ISRCTN53999031 https://doi.org/10.1186/ISRCTN53999031

Gum stain removal using a ceramic drill

Submission date 03/12/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 13/12/2024	**Overall study status** Completed	
Last Edited 13/12/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Gingival pigmentation is a cosmetic problem that patients complain about. This pigmentation occurs in patients with dark skin and is a physiological pigmentation. This study aims to test the pain and healing effect of a new method for removing gingival pigmentation, namely ceramic burs, as it is believed to be better than the surgical blade in terms of pain and healing.

Who can participate?
Adult patients aged between 18 and 45 years old who have moderate to severe gingival pigmentation

What does the study involve?
The removal of gingival pigmentation was undertaken using two techniques: ceramic bur and blade under local anesthesia. This study is expected to continue for one year from the beginning of patient recruitment.

What are the possible benefits and risks of participating?
Gingival pigmentation removal helps get rid of the dark color of the gums, which is a cosmetic problem, especially for patients with a gummy smile. This method does not pose any risks to the gums, bones, or general health of the patient.

Where is the study run from?
Damascus University, Syria

When is the study starting and how long is it expected to run for?
August 2021 to January 2023

Who is funding the study?
Damascus University, Syria

Who is the main contact?
Prof Ahmad Alnada, ahmad.alnada@damascusuniversity.edu.sy, dent.ahmad.1996@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Assessing the gingival depigmentation of ceramic bur compared with surgical blade – randomized clinical trial

Study objectives
Healing is faster and pain is less when removing gum stains with ceramic burs. Ceramic burs are able to remove gum stains with similar efficiency to a blade.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/08/2021, Scientific Research and Postgraduate Studies Council (Damascus University, Baramkeh, Damascus, 00258, Syria; +963 1133923192; ap.srd@damascusuniversity.edu.sy), ref: DN-160822-179

Study design
Randomized controlled clinical trial in the split-mouth design with a 1:1 allocation ratio

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Gingival pigmentation

Interventions
This study examines physiological gingival depigmentation for cosmetic reasons using two methods. The control group uses the gold standard surgical blade to remove the superficial epithelium after local anesthesia. The study group uses ceramic burs mounted on a high-speed dental handpiece without irrigation to remove the superficial epithelium after local anesthesia. A single periodontist at the Periodontology Department, Faculty of Dentistry, Damascus University, performs all procedures. Healing is monitored for a month after a single application.

Randomization is done using closed envelopes specifying the method and direction. Patients draw an envelope before the procedure to determine the method. Ten envelopes are prepared for the first patient, with methods distributed equally between the upper and lower jaws in a 1:1 ratio.

Intervention Type
Mixed

Primary outcome(s)
1. Gingival pigmentation is measured using the Dummet-Gupta Oral Pigmentation Index (DOPI) at baseline and 4 weeks
2. Pain is measured using the DOPI index at baseline, 24, 48, 72, 96, 120, 144 and 168h

Key secondary outcome(s))
Healing was measured using the Landry Wound Healing Index at 4 weeks

Completion date
01/01/2023

Eligibility

Key inclusion criteria
1. Non-smoker patients
2. Moderate to severe gingival pigmentation, class 2 or 3, according to the Oral Pigmentation Index (DOPI)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Systemic diseases
2. Hormonal disorders (thalassemia, Addison's disease)
3. Medication that may cause gingival pigmentation

Date of first enrolment
01/01/2022

Date of final enrolment
01/06/2022

Locations

Countries of recruitment
Syria

Study participating centre
Faculty of Dentistry, Damascus University.
Fayez Mansor St, Almazeh.
Damascus
Syria
00258

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 data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

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