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# The effectiveness of biomaterials filling for protecting exposed dental pulp

**Submission date**
29/04/2024

**Recruitment status**
No longer recruiting

**Registration date**
01/05/2024

**Overall study status**
Completed

**Last Edited**
10/06/2026

**Condition category**
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
Direct pulp capping (DPC) is a dental procedure that aimed to protect the vital exposed pulp. The aim of this study is to evaluate the clinical and radiographical success rate of 3 DPC bioceramic materials (TotalFill Fast Set Putty, TotalFill Paste, and Neo Putty) on vital permanent teeth compared to golden standard DPC material (Neo MTA Plus).

Who can participate?
Adult patients aged 15-25 years old with deep carious lesions on permanent teeth.

What does the study involve?
Participants will be randomly divided into 4 groups to be treated with Neo MTA Plus, TotalFill Fast Set Putty, TotalFill Paste, and Neo Putty as DPC materials. 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 teeth, preserving dental pulp appears to be more effective than complete root canal treatment and obturation due to the potential complications following endodontic treatment. In addition, we assessed the impact of modern bioceramic materials (which exhibit suitable consistency and ease of use) on the human dental pulp.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
June 2020 to December 2023

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Alaa Mahmoud Muhamad, alaa3m.muhamad@damascusuniversity.edu.sy

# Contact information

### Type(s)
Public, Scientific, Principal investigator


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# Additional identifiers

### Protocol serial number
UDDS-380-22062020/SRC-89

# Study information

### Scientific Title
The ability of new bioceramic materials used in direct pulp capping in repairing dentine pulp complex: a randomized controlled trial

### Study objectives
This study is designed to assess the hypothesis that new bioceramic materials can be used as direct pulp capping materials on exposed pulps in teeth with deep carious lesions as an alternative to the golden standard material (MTA) in the term of clinical and radiographical success and evaluating their potential for pulp healing clinically and radiographically

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 22/06/2020, Damascus University (Almazzeh ST, Damascus, 20872, Syria; +963 (0) 90404840; Osama.aljabban@gmail.com), ref: 380

### Primary study design
Interventional

### Study design
Interventional randomized controlled trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Deep carious lesions in asymptomatic permanent teeth

## Interventions
Forty asymptomatic closed-apex teeth in healthy patients aged between 15-25 years were randomly divided into four groups using http://www.randomization.com:
Group A (control): teeth will be treated with Neo MTA Plus as direct pulp capping therapy.
Group B (study): teeth will be treated with Neo Putty as direct pulp capping therapy.
Group C (study): teeth will be treated with Total Fill Paste as direct pulp capping therapy.
Group D (study): teeth will be treated with Total Fill Fast Set Putty as direct pulp capping therapy.

The intervention steps were as follows:
Administer local anesthesia.
Apply rubber dam isolation on the tooth being studied.
Prepare a cavity of appropriate depth for pulp exposure with a size of 1 mm and a width of approximately 2 mm, lingually or buccolingually.
Continuous irrigation and washing with physiological saline.
Control bleeding by applying pressure with a cotton roll at the exposure site.
Appling the studied material (according to the randomization) as a direct pulp capping material.
Restoring the cavity with resin bonded restoration.

## Intervention Type
Other

## Primary outcome(s)
1. Clinical evaluation: Patients of both groups were recalled after 7 and 30 days of treatment and during radiographical assessment periods (1, 6 and 12 months), where they were asked to rate their pain on the following:
0 No pain.
1 Mild pain.
2 Moderate pain.
3 Severe pain.
2. Radiographical assessment: After coronal restoration was completed a radiograph was taken immediately (R0), After 1 month (R1), After 6 months, and After 12 months (R2). The integrity of the periapical tissue was assessed. Moreover, the following values were given to evaluate the degree of formation of the dentinal bridge radiographically:
0 No dentinal bridge
1 The dentinal bridge begins to form
2 There is complete formation of the dentinal bridge

## 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 bleeding control of each case (in minutes) measured using a timer.

## Completion date
31/12/2023

# Eligibility

### Key inclusion criteria
1. Teeth with closed apex.
2. No history of trauma.
3. Healthy patients.
4. No radiographic or clinical signs of periapical lesions.
5. Radiographic or clinical symptoms of pulpal necrosis are present.
6. Positive vitality testing (Vital pulp).

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
15 Years

### Upper age limit
25 Years

### Sex
All

### Total final enrolment
40

### Key exclusion criteria
1. Presence of any clinical or radiographic symptoms of acute pulpitis or necrosis.
2. Patients with systematic disease.

### Date of first enrolment
22/06/2022

### Date of final enrolment
31/12/2022

# Locations

### Countries of recruitment
Syria

### Study participating centre

**Damascus University-Department of Endodontics**
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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**
Published as a supplement to the results publication

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 05/11/2025 | 10/06/2026 | Yes | No |