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ORIGINAL SCIENTIFIC ARTICLE

# Clinical evaluation of instrumentation time and quality of obturation using paediatric hand and rotary file systems with conventional hand K-files for pulpectomy in primary mandibular molars: a double-blinded randomized controlled trial

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## Abstract

**Aim** The present study aims to comparatively evaluate the instrumentation time and obturation quality using paediatric manual (Kedo-SH) and rotary (Kedo-S and Kedo-SG Blue) with conventional manual (Hand K-files) instrumentation technique for pulpectomy in primary mandibular molars.

**Materials and methods** A double-blinded randomized controlled trial was designed, recruiting participants with pulpally involved primary mandibular molars requiring pulpectomy in the age group of 6–9 years old. Sixty primary mandibular molars were randomly allocated to either of the four intervention groups: Group I: 15 teeth were instrumented using hand K-files (control group); Group II: 15 teeth were instrumented with paediatric rotary files (Kedo-S); Group III: 15 teeth were instrumented with paediatric hand files Kedo-SH (experimental group) and Group IV: 15 teeth were instrumented with paediatric rotary file system Kedo-SG Blue. Instrumentation time was recorded during root canal preparation and post-operative quality of obturation in each group was also assessed. Extracted data was subjected to statistical analysis using Chi-square, One-way ANOVA and post hoc Tukey test.

**Results** Mean instrumentation time was significantly reduced for Kedo-SG Blue ($2.7840 \pm 0.34217$) min-s followed by Kedo-S ($3.4827 \pm 0.48657$), Kedo-SH ($5.8800 \pm 0.48345$) min-s and hand K-files ($6.2167 \pm 0.30978$) min-s ($p = 0.0005$). A statistically significant difference was found in the obturation quality ($p = 0.001$) between the four groups with higher percentage of optimal fillings observed with rotary Kedo-SG Blue (80%) followed by Kedo-SH (46.7%); Kedo-S (40.0%) and hand K-files (20%).

**Conclusions** On comparative evaluation, a marked reduction in instrumentation time and superior quality of obturation was found with rotary Kedo-SG Blue file system followed by Kedo-SH, Kedo-S and hand K-files.

**Keywords** Hand K-files · Kedo-S · Kedo-SH · Kedo-SG blue · Primary mandibular molars · Pulpectomy

## Introduction

The primary objective of pulpal treatment is to preserve the integrity and health of the oral tissues (AAPD 2014; Fuks et al. 2002). Endodontic intervention is considered to be the only viable option available to restore the dentition to a functional state (Garcia-Godoy 1987). Pulpectomy aids in the retention of primary teeth with irreversible pulp pathosis in a symptom-free state and is considered to be a conservative treatment approach, preventing the premature loss of primary teeth which could result in loss of arch length leading to insufficient space for the eruption of permanent teeth (Barcelos et al. 2011; Berk et al. 1972; Dummett and Kopel 2002). However endodontics in primary teeth is more challenging because of the anatomic complexities, dynamic alteration at the root apex, close proximity to the succedaneous tooth bud coupled along with perceived difficulties in behavioural management, making paediatric endodontics a demanding task (Garcia-Godoy 1987; Rifkin 1980). This

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intervening hurdle however can be efficiently handled by choosing an appropriately designed file system which is helpful in effective canal preparation within minimal time span leading to optimal quality of obturation.

The success of pulpectomy is greatly determined by the biomechanical preparation (Haapasalo et al. 2005). Proper cleaning and shaping of the canals aids in adequate removal of the infected tissue and provides a pathway for the irrigating solution to reach the apical third of the root thereby accomplishing a smooth and tapered canal preparation leading to optimal quality of obturation (Siqueira et al. 1997). Conventionally used hand files for cleaning and shaping are generally time-consuming (Silva et al. 2004). Length of an appointment in paediatric practice is strongly associated with the child's behaviour and his/her eventual acceptance of the dental treatment (Rosa et al. 2014). Hand instrumentation, though considered to be the most acceptable method for canal debridement and shaping, can result in iatrogenic errors such as perforation, ledge formation and even injury to periapical tissues (Silva et al. 2004).

The use of Nickel Titanium (NiTi) rotary files in primary teeth root canals was first described by Barr et al. (2000) using Profile 0.04 taper rotary instruments. Since then, use of rotary instrumentation for pulpectomy has become an emerging practice in paediatric dentistry and to add on to its greatest advantage is the fact that rotary files do not need to be precurved, due to its inherent elastic memory resulting in efficient and quicker canal preparation (Pruett et al. 1997). Rotary instrumentation in primary teeth was principally advocated for its ability to provide conical-shaped canals and reduction in instrumentation time (Barr et al. 2000; Crespo et al. 2008; Kuo et al. 2006; Pinheiro et al. 2012; Silva et al. 2004). Ever since the emergence of rotary instrumentation, there has been both in-vitro and in-vivo studies conducted with various rotary file system available to demonstrate the cleaning efficacy, instrumentation time and quality of obturation (Azar et al. 2012; Govindaraju et al. 2017a, b, c; Ochoa-Romero et al. 2011; Ramezanali et al. 2015; Vieyra et al. 2014). However in all of the trials, rotary instrumentation performed in primary teeth was by using rotary files designed specifically for permanent teeth, which reflected a huge dearth and a need for the designing of an exclusive paediatric rotary file system to be used in children.

A revolution that spearheaded in the arena of paediatric endodontics was the introduction of an exclusive paediatric rotary file system Kedo-S (Reeganz Dental Care Pvt. Ltd, India). Kedo-S is the first generation rotary file system which was introduced in paediatric endodontics, to suit the needs towards primary dentition. Kedo-S is a three file system consisting of $D_1$, $E_1$ and $U_1$ files made up of Ni–Ti. The total length of these files is 16 mm and the working area is 12 mm. One of the remarkable feature of this file system is the presence of variably variable taper design which imparts flexibility and efficacy to the files in rendering efficient treatment. Additional to it, the files also have a varying tip diameter ($D_1$-0.25, $E_1$-0.30, $U_1$-0.40) according to the diameter of narrow and wide root canal system in primary teeth which results in significant preparation at the coronal-third with sufficient preparation at the middle and apical-third resulting in an easy flow of obturating material and avoiding lateral perforation at the apical region (Jeevanandan 2017). Another innovative landmark in the field of paediatric endodontics is the emergence of an exclusively designed hand file system Kedo-SH (Reeganz Dental Care Pvt. Ltd, India) for use in the primary teeth. Kedo-SH file system consists of six manual files of length 16 mm each and with a working length of 12 mm, contributing to efficient manual instrumentation in primary teeth. The important features of this file system comprise mainly of files made up of two different materials (i.e.; stainless steel and Ni–Ti). The file system consists of size No. 15 (K-file), 20 (H-file), 35 (H-file) file made up of stainless steel while size No. 25 (0.25), 30 (0.30), 40 (0.40) are made up of Ni–Ti with variably variable taper design and tip diameter aiding in efficient preparation of root canal walls.

Latest to join in the bandwagon of paediatric rotary file series is the Kedo-SG Blue file system (Reeganz Dental Care Pvt. Ltd, India). Kedo-SG Blue is a three file system consisting of $D_1$, $E_1$ and $U_1$ files coated with titanium, adding greater flexibility to reach even the tortuous rootcanal system resulting in an effective and consistently successful cleaning and shaping. The uniqueness of this rotary file system lies in its variably variable (VV) taper, varying tip diameter ($D_1$-0.25, $E_1$-0.30, $U_1$-0.40) and the titanium coat, enhancing supreme flexibility and preventing inadvertent breakage of the files in the tortuous root canals of the primary teeth. Till date a few clinical trials have been conducted to demonstrate the efficacy of the Kedo-S rotary file system (Jeevanandan and Govindaraju 2018; Panchal et al. 2019). A study comparing the instrumentation time and obturation quality between hand-K files and rotary Kedo-S file system accounted for significantly less instrumentation time and improved quality of obturation with rotary Kedo-S system than the hand K-files (Jeevanandan and Govindaraju 2018). Another study also compared the instrumentation time and quality of obturation between hand K-files, H-files and rotary Kedo-S file system, which reported reduced instrumentation time and better obturation quality with rotary Kedo-S system than the other two groups (Panchal et al. 2019). However there is no comparative study in literature, that have been conducted to evaluate the instrumentation time and quality of obturation using Kedo-S, Kedo-SG Blue and Kedo-SH files with the conventional hand K-files.

Hence, the present study aims to comparatively evaluate the instrumentation time and quality of obturation using

hand K-files, Kedo-S, Kedo-SH and Kedo-SG Blue file system for pulpectomy in primary mandibular molars.

## Materials and methods

### Study design and ethical consideration

The present study was conducted in the Department of Paediatric and Preventive Dentistry from September, 2018 till December, 2018 in India. A double-blinded randomized controlled trial design was formulated to carry out the current study. The trial design was approved by the Institutional Scientific Review Board (SRB/MDS/PEDO/18-19/0019) and Ethical Committee (SDC/MDS/18-19/0142) in accordance to the ethical standards laid down in the 1964 declaration of Helsinki and its later amendments. Prior to the start of the clinical trial, written informed consent was obtained from the parents or care-takers of the children recruited for the study. CONSORT guidelines for planning and reporting of the clinical trials in paediatric endodontics was followed during the various stages of the study (Altman et al. 2001) (Fig. 1).

### Sample size estimation and recruitment of study participants

A sample of 60 children in the age group of 6–9 years indicated for pulpectomy procedure in primary mandibular molars were recruited into the present trial. The sample

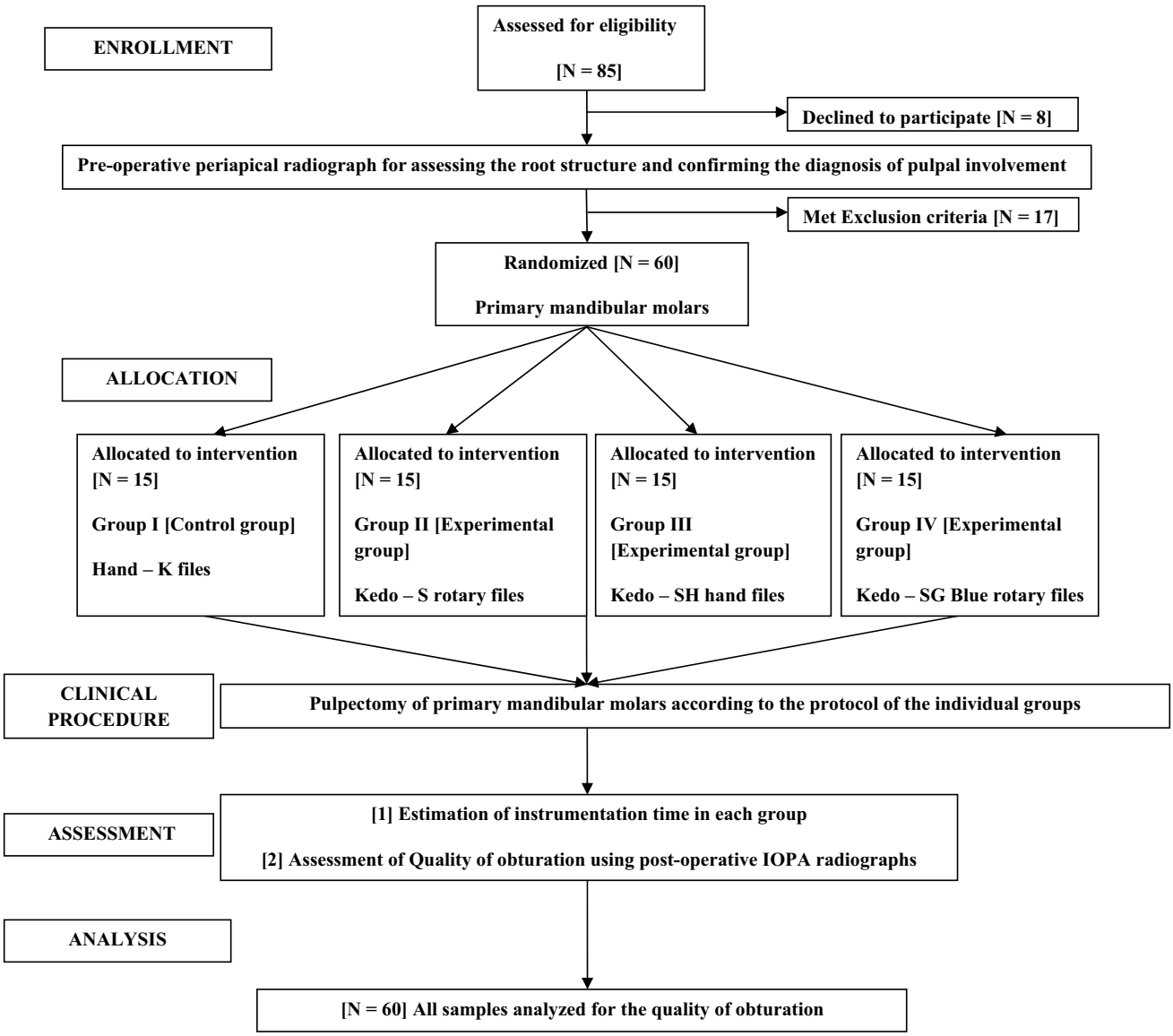


**Fig. 1** CONSORT Flowchart depicting the different stages followed during the double-blinded randomized controlled trial

size was calculated from a previously published in-vivo study with 95% power using G Power analysis software (Ochoa-Romero et al. 2011). Preset inclusion and exclusion criteria were followed for recruiting participants into the trial. Healthy children with complaint of night pain, having pulpally involved primary mandibular molars with minimum of two-thirds of remaining root length and adequate coronal tooth structure to support placement of a rubber dam and for receiving stainless steel crown were included into the trial. Children with special-care needs or with any underlying systemic diseases, non-restorable teeth with internal or external root resorption exceeding two-thirds of root length were excluded from participating in the study. A computer-generated randomization method was used to allocate the participants into either of the four groups. In group I (15 teeth/control group) the root canals were instrumented using hand K-files, group II (15 teeth/experimental group) the canal system was instrumented using Kedo-S rotary files, group III (15 teeth/experimental group) the canals were instrumented using Kedo-SH and in group IV (15 teeth/experimental group) the root canals were instrumented using Kedo-SG Blue file system.

## Clinical procedure

All the procedures were performed by a single trained paediatric dentist. A full mouth examination with intraoral periapical radiographs of the teeth indicated for pulpectomy was obtained prior to the start of the clinical procedure. On clinical and radiographic confirmation of the diagnosis, local anaesthesia using 2% lignocaine with 1:200,000 adrenaline (LOX* 2% ADRENALINE, Neon Laboratories limited, India) was administered to the tooth indicated for pulpectomy and was isolated using rubber dam (GDC Marketing, India). After assessing both subjective and objective signs of action of local anaesthesia, a No.330 pear-shaped carbide bur (Mani, Inc, Tochigi, Japan) in a high-speed handpiece (NSK PANA AIR PA-SU B2) was used for the removal of superficial caries and endodontic access opening. Coronal pulp amputation was done with a sterile spoon excavator (Hu-Friedy Mfg. Co. LLC) followed by the use of a DG 16 endodontic explorer (Hu-Friedy Mfg. Co. LLC) to locate the canals in the dentinal map. A No. 10 size K-file (Dentsply Maillefer, OK, USA) was used to determine the patency of the root canals and No. 15 size K-file (Dentsply Maillefer, OK, USA) was then used for initial enlargement in teeth selected for rotary instrumentation. Working length (WL) was determined using ProPex Pixi electronic apex locator (Dentsply Maillefer, OK, USA). A No. 15 size K-file was used to record the working length of each canal with 1 mm shorter than the '0.0' mark in the ProPex Pixi apex locator.

Group I ($N = 15$/control group): the root canals were instrumented using hand K-files (Dentsply Maillefer, OK, USA) from No. 15 size file till 35 size by a quarter-turn-pull technique. The mesial (narrower) canals were instrumented till No. 30 size K-files and the wider distal canals were instrumented till No. 35 size K-files. Each K-file was used upto five teeth in order to maintain uniformity during canal preparation. In group II ($N = 15$/experimental group) the root canals were instrumented using Kedo-S file system (Reeganz Dental Care Pvt. Ltd. India) according to the manufacturer's instructions. The mesial canals were instrumented using the $D_1$ (red colour coded, tip diameter 0.25, variably variable [VV] taper) file in a lateral brushing motion. The distal canals were instrumented by $D_1$ file followed by $E_1$ file. All the rotary files were used with an X-Smart endodontic motor (Dentsply Maillefer, OK, USA) at 300 rpm and 2.4 N/cm torque till the entire working length in a to-and-forth motion for a minimum of 1–2 times in each canal of the tooth. Each Kedo-S file was used for upto five teeth as per the manufacturer's instructions and in order to maintain uniformity during canal preparation. In group III ($N = 15$/experimental group): the root canals were instrumented using Kedo-SH manual files (Reeganz Dental Care Pvt. Ltd. India) in a sequential manner. The No. 15 size (white colour coded) stainless steel Kedo-SH file with 2% taper was used for achieving initial patency followed by No. 20 size (yellow colour coded) stainless steel Kedo-SH file (2% taper) for complete extirpation of pulp tissue. Final cleaning and shaping of the canals was done using No. 25 Ni–Ti $D_1$ (red colour coded, tip diameter 0.25, VV taper) and No. 30 Ni–Ti $E_1$ (blue colour coded, tip diameter 0.30, VV taper) files. $D_1$ file was used for shaping and finishing of narrower mesiobuccal and mesiolingual canals while $E_1$ file was used for the wider distal canals. Each Kedo-SH file was also used upto five teeth in order to maintain uniformity during canal preparation. Lastly in group IV (N = 15/experimental group): the root canals were instrumented using advanced rotary Kedo-SG Blue file system (Reeganz Dental Care Pvt. Ltd. India). $D_1$ (red colour coded, tip diameter 0.25 and VV taper) rotary file was used for instrumentation of the mesiobuccal and mesiolingual canals. For ease in preparation of distal canals, $D_1$ rotary file was first used followed by $E_1$ in a lateral brushing motion. Each file was used for upto seven teeth according to the manufacturer's recommendation and to maintain uniformity during canal preparation.

The root canals were irrigated with 1% sodium hypochlorite (SEPTODONT, HEALTHCARE, Pvt, Ltd) after use of each file followed by normal saline (Fresenius Kabi India, Pvt. Ltd). 17% EDTA gel (RC Help, Prime dental products, Pvt. Ltd. India) was used for lubrication of files during instrumentation. Finally the canals were dried using sterile paper points and obturation was performed using Metapex (Meta Biomed Co. Ltd, Chungbuk, Korea) by pressure syringe technique followed by final compaction

of the material done using wet cotton pellets technique. The access cavity was restored using type II glass ionomer cement (Shofu, Shofuinc. Japan) and an immediate post-operative intraoral periapical radiograph was obtained for assessment of quality of obturation. Final coronal restoration of the pulpectomized tooth was achieved using a preformed stainless steel metallic crown (3 M ESPE) luted with type I glass ionomer cement (Shofu, Shofuinc. Japan) in next appointment.

### Assessment of instrumentation time and quality of obturation

The instrumentation time was recorded using a digital stopwatch by a trained dental assistant. Time taken during instrumentation was recorded in (minutes-seconds) which 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. The quality of obturation was assessed using the criteria laid down by Coll and Sadrian (1996) as underfilled, optimal filled or overfilled by two trained paediatric dentists who were blinded to the study groups (Fig. 2). Kappa statistics was performed to assess the consistency and reliability of the two blinded examiners, which reported a Cronbach's alpha value of 0.685 (moderate level of agreement) between the two examiners.

### Statistical analysis

The statistical analysis was performed using IBM.SPSS statistics software version 23.0 (SPSS Inc., Chicago., USA). For descriptive data (i.e., age, gender and tooth type) descriptive statistics frequency analysis and percentage analysis was done followed by ANOVA and Pearson's Chi-square test to find the significance level between the four groups. One-way ANOVA test was used to compare the instrumentation time between the four groups followed by the Tukey Post-hoc analysis to find out the significant group with a significance level set at 0.05. Pearson's Chi-square test was used to compare the quality of obturation between the four groups. A significance level of $p < 0.05$ was set for the present study.

## Results

A total of 60 children (28 females and 32 males) in the age group of 6–9 years participated in the study and the mean age of the participants was $6.45 \pm 8.52$ years. The distribution of the participants and the tooth type is tabulated in (Table 1). An intergroup comparison using one-way ANOVA and Chi-square test reflected an equal distribution of the participants between the three groups with respect to age ($p = 0.234$), gender ($p = 0.290$) and distribution of tooth type ($p = 0.969$) thereby eliminating selection bias.

The mean instrumentation time was significantly less with the use of rotary Kedo-SG Blue file system ($2.7840 \pm 0.34217$ min-s) followed by Kedo-S ($3.4827 \pm 0.48657$ min-s), Kedo-SH manual files ($5.8800 \pm 0.48345$ min-s) and hand K-files ($6.2167 \pm 0.30978$ min-s) (Table 2). The Tukey post-hoc analysis confirmed a higher significance in the instrumentation time between rotary ( Kedo-S and Kedo-SG Blue) and manual instrumentation (Hand K-files and Kedo-SH) (Table 3).

With regard to the quality of obturation between the four groups, 80% ($n = 12$) of teeth instrumented with rotary Kedo-SG Blue files, 46.7% ($n = 7$) of teeth instrumented with Kedo-SH manual files, 40.0% ($n = 6$) of teeth instrumented with Kedo-S, 20% ($n = 3$) of teeth instrumented with hand K-files had optimal filling (Table 4). Chi-square test done between the four groups showed a high statistically significant level of optimal quality of obturation with rotary Kedo-SG Blue file system compared to Kedo-SH, Kedo-S and hand K-files ($p = 0.001$) (Table 4).


**Fig. 2** Immediate post-operative IOPA radiograph depicting different levels of quality of obturation according to Coll and Sadrian criteria (1996). **a** Under filling. **b** Optimal filling. **c** Overfilling

**Table 1** Demographic variables depicting sample size, age, gender and tooth type distribution in each group with over-all *p* value

| Treatment groups | Hand-K files (control group) [*N* = 15] | Kedo-S files (experimental group) [*N* = 15] | Kedo-SH files (experimental group) [*N* = 15] | Kedo-SG Blue files (experimental group) [*N* = 15] | Total [*N* = 60] | Over-all *p* value |
|---|---|---|---|---|---|---|
| Age (years) mean ± standard deviation | 6.66 ± .899 | 6.13 ± .516 | 6.66 ± .975 | 6.33 ± .899 | 6.45 ± .852 | 0.234 |
| Females, *N* (%) | 8 (53.3%) | 4 (26.7%) | 9 (60.0%) | 7 (46.7%) | 28 (46.7%) | 0.290 |
| Males, *N* (%) | 7 (46.7%) | 11 (73.3%) | 6 (40.0%) | 8 (53.3%) | 32 (53.3%) | |
| Tooth type distribution, *N* (%) | Tooth 74 | Tooth 74 | Tooth 74 | Tooth 74 | Tooth 74 | 0.969 |
| | 4 (26.7%) | 3 (20.0%) | 2 (13.3%) | 4 (26.7%) | 13 (21.7%) | |
| | Tooth 75 | Tooth 75 | Tooth 75 | Tooth 75 | Tooth 75 | |
| | 2 (13.3%) | 2 (13.3%) | 3 (20.0%) | 3 (20.0%) | 10 (16.7%) | |
| | Tooth 84 | Tooth 84 | Tooth 84 | Tooth 84 | Tooth 84 | |
| | 5 (33.3%) | 4 (26.7%) | 4 (26.7%) | 5 (33.3%) | 18 (30.0%) | |
| | Tooth 85 | Tooth 85 | Tooth 85 | Tooth 85 | Tooth 85 | |
| | 4 (26.7%) | 6 (40.0%) | 6 (40.0%) | 3 (20.0%) | 19 (31.7%) | |
| Total, *N* (%) | 15 (100%) | 15 (100%) | 15 (100%) | 15 (100%) | 60 (100%) | |

## Discussion

The field of dentistry has witnessed great developments and innovations in the past decades and many more major paradigm changes are yet to arrive in the near future. Similarly in the field of paediatric endodontics, not only have the materials been improved but also the techniques and instrumentation, rendering a better and an improved quality of work (Crespo et al. 2008). It was until the mid 90's when research started regarding the use of rotary files in primary teeth for pulpectomy and Barr et al. was the first to describe rotary instrumentation in primary teeth using the Profile system (Barr et al. 1999, 2000; Silva et al. 2004). The primary objective of performing pulpectomy in children is not just to remove the infected pulp tissue or canal debridement but to successfully maintain the pulpectomized tooth as a natural space maintainer in the dental arch till its normal exfoliation, thereby considering pulpectomy to be an important treatment protocol for pulpally involved primary teeth (Mohamed 2014). Cleaning and shaping of the root canals is an important step in pulpectomy. The success of an endodontic procedure depends on an effective mechanical debridement and obturation quality (Tabassum and Khan 2016).

In the existing literature, all the studies conducted both in-vitro and in-vivo had explored the multiple dimensions of instrumentation technique such as cleaning efficacy, instrumentation time and obturation quality in primary teeth by using Ni–Ti files designed for permanent teeth (Azar et al. 2012; Govindaraju et al. 2017a, b, c; Ochoa-Romero et al. 2011; Ramezanali et al. 2015; Vieyra et al. 2014). Morphologically primary dentition differs greatly and variably from their permanent counterparts in having short, thin and curved roots with softer and less dense root dentine with undetectable root resorption (Finn 1973). Additionally, the complex root canal architecture in primary teeth comprises of thin ribbon-shaped canals which are generally difficult to negotiate, thus necessitating the need of designing an exclusive paediatric rotary file system for cleaning and shaping of the primary root canals (Kuo et al. 2006). Also usage of permanent teeth rotary files in primary teeth often results in lateral perforation and high fracture rate of the instruments (Nagaratna et al. 2006). Alteration in length, taper, appropriate flexibility in rotary files to reach even the narrowest channels in root canal system of the primary teeth, were the necessary properties to be considered while designing rotary files in primary teeth (Kuo et al. 2006; Govindaraju et al. 2017a, b, c).

Advent of rotary files in paediatric endodontics earmarked with the emergence of rotary Kedo-S files (Reeganz Dental Care Pvt. Ltd, India). Kedo-S was the first exclusively designed paediatric rotary files, introduced to overcome the disadvantages caused on using permanent teeth rotary files as well as for quicker and effective delivery of treatment. In the present study a significant reduction in instrumentation time was observed with the rotary Kedo-S group (3.4827 ± 0.48657 min-s) compared to the hand K-files (6.2167 ± 0.30978 min-s) which is in accordance to the findings mentioned in the earlier clinical trials (Jeevanandan and Govindaraju 2018; Panchal et al. 2019). In the present study instrumentation time was also found to be reduced on using paediatric hand files (Kedo-SH) in comparison to the conventional hand K-files, however the difference was not significant ($p = 0.128$). Two important factors can be held responsible for reduced instrumentation time with Kedo-SH compared to hand K-files. Firstly lesser number of files (i.e., four) is used sequentially in each canal

**Table 2** Depicting instrumentation time in each group with over-all p-value

| Treatment groups | Hand-K files (control group) [$N=15$] | Kedo-S files (experimental group) [$N=15$] | Kedo-SH files (experimental group) [$N=15$] | Kedo-SG Blue files (experimental group) [$N=15$] | Total [$N=60$] | Over-all $p$ value |
|---|---|---|---|---|---|---|
| Instrumentation time (min-s), mean ± standard deviation | 6.2167 ± 3.0978 | 4.5908 ± 1.54886 | 5.8800 ± 4.8345 | 2.7840 ± 3.4217 | 4.5908 ± 1.54886 | $p=0.0005$ (Sig)** |

One-way ANOVA, $p<0.05$

**Statistically Highly significant values

**Table 3** Depicting intergroup comparison of instrumentation time with over-all $p$ value

| Treatment groups | Intergroup comparison | Over-all $p$ value |
|---|---|---|
| Hand-K files | Kedo-SH files | 0.128 |
| | Kedo-SG Blue files | 0.0005** |
| | Kedo-S Files | 0.0005** |
| Kedo-S Files | Hand-K files | 0.0005** |
| | Kedo-SH files | 0.0005** |
| | Kedo-SG Blue files | 0.0005** |
| Kedo-SH files | Hand-K files | 0.128 |
| | Kedo-SG Blue files | 0.0005** |
| | Kedo-S Files | 0.0005** |
| Kedo-SG Blue files | Hand-K files | 0.0005** |
| | Kedo-SH files | 0.0005** |
| | Kedo-S files | 0.0005** |

for efficient cleaning and shaping compared to the use of size No. 15 to No. 35 hand K-files (i.e. five) for effective canal preparation. Secondly the other factor responsible in achieving lesser instrumentation time on using Kedo-SH hand files, is an easier and complete extirpation of pulp tissue by using No. 20 size Kedo-SH file (i.e., a type of H-file) whereas sequentially used increased sizes of hand K-files are needed to accomplish this task. A significantly reduced instrumentation time was also noted using rotary Kedo-SG Blue file system (2.7840 ± 0.34217, $p=0.0005$), infact the least instrumentation time in the present study was observed with the use of rotary Kedo-SG blue files. Reduced instrumentation time is highly pivotal in influencing the behaviour and co-operation of the child in the dental chair and thereby reduces fatigue caused in the operator due to shorter working hours, resulting in faster delivery of treatment (Musale and Mujawar 2014).

The quality of obturation is another key factor that determines the success of pulpectomy (Ranly and Garcia-Godoy 2000). According to the findings of the present study, higher percentage of optimal fillings (40.0%, $n=6$) were observed with Kedo-S group on comparison to hand K-files (20.0%, $n=3$) which is similar to the findings stated in the previous clinical trials using rotary Kedo-S file system (Jeevanandan and Govindaraju 2018; Panchal et al. 2019). The attributing factors responsible for better quality of obturation using Kedo-S file system can be due to its Ni–Ti nature, varying tip diameters, VV taper design and a working length of 12 mm which aids in an efficient preparation of root canal walls. However, in the present study maximum cases (80%, $n=12$) reported optimal quality of filling with rotary Kedo-SG Blue file system followed by Kedo-SH files (46.7%, $n=7$), Kedo-S (40.0%, $n=6$) and hand K-files (20%, $n=3$). Kedo-SG Blue rotary file system has an improved higher flexibility to negotiate even the narrowest canal in primary teeth because

**Table 4** Depicting different Quality of obturation in each group with over-all p-value

| Quality of obturation | Treatment groups | | | | | |
|---|---|---|---|---|---|---|
| | Hand-K files (control group) [$N=15$] | Kedo-S files (experimental group) [$N=15$] | Kedo-SH files (experimental group) [$N=15$] | Kedo-SG blue files (experimental group) [$N=15$] | Total [$N=45$] | Over-all $p$ value |
| Under filling, $N$ (%) | 1 (6.7%) | 5 (33.3%) | 0 (0.0%) | 0 (0.0%) | 6 (10.0%) | $p=0.001$ (Sig)** |
| Optimal filling, $N$ (%) | 3 (20.0%) | 6 (40.0%) | 7 (46.7%) | 12 (80.0%) | 28 (46.7%) | |
| Over filling, $N$ (%) | 11 (73.3%) | 4 (26.7%) | 8 (53.3%) | 3 (20.0%) | 26 (43.3%) | |
| Total, $N$ (%) | 15 (100%) | 15 (100%) | 15 (100%) | 15 (100%) | 60 (100%) | |

Chi-square test, $p<0.05$

*Statistically highly significant values

of the additional titanium coat leading to an easier flow of obturating material and optimal quality of obturation. Its supremely higher flexibility prevents inadvertent file breakage thereby increasing its efficacy and effectiveness in root canal preparation over its earlier predecessor Kedo-S. In the present study rotay Kedo-S and Kedo-SG Blue file system was compared with paediatric hand files (Kedo-SH) and conventional hand K-files. Though the other rotary files used for root canal preparatrion in primary teeth resulted in a reduced instrumentation time, however no significant difference was observed in the quality of obturation when compared to manual instrumentation (Govindaraju et al. 2017a, b, c; Ochoa-Romero et al. 2011; Vieyra et al. 2014). However, in the present study a significant difference was found in the quality of obturation between the rotary and manual instrumentation, except between Kedo-S and Kedo-SH group which shown greater percentage of optimal fillings with Kedo-SH (46.7%, $n=7$) compared to rotary Kedo-S group (40.0%, $n=6$). The factor behind such a finding might be due to more number of files of different nature used for instrumentation in Kedo-SH group (K-file, H-file, files of Ni–Ti nature) compared to rotary Kedo-S group. A marked difference in obturation quality was also observed between paediatric hand files (Kedo-SH) and conventional hand K-files. Factors contributing to it might be the exclusive design of Kedo-SH files which are made up of Ni–Ti alloy with a VV taper corresponding to the varying diameter of the root canals in primary teeth thereby imparting 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 while hand K-files lack the above mentioned properties necessary for effective canal preparation, thereby resulting in reduced number of optimal fillings. In our study, superior quality of obturation was observed in the Kedo-SG Blue rotary file system. Paediatric hand files (Kedo-SH) also produced better results with improved quality of obturation than the conventional hand K-files and rotary Kedo-S group. Use of two-dimensional imaging modality, employed to evaluate the quality of obturation could be considered as a potential limitation of the present study.

## Conclusions

Kedo-SG Blue rotary file system showed a marked reduction in instrumentation time with superior quality of obturation in primary mandibular molars followed by Kedo-SH, Kedo-S and conventional hand K-files. It can be used as an appropriate and advanced alternative to the existing Kedo-S and permanent rotary file system in rendering effective and faster dental treatment in children.

### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (SDC/MDS/18-19/0142) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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