

Comparative Evaluation of Instrumentation Time and Quality of Obturation between Different File Systems in Primary Molars: A Randomised Clinical Trial

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ABSTRACT

Introduction: Pulpectomy has been a treatment of choice in all necrotic primary teeth. With the advancement of technology, the rotary system is developed to reduce skill and enhance the quality of pulpectomy therapy. In paediatric dentistry, new technologies should be leveraged to improve treatment protocols.

Aim: To evaluate and compare the instrumentation time and quality of obturation between the different file systems {Hyflex Controlled Memory (CM), Flexicon X7 and Hedstrom files} in primary molars.

Materials and Methods: In the present randomised clinical trial, a total number of 60 primary molars were selected from healthy children of both sexes from 5-9 years of age attending Department of Paedodontics and Preventive Dentistry at KD Dental College and Hospital, Mathura, Uttar Pradesh during the study period from January 2017 to March 2018. The samples were divided into three groups. Instrumentation was done by using Hedstrom files (H-files) in group 1; Flexicon X7 in group 2;

Hyflex CM in group 3; and instrumentation time was recorded in seconds. The quality of obturation was categorised as underfill, optimal fill, and overfill. Statistical analysis was done by using the Chi-square test, Analysis of Variance (ANOVA), and Post-hoc Tukey test with significance level at $p < 0.05$.

Results: Total 60 healthy children were included in the present study. Of which, 26 were females and 34 were males. Each group consisted of 20 participants each. No significant difference was found with regard to the quality of obturation between the three groups ($p = 0.519$). Flexicon X7 had significantly lesser instrumentation time when compared to that of Hyflex CM and H-file ($p < 0.001$).

Conclusion: The application of the rotary file system in the primary molar significantly reduces the instrumentation time although there was no significant difference noted in the quality of obturation between the different file systems.

Keywords: Manual instrumentation, Paediatric endodontics, Pulpectomy, Rotary instrumentation

INTRODUCTION

In primary dentition, pulp therapy is done to retain the tooth in the dental arch [1]. Premature loss of primary teeth due to dental caries and root canal infection has a negative impact on the formation of the facial skeletal complex, especially in terms of the dental complex's full development, occlusion, aesthetic aspects, and soft tissue support [2].

Endodontic therapy involves the cleaning and contouring of the root canal system. The principle behind cleaning and contouring of the root canals is to eliminate debris as it contains bacteria, hence preparing the canal to receive irrigants and medicament with subsequent obturation material in the radicular canal space [3]. Cleaning and shaping have traditionally been performed with stainless steel hand files. Manual instrumentation for cleaning root canals can be done by Kerr-files (K-files) and H-files. H-files are highly recommended for paediatric use since they remove hard tissue only on withdrawal and penetrate readily with a minimum of resistance, which prevents pushing of the infected material through the apices [4]. The usage of these files has been related to root canal morphology with undesired curvatures that make effective canal filling difficult. [5].

Recent advancement observed in the field of paediatric endodontic, that includes the diagnostic procedures, improvement in instrumentation and obturation techniques. Barr ES et al., were the first to demonstrate that mechanically cleaning of primary teeth using NiTi rotary files were cost-effective, quicker, and resulted in dependably uniform fillings [6]. Kuo C et al., described that canal preparation for extracted teeth using NiTi rotary file was easier than hand preparation [7]. Azar MR et al., showed that the NiTi rotary system simplified root canal preparation

in primary teeth and reduced the operating time [8]. Morankar R et al., also confirmed that rotary instrumentation saves time over manual instrumentation, and that there was no difference in obturation time, quality, or success rates after 24 months [9]. Recently, introduced newer file systems are Hyflex CM and Flexicon X7.

In the year 2011, Ricardo C and Clark SJ, introduced Hyflex CM rotary instruments (Coltene/Whaledent Inc; USA). It is a new wire called controlled memory wire which has been prepared from the thermomechanical processing. It has been reported that the shape and strength of files with straightened spirals can be restored during autoclaving [10].

Another rotary file system introduced in 2015 is Flexicon X7 (Edgeendo, Canada) which is made of an annealed heat treated of nickel-titanium alloy. These files may be slightly curved and can be easily straightened with the fingers. All files are found to be with a constant taper [11].

An investigation of the instrumentation time and quality of obturation between H-file, Flexicon X7, Hyflex CM file systems has not yet been compared in primary teeth, thereby creating paucity in the literature. Thus the current research aimed to compare and assess the quality of obturation and instrumentation time between H-file, Hyflex CM, Flexicon X7 file systems in primary molar teeth.

MATERIALS AND METHODS

A randomised clinical trial was carried out in the Department of Paedodontics and Preventive Dentistry at KD Dental College and Hospital, Mathura, India following the approval from the Institutional Ethics Committee between January 2017 to March 2018. The

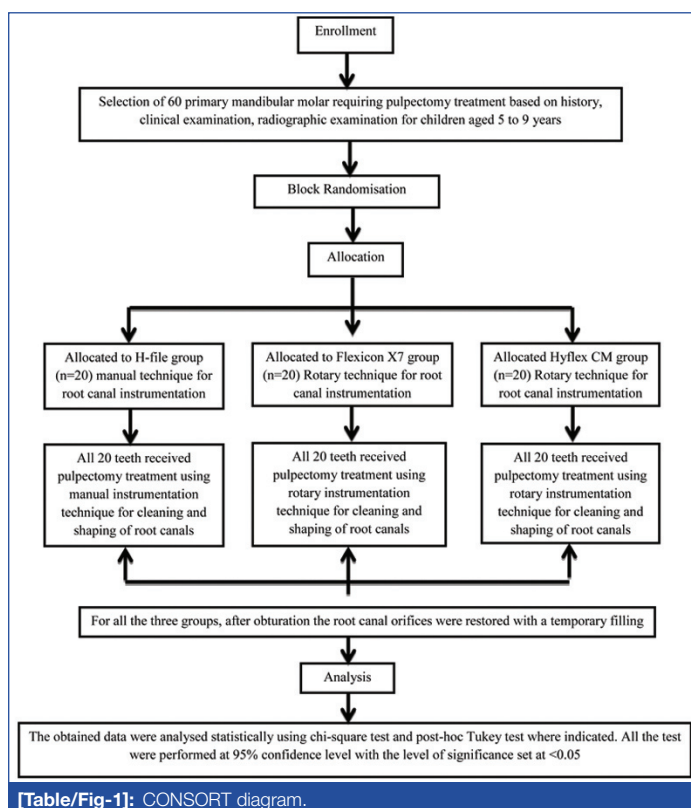
informed consent was obtained from the parent or the caretaker by providing them with the detailed written procedure that was duly signed by them thereby permitting the participation of their children.

Sample size calculation: G Power analysis was used to calculate the sample size from a previous study with 95% power [2]. A total of 60 healthy children (26 girls and 34 males) aged 5-9 years age who needed pulpectomy in either of their primary mandibular molars were randomly assigned to three treatment groups using a computer-generated sequence employing the block randomisation technique. Block randomisation assures that each participant has an equal chance of being chosen without any allocation bias, and that the sample remains evenly distributed at all times.

Inclusion criteria: The inclusion criteria included, Frankel's behaviour rating scale of definitely positive and positive children, primary teeth with clinical and radiographical evidence of chronic irreversible pulpitis, pulp necrosis or periapical abscess, atleast 2/3rd of root remaining, sufficient tooth structure to support rubber dam placement.

Exclusion criteria: The exclusion criteria included Frankel's behaviour rating scale of definitely negative and negative children, teeth with root resorption more than 1/3rd of the actual root length, non restorable tooth, perforated pulpal floor, excessive mobility, limited mouth opening and children with special healthcare needs.

In the present study, a total number of 60 healthy children (26 females and 34 males) aged from 5-9 years of age were selected. A total number of 60 primary mandibular first and second molars were selected for the study. The brief medical and dental history of the patient was taken on the first visit. Prior to the start of the clinical procedure, an intraoral radiograph of the teeth indicated for pulpectomy was taken. The CONSORT diagram depicting the flowchart of the study is given in [Table/Fig-1].



[Table/Fig-1]: CONSORT diagram.

Study Procedure

Clinical procedures were done by a single operator using the single blinded method. After obtaining the diagnosis, local anaesthesia was administered using 2% lignocaine with 1:80,000 adrenaline (LIGNOX 2% AD). A rubber dam (Hygenic® Dental Dam Kits) was used to isolate the tooth that required pulpectomy. To eliminate superficial caries and roof the pulp chamber, a round carbide bur was employed in a high-speed handpiece. A spoon excavator was

used to remove the coronary pulp. Canals were accessed using a number 10K size file (Mani Inc. Japan). On a radiograph, the working length was established and kept 1 mm short of the apex. The pulp chamber was copiously irrigated with 2.5% sodium hypochlorite and normal saline alternatively; followed by biomechanical preparation. The study population was then divided into three different groups having 20 teeth in each group according to the randomisation technique for pulpectomy procedure in a primary molar.

Group 1: H-files (Mani) from size 15 to size 30 in the pull motion method.

Group 2: Flexicon X7 file system. The sequence of instrumentation was as follows: (1) 4% taper, #20; (2) 4% taper, #25; and (3) 4% taper, #30 in light pull and push motion till the working length using CanalPro2™ Endomotor (Coltène AG, CHE) at 350 rpm and slow torque.

Group 3: Hyflex CM file System. The sequence of Hyflex CM instrumentation was as follows: (1) 4% taper, #20; (2) 4% taper, #25; and (3) 4% taper, #30 in light pull and push motion till the working length using CanalPro2™ Endomotor (Coltène AG, CHE) at 350 rpm and slow torque.

The time taken for the instrumentation of the canals were recorded in seconds from the onset of filing to its termination (after using #10 K-file) by using a stopwatch by an assistant. After the use of each file, the root canals were irrigated with 2.5% sodium hypochlorite and normal saline alternatively. The canals were dried with paper points after final irrigation and filled with calcium hydroxide and iodoform paste (Metapex, META Biomed Co, PA, USA) by gently pushing the paste with cotton pellets in all three groups. The root canal orifices were restored with a temporary restorative material. The postobturation intraoral periapical radiographs of the mandibular primary molars were taken by using the paralleling technique to assess the quality of obturation and the operator evaluated the quality of obturation.

The obturation quality was assessed as underfill, optimal fill and overfill [Table/Fig-2] [12]. The patient was recalled after one week and checked for any postoperative pain. In case of the absence of any type of pain or discomfort, the access cavity was restored with glass ionomer cement (GC Corporation, Tokyo, Japan) followed by cementation of Stainless Steel crowns.

Obturation grading	Criteria
Underfilling	All the canals were filled more than 2 mm short of the apex
Optimal filling	One or more of the canals having Metapex ending at the radiographic apex or upto 2 mm short of the apex
Overfilling	Any canal showing Metapex outside the root

[Table/Fig-2]: Showing obturation grading criteria.

STATISTICAL ANALYSIS

After completing the clinical trial, the obtained data were subjected to statistical analysis by using Statistical Package for the Social Sciences (SPSS) software version 16.0 (SPSS INC., CHICAGO, IL, USA). The instrumentation time was compared using an ANOVA and a Post-hoc Tukey test. To assess the quality of obturation between the groups, a Chi-square test was used. All tests were done at a 95% confidence level, and level of significance considered was $p < 0.05$.

RESULTS

In the present study, a total number of 60 healthy children (26 females and 34 males) participated. The distribution of the demographic details of the participants is tabulated [Table/Fig-3]. Of 60 treated primary mandibular molars having 20 teeth in each group, in group 1 (H-files) eight teeth were D and 12 teeth were E, (D- First molar, E-Second molar) group 2 (Flexicon X7) nine teeth were D and 11 teeth were E, group 3 (Hyflex CM) five teeth were D and 15 teeth were E.

Groups	N	Mean age±SD (years)	Male n (%)	Female n (%)
H-file	20	6.60±1.314	12 (60%)	8 (40%)
Flexicon X7	20	6.80±1.508	12 (60%)	8 (40%)
Hyflex CM	20	6.95±1.504	10 (50.0%)	10 (50.0%)
Total	60	6.78±1.427	34 (56.7%)	26 (43.3%)

[Table/Fig-3]: Demographic variables of the participants in each group. SD=Standard deviation, N=Sample size

Using ANOVA and Chi-square test, an intergroup comparison was made in terms of age and gender. There was no statistically significant difference between the groups in terms of age ($p=0.745$) and gender ($p=0.847$). Regarding the quality of obturation among the three groups, a total of 20 mesial canals and 20 distal canals were evaluated in each group. In the intergroup analysis, no statistically significant difference was observed in mesial ($p=0.993$) and distal canals ($p=0.651$) between the three groups [Table/Fig-4]. In the mesial canal (intergroup analysis), for group 1 (H-files): 12 (60%) of the mesial canals were optimally filled; 5 (25%) and 3 (15%) were underfilled and overfilled, respectively. For group 2 (Flexicon X7): 13 (65%) of the mesial canals were optimally filled; 4 (20%) and 3 (15%) were underfilled and overfilled, respectively. For group 3 (Hyflex CM): 11 (55%) of the mesial canals were optimally filled; 6 (30%) were underfilled and 3 (15%) was overfilled. In the distal canals, for group 1 (H-files), 9 (45%) of the distal canals were optimally filled, 7 (35%) were underfilled, and 4 (20%) were overfilled. In Group 2 (Flexicon X7): 11 (55%) of the distal canals were optimally filled; 6 (30%) and 3 (15%) were underfilled and overfilled, respectively. In Group 3 (Hyflex CM): 14 (70%) of the distal canals were optimally filled; 4 (20%) were underfilled, and 2 (10%) were overfilled.

Canals	Overall p-value
Mesial canal	0.993
Distal canal	0.651

[Table/Fig-4]: Intergroup analysis of quality of obturation. Pearson Chi-square test

In the intragroup analysis, there was no significant difference in the teeth instrumented with H-file ($p=0.655$), Flexicon X7 ($p=0.088$), and Hyflex CM ($p=0.232$) [Table/Fig-5]. The intergroup comparison of quality of complete obturation showed no statistically significant differences ($p=0.519$) [Table/Fig-6].

Groups	Overall p-value
H-file	0.655
Flexicon X7	0.088
Hyflex CM	0.232

[Table/Fig-5]: Quality of obturation between mesial and distal canals- Intragroup analysis. Pearson Chi-square test

Groups	(Mesial canal+ Distal canal) N	Optimally filled	Underfilled	Overfilled	p-value*
H-file	20+20	52.5%	30.0%	17.5%	0.519
Flexicon X7	20+20	60%	25.0%	15.0%	
Hyflex CM	20+20	62.5%	25.0%	12.5%	

[Table/Fig-6]: Comparison of quality of obturation between all the three groups. Pearson Chi-square test

The instrumentation time of primary molars with Flexicon X7 system (137.75 seconds) was significantly lesser as compared to the Hyflex CM (168.30 seconds) and manual instrumentation (284.75 seconds) and a statistically significant difference ($p<0.001$) was noted between the three groups [Table/Fig-7]. The post-hoc Tukey analysis showed that all three groups had a significant difference in instrumentation time (p -value <0.001) [Table/Fig-8].

Instrumentation Time (in seconds)	N	Mean	Standard Deviation	F	Overall p-value
H- file	20	284.75	5.562	7.658E3	$<0.001^*$
Flexicon X7	20	137.75	3.160		
Hyflex CM	20	168.30	2.494		

[Table/Fig-7]: Comparison of instrumentation time among three groups. Pearson Chi-square test Overall p-value is significant ($p<0.05$)

Group (I)	Group (J)	Mean difference (I-J)	Standard error	p-value
H-file	Flexicon X7	147.000	1.254	<0.001
	Hyflex CM	116.450	1.254	<0.001
Flexicon-X7	H-file	-147.000	1.254	<0.001
	Hyflex CM	-30.550	1.254	<0.001
Hyflex-CM	H- file	116.450	1.254	<0.001
	Flexicon X7	30.550	1.254	<0.001

[Table/Fig-8]: Intergroup comparison of instrumentation time among the groups. one-way ANOVA, p-value <0.05 considered significant

DISCUSSION

The treatment objective of pulpectomy is to maintain the tooth free of infection contamination, biomechanically cleanse and obturate the basis canals, promote physiologic root resorption [13]. In recent years, many Nickel-Titanium (NiTi) rotary instruments of different designs are available. It has been reported in various studies that NiTi rotary files can create smooth, funnel shaped canals with minimal risk of transportation and ledging although, many studies have been done to compare different rotary instrumentation systems with manual instrumentation in primary teeth, but no in-vivo study has been done to compare Hyflex CM, Flexicon X7, and hand file [14-19].

The present investigation is notable in that it compares three file systems in primary teeth: the Hyflex CM, Flexicon X7, H-files. Each file system has its own file design and is easily accessible and inexpensive. It was observed that Hyflex CM and Flexicon X7 rotary files had lesser instrumentation time than H-files. The reduction in the instrumentation time significantly reduces the chairside time and removes the necrotic debris more easily and efficiently. These findings were in concurrence with Romero TO et al., Vieyra JP and Enriquez FJJ, Makarem A et al., Panchal V et al., Girish Babu KL and Kavyashree GH, and Priyadarshini P et al., who suggested that there was an evident reduction in instrumentation time with different rotary systems as compared to manual instrumentation [2,16,20-23]. Romero TO et al., Kuo C et al., and Morankar R et al., showed longer rotary instrumentation time than the present study [2,7,9]. On the contrary, Katge F et al., carried out in-vitro study and reported that the instrumentation time recorded for H-files was significantly less than that of Mtwo rotary files but no significant difference was seen in cleaning efficacy between H-files and Mtwo files [24]. Madan N et al., also carried out an in-vitro study demonstrated an increased instrumentation time in primary teeth on comparing ProFiles and K-files [25]. Tabulation and comparison of instrumentation time as shown in [Table/Fig-9] [2,7,9,16,20-25].

One of the most important factors in determining the success of pulpectomy is the obturation quality. Radiographs, digital radiography such as Cone Beam Computed Tomography (CBCT), radiovisiography, dye penetration, bacterial leakage are some of the other methods which can be used to assess this. There was no significant difference in the quality of obturation between the three groups in this study. Morankar R et al., and Govindaraju L et al., also reported a similar result with respect to the quality of obturation [9,26]. Whereas, Romero TO et al., Makarem A et al., Panchal V et al., and Girish Babu KL and Kavyashree GH, showed a statistically significant difference in the quality of obturation [2,20-22]. The

S. No.	Author's name and year	Place of study	Number of subjects	File systems compared	Parameters compared	Conclusion
1	Kuo C et al., (2006) [7]	Taiwan	51 primary molars in 22 children	Protaper® NiTi Rotary Files, SX (19 mm) and S2 (21 mm)	Instrumentation time	4~5 minutes.
2	Romero TO et al., (2011) [2]	Mexico	20 experimental groups (K3 rotary NiTi) 20 control group (K-Files)	K3 Rotary NiTi instrument System and Stainless Steel K-Files	Instrumentation time, obturation time, and quality of the root canal filling	K3 Rotary NiTi-11.9±4.6 minutes Stainless Steel K-files 18.8±6.6 minutes
3	Madan N et al., (2011) [25]	Belgaum	75 primary molar root canals	Manual K-Files and rotary profiles	Cleaning capacity and instrumentation time	In maxillary teeth, Pro-files- 4.97 minutes K-files 3.61 minutes In the mandibular teeth Pro files- 4.30 minutes K-files- 3.52 minutes
4	Vieyra JP and Enriquez FJJ, (2014) [16]	Mexico	45 teeth (N=15 for each group)	K-Files, H Rotary light speed LightSpeed@LSX™ instruments, Pro-Taper file	Instrumentation time	K-files-20.10±7.86, H Rotary light speed LSX Instrument-: 9.37±2.19 minutes Pro Taper file-10.45±4.77 minutes,
5	Makarem A et al., (2014) [20]	Iran	46 children	Hedestrom Files, the Rotary FM system	Instrumentation time	Hedestrom files-18.73±3.15 minutes, Rotary FM system-10.1±1.71 minutes
6	Katge F et al., (2016) [24]	Maharashtra	90 primary root canals (30 root canals for each group)	H-Files, M two files, control group	Cleaning efficacy and instrumentation time	H-files-3.41±0.38 minutes Mt two files-4.81±0.52
7	Morankar R et al., (2018) [9]	Chandigarh	60 decayed primary mandibular second molars	Hyflex CM NiTi Rotary files and Stainless Steel K-files	Instrumentation time and obturation time	Stainless steel K-files-25.71±3.8 Hyflex CM Rotary-19.37±4.94
8	Panchal V et al., (2019) [21]	Chennai	75 teeth (25 teeth for each group)	Hand K-file, Hand H-file, Kedo-S Rotary files	Instrumentation time and quality of obturation	K-file-12.8096 minutes H-file- 13.3604 minutes Kedo-S files- 9.3804 minutes
9	Priyadarshini P et al., (2020) [23]	Chennai	60 primary mandibular molars (N=15 for each group)	Hand- K-Files Kedo- S Rotary files Kedo- SH Hand files Kedo- SG Blue Rotary files	Instrumentation time and quality of obturation	Hand K-files- 6.2167±0.30978 minutes Kedo-SG Blu -2.7840±0.34217 minutes Kedo-S- 3.4827±0.48657 minutes, Kedo-SH manual Files- 5.8800±0.48345 minutes
10	Girish Babu KL and Kavyashree GH, (2021) [22]	Hassan	150 primary molars (50 teeth for each group)	Kedo-S Paediatric rotary files, HERO Shaper rotary files, and manual NiTi K-files	Instrumentation time and quality of obturation	Kedo-S Rotary File-14.56±2.89 minutes, HERO Shaper Rotary File-17.93±3.51 minutes, Manual NiTi K-files- 29.00±2.08
11.	Present study	Uttar Pradesh	60 primary molars	H-files in group 1; Flexicon X7 in group 2; Hyflex CM in group 3	Instrumentation time and quality of obturation	The application of the rotary file system in the primary molar significantly reduces the instrumentation time although there was no significant difference noted in the quality of obturation between the different file systems

[Table/Fig-9]: Comparative evaluation of instrumentation time [2,7,9,16,20-25].

authors concluded that the rotary instrumentation techniques in primary teeth prepare conical canal which results in a better quality of obturation as compared to manual techniques. The findings of this study highlight the need for more clinical studies with a larger sample size and longer follow-up.

Limitation(s)

The two-dimensional evaluation of quality of obturation of the three dimensional tooth can be one of the limitation of the present study. Proper removal of necrotic pulp tissue by various techniques like newer file system, irrigating solutions, obturation techniques and materials are the confounders in limitations.

CONCLUSION(S)

This study indicates that the use of new NiTi rotary files systems needed much less time for instrumentation of primary molar root canals than manual instrumentation. The quality of obturation was not affected by using the manual or rotary approaches. As a result, in primary teeth, rotary instrumentation can be a viable alternative to manual instrumentation. The findings of this study highlights the need for more clinical studies with a larger sample size and longer follow-up utilising various instrumentation techniques to assess the clinical and radiographic success of pulpectomy.

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