

# Clinical Efficacy of Kedo S Square Files versus Manual K Files in Root Canal Preparation of Deciduous Molars: A Randomised Clinical Trial

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## ABSTRACT

**Introduction:** The conventional approach to root canal preparation in primary molars involves hand instrumentation. However, the disadvantage of longer instrumentation time poses a challenge for dentists treating paediatric patients. As a solution, rotary file systems have been introduced to reduce chairside time and improve patient cooperation. Among the various rotary file systems available, the “Kedo S Square” rotary files are exclusive single files made of Nickel-titanium (NiTi), offering increased flexibility and variable taper to adapt to the curved canals of deciduous molars.

**Aim:** To assess and compare the instrumentation time and obturation quality of rotary “Kedo S Square” files with manual K files in deciduous molars.

**Materials and Methods:** This randomised clinical trial was conducted from July 2022 to February 2023 included 40 primary molars from four to six-year-old children requiring root

canal therapy. The teeth were evenly allocated to two groups: Group 1 underwent instrumentation using “Kedo S Square” files, while Group 2 underwent instrumentation using manual K files. The instrumentation time was recorded, and post-treatment radiographs were taken to evaluate the quality of obturation by a single-blinded investigator. Statistical analysis included the Independent t-test, Levene’s Test for Equality of Variances, Chi-square test, and Fisher’s-exact test.

**Results:** The use of Kedo S Square files resulted in significantly less instrumentation time ( $p < 0.001$ ) with a mean time of  $3.91 \pm 1.462$  minutes. There was no statistically significant difference in obturation quality between the two groups, with a  $p$ -value of 0.427.

**Conclusion:** Kedo S “Square” files demonstrated comparable obturation quality with shorter instrumentation time compared to manual K files in root canals of primary molars.

**Keywords:** Deciduous teeth, Obturation, Pulpectomy, Rotary file

## INTRODUCTION

The major concern in the field of Paediatric Dentistry is the premature loss of primary teeth despite various efforts to prevent dental caries in children. The main objective of Paediatric Dentistry is to preserve the primary teeth in the oral cavity until their physiological exfoliation in order to retain the integrity of the dental arch [1]. Pulpectomy, a therapeutic option for primary molars with pulp involvement, offers several advantages over extraction [2]. The pulpectomy procedure involves complete removal of the pulp, root canal preparation, and subsequent obturation with a suitable resorbable material [3]. However, it presents challenges due to the continuous physiological resorption of deciduous teeth and the presence of complex and narrow roots with extensive pulpal tissues [4]. Consequently, pulpectomy of posterior teeth poses a challenge for clinicians treating children [5]. The success of pulpectomy largely depends on the instrumentation of root canals in primary teeth, which aims to eliminate infection [6].

The literature describes the conventional approach of using hand files for cleaning and shaping the canals of primary teeth. However, the difficulties in instrumentation, complex canal anatomy, lengthy preparation time, and challenges related to patient behaviour necessitate the development of advanced techniques [7]. In recent years, rotary nickel-titanium instrumentation techniques have been developed to overcome these challenges [8]. Following the report by Barr et al., which described the use of permanent rotary instruments with a Profile 0.04 taper for biomechanical preparation of primary teeth, this technique gained popularity. However, it has limitations such as over-instrumentation in primary roots due to their relatively

thin canal walls and difficulties in fully instrumenting oval, flat, curved, and irregularly shaped canals [9,10]. Furthermore, the longer length of adult rotary files makes their use challenging in paediatric patients due to their smaller mouth opening. Kuo CI et al., suggested that a paediatric-specific rotary file with modified length, tip size, and taper would be more suitable for performing pulpectomy in primary teeth [11].

An advancement in paediatric endodontics was the introduction of the exclusive paediatric Kedo S rotary file system. This system consists of U1 for primary anterior teeth, D1 for mesiobuccal and mesiolingual canals, and E1 for distal and palatal canals of primary molars. These files are unique as they have a variable taper (4-8%) and a variable tip diameter (D1-0.25 mm) [12]. The more recent generation of Kedo S ‘Square’ files includes P1 for molars and A1 for anterior teeth. These files offer advantages such as increased flexibility, reduced dentin removal, and higher resistance to cycle fatigue due to their TiO<sub>2</sub> coating [13]. Studies in the literature have demonstrated that nickel-titanium rotary devices are superior to manual instrumentation in terms of time efficiency and cleaning ability for root canal instrumentation in primary teeth [14-19].

Currently, limited data are available on the performance of Kedo S ‘Square’ files in curved and narrow canals of deciduous teeth [20-23]. An in-vitro study using Kedo S ‘Square’ files showed varying cleaning efficiency for both Kedo S ‘Square’ and manual K files in different thirds of root canals in primary molars [23]. Therefore, to further contribute to this research, the current study was conducted with the hypothesis: “Does the use of paediatric rotary Kedo S ‘Square’ files improve the quality of obturation and

reduce instrumentation time compared to manual K files in primary molars?”.

The aim of the present research was to clinically evaluate and compare the time required for mechanical preparation and assess the quality of obturation using Kedo S ‘Square’ files and manual K files in root canal preparation of primary molars.

## MATERIALS AND METHODS

Based on Consolidated Standards of Reporting Trials (CONSORT) clinical guidelines and in compliance with the Institutional Ethical Review Board (IGIDSIEC2022NRP01PGBAPPD) and the Helsinki Declaration, the present randomised clinical trial was conducted from July 2022 to February 2023. The present single-blinded randomised clinical trial was registered in the Clinical Trials Registry-India (CTRI/2022/04/041853).

**Sample size calculation:** The sample size calculation was based on the research by Jeevanandan G and Govindaraju L, using the following formula [24,25]:

$$n = \frac{2(\bar{p})(1-\bar{p})(Z_{1-\beta} + Z_{1-\alpha/2})^2}{(p_1 - p_2)^2}$$

Where,

n is the desired number of samples,

$\bar{p}$  is the desired proportion of the population=(P1+P2)/2

$Z_{1-\beta}$  is the power,

$Z_{1-\alpha/2}$  is the critical and standard values for the corresponding confidence level,

P1 is the proportion in cases

P2 is the proportion in controls

$$P_1=76.7\%, P_2=40\% \text{ and } \alpha=0.05, \beta=0.2$$

Calculated sample size=20 per each groups

**Inclusion and Exclusion criteria:** Based on the inclusion and exclusion criteria, 40 teeth (18 boys and 22 girls) with decayed primary molars indicated for single visit pulpectomy, who had at least two-thirds of the remaining root, sufficient crown architecture to sustain rubber dam placement, and Frankel's behaviour rating of 3 and 4, were included in the study. Children and parents who refused to participate in the study, special needs children, children with severe tooth mobility, internal or external root resorption, perforation in the pulpal floor, and non restorable teeth were excluded from the study.

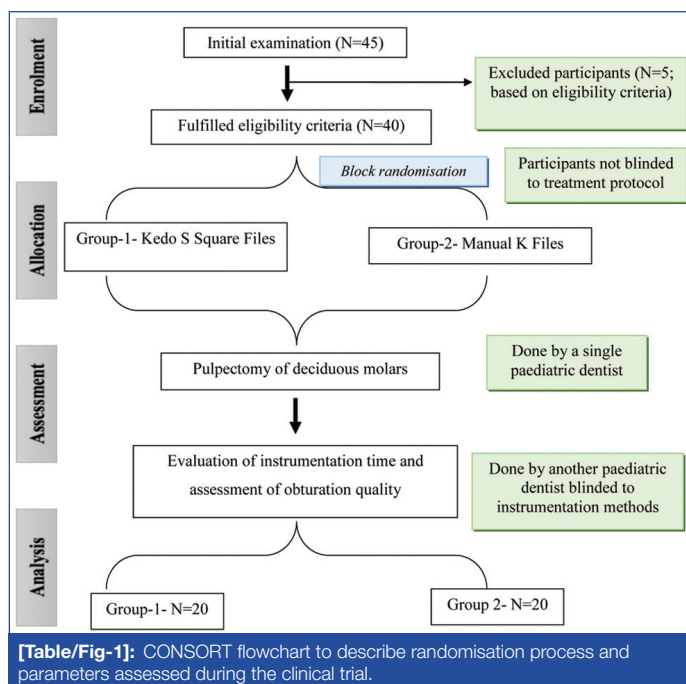
### Study Procedure

Demographic details and a brief case history were recorded for all the children included in the present study. Random allocation for the sequence of children requiring pulpectomy in either of their primary molars was done by a single operator using computer-generated sequence employing the block randomisation technique (blocks 2 and 4). Slips of paper with either Kedo S ‘Square’ or manual K files printed on them were placed in sealed envelopes by another investigator not associated with the present study. The outside of the envelope was sequentially numbered, and each child accepted into the study was given an individual number for identification. The present prevented allocation bias, and the paediatric dentist conducting the outcome assessment was kept blinded about the group to which the child had been assigned.

The primary molars included for pulpectomy in the present study were grouped into two groups:

- Group 1- Rotary instrumentation using Kedo S ‘Square’ Files (n=20, Kedo Dental, India)
- Group 2- Manual instrumentation using K files (n=20, NeoEndo K file, M/s Orikam Healthcare India Pvt., Ltd.,)

The CONSORT guidelines for planning and reporting clinical trials were followed during different stages of the study [Table/Fig-1].



**[Table/Fig-1]:** CONSORT flowchart to describe randomisation process and parameters assessed during the clinical trial.

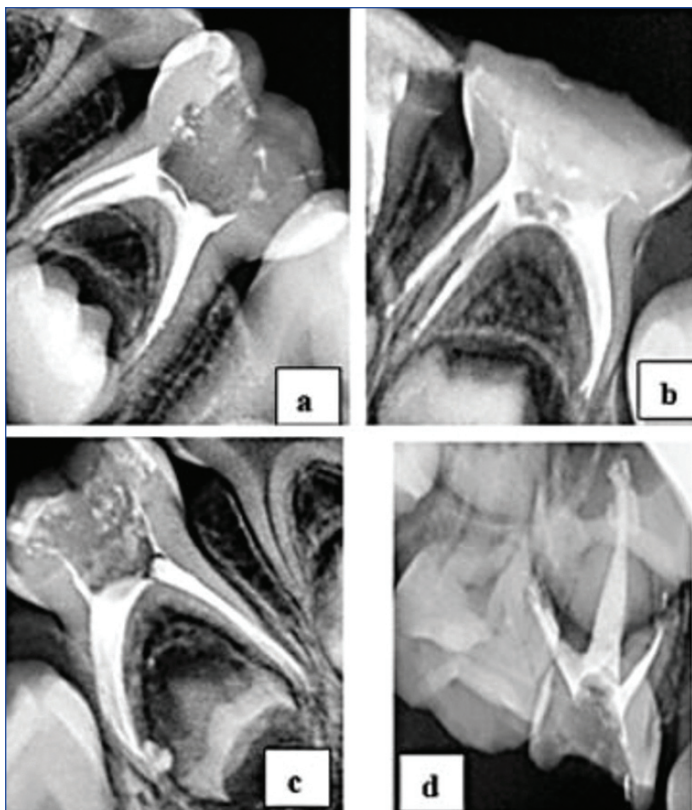
**Treatment procedure:** Single-visit pulpectomy was performed on all the teeth included in the present study by a single operator. Local anaesthesia (LOX\* 2% Adrenaline, Neon Laboratories Limited, India) was administered, followed by rubber dam isolation (GDC Marketing, Hoshiarpur, Punjab, India). The roof of the access cavity was removed using a safe-ended diamond tapered fissure bur with an outward brushing action, after opening the access with a number 4 round carbide bur. Patency of canals and working length were determined using a number 10 K file and digital radiographs. In Group 1, initial canal preparation was done using a number 20 K file, followed by Kedo S ‘Square’ rotary files (P1) and an Endodontic motor (Woodpecker E-com plus Cordless Endomotor, India) at 300 rpm and 2.2 N/cm torque. In Group 2, instrumentation was carried out using manual K files up to number 35, using a quarter turn and pull motion. Saline irrigation was done to flush out debris between files for all the groups. The total instrumentation time was measured using a digital stopwatch, starting from the introduction of the first manual #10 K file until the final saline irrigation.

After complete instrumentation and irrigation, the canals were dried using no. 30 sterile paper points (Dentsply Maillefer, OK, USA) and obturated with Metapex (Meta Biomed Co. Ltd., Chungcheongbuk-do, Korea). The paste was gently pushed into the canals with cotton pellets and an endodontic plugger. Coronal sealing was achieved using type IX glass ionomer cement (GC, India), and final restoration was completed using stainless steel crowns (Kids crown SS Primary Molar, India). Postoperative radiographs were taken to evaluate the quality of obturation. Another investigator, who was blinded to the type of instrumentation protocol, assessed the quality of obturation in each tooth according to the Coll JA and Sadrian R criteria (1996) [26]. The obturation was scored as follows:

- **Score 1: Short fill-** All the canals were filled 1 mm or more short of the apex.
- **Score 2: Complete fill-** One or more of the canals had obturating material ending at the radiographic apex.
- **Score 3: Long fill-** Any molar canal showed obturating material outside the root [Table/Fig-2a-d].
- **Voids:** Presence or absence.

### STATISTICAL ANALYSIS

The data obtained were entered into an excel sheet and subjected to statistical analysis using Statistical Package for Social Sciences (SPSS) software version 16.0 (Chicago, SPSS Inc). An independent



**[Table/Fig-2]:** a) Complete fill-rotary; b) Complete fill-manual; c) Long fill-rotary; d) Long fill-manual.

Groups	Scores	Count (% within groups)	Chi-square	Fisher's-exact test	p-value
Group 1- Kedo S 'Square' files	2- Complete fill	17 (85.0%)	0.630	0.695	0.427
	3- Long fill	3 (15.0%)			
Group 2- Manual K files	2- Complete fill	15 (75.0%)			
	3- Long fill	5 (25.0%)			

**[Table/Fig-4]:** Quality of obturation observed between Groups 1 and 2.

Groups	Presence/Absence	Count (% within groups)	Chi-square	Fisher's-exact test	p-value
Group 1- Kedo S 'Square' files	Absent	20 (100.0%)	9.382	0.020	0.002*
	Present	0 (0.0%)			
Group 2- Manual K files	Absent	14 (70.0%)			
	Present	6 (30.0%)			

**[Table/Fig-5]:** Presence/Absence of voids observed between Groups 1 and 2.

\*Statistically significant

## DISCUSSION

There has been a significant shift in the management of primary molars with deep caries, moving from extractions to pulpectomy [27]. Adequate remaining dentin thickness is crucial for an endodontically treated tooth to resist lateral and occlusal stresses. Conventional hand files may not allow for the present, which is why rotary files were introduced [20,28]. NiTi rotary files, such as the Kedo S 'Square' rotary file, are designed to adapt to the curvature of primary root canals, reducing the chances of zipping, transportation, and creating smooth, funnel-shaped canals [29].

The Kedo S 'Square' rotary file is a fourth-generation, exclusively paediatric rotary file with a variable taper and a working length of 17 mm. It effectively scrapes the dentin, removes a small layer from the entire root canal circumference, and maintains the structural integrity of the dentin to facilitate three-dimensional obturation [20,21]. While several studies have evaluated the clinical efficacy of rotary files in achieving optimal obturation quality, there are fewer clinical studies specifically using the exclusive Kedo S 'Square' files in primary teeth [29-31]. Therefore, the present study aimed to compare the quality of obturation and instrumentation time of the paediatric rotary Kedo S 'Square' file with manual K file systems in primary molars.

The participants in the present study were between four and six years of age, as primary molars complete the development of their roots by four years and root resorption typically begins at six years. The mean age of the children included in the present study was 5.018±0.564 years, which was lower compared to a study by Kumar D and Ravindran V where the age range was four to eight years [32].

Single-visit pulpectomy was performed in all the primary molars included in the present study, as the teeth were vital, the pulp was superficially infected, and the root canals were free of bacteria, allowing for aseptic conditions during intracanal procedures [32,33].

The instrumentation time was significantly shorter in the Kedo S 'Square' file group compared to the conventional K files group, with a statistically significant difference between them. The mean instrumentation time observed in the rotary technique used in this study was 3.91±1.462 minutes. In contrast, Mohamed RH et al., reported a mean instrumentation time of 2.12±0.82 minutes, Lakshmanan L et al., reported 73.46±8.62 seconds, Kumar D and Ravindran V reported 72.6±9.8 seconds using Kedo S 'Square' files in primary molars, and Lakshmanan L et al., reported 53.23±9.60 seconds, respectively [20,22,32,34].

Regarding the quality of obturation, no significant difference was observed between the two file systems used in the present study.

t-test was performed to compare the instrumentation time between groups. Chi-square test and Fisher's-exact test were used to analyse the quality of obturation and the presence of voids. A p-value less than 0.05 was considered statistically significant.

## RESULTS

In the present study, 40 primary molars (20 in each group) were treated in four to six-year-old children, consisting of 18 boys and 22 girls. The mean age of the children was 5.018±0.564 years. Among the treated teeth, the majority were mandibular primary second molars (n=32), followed by maxillary primary second molars (n=8).

**Instrumentation time:** The mean instrumentation time was observed to be higher in the conventional K files group (10.01±2.055 minutes) compared to the Kedo S 'Square' rotary files group (3.91±1.462 minutes) (p<0.001) [Table/Fig-3].

Groups	N	Mean±Standard deviation (Minutes)	Frequency	p-value
Group 1- Kedo S 'Square' files	20	3.91±1.462	1.268	0.001*
Group 2- Manual K files	20	10.01±2.055		

**[Table/Fig-3]:** Independent t-test to compare instrumentation time between Kedo S 'Square' and K files.

\*Statistically significant

**Quality of obturation:** In terms of the quality of obturation, the Kedo S 'Square' group (85%) showed a higher number of complete fill (Score 2) compared to the K file group (75%). The occurrence of long fill (Score 3) was observed in 25% of canals instrumented with manual K files, while it was 15% in the Kedo S 'Square' file group [Table/Fig-2]. However, the Chi-square test showed no statistically significant difference in the quality of obturation between the two groups, with a p-value of 0.427 [Table/Fig-4].

**voids:** When examining the radiographic quality of obturation after K file instrumentation (Group 2), 30% of canals showed voids. In contrast, the canals instrumented with Kedo S 'Square' files (Group 1) showed complete absence of voids, and this difference was statistically significant (p<0.002) [Table/Fig-5].



However, Lakshmanan L et al., reported good obturation quality with Kedo S 'Square' files compared to manual files in primary molars [22]. Similarly, Kumar D and Ravindran V et al., and Lakshmanan L et al., observed higher rates of optimal fill (76.7%, 67%, and 66.6%) with the Kedo S 'Square' file system in primary mandibular molars, which is consistent with the present study where 85% of canals showed optimal fill. Additionally, a higher occurrence of long fill (25%) was observed in primary molars instrumented with manual K files compared to Kedo S 'Square' files (15%) in the present study. This contrasts with the findings of Kumar D and Ravindran V et al., and Lakshmanan L et al., where more underfillings (33.3% and 54%) were observed with manual instrumentation using K files [32,34]. The rotary group had a higher rate of optimal fill and lower rate of underfill. This may be attributed to its elastic memory and radial land, which help keep the file in the centre of the root canal through wall support and create conical-shaped canals [16].

The presence or absence of voids is another important factor that affects the quality of obturation. Voids can create pathways for leakage and increase the likelihood of bacterial and toxin retention, leading to post-treatment failures [35]. No voids were observed in primary molars instrumented with Kedo S 'Square' files compared to manual files. A statistically significant difference in the presence of voids in obturation was observed between the rotary and manual techniques used in the present study. Similarly, more voids were observed in primary mandibular molars instrumented with manual K files compared to rotary files, as reported by Shah HS et al., and Lakshmanan L et al., In Lakshmanan L et al.,'s study, voids were equally present in primary root canals instrumented with Kedo S 'Square' files and K files (20%). Procedural errors, the presence of moisture in the canals, and the consistency and viscosity of the obturating material used can contribute to the formation of voids and compromise the quality of obturation [28,34].

### Limitation(s)

The present study had certain limitations, including the use of a two-dimensional radiographic assessment method to determine the quality of obturation and the lack of follow-up to assess treatment outcomes. Therefore, further studies with larger sample sizes and long-term follow-up are needed to accurately evaluate the patients' acceptance of exclusive Kedo S 'Square' rotary files and determine the clinical and radiographic success rates.

### CONCLUSION(S)

Within the limitations of the present study, it can be concluded that the use of Kedo S 'Square' rotary files in primary molars resulted in reduced instrumentation time, fewer voids, and a higher rate of optimal fill compared to manual K files. Therefore, incorporating an exclusive single-file rotary system like Kedo S 'Square' files into routine paediatric dental practice can lead to more effective, efficient, and safer dental treatments, ultimately reducing chair-side time.

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**PLAGIARISM CHECKING METHODS:** [\[Jain H et al.\]](#)

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- iThenticate Software: Sep 16, 2023 (16%)

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