

# Comparative Evaluation Of Two Paediatric Niti Rotary File System With Iso K Hand Files In Pulpectomy Of Primary Mandibular Molars: A Double Blind Randomised Invivo Study.

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## ABSTRACT

**Background:** Pulpectomy is the treatment of choice for primary teeth with irreversible pulpitis or pulpal necrosis. Mechanical instrumentation is of utmost importance and can be accomplished by instrumentation with hand, rotary or reciprocating systems.

**Aims:** The study aims to assess and compare the instrumentation time taken and quality of obturation using two paediatric NITI rotary files e.g., Kedo SG Blue and Prime Pedo™ with ISO hand K File in deciduous teeth.

**Materials and Methods:** A double blinded study was planned where pulpectomy was performed on primary mandibular second molars in children of age 4–9 years. Sixty primary mandibular second molars were randomly divided into three groups: 20 were instrumented with paediatric rotary files Kedo-SG Blue (experimental group), 20 were instrumented with paediatric rotary file Prime Pedo™ (experimental group) and 20 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.

**Results:** Mean instrumentation time with paediatric rotary files was significantly less compared to hand K files. In our study, 14 cases with hand K file, 20 cases with Prime Pedo and 22 cases with Kedo-SG Blue in both mesial and distal canal were optimally filled. Though, a difference is seen in optimal fill between hand and rotary files, but the difference was not statistically different.

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

**Keywords:** Paediatric, NITI Rotary File, ISO K Hand Files and Primary Mandibular Molars.

Date of Submission: 02-06-2023

Date of Acceptance: 12-06-2023

## I. INTRODUCTION

The beginning of eruption of primary teeth in the oral cavity occurs in around 6 to 7 months of age, and kids normally have up to 20 teeth in their mouth till the age of 3 years.<sup>1</sup> These teeth serve the function of mastication, phonation and aesthetics until the permanent teeth erupt.<sup>2</sup> Chewing, talking, and aesthetic being its three significant functions, primary teeth serves a significant role in permanent teeth eruption.<sup>3,4</sup> Underneath the primary teeth remains the follicle of permanent teeth which sustain requisite space for its eruption.<sup>5,6</sup> Primary teeth serves as a beneficial tool for brushing practices, keeping great oral cleanliness, and this practice once acquired is sustained for life.<sup>7</sup> When a child presents with a deep dentinal caries with pulp involvement, a dentist has only two options left – either to remove the tooth or to proceed with the endodontic treatment.

The procedure incorporates the chemical and mechanical evacuation of irreversibly aroused or necrotic pulpal tissue, and the prepared space is filled with suitable material which resorbs along with the primary teeth.<sup>8</sup> In any case, endodontic treatment in primary teeth presents more difficulties due to the anatomic intricacies, dynamic variations of apex because of biological root resorption, nearness to the underlying permanent tooth bud alongside with proper behaviour management makes a work of a paediatric dentist a challenging one.<sup>9</sup>

Biomechanical preparation holds an indispensable role in both the cases of primary and permanent teeth. Traditionally stainless steel hand files had a vital role in endodontic procedures and were the primary instruments used for root canal shaping till the NiTi file system were introduced. A remarkable feature of the NiTi files were that the biomechanical preparation of curved canals could be easily performed using continuous rotary motion.

Use of first NiTi rotary instrument in primary teeth was introduced by Barr et al in the year 2000. The most remarkable feature of using NiTi rotary instruments is that it produced a predefined conical shaped canals with exceptionally reduced instrumentation time.<sup>11,12</sup> It was also reported that it would be more effective if pulpectomy in primary tooth is performed with an exclusive paediatric rotary file system with revised length, taper and tip diameter.<sup>13</sup> Kedo-S was the first generation rotary file that came with variable taper, shorter length and tip diameter. Other file system like Kedo-SG Blue and Prime Podo™ are some of the recently developed NiTi rotary file system to be used in primary teeth.

Many studies have been undertaken to compare various rotary file systems with standard K files. However, no comparative study have been reported in the literature comparing the instrumentation time and quality of obturation using the two new rotary files Kedo SG Blue file, Prime Podo™ file with ISO hand K file.

Hence the present study was conducted to assess and compare the time taken for instrumentation and quality of obturation of root canal in deciduous teeth using NiTi rotary Kedo SG Blue and NiTi Prime Podo™, with the ISO hand K file system.

## **II. MATERIALS AND METHODS**

The study sample comprised of a total of 60 primary second mandibular molars of children in the age group of 4 - 9 years visiting the Outdoor Patient Department for dental treatment in the Department of Pedodontics and Preventive Dentistry of Awadh Dental College & Hospital, Jamshedpur, Jharkhand.

**Study Design :** A double blind randomised invivo study.

**Study Location :** Department of Pedodontics and Preventive Dentistry of Awadh Dental College & Hospital, Jamshedpur, Jharkhand.

### **Inclusion Criteria:**

- Intellectually and physically sound children between age of 4 – 9 years accompanied by their parents were included in the study.
- Children with acute and chronic pulpitis in primary mandibular molars with minimum periapical / inter radicular radiolucency were included in the study.

### **Exclusion Criteria:**

- Medically and mentally compromised children were excluded from the study. Mandibular second molars with sinus or fistula or large inter radicular lesions or perforations in the pulpal floor were excluded from the study.
- Non restorable mandibular second molars were also excluded from the study.

A total of 60 human primary second mandibular molars of children in the age group of 4-9 years were included in the present study. A double-blind study with a null hypothesis that was planned. An equal number of primary second mandibular molars were randomly allocated to the following three groups:

**Group I:** Root canals instrumented with manual ISO hand K file. (Control Group N = 20)

**Group II:** Root canals instrumented with pediatric NiTi rotary Kedo SG Blue file (Experimental Group N = 20)

**Group III:** Root canals instrumented with pediatric NiTi rotary PrimePodo™ file. (Experimental Group N = 20)

### **Procedure Methodology:**

Ethical approval was taken from the institutional ethical committee. CONSORT (Altman et al. 2001) guidelines for planning and reporting of the clinical trials in paediatric endodontics was followed during the various stages of the study.

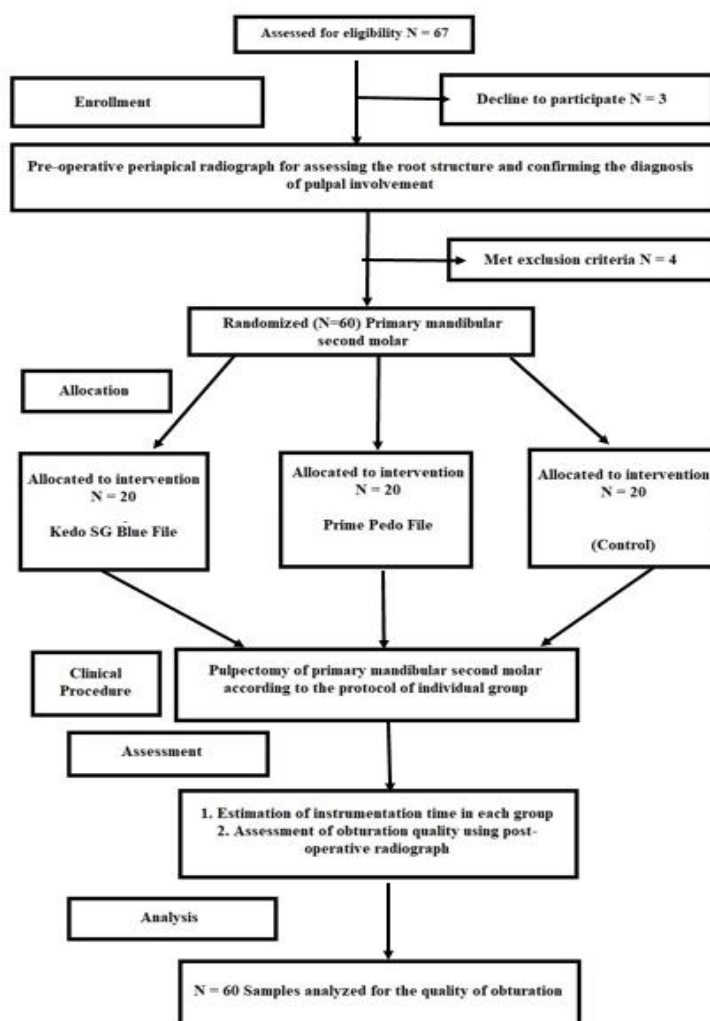


Figure 1 – Consort Flow Chart

### III. CLINICAL PROCEDURE

A full mouth clinical examination was made and intraoral periapical radiographs assessment of the teeth indicated for pulpectomy was done before the beginning of the clinical procedure. Inferior alveolar nerve block was given to anesthetise the mandibular second molar with 2% lignocaine (1,20,000 Adrenalin) solution. After assessing both subjective and objective signs of local anaesthesia, the tooth was isolated with rubber dam. Working length (WL) was determined using electronic apex locator (Woodpecker Apex V). A 15 size K-file was used to record the working length of each canal which was kept 1 mm shorter than the '0.0' mark in the apex locator.

**Group I (Control group):** The root canals was instrumented utilizing hand ISO K file from No. 15 size file till 35 size by a quarter-turn pull back method. The mesial canals were instrumented till No. 30 size K-file and the wider distal canals were instrumented till No. 35 size K-file.

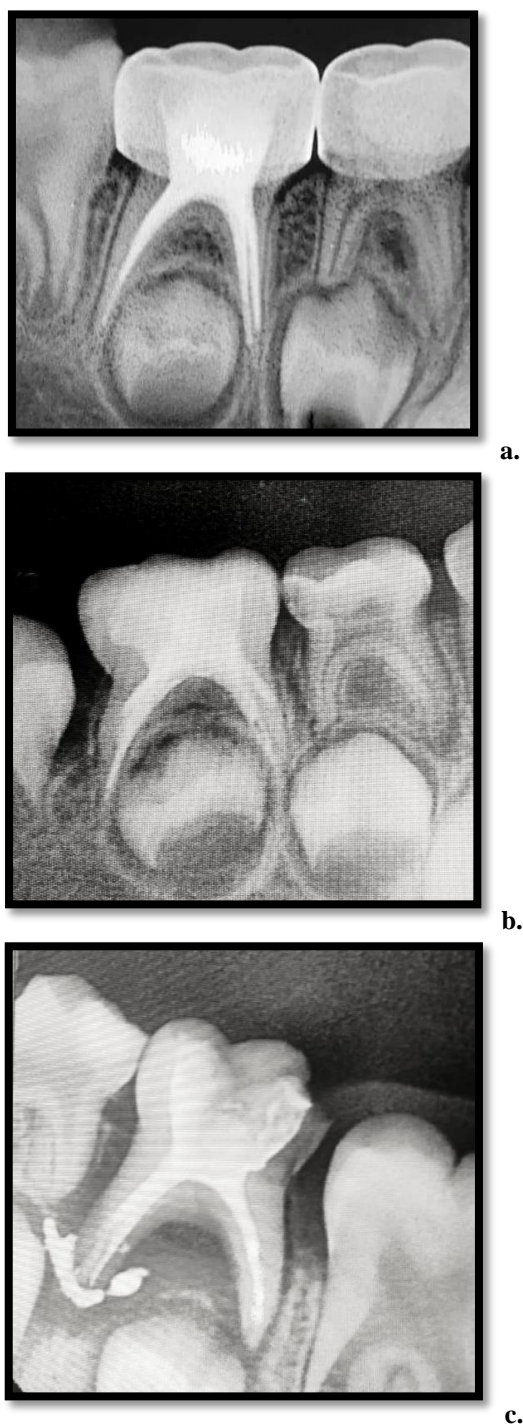
**Group II (Experimental group):** The root canals were instrumented utilizing NiTi rotary Kedo-SG Blue file system (Reeganz Dental Care Pvt. Ltd. India). Root canal instrumentation was done at recommended speed and torque (300 RPM speed and 2.2Ncm torque). D1 file was utilized for instrumentation of the mesiobuccal and mesiolingual canals. For wider distal canal, D1 rotary file was first utilized followed by E1 in a brushing movement.

**Group III (Experimental Group):** Instrumentation was done with Prime Pedro™ NiTi rotary files (Sky International Enterprises, India) at a speed of 300 rpm and at torque of 2.4 N/cm as suggested by the manufacturer. Starter file (8% shape, 16 mm) was utilized for enlarging the orifice of the canal. After this point P1 file (#15, 6% shape, 18 mm) and P2 (#25, 6% shape, 18 mm) files were used for instrumentation in narrower and wider canals respectively.

Calcium and iodoform based obturating material (Calcipex) was used to obturate the canals. The prepared cavity space was filled with type II Glass Ionomer Cement (GC, India).

**IV. Assessment of efficacy of two paediatric NiTi Rotary files and ISO K hand files:**

Two parameters were analysed during the study; the instrumentation time and the quality of obturation as seen on post-operative radiographs. For the three groups only active instrumentation time was recorded using a stopwatch. Post-operative radiographs were taken immediately after obturation and the quality of obturation was evaluated using criteria laid down by Coll and Sadrian (1996) as underfilled, ideal or overfilled by two paediatric dental specialists who were blinded to the groups.



**Figure 2 - Immediate post-operative radiograph depicting different levels of quality of obturation – a. Optimal filling b. Under filling c. Overfilling**

**V. RESULT**

**Table 1: Distribution of mean Instrumentation Time In Seconds**

		Number	Mean	SD	Minimum	Maximum	Median	p-value
<b>Instrumentation Time In Seconds</b>	Hand K File	20	372.3500	87.0912	239.0000	547.0000	373.5000	<0.0001
	Kedo SG Blue File	20	195.1000	25.0765	151.0000	240.0000	195.0000	
	Prime Pedo File	20	200.8000	43.3961	133.0000	280.0000	202.0000	

The study compared the instrumentation time taken for cleaning and shaping of root canal using Hand K files ( Group I), Kedo SG Blue files (Group II) and Prime Pedo files (Group III)

Table 1 represents the mean instrumentation time in seconds for Hand K files ( Group I), Kedo SG Blue files (Group II) and Prime Pedo files (Group III). The mean instrumentation time for Group I was 372.3500± 87.0912 seconds, for Group II was 195.1000± 25.0765 and for Group III was 200.8000± 43.3961 seconds. The p vaule was (p<0.0001) confirming that the instrumentation time for rotary files was significantly less as compared to hand K files.

**Table 2: Quality of obturation in distal canal using three file systems**

Distal Canal	Hand K File Group I	Kedo Sg Blue File Group II	Prime Pedo File Group III	Total
<b>Optimal Fill</b>	7	11	10	28
Row %	25.0	39.3	35.7	100.0
Col %	35.0	55.0	50.0	46.7
<b>Under Fill</b>	9	4	4	17
Row %	52.9	23.5	23.5	100.0
Col %	45.0	20.0	20.0	28.3
<b>Over Fill</b>	4	5	6	15
Row %	26.7	33.3	40.0	100.0
Col %	20.0	25.0	30.0	25.0
<b>Total</b>	20	20	20	60
Row %	33.3	33.3	33.3	100.0
Col %	100.0	100.0	100.0	100.0

**Chi-square value: 4.2697; p-value: 0.8291**

Quality of obturation among the three groups in terms of optifill, underfill and overfill is described in Table 2.

In distal canal the number of optifill cases were highest in case of Kedo SG Blue file (Group II) 55% followed by Prime Pedo (Group III) 50% and hand K files (Group I) 35%. The defference in the quality of obturation in the distal canals was not statistically significant (p = 0.8291)

**Table 3: Quality of obturation in mesial canal using three file systems**

Mesial Canal	Hand K File Group I	Kedo Sg Blue File Group II	Prime Pedo File Group III	Total
<b>Optimal Fill</b>	7	11	10	28
Row %	25.0	39.3	35.7	100.0
Col %	35.0	55.0	50.0	46.7
<b>Under Fill</b>	9	4	4	17
Row %	52.9	23.5	23.5	100.0
Col %	45.0	20.0	20.0	28.3
<b>Over Fill</b>	4	5	6	15
Row %	26.7	33.3	40.0	100.0
Col %	20.0	25.0	30.0	25.0
<b>Total</b>	20	20	20	60
Row %	33.3	33.3	33.3	100.0
Col %	100.0	100.0	100.0	100.0

**Chi-square value: 4.2697; p-value: 0.3707**

The quality of obturation in the mesial canal is described in Table 3.

In mesial canal the number of optifill cases were highest in case of Kedo SG Blue file (Group II) 55% followed by Prime Pedo (Group III) 50% and hand K files (Group I) 35%. The defference in the quality of obturation in the mesial canals was not statistically significant ( $p = 0.3707$ )

**Table 4: Comparison of quality of obturation in Distal and Mesial Canal in three groups**

		Hand K File Group I	Kedo Sg Blue File Group II	Prime Pedo File Group III	Total	Chi-square value	p-value
Distal Canal	<b>Optimal Fill</b>	7	11	10	28	4.2697	0.8291
	Row %	25.0	39.3	35.7	100.0		
	Col %	35.0	55.0	50.0	46.7		
	<b>Under Fill</b>	9	4	4	17		
Row %	52.9	23.5	23.5	100.0			
Col %	45.0	20.0	20.0	28.3			
<b>Over Fill</b>	4	5	6	15			
Row %	26.7	33.3	40.0	100.0			
Col %	20.0	25.0	30.0	25.0			
<b>Total</b>		20	20	20	60		
Row %		33.3	33.3	33.3	100.0		
Col %		100.0	100.0	100.0	100.0		
Mesial Canal	<b>Optimal Fill</b>	7	11	10	28	4.2697	0.3707
	Row %	25.0	39.3	35.7	100.0		
	Col %	35.0	55.0	50.0	46.7		
	<b>Under Fill</b>	9	4	4	17		
Row %	52.9	23.5	23.5	100.0			
Col %	45.0	20.0	20.0	28.3			
<b>Over Fill</b>	4	5	6	15			
Row %	26.7	33.3	40.0	100.0			
Col %	20.0	25.0	30.0	25.0			
<b>Total</b>		20	20	20	60		
Row %		33.3	33.3	33.3	100.0		
Col %		100.0	100.0	100.0	100.0		

Table 4 compares the quality of obturation in both mesial and distal canals in all the three groups hand K files ( Group I), Kedo SG Blue files (Group II) and Prime Pedo files (Group III). The p value for the obturation of mesial and distal canals was more than 0.05 which is statistically non significant indicating that radiographically obturation upto the apical third was equally good for all the three groups.

## VI. DISCUSSION

In recent decades, significant paradigm shifts in the field of dentistry has occurred, and many more significant shifts are yet to come. In a similar vein, in the field of pediatric endodontics, improvements are seen not only in the materials used but also in the methodology and in the nature of instrumentation resulting in work of a higher and superior quality.

In children, the primary objective of a pulpectomy is to successfully maintain the tooth as a natural space maintainer in the dental arch until its normal exfoliation, in addition to completely removing the infected tissue and applying a biocompatible material to the canal. <sup>9</sup>

Biomechanical preparation by rotary instrument has been proven to be efficient in primary teeth with curved canals due to their greater flexibility and automated nature of instrumentation.

Barr et al in 2000 was the first to use rotary files for biomechanical preparation in primar teeth. Since then these files have been frequently used for primary teeth.

For pulpectomy of primary teeth, all of the published studies have used Ni-Ti files designed for permanent teeth. Govindaraju et al. (2017) in a survey on the use of rotary files among Indian Dentists found that 34% of them used the ProTaper system designed for permanent teeth. However, primary teeth have short, thin, curved roots, with softer, less dense root dentine and undetectable root resorptions, make them significantly different from the morphology of permanent teeth (Finn, 1973). Also, the utilization of rotary files in deciduous teeth have higher chances of breakage and separation within the canals (Nagaratna et al.2006), Govindaraju et al. (2017) provided evidence to support this, approximately 26% of practitioners admitted instrument breakage in the primary root canal.

Changes in the taper, length of the files and flexibility of the available rotary files had to be done so that they can reach the narrowest canals of primary teeth; these are the specifications that were considered before introducing rotary files for primary teeth in the market (Kuo et al.2006; Govindaraju et al 2017).

Taking these factors into consideration research was done to assess and compare instrumentation time and quality of obturation in paediatric patients using two recently introduced file system Kedo-SG Blue and Prime Pedo with conventional hand K file as control.

Many studies have been done comparing the Hand K files and rotary files separately but Kedo SG Blue and Prime Pedo files have never been compared together with Hand K files.

In our study, the mean instrumentation time for Group II (Kedo-SG Blue) was 195.1000 seconds and for group III (Prime Pedo) file was 200.8000 seconds which was considerably lower than the instrumentation time of Group I (Hand K file). The statistical difference of the instrumentation time between the hand file and rotary file was significant.

Our results were similar to other studies by Pinhero et al (2011) where they compared instrumentation time and clinical efficacy of rotary instruments with hand K files.

Katge et al (2019) also concluded that reciprocating (DXL pro files) and rotary (Prime Pedo) system shows lower instrumentation time as compared to hand H file.

Govindraju et al in 2017 also reported significantly lower instrumentation time in rotary files when K3 rotary file and hand K files were compared.

Instrumentation time for Kedo-S rotary file were also significantly lower when compared to instrumentation done by K and H files in deciduous teeth as concluded by Panchan V et al in 2019.

The reduced instrumentation time influences the behaviour of the child in the dental operator, therefore, reduces operator's fatigue and the treatment is delivered faster. (Musale et al 2013)

In our study, optimal fill was seen in 14 cases with hand K file, 20 cases with Prime Pedo and 22 cases with Kedo-SG Blue in both mesial and distal canal. Though, a difference is seen in optimal fill between hand and rotary files, but the difference was not statistically different.

Our study is not in coherence with other studies done by Priyadarshini et al (2020), Jeevanandan G et al (2018), Govindraju (2017) where radiographically measured quality of obturation was better where rotary instrumentation was done in primary teeth. This could be due to a bias introduced during working length determination and also because of differential morphology of the deciduous second molar.

In a study conducted by Jeevanandan G et al in 2018, it was found that the quality of obturation was better when biomechanical preparation was done with rotary Kedo-S files compared to hand K files.

Priyadarshini P et al (2020) in their study concluded that among the four file systems they used, Kedo-SG Blue gave the best result (80%) followed by Kedo-SH (46.7%), Kedo-S (40%) and hand K file (20%) in terms of quality of obturation.

However, a study done by Govindraju L et al in 2017 showed no statistical difference in the quality of obturation between manual and rotary instruments in the second molar.

## **VII. CONCLUSION**

The introduction of rotary instruments in dentistry has utterly modified the vision of biomechanical preparation. With the outstanding reduction in chairside time to the quality of obturation, rotary instruments have taken odontology to an interesting level. With the advancement of information and technology, varied new rotary file systems are being introduced that have higher scientific discipline and sturdiness.

Various studies are conducted concerning the employment of rotary files in milk teeth and compared how they dissent from the manual hand instruments in respect of instrumentation time and quality of obturation.

In our study, the rotary file systems Kedo-SG Blue and Prime Pedo have demonstrated shorter instrumentation times when compared to manual hand K files. However, in terms of quality of obturation all three file systems, hand K file, Kedo-SG Blue and Prime Pedo performed equally well. Hence, it can be concluded that pulpctomy for primary molars can be performed with great ease using these systems, which can help dentists and children feel less tired.

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