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Comparison of Postoperative Pain after using Passive Ultra Sonic Activation (PUA) and Manual Dynamic Agitation (MDA) during Root Canal Treatment

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ABSTRACT

Objective: To evaluate post-treatment pain after using manual dynamic agitation and passive ultrasonic activation as final irrigation activation protocols in endodontic therapies.

Study Design: Randomized Controlled Trial (clinicialtrials.gov: NCT05852444).

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

Methodology: In total, 90 patients were randomly split into 2 Groups. In Group MDA, master GP cones were used for irrigant agitation while in Group PUA, an ultrasonic device (Ultra-X) was used. Pain at three different intervals (8h, 24h, and 48h) was evaluated using VAS and NSAIDs were prescribed for pain relief.

Results: Pain scores differed substantially between the two Groups at 8, 24, and 48 hour time intervals ($p<0.05$). The Group PUA consistently showed a lower mean score at all three time intervals with the statistical analysis revealing significant differences in pain experience between Group PUA and Group MDA with a highly significant difference in pain distribution across all times.

Conclusion: Manual irrigant agitation with gutta percha cones causes significantly more pain than passive ultrasonic activation.

Keywords: Manual Dynamic Agitation, Post-Operative Pain, Root Canal Treatment, Ultrasonic Activation.

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INTRODUCTION

Patient comfort has a paramount importance in endodontic treatment outcomes, yet the prevalence of postoperative pain remains very high.[1] Pain or discomfort after root canal therapy could be due to multiple factors, including chemical or mechanical irritation of the periradicular tissue, iatrogenic accidents, or due to microbial provocation.[2] Maintenance of apical constriction integrity are crucial to the success of endodontic therapy. Overzealous instrumentation, loss of apical patency, and forceful use of positive-pressure irrigation needles can lead to the extrusion of necrotic debris, or irrigants beyond the apex and cause post-operative pain.[3] Endodontic irrigants, e.g., sodium hypochlorite, chlorhexidine, and (EDTA), are cytotoxic and provoke tissue damage, and inflammation of periapical tissue if extruded.[4]

The complete disinfection of root canals hasn't been successfully reported due to the intricate anatomical complexities of root canal systems which comprise apical deltas, anastomoses, fins, and ramifications. These minute portals cannot be explored and debrided with manual or rotary endodontic instruments, and remain virtually uncontacted by any irrigation agent.[5] Agitation of irrigation solution, by manually activating a gutta-percha cone, has been recommended to improve the flushing/cleaning effect of the irrigants. Studies report enhancement in the cleaning efficacy of irrigants by generating bubbles and undulating waves that disrupt the smear layer.[6] Activation of root canal irrigants using passive ultrasonic activation devices has recently gained traction. This technology utilizes the placement of a thin ultrasonic tip inside the root canal and activation at 20,000 Hz. This generates micro bubbles which burst when they come into contact with root canal walls and disrupt the smear layer and debris. Moreover, it also leads to acoustic streaming of the liquid irrigant which enhances its flushing capability. Ultra X (Eighteeth Medical) is one such device that uses ultrasonic technology for the activation of irrigation solutions.[7]

Despite their meticulous cleaning capability, both manual dynamic agitation and passive ultrasonic activation can cause some degree of post-operative

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pain.[8,9] It can be either due to the extrusion of debris or microbial agents beyond the apical foramen into periapical tissue, causing inflammation and infection.[10] There is currently very limited literature available that compares the efficacy of passive ultrasonic activation and manual dynamic agitation in the reduction of post-treatment pain after endodontic therapy, particularly in Pakistan. Therefore, the goal of this study is the compare postoperative pain after using Passive Ultra Sonic Activation (PUA) and Manual Dynamic Agitation (MDA) during endodontic treatment.

METHODOLOGY

The randomized controlled trial was conducted at Department of Operative Dentistry and Endodontics, Armed Forces Institute of Dentistry, Rawalpindi, Pakistan from May to November 2023. (registered at clinicialtrials.gov: NCT05852444) after approval from the Institutional Review Board (IRB) of the Armed Forces Institute of Dentistry, Rawalpindi Pakistan, vide letter no. 918/Trg dated 13 May 2020. The Sample size was calculated using the WHO sample size calculator taking confidence interval 95%, level of significance 5%, power of test 80%, with test value of population mean 0.8, anticipated population mean 0.3, and population standard deviation 0.95.[11] The estimated sample size came out to be 90 patients. The participants were divided equally into two Groups; Group MDA (Manual dynamic agitation) using 25/.04 gutta-percha cone (Dentsply, USA), and Group PUA (Passive Ultrasonic Activation) using Ultra X (Eighteeth, China) (Figure).

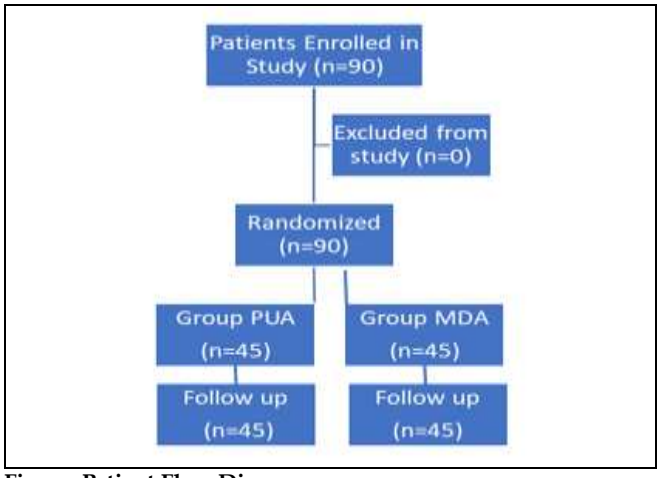

Figure: Patient Flow Diagram

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 participating individuals were guided comprehensively about the study design and treatment protocol and written consent was then taken from each participant. Even though the patients were briefed regarding the study protocols and the type of devices used, they were not told about the device used particularly in their case.

The endodontic procedures were performed by a single practitioner, a second-year postgraduate resident at the Operative Dentistry department, AFID, to ensure uniformity in outcome and reduce any probability of bias in the procedures. The endodontic therapy in all patients was initiated by the application of topical anesthetic gel, followed by the administration of local anesthesia, using 1.8 milliliters of 2% lignocaine compounded with 1:200,000 epinephrine (Septodont, USA). The confirmation of anesthesia was verified by a lack of patient response to electric and thermal tests. Subsequently, strict adherence to rubber dam isolation protocols was maintained across all cases to ensure the establishment of a completely aseptic clinical environment. The use of a dental microscope (Zeiss, Germany) facilitated the preparation of precise and conservative access cavities with sterile diamond-coated burs. Following the access cavity preparation, the preliminary glide path was established with manual endodontic files (MicroMega, France).

For a precise working length, size #10 hand K-files (MicroMega, France) were employed in conjunction with continuous irrigation using 2.5%

sodium hypochlorite (NaOCl), saline, and ethylene-diaminetetraacetic acid (EDTA) lubricant (Glyde, Dentsply-USA) in intervals. The working length was taken with an electronic apex locator (Propex Pixi, Dentsply USA), and further authenticated by taking 2 intraoral periapical radiographs. Afterward, the root canals were mechanically prepared with Trunatomy rotary files (Dentsply, Germany), using a reduction gear electric endomotor (X-Smart; Switzerland), within 0.5 millimeters of the apical constriction.

The irrigant activation protocol was different for both Groups; for Group MDA: 5 milliliters of 2.5% NaOCl (Septodont, USA) were introduced into each canal via a 30-gauge side-vented Trunatomy needle (Dentsply, USA), carefully positioned 2 mm short of the determined working length. The master gutta percha cone (Dentsply, USA) was then activated inside the irrigant in a to and fro motion at 100 strokes/min, keeping 4 mm short of the working length. For Group PUA (Ultra X): 5 milliliters of 2.5% NaOCl (Septodont, USA) were introduced into the pulp chamber using a 30-gauge side-vented Trunatomy needle (Dentsply, USA). The activation tip (blue) size (18mm/0.02 taper) was positioned cautiously inside the canal 2 mm short of the working length. It was ensured that the tip did not touch the canal walls (passive ultrasonic activation) and was kept static in position while generating a 20 kHz frequency.

During the irrigation process, care was taken not to show the patients the particular device being used in their treatment. The canals were dried at the final step, with sterile absorbent paper points and restored with intermediate restorative material (Cavit – 3M, USA) without any intracanal dressing. A VAS data sheet was provided to each patient. They were advised against any analgesic consumption without a prior discussion with the operator, and in case of pain, proper documentation was required. A dose of 200 mg Ibuprofen was prescribed as an escape medication if required.

Patients were called at 8, 24, and 48 h intervals after the treatment via telephone to note their responses. The pain intensity was recorded using the VAS pain scale, 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.

Data was analyzed by using Statistical Package for Social Sciences (SPSS) 22.00. Quantitative data was represented using Mean±SD and median (IQR). Qualitative data was represented by using percentage and frequency. Chi square test (for qualitative variables), Student t-test (for normally distributed variables) and Mann-Whittney U-test (for discrete data i.e pain) were applied and *p*-value of ≤0.05 was considered as statistically significant.

RESULTS

The total outcomes of this study included 45 patients in each Group with a mean age was 39.8±11.45 years in Group MDA and 38.9±10.93 years in Group PUA. The overall age range for both Groups was 20-65 years, with a median age of 35 years in Group MDA and 39 years in Group PUA, with no significant difference in age distribution (p=0.583). There was no significant difference in gender distribution, with 19(42.2%) males and 26(57.7%) females in Group MDA, and 22(48.8%) males and 23(51.1%) females in Group PUA (p=0.525).

Table-I: Demographic Distribution of patients (n=90)

Variables		Group-MDA (n=45)	Group-PUA (n=45)	*p*-value
Age (Mean±SD)		39.8±11.4	38.97±10.9	0.583*
Gender	Male n(%)	19(42.22)	22(48.89)	0.525**
	Female n(%)	26(57.77)	23(51.11)	

**Passive Ultra Sonic Activation: PUA), Manual Dynamic Agitation: MDA*

Pre-operative pain scores ranged from 5 to 8 in both Groups, with no significant difference in pain levels (p=0.373). At 8 hours post-operatively, pain scores ranged from 7 to 2 in Group MDA and 5 to 0 in Group PUA, with mean pain scores of 5.8 and 3.4, respectively. At 24 hours, pain scores ranged from 0 to 5 in both Groups, with mean pain scores of 2.8 in Group MDA and 1.5 in Group PUA. At 48 hours, pain scores ranged from 0 to 3, with mean pain scores of 1.17 in Group MDA and 0.46 in Group PUA. A highly significant difference in pain distribution was observed between the two Groups at all times (p=0.001).

Table-II: Distribution of Visual Analogue Scale (VAS) Scores at Different Time Intervals in Groups MDA and PUA (n=90)

Visual Analogue Scale Score	Group MDA n(%)			Group PUA n(%)		
	Time: 8-hr	Time: 24-hr	Time: 48-hr	Time: 8-hr	Time: 24-hr	Time: 48-hr
0	0(0)	3(4.76)	15(23.8)	1(1.59)	13(20.63)	31(49.22)
1	0(0)	7(15.91)	12(27.27)	2(4.55)	15(34.09)	8(18.18)
2	1(2.5)	8(20)	13(32.5)	7(17.5)	6(15)	5(12.5)
3	1(3.23)	8(25.81)	5(16.13)	11(35.48)	5(16.12)	1(3.23)
4	1(3.13)	13(40.63)	0(0)	15(46.86)	3(9.38)	0(0)
5	13(41.94)	6(19.35)	0(0)	9(29.03)	3(9.68)	0(0)
6	16(100)	0(0)	0(0)	0	0(0)	0(0)
7	13(100)	0(0)	0(0)	0(0)	0(0)	0(0)

**Passive Ultra Sonic Activation: PUA), Manual Dynamic Agitation: MDA*

Table-III: Pain Distribution across Group MDA and Group PUA at Different Time Intervals (n=90)

Time Interval	Pain intensity Score		*p*-value
	Group MDA Median (IQR)	Group PUA Median (IQR)	
Pre-operation	7 (1)	7 (2)	0.373
8 hr	6 (2)	4 (1)	<0.001
24 hr	3 (2)	1 (3)	<0.001
48 hr	1 (2)	0 (1)	<0.001

**Passive Ultra Sonic Activation: PUA), Manual Dynamic Agitation: MDA*

Regarding analgesic intake, within the 0-8 hour interval, a total of 50 tablets were consumed in Group MDA and 27 in Group PUA, with 6 patients in Group MDA and 22 in Group PUA not taking any pills. During the 8-24 hour interval, 27 pills were taken by Group MDA and 16 by Group PUA, with 18 patients in Group MDA and 29 in Group PUA not taking any analgesics. In the 24-48 hour interval, 34 patients in Group MDA and 42 in Group PUA did not consume any analgesics, while 11 patients in Group MDA and 3 in Group PUA took one pill. A significant difference in analgesic intake was observed between the Groups at all time intervals (p<0.001).

Table-IV: Intake of Nonsteroidal Anti-Inflammatory Drugs during three Different Time Periods (n=90)

No of Nonsteroidal Anti-Inflammatory Drugs Taken	Between 0-8 hr		Between 8-24 hr		Between 24-48 hr	
	Group MDA n(%)	Group PUA n(%)	Group MDA n(%)	Group PUA n(%)	Group MDA n(%)	Group PUA n(%)
2	11(24.5)	4(8.9)	0(0)	0(0)	0(0)	0(0)
1	28(62.2)	19(42.2)	27(60)	16(35.6)	11(24.4)	3(6.7)
0	6(13.3)	22(48.9)	18(40)	29(64.4)	34(75.6)	42(93.3)
p-value	<0.001		0.021		0.021	

**Passive Ultra Sonic Activation: PUA), Manual Dynamic Agitation: MDA*

DISCUSSION

The ultimate goal of endodontic therapy is to alleviate the pain and eradicate infection by proper shaping and cleaning. The aim is to achieve chemo-mechanical disinfection using different irrigants and hermetically seal the coronal and apical areas of the root canal. Subsequently, the tooth is restored either with a direct or an indirect restoration for adequate functioning.[12]

The method of delivery and activation of irrigation solution can influence the outcome of endodontic treatment and may cause postoperative discomfort. Several factors play a significant part in post-treatment pain; noticeably the extrusion of debris, irrigant, or bacterial agents outside the confines of apical constriction due to positive pressure, wedging of the needle inside the canal, and forceful movement of gutta percha cone in the irrigation solution.[13]

In this study, the endodontic treatment was performed using the same standards and techniques (except final irrigation) in both Groups, to ensure uniformity. A two-visit endodontic therapy with chemo-mechanical preparation on the first visit and temporization without intracanal medication was performed. Subsequently, the Obturation and permanent restoration with composite were done on the second visit. In this clinical study, postoperative pain was noted to be significantly elevated in the Group MDA in contrast to Group PUA at all three time intervals. A few justifiable factors behind this could be; the inability to control the flow of irrigating agent in the apical zone of the canal, extrusion of debris and bacterial agents beyond the apical foramina, overextension of gutta percha cone, and direct irritation of periapical tissue.[14] Passive ultrasonic activation, on the other hand, is much safer and predictable in application. It disrupts the smear layer and cleans the deep crevices (isthmuses, fins, deltas, and ramifications) without extrusion of debris. As the tip also doesn't touch the dentinal walls, there's no physical damage to the tooth structure, and with the presence of irrigant in the canals, there's a negligible rise in the temperature and hence, minimal damage to the periodontal tissue.[15] It is crucial to note that there was significantly higher analgesic intake in Group MDA as opposed to Group PUA at all three time intervals, indicating a higher intensity of pain encountered by members of Group MDA.

An in-vivo study conducted by Sayed *et al.*, assessed the effect of manual dynamic agitation on postoperative pain after endodontic therapy. The authors of the study deduced that there was substantial post-operative pain at different time intervals after using MDA. According to this study, the main reason for postop pain was the release of inflammatory cytokines due to agitation of periapical tissue.[16] In another study, postoperative pain after 4 different irrigation methods was evaluated. The authors of the study found that the Group with manual dynamic agitation experienced significantly more post-treatment pain as compared to the other three Groups. The authors emphasized that the extrusion of debris and agitation of periapical tissue led to increased pain.[17] Elzainy also conducted a study comparing pain after endodontic therapies with different irrigant activation techniques. The authors in this study concluded that manual dynamic agitation (MDA) led to substantially more post-treatment pain as compared to the control Groups.[18]

With ultrasonic activation, laser, and photodynamic cleaning technology in endodontics, manual dynamic activation shall not be used due to the propensity of this technique to cause postoperative pain and discomfort to the patient. More research is needed in this field to improve the standards of cleaning and disinfection during root canal therapies and enhance treatment outcomes.

LIMITATION OF STUDY

The current study was subject to a few noticeable limitations, majorly operator-influenced. The injury and pain elicited due to anesthetic injection, rubber dam clamp application, and unable to limit the motion of gutta-percha cones during manual activation and keeping the count of strokes in each canal could lead to different outcomes and magnitude of pain.

CONCLUSION

It can be concluded from the results of this study that agitation of irrigants using passive ultrasonic activation (PUA) leads to significantly less postoperative pain in contrast to manual dynamic agitation (MDA). Further research is required in this area for enhanced disinfection techniques and methods to improve the quality of endodontic therapies.

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Authors' Contribution

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

AA & SMH: Data acquisition, data analysis, critical review, approval of the final version to be published.

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

SSHN: Conception, data acquisition, 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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