

Evaluation and Comparison of Effectiveness of Kedo-S Pediatric Rotary Files vs Manual Instrumentation for Root Canal Treatment in Primary Molars

Tanu Rajain¹, Kesang Tsomu², Ritu Namdev³

ABSTRACT

Purpose: To evaluate and compare the clinical and radiographic success of Kedo-S pediatric rotary files vs manual K-Files for pulpectomy in primary mandibular molars.

Materials and methods: A sample of 30 primary mandibular molars with irreversible pulpitis was taken per group. The groups were divided as below mentioned—group I ($n = 30$) was treated using the Kedo-S file system. Group II ($n = 30$)—treated using manual stainless steel K-File. The clinical and radiographic success was compared of both techniques. Statistical analysis involved *t*-test, Chi-squared test, and Cochran's Q test.

Results: The overall clinical success at 3, 6, and 9 months in group I were 72.4, 89.7, and 93%, respectively and in group II were 82.1, 92.9, and 92.9%, respectively. The overall radiographic success in group I at 3, 6, and 9 months were 6.9, 17.2, and 69%, respectively and in group II were 0, 7.1, and 35.7%, respectively. According to the Frankl behavior rating scale, 19 children in group I (65.5%) showed negative behavior, and 15 children in group II (53.57%) showed positive behavior. The mean instrumentation time in group I (Kedo-S pediatric rotary file group) and group II (hand K-File group) was 8.03 ± 0.823 and 11.25 ± 0.928 , respectively.

Conclusion: There was a statistically significant/highly significant difference in intergroup comparison postoperative behavior among the children in the two study groups. There was a statistically significant difference between the two study groups with relation to instrumentation time. The trend that was observed in the clinical and radiographic profile was that group I (Kedo-S rotary files) cases had more success when absolute numbers and figures were compared than group II (hand stainless steel K-File) in which success rates were comparable; however, the difference between the groups were found to be statistically nonsignificant.

Keywords: K-files, Kedo-s files, Primary molars, Pulpectomy.

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INTRODUCTION

As an integral part of our dental arch, primary teeth maintain space by guiding the eruption of permanent teeth to their ideal position in the dental arch. It is extremely important to retain and preserve the primary teeth in their ideal position and free from pathology.¹ In pediatric dentistry, the most significant concern is necrotic primary molar loss causing space loss and a change in the eruption sequence of permanent teeth.² The preservation of arch integrity, mastication, phonation, esthetics, and prevention of harmful habits in youngsters are all benefits of keeping primary teeth until physiological exfoliation.² Pulpotomies are recommended for deciduous teeth with caries pulp exposure if, after removal of coronal pulp, the radicular pulp shows clinical signs of hyperemia or evidence of radicular pulp necrosis with or without caries involvement, according to the American Academy of Pediatric Dentistry.³ Deciduous teeth's root canals can be disinfected using root canal instrumentation either manually or with a rotary system with nickel–titanium (NiTi) files (Barr et al.).

Traditionally, stainless steel files have been used for cleaning and shaping the primary tooth root canal.⁴ When compared to rotary systems, which efficiently provide smooth, predefined conical shapes with the least amount of risk, manual preparation techniques cause iatrogenic errors, such as ledging, zipping, canal transportation, and apical blockage (Kandaswamy et al.).⁵ Barr et al. were the first to review the use of NiTi rotary files for root canal instrumentation in primary teeth and considered this technique to

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be more effective to debride the uneven walls of primary.^{4,21} The advent of the Kedo-S file system, a specialized pediatric rotary system, represents an advancement in the area of pediatric dentistry endodontics (Reeganz Dental Care Private Limited, India). D1, E1, and U1 files constitute the single file system known as the Kedo-S rotary file.⁶ The study's purpose is to evaluate and assess the clinical and radiological performance of manual K-Files and Kedo-S pediatric rotary files for pulpectomy in primary mandibular molars.⁶

MATERIALS AND METHODS

Study Setting and Study Design

The present study was conducted in the Department of Pedodontics and Preventive Dentistry, PGIDS, Rohtak, Haryana, India. All of the parents or guardians of the study participants provided their voluntarily given informed consent. Ethical clearance was taken from Institutional Ethical Committee for Human Research prior to the commencement of research. It was a randomized and follow-up study. Patients were reviewed periodically and clinical and radiographic evaluations of all the subjects were done at 3rd, 6th, and 9th month, respectively (Figs 1 and 2).

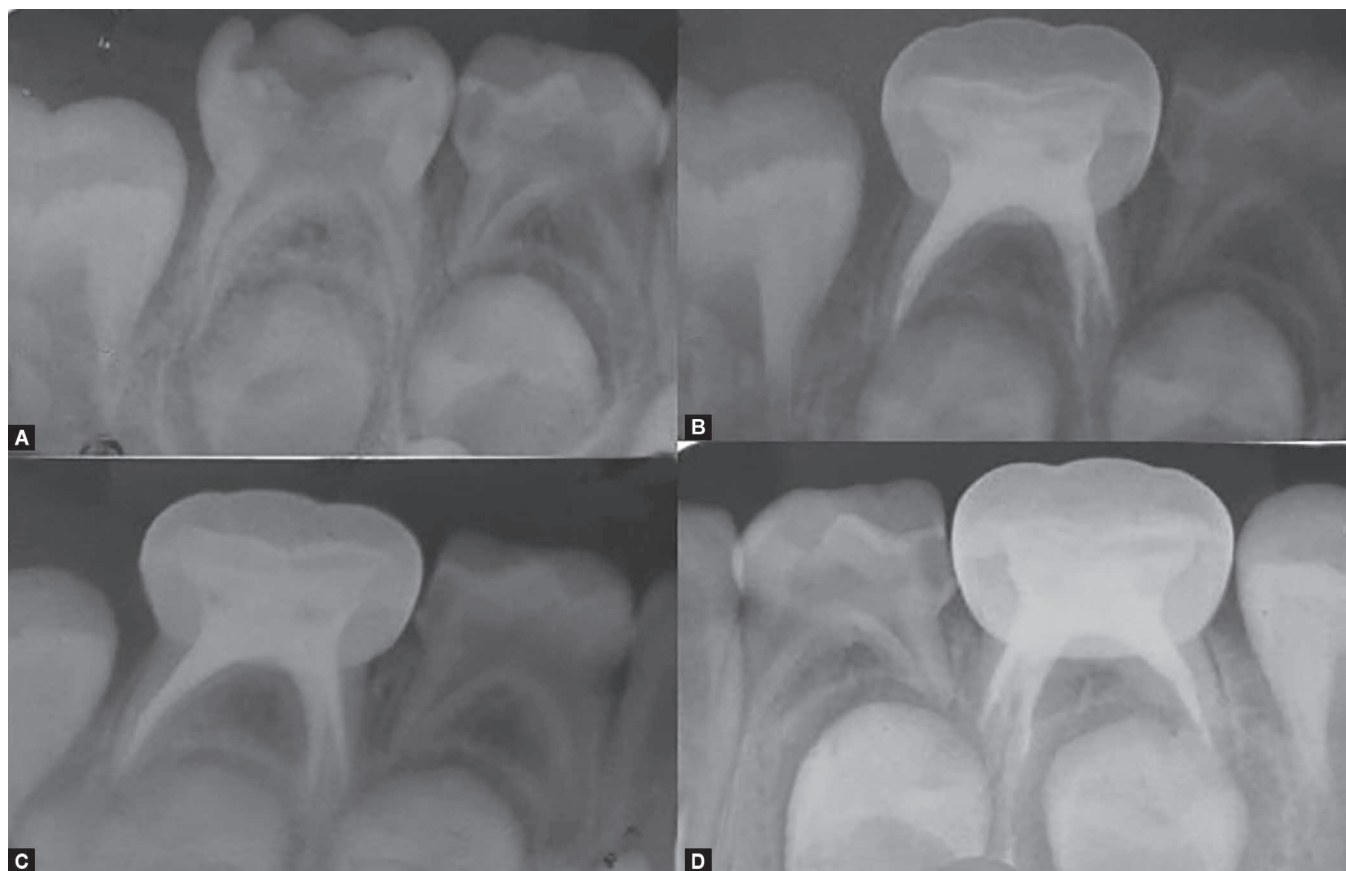
Computing the Sample Size and Choosing the Study Participants

In order to account for 10% attrition, the sample size of 20 was determined with 90% power to detect a mean difference of 9.5 with a variance of 12.71. The final sample of 30 was taken per group. The randomization was done using computer-generated randomization table. Concealed allocated sealed opaque envelopes were prepared. The groups were divided as below mentioned—group I ($n = 30$) was treated using the Kedo-S file system. Group II ($n = 30$)—treated using manual stainless steel K-file. Children aged 4–7 years with irreversible pulpitis relating to primary mandibular molars were recruited from the outpatient Department of Pedodontics and Preventive dentistry. Inclusion criteria—(1) primary molars with irreversible pulpitis [pain/tenderness on percussion (TOP)]; (2) minimum two-thirds of root length remaining; (3) teeth must be restorable; (4) and teeth with the presence of furcation radiolucency. Exclusion criteria—

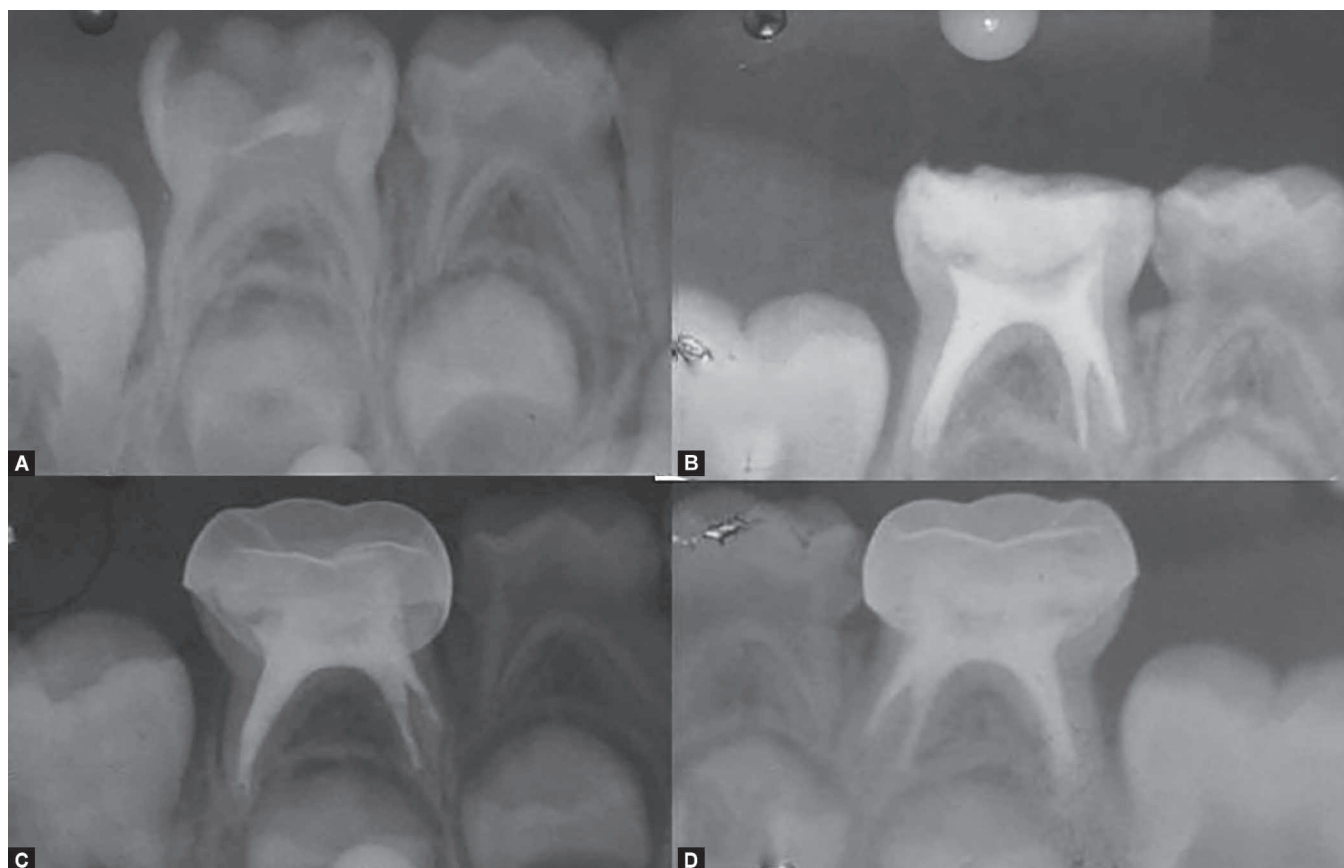
(1) pulpal floor perforation; (2) excessive tooth mobility or tooth near exfoliation stage; (3) teeth with internal or external resorption; (4) excessive root resorption involving more than half of root length; (5) and children with medical condition making them unfit for the endodontic procedure. Randomization was done using the lottery method. One patient from group I and two patients from group II were lost on follow-up. The clinical success criteria included absence of pain/TOP, absence of swelling and radiographic success criteria included absence of furcation radiolucency, quality of obturation and absence of pathologic root resorption.

Clinical Procedure

For the tooth that needed a pulpectomy, local anesthesia was provided using lignocaine hydrochloride and 1:80,000 epinephrine, and rubber dam isolation was used. Caries was excavated using a spoon excavator and a large round bur at a slow speed. Endodontic access was made with a sterile high-speed carbide bur. Barbed broaches were used to remove necrotic pulp. The canals were found using the DG16 instrument. The next step was to obtain the root canal patency using a K-File of size 10. With an intraoral periapical radiograph, the length of each canal was measured using a number 15 stainless steel K-File. Working length terminated 1 mm short of radiographic apex to minimize the chance of overinstrumentation apically and causing periapical damage. The biomechanical preparation of root canals was performed by using two different instrumentation techniques as follows—root canals in group I were prepared using Kedo-S pediatric rotary files with endomotors. Kedo-S pediatric rotary files were used to prepare the root canals. Using lateral brushing motions, D1 rotary



Figs 1A to D: GROUP I: Kedo-S Files. (A) Preoperative IOPA; (B) 3 months follow-up; (C) 6 months follow-up; (D) 9 months follow-up



Figs 2A to D: GROUP II: Hand K-Files. (A) Preoperative IOPA; (B) 3 months; (C) 6 months follow-up; (D) 9 months follow-up

files were used to prepare the mesiobuccal and mesiolingual canals, and E1 rotary files were used to prepare the distal canal. An endodontic motor was used with the rotary files. In order to achieve uniformity during canal preparation and in accordance with the manufacturer's instructions, each file was used for up to five teeth. Group II's root canals required hand preparation with stainless steel K-Files. K-files ranging in size from 15 to 35 were used to prepare the root canals. Using a quarter-turn-pull technique, the mesial canals were prepared with K-Files up to size 30 and the distal canals with K-Files up to size 35. Up to five teeth were filed with each K-file in order to keep the canal preparation uniform. To eliminate debris, root canals were thoroughly irrigated with 5% sodium hypochlorite and saline. In both groups, the instrumentation time was accurately recorded using a stopwatch. During the preparation of the canal, a lubricating paste made of 17% ethylenediaminetetraacetic acid gel was employed. Using paper points of the proper size, the canals were dried. Calcium hydroxide paste was then used as an intracanal medicament, if necessary. Root canals were then filled with calcium hydroxide with iodoform (Metapex), available as preformed syringes. Excess coronal filling material was removed and the access cavity was filled using restorative glass ionomer cement. Finally, a preformed stainless steel crown was adapted and cemented using luting type glass ionomer cement.

Procedure for Taking Intraoral Periapical Radiograph (IOPA) X-ray

The long cone paralleling technique was used to take the periapical radiograph using radiographic film holders (Rinn XCP) utilizing a

customized putty jig in order to standardize the projection and film positioning for radiographs to be taken at subsequent follow-up visits. The patient was erect in his or her seat. Using the putty index, the IOPA film was properly positioned in the patient's mouth after being put in the film holder. IOPA radiographs were taken once the X-ray tube head was positioned against the film holder's localizing ring⁷ (Figs 3 and 4).

RESULTS

The study's participants had a mean age of 5.77 ± 0.78 years, consisting of a total of 25 girls and 35 boys (Table 1). The average instrumentation time was 8.03 ± 0.823 and 11.25 ± 0.928 , respectively, in groups I (Kedo-S pediatric rotary file group) and II (Table 2). There was a statistically significant difference between the two study groups with relation to instrumentation time (Fig. 4). The overall clinical success at 3, 6, and 9 months in group I were 72.4, 89.7, and 93%, respectively and in group II were 82.1, 92.9, and 92.9%, respectively (Table 3). The overall radiographic success in group I at 3, 6, and 9 months were 6.9, 17.2, and 69%, respectively and in group II were 0, 7.1, and 35.7%, respectively (Table 4). When assessing absolute numbers and figures, it was found that group I (Kedo-S rotary files) cases had a higher success rate in the clinical and radiological profiles than group II (hand stainless steel K-File) in which success rates were comparable; however, the difference between the groups were found to be statistically nonsignificant (Figs 5 and 6). According to the Frankl behavior rating scale, 19 children in group I (65.5%) showed negative behavior and 15 children in group II (53.57%) showed positive behavior (Table 5). There was a statistically significant/highly significant



Fig. 3: Patient with the putty jig

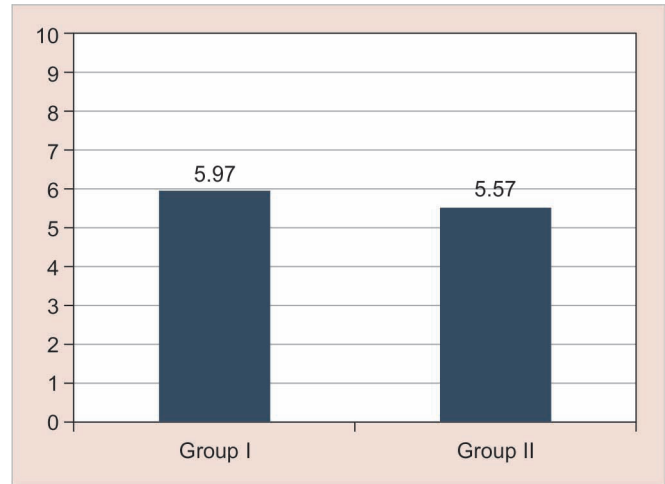


Fig. 5: Graph showing intergroup comparison of the mean age of the subjects



Fig. 4: Putty jig index

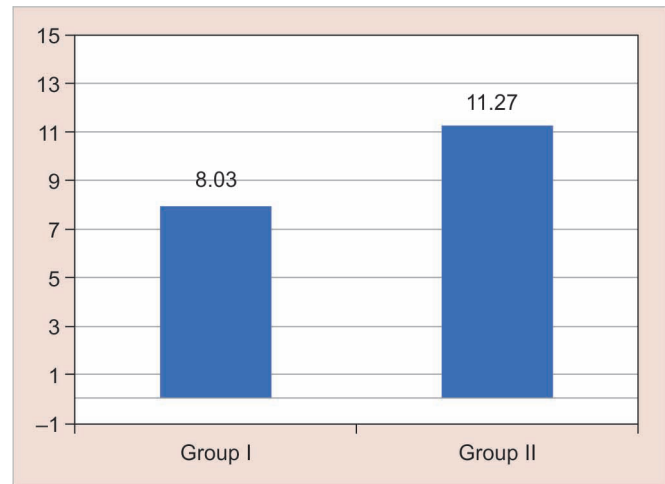


Fig. 6: Graph showing intergroup comparison of instrumentation time (in minutes)

Table 1: Intergroup comparison of mean age of subjects

	Group	N	Mean	Standard deviation	Standard error mean	t-value	p-value of t-test
Age in years	I	30	5.97	0.718	0.131	2.014	0.049*
	II	30	5.57	0.817	0.149		

Table 2: Intergroup comparison of instrumentation time in minutes

	Groups	N	Mean	Standard deviation	p-value of t-test
Instrumentation time (minutes)	I	29	8.03	0.823	0.000**
	II	28	11.27	0.928	

Table 3: Overall clinical success of root canal treatment

Group	3 months	6 months	9 months
Group I	72.4%	89.7%	93.1%
Group II	82.1%	92.9%	92.9%

Table 4: Overall radiographic success of root canal treatment

Group	3 months	6 months	9 months
Group I	6.9%	17.2%	69%
Group II	0%	7.1%	35.7%

difference in intergroup comparison postoperative behavior among the children in the two study groups (Fig. 7). Primary molars with short fill, complete fill, and long fill obturation in group I were 24.13, 68.96, and 6.89%, respectively and in group II were 39.28, 53.57, and 14.28%, respectively (Table 6). There was a statistically nonsignificant difference seen for the frequencies of quality of obturation between the groups (Figs 8 to 10 and Flowchart 1).

DISCUSSION

When the pulp tissue becomes irreversibly diseased and necrotic owing to caries or trauma, pulpectomy is the root canal treatment used (Guideline on Pulp Therapy for Primary and Immature Permanent Teeth 2016).⁸ The primary teeth's biomechanical preparation is a crucial step in an effective endodontic procedure. To clean the root canal of necrotic tissue, debris, dentin filler, and germs, adequate biomechanical preparation and irrigation are required.⁹

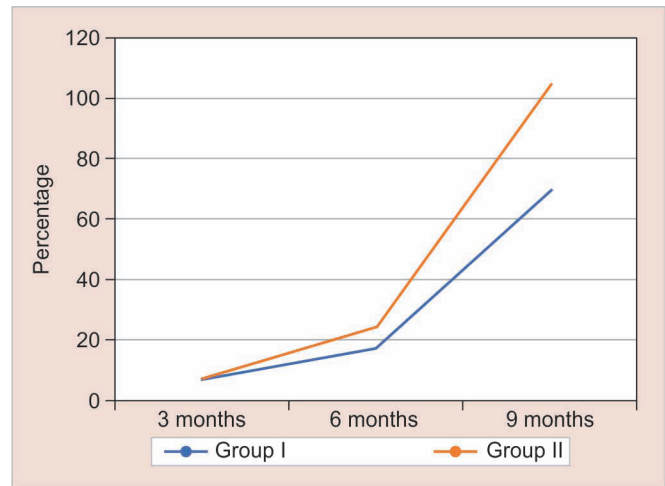


Fig. 8: Graph showing overall radiographic success of root canal treatment

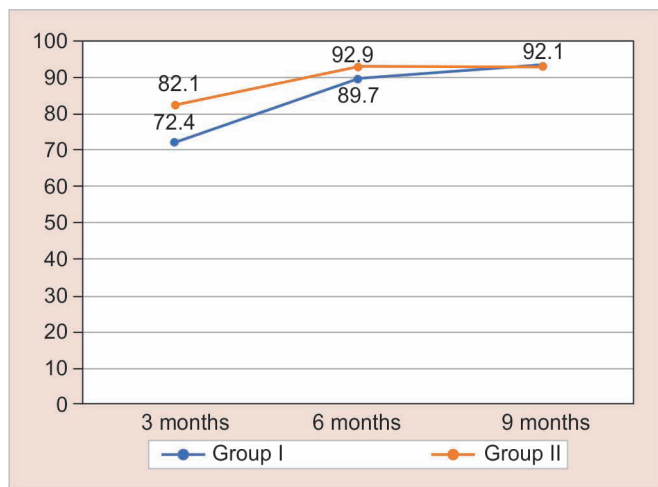


Fig. 7: Graph showing overall clinical success of root canal treatment

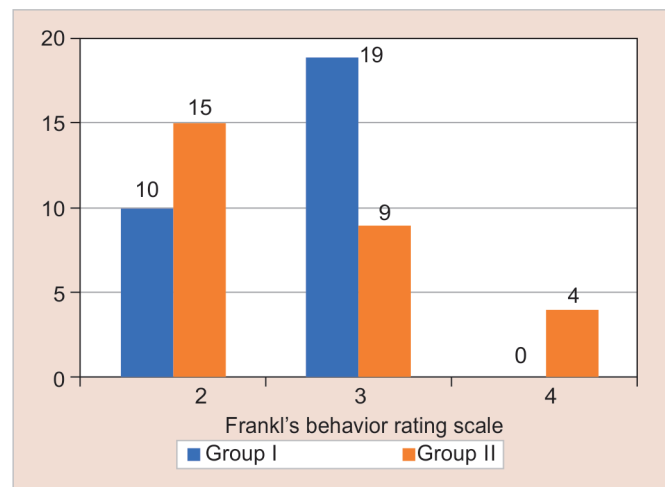


Fig. 9: Graph showing intergroup comparison of rating of Frankl's behavior rating scale

Table 5: Intergroup comparison of rating of Frankl's behavior rating scale

Frankl's behavior rating scale	Group			p-value of Chi-squared test
	I	II	Total	
2	10	15	25	0.014*
3	19	9	28	
4	0	4	4	
Total	29	28	57	

Table 6: Intergroup comparison of the frequency of quality of obturation

Quality of obturation	Group			p-value of Chi-squared test
	I	II	Total	
1. Short fill	7	11	18	0.452
2. Complete fill	20	15	35	
3. Long fill	2	2	4	
Total	29	28	57	

Files, reamers, burs, acoustic devices, mechanical tools, and NiTi rotary file systems are used for root canal preparation.¹⁰ According to the European Society of Endodontology in 1994, the purpose of root canal instrumentation is to produce a tapered shape with enough capacity to provide efficient irrigation and obturation.¹¹

The Kedo-S file system, a unique pediatric rotary system, is a development in pediatric dentistry endodontics (Reeganz Dental Care Private Limited, India). D1, E1, and U1 files make up

the single file system known as the Kedo-S rotary file. These files have a 16 mm overall length and a 12 mm working area (cutting flutes). These files are distinctive due to their unique tip diameters (D1—0.25, E1—0.30, and U1—0.40) and varying taper (4–8%), which correspond to their use on deciduous teeth. The distal and palatal canals of primary molar teeth, which are wider canals, are instrumented using a Kedo-S D1 file, whereas the mesiobuccal and mesiolingual canals are prepared using a Kedo-S E1 file. Endodontic motors with clockwise rotation at 300 RPM and 2.2 Ncm torque are advised for use with Kedo-S rotary files. Primary teeth canals are thoroughly lubricated and irrigated. Kedo-S rotary files should only be used 1–2 times along the working length and never >3–4 times in order to prevent instrument deformation and separation.⁶

In the present study, the subjects were periodically reviewed during the course of the study. Clinical and radiographic findings were recorded at 3, 6, and 9-month intervals. A period of 3 months was kept between recall visits with rationale that if there was healing of the periapical lesion, it would take minimum of 3 months to achieve the bone density to become appreciable radiographically. In the literature also, Nadkarni and Dame¹² also followed their sample every 3 months for 9 months. Nurko and Garcia-Godoy¹³ in their study, followed up the cases every 3 months; similarly, Mortazavi et al.,¹⁴ in their study with a follow-up of 10–16 months, did a periodic follow-up every 3 months.

In the Kedo-S pediatric rotary file group (group I), out of 29 primary molars available for evaluation, 100% reported preoperative pain and 68.96% reported preoperative abscess and swelling. Furcation radiolucency was present in the 100% sample

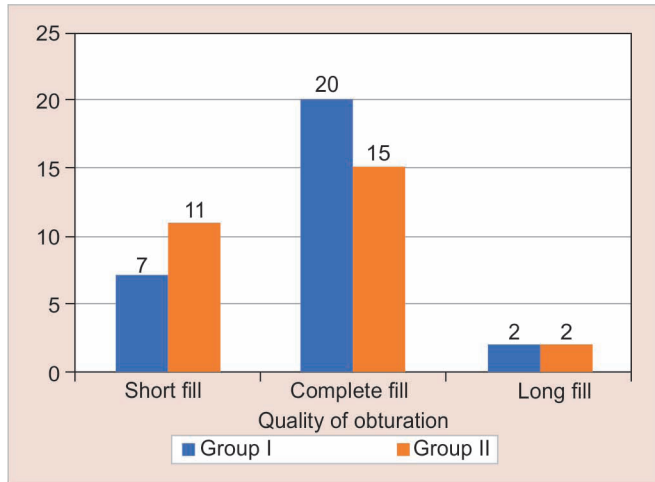
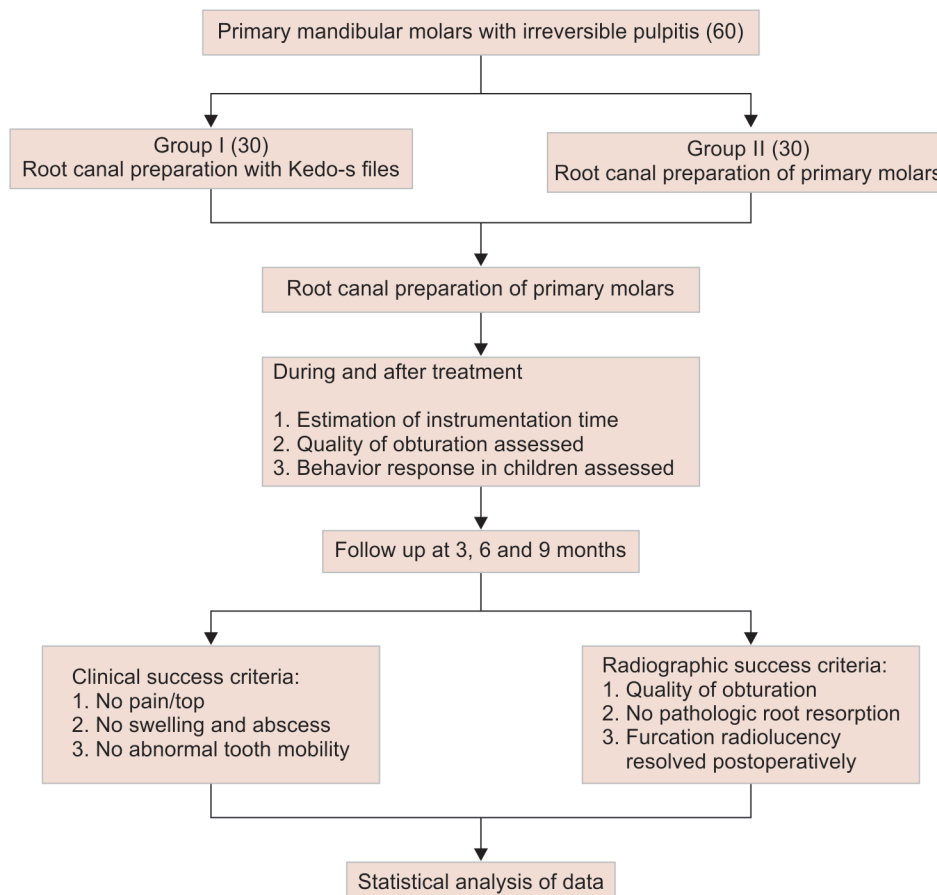


Fig. 10: Graph showing intergroup comparison of the frequency of quality of obturation

Flowchart 1: Flow diagram of study in methodology



and pathological root resorption was present in the 6.89% sample. After treatment, clinical signs and symptoms improved significantly, as evident in postoperative results. In hand K-files (group II), out of 28 primary molars available for evaluation, 100% reported preoperative pain and 64.28% showed the presence of swelling and abscess. However, Chawla et al.¹⁵ reported preoperative history of pain in about 88% of the cases.

When absolute numbers and statistics were analyzed, it was found that group I (Kedo-S rotary files) cases had a higher success rate than group II (hand stainless steel K-File) cases in the clinical and radiological profiles in which success rates were comparable; however, the difference between the groups were found to be statistically nonsignificant. These follow-up findings were in close agreement with those reported by Thomas et al.,¹⁶ Reddy and Fernandes,¹⁷ Chawla et al.,¹⁵ and Chawla et al.¹⁸ that there was statistically no significant difference in the presence of pain or tenderness on percussion, abscess, and swelling for pulpectomy procedures in primary teeth when manual stainless steel files were compared with rotary files for instrumentation of root canals, at various follow-up evaluation. However, the radiographic success rate in both groups was not in pace with the clinical success rate. Radiographic failure in some of the samples in both groups could possibly be a result of the inflammatory response of residual pulp. These findings support those of Guler et al.¹⁹ and Morankar et al.,²⁰ who compared and contrasted manual and rotary root canal instrumentation techniques during pulpectomy procedures in primary molars and discovered a statistically significant difference in radiographic success between the two instrumentation techniques in their 12-month follow-up study. To determine the effectiveness of the rotary NiTi file system in deciduous molars, further clinical and radiographic studies with extended follow-up, preferably until the period of tooth exfoliation, are advised.

The postoperative behavior of the children in the two study groups was observed and documented using the Frankl behavior rating scale in order to measure the patient's acceptability during the instrumentation technique. Using Frankl's scale for rating behavior, 19 children in group I (65.5%) showed negative behavior and 15 children in group II (53.57%) showed positive behavior. There was a statistically significant/highly significant difference in intergroup comparison postoperative behavior among the children in the two study groups. The high percentage of such positive behavior in group I can be attributed to the higher mean age of the children included in the present study in group I (5.97) than in group II (5.57).

The mean instrumentation time in groups I and II were 8.03 ± 0.823 and 11.25 ± 0.928 , respectively. Regarding instrumentation time, there was a statistically significant difference between the two study groups. This study's results were in line with those from Barr et al.,²¹ Silva et al.,²² Nagaratna et al.,²³ Bahrololoomi et al.,²⁴ Crespo et al.,²⁵ Kummer et al.,³ Ochoa-Romero et al.,²⁶ and Makarem et al.⁴ who also reported a statistically significant difference in mean instrumentation time with rotary technique requiring less time than manual technique. The results of other research were consistent with the present investigation's considerable reduction in instrumentation time for canal preparation in primary teeth employing the rotational method of root canal instrumentation. This decrease in pediatric patient instrumentation time enables quick, secure, and effective treatments, decreasing patient and professional tiredness. In contrast to this finding, Madan et al.²⁷ showed that using rotational profiles as opposed to manual K-Files lengthened the instrumentation process. This might be explained by the operator's expertise and how frequently instruments need to be changed.

An independent evaluator evaluated the two study groups' obturation quality using the postobturation radiographs. The obturation's quality was assessed using the following standards established by Coll and Sadrian²⁸ all of the canals that had filling that was 1 mm or less short of the apex are considered a short fill. Complete fill [zinc oxide eugenol (ZOE) finishing at the radiographic apex] refers to one or more of the canals. Any molar canal with ZOE outside the root is considered long filled. The method of obturation, as well as obturating material, was the same in both groups; the only difference was the method of preparation of the root canal. In an *in vitro* study, Nagaratna et al.²³ discovered that rotary NiTi files produced canals with good canal taper and smoothness compared to manual stainless steel K-Files. In their study, Barr et al. discovered that the use of rotary instrumentation was a successful method for debriiding the irregular walls of primary teeth. This technique also made it simpler to introduce obturation paste and resulted in less overobturation. Ochoa-Romero et al.,²⁶ in 2011 reported that the rotary technique resulted in 80% optimal tooth filling, 10% underfilling, and 10% overfilling, compared to 50% optimal tooth filling, 40% underfilling, and 10% overfilling with the manual technique, this difference was statistically significant. Makarem et al.,⁴ in 2014 in his study found that the obturation quality of root canals was significantly better with rotary instrumentation when compared with the manual. The results of the current investigation do not correspond with these conclusions. Regarding the quality of obturation, there was no statistically significant difference between the two study groups in the current study.

CONCLUSION

The Kedo-S pediatric rotary files show significantly lesser instrumentation time and better overall clinical and radiographic success than K-Files. To shed light on the long-term consequences and advantages of this method, comprehensive studies, including clinical and radiographic evaluation and prolonged follow-up, preferably until the period of tooth exfoliation, are required.

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