



# 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

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## Abstract

**Purpose** To compare the post-operative pain after root canal instrumentation with hand K-files, H-files and rotary Kedo-S in primary teeth.

**Method** All 4–6-year-old children were invited and 69 agreed to participate. The participants were randomly divided and distributed for instrumentation with K-file (Group 1), H-file (Group 2) and rotary Kedo-S files (Group 3). After completion of root canal procedure, the post-operative pain was evaluated at intervals of 6, 12, 24, 48, and 72 h using modified Wong-Baker pain scale and compared between the groups.

**Results** Post-operative pain between three groups at 6, 12, 24, 48 and 72 h was compared using Chi square test. There was decreased post-operative pain with Kedo-S rotary files as compared to other two groups ( $P$  value < 0.001). The post-operative pain decreased after 12 h for all the groups with no pain at 24, 48 and 72 h intervals.

**Conclusion** Paediatric rotary files Kedo-S showed significantly less post-operative pain as compared to K-file and H-file at 6 h and 12 h intervals. However, follow-up interval of 24, 48 and 72 h showed no significant difference between the rotary and hand file groups.

**Keywords** Kedo-S · Post-operative pain · H-file · K-file · Primary teeth

## Introduction

Pulpectomy is the root canal treatment for pulp tissue which is irreversibly infected and necrotic due to caries or trauma (Guideline on Pulp Therapy for Primary and Immature Permanent Teeth 2016). Biomechanical preparation of the primary teeth is an important phase for a successful endodontic treatment. Adequate biomechanical preparation and irrigation is necessary to eliminate necrotic tissue, debris, dentin filling material and bacteria from the root canal (Kuştarıcı et al. 2008). With technological advancement, there is a progressive transition from the use of hand instrumentation to rotary systems for biomechanical preparation of root canal of primary teeth. Barr et al. (2000) was the

first to review the use of nickel–titanium rotary file for root canal instrumentation in primary teeth and considered this technique to be more effective to debride the uneven walls of primary teeth. After this, various authors (Musale and Mujawar 2013; Ochoa-Romero et al. 2011) have compared the different rotary systems and hand instrumentation based on their cleaning efficacy, instrumentation time and quality of obturation clinically as well as in vitro, each technique giving its own advantages and disadvantages.

Post-operative pain is the most common complication after root canal instrumentation in primary as well as permanent teeth. Post-operative pain is defined as the sensation of discomfort after endodontic intervention (Nekoofar et al. 2003; Genet et al. 1987). A systematic review by Pak and White (2011) gives the prevalence of post-operative pain to be 40% in the first 24 h, falling to 11% after 7 days with the peak pain being at 6 h post-operatively. Genet et al. (1987) have associated post-operative pain to several clinical factors, the most common being asymptomatic necrotic pulp with a periapical lesion. The multifactorial aetiology of pain is associated with the interaction between the host immune

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response, infection and physical damage. Seltzer and Naidorf (2004) have reported extrusion of debris as most common cause of post-operative pain.

The degree of debris and bacterial extrusion has been associated with the type of mechanical preparation of the root canal (Cunningham and Mullaney 1992; Wang et al. 2010). Multifactorial nature of post-operative pain being attributed to age, sex, pulpal and peri-radicular status, type of tooth, sinus tract, pre-operative pain and technical factors, the only variable controlled by the operator is the technical factor. The technical factors include the instrumentation, irrigation and obturation protocol (al-Omari and Dummer 1995).

Rotary instrumentation shows increased cleaning efficiency in shorter duration of time as compared to hand instrumentation. The rotary system for canal preparation leads to uniform and consistent filling of root canal, thus increasing their cost effectiveness. On the other hand, hand K-file and H-files show increased tactile sensation, thus making the procedure less technique sensitive. There exists variability in the cutting and cleaning efficiency in between rotary systems, hand K-file and H-file, thus influencing the effectiveness of cleaning and extrusion of debris.

Various studies in permanent teeth have compared post-operative pain in between hand and rotary instrumentation (al-Omari and Dummer 1995; Reddy and Hicks 1998). A study by Topçuoğlu et al. (2017) is the first study to compare the post-operative pain in primary teeth. However, this study compares only two groups of instrumentation techniques. With the existing variability in the functional capacity of different hand and rotary instrumentation, the primary objective of this present study was to compare the intensity and duration of post-operative pain between three groups of file system used for canal preparation in primary teeth.

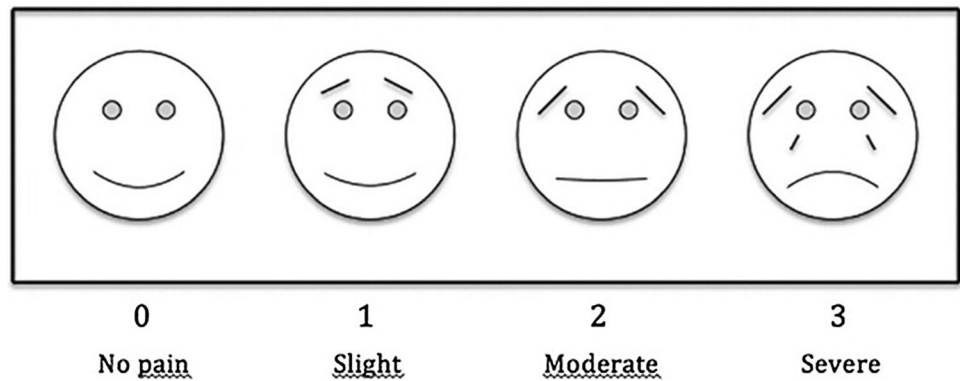
## Materials and methods

A randomised controlled study design was followed for the present study. The ethical approval for the randomised controlled trial was obtained from the Institutional review board (STP-SDMDS17PED3-A). Since no previous study has been done using three groups, a pilot study was conducted with 20 participants in each group. The results of the pilot study followed a normal distribution and the result value showed a post hoc power of 95%, the sample size for the main study was taken 25 participants in each group.

Patient's parents were given detailed information regarding the study and an informed consent was obtained from the parents on behalf of the children for the participation in the study. Children between the age group of 4–6 years requiring pulpectomy treatment of the posterior primary tooth were included in the study. Asymptomatic primary posterior teeth

with a minimum of two-third of the root structure remaining and with diagnosis of pulpal necrosis were included. Patients with underlying systemic condition and those who have taken analgesic prior to 12 h of treatment were excluded. In addition, the children whose parents were not able to understand the instruction properly and who did not give consent for the participation in the study were excluded. The randomization was done for the included participants by computer-generated sequence and treatment protocol was determined accordingly for each patient.

A single visit pulpectomy was performed by a single experienced clinician who was blinded for the purpose of the study. The participants selected were blinded for the protocol used. Local anaesthesia with 2% Lignocaine hydrochloride (LOX\*2% ADRENALINE, Neon Laboratories limited, India) with 1:200,000 adrenaline using a 2-ml syringe (UNOLOCK single use syringe, Hindustan Ltd., Chennai, India) attached to a 25-gauge 20 mm needle was administered. After the positive subjective and objective signs of the effect of local anaesthesia administration, rubber dam isolation (GDC Marketing, Hoshiarpur, Punjab, India) was done. After initial caries removal, access opening was done with no. 4 round Carbide bur (DENTSPLY Maillefer, OK, USA) using high speed hand piece. The dentinal overhangs of the roof of the pulp chamber was removed using safe ended Tungsten carbide bur (Endo-Z, FG, DENTSPLY Maillefer, OK, USA) with outward brushing motion. Initial orifices of the canals were located with DG-16 explorer (Hu-Friedy, IL, USA) after which the canal length was determined with no 15 stainless steel K-file (DENTSPLY Maillefer, OK, USA) using radio graphic method. The working length was considered to be 1 mm short of radiographic apex. Instrumentation protocol was followed according to the randomization sequence for the three groups. In Group 1, manual instrumentation was carried up to no 35 stainless steel K-file (DENTSPLY Maillefer, OK, USA) with quarter turn pull technique. In Group 2, manual instrumentation was carried up to no 35 stainless steel H-file (DENTSPLY Maillefer, OK, USA) with retraction technique. In Group 3, initial instrumentation canal patency was carried out using no 15 stainless steel hand K-file (DENTSPLY Maillefer, OK, USA) followed by rotary instrumentation using X-Smart motor (DENTSPLY Maillefer, OK, USA) with D1 and E1 Kedo-S paediatric rotary files (Reeganz dental care Pvt Ltd, India) using crown down motion. In between each instrumentation sequence, root canal irrigation was done with 1 ml normal saline for all the three groups. After final irrigation, the canals were dried using no 30 paper points (DENTSPLY Maillefer, OK, USA) and the root canals were obturated with calcium hydroxide and iodoform paste (Metapex, META Biomed Co, PA, USA). The obturation quality was evaluated by periapical radiograph, and the teeth were then restored with composite filling material.

**Fig. 1** Modified Wong-Baker Pain Rating Scale<sup>12</sup>

The parents were trained to use the pain scale and were asked to note down the pain response at 6 h, 12 h, 24 h, 48 h and 72 h as told by the child. All the parents participated in the study were blinded about the treatment protocol used for the children. All the participants were given a prescription of ibuprofen (if contraindicated, paracetamol) to be taken in case of high-intensity pain. The pain was recorded using 4-point pain scale as given by Topçuoğlu et al. (2017). The 4-point scale used measures pain as: (1) zero—no pain, (2) one—slight pain, (3) two—moderate pain, (4) three—severe pain (Fig. 1). The parents were asked to record the pain at the timeline given according to the scores in the pain scale as told by the child. These findings were recorded by the observer through telephonic conversation with the parents at 6 h, 12 h, 24 h, 48 h and 72 h. This eliminated the chances of the patients being failed to record the pain at a given time frame.

The data obtained was recorded using a spreadsheet and statistical analysis was done using SPSS software version 22 (IBM Corp, Armonk, NY, USA). Chi square test was used to compare the proportions between the three groups.

## Results

A total of 69 children were included in the study with 64 children being treated and observed once, 4 children being treated and observed for 2 pulpectomies in two different appointments and 1 child being treated and observed for 3 pulpectomies in 3 different appointments. This makes a total sample size of 75 teeth being treated, equally divided into 3 groups based on randomization. Out of the 69 children being treated, 38 were girls and 31 were boys in the age group of 4–6 years with the mean age of 5.25 years (Table 1).

The normality tests Kolmogorov–Smirnov and Shapiro–Wilk’s results reveal that the variable follows normal distribution. Therefore, to analyse the data, parametric methods are applied.

**Table 1** Demographic data and clinical features of the patient receiving treatment with K-file, H-files and Kedo-S

	K-file	H-file	Kedo-S
Gender			
Girl	11	12	16
Boy	14	13	9
Age (mean years)			
Mean = 5.25 years			

**Table 2** Mean post-operative pain scores for K-file, H-file and Kedo-S instrumentation at different time intervals

Hours	K-file	H-file	Kedo-S
6	1.28	1.64	0.88
12	0.56	0.52	0.16
24	0	0	0
48	0	0	0
72	0	0	0

Table 2 shows the mean post-operative scores for the three groups at different time interval. The pain decreased over the period of 6 h for teeth instrumented with rotary Kedo-S as compared to a decrease in 12 h interval in teeth instrumented with K-file and H-file. There was no pain reported in any groups at 24, 48 and 72 h (Fig. 2).

Chi square test reveal teeth instrumented with Kedo-S showed less post-operative pain at 6 h and 12 h as compared to instrumentation with K-file and H-file ( $P < 0.05$ ). At 6 h, instrumentation with K-file showed less post-operative pain as compared to H-file ( $P < 0.05$ ). At 12 h, there was no significant difference between post-operative pain after instrumentation with K-file and H-file ( $P > 0.05$ ). At 24, 48 and 72 h interval there was no significant difference in the post-operative pain between three groups ( $P < 0.05$ ) (Tables 3, 4, 5; Fig. 3).

Post-Operative pain evaluation at different time interval

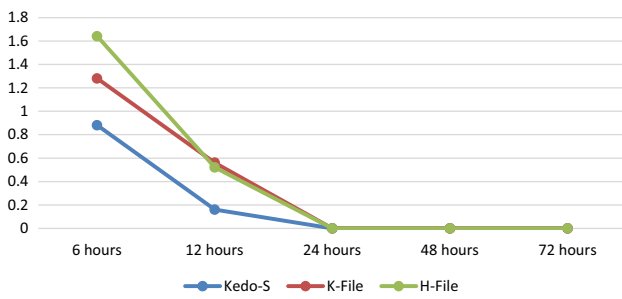


Fig. 2 Mean post-operative pain for K-file, H-file and Kedo-S at various time intervals

### Discussion

Post-operative pain is an important parameter which determines the clinical success of endodontic treatment in both primary and permanent dentition (Genet et al. 1987). In case of young children, increased post-operative pain is frequently associated with increased anxiety (Perković et al. 2014). Rendering optimal treatment with minimum post-operative pain should be the goal to achieve clinical success of endodontic treatment.

Post-operative pain is usually controlled by the use of analgesics. Non-steroidal anti-inflammatory drugs and opioids are frequently used to reduce the post-operative endodontic pain (Ashkenazi et al. 2007). However, multiple dosages of analgesics have been associated with side effects

Table 3 Frequency and percentage of post-operative pain in patients receiving treatment from K-file, H-file and Kedo-S at 6 h interval

Pain after 6 h	Group								P value
	K-file		H-file		Kedo-S		Total		
	N	%	N	%	N	%	N	%	
No pain	3	12.0	0	0.0	9	36.0	12	16.0	<0.05*
Slight pain	10	40.0	10	40.0	10	40.0	30	40.0	
Moderate pain	12	48.0	14	56.0	6	24.0	32	42.7	
Severe pain	0	0.0	10	4.0	0	0	1	1.3	
Total	25	100.0	25	100.0	25	100.0	75	100.0	

\*P < 0.05, statistically significant

Table 4 Frequency and percentage of post-operative pain in patients receiving treatment from K-file, H-file and Kedo-S at 12 h interval

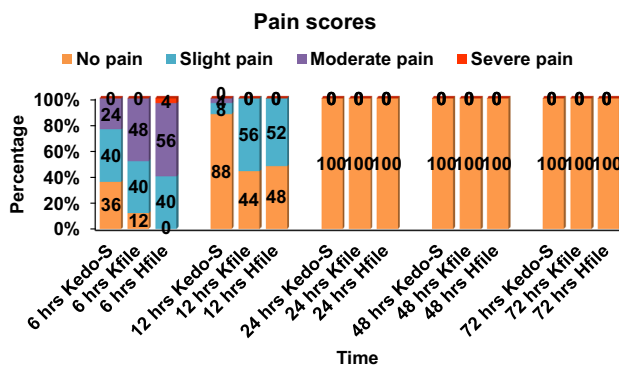
Pain after 12 h	Group								P value
	K-file		H-file		Kedo-S		Total		
	N	%	N	%	N	%	N	%	
No pain	12	44.0	12	48.0	22	88.0	45	60.0	<0.05*
Slight pain	14	56.0	13	52.0	2	8.0	29	38.7	
Moderate pain	0	0	0	0.0	1	4.0	1	1.3	
Severe pain	0	0.0	0	0.0	0	0.0	0	0.0	
Total	25	100.0	25	100.0	25	100.0	75	100.0	

\*P < 0.05, statistically significant

Table 5 Frequency and percentage of post-operative pain in patients receiving treatment from K-file, H-file and Kedo-S at 24, 48 and 72 h time intervals

Pain after 24, 48 and 72 h	Group								P value
	K-file		H-file		Kedo-S		Total		
	N	%	N	%	N	%	N	%	
No pain	25	100.0	25	100.0	25	100.0	75	100.0	> 0.05
Slight pain	0	0.0	0	0.0	0	0.0	0	0.0	
Moderate pain	0	0.0	0	0.0	0	0.0	0	0.0	
Severe pain	0	0.0	0	0.0	0	0.0	0	0.0	
Total	25	100.0	25	100.0	25	100.0	75	100.0	

\*P > 0.05, statistically not significant



**Fig. 3** Frequency and percentage of post-operative pain in patients receiving treatment with K-file, H-file and Kedo-S at different time interval

such as respiratory depression, sedation, nausea vomiting (Lee and Jo 2014). In this regard, reducing the post-operative pain with the endodontic treatment employed is the present need.

Rotary instrumentation using Ni–Ti instruments have reduced the working time as well as known to reduce post-operative pain. Previous studies in permanent teeth have reported decreased post-operative pain in both single and multiple visit root canal treatment with rotary instrumentation as compared to hand instrumentation (Talebzadeh et al. 2016; Kashefinejad et al. 2016). Another study by Topçuoğlu et al. (2017) reveals decreased post-operative pain with rotary instrumentation as compared to hand instrumentation in primary teeth. However, all these studies use rotary instruments for permanent teeth. The present study used rotary instrument designed specially to compensate the anatomical difference of primary and permanent teeth, thus aiding in achieving more reliable results for primary teeth (Jeevanandan 2017).

Apical extrusion of the debris and irritants is known to cause increased post-operative discomfort (Reddy and Hicks 1998). Working length is an important determinant for debris extrusion. Martin and Cunningham (1982) demonstrated higher debris extrusion with working length at or beyond the apex. Thus the present study has determined the working length to be 1 mm short of the radiographic apex for all teeth, thus minimising the bias and preventing the risk of over instrumentation.

Crown down technique and use of engine-driven instruments control the preparation in the apical third of the canal (al-Omari and Dummer 1995). The present study uses a rotary system with variable taper which limits the apical preparation of the canal and provides a wider cervical preparation (Jeevanandan 2017). This prevents over instrumentation and debris extrusion in the apical third of the canal, contributing to the success of the present study using rotary instrumentation with less post-operative pain. Studies have

demonstrated rotary motion of the engine-driven instruments which directs the debris coronally as compared to the increased extrusion of debris with hand instrumentation (Goerig et al. 1982). Increased extrusion of debris associated with hand instrumentation can be attributed to the piston-like motion of the usage of instrument (Madhusudhana et al. 2010). This is another factor determining decreased post-operative pain reported in the present study with rotary instrument as compared to hand instrument.

In the present study, the pain decreased after 6 h for Kedo-S rotary instrumentation whereas the pain decreased after 12 h for hand instrumentation. Similar findings can be reported in other studies (DiRenzo et al. 2002). This can be attributed to increased preparation of the canal in the apical region with hand instrumentation as compared to rotary as noted by a previous study (Pinheiro et al. 2012).

The present study uses a subjective method of evaluation of pain. This is the major limitation of the present study and other studies evaluating post-operative pain creating bias. In addition, the present study does not evaluate the exact cause of the post-operative pain. The probable cause can, however, be determined by comparison on the findings with previous studies. In this regard, a scope of further studies using objective signs of pain measurement and determination of exact cause of pain may provide stronger evidence regarding the hypothesis.

## Conclusion

Post-operative pain was found to be significantly less with Kedo-S rotary instrumentation as compared to hand instrumentation at 6 h and 12 h intervals. At 24, 48 and 72 h, there was no significant difference between the post-operative pain after instrumentation with rotary and hand files. However, these results are based on the clinical subjective criteria. Hence, further studies with more objective parameters are required to strengthen the evidence.

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## Compliance with ethical standards

**Conflict of interest** The author declares that there are no conflicts of interest.

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