ORIGINAL RESEARCH

Postendodontic Pain Using Single File System with Different Irrigation Protocols in Single-visit Root Canal Treatment: A Randomized Control Trial

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ABSTRACT

Aim: To evaluate the intensity of postendodontic pain (PEP) using final irrigation with side-vented needle (SV), EndoActivator (EA), and Ultra X (UX) in single-visit endodontics (SVE) with F-One rotary files.

Materials and methods: A total 150 patients indicated for endodontic treatment were selected. Single-visit endodontics treatment was performed under local anesthesia. For the final irrigation protocol, they were divided into three groups: group I (SV), group II (EA), and group III (UX). The severity of PEP was assessed using visual analogue scale (VAS) score after 6, 12, 24, and 48 hours. Analgesics taken by patients, for pain, were also recorded. Finally, the data were tabulated and statistically analyzed using SPSS 20.0 software at a level of significance being 0.05.

Results: Postendodontic pain was less in group III (UX) and group II (EA) compared with group I (SV) at 6 and 12 hours, which is statistically

Results: Postendodontic pain was less in group III (UX) and group II (EA) compared with group I (SV) at 6 and 12 hours, which is statistically significant (p < 0.05). There was no statistically significant difference found after 24 hours and 48 hours.

Conclusion: The intensity of PEP was minimum in patients treated with EndoActivator and ultrasonic along with single rotary file systems. The incidence of analgesic intake was similar in all three groups.

Keywords: EndoActivator, F-One, Postendodontic pain, Side-vented needle, Single-visit endodontics, Ultrasonic.

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Introduction

The main objective of endodontic treatment is to eliminate the pain caused due to microorganisms. Postendodontic pain (PEP) is a very usual but an unfortunate complication of endodontic treatment also the occurrence rate of PEP varies from 3 to 58%. Postendodontic pain is developed due to the extrusion of microorganisms along with dentinal and necrotic debris through the apical area during the biomechanical preparation, resulting in the acute inflammatory response. ²

To prevent PEP, many researcher have suggested maintenance of aseptic environment throughout endodontic procedure and choosing correct instruments for biomechanical preparation in order to produce less apical extrusion in periapical area.² Aminsobhani et al. concluded that postinstrumentation pain with a single file system is less than the multiple file system.³ The newer F-One file (Shanghai, Fanta Dental Materials Co. Ltd.) has the vertical blades swipe the debris from the flutes to the relief area, which results in better cutting by the flutes and less stress on radicular dentin.⁴

Elimination of all debris from the root canal system can be difficult many a times, even with accurate application of rotary instrumentation, due to various reasons, especially from inaccessible areas of the root canal system. Thus, irrigation forms an integral part of cleaning and shaping.⁵ Extrusion of irrigants beyond the apical constriction is routine with endodontic syringe. Due to positive apical pressure generated during irrigant delivery, sodium hypochlorite and ethylenediaminetetraacetic acid (EDTA) may be pushed out into the periapical tissue and subsequently lead to PEP. Various modifications of open-ended needle and closeended needles are seen such as flat, beveled, and notched-ended needle, and side-vented, double-side-vented, and multivented,

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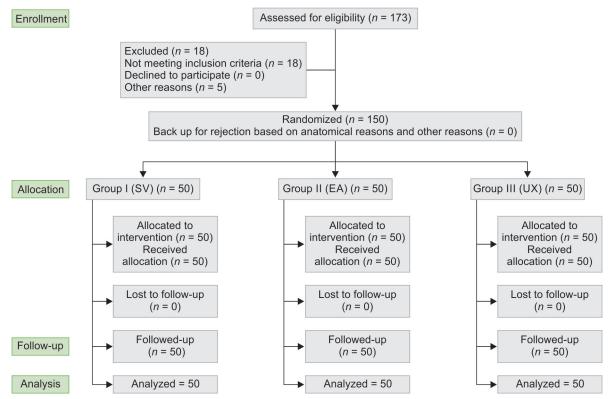
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respectively. Among which modifications from side-vented needle claims to reduce the chance of apical extrusion of debris. ⁶

Similarly, to improve the effectiveness and safety of irrigation procedure, sonic (1–6 kHz) and ultrasonic (25–30 kHz) devices such as EndoActivator (Dentsply-Maillefer, Ballaigues, Switzerland) and Ultra X (Ultra X, Changzhou Sifary Medical Technology Co. Ltd.) are used, respectively. ^{7,8} The tip of the devices oscillates and vibrates, producing cavitation and acoustic streaming, which enhances the disruption of smear layer, unplugging dentinal tubules, and biofilm disruption. Also, it is effective in complex root canal anatomy. ^{9,10}

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Flowchart 1: Flowchart for consort criteria



However, there is a lack of evidence on the influence of final irrigation using side-vented needles, EndoActivator, and Ultra X on PEP with different file systems. Therefore, the purpose of the study is to compare newer irrigation apparatus using a single file system, to evaluate its influence on PEP.

Hence, the aim of this study was to compare PEP after using side-vented needles, EndoActivator, and Ultra X during the final root canal irrigation protocol with a single file system. The null hypothesis stated that there was no difference in PEP after using these three irrigation techniques.

MATERIALS AND METHODS

This was a factorial, randomized clinical trial which was conducted for 6 months from June 2022 to December 2022 and has been approved by the Research & Ethical Committee of Narsinhbhai Patel Dental College and Hospital, Sankalchand Patel University, Visnagar, Gujarat (ref. no. NPDCH/2021/55). The CTRI registration number allotted is as follow: CTRI/2022/04/041662. The study was designed following the CONSORT statement and conducted in obedience to the declaration of Helsinki. Before starting the treatment, all the protocol was explained to the patients, and the consent form was filled. According to $\alpha=0.05$ and power of study 0.8, the minimum sample size decided was 50 per group.

Patient Selection

The details, including the number of patients enrolled, allocated, and analyzed are demonstrated in the flow diagram (Flowchart 1).

Inclusion Criteria

Only asymptomatic irreversible pulpitis in permanent maxillary and mandibular molars in 20–60 years of age patients were selected.

Exclusion Criteria

Calcified canals, root canal-treated teeth, cracked teeth, resorption, and immature tooth, pregnant, lactating mothers who had a history of any medical conditions, who had taken analgesics within the last 24 hours, and those allergic to nonsteroidal anti-inflammatory drug (NSAID) were excluded from the study.

Out of 173 patients, a total of 150 patients were selected, 18 patients were excluded, as they did not meet the inclusion criteria, and 5 patients were rejected due to anatomical variations. On clinical examination, the vitality of the pulp was checked using a cold test followed by an electric pulp test. Palpation, percussion, and periodontal status were evaluated. Radiographic examination was done to check periapical radiolucency. Hence, diagnosis of tooth was confirmed with asymptomatic irreversible pulpitis.

Randomization Protocol

A total of 150 patients were selected and were allocated to three different groups (n = 50) through double-blinded randomization to minimize the bias. A 150 sealed opaque envelopes were made and picked up by the dental assistant before treatment. Other than the operator, no one was aware of the system being used.

Treatment Protocol

All the patients were examined and treated by a single operator. All the selected teeth were anesthetized by 2% lignocaine with 1:1,00,000 epinephrine, followed by rubber dam isolation. Complete caries excavation and standardized access cavity were prepared. An estimated working length was measured using # 10K file and Propex Pixi apex locator (Dentsply-Maillefer, Ballaigues, Switzerland) and then confirmed radiographically. Canals were prepared with F-One (Shanghai, Fanta Dental Materials Co. Ltd.) single file system in

crown down technique according to the manufacturer's instruction, i.e., 2.5 controlled torque and at 500 RPM with X Smart EndoMotor (Dentsply–Maillefer, Ballaigues, Switzerland). Orifice enlargement followed by cleaning and shaping was done using 17/12 and 25/06 rotary files, respectively. Apical diameter was prepared up to #25 file.

Irrigation Protocol

During biomechanical preparation, canals were irrigated with 10 mL of 3% NaOCI with a conventional endodontic syringe. Then, the canals were flushed with 2 mL of 17% EDTA solutions for 1 minute.

Based on different final irrigation protocol, patients were divided into three different groups. Group I: side-vented needle (SV), group II: EndoActivator (EA), and group III: Ultra X (UX).

Group I (SV): 4 mL of 3% NaOCI was flushed into all the canals using a side-vented 30-Gauge needle (Fanta Dental Materials Co. Ltd., Shanghai), 2 mm short from working length.

Group II (EA): 2 mL of 3% NaOCI was flushed into a pulp chamber with conventional endodontic needle, and EndoActivator tip (size 20/0.02) was placed loosely at 2 mm from working length and activated at 10,000 cycles/minute which was used in pumping action to move the tip, 2–3 mm vertical strokes for 1 minute.

Group III (UX): 2 mL of 3% NaOCI was flushed in the canal and irrigated using ultrasonic tip (Ultra X, Eighteenth, Changzhou Sifary Medical Technology Co. Ltd.) at 2–3 mm to the working length. The solution was activated by vertical up and down strokes for 20 seconds. Repeat the cycle for 3–4 times.

Final irrigation was done with sterile normal saline. All the canals were dried using corresponding paper points. Obturation was done using AH PLUS resin-based sealer along with gutta-percha points with lateral condensation technique. Postoperative radiograph, to confirm accuracy, was recorded. Postendodontic restoration was done with composite.

Postoperative Instructions

In case of pain, the patient was advised to take an analgesic (Brufen 400 mg). Patients were given a questionnaire based on VAS for recording their pain after 6 hours, 12 hours, 24 hours, and 48 hours. Patients were given a reminder call to keep a note of their pain scale on the form given to them.

Follow-up Evaluation

The pain assessment sheet given to the patient was collected after 48 hours during a follow-up appointment.

Statistical Analysis

The obtained data were analyzed statically using SPSS software (statistical package for social sciences). Visual analogue scale scores for pain were summarized as mean and standard deviation (SD) (Table 1; Fig. 1).

Intergroup comparison of mean VAS score to obtain the primary and secondary outcome was done using ANOVA test with Scheffe's *post-hoc* test. The degree of statistical significance was set at 0.05 (Table 2).

RESULTS

The mean value of the age of the patient is 42.76, 42.68, and 42.48 in SV, EA, and UX, respectively. To minimize the bias, the gender distribution of males/females was 25/25 in each group, respectively.

Table 1: Comparison of mean pain score

		$Mean \pm SD$	
	Group I (SV)	Group II (EA)	Group III (US)
6 hours	2.85 ± 1.45	2.25 ± 0.45	1.34 ± 0.67
12 hours	1.44 ± 0.93	1.02 ± 0.81	0.12 ± 0.21
24 hours	0.35 ± 0.51	0.26 ± 0.35	0
48 hours	0.11 ± 0.21	0	0

SD, standard deviation

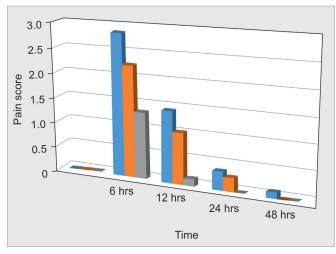


Fig. 1: Comparison of mean pain score

Table 2: Intragroup and intergroup comparison of VAS score using post-hoc test

post-noc test			
Time (I)	Groups (J)	Mean difference (I–J)	p-value
6 hours	SV-EA	2.76	0.038*
	EA-UX	0.26	1.000
	UX-SV	3.01	0.012*
12 hours	SV-EA	0.83	1.000
	EA-UX	1.80	1.580
	UX-SV	2.63	0.020*
24 hours	SV-EA	0.65	1.000
	EA-UX	0.28	1.000
	UX-SV	0.69	1.000
48 hours	SV-EA	0.23	1.000
	EA-UX	0.00	1.000
	UX-SV	0.23	1.000

^{*}p-value < 0.05 statistically significant

Similarly, for the location of the tooth, maxillary/mandibular molars were 25/25, respectively, for each group.

The maximum score obtained on VAS score is 6. In group SN, at 6 hours, n=3 reported pain score 6, n=2 reported 5, n=3 reported 4, n=11 reported 2, and n=5 reported 5. At 12 hours, the greater number of patients reported (n=11) pain score 1. The maximum number of patients showed a pain score of 0 at 48 hours (n=22). In group EA, at 6 hours, n=2 reported pain score 6, while n=18 reported score 2. At 12 hours, n=11 reported a pain score of 1 and n=19 reported a score of 0 at 24 hours. All the patients (n=25) reported 0 score at 48 hours. In group UX, the maximum score



Table 3: Comparison of mean value of pain intensity in maxillary and mandibular molars

		Maxillary				Mandible				
	6 hours	12 hours	24 hours	48 hours	6 hours	12 hours	24 hours	48 hours		
SV	1.9 ± 1.3	0.9 ± 1.0	1.6 ± 0.5	0.08 ± 0.2	3.8 ± 1.4	2.0 ± 0.9	0.5 ± 0.6	0.16 ± 0.3		
EA	2.0	0.44 ± 0.5	0	0	3.4 ± 1.4	1.6 ± 0.9	0.5 ± 0.1	0		
UX	0.8 ± 0.5	0	0	0	1.8 ± 0.5	0.2 ± 0.4	0	0		

Table 4: VAS score for each group

	SN				EA				UX			
Score	6 hours	12 hours	24 hours	48 hours	6 hours	12 hours	24 hours	48 hours	6 hours	12 hours	24 hours	48 hours
6	5	0	0	0	2	0	0	0	0	0	0	0
5	2	0	0	0	0	0	0	0	0	0	0	0
4	3	2	0	0	4	1	0	0	0	0	0	0
3	0	2	0	0	1	0	0	0	0	0	0	0
2	11	5	2	0	18	5	0	0	11	0	0	0
1	3	11	5	3	0	11	6	0	11	11	3	0
0	0	4	18	22	0	8	19	25	3	14	22	25

Table 5: Comparison of mean value of pain intensity in male and female

		Male				Female				
	6 hours	12 hours	24 hours	48 hours	6 hours	12 hours	24 hours	48 hours		
SV	2.08 ± 1.1	0.88 ± 0.74	0.8 ± 0.28	0	3.62 ± 1.8	2.00 ± 1.1	0.62 ± 0.7	0.23 ± 0.4		
EA	2.1 ± 0.4	0.56 ± 0.58	0.4 ± 0.2	0	3.2 ± 1.5	1.4 ± 1.0	0.48 ± 0.5	0		
UX	1.0 ± 0.6	0	0	0	1.6 ± 0.7	0.2 ± 0.4	0	0		

reported was 2 and 1 at 6 hours by 11 patients for each score. At 12 hours, n = 14 reported 0 score, and at 24 hours and 48 hours 0 score was recorded by 22 and 25 patients, respectively (Table 3).

The primary outcome of this study showed a statistically significant difference in PEP at 6 hours in all three groups. Male patients showed less PEP when compared with female patients at 6 hours (Table 4). Also, there was a significant difference at 6 hours and 12 hours in mandibular than maxillary molars (Table 5).

As a secondary outcome, there was no statistically significant difference in PEP found at 12, 24, and 48 hours. Whereas, at 24 hours and 48 hours, no statistical difference was seen in mandibular molars. There was no statistically significant difference found in all the three groups regarding the quantity of analgesics intake.

The highest level of PEP was seen in SN, and the lowest level in EA and UX for every period of time. Among these, no participants were lost to follow-up and reported no severe pain or flare-up during the time period of study.

Discussion

It is very difficult to differentiate which factor causes pain after root canal treatment. Some of the reasons are like mechanical and chemical cause that occurs due to over instrumentation and extrusion of irrigants or filling materials, respectively. Many irrigants are available in the market, but none meet the expectations for an ideal irrigant solution. So, in order to remove the bacterial biofilm, other disinfecting agitation devices were used. 11

Literature shows that single-visit endodontic treatment is less painful than multi-visit. Although interappointment flare-ups are not very common, PEP is frequent even when the appropriate treatment is done. $^{12,13}\,$

Teeth with apical periodontitis or necrotic pulp or periradicular lesion or sinus tract stomas were not incorporated, due to chances of microbial infection, in such cases, the irrigant may go beyond the apex and cause infection. Hence, the teeth affected with asymptomatic irreversible pulpitis only were included in the study.^{12,14}

In this study, multi-rooted teeth were taken as they are more susceptible to pain. And also, it is more likely to happen that the practitioner faces more multi-rooted teeth than single-rooted teeth in day-to-day clinical practice.¹⁵

To minimize the bias of PEP, F-One single rotary file system was chosen as it has R-wire NiTi alloy file, a designed unique cross-section with flat cut processed for better flexibility and cyclic fatigue resistance. It has a vertical blade system that swipes debris from flutes better to relieve the area and also provides a better room for irrigating solution, thus helping in decreased rate of smear layer formation.^{4,16}

Various methods are used for the assessment of pain in patient like Numerical Rating Scale (NRS), Defense and Veterans Pain Rating Scale (DVPRS), Adult Nonverbal Pain Scale (NVPS), etc.¹⁶ Here, in the study, VAS is resorted to assess pain, because of its confirmed reliability. To avoid the shortcoming, a questionnaire was formatted in such a way that it is easily understood by the patient. None of the patients experienced severe pain, which was equivalent to more than score 6.

Nonsteroidal anti-inflammatory drugs (NSAIDs) have been the first choice medication for PEP, and Brufen 400 mg, being one of the most efficient NSAIDs was used to manage PEP in the study.¹⁷

In this study, 3% NaOCI is used as an irrigation solution due to its antibacterial efficacy and great ability to dissolve organic material, but when it comes to inorganic material, 17% EDTA was used for better results, followed by sterile saline irrigation was used to avoid the prolong chelating effect on micro hardness of root dentin as well as good bonding with resin sealer. Also, in pretext to Boutsioukis et al., the needles were placed 2–3 mm short from WL as it would ensure adequate irrigant exchange without causing high apical pressure.

The result of this study, SV had more pain when compared with EA and UX groups at 6 hours, but there was no statistically significant after that. So the null hypothesis was rejected.

Najim MA et al. evaluated the postoperative pain after irrigation using side-vented Navi Tips and showed less pain than end-vented Navi Tips at 4, 12, and 24 hours. They suggested that due to excessive pressure during irrigation, a large amount of sodium hypochlorite may extrude to periapical area and cause necrosis of tissue, which can result into PEP. Hence, to reduce this effect side-vented needles were selected in this study.

Results showed that there was no statistically significant difference between EndoActivator and Ultra X at 6 hours follow-up. In case of EndoActivator, vibrating the tip in up and down motion in short vertical strokes synergistically produces a powerful hydrodynamic phenomenon. The irrigating solution is exchanged at the apex each time, which prevents extrusion of the irrigant apically. These justify the reduction of PEP due to a decrease in debris extrusion. Ramamoorthi et al. found that the EA group resulted in significantly less postoperative pain and the necessity for analgesic medication than a conventional needle protocol, which is similar to the current study. 1

Acoustic streaming is an action by which PUI works in a continuous movement of irrigants and increases debris removal.²¹ The activation of NaOCI by ultrasonic can cause a rise in the temperature of the fluid, speeding up its effects and responses between agents in the fluid, hard tissue, and soft tissue, also speeding up the removal of smear layer.^{22,23} Damage to microorganisms and physical destruction of biofilm is the result of explosive and implosion, which is created by sheer stress. This might be the reason for less pain after 6 hours of follow-up with UX.^{7,22}

The other reasons for less pain could be, during agitation, the amount of debris extrusion due to the large amount of irrigant. Theoretically, 2 mL of irrigant was delivered in the chamber, but only small amount was present inside the canal during agitation, the remaining amount might have been contained in the coronal access cavity and canal irregularities. Hence, extrusion may be less compared with syringe delivery.^{7,8}

In this study, females were more sensitive than male patients when it comes to PEP, this could be due to fluctuation of two hormone levels: serotonin and non-adrenalin, which is also stated by Marcus DA.²⁴ Mandibular teeth showed more PEP, and the reason behind this was explained by Ali et al. as the mandibular bone has a dense trabeculae pattern, which can cause reduced blood flow and localization of infection, leading to delayed healing patterns.²⁵

Limitation

Limitations of the study, only sonic and ultrasonic devices, for a specific time were evaluated. Moreover, a sole asymptomatic pulpitis is taken into the study. Furthermore, the characteristics of pulpal disease are in need of discussion. And also, studies are suggested with different irrigation activation devices along with different agitation mechanisms in regard to PEP.

Conclusion

Within the limitation of the current study, it can be concluded that newer advancement of agitation technique of irrigating solution with sonic and ultrasonic device brings down the level of PEP. The EndoActivator and Ultra X showed comparatively less pain than side-vented needle. But within the first-time interval, the influence of pain was higher in all three groups. After 6 hours, there was a gradual decrease in pain using EndoActivator and Ultra X.

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