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Assessing full pulpotomy in permanent teeth with irreversible pulpitis using three calcium silicate cements

Submission date 15/03/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/03/2025	**Overall study status** Completed	
Last Edited 09/12/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims

Symptomatic irreversible pulpitis (SIP) is a painful condition where the inflamed pulp tissue in a tooth cannot heal and requires root canal treatment or extraction. Pulpotomy is a simple treatment which is less invasive than root canal treatment. This study aimed to evaluate the response of mandibular (jaw) mature premolars with SIP following cervical pulpotomy using three bioactive materials: Mineral Trioxide Aggregate (MTA), Biodentine, and Bioceramic Putty.

Who can participate?

Patients aged between 15 and 20 years with a mandibular premolar with SIP

What does the study involve?

Participants were randomly divided into three groups to be treated with MTA pulpotomy, Biodentine pulpotomy, or Bioceramic Putty pulpotomy. All the teeth will be evaluated clinically and radiographically for up to 1 year.

What are the possible benefits and risks of participating?

The possible benefit of this study is to eliminate SIP without a full root canal treatment. Possible risks are flare-ups and post-operative pain.

Where is the study run from?

Hama University (Syria)

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

December 2013 to August 2024

Who is funding the study?

Damascus University (Syria)

Who is the main contact?
Dr Yasser Alsayed Tolibah, yasser94.tolibah@damascusuniversity.edu.sy or Yasseralsayedtolibah@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Yasser Alsayed Tolibah

ORCID ID
https://orcid.org/0000-0001-5498-9991

Contact details
Almazzeh Street
Damascus
Syria
20872
+963 (0)988812044
yasseralsayedtolibah@gmail.com

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Sarah Nassri

Contact details
Almazzeh Street
Damascus
Czech Republic
20872
+963 (0)933092075
Sarahnassri@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
UDDS-94-04012021/SRC-226

Study information

Scientific Title
Evaluation of vital full pulpotomy techniques in permanent mature teeth with symptomatic irreversible pulpitis using three calcium silicate cements

Study objectives
The first null hypothesis suggests no differences between the bioactive materials in the two-time intervals regarding the histological evaluations. At the same time, the second null hypothesis indicates that similar results will be found in the two-time intervals among the groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/01/2021, Hama University (Hama, Hama, C2987, Syria; +963 (0)33 222 3790; dentist@hama-univ.edu.sy), ref: 286

Study design
Single-center interventional double-blinded randomized controlled clinical, radiographical and histological trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Irreversible pulpotomy treatment

Interventions
Patients were assured that their medical care would not be affected should they choose not to participate. Documentation explicitly noted that the treated premolars would be extracted after the agreed-upon observation period to fulfill ethical standards.

Patients rinsed with a 2% chlorhexidine mouthwash prior to local anesthesia administration using one carpule of 1.8 ml of 2% lidocaine with epinephrine (1:100,000) (Huons Lidocaine HCL, Seoul, Korea), delivered via mandibular block anaesthesia and another carpule of 1.8 ml of 2% lidocaine with epinephrine (1:100,000) in buccal infiltration to achieve sufficient anesthesia. Rubber dam isolation (Sanctuary, Perak, Malaysia) was applied, and the premolar surface was disinfected with a 5.25% sodium hypochlorite-soaked gauze for 5 minutes. Initial cavity preparation was performed using a high-speed handpiece with sterile diamond burs, followed by caries excavation with slow-speed rotary instruments under copious water irrigation to remove dentin from the cavity walls without disturbing the pulpal floor.

Cavity refinement was completed by finishing enamel margins and slowly removing carious dentin from the pulpal floor to prevent pushing necrotic debris into the pulp exposure site. From the pulp exposure point, sterile Endo-Z burs (Dentsply Maillefer, Tusla, Oklahoma, USA)

were used to remove the chamber roof, followed by sterile curettes to amputate the coronal pulp until canal orifice exposure without damaging the pulp tissue. The conservative access cavity was irrigated with saline to verify the fresh bleeding from exposed pulp tissue and bleeding cessation within 10 minutes, achieved by continuous saline irrigation and application of a 2.5% sodium hypochlorite (Merck, Darmstadt, Germany) soaked cotton pellet. If haemostasis was not achieved, or if the exposed pulp tissue lacked bleeding, the tooth was excluded from the study and extracted directly to complete the orthodontic treatment.

Following haemostasis, the amputation site was covered with one of the study materials MTA (White ProRoot MTA, Dentsply, Tulsa, OK, USA), Biodentine (Septodont, St Maur-des-Fossés, France), and BiCeramic putty (TotalFill® BC RRM™, FKG Dentaire, Le Crêt-du-Locle, Switzerland) according to the randomization process, following the manufacturer's instructions, ensuring uniform coverage (3 mm thick) without excessive pressure. A thin layer of glass ionomer cement (Medifil; Promedica Dental Material GmbH, Neumunster, Germany) was applied to avoid interference with the material setting, followed by composite resin restoration Tetric N Ceram; Lichtenstein, Ivoclar Vivadent, Leicester, United Kingdom in the same session.

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))
Histological evaluations at 1 week and 6 months:
1. Pulp inflammation was assessed based on inflammatory cell presence and graded as: 1 = No inflammation, 2= Mild inflammation (few inflammatory cells), 3 = Moderate inflammation, and 4 = Severe inflammation (dense inflammatory infiltrate).
2. Pulpal tissue disorganization was evaluated as: 1 = Normal pulp morphology, 2 = Slight superficial imbalance with a central intact pulp, 3 = Moderate imbalance extending beyond superficial layers, 4 = Severe imbalance with diffuse degeneration, and Complete pulp necrosis.
3. Dentinal bridge formation was assessed and classified as: 1 = No evidence of formation, 2= Initial formation, 3 = Incomplete or defective bridge, and 4 = Complete bridge without defects.

Completion date
20/08/2024

Eligibility

Key inclusion criteria
Radiographic Criteria:
1. Fully developed first or second permanent mandibular premolars with deep carious lesions
2. A relatively normal-sized pulp chamber without degenerative changes (e.g., pulp stones, diffuse calcifications, or significant chamber narrowing)
3. No periapical or furcal radiolucency
4. No internal or pathological external resorption
5. No signs of periodontal involvement, such as alveolar bone resorption

Clinical Criteria:
1. Symptoms and clinical signs indicate symptomatic irreversible pulpitis, characterized by spontaneous, intermittent, sharp pain or prolonged pain after stimulus removal
2. The tooth is restorable without requiring a crown, post, or core-supported restoration
3. No periodontal disease; the gingival sulcus depth ranges from 1–3 mm from the free gingival margin to the epithelial attachment
4. No periodontal involvement, with tooth mobility within normal limits

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
15 years

Upper age limit
20 years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Patients with immune, bleeding disorders, systemic conditions affecting bleeding and clotting time, or those taking medications that alter metabolism
2. Immature premolars with open apices
3. Non-restorable teeth or those with periodontal disease
4. Severely narrowed pulp chambers or significant calcifications within the root canal system (e.g., pulp stones, diffuse calcifications)
5. Presence of periapical or furcal radiolucency
6. Internal or pathological external resorption
7. Signs of pulp necrosis, including negative responses to vitality tests, swelling, sinus tract, or positive percussion and palpation tests

8. Uncontrolled bleeding after pulpotomy for more than 10 minutes or abnormal pulp tissue appearance
9. Absence of bleeding or minimal dark red bleeding after pulp exposure or pulpotomy

Date of first enrolment
01/02/2021

Date of final enrolment
12/12/2023

Locations

Countries of recruitment
Algeria

Syria

Study participating centre
Damascus University
Almazzeh Street
Damascus
Syria
20872

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
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/12/2025	09/12/2025	Yes	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes