



## Comparative evaluation of post-operative pain after pulpectomy with K-files, Kedo-S files and MTwo files in deciduous molars -a randomized clinical trial

Avaliação comparativa da dor pós-operatória após pulpectomia com limas k, Kedo-S e MTwo em molares decíduos - um ensaio clínico randomizado

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### ABSTRACT

**Objective:** Despite the tortuous course of primary root canal system, a paradigm shift occurred from conventional hand files to rotary system, which lead to faster, cost-effective, uniform and predictable fillings. One of the many advantages being, reduction in post-operative pain with the use of rotary system. Many rotary file systems were introduced, with the recent one, the Kedo-S. So the present study aimed to compare and evaluate the post – operative pain after pulpectomy using K-files, MTwo files and Kedo-S files in deciduous molars. **Material and Methods:** 75 teeth were randomly divided into three groups (group A – K-files, group B - Kedo-S files and group C - MTwo files) for pulpectomy of primary molars. Post – operative pain was assessed every 6,12,24,48 and 72 hours using facial pain scale. **Results:** 44% of volunteers in K-file group had moderate pain followed by Kedo-S group (8%) and then MTwo files (4%). **Conclusion:** The least post-operative pain was found in Mtwo group followed by Kedo-S group and K-file group.

### KEYWORDS

Pulpectomy; Post-operative pain; MTwo; Kedo-S.

### RESUMO

**Objetivo:** Apesar do curso tortuoso do sistema de canais radiculares de dentes molares decíduos, uma mudança de paradigma ocorreu das limas manuais convencionais para o sistema rotatório, o que leva a obturações mais rápidas, econômicas, uniformes e previsíveis. Uma das muitas vantagens é a redução da dor pós-operatória com o uso do sistema rotatório. Muitos sistemas de limas rotatórias foram introduzidas, como o recente Kedo-S. Assim, o presente estudo objetivou comparar e avaliar a dor pós-operatória após pulpectomia utilizando limas K, MTwo e Kedo - S em molares decíduos. **Material e Métodos:** Setenta e cinco dentes foram divididos aleatoriamente em três grupos (grupo A - limas K, grupo B - limas Kedo-S e grupo C - limas MTwo) para pulpectomia de molares decíduos. A dor pós - operatória foi avaliada a cada 6,12,24,48 e 72 horas, utilizando a escala de dor facial. **Resultados:** 44% dos voluntários do grupo K apresentaram dor moderada, seguidos pelo grupo Kedo-S, com 8%, e MTwo, com 4%. **Conclusão:** A menor dor pós-operatória foi encontrada no grupo Mtwo, seguido pelo grupo Kedo-S e pelo grupo K-file.

### PALAVRAS-CHAVE

Pulpectomia; Dor pós-operatória; MTwo; Kedo-S.

## INTRODUCTION

The best space maintainer in primary dentition is the natural tooth itself. Despite various advances in the preventive methods against dental caries, it still remains as a potent threat for infants and children. When the pulp has potential to recover after the irritation has been removed, conservative treatments are recommended. However, pulpectomy is recommended where there is evidence of chronic inflammation involving radicular pulp or pulp necrosis with or without periapical involvement. [1]

Due to the tortuous course of root canals of primary teeth, endodontic treatment is more challenging and time consuming with the use conventional hand files.[2] A short term complication is the postoperative pain, which commences within few hours or days after endodontic treatment. [3] The development of pain following endodontic treatment is usually due to acute inflammatory response to microbial/physical/ chemical injury to the periradicular tissues. [4]

A remarkable paradigm shift in endodontic treatment occurred with introduction of Ni-Ti rotary files by Barr et al in 2000. [5] This made the treatment cost-effective, faster and also resulted in uniform and predictable fillings. Regarding the post-operative pain, Topçuoğlu et al in 2017 concluded that Revo-S rotary system caused lesser post-operative pain in primary teeth when compared to K-files. [2]

Kedo-S file system (ReeGanz Pvt Ltd) has been introduced recently and is indigenously designed for deciduous root canals with a 3-file system namely; D1, E1, U1. A case-report suggests the use of Kedo-S files due to its better root canal preparation and quality of obturation. [6] But its effect on post-operative pain is not yet studied. So the current study aims to compare and evaluate the post – operative pain after pulpectomy using K-files, MTwo files and Kedo-S files in deciduous molars.

## MATERIALS AND METHODOLOGY:

This randomized controlled trial was

approved by the Institutional Review Board of Saveetha Institute of Medical and Technical Sciences. A pilot study was conducted initially with 20 participants in each group. The result value showed a power analysis of 95%, the final sample size in each group came to 25. The patients' parents/caregivers/guardians were given proper information regarding the research and the treatment protocol and written consent was obtained from them prior to the trial. The inclusion criteria were children aged between the age-group of 4-6 years; no history of systemic conditions; no intake of analgesics 12 hours before the treatment; and asymptomatic deciduous molars with presence of two-third of the roots with diagnosis of pulpal necrosis due to carious lesion. Children with compromised physical/psychological status were excluded from the trial. All the 75 pulpectomies were performed by a single operator in a single visit. All the volunteers of the study were randomly divided into three groups with 25 in each group. In order to randomize the volunteers, each volunteer was assigned a number. The numbers in each group were written on papers and were sealed in envelopes. Each parent was advised to choose one of the envelopes for their children to allot in the respective group. Allocation was accomplished by another operator who was blinded about the procedure to avoid bias.

Local anaesthesia was administered prior to the procedure. The area to be anaesthetized was dried and isolated with cotton rolls and then topical anaesthesia was applied over it. After application of topical anaesthetic agent, the tooth was anaesthetized using 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). The tooth was isolated using rubber dam (GDC, Hoshiarpur, Punjab, India), followed by caries removal and access opening using high speed no.4 round bur (Dentsply Maillefer, OK, USA). Absence of bleeding in the canals confirmed necrotic status of the pulp. The canals were negotiated with size 8 K-file to

check the patency of the canal. Working length determination was performed using apex locator (ProPex Pixi; Dentsply, Maillefer).

For Group A (N=25), 12 maxillary teeth and 13 mandibular teeth were instrumented with k-files (Figure 1) (Mani files, Japan) till #35 size using balanced force technique. The canals were irrigated with 2mL of 3% sodium hypochlorite with 29 gauge syringe.

For the next group that is, Group B (N=25), 13 maxillary teeth and 12 mandibular teeth root canals were prepared using Kedo-S files (Figure 2) (Reeganz Dental Care, Pvt, Ltd). Initial instrumentation was performed using #15 size K-file followed by D1 and E1 of Kedo-S file system using X-Smart endomotor (Dentsply Maillefer, OK, USA). The canals were irrigated same as that in Group A.

For the third group, that is, Group C (N=25), 11 maxillary teeth and 14 mandibular teeth root canals were biomechanically prepared using MTwo files (Figure 3) (MICRO-MEGA(c) 5-12 rue du Tunnel-BP1353, France). Initial instrumentation was done using #15 and #20 K-size files followed by MTwo files using X-Smart endomotor (Dentsply Maillefer, OK, USA). The canals were irrigated in the same fashion. The root canals were dried using paper points and obturated using metapex (META Biomed Co, PA, USA). The teeth were restored with GIC and final restoration was done using preformed stainless-steel crowns (3M ESPE).

The parents /guardians were instructed on how to use the pain scale and were advised to record the pain status every 6, 12, 24, 48 and 72 hours. All the parents/caregivers were blinded of the treatment protocol used. Postoperative pain was measured using a four-point pain intensity scale (Figure 4). [2] The pain scale is interpreted as : (1) zero- no pain, (2) one-slight pain, (3) two- moderate pain, (4) three-severe pain. The findings were recorded by the parents and also by the operator over telephone conversation after 6 , 12 , 24 , 48 and 72 hours. The statistical analysis was done using SPSS software (IBM Corp, Armonk, NY, USA). Chi-Square test was used to compare the proportion of pain between all the three groups.



Figure 1 - K files.



Figure 2 - MTwo file system.



Figure 3 - Kedo-S Paediatric Rotary File System (Reeganz Dental Care Pvt Ltd).

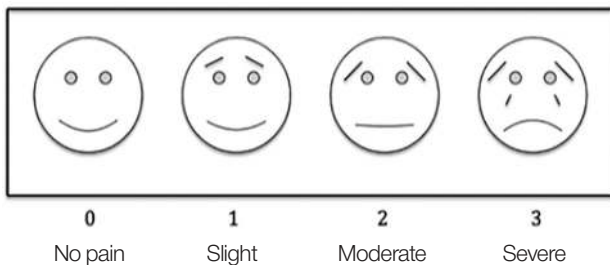


Figure 4 - Pain scale used in this study.

**RESULTS**

Table 1 describes the demographic data of the study population included in the study. Among the study population, 44% children of Group A (Manual files) experienced moderate pain after 6 hours (Table 2). A total of 32% of the children had slight pain after 12 hours in Group A (Table 3). After 24 hours, Only 4 % of children in Group A experienced slight pain

and there was no incidence of pain in Group B (Kedo-S) and Group C (MTwo) (Table 4). All the children in all the groups did not experience any post-operative pain after 48 and 72 hours (Table 5 and 6).

Table 1 - Demographic data and clinical features of the patient receiving treatment with K-file, Kedo-S and MTwo File.

	K-File	Kedo-S File	MTwo File
<b>Gender</b>			
<b>Girl</b>	10	14	12
<b>Boy</b>	15	11	13
<b>Age (mean years)</b>			
<b>Mean=5.50 years</b>			

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

	K-File	Kedo-S File	MTwo File
<b>6 hours</b>	1.12	0.4	0.24
<b>12 hours</b>	0.32	0.32	0.12
<b>24 hours</b>	0.04	0	0
<b>48 hours</b>	0	0	0
<b>72 hours</b>	0	0	0

Table 3 - Frequency and Percentage of Post-Operative Pain in patients receiving treatment from K-file, Kedo-S and MTwo File at 6 hour interval.

Pain after 6 hours	Group							
	K file		Kedo-S		MTwo		Total	
	N	%	N	%	N	%	N	%
<b>No pain</b>	8	32.0	17	68.0	20	80.0	45	60.0
<b>Slight pain</b>	6	24.0	6	24.0	4	16.0	16	21.3
<b>Moderate pain</b>	11	44.0	2	8.0	1	4.0	14	18.7
<b>Severe pain</b>	0	.0	0	.0	0	.0	0	.0
<b>Total</b>	25	100.0	25	100.0	25	100.0	75	100.0

p value =0.001, p value <0.05 (statistically significant)



**Table 4** - Frequency and Percentage of Post-Operative Pain in patients receiving treatment from K-file, Kedo-S and MTwo File at 12 hour interval.

Pain after 12 hours	Group							
	K file		Kedo-S		MTwo		Total	
	N	%	N	%	N	%	N	%
No pain	17	68.0	18	72.0	22	88.0	57	76.0
Slight pain	8	32.0	6	24.0	3	12.0	17	22.7
Moderate pain	0	.0	1	4.0	0	.0	1	1.3
Severe pain	0	.0	0	.0	0	.0	0	.0
Total	25	100.0	25	100.0	25	100.0	75	100.0

$p$  value= 0.242,  $p$  value >0.05.

**Table 5** - Frequency and Percentage of Post-Operative Pain in patients receiving treatment from K-file, Kedo-S and MTwo File at 24 hour interval.

Pain after 24 hours	Group							
	K file		Kedo-S		MTwo		Total	
	N	%	N	%	N	%	N	%
No pain	24	96.0	25	100.0	25	100.0	74	98.7
Slight pain	1	4.0	0	.0	0	.0	1	1.3
Moderate pain	0	.0	0	.0	0	.0	0	.0
Severe pain	0	.0	0	.0	0	.0	0	.0
Total	25	100.0	25	100.0	25	100.0	75	100.0

$p$  value= 0.997,  $p$  value >0.05.

**Table 6** - Frequency and Percentage of Post-Operative Pain in patients receiving treatment from K-file, Kedo-S File and MTwo File at 48 and 72 hours' time interval.

Pain after 72 hours	Group								P-value
	K file		Kedo-S		MTwo		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	
Moderate pain	0	.0	0	.0	0	.0	0	.0	
Severe pain	0	.0	0	.0	0	.0	0	.0	
Total	25	100.0	25	100.0	25	100.0	75	100.0	

## DISCUSSION

Prevention and management of postoperative pain after endodontic treatment is a vital part of root canal treatment. Informing the patients about the expected post-operative pain and prescribing medications to manage it can improve trust of the patients on dentist, increase the pain threshold of the patients and develop their attitude towards future treatment. [7] The etiology of this pain is multi-factorial and depends on the interaction between the host immunological response, infection, and physical damage. [8] During chemo-mechanical preparation, dentinal chips, pulpal fragments, necrotic debris, irrigation solution, and microorganisms are inevitably pushed into periapical tissues. Extrusion of these elements into periapical tissues may cause undesired consequences such as induction of inflammation, postoperative pain, and delay of peri-apical healing. [9] NSAIDs have no much effect on young children. Although there is well-documented literature that Ibuprofen has both anti-inflammatory and analgesic properties that control post-operative dental pain. [10,11] So pulpectomy has to be carried out effectively and efficiently to avoid post-operative complications. Also, microorganisms play a major role in causing periapical infection and pain. The foremost goal of pulpectomy is to clean and shape the root canals in a way that all the debris and bacteria-containing tissue are eliminated and hence post-operative pain would be reduced. [12] Conventionally, cleaning and shaping in primary root canals is done using manual file system. But the manual technique is time consuming and it sometimes results in iatrogenic errors like zipping, apical blockade, canal transportation; etc. Henceforth, there took place a paradigm shift from manual technique to machine-driven file system which proved to be unassailable. The first study in pulpectomy using Ni-Ti rotary file system was performed by Barr et al. [5] Ni-Ti files have gained popularity over the time and have proved to be highly flexible which allow them to follow the original root canal anatomy. [13]

Few clinicians preferred using MTwo file system over manual file system in root canal treatment. The precursor to this was quite clear because there are various studies which have documented success rate of MTwo file system. MTwo files are highly efficient for cleaning and shaping of curved canals in permanent teeth due to its high flexibility. This flexibility can be utilized in deciduous teeth as they have flared roots and accessory canals. In a study, MTwo file was compared with ProTaper files and the authors documented that sparse change was seen the canal curvature and minimum canal transportation occurred, whereas, ProTaper caused more of apical transportation. Also, the disruption of canal anatomy was inevitable in ProTaper group. [14] An in-vitro study compared MTwo with ProTaper on the basis of debris-cleaning efficiency and it was concluded that both the file systems were equally competent. [15]

This study included primary molar teeth that had asymptomatic pulp necrosis to ensure standardization and to eliminate variables such as tooth type, preoperative pain, and preoperative condition of pulp. All treatment procedures were performed by one operator and pain measurement was evaluated by the modified-Wong-Baker facial pain scale used in many previous studies. [16,17] Randomization and blinding were performed to avoid selection bias.

Rotary file system has taken over the conventional hand file system during the past decade and its use has momentarily increased in pediatric dentistry. Kedo-S (Reeganz dental care Pvt. Ltd. India) is a de-novo file system extravagantly designed for the tortuous roots of deciduous teeth. It consists of three Ni-Ti rotary files with the total length being 16 mm, while it's working length being 12 mm. In the present study both MTwo and Kedo-S rotary files were compared with the conventional K-files to evaluate post-operative pain following pulpectomy. The current study's results showed that there was less post-operative pain in rotary file system than manual file system which corresponded with the findings of previous study on post-pulpectomy pain. [2]

Crown-down technique, which is used with many NiTi rotary systems during root canal preparation, is associated with less debris extrusion compared with other preparation techniques. Studies have shown that MTwo and Kedo-S file systems causing lesser apically extruded debris during canal preparation. Therefore, it could be due to early preflaring, that is associated with less debris extrusion and finally lesser postoperative pain. [2]

## CONCLUSION

From the results of the present study, it can be concluded that chemomechanical preparation using Kedo-S and MTwo rotary systems cause lesser postoperative pain when compared to hand file system.

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