The Effect of Foraminal Enlargement of Necrotic Teeth with the Reciproc System on Postoperative Pain: A Prospective and Randomized Clinical Trial

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Abstract

Introduction: The aim of this prospective study was to evaluate the postoperative pain that followed root canal treatments performed with a single-file reciprocating system on asymptomatic uniradicular necrotic teeth with and without foraminal enlargements (FEs). **Methods:** Forty-six volunteers were randomly divided into 2 groups according to the established working lengths. The FE group had a working length of 0.0 mm from the apex, and the control group had a working length of 1.0 mm short of the apex. The treatments of both groups were performed with a Reciproc R40 (VDW, Munich, Germany) instrument. Both groups underwent the same treatment protocol with the exception of the established working length. The volunteers were instructed to record their pain (none, mild, moderate, or severe) on a visual analog scale at 24 hours, 72 hours, and 1 week after the procedures. The Kruskal-Wallis test was used to identify significant differences. **Results:** Overall, 82.22% of the patients indicated no pain or mild pain. A greater proportion of the patients in the FE group reported mild pain compared with patients in the control group in the first 24 hours ($P < .05$). At 72 hours and 1 week, there were no statistically significant differences between the groups ($P > .05$). **Conclusions:** FEs during endodontic treatments of asymptomatic necrotic, uniradicular teeth that were performed in single visits using the Reciproc R40 reciprocating file resulted in a low incidence of pain. After 24 hours, the FEs resulted in more patients reporting mild pain compared with the control group, but no differences were observed at 72 hours or 1 week. *(J Endod 2016;42:8–11)*

Key Words

Foraminal enlargement, postoperative pain, reciprocating motion, visual analog scale

Root canal therapy (RCT) involves the treatment of vital and necrotic pulpal tissue with the aim of maintaining the natural teeth. The removal of biofilm, pulpal tissue, and bacteria from the root canal system is achieved by root canal preparation, which is considered to be 1 of the most challenging procedures in endodontics (1). The apical third has been shown to be an area that exhibits ramifications and lateral canals that harbor a high prevalence of bacterial biofilms; therefore, failure to properly clean this area may lead to unsuccessful treatments (2).

Apical enlargements improve bacterial removal from the apical portion (3) and lead to more predictable results, whereas foraminal enlargements (FEs) have been claimed to be helpful in the cleaning of the apical portion of the apical constriction without increasing postoperative pain (4). However, the possibility of pain because of injury to the periapical tissues during FE remains controversial (5, 6).

The occurrence of pain after root canal treatments has been examined in several studies, and such pain is a major concern for both patients and professionals (4, 7, 8). The development of postoperative pain after RCT is usually because of an acute inflammatory response in the periradicular tissues. Several factors may be involved in the development of pain, such as mechanical injury, chemical irritation, and microorganisms (6). Despite being affected by many factors, the performance of treatments in 1 or more appointments does not seem to elicit different outcomes (9–11).

Single-file reciprocating systems have been claimed to facilitate root canal preparation by decreasing the required number instruments and steps for root canal shaping (12). Using a crown-down technique, the Reciproc single-file instrument (VDW, Munich, Germany) is able to shape canals with a minimum of previous procedures. However, little is currently known about the incidence of postoperative pain when FE is performed with a reciprocating instrument. The purpose of this prospective clinical study was to evaluate postoperative pain after the use of a Reciproc R40 single-file reciprocating file (VDW) at 2 different working lengths (WLs) (0.0 mm and 1.0 mm) from the apex. The tested hypothesis was that the preparation with FE using a Reciproc R40 would result in the same level of postoperative pain as treatments performed without FE.

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Materials and Methods

Case Selection

This prospective, randomized clinical trial was conducted in adult female patients ranging in age from 18–40 years who enrolled for endodontic treatment at a private endodontic practice between 2012 and 2013 (Table 1). The patients were informed about the postoperative care, clinical and radiographic examinations, and the available alternative treatment options. All of the volunteers provided written consent after they were provided information about the study and the treatment protocol. The study protocol was reviewed and approved by the research ethics committee (protocol number 2012/0302).

The inclusion criteria for this research were asymptomatic necrotic teeth presenting with single straight root canals with or without apical radiolucency and periodontal probing of at most 3 mm. Only teeth without any type of earlier endodontic management were included. Patients who had taken anti-inflammatories, analgesics of any type, or antibiotics within the last 10 days were excluded from the study. The patients were randomly allocated by a computer program (http://www.random.org) into 2 groups (ie, an FE group [group 1] and a control group [CG, group 2]) (Table 1). All of the treatments of both protocols were performed in single visits by the same operator, an endodontic specialist experienced in reciprocating instrumentation.

Treatment Protocol

After a clinical examination and an evaluation of the patient's health condition, the teeth were isolated with cotton rolls, and thermal tests were performed. A cold spray (Endo-Frost; Coltene-Whaledent, Langenau, Germany) on a cotton pellet was positioned at the middle third of the buccal surface of the tooth, and the absence of a response within 10 seconds confirmed the negative result. Warm gutta-percha was also used at the middle third of the buccal surface as a thermal test. A negative response confirmed the inclusion of the patient in the study.

The teeth were anesthetized with 3.6 mL 2% lidocaine with 1:100,000 epinephrine. After rubber dam placement and disinfection, an access cavity was created using a sterile diamond bur. As the pulp chamber was reached, copious irrigation with 5 mL 2.5% sodium hypochlorite (NaOCl) was applied, and the canal was continuous flooded with the solution. An initial exploration was performed with a 15 K-file (Dentsply Maillefer, Ballaigues, Switzerland). In all cases selected, a size 20 instrument went passively to the WL. A Reciproc R40 instrument was used in a Sirona 6:1 handpiece (Sirona Dental Systems GmbH, Bensheim, Germany). The handpiece was used with a VDW SILVER motor (VDW) that was adjusted to the recommended setting of the "RECIPROC ALL" mode. The instrument was used with in-and-out movements with amplitudes not exceeding 3–4 mm. After each insertion, the file was removed and cleaned with gauze, the canal was irrigated with a NaviTip 31 G (Ultradent, South Jordan, UT) needle, and the patency was confirmed with a 15 K-file. When the R40 instrument reached the middle third of the canal, the WL was established with an electronic apex locator (EAL) (Novapex; Forum Technologies, Rishon Le-Zion, Israel).

TABLE 1. Mean Ages and Tooth Distributions of the 2 Groups

	Foraminal enlargement	Control group
Mean age	29.39	32.00
Mandibular premolar	10	8
Maxillary incisor	9	10
Mandibular incisor	2	2
Maxillary canine	2	2

In group FE, the WL used was 0.0 mm from the apex as determined with the apex locator. In the CG, the WL was 1 mm short of the 0.0 signal of the EAL. In both groups, x-ray images were used to confirm the WLs.

Both groups underwent the same treatment protocol with the exception of the utilized WL. The same irrigation protocol was followed including the use of equivalent volumes of irrigant composed of 40 mL 2.5% NaOCl and 5 mL 17% EDTA. Passive ultrasonic irrigation was used in 3 cycles of 20 seconds each with a 20-mm-long ultrasonic tip for both the final NaOCl and EDTA irrigations. A final flush with 5 mL 2.5% NaOCl was performed, and the canals were dried with the aid of the paper points of the Reciproc System.

The canals in both groups were filled with R40 gutta-percha cones using AH Plus Sealer (Dentsply, DeTrey, Konstanz, Germany) and the warm condensation technique with a size 50 Gutta-Condensor (Dentsply Maillefer).

After the filling of the root canal, Coltosol F (Vigodent, Coltene, France) was used as an intraorifice barrier, a composite restoration was placed, and the occlusion was checked and adjusted. No medication was prescribed, and the patients were instructed to take either paracetamol (750 mg every 6 hours) or ibuprofen (600 mg every 6 hours) if they experienced pain.

Postoperative Pain Evaluation

Postoperative pain was assessed with a visual analog scale (VAS) at 24 hours, 72 hours, and 1 week after the procedures. The VAS consisted of a 100-mm horizontal ruler with marks every 10 mm and no numbers except a 0 at the first part of the scale and a 10 in the last part of the scale. The patients were asked to mark the point that was equivalent to their pain perception, with 0 indicating no pain and 10 indicating extreme pain. The distance from 0 to the mark made by each patient was measured with a ruler, and the resulting quantitative values were used in the statistical analysis. Three different cards were used for each separate assessment time point. According to the values recorded on the VAS, the pain levels were classified as no pain (0), mild pain (1–3), moderate pain (4–7), or severe pain (8–10). Additionally, the need for analgesics was also recorded by the patients on their cards. The volunteers were informed to contact the professional if they experienced severe pain.

The results were submitted to statistical analyses with the Biostat 4.0 program (Analystsoft Inc, Walnut, CA). The Kruskal-Wallis (Student-Newman-Keuls) test was used to identify the significant differences at $P < .05$.

Results

A total of 46 female patients were enrolled in this study. One patient (group 2) failed to return the VAS card and was excluded. In both groups, the pain sensations were higher at 24 hours and had decreased by 72 hours and 1 week. At 24 hours, the FE group reported more pain (2.30) than the CG group (1.09, $P < .05$; Fig. 1).

At the observation time point of 24 hours, the FE group reported an average pain value of 2.30; at 72 hours, the mean value was 0.56; and at 1 week, the mean value was 0.13 (Table 2). At 24 hours, 72 hours, and 1 week, the control group reported mean values of 1.09, 0.40, and 0.00, respectively (Table 3).

Overall, at 24 hours, 23 patients (51.11%) reported no pain, 14 (31.11%) reported mild pain, and 8 (17.78%) reported moderate pain. At 72 hours, 71.11% of the subjects reported no pain, and 28.89% reported mild pain. After 1 week, 95.55% of the patients reported no pain, and only 4.45% reported mild pain. The percentages of FE and CG patients who reported values corresponding to moderate, mild, and no pain are shown in Figure 2.