ORIGINAL ARTICLE

Effectiveness of mechanical vs. chemomechanical methods in removing intracanal calcium hydroxide medication: a randomised trial

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Abstract

Objective: To compare the mechanical and chemomechanical methods for removing calcium hydroxide medication from the root canal system.

Method: The triple-blind, randomised clinical trial was conducted at the Department of Operative Dentistry and Endodontics, School of Dentistry, Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad, Pakistan, from December 16, 2022, to June 15, 2023, and comprised patients having necrotic teeth and chronic apical pathosis. They were randomised into groups A and B. On the initial visit, after access opening and chemomechanical preparation, calcium hydroxide paste was placed as an intracanal medication in both groups. the patients were recalled after two weeks. In Group A, calcium hydroxide was removed from the canals using a rotary master apical file, while in Group B, an endoactivator was used to sonically agitate the endodontic irrigant. Verification of placement was done by using a periapical radiograph. Data was analysed using SPSS 26.

Results: Of the 98 individuals assessed initially, 60(61.22%) were included; 34(57%) females and 26(43%) males with age ranging from 19 to 57 years. There were 27(45%) incisors, 22(36.7%) premolars and 11(18.3%) canines. There were 30(50%) patients in each of the 2 groups. The intergroup difference was not statistically significant (p=0.43). Tooth arch did not significantly correlate with the removal method (p=0.79).

Conclusion: Both methods were found to be equally effective in removing water-based calcium hydroxide medication from the endodontic system.

Clinical Trial Number: NCT05744661.

Key Words: Calcium hydroxide, Dental pulp necrosis, Microbiota, Periapical periodontitis, Root canal therapy.

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Introduction

The ultimate target of endodontic therapy is to completely eradicate microbiota from the root canal system.[1] Pulpal necrosis and apical periodontitis are principally caused by microorganisms and their toxic by-products. Lipopolysaccharide, an endotoxin present in all gram-negative bacteria, is responsible for inflammatory reactions and periapical bone resorption.[2] The eradication of these microorganisms is unavoidably the main objective of endodontic therapy.[3] The microbial load in an infected root canal cannot be completely reduced by chemomechanical preparation alone. Owing to the intricate nature of the endodontic system, some microbes can reside in dentinal tubules, apical deltas, isthmus and ramifications.[4] To counteract these hidden microbes, disinfection of the endodontic system by using intracanal medication has been advocated. The most popular intracanal medication in endodontics is calcium hydroxide (Ca[OH]2).[2,3] The universal acceptance is due to its bactericidal potential, anti-osteoclastic activity, and ability to generate a favourable periapical healing response.[5] According to a study[4], $Ca(OH)_2$ medication effectively cleaned 92.5% of root canal systems. Various formulations of $Ca(OH)_2$ are commercially available. These formulations, however, are challenging to eliminate from the endodontic system.[6] $Ca(OH)_2$, if left within the canal, can impose negative implications on the quality of endodontic therapy.[7] Residues of intracanal medication can interact with endodontic sealer and alter its attributes by producing modifications in viscosity, flow and setting time.[8] As a result, it hinders the adherence of sealers to dentinal tubules, impairing their ability to seal. When a zinc oxide-eugenol-based sealer is used, it also encourages apical leakage after obturation. Additionally, prolonged exposure can drastically weaken the mechanical properties of radicular dentin.[3,5] Therefore, before obturation, it is fundamental to eliminate $Ca(OH)_2$ from the endodontic system.[9] Many methods have been proposed to wash out $Ca(OH)_2$ from the endodontic system in an efficient manner, like chemical methods, mechanical methods, chemomechanical methods and lasers. Chemically, chelating agents, like ethylenediaminetetraacetic acid (EDTA), citric acid and maleic acid, have been used for the purpose, along with

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irrigants, like sodium hypochlorite (NaOCl), distilled water, saline and others. Mechanical instrumentation using a manual or rotary file system can efficiently remove $Ca(OH)_2$ medicament.[3-5] The chemomechanical method involves the mechanical agitation of endodontic irrigants by sonic or ultrasonic activation. Rotary and mechanical agitation of irrigants is far more efficacious in removing calcium hydroxide than other techniques.[4,8]

The current study was planned to compare the efficacy of mechanical and chemomechanical methods in removing $Ca(OH)_2$ medication from the canal. The null hypothesis stated that there was no difference between the two methods.

Materials and Methods

The triple-blind, randomised clinical trial was conducted at the Department of Operative Dentistry and Endodontics, School of Dentistry, Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad, Pakistan, from December 16, 2022, to June 15, 2023.

After approval from the institutional ethics review committee, the sample size was calculated using the World Health Organisation (WHO)[10] calculator with 5% level of significance and 90% power. The population mean percentage of remaining Ca(OH)2 under test was taken as 35.49, while the expected population mean with a standard deviation of 5.72 percentage of remaining Ca(OH)2 was 25.82.4 The study followed the Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines[11], and was registered with ClinicalTrials.gov (NCT05744661.

The sample was raised using consecutive non-probability sampling technique. Those included were individuals aged at least 18 years who were visiting the outpatient department (OPD) to receive treatment for single-rooted necrotic teeth with chronic apical periodontitis and straight to moderately curved root canals. Pregnant women, immunocompromised patients, those with any systemic illness, or having non-restorable, periodontally compromised teeth, or teeth that could not be isolated by a rubber dam were excluded.

A trial-independent person randomly assigned the participants to mechanical method Group A and chemomechanical method Group B using the lottery method. Using sealed envelopes with assigned codes for each method, the allocation was concealed. The participants were given all possible information about their inclusion, the intervention, and the trial's risks and benefits. None of the participants, data collectors, or outcome assessors was aware of the assigned groups. A single clinician carried out all the interventions. The type of intervention precluded the possibility of blinding the clinician.

Root canal therapy was performed in accordance with the standard protocols of endodontic treatment. On the first visit, isolation was achieved using a rubber dam after adequate local anaesthesia with 2% lidocaine and 1:100,000 epinephrine. Access opening was done, and canal patency was achieved to working length using an international standard organisation (ISO) 15K endodontic file. Working length was confirmed using a digital periapical radiograph supplemented by an electronic apex locator (Woodpex V, Woodpecker, China). Chemomechanical preparation was done using a file system (Protaper Universal, Dentsply Sirona, United States) under optimum irrigation with 5.25% sodium hypochlorite (NaOCl) in a 5ml volume. The canals were dried using absorbent paper points. Using a lentulospiral, water-based $Ca(OH)_2$ (UltraCal XS paste, Ultradent, US) was then placed inside the canals. Verification of medication placement was done using periapical radiography. The tooth was temporarily restored using provisional restorative material (Fermin, DETAX, Ettlingen, Germany). The patients were recalled after two weeks. On the second visit, the water-based $Ca(OH)_2$ medication was eliminated using one of the two methods.

In Group A, a rotary master apical file, which was used previously for canal preparation, was used at a rotational speed of 250rpm and 2.0N/cm torque to remove $Ca(OH)_2$paste along with copious irrigation using 5ml of 5.25% NaOCl solution. In Group B, the access cavity was filled with 5.25% NaOCl irrigant in a 5ml volume. Consequently, EndoActivator (Dentsply Sirona, US) with a flexible polymer tip #25 with a 0.04 taper set at 10,000 cycles per minute and fitting loosely within 2mm of working length was used to hydrodynamically agitate the intracanal irrigant solution. This enabled the sonic activation of the irrigant for 30-60 seconds to effectively remove $Ca(OH)_2$.

Periapical radiography was performed to assess the removal of $Ca(OH)_2$ medication following each method. Two periapical radiographs were taken; one after the placement of the medication, and the other following its removal. All interventions were performed by the principal investigator, while the radiographs for outcome assessment were evaluated by two calibrated evaluators blinded to the study groups.

A 4-point scoring system for radiographic evaluation of the intracanal medication removal was used[4,12] to assess the primary outcome, with score 0 indicating no visible

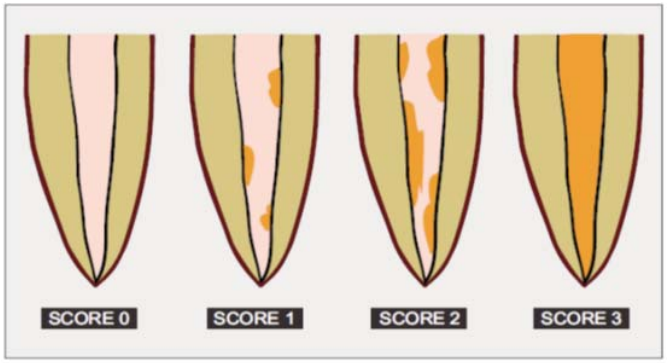

Figure-1: A 4-point scoring system for the effectiveness of calcium hydroxide removal from the root canal system.

$Ca(OH)_2$ residue, score 1 showing scanty deposits, score 2 indicating distinct Ca(OH)2 clumps, and score 3 meaning densely packed residues (Figure 1).

Data was analysed using SPSS 26. Shapiro-Wilk and Kolmogorov-Smirnov tests were used to assess data normality, and a significant deviation from normality was noted in the score distribution for both the methods. To observe the variation between the two methods for the efficient elimination of water-based $Ca(OH)_2$ medication, non-parametric Mann-Whitney U test was used. To ascertain the relationship between tooth arch and removal technique, chi-square test was performed. $P<0.05$ was taken as significant.

Results

Of the 98 individuals assessed initially, 60(61.22%) were included; 30(50%) in each of the 2 groups (Figure 2). There were 34(57%) females and 26(43%) males with age ranging 19-57 years. There were 27(45%) incisors,

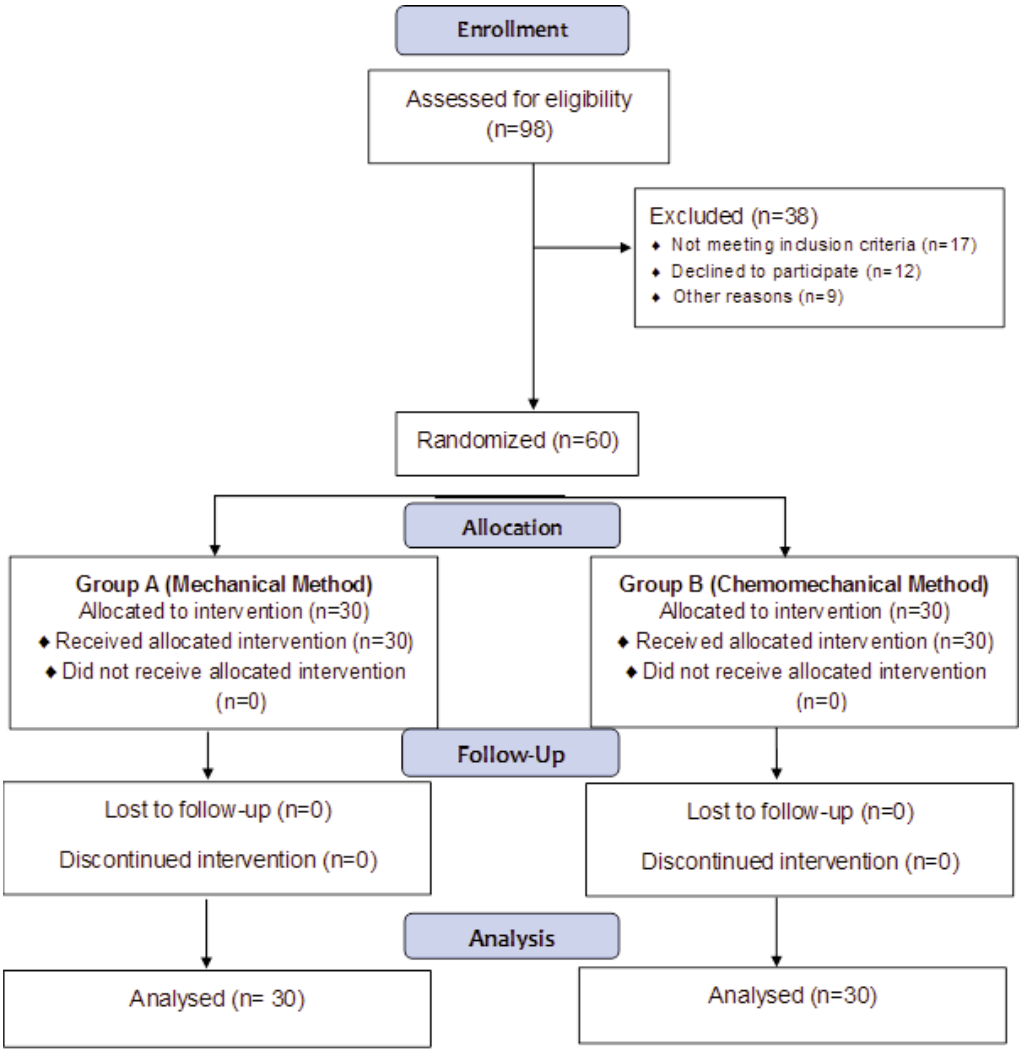

Figure-2: Consolidated standards of reporting trials (CONSORT) flowchart[11]

Table-1: Intergroup comparison of water-based calcium hydroxide removal efficiency

Group	Removal Method	n	Mean Rank	Sum of Ranks	Mann-Whitney U	p-value
A	Mechanical Method	30	32.00	960.00	405.00	0.43
B	Chemo mechanical Method	30	29.00	870.00		

* p-value ≤ 0.05. Mann-Whitney U test

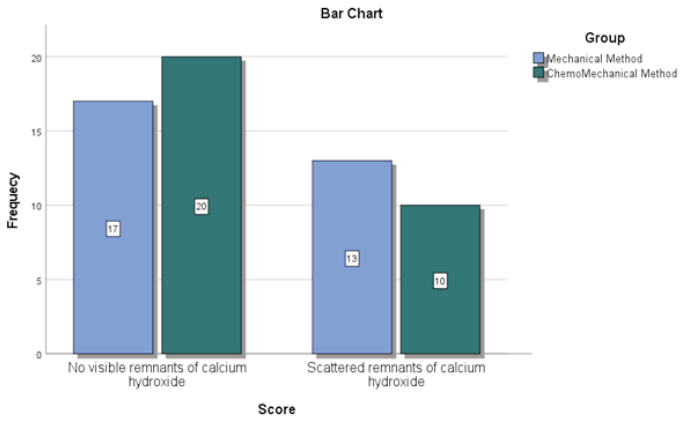

Figure-3: Independent sample distribution. The X-axis depicts the frequency of participants, while the Y-axis represents the sum of each group's scores.

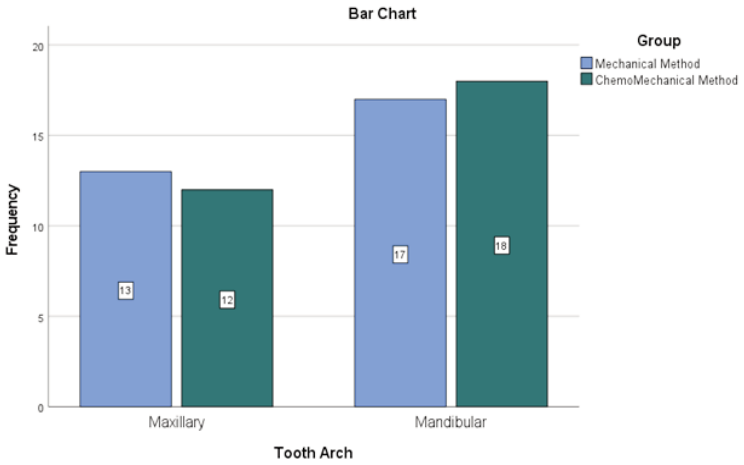

Figure-4: Association between study groups for calcium hydroxide removal method and tooth arch.

Table-2: Association between tooth arch and water-based calcium hydroxide removal method.

Removal Method	Arch		Chi-square Value	p-value
	Maxilla	Mandible		
Mechanical Method	13	17	0.06	0.79
Chemo mechanical Method	12	18		

* p value ≤ 0.05. Chi-square Test.

22(36.7%) premolars and 11(18.3%) canines in the overall sample.

The intergroup difference was not statistically significant (p=0.43) (Table 1, Figure 3).

Table-3: Gender and age distribution.

	Tooth Arch		Group	
	Maxillary	Mandibular	Mechanical Method	Chemomechanical Method
Gender				
Male	12	14	14	12
Female	13	21	16	18
Age				
(19-26) years	10	9	9	10
(27-34) years	6	9	7	8
(35-42) years	5	9	6	8
(43-49) years	3	5	6	2
(50-57) years	1	3	2	2

Tooth arch did not significantly correlate with the removal method (p=0.79) (Table 2, Figure 4). During trial, no negative effects were noticed in any of the patients.

Female patients had a higher number of teeth in both the maxillary and mandibular arches regardless of the tooth arch groupings and treatment methods, while age group 19-26 years had the highest number of instances, with the number of cases decreasing with increasing age (Table 3).

Discussion

Disinfection of the endodontic system is an indispensable constituent of successful root canal therapy. Chemomechanical preparation alone cannot accomplish this objective, especially in situations with chronic apical pathosis. The prodigious load of endodontic microflora necessitates the application of intracanal medicaments in routine clinical practice. Intracanal medicaments not only preclude interappointment bacterial proliferation, but also provide a physiochemical barrier against root canal infection.[9,12] $Ca(OH)_2$, being the most common intracanal medicament, has an eminent role in root canal disinfection. $Ca(OH)_2$'s ability to kill bacteria is comparable to the delivery of hydroxyl ions. These extremely reactive ions generate alkalinity in the medium that leads to deoxyribonucleic acid (DNA) damage and protein denaturation, and alters bacterial cytoplasmic membranes.[13] Absolute elimination of

medicament is required before obturation to accomplish predictable bonding between the endodontic system and the root canal sealer.[14] Owing to its small particle size, $Ca(OH)_2$ can easily block dentinal tubules by forming calcium carbonate crystals.[7,10] As a result, endodontic sealers' permeability and sealing capacity are affected.

The effectiveness of medication removal has been examined in numerous trials using a variety of methods and equipment. In a study[12], the EndoActivator was found to be more effective than Wave One file alone while eliminating $Ca(OH)_2$ from the middle and apical thirds of canals ($p<0.05$). Its supremacy was attributed to the sonic agitation of intracanal fluids through acoustic streaming and cavitations that eliminate $Ca(OH)_2$ from inaccessible areas and lateral canals.[3,14] In another study[13], residual $Ca(OH)_2$ was significantly less in the root canal as a whole using sonic and ultrasonic systems compared to Protaper rotary files ($p=0.0001$). However, the results of the current trial delineated no significant variation between the effectiveness of the Protaper rotary file system and the sonic agitation of irrigants by EndoActivator in the elimination of intracanal medicaments ($p>0.05$). The direct applicability of these results can benefit patients treated under optimal clinical conditions regarding endodontic treatment and disinfection of canals.

Residual $Ca(OH)_2$ in the endodontic system has been measured using a multitude of techniques, including cone beam computed tomography (CBCT), spiral CT, stereo microscopes, scanning electron microscopes, and digital imaging software.[14] Owing to its cost-effectiveness and low radiation dose, the current study utilised periapical digital radiography to determine the efficacious removal of medicament from the endodontic system.[15] Additionally, the presence of a positive correlation between periapical radiographs and clinical inspection signifies the importance of periapical radiographs in the confirmation of intracanal medicament removal.[16]

A study[5] highlighted the significance of the vehicle used for $Ca(OH)_2$ medicament in the ease of its removal. The vehicle mixed with $Ca(OH)_2$ powder not only influenced the velocity of ionic dissociation, but also its rate of resorption within the root canal and by periapical tissues.[17] The current study used $Ca(OH)_2$ medication in a water-based formulation. The significance of using an aqueous formulation in this trial was on account of its ease of availability and widespread acceptance as an intracanal medicament.[17,18] Besides the role of viscosity and water- or oil-based vehicles on the retention of $Ca(OH)_2$, other significant factors include canal shape and its curvature.[4,19] By using Schneider's method[20], the current study was conducted on single-rooted teeth with root canals that were either straight or moderately curved. In the current study, $Ca(OH)_2$ medication was placed inside the root canal for two weeks. This was in conformity with the literature dictating that $Ca(OH)_2$ requires a minimum duration of 14 days to achieve a satisfactory outcome.[21] Secondly, follow-up after two weeks was feasible for patients as well. The strength of the current clinical trial was the blinding of the outcome assessor about group allocation and the practicality of follow-up duration.

The current study has its limitations as it compared only mechanical methods for the elimination of $Ca(OH)_2$ (rotary master apical file) with one of the chemomechanical methods (sonic agitation of intracanal irrigant). However, the chemomechanical method also involves an ultrasonic system for the effective removal of intracanal medicaments. A study[20] suggested that ultrasonic systems were more effective than sonic activation of irrigants in removing $Ca(OH)_2$. The EndoActivator was proven to be better than other methods in a subsequent study[3]. Both sonic and ultrasonic systems should be compared in future studies. Also, the current study did not compare medicament removal at three-thirds of the root canal (coronal, middle, and apical). Furthermore, periapical digital radiography was used to assess medication removal. The two-dimensional (2D) nature of such radiographs results in greater errors in evaluation than advanced imaging modalities.[16] An in-vitro study could complement the clinical findings of the current trial.

Conclusion

There was no significant variation between the two removal techniques, as both were found to be equally effective in eliminating water-based Ca(OH)2medication from the root canal system.

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Conflict of Interest: None.

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Authors' Contribution:
NA: Concept, methodology, data acquisition and writing.
NN: Supervision, critical review and final approval.