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ORIGINAL SCIENTIFIC ARTICLE

Clinical comparison of Kedo-S paediatric rotary files vs manual instrumentation for root canal preparation in primary molars: a double blinded randomised clinical trial

G. Jeevanandan[1] · **L. Govindaraju**[1]

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Abstract

Aim This was to compare and evaluate the instrumentation time and quality of obturation between paediatric rotary file (Kedo-S) and manual instrumentation techniques in primary molars.

Methods A double blinded randomised control trial was performed that included mandibular primary molars in children of age 4–7 years with pulp necrosis. Sixty primary mandibular molars were randomly divided into two groups: 30 were instrumented with paediatric rotary files Kedo-S (experimental group) and 30 with hand K-files (control group). During the preparation of the primary root canals the instrumentation time was recorded in seconds. The quality of obturation was recorded as optimal, under filled or over filled using immediate post-operative radiographs. The instrumentation time and quality of obturation were analysed using independent t-test and Chi-square test.

Results Mean instrumentation time with paediatric rotary files Kedo-S (78.53 s) was significantly less than K-files (95.46 s) ($p < 0.05$). There was a significant improvement in the quality of obturation ($p < 0.05$) with paediatric rotary files (Kedo-S).

Conclusion Clinical use of paediatric rotary files Kedo-S was effective during root canal preparation of primary teeth with reduction in instrumentation time and better quality of obturation.

Keywords Kedo-S files · K-files · Primary molars · Pulpectomy

Introduction

The major concern in the field of paediatric dentistry is the loss of primary teeth despite various efforts available in the prevention of dental caries in children. The principal goal in paediatric dentistry is to retain the primary teeth in the oral cavity until its physiological exfoliation to preserve arch integrity (Ranly and Garcia-Godoy 2000). Pulpectomy is the choice of treating symptomatic primary teeth with chronic inflammation or necrosis of the radicular pulp (Pinkham and Casamassimo 2005). The pulpectomy procedure involves complete removal of the pulpal tissue, debridement, and preparation of the canal space followed by obturation with a suitable resorbable material (Fuks and Papagiannoulis 2006). The success of pulpectomy is greatly determined by the biomechanical preparation (Haapasalo et al. 2005). Proper cleaning and shaping of the canals aid in adequate removal of the infected tissue and provide a pathway for the irrigating solution to reach the apical third of the root (Siqueira et al. 1997).

The standardised method of cleaning and shaping of the canals in primary teeth as described in the literature is using hand files. Hand instrumentation, despite being the most acceptable and widely used method for canal debridement and shaping, it is time consuming and can result in iatrogenic errors (Silva et al. 2004). Nickel–titanium (Ni–Ti) rotary instrumentation maintains the original canal space during root canal preparation and widely used in permanent teeth. Bio-mechanical preparation with rotary files in primary teeth gained popularity when the first case was reported by Barr et al. (2000) using Profile 0.04 taper rotary instruments. Since then the practice of using various rotary Ni–Ti systems for instrumentation of the primary root canal is emerging among paediatric dentists. Studies have been conducted to evaluate the efficiency of using rotary instrumentation

✉ G. Jeevanandan
helloganz@gmail.com

[1] Department of Paediatric and Preventive Dentistry, Saveetha Dental College and Hospitals, Chennai, Tamil Nadu, India

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for pulpectomy in primary teeth (Selvakumar et al. 2016; Subramaniam et al. 2016).

A survey conducted among Indian dentists showed that about 50% of them used rotary systems for pulpectomy in children and 27% of the practitioners felt both length and taper of the existing rotary files caused potential difficulties in using them in children. Also, 66% of them felt that an exclusive paediatric rotary file should be invented for the ease of using it in children (Govindaraju et al. 2017). Kuo et al. (2006) also reported that an exclusive paediatric rotary file with modified length, taper and tip size would be more effective for performing pulpectomy in primary teeth.

An evolution in the field of endodontics in paediatric dentistry is the introduction of an exclusive paediatric rotary system—Kedo-S file system (Reeganz Dental Care Pvt. Ltd. India). Kedo-S rotary files is a single file system consisting of D1, E1 and U1 files. The total length of these files is 16 mm and the working area (cutting flutes) 12 mm in length. The uniqueness of these files is the presence of variable taper (4–8%) with varying tip diameter D1-0.25, E1-0.30 and U1-0.40 corresponding to its use in primary teeth (Jeevanandan 2017). D1 Kedo-S file is designed to prepare the narrower canals of the primary teeth namely the mesiobuccal and mesiolingual canals and E1 Kedo-S file is to prepare the wider canals namely the distal and palatal canals of the primary molar teeth. The U1 Kedo-S file is used to prepare the upper and lower anterior primary teeth. Kedo-S rotary files are recommended to be used with an endodontic motor in clockwise rotation at 300 (Revolutions Per Minute) RPM and 2.2 N cm torque. Kedo-S rotary files are to be used only in well lubricated and irrigated canals of primary teeth. In order to avoid instrument deformation and separation, Kedo-S rotary files are recommended to be used till the entire working length 1–2 times and for not more than 3–4 s in primary teeth. There are no studies in the literature evaluating the efficiency of the use of Kedo-S rotary file in primary teeth. The aim of the present study, therefore, was to compare the quality of obturation and instrumentation time between manual instrumentation and Kedo-S paediatric rotary system in primary molars.

Materials and methods

The current study was conducted in the Department of Paedodontics and Preventive Dentistry. Ethical approval was obtained from the institutional review board (STP/SDMD-S2015PED42D) in accordance to the ethical standards laid down in the 1964 declaration of Helsinki and its later amendments. The consent was obtained from the parents or the care-takers of the children who participated in the study prior to the start of the clinical procedure. CONSORT guidelines (Altman et al. 2001) for planning and reporting clinical trials in paediatric endodontics was followed during the different stages of the study (Fig. 1).

Sample size estimation and study participant's selection

A sample of 60 primary mandibular second molars of children between 4 and 7 years of age indicated for pulpectomy participated in this double-blinded randomised control trial. The sample size was calculated considering the previously published studies with 95% power in detecting the true statistical significance among the two groups. Inclusion criteria were as follows: children with good health having (1) mandibular primary molar with necrotic pulp, abscess or sinus tract, (2) furcation or periapical radiolucent area, (3) minimum of two-thirds of root remaining and (4) adequate tooth structure to support a rubber dam. Children with medical complications, non-restorable teeth, perforation in the pulpal floor, excessive tooth mobility and internal or external root resorption were excluded. A computer-generated randomisation method was used to allocate the selected tooth into two groups. Group A (30 teeth) (experimental group) the root canals were instrumented with Kedo-S rotary files and in Group B (30 teeth) (control group) the canals were instrumented with conventional hand K-files.

Clinical procedure

All the procedures were performed by a single paediatric dentist having adequate knowledge with rotary and hand instrumentation techniques. Local analgesia (LOX* 2% adrenaline, Neon Laboratories limited, India) was administered for the tooth indicated for pulpectomy and rubber dam (GDC Marketing, India) isolation was applied. No.330 pear-shaped bur (Mani, Inc, Tochigi, Japan) was used for endodontic access opening and removal of decayed tissue. A spoon excavator (Hu-Friedy Mfg. Co. LLC) was used for removal of the coronal pulp followed by the use of a DG 16 (Hu-Friedy Mfg. Co. LLC) instrument to locate the canals. No.10 size K-File (Mani, Inc, Tochigi, Japan) was then used to access the root canal patency. Working length (WL) was determined using ProPex Pixi electronic apex locator (Dentsply Maillefer, OK, USA). No 15 size K-file was used to record the working length of each canal with one mm shorter than the '0.0' mark in ProPex Pixi apex locator.

Group A (N = 30): The root canals were instrumented with Kedo-S paediatric rotary files (Reeganz Dental Care Pvt. Ltd. India) as per 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 using a lateral brushing motion. The rotary files were used with an X-Smart endodontic motor (Dentsply Maillefer, OK, USA) at 300 rpm and 2.2 N cm

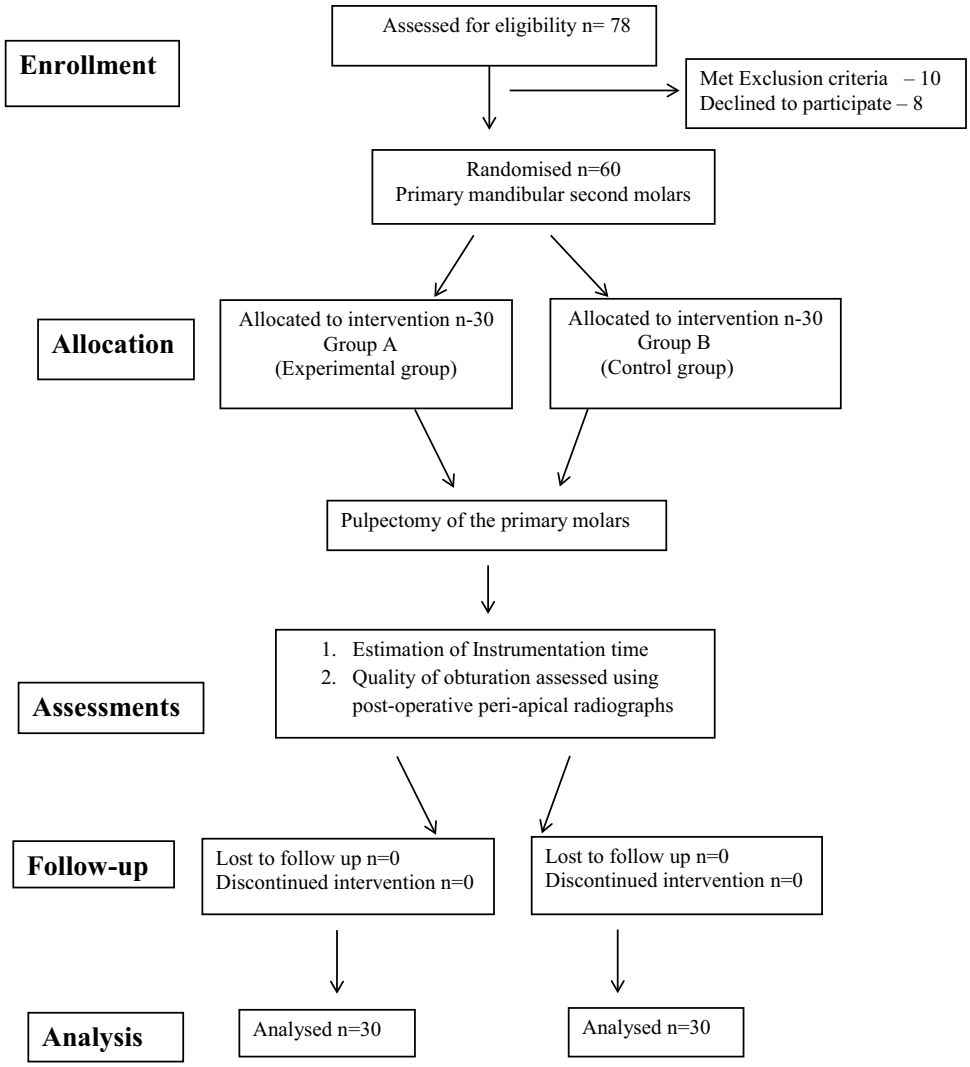

Fig. 1 CONSORT flow chart followed during the different stages of this randomised clinical trial

torque. Each file was used for up to five teeth as per the manufacturer's recommendation and to maintain uniformity during canal preparation.

Group B (N = 30): the root canals were instrumented from no 15 size—till 35 size K-files (Mani, Inc, Tochigi, Japan). The mesial canals were instrumented till 30 size K-files and the distal canal(s) were instrumented till 35 size K-files using a quarter-turn-pull technique. Each K-file was used up to five teeth in order to maintain uniformity during canal preparation.

Root canals were irrigated with 1% sodium hypochlorite after use of each file followed by normal saline. EDTA gel 17% (RC help, Prime dental products, Pvt. Ltd. India) was used as a lubricating paste during the canal preparation. The canals were dried using sterile paper points and the root canal space was obturated using Metapex (Meta Biomed Co. Ltd. Chungbuk, Korea) using pressure syringe technique. The access cavity space was restored using type II glass ionomer cement (GC, India). The coronal seal of the tooth was achieved using a preformed metallic crown (3M ESPE) luted with type I glass ionomer cement (GC India).

Assessment of instrumentation time and quality of obturation

Two examiners were allotted to evaluate the quality of obturation. Kappa test was performed to access the consistency and reliability of the examiners which resulted in a score of 0.90 (excellent). The time taken during instrumentation was recorded in seconds which included only the total active instrumentation time of the files in both the groups. The instrumentation time was recorded using a stopwatch by a trained dental assistant. Immediate post-operative radiographs were taken and the quality of obturation was assessed using the criteria laid down by Coll and Sadrian (1996) underfilled, optimal, or overfilled by two paediatric dentists who were blinded to the groups.

Table 1 Summary of demographic variables describing sample size, age (mean + standard deviation) and number of male and female participants in each group

Treatment Groups	Sample size	Age (years)	Gender Female/male
Kedo-S files (experimental group)	30	5.10 + 1.185	16/14
Hand K-files (control group)	30	5.80 + 1.324	18/12

Table 2 Instrumentation time (mean + standard deviation) in seconds and the statistical comparison of the instrumentation time of Kedo-S files and K-files in primary molars

Treatment groups	n	Mean + standard deviation	Over all *P* value
Kedo-S files (experimental group)	30	78.53 + 9.64	< 0.001 (sig)*
Hand K-files (control group)	30	95.46 + 12.71	

Independent T test, $p < 0.05$

*Statistically significant values

Statistical analysis

The statistical analysis was performed using SPSS software version 17.0. Independent t-test was used to compare the mean values of the instrumentation time during the biomechanical preparation with Kedo-S paediatric rotary files and hand K-files in primary molars. Chi square test was used for assessment of the obturation quality in the primary molars. The significance level was set at 5% for the present study.

Results

A total of 34 girls and 26 boys in each group with a mean age of 5.80 + 1.3 years participated in the study (Table 1). The mean instrumentation time on using Kedo-S paediatric rotary files group (78.53 + 9.6 s) was significantly less than hand K-files group (95.46 + 12.7 s) with a statistically significant difference ($P < 0.05$, Independent T-test) (Table 2). For the Kedo-S paediatric rotary file group, 3 of 30 teeth (10%) were underfilled, 23 (77%) were optimally filled and 4 (13%) were overfilled. For hand K-file group, 6 of 30 teeth (20%) were underfilled, 12 (40%) were optimally filled and 12 (40%) were overfilled. There was a statistically significant difference ($P < 0.05$, Chi square test) (Table 3).

Discussion

There has been a paradigm shift in treating infected primary teeth in children from extractions to pulpectomy which has become an important endodontic procedure in children so as to preserve the arch length and guide the underlying successors eruption (Pinkham and Casamassimo 2005). In children, the objective of root canal treatment is to completely remove the infected tissue and seal the canal(s) with a biocompatible material. Completing the root canal procedure in a shorter time and at the same time providing good quality treatment is the choice of interest for most practitioners.

An evolution in the field of paediatric endodontics is the use of Ni–Ti rotary instruments for canal shaping and preparation of the primary teeth. Primary root canal instrumentation with Ni–Ti rotary files have reduced the instrumentation time and have also resulted in a more uniform, funnel-shaped obturation (Barr et al. 2000). However, in all the studies of the literature Ni–Ti files designed for permanent teeth have been used for pulpectomy in primary teeth (Nagaratna et al. 2006; Subramaniam et al. 2016). A survey conducted on the use of rotary files by Indian dentist revealed 34% of the practitioners used ProTaper system for pulpectomy in primary teeth (Govindaraju et al. 2017). 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 (Finn 1973). In addition, the morphology of the root canals is ribbon-shaped which necessitates the need for an exclusive rotary file for cleaning and shaping of the

Table 3 Quality of obturation among the groups described in percentage

Treatment groups	n	Under fill	Optimal fill	Over fill	Over all *P* value
Kedo-S files (experimental group)	30	3 (10%)	23 (76.7%)	4 (13.3%)	< 0.015 (sig)*
Hand K-files (control group)	30	6 (20%)	12 (40%)	12 (40%)	

Chi square test, $p < 0.05$

*Statistically significant values

primary root canals (Kuo et al. 2006). Also, the use of existing rotary systems in primary teeth has resulted in a higher fracture rate of the instruments (Nagaratna et al. 2006). This was supported by Govindaraju et al. (2017), who stated that about 26% of the practitioners experienced instrument breakage in the primary root canals.

Alteration in the length and taper of the existing rotary files was needed to facilitate its use in primary teeth (Kuo et al. 2006; Govindaraju et al. 2017). With all these facts considered, an exclusive paediatric rotary file, Kedo-S file system (Reeganz Dental Care Pvt. Ltd. India) was introduced (Jeevanandan 2017). It consists of three Ni–Ti files (D1, E1, U1) with an altered working length of 12 mm to expedite its use only in primary teeth. Another added feature of these files is the presence of variably variable taper. D1 and E1 files have been designed for instrumentation of molars and they have a tip diameter of 0.25 and 0.30 mm respectively. D1 file has 4, 5, 6, 8% tapers in different lengths enabling the file to be used only in narrower canals in primary molars namely mesiobuccal and mesiolingual. E1 file has 4, 6, 8% tapers in different length corresponding to be used in wider canals in primary molars namely distal canal(s).

In the present study, D1 files were used for the canal preparation of mesiolingual and mesiobuccal canals and E1 files were used for the distal canals as recommended by Jeevanandan (2017) and were compared with the standard method of preparing the canals with K-files (15–35) with regard to instrumentation time and quality of obturation. During root canal instrumentation, there was no evidence of instrument deformation or breakage in both the groups. Silva et al. (2004) stated that there is no difference in the cleaning efficacy of rotary files with manual instrumentation but the instrumentation time was less with rotary files. A contradicting report was stated by Crespo et al. (2008) that the use of rotary files in primary teeth was efficient in root canal preparation and the time taken compared to manual instrumentation.

In this study, there was a significantly decreased instrumentation time ($P < 0.05$) observed with Kedo-S rotary systems for canal preparation in primary teeth which is similar to the previous studies conducted with various adult rotary systems (Barr et al. 2000; Kuo et al. 2006, Ochoa-Romero et al. 2011; Vieyra and Enriquez 2014). Rosa et al. (2014) stated that the length of the appointment had a paramount influence on the behaviour of the children. The reduced instrumentation time with the use of Kedo-S files will create a positive impact on the child's behaviour and co-operation to the procedure. Also, it helps in reducing the fatigue of the operator (Musale and Mujawar 2014). The quality of obturation is another key element that determines the success of pulpectomy (Ranly and Garcia-Godoy 2000). Ochoa-Romero et al (2011) reported that clinical use of k3 adult NiTi rotary files showed a reduction of instrumentation time with an improved quality of obturation in primary teeth. In the present study, 77% of the cases showed optimal fill on using Kedo-S file system while only 40% of the molars instrumented with hand files showed optimal fill. A superior obturation quality was observed by using Kedo-S rotary files in primary molars, which was statistically significant ($P < 0.05$). Ni–Ti rotary instruments have an ability to prepare the curved canal(s) due to its shape memory capacity with minimal canal transportation. Ni–Ti instruments compared to stainless steel files had better flexibility with superior resistance to torsional fracture. The flexibility of the Ni–Ti rotary files enables the dentist to use the files with greater confidence in a curved primary canal(s). In this study, Kedo-S paediatric rotary files were used to evaluate if the newly designed exclusive rotary files for primary teeth with a shorter length and modified taper can be an alternative to the existing different adult rotary files used in primary teeth.

Use of two-dimensional radiographic assessment method for determination of the quality of obturation can be a potential limitation of this clinical investigation. Further studies evaluating the patient's acceptance of exclusive Kedo-S rotary files and long-term clinical and radiographic success rates should be performed to arrive at precise conclusions.

Conclusions

Kedo-S exclusive paediatric rotary file system has shown reduced instrumentation time and superior obturation quality in primary molars. This system can be an effective alternative in performing root canal treatment in primary molars with great ease, thereby reducing the fatigue of dentists as well as the 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 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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