

Original Article

Assessing quality of obturation and instrumentation time using Kedo-SG blue, Kedo-SH, and reciprocating hand K-files in primary mandibular molars: A double-blinded randomized controlled trial

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ABSTRACT

Background: Pulpectomy is the treatment of choice for severely infected primary molars. The aim of the study is to evaluate the instrumentation time and obturation quality using Kedo SG blue, Kedo SH, and reciprocating hand K files in primary mandibular molars. To evaluate the instrumentation time and obturation quality using Kedo-SG blue, Kedo-SH, and reciprocating hand K-files in primary mandibular molars.

Materials and Methods: A double-blinded randomized controlled trial was conducted on 45 mandibular molars and were randomly assigned to three experimental groups ($n = 15$). Group I was instrumented using Kedo-SG blue pediatric rotary files, Group II with Kedo-SH pediatric hand files, and Group III with reciprocating hand K-files. Standardized digital radiographs were taken before and after root canal instrumentation. Root canal preparation time was also recorded. Statistical analysis of the obtained data was done using SPSS software version 17.0. An intergroup comparison of the instrumentation time and the quality of obturation were done using ANOVA and Chi-square test with the level of significance set at 5%. $P < 0.05$ was considered statistically significant.

Results: No significant differences were noted with regard to the quality of obturation between the three groups ($P < 0.14$). However, a statistically significant difference was noted in the instrumentation time between the three groups ($P = 0.000$). Kedo-SG blue rotary file had significantly lesser instrumentation time when compared to that of Kedo-SH hand files and reciprocating hand K-files.

Conclusion: On comparative evaluation, Kedo-SG blue pediatric rotary file showed a marked reduction in instrumentation time, followed by Kedo-SH pediatric hand files and reciprocating hand K-files.

Key Words: Pediatric rotary files, primary tooth, pulpectomy, root canal obturation

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INTRODUCTION

The main goal of pulpectomy is to eliminate the infection and prevent its further spread, at the same time retain the primary tooth until its exfoliation.^[1] Instrumentation of the root canals,

irrigation, disinfection, and obturation are the key factors that determine the success of pulpectomy. Root canal cleaning and shaping destroys the microbes and

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removes the infected content of the pulp chamber and canal, when maintaining the integrity of the root canal.^[2] Furthermore, the root canal instrumentation should create a continuous tapered preparation to facilitate the antiseptic irrigation and guide the placement of filling materials.^[3] For a proper canal shaping, two factors should be considered: (a) type of instrument used and (b) technique used. Various techniques have been proposed for root canal preparation, which includes the coronapical and apicocoronal technique.^[4] In endodontics, instruments made of Ni-Ti and stainless steel have been used for the shaping of root canals.^[5]

Although hand filing is the standard method of instrumentation of the primary root canals, it has certain limitations such as increased canal preparation time, uneven preparation of root canal space, and other iatrogenic errors.^[6,7] To overcome these disadvantages of the hand instrumentation and improve the accuracy of endodontics in primary teeth, rotary instrumentation was introduced into pediatric dentistry. There are many advantages of using Ni-Ti rotary instruments over stainless steel files, which makes it easier to use in pediatric dental practice, which includes limited procedural errors and reduction in operator fatigue and preparation time.^[8]

Various Ni-Ti instruments which were proposed for use in permanent teeth were incorporated for use in primary teeth. ProTaper, M₂, and K₃ files were used for canal instrumentation with modified sequence to facilitate its use in primary teeth.^[9,10] Use of these files, despite being successful, had limitations such as increased file length and taper, which made it difficult for the practitioners to use it in children. There arrived the need for an exclusive pediatric rotary file with altered length and taper.^[11]

Ganesh Jeevanandan in 2017 introduced the exclusive pediatric rotary file which served the purpose, reducing the instrumentation time, resulting in an acceptable quality of obturation, favoring its use in pediatric endodontics.^[12] Continuous evolution of this version is the launch of Kedo-SG and Kedo-SH. Kedo-SG blue rotary file consists of D1, E1, and U1 files coated with titanium. They have greater flexibility to reach even the tortuous canal. This results in an effective and consistently successful cleaning and shaping. The unique feature of this file is its variably variable taper. Kedo-SH hand file consists of P1, P2, and P3 stainless steel files and D1, E1, and

U1 nickel–titanium files. The total length of the file is 16 mm with a flute length of 12 mm.

Another rotary file that has been used for comparison in the present study is the reciprocating hand K-file. The unique feature of this file is that it minimizes the torsional and flexural stresses, increases the canal centering ability, and reduces the taper lock of the instrument within the canal, moving it more apt for application in primary tooth. There are no studies in the literature evaluating the application of reciprocating hand K-file in primary teeth. Hence, for use in primary teeth, these three instruments were selected for evaluation in the current study.

Hence, the aim of the present study was to comparatively evaluate the instrumentation time and the quality of obturation using Kedo-SG, Kedo-SH, and reciprocating hand K-files in primary molars.

MATERIALS AND METHODS

A double-blinded randomized controlled trial was carried out in the Department of Paediatric and Preventive Dentistry, Saveetha Dental College, following the approval from the Institutional Review Board (SRB/MDS/PEDO/18-19/0009) from September 2018 to January 2019 in accordance with the ethical standards laid down in the 1964 declaration of Helsinki and its later amendments. Informed consent was obtained from the parents of the children who participated in the study. CONSORT guidelines (Altman *et al.* 2001) for planning and reporting clinical trials in pediatric endodontics were followed during the different stages of the study [Figure 1].

Sample size estimation and study participant's selection

The sample size was calculated from a previous study with 95% power, alpha error at 5%, using G Power analysis, and arrived to a total sample of 45.^[13]

Healthy children between the age group of 4 and 8 years with complaint of night pain, having pulpally involved primary mandibular molars with minimum of two-thirds of remaining root length, and adequate coronal tooth to support the placement of rubber dam and to receive stainless steel crowns were included in the study. Children with systemic diseases, lacking cooperative ability, were excluded from the study. Furthermore, teeth with sinus opening, pathological root resorption, and inadequate coronal tooth structure

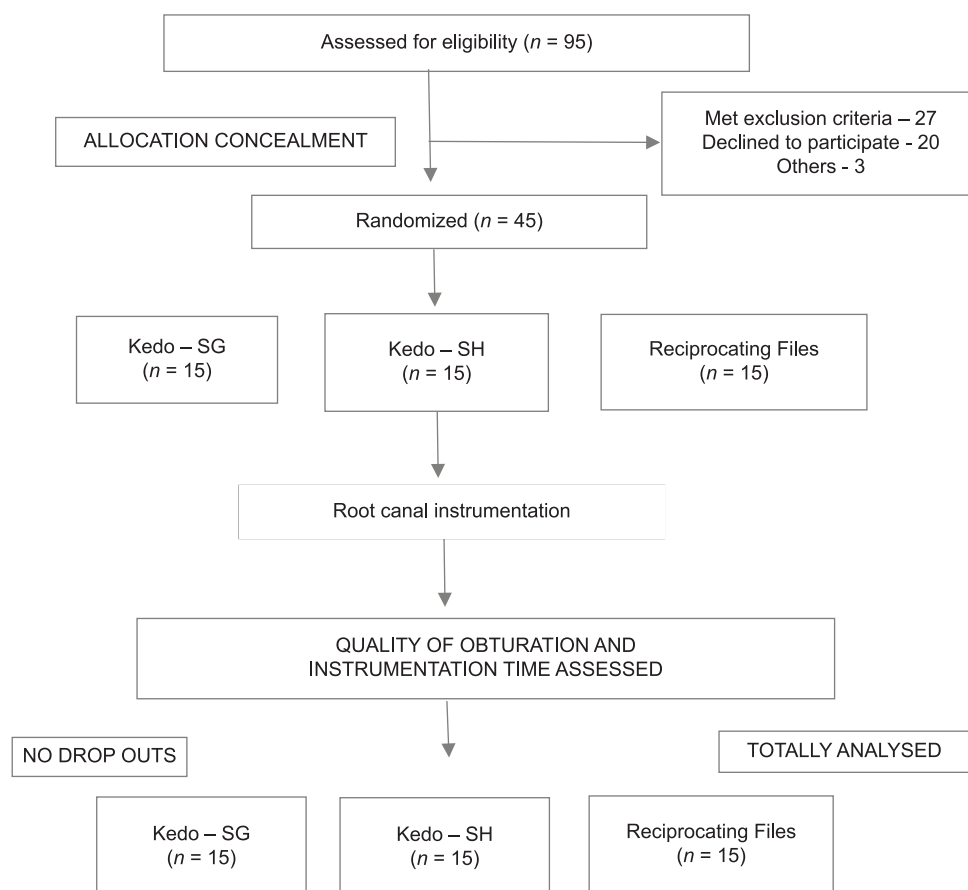


Figure 1: Flowchart describing the randomization of the participants and the parameters evaluated during the clinical trial.

to receive stainless steel crown were excluded from the study.

Before the study, an operator randomly allocated the sequence of the children to either a test or control group using computer-generated random numbers. Slips of paper with either Kedo-SG blue, Kedo-SH, and reciprocating files printed on them were placed in opaque envelopes and sealed. This was carried out by a person who was not associated with the study. These envelopes had been numbered sequentially on their outside with the patient identity number. Following the screening, as a child was accepted into the study, he or she was given their patient identity number. This ensured that the patient and the dentist carrying out the assessment were blind as to which group the child had been allocated.

Clinical procedure

Before the start of the clinical study, a full-mouth dental examination and appropriate standardized periapical radiographs were taken of mandibular posterior teeth with possible indication for pulpectomy.

To obtain accurate radiographs, the Rinn XCP instrument (Dentsply Rinn, Elgin) and radiographic parallelism and standard exposure technique were used to permit good visualization of the tooth structure as well as reproducibility.

A full-mouth dental examination with appropriate standardized intraoral periapical radiographs of the teeth indicated for pulpectomy was taken before the start of the clinical procedure. The working length was determined using the preoperative radiograph. To obtain accurate radiographs, the Rinn XCP instrument (Dentsply Rinn, Elgin) and radiographic parallelism and standard exposure technique were used to permit good visualization of the tooth structure as well as reproducibility. The primary tooth pulpectomy was carried out by the same operator in all cases after local anesthesia was administered using lignocaine (LOX *2% adrenaline, Neon Laboratories Limited, India). The tooth indicated for pulpectomy was isolated using rubber dam (GDC Marketing, India) for better visibility and to improve the efficiency of the operator. No. 6 round bur was used in a high-speed

hand piece (NSK PANA AIR PA-SU B2) to remove the superficial caries, and complete deroofing of the pulp chamber was done using No. 330 pear shaper bur (Mani, Inc., Tochigi, Japan). No. 10 size K-file (Dentsply Maillefer, OK, USA) was used to determine the patency of the canals. The canal preparation was done as follows:

- Group 1: Fifteen teeth were instrumented using Kedo-SG blue pediatric rotary files (Reeganz Dental Care Pvt. Ltd. India) as per the manufacturer's recommendation. D1 rotary files were used for canal preparation of the mesiobuccal and mesiolingual canals and E1 rotary files were used for distal canal preparation. The rotary files were used with an X-smart endodontic motor (Dentsply India Pvt. Ltd., Delhi, India) at 300 rpm and 2.2 N cm torque
- Group 2: Fifteen teeth were instrumented using Kedo-SH pediatric hand files (Reeganz Dental Care Pvt. Ltd. India) as per the manufacturer's recommendation. P1 pediatric hand K-file was used for initial patency of molar canals, P2 pediatric H file was used to extirpate the pulp, D1 to shape the narrower canals, and E1 to shape the wider canals
- Group 3: Fifteen teeth were instrumented from No. 15 size till No. 30 size K-files (Mani, Inc., Tochigi, Japan), which was coupled with NSK Endodontic Contra-Angle Reciprocating hand piece (TEP-ER10, Japan).

17% EDTA gel (RC help, Prime dental products, Pvt. Ltd. India) was used as a lubricating paste to coat the files before instrumentation into the canals. The irrigation solution was standardized to 1 ml of 1% sodium hypochlorite (SEPTODONT, HEALTHCARE, Pvt, Ltd) and 15 ml of saline in all the three groups. The canals were dried using sterile paper points. The root canals were obturated using Metapex (Meta Biomed Co. Ltd. Chungbuk, Korea) by gently pushing the material with cotton pellets. All the clinical procedures were done by a single operator to avoid operator bias.

The instrumentation time was measured using a digital stopwatch and was recorded in seconds by a trained dental assistant. Instrumentation was done until there was no bleeding from the canals in vital teeth. A postobturation radiograph was taken to assess the quality of obturation. It was obtained for each tooth using the same radiographic settings as for preoperative. The assessment of obturation quality was based on Coll and Sadrian criteria as underfilled

if all the canals were filled more than 2 mm short of the apex, optimally filled if one or more of the canals having Metapex ending at the radiographic apex or up to 2 mm short of the apex, and overfilled if any canal showing Metapex outside the root^[14] by two trained pediatric dentists who were blinded to the study groups [Figure 2]. All possible measures were taken to prevent any sort of bias. Type II glass-ionomer cement (Shofu, Shofuinc. Japan) was used as the entrance filling and was restored with stainless steel crown (3 M ESPE) luted with type I glass-ionomer cement (Shofu, Shofuinc. Japan) on the same appointment.

Statistical analysis

The statistical analysis was done using SPSS software version 17.0 (SPSS Inc., Chicago, IL, USA). The mean values of different study groups were compared using ANOVA and Chi-square test. One-way ANOVA test was used to compare the instrumentation time between the three groups. Chi-square test was used to compare the quality of obturation between the three groups. The significance level was set at 5% for the present study.

RESULTS

A total of 45 children with a mean age of 6.14 years participated in the present study. Chi-square test between the groups with respect to age and sex shows an equal distribution of participants among the three groups [Table 1]. A high statistically significant reduction in the instrumentation time was noted in the group instrumented with Kedo-SG blue rotary file, followed by Kedo-SH and reciprocating hand K-files ($P = 0.000$) [Table 2]. When subjected to *post hoc* Tukey's test, it was seen that there was a significant difference in the instrumentation time between all the three groups [Table 3]. However, no significant differences were noted on the quality of obturation between the three groups ($P < 0.14$) [Table 4].

DISCUSSION

The current study compared the instrumentation time and quality of obturation of the pediatric manual, rotary, and reciprocating file system in the canal preparation of primary mandibular molars. There has been a phenomenal paradigm move in managing the infected primary teeth in children from extractions to pulpectomy. Pulpectomy has become an extensive pediatric endodontic procedure to preserve the arch



Figure 2: Immediate postoperative IOPA radiographs depicting different levels of quality of obturation. (a) Underfilling; (b) Optimal filling; (c) Overfilling.

length and guide the eruption of the underlying successional permanent tooth.^[15] In children, the purpose of pulpectomy is to completely remove the infected tissue and seal the canal with a bioresorbable material which resorbs at the same rate as that of the tooth. Completing the pulpectomy procedure in a short duration and at the same time providing good quality treatment is the main goal of a pediatric dentist.

Primary root canal instrumentation with Ni-Ti rotary files has decreased the instrumentation time and has also resulted in a more uniform, funnel-shaped obturation. However, in previous studies, Ni-Ti files designed for permanent teeth have been used for pulpectomy in primary teeth.^[16,17] The morphology of the primary teeth differs greatly from that of the permanent teeth as the roots of the primary teeth are short, thin, curved, and have softer and less dense root dentine with undetectable root resorptions.^[18] In addition, the morphology of the root canals is ribbon shaped, which requires the need for an exclusive rotary file for cleaning and shaping of the primary root canals.^[19]

In a survey conducted by Govindaraju *et al.* among the Indian dentists in 2017, it was observed that 66% of practitioners found that an exclusive pediatric rotary file would make pulpectomy procedure in primary teeth much easier and simpler in a clinical practice.^[11] Furthermore, earlier studies mentioned that an exclusive pediatric rotary file with modified length, taper and tip size would be more effective and efficient for performing pulpectomy in primary teeth.^[11,19] Hence, Kedo-SG rotary file system was preferred in the current study, which is a patented file system for use in primary teeth.

Kedo-S (Reeganz Dental Care Pvt. Ltd. India), an exclusively designed pediatric rotary file, was introduced to overcome the limitations caused on using permanent rotary files. Clinical trials comparing Kedo-S rotary file with hand files have shown remarkable reduction in instrumentation time

Table 1: Demographic variables describing age and distribution of male and female participants in each group

	Kedo-SG blue	Kedo-SH	Reciprocating Hand K-file	P
Age (years), mean±SD	6.22±1.31	6.35±1.11	6.1±1.07	0.840
Female, n (%)	6 (40)	8 (53.3)	11 (73.3)	0.181
Male, n (%)	9 (60)	7 (46.7)	4 (26.7)	

SD: Standard deviation

Table 2: Comparison of instrumentation time between three groups

Group (n=45)	Mean instrumentation time (s), mean±SD	Overall P
Kedo-SG blue (n=15)	83.00±13.185	0.000
Kedo-SH (n=15)	135.135±11.401	
Reciprocating hand K-file (n=15)	190.60±10.273	
Total	136.24±45.873	

SD: Standard deviation

Table 3: Intergroup comparison of instrumentation time with overall P value

Groups	Intergroup comparison	Overall P
Kedo-SG blue	Kedo-SH	0.000
	Reciprocating hand K-file	0.000
Kedo-SH	Kedo-SG blue	0.000
	Reciprocating hand K-file	0.000
Reciprocating hand K-file	Kedo-SG blue	0.000
	Kedo-SH	0.000

Table 4: Comparison of obturation quality between the three groups

Obturation quality	Group, n (%)			Overall P
	Kedo-SG blue	Kedo-SH	Reciprocating hand K-file	
Optimal	11 (73.3)	10 (66.6)	3 (20)	0.14
Over	2 (13.3)	3 (20)	3 (20)	
Under	2 (13.3)	2 (13.3)	9 (60)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	

and improvement in the quality of obturation.^[20,21] Advancement of Kedo-S is the Kedo-SG blue rotary file system.

The present study compared the quality of obturation and instrumentation time using Kedo-SG blue rotary files, Kedo-SH pediatric hand files, and reciprocating hand K-files. With respect to the quality of obturation in the present study, optimal filling was observed to be highest using Kedo-SG blue rotary files (73.3%), followed by Kedo-SH pediatric hand files (66.6%) and reciprocating hand K-files (20%). There was no statistically significant difference noticed among the three groups. The present study was similar to a study conducted by Priyadarshini *et al.*, who reported 80% optimal filling with Kedo-SG rotary files.^[22] Kedo-SG files have higher flexibility to negotiate even the narrowest canal in primary teeth because of titanium coat leading to an easy flow of obturating material and optimal quality of obturation, which could be the reason for better quality of obturation. In addition, its high flexibility prevents file breakage, thereby increasing its efficacy and effectiveness in canal preparation over its earlier file system. Pediatric hand files (Kedo-SH) also produced better results with improved quality of obturation than the reciprocating hand K-files. This might be due to the exclusive design of Kedo-SH files which are made up of Ni-Ti alloy with a variably variable taper corresponding to the diameter of the root canals in primary teeth. Therefore, it has sufficient flexibility to effectively clean and shape within the canals as well as avoiding lateral perforation at the apical region because of its well-designed tip diameter and working length, whereas reciprocating hand K-files lack the abovementioned properties necessary for effective canal preparation, thereby resulting in reduced number of optimal fillings.

A statistically significant reduction was noticed in the instrumentation time on using Kedo SG rotary files (83.00 ± 13.18 s) for canal preparation in primary mandibular molars when compared to Kedo SH pediatric hand files (135.13 ± 11.40 s) and reciprocating hand K files (190.60 ± 10.27 s). Earlier studies conducted comparing adult rotary files in primary tooth and pediatric rotary files with hand files showed reduced instrumentation time which is in accordance with the results of the present study.^[13,20-23] In the present study, instrumentation time was also found to be reduced on using pediatric hand files (Kedo-SH) in comparison with the reciprocating hand K-files; however, the difference was not significant. The probable reason for minimal instrumentation time with Kedo-SG blue rotary

file system is that each canal is prepared with one file, whereas pediatric hand files (Kedo-SH) and reciprocating file system require sequential preparation with 15–30 or 35 size files in each canal.

Clinically, reduced instrumentation time has high influence on the behavior and cooperation of the child in the dental chair. It also lessens the fatigue caused by the operator, resulting in faster delivery of treatment.^[24]

CONCLUSION

Kedo-SG blue pediatric rotary file showed a marked reduction in instrumentation time, followed by Kedo-SH pediatric hand files. Hence, exclusive pediatric rotary and hand files should be incorporated into pediatric dental practice for an effective, faster, and safer dental treatment in children.

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Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or non-financial in this article.

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