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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

Registration date
13/11/2023

Overall study status
Completed

Last Edited
13/11/2023

Condition category
Oral Health

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

Secondary study design
Randomised controlled trial

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

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Secondary outcome measures
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.

Overall study start date
05/01/2021

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

Age group
Adult

Lower age limit
15 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
4 groups, 10 patient in each group

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
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Study participating centre
Damascus University
High institute for Laser researches and applications
Faculty of mechanical and electrical engineering
Airport road
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

Sponsor details
Albaramkeh
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Sponsor type
University/education

Website
http://damasuniv.edu.sy/

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

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

Intention to publish date
30/12/2023

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