

Comparing benzoin resin and Coe-Pak for gum healing after pigmentation removal surgery

Submission date 05/08/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/08/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/08/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This clinical study investigates whether a natural product called benzoin resin tincture can improve healing and reduce pain after a cosmetic dental procedure known as gingival depigmentation, which removes dark pigmentation from the gums. While this pigmentation is harmless, it can be a cosmetic concern for individuals with a prominent smile. The standard post-surgical dressing, Coe-Pak, protects the wound but does not actively support healing. Benzoin resin, on the other hand, has known healing, anti-inflammatory, and antimicrobial properties.

Who can participate?

Healthy adults aged 18–40 years with natural gum pigmentation.

What does the study involve?

Participants underwent gum depigmentation on both sides of the upper jaw. One side was treated with Coe-Pak, and the other with benzoin resin tincture. Researchers assessed healing, pain levels, and recovery over four weeks.

What are the possible benefits and risks of participating?

Participants will help to determine whether benzoin resin tincture offers a better, low-cost alternative to traditional periodontal dressings.

Participants may experience temporary pain, swelling, or mild bleeding after surgery, similar to standard gum procedures. There is a small risk of infection or allergic reaction to the dressing materials, which will be managed promptly if it occurs.

Where is the study run from?

The Faculty of Dentistry, Damascus University, Syria.

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

April 2024 to June 2025

Who is funding the study?

The Faculty of Dentistry, Damascus University, Syria.

Who is the main contact?
MHD Bahaa Aldin Alhaffar, bhaa.alhaffar@gmail.com

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

Nil known

Study information

Scientific Title

Benzoin resin tincture versus Coe-Pak for postoperative healing after gingival depigmentation: a randomized controlled split-mouth clinical trial

Study objectives

To evaluate the clinical effectiveness of benzoin resin tincture compared to Coe-Pak as a postoperative dressing following surgical gingival depigmentation, with a specific focus on wound healing, epithelialization, and postoperative pain.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 15/04/2024, Higher Committee for Scientific Research at Damascus University (Almazzah, Damascus, 00000, Syria; +963-11-33923192; info@damascusuniversity.edu.sy), ref: n/a162536

Study design

Randomized controlled split-mouth design trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

University/medical school/dental school

Study type(s)

Quality of life, Treatment, Efficacy

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Physiological gingival pigmentation

Postoperative healing after depigmentation surgery

Interventions

Healthy adult participants aged 18–40 years with bilateral physiological gingival pigmentation in the upper anterior region were enrolled after providing written informed consent. Each participant underwent gingival depigmentation surgery on both sides of the upper front gums using a standard scalpel technique.

In a split-mouth randomised design, one side was allocated to the test intervention and the other to the control. Allocation was determined by a simple coin toss before surgery.

- Test intervention: Application of benzoin resin tincture (Myzotect) to the depigmented site using a sterile microbrush, forming a protective film. No reapplication was required unless dislodgement occurred.
- Control intervention: Placement of Coe-Pak periodontal dressing over the depigmented site, left in place for 7 days unless dislodged.

Participants were reviewed on days 1, 2, 3, 5, and 7, and at weeks 2, 3, and 4 postoperatively. The total observation period was 4 weeks per participant, with both clinical (epithelialization index, wound healing index) and patient-reported (pain via VAS, analgesic use) outcomes recorded.

Intervention Type

Procedure/Surgery

Primary outcome measure

Epithelialization index measured using the degree of epithelial coverage at the surgical site (Grade 0–3), weekly for 4 weeks postoperatively

Secondary outcome measures

1. Healing measured using the Wound Healing Index (H1–H5) assessed weekly for 4 weeks
2. Pain measured using a Visual Analog Scale (VAS) daily from Day 1 to Day 7
3. Rescue medication usage measured using the number of analgesic tablets consumed over 7 days

Overall study start date

01/04/2024

Completion date

01/06/2025

Eligibility

Key inclusion criteria

1. Aged 18–40 years
2. Presence of physiological melanin pigmentation in the upper anterior gingiva (Hedin index 3 or 4)
3. Confirmed absence of systemic or pathological causes of pigmentation
4. Good general health (ASA I)
5. Adequate width and thickness of attached gingiva
6. No signs of active periodontal disease
7. No prior surgical intervention in the target area
8. Informed consent provided and willingness to comply with follow-up visits

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

40 Years

Sex

Both

Target number of participants

12

Total final enrolment

12

Key exclusion criteria

1. Smoking or tobacco use
2. Alcohol abuse
3. Pregnancy or lactation
4. Use of anti-inflammatory, immunosuppressive, or photosensitizing medications
5. Systemic diseases affecting healing (e.g. uncontrolled diabetes)
6. History of radiation therapy
7. Known allergy to any component of benzoin resin tincture or Coe-Pak dressing

Date of first enrolment

01/06/2024

Date of final enrolment

01/02/2025

Locations**Countries of recruitment**

Syria

Study participating centre

Damascus University, Faculty of Dental Medicine

Almazzah

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Sponsor information**Organisation**

Damascus University

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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

We intend to publish the study results in a peer-reviewed scientific journal. The manuscript is currently being prepared for submission. In addition, the findings will be presented at relevant dental and periodontology conferences. A plain language summary will also be made available upon publication for broader dissemination.

Intention to publish date

01/01/2026

Individual participant data (IPD) sharing plan

The anonymised aggregate datasets and analysis results generated during and/or analysed during the current study are/will be available upon request from MHD Bahaa Aldin Alhaffar, bhaa.alhaffar@gmail.com.

There is no plan to share individual participant data (IPD) due to ethical restrictions and the small sample size.

IPD sharing plan summary

Available on request