

Comparison of two different laser techniques in the removal of gingival pigmentation

Submission date 18/06/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/06/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/06/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Gingival hyperpigmentation (dark-coloured gums) can cause aesthetic concerns and negatively affect self-confidence and the ability to socialize, especially in patients with a high smile line. Gingival depigmentation is an aesthetic correction of hyperpigmented gingiva. Many treatments have been used and there are a lot of studies looking for the most effective, comfortable and safest treatment, including conventional surgical techniques, electrosurgery, cryosurgery, and laser techniques. Lasers have shown good aesthetic results and are associated with fewer complications. This study aims to compare the effectiveness of the ablative diode laser 980 nm, the ablative carbon dioxide laser 10600 nm, and the non-ablative diode laser 450 nm in the removal of gingival pigmentation.

Who can participate?

Patients aged 18-45 years with gingival pigmentation

What does the study involve?

The study involves three groups (diode laser 980 nm, carbon dioxide laser 10600 nm, and diode laser 450 nm). Each patient will be randomly allocated to one of the three groups.

What are the possible benefits and risks of participating?

The patients may get an esthetic result after 10-15 days following the treatment session. Possible risks could be pain and discomfort after laser surgery.

Where is the study run from?

Damascus University (Syria)

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

February 2022 to December 2024

Who is funding the study?

Damascus University (Syria)

Who is the main contact?

Dr Raneem Darkazali, raneem.dar96@gmail.com or raneem96.darkazali@damascusuniversity.edu.sy

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

3031

Study information

Scientific Title

Laser-assisted physiologic gingival melanin depigmentation: surgical technique versus selective photo thermolysis (randomized comparative clinical trial)

Study objectives

H0: There is no significant difference among the three groups (ablative diode 980 nm, ablative carbon dioxide laser 10600 nm, and non-ablative diode 450 nm) in the removal of physiologic gingival melanin pigmentation in the studied indices.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 20/06/2022, Scientific ethics committee at Damascus University (Baramkeh, Damascus, 4671, Syria; +963 (11) 339 23223; ap.srd@damascusuniversity.edu.sy), ref: 2721

Study design

Randomized comparative clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Physiologic gingival melanin pigmentation

Interventions

The study is designed to compare the effectiveness of both the ablative technique (surgical technique) of diode 980 nm and carbon dioxide laser (10600 nm), and the non-ablative technique (selective photo thermolysis) of diode 450 nm in the removal of physiologic gingival pigmentation using several indices. Patients will be randomly allocated to one of the three groups. All patients will receive initial treatment (scaling and root planing) and after 1 week they will undergo laser treatment with one of the three lasers.

The laser treatment will take one session. The enrolled patients will be followed up after 10 days to assess the healing, and after 1, 3, 6 and 9 months to assess the recurrence of the gingival pigments. Random allocation software was used to generate the randomisation sequence.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Gingival pigmentation recurrence measured using Dummet et al index for gingival pigmentation color and Takashi index for gingival pigmentation extension after 1, 3, 6, and 9 months

Key secondary outcome(s)

1. Bleeding assessed using a bleeding index (0 to 3) directly after surgery
2. Healing assessed using a healing index 10 days and 1 month postoperatively
3. Procedure duration recorded in minutes for each jaw (this is the laser surgery duration which will be recorded after local anesthesia for each jaw separately), during the clinical procedure
4. Procedure difficulty assessed by the researcher directly after the procedure (laser surgery)
5. Gingival appearance assessed using a gingival appearance score at 1, 3, 6, and 9 months postoperatively
6. Pain, edema, and discomfort evaluated using a self-modified McGill questionnaire immediately after the procedure, 1 day, and 10 days postoperatively
7. Patient satisfaction assessed using questionnaire at the end of follow-up sessions

Completion date

01/12/2024

Eligibility

Key inclusion criteria

1. Patients exhibiting physiologic gingival melanin pigmentation of score 2 or more according to Dummet et al.
2. Aged 18-45 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

45 years

Sex

All

Key exclusion criteria

1. Pathologic hyperpigmentation
2. Patients with periodontitis or acute gingivitis
3. Taking medications that may induce gingival pigmentations such as antimalarial agents, and tricyclic antidepressants
4. Systemic diseases that could affect tissue healing (e.g autoimmune diseases)
5. Pregnancy and lactation
6. Current smokers
7. Previous mucogingival surgery at the region to be treated

Date of first enrolment

03/09/2022

Date of final enrolment

01/01/2024

Locations**Countries of recruitment**

Syria

Study participating centre**Damascus University**

Faculty of Dental Medicine, Oral Medicine Department

Mazzeah Highway

Damascus

Syria
4671

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 analyzed during the current study will be available upon request from Raneem Darkazali (raneem.dar96@gmail.com or raneem96.darkazali@damascusuniversity.edu.sy). Any data that support the results of the study (raw data and processed data) will be shared, not including any personal information of the participants such as their names, after publication of the results. Written informed consent will be obtained from each participant. Any personal data or any photos that identify the patient's identity will be anonymized.

IPD sharing plan summary

Available on request

Study outputs

Output type

[Participant information sheet](#)

Details

Date created

Date added

27/06/2023

Peer reviewed?

No

Patient-facing?

Yes