

Mineral trioxide aggregate (MTA) as an alternative root canal filling material

Submission date 08/06/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/06/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/08/2016	Condition category Oral Health	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Periapical periodontitis is a lesion around the top (apex) of a tooth root caused by bacterial invasion of the pulp of the tooth. The primary goal of root canal obturation is to prevent the spread of bacteria and bacterial toxins from the canals into the periapical tissues. Any residual bacteria not eliminated during root canal instrumentation should be sealed by the obturation material and rendered harmless by nutrient deprivation. Gutta percha cones are standard core obturation materials that are compacted into the prepared root canal system using lateral or vertical compaction. However they do not adhere to the dentin surface, thus leaving a gap. Therefore, root canal sealers must be used to seal the space between the gutta percha cones and dentinal walls.

Mineral Trioxide Aggregate (MTA) cement without gutta percha cones has been demonstrated as a successful root canal filling material in immature (young) teeth. The aim of this study is to compare MTA cement with conventional root canal filling (gutta-percha cones and root canal sealers) in mature (adult) teeth.

Who can participate?

Healthy female volunteers requiring root canal treatment

What does the study involve?

Participants will be randomly allocated to one of two groups: control or intervention.

Control group: gutta-percha cones and root canal sealer (AH plus) will be used in warm vertical technique to create 4 mm apical plug after complete cleaning and shaping. The remaining root canal space will be either filled with thermo-plasticized gutta-percha or left for post cementation, depending on the remaining tooth structure.

Treatment group: MTA cement (ProRoot MTA) will be used to create 4 mm apical plug after complete cleaning and shaping. The remaining root canal space will be either filled with thermo-plasticized gutta-percha or left for post cementation, depending on the remaining tooth structure.

What are the possible benefits and risks of participating?

Participants will receive root canal treatment and referral for final coronal restoration, follow up visits for 5 years. The treatment and follow up are free of charge.

Where is the study run from?
College of Dentistry, King Saud University (KSU) and under the care of College of Dentistry Research Center. Saudi Arabia.

When is the study starting and how long is it expected to run for?
February 2010 to June 2024.

Who is funding the study?
King Saud University (KSU)

Who is the main contact?
Reem Alsulaimani
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CDRC FR0235

Study information

Scientific Title
Evaluation of periapical healing following apical filling with mineral trioxide aggregate in mature teeth: a randomized controlled trial

Acronym
MTAO - Mineral Trioxide Aggregate Obturation

Study objectives

H0: Periapical healing is not significantly affected by MTA obturation when compared to conventional gutta-percha cones and root canal sealers.

H1: Periapical healing is significantly affected by MTA obturation when compared to conventional gutta-percha cones and root canal sealers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board and Ethical Approval Committee at the College of Dentistry, King Saud University, 18/05/2015, ref 353621 (FR 0235).

Primary study design

Interventional

Study design

Interventional single-centre study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patient requires root canal treatment for teeth with apical periodontitis.

Interventions

Control group: conventional root canal filling with gutta-percha cones and root canal sealer.

Treatment group: Mineral Trioxide Aggregate cement

Intervention Type

Procedure/Surgery

Primary outcome(s)

Periapical healing assessed by conventional periapical radiographs.

Measured 5 times, every 12 month post-operative for 5 years.

Key secondary outcome(s)

Periapical healing assessed by cone beam computed tomography.

Measured twice, 1st and 5th year only.

Completion date

01/06/2024

Eligibility

Key inclusion criteria

Included patients will be adult, healthy females who agreed to participate in the study and signed a consent form. The study will include mature teeth with radiographic periapical pathosis greater than 5mm in diameter.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

The study sample will exclude teeth that are not restorable, teeth diagnosed with chronic periodontitis with advanced loss of periodontal support, third molars, and teeth with open apex.

Date of first enrolment

07/03/2010

Date of final enrolment

26/06/2018

Locations**Countries of recruitment**

Saudi Arabia

Study participating centre

King Saud University

King Abdullah Road

P.O. Box 60169

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Saudi Arabia

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Sponsor information**Organisation**

King Saud University

ROR

<https://ror.org/02f81g417>

Funder(s)

Funder type

University/education

Funder Name

King Saud University

Alternative Name(s)

, KSU

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/08/2016		Yes	No