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Torque in root canal preparations

Submission date	Recruitment status	[_] Prospectively registered
13/04/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/05/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/09/2020	Oral Health	

Plain English summary of protocol

Current plain English summary as of 16/07/2018:
Background and study aims
Root canal treatment (endodontic treatment) is given to patients that have infection or inflammation on the pulp (nerve) inside a tooth, or in the bone surrounding the root area (lower area of the tooth).
Preparing a tooth for root canal treatment using rotary instruments generates torque. Torque generated during root canal preparation depends on the anatomy of the tooth, the type of instruments being used, and how the dentist prepares the canal. Torque can be measured in order to analyse how safe instruments are to use for root canal treatment. This study aims to describe a new method for measuring torque generated during root canal preparation in order to assess safety of different instruments and techniques.

Who can participate?
Adults requiring root canal treatment

What does the study involve?
Participants receive routine root canal treatment under anaesthetic in a single session. The canals are prepared using two types of rotary files and torque values (rotational force) are measured throughout this preparation or both instruments. Participants receive follow up for one year, but this is not part of the study.

What are the possible benefits and risks of participating?
Being an observational study using standard root canal procedures, it does not offer any additional benefits or risks to the participants.

Where is the study run from?
Sapienza University of Rome (Italy)

When is the study starting and how long is it expected to run for?
October 2016 to March 2018

Who is funding the study?
Sapienza University of Rome (Italy)

Who is the main contact?
Dr Gianluca Gambarini (Scientific)

Previous plain English summary:
Background and study aims
Root canal treatment (endodontic treatment) is indicated for patients that present infection or inflammation in the pulp (nerve) inside of a tooth or in the bone surrounding the root area. This study aims to describe a new method for analyzing operative torque (rotational force) by measuring the torque provided by a motor during the clinical use of nickel-titanium rotary instruments.

Who can participate?
Adults requiring root canal treatment

What does the study involve?
Participants receive routine root canal treatment under anaesthetic in a single session. The canals are prepared using two types of rotary files and torque values (rotational force) are measured throughout this preparation or both instruments. Participants receive follow up for one year, but this is not part of the study.

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Dr Gianluca Gambarini (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Gianluca Gambarini

Contact details
University of Rome
Via Caserta 6
Rome
Italy
00187

Additional identifiers

Protocol serial number
0001

Study information

Scientific Title
Measurement of operative torque generated during the preparation of root canals in vivo

Study objectives
The hypothesis is that different endodontics instruments create different torque values during intracanal instrumentation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sapienza University of Rome, 10/04/2017, ref: 528/17

Primary study design
Observational

Study design
Pilot single-center observational study

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Root canal treatments

Interventions
This study aims to describe a new method for analyzing operative torque in vivo by measuring the torque provided by an endodontic motor during the clinical use of nickel-titanium rotary instruments.
Participants are recruited in the dental clinic of the university. All have a prior indication for root canal treatment, and are being evaluated and supervised by the faculty of the institution.
Participants are subjected to the regular endodontic treatment under anesthesia and rubber dam in a single session. Access is created with round burs and a manual glide-path is performed up to the apical limit. Then, the canals are prepared using rotary files ProTaper Next X 1 and EdgeEndo X7 (EdgeEndo). The observational study is limited to about 15 minutes during the root canal preparation. Torque values during the progression of the instruments into the canals are recorded every 0.1s. After the preparation, the teeth receive conventional obturation and restoration.
Data regarding torque is analyzed statistically with significance set at $P<0.05$.
Participants are subjected to the regular 1 year follow up in the clinic, which is not related to the aim and scope of the present study.

Intervention Type

Procedure/Surgery

Primary outcome(s)
Torque values were measured using a prototype device connected to a regular endodontic motor every 0.1 seconds during the procedure

Key secondary outcome(s)
The occurrence of mishaps such as torsional lock or breakage of files were recorded during the procedure

Completion date
15/12/2018

Eligibility

Key inclusion criteria
1. No significant medical history
2. Need root canal treatment in the maxillary premolar tooth

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Present any medical systemic condition
2. Teeth presenting root fracture, open apex, root resorption or previous root canal treatment.

Date of first enrolment
01/01/2018

Date of final enrolment
01/03/2018

Locations

Countries of recruitment
Italy

Study participating centre
Sapienza Università di Roma - Clinica odontoiatrica
Viale Regina Elena, 287
Rome
Italy
00161

Sponsor information

Organisation
Sapienza University of Rome

ROR
https://ror.org/02be6w209

Funder(s)

Funder type
University/education

Funder Name
Sapienza Università di Roma

Alternative Name(s)
Sapienza University of Rome, Università degli Studi di Roma "La Sapienza”, Sapienza-Università di Roma, Sapienza, Uniroma1

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
Data of the present study is stored in the DIPARTIMENTO DI SCIENZE ODONTOSTOMATOLOGICHE E MAXILLO FACCIALI of the La Sapienza University. Access to the

data should be requested to the principal investigator Dr. Gianluca Gambarini.
Participants of this study signed a consent form. Their personal information was stored only on the dental clinic's charts, under the privacy policy of the university. Their information was linked only to the chart number and a new code was addressed for each participant to ensure that stored data is non-identified.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2019	11/09/2020	Yes	No