

# POSTOPERATIVE PAIN FOLLOWING SINGLE VISIT ROOT CANAL TREATMENT WITH RECIPROC BLUE AND HYFLEX EDM INSTRUMENTATION; A PROSPECTIVE RANDOMIZED CLINICAL TRIAL

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## ABSTRACT

**Objective:** Single file systems with continuous rotation or reciprocation produced with many new technologies promising in terms of postoperative pain. The aim of this study was to investigate the efficacy of using novel Reciproc Blue (RBlue) and HyFlex EDM (HEDM) files on postoperative pain after single visit root canal treatment.

**Materials and Methods:** 72 patients with asymptomatic pulp necrosis in mandibular molar and premolar teeth were included. The root canals were prepared using HEDM (n=29) or RBlue (n=28) and hand-instruments (n=15) in single visit. Pain presence using verbal rating scale (VRS) and analgesic intake were recorded after 24h, 48h, 72h and 7 days.

**Results:** Postoperative pain at 24h and 48h was statistically higher at RBlue group than HEDM and control groups (p <0.05). After 72 hours, the incidence of postoperative pain decreased and on the 7th day, none of the patients reported pain (p >0.05). There was no difference between groups in terms of analgesic intake (p >0.05). RBlue files were associated with higher incidence of postoperative pain and higher VRS scores than HEDM and hand-instruments.

**Conclusion:** RBlue files working with reciprocating motion caused much more postoperative pain than HEDM files and manual files.

**Keywords:** Analgesic intake; Continuous rotation; Endodontics; Reciprocation; Root canal treatment

## ÖZET

**Amaç:** Yeni teknoloji ile üretilmiş sürekli rotasyonlu veya resiprokasyonlu tek ege sistemleri postoperatif ağrı açısından umut vadecidir. Bu çalışmanın amacı, yeni Reciproc Blue (RBlue) ve HyFlex EDM (HEDM) eğelerinin tek seans kanal tedavisi sonrası postoperatif ağrı üzerindeki etkinliğini araştırmaktır.

**Materyal ve Metot:** Mandibular molar ve premolar dişlerde asemptomatik pulpa nekrozu olan 72 hasta çalışmaya dahil edildi. Tek seansta HEDM (n=29) veya RBlue (n=28) ve el aleti (n=15) kullanılarak kök kanalları hazırlandı. Sözel derecelendirme ölçeği (SDÖ) kullanılarak ağrı varlığı ve analjezik alımı 24 saat, 48 saat, 72 saat ve 7 gün sonra kaydedildi.

**Bulgu:** Postoperatif 24. ve 48. saatte ağrı, RBlue grubunda HEDM ve kontrol gruplarına göre istatistiksel olarak daha yüksekti (p <0.05). 72 saat sonra postoperatif ağrı insidansı azaldı ve 7. günde hiçbir hasta ağrı bildirmede (p >0.05). Analjezik alımı açısından gruplar arasında fark yoktu (p >0.05). RBlue ege sistemi, HEDM ve el aletlerinden daha yüksek postoperatif ağrı insidansı ve daha yüksek VRS skorları ile ilişkilendirildi.

**Sonuç:** Resiprokal hareketle çalışan RBlue eğeleri, HEDM eğelerine ve el egesine göre çok daha fazla ameliyat sonrası ağrıya neden olmuştur.

**Anahtar Kelimeler:** Analjezik alımı; Devamlı rotasyon; Endodonti; Resiprokal; Kök kanal tedavisi

## INTRODUCTION

The main goal of endodontic treatment is to eliminate the disease and preoperative symptoms. (1) However, even if there is no preoperative symptoms, pain may occur after root canal treatment and its prevalence was reported to be 25%-40% of patients (2). The most probable relationship was found in teeth with asymptomatic necrotic pulp and periapical lesion, however, it was also reported that the etiology was multifactorial, and the extent of physical damage by procedural factors and the host immune response may be effective on experienced pain (3). Debris extrusion has been defined as one of the procedural etiological factors associated with postoperative pain (4) and many studies have been published in this field, considering that the preparation technique and the design of the canal file used may also be effective in extrusion of debris and thus in postoperative pain (5). Following the recommendation to prepare root canals using a single file with a reciprocating motion (6), many companies have introduced single file systems in different designs that provide preparation with continuous or reciprocating motion. Reciproc Blue files (RBlue; VDW, Munich, Germany), which have a file design similar to its previous version, Reciproc (VDW), that is, S-shaped horizontal section and 2 cutting edges, are produced with a special heat treatment method that gives the file its specific blue color and more flexibility (7). HyFlex EDM (HEDM; Coltene/Whaledent, Alstatten, Switzerland) is a single-file system with continuous rotation, manufactured from a controlled memory alloy using the non-contact manufacturing method, electrical discharge machining (8). HEDM has 3 different horizontal cross section along their length that transforms from apical to coronal quadratic, trapezoidal and triangular (9). Single visit root canal treatment with single file systems takes less time, less cost, prevents the root canals from being contaminated between sessions, and reduces the number of anesthesia, instruments and appointments, creating less stress for the patient (10). It has been reported that the recovery rates after single visit and multiple visit root canal treatment are similar, and patients feel less postoperative pain after single visit root canal treatment compared to multiple visit root canal treatment (11). Single file systems with continuous rotation or reciprocation produced with many new technologies have given rise to the need to examine the effectiveness of these instruments after a single visit treatment in necrotic teeth with a high incidence of postoperative pain. Therefore, in this study, it was aimed to examine the effectiveness of current single file systems working with different kinematics on postoperative pain in teeth with asymptomatic necrotic pulp. The null hypothesis of the study is that there would be no difference between the incidence of postoperative pain in the new generation file systems examined.

## MATERIALS AND METHODS

### *Sample size calculation*

Minimum required sample size were determined for each groups using a power analysis software (G\*Power 3.1 soft-

ware; Heinrich Heine University, Dusseldorf, Germany) based on results of a previous study (12). Using following input conditions; effect size as 0.644, power as 0.95, and alpha-type error as 0.05, the calculation indicated the total sample size should be a minimum of 42. Considering the possibility of drop-outs, the study was conducted on 75 teeth.

### *Inclusion and exclusion criterias*

Standarts of Reporting Trials Guidelines were followed in this study. After Marmara University Clinical Research Ethics Committee approval (71146310-511.06-E.81380 and 2017-158), a total of 62 patients who referred to the Endodontic Department of Marmara University, Faculty of Dentistry and met the inclusion criterias were included in the study. Inclusion criterias were as follows:

- Systematically healthy patients aged between 16 and 70 years.
- Not having recently used antibiotics, corticosteroids or non-steroidal antiinflammatory
- Drugs (NSAIDs) for dental or any reason.
- Asymptomatic pulpal necrosis diagnosed as a result of cold spray (Endo-Frost, Coltène/Whaledent, Langenau, Germany), and electric pulp testing (Parkell, NY, USA) in mandibular premolar and molar teeth.
- The tooth to be treated is in a condition that can be restored in radiographic and clinical examination, there is no periodontal problem, there is no radiolucent lesion in the apical area of the tooth.

Exclusion criterias were as follows:

- Pregnant or lactating patients
- Patients were using antibiotics, steroids or NSAIDs and allergic to any of these drugs.
- Patients were symptomatic and sensitive to percussion and palpation ,with traumatic occlusion and bruxism

Teeth which were previously treated, associated with resorption, calcification, periodontal disease and mobility more than Grade I, open apex, severe damage. Patients who met the inclusion criterias were informed in detail about the procedures and treatment groups, and after their informed consent was obtained, root canal treatments were applied to 75 mandibular premolar and molar teeth of a total of 62 patients diagnosed with asymptomatic pulpal necrosis. The treatments of different jaws and different teeth meeting the inclusion criterias in the same patient were not performed simultaneously. The methods to be applied for 75 teeth were predetermined as 30 RBlue, 30 HEDM and 15 manually using hand instruments. For each patient, the number was selected with a random numbers generator, and a predetermined instrumentation technique was applied to that number. CONSORT Flow Diagram shown in Figure 1. Root canal treatments of the teeth were

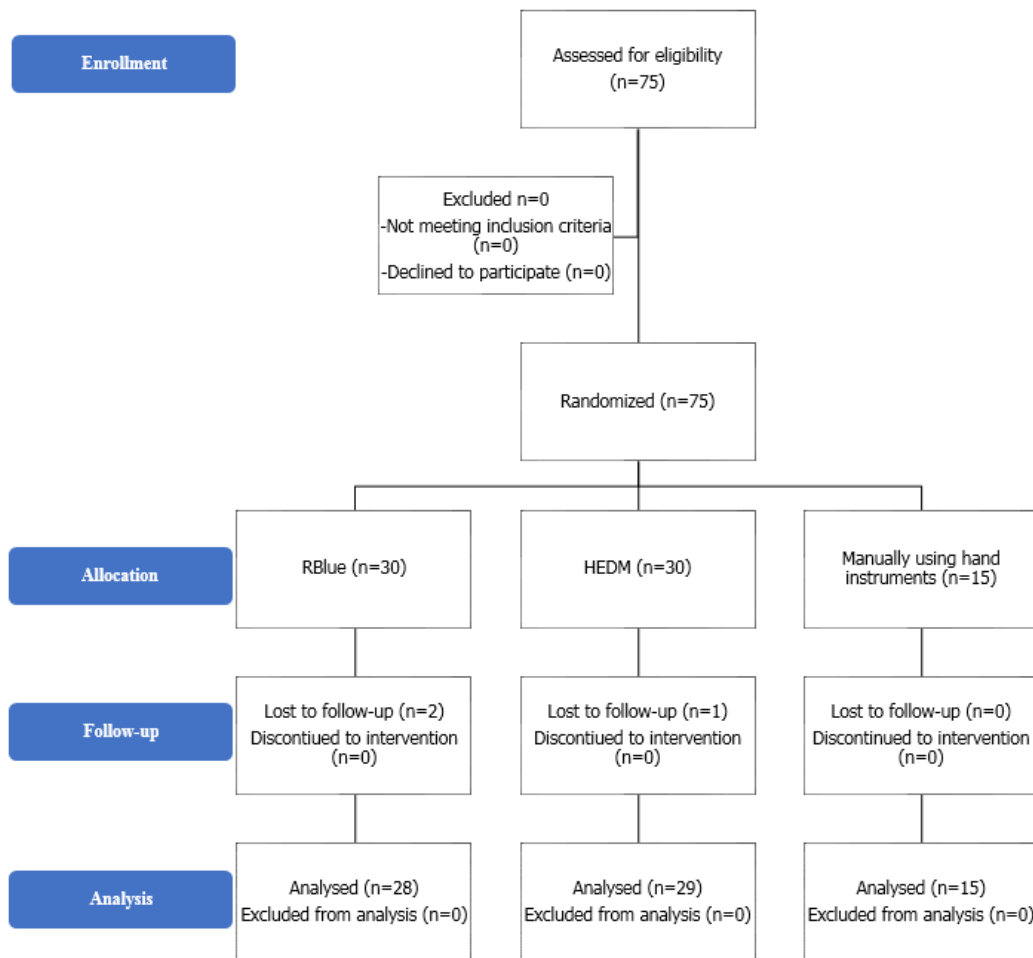


Figure 1: CONSORT Flow diagram for randomized clinical trials

performed in a 6-month period by a single operator experienced in techniques and materials. After getting local anesthesia with 4% articaine and 1:200,000 epinephrine solution (Ultracaine DS Fort; Hoechst-Marion Roussel, Frankfurt, Germany) and rubber dam isolation, endodontic access cavities were opened with sterile diamond and carbide burs. Patency establishments and working length determinations were done with size #10 and size #15 K-files (VDW, Munich, Germany) using the apex locator integrated into an endodontic motor (VDW Gold Reciproc, Munich, Germany), radiographically verified and controlled throughout the preparation. Following working length determination, glide path preparation was performed manually with size 15 hand file (VDW).

**RBlue Group**

Mesial canals of mandibular molars R25 (size 25, .08 taper) and mandibular premolars were prepared using Reciproc Blue single file system (RBlue, VDW, Munich, Germany) R25 (size 25, .08 taper) files. Distal canals of mandibular molars were prepared using R25 (size 25, .08 taper) and R40 (size 40, .06 taper) files in accordance with the manufacturer’s recommendations (preprogrammed Reciproc ALL Mode). After three pecking motions, instrument were removed from the canals, debris on file removed with alcohol impregnated gauze. A total of 28 teeth were treated

in this group. Each RBlue file was used up to four canals and replaced with new ones (13).

**HEDM Group**

HyFlex EDM (Coltene/Whaledent) files were used in a total of 29 patients. HEDM One file (size 25, .08 taper) were used in the mesial canals of mandibular molars and premolar teeth. HEDM size 25 and HEDM finishing file (size 40, .04 taper) were used in the distal canals of mandibular molar teeth. HEDM files were used in the rotary mode of the endodontic motor in accordance with the manufacturer’s recommendations (500 rpm, 2.5 Ncm), and the files that did not return to their original shape after the normal autoclave procedure were replaced with new ones.

**Control Group**

In the control group, mesial canals of the mandibular molars and mandibular premolars were done with an apical width of ISO size 25 and the distal canals apical width of ISO size 40 in accordance with the step back technique and balanced-forced motion with manual stainless steel K-type files (VDW). The coronal two-thirds of the teeth were first enlarged with size 1, 2 and 3 Gates-Glidden burs after the glide path achieved with size 15 file. All hand files were used up to 4 canals, and the files with deformation signs were replaced with new ones. A total of 15 teeth were prepared in the control group.

After each file removal from the root canals, canals were irrigated with 3 ml of 5 % NaOCl solution (Werax, İzmir, Turkey) using 31 G side-vented irrigation needle (NaviTip; Ultradent, South Jordan, UT) placing 1 mm short of the working length for disinfection and debris removal. At least 15 ml NaOCl for used for one canal for standardization. Canals were checked for corresponded gutta-percha cone fitting with radiologically and final irrigation procedure was conducted using 2 ml of 17% etilendiamin tetra acetic acid (EDTA) for 1 min followed by 2 ml of saline solution for each canal. After the canals were dried with sterile paper points, the canal fillings were completed in the same visit with gutta-percha cones of the same brand and equivalent to the master apical file and root canal sealer (AH Plus; Dentsply-Sirona, Ballaigues, Switzerland) using lateral compaction technique. The fillings of the teeth were temporarily made with glass ionomer cement and occlusal reduction was applied to the teeth. After the completion of the root canal treatments, the patients were informed about the VRS scale (verbal rating scale) and a paper containing 4 scales was given to the patients to take home and fill in after 24, 48, 72 hours and 7 days. VRS scales were consisted of 4 level of pain; 0: no pain or discomfort, 1: mild pain that does not require analgesic intake, 2: moderate pain without the need of analgesic, 3: severe pain that a situation where analgesics have little or no effect, with pain so that patient cannot do any activities and need to lie down and rest (14). The patients were prescribed 600 mg of ibuprofen to be used every 6 hours in case of severe and unbearable pain, and an additional 1000 mg of acetaminephene when ibuprofen was insufficient. Patients were also asked to record the number of drugs they used.

*Statistical analysis*

Data were analyzed using SPSS 21.0 (SPSS Inc., Chicago, IL). The Shapiro-wilk test was used to determine whether the data were normally distributed, and the age-related data between the groups and VRS scores at different periods were examined with the Kruskal Wallis test. The gender differences between the groups and the presence of pain and analgesic intake in different time periods were examined with the Chi-Square test. Statistical differences were examined at  $p < 0.05$ .

**RESULTS**

Table 1 shows the demographic data of the groups and the prevalence and percentages of postoperative pain at 24, 48, 72h and 7 days. There was no statistically difference in age and gender distribution of the patients between the groups ( $p = 0.673$  and  $p = 0.485$ , respectively). While significant differences were observed in the prevalence of pain felt between the groups at 24 hours and 48 hours ( $p < 0.001$ , and  $p = 0.029$ , respectively), no difference was found between the groups after 72 hours and 7th day ( $p = 0.116$ , and  $p > 0.05$ , respectively). The highest postoperative pain prevalence at 24 and 48 hours was found in the RBlue group. VRS scores at different time periods were shown in Table 2. Since no pain was felt in any group on the 7th day, it was not analysed and included in the table.

The highest postoperative pain scores were found in the RBlue group at 24, 48 and 72 hours, and the pain scores at these levels were significantly lower in the HEDM and control group ( $p < 0.001$ ,  $p = 0.002$ , and  $p = 0.028$ , respectively). Pain scores of HEDM and control groups did not differ in all time periods ( $p > 0.05$ ). There was no difference between the groups in terms of using analgesic, and 3 patients reported that they drank analgesic within 24 hours ( $p > 0.05$ ).

Table 2: VRS scores of postoperative pain at different time periods for each groups.

Groups	Median (Minimum-Maximum)	P value
<b>Postoperative pain at 24 h</b>		
RBlue	3.00 (1.00-3.00) <sup>a</sup>	0.001
HEDM	0.00 (0.00-1.00) <sup>b</sup>	
Control	0.00 (0.00-3.00) <sup>b</sup>	
<b>Postoperative pain at 48 h</b>		
RBlue	0.00 (0.00-3.00) <sup>a</sup>	0.002
HEDM	0.00 (0.00-1.00) <sup>b</sup>	
Control	0.00 (0.00-3.00) <sup>b</sup>	
<b>Postoperative pain at 72 h</b>		
RBlue	0.00 (0.00-3.00) <sup>a</sup>	0.028
HEDM	0.00 (0.00-3.00) <sup>b</sup>	
Control	0.00 (0.00-0.00) <sup>b</sup>	

*a-b: There is no difference between groups with the same uppercase letters.*

**DISCUSSION**

Many factors have been defined that may affect the occurrence of postoperative pain after endodontic therapy. (15) Postoperative pain may result from microbial, chemical or mechanical injury due to usage of motor-driven files or manual file to the pulp and periapical tissues (16). Studies have shown that preparing root canals with a single file reduces the preparation time, cost and risk of cross-infection (6, 17). Despite all these advantages, preparation of root canals with a single file is suspected to increase apical debris extrusion or postoperative pain (18). Therefore, in this study, it was aimed to investigate the incidence of postoperative pain caused by RBlue and HEDM, the current single file systems working with different kinematics, in teeth with necrotic pulp. In this study, it was preferred to perform root canal treatment in a single visit, since the patients' root canal treatment caused short term and less postoperative pain compared to multiple visits and similar healing rates (11) and the patients were asymptomatic at the beginning of the treatment. Mandibular posterior teeth were included in this study, as more postoperative pain was reported in mandibular teeth than in maxillary teeth (19). Occlusal reduction was performed on teeth that underwent root canal treatment. In the most recent study of Ahmet et al. (20) It has been observed that occlusal reduction reduces the risk of moderate and severe pain by 40% after 12 hours in teeth with percussion sensitivity. The pulpal and periapical condition before treatment is also one of the most important conditions that can af-

Table 1: Median (minimum and maximum) values for the data related to age, frequency and percentage for gender and experienced pain according to the groups at different time intervals.

	RBlue	HEDM	Control	P value
<b>Demographics</b>				
<b>Age</b>	32.50 (16-70)	29.00 (16-68)	24.00 (16-56)	0.673 <sup>a</sup>
<b>Sex</b>				
<b>Male</b>	12 (42.9)	17 (58.6)	8 (53.3)	0.485 <sup>b</sup>
<b>Female</b>	16 (57.1)	12 (41.4)	7 (46.7)	
<b>Pain</b>				
<b>Postoperative pain at 24 h</b>	28 (100.0)	1 (3.4)	1 (6.7)	0.001 <sup>b</sup>
<b>Postoperative pain at 48 h</b>	10 (35.7)	1 (3.4)	1 (6.7)	0.029 <sup>b</sup>
<b>Postoperative pain at 72 h</b>	6 (21.4)	1 (3.4)	0 (0.0)	0.116 <sup>b</sup>
<b>Postoperative pain at 7 days</b>	0 (0.0)	0 (0.0)	0 (0.0)	0.05 <sup>b</sup>

a: Kruskal Wallis test b: Chi-square test

fect postoperative pain. Among the patients who could benefit most from occlusal reduction, the absence of periapical lesion, which was one of the inclusion criteria in this study, was counted (21). Since many factors can be effective in the formation of postoperative pain, many factors such as the amount of irrigation solution, preoperative inclusion and exclusion criterias, and canal filling materials and technique have been standardized in the present study. Since it is known that it can be effective in postoperative pain (16), the length of the canal was determined simultaneously during the preparation and the damage to the periapical tissues was tried to be kept as minimal as possible. According to the results obtained from this study, the highest incidence of pain and the highest VRS scores were seen in RBlue files. Therefore, the null hypothesis of the study was rejected. It has been reported that the preparation technique and the file systems used can trigger inflammation in the periodontium by causing neuropeptide expression (22). When single file systems operating with reciprocating motion were first introduced, Gambarini et al. have reported that these files will cause more debris extrusion and postoperative pain compared to multi-file systems (18). But in their systematic review and meta-analysis, Caviedes-Bucheli et al. (22) reported that the type of movement and instrument design may be more effective in postoperative pain than the number of instruments used. In this study, more than one file was used in the control group and the incidence of postoperative pain was lower than RBlue files. Although it is thought that manual files may cause more postoperative pain (23), the careful use of manual files with a balanced force technique similar to reciprocal RBlue files working with asymmetrical rotation movement suggests that the difference between these files may be mostly due to design and geometric reasons. The use of Gates Glidden burs for coronal enlargement before apical enlargement with manual files with the modified method may have caused less extrusion of necrotic tissue contents into the periapical area and less pain felt in this group. Çiçek et al. (24) reported that in their studies which they used the modified step-back technique, the preparation with manual files resulted in less postoperative pain than the files working with rotary and reciprocating motion. The type of motion of the file used may also affect the incidence of postoperative pain. Collobarated

to our findings, Hou et al. (25) also demonstrated higher post operative pain with reciprocating system in single visit endodontic treatment. Root canal preparation procedures may initiate postoperative symptoms by extruding necrosis products, microorganisms and canal contents to the periapical region (26). In their study examining the amount of apical extrusion of debris, Uslu et al. (27) reported that RBlue extruded more debris than HEDM and manual files. It is thought that the rotational motion may cause the debris to accumulate in the flutes of the files, allowing the debris to move outward from the root canals. The different movement types of NiTi files used in the study may explain the increased postoperative pain caused by RBlue files. More postoperative pain in RBlue files may also be related to the metallurgical and geometric properties of the files. The higher flexibility of HEDM files than RBlue files may be due to alloy differences, transformation temperatures and differences in production methods. The greater material removal during cutting due to the horizontal cross-section of the RBlue files (28), may also have resulted in more extrusion of debris and postoperative pain. In their study Karatekin et al. (29) reported that C1 type canals instrumented with RBlue or HEDM, Rblue has shown to be more aggressive than HEDM in groove area. When examined in terms of cross-section, it is known that files with S-shaped cross-section (RBlue) cut more dentin than files with different horizontal cross-sections (30). The fact that HEDM files have different cross-sectional design along their length may also have enabled these files to better transport debris coronally. Statistical differences in the incidence of postoperative pain were observed within the first 48 hours. This result is in agreement with other studies reporting that postobturation pain lasts up to 48 hours. (15, 20, 31). Consistently, a systematic review reported that pain intensity and incidence would decrease after 2 days of treatment (31). Despite all these results, the fact that only 3 patients in total used analgesics made us think that this pain did not last long, although the patients reported that they felt severe pain. For this reason, care should be taken when adapting the difference between the groups to the clinic, and the duration of pain should be examined in future postoperative pain studies, and inquiries and analyzes should be made on the quality of life.

## CONCLUSION

RBlue files working with reciprocating motion caused much more postoperative pain than HEDM files and manual files. Kinematics and geometric properties of novel single file systems seems to be effective on postoperative pain.

## Ethics

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

## Authorship Contributions

All authors have contributed equally to the work

## Declaration of competing interest

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

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