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

Submission date 07/11/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/11/2023	**Overall study status** Completed	
Last Edited 08/11/2023	**Condition category** Oral Health	

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 (Almazzeh 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

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

Participant information sheet
Patient information sheet in Arabic: https://www.dropbox.com/scl/fi/jfam6kzqxlteuv4oohdev/draft-for-me2.pdf?rlkey=seap4houskmuv7hey6vygf4cp&dl=0

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 measure
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.

Secondary outcome measures
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

Overall study start date
06/02/2023

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

Age group
Child

Lower age limit
7 Years

Upper age limit
11 Years

Sex
Both

Target number of participants
30

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
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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

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

Intention to publish date
15/12/2024

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