Original Article

Reduction of Postendodontic Pain after One-visit Root Canal Treatment Using Three Irrigating Regimens with Different Temperature

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Abstract

Objective: The aim of this clinical trial was to assess whether controlled irrigation with three different irrigation regimens with different temperature would result in reduction of post-endodontic pain after one-visit root canal treatment (RCT). **Materials and Methods:** A total of 240 (129 females and 111 male) aged 18 – 65 years were referred and integrated in this clinical trial, All patients presented with a vital maxillary or mandibular molar, premolar or front teeth designated for conventional root canal treatment for *prosthetic reasons* detected with only vital pulps. All canals were cleaned and shaped with Reciproc instruments, and were used with a micro motor (VDW, Munich Germany). Final irrigation was done with cold (4°C, 2.5°C, and room temperature) 17% EDTA and 10 mL of cold saline solution. **Results:** A total of 240 of 279 patients (129 females and 111 male) aged 18 – 65 years were referred and integrated in this clinical trial, whereas 29 were rejected as not completing the requirements needed. All patients presented with a vital maxillary or mandibular molar, premolar, or front teeth designated for intentional endodontic RCT for *prosthetic reasons.* No statistically significant difference ($P > 0.05$) among the groups was found regarding degree or duration of pain. There was no statistically significant difference ($P > 0.05$) among the 4°C and 2.5°C groups. **Conclusion:** The approach in both selecting the patients participating in the study and analyzing the data in this randomized clinical trial allows us to conclude that cryotherapy is an aid of clinical procedures to clean and shape the canals to reduce the occurrence of postendodontic pain and the need for medication in patients presenting with a diagnosis of vital pulp.

Keywords: *Apical healing, flare ups, pain, postendodontic pain, postoperative pain*

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Introduction

Postendodontic pain is an unwanted but common sensation reported by more than 35% of patients regardless of the preoperative periapical condition of the tooth treated. Therefore, prevention and management of postendodontic pain are essential in endodontic practice.[1]

Debris, organic tissue, microbes, and irrigants solutions extruding beyond the apical foramen during root canal treatment (RCT) will initiate inflammation and post-operative problems, such as mild to severe pain or flare-ups. It must be noticed that the amount of extruded material (debris and/or irrigant) varies widely in the reported studies which indicates problems and inconsistencies in treatment methodologies.[2-4]

In addition, the composition and the degree of bacterial contamination of the debris and the reactions of the patient`s immune system will play an important role in post-operative pain. Meticulous determination and maintenance of working length (WL) may reduce

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the extrusion of any kind of debris through the apical foramen but may not avoid this entirely.[5]

Accumulation of tissue remnants and dentin in the apical constriction is usual and can produce obstruction of root canal.[6,7] This condition can be prevented if patency of the apical foramen is maintained.[8] Presently, maintaining apical patency during root canal instrumentation is controversial.[9] Antimicrobial debridement is an essential phase in root canal therapy. Mechanical instrumentation alone is not sufficient to get canals free from bacteria.[10] Main improvements in mechanical shaping and in the metallic properties of endodontic instruments have improved root canal preparation.[6,11-13]

All root canal preparation techniques to some degree cause apical extrusion; however, the amount of extrusion may vary, as well as the composition and microbial contamination of the extruded material.[12,14,15] This is also true for single-file-system such as Reciproc and WaveOne in a controlled and safe manner.[16] Data for post-operative pain using a patency technique are controversial.[9]

Some authors indicated that maintaining apical patency would not produce more postoperative complications.[17] A newly issued *in vitro* study exhibited that intracanal carriage of cold irrigant at 2.5°C with negative pressure irrigation decreased the exterior surface temperature to about 10°C, preserving such a temperature for 5 minutes,[18] which, according to the aforementioned scenario, would be enough to produce a local anti-inflammatory beneficial consequence in periradicular tissues. Cryotherapy by itself suggests that applying cold through various methods may decrease the conduction velocity of nerve signals, hemorrhage, edema, and local inflammation and is therefore effective in the reducing of musculoskeletal pain, muscular spasm, and connective tissue distension.[18]

Therefore, the aim of this clinical trial was to assess whether controlled irrigation with three irrigating regimens with different temperature would result in reduction of postendodontic pain after one-visit RCT.

This clinical study was performed at the Autonomous University of Baja California, School of Dentistry, Tijuana BC, Mexico. The study protocol was approved by the Ethics Committee of the University (number: 39/2018 and registered under the ClinicalTrials. gov Identifier: NCT03559127 and conducted in accordance with ethical principles of the last update of the Declaration of Helsinki.[19]

Three specialized endodontists with an average private clinical practice of 18 years and qualified in the techniques, strategies, and methods studied were included in the study and performed 80 RCTs each (a total of 240) in maxillary/mandibular anterior or posterior teeth having irreversible pulpitis established by pulp sensitivity testing with heat and cold. Pulpal sensibility was assessed in previous RCT using EndoIce (Hygenic Co, Akron, OH, USA), and proper palpation and percussion tests were achieved.

Other condition to participate was nonexistence of roentgenographic signs of apical pathology.

The aforementioned analysis was based on a sample size calculation expected that at least 40 subjects per clinician were essential in order to identify changes among the two experimental and control groups for an effect size of 0.85 with an alpha error of 0.05.[20] All treatments were performed in one-visit RCT. RCTs were done in one-visit and assumed with the accepting and written agreement of all subjects included in the study.

Pulpal sensibility tests were performed by the principal author, and digital radiographic diagnosis was recognized by three certified clinicians. Further clinical requirements for *patients' inclusion* were as follows: (1) requirements of the clinical trial were understood and freely accepted, (2) patients in physical and mental health were included, (3) teeth with sufficient coronal structure and diagnosed with irreversible pulpitis, (4) no previous RCT, and (5) no intake of analgesics or antibiotics 7 days prior to the RCT.

Exclusion criteria were as follows*:* previously root canal-treated teeth, pregnancy, failure to obtain patient's authorization, patients with record of treatment for long-lasting pain, and patients with less than 18 years and more than 65 years. Non-vital teeth and teeth with apical radiolucency, internal or external resorption, open apex, severe curvatures (>36°), or a radiographically canal calcifications were all rejected from the study. Mishaps or difficulties during RCT (impossibility to achieve WL) also resulted in exclusion of patients from the study.

The diagnosis of vital pulp was confirmed by the existence of bleeding after gaining access to the pulp chamber. If the sensibility test was affirmative and there was bleeding following pulp exposure, the tooth was recognized as vital. Presence or absence of pain 7 days previous to the event (yes/no) was observed.

Materials and Methods

Patient selection and distribution

A total of 240 of 279 patients (129 females and 111 male) aged 18 – 65 years were referred and integrated in this clinical trial, whereas 29 were rejected as not completing

the requirements needed. All patients presented with a vital maxillary or mandibular molar, premolar or front teeth designated for intentional endodontic RCT for *prosthetic reasons*.

Any patient declining to agree with the study or rejecting, one-visit RCT and consuming analgesics or nonsteroidal anti-inflammatory drugs were also eliminated also. Each qualifying patient was informed on the intentions, hazards, and plan of the trial, and written informed consent authorizations were obtained prior to their enrollment.

A clinician who had not contributed to the study made the randomization arrangement using a computer random table generator (www.random.org). Each patient receives a consecutive number. A total of 240 patients met the inclusion requirements and were incorporated in the study. Of the complete sample, 80 were randomly allocated to the one of the three irrigating regimes with different temperatures [Figure 1].

Clinical methodology

RCT was planned to complete in one visit. Topical anesthetic (Anestesia Topica, Astra, Mexico) was applied before infiltration. Patients received two carpules of articaine 2% with epinephrine 1:200,000 (Septodont, Saint-Maur des-Fosses, France). Circumstances in which additional anesthesia was necessary, intra-ligamental anesthesia (2 mL articaine 2%) was administered. For the upper teeth, the solution was injected by gentle and gradual local infiltration. For the lower teeth, one of the carpules was used for an inferior alveolar nerve block and the other one for a gentle labial infiltration near the tooth to be treated.

Rubber dam was placed and the tooth was cleaned with sterile gauze embedded with 2.5% NaOCl. Preparation of the access cavity was accomplished using sterile # 331 bur (Dentsply Int, York, PA, USA), at high-speed and refrigeration. About 2.5% NaOCl was used to disinfect the coronal access. The canals were cautiously probed with #10 K-type file (Flex-R files; Moyco/Union Broach, York, PA, USA).

A total of 1.5 mL of liquid 17% EDTA (Roth International, Chicago, IL, USA) was administered at the entrance of the canals. The WL was established with a #15 k-file and the Root ZX electronic apex locator (EAL; J Morita, Irvine, CA, USA), and confirmed radiographically (Schick Technologies, NY, USA). Cervical and middle thirds of the canal were flared with a K3XF 25/10 rotary instrument (Kerr Endo, Orange County, CA, USA) at 500 rpm. The root canal was flushed with 3 mL of 5.25% sodium hypochlorite (NaOCl). A glide path to the WL was then established.

Preparations of the canals were completed with an electric motor (VDW Silver Motor, VDW, Munich, Germany). Torque and rotation were predetermined for each Reciproc instrument, and were used in continuous reciprocating mode.

Dentinal remains were removed from the instrument with a sterile gauze embedded with 2.5% NaOCl, immediately to the instrument change after two to three pull-in and pull-out (pecking) movements (Reciproc) following the manufacturers' recommendations.

Each root canal was flushed with 2.5 mL of 2.5% NaOCl. Irrigation was achieved using a 24-G needle (Max-I-Probe; Tulsa Dental, York, PA, USA) and a 31-G NaviTip needle (Ultradent Products, Inc., South Jordan, UT, USA) when getting the WL after each instrument insertion. A size #10 K file was used to maintain WL after each Reciproc instrument. The established WL was checked repeatedly throughout the clinical procedures.

After instrumentation, the root canals were flushed with 3 mL of 2.5% NaOCl, activated ultrasonically. It was achieved by means of an IrriSafe ultrasonic 20.00 tip (Satelec, Merignac, France) at 50% power of the Mini-Endo ultrasonic device (Kerr Endo) with the tip placed 3 mm from the WL for 30 s per root canal.

Irrigating regimens

Group A

The R25 (size 25/.08) instrument was used in thin and curved canals, and R40 files (40/.06) were used in broad root canals. Three in-and-out pecking cycles were used with a fullness of not more than 3 mm until reaching the established WL. Patients assigned to this group receive a final irrigation with 5 mL of cold (4°C) 17% EDTA followed by 10 mL of cold (4°C) sterile saline solution dispensed to the WL using a cold (4°C) metallic micro-cannula included in the Endo Vac System (Kerr Endo) and maintained intracanally for 1 minute.

Group B

Canals were prepared as in group A. Patients assigned to this group received a final irrigation with 5 mL of cold (2.5°C) 17% EDTA followed by 10 mL of cold (2.5°C) sterile saline solution dispensed to the WL using a cold (2.5°C) metallic micro-cannula included in the Endo Vac System for 1 minute.

Control group

The R25 (size 25/.08) instrument was used in thin and curved root canals, and R40 files (40/.06) were used in wide root canals. Three in-and-out cycles were used with a distance of not more than 3 mm until getting the

established WL. Reciproc instruments were used in one tooth only (single use). Patients assigned to this control group were treated identically to the experimental groups, except that they received a final flush with 5 mL (*room temperature*) of 17% EDTA followed by 10 mL (*room temperature*) of sterile saline solution delivered to the WL using a metallic micro-cannula included in the Endo Vac System for 1 minute.

Each experimental and control group was flushed with the irrigant described above. Care was taken to confirm that the metallic cannula would aspirate properly by noticing the system's translucent evacuation duct. In case there was some obstacle, the metallic device was promptly replaced.

Recapitulation of the WL was performed again by using an apex locator as described before using #35 and #40 files.

The root canals were desiccated with disinfected paper cones and filled at the same visit. Gutta-percha points (Dentsply Maillefer, Tulsa, Ok, USA) were laterally condensed with #25 nickel-titanium spreaders (Dentsply Maillefer) and AH-plus as the sealer (Dentsply Maillefer). The access cavities were etched and fixed with Fuji IX (GC Corp., Tokyo, Japan).

After these irrigation regimens, the patients were warned of the possible occurrence of pain for hours following RCT and received an evaluation form (Visual analog scale: VAS questionnaire) to be completed and returned by 72 hours after. In it, they confirmed the presence/absence of pain. The pain level was measured using a validated pain scale known as the *VAS*.[21] The *VAS* scale is a continuous measure comprising a horizontal line, which is 10 cm in length. For pain intensity, the VAS is anchored by "no pain" (score of 0) and "pain as bad as it could be" (score of 10). The cut points on the pain *VAS* are no pain (0–0.5 cm), mild pain (0.6–4.0 cm), moderate pain (0.45–7.4 cm), and severe pain (7.5–10 cm).[22] The pain *VAS* was completed by the patients. The patients were asked to put a mark perpendicular to the pain *VAS* line at the point that indicated their pain severity during the 3 days after the endodontic treatment.

The outcomes for the groups A, B, and CG related to existence (yes/no), kind (mild, moderate, severe), and period (days) of pain were evaluated, and related to the following diagnostic factors: vital teeth, presence or absence of preoperative pain, group of teeth, or ubication, age and sex, and presence of occlusal contacts.

Statistical analysis

The associated issues preoperatively recorded were incorporated into the analysis as follows: age and sex, presence of occlusal contacts, and maxilla or mandibular teeth.

Differences in the general intensity of pain between groups were analyzed using the ordinal (linear) Chi-square test. Differences in VAS-recorded values after 24, 48, and 72 h and in the amount of analgesic intake between the two groups tested.

The results were statistically evaluated with the ordinal Chi-square test for the existence of post-endodontic pain with a level of significance of $P = 0.05$.

Results

Table 1 shows the distribution of clinical variables; a total of 240 patients took part in this study: 129 (53.75%) were women, and 111 (46.25%) were men. Their ages ranged between 18 and 65 years; 118 (49.16%) of the treated teeth were in the maxilla, and 122 (52.83%) were in the mandible.

The clinical organization of the participants is presented in Table 1. The standard age of the 216 patients included in this trial was 54 years. No statistically relevant modification ($P > 0.05$) between the groups was encountered concerning level or period of pain. According to the VAS examination, marks were seen 24 – 72 hours later in the three groups with an important decline subsequently.

Table 1: Distribution by group of teeth and location

Variables	Irrigant protocols		
	Control group (*n*=80)	Group A (*n*=80)	Group B (*n*=80)
Sex			
Male	37	37	37
Female	43	43	43
Age group			
18-30	25	21	29
31-43	40	43	41
44-56	11	13	7
57-65	4	3	3
Arch			
Maxilla	41	38	39
Mandible	39	42	41
Occlusal contact			
Yes	6	4	4
No	74	76	76

Table 2: Distribution of patient's by quantity of analgesic intake

24 h after	Control group (*n*=80), *n* (%)	Group A (*n*=80), *n* (%)	Group B (*n*=80), *n* (%)
Quantity			
None	54 (70.83)	57 (70.83)	57 (75)
One tablet	14 (16.66)	13 (18.05)	13 (15.27)
Two tablets	12 (12.5)	10 (9.72)	10 (9.72)
Three tablets	0	0	0

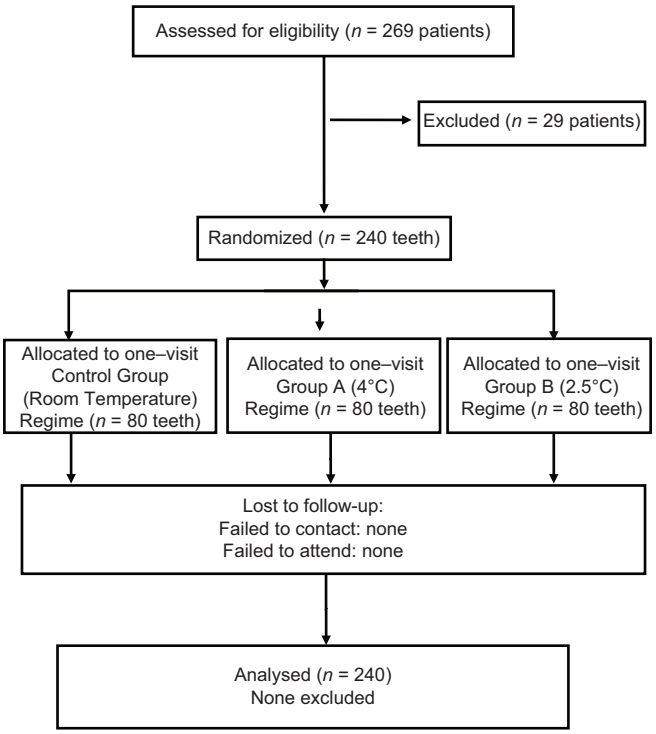

Figure 1: Flow diagram of the progress of phases of the study

Table 3: Kruskal-Wallis test applied to the postendodontic pain

Occurrence of pain	*n*	Mean	SD
Pain after 24 h			
Control Group	80	0.58	0.82
Group A	80	0.66	0.83
Group B	80	0.88	0.97
Pain after 48 h			
Control group	80	0.23	0.44
Group A	80	0.25	0.43
Group B	80	0.26	0.60
Pain after 72 h			
Control group	80	0.02	0.83
Group A	80	0.04	0.82
Group B	80	0.05	0.97

P=0.05. SD=Standard deviation

Table 4: Results of visual analog scale intensity of pain

Ocurrence	Control group (*n*=80)	Group A (*n*=80)	Group B (*n*=80)
No	54	57	57
Yes	26	23	23
Mild	13	10	11
Moderate	13	12	12
Intense	1	1	0

No statistically relevance distinction was appreciated among the three groups assessed in the trial in terms of level and quantity of analgesic intake [$P > 0.05$, Tables 2 and 3]. Analgesic intake was regulated to the following 24 h subsequently to RCT in all the groups assessed. Two of the 240 patients indicated severe pain or through the phase of the investigation corresponding one to group A and one to control group, respectively [Table 4].

There was no statistically relevant difference ($P > 0.05$) among groups A, B, and CG in relation to the existence of pain at any of the three time points measured [Table 2].

Patients in the CG had a significantly higher occurrence of postendodontic pain than the rest [Tables 2 and 4]. Patients in the groups A and B suffered significantly less pain after 24, 48, and 72 h and needed fewer analgesics postoperatively ($P < 0.05$). Patients in the control group also showed significantly higher intensity of pain in general and longer duration ($P < 0.05$).

Discussion

Pain by itself is difficult to understand and measure Especially when it happens suddenly in patients. The principal difficulty in learning aching and discomfort is the participant's idiosyncratic assessment and its dimension. For this purpose, planning the evaluation form has to be completely comprehended by participants.

In our research, a simple spoken classification was followed in the feedback procedure with four classes: no pain, mild, moderate, and severe pain. These classes were clearly comprehended by participants and were described by the occurrence or nonappearance of the necessity for pain-relieving treatment.

Preoperative pain is one of the highest predictors of postendodontic pain.[21] Thus, only teeth with irreversible pulpitis indicated for RCT because of prosthodontic purposes were chosen for this research.

All treatments were performed in one visit to avoid any the possible influence of intra canal medication or other issues generating pain, and the involucrate teeth in the three groups were released of any early occlusal points after endodontic procedures so that unsuitable traumatic occlusion would not disturb the outcomes. WL was estimated with an EAL and confirmed with a radiograph. Root ZX EAL was used because its exactitude has been established in two clinical environments.[22-26] As suggested by Herrera *et al*.,[27] electronic WL measurement was repetitive after cervical and middle thirds' shaping.

When clinicians combine radiographic interpretation and digital root canal dimensions, occasionally outcomes do not match. In the occasion of inconsistency among both magnitudes, the electronic assessment would be chosen,[28-30] as in this study.

In a recent study,[31] the dimension of the file used to preserve apical foramen open varied. We methodically used a #10 width file to maintain apical patency. Operating major widths to maintain apical patency can damage the surrounding tissues. All of these situations predispose the occurrence of postendodontic pain. In our study, care was taken to rule out avoidable preoperative factors and minimize any inevitable cause of postendodontic pain. Even with all the precautions followed, one cannot be certain in a clinical study whether pain is coming from the single factor under investigation, because possible sources of pain can never be controlled entirely.

It is well known that forcing of endodontic files outside the apical foramen can send a diversity of toxic materials to the surrounding tissues, which can generate pain.[32] Georgopoulou *et al.* showed a significantly major occurrence of pain if through the modeling procedure, instruments or materials were involuntary placed outside the apical foramen instead of maintaining them inside the canal.[33] In our protocol, there is no over instrumentation, WL was maintained in all cases. Nevertheless, apical patency does not appear to be related to postendodontic pain in vital condition because of its control during RCT.[34] In this study, we used only one time the small instrument (K file size #10) only one time after instrumentation phase.

Furthermore, Torabinejad *et al.*[5] stated that inadvertent over-passage of instrument can occur while determining WL, but it does not interfere with the incidence of postendodontic pain. Our methodology was similar to theirs, because also we used only thin files to establish the WL. Though, it varies from our research in that they did not maintain apical patency during all the RCT.

Siqueira *et al*.[35] found low frequency of flare-ups following RCT in teeth with necrotic tissue or teeth with previous RCT if AP was maintained. They found that maintenance of AP does not affect postendodontic pain. This was not measured in our research. In our report, we did not treat clinical cases for retreatment procedures, and flare-ups were not evaluated.

In our research, we reduced the variation in the procedures following protocols based on recommendations by authors and manufacturers. Although successful endodontic treatment depends on various factors, one of the most significant factors is the shaping of the root canal system. Proper cleaning and filling of the root canal system is facilitated by the maintenance of its original shape from the coronal to the apical thirds, without any iatrogenic event.

This study is in agreement with that of Yaylali *et al*.[36] who reported that the incidence of postoperative pain was significantly lower when apical patency was maintained but in nonvital teeth.

In our study, clean and shape procedures were performed on root thirds using reciprocating movements, respectively, followed by a final irrigation with cold (4°C and 2.5°C) 17% EDTA gently delivered to the WL using a cold (4°C and 2.5°C) sterile metallic micro-cannula attached to the EndoVac supported in an early scientific reports.[37-42] The standardized and controlled procedures used in this study may also have contributed to reduce the postendodontic pain. We used 10 mL of cold saline solution in the two experimental groups as the final irrigant that decreases the external root surface temperature which may be sufficient to generate a local anti-inflammatory result in the periradicular tissues.

Conclusion

The approach in both selecting the patients participating in the study and analyzing the data in this randomized clinical trial allow us to conclude that cryotherapy is an aid of clinical procedures to clean and shape the canals to reduce the occurrence of postendodontic pain and the need for medication in patients presenting with a diagnosis of vital pulp.

According to the conditions established for this study, there was no statistically significant difference among the instrumentation systems assessed.

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Conflicts of interest

There are no conflicts of interest.

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