

Comparative Evaluation of Postoperative Pain After Using Endoactivator, Side Vented, And Open Ended Endodontic Needles As Final Irrigation Protocols During Root Canal Treatment

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ABSTRACT

Objective: To compare the postoperative pain following root canal therapy using different final irrigation modalities, such as a side-vented endodontic needle, an open-ended irrigation needle, and the Endoactivator system.

Study Design: Randomized controlled trial (ClinicalTrials.gov: NCT05840783)

Place and Duration of the Study: Department of Operative Dentistry and Endodontics, Armed Forces Institute of Dentistry, Rawalpindi, Pakistan from Apr to Oct 2023.

Methodology: A total of 105 participants were randomly divided into three groups based on the irrigation protocol (IP): Group IP-1 was the final irrigation with a 30-gauge open-ended needle, Group IP-2 was with a 30-gauge side-vented needle, and Group IP-3 was with the Endoactivator system. The postoperative pain perception was measured using the Visual Analogue Scale (VAS) at 8, 24, and 48 hours. NSAIDs were prescribed to all subjects to manage pain.

Results: The postoperative pain scores showed significant differences among the three groups at 8, 24, and 48 hours of $p < 0.05$. Group IP-3 always presented with the lowest mean pain scores in each timeframe. Group IP-1 showed significantly higher pain than Groups IP-2 and IP-3 at 8, 24, and 48 hours ($p < 0.05$). There was also significant differences among groups in all time intervals in terms of NSAID consumption ($p < 0.05$).

Conclusion: Final irrigation with open-ended needles causes significantly higher postoperative pain when compared to side-vented needles and the Endoactivator system in the course of root canal therapy.

Keywords: Endoactivator, Open-ended needles, Operative Dentistry, Root canal treatment, Side-vented needles.

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INTRODUCTION

The complete elimination of infective microorganisms, organic tissue, and inorganic debris from the complex infrastructure of root canals is crucial to the success of endodontic therapies.¹ Advanced imaging modalities have disclosed the root canal systems to be very complex anatomical structures, consisting of small accessory channels, multiple extensions, and inter-canal connections. These are called anastomosis, fins, ramifications, and apical deltas, making optimal cleaning and debridement even more difficult.² The smear layer is a thin film that comprises dentinal debris, bacteria, odontoblastic processes, and pulpal residuum, that binds firmly to the walls of the root canal and must be removed by chemo-mechanical methods.³

A thorough disinfection of intricate root canal anatomies remains challenging for clinicians, even with diligent use of manual, rotary, or hybrid instrumentation. Consequently, this makes irrigation

and chemical lavage of root canals even more important during root canal therapy, as chemical disinfection and flushing play a crucial role in eliminating the smear layer. Despite researchers' and clinicians' best efforts, irrigation remains one of the most neglected procedures, particularly in the apical zone of canals.⁴

The conventional open-ended needle is commonly used in endodontics due to its ease of manipulation, depth control, and volume of irrigants. On the other hand, these needles also exert an apical pressure which leads to the extrusion of debris beyond the apex.⁵ Different modifications in this design such as closed-ended, side-vented channels, have been introduced to minimize the likelihood of extrusion of debris beyond the root apex. Side-vented needles allow the flow of irrigants sideways, preventing apical pressure and extrusion through the apical foramen.^{6,7} Different irrigation tools such as the Endoactivator have also been developed for use in root canal treatment to improve the safety and effectiveness of the irrigation procedures (DENTSPLY, USA). The Endoactivator utilizes sonic activation technology to

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generate oscillatory vibrations in endodontic tips at high frequencies, producing the cavitation effect and acoustic streaming phenomena.⁸ This mechanism actively removes the bacterial biofilm, and smear layer and enhances disinfection of fins, anastomoses, accessory canals, and apical deltas.⁹

Despite meticulous root canal therapy, the occurrence of postoperative pain is relatively common. Post-treatment pain etiology is based on multiple factors, with extrusion of intracanal debris or irrigants during endodontic irrigation being the main culprits behind frequent flare-ups.¹⁰ Therefore, selecting appropriate irrigation delivery and agitation systems is critical. Although open-ended needles are routinely used for irrigation in dental practice, no study has directly compared and analyzed the impact of final irrigation using an Endoactivator (Dentsply, USA), closed-ended and side-ported irrigation needles on postoperative pain in the Pakistani population.

Therefore, the current trial's goal is to compare and collate the effect (pain) by using the three different final irrigation techniques including open-ended, side-vented endodontic irrigation needles and the sonic irrigation device during endodontic therapy. The null hypothesis of this study states that no difference is observed in the intensity of pain after post-treatment when using open-ended, side-vented irrigation needles and the Endoactivator for canal irrigation while performing endodontic therapies.

METHODOLOGY

The approval for this randomized controlled trial was obtained from the Institutional Review Board of the Armed Forces Institute of Dentistry, Rawalpindi, Pakistan (letter no. 918/Trg dated 13 May 2020) and registered in clinicaltrials.gov (NCT05840783). Sample size was calculated using the WHO sample size calculator using the standard formula for comparison of two means, taking confidence interval 95%, margin of error 5%, an expected mean difference of 9.44 with a standard deviation of ± 12.5 in postoperative pain reduction between irrigation techniques.¹¹ The minimum required sample size was calculated as 28 participants per group. To compensate for multiple postoperative assessments and potential attrition, the sample size was increased to 35 participants per group, resulting in a total sample size of 105 participants.

A total of 105 volunteers fulfilling the eligibility criteria from the OPD of the Operative Dentistry Department of AFID were selected. The participants

were then randomly distributed into three Groups (using randomizer.org); Group IP-1: Open-ended needle (Septodont, USA). Group IP-2: side-vented, Trunatomy 30-gauge irrigation needle (Dentsply, Germany). Group IP-3: Endoactivator (Dentsply, USA) (Figure).

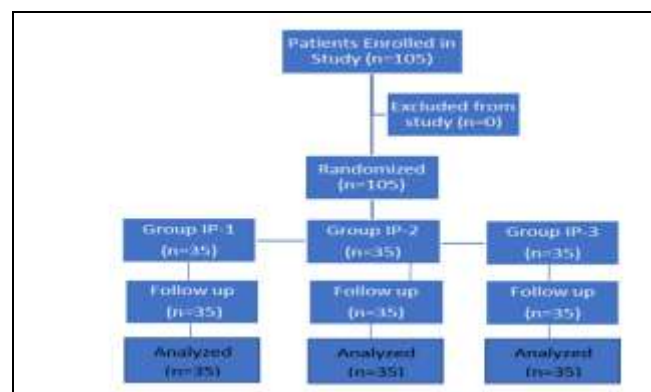


Figure: Patient Flow Diagram

Inclusion Criteria: Individuals aged 18 to 65 with a noncontributory medical history and pain scores in the range of 4-10 (moderate to severe pain) according to VAS were selected. Also, only permanent molar teeth with symptomatic irreversible pulpitis and patients with no allergy to drugs or dental materials used in the study were included.

Exclusion Criteria: Patients with a history of medication 12 hours before the treatment, Pregnancy or lactation, and patients with immunocompromised health, suffering from severe occlusal abnormalities, teeth having sclerosed or obliterated canals on radiographs and teeth with internal or external root resorption or fractures were excluded from this study.

A comprehensive dental and medical history and a pre-op data chart were recorded before the treatment. In an attempt to estimate the intensity of pain the Visual Analog Scale (VAS) was used. The pain score was measured verbally and in standard numerical values with VAS, in the range of 0-10; (0=painless, 1-3= mild pain, 4-6= moderate pain, 7-10= severe pain).

All the eligible participants were guided regarding the study design and treatment protocols in detail and informed written consent was received. The idea about the irrigation tools was given to the participants but they were not informed about the specific device that was utilized in their case.

To ensure uniformity in outcome, all the procedures were performed by a single clinician, a

second-year resident at the Department of Operative Dentistry and Endodontics, awarded two years of clinical experience. The treatment began with the application of topical anesthetic gel, followed by local anesthesia administration with 1.8 ml of 2% lignocaine with 1:200,000 epinephrine (Septodont, USA), and effectiveness was confirmed by a negative result to electric pulp and thermal vitality tests. Afterward, rubber dam isolation was strictly followed in all the cases to ensure an aseptic environment, under a dental operating microscope (Zeiss, Germany). The access cavity preparation was done using sterile diamond-coated burs and the initial glide path was obtained using manual stainless steel endodontic files (Mani, Japan).

For working length determination, size #10 hand K-files (Mani, Japan) were used in conjunction with an electronic apex locator (Morita root ZX, Japan), followed by confirmation with 2 different periapical radiographs for accuracy. Preparation was achieved with Hyflex EDM rotary files (Coltene, Switzerland) within 0.5 mm of the estimated working length. An electric endomotor (X-Smart Dentsply, Switzerland) was used for rotary preparation with recommended speed (500 rpm), torque (2.5 Ncm), and motion (clockwise rotation) settings.

The irrigation protocol for each group was different; Group IP-1 (Open-ended needle): 5 milliliters of 2.5% sodium hypochlorite (Septodont, USA) were distributed in each canal with a 30-gauge notched tip needle (Septodont, USA) 3mm short of the working length. Group IP-2 (Side vented needle): 5 milliliters of 2.5% sodium hypochlorite (Septodont, USA) were distributed in each canal via a 30-gauge side-vented Trunatomy needle (DENTSPLY, USA), carefully placed 1 mm short of the working length. Group IP-3 (Endoactivator): 3 milliliters of 2.5% sodium hypochlorite (Septodont, USA) were distributed into the pulp chamber using a 30-gauge notched tip needle (Septodont, USA). The Endoactivator device with a tip size #20 (yellow) was then carefully positioned 3 mm shy of working length and operated at a standard frequency of 10,000 cycles/minute with 2mm vertical strokes for 2 minutes. Afterward, standard sterile absorbent paper points were used to dry the canals and teeth restored with intermediate restorative material (Cavit - 3M, USA) without any intracanal dressing.

After the procedure, all the participants received a VAS data sheet with all the necessary information.

They were advised against consumption of any medication without the operator's advice and to contact the operator in case of pain, for proper prescription and documentation. In case any patient complained of pain, a dose of 400 mg Ibuprofen was prescribed.

Patients were called at 8, 24, and 48 h intervals after the treatment via telephone to document their responses. The intensity of pain was recorded using visual analog (VAS) pain scales, and the number of ibuprofen pills consumed by the patient at each follow-up interval, with data being categorically recorded and organized for each individual.

The data was analyzed using Statistical Package for the Social Sciences (SPSS) version 23.0 for Windows. The Kruskal-Wallis test was used for the comparison between the three Groups at each time interval, and the Mann-Whitney U test was then used as a post-hoc test. At all different time intervals (8, 24, and 48 hours) the change in VAS score in each Group was analyzed and compared using the Kruskal Wallis test and Mann-Whitney U test. It was considered statistically significant if the value of $p \leq 0.05$.

RESULTS

A total of 105 participants were considered for this study with equal distribution into the three groups ($n=35$). In terms of gender representation, the number of males in Group IP-1, Group IP-2, and Group IP-3 comprised 51%, 54%, and 51%, respectively, while that of females was 49%, 46%, and 49%, respectively. There was no statistically significant difference in gender representation between the groups ($p=0.963$).

Baseline variates did not reveal any difference in the age distribution among the groups, which had median ages of 38 years in both Group IP-1 and IP-2, and Group IP-3 of 36 years, p -value=0.742. Pain levels prior to the surgery were equal in all groups, as the median was 6 (IQR 2) in all groups, p -value=0.542. There was a progressive decrease in the postoperative pain intensity in all groups; nonetheless, Group IP-3 had lower pain at all postoperative times. At 8 hours, the median pain scores were 5 (IQR 2) in Group IP-1, 4 (IQR 2) in Group IP-2, and 3 (IQR 1) in Group IP-3; this difference was statistically significant ($p<0.001$). Almost similar statistically significant intergroup variations were found at 24 hours ($p=0.003$) and 48 hours ($p<0.001$) postoperative times, implying active irrigation methods and effective postoperative pain management (Table-I). This finding suggests that the

application of Endoactivator and side-vented needles could be useful during the postoperative phase in reducing discomfort.

The analgesic consumption had a similar trend, with more utilization of NSAIDs in Group IP-1 and the least demand in Group IP-3 for all intervals of time. The median analgesic consumption of 2 doses in Group IP-1 was significantly different from Group IP-2 and Group IP-3, which was just 1 dose at 8 hours ($p=0.006$), and this remained significant for both intervals of 8–24 hours and 24–48 hours ($p<0.001$). This reinforces the clinical usefulness of more sophisticated irrigation techniques in preventing postoperative pain and conserving analgesic demand (Table-I).

Table-I: Comparison of Age, Postoperative Pain Scores, and Analgesic Intake among the Three Irrigation Protocol Groups (n = 105)

Parameters	Groups			p-value*
	Group IP-1 n=35	Group IP-2 n=35	Group IP-3 n=35	
Age Median (IQR)	38 (13)	38 (10)	36 (12)	0.742
Pain Median (IQR)				
Pre-operative	6(2)	6(2)	6(2)	0.542
8 hours	5(2)	4(2)	3(1)	<0.001
24 hours	4(1.5)	2(1)	2(1.5)	0.003
48 hours	3(1.5)	2(0)	1(0)	<0.001
Analgesic Intake Median (IQR)				
8 hours	2(1)	1(1)	1(1)	0.006
8-24 hours	1(1)	1(0.5)	0 (0)	<0.001
24-48 hours	1(1)	0(0)	0 (0)	<0.001

* Kruskal-Wallis test

Pairwise comparisons showed that Group IP-1 had significantly higher pain and analgesic consumption than Group IP-2 and Group IP-3 at all times after surgery ($p<0.05$). There were no statistically significant differences between Group IP-2 and Group IP-3 on pain scores at any time point, which indicates that side-vented and Endoactivator needles were equally effective (Table-II).

Table-II: Pairwise comparison of Postoperative Pain Intensity and Analgesic Intake among Irrigation Protocol Groups at Different Time Intervals (n = 105)

Variables	Group Comparisons (p-values)**		
	Gr IP-1 vs. Gr IP-2	Gr IP-1 vs. Gr IP-3	Gr IP-2 vs. Gr IP-3
Pain			
Pre-operative	0.821	0.361	0.679
8 hours	0.005	<0.001	0.319
24 hours	0.018	0.001	0.203
48 hours	<0.001	<0.001	0.101
Analgesic Intake			
8 hours	0.852	0.005	0.007
8-24 hours	0.003	<0.001	0.270
24-48 hours	<0.001	<0.001	0.033

** Mann-Whitney U test

DISCUSSION

Pain evaluation is a crucial factor in any clinical intervention, to understand the efficacy of a certain procedure. Evaluation of pain is very difficult due to a multitude of contributing factors and the subjective nature of pain perception.^{11,12}

VAS is a commonly used pain assessment tool due to its easy applicability, and reproducibility.¹³ Our data showed an insignificant difference ($p\text{-value}>0.05$) in gender, age, and pre-operative pain among the three Groups. To ensure uniformity in results, an identical concentration (2.5%) of sodium hypochlorite was used in all three Groups, and a 30-gauge notched tip needle was used among the participants of Group IP-3 and Group IP-1.

In this trial, the highest post-treatment pain intensity was recorded in Group IP-1 (open-ended needle) at all three time intervals. In contrast, Group IP-3 (Endoactivator) and Group IP-2 (side-vented needle) showed less postoperative pain. The main reason is the design of the needle and how it directs the outflow of irrigant, direction, and the shear pressure exerted. The open-ended needle usually gets wedged inside the canal, exerts an apical pressure of irrigant due to unidirectional flow, and doesn't allow the escape of irrigation fluid in the orthograde direction.^{14,15} Side-vented needles have notches on the lateral walls that allow a sideways flow of the irrigant, hence fewer chances of apical extrusion and more coronal flow. These tips can be safely placed within 2mm of the apical constriction, allowing better cleaning and disinfection. These facts explain less post-treatment pain with side-vented needles in contrast to open-ended needles.^{16,17}

Different studies have proven sonic activation to reduce the intracanal bacterial load and enhance the cleaning efficiency of irrigants by generating microbubbles that expand and collapse to generate acoustic waves, disrupting the biofilm and improving the flushing effect of irrigants.^{18,19} This explains the reduced post-treatment pain in Group IP-3 (Endoactivator), as compared to Group IP-1. It is noteworthy to mention that Group IP-2 and Group IP-3 showed no significant pain difference.

In a similar study by Vishwakarma *et al.*, the authors compared the values of postoperative pain by engaging three different irrigation technologies in patients and concluded that activation with the Endoactivator produced considerably less post-treatment pain as compared to irrigation with open-

ended needles.^{20,21} In another study, the difference in pain after endodontic therapy with an endodontic needle and Endoactivator was evaluated. The postop pain was evaluated at 8, 24, and 48-hour time intervals and it was concluded that the group with Endoactivator had significantly less pain at all three intervals than the endodontic needle irrigation group.²² Yilmaz et al compared the response of 4 diverse irrigating solutions and irrigation techniques, on endodontic pain. The results concluded that the irrigation with an Endoactivator produced less pain after root canal therapy, as compared to conventional irrigation syringes at 4 different time intervals.²³

It is crucial to realize that the participants of the open-ended needle group consumed substantially more NSAIDs than the participants in the other two Groups. However, Group IP-3 and Group IP-2 showed no major difference in analgesic intake when compared.

At present, there is no universal consensus on the ideal agitation system, control of the irrigant flow mechanism and rate, and apical pressure due to the scarcity of evidence-based data. With new technologies like Gentle Wave and Safe Clean, and advanced laser modulation, an enhanced disinfection of the root canal systems and control over irrigation can be anticipated.

LIMITATIONS OF STUDY

The measurement of pain as a variable presents inherent challenges, primarily due to the intricacies involved in pinpointing the pain etiology. Several other factors could also influence this, such as trauma from sharp rubber dam jaws and soft tissue agitation resulting from anesthetic injections. Despite the scrupulous instrumentation, the extrusion of debris remains a potential hazard, rendering its detection an insurmountable challenge within the confines of such a study model.

CONCLUSION

It can be inferred from this study that the irrigation with an Endoactivator and side-vented needles during root canal therapy produces considerably less pain than open-ended needle irrigation. More evidence is required on this subject, and future trials must be conducted for better clinical implementation.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

AA & SMH: Study design, drafting the manuscript, data interpretation, critical review, approval of the final version to be published.

ASK & MZ: Data acquisition, data analysis, approval of the final version to be published.

SSHN & TK: Critical review, concept, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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