

Evaluation of Paste and Aqueous Lubricants on the Incidence of File Breakage, Quality of Obturation and Postoperative Pain in Children after Pulpectomy in Primary Teeth: A Randomised Clinical Trial

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ABSTRACT

Introduction: Pulpectomy in primary teeth involves various steps, including tooth isolation, access opening, canal instrumentation, and obturation. Lubricants are commonly used in the biomechanical preparation of root canals to suspend and emulsify debris generated by the mechanical action of hand and rotary files. While paste-type lubricants (Prime Dental RC Help) and aqueous lubricants (17% aqueous Ethylenediaminetetraacetic acid [EDTA]) are available for use, there is a lack of studies in the literature documenting the effects of these lubricants on file fracture, obturation quality, and postoperative pain.

Aim: To compare the effects of paste-type lubricants with aqueous lubricants on file breakage, quality of obturation, and postoperative pain in children treated with pulpectomy in primary teeth.

Materials and Methods: This randomised clinical trial involved 40 primary teeth, evenly distributed for instrumentation using Kedo-S Plus pediatric rotary files. In Group 1 (n=20), paste-type lubricant was used during canal preparation, while in Group 2 (n=20), aqueous lubricant was used. The clinician recorded

data on file fractures, evaluated the quality of obturation using immediate postoperative radiographs, and measured postoperative pain using the Four-point facial pain intensity rating scale. Descriptive statistics were performed once the data was tabulated.

Results: Total of 40 primary teeth were included, participants aged 4-9 years, 22 girls and 18 boys. There was no incidence of file fracture in the group-2 treated with aqueous lubricants. Regarding the quality of obturation, the group-1 treated with paste-type lubricant had a higher number of under-fill and over-fill cases (p=0.002, 0.001), while no statistically significant difference was observed between the groups in terms of optimal fill (p=0.661). At 6, 12, 24, and 48 hours, there was no difference in pain experienced by the participants in both groups (p>0.05).

Conclusion: During rotary instrumentation in primary teeth, aqueous lubricants were found to be more effective than paste-type lubricants in preventing file breakage, providing optimal obturation quality, and reducing postoperative pain.

Keywords: Biomechanical preparation, Disinfection, Root canal lubricants, Smear layer

INTRODUCTION

Biomechanical preparation, which involves shaping and cleaning the root canals, is an essential step in pulpectomy or root canal therapy. Lubricants are commonly used to emulsify and suspend the debris produced during the mechanical instrumentation of the root canals [1]. These lubricants are available in liquid or paste form. The commercially available paste-type lubricants for this purpose include Prime Dental RC Help, Glyde, and Dentsply, which contain 10% carbamide peroxide and 15% EDTA. Aqueous lubricants such as Prime Dent Wash and Vista 17% EDTA solution are also commercially available.

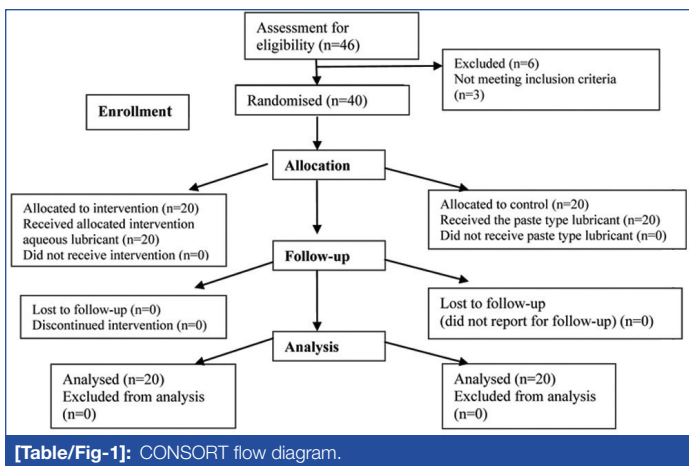
When EDTA is used along with irrigants like NaOCl, it enhances effective clearance by lifting dentinal shavings and debris through effervescing action [2]. Chelating chemicals like EDTA form complexes with dentine mud, calcific deposits, or smear layers on canal walls, resulting in the production of calcium complexes. These complexes replace calcium ions with sodium ions, leading to the formation of less soluble mixtures that interact with dentine and generate soluble salts. By removing the smear layer and making solutions more accessible, this process may aid in preventing apical obstruction and promoting disinfection [3]. While NaOCl acts on organic components, calcium-chelating lubricants dissolve root canal debris by targeting the inorganic components. Unlike paste-type lubricants, smear layer,

liquid or aqueous lubricants containing 17% EDTA do not produce smear layer [2,4].

Several in-vitro experiments have compared the effectiveness of liquid and paste-type lubricants in eliminating the smear layer during root canal instrumentation [5,6]. However, to the best of our knowledge, no clinical trials have evaluated the effects of lubricants on clinical parameters such as the occurrence of file fractures, quality of obturation, and postoperative pain experienced by patients. Furthermore, no research has explored the effects of lubricants in primary teeth. In light of these gaps, this study was conducted to assess the effectiveness of paste-type and aqueous lubricants during root canal preparation in primary teeth. The clinical factors evaluated in this study were the incidence of file fractures, quality of obturation, and postoperative discomfort in children.

MATERIALS AND METHODS

This randomised clinical trial was conducted in the Department of Paediatric and Preventive Dentistry at Saveetha Dental College and Hospital from December 2021 to April 2023, following ethical approval from the Institutional Review Board (IHEC/SDC/PEDO-2003/21/664). The study adhered to the ethical standards outlined in the 1964 declaration of Helsinki and its subsequent amendments. The CONSORT checklist was used to report the findings [Table/Fig-1].



Sample size: The sample size for the study was calculated based on a previously published study [5]. Using G-Power software Version 3.1.9.2 (Kiel University, Germany), a sample size of 40 was determined with 95% power. All 40 primary molars were instrumented using a standard rotary file system (Kedo S Plus) by a single operator to maintain uniformity and prevent bias. The participants were equally distributed and randomly assigned to two groups. Randomisation was performed using a computer-generated sequence of random numbers. The sequence was pre-numbered and sealed in opaque envelopes to ensure concealment. As each participant was recruited, the operator who performed the procedure opened the envelope to determine the type of root canal lubricant to be used for that particular participant.

In Group-1 (n=20), Paste type lubricant (Prime Dental RC) was used during instrumentation and in Group-2 (n=20), aqueous lubricant (17% EDTA solution) was used during instrumentation.

Inclusion criteria: The study included primary molars requiring pulpectomy as definitive treatment with adequate amount of crown structure and at least two-thirds of the root intact.

Exclusion criteria: Primary molars with pathological root resorption or sinus openings were excluded from the study.

Procedure

After applying local anesthesia with 2% lidocaine containing 1:200,000 adrenaline (LOX*2% ADRENALINE, Neon Laboratories Limited, India), the primary molar to be treated was isolated using the rubber dam isolation technique (GDC Marketing, India). Dental caries was excavated, and access opening was performed using a #6 round bur (Dentsply Maillefer, OK, USA). After establishing patency with a #15 hand K-file (Mani, Inc., Tochigi, Japan), chemo-mechanical preparation of the primary root canals was performed using the Kedo-S Plus rotary file system (Reeganz Dental Care Pvt., Ltd., India) until the working length was reached. X-smart endodontic motor (Dentsply Maillefer, OK, USA) was used at 300 rpm and 2.2 N cm torque. Total of 40 teeth included, were divided into two samples:

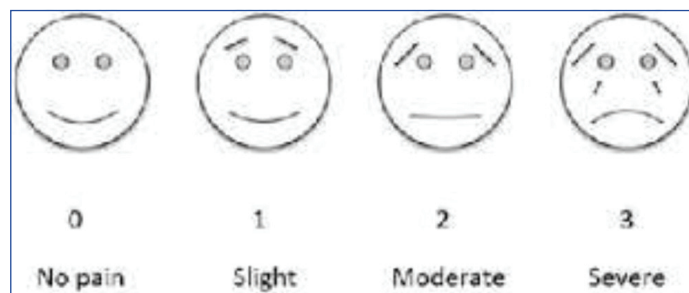
- In Group 1 (n=20), the rotary file was coated with paste-type lubricant (Prime Dental RC) and used during instrumentation,
- In Group 2 (n=20), aqueous lubricant (17% EDTA solution) was used in a syringe to rinse the canal during instrumentation.

After each use, the rotary file was examined under a magnifying glass for signs of fracture. Saline irrigation was performed, followed by drying and obturation of the canals with metapex. The quality of obturation was evaluated immediately after the procedure using radiographs and classified as optimal, underfilled, or overfilled according to Coll and Sadrian's criteria [7] [Table/Fig-2]. Additionally, postoperative pain experienced by the children was assessed at 6, 12, 24, and 48 hours after pulpectomy using the Four-point facial pain intensity rating scale [8] [Table/Fig-3]. The primary investigator instructed parents on how to use the pain scale. A score of 0

indicated no pain, while a score of 3 indicated severe pain. Phone calls were made to the parents or guardians at 6, 12, 24, and 48 hours to record the pain scale value. The patient was advised to take analgesics if any pain occurred during this time.



[Table/Fig-2]: Quality of obturation classified according to coll and Sadrian's criteria namely, a) Under-filled obturation; b) Over-obturation; c) Optimal obturation.



[Table/Fig-3]: Four-point facial pain intensity rating scale used to record pre- and postoperative pain.

STATISTICAL ANALYSIS

The obtained data was tabulated, and descriptive statistics were performed using Statistical Package for Social Sciences(SPSS) software version 23.0 (SPSS Inc., Chicago, Illinois, USA). The quality of obturation and postoperative pain were compared between groups using the chi-square test. Statistical significance was set at p<0.05.

RESULTS

All participants included in the study were between the ages of 4 and 9 years, with 22 girls and 18 boys, and a mean age of 5.9±0.5 years. A total of 20 maxillary molars (10 per group) and 20 mandibular molars (10 per group) were included in the study, as shown in [Table/Fig-4].

Groups	No. of maxillary teeth	No. of mandibular teeth	No. of maxillary canals	No. of mandibular canals
Group-1	10	10	30	35
Group-2	10	10	30	35
Total	40 teeth		130 canals	

[Table/Fig-4]: Distribution of samples based on tooth type and number of root canals.

Fracture incidence was observed in only two out of the 40 assessed teeth, both of which occurred in teeth instrumented with paste-type lubricant. The difference between the groups was statistically significant (p=0.001), as shown in [Table/Fig-5].

Groups	No. of fractured instrument	%	p-value	Canal/Tooth
Group-1	2	5	0.001	Mesiobuccal canal of maxillary second primary molar
Group-2	0	0		-

[Table/Fig-5]: Incidence of fracture.

The quality of obturation was the second major criterion assessed, and the majority of teeth in both groups showed optimal filling. However, there was no statistically significant difference between the groups (p=0.661). The number of underfilled and overfilled teeth was higher in the group treated with paste-type lubricant, and this difference was statistically significant (p=0.002) (p=0.001), suggesting that the quality of obturation was better with the use of aqueous lubricant, as shown in [Table/Fig-6].

Quality of obturation	Group-1 (Paste type)	Group-2 (Aqueous type)	p-value
Under fill	20% (n=4)	10% (n=2)	0.002*
Optimal fill	45% (n=9)	65% (n=13)	0.661
Over fill	35% (n=7)	25% (n=5)	0.001*

[Table/Fig-6]: Quality of obturation.

*p-value <0.05 statistically significant

Postoperative pain measured at 6, 12, 24, and 48 hours was evaluated and tabulated. After 6 and 12 hours, the children in both groups either felt no discomfort or had slight pain, with no statistically significant difference between the groups (p=1.000). However, after 24 hours, 10% of the children treated with paste-type lubricant showed moderate pain, but this difference was not statistically significant (p=0.561). At the end of 48 hours, none of the children in both groups complained of pain, as shown in [Table/Fig-7].

Data on pain intensity	Group-1 (Paste type lubricant)	Group-2 (Aqueous type lubricant)	p-value
Pain after 6 hours			
No pain (0)	60% (n=12)	75% (n=15)	1.000
Slight pain (1)	40% (n=8)	25% (n=5)	
Moderate pain (2)	0	0	
Severe pain (3)	0	0	
Pain after 12 hours			
No pain	85% (n=17)	90% (n=18)	1.000
Slight pain	15% (n=3)	10% (n=2)	
Moderate pain	0	0	
Severe pain	0	0	
Pain after 24 hours			
No pain	65% (n=13)	85% (n=17)	0.561
Slight pain	25% (n=5)	15% (n=3)	
Moderate pain	10% (n=2)	0	
Severe pain	0	0	
Pain after 48 hours			
No pain	100% (n=20)	100% (n=20)	1.000
Slight pain	0	0	
Moderate pain	0	0	
Severe pain	0	0	

[Table/Fig-7]: Frequency and intensity of postoperative pain after six hours.

DISCUSSION

Successful pulpectomy relies on complete root canal cleansing, which is influenced by the type of mechanical instrumentation, chelators, and irrigants used, even in primary teeth. The removal of the smear layer, achieved through chelating agents like EDTA, is crucial for complete disinfection of the root canal [5]. EDTA has been recommended as a lubricant for rotary root canal instrumentation in

both primary and permanent teeth [9]. EDTA works by replacing sodium ions with calcium ions, aiding in the removal of the smear layer and preventing obstruction of the canal [1-3,10].

Debates exist regarding the cleansing potential of EDTA in rotary instrumentation and the preference for paste-type or liquid lubricants [1-3,10]. Liquid EDTA, combined with detergents and surfactants, has been proposed as a lubricant for root canal preparation, particularly during rotary nickel-titanium instrumentation, which is the preferred technique in pediatric endodontics [11-13].

This study aimed to compare the incidence of file fracture, quality of obturation, and postoperative pain using a single rotary file system with two different lubricants. These outcomes help determine the ideal lubricant for biomechanical preparation in primary teeth [14]. While some studies have examined the effectiveness of chelating agents with paste or gel consistency in smear layer removal during rotary root canal instrumentation, none have specifically compared them in primary teeth [3,4,9,10].

The present study found a lower incidence of file fracture when using aqueous EDTA compared to paste lubricants. The formation of a smear layer-like compound with paste lubricants may contribute to file fracture [15], which was not observed with aqueous lubricants. This difference was statistically significant, highlighting the potential for paste-type lubricants to cause file fracture in primary teeth.

Regarding the quality of obturation, the percentage of underfill and overfill was higher with paste-type lubricants, and this difference was highly statistically significant (p=0.002, 0.001). This suggests that obturation quality was better with the use of aqueous lubricants, which could access all apical regions of the root canals as a final rinse.

These findings align with similar studies by Chen G and Chang YC, who reported that paste-type lubricants were more challenging to use in narrow or calcified canals, resulting in limited effects on smear layer removal [3]. Peters OA et al., also found that aqueous lubricants performed better in reducing torque and force during rotary instrumentation and recommended their use as a final rinse after rotary biomechanical preparation [4].

Based on these findings and comparisons with previous studies [3,4], it is advisable to use paste-type lubricants for initial preparation and to obtain canal patency, followed by the use of aqueous lubricants as a final rinse after complete biomechanical preparation.

Limitation(s)

This study did not compare different types and concentrations of aqueous and paste-type lubricants. Further research comparing the effects of these lubricants on torque and force in pediatric rotary files used during pulpectomy could provide more detailed analysis and insights.

CONCLUSION(S)

The aqueous lubricants are found to be more effective than paste-type chelators in achieving optimal quality of obturation and preventing file breakage. Future studies should include larger sample sizes and consider analysing the torque values of files used during biomechanical preparation, as done in permanent teeth. Additionally, further research should explore the interaction of these lubricants with the irrigating solutions used in primary teeth.

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