

Evaluation of Hand Files and Two Rotary Systems for Pulpectomy in Children Aged 4-9 Years: A Randomised Clinical Trial

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ABSTRACT

Introduction: Hand instrumentation has long been used for pulpectomy procedures; however, it is often associated with prolonged treatment time. In comparison, Nickel-Titanium (NiTi) rotary files used for root canal preparation in primary teeth are more efficient and economical, enabling quicker procedures with consistent and predictable outcomes.

Aim: To evaluate and compare hand files and two rotary systems for pulpectomy in children aged 4-9 years.

Materials and Methods: The present prospective, in-vivo, three-arm, parallel-group, randomised clinical trial was conducted in Department of Paediatric and Preventive Dentistry at KLE VK Institute of Dental Sciences, Belagavi, Karnataka, India, from 6th January 2026 to 31st January 2026. A total of 75 healthy children aged 4-9 years meeting primary inclusion criteria (positive/definitely positive behaviour on Frankl's scale, primary molars with spontaneous pain/irreversible pulpitis and at least two-thirds root length remaining) were randomly allocated into three groups (n=25 each). Group I was instrumented using hand K-files, Group II using Kedo Nano Plus rotary files and Group III using Neoendo Pedoflex rotary files. Instrumentation time was recorded using a stopwatch. Obturation quality was evaluated

using Modified Coll and Sadrian criteria and postoperative pain was assessed using Wong-Baker Faces Pain Rating Scale at 24, 48 and 72 hours. Inferential analysis used chi-square test for categorical associations; Analysis of Variance (ANOVA)/Kruskal-Wallis for multiple group comparisons; independent t-test/Mann-Whitney U for two-group comparisons. p-value<0.05 is considered statistically significant.

Results: Participants (mean age 6.01±1.45 years) showed no significant intergroup differences in age or gender (p>0.05). Obturation quality differed significantly ($\chi^2=22.419$, p<0.001), with optimal fills highest in Group II with 21 (84%) canals and Group III with 19 (76%) canals versus Group I with 6 (24%) canals. Instrumentation time was significantly lower with 6.88 min for Group II and 8.85 min for Group III compared to 16.35 min with Group I (ANOVA, p<0.001). Postoperative pain showed significant differences at 24 h (p<0.001) and 72 h (p<0.05), with higher pain in hand file group.

Conclusion: Kedo Nano Plus rotary system demonstrated enhanced obturation quality, followed by Neoendo Pedoflex rotary files, making it viable alternative to conventional hand K-files for pulpectomy in primary molars.

Keywords: Dentistry, Hand instrumentation, Nickel-Titanium rotary files, Rotary instrumentation

INTRODUCTION

Preservation of primary teeth until natural exfoliation is a key objective of paediatric dentistry, as premature loss may result in space loss, malocclusion, functional disturbances, and psychological effects. Pulpectomy is a well-established procedure for primary teeth with irreversible pulpitis or necrotic pulp, aiming to eliminate infection and maintain the tooth in a functional state until exfoliation. The success of pulpectomy depends on effective biomechanical preparation, adequate disinfection, and proper obturation using resorbable materials compatible with physiological root resorption [1,2].

Root canal instrumentation in primary teeth is challenging due to complex canal morphology, thin dentinal walls, accessory canals, and ongoing physiological root resorption [3]. Stainless steel hand files have traditionally been used because of their tactile control; however, they are time-consuming, technique-sensitive, and associated with procedural errors such as canal transportation and perforation, particularly in curved canals [4].

NiTi rotary instrumentation has improved endodontic practice by providing greater flexibility, better preservation of canal anatomy, and reduced instrumentation time. In paediatric dentistry, rotary systems have gained acceptance due to their efficiency and improved canal shaping [5]. Paediatric-specific rotary files adapted to primary tooth

anatomy have been reported to enhance canal preparation, obturation quality, and child behaviour management [6,7].

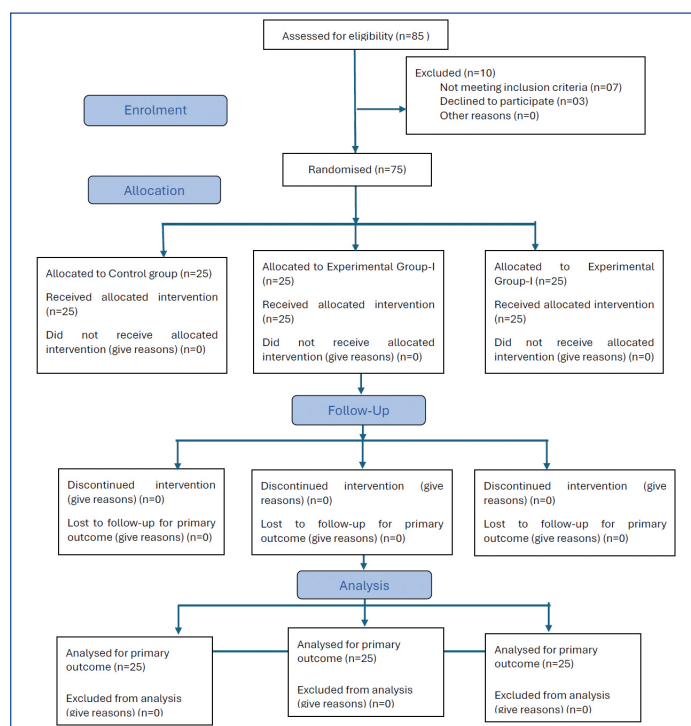
Nevertheless, concerns remain regarding rotary instrumentation in primary teeth, including over-instrumentation, apical extrusion of debris, instrument separation, and potential injury to the developing permanent tooth germ [8]. Variations in rotary system design further necessitate clinical evaluation, as comparative evidence regarding obturation quality remains limited and inconclusive [9-11].

The null hypothesis stated that there is no difference between hand files and two rotary systems for pulpectomy in children aged 4-9 years, whereas the alternative hypothesis proposed that a significant difference exists among them. The aim of the present study was to evaluate and compare hand files and two rotary systems for pulpectomy in children aged 4-9 years. The primary objective was to assess and compare the obturation quality achieved with hand files and rotary systems, while the secondary objectives were to compare instrumentation time and postoperative pain following pulpectomy using these systems.

MATERIALS AND METHODS

The present prospective, in-vivo, three-arm, parallel-group, randomised clinical trial was conducted in the outpatient clinic of

the Department of Paediatric and Preventive Dentistry, KLE VK Institute of Dental Sciences, Belagavi, Karnataka, India, from 6th January 2026 to 31st January 2026, in accordance with CONSORT (Consolidated Standards of Reporting Trials) guidelines [Table/Fig-1] [12].



[Table/Fig-1]: CONSORT flow diagram of methodology followed in the study.

Ethical approval was obtained from the Institutional Research and Ethics Committee (EC/NEW/INST/2021/2435/499) and the study was prospectively registered with the Clinical Trials Registry-India (CTRI/2026/01/100014).

Sample size calculation: The sample size was calculated using mean difference (d) of 2.25 between the groups. The pooled Standard Deviation (S) was computed as $(S_1 + S_2)/2$. The calculated effect size was 0.7776. Considering an alpha error of 5% (two-sided) and a statistical power of 90%, the corresponding Z values were taken as $Z_{1-\alpha}=1.96$ (at 95% confidence interval) and $Z_{1-\beta}$ as per the desired power. Using the standard sample size formula $(n=2S^2(Z_{1-\alpha} + Z_{1-\beta})^2/d^2)$ for comparison of two means, the required sample size was 75 primary molars, which were randomly allocated into three equal groups (n=25 each) using simple random sampling (lottery method).

Inclusion and Exclusion criteria: Children aged 4-9 years with positive or definitely positive behaviour according to Frankl's Behaviour Rating Scale [13], presenting with primary molars having spontaneous pain or diagnosed irreversible pulpitis and at least two-thirds root length remaining, were included. Children with systemic diseases, special healthcare needs, non-vital teeth with abscess/sinus tract/fistula, pathological mobility, root fractures, furcation radiolucency, internal resorption, calcified canals, developmental anomalies, or root resorption exceeding two-thirds were excluded. However, children requiring treatment with multivisit protocol were excluded from the study. This age range was deliberately selected because root development in primary molars is generally completed by approximately three years, while physiological root resorption commonly commences around six years of age [14].

Study Procedure

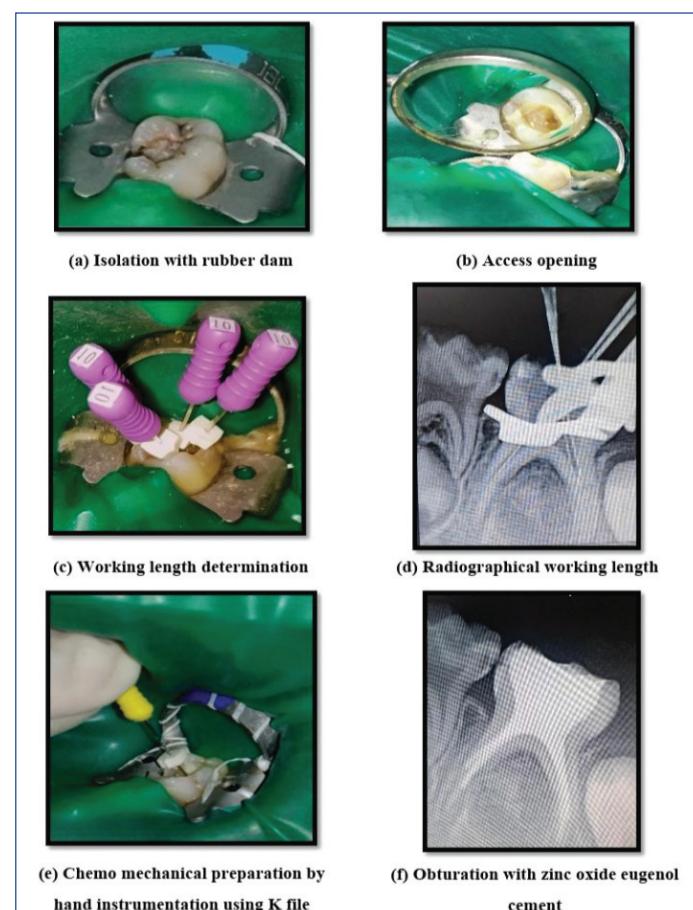
Single sitting pulpectomy was performed by a single operator under standardised protocol. After administration of local anaesthesia and rubber dam isolation, access opening and working length determination (Ingle's technique) were completed. Group-I underwent instrumentation with stainless steel K-files (Mani K-files);

Group-II with Kedo Nano Plus rotary system (250-300 rpm, 2.2-2.4 Ncm); and Group-III with Neoendo Pedoflex rotary system (350 rpm, 1.5 Ncm) [Table/Fig-2]. Instrumentation time was recorded using a stopwatch. Following canal preparation, canals were dried and obturated using the moist cotton pellet technique described by Damle SG [15]. Zinc oxide eugenol cement was placed, and an intraoral periapical radiograph was taken to evaluate obturation quality. Canals were then sealed with an appropriate post-endodontic restorative material. Adequacy of endodontic fill was recorded using Modified Coll and Sadrian criteria. Obturation was gauged on postoperative radiograph as underfilled, optimally filled and overfilled. Underfilled was defined as all canals being filled 1 mm or more short of the apex. Optimally filled was defined as one or more canals having Zinc Oxide Eugenol (ZOE) ending at the radiographic apex. Overfilled was defined as any molar canal showing ZOE beyond the root [16].

Postoperative pain was assessed using the Wong-Baker Faces Pain Rating Scale. This scale features six facial expressions with numerical values ranging from 0 (No hurt) to 10 (Hurts worst) [Table/Fig-3] [17]. Principal investigator called up telephonically for postoperative pain evaluation at 24, 48 and 72 hours after treatment, during which the parent or guardian reported the face selected by the child that best represented their pain intensity. The corresponding numerical score was recorded for analysis. Patients were recalled after one week for placement of stainless steel crowns. In the present study, all outcomes were evaluated by a single examiner who was blinded to the group allocation, thereby minimising assessment bias. Intra-observer reliability was assessed by reevaluating 20% of the total samples (n=15) after an interval of two weeks by the same examiner. The agreement was analysed using Cohen's kappa statistics, which yielded a value of 0.88, indicating good to excellent reliability.

STATISTICAL ANALYSIS

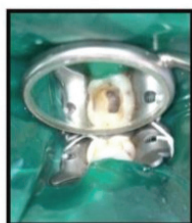
The collected data were systematically compiled, coded and entered into a master Microsoft Excel spreadsheet, after which



[Table/Fig-2a]: Photograph showing procedure of pulpectomy using Hand K-files in Group-I.



(a) Isolation with rubber dam



(b) Access opening



(c) Working length determination



(d) Radiographical working length

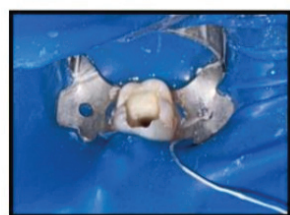


(e) Chemo mechanical preparation by rotary instrumentation using Kedo Nano Plus rotary files



(f) Obturation with zinc oxide eugenol cement

[Table/Fig-2b]: Photograph showing procedure of pulpectomy using Kedo Nano Plus rotary files in Group-II.



(a) Isolation with rubber dam



(b) Access opening



(c) Working length determination



(d) Radiographical working length



(e) Chemo mechanical preparation by rotary instrumentation using Neoendo Pedoflex files



(f) Obturation with zinc oxide eugenol cement

[Table/Fig-2c]: Photograph showing procedure of pulpectomy using Neoendo Pedoflex rotary files in Group-III.

they were subjected to statistical analysis. Descriptive statistics, including frequency distribution, percentages, mean and Standard

Wong-Baker FACES Pain Rating Scale



[Table/Fig-3]: Photograph showing Wong-Baker Faces Pain Rating Scale (WB-FPS) used for postoperative pain evaluation [17].

Deviation (SD), were calculated to summarise the data. Inferential statistical analysis was performed using the chi-square test to assess associations between categorical variables. Intergroup comparisons among more than two groups were carried out using one-way ANOVA or the Kruskal-Wallis test, depending on the normality of data distribution. Comparisons between two independent groups were analysed using the independent t-test or Mann-Whitney U test, as appropriate. Statistical significance was established at a 5% level, with a p-value of <0.05 considered statistically significant.

RESULTS

The current study included total of 75 children with mean age of 6.01 ± 1.45 . Among them, 33 (44%) were male, while 42 (56%) were female. An intergroup comparison was done with respect to age and gender and no statistically significant difference was noted between the groups with respect to age ($p > 0.05$) and gender ($p > 0.05$), indicating that there was an equal distribution of participants between all three groups [Table/Fig-4].

Gender distribution (n=75)		n (%)			Age mean±SD
		Male	33 (44%)		6.01±1.45
		Female	42 (56%)		
Variables		Group-I (Hand K-files) (n and %)	Group-II (Kedo Nano Plus rotary files) (n and %)	Group-III (Neoendo Pedoflex rotary files) (n and %)	p-value
Age	Mean±SD	6.08±1.66	6.36±1.35	5.60±1.26	F=0.33 p>0.05
Gender	Male	13 (52)	9 (36)	11 (44)	χ ² =1.30 p>0.05
	Female	12 (48)	16 (64)	14 (56)	
	Total	25 (100)	25 (100)	25 (100)	

[Table/Fig-4]: Comparison of three groups (Control, Experiment 1 and Experiment 2) with age and gender.

(* $p < 0.05$; One-way ANOVA test and Chi-square test has been used)

The quality of obturation was evaluated between three groups (Group-I, Group-II and Group-III) using chi-square test ($\chi^2=22.4190$). In Group-I (Hand K-files) 6 (24%) canals were optimally filled; 13 (52%) were overfilled and 6 (24%) were underfilled. In Group-II (Kedo Nano Plus rotary files) 21 (84%) canals were optimally filled; 3 (12%) were overfilled and 1 (4%) were underfilled. While in Group-III (Neoendo Pedoflex rotary files) 19 (76%) canals were optimally filled; 4 (16%) were overfilled and 2 (8%) were underfilled. A very highly statistically significant difference was noticed between Group-I and Group-II, $p < 0.001$ (* $p < 0.05$). This indicates that rotary instrumentation resulted in superior obturation quality [Table/Fig-5].

Intergroup comparison was done using one way ANOVA for instrumentation time between all the three groups. Mean instrumentation time for Group-I was 16.35 min; for Group-II it was 6.88 min and for Group-III it was 8.85 min. A very highly statistically significant difference was noted between all the three groups for instrumentation time, $p < 0.001$ (* $p < 0.05$). Post-hoc Tukey analysis confirmed that there was significantly less instrumentation time between the rotary and hand instrumentation [Table/Fig-6].

Obturation quality	Group-I n (%)	Group-II n (%)	Group-III values- n (%)	Total n (%)
1 mm or more short of the apex	6 (24.00)	1 (4.00)	2 (8.00)	9 (12)
Ending at the radiographic apex	6 (24.00)	21 (84.00)	19 (76.00)	46 (61.3)
Outside the root canal	13 (52.00)	3 (12.00)	4 (16.00)	20 (26.6)
Total	25 (100.00)	25 (100.00)	25 (100.00)	75 (100)
Chi-square=22.4190, p<0.001*				
Pairwise comparison				
Group-I vs Group-II (Hand K-files vs Kedo Nano Plus rotary files)		$\chi^2=18.15$, p<0.001*		
Group-I vs Group-III (Hand K-files vs Neoendo Pedoflex rotary files)		$\chi^2=13.52$, p<0.001*		
Group-II vs Group-III (Kedo Nano Plus rotary files vs NeoendoPedoflex rotary files)		$\chi^2=0.58$, p>0.05		
[Table/Fig-5]: Comparison of obturation quality in three study groups (Group-I, Group-II and Group-III). (*p<0.05; Chi-square test for association and Pairwise Chi-square test for intergroup comparison)				

Groups	Mean	SD	Std. err.	95% CI for mean	
				Lower	Upper
Group-I (Hand K-files)	16.35	2.51	0.50	15.31	17.38
Group-II (Kedo Nano Plus rotary files)	6.88	0.63	0.13	6.62	7.14
Group-III (Neoendo Pedoflex rotary files)	8.85	1.22	0.24	8.34	9.35
Total	10.69	4.42	0.51	9.68	11.71
F-value	227.7642				
p-value	<0.001*				
Pair wise comparisons by Tukeys multiple post-hoc procedure					
Group-I vs Group-II (Hand K-files vs Kedo Nano Plus rotary files)	p<0.001*				
Group-I vs Group-III (Hand K-files vs Neoendo Pedoflex rotary files)	p<0.001*				
Group-II vs Group-III (Kedo Nano Plus rotary files vs Neoendo Pedoflex rotary files)	p<0.001*				
[Table/Fig-6]: Comparison of three study groups (Group-I, Group-II and Group-III) with mean Instrumentation time (in min) by One-way ANOVA. (*p<0.05; One-way ANOVA test has been used)					

Comparison of three groups with postoperative pain at 24, 48 and 72 hours time duration was done by Kruskal Wallis ANOVA test. This showed a statistically significant difference between Group-I, Group-II and Group-III at 24 and 72 hours, with p<0.001 and p<0.05 respectively (*p<0.05). Hence, maximum pain has been experienced by participants in Group-I after 24 hours. However, when postoperative pain was evaluated telephonically at 24, 48 and 72 hours after treatment, the parent or guardian reported the

face selected by the child on the Wong-Baker Faces Pain Rating Scale that best represented the child's pain intensity; a statistically significant difference was observed among all three groups with p<0.05 and p<0.001 respectively (*p<0.05) [Table/Fig-7]. Pair wise comparison of three groups with pain scores at different treatment time points was done using Mann-Whitney 'U' test. Comparison of Group-I and Group-II at 24 hours showed a very highly statistically significant difference, p<0.001 (*p<0.05). When Group-I was compared with Group-III, there was a statistically significant difference, p<0.05 (*p<0.05). Comparison of Group-II and Group-III at 24 hours showed statistically significant difference, p<0.05 (*p<0.05). However, when pain score was compared in time interval of 24-48 hours and 24-72 hours between Group-I and Group-II there was a statistically significant difference seen with p<0.05 and p<0.0001 respectively (*p<0.05) [Table/Fig-8].

DISCUSSION

Instrumentation time is a critical factor in paediatric endodontics, as it directly influences child cooperation, behaviour management, operator fatigue, and overall treatment efficiency. Children aged 4-9 years often have limited attention spans and low tolerance for prolonged dental procedures; therefore, minimising chairside time is essential. In the present study, a statistically significant difference in instrumentation time was observed among the groups, with the longest duration recorded in the hand file group, followed by Neoendo Pedoflex, while the shortest instrumentation time was achieved using the Kedo Nano Plus rotary system.

Conventional hand instrumentation using stainless steel K-files has long been considered the gold standard for pulpectomy in primary teeth because of its simplicity and tactile control. However, manual instrumentation is inherently time-consuming, requiring repeated filing motions and frequent file changes to achieve adequate canal shaping. The complex and irregular morphology of primary molar canals further prolongs instrumentation when hand files are used. Several studies have reported significantly longer instrumentation time with hand files compared to rotary systems, supporting the findings of the present study [4,5].

The advent of NiTi rotary systems has transformed endodontic practice by enabling faster and more efficient canal preparation while maintaining original canal anatomy. Continuous rotational motion allows rapid dentin removal with reduced operator effort. In paediatric dentistry, rotary instrumentation has been shown to significantly reduce instrumentation time, thereby improving patient compliance and clinical workflow [8]. Kummer TR et al., demonstrated that rotary instrumentation in primary molars required considerably less time than manual techniques, attributing this to the superior cutting efficiency and flexibility of NiTi alloys [6].

Among paediatric-specific rotary systems, file design, taper, length, and metallurgy play a crucial role in determining clinical efficiency. The Kedo Nano Plus rotary system, specifically designed for primary teeth, incorporates shorter file lengths, variable taper and enhanced flexibility, making it particularly suitable for primary molar anatomy. Previous studies have consistently reported reduced instrumentation time with Kedo rotary systems compared to hand files and other

Time duration	Group-I (Hand K-files)			Group-II (Kedo Nano Plus rotary files)			Group-III (Neoendo Pedoflex rotary files)			H-value	p-value
	Mean	Median	SD	Mean	Median	SD	Mean	Median	SD		
24 hrs	1.9	2.0	1.4	0.3	0.0	0.7	1.0	0.0	1.2	19.5110	<0.001*
48 hrs	0.8	0.0	1.0	0.4	0.0	0.8	0.6	0.0	1.0	2.3510	>0.05
72 hrs	0.5	0.0	0.9	0.0	0.0	0.0	0.2	0.0	0.7	6.7270	<0.05*
24-48 hrs	1.1	2.0	1.8	-0.1	0.0	1.2	0.4	0.0	1.6	6.2770	<0.05*
24-72 hrs	1.4	2.0	1.6	0.3	0.0	0.7	0.8	0.0	1.2	9.6840	<0.001*
[Table/Fig-7]: Comparison of three study groups (Group-I, Group-II and Group-III) with postoperative pain scores at 24, 48 and 72 hours time duration by Kruskal Wallis ANOVA. (*p<0.05; Kruskal Wallis ANOVA Test has been used)											

Time point	Group-I vs Group-II (Hand K-files vs Kedo Nano Plus rotary files)	Group-I vs Group-III (Hand K-files vs Neoendo Pedoflex rotary files)	Group-II vs Group-III (Kedo Nano Plus rotary files vs Neoendo Pedoflex rotary files)
24 h	p<0.001*	p<0.05*	p<0.05*
48 h	p>0.05	p>0.05	p>0.05
72 h	p>0.05	p>0.05	p>0.05
24-48 h	p<0.05*	p>0.05	p>0.05
24-72 h	p<0.0001*	p>0.05	p>0.05

[Table/Fig-8]: Pairwise comparison of three groups (Group-I, Group-II and Group-III) with pain scores at different treatment time points by Mann-Whitney U test. (*p<0.05; Mann-Whitney 'U' Test has been used)

rotary systems not exclusively designed for paediatric use [18,19]. These findings explain the significantly shorter instrumentation time observed with Kedo Nano Plus in the present study. Neoendo Pedoflex rotary files, although paediatric-specific, demonstrated slightly longer instrumentation time than Kedo Nano Plus, possibly due to differences in file geometry and taper. Nevertheless, they performed significantly better than hand files, corroborating earlier findings reported by Govindaraju L et al., [7].

Postoperative pain is an important clinical outcome in paediatric endodontics, as it directly affects child comfort and parental perception of treatment success. In the present study, a higher incidence of postoperative pain within the first 24 hours was observed in children treated with hand files, whereas rotary systems were associated with significantly reduced postoperative discomfort. Manual instrumentation involves repeated filing motions and prolonged canal manipulation, which can increase irritation of periapical tissues. Greater apical extrusion of debris with hand files, owing to their push-pull motion and lack of early coronal flaring, has been identified as a major cause of postoperative pain [20,21]. Prolonged instrumentation time further aggravates periapical tissues, especially in primary teeth with wider apical foramina and physiological root resorption [2].

In contrast, NiTi rotary systems promote controlled canal preparation using a crown-down approach, allowing debris to be directed coronally and minimising apical extrusion and periapical inflammation [22]. Several studies have reported lower postoperative pain scores following rotary instrumentation compared to hand filing [23]. Paediatric-specific rotary systems such as Kedo Nano Plus and Neoendo Pedoflex, with shorter file lengths and appropriate tapers, further reduce mechanical stress on periapical tissues [7].

Obturation quality is a key determinant of pulpectomy success in primary teeth. Coll and Sadrian classified obturation into optimally filled, underfilled and overfilled canals, a widely accepted criterion in paediatric endodontic research [16]. The present study demonstrated superior obturation quality with rotary instrumentation compared to hand files, with Kedo Nano Plus showing the highest percentage of optimally filled canals, followed by Neoendo Pedoflex, while hand files exhibited a higher incidence of overfilling. These findings are consistent with previous reports indicating that rotary NiTi systems create more uniform and tapered canal preparations, facilitating controlled obturation [4,24]. Overfilling associated with hand files may result from irregular canal preparation and increased apical extrusion, which can cause inflammation, delay physiological root resorption, and affect the developing permanent tooth germ [4,7,18].

Based on the statistically significant differences observed in obturation quality, instrumentation time, and postoperative pain among the groups (p<0.05), the null hypothesis was rejected and the alternative hypothesis was accepted, indicating that a significant difference exists between hand files and rotary systems for pulpectomy in children aged 4-9 years.

Limitation(s)

The present study was conducted at a single centre, which may limit the generalisability of the findings. The procedures were performed by a single operator, and operator expertise may have influenced instrumentation efficiency and obturation quality. Radiographic assessment was based on two-dimensional intraoral periapical radiographs, which may not precisely detect minor voids. Additionally, the follow-up period was limited, restricting evaluation of long-term treatment outcomes. Although baseline variables such as age and gender were comparable between groups, potential confounding factors including tooth type, root canal morphology, degree of physiologic root resorption, canal curvature, and patient cooperation were not fully standardised and may have influenced the results.

CONCLUSION(S)

The present study showed that rotary instrumentation systems are superior to hand files for pulpectomy in primary molars. Kedo Nano Plus files achieved the best obturation quality, followed by Neoendo Pedoflex, reflecting more effective canal shaping and better adaptation of the obturating material. Hand files demonstrated poorer obturation outcomes, likely due to difficulties in managing the complex anatomy of primary teeth. Postoperative pain within 24 hours was more common in the hand file group, possibly related to longer instrumentation time and greater periapical irritation. Instrumentation time was highest with hand files, intermediate with Neoendo Pedoflex, and lowest with Kedo Nano Plus.

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