

Comparing two lasers for treating gingival overgrowth in patients who uses braces

Submission date 30/04/2025	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/05/2025	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 12/05/2025	Condition category Oral Health	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Gingival overgrowth continues to concern patients due to its effects on both aesthetic and functional aspects (such as speech and chewing), and in some cases, it may hinder the progress of orthodontic treatment and prevent the orthodontist from continuing their work.

Therefore, it is necessary to find an effective and comfortable treatment for our patients that ensures optimal control over the aesthetic and functional complications in patients suffering from orthodontics-induced gingival overgrowth.

This study aims to evaluate the effects of CO2 laser compared to the 450 nm diode laser by assessing the following indices:

gingival overgrowth index, mucosal scarring, periodontal pocket depth, clinical crown length, bleeding during and after the surgical procedure, pain, recurrence, operation time and healing.

Who can participate?

Patients with gingival overgrowth induced by fixed orthodontics.

What does the study involve?

We divided the patients into two groups, the first group was treated using a CO2 laser, and the second group using a 450nm Diode laser. The following variables were studied: gingival overgrowth, periodontal pocket depth, clinical crown length, gingival bleeding index, visual analog scale for pain, recurrence index, healing index, and operation time.

What are the possible benefits and risks of participating?

assisting the orthodontist with the orthodontic treatment while also treating gingival overgrowth.

No harmful side effects are expected .

Where is the study run from?

Damascus university, Faculty of dentistry (Syria)

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

September 2024 to September 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Rose Assaf
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
3337

Study information

Scientific Title
A comparative study between CO₂ laser and the diode laser 450nm in the management of gingival overgrowth during orthodontic treatment

Study objectives
Null Hypothesis (H₀):
There are no statistically significant differences between the CO₂ laser group and the diode laser group in any of the research variables.

Alternative Hypothesis (H₁):
There are statistically significant differences between the CO₂ laser group and the diode laser group in all of the research variables.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/09/2024, Research Ethics Committee-Faculty of Dentistry, Damascus University (Mazzeah highway, Damascus, -, Syria; +963 1133926091; Dean.dent@damascusuniversity.edu.sy), ref: 3337

Primary study design

Interventional

Study design

Interventional randomized controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Gingival overgrowth during orthodontic treatment

Interventions

The sample was divided into two groups: the first group was treated using a CO2 laser, and the second group using a 450nm Diode laser. The following variables were studied: gingival overgrowth, periodontal pocket depth, clinical crown length, gingival bleeding index, visual analog scale for pain, recurrence index, healing index, and operation time.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. The clinical crown length, gingival overgrowth index, and periodontal pocket depth will be measured over the following periods: before intervention, after 15 days, 1 month, 3 months, and 6 months.
2. The pain index will be measured over the following periods: day of treatment, after 1 day, 2 days, 3 days, and after 1 week.
3. The bleeding index will be measured during the surgical procedure and after the procedure.
4. Operation time will be measured separately for each group.
5. The clinical healing index will be measured over the following periods: after 1 week and after 1 month.
6. The scar will be evaluated over the following periods: after surgery, after 1 month, 3 months, and 6 months.
7. The recurrence index will be measured over the following periods: after 1 month, 3 months, and 6 months.

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

05/09/2026

Eligibility

Key inclusion criteria

1. Patients treated with fixed orthodontics
2. Patients with gingival overgrowth

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

1. Pregnant and breastfeeding women.
2. Smokers.
3. Patients taking medications that cause gingival enlargement, such as (calcium channel blockers, anticonvulsants, immunosuppressants), and patients taking blood thinners or bisphosphonate medications.
3. Patients with diabetes.
4. Patients with infectious diseases such as (hepatitis, acquired immunodeficiency virus).
5. Endocrine disorder.

Date of first enrolment

05/09/2024

Date of final enrolment

28/02/2026

Locations

Countries of recruitment

Syria

Study participating centre

Damascus University

Syria, Damascus, Rabwa Neighborhood

Damascus

Syria

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Sponsor information

Organisation

Damascus University

ROR

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from (Dr. Rose Assaf, roseassaf024@gmail.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Arabic		02/05/2025	No	Yes