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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	[_] Prospectively registered [_] Protocol
Registration date 16/01/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/01/2024	**Condition category** Oral Health	[_] Individual participant data [_] 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

Contact name
Dr Alaa Shaker

Contact details
Department of Endodontics, Faculty of Dentistry, Damascus University, Fayez Mansour Street, Al Mazzeh
Damascus
Syria
011
+963949826303
alaa1.shaker@damascusuniversity.edu.sy

Type(s)
Public

Contact name
Dr Alaa Shaker

Contact details
Department of Endodontics, Faculty of Dentistry, Damascus University, Fayez Mansour Street, Al Mazzeh
Damascus
Syria
011
+963949826303
dr.alaashaker@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment, Efficacy

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/01/2020

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

Age group
Mixed

Lower age limit
9 Years

Upper age limit
25 Years

Sex
Both

Target number of participants
20

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
[-]

Sponsor information

Organisation
Damascus University

Sponsor details
Mousalam Baroudy Street
Damascus
Syria
011
+963-11-33923192
info@damascusuniversity.edu.sy

Sponsor type
University/education

Website
https://www.damascusuniversity.edu.sy/

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
10/01/2024

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