Official Title: 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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Study Protocol

A detailed dental and medical history was taken for each patient before the commencement of treatment. A preoperative data chart for each patient was recorded that included tooth number, age, sex, and pain intensity before the treatment. The Visual Analog Scale (VAS) was used to measure the intensity of pain. The pain intensity was measured verbally and in standard numerical values with VAS, in the range of 0–10 as;

0	No pain
1-3	Mild pain
4-6	Moderate pain
7-10	Severe pain

All the eligible participants were guided about the study design and treatment protocol in detail and informed written consent was obtained from the patients. Although the patients were briefed about the study protocols and the type of irrigation devices used, they were not told about the device used particularly in their case.

Treatment Protocol

To ensure uniformity in outcome, procedures on all the patients were performed by a single practitioner who was a second-year postgraduate resident at the Department of Operative Dentistry and Endodontics, with two years of clinical experience.

Endodontic Protocol

The endodontic treatment for all the patients began with the application of topical anesthetic gel, followed by local anesthesia with 1.8 ml of 2% lignocaine with 1:200,000 epinephrine. The effectiveness of anesthesia was ensured by a negative response to cold and electric pulp tests. Afterward, rubber dam isolation was strictly followed in all the cases to ensure an aseptic environment, and a dental operating microscope (Zeiss – OPMI PICO, Germany) was used for access cavity preparation using sterile diamond-

coated burs. After access cavity modification, the initial glide path was obtained and maintained using manual stainless steel endodontic instruments (hand files).

For working length determination, size #10 hand K-files (Mani, Tochigi, Japan) were used with copious irrigation (2.5% NaOcl) and lubrication (EDTA). The working length was estimated with an electronic apex locator (Root ZX II - J.Morita, Tokyo, Japan), and confirmed with 2 periapical radiographs at different angles for accuracy. The root canals were then prepared with Hyflex EDM rotary files (Coltene, Switzerland) within 0.5 mm of the estimated working length following the manufacturer's guidelines up to 25/VT size. An electric endomotor (X-Smart; Dentsply Maillefer, Switzerland) with a reduction gear handpiece (16:1) was used for rotary preparation with recommended speed (500 rpm), torque (2.5 Ncm), and motion (clockwise rotation) settings. To maintain the glide path, and apical patency and prevent the extrusion of debris beyond the apex, recapitulation was done continuously during the procedure using #10 K-file.

Irrigation Protocol

The irrigation protocol was different for each group and was performed using the designated devices for the patients of each particular group.

- For group A (Open ended needle): 5 mL of 2.5% NaOCl (Septodont, USA) was introduced into each canal with a 30-gauge notched tip needle (Septodont, USA) 3mm short of the working length, without any vertical strokes and wedging the needle inside canals.
- For group B (Side vented needle): 5 mL of 2.5% NaOCl (Septodont, USA) was introduced into each canal via a 30-gauge side-vented Trunatomy needle (DENTSPLY, USA), carefully placed 1 mm short of the working length.
- For group C (Endoactivator): 3 mL of 2.5% NaOCl (Septodont, USA) was introduced into the pulp chamber using a 30-gauge notched tip needle (Septodont, USA). The Endoactivator with a tip size #15/0.02 was then carefully positioned 2 mm short of the working length and activated at a frequency of 10,000 cycles/minute with 2mm vertical strokes inside each canal for 2 minutes.

The patients were briefed about the different irrigation protocols but not the one used particularly in their case, to ensure blinding. During the irrigation process, the patients were not shown the devices used. After irrigation, the canals were dried with sterile absorbent paper points and restored with intermediate restorative material (Cavit – 3M, USA) without any intracanal dressing.

Outcome Measure

After the procedure, all the participants received a VAS data sheet with all the necessary information. The patients were also advised not to take any medication without the operator's advice and should call the operator in case of pain, for proper prescription and documentation. In case any patient complained of pain, a dose of 200 mg Ibuprofen was prescribed as an escape medication.

Patients were called at 8, 24, and 48 h intervals after the treatment via telephone to note their responses and feedback. The pain intensity was recorded using both the numeric and verbal (VAS) pain scales, and the quantity of ibuprofen pills consumed by the patient at each follow-up interval. All the collected data was then carefully recorded on the patient's chart.

Statistical Analysis

All the data was presented and organized in Microsoft Excel. SPSS version 23.0 for Windows was used for the descriptive analysis, and calculation of mean and standard deviation. 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 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 $P<0.05$.

Results

No significant difference in age distribution ($p=0.742$) evaluated by Kruskal-Wallis and gender ($p=0.963$) evaluated by Pearson Chi-square was observed across all three groups.

Variables (mean ±SD)		GROUP-A	GROUP-B	GROUP-C	p-value
Age (years)		38.91±13.42	38.34±10.23	36.8±12.35	0.742*
Gender	Male n (%)	18 (51%)	19 (54%)	18 (51%)	0.963**
	Female n (%)	17 (49%)	16 (46%)	17 (49%)	

Table 1 Demographics of the Population Data

*Kruskal Wallis test; **Pearson Chi-square test

Pre-operative pain ranged from 4-10 among the participants with an average pain score of 6.34 in GROUP-A, 6.34 in GROUP-B, and 6.11 in GROUP-C. Mann-Whitney test and Kruskal Wallis ($p>0.05$) test showed no difference in pain distribution across the groups.

The pain scores at 8 hrs post operation ranged from 0-10 with the lowest mean score of 3.31 in group GROUP-C followed by 4.02 in group GROUP-B and 5.77 in group GROUP-A. Pain scores at 24 hr post operation ranged from 0-7 with the lowest mean score of 2.31 in group GROUP-C followed by 2.66 in group GROUP-B and 3.74 in group GROUP-A. Pain scores at 24 hr post operation ranged from 0-6 with the lowest mean score of 1.28 in group GROUP-C followed by 1.65 in group GROUP-B and 2.94 in group GROUP-A. A significant difference between the three groups (GROUP-A, GROUP-B, and GROUP-C) was observed at all times (at 8 hr, 24 hr, and 48 hr) post operation with p values less than 0.05.

Mann-Whitney test conducted to assess a significant difference in the pain distribution across the groups revealed a significant difference observed in pain experience at the 8-hour time interval between GROUP-A and GROUP-B with $p=0.005$ and a highly significant difference between GROUP-A and GROUP-C with $p=0.000$ was observed. A significant difference between GROUP-A and GROUP-C with $p=0.001$ and between GROUP-A and GROUP-B with $p=0.018$ at 24 hr time interval and between GROUP-A and GROUP-C and between GROUP-A and GROUP-B with $p=0.000$ at 48 hr time interval. No significant difference was observed in the intensity of pain experienced between the Endoactivator and side-vented needle irrigation groups.

The data represented in Table /Fig 4 shows the comparison between the three groups with respect to NSAIDS taken by patients as a relief from post-operative pain revealing a significant difference ($p<0.05$) by Kruskal Wallis test between the groups under study at 8 hours, 8-24 hours and 24-48 hours. Mann-Whitney test found a significant difference in NSAIDS intake between GROUP-A and GROUP-C ($p=0.005$) and between GROUP-B and GROUP-C ($P=0.007$) at 8-hour time intervals. No significant difference ($p=0.852$) was observed between GROUP-A and GROUP-B when NSAIDs intake was evaluated at this time interval. During 8-24 hours a high significant difference between GROUP-A and GROUP-B with $p=0.003$ and between GROUP-A and GROUP-C with $p=0.000$ was observed. In contrast, no significant difference ($p=0.270$) was observed between GROUP-B and GROUP-C. A highly significant difference at 24-48 hr time interval was observed between GROUP-A and GROUP-B and between GROUP-B and GROUP-C ($p=0.000$) and also between GROUP-B and GROUP-C ($p=0.033$).

Pain	**Group**	**N**	**MGroup-An (SD)**	**Range**	**Median (Q1-1 Q3)**	**Kruskal Wallis test**		**Mann-Whitney U test (p-value)**		
						Chi-square value	**p-value**	**GROUP-A vs GROUP-B**	**GROUP-A vs GROUP-C**	**GROUP-B vs GROUP-C**
Preoperative	GROUP-A	35	6.34 (1.30)	4-10	6	0.902	0.542 (NS)	0.821	0.361	0.679 (NS)
	GROUP-B	35	6.34 (1.89)	4-10	6					
	GROUP-C	35	6.11 (1.62)	2-10	6					
8 hours	GROUP-A	35	5.77 (2.15)	2-10	5	18.86	0.000	0.005	0.000	0.319 (NS)
	GROUP-B	35	4.02 (2.47)	1-8	4					
	GROUP-C	35	3.31 (1.76)	1-6	3					
24 hours	GROUP-A	35	3.74 (1.89)	1-6	4	11.668	0.003	0.018	0.001	0.203 (NS)
	GROUP-B	35	2.65 (1.47)	0-6	2					
	GROUP-C	35	2.31 (1.51)	1-6	2					

48 hours	GROUP-A	35	2.94 (1.49)	1-6	3	25.543	0.000	0.000	0.000	0.101 (NS)
	GROUP-B	35	1.65 (0.90)	0-3	2					
	GROUP-C	35	1.28 (0.78)	0-3	1					

Pain	Group	N	MGroup-An (SD)	Range	Median (Q1-1 Q3)	Kruskal Wallis test		Mann-Whitney U test (p-value)		
						Chi-square value	p-value	GROUP-A vs GROUP-B	GROUP-A vs GROUP-C	GROUP-B vs GROUP-C
8 hours	GROUP-A	35	1.34 (0.76)	0-2	2	10.23	0.006	0.852 (NS)	0.005	0.007
	GROUP-B	35	1.31 (0.76)	0-2	1					
	GROUP-C	35	0.82 (0.71)	0-2	1					
8-24 hours	GROUP-A	35	1.06 (0.72)	0-2	1	16.180	0.000	0.003	0.000	0.270 (NS)
	GROUP-B	35	0.56 (0.49)	0-1	1					
	GROUP-C	35	0.43 (0.47)	0-1	0					
24-48 hours	GROUP-A	35	0.91 (0.61)	0-2	1	38.416	0.000	0.000	0.000	0.033
	GROUP-B	35	0.28 (0.46)	0-1	0					
	GROUP-C	35	0.08 (0.28)	0-1	0					

Informed Consent Form

DEPARTMENT OF OPERATIVE DENTISTRY

ARMED FORCES INSTITUTE OF DENTISTRY

RAWALPINDI

I _____ hereby authorize, Dr. Ahmed Abdullah, Department of Operative Dentistry, Armed Forces Institute of Dentistry to perform treatment using digital radiography and an electronic apex locator.

I have been fully informed about the complete procedure and its chances of success and failure.

I acknowledge that the information provided to me was in simple language and was fully understood along with being sufficient for me to consent to the procedure. I was given the opportunity to ask questions that were answered satisfactorily.

I have been fully informed about the benefits of the study.

All treatment will be provided free of cost to me.

I am willing to undergo treatment.

Signature of Patient: _____ Signature of Doctor: _____

Date: _____