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

Submission date
18/06/2023

Recruitment status
No longer recruiting

Registration date
29/06/2023

Overall study status
Completed

Last Edited
29/06/2023

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

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 measure
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

Secondary outcome measures
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

Overall study start date
17/02/2022

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Both

Target number of participants
33

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
Mazzeh Highway
Damascus
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4671

Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

Website
http://www.damascusuniversity.edu.sy

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

Publication and dissemination plan
Planned publication in a high-impact peer review journal

Intention to publish date
01/12/2025

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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			27/06/2023	No	Yes