Original Article

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Incidence of postoperative pain after using single continuous, single reciprocating, and full sequence continuous rotary file system: a prospective randomized clinical trial

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Background: Extrusion of debris is a major factor that results in postoperative pain during root canal treatment with various instruments and instrumentation techniques. Therefore, instrumentation techniques that extrude minimal debris into the periapical area while reducing pain are desirable. This study aimed to compare the incidence of postoperative pain and intake of analgesic medication (frequency and quantity) after endodontic treatment of mandibular posterior teeth using two single files and full-sequence continuous rotary systems with different kinematic motions.

Methods: Thirty-five of 105 patients were assigned equally to three groups according to the instrumentation system used: ProTaper Next (PN) X2, 25/06 (Dentsply, Maillefer, Ballaigues, Switzerland), One Shape (OS), #0.25/06 (Micro Mega, Besancon, France), and Wave One Gold (WG), Red - #0.25, 0.07 (Dentsply, Maillefer, Ballaigues, Switzerland). Five specialists were included in this study design; each professional prepared 21 teeth, and randomly selected 7 per instrument system. The VAS sheet ranging from 0 to 10 was used to record the initial and postoperative pains at 24, 48, and 72 h, and 7th day after single visit endodontic treatment in mandibular premolars and molars with a diagnosis of asymptomatic irreversible pulpitis with or without apical periodontitis. Postoperatively, an analgesic, ibuprofen 400 mg was administered for intolerable pain at a dose of 1 tablet for 6 h. The patients were asked over the telephone regarding postoperative pain at intervals of 24, 48, and 72 h, and 7th day using a visual analogue scale.

Result: There were no statistically significant differences among the PN, OS, and WG systems ($P > 0.05$) with regard to the incidence of postoperative pain at any of the four time points assessed.

Conclusion: The intensity of postoperative pain, frequency, and analgesic intake were similar across all three types of instrument systems; however, the reciprocating single file (WG) was associated with less postoperative pain than the full sequence continuous rotary file.

Keywords: Continuous Rotary; Instrumentation; Postoperative Pain; Reciprocation; Root Canal Therapy.

INTRODUCTION

Successful endodontic treatment depends on the accuracy of diagnosis, adequate mechanical preparation of the pulp space for the elimination of infection from the teeth, and management of the patient's symptoms [1]. The most commonly reported symptom that occurs immediately after root canal treatment is postoperative pain. It is defined as the sensation of discomfort after

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root canal therapy and is associated with an inflammatory response in the periapical tissues. Almost 50% of patients who have undergone endodontic treatment experience postoperative pain [2,3]. The factors that influence pain include age, sex, pulpal status before treatment, type of teeth, and operative factors such as microbial, chemical, and mechanical. Mechanical factors, such as instrumentation and irrigation of the root canal during root canal preparation, result in postoperative complications such as pain and swelling due to the extrusion of dentinal debris, pulpal tissue, microorganisms, and irrigating solutions into the periapical area. The extrusion of debris is associated with the inflammation of the periodontal ligament, which may be influenced by the motion design of the instrument. A clinical trial found that a continuous motion induced less pain than a reciprocating motion. This may be related to the amount of extruded debris, which was reported to be the lowest when continuous motion was used [4,5].

The extrusion of debris is a major factor that results in postoperative pain during root canal treatment using various instruments and instrumentation techniques. Therefore, the instrumentation techniques that extrude minimal debris into the periapical area and cause less pain are desirable [6].

Currently, various instruments and instrumentation techniques are being used to improve the shaping of canals during root canal preparation. Studies have shown that the prevalence of postoperative pain is greater when using rotary instrumentation with series of rotary files [7].

Currently, the rotary file systems are categorized into rotating and reciprocating files [8]. Two single-file (rotational) reciprocating systems, Reciproc (VDW, Munich, Germany) and Wave One (Dentsply/Maillefer), were introduced in 2010 by Dentsply based on the concept developed by Yared in 2008 which used the ProTaper F2 instrument (DentsplyMaillefer, Ballaigues, Switzerland) in reciprocation. Single-file systems have advantages such as decreased working time and less cross-contamination [9,10]. The evaluation and comparison of post-instrumentation pain with continuous rotary and reciprocating single-file systems with that of full-sequence continuous rotary file systems have not been studied much. Hence, this clinical trial was conducted to assess the incidence and intensity of postoperative pain with continuous rotary single-file systems using One Shape (Micro Mega, Besancon, France), reciprocating single-file system using Wave One Gold (DENTSPLY Tulsa, Dental Specialties, Johnson City, TN), and the full-sequence continuous rotary file system ProTaper Next (DENTSPLY Tulsa, Dental Specialties, Johnson City, TN). The null hypothesis was that the three different instruments according to the number of files and their motions showed no difference in postoperative pain. The alternate hypothesis was that there may be differences in postoperative pain among the three instruments and their motions.

METHODS

This single-center study was conducted at the endodontics unit after approval from the ethical committee (No. INT/IEC/2019/001765). The trial was registered in the Clinical Trial Registry of India (CTRI/2021/05/043472).

1. Patient selection

The samples were enrolled from the OPD and the sample size was calculated based on a previous study using Openepi software version 3.01. In each group, the 5% alpha error was fixed with a 10% drop out rate and a statistical power of 80%. Using the 24, 48, and 72 h, and 7th day post-instrumentation pain mean score and standard deviation from a previous study, the sample size was estimated to be 30 + 5 = 35 in each group. Mandibular premolars and molars of patients aged 20 and 60 years with fully mature roots were used in this study. The teeth were asymptomatic, with a diagnosis of irreversible pulpitis with or without apical periodontitis, which was determined using cold and electric pulp tests. The exclusion criteria were consumption of analgesics

within the past 24 h, root canal curvature > 25°, complex root canal morphology, retreatment cases, allergic reactions, sinus tract, resorption in the relevant tooth, periapical abscess, systemic diseases, and inability to understand the treatment procedure.

2. Randomization

Out of 185 participants, 80 were excluded and the remaining 105 participants were equally divided into three groups (35 participants in each group) of the instrumentation system. Five specialists were included in this study design to ensure random selection; each specialist had a chairside dark box containing seven of each yellow, blue, and green tokens. Each color represented one of the three systems of the study so that each specialist prepared 21 teeth, and selected seven per instrument system randomly. 1 in group OS and 3 in group WG did not received allocated intervention. Written informed consent was obtained from all the patients after explaining the treatment protocol and the benefits and risks of the treatment procedure. All patients received a copy of the questionnaire, including a VAS sheet ranging from 0 to 10, which was used to record pain assessment at 24, 48, and 72 h, and 7th day after a single visit endodontic treatment (Fig. 1).

3. Treatment protocol

After the administration of local anesthesia by an inferior alveolar nerve block with 4% articaine and 1:100000 adrenaline (Septanest; Saint-Maur-des-Fossés, France), the tooth was isolated with rubber dam. A conventional access cavity was initially prepared using a round diamond bur (ISO 016/25mm). After the initial preparation, an ENDO-Z Bur was used to create a funnel shape for easier access to the pulp chamber. The rounded, non-cutting, safe-ended tip of the ENDO-Z bur prevents penetration of the pulp chamber floor or root canal walls. A glide path was established using #8, #10, and #15 K hand files (Dentsply; Maillefer, Ballaigues, Switzerland). The working length was established with a Root ZX apex locator (J Morita Corp, Kyoto, Japan) using a 15 K file, and confirmation was accomplished using a digital intraoral periapical radiograph after subtracting 0.5 mm. An electric motor with a limited torque value (XsmartPlus, Dentsply, Maillefer, Ballaigues, Switzerland) was used to drive all instruments in each group. The rotational speed and torque limits were set according to the manufacturer's recommendations for each file system. The debris removal from the instruments was performed using an alcohol-soaked gauze, either immediately for ProTaper Next (PN) or after 3 in-out motions (pecking) for Wave One Gold and One Shape, as recommended by the manufacturer. Five milliliters of 2.5% NaOCl and 5 mL of 17% of EDTA solutions were used in between and after each instrument change in each group for irrigation of the canals. The instrumentation procedures for each group were performed as recommended by the respective manufacturer. The apical patency of the canal was maintained using a #10 K file, 1 mm beyond the registered working length.

1) ProTaper Next: a full sequence file continuous rotary system - (PN) group

The root canals were prepared for the final apical size of ProTaper Next X2, 25/06 (Dentsply, Maillefer, Ballaigues, Switzerland) after pre-flaring with the Sx file of ProTaper Universal and X1 (Dentsply, Maillefer, Ballaigues, Switzerland) at 300 rpm and 2.0 N cm torque.

2) One Shape: a single file continuous rotary system - (OS) group

For the One Shape group, using one file size of #0.25/06 taper (Micro Mega, Besancon, France), a gentle down to two-thirds of the working length was performed using an in-and-out motion (picking motion) without any pressure while performing an upward circumferential filling movement to pre-enlarge the canal. Using the aforementioned picking motion, the remaining canal was prepared until the working length was established.

3) Wave One Gold: a single file reciprocating rotary system - (WG) group

The final apical size was established as size primary

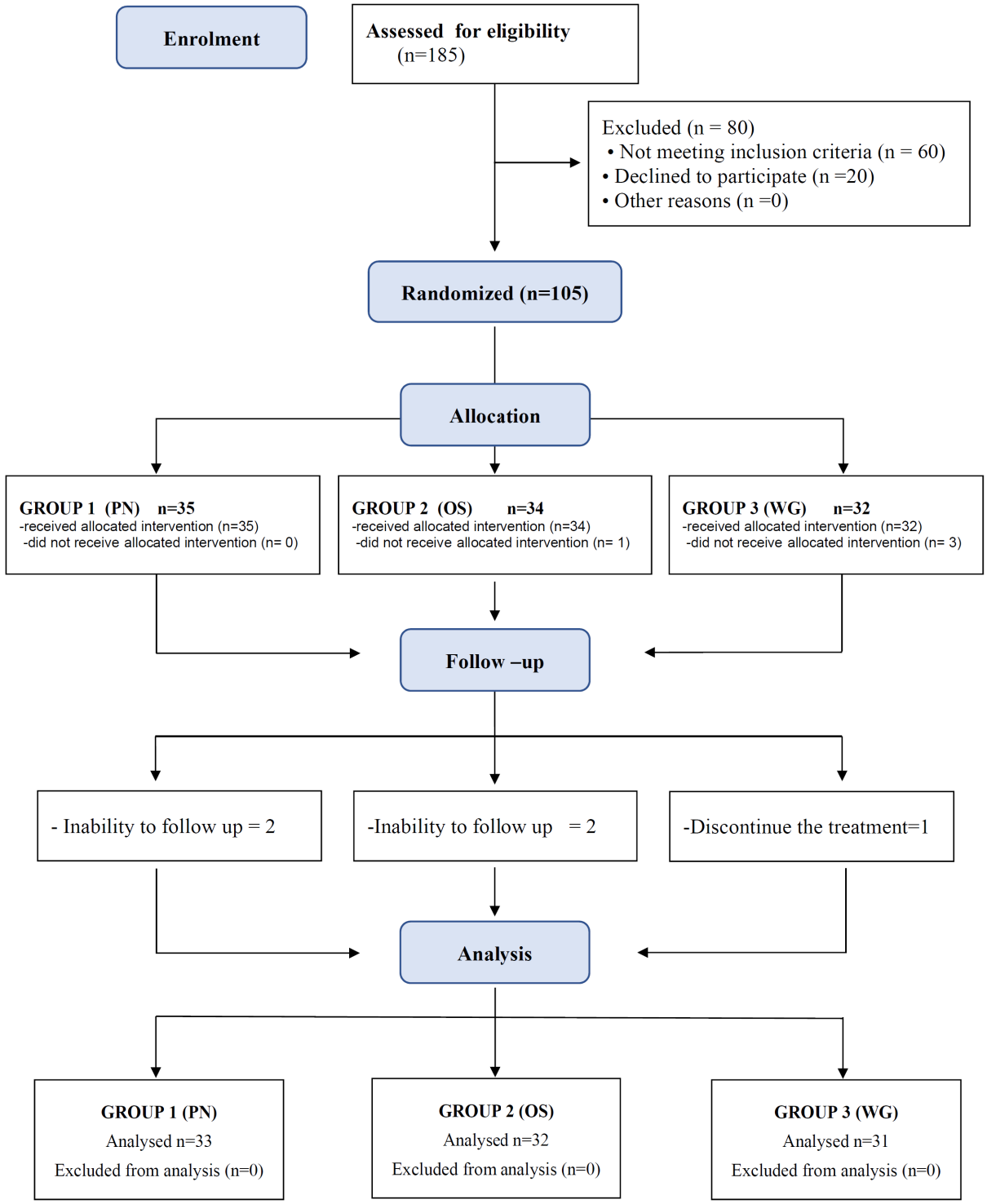

Fig. 1. A CONSORT diagram showing the study protocol. CONSORT, consolidated standards of reporting trials; n, number; OS, One Shape; PN, ProTaper Next; WG, Wave One Gold.

red #0.25, 0.07 variables taper (Dentsply, Maillefer, Ballaigues, Switzerland) for all canals of the molars. The root canal preparation was completed in each cervical, middle, and apical third with a length not exceeding 3 mm, using a three-in-and-out reciprocating motion, according to the manufacturer's instructions.

Table 1. Baseline Demographic and clinical details of each group

Baseline demographic and clinical features	Pro Taper Next (n = 33)	One shape (n = 32)	Wave One Gold (n = 31)	Total (n = 96)
Age	40.86 ± 7.30	39.51 ± 8.19	42.27 ± 11.30	P > 0.05
Male	21 (63.6%)	18 (56.2%)	23 (74.2%)	62
Female	12 (36.4%)	14 (43.8%)	08 (25.8%)	34
Mandibular premolars	10 (30.3%)	13 (40.6%)	13 (41.9%)	36
Mandibular molars	23 (69.7%)	18 (58.1%)	19 (59.4%)	60

Data are expressed as mean ± standard devation and number (%). n, number.

Table 2. Mean VAS score of post-operative pain at different time interval for each group

TIME	Mean ± SD			
	Pro Taper Next (n = 33)	One shape (n = 32)	Wave one Gold (n = 31)	P value
24 Hours	3.76 ± 2.05	2.02 ± 1.88	1.06 ± 0.92	0.029
48 Hours	2.97 ± 1.38	1.39 ± 0.81	0.61 ± 0.49	0.722
72 Hours	2.21 ± 1.34	1.30 ± 1.07	0.55 ± 0.38	0.308
7 days	0.01 ± 0.12	0.00 ± 0.00	0.00 ± 0.00	0.227

n, number; SD, standard deviation.

Finally, the canals were irrigated, rinsed with 0.9% normal saline solution, and dried with absorbent paper points; AH Plus sealer (Dentsply, Maillefer) and gutta-percha of respective instrument system were used for obturation followed by the coronal sealing with a dental adhesive and composite resin (3M, Dental Product, St. Paul, MN). A postoperative instruction for intolerable pain was given by a specialist who performed the treatment in all the patients: ibuprofen 400 mg at a dose of 1 tablet every 6 h.

4. Postoperative pain assessment

Postoperative pain in all patients was recorded using the VAS ranging from 0 to 10. Patients were instructed to record the value of perceived pain after 24, 48, and 72 h, and 7th day based on the VAS. Pain intensity on the VAS was categorized as no pain (0) or severe pain (7-10). The patients were also asked to record their analgesic intake (frequency and quantity). The patients were asked over the telephone by the outcome assessor, who was not a part of the treatment, to record their pain experience at 24, 48, and 72 h, and 7th day using a visual analog scale.

5. Statistical analysis

Statistical analysis was performed using the IBM SPSS Statistics (version 25.0; IBM Corp., Armonk, NY, USA). The levels of pain of the patients were summarized by using means and standard deviations at a 5% level of significance (P < 0.05). The chi-square test was used to analyze the data (sex, analgesic intake, and number of teeth).

RESULTS

A total of 96 patients, including 34 females and 62 males, completed a 7-day follow-up of the treatment protocol. The baseline demographic characteristics of the study groups are summarized in (Table 1). The demographic data showed non-significant results (P > 0.05). After the single-visit endodontic treatment, the postoperative pain was assessed at four time points: 24, 48, and 72 h, and 7th day using a visual analogue scale. All the instrumentation groups reported the highest mean postoperative pain scores at 24 h with a significant

Table 3. Frequency and percentage of analgesic intake according to groups

Analgesic intake	Pro Taper Next (n = 33)	One shape (n = 32)	Wave One gold (n = 31)	P value
None	16 (48.9)	14 (43.8)	11 (35.4)	0.307
Tablet 1	12 (36.4)	10 (31.3)	08 (25.8)	
Tablet 2	04 (12.1)	03 (9.4)	08 (25.8)	
Tablet 3	01 (3.0)	05 (15.7)	04 (12.9)	
Total	33	32	31	

Data are expressed as number (%). n, number.

decline thereafter (Table 2). However, these levels decreased 48 h, 72 h, and 7 days after endodontic therapy, with no statistically significant difference ($P > 0.05$) among the ProTaper Next, One Shape, and Wave One Gold (WG) systems with regard to the incidence of postoperative pain at any of the four time points assessed. One way ANOVA test was used to evaluate one variable i.e., the file type. A post-hoc analysis was performed using the Kruskal–Wallis test. Among the three groups assessed in terms of the frequency and quantity of analgesic intake, no statistically significant difference was found ($P > 0.05$, Table 3), and the analgesic intake was only confined to 48 h. None of the patients received antibiotics after the treatment. The percussion test was performed on the endodontically treated teeth 7 days after the clinical intervention in all groups.

DISCUSSION

The management of postoperative pain after the non-surgical endodontic intervention is very important, and the estimated range of incidence of pain in the literature is from 3 to 58%. Many variables, such as preoperative pain, pulpal status, and patient-specific factors, influence the sense of postoperative pain. It is even more challenging to relate the incidence of pain to its probable cause because of the subjective nature of pain evaluation [4,11,12]. Therefore, several strategies have been used for the evaluation of postoperative pain and to minimize it. These include patient communication about the procedure and postoperative effects, use of NSAIDs, occlusal reduction, reduction in instrument number, cross-sectional design, instrument techniques, and kinematic motion, which directly or indirectly affect the quantity of extruded debris, and ultimately, the incidence of postoperative pain [13,14].

With the available current data in the literature, all instrumentation techniques and instruments are associated with the extrusion of debris into the periapical tissue area. Based on the file motion, such as reciprocating and continuous rotary motion, and its effect on postoperative pain due to apical extrusion of debris, this study used the instrument system of full sequence files and a single file for the assessment of postoperative pain [5,7,15]. To date, no study has investigated and compared the impact of a single-file system using two different kinematic motions with a full-sequence rotary file with continuous rotary motion on postoperative pain.

In this study, only patients with asymptomatic non-vital pulp with a VAS score of no pain to mild pain (level 1) were selected. The VAS was selected based on its confirmed reliability for pain assessment [16]. The demographic variables and tooth-related factors in all the three groups (PN, OS, and WG) were similar and allocated by randomization. Ibuprofen 400 mg was the first choice of analgesic for control of postoperative pain [17,18]. Postoperative pain significantly decreased at 24, 48, and 72 h, and 7 days ($P < 0.05$), and no significant differences were observed. Our results are similar to those of previous studies, in which pain decreased significantly with the passage of time after a single-visit root canal treatment [19-21]. Park et al. in a systematic review found that the prevalence and intensity of pain decreased

significantly with time, from 40% in the first 24 h to 11% after 1 week, which are similar to this study [22].

Postoperative pain is a multifactorial phenomenon generally associated with the extrusion of debris during instrumentation, and the amount can vary depending on the instrument design, instrumentation, instrument kinematics, and filling materials [2,5,7]. Although in this study no statistically significant difference was observed between the groups, the single file system group, especially the WG using reciprocating motion, significantly decreased ($P < 0.05$) in the full sequence rotary file system of continuous rotary motion (PN). Similarly, Tunoco et al. observed less debris extrusion using a single-file system with reciprocating motion [23]. Eliasz et al. [24] demonstrated less extrusion of debris with the Wave One system than with the ProTaper Next and a twisted file (Kerr Endodontics Formely Axis/ Sybron Endo, Orange, CA, USA). Ehsani et al. reported less extension of debris with an instrument file system using reciprocating motion than with the ProTaper Universal and Mtwo systems [25]. In contrast to the above studies, Burkin et al. concluded that less debris extrusion resulted in less postoperative pain when using continuous rotary motion than when using reciprocating motion [26]. Lu et al. stated that instruments reciproc lead to significantly greater quantity of debris extrusion during retreatment than Mtwo [27]. Adiguzel M et al. [28] carried out instrumentation with XP-endo shape (XPS; FKG Dentaire SA, La Chauxade-Fonds, Switzerland), Reciproc Blue (REC. Blue; VDW, Munich, Germany) files and iRace (iRC; FKG Dentaire SA), and found that a higher level of postoperative pain was observed with REC blue at 24–48 h ($P < 0.05$). Shaik RP et al. reported that postoperative pain was lower in the WOG file system than in the HEDM file system after a single-visit root canal therapy at 8, 24, and 48 h [29]. Jose et al. 2020 reported that the individuals who had undergone a manual glide-path preparation showed a higher incidence of postoperative pain than other systems [30].

Thus, the use of a single file system group (OG or WO) with different kinematic motions had no effect on the intensity of postoperative pain. Similarly, Mollashahi et al. compared a single file using reciprocating and continuous rotary with hand files; no significant difference in the mean value was seen at five time points on the VAS [31]. Adiguzel et al. found no statistically significant difference in the three groups (n = 31): the R-pilot (RP), One G (OG), and control groups [32]. However, the intensity and duration of postoperative pain reported by Neelakantan et al. was different and significantly lower in patients undergoing root canal instrumentation with Reciproc as compared with One Shape [33]. Oliveira PS et al. reported that the ProTaper Next and Reciproc® caused a slight risk of tenderness on biting and contributed to similar self-reported postoperative pain (low intensity) up to 7 days following root canal shaping [34].

There is a contrast in the results of previous studies, and it should be noted that one clinical study cannot be generalized, and more studies with larger sample sizes are required to further investigate the drawbacks and benefits of instrument systems. The limitations of this study included the sample size and the subjective nature of pain, which were difficult to quantify. Another possible limitation of the study was the difference in taper between two files than the other groups (7% vs. 6%). This can also be attributed to debris extrusion, which results in pain.

In conclusion, the intensity of postoperative pain, frequency, and analgesic intake were similar across all three types of instrument systems but reciprocated single file system (WG) was associated with less post operative pain than a full-sequence continuous rotary file. Higher pain scores were observed at 24 h, which gradually decreased in intensity after 24 and 48 h and 7th day. However, further studies are needed on this subject; the number, cross-sectional design, and kinematic motion of the rotary file system need to be considered, and such differences may have affected the results of the present study.

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Pragnesh Parmar: Investigation, Methodology
Ruchi Vashisht: Formal analysis, Methodology, Validation, Writing - original draft
Namita Tandon: Investigation, Methodology, Writing - original draft
Charan Kamal Kaur: Data Curation, Investigation, Methodology, Writing - original draft

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