

"Evaluating the quality of obturation after pulpectomy of primary molars in children aged 4-9 years using hand and rotary instrumentation - A randomised clinical trial"

Running Title: "Evaluating the Quality of Root Canal Fillings in Primary Molars of Children Aged 4-9 Years Using Hand and Rotary Instruments: A Randomized Clinical Trial"

Dr. Shivayogi M. Hugar^{1*}, Dr. Snehal S. Kumthekar¹, Dr. Vedika Pitta¹, Dr. Chandrashekhar Badakar¹, Dr. Shweta Kajjari¹, Dr. Shweta S Hugar¹, Dr. Aishwarya A. Patil¹, Dr. Akanksha Dumbare¹

^{1*}Department of Pediatric and Preventive Dentistry, KAHER'S KLE VK Institute of Dental Sciences, KLE Academy of Higher Education and Research, Belagavi, Karnataka, India

¹Professor (Dr. Shivayogi M. Hugar) | Post Graduate Student (Dr. Snehal S. Kumthekar, Dr. Vedika Pitta, Dr. Aishwarya A. Patil, Dr. Akanksha Dumbare) | Professor and Head (Dr. Chandrashekhar Badakar) | Reader (Dr. Shweta Kajjari)

¹Department of Periodontics (Dr. Shweta S Hugar) | Reader

¹ORCID: <https://orcid.org/0000-0003-3657-6709> | ORCID: <https://orcid.org/0009-0009-4797-0016> |
ORCID: <https://orcid.org/0009-0003-1462-261X> | ORCID: <https://orcid.org/0000-0002-5590-6534> |
ORCID: <https://orcid.org/0000-0003-2328-1936> | ORCID: <https://orcid.org/0000-0003-1124-4388> |
ORCID: <https://orcid.org/0009-0000-7521-6138> | ORCID: <https://orcid.org/0009-0000-3086-9872>

¹Email: dr.hugarsm@gmail.com | Phone: +91 9986436448

***Corresponding Author:** Dr. Shivayogi M. Hugar, Professor, Department of Pediatric and Preventive Dentistry, KAHER'S KLE VK Institute of Dental Sciences, KLE Academy of Higher Education and Research, Belagavi, Karnataka, India | ORCID: <https://orcid.org/0000-0003-3657-6709> | Email: dr.hugarsm@gmail.com | Phone: +91 9986436448

Abstract

Background: Hand K-files have traditionally been used for chemo-mechanical preparation in primary teeth, but process is time-consuming and technique-sensitive. Rotary files offer more efficient, enabling faster instrumentation and improved clinical outcomes in Pediatric endodontics.

Aim: Aim of this study was to evaluate and compare obturation quality after pulpectomy using hand and rotary instrumentation in primary molars of children aged 4-9 years.

Materials and Methods: Randomized clinical trial was conducted in healthy children aged 4-9 years, assigned to two groups: Control group (Group A) underwent chemo-mechanical preparation with hand K-files, while experimental group (Group B) was treated using Kedo Nano Plus rotary system. Instrumentation time was recorded with stopwatch. Obturation quality was assessed using Modified Coll and Sadrian criteria and Postoperative pain was evaluated using Wong Baker Faces Pain Rating Scale (WBPS) at 24, 48 and 72 hours. Statistical analysis included descriptive statistics, Chi-square, Independent and Dependent t-tests, Mann-Whitney U, and Wilcoxon matched-pair tests, with significance set at $p < 0.05$.

Results: Instrumentation time was lower in rotary files (Experimental Group) with very highly statistically significant 'p' value of 0.0001. Rotary instrumentation resulted in superior obturation quality, with higher number of optimally filled canals ($p = 0.0001$). Postoperative pain at 24 hours was lower with rotary files which was very highly statistically significant ($p = 0.0001$) than with conventional files.

Conclusion: Kedo Nano Plus rotary system demonstrated superior efficiency, enhanced obturation quality and reduced postoperative pain, making it viable alternative to conventional hand K-files for pulpectomy in primary molars.

Keywords: Children, Dentistry, Hand instrumentation, Pulpectomy, Rotary instrumentation

How to cite this article: Hugar SM, Kumthekar SS, Pitta V, Badakar C, Kajjari S, Hugar SS, Patil AA, Dumbare A. Evaluating the quality of obturation after pulpectomy of primary molars in children aged 4-9 years using hand and rotary instrumentation - A randomised clinical trial. Int J Drug Deliv Technol. 2026;16(71s): 1219-1230. DOI: 10.25258/ijddt.16.71s.143

"Evaluating the quality of obturation after pulpectomy of primary molars in children aged 4-9 years using hand and rotary instrumentation - A randomised clinical trial"

Introduction

Dental caries is one of the most prevalent chronic diseases affecting children worldwide, with a significant impact on oral health and overall well-being.^[1] Untreated caries in primary teeth can progress rapidly due to thinner enamel and dentin, leading to pulpal involvement, pain and infection.^[2]

Pulpectomy is the treatment of choice for primary teeth with pulp involvement due to caries or trauma. Performing root canal therapy in primary dentition is complex, demanding and time-intensive due to intricate and irregular canal morphology, proximity to developing permanent tooth bud and additional challenge of managing pediatric patient behavior.^[3]

Premature loss of primary teeth can disrupt arch integrity, leading to reduction in available space for succedaneous teeth. As a consequence of this, an increased risk of premolar impaction and mesial drifting of adjacent molars can be seen. Therefore, maintaining primary teeth through effective endodontic management is essential for ensuring proper occlusal development and long-term dental stability.^[4] The field of Pediatric Dentistry has transitioned from a surgically driven approach to a more conservative strategy focused on preserving primary teeth until their natural exfoliation. This retention plays a crucial role in maintaining proper occlusal development and ensuring efficient mastication.^[5]

In Pediatric Dentistry, pulpectomy is a vital therapeutic intervention designed to preserve primary dentition until its physiological exfoliation.^[4] This therapy aims to achieve complete disinfection of root canal system by eradicating infected pulp tissue and thoroughly debriding canal space to facilitate its obturation with a biocompatible material. This process is critical in preventing microbial recolonization and minimizing risk of reinfection. However, non-adherence to established clinical protocols can compromise treatment outcomes, leading to endodontic failure.^[6]

Primary teeth exhibit significantly greater constriction at dentino-enamel junction (DEJ) as compared to permanent teeth. This causes increased risk of pulpal exposure at cervical constriction during proximal cavity preparation, particularly when cavity depth is excessive. The contact regions in primary dentition are broader, flatter and positioned more gingivally, whereas in permanent teeth, they tend to be narrower and located occlusally. Consequently, proximal cavity preparations in primary teeth should be wider at gingival margin than those in permanent teeth. Additionally, roots of primary molars are relatively more elongated and slender compared to those of permanent molars.^[7] The pulp chambers in primary teeth are proportionally larger than in

permanent teeth, with pulp horns, especially mesial horns, extending higher in primary molars. Hence, this anatomical variation increases risk of accidental pulp exposure.^[8]

Mechanical shaping and cleaning of root canals is a fundamental phase in pulpectomy for primary teeth, with primary emphasis placed on thorough canal decontamination.^[9] Previously, manual files were utilized for root canal cleaning and shaping in primary teeth; however, they presented certain drawbacks, including prolonged procedure duration and higher likelihood of procedural errors such as zipping, lateral perforations and canal misalignment.^[10]

Advent of nickel-titanium (NiTi) rotary systems has streamlined endodontic procedures in permanent dentition, offering greater efficiency and speed as compared to conventional manual techniques while ensuring uniform and reliable canal shaping. Same fundamental principles of root canal cleaning and dentin contouring with NiTi instruments can be effectively adapted for primary teeth. Rotary instrumentation was first introduced in Pediatric endodontics by Barr et al in 2000.^[11] Over past decade, various rotary nickel-titanium (NiTi) file systems have been developed to enhance the efficiency of canal preparation. Despite these advancements, most of these systems require multiple sequential files to achieve desired canal shape. More recently, introduction of single-file system has sparked discussion regarding their feasibility and effectiveness in modern endodontic practice.^[12]

Recently, specialized Pediatric rotary files have been introduced as an alternative to traditional manual instrumentation. When literature review was conducted, it revealed limited research on clinical effectiveness of Kedo Nano Plus rotary files. Therefore, this study aimed to evaluate and compare obturation quality after pulpectomy using hand and rotary instrumentation in primary molars of children aged 4-9 years.

Materials and methods

This study is a prospective, in vivo, two-arm, parallel-group randomized clinical trial conducted on patients attending the outpatient clinic of Department of Pediatric and Preventive Dentistry. Ethical approval was granted from Research and Ethics Committee and permission to conduct the study was obtained from Institutional Review Board. Furthermore, study was prospectively registered in the Clinical Trials Registry-India (CTRI)^[13] under registration number of CTRI/2025/02/080459 and was conducted in adherence to the CONSolidated Standards of Reporting Trials (CONSORT)^[14] guidelines [Figure 1].

"Evaluating the quality of obturation after pulpectomy of primary molars in children aged 4-9 years using hand and rotary instrumentation - A randomised clinical trial"

Before initiating the study, written informed consent was obtained from the parents of all participating children. The study included children aged 4 to 9 years who exhibited definitely positive (++) or positive (+) behavior on Frankl's Behavior Rating Scale, with primary molars showing history of spontaneous pain or diagnosis of irreversible pulpitis and at least two-thirds of root structure remaining intact. Children were excluded from study if they had systemic diseases or special healthcare needs. Non-vital primary molars exhibiting signs of abscess, sinus tract formation or fistula were also excluded. Additionally, teeth with pathological mobility, root fractures or history of trauma were not considered. Primary molars presenting with furcation radiolucency, calcified root canals or significant root resorption exceeding two-thirds of root length were excluded, along with those showing internal resorption

$$n = \frac{2S^2(z_{1-\alpha} + z_{1-\beta})^2}{d^2}$$

or developmental anomalies. Furthermore, children who were unwilling to undergo treatment were not included in the study.

The sample size was determined using a standard statistical formula, based on a prior study, with a 90% confidence level and a significance level of $p = 0.05$.^[15] A total of 50 samples were randomly allocated into two equal groups through simple random sampling, employing lottery method to maintain standardization. To ensure unbiased allocation, an independent Pediatric dentist from Department of Pediatric and Preventive Dentistry was responsible for assigning children to respective groups. Detailed case history was documented, followed by clinical evaluation to determine nature of pain and type of pulpal pathology.

All clinical procedures were performed by a single operator following standardized protocols. Pulpectomy was carried out on primary molars in both groups. Local anesthesia was administered and isolation was achieved using a rubber dam. Access cavity preparation was performed with a No. 330 endo access bur, ensuring complete removal of coronal pulp tissue. Pulp extirpation from all root canals was carried out using an endodontic file. Working length was determined using Ingle's radiographic technique.

In control group (Group A), chemomechanical preparation was initiated using first endodontic K-file that exhibited binding within canal. Canals were then progressively enlarged by three to four instrument sizes beyond initial file that could reach the apex, utilizing a linear filing motion [Figure 2(a)].

In experimental group (Group B), chemo-mechanical preparation began with first endodontic K-

file that exhibited binding within canal. Canals were initially prepared up to No. 20 K-file, followed by instrumentation using Kedo Nano Plus rotary file with rotary endomotor. The rotary system operated at a speed of 250–300 rpm with a torque setting of 2.2–2.4 N/cm [Figure 2(b)]. All files were lubricated with ethylenediaminetetraacetic acid (EDTA) gel before use. Following instrumentation, canals were irrigated to facilitate effective debris removal. Additionally, total instrumentation time was recorded using a stopwatch, i.e. the time required to negotiate and shape all root canals of tooth to desired size after root canal access opening and working length determination.

After thoroughly drying the canals with cotton pellets and paper points, obturation was performed using moist cotton pellet technique described by Donnenberg et al.^[16] A thin mix of zinc oxide eugenol (ZOE) cement was applied to a file and inserted into canals, ensuring uniform coating. This was followed by condensation of thick mix of ZOE using moist cotton pellet as a condenser. An intraoral periapical radiograph was taken to verify quality of obturation. Subsequently, canals were sealed with an appropriate post-endodontic core buildup restorative material. Additionally, quality of obturation was evaluated using Modified Coll and Sadrian criteria [Figure 3]. According to this criteria, 'Underfilled canals refer to those where obturation is more than 1 mm short of radiographic apex. Optimally filled canals are those where obturation ends at radiographic apex or is up to 1 mm short of it. Overfilled canals occur when obturation extends beyond root canal'.^[9]

Postoperative instructions were provided to both child and their parents. Postoperative pain assessment was conducted using WBPS. Parents or guardians were instructed to document child's pain levels on WBPS at 24, 48 and 72 hours. They received scale along with a patient information sheet for reference. Pain scores were recorded via telephone follow-up and patient information sheet was collected during subsequent visit. Participants were recalled after one week for placement of stainless steel crown.

Results

The current study included total of 50 children with mean age of 6.22 ± 1.50 . Among them, 22 (44%) were male, while 28 (56%) were female [Table 1].

Quality of obturation was evaluated between Group A and Group B using Chi-square test ($\chi^2 = 18.1550$). Group B demonstrated higher number of optimally filled canals as compared to Group A, with very highly statistically significant difference, $p = 0.0001$ ($*p < 0.05$). This indicates that rotary instrumentation resulted in superior obturation quality, achieving 84% optimally filled root canals. In contrast, hand instrumentation, exhibited higher number of

"Evaluating the quality of obturation after pulpectomy of primary molars in children aged 4-9 years using hand and rotary instrumentation - A randomised clinical trial"

overfilled canals, accounting for 52% [Table 2 and Graph 1].

Instrumentation time was analysed between Group A and Group B using t-test ($t = 18.2535$). Results revealed that Group B, which utilized rotary instrumentation, required significantly less time (mean = 6.88) compared to Group A, which used hand instrumentation and exhibited longer mean instrumentation time of 16.35. This difference was very highly statistically significant, $p = 0.0001$ ($*p < 0.05$) [Table 3 and Graph 2].

Postoperative pain was compared between two groups using Mann-Whitney 'U' test. This showed U-value of 115.00 and very highly statistically significant difference, $p = 0.0001$ ($*p < 0.05$) between Group A and Group B after 24 hours [Table 4 and Graph 3]. Hence, maximum pain was experienced by participants in Group A after 24 hours. When intragroup analysis was done using Wilcoxon matched-pair test, statistically significant difference in pain levels was observed in Group A at 24-48 hour and 24-72 hour with 'p' values of 0.01215 ($*p < 0.05$) and 0.00147 ($*p < 0.05$) respectively [Table 5]. Similarly, in Group B, a statistically significant difference was noted between 48-72 hour period, $p = 0.0431$ ($*p < 0.05$) [Table 6].

Discussion

The therapeutic approach to primary dentition exhibits substantial variation owing to aspects such as lifespan of deciduous teeth, structural integrity of coronal portion, complexity of root canal configuration and process of physiological resorption. These considerations contribute to complexity of performing endodontic procedures in primary teeth.^[17,18]

Sharma et al and Cademartori et al have shown that children under the age of four are more sensitive to pain and are more likely to exhibit negative behavior than older children. Consequently, selected age group for this study was between four and nine years, ensuring inclusion of primary teeth with fully formed, non-resorbed or minimally resorbed roots, which are essential prerequisites for performing pulpectomy.^[19,20]

Pulpectomy is widely accepted endodontic procedure for managing irreversible pulpitis or necrotic pulp in primary teeth, aiming to preserve tooth until its natural exfoliation.^[21] The success of pulpectomy largely depends on efficient canal preparation, thorough disinfection, and optimal obturation quality. This ensures complete sealing of root canal system and prevents reinfection.^[22] Traditionally, hand K-files have been a standard instrumentation technique; but introduction of rotary files in Pediatric endodontics has transformed clinical practice by improving efficiency and treatment

outcomes.^[23] However, conventional method using hand K-files requires significant amount of time and frequently leads to fatigue for both clinician and pediatric patient. In contrast, rotary instrumentation is effective in shaping canals into pre-designed conical forms while minimizing potential complications. Stainless steel (SS) files possess inherent rigidity, which contributes to various irregularities that may occur during root canal preparation.^[24]

Rotary systems, such as Kedo Nano Plus, are specifically designed for primary teeth, offering advantages like reduced instrumentation time, uniform canal preparation and improved obturation quality.^[25] The Kedo Nano Plus rotary file system consists of a single NiTi rotary instrument measuring 16 mm in total length, with an active working portion of 12 mm. The optimal operating speed ranges between 250 and 300 rpm, while recommended torque setting is 2.2 to 2.4 N/cm.

Studies have shown that rotary files preserve original canal anatomy better than hand files, leading to more consistent and homogeneous obturation.^[26] Additionally, the reduced working time associated with rotary instrumentation minimizes patient discomfort and enhances cooperation, which is a crucial factor in pediatric dental care.^[27]

Postoperative pain is another critical parameter influencing treatment success and patient acceptance. Research indicates that rotary instrumentation results in lower postoperative pain levels compared to manual filing, likely due to less aggressive dentin removal and reduced apical extrusion of debris.^[28] Primary etiology of postoperative pain is apical extrusion of exogenous particles, including dentinal debris and obturating materials, into periradicular tissues, provoking localized irritation, inflammatory responses and subsequent release of pro-inflammatory mediators. In present study pediatric patients who underwent pulpectomy utilizing rotary file systems exhibited significantly lower postoperative pain levels compared to those treated with conventional manual instrumentation. The continuous rotational movement of rotary files facilitate efficient canal preparation while minimizing apical debris extrusion, thereby reducing postoperative pain.^[29,30]

Rotary instrumentation generates less apical debris due to its implementation of crown-down technique, which prioritizes early coronal flaring and directs debris coronally rather than apically.^[31,32] Additionally, increased taper of Pediatric rotary files restricts excessive apical preparation while optimizing cervical enlargement.^[29,33] Hence, it reduces the risk of over-instrumentation and limiting apical debris displacement. In contrast, hand K-files, which operate through a reciprocating linear motion, tend to induce

"Evaluating the quality of obturation after pulpectomy of primary molars in children aged 4-9 years using hand and rotary instrumentation - A randomised clinical trial"

greater apical debris extrusion, resulting in elevated postoperative pain and inflammatory response.^[30,31,33]

Furthermore, the reduced instrumentation time associated with rotary file systems may serve as an additional contributing factor to attenuation of postoperative pain.^{29,32} Variability in severity and persistence of postoperative pain can be attributed to differences in root canal instrumentation techniques, which directly influence the extent of dentinal debris extrusion and activation of neuropeptides, particularly those released from C-fibers within periodontal ligament, thereby modulating nociceptive responses.^[34]

Given these advantages, evaluating quality of obturation using hand and rotary techniques provides valuable insights into their clinical effectiveness. Thus, this randomized clinical trial aims to compare obturation quality, instrumentation time and postoperative pain between hand K-files and Kedo Nano Plus rotary files, contributing to growing evidence supporting the use of rotary system in primary teeth pulpectomy.

Several studies have explored the efficiency of hand and rotary instrumentation in Pediatric endodontics. Our study revealed significant differences between two techniques, where rotary instrumentation resulted in superior obturation quality. These findings align with those of Govindaraju et al, who reported that rotary files ensured better quality with more uniform obturation and reduced chairside time, making them more suitable for pediatric patients.^[35]

Similarly, Musale et al in 2014 found that rotary instrumentation using ProFile, ProTaper File and Hero Shaper File resulted in better canal debridement and more uniform obturation compared to manual methods. They attributed this to the design and flexibility of rotary files, which allow for enhanced canal preparation with minimal procedural errors.^[36] Our study supports these conclusions, as rotary group demonstrated fewer underfilled or overfilled canals, indicating better control over obturation length.

In contrast, some studies, such as those by Prabhakar et al, suggested that although rotary instrumentation offers advantages in time efficiency and operator convenience, quality of obturation may not always be significantly superior to hand instrumentation.^[37] Our findings diverge slightly, as we observed a notable improvement in obturation quality with rotary techniques, possibly due to use of contemporary rotary file systems with enhanced cutting efficiency and better adaptation to primary root canal morphology.

Superiority of rotary instrumentation in achieving optimal obturation has direct clinical implications. Pediatric dentistry often demands

techniques that are both efficient and child-friendly. Reduced instrumentation time, fewer procedural errors, and superior obturation quality makes rotary files a preferred choice for pulpectomy in primary teeth. Additionally, our study observed higher patient compliance and reduced discomfort in rotary group, consistent with earlier findings by Panchal et al in 2019, who highlighted the importance of reduced treatment duration in improving child cooperation.^[38]

Moreover, higher success rate of rotary instrumentation suggests its potential to improve long-term outcomes of pulpectomized primary teeth. Even distribution of obturating material ensures better sealing, minimizing microleakage and reducing risk of reinfection. This aligns with the findings of Kuo et al, who demonstrated that well obturated primary canals significantly lowers the incidence of post-treatment complications.^[39]

This randomized clinical trial emphasizes the advantages of rotary instrumentation over hand instrumentation in primary molar pulpectomy. The findings support its use for achieving superior obturation quality, enhanced efficiency and better patient compliance. Despite certain limitations, rotary instrumentation emerges as a promising technique for Pediatric endodontics. Future research should continue to refine and validate these findings to optimize clinical protocols and improve treatment outcomes in children requiring pulpectomy.

Despite the promising results, our study has certain limitations. First, the sample size was relatively small, limiting generalizability of findings. Larger multi-center study could provide more robust conclusions. Second, the assessment of obturation quality was primarily radiographic, which may have limitations in detecting minor voids or assessing three-dimensional adaptation of material.

To further explore efficacy of rotary instrumentation in Pediatric Dentistry, future research should consider larger sample sizes with diverse population groups to validate findings. Comparative studies evaluating different rotary file systems to determine most effective system for primary molars.

Conclusion

Our study concluded that, Kedo Nano Plus rotary files demonstrated superior performance compared to hand K-files in several key aspects of pulpectomy in primary molars. Use of rotary files significantly reduced instrumentation time, enhancing clinical efficiency. Additionally, obturation quality was notably better with rotary files, ensuring more effective canal filling and potentially improving long-term treatment outcomes. Furthermore, children who underwent pulpectomy with rotary files experienced less postoperative pain, contributing to greater patient comfort and compliance. These findings highlights the

"Evaluating the quality of obturation after pulpectomy of primary molars in children aged 4-9 years using hand and rotary instrumentation - A randomised clinical trial"

advantages of rotary instrumentation in Pediatric endodontics, reinforcing its efficacy over conventional hand files.

CTRI registration number: CTRI/2025/02/080459

References

1. Kassebaum NJ, Bernabé E, Dahiya M, et al. Global burden of untreated caries: A systematic review and metaregression. *J Dent Res*. 2015;94(5):650-8.
2. Tinanoff N, Baez RJ, Diaz-Guallory C, et al. Early childhood caries epidemiology, etiology, risk assessment, societal burden, management, education, and policy: A global perspective. *Pediatr Dent*. 2019;41(3):E12-E34.
3. Govindaraju L, Jeevanandan G, Subramanian EMG. Comparison of quality of obturation and instrumentation time using hand files and two rotary file systems in primary molars: a single-blinded randomized controlled trial. *Eur J Dent*. 2017;11(3):376-9.
4. Dummett CO Jr, Kopel HM. Pediatric endodontics. In: Ingle JI, Bakland LK, editors. *Endodontics*. 5th ed. Hamilton: BC Decker Inc.; 2002. p. 861-902.
5. Fuks A, Peretz B. Pulpectomy and Root Canal Treatment (RCT) in primary teeth: Techniques and methods. In: *Pediatric Endodontics: Current Concepts in Pulp Therapy for Primary and Young Permanent Teeth*. 4th ed., Ch. 6. Switzerland: Springer International Publishing; 2016. p. 71-101.
6. Aljabri MK, Kensara JA, Mandorah AO, Sunbul MA. Causes of root canal treatment failure: A prospective study in Makkah City, Saudi Arabia. *Saudi J Oral Sci* 2020;7:40-5.
7. Curzon ME and Roberts JF. Anatomy of primary and permanent teeth. In: Kennedy's paediatric operative dentistry. 4th ed., Ch. 2. Wright; 1996. P. 15-9.
8. Garg N and Garg A. Pediatric endodontics. In: *Textbook of endodontics*. 2th ed., Ch. 33. Boydell and Brewer Ltd; 2010. P. 481-95.
9. Coll JA, Sadrian R. Predicting pulpectomy success and its relationship to exfoliation and succedaneous dentition. *Pediatr Dent*. 1996;18(1):57-63.
10. Silva LA, Leonardo MR, Nelson-Filho P, Tanomaru JM. Comparison of rotary and manual instrumentation techniques on cleaning capacity and instrumentation time in deciduous molars. *J Dent Child*. 2004;71(1):45-7.
11. Barr ES, et al. Use of nickel-titanium rotary files for root canal preparation in primary teeth. *Pediatric Dentistry* 22.1 (2000): 77-8.
12. Thakkar TK. Advances in rotary endodontics in Pediatric dentistry. *EC Dent Sci* 2019;18:1320-30.
13. Available from: <http://ctri.nic.in/Clinicaltrials/faq.php>. [Last assessed on 2020 Dec 05].
14. Available from: <http://www.consort-statement.org> [Last accessed on 2021 Sep 01].
15. Saxena N, Hugar SM, Dialani PK, Kohli N, Kajjari S, Gokhale NS. Comparative evaluation of postoperative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children – A randomized control study. *Indian J Health Sci Biomed Res* 2023;16:366-75.
16. Damle SG. Pediatric endodontics. In: *Text Book of Paediatric Dentistry*. 5th ed., Ch. 33. New Delhi, India; 2012. p. 704-34.
17. Hedge V. Pediatric Endodontics-Endodontist's view. *People's J Sci Res* 2011;4:71-4.
18. Finn SB. Morphology of primary teeth. In: *Clinical Pedodontics*. 4th ed. Finn SB: Saunders Co, Philadelphia; 1973. p. 59-70.
19. Sharma A, Kumar D, Anand A, Mittal V, Singh A, Aggarwal N. Factors predicting Behavior Management Problems during Initial Dental Examination in Children Aged 2 to 8 Years. *Int J Clin Pediatr Dent* 2017;10:5-9.
20. Cademartori MG, Corrêa MB, Silva RA, Goettems ML. Childhood social, emotional, and behavioural problems and their association with behaviour in the dental setting. *Int J Paediatric Dent* 2019;29:43-9.
21. American Academy of Pediatric Dentistry. Pulp therapy for primary and immature permanent teeth. *Pediatr Dent*. 2020;42(6):343-51.
22. Coll JA, Vargas K, Marghalani AA, Chen CY. Clinical practice guidelines for vital and nonvital pulp therapy in primary teeth. *Pediatr Dent*. 2017;39(6):146-59.
23. Jeevanandan G, Govindaraju L. Clinical comparison of Kedo-S rotary files and manual instrumentation in primary molars: A randomized clinical trial. *J Clin Pediatr Dent*. 2018;42(4):257-62.
24. Rashid AA, Saleh AR. Shaping ability of different endodontic single-file systems using simulated resin blocks. *Indian J Multidisciplinary Dent* 2016;6:61.
25. Panchal V, Jeevanandan G, Subramanian EMG. Comparison of instrumentation time and obturation quality between Kedo-S and

"Evaluating the quality of obturation after pulpectomy of primary molars in children aged 4-9 years using hand and rotary instrumentation - A randomised clinical trial"

- hand K-files in primary teeth. J Indian Soc Pedod Prev Dent. 2019;37(1):75-80.
26. Govindaraju L, Jeevanandan G, Subramanian EM. Rotary vs. manual instrumentation in primary molars: A systematic review and meta-analysis. Int J Paediatr Dent. 2020;30(5):580-91.
 27. Musale PK, Digraaskar D, Borle A, Shingane S, Gupta H. Comparison of post-instrumentation pain using rotary and manual techniques in primary molars: A randomized controlled trial. Eur Arch Paediatr Dent. 2021;22(3):395-402.
 28. Katge F, Patil D, Poojari M, More P. Postoperative pain and instrumentation time in primary teeth: A comparative study of manual and rotary systems. Pediatr Dent J. 2022;32(4):211-8.
 29. Panchal V, Jeevanandan G, Subramanian EM. Comparison of post-operative pain after root canal instrumentation with hand K-files, H-files and rotary Kedo-S files in primary teeth: A randomised clinical trial. Eur Arch Paediatr Dent 2019;20:467-72.
 30. Topçuoğlu G, Topçuoğlu HS, Delikan E, Aydınbelge M, Dogan S. Postoperative pain after root canal preparation with hand and rotary files in primary molar teeth. Pediatr Dent 2017;39:192-6.
 31. Pandranki J, V Vanga NR, Chandrabhatla SK. Zinc oxide eugenol and Endoflas pulpectomy in primary molars: 24-month clinical and radiographic evaluation. J Indian Soc Pedod Prev Dent 2018;36:173-80.
 32. Babji P, Mehta V, Manjooran T. Clinical Evaluation of rotary system over manual system in deciduous molars: A clinical trial. Int J Pedod Rehabil 2019;4:13-6.
 33. Jeevanandan G, Govindaraju L. Clinical comparison of Kedo-S paediatric rotary files vs. manual instrumentation for root canal preparation in primary molars: A double blinded randomised clinical trial. Eur Arch Paediatr Dent 2018;19:273-8.
 34. Caviedes-Bucheli J, Moreno JO, Carreño CP, Delgado R, Garcia DJ, Solano J, et al. The effect of single-file reciprocating systems on Substance P and Calcitonin gene-related peptide expression in human periodontal ligament. Int Endod J 2013;46:419-26.
 35. Jeevanandan G, Govindaraju L. Clinical comparison of rotary and manual instrumentation in primary molars using a new pediatric rotary file system: An in vivo study. Int J Clin Pediatr Dent. 2017;10(4):377-81.
 36. Musale PK, Mujawar SA. Evaluation of the efficacy of rotary vs hand files in root canal preparation of primary teeth using CBCT: An in vitro study. J Clin Diagn Res. 2014;8(10):77-80.
 37. Prabhakar AR, Raju OS, Yavagal C. Comparative evaluation of manual and rotary instrumentation on clinical and radiographic success of pulpectomy in primary molars: A randomized controlled trial. J Indian Soc Pedod Prev Dent. 2018;36(4):357-63.
 38. Panchal V, Jeevanandan G, Subramanian EM. Comparison of instrumentation time and obturation quality between manual, rotary, and reciprocating systems in primary molars: A randomized clinical trial. J Dent Child (Chic). 2019;86(3):144-9.
 39. Kuo C, Wang Y, Chang H, Lin C. Success rates of different obturation techniques for pulpectomy in primary teeth: A systematic review and meta-analysis. Eur J Paediatr Dent. 2020;21(3):181-8.

TABLES

Table 1: Comparison of control group and experiment group with Obturation quality

Obturation quality	Control group	%	Experiment group	%	Total	%
Obturation that is more than 1mm short of the apex	6	24.00	1	4.00	7	14.00
Obturation that is ending at the radiographic apex or up to 1mm short of the apex	6	24.00	21	84.00	27	54.00
Obturation that is seen outside the root canal	13	52.00	3	12.00	16	32.00
Total	25	100.00	25	100.00	50	100.00
Chi-square=18.1550, p=0.0001***						

*p<0.05

Table 2: Comparison of control group and experiment group with instrumentation time by t test

"Evaluating the quality of obturation after pulpectomy of primary molars in children aged 4-9 years using hand and rotary instrumentation - A randomised clinical trial"

Groups	n	Mean	SD	SE	t-value	P-value
Control group	25	16.35	2.51	0.50	18.2535	0.0001***
Experiment group	25	6.88	0.63	0.13		

*p<0.05

Table 3: Comparison of control group and experiment group with pain scores at different treatment time points by Mann-Whitney U test

Pain at	Control group			Experiment group			U-value	Z-value	P-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
After 24hrs	1.92	1.35	33.40	0.32	0.75	17.60	115.00	3.8224	0.0001***
After 48hrs	0.80	1.00	28.00	0.40	0.82	23.00	250.00	1.2030	0.2290
After 72hrs	0.48	0.87	28.50	0.00	0.00	22.50	237.50	1.4455	0.1483

*p<0.05

Table 4: Comparison of different treatment time points with pain scores in control group by Wilcoxon matched pairs test

Time points	Mean	Std.Dv.	Mean Diff.	% of effect	Z-value	p-value
After 24hrs	1.92	1.35	1.12	58.33	2.50788	0.01215*
After 48hrs	0.80	1.00				
After 24hrs	1.92	1.35	1.44	75.00	3.18009	0.00147**
After 72hrs	0.48	0.87				
After 48hrs	0.80	1.00	0.32	40.00	1.12122	0.26219
After 72hrs	0.48	0.87				

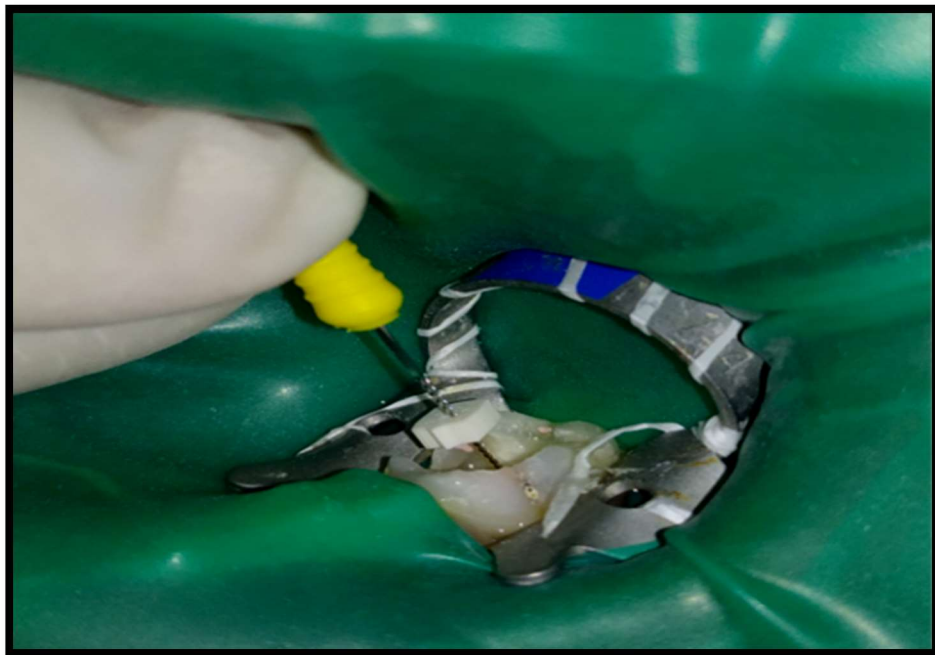
*p<0.05

Table 5: Comparison of different treatment time points with pain scores in experiment group by Wilcoxon matched pairs test

Time points	Mean	Std.Dv.	Mean Diff.	% of effect	Z-value	p-value
After 24hrs	0.32	0.75	-0.08	-25.00	0.2962	0.7671
After 48hrs	0.40	0.82				
After 24hrs	0.32	0.75	0.32	100.00	1.8257	0.0679
After 72hrs	0.00	0.00				
After 48hrs	0.40	0.82	0.40	100.00	2.0226	0.0431*
After 72hrs	0.00	0.00				

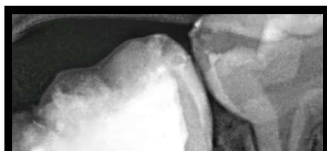
*p<0.05

"Evaluating the quality of obturation after pulpectomy of primary molars in children aged 4-9 years using hand and rotary instrumentation - A randomised clinical trial"

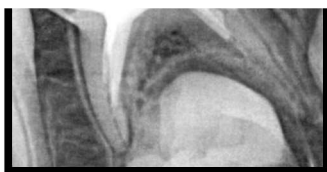


(b) Rotary Instrumentation In Experimental Group (Group B)

Figure 3: Photograph showing radiographs of (a) Underfilled (b) Optimally Filled (c) Overfilled root canals of primary molars in the study according to Modified Coll and Sedrian criteria



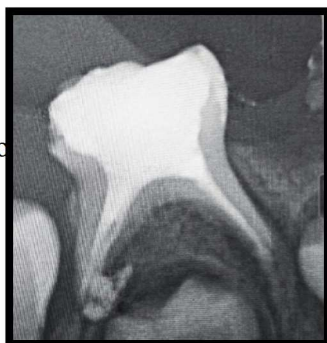
(a) underfilled root canals



(b)



(c)



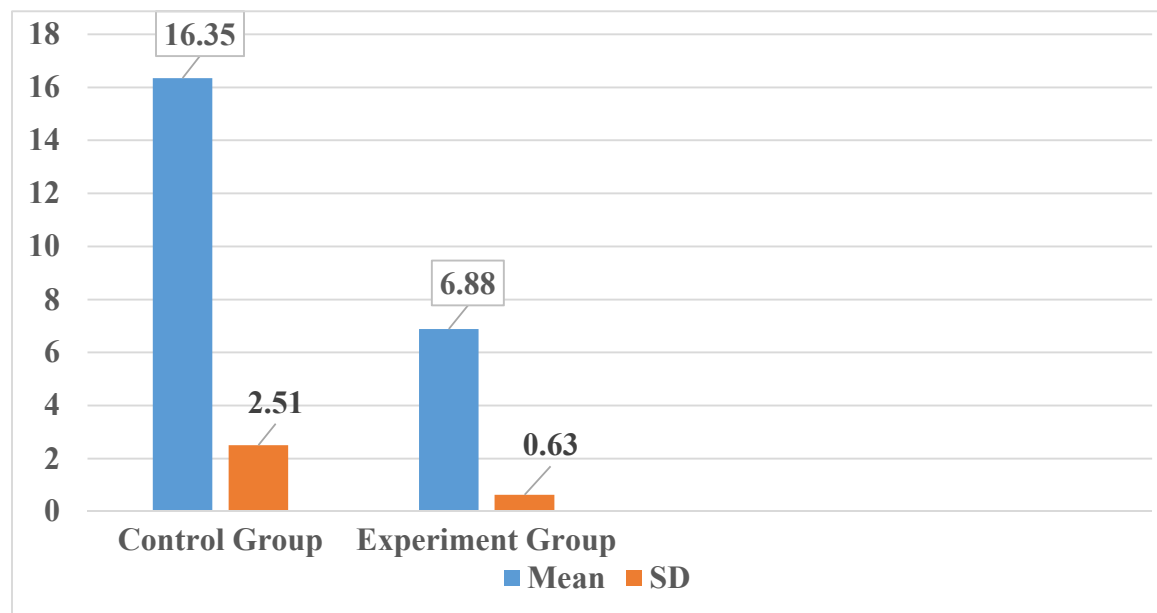
"Evaluating the quality of obturation after pulpectomy of primary molars in children aged 4-9 years using hand and rotary instrumentation - A randomised clinical trial"

GRAPHS:

Graph 1: Comparison of control group and experimental group with Obturation quality

Graph 2: Comparison of control group and experimental group with instrumentation time

Graph 3: Comparison of control group and experimental group with pain scores at different treatment time points



"Evaluating the quality of obturation after pulpectomy of primary molars in children aged 4-9 years using hand and rotary instrumentation - A randomised clinical trial"

