

The effectiveness of a pre-made filling for closing an open-apex tooth root

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Registration date 08/11/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/11/2023	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

Apexification is a dental procedure to close incomplete tooth roots. The aim of this study is to evaluate the success rate of a pre-made filling (prefabricated bio-root inlay made externally from bioceramic putty and fiber post) on necrotic (dead) permanent teeth compared to traditional apical plugs made from mineral trioxide aggregate (MTA).

Who can participate?

Children aged 7-11 years old with necrotic immature permanent maxillary incisors (the front teeth in the upper jaw)

What does the study involve?

Participants will be randomly divided into two groups to be treated with MTA apical plugs or prefabricated bio-root inlay. All the teeth will be evaluated clinically and radiographically for up to 1 year.

What are the possible benefits and risks of participating?

Because of the complexity of the root canal system in primary molars, long or multiple visits are needed to complete apexification treatment, especially with non-cooperative children. Prefabricated bio-root inlay seems to be a good alternative choice to traditional apexification with apical plugs as it's an easier and less time-consuming treatment and causes less trauma to the dental ligament.

Where is the study run from?

Damascus University (Syria)

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

February 2023 to June 2024

Who is funding the study?

Damascus University (Syria)

Who is the main contact?

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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

UDDS-361-13032023/SRC-2654

Study information

Scientific Title

Evaluating the efficacy of prefabricated bio-root inlay in apexification success in necrotic immature permanent teeth: a randomized control trial

Study objectives

This study is designed to assess the hypothesis that prefabricated bio-root inlay can be a good alternative treatment to traditional apexification by apical plugs in the term of clinical and radiographical success and the time required to complete the procedure.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 13/03/2023, Damascus University (Almazzeah ST, Damascus, 20872, Syria; +963 (0) 90404840; Osama.aljabban@gmail.com), ref: 361

Study design

Single-center interventional double-blinded randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Necrotic immature permanent upper incisors in children

Interventions

Thirty necrotic maxillary immature incisors from healthy children aged between 7-11 years will be randomly divided into two groups using <http://www.randomization.com>:

Group A (control): teeth will be treated with MTA apical plugs as a traditional apexification procedures

Group B (study): teeth will be treated with prefabricated bio-root inlay as a novel apexification technique.

MTA apical plugs:

Under local anesthesia and rubber dam isolation, the canal orifice will be prepared gently. The working length and apex diameter value will be recorded as a reference. Afterwards, shaping and debridement of the root canals will be achieved by gentle instrumentation. The canal will be irrigated copiously with NaOCl, then dried, and filled with Ca(OH)₂ dressing. Afterwards, the incisor will be temporarily restored. After 14 days the temporary filling and Ca(OH)₂ will be removed. Afterwards, canals will be irrigated with NaOCl and EDTA and dried. The MTA will be inserted into the apical 4 mm of the canal using the modified cannula and adapted to the canal walls with a hand plugger. The correct placement and thickness of the apical plug will be verified with a periapical radiograph. Afterwards, the remainder of the root canal will be filled with gutta-percha with sealer. Finally, a suitable immediate final restoration was made for each case individually.

Prefabricated bio-root inlay group:

Under local anesthesia and rubber dam isolation, the canal orifice will be prepared gently. The working length and apex diameter value will be recorded as a reference. Afterwards, shaping and debridement of the root canals will be achieved by gentle instrumentation. The canal will be irrigated copiously with NaOCl, and dried. An impression of the canal will be taken with light silicon, then the canal will be filled with Ca(OH)₂ dressing. Afterwards, the incisor will be temporarily restored. The canal impression will be scanned. The scan will be exported as an STL file. The STL file will be imported to a designing application and an offset coping will be the design of choice in the application to make the 3D Prefabricated Root Canal Models of immature permanent teeth (PRCM). Afterwards, within the PRCM, the bioceramic putty and a fiber post with special surface treatment will be applied in the middle of the bioceramic putty with an appropriate cementation system. Then the PRCM will be removed to obtain the prefabricated bioroot inlay. After 14 days the temporary filling and Ca(OH)₂ will be removed. Afterwards, canals will be irrigated with NaOCl and EDTA and dried. Afterwards, the bioceramic sealer will be

injected in the canal and the bio-root inlay will be placed in the canal. Finally, a suitable immediate final restoration was made for each case individually.

Intervention Type

Other

Primary outcome(s)

1. Clinical evaluation: Patients of both groups will be recalled after 1, 3, 7, and 14 days of treatment and during radiographical assessment periods (3, 6 and 12 months), where they will be asked to rate their pain on the Wong-Baker Faces Scale, where children will set their pain levels by choosing a face; 0 = no hurt, 1 = hurts a little bit, 2 = hurts a little more 3 = hurts even more, 4 = hurts a whole lot, and 5 = hurts worst. Moreover, the presence of fistula, swelling, and movement will be recorded.
2. Radiographical assessment: After coronal restoration is completed a control x-ray will be taken. The periapical status will be assessed at the time of obturation-restoration, 3, 6, and 12 months following endodontic treatment. The outcome will be determined according to the Periapical Index scoring system: (1) normal periapical structures; (2) small changes in bone structure; (3) changes in bone structure with some mineral loss; (4) periodontitis with well-defined radiolucent area; (5) severe periodontitis with exacerbating features. The teeth will be evaluated according to healed, healing or unsuccessful as a primary radiographical outcome.

Key secondary outcome(s)

1. Patient age (in years) and sex (male or female) determined during patient examination at the start of treatment
2. Required time for obturation of each case (in minutes) measured using a timer during the obturation phase
3. Child behavior (definitely positive, positive, and negative) will be determined by an external examiner during overall treatment visits
4. Extrusion of bioceramics (extrusion, or not extrusion) measured using a digital X-ray image at the end of the obturation phase
5. Apex diameter (in mm) and working length (in mm) measured using large sized K-file at the preparation phase

Completion date

01/06/2024

Eligibility

Key inclusion criteria

Patients with one or more maxillary incisors with an open apex root (defined as root with root canal size equal to or larger than #80 K-file) and presented with pulp necrosis and radiographic evidence of chronic apical periodontitis and periapical radiolucency greater than 3 mm

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 years

Upper age limit

11 years

Sex

All

Key exclusion criteria

1. Children with systemic diseases that compromised their general immune status
2. Uncooperative (definitely negative on the Frankl's behavioral scale)
3. Unrestorable incisors

Date of first enrolment

15/11/2023

Date of final enrolment

25/03/2024

Locations

Countries of recruitment

Syria

Study participating centre

Damascus University

Department of Pediatric Dentistry

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Sponsor information

Organisation

Damascus University

ROR

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

Funder(s)

Funder type

University/education

Funder Name

Damascus University

Alternative Name(s)

University of Damascus, , DU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Syria

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes