The Effect of Foraminal Enlargement of Necrotic Teeth with a Continuous Rotary System on Postoperative Pain: A Randomized Controlled Trial

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Abstract

Introduction: This single-blind, randomized controlled trial aimed to evaluate whether foraminal enlargement (FE) with a continuous rotary system during endodontic treatment causes more postoperative pain than nonforaminal enlargement (NFE). **Methods:** Seventy qualified patients were randomized into 1 of 2 groups in a 1:1 ratio using a series of random numbers: the FE group and the NFE group. The patients were followed up for 7 days to evaluate between-group differences in the outcome measures. The study participants were selected from among patients who had necrosis and apical periodontitis in the maxillary or mandibular molar teeth. The primary outcome was to assess postoperative pain severity, and the secondary outcome was to evaluate analgesic consumption during the follow-up period. Pain severity was evaluated for the first 7 days using a visual analog scale (VAS). The VAS consisted of a 100-mm line. Pain severity was assessed as no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm). The quality of life of patients during the follow-up period was assessed using a quality of life scale. The Student *t* test was used to identify statistically significant differences between the study groups ($P < .05$). **Results:** A significant difference was noted in postoperative pain in the first 2 days; the FE group experienced more pain than the conventional NFE group ($P < .05$). In the FE group, 12 and 11 patients (34% and 31%) had severe postoperative pain (VAS score, >74 mm) on the first day and second day, respectively. VAS pain scores between the groups were not different ($P > .05$) on other days. No significant difference was found in analgesic consumption between the groups ($P > .05$). **Conclusions:** On the basis of the VAS results, this randomized controlled trial indicates that FE causes more pain on the first 2 days after an endodontic treatment. *(J Endod 2017;43:359–363)*

Key words

Endodontics, foraminal enlargement, postoperative pain, rotary systems

Significance

This randomized controlled trial indicated that foraminal enlargement with a continuous rotary system caused more postoperative pain in the first 2 days. Although foraminal enlargement caused severe pain in 30% of patients, none of these patients needed an additional and unscheduled visit.

Pulp necrosis and apical periodontitis are conditions that affect periapical tissues and the entire root canal system (1, 2). Molecular analyses have indicated the presence of bacterial biofilms not only within the apical part of the root canal system but also within the apical lesion itself (3–5). Furthermore, some studies have shown that bacteria can form a biofilm by extending the extraradicular area from the root canal through the apical foramen and then adhere to the cementum over the root apex (4, 6). Thus, it seems acceptable to enlarge the apical foramen for the healing of apical periodontitis (7).

Foraminal enlargement (FE) refers to intentional and mechanical enlargement of the apical foramen to reduce the bacterial load by excising the infected cementum and dentin (7). In an animal study, Borlina et al (7) showed that such enlargement of the apical foramen could decrease the microbial load and facilitate the healing of chronic periapical lesions. In another animal study, de Souza-Filho et al (8) indicated periapical tissue repair in pulp necrosis cases in which the apical foramina was enlarged during shaping. Therefore, intentional enlargement of the apical foramen may be necessary from a microbiological viewpoint for reducing microbial load when endodontic infection extends beyond the limits of apical constriction and for repairing periapical tissues (7, 8).

Some concerns have been raised over the apical limit of root canal instrumentation during cleaning and shaping. Siqueira (9) reported that FE may cause a higher incidence of pain because of mechanical irritation of periapical tissues. Furthermore, debris extrusion may lead to periapical inflammation, which ranges between 1.4% and 16% (9), and pain, which ranges between 3% and 58% (10). One study indicated that the disruption of apical constriction may cause considerable apical debris extrusion (11). Therefore, there exists uncertainty regarding postoperative pain caused by the disruption of apical constriction during the enlargement of the apical foramen.

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Several randomized controlled trials (RCTs) have evaluated the effect of FE on postoperative pain. Silva et al (12) assessed postoperative pain after enlarging the apical foramen created with hand files; they concluded that both FE and nonforaminal enlargement (NFE) caused the same level of postoperative pain. Cruz Junior et al (13) reported that FE using a reciprocating system caused more pain than NFE at 24 hours. Recently, in an RCT, Saini et al (14) concluded that FE created with hand files increased the intensity of postoperative pain. To the best of our knowledge, the incidence of postoperative pain after FE with a continuous rotary system has not been assessed yet.

This RCT was conducted to evaluate postoperative pain after the use of ProTaper Next rotary files (Dentsply Tulsa Dental Specialties, Tulsa, OK), a continuous rotary system. The following was the primary research question: "What is the effect of FE created with a continuous rotary system on postoperative pain in patients with necrotic pulp and apical periodontitis?" The null hypothesis was that there would be no differences in the level of postoperative pain between the 2 interventions.

Materials and Methods

This study is a randomized, controlled, single-blinded, and single-center clinical trial. It was designed and reported by adhering to the Consolidated Standards of Reporting Trials statement (15). This study was approved by the Ethics Committee of Yakin Dogu University (ref. no.: 2016/37-274), and the study protocol was registered in the www.clinicaltrials.gov database with identifier number NCT02770053. All participants received written information about the trial and provided written informed consent for study participation.

Participants

From February to August 2016, consecutive patients referred for endodontic treatment were screened for enrollment at the Isparta State Hospital, Isparta, Turkey. After comprehensive clinical and radiologic examinations, 96 consecutive subjects, aged 21–45 years, were enrolled in the study (Fig. 1).

Only patients who had maxillary or mandibular molar teeth with pulp necrosis and radiographic evidence of apical periodontitis (minimum lesion size: 2 × 2 mm) were included. The exclusion criteria were pregnancy, systemic disorders, preoperative pain, treatment with antibiotics in the past 1 month, and analgesic treatment within the past 3 days. The baseline data of the patients were obtained before the randomization. Only 1 tooth per patient was included in the study.

The power analysis was performed on the basis of the minimum clinically significant difference in the visual analog scale (VAS) score. The result of the sample size calculation showed that 35 subjects would be required in each group to detect clinically significant differences in pain, with an alpha risk of 0.05, power of 0.8, and standard deviation of 0.75 (14).

Sequence Generation and Blinding

The randomization sequence was created with a computer random table number generator (www.random.org) with a 1:1 allocation ratio. The participants were randomized into an FE group or an NFE group. Because of the nature of the interventions, the operator (I.E.Y.) was not blinded to the interventions. However, the patients were blinded and not informed of the allocation. In this RCT, the outcome assessors were the patients themselves. The success of blinding was tested by asking the patients to guess their study groups (16). All participants (N = 70 [100%]) reported that they were not able to guess their study groups. The allocation sequence was placed in sequentially numbered, sealed, and opaque envelopes. To prevent the disruption of the allocation sequence, the names and dates of birth of the patients were written on the envelopes. Before treatment, the operator opened the sealed envelopes in which the type of intervention method was noted.

Interventions

All endodontic treatments were performed by the principal investigator (I.E.Y.) during a single visit using a standardized treatment protocol. The vitality of pulp was determined using a hot and cold test and confirmed visually by the absence of bleeding when entering the pulp chamber. In all cases, rubber dam isolation was maintained. Patients

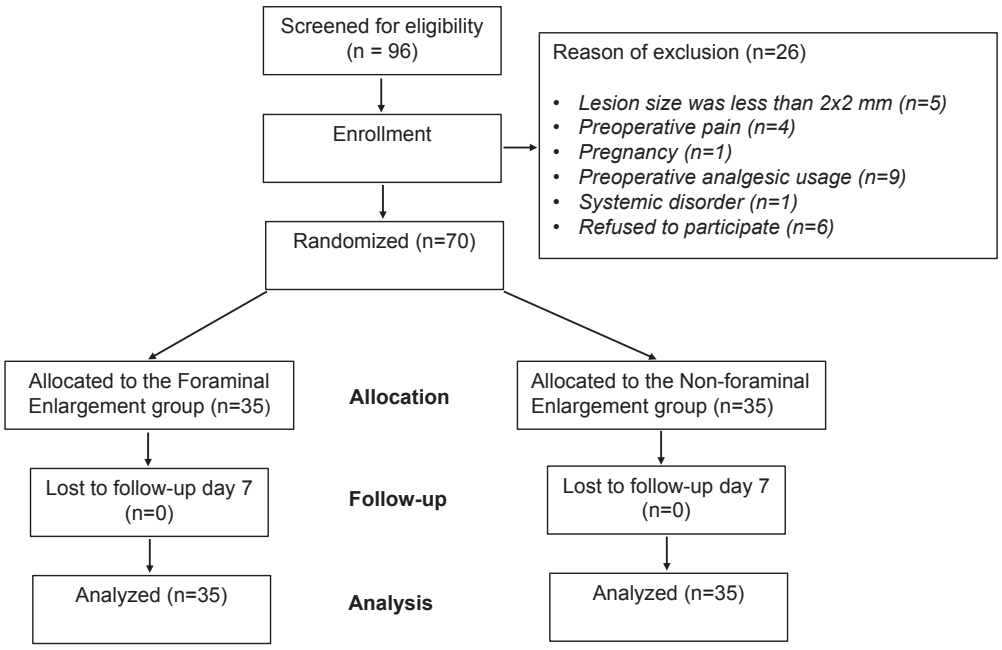

Figure 1. Consolidated Standards of Reporting Trials flow diagram showing the progress of subjects at each stage of the clinical trial.