ORIGINAL ARTICLE

Postoperative Pain with Hand, Reciprocating, and Rotary Instrumentation Techniques after Root Canal Preparation in Primary Molars: A Randomized Clinical Trial

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Abstract

Aim: The purpose of this randomized clinical trial was to evaluate the intensity and duration of postoperative pain after pulpectomy of primary teeth using three preparation techniques.

Materials and methods: A total of 60 patients were randomly allocated to three groups of 20 patients each, according to the root canal instrumentation techniques used. In group I, the teeth were prepared using manual NiTi K flex files till size 35. In group II, the teeth were prepared using NiTi K flex files till size 35 in reciprocating motion. In group III, the teeth were prepared using Kedo-S pediatric rotary files. After root canal preparation, the canals were obturated with endoflas paste and were restored permanently with composite filling material. The intensity and duration of postoperative pain were evaluated after 6, 12, 24, 48, and 72 hours, using a four-point pain-intensity scale.

Results: There was a statistically significant difference among the groups, wherein the postoperative pain was more in NiTi K flex files used in reciprocating motion followed by manual NiTi K flex files and Kedo-S pediatric rotary files.

Conclusion: Postoperative pain was more with NiTi K flex files in reciprocating motion and was less with Kedo-S rotary files after root canal preparation in primary maxillary molars.

Keywords: Pediatric rotary files, Postoperative pain, Reciprocating files.

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Introduction

Root canal preparation in primary teeth is a challenging and time-consuming step during pulpectomy. Root canal treatment in primary teeth is an intricate process due to the untraversable morphology of the root canals.[1] The primary objective of root canal preparation is to completely debride the infected content and provide a sterile space for obturation. During root canal preparation, there may be unpredictable irritation to the periapex resulting in postoperative pain.[2] Postoperative pain can occur due to the extrusion of necrotic debris, dentinal chips, or pulpal remnants into the apical region during root canal preparation.[3] The extruded material can induce an acute inflammatory reaction resulting in increase of periapical tissue pressure causing unendurable pain.[4]

Nickel titanium (NiTi) files have shape memory capacity and are more flexible when compared with stainless steel files. The NiTi files follow the original canal anatomy during root canal preparation, resulting in funnel-shaped canal preparation with minimal risk of procedural errors.[5] Various root canal instrumentation techniques, such as manual, reciprocating, and rotary instrumentation, are used in primary teeth.[6–8] Conventionally, root canals of primary teeth were instrumented using hand files followed by engine-driven rotary files. These rotary file systems have been proven to be better than manual preparation in primary teeth with respect to quality of preparation and instrumentation time.[8,9] However, these rotary systems are designed for use in permanent teeth, and they do not fulfill the requirements of usage in primary teeth. Recently, an exclusive rotary file for root canal preparation of primary teeth has been introduced.[10]

The study by Topçuoğlu et al.[11] is the first study to evaluate the intensity and duration of pain after root canal preparation using stainless steel hand files and NiTi rotary files in primary teeth. There is no study in the literature evaluating the intensity and duration of postoperative pain using NiTi K flex files, NiTi K flex files in reciprocating motion, and exclusive pediatric rotary files Kedo-S after pulpectomy in primary maxillary molars. Therefore, the purpose of this study was to evaluate three instrumentation techniques and the postoperative pain after pulpectomy in primary maxillary molars.

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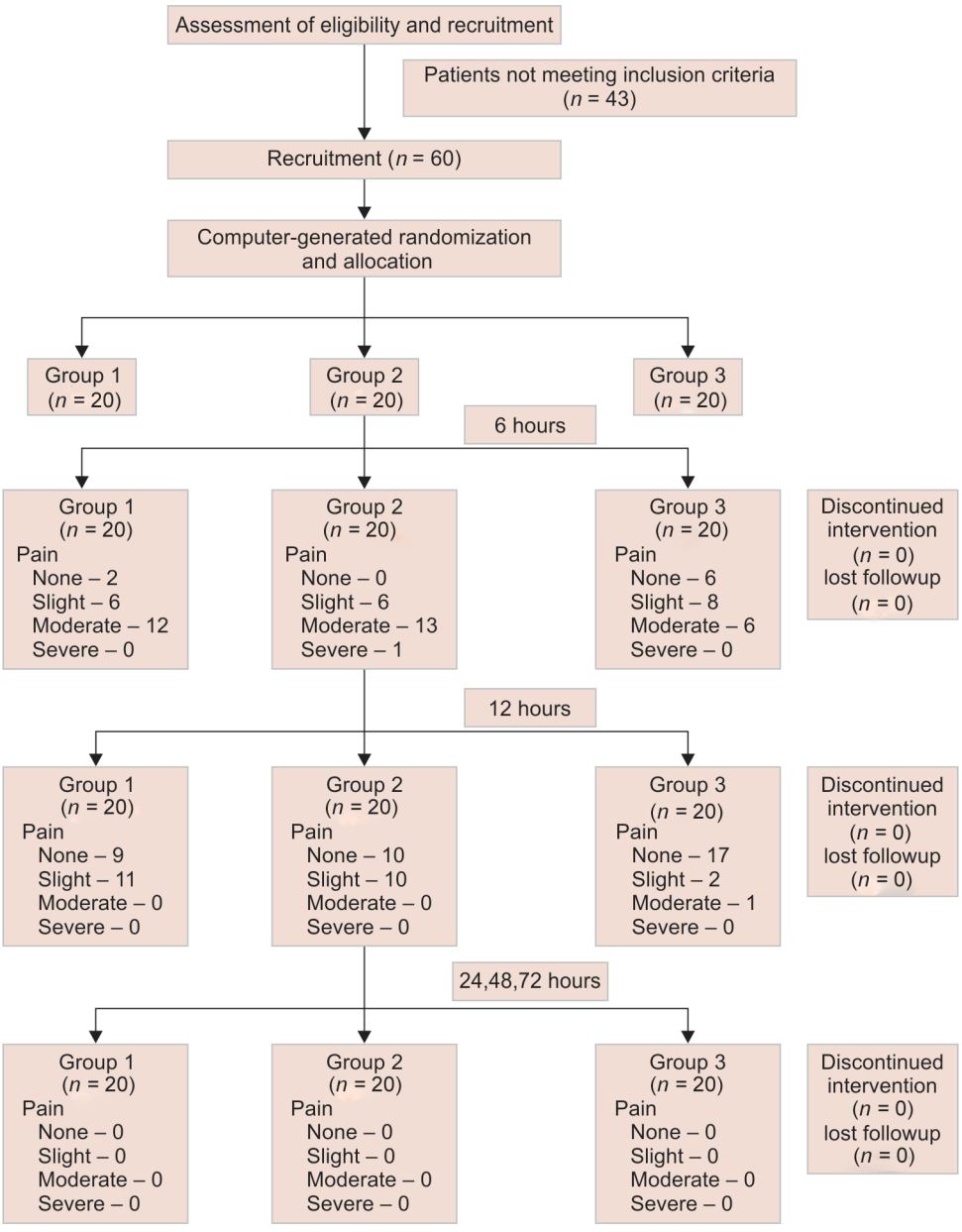
Conflict of interest: None

Materials and Methods

The randomized clinical trial study was planned according to the revised Consolidated Standards of Reporting Trials statement.[12] The

study design was approved by the ethical review board for clinical trials of Saveetha Institute of Medical and Technical Science, Chennai, India. A pilot study was done to estimate the sample size for this study, as there are no previous studies comparing the postoperative pain after pulpectomy in primary teeth with three instrumentation techniques. The study was carried out between May 2017 and July 2017. Sample size was calculated as 20 per group, (allocation ratio 1:1:1) at 80% power with a possibility of detecting 30% difference in mean values, while carrying out a priori: computer generated required sample size using *F* test (analysis of variance: fixed effects, Omnibus, one-way) at 5% significance level with G*Power version 3.0. For this clinical study, 103 children between 6 years and 8 years were examined in the dental outpatient unit at a private dental college. Finally, 60 participants with no systemic illness and no history of taking analgesics 12 hours before the pulpectomy procedure were included in the study (Flowchart 1). Only primary maxillary teeth with asymptomatic irreversible pulpitis (children having nocturnal tooth pain without swelling, pus discharge, or mobility) due to dental caries with a minimum of two-thirds of the root length remaining were included in the study. Preoperative radiographic examination revealing absence of periapical lesion or interradicular radiolucency was included in the study. Participants with any disabilities or incompetent to understand instructions of the study were excluded. The participant's parents were given complete information about the required treatment, and both written and verbal consents were obtained. Baseline data, such as age, gender, tooth number, and preinstrumentation pain, were recorded. The preinstrumentation pain score was recorded prior to the pulpectomy procedure using four-point pain scale.[11] The four-point scale used to measure pain is as follows: (1) zero-no pain, (2) one-slight pain, (3) two-moderate pain, and (4) three-severe pain (Fig. 1). Computer-generated randomization was carried out

Flowchart 1: Flowchart showing trial profile



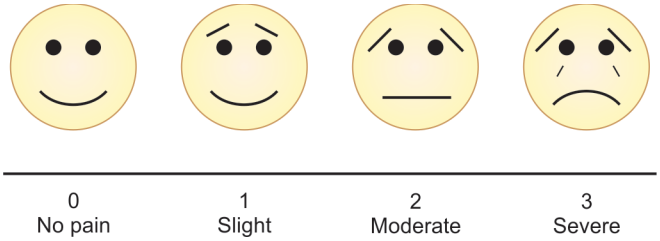


Fig. 1: Pain scale used to record pre- and postoperative pain

by a trained clinical assistant who was not involved in the study to prevent bias, and the allocation concealment was performed using the closed envelope method.

An experienced clinician performed single visit pulpectomy after application of topic anesthesia followed by administration of local anesthetic solution containing 2% lignocaine with one in 200,000 epinephrine (LOX* 2% A, Neon Laboratories Limited, India). The anesthetized tooth was isolated with a rubber dam. Initial access cavity was prepared with no. 6 sterile high-speed round bur (Mani, Utsunomiya, Tochigi, Japan). Complete deroofing of the pulp chamber was performed using sterile high-speed Endo-Z bur (FG, Dentsply Maillefer). Canal orifices were located with a DG-16 explorer (Hu-Friedy, IL, USA). The working length was determined with a Root ZX apex locator (J Morita Europe GVBH, Frankfurt, Germany). N0.15 k stainless steel file (Mani, Utsunomiya, Tochigi, Japan) was advanced into the canal till the device signaled 1 mm short of the apex.

In group I ($n = 20$), 11 primary maxillary first molars and 9 primary second molars were circumferentially instrumented using no. 15 NiTi K flex file till no. 35 NiTi K flex files (Mani, Utsunomiya, Tochigi, Japan). The canals were irrigated with 2 mL 1% sodium hypochlorite (NaOCl) followed by 2 mL sterile saline between each file size. During instrumentation, each file was coated with ethylenediaminetetraacetic acid (EDTA; RC Help, Prime Dental Product Pvt Ltd, Thane, India). After the final instrumentation, the canals were rinsed with 2% chlorhexidine followed by saline. Irrigants were carried using a syringe attached to a 29-gauge double side port NaviTip irrigation needle (Ultradent, South Jordon, Utah, USA) and were placed 1 mm short of the working length during irrigation.

In group II ($n = 20$), 12 primary maxillary first molars and 8 primary second molars were instrumented using no. 35 NiTi k-flex files coupled with NSK Endodontic contra-angle Reciprocating hand piece (TEP-ER10, Japan). The canals were irrigated in the same manner as in group I.

In group III ($n = 20$), 9 primary maxillary first molars and 11 primary second molars were instrumented using Kedo-S pediatric rotary files (Reeganz Dental Care Pvt Ltd, Chennai, India). Preinstrumentation of the canals was done using no. 15 NiTi-K flex file followed by Kedo-S rotary files. The rotary files were operated using X Smart endodontic motor (Dentsply India Pvt Ltd, Delhi, India) at 300 rpm, 2.4 N cm torque in a sequence of D1 followed by E1 till the working length. The canals were irrigated in the same manner as in group I. The prepared root canals were dried with paper points and were obturated with endoflas (Sanlor and Cia, Cali, Colombia). The obturating material was inserted into the prepared canals using no. 30 lentulo spiral (Mani, Utsunomiya, Tochigi, Japan) mounted in a low-speed hand piece. A postoperative periapical radiograph was taken to assess the quality of obturation and was then resorted permanently with composite restorative material.

A questionnaire was prepared and was distributed to each of the participant's parent(s) to evaluate the intensity of pain after pulpectomy procedure at a time interval of 6, 12, 24, 48, and 72 hours. Each participant and their parents were educated to use pain-intensity scale by an outcome assessor, who was blinded to the study groups. To avoid bias, the participant's parent was also contacted through phone calls by the outcome assessor, who was blinded to the study groups at different intervals to record the intensity of the postoperative pain. All the participants were given ibuprofen (if contraindicated, paracetamol) with an instruction to use it as an escape medicine in case of severe pain. The postoperative pain was also noted using a four-point scale, which was used to record the preoperative pain. After 5 days, an appointment was given to the participants for a full coronal restoration with stainless steel crown. The questionnaire was also collected from the participant's parent(s) during the second appointment and was crosschecked by the outcome assessor regarding the correlation of the values recorded.

Results

A total of 103 participants were screened, out of which 43 participants were excluded from the study. The study design included 60 children: 30 (50%) boys and 30 (50%) girls. There were no dropouts in the study population. There was no statistical difference in the study population with respect to baseline parameters (age, distribution of participants) among the groups (Table 1). Kruskal–Wallis nonparametric statistical test was used to compare the intensity and duration of pain among the three groups at each time interval. Bonferroni-corrected Mann–Whitney test was used for pairwise comparison. All dates were statistically analyzed using SPSS 20.0 software (SPSS Inc., Chicago, IL, USA) set at a significance level of $p < 0.05$. The intensity of postoperative pain at various time intervals is shown in Table 2. At 6 and 12 hours, there was a statistically significant difference among the groups $p = 0.008$ (6 hours) and $p = 0.036$ (12 hours). At 6- and 12-hour interval, the intensity of pain experienced was more in NiTi K flex files in the reciprocating motion group followed by the manual NiTi-K flex files group and least in the Kedo-S rotary file group. Pairwise comparison at 6- and 12 hour-intervals is shown in Table 3. At 6-hour interval, there was a statistically significant difference in manual NiTi-K flex files compared with NiTi K flex files in reciprocating motion ($p = 0.035$) and manual NiTi-K flex files compared with Kedo-S rotary files ($p = 0.026$). Moreover, there was a highly significant difference in NiTi-K flex files in reciprocating motion compared with Kedo-S rotary files ($p = 0.001$) at 6-hour interval. At 12-hour interval, there was a highly significant difference in manual NiTi-K

Table 1: Demographic data and preoperative score among three groups; $p > 0.05$, statistically not significant

Parameters	*K file*	*RH file*	*Kedo-S file*	*p value*
Girls	11	10	9	1.00 ($p > 0.05$)
Boys	9	10	11	1.00 ($p > 0.05$)
Age	6.70 ± 0.80	6.40 ± 1.04	6.95 ± 0.88	0.26 ($p > 0.05$)
Mean VAS score	2.40 ± 0.50	2.45 ± 0.51	2.40 ± 0.50	0.93 ($p > 0.05$)

VAS, visual analog scale

Table 2: Frequency and percentage of postoperative pain at different time intervals among the groups; $p < 0.05$, statistically significant

Time periods	*Pain score*	*K file (n = 20) n (%)*	*RH file (n = 20) n (%)*	*Kedo-S file (n = 20) n (%)*	*p value*
6 hours	None	2 (10)	0 (0)	6 (30)	0.008 ($p < 0.05$)
	Slight	6 (30)	6 (30)	8 (40)	
	Moderate	12 (60)	13 (65)	6 (30)	
	Severe	0 (0)	1 (5)	0 (0)	
12 hours	None	9 (45)	10 (50)	17 (85)	0.036 ($p < 0.05$)
	Slight	11 (55)	10 (50)	2 (10)	
	Moderate	0 (0)	0 (0)	1 (5)	
	Severe	0 (0)	0 (0)	0 (0)	
24 hours	None	20 (100)	20 (100)	20 (100)	1.000 ($p > 0.05$)
	Slight	0 (0)	0 (0)	0 (0)	
	Moderate	0 (0)	0 (0)	0 (0)	
	Severe	0 (0)	0 (0)	0 (0)	
48 hours	None	20 (100)	20 (100)	20 (100)	1.000 ($p > 0.05$)
	Slight	0 (0)	0 (0)	0 (0)	
	Moderate	0 (0)	0 (0)	0 (0)	
	Severe	0 (0)	0 (0)	0 (0)	
72 hours	None	20 (100)	20 (100)	20 (100)	1.000 ($p > 0.05$)
	Slight	0 (0)	0 (0)	0 (0)	
	Moderate	0 (0)	0 (0)	0 (0)	
	Severe	0 (0)	0 (0)	0 (0)	

flex files compared with Kedo-S rotary files ($p = 0.009$) and NiTi-K flex files in reciprocating motion compared with Kedo-S rotary files ($p = 0.012$). There was no significant difference in manual NiTi-K flex files compared with NiTi-K flex files in reciprocating motion ($p = 0.50$) at 12-hour interval. However, there is gradual reduction in the intensity of pain during 12 hours, when compared with 6 hours (Fig. 2). After 24 hours, no significant difference was noted among the three groups ($p > 0.05$).

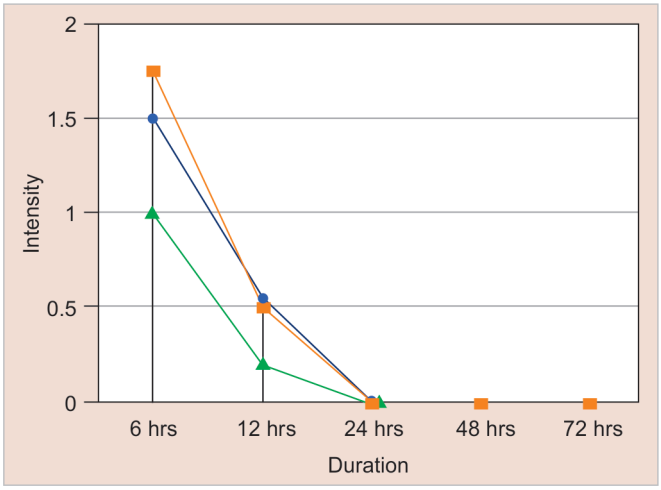


Fig. 2: Graph comparing the duration of postoperative pain based on the file systems used

Discussion

Pulpectomy is a root canal procedure involving complete removal of necrotic pulp tissue caused due to caries or traumatic injuries. Proper cleaning and shaping during pulpectomy will aid in the success of the endodontic procedure. In pediatric dentistry, root canal preparation is the most time-consuming step of the pulpectomy procedure.[13] This drawback during pulpectomy is diminished with the use of different rotary systems in pediatric dentistry. This study was performed to analyze the effect of three root canal preparation techniques on the postoperative pain following pulpectomy in primary maxillary molars. Single-visit pulpectomy was found to have significantly lesser pain compared with mutivisit pulpectomy treatment as reported by Su et al.[14] Topçuoğlu et al.[11] reported that postoperative pain is less in rotary instrumentation technique compared with manual instrumentation in primary teeth. However, the aforementioned evaluation was performed using the rotary file system (Revo-S) designed for its use in permanent root canal preparation.

There are numerous limitations, such as preoperative condition of the tooth, definition of pain, and pain measurement during evaluation of postoperative pain after root canal treatment.[15] There are some procedural limitations, such as pain caused by a rubber dam or matrix/wedge or pain caused by the coronal restoration of heavy occlusal contact. One of the major constraints in evaluating the pain is the patient's subjective evaluation and its measurement.[16] In this study, a simple, valid, and reliable modified four-point scale was used to evaluate the postoperative pain.[11] Statistical analysis of the baseline parameters revealed that there was no significant difference in the sex, age, and preinstrumentation pain between the groups. In order to avoid bias, the principal investigator, outcome assessor, and the parent(s) were blinded in the clinical trial. The study was standardized, as the procedure was performed by a single operator in the primary maxillary first or second molars with asymptomatic irreversible pulpitis. Use of an apex locator was found to be highly accurate for determining working length in primary teeth with or without root resorption.[17–19] In this study, an apex locator was used to determine the working length of the root canals to be instrumented. Martin and Cunningham demonstrated that

Table 3: Intergroup comparison between three groups; $p < 0.05$, statistically significant

Time intervals	*Groups (mean ± SD)*		*Mann–Whitney U value*	*p value*
6 hours	K file (1.5 ± 0.68)	RH file	168.00	0.035
		Kedo-S file	130.00	0.026
	RH file (1.75 ± 0.55)	K file	168.00	0.035
		Kedo-S file	66.00	0.001**
	Kedo-S file (1.00 ± 0.79)	K file	130.00	0.026
		RH file	66.00	0.001**
12 hours	K file (0.55 ± 0.51)	RH file	190.00	0.50
		Kedo-S file	125.50	0.009**
	RH file (0.50 ± 0.51)	K file	190.00	0.50
		Kedo-S file	98.50	0.012
	Kedo-S file (0.20 ± 0.52)	K file	125.50	0.009**
		RH file	98.50	0.012

**High statistical significance

the extrusion of the debris was higher with working length at or beyond the apex.[20] Hence, in this study, working length was kept 1 mm short of the radiographic apex for all teeth to prevent the risk of over instrumentation and apical extrusion of debris.

The American Academy of Pediatric Dentistry recommends the use of NaOCl and/or chlorhexidine irrigant(s) for bacterial decontamination of the infected root canals.[21] Two percent chlorhexidine resulted in reduction of intracanal bacterial after pulpectomy of necrotic primary teeth.[22] Ethylenediaminetetraacetic acid used along with NaOCl aids in the removal of the smear layer during root canal treatment.[23] In this study, 1% NaOCl was used along with EDTA gel during canal preparation and was rinsed with saline after use of each file to remove the debris and remnants of the irrigant. Chlorhexidine was used as the disinfectant solution after the final instrumentation of the root canal space. Rewal et al.[24] concluded that obturation of primary teeth with endoflas had better clinical success compared with zinc oxide eugenol. Hence, in this study, endoflas was used as an obturating material.

NiTi files have ameliorated the quality of root canal preparation due to their flexibility allowing the preparation of the tortuous and irregular canal walls of primary teeth.[7] In this study, 2% constant taper hand NiTi K flex files were used to prepare the root canals. The same hand NiTi K flex was coupled with reciprocating hand piece in the present clinical trial to evaluate the influence of motion kinematics in the reduction of postoperative pain. Kedo-S pediatric rotary file has been designed exclusively for preparing root canals of primary teeth. Kedo-S consists of three rotary files D1, E1, and U1. D1 files are used to prepare the narrower molar canals of the primary teeth, whereas E1 for the wider molar canals and U1 for the incisors, respectively. These files have a standard length of 16 mm with 12 mm flutes (working area). The files are named as variable taper files, wherein every segment of the files have different taper.[10] In this study, D1 was used to prepare the narrower canals (Mesiobuccal and Distobuccal) having 0.25 tip diameter with 4%–8% taper at different segments. E1 was used to prepare the wider canals (palatal canals) having 0.30 tip diameter with 4%–8% taper.

In this study, it was found that postoperative pain was present during 6- and 12-hour intervals and reduced over a period of time. The postoperative pain was significantly more with NiTi K flex files used in reciprocating motion followed by manual NiTi K flex files, and least pain was associated with Kedo-S rotary files. The results of this study correlate with those of the clinical trial by Topçuoğlu et al.[11] comparing hand files and rotary files with rotary file having less postoperative pain after pulpectomy. The amount of debris extruded during root canal instrumentation is proportional to the postoperative pain and swelling after pulpectomy. Topçuoğlu et al. have reported that the amount of debris extruded during root canal preparation is more with hand files compared with three rotary files. This relates why manual instrumentation with NiTi K flex files experienced greater postoperative pain compared with Kedo-S rotary files.

In future, more clinical and experimental model studies are required with different instrumentation techniques, such as hand, reciprocating, and rotary motion, using primary teeth to divulge the significant difference in apical extrusion of debris after root canal preparation.

Conclusion

Based on the study results and within the limitations of the clinical study, it is concluded that:

- Root canal instrumentation with NiTi K flex files in reciprocating motion causes more postoperative pain compared with manual NiTi K flex and Kedo-S rotary files instrumentation.
- Postoperative pain is significantly more within the first 12 hours after pulpectomy and reduces over a period of time irrespective of the root canal instrumentation techniques.

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