



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

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Authors' contributions

This work was carried out in collaboration among all authors. Author SG designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors FK and MP managed the analyses of the study. Authors DP and KJ managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Aim: This study was conducted to evaluate and compare extent and quality of obturation in root canal of primary molars with Pediatric rotary file (Prime Pedo™), rotary endodontic file (Protaper Universal™) and conventional H files using photo stimulated phosphor plates.

Study Design: Randomized controlled trial.

Place and Duration of Study: The study was conducted in the Department of Pediatric and Preventive Dentistry at Terna Dental College, Navi Mumbai between February 2019 to June 2019.

Methodology: A total of 45 primary mandibular molars were randomly divided into 3 groups. Instrumentation was done in Group 1 with Pediatric rotary file (Prime Pedo™), Group 2 with rotary

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endodontic file (Protaper Universal™) and in Group 3 with H files. Irrigation was done with 10 ml sodium hypochlorite and 20 ml saline followed by drying with paper points and obturation using endoflas with a motor driven lentulospiral. Post-operative radiographs taken using photo stimulated phosphor plates were assessed by a blinded examiner and scored as underfilling, optimal or overfilling. Voids were assessed as present or absent. Scores obtained were analysed statistically using Chi square test.

Results: On comparison of the extent of obturation, maximum number of mesial canals instrumented with pediatric rotary files (96.7%) were optimally filled, followed by rotary endodontic file (83.3%) and H files (63.3%). The difference between three groups was statistically significant (P=0.026). 96.2% of distal canals instrumented with pediatric rotary files were optimally filled followed by 92.3% with rotary endodontic files and 84.6% with H files. However, no statistical difference was found (P=0.331). Minimal number of voids were observed with both pediatric rotary file and rotary endodontic files as compared to H files (P=0.012).

Conclusion: Pediatric rotary files resulted in better extent and quality of obturation as compared to Protaper Universal™ and conventional H files.

Keywords: H files; obturation; pediatric rotary file; pulpectomy; prime pedo; protaper universal.

1. INTRODUCTION

Pulpectomy is the treatment of choice for symptomatic irreversible pulpitis in primary teeth [1]. Success of endodontic procedure depends on effective chemo mechanical preparation [2]. Hand instrumentation is one of the conventionally used method of instrumentation [3]. Advent of rotary instrumentation has resulted in faster and efficient instrumentation [4]. The properties of super elasticity and shape memory exhibited by Nickel-Titanium files have proven beneficial for root canals of permanent teeth.

Primary molars have varying anatomy as compared to permanent molars like widely divergent curved roots with thinner dentinal walls [5]. Studies in the literature have evaluated the efficacy of rotary files designed for permanent teeth in primary molars [6,7,8]. But considering the anatomical differences in root canals of primary molars, pediatric rotary files have been developed. These files have shorter length which provides operator ease of working in children.

Prime Pedo™ rotary files are the pediatric rotary files used in this study. These files are heat treated, have shorter length, controlled memory and 6% taper. Controlled memory is a property of Nickel Titanium files which provides superior flexibility and fatigue resistance [9]. This property can be beneficial in curved canals of primary molars.

The success of the primary root canal treatment depends on various factors such as good chemo-mechanical preparation, type of obturating material used and achievement of a good hermetic seal with minimum voids.

Extent and quality of obturation is one of the factors determining success of pulpectomy [10]. There are few studies in the literature which have evaluated the extent and obturation quality using pediatric rotary files. Hence, the aim of this study was to compare the extent and quality of obturation using Prime Pedo™, Protaper Universal™ and H files in root canals of primary mandibular molars.

2. MATERIALS AND METHODS

2.1 Study Setting, Study Design, Ethical Considerations

During various phases of study, CONSORT guidelines for planning and reporting clinical trials were followed [11] (Fig. 1).

2.2 Sample size

Sample size of n=45 primary mandibular molars was calculated in concordance to results from a previous study through G* power software (version 3.0.10) with alpha at 0.05 and 80% power of study [12]. 45 primary mandibular molars were randomly divided using sequentially labelled opaque envelopes in to three groups with 15 primary mandibular molars in each group.

2.3 Methodology

In Group 1, instrumentation was done with Prime Pedo™ rotary files. In Group 2, Protaper Universal™ rotary files and in Group 3 conventional H files were used for instrumentation of primary root canals.

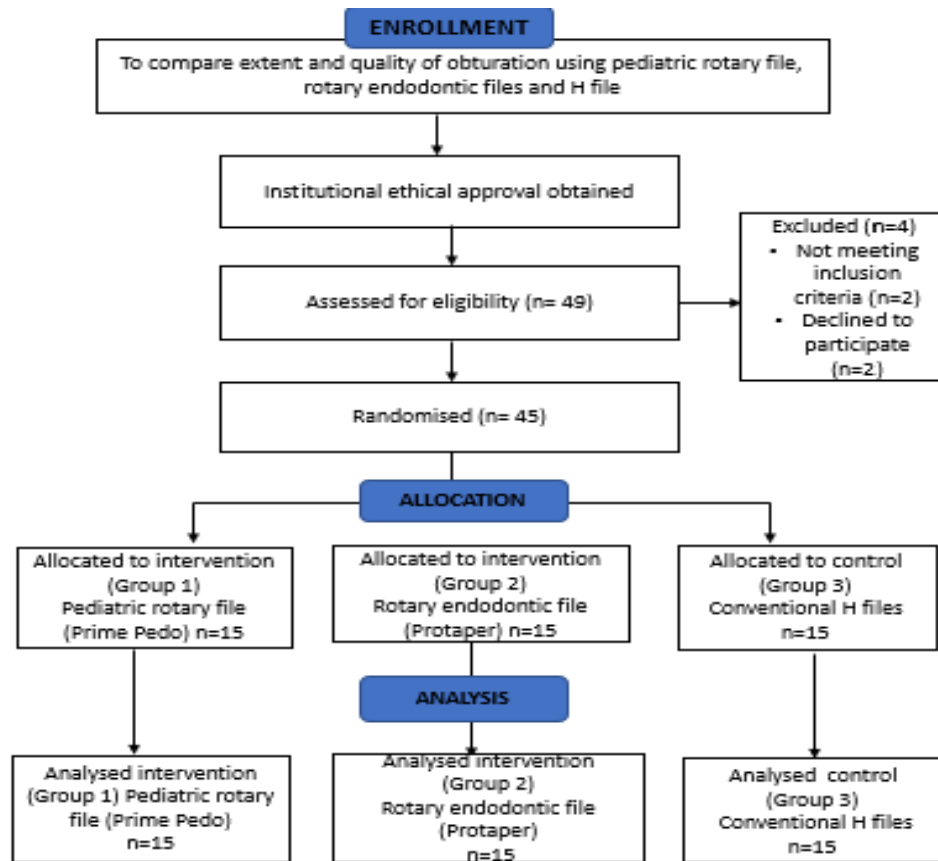


Fig. 1. Consort guidelines for planning and reporting clinical trials

A total of 49 children were assessed for eligibility out of which 45 children aged 5-9 years with Frankl Behaviour rating 3 and 4 were included in the study. Primary mandibular molars with clinical signs of irreversible pulpitis were included in the study. Radiographically the molars had deep occlusal or proximal caries involving enamel, dentin and pulp with at least two third of root intact.

Teeth which were non restorable, having furcal radiolucency, sinus opening, pathologic external or internal resorption or severe mobility were excluded from the study. All treatments were performed in a single visit by the same operator. Participants, assessing observer and analyst were blinded with regard to technique of instrumentation used in each group.

Pulpectomy was performed on the selected molar using the following technique: Local anaesthesia was administered using 2% lignocaine with adrenaline in concentration of

1:80,000. Rubber dam isolation was done in all the samples. The decayed tissue was removed and an access opening was made using a BR-46 (Mani Inc. Japan) round bur at high speed. Endo Z bur (Dentsply Sirona Inc. United States) was used for deroofting the pulp chamber. Working length was determined by radiographic method using a no. 10 K file which was placed 1 mm short of apex. Patency of canal was established with a 10 K file till the radiographic apex. Instrumentation was carried out in all three groups according to manufacturer's instructions.

Group 1: Instrumentation was done with Prime Pedo™ rotary files (Sky International Enterprises, India) using an Endo-mate DT (NSK, Nakanishi, Japan) hand piece at speed of 300 rpm and a torque of 2.4 N/cm as recommended by the manufacturer. Prime Pedo™ file system includes: Starter- 8% taper of 16 mm length, P1- (#15) 6% taper, 18 mm P2- (#25) 6% taper of 18 mm length and endosonic file- 2% taper 18 mm.

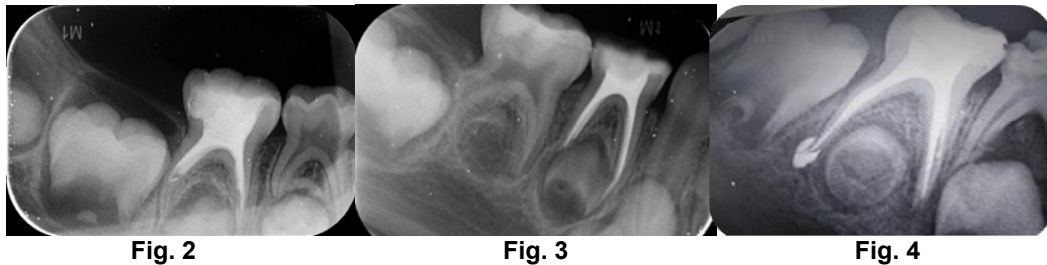


Fig. 2. Underfilling- Canals filled more than 2 mm short of apex
Fig. 3. Optimal- Canals having Endoflas ending
Fig. 4. Overfilling- Canals showing Endoflas outside the root

Crown down technique of instrumentation was used for biomechanical preparation. Orifice enlargement was done with starter file. Then P1 file was used in mesial canals. P2 file was used in distal canals. P1 or P2 files were used for preparation up to apical third of root canal. Endosonic file was used for apical preparation [9].

Group 2: Instrumentation was done using crown down technique with Protaper Universal™. SX file was used for orifice enlargement followed by S2 file. Technique of instrumentation followed was according to study by Lin CP and Katge F [13,7]. Files used were SX- 3.5% taper, 19 mm and S2- 4% taper, 21 mm.

Group 3: The canals were instrumented with H Files (Mani Inc, Japan) using in and out filing motion. Step back technique was used with file of size 15 to 30 in an ascending order [3].

Intermittent irrigation was done with 10 mL of 3% NaOCl. Final irrigation was done with 2 ml of saline. For all the three groups, the canals were dried with paper points. After this obturation was done using endoflas with rotary held lentulospiral at 10,000 rpm.

2.4 Data Collection, Evaluation Criteria

Postoperative radiographs were taken by photo stimulated phosphor plates. The digital images so obtained were used to grade the quality and extent of obturation using modified Coll and Sadrian criteria [10].

- Underfilling- Canals filled more than 2 mm short of apex (Fig. 2).
- Optimal- Canals having Endoflas ending at the radiographic apex or up to 2 mm short of apex (Fig. 3).

- Overfilling- Canals showing Endoflas outside the root (Fig. 4).

Voids were graded as present or absent. This grading was done by a blinded examiner. The scores so obtained were tabulated and analysed statistically.

2.5 Statistical Analysis

The statistical analysis was done using SPSS software version 17.0. (Chicago, SPSS Inc). Analysis of extent and quality of obturation and voids was done by Chi-square test with significance level at $P < 0.05$.

3. RESULTS

3.1 Demographic Characteristics

The demographic details of samples are presented in Table 1, there was an equal distribution of the samples with respect to age, number and type of canals in all the three groups.

3.2 Extent of Obturation

With respect to extent of obturation in mesial canals of Group 1 (Prime Pado™), 96.7% canals were optimally filled. 3.3% canals were underfilled while no canals showed overfilling. In distal canals 96.2% canals were optimally filled, 3.8% canals were overfilled and no canals were underfilled.

In Group 2 (Protaper Universal™), 83.3% mesial canals were optimally filled. 13.3% of mesial canals were underfilled while 3.3% mesial canals were overfilled. In distal canals, 92.3% canals were optimally filled, 7.7% canals were overfilled and no canals were underfilled.

Table 1. Descriptive data of samples included in study

Groups	Sample	Canals		Mean age	Female	Male	Primary mandibular first molar	Primary mandibular second molar
		N	Mesial					
Pediatric rotary file	15	30	26	5.42	8	7	3	12
Rotary endodontic file	15	30	26	5.67	9	6	4	11
H files	15	30	26	5.73	7	8	3	12

In Group 3 (H files), 63.3% mesial canals were optimally filled. 30% mesial canals were underfilled while 6.7% mesial canals were overfilled. In distal canals, 84.6% canals were optimally filled and 7.7% canals were overfilled and underfilled respectively.

Prime Pedo™ rotary files showed significantly higher number of optimally filled canals as compared to Protaper Universal™ and H files in mesial canals ($P = 0.026$). In distal canals no significant difference was found between three groups ($P = 0.331$) (Table 2).

3.3 Voids in Obturation

On comparison of voids between three groups, Prime Pedo™ and Protaper Universal™ rotary files displayed significantly lesser number of voids in obturation as compared to H files (Table 3).

4. DISCUSSION

Pulpectomy is a common endodontic procedure for teeth with irreversible pulpitis [1]. One of the goals of pulpectomy procedure is to obtain an optimally filled obturated canal with no voids [10]. Studies in literature have evaluated the extent and quality of obturation with rotary files designed for permanent teeth [5,6,7]. The use of rotary files for pulpectomy in primary teeth was advocated by Barr [4]. However, as there are morphological variations in root canals of primary molars, rotary files designed for primary teeth have been developed [8]. One such file used in this study is Prime Pedo™. This study evaluated the efficacy of these files in terms of the extent and quality of obturation and compared it with the adult rotary files and conventional H files. Hence the aim of study was to evaluate and compare the extent and quality of obturation using Prime Pedo™, Protaper Universal™ and conventional H files.

Table 2. Comparison of extent of obturation in mesial and distal canals

Type of canals	Extent of obturation	Under fill	Optimal fill	Over fill	Pearson Chi square value	P
Mesial	Pediatric rotary file	1 (3.3%)	29 (96.7%)	0 (0.0%)	11.082	0.026*
	Rotary endodontic file	4 (13.3%)	25 (83.3%)	1 (3.3%)		
	H files	9 (30.0%)	19 (63.3%)	2 (6.7%)		
Distal	Pediatric rotary file	1 (3.8%)	25 (96.2%)	0 (0.0%)	4.597	0.331
	Rotary endodontic file	2(7.7%)	24 (92.3%)	0 (0.0%)		
	H files	2(7.7%)	22 (84.6%)	2 (7.7%)		

Table 3. Comparison of voids in obturation in mesial and distal canals

Groups	Voids		Pearson Chi square value	P
	Present	Absent		
Pediatric rotary file	0 (0.0%)	15 (100.0%)	8.780	0.012*
Rotary endodontic file	0 (0.0%)	15 (100.0%)		
H files	4 (26.7%)	11 (73.3%)		

The extent and quality of obturation depends on factors like type of teeth, the amount and type of irrigant used, the obturating material and the method of obturation. All of these factors were standardized for the three groups to eliminate their effect on the extent and quality of obturation. In the present study mesial and distal canals were evaluated separately for the extent and quality of obturation. H files showed the lowest percentage of optimally filled mesial and distal canals as compared to Protaper Universal™ rotary files and Prime Pedo™ rotary files. H files have a single helix, tear drop shaped cross section. It has reduced central mass and thereby weakened structure. It has 2% taper which does not provide more conical enlargement [14]. This would have resulted in limited distribution of obturating material. Also, H files displayed voids in obturation. These voids provide pathways for leakage allowing bacterial reinfection [15].

Protaper Universal™ rotary files also displayed high percentage of optimally filled mesial and distal canals as compared to H files but lower percentage as compared to Prime Pedo™. Protaper Universal™ files have a triangular cross section which imparts superior cutting efficiency to these files [16].

Prime Pedo™, pediatric rotary files showed highest percentage of optimally filled mesial canals as compared to Protaper Universal™ and H files. This can be attributed to better cleaning efficacy of root canals by these files [9]. Prime Pedo™ rotary files have controlled memory which helps in centring of files and follow the anatomical curvature of root canals. Endosonic file with 2% taper allows for conservative apical preparation and better cleaning of canals. Increased taper of files provides more conical preparation of canals which allows better flow of irrigating solution. This would have attributed for better quality of obturation.

On comparison of extent of obturation in distal canals no significant difference was found between all the three groups. This could be due to larger size of distal canals as compared to mesial canals. Superior quality of obturation and optimal filling were observed on instrumentation with pediatric rotary files as compared to H files in this study. The results of this study are similar to that by Jeevnandan G in 2018 and Panchal V in 2018 who showed significantly better extent and quality of obturation with Kedo S rotary files as compared to hand instrumentation due to

modified progressive taper, shape memory and super elasticity [17,18]. A study done by Morankar R showed no significant difference in obturation quality between rotary and hand instrumentation [19].

Endoflas has certain advantages like resorption limited to the extraradicular region without washout of materials in the canal [20]. Hence, it was used as an obturating material in this study. Distribution of obturating material is influenced by method of obturation. Sigurdsson et al. reported that lentulospiral presented best results when compared to endodontic file, syringe and lentulospiral [21]. In a study by Walia T superior quality of obturation with few voids were seen with lentulospiral as compared to pressure syringe [22]. Hence, motor driven lentulospiral was used with stopper at 1 mm short of radiographic apex at 1000 rpm in this study.

Photo stimulated phosphor plates allow for high quality and consistent digital images. So, they were used in this study. The primary advantage is reduction in exposure, wider dynamic range and lower spatial resolution as compared with direct sensors and film [23]. In the present study, evaluation of quality of obturation was done radiographically. As radiographs provide two-dimensional view, the exact dimension and location of voids cannot be measured. This could be a potential limitation of this study. In a study by Dandashi, voids were measured with the help of anterior/posterior and lateral radiographs. However, it was an *in vitro* study and multiple views were taken [24]. As this was a clinical study, multiple views were not possible owing to increased risk of exposure to patients. Cone beam computed tomography provides a three dimensional view of the root canal anatomy but its use is recommended only when conventional radiographs are ineffective in revealing the anatomy. The Image Gently in Dentistry campaign which focuses on radiation safety in pediatric maxillofacial radiology suggests the use of radiographic imaging based on the concepts of justification for use and reduction of radiographic exposures as low as diagnostically acceptable (ALADA) [25].

A long term clinical and radiographic follow up is required to assess the clinical and radiographic success of the pulpectomy procedure performed using different file systems and obturating materials.

5. CONCLUSION

According to the results of this study, it can be concluded that instrumentation with Prime Pedo™ rotary files resulted in better extent of obturation as compared to Protaper Universal™ and conventional H files. Prime Pedo™ and Protaper Universal™ rotary files displayed superior quality of obturation as compared to conventional H files.

CLINICAL SIGNIFICANCE

The use of these files will offer advantage to clinician such as shorter length, controlled memory and superior instrumentation resulting in good quality of obturation.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT AND ETHICAL APPROVAL

The study was conducted in the Department of Pediatric and Preventive Dentistry. The design of study was a randomised controlled trial. Ethical approval was obtained from Institutional Review Board (IRB). Written informed consent was taken from the parent/ guardian of children who participated in the study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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