Comparative Evaluation of Cleaning Efficiency and Apical Extrusion of Debris Using Two Pediatric Rotary Endodontic Files: An *In Vitro* Study

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ABSTRACT

Aim and objective: Apical extrusion of debris and cleaning efficacy in primary root canal treatment has not been well elucidated by using specialized pediatric rotary endodontic files. The purpose of this study is to compare the amount of apically extruded debris and cleaning efficacy during the preparation of primary molar root canals using Pro AF Baby Gold and Kedo-S pediatric rotary files.

Materials and methods: Twenty extracted primary molar teeth were assigned randomly to two groups (n = 10 teeth for each group), injected with Indian Ink and instrumented using Kedo-S and Pro AF Baby Gold pediatric rotary files, respectively. The apically extruded debris was collected and dried in pre-weighed using Eppendorf tubes. The dry weight was calculated by subtracting the preoperative weight from the postoperative weight. The cleaning efficacy was evaluated after the diaphanization process. Statistics: Data were analyzed statistically using the independent sample *t*-test.

Results: The amount of apically extruded debris was significantly less for the Pro AF Baby rotary files group compared to the Kedo-S rotary files group (p < 0.05). Cleaning efficacy was significantly better with Pro AF Baby Gold when compared to Kedo-S rotary files in the apical region of the tooth.

Conclusion: All instruments caused apically extruded debris in primary teeth. Pro AF baby Gold files can be used with less apical extrusion of debris. Cleaning efficacy was shown to be better with the Pro AF Baby Gold pediatric rotary endodontic file.

Keywords: Apical extrusion of debris, Cleaning efficacy, Kedo-S, Pediatric rotary endodontic files, Pro AF baby gold.

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INTRODUCTION

Primary teeth with signs and symptoms of irreversible pulpitis and also pulpal necrosis are indication for root canal therapy.¹ Hand instrumentation is a traditional approach to perform an endodontic procedure. Although a conventional procedure, hand instrumentation may lead to canal aberrations, perforations, inadequate cleaning, transportation, instrument failure, and long chair time for children.^{2–4} Nickel-titanium instruments, which were introduced, have revolutionized the practice of endodontics in an efficiently beneficial way.⁵

Use of the NiTi rotary instruments in primary teeth was initiated by Barr et al.⁶ and others.^{3,7} As per Barr et al.,⁶ a quicker preparation with cost efficiency and consistent results can be achieved with the help of NiTi instruments. But a rotary NiTi file specially designed for permanent dentition was used for performing cleaning and shaping during pulpectomy. According to Silva et al.,⁷ the important factor is the reduction of procedural time while using NiTi instruments during pediatric endodontic therapy without hampering the quality of treatment. Additionally, this will also reduce the fatigue of the patient as well as the dental team. Contemporary endodontics aims to complete the cleaning of the root canals with the help of chemomechanical preparation.⁸ However, the success is questionable even with this advancement in endodontics.⁹ Cleaning efficacy of the file defines its ability to efficiently and completely remove the pulpal remnants and microorganisms from the root canal space.

The apical extrusion of debris, as per several studies, resulted in postoperative/post instrumentation inflammation, pain, and

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failure. The rationale for this study was based on the argument that endodontic treatment in deciduous dentition differs from adult endodontics since primary teeth exhibit anatomical differences from permanent teeth in terms of size and morphology (internal and external).^{10–12} Also, the morphological changes in terms of physiological or pathological radicular resorption should be taken into consideration.¹³ Thus, the results concluded from the adult endodontics cannot be applied to pediatric endodontics. Moreover, even if a correctly determined working length (WL) is used but the instrumentation is done using files designed for permanent dentition, it may extrude debris periapically and may cause damage

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to the permanent tooth bud. Limited data concerning the use of NiTi files specially designed for pediatric endodontics are available.^{6,7}

The apical extrusion of debris as well as cleaning efficacy in primary root canal treatment has not been well elucidated. Thus, the aim of this *in vitro* study to compare the amount of apically extruded debris and cleaning efficacy during the preparation of primary molar root canals using Pro AF Baby Gold and Kedo-S pediatric rotary files. The null hypotheses tested were that (a) no difference exists between the amounts of apically extruded debris associated with various pediatric NiTi rotary files systems and (b) no difference exists between the cleaning efficacy of various pediatric NiTi rotary files systems.

MATERIALS AND METHODS

This *in vitro* study was carried out in the Department of Pediatric and Preventive Dentistry in collaboration with the Department of Oral Pathology and Microbiology, Sharad Pawar Dental College, Sawangi (Meghe), Wardha, for evaluating cleaning efficacy and in collaboration with College of Pharmacy, Wardha, for evaluation of apical extrusion of debris. Institutional ethical committee clearance was obtained from Datta Meghe Institute of Medical Sciences (Deemed to be University), Sawangi (Meghe), Wardha, with reference number DMIMS (DU)/IEC/2017-18/6746. The sample for each group consisted of 10 teeth.

Human primary molars that had recently been extracted were collected from patients aged 5-8 years, for periapical pathology and orthodontic reasons, and stored in distilled water at 4°C. Teeth with root lengths affected by resorption were included in the study since primary root canal treatment is indicated where pathologic root resorption involves less than one-third (minimum 7 mm of root length) of the root. Primary molar teeth with any previous pulp therapy, cracks, any restorations, perforation in the furcation area, periapical cyst, root fracture, and internal resorption were excluded from the study. Twenty teeth that met all of the inclusion criteria were finally divided into two groups randomly; group I-Pro AF Baby Gold (DentAlyze) (n = 10) and (b) Kedo-S (n = 10). A #10 K-file was inserted into the root canal such that it was visible apically under a magnifying loupe, for determination of the WL, which is 1 mm less than the real length. A # 15 No. K-file (Mani, Japan) was then introduced into the root canal followed by the introduction of India ink with an insulin syringe. This was done until the Indian ink leaked from the apical foramen. The ink was again injected 3-4 times into the canals after diffusion and dried for at least 48 hours after each application.

ROOT CANAL PREPARATION

Group I

Negotiation of all root canals was done with files lubricated with 17% EDTA. Initial patency with #15 No. K-File (Mani, Japan) was checked passively with watch winding motion. Following recommended protocol for the Pro AF Baby Gold NiTi pediatric rotary file, the endomotor handpiece (X-Smart, Dentsply Maillefer, USA) was set at 300 RPM, 2N torque, and in auto-reverse mode. Preparation was started with a B0 (#15/0.10) orifice enlarger. It was first used for enlarging 4 mm of the canal cervically. Irrigation was done with 1 mL distilled water and recapitulation was done with #10 K-file (Mani, Japan). This was followed by the introduction of the B1 (#20/0.04) file (Pro AF Baby Gold) along with 17% EDTA till the WL. Irrigation with 1 mL distilled water and recapitulation

was done with #10 K-file (Mani, Japan). Then, Pro AF Baby Gold B2 (#25/0.04) file was used for the canal preparation in presence of 17% EDTA. Irrigation with 1 mL distilled water and recapitulation was done with #10 K-file (Mani, Japan). The canals were instrumented in pecking motion till the WL is achieved and withdrawn in a lateral brushing motion.

Group II

Initial patency with #15 No. K-File (Mani, Japan) was checked passively with watch winding motion. Following recommended protocol for Kedo-S NiTi pediatric rotary file, the endomotor handpiece (X-Smart, Dentsply Maillefer, USA) was set at 300 RPM, 2.2 N torque, and in auto-reverse mode. Kedo-S D1 (Red-0.25 tip diameter) file was used for the canal preparation along with 17% EDTA. Kedo-S D1 file was used to file the canal 2 times in brushing motion till the WL and in-between the filing process canal was irrigated with the help of 1 mL distilled water.

Each time after retrieving, the files were inspected for deformation with a handheld magnification glass under light illumination. The distorted files were disposed of. The files which did not show deformation were discarded after the second use. The files were also inspected for clogging in-between the flutes. The files were made free of clogs with the help of tissue paper. The primary investigator did instrumentation for a maximum of five teeth at a time, to avoid error in relation to operator fatigue.

Assessment of Cleaning Efficacy

The cleaning efficacy analysis, the teeth sample was assessed by process of diaphanization following the protocol given by Silva et al.^{7,14} The samples were placed in different containers with a cover, i.e., tissue cassettes (HiMedia). Then, these cassettes were placed in individual containers containing 10% nitric acid for 72 hours. It was replenished every day until the roots were completely decalcified, which was confirmed when a needle transpassed through the root. Then, the samples were washed under running water for 8 hours. Further, teeth were dehydrated using 70% alcohol which was changed after every 8 hours for 16 hours. Followed by 90% alcohol for 3 hours, changed every hour, and then in absolute alcohol which was changed every hour for 3 hours. Following dehydration of the teeth samples, they were placed in a container filled with methyl salicylate to render transparency. After cleaning, stereomicroscope was used at 10× magnification to assess the India ink removal from the apical third, middle third, and cervical third and were scored: "0 = total cleaning; 1 = >50% ink removal (traces of ink found in some areas); $2 = \langle 50\% \rangle$ ink removal (ink found on some walls in some areas); and 3 = no ink removal". A stereomicroscopic evaluation was performed with the help of a second investigator who did not know about the study.

Debris Collection

The methodology used by Myers and Montgomery¹⁵ was taken as the basis in the present study to evaluate debris extrusion. The Eppendorf tubes we weighted with the rubber stopper before the commencement of the procedure. An electronic weighing machine was used (Precisa, Dietikon, Switzerland) with an accuracy of 10^{-4} g to determine the pre-procedural weight. To avoid any problem with weight, three consecutive measurements of the tube weights were recorded for each tube and the mean values calculated were taken into consideration. Teeth were made to fix in the stoppers by creating holes such that teeth stay in the hole at CEJ level. The internal and external air pressure was equalized by placing a 27-gauge needle alongside the stopper. After this, the assembly (tooth, needle stopper) was fixed to the Eppendorf tube. The tubes were fitted into vials to hold the device during canal instrumentation. All the tubes were covered using aluminum foil to avoid the examiner's bias of looking at debris extruding. After instrumentation, the primary teeth were removed from the assembly. This was followed by washing the root surface with 1 mL distilled water to collect the debris that adhered along the root surface. The tubes were incubated for 5 days at 70°C. Then the same weighing procedure was repeated for the Eppendorf tubes as it was done during pre-instrumentation. The dry weight of the apically extruded debris was calculated by subtracting the pre-instrumentation weight from the post-instrumentation weight.

Statistical Analysis

Data were analyzed statistically using the independent sample *t*-test at a significance level of p < 0.05. All data were processed by SPSS 24.0 software (SPSS Inc., Chicago, IL, USA).

RESULTS

The mean values and standard deviations of the amount of apically extruded debris (g) for all groups are shown in Table 1. The results showed that all instrumentation techniques caused a significant amount of extruded debris. The amounts of apically extruded debris were significantly less for the Pro AF Baby Gold (group I) (0.000073 g) compared to the Kedo-S (group II) (0.000126 g) (p < 0.05). Similarly, Table 2 shows the results related to cleaning efficacy. Scoring criteria are depicted in Figure 1 for the cleaning efficacy.

DISCUSSION

Endodontic procedures are ideally performed efficiently with the help of rotary files as per literature.⁵ Studies in the literature have evaluated instrumentation time, the cleaning efficacy of the files, canal aberrations, etc.^{3,10,16} Among these factors, the cleaning efficiency of an instrument along with its ability to limit the extrusion of the debris periapically, is the most important consideration to be taken into account while deciding a file for cleaning and shaping. The instruments which are used in coronalapical direction are bound to extrude a certain amount of debris periapical but this should be minimal, as it might cause have toxic effects on the underlying bud of the permanent tooth.^{11,17}

There are many techniques to evaluate cleaning efficacy in the root canal system, such as scanning electron microscopy (SEM), micro-CT, stereomicroscopy, splitting the tooth longitudinally for microscopic evaluation. According to Tomar et al.¹⁸ in 2018, stereomicroscopy with diaphanization process is a more sensitive and reliable technique to evaluate root canal three-dimensionally and is a cost-effective method when compared with other methods. Silva et al.⁷ in 2004, Honardar et al.¹⁹ in 2014, and de Souza et al.¹⁴ in 2015 have successfully used stereomicroscope for assessment of cleaning efficacy in their study. Therefore, stereomicroscopy was considered for evaluating the cleaning efficacy of the pediatric rotary files systems in root canals at three different levels namely

Tuble 1. companyon of apical extrasion between the two groups	Table	1:	Com	parison	of a	pical	extrusion	between	the	two groups
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Group	Ν	Mean	SD	p value [#]
Group I	10	0.001490	0.000073	< 0.001 ⁺
Group II	10	0.001140	0.000126	

[#]*p* value derived from independent sample *t*-test; [†]Significant at p < 0.05

apical, middle, and coronal one-thirds. The stereomicroscopy for evaluating cleaning efficacy requires the introduction of Indian Ink in the root canals followed by diaphanization process.¹⁴

Studies conducted by different authors took root apex as a reference point for evaluating canal centricity (at different levels from the apex).^{19–21} However, considering the continuous physiological root resorption associated with primary roots, CEJ was considered as a reference point for this study. This also helped in standardizing the protocol for evaluating canal centricity. Levels at which canal centricity was evaluated were—1 mm from CEJ, 3 mm from CEJ, and 6 mm from CEJ.

In the current study, cleaning efficacy was also evaluated between the second- and third-generation rotary files in primary teeth. In comparison, there was a significant difference at apical levels of maxillary mesial root canals with a mean score of 0.28 \pm 0.48 for Pro AF Baby Gold and 1.00 \pm 0.00 for Kedo-S. Similarly, maxillary distal root canals had a mean score of 1–0.14 \pm 0.37 for Pro AF Baby Gold and 83 \pm 0.40 for Kedo-S files. Whereas no significant difference was found at middle and cervical levels of distal roots and at all levels of under-prepared palatal roots (Table 2).

In the mandibular teeth, statistically significant differences were found at the apical level of all roots except disto-lingual roots (p > 0.05) in cleaning efficacy. No significant differences were found at the middle and cervical of all the roots of the mandibular primary molar teeth (Table 2). These results obtained are in contrast with the study done by Katge et al.,²² who showed that the secondgeneration files had superior cleaning ability in primary teeth at both middle and coronal third rather than apical third. The results are also contrasting with the study done by Javan et al.²³ in 2006 on primary molars, in which no significant was found between the second- and third-generation rotary files in terms of cleaning efficacy at various levels in all the canals and this was in accordance with Silva et al.⁷ in 2004. Foschi et al.²⁴ in 2004 found that when hand and rotary files were compared in primary teeth, no significant difference was found among the two for cleaning ability. The contrasting results may also be attributed to the "taper lock" lock effect. The taper lock effect states that NiTi instruments may cause aggressive preparation of root canal which results in to increase in torsional stress which may affect cleaning efficacy.25

Cleaning efficacy measured in the present study as seen in Table 1 shows that the results were in favor of Pro AF Baby Gold rotary files over Kedo-S with a significant difference in the apical region. These findings are supported by Devi et al.²⁶ who mentioned that a wider portion of the variable taper file engages in the coronal and middle regions. This leaves the apical region un-instrumented. While efficient circumferential filling of canals with thin constant taper files will engage the canal intimately. According to Gu et al.,²⁷ heat-treated third-generation NiTi instruments maintained better canal centricity.²⁷ Thus by maintaining centricity, the endodontic file comes in contact with the root canal in 360°, thereby cleaning the canal efficiently. Whereas, when the files are comparatively stiffer, like in second-generation rotary files, they tend to straighten in the root canal, thereby partially contacting the anti-curve portion of the canal and hence results in reduced cleaning efficacy. It is also seen in the results that the values are most significant in relation to the mesial canals. In the present study, root canal preparation was done till #25/0.04 file only, which binds efficiently with the walls of the mesial canals. This is also suggestive that in wider canals we should use 25/0.06, 30/0.04 of Pro AF Baby Gold file and E1 of Kedo-S files. But may again affect the centricity of the canal significantly, especially with Kedo-S files.

			Group I	Group II	
Tooth	Root	Level	Mean \pm SD	Mean \pm SD	p value [#]
Maxillary molar	Mesial	Apical	0.28 ± 0.48	1.00 ± 0.00	0.004 [†]
		Middle	0.71 ± 0.75	1.00 ± 0.63	0.480
		Cervical	0.14 ± 0.37	0.16 ± 0.40	0.915
	Distal	Apical	0.14 ± 0.37	0.83 ± 0.40	0.009 ⁺
		Middle	0.57 <u>±</u> 0.53	0.83 ± 0.75	0.479
		Cervical	0.28 ± 0.48	0.50 ± 0.54	0.471
	Palatal	Apical	1.42 ± 0.53	1.50 ± 0.54	0.817
		Middle	1.28 ± 0.48	1.50 ± 0.54	0.471
		Cervical	2.00 ± 0.57	2.00 ± 0.63	1.000
Mandibular molar	Mesiobuccal	Apical	0.33 ± 0.57	1.50 <u>+</u> 0.57	0.047 [†]
		Middle	0.33 ± 0.57	0.75 ± 0.50	0.352
		Cervical	0.00 ± 0.00	0.00 ± 0.00	-
	Mesiolingual	Apical	0.33 ± 0.57	1.75 <u>+</u> 0.57	0.018 ⁺
		Middle	0.33 ± 0.57	0.75 <u>+</u> 0.95	0.538
		Cervical	0.33 ± 0.57	0.50 ± 0.57	0.721
	Distobuccal	Apical	0.33 ± 0.57	1.50 <u>+</u> 0.57	0.047 [†]
		Middle	1.33 ± 0.57	1.25 ± 0.50	0.846
		Cervical	1.66 ± 0.57	1.50 <u>+</u> 0.57	0.721
	Distolingual	Apical	0.33 ± 0.57	0.50 ± 0.57	0.721
		Middle	1.00 ± 0.00	1.25 <u>+</u> 0.50	0.437
		Cervical	1.00 ± 1.00	1.00 ± 0.81	1.000

Table 2: Comparison of cleaning efficiency in deciduous maxillary (group I, n = 7; group II, n = 6) and mandibular molar (group I, n = 3; group II, n = 4)

[#]*p* value derived from independent sample *t*-test; [†]Significant at p < 0.05





Myers and Montgomery and also Tanalp and Gungor have suggested many different methodologies for the quantifiable evaluation of periapically extruded debris.^{15,28} The abovementioned methodology also describes the one used by Myers and Montgomery, which is also one of the most-used methods in the dental literature.²⁸ In our study, the simulation of periapical tissue was not done. This was due to the simulations done using materials to close the apical foramen may hamper the results by the absorption of the irrigant and debris as per Burklein and Schafer.¹⁰ Sodium hypochlorite (NaOCI) is the common irrigation material used in endodontics,¹⁷ still distilled water was used for the present study as an irrigant to avoid the possibility of crystallization by NaOCI, which may alter the results.

As per the literature, all the endodontic instruments cause some amount of apical extrusion of debris.^{10,28} To the best of our knowledge, no previous study has compared the amount of apically extruded debris with Pro AF Baby Gold and Kedo-S. However, in a study on primary molars by Topcuoglu et al.,¹⁷ the amount of periapical extrusion of debris was studied using Revo-S, Mtwo, ProTaper Next, and hand files. Their work also revealed that all the instruments caused apical extrusion of debris with no significant difference. Although the results of the present study show that ProAF Baby Gold pediatric rotary files have significantly less periapical extrusion of debris (Table 1).

The results of the present study support the "taper lock effect". In the taper lock effect, the file gets engaged in the coronal region of the root canal, thereby not allowing the collected debris to come out of the canal and thereby pushing the debris apically.

The findings of the present study may be due to the difference in a cross-sectional design, working mechanism, and the number of instruments used. In terms of the number of instruments used in each canal, Albrecht et al. have shown that reducing the number of files will help in reducing the canal aberrations along with reduced apical extrusion.²⁹

Fully formed non-resorbed roots should be taken into consideration for future studies as apical extrusion with closed apex will be comparatively less when compared to resorbed roots.

CONCLUSION

The null hypothesis was rejected, as significant differences were found among the instruments used. Cleaning efficacy is better with Pro AF Baby Gold in all the regions of the canals but was significantly better in the apical region when compared to Kedo-S. Within the limitations of the present *in vitro* study, both the instrumentation systems caused debris extrusion. However, Pro AF Baby Gold pediatric rotary files extruded significantly less debris than did Kedo-S pediatric rotary files.

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