

Removing an abnormal maxillary labial frenum (a small band of tissue that connects the upper lip to the gums) using a scalpel and laser

Submission date 09/11/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/11/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/11/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The frenum is a fold in the mucous membrane that connects the lip and the cheek to the tissues around the upper teeth. When these folds, called frena, are too closely attached to the gum line, it can potentially impact gum health. This can happen due to issues like difficulty in cleaning plaque or tension from muscle pull.

The aim of this study is to evaluate the pain and reinsertion of the frenum following conditional and laser assisted treatment in patients with abnormal upper labial frenum.

Who can participate?

Patients aged 15 years and over with abnormal upper labial frenum

What does the study involve?

Frenectomy with classical surgery and laser surgery and follow up for 3 months

What are the possible benefits and risks of participating?

Decrease the pain and promote the healing of the wounds and make the patients more comfort
The methods are safe and there are no expected risks.

Where is the study run from?

Damascus University (Syria)

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

January 2021 to November 2023

Who is funding the study?

Damascus University (Syria)

Who is the main contact?

Dr Aisha Sayed Taha

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Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

21/S.M

Study information

Scientific Title

A comparative clinical study between conventional surgical technique and different types of laser for frenectomy procedure

Study objectives

There is no difference between laser assisted technique and conventional technique for Frenectomy

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 04/01/2021, Scientific Research and Postgraduate Studies Council (Baramkeh, Damascus, -, Syria; +963 (0)1133923192; ap.srd@damascusuniversity.edu.sy), ref: None provided

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Frenectomy in patients with abnormal labial frenum

Interventions

In this study, individuals with abnormal maxillary labial frenum were randomly treated with a conventional technique and different types of laser. Clinical measurements will be taken every month during the 3-month follow-up period.

1st group: conventional surgical technique

2nd group: conventional surgical technique followed by application diode laser 808nm for photobiomodulation

3rd group: laser Er:YAG for surgery

4th group: laser Diode 810nm for surgery

Follow up after one week, one month, 3months

Randomization by website:

www.random.org

Intervention Type

Procedure/Surgery

Primary outcome(s)

Pain is measured using a numerical scale (NS) at baseline, 24, 48, and 72 h.

Key secondary outcome(s)

1. Reepithelialization assessment by H₂O₂ after one week, two weeks, three weeks, 1 month, 3 months.
2. Reinsertion of the frenum by UNC15 probe after 1 month, 3 months.

Completion date

05/11/2023

Eligibility

Key inclusion criteria

1. Systemically healthy
2. Non smoker
3. Between 15 and 55 years old
4. Not received any periodontal treatment within the last 3 months
5. Presence of at least central incisors, lateral incisors, and canines at the maxilla
6. Consent to participate in the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

15 years

Upper age limit

55 years

Sex

All

Total final enrolment

40

Key exclusion criteria

1. Any systematic disease that might interfere with wound healing process (i.e., diabetes mellitus and HIV infection)
2. Smoking
3. Antibiotics, anti-inflammatory drugs, or any other medication taken within the last 6 months that might affect the outcome of the study
4. Any hypersensitivity reactions against to paracetamol
5. Any physical limitations or restrictions that might preclude normal oral hygiene procedures

Date of first enrolment

01/10/2021

Date of final enrolment

05/08/2023

Locations

Countries of recruitment

Syria

Study participating centre

Damascus University

Department of Periodontology

Faculty of Dentistry

Mezzah

Damascus

Syria

-

Study participating centre

Damascus University

High institute for Laser researches and applications

Faculty of mechanical and electrical engineering

Airport road

Damascus

Syria

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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 are/will be available upon request from Prof. Dr Wael Almahdi (w.almahdi76@gmail.com). All of data of the patients will be available on request.
Consent from participants was obtained.

IPD sharing plan summary

Available on request