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Evaluation of a new device for taking X-rays during a root canal

Submission date 04/10/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/04/2025	**Overall study status** Completed	
Last Edited 16/04/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Root canal treatment (endodontics) is a dental procedure used to treat infection at the centre of a tooth. During endodontic treatment, several x-rays are necessary and students often have difficulty performing them. This study aims to evaluate a new device developed for positioning the x-ray film. The main objective of this device is to reduce the number of errors during x-rays, optimise working time and reduce patient exposure to radiation.

Who can participate?
Patients who need root canal treatment in upper premolar teeth

What does the study involve?
The same radiographs already taken in conventional treatment will be taken in this study, but patients will be randomly divided into three groups to be treated without the dental x-ray holder, with the conventional dental x-ray holder, and with the articulated dental x-ray holder.

What are the possible benefits and risks of participating?
The new device aims to facilitate the procedure for undergraduate students as it tends to reduce errors and subjects the patient to fewer x-rays.

Where is the study run from?
Pontifícia Universidade Católica do Paraná (Brazil)

When is the study starting and how long is it expected to run for?
June 2022 to June 2025

Who is funding the study?
Pontifícia Universidade Católica do Paraná (Brazil)

Who is the main contact?
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Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Clinical evaluation of a new adjustable dental x-ray holder for endodontics

Acronym
CENADXHE

Study objectives
The new adjustable dental X-ray holder for endodontics will significantly improve the quality of radiographic images and reduce the frequency of errors compared to conventional holders and freehand techniques when used by dental students during endodontic treatments on upper premolars

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/06/2022, Comitê de Ética e Pesquisa Pontifícia Universidade Católica do Paraná (Imac. Conceição, 1155 - Prado Velho, Curitiba - PR, 80215-901, Brazil; +55 (41) 3271 2103; nep@pucpr.br), ref: 5.480.291

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Endodontic treatment

Interventions
A total of 30 teeth (maxillary premolars) requiring endodontic treatment will participate in this study. The adjustable radiographic dental x-ray holder will be used and tested on 30 patients. Patients will be randomly divided into three groups according to a randomized draw (without dental x-ray holder, with conventional dental x-ray holder, and with articulated dental x-ray holder). For all three groups, initial periapical radiography, odontometry, cone fit, and final radiographs will be taken.

After applying the inclusion criteria, patients will be selected and treated, and the new dental x-ray holder will be used at three different times, which will be chosen randomly for each patient.
1. The working length radiograph (n = 10)
2. The cone fit radiograph (n = 10)
3. The final radiograph (after root canal obturation and before restoration)

Patients will be anaesthetized using 1.8 ml of 2% mepivacaine with 1:100,000 epinephrine. The teeth will be isolated and the opening of the pulp
chamber will be done using a spherical diamond bur at high speed. After finding the pulp chamber, a truncated conical drill will be used to eliminate the remains of the ceiling and refine the walls of the pulp chamber. With the aid of a type K #10 instrument, the channels will be explored and located. Establishing the working length (CT) will be done using the periapical radiograph with one of the techniques (without a dental x-ray holder or with the new one, or with the conventional endodontics x-ray holder). After that, a K-type instrument of the most appropriate diameter for the
canal anatomy. The CT will be set 1 mm short of the radiographic apex.

Root canal preparation will be performed using a Protaper Next instrument mounted on a Smart plus motor (Dentsply). The canals will be irrigated with 2.5% sodium hypochlorite. The second radiograph will be done after the root canal preparation, to do the cone fit radiograph, at this time another technique will be used.

After that, the final irrigation will be done using EDTA 17% + 2,5% sodium hypochlorite. In all cases, filling will be performed with AH PLUS (Dentsply) endodontic cement and calibrated gutta-percha cones, using the single cone technique. Gutta-percha cones will be cut with a heated instrument at the cemento-enamel junction.

At this moment, the last radiographic will be taken using the technique that was not used before.

Finally, the restoration will be done.

The data will be tabulated, analyzed, and statistical analysis will be performed. The perception of undergraduate students and specialization students regarding the tested adjustable radiographic dental x-ray holder will also be evaluated. Its operational effects can be compared with other methods.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The ease of use of the new radiographic dental x-ray holder is measured by the number of errors during the radiographic technique, until the student successfully obtains the correct radiograph.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
01/06/2025

Eligibility

Key inclusion criteria
Maxillary first premolar with a diagnosis that needs an endodontic treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. Teeth with incomplete rhizogenesis
2. Teeth that present positioning alterations that hinder the acquisition of radiographic images
3. Teeth with previous endodontic treatment

Date of first enrolment
01/10/2024

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
Brazil

Study participating centre
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Sponsor information

Organisation
Pontifícia Universidade Católica do Paraná

ROR
https://ror.org/02x1vjk79

Funder(s)

Funder type
University/education

Funder Name
Pontificia Universidade Católica do Paraná

Alternative Name(s)
Pontifical Catholic University of Paraná, PUCPR

Funding Body Type

Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Brazil

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication