Comparison of Quality of Obturation, Instrumentation Time and Post Operative Pain in the Primary Mandibular Molar Teeth using Three Different Manual Instrumentation system - a Randomized Clinical Trial

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Abstract

The aim of the study was to compare the quality of obturation, instrumentation time and post operative pain in the primary mandibular molar teeth using three different manual instrumentation systems.

Forty five primary mandibular molars were randomly divided into three experimental groups each containing fifteen teeth. Group A was instrumented using K- files, Group B was instrumented using Kedo- SH and Group C was instrumented using hand ProTaper files. Intra oral periapical radiograph was taken before instrumentation and after obturation. Instrumentation timing was recorded. Post operative pain was assessed after 6,12, 24, 48,72 hours post operatively. Statistical analysis was done using SPSS software version 17.0. An intergroup comparison was made using ANOVA and Chi-square test with 0.05 significance level.

There is no statistically significant difference in the quality of obturation and post operative pain between the ProTaper hand files and Kedo-SH. Kedo-SH had decreased instrumentation time when compared to the hand ProTaper files and K files. Kedo-SH and ProTaper files produced lesser postoperative pain when compared to Kfiles(p<0.005).

Kedo-SH and hand ProTaper files produced similar obturation quality and post operative pain while instrumentation time was lesser with Kedo-SH which makes it superior than the other files

Experimental article (J Int Dent Med Res 2023; 16(4): 1462-1468) Keywords: Obturation quality, instrumentation time, Post operative pain, Pulpectomy, Primary teeth.

Received date: 19 September 2023

Accept date: 21 October 2023

Introduction

Primary teeth are important for the normal development of jaw bone and the surrounding musculature. They are the best space maintainer

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Ganesh Jeevanandan, MDS, PhD* Associate professor Department of Pediatric and Preventive Dentistry Saveetha Dental College and Hospitals Saveetha Institute of Medical and Technical Sciences Saveetha University. Chennai-77 E-mail: helloganz@gmail.com for the successor permanent teeth¹. Premature loss of primary tooth can lead to space discrepancy, aberrant habits development and can also leads to altered phonation^{2,3}. Endodontic treatment of the symptomatically affected teeth is the treatment of choice to preserve the primary teeth⁴. The success of the endodontic treatment is effected by the thorough chemomechanical preparation of the root canals⁵.

The primary goal of the root canal instrumentation is to remove the necrotic pulp tissue, organic debris and to shape the root canal to facilitate root canal irrigation and placement of obturating material⁶. There are different file systems available for these purposes which

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include both hand files and rotary files. K-files are the conventional instrumentation system for biomechanical preparation. The two characteristic features of Nickel Titanium alloys are its shape memory and superelasticity. NiTi files are more elastic, flexible, durable and are fracture resistant than the stainless steel files^{7,8}. The main advantage of using rotary files is the reduction in the working time and increased efficacy in the chemomechanical preparation. Despite its advantages, the frequency of its usage is low because of its increased cost, frequent instrument separation inside the canal lack of adequate knowledge in using the rotary files^{9,10}

Α short term complication of the pulpectomy procedure is the post operative pain which occurs within a few hours to days after the endodontic procedure¹¹ Acute inflammatory response of the peri radicular tissues is one of the causes for the post operative pain. This occurs due to physical, chemical or microbial injury to the peri radicular tissues ^{12,13}. Post operative pain following pulpectomy is an undesirable and unpleasant experience for both the clinicians and the patients¹⁴.

Endodontic treatment in primary teeth is challenging due to the tortuous course of the root canals⁴. The NiTi hand files have the advantage of producing more appropriate canal shapes¹⁵. Hand ProTaper has some advantages compared to the stainless steel files due to its convex triangular cross section, its tip design and that its helical angle and slope are variable¹⁶. Manual ProTaper files and Kedo-SH files are NiTi hand instruments which has the advantage of both hand and NiTi instrumentation.

Thus, the present in vivo randomized clinical trial was undertaken to compare the quality of obturation, the instrumentation time and post operative pain using three different manual instrumentation systems ie., K-file. hand ProTaper files and Kedo-SH files. The null hypothesis of the present study was that, there was no significant difference in the quality of obturation, instrumentation time and post operative pain using three different manual instrumentation systems.

Materials and methods

This randomised, controlled clinical trial was approved by the Institutional Review Board.

The study was carried out in the Department of Paediatric and Preventive Dentistry in a Dental College, Chennai from August 2018 to November 2018. The sample size was determined to be 45 with 15 children in each group, calculated from a previous in vivo study with 95% power using G Power analysis.

A total of 45 healthy, cooperative children aged 4–8 years visiting the Department of Paediatric and Preventive dentistry and having at least one primary mandibular molar with deep carious lesion requiring pulpectomy were included in the study after thorough clinical and radiographic evaluation.

Inclusion Criteria:

Vital or nonvital mandibular primary first and second molars without abscess and sinus tract, absence of internal or external pathologic root resorption and teeth with adequate coronal tooth structure to receive preformed metal crown. Exclusion Criteria:

Patients with underlying systemic conditions, special health-care needs and teeth with more than one third of the root resorbed were excluded from the study

The parents/guardians accompanying the participants were explained about the purpose of the study, the procedure, the possible discomfort, risks, benefits, in a language well understood by them and the written informed consent was obtained.

The participants were assigned randomly into three groups (15 children each) by block randomization, and allocation concealment was done with a closed envelope method. The groups include

Group A: K- files (Mani, Tochigi, Japan)

Group B: Kedo- SH (Kedo Dental, India)

Group C: Hand ProTaper files (Dentsply India Pvt. Ltd., Delhi, India)

Randomization, enrollment, and assignment of participants to interventions were done by a specialist pedodontist who was not involved in the study.

Clinical Procedure

All the procedures were done by a single operator. After confirmation of the diagnosis with intra oral periapical radiograph, topical anaesthesia was applied and local anaesthesia was administered using 2% lignocaine with 1:200,000 adrenaline (LOX* 2% ADRENALINE, Neon Laboratories limited, India). The procedure was carried under rubber dam isolation(GDC Marketing, India). All the instruments, and burs used were sterilised/disinfected. Using a round carbide bur in a high-speed handpiece, the superficial caries were removed. Access to the pulp chamber was gained using No. 330 high speed bur with water spray to unroof the pulp chamber. Coronal pulp amputation was done with a spoon excavator. No. 10 size K-file was used to determine the patency of the canals and the working length was determined with radiograph and was kept 1 mm short of the apex. Endodontic files were selected and the rubber stopper was adjusted to the working length. The canal preparation was done using:

Group A: K-files from size 15 to size 30 in quarter pull turn method.

Group B: P2 was used to extirpate the pulp. D1 was used in mesial canals, D1 and E1 was used in distal canals.

Group C: S1, S2, F1 was used in all the canals.

During the canal preparation, the instrumentation time was recorded using a stopwatch by an assistant. Irrigation was done with 2.5% sodium hypochlorite (Novodent Equipment & Materials Ltd., Bombay, India) and final irrigation was done with saline. The canals were then dried using sterile paper points. The obturation was done using calcium hydroxide and iodoform paste (Metapex, Meta Biomed Co., Ltd., Korea) by injection technique followed by gentle mechanical pressure with cotton pellets. A postoperative radiograph was taken using PSP plates to assess the quality of obturation. The obturation quality was graded as under obturation, over obturation, optimal obturation based on Coll's criteria¹⁷. The radiographs were assessed by two precalibrated examiners who were blinded to the type of instrumentation used for canal preparation.

Entrance filling was done with glass ionomer cement (Shofu, Shofuinc. Japan) and the teeth were restored with stainless steel crowns (3M ESPE, Germany) in the next appointment after a week.

Post- operative pain was assessed using a four-point pain intensity scale. The four pain categories were: zero-no pain, one-slight pain, two-moderate pain, three-severe pain. A questionnaire with a four point intensity scale was given to each parent and all the participants and their parents were trained to use the painintensity scale. Same parent was instructed to note the pain level and fill the questionnaire in

the time intervals to ensure standardisation. The findings were recorded by the parents and by the operator over telephone conversation after 6, 12, 24, 48 and 72 hours.

The statistical analysis was done using SPSS software version 17.0. (Chicago, SPSS Inc). Chisquare test was used for inter- and intra-group analysis of quality of obturation. ANOVA and post hoc Tukey test were used to compare the instrumentation time.

Statistical Analysis

The statistical analysis was done using SPSS software version 17.0 (SPSS Inc., Chicago, IL, USA). The mean values of the study groups were compared using ANOVA and Chi-square test. ANOVA test was used to compare the instrumentation time between the groups followed by Tukey post-hoc analysis was done to list out the significant groups with a significance set at 5% level. Pearson's Chi-square test was used to compare the quality of obturation between the groups. Chi-square test was used for comparison of postoperative pain. In the current study, p<0.05 was considered as the level of significance.

Results

A total of 45 children (25 females and 20males) participated in the study. Of 45 treated primary mandibular molars, 11(24.4%) were mandibular left primary first molar and 13 (28.8%) were mandibular right primary first molar. 10(22.2%) were mandibular left primary second molar and 11(24.4%) were mandibular right primary second molar.

An intergroup comparison was done with respect to the age, gender, and distribution of the teeth using Chi-square test. No statistically significant difference was noted between the groups with respect to the age (P = 0.708), gender (P = 0.533), and distribution of teeth (P = 0.732) indicating that there was an equal distribution of the participants and the teeth between all the three groups.

With respect to the quality of obturation among, 46.7% (n=7) of the teeth instrumented with hand files; 66.7% (n=10) of the teeth instrumented with Kedo-SH and 60% (n=9) of the teeth instrumented with hand ProTaper files showed optimal obturation. Intergroup comparison between the three groups showed no significant differences (p=0.791)

The mean instrumentation time was recorded and an intergroup comparison was done using ANOVA test. Kedo-SH had lesser instrumentation time when compared to the other two groups which was statistically significant (p<0.001). There was no difference in the instrumentation time between K-files and hand ProTaper files. Tukey post-hoc analysis Kedo-SH confirmed that had reduced instrumentation time.

	Group			
obturation quality	K- file	kedo-SH	ProTaper	P value
Optimal	7	10	9	0.626
	46.7%	66.7%	60.0%	
Over	3	2	4	1
	20.0%	13.3%	26.7%	
Under	5	3	2]
	33.3%	20.0%	13.3%	

Table 1. Comparison of quality of obturation with different groups.

	Ν	Mean	Std. Deviation	p- value
kfile	15	13.06	.652	<0.001
kedo-SH	15	9.82	.671	
ProTaper	15	12.57	.734	
Total	45	11.81	1.591	

Table 2. Comparison of instrumentation timeamong three groups.

(I) Group	(J) Group	p- value			
kfile	kedo-SH	<0.001			
	ProTaper	0.133			
kedo-SH	kfile	<0.001			
	ProTaper				
ProTaper	kfile	0.133			
	kedo-SH	<0.001			
Table 3	able 3 Intergroup comparison o				

instrumentation time.

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With respect to postoperative pain, after 6 hours, one child had severe pain, 21 children had moderate pain, 17 children had slight pain and 6 children had no pain. After 12 hours, 18 children had slight pain and 27 children had no pain. No pain was present in any of the children after 48,72 hours of follow up (Table 4-9).

	Group			
Pain after 6 hours	kfile	kedo-SH	ProTaper	Total
No pain	0	4	2	6
	0%	26.7%	13.3%	13.3%
Slight pain	4	6	7	17
	26.7%	40.0%	46.7%	37.8%
Moderate pain	10	5	6	21
	66.7%	33.3%	40.0%	46.7%
Severe pain	1	0	0	1
	6.7%	.0%	.0%	2.2%

Table 4-Frequency and percentage of postoperative pain after 6 hours.

Pain after 12 hours	Group			
	kfile	kedo-SH	ProTaper	Total
No Pain	4	12	11	27
	26.7%	80.0%	73.3%	60.0%
Slight	11	3	4	18
Pain	73.3%	20.0%	26.7%	40.0%

Table 5-Frequency and percentage of postoperative pain after 12 hours.

Pain after 24 hours	Group			
	kfile	kedo-SH	ProTaper	Total
No pain	15	15	15	45
	100.0%	100.0%	100.0%	100.0%

Table 6-Frequency and percentage of postoperative pain after 24 hours.

Pain after 48 hours	Group			
	kfile	kedo-SH	ProTaper	Total
No pain	15	15	15	45
	100.0%	100.0%	100.0%	100.0%

Table 7-Frequency and percentage of postoperative pain after 48 hours.

Pain after 72 hours	Group			
	kfile	Total		
No pain	15	15	15	45
	100.0%	100.0%	100.0%	100.0%

Table 8-Frequency and percentage of postoperative pain after 72hours.

Dependent variable	(I) Group	(J) Group	Sig.		
	K file	Kedo-SH	.016		
Pain after 6		Protaper	.101		
hours	Kedo SH	K file	.016		
		ProTaper	.712		
	Protaper	K file	.101		
		Kedo SH	.712		
	K file	Kedo-SH	.006		
Pain after		Protaper	.017		
12 hours	Kedo SH	K file	.006		
		ProTaper	.911		
	Protaper	K file	.017		
		Kedo SH	.911		
*The mean difference is significant at the 0.05 level.					

Table 9- Intergroup comparison of post operative pain using Tuckey Post Hoc analysis.

Discussion

Pulpectomy is the treatment of choice to preserve the pulpally affected tooth and to prevent the premature loss of primary tooth. The success of an endodontic treatment depends on thorough debridement of the root canal and the quality of obturation¹⁸. There are studies

available in the literature which have evaluated the quality of obturation and instrumentation time comparing hand files with rotary files^{19,20}. Also there are studies available in the literature comparing the post operative pain following instrumentation with hand files and rotary files^{21,22}. There are no studies evaluating post operative pain using three different manual instrumentation system. The present study is the first study to compare three different manual instrumentation system in the primary teeth.

Ni-Ti instruments are efficient in preparing the root canals due to their flexibility and elasticity. Disadvantages of using rotary files include increased cost, lack of knowledge in using rotary instruments and instrument breakage inside the root canal⁹. Nagaratna et al reported that rotary instruments have an increased risk of instrument separation inside the canal¹⁰. Hence this study was carried out to compare the conventional K file with that of two different NiTi hand instrumentation systems.

In the present study there is no statistically significant difference in the quality of obturation between the ProTaper hand files and Kedo-S. But there is a statistically significant difference in the quality of obturation produced by the K files and the other two groups. Kedo-SH had decreased instrumentation time when compared to the hand ProTaper files and K files. This could be because of the decreased file length and reduction in the number of file sequences used.

Single visit pulpectomy produces less post operative pain when compared to the multiple visits pulpectomy²³. Therefore, in the present study pulpectomy was done in single visit. Stainless steel crown was delivered in the next visit as it can be a confounding factor to eliminate pain of gingival origin.

The present study was done on primary mandibular molar teeth with asymptomatic pulp necrosis to eliminate variable like tooth type, pre operative pain, pre operative conditions of the pulp. This was done to ensure standardization²¹. All the procedure was done by a single operator and a standardized pain measurement scale was used^{21,24,25}.

The etiology of postoperative pain is multifactorial and one of the important reasons is the extrusion of apical debris²⁶. It usually depends on the interaction of the host response, infection and physical damage²⁷. For a successful endodontic treatment, it is important

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to minimize the extrusion of apical debris during canal instrumentation. The apical extrusion depends on the root canal morphology, instrument type and size, working length, type and amount of irrigant used, type and technique of instrumentation²⁸.

Apical extrusion of debris occurs more easily in primary teeth due to physiologic root resorption. In the present study, k-files produced more post operative pain than the hand ProTaper files and Kedo-SH files. K- files are instrumented in filing motion which tends to push the debris apically and also it has a taper of 0.02 which creates less space for the debris to get flushed coronally²⁹. Kedo-SH and ProTaper files are used with crown-down technique, which is known to cause lesser apical debris extrusion³⁰.

In the present study, the post operative pain was maximum during the first 6 hours after the procedure and the pain decreased with time. These results are consistent with the other studies evaluating postoperative pain^{14,21,31}. The disadvantage of the study was that the evaluation of pain is subjective and that the pain threshold of each individual varies from one another.

The limitation of the present study is that the quality of obturation is evaluated only two dimensionally using intra oral periapical radiographs. Long term follow up is required to assess the clinical and radiographic success of the treatment with different instrumentation systems.

Conclusions

Within the limitations of the present study, it can be concluded that Kedo-SH and hand ProTaper files produced better obturation. Kedo-SH had decreased instrumentation time. Kedo-SH and hand ProTaper files produced lesser post operative pain when compared to K files

Acknowledgments

The work was supported by the White lab, Saveetha Dental College and Hospitals, Saveetha Institute of Medical and Technical Sciences, Saveetha University - project number (SDC/2023/101), Chennai, India.

The work was also supported by the Researchers Supporting program, AlMaarefa University, Riyadh, Saudi Arabia and via funding from Prince Sattam bin Abulaziz University

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Declaration of Interest

The authors report no conflict of interest.

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