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How dental pulp reacts after treatment: a tissue-level study comparing reversible and irreversible pulpitis in adult teeth

Submission date
12/05/2025

Recruitment status
No longer recruiting

Registration date
12/05/2025

Overall study status
Completed

Last Edited
14/05/2025

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to evaluate the effectiveness of three materials (MTA, Bioceramic, and Biodentine) in treating teeth with pulpitis (inflamed pulp). Pulpitis can cause pain and may require tooth extraction. The study will test how well these materials help the tooth heal before extraction, which is planned for other clinical reasons.

Who can participate?
Adults with teeth showing symptoms of reversible or irreversible pulpitis, and who are scheduled for tooth extraction for clinical reasons, are eligible to participate.

What does the study involve?
Participants will undergo a pulpotomy, where the infected pulp is removed, and one of the study materials will be used to treat the tooth. The procedure will be followed by regular check-ups at one week and three months to monitor healing. The teeth will be extracted as planned.

What are the possible benefits and risks of participating?
Benefits:
Potential to improve tooth healing. Regular follow-up care and monitoring.

Risks:
Pain, infection, or complications. The treatment may not succeed, requiring further procedures.

Where is the study run from?
The Department of Endodontics, Faculty of Dentistry, University of Hama, Syria.

When is the study starting and how long is it expected to run for?
February 2021 to October 2024

Who is funding the study?
This study has no external funding. This study is self-funded by the principal investigator and the Faculty of Dentistry, University of Hama

Who is the main contact?
1. Abdulghani Mardini, Abdalganymardini@gmail.com
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Contact information

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Principal investigator

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Additional identifiers

Protocol serial number
UHHS-226-09022021/SRC-94

Study information

Scientific Title
Histopathological and immunohistochemical evaluation of pulpal inflammatory responses following pulpotomy in mature permanent teeth with reversible and irreversible pulpitis

Acronym
HIPPI Study

Study objectives
The null hypothesis was that there are no differences between (MTA – Bioceramic - Biodentine) in inflammatory dental pulp responses after pulpotomy of mature permanent teeth with symptoms of reversible or irreversible pulpitis.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/02/2021, Scientific Research and Postgraduate Board of Hama University (Assi Square, Hama, 00000, Syria; +963 33 222 3790; webadmin@hama-univ.edu.com), ref: 226

Study design
Single-centre interventional double-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment reversible and irreversible pulpitis in mature permanent teeth

Interventions
The clinical assessment began with a comprehensive evaluation including medical history, chief complaint, pulp sensitivity via cold testing (ethyl chloride), percussion testing for periapical condition, and assessment of periodontal status through gingival sulcus probing and mobility testing. Periapical radiographs were obtained to ensure full root visualization with at least 2 mm beyond the apex. Teeth diagnosed with reversible or irreversible pulpitis—based on clinical and radiographic findings—were selected. After patient consent, local anesthesia was administered and rubber dam isolation was achieved. Disinfection with 5.25% sodium hypochlorite was followed by caries removal, pulp chamber access, and coronal pulp amputation using sterile burs. Hemostasis within 10 minutes was a key inclusion criterion. Pulp wounds were treated with one of the three bioactive materials:
1. MTA (Control)
2. Bioceramic (Experimental)
3. Biodentine (Experimental)

This was followed by restoration with a base layer of Fuji IX GIC and final composite restoration. All procedures were conducted at the Department of Endodontics and Restorative Dentistry, Hama University. Participants with reversible or irreversible pulpitis were randomly assigned to one of three groups (MTA, Bioceramic, Biodentine) using computer-generated block randomization (block size = 6). An independent researcher created the sequence and prepared

sealed, opaque envelopes to ensure allocation concealment. Envelopes were opened only after eligibility confirmation.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The severity of inflammation was measured using histology after a week and 3 months by examining inflammatory cells, and the severity of inflammation was classified as follows: score 0: There are no inflammatory cells at or adjacent to the site of exposure, score 1: slight inflammation; presence of a small number of inflammatory cells, score 2: moderate inflammation medium number of inflammatory cells, score 3: Acute inflammation; abundant presence of inflammatory cells.

Key secondary outcome(s))
The expression of the inflammatory immune marker was measured after a week and 3 months using the amputation materials used according to the following index: score 0: no inflammation (no staining), score 1: mild inflammation (mild staining), score 2: moderate inflammation (moderate staining), score 3: severe inflammation (severe staining)

Completion date
28/10/2024

Eligibility

Key inclusion criteria
1. A mature permanent tooth indicated for extraction for orthodontic reasons that does not have any carious lesions for the reversible pulpitis groups
2. Mature permanent tooth requiring extraction (such as third molars) has deep carious lesions with clinical signs and symptoms of irreversible pulpitis (spontaneous or intermittent acute pain) for irreversible pulpitis groups
3. A positive response to pulp sensitivity tests with no signs of pulp necrosis (such as edema, fistula or severe sensitivity to percussion)
4. Restorable tooth without the need for a crown or posts, the gingival sulcus depth between 1-3 mm, and normal tooth mobility
5. The periapical radiograph showed a pulp chamber with relatively normal dimensions without degenerative activity (pulp stones, calcification, severe canal narrowing in the vertical direction)
6. Absence of periapical and furcation radiolucency
7. Absence of internal or external absorption

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

16 years

Upper age limit
35 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. History of immune or bleeding diseases
2. Medications that may affect the metabolism
3. Uncontrolled pulp hemorrhage after pulpotomy procedures within 10 minutes of hemostasis
4. Abnormal color and appearance of the pulp tissue
5. Absence of hemorrhage or little hemorrhage in a dark red color after pulp exposure or after pulpotomy procedures

Date of first enrolment
25/01/2022

Date of final enrolment
15/03/2024

Locations

Countries of recruitment
Syria

Study participating centre
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Study participating centre
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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 are/will be available upon request from Hasan Alzoubi, dr.hasan.alzoubi.93@gmail.com.

Data Availability:
IPD will be made available to researchers after the study’s final publication in a de-identified format to protect participant privacy.

Access:
Researchers can request access to the data by submitting a research proposal for review by the study's ethics or data access committee.

Timeline:
Data will be shared within [6 months] after the study’s final publication.

Security:
Data will be anonymized and stored in secure, password-protected databases with access restricted to authorized personnel.

Ethics and Consent:
Participants have given consent for their de-identified data to be used for future research. Data sharing will comply with the study’s ethical guidelines.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			14/05/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes