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

Submission date 05/08/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/08/2025	**Overall study status** Completed	
Last Edited 08/08/2025	**Condition category** Oral Health	

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?
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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

Study type(s)
Quality of life, Treatment, Efficacy

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
All

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
Damascus
Syria
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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 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.alhafar@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