

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

<b>Submission date</b> 30/04/2025	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/05/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/05/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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  
rose.assaf@damascusuniversity.edu.sy, roseassaf024@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**  
3337

## Study information

**Scientific Title**  
A comparative study between CO<sub>2</sub> laser and the diode laser 450nm in the management of gingival overgrowth during orthodontic treatment

**Study objectives**  
Null Hypothesis (H<sub>0</sub>):  
There are no statistically significant differences between the CO<sub>2</sub> laser group and the diode laser group in any of the research variables.

Alternative Hypothesis (H<sub>1</sub>):  
There are statistically significant differences between the CO<sub>2</sub> 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 (Mazze highway, Damascus, -, Syria; +963 1133926091; Dean.dent@damascusuniversity.edu.sy), ref: 3337

### **Study design**

Interventional randomized controlled trial

### **Primary study design**

Interventional

### **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

<https://ror.org/03m098d13>

## 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](mailto:roseassaf024@gmail.com)).

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	in Arabic		02/05/2025	No	Yes