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ORIGINAL ARTICLE

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Clinical and radiographic success following pulpectomy of primary molars with rotary instrumentation versus manual instrumentation: a 12-month randomized clinical trial

Acompanhamento do sucesso clínico e radiográfico de pulpectomia em molares decíduos com instrumentação rotatória versus instrumentação manual: um estudo clínico randomizado de 12 meses

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ABSTRACT

Objective: This 12-month randomized clinical trial aimed to estimate the postoperative pain, quality of obturation and clinical and radiographic success in pulpectomy of primary molars using Fanta baby rotary files versus manual K-files. **Material and Methods:** This randomized clinical trial included 46 lower second primary molars in 4-6 years old children. In intervention group, canals were prepared using Fanta baby rotary files, while in control group, manual K-files were used. The postoperative pain was assessed at 12, 24, 48 and 72 hours using modified Wong-baker pain scale. Clinical assessment was carried on 1w, 3, 6, 9, 12 months in terms of tenderness to percussion, mobility, and presence of swelling or fistula; while radiographically was on 1 week, 6 and 12 months using digital imaging technique in terms of size of the radiolucency, no development of new radicular or furcation radiolucency and no pathologic internal or external resorption. The quality of root canal obturation was assessed based on the presence of voids and the extent of the filling. **Results:** At 12 and 48 hours postoperative pain was significantly lower in the group prepared with rotary files compared with the manual K-files. At 12 months, the clinical success was 82.6% and the radiographic success was 78.3% in both groups. No significant difference was reported between both groups regarding the presence of voids and the extent of filling (p=0.667, p=0.261) respectively. **Conclusion:** Fanta baby rotary files showed marked reduction in postoperative pain compared to K- files. Regarding clinical and radiographic success, no significant differences were observed in both groups in different follow up intervals. There were no significant differences in obturation quality after one year.

KEYWORDS

Canal obturation; Deciduous teeth; Digital dental radiography; Metapex; Pulpectomy; Root canal therapy; Root canal preparation.

RESUMO

Objetivo: este estudo clínico randomizado de doze meses teve como objetivo estimar a dor pós operatória, qualidade da obturação e sucesso clínico e radiográfico de pulpectomias em molares decíduos utilizando a instrumentação de sistema rotatório Fanta baby em comparação a instrumentação com limas manuais K-files. **Material e Métodos:** este estudo clínico randomizado incluiu 46 segundos molares decíduos inferiores de crianças de 4 a 6 anos de idade. No grupo experimental, os canais radiculares foram preparados utilizando limas rotatórias Fanta Baby, enquanto no grupo controle, foi utilizado limas manuais k-file. A dor pós operatória foi avaliada após 12, 24, 48 e 72 horas, utilizando-se a escala de dor Wong-baker modificada. A avaliação clínica foi realizada após 1

semana, 3, 6, 9 e 12 meses em relação a sensibilidade a percussão, mobilidade e presença de inchaço ou fístula; já a avaliação radiográfica foi realizada após 1 semana, 6 e 12 meses utilizando-se de radiografia digital para avaliar o tamanho da radioluscência, o não desenvolvimento de nova região radiolúcida na raiz ou furca; e não ocorrência de reabsorção radicular interna ou externa patológica. A qualidade da obturação do canal foi avaliada baseada na presença de regiões vazias no conduto e pela extensão do preenchimento. **Resultados:** após 12 e 48 horas a dor pós operatória era significativamente menor no grupo que foi utilizado os instrumentos rotatórios se comparados ao grupo de instrumentação manual. Após 12 meses, o sucesso clínico foi de 82,6% e o sucesso radiográfico foi de 78,3% em ambos os grupos. Não houve diferença significativa entre os grupos em relação a espaços vazios e extensão do preenchimento (p= 0.0667; p=0,261) respectivamente. **Conclusão:** o sistema rotatório Fanta baby apresentou redução acentuada na dor pós-operatória se comparado a instrumentação manual k-files. Em relação ao sucesso clínico e radiográfico, não foram observadas diferenças significativas em ambos os grupos nos diferentes intervalos de acompanhamento. Não houve diferenças significativas na qualidade da obturação após um ano.

PALAVRAS-CHAVE

Obturação de canal; Dente decíduo; Radiografia odontológica digital; Mentapex; Pulpectomia; Tratamento de canal radicular; Preparo de canal radicular.

INTRODUCTION

Worldwide, dental caries is the most prevalent noncommunicable disease in children. Progression of caries lesions and dental trauma can cause pain, infection, swelling and lead to early tooth loss [1]. Premature loss of primary teeth leads to serious negative effects (e.g., loss of space, mesial movement of first permanent molars, increased risk of severe crowding, impacted premolar teeth and psychosocial problems) [2,3]. Therefore, maintenance of primary teeth in the oral cavity is crucial for a smoother shift from primary to permanent dentition [4]. Accordingly, pulpectomy is considered one of the most pivotal ways of preserving irreversibly inflamed and necrotic primary teeth [4]. The correct diagnosis, mechanical root canal preparation and obturation are predictive factors that have a critical role in the pulpectomy success [4].

Currently, Biomechanical preparation performed with manual instrumentation using stainless steel files is the standard method, despite its low flexibility, undesirable cleaning and shaping of the canal, potential ledge formation and lateral perforations, fracture of the instrument and time-consuming [5]. In addition to these drawbacks, it causes undesirable impact on the child's behavior and cooperation during pulpectomy [5].

To address these challenges, Barr et al. [6] initiated the use of Ni-Ti rotary files in primary teeth and reported that it is cost effective, has greater cutting efficacy in dentin, minimizes debris extrusion and presents variable tapers to allow better cleaning with apical control and obturation with a shorter instrumentation time. Thereafter, Pinheiro et al. [7] reported that using rotary instrumentation allows an easier and faster technique, improves behavior and cooperation especially for children with behavior management problems and decreases the professional's fatigue. In addition, Topçuoğlu et al. [8] and Nair et al. [9] proved that their application of rotary files reduced the intensity and duration of postoperative pain which is considered unpleasant experiences for both patients and clinicians.

With the constant progression in the endodontic field of pediatric dentistry, some pediatric rotary systems such as Kedo-S (Kedo Dental, India), PrimeTM Pedo (Sky International Enterprises, India), DXL-ProTM Pedo (Kraft marketing, India), Pro AF Baby Gold (Kids-e-dental, India), Zaunba Kids and AF baby rotary files (Fanta Dental, Shanghai, China) were exclusively launched for primary teeth with a total length of 16-17 mm to improve accessibility and ease of working.

Despite, several studies [10-12] were conducted to compare the root canal preparation using manual files versus rotary, no studies have investigated the postoperative outcome related to the application of Fanta baby rotary files. Hence, we aimed to assess the postoperative pain, quality of obturation and clinical and radiographic success associated with Fanta baby rotary files compared with that of manual instrumentation.

MATERIAL AND METHODS

Trial design and setting

This randomized clinical trial with two parallel groups was conducted in the post-graduate clinic, in Pediatric Dentistry and Dental Public Health Department - Faculty of Dentistry. Prior to the beginning of this study, the research protocol was reviewed and approved by the Research Ethics Committee, Faculty of Dentistry, with a number (34-9-19) in relation to the scientific content and compliance with the applicable regulations regarding human subjects' research as well as registered at clinical trial.gov on 17/07/2019 with identifier (NCT03964766).

Selection of participants

Forty-six primary lower second molars in (36) children between the ages 4 to 6 years were randomly selected from diagnostic clinic. Intraoral examinations were performed and standardized digital periapical radiographs using X-ray machine (Minray, Soredex, Tuusula, Finland) were taken for the teeth to determine whether pulpectomy was indicated. Each tooth was treated as an independent observation.

Examination

Soft and hard tissue clinical examination

Visual examination was performed to determine presence or absence of sinus or fistula and presence or absence of swelling, while palpation of the buccal tissues related to the apex of the suspected tooth was performed to record any tenderness and the degree of swelling if present. The suspected tooth was examined using a mirror and probe under good lighting conditions to evaluate the degree of carious involvement and the amount of remaining tooth structure, also for presence of pain on percussion. Mobility test used for the presence or absence of mobility.

Radiographic examination

A preoperative periapical radiograph was taken using size 1 digital radiographic sensor and Soredex, x-ray machine with exposure parameters (70Kvp, 10 mA, and a 0.08 second exposure time). This was performed to determine the extent of the carious lesion, the root development, periapical radiolucency and internal or external root resorption.

The study's inclusion and exclusion criteria

Inclusion criteria

- Lower second primary molar requiring pulpectomy.
- Cooperative children in age range from 4 to 6 years
- Two-thirds of each root remaining.
- No internal or external pathologic root resorption.
- Presence of adequate coronal tooth structure.
- Healthy children.
- Parent or guardian agree to participate in the study.

Exclusion criteria

- Tooth with pathologic mobility.
- Children with special health care needs.

Sample size calculation

To obtain a 90% power, and significant at the 5% level, the primary outcome measure 44% in the control group and 88% in the intervention group at 12 hours and it was based on Panchal et al. [13]. Thus, the required sample size was 40 primary molars. The sample size was then increased by 15% to compensate for dropouts to be 46 primary molars. Sample calculated using G-power* software version (3.1.9.7) [14].

Participant's randomization and allocation

Eligible consented participants were randomly assigned according to a sequence generated on website [15]. The table of sequence generation was generated and kept with the assistant supervisor. The study was explained to the parent/guardian and a written informed consent was signed, principal investigator prepared the child for the procedure after opening the access cavity, cleaning the pulp chamber, a phone call was performed to the assistant supervisor to assign the group according to the sequence generated.

Blinding

Statistician, clinical and radiographic outcome assessor were blinded to whether it is an intervention or a control group.

Pulpectomy procedures and mechanical instrumentation

a- Preparation of the tooth for both groups

In all patients, topical anaesthesia (Iolite, Dharma, USA) was applied, followed by inferior alveolar nerve block injections with (1 ml) of Articaine 4% with 1:100,000 epinephrine (Inibsa Dental S.L.U., Lliçà de Vall, Barcelona, Spain), then the tooth was isolated with rubber dam. Dental caries was removed using a high-speed round bur with copious water spray. An Endo Z bur (Dentsply, Maillefer, Johnson City, TN) was used to remove the pulp chamber roof's and all of the overlying dentin to create a straight path into the canals, with removal of coronal pulpal tissues using excavator and the canal orifices were localized using a DG-16 explorer (Hu-Friedy, Chicago, IL, USA). Then, each canal's working length was determined by inserting 15 K-file 1 mm away from its apex radiographically.

b- Mechanical Preparation

In rotary group (A)

The root canals preparation was performed by Fanta baby rotary files (FANTA™ Dental Material Co., LTD, China) under 350 rpm speed and torque of 2N/cm using E connect pro motor (Hangzhou Eighteeth Medical Technology Co., Ltd., China). Rotary instrumentation was preceded by manual instrumentation using no.15 manual Kfile in a watch winding motion to full working length, to scout canal, get a patent canal pathway and extirpate pulpal tissues. First, the orifice opener file (17/.08) of 0.08 taper and 0.17 tip was used to prepare 3m of each canal in brushing motion on the outer wall and get straight line access [16]. Following that, canals were prepared with different sizes of files depending on their width and anatomy [16,17]:

- In narrow and curved canals, preparation was carried out using 20/04 and 25/04 rotary files in a pecking motion to full working length.
- For wide and straight canals, preparation was continued till 30/04 file in a pecking motion to full working length.

After completion of each file size and at the end of instrumentation, the canals were irrigated with 5ml normal saline using disposable syringe. After each insertion, file was removed and the flutes were cleaned of debris by wiping the file with alcohol-soaked cotton, file can then be inserted into canal. EDTA gel (MD-ChelCream, META BIOMED Co, Ltd., Korea) was used as a lubricating paste with each rotary file.

In manual group (B)

Pulpal tissues were removed and extirpated using manual K-file # 15. Using the standardized technique, root canals were prepared by sequentially enlarging #15 to #35 K-files with a quarter-turn-pull motion. The mesiobuccal and mesiolingual canals were instrumented in a sequence of size (15/0.02, 20/0.02, 25/0.02 and30/0.02) manual K-files (Mani, Tokyo, Japan) using a quarter-turn-pull motion to full working length. While, the wide distal canals were instrumented using no.20 up to 35 K-files [18].

c- Obturation of the canals and restoration of the tooth for both groups

Absorbent paper points (size 35 and 40) were used to dry the canals in preparation for obturation. Root canals were filled using calcium hydroxide with iodoform paste (Metapex, Biomed Co, Ltd., Korea). The metapex syringe was inserted into the root canal space, to full working length. The syringe was gradually withdrawn as paste was pressed into the canals. The access cavity was sealed using a glass ionomer capsule (Riva Self Cure GIC, SDI Limited, Australia). Then, the quality of obturation was checked by the immediate postoperative radiograph. Following that, modified Wong-baker pain scale was provided to the participants' parents for the purpose of asking their children about their postoperative pain levels and indicating the face that depicted their level of pain at 12, 24, 48 and 72 hours. Each child was provided a prescription for analgesic (ibuprofen) with instructions to take only if needed for severe pain after contacting the investigator, antibiotic was also provided in case of intraoral swelling postoperatively.

After 5 days from pulpectomy, an appointment was given to prepare the tooth for stainless steel crown (Kids Crowns shunghung Co. Ltd., Korea) that was cemented by glass ionomer luting cement (Nova G.I.C,Imicryl, Konya Turkey). The questionnaire was then taken from the children's parents/guardians and an alginate impression was performed to fabricate acrylic radiographic stent on the cast for each patient during the second appointment. At 1

week of pulpectomy, standardized postoperative periapical radiograph was taken using size 1 digital sensor (Digora Optime, Soredex, Tuusula, Finland) through Soredex x-ray machine (Minray, Soredex, Tuusula, Finland) with subsequent exposure parameters: 70kVp, 10Ma and 0.08 seconds exposure time as a baseline record using acrylic radiographic stent attached to Rinn XCP (Extension Cone paralleling, Dentsply, United Kingdom) film holder and held upright for the paralleling technique Figure 1.

Outcome assessment

a- Postoperative pain

Intensity of postoperative pain was recorded by providing the parents with a modified Wong-baker pain scale at different time intervals and instructed on how to use it and asked them to record the pain response at 12, 24, 48 and 72 hours as told by the child. It was scored from zero to three according to fourpoint facial pain intensity rating scale, as follows: zero=no pain, one=slight pain, two=moderate pain and three=severe pain [13].

b- Instrumentation time

In both groups, time was measured and compared for both techniques. The time including irrigation and instrument exchange was recorded in minutes using a stopwatch from the beginning of instrumentation until the preparation of canals was completed [10].

c- Quality of obturation according to Shah et al. [11]

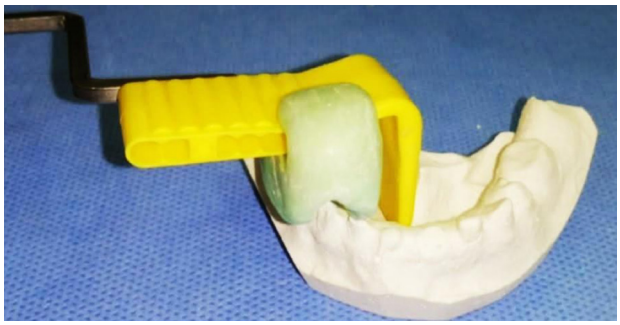

Figure 1 - Photograph showing acrylic radiographic stent attached to Rinn XCP.

Two blinded independent assessors evaluated the quality and extent of root canal obturation by assessing voids and filling based on the following criteria:

Score 0 – Complete absence of voids

Score 1 – Presence of one void

Score 2 – Presence of two voids

Score 3 – Presence of three voids

Score 4 – Presence of four voids

Score 5 – Presence of five voids.

Extent of filling:

Grade A – Less than one half of the canal obturated

Grade B – Greater than one half but less than optimal fill

Grade C – Optimal fill

Grade D – Extrusion of material beyond apex

d- Assessment of clinical and radiographic outcome (Morankar et al. [10]):

Clinical evaluation was carried on 1w, 3, 6, 9, 12 months; while radiographically was on 1 week, 6 and 12 months by two assessors who were blinded to the treatment group. The teeth were considered successful depending on the clinical and radiographic criteria (Table I). As these are considered composite outcomes. To consider clinical success all clinical criteria should be present. Otherwise, it was considered failure. The same applied to the radiographic success.

Statistical analysis

Categorical and ordinal data were presented as frequency and percentage values. Categorical data were compared using chi-square test. Parametric data (age) were compared using independent t-test. Numerical data were presented as mean and standard deviation values. They were analysed for normality using Shapiro-Wilk's test. A Mann-Whitney U test was used to compare ordinal data across groups, while Friedman's test followed by a Nemenyi

Table I - clinical and radiographic criteria

Clinical success criteria	Radiographic success criteria
- Absence of tenderness to percussion. - No abnormal mobility. - Absence of swelling. - Absence of fistula	- Decrease in the size of pre-operative radiolucency. - No development of new radicular or furcation radiolucency. - No development of pathologic internal or external resorption.

post hoc test was used to compare intragroup data. Interexaminer reliability was analysed using Cohen's Kappa coefficient. Statistical analysis was conducted using R statistical analysis software version 4.1.3 for Windows (2022). A significance level of < 0.05 was used for all tests.

RESULTS

The study was conducted on 46 teeth that were randomly and equally assigned to both groups (i.e., 23 teeth each). The baseline characteristic table (demographic data) in terms of gender, age, number of root canals, caries indices, extra and intraoral examinations are shown in Table II.

An interexaminer reliability kappa test was performed for the assessors, producing scores with a statistically significant strong agreement between both ($k=0.756$, $p<0.001$).

Table III describes intergroup and intragroup comparisons, after 12 and 48 hours, the intervention group (A) had significantly lower pain severity than group (B) ($p<0.05$), while for other intervals the difference was not statistically significant ($p>0.05$). In addition, for both groups, there was a statistically significant difference between values measured at other intervals with the highest pain severity measured at 12 hours ($p<0.001$) and decreased over a period of time. Analgesics were provided only for one case in each group (the rotary and the control group).

The cases were evaluated at 2, 6, 9 and 12 months according to clinical and radiographic criteria. The number of teeth per group at different study periods is shown in the consort flowchart Figure 2.

Table IV describes intergroup comparisons, values of frequency and percentage for clinical outcomes in different groups at 12 months. After 12 months, there was a 4(17.4%) failed cases in group (A) and no dropout, while in group (B) there was 3(13.0%) failed cases and a single dropout and the difference between both groups was not statistically significant ($p=0.565$).

While Table V describes intergroup comparisons, values of frequency and percentage for radiographic outcomes in different groups at 12 months. The result revealed that there was 5(21.7%) failed cases in group (A) and no dropout, while in group (B) there was a 4(17.4%) failed cases and a single dropout and the difference between both groups was not statistically significant ($p=0.574$).

Table II - Baseline characteristic table

Parameter			Group (A)	Group (B)	*p*-value
Gender[1]	Male	n	13	14	0.765ns
		%	56.5%	60.9%	
	Female	n	10	9	
		%	43.5%	39.1%	
Age[2]		Mean±SD	5.24±0.61	5.28±0.61	0.812ns
Extra-oral examination[1]	Yes	n	1	1	1ns
		%	4.3%	4.3%	
	No	n	22	22	
		%	95.7%	95.7%	
Dmf[3]		Mean±SD	6.00±2.19	6.26±3.30	0.690
Def[3]		Mean±SD	7.71±2.87	8.50±1.29	0.443ns
DMF		Mean±SD	0.00±0.00	0.00±0.00	NA
Number of canals[1]	Three	n	5	9	0.200ns
		%	21.7%	39.1%	
	Four	n	18	14	
		%	78.3%	60.9%	
Tenderness [1]	Yes	n	15	18	0.326ns
		%	65.2%	78.3%	
	No	n	8	5	
		%	34.8%	21.7%	
Fistula[1]	Yes	n	2	2	1ns
		%	8.7%	8.7%	
	No	n	21	21	
		%	91.3%	91.3%	
Mobility[1]	Yes	n	0	0	NA
		%	0.0%	0.0%	
	No	n	23	23	
		%	100.0%	100.0%	
Swelling[1]	Yes	n	3	3	1ns
		%	13.0%	13.0%	
	No	n	20	20	
		%	87.0%	87.0%	
Furcation radiolucency[1]	Yes	n	5	3	0.437ns
		%	21.7%	13.0%	
	No	n	18	20	
		%	78.3%	87.0%	
Periapical radiolucency[1]	Yes	n	4	4	1ns
		%	17.4%	17.4%	
	No	n	19	19	
		%	82.6%	82.6%	
External root resorption[1]	Yes	n	0	0	NA
		%	0.0%	0.0%	
	No	n	23	23	
		%	100.0%	100.0%	
Internal root resorption[1]	Yes	n	0	0	NA
		%	0.0%	0.0%	
	No	n	23	23	
		%	100.0%	100.0%	

ns; non-significant (p>0.05) NA; Not Applicable; Standard deviation (SD); 1; Chi-square test, 2; Independent t-test, 3; Mann-Whitney U test.

Table III - Inter, intragroup comparisons, frequency and percentage values for postoperative pain in different groups

Time	Pain	Rotary Group (A) N (%)	Manual Group (B) N (%)	*p* value[1]
12h	None	7[A] (30.4%)	2[A] (8.7%)	0.004*
	Mild	11 (47.8%)	6 (26.1%)	
	Moderate	1 (4.3%)	3 (13.0%)	
	Severe	4 (17.4%)	12 (52.2%)	
24hr	None	17[B] (73.9%)	11[B] (47.8%)	0.052ns
	Mild	2 (8.7%)	2 (8.7%)	
	Moderate	3 (13.0%)	6 (26.1%)	
	Severe	1 (4.3%)	4 (17.4%)	
48hr	None	20[B] (87.0%)	13[B](56.5%)	0.022*
	Mild	2 (8.7%)	5 (21.7%)	
	Moderate	1 (4.3%)	5 (21.7%)	
	Severe	0 (0.0%)	0 (0.0%)	
72hr	None	19[B] (82.6%)	15[B](65.2%)	0.189ns
	Mild	4 (17.4%)	8 (34.8%)	
	Moderate	0 (0.0%)	0 (0.0%)	
	Severe	0 (0.0%)	0 (0.0%)	
p-value[2]		<0.001*	<0.001*	

Different superscript letters indicate a statistically significant difference within the same vertical column*. significant ($p \leq 0.05$) ns; non-significant (p>0.05). 1; Mann-Whitney U test, 2; Friedman's test.

Table VI - Intergroup comparisons, frequency and percentage values for overall clinical and radiographic outcomes in different groups.

Parameter	Groups				*p*-value[1]
	Rotary Group (A)		Manual Group (B)		
	n	%	N	%	
Success	18	78.3%	17	73.9%	0.598ns
Failure	5	21.7%	5	21.7%	
Dropout	0	0.0%	1	4.3%	

ns; non-significant (p>0.05). 1; Chi-square test.

Table V - Intergroup comparisons, frequency and percentage values for radiographic outcomes in different groups at 12 months

Parameter	RADIOGRAPHIC EVALUATION				*p*-value[1]
	Rotary Group(A)		Manual Group (B)		
	n	%	N	%	
Success	18	78.3%	18	78.3%	0.574ns
Failure	5	21.7%	4	17.4%	
Dropout	0	0.0%	1	4.3%	

ns; non-significant (p>0.05). 1; Chi-square test.

For a case to be considered having overall outcome success, it should have both clinical and radiographic success.

Table VI shows the overall clinical and radiographic outcomes after 12 months, there was a 5(21.7%) failed cases in both groups, a single dropout in group (B), and the difference between both groups was not statistically significant (p=0.598).

Table VII states the instrumentation time per group of treatment (min:sec) (minutes/seconds). The instrumentation time in the control group was significantly higher than the intervention group (p<0.001).

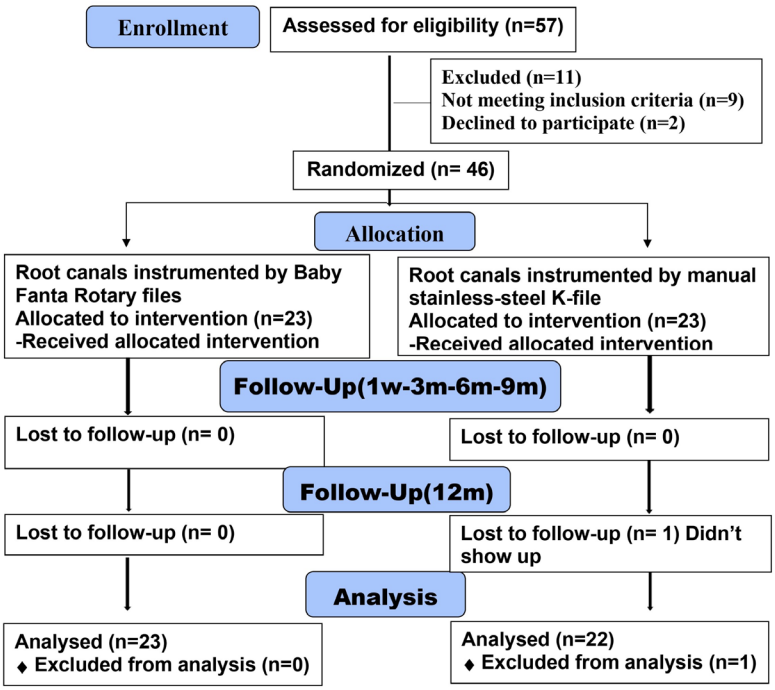

Figure 2 - CONSORT Flow chart showing the number of teeth involved in the two groups at different study periods.

Table IV - Intergroup comparisons, frequency and percentage values for clinical outcomes in different groups at 12 months

Parameter	CLINICAL EVALUATION				*p*-value[1]
	Rotary Group (A)		Manual Group (B)		
	n	%	n	%	
Success	19	82.6%	19	82.6%	
Failure	4	17.4%	3	13.0%	0.565ns
Dropout	0	0.0%	1	4.3%	

ns; non-significant (p>0.05). 1;Chi-square test.

Table VII - Showing instrumentation time per group of treatment (min: sec)

Groups of treatment	N	Mean±SD	*P* Value[1]
Rotary group (A)	23	12:05±02:09	<0.001*
Manual group (B)	23	17:14±02:17	

*; significant (p ≤ 0.05) ns; non-significant (p>0.05); Standard deviation (SD). 1; Independent t-test.

Table VIII describes intergroup comparison, frequency and percentage values for quality of obturation in different groups, no significant difference was observed between both groups regarding the presence of voids (p=0.667) and the extent of filling (p=0.261).

Case presentation for both groups are shown in Figure 3 and Figure 4.

DISCUSSION

Pulpectomy in primary teeth has high success rates, which make most of the practitioners choose them over tooth extraction and space maintainer. However, pulpectomy is considered a challenge in pediatric dentistry [19].

To our knowledge, this is the first study that compared the postoperative pain, clinical and radiographic success of Fanta baby rotary files file with Manual K-files in primary molars teeth.

Our study focused on children aged 4-6 years old because this is the most suitable age group with significant root length and to perform the study away from the age of normal physiologic root resorption as well as children younger than

Table VIII - Intergroup comparisons, frequency and percentage values for quality of obturation in different groups

Parameter		Groups				*p*-value[1]
		Rotary Group (A)		Manual Group (B)		
		n	%	n	%	
Presence of voids	Complete absence of voids	13	56.5%	15	65.2%	0.667ns
	Presence of one void	6	26.1%	6	26.1%	
	Presence of two voids	4	17.4%	2	8.7%	
Extent of filling	Greater than half but less than optimal fill	5	21.7%	10	43.5%	0.261ns
	Optimal fill	11	47.8%	9	39.1%	
	Extrusion of material beyond apex	7	30.4%	4	17.4%	

ns; non-significant (p>0.05).1; Chi-square test.

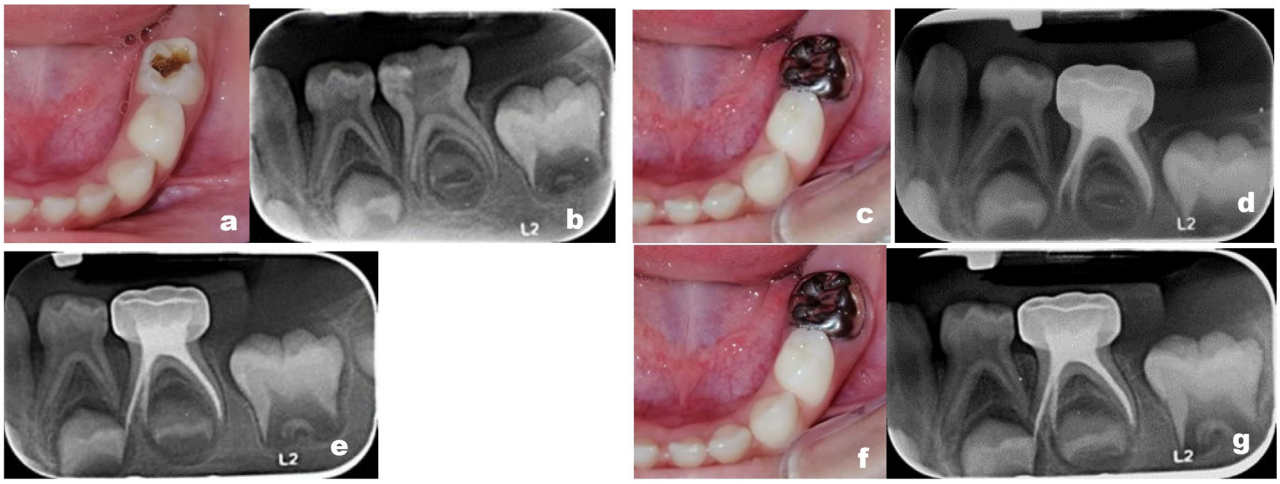

Figure 3 - Photograph showing clinical and radiographic photos for a case from the rotary instrumentation group at different intervals. (a) preoperative clinical photo showing lower left second primary molar, (b) preoperative radiograph showing lower left second primary molar, (c) immediate post-operative clinical photo showing lower left second primary molar with stainless steel crown, (d) immediate post-operative radiograph showing lower left second primary molar with stainless steel crown, (e) radiograph showing lower left second primary molar with stainless steel crown at 6 months, (f) clinical photo showing lower left second primary molar with stainless steel crown at 12 months and (g) radiograph showing lower left second primary molar with stainless steel crown at 12 months. Case I: Baby Fanta rotary files instrumentation group.

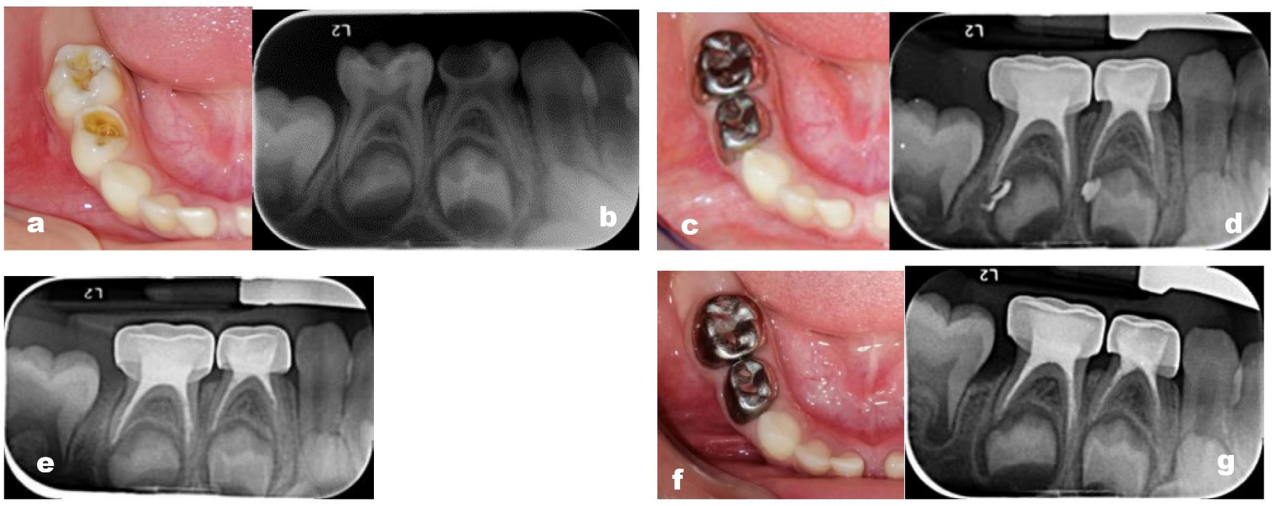

Figure 4 - Photographs showing clinical and radiographic photos for a case from the manual instrumentation group at different intervals. (a) preoperative clinical photo showing lower right second primary molar, (b) preoperative radiograph showing lower right second primary molar, (c)immediate post-operative clinical photo showing lower right second primary molar with stainless steel crown, (d) immediate post-operative radiograph showing lower right second primary molar with stainless steel crown, (e) radiograph showing lower right second primary molar with stainless steel crown at 6 months, (f) clinical photo showing lower right second primary molar with stainless steel crown at 12 months and (g) radiograph showing lower right second primary molar with stainless steel crown at 12 months. Case II: Manual K-file instrumentation group.

the age of 4 are easily affected by any stimuli and have more a propensity to show negative behaviors. Teeth with pathologic root resorption and teeth with less than two third of each root remaining were excluded from the study similar to Shah et al. [11] and Cademartori et al. [20].

Lower second primary molars were selected in this study for standardization as it is easier and accessible for practical work and for more precisely diagnosis of radiographic changes (pathology and healing) than in upper molars due to the reduced overlap of permanent lower tooth buds on the bifurcation of the lower primary molars [11,21].

Since the angle at which the radiograph is taken is extremely critical. All postoperative radiographs were taken with a custom-made stent for each child and the Rinn XCP film holding instrument with the same exposure parameters. So, we will be able to compare the preoperative and immediate postoperative x-rays without consideration of differences in the radiographic angle [21].

The intensity of postoperative pain was greatest at 12 hours after treatment and gradually decreased irrespective of instrumentation techniques. This is in agreement with several studies evaluating the duration of postoperative pain after RCT [8,9]. This could be due to the possible irritation of the periapical area during endodontic treatment that causes local inflammatory response and decreases after healing of the periapical area [22].

Postoperative pain in the control group was significantly higher than in the rotary group with statistically significant differences at 12 and 48 hours. These results were consistent with those of previous trials of Topçuoğlu et al. [8] and Nair et al. [9] The less postoperative pain in the rotary group might be explained by early preflaring using Fanta baby's orifice opener file. By preflaring, any cervical obstruction is eliminated, so irrigants can reach the canal easily according to Subramaniam et al. [23] and less debris and microorganisms are extruded apically during instrumentation as stated by Topçuoğlu et al. [8].

Regarding instrumentation time, the study results showed that the manual group provided significantly longer time than the rotary group during canals preparation which corresponded with the findings of several previous studies [24,25]. It is possible that the higher time required for the manual instrumentation is due to a greater number of manual files with a lower cutting potential. In turn, this will cause fatigue during instrumentation and ultimately result in a decrease in the operator performance. Our findings, however, were contradicted by Madan et al. [26] and Katge et al. [27] who found that rotary file systems increased root canal instrumentation time in primary teeth. This was attributed to the number of rotary instruments used and operator's experience.

In other word, the instrumentation time in rotary group was at a lower rate (mean 12:05±02:09) than the instrumentation time found by Morankar et al. [10] (19.37 ± 4.94 min) and Babu and Kavyashree [24] (mean 14.56 ± 2.89 min), while it was longer than that by Makarem et al. [28] (10.1±1.71 min) and Priyadarshini et al. [18] (3.4827 ± 0.48 min). This is explained by variations the number of rotary files used.

Regarding the quality of obturation, the manual group in our study showed a higher percentage of underfilled root canals than the rotary group. The problem could be due to the use of a less elastic and tapered manual file, resulting in narrow irregular debrided canals that prevent proper obturating material flow. Although there was no statistically significant difference between both groups. This result is in accordance with Govindaraju et al. [29], Sruthi et al. [30] and Lakshmanan et al. [31] reported higher optimal filled teeth in rotary group and higher underfilled teeth in manual group respectively with no statistically significant difference between the two groups. On the contrary, Priyadarshini et al. [18] and Babu and Kavyashree [24] reported statistically significant differences in obturation quality between both groups. Extrusion of material beyond apex was more in rotary group than manual group, although there were no significant differences in both groups. This result is similar with Divya et al. [32] who found more overfilling in rotary group with statistical significant difference between both groups.

Another critical aspect of obturation is the voids' incidence. In our study, the presence of voids in obturation was not significantly different between the rotary and manual groups. Accordingly, this suggests that rotary files

allow for proper obturations with less chairside time required. This result is in consistent with Shah et al. [11] and Lakshmanan et al. [33].

Based on a prior paper conducted by Morankar et al. [10], clinical and radiographic follow up visits were after 3, 6, 9 and 12 months. The two blinded independent assessors interpreted radiographs with strict success/failure criteria. Then, an interexaminer reliability kappa test was performed for these assessors, producing scores with a statistically significant strong agreement between both assessors.

Regarding clinical evaluations, our study showed no statistically significant difference in clinical parameters including tenderness to percussion, gingival swelling, fistulas, and pathological tooth mobility between the two groups at the different follow up period. However, there was significant reduction in tenderness within each group through follow up period with marked improvement after treatment. This result is in accordance with Elheeny et al. [34] who stated no statistical significant difference in all clinical parameters between both groups, while there was high statistical significant difference in all clinical parameters within each groups.

At 12 months, the clinical success at our study was 82.6% with no statistically significant difference in both groups. These findings are in line with those obtained by Elheeny et al. [34] , who revealed no statistically significant difference in term of clinical success rates in the rotary and manual groups. On the contrary, Babu and Kavyashree [24] and Amorim et al. [35] reported that clinical success rate during the 12 months follow up was 100% in both groups.

The first sign of failure may be periapical or/and furcation radiolucency followed by external root resorption, especially as the failure progresses. This failure was observed in both groups and continued until the end of the study period. There was no statistically significant difference between both groups. This result goes in accordance with Babu and Kavyashree [24] who reported development of a new radiolucency.

At 12 months, radiographic success in both groups was 78.3% and statistically significant difference was not observed. Our finding was higher than radiographic success in rotary and manual group (66.7%,65.4% respectively) obtained by Morankar et al. [10], while it was relatively lower than those (100%, 95.8% respectively) obtained by Babu and Kavyashree [25].

Apart from the type of instrumentation technique in both groups, a possible explanation of these similar success rates in both groups may be attributed to proper field isolation, use of copious amounts of suitable irrigants, type of obturation material and hermitic seal post restoration, all of which are considered critical factors for pulpectomy success.

In our study, the possible reasons for radiographic failure observed in both groups may be attributed to the inherent problems in primary molars as (connecting fibrils, partial fusion of canals, accessory canals, lateral branching, apical ramification, thin apical isthmus and root curvature) leading to incomplete removal of inflamed/necrotic tissues.In addition to persistence of bacteria in the canals and apex and the presence of more resistant microorganisms [36].

While the differences between our findings and those of previous studies may likely be attributed to differences in teeth chosen, type of rotary instruments used and type of irrigating solutions as well as operator skills and experience.

Our study found that the clinical success was higher than radiographic success in both groups, this result was evident in study previously conducted by Morankar et al. [10] which declare that, radiographic success rates have been found to be lower than the clinical success rates. As cited by Elheeny et al. [34], this may be because failure of pulp therapy treatment is first detected radiographically and tooth could be remained asymptomatic clinically until natural exfoliation of the patient teeth.

Additionally, our study showed that the overall clinical and radiographic success in rotary and manual groups were 78.3% and 73.9% respectively. These results differ from those obtained by Kuo et al. [37] who reported overall clinical and radiographic success rates in rotary group was 95%. This higher success rate may be accounted for that majority of the selected teeth had acute pulpitis as cited by Elheeny et al. [34].

In our study, the difference between both groups was not statistically significant regarding clinical and radiographic failure. This result was supported by Elheeny et al. [34] who found nearly similar number of failed cases in rotary group and in manual group, while Morankar et al. [10]

found similar number in rotary group but higher in manual group.

It is worth to mention that we faced some difficulties in comparing our results with other studies having the same aim due to differences in the type of rotary systems used in other studies. Furthermore, there have been limited clinical trials that evaluate the clinical and radiographic outcomes of using rotary systems for instrumenting primary molars. Consequently, there were no comparison data available for Fanta baby rotary files regarding clinical and radiographic success.

Study strength:

This is the first randomized clinical trial using the Fanta baby rotary files compared to manual files. Thus, there is no clinical data available for Fanta baby rotary files. A standardized technique was performed through this trial in both groups.

Study limitations:

1- The postoperative pain used is a subjective method of evaluation where children can state that they are in pain but actually they do not feel pain, they might recall their previous pain as if it is present.

2- A further limitation was the inability to blind the operator and participating children due to notable differences in instrumentation techniques.

3- It is also worth mentioning that we followed manufacturers recommendations, to use EDTA with rotary systems; whereas EDTA was not used with the manual files group. Thus, the imputation of using EDTA with both rotary and manual systems need to be furtherly investigated.

Despite these limitations, the study contributes meaningful preliminary data on the relationship between [rotary /manual] which can guide subsequent research in this area.

CONCLUSIONS

We concluded that Fanta baby rotary files provide less postoperative pain after pulpectomy procedures compared to the manual files. In addition, there was no statistically significant difference between both groups in clinical and radiographic success after 12 months. No significant difference was observed between both groups regarding the presence of voids and the extent of filling. Further studies are needed using larger sample sizes and diverse materials and more objective parameters are required to strengthen the evidence. Also, future studies with larger sample sizes specifically powered for secondary outcomes are recommended to confirm our findings and further explore their clinical implications.

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Author's Contributions

AAW: conceptualization, methodology, investigation, formal analysis, writing-review&editing, writing-Original draft preparation. KE: conceptualization, methodology, formal analysis, writing- review & editing. AMAA: conceptualization, methodology, investigation, formal analysis, writing-review & editing. FA: conceptualization, methodology, investigation, formal analysis, writing- review &editing, writing-Original draft preparation.

Conflict of Interest

No conflicts of interest were declared concerning the publication of this article.

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Regulatory Statement

Before the commencement of research, the ethical approval for the current study was obtained from Research Ethics Committee, Faculty of Dentistry, Cairo University with approval number (34-9-19) following the declaration of Helsinki for human subject research. Prior to the beginning of the study, an informed consent was obtained from the parents/guardians of all the children who had enrolled for the study.

LIST OF ABBREVIATIONS

dmf = decay, missing, filling

EDTA= Ethylenediaminetetraacetic acid

min: sec = minuets: second

Ni-Ti = Nickel-titanium

REFERENCES

1. Gadallah L, Hamdy M, El Bardissy A, Abou El Yazeed M. Pulpotomy versus pulpectomy in the treatment of vital pulp exposure in primary incisors. A systematic review and meta-analysis. F1000 Res. 2018;7:1560. http://doi.org/10.12688/f1000research.16142.2. PMid:31249668.
2. Ahmed HMA. Pulpectomy procedures in primary molar teeth. Eur J Gen Dent. 2014;3(01):3-10. http://doi.org/10.4103/2278-9626.126201.
3. Spodzieja K, Olczak-Kowalczyk D. Premature loss of deciduous teeth as a symptom of systemic disease: a narrative literature review. Int J Environ Res Public Health. 2022;19(6):3386. http://doi.org/10.3390/ijerph19063386. PMid:35329073.
4. Ochoa-Romero T, Veronica Mendez-Gonzalez HF-R, Pozos-Guillen AJ. Comparison between rotary and manual techniques on duration of instrumentation and obturation times in primary teeth. J Clin Pediatr Dent. 2011;35(4):359-64. http://doi.org/10.17796/jcpd.35.4.8k013k21t39245n8. PMid:22046692.
5. Kirmizigül I, Demir P. Usage of rotary instruments in root canal therapy of deciduous teeth - review. Cumhuriyet Dent J. 2019;22(3):351-7. http://doi.org/10.7126/cumudj.554999
6. Barr ES, Kleier DJ, Barr NV. Use of nickel-titanium rotary files for root canal preparation in primary teeth. Pediatr Dent. 2000;22(1):77-8. PMid:10730297.
7. Pinheiro SL, Neves LS, Imparato JCP, Duarte DA, Bueno CES, Cunha RS. Analysis of the instrumentation time and cleaning between manual and rotary techniques in deciduous molars. Rsbo. 2012;9(3):238-44. http://doi.org/10.21726/rsbo.v9i3.995.
8. Topçuoğlu G, Sinan H, Delikan E, Aydınbelge M, Dogan S. Postoperative pain after root canal preparation with hand and rotary files in primary molar teeth. Pediatr Dent. 2017;39(3):192-6. PMid:28583242.
9. Nair M, Jeevanandan G, Vignesh R, Emg S. Comparative evaluation of post-operative pain after pulpectomy with k-files, kedo-s files and mtwo files in deciduous molars-a randomized clinical trial. Braz Dent Sci. 2018;21(4):411-7. http://doi.org/10.14295/bds.2018.v21i4.1617.
10. Morankar R, Goyal A, Gauba K, Kapur A, Bhatia SK. Manual versus rotary instrumentation for primary molar pulpectomies- A 24 months randomized clinical trial. Pediatr Dent J. 2018;28(2):96-102. http://doi.org/10.1016/j.pdj.2018.02.002.
11. Shah HS, Patil VM, Kamath AP, Mathur AA. 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. http://doi.org/10.4103/ccd.ccd_83_20. PMid:33967539.
12. Abd El fatah YAM, Khattab NMA, Gomaa YF, Elheeny AA. Cone beam computed tomography analysis of primary root canals transportation and dentin loss after instrumentation with two pediatric rotary files. BMC Oral Health. 2022;1-8. http://doi.org/10.1186/s12903-022-02245-8.
13. Panchal V, Jeevanandan G, Subramanian EMG. Comparison of post-operative pain after root canal instrumentation with hand K-files, H-files and rotary Kedo-S files in primary teeth: a randomised clinical trial. Eur Arch Paediatr Dent. 2019;20(5):467-72. http://doi.org/10.1007/s40368-019-00429-5. PMid:30864090.
14. UCLA. G*Power [Internet]. UCLA: Statistical Consulting Group; 2024 [cited 2024 Oct 6]. Available from: https://stats.oarc.ucla.edu/other/gpower/.
15. Random.Org. [Internet]. Random.Org; 2024 [cited 2024 Oct 6]. Available from: http://www.random.org/.
16. Bnaiyan AH, Altinawi MK, Lazkani T, Alzoubi H. Evaluation time and efficacy of root canal rotary preparation in primary teeth : an in-vitro study. Cureus. 2022;14(4):e24558. http://doi.org/10.7759/cureus.24558. PMid:35664392.
17. 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. Egypt Dent J. 2021;67(4):2865-74. http://doi.org/10.21608/edj.2021.79035.1661.
18. Priyadarshini P, Jeevanandan G, Govindaraju L, Subramanian EMG. Clinical evaluation of instrumentation time and quality of obturation using paediatric hand and rotary file systems with conventional hand K-files for pulpectomy in primary mandibular molars: a double-blinded randomized controlled trial. Eur Arch Paediatr Dent. 2020;21(6):693-701. http://doi.org/10.1007/s40368-020-00518-w. PMid:32185634.
19. Ramazani N, Mohammadi A, Amirabadi F, Ramazani M, Ehsani F. In vitro investigation of the cleaning efficacy, shaping ability, preparation time and file deformation of continuous rotary, reciprocating rotary and manual instrumentations in primary molars. J Dent Res Dent Clin Dent Prospect. 2016;10(1):49-56. http://doi.org/10.15171/joddd.2016.008. PMid:27092215.
20. Cademartori MG, Corrêa MB, Silva RA, Goettems ML. Childhood social, emotional, and behavioural problems and their association with behaviour in the dental setting. Int J Paediatr Dent. 2019;29(1):43-9. http://doi.org/10.1111/ipd.12436. PMid:30381852.
21. Mohammad G, Jerin F, Jebin S. Pulpal diagnosis of primary teeth: guidelines for clinical practice. Bangladesh J Dent Res Educ. 2013;2(2):66-8. http://doi.org/10.3329/bjdre.v2i2.16248.
22. Al-Nahlawi T, Hatab TA, Alrazak MA, Al-Abdullah A. Effect of Intracanal Cryotherapy and Negative Irrigation Technique on Postendodontic Pain. J Contemp Dent Pract. 2016;17(12):990-6. http://doi.org/10.5005/jp-journals-10024-1969. PMid:27965485.
23. Subramaniam P, Tabrez TA, Girish Babu KL. Microbiological assessment of root canals following use of rotary and manual instruments in primary molars. J Clin Pediatr Dent. 2013;38(2):123-7. http://doi.org/10.17796/jcpd.38.2.j84265t82u60271u. PMid:24683774.
24. Babu KG, Kavyashree GH. Evaluation of the clinical efficiency of rotary and manual files for root canal instrumentation in primary teeth pulpectomies: a comparative randomized clinical trial. Contemp Pediatr Dent. 2021;0(2):21-34. http://doi.org/10.51463/cpd.2021.42.
25. Preety R, Jeevanandan G, Chaudhary M. Pulpectomy performed in children between the age group of 5 to 10 years: a retrospective study. Ann Med Health Sci Res. 2021;11(52):205-9.
26. Madan N, Rathnam A, Shigli AL, Indushekar KR. K-file vs ProFiles in cleaning capacity and instrumentation time in primary molar root canals: an in vitro study. J Indian Soc Pedod Prev Dent. 2011;29(1):2-6. http://doi.org/10.4103/0970-4388.79907. PMid:21521910.
27. Katge F, Chimata VK, Poojari M, Shetty S, Rusawat B. Comparison of cleaning Efficacy and Instrumentation Time between Rotary and Manual Instrumentation Techniques in Primary Teeth: An in vitro Study. Int J Clin Pediatr Dent. 2016;9(2):124-7. http://doi.org/10.5005/jp-journals-10005-1347. PMid:27365932.

28. Makarem A, Ravandeh N, Ebrahimi M. Radiographic assessment and chair time of rotary instruments in the pulpectomy of primary second molar teeth: a randomized controlled clinical trial. J Dent Res Dent Clin Dent Prospects. 2014;8(2):84-9. PMid:25093051.

29. Govindaraju L, Jeevanandan G, Emg S, Vishawanathaiah S. Assessment of Quality of Obturation, Instrumentation Time and Intensity of Pain with Pediatric Rotary File (Kedo-S) in Primary Anterior Teeth: A Randomized Controlled Clinical Trial. Int J Clin Pediatr Dent. 2018;11(6):462-7. http://doi.org/10.5005/jp-journals-10005-1558. PMid:31303731.

30. Sruthi S, Jeevanandan G, Govindaraju L, Subramanian E. Assessing quality of obturation and instrumentation time using Kedo SG blue, Kedo SH, and reciprocating hand K files in primary mandibular molars : A double blinded randomized controlled trial. Dent Res J (Isfahan). 2021;18(1):76. http://doi.org/10.4103/1735-3327.326649. PMid:34760067.

31. Lakshmanan L, Mani G, Jeevanandan G, Ravindran V, Ganapathi S. Assessing the quality of root canal filling and instrumentation time using kedo-s files, reciprocating files and k-files. Braz Dent Sci. 2020;23(1):1-7. http://doi.org/10.14295/bds.2020.v23i1.1822.

32. Divya S, Jeevanandan G, Sujatha S, Subramanian E, Ravindran V. Comparison of quality of obturation and post-operative pain using manual vs rotary files in primary teeth - A randomised clinical trial. Indian J Dent Res. 2019;30(6):904-8. http://doi.org/10.4103/ijdr.IJDR_37_18. PMid:31939369.

33. Lakshmanan L, Ramakrishnan M, Jeevanandan G. Comparison of obturation quality, instrumentation time and post-operative pain using manual K-files and pediatric rotary files in primary molars–a double blinded randomised clinical trial. Braz Dent Sci. 2023;26(2):e3497. http://doi.org/10.4322/bds.2023.e3497.

34. Elheeny A, Khattab N, Fouda T. Comparative study of two rotary systems for endodontic endodontic treatment of infected primary molars. Egypt Dent J. 2015;2015(61):4293-300.

35. Amorim AC, Caldeira AV, Sampaio SC, Lourenço N No, Oliveira TM, Nogueira DA, et al. Comparison between the rotary (Hyflex EDM®) and manual (k-file) technique for instrumentation of primary molars: a 12-month randomized clinical follow-up study. J Appl Oral Sci. 2022;30:e20210527. http://doi.org/10.1590/1678-7757-2021-0527. PMid:35319604.

36. Tabassum S, Khan FR. Failure of endodontic treatment: the usual suspects. Eur J Dent. 2016;10(1):144-7. http://doi.org/10.4103/1305-7456.175682. PMid:27011754.

37. Kuo C-I, Wang Y-L, Chang H-H, Huang G-F, Lin C-P, Li U-M, et al. Application of Ni-Ti rotary files for pulpectomy in primary molars. J Dent Sci. 2006;1:10-5.

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