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The surgical scalpel versus carbon dioxide laser in conventional lip repositioning

Submission date
27/08/2023

Recruitment status
No longer recruiting

Registration date
12/09/2023

Overall study status
Completed

Last Edited
14/08/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
An excessive gingival display while smiling prevents many people from showing their smiles when laughing or taking pictures. The gummy smile also gives an appearance that is not preferred by individuals. There are many studies investigating the best method to manage this condition, but new studies are required to further develop therapeutic methods and overcome the disadvantages of the previous methods. The use of dental lasers to treat a gummy smile has shown benefits, especially in reducing post-operative complications. Therefore, this study is being undertaken to compare the effectiveness of a carbon dioxide (CO2) laser (10600) nm with the conventional surgical scalpel in lip repositioning surgery.

Who can participate?
Patients aged 18-35 years old with gummy smiles caused by soft tissue disorders (short or hyperactive upper lip)

What does the study involve?
The study involves two groups (carbon dioxide laser 10600 nm, and conventional scalpel) in lip repositioning surgery. Each patient will be randomly allocated to one of the two groups.

What are the possible benefits and risks of participating?
Using dental lasers in this oral surgery may be beneficial in reducing the trauma caused during the operation compared with conventional surgical methods, and make it more conservative. The results could have both good aesthetic and functional effects in managing this issue. There are possible risks of pain and edema after laser surgeries.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is expected to run for?
April 2022 to April 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr.Sara Alkari, dr.sara.alkari96@gmail.com, sara.alkari96@damascusuniversity.edu.sy (Syria)

Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2609

Study information

Scientific Title
A comparison between a surgical scalpel and CO2 laser in conventional lip repositioning (randomized controlled clinical study)

Study objectives

At the 95% confidence level (or at the 0.05 level of significance):
For parametric variables (mm):
Null Hypothesis (H0):
1. There are no statistically significant differences between the average of each of the carbon parametric uses (visual and radial dimensions of the bed) (in mm) and the reduction of the decrease in the speed loss after the processor (in mm) between the binary laser group.
2. There are no statistically significant differences between the mean of each of the typical parametric parameters (visual and radial dimensions of the bed) (in mm), reduction of the decrease in speed loss after the processor (in mm) between the time periods studied in each of the traditional dual-disk laser group in the long term in technical research.

Alternative Hypothesis (H1):
1. There are statistically significant differences between the mean of each of the measured parametric variables (clinical and radiological dimensions of the lips) (in mm), the amount of decrease in the appearance of the gums after treatment (in mm) between the carbon dioxide laser group and the traditional surgical method group in each of the time periods studied on the unit in the research sample.
2. There are statistically significant differences between the average of each of the measured parametric variables (the dimensions of the lips clinically and radiologically) (in mm), the amount of decrease in the appearance of the gums after treatment (in mm) between the time periods studied in each of the carbon dioxide laser group and the group of the traditional method separately in the research sample.

For non-parametric variables:
Null Hypothesis (H0):
1. There are no statistically significant differences in the frequencies of the categories of each of the ordinal and nominal variables studied (degree of patient satisfaction, pain, edema, clinical recovery) between the carbon dioxide laser group and the traditional method group in each of the time periods studied separately in the research sample.
2. There are no statistically significant differences in the frequencies of the categories of each of the ordinal and nominal variables studied (degree of patient satisfaction, pain, edema, clinical recovery) between the time periods studied in each of the carbon dioxide laser group and the traditional method group separately in the research sample.

Alternative Hypothesis (H1):
1. There are statistically significant differences in the frequencies of the categories of each of the ordinal and nominal variables studied (degree of patient satisfaction, pain, edema, clinical recovery) between the carbon dioxide laser group and the traditional method group in each of the time periods studied separately in the research sample.
2. There are statistically significant differences in the frequencies of the categories of each of the ordinal and nominal variables studied (degree of patient satisfaction, pain, edema, clinical recovery) between the time periods studied in each of the carbon dioxide laser group and the traditional method group separately in the research sample.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 09/05/2022, Scientific ethics committee at Damascus University (Baramkeh, Damascus, 00963, Syria; + 963 (11) 339 23223; ap.srd@damascusuniversity.edu.sy), ref: 2609

Study design
Randomized comparative clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gummy smile caused by a short or hyperactive upper lip

Interventions
The study is designed to evaluate the effectiveness of the conventional surgical lip repositioning (the removal of a partial thickness flap) with a surgical scalpel compared to a carbon dioxide laser using specific parameters (wavelength:10600 nm - power: 4 Watts - mode: continuous) in the management of gummy smiles causing soft tissue disorders. Patients will be randomly allocated to one of the two groups using cards numbered (1) for the first group (scalpel group) and (0) for the second one (co2 laser group). The patient is asked to pick up one of the cards in a random way and then according to the number inside it, they will be involved in the indicated group. The patients will be recalled to follow-up appointments in the first week after the operation, 14 days, and 1, 3 and 6 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Pain measured using a visual analogue scale (VAS) on the first day post-surgery
2. Edema measured using a VAS; the number 0 indicates the absence and the number 1 indicates the presence of edema on the third day post-surgery

Key secondary outcome(s))
1. The amount of gingival coverage after completion of treatment and the stability of the results measured from the edge of the lower lip to the midpoint of the gingival margin in each tooth in the smile position in mm before surgery and after 1,3, and 6 months
2. Patient satisfaction measured using a scale after 6 months post-surgery
3. The following clinical changes in the dimensions of the upper lip are measured using a millimeter scale ruler, specially designed to conduct research and hollowed out at the upper lip frenum after delineating the solar images in the lateral position at the first session before surgery and 1,3, and 6 months post-surgery: the external length of the upper lip from the base of the nose to the lower edge of the upper lip; the internal length of the upper lip; the length of the oral philtrum measured by placing the ruler on one of the sides of the oral philtrum and measuring the extension from the base of the nose to the upper edge of the upper lip; width of the red area of the upper lip from the upper edge to the lower edge of the upper lip; and, the amount of protrusion of the upper lip by measuring the distance between the upper lip and the nasolabial E-line (the line between the tip of the nose and the most prominent point on the soft tissues of the chin).
4. The following radiological measurements of the upper lip measured using cephalometric images before surgery and 6 months post-surgery: for upper lip thickness a horizontal line is drawn from the most prominent point of the upper lip towards the socket of the front teeth; the

external length of the upper lip is measured from the base of the nose to the lower edge of the upper lip (interlabial cleft point); the internal length of the lip is measured from the deepest point in the groove of the upper lip to the edge of the incisive border of the teeth.

Completion date
09/04/2024

Eligibility

Key inclusion criteria
1. 4-6 mm of gum showing when smiling
2. Aged between 18 to 35 years old
3. The gummy smile is caused by soft tissue disorders only (shortness of the upper lip - hyperactivity of the muscles that lift it)
4. Healthy patients or those with controlled systemic diseases that do not prevent them from undergoing a surgical procedure
5. Good gingival and periodontal health

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Smoking
2. Pregnancy
3. Breastfeeding
4. A gummy smile of more than 6 mm of gum showing when smiling
5. Attached gingiva of less than 3 mm thick, which makes slide design and stability difficult

Date of first enrolment
09/05/2022

Date of final enrolment

09/11/2023

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Oral Medicine Department/Faculty of Dentistry
Mazzah High Way
Damascus
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00963

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 generated during and/or analysed during the current study will be available upon request from Dr Sara Alkari, sara.alkari96@damascusuniversity.edu.sy

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/08/2025	14/08/2025	Yes	No
Participant information sheet			08/09/2023	No	Yes
Participant information sheet			08/09/2023	No	Yes