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Evaluating the effects of two different lip lift techniques on the relapse and nasal facial proportions

Submission date
19/03/2025

Recruitment status
No longer recruiting

Registration date
21/03/2025

Overall study status
Completed

Last Edited
21/03/2025

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
This study aims to compare two different techniques for lip lift surgery to see how they affect the appearance of the upper lip and nose. The goal is to improve the look of the upper lip by making it shorter and enhancing overall facial harmony.

Who can participate?
Adults aged 18 or older who have a long upper lip and have not had any previous lip-enhancing procedures, like fillers, can participate. Participants should be in good health and not have any conditions that affect wound healing.

What does the study involve?
Participants will undergo one of two types of lip lift surgery at Damascus University. Before-and-after photos will be taken before the surgery and six months after. Measurements will be made to analyze changes in lip length, nasal shape, and overall aesthetics. Participants will also complete surveys to share their satisfaction with the results.

What are the possible benefits and risks of participating?
Benefits:
Improved lip and facial aesthetics.
Evaluation of surgical outcomes.
Risks:
Swelling, bruising, scarring, and minor discomfort, which are common with any surgery.
Temporary numbness or tightness in the upper lip for some patients.

Where is the study run from?
The study is conducted at Damascus University, Oral and Maxillofacial Surgery Department (Syria)

When is the study starting and how long is it expected to run for?
March 2022 to April 2025.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Sleiman Zayoud, dr.sleiman.zayoud@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Comparison between the modified bullhorn lip lift and the endonasal technique on the nasal facial proportions and relapse: a randomized clinical trial (RCT)

Study objectives
1. There is no significant difference in the impact of Endonasal Lip Lift and Modified Upper Lip Lift on the nasal shape postoperatively
2. There is no significant difference in the skin relapse between the two mentioned techniques

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 27/04/2022, Biomedical Research Ethics Committee at Damascus University (Damascus University, Damascus, -, Syria; +963 1133923476; sdg@damascusuniversity.edu.sy), ref: DN-210125-390

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Enhancing the cosmetic proportions of the upper lip skin, vermillion, and teeth show during rest by reducing the upper lip skin length.

Interventions
Performing upper lip lift surgery using one of the two techniques: Modified Upper Lip Lift Technique described by Talei, et al, and Endonasal Lip Lift Technique Described by Raphael, et al.

The study includes: Preoperative assessment (clinical examination, photography, and measurements. Postoperative follow-up at 6 months (T2) to evaluate the following: Changes in lip and nasal measurements, relapse, patient satisfaction using PSQ questionnaire, and scar assessment using POSAS method.

The randomization process was conducted using Randomizer.org. Patients assigned number one were placed in the modified lip lift technique group, while those assigned number two underwent the endonasal lip lift procedure.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Skin Relapse in millimeters measured using a caliper at preoperative (T0), 6 months post surgery (T1)

Key secondary outcome(s))
Preoperative (T0), 6 months post surgery (T1):
1. Upper lip relationship with the E-Line
2. Nasal tip changes according to Powel
3. Nasal width (mm)
4. Nostrils width (mm)
5. Nasolabial angle
6. Upper lip projection
7. Patient satisfaction using PSQ questionnaire
8. Scar assessment using POSAS method

Direct measurements are taken using a caliper, while photographic measurements are analyzed using ImageJ software

Completion date
03/04/2025

Eligibility

Key inclusion criteria
1. Patients aged 18 years or older.
2. No prior lip augmentation procedures.
3. Nasolabial height to vermilion height ration grater than 3, classiftying them as lip type 2 or 3 according to Raphael and Harris.
4. No congenital syndromes or systemic diseases that could affect wound healing.
5. No bleeding disorders or anticoagulants.
6. No planned facial surgical interventions during the study period.
7. Commitment to regular follow ups.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
Female

Total final enrolment
12

Key exclusion criteria
1. Chronic diseases and infections.
2. Bleeding disorders or on anticoagulants.
3. Undergoing immunosuppressive therapy.
4. Patients undergoing orthodontic treatment.
5. Severe gummy smile.
6. History of lip augmentation procedure.
7. Patients scheduled for orthognathic surgery.
8. Lip type 1 according to Raphael and Harris (2014).
9. Pregnant, or breastfeeding women.

Date of first enrolment
16/05/2022

Date of final enrolment
03/10/2024

Locations

Countries of recruitment
Syria

Study participating centre
Oral and Maxillofacial Hospital
Faculty of Dentistry, Damascus University
Damascus
Syria
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date