

Evaluation of Instrumentation Period, Procedural Pain and Quality of Obturation Using Different Single File Systems in Deciduous Molars: A Randomized Clinical Trial

Received: 10 February 2023, **Revised:** 12 March 2023, **Accepted:** 16 April 2023

Foram Patel¹, Megha Patel², Rohan Bhatt³, Rupal Vadher⁴, Chhaya Patel⁵, Dishamakwani⁶

¹Senior Lecturer, Department of Pediatric and Preventive Dentistry, Karnavati School of Dentistry, Karnavati University, Gandhinagar, Gujarat, India. Email: forampatel281095@gmail.com

²Professor and Head, Department of Pediatric and Preventive Dentistry, Karnavati School of Dentistry, Karnavati University, Gandhinagar, Gujarat, India. Email: drmegha1782@gmail.com

³Professor, Department of Pediatric and Preventive Dentistry, Karnavati School of Dentistry, Karnavati University, Gandhinagar, Gujarat, India. Email: drrohanbhatt@gmail.com

⁴Postgraduate student, Department of Pediatric and Preventive Dentistry, Karnavati School of Dentistry, Karnavati University, Gandhinagar, Gujarat, India. Email: rupalvadher3060@gmail.com

⁵Reader, Department of Pediatric and Preventive Dentistry, Karnavati School of Dentistry, Karnavati University, Gandhinagar, Gujarat, India. Email: drchhayachildcare@gmail.com

⁶Senior lecturer, Department of Pediatric and Preventive Dentistry, Karnavati School of Dentistry, Karnavati University, Gandhinagar, Gujarat, India. Email: dishamakwani@gmail.com

Corresponding Author: Dr. Foram Patel

Address: 10- Ganesh 3 bungalows, B/H Jhanvi Farm, PDPU Road. Raysan. Gandhinagar.
Contact: 9426477469 Email: forampatel281095@gmail.com

Keywords

rotary endodontics, reciprocating instruments, quality of obturation, primary molars

Abstract

Background: There are many file systems available for chemo-mechanical preparation during pulpectomy procedures, however, the development of single file systems has led to advancements in pediatric endodontics.

Materials & Method: After taking into account the selection criteria, pulpectomy was carried out on 60 carious mandibular primary molars that were recommended for pulpectomy in kids between the ages of 4 and 8. These teeth were divided into three groups of twenty each and canal preparation was done utilizing different single file systems namely: Group 1: Kedo-S Square pediatric rotary file, Group 2: Kedo S Plus pediatric rotary file and Group 3: WaveOne Gold primary reciprocating file. A stopwatch was used to note down instrumentation time in seconds, Wong-Baker's scale assessed the intensity of procedural pain and intraoral radiographs were used to evaluate the quality of the obturation. Utilizing the Chi-Square test, One Way ANOVA, and HSD post hoc test, collected data was analysed.

Results: There was no statistically significant difference in mean instrumentation time among the three groups. The procedural pain was least for WaveOne Gold reciprocating file system and there was no statistically significant difference regarding pain for both the Kedo file systems. The quality of obturation was seen to be best for Kedo-S Plus file system followed by Kedo-S Square and WaveOne Gold reciprocating system but this difference was not statistically significant.

Conclusion: The advent of single file systems in pediatric dentistry has contributed to effective behaviour management by aiding in completing the treatment procedures in comparatively lesser time.

1. Introduction:

In contemporary pediatric dentistry, pulpectomy is preferred to extraction for the treatment of carious teeth. The technique includes gaining access to the root canals, cleaning them out, irrigating them, and then filling them. Debridement of the canals of deciduous

molars is laborious due to their ribbon-shaped canals, therefore, choosing the right file system is crucial to the overall outcome of pulp therapy.

Hand files are often responsible for iatrogenic mistakes like zipping, blockage, transportation and ledging.¹

This was the reason responsible for the introduction of NiTi files in pediatric dentistry by Barr et al.,²

Various in-vivo and in-vitro studies have been done for preparation of canals in baby teeth using rotary instruments resulting in decreased time of instrumentation as well as canal preparations that are more uniform and conical. There are currently few systems like ProFile, ProTaper, Hero 642, Mtwo, K3, FlexMaster and Wave One which are used in dentistry.

The biggest factor affecting the success of pediatric endodontic treatment is patient co-operation. Patient co-operation is directly related to length of treatment procedure. Lengthy procedures lead to increased patient anxiety and make them uncooperative, compromising the quality of treatment. Hence, need arose for single file systems in pediatric dentistry that aid in quick treatment completion.

Kedo-S Square is a variant of the Kedo-S pediatric rotary file system invented by Dr. Ganesh Jeevanandan in Nov 2016. It has gradual, variably variable, controlled taper (4-8%) with a tip diameter 0.28 for its use in primary posterior teeth [P1: red and blue coded] and 0.38 tip diameter and 6-8% taper for its use in anterior teeth [A1: green and black coded]. It is used with an endomotor in a rotation that is clockwise at 300 RPM and 2.2 N cm torque only in well-lubricated and irrigated canals.³ As it is a single file system, it is expected to prepare the canals more quickly than other file systems.

Kedo S Plus is also a newer member of the Kedo family that employs single file for preparation but with added advantage of more coronal preparation helping in easy flow of obturating material. Compared to S² the preparation is 25% more at the apical region and 40% more in the coronal region.³

Recently, the use of reciprocating movement for canal shaping and debridement has gained popularity in pediatric dentistry. Rotation was replaced with a 90° horizontal reciprocating motion, which decreased the torsional stress and cyclic fatigue of Ni-Ti instruments. When employed in a reciprocating motion, Ni-Ti instruments are less dangerous than when used in continuous rotation.⁴ A new generation of reciprocating files called WaveOne® Gold was launched recently. Webber (2015) claims that these single-use shaping files provide the clinician greater

simplicity, safety, enhanced cutting efficiency, and mechanical qualities. WaveOne Gold primary file with tip of 25 is most suitable for use in primary teeth.

By far, no studies in the literature have evaluated the clinical efficacy and procedural pain using single file systems in pediatric dentistry, hence, the purpose of this study was to evaluate the instrumentation time, quality of obturation and procedural pain using two rotary and one reciprocating single file system in deciduous molars.

2. Materials and Methods:

Ethical Clearance: This study was ethically approved by Institutional Ethical Committee.

Study Design: This randomised trial was exploratory and comparative in that it sought to gather new evidence regarding the clinical efficacy of single pediatric file systems. The study had a double-blinded design as the examiner who assessed the quality of obturation and the child who pointed out the pain score were blinded about the file system used. All the data collection was done by a single examiner to reduce the inter-examiner bias. Inclusion criteria were: (1) primary mandibular molars with irreversible pulpitis (2) absence of pathological mobility (3) no signs of periapical pathology or furcal involvement (4) roots with not more than 1/3rd resorption. (5) absence of mobility. Grossly decayed teeth that do not have adequate tooth structure to receive SS crown, children with physical & psychological disabilities and not giving consent were excluded from the study. Considering the inclusion and exclusion criteria total of 60 primary molars were selected that were divided randomly using computer randomization method into three groups of 20 each namely Group 1– Kedo S Square group, Group 2– Kedo S Plus group and Group 3– WaveOne Gold group. **Figure 1** shows the CONSORT diagram for flow of patients.

Procedure: After full mouth examination with intraoral periapical radiographs, single pediatric dentist performed procedure in all samples in single visit. Topical anaesthetic in the form of 2% Lignocaine spray was administered for a more acceptable injection procedure and anesthesia was achieved by Inferior Alveolar Nerve block at 1ml/min rate with 2% lignocaine hydrochloride containing adrenaline 1:80,000. Tooth isolation was done using rubber dam.

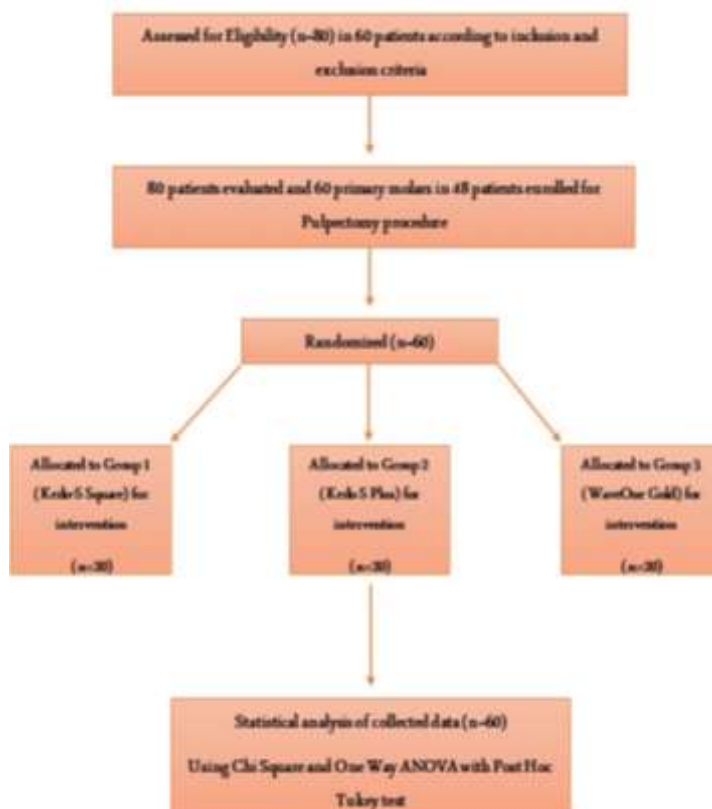
No.4 round bur was used for caries excavation after subjective symptoms of LA were achieved. No.330 pear-shaped bur was used for complete de-roofing of the pulp chamber and ultrafine yellow band burs were used to refine access opening. A spoon excavator was used for scooping out coronal pulp and canal orifices were located using DG-16 explorer. No 10 K file was used to check the root canal patency and working length was determined by Ingle's Radiographic Method and was kept 1mm short of apex. Root canals were instrumented with single Kedo-S square file P1 → 0.28 tip and 4-8% variable taper in Group 1 as per manufacturer's instructions in a lateral brushing motion till the working length. In Group 2 Kedo-S Plus file was used as per the manufacturer's instructions in lateral brushing motion and in Group 3 WaveOne primary file, on starting the reciprocating motor, was passively moved inward and downwards the canal at 350 rpm speed in 170° counter clockwise and 50° clockwise direction to complete 360° in 3 cycles. With all the groups, EDTA gel 17% was used as a lubricating paste during the canal preparation and irrigation was done with 1.25-1.5% sodium hypochlorite and normal saline after use of each file and 10 ml of irrigant was used per tooth. Metapex Plus was used as obturating material

and was administered directly from prepacked polypropylene syringe by pressure syringe method. Glass ionomer cement (GC Gold Label 9 EXTRA) was used as temporary restorative material and preformed metallic crown (3M ESPE) acted as permanent restoration following pulpectomy procedure in all the three groups.

Assessment of parameters: The time taken during instrumentation was recorded with a stopwatch by assistant from beginning to end of canal preparation. Post-operative radiograph was taken to assess the quality of obturation using criteria laid down by Coll and Sadrian (1996)⁵ as underfilled, optimal filled and overfilled by a single pediatric dentist who were blinded to the groups. Using the Wong-Baker FACES discomfort Scale, the child's impression of discomfort during instrumentation was evaluated after canal preparation..⁶

Statistical Analysis: All the data were recorded in the excel sheet and data analysis was done by Statistical Package for Social Sciences (SPSS version 20.0, IBM Corporation, USA) for MS Windows.

Figure 1: Consort Diagram showing the flow of patients



Journal of Coastal Life Medicine

3. Results And Observations:

Demographic distribution: The overall mean age of the participants was 5.56 ± 1.02 which showed an equal distribution of the participants in terms of age. The teeth included in the study were all primary mandibular molars. Out of 60 teeth, 18 teeth (30%) were first primary molars and 42 teeth (70%) were second primary molars.

Comparison of Instrumentation time: Table 2.1 shows that the mean instrumentation time for Group 1 was 59.23 seconds that for Group 2 was 56.19 seconds and for Group 3 was 57.47 seconds. One Way ANOVA did not show any significant differences in the instrumentation times of the three groups as the p value was 0.620 (Table 2.2).

Comparison of Quality of Obturation among three groups (Table 3.1 and 3.2): It was noted that maximum number of optimally filled canals were found in Kedo-S Plus group (85%) followed by WaveOne Gold group (70%) and least number of optimally filled canals were noted in Kedo-S Square group (65%). However, Chi-Square test showed no statistically significant differences among the three groups.

Comparison of Pain Score among the three groups: Mean pain scores were calculated and compared using one way ANOVA test as shown in Table 4.1 which confirmed lowest mean pain score of 0.50 for WaveOne Gold file followed by Kedo S Plus and Kedo-S Square. One Way ANOVA and Post-Hoc Tukey tests showed statistically significant differences between WaveOne and Kedo-S groups. (Table 4.2 $p=0.041$ and Table 4.3)

Table 1: Demographic distribution of Participants

Groups	N	Age Mean \pm SD	Female		Male	
			No.	%	No.	%
Kedo-S Square	20	5.30 \pm 0.85	11	55	9	45
Kedo-S Plus	20	5.75 \pm 0.96	7	35	13	65
WaveOne Gold	20	5.65 \pm 1.20	12	60	8	40
Total	60	5.56 \pm 1.02	32	53.33	28	45.67

Table 2.1: Descriptives of instrumentation time with mean and standard deviation

	N	Mean	Std. Deviation	Std. Error
Kedo-S Square	20	59.2375	10.69657	2.39183
Kedo S Plus	20	56.1910	9.55935	2.13754
WaveOne Gold	20	57.4700	9.26309	2.07129
Total	60	57.6328	9.77203	1.26156

Journal of Coastal Life Medicine

Table 2.2: One Way ANOVA for comparison of instrumentation time

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	93.607	2	46.804	.482	.620
Within Groups	5540.450	57	97.201		
Total	5634.057	59			

Table 3.1: Descriptives for Quality of obturation according to the file system used

			QUALITY OF OBTURATION			Total
			Underfill	Optimal fill	Over fill	
FILE SYSTEM USED	Kedo-S Square	Count	3	13	4	20
		% within FILE SYSTEM USED	15.0%	65.0%	20.0%	100.0%
	Kedo S Plus	Count	1	17	2	20
		% within FILE SYSTEM USED	5.0%	85.0%	10.0%	100.0%
	WaveOne Gold	Count	3	14	3	20
		% within FILE SYSTEM USED	15.0%	70.0%	15.0%	100.0%
Total	Count	7	44	9	60	
	% within FILE SYSTEM USED	11.7%	73.3%	15.0%	100.0%	

Table 3.2: Chi-Square Test for comparison of quality of obturation

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.400 ^a	4	.663
Likelihood Ratio	2.582	4	.630
Linear-by-Linear Association	.093	1	.761
N of Valid Cases	60		

Table 4.1: Descriptives for mean pain scores for three groups

	N	Mean	Std. Deviation
Kedo-S Square	20	1.7	2.08
Kedo S Plus	20	1.8	2.042
WaveOne Gold	20	0.5	0.889
Total	60	1.33	1.829

Table 4.2: ANOVA for comparison of mean pain scores among three groups

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	20.933	2	10.467	3.382	0.041
Within Groups	176.4	57	3.095		
Total	197.333	59			

Table 4.3: Post Hoc Test to test mean difference in between the groups

(I) FILE SYSTEM USED	(J) FILE SYSTEM USED	Mean Difference (I-J)
Kedo-S Square	Kedo S Plus	-0.1
	WaveOne Gold	1.2
Kedo S Plus	Kedo-S Square	0.1
	WaveOne Gold	1.3
WaveOne Gold	Kedo-S Square	-1.2
	Kedo S Plus	-1.3

4. Discussion:

A successful pediatric dentistry practice is built on the foundation of behavior management, and it has been found that chairside time is crucial to behavior management. Children's anxiety is reduced during shorter treatment periods, which aids in behavior management. Therefore, as suggested by earlier studies, using rotational instrumentation can aid in behavior management by shortening the instrumentation process.⁷

Because primary teeth have relatively thin canal walls and it is challenging to adequately instrument flat, oval, curved, and irregularly shaped canals, using file systems made for permanent teeth in primary teeth can result in over instrumentation. Additionally, the use of adult rotary files with greater lengths is restricted by the reduced mouth opening of juvenile patients. As a result, the Kedo file system was developed in response to the

requirement for a file system that is specifically designed for child teeth.

Kedo S Square file system was selected because it offers advantages such as variably variable taper(4-8%), modified working length of 12 mm suitable for use in primary teeth, and it is a single file that can be used for preparation of all the molars leading to reduction in treatment times which can positively affect the behaviour of child.

Kedo S Plus system is similarly a single file system but the unique dual core material in Kedo S plus has a consistent cross section and is coated with titanium oxide at the apical and intermediate regions and is only heated at the coronal region that differs from Kedo-S Square system alongwith its ability to prepare more wider coronal portions. These properties might improve its clinical efficacy which was necessary to study, hence this system was selected.

Journal of Coastal Life Medicine

According to Sattapan et al., the two main causes of endodontic rotary instrument failure are an excessive torsional and/or flexural load that generates stresses that are greater than the instrument's elastic deformation capacity, leading to the instrument's first deforming plastically and then breaking.⁸ Hence, instruments working in reciprocating motion were invented that lead to less canal transportation and apical debris extrusion. So, WaveOne Gold file system for selected in this study.

For our study, mandibular primary molars were selected for standardization purposes. Also, it becomes easy to work with mandibular molars due to easy access and working in direct vision when compared to maxillary molars. Many studies in the literature have shown similar type of sample selection.^{9,10}

In the present study, calcium hydroxide-iodoform paste (Metapex Plus, Meta Biomed) was used for obturating the primary molars which also contains silicon oil that neutralizes some of the alkalinity of the paste causing minimal injury to the periapical tissues and gives the material its desired flow. This paste gives excellent results when used as an obturating material in pulpectomy. The material does not set to a hard mass and shows good resorbable properties. It can be easily delivered and removed from the canals, is radiopaque in nature, and harmless to permanent tooth germs.

In our study, instrumentation time was recorded by a trained assistant using a stopwatch in seconds. The least mean time was taken by Kedo S Plus file system followed by WaveOne Gold and Kedo-S Square systems but this difference was not statistically significant. The possible reason could be that all three systems were single file systems that did not need a change of instruments in between the procedure or sequential use. No such study has been conducted by far so, further studies are needed to support our results.

Assessment of quality of obturation showed maximum number of optimally filled canals with Kedo-S Plus file system followed by WaveOne and Kedo-S Square. Although this difference was not statistically significant, the possible reason could be the ability of Kedo-S Plus system to prepare 40% more in coronal regions and 25% more in apical regions that helps in easy insertion and flow of obturating material due to a wider preparation when compared to other two

systems. this is the first study on Kedo-S Plus system hence, further trials may be required to prove our point.

The mean pain score was found to be the least with WaveOne system that works on reciprocating motion and the difference in pain scores between rotary and reciprocating systems was statistically significant. This result has been supported by Jain et al.¹¹ who showed less pain in cases treated with reciprocating system than with rotary systems. the possible reason for this finding may be that the rotary instruments work in a crown-down manner which is dependent on early coronal expansion that forces the debris in apical direction leading to their apical extrusion alongwith pain. On the contrary, WaveOne system files have a modified convex, triangular cross-section in the tip region that limit the movement of the residue and lessen its thrust in the apical direction, employing a sort of balanced force that does not lead to pain.¹²

Based on the results if this study, it was seen that reciprocating systems resulted in less pain than rotary systems and there was no statistically significant difference in clinical efficacy of all the three systems.

LIMITATIONS:

- Larger sample size could have led to more confirmatory results.
- Amount of apical debris extrusion could have been assessed alongwith CBCT evaluation of quality of obturation.

STRENGTHS:

- This study was first of its kind in comparing two rotary and one reciprocating single pediatric file systems in terms of their clinical efficacy and procedural pain.

5. Conclusion:

Within the limitations of the study it can be concluded that single file systems aid in faster preparation of the root canals that contribute to effective behavior management in pediatric patients. Also, reciprocating systems result in less pain and discomfort than the rotary systems however, there are no significant differences among them in terms of instrumentation time and quality of obturation.

Journal of Coastal Life Medicine

References:

- [1] Nagaratna PJ, Shashikiran ND, Subbareddy VV. In vitro comparison of NiTi rotary instruments and stainless steel hand instruments in root canal preparations of primary and permanent molar. *J Indian Soc Pedod Prev Dent.* 2006;24:186-91.
- [2] Barr E.S., Kleier D.J., Barr N.V. Use of nickel-titanium rotary files for root canal preparation in primary teeth. *Pediatr. Dent.* 2000;22(1):77-78.
- [3] Jeevanandan G. Kedo-S Paediatric Rotary Files for Root Canal Preparation in Primary Teeth – Case Report. *J CliDiag Res* 2017;11(3): 3-5.
- [4] Varela-Patino F, Martin Biedma B, Rodriguez Nogueira J. Fracture rate of nickel- titanium instruments using continuous versus alternating rotation. *Endod Pract Today.* 2008;2:193-7.
- [5] Coll JA, Sadrian R. Predicting pulpectomy success and its relationship to exfoliation and succedaneous dentition. *Pediatr Dent* 1996;18(1):57-63.
- [6] Hockenberry MJ, Wilson D. *Wong's Essentials of Pediatric Nursing.* 8th ed. St. Louis, Mo: Mosby, Inc; 2009: 162.
- [7] Guelzow A, Stamm O, Martus P, Kielbassa AM. Comparative study of six rotary nickel-titanium systems and hand instrumentation for root canal preparation. *Int Endod J.* 2005 Oct;38(10):743-52.
- [8] Sattapan B, Nervo GJ, Palamara JE, Messer HH. Defects in rotary nickel-titanium files after clinical use. *J Endod.* 2000;26:161-5.
- [9] Crespo S, Cortes O, Garcia C, Perez L. Comparison between rotary and manual instrumentation in primary teeth. *J Clin Pediatr Dent.* 2008 Summer;32(4):295-8.
- [10] Kummer TR, Calvo MC, Cordeiro MM, de Sousa Vieira R, de Carvalho Rocha MJ. Ex vivo study of manual and rotary instrumentation techniques in human primary teeth. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod.* 2008 Apr;105(4):e84-92.
- [11] Jain P, Sanjyot M, Bhosale S. Assessment of Postoperative Pain after Single-Visit Root Canal Treatment using Wave One® and One Shape® Single File System: A Clinical Study. *J Pharm Bioallied Sci.* 2021 Nov;13(Suppl 2):S1506-S1512.
- [12] Alnassar I, Altinawi M, Rekab MS, Katbeh I, Khasan A, Almokaddam H. Pain assessment following endodontic treatment using two automated systems compared to manual treatment in primary molars. *Dent Med Probl.* 2021 Jul-Sep;58(3):305-310. doi: 10.17219/dmp/130083. PMID: 34432394.