



**POSTOPERATIVE PAIN AFTER ENDODONTIC RETREATMENT USING DIFFERENT
RETREATMENT SYSTEMS: A RANDOMIZED CLINICAL TRIAL**

**FARKLI RETREATMENT SİSTEMLERİ KULLANILARAK YAPILAN KÖK KANAL
TEDAVİSİ YENİLEME İŞLEMİNDEN SONRA AĞRI: BİR RANDOMİZE KLİNİK
ARAŞTIRMA**

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ABSTRACT

Aim: This study aimed to compare the effect of various nickel-titanium rotary retreatment systems on intensity of postoperative pain after non-surgical endodontic retreatment.

Materials and methods: One hundred and eighty patients requiring endodontic retreatment were included in the study. The patients were randomly assigned into three groups of 60 patients, according to the method used to remove old canal filling material. In group 1, canal filling material was removed using ProTaper Universal retreatment (PTUR) instruments. In group 2, the canal filling material was removed with D-Race retreatment instruments. In group 3, Mtwo instruments were used to remove canal filling material. Teeth were then medicated with calcium hydroxide and sealed using temporary filling material. The presence of postoperative pain was assessed after 6, 12, 24, 36 and 72 h, 7 days.

Results: Among the three groups, the highest postoperative pain scores were recorded 6 hours after the procedure; the postoperative pain scores decreased over time in all time intervals. In 6 hours, Mtwo group exhibited higher pain score than those of D-RaCe group ($P < .05$), but there was no difference in the pain scores between D-RaCe and PTUR group; Mtwo and PTUR ($P > .05$).

Conclusions: Retreatments files tested in this study caused similar postoperative pain levels after non-surgical endodontic retreatment, except at 6 hours.

Keywords: Endodontics; postoperative pain; retreatment

ÖZ

Amaç: Bu çalışmada, çeşitli nikel-titanyum döner tedavi sistemlerinin cerrahi olmayan endodontik tedavi sonrası postoperatif ağrının yoğunluğu üzerindeki etkisi karşılaştırıldı.

Materyal ve metod: Endodontik tedavi gerektiren 180 hasta çalışmaya dahil edildi. Eski kanal dolgu materyalini çıkarmak için kullanılan yöntemlere göre hastalar rastgele 60 hastadan oluşan üç gruba ayrıldı. Grup 1'de, kanal dolgu materyali ProTaper Universal retreatment (PTUR) eğeleri kullanılarak uzaklaştırıldı. Grup 2'de, kanal dolgu materyali D-Race retreatment eğeleri ile uzaklaştırıldı. Grup 3'te, kanal dolgusunu uzaklaştırmak için Mtwo retreatment eğeleri kullanıldı. Daha sonra dişlere kalsiyum hidroksit uygulandı ve geçici dolgu materyali kullanılarak kapatıldı. Postoperatif ağrı varlığı 6, 12, 24, 36 ve 72 saat 7 gün sonra değerlendirildi.

Bulgular: Üç grup arasında en yüksek postoperatif ağrı skorları işlemden 6 saat sonra kaydedildi; postoperatif ağrı skorları tüm zaman aralıklarında zamanla azaldı. 6 saat içinde Mtwo grubu D-RaCe grubuna göre daha yüksek ağrı skoru gösterdi ($P < .05$), ancak D-RaCe ve PTUR grubu arasında ve Mtwo ve PTUR arasında ağrı skorlarında fark yoktu ($P > .05$).

Sonuç: Bu çalışmada test edilen retreatment sistemleri, cerrahi olmayan endodontik retreatment sonrasında 6 saat dışında benzer postoperatif ağrı düzeylerine neden olmuştur.

Anahtar Kelimeler: Endodonti; kök kanal yenileme; postoperatif ağrı

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INTRODUCTION

Non-surgical endodontic retreatment (NSER) is primarily performed when initial root canal therapy fails. Non-surgical endodontic retreatment aims to reestablish healthy periapical tissues by regaining access to the root canal system through removal of the old root canal filling, further cleaning and refilling.^{1,2} Dentine chips, pulp tissue, microorganisms and/or irrigants may be extruded into the periradicular tissues as a result of root canal preparation and removal of root canal filling material during NSER. This can be associated with undesirable consequences such as induction of inflammation, postoperative pain and delayed periapical healing.^{3,4}

A variety of file systems and shaping techniques were used during the NSER. At first, the removal of the old root canal filling was mostly performed by hand files. Today, nickel-titanium (NiTi) rotary instrument systems are widely used in the removal of root canal fillings in addition to root canal shaping.^{5,6} Various NiTi rotary retreatment systems, such as Mtwo (VDW, Munich, Germany), ProTaper (Dentsply Sirona, York, PA, USA) and D-RaCe (FKG Dentaire, La Chaux-de-Fonds, Switzerland) have also been developed to serve only this purpose. Some studies compared the effects of different NiTi rotary retreatment systems on the amount of apically extruded debris during the removal of root canal filling material and these studies showed that all of the retreatment systems caused apical extrusion of debris.⁷⁻⁹

Several studies evaluated the effect of different NiTi rotary systems on the postoperative pain after primary root canal treatment.¹⁰⁻¹² However, there are limited studies evaluating the intensity of postoperative pain following NSER.^{13,14} Moreover, to the best of our knowledge, no study has compared the effect of different retreatment systems on the intensity of postoperative pain. Therefore, the aim of this study was to compare the effect of Mtwo, ProTaper and D-RaCe retreatment systems on postoperative pain after NSER. The null hypothesis is that the intensity of postoperative pain is not affected by the type of retreatment system used.

MATERIALS AND METHODS

This study was approved by Erciyes University Medical Ethics Committee (569/2016). In this clinical trial, Consolidated Standards of Reporting Trials guidelines were followed and the study was registered

at www.clinicaltrials.in.th (identification number: 20190309003). Based on data from a pilot study, power analysis results showed that each of the sample size of the group should be at least fifty. This number was determined by estimating power=0.92, effect size = 0.80 and significance level = 0.50. The number of patients to be included in the study was determined as sixty for each group (Fig. 1), considering the patients who could not attend the appointments in each group.

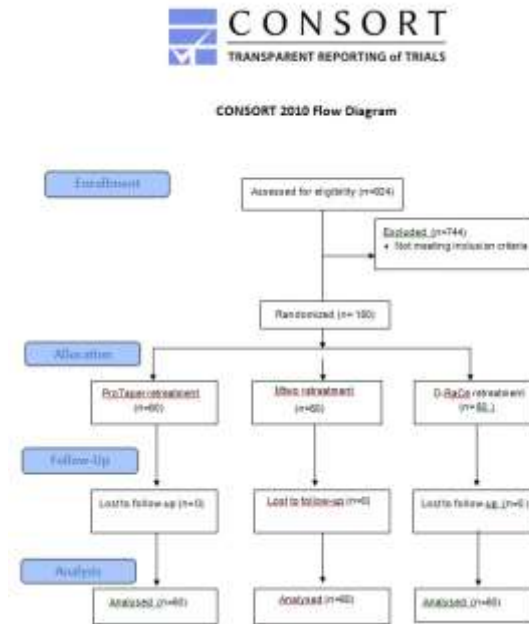


Figure 1. The Consolidated Standards of Reporting Trials 2010 flow diagram

Eligibility Criteria

Inclusion criteria

1. Healthy patients without systemic disease between the age group of 18 and 70 years.
2. Patients who had previously been treated with root canal therapy, which had failed and who needed NSER (diagnosed by clinical symptoms and radiographic findings).
3. Teeth with an initial root canal filling maximum of 4 mm short from the apex.

Exclusion criteria

1. Patients who had taken analgesics, anti-inflammatory or antibiotic drugs within the last twelve hours.
2. Pregnancy or lactation
3. Teeth with external or internal root resorptions
4. Patients having acute apical abscess

5. Teeth with an open apex
6. Teeth with periapical lesions with score of 5 in accordance with the periapical index classification introduced by Ørstavik *et al.*¹⁵
7. Teeth with a separated file into the root canal
8. Teeth with overfilled canals
9. Patients having severe malocclusion associated with a traumatic occlusion
10. Patients having adjacent tooth presenting signals of inflamed pulp

Randomization and allocation

One hundred and eighty patients who fitted the inclusion criteria were randomized into three groups, by one of the investigators, according to NSER methods using the Research Randomizer program (version 4.0; Geoffrey C. Urbaniak & Scott Plous, Lancaster, PA; available at www.randomizer.org). Because of the nature of the interventions, the operator who performed the NSER procedures was not blinded to the interventions. However, the patients were not informed of the allocation.

All patients agreed to participate in this study before the treatment, the treatment protocol to be applied and the possible results were clear and understandable and they signed a consent form. Preoperative and postoperative pain were assessed using a visual analogue scale (VAS). The lowest value in this scale is '0' and indicates no pain. The highest value is '10cm' and indicates the presence of severe pain. Intermediate values from 1 to 9 indicate the severity of pain at increased levels from less to more. The patient was asked to mark on this line in order to express his/her own condition. Patients were asked to record their pre-treatment status on the VAS given to them after they were informed clearly about the scale and how they should use this scale. A preoperative pain record was performed under the observance of an operator and patients were asked to evaluate the pain and record it on the form at the same time.

Treatment Protocol

All treatments were performed by one operator. In the first visit, a local anesthetic solution (Ultracaine DS fort; Hoechst-Marion Roussel, Frankfurt, Germany) with 1: 200,000 epinephrine and 4% articaine was administered to the tooth. After the isolation of the tooth with rubber-dam, the tooth was cleaned with 2.5% sodium hypochlorite (NaOCl). The coronal restoration was removed under water cooling using a sterile rond (Dentsply Sirona) and fissure burs (Dentsply Sirona) with a high-speed handpiece. The endodontic access cavity was prepared and canals

were detected. The old root canal filling material was removed with one of ProTaper Universal, Mtwo and D-RaCe retreatment systems in accordance with the manufacturer's instructions. Each file set was used in one tooth and then discarded.

ProTaper Universal Retreatement (PTUR) Group

The ProTaper Universal retreatment files were used at a constant speed of 500 rpm for D1 and 400 rpm for D2 and D3, with a torque of 3 Ncm using a 16:1 reduction hand piece powered by a torque-controlled electric motor (X-Smart Plus; Dentsply Sirona). The coronal part of the root canal filling material was removed using D1 (#30/.09 taper) file. Following this, 0.1 ml of orange oil was applied into each root canal to soften the gutta-percha. Then, in order to determine electronically the working length, a # 15 K-file to a Root ZX mini (J. Morita Corp., Kyoto, Japan) apex locator was connected and the file was inserted into the apical of the canal in softened gutta-percha until the "0.0" value was obtained. The working length was determined to be shorter than 1 mm from this length and confirmed using periapical radiographs. D2 (#25/.08 taper) files were used in the middle thirds of the root canal and the D3 (#20/.07 taper) file was then used until the WL was reached. Finally, the apical preparation of the canals was performed with F2, F3, F4 and F5 ProTaper rotary files (Dentsply Sirona).

Mtwo Retreatement Group

The Mtwo retreatment files were used at a constant speed of 280 rpm for R15 and R25 files. The coronal root canal filling material was removed using an R25 (#25/.05 taper) file. Following this, 0.1 ml of orange oil was applied into each root canal to soften the gutta-percha. Then, the working length was determined and confirmed radiographically as in the ProTaper Universal retreatment group. An R25 file was used with brushing movements at the 1.2 Ncm torque until reaching the working length. When resistance was encountered in the canal, an R15 file was used with brushing movements on the canal walls until the working length was reached. The apical preparation of the canals was performed with #30/.04 taper, #35/.04 taper, #40/.04 taper and #50/.04 taper Mtwo rotary files.

D-RaCe Retreatement Group

In this group, the coronal part of the root canal filling material was removed using a DR1 (#30/.10 taper) file at a constant speed of 1000 rpm in accordance with the manufacturer's instructions. Following



this, 0.1 ml of orange oil was applied into each root canal to soften the gutta-percha. Then, the working length was determined and confirmed radiographically as in the ProTaper Universal retreatment group. A DR2 (25/.04) file was used with brushing movements at a constant speed of 600 rpm until reaching the working length. The apical preparation was performed with #30/.04, #35/.04, #40/.04, and #50/.04 taper RaCe rotary files at 300 rpm speed and 1 Ncm torque.

In all groups, the curved canals of molar teeth were shaped up to size 40 file maximum, whereas the straight canals were mostly shaped up to size 50 file maximum. In curved canals, the working length was re-calculated by the apex locator after the preparation of the coronal and middle part of the canal. During the removal of the root canal filling material and the re-shaping of the canals, 10 mL of 2.5 NaOCl for each canal was used as an irrigant using a syringe and a 29-gauge NaviTip needle (Ultradent Products Inc., South Jordan, UT, USA). Final irrigation was performed with 10 mL of 17% ethylenediaminetetracetic acid (EDTA) and 10 ml sterile saline solution. After the final irrigation, the canals were dried with sterile paper and calcium hydroxide paste (CalciCur, Voco GmbH, Germany) was placed into the root canal using a Lentulo spiral. A control radiograph was taken to verify the quality of calcium hydroxide placement. The access cavity was sealed with a temporary filling material (Cavit; 3M ESPE, Seefeld, Germany). All procedures were performed under a dental operating microscope (Carl Zeiss, Oberkochen, Germany). At the end of the first visit, patients were given a form containing the pain scale (VAS) to fill in. The pain scale on the form contained tables for evaluating their pain conditions before the treatment of patients and after 6, 12, 24, 36, 72 hours and 1 week. They were reminded that they should come with this form to the second visit and they were scheduled for seven days later.

In the second visit, if the patient's complaints in the related tooth had disappeared, the temporary filling material was removed after the isolation of the tooth with rubber-dam. Calcium hydroxide was removed with 10 ml 17% EDTA agitated sonically with Endoactivator (Dentsply Sirona). Finally, the canals were irrigated with 10 ml saline solution and then dried with paper points. Root canals were obturated using gutta-percha and a resin-based sealer (MM-Seal, MicroMega, Besancon, France) with warm vertical compaction technique (Calamus, Dentsply Sirona). Radiographs were taken to confirm adequate canal

filling. Coronal restoration was made using composite resin (Filtek, 3M ESPE). Teeth that needed prosthetic restoration were treated using a fiber post (Cytec Blanco, Hahnenkratt, Germany), self-adhesive resin cement (RelyX Unicem; 3M ESPE, Seefeld, Germany) and core material. Then, crown restoration was performed for those teeth that needed it.

Statistical Analysis

Data were analyzed with the R 3.2.2 (www.r-project.org) program. A Shapiro-wilk test was used to test normality. The homogeneity of variance was tested using the Levene test. Data were analysed statistically using the Kruskal–Wallis test followed by the Mann–Whitney U test for multiple comparisons. Comparisons between repeated measurements were evaluated by Friedman's test. For multiple comparisons, the Dunn-Bonferroni test was applied. The level of significance was accepted as $P < 0.05$.

RESULTS

No file fracture occurred during the removal of root canal filling material in any of the groups. There was no significant difference in age, sex and preoperative pain between the three groups ($p > 0.05$) (Table 1). Thirty-nine patients (nineteen from the PTUR group, thirteen from the Mtwo group, and seven from the D-RaCe group) reported taking analgesics postoperatively. There was a statistical difference between only the PTUR and D-RaCe groups regarding taking analgesics ($p < 0.05$). The distribution of all teeth on which NSER was performed was seventy-two mandibular teeth and one hundred and eight maxillary teeth. When the distribution of the teeth, according to the jaws, was examined, there was a significant difference regarding the numbers of teeth treated in the D-RaCe groups compared with the other groups ($p < 0.05$). However, there was no difference regarding the distribution of teeth in the Mtwo and PTUR groups ($p > 0.05$). There was no significant difference among the groups regarding the preoperative PAI score and the periapical lesion size (Table 1) ($p > 0.05$). In the Mtwo group, intensity of postoperative pain at six hours was significantly higher than in the D-RaCe group ($p < 0.05$). However, there was no significant difference between the Mtwo and PTUR groups and the D-RaCe and PTUR groups at six hours ($p > 0.05$). At 12h, 24h, 36h, 72 h and 7 days, there was no difference between the three groups regarding the intensity of postoperative pain ($p > 0.05$) (Fig. 2). There was no statistical difference



among D-RaCe (no patients), PTUR (two patients) and Mtwo (one patient) regarding the number of patients having flare-up ($p > 0.05$).

Table 1. Demographic and preoperative features

Preoperative data	Groups			p value among the groups
	PTUR n(%)	D-RaCe n(%)	Mtwo n(%)	
Age				
<30	14(23.3)	25(41.6)	22(36.6)	.072
30-50	36(60)	32(53.3)	30(50)	
>50	10(16.6)	3(5)	8(13.3)	
Gender				
Female	38(63.3)	35(58.3)	38(63.3)	.386
Male	22(36.6)	25(41.6)	22(36.6)	
Tooth type				
Maxillary anterior	9(15)	5(8.3)	5(8.3)	.034
Maxillary premolar	8(13.3)	12(20)	8(13.3)	
Maxillary molar	14(23.3)	28(46.6)	19(31.6)	
Mandibular anterior	4(6.6)	2(3.3)	4(6.6)	
Mandibular premolar	7(11.6)	3(5)	9(15)	
Mandibular molar	18(30)	10(16.6)	15(25)	
Preoperative PAI score				
1	13(21.6)	11(18.3)	9(15)	.183
2	15(25)	16(26.6)	14(23.3)	
3	18(30)	21(35)	23(38.3)	
4	14(23.3)	12(20)	14(23.3)	
Periapical lesion size				
<2mm	35(58.3)	32(53.3)	29(48.3)	.578
≥2 mm	25(41.6)	28(46.6)	31(51.6)	
Canal filling density				
Good	13(21.6)	15(25)	14(23.3)	.252
Poor	38(63.3)	36(60)	41(68.3)	
Unobturated canal	9(15)	9(15)	5(8.3)	
Length of canal filling				
Adequate (0-2mm)	13(21.6)	15(25)	19(31.6)	.731
Short (>2mm)	44(73.3)	43(71.6)	39(65)	
SealerExtruded	3(5)	2(3.3)	2(3.3)	

could occur more often at teeth performed endodontic retreatment compared to teeth performed primary root canal therapy.¹⁸ When endodontic literature is examined, the one of most important reason affecting the intensity of postoperative pain is apically extruded debris during the canal shaping or the removal of the canal filling.^{19,20} Several studies showed that the design of the endodontic file (i.e, cross-section) or movement type (rotation or reciprocating) of file are factors affecting the amount of apically extruded debris.^{21,22} In the light of this information, the present clinical study aimed to compare the effect of three retreatment systems on the intensity of postoperative pain following NSER. In the present study, when the pain scores at each time interval in all the groups was examined, the highest pain scores were six hours after treatment, except 12 h in the D-RaCe group. This finding was compatible with the results of previous studies.^{23,24} Also, there was only a significant difference between Mtwo and D-RaCe retreatment groups at six hours, but not at the other time intervals. In consideration of these results, the null hypothesis was rejected. The Mtwo retreatment file (R25), used at working length, has an active cutting tip, however, D-RaCe DR2 has a non-cutting tip. NiTi files with a cutting tip design cause more disruption of apical constriction compared to files with a non-cutting tip during the canal preparation. The disruption of apical constriction may be speculated to yield increased apical extrusion during treatment.²⁵ The difference in the pain scores between these two groups could be the difference in tip design.

There is no consensus among clinicians about the fact that NSER can be performed in a single visit or in two visits. Ashraf *et al.*²⁶ evaluated the success rate of NSER performed in one visit and they observed a high success rate for treatments in one visit. However, teeth with failed root canal treatment are known to contain more bacteria than the bacteria present during the primary root canal treatment. Vera *et al.*²⁷ tested the microbiological status of the root canal system in vivo, and they reported that the microbiological condition in teeth placed calcium hydroxide as an intracanal medicament between the sessions was more favorable than the treatments performed in one visit. Yoldas *et al.*²⁸ evaluated the effect of root canal treatment on postoperative pain in one or two visits by non-surgical means, and they determined that the treatment in two visits with intracanal medicament was effective in reducing postoperative pain. In the current study, NSER was

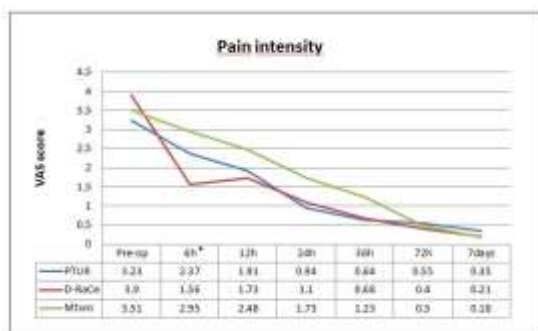


Figure 2. Pain intensity at different time intervals for each group

DISCUSSION

In endodontics departments of dentistry faculties and private clinics all over the world, the NSER is often preferred because it is a conservative method for patients with failed root canal treatment, compared to surgical endodontic retreatment.¹⁶ NSER should aim to reduce the pain felt by the patient during and after treatment, as well as biological targets such as healing of periapical tissues.¹⁷ It has been well-known that postoperative pain and swelling



completed in two visits to ensure effectively intracanal disinfection of all included teeth.

There are various opinions in the literature about the use of solvents during the removal of a root canal filling. Chloroform had been one of the most frequently used solvents for removing the root canal filling material until it was found that it had carcinogenic and neurotoxic potential. Orange oil is an essential oil recommended as a biologically compatible alternative to chloroform to soften gutta-percha.^{29,30} In a study conducted by Keskin *et al.*³¹, the effect of solvents on apically extruded debris was evaluated and it was determined that the use of solvents reduced significantly the amount of apically extruded debris compared to the control group (without solvents). In this study, it was also observed that chloroform caused significantly more debris extrusion than orange oil and terabentine oil. In the present study, orange oil was used as a solvent.

In previous studies^{2,32}, it has been reported that the amount of remaining filling material at the apical third of the canal, following the removal of root canal filling material, was more than in the middle and coronal thirds of the canal. Therefore, after the removal of canal filling material, the re-shaping of the apical third of the canal is essential to allow effective intracanal disinfection. Although there is no consensus about the size of the final apical preparation in the NSER procedure, it has been suggested to re-shape with files having a larger apical diameter than those of the final apical file used at the initial canal preparation.³³ Rodig *et al.*³⁴, reported that the apical preparation up to the size 40 file could provide sufficient cleaning and, in addition, it prevented the formation of procedural errors in the curved canals and the dental structure was preserved in this way. In the present study, the curved canals of molar teeth were shaped up to size 40 file maximum, whereas the straight canals were mostly shaped up to size 50 file maximum.

Pain is a subjective perception, and each person's pain threshold varies depending on the patient's cultural, individual and economic background. Therefore, the main problem, in the studies where pain is evaluated, is the subjective evaluation of the patient's pain and the subjectivity of the evaluation performed. Therefore, the design of the pain form is important.³⁵ This form should be understood easily by patients and facilitate the evaluation by the researcher. Various studies have shown that VAS is more reliable and valid than other

methods in pain measurement.^{36,37} The present study used VAS to determine the intensity of the postoperative pain following NSER. All possible sources of pain can never be controlled or eliminated completely. Therefore, the presence of postoperative pain after NSER may be related to apical trauma because of overinstrumentation or canal filling materials being extruded into periapical tissues.³⁸ However, the other causes may be soft tissue injury caused by rubber dam application or pain from the site of the local anesthetics.³⁹ These causes could be considered as limitations of studies evaluating the incidence of postoperative after NSER. Another cause of postoperative pain may be apically extruded calcium hydroxide. In the current study, it was observed extrusion of calcium hydroxide in 7 teeth (3 teeth in D-RaCe group, 2 teeth in PTUR group, and 2 teeth in Mtwo group). This could be considered as another limitation of the present study.

21.7% of the patients, included in the current study, took analgesics between the visits. There was a significant difference between the D-RaCe and PTUR groups in terms of analgesic consumption, whereas there was no difference between the groups in terms of Mtwo and the other two groups. Comparin *et al.*¹³ evaluated postoperative pain intensity and analgesic intake between visits after the removal of root canal filling material with files working with different kinematics, and they reported analgesic consumption at five out of sixty-five patients. The differences between analgesic consumption may be due to the fact that patients without preoperative pain are included and the number of patients is low in the study by Comparin *et al.*¹³. In another study, Garcia-Font *et al.*¹⁴ evaluated postoperative pain after the removal of root canal filling material from root canals in NSER, using rotary or reciprocating files and they reported analgesic intake at 25.6 % of the patients. This finding is compatible with the findings of the present study. This similarity could be due to the inclusion of patients having preoperative pain and satisfactory patient numbers.

CONCLUSION

This study showed that the intensity of postoperative pain was similar for all retreatment file groups on the other time intervals, except at six hours. Further clinical studies should be carried out to analyze the effect of different variables on postoperative pain after NSER.



Declaration

The authors deny any conflicts of interest related to this study.

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