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Patient intraoperative discomfort after using rotary or reciprocating systems

Submission date
11/04/2016

Recruitment status
No longer recruiting

Registration date
14/04/2016

Overall study status
Completed

Last Edited
18/11/2021

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Root canal treatment is a dental procedure that is used to treat infection at the centre of a tooth. The centre of the tooth is made up of soft tissue called the dental pulp. It includes nerves and blood vessels. The root canal system itself is made up from the dental pulp which extends from the crown of the tooth until the end of the tooth root. If infected, the dental pulp will start to die and the bacteria (and substances that the bacteria release) will eventually pass though and out of the end of the root canal though the tooth root. This can make the tooth painful and can even lead to a tooth (or dental) abscess. One way to treat this is via root canal treatment. This involves removing the decaying dental pulp and therefore the bacteria from the centre of the tooth. The root canal is then filled with a rubber-like material called gutta-percha. The tooth is then sealed with a filing or crown. In order to fill the root canal after removal of the dental pulp, it has to be widened. This is done by using a series of small files. This study is investigating two types of file, comparing the amount of discomfort a patient experiences when treated using the multi-file rotary (Mtwo) system with those treated using the single-file reciprocating [Reciproc (VDW)] system.

Who can participate?
Healthy adults (aged at least 18) that are in need of root canal treatment.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are treated using the Mtwo system. Those in group 2 are treated using the VDW system. Immediately after the root canal treatment has been performed, each participant is asked to assess how painful their procedure was, using a scale from 1010 (with 10 being the most painful).

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Campinas State University (Brazil)

When is the study starting and how long is it expected to run for?
January 2015 to December 2015

Who is funding the study?
National Council for Scientific and Technological Development (Brazil)

Who is the main contact?
Professor Emmanuel Silva

Contact information

Type(s)
Scientific

Contact name
Prof Emmanuel Silva

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Additional identifiers

Protocol serial number
058/2015

Study information

Scientific Title
Patient intraoperative discomfort after using rotary or reciprocating systems: a prospective and randomized clinical trial

Study objectives
The hypothesis tested was that there are differences in patients' intraoperative discomfort among the different root canal treatment instrumentation systems.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee in Research of the Piracicaba Dental School, University of Campinas, 12/2014, ref: 058/2015.

Study design
Randomized clinical trial

Primary study design

Interventional

Study type(s)
Treatment

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

Interventions
After local anesthesia with 2% lidocaine with 1:100,000 epinephrine, a rubber dam was placed and the access cavity was prepared using sterile diamond burs. If patients recorded any pain sensation during the procedure, supplemental injection of local infiltration with 1.8 mL 2% lidocaine with 1:100.000 epinephrine was administered.

An initial exploration of the root canals was performed with size 10-K files (VDW), to establish the root canal length using an electronic apex locator (Root ZX II; J. Morita Corp., Tokyo, Japan). Working length (WL) was established by deducting 1 mm from the canal length. Only cases where a 10-K file go passively and a 15-K file did not got passively to the WL in both canals (mesiobuccal and distobuccal canals for maxillary molars; mesiobuccal and mesiolingual canals for mandibular molars) were selected. These cases were classified as small and R25 was recommended, according to the manufacturer´s protocol. All teeth received the two different instrumentation protocols (Mtwo rotary system or Reciproc reciprocation system). A web-based program determined randomized allocation of the instrumentation systems per canal. While the endodontist were not blinded to the allocated file system, patients were kept blinded to the allocation. Instruments were driven with the VDW Silver motor (VDW) according to each manufacturer`s instructions:

1. Reciproc R25 (25/0.08) was introduced into the canal until resistance was felt and then activated in reciprocating motion. The instrument was moved in an apical direction using an in-and-out pecking motion of about 3 mm in amplitude with a light apical pressure. After 3 pecking motions, the instrument was removed from the canal, and its flutes were cleaned off. This procedure was performed until the instrument reached the WL.
2. Mtwo instruments were used according to the manufacturer´s instructions using the follow sequence: 10/0.04, 15/0.05, 20/0.06 and 25/0.06. The motor was adjusted to 500-600 rpm and 1 N /cm2. After 3 gentle in-and-out motion strokes, the instrument was removed from the canal and cleaned until the WL was reached.

In both systems, before each file, 2% Chlorhexidine gel was inserted into root canal. After each file, root canals were irrigated with 2 mL 0.9% saline sterile solution dispensed using a 30-G Max-i-Probe needle (Dentsply-Maillefer) up to 3 mm from the WL. After canal preparation, an additional rinse with 5 mL 0.9% saline solution was performed. The total amount of solution used per canal was 20 mL. A final rinse with 5 mL 17% EDTA delivered for 3 minutes followed by a 5 mL rinse with 0.9% saline solution was performed for both groups. Then, canals were dried with absorbent paper points (VDW) and filled with gutta-percha and Endomethasone N using warm vertical compaction with the continuous-wave technique and gutta-percha backfill. The study was finished when all the selected volunteers had the endodontic treatment completed.

Intervention Type
Procedure/Surgery

Primary outcome(s)

Intraoperative discomfort, measured using the visual analogue score (VAS), during the procedure, between the two different instrumentation groups

Key secondary outcome(s))
N/A

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Healthy (ASA I) adults older than 18 years of age that had been admitted to the Endodontics Department of FOP-UNICAMP, from January 2015 to December 2015 with a clinical diagnosis of irreversible pulpitis or necrosis in the first or second maxillary and mandibular molars
2. Pulpal status that has been confirmed by a cold test

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
55

Key exclusion criteria
1. Taking any medication that could alter their perception of pain (analgesic or non steroidal anti-inflammatory drugs)
2. Radiographic findings that included absence of periapical radiolucency except for a widened periodontal ligament

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment

Brazil

Study participating centre
Campinas State University
São Paulo
Brazil
13414903

Sponsor information

Organisation
National Council for Scientific and Technological Development (Conselho Nacional de Desenvolvimento Científico e Tecnológico - CNPq)

ROR
https://ror.org/03swz6y49

Funder(s)

Funder type
Government

Funder Name
Conselho Nacional de Desenvolvimento Científico e Tecnológico

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/04/2017	18/11/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes