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Postoperative pain after endodontic treatment of mandibular molars with two different instrumentation techniques: A randomized clinical trial

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ABSTRACT

Background: This study compared postoperative pain after endodontic treatment of mandibular molars with asymptomatic irreversible pulpitis with the RaCe rotary system and the crown-down versus the step-down technique.

Materials and Methods: In this randomized clinical trial, 70 mandibular 1st and 2nd molars with asymptomatic irreversible pulpitis and normal periradicular state were randomly assigned to two groups for single-visit endodontic treatment with RaCe rotary system and the crown-down and the step-down technique (n = 35). Postoperative pain was assessed at 6, 12, 24, 48, 72, and 168 h postoperatively, using a Visual Analog Scale. Data were analyzed using SPSS 17 by repeated measures ANOVA, Chi-square test, independent sample t-test, and lLeast sSignificant Ddifference test. $P < 0.05$ was considered statistically significant.

Results: The two groups were not significantly different regarding the pain scores at any time point ($P > 0.05$). Within-group comparisons showed a significant reduction in pain score over time, starting from 12 to 168 h, postoperatively ($P < 0.05$).

Conclusion: The crown-down and step-down techniques had no significant difference regarding postoperative pain after endodontic treatment of mandibular molars with asymptomatic irreversible pulpitis with the RaCe rotary system.

Key Words: Clinical trial, mandible, molar, pain, root canal therapy

INTRODUCTION

Dental clinicians are always in search of strategies to minimize pain during and after the endodontic treatment of their patients.[1] Although evidence shows that a relatively small percentage of patients experience postendodontic pain, approximately 20% of patients report moderate-to-severe pain after endodontic treatment.[2-4] Moreover, a small percentage (1%–2%) suffer severe pain or flare-up after the procedure.[5]

The severity of postendodontic pain depends on several factors such as the gender of the patient, tooth type, the presence and size of the periapical lesion, and the number of treatment sessions.[6] Among others, the extrusion of infected debris into

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the periapical tissue is one of the main causes of postendodontic pain.[7] Evidence shows that almost all root canal instrumentation techniques cause apical extrusion of debris and irrigants into the periapical tissue. Nonetheless, some techniques push lower amounts of debris into the periapical region.[8-11] The amount of extruded debris plays an important role in the occurrence of postoperative pain, and techniques with lower amounts of extruded debris often cause lower levels of postendodontic pain.[12] Extrusion of debris depends on the type of file and technique of instrumentation. Rotary files usually cause lower extrusion of debris compared with manual instrumentation of the root canal system.[12] Furthermore, some *in vitro* studies showed that RaCe rotary system (FKG, La Chaux-de-Fonds, Switzerland) caused lower extrusion of debris compared with other commonly used rotary files.[12,13]

Due to its nonconvex triangular cross-sectional design and decreased core diameter, which allows for more space to transport debris toward the root canal orifices, the RaCe system possesses characteristics that may account for reduced debris extrusion. In addition, other characteristics of RaCe, such as its short twisted cutting edges interspersed with straight edges, may create favorable debris-transporting spaces.[14]

The crown-down technique is commonly used for root canal instrumentation with rotary files. This technique was first introduced by Marshall[15] in 1980. In this technique, the root canal space is instrumented corono-apically using a descending sequence of files from large to small diameter. Minimizing the contact of the instrument with the canal wall and decreasing the screw-in effect contributed to the increasing popularity of this technique as the main root canal instrumentation technique with rotary files.[16]

Recently, the manufacturer of the RaCe rotary system suggested the use of the step-down technique with this rotary system. The step-down technique was introduced by Goerig *et al*.[16] in 1982. In this technique, preparation of the root canal system initially starts from the coronal region, similar to the crown-down technique, and continues to the mid-root. Next, root canal instrumentation continues apico-coronally from the apex toward the mid-root.[17] This technique aims to minimize the apical extrusion of debris during instrumentation. In this technique, primary instrumentation of the coronal region creates a path for the coronal extrusion of debris, which is referred to as the cylinder effect.[17] Furthermore, the working length is significantly better preserved in this technique.[18,19] The last three advantages mentioned above are also applicable to the crown-down technique, and help in the reduction of postoperative pain, more efficient cleaning of the apical region, and achieving a hermetic apical seal.[20]

An *in vitro* study demonstrated that the step-down and crown-down techniques caused lower apical extrusion of debris compared with the step-back technique.[21] Thus, it appears that root canal instrumentation with RaCe rotary system and these two techniques may cause lower extrusion of debris and consequently lower postoperative pain. However, it is not known which one of these two techniques results in lower postoperative pain. Considering the increasing use of rotary instruments and lack of clinical studies on this topic, this study aimed to compare postoperative pain after root canal treatment of mandibular molars with asymptomatic irreversible pulpitis with the RaCe rotary system and the crown-down versus the step-down technique. The null hypothesis was that postoperative pain would not be significantly different after root canal treatment of mandibular molars with asymptomatic irreversible pulpitis with the RaCe rotary system and the crown-down and step-down techniques.

MATERIALS AND METHODS

This randomized clinical trial was conducted at the Endodontics Department of the School of Dentistry, Tabriz University of Medical Sciences. The study was approved by the Ethics Committee of this University (TBZMED.REC.1394.40) and registered in the Iranian Registry of Clinical Trials (IRCT2015022221177N1).

Trial design

A randomized clinical trial was conducted, in which mandibular molars with asymptomatic irreversible pulpitis underwent endodontic treatment with RaCe rotary system and the crown-down technique in Group 1 and RaCe rotary system and the step-down technique in Group 2. The results were reported in accordance with the guidelines of the Consolidated Standards of Reporting Trials.

Participants, eligibility criteria, and settings

The inclusion criteria were age over 18 years, having mandibular molar teeth with asymptomatic irreversible pulpitis that were restorable and

required nonemergency single-session endodontic treatment, normal periradicular state as confirmed by radiography, and no systemic condition.

The exclusion criteria were pregnancy, nursing, allergy to lidocaine, teeth under crowns, the absence of lip sign after anesthetic administration, no bleeding after pulpal exposure, intake of analgesic and antibiotic medications 12 h before treatment, severe labial or lingual malposition of the tooth complicating access cavity preparation, and requiring root canal therapy of two or more teeth in the same quadrant.

The sample consisted of 70 eligible patients with mandibular 1st and 2nd molars with asymptomatic irreversible pulpitis requiring endodontic treatment.

Interventions

After ensuring the general health of patients by taking a medical history, the pulp and periapical status of the teeth was assessed by thermal and electric tests, percussion, palpation, and radiography by the same operator. The patients were then briefed about the study, and written informed consent was obtained from them.

Local anesthesia was administered by an inferior alveolar nerve block with the injection of 1.8 mL lidocaine plus 1:80,000 epinephrine. Optimal depth of anesthesia was ensured by electric and thermal tests. In cases with an inadequate depth of anesthesia, supplemental injections were performed. After ensuring optimal depth of anesthesia, the access cavity was prepared, and the orifices were negotiated. Rubber dam isolation was performed, and the canals were instrumented by the crown-down or step-down technique based on the group allocation of the teeth, which was done randomly.

Crown-down technique

First, a glide path was created in the ½ to ¾ of the estimated working length (determined on the preoperative periapical radiograph using a #10 K-file). The calcified canals and those without a glide path were excluded and replaced. The coronal part of the root was prepared using #40/10% and #35/8% RaCe rotary files (FKG, La Chaux-de-Fonds, Switzerland) with gentle pressure. The working length was determined by an apex locator (Dentaport ZX, Morita, Japan) and radiographically confirmed. The middle third was instrumented with #30/6% file until no resistance was felt. For large distal canals, instrumentation was started with #35/4% or #40/4% file. A #30/4% file was used for the preparation of the apical third until no pressure was felt. If this file reached the working length, instrumentation was terminated here. If it was shorter than the working length, apical preparation was continued with a #25/6% file until no pressure was felt. If this file reached the working length, instrumentation was terminated here. If it was shorter than the working length, apical preparation was continued with a #25/4% file until no pressure was felt. If this file did not reach the working length, a #20/4% file was used for apical preparation to the working length. To standardize the final size of apical preparation, and considering the minimum diameter required to allow the irrigant to reach the apical region, all teeth were finally prepared with a #30/4% file. After using each file, the root canals were rinsed with 2.5% sodium hypochlorite (Taj Corp, Tehran, Iran) with a side-vented needle (Endo tip-PPH CERKAMED Wojciech Pawlowski). Next, the root canals were rinsed with 2 mL of ethylenediaminetetraacetic acid (EDTA) 17% (Endo-solution-PPH CERKAMED Wojciech Pawlowski) for 1 min with sonic activation (EDDY VDW, Munich, Germany), followed by 2 mL of 2.5% sodium hypochlorite (Taj Corp, Tehran, Iran) for 30 s with sonic activation, and finally, with 4 mL of saline for 1 min. The root canals were dried with paper points (Aria Dent, Iran).

Step-down technique

Glide path creation, preparation of coronal third, and working length determination were all performed similarly to the crown-down technique. For apical preparation, a #20/4% file was used to the working length. Apical preparation was completed using a #25/4% file. Cleaning and shaping of the apical third were performed by a #25/6% file. To standardize the final size of apical preparation, and considering the minimum diameter required to allow the irrigant to reach the apical region, all teeth were finally prepared with a #30/4% file. For large distal canals, root canal preparation was continued to #35/4% or #40/4%. The middle third was prepared using a #30/6% file. EDTA paste was used as a lubricant before using each file, and the canal was rinsed with 3 mL of 2.5% NaOCl after using each instrument.

After instrumentation, the root canals were dried with paper points (Aria Dent, Iran) and filled with gutta-percha and AH-plus sealer (Dentsply DeTrey, Germany) with a cold lateral compaction

technique. Finally, the access cavity was sealed with zonalin (Zoliran, Golchai, Iran).

Assessment of postoperative pain

The patients were provided with a visual analog scale (VAS) and were instructed (both orally and written) on how to quantify their pain level using this scale. The patients were requested to record their level of postoperative pain at 6, 12, 24, 72, 48, and 168 h after the procedure. Scores 0–4 mm indicated no pain, scores 5–44 mm indicated mild pain, scores 45–74 mm indicated moderate pain, and scores 75–100 mm indicated severe pain.[22]

Outcomes (primary and secondary)

The main objective of this study was to compare postoperative pain after root canal treatment of mandibular molars with asymptomatic irreversible pulpitis with the RaCe rotary system and the crown-down versus the step-down technique.

Sample size calculation

Since no similar previous study was available on this topic, a pilot study was carried out on 10 samples. Accordingly, assuming alpha = 0.05, study power of 80%, the mean difference of 6 units in pain intensity between the two groups, and the reduction in pain score from 18.40 ± 2.3–2.27 ± 0.85 in Group 1 to 17.13 ± 2.8–1.90 ± 0.34 in Group 2, the sample size was calculated to be 27 in each group (a total of 54). To compensate for the possible dropouts, 70 patients were enrolled.

Interim analyses and stopping guidelines

No interim analyses were performed, and no stopping guidelines were established.

Randomization

The patients were randomly assigned to two groups for root canal instrumentation with the crown-down or step-down technique using a table of random numbers.

Blinding

The patients were not aware of the technique used for their endodontic treatment. The statistician who assessed the VAS scores of patients and analyzed the data was also blinded to the group allocation of patients since the VAS forms were coded.

Statistical analysis

Data were analyzed using SPSS version 17 (SPSS Inc., Chicago, IL, USA) by repeated measures ANOVA, Chi-square test, independent sample *t*-test, and Least Significant Difference (LSD) test. $P < 0.05$ was considered statistically significant.

RESULTS

Participant flow

Of 70 patients, 8 were excluded due to reasons explained in the study flow diagram [Figure 1]. Thus, the final sample consisted of 62 patients including 29 males (46.8%) and 33 females (53.2%). There were 18 females (58.1%) and 13 males (41.9%) in the crown-down and 15 (48.4%) females and 16 males (51.6%) in the step-down group. The Chi-square test showed no significant difference in gender distribution between the two groups ($P = 0.445$). The mean age of patients was 29.3 ± 8.8 years (range: 18–49 years). The mean age was 29.1 ± 8.6 years in the crown-down and 29.5 ± 9.2 years in the step-down group. Independent sample *t*-test showed no significant difference in the mean age of the two groups ($P = 0.875$).

Harms

No patients were harmed during the study.

Group analyses

Table 1 presents the frequency of patients in the two groups based on tooth type and number of canals. The Chi-square test showed no significant difference between the two groups regarding the tooth type ($P = 0.610$) or frequency of different numbers of canals ($P = 0.579$).

Table 2 presents the mean VAS pain scores of patients in the two groups at different time points. Repeated measures ANOVA [Table 3] showed that the effect of the group on postoperative pain was not significant ($P = 0.558$). However, the time of assessment had a significant effect on postoperative pain ($P < 0.001$). The interaction effect of group

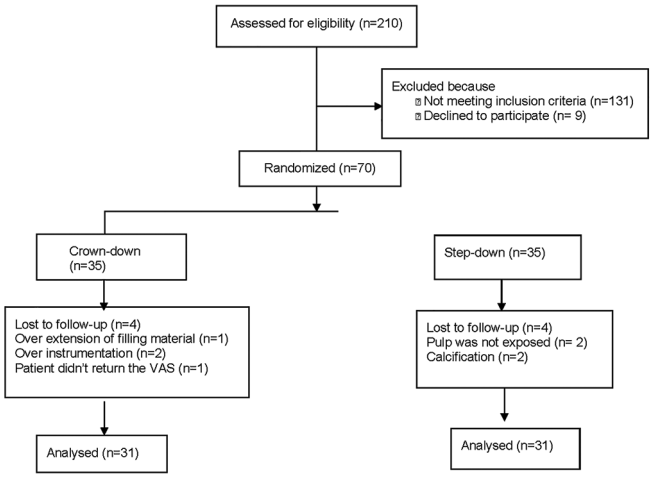

Figure 1: Flow diagram of the study. VAS: Visual Analog Scale.

and time of assessment on postoperative pain was not significant ($P = 0.741$). Accordingly, the two groups had no significant difference in postoperative pain ($P > 0.05$). However, within-group comparisons of pain scores at different time points by repeated measures ANOVA revealed significant differences ($P < 0.05$). Thus, pairwise comparisons of the time points were carried out by the LSD test [Table 4]. The results showed that the pain score significantly decreased over time; significant differences were noted between all the time points ($P < 0.05$) except for 12 and 24 h ($P > 0.05$).

Figure 2 shows the frequency of patients with no pain, mild pain, moderate pain, and severe pain in the two groups. The Chi-square test showed that the frequency of patients with different pain levels was not significantly different between the two groups at any time point ($P > 0.05$).

DISCUSSION

This study compared postoperative pain after root canal treatment of mandibular molars with asymptomatic irreversible pulpitis with the RaCe rotary system and the crown-down versus the step-down technique. The null hypothesis was that postoperative pain would not be significantly different between the two groups. VAS was used for self-reporting the level of pain by patients due to its high accuracy and reliability.[23] The results showed that the two groups were not significantly different regarding the recorded VAS pain scores at any of

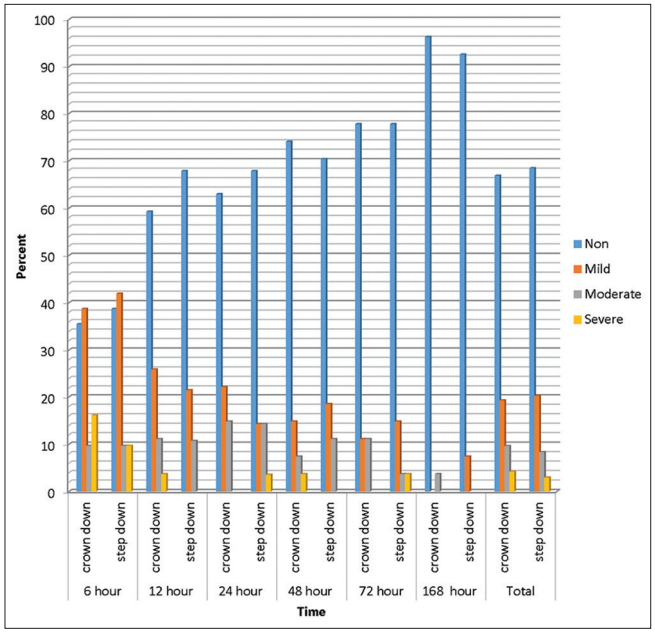

Figure 2: Frequency percentage of patients with no pain, mild pain, moderate pain, and severe pain in the two groups. No significant difference was noted in any category between the two groups at any time point ($P > 0.05$).

Table 1: Frequency of patients in the two groups based on tooth type and number of canals

Variable	Category, *n* (%)	Crown-down, *n* (%)	Step-down, *n* (%)
Tooth type	First molars	13 (41.9)	15 (48.4)
	Second molars	18 (58.1)	16 (51.6)
Number of canals	2	7 (22.6)	8 (29)
	3	20 (64.5)	16 (51.6)
	4	4 (12.9)	7 (19.4)

Table 2: Mean Visual Analog Scale pain scores of patients in the two groups at different time points

Assessment time (h)	Mean±SE*		
	Crown- down	Step- down	Total
6	4.2±20.6	3.2±15.8	3.7±18.2
12	4.1±16.6	3.1±12.4	3.6±14.5
24	3.8±14.9	3.1±11.9	3.5±13.4
48	3.9±11.4	3±10.3	3.4±10.9
72	3.4±8.9	3.2±7.8	3.3±8.4
168	1.5±2.4	0.8±1.9	1.2±2.1

*Since SD values were larger than the means, SE was reported instead of SD. SD: Standard deviation; SE: Standard error

Table 3: Results of repeated measures ANOVA

Variable	Df	*F*	*P*
Group	1	0.348	0.558
Assessment time	2.970	15.420	<0.001*
Interaction of group and time	2.970	0.414	0.741*

*Huynh-Feldt test. df: Degree of freedom

Table 4: Pairwise comparisons of the time points regarding pain score using the Least Significant Difference test

Time points (j, i) (h)	Mean difference (i−j)	*P**
6 and 12	3.71	0.023
6 and 24	4.85	0.016
6 and 48	7.38	0.003
6 and 72	9.89	0.001
6 and 168	16.1	<0.001
12 and 24	1.14-	0.251
14 and 48	3.68	0.033
12 and 72	0.618	0.011
12 and 168	12.4	<0.001
24 and 48	2.53	0.027
24 and 72	5.04	0.008
24 and 168	11.25	<0.001
48 and 72	2.50	0.04
48 and 168	8.71	<0.001
72 and 168	6.21	0.003

*: $P<0.05$ was considered statistically significant

the assessment time points ($P > 0.05$). Thus, the null hypothesis of the study was accepted. However, within-group comparisons showed a significant reduction in pain score over time, starting from 12 to 168 h, postoperatively ($P < 0.05$).

Evidence shows that patients often experience maximum pain in the early hours after endodontic treatment.[24] As time passes, the number of patients with moderate and severe pain decreases, and the number of patients with no or mild pain increases.[24] The same pattern was observed in the present study. Genet *et al*.[25] reported that the severe pain experienced by the majority of patients decreased and turned into mild pain in the first 3 days, postoperatively. A systematic review and meta-analysis on postendodontic pain demonstrated a significant reduction in postendodontic pain within 2 days after treatment.[26] In the present study, the trend of reduction in pain was significant in both groups (except for 12–24 h), and 60% and 70% of patients had no pain at 48 and 72 h after treatment, respectively.

Although Milani *et al*.[27] reported that the use of anti-biotics before root canal therapy has no effect on postoperative pain, Alsomadi and Al Habahbeh[28] reported that prophylactic anti-biotics reduce postoperative pain. Thus, one of the exclusion criteria in the present study was the administration of anti-biotics within 12 h before treatment.

Age, gender, tooth type, pulp status, the presence of sinus tract, preoperative sensitivity, and pain affect postendodontic pain.[25] The correlation between the incidence of postendodontic pain and some demographic criteria such as age and gender is still controversial. While a report showed the absence of correlation between the incidence of postoperative pain and the age and gender of the patient.[29] A report from El Mubarak *et al*.[30] showed that postoperative pain often occurs among patients with age ranging between 18 and 33 years old. Moreover, Azim *et al*.[31] stated that age is a strong predictor for flare-ups, especially in patients older than 50 years. This result correlates with the one obtained by Nair *et al*.[32] showing that patients in the age group of 40–60 years had a higher risk of developing flare-ups. Concerning the gender factor, some studies showed that women are more susceptible to developing flare-ups than men.[33,34] Reduced pain threshold is being observed in females than males.[35] Another report showed no correlation between gender and pain after endodontic treatment.[6] Endodontically treated mandibular molars are related to a high incidence of postoperative pain.[34] This can be attributed to the fact that the mandibular arch has a cortically thicker plate compared to the maxilla, especially at the level of molars. This, in turn, results in the accumulation of exudates in addition to lower blood circulation, which will lead to delayed healing.[36] On the contrary, other reports showed no significant association between the tooth type and the incidence of flare-ups after endodontic treatment.[29,32]

In the present study, the two groups had no significant difference regarding the mean age, gender, tooth type, and the number of canals, and all teeth had irreversible pulpitis and normal periapical status (ensured both clinically and radiographically). Furthermore, the same endodontist performed all the procedures. Thus, the two groups were only different in the technique of root canal instrumentation.

As mentioned earlier, the extrusion of debris through the apex during the chemomechanical preparation of the root canal system is the main cause of postoperative pain.[26,37] A number of factors affect the extrusion of debris such as the irrigation technique, concentration and volume of irrigant, final size of apical foramen, anatomy of apical constriction, duration of root canal cleaning, the technique of cleaning, and instrument design.[8,15-21,38] In the present study, the technique of irrigation, the amount and type of irrigant, and the final size of apical foramen were standardized in the two groups. Parirokh *et al*.[39] reported that 2.5% sodium hypochlorite caused lower extrusion of debris than 5.25% sodium hypochlorite. Thus, the former concentration was used for root canal irrigation in the present study. A new study comparing two varieties of irrigation needles found that side-vented needles are more effective than conventional open-ended needles at reducing postoperative pain.[40] Recently, Susila and Minu[41] demonstrated that mechanical active irrigation devices are advantageous in reducing postoperative pain and enhancing canal and isthmus cleanliness during endodontics compared to conventional irrigation. Along with EndoActivator, irrigation activation was effective in alleviating postoperative discomfort.[42] At 24 h, pain in teeth irrigated with side-port endodontic needles was found to be greater than pain in teeth irrigated with side-port endodontic needles and EDDY sonic activation.[43] Therefore, we used a side-vented needle with EDDY sonic activation in the present study.

The literature varies regarding the relationship between apical diameter and postoperative pain. Although Saini *et al*.[44] reported that enlargement of the apical foramen during root canal treatment increased the incidence and intensity of postoperative pain, a recent randomized clinical trial found that different apical preparation sizes have no significant effect on postoperative pain.[45] In the present study, all teeth were finally prepared with a #30/4% file.

Furthermore, it has been reported that mechanical allodynia (sensitivity to percussion) has a significant correlation with postendodontic pain and indicates abnormal periapical status.[46] It appears that periapical status can significantly affect postendodontic pain, which has not been addressed in the literature;[47] thus, the presence of periapical conditions was among the exclusion criteria in the present study. Furthermore, it appears that the presence of a natural barrier (periodontal ligament) at the apex, especially in the presence of sound lamina dura, and the absence of inflammatory conditions and periapical resorption create a different scenario clinically for extrusion of debris compared with *in vitro* conditions.[17] Extrusion of debris also depends on the design of cleaning instruments, which may explain the differences in postendodontic pain among patients.[11,39,48-50]

In the present study, the absence of a significant difference in postendodontic pain between the two groups may be due to one of the following two scenarios: (I) Despite the presence of a difference in the amount of debris produced, the presence of a natural barrier at the apex prevented the extrusion of debris, and minimized the difference between the two groups in extrusion of debris, and subsequent postoperative pain;[17] (II) Alternatively, no difference existed between the two groups in the amount of generated debris due to the use of RaCe file and its design in the two groups. The RaCe file has a smooth area between each two flutes, which is designed for the collection and coronal extrusion of debris to minimize their apical extrusion.[51] Several *in vitro* studies have demonstrated that RaCe rotary system causes lower extrusion of debris compared with other systems.[52,53] Al-Omari and Dummer[54] found no significant difference in the extrusion of debris among eight tested instrumentation techniques when one single type of file was used by the same operator. Gambarini *et al*.[7] compared root canal preparation with twisted files and two different instrumentation techniques and found no significant difference in the level of postoperative pain. It appears that file design has a more prominent effect than the cleaning method on the extrusion of debris and postoperative pain. Thus, the use of the RaCe system in both groups may explain the lack of a significant difference in postendodontic pain in the present study. Moreover, coronal flaring was performed before apical preparation in both groups in the present study, which could have enhanced the coronal extrusion of debris, and may explain no difference in postendodontic pain between the two groups.

In the present study, the patients were asked to record the exact time of analgesic intake if they had to take analgesics due to severe pain, similar to previous studies.[55-57] However, analysis of the pain scores after taking an analgesic would not yield accurate results; this issue has not been addressed in previous studies.[47,58,59] To solve this problem, in the present study, only the pain scores before taking an analgesic were included in statistical analysis, and the values recorded after analgesic intake were excluded from statistical analysis.

It should be noted that the present study was conducted on mandibular 1st and 2nd molars with asymptomatic irreversible pulpitis. Thus, the results cannot be generalized to other tooth types with different conditions. Future studies with a larger sample size are required on other teeth with symptomatic and asymptomatic irreversible pulpitis to further elucidate this topic.

CONCLUSION

The crown-down and step-down techniques had no significant difference regarding postoperative pain after endodontic treatment of mandibular molars with asymptomatic irreversible pulpitis with RaCe rotary system, and can both be used for this purpose.

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Conflicts of interest
The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or non-financial in this article.

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