RESEARCH ARTICLE

Comparative Evaluation of Hand K-flex Files, Pediatric Rotary Files, and Reciprocating Files on Instrumentation Time, Postoperative Pain, and Child's Behavior in 4–8-year-old Children

Rishi Tyagi[1], Amit Khatri[2], Namita Kalra[3], Puja Sabherwal[4]

Abstract

Background: A pulpectomy is regarded as the choice modality of treatment for necrotic teeth. The use of hand files, though popular traditionally as a gold standard, may be challenging due to increased chairside time. Postoperative pain is one of the most common complications of pulpectomy and may be unpleasant for a child/pedodontist. Rotary files were found to reduce instrumentation time, reduce apical extrusion, and in turn reduce pain but there is a lack of studies in primary teeth particularly for pediatric and reciprocating file systems. The increased number of options available today makes it a dilemma for the operator to choose a suitable file system.

Aim and objective: The study aimed to evaluate and compare the instrumentation time, postoperative pain, and effect on child's behavior among three groups, i.e., hand K-flex files (group I), pediatric rotary files (group II), and reciprocating files (group III).

Materials and methods: A total of 75 primary molar teeth after meeting inclusion criteria were randomly allocated into three groups. During the procedure, step-wise instrumentation time was recorded using a stopwatch. The child's behavior pre- and postoperatively was assessed by an evaluator. The postoperative pain (up to 1 week) was assessed by a questionnaire.

Results: The mean age of children taken for the study was 6.03 ± 1.2 years with 46 males and 29 females. The mean biomechanical preparation time was observed to be significantly shorter in the pediatric rotary and reciprocating file groups vs hand K-flex files ($p < 0.001$**). The postoperative pain after 6 hours had a mean value of 0.88 + 0.9 for the hand K-flex file group which was significantly higher than both rotary file groups ($p < 0.05$*). The pre- and postoperative behavior revealed no significant difference.

Conclusion: The clinical performance of pediatric and reciprocating files was superior, but the choice of file system did not significantly alter behavior.

Keywords: Behavior assessment, Hand files, Instrumentation time, Pediatric rotary files, Postoperative pain, Primary dentition, Pulpectomy, Reciprocating files.

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Introduction

The loss of primary dentition prematurely is a common problem that may prevent a normal eruption of succedaneous teeth, hamper esthetics, and lead to abnormal tongue habits.[1] Pulpectomy is regarded as the choice modality of treatment for pulpally involved necrotic teeth.[2] Hand files are used for chemo-mechanical preparation conventionally during the pulpectomy procedure. Although traditionally used, the use of hand files may be challenging due to narrow, curved canals in primary teeth with ongoing physiological resorption. The use of hand files may lead to difficulty in proper filling and increased time of treatment.[3] The long duration of treatment time may negatively influence the child's behavior.[4]

To overcome these challenges, Barr et al. first introduced the rotary technique for primary teeth.[5] Rotary technique has advantages of reduced instrumentation time and superior quality fillings.[5,6] However, the rotary instruments of permanent teeth may be unsuccessful in cleaning the isthmus in primary teeth[7] and may have added disadvantages of increased cost and breakage. The introduction of pediatric rotary systems may overcome the above-mentioned disadvantage and may have improved canal centricity, conservative canal preparation with better obturation quality. There are few *in vivo* studies comparing instrumentation time of pediatric rotary systems with hand files in primary teeth and thereby their effect on the child's behavior.[8]

Furthermore, the overall success of pulpectomy depends on canal disinfection, irrigation, and obturation.[9,10] Postoperative pain/swelling is one of the most common complications of pulpectomy and may be unpleasant for both patient/dental surgeon.[11] There is a

[1–3]Department of Pedodontics, UCMS and GTB Hospital, Ghaziabad, India

[4]Department of Pedodontics and Preventive Dentistry, University College of Medical Sciences, Delhi, India

Corresponding Author: Rishi Tyagi, Department of Pedodontics, UCMS and GTB Hospital, Ghaziabad, India, Phone: +91 9868575552, e-mail: tyagi_rishidoc@hotmail.com

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direct relation between periradicular inflammation, apical extrusion, and the presence of pain postoperatively.[12] NiTi Rotary files were found to reduce apical extrusion of debris.[13,14] As per the study by Shokraneh et al., there was significantly lower postoperative pain seen with reciprocating systems compared with conventional NiTi Rotary and hand systems. However, there is a lack of studies evaluating the intensity and duration of postoperative pain after pulpectomy in primary teeth.[15] Upon, a perusal of literature, there was a lack of studies drawing a clinical comparison among hand, pediatric and reciprocating file systems in primary teeth.

Therefore, the study aimed to evaluate and compare the instrumentation time, postoperative pain, and effect on child's behavior among three groups, i.e., Hand K-flex files (group I), Pediatric rotary files (group II), and Reciprocating files (group III).

Materials and Methods

Power analysis for a one-way ANOVA (Fixed Effects, Omnibus, One way) with three groups was conducted in G*Power[16] to determine sufficient sample size using an alpha of 0.05, a power of 0.80, and an effect size ($f = 0.48$).[17] Based on the aforementioned assumptions, the desired total sample size was 60 (i.e., 20 per group). Assuming a loss to follow-up of 20%, the final sample was 72 (24 per group). After further rounding off, the final sample size was 75, i.e., 25 in each test group.

All patients between the age-group 4 years and 8 years with primary molar teeth indicated for pulpectomy were chosen for the study. Teeth exhibiting one or more of the following with 2/3rd of the root remaining were included in the study—(a) necrotic pulp, (b) symptoms of irreversible pulpitis, and (c) radiolucencies in the periapical or furcation region. Teeth exhibiting one or more of the following were excluded from the study—(a) swelling, (b) excessive mobility, (c) cellulitis, (d) perforated pulpal floor, and (e) fistula. Children lacking cooperative ability, those having a systemic illness, or special care needs were excluded from the study.

The subjects were divided into three groups using the block randomization (block of 3) technique. The randomization sequence was developed by a statistician and opaque envelopes were used for allocation concealment. The patients and parents were blinded about the treatment protocol, the evaluator recording the instrumentation time and behavior was also blinded. The principal operator performing the treatment could not be blinded as the treatment was being administered by the operator. Informed consent was obtained from each parent/guardian and ethical clearance was obtained from the Departmental Review board.

The pulpectomy procedure was performed in a single visit by the same operator. Non-pharmacological techniques of behavior management were used to alter the child's behavior and gain cooperation. Local anesthesia infiltration was done (2% lignocaine, 1:200,000 adrenaline) followed by isolation of the tooth using the rubber dam (GDC Dental Dam Kit, Hoshiarpur, India).

Access cavity preparation was done using No 2, 4-round bur, the pulp chamber was deroofed and orifices located using the DG-16 explorer (Hu-Friedy, IL, USA). Size 10 K-file NiTi flex (Dentsply Maillefer, Switzerland) was used to determine canal patency. The working length was determined using the radiographic method and kept 1 mm short of the radiographic apex. Instrumentation in group I was done using hand K-files NiTi Flex (size 15–30K, Dentsply Maillefer, Switzerland) in a quarter pull turn motion. Instrumentation in group II was done using Pro AF Baby Gold (Dentobizz, India) which is a specialized pediatric file with a short length of 17 mm, heat-treated NiTi control memory files. Hand files 15K, 20K were used for initial glide path formation. The sequence B1 (4%, 20) and B2 (4%, 25) were used at speed 350 rpm, auto continuous motion at a torque of 1.5 N for narrow canals, and sequence B2 (4%, 25) and B3 (6%, 25) were used for medium-sized canals commonly the palatal canal in the upper molars and distal canals in the lower molars. In group III, WaveOne GOLD files (Dentsply Sirona Maillefer) were used for benefits of gold thermal treatment, reciprocating motion, evolving cross-section, and single file technique for shaping canal. 10–15 K-files NiTi flex was used up to 2/3rd of working length. This was followed by size small (#020.07) (Dentsply Sirona, USA) WaveOne Gold file at a speed of 350 rpm, reciprocating motion till 2/3rd of working length. This is followed by using 10K and 15K files till full working length. Then, the small WaveOne GOLD file or by Primary WaveOne Gold file (#025.07) (Dentsply Sirona, USA) for the wider canals is used until the complete working length.

The irrigant used was 1% sodium hypochlorite followed by normal saline. The canals were dried using sterile paper points and obturation was done using calcium hydroxide and iodoform paste (Metapex, META Biomed Co, PA, USA). The canals and chamber were cleaned using moist cotton pellets followed by seal using Glass Ionomer Cement (Shofu FX Ultra, Shofu Inc, Japan). At the second visit after approximately 1-week, Stainless Steel crowns (3M ESPE, USA) were delivered.

The instrumentation time was recorded by an evaluator blinded to the treatment modality used for access opening, biomechanical preparation, and obturation. The child's behavior was also recorded as per the modified Frankel Scale (Table 1)[18] preoperatively and postoperatively by the evaluator.

To assess the postoperative pain, a questionnaire was given to the parent or guardian and they were trained to use the 4-point pain scale (Flowchart 1)[19] to record the postoperative pain felt by the child after 6 hours, 24 hours, 72 hours, and 1 week. At the end of 1 week, the parents/guardians returned with the questionnaire (Materials and Methodology step-wise illustration; Fig. 1).

Results

The data were entered into digital spreadsheets and statistical analysis was done using SPSS (Statistical Package for Social

Table 1: Modified Frankel scale used in the study to assess child's behavior[18]

- **Rating 1:** DEFINITELY NEGATIVE (–): Refusal of treatment, crying forcefully, fearful, or any other overt evidence of extreme negativism.
- **Rating 2:** NEGATIVE (–): Reluctant to accept treatment, uncooperative, some evidence of negative attitude but not pronounced, i.e., sullen, withdrawn.
- **Rating 3:** NEGATIVE POSITIVE (–+): Fluctuation between uncooperativeness and some evidence of unpronounced negative attitude, and cautious acceptance to treatment with reservation shifting throughout the visit.
- **Rating 4:** POSITIVE (+): Acceptance of treatment; at times cautious, willingness to comply with the dentist, at times with reservation but patient follows the dentist's directions cooperatively.
- **Rating 5:** DEFINITELY POSITIVE (++): Good rapport with the dentist, interested in the dental procedures, laughing and enjoying the situation.

Sciences) version 16. Descriptive results were obtained in frequency (percentage) and mean ± standard deviation. The association between quantitative variables was obtained using Kruskal–Wallis non-parametric test. Level of significance was set at 5% ($p < 0.05$).

The mean age of children taken for the study was 6.03 ± 1.2 years with 46 males and 29 females (Table 2).

Instrumentation time showed no statistical significance in the mean time for access opening. However, the mean time for biomechanical preparation was found to differ significantly among the three groups ($p < 0.001$**). The mean time (in minutes) was 40.02 ± 7.08 for group I (hand K-flex files) was significantly higher than groups II and III. The mean instrumentation time for obturation was also higher for group III which was also found to be statistically significant ($p < 0.05$*) (Table 3).

There was no significant difference in the mean preoperative pain among the three groups. The postoperative pain after 6 hours had a mean value of 0.88 + 0.9 for the hand K-flex files (group I), 0.44 + 0.71 for pediatric rotary files (group II), and 0.31 + 0.61 for the reciprocating files (group III) proving to be statistically significant

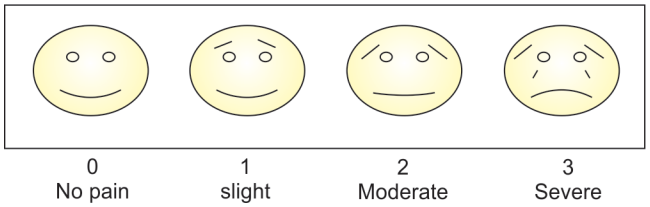

Fig. 1: Materials and methodology step-wise illustration

Table 2: Demographic details of the study sample

Demographic parameter	*Overall (mean ± SD)*	*Group I (mean ± SD)*	*Group II (mean ± SD)*	*Group III (mean ± SD)*
Age	6.04 ± 1.1	6.34 ± 1.27	5.76 ± 1.11	5.92 ± 1.02
Gender				
Male	46	18	17	11
Female	29	6	9	14

Flowchart 1: Flow diagram of study methodology

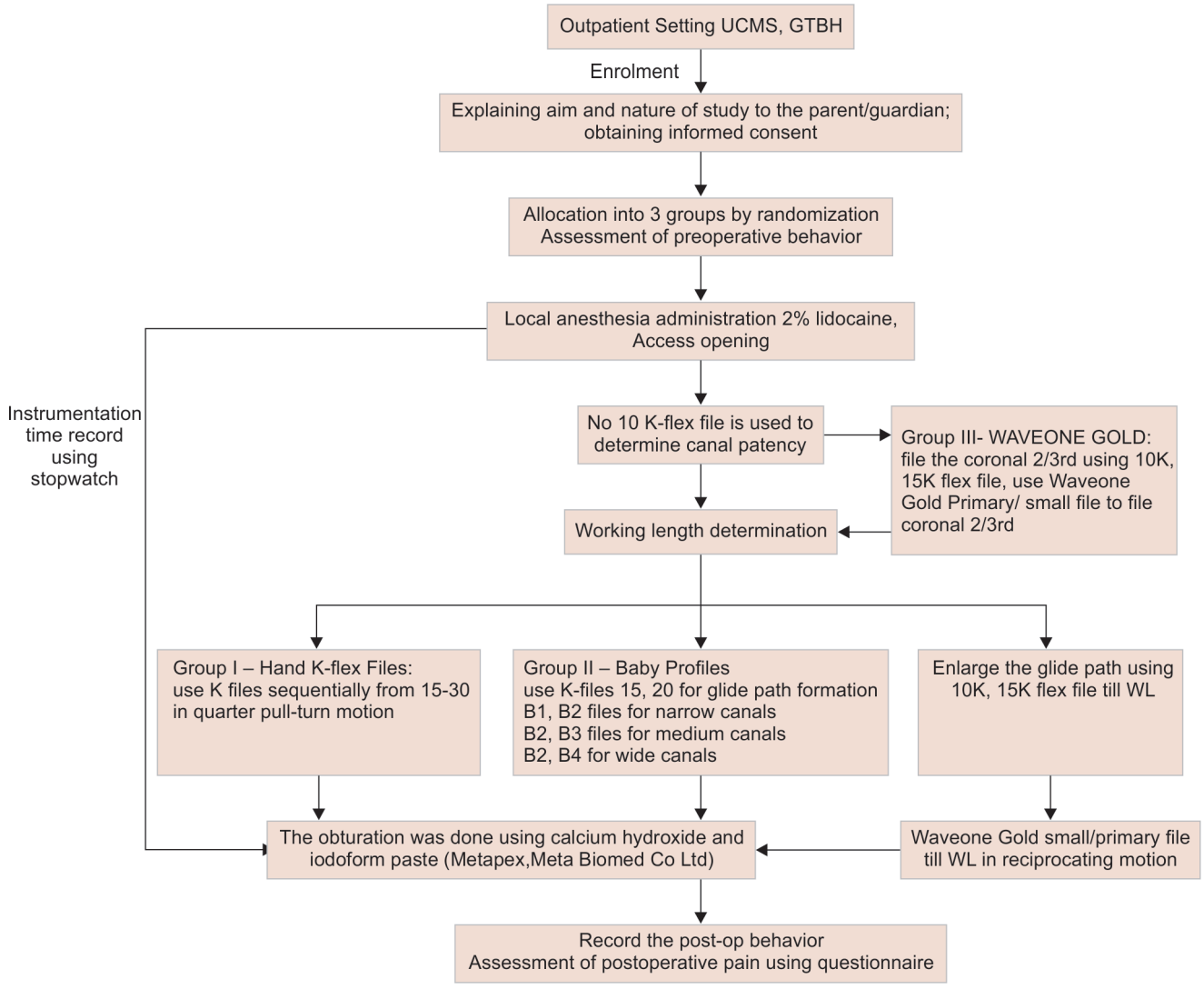

Table 3: Group-wise comparison of the segregated instrumentation time for access opening, biomechanical preparation, and obturation

Instrumentation time	*Mean ± SD (in minutes)*	*p value*[a]	*Minimum (in minutes)*	*Maximum (in minutes)*
(Access opening)				
Group I	6.4 ± 2.00	$p > 0.05$	3	10.1
Group II	6.0 ± 1.87		3.1	10.3
Group III	6.02 ± 1.91		4	11.5
Instrumentation time (BMP)				
Group I	40.02 ± 7.08	$p < 0.001$**	20.3	50.3
Group II	27.40 ± 6.27		19.7	40.3
Group III	25.26 ± 7.86		15.4	45.3
Instrumentation time (obturation)				
Group I	7.39 ± 2.4	$p < 0.05$*	2.5	13.1
Group II	6.1 ± 1.9		3.3	10.1
Group III	5.6 ± 2.00		3.2	10.0

SD, standard deviation, [a]Kruskal–Wallis non-parametric test, $p < 0.05$ Significant*, $p < 0.001$ highly significant**

Table 4: Group-wise comparison of the mean pain scores preoperatively, after 6 hours, 24 hours, 72 hours, and 1 week

Pain	*Mean ± SD*	*p value*[a]	*Minimum*	*Maximum*
Preoperative pain				
Group I	1.92 ± 0.83	$p > 0.05$	1	3
Group II	1.76 ± 0.77		1	3
Group III	1.96 ± 0.72		1	3
Postoperative pain at 6 hours				
Group I	0.88 ± 0.9	$p < 0.05$*	0	3
Group II	0.44 ± 0.71		0	3
Group III	0.31 ± 0.61		0	2
Postoperative pain at 24 hours				
Group I	0.29 ± 0.69	$p > 0.05$	0	2
Group II	0.12 ± 0.44		0	2
Group III	0.12 ± 0.43		0	2
Postoperative pain at 72 hours				
Group I	0		0	0
Group II				
Group III				
Postoperative pain at 1 week				
Group I	0		0	0
Group II				
Group III				

SD, standard deviation
[a]Kruskal–Wallis non-parametric test, $p < 0.05$, significant*

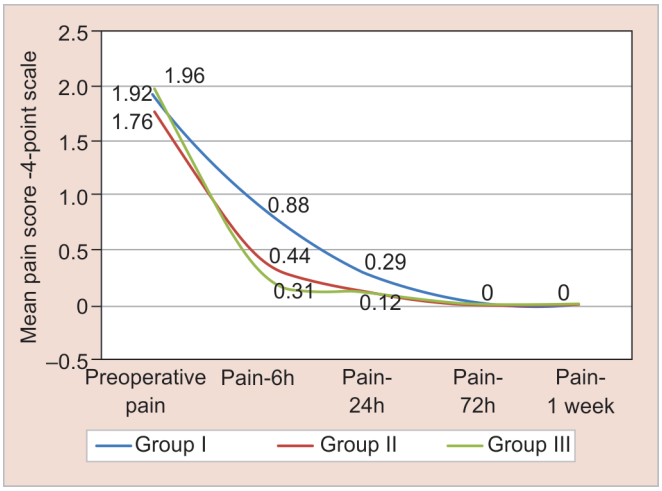

Fig. 2: Group-wise comparison of the mean pain scores preoperatively, after 6 hours, 24 hours, 72 hours, and 1 week

($p < 0.05$*). The mean postoperative pain after 24 hours, 72 hours, and 1 week showed no statistically significant difference among all the three groups (Table 4 and Fig. 2).

The preoperative and postoperative behavioral comparison revealed no statistically significant difference among the three groups (p value > 0.05) (Fig. 3).

Discussion

The study intended to compare the instrumentation time of the hand and rotary systems (pediatric, reciprocating) in primary molar teeth. A statistically significant reduction was found in the time required for biomechanical preparation for both rotary systems. These findings are consistent with a study by Panchal et al.,[20] which compared K-files, H-files, and rotary Kedo-S files.

A study by Morankar et al.[21] compared instrumentation time between hand files (SS K-files) and Hyflex rotary files and found a significant reduction in instrumentation time using rotary files in primary molar teeth.

Other studies which support the above-mentioned findings include Crespo et al.,[6] Govindaraju et al.,[22] and Makarem et al.[23] Rotary systems are efficient for cleaning and shaping with better debris and tissue removal and less chairside time.[24]

On the contrary, Katge et al.[25] reveal more instrumentation time using rotary Mtwo files *vs* hand H-files in an *in vitro* study on primary molars. Similar findings by Madan et al. attributed the increased time to the experience of the operator.[26]

The study also reveals a statistically significant reduction in the time taken for obturation for both rotary groups, i.e., pediatric and reciprocating file systems. This was consistent as per the study by Babaji et al.[24] where the mean obturation time of rotary files

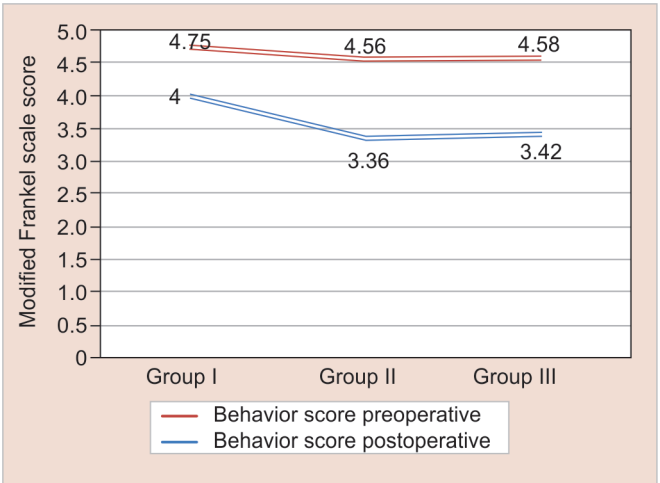

Fig. 3: Group-wise comparison of the mean pre- and postoperative behavior rating scores

(1.4 minutes) was found to be less than hand-files (2.6 minutes). A significant time reduction was seen for obturation of mandibular molars vs maxillary molars. The reduced time may be attributed to the funnel-shaped canal preparations to help smooth, uniform quality of obturation.[27]

Although the relative time required for instrumentation for both rotary groups was less compared to the hand file group, the reciprocating file system (group III) took the least time for biomechanical preparation and the obturation among the three groups. The variations between the two rotary systems were not statistically significant.

The values of time taken in the present study were found to be overall higher than previous studies Morankar et al.[21] and Panchal et al.[20] which may be attributed to less clinical experience of the operator in the present study.

The study also examines the effect of the three groups on postoperative pain. Lower levels of postoperative pain (6 hours) is seen for both rotary groups *vs* hand file group, whereas no significant difference was found for pain (12 hours, 24 hours, 72 hours, and 1 week). This is seen to be on the lines of a study done by Topçuoğlu et al.[15] where the intensity of pain experienced by the manual group was higher than rotary Revo-S files 6 hours, 12 hours, 24 hours, and 48 hours with no significant differences at 72 hours and 1 week.

Another study by Kashefinejad et al.[17] showed rotary instruments led to less postoperative pain and there was a reduced requirement of analgesics in the rotary (13.3%) *vs* hand group (56.7%). Apical extrusion of the debris may be responsible for increased postoperative pain and increased resorption rates in the manual group. The preflaring and crown down technique used with various rotary systems may be the reason for less postoperative pain.[28]

The values of postoperative pain (6 hours) were found to be higher in all three groups. This is in unison with a study by Topçuoğlu et al.[15] where the reason was attributed to the time required for the effect of anesthesia to dissipate.

Factors like sex, age, the status of pulpal and periradicular tissues, and clinical technique may influence postoperative pain.[29] The postoperative pain is also found to have a direct relation to preoperative pain.[30] To minimize the role of the confounding factors, the randomization ensured no significant variation of preoperative pain, age, and sex among the three groups. All procedures were performed by a single operator to ensure technique standardization and a single evaluator explained the questionnaire and recorded the time values.

Finn states a positive correlation between the short appointment duration with cooperative behavior of the child in the dental clinic.[31] Rotary files due to their short instrumentation time may influence behavior positively.[22] However, a study by Morankar et al.[21] showed greater patient acceptability by the manual group (83.3%) than the rotary group (66.7%) which was attributed to the fear of the rotary handpiece and increased visibility of the files to the patient. A study by Krishna et al. comparing H files with Mtwo rotary files showed that 66.7% of children preferred H-files which was attributed to the air-rotor-like appearance of the motor which may provoke fear/anxiety.[32] The operator's comfort was more for the Mtwo file group, though not statistically significant possibly due to less fatigue and improved cutting efficacy of the rotary files.[33]

In the present study, no statistically significant variations were observed in the child's behavior among the three groups. The author attributed this to the initial non-pharmacological strategies used with each child to ensure patient comfort before starting the procedure. Due to the variation of findings in different studies, this aspect should be focused upon in the years to come.

Conclusion

The study aimed to evaluate and compare the effect of hand, pediatric, and reciprocating file systems on instrumentation time, postoperative pain, and child behavior. The overall performance of the rotary groups was found to be better than the hand file group.

- There is shorter instrumentation and obturation time for rotary (both pediatric and reciprocating) over manual files.
- The study also shows lower postoperative pain (6 hours) for rotary files vs manual files, whereas the pain values at 24 hours, 72 hours, and 1 week showed no significant intergroup variations.
- No significant differences in the child's behavior among the three groups.

A limitation to the present study could be the lack of a cross-over type study design where all three groups could be compared in a single child, which could not be done due to its impending sensitivity in sample selection.

The future scope of the studies could be analysis of segregated instrumentation time along with an inter-arch comparison of the same, the effect on the child' behavior could also be evaluated by the child's preference/feedback form in place of the operator's perception of the same and operator's experience could also be taken into account.

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