ASDJ
AINSHAMS DENTAL JOURNAL

Print ISSN 1110-7642
Online ISSN 2735-5039

AIN SHAMS DENTAL JOURNAL
Official Publication of Ain Shams Dental School
June 2025 • Vol. 38

Comparative Evaluation of Two Different Pediatric Rotary File Systems and Manual K-file in Root Canal Treatment of Primary Teeth (RCT)

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Aim: To evaluate the clinical efficacy of pediatric rotary files and compare it to manual K-files.
Materials and Methods: Thirty-six second primary molars in 26 children aged 4-7 years were allocated into three groups according to the instrumentation system received as follows (n=12 teeth / group): Group 1, Kedo-S plus file, Group 2, Kidzo file and Group 3, manual K-file. Each molar underwent a single-visit pulpectomy; instrumentation time was documented, and the quality of the obturation was evaluated using immediate postoperative periapical radiographs. After that, the results were statistically assessed.
Results: Kedo-S plus (Group 1) file required the least instrumentation time followed by Kidzo files (Group 2) and K-files (Group 3) subsequently and the difference was statistically significant ($p<0.001$). Optimum quality of obturation was achieved using Kedo-S plus file (Group 1) followed by Manual K-files (Group 3) and Kidzo files (Group 2) subsequently and the difference was not statistically significant ($p=0.665$).
Conclusion: The rotary file Kedo-S plus had the fastest time of instrumentation and improved obturation quality.

Keywords: Rotary files, Manual files, Primary molars, Pulp therapy

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Introduction

Primary teeth maintenance in the dental arch has always been a prime concern in pediatric dentistry as they serve well as a natural space maintainer and prevent many further occlusion problems later on. For primary teeth with irreversible pulpitis or even a necrotic pulp, pediatric dentists choose to use pulpectomy as the preferred course of treatment in order to save these teeth that may have been subjected to various insults from chronic decay.[1] The main objective of pulpectomy is the efficient elimination of microorganisms and bacteria that are present along the pulp canals.[2] The instrumentation of the pulp canals adjunct with irrigants and perhaps other medicaments is mandatory to reach a sufficient level of cleaning these infected canals. [2]

Yet, in pediatric patients and especially in primary molar teeth, the cleaning process is not that subtle owing to various factors among which are the: extreme divergence of the roots, presence of accessory canals, lateral ramifications. In addition, the child tolerance, co-operation and limited mouth opening are factors that cannot be underweighted.[3] To overcome these challenges rotary instrumentation systems were suggested.

The first reports of rotary instruments date back to 2000. They are said to be able to supply canals with a conical shape. However, the shorter preparing time for the canal makes it more suitable for usage with younger patients. [4,5,6] Although these rotational devices were intended for permanent teeth, they have also been studied for primary tooth root canal preparation.[5,6,7] Unfortunately, using the current rotary systems in primary teeth was still hindered by the taper and length of such files.

There are currently pediatric rotary files made especially for use with primary teeth. However, the therapeutic effectiveness of these pediatric rotary files in pulpectomized primary teeth is not well documented in the literature. A randomized clinical experiment was designed to evaluate and compare the instrumentation time and obturation quality of two pediatric rotary devices with manual K-files in primary molars.

The null hypothesis was that there is no difference in clinical success, instrumentation time ,quality of obturation and apical debris extrusion between the two different pediatric rotary systems and manual K-file system in pulpectomy in primary molars

Materials and Methods

This randomized clinical trial investigation was carried out by the outpatient clinic of the Department of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Ain Shams University, following CONSORT criteria. Twenty-six children were selected as a convenient sample based on the eligibility criteria.

Inclusion and exclusion criteria

The children who were chosen were between the ages of 4 and 7 years old, medically free, and had primary mandibular second molars that had irreversible pulpitis or necrotic pulp that required pulpectomy. At least two thirds of the root structure being present. Sufficient tooth structure to allow for the subsequent implantation of stainless-steel crowns. Children have to be completely able to see and comprehend the explained assent. A child who was recalcitrant or primary second molars with an abscess, movement, sinus, or severe bone resorption with a poor prognosis were disposed of.

Sample size calculation

A power analysis was designed to have adequate power to apply a statistical test of the null hypothesis that there will be no difference between different tested groups.

By adopting an alpha and beta levels of (0.05) i.e. power=95% and an effect size (f) of (0.760) calculated based on the results of Priyadarshini P, et al.[9] the predicted sample size (n) was found to be (30) teeth (i.e. 10 teeth per group). Sample size calculation was performed using G*Power version 3.1.9.7. [10] The sample size was increased by about 10% to compensate for the drop out. Final sample size was (36) teeth (i.e 12 teeth per group).

Ethical considerations

The study-received approval by the Research Ethics Committee of the Faculty of Dentistry, Ain Shams University in Cairo, Egypt, under the FDASU-Rec approval number ID032104. NCT05234918 is the registration number for the trial on clinicaltrial.gov's PRS (Protocol Registration and Result System).

Methods

An independent researcher not associated with the study randomly divided 36 primary second molars into three groups using sealed envelopes. After the trial supervisor determined the working length, the participants were placed into the appropriate study group using serial-numbered concealed envelopes that were opened.

Group1: Kedo-S plus file study group
Group2: Kidzo file study group
Group3: Manual K-file control group

Blinding

The trial was double blinded, in which outcome assessor and data statistician were blinded. Blinding was not possible neither for participant nor for main investigator due to nature of the study.

The following steps were done for all participants

After administering local anesthesia, Rubber dams were used to isolate the teeth. A single operator for consistency purposes carried out Pulpectomy for all cases in a single visit per tooth. Caries was completely removed using a round diamond bur, access cavity was completed using tapered diamond bur making a clear access to the root canal orifices. Coronal pulp tissue was removed using a sharp excavator. All of the canals were located using a double-ended endodontic explorer. Prior to instrumentation, the pulp chamber was irrigated with 3 ml saline using sterile, disposable plastic syringes, and the type of file system was used.

Using the apex locator, the working length was determined to be one mm less than the '0.0' mark. The manufacturer's instructions state that using manual stainless steel file K file #10 produced a smooth glide path.

Group 1: Preparing the root canal was completed using rotary Kedo-S plus file (single file system) #30 variable taper, which was mounted on wireless endomotor "Estus Drive with RT head" (Geosoft Dent, Moscow, Russia) and speed and torque were adjusted according manufacturer instructions, file was then lubricated with EDTA gel "17%" and inserted into the canal to complete the crown down technique and brushing motion preparation. Each canal was irrigated with 3 ml chlorohexidine before the next file, and the canal patency was verified with a #10 K-file. Following the final file, each canal received another 3 ml chlorohexidine irrigation.

Group 2: Root canal instrumentation was done using Kidzo rotary files, after using #15 K−file. The files sizes #25/4%, #30/4%, #30/6% were mounted on wireless endomotor, speed and torque were adjusted according to the manufacturer instruction, files were then lubricated with EDTA gel "17%" and they were used subsequently to finish the preparation in brushing movement and crown-down technique. The irrigation protocol was done as mentioned before.

Group 3: Instrumentation of root canals was done using manual K−file up to #30 with quarter−turn pull technique. The irrigation protocol was followed as previously described.
The instrumentation time for each group was measured in seconds using a digital timer. This did not provide the interval irrigation time, but it did include the instrumentation time of the file that was used. After that, sterile paper tips of size #30 were used to dry the canals. After utilizing a pressure syringe to inject Metapex into each canal, the material was finally compacted using wet cotton pellets. Utilizing eugenol and reinforced zinc oxide, the access cavity was repaired. The pulpectomized teeth were covered by a prefabricated stainless steel metallic crown that was luted with glass ionomer cement.

Immediately following the procedure, intraoral periapical radiographs were collected in order to assess the quality of the obturation. Based on Coll and Sandrian criteria as follows.[11]

- Overfilled (metapex was found outside the root)
- Underfilled (metapex shorter than radiographic apex by more than 2mm)
- Optimum filling (metapex was found up to 2mm shorter of radiographic apex)

After 3, 6,9, and 12 months, the treated teeth of the participants were reassessed clinically and radiographically by co-investigator. Using the same standards established by Coll and Sandrian, clinical signs and symptoms as well as radiographic appearance were assessed at each follow-up. [11]

a) Clinical Criteria

The clinical criteria investigated the following conditions; spontaneous pain, mobility, pain on palpation, gingival swellings or fistulas tract, sensitivity to percussion and any sign of gingival inflammation (pain, redness, or bleeding around the tooth/crown). If any of the above mentioned criteria was reported, it was interpreted as failure of the treatment. To document any failure, a binary scoring system was used (1=failure, 0=success). [12]

b) Radiographic criteria

Any external or internal root resorption, interradicular or periapical bone resorption, periodontal ligament space widening and newly created radiographic lesion were all analyzed by the radiographically. If any of the above mentioned criteria was reported, it was interpreted as failure of the treatment. If the none of the above mentioned conditions as well as healing, static or reduction of the size of the periapical /furcation bone radiolucency was noted, it was interpreted as success of treatment. To precisely monitor the changes of radiographic radiolucency and root resorption the following scores were given: [12]
0 = No furcation/periapical radiolucency at baseline. Complete healing of the radiographic lesion at follow-up.
1= periapical/furcation radiolucency at baseline. The static state of the radiographic lesion. Not more than >1/3 root resorption at follow-up.
2 = Increase in the size of the radiographic lesion. more than one-third of newly developed lesions and root resorption. Success was indicated by a score of 0, 1, and failure was indicated by a score of 2.

Statistical analysis

Statistical analysis was calculated just for convenient cases in the study and it excluded the cases that were not regular during follow up period (10 cases /group were analysed). The mean and standard deviation were used to present numerical data. They were examined for normality and variance homogeneity by examining the data distribution and applying Shapiro-Wilk's and Levene's tests, respectively. They were found to be normally distributed with homogenous

variances across groups. They were analyzed using one-way ANOVA followed by Tukey's post hoc test. The significance level was set at $p<0.05$ within all tests. Statistical analysis was performed with R statistical analysis software version 4.3.3 for Windows. [13]

Results

Demographic data

30 cases were involved into the statistical analysis, with 10 cases in each group. Intergroup comparisons and summary statistics for the demographic data was reported. Both genders were equally represented in the manual files group, with a mean age of 5.54±0.91 years. In the other groups, there were three females and seven men. The mean age of the cases in the Kidzo group was 5.75±0.95 years, whereas it was 5.62±0.78) years in the Kedo S plus group. No significant difference was founded regarding the distribution of age and gender among the examined groups.

Instrumentation time (seconds)

Intergroup comparison showed a significant difference between different groups ($p<0.001$). The longest time was measured with manual files (100.74±2.92) (seconds), followed by Kidzo files (95.81±1.91) (seconds), while the shortest time was measured with Kedo S plus files (74.99±1.52) (seconds). Statistically significant difference was found after post hoc pairwise comparison ($p<0.001$).

Quality of obturation

Intergroup comparison are presented in table (1), figure 1. Seven cases treated with manual files, eight treated with Kedo S, and six treated with Kidzo were optimally filed, and no statistically significant difference was founded (p=0.665)

Table 1: Intergroup comparisons and summary statistics for filling extent

Filling extent	N (%)			p-value
	Manual files	Kedo S Plus file	Kidzo files	
Underfilled	2 (20.00%)	1 (10.00%)	1 (10.00%)	0.665ns
Optimum	7 (70.00%)	8 (80.00%)	6 (60.00%)	
Overfilled	1 (10.00%)	1 (10.00%)	3 (30.00%)	

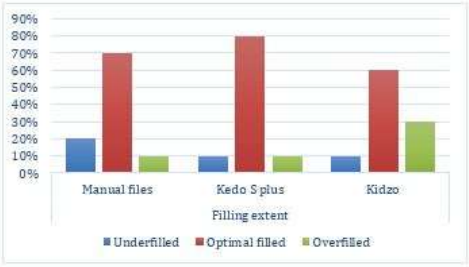

Figure (1): Bar chart showing the filling extent

IV- Clinical evaluation

a-Gingival swelling/abscess

Inter, intragroup comparisons for gingival swelling/abscess incidence are presented in table (2), figure 2. At baseline, 3 cases treated with manual files, a single case treated with Kedo S plus, and two cases treated with Kidzo were affected, and the difference was not statistically significant (p=0.535). After 3 months, only a single case treated with Kidzo was affected, and there was not statistical significance difference (p=0.355). Starting from 6 months, all the cases were free. The incidence recorded at baseline was much higher than the incidence measured at later intervals for the manual files group, with a significant difference observed between the intervals (p=0.017). The difference was not statistically significant for the other groups.

Table 2: Inter, intragroup comparisons and summary statistics for gingival swelling/abscess incidence.

Time	Gingival swelling/ abscess	N (%)			p-value
		Manual files	Kedo S Plus	Kidzo	
Baseline	No	7 (70.00%)[A]	9 (90.00%)	8 (80.00%)	0.535ns
	Yes	3 (30.00%)	1 (10.00%)	2 (20.00%)	
3 months	No	10 (100.00%)[B]	10 (100.00%)	9 (90.00%)	0.355ns
	Yes	0 (0.00%)	0 (0.00%)	1 (10.00%)	
6 months	No	10 (100.00%)[B]	10 (100.00%)	10 (100.00%)	NA
	Yes	0 (0.00%)	0 (0.00%)	0 (0.00%)	
9 months	No	10 (100.00%)[B]	10 (100.00%)	10 (100.00%)	NA
	Yes	0 (0.00%)	0 (0.00%)	0 (0.00%)	
12 months	No	10 (100.00%)[B]	10 (100.00%)	10 (100.00%)	NA
	Yes	0 (0.00%)	0 (0.00%)	0 (0.00%)	
p-value		0.017*	0.406ns	0.171ns	

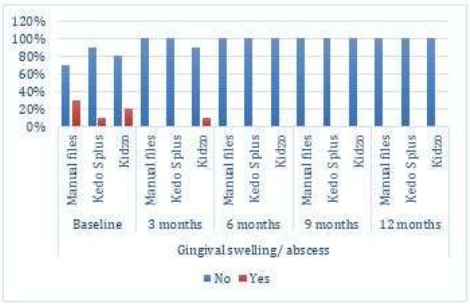

Figure (2): Bar chart showing gingival swelling/abscess incidence

b- Pain on percussion

Inter, intragroup comparisons for pain on percussion incidence are presented in table (3), figure 3. A single case treated manually had an impact at baseline, and the difference was not statistically significant (p=0.355). All the cases were free for the first three months. For every group, there was no discernible variation in the incidents assessed at various periods.

Table 3: Inter, intragroup comparisons and summary statistics for pain on percussion incidence.

Time	Pain on percussion	n (%)			p-value
		Manual files	Kedo S Plus	Kidzo	
Baseline	No	9 (90.00%)	10 (100.00%)	10 (100.00%)	0.355ns
	Yes	1 (10.00%)	0 (0.00%)	0 (0.00%)	
3 months	No	10 (100.00%)	10 (100.00%)	10 (100.00%)	NA
	Yes	0 (0.00%)	0 (0.00%)	0 (0.00%)	
6 months	No	10 (100.00%)	10 (100.00%)	10 (100.00%)	NA
	Yes	0 (0.00%)	0 (0.00%)	0 (0.00%)	
9 months	No	10 (100.00%)	10 (100.00%)	10 (100.00%)	NA
	Yes	0 (0.00%)	0 (0.00%)	0 (0.00%)	
12 months	No	10 (100.00%)	10 (100.00%)	10 (100.00%)	NA
	Yes	0 (0.00%)	0 (0.00%)	0 (0.00%)	
p-value		0.406ns	NA	NA	

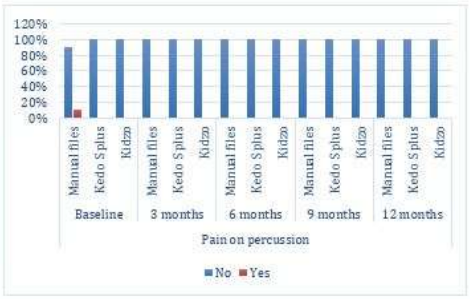

Figure (3): Bar chart showing the incidence of pain on percussion

Figure (4): Bar chart showing the clinical outcome

c- Clinical outcome

Inter, intragroup comparison and summary statistics for clinical outcome are presented in table (4), figure 4. After 3 months, a single case in the Kidzo group failed. All cases were successful in later intervals, and there were no statistical significance ($p>0.05$) differences between the groups and intervals.

Table 4: Inter, intragroup comparisons and summary statistics for clinical outcome.

Time	Clinical outcome	N (%)			p-value
		Manual files	Kedo S Plus	Kidzo	
3 months	Success	10 (100.00%)	10 (100.00%)	9 (90.00%)	0.355ns
	Failure	0 (0.00%)	0 (0.00%)	1 (10.00%)	
6 months	Success	10 (100.00%)	10 (100.00%)	10 (100.00%)	NA
	Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	
9 months	Success	10 (100.00%)	10 (100.00%)	10 (100.00%)	NA
	Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	
12 months	Success	10 (100.00%)	10 (100.00%)	10 (100.00%)	NA
	Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	
p-value		NA	NA	0.392ns	

V- Radiographic evaluation

a-Periapical/furcation radiolucency

Inter, intragroup comparisons for periapical/furcation radiolucency incidence and status are presented in table (5), figure 5. At baseline, 6 affected cases were in the manual and Kedo S Plus groups and 8 cases in the Kidzo group, and the difference was not statistically significant ($p=0.549$). After 3 months, 3 lesions in the manual group and 4 in other groups decreased in size, and there was no statistical significant difference ($p=0.800$). Starting from 6 months, another case in the manual group and two cases in the Kedo S Plus groups decreased in size, and the difference was again not statistically significant ($p=0.251$). Within all groups, there was a significant difference between the state of the lesions, with the percentage of affected cases decreasing significantly starting from 3 months ($p<0.05$).

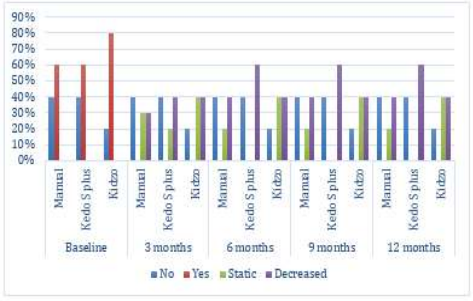

Figure (5): Bar chart showing periapical/furcation radiolucency incidence and status.

Table 5: Inter, intragroup comparisons and summary statistics for periapical/furcation radiolucency incidence and status.

Time	Periapical/furcation radiolucency size	N (%)			p-value
		Manual files	Kedo S Plus	Kidzo	
Baseline	No	4 (40.00%)^{A}	4 (40.00%)^{A}	2 (20.00%)^{A}	0.549ns
	Yes	6 (60.00%)	6 (60.00%)	8 (80.00%)	
3 months	No	4 (40.00%)	4 (40.00%)	2 (20.00%)	0.800ns
	Static	3 (30.00%)	2 (20.00%)	4 (40.00%)	
	Decreased	3 (30.00%)	4 (40.00%)	4 (40.00%)	
6 months	No	4 (40.00%)^{B}	4 (40.00%)^{B}	2 (20.00%)^{B}	0.251ns
	Static	2 (20.00%)	0 (0.00%)	4 (40.00%)	
	Decreased	4 (40.00%)	6 (60.00%)	4 (40.00%)	
9 months	No	4 (40.00%)^{B}	4 (40.00%)^{B}	2 (20.00%)^{B}	0.251ns
	Static	2 (20.00%)	0 (0.00%)	4 (40.00%)	
	Decreased	4 (40.00%)	6 (60.00%)	4 (40.00%)	
12 months	No	4 (40.00%)^{B}	4 (40.00%)^{B}	2 (20.00%)^{B}	0.251ns
	Static	2 (20.00%)	0 (0.00%)	4 (40.00%)	
	Decreased	4 (40.00%)	6 (60.00%)	4 (40.00%)	
p-value		0.010*	<0.001*	0.003*	

Table 6: Inter, intragroup comparisons and summary statistics for radiographic outcome

Time	Radiographic outcome	N (%)			p-value
		Manual files	Kedo S Plus	Kidzo	
3 months	Success	10 (100.00%)	10 (100.00%)	10 (100.00%)	NA
	Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	
6 months	Success	10 (100.00%)	10 (100.00%)	10 (100.00%)	NA
	Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	
9 months	Success	10 (100.00%)	10 (100.00%)	10 (100.00%)	NA
	Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	
12 months	Success	10 (100.00%)	10 (100.00%)	10 (100.00%)	NA
	Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	
p-value		NA	NA	NA	

b- Radiographic outcome

Inter, intragroup comparison for radiographic outcome are presented in table (6), figure 6. Within all intervals, all cases were considered successful.

Figure (6): Bar chart showing the radiographic outcome

Discussion

The use of conventional manual K-files for root canal preparation in primary teeth has a number of potential disadvantages. such as lengthy procedure, canal transportation and zipping of the apical foramen. These incidents can be avoided by using of rotary instrumentation in the pulpectomy procedure for primary. Additionally, the child behavior can be managed by reducing the instrumentation time when rotary instrumentation tecqnique used in pulpectomy procedure.[14-16]

Recently, specifically designed pediatric rotary file systems were developed for primary teeth to eliminate over instrumentation that might be happen after using permanent teeth file system in preparation of root canals. [17] Debatable has been the usefulness of single file systems, which have recently been developed, in the pulpectomy procedure of primary teeth.[18,19]

Thus, the present study compared a single file system (Kedo-S plus) with multible Kidzo files system and manual K-files regarding the following parameters in pulpectomized primary molars:

- Instrumentation time
- Obturation quality
- Radiographic and clinical outcomes

In the current study, Kedo-S Plus file (Fifth generation of the Kedo S file) was selected. It is a single rotary file with a triangular cross section. It has a three-point contact design and a non-cutting tip, as well as it incorporates two different metallurgies within a single file system.

The rationale beyond choosing the kedo-S plus file system, is the special manufacturing process of two stage heat treatment technology of the file inorder to be color coded in blue and gold colors, the apical 7mm part has under gone a heat treatment before and after as well as special titanium oxide layer coating to give the file blue color at the apical part, the file's coronal section has undergone heat treatment only before the manufacturing to give the file gold color coronally which collectively improve the clinical efficacy of the file system. [20]

A new era of heat treated pediatric rotary files system (Kidzo rotary files) consists of three Ni-Ti files with different sizes and tapers (25/4, 30/4, 30/6) with a semi-active tip and The produced alloy, with its triangle-shaped cross section, is what provides the file its resistance to cycle fatigue and flexibility.[21] The two pediatric rotary file systems previously discussed were compared to a control group using manual K-files as the gold standard for primary molar root canal instrumentation. [22]

All procedures clinically and radiographically were performed by the main investigator to ensure reproducibility, the pulpectomy procedure was completed in a single visit for all participants to minimize the hazard arising from loss of temporary restoration. [23] In our study the participants were selected between age of 4 and 7 years to ensures good communication and improve the cooperation to rubber dam isolation and pulpectomy procedure, as well as to ensure that primary molars finished developing their roots by the time they were 4 years old, and to exclude root resorption that begins at age of 6 years .[24]

Therefore, mandibular primary second molars were chosen for standardization in this randomized clinical experiment. Furthermore, mandibular molars are easier to work with than maxillary primary molars because they are more accessible, particularly in the mouths of young children.[25] Because a pulpectomy treatment must be completed quickly in pediatric clinical practice, the instrumentation time was measured for three separate groups in the current study.[26] A skilled helper used a stopwatch to record the instrumentation time in seconds.

The current study found that the longest instrumentation time was measured with manual files (100.74 ± 2.92 seconds), followed by Kidzo files (95.81 ± 1.91 seconds). The shortest instrumentation time was measured with the Kedo S plus files (74.99 ± 1.52 seconds). This could be attributed to the fact that the Kedo-S plus system requires only a single file for instrumentation, while the Kidzo rotary files and manual instrumentation methods require preparation with different file sizes for each canal.

Silva et al [27] was consistent with the findings of the current investigation, which shown that instrumentation for the rotary Profile 0.04 required much less time (3.46 min) than for the manual K-file (9.06 min.). Moreover, the findings of Panchal et al.'s [28] study, which compared the instrumentation times for pediatric rotary files (Kedo-S files), hand K-files, and H-files following root canal instrumentation in primary molars, were consistent with our own findings. Kedo-S

files had the shortest instrumentation times when compared to the other groups.

Contrary to current study findings, Katge et al [29] reported that manual H-files (3.41 min) required less time for primary root canal preparation compared than Mtwo rotary files (4.81 min) during primary root canal preparation. Additionaly, Madan et al [30] According to the study, utilizing the ProFiles rotary system required more instrumentation time than using manual K-files, which took less time. The operator carrying out the processes may have varying levels of experience, which could explain this disparity.

The method suggested by Coll and Sandrian[10] was used in the study to assess the quality of obturation which categorized the obturation as overfilled (beyond the apex), underfilled (2 mm short of the apex) and optimal (1 mm short of the apex). This evaluation approach did not consider other potential criteria for assessing the quality of obturation.

In the current study, quality of obturation was assessed by extent of filling, as the results concluded that the primary molars which treated by rotary Kedo-S plus file had the most optimal filling (80%), followed by the manual K file and rotary Kidzo file groups (70%, 60%). There was no statistically significant difference seen between any of the groups (p=0.665). The results mainly attributed to the design of Ni Ti Kedo-S plus files, which allows a higher flexibility in the apical 7 mm that pertains to the highly curved canals of primary molars. The coronal portion is slightly flexible causing a slightly rigid nature leading to increased canal preparation near the orifice that would allow an easier flow of the obturating material into the prepared canal space and thus results in more optimal canal obturation.

The found result is consistent with Hadwa et al [31] study that concluded that The Kedo-S Square and Fanta AF™ Baby groups had the maximum ideal filling, with no discernible difference from the manual K-file group (p = 0.424). In addition, Ranjith et al [32] concluded that there was no significant statistical difference in the obturation quality between Kedo-S plus, Kedo-S rotary and manual K-files (p= 0.32) which came in line with the current study.

Patel et al [33] published findings comparable to ours in their first investigation on the Kedo-S Plus system for evaluating the quality of obturation in primary molars. With the Kedo-S Plus file system, they discovered the greatest number of optimally filled canals, followed by WaveOne and Kedo-S Square. It's probable that the Kedo-S Plus system's wider preparation compared to the other two systems—40% more in coronal regions and 25% more in apical regions—makes it easier to insert obturating material, even though these differences were not statistically significant.

There was no statistical significant differences (p>0.05) among the three groups regarding to the clinical parameters (gingival swelling, fistula and pain on percussion) during the 12-month follow-up. Each group demonstrated a decrease in the prevalence of clinical parameters at 3, 6, 9 and 12 months, which is indicated to the effectiveness of the pulpectomy procedure in improving clinical signs and symptoms, except for a single case in the Kidzo group that continued to exhibit clinical signs and symptoms at the 3 months follow-up period but it was improved at 6, 9 and 12 months.

All radiographic parameters (periapical and furcation radiolucency) reveled no statistically significant differences (p>0.05) among the three groups over the 12-month follow-up period. Furthermore, during the follow up period no new radiographic lesions were detected in all treated teeth, and all teeth with existing lesions remained

stable, meeting the criteria for successful outcomes as defined in a previous study.[12]

The current study's findings were consistent with previous studies by Thomas et al[34] , Reddynand et al,[35] Ozalp et al[36] and Chawla et al [37] they reported high rates of clinical success (ranging from 80% to 100%) for pulpectomy procedures in primary molars using manual canal instrumentation. Furthermore, these finding were in line with finding of Morankar et al[38] who concluded that the difference in clinically and radiographicaly success between manual and rotary instrumentation groups in pulpectomy procedures was not statistically significant.

Conclusion

Compared to Kidzo rotary file and manual-K files, Kedo-S plus special paediatric rotary file (single file) showed a shorter time of instrumentation and higher quality of obturation in primary molars during pulpectomy procedures.

Declaration

Ethics approval and consent to participate

The study received approval by the Research Ethics Committee of the Faculty of Dentistry, Ain Shams University in Cairo, Egypt, under the FDASU-Rec approval number ID032104. NCT05234918 is the registration number for the trial on clinicaltrial.gov's PRS (Protocol Registration and Result System).

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

None

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