

CLINICAL AND RADIOGRAPHIC EFFICACY OF PEDIATRIC ROTARY FILE SYSTEM USING KEDO- SG BLUE FILES VERSUS HAND INSTRUMENTATION USING K- FILES FOR ROOT CANAL PREPARATION IN MANDIBULAR PRIMARY MOLARS: A 12- MONTH FOLLOW-UP RANDOMIZED CONTROLLED CLINICAL TRIAL

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Abstract

Objectives: The study aimed to evaluate and compare the clinical and radiographic efficacy of Kedo –SG Blue rotary file system versus hand instrumentation using k- files for root canal preparation in mandibular primary molars through 12 months follow up. **Materials and Methods:** The study was conducted on 40 mandibular primary molars presented in 17 children aged 4 to 6 years using the split mouth technique and were randomly and equally allocated into two groups according to type of instrumentation technique used for root canal preparation, group I (k-file) & group II (Kedo-SG blue rotary files), each group included 20 mandibular primary molars. Time for root canal instrumentation and filling was recorded and overall quality of root canal filling was assessed for all teeth using Technical Scoring System. Clinical and radiographic follow ups for all cases were carried out for 12 months. **Results:** group II (Kedo-SG Blue) showed statistically significant shorter instrumentation and filling time in comparison to group I (K-file). There were no statistically significant differences between both groups regarding overall quality of root canal filling. Both groups maintained a 100% clinical success rate at 6 and 12 months, but the overall radiographic success rates declined from 90% at 6 months to 80% for group I (K- file) and 85% for group II (Kedo -SG Blue) at 12 months. **Conclusions:** Kedo- SG Blue rotary file system is an effective and efficient file system for pulpectomy in primary teeth. Kedo - SG Blue rotary file system decrease dental chair side time. Both hand and rotary file systems can achieve equal quality of root canal filling, however, (Kedo- SG Blue) offers a slight advantage in terms of achieving higher quality outcomes, particularly in the 1st primary molars.

Keywords: Pulpectomy, Pediatric Rotary File Systems, Kedo- SG Blue Files, k - Files, Primary Molars.

INTRODUCTION

The most important goal of pediatric dentistry is to preserve primary teeth for functional and esthetic purposes. In addition to, maintain arch length and guiding normal eruption of succedaneous permanent teeth^{1,2}. Pulp therapy becomes mandatory when deep caries affects primary teeth. Pulpectomy procedure is considered the treatment of choice if pulpal inflammation extends to the root canal. Pulpectomy is a procedure involving complete removal of pulp tissue from the root canal space in primary teeth using hand or rotary files followed by filling it with an inert resorbable material³.

An ideal pulpectomy technique for primary teeth should be fast and involves a few number of visits, during which effective preparation of root canal is made without weakening the tooth structure or endangering the underlining permanent teeth. It aims to maintain tooth function until it is naturally exfoliated³. Proper root canal shaping is a key factor for success of endodontic treatment. The primary objectives of cleaning and shaping of the root canal system are to remove pulp tissues containing soft and hard bacteria, and provide continuous tapered canal preparation to obtain an irrigation path to the apical third allowing the placement of filling material and retaining the integrity of radicular structures².

Traditionally, stainless steel files have been used for pulpectomies, However, there are certain potential limitations for manual instrumentation technique with stainless steel files. These limitations include time consumption, operator fatigue and iatrogenic errors like ledging, canal transportation and apical blockage².

Nickel titanium (Ni-Ti) alloy was developed in the 1960s, and the first Ni-Ti rotary file appeared in the market around 1993. The Ni-Ti rotary systems came into existence in the field of endodontics to overcome the shortcomings of conventional manual files.^{4,5}

Barr et al., 2000⁶ were the first to utilize Ni-Ti rotary files for root canal instrumentation in primary teeth using ProFile system. They concluded that its use was expeditious and cost effective, rapid, resulting in homogenous and uniform obturation. Several previous studies evaluated different Ni-Ti rotary file systems which were designed specifically for permanent teeth in primary teeth ; such as, ProFile, ProTaper Hero Shaper, Mtwo, FlexMaster, Light Speed LSX, Hero 642, K3, wave One, ProTaper Next and Hyflex EDM. Their results revealed the advantages and drawbacks of using them in primary teeth^{3,7}.

The advantages of using rotary files for primary teeth are diverse, which have been evaluated in previous studies, such as; the unique design and flexibility of Ni-Ti rotary files enhance the preservation of the original morphology of curved canals, characteristic of primary molars, by reducing the procedural errors^{1,7}. As the canal preparation is a funnel shaped, the obturation material can be placed with ease and less overfilling occurs with resultant in a more predictable uniform of obturation paste^{7,8}. Additionally, cooperative behavior from child can be achieved as the chair time is decreased. The shorter duration helps in maintaining quality and security as well as reducing patient's and professional's fatigue. Therefore, better quality treatment can be performed in a shorter time⁷.

The Ni- Ti rotary files do not need pre-curvature due to their elastic memory. They are motor activated and can prepare the root canal with high speed. The probability of root canal deformation and transportation is reduced due to this elastic memory and radial aspect that keep fill in the center of the wall support and inactive tips².

Despite the efficacy of Ni Ti rotary system in primary teeth, rotary instrumentation has drawbacks such as the high cost of Ni-Ti rotary systems and the possibility of lateral perforation on the inner surface of primary teeth. These lateral perforations are due to predesigned greater taper of the rotary files, besides, the primary dentin is softer and less dense than that of permanent teeth¹. In addition, primary teeth have shorter, thinner, more curved ribbon shaped roots compared to permanent teeth, making the use of Ni Ti rotary instrumentation technique sensitive and requiring proper training of the operators to control the working length due to the reduction in tactile sensitivity during apical preparation compared with manual mechanical preparation^{1,2,9}

The advantages and drawbacks of using the Ni-Ti rotary systems, designed for permanent teeth, in primary teeth have led to the development of different Ni-Ti rotary systems especially designed for use in primary teeth. Such Ni –Ti rotary instruments with different designs of taper, blades, grooves, and tips have been suggested for efficient biomechanical preparation and to decrease the procedural time which is one of very important factors for cooperation of children.^{2,10-12}

Pediatric Rotary files are generally designed with shorter length; this provides ease of operation when working in pediatric patients. Kedo –S rotary files (Kids Endodontic Shaper) file system is the first and most commonly used rotary system to be designed for root canal instrumentation for primary teeth in India, that introduced by Ganesh Jeevanandan in 2016-2017. Ked-S files are available in six generations according to manufacturing modifications.^{11,13-15}

Kedo –SG Blue files is the third generation. This system consists of three files which made by heat treatment of Ni-Ti alloy and have controlled memory which provide super flexibility and resistance to cyclic fatigue up to 75% due to presence of titanium oxide. These files should be operated at a speed of 250 – 300 rpm and 2.2 – 2.4 Ncm torque. The overall length of 16 mm whereas working length is 12mm. The files available are D1, E1 and U1. These files have gradual variable taper (4%-8%). This gradual tapering aids in efficient canal preparation with preservation of the original anatomy of the curved canals and avoids over instrumentation of the inner wall of the root surface.^{11,13-14}

Previous studies were carried out to evaluate using rotary systems in primary teeth in terms of instrumentation time, obturation time, quality of obturation, postoperative pain and clinical and radiographic success.^{11,16-24} Although the number of studies assessing and comparing the efficacy of different types of pediatric rotary files in comparison to hand instrumentation for root canal preparation are numerous, up to our knowledge, given that evidence regarding the long-term performance of Kedo-SG Blue files remains limited, and no previous study combined clinical and radiographic evaluation of Kedo- SG Blue for a 12 month follow up period.

Therefore, the aim of the present study was to evaluate and compare the clinical and radiographic efficacy of Kedo –SG Blue rotary file system versus hand instrumentation for root canal preparation in primary molars with 12 months follow up. The null hypothesis was; there were no significant differences in the clinical and radiographic efficacy of Kedo –SG blue rotary file system versus hand instrumentation using K- file for root canal preparation in mandibular primary molars.

MATERIALS AND METHODS

Study Design

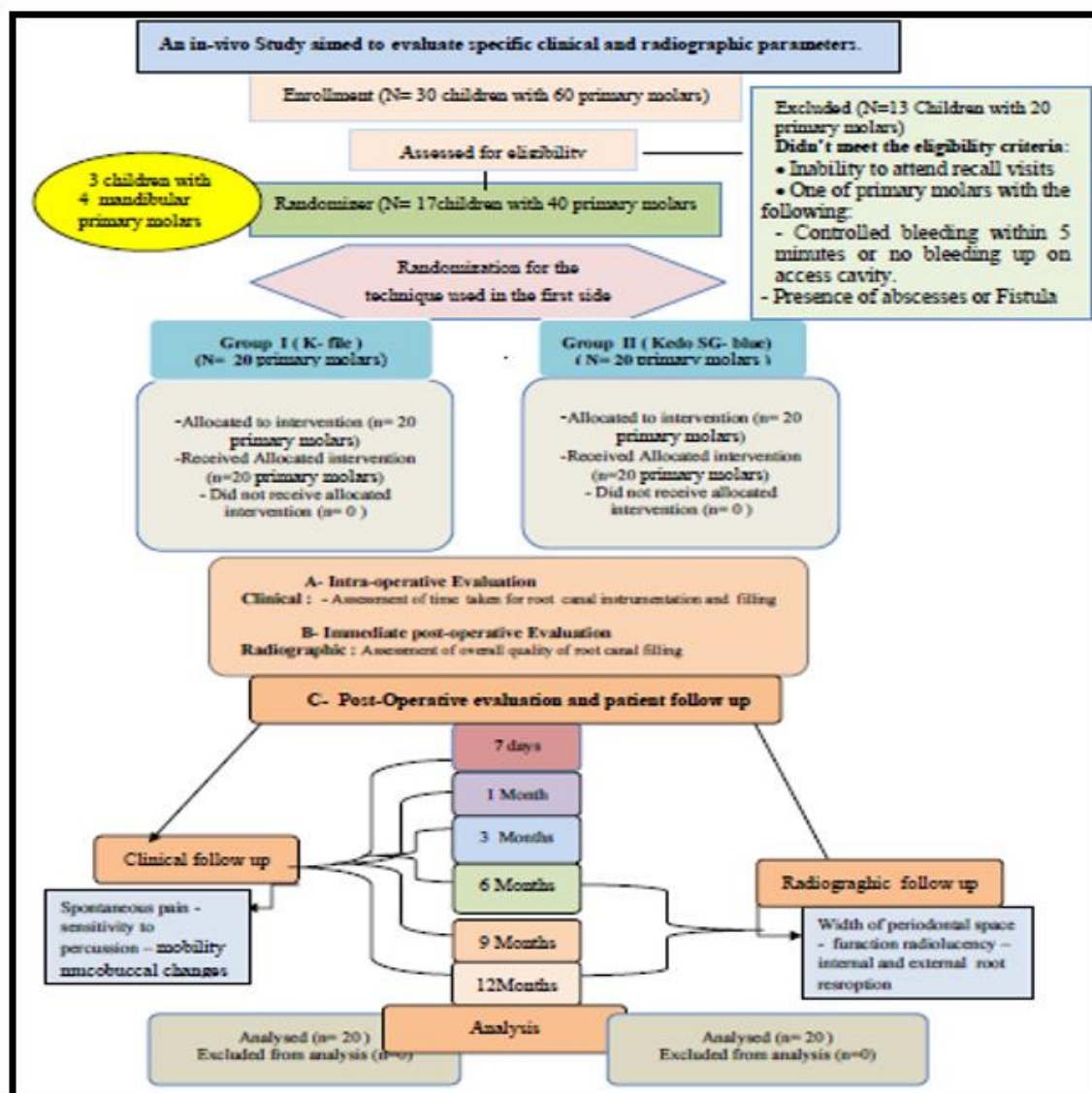


Figure (1): CONSORT Clinical Flow Chart of Study

The present study was carried out to evaluate and compare the clinical and radiographic efficacy of Kedo –SG Blue rotary file system versus hand instrumentation using k- files for root canal preparation in mandibular primary molars through 12 months follow up. This study was set as a randomized clinical controlled trial, it was registered on **www. Clinical trial.gov** with ID (NCT06152354) and registration date (18/10/2023). **CONSORT guidelines** for planning and reporting of the Clinical Trials in pediatric endodontics were followed during the different stages of the study as in **figure (1)**.²⁵

Study Setting and Ethical consideration:

The study was conducted in the department of Pediatric Dentistry, Preventive Dentistry and Dental Public Health, Faculty of Dentistry, Suez canal University, Egypt, after the approval of Research Ethics Committee (REC), Faculty of Dentistry, Suez canal University, Egypt with approval no. (124 / 2018).

The study was conducted on 40 mandibular primary molars presented in 17 children using the split mouth technique (20 mandibular primary first molars and 20 mandibular primary second molars).

Three children of the seventeen participating in the present study received pulpectomy in their four mandibular primary molars. The children were selected from the out- patient clinic of the Pediatric Dentistry, Preventive Dentistry and Dental Public Health Department, Faculty of Dentistry, Suez Canal University, Egypt. Informed written consents were obtained from parents or guardians of the children after full explanation of clinical procedures and detailed treatment plan before participating in the study.

Sample Size Calculation:

Sample size calculation was performed using G*Power version 3.1.9.2,.The effect size was 1, using alpha (α) level of 0.05 and Beta (β) level of 0.10, i.e., power = 90%. Based on the previous study, the estimated minimum sample size (n) was a total of 36 primary molars, 18 primary molars for each group.

In order to compensate for possible patients'dropout during follow ups, the sample size was increased by 10% to become **40 primary molars**, 20 primary molars in each group.^{26,27}

Patient Selection:

The children participating in the present study were selected to fulfill the following eligibility criteria:- ^{16,28,29}

Inclusion Criteria: Apparently healthy children free from systemic diseases, their age ranging from 4- 6 years, both boys and girls were included, cooperative children with Frankle behaviour rating scale score 3 (positive) and 4 (definitely positive),and children having at least two similar bilateral mandibular primary molars (first or second primary molars) with deep caries diagnosed with symptomatic irreversible pulpitis as well as symptomatic apical periodontitis and indicated for pulpectomy.The primary molars were selected according to the following criteria:-restorable mandibular primary molars with

sufficient amount of tooth structure, history of severe spontaneous pain or pain that is not relieved by analgesics, presence of pain with percussion, and excessive bleeding from the root canals up on access cavity.

Exclusion Criteria: Children with any of the following criteria were excluded from the present study:- children with known or suspected allergies to any medications used, inability to attend the recall visits periodically and children having mandibular primary molars with the following exclusion criteria:- controlled bleeding within 5 minutes upon access cavity that shifted to pulpotomy, no bleeding upon access cavity, acute or chronic abscess or fistula, mobility grade II or III, inter-radicular or periapical bone destruction (radiolucency), and internal root resorption & external root resorption more than 1/3 of root's length.

Sample Grouping and Randomization:-

Forty mandibular primary molars in 17 children (using the split mouth technique) were randomly and equally allocated into two groups according to type of instrumentation technique used for root canal preparation. Both groups incidentally included equal number of mandibular primary first molars (10 in each group) and mandibular primary second molars (10 in each group) as follows: -

Group (I):- Included 20 mandibular primary molars in which pulpectomy was performed by hand instrumentation using K- files (Mani, Inc, Tochigi, Japan) from size 15 to size 35, **group I** was considered **the control group**.

Group (II):- Included 20 mandibular primary molars in which pulpectomy was performed by rotary instrumentation system using Kedo-SG blue file (Reeganz Dental Care Pvt Ltd. Chennai, India), **group II** was considered **the study group**.

Randomization for the technique used in the first visit was done according to lottery method using 20 cards in a white envelope, 10 cards for group I (K- file) and 10 cards for group II (Kedo-SG blue). Each child was asked to pick up one card from the envelope which represented the group of the **first side** to be treated according to the child's complaint.

Performance bias was avoided as only one operator performed the clinical trial with a standardized method for all patients. Postoperative radiographic outcomes were assessed by another examiner blinded to the group each molar belonged to for reduction of detection bias.

Study Procedures:

Personal, medical and dental histories were recorded in a specially designed diagnostic chart and were reviewed by supervisors. Preoperative evaluation was conducted on the primary molars to be treated to ensure their compliance with the study's criteria through clinical examination using dental mirror and probe, and radiographic examination using digital periapical radiographs. In the first visit, pulpectomy was done using the selected technique in the side according to child's chief complaint. In the second visit, which was

after one day, pulpectomy was done using the other technique in the opposite side. Single visit pulpectomy was done for all mandibular primary molars in both groups as follows:-

A-Clinical Procedures

• Access Cavity Preparation

Topical anaesthetic gel 20 %Benzocaine (I-Gel, Vendor: B, Dent., USA) was applied on the injection site using a cotton swab and left for 2 minutes before administering local anaesthesia. Inferior alveolar nerve block anaesthesia was achieved using Mepivacaine hydrochloride 2% with epinephrine 1:100,000 (Mepicaine, Alexandria company, Egypt). The tooth to be treated was then completely isolated using rubber dam (Snactuary, Perak, Malaysia). Caries was removed using a large spoon excavator. Access cavity was done under constant water cooling and suction using high speed round bur No.330. Pulp chamber was completely de roofed using Endo Z bur. Endodontic explorer was used to locate orifices of the canals.

• Root Canal Instrumentation ¹¹

No.10 size K- file was used to determine patency of canals. The working length of each canal was determined using No.15 size k-file by an apex locator and then confirmed by digital periapical radiograph where the file was set one mm shorter from apex. Depending on the group allocation, the canal instrumentation was conducted as follows:-

In **Group I (K- file group)**:- Root canals were prepared by hand instrumentation using K- file (Mani, Inc, Tochigi, Japan) in apical coronal direction from size 15/0.02 to size 35/0.02 taper. Motion of the files was in watch winding until reaching working length. Then, a quarter turn and pull motion was advocated. Root canal instrumentations for mandibular first and second primary molars were conducted in the following sequence:- Mesio Buccal and mesio lingual canals were prepared using K -files from size 15 /0.02 taper size to size 30 /0.02 taper. Distal canal(s) were prepared from size 15 /0.02 taper to size 35/0.02 taper.

In Group II (Kedo- SG Blue group):-

Root canals were prepared by rotary instrumentation using Kedo- SG blue rotary files (Reeganz Dental Care Pvt Ltd. Chennai, India) with crown down technique using endodontic motor (Smart C1 Endodontic motor and Apex locator, COCSO, China) at 300 rpm and 2.2 N cm torque, according to manufacturer`s recommendations. D1 rotary files (red colour coded, tip diameter 0.25, variably variable taper) were used to prepare narrower canals (mesio Buccal and mesio lingual canals) while E1 rotary files (blue colour coded, tip diameter 0.30, variably variable taper) were used to prepare wider distal canal(s), for ease of preparation in the distal canal (s), D1 was first used followed by E1. EDTA gel 17% (MD-Chelcream METABIOMED Co.LTD, Korea) was used as a lubricating paste during canal preparation. Each rotary file was used to prepare the canals using a lateral brushing motion for one time in each canal of the tooth till the working length, then, the file was withdrawn once the working length was reached. Root canal instrumentation for mandibular first primary molar was conducted in the following sequence:- mesio Buccal

and mesio lingual canals were prepared using D1 file while distal canal was prepared using D1 followed by E1¹³. Root canal instrumentation for mandibular second primary molar was conducted in the following sequence: - Mesio buccal canal was prepared using D1 file first followed by E1 while mesiolingual canal was prepared using D1 only because the canal was narrower than mesio buccal canal. The distal canal was prepared using D1 followed by E1¹³. Each canal was irrigated before engaging a file which was used in and out action. Each file was cleaned after each use with an alcohol pad and checked for distortion. 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.

- **Protocol of Irrigation**

Four ml of 1% sodium hypochlorite was used in each canal of mandibular primary molars in both groups in between each instrument sequence followed by 1mL saline. Then, the canals were irrigated with 1mL of 17 % EDTA solution (Jk Dental vision, India) for 1 minute for removing smear layer followed finally by 1ml saline. After irrigation, canals were dried with absorbent paper points (#30 & #35).¹⁹

- **Root Canal Filling and Final Coronal Restoration**

Root canals for both groups were filled with equal amounts of homogenous thick mix of zinc oxide & eugenol (ZnOE) (PREVEST Denpro, Bari Brahmana, India), approximately 3 scoops of powder and 4 drops of liquid was used. The thick mix was applied in to the canals by incremental filling technique using endodontic plugger and wet cotton pellets. The plugger was coated with zinc oxide powder to avoid the stickiness of thick mix to the instrument³⁰. Zinc phosphate cement (Adhesor, Spofa Dental A.s, Jicin CZECK Republic) was placed over zinc oxide & eugenol then, the tooth was finally restored using stainless steel crown (3M Oral Care, USA) at the same visit. Immediate postoperative digital periapical radiographs were taken using standardized paralleling periapical technique using XCP device to assess overall quality of root canal filling and serve as a baseline radiograph for future assessments.

B- Intra oral Paralleling Periapical Radiographic Procedures

All patients were examined radiographically using Fona XDC digital intra oral x-ray machine (FONA XCD, via Galilei, Assago, Italy), installed in the Pediatric Dentistry post-graduate clinic, Faculty of Dentistry, Suez Canal University, Egypt. Children were examined using standardized intra oral paralleling periapical semi - direct digital radiographic technique using the rinn (XCP) periapical film holder and a long cone. Semi - direct standardized digital imaging was performed using KaVo Scan examTM One exam one, TUUSULA, 2017, K11711221, Finland). KaVo Scan examTM One is an intra oral digital imaging plate system using imaging phosphorous plates (Photo - Stimulable Phosphor plate PSP). The imaging plate (PSP) (X mind AC de Gotzen, Italy) used was size 1 with an active surface area of 24x40 mm. Pixel size is 800 x 1334 microns with a total pixel number of 1,067,200 pixels, and image size 2.03 megabytes. The imaging plate (PSP) was covered with a plastic wrap and it was placed in the film holder. The imaging

plate was exposed using Fona x-ray machine using exposure parameters: 70 kilovolt and 7 milliamperere for 0.125 seconds, which were considered fixed for all patients at each follow up. After the exposure was terminated, the imaging plate was scanned using Scan eXam™ one laser scanner unit. Digital images then appeared on the screen. Digital analysis of the radiographs was carried out using the software of Digora (2.5) system. The radiographs were evaluated by another examiner at different time that was blinded to the group being assessed and the average value of each parameter was used for future comparisons to reduce operator variability.

Methods of Evaluation

The following evaluations were conducted for all mandibular primary molars in both groups:-

I- Intra- operative clinical evaluations:

- **Time for root canal instrumentation:** The instrumentation time for each molar was recorded in minutes using a digital stopwatch by the dental assistant. The recorded time included the total instrumentation time of used files (active instrumentation time), starting from the first file inserted into the canal, excluding the in- between time taken for the irrigation protocol to assess the accurate time period needed for actual instrumentation in both groups.^{11,16}
- **Time for Root Canal Filling:** The filling time was recorded in minutes for each molar in both groups using a digital stopwatch by the dental assistant.²⁸

II- Immediate Post- operative radiographic evaluations:

Overall quality of root canal filling: Overall quality of root canal filling was evaluated using digital periapical radiographs taken immediate post-operatively through assessment of three parameters: length, density and taper of root canal fillings according to criteria of **Robia,2014**³¹:

- a) **Length of Root Canal Filling:** The distance between the radiographic root apex to actual filling level of the mesial and distal roots in millimeters was measured using the linear tool of the Digora 2.5 software, and then, the root canal filling was classified into under filling, optimal filling or overfilling according to the criteria described by **Coll and Sadrian, 1996**³² as in table (1).^{11,16, 28}

Table (1): Length of root canal filling according to Coll and Sadrian criteria³²

Criteria	Description
Under filling	More than 2 m.m short from radiographic apex
Optimal filling	End at radiographic apex or upto 2 m.m short
Over filling	Outside the root

- b) **Density of root canal filling:** Density of root canal filling was assessed as adequate or inadequate based on the presence or absence of voids evaluated by visual inspection as in table (2)³¹.

Table (2): Density of root canal filling³¹

Criteria	Description
Adequate	Complete absence of voids in root canal filling or between root canal filling and root canal walls
Inadequate	Presence of one or more voids in root canal filling or between root canal filling and root canal walls

c) Taper of root canal filling: Taper of root canal filling was assessed as adequate (consistent) or inadequate (inconsistent) of root canal filling based on visual inspection as in table (3).³¹

Table (3): Taper of root canal filling³¹

Criteria	Description
Adequate	Consistent taper from the orifice to the radiographic apex.
Inadequate	Inconsistent taper from the orifice to the radiographic apex

On basis of the three previously mentioned criteria, a **Technical Scoring System (T-scoring system)** was used to score overall quality of root canal filling as seen in table (4).³¹

Table (4): Technical scoring system for quality of root canal filling³¹

Score	Description
Score 3	Root canal fillings have all three qualities of ideal canal filling: Optimal filling with smooth taper and no voids.
Score 2	Root canal fillings have any two qualities of ideal canal filling.
Score 1	Root canal fillings have any one quality of ideal canal filling.
Score 0	Root canal fillings have no quality of ideal canal filling.

III- Patient follow up evaluation:

During patient follow up visits, clinical and radiographic evaluations of all teeth in both groups were conducted. Dates of follow up visits were written on the patients recall card, parents were asked to call if any symptoms of pain or discomfort occurred at any time in-between recall visits. If there were any complications before follow up dates, different techniques of treatment were done according to the case.

Clinical follow up evaluation: - it was set at the first patient follow up after 7 days postoperatively. Then, clinical follow ups were performed after 1, 3, 6, 9 and 12 months. At each follow up, the following clinical parameters were evaluated and recorded in the patient evaluation form: Assessment of spontaneous pain was assessed based on severity according to the criteria described by **Oginin and Undoye 2004³³** and listed in table (5).

Table (5): Severity of pain according to Oginin and Undoye³³

Severity		Description of Pain
Absent		– The treated tooth felt normal and patient didn't have any pain
Present	Slight	– Any discomfort no matter how brief in duration that didn't require medication.
		– Didn't impair masticatory function in any way

	Moderate	– Pain require medication (Non-steroidal Anti Inflammatory Drugs NSAID`s) – Impairment of masticatory function
	Flare ups	– Pain not controlled with medication and or swelling/ sinus /pus discharge

The parents were asked if there was pain from the previous follow up.³⁴ Also, presence or absence of sensitivity to percussion, tooth mobility and any changes of the mucobuccal folds were evaluated at each follow up. If the tooth recorded as **absence** of any of above mentioned clinical criteria, the pulpectomy was considered as **clinical success (S)**; otherwise, it was regarded as **clinical failure (F)**.^{17, 35}

Radiographic follow up evaluation:- it was performed postoperatively after cementation of stainless steel crowns for assessment of quality of root canal filling. The immediate postoperative radiograph was considered the baseline (time zero) and was used for comparison with subsequent radiographs. The radiographic parameters were assessed from the digital images at base line, 6 months and 12 months follow ups and recorded in the patient evaluation form. Width of the periodontal ligament space in millimeters: the measurements were carried out at 3 locations: mesial root apex, distal root apex and furcation area as follows. It was assessed in mms and compared at each follow up. Presence or absence of furcation radiolucency, internal and external root resorption. They were evaluated by visual assessment in comparison to previous radiographs and was recorded as present or absent. If the tooth recorded as **absence** of any of the last three above mentioned radiographic criteria (Furcation radiolucency, internal and external root resorption), the pulpectomy was considered as **radiographic success (S)**; otherwise, it was regarded as **failure (F)**.^{17,35}

Statistical Analysis:

Normality of all quantitative variables (instrumentation and filling time, and width of periodontal ligament) was checked using **Shapiro Wilk test** and **Q-Q plots**. Normal distribution was confirmed, and data were summarized using mean and standard deviation (SD). Distribution of all qualitative variables was presented using frequencies and percentages. Comparison between groups was done using **paired t test** and **McNemar test**. **Kaplan-Meier analysis** was used to evaluate the survival rate of both groups. **Repeated measures ANOVA** and **Cochran's Q tests** were used for analyzing difference periodontal width and radiographical success across follow up intervals. Association between clinical and radiographical success was analyzed using **Pearson Chi Square test**. All tests were two tailed and the significance level was set at p value<0.05. Data were analyzed using IBM SPSS, for Windows, version 23, Armonk, NY, USA.

RESULTS

Forty mandibular primary molars in 17 children (using the split mouth technique) were involved in this study. The gender distribution was nearly equal, with 8 boys (47.1%) and 9 girls (52.9%). The mean age of the children was 5.09 ± 0.60 years. On average, each child had 2.35 ± 0.79 treated mandibular primary molars, only 3 children had 4 treated mandibular primary molars. The types of treated mandibular primary molars were

incidentally equally distributed, with 20 primary molars (50%) being the mandibular first primary molar and 20 teeth (50%) being the mandibular second primary molar (10 first and 10 second mandibular primary molars in each group).

I- Results of Intra- operative clinical evaluations:

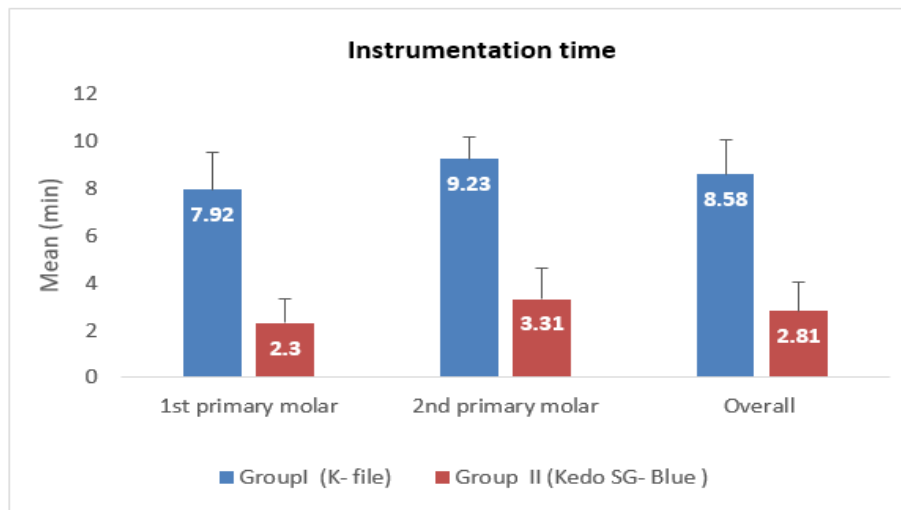


Figure (2): Bar chart showing comparison of instrumentation time (in minutes) between the two groups

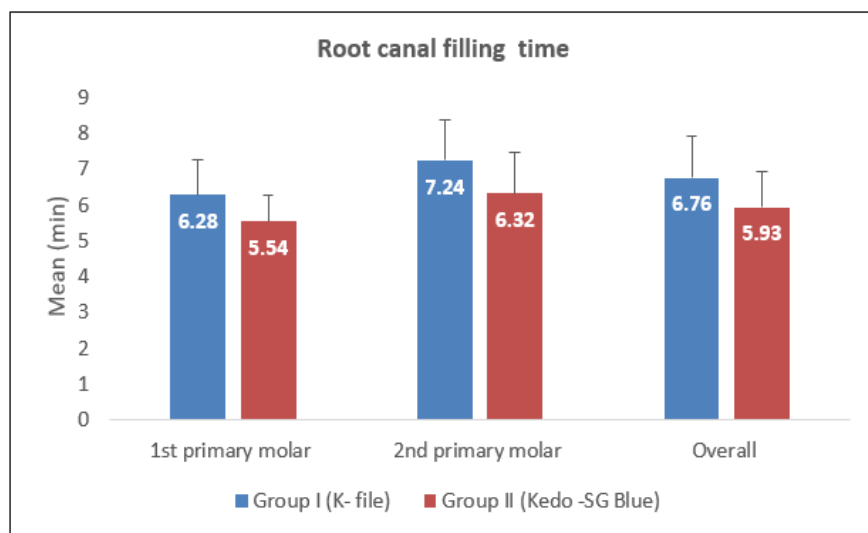


Figure (3): Bar chart showing comparison of root canal filling time (in minutes) between the two groups

Results showed **statistically significant difference** between both groups for the **instrumentation time** of the first and second primary molars as well as for the combined overall instrumentation time where group II (Kedo-SG Blue) showed **statistically significant shorter** instrumentation time in comparison to group I (K-file) as in figure (2).

Regarding root canal filling time, results showed **statistically significant difference** between both groups for first and second primary molars as well as for the combined overall root canal filling time where group II (Kedo-SG Blue) showed **statistically significant shorter** canal filling time in comparison to group I (K-file) as in figure (3).

II- Results of Immediate Post- operative radiographic evaluations:

Concerning **length of root canal filling**, for **both 1st and 2nd primary molars**, under filling occurred in 55% of mesial roots and 20% of distal roots in group I (K- file), compared to 25% of mesial roots and 10% distal roots in group II (Kedo- SG Blue). Optimal filling was more frequent in group II (Kedo- SG Blue) (70% mesial, 85% distal) in comparison to group I(K- file) (40% mesial, 70% distal), with **no statistically significant differences** between the two groups ($p > 0.05$). Overfilling was minimal within all molars in both groups.

Regarding density of root canal filling, for **both 1st and 2nd primary molars**, the results revealed that both group I (K- file) and group II (Kedo- SG Blue) achieved high percentages of adequate filling density, with 95% for the mesial roots and 90% of the distal roots in group I (K- file) and 90% for both roots in group II (Kedo- SG Blue). The p-values for the overall adequacy of root canal filling (mesial $p = 1.00$, distal $p = 1.00$) suggest that both systems performed comparably well in achieving adequate filling density with **no statistical significant difference** between them.

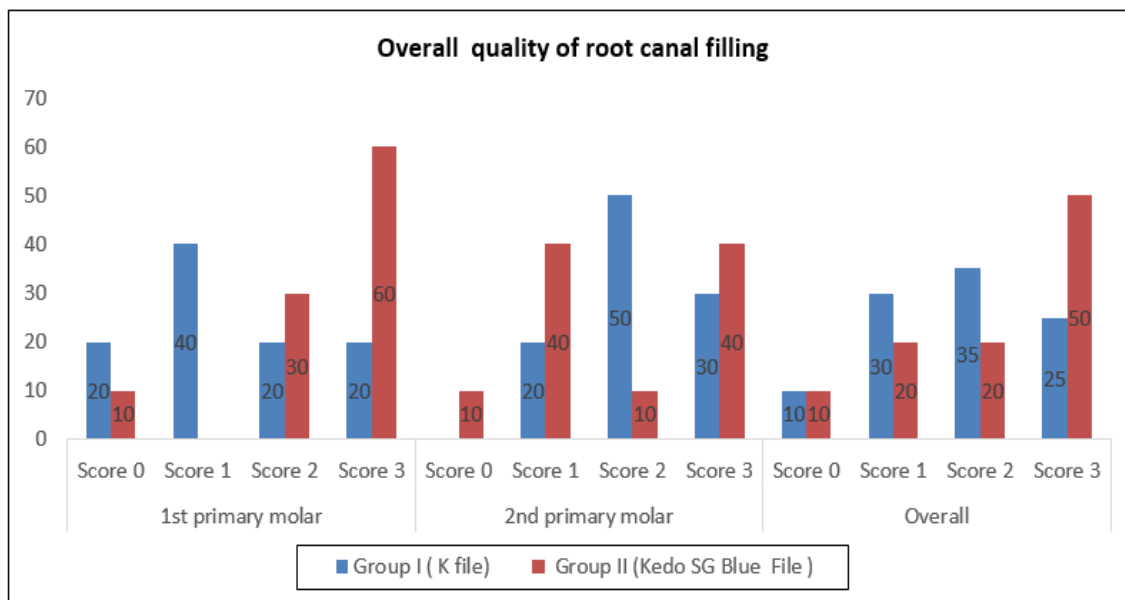


Figure (4): Bar chart showing comparison of the overall quality of root canal filling between the two groups in 1st, 2nd primary and overall combined both 1st and 2nd primary molars

Regarding taper of root canal filling, for **both 1st and 2nd primary molars**, group II (Kedo- SG Blue) demonstrated adequate taper in 80% of mesial roots and 85% of distal roots,

compared to 70% and 75%, respectively, for group I (K- file). Although inadequate taper was more common in group I (K- file), in comparison to group II (Kedo- SG Blue), however, the differences in overall taper quality between the two groups were **statistically insignificant** for the mesial ($p = 0.687$) and distal roots ($p = 0.727$) in both primary molars.

Based on the results of the three previously assessed parameters (length, density and taper), **the overall quality of the root canal filling** was assessed using Technical Scoring System (T- Scoring System). For **both 1st and 2nd primary molars**, the scores indicated no significant difference between both groups for score 0 (10% for both groups), and a similar pattern for scores 1 and 2. However, group II (Kedo- SG Blue) demonstrated greater percentage of high-quality fillings, with 50% receiving a score of 3 compared to 25% for group I (K- file).

These findings suggest that while both systems can achieve adequate root filling quality, group II (Kedo- SG Blue) offers a slight advantage in terms of achieving higher quality outcomes, particularly in the 1st primary molar. However, the difference between both groups was **statistically insignificant** where ($p = 0.669$) as in figure (4).

III- Results of Patient follow up evaluation:

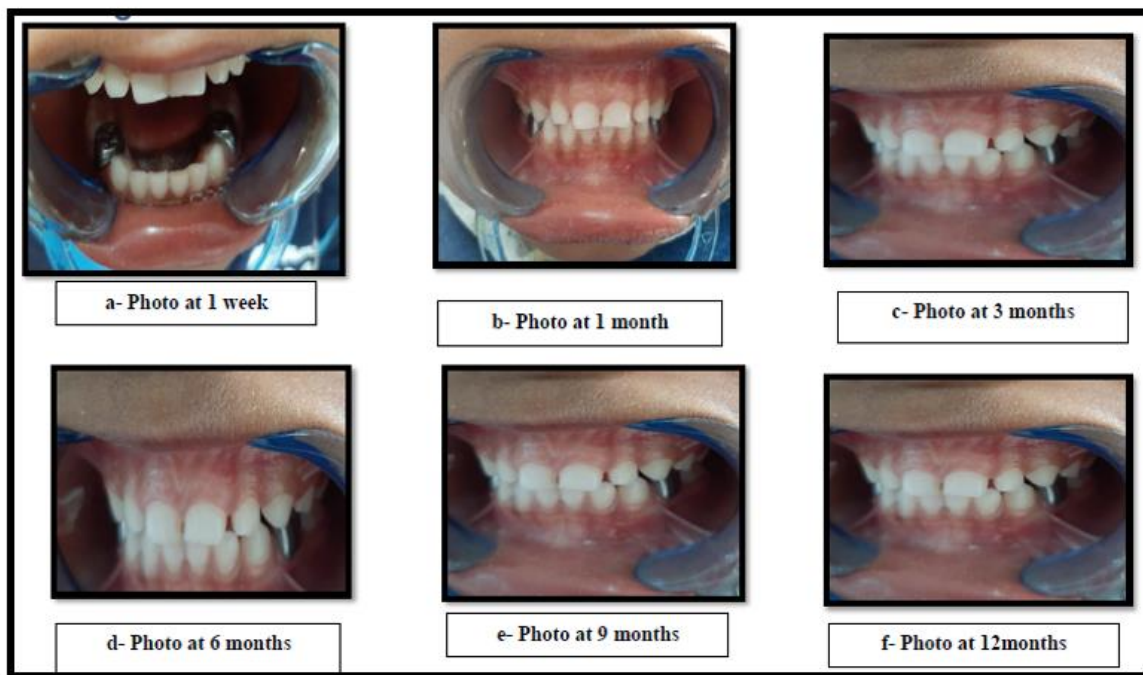


Figure (5 a-h): Clinical Case presentation for group I (K-file) at right mandibular 1st primary molar and group II (Kedo-SG Blue) at left mandibular 1st primary molar

Results of clinical analysis revealed that across all follow-up periods (1 week, 1 month, and 3 months, 6months, 9 months, and 12 months) for **both 1st and 2nd primary molars**,

neither group I (K-file) nor group II (Kedo –SG Blue) exhibited any clinical complications, regarding spontaneous pain, pain on percussion, mobility, or soft tissue changes (redness, swelling or sinus) with all values recorded as 0% (n=0) in each category. Results revealed that both groups exhibited overall 100 % clinical success at different follow up periods as in figure (5). Therefore, evaluation of p-value was non- applicable.

Results of Radiographic analysis:

Results of changes in width of periodontal ligament (at mesial root, distal root and furcation area) in each group throughout the follow up period and comparison between both groups at different time intervals as follows presented in figure (6):

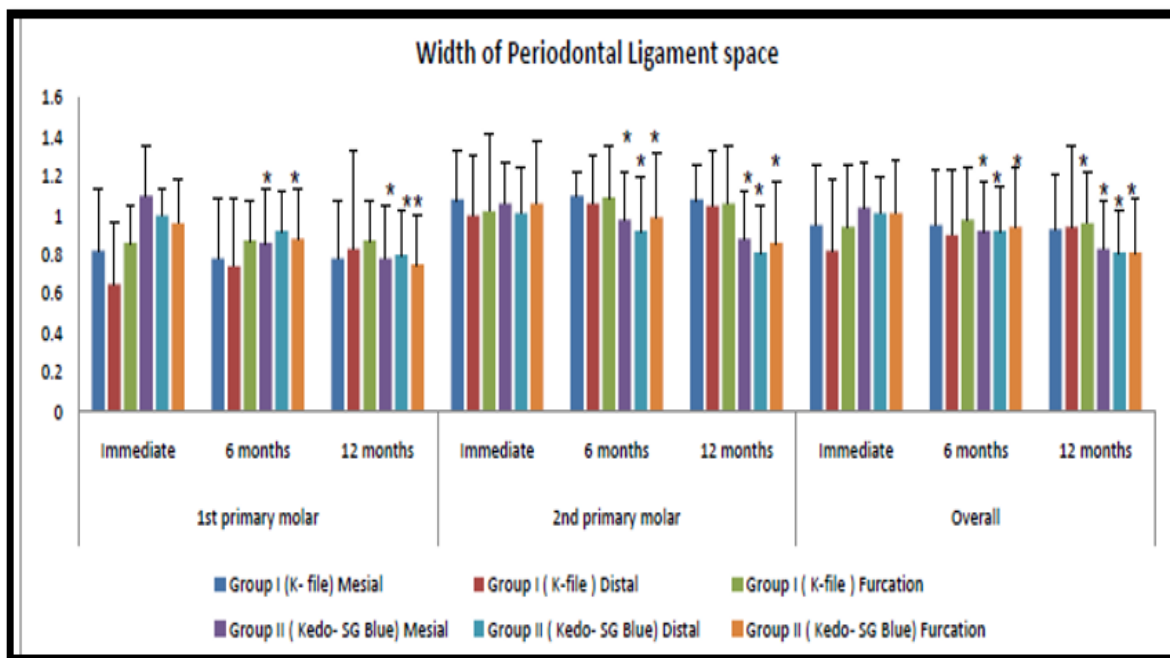


Figure (6): Bar chart showing changes in width of periodontal ligament space and comparison between the two groups at different time intervals

For Group I: (K- file) regarding both 1st & 2nd primary molars, for the mesial root at immediate postoperative, the width was 0.95 ± 0.31 , at 6 months was 0.95 ± 0.28 , while at 12 months, it was 0.93 ± 0.28 . Results showed a non significant decrease in width. **For the distal root** at immediate postoperative, the width was 0.82 ± 0.36 , at 6 months was 0.90 ± 0.33 , while at 12 months, it was 0.94 ± 0.41 . Results showed a **non significant increase** in width. While for **the Furcation**, the width was 0.94 ± 0.32 at immediate postoperative, 0.98 ± 0.26 after 6 months and 0.96 ± 0.26 after 12 months. A **non-significant change** in width of periodontal ligament space was seen through the study period.

For Group II: (Kedo -SG Blue) regarding both 1st & 2nd primary molars, for the mesial root at immediate postoperative, the width was 1.04 ± 0.23 mm, at 6 months was 0.92 ± 0.28 mm, while at 12 months, it was 0.88 ± 0.25 mm. Results showed a non significant decrease in width. **For the distal root** at immediate postoperative, the width was 0.85 ± 0.30 mm, at 6 months was 0.95 ± 0.35 mm, while at 12 months, it was 0.90 ± 0.32 mm. Results showed a non significant increase in width. While for **the Furcation**, the width was 0.95 ± 0.30 mm at immediate postoperative, 0.98 ± 0.28 mm after 6 months and 0.96 ± 0.27 mm after 12 months. A non-significant change in width of periodontal ligament space was seen through the study period.

± 0.25 mm while at 12 months, it was 0.83 ± 0.25 mm. Results showed a **significant decrease** in width with the time. For the **distal root** at immediate postoperative, the width was 1.01 ± 0.18 mm, at 6 months was 0.92 ± 0.23 mm while at 12 months, it was 0.81 ± 0.22 mm. Results showed a **significant decrease** in width with the time similar to mesial root. While for the **Furcation**, the width was 1.01 ± 0.27 mm at immediate postoperative, 0.94 ± 0.30 mm after 6 months and 0.81 ± 0.28 mm after 12 months. A **significant decrease** in width of periodontal ligaments was seen through the study period.

Concerning comparison between two groups, for both 1st & 2nd primary molars, group II (Kedo- SG Blue) showed immediate post operative **significantly wider** periodontal ligament space at **distal root** compared to group I(K-file). The width at the **mesial root** and the **furcation area** was **statistically insignificant** at this time between the two groups.

After 6 months, group I (K-file) showed **insignificantly higher** width of periodontal space at mesial root and furcation area in comparison to group II (Kedo- SG Blue). While at distal root, group I (K-file) showed **insignificantly narrower** width in group I(K-file) compared to group II (Kedo- SG Blue). After 12 months, the **width at furcation area** for group I (K-file) was **significantly higher** than that of group II (Kedo- SG Blue). On the other hand, the width of periodontal membrane space at mesial and distal roots was insignificantly higher in group I(K-file) in comparison to group II (kedo- SG Blue).

Table (6): Incidence of radiographic signs in each group and comparison between the two groups for 1st, 2nd primary molars and overall combined both 1st and 2nd primary molars at different follow up periods

Tooth	Follow up	Group I (K- file) n= 20			Group II (Kedo – SG Blue) n= 20			p- value
		Furcation radiolucency	Internal Resorption	External Resorption	Furcation radiolucency	Internal Resorption	External Resorption	
1 st primary molar (n=10)	6 M	0 (0%)	0 (0%)	1 (10%)	0 (0%)	0 (0%)	1 (10%)	NA
	12M	0 (0%)	0 (0%)	3 (30%)	0 (0%)	0 (0%)	2 (20%)	NA
2 nd primary molar (n=10)	6 M	0 (0%)	1 (10%)	1 (10%)	0 (0%)	0 (0%)	1 (10%)	NA
	12M	0 (0%)	1 (10%)	1 (10%)	0 (0%)	0 (0%)	1 (10%)	NA
Overall both 1 st & 2 nd primary molars	6 M	0 (0%)	1 (5%)	2 (10%)	0 (0%)	0 (0%)	2 (10%)	NA
	12M	0 (0%)	1 (5%)	4 (20%)	0 (0%)	0 (0%)	3 (15%)	NA

Results of **Incidence of radiographic signs** was presented in **table (6) & figure (7)**. The results revealed that absence of **furcation radiolucency** in both groups at different follow up periods. Only one case of **internal root resorption** was reported in group I (K-file) at

6 and 12 months with a **non -significant difference** between the two groups, and no cases of **internal root resorption** were reported in group II (Kedo-SG Blue).

For **external root resorption**, both groups showed two cases after 6 months, while after 12 months, group I (k-file) showed 4 cases of external root resorption, while group II (Kedo – SG Blue) showed 3 cases with external root resorption with **non-significant difference** between both groups at these time intervals.

The overall radiographic success rates for both groups were 90% at 6 months and declined to 80% for group I (K-file) and 85% for group II (Kedo-SG Blue) at 12 months, with **no significant difference** between both groups. These results denoting higher radiographic success of group II (Kedo -SG Blue) at 12 months follow up period.

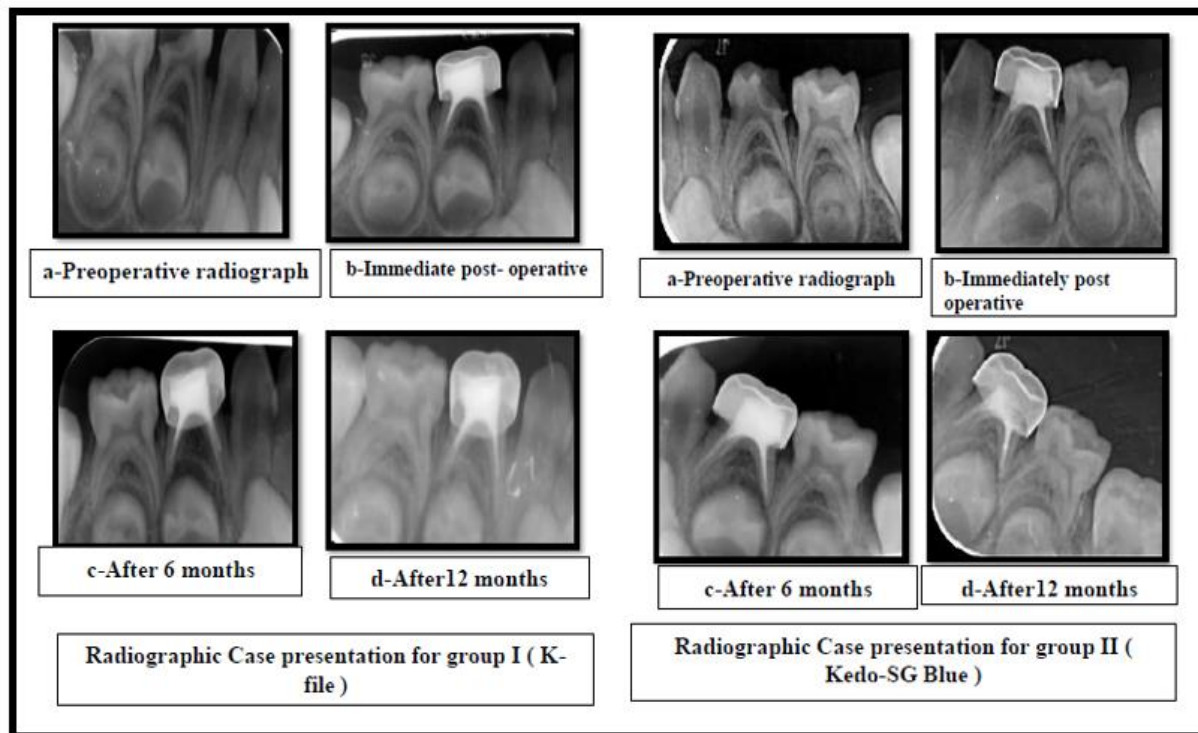


Figure (7a-d): Radiographic Case presentation for group I (K-file) at right mandibular 1st primary molar and group II (Kedo-SG Blue) at left mandibular 1st primary molar

As both groups exhibited overall 100 % clinical success at different follow up periods, the results of **association analysis** between clinical success and radiographic success after 12 months revealed the following: **For both 1st & 2nd primary molar**, in group I (k-file), 80% of cases with clinical success achieved radiographic success, while in group II (Kedo –SG Blue), 85 % of cases with clinical success recorded a radiographic success. The results revealed that there was **no significant association** between clinical success and radiographic success for the two groups after 12 months as in **figures (8)**.

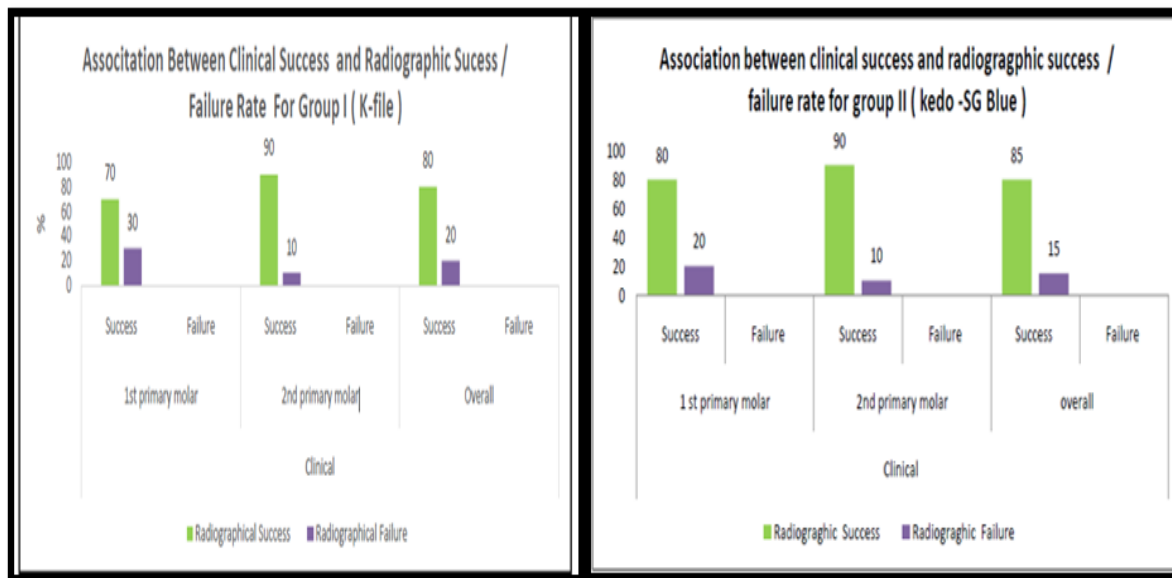


Figure (8): Bar chart showing association between clinical and radiographic success rate / failure rate for group I (K-file) & group II (Kedo SG blue)

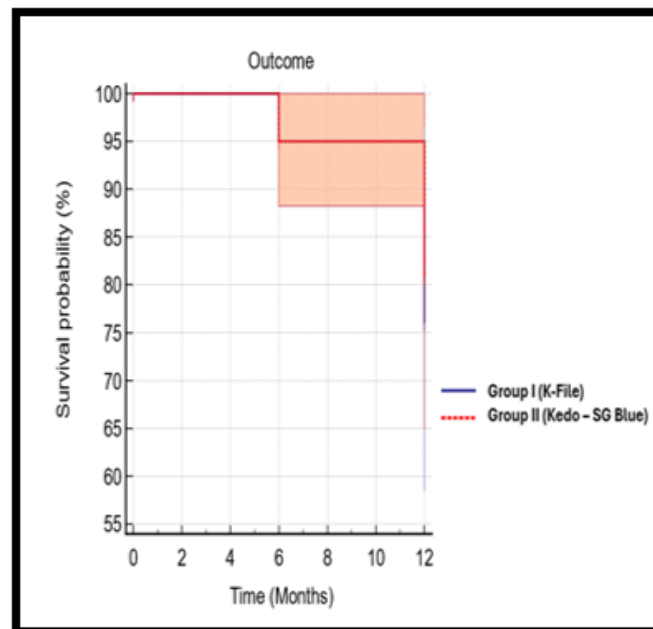


Figure (9): Kaplan-Meier survival curve showing survival rate for the two groups

Concerning results of Survival **rate**, both of which exhibited an identical mean survival time of **11.70 months** with a standard error of **0.23** and a 95% confidence interval ranging from **11.26 to 12.14** for group I (k-file) and **11.25 to 12.15** for group II (Kedo-SG Blue). The **p-value** for the comparison was **0.749**, indicating no statistically significant difference in survival rate between the two groups as in figure (9).

DISCUSSION

Kedo- S rotary files were introduced in the dental market in 2016- 2017, belonging to the second generation of Ni Ti rotary files. It was the first designed pediatric rotary files, introduced to overcome the disadvantages caused by using permanent teeth rotary files. The **Kedo-SG Blue file** system is the third generation of Kedo -S systems, it has an improved higher flexibility to navigate even the narrowest canal in primary teeth because of the additional titanium oxide coat leading to an easier flow of root canal filling materials and optimal quality of root canal filling. Its higher flexibility prevents inadvertent file breakage thereby increasing its efficacy and effectiveness in root canal preparation over its earlier predecessor Kedo-S.^{11,13}

The current study used conventional hand instrumentation technique using K- file (Mani) as the control group since it has been considered the gold standard technique for root canal preparation in primary teeth. Although the hand technique has been used for decades, the main disadvantage is that it is time consuming, which plays a major role in the concept of behavior management in pediatric dentistry. In addition to, undesirable aberrations such as canal transportation and ledges that occur during preparation with hand files due to indiscriminate and aggressive cutting action of stainless-steel files. This was in agreement with the recommendations of **Azar and Mokhtare, 2011**³⁶ and **Lakshmanan et al., 2020**.³⁷

Children were selected with an age range of 4-6 years old, irrespective of their gender; children younger than 4 years were excluded due to possible lack of cooperation, and children older than 6 years were also excluded due to expected physiological resorption of primary molar roots that might affect the parameters tested, which was in accordance with the suggestions of **Mokhtari et al., 2017**²⁹ and **Aminabadi et al., 2020**.³⁸

Children were chosen with having at least two similar bilateral mandibular primary molars (first or second primary molars) utilizing the split mouth technique, as the split-mouth design aims to balance conditions related to the oral environment, health and hygiene habits of the two study groups, therefore minimizing any individual variations that may affect the study results and outcomes.⁴¹ Only mandibular primary molars were included in the study due to the ease of visualization and direct access to the root canals, in addition; mandibular molars show more accurate radiographic interpretation than maxillary ones due to lack of anatomical superimpositions. This was in agreement with **Shah et al., 2021**.²²

The specific inclusion and exclusion criteria of selected mandibular primary molars were determined aiming to equalize conditions for all selected teeth in both groups and to decrease variables that might affect the prognosis and the success rate of the treated teeth. This was in agreement with **Talekar et al., 2021**.³⁹

Single visit pulpectomy was the treatment choice in present study because it is less painful, and is expected to be less stressful to an anxious child than multi- visit pulpectomy, as a second visit means added discomfort due to local anesthesia or trauma from a rubber dam application. Furthermore, it prevents the contamination and /or

bacterial re- growth in the root canal that might take place on prolonging the treatment period, save time and reduces treatment cost, as agreed by **Bharuka and Mandroli, 2016**⁴⁰ ; **Shah et al., 2021**²² and **Elsherbeny et al., 2023**.³⁵

The working length of files for both groups was determined using apex locator and then confirmed by digital radiographs, to decrease in- accuracy in measurements as much as possible, as it is difficult to determine the actual position of apical foramen, especially being more variable in primary teeth due to asymmetric resorption patterns of roots as confirmed by **Mokhtari et al., 2017**.²⁹

Concerning the instrumentation and filling time results showed statistically significant difference between both groups regarding the instrumentation time of the first primary molar and second primary molars as well as for the combined overall instrumentation time, where group II (Kedo-SG Blue) showed statistically significant shorter instrumentation and filling time in comparison to group I (K-file). This was in agreement with **Priyadarshini et al., 2020**²¹; **Babu and Kavyashree, 2021**⁴¹; **Sruthi et al., 2021**²³ and **Jeepalyam et al., 2024**²⁴. These findings regarding time taken for root canal instrumentation and filling confirm the superiority of Kedo –SG Blue in reducing chair side time. Therefore, significantly increasing patient acceptance and cooperation.

With respect to the quality of root canal filling, the results for **length** of root canal filling showed that optimal filling was more frequent in group II (Kedo- SG Blue) than in group I(K- file).Overfilling was minimal across both groups and root types. These results are similar to those concluded by **Priyadarshini et al., 2020**²¹; **Sruthi et a., 2021**²³; **Jeevanandan et al., 2021**⁴² and **Jeepalyam et al., 2024**.²⁴

Results of **density** of root canal filling revealed that both, group I (K- file) and group II (Kedo- SG Blue) achieved high percentages of adequate filling density. This was in agreement with **Shah et al., 2021**.²² Regarding the results of **taper** of root canal filling, it was revealed that group II (Kedo- SG Blue) demonstrated higher percentage of adequate taper compared to group I (K- file).

Based on the results of the three previously parameters (length, density and taper), the overall quality of the root canal filling was assessed using Technical Scoring System (T- Scoring System). The scores indicated no significant difference between both groups for score 0 (10% for both) as well as for scores 1 and 2. However, group II (Kedo- SG Blue) demonstrated greater percentages of high-quality fillings, with 50% receiving a score of 3 compared to 25% in group I (K- file). These findings suggest that while both systems can achieve adequate root filling quality, group II (Kedo- SG Blue) offers a slight advantage in terms of achieving higher quality outcomes, particularly in the 1st primary molar. Nevertheless, the difference between both groups was statistically insignificant.

Regarding results of clinical success, across all follow-up periods for both **the mandibular 1st and 2nd primary molars**, no cases in group I (K-file) or group II (Kedo – SG Blue) exhibited any clinical signs of failure regarding the tested parameters. These results were consistent with **Babu and Kavyashree, 2021**⁴¹, even though using the

another generations of Kedo-S system. They concluded that the clinical success rate was %100 in both Kedo -S group and manual Ni-Ti K-file group.

On the other hand, these findings disagreed with **Rajain et al., 2023**⁴³ who concluded that Kedo-S group showed higher clinical success than manual K- file group, but the difference was insignificant. This difference in success rate may be probably due to influence of the individual body resistance and variation of selection criteria for primary molars. Concerning the results of radiographic evaluation, the current study showed insignificantly decrease in the width of periodontal ligament space in group I (K-file) at mesial root and furcation area but at distal root, the width insignificantly increased throughout the study period. While in group II (Kedo –SG Blue) the width **significantly decreased** throughout the study at mesial, distal and furcation area. The significant decrease in width in group II (Kedo- SG Blue) suggests less apical inflammatory reaction in this group.

Based on the radiographic results obtained from furcation radiolucency, internal root resorption and external root resorption, the radiographic success rate was evaluated throughout the study period.^{17,37} The overall radiographic success rates were 90% at 6 months for both groups, then decreased to 80% for group I (K-file) and 85% for group II (Kedo-SG Blue) at 12 months, with p-values consistently indicating no significant differences between two groups. These were in agreement with **Babu and Kavyashree, 2021**⁴¹ and **Rajain et al., 2023**⁴³ even though using the another generations of Kedo-S system.

Nevertheless, there was non- significant decrease in the radiographic success rate for both groups, except for group I (K-file) in the combined results for 1st and 2nd primary molars throughout the follow up periods. The above mentioned findings suggest that both hand and rotary instrumentation yield comparable radiographic results with no superiority to either group over the other. The teeth exhibiting one of the radiographic signs of failure were not instantly retreated and were monitored for subsequent evaluation, as they remained asymptomatic and had no indications of clinical failures.^{44,45}

Concerning over all clinical and radiographic success rate, both groups maintained a 100% clinical success rate at 6 and 12 months, but the overall radiographic success rates declined from 90% at 6 months to 80% for group I (K- file) and 85% for group II (Kedo - SG Blue) at 12 months. This may be explained on the basis that chronic signs of radiographic failure take longer periods of time to be expressed clinically. While radiographic findings can be indicative of treatment success, they don't always align with clinical observations. Such results were in agreement with **Yousry et al., 2021**.⁴⁶

Regarding the results of the survival rate; both groups showed similar survival rate (11.70) months, reinforcing their comparable effectiveness in clinical applications. It is worthy to mention that, no previous study was conducted to evaluate the survival rate between rotary and manual files. According to the results of the present study, the **null hypothesis was partially rejected**. Since group II (Kedo – SG Blue) exhibited **significantly shorter time** for root canal instrumentation and filling than group I (K-file), as well as group II

(Kedo – SG Blue) showed **significantly narrower** periodontal membrane space at furcation area than group I (K-file). However, there were **insignificant differences** between the two groups regarding the other assessed parameters.

CONCLUSIONS

Kedo- SG Blue rotary file system is an effective and efficient file system for pulpectomy in primary teeth. Kedo - SG Blue rotary file system decrease dental chair side time leading to increase in the cooperativeness of the children for dental treatment and reduces fatigue of the operator. Both hand and rotary file systems can achieve equal quality of root canal filling, however, (Kedo- SG Blue) offers a slight advantage in terms of achieving higher quality outcomes, particularly in the 1st primary molars. Both hand and rotary file systems achieve high clinical and radiographic success after puplectomy of primary molars.

The Strength of Current Study:

- The study was a randomized clinical control trial with long period follow up for one year.

The Limitation of Current Study:

- Although 3 D imaging is preferred for assessment of the quality of root canal filling, it was not applied in the present study due to the radiation dose it delivers to the children, even though radiographic follow up was applied only twice during the one- year duration of the current study. The quality of root canal filling and radiographic follow up were assessed using two dimensional radiographic imaging modality.
- Impossibility of blinding the operator and participating children due to the remarkable differences in instrumentation techniques.

Author's Contributions

DFMMR & 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.

References

- 1) Kuo C., Wang Y., Chang H., Huang G., Lin C. and Liu M.. Application of Ni-Ti rotary files for pulpectomy in primary molars. *Dent Sci J*, 2006, 1(1): 10-5.
- 2) George S., Anandaraj S., Issac J., John S. and Harris A.. Rotary endodontics in primary teeth – A review. *Saudi Dent J*, 2016, 28(1): 12-17. doi:10.1016/j.sdentj.2015.08.004
- 3) Kalra P., Rao A., Suman E., Shenoy R. and Suprabha B.. Evaluation of conventional, protaper hand and protaper rotary instrumentation system for apical extrusion of debris, irrigant and bacteria – An in vitro randomized trial. *Clin Exp Dent J*, 2017, 9: 254-58. doi:10.4317/jccd.53340
- 4) Gutmann J. and Gao Y.. Alteration in the inherent metallic and surface properties of nickel titanium root canal instruments to enhance performance, durability and safety: A focused review. *Int Endod J*, 2012, 45(2): 113-28. doi:10.1111/j.1365-2591.2011.01957.x

- 5) Kuzekanani M.. Nickel–Titanium rotary instruments: Development of the single-file systems. *J Int Soc Prev Community Dent*, 2018, 8(5): 386-90. doi:10.4103/jispcd.JISPCD_225_18
- 6) Barr E., Kleier D. and Barr N.. Use of nickel titanium rotary files for root canal preparation in primary teeth. *Pediatr Dent*, 2000, 22(1): 77-78.
- 7) Parimala K., Singh T., Shilpi T. and Barkha C.. Literature review on rotary endodontics in primary teeth. *J Res Dent Sci*, 2021, 12(2): 95-100. doi:10.4103/srmjrds.srmjrds_132_20
- 8) Silva L., Leonardo M., Nelson-Filho P. and Tanomaru J.. Comparison of rotary and manual instrumentation techniques on cleaning capacity and instrumentation time in deciduous molars. *J Dent Child*, 2004, 71(1): 45-47.
- 9) Finn S.. Morphology of primary teeth in clinical pedodontics. 4th ed. Philadelphia: Saunders Co, 1973, 59-70.
- 10) Nagarata P., Shashikiran N. and Subbareddy V.. In vitro comparison of Ni-Ti rotary instruments and stainless steel hand instruments in root canal preparations of primary and permanent molar. *J Indian Soc Pedod Prev Dent*, 2006, 24(4): 186-91.
- 11) Jeevanandan G. and Govindaraju L.. Clinical comparison of Kedo-S pediatric rotary files vs manual instrumentation for root canal preparation in primary molars: a double blinded randomized clinical trial. *Eur Arch Paediatr Dent*, 2018, 19: 273-78.
- 12) Chugh V., Patnana A., Chugh A., Kumar P., Wadhwa P. and Singh S.. Clinical differences of hand and rotary instrumentations during biomechanical preparation in primary teeth—A systematic review and meta-analysis. *Int J Paediatr Dent*, 2021, 31(1): 131-42.
- 13) Jeevanandan G.. Kedo –S Paediatric rotary files for root canal preparation in Primary teeth – Case report. *J Clin Diagn Res*, 2017, 11(3): 3-5. doi:10.7860/JCDR/2017/25856.9508
- 14) Pitchiah P. and Shivashankarappa P.. Rotary files in pediatric: from then till now. *J Sci Dent*, 2020, 10(2): 55-57. doi:10.5005/jp-journala-10083-0926
- 15) Kaushik H., Singhal R., Kakram A., Negi S., Dayma C. and Namdev R.. Rotary file systems designed exclusively for pediatric patients: a literature review. *Int J Health Sci Res*, 2023, 13(7): 212-16. doi:10.52403/ijhsr.20230730
- 16) Govindaraju L., Jeevanandan G. and Subramanian E.. Clinical evaluation of quality of obturation and instrumentation time using two modified rotary file systems with manual instrumentation in primary teeth. *J Clin Diagn Res*, 2017, 11(9): 55-58. doi:10.7860/JCDR/2017/30069.10602
- 17) Morankar R., Goyal A., Gauba K., Kapur A. and Bhatia S.. Manual versus rotary instrumentation for primary molar pulpectomies- A 24 months randomized clinical trial. *Pediatr Dent J*, 2018, 28(2): 96-102. doi:10.1016/j.pdj.2018.02.002
- 18) Albarshah M., Hamadan M. and Kabbesh K.. Comparison of quality of obturation and instrumentation time using different in primary molars. *Int J Appl Dent Sci*, 2020, 6(4): 292-95. doi:10.22271/oral.2020.v6.i4e.1079
- 19) Amorim A., Caldeira A., Sampaio S., Lourenco Neto N., Oliveira T., Nogueira D., Moretti A. and Sakai V.. Comparison between the rotary (Hyflex EDM R) and manual (K-file) technique for instrumentation of primary molars: a 12-month randomized clinical follow up study. *J Appl Oral Sci*, 2022, 30: 20210527. doi:10.1590/1678-7757-2021-0527
- 20) Panchal V., Jeevanandan G. and Subramanian E.. Comparison of postoperative pain after root canal instrumentation with hand K-files, H-files and rotary Kedo-S files in primary teeth: a randomized clinical trial. *Eur Arch Paediatr Dent*, 2019, 20: 467-72. doi:10.007/s40368-019-00429-5

- 21) Priyadarshini P., Jeevanandan G., Govindaraju L. and Subramanian E.. 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. *Eur Arch Paediatr Dent*, 2020, 21: 693-701. doi:10.007/s40368-020-00518-w
- 22) Shah H., Patil V., Kamath A. and 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. *Contemp Clin Dent*, 2021, 12(1): 55-62. doi:10.4103/ccd.ccd_83_20
- 23) Sruthi S., Jeevanandan G., Govindaraju L. and Subramanian E.. Assessing quality of obturation and instrumentation time using Kedo SG blue, Kedo SH, and reciprocating hand K files in primary mandibular molars. *Dent Res J*, 2021, 18: 76-83. doi:10.4103/1735-3327.326649
- 24) Jeepalyam S., Nirmala S. and Nuvvula S.. Efficacy of two paediatric rotary systems: Kedo-SG Blue™ and Prime Pedro™ files in primary mandibular molars. *J Clin Diagn Res*, 2024, 18(1): 36-41. doi:10.7860/JCDR/2024/63534.18917
- 25) Altman D., Schulz K. and Moher D.. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med*, 2001, 134(8): 663-94. doi:10.7326/0003-4819-134-8-200104170-00012
- 26) Faul F., Erdfelder E., Lang A. and Buchner A.. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods*, 2007, 39: 175-91
- 27) Ochoa-Romero T., Mendez-Gonzalez V., Flores-Reyes H. and Pozos-Guillen A.. Comparison between rotary and manual techniques on duration of instrumentation and obturation times in primary teeth. *J Clin Pediatr Dent*, 2011, 35(4): 359-63. doi:10.17796/jcpd.35.4.8k013k21t39245n8
- 28) Makarem A., Ravandeh N. and Ebrahimi M.. Radiographic assessment and chair time of rotary instrument in pulpectomy of primary second molar teeth. *J Dent Res Dent Clin Dent Prospects*, 2014, 8(2): 84-89. doi:10.5681/joddd.2014.015
- 29) Mokhtari N., Sarraf-Shirazi A. and Ebrahimi M.. A smart rotary technique versus conventional pulpectomy for primary teeth. *J Clin Exp Dent*, 2017, 9(11): 1292-96. doi:10.4317/jced.53968
- 30) Chandrasekhar S., Prasad M., Radhakrishna A., Saujanya K., Raviteja N., Deepthi B. and Ramakrishna J.. A comparative in-vivo efficacy of three spiral techniques versus incremental technique in obturating primary teeth. *J Indian Soc Pedod Prev Dent*, 2018, 36(1): 71-75. doi:10.4103/JISPPD.JISPPD_365_16
- 31) Robia G.. Comparative radiographic assessment of root canal obturation quality: manual versus rotary canal preparation technique. *Int J Biomed Sci*, 2014, 10(2): 136-42
- 32) Coll J. and Sadrian R.. Predicting pulpectomy success and its relationship to exfoliation and succedaneous dentition. *J Pediatr Dent*, 1996, 18(1): 57-63
- 33) Oginni and Udoeye C.. Endodontic flare-ups: comparison of incidence between single and multiple visits procedures. *BMC Oral Health*, 2004, 4: 1-6. doi:10.1186/1472-6831-4-4
- 34) Sevekar S. and Gowda S.. Postoperative pain and flare-ups: comparison between single and multiple visit pulpectomy. *J Clin Diagn Res*, 2017, 11(3): 9-12. doi:10.7860/JCDR/2017/22662.9377
- 35) Elsherbeny S., Al-Bauomy S. and Hassan M.. Clinical, radiographic and microbiological evaluation of different obturating materials in pulpectomy of primary molars. *Al-Azhar J Dent*, 2023, 10(1): 259-66. doi:10.58675/2974-4164.1474
- 36) Azar M. and Mokhtare M.. Rotary Mtwo system versus manual K-file instruments: efficacy in preparing primary and permanent molar root canals. *Indian J Dent Res*, 2011, 22(2): 363

- 37) Lakshmanan L., Mani G., Jeevanandan G., Ravindran V. and Subramanian E.. Assessing quality of root canal filling and instrumentation time using Kedo-S files, reciprocating files and K-file. *J Braz Dent Sci*, 2020, 23(1): 1-7. doi:10.14295/bds.2020.v23i1.1822
- 38) Aminabadi N., Asl Aminabadi N., Jamali Z. and Shirazi S.. Primary tooth pulpectomy overfilling by different placement techniques: systematic review and meta-analysis. *J Dent Res Dent Clin Dent Prospects*, 2020, 14(4): 250-61. doi:10.34172/joddd.2020.043
- 39) Talekar A., Chaudhar G., Waggoner W. and Chunawalla Y.. An 18-month prospective randomized clinical trial comparing zirconia crowns with glass-reinforced fiber composite crowns. *Pediatr Dent*, 2021, 43(5): 355-62
- 40) Bharuka S. and Mandroli P.. Two-visit pulpectomy treatment in primary teeth with apical periodontitis. *J Indian Soc Pedod Prev Dent*, 2016, 34(4): 383-90. doi:10.4103/0970-4388.191429
- 41) Babu K. and Kavyashree G.. Evaluation of clinical efficiency of rotary and manual files in primary teeth pulpectomies. *J Contemp Pediatr Dent*, 2021, 2(1): 21-34. doi:10.51463/cpd.2021.42
- 42) Jeevanandan G., Govindaraju L., Subramanian E. and Priyadarshini P.. Comparative evaluation of obturation quality and postoperative pain between pediatric hand and rotary files. *Int J Clin Pediatr Dent*, 2021, 14(1): 88-96. doi:10.5005/jp-journals-10005-1895
- 43) Rajain T., Tsomu K. and Namdev R.. Evaluation of Kedo-S pediatric rotary files vs manual instrumentation in primary molars. *Int J Clin Pediatr Dent*, 2023, 16(1): 22-29. doi:10.5005/jp-journals-10005-2511
- 44) Durmus B. and Tanboga I.. In vivo evaluation of pulpotomy using diode laser, formocresol and ferric sulphate. *Photomed Laser Surg*, 2014, 32(5): 289-95. doi:10.1089/pho.2013.3628
- 45) Gaber R., Mhmoud S. and Nagi P.. Clinical and radiographic success of TheraCal PT versus MTA in pulpotomy. *Alex Dent J*, 2024, 49(1): 162-69. doi:10.21608/adjalexu.2024.261358.1463
- 46) Yousry Y., Abd Allatif A. and Abd Al Gawad R.. Clinical and radiographic evaluation of vital pulpotomy using antioxidant mix versus formocresol. *Adv Dent J*, 2021, 3(1): 12-23. doi:10.21608/adjc.2020.21483.1053