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Physiodispenser versus conventional rotary instrument in transalveolar extraction of impacted mandibular third molars- A randomized controlled clinical trial

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Abstract
The purpose of the study was to compare perioperative effects of physiodispenser and conventional rotary in transalveolar extraction of impacted mandibular third molar. This randomized controlled clinical trial was conducted from September 2017 to April 2018 at a tertiary care hospital. Applying open labeled allocation concealment, patients were divided into two groups: conventional rotary instrument and physiodispenser group. Patients with Pell and Gregory classification class 2, 3 and position B, C impactions were treated surgically; using either physiodispenser or conventional rotary instrument. Assessment was done for following outcomes-intraoperatively: bone cutting time, bone cutting resistance, heat produced during bone cutting procedure; and, post operatively: pain, trismus, swelling and healing. The data was statistically analysed using chi square test and Mann Whitney U test. Out of 70 patients screened, 48 patients were included (24 patients in each group) in the study. The time required for bone cutting in two groups showed no significant difference (p=0.09). 'Mild heat' production while bone-cutting was seen in a significantly higher proportion of patients in the physiodispenser group (95.8%) as compared to conventional rotary (41.7%; (p<0.0001). Significantly higher proportion of 'mild' resistance was felt in patients from the physiodispenser group (91.7%) as compared to conventional rotary method (8.3%; p< 0.001). Postoperative outcomes recorded on Day 1, Day 3 and Day 7 (pain, trismus, wound healing and swelling) showed no significant difference between two groups. Physiodispenser offered significant ease to perform surgical procedure; however, bone cutting time and postoperative complications were comparable between both the instruments.

Keywords: Physiodispenser, perioperative effects, conventional rotary instrument, bone cutting resistance, bone cutting heat production

1. Introduction
With evolution, the jaw size is decreasing; failing to accommodate all 32 set of teeth. This results in increasing number of teeth being impacted; making surgical removal of impacted teeth the second most common procedure in exodontia [1].
Bone cutting is a crucial step in surgical removal of an impacted tooth and is done by several methods which utilize different instruments such as the conventional rotary instrument, physiodispenser, Er: YAG laser, Piezo electric method [2-5].
Surgical trauma leads to postoperative complications such as pain, trismus, swelling and delay in healing. Surgical times as well as difficulty of tooth extraction are major contributors to postoperative complications [6, 7].
Since initial years, the method of choice for bone cutting has been conventional rotary instrument due to its easy availability and ease of operation. However, it is associated with more surgical trauma [8]. Physiodispenser, on the other hand, is primarily concerned with 'bone cutting with controlled torque', which may be beneficial to the patients receiving the treatment [3].
A thorough literature search could not find any studies comparing perioperative effects of physiodispenser and conventional rotary instrument in India. The present study aims to compare the perioperative bone cutting effects of physiodispenser with conventional rotary instrument in patients with impacted mandibular third molar teeth.

2. Materials and Methods
An'open label with allocation concealment' randomized controlled clinical trial was carried

out in outpatient department of a tertiary care hospital for a period of eight months from September 2017 to April 2018.

2.1 Study population

2.1.1 Inclusion Criteria: All patients; male and female, aged 20-40 years, and visiting the outpatient department (OPD) with impacted mandibular third molars (as per Pell and Gregory classification: Position B, C; Class II, III) requiring bone cutting during surgical extraction [9].

2.1.2 Exclusion Criteria: Patients with acute infection, patients otherwise medically compromised, pregnant females, lactating mothers, and patients not willing to give the consent.

2.2 Pre-operative phase

All patients with impacted third molar were screened for exclusion or inclusion into the study. This was based on brief history to decide diagnosis and treatment, blood investigations (complete blood cell count, random blood sugar level, HIV, hepatitis B) and x ray (lateral oblique mandible with tracing).

Patients who fit into the inclusion criteria were explained about the study and patient information sheet was given to them. Written informed consent was obtained from those who took part in the study and they were given a unique identification number.

2.2.1 Randomization and allocation concealment:

A person independent of the study used website www.randomization.com to obtain the random allocation sequence of simple randomization (single block; 1:1 allocation) for treatment with physiodispenser and conventional rotary instrument. This independent person also placed this assignment in a consecutively numbered sealed opaque envelope. The study investigator opened this envelope only after obtaining informed consent from the participants fulfilling the eligibility criteria.

The patients were divided into two groups - control group and intervention group; each comprising of 24 patients. The control group received treatment with conventional rotary instrument and the intervention group received treatment with physiodispenser.

The co-investigator filled up the preoperative data in the pre-designed questionnaire. Assessment of fixed point distance measurements from the angle of mouth to lateral canthus of eye, angle of mouth to angle of mandible, and angle of mouth to midpoint of tragus of the ear (all in millimeters), were done to compare and conclude presence or absence of swelling; and assessment of trismus was done by measuring the interincisal distance between mesial angle of incisal edge of upper and lower central incisors (in millimeters) at the maximum mouth opening.

All patients received pre-operative coverage of antibiotic (Tablet Amoxicillin Clavulanic Acid 625mg twice a day) and analgesic (Tablet Diclofenac Sodium 50 mg twice a day) two days prior to the surgery.

2.3 Surgical phase and data collection

The standard surgical procedure for transalveolar extraction of impacted mandibular third molar teeth was carried out by the same surgeon, for all patients, in both the groups. The procedural sequence was administration of local anesthesia (2% lignocaine with adrenaline 1: 80000) followed by incision (conventional extended buccal incision) and elevation of full thickness flap (with Molt number 9 periosteal elevator). The next step included bone cutting by gutter technique using either the conventional rotary instrument or physiodispenser (using S S White straight fissure bur no 702); as per the random allocation. The next few steps included delivery of tooth, toileting of the wound (with 0.9% normal saline), hemostasis, primary closure (with 3/0 black braided silk) and pressure pack.

The surgery was carried outunder strict aseptic precautions with pre-decided speed and torque of conventional rotary instrument (marking 9) and physiodispenser (1500 rotations per minute (rpm), 35 N/cm^2). The day of surgery was considered as day zero.

All the peri-operative data required were carefully filled in the proforma by the co-investigator. Time period (in minutes) for bone cutting (till gutter preparation) and for complete surgery (from incision to suturing) was noted by the surgical assistant using a stopwatch. Amount of resistance felt during the bone cutting and heat produced during bone cutting (performed and assessed by the principal investigator, who is well qualified to use the instrument and assess the resistance and thermal changes); were measured by Likert scale as mild, moderate and severe.

All patients received a three daypostoperative coverage of the same antibiotic and analgesic, as used preoperatively.

2.4 Postoperative observations and data collection

Patients were called for follow up on the first, third and seventh postoperative day and all the post-operative data (pain, trismus, swelling and healing) were filled in the proforma by the co-investigator. Post-operative painwas assessedwith Visual Analogue Scale (VAS having a score from 0-10; considering 0 as no pain and 10 as excruciating pain) [10].

Post operative swelling was assessed by fixed point distance measurement from angle of mouth to lateral canthus of eye, angle of mandible, and midpoint of tragus of the ear in mm. The difference of pre-operative and post-operative measurements was calculated respectively and a positive difference was noted as 'swelling present'.

Post-operative trismus was assessed by measuring inter-incisal distance between mesio-buccal angle of upper and lower central incisors with the caliper at maximum mouth opening.

Healing of wound was assessed as smooth or interrupted, based on presence or absence of persistent post-operative pain, swelling, change in color of mucosa, pus discharge, and palpable lymph nodes.

2.5 Outcome measures

1) Intra-operative production of heat while cutting the bone, resistance felt while cutting the boneand time duration required for cutting the bone.
2) Post-operative pain, swelling, trismus, and healing of the wound.

2.6 Sample size and sampling methods: Based on previous study, the mean (SD) pain score on day 7 in control group using conventional rotary instrument was 4.11(3.66) and that in the intervention group using physiodispenser instrument was 1.58(2.45) [3]. Taking α as 0.05 and power of the study (β) as 80%, sample size estimated using Open Epi software was 24 in each of the groups. Thus, the total sample size was 48.

2.7 Data management: Data from the proformawas entered in tabular form in the Microsoft excel sheet version 2010

using strict check files. Forms were cross-checked and verified for errors; which, if any, were rectified. These data were exported to Epi Info™ 7.2.2.6 software for analysis.

2.8 Data analysis: Gender, type of tooth impaction, type of resistance and degree of heat produced during operative procedure and post-operative healing were analysed as percentages and proportions, and association between physiodispenser and conventional rotary method was done using chi square test.

Age was reported as mean (SD), intra-operative outcomes such as time for bone cutting and time required for surgery (in minutes), and postoperative complication like pain (VAS score) and trismus- interincisal distance (in mm) was reported as median (IQR). The difference between the two groups was analyzed using Mann Whitney U test. A p value of <0.05 was considered statistically significant.

3. Results and Discussion

During the study duration of eight months, 70 patients were screened for the study. Out of these, 22 patients were excluded due to acute infection (n= 5), type of impaction (n= 6), being medically compromised (n =5), pregnancy (n= 1) and failure for follow up (n=5). Total 48 patients were enrolled for the study; 24 each in the conventional rotary (control) and the physiodispenser (intervention) group. All the enrolled participants completed the required follow up of three visits. (Figure 1)

The participants in the conventional rotary and physiodispenser group were comparable with regards to gender and age (p=0.25 and p=0.08 respectively). In both control and intervention groups, the most common type of tooth impaction noted was class II, position B; with no significant difference between two groups (p=0.26) (Table 1).

Median time required for bone cutting using the conventional rotary instrument and physiodispenser instrument was three and two minutes respectively, while median time for surgery for 18.5 minutes and 17 minutes respectively. There was no statistically significant difference in the time required for bone cutting or surgery in the two groups (p=0.09 and p=0.83 respectively) (Table 2).

No observations were recorded in severe category of heat production while bone cutting and bone cutting resistance outcomes; hence table 2 shows only 2 categories.

Comparing the resistance felt during bone cutting; significantly higher proportion of mild resistance was felt in patients of the physiodispenser group (91.7%) as compared to the conventional rotary method (8.3%; $p< 0.001$) (Table 2).

'Mild heat' production while bone-cutting was seen in a significantly higher proportion of patients in the physiodispenser group (95.8%) as compared to control group (41.7%; $p<0.0001$) (Table 2).

Postoperative complications like pain, trismus, wound healing and swelling were recorded as post-operative outcomes.

No statistically significant difference was observed in the post-operative pain score on Day 1, Day 3, Day 7 of the procedure using both the instruments.(p-value of 0.67, 0.49, 0.83 respectively) (Table 3).

Median interincisal distance (measured to find out trismus) was 21 mm, 25.5 mm and 34 mm on day 1, 3 and 7 respectively in conventional rotary group; and it was 22.5 mm, 25.5 mm and 34 mm on day 1, 3 and 7 respectively in physiodispenser group. There was no statistically significant difference in post-operative trismus recorded in both the groups (Table 3).

Interrupted healing was noted in 22 (91.67%), 21 (87. 5%) and 9(59.4%) patients on day 1, 3 and 7 respectively in conventional rotary group; while among patients of the physiodispenser group it was noted in 21(87.5%), 21(87.5%) and 10 (41.7%) on day 1, 3 and 7 respectively (Figure 2).

There was no statistically significant difference found in presence of swelling on Day 1, Day 3, Day 7 (p=0.15, 0.64, and 1 respectively) and pattern of wound healing (p=0.64, 1, and0.77 respectively) in both the groups (Figure 3).

Transalveolar extraction of impacted mandibular third molar occupies a major role inday to day dentistry practice [1]. Though Physiodispenser is commonly available in clinics for placement of dental implants, it is hardly used for surgeries of impacted molars; and conventional rotary instrument is being widely used. Physiodispenser and conventional rotary instruments are used for osteotomies in different dento-alveolar surgeries in routine dental setups. However, comparison of peri-operative effects during surgery of mandibular impacted teeth using these tools has not been documented in India [3].

In this study, findings showed that the physiodispenser offered significant ease to perform surgical procedure. In terms of intra-operative observations, time taken for bone cutting was similar using physiodispenser and conventional rotary instruments. The resistance experienced during bone cutting and the amount of heat produced was significantly lesser while using Physiodispenser.

It is well known that, the use of physiodispenser allows a surgeon to control the speed and torque, and power of the mechanical drill; thus reducing the damage to bone while surgical placement of dental implants [11, 12]. The results of physiodispenser in implant surgeries are also well documented; the advantages being the motor speed range between 300 to 40000 rpm. This provides for an integrated coolant system to avoid tissue damage during surgery and allows a torque control up to 70 N/cm^2. In routine practice now days,the physiodispenser is readily available in most of the set-ups of general dentists as well as surgical set-ups. Thus, advantages of physiodispensercan be utilized for surgical removal of impacted teeth [11, 12].

On the other hand the Conventional Rotary does not allow for any torque control and produces heat, at times above 47°C during bone cutting, which may lead to bone necrosis and swelling [13-15].

As compared to the conventional rotary instrument technique in lower third molar surgery, the results of previously done four meta-analysis showed that piezoelectric surgery significantly reduced the occurrence of postoperative sequelae (oedema, trismus, and pain) but required a longer surgery time [2, 5, 8, 14, 16]. Results of other three RCTs stated that the Piezo-surgery method reduces postoperative pain, trismus and swelling as compared to conventional rotary instrument [1, 7, 13, 16]. Also, conventional rotary instrument increased the amount of bone loss of adjacent tooth [17].

Thus, though the initial cost of physiodispenser is considerably higher than the other instruments; it increases efficiency of operating surgeon by minimizing bone cutting resistance and heat production with less bone cutting and surgical time

Based on these findings of intra-operative outcomes, the operative procedure being easier in case of physiodispenser, it may be expected that post operative complications would have been lesser [2, 5, 8]. However, in this study, the bone cutting timeandpost-operative complications were comparable between both, the Conventional Rotary and

Physiodispenserinstruments.

There are various factors affecting post-operative complications after transalveolar extraction of mandibular third molar [18-21]. Some of them are pain, trismus, swelling, paresthesia, infection, bleeding, dry socket, fracture of mandible [20, 21]. In this study, we evaluated and compared the pain, trismus, swelling, healing for both thegroups. Post-operative complications in terms of post-operative pain, trismus, swelling and healing on day one, three and seven of follow up in both the groups treated using conventional rotary and physiodispenser were not significantly different in this study. This shows that no instrument has an added advantage over the other in terms of post operative complications.

There are many anatomical and patient related factors that play a role in surgical difficulty

affecting the peri operative outcomes in transalveolar extraction of mandibular third molar

tooth [6, 18-22]. There were some unusual anatomic factors encountered in patients treated withphysiodispenser in this study; two patients had bulbous third molar, one patient had a third molar with four roots, two patients had very dense cortical bone that required additional bone cutting [18-20]. In addition to these, some patient related factors may have affected the

final outcome in terms of postoperative complications; one patient had oral sub mucous fibrosis, two patients reported to havesmoked in the first week post surgery, two patients did not follow post-operative instructions [19].

The limitations of this study were that assessor blinding was not done and that it was not a split mouth design study wherein both instruments could be used on either side in same patient [13].

Future implications

1. We can start using physiodispenser in place of conventional rotary instrument as a departmental policy wherever it's available.
2. Studies for cost effectiveness and detailed study of post-operative complications in patients treated with physiodispenser is the way forward.

3.1 Tables and Figures

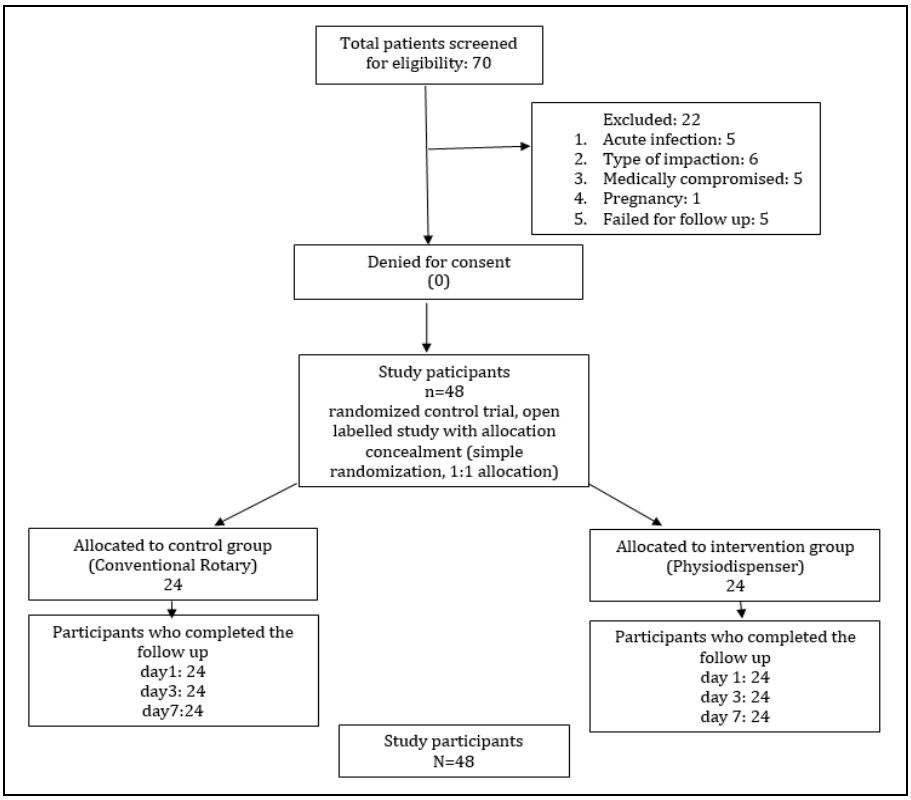

Fig 1: Screening and patient inclusion in the groups using Physiodispenser and Conventional Rotary instrument.

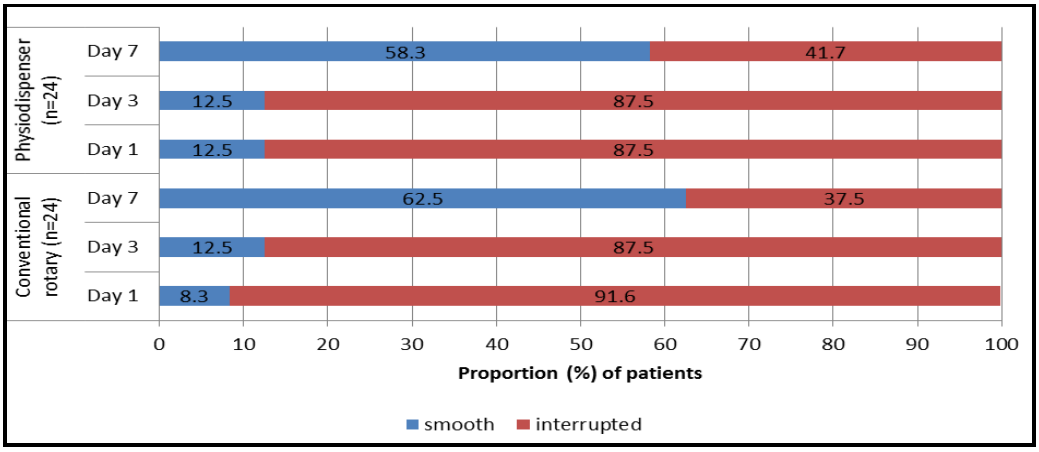

Fig 2: Postoperative healing on day 1, day3 and day 7 in case of physiodispenser and conventional rotary groups (in form of percentages).

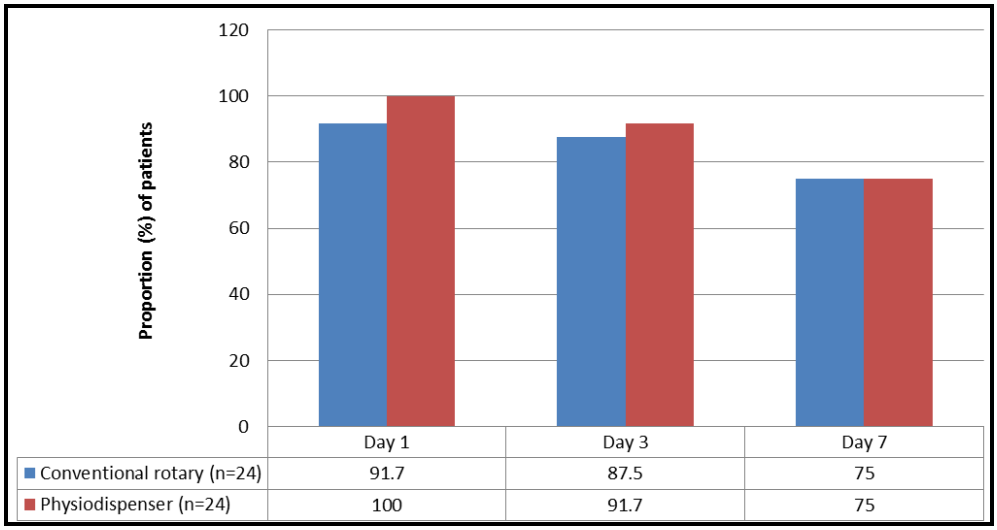

Fig 3: Presence of swelling on postoperative day 1, day 3, and day 7 in case of physiodispenser and conventional rotary groups (in form of percentages).

Table 1: Baseline data of patients with impacted third molar tooth coming to the outpatient department of a tertiary care hospital

Study Group		Conventional rotary group (n=24) N (%)	Physiodispenser Group (n=24) N (%)	P value
Age (mean, SD) in years		29.8 (5.7)	32.1 (6.1)	0.25
Sex	Male	09 (37.5)	15 (62.5)	0.08
	Female	15 (62.5)	09 (37.5)	
Type Of Tooth Impaction**	Class 2 position B	22 (91.7)	23 (95.8)	0.26
	Class 2 position c	02 (08.3)	00	
	Class 3 position B	00	00	
	Class 3 position c	00	01 (04.2)	

**Pell and Gregory Classification [9]

Table 2: Comparison of intra-operative outcomes between patients with impacted third molar operated using conventional rotary and physiodispenser instruments.

Outcome	Conventional rotary Group(n=24)	Physiodispenser Group(n=24)	P value
Time required for bone cutting (minutes) Median (IQR)	3 (2-4)	2 (2-3)	0.09
Resistance while cutting the bone*#			
Mild	02 (08.3)	22 (91.7)	0.00
Moderate	22 (91.7)	02 (08.3)	
Heat produced while bone cutting*#			
Mild	10 (41.7)	23 (95.8)	<0.0001
Moderate	14 (58.3)	01 (04.2)	

*Resistance and Heat measured on a Likert Scale of 1-5
#Mantel Haenszel chi square test.

Table 3: Comparison of post operative pain and trismus among patients with impacted third molar operated using conventional rotary and physiodispenser instruments.

Outcome		Conventional rotary group Median (IQR)	Physiodispenser Group: Median (IQR)	P value#
Pain score*	Day 1	4 (2-5)	4.5 (2-7)	0.67
	Day 3	4 (2-5)	3 (0.5-5)	0.49
	Day 7	1 (0-2)	0 (0-3)	0.83
Mouth opening (Interincisal distance in mm)	Day 1	21(18.5-25.5)	22.5(18.5-26.5)	0.65
	Day 3	25.5(16.5-30)	25.5(18.5-31)	0.69
	Day 7	34(26-38.5)	34(21-37)	0.75

*VAS Score for pain (0-10)
Mann Whitney U test

4. Conclusions

Bone cutting time and postoperative complications were comparable between physiodispenser and conventional rotary instrument; the ease of performing surgery was significantly higher with physiodispenser.

Ethical considerations

The use of human subjects in this study was reviewed and

approved by the Institutional Human Ethics Committee. The patients were informed about every aspect of their involvement in the study and exposure to the procedure of the study. A written informed consent was obtained. Patient's information was kept confidential and the guidelines of Declaration of Helsinki were followed.

Conflict of interest

The authors report no conflict of interest related to this study.

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References

1. Hani A, Mohamed NA. Comparison of piezosurgery and conventional rotary instruments for removal of impacted mandibular third molars: a randomized controlled clinical and radiographic trial. Int J Dent. 2016, 1-7.
2. Magesty RA, Galvo EL, Castro MC, Santos CRR, Falci SGM. Rotary instrument or piezoelectric for the removal of third molars: a meta-analysis. J Maxillofac Oral Surg. 2017; 16:13-21.
3. Hussain A, Azam K, Maqsood A, Farooqui W. Effects of surgery duration on post-extraction sequelae following impacted third molar surgery by using two different bone cutting methods ; a double blind randomized trial. Pakistan Oral & Dental Journal. 2016; 36(1):8-13.
4. Passi D, Pal US, Mohammad S, Singh RK, Mehrotra D, Singh G *et al*. Laser vs bur for bone cutting in impacted mandibular third molar surgery: a randomized controlled trial. J Oral Biol Craniofac Res. 2013; 3:57-62.
5. Al-Moraissi EA, Elmansi YA, Al-Sharaee YA, Alrmali AE, Alkhutari AS. Does the piezoelectric surgical technique produce fewer postoperative sequelae after lower third molar surgery than conventional rotary instruments? A systematic review and meta-analysis. Int J Oral Maxillofac Surg. 2016; 45:383-91.
6. Bello SA, Adeyemo WL, Bamgbose BO, Obi EV, Adeyinka AA. Effect of age, impaction types and operative time on inflammatory tissue reactions following lower third molar surgery. Head Face Med. 2011; 28:7-8.
7. Middlehurst RJ, Barker GR, Rood JP. Postoperative morbidity with mandibular third molar surgery: comparison of two techniques. J Oral Maxillofac Surg. 1988; 46:474-6.
8. Jiang Q, Qiu Y, Yang C, Yang J, Chen M, Zhang Z. Piezoelectric versus conventional rotary techniques for impacted third molar extraction: A meta-analysis of randomized controlled trials. Medicine. 2015; 94:1685.
9. Gintaras J, Povilas D. Mandibular third molar impaction: review of literature and a proposal of a classification. J Oral Maxillofac Res. 2013; 4:1-12.
10. Khatri A, Kalra N. Clinical study: A comparison of two pain scales in the assessment of dental pain in East Delhi children. Int Sch Res Netw ISRN Dent. 2012, 1-4.
11. Kalindi, Varahalaraju. "Optimization of drill design and coolant systems during dental implant surgery" University of Kentucky Master's Theses, 2004, 314 https://uknowledge.uky.edu/gradschool_theses/314.
12. Ozkan D, Emre T, Mert D. Required minimum primary stability and torque values for immediate loading of mini dental implants: An experimental study in nonviable bovine femoral bone. Oral med Oral pathol Oralradiol Endod. 2008; 105:20-27.
13. Mantovani E, Arduino PG, Schierano G. A split-mouth randomized clinical trial to evaluate the performance of piezosurgery compared with traditional technique in lower wisdom tooth removal. J Oral Maxillofac Surg. 2014; 72:1890-7.
14. Freddy M Nidarsh H, Mithra H. Postsurgical consequences in lower third molar surgical extraction using micromotor and piezosurgery. Ann Maxillofac Surg. 2016; 6:251-259.
15. Goran A, Slavko D, Toma U. Temperature changes during cortical bone drilling with a newly designed step drill and an internally cooled drill. International Orthopaedics (SICOT). 2012; 36:1449–56.
16. Basheer SA, Govind RJ, Daniel. A comparative study of piezoelectric and rotary osteotomy technique for third molar impaction. J Contemp Dent Pract. 2017; 18:60-64.
17. Rullo R, Addabbo F, Papaccio G. Piezoelectric device vs. conventional rotative instruments in impacted third molar surgery: relationships between surgical difficulty and postoperative pain with histological evaluations. J Craniomaxillofac Surg. 2013; 41:33-8.
18. Yuasa H, Kawai T, Sugiura M. Classification of surgical difficulty in extracting impacted third molars. Br J Oral Maxillofac Surg. 2002; 40:26-31.
19. Voegelin TC, Suter VG, Bornstein MM. Complications during and after surgical removal of mandibular third molars. Impact of patient related and anatomical factors. SchweizMonatsschr Zahnmed. 2008; 118:192-8.
20. Elitsa G, Deliverska, Milena P. Complications after extraction of impacted third molars- literature review. Journal of IMAB. 2016; 22:1202-11.
21. Pièrre P, Pourmand GR, Sigron B, Mache B, Michael C. The most common complications after wisdom-tooth removal part 2: A retrospective study of 1,562 cases in the maxilla. Swiss Dental Journal SSO. 2014; 124:1047-51.
22. Gbotolorun OM, Arotiba GT, Ladeinde. Assessment of factors associated with surgical difficulty in impacted mandibular third molar extraction. A J Oral Maxillofac Surg. 2007; 65:1977-83.