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Published study

RBR-10kbw6nx Postoperative pain and quality of life after Canal Treatment with mechanized instruments: clinical study

Registration date: 04/06/2024 (dd/mm/yyyy) **Last approval date:** 04/06/2024 (dd/mm/yyyy)

Kind of study:

Interventions

Scientific title:

en

Postoperative pain and quality after of life
Endodontic Preparation with
Protaper Ultimate and
Reciproc Blue instruments:
randomized clinical study

pt-br

Postoperative pain quality of life after
Endodontic preparation with instruments Protaper
Ultimate and Reciproc Blue:
randomized clinical study

is

Postoperative pain and quality after of life
Endodontic Preparation with
Protaper Ultimate and
Reciproc Blue instruments:
randomized clinical study

Assay identification

- **UTN Number:** U1111-1292-5047
- **Public title:**

en

Postoperative pain and quality of life after Canal
Treatment with
mechanized instruments:
clinical study

pt-br

Postoperative pain and quality of life after
Root canal treatment with
instruments
mechanized: study
clinical

- **Scientific acronym:**
- **Public acronym:**
- **Secondary identifiers:**
  - **74336923.0.0000.5084**
    Issuing body: Plataforma Brasil
  - **6,581,650**
    Issuing body: Research Ethics Committee of the Maranhão University Center

Sponsors

- **Primary sponsor:** Centro Universitário do Maranhão - UNICEUMA
- **Secondary Sponsor:**
  - **Institution:** Maranhão University Center - UNICEUMA
- **Sources of financial or material support:**
  - **Institution:** Foundation to Support Research and Scientific and Technological Development of Maranhão - FAPEMA

Health conditions

- **Health conditions :**

en

Pulp degenerates uncle n

pt - br

Pulp degeneration

- **From general writers for health conditions:**

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C 0 7.7 9 3 .2 3 7 Dental Pulp Diseases

- **From specific descriptors for health conditions:**

en

K 0 4.2 p ulp degenerates uncle n

pt - br

K 0 4.2 D egeneration of dap olp a

Interventions

- **Interventions:**

en

T his is adou ble - blin d, two - armrando miz edcontr olle d clinic al stud y. P a tie nts will be randomly allocated according to the type of endodontic instrument used: Reciproc Blue (R) and Protaper Ultimate (PN). Experimental group 74 patients: with indication for endodontic treatment using the Protaér Ultimate system. Control group: 74 patients with indication for endodontic treatment using the Reciproc Blue system. Both the researcher who will evaluate the outcomes and the participants will not know which group each participant belongs to. The allocation will be made by a person who will not perform endodontic treatment using the www.radom.org software.

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, and then the envelope will be given to the operator. After determining the actual working length (CRT), the operator will open the envelope and use the instrumentation technique assigned to that patient.

Deep local anesthesia will be applied using 2% mepivacaine with 1/80,000 epinephrine (Nova DFL, Taquara, Rio de Janeiro,

pt - br

T rata - sedeumestudio clinic rando mizado double - blind control. The allocated spa be – the ale ato ria mentedeacordo as a type of endodontic instrument or used: Reciproc Blue (R) and Protaper Ultimate (PN).

Experimental group 74 patients: with indication of treatment endodontic using the Protaér Ultimate system. Control group: 74 patients with indication for endodontic treatment using system Reciproc Blue. Both the researcher who will evaluate the outcomes and the participants will not know which group each participant belongs to.

The allocation will be made by a person who will not perform the treatment endodontic treatment using the software www.radom.org. After patient anamnesis and assessment of the need for treatment endodontic examination of the tooth, information about each patient and the instrumentation technique assigned to the patient will be written and sealed within a envelope, and then the envelope will be given to the operator. After determining the actual working length (CRT), the operator will open the envelope and use the instrumentation technique assigned to that patient.

Deep local anesthesia will be applied using

Brazil). N ext, the accessca vit y will be prepared, and the tooth is hello tedu sin garubberda m. T heempt yin gofthecan als will becar rie d out wit htype K file s (Dents ply Maille fer, Ballaigues, Switzerland), number 15, in the presence of a 2.5% sodium hypochlorite solution (Fórmula e Ação, São Paulo, SP, Brazil). The initial working length will be determined with foraminal locator (Dentsply, Munich Germany) established 1 millimeter from the radiographic apex. Subsequently, root canal preparation will be performed with one of the following instrumentation systems according to the manufacturer's instructions. 2.5% sodium hypochlorite and pH 11 will be used, and all teeth will receive the same volume of irrigating solution (15ml) during instrumentation. At the end of this, they will receive 2 ml of 17% EDTA, which will remain inside the channel for 3 minutes and final irrigation with 2ml of 2.5% sodium hypochlorite. For instrumentation with reciprocity kinematics – Reciproc Blue (VDW, München, Germany). An initial instrument selection will be made after the radiographic examination. These instruments must be introduced and removed with a width of 3 millimeters, after three back and forth movements, removed from the root channel and the instrument cleaned and the root canal irrigated. After these procedures, the root channel path will be recapitulated with a 15 manual file, and then with a Reciproc Blue instrument until reaching the CRT. The protocol used for rotational instrumentation of the ProTaper Ultimate system will be carried out in according to the manufacturer's recommendation: after exploration/emptying and determination of the current working length, sequence the of instruments (Slider, Shaper, F1, F2 and me piv ac ain a 2 % with 1 / 8 0.0 0 0 dee pin efrin a (New DFL, Taquara, Rio de Janeiro, Brazil).

Then, the access box will be prepared, and carefully isolate it using a rubber dam.

O empty mentodoscan ais It will be carried out with type K files (Dents ply Maillefer, from Switzerland), Ballaigues, number 15, in the presence of 2.5% sodium hypochlorite solution (Fórmula e Ação, São Paulo, SP, Brazil). The working length initial it will be determined with a locator foraminal (Dentsply, Munich Germany) established 1 millimeter from the radiographic apex.

Subsequently, the root canal preparation will be carried out with one of the following instrumentation systems in accordance with the manufacturer's instructions. Will be used 2.5% sodium hypochlorite and pH 11, with all teeth receiving the same volume of irrigating solution (15ml) during instrumentation. At the end of this you will receive 2 ml of EDTA 17%, which will remain inside the canal for 3 minutes and final irrigation with 2ml of 2.5% sodium hypochlorite.

For instrumentation with kinematics of reciprocity – Reciproc Blue (VDW, München, Germany) an initial instrument selection will be made after the radiographic examination. These instruments must be introduced and removed with an amplitude of 3 millimeters, after three back and forth movements, removed from channel root and carried out cleaning the instrument and irrigating the root canal. After these procedures, a recapitulation of the root canal path with a file manual 15, and then with the Reciproc Blue instrument until reaching the CRT. The protocol used for rotational instrumentation of the ProTaper Ultimate system will be carried out in agreement with recommendation of

F 3) in accordance wit htheanatomyofthecan al andthe kin ema tic sofbackand forth alo ngtherootcan al.

For both systems, the VDW Silver engine (VDW, Germany) will be used. For the Reciproc system, it will be used in RECIPROC ALL mode (400 rpm speed and 2.5 Ncm of torque), while in the Protaper Ultimate system it will be programmed at a speed of 400 rpm, 4-5.2 Ncm of torque and continuous Finished movement.

instrumentation, the canals will be dried by aspiration with cannulas (Ultradent Products Inc, Salt Lake city, Utah, USA) complementing the drying with absorbent paper cones from the Reciproc file system (VDW, Germany) and Protaper (Dentsply Maillefer , Ballaigues, Switzerland), and then temporary restoration will be carried out with Vitro Fill LC restorative glass ionomer (Nova DFL, Taquara, Rio de Janeiro, Brazil). The working time from the beginning to the end of the instrumentation of each root preparation system will be counted and recorded. After the first session, patients receive will a form with two pain assessment scales: the numerical scale (NRS-10 cm) and the visual analogue scale (VAS-0-10 cm). The NRS-10 cm is a ten-point scale (0 = no pain, 1 - 2 = mild pain, 3 - 4 = moderate pain, 5 – 7 = considerable pain and 8 - 10 = severe pain).

Participants will also be instructed to record pain intensity using the VAS (0- 10 cm). This scale is a 10 cm horizontal line with scores of 0 (no pain) and 10 (severe pain) at the ends. Patients will mark the scale by drawing a vertical line through the horizontal line of the scale to indicate pain intensity. The distance in millimeters from zero will be measured with the aid of a millimeter ruler. Patients will fill out the form according to the level of spontaneous pain every 6, 12, 24 hours. Then new reviews will be recorded

factory rich before: after six ploration/emptying the mind and determining the length of the work, following in instruments (Slider, Shaper, F1, F2 and F3) according to the anatomy of the channel and kinematics back and forth along the root canal. For both the systems will be used VDW Silver engine (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 in the Protaper Ultimate system it will be programmed at a speed of 400 rpm, 4- 5.2 Ncm of torque and movement continuous.Finished instrumentation, channels will be dried per aspiration with cannulas (Ultradent Products Inc, Salt Lake City, Utah, USA) complementing drying with absorbent paper cones from the filing system itself Reciproc (VDW, Germany) and Protaper (Dentsply Maillefer, Ballaigues, Switzerland), and then temporary restoration will be carried out with Vitro restorative glass ionomer Fill LC (Nova DFL, Taquara, Rio de Janeiro, Brazil). The working time from the beginning to the end of the instrumentation of each root preparation system will be accounted for and recorded. After the first session, patients will receive a form with two pain assessment scales: the numerical scale (NRS-10 cm) and the visual analogue scale (VAS-0-10 cm). The NRS-10 cm is a ten points (0 = no pain, 1 - 2 = mild pain, 3 - 4 = moderate pain, 5 – 7 = considerable pain and 8 - 10 = pain serious). Participants will also be instructed to record the intensity of pain using the VAS (0-10 cm). This scale is a 10 cm horizontal line with scores of 0 (no pain) and 10 (severe pain) in the extremities. You Patients will mark the scale by drawing a vertical line through horizontal scale line

daily for 3 days. In thesecondses sio n, beforethe sia andafter

choo sin gthescores, thepa tie nt will be in structuredto bit eonanauto cla ved

latex device (3 x 2 cm) to simulate sensitivity when biting. The patient will be instructed to bite the

device in the region of the tooth being treated and record on the form the

presence or absence of pain caused when biting the device. Each

participant will answer, during the anamnesis and after 3 days of completed treatment, a

questionnaire that aims to measure the

impact of oral health on quality of life (OHIP-14) reporting whether

there was always, frequently, occasionally, rarely or never, any of the problems assessed by the 14 OHIP items. The items included

in the questionnaire are grouped into sections: seven functional

limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and disadvantage. containing demographic, socioeconomic A and clinical questionnaire

characteristics information will be applied to patients

to indicate in ten sid adedado r. The distance in millimeterszeroser

He helped me accommodate umar is gua milim is tric a. Please complete the form according to the agreement

of spontaneous pain every 6, 12, 24 hours. Then new reviews will be recorded daily for 3 days. In the second session, before anesthesia and after choosing the scores, the patient will be instructed to bite

autoclaved device (3 latex x 2 cm) to simulate sensitivity to

to bite. The patient will be instructed to bite the

device in the region of the tooth being treated and

record on the form the presence or absence of pain caused when biting the device.

Each participant will respond, during the anamnesis and after 3 days of treatment

completed, a questionnaire that aims to measure the impact of oral health on

quality of life (OHIP-14) reporting whether there was always, frequently, occasionally, rarely or never any of the problems assessed by the 14 OHIP items. 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, socioeconomic information

It is

clinical characteristics will be

applied to patients

- **From descriptors for the interventions:**

en	pt - br
E 0 6 . 3 9 7.7 7 8 . 8 8 9 Root C an al P repair uncle n	**E 0 6 . 3 9 7. 7 7 8 . 8 8 9** R adic u r C an al P repair
en	**pt - br**
E 0 6 . 3 9 7.7 7 8 Root C an al Treatment	**E 0 6 . 3 9 7.7 7 8** T reatment do C an al R adic ula r

R ecruitment

- **Recruitment status:** Recruitment completed
- **Recruitment country**
  - Brazil
- **From first interview and recruitment:** 0 1 / 0 3 / 2 0 2 3 (dd/mm/yyyy)

- **Target sample size: Gender for inclusion: Minimum age for inclusion: Maximum age for inclusion:**

148	-	18 Y	50Y

- **Inclusion criteria:**

en

Ages between 18 and 50 years old; patients of both genders; diagnosed with pulp alteration with indication of radical endodontic treatment in molars; painless; at the periapical lesion; with curvature of up to 25º and who signs the informed consent form

pt-br

Ages between 18 and 50 years old; patients from both genres; diagnosed with pulp alteration with treatment indication radical endodontic in molars; painless; without lesion periapical; with curvature of up to 25º and which sign the term of consent free enlightened

- **Exclusion criteria:**

en

Presence of internal or external resorption; trismus; ankylosis; periodontal condition index less than 3; systemic illness; tooth positioning out of normal alignment; history of trauma; pregnancy; lack of patient compliance; and presence of teeth that require endodontic retreatment

pt-br

Presence of resorption internal or external; trismus; ankylosis; condition index periodontal smaller than 3; systemic disease; tooth positioning out of alignment normal; history of trauma; pregnancy; presence of teeth require what endodontic retreatment

Kind of study

- **Study design:**

Access Program expanded	Focus of study	Design from the intervention	Number in arms	Type masking	in	Allocation type	Phase of study
	Treatment	Parallel	two	Double-blind		Randomized controlled	AT

Outcomes

- **Primary outcomes:**

en

Evaluate the painful response between the two systems over a period of 6, 12, 24 hours and daily for 3 days; using the visual scales method (NRS-10 cm and VAS-0-10 cm), based on the observation of a variation of at least 10% in pre- and post-intervention measurements

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Assess the painful response between the two systems in period of 6, 12, 24 hours and daily for 3 days; using the method of visual scales (NRS-10 cm and VAS-0-10 cm), from observation of a variation of at least 10% on pre and post-intervention

- **Secondary outcomes:**

en

It is expected to find an improvement in the patient's quality of life after endodontic treatment using the OHIP-14 scale method; based on the observation of a

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It is expected to find a improves the quality of patient's post-life endodontic treatment using the scale method OHIP-14; from observation of a

variation of at least 10% in pre- and post-intervention measurements

variation of at least 10% in pre- and post-intervention measurements

Contacts

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Additional links:

- Download in ICTRP format