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Postoperative Endodontic Pain after Treatment Using XP-endo Finisher: A Randomized Clinical Trial

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Introduction: This randomized clinical trial aimed to determine whether the XP-endo finisher combined with or without foraminal enlargement has any significant effect on the incidence and intensity of postoperative pain in necrotic pulps. **Materials and Methods:** Clinical pain levels were measured after 6, 12, 24, 48, and 72 hours and at 7 postoperative days. All treatments were performed by an endodontist in a single visit. One hundred and twenty patients were included. All patients had a single tooth treated. The patients were divided into four groups: No FE (None Foraminal Enlargement) (n=30), FE (Foraminal Enlargement) (n=30), No FE+XPF (None Foraminal Enlargement+XP-endo Finisher) (n=30) and XPF+FE (XP-endo Finisher and Foraminal Enlargement) (n=30). The canals were irrigated with sodium hypochlorite, shaped using WaveOne Gold Medium file, and then filled by using a matching single cone and AH-Plus sealer. The cavity was filled using glass ionomer cement. Pain intensity was assessed using the visual analog scale. The data were analyzed with the ANOVA and Games-Howell test. The significance level was 5%. **Results:** The XPF+FE group experienced a higher level of pain, being classified on the visual analog scale as moderate for 48 postoperative hours and mild for 7 postoperative days (P<0.05). In the other groups, the pain was mild, only with different time intervals (P>0.05). **Conclusions:** Foraminal enlargement associated with XP-endo Finisher may cause moderate postoperative pain.

Keywords: Foramen Enlargement; Postoperative Pain; Pulp Necrosis; Sodium Hypochlorite; XP-endo Finisher Instrument

Introduction

In endodontics, pain is the primary concern of both patients and health professionals [1]. Acute inflammation response is the main cause of postoperative pain after root canal treatment (RCT) and it may occur due to mechanical preparation and obturation beyond the apex, preservation of bacteria after disinfection, and the extrusion of irrigants beyond the apex [2, 3]. If mechanical and chemical factors are identified, dentists could implement steps to minimize pain and reduce patient discomfort preoperatively [1]. The instrumentation and irrigation of the canal are crucial steps of RCT. The adequate delivery of irrigants depend on the canal instrumentation. Additionally, the apical limit of root canal preparation should be considered. Foraminal enlargement is performed particularly in teeth with necrotic pulp [4] and can improve disinfection at the apical portion of root canals. This procedure may favor the healing of chronic periapical lesions [5, 6]. Foraminal enlargement in RCT is considered a mechanical factor that may result in postoperative pain [7]. It is argued that disrupting the apical constriction may extrude debris and lead to increased postoperative discomfort. However, this is controversial [8, 9].

The XP-endo Finisher instrument (FKG, La Chaux-de-Fonds, Switzerland) is made of MaxWire alloy and can undergo phase transformation at body temperature, adapting itself to the root canal by expansion and contraction [10]. It was introduced to be used after any root canal instrumentation, as a final step to improve root canal cleaning [11, 12].

Predictors of pain following RCT have been studied [1, 5, 9, 13-15]. However, currently, no studies report the possibility of any influence that endo finisher may have on postoperative endodontic

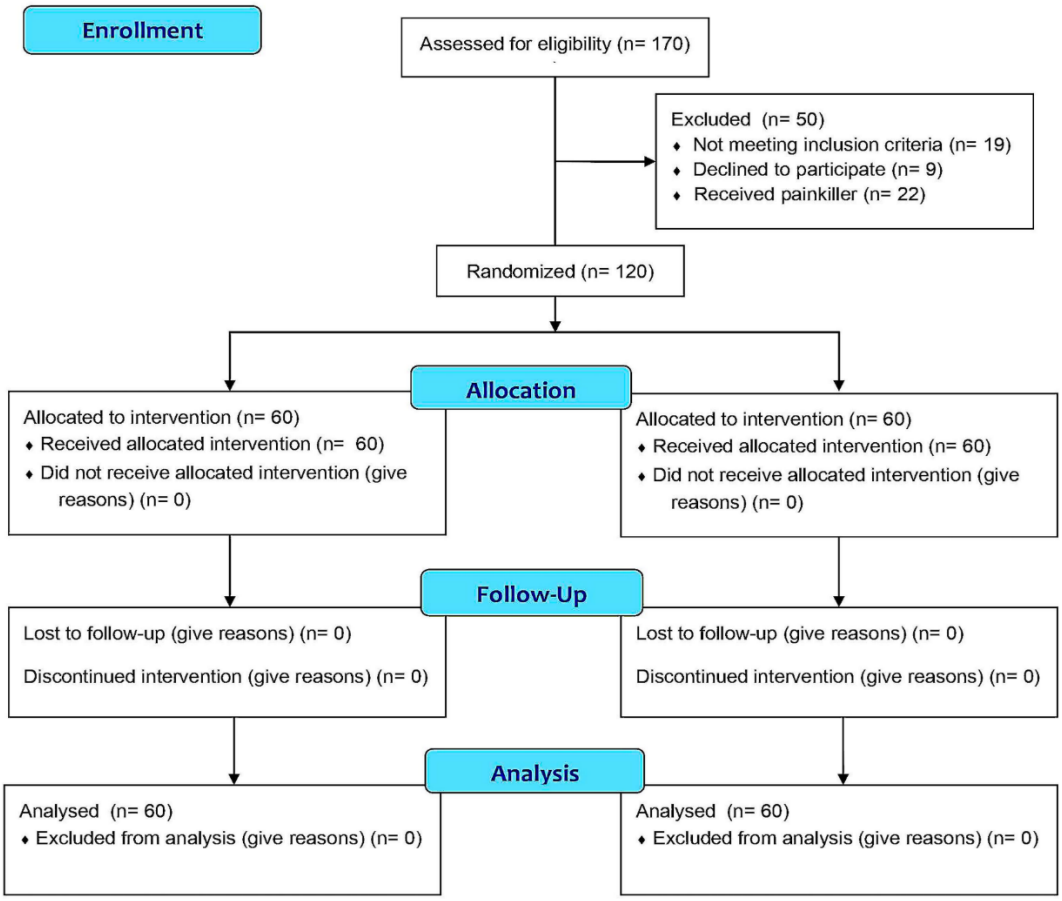

***Figure 1*:** Flow diagram of this trial. XP-endo Finisher groups and non XP-endo Finisher groups were allocated to intervention (with and without foraminal enlargement)

pain. This randomized clinical trial aimed to determine whether the XP-endo finisher significantly increases the incidence and intensity of postoperative pain in pulp necrosis, with or without foraminal enlargement. Pain levels were measured after 6, 12, 24, 48, and 72 h and at 7 postoperative days. The null hypothesis was that there is no difference in the incidence or intensity of postoperative pain after treatment using XP-endo Finisher in pulp necrosis.

Materials and Methods

Study design and attendant selection

This study followed the standards of the Consolidated Standards of Reporting Trials (CONSORT) (Figure 1). It was registered under the International Standard Randomized Controlled Trial #ISRCTN16405594 and was approved by the Ethics Committee of the Pontifical Catholic University of Paraná, #3056118. This study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Subject population

The population was selected from patients referred for endodontic treatment seen at a dental clinic. The procedure and purpose of the study was explained, and written informed consent was obtained from the participants. Before treatment, the medical and dental history of the patients was taken; gender, age, tooth and arch location, presence of any preoperative pain, and periapical condition were recorded. Only one tooth per participant was included in the trial.

Inclusion and exclusion criteria

The patients participating in this study were aged 18 years or above, referred for endodontic treatment, and had a negative response to the sensitivity test. The included teeth were the central and lateral incisors, canines, and upper or lower premolars. All teeth had pulp necrosis and radiographic evidence of periapical radiolucency with a diameter greater than 2 mm.

Exclusion criteria included the following:

1) Teeth with immature apices, teeth with apices located in the

maxillary sinus, teeth with root resorption, endodontic retreatment and with an anatomical diameter by endodontic instrument at apical length greater than the K-type file#20 or less than the K-type file #10.

2) Participants with preexisting health or oral conditions that placed them at risk during the trial, who did take painkillers, antibiotics, corticosteroids in the past 7 days, or those requiring extensive prosthetic rehabilitation were excluded.
3) Patients with generalized periodontal disease, and those who were pregnant or breastfeeding were also excluded.

According to the exclusion criteria, 50 patients were excluded from the total of 170 patients that had a root canal therapy done. Twenty-two for taking painkillers; nine for abandoning the study; nineteen for presenting teeth that could not be treated using the Wave One Gold Medium 35-06 file due to the canal diameter by endodontic instrument at apical length being larger than K-type file #20. After exclusion criteria, a total of 120 patients were included in this study. Table 1 shows the distribution of the patients in the four groups. The sample size was calculated using the method by Walters, with the assumption of relative normal distribution [16].

Randomization and blinding

Randomization was performed to eliminate biases and equalize the distribution of patients in the groups. A random list for each study setting was created using the website www.sealedenvelope.com. The treatment plan for each patient was placed into an opaque and sealed envelope (30 envelopes per study setting) by a third party not involved in the study intervention. The patients were not informed of which group they were allocated to. The dentist who performed the clinical procedures opened the envelope at the moment of the intervention and only the dentist knew which technique was to be used. Once allocated, the patient's name was written on the patient's chart to allow decoding during data management. None patient with a particular characteristic was allocated to the groups in which this characteristic was under-represented at the time of randomization.

Table 1. Group distribution based on the apical foramen enlargement and use of XP-endo Finisher

Groups	Foraminal enlargement	XP-endo Finisher	N
No FE	No	No	30
FE	Yes	No	30
No FE+XPF	No	Yes	30
XPF+FE	Yes	Yes	30

No FE (None Foraminal Enlargement), FE (Foraminal Enlargement), No FE+XPF (None Foraminal Enlargement+XP-endo Finisher) XPF+FE (XP-endo Finisher and Foraminal Enlargement)

Study intervention

Endodontic treatments were performed by a single endodontic specialist in a single visit. After the check-up, the cold test (Endo Frost; Coltène Whaledent, Langenau, Germany) was conducted to determine pulp vitality, followed by confirmation of the presence or absence of bleeding in the root canals during endodontic access preparation. The patient was recruited only if the tooth exhibited a negative response to the cold test and clinical evidence of pulp necrosis and digital radiographic evidence of apical periodontitis (minimum size 2×2 mm).

Anesthesia was obtained with 3, 6 mL of 2% mepivacaine hydrochloride with 1:100,000 epinephrine (DFL, Rio de Janeiro, Brazil) by inferior alveolar nerve block. Buccal infiltration was performed using a 30 G needle. Teeth were isolated using a rubber dam (Madeitex, São José dos Campos, Brazil). The carious lesions were removed using a spherical diamond bur 101 (KG Sorensen, Sao Paulo, Brazil) on a high-speed handpiece, which was cooled with water. Manual instruments were also used [17].

With the spherical bur 1014 sterilized and cooled, the pulp chamber was accessed and refined with a 4138 sterile round-top truncated cone bur (KG Sorensen, São Paulo, Brazil). A glide path was established with manual K-files #10, #15 and #20 (Dentsply Maillefer, Ballaigues, Switzerland). The working length was established using the Root ZX II apical locator (J. Morita, Irvine, CA, USA) with the K-type file (Dentsply Maillefer, Ballaigues, Switzerland) that was best adapted to the root canal, and radiography was obtained for confirmation.

Instrumentation was performed with the X-Smart Plus motor (Dentsply Maillefer, Ballaigues, Switzerland). The Wave-One Gold Medium 35-06 file (Dentsply Maillefer, Ballaigues, Switzerland) was used on each tooth and was discarded after use. 1 mL of sodium hypochlorite was placed in the pulp cavity before the introduction of the reciprocating instrument into the canal in slow inlet and outlet movements, without completely removing the file from the canal. The range of motion did not exceed 3-4 mm. During preparation, the instrument was removed and cleaned with gauze, followed by 15 mL of irrigation with 2.5% sodium hypochlorite, for approximately four to five times. A size 15 K-file was used to verify patency in the working length during endodontic treatment [17]. In the groups with apical foramen enlargement, verification was performed by using the K-type file #40 (Dentsply Maillefer, Ballaigues, Switzerland) at apical foramen [8].

Positive pressure irrigation was performed between each of the instruments being used with a total of 40 mL of sodium hypochlorite into the canal by the Max-i-Probe 30 G needle (Dentsply, Maillefer; Ballaigues, Switzerland) up to 3 mm of the working length, which was measured by a silicone stop. The irrigating solution remained in the root canal during the procedure.

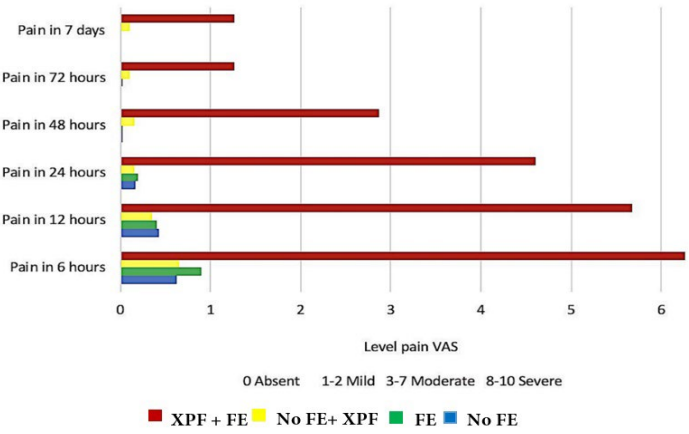

Figure 2. Duration and intensity of pain at 6, 12, 24, 48, 72 hours according to four groups

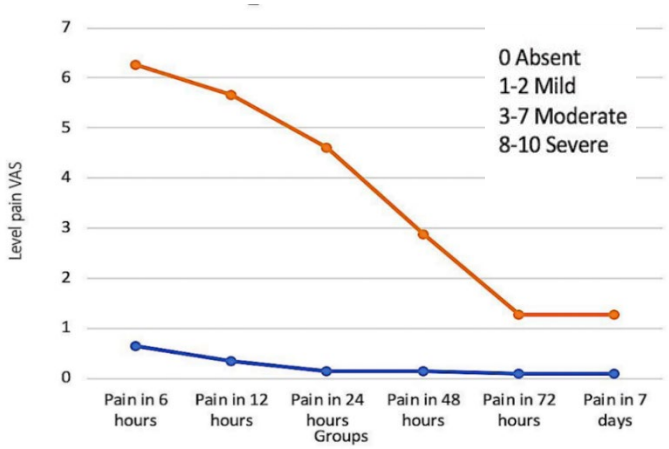

Figure 3. Duration and intensity of pain at 6, 12, 24, 48, 72 hours according to XP-endo Finisher groups

In the XPF+FE and No FE+XPF, activation of sodium hypochlorite was performed with the XP-endo Finisher instrument (FKG Dentaire, La Chaux-de-Fonds, Switzerland). Following the manufacturer's instructions, the instrument was moved from the sterile blister pack and inserted into X-Smart Plus motor. The working length was set using a plastic tube to adjust the rubber stop, and a cooling spray was used through the tube. The XP-endo Finisher instrument was rotated and removed from the tube, applying pressure on the sides to keep it straight. Subsequently, the rotation was interrupted. Only the tip of the tube was touched to avoid heating the file. When the instrument straightened out of the tube, a gauze soaked in alcohol was used to prevent contamination and heating [18].

Sodium hypochlorite was injected in the root canal, and the tip of the XP-endo Finisher instrument was inserted, followed by rotation at a rate of 800 revolutions per minute and torque of 1 Ncm. Sodium hypochlorite was injected in the cavity, and the instrument was inserted at the working length, with slow and gentle (7-8 mm) penetration and recoil rotational movements for a minute, maintaining the instrument inside the root canal. After one minute, the instrument, still under rotation, was removed [19]. Finally, canal irrigation was performed with 1 mL sodium hypochlorite to remove the suspended debris. Only one round of cleaning at the end of the preparation was performed using irrigating solutions [18].

In all groups, a single round of irrigation was performed in each root canal with 5 mL of 17% ethylenediaminetetraacetic acid (EDTA) (Biodynamic, Ibiporã, Brazil) for one min, followed by a final discharge with 5 mL of 2.5% sodium hypochlorite.

The canals were dried using sterile paper tips (Dentsply Maillefer, Ballaigues, Switzerland) and filled with AH-Plus endodontic sealer (Dentsply Maillefer, Ballaigues, Switzerland) and a gutta-percha cone (Dentsply Maillefer, Ballaigues, Switzerland) calibrated on a millimeter ruler (Dentsply Maillefer, Ballaigues, Switzerland) using warm vertical condensation technique. The main cone length was 1 mm short of the radiographic apex. The gutta-percha cones were cut with a heated instrument at the cementoenamel junction. The excess sealer was removed from the pulp chamber using cotton soaked in 70% alcohol. The access cavity was sealed temporarily with glass ionomer cement (FGM, Joinville, SC, Brazil). In all treated cases in four groups, the occlusal reduction was performed after the treatment as a strategy for the prevention of postoperative pain.

Assessment of postoperative pain

Pain intensity was assessed using the visual analog scale (VAS), which is considered valid and reliable. The scores ranged from 0 to 10, where 0 (absence of pain), 1-2 (mild pain), 3-7 (moderate pain), and 8-10 (severe pain) was used [18, 20, 21]. Before the administration of local anesthesia, patients were asked to record their preoperative pain on the VAS to confirm the complete absence of pain. After the endodontic treatment, postoperative pain was recorded at 6, 12, 24, 48, and 72 h and 7 days. To record the pain on the VAS, scale cards were provided for the patients who made the note without any interference. Patients did not have to return for follow-up evaluation, as they were contacted by phone calls.

Statistical analysis

Statistical analyses were performed using SPSS 25.0 (IBM Brazil, São Paulo, Brazil). The average age was assessed using the parametric analysis of variance. The chi-square test was used to verify the association among age range and group; gender and group; and age range and gender. The ANOVA test was performed in order to assess the level of pain scale according to the variables "group" and "time of evaluation".

Levene's homogeneity test indicated heterogeneous variances in the level of pain by group, by time and in the interaction between groups versus time. Therefore, the pairwise comparisons among "group" and "assessment times" were analyzed using the Games-Howell test. The level of significance adopted in each test was 5%.

Results

The participants' flow diagram in the different phases of the study is depicted in Figure 1. We selected 170 patients to participate in this study. However, 50 were excluded. In total, 120 patients (n=120) were selected and received RCT in one tooth. There were no serious adverse effects reported from patients.

The chi-square test indicated that no association was found between the level of postoperative pain in the four groups and gender and age range (P>0.05) (Table 2).

Among the teeth treated, 26.67 % (32) were incisors, 10 % (12) were canines, and 63.33% (76) were premolars. According to the parametric analysis of variance the mean age of the patients was 43.4 years for the female patients and 43.7 years for the male patients, with no statistical difference between the groups (P>0.05). Pain positive percussion characteristics of the included study participants in the groups was performed (Table 3).

The ANOVA test showed statistical difference between groups and pain evaluation time (P<0.05). The Games-Howell test indicated that the XPF+FE group suffered from higher postoperative pain-classified in the VAS as moderate at 6, 12, 24, 48, and 72 h and 7 postoperative days (P<0.05). In the No FE+XPF group, the pain was mild at 6, 12, 24, 48, 72 h and 7 postoperative days (Figure 2).

The XPF+FE had the longest postoperative pain duration (Figure 2), varying in intensity (P<0.05) (Figure 3) when it was compared with No FE+XPF.

Discussion

In this study, the postoperative pain was evaluated in teeth with pulp necrosis and digital radiographic evidence of apical periodontitis (minimum 2×2 mm), in all treated cases in four groups the occlusal reduction was performed after the treatment as a strategy for the prevention of postoperative pain.

The mean of the postoperative pain intensity was higher in the XPF+FE group. In four patients, mild edema was observed, which disappeared after 72 h with applying an ice pack. The pain spread moderately in the first 48 h and remained mild on the seventh day. The XP-endo Finisher instrument combined with the foraminal enlargement may cause a greater apical extrusion of debris and sodium hypochlorite, which can lead to continuous, moderate-to-severe pain that can last for several days after the endodontic treatment [5, 9, 22]. In combination with high-speed rotation and foramen enlargement, XP-endo Finisher can allow the irrigant solution with the apical tissue. It could explain the elevated pain levels and also for the edema reported in some cases in this group.

Table 2. Dependence among sex and age among groups. The chi-square test indicated that regarding the level of postoperative pain in the four groups there was no association in gender and age range.

			No FE	FE	No FE+XPF	XPF+FE	Total
Gender	Female	Count	21_a	20_a	21_a	22_a	84
		% in group	70,0%	66,7%	70,0%	73,3%	70%
	Male	Count	9_a	10_a	9_a	8_a	36
		% in group	30,0%	33,3%	30,0%	26,7%	30%
Age (Years)	18 - 33	Count	8_a	4_a	14_a	8_a	34
		% in group	26,7%	13,3%	46,7%	26,7%	28,3
	34 - 49	Count	13_a	17_a	9_a	12_a	51
		% in group	43,3%	56,7%	30,0%	40,0%	42,5
	50 - 65	Count	4_a	8_a	4_a	6_a	22
		% in group	13,3%	26,7%	13,3%	20,0%	18,4
	66 - 81	Count	5_a	1_a	3_a	4_a	13
		% in group	16,7%	3,3%	10,0%	13,3%	10,8

Table 3. Pain percussion characteristics of the included study participants in the No FE, FE, No XPF and XPF+FE groups. Each the groups with n=30 participants

Positive Percussion	6 hours	12 hours	24 hours	48 hours	72 hours	7 days
No FE	7 (23.3%)	5 (16.6%)	3 (10%)	1 (3.33%)	0 (0%)	0 (0%)
FE	10 (33.3%)	7 (23.3%)	4 (13.3%)	1 (3.33%)	1 (3.33%)	0 (0%)
No FE+XPF	12 (40%)	10 (33.3%)	4 (13.3%)	3 (10%)	1 (3.33%)	0 (0%)
XPF+FE	28 (93.3%)	26 (86.6%)	22 (73.3%)	19 (63.3%)	12 (40%)	6 (20%)

Moreover, in the XP-endo Finisher group, in which there was no foraminal enlargement, the duration of mild pain occurred, remaining for seven postoperative days, but no elevated pain levels and edema was observed. Therefore, we recommend avoid to use of XP-endo Finisher and Sodium hypochlorite irrigation in root canals with foramen enlargement or any similar clinical condition, such an apical resorption.

On the other hand, the final radiography showed a greater number of sealed accessory canals when XP-endo Finisher was used. Other studies have shown that XP-endo Finisher provides a greater bacterial reduction in the main canal space (98.2%) and greater elimination of bacteria at a depth of 50 μm (ranging from 78% to 82%) in the dentinal tubules compared to standard needle irrigation [23].

For foramen enlargement, clinical studies emphasize that apical foramen cleaning could be a strategy and provide higher percentages of periapical healing and tooth survival [8, 9]. The opponents of foramem enlargment enhance that this procedure cause inflammation and lead more postoperative discomfort, probably by greater amounts of debris in the periapical region [24]. The results of this clinical trial showed that the pain was mild, with no increase in intensity in any patient in the groups in which foraminal enlargement without irrigation activation was performed. The foraminal enlargement was performed using a manual instrument, which may have caused the lower incidence of pain [4].

In this study, postoperative pain was not associated with the participants' gender, similar to the findings previously reported [25]. However, some studies have shown that women experience higher levels of postoperative pain [1, 26].

Endodontic treatment was performed in a single session, which may influence postoperative pain. Pain levels tend to be lower in treatments performed in one visit [27, 28]. This lower incidence can be attributed to immediate obturation, avoiding the passage of medication, repeated instrumentation, and irrigation via the foramen, causing less irritation to the periradicular tissues [13, 26, 29]. However, based on recent studies, the cure rates of single-or multiple- session RCTs are similar for infected teeth [30]. A post-obturation pain analysis showed no difference between vital and non-vital teeth [13, 22]. However, the shorter procedure time (mainly during instrumentation) obtained with a reciprocating file can also reduce the antimicrobial efficacy of solutions, which depends on the time [31] and volume [3] of irrigation to effectively disinfect the root canal. A reduced effect of irrigating solutions can compromise the reduction of the microbial content in the root canal system and therefore hinder the pulp necrosis healing. To prevent this from occurring, an abundant irrigation is recommended [32].

The results of the presented study show that after 72 h in all of the groups, the patients' pain levels had significantly decreased. Moreover, during the early stages after the RCT, the patients may experience some kind of postoperative pain [33]. The occurrence of mild pain is common even when root canal treatment is correctly performed and, as such, should be expected [2].

In the presented study, only patients who did not take painkillers in the past 7 days were included, since pretreatment with anti-inflammatory medications has been reported to reduce postoperative pain considerably [34, 35].

A limitation of this study was that the operator was not blinded. However, a large bias is unlikely. The participants were randomly selected to decrease selection bias. The patients were blinded to the technique, reducing the performance bias. Differences in pain thresholds among participants may affect the VAS, so only the results reported by the patients was evaluated.

Conclusion

Under the present clinical trial conditions, the null hypothesis was rejected since pain occurred at a higher intensity when 2.5% sodium hypochlorite was associated with XP-endo Finisher and combined with foraminal enlargement.

Acknowledgments

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Conflict of Interest: 'None declared'.

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