been useful for application in complex surgical sites, such as the posterior mandible, where the osteotomy lines are of necessity close to vulnerable structures such as nerves and blood vessels; ultrasonic vibrations allow a selective and defined cutting action, leading to a higher level of precision, safety and less tissue damage than using common rotating instruments (burs).[15-17]

Ultrasonic tools have been reported to be of clinical usefulness in reducing the risk of surgical trauma to the adjacent tissues, and ultrasonic dissection has been classified as a tissue-selective technique that might improve the efficiency of dissections reducing the morbidity from collateral iatrogenic injuries. Moreover, the bone wound healing response after osteotomy shows a more positive response with piezoelectric surgical devices, when compared with diamond or carbide burs.[16]

However, despite the apparent advantages, few studies have been performed to evaluate the use of piezosurgery, in comparison with traditional bur, in third molar surgery, and there have been conflicting results and with limited power.[15-17]

The purpose of this study was to investigate, in a randomized-controlled clinical trial, the performance of piezosurgery compared with traditional rotating instruments during mandibular third molar removal. The investigators hypothesized that piezosurgery could have an enhanced

positive impact in post-operative pain and objective orofacial swelling, also reducing possible adverse events.

Patients and Methods

SAMPLE AND STUDY DESIGN

To address the research purpose, a single-centre, randomized, split-mouth study was designed and implemented.

The study population was composed of all patients attending the Oral Surgery Unit (CIR - Dental School) of the University of Turin, between June 2010 and September 2013, for evaluation of surgical removal of bilateral mandibular third molar teeth.

To be included in the study sample, the third molar in question had to be Class A or B and in position 1, 2 or 3, according to the Pell and Gregory radiographical classification,[18] based on the spatial relationships of the tooth to the ascending ramus of the mandible and to the occlusal plane; bilateral molars had to be in the same angulation (horizontal, mesioangular or vertical) as each other (Fig. 1). The indication for surgery was based on a diagnosis of pericoronitis.[19]

Exclusion criteria were a clinically significant medical history (*e.g.*, systemic infective disease, cardio-vascular disease, liver disease, haematological disease, bleeding tendency, diabetes or neoplastic disease), recent anti-inflammatory treatment, regular use of medications with possible anti-inflammatory activity (*e.g.*, antihistamines, NSAIDs, corticosteroids, and antidepressants), pregnant or breast-feeding females, heavy current tobacco smokers (> 10 cigarettes daily), patients undergoing orthodontic therapy, and patients unwilling to undergo the data collection procedures.

The study protocol was approved by the local ethical committee (CIR- Dental School), in accordance with the Helsinki statements. All patients were fully informed about the surgery

process, post-operative period, and possible complications, and valid informed consent was obtained before surgery.

The split-mouth design was applied and each patient was treated to remove the impacted molars using the bur on one random side of the mandible and the piezoelectric (ultrasound) device on the contralateral side. Randomisation was performed with a table of random numbers by a researcher not involved in the study and who was blind to the identity of the procedures. Group A included all the operations carried out with the bur, while surgeries carried out with the piezoelectric technique were assigned to Group B.

For ultrasound osteotomies, the Mectron Piezosurgery Device®, (Mectron Medical Technology, Carasco, Italy) was used according to the manufacturer's instructions (water flow set at maximum) utilizing a special application tip designed for osteotomy (ES007). The osteotomies using the conventional rotating bur were carried out with a Lindemann stainless steel bur (shank diameter 2.35 mm; length 44 mm) mounted on a surgical high-speed straight hand piece (W&H; reduction factor 1:1) at a speed of 20.000 r.p.m. A new piezo tip and a new Lindemann bur were used for each patient.

SURGICAL AND POST-SURGICAL VARIABLES

Three oral surgeons, with different ages and experience, performed the surgical removals according to a standardized technique. Inferior dental (alveolar) nerve and buccal nerve local anaesthesia was administered using mepivacaine hydrochloride (30mg/ml) with epinephrine 1:100,000. A triangular full thickness mucoperiosteal flap with releasing incision on the mesio-buccal aspect of the second molar was routinely used. After ostectomy, the tooth was sectioned, elevated and removed. Then the socket was carefully inspected, debrided if necessary and the flap sutured with interrupted sutures using a braided and coated synthetic absorbable suture 3.0 (Glicofil® Lac, Assut Europe S.p.A., Rome, Italy). The surgical time duration was recorded from initial incision to final suture completion.

All patients received 2 g of amoxicillin–clavulanic acid 1 hour before the surgical procedure and 2 g/d for the subsequent 5 days[16]. The same post-operative instructions were given to all patients: asking them to take a soft and cold diet for 24 hours; to use 550 mg of naproxen sodium, when needed; and to gargle with 15 ml of 0.12% aqueous chlorhexidine mouth rinse three times daily for 1 min for 10 days.

Patients were given a questionnaire about their subjective experience of the two different surgeries, regarding the presence of vibrations and/or noise, which intervention was more comfortable and, if further dental surgery was necessary, which one they would prefer.

Patients were also asked to detail the pain suffered; the symptoms score was obtained using a Visual Analogue Scale (VAS). The VAS consisted of a 100 mm-horizontal line marked 0 (= no pain) to 100 (= most severe pain ever experienced). They were requested to mark the scale, late in the evening, daily for 6 days after surgery.

Post-surgical clinical assessments were performed by a single blinded examiner (E.M.) at 2, 7, 14 and 28 days after the surgical procedure.

Facial measurements were collected at baseline pre-operatively and on the 7th day, after suture removal, in order to evaluate any swelling. This was achieved using a 2/0 silk wire to measure the distance between the angle of lower jaw (G) and 4 facial reference points: tragus (T), outer canthus of the eye (C), subnasal point (S), and pogonion (P). Those points were marked with a dermographic pen (Fig. 2). We also calculated the overall swelling/oedema (E), which was expressed as: $E = [\Sigma d_i^2/4]^{0.5}$, where Σd_i is the sum of the 4 measurements previously reported (G-T, G-C, G-S, G-P).

DATA ANALYSIS

The primary outcomes reported were post-operative pain, objective orofacial swelling and the duration of surgical time; secondary outcomes were gender, age, radiological position and possible adverse events (e.g. paraesthesia or infection).

The sample size was estimated based on supposed differences between the two techniques, because of the lack of any previously reported changes in pain and swelling as a split-mouth study. With a power of 85% and a type I error of 0.05, a minimum of 100 patients (100 extractions for each arm of the study) had to be recruited.

To avoid observer bias, because of physiological asymmetry, the amount of extraoral swelling was normalized with the baseline measurement. Describing general information, data was reported as means and standard deviation (±SD). Differences from baseline preoperative values in swelling/oedema, and pain measurements were not normally distributed (Shapiro-Wilk test); therefore a logarithmic transformation was utilized before any parametric analysis. Anova or paired *t*-test were used as appropriate to test any significant differences at baseline according to each treatment subgroups. Categorical variables were analysed by χ^2 test. An alpha value <0.05 was considered significant; SPSS (SPSS for windows, version 18, SPSS inc, Chicago, IL, USA) statistical software was utilized.

Results

The study sample was derived from 140 patients. Fifteen of these patients did not show periodontal parameters lower than 20% and so were excluded; 14 patients underwent only one intervention and 11 patients did not attend all the follow-up visits. The final study sample thus consisted of 100 patients. Fig. 3 shows the flow diagram for patients' enrolment and selection.

The mean age at presentation was 24.02 years (± 4.21). Fifty-nine patients (59%) were women. According to the Pell and Gregory classification, 27 cases were described as A1 (27%), 12 as B1 (12%), 28 as A2 (28%), 18 as B2 (18%), 12 as A3 (12%) and 3 cases as B3 (3%).

Each of the 100 patients had bilateral surgical mandibular third molars removals at the same appointment.

The mean pain evaluation reported by patients who underwent tooth removal using piezosurgery was significantly lower than that experienced after bur bone removal, reaching a statistical difference after 4 days (Table 1). In all cases the reported post-operative pain evaluated on the VAS was greatest on the day of surgery, subsequently declining progressively daily until day 6th after surgery.

The clinical value of facial swelling at 7th day, normalized to baseline, was 1.10 in rotating group while 1.02 in ultrasound group ($P<0.005$) (Table 1).

The average duration of surgery was 18.16 minutes in group A (bur), and 20.49 minutes in group B (piezosurgery, $P<0.05$). However, the surgeon with five years' experience with piezosurgery performed the two different interventions without variance ($P=0.11$) (Table 2).

The piezoelectric device was evaluated by the patients as more comfortable by 65 (65%), while the other patients reported no difference (with no statistical difference).

No complications were encountered in patients treated with the piezoelectric device but three patients having bur removal of the teeth, experienced short-term surgical complications, two dry sockets and one temporary paraesthesia, both totally resolved by 4 weeks (with no statistical difference).

Finally, no differences were found between the two groups, in the pain reported and duration of surgery, considering gender, age and surgical difficulty (due to the radiographical position) (data not showed).

Discussion

The aim of this study was to investigate the performance of piezosurgery compared with traditional rotating instruments during mandibular third molar removal in a large split-mouth study. To the best of our knowledge, the present prospective investigation is the largest split-

mouth study of piezosurgery for mandibular third molar tooth removal, also comparing surgeons with different degrees of experience in piezosurgery use.

The obtained results indicated that the piezoelectric device could have a positive impact on the patients' operative experience and post-operative clinical sequelae of mandibular third molar tooth removal, with only a minimal increase in duration of the technical procedure.

Nowadays, piezoelectric surgery is considered an alternative technique, to the classical one with bur instruments, which can be used in oral and maxillofacial bone surgery, definitively producing minor postoperative complications.[20]

Acute post-operative pain following third molar extraction is predominantly a consequence of inflammation caused by tissue injury. Our study has shown that, despite minimally extended operating time, the pain VAS was lower in the piezosurgery than in the bur group. The main advantages of piezosurgery include soft tissue protection, optimal visibility in the surgical field, decreased blood loss, less vibration and noise, increased comfort for the patient and protection of tooth structures.[20] Several authors have reported that piezoelectric osteotomy reduces the post-operative facial swelling and trismus,[15-17,21-23] although a slightly longer surgery time is required.[17,23] Our present results also indicated that piezosurgery required a slight lengthening in terms of surgical duration, compared to the use of conventional rotary instruments, but this difference was limited in surgeons with greater experience. This is similar to previous report which showed that the main disadvantage of piezosurgery (besides cost and the risk of breakage of the surgical tips), was the increased operating time, but the time needed decreases as the operator gains experience.[22,24,25]

Facial swelling usually occurs in response to the trauma to tissues in the third molar region. Onset is gradual, with peak swelling around 48 hours after surgery. However, some authors have reported that swelling can increase on the third day following surgery, and last until the 7th.[26] Our current results showed that the facial swelling on the side treated with rotating

instruments was greater than that following piezosurgery - especially at the 7th day post-operatively.

Piezosurgery can cut the bone more selectively, with less damage to the surrounding tissues than experienced by bur removal, and may thus be a preferred modality.[27,28] This is also evidenced from the current study, comparing the short-term outcomes between the two surgical techniques: in the piezosurgery group nothing untoward was reported, while in the bur group 2 adverse events occurred, even if promptly resolved and without any statistical differences.

The piezoelectric device was efficient in reducing the short-term outcomes of pain and swelling. The piezoelectric technique was also preferred by patients – despite a minimally increased operating time- because of improved comfort, less vibration and noise –features which can well minimise a patient's psychological stress and anxiety.[20]

Of course, two of the main limitations of our study are the limited sample size, which could result in restricted power, particularly for multivariate analyses, remembering however, that our population was remarkably selected, and the fact that the post-surgical clinical assessment was only single-blinded. Further randomized multicentre studies, are needed to evaluate the post-operative period of third molar removal and analyse all variables that can influence third molar surgery.

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Table 1. COMPARISON OF POSTOPERATIVE SYMPTOMS AND NORMALIZED FACIAL SWELLING BETWEEN THE TWO GROUPS STUDIED

	Group A (n°100) Bur surgery	**Group B (n°100) Piezo surgery**	**P***
Post-operative symptoms			
VAS[§] at day 2	6.09 (± 2.08)	5.97 (SD ± 2.14)	0.118
VAS at day 4	3.14 (± 2.11)	2.81 (SD ± 2.13)	*0.043*
VAS at day 6	1.27 (± 1.87)	0.82 (SD ± 1.69)	*0.005*
Post-operative swelling at day 7			
D_i°(G-T)	1.11 (± 0.02)	1.03 (SD ± 0.04)	*<0.005*
D_i (G-C)	1.06 (± 0.02)	1.01 (SD ± 0.01)	*<0.005*
D_i (G-S)	1.09 (± 0.03)	1.02 (SD ± 0.03)	*<0.005*
D_i (G-P)	1.11 (± 0.17)	1.02 (SD ± 0.05)	*<0.005*
E[ç]	1.10 (± 0.04)	1.02 (SD ± 0.02)	*<0.005*

* *t*-test
[§]VAS = visual analogue scale (cm) for pain.
°D_i = facial swelling parameters [the angle of lower jaw (G) and 4 facial reference points: tragus (T), outer canthus of the eye (C), subnasal point (S), and pogonion (P)].
[ç]E = overall swelling/oedema, which was expressed as: $E = [\Sigma d_i^2/4]^{0.5}$, where Σd_i is the sum of the 4 measurements previously reported (G-T, G-C, G-S, G-P).

Table 2. COMPARISON BETWEEN SURGEONS' EXPERIENCE AND SURGERY DURATION: GROUP A (BUR SURGERY) AND GROUP B (PIEZOELECTRIC TECHNIQUE)

	TIME OF SURGERY		
	Group A (n°100) Bur surgery	**Group B (n°100) Piezo surgery**	**P[§]**
Surgeon A (< 3 yrs)*	18.75 minutes (±5.87)	21.50 minutes (±8.64)	*<0.005*
Surgeon B (3-5 yrs)	16.52 minutes (±5.22)	19.33 minutes (±6.45)	*<0.005*
Surgeon C (> 5 yrs)	18.74 minutes (±5.69)	20.16 minutes (±7.11)	0.11
P°	0.30	0.85	

*Three different surgeons did the interventions: the first one had less than three years of experience with piezosurgery, the second one had intermediate practice (between three and five years) and the last had more than five years of experience.
§ *t*-test on B-A
° *t*-test on single surgeon

FIGURE 1. Pell and Gregory radiographical classification.

FIGURE 2. The 4 facial reference points used.

FIGURE 3. Study flow diagram.