EGYPTIAN DENTAL JOURNAL
www.eda-egypt.org
VOL. 70, 1077:1090, APRIL, 2024
PRINT ISSN 0070-9484 • ONLINE ISSN 2090-2360
ORTHODONTICS, PEDIATRIC AND PREVENTIVE DENTISTRY
Submit Date : 08-02-2024 • Accept Date : 27-02-2024 • Available online: 05-04-2024 • DOI : 10.21608/EDJ.2024.267393.2919

CLEANING EFFICACY, INSTRUMENTATION TIME, INTRACANAL BACTERIAL LOAD AND QUALITY OF OBTURATION OF THREE DIFFERENT ROTARY FILE SYSTEMS IN PRIMARY MOLARS (AN IN VITRO STUDY)

Mona Wael Amin*, Mariem Osama Wassel**
and Dina Hamdy Abd El Rahman***

ABSTRACT

Aim : the study compared three different rotary file systems: Kedo-S, M Pro Pedo, and ProTaper Gold in respect to Cleaning efficacy, Instrumentation time, Bacterial load, and Quality of obturation in pulpectomy of primary molars.

Methods: Seventy two maxillary primary molars were divided into three groups: **Group I** (Kedo-S), **Group II** (M Pro Pedo) **Group III** (ProTaper Gold) then each group was subdivided into two subgroups (A, B), subgroups **IA**, **IIA, III**A assessing cleaning efficacy and instrumentation time, subgroups **IB, IIB, III**B assessed bacterial load and obturation quality. India ink was injected into palatal canals before instrumentation, then teeth were decalcified, dehydrated and cleared, the post-instrumentation traces of ink were evaluated using stereomicroscope and teeth were scored according to the India ink remaining in each third of the canal separately to evaluate cleaning efficacy. A digital chronometer measured total active instrumentation time. Teeth in subgroups IB, IIB, IIIB were immersed in *E. Faecalis* suspension and bacterial colonies were counted after instrumentation to assess bacterial load reduction. Palatal canals were obturated using Metapex and postoperative radiographs were taken to assess obturation quality.

Results: : No significant differences were found between groups in cleaning efficacy in coronal and middle thirds, PTG showed the best cleaning efficacy at the apical third. M Pro Pedo consumed the least instrumentation time followed by Kedo-S then PTG . No significant difference between different groups regarding bacterial load reduction. PTG showed the best obturation quality

Conclusion: M Pro Pedo is a promising file system

KEYWORDS: Kedo-S, M Pro Pedo, ProTaper Gold, Cleaning efficacy, Pulpectomy.

* Faculty of Dentistry, Ain Shams University.
** Head of Pediatric Dentistry and Dental Public Health Departement, Faculty of Dentistry, Ain Shams University
*** Lecturer of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Ain Shams University

INTRODUCTION

Primary teeth play a crucial role in the oral cavity. They serve as a natural space maintainer by acting to preserve the necessary distance for the eruption of permanent teeth, even though their primary role is mastication. This space should be maintained until the time is right for their exfoliation.[1] The best option for treating primary teeth with irreversible pulpitis or necrosis is pulpectomy.[2] The primary objective of endodontic therapy is the removal of germs from the root canal structure. The reduction of microbes in the root canal system, which is accomplished via chemo-mechanical preparation, is directly associated with the efficacy of endodontic treatment.

Primary and permanent teeth differ anatomically in certain ways. These consist of partial canal fusion, apical ramifications, linking fibrils, and lateral branching. Furthermore, the roots of primary molars have a greater curvature to accommodate the growing successor, which presents challenges for dentists treating primary molars with root canal therapy.[3] Despite being widely used, manual instrumentation can lead to iatrogenic mistakes because of the forceful and indiscriminate cutting activity of stainless-steel files, which can cause complications such as strip perforation, pushing necrotic debris apically, or canal transportation.[4, 5] Consequently, studies focused on the use of Ni-Ti files for pulp treatment in primary teeth.

Barr et al.[6] (2006) initially reported on the use of Ni-Ti rotary files in primary teeth endodontic procedures, promoting the same biomechanical preparation concepts as those for permanent teeth.[7] Primary molar root canals typically exhibit several anatomic differences. Regrettably, there is insufficient data in the literature to investigate how the new rotary file design adjustment affects these canals during preparation.

The Kedo S file system is the first rotary file designed specifically for primary tooth shaping in history. It is a 16 mm long three-file system with a 12 mm active length (D1, E1, U1). D1 is made especially for molars whose canals are less wide. E1 is meant for molars with broader canals while U1 is designed for incisors.[8]

The M-Pro Pedo rotary system was just released consisting of 3 files (#20,25, 30). The X-wire used in this system has been carefully treated to increase its flexibility, resilience to cycle fatigue, and pre-bending ability.[9]

ProTaper Gold files are of the third generation; they are more flexible and resistant to cycle fatigue than its predecessor ProTaper Universal files, which goes back to the heat treatment. Eight sizes of PTG are available: SX (tip size 19 with a taper of 0.04), S1 (tip size 18 with a taper of 0.02), S2 (tip size 20 with a taper of 0.04), F1 (tip size 20 with a taper of 0.07), F2 (tip size 25 with a taper of 0.08), F3 (tip size 30 with a taper of 0.09), F4 (tip size 40 with a taper of 0.06), and F5 (tip size 50 with a taper of 0.05).[10]

In light of this, the goal of the current study was to evaluate the cleaning efficacy, instrumentation time, bacterial load reduction, and obturation quality of ProTaper Gold (PTG, Dentsply, Maillefer, Ballaigues, Switzerland) and newly introduced rotary Ni-Ti files for primary teeth.

MATERIALS AND METHODS

Aim:

The aim of the present study was to compare three different rotary file systems used in pulpectomy of primary molars: Kedo-S Rotary File System, M Pro Pedo Rotary File System, and ProTaper Gold Rotary File System in respect to the following:

1. Cleaning efficacy.
2. Instrumentation time.
3. Intra-canal bacterial load.
4. Quality of obturation.

2. Study design:

The present study was an in vitro study. This study was approved by the Ethics Committee of Faculty of Dentistry Ain Shams University (Research ethics approval code: FDASU-Rec PC 052314).

3. Study settings:

1. Outpatient's clinic of Pediatric Dentistry and Dental Public Health department, Faculty of dentistry, Ain Shams University.
2. Oral Pathology department at Faculty of Dentistry, Ain Shams University.
3. Private Microbiology lab.

4. **Materials**:

- kedo S rotary files (E1 file).
- M Pro Pedo files (Files #20,25,30)
- Pro Taper Gold files (Files SX, S1, S2, F1, F2, F3)
- India ink and insulin syringe
- Metapex
- Enterococcus faecalis isolate

5. Power analysis:

A power analysis was designed to have adequate power to apply a 2 sided statistical test of the research hypothesis (null hypothesis) that there is no difference between the three different rotary systems regarding cleaning efficacy, instrumentation time, bacterial load and quality of obturation according to results of Al Rwaily. [11] Assuming an alpha (α) level of 0.05 (5%), a Beta (β) level of 0.20 (20%) i.e. power=80% the predicted size(n) was 72 among three groups (24 in each group;12 in each subgroup) was calculated using Epicalc program version 1.02.

6. Teeth selection and grouping:

Seventy-two extracted maxillary primary molars were gathered from the outpatients' clinic of Pediatric Dentistry Department, Faculty of Dentistry, Ain Shams University as well as from other private clinics. Teeth should have minimal apical resorption, no external resorption, and no furcation involvement. The study excluded teeth with root caries or calcified palatal root canals. To get rid of all the soft tissue from the root surfaces, the teeth were washed under tap water. Using a wheel stone, occlusal reduction was carried out on all teeth up to the Cemento-Enamel Junction level, resulting in a mean working length of 12 mm ± 2.[12] For a whole day, teeth were submerged in 3% sodium hypochlorite to ensure disinfection. Teeth allocated for measuring bacterial load were further packed in sterilization pouches and autoclaved. [13] Teeth were divided into 3 groups: Group I (n=24 palatal root canals) prepared with Kedo S; Group II (n= 24 root palatal canals) prepared with M Pro Pedo rotary files and GroupIII (n= 24 root canals of primary molars) prepared with ProTaper Gold files. Each group was subdivided to two groups; Group A for cleaning efficacy and instrumentation time assessment, and Group B for evaluation of bacterial load reduction and quality of obturation.

7. Mechanical preparation of teeth:

Using a big round bur mounted in a high-speed hand piece under copious water irrigation, access cavities were prepared for all maxillary primary molars. In order to access the root canals, the pulp chamber's roof was removed as it was reached. A tapered diamond bur was used to remove all of the underlying dentine in order to provide a straight path into the root canals. The working length of the Palatal Canal was measured using #15 K-files and the canal was washed with saline. [14] After inserting the file into the canal, the working length was measured 1 mm below the apex. [15]

8. Cleaning efficacy evaluation:

Using an insulin syringe (30 gauge), Indian ink dye was injected into the palatal canals of subgroups IA, IIA, and IIIA until it seeped from the foramen. To guarantee dye penetration all the way down the

canals, the ink dye was reinjected.[15] To make sure there was no bubble developed, a #10 K-file was put back into the canals. After that, the teeth were kept in a moist environment for 48 hours.

As advised by the manufacturer, a number of 12 palatal root canals in group IA were instrumented using a Kedo-S single rotary file system. Initially, size 15 K-file was used for manual instrumentation to prepare root canals and ensure patency. The crown-down preparation of palatal canal was carried out with an E1 rotary file using an NSK Endomate DT endomotor. Lateral brushing motion was employed at 300 rpm and 2.2 N cm torque.[16,17] Prior to instrumenting the root canal, EDTA gel was used to lubricate the rotary files, the canal was instrumented to the predefined working length up till no resistance was found inside the canal.[18]

12 palatal root canals in group IIA were instrumented with NSK Endomate DT endomotors at 500 rpm and 300 Gcm, along with M Pro Pedo Files in sizes 20, 25,30 taper of 4%, per the manufacturer's recommendations. Size 15 K-file was used to ensure patency. Before inserting the rotary files into the canal, EDTA gel was always used to lubricate them. The canal was instrumented to the predetermined working length using the crown-down approach till no resistance was found inside the canal.[18] Using disposable syringes, 5 ml of normal saline was used to irrigate the canals after every file change. A number of 12 palatal root canals in group IIIA were instrumented with ProTaper Gold file system in crown-down technique in the following sequence : Orifice opener SX #15 taper (300 rpm, 5.10N cm), S1 file #10 taper 4% (300 rpm, 5.10 N cm), S2 file #15 taper 4% (300 rpm, 1.50 N cm), F1 file #20 taper 6% (300 rpm, 1.50 N cm), F2 file #25 taper 6% (300 rpm, 3.10 N cm), F3 file #30 taper 9% (300 rpm, 3.10 N cm). Similar to the other two groups irrigation and patency were done and EDTA was used.

Following instrumentation, teeth were decalcified using 7% HCl [19,20] then a serially concentrated ethyl alcohol was used to dehydrate teeth as follows: 70% alcohol for 16 hours (changed after eight hours) ,80% alcohol for 8 hours,95% alcohol for 8 hours,100% alcohol for 8 hours [21, 22, 23] . All teeth were left in methyl salicylate till they appeared translucent. The teeth needed six hours to be fully cleared. [21, 22]

Teeth were sectioned in a bucco-palatal direction, to be carefully examined under a stereomicroscope (Olympus, Japan) with a ×10 magnification. The efficacy of cleaning of the root canal system was scored using a four-grade scoring system after assessing the removal of Indian ink from the cervical, middle, and apical thirds. Two examiners separately rated the images of the apical, middle, and coronal third of the canal in a blinded manner. The scoring system was initially tuned to the examiners. After then, the two examiners decided on a final score on their own and recorded it. They discussed the sample and its grading and decided on a score if there was a disagreement. On a scale of 0–3 for each third of the canal, teeth were assessed based on how much India ink was still present in each (figure 1): [22]

- Score 0= Total clearing, (the canal was completely clean and without ink)
- Score 1= Almost complete ink removal, (traces of ink found in some areas\ more than 50% ink removal)
- Score 2= Partial ink removal, (less than 50% ink removal \ ink found on some walls in some areas larger than pinpoints or as interrupted short lines of ink less than 0.5mm on the walls).
- Score 3= No ink removal.

9. Instrumentation time measurement:

Using a chronometer, the amount of time needed to instrument subgroups IA, IIA, and IIIA was measured in seconds. The term "instrumentation time" refers to the total amount of time that was spent actively instrumenting the canal using a rotatry file system, including time spent in irrigation and instrument changes, from the first file to the last.[4,20,24,25]

10. Evaluation of Bacterial load reduction:

E. Faecalis suspended in sterile BHI media (0.5 McFarland scale =1.5 x 10^8 cells) was distributed in sterile tubes. Subgroups IB, IIB, IIIB were sterilized and immersed in the enumerated tubes and incubated at 37°C for 24 hours. After that, the media in the tubes was changed by sterile BHI media and incubated at 37°C for 24 hours and this step was repeated day after day for 2 weeks before instrumentation in addition to centrifugation to ensure biofilm development and penetration of bacteria into dentinal tubules. [24] After 14 days, each palatal root was irrigated with 5ml of saline. Pre-instrumentation samples were obtained by inserting two sequentially placed sterile #25 paper points. Each paper point was placed inside the palatal canal till full working length for 30 seconds, then absorbent paper points were transferred to separate sterile tubes containing 1 ml of sterile Phosphate Buffer Saline. [24]

Palatal canals in subgroups IB, IIB, IIIB were mechanically prepared with the three rotary files systems as described before in subgroups IA, IIA, IIIA. After instrumentation final irrigation was done using 5ml of saline and two paper point #30 were sequentially placed as described prior to instrumentation. Samples were spreaded on blood agar media incubated at 37 C for 24 hours. [24] After incubation, visible colonies of *E. faecalis* were counted in every plate. [24] (figure 2)

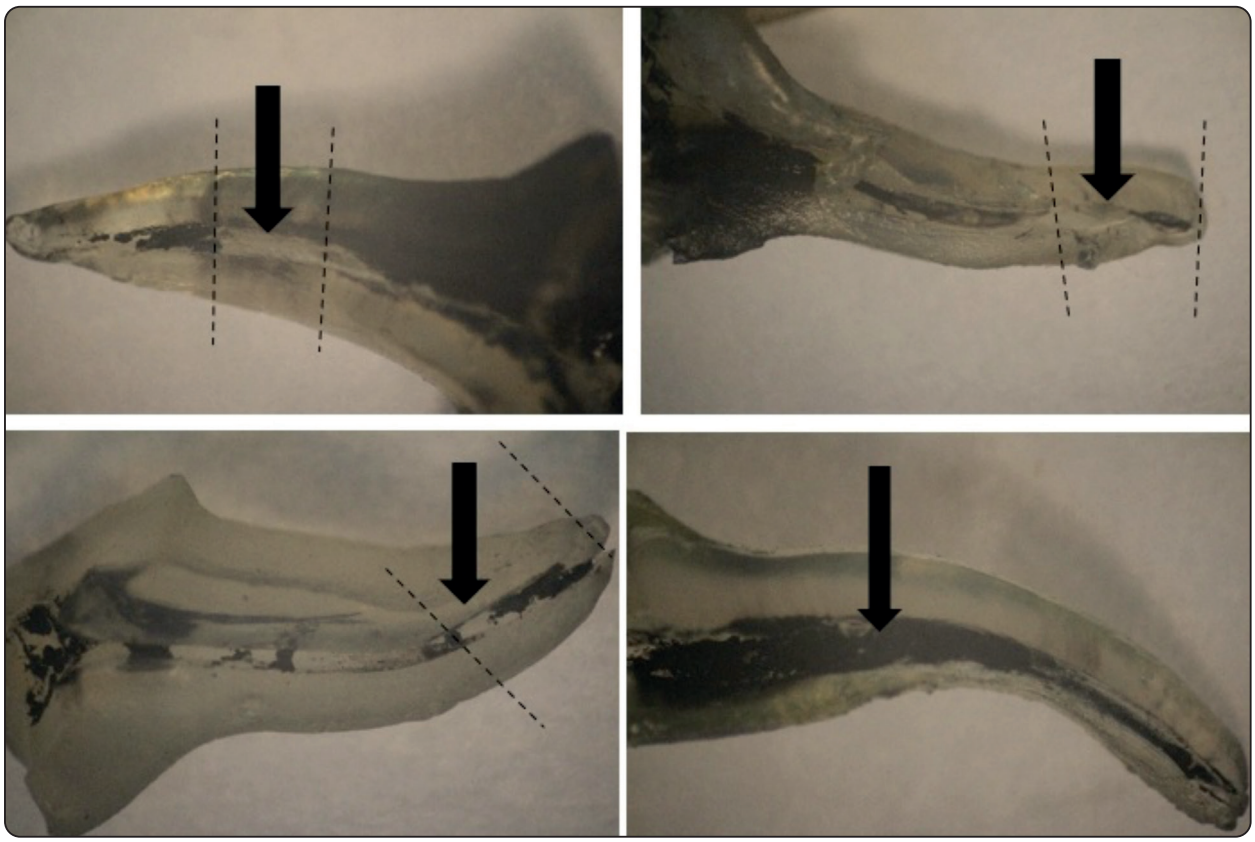

Fig. (1) Cleaning efficacy scores: (a) Score 0, arrows show complete ink removal in the middle third (b) Score 1, arrows show almost complete ink removal>50% at apical third (c) Score 2, arrows show <50% ink removal (d) Score 3, no ink removal.

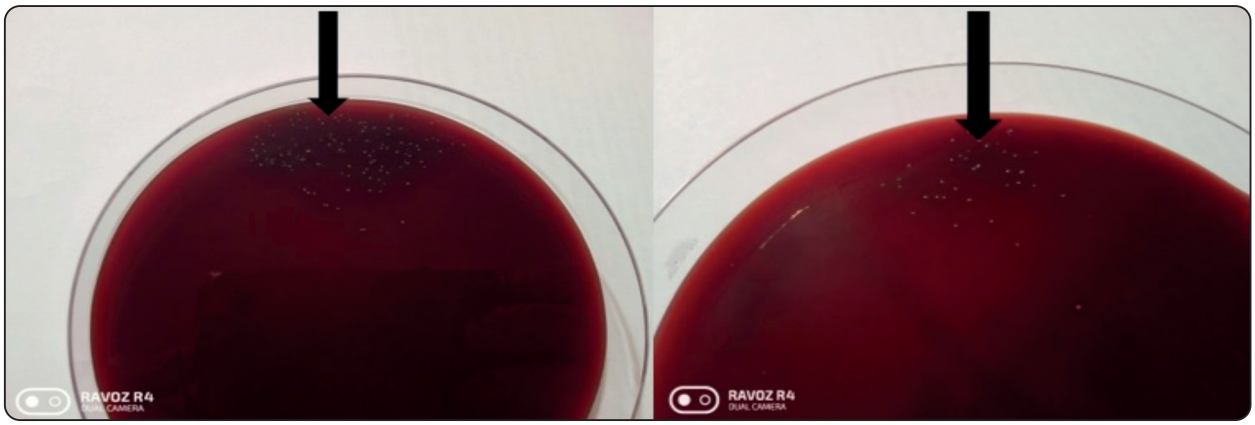

Fig. (2) Blood agar plates showing bacterial colonies

11. Assessment of quality of obturation:

After preparation palatal roots of subgroups **IB, IIB** and **IIIB** were irrigated using 5ml saline. Absorbent paper points were then utilized to dry the canals, which were then obturated using Metapex (a mixture of Calcium Hydroxide and Iodoform).

Obturation of palatal canals was done using disposable injection technique in which a 24 gauge disposable plastic needle tip was used to fill the canals. A rubber stopper was adjusted to working length, after this the needle was gradually withdrawn while pushing the material till the needle reaches the pulp chamber. The tooth was then restored with temporary filling. [26] Immediate post-operative radiographs were taken using paralleling technique in which the root to be studied is parallel to the plane of the sensor while the central axis of the X-ray is perpendicularly adjusted to both planes.

The quality of obturation was assessed using the criteria laid down by Coll and Sadrian (1996) by two pediatric dentists who were blinded to the groups as follows: [3, 27, 28]

- Under filled: filling material extends less than or equal to half the root canal length filled.
- Sub optimal filled: filling material extends more than half of root canal filled but less than optimal.
- Optimal filled: filling material extends to the radiographic apex or up to 1.5 mm short of the apex.

Statistical analysis

Categorical data were presented as frequency and percentage values and were analyzed using chi-square test followed by Pairwise comparisons utilizing multiple z-tests with Bonferroni correction. Numerical data were presented as mean and standard deviation (SD) values. They were explored for normality by checking the data distribution, and using Shapiro-Wilk test. Cleaning efficiency score data were non-parametric and were analyzed using Kruskal-Wallis test followed by Dunn's post hoc test with Bonferroni correction for intergroup comparisons and Friedman's test followed by Nemenyi post hoc test for intragroup comparisons. Other data showed parametric distribution and were analyzed using one-way ANOVA followed by Tukey's post hoc test. The significance level was set at $p < 0.05$. Statistical analysis was performed with R statistical analysis software version 4.1.3 for Windows.

Fig. (3): Postoperative radiograph for one sample prepared by Kedo S files showing suboptimal filling

Fig. (4): Postoperative radiograph for one sample prepared by M Pro Pedo files showing underfilled filling

Fig. (5): Postoperative radiograph for one sample prepared by ProTaper Gold files showing optimal filling

RESULTS

1-Cleaning efficacy

A) Intergroup comparisons:

Kruskal-Wallis test followed by Dunn's post hoc test with Bonferroni correction showed that in the coronal third there was no significant difference between different groups (p=0.185). there was no significant difference between different groups in middle third (p=0.209).

There was a significant difference between Kedo S (**Group I)** and other two groups in apical third (p=0.001). The highest value was found in Kedo S (2.08±0.51), followed by M Pro Pedo (1.08±0.90), while the lowest value was found in ProTaper Gold (0.83±0.72), while **Group II** and **Group III** showed no significant difference. Post hoc pairwise comparisons showed Kedo S to have a significantly higher value than other groups (p<0.001). (table 1)

TABLE (1) Inter and intragroup comparisons, mean and standard deviation (SD) values of cleaning efficiency score

Root section	Cleaning efficiency score (mean±SD)			p-value
	Kedo S	M Pro Pedo	Protaper gold	
Coronal	2.58±0.67^{Aa}	2.50±0.90^{Aa}	2.08±0.79^{Aa}	**0.185ns**
Middle	1.75±1.14^{Aa}	1.75±0.75^{Aab}	1.17±0.72^{Ab}	**0.209ns**
Apical	2.08±0.51^{Aa}	1.08±0.90^{Bb}	0.83±0.72^{Bb}	**0.001***
p-value	**0.187ns**	**0.015***	**0.001***	

Means with different upper case within the same horizontal row indicate significant difference and lowercase superscript letters in vertical column means they are significantly different *; significant ($p \leq 0.05$) ns; non-significant (p>0.05)

B) Intragroup comparisons:

Friedman's test followed by Nemenyi post hoc test showed that in Kedo S there was no significant difference between values measured at different sections (p=0.187). In M Pro Pedo there was a significant difference between values measured at different sections (p=0.015). The highest value was measured at the coronal section (2.50±0.90), followed by the middle section (1.75±0.75), while the lowest value was found at the apical section (1.08±0.90). Post hoc pairwise comparisons showed value measured at the coronal section sections to be significantly higher than value measured at the apical section (p<0.001). ProTaper Gold group showed there was a significant difference between values measured at coronal section and other two sections (p=0.001). The highest value was measured at the coronal section (2.08±0.79), followed by the middle section (1.17±0.72), while the lowest value was found at the apical section (0.83±0.72). Post hoc pairwise comparisons showed value measured at the coronal section sections to be significantly higher than values measured at other sections (table 1)

2- Instrumentation time

One-way ANOVA followed by Tukey's post hoc test showed there was a significant difference between different groups (p=0.001). The highest value was found in ProTaper Gold (02:34.68±00:21.09), followed by Kedo S (01:46.90±00:22.70), while the lowest value was found in M Pro Pedo (01:02.29±00:10.14). Post hoc pairwise were all statistically significant (p<0.001). (table 2)

TABLE (2) Intergroup comparisons, mean and standard deviation (SD) values of instrumentation time (mm:ss:ms)

Instrumentation time (mm:ss:ms) (mean±SD)			p-value
Kedo S	M Pro Pedo	ProTaper Gold	
01:46.90± 00:22.70^{B}	01:02.29 ±00:10.14^{C}	02:34.68 ±00:21.09^{A}	**<0.001***

Means with different superscript letters within the same horizontal row are significantly different *; significant (p ≤ 0.05) ns; non-significant (p>0.05)

3- Bacterial load reduction (%):

There was no statistically significant difference between different groups (p=0.709). The highest value was found in Kedo S (99.76±0.72), followed by M Pro Pedo (98.89±3.33), while the lowest value was found in Protaper Gold (98.52±4.44). (table 3)

TABLE (3) Intergroup comparisons, mean and standard deviation (SD) values of bacterial load reduction (%)

Bacterial load reduction (%) (mean±SD)			p-value
Kedo S	M Pro Pedo	Protaper gold	
99.76±0.72^{A}	98.89±3.33^{A}	98.52±4.44^{A}	**0.709ns**

Means with different superscript letters within the same horizontal row are significantly different *; significant (p ≤ 0.05) ns; non-significant (p>0.05)

4- Quality of obturation:

There was a significant difference between different groups with ProTaper Gold having significantly higher percentage of optimum fillings and significantly lower percentage of suboptimal fillings than other two groups (p=0.004), while M Pro Pedo (**Group II**) is the only group that showed a percentage of underfilled obturation. (figure3-5) (table 4)

TABLE (4) Intergroup comparison, frequency and percentage values for quality of obturation for different groups

Quality of obturation		Kedo S	M Pro Pedo	ProTaper Gold	p-value
Optimum filling	n	7^{A}	4^{A}	12^{B}	**0.004***
	%	58.3%	33.3%	100.0%	
Suboptimal filling	n	5^{A}	5^{A}	0^{B}	
	%	41.7%	41.7%	0.0%	
Underfilled	n	0^{A}	3^{A}	0^{A}	
	%	0.0%	25.0%	0.0%	

Values with different superscript letters within the same horizontal row are significantly different *; significant (p ≤ 0.05) ns; non-significant (p>0.05)

DISCUSSION

The intricate process of root canal therapy involves removing the diseased dentin, debris, and any remaining necrotic materials from the pulp tissue. Because primary teeth have more accessory canals, lateral canals, fins, anastomoses between canals, an apical delta, and short, thin roots than permanent teeth, the architecture of the primary tooth pulp is more complex.[29,30] Furthermore, treating primary teeth becomes more challenging when dealing with behavioral issues in youngsters.[28] The major goal is to provide high-quality root canal therapy, which involves fully removing diseased tissue and quickly sealing the canals with a biocompatible substance.[31]

In terms of cleaning effectiveness, instrumentation time, bacterial load reduction, and primary molar obturation quality, the three rotary file systems (Kedo S, M Pro Pedo, and Protaper Gold) were examined in this study. Since no study has been done to yet to examine the three systems collectively, this is thought to be especially important. These three systems were chosen in particular because the Kedo S file system was the first to be created especially for primary molars,[16] and the M Pro Pedo file system was just released, so it was critical to assess its effectiveness and compare it to other products on the market, and lastly ProTaper Gold (PTG) rotary files, a third-generation rotary system, was selected for this investigation because few studies have assessed its efficacy in primary teeth[27] , and it is thought to be superior to the successor ProTaper Universal, a second-generation rotary system due to integrating gold heat-treatment.[32, 33]

The current study's findings showed that while cleaning efficacy did not significantly differ between the three groups in the coronal or middle thirds, it did significantly differ in the apical third. Group III (ProTaper Gold) had the lowest cleaning efficacy scores in the coronal third of the root, followed by Group II (M Pro Pedo) and Group I (Kedo S). This may be explained by the higher percentage of taper (9% and 6%, respectively) seen in Protaper Gold and M Pro Pedo files compared to Kedo S (4–8%). More dentine is engaged by the larger diameter rotary files in the coronal one-third, which improves cleaning effectiveness.

The outcomes aligned with the findings of **Sennain, et al. (2021)** [15] and **Reddy, et al. (2021)**[34] The findings, however, were at odds with those of **kalita, et al. (2021)** [13] who demonstrated that Kedo-S rotary files outperformed ProTaper Universal and K files in cleaning the primary root canals in the coronal third, and **Tofangchiha, et al. (2022)**[35] who demonstrated that Kedo S files outperformed RaCe (2nd generation) and hand files in the coronal area. This could be related to the sample collecting methods used in the two earlier investigations, which included both mandibular and maxillary teeth, leading to differences in the root length and curvature.

Group III (ProTaper Gold) had the lowest mean score when comparing cleaning efficacy in the middle third of the root, followed by Group II (M Pro Pedo) and Group I (Kedo S). Nevertheless, the difference was not statistically significant. According to **Eduardo, et al. (2012)**[36], **Azar, et al. (2012)**[37] **and Al Obaidy, et al. (2020)** [38] these results are consistent. On the other hand, a study by **Kalita et al. (2021)**[13] demonstrated that in primary mandibular and maxillary root canals, Kedo S outperformed ProTaper in the middle part of the root canal. The instrumentation technique used with the ProTaper file system may be to blame for this. Sx files were only used up to 3 mm past the orifice; S2 files were then used to finish the preparation; on the other hand, Kedo S files were used to the full working length, which may have led to better cleaning in the middle third. Furthermore, the sample had both mandibular and maxillary teeth, which could have an impact on the outcomes because the mandibular and maxillary canals differ in terms of root length and curvature.

There was a significant difference in the cleaning efficacy in the apical third of root canals between the groups. Group III (Protaper Gold) had the lowest mean value (highest cleaning efficacy), followed by Group II (M Pro Pedo) and Group I (Kedo S) (lowest efficacy). This could be explained by the fact that ProTaper Gold file's metallurgy is a gold heat-treated system made via an intricate heating-cooling process that leaves a visible layer of gold oxide on the surface and gives the system characteristics like shape memory, superelasticity, and a high resistance to cyclic fatigue.[39] Furthermore, under clinical conditions, ProTaper Gold's transformation temperature is significantly higher than body temperature, resulting mostly in the martensitic phase, or R-phase, which allows the file to navigate a limited apical third because of this phase's enhanced flexibility. [40]

The above results are in line with **Selviany, et al. (2016)** [41] While **Kalita, et al. (2021)** [13] demonstrated a non-significant difference between Kedo S and ProTaper system in the apical third. This can be because only one Protaper file out of the whole kit was used to achieve the desired working length. Furthermore, **Afreen, et al. (2021)**[42] reported that in the apical third of single-rooted permanent teeth, ProTaper Gold had inferior efficacy compared to the Revo S file system (5th generation). The file design in which Revo S starts a snake-like movement inside the canal was blamed by the authors for this. Additionally, Revo S has greater flexibility and a superior capacity to handle curves.

When the cleaning efficacy of several root sections within the same file system group was compared, Group I (Kedo S) did not exhibit any statistically significant variation in the values measured at various root sections. This could be related to the file design's varying taper (4–8%) throughout its length, which reduces the file's engagement against the canal wall at areas of low taper while areas of high taper engage more dentin. [16]

Regarding Group II (M Pro Pedo File), the values obtained at various parts differed significantly from one another. The apical part (greatest cleaning efficacy) had the lowest value, whereas the coronal had the highest. Its low taper (4%) accounts for this, as it engages less dentin at the coronal third. The reason for the high efficacy in the apical third is the metallurgy of Controlled Memory wire, which has a lower nickel content than other systems. A metal that is softer, less hard, and less likely to cause canal transportation is produced when the amount of nickel is reduced.[43] There was a significant difference in the values measured at the different sections in Group III (ProTaper Gold). The lowest value was found at the apical section (highest cleaning efficacy), while the highest value was measured at the coronal section (lowest cleaning efficacy). The results indicated a low efficacy, despite ProTaper Gold having the maximum taper (9%) among the employed systems and a bigger diameter at the coronal third, which predicts achieving high cleaning scores at the coronal third. This may be related to the file design; the Protaper Gold file is 21 mm long, which is longer than the primary root canal length which makes the widest part of the ProTaper Gold file is outside the canal. In contrast, the other two systems are made for primary teeth with 16 mm length. [10,16]

These current results are consistent with the findings of **Elnagar, et al. (2018)** [44] which shown that ProTaper Universal was most effective at the apical third of single-rooted primary teeth as opposed to the coronal and middle thirds. Our findings, however, differed with those of **Azar, et al. (2012)**[37] who found that Protaper Gold had superior cleaning performance in the coronal and middle thirds of mandibular primary molars as opposed to the apical third of the mesiobuccal and distal root canals. However, the author explained this result by pointing out that the operators tended to position instruments above the apical third mainly in the coronal two thirds of the canal to gain better cleaning and shaping.

In terms of instrumentation time, there was a significant difference in the between the groups. Group III (ProTaper Gold) had the highest value, followed by group I (Kedo S), while group II (M Pro Pedo) had the lowest value. This may be connected to how the amount of files used in each system and their cutting efficiency affect the instrumentation time. [15] The Kedo S is a single file system; the M Pro Pedo file kit has three files (#20, #25, and #30); and the ProTaper Gold system assorted kit has six files (three finishing files F1, F2, and F3) and three shaping files (SX, S1, S2), because of this, ProTaper Gold required the most instrumentation time. [10] Conversely, Group II M Pro Pedo file took up the least amount of time, despite each kit containing three files, whilst Group I Kedo S only had one file. This could be because of the amount of taper of each file, M Pro Pedo has less taper than Kedo S, which enables the file to fully negotiate and clean the canal while running into less resistance over its whole working length. The M Pro Pedo file is a recently introduced system that needs more research and comparisons with other rotary systems because there is currently no information about it in the literature.

These findings are supported by **Juliet, et al. (2020)**[3] , **Pawar, et al. (2021)** [9] and **Priyadarshini, et al. (2020)**[45] , who revealed longer instrumentation times in the Kedo S group in primary mandibular molars as opposed to Kedo SG blue. On the other hand, Kedo S demonstrated the least amount of instrumentation time when compared to reciprocating files in primary molars, according to **Lakshmanan, et al. (2020)**[46] , this is explained by the fact that the reciprocating file system uses a large number of files (five files for each canal in a primary molar).

Regarding the reduction of bacterial burden, there was no discernible variation among the three groups. Significantly high bacterial reduction was observed in all three rotary systems. This is because the three systems rotate inside the canal in a circumferential motion until reaching the full working length and instrumentation continues until no resistance is encountered which eradicates the bacteria in the root canal system in assistance with the irrigant used. These outcomes were consistent with those of **Pinheiro, et al. (2012)**[24], who examined manual files, hybrid techniques, and the ProTaper Universal system in primary molars and discovered no discernible variation in the three groups' reductions in bacterial load. On the other hand, ProTaper Gold achieved a larger bacterial reduction in maxillary central incisors than the Wave One system (4th generation), according to **Otero, et al. (2021)** [47]. This could be because Wave One is a single file system (taper 8%), whereas ProTaper Gold is a multi-file system.

In terms of obturation quality, the ProTaper Gold group's higher percentage of optimal filling of the canals in comparison to the other groups may be attributable to a larger coronal enlargement that facilitates easy passage of obturating material within the prepared canal space. [3] Conversely, only the M Pro Pedo group had underfilled canals because they had the least amount of taper and coronal expansion in relation to the other. **Shah, et al.** (2021)[4] findings were in line with these results where Kedo-S produced less quality of obturation compared to Pro-AF files (pedodontic designed multi file system with taper 6%) in primary molars. However, in comparison to XP Endoshaper, **Pawar, et al. (2021)** [9] found that Kedo S demonstrated lower obturation quality. This might be because XP Endoshaper's 3D instrumentation is superior to Kedo S's. Furthermore, the results of **Priyadarshini, et al. (2020)**[45] were not consistent with the current findings, which revealed that Kedo-SH and Kedo-SG Blue had the highest proportion of ideal fillings when compared to Kedo-S. This could be explained by the increased usage of various types of instruments in the Kedo-SH system (k file, H file, Ni-Ti file) and Kedo-SG Blue (Titanium-coated Ni-Ti files).

CONCLUSIONS

Within the limitations of the present study, it can be concluded that M Pro Pedo is a promising rotary file system. It showed the shortest instrumentation time that has a strong impact on patients' compliance, high reduction in the bacterial load and good results in cleaning efficacy. Further studies are required to enhance its quality of obturation that can be improved by using different instrumentation techniques.

REFERENCES

1. Amit K. Esthetic zirconia crown in Pedodontics. International Journal of Pedodontic Rehabilitation. 2017; 3(1): 46–50.
2. Thakur B, Pawar AM, Kfir A . Extrusion of debris from primary molar root canals following instrumentation with traditional and new file systems. Journal of Contemporary Dental Practice. 2017 Nov 1;18(11):1040-1044.
3. Juliet S, Jeevanandan G, Govindaraju L. Comparison between Three Rotary Files on quality of obturation and instrumentation time in primary Teeth-A double blinded Randomized Controlled Trial. Journal of Orofacial Sciences. 2020;12(1):30-34.
4. Shah H, Patil V, Kamath A, Mathur A. Comparative evaluation of instrumentation time, obturation time, and radiographic quality of obturation using two rotary systems and manual technique for primary molar pulpectomies - In vivo study. Contemporary Clinical Dentistry Journal. 2021 Jan 1;12(1):55–62.
5. Crespo S, Cortes O, Garcia C, Perez L. Comparison between Rotary and Manual Instrumentation in primary teeth. Journal of Clinical Pediatric Dentistry. 2008 Jul 1;32(4):295–298.
6. Barr ES, kleier DJ, Barr NV. Use of nickel titanium rotary files for root canal preparation in primary teeth. Pediatric dentistry journal. 2000;22(1):77–78.
7. Jeevanandan G, Thomas E. Volumetric analysis of hand, reciprocating and rotary instrumentation techniques in primary molars using spiral computed tomography: An in vitro comparative study. European Journal of Dentistry. 2018 Jan 1;12(1):21–6.
8. Garg S, Namdev R, Swati Garg C, Dengre A. Kedo-SG pediatric rotary files: A boon for rotary endodontics in primary teeth. International Journal of Applied Dental Sciences.2019;5(3):391–393.
9. Pawar BA, Pawar AM, Bhardwaj A. Effect of adaptive, rotary, and manual root canal instrumentation in primary molars: A triple-armed, Randomized Controlled Clinical Trial. Biology journal. 2021 Jan 1;10(1):1–11.
10. Elnaghy AM, Elsaka SE. Mechanical properties of ProTaper Gold nickel-titanium rotary instruments. International Endodontic Journal. 2016 Nov 1;49(11):1073–8.
11. Al Rwaily AK. Rotary systems versus manual K-file system in primary molar root canals -In Vitro study. International Pediatric Dentistry Journal.2018 Oct 3;2(2):115-120.
12. Sruthi SA, Gurunathan D. Working Length of Maxillary Primary Molars In children aged 2-6 years-A Retrospective Study. International Journal Of Dentistry and Oral Science.2021;08(02):1780–4.
13. Kalita S, Agarwal N, Jabin Z, Anand A. Comparative evaluation of cleaning capacity and efficiency of Kedo-S pediatric rotary files, rotary ProTaper, and hand K files in primary molar pulpectomy. International Journal of Clinical Pediatric Dentistry. 2021 May 1;14(3):383–7.
14. Ramezanali F, Afkhami F. Comparison of cleaning efficacy and instrumentation time in primary molars: Mtwo rotary instruments vs. Hand K-files. Iranian Endodontic Journal. 2015 Sep 1;10(4):240–3.
15. Sennain S, Wassel M, Awad B. Evaluation of cleaning efficacy and instrumentation time of Manual K- Files and two different rotary systems (ProTaper Next and Pro AF Rotary Files) in pulpectomy of primary molars: An In Vitro study. Egyptian Dental Journal. 2021 Oct 1;67(4):2865–74.
16. Jeevanandan G. Kedo-S Paediatric Rotary Files for Root Canal Preparation in Primary Teeth- Case Report. Journal of Clinical Diagnosis and Research. 2017;11(3):3–5.
17. 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 Randomized Clinical Trial. European Archives of Paediatric Dentistry .2018;19(4):273–8.
18. Chandler N, Chellappa D. Lubrication during root canal treatment. Australian Endodontic Journal. 2019;45(1): 106–110.
19. Pinheiro SL, Araujo G, Bincelli I. Evaluation of cleaning capacity and instrumentation time of manual,hybrid and rotary instrumentation techniques in primary molars. International Endodontics Journal. 2012 Apr;45(4):379–85.

20. Katge F, Patil D, Poojari M. Comparison of instrumentation time and cleaning efficacy of manual instrumentation, rotary systems and reciprocating systems in primary teeth: An in vitro study. Journal of Indian Society of Pedodontics and Preventive Dentistry. 2014;32(4):311-316.

21. Katge F, Ghadge S, Poojari M, Jain K. Comparative evaluation of cleaning efficacy of Prime PedoTM and DXL-ProTM Pedo rotary files with conventional H files in root canals of primary teeth: An In Vitro study. Journal of Clinical and Diagnostic Research. 2019;13(7):6-9.

22. Pathak S. In vitro comparison of K-file, Mtwo, and WaveOne in cleaning efficacy and instrumentation time in primary molars. CHRISMED Journal of Health and Research. 2016;3(1):60-64.

23. Rao A, Pandya D, Roy S. Comparison of instrumentation time and cleaning efficacy of manual K-file, Rotary Protaper Universal and Rrotary Protaper Next in primary anterior teeth: An In-Vitro Study. International journal Of Scientific Research. 2018;7(1):27-30.

24. Govindaraju L, Vishawanathaiah S. Assessment of quality of obturation, instrumentation time and intensity of pain with pediatric rotary File in primary anterior teeth: A Randomized Controlled Clinical Trial. International Journal of Clinical Pediatric Dentistry. 2018 Dec;11(6):462–7.

25. JP V. Instrumentation time efficiency of rotary and hand instrumentation performed on vital and necrotic human primary teeth: A Randomized Clinical Trial. Dentistry Journal. 2014;4(4):1-5

26. Gupta S, Das G. Clinical and Radiographic evaluation of Zinc oxide eugenol and Metapex in root canal treatment in primary teeth. Journal of Indian Society Pedodontics and Preventive Dentistry. 2011;29(3):222-228.

27. Showkat I, Chaudhary S. Comparison of instrumentation time and obturation quality between hand K-files, rotary Kedo SG and rotary ProTaper Gold files in root canal treatment of primary teeth. International Journal Of Scientific Research.2020;9(6):79-81.

28. Nerkar R, Yadav S, Mehta V. Root Canal Preparation in Primary Teeth with Nickel-Titanium Rotary Files: A Review. Journal of Advanced Oral Research. 2015;6(2):1-4

29. Ahmed HM. Anatomical challenges, electronic working length determination and current developments in root canal preparation of primary molar teeth. International Endodontic Journal. 2013;46:1011–1022.

30. Rimondini L, Baroni C. Morphologic criteria for root canal treatment of primary molars undergoing resorption. Dental Traumatology journal. 1995;11(3):136-141

31. Hulsmann M, Peters OA. Mechanical preparation of root canals: shaping goals, techniques and means. Endodontic Topics Journal. 2005;10(1):30-76.

32. Hieawy A, Haapasalo M, Zhou H, Wang ZJ, Shen Y. Phase transformation behavior and resistance to bending and cyclic fatigue of ProTaper Gold and ProTaper Universal instruments. Journal of Endodontics. 2015 Jul 1;41(7):1134–8.

33. Siddique R, Nivedhitha MS. Comparison of antibacterial effectiveness of three rotary file system with different geometry in infected root canals before and after instrumentation–a double-blinded Randomized Controlled Clinical Trial. British Dental Association Journal (BDJ). 2020;6(1):8.

34. Reddy G, Kalaiselvam R, Rajakumaran A. Evaluation of root dentin thickness and smear layer removal efficacy of two novel nickel titanium rotary instruments - An in Vitro cone-beam computed tomography and scanning electron microscopy study. Journal of Pharmacy and Bioallied Science. 2021;13(6):1628-1632

35. Tofangchiha M, Ebrahimi A, Adel M. In vitro evaluation of Kedo-S and RaCe rotary files compared to hand files in preparing the root canals of primary molar teeth. Frontiers in Bioscience-Elite Journal. 2022;14(2):14.

36. Eduardo C, Cunha RS, Cunha RS. Analysis of the instrumentation time and cleaning between manual and rotary techniques in deciduous molars. South Brazilian Dentistry Journal (RSBO). 2012;9(3):238-244.

37. Azar MR, Safi L, Nikaein A. Comparison of the cleaning capacity of Mtwo and ProTaper rotary systems and manual instruments in primary teeth. Dental Research Journal (Isfahan). 2012;9(2):146-150.

38. Alobaidy SS, Shukri BMS. Evaluation of the cleaning efficiency of 2 Shape, Hyflex EDM and ProTaper Gold systems using digital image morphometric analysis :An in Vitro Study. Indian Journal of Forensic Medicine & Toxicology.2020;14(3), 2584–2591.

39. Plotino G, Grande NM, Cotti E, Testarelli L, Gambarini G. Blue treatment enhances cyclic fatigue resistance of vortex nickel-titanium rotary files. Journal of Endodontics. 2014;40(9):1451-1453.

40. Tabassum S, Zafar K, Umer F. Nickel-titanium rotary file systems: What's new?. European Endodontics Journal. 2019;4(3):111-117.

41. Jaafar Selivany B. Cleaning efficacy of Wave One, ProTaper and manual instruments in preparation of permenant teeth: A comparative in vitro study. Duhok Medical journal. 2015;9(1):19-25.

42. Afreen L, Chandra R, Jain J, Mehrotra A. Comparative evaluation of removal of smear layer using newer rotary endodontic files: A scanning electron microscope study. Journal of Conservative Dentistry. 2021;24(6):616-621.

43. El Khodary SA, Roshdy NN. Influence of different rotary systems on the amount of apically extruded debris in mandibular molars.Egyptian dental journal. April 2019;65(2):1663-1670

44. Elnagar M, Ghoname N, Ghoneim W. Cleaning efficacy of rotary versus manual system for root canal preparation in primary teeth. Tanta Dental Journal. 2018;15(1):14-18.

45. Priyadarshini P, Jeevanandan G, Govindaraju L, Subramanian EMG. Clinical evaluation of instrumentation time and quality of obturation using pediatric hand and rotary file systems with conventional hand K-files for pulpectomy in primary mandibular molars: a double-blinded Randomized Controlled Trial. European Archives of Pediatric Dentistry. 2020 Dec 1;21(6):693–701

46. Lakshmanan L, Geo M, Ganesh J, Vignesh R. Assessing the quality of root canal filling and instrumentation time using kedo-s files, reciprocating files and k-files. Brazilian Dental Science Journal. 2020;23(1):1-7.

47. Otero D, Selvaraju SB, Kathpalia A. Evaluation of bacterial reduction after root canal shaping using ProTaper Gold and Waveone Gold rotary systems. European Joural of General Denistryt. 2021;10(2):73-77.