

## The Effect of Final Irrigation Agitation Techniques on Postoperative Pain after Single Visit Root Canal Treatment of Symptomatic Irreversible Pulpitis: A Randomised Clinical Trial

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### ABSTRACT

**Objective:** To evaluate the degree of postoperative pain and rate of analgesic intake in patients with symptomatic irreversible pulpitis in mandibular first molar teeth at 6 h, 12 h, 24 h, 48 h, and 72 h after using different irrigation activation techniques in single-visit endodontic treatment.

**Methods:** A total of 78 patients with symptomatic irreversible pulpitis with no signs of periapical pathology were randomly divided into 3 groups according to the final irrigation activation technique; Group XP-endo Finisher, Group Ultra X ultrasonic device, and Group side-vented needle. The teeth underwent standardised single-visit root canal treatment procedures using 2.5% sodium hypochlorite for irrigation. Each patient was given a chart to record postoperative pain at 6, 12, 24, 48 and 72 hours intervals. Ibuprofen, 400 mg tablets, was prescribed to be taken when the pain was unbearable. The incidence and number of analgesic tablets taken were recorded. Data were analysed using a Kruskal-Wallis test followed by a pairwise Mann-Whitney U test with Bonferroni correction for intergroup comparisons and Freidman's test followed by Dunn's post hoc test for intragroup comparisons.

**Results:** No statistically significant difference was found between all groups regarding the incidence and intensity of pain at different time intervals ( $p > 0.05$ ). There was no significant difference in analgesic intake between different groups, with most cases in all groups not taking analgesics ( $p > 0.05$ ).

**Conclusion:** Adding XP-endo Finisher or passive ultrasonic irrigation to the final irrigation protocol in single-visit endodontic treatment had no significant effect on postoperative pain or analgesic intake.

**Keywords:** Postoperative pain, pulpitis, root canal therapy, sodium hypochlorite, ultrasonic

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### HIGHLIGHTS

- PUI or XPF is considered reliable as a final step irrigation protocol with a normal range of postoperative pain.
- Adding XPF or PUI to the final irrigation protocol in a single-visit endodontic treatment had no significant effect on postoperative pain or analgesic intake.
- The incidence of postoperative pain decreased with time, regardless of the final irrigation protocol.

### INTRODUCTION

Irrigation plays a major role in the disinfection of the root canal system, thereby increasing the chance of endodontic treatment success (1). It

also removes dentine chips and the smear layer caused by instrumentation of the root canal walls (2). Sodium hypochlorite (NaOCl) is the most commonly used endodontic irrigating solution due to

its ability to dissolve organic tissues and disinfection capability (3). In addition, NaOCl can dissolve vital and necrotic tissues (4).

Delivering the irrigant using traditional syringes results in ineffective disinfection in areas such as the isthmus and apical regions of the root canal (5). Irrigant delivery is primarily determined by the needle's placement depth, which is determined by the needle's diameter. The irrigant can only progress 1 mm beyond the needle tip, and thus its effect is relatively weak (6). Therefore, different irrigation activation techniques have been developed to improve irrigant penetration and efficiency (6).

Ultrasonic irrigation was introduced as an irrigant activation technique in the final phase of root canal treatment after instrumentation. According to the manufacturer, passive ultrasonic activation using Ultra X (Eighteenth Medical Technology Co. Ltd., Jiangsu, China) improves the elimination of microorganisms and the smear layer. Furthermore, passive ultrasonic irrigation creates high-speed flow during canal irrigation, which results in more debris elimination and better reach of the irrigant to the accessory canals (7). In addition, the ultrasonic tip moves freely in the canal without causing dentine injuries or related complications (7).

The XP-endo Finisher (XPF) (FKG Dentaire, La Chaux-de-Fonds, Switzerland) was introduced to the final root canal irrigation protocol to enhance the cleaning efficacy by removing hard tissue debris and smear layer (8). The XPF has a small core size with improved flexibility and a unique characteristic ability to change its shape inside the root canal (9). Therefore, it allows the file to adapt to its three-dimensional anatomy and clean the inaccessible irregularities whilst respecting the original root canal anatomy (10, 11).

There is insufficient data on the efficacy of adding XPF or passive ultrasonic irrigation (PUI) to the final irrigation protocol on postoperative pain after single-visit endodontic treatment in cases with symptomatic irreversible pulpitis. Therefore, this study aimed to evaluate postoperative pain in terms of incidence and intensity after single-visit endodontic treatment using PUI or XPF in the final irrigation protocol in a randomised clinical trial. The null hypothesis was that no significant difference would exist among the tested groups.

## MATERIALS AND METHODS

### Sample Size

The university ethics committee approved the clinical research under the code FUE.REC (25/12-2019). A sample size of 60 (20 per group) was sufficient to detect an effect size of 0.2, a power of 80%, and a significance level of 5%. The number of samples was increased to 66 to allow for the non-parametric distribution of the outcome variable. There was a further increase of 25% to allow for Least Frequently Used (LFU), so a total sample size of 78 (26 per group) was needed to compensate for possible losses during follow-up (Fig. 1). The sample size was calculated using the G\*Power programme.

### Patient Selection Criteria

Systemically healthy patients with mandibular first molar teeth diagnosed with symptomatic irreversible pulpitis were

included in the study. The diagnosis was based on clinical findings, including pain degree and its characteristics, intensity, duration, frequency, and provoking and relieving factors. An intraoral clinical examination was carried out using a diagnostic mirror and probe. The presence of extensive caries or large restoration was identified. Periapical radiographs were obtained to evaluate tooth structure, deep caries proximity, previous defective restorations, periapical status, and periodontal support.

The exclusion criteria included patients suffering from any significant systemic disorder; patients incapable of providing informed self-consent or below the age of 18; patients over the age of 45, patients having a mandibular first molar with periapical involvement; patients who were allergic to local anaesthetic agents; and patients who took medications (antibiotics, analgesics, or anti-inflammatory drugs) seven days before the procedure. All participants were informed about the study, and their consent was obtained before treatment. A list for random participant assignment was generated by a randomisation software (<http://www.random.org/>). This randomisation was performed by an operator not involved in the study.

An ethyl chloride cold pulp tester was used to detect the affected tooth's response and the adjacent and contralateral teeth (used as control) to ensure that the tester was working properly and that the participants responded adequately. The preoperative pain level was assessed by giving each participant a pain scale chart (VRS) to record the pain level before any intervention. Radiographic examination was performed with a periapical film (Dental film, speed D, size 2, Kodak Co., NY, USA) using the parallel technique to detect the presence of any periapical radiolucency, widening of the periodontal membrane space, recurrent caries below large restoration, or deep caries approximating the pulp. Clinical and radiographic data of each patient were attached to their clinical notes and analysed by 2 experienced endodontists.

### Clinical Steps

All root canal procedures were performed in a single visit by an experienced clinician. An inferior alveolar nerve block (4% Mepivacaine HCl & 1:100,000 Adrenaline) was used to anaesthetise the tooth. After the removal of decay and restoration buildup, a rubber dam (Sanctuary Dental Dam Systems, Ipoh, Malaysia) was applied, and an access cavity was performed using a size 2 round bur (Dentsply Maillefer, Ballaigues, Switzerland) and an Endo-Z bur (Dentsply Maillefer). Canal patency was confirmed with a 15 K file (Dentsply Maillefer). The working length, set at 1 mm short of the radiographic apex, was determined using an electronic apex locator (Root ZX, J. Morita, Tokyo, Japan), and then confirmed radiographically. ProTaper Next (PTN) instruments (Dentsply Maillefer) were used to mechanically prepare the root canals in a crown-down technique using an endodontic motor (X-Smart, Dentsply Maillefer, Ballaigues, Switzerland) with an adjusted torque of 2 Ncm and speed of 300 rpm according to the manufacturer's instructions. The PTN rotary system was used as follows: X1, X2, followed by X3 as the master apical file. All files were used in a pecking motion to the full working

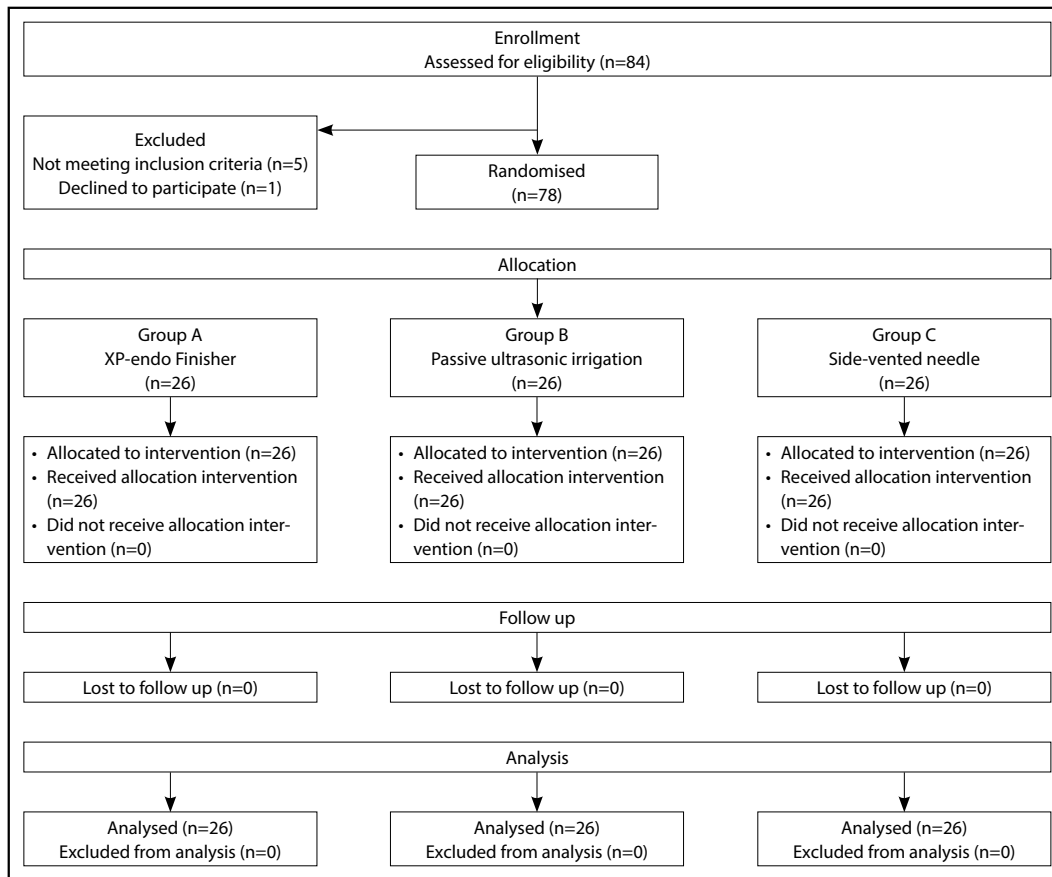


Figure 1. Consort flow diagram

length. Irrigation of the root canals was performed using 3 ml of 2.5% NaOCl solution delivered by a plastic disposable syringe (S-S disposable syringe, Sung Shim Medical, Bucheon, Korea) with a 30-gauge needle (NaviTip, Ultradent, UT, USA) after each file for 1 minute. Then, it was introduced passively without forcefully dispensing the irrigant and placed 2 mm from the working length. Participants were divided into three groups according to the final irrigation protocol.

#### Group XP-endo Finisher (n=26)

After 3 ml of 2.5% NaOCl solution was passively introduced in each canal, XPF (size 25 taper zero) was used while being installed in an endodontic motor (X-Smart). XPF was used according to the manufacturer's instructions, initially cooled by Endo-frost spray (Roeko, Coltene Whaledent, Langenau, Germany), then removed from the tube in rotational mode with lateral movement to ensure the file remained straight. Next, the file was inserted into the canal while still being straight, then turned on at 800 rpm and torque set to 1 Ncm in 7–8 mm vertical lengthwise movement to the full working length for 1 minute in each canal.

#### Group Passive Ultrasonic Irrigation (n=26)

After 3 ml of 2.5% NaOCl solution was passively introduced in each canal, Ultra X at the maximum power of 45 kHz with flexible and soft silver tip (21 mm, size 20 taper 2) was fitted passively reaching 2 mm short from the working length in short vertical strokes. The irrigation solution was activated for 1 minute in each canal.

#### Group Side-vented Needle (Control Group) (n=26)

In the control group, 3 ml of 2.5% NaOCl solution was passively introduced in each canal by a side-vented needle that was passively placed at 2 mm short from the working length and was constantly pulsed in 1–2 mm vertical strokes for 1 minute in each canal.

Irrigant replenishment and suction were performed in all groups to remove loose debris. Afterwards, agitation and replenishment cycles were repeated twice. The canals were finally flushed with 3 ml of saline for 1 minute. Sterile paper points (Meta Biomed, Cheongju City, Korea) that correspond to the master cone size were used to dry the canals. Then, a master cone fit radiograph was taken with the gutta-percha master cone that corresponds to the size of the master apical file (ProTaper® Next Gutta-Percha Points X3, Dentsply Maillefer, Ballaigues, Switzerland) fitted to the full length of the canal to confirm the appropriate length and preparation. After mixing the sealer (AdSeal, Meta Biomed) to obtain a homogenous mix, it was applied into the root canal using a master apical file in an up and down motion circumferentially to have a uniform coat of sealer. The canals were then obturated using a modified single-cone technique. When the canal was completely obturated, it was sealed off using a hot instrument. After obturation, the access cavity was sealed with temporary filling material of sufficient thickness. A postoperative radiograph was taken, and each patient was instructed to take 400 mg of ibuprofen every 6 hours in case of severe pain.

**TABLE 1.** Summary of statistics of demographic data

Parameter	XP-endo Finisher irrigation		Passive ultrasonic		Side-vented needle		p
	n	%	n	%	n	%	
Age (Mean±SD)	30.42±5.00		29.75±5.24		28.42±5.18		0.629 ns
Sex							
Male	13	50.0	13	50.0	15	57.7	0.895 ns
Female	13	50.0	13	50.0	11	42.3	

n: Number, SD: Standard deviation, ns: Non-significance

**TABLE 2.** Frequencies and percentages of (VRS) values

Time	Pain level	Irrigation protocol					
		XP-endo Finisher		Passive ultrasonic irrigation		Side-vented needle	
		n	%	n	%	n	%
6 hours	No discomfort	12	46.2	16	61.5	10	38.5
	Mild	12	46.2	8	30.8	10	38.5
	Moderate	2	7.7	2	7.7	4	15.4
	Severe	0	0.0	0	0.0	2	7.7
12 hours	No discomfort	14	53.8	18	69.2	14	53.8
	Mild	10	38.5	6	23.1	6	23.1
	Moderate	2	7.7	2	7.7	6	23.1
	Severe	0	0.0	0	0.0	0	0.0
24 hours	No discomfort	20	76.9	24	92.3	18	69.2
	Mild	6	23.1	2	7.7	8	30.8
	Moderate	0	0.0	0	0.0	0	0.0
	Severe	0	0.0	0	0.0	0	0.0
48 hours	No discomfort	26	100.0	26	100.0	24	92.3
	Mild	0	0.0	0	0.0	2	7.7
	Moderate	0	0.0	0	0.0	0	0.0
	Severe	0	0.0	0	0.0	0	0.0
72 hours	No discomfort	26	100.0	26	100.0	26	100.0
	Mild	0	0.0	0	0.0	0	0.0
	Moderate	0	0.0	0	0.0	0	0.0
	Severe	0	0.0	0	0.0	0	0.0

VRS: Verbal rating scale, n: Number

### Postoperative Pain Evaluation

Patients were informed about the possible development of pain. Postoperative pain was assessed using a VRS 6, 12, 24, 48, and 72 hours after completion of root canal treatment. The VRS consisted of a four-step pain scale: no discomfort, mild (recognisable, not discomforting), moderate (discomforting, but bearable), and severe (considerable discomfort, difficult to bear) (Muysoms et al., 2016 (12)). Each participant was given a chart to record postoperative pain and the intake of any analgesics.

### Statistical Analysis

Categorical data were presented as frequencies and percentages and were analysed using the Chi-square test. Numerical data of age was tested and represented by mean and standard deviation values and were analysed using an independent t-test. Ordinal data were presented as frequencies and

percentages. They were analysed using the Kruskal-Wallis test followed by a pairwise Mann-Whitney U test with Bonferroni correction for intergroup comparisons and Freidman's test followed by Cunn's post hoc test for intragroup comparisons. The significance level was set at  $p \leq 0.05$  within all tests.

### RESULTS

A summary of demographic data is presented in Table 1. Analysis showed that demographic variables such as gender and age were similarly distributed among the experimental groups ( $p > 0.05$ ). Furthermore, no significant difference was noted among the tested groups regarding both parameters.

Regarding postoperative pain, as presented in Table 2, the difference in pain incidence and intensity among the three groups at all intervals was insignificant. In addition, there was

**TABLE 3.** Frequencies and percentages of postoperative analgesic intake

Time	Pain level	Irrigation protocol					
		XP-endo Finisher		Passive ultrasonic irrigation		Side-vented needle	
		n	%	n	%	n	%
6 hours	None	22	84.6	24	92.3	18	69.2
	Once	4	15.4	2	7.7	8	30.8
	Twice	0	0.0	0	0.0	0	0.0
	More than twice	0	0.0	0	0.0	0	0.0
12 hours	None	22	84.6	24	92.3	20	76.9
	Once	4	15.4	2	7.7	6	23.1
	Twice	0	0.0	0	0.0	0	0.0
	More than twice	0	0.0	0	0.0	0	0.0
24 hours	None	24	92.3	24	92.3	24	92.3
	Once	2	7.7	2	7.7	2	7.7
	Twice	0	0.0	0	0.0	0	0.0
	More than twice	0	0.0	0	0.0	0	0.0
48 hours	None	26	100.0	26	100.0	26	100.0
	Once	0	0.0	0	0.0	0	0.0
	Twice	0	0.0	0	0.0	0	0.0
	More than twice	0	0.0	0	0.0	0	0.0
72 hours	None	26	100.0	26	100.0	26	100.0
	Once	0	0.0	0	0.0	0	0.0
	Twice	0	0.0	0	0.0	0	0.0
	More than twice	0	0.0	0	0.0	0	0.0

n: Number, ns: Non-significance

no significant difference between the groups regarding postoperative analgesic intake, with most of the cases not taking analgesics, as shown in Table 3.

**DISCUSSION**

Irrigant and debris extrusion during endodontic procedures is considered one of the main causes of postoperative pain (13). Irrigation technique impacts the amount of irrigation and debris extrusion apically (13). Thus, any irrigation delivery system that reduces the apical extrusion of debris and irrigant into periapical tissues will help decrease postoperative pain (13). The null hypothesis was that there was no difference in postoperative pain or analgesic intake after using two different activation techniques in patients with symptomatic irreversible pulpitis in single-visit endodontic treatment. Based on the findings of this study, the null hypothesis was accepted.

All endodontic treatments in this study were performed in a single visit to avoid contamination or bacterial regrowth in the root canal system. However, pain may occur if the treatment is administered over multiple visits. (14–16). Additionally, according to multiple systemic reviews and meta-analyses, patients reported a significantly lower degree of pain after receiving single-visit root canal treatment than those who received root canal treatment conducted over multiple visits (17–19).

The use of the PTN rotary system was based on the fact that it gives maximum safety during canal instrumentation, has a very high durability and resistance to fracture, a low chance of transportation, and causes the least amount of apical ex-

trusion of debris (20–23). As an irrigation solution, 2.5% NaOCl was used between every subsequent file. Previous studies showed it could reduce intracanal microbial infection and maintain the tissue dissolution capacity with less cytotoxic action than 5.25% NaOCl (24, 25).

The verbal rating scale (VRS) is most commonly used to evaluate pain severity and relief (26). It was reported to be easily understood, independent of language, reproducible, and does not require patients to be literate (27, 28). Previous studies stated that variables such as age and gender have a role in postoperative pain (29, 30). However, in our study, the analysis of these variables showed similar distributions between the three groups. In addition, p-values for age and gender showed suitable randomisation of the subjects. Therefore, the effect of these variables was ignored in accordance with previous studies (31–33).

In this study, no significant difference was detected among the three groups regarding the incidence and severity of postoperative pain. However, the PUI group showed the lowest incidence of postoperative pain and the lowest need for analgesic administration, followed by the XPF group. XPF is designed to reach spaces and aspects in the root canal system that were not shaped using either rotary or reciprocating techniques (34, 35). Leoni et al. (36) proved the ability of XPF to reach the inaccessible areas in the root canal system, which provides an enhanced cleansing action and smear layer removal. This ability might be attributed to its highly flexible alloy, small core size and zero taper. This unique characteristic allows the file to expand its reach while rotating. The file is straight at room temperature

(the martensitic phase). When introduced into the root canal, the file's shape and phase change to adapt to the three-dimensional root canal anatomy, gain accessibility to the root canal irregularities, and remove debris from the root canal system (37).

The amount of irrigant and debris extruded could initiate chemical irritation of periapical tissues, thereby causing postoperative pain. PUI induces small, intense, and circular fluid movement around the instruments, causing movement of the irrigating solution inside the root canal in the cervical direction and thereby reducing the amount of irrigant and debris extrusion to the periapical region (38, 39). These findings are in accordance with Živković et al. (8), Bao et al. (40), Sanabria-Livić et al. (41) and Elnaghy et al. (9) in addition to Alves et al. 2016 (42) and Azim et al. (43) who demonstrated that XPF shows high efficiency in reducing bacterial counts and increasing disinfection. Also, Saryilmaz and Keskin (37) showed that using PUI and XPF did not increase the risk of debris extrusion. However, this does not coincide with the results of Hizarci et al. (13), who showed that PUI and XPF produced a greater amount of debris extrusion than conventional irrigation, causing periapical tissue inflammation and postoperative pain (8). In addition, Hanafy et al. (34) found that adding XPF to the final irrigation protocol resulted in more postoperative pain. This effect was assumed to result from the apical extrusion of debris during instrumentation.

Among each group, there was a significant difference in pain status between different follow-up intervals ( $p < 0.001$ ). The postoperative pain intensity was higher at 6- and 12-hour time intervals. Then it decreased along the following time intervals within each group. The mean pain scores decreased to their lowest at 72 hours. 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 hours, followed by an increase in the release of inflammatory mediators and neuropeptides (44). The proliferative process begins after 48 hours, which is characterised by a decrease in the PMNs population, in addition to the macrophages beginning to enter the wound site (44). Furthermore, comparable findings were detected in a systematic review conducted by Pak and White (2011) (45), in which pain incidence was 40% in the first 24 hours and then sharply declined after chemo-mechanical preparation over the first two days.

In the present study, the incidence of analgesic intake has also been assessed as a secondary outcome. The frequency of analgesics taken by patients decreased over time in each tested group. There was a significant difference between groups, with the highest mean value recorded at 6 hours for all groups, while no pain was recorded after 48 hours in the PUI and XPF groups. No pain was recorded after 72 hours in the side-vented needle group. These findings might be because of the positive pressure exerted by the needle, which leads to greater hydraulic pressure that may result in postoperative pain (43, 46).

## CONCLUSION

Within the limitations of this study, it can be concluded that the addition of XPF or PUI to the conventional irrigation protocol does not increase postoperative pain in single-visit endodontic treatment.

## Disclosures

**Conflict of interest:** The authors deny any conflict of interest.

**Ethics Committee Approval:** This study was approved by The Future University in Egypt Ethics Committee (Date: 25/12/2019, Number: FUE.REC (25/12-2019)).

**Peer-review:** Externally peer-reviewed.

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