ISRCTN17755133 https://doi.org/10.1186/ISRCTN17755133

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

Submission date 30/04/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/05/2025	**Overall study status** Ongoing	
Last Edited 12/05/2025	**Condition category** Oral Health	

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 (H_0):
There are no statistically significant differences between the CO_2 laser group and the diode laser group in any of the research variables.

Alternative Hypothesis (H_1):
There are statistically significant differences between the CO_2 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 (Mazzeh highway, Damascus, -, Syria; +963 1133926091; Dean.dent@damascusuniversity.edu.sy), ref: 3337

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
05/09/2024

Completion date
05/09/2026

Eligibility

Key inclusion criteria
1. Patients treated with fixed orthodontics
2. Patients with gingival overgrowth

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
30

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

Sponsor details
Mazzeh Highway
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Syria
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Sponsor type
University/education

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

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date

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