



Postoperative Pain Following Single-visit Root Canal Treatment with Reciproc Blue and HyFlex EDM Instrumentation; A Prospective Randomized Clinical Trial

Reciproc Blue ve HyFlex EDM Enstrümantasyonu ile Tek Seans Kök Kanal Tedavisini Takiben Postoperatif Ağrı; Prospektif Randomize Bir Klinik Çalışma

© Nimet Gençöglü¹, © Anıl Özgün Karatekin¹, © Mustafa Gündoğar²

¹Marmara University Faculty of Dentistry, Department of Endodontics, İstanbul, Turkey

²Medipol University Faculty of Dentistry, Department of Endodontics, İstanbul, Turkey

Abstract

Objective: This study aimed to investigate the efficacy of novel Reciproc Blue (RBlue) and HyFlex EDM (HEDM) single file systems on postoperative pain (POP) after single-visit root canal treatment.

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

Results: POP at 24 h and 48 h was statistically higher in the RBlue group than in the HEDM and control groups ($p<0.05$). After 72 h, the incidence of POP decreased and, on the 7th day, none of the patients reported pain ($p>0.05$).

Conclusion: RBlue files working with reciprocating motion caused much more POP than HEDM files and manual files during the first 48 h of the postoperative period.

Keywords: Analgesic intake, continuous rotation, endodontics, reciprocation, root canal treatment

Öz

Amaç: Bu çalışmanın amacı, yeni Reciproc Blue (RBlue) ve HyFlex EDM (HEDM) eğelerinin tek seans kanal tedavisi sonrası postoperatif ağrı üzerindeki etkinliğini araştırmaktır.

Gereç ve Yöntemler: 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 dişler hazırlandı. Sözel derecelendirme ölçeği kullanılarak ağrı varlığı ve analjezik alımı 24 saat, 48 saat, 72 saat ve 7 gün sonra kaydedildi.

Bulgular: Postoperatif ağrı 24. ve 48. saatte, RBlue grubunda HEDM ve kontrol gruplarına göre istatistiksel olarak daha yüksekti ($p<0.05$). Yetmiş iki saat sonra postoperatif ağrı insidansı azaldı ve 7. günde hiçbir hasta ağrı bildirmedi ($p>0.05$).

Sonuç: Resiprokal hareketle çalışan RBlue eğeleri, HEDM eğelerine ve el eğesine göre ilk 48 saat içerisinde çok daha fazla ameliyat sonrası ağrıya neden olmuştur.

Anahtar Kelimeler: Analjezik alımı, devamlı rotasyon, endodonti, resiprokal, kök kanal tedavisi

Address for Correspondence/Yazışma Adresi: Anıl Özgün Karatekin, MD, Marmara University Faculty of Dentistry, Department of Endodontics, İstanbul, Turkey
Phone: +90 535 586 47 95 **E-mail:** dtogunkaratekin@gmail.com
ORCID ID: orcid.org/0000-0001-7383-7037

Received/Geliş Tarihi: 07.06.2022
Accepted/Kabul Tarihi: 10.03.2023



Introduction

Postoperative pain (POP) may occur after root canal treatment (RCT) even if there is no preoperative symptoms and its prevalence was reported to be 25-40% (1). The most probable risk factors related to POP were found in teeth with asymptomatic necrotic pulp and periapical lesion, however the etiology is reported to be multifactorial mostly due physical damage by procedural factors and the host immune response (2). Debris extrusion is one of the procedural etiological factors associated with POP (3), preparation technique and the design of the file may also be effective in extrusion of debris and in POP (4).

Following the recommendation to prepare root canals using a single file with reciprocating motion (5), many companies have introduced single file systems (SFS) in different designs and motions.

Single visit RCT with SFS takes less time, prevents the root canals from contamination between sessions and reduces the number of anesthesia, instruments and appointments, creating less stress for the patient (6). It has been reported that the recovery rates after single and multiple visit RCT are similar, but patients feel less POP after single visit RCT (7).

SFS with continuous rotation or reciprocation produced with novel technologies have given rise to the need to examine the effectiveness of these instruments after single visit treatment in necrotic teeth with a high incidence of POP. Therefore, in this study, it was aimed to examine the effectiveness of current SFS working with different kinematics on POP in teeth with asymptomatic necrotic pulp. The null hypothesis of the study is that there would be no difference between the incidence of POP in the new generation file systems examined.

Materials and Methods

Sample Selection

Minimum required sample size were determined for each groups using a power analysis software (G*Power 3.1 software; Heinrich Heine University, Dusseldorf, Germany) based on results of a previous study (8). 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.

Standards of Reporting Trials Guidelines were followed in this study. After Marmara University Faculty of Dentistry Clinical Research Ethics Committee approval (decision no: 2017-147, date: 28.12.2017), a total of 62 patients who referred to the Endodontic Department of Marmara University 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 anti-inflammatory drugs (NSAIDs).
- 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.

Pregnant or lactating patients, patients using antibiotics, steroids or NSAIDs and allergic to any of these drugs, patients symptomatic and sensitive to percussion and palpation, patients with traumatic occlusion and bruxism and patients with teeth which were previously treated, associated with resorption, calcification, periodontal disease and mobility more than grade I, open apex, severe damage were excluded.

Patients who met the inclusion criterias were informed in detail about the procedures and treatment groups, and after their informed consent was obtained, RCTs 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 Reciproc Blue (RBlue), 30 HEDM and 15 manual 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.

Treatment Protocols

RCTs of the teeth were 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 #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, glidepath preparation was performed manually with size #15 hand file (VDW).

RBlue and HyFlex EDM Group

Mandibular premolars and mesial canals of mandibular molars and were prepared using RBlue (VDW, Munich, Germany) R25 files or HyFlex EDM (HEDM) (Coltène/Whaledent) files. Distal canals of mandibular molars were prepared using RBlue R25 and R40 files or HEDM size 25 and HEDM finishing file according to manufacturer's recommendations (preprogrammed Reciproc ALL Mode/rotary mode 500 rpm, 2.5 Ncm). A total of 28 teeth were treated in RBlue and 29 teeth in HEDM group consecutively. Each RBlue and HEDM file was used up to four canals and replaced with new ones (9).

Control Group

Mandibular premolars and mesial canals of the mandibular molars and were prepared to apical width of ISO size 25 and distal canals of mandibular molars to size 40 using step back technique and balanced-forced motion with manual stainless steel K-type files (VDW). All hand files were used up to 4 canals. A total of 15 teeth were prepared.

After each file removal from the root canals, canals were irrigated with 3 mL of 5% NaOCl (Werax, İzmir, Turkey) using 31 G side-vented needle (NaviTip; Ultradent, South Jordan, UT). At least 15 mL NaOCl was used per canal for standardization. Final irrigation was conducted using 2 mL of 17% ethylenediaminetetraacetic acid 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 equivalent to the master apical file and root canal sealer (AH Plus; Dentsply-Sirona, Ballaigues, Switzerland) using lateral compaction technique. Restorations were temporarily made with glass ionomer cement and occlusal reduction was applied. After the completion of the RCTs, the patients were informed about the verbal rating scale (VRS) 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 (0-4) (10). 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 acetaminophene 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 $p < 0.05$.

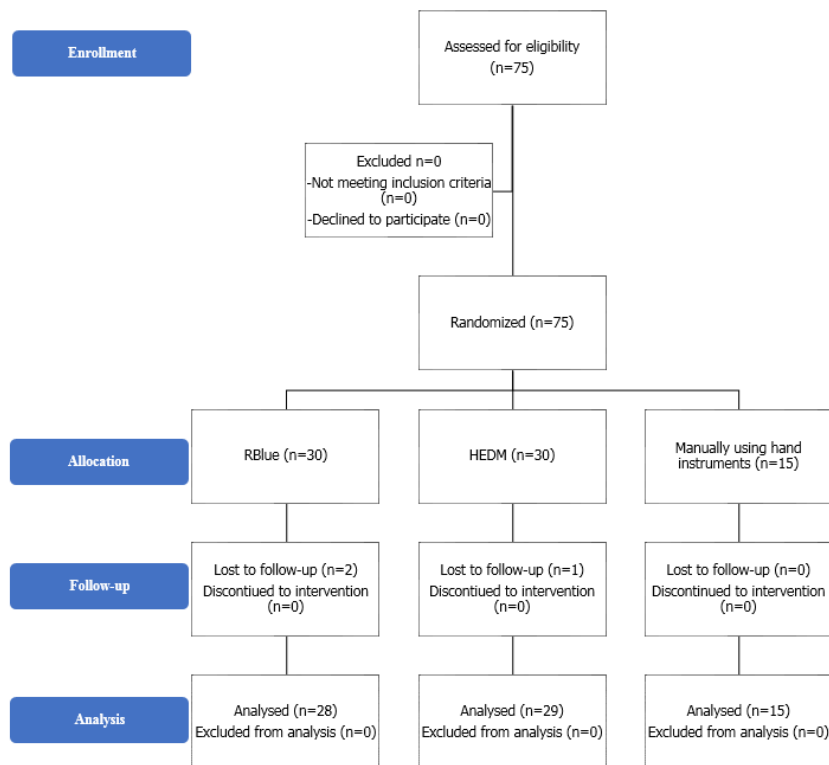


Figure 1. CONSORT Flow diagram for randomized clinical trials

HEDM: HyFlex EDM

Results

Table 1 shows the demographic data of the groups and the prevalence and percentages of POP at 24, 48, 72 h 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 POP 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 POP 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 ($p>0.05$).

Discussion

POP may result from microbial, chemical or mechanical injury to the pulp and periapical tissues due to usage of motor-driven files or manual file (11). Studies have shown that preparing root canals with a single file reduces the

Table 1. Descriptive data for demographic and pain related values

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

^aKruskal-Wallis, ^bChi-square (χ^2) test, HEDM: HyFlex EDM, POP: Postoperative pain

Table 2. VRS scores of POP at different time periods for each groups

Groups	Median (Minimum-Maximum)	p-value
POP at 24 h		
RBlue	3.00 (1.00-3.00) ^a	<0.001
HEDM	0.00 (0.00-1.00) ^b	
Control	0.00 (0.00-3.00) ^b	
POP at 48 h		
RBlue	0.00 (0.00-3.00) ^a	0.002
HEDM	0.00 (0.00-1.00) ^b	
Control	0.00 (0.00-3.00) ^b	
POP at 72 h		
RBlue	0.00 (0.00-3.00) ^a	0.028
HEDM	0.00 (0.00-3.00) ^b	
Control	0.00 (0.00-0.00) ^b	

^{a-b}: No difference between groups with the same uppercase letters, HEDM: HyFlex EDM, POP: Postoperative pain

^{a-b}: No difference between groups with the same uppercase letters, HEDM: HyFlex EDM, POP: Postoperative pain

preparation time, cost and risk of cross-infection (5). Despite all these advantages, preparation of root canals with a single file is thought to increase apical debris extrusion or POP (12). Therefore, in this study, the incidence of POP caused by RBlue and HEDM, the current SFS working with different kinematics, in teeth with necrotic pulp was investigated.

In this study, it was preferred to perform RCT in a single visit, since in this approach the patients' RCT caused less POP compared to multiple visits with similar healing rates (7). Mandibular posterior teeth were included in this study, as more POP was reported in mandibular teeth than in maxillary teeth (13). Occlusal reduction was performed on teeth that underwent RCT according to the suggestion of Ahmed et al. (14). Many factors (the amount of irrigation solution, preoperative inclusion and exclusion criterias, and canal filling materials and technique) which can be effective in the formation of POP have been standardized in the present study. Since it is known that damage to periapical tissues could be contributing factor to POP (11), the length of the canal was determined simultaneously during the preparation to keep the damage to the periapical tissues minimal.

In this study, the highest incidence of pain and the VRS scores were in RBlue files. Therefore, the null hypothesis was rejected. It has been reported that the preparation technique and the file systems can trigger inflammation in the periodontium by causing neuropeptide expression (15). In their systematic review and meta-analysis, Caviedes-Bucheli et al. (15) reported that the type of movement and instrument design may be more effective in POP than the number of instruments used. In this study, more than one file was used in the control group and the incidence of POP was lower than RBlue files. Although it is thought that manual files may cause more POP (16), the difference of POP between control group and RBlue may be mostly resulting from file designs and geometric reasons (17) considering manual files were used with a balanced force technique similar to asymmetrical rotation movement of RBlue files.

The motion type of the file may also affect the incidence of POP. Consistent with our findings, Hou et al. (18) also demonstrated higher POP 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 (19). In their study examining the amount of apical extrusion of debris, Uslu et al. (20) 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 POP caused by RBlue files.

More POP in RBlue files may also be related to the metallurgical and geometric properties of the files. The greater material removal during cutting due to the

horizontal cross-section of the RBlue files (21), may also have resulted in more extrusion of debris and POP. In their study Karatekin et al. (22) reported that, RBlue has shown to be more aggressive than HEDM in groove area of 3D printed teeth with C1 type canals. It is known that files with S-shaped cross-section (RBlue) cut more dentin than files with different horizontal cross-sections (23). 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 POP were observed within the first 48 hours. In literature there are studies reporting that postobturation pain lasts up to 48 hours (14,24,25) and would decrease after 2 days of treatment (24).

Further clinical studies should investigate the etiopathological causes of pain decrease after 48 hours of postoperative period and quality of life assessment during postoperative period.

Conclusion

RBlue files working with reciprocating motion caused much more POP than HEDM files and manual files for the first 48 hour of postoperative period. Kinematics and geometric properties of novel SFS seems to be effective on POP.

Ethics

Ethics Committee Approval: The ethics committee approval of the study was obtained from Marmara University Faculty of Dentistry Clinical Research Ethics Committee (decision no: 2017-147, date: 28.12.2017).

Informed Consent: Informed consent was obtained from all individual participants included in the study.

Authorship Contributions

Surgical and Medical Practices: N.G., A.Ö.K., Concept: N.G., A.Ö.K., M.G., Design: N.G., A.Ö.K., M.G., Data Collection or Processing: N.G., A.Ö.K., M.G., Analysis or Interpretation: N.G., A.Ö.K., M.G., Literature Search: N.G., A.Ö.K., M.G., Writing: N.G., A.Ö.K., M.G.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: This study was funded by Scientific Research Projects Support Commission of Marmara University (grant no. SAG-A-120917-0494).

References

1. Kherlakian D, Cunha RS, Ehrhardt IC, Zuolo ML, Kishen A, da Silveira Bueno CE. Comparison of the Incidence of Postoperative Pain after Using 2 Reciprocating Systems and a Continuous Rotary System: A Prospective Randomized Clinical Trial. *J Endod* 2016; 42: 171-6.
2. Shokraneh A, Ajami M, Farhadi N, Hosseini M, Rohani B. Postoperative endodontic pain of three different instrumentation techniques in asymptomatic necrotic mandibular molars with

- periapical lesion: a prospective, randomized, double-blind clinical trial. *Clin Oral Investig* 2017; 21: 413-8.
3. Seltzer S, Naidorf IJ. Flare-ups in endodontics: I. Etiological factors. 1985. *J Endod* 2004; 30: 476-81.
 4. Martins CM, De Souza Batista VE, Andolfatto Souza AC, Andrada AC, Mori GG, Gomes Filho JE. Reciprocating kinematics leads to lower incidences of postoperative pain than rotary kinematics after endodontic treatment: A systematic review and meta-analysis of randomized controlled trial. *J Conserv Dent* 2019; 22: 320-31.
 5. Yared G. Canal preparation using only one Ni-Ti rotary instrument: preliminary observations. *Int Endod J* 2008; 41: 339-44.
 6. Alomaym MAA, Aldohan MFM, Alharbi MJ, Alharbi NA. Single versus Multiple Sitting Endodontic Treatment: Incidence of Postoperative Pain - A Randomized Controlled Trial. *J Int Soc Prev Community Dent*. 2019; 9: 172-7.
 7. Su Y, Wang C, Ye L. Healing rate and post-obturation pain of single-versus multiple-visit endodontic treatment for infected root canals: a systematic review. *J Endod* 2011; 37: 125-32.
 8. Adigüzel M, Yılmaz K, Tüfenkçi P. Comparison of postoperative pain intensity after using reciprocating and continuous rotary glide path systems: a randomized clinical trial. *Restor Dent Endod* 2019; 44: e9.
 9. Bürklein S, Flüch S, Schäfer E. Shaping ability of reciprocating single-file systems in severely curved canals: WaveOne and Reciproc versus WaveOne Gold and Reciproc blue. *Odontology* 2019; 107: 96-102.
 10. Lopes LPB, Herkrath FJ, Vianna ECB, Gualberto Júnior EC, Marques AAF, Sponchiado Júnior EC. Effect of photobiomodulation therapy on postoperative pain after endodontic treatment: a randomized, controlled, clinical study. *Clin Oral Investig* 2019; 23: 285-92.
 11. AlOmari T, AlThobiti G, AlThobaiti S, AlOufi F, Masuadi E, Jamleh A. Incidence of postoperative pain after canal shaping by using Reciproc and Twisted File Adaptive systems: a prospective, randomized clinical trial. *Clin Oral Investig* 2020; 24: 2445-50.
 12. Gambarini G, Testarelli L, De Luca M, Milana V, Plotino G, Grande NM, et al. The influence of three different instrumentation techniques on the incidence of postoperative pain after endodontic treatment. *Ann Stomatol (Roma)* 2013; 4: 152-5.
 13. Nagendrababu V, Gutmann JL. Factors associated with postobturation pain following single-visit nonsurgical root canal treatment: A systematic review. *Quintessence Int* 2017; 48: 193-208.
 14. Ahmed YE, Emara RS, Sarhan SM, El Boghdadi RM, El-Bayoumi MAA, El-Far HMM, et al. Post-treatment endodontic pain following occlusal reduction in mandibular posterior teeth with symptomatic irreversible pulpitis and sensitivity to percussion: a single-centre randomized controlled trial. *Int Endod J* 2020; 53: 1170-80.
 15. Caviedes-Bucheli J, Castellanos F, Vasquez N, Ulate E, Munoz HR. The influence of two reciprocating single-file and two rotary-file systems on the apical extrusion of debris and its biological relationship with symptomatic apical periodontitis. A systematic review and meta-analysis. *Int Endod J* 2016; 49: 255-70.
 16. Sun C, Sun J, Tan M, Hu B, Gao X, Song J. Pain after root canal treatment with different instruments: A systematic review and meta-analysis. *Oral Dis* 2018; 24: 908-19.
 17. Çiçek E, Koçak MM, Koçak S, Sağlam BC, Türker SA. Postoperative pain intensity after using different instrumentation techniques: a randomized clinical study. *J Appl Oral Sci* 2017; 25: 20-6.
 18. Hou XM, Su Z, Hou BX. Post endodontic pain following single-visit root canal preparation with rotary vs reciprocating instruments: a meta-analysis of randomized clinical trials. *BMC Oral Health* 2017; 17: 86.
 19. Ruiz-Hubard EE, Gutmann JL, Wagner MJ. A quantitative assessment of canal debris forced periapically during root canal instrumentation using two different techniques. *J Endod* 1987; 13: 554-8.
 20. Uslu G, Özyürek T, Yılmaz K, Gündoğar M, Plotino G. Apically Extruded Debris during Root Canal Instrumentation with Reciproc Blue, HyFlex EDM, and XP-endo Shaper Nickel-titanium Files. *J Endod* 2018; 44: 856-9.
 21. S Silva RV, Alcalde MP, Horta MC, Rodrigues CT, Silveira FF, Duarte MA, et al. Root canal shaping of curved canals by Reciproc Blue system and Pro Taper Gold: A micro-computed tomographic study. *J Clin Exp Dent* 2021; 13: 112-8.
 22. Karatekin AÖ, Keleş A, Gençoğlu N. Comparison of continuous wave and cold lateral condensation filling techniques in 3D printed simulated C-shape canals instrumented with Reciproc Blue or Hyflex EDM. *PLoS One* 2019; 14: e0224793.
 23. P Plotino G, Giansiracusa Rubini A, Grande NM, Testarelli L, Gambarini G. Cutting efficiency of Reciproc and waveOne reciprocating instruments. *J Endod* 2014; 40: 1228-30.
 24. Pak JG, White SN. Pain prevalence and severity before, during, and after root canal treatment: a systematic review. *J Endod* 2011; 37: 429-38.
 25. Ng YL, Glennon JP, Setchell DJ, Gulabivala K. Prevalence of and factors affecting post-obturation pain in patients undergoing root canal treatment. *Int Endod J* 2004; 37: 381-91.