

The Impact of Different Final Irrigation Activation Techniques on Postoperative Pain in Single Rooted Mandibular Premolar Teeth: A Randomised Clinical Trial

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ABSTRACT

Objective: The trial was conducted to assess the impact of passive ultrasonic irrigation, XP endo finisher, AF max file, and manual dynamic agitation on postoperative pain and analgesic consumption at 6 h., 12 h., 24 h., 48 h., 72 h., and a week later on single-rooted lower premolar teeth with acute irreversible pulpitis and apical periodontitis.

Methods: A total of 64 eligible patients were randomized into four equal groups (n=16 per group). Considering the irrigation activation approach, participants were separated into four groups as follows: passive ultrasonic irrigation, XP-endo Finisher, Fanta AF max file, and manual dynamic agitation. Following the root canal procedure, the intensity of postoperative discomfort was measured by a verbal rating scale. The frequency and quantity of analgesics used were recorded. The data were analysed by using analysis of variance (ANOVA) and chi square tests ($p=0.05$).

Results: There was a statistically significant difference between the percentage of preoperative and postoperative pain at most of the follow-up period in each group ($p<0.001$). A significant difference in the postoperative pain level and analgesic consumption was found among groups and most of the time intervals ($p<0.05$). The excessive percentage of postoperative pain and analgesic intake was found in the MDA group, followed by the Max file and the XPF, while the lowest postoperative pain and analgesic intake were related to the PUI group. There was significant difference between the PUI and MDA groups in the degree of pain severity and increase in analgesic intake at 72 h ($p<0.05$). Regarding the percentage of swelling, there was a statistically notable difference between groups after 24 h time intervals ($p<0.05$).

Conclusion: Minimal postoperative pain and minimal analgesic intake were significantly accompanied by passive ultrasonic irrigation.

Keywords: Fanta AF max file, passive ultrasonic irrigation, postoperative pain, XP-endo Finisher

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HIGHLIGHTS

- PUI has the lowest potential for severe postoperative pain or swelling to occur, followed by XPF or Fanta AF Max File and MDA.
- The incidence of postoperative pain and analgesic intake declines by time, regardless of the final activation irrigation protocol.

INTRODUCTION

Irrigation played a critical role in enhancing the cleaning efficacy of the root canal system (1). The portions of the canal walls that were inaccessible to mechanical instrumentation

can only be affected by irrigation (2). The effectiveness of an irrigation delivery system's mechanical debridement depends on its capacity to supply the irrigant to the apical and uninstrumented areas of the canal space, such

as the fins, deltas, isthmus, and apical ramifications, in order to generate a powerful enough current to move the debris away from the canal walls (3). There may be more bacteria that harbored and penetrated deeply into dentinal tubules because the apical area of the tubules had fewer and smaller dentinal tubules (4). Even when there was sufficient apical sealing, bacteria arranged in biofilms within lateral canal result in a lateral or apical periodontal lesion (5). As the root was enclosed by the bone socket during *in vivo* cleaning and shaping (6). During irrigant delivery, the canal's closed-end behavior caused gas entrainment at its closed end, creating a vapor lock effect. Additionally, gas entrapment in the apical section of the canal caused by apical vapor lock makes it impossible for irrigant solutions to chemically reach those locations, increasing the likelihood of failures and relapses the canal behaved as a closed-end channel which resulted in gas entrainment at its closed end (7). Sodium hypochlorite (NaOCl) was the most popular endodontic irrigating solution because it was effective in disinfecting the region and breaking down organic tissues, causing hydrolysis that released ammonia and carbon dioxide. In the apical section of the root canal, this creates tiny gas bubbles that eventually combine to produce a large apical vapor bubble (8). The existence of an apical "vapor lock" can significantly impair canal debridement by preventing the root canal system's ability to exchange irrigant optimally when using a syringe and needle during positive pressure irrigation of conventional methods of irrigation (9).

Activated irrigation is a potentially useful technique by increasing the antibacterial, tissue-dissolving efficacy of the irrigants and facilitating their penetration into the inaccessible area of the root canal anatomy (10). Manual dynamic agitation (MDA), one of the irrigation activation method, was reported to be economical for cleaning the root canal walls. It involved repeatedly placing a cone-shaped gutta percha that was well-fitting to the working length (WL) to activate the irrigant hydrodynamically with light vertical movements (11). Passive ultrasonic irrigation (PUI) was established to boost the efficacy of canal disinfection through passive movement up and down (12). files alone (13). Two novel techniques for irrigant activation were investigated in the present trial: the XP endo finisher file (XPF) (FKG Dentaire, La Chaux-de-Fonds, Switzerland) and Fanta AF Max file (AF Max) (Fanta Shanghai Dental Materials Co., Ltd., China) (9). The XPF had a small core size with ISO size #25 without taper. It was manufactured with a proprietary NiTi alloy (Martensite-Austenite Electropolish-FleX) that claimed to have a high flexibility. According to reports (13), when the file tip is squeezed or 100 times the size of a matching file, the XPF curved bulb can grow to a diameter of 6 mm. The manufacturer claimed that it was composed of a special alloy that underwent various temperature reactions. The file was straight (M phase) when it was chilled, but it changed shape to the A-phase when it came into contact with body temperature. This allowed the instrument to expand to a diameter of 6 mm, or 100 times the size of an equivalent size file when rotated (14). In order to improve cleaning effectiveness by eliminating smear layer and hard tissue debris without endangering dentine, XPF was added to the final root canal irrigation routine (15).

Another approach for irrigant activation was the Fanta AF Max file. It was made of flexible NiTi wire with size ISO #25, 30 taper 1% and squared cross section. With its distinctive sickle shape, the manufacturer asserted that it was extremely flexible and could contact any canal wall without shaping but just to activate the irrigant and break up the bacterial biofilm within the canal (9).

It was speculated that postoperative discomfort may be caused by bacteria found in the root canal system (16). Clinically, postoperative endodontic discomfort from root canal therapy has a big impact on treatment results and patient satisfaction. Effectively managing this pain is essential for a number of reasons, including recovery and healing, improving patient satisfaction, attaining favorable endodontic treatment results, and making sure the tooth healed correctly and continued to function. Supplemental anesthetic procedures and treatment with nonsteroidal anti-inflammatory medications were pharmacologic strategies for minimizing postoperative pain. Different activation irrigation techniques and the use of a flexible rotary system during root canal treatment had been employed as non pharmacologic methods to reduce postoperative pain (17, 18). Reducing postoperative pain may reduce the need for prescription drugs, follow-up care, and emergency visits (18). Therefore, for improved patient comfort, it is crucial to know the incidence of postoperative discomfort following root canal therapy (19). However, insufficient data on the efficacy of adding XPF or AF Max File to the final irrigation protocol in association with PUI and MDA on the postoperative discomfort after single visit endodontic treatment of single-rooted lower premolar teeth with acute irreversible pulpitis with apical periodontitis. As a result, the goal of this trial was to evaluate the impact of PUI, XPF, AF Max File, and MDA on the postoperative pain and analgesic consumption at 6 h, 12 h, 24 h, 48 h, 72 hours, and a week later following the endodontic procedure of single-rooted lower premolar teeth with acute irreversible pulpitis with apical periodontitis. The null hypothesis would be no discernible difference between the tested groups on the decreasing effect of the postoperative pain.

MATERIALS AND METHODS

The ethical approval of this randomised clinical trial was obtained in July 2024 under the final code (REC-832/2024). The trial was planned to be a double-blinded, including participants and assessors. The trial was a randomized clinical trial with parallel groups that had the same ratio of allocation. The trial protocol was formally recorded on ClinicalTrials.gov with the ID number NCT06501703 on 15/7/2024. In order to guarantee straightforward and open reporting throughout the study, the CONSORT 2010 standards (Consolidated Standards of Reporting Trials) were followed. The study was conducted in accordance with the Declaration of Helsinki. The outpatient clinic of the faculty of dentistry served as a site for the trial from June to July of 2024. Each participant signed informed consent papers in writing before starting the trial. All of the permission forms were prepared in Arabic for the volunteers' convenience. The goals, advantages, dangers, and expected duration of the experiment were all explained to participants in simple terms.

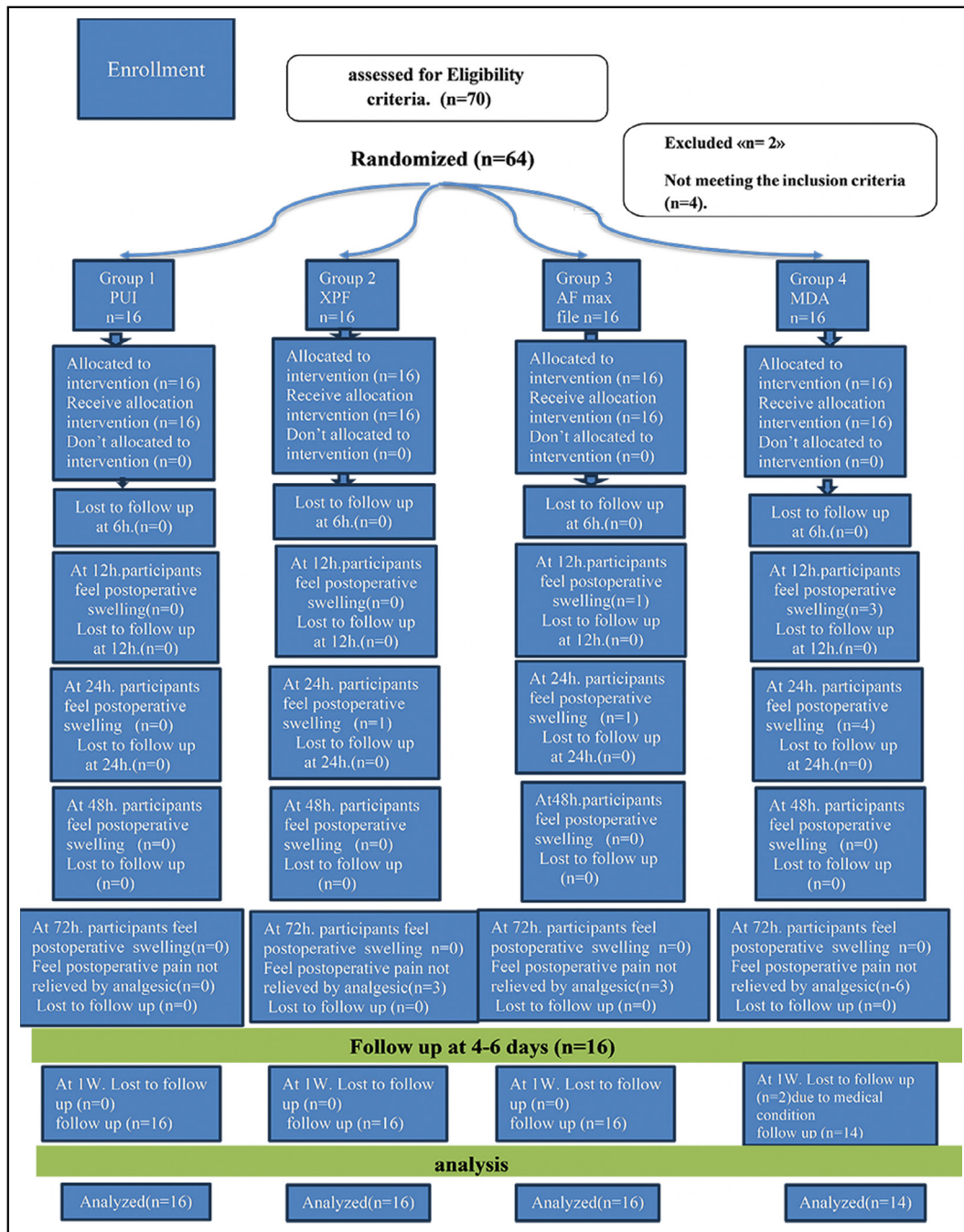


Figure 1. Photograph displayed the flow chart of the postoperative pain of the whole participants in the trial

PUI: Passive ultrasonic irrigation, XPF: XP endo finisher file, MDA: Manual dynamic agitation

Sample Size Calculation

G*Power version 3.1.9.7 was done to assess the sample size. Considering the results of previous research (20, 21), the statistical calculation for gaining sufficient power to run a two-sided statistical test, a power analysis, was created. By using a beta of 0.2 and an alpha level of 0.05, or a power of 80%, and an effect size (d) of 0.55. With 16 samples per group, the expected sample size (n) was 64 to identify whether postoperative discomfort varied throughout groups.

Eligibility Criteria

Seventy-two patients were contributed in the trial. A total of 64 eligible patients were randomized into four equal groups

(n=16 per group), as illustrated in Figure 1. The study comprised sixty-four patients with single-rooted lower premolar teeth with acute irreversible pulpitis and apical periodontitis who were in the age range between 18 and 40 years old. Each patient received root canal treatment in one session. Clinical findings, such as the degree and nature of the pain, its intensity, length, and frequency, and the circumstances that provoked and relieved it, were used for the diagnosis. Intraoral clinical examination had revealed either extensive restoration or a history of significant caries. Digital periapical x-rays were used to assess the following factors: tooth structure, extensive caries, improper fillings, periapical tissue condition, and periodontal support. Whenever the regular x-rays disclosed participants

with doubt of more than one canal, cone beam computed tomography (CBCT) was used to exclude. The inclusion guidelines for individuals' restorable teeth with a normal periodontal score index of less than two were as follows: severe preoperative pain, discomfort response on biting/mastication or percussion but no mobility. Discomfort response on palpation of surrounding tissue but with no intraoral swelling. The inclusion criteria also included patients who stopped medications for the last 12 hours before the procedure. Additionally, the radiograph showed only normal or slight widening in the periodontal ligament space of the affected root. The exclusion criteria included patients with any serious systemic disease, those under the age of eighteen or incapable of giving informed consent, those over forty, those with severe preoperative pain on biting/mastication or percussion, those with a mandibular premolar involving multiple canals or huge periapical pathosis, open apices, periodontal involvement, retreated cases, sinus tract presence, and swelling of surrounding soft tissues; in addition to those, patients who were pregnant and allergic patients with local anesthetic agents (22). By checking the vitality, the positive response of the affected tooth was monitored using an ethyl chloride cold pulp tester, compared with that of the neighboring and contralateral teeth. Each participant was given a pain scale chart of the verbal rating scale (VRS) to record their level of pain prior to the root canal procedure in order to determine their preoperative pain. Each patient's radiographic and clinical data were examined by two skilled endodontists and appended to their clinical notes.

Randomization

After root canal preparation, the clinical trial's assigned participants were randomized according to final irrigation using computer-generated randomization software called Microsoft® Excel. A series of consecutive numbers was generated, and each randomly selected participant was allocated a number in sequence (ID) ranging from "1 to 64" in addition to receiving a second randomly assigned number that corresponded to either group 1, 2, 3, or 4. Sequential numbering of the participants was kept in an opaque, sealed envelope (SNOSE) technique. These sealed envelopes were opened at the time of beginning the clinical procedures. At the time of group allocation for the present study, the operator was not blind by the assigned activation irrigation technique (intervention) that received by the participants.

Clinical Procedure

The root canal treatment was completed in one session by single endodontist (). The tooth was anesthetized using a mental nerve block (4% Mepivacaine HCl & 1:100,000 adrenaline) and an intraligamentary technique of at least 0.2 ml of the anesthetic solution was injected directly in the periodontal space mesial and distal to the anesthetized tooth. Following the removal of decay or restorations, an access cavity was opened. Next, a rubber dam was applied (Sanctuary Dental Dam Systems, Ipoh, Malaysia). If the patients still complained of pain after giving the anesthesia, around of 0.2 mL of anesthetic solution was injected with adequate pressure to attain intra pulpal anesthesia. Using a 15 K file, canal patency was verified (Dentsply Maillefer). Regarding the electronic apex loca-

tor (Root ZX, J. Morita, Tokyo, Japan), the W.L. was established at the apical constriction and then radiographically verified. Following the manufacturer's recommendations, the root canals was instrumented through the Protaper Next rotary system (PTN) (Dentsply Maillefer) utilizing an endodontic motor (X Smart, Dentsply Maillefer, Ballaigues, Switzerland) with an adapted torque of 2 Ncm and speed of 300 rpm. The rotary system X4 (40/6%) was worked as the master apical file until it reached the full W.L. Using a 30-gauge side-ventilated needle (NaviTip, Ultradent, UT, USA) that was placed 2 mm coronal from the W.L. to deliver the irrigating solution. A 2.5% NaOCl solution was injected at a flow rate of 3 ml per minute following each file. The volume of the irrigation delivery during instrumentation was 12 ml. The final active irrigation was dispensed at a flow rate of 5 mL/minute following endodontic preparation. The time for active irrigation had been standardized in every group to be one minute. The cycles of agitation and replenishment were carried out twice. Based on the final activation irrigation protocol, participants were separated into four groups as follows: PUI, XPF, AF max file, MDA.

PUI

Following the passive introduction of 5 ml of 2.5% NaOCl solution, an Ultra X device was fitted with a tip of 21 mm and size #20/0.02 taper at a maximum power of 45 kHz for one minute. The tip was adapted to reach short of the WL by 2 mm in vertical movements (22).

XPF

Following the passive introduction of 5 ml of 2.5% NaOCl solution. XPF with a size #25 and 0% taper was used while being positioned in an endodontic motor (X-Smart) following the manufacturer's recommendations. After being chilled with Endo-ice spray (Roeko, ColteneWhaledent, Langenau, Germany), it was rotated out of the tube while moving laterally to keep the file in a straight way. Subsequently, XPF was positioned inside each canal while still being straight and allowed to work at 1000 rpm and torque set to 1 Ncm in 7–8 mm for one minute in longitudinal movements to the entire W.L (22).

AF Max File

After 5 ml of 2.5% NaOCl irrigating solution was placed. The irrigant was activated with AF Max file installed on the X smart motor device with an 800–1000 rpm speed and 1 N/cm torque in accordance with the manufacturer's recommendations. The file was allowed to move on gradual, up-and-down movements in the vertical direction for one minute till it reached the adjusted W.L (9).

MDA

5 ml of 2.5% sodium hypochlorite was passively introduced into the canal. A manual activation had been performed in a coronal apical movement for one minute using a cone-shaped gutta percha X4 # (40/6%). Hundred strokes as an average rate per minute had been used for the sporadic vertical gutta-percha. By choosing a cone-shaped gutta percha cone that was equivalent to the size and taper of canal preparation, it was proved that air inside the canal apically was dislodged by the cone when it was introduced to W. L (21). For all groups, 5 ml

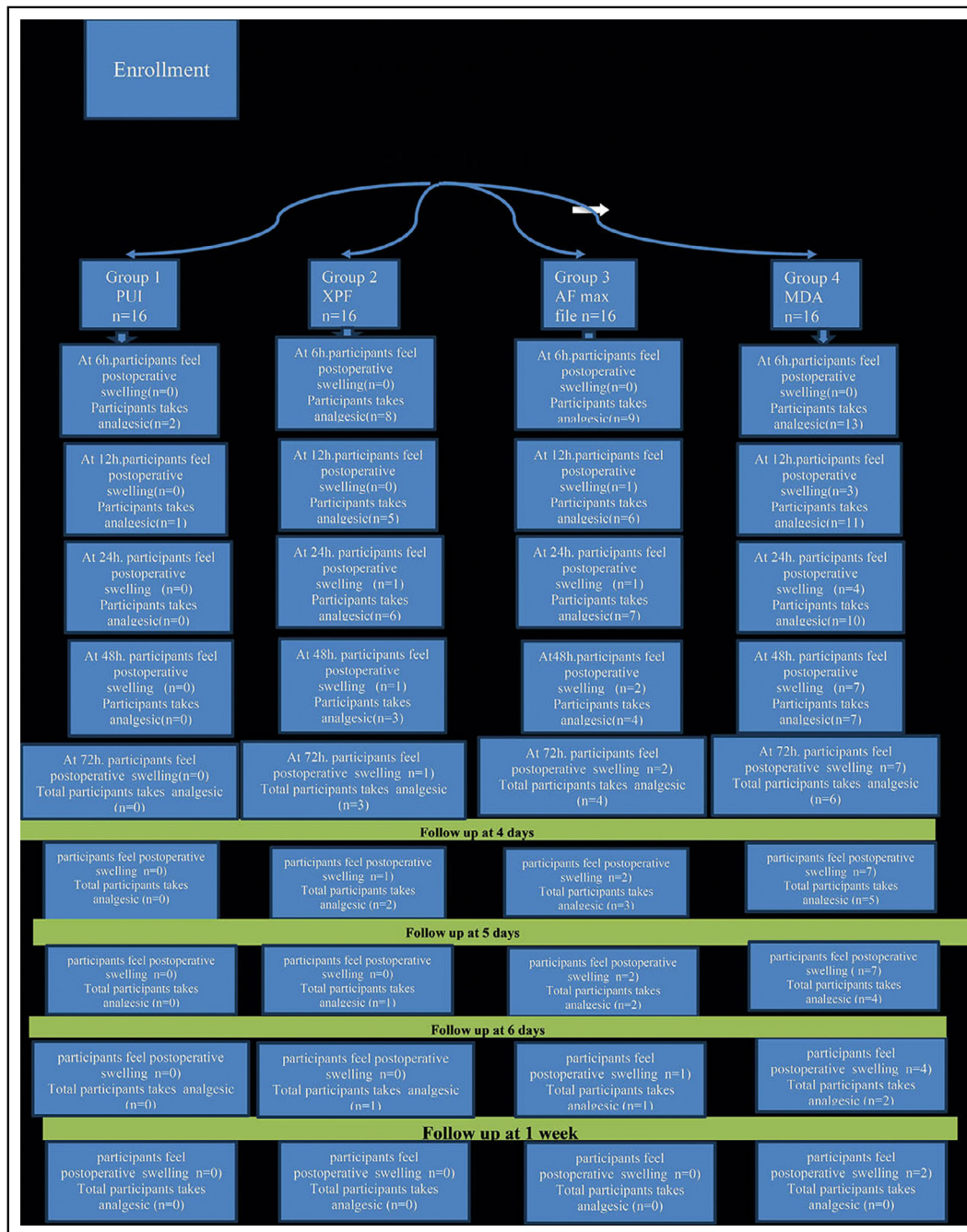


Figure 2. Photograph displayed the flow chart of the swelling and analgesic use of the whole participants in the trial

PUI: Passive ultrasonic irrigation, XPF: XP endo finisher file, MDA: Manual dynamic agitation

of sterile saline was transported into the canals for one minute to cancel out the carryover effect of NaOCl. After that, 2 ml of 17% ethylene diamine tetraacetic acid (EDTA) solution was passively injected in every group for one minute for smear layer removal. Lastly, 5 ml of sterile saline was delivered for one minute. The canals were dried using aseptic paper points size #40 (Meta Biomed, Cheongju City, Korea). Then, a radiograph was taken using ProTaper® Next Gutta-Percha Points X4# (40/6%) as a master cone. After that, the canals were sealed using the lateral compaction technique. A thick glass ionomer (GI; KetacTM Molar, 3M Deutschland GmbH) was temporarily filled in the access cavity for all groups. An intraoral periapical radiograph was done immediately following root canal obtu-

ration by a Carestream RVG 5200 digital imaging system (Carestream Health Inc.). Every participant was instructed to return to the doctor for taking analgesics (ibuprofen 400 mg every 8 hours) to relieve the pain if needed and if severe pain persisted even after taking the prescribed analgesic or swelling appeared. At this point, similar to other patients in the trial, these patients were assessed again at 24, 48, and 72 hours and continued till the seventh day.

Post Operative Evaluation

The possibility of pain developing was explained to patients. After the root canal procedure was finished, postoperative pain was recorded through the VRS at 6h., 12h., 24h., 48h., and 72

TABLE 1. Group comparison based on demographic information

Demographic data	Activation irrigation protocol				Test value	p
	PUI	XPF	Max Fanta	MDA		
Age “years”						
Mean±SD	31.61±5.69	32.56±7.16	31.58±6.95	33.16±7.63	1.583	0.486
Range	18–40	18–40	18–40	18–40		
Sex, n (%)						
Male	8 (50.0)	7 (43.8)	8 (50.0)	9 (56.3)	2.558	0.681
Female	8 (50.0)	9 (56.3)	8 (50.0)	7 (43.8)		

Using: One way Analysis of Variance test was performed for Mean±SD. Using: χ^2 : Chi-square test for Number (%). p-value >0.05 is insignificant; *: p-value <0.05 is significant, **: p-value <0.001 is highly significant. PUI: Passive ultrasonic irrigation, XPF: XP endo finisher file, MDA: Manual dynamic agitation, SD: Standard deviation

hours and following one week. The VRS was a pain scale with pain scores (23) of none at all; the patient reported no discomfort. Mild (noticeable but not uncomfortable). Moderate (uncomfortable but manageable). Severe (significant discomfort that was difficult to tolerate). Every participant received a chart to document their level of discomfort following the procedure as well as how often they take analgesics postoperatively.

Statistical Analysis

The recorded data was assessed by statistical software for social sciences, version 26.0 (SPSS Inc., Chicago, Illinois, USA). Mean±standard deviation and ranges were used to represent the parametric distribution of the quantitative data, while the median with interquartile range (IQR) was utilized to represent the non-parametric distributed variables. Numbers and percentages were used to display the qualitative characteristics. Using the Shapiro-Wilk and Kolmogorov-Smirnov tests, data were examined for normality. A one-way analysis of variance (ANOVA) was used. Post hoc tests and Tukey's test were used for multiple comparisons between different variables. The comparison between groups with qualitative data was done by using the Chi-square test, Fisher's exact test, and the McNemar test.

RESULTS

A total of 64 eligible patients were randomized into four equal groups (n=16 per group), as illustrated in Figure 1. Overall, ten participants complained of swelling at 12 h. (PUI=0, XPF=0, Max File=1 and MDA=3) and at 24 h. (PUI=0, XPF=1, Max File=1 and MDA=4). Those patients were given antibiotics (Augmentin 1 gm /12 h/5 days). Twelve participants (PUI=0, XPF=3, Max File=3 and MDA=6) in the trial complained of severe pain at 72 h. even after prescription of analgesics and given more potent dose (ibuprofen 600 mg every 6 hours) as shown in Figure 2. Only two participants in the MDA group did not complete the trial due to medical conditions.

Postoperative Pain

An overview of the demographic statistics was provided in Table 1. The results indicated that age and gender were comparable, with no significant difference ($p>0.05$). A significant difference had been seen between the tested groups with respect to all variables ($p<0.05$). Table 2 showed a significant difference between preoperative and postoperative pain ($p<0.001^{**}$) among groups at most of the time intervals. Table 3 recorded

a significant difference ($p<0.05$) in the incidence of postoperative discomfort across groups at most of the time intervals.

Analgesic Use

Table 4 determined a statistically significant difference ($p<0.05$) in analgesic intake among groups at most of the time intervals. The results showed that the excessive percentage of postoperative pain and analgesic intake had been found in the MDA group, followed by Max File and XPF, while the lowest postoperative pain and analgesic consumption was related to the PUI group. Moreover, no significant difference was found between Max file and XPF ($p>0.05$) in both variables. Postoperative pain peaked at 6 hours post-treatment, followed by a secondary increase on days 4 to 6. By day 7, pain and analgesic intake had diminished significantly across all groups. Table 5 displayed that there was a significant difference ($p<0.05$) between PUI and MDA groups in the persistence of severe pain and increase in analgesic intake at 72 h. The excessive percentage of severe postoperative pain had been observed in the MDA group, while the lowest severity of postoperative pain was related to the PUI group.

Swelling Incidence

Table 6 denoted that there was a significant difference ($p<0.05$) between groups in the percentage of swelling after 24-hour time intervals. The highest percentage of swelling was recorded in the MDA group, followed by Max file and XPF, while the least percentage of swelling was recorded in the PUI group. While there was no significant difference ($p>0.05$) between all-time intervals in each group. All of the participants in the trial stopped using analgesics and complained of no swelling after one week.

DISCUSSION

The purpose of the endodontic procedure was to repair the peri-radicular tissues while providing biomechanical preparation, hermetic sealing, and no unpleasant side effects (24). This current study aimed to assess how various irrigation agitation techniques affected the percentage of postoperative discomfort and the analgesic intake at various time intervals. The null hypothesis was partially rejected as final activation irrigation using the PUI, XPF, AF Max file and MDA impacted the postoperative pain with a significant difference while the XPF, AF Max file affected the postoperative pain without significant difference. Premolar teeth with a single root were chosen because

TABLE 2. Multiple comparison between time intervals according to pain level

Pain level	PUI	XP	Max Fanta	MDA
Preoperative vs. 6h.	<0.001**	<0.001**	<0.001**	<0.001**
Preoperative vs. 12h.	<0.001**	<0.001**	<0.001**	<0.001**
Preoperative vs. 24h.	<0.001**	0.014*	0.006*	<0.001**
Preoperative vs. 48h.	<0.001**	0.206	0.039*	<0.001**
Preoperative vs. 72h.	<0.001**	0.225	0.117	0.011*
Preoperative vs. at 4 days	<0.001**	0.465	0.191	0.050*
Preoperative vs. at 5 days	<0.001**	1.000	0.465	0.225
Preoperative vs. at 6 days	<0.001**	1.000	1.000	0.465
Preoperative vs. at 1 week	<0.001**	1.000	0.859	0.855
6h vs. 12h	0.344	0.511	0.346	0.269
6h vs. 24h	0.154	0.042*	0.211	0.269
6h vs. 48h	<0.001**	0.002*	0.019*	0.091
6h vs. 72 h	<0.001**	<0.001**	<0.001**	0.028*
6h vs. at 4 days	<0.001**	<0.001**	<0.001**	0.005*
6h vs. at 5 days	<0.001**	<0.001**	<0.001**	<0.001**
6h vs. at 6 days	<0.001**	<0.001**	<0.001**	<0.001**
6h vs. at 1 week	1.000	<0.001**	<0.001**	<0.001**
12h vs. 24h	0.762	0.435	0.479	1.000
12h vs. 48h	0.011*	0.025*	0.095	0.911
12h vs. 72 h	0.011*	0.002*	0.007*	0.021*
12h vs. at 4 days	0.011*	<0.001**	0.009*	0.021*
12h vs. at 5 days	0.011*	<0.001**	0.002*	0.004*
12h vs. at 6 days	0.011*	<0.001**	0.002*	<0.001**
12h vs. at 1 week	0.011*	<0.001**	<0.001**	<0.001**
24h vs. 48h	0.050*	0.402	0.682	0.911
24h vs. 72 h	0.050*	0.060	0.123	0.133
24h vs. at 4 days	0.050*	0.055	0.112	0.021*
24h vs. at 5 days	0.050*	0.037*	0.036*	0.004*
24h vs. at 6 days	0.050*	0.014*	0.019*	<0.001**
24h vs. at 1 week	0.050*	0.014*	0.006*	<0.001**
48h vs. 72 h	1.000	0.524	0.335	0.187
48h vs. at 4 days	1.000	0.541	0.313	0.035*
48h vs. at 5 days	1.000	0.446	0.184	0.009*
48h vs. at 6 days	1.000	0.206	0.113	0.004*
48h vs. at 1 week	1.000	0.206	0.039*	<0.001**
72 h vs. at 4 days	1.000	0.272	0.919	0.524
72 h vs. at 5 days	1.000	0.593	0.547	0.256
72 h vs. at 6 days	1.000	0.225	0.347	0.129
72 h vs. at 1 week	1.000	0.225	0.117	0.018*
At 4 days vs. at 5 days	1.000	1.000	0.595	0.683
At 4 days vs. at 6 days	1.000	0.465	0.478	0.392
At 4 days vs. at 1 week	1.000	0.465	0.191	0.072
At 5 days vs. at 6 days	1.000	1.000	1.000	1.000
At 5 days vs. at 1 week	1.000	1.000	0.465	0.272
After 6 days vs. at 1 week	1.000	1.000	1.000	0.525

Using: McNemar test for Number (%). p-value>0.05 is insignificant; *: p-value<0.05 is significant, **: p-value<0.001 is highly significant. PUI: Passive ultrasonic irrigation, MDA: Manual dynamic agitation

of their oval-cross-section roots with intricate canal morphology (25). In order to prevent root canal bacterial regrowth, the whole root canal procedure had been completed in one session (17). The VRS was used to assess the degree of pain, as it was simply understood and repeatable (26). The anesthetic solution's effect begins to wear off after six hours, and post-operative pain peaks between 24 and 48 hours, lasting up to seven days. For these reasons, pain measurements were taken at these intervals (27). The results indicated that the MDA group recorded significantly the highest scores of pain after endodontic therapy, swelling incidence and consumed signif-

icantly the most analgesics, followed by XPF and AF Max file, while the least scores were recorded in the PUI group. These findings might be related to the swaying motion of the irrigant within the root canals caused by PUI, which transported debris in an upward direction and minimized the quantity of debris and irrigant extrusion (22). PUI exerted a higher velocity that led to acoustic streaming and cavitation bubbles to break down organic contaminants and change poisonous inorganic pollutants into less harmful compounds, all of which assisted in removing bacterial biofilm and dentine debris (28). When irrigating the canal, PUI created a rapid flow that increased

TABLE 3. Comparison of groups based on degree of pain

Time	Pain level	Activation Irrigation protocol								x ²	p
		PUI		XPF		Max Fanta		MDA			
		n	%	n	%	n	%	n	%		
Preoperative	Severe	16	100.0	16	100.0	16	100.0	16	100.0	0.000	1.000
At 6hrs.	No discomfort	6	37.5	2	12.5	2	12.5	2	12.5	43.701	<0.001**
	Mild	8	50.0	3	18.8	3	18.8	1	6.3		
	Moderate	2	12.5	9	56.3	7	43.8	0	0.0		
At12hrs.	Severe	0	0.0	2	12.5	4	25.0	13	81.3	24.779	0.003*
	No discomfort	9	56.3	4	25.0	5	31.3	3	18.8		
	Mild	4	25.0	5	31.3	4	25.0	1	6.3		
	Moderate	3	18.8	5	31.3	6	37.5	3	18.8		
At 24hrs.	Severe	0	0.0	2	12.5	1	6.3	9	56.3	19.502	0.021*
	No discomfort	11	68.8	8	50.0	7	43.8	3	18.8		
	Mild	3	18.8	4	25.0	3	18.8	1	6.3		
	Moderate	2	12.5	2	12.5	3	18.8	3	18.8		
At 48hrs.	Severe	0	0.0	2	12.5	3	18.8	9	56.3	25.807	0.002*
	No discomfort	16	100.0	12	75.0	10	62.5	4	25.0		
	Mild	0	0.0	1	6.3	3	18.8	1	6.3		
	Moderate	0	0.0	1	6.3	1	6.3	4	25.0		
At 72hrs.	Severe	0	0.0	2	12.5	3	18.8	7	43.8	10.022	0.124
	No discomfort	16	100.0	13	81.3	13	81.3	9	56.3		
	Mild	0	0.0	0	0.0	0	0.0	0	0.0		
	Moderate	0	0.0	0	0.0	1	6.3	1	6.3		
At day 4	Severe	0	0.0	3	18.8	3	18.8	6	37.5	9.630	0.141
	No discomfort	16	100.0	14	87.5	13	81.3	11	68.8		
	mild	0	0.0	0	0.0	0	0.0	0	0.0		
	moderate	0	0.0	0	0.0	1	6.3	0	0.0		
At day 5	severe	0	0.0	2	12.5	2	12.5	5	31.3	3.678	0.298
	No discomfort	16	100.0	15	93.8	14	87.5	13	81.3		
	mild	0	0.0	0	0.0	0	0.0	0	0.0		
	moderate	0	0.0	0	0.0	0	0.0	0	0.0		
At 6 days	severe	0	0.0	1	6.3	2	12.5	3	18.8	3.847	0.278
	No discomfort	16	100.0	16	100.0	15	93.8	14	87.5		
	mild	0	0.0	0	0.0	0	0.0	0	0.0		
	moderate	0	0.0	0	0.0	0	0.0	0	0.0		
At 1week	severe	0	0.0	0	0.0	1	6.3	2	12.5	0.194	0.979
	No discomfort	16	100.0	16	100.0	16	100.0	14	100.0		
	Mild	0	0.0	0	0.0	0	0.0	0	0.0		
	Moderate	0	0.0	0	0.0	0	0.0	0	0.0		
Chi-square test	Severe	0	0.0	0	0.0	0	0.0	0	0.0		
	x ²	27.386		25.882		29.117		22.009			
	p	<0.001**		<0.001**		<0.001**		<0.001**			

Using: x²: Chi-square test for Number (%). p-value >0.05 is insignificant; ; p-value <0.05 is significant, **: p-value <0.001 is highly significant. PUI: Passive ultrasonic irrigation, XPF: XP endo finisher file, MDA: Manual dynamic agitation

irrigation reach into accessory canals and removed more debris (29). The strongest antibacterial impact occurs when PUI was used in conjunction with NaOCl irrigation. This combined technique increased the cleaning impact by enhancing the exchange of substances in the canal, allowing the irrigating liquid to be heated, and removing dentine debris and the smear layer (30). Placement of the ultrasonic tip at 2 mm before the W.L., which allowed enough room for excessive irrigant activation (31). Additionally, large final apical preparations, such as size 40 taper 6%, could improve irrigant penetration and cleaning effectiveness (32). On the other side, XPF induced more disorganized movement, which could be the cause of apical extrusion (33). These findings aligned with previous re-

search (34) and contradicted with another published research which concluded that the diode laser had the better bacterial elimination and extrusion outcome compared to that of PUI (35). A different study design could be the cause of the discrepancy. The results of this trial indicated that there wasn't any statistically significant discrepancy between AF Max file and XPF. However, the XPF file exhibited a slightly lower frequency of pain following the root canal procedure and a minimal need for analgesics than the AF Max file. This was likely due to XPF file's unique spoon-like shape and unique metallurgy, which scraped the canal walls more effectively (9). These findings matched other published studies (22). At every time point, the postoperative pain that was associated with the MDA group

TABLE 4. Comparison of groups based on how often they take analgesics

Time	Frequency of analgesic intake	Activation Irrigation protocol								x ²	p
		PUI		XPF		Max Fanta		MDA			
		n	%	n	%	n	%	n	%		
At 6hrs.	None	14	87.5	8	50.0	7	43.8	3	18.8	35.979	<0.001**
	Once	2	12.5	6	37.5	5	31.3	0	0.0		
	Twice	0	0.0	1	6.3	1	6.3	3	18.8		
	Three times or more	0	0.0	1	6.3	3	18.8	10	62.5		
At 12 hrs.	None	15	93.8	11	68.8	10	62.5	6	37.5	31.195	<0.001**
	Once	1	6.3	3	18.8	3	18.8	2	12.5		
	Twice	0	0.0	2	12.5	2	12.5	0	0.0		
	Three times or more	0	0.0	0	0.0	1	6.3	9	56.3		
At 24 hrs.	None	16	100.0	10	62.5	9	56.3	6	37.5	23.670	<0.001**
	Once	0	0.0	4	25.0	4	25.0	1	6.3		
	Twice	0	0.0	0	0.0	0	0.0	0	0.0		
	Three times or more	0	0.0	2	12.5	3	18.8	9	56.3		
At 48 hrs.	None	16	100.0	13	81.3	12	75.0	9	56.3	12.667	0.049*
	Once	0	0.0	1	6.3	1	6.3	0	0.0		
	Twice	0	0.0	0	0.0	0	0.0	0	0.0		
	Three times or more	0	0.0	2	12.5	3	18.8	7	43.8		
At 72 hrs.	None	16	100.0	13	81.3	13	81.3	10	62.5	12.013	0.213
	Once	0	0.0	0	0.0	1	6.3	0	0.0		
	Twice	0	0.0	0	0.0	0	0.0	1	6.3		
	Three times or more	0	0.0	3	18.8	3	18.8	5	31.3		
At 4 days	None	16	100.0	14	87.5	13	81.3	11	68.8	9.630	0.141
	Once	0	0.0	0	0.0	0	0.0	0	0.0		
	Twice	0	0.0	0	0.0	1	6.3	0	0.0		
	Three times or more	0	0.0	2	12.5	2	12.5	5	31.3		
At 5 days	None	16	100.0	15	93.8	14	87.5	12	75.0	6.947	0.326
	Once	0	0.0	0	0.0	0	0.0	1	6.3		
	Twice	0	0.0	0	0.0	0	0.0	0	0.0		
	Three times or more	0	0.0	1	6.3	2	12.5	3	18.8		
At 6 days	None	16	100.0	16	100.0	15	93.8	14	87.5	2.167	0.538
	Once	0	0.0	0	0.0	0	0.0	0	0.0		
	Twice	0	0.0	0	0.0	0	0.0	0	0.0		
	Three times or more	0	0.0	1	6.3	1	6.3	2	12.5		
At 1 week	None	16	100.0	16	100.0	16	100.0	14	100.0	0.194	0.978
	Once	0	0.0	0	0.0	0	0.0	0	0.0		
	Twice	0	0.0	0	0.0	0	0.0	0	0.0		
	Three times or more	0	0.0	0	0.0	0	0.0	0	0.0		
Chi-square test	x ²	18.349		17.341		19.508		14.746			
	p	<0.001**		<0.001**		<0.001**		<0.001**			

Using: x²: Chi-square test for Number (%). p-value>0.05 is insignificant; *: p-value<0.05 is significant; **: p-value<0.001 is highly significant.

was considerably higher than the other groups. These results were attributed to the inflammation that results from a significant amount of debris extrusion after many vertical movements in the periapical tissues. These results were in agreement with earlier research (21) and disagreed with another reported research that indicated that MDA can be considered an alternative to PUI, in the case of non-availability of PUI (36). There was a statistically significant difference in the percentage of preoperative and postoperative pain at most of the follow-up period (p<0.001**) in each group. Postoperative pain peaked at 6 hours post-treatment, followed by a secondary increase on days 4 to 6. By day 7, pain and analgesic intake had diminished significantly across all groups. This could be linked to an exacerbation of the inflammatory response within

six hours as PMNs (polymorphonuclear leukocytes) started to infiltrate the periapical area with a subsequent rise in the production of neuropeptides and inflammatory substances. At 48 h., the process for proliferation starts, which was marked by a decrease in PMNs and the presence of macrophages (37). These results were compatible with previously published research (38). In every investigated group, the use of analgesics decreased over time. These findings could be connected to a decrease in postoperative pain level and in accordance with another study (39). Patients who feel less pain are more likely to be able to return to their regular activities without experiencing any discomfort, which will preserve their general dental health and improve their quality of life. In clinical practice, PUI is more effective than other activation irrigation strategies

TABLE 5. Several comparisons between groups based on how frequently analgesics are used

Time	G1 vs. G2	G1 vs. G3	G1 vs. G4	G2 vs. G3	G2 vs. G4	G3 vs. G4
At 6h.	0.131	0.055	<0.001**	0.763	<0.001**	0.009*
At 12h.	0.164	0.172	<0.001**	0.789	0.006*	0.023*
At 24h.	0.025*	0.011*	<0.001**	0.881	0.026*	0.067
At 48h.	0.191	0.102	0.010*	0.887	0.105	0.220
At 72 h.	0.225	0.117	0.025*	0.616	0.388	0.413
At 4 days	0.465	0.191	0.050*	0.595	0.392	0.293
At 5 days	1.000	0.465	0.102	1.000	0.311	0.508
At 6 days	0.975	1.000	0.465	0.493	0.956	1.000
At 1 week	1.000	1.000	0.855	1.000	0.855	0.855

G1: PUI ([Passive ultrasonic irrigation), G2: XP (XP Endo Finisher), G3: Max Fanta, G4: MDA (Manual dynamic Agitation). Using: χ^2 : Chi-square test for Number (%) or Fisher's exact test, when appropriate. p-value>0.05 is insignificant; *: p-value<0.05 is significant, **: p-value<0.001 is highly significant.

TABLE 6. Comparison of groups based on swelling

Time	Swelling	Activation Irrigation protocol								x ²	p
		PUI		XPF		Max Fanta		MDA			
		n	%	n	%	n	%	n	%		
At12 hrs.	Swelling	0	0.0	0	0.0	1	6.3	3	18.8	6.400	0.094
	No swelling	16	100.0	16	100.0	15	93.8	13	81.3		
At24 hrs.	Swelling	0	0.0	1	6.3	1	6.3	4	25.0	6.621	0.085
	No swelling	16	100.0	15	93.8	15	93.8	12	75.0		
At48 hrs.	Swelling	0	0.0	1	6.3	2	12.5	7	43.8	13.512	0.004*
	No swelling	16	100.0	15	93.8	14	87.5	9	56.3		
At72 hrs.	Swelling	0	0.0	1	6.3	2	12.5	7	43.8	13.748	0.003*
	No swelling	16	100.0	15	93.8	14	87.5	9	56.3		
At 4 days	Swelling	0	0.0	1	6.3	2	12.5	7	43.8	13.748	0.003*
	No swelling	16	100.0	15	93.8	14	87.5	9	56.3		
At 5 days	Swelling	0	0.0	0	0.0	2	12.5	7	43.8	16.937	<0.001**
	No swelling	16	100.0	16	100.0	14	87.5	9	56.3		
At 6 days	Swelling	0	0.0	0	0.0	1	6.3	4	25.0	9.329	0.025*
	No swelling	16	100.0	16	100.0	15	93.8	12	75.0		
At 1 week	Swelling	0	0.0	0	0.0	0	0.0	2	14.3	7.086	0.069
	No swelling	16	100.0	16	100.0	16	100.0	12	85.7		

Using: χ^2 : Chi-square test for Number (%). p-value>0.05 is insignificant; *: p-value<0.05 is significant, **: p-value<0.001 is highly significant. PUI: Passive ultrasonic irrigation, XPF: XP endo finisher file, MDA: Manual dynamic agitation

for reducing postoperative pain. The limitations of this clinical trial included several factors such as that this trial didn't investigate the postoperative pain at longer time intervals, screening a lot of patients to standardize the criteria of preoperative pain for the patients that was participated in the trial. Furthermore, Pain was a complex, individualized feeling that was hard to measure precisely. Although VRS was straightforward and helpful in assessing the administration of analgesics, VRS had a number of drawbacks, such as the possibility of descriptor misinterpretations, a restricted vocabulary for certain individuals, The meaning of the same word varied from patient to patient. Future *in vivo* trials should indicate the impact of various factors on the postoperative pain.

CONCLUSIONS

Within the limitations of the trial, minimal postoperative pain and minimal analgesic intake had been significantly accompanied by PUI, while postoperative pain and analgesic intake had been increased in MDA.

Disclosures

Ethics Committee Approval: The study was approved by the Suez Canal University's Research Ethics Committee (no: REC-832/2024, date: 02/07/2024).

Informed Consent: Written informed consents were obtained from all participants before starting the trial.

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