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The Effect of Passive Ultrasonic Irrigation or XP-Endo Finisher on Post-Operative Pain in Patients with Necrotic Teeth with Apical Periodontitis (Randomized Controlled Clinical Trial)

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Abstract

AIM: The objective of the study was to evaluate the effect of passive ultrasonic irrigation or XP-Endo Finisher on post-operative pain in patients with necrotic teeth with apical periodontitis using (VAS) scale at 6, 12, 24, 48, 72 h, and 7 day time intervals.

METHODS: Seventy-eight patients diagnosed with necrotic mandibular first molar with symptomatic apical periodontitis were randomly allocated into 1 of 3 separate groups (n = 26); Navitip group (control), XP-Endo Finisher group, or Ultra X group. After a single visit root canal treatment and a specific method of agitation, depending on each group, the patients were given a questionnaire on which the patient would mark the degree of pain in a scale from 0 to 10 at 6, 12, 24, 48, and 72 h and 7 days post-obturation. Data were statistically analyzed with a significance level of $p \leq 0.05$.

RESULTS: Passive ultrasonic agitation using Ultra X and XP-Endo Finisher agitation as a final irrigation protocol showed significantly lower pain values than the control group, but there was no significant difference in pain values between the experimental groups.

CONCLUSION: There was significantly less pain associated with ultrasonic and XP-Endo Finisher agitation compared to Navitip irrigation.

Introduction

The purpose of preparing and shaping the root canal is to facilitate canal irrigation, disinfection, and obturation. Instruments used to shape the root canal do not touch all canal walls. There are always parts of the canal, especially in the apical one third and the isthmus region, left untouched by the tools used in mechanical preparation of the canal. Irrigation plays a major role in the cleaning and disinfection of the root canals, thus improving the success rate of the root canal treatment [1].

Delivering the irrigants using the traditional syringe and needle irrigation technique (SNI) results in an ineffective disinfection in particular areas such as isthmus and apical regions. Adequate agitation following proper instrumentation improves the irrigant penetration to reach the untouched part. There is a couple of methods that can be performed to deliver the irrigant during ultrasonic activation; continuous and intermittent flush. The use of an ultrasonic device such as Ultra X (Eighteeth, Changzhou sifary technology, China) utilizes the principle of acoustic microstreaming, agitation and cavitation. Its rapid movement enables penetration into untouched areas and enhances shear stress on tissue remnants leading to minimize the post-operative pain [2].

On the other hand, XP-Endo Finisher (FKG Dentaire, La Chaux de Fonds, Switzerland) has been introduced to be used in the final root canal irrigation protocol to enhance the cleaning efficacy by removing hard tissue debris and smear layer especially in irregular areas while maintaining the original root canal anatomy [3].

Methods

Sample size calculation

Based on a previous study [4], the outcome variable was post-operative pain assessed by visual analogue scale (VAS). Using power 80% and 5% significance level, we needed to study a total sample size of 60 in which divided into three groups (20 per

each group). This number is to be increased to a total sample size of 66 to adjust for using a nonparametric test. Further increase of 25% to allow for least frequently used, the number is increased again to a total sample size of 78 (26 in each group) to compensate for losses during follow-up. The sample size was calculated by PS (Power and sample size) G* program [5].

Sample selection

After approval of the local ethics committee, 78 patients from the outpatient clinic of endodontics at the faculty of oral and dental medicine, future university were diagnosis with necrotic mandibular first molars with symptomatic apical periodontitis. The exclusion criteria comprised medically compromised patients, pregnant or lactating females, psychologically disturbed patients, patients allergic to any medication used in this study, patients with swelling or acute periapical abscess, patients who administered anti-inflammatory analgesics or antibiotics 12 h preoperatively. The exclusion criteria also comprised teeth with wide or open apex, vital pulp tissues, association with swelling or fistula tract, no possible restorability, abnormal anatomy or calcified canals, previous root canal treatment, or periodontally affected with Grade 2 or 3 mobility.

Root canal preparation

The tooth was isolated using rubber dam (Sanctuary Powder Free Latex Dental Dam, Malaysia) then patency of the canals was done using stainless steel hand K-file (MANI-MANI, INC. Industrial Park, Utsunomiya, Tochigi, Japan) sizes 15. Working length was measured using electronic apex locator (Root ZX, J. Morita USA, Irvine, USA) and was then confirmed with intraoral periapical radiograph (Ateco AT303, Ateco technology, London, UK) to be 0.5–1 mm shorter than radiographic apex using paralleling technique.

Root canals were mechanically prepared by crown down technique using ProTaper Next (DENTSPLY, Tulsa Dental, DENTSPLY Maillefer, TN, USA) nickel-titanium rotary instruments according to the manufacturer's instructions as follows:

- ProTaper Next rotary file set on electric motor (X-Smart, DENTSPLY, Tulsa Dental, DENTSPLY Maillefer, TN, USA) at a rotational speed of 300 rpm and 2 N cm torque using a gentle in and out brushing motion until the working length was passively reached
- In the presence of NaOCl solution, X1 (17/04) file was used in one or more passes, alternatively with small-sized hand files, if necessary, until the working length was reached
- X2 (25/06) file was exactly used as described for X1 file, until the working length was passively reached. Afterwards, the canal was gauged with a size 25 K-file and, if the size 25 K-file was loose at length, canal shaping was continued with X3 (30/07) master apical file
- Preparation of all canals was completed when a hand K-file whose ISO size corresponding to the tip size of the used ProTaper next file snugly fits the apical third of the canal at the working length.

The canals were thoroughly irrigated with 2 ml of freshly prepared 2.6% sodium hypochlorite (NaOCl) solution using plastic disposable syringe with side-vented needle (NaviTip; Ultradent, South Jordan, UT, USA) gauge 30 between every subsequent instrument. It was used passively into the canal, without forceful dispensing of the irrigant, placed 2 mm short from the working length, which was verified by rubber stoppers. To achieve standardization, the volume of irrigating solution was fixed (2 ml) after each file. A lubricant of 17% EDTA gel (EDTA, META, BIOMED, CO, LTD, Korea) was used with each file.

Final irrigation protocol

Side Vented Needle group (control group) Root canals were irrigated using 2 ml of 2.6% NaOCl with NaviTip double Sideport 31 G/27 mm 1 mm shorter than the working length but without agitation.

XP-Endo Finisher group 2 ml of 2.6 % NaOCl was delivered into the canal using double side-port irrigation needle (Navitip Side port 31 G/27 mm) which was used passively without forceful dispensing of the irrigant. Working length for each canal was determined using plastic ruler tube to adjust the rubber stop. After which, XP-Endo Finisher was cooled using spray ENDO Frost through the plastic tube. The XP-endo Finisher putted in rotation mode and removed from the tube by applying a lateral movement to ensure the XP-endo Finisher remains straight then the rotation was turn off.

The XP-endo Finisher then taken from sterile packaging and placed in the hand piece. The XP-endo Finisher was then inserted into the first canal of the tooth while straight, speed, and torque were adjusted on the endodontic motor to be 800 rpm and 1N cm, respectively, according to the manufacturer's instructions [3]. Once the tip is inside, rotation was turned on and file was inserted further in. The irrigant was mechanically agitated for 60 s with XP-Endo Finisher using slow and gentle 7–8 mm lengthwise (in and out) small multidirectional movements to contact the full length of the canal. After 1 min, the XP-endo Finisher was removed from the canal while it's still in rotation. Then the canal was irrigated with distilled water to remove the suspended debris.

Ultra X group 2 ml of 2.6% NaOCl was delivered into the canal using double side-port irrigation needle (Navitip Side port 31 G/27 mm) which was used passively without forceful dispensing of the irrigant. Then irrigant was ultrasonically activated for 60 s with

an ultrasonic device (Ultra X) at power 3 (40 kHz) using X-blue (bendable) metal ultrasonic tip (Length: 18 mm, Size: 20/2%) in an up-and-down motion where the tip was 1 mm short of the canal's working length.

For all root canals in tested groups, 2 ml of 17% EDTA solution was then introduced into each canal for 1 min to remove smear layer, followed by 10 ml of distilled water were used as a final flush of the canals to prevent erosion of the dentinal tubules.

Root canal obturation

After completion of the biomechanical instrumentation of the root canals, each root canal was completely dried using ProTaper Next absorbent paper points corresponding to the same size of the master file (X3). The root canals were obturated using the modified single cone technique by proper selection of gutta percha master cone corresponding to the same size as the master apical file (X3) and ADSEAL (ADSEAL, META BIOMED CO., LTD, Chungbuk) resin root canal sealer were used for obturation.

Cone fitness radiograph was taken to ensure proper length and preparation of the root canals. The ADSEAL sealer base and the catalyst were mixed till forming a mix with homogenous consistency. The mixed sealer was introduced into the canal through the master cone coated with sealer to the full working length. A spreader of # 25 was selected and auxiliary cones of # 25 were placed, Obturation was considered completed when the spreader no longer penetrates beyond the cervical line, excess gutta percha was sealed off using heated condenser tip.

Post-operative radiographs were taken to ensure proper obturation. No apical extrusion of gutta-percha beyond the apex was observed in any of the cases included. The access cavity was sealed using Resin-modified glass ionomer.

All canals were shaped, cleaned, and obturated in a single visit. The details of each step were recorded in the patient's endodontic procedure form.

Post-operative instructions

Every patient was instructed to mark the VAS scale between (0–10) to determine incidence and intensity of pain pre-operatively and post-operatively after obturation at 6, 12, 24, 48, 72 h, and 1 week. VAS scale was explained in different ways to the patient to facilitate the understanding and recording of the pain intensity. It expressed pain numerically and verbally in Arabic. Numerical description was presented as a scale beginning from zero representing no pain to ten representing maximum possible pain. Pain level and was documented in the range of 0–10 numerically as no pain (0), mild pain (1–3), moderate pain (4–6), and severe pain (7–10).

The participants were instructed in case of the presence of moderate (4–6 on VAS) or severe (7–10 on VAS) post-operative pain to take only one capsule of placebo which was given to him/her (powdered milk packed in opaque capsules). If the moderate or severe pain persist, patients were instructed to call the operator and were allowed to take 600mg Ibuprofen (Dailymed, USA). They were instructed to record the number of analgesic tablets taken. If there was still pain indicating a flare up (emergency), the patients were informed to contact the dentist and came to the clinic for an emergency intervention.

Each patient was given a chart to record post-operative swelling. If swelling was recorded, the patient would have been appointed for clinical examination to contact the operator to assess the severity in a swelling rating scale and determine if systemic antibiotics (Augmentin 625 mg/8 h/5 days) or drainage would have been needed.

After 7 days, the patient delivered the assigned paper record.

Statistical analysis

The mean and standard deviation values were calculated for each group in each test. Data were explored for normality using Kolmogorov–Smirnov and Shapiro–Wilk tests and showed parametric (normal) distribution. The mean and standard deviation values were calculated for each group in each test (Pain Evaluation and Bacterial count). Data were explored for normality using Kolmogorov–Smirnov and Shapiro–Wilk tests. Friedman test was used to test the difference between more than two groups in related samples while Wilcoxon test was used to test the difference between two groups in related samples. Mann–Whitney U test was used to compare the difference between two groups in non-related samples for pain evaluation. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

Results

In the present study, 78 patients were included in the study. The flow chart of the patients through the study is presented in the consort flow diagram in Figure 1.

XP-Endo Finisher group (Group B) and Ultra X group (Group C) showed significantly lower incidence and intensity of pain and pain on biting than the control group at 6, 12, and 24 follow-up periods. Figures 2 and 3 show the incidence of pain and pain on biting, respectively, at different time intervals for each group. Tables 1 and 2 show the intensity of preoperative

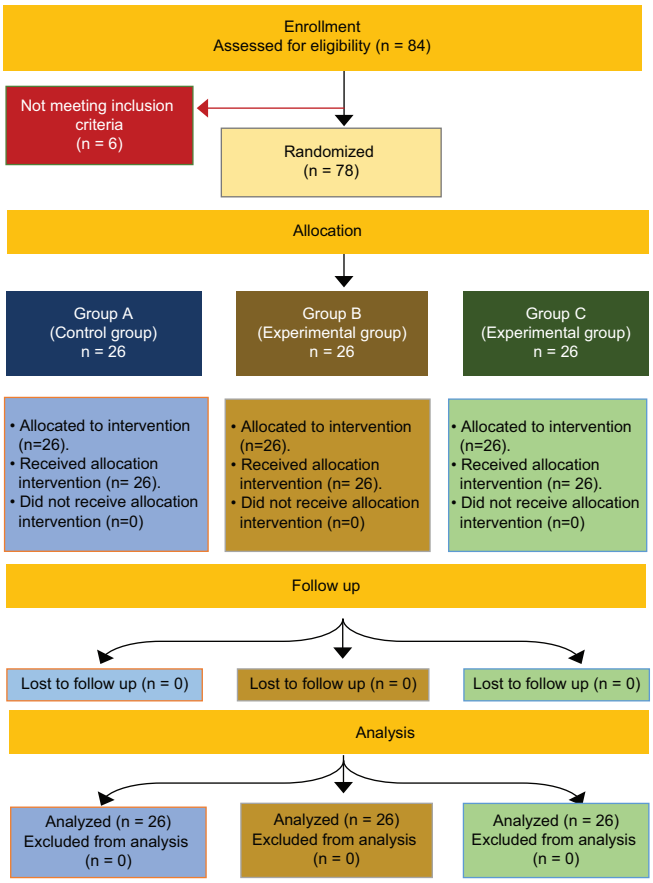

Figure 1: Consort flow diagram

and post-operative pain and pain on biting, respectively, of the tested groups at different time intervals.

Table 1: Intensity of pre- and post-operative pain of the tested groups after 6 h, 12 h, 24 h, 48 h, 72 h, and 7 days

Period	Pain intensity						
	Control		XP Finisher		Ultra X		P-value
	Mean	SD	Mean	SD	Mean	SD	
Pre-operative	0.00	0.00	0.00	0.00	0.00	0.00	1ns
After 6 h	2.88	1.73	2.04	1.51	2	1.55	0.8ns
After 12 h	1.92	1.26	1.38	1.27	1.38	1.24	0.2ns
After 24 h	1.08	0.8	0.77	0.86	0.69	0.74	0.19ns
After 48 h	0.58	0.5	0.5	0.65	0.5	0.65	0.8ns
After 72 h	0.00	0.00	0.00	0.00	0.00	0.00	1ns
After 7 days	0.00	0.00	0.00	0.00	0.00	0.00	1ns
p-value	< 0.001*		< 0.001*		< 0.001*		

*Significant (p < 0.05) ns; non-significant (p>0.05)

The frequency of analgesics taken by patients decreased by the time in each tested group. The highest mean value was recorded at 6 h for all groups, while no pain after 48 h in PUI group and 72 h in the side vented needle and XP-Endo Finisher groups.

Table 2: Intensity of pre- and post-instrumentation pain on biting of the tested groups after 6 h, 12 h, 24 h, 48 h, 72 h, and 7 days

Period	Pain on biting intensity						
	Control		XP Finisher		Ultra X		p-value
	Mean	SD	Mean	SD	Mean	SD	
Pre-operative	5.62	2.06	4.58	2.42	4.54	2.25	0.122ns
After 6 h	5.00	1.52	3.42	1.27	3.38	1.63	< 0.001*
After 12 h	3.54	1.77	2.42	1.14	2.35	1.26	0.018*
After 24 h	2.35	1.72	1.27	0.72	1.23	0.71	0.022*
After 48 h	1.19	1.27	1.00	0.63	0.88	0.59	0.820ns
After 72 h	0.12	0.33	0.04	0.20	0.00	0.00	0.162ns
After 7 days	0.00	0.00	0.00	0.00	0.00	0.00	1ns
p-value	< 0.001*		< 0.001*		< 0.001*		

*Significant (p<0.05) ns; non-significant (p>0.05)

Discussion

The goal of performing root canal treatment is biomechanical preparation and hermetic sealing of the root canal without any unpleasant outcome to the patient, and provides favorable conditions for the periradicular tissues to heal [6].

As root canal treatment induce more frequent and more severe post-operative pain than do other dental operative procedure, so prevention and management of post-operative pain are an integral part of endodontic treatment. Mechanical, chemical, host, and microbiological factors have been described as important for inducing pain following root canal treatment [7].

Post-operative pain was found to be significantly higher in the mandible compared to the maxilla because the mandible has a dense trabecular pattern, thus there is reduced blood flow and more localization of infection and inflammation, which might delay healing.

Necrotic teeth were selected since microorganisms have been identified as the major causative factor for flare-ups [8]; It has been shown that occurrence of post-operative pain and flare-up in patients with pulpal necrosis are more common than in vital pulps [9].

In the present study, doses of anesthetic solutions selected were 3.6 mL (equivalent to two cartridges) of 2% mepivacaine with 1:100,000 epinephrine. A waiting period of 15 min was allowed before initiation of endodontic treatment to allow for blockage of the nerve induction.

In the present study, patients with medical conditions or any medication (analgesic or antibiotics) in the past 12 h before the endodontic visit and pregnant females were excluded from the study. Moreover, teeth associated with swelling and retreatment cases were not included so as not to be considered additional factors influencing the incidence and intensity of post-operative pain [10].

In this study, the pain intensity was recorded preoperatively as base line data and postoperatively at different time intervals. 6 h was chosen as it is the time that the effect of anesthetic solution start to fade [11]. 12, 24, and 48 h were chosen as it was proven that most of post-operative pain occurred between these time intervals after chemo-mechanical preparation [12].

In the current study, the VAS was used for measuring the pain intensity, after treatment, the participants were given placebo and asked to take it in case of moderate or severe pain. Placebo is a pharmacologically inert substance that has no therapeutic effect, but it has been used as a pain reducing and anxiety control agent [13].

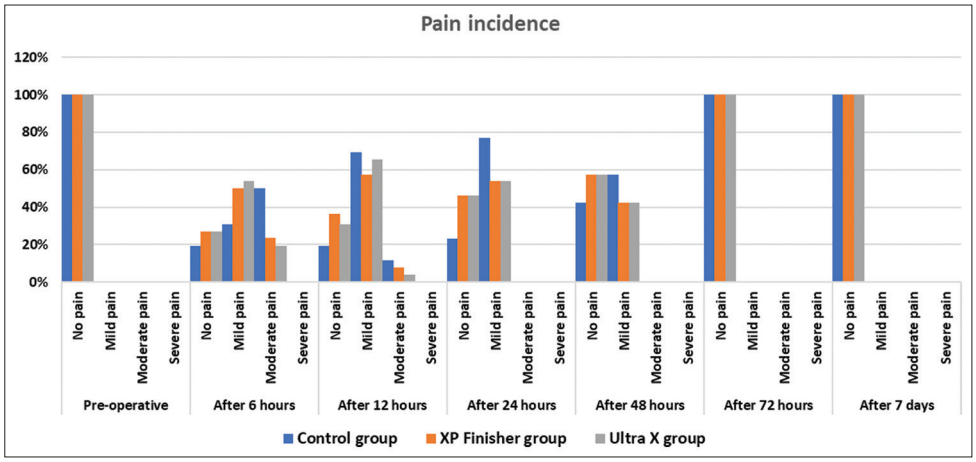

Figure 2: Bar chart representing the incidence of pain at different time intervals for each group

XP-Endo Finisher group (Group B) and Ultra X group (Group C) showed significantly lower incidence of pain than the control group, which is supported by other studies, Alves *et al.* [14] and Azim *et al.* [15] who demonstrated that the use of XP-Endo Finisher showed high efficiency in reducing bacterial counts and exhibited adequate disinfection, and Chen *et al.* [16] who stated that PUI generates high shear stress in apical third of the root canal that enhanced reduction of strictly adherent bacterial biofilm in comparison to syringe irrigation. Better microbial control of PUI may be attributed to the advantage of PUI over the other irrigation techniques, in which PUI enhances delivery of irrigation to uninstrumented areas of root canal and helps in removal of remnant bacteria by inducing acoustic streaming and cavitation of the irrigant [17]. Seltzer and Naidorf [18] suggested that bacteria present in the root canal system can be responsible for post-operative pain. Furthermore, the inability of SVN to completely reach the full working length can leave behind vital pulp remnants and microbes that could contribute to the reported post-operative pain [19].

Regardless of the chief complaint, the mean scores of post-operative pain intensity were higher in control group (SVN) than in intervention groups (Ultra X and XP-Endo Finisher) at 6, 12, and 24 follow-up periods. These results are in accordance with Elnaghy *et al.* [3], Carvalho *et al.* [20], Xin *et al.* [21], Nangia *et al.* [22], Gundogar *et al.* [23], and Yusufoglu *et al.* [24].

This may be attributed to, in the use of XP-Endo Finisher, the highly flexible proprietary alloy together with the small core size and zero taper which allowed it to expand its reach while rotating [25]. The file is straight in the Martensitic phase at the room temperature. However, the phase and the shape of file changes when inserted into the root canal to adapt to the three dimensional root canal anatomy to access and clean the root canal irregularities, in addition to remove packed debris from the complexities of the root canal system [26].

XP Endo Finisher is designed to reach spaces and aspects in root canal system that were not shaped using either rotary or reciprocating techniques [27], [28]. XP-Endo Finisher showed high ability in reaching the inaccessible and untouched canal areas, thereby, providing improved cleaning and superior removal of smear layer and bacterial biofilms, in accordance with Živković *et al.* [29], Bao *et al.* [30], Liviac *et al.* [31], and El Naghy *et al.* [3].

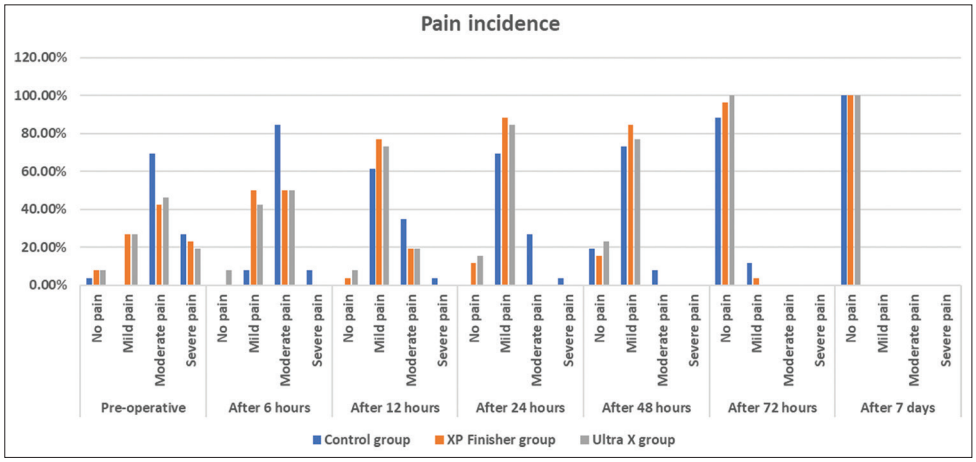

Figure 3: Bar chart representing the incidence of pain on biting at different time intervals for each group

On the other hand, regardless of different times used for evaluation, passive ultrasonic irrigation (Ultra X) as a final irrigation protocol showed lowest pain intensity which may be explained by the irrigation method using apical negative pressure preventing the apical extrusion of the irrigant compared with methods using positive pressure (MDA and needle). Ultra X (Eighteenth, Orikam) is a cordless ultrasonic irrigation device that oscillates at 45,000 kHz ultrasonic frequencies using the acoustic microstreaming, agitation, and cavitation principle that can reach difficult inaccessible areas (almost 35%) of the complex root canal system.

These results are against Kfir *et al.* [32] and Azimian *et al.* [33]. Furthermore, De-Deus *et al.* [34] reported that neither XP-Endo finisher nor PUI completely removed the AHTD from oval-shaped canals. Debris and irrigant extrusion during endodontic procedures is considered to be one of the main causes of post-operative pain.

On the other hand, at 48, 72 h, and 7 days post-operative, there was statistically no significant difference in pain between tested groups (Intensity of post-operative pain was higher at 6, 12, and 24 h' time intervals. Then it decreased along the following time intervals within each group). This is in accordance to Singh *et al.* who stated that most of the post-operative pain occurred on the 1st day after chemo mechanical preparation [35]. This may be related to the exacerbation or induction of the inflammatory response in the periapical tissues due to endodontic treatment. The polymorphonuclear leukocytes PMNs begin to enter the injured site within 6 h followed by increase in the release of inflammatory mediators and neuropeptides. The proliferative process begins after 48 h which is characterized by decrease in the PMNs population, and the beginning of the macrophages entering the wound site [36].

In the present study, the incidence of analgesics intake also has been assessed as a secondary outcome. The frequency of analgesics taken by patients decreased by the time in each tested group. The highest mean value was recorded at 6 h for all groups, while no pain after 48 h in PUI group and 72 h in the side vented needle and XP-Endo Finisher groups. This in accordance to systematic review published by Romualdo *et al*. [19]; they reported that the irrigation method using apical negative pressure prevents the apical extrusion of the irrigant compared with methods using positive pressure (MDA and needle). Shetty *et al.* [36] stated that positive pressure of conventional irrigation extruded greater weight of debris apically. This might be because of the positive pressure exerted by the needle leads to greater hydraulic pressure which may result in post-operative pain.

The amount of irrigant and/or debris extruded could initiate chemical irritation of periapical tissues, thereby causing post-operative pain. Passive ultrasonic irrigation induces small, intense, and circular fluid movement around the instruments causing movement of the irrigating solution inside the root canal in the cervical direction, thereby reducing the amount of irrigant and/or debris extrusion to the periapical region [37].

The null hypothesis is not accepted since post-operative pain incidence and intensity were significantly less in the experimental groups at 6, 12, and 24 h than the control group.

Conclusion

Machine-assisted irrigation agitation devices are considered reliable and safe to clinicians, and effective method as a final step irrigation protocol with successful management of post-operative pain of root canal treatment in necrotic permanent mandibular molar teeth with symptomatic apical periodontitis. Analgesic intake was not necessary when machine-assisted agitation irrigation was used as a final step irrigation protocol for endodontic treatment of necrotic multirooted teeth with symptomatic apical periodontitis.

Moreover, the incidence and intensity of post-operative pain decreased with time regardless the final irrigation protocol used. Furthermore, adding the XP-Endo Finisher or ultrasonic irrigation compared to conventional irrigation protocol had no negative influence on post-operative swelling.

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