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Assessment of the clinical outcome of the use of 3D printed guides for endodontic treatment

Submission date
20/01/2023

Recruitment status
No longer recruiting

Registration date
17/02/2023

Overall study status
Completed

Last Edited
07/11/2024

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The use of 3D-printed guides in dentistry offers a highly predictable outcome and lowers the risk of damage to the tooth. Up to five times less tooth substance is lost when drilling is guided compared with conventional treatment, allowing for minimally invasive treatment and a shorter treatment time. The aim of this study is to treat patients with the aid of a guiding system and assess the clinical outcome of guided endodontic treatment compared with freehand drilling (from a historical control group) in the context of quality control. Endodontics is a dental procedure used to treat infection at the centre of a tooth.

Who can participate?
Patients who need complex endodontic treatment in otherwise hopeless teeth

What does the study involve?
Endodontic treatment will be performed with the aid of a 3D printed guide that will fit snugly on the patient's teeth and will help to guide the bur through a metallic sleeve for the drilling of an access cavity up to the root canal entrance. The clinical outcome of the patients will be compared to the outcome of patients from a historical control group, in which endodontic treatment was performed freehanded (without the assistance of a guiding system). The clinical outcome will be evaluated during treatment and the patients will be followed up at 6 months, 1 year and yearly after treatment, until healed.

What are the possible benefits and risks of participating?
Known potential benefits of the use of a guiding system are: a reduced likelihood of damage to the tooth, minimally invasive treatment, a high accuracy or likelihood of finding the target, reduced treatment time and increased safety. Potential risks are: damage to the root due to poor fitting of the guide or poor design, the persistence of bacteria (inside or outside of the canal), inadequate filling of the root canal and overextensions of root filling materials.

Where is the study run from?
UZ Leuven (Belgium)

When is the study starting and how long is expected to run for?
January 2018 to November 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Andres Torres, andres.torres@kuleuven.be

Contact information

Type(s)
Principal investigator

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Additional identifiers

Study information

Scientific Title
Controlled clinical trial on the clinical outcome of guided endodontics vs freehand drilling for the treatment of pulp canal obliteration

Study objectives
Guided endodontics has a greater success rate than freehand drilling for the treatment of pulp canal obliteration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/04/2022, Ethics Committee Research UZ/KU Leuven (Herestraat 49B, 3000 Leuven, Belgium; +32 (0)16 34 86 00; ec@uzleuven.be), ref: S64630

Primary study design

Interventional

Study design
Prospective non-randomized single-center study with an external (historical) control group

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Apical periodontitis in teeth presenting with pulp canal obliteration

Interventions
Endodontic treatment will be performed in every patient with the aid of a 3D printed guide that will fit snugly on the patient's teeth and will help to guide the bur through a metallic sleeve for the drilling of an access cavity up to the root canal entrance. Every treatment will be performed under a dental microscope and adhering to the quality guidelines for endodontic treatment from the European Society of Endodontics. Such treatment can have a total duration of between 1 and 2 hours. Root canal treatment will be assessed at 6 months, 1 year and yearly as required, with a thorough clinical examination and acquisition of intraoral radiographs.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The clinical outcome of the use of a guiding system (root canal found, not found or perforation of the root), assessed during treatment

Key secondary outcome(s)
1. Precision measurements (i.e. deviation of the access cavity) will be recorded by acquiring a digital intraoral impression during treatment. This second impression is then registered with the planning and the exact deviation of the drilling path can be calculated using 3D software. The deviation at the entry point and end of cavity will be measured and recorded in millimeters. The drilling angulation in comparison to the planned trajectory will be measured and recorded in degrees.
2. Outcome of root canal treatment assessed at 6 months, 1 year and yearly as required with a thorough clinical examination and acquisition of intraoral radiographs. The following findings indicate a favorable outcome: absence of pain, swelling and other symptoms, no sinus tract, no loss of function and radiological evidence of a normal periodontal ligament space around the root.
3. Tooth survival, defined as the continuous function of the tooth in the mouth with an absence of clinical symptoms, but regardless of their radiographic periapical status, measured together with the planned follow-up at 6 months, 1 year and yearly until healing of the case

Completion date
01/11/2023

Eligibility

Key inclusion criteria

Male or female patients attending the Endodontic Department at the University Hospitals of Leuven, Campus Sint-Rafaël with the need for complex endodontic treatment. To classify as complex, the tooth may present one or more of the following:
1. Pulp canal obliteration (PCO) or canal not seen on a periapical radiograph
2. Anatomical deviations (dens in dente or other) where localizing the root canal may be challenging or compromise the tooth by free-handed treatment
3. Present an obstruction in the canal
4. Resorption, either internal or external
5. Root perforation
6. Presenting symptoms and/or radiographic signs of apical periodontitis (AP)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Patient unwilling or unable to comply with the endodontic treatment and follow-up periods
2. Tooth in need of extraction or with an unfavorable prognosis

Date of first enrolment
24/05/2018

Date of final enrolment
23/09/2022

Locations

Countries of recruitment
Belgium

Study participating centre
UZ Leuven Sint-Rafaël
Kapucijnenvoer 7
Leuven
Belgium
3000

Sponsor information

Organisation
St Raphael Hospital

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/11/2024	07/11/2024	Yes	No