Original Article

DOI: 10.7860/JCDR/2024/63534.18917

Dentistry Section

Efficacy of Two Paediatric Rotary Systems: Kedo-SG Blue™ and Prime Pedo™ Files in Primary Mandibular Molars: A Randomised Clinical Trial

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ABSTRACT

Introduction: The success of root canal procedures depends on cleaning and shaping of canals. There are several instrumentation techniques available for root canal preparation. Recently, exclusive rotary file systems called Kedo-SG Blue and Prime-Pedo have been introduced for root canal preparation in primary teeth. The inherent flexibility of these files allows them to preserve the anatomy of curved canals in primary molars.

Aim: To compare the instrumentation time, obturation time, and quality of obturation using two paediatric rotary file systems, Kedo-SG Blue™ and Prime-Pedo™, in mandibular primary molars.

Materials and Methods: A randomised clinical trial was conducted in the outpatient Department of Paediatric and Preventive Dentistry, Narayana Dental College and Hospital, Nellore Andhra Pradesh, India, from February 1, 2019 to January 20, 2020. Fifty primary molars with necrotic pulp were included and randomly divided into two groups, with 25 teeth in each group. Group 1 and Group 2 were instrumented with Kedo-SG Blue™ and Prime-Pedo™, respectively. The time taken for instrumentation and obturation was noted in minutes, and the quality of root canal filling was recorded as optimal, underfilled, or overfilled. The data were statistically analysed using an independent Student's t-test for time measurements and a Chi-square test for the quality of obturation.

Results: There was a statistically significant difference in instrumentation time and obturation time between the two groups (p-value=0.009; 0.011). The Kedo-SG Blue™ rotary system showed a better quality of obturation compared to the Prime-Pedo™ rotary system, although the difference was not statistically significant (p-value=0.22).

Conclusion: The Kedo-SG Blue™ rotary system demonstrated shorter instrumentation and obturation times, as well as a higher number of optimally filled canals compared to the Prime-Pedo™ rotary system. Therefore, the Kedo-SG Blue™ rotary system exhibited better clinical performance in primary molars than the Prime-Pedo™ rotary system.

Keywords: Children, Instrumentation time, Paediatric endodontics, Primary teeth, Pulpectomy

INTRODUCTION

Dental caries is ubiquitous worldwide, causing dental pain and tooth loss in the population. If left untreated, dental caries can progress into the pulp, resulting in severe pain and infection, leading to premature exfoliation of primary teeth and affecting the permanent teeth. The most commonly used procedure in paediatric endodontics is pulpectomy, which aims to restore the form and function of primary teeth to prevent these problems [1]. According to the AAPD, pulpectomy is a root canal procedure for irreversibly infected or necrotic pulp tissue due to caries or trauma [2]. The purpose of pulpectomy is to maintain arch length, preserve occlusal function, and promote the eruption of permanent teeth [3,4].

Endodontic treatment is performed to control infection in the root canals and promote the healing of periapical tissues [5]. This objective is achieved through biomechanical instrumentation and canal irrigation [6]. Cleaning and shaping of the root canals are critical aspects of endodontic therapy, aiming to remove all pulp tissue, bacteria, and bacterial toxins from the root canal system [7].

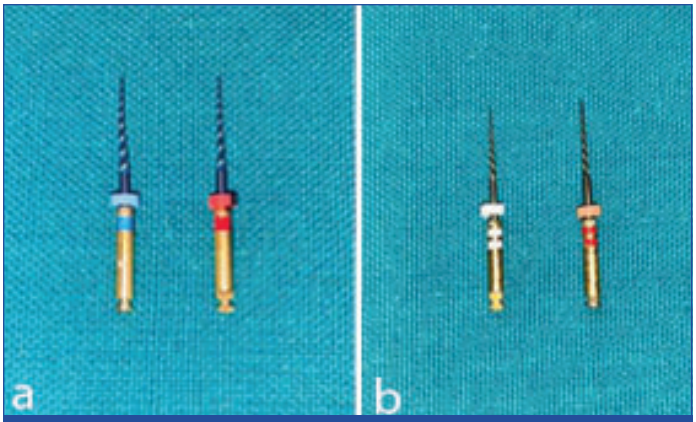
Rotary nickel-titanium (Ni-Ti) systems have been developed to preserve the original canal shape and are widely used in permanent teeth due to reduced instrumentation time in curved molar root canals and enhanced patient comfort [8-10].

Barr ES et al., introduced rotary instruments in paediatric endodontics, highlighting that the inherent flexibility of these files allows them to preserve the anatomy of curved canals in primary molars [11]. They concluded that using Ni-Ti rotary files in root canal preparation was cost-effective, time-saving, and resulted in predictable and uniform fillings [12]. Kuo C et al., suggested that a rotary file with modified dimensions (length, taper, and tip size) would be more beneficial for pulpectomy in primary teeth [13].

Various designs of Ni-Ti rotary instruments are available in the market. Manufacturers have modified their designs to enhance the cleaning efficiency of root canal preparations, simplify the procedure, and reduce instrumentation time. Some of the commercially available paediatric rotary files include Kedo-S™, Kedo-SG™, Kedo-SG Blue™ (India), Prime-Pedo™ (India), DXL-Pro Pedo™ (India), Pro AF Baby Gold™ (India), Neolix™ (France), Denco® Kids files (China), and Sani® Kid rotary files (China).

The Kedo-SG Blue™ file system has an innovative feature of the triangular cross-section with variably variable taper design (4-8%) and tip diameter, facilitating efficient root canal wall preparation. The Kedo-SG Blue™ rotary files are a single file system that includes D1, E1, and U1 files, with a total length of 16 mm and a working area (cutting flutes) of 12 mm in length [Table/Fig-1]. These files are made of heat-treated NiTi with an additional titanium oxide coating formed through special thermomechanical processing, providing increased flexibility, enhanced safety, and improved resistance to cyclic fatigue, with 75% greater resistance to cyclic fatigue. This design reduces the chances of instrument fracture [14].

Another paediatric rotary system, the Prime Pedo™, consists of four files: Starter, P1, P2, and Endosonic file. The Prime Pedo™ file system includes the Starter file (8% taper, 16 mm), P1 file (#15, 6% taper, 18 mm), P2 file (#25, 6% taper, 18 mm), and endodontic file (2% taper, 18 mm). The length markings on the file are as follows: 12 mm up



[Table/Fig-1]: (a) Kedo-SG Blue™ Rotary files Rotary; (b) Prime Pedo™ Rotary files.

to the flutes, 13 mm stopper above the flutes, 14 mm marker ring present, and 15 mm above this mark, with a marker ring at 16 mm [Table/Fig-1]. As a result, a ruler or scale is not required to align the stopper for repeatedly setting the working length. The Prime Pedo™ files have a gold treatment and controlled memory, which allows them to be centered in the curved canals of primary molars [15].

Existing literature does not provide any studies comparing the Kedo-SG Blue™ and Prime Pedo™ rotary systems. Therefore, the aim of this study was to compare the efficacy of these two rotary systems in primary molars. Hence this study was conducted to compare the instrumentation time between the rotary Kedo-SG BlueTM and Prime PedoTM filing techniques in primary molars along with the time taken for obturation with Metapex after instrumentation using either of the two rotary files and compare and analyse the quality of root canal filling with Metapex in primary molars instrumented using either of the two rotary files.

MATERIALS AND METHODS

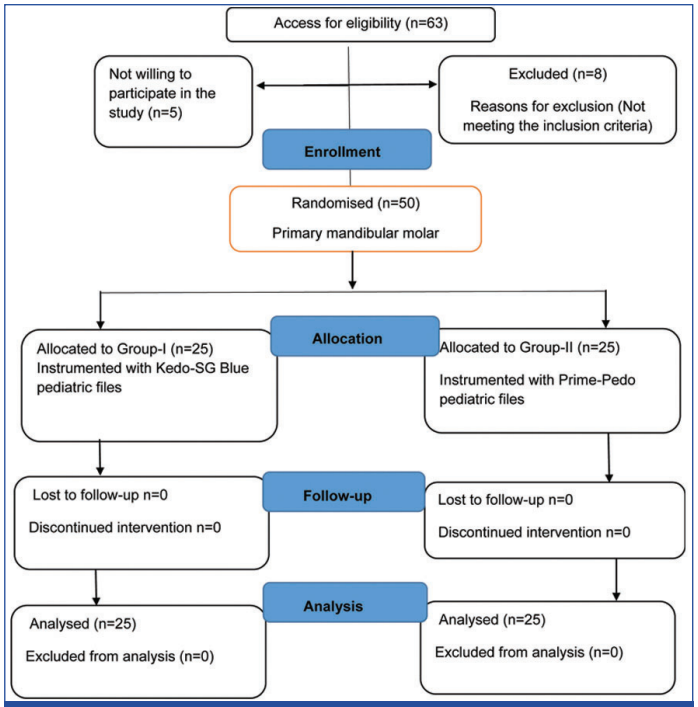
This double-blinded, two-parallel-arm quantitative study with a balanced allocation of a 1:1 ratio was conducted in the outpatient Department of Paediatric and Preventive Dentistry, as well as school dental health programs conducted by Narayana Dental College and Hospital, Nellore, Andhra Pradesh, India, from February 1, 2019, to January 20, 2020. Ethical clearance was obtained from the institutional ethical committee (IEC Ref No: NDC/IECC/PEDO/DISS/12-18/02), and the trial was registered in the Clinical Trials Registry-India (CTRI) (registration number CTRI/2019/08/020947 given in August 2019). The parents or legal guardians were provided with an explanation of the clinical procedure, and informed consent was obtained from the parents of the participants before starting the procedure.

Inclusion criteria: Healthy children irrespective of race or socio-economic status, aged 4-9 years with indication of mandibular molars for pulpectomy, absence of internal or external pathological root resorption with atleast two-thirds of the root length present were included in the study by block randomisation technique.

Exclusion criteria: Those children with any systemic illness, or tooth with perforated pulpal floor, extensive mobility,furcal abscess or presence of less than two-thirds of the root were excluded from the study.

Sample size calculation: Based on the requirement for the randomised clinical trial, a minimum sample of 49.6 was required with 80% power and a 5% error [16]. Therefore, the authors considered sample of 50 for this study.

The simple block randomised clinical trial included 50 primary mandibular molars from 50 children (25 boys and 25 girls) [Table/Fig-2]. Among the 50 primary mandibular molars, there were 12 first molars and 38 second molars with carious lesions that indicated the need for pulpectomy. The teeth were divided into two groups (n=25 in each group) based on the paediatric rotary systems used.



[Table/Fig-2]: CONSORT flow chart.

The two groups were divided according to the interventions:

- **Group I:** Instrumented with Kedo-SG Blue™ using a standard protocol [14].
- **Group II:** Instrumented with Prime Pedo™ using a modified protocol [13].

Procedure

A single operator performed all the procedures in a single-visit treatment, following the manufacturer's instructions. An intraoral investigation with periapical radiographs of the indicated tooth for pulpectomy was obtained before the start of the clinical procedure. Pulpectomy was performed on the selected molars under appropriate local anaesthesia using 2% lignocaine with 1:200,000 adrenaline, and the tooth was isolated using a rubber dam. After assessing both subjective and objective signs of the action of local anaesthesia, a no.4 carbide bur was used to remove caries, and access opening was performed using a high-speed aerator. The pulp tissue in the pulp chamber was removed using a round bur, and the canals were located using a DG16 endodontic explorer (Hu-Friedy Mfg. Co. LLC). Pulpal tissue was then extirpated from the root canals using barbed broaches. A No.10 size K-file (Dentsply Maillefer, OK, USA) was used to check the root canal's patency, and a No.15 K-file was placed into each canal to determine the canal length. The working length was determined using the radiographic technique, with the file positioned 1 millimeter short of the apex.

In Group I (n=25), the root canals were instrumented with Kedo-SG Blue™ rotary files using a crown-down technique with a lateral brushing motion. The canal working length was determined using a No.15 K-file. The D1 rotary file (red colour-coded, tip diameter 0.25, VV taper) was used to instrument the narrow mesiobuccal and mesiolingual canals. The E1 rotary file (blue colour-coded, tip diameter 0.30, VV taper) was used to instrument the wider distal canals to the full working length. The instrumentation was performed at a speed of 300 rpm and torque of 2.2 N.cm using the ENDO-MATE DT (NSK, Nakanishi Inc., Japan), following the manufacturer's instructions (Reeganz Dental Care Pvt., Ltd., India).

In Group II (n=25), the root canals were instrumented with Prime Pedo™ paediatric rotary files using a crown-down technique. The Kuo's protocol [13] was modified in this study to standardise the number of rotary files used during instrumentation. The P1 file (#15, 6% taper, 18 mm) was used to instrument the narrower canals

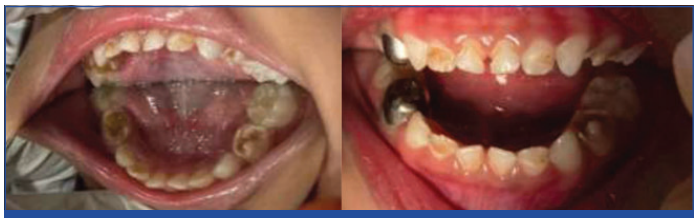
(mesiobuccal and mesiolingual), and the P2 file (#25, 6% taper, 18 mm) was used for the wider distal canals. The instrumentation was performed using the ENDO-MATE DT (NSK, Nakanishi Inc., Japan) at a rotational speed of 300 rpm and torque of 2.4 N/cm, following the manufacturer's instructions (Sky International Enterprises, India).

During instrumentation, each file was used gently with an in-and-out brushing motion, and each canal was irrigated with 2 mL of normal saline after instrumentation in both groups. For both groups, during instrumentation, each canal was lubricated with Ethylenediaminetetraacetic Acid (EDTA) to remove the smear layer and smoothen the canals, preventing file fracture within curved canals. A digital stopwatch was used to record the instrumentation time for each group in minutes. The timer was started, which included the total instrumentation time of the used files, excluding the time for irrigation between files, in order to assess the accurate time needed for instrumentation in each group. An operator noted the corresponding instrumentation time for each group.

After the last irrigation, the canals were dried with sterile paper points and obturated with Metapex material during the same appointment. The Metapex material was gently pushed into the canals using cotton pellets. The time taken for obturation was also recorded using the same digital stopwatch in minutes. Excess material was removed, and the coronal space was filled with conventional Glass ionomer cement.

Post-operative radiographs were taken, and an investigator and two paediatric dentists assessed the quality of obturation as optimal, underfilled, or overfilled based on the criteria established by Coll JA and Sadrian R (1996) [17]. Stainless steel crowns (3M, ESPE, USA) were placed as the final restoration in all the pulpotomised teeth to prevent restoration fracture and microleakage. The crowns were placed within seven days after obturation in the second appointment, as some younger children could not tolerate long appointments. Therefore, in the second visit, all the crowns were placed in all the children to ensure a standardised procedure [Table/Fig-3,4].

[Table/Fig-3]: Pre-treatment and post-treatment with SSC crowns in Kedo-SG Blue™ files.



[Table/Fig-4]: Pre-treatment and post-treatment with SSC crowns in Prime-Pedo™ files.

In this study, both the participants and the assessing reviewers were blinded to the technique used. Since both rotary systems have distinguishable characteristics, they could not be confounded to the operator, thus minimising bias.

STATISTICAL ANALYSIS

Data were collected using predesigned case record forms and entered into Microsoft Excel sheets. Statistical analysis was conducted using independent Student's t-test for continuous parameters and Chi-square tests for categorical parameters to determine statistical significance. The statistical analysis was performed using SPSS version 20.0 software (IBM Corp., Somers, NY, USA). A reliability analysis was conducted to assess the reliability of the observations/data by Cronbach's alpha value and Kappa value was calculated to measure the concordance or agreement between the observations recorded by the blinded examiners.

RESULTS

Fifty primary mandibular molars from 50 children aged between 4-9 years were included in the study. The mean age of the children was 6.8±0.8 years in the Kedo-SG Blue™ group and 6.5±1.0 years in the Prime-Pedo™ group [Table/Fig-5].

Age (years)	Group 1 (Kedo-SG Blue™)	Group 2 (Prime Pedo™)	p-value
Mean±SD	6.8±0.8	6.5±1.0	p=0.247
Median (Range)	(5.0-8.0)	(5.0-8.0)	

[Table/Fig-5]: The mean age and standard deviation distribution in each group.

The Kedo-SG Blue™ group consisted of 13 boys and 12 girls, while the Prime-Pedo™ group had 12 boys and 13 girls. There was no statistically significant difference in gender distribution between the two groups (p-value=0.77) [Table/Fig-6].

Gender distribution	Kedo-SG Blue™	Prime-PEDO™	p-value
Male	13	12	0.77
Female	12	13	

[Table/Fig-6]: The gender distribution in each group.
Chi-square exact test

When comparing the mean instrumentation time between the two groups using an independent Student's t-test, it was found that the Kedo-SG Blue™ group had significantly less instrumentation time compared to the Prime-Pedo™ group (p-value=0.009) [Table/Fig-7].

Group	Sample (n)	Mean±SD (min)	Median (Range)	p-value
Kedo-SG Blue™	25	1.76±0.33	1.58 (1.34-2.31)	**0.009***
Prime-PEDO™	25	2.03±0.37	2.09 (1.45-2.65)	

[Table/Fig-7]: Comparison of mean values of instrumentation time between the groups.
*=Significant, independent student's t-test

The obturation time was also found to be significantly less in the Kedo-SG Blue™ group compared to the Prime-Pedo™ group (p-value <0.05) [Table/Fig-8]. Regarding the quality of obturation, there was no statistically significant difference observed between the Kedo-SG Blue™ and Prime-Pedo™ groups (p-value=0.486) [Table/Fig-9-11].

Group	Sample (n)	Mean±SD	Median (Range)	p-value
Kedo-SG Blue™	25	1.04±0.26	1.09 (0.56-1.37)	**0.011***
Prime-PEDO™	25	1.21±0.19	1.22 (0.59-1.56)	

[Table/Fig-8]: Comparison of mean values of obturation time among between the groups using Independent Student's t-test.
*=Significant, Independent Student's t-test

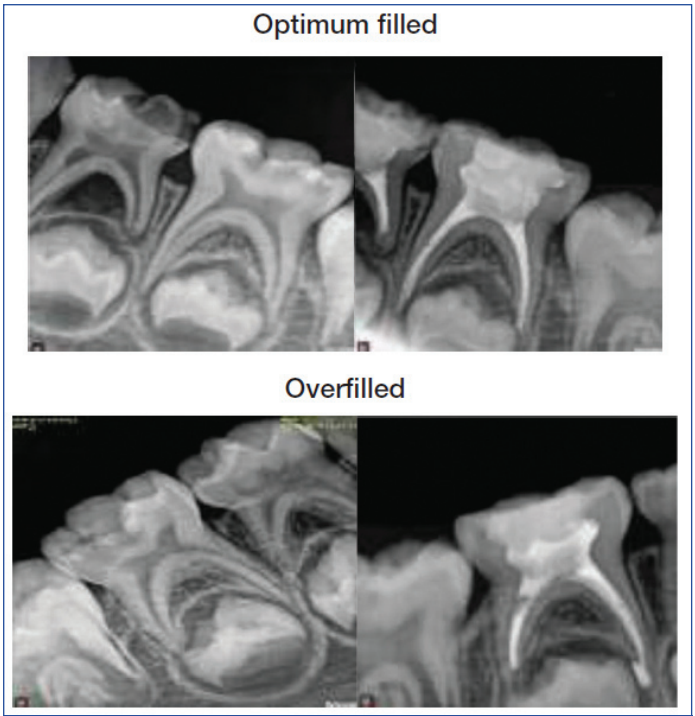
Group	Sample (n)	Underfilled	Optimal	Overfilled	p-value
Kedo-SG Blue™	25	0	23 (92%)	2 (8%)	0.22
Prime Pedo™	25	1(4%)	19 (76%)	5 (20%)	
Total	50	01 (2%)	42 (84%)	07 (14%)	

[Table/Fig-9]: Comparison of obturation quality between the two groups.
NS: Not significant; Chi-square exact test

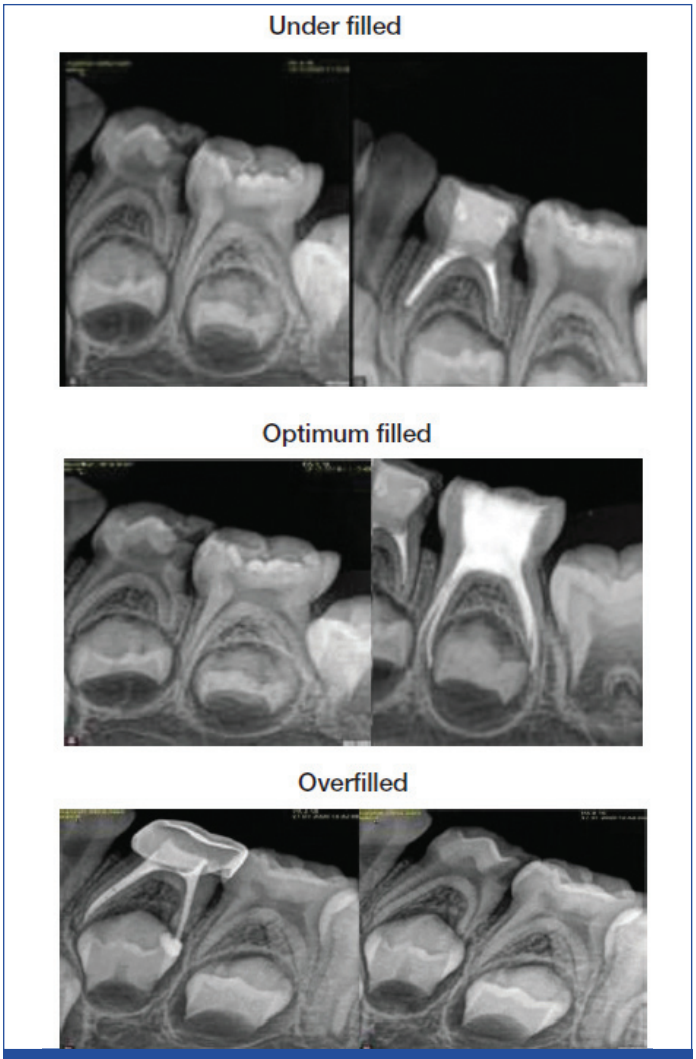
DISCUSSION

The field of dentistry is continuously evolving with the introduction of advanced technology, allowing dental professionals to provide the best services to their patients. Each year, innovative technologies emerge in the dental field, improving patient comfort worldwide.

Root canal preparation can be performed using hand instruments such as files, reamers, drills, and rotary files. However, hand



[Table/Fig-10]: Quality of obturation in Group-I (Kedo-SG Blue™).



[Table/Fig-11]: Quality of obturation in Group-II (Prime Pedo™).

instrumentation techniques are time-consuming and can result in iatrogenic errors. As trends change, there has been a growing focus on making pulpectomy procedures more efficient and time-saving [17]. Rotary instrumentation has made significant advancements in the field of endodontics, including its application in paediatric dentistry [18].

Therefore, in the present study, the authors compared the instrumentation time, obturation time, and quality of obturation using the Kedo-SG Blue™ and Prime-Pedo™ rotary file systems, which are specifically designed for paediatric patients. Previous studies by Kuo CI et al., used a combination of a manual file and two Protaper™ instruments (S.X. and S2) and concluded that the modified protocol was effective for root canal preparation in primary molars [13]. Other studies have also reported clinical success in primary molars using a modified protocol with ProTaper files [13,19,20]. In the present study, the authors modified the instrumentation protocols for the Prime-Pedo rotary systems (P1, P2) to ensure safe and efficient use of rotary files in root canal preparation for primary molars. Additionally, the authors modified Kuo's protocol in this study to standardise the number of rotary files used during instrumentation and prevent bias when calculating the instrumentation time.

In the current study, the preparation time included both the time for instrumentation and the time required for canal irrigation. However, the time taken for changing files was excluded.

The mean instrumentation time for the Kedo-SG Blue group was 1.76±0.33, while for the Prime Pedo™ group it was 2.03±0.37. The Kedo-SG Blue group had significantly less instrumentation time. The duration of instrumentation is influenced by the technique employed and the type of instruments used [14]. In paediatric rotary endodontics, reducing the instrumentation time is crucial as it can positively impact a child's behaviour and cooperation during dental treatment. It also helps to minimise operator and patient fatigue due to shorter working time and improves treatment quality [21]. This finding regarding instrumentation time is consistent with the results of a study by Priyadarshini P et al., [14], who concluded that the mean instrumentation time for Kedo SG-Blue was shorter. The reduced instrumentation time in the Kedo SG-Blue group can be attributed to the file's reduced stress due to its triangular cross-section, which minimises contact areas with dentin [22]. This design provides higher flexibility and potential fatigue resistance. Increased fatigue resistance can reduce the risk of rotary file fracture in curved root canals of primary molars [23]. Similar results have been reported in other studies [24-27].

This study is the first to compare two paediatric rotary systems in terms of obturation time. The mean obturation time for the Kedo-SG Blue system was (1.04±0.26), which was lower than the Prime-Pedo™ system (1.21±0.19). Both rotary systems demonstrated a statistically significant difference in obturation time.

These findings are in line with a study conducted by Ochoa-Romero T et al., who concluded that the use of the rotary technique in primary teeth reduced obturation time in 68% of cases [28]. Similar results were also reported by Babaji P et al., and Morankar R et al., where they found that rotary files had shorter obturation times compared to manual K-Files [26,29].

The ultimate goal of root canal treatment is to create a fluid-tight seal throughout the entire length of the root canal system, from the coronal opening to the apical termination. Therefore, the success of root canal treatment in primary teeth depends on achieving complete obturation of the canal space [29].

The quality of obturation is a critical factor in determining the success of pulpectomy [30]. A higher conicity of the root canal shape allows for easier placement of the filling material and facilitates condensation. This shape also helps in retaining the material inside the canal, preventing apical extrusion of the filling material. This is crucial because clinical research studies analysing the quality of filling in pulpectomies have shown high success rates with optimally and underfilled canals, regardless of the material used. However, there is a significant decrease in success rates when overfilling occurs, irrespective of the material used. Other factors that can

S. No.	Author's name and year	Place of study	Number of subjects	File systems compared	Parameters assessed	Conclusion
1	Priyadarshini P et al., (2020) [14]	India	60 primary mandibular molars	Kedo-SG blue Kedo-S Kedo-SH Hand h files	Instrumentation time and obturation quality	Reduced instrumentation time and superior obturation quality seen in kedo-SG Blue file
2	Lakshmanan L et al., (2020) [30]	India	45 primary mandibular molars	Kedo-S Reciprocating files, k file	Obturation quality and instrumentation time	Kedo-s rotary files provide better quality of root canal filling and reduced instrumentation time
3	Ramazani N et al., (2016) [39]	Iran	64 extracted primary mandibular molars	K file Mtwo continuous motion and reciproc motion	Preparation time and shaping ability	Mtwo reciproc motion has better shaping ability and less time
4	Katge F et al., (2019) [15]	India	54 extracted primary molars	Prime pedo™ DXL-Pro™ H file	Cleaning efficacy	Paediatric files show better cleaning efficacy compared to H files
5	Ramezanali F et al., (2015) [38]	Iran	100 extracted primary mandibular molars	Mtwo rotary system and hand K-file	Instrumentation time and cleaning efficacy	No difference in cleaning efficacy in both files but time was reduced in Mtwo file
6	Present study	India	50 Primary mandibular molar	Kedo-SG Blue and Prime-PedoTM	Instrumentation time and Obturation time and quality of quality	Kedo-SG Blue™ rotary system shows less instrumentation time, obturation time, and the highest number of optimum filled canals than the Prime-PedoTM rotary system

[Table/Fig-12]: Comparison of previous studies [14,15,30,38,39].

influence the success of treatment include previous pulp pathology and resorption [31].

In this study, the quality of obturation was assessed using the criteria established by Coll JA and Sadrian R (1996). Their study reported an overall significant success rate for teeth (incisors and molars) that were filled to the apex (89%) or filled short (87%), compared to teeth that were overfilled, which had a success rate of 58% [17]. It is important to note that achieving a tight apical seal is not always possible in primary teeth after pulpectomy, even in cases where the pulpectomy is considered successful [32].

In the present study, regarding the quality of obturation, 2 (8%) teeth were overfilled, 23 (92%) teeth were optimally filled, and no teeth were underfilled in the Kedo-SG Blue group. In the Prime-Pedo™ group, 19 (76%) teeth were optimally filled, 5 (20%) teeth were overfilled, and 1 (4%) tooth was underfilled. However, there was no statistically significant difference observed between the two rotary systems. The Kedo-SG Blue group showed superior quality of root canal filling. This may be attributed to the progressively increased taper, which results in higher cervical enlargement and restricted apical preparation. Additionally, the increased flexibility of the Kedo-SG Blue files aids in negotiating even the narrowest canals and adapting to the primary canal curvature. The additional titanium oxide coating of the file also contributes to a smoother flow of obturating material and optimal quality of obturation [14].

The results of this study were similar to the study conducted by Priyadarshini P et al., who reported that 80% of teeth were optimally filled, 20% were overfilled, and none were underfilled with Kedo-SG Blue [14]. Similar findings were also reported in other studies [24,26,27,33-36].

In this study, for the prime Pedo group, 76% of teeth were optimally filled, 20% were overfilled, and 4% were underfilled. However, Ghadge S et al., reported that 3.8% were underfilled, which is consistent with the present study, while 96.2% of teeth were optimally filled and none were overfilled, which is inconsistent with this study findings. [37] This discrepancy can be attributed to variations in operator skill, irrigating solution, and the type of obturating material used. Similar studies from the literature have been compared in [Table/Fig-12] [14,15,30,38,39].

The Prime Pedo™ group exhibited the highest number of overfilled canals compared to the Kedo-SG Blue™ group. This difference may be attributed to variations in working length, as well as the gradual taper design of each file. It is important to note that when working with rotary files, exceeding the working length should be avoided due to their conicity.

Calcium hydroxide-based obturating materials possess beneficial properties such as bio-absorbability, anti-bacterial activity, induction of mineralised tissue formation, activation of alkaline phosphatase, collagen synthesis, and the ability to hydrolyse bacterial endotoxin [36,40-42]. Additionally, iodoform-based materials resorb within two weeks if pushed beyond the apex, and their rate of resorption is faster than that of the root [43]. Therefore, in the present study, although the Prime Pedo™ group had more overfilled canals than the Kedo-SG Blue™ group, it does not hinder the eruption of permanent teeth or cause any foreign body reaction.

Paediatric patients often have limited mouth opening, making it challenging to use longer instruments. To address this issue, paediatric rotary files were specifically designed with shorter lengths. These files offer several advantages when working with paediatric patients, including ease of operation, reduced chairside time, improved debris and tissue removal, increased patient cooperation, and effective cleaning and shaping of canals.

It is important to note that the procedure is technique-sensitive and relies on the experience of the operator and cooperation of the child. Therefore, caution should be exercised when generalising the results obtained with these rotary instruments to clinical practice.

Limitation(s)

The quality of obturation was assessed using 2D radiographs. However, the quality of obturation can be better evaluated using three-dimensional imaging. It is important to assess the clinical and radiographic success of pulpectomy procedures performed with different file systems through long-term follow-up.

CONCLUSION(S)

The instrumentation time was shorter for the Kedo-SG Blue™ rotary system compared to the Prime-Pedo™ rotary system. Similarly, the obturation time was shorter for the Kedo-SG Blue™ rotary system than the Prime-Pedo™ rotary system. The Kedo-SG Blue™ rotary system exhibited the highest number of optimally filled canals, indicating that the cleaning efficacy of Kedo-SG Blue™ files was superior to that of Prime-Pedo™ files. Therefore, based on this study, the Kedo-SG Blue™ paediatric rotary file system can be recommended for use in primary teeth to enhance root canal preparation and achieve good quality root canal filling.

REFERENCES

[1] Rotstein I, Ingle JI. Ingle's Endodontics 7th edition, PMPH, USA. (Pp.832).
[2] AAPD. Guideline on pulp therapy for primary and immature permanent teeth. Pediatr Dent. 2009;34:12-13. https://www.aapd.org/media/Policies_Guidelines/BP_PulpTherapy.pdf.
[3] Primosch RE, Ahmadi A, Setzer B, Guelmann M. A retrospective assessment of zinc oxide-eugenol pulpectomies in vital maxillary primary incisors successfully restored with composite resin crowns. Pediatr Dent. 2005;27(6):470-77.
[4] Fuks AB. Current concepts in vital primary pulp therapy. Eur J Paediatr Dent. 2002;3(3):115-20.
[5] Takahashi K. Microbiological, pathological, inflammatory, immunological and molecular biological aspects of periradicular disease. Int Endod J. 1998;31(5):311-25.
[6] Shuping GB, Ørstavik D, Sigurdsson A, Trope M. Reduction of intracanal bacteria using nickel-titanium rotary instrumentation and various medications. J Endod. 2000;26(12):751-55.
[7] Pinheiro SL, Araujo G, Bincelli I, Cunha R, Bueno C. Evaluation of cleaning capacity and instrumentation time of manual, hybrid and rotary instrumentation techniques in primary molars. Int Endod J. 2012;45(4):379-85.
[8] Short JA, Morgan LA, Baumgartner JC. A comparison of canal centering ability of four instrumentation techniques. J Endod. 1997;23(8):503-07.
[9] Gergi R, Rjeily JA, Sader J, Naaman A. Comparison of canal transportation and centering ability of twisted files, Pathfile-ProTaper system, and stainless steel hand K-files by using computed tomography. J Endod. 2010;36(5):904-07.
[10] Johnson E, Lloyd A, Kuttler S, Namerow K. Comparison between a novel nickel-titanium alloy and 508 nitinol on the cyclic fatigue life of Profile 25/.04 rotary instruments. J Endod. 2008;34(11):1406-09.
[11] Barr ES, Kleier DJ, Barr NV. Use of nickel-titanium rotary files for root canal preparation in primary teeth. Pediatr Dent. 2000;22(1):77-78.
[12] Siqueira JF Jr, Araújo MC, Garcia PF, Fraga RC, Dantas CJ. Histological evaluation of the effectiveness of five instrumentation techniques for cleaning the apical third of root canals. J Endod. 1997;23(8):499-502.
[13] Kuo CI, Wang YL, Chang HH, Huang GF, Lin CP, Li UM, et al. Application of Ni-Ti rotary files for pulpectomy in primary molars. J Dent Sci. 2006;1:10-15. https://www.semanticscholar.org/paper/Application-of-Ni-Ti-Rotary-Files-for-Pulpectomy-in-Kuo-Wang/a3be85d9dbfacfebb870f3fe037d88c2ee9948fe.
[14] Priyadarshini P, Jeevanandan G, Govindaraju L, Subramanian EM. Clinical evaluation of instrumentation time and quality of obturation using paediatric hand and rotary file systems with conventional hand K-files for pulpectomy in primary mandibular molars: A double-blinded randomised controlled trial. Eur Arch Paediatr Dent. 2020;21(6):693-701.
[15] Katge F, Ghadge S, Poojari M, Jain K, Patil DP. Comparative evaluation of cleaning efficacy of Prime Pedo™ and DXL-Pro™ Pedo Rotary Files with Conventional H files in root canals of primary teeth: An in vitro study. J Clin Diagn Res. 2019;13(7):06-09.
[16] Charan J, Biswas T. How to calculate sample size for different study designs in medical research? Indian J Psychol Med. 2013;35(2):121-26.
[17] Coll JA, Sadrian R. Predicting pulpectomy success and its relationship to exfoliation and succedaneous dentition. Pediatr Dent. 1996;18(1):57-63.
[18] Moghaddam KN, Mehran M, Zadeh HF. Root canal cleaning efficacy of rotary and hand files instrumentation in primary molars. Iran Endod J. 2009;4(2):53-57.
[19] Finn SB. Morphology of the primary teeth. Clinical pedodontics. 1973;4:59-70.
[20] Govindaraju L, Jeevanandan G, Subramanian EM. Knowledge and practice of rotary instrumentation in primary teeth among Indian dentists: A questionnaire survey. J Int Oral Health. 2017;9(2):45.
[21] Mortazavi M, Abbasi A, Khodadadi E. Comparison of canal cleansing time and pulpectomy success rate in deciduous molars by use of hand and rotary files. Dental Journal of Shiraz University of Medical Science. 2006;2:111-19.
[22] Musale PK, Mujawar SA. Evaluation of the efficacy of rotary vs. Hand in root canal preparation of primary teeth in vitro using CBCT. Eur Arch Paediatr Dent. 2014;15(2):113-20.
[23] Versluis A, Kim HC, Lee W, Kim BM, Lee CJ. Flexural stiffness and stresses in nickel-titanium rotary files for various pitch and cross-sectional geometries. J Endod. 2012;38(10):1399-403.
[24] de Arruda Santos L, de Azevedo Bahia MG, de Las Casas EB, Buono VT. Comparison of the mechanical behavior between controlled memory and super elastic nickel-titanium files via finite element analysis. J Endod. 2013;39(11):1444-47.
[25] Jeevanandan G, Govindaraju L. Clinical comparison of Kedo-S paediatric rotary files vs manual instrumentation for root canal preparation in primary molars: A double blinded randomised clinical trial. Eur Arch Paediatr Dent. 2018;19(4):273-78.
[26] Babaji P, Mehta V, Manjooran T. Clinical evaluation of rotary system over manual system in deciduous molars: A clinical trial. Int J Pedod Rehabil. 2019;4(1):13-16.
[27] Panchal V, Jeevanandan G, Subramanian EM. Comparison of instrumentation time and obturation quality between hand K-file, H-files, and rotary Kedo-S in root canal treatment of primary teeth: A randomised controlled trial. J Indian Soc Pedod Prev Dentistry. 2019;37(1):75-79.
[28] Ochoa-Romero T, Mendez-Gonzalez V, Flores-Reyes H, Pozos-Guillen AJ. Comparison between rotary and manual techniques on duration of instrumentation and obturation times in primary teeth. J Clin Pediatr Dent. 2011;35(4):359-63.
[29] Morankar R, Goyal A, Gauba K, Kapur A, Bhatia SK. Manual versus rotary instrumentation for primary molar pulpectomies-A 24 months randomised clinical trial. Pediatr Dent J. 2018;28(2):96-02.
[30] Lakshmanan L, Mani G, Jeevanandan G, Ravindran V, Ganapathi SE. Assessing the quality of root canal filling and instrumentation time using Kedo-s files, reciprocating files and k-files. Braz Dent Sci. 2020;23(1):01-07.
[31] Chonat A, Rajamani T, Ephraim R. Obturating Materials in Primary Teeth-A Review. Research & Reviews: Journal of Dental Sciences. 2018;6(1):20-25.
[32] Ranly DM, Garcia-Godoy F. Current and potential pulp therapies for primary and young permanent teeth. J Dent. 2000;28(3):153-61.
[33] Crespo S, Cortes O, Garcia C, Perez L. Comparison between rotary and manual instrumentation in primary teeth. J Clin Pediatr Dent. 2008;32(4):295-98.
[34] Sunitha B, Kiran KP, Puppala R, Kethineni B, Ravigna, Dandotikar DR. Resorption of extruded obturating material in primary teeth. Ind J Med Allied Sci. 2014;2(1):64-67.
[35] Divya S, Jeevanandan G, Sujatha S, Subramanian EMG, Ravindran V. Comparison of quality of obturation and post-operative pain using manual vs rotary files in primary teeth-A randomised clinical trial. Indian J Dent Res. 2019;30(6):904-08.
[36] Juliet S, Jeevanandan G, Govindaraju L, Ravindran V, Subramanian EM. Comparison between three rotary files on quality of obturation and instrumentation time in primary teeth-a double blinded randomized controlled trial. J Orofac Sci. 2020;12:30-34.
[37] Ghadge S, Katge F, Poojari M, Jain K, Patil D. Clinical evaluation and comparison of obturation quality using pediatric rotary file, rotary endodontic file and H file in root canal of primary molars: A double blinded randomized controlled trial. Int J Res Rep Dent. 2020;3(4):12-19.
[38] Ramezanali F, Afkhami F, Soleimani A, Kharrazifard MJ, Rafiee F. Comparison of cleaning efficacy and instrumentation time in primary molars: Two rotary instruments vs. Hand K-Files. Iran Endod J. 2015;10(4):240-43.
[39] Ramazani N, Mohammadi A, Amirabadi F, Ramazani M, Ehsani F. In vitro investigation of the cleaning efficacy, shaping ability, preparation time and file deformation of continuous rotary, reciprocating rotary and manual instrumentations in primary molars. J Dent Res Dent Clin Dent Prospects. 2016;10(1):49-56.
[40] Gupta S, Das G. Clinical and radiographic evaluation of zinc oxide eugenol and metapex in root canal treatment of primary teeth. J Indian Soc Pedod Prev Dent. 2011;29(3):222-28.
[41] Fuks AB, Papagiannoulis L. Pulpotomy in primary teeth: Review of the literature according to standardised criteria. Eur Arch Paediatr Dent. 2006;7(2):64-71.
[42] Rifkin A. The root canal treatment of abscessed primary teeth-A three to four year follow-up. ASDC J Dent Child. 1982;49(6):428-31.
[43] Garcia-Godoy F. Evaluation of an iodoform paste in root canal therapy for infected primary teeth. ASDC J Dent Child. 1987;54(1):30-34.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Mar 04, 2023
- Manual Googling: May 04, 2023
- iThenticate Software: Sep 16, 2023 (19%)

ETYMOLOGY: Author Origin

EMENDATIONS: 8

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Feb 17, 2023**
Date of Peer Review: **Apr 28, 2023**
Date of Acceptance: **Sep 20, 2023**
Date of Publishing: **Jan 01, 2024**