# Gum stain removal using a ceramic drill

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

### 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

#### Contact name

Prof Ahmad Alnada

#### Contact details

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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