

Evaluation of two dental materials in regenerative treatment of non-vital teeth with incomplete root development

Submission date 07/01/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/01/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/01/2024	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Traumatic injuries in anterior teeth commonly occur among young children. These injuries may lead to loss of tooth vitality and inflammation of the surrounding tissues, which requires endodontic treatment. Loss of vitality leads to the growth of the root stopping, resulting in the formation of a weak root with thin and short walls that are more prone to fracture. These teeth are called "immature teeth". Several methods have been described to treat these teeth and regenerative endodontics treatment has gained great interest recently because it focuses on restoring damaged structures and thus promoting root development and strengthening the walls. The main goal of regenerative treatment is to keep the pulp space free of bacteria and prevent the recurrence of infection. Bacteria from the mouth may penetrate the pulp space if the coronal seal is not adequate, leading to the recurrence of infection, which is one of the main reasons for treatment failure. This study aims to evaluate two bioceramic types of cement clinically and radiographically as coronal sealing materials in the regenerative treatment of non-vital immature teeth with apical periodontitis.

Who can participate?

Patients aged 9 to 25 years old with non-vital permanent anterior teeth with open apex and apical periodontitis

What does the study involve?

Participants were randomly divided into two groups based on the used coronal sealing material. Well Root PT (Vericom, Gangwon-Do, Korea) was applied in the first group, and MTA Biorep (Itena Clinical, Paris, France) in the second group. All patients in both groups were treated with the same protocol except for the application of the coronal plug material. The clinical and radiographic variables were registered at baseline and at 12 months after treatment. The clinical variables were pain on biting or percussion, soft tissue swelling, sinus tract, mobility, and response to pulp sensitivity test. The radiographic variables were changes in root length, root thickness, and healing of the periapical lesions.

What are the possible benefits and risks of participating?

Participants may benefit from continued development of the roots of non-vital teeth, leading to better prognosis and longer tooth durability, in addition to the potential for restoring tooth vitality. One possible risk of participating in this study is the appearance of clinical symptoms, such as pain or swelling. In such cases, conventional treatment will be performed.

Where is the study run from?

The Department of Endodontics, Faculty of Dentistry, Damascus University (Syria)

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

January 2020 to May 2023

Who is funding the study?

Investigator initiated and funded (Syria)

Who is the main contact?

Alaa Shaker, dr.alaashaker@gmail.com (Syria)

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

848/SM

Study information

Scientific Title

Revascularization of non-vital immature permanent teeth with two bioceramic cements: a randomized controlled trial

Acronym

BIOCERAMIC

Study objectives

The null hypothesis was that there is no difference between both materials (MTA Biorep and Well Root PT) on the clinical and radiographical success of revascularization procedure

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 01/05/2020, Ethics Committee of Damascus University (Mousalam Baroudy Street, Damascus, 011, Syria; +9631133923010; vice.research@damascusuniversity.edu.sy), ref: MD-160124-179

Study design

Singlecentre interventional double-blinded randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment, Efficacy

Health condition(s) or problem(s) studied

Treatment of necrotic immature teeth with apical periodontitis

Interventions

Twenty non-vital immature permanent anterior teeth with apical periodontitis were included in this study. Samples were randomly distributed at www.randomizer.org into two groups (n=10) based on the used coronal plug materials; group I (GI): Well Root PT (Vericom, Gangwon-Do, Korea), and group II (GII): MTA Biorep (Itena Clinical, Paris, France). Treatment was conducted according to the American Association of Endodontics guidelines (18/05/2021). All patients in

both groups were treated with the same protocol except for the application of coronal plug material. The sodium hypochlorite (1.5 %) was used for irrigation and the triple antibiotic paste (5 mg/mL) was used as a medication. The scaffold used was a blood clot. Follow-up was done clinically and radiographically for up to 12 months for the two groups.

Intervention Type

Procedure/Surgery

Primary outcome(s)

The degree of success is measured using the American Association of Endodontists' criterion at baseline and 12 months

Key secondary outcome(s)

The following secondary outcome measures were assessed at baseline and 12 months:

1. Pain on biting is measured by asking the patient if it is present or absent
2. Pain on percussion is measured by tapping the tooth with a mirror
3. Soft tissue swelling is measured using visual examination
4. Sinus tract is measured using visual examination
5. Mobility is measured by applying pressure with two metal instruments
6. Pulp sensitivity is measured using Ethyl Chloride spray
7. Root length is measured radiographically using Image J software
8. Root thickness is measured radiographically using Image J software
9. The area of the periapical lesion is measured radiographically using Image J software

Completion date

01/05/2023

Eligibility

Key inclusion criteria

1. Patients are free from any systemic diseases that may hinder the normal healing process
2. Non-vital permanent anterior teeth with open apex and apical periodontitis
3. Single-rooted teeth
4. The tooth does not require post and core for the final restoration
5. Age range from 9-25 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

9 years

Upper age limit

25 years

Sex

All

Total final enrolment

20

Key exclusion criteria

1. Tooth with vital pulp or complete root formation
2. Tooth with previous endodontic treatment
3. Patients allergic to the medications and antibiotics necessary to complete the treatment
4. Un-cooperative patients

Date of first enrolment

01/07/2020

Date of final enrolment

15/03/2022

Locations**Countries of recruitment**

Syria

Study participating centre**Damascus University**

Department of Endodontics, Faculty of Dentistry, Damascus University, Fayez Mansour Street, Al Mazzeh

Damascus

Syria

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Sponsor information**Organisation**

Damascus University

ROR

<https://ror.org/03m098d13>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from Dr. Alaa Shaker (dr.alaashaker@gmail.com)

IPD sharing plan summary

Available on request