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EVALUATION OF APICALLY EXTRUDED DEBRIS OF PEDIATRIC ROTARY FILE SYSTEM USING KEDO- SG BLUE FILES VERSUS HAND INSTRUMENTATION USING K- FILES FOR ROOT CANAL PREPARATION IN PRIMARY CANINES: AN IN -VITRO STUDY

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Abstract

Objectives: The study aimed to evaluate the amount of apical extrusion of debris of pediatric rotary file system using Kedo- SG Blue files versus hand instrumentation using K- files for root canal preparation in primary canines. **Materials and Methods:** The study was carried out on 40 unidentified extracted primary canines, which were randomly and equally allocated into two groups according to the type of root canal instrumentation technique used: group (A) (K- file Group) and group (B) (Kedo SG- Blue Group). The experimental model of **Myers and Montgomery** was followed in the present study. **Results:** group B (Kedo-SG Blue) exhibited **a significantly less** amount of extruded debris compared to group A (K-file). **Conclusions:** Kedo -SG Blue rotary file system exhibits less amount of extruded debris compared to hand (K-file) which could result in decreased apical irritation after treatment.

Keywords: Pulpectomy, Pediatric Rotary File Systems, Kedo- SG Blue Files, k - Files, Apical Extrusion of Debris. Primary Canines.

INTRODUCTION

The principle goal in pediatric dentistry is to retain the primary teeth in the oral cavity until its physiological exfoliation to preserve arch integrity. Primary teeth present unique anatomical and physiological challenges for endodontic treatment. Their complex, tortuous and ribbon-shaped root canal systems, multiple accessory canals, physiological

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resorption, and the proximity to developing permanent tooth buds necessitate special considerations in treatment planning.[1]

One of the treatment options for pulpally involved primary teeth is pulpectomy, which is a critical endodontic procedure in pediatric dentistry aimed at preserving primary teeth that have undergone irreversible pulpitis or necrosis. The biomechanical preparation of the canals in pulpectomy plays a significant part in achieving a successful outcome as adequate shaping of the canal system removes contaminated pulpal tissue, giving adequate path for the irrigation in the canals hence providing the successful root canal filling.[2,3]

Although hand instrumentation with stainless steel files is considered the standardized method for preparing the canals of the primary teeth, it has certain shortcomings regarding child cooperation, time consuming, and iatrogenic errors including ledging, canal transportation and apical blockage. As rotary endodontics has gained great popularity in permanent teeth, rotary instrumentation with Nickel – Titanium files (Ni -Ti files) was introduced for primary teeth by **Barr *et al.*, 2000**[4] to overcome the limitations of hand instrumentation.[5]

Despite using Ni Ti rotary files in pulpectomy becoming a trend in pediatric dentistry, using Ni Ti rotary files designed for permanent teeth in pulpectomy of primary teeth has limitations; such as increasing the chance of lateral perforation due to thinner curved roots with ribbon –shaped morphology. Additionally, longer file length makes it difficult to work in a child.This creates the need for designing pediatric rotary systems to overcome such problems[6.]

Accordingly, various file systems were specially designed for primary teeth. The Kedo -S files are considered the first pediatric rotary file systems that were introduced into the market. This system was under continuous advancements, until it reached six generations, Kedo- SG blue is the third generation of these systems with controlled memory NiTi wire, giving it characteristics of higher flexibility and more resistance to cyclic fatigue.[7,8]

One of the most common issues encountered during root canal treatment is extrusion of intra-canal debris. The amount of apically extruded debris is influenced by the type of canal, apical diameter, working length, irrigation technique and solution used, number of files, instrumentation system, design and kinematics. Primary teeth may be prone to increased debris extrusion due to larger and irregular apical foramina and physiological root resorption leading to enlargement of apex[9,10].

Apical extrusion of debris is a significant concern in root canal therapy in primary teeth due to its implications on both immediate and long-term outcomes. This extrusion of debris after canal instrumentation may trigger undesirable consequences of postoperative pain, inflammation, flare –ups, delayed healing of periapical tissue and possibility of damage to permanent successors[11-13].

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Although the apical extrusion of debris is an unavoidable factor during canal preparation in both manual and rotary file systems, but it may be controlled by the design of the file system and the technique used for instrumentation.

For measuring debris extrusion, in- *vitro* quantification by Myers and Montgomery method has been found to be one of the most popular methods. Many *in vitro* studies have been pursued to evaluate debris extrusion by manual as well as rotary file systems in pediatric endodontics.[14,15]

Although previous studies have evaluated apical debris extrusion associated with Kedo-S rotary files (first generation), only a limited number of studies have conducted on Kedo SG Blue rotary files (third generation). Therefore, further comparative studies are needed to provide stronger evidence regarding their relative ability to minimize apical debris extrusion during root canal preparation in primary teeth.

So, this study aimed to evaluate the amount of apical extrusion of debris of pediatric rotary file system using Kedo- SG Blue files versus hand instrumentation using K- files for root canal preparation in primary canines.The **null hypothesis** stated that; there was no significant difference in the weight of apical extrusion of debris of Kedo –SG blue rotary file system versus hand instrumentation using K- file for root canal preparation primary canines.

METHODS

Study Design and Setting:

This an *in- vitro* study was conducted to evaluate the amount of apical extrusion of debris. The study was waived from approval of Research Ethics Committee, Faculty of Dentistry, Suez Canal University, Ismailia, Egypt, since it was carried out on 40 unidentified extracted primary canines, which were extracted for orthodontic reasons.

The unidentified primary canines were collected from clinics of Pediatric Dentistry and Orthodontics, Faculty of Dentistry, Suez Canal University, Ismailia, Egypt. This study was conducted in the research lab at the Center of Excellence in Molecular and Cellular Medicine, Faculty of Medicine, Suez Canal University, Ismailia, Egypt.

Sample Size Calculation:

Sample size estimation was performed using G*Power version 3.1.9.2.The effect size was 1.06, using alpha (α) level of 0.05 and Beta (β) level of 0.10, i.e., power = 95%; the estimated minimum sample size (n) was a total of 40 samples, 20 teeth in each group[16,17].

Teeth Selection

Forty unidentified extracted primary canines were selected after taking preoperative digital periapical radiographs to ensure that the selected teeth fullfiled the following inclusion criteria: maxillary or mandibular primary canines with single canals., teeth with no root resorption and no internal resorption or intracanal calcifications.[17,18]

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Sample Grouping, Randomization and blind allocation figure (1)

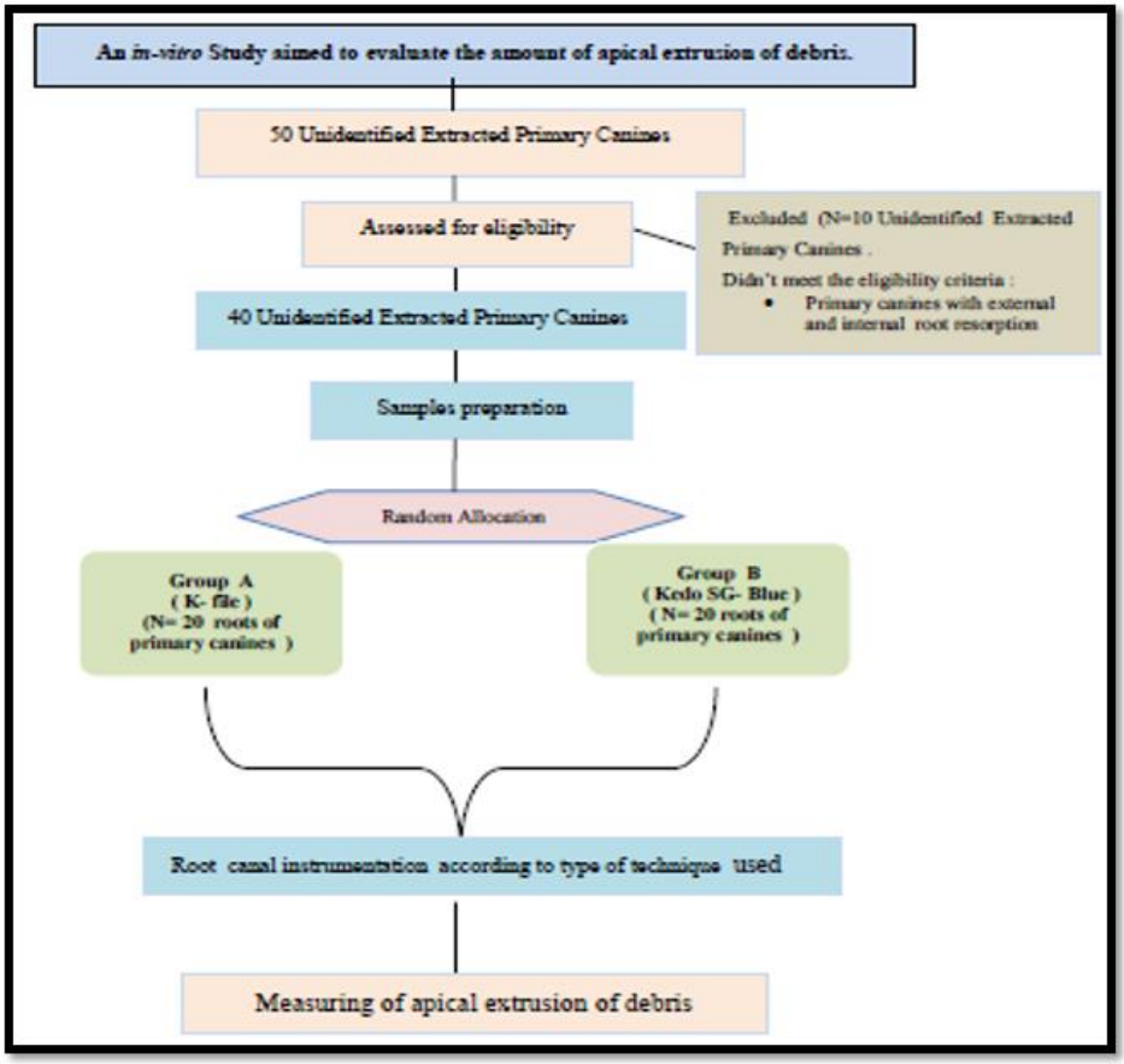

Figure (1): Flow Chart of the In-Vitro Study

The forty primary canines were numbered from 1 to 40 and then, they were randomly and equally allocated into two groups according to the type of root canal instrumentation technique using www.randmaizer.org, then allocation concealment was conducted through placing closed serial papers represented from 1 to 40 in white opaque envelope to choose which technique to be done at each time.

Group (A) (K- file Group): Included 20 primary canines in which pulpectomy was performed by hand instrumentation system using K- file (Mani, Inc, Tochigi, Japan) as the control group.

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Group (B) (Kedo SG- Blue Group): Included 20 primary canines in which pulpectomy was performed by rotary instrumentation system using Kedo-SG Blue file (Reeganz Dental Care Pvt Ltd. Chennai, India) as the study group

Study Procedures

I: Sample Preparation[6,19-21]

The collected teeth were washed under running water and cleaned from any remaining soft tissue fragments from their root surfaces. Then, the teeth were stored in sterile saline solution at room temperature until starting the study. Access preparation was done for all teeth using high speed large round bur size 330 under constant water cooling. Pulp chamber was completely deroofed. No.10 size K file was used to determine patency of canals. Then, decoronation was done for all teeth using disc with a low speed hand piece at fixed length 10 mm measured from tooth apex for standardization purpose[22].

The experimental model of **Myers and Montgomery, 1991**[23] was followed in the present study. Forty 2 mL eppendorf tubes and 40 glass vials were utilized. The eppendorf tubes acted as collectors for the debris and irrigant produced during instrumentation while the glass vials acted as holders for tubes during procedures. The caps were removed from the eppendorf tubes. Then, the empty eppendorf were pre-weighted using 10^{-4} precision digital electronic microbalance (Sartorius, Germany).

Three consecutive weight measurements were taken for each tube, then the mean value **(W1)** was calculated. The values were recorded in terms of gram fractions. Holes were created in the caps of tubes using round bur size 330, and each canine was inserted into each holes up to cement enamel junction with the apex facing down. The roots of canines were fixed in place with gingival gel barriers.

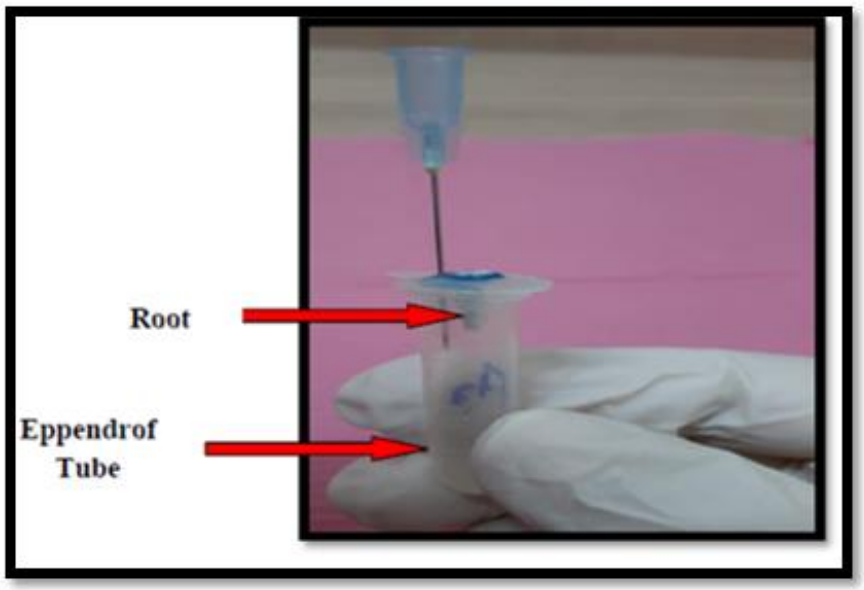

Figure (2): Eppendrof with root

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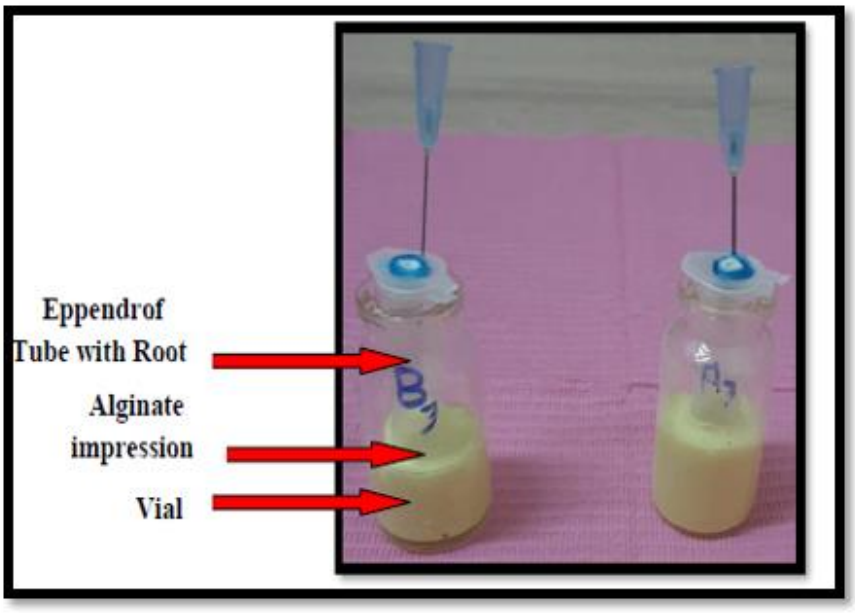

Figure (3): Vial containing eppendrof tube with root

Syringe needles with 27 gauges were placed in the caps of tubes next to the fixed roots to equalize the external and internal pressures**.** The eppendorf tubes with the roots and needles were fitted into the glass vials to hold the tube during preparation**,** and were fixed to the vials with aligante impression material to prevent movement of eppendorf tubes **figures (2)& (3).** The vials were covered with foil to prevent operator from seeing extruded debris during root canal instrumentation and eliminate performance bias **figure (4)**. During the procedures, the eppendorf tubes were not touched, and the entire apparatus was handled only by the vial.

Figure (4): Vial covered with foil

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II: Root Canal Instrumentation[6,13,21,24,25]

The working length for all roots of primary canines was pre-determined using No. 15 k-file by subtracting 1mm from the apex with fixed length 9 mm for all roots of primary canines. Depending on the group allocation, the canal instrumentation was conducted as follows:

- **In Group A (K- file group):**

Twenty root canals of primary canines were prepared using hand instrumentation with K-file (Mani, Inc, Tochigi, Japan) in apical coronal direction with the following sequence: size 25 /0.02 taper, size 30 /0.02 taper, size 35 / 0.02taper and size 40/ 0.02 taper. Motion of the files was in watch winding until reaching working length. Then, a quarter turn and pull motion was advocated.

The root canals were irrigated with distilled water using syringe and Navi tip gauge needle - 29 at 2mm short of working length which was 9 mm. The irrigation of canals was carried out four times during instrumentation with total irrigation volume of 4 ml per root as follows: one ml of distalled water was used before and after each insertion of the file into the canal with total irrigation volume of 4 mL per root canal.

- **In Group B (Kedo -SG Blue group):**

Twenty root canals of primary canines were prepared by crown down technique using U1 rotary files from Kedo -SG blue rotary files (black coded, with tip diameter 0.40 mm, variably variable taper from 0.04 to 0.08) (Reeganz Dental Care Pvt Ltd. Chennai, India) with endodontic motor (Smart C1 Endodontic motor and Apex locator, COCSO, China) at 300 rpm and 2.2 N cm torque, according to manufacturer`s recommendation. The U1 rotary files were used in lateral brushing motion in 2 times till the working length was reached, then the files were withdrawn. EDTA gel 17% (MD-Chelcream METABIOMED Co.LTD, Korea) was used as a lubricating paste for files during canal preparation. The files were cleaned after each use with an alcohol pad.

The root canals were irrigated with distilled water using syringe and Navi tip gauge needle - 29 at 2mm short of working length (10 mm). The irrigation of canals was carried out four times during instrumentation with total irrigation volume of 4 ml per root canal ;as follows: one ml of distalled water was used before insertion the file into the canal, 1 ml after the first withdrawal of the file for cleaning, 1ml after reaching working length and 1 ml after completing the instrumentation. Forceful preparation was avoided during instrumentation by avoiding excess pressure on the files. Each file was used for up to only 7 teeth as per the manufacturer`s recommendations.

Method of Evaluation[12,19,20,25,26]

After root canal instrumentation, the caps of the tubes with the roots were unscrewed. The surface of the root was washed with 1 ml of distilled water to collect adhered debris into the eppendrof tubes. The tubes with irrigants and debris were then stored in an

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incubator (JSR, Korea) at 37^0 C for 15 days to evaporate the moisture before the dry debris was weighed **figure (5)**...

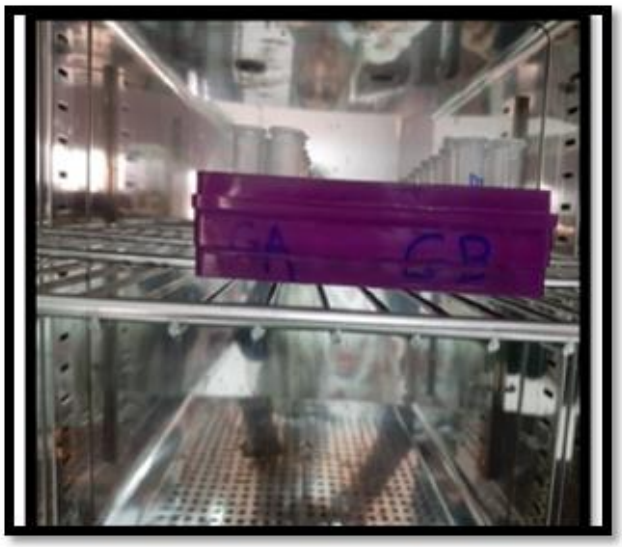

Figure (5): Eppendrof tube with irrigants and debris in incubator

The tubes with the dried debris were reweighted using the same digital electronic microbalance 10^{-4}**.** Three consecutive weight measurements were taken for each tube, and the mean value **(W2)** were calculated. The values were recorded in terms of gram fractions. **Figure (6)**.

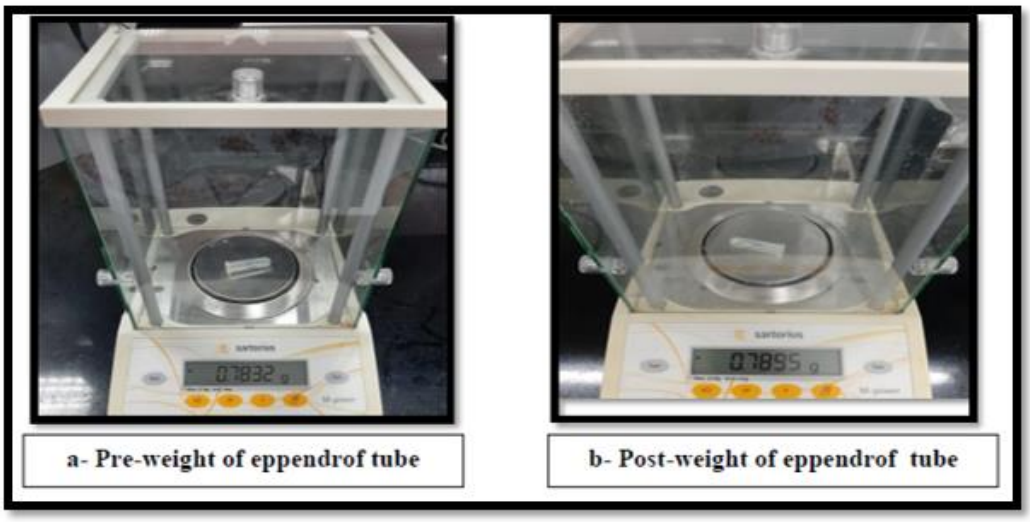

Figure (6 a, b): Pre and post -weight of eppendrof tube

The weight of extruded debris were determined by subtracting the weight of the pre-weighted empty tubes from the weight of the tubes plus the dried debris **(W2-W1)** to assess the weight (amount) of apical extrusion of debris **(W3)** where **(W3 = W2- W1).**

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RESULTS

The results of the comparison of extruded debris weight between group A (K-file) and group B (Kedo-SG Blue). Results showed that the mean value for group A (K-file) was 0.011 ±0.011 grams. In contrast, group B (Kedo-SG Blue) showed a mean value of 0.004 ±0.005 grams. The difference between the two groups was **statistically significant**, with a p-value of 0.001, where group B (Kedo-SG Blue) exhibited **a significantly less** amount of extruded debris compared to group A (K-file) as presented in **table (1) and figure (7).**

Table (1): Comparison of the weight of apically extruded debris (in grams) between the two groups

	Group A (K-file) (n=20)	Group B (Kedo SG Blue) (n=20)	*p* value
Mean ±SD	0.011 ±0.011	0.004 ±0.005	0.001*

*Statistically significant difference at p value<0.05, *p* value[1]

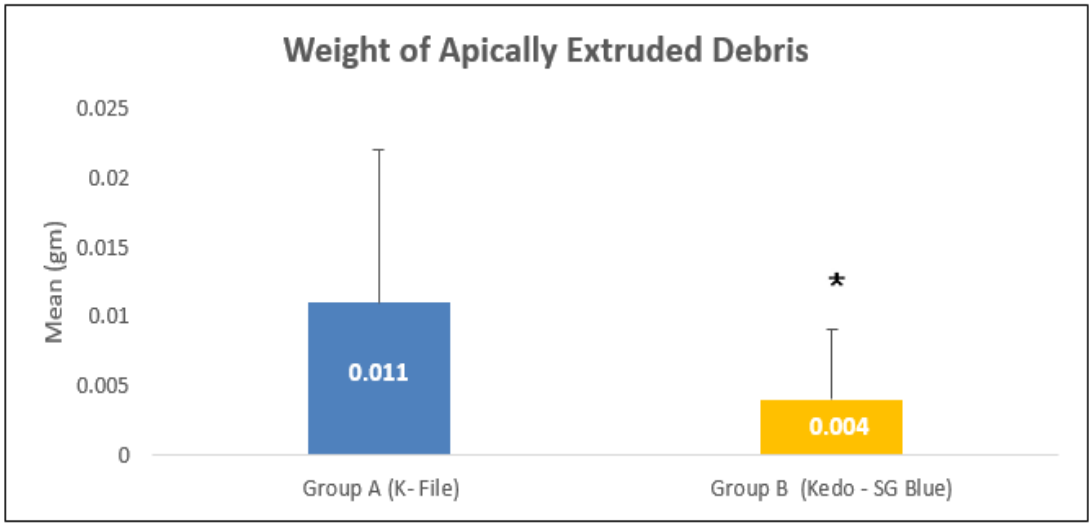

Figure (7): Bar chart showing comparison of the weight of apically extruded debris (in grams) between the two groups

DISCUSSION

The present study was an in- *vitro* study, that aimed to assess amount of apically extruded debris, which is one of the important concern during root canal instrumentation as the amount of extruded debris during root canal instrumentation may trigger undesirable consequences of postoperative pain, inflammation, flare–ups, delayed healing of periapical tissue and possibility of damage to permanent successors.[11,12]

This study was conducted on 40 unidentified extracted primary canines, extracted for orthodontic reasons. Only single rooted , maxillary and manibular primary canines, with no root resorption were included in the present study to overcome morphological variations and maintain uniformity between the two groups for standardization as agreed

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with **Elnagar *et al.*, 2018**[17]; **Madalena *et al.*, 2018**[18]**, Asif *et al.,* 2019**[25] **and Preethy *et al.,* 2019**[21]**.** Radiographs were taken preoperatively to confirm that all included primary canines had straight and single canals.

The selected primary canines were randomly allocated into two groups (A&B) according to types of instrumentation technique used for root canal preparation. Working length was determined 1mm short from apex as recommended by **Madhusudhana *et al.,* 2010**[19], **Asif *et al.,* 2019**[25] **and Preethy *et al.,* 2019**[21]**.** Their studies stated that when working length was performd until the root apex,more apical extrusion of debris occurred than when it was perfomed 1mm short as denoted by **Beeson *et al.,* 1998** [27].In the present study, working length was set at 9 mm length for standardization purpose.

In the current study, **Myers and Montgomery model** was followed for collecting apically extruded debris, which is the common method used for this purpose. In present study , absence of simulation of periapical tissue using flora foam due to its disadvantage of absorption of irrigant and debris when getting close to the apical foramen that alter the results as denoted by **Burklein and Schafer, 2012**[28]**; Asif *et al.,* 2019** [25] **; Preethy *et al.,* 2019**[21] **and Rathi *et al.,* 2021**[6].

In the present study, distilled water was used as an irrigant instead of 1% sodium hypochlorite to avoid any misleading weight measurements resulting from residue of 1% sodium hypochlorite after evaporation of the solution. This is in agreement with **Kalra *et al.*, 2017**[20] who used the same method of evaporation. In addition, studies conducted by **Asif *et al.,* 2019**[25]**; Preethy *et al.,* 2019** [21] **and Rathi *et al.,* 2021**[6] used distalled water as an irrigant**,** in spite of the different temperature and duration for evaporation in comparison to the present study.

The method of evaporation of distalled water in this study was incubation of the eppendrof tubes at $37C^0$ for 15 days due to available facilities. This was in agreement with **Madhusudhana *et al.,* 2010**[19]; **Kalra *et al.*, 2017**[20] **and El Asfouri and Bedier, 2021**[26]**,** but disagreed with **Asif *et al.,* 2019**[25]**; Preethy *et al.,* 2019**[21] **and Rathi *et al.,* 2021**[6] who used the method of evaporation of distalled water by incubating the eppendrof tubes at $70C^0$ for 5 days. The amount of irrigant used was kept constant for the two study groups. The results of current study revealed that group B (kedo SG Blue file) exhibited statistically significant less amount of apical extrusion of debris in comparison to group A (K- file). The possible reasons for these findings are less number of files used, dissimilarity of taper and motion of files as reducing the number of files helps in reducing the canal aberrations along with reduced apical extrusion.

The kedo -SG Blue files have variable taper which prepares the canal less apically and more coronally leading to less apical extrusion of debris while k- file have a constant taper (0.02) which may provide less space for the debris to get flushed coronally, consequently the debris may be pumbed apically.[12, 21]**,** [25] Additionally , the motion of rotary files tend to direct debris towards the orifice rather than pushing it apically as happens with filing motion with quarter pull motion of hand K-files.[13,21]

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The results of the current study were in accordance with previous studies conducted by **Asif *et al.*, 2019**[25]**; Preethy *et al.*, 2019**[21] **and Pawar *et al.*, 2021**[13] who evaluated weight of apically extruded debris in primary teeth using Kedo -S file system and they found that using the rotary system during root canal instrumentation in primary teeth extruded less debris than manual files.

The findings that less apical extrusion of debris in primary teeth were achieved when using rotary file systems other than that used in the present study in comparison hand files were concluded by **Buldur *et al.*, 2018**[24]; **Habib *et al.*, 2022**[29] **and Karaagac Eskibaglar and Ipek, 2024** [30] and their findings were consistent with results of the current study. Based on the results of the present study, the **null hypothesis** was **rejected.** Since the weight of apical extrusion of debris was **significantly lesser** in group B (Kedo-SG Blue) than in group A (K-file).

CONCLUSIONS

Kedo -SG Blue rotary file system exhibits less amount of extruded debris compared to hand (K-file) which could result in decreased apical irritation after treatment.

Author's Contributions

DFMAR & SMMO conceived the idea and designed the study. DFMMR wrote the main manuscript text. GAEE, GGD& MES revised the manuscript. All listed authors participated in study and data collection. All authors have read and approved the final manuscript.

Data Availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

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