Trials

STUDY PROTOCOL

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Postoperative pain and quality of life assessment after endodontic preparation with rotary and reciprocating endodontic instruments: randomized clinical trial

Wallace Vieira Mendes[1,2], Suellen Nogueira Linares Lima[1,2], Jacqueline Vitória do Nascimento Azevedo[2,3], Hadda Lyzandra Austríaco Leite[4], Patrícia Santos Oliveira[1,2], Meire Coelho Ferreira[2,5] and Ceci Nunes Carvalho[2,6*]

Abstract

Background Postoperative pain is a common complication following endodontic treatment, often caused by acute inflammatory responses in the periapical tissues. Several factors contribute to this, including inadequate instrumentation, apical extrusion of debris during canal preparation, and other aspects of the procedure. Advances in technology have led to the development of nickel-titanium (NiTi) instruments that have shown potential to reduce postoperative discomfort. The purpose of this study was to evaluate postoperative pain in patients undergoing endodontic treatment with different NiTi systems.

Methods This randomized clinical trial will include 128 patients between the ages of 18 and 50 years with a diagnosis of pulp changes in molars without pain or radiographic lesions requiring endodontic treatment. Patients will be randomized to receive root canal preparation with the rotary ProTaper Ultimate rotary system or the Reciproc Blue reciprocating single-file system. The primary outcome will be the intensity of postoperative pain measured by a numerical rating scale (NRS-10 cm) in 24 h postoperatively. Secondary outcomes will include the intensity of postoperative pain measured by a visual analog scale (VAS-0–10 cm) at 6 and 12 h and spontaneous pain, occlusion sensitivity, and quality of life, assessed by the OHIP-14 questionnaire.

Discussion Our null hypothesis is that there will be no significant difference in postoperative pain between the two systems. The results of this study will provide information on the incidence and intensity of postoperative pain after instrumentation of root canal instrumentation with different NiTi systems and may help improve patient outcomes and quality of life.

Trial registration Brazilian Clinical Trials Registry (REBEC): RBR-10kbw6nx. Registered on April 6, 2024.

Keyword Root canal therapy, Toothache, Endodontics

*Correspondence:
Ceci Nunes Carvalho
ceci.carvalho@ceuma.br
Full list of author information is available at the end of the article

Introduction

Endodontic treatment consists of technical maneuvers aimed at restoring the normality of dental tissues when they are affected by caries, dental fractures, dental trauma, orthodontic trauma, endo-periodontal lesions, prosthetic needs, and other endodontic pathologies. In most cases, episodes of pain and discomfort are the reason for seeking treatment and may persist after treatment is initiated. Technological advances in dentistry and the updating of procedural techniques have made it possible to carry out this treatment rapidly [1].

Pain following endodontic treatment is a common complication, with an incidence ranging from 3 to 58% [2, 3], and is usually due to an acute inflammatory response in the periapical tissues that begins within hours or days after endodontic treatment [4–6]. Many factors can influence the occurrence of this postoperative pain, including inadequate instrumentation, apical extrusion of debris during canal debridement or preparation, unidentified canals, irrigation extrusion, intracanal medication extrusion between sessions, hyperocclusion, presence of periapical lesions [7–9], or even extravasation of endodontic cements. The most important factors are apical extrusion of dentin debris and bacteria during root canal preparation [10].

Studies have investigated postoperative pain associated with endodontic instrumentation techniques. For example, Neelakantan and Sharma [10] found that different instrumentation systems result in different degrees of apical debris extrusion, a significant factor in post-treatment pain. Their study, which compared rotary and reciprocating systems, showed that the type of kinematics influences the amount of debris expelled beyond the apex. Kherlakian et al. [11] further demonstrated that while both rotary and reciprocating systems can lead to postoperative discomfort, operator experience and standardization of technique play a critical role in minimizing patient pain. These findings highlight the need for further research into the comparative effects of newer instrumentation systems on patient outcomes.

All root canal preparation techniques are associated with apical extrusion of debris [12, 13]; however, with the evolution of technology and the advent of nickel-titanium (NiTi) instruments, it has been observed that most of these continuously rotating instruments expel less debris when compared to manually used stainless steel K-type instruments and have the potential to reduce postoperative discomfort [14]. To reduce working time and increase flexibility and fracture resistance of NiTi instruments, systems have been developed with design innovations and faster preparation techniques that preserve the original shape of the root canal [15]. The ProTaper Ultimate system (Dentsply Maillefer, Ballaigues, Switzerland) is one of the latest rotary mechanized systems. Among its main features and advantages, its rotary mode stands out, which increases the removal of apico-cervical dentin chips, thus reducing spiral twisting and consequently file fractures [16, 17].

Another innovation in root canal preparation was introduced in endodontics with the introduction of the Reciproc Blue system (VDW, Munich, Germany), which advocates the use of a single file. This instrument is made of NiTi alloy and has a reciprocating motion, meaning it initially rotates first counterclockwise and then clockwise [18]. It offers advantages such as lower fracture rates, shorter preparation time, which reduces the operator and patient working time, effectiveness in root canal preparation, reduced number of instruments, lower cost, and reduced instrument fatigue [19].

Despite these technological advances, few studies have directly compared the effects of these systems on postoperative pain and patient-reported quality of life. Therefore, the present study aims to evaluate postoperative pain in patients undergoing endodontic treatment with these two systems and to analyze their impact on daily activities.

Design and methods

Aims of the study

To evaluate and compare the incidence of postoperative pain after root canal instrumentation using the ProTaper Ultimate rotary system and the Reciproc Blue single file system in human permanent molars before, during, and after the root canal preparation phase. As sequentially, the patient will be enrolled and signed the terms, OHIP-14 before the beginning (baseline), an instrumentation will be performed and the measurement will be evaluated, which will be measured using visual scales (NRS-10 cm VAS-0–10 cm) at intervals of 0 h, 6 h, 12 h and 24 h, 2 days, 3 days, 4 days, 5 days, 6 days, and 7 days after instrumentation evaluated and compared with bite sensitivity using an autoclaved latex device at 0 h, 6 h, 12 h, 24 h, 2 days, and 3 days, OHIP-14 and 3 days after instrumentation (Fig. 1). The assessment times were chosen based on previous studies showing that postoperative pain usually peaks within the first 24 h after treatment. Longer follow-up periods, such as 3 and 7 days, were also included to assess pain resolution and possible late complications, as the literature emphasizes that these can occur. Our null hypothesis is that there will be no significant difference in postoperative pain between the

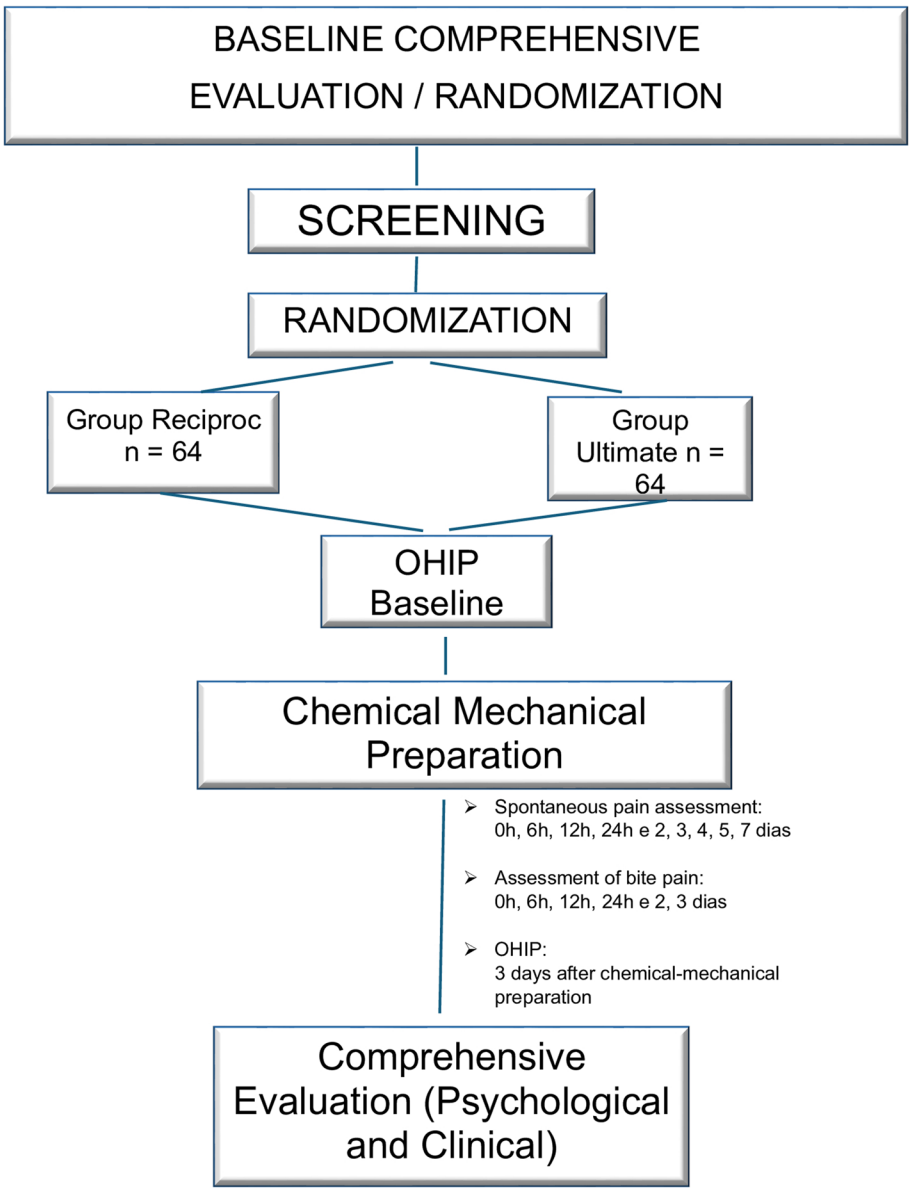

Fig. 1 Template of recommended content for the schedule of enrolment, interventions, and assessments

two systems, while the alternative hypothesis suggests an improvement in quality of life.

Overall design

A randomized, blinded (patient and biostatistician) clinical trial will be conducted according to the Consolidated Standards of Reporting Trials Statement [19, 20], registered in the Brazilian Clinical Trials Registry Platform (REBEC) RBR-10kbw6nx on April 6, 2024. Launched on 12/16/2010, REBEC is an open access platform with the objective of registering clinical trials carried out on human beings, in progress or completed, carried out by Brazilian and foreign researchers. In this study, it helps to standardize it. The study was approved by the Research Ethics Committee of CEUMA University (CAAE 64132322.6.0000.5084). The Research Ethics Committee (CEP) of the Maranhão University Center (UNICEUMA) is a collegiate body that analyzes research projects involving human beings, an independent and interdisciplinary collegiate body, which acts in a consultative, deliberative, and educational manner. Informed consent will be obtained from patients participating in the study by the

	STUDY PERIOD												
	Enrolment	Allocation	Post-allocation										Close-out
TIMEPOINT**	$-t_1$	0	t_1	t_2	t_3	t_4	t_5	t_6	t_7	t_8	t_9	t_{10}	t_{11}	t_x
ENROLMENT:													
Eligibility screen	X												
Informed consent	X												
Allocation		X											
INTERVENTIONS:													
Reciproc Blue (R)			X										
Protaper Ultimate (PN)			X										
ASSESSMENTS:													
OHIP-14 (Oral Health Impact Profile)		X							X				
NRS and VAS (Numeric Rating Scale / Visual Analog Scale)				X	X	X	X	X	X	X	X	X	X
Autoclaved latex device				X	X	X	X	X	X				
Formulation of data, results and conclusions													X

Fig. 2 SPIRIT

operator [21]. Sample size calculation was performed to compare mean pain intensity, considering a confidence level of 95%, a power of 80%, and a standard deviation of 2.3 [8]. A minimum of 58 patients was identified for each group, for a total of 116 patients. To compensate for possible losses, 10% was added to the sample size, totaling 128 patients, 64 per group according to the study design. Looking for patients and they will be will be treated and evaluated at the CEUMA University School Clinic in São Luís, MA, Brazil and will be randomized according to the type of endodontic instrument used: Reciproc Blue (R) and ProTaper Ultimate (PN), SPIRIT (Fig. 2). Allocation is performed by a person not involved in the endodontic treatment using the software www.radom.org. After patient history and assessment of the need for endodontic treatment of the tooth, information about each patient and the instrumentation technique assigned to the patient will be written and sealed inside an envelope, which will then be given to the operator. After determining the real working length (RWL), the operator will open the envelope and use the instrumentation technique assigned to that patient. All violations of inclusion

and exclusion criteria, reasons for randomization failure, including significant deviations from the protocol, loss to follow-up, voluntary withdrawals, and study discontinuations, will be reported to the study statistician. All data collected during the research will be simultaneously in an electronic spreadsheet, an online spreadsheet that will be accessible to all involved in the research, but only one operator will be able to modify it.

Participants

To be eligible to participate in this study, individuals must meet all of the following criteria:

1. Aged between 18 and 50 years old
2. Molars diagnosed with pulp changes requiring endodontic treatment (irreversible pulpitis and pulp necrosis without radiographic periapical lesion)
3. Absence of pain
4. Absence of radiographic lesions
5. Canal curvature of up to 25° according to the Schneider method [22]

Age: Participants should be between 18 and 50 years old. This age range was chosen to ensure homogeneity of the sample, as pain response and treatment efficacy can vary significantly between age groups. Diagnosis of pulp disease: Individuals should be diagnosed with pulp disease requiring endodontic treatment. Diagnosis will be based on clinical and radiographic examination. Clinicians will use well-defined criteria, including pulp vitality tests (such as cold and electrical tests) to confirm necrosis or asymptomatic irreversible pulpitis, and thus the need for treatment, in teeth without no pain or radiographic periapical lesions. Absence of pain: To ensure that the study focuses on patients with postoperative pain related to treatment and not to other conditions, inclusion will be restricted to patients who do not have pre-treatment pain. This condition helps to isolate the effect of the treatment itself on postoperative pain. Absence of radiographic lesions: Participants should not have significant radiographic lesions, such as periapical or periodontal, that could influence postoperative pain or the need for additional interventions. The presence of lesions could confound the results by introducing extraneous variables that could influence pain. Canal curvature: Treated canals should have a curvature of up to 25°, according to the Schneider classification. This criterion is important because more curved canals may present additional difficulties in instrumentation and cleaning, which may affect pain scores and treatment efficacy.

Individuals with any of the following criteria will be excluded from participation in this study:

- Presence of internal or external resorption
- Trismus
- Ankylosis
- Periodontal status index less than 3
- Systemic disease
- Teeth out of normal alignment
- History of trauma
- Pregnancy
- Presence of teeth requiring endodontic retreatment

Presence of resorption: Patients with internal or external resorption are not included, as these conditions may alter the dynamics of endodontic treatment and influence postoperative pain. Trismus and ankylosis: Conditions that limit mouth opening and mandibular mobility (trismus and ankylosis) are excluded because they may affect the patient's ability to perform and respond to treatment. Periodontal condition index less than 3: Patients with compromised periodontal health may be at greater risk of complications during endodontic treatment and are therefore be excluded to ensure the safety and efficacy of the treatment. Systemic diseases: The presence of systemic diseases that may interfere with healing or the body's inflammatory response, such as uncontrolled diabetes or autoimmune diseases, will result in patient exclusion. Abnormal tooth position: Patients with teeth that are abnormally positioned or with a history of trauma that may interfere with endodontic treatment are also be excluded. History of trauma: Patients with a history of significant dental trauma that may affect the pulpal or periodontal health of the tooth in question will be excluded. Pregnancy: Pregnant women will not be included in the study for ethical and fetal safety reasons. Need for endodontic retreatment: Patients requiring endodontic retreatment will be excluded, as their baseline conditions may be significantly different from those treated for the first time.

Patients who are undergoing or have a history of treatment with immunosuppressive drugs, chemotherapy, radiotherapy, or any other treatment for cancer, as well as ongoing use of opioid analgesics, corticosteroids, or therapies that may interfere with pain perception and postoperative recovery, will be excluded from the study. These treatments may significantly affect postoperative pain and quality of life outcomes, and their inclusion could distort the analysis of the effects of the instrumentation systems used. The objective is to ensure that the observed results refer solely to the differences between the rotary and reciprocating instrumentation systems, without the interference of other therapeutic factors [23–25].

Informed consent and biospecimens

Informed consent will be obtained from all participants. No biospecimens will be collected in this study.

Treatment procedure

Instrumentation will be performed in a single session and pain symptoms and quality of life will be assessed. Deep local anesthesia will be applied with 2% mepivacaine with 1/80,000 epinephrine (Nova DFL, Taquara, Rio de Janeiro, Brazil). The access cavity is then prepared, and the tooth is isolated with a rubber dam. The canal was emptied using K-type files (Dentsply Maillefer, Ballaigues, Switzerland), size 15, in the presence of 2.5% sodium hypochlorite solution (Fórmula e Ação, São Paulo, SP, Brazil). The initial working length was determined with a foraminal locator (Dentsply, Munich, Germany) placed 1 mm from the radiographic apex. Root canal preparation was then performed with one of the following instrument systems according to the manufacturer's instructions. A 2.5% sodium hypochlorite solution/pH 11 will be used, with all teeth receiving the same volume of irrigation solution (15 ml) during instrumentation. This is followed by 2 ml of 17% EDTA, which will remain in the canal for 3 min, and a final irrigation with 2 ml of 2.5% sodium hypochlorite [2].

For instrumentation with the Reciproc Blue (VDW, Munich, Germany), the selection of the initial instrument is made after radiographic examination, evaluation of the root canal thickness and with the help of an initial size #15 file assessing the free access to the real working length. Once selected, these instruments should be inserted and removed with a range of 3 mm, after three back and forth movements until reaching the RWL. On completion and/or after each instrument, the root canal path is recapitulated with a manual #15 file up to the RWL. The choice of the #15 file was based on a study by Yu et al. [26], which showed its effectiveness in the patency of wider canals, in addition, the #15 file provides greater stability to the operator during the initial unblocking phase, however if it is impossible to use of file #15, in narrower canals, the smaller caliber file of type #10 was selected. The protocol used for rotary instrumentation of the ProTaper Ultimate system is carried out according to the manufacturer's recommendations: after exploration/emptying and determination of the real working length, the sequence of instruments (Slider, Shaper, F1, F2, and F3) according to the canal anatomy and with back-and-forth kinematics along the root canal. Both systems use the VDW Silver motor (VDW, Germany). For the Reciproc system, it will be used in RECIPROC ALL mode (speed of 400 rpm and 2.5 Ncm of torque), while for the ProTaper Ultimate system, it will be programmed at a speed of 400 rpm, 4–5.2 Ncm of torque, and continuous movement [27].

After the completion of instrumentation, the canals will be dried by aspiration with cannulas (Ultradent Products Inc, Salt Lake City, UT, USA), supplemented with absorbent paper points from the Reciproc Blue (VDW, Germany) and ProTaper Ultimate (Dentsply Maillefer, Ballaigues, Switzerland) file systems, and then temporary restoration will be performed with Vitro Fill LC restorative glass ionomer (Nova DFL, Taquara, Rio de Janeiro, Brazil). The working time from the beginning to finish of instrumentation of each root preparation system will be counted and recorded.

After root canal preparation, patients will receive a form with two pain assessment scales: the numerical rating scale (NRS) and the visual analog scale (VAS-0–10 cm). The NRS is a 10-point scale (0 = no pain, 1–2 = mild pain, 3–4 = moderate pain, 5–7 = considerable pain, and 8–10 = severe pain), with the first and the second scales being 20 points (0–100 with 5-point intervals, with closer to 0 indicating no pain and closer to 100 indicating worst possible pain). Patients complete the form according to the level of spontaneous pain every 0, 6, 12, and 24 h and daily for 2, 3, 4, 5, 6, and 7 days. Studies [28–30] show that the prevalence and severity of pain is highest in the first 24 h, dropped substantially within 24 h of treatment, and continued to drop to minimal levels in 7 days, or no pain was reported after 7 days. In addition to these, the patient will be instructed to bite on an autoclaved latex device (3 × 2 cm) to simulate biting sensitivity, instructed to bite on the device in the region of the treated tooth at 0, 6, 12, 24 h, and 2 and 3 days and record on the form the presence or absence of pain provoked by biting on the device. The patient will be instructed to set alarms on their mobile phone to remember to fill out the form correctly, and on the seventh day the operator will remind them to return the next day to submit the completed data.

Each participant will answer a Questionnaire on the Impact of Oral Health on Quality of Life (OHIP-14) during the anamnesis, after 3 days of instrumentation, and after 3 days of completion preparation, indicating whether they have always, often, occasionally, rarely, or never experienced any of the problems assessed by the 14 items of the OHIP. The items included in the questionnaire are grouped into seven sections: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and disadvantage. A questionnaire containing demographic, socio-economic, and clinical characteristics information will be applied to the patients. The patient will be referred for root canal treatment after 7 days. Exacerbation of an infectious process, fracture that compromises the integrity of the tooth, flare-up, or lack of contact or interest by the patient in continuing the process, these will be

criteria for modification the treatment or exclusion from the study, observing the cause and the most appropriate solution according to the literature. All adverse events will be systematically collected and recorded when spontaneously reported by participants. The investigators will assess the severity and causality of the adverse events. Serious adverse events will be reported to the Research Ethics Committee (CEP) of the University CEUMA (CAAE 64132322.6.0000.5084), while non-serious events will be reported according to regulatory guidelines with auxiliary care and judgment. Adverse events, if necessary, may be withdrawn from the study. Other adverse events will be documented and managed in a similar manner. All data will be recorded in a secure and confidential database, with access restricted to the principal investigators and authorized personnel. These procedures ensure the safety of the participants and the integrity of the study. Should any patient experience unexpected complications, they have direct access to the research team, which includes experienced endodontists, to manage any complications. This care is provided at no additional cost to patients. No financial compensation is expected, as the risk involved is minimal and the treatment performed is equivalent to high-quality standard procedures. Our priority is the well-being of the participants and we follow ethical standards and regulations for conducting human research. Patients will be advised not to take pain medication, as it may interfere with the outcome; in serious cases, they should contact the team.

Assessments

Treatment is performed by two calibrated endodontists, both with more than 3 years of experience in endodontic treatment, who were previously trained in the pilot study. The calibration process was performed by a specialist with more than 15 years of clinical experience who used simulated clinical cases to standardize the instrumentation technique with both systems (rotary and reciprocating), and the biostatistical analysis of the results will be performed by dentists not involved in the restorative procedures and therefore blinded to group allocation.

Data analysis

Statistical Package for Social Sciences (IBM SPSS version 21.0; IBM Corporation, Armonk, NY, USA) will be used for the analysis, and statistical significance was set at $p < 0.05$. Baseline demographic and clinical features (a patient and tooth-related factors), as well as time of instrumentation and number of analgesics taken, will be compared between groups. A multiple intra-group analysis (ProTaper Ultimate rotary and Reciproc Blue groups) of postoperative pain intensity for the evaluated time intervals (6, 12, and 24 h and from day 2 to day 7) will be assessed using a parametric or non-parametric test ($p < 0.05$). A parametric or non-parametric test will be applied every two time intervals, with significance corrected using a correction method. The Mann–Whitney test will be used to compare the postoperative pain intensity between the groups and considering each time and pain measurement scale (NRS and VAS). The effect size will be calculated for standardized differences between the means of postoperative pain intensity in the groups using Cohen's *d*. A test with repeated measures will be applied to evaluate if the ingestion of analgesics (using the time intervals that patients took more analgesics) has interaction with postoperative pain, considering each group (ProTaper Ultimate rotary and Reciproc Blue). The Mann–Whitney test was used for the comparison between groups of the mean total OHIP-14 and domain scores. The number of events (postoperative pain and bite/occlusion sensitivity) will be compared between groups (using the chi-squared test) and evaluating the absolute and relative risks for the outcomes tested. Poisson regression will be used to postoperative pain (absent/present) at the time interval that have the highest postoperative pain recorded by the NRS or VAS as the dependent variable and gender, oral hygiene status (good < moderate < poor), tooth location (mandibular/maxillary), and instrumentation technique (ProTaper Ultimate rotary and Reciproc Blue) as independent variables. All the associations with $p < 0.20$ in the non-adjusted analysis will be included in the adjusted analysis. The study is designed as a randomized clinical trial with a superiority framework. The primary objective is to assess whether postoperative pain outcomes and the impact on quality of life differ significantly between rotary (ProTaper Ultimate) and reciprocating (Reciproc Blue) instrumentation systems. The null hypothesis posits that there is no significant difference between the two systems, while the alternative hypothesis suggests that a significant difference may exist.

Discussion

The proposed study will be the first to examine the pain relationship of a pilot instrument (Reciproc Blue) with a new one instrument on the market with a different kinematics (ProTaper Ultimate). Thus, relating them in terms of post-treatment symptoms and patients' quality of life. If there are promising results in clinical trials, this would suggest that individuals would benefit from the intervention using the proposed protocol, an alert to manufacturers and endodontists, and could be a precursor for future studies.

Trial status

Recruitment began in April 2024 with an estimated completion date of August 2024.

Abbreviations

NRS	Numerical rating scale
VAS	Visual analog scale
NiTi	Nickel-titanium
CONSORT	Consolidated Standards of Reporting Trials Statement
REBEC	Registro Brasileiro de Ensaios Clínicos
OHIP	Oral Health Impact Profile-short form
EDTA	Ethylenediaminetetraacetic acid

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-08766-1.

Supplementary Material 1.

Supplementary Material 2.

Supplementary Material 3.

Authors' contributions

Conceptualization: C.N.C., K.L.M.S.; methodology: K.L.M.S., L.G.D., C.C.R.M.; validation: M.C.F., G.R.S.; formal analysis: C.N.C., R.G.S.; investigation: K.L.M.S.; resources: C.N.C.; data curation: M.C.F.; writing—original draft preparation: K.L.M.S., L.G.D., C.N.C.; writing—review and editing: M.C.F., R.G.S., H.L.A.L.; supervision: C.N.C.; project administration: C.N.C.; funding acquisition: C.N.C. All authors have read and agreed to the published version of the manuscript.

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Data availability

The data sets used and analyzed in the current study are available from the corresponding author on reasonable request. Upon completion of the study, the data obtained will be in possession of the corresponding author and the results will be published in journals.

Declarations

Ethics approval and consent to participate

All procedures were carried out in accordance with relevant guidelines and regulations and performed in accordance with the Declaration of Helsinki. Patients' parents had signed an informed consent as well as REBEC and the financed. The use of patient information to prepare this article was approved by the research ethics committee at the university school where the treatments took place (approval number: #2.997.609). Any changes to the study will be reported to the ethics committee and all approving bodies.

Competing interests

The authors declare that they have no competing interest related to this study.

Author details

[1]UniCEUMA: Universidade Ceuma, São Luís 125287, Brazil. [2]Postgraduate Program of Dentistry, CEUMA University, São Luís, Brazil. [3]Ceuma University: Universidade Ceuma, São Luís, Brazil. [4]UFMA: Universidade Federal Do Maranhao, Maranhão, Brazil. [5]Universidade Ceuma, São Luís 125287, Brazil. [6]School of Dentistry, Universidade Ceuma, São Luís 125287, Brazil.

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