

Comparison of Quality of Obturation and Lateral Canal Fill (by Sealer) : Ultrasonic Activated versus Non-Ultrasonic Conventional Irrigation Techniques in Root Canal Treatment: A Randomized Controlled Trial

Dated: April 30, 2024

INTRODUCTION

Root canal therapy (RCT) stands as the primary treatment modality for pulpal and periapical diseases ^[1]. An indispensable facet of Root canal therapy involves the meticulous processes of cleaning, shaping, and subsequent obturation of the root canal system, establishing a robust and impermeable seal ^[1,2]. The prognosis of Root canal therapy hinges upon various factors, including irrigation techniques and the technical proficiency of the root filling ^[3].

Throughout its evolution, root canal irrigation has seen diverse methodologies employed to effectively disinfect the root canal space. Traditionally, techniques such as syringe irrigation and passive ultrasonic irrigation have been prevalent ^[4]. However, the introduction of ultrasonic activation irrigation systems has added a dynamic dimension, utilizing ultrasonic energy to augment irrigant flow and disrupt biofilms. Root canal irrigation plays a pivotal role in Endodontics, facilitating instrumentation through lubrication, removal of debris, microorganisms, smear layer, and preventing apical debris packing. Irrigants exert their effects through mechanical, chemical, and biological actions ^[5].

Activated irrigation involves agitating and enhancing the flow of irrigants into the intricacies of the root canal system using mechanical or other energy forms. Unlike conventional irrigation, which relies solely on positive pressure and the viscosity of the irrigant for flow in the root canal system ^[5,6], various mechanical irrigant activation systems are available. These include ultrasonic activation using high or low frequency (e.g., EndoActivator), continuous ultrasonic irrigation (CUI), special holding devices during ultrasonics like Nusstein's needle holding device, sonic energy (RispiSonic file), vibrations (Vibringe), passive ultrasonic irrigation (PUI-IrriSafe), and positive or negative pressure alternating devices (EndoVac, RinsEndo), or manual agitation of

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the irrigant with high amplitude/frequency (MDA) ^[5-7]. The efficacy of irrigation depends on both the mode of delivery and the irrigant itself ^[5].

The primary objective of root canal obturation is to achieve a fluid-tight seal to prevent future microbial contamination ^[8]. Obturation quality encompasses the length of the filling, density of the filling material, and the absence of voids ^[9]. The significance of achieving high-quality obturation cannot be overstated, directly impacting the prevention of microbial ingress and reinfection. Poor obturation may lead to treatment failure, necessitating retreatment and underscoring the importance of a comprehensive understanding of factors influencing obturation quality ^[10,11].

Studies, such as the one by Chen S et al., have compared ultrasonic irrigation with syringe irrigation, revealing a higher incidence of lateral canal fill with ultrasonic irrigation (27% vs. 7% in syringe irrigation) ^[12]. Another study found no statistical difference in irrigant penetration in the main canal compared to control, passive ultrasonic irrigation, continuous ultrasonic irrigation, and easy clean groups ^[13]. Yet, a study demonstrated a significant difference in radiographic healing rates among three groups ($\chi^2=12.29$, $p=0.05$), with higher healing rates observed in the Passive ultrasonic irrigation group (36.8%) and Laser activated irrigation group (42.1%) compared to the Conventional Syringe irrigation group (10.5%) ^[14].

While many studies have explored outcomes such as post-operative pain, periapical healing, antibacterial efficacy, canal cleanliness, debridement efficacy, and delivery up to working length, limited research has directly compared obturation results between irrigation methods. Given the scarcity of data on this outcome and the direct impact of irrigation technique on the obturation quality and lateral canal fill, a systematic investigation is warranted. This study aims to address

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this gap, contributing to the existing knowledge base and guiding clinicians in optimizing their endodontic procedures.

OBJECTIVE

To compare the quality of Obturation and lateral canal fill (by sealer) during root canal treatment between two irrigation techniques—ultrasonic activated irrigation and non-ultrasonic conventional irrigation

OPERATIONAL DEFINITIONS

Obturation Quality and Lateral canal fill

It will include assessing the length of the root canal filling of main canals, evaluating the density of the filling material, determining the taper of root canal filling, and accessing the lateral canal fill by sealer by post- operative radiographs. The radiographs will be evaluated independently by two senior endodontists. A scoring system will be employed and each of three components will be given a score of 0 and 1 with higher scores indicating better obturation quality (Table 1, 2 and 3).

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Table 1. Parameters used to evaluate and score the quality of RCTs

Parameters	Criteria	Definition
Length of root canal filling	Adequate(=1)	Root filling ending \leq 2 mm from the radio-graphic apex
	Inadequate(=0)	Overfilled: root filling extruded beyond the radio-graphic apex
		Under-filled: root filling \geq 2 mm from the radio-graphic apex
Density of root canal filling	Adequate(=1)	Correct density of filling material and no voids present in the root filling nor between root filling and root canal walls
	Inadequate(=0)	Low density of filling material and/or voids present in the root filling or between root filling and root canal walls
Taper of root canal filling	Adequate(=1)	Consistent taper from the coronal to the apical part of the filling

	Inadequate(=0)	No consistent taper from the coronal to the apical part of the filling
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Table 2

T-Score

Score 3	Obtured canals have all three qualities of ideal Obturation. Adequately filled (with in 2mm from radiographic apex). Smooth coronal apical taper. No voids
Score 2	Obtured canals have any two qualities of ideal obturation.
Score 1	Obtured canals have any one quality of ideal obturation.
Score 0	Obtured canals have no quality of ideal obturations

Lateral canal :

A type of accessory canal located in the coronal or middle third of the root, usually extending horizontally from the main canal space.

Table 3

Parameters used to evaluate and score of lateral canal fill

Score 1	Adequate	Lateral canals were filled with
Score 0	Inadequate	Lateral canals were not filled

Non-Ultrasonic Conventional Irrigation

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This group involves the application of irrigating solutions through syringes or irrigation needles during the root canal procedure. 5 ml of 3% sodium hypochlorite (NaOCl) solution will be introduced into each canal via 5cc syringes.

Ultrasonic Activated Irrigation Technique

This group involves the use of ultrasonic device to agitate and activate irrigating solutions within the root canal. VAT-3 ultrasonic activator high frequency device (45KHz \pm 5kHz) [Refine] will be used for this study and 3% sodium hypochlorite (NaOCl) solution will be used for irrigation.

HYPOTHESIS

There is a difference in obturation quality and lateral canal fill between ultrasonic activated irrigation results as compared to conventional irrigation technique in root canal treatment.

MATERIAL AND METHOD

STUDY DESIGN: Double Blinded Randomized Controlled Trial

STUDY SETTING: Operative Dentistry and Endodontics, Peshawar Dental College Peshawar

DURATION OF STUDY: Minimum six months, after the synopsis approval

SAMPLING METHOD: Non-Probability Consecutive Sampling

SAMPLE SIZE: Sample size is calculated using WHO calculator keeping 5% level of significance, 90 % power of test, based on reference study, 27% of sampled population achieved adequate obturation and lateral fill of canals in ultrasonic activated irrigation group as compared

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to conventional non irrigation group which was 7% as shown in (table 4) ^[12]. Expected sample size is 59 participants in each group, total 118 patients.

Table 4 Comparison of lateral canal filling between the two groups

Variable	Group S (n = 30)	Group U (n = 30)	X ²	P value
Lateral canal root canal filling	2 (7)	8 (27)	4.320	0.038

SAMPLE SELECTION:

Inclusion Criteria:

- Both male and female
- Age Group: Adults (18-70) Years
- Patients presenting with pain and sensitivity in the mandibular molars and are advised root canal treatment at our institute after examination and Xray

Exclusion Criteria:

- Teeth with complex root canal anatomy that may complicate the obturation process.
- Pregnancy
- Medically compromised patient including those with uncontrolled diabetes, cardiovascular diseases, immunodeficiency disorders, bleeding disorders, and severe respiratory diseases
- Patients who refused to participate in this study.

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DATA COLLECTION PROCEDURE:

Ethical approval will be obtained from institutional research board of the hospital. Synopsis will be submitted for approval by CPSP. Once approved, patients will then be recruited from the endodontics department of Peshawar dental college who presents complaining of pain and sensitivity in the mandibular teeth and are candidates for RCT after dental examination and Xray teeth. Patients who get enrolled in the study will be screened for eligibility using the inclusion and exclusion criteria. This will be a double blinded study (the participant and the outcome assessor both will be kept blind). A written informed consent will be taken after explaining the purpose of study and will be given the opportunity to ask any questions they may have about the study. Demographic data regarding age, gender, will be noted. Similarly, additional information about the specific tooth under consideration, will be documented. After randomization into either the Non-Ultrasonic Conventional Irrigation or Ultrasonic Activated Irrigation group via block randomization, pre-operative radiographs will be taken to establish baseline conditions. A block size of 6 will be used to ensure equal allocation of participants into each group. The root canal treatment is then performed as per the assigned group, with conventional irrigation involving the use of syringes and 3% sodium hypochlorite solution and Tg Sealer for the Non-Ultrasonic Conventional Irrigation group, and the utilization of the VAT-3 ultrasonic activator high frequency device (45KHz \pm 5kHz) [Refine] for the Ultrasonic Activated Irrigation group and same solution of 3% sodium hypochlorite and Tg Sealer will be used. Post-operative radiographs will be obtained to assess the obturation quality and lateral canal fill. A detailed radiographic proforma

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will be employed to evaluate the length, density, taper of the root canal filling, and lateral canal fill . Each of these components will be scored individually, and an overall

Obturation Quality Score is calculated by summing these scores. Care will be taken in the

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documentation of information so that information bias is reduced. All these information and other demographic will also be recorded into a predesigned proforma. Throughout the data collection process, the research team will maintain strict adherence to data protection and confidentiality guidelines.

DATA ANALYSIS PROCEDURE

Data will be analyzed by using statistical package for social sciences (SPSS) version 25. Mean \pm SD will be measured for numerical data i.e age of the patient. Normality of the data will be calculated by Shapiro Wilk test and Non-normal data will be presented as median (IQR). Frequencies and percentages will be measured for categorical data i.e gender, residence, socioeconomic status, type of tooth (Molars), side of tooth, teeth involved (Mandibular), and categorization of obturation score. Lateral canal Fill quality will be compared in each group by using the chi-square or fischer exact test, keeping p-value ≤ 0.05 as significant. Effect modifiers i.e age, gender, side of tooth and tooth involved will be controlled through stratification. Post stratification chi-square or fischer exact test will be performed by keeping the p-value ≤ 0.05 considered as significant.

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TREATMENT:- A Randomized Controlled Trial**

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Data Collection Proforma

Participant Information:

Participant ID: _____

Age [years]: _____

Gender: [male / female] _____

Residenc [Rural / Urban]: _____

Socioeconomic status [Low / Moderate / High]: _____

- Low = <50K PKR monthly Household income
- Moderate = 50K to 150K PKR monthly household income
- High = > 150K PKR monthly Household income

Type of Tooth: [Mandibular 1st Molar/ 2nd Molar] _____

Side of the Tooth: [Right / Left] _____

Group Allocation:

- Non-Ultrasonic Conventional Irrigation
- Ultrasonic Activated Irrigation.

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Radiographic evaluation of obturation:

Scoring

- Length Score (0/1). _____
- Density Score (0/1). _____
- Taper Score (0/1). _____
- Overall Obturation Quality Score (Sum of individual scores). _____

Radiographic evaluation of Lateral canal Fill :

Lateral canal filling (0/1). _____

Signature of Researcher

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Inform consent form

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Date: 30/04/2024

Patient Name: _____

Father/ Husband Name: _____

I hereby, authorize concern doctor to include me in this study. The doctor has explained to me the procedure of collection of data in detail and I fully understand that being part of this study sample does not make me prone to any complications/ hazards. I have no binding or compulsion to be part of this study and I have freedom to refuse from being part of this sample.

I have read this form and I am satisfied.

Name and signature of patient: _____

