



# Comparison of obturation quality, instrumentation time and post-operative pain using manual K-files and pediatric rotary files in primary molars – a double blinded randomised clinical trial

Comparaç o da qualidade de obturaç o, tempo de instrumenta o e dor p s-operat ria usando Limas manuais K e Limas rotativas pedi tricas em molares dec duos – um estudo cl nico randomizado duplo-cego

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**How to cite:** Lakshmanan L, Ramakrishnan M, Jeevanandan G. Comparison of obturation quality, instrumentation time and post-operative pain using manual K-files and pediatric rotary files in primary molars – a double blinded randomised clinical trial. *Braz Dent Sci.* 2023;26(2):e3497. <https://doi.org/10.4322/bds.2023.e3497>

## ABSTRACT

**Objective:** to compare the quality of obturation, instrumentation time and post-operative pain after pulpectomy in primary molars using manual K-files, Kedo-S and Kedo-S Square rotary file systems. **Material and Methods:** a double blinded randomized control trial was conducted in 45 children, who were indicated for pulpectomy in any one of the primary mandibular molars. The canal preparation was done using either hand K-files, Kedo-S files, or Kedo-S Square files based on the groups assigned. The time taken for instrumentation was recorded using a stopwatch. The quality of obturation was evaluated using post-operative radiograph and post-operative pain was assessed with modified Wong-Baker Faces Pain scale. **Results:** instrumentation time was minimum in rotary Kedo-S Square files (53.23 ± 9.60 seconds) followed by Kedo-S files (82.70 ± 11.86 seconds). The preparation time was maximum with manual K-files (121.43 ± 20.18 seconds). Kedo-S square files provided a higher number of optimally filled canals (66.4%). All the three instrumentations equally showed the tendency to produce voids in the obturation. Rotary files Kedo-S Square followed by Kedo-S showed less post-operative pain compared to K-files. **Conclusion:** the use of pediatric rotary instruments for canal preparation during pulpectomy will result in better quality of obturation in reduced time with least post-operative pain.

## KEYWORDS

Children; Hand files; Instrumentation; Pulpectomy; Rotary files.

## RESUMO

**Objetivo:** comparar a qualidade de obturaç o, tempo de instrumenta o e dor p s-operat ria ap s pulpectomia em molares dec duos usando limas manuais K, limas rot rias Kedo-S e limas rot rias Kedo-S Square. **Material e M todos:** um estudo cl nico randomizado duplo-cego foi conduzido com 45 crian as que foram submetidas   pulpectomia de algum molar dec duo indicado. A prepara o do canal foi feita usando limas manuais K, ou limas Kedo-S, ou ainda Limas Kedo-S Square, com base nos grupos que foram selecionados. O tempo para a instrumenta o foi registrado com um cron metro. A qualidade de obtura o foi avaliada por meio de uma radiografia ap s o procedimento e a dor p s-operat ria foi avaliada com a escala de dor Wong-Baker Faces modificada. **Resultados:** o tempo de instrumenta o foi m nimo para as limas rot rias Kedo-S Square (53,23 ± 9,60 segundos) seguido pelas limas Kedo-S (82,70 ± 11,86 segundos). O tempo de prepara o foi maior com as limas manuais K (121,43 ± 20,18 segundos). As limas Kedo-S Square promoveram um maior n mero de canais otimamente obturados (66,4%). Todas as tr s instrumenta es mostraram igualmente a tend ncia em se

produzir vazios na obturação. As limas rotatórias Kedo-S Square seguidas pelas limas Kedo-S produziram menos dor pós-operatória comparadas às limas manuais K. **Conclusão:** o uso de instrumentos rotatórios pediátricos para a preparação do canal durante a pulpectomia resultará em melhor qualidade de obturação em tempo reduzido e com menos dor pós-operatória.

## PALAVRAS-CHAVE

Crianças; Limas manuais; Instrumentação; Pulpectomia; Limas rotatórias.

## INTRODUCTION

Pulpectomy is the only viable option for preserving a primary tooth with irreversible pulpal pathosis in a symptom-free condition and preventing it from being lost prematurely since a natural tooth is considered to be the ideal space maintainer [1].

The complex anatomical morphology, dynamic alteration of canals at root apex and close proximity of primary roots to the succedaneous tooth bud added to difficulties in behavior management in children, makes pediatric endodontics a challenging task [2]. The favorable outcome of pulpectomy is established by aseptic canal preparation and three dimensional fluid-tight seal of the root canal system [3]. Effective cleaning and shaping of root canals not only facilitates the removal of infected tissue, but also permits a pathway for the irrigants to reach the apical third of root canals and provides space for three-dimensional obturation [4].

A brief complication associated with pulpectomy is the post-operative pain that commences within a few hours or days following treatment [5]. Post-endodontic pain debilitates a patient's trust in the clinician and mentality towards endodontic treatment [6]. Post-operative pain is considered to develop as a response to the acute inflammation caused by extrusion of dentinal debris, microorganisms, pulpal tissue, and irrigants into the periapical tissues during biomechanical preparation [7]. Only limited studies have evaluated the association of instrumentation technique in causing post-operative pain following pulpectomy in primary teeth [8].

Traditionally, hand instruments were utilized for primary root canal preparation. Though extensively used, hand instruments resulted in iatrogenic errors such as lateral perforation, zipping, ledge formation and transportation during canal preparation and also consumed more duration [9]. Rosa FM et al. [10], have stated that the duration of appointment

is strongly associated with the behavior of the child and reduced duration has a positive influence on the child's behavior towards dental treatment [10].

To overcome such hurdles, Barr et al. [11], utilized nickel titanium (NiTi) rotary instrumentation in primary root canals [11]. However, the rotary files designed for permanent teeth resulted in over-instrumentation when employed in relatively thin root canals of primary teeth [12]. Further, the longer length of adult rotary files made it difficult to utilize in pediatric patients due to limited mouth opening [13]. These necessitated the designing of an exclusive pediatric rotary file system to be utilized in children.

Kedo-S (KEDO Dental, India) is the first generation rotary file system introduced in pediatric endodontics with altered length, taper, and tip diameter to accomplish pulpectomy in an efficient and comfortable means. The Kedo-S system consists of three NiTi files with a total length of 16 mm and working length of 12mm with gradual taper. The efficacy of other rotary systems in primary teeth were compared with Kedo-S files, considering it as a norm in pediatric endodontics [14-16]. Latest to join the pediatric rotary file series is the Kedo-S Square system (KEDO Dental, India). It is a single file system for primary molars with smaller tip diameter, variably variable taper and dual cross-section introduced with the notion of less root dentin preparation.

The purpose of the current study was to compare the quality of obturation, instrumentation time and post-operative pain after pulpectomy in primary molars using manual K-files, Kedo-S and Kedo-S Square rotary file systems.

## MATERIAL AND METHODS

### Study design

The present study was a double blinded randomized clinical trial conducted in the

Department of Paediatric and Preventive Dentistry, Saveetha Dental College and Hospitals, Tamil Nadu, India. Ethical approval was acquired from the Institutional Ethical Committee of Saveetha Institute of Medical and Technical Sciences (SRB/SDC/PEDO-1803/20/04) and registered the trial at clinical trials.gov (CTRI/2021/02/031512) prior to the commencement of the study.

### Sample size calculation

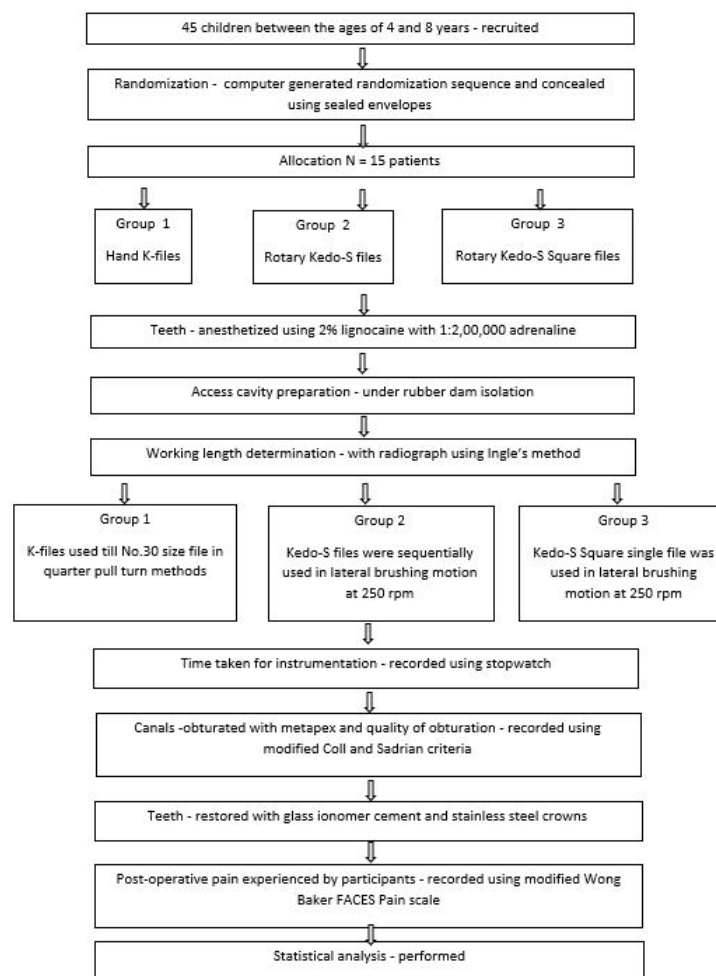
Sample size was determined from a previous study by Topçuoğlu et al. [17], using G power analysis [17]. With 95% power,  $P \leq 0.05$  and alpha error set at 5%, the minimum sample size requirement was calculated to be 24. The total sample size for the current study was set at 45 (15 per group) to account for the participant dropouts during follow-up.

### Study population

The target population was 4-8 years old children visiting Saveetha Dental College & Hospitals for pulpectomy in one of the primary mandibular molars. Participation in the study was voluntary. The participants' parents were explained about the complete study protocol and a written informed consent was obtained prior to the start of the study. The CONSORT criteria for planning and reporting clinical trials were followed throughout the investigation [Figure 1].

### Inclusion criteria

- Healthy cooperative children aged between 4 and 9 years
- No intake of analgesics 12 hours prior to treatment



**Figure 1** - CONSORT flowchart describing the participant randomization and the parameters assessed during investigation.

- Primary mandibular molars with signs of chronic irreversible pulpitis and pulp necrosis without sinus tract
- Tooth with adequate coronal structure and minimum of 2/3<sup>rd</sup> root structure

### Exclusion criteria

- Children with underlying systemic diseases and requiring special health care needs
- Uncooperative children with “negative” or “definitely negative” behavior rating according to Frankel’s scale
- Parents/ guardians who were not willing to participate and those who refused to sign the informed consent
- Teeth with signs of internal / pathological resorption
- Teeth which were unrestorable

### Randomization and allocation concealment

The participants were equally distributed and randomly assigned into three groups. Randomization was performed according to a computer generated sequence of random numbers using Random Allocation Software (Version 1.0). The sequence was numbered in advance and was sealed in opaque envelopes to ensure sufficient concealment.

### Clinical procedure

Single visit pulpectomy was performed in all the included teeth by a single pediatric dentist, who could not be blinded. Topical anesthetic agent (Precaine B, Pascal International, USA) was applied, and inferior alveolar nerve block was administered with local anesthetic solution containing 2% lignocaine with 1:2,00,000 adrenaline (LOX\* 2% ADRENALINE, Neon Laboratories limited, India) using 2ml syringe with 25 gauge needle (UNOLOCK single use syringe, Hindustan Ltd., Chennai, India). Rubber dam isolation (GDC Marketing, India) was done after confirming the subjective and objective signs of local anesthesia. The caries removal and access opening was done using No.4 round carbide bur in a high-speed handpiece. Roof of the access cavity was removed using a safe ended diamond tapered fissure bur. Coronal pulp amputation was done with a spoon excavator. No.15 size conventional K-file (Mani, Inc., Japan)

was used to determine the patency of all the canals and working length was determined using Ingle’s radiographic method.

Biomechanical preparation was carried out based on the groups assigned:

Group I: The canals were prepared using manual K-files (Mani, Inc., Japan) till No.30 size file in quarter turn pull technique.

Group II: The root canals were instrumented using Kedo-S file system (KEDO Dental, India) according to the manufacturer’s instructions. The mesial canals were instrumented using the D1 file in a lateral brushing motion. The distal canals were instrumented by D1 file followed by E1 file.

Group III: The canals were prepared using the single file system Kedo-S Square (KEDO Dental, India) in brushing motion.

All the rotary files were used with an X-Smart endodontic motor (Dentsply Maillefer, OK, USA) at 250 rpm and 2.4 N/cm torque till the determined working length. 17% EDTA (Endo Prep RC) was utilized for lubrication during instrumentation and intermittent irrigation was carried out manually using normal saline (Fresenius Kabi India Pvt. Ltd., India). After drying, the canals were obturated with Metapex (Meta Biomed Co., Ltd., Korea). Following which, the access cavity was sealed with type II glass ionomer cement (GC, India). In the same appointment, the teeth were restored with preformed stainless steel crowns (3M ESPE, Germany).

### Assessment of instrumentation time

The instrumentation time was recorded in seconds using a digital stopwatch by an investigator who was blinded to the study groups. The recorded instrumentation time included only the total instrumentation time of the used files excluding the in-between irrigation protocol for assessing the accurate time period needed for instrumentation in each group.

### Assessment of quality of obturation

The quality of obturation was assessed using immediate post-operative radiographs based on the criteria laid down by Coll and Sadrian [18] as underfilled, optimal filled or overfilled [18]. Evaluation of voids was based on their presence/absence in root canals. The quality of obturation and evaluation of voids was assessed by a single



investigator who was blinded to the study groups. The radiographs were examined three times with a time interval of approximately 4 weeks. In case of any discrepancy, that particular sample was excluded from the study.

### Assessment of post-operative pain

The post-operative pain was recorded using Modified Wong-Baker Pain Rating Scale as utilized by Topçuoğlu et al. [17]. This 4-point scale measures pain as: (1) zero—no pain, (2) one—slight pain, (3) two—moderate pain, (4) three—severe pain [Figure 2]. All participants and their parents who were blinded to the treatment protocol, were instructed on how to use this pain scale, and were advised to record the pain status every 6, 12, 24, 48, 72 hours and after a week. These data were verified by the observer through telephonic communication with the parents/ guardians.

### Statistical analysis

The collected data were tabulated and analyzed using SPSS software version 23.0 (SPSS Inc., Chicago, IL, USA) with statistical significance set at  $p \leq 0.05$ . The instrumentation time between the three groups were compared using ANOVA test followed by Tukey post-hoc analysis to list out the significant groups. Chi square test was used to assess the quality of root canal filling in the primary molars. Non-parametric tests were used to compare the intensity of pain and duration of post-operative pain for the 3 groups at each time interval.

## RESULTS

### General characteristics

A total of 45 children, comprising 23 males and 22 females, participated in the study. The mean ages of the participants were  $5.3 \pm 1.3$  years in the K-file group,  $5.2 \pm 1.3$  years in the Kedo-S group

and  $5.9 \pm 1.3$  years in the Kedo-S Square group. Of the 45 included primary teeth, 19 (42.2%) were mandibular 1<sup>st</sup> molars and 26 (57.8%) were mandibular 2<sup>nd</sup> molars. Comparative analyses using Chi square test reflected an equal distribution of participants between the three groups with respect to age ( $P=0.215$ ), gender ( $P=0.315$ ) and teeth ( $P=0.260$ ) was observed between the groups eliminating selection.

### Instrumentation time

Time taken for canal preparation was recorded and intergroup comparison was performed using ANOVA test followed by Tukey post-hoc test. Preparation with Kedo-S Square files consumed least time (Mean= 53.2 seconds) followed by Kedo-S files (Mean= 82.7 seconds). Whereas preparation time was maximum with hand K-files (Mean= 121.4 seconds). The results were statistically highly significant ( $P < 0.05$ ) [Table I].

### Quality of obturation

66.6% ( $n=10$ ) of teeth instrumented with rotary Kedo-S Square files, 33.3% ( $n=5$ ) of teeth instrumented with Kedo-S files, 33.3% ( $n=5$ ) of teeth instrumented with hand K-files had optimal filling [Figure 3] [Figure 4]. The results were not statistically significant ( $P=0.18$ ).

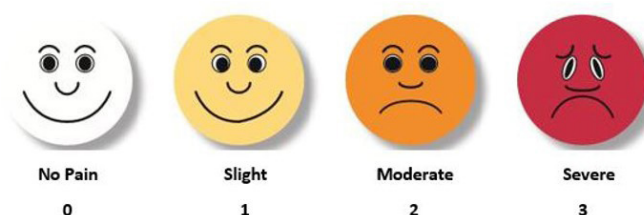
### Voids

Voids in the root canal after obturation with metapex were present in all the three experimental groups. In both Kedo-S square files

**Table 1** - Comparison of instrumentation time (in seconds) among the groups

Treatment groups	Sample size	Mean $\pm$ Standard deviation (Seconds)	P value
K-file	15	121.4 $\pm$ 20.1	0.0001*
Kedo-S file	15	82.7 $\pm$ 11.8	
Kedo-S Square file	15	53.2 $\pm$ 9.6	

\* $P < 0.05$ , statistically highly significant (ANOVA test).



**Figure 2** - Modified Wong-Baker pain rating scale.

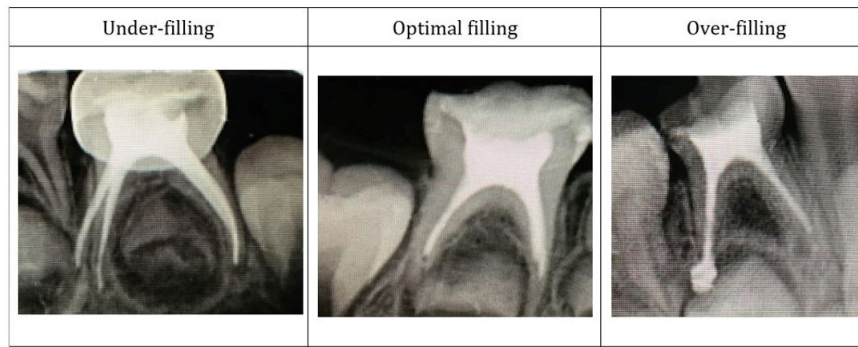


Figure 3 - Assessment of quality of obturation.

and K-files, voids (20%; 3 of 15 teeth) were noted in the middle third of root canals. In Kedo-S files, 6% voids (1 of 15 teeth) were in the apical third of root canals and 13% (2 of 15 teeth) were in the middle third of root canals. The results were not statistically significant ( $P=0.58$ ).

### Post-operative pain

At 6-hour, the intensity of pain experienced by participants in the hand K-file group was significantly higher than those in the rotary Kedo-S and Kedo-S Square group ( $P=0.02$ ). At 12 and 24-hour intervals, there was no significant difference in the post-operative pain between the three groups ( $P>0.05$ ). None of the participants in all the groups experienced any pain at 48, 72 hours and 1-week intervals. In all the three groups, the highest post-operative pain scores were recorded at a 6-hour interval and decreased over time [Figure 5].

## DISCUSSION

Pulpectomy is the recommended means of treating symptomatic primary teeth, and it is statistically more effective than extraction [18]. The quality of mechanical debridement and obturation determines the effectiveness of an endodontic treatment [19]. In the published literature, both in-vitro and in-vivo studies using Ni-Ti files designed for permanent teeth had investigated the multiple facets of instrumentation technique such as cleaning effectiveness, instrumentation time, obturation quality, and association with post-operative pain in primary teeth [20,21].

The use of rotary files in paediatric endodontics was heralded by the introduction of rotary Kedo-S files. The first explicitly developed

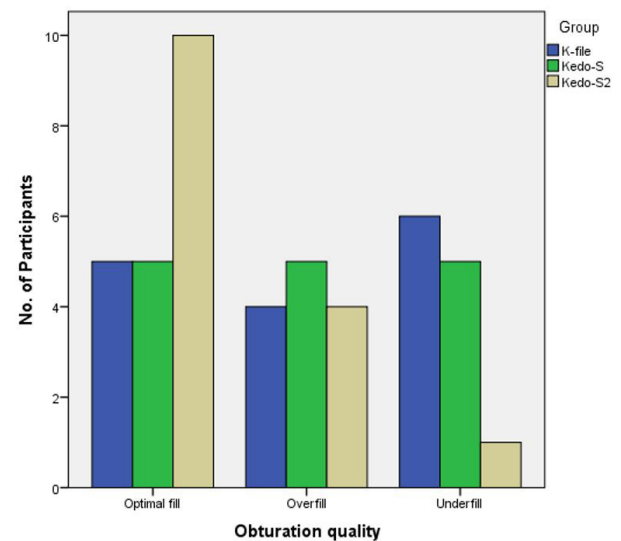


Figure 4 - Comparison of quality of obturation with three different instrumentations.

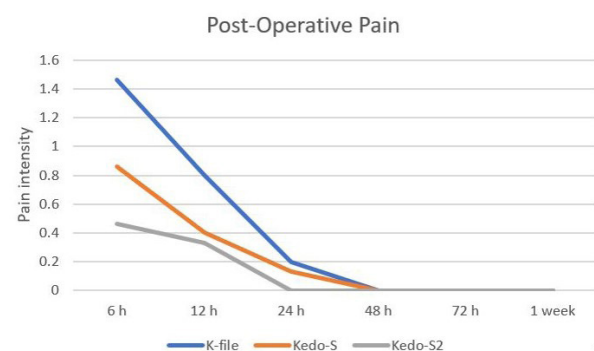


Figure 5 - Comparison of post-operative pain experienced by the participants at different time intervals.

paediatric rotary files, Kedo-S, were implemented to address the limitations of using permanent teeth rotary files, as well as to provide faster and more efficient outcomes in primary teeth. The 4th generation Kedo-S Square file with single file system for molars is one such development in the paediatric endodontics.

In the present study, only primary mandibular molars were included to maintain uniformity and for convenience. Children aged between 4 and 8 years were included, and the study population was evenly distributed among the three groups with respect to age. In addition, there was an equal distribution of the teeth and participants with respect to gender, minimizing the risk of selection bias. Children who took analgesics 12 hours before treatment were excluded from the study due to the possibility of bias in the assessment of post-operative pain.

Mandrolu and Baruka found no statistically significant difference in clinical and radiographic success rates between single and multi-visit pulpectomy in primary teeth with apical periodontitis after 6 months of follow-up [22]. Furthermore, the single visit pulpectomy technique saves time, decreases treatment costs, and reduces child anxiety by obviating the need for a second visit with an added anesthetic injection, rubber dam placement. Hence, single visit pulpectomy was preferred in the present study.

All the pulpectomy procedures were performed by a single operator, thereby eliminating the operative bias in the study. The rotary instruments were operated based on manufacturer's recommendation. In the Kedo-S file group, mesial canals were instrumented with D1 files and distal canals were instrumented with D1 followed by E1 files in lateral brushing motion. Whereas in the Kedo-S Square file group, the single file was used in brushing motion in both mesial and distal canals. In hand K-file group, instrumentation was carried out till no.30 size file as recommended by Kennedy et al. [23].

In paediatric dentistry, the length of treatment plays an important role in assessing the effectiveness of the procedure, as a shorter treatment time reduces children's anxiety, resulting in more positive behavior. The probable reason for the shorter instrumentation time with Kedo-S Square rotary system in current study is that each canal is prepared with only one file, while hand instrumentation involves sequential preparation with 15 to 30 size files in each canal, and Kedo-S file uses two files for canal preparation. This is consistent with the results from previous clinical trials utilizing various rotary systems [24-26].

The radiographic evaluation of the obturation is the most conservative of these approaches in terms of in-vivo studies. This is accomplished using

both traditional and digital imaging techniques. Despite their two-dimensional nature, radiographs are reliable for voids smaller than 300 $\mu$ m [27]. Based on the present study, the increased efficiency of Kedo-S Square files in canal preparation over its earlier predecessor Kedo-S can be attributed to the additional titanium oxide coat that increases the flexibility of the file to negotiate even the narrowest canal in primary teeth allowing easier flow of obturating material. Coll and Sadrian [18] found that teeth filled up to the apex had a higher success rate than teeth that were underfilled or overfilled [18]. Whereas Bawazir and Salama [28] found that canals that were optimally filled and overfilled performed better than canals that were underfilled [28]. The present study findings were similar to that of Govindaraju et al. [29], and Ochoa-Romero et al. [20], where overfilling was commonly encountered with Kedo-S files, and underfilling were found in manual files group [20,29]. In this study, voids were found in all the three groups. This matches the findings of previous research [28,30]. The form, consistency, and viscosity of the obturation material, the technique used to deliver the material, and the operator's expertise and experience all play a role in the position and size of voids [31,32].

Pain assessment is critical for assessing the level of discomfort and reaction to any treatment. Pain is a subjective phenomenon with numerous mitigating variables that are difficult to monitor in an in vivo condition. Modified Wong Baker FACES pain scale was chosen for the analysis because it was stated to be more sensitive and easier to understand by participants than other pain scales [33,34]. The study results indicated that the significant post-operative pain occurred 6 hours after pulpectomy in all the three groups, and that pain scores decreased over time. Comparatively, the pain score was least with the rotary groups than hand K-files. This is consistent with previous research that focused on the frequency and intensity of post-operative pain at various time intervals [14,33]. It is well recognized that apically extruded debris is one factor that leads to postoperative pain and swelling following pulpectomy. Using manual files and three different rotary files, Topçuoğlu et al. [33], determined the amount of debris extruded during root canal preparation in primary molars and found that manual files extruded more debris than rotary files [33]. When compared to other preparation techniques, the crown-down technique used with NiTi rotary systems during canal preparation

has been shown to be associated with less debris extrusion. As a result, it is conceivable that early pre-flaring is related to less debris extrusion and postoperative pain [35,36]. Furthermore, K-files are instrumented in filing motion that moves the debris apically, and it has a taper of 0.02, which provides less space for the debris to be flushed coronally [37].

The limited sample size and use of a two-dimensional imaging tool to assess obturation quality cannot specify the precise size and number of voids, which may be the possible drawbacks of the current research. Further research evaluating the shaping ability of each file system, as well as long-term clinical and radiographic success should be performed to establish definitive conclusions.

## CONCLUSION

The results of the present study draw to the following conclusions:

- Instrumentation time using Kedo-S Square files was least compared to Kedo-S files and manual K-files.
- Kedo-S Square files provided better quality of obturation with a higher number of optimal obturation.
- Root canal preparation with the rotary file system resulted in less intense post-operative pain when compared to the hand file system.
- The use of pediatric rotary instruments for canal preparation during pulpectomy will result in better quality of obturation in reduced time with least post-operative pain.

## Author's Contributions

LL, MR, GJ: Conception. LL: Methodology. LL: Data Acquisition and Interpretation. MR, GJ: Design. LL: Writing – Original Draft Preparation. LL, MR, GJ: Writing – Review.

## Conflict of Interest

No conflicts of interest declared concerning the publication of this article.

## Funding

The authors declare that no financial support was received.

## Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of: Institutional Ethical Committee of Saveetha Institute of Medical and Technical Sciences. The approval code for this study is: (SRB/SDC/PEDO-1803/20/04). Clinical Trial Registration No.: CTRI/2021/02/031512; Clinical Trial Registry - India (CTRI).

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Date submitted: 2022 Apr 28  
Accept submission: 2022 Nov 14