ORIGINAL RESEARCH

Comparative Evaluation of Single Rotary File System and Sequential Multi-file Rotary Systems on Time for Biomechanical Preparation and Obturation Quality in Singlevisit Pulpectomy Protocol: A Double-blind Randomized Clinical Trial

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Abstract

Background: Single-visit pulpectomy (SVP) protocol with rotary files is highly recommended for the treatment of teeth with irreversible pulpitis. Various rotary endodontic files specially designed for use in the pediatric population are available. The aim is to clinically assess the parameters related to the time required for biomechanical preparation (T_{BMP}) and quality of filling using a single file system vs a sequential multi-file system in infected primary mandibular molars.

Materials and methods: A total of 45 infected primary molars were allocated to three groups (two experimental groups (n = 15) and a control group. The first experimental group was instrumented using NiTi K-Flex files, the second group with a single file rotary system with variably variable (VV) taper, and the third with a sequential multi-file system with constant taper. Biomechanical preparation time was recorded and standardized digital radiograph (RVG) were taken pre- and postinstrumentation. The data recorded was sent for statistical analysis.

Conclusion: There is a substantial reduction of T_{BMP} in primary molars using single file VV taper and multi-sequential file constant taper. Obturation time for all three file systems was comparable and there were no differences between the three file systems used (p > 0.05). Multi-sequential file constant taper files showed a higher probability of optimal obturations and minimal voids followed by NiTi "K-Flex" files and single file system but the difference was nonsignificant (p > 0.05). However, using a rotary in primary teeth results in better canal shape, and less T_{BMP} leading to a better quality of treatment in less time.

Keywords: Multi-file system, Pediatric rotary files, Primary tooth, Pulpectomy, Root canal obturation, Single file system. *International Journal of Clinical Pediatric Dentistry* (2023): 10.5005/jp-journals-10005-2685

INTRODUCTION

A pulpectomy is a procedure that is used to treat pulp-involved primary teeth, which involves extirpation of the infected pulp tissue, cleaning and preparing the root canal system further facilitating the obturation.¹ Biomechanical canal preparation is an important factor that determining the success of pulp therapy in irreversible pulpitis.² In the realm of pediatric endodontics, rotary instrumentation has taken a quantum leap. Biomechanical preparation with pediatric NiTi rotary files gained popularity in recent times. Instruments made of NiTi are two to three times more flexible than those made of stainless steel (SS). The ability of NiTi files to mechanically prepare curved channels by rotating them continuously was a game-changer.^{3,4}

A child's conduct in a dental setting is the product of interwoven relationships between personal qualities and situational and environmental circumstances. These are the most critical factors in the success of endodontic procedures. Treatment length is a critical situational component that contributes to a child's deteriorating behavior during or after dental treatment. Shorter sessions have been recommended as a way to improve cooperation among them. As a result, it's critical to strike a balance between the procedure's time, the number of sessions, and effective behavior control.^{5–8}

In vitro and in vivo investigations for canal preparation using rotary instrumentation in primary molars revealed shorter

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instrumentation times (IT) and more conical canal preparation, resulting in improved obturation quality (OQ). All of the aforementioned investigations, however, were conducted with a rotary file intended for use in permanent teeth.^{9–16}

Recently, for more efficient and convenient pulpectomy in primary teeth, exclusively designed pediatric rotary files with altered length, tip size, and taper have been proposed. With the

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Fig. 1: Hand files NiTi K-Flex



Fig. 2: Single file system ("Kedo-SG" blue files)

evolution of pediatric endodontics, exclusive pediatric rotary file systems like Baby Gold ("Pro AF") and Kedo-S, "Kedo-SG" blue, Neoendo Flex, and Pedo-Flex rotary files have been launched. With an increasing number of clinicians using different rotary systems in primary tooth pulpectomy, it is important to know which rotary system provides the best clinical outcomes for obtaining goodquality obturation.

Therefore, this study intends to assess the surface modification and taper on the clinical time required for biomechanical preparation (T_{BMP}) for biomechanical preparation, obturation, and OQ in primary molar pulpectomies.

MATERIALS AND METHODS

The current study was a parallel, double-blinded randomized control trial with an allocation ratio of 1:1:1. Consolidated Standards of Reporting Trials guidelines were followed and were approved by the Institutional Ethical Committee. The current study was conducted at Dr. D. Y. Patil Dental College & Hospital in Pune, Maharashtra, India, in the Department of Pediatric and Preventive Dentistry. Informed consent was taken prior to the start of the study.

A total of 45 children (aged 5–9 years) with pain as the major complaint and requiring pulpectomy were selected for the study. Healthy children exhibiting positive behavior (Frankl 3 and 4), and who show clinical and radiographic justification for performing pulpectomy procedures are included in the study.



Fig. 3: Sequential multi-file system ("Pro AF" Baby Gold)

Children who are very uncooperative, systemically ill, in conditions where single-visit pulpectomy is not possible or grossly mobile tooth or with swelling are not involved. Children who met the inclusion criteria participated in the trial and were assigned at random based on the generated sequence. Group I (control n = 15 teeth) used NiTi K-Flex files were used (Fig. 1). Group II (experimental group, n = 15) used blue surface-treated variably variable (VV) single-file rotary system (Kedo-SG blue files) (Fig. 2). In group III (experimental group, n = 15), gold-treated constant taper multi-file system (Pro AF Baby Gold files, Dentobizz, India) was used (Fig. 3).

Clinical Treatment Procedure

A trained pediatric dentist operated on all the patients and performed all the pulpectomy procedures. All the participants were blinded to the intervention. Single-visit pulpectomy (SVP) was carried out for each molar in all three groups. After applying topical anesthesia, local anesthesia (LA) was administered using an inferior alveolar nerve block for the selected mandibular molars. Under LA, a rubber dam was placed for the isolation of all the selected teeth (Fig. 2). Under LA and rubber dam isolation, excavation was performed (Fig. 4) and an access opening was done using round carbide bur (number 4) at high speed. Using a spoon excavator coronal pulp amputation was done. Canal location was done using DG16 explorer and initial pulp extirpation was done using K-files. Copious irrigation of the pulp chamber was done using 3% hypo and normal saline. After copious irrigation of the pulp chamber radiographic working length was determined. A digital radiograph (RVG) was taken using the bisecting angle technique at different angulations using standardized settings (70 kV, 0.4 mA, and 0.08 seconds).

Biomechanical Preparation

Group I (control group)—the instrumentation was performed using the conventional step-back method with NiTi K-Flex hand files from size 15 to 30. Group II— the root canals will be instrumented using single file VV taper (SG blue-Kedo) rotary files after using K-file (number 15) in primary molars. Group III—the root canals will be instrumented using a sequential multi-file system with constant taper (Pro AF Baby Gold) rotary files according to manufacturer recommendation after creating an initial glide path using file number 20 NiTi K-Flex.

Rigorous irrigation protocol was performed with 3% sodium hypochlorite and normal saline. Additionally, 17% of





Fig. 4: Difference in extent of fill with different file system

Table 1: Table showing different IT in various groups

File systems	Ν	Mean	F-value	Significance (p < 0.05)
K-Flex file manual IT	15	27.25	356.02	0.000*
Kedo-SG blue file rotary IT	15	14.19		
Pro AF file rotary IT	15	18.57		

*Highly significant

ethylenediaminetetraacetic acid-coated files were used during instrumentation. After drying the canals, Metapex obturation was performed. The coronal space was restored with type IX glassionomer cement and postoperative RVG was taken to assess the OQ.

Radiographic Evaluation

Immediate postoperative RVG was evaluated for the quality and length of root canal obturation. The quality of obturation was recorded by two blinded evaluators. Presence/absence of voids and level of fill were evaluated: The number represents the number of voids, with scores 0, 1, 2, 3, and 4—indicating the presence of 0, 1, 2, 3, and 4 voids.

The degree of obturation was recorded from rating A to D based on the subsequent criteria: optimal fill is given a score of C, while if there is extrusion of material beyond the apex, then a grading of D is given. Obturation time was also calculated for each group separately. Two independent examiners evaluated the quality of obturation and gave the scoring criteria. The interexaminer reliability was examined with Cohen's κ statistics.

Statistical Analysis

Descriptive statistics percentage analysis was done followed by "one-way analysis of variance" and "Pearson's Chi-squared test" to find the level of significance between the three groups.

RESULTS

Instrumentation Time (IT)

Time spent on instrumentation was noted down for all three groups in minutes. Instrumentation with "K-Flex" files (group I) took a minimum of 24.42 minutes and a maximum of 29.53 minutes. The mean duration was 27.25 minutes. Similarly, the Kedo-SG group (group II) took a minimum of 12.43 minutes and a maximum of 16.11 minutes. The mean duration was 14.19 minutes. Pro AF Baby Gold files (group III) took a mean time of 18.57 minutes, with a minimum of 17.20 minutes and a maximum of 21.49 minutes. The IT for all three groups are given in Table 1. There was a significant difference in the length of time taken for instrumentation by "K-Flex" file, Kedo-SG blue, and Pro AF. In the *post hoc* Tukey HSD test, the *p*-value of 0.05 revealed a substantial difference in the K-Flex file (group I), Kedo-S File (group II), and Pro AF file (group III). Kedo-SG blue rotary instruments took the minimum amount of time to instrument, followed by Baby Gold ("Pro AF") files, while "K-Flex" files took the most time using the manual method. The difference in time for biomechanical preparation between the three groups is shown in Table 1 and Figure 4.

Quality of Obturation

Radiographs (RVG) were examined for length of obturation following instrumentation with all three files and it was found that material extrusion beyond the apex was seen in 23.6% (13/55) of the canals instrumented with "K-Flex" files, 12.3% (7/57) with "Kedo-SG" blue and 13.8% (8/58) with "Pro AF" Baby Gold files. Optimally filled canals were seen in 65.5% (36/55) of the cases instrumented with "K-Flex" files, 78.9% (45/57) with "Kedo-SG" blue, and 8.6% (5/58) with "Pro AF" Baby Gold files whereas more than half but less than optimal fill was found in 9.1% (5/55) of canals instrumented with "K-Flex" files. 8.8% (5/57) and 8.6% (5/58) canals were less than optimally filled with canals instrumented with "Kedo-SG" blue and "Pro AF" Baby Gold files, respectively. Statistical analysis revealed no significant differences between the three groups. Both Pro AF files and "Kedo-SG" blue files had a similar number of canals that had optimal filling; however, "K-Flex" files had the maximum number of canals that had material extrusion beyond the apex. The canals were then evaluated according to the criterion for the presence of voids for all three groups, statistical analysis for the presence of voids in obturation revealed no significant differences. Instrumentation using Pro AF files found the most canals with no voids 31.1% (53/58), followed by "K-Flex" files 29.2% (50/56), and "Kedo-SG" blue files

Table 2: Table showing obturation quality times in various groups

File systems	Ν	Mean	F-value	Significance (p < 0.05)
K-Flex file manual obturation time	15	5.31	2.530	0.092
Kedo-SG blue file rotary obturation time	15	4.84		
Pro AF file rotary obturation time	15	4.75		



Fig. 5: Difference in the number of voids with different file systems

25.1% (43/57). Kedo-SG blue 5.8% (10/57) had the most single voids, followed by Pro AF files at 2.9% (5/58) and "K-Flex" files at 1.8% (3/36). Two voids were not present in the canals instrumented by Pro AF files, while an equal number were observed in both Kedo-S 1.8% (3/57) and K-files 1.8% (3/56) (Table 2 and Fig. 5).

DISCUSSION

Advanced or extensive dental caries necessitates intervention, and pediatric dentists are presented with treatment choices after appropriate diagnosis. Treatment options include pulpotomy, pulpectomy or extraction depending on the progression of the infection. Pulpectomy procedures necessitate the removal of inflamed tissue throughout the root canal system, mostly necrotic nonvital pulp.^{17,18} This present study mainly aims to evaluate two different file systems (single file vs multi-file systems) clinically in terms of T_{BMP} and quality of obturation.

Single File System

The "Kedo-SG" has three different file systems for different purposes (D1, E1, and U1). The E1 file has a tip diameter of 0.30 mm and is utilized for molar canals that are wider. The U1 file has a tip diameter of 0.40 mm and should be used on deciduous anterior teeth. When utilizing these files, a low-speed constant torque handpiece should be used. The optimal speed is 150–300 rpm, with a torque of 2.2–2.4 N. The canals should be fully lubricated and irrigated before using the "Kedo-SG" blue file.

Multi-file System (Baby Gold "Pro AF" File)

Baby Gold file (Dentobizz) is made up of five files consisting of NiTicontrolled memory wire that is flexible but has constant tapering at 4–6%. It is advised to utilize "Pro AF" Baby Gold rotary files at 250–300 rpm in a clockwise rotation and 2.0–2.2 N torque. Baby Gold ("Pro AF") rotary files should only be used in primary canals that are properly lubricated and irrigated.

The current study represents scalable differences in IT between rotary and manual techniques. Kedo-SG blue rotary files required the least amount of time to instrument, followed by Baby Gold ("Pro AF") files, while "K-Flex" files took the greatest time. These findings were similar to the study done by Sruthi et al.¹⁹ wherein they compared the T_{BMP} of "Kedo-SG" blue, Kedo-SH and reciprocating hand k file and found the least T_{BMP} with "Kedo-SG" blue. Lesser T_{BMP} needed by the rotary instrument when compared to hand files was noted by Ochao-Romero et al. in 2011,¹⁵ and Govindaraju et al. in 2017.¹¹ Similarly, Jeevanandan and Govindaraju²⁰ compared the T_{BMP} between Kedo-S rotary file and Hand K files and found a significant reduction in T_{BMP} using rotary files in primary molar teeth. Other studies that support the above-mentioned findings include Katge et al.,²¹ Babaji et al.,²² Panchal et al.,²³ Priyadarshini et al.,²⁴ and Kalita et al.²⁵ However, a recent systematic review by Panchal et al.²⁶ concluded that depending on the instrumentation system and procedures using rotary instruments have the same cleaning efficiency as manual files. Another systematic review by Panchal et al.²⁶ compared clinical and radiographic success between hand files and rotary files in primary teeth and concluded that both file systems had comparable success rates. Nevertheless, using a rotary in primary teeth leads to better shaping of canals, resulting in a higher quality of treatment in less time. The use of rotary files reduces dexterity and hence increases operator effectiveness. This could be a clarification for the shorter IT, and could favorably impact the child's conduct in the dentist chair. In the present study, the two rotary systems differed significantly in terms of IT, with the "Kedo-SG" blue system requiring the least amount of time. The lesser time required is most likely due to the reduced number of instruments. Recently two studies conducted by Waly et al.²⁷ and Shah et al.²⁸ in 2021 compared the T_{BMP} of "Pro AF" Baby Gold files, Kedo-S files, and hand K files and concluded that Kedo-S files require less time when compared to other two file systems with results being statistically significant. Fewer studies have been conducted evaluating the T_{BMP} of hand NiTi "K-Flex" files. A study was conducted by Tyagi et al.²⁹ which compared NiTi "K-Flex" file, "Pro AF" Baby Gold files, and wave one gold reciprocating file. Results showed that the mean $\rm T_{\rm BMP}$ for hand NiTi "K-Flex" files were significantly higher than the other two groups. In order to avoid the above-mentioned iatrogenic errors caused by SS hand files, Niti "K flex" hand files were included in the present study, keeping the same NiTi metallurgy for all three groups.

When compared to the Kedo-S File rotary system, instrumentation using the Pro AF rotary system needed the least time for obturation, while obturation using "K flex" files required the most time using the manual technique. Results revealed no significant difference between the "K flex" file group (group I) and the rotary systems - Kedo-S (group II) and Pro AF (group III). Results on similar lines were noted by Makarem et al.³⁰ and Gomes et al.³¹ On the contrary, notable differences between the rotary and manual instrumentation were noted by Ochao-Romero et al. 2011,¹⁵ Tyagi et al.,²⁹ Babaji et al.,²² and Shah et al.²⁸ where the obturation time was less with rotary instrumentation.



Several factors influence the success of pulpectomy. The length of the obturation is a significant consideration. According to Coll and Sadrian,³² pulpectomies that were filled short or optimally had a considerably higher success rate (p = 0.011) than overfilled canals. In deciduous teeth, Yacobi et al.³³ found that underfilled canals failed much more frequently than optimally filled canals. A recent research by Jeevanandan et al.³⁴ assessed the quality of obturation and its influence on postoperative pain during follow-up and found that optimally filled canals had less postoperative pain than overfilled and underfilled canals. Hence, optimal canal filling ensures greater pulpectomy success. It has also been stated by Mortazavi and Mesbahi,³⁵ and Garcia-Godoy³⁶ that extruding paste beyond the apex of iodoform is acceptable because it resorbs within 2 weeks. Also, the quality of obturation was assessed with digital RVG which aids in obtaining an image of high quality while exposing patients to minimum radiation.^{37,38}

Statistical analysis found no significant differences between the three groups (i.e., rotary vs manual) based on the degree of canal fill. Both the Pro AF and "Kedo-SG" blue files exhibited a comparable number of canals with optimal filling; however, the "K-Flex" files had the most canals with material extrusion beyond the apex. Similar results were noted by Govindaraju et al., Jeevanandan and Govindaraju, Sruthi et al., and Shah et al. On the other hand, significant differences between rotary and manual instrumentation were observed in the studies conducted by Ochao-Romero et al.,¹⁵ Makarem et al.,³⁰ Robia,³⁹ Jeevanandan and Govindaraju, and Divya et al.⁴⁰ However, a recent cone-beam computed tomographic study conducted to evaluate the extent of fill by Vaishali Naidu et al. showed result contradicting to the present study wherein "Kedo-SG" blue files had the most optimally filled teeth with the fewest voids, followed by "Pro AF" Baby Gold and "Pedo flex."⁴¹

Another criterion for determining the effectiveness of obturation is the presence or absence of voids in the obturation. The presence of voids may be associated with posttreatment failures.^{38,42-44} A procedural error could compromise the ability to clean and shape canals, resulting in an incomplete or less-than-optimal filling in the canal itself, which could compromise treatment success. The presence of moisture within the canals can also lead to the creation of voids. Therefore, in the present study, voids were evaluated for their presence or absence followed by postoperative radiograph.

Ideally, optimal filling of the canal with the least number of voids should be aimed for a successful treatment.⁴⁵ In our study, the Baby Gold ("Pro AF") group had minimal voids (group III), followed by "K-Flex" files (group I) and "Kedo-SG" blue -files (group II). Statistical analysis for the presence of voids in obturation found no significant differences between the three groups. This was in accordance with the study by Shah et al.²⁸ The results were in agreement with Makarem A et al. where the number of voids was lesser when canals were prepared with rotary systems.³⁰

CONCLUSION

The results of our study elicit that the T_{BMP} in primary molars is lowest using single file VV taper and multi-sequential file constant taper. Obturation time for all three file systems was comparable, and no differences were observed. The sequential multi-file system showed a maximum number of optimal obturations, but the difference was not statistically significant. However, using a rotary in primary teeth results in better canal shape, and less T_{BMP} leading to a better quality of treatment in less time hence should be considered as the standard of care for treatment in pediatric endodontics.

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