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Clinical evaluation of two pediatric rotary systems versus a conventional system for pulpectomy of primary mandibular molars: A single blind randomized clinical trial

Monika Redhu[1], Rashmi Dalal [2], Neetika [3], Shalini Garg[4], Ankit Srivastava [5], Anil Gupta [6]

[1]Ex-Postgraduate Student, Department of Pediatric and Preventive Dentistry,Faculty of Dental Sciences, Sgt University, Gurugram,Haryana, India

[2]Ex-Junior Resident, Department of Pediatric and Preventive Dentistry, Faculty of Dental Sciences, Sgt University, Gurugram, Haryana, India

[3]Ex-Postgraduate Student, Department of Pediatric and Preventive Dentistry, Faculty of Dental Sciences, Sgt University, Gurugram, Haryana, India

[4]Professor, Department of Pediatric and Preventive Dentistry, Faculty of Dental Sciences, Sgt University, Gurugram,Haryana, India

[5]Professor, Department of Pediatric and Preventive Dentistry, Faculty of Dental Sciences, Sgt University, Gurugram,Haryana, India

[6]Professor & Head, Department of Pediatric and Preventive Dentistry, Faculty of Dental Sciences, Sgt University, Gurugram,Haryana, India

***Corresponding author:**

Dr. Rashmi Dalal,

Email ID : rashmipedo30@gmail.com

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ABSTRACT

Objectives: The objective was to evaluate the efficacy of paediatric rotary system Kedo-S file and Neoendopedoflex file with conventional system in pulpectomy of primary mandibular molars in term of instrumentation time, procedural errors, obturation quality and post-operative pain.

Materials and method: 45 primary mandibular molars indicated for pulpectomy in 4-8 years old children were randomly assigned into three groups (n=15). Group I was instrumented using K-hand files, Group II with Kedo-S rotary file and Group III with Neoendopedoflex file. Standardized radiographs were taken before and after instrumentation. Root canal preparation time was recorded using stopwatch. Statistical analysis of the obtained data was done using SPSS Software version 20.

Results: Instrumentation time was significantly less with rotary system when compared to manual system (P=0.00). In term of procedural errors 30% cases of stripping and 10% cases of instrument fracture were observed in Kedo-S group. Higher number of over obturation were seen with Kedo-S file (30%) and under obturation was observed with K-file (18.2%) and 9.1% cases were observed in Neoendopedoflexgroup. Under-obturation was observed more in K -file than that of Neoendopedoflex file. Stripping was noticed in 30% cases and instrument fracture in 10% cases in Kedo-S group. However, no significant difference was observed among rotary system and conventional hand file system for procedural error and quality of obturation. Significant difference was noted among three groups with respect to post operative pain at 24 hours (P value=0.05).

Conclusion : The present study demonstrates that Neoendopedoflex rotary system performed overall better in term of procedural errors, quality of obturation and post-operative pain followed by Kedo-S file and manual K file.

Keywords: *Hand files, Ni-Ti files, Rotary files*

1. INTRODUCTION

Premature shedding of primary teeth has been a subject of significant concern over the years. Preservation of primary teeth till the eruption of permanent teeth is vital from both the functional and aesthetic aspects [1-3]. Functional restoration along

with the pain management is usually achieved through an endodontic treatment in such cases. It includes pulpotomy or pulpectomy depending upon the extent of tissue involvement or demineralization caused by the infection. Pulpotomy involves removal of coronal pulp and application of an appropriate medicament [4]. On the other hand, pulpectomy refers to the extirpation of pulpal tissue both coronal and radicular followed by debridement of infected dentin and preparation of canal space for obturation with suitable resorbable material [5,6].An ideal pulpectomy procedure for the primary teeth includes:Effective and thorough cleaning of the root canal with the specific solutions without additional weakening of the tooth structure or causing any damage to the underlying permanent tooth, minimum or no complications during the procedure, conserving and rehabilitating function of tooth, brief sitting and least number of appointments, fast and simple technique [7].

The success of the procedure is hugely dependent upon the patients'/ child's cooperation which is best achieved by shorter procedural time [8]. The duration of the treatment may be increased due to anatomical and physiological constraints of the tooth such as proximity to permanent tooth germ, irregular physiological root resorption and its tortuous canals [9]. Therefore, over the time, efforts are being made in making this procedure less time consuming and more efficient.

Regular rotary system has proven to be quite successful in permanent teeth. But it has certain constraints such as increased file length and taper when it comes to their use in children [10-15]. This leads to the introduction of rotary file system specific to paediatric dentistry with smaller length and altered taper to be used in children more effectively. The concept of single-file systems has been launched by Kedo-S file system and Neoendopedoflex file quite recently to allow instrumentation and preparation of root canal with only one file [16,17]. These systems forego the usage of multiple endo files thereby saving time and making the procedure more efficient.

However, both these systems are new and there is dearth of published literature evaluating the efficacy of Kedo-S and NeoendoPedoflex rotary system in the pulpectomy of primary molars. Hence, this clinical study was planned to know the efficiency of two pediatric rotary system (Kedo-S and NeoendoPedoflex) and manual system in pulpectomy cases of primary mandibular molars in terms of procedural time and errors, quality of obturation and post-operative pain.

2. MATERIALS AND METHODS

Study design and ethical consideration

This single blinded randomized clinical trial was carried out in the Department of Pediatric and Preventive Dentistry, Faculty of Dental Sciences, SGT University, Haryana, India following the ethical clearance from the Institutional Review Board (STP/SDMDS2015PED42) from August 2020-August-2021. The trial was registered under the Clinical trials registry (CTRI/2020/07/026859). An informed written consent was taken from the parents or the care-takers of the children who participated in the study. Benefits of the treatment along with possible complications and prognosis were explained prior to the clinical procedure.

Sample size estimation

The sample size was calculated using G Power analysis where power of study was kept as 0.80 and effect size was 0.80. The total sample size was estimated to be 45.

Randomization and allocation concealment

A total of 45 children from the age of 4-8 years and has indication for pulpectomy in primary mandibular molars were randomly selected through a lottery method. They were then allocated to one of the three groups through a computer-generated sequence and the treatment was carried out according to the group allocated i.e. Group 1: Manual K-files (n=15), Group 2: Kedo-S rotary file (n=15), Group 3: Neoendopedoflex file (n=15 per group). Children with Frankel [(+), (++)] behaviour requiring pulpectomy of primary restorable mandibular molars having minimum of 2/3rd of root remaining were included in the study. The exclusion criteria comprised of non restorable teeth or tooth with poor prognosis, perforation in pulpal floor, internal or external root resorption, excessive tooth mobility, teeth with sinus tract or abscess.

Clinical procedure

Complete procedure of pulpectomy was performed by the same single trained doctor. A complete examination of oral cavity was done along with the intra-oral periapical radiographs of teeth diagnosed with irreversible pulpitis. After selecting the tooth indicated for pulpectomy following procedure was performed:

The tooth was first anaesthetized using 2% lignocaine with 1:200000 adrenaline followed by rubber dam isolation. Initially with a round bur no.4 at slow speed all the carious part from the floor and lateral walls of cavity was removed before entering pulp chamber. Further, a spoon excavator was used for removal of coronal pulp. This was followed by use of explorer to locate the canals. Thereafter, a number 10 size K-file was used to access the root canal patency. No. 15 size K- file was used to record the working length. The root canal was then instrumented and shaped with No. 20 K-file. In each group after the use of each file, root canal was irrigated with 1% sodium hypochlorite followed by normal saline. EDTA gel (17%) was used intermittently to remove the smear layer.

Following this, root canal instrumentation was done differently in each group:

Group 1(Hand-file group): Mesial canal was instrumented till 30 number hand file and distal canal was prepared till file no.35 using a quarter turn pull technique.

In group 2 (Kedo-S group) the root canal was instrumented with Kedo-S pediatric rotary files. D1 rotary files was used for mesiobuccal and mesiolingual canals, E1 rotary file for distal canal using lateral brushing motion. Endomotor was used at 300 RPM and 2.2 Ncm torque.

In group 3 (NeoendoPedoflex group) root canal was instrumented with Neoendopedoflex file (Orikam Healthcare India Pvt Ltd) as per manufactures' recommendation. Pedoflex 20/4 rotary file was used for narrow root canal preparation, pedoflex 25/4 rotary file for medium root canal preparation canal and pedoflex 30/4 rotary file was used for wider root canal preparation.

Lastly, sterile paper points were used for drying the canals and then obturated using Endoflas (Sanlor Laboratories, Miami, Florida, U.S.A). Type II glass ionomer cement was then used to restore the access cavity. After that, immediate post-operative periapical radiograph was taken using standardize technique to assess the obturation quality. Patient was followed up after one week and was given a preformed metallic crown to achieve the coronal seal. The crown was luted with type I glass ionomer cement.

Evaluation of instrumentation time, obturation quality, procedural errors, and post-operative pain

The time taken during active instrumentation was recorded by assistant using stopwatch.Immediate post canal preparation periapical radiograph was taken using standardize technique and canal preparation evaluation was done for the procedural errors i.e.(a) ledge formation, (b) stripping (c) apical transportation (d) instrument separation. The obturation quality was assessed using the modified criteria laid down by Coll JA and Sadrian R (1996) under-filled (> 2mm short of apex), optimal (obturation ending at the radiographic apex or up to 2 mm short of apex) or over-filled (obturation outside the root). Post-operative pain was assessed using Modified Wong-Baker Pain Rating Scale given by Donna Wong and Connie Baker (1995). Since this scale is self-reported, it was explained to the children explicitly. They were then asked to point out the face that depict their pain level at 6, 12, 24, 48, 72 hours and 1 week. Outcomes were analyzed and evaluated by a pre calibrated examiner who was neither the part of the allocation procedure nor clinical treatment on the basis of defined criteria.

3. STATISTICAL ANALYSIS

Statistical analysis was carried out using SPSS Software version 20. Since the parameters recorded was a categorical data, it was presented in the form of proportion and chi square test was used for the test of significance. All the three groups were compared with each other and the statistical test were performed at 5% significance level.

4. RESULTS

In the current study, data collected from 32 participants were analyzed statistically. 13 patients from all the groups i.e. 4 patients in group 1 (Hand file group), 5 patients in group 2 (Kedo-S file group) and 4 patients in group 3 (Neoendopedoflex group) did not report after a week.There were total of 18 males and 14 females who were included in the analysis. The distribution of the participants is depicted in [Table1]. An intergroup comparison among three groups using chi-square test showed an equal distribution of participants in both the groups with respect to the age (P=0.16), gender (P=0.45), and distribution of the teeth (P=0.15) with no significant difference.

Table 1: Demographic details of the participants

	GROUP 1 (Hand file) N%	GROUP 2 (Kedo-S file) N%	GROUP 3 (Neoendopedoflex file) N%	P value
MEAN AGE (years)	6.0 + 1.3	7.0 + 1.0	6.0 + 1.3	0.16
GENDER N (%)				0.45
Male	7 (63.6)	4 (40.0)	7 (63.6)	
Female	4 (36.4)	6 (60.0)	4 (36.4)	
TOOTH INVOLVED				0.15
Mandibular left first molar	2 (18.2)	3 (30.0)	1 (9.1)	

Mandibular left second molar	5 (45.5)	2 (20.0)	4 (36.4)	
Mandibular right first molar	1 (9.1)	5 (50.0)	2 (18.2)	
Mandibular right second molar	3 (27.3)	-	4 (36.4)	

*P<0.05 statistically significant values.

An intergroup comparison between three groups using chi-square test was done with respect to instrumentation time, instrumentation error, quality of obturation & post operative pain. [Table 2]

Parameters recorded	**GROUP 1 (Hand file) N%**	**GROUP 2 (Kedo-S file) N%**	**GROUP 3 (Neoendopedoflex file) N%**	**P-value**
Instrumentation time (seconds)				
200-500	-	10 (100)	9 (81.8)	
501-800	10 (90.9)	-	2 (18.2)	0.00
801-1300	1 (9.1)	-	-	
Instrumentation errors				
Absent	11 (100)	7 (70)	11 (100)	0.10
Stripping	-	3 (30)	-	0.35
Instrument fracture	-	1 (10.0)	-	0.32
Quality of obturation				
Optimal	9 (81.8)	7 (70)	9 (81.8)	0.75
Underfill	2 (18.2)	-	1 (9.1)	0.75
Overfill	-	3 (30.0)	1 (9.1)	0.18
Pre-operative pain	9 (81.8)	8 (80.0)	7 (63.6)	0.67
Post-operative pain				
Persisted for 6 hours	7 (64)	4 (40)	5 (45.5)	0.90
Persisted for 12 hours	5 (45.4)	3 (30)	2 (18.1)	0.35
Persisted for 24 hours	4 (36.4)	1 (10)	-	0.05
Persisted for 48 hours	1 (9.1)	-	-	1.00
Persisted for 72 hours	1 (9.1)	-	-	1.00

*P<0.05 statistically significant values.

Table 2: Comparison of manual (K file), Kedo-S and Neoendopedoflex file systems

The instrumentation time recorded with rotary system was significantly less when compared to hand file (P=0.00). However, no such significant difference was observed among two rotary system.

With respect to obturation quality, under obturation was observed more in hand file group (2/11) 18.2 % cases> neoendopedoflex (1/11) 9.1% case while in Kedo-S file group over obturation was observed in (3/10) 30 % cases**. (Figure 1 a, b, c d, e, f)**

Stripping was observed in (3/10) 30% cases and instrument fracture in (1/10) 10% cases in Kedo-S file group. **(Figure 1 g)**

However no significant difference was noted among three groups with respect to quality of obturation and procedural errors.

A statistically significant difference was noted among three groups with respect to post operative pain at 24 hours (P value=0.05). At 24 hours interval in neoendopedoflex file group all patients became pain free followed by Kedo-S file group and K file group. Though there was no significant difference observed among three groups with respect to pre-operative and post-operative pain at 6,12,48,72 hours.

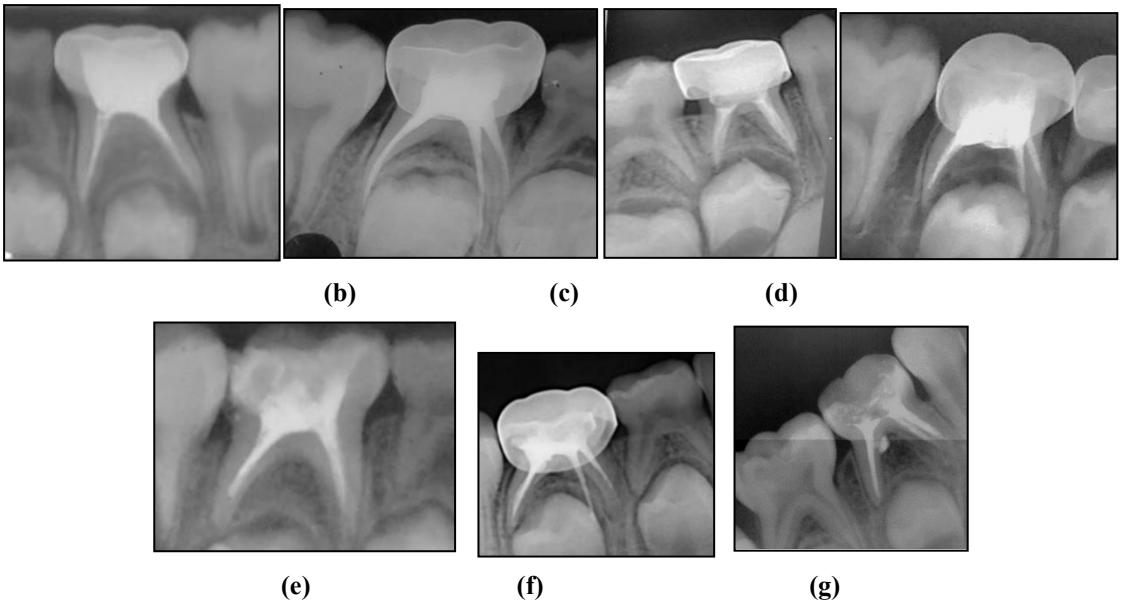

Figure 1: Showing different quality of obturation observed among three groups and procedural error (stripping) (a) Optimum obturation in group 1 (hand file), (b) optimum obturation in group 2 (Kedo-S file), (c) Optimum obturation in group 3 (Neoendopedoflex file),

(d) Under-obturation in group 1 (hand file), (e) Under-obturation in group 3 (Neoendopedoflex file), (f) Overobturation in group 2 (Kedo-S file), (g) Stripping in group 2 (Kedo-S file).

5. DISCUSSION

The success of endodontic treatment largely depends upon the chemico-mechanical preparation as it is essential for effective canal disinfection. It provides a patent route for the irrigants, medicaments and obturating paste to reach the apical third of root canal [2].

The standard method for this mechanical preparation as documented in the literature is the use of hand files. However, canal preparation through hand files is more tedious and can lead to iatrogenic errors such as zipping, ledging, canal transportation (due to stiffness of stainless-steel hand file and apical blockage). Over the time, with the advent of Ni-Ti rotary instruments and more exclusively pediatric rotary file, pulpectomy became a quicker, smooth efficient process thereby making it favourable to both patients and the clinicians [1, 2]

The present study compared the instrumentation time, procedural errors, quality of obturation and post-operative pain between manual and two rotary system (Kedo-S and Neoendopedoflex) in canal preparation of primary mandibular molars. The present study shows statistically significant decreased instrumentation time as compared to hand instrumentation (P=0.00). Less time was required to complete the procedure in Group 2 (Kedo-S rotary system), where 100% of the cases were finished within 3.33–8.33 minutes, compared to Group 3 (Neoendo Pedo Flex rotary system), where 81.8% of the cases were completed within 3.33–8.33 minutes and 18.2% within 8.35–13.3 minutes. There was a significant difference in the time of instrumentation with respect to hand files and rotary system, however, there was no statistically significant difference between Kedo-S and Neoendopedoflex group (p value=0.47). This finding is accordance to that reported by Jeevanandan et al. (2018) [5] and Panchalet al. (2019) [18]. Similar findings have been reported by other studies both in vitro and in vivo [4, 8, 16, 19-23].

The limitation of manual dexterity is usually curbed with the use of rotary instrumentation, thus increasing the operator's efficiency and reduced instrumentation time [2]. Another plausibility for the reduced instrumentation time could be because

of reduced working length of the exclusive pediatric file, which is about 12 mm. A decrease in the length of the rotary file allows easy insertion and removal of the file into the oral cavity of the children, making the treatment much easier and simpler [15].

Post-operative pain is another important factor for the assessment of outcome of pulpectomy procedure. In the present study, 24-hour post operatively, none of the patents reported any pain or discomfort in group 3 (Neoendopedoflex) while 1 and 4 patients complained of pain in group 2 (Kedo-S file) and group 1 (hand file) respectively. Statistically significant difference was observed with respect to pain at different interval among three groups (p value=<0.05). Similar outcomes were observed by Govindaraju et al. [8], Panchal et al. [19], Jeevanandan G et al. (2020) [24] and Priyadarshini et al. (2021) [25] i.e. pediatric rotary files Kedo-S showed significantly less post-operative pain as compared to K-file and H-file at different intervals. However, in contrary, S Divya, et al. [26] reported no significant difference in post-operative pain among rotary and manual instrumentation. Apical extrusion of debris and irritants are two important factors that can affect the post-operative discomfort. Manual hand instrumentation tends to push the debris apically as compared to rotary instrumentation which directs the debris coronally [9].

In the present study, (3/10) 30% cases of stripping and (1/10) 10% case of instrument fracture was observed in group 2 (Kedo-S). Although no cases of stripping and instrument fracture was observed in another two groups (hand file and Neoendopedoflex file). However, no statistically significant difference was observed among three groups in term of procedural errors. In this study, the cause of stripping may be attributed to the factor that Kedo-S file presented with variably variable taper (4-8%) results in excessive coronal dentin removal due to its increased core diameter in primary molars, as the primary tooth dentin is softer and less dense than that of permanent tooth, and the roots are thinner and more curved. The findings of present study are consistent with Haridoss Selvakumar et al. [27] who compared the stainless steel K file and K_3 rotary instrumentation (0.2% and 0.4% taper) in primary teeth in term of lateral perforation. K_3 rotary files.04 tapers produced more perforation compared to the other two groups.However, this result is in contradiction to the study reported by Seema Thakur et al. [21] who observed that Kedo-S removed significantly less amount of dentin as compared to the H and K file on the mesial side and on the distal side all the three file systems performed almost similarly.

The quality of obturation is another key factor that affects the success of endodontic treatment [20]. According to the findings of current study, higher cases of over obturation were observed with Kedo-S file and more cases of under obturation were seen with K-file. Similarly, Lavanya Govindaraju et al [8] compared pediatric rotary file Kedo-S with hand K files and ProTaper rotary files and concluded that there was no significant difference present in the obturation quality with the exclusive pediatric rotary file when compared with the other two groups. Veerale Panchal et.al. [18] and S Divya et al. [26] on contrary reported superior obturation quality in the rotary group (Kedo-S) as compared to manual group.

In the present study, inadequate obturation in hand group might be because stainless steel hand files are less elastic causing difficulty in reaching the desired working length. Hand instrumentation might also contribute to apical blockage due to debris accumulation. Over-obturation in treatment with rotary system can occur if there is no good control of working length (loss of tactile sense), leading to over-obturation. Another factor for over-obturation in rotary group might be loss of apical stop with repeatedly use of rotary file until it becomes loose in the canal [28].

6. CONCLUSION

In this study, Neoendopedoflex rotary system performed overall better in term of procedural errors, quality of obturation and post-operative pain followed by Kedo-S file and manual hand file. Neoendopedoflex rotary files should be preferred over existing Kedo-S and permanent rotary file system. More studies with large sample size are required to assess the efficacy of both pediatric rotary files.

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