

Comparative Evaluation of Hand File with Two Pediatric Rotary Files in Primary Molars - An Invivo Study

Type of the study: Original study

Running title: Comparative evaluation of hand file with Kedo-S and Kedo-S Plus files in primary molars

V. Ranjith Akshay Seshadri

Postgraduate Student
Saveetha Dental College and Hospitals,
Saveetha Institute Of Medical and Technical Sciences,
Saveetha University,
Chennai, India
Mail Id: 152011006.sdc@saveetha.com

Ganesh Jeevanandan

Reader,
Department of Pediatric and Preventive Dentistry,
Saveetha Dental College and Hospitals,
Saveetha Institute Of Medical and Technical Sciences,
Saveetha University,
Chennai, India
Mail Id: ganesh.sdc@saveetha.com

Corresponding Author

Ganesh Jeevanandan

Reader,
Department of Pediatric and Preventive Dentistry,
Saveetha Dental College and Hospitals,
Saveetha University,
162, PH Road, Chennai-77
Tamilnadu, India
Contact No: +91 9884293869
Mail Id: ganesh.sdc@saveetha.com

ABSTRACT:

Background: Pulpectomy is the choice of treating symptomatic primary teeth with chronic inflammation or necrosis of the radicular pulp.

Aim: This study's objective is to contrast the instrumentation time and quality of obturation of pediatric rotary file system Kedo-S, Kedo-S Plus and hand file

Material and Methods: This study included 45 patients between 4-7 years of age, who underwent pulpectomy in the necrotic posterior teeth with a minimum of 2/3rd of tooth structure remaining. There were 3 groups namely Group 1 with Kedo S plus preceded by initial hand instrumentation up to 15H file. Group 2 with Kedo S rotary with D1 and E1

antedeceded by initial hand instrumentation up to 15H file and Group 3 with hand file instrumentation up to 35 H file. These were then graded using the Coll and Sadrian obturation grading system into optimal fill, underfilled and overfilled. The data collected was transferred to MS Excel Sheet and datas collected were then imported to SPSS IBM Version 20.0.

Results and Discussion: The results showed that the mean instrumentation time on using Kedo-S Plus (74.65+7.45s) was significantly less than the Kedo-S pediatric rotary files and hand files with $p < 0.05$ (statistically significant).

Conclusion:

Kedo S plus rotary files has better obturation quality and time of instrumentation.

INTRODUCTION

Primary teeth plays an indispensable role in the dental and facial development.(1) They are significant as they not only hold on the space for permanent teeth, but also helps in chewing, biting, speaking and the appearance.Over and above, they guide the eruption of permanent teeth . Hence, preserving the primary teeth in its position without any infection is of utmost importance.(1) For the management of necrotic primary teeth, pulpectomy remains as the first choice of treatment. This endodontic treatment is done to debride the tortuous primary root canals and maintain it in a non-pathologic condition until exfoliation.(2)

Endodontic instruments plays a starring role in the root canal preparation.(3) In the modern era, the chemo-mechanical preparation in primary teeth is performed using the pediatric files. The first exclusive pediatric rotary file introduced was Kedo-S(KEDO dental,Chennai,India) in the year 2017 (4). Kedo-S file system consists of three files made of NiTi, two for posteriors (D1,E1) and one for anteriors(U1) . The Kedo-S rotary file's master stroke brought in a revolutionary change in the domain of pediatric endodontics. Subsequently, a lot more new innovative modifications in the antecedent Kedo-S rotary file was launched which include file systems from Kedo include the SG, SG Blue, and S Square.(5) The clinical trials in the literature bespeaks the efficacy and success of the above files.(6)The state of art to team up the inventory of Kedo rotary files is the Kedo-S Plus files. Kedo S plus rotational file system has the benefit of being a single file system- One for posterior and one for anterior with Variably Varying Taper. The apical third of the files appears blue in colour because they are heat treated with titanium oxide to minimize the chances of breakage whereas the coronal third is golden in colour which is also heat treated for better coronal preparation. The clinical efficiency of these files are still not explored. Therefore, the current study compares how long it takes to instrument primary molars and how well they obturate utilising Hand H files, Kedo-S, and Kedo-S + paediatric rotary files.

MATERIALS AND METHODS

Study Design

The current investigation was carried out as a clinical trial that was randomised controlled and double blinded. The institutional review board of Saveetha Dental College in Chennai granted the study ethical permission.(IHEC/SDC/PEDO-1601/21/292).

Selection of the samples

The sample size was calculated from the previously published clinical trial with 90% power and arrived to a study population of 45 pediatric patients.(Lakshmi et al 2020). The study included all patients visiting Saveetha Dental College in Chennai between the ages of 4 and 7 who required pulpectomy treatment in any one of their necrotic posterior primary teeth.Primary molars with at least a 2/3-inch root length, adequate crown structure for rubber dam placement, and a crown were chosen. The study eliminated patients with systemic illnesses, non-restorable teeth with furcal perforations, and abnormal mobility as well as parents who refused to sign the informed consent form.

Informed consent and Randomisation

An informed consent form was acquired from every parent or the guardian regarding the participation of their children in the trial. The allocation concealment was carried out using the closed envelope approach, and the randomization was based on the computer-generated sequence of random numbers. The instrumentation was done using-

Group A (15 teeth): Kedo S plus rotary file system-P1

Group B (15 teeth): Kedo S file system-D1,E1

Group C (15 teeth): Hand file (H files)

Blinding

The therapy strategy was concealed from the kids and the parents. The Quality of obturation was assessed by an evaluator who was also blinded. The operator could not be rendered blind because they were aware of the type of treatment being given.

Study protocol

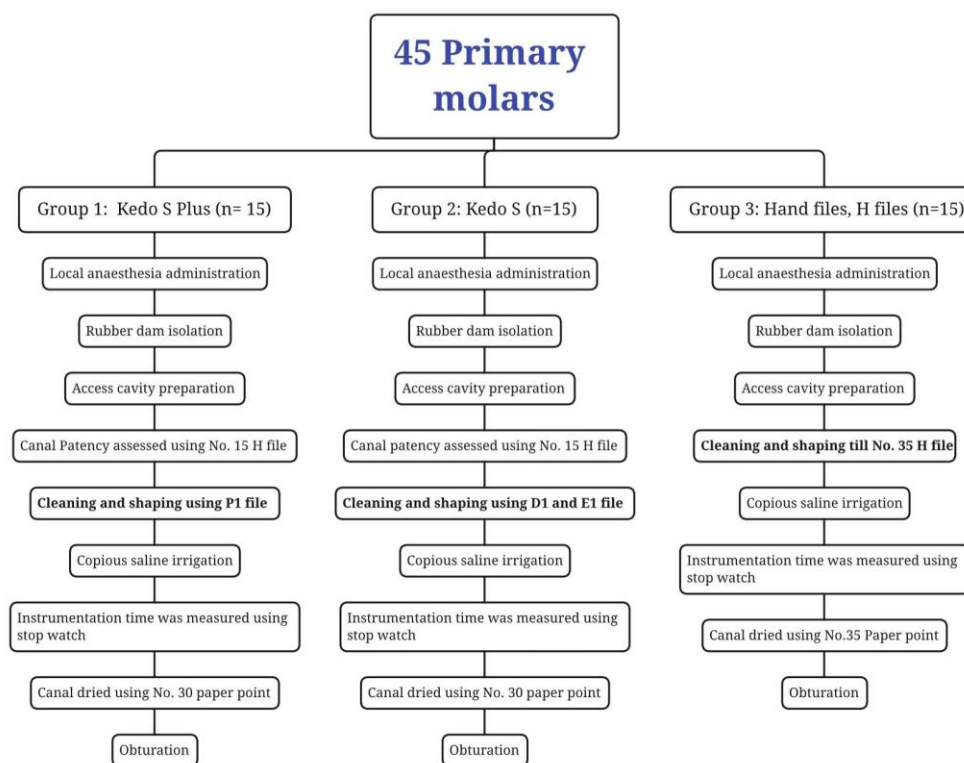
All of the primary teeth underwent a single-visit pulpectomy. Local anesthesia was given. Before continuing with the additional treatment method, the subjective and objective indicators of the local anaesthetic were confirmed. The teeth were isolated with rubber dam for all the procedures. Access cavity was prepared using BR 31 after initial caries removal. The access cavity's roof was removed. DG-16 Explorer was used to locate the starting orifice, and no. 15 hand H files were then used to determine the working length. The radiographic method was used to determine the working length and was kept 1-mm short of radiographic apex. Depending on the randomisation sequence, the instrumentation type was chosen. In group 1, Kedo S plus rotary instrumentation (P1) anteceded by initial hand instrumentation with no. 15 H file was done. In group 2, Kedo S rotary instrumentation anteceded by initial hand instrumentation with no. 15 H file. The canals were then instrumented with D1 and E1 Kedo rotary files. In group 3, manual preparation of the canals was done using hand H-file up to no. 35 H-file using push and pull motion. All the canals irrespective of the filing system were irrigated by saline.

Digital stopclock was used to measure the instrumentation time. The timer was paused during saline irrigation and starts when the first file is presented. The operator recorded the matching instrumentation time for each group.

The canals were dried with no. 30 paper points and obturated with Metapex following the instrumentation and irrigation. The initial entry filling was given with GIC after the surplus coronal filling was removed. Stainless steel crown was given on the same visit. A size 0 phosphor plate sensor and portable x-ray device were used to take the radiograph in order to assess the quality of obturation. Paralleling technique was used. The quality of obturation was assessed by the evaluator who was blinded for the treatment type. Based on the standards provided by Coll and Sadrian, the evaluator assigned each radiograph an optimal, over, or underfilled rating. The criteria used is given in Table 1.

Table 1: Coll and Sadrian criteria for grading of quality obturation

Optimal	at or within 1 mm of apex
Over-fill	2mm beyond apex
Under-fill	2mm short of apex



Statistical Analysis

Data was entered in Microsoft Excel spreadsheet and analyzed using SPSS software (IBM SPSS Statistics, Version 20.0, Armonk, NY: IBM Corp.). Descriptive statistics were used for data summarisation and presentation. Shapirowilks test was used to determine the normality of the data distribution. Data was normally distributed. The mean Instrumentation time was compared using one-way ANOVA. Obturation quality was assessed using chi square test. The level of statistical significance was set at a value of $P < 0.05$.

RESULTS:

The demographic details of the participants is depicted in Table 1. With regards to the instrumentation time, a statistically reduced time of instrumentation was noticed with Kedo S Plus rotary files, followed by Kedo S Rotary files. (Table 2, Graph 1) Post Hoc Tukeys test depicted that this difference in reduced time of instrumentation was significant between all the three groups. (Table 3) However, no significant changes was found in the quality of obturation with the use of these files. (Table 4)

Table 1 : Demographic details of the participants

	Hand Files	Kedo S Rotary	Kedo S Plus Rotary	P Value
AGE	5.76 ± 0.80	4.38 ± 0.60	4.43 ± 0.64	
GENDER				

MALE	8 (53.3%)	9 (60.0%)	5 (33.3%)	0.315
FEMALE	7 (46.7%)	6 (40.0%)	10 (66.7%)	

Table 2: Comparison of the groups' average instrumentation times, $p < 0.05$ statistically significant

GROUPS	N	Mean	Std. Deviation	P value
KEDO S PLUS	15	74.65	3.36	0.001**
KEDO S	15	78.26	2.85	
HAND FILES	15	95.33	2.77	

Graph 1 : Mean instrumentation time between the groups

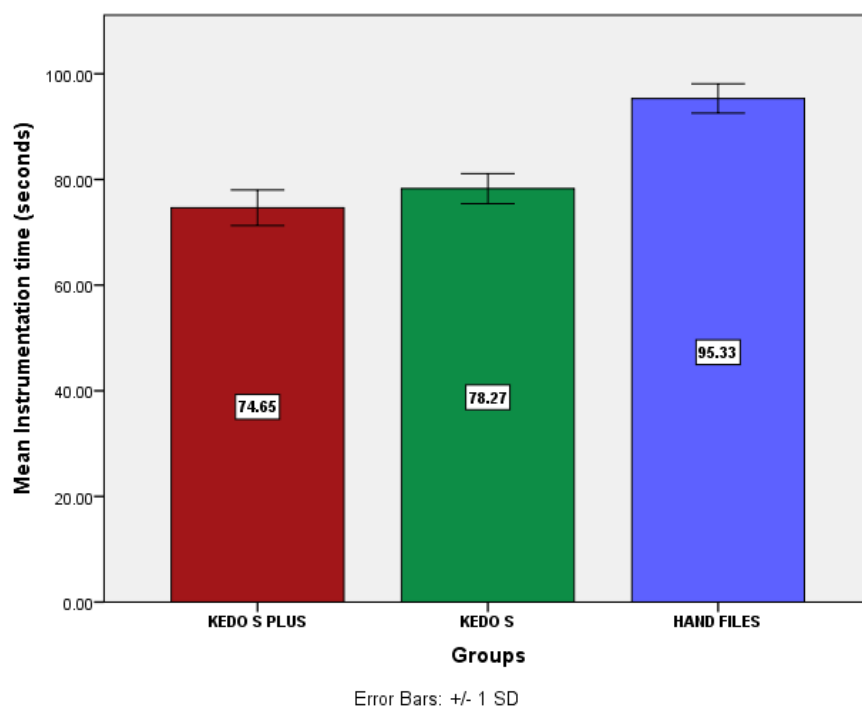


Table 3: Post hoc Tukeys Multiple comparison, $p < 0.05$ statistically significant

(I) GROUPS	(J) GROUPS	P value
KEDO S PLUS	KEDO S	0.006
	HAND FILES	0.001

KEDO S	KEDO S PLUS	0.006
	HAND FILES	0.001
HAND FILES	KEDO S PLUS	0.001
	KEDO S	0.001

Table 4: Comparison of Obturation quality between the groups, $p < 0.05$ statistically significant

GROUPS	UNDER FILL n(%)	OPTIMAL FILL n(%)	OVER FILL n(%)	P value
KEDO S PLUS	3 (20.0%)	8 (53.3%)	4 (26.7%)	0.32
KEDO S	7 (46.7%)	3 (20.0%)	5 (33.3%)	
HAND FILES	4 (26.7%)	5 (33.3%)	6 (40.0%)	

DISCUSSION:

The primary goal of endodontic therapy in children is to completely remove sick tissue from the pulp canal and seal it with a biocompatible, resorbable substance. (7) A through chemo-mechanical preparation aids in the complete debridement of the primary root canals, which is reciprocated by the instrumentations used. (8) For decades, Hand files has been used and though it serves as a gold standard, it has its own pitfalls. and the present study aims at comparing one such recently introduced exclusive pediatric rotary file - Kedo S Plus with its fountain-head Kedo S rotary files and the gold standard Hand files (H Files) Introduction of exclusive pediatric rotary files for canal instrumentation has brought about a revolutionary change in the pediatric dental practice (9) with regards to the time of instrumentation and Obturation quality.

Regarding instrumentation time, it was noticed in the current investigation that with the newly developed rotary file (Kedo S Plus), the time taken to clean the canals were much lesser when compared to its antecedent Kedo S pediatric rotary files and hand files. It was determined that this variation in the instrumentation time was extremely statistically significant ($p = 0.001$) The reduction in the instrumentation time can be attributed majorly to the single file system of Kedo S Plus files as the Kedo S rotary file is a two file system and hand files requires multiple files to effectively clean the primary root canals. (10)

In contrast to other studies that claimed Kedo rotary files improved the quality of obturation, the current study found no appreciable variation in obturation quality amongst the three groups ($p = 0.32$) (Ganesh et al 2018). However, the Kedo S Plus rotary files showed highest incidence of optimal fillings when compared to the other two file systems, similarly it has the lowest incidence of under-fillings and over fillings (Table 4). The design of the Kedo S Plus files facilitates better coronal preparation which in turn allows the better flow and seal of the obturating material in the primary root canals.

CONCLUSION:

Compared to Kedo S files and hand files, Kedo S plus special paediatric rotary files offer faster instrumentation and higher-quality obturation. Kedo S plus is a single file system that assists in quicker root canal preparation and improved patient management.

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