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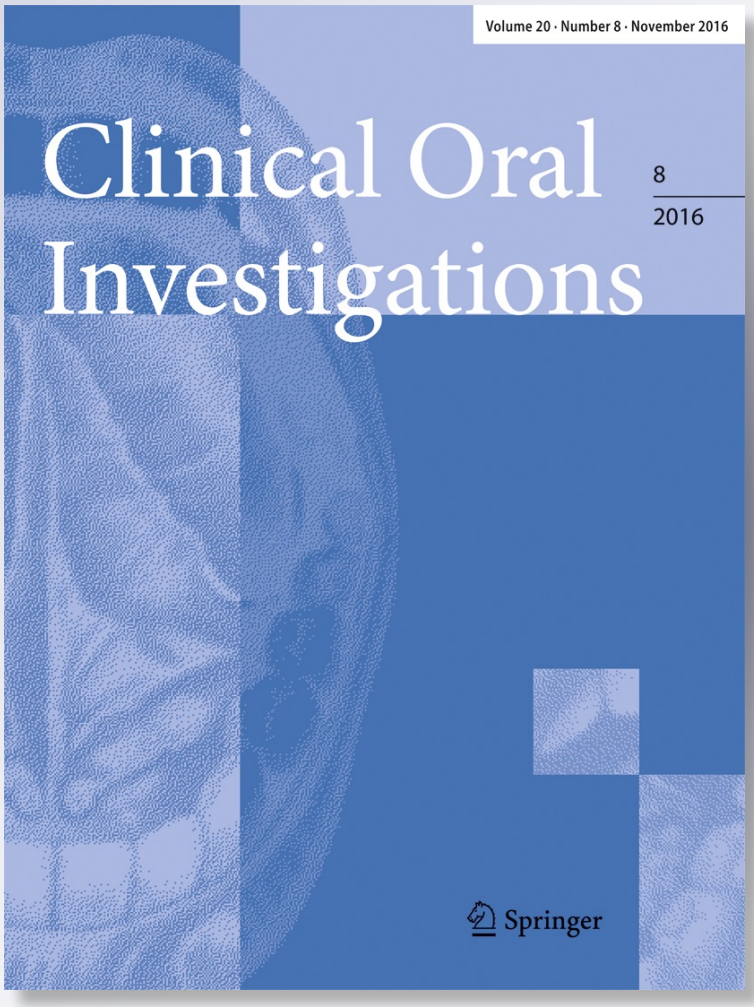

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ORIGINAL ARTICLE

Assessment of postoperative pain after reciprocating or rotary NiTi instrumentation of root canals: a randomized, controlled clinical trial

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Abstract

Objectives The aim of this study was to assess postoperative pain in a prospective randomized clinical trial comparing two groups, using the Reciproc® system in one group and the ProTaper® rotary system in the other.

Material and methods The study included 78 male patients, aged 18–64 years (mean age of 26 years), with asymptomatic pulp necrosis in mandibular molar teeth ($n = 78$). The single-session endodontic treatment was performed by a single operator specialized in Endodontics. Mechanical preparation of the root canals was performed using the ProTaper® and Reciproc® instrumentation techniques. Postoperative pain was recorded using a verbal rating scale (VRS) and verbal description with well-defined categories at the three following time intervals: 24 h, 72 h, and 7 days after the endodontic procedure. The assessment of postoperative pain was recorded as no pain, mild pain, moderate pain, and severe pain or flare-up. Data were analyzed using the nonparametric Mann-Whitney test with the aid of the STATA® software.

Results The incidence of postoperative pain in the ProTaper group (PT) 24 h after the endodontic procedure was 17.9 and 5.1 % after 72 h. In the Reciproc group (RP), the incidence after 24 h was 15.3 and 2.5 % after 72 h. No patients presented severe pain at the time intervals assessed.

Conclusions No significant difference ($p > 0.05$) in postoperative pain was found between the ProTaper® and Reciproc® instrumentation technique during endodontic treatment in this study.

Clinical relevance According to our findings and the results of the clinical trial, the occurrence of postoperative pain was low and similar between the reciprocating and rotary techniques during the time intervals assessed. These results are different from basic laboratory studies that affirm that the reciprocating techniques tend to promote more postoperative pain since extrusion of debris is greater.

Keywords Postoperative pain · Root canal treatment · Instrumentation · Rotary · Reciprocating

Introduction

During chemomechanical preparation of the root canals, all instrumentation techniques can produce apical extrusion of debris, even when short of the apical foramen [1–4]. Some debris, such as dentin and necrotic debris, microorganisms, pulp tissue remnants, and irrigating solutions cause irritation to the periradicular tissue, thereby provoking different levels of postoperative pain [5, 6].

Endodontic postoperative discomfort is defined as any degree of pain that occurs after endodontic treatment [7]. This phenomenon is known in literature as flare-up, which is characterized by the development of pain, swelling or both, beginning within a few hours or days after the surgical procedures [8].

Recent studies have shown that the treatment protocols of new reciprocating systems can also produce extrusion of debris in the apical region, which could be related to

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postoperative pain when compared with other traditional instrumentation techniques [3, 9–13]. However, there are few clinical studies on postoperative pain using reciprocating instrumentation protocols.

Thus, on the premise that an innovative reciprocating system can cause different levels of pain after endodontic treatment, the aim of this study was to assess postoperative pain in a prospective randomized clinical trial comparing two groups, using the Reciproc® system in one group and the ProTaper® rotary system in the other. The primary outcome measure of the study was to assess if different instrumentation techniques influence the occurrence of postoperative pain.

Materials and method

This clinical study was approved (CAAE 23141013.0.0000.5020) by the Research Ethics Committee involving human subjects at the Federal University of Amazonas and registered in the Brazilian Registry of Clinical Trials-REBEC (U1111-1168-3912). This is a randomized, controlled, double-blinded parallel-group trial with an equal allocation rate between groups. The study was conducted with the available population who attended the dental clinic of the Federal University of Amazonas, Manaus, from February 13 to November 15, 2014.

The sample consisted of men over the age of 18, who had had previous indication for endodontic treatment in permanent mandibular molar teeth and had been diagnosed with asymptomatic pulp necrosis. The pulpal status was confirmed by a negative response to cold and electric pulp tests and was confirmed later by the absence of bleeding on opening of the pulp chamber (Table 1). Immunocompromised patients who were on antibiotics, analgesics, or corticosteroids preoperatively or during treatment did not participate in the study as these factors could alter the perception of pain or interfere in the analysis of the presence of postoperative pain. During the root canal procedure, teeth that could not be treated in a single-session or patients who interrupted treatment were excluded.

Table 1 Demographic and clinical characteristics of study recruits

Baseline of demographic and clinical characteristics	Reciproc ($n = 39$)	ProTaper ($n = 39$)
Mean age	25.8 ± 10.2	25.9 ± 8.3
Systemic disease	None	None
Pulp necrosis without periapical lesion	16	18
Pulp necrosis with periapical lesion	23	21
Mandibular first molar	25	23
Mandibular second molar	14	16
Single session	39	39
Preoperative pain	None	None

The estimate number of participants was 39 patients per group. If there were truly no difference between the standard and experimental treatment, then 78 patients would be required in order to be 90 % sure that the upper limit of a 95 % one-sided confidence interval (or equivalent to 90 % two-sided confidence interval) will exclude a difference in favor of the standard group of more than 20 %.

Randomization was done through a table generated by the Sealed Envelope™ software by a third investigator not involved in the research protocol. A list of 80 numbers was prepared, divided into four blocks, 40 in each group. Each number from the list with the sequence of the experimental and control groups was individually placed in a numbered, opaque, sealed envelope. Once the patient was considered eligible for the procedure, prior to the endodontic treatment, the envelope was opened by the researcher-operator to identify which individual belonged to which group. The study used 78 numbers provided by a third investigator, as the sample consisted of 78 individuals. Both the patient and researcher-evaluator were blinded to the treatment protocol until the access to the root canal system was performed.

Of the 138 patients eligible for the study, 50 were excluded from the study because they did not meet the inclusion criteria. Thus, only 78 individuals were selected for allocation in groups and the individuals were randomly assigned to two groups, that is, 39 patients in the Group Reciproc® (RP) and 39 in ProTaper®group (PT). The study flow diagram is shown in Fig. 1.

Study intervention

Endodontic treatment followed a treatment protocol according to the two techniques used in the study. The cold test was performed by spraying (Endo-Frost; Coltene-Whaledent, Langenau, Germany) a cotton swab, which was then placed on the occlusal surface of the tooth. If there was no response after 5 s, the test result was considered negative.

Anesthesia was performed with local infiltration using 3.6 mL of 2 % lidocaine with 1:100,000 epinephrine (ALPHACAINE; DFL Indústria e Comércio Ltda, Rio de Janeiro, RJ, Brazil). A rubber dam was placed before endodontic access cavity preparation was performed. A glide path was established using PathFiles 0.13, 0.16, and 0.19 for both groups (Dentsply Maillefer, Ballaigues, Switzerland). The working length was confirmed with an electronic apex locator and a radiography was performed (Joypex 5, Denjoy Dental Co., Ltd., Changsha, China).

Instrumentation of the root canals was performed in accordance with the manufacturer's recommendations and began with the canal negotiation using size 10 K-file and the PathFile instruments #0.13, 0.16, and 0.19. For the Reciproc® system, the instrument selection was as follows: if the size 30 K-file was passively introduced into the root canals up to the

working length, the canal was considered large and the R50 instrument (50.05) was selected. If the size 20 file was passively introduced into the canal by the operator, the canal was considered medium and the R40 instrument (40.06) was selected; if the size 20 K-file failed to achieve the working length passively, then the R25 instrument (25.08) was selected. After selecting the file, the Reciproc® instrument (VDW, Munich, Germany) was introduced into the root canal with short in-and-out movements without completely removing the file from the root canal and the range of motion could not exceed 3–4 mm. A bit of pressure was applied and the instrument was removed and cleaned after each insertion, followed by irrigation of the root canals. A size 10 file was used to verify the patency in the WL and this kinematics was performed at least three times until the WL was reached. The instruments were driven by the VDW Silver® motor (VDW GmbH), specifically programmed for reciprocating instrumentation [14].

The instrumentation of the root canals with the ProTaper® system began with the canal negotiation with the size 10 K-file and the PathFile instruments #0.13, 0.16, and 0.19. Canal shaping was achieved with ProTaper rotary instruments following the manufacturer's instructions using finishing files F1, F2, F3, or F4, as determined by the operator. After enlargement with finishing file F1, preparation was assessed using the size 20 K-file. If the instrument was snug at length, preparation was considered adequate. If the size 20 K-file was loose at length, preparation was enlarged with the F2 instrument and, if necessary, with the F3 or F4 instrument, gauging after each finishing file with the corresponding hand file until a snug was obtained. The instruments were driven by the VDW Silver® motor (VDW GmbH), specifically programmed for each instrument used [3, 15].

The root canals were abundantly irrigated with 2.0 mL of 2.5 % sodium hypochlorite after each instrument exchange, and the irrigating solution remained in the root canal during the procedure. For both groups, sodium hypochlorite was applied with the aid of the 30-G Max-i-Probe needle (Dentsply Maillefer) up to 4 mm short of the working length, which was verified by a silicone stop. The amount of irrigating solution did not exceed 40 mL. For all the root canals, patency was performed with a size 10 K-file.

All teeth received the same amount of irrigating solution and the root canals were also irrigated with 17 % EDTA prior to obturation. First, the root canals were completely dried using sterile absorbent paper points compatible with the root canal diameters (Dentsply Maillefer or VDW, Munich, Germany). The gutta-percha master cone, compatible with the root canal instrumentation (ProTaper F1–F4, Dentsply Maillefer or R25–R50, VDW, Munich, Germany), was then inserted into the root canal and the first 5 mm were coated with AH Plus sealer (Dentsply Maillefer). Obturation of the root canal system was performed by the single cone using a thermomechanical compaction method, using size 60 McSpadden bur (Dentsply/Maillefer). Upon completion of the obturation, temporary sealing with glass ionomer cement,

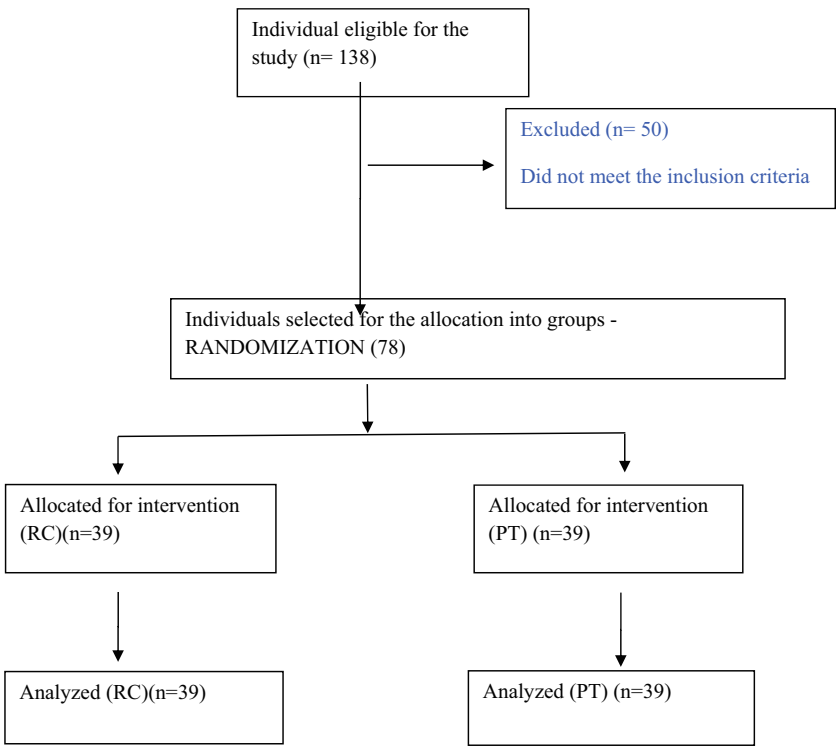

Fig. 1 Flow diagram CONSORT for randomized clinical trials

occlusal adjustment (completely taken out of occlusion), and final radiography were performed. Patients were referred to their clinic of origin for tooth rehabilitation.

After endodontic treatment, all patients were asked to fill out a verbal description scale according to the operator's instructions (primary outcome).

Assessment of postoperative pain

The questionnaires were assessed by the researcher-evaluator who did not have access to the data regarding the type of treatment performed by the operator. To assess postoperative pain, a scale of pain intensity was applied 24 h, 72 h, and 7 days after endodontic treatment. Pain was recorded on a verbal rating scale (VRS) (Fig. 2).

The researcher-evaluator telephoned the research individuals, which had been previously scheduled, 24 and 72 h after treatment to monitor postoperative pain and fill out the verbal description scale, as follows:

0. no pain or discomfort;
1. mild pain: feeling pain, but no oral medication (analgesics) required;
2. moderate pain: feeling pain, but no oral medication (analgesics) required;
3. Severe pain: feeling pain and is no longer able to perform any type of activity, feeling the need to lie down and rest (analgesics have little or no effect on pain relief).

Seven days after the procedure, a postoperative clinical assessment was conducted to assess the condition of the periapical region using palpation and percussion routine tests. The vertical percussion test was recorded as yes or no, depending on the patient's response to the stimulus. On the second visit, all patients returned and pain assessment forms were reviewed.

Statistical analysis

Statistical analysis was performed using the STATA® software. The original data were compared in pairs by the nonparametric Mann-Whitney test. Statistical analysis was performed by comparing the outcome between the techniques at the three time intervals assessed. Differences between postoperative pain for each instrumentation technique, at different time intervals, were assessed by the Friedman test.

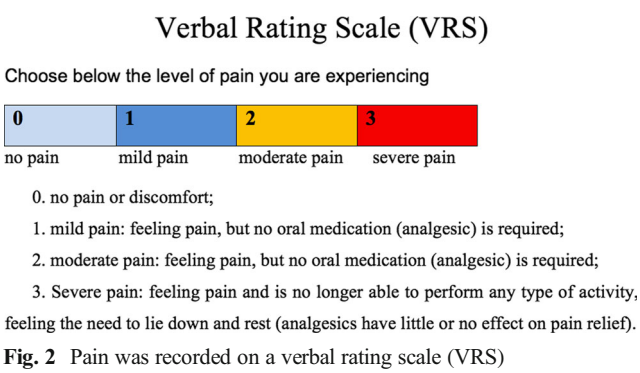

Fig. 2 Pain was recorded on a verbal rating scale (VRS)

Results

In the ProTaper® group, 32 (82.0 %) patients reported no pain after the first 24 h, 5 (12.8 %) experienced mild pain, and 2 (5.1 %) reported moderate pain, but none reported severe pain; 37 (94.8 %) patients did not present any kind of pain and 2 (5.1 %) individuals reported mild pain after 72 h. Seven days after the endodontic treatment, 38 (97.4 %) individuals reported no pain and only 1 (2.5 %) reported mild pain. The percussion test was performed on the endodontically treated tooth 7 days after the clinical intervention. Only two individuals responded positively to this test, corresponding to 5.1 % of the total sample.

In the Reciproc group, 33 (84.6 %) individuals reported no pain after the first 24 h, 3 (7.7 %) experienced mild pain, and 3 (7.7 %) reported moderate pain, but none reported severe pain; 38 (97.4 %) individuals reported no pain and only 1 (2.5 %) reported moderate pain after 72 h; no patients reported any kind of pain 7 days after the endodontic treatment. No patients responded positively to the percussion test 7 days after treatment (Table 2).

Primary outcome

The intensity of pain experienced by patients after endodontic treatment in the Reciproc group was similar to those in the ProTaper group ($p > 0.05$). In both groups, the highest levels of postoperative pain were recorded 24 h after each procedure, but these levels decreased after 72 h and 7 days after endodontic therapy, although differences were not significant ($p = 0.55$).

Discussion

In vitro studies comparing endodontic instrumentation techniques using rotary and reciprocating systems with apical extrusion of debris have effectively concluded that manual, rotary, or reciprocating instrumentation techniques produce an amount of debris extrusion into the periapical tissues and that extruded debris could cause different levels of postoperative pain [10–13, 16]. Although the ProTaper® technique, which served as control group for the present study, is more conventionally used, some studies show that this technique produces less debris extrusion when compared with the Reciproc® system, which produces a greater amount of debris extrusion due

Table 2 Descriptive results of the ordinal analogue pain score

Technique used	Reciproc ($n = 39$)			ProTaper ($n = 39$)		
Time intervals	24 h	72 h	7 days	24 h	72 h	7 days
Scores						
0	33 (84.61 %)	38 (97.43 %)	39 (100 %)	32 (82.05 %)	37 (94.8 %)	38 (97.43 %)
1	3 (7.69 %)	–	–	5 (12.82 %)	2 (5.12 %)	1 (2.56 %)
2	3 (7.69 %)	1 (2.56 %)	–	2 (5.12 %)	–	–
3	–	–	–	–	–	–
Total	39 (100 %)	39 (100 %)	39 (100 %)	39 (100 %)	39 (100 %)	39 (100 %)

to its kinematics [12, 13, 16]. In the present clinical trial, a low incidence of postoperative pain was observed after using the two instrumentation techniques.

Extrusion of debris into the periapical tissues can be related to postoperative pain after endodontic instrumentation [5, 6]. But, when instrumentation techniques and postoperative pain are compared in vivo in a controlled and randomized manner, the incidence of debris extrusion was lower when the ProTaper® rotary technique was used [3, 17], even though all instrumentation techniques have a significant incidence of apical extrusion of debris.

Although recent studies do not specifically compared instrumentation and postoperative pain, they all refer to the use of instrumentation techniques on the outcome of endodontic treatment [3, 4, 18–24]. Some studies report low postoperative pain [3, 4, 19–22, 24], while others report higher levels of pain [18, 21]. However, the lack of method standardization of these studies can trigger the incidence factor of postoperative pain such as preoperative pain, more than one operator conducting the research, differences in the clinical protocol of endodontic treatment, and different methods for collecting the clinical findings.

In the present study, the incidence of postoperative pain in the Reciproc® group was low. There are few published studies that refer to postoperative pain after instrumentation with the reciprocating systems. However, Gambarini et al. [21] conducted a clinical trial that assessed postoperative pain after using the WaveOne® system, which also uses the single-file system with reciprocating motion, but their results differ from the findings of the present research because the author's method differed in some aspects such as including men and women in the study, patients with preoperative pain, and root canal irrigation with 5 % sodium hypochlorite. Of these aspects, preoperative pain seems to be considerably significant for the high level of postoperative pain [25, 26].

Caviedes-Bucheli et al. [24] also conducted a clinical trial with reciprocating systems, but the study design of the author differs from the method used in the present study. These researchers assessed postoperative pain by identifying two substances present in the periodontal ligament after the instrumentation of the root canals: high levels of substance P (SP) and calcitonin gene-related peptide (CGRP), which trigger the incidence of postoperative pain. These levels were defined by radioimmunoassay. As the result of the research, instrumentation with the Reciproc® system showed similar levels of these substances in the periodontal ligament as those found in the negative control group, suggesting that this system causes little or no inflammatory response to the periapical tissues, which corroborates the present study that showed low levels of postoperative pain after instrumentation using a single-file system.

The results of the present clinical trial also corroborate the clinical findings of Wang et al. [17] who used the ProTaper® system for the instrumentation of the root canal system, comparing postoperative pain after a single-session and multiple sessions.

The incidence of mild postoperative pain was observed in the ProTaper® control group, corroborating the study of Almeida et al. [27] who conducted a study using the ProTaper® system in which mild pain was observed in 19 % of cases after 24 h, 10 % of cases after 48 h, and 3 % after 72 h; and moderate pain was recorded only in 3 % of the cases after 24 h.

In contrast to the findings of our study regarding the ProTaper® group, the study conducted by Tuncer and Gerek [28] reported a high incidence of postoperative pain after instrumentation with this system. In the study conducted by the author, the research was designed for men and women with maxillary and mandibular single-rooted teeth diagnosed with asymptomatic irreversible pulpitis or teeth with indication for prosthetic rehabilitation. But, the high level of pain is due to the fact that the time intervals analyzed to assess postoperative pain were 4, 6, 12, 24, and 48 h, and the highest level of postoperative pain was observed between 4 and 6 h.

The limitations of the studies on postoperative pain are related to the difficulty and differences in the research study designs, preoperative conditions of the tooth, treatment protocol, definition of pain, pain measurement, collection methods of results, and data analysis of postoperative pain [29]. Regarding the collection method of clinical findings of postoperative pain, the VRS method was used because it reduces these effects and it is considered the most adequate method

for reporting pain experienced by the patient [30]. In our study, the records of mild and moderate pain were considered for the incidence of postoperative pain because we needed to verify when the patient felt pain, regardless of the use of analgesics. Other studies conducted a similar analysis of the results [2, 3, 24, 28, 29]. However, Wang et al. [17] considered postoperative pain as moderate pain since the patient required the use of oral medication.

In the present clinical trial, no patients reported severe pain at the time intervals assessed, which would characterize endodontic flare-up. For the ProTaper® system, studies corroborate the findings of the present study, namely the absence of flare-up [3, 28]. Seven days after the clinical intervention, the percussion test was performed on endodontically treated tooth. In the present study, only two individuals responded positively to this test, corresponding to 2.5 % of the total sample ($n = 78$), and these two individuals belonged to the ProTaper® group.

The study of Almeida et al. [27] found low levels of postoperative pain in patients with necrotic pulp with apical periodontitis. According to this author, periapical lesions represent an increased risk for postoperative pain. Siqueira Jr et al. [31] argues that a meticulous aseptic technique helps to minimize the risk of microbial exacerbation of pain. Similarly, preoperative pain is a predisposing factor for postoperative pain and both studies were careful to restrict the participation of patients without preoperative pain. Randomization has ensured that these variables were equally distributed according to the instrumentation techniques, considering the primary outcomes. Sixteen teeth with pulp necrosis without apical periodontitis and 23 with apical periodontitis were treated with the Reciproc® technique and 18 and 21 teeth were treated with ProTaper®. Twenty-five first molars and 14 s molars were treated with the Reciproc® technique and 23 and 16 with the ProTaper®.

The limitations of the present study include the presence of male patients due to an insufficient number of female patients during recruitment, which would have resulted in a biased sample. However, studies have reported that women are more susceptible to postoperative pain than men [32]. The sample selection criteria were teeth with asymptomatic pulp necrosis and some items of standardization of treatment such as the irrigation protocol were established at 4 mm short of the apex to prevent leakage of irrigating solution and by completely removing occlusion after the endodontic procedure may have contributed to the low incidence of postoperative pain in this study.

The following factors may have contributed to the low incidence of postoperative pain found in this study: teeth with asymptomatic pulp necrosis, occlusion adjustment after the endodontic procedure, and items of standardization of treatment such as the irrigation protocol, which was established at 4 mm short of the apex to prevent leakage of irrigating solution.

Conclusion

The different instrumentation techniques did not affect the occurrence of postoperative pain during the time intervals analyzed.

Compliance with ethical standards All procedures performed were in accordance with the ethical standards of the Research Ethics Committee involving human subjects at the Federal University of Amazonas and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Conflict of interest The authors declare that they have no competing interests.

Informed consent Informed consent was obtained from all individual participants included in the study.

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