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ORIGINAL RESEARCH

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Comparative evaluation of clinical efficacy and volumetric changes in pulpectomized primary molars using hand K-file, ProTaper rotary file, and Kedo-SG blue file: an *in-vitro* cone beam computed tomography analysis

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Abstract

The accomplishment of a successful pulpectomy depends on multiple factors that involve targeted removal of the causative irritants and soft and hard tissue debris by mechanical and chemical means. Compare and evaluate the efficacy of canal preparation and volumetric filling using conventional files and two rotary file systems using cone beam computed tomography (CBCT). Thirty freshly extracted human primary second molars were randomly divided into three groups of 10 teeth each. After access opening and working length determination, pre-operative volume analysis was done using CBCT. The canals were then instrumented by either hand K-files, ProTaper rotary files or Kedo-SG Blue rotary files. Post-operative volume analysis was performed using CBCT. All the canals were obturated using Metapex and scanned again using CBCT. Mean values of the pre- and post-operative canal volumes were analyzed using one-way Analysis of Variance (ANOVA). Inter- and intra-group volumetric changes were analyzed statistically using a *post hoc* test. The mean difference in volume after canal preparation and obturation was the highest in the Kedo-SG Blue group, followed by the ProTaper group and the least in the hand K group ($p = 0.001$). Inter-group comparison showed statistically significant differences between the hand K group and ProTaper group ($p = 0.001$), the ProTaper group and Kedo-SG Blue group ($p = 0.001$), and the hand-K group and Kedo-SG Blue group ($p = 0.02$). The volume of preparation and obturation was the highest using Kedo-SG Blue, followed by the ProTaper file systems.

Keywords

Cone beam computed tomography; Post obturation volume; Primary molar; Rotary files

1. Introduction

The pediatric endodontic practice has undergone evolutionary modifications over the last decade with minimal retention of traditional steps. Preserving deciduous dentition until exfoliation, being the primary objective in pediatric dental practice, has long been an achievable target [1, 2]. Manufacturing of instruments used for canal preparation has undergone radical change from carbon steel to stainless steel and then finally to nickel titanium, which have been tested periodically since the early 90s [3–5]. The accomplishment of a successful pulpectomy depends on multiple factors that involve targeted removal of the causative irritants and soft and hard tissue debris by mechanical and chemical means [6].

Mechanical preparation of the root canals involves uniform and tapered preparation. The preparation is easier in straight canals than in curved and more tortuous canals, as in primary molars [7]. Designs with variable tapers, non-cutting safe ends, and different positions and angulations of cutting blades have paved the way for newer generations of file systems that have immensely affected the preparation of the root canals [8].

ProTaper file systems (Dentsply Sirona) have been introduced for root canal preparation in permanent dentition. Such file systems have also been used in primary teeth during pulpectomy, and they have shown variable results until the recent introduction of rotary files designed specifically for primary dentition. Kedo files (Kedo Dental) has reformed pediatric dental practice since its introduction in early 2017. The files were redesigned specifically for use in primary teeth with reasonable taper, flute design and cutting length. Its use in performing pulpectomy in primary teeth has exceeded the expectations of the treatment outcome for all dental practitioners.

However, recently introduced file systems must be tested for efficacy and efficiency to substantiate their clinical usage. So, the present *in-vitro* study aimed to compare and evaluate

the efficacy of canal preparation and volumetric filling using conventional files and two rotary file systems using cone beam computed tomography (CBCT).

2. Materials and methods

2.1 Selection of sample teeth

Freshly extracted human primary second molars were collected from the outpatient pediatric dental department. The teeth were extracted due to the following reasons: non-restorable crown structure, severe extraoral swelling, and when parents were not willing to preserve the tooth by performing pulp therapies. The inclusion criteria for the samples was zero or minimal physiologic resorption up to one-third of the root from the apex. Teeth with resorption of more than two-thirds root length and the presence of calcified canals led to the exclusion of the sample.

2.2 Sample selection and randomization

The study sample size was derived from a previous *in-vitro* study [9], with 95% power using G*Power analysis (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany; http://www.gpower.hhu.de/). The total sample size was determined to be 30 teeth.

2.3 Preparation of the teeth samples

All the teeth samples were cleaned by using ultrasonic scalers to remove any dirt, stain or calculus on the tooth surface. After the cleansing process, the teeth were stored in 0.5% sodium hypochlorite solution until their use in the *in-vitro* study. For standardization of the samples for canal preparation, only the mesiobuccal root of the primary second molars was considered for the study. A total of 30 teeth were collected, numbered and randomly divided into three groups of 10 teeth each. The entire procedure was performed by a trained pedodontist with 20 years of experience. Access opening of the primary second molars was performed using a small round carbide bur in a high-speed handpiece. Any remnant necrotic coronal pulp was amputated using a spoon excavator. A size #10 K-file was used to determine the patency of the mesiobuccal canal. After confirming the patency of the canals, the canals were irrigated using 0.9% normal saline through a 31-gauge irrigation needle. The working length was established by subtracting 1 mm from the visible length seen at the root apex.

2.4 Mounting of samples and pre-operative volumetric analysis

Pre-operative volume analysis was done using CBCT (Fig. 1). All the samples were mounted in a vinyl polysiloxane impression material (3M ESPE, GERMANY) (Fig. 2) to form a template that was prepared for reciprocating the position both in the pre- and post-operative volume analysis. To maintain the uniformity of the samples, they were arranged to ensure the teeth's mesial surface was on the right side, similar to the methodology from the previous study [1]. The samples were then subjected to light speed plus SCT scanner (Sagittal scanner, GE electricals, Milwaukee, MIL, USA) in axial, coronal and sagittal planes by an experienced operator who was blinded by the instrumentation sequence. Volume rendering and multiple planar volume reconstruction for root canal measurement were done using Advantage Windows Workstation Version V (GE System, Milwaukee, WI, USA). A constant thickness of 0.65 mm per slice and a constant spiral or table speed of 0.75 and 120 KVP (Kilovoltage peak) were used. The volume of all the samples was calculated from the canal orifice to 1 mm short of the apical fora.

2.5 Root canal instrumentation

The instrumentation of the selected teeth was performed by a single experienced pedodontist with expertise in utilizing manual and rotary instrumentation techniques.

Group A: The teeth samples were prepared using hand K-files (Mani, Tochigi, Japan). These hand K-files have an International Organization for standardization (ISO)-standardized 2% constant taper with a working length of 21 mm. The canals were prepared till the determined working length of each sample using no. 15, 20, 25 and 30 size hand K-files in consecutive sequences. The files were regularly wiped using wet gauze to remove tissue debris. With every increase in file size, the canals were irrigated using 0.9% normal saline to flush out the dentinal debris. Canal recapitulation was performed after each file was used.

Group B: The teeth samples were prepared using ProTaper rotary files (Dentsply Maillefer, Ballaigues, Switzerland) that have a progressive taper. The patency was rechecked using a #15 hand K-file, and then the ProTaper Sx (0.19/0.04; D0 diameter of 0.19 mm) file was used to instrument the first 3 mm beyond the orifice. ProTaper S2 (0.20 mm/0.02; D0 diameter of 0.20 mm) file was then used to complete the canal instrumentation up to the determined working length of the samples. Irrigation was performed using 0.9% normal saline to flush out the dentinal debris.

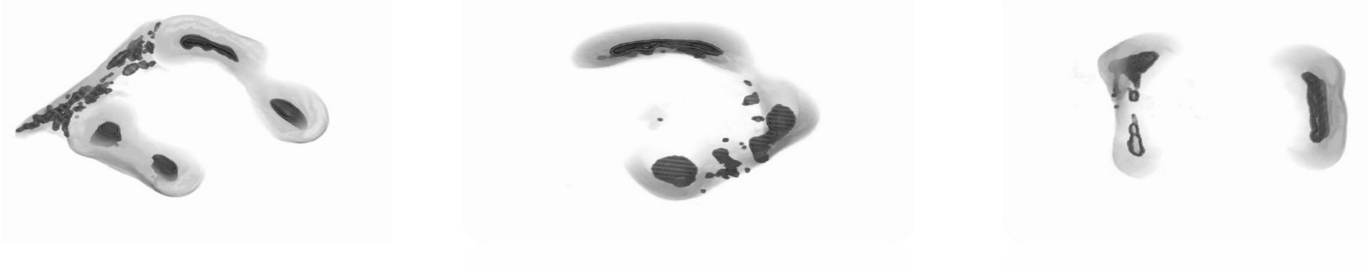
Group C: The teeth samples were prepared using Kedo-SG Blue rotary files (Kedo Dental, India) with a variably variable (VV) taper. A Kedo-SG Blue D1 (0.25/VV taper) file was used to instrument the canals up to the samples' determined working length. Irrigation was performed using 0.9% normal saline to flush out the dentinal debris.

2.6 Post-operative volumetric analysis

All the canals were then dried using paper points before subjecting to CBCT. The samples in all the groups were again placed in the same template in the same position and scanned similarly to the pre-operative volumetric analysis. Similar to the pre-operative volumetric analysis, the canal volume for each sample was measured from the canal orifice to 1 mm short of the apex (Fig. 3).

2.7 Obturation and post-obturation volumetric analysis

All the canals were obturated using Metapex (Meta BioMed, Cheongju, Korea), and entrance filling was provided using glass ionomer cement. The samples were placed back in the template, and the final scanning was done. An experienced



Group A: Hand K-file Group B : Protaper Group C : Kedo SG blue

FIGURE 1. Pre-operative volumetric analysis.

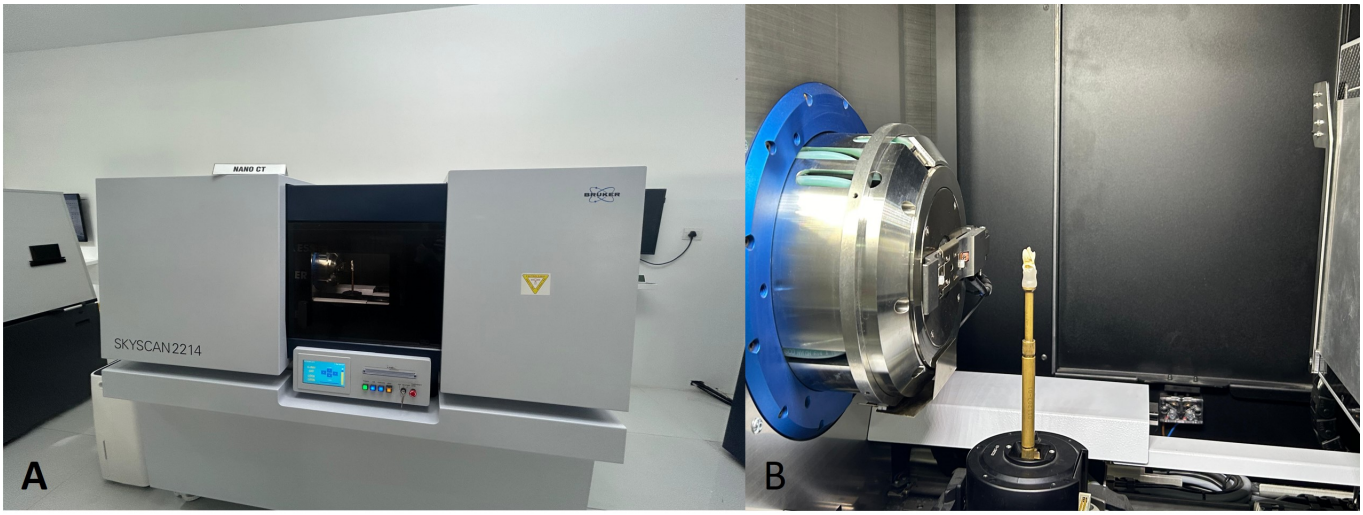


FIGURE 2. Mounting of the samples for analysis. (A) mounted samples on the scanner; (B) Samples mounted on vinyl polysiloxane impression material.

Group A: Hand K-file Group B : Protaper Group C : Kedo SG blue

FIGURE 3. Post-operative volumetric analysis.

radiograph analyst with eight years of expertise in the field, who was blinded to the methodology used in the present study, evaluated all the samples in the pre-operative, post-operative and post-obturation analyses using CBCT.

2.8 Statistical analysis

The Statistical Package for Social Studies version no. 22 produced by IBM, Illinois, Chicago, USA was used to arrange, tabulate and statistically analyze the gathered data. Mean values of the pre- and post-operative canal volumes after canal preparation, post-operative canal volumes after obturation, and the differences in canal volume of all the samples were analyzed using one-way ANOVA. Inter- and intra-group volumetric changes were analyzed statistically using a *post hoc* test. A *p*-value of less than 0.05 was considered statistically significant.

3. Results

The mean difference in volume after canal preparation was the highest in the Kedo-SG Blue group, followed by the ProTaper group and the least in the hand-K group (Fig. 1). Comparison within the groups showed highly statistically significant differences for all the file groups used ($p < 0.001$) (Table 1). Inter-group comparison showed statistically significant differ-

TABLE 1. Mean pre- and post-operative volumes before obturation and difference in volumes of canals prepared under each group of files used in the present study.

Files Group	Pre-Operative Volume Mean ± SD (cm^3)	Post-Operative Volume (before obturation) Mean ± SD (cm^3)	Volume Difference Mean ± SD (cm^3)	*p*-value
Hand-K	0.0050 ± 0.00050	0.0072 ± 0.00032	0.0022 ± 0.00037	0.001*
ProTaper	0.0048 ± 0.00037	0.0075 ± 0.00035	0.0027 ± 0.00065	0.001*
Kedo-SG Blue	0.0050 ± 0.00025	0.0083 ± 0.00044	0.0033 ± 0.00042	0.001*

**Statistically significant differences by Tukey's post hoc test. SD: Standard deviation.*

TABLE 2. Intergroup comparison of mean difference in volumes of canals prepared before obturation.

Comparison between groups (before obturation)	*p*-value
Hand-K *vs.* ProTaper	0.047*
Hand-K *vs.* Kedo-SG Blue	0.001*
ProTaper *vs.* Kedo-SG Blue	0.020*

**Statistically significant differences by paired t-test.*

TABLE 3. Mean pre- and post-operative volumes after obturation and difference in volumes of canals prepared under each group of files used in the present study.

Files Group	Pre-Operative Volume Mean ± SD (cm^3)	Post-Operative Volume (after obturation) Mean ± SD (cm^3)	Volume Difference Mean ± SD (cm^3)	*p*-value
Hand-K	0.0050 ± 0.0005	0.0064 ± 0.00035	0.0014 ± 0.00028	0.001*
ProTaper	0.0048 ± 0.00037	0.0070 ± 0.00018	0.0022 ± 0.00031	0.001*
Kedo-SG Blue	0.0050 ± 0.00025	0.0076 ± 0.00043	0.0026 ± 0.00033	0.001*

**Statistically significant differences by Tukey's post hoc test. SD: Standard deviation.*

ences between the hand-K group and the ProTaper group ($p = 0.047$) and the ProTaper group and Kedo-SG Blue group ($p = 0.02$) and highly statistically significant differences between the hand-K group and Kedo-SG Blue group ($p < 0.001$) (Table 2).

The mean difference in volume after obturation was the highest in the Kedo-SG Blue group, followed by the ProTaper group and the least in the hand-K group. Comparison within the groups showed highly statistically significant differences for all the file groups used ($p < 0.001$) (Table 3). Inter-group comparison showed highly statistically significant differences between the hand-K group and ProTaper group ($p < 0.001$) and the ProTaper group and Kedo-SG Blue group ($p < 0.001$) and statistically significant differences between the hand-K group and Kedo-SG Blue group ($p = 0.02$) (Table 4).

4. Discussion

The results of the present study suggest that rotary files had more preparatory canal volume than the hand file system. The Kedo-SG Blue file system had better canal preparation volume than the ProTaper file system. Post-obturation analysis also suggested a superior obturating volume in rotary file systems, especially with Kedo-SG Blue, when compared to the conventional hand file system. The results also showed that primary root canal space was well prepared using both the rotary files compared to conventional hand file systems. The majority of the previous studies supported this result since the introduction of the rotary endodontics concept in primary teeth [10, 11]. Kedo-SG Blue had the highest mean difference in the canal preparation volume compared to the ProTaper file system. This could be due to the shorter length and variable taper (4%–8%) noticed in the Kedo-SG Blue file system as compared to the ProTaper file system. This result contradicted the study done by Nabeeh *et al.* [12], which stated that hand files had the highest preparation followed by ProTaper and Kedo-S file systems. Studies by Swaminathan *et al.* [13], (2022) and Seema *et al.* [14], (2020) suggested minimal coronal preparation compared to apical preparation using the Kedo-S rotary file system. However, the results of the study performed by Swaminathan *et al.* [13], (2022) stated that although statistically not significant, there was more dentin removal using the Kedo-S file system than the MTwo file system.

The taper design of the file can influence the preparation of the canal [15]. Kedo-S rotary file systems using a VV taper

TABLE 4. Intergroup comparison of mean difference in volumes of canals prepared after obturation.

Comparison between groups (after obturation)	*p*-value
Hand K *vs.* ProTaper	0.001*
Hand K *vs.* Kedo-SG Blue	0.027*
ProTaper *vs.* Kedo-SG Blue	0.001*

**Statistically significant differences by paired t-test.*

(4%–8%) aided in improved coronal enlargement, thereby facilitating straight-line access and better flow of obturating material [16]. More specifically, the utilization of a 0.25 tip with a 4% taper file proves essential for achieving adequate canal preparation in the apical and middle thirds. Simultaneously, the use of a 6% taper file in the coronal one-third enhances the overall preparation of the canal [1, 15]. This could be the reason for better preparation in the Kedo-SG blue group.

Post-obturation analysis showed that the rotary file systems had better obturation volume when compared to the hand file system, which was similar to the previous published research [1]. This was due to the fact that rotary files prepared the canals uniformly in conical shape with a slight coronal flare and minimal apical preparation to enhance the flow of the obturating paste through the orifice and maintain dentin thickness in the radicular aspect [17]. Also, the highest statistically significant obturation volume was obtained using Kedo-SG Blue, followed by ProTaper and hand K-file systems. This result was similar to study done by Vaishali Naidu *et al.* [18], (2021) which showed minimal voids and better obturation volume of Kedo-SG Blue compared to Pro AF Baby gold and Pedo Flex file systems.

Various methods have been formulated to evaluate and assess the quality of canal preparation like sectioning, computed tomography (CT), CBCT and micro-CT [19]. Radiographic assessment is essential for validating the results of the performed study. Conventional radiographic techniques provide a two-dimensional view of a three-dimensional object, which would lack a complete piece of information in one of the planes. However, CBCT is a non-invasive, cost-effective reproducible radiographic tool for such assessment, which takes two-dimensional images at multiple angles to produce three-dimensional representation for better visual representation [20]. A recent systematic review comparing CBCT and micro-CT showed that there were no significant differences between both, and CBCT can be as accurate as micro-CT in terms of assessment canal morphology [21]. The current study thus uses this CBCT to perform a thorough assessment of canal preparation and obturation.

No clear guidelines or design have been provided by any professionals for its use in primary teeth [22]. Rotary file systems for permanent teeth have been suggested for use in primary teeth. ProTaper Nickel Titanium (Ni-Ti) rotary file systems were commonly suggested in many previous studies due to their progressive taper, which effectively prepared the canals of primary molars, and better flexibility compared to hand files to safely prepare the canals without breakage. However, the file's length and taper tend to be designed for the dimensions and taper of permanent teeth [15].

Kedo-S brand was the first rotary file system for preparing canals of primary teeth. With the VV taper design and the cutting length of the file designed specifically for the length of primary teeth, the Kedo-S file system tends to be an ideal rotary system for the mechanical disinfection of root canals [23]. Kedo-SG Blue, being heat treated with titanium oxide coating, is preferably super flexible and can efficiently prepare the tortuous ribbon-shaped canal space. However, its canal preparation would need to be assessed three-dimensionally to evaluate the obturation canal volume. Thus, a CBCT analysis was performed to evaluate the efficacy of both the rotary file systems. Obturating the prepared canal space will prevent the re-entry of contaminants and provide a three-dimensional fluid-tight seal, thus providing long-term success of the endodontic treatment [24]. Hence, the assessment of the obturation volume was one of the objectives of the present study.

Pediatric endodontic therapy requires a clinician to accomplish complete disinfection of the canals, eliminate the microorganisms, prevent the inflammation from progressing to periradicular tissues and spaces, and eventually favor periapical healing. A method commonly practiced to achieve this goal is chemomechanical preparation of the canal space that requires filing of the canals with intermittent use of irrigants [25]. Decades of use of hand instruments for proper biomechanical preparation has its own drawbacks. Curved, tortuous and ribbon-shaped canals of primary teeth tend to be underprepared due to the minimal flexibility of the stiff hand file systems that compromise the reach of the file in the apical regions. There would also be canal transportations and ledge formations in curved canals, which could be noticed along the concavity in the coronal aspects and along the convexity in the radicular aspect. With the concept of Barr *et al.* [26], these drawbacks were overcome by the use of rotary file systems in primary teeth [27]. The current study was thus designed to inspect the clinical efficacy and volumetric changes using hand files and two rotary file systems, one designed for permanent teeth and the other designed for primary teeth. The results suggest the use of Kedo-SG Blue can provide an effective and efficient method for better preparation and obturation in primary molars.

The present study's limitation is that the results are commonly attributed to the *in-vitro* setup used. However, clinical trials and *in-vivo* assessment of the quality of obturation could provide insight into the clinically relevant aspects. Apart from preparation and obturation volume analysis, canal centering ability, transportation, and uninstrumented regions, microc-

racks can also be assessed to obtain further knowledge of the mechanical aspects. The use of different tapers of the file systems could provide an overt expression of the results toward the more tapered file system. Also, the curvature of the roots was not standardized before the start of the study. This could also have influenced the study as the more curved canals could have had a minimal preparation and obturation volume due to unavoidable human errors.

5. Conclusions

The present study suggests higher preparation and obturation volumes using rotary file systems compared to hand K-file systems. The volume of preparation and obturation was the highest using Kedo-SG Blue, followed by the ProTaper file systems.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

SV—designed the research study, performed the research, analyzed the data, wrote the manuscript, reviewed it and edited it. The author contributed to editorial changes in the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

A signed written informed consent was obtained from the parents or guardians regarding the use of the extracted tooth for research purposes, which the institutional ethical committee also approved. The study was conducted in accordance with the Scientific research committee and approved by the Institutional Review Board of Jazan University Vide no CODJU-1706I.

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CONFLICT OF INTEREST

The author declares no conflict of interest.

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