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Surgical versus filler technique to increase lip volume

Submission date 13/09/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/09/2024	**Overall study status** Completed	
Last Edited 31/10/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
A full and prominent appearance of the upper lip is considered particularly attractive, and there is currently a significant trend towards achieving this look. Enhancing this appearance is one of the most common and increasingly demanded procedures in cosmetic surgery. To achieve this goal, surgeons have employed various techniques throughout the ages, including surgical and non-surgical approaches, which can be classified into temporary and permanent effects. the objective of the current study was to compare two different techniques for lip augmentation: a surgical technique (V-Y in V-Y) and a filler technique (autogenous micro-fat injections), with a focus on comparing the amount of change in the linear height of the upper lip, the amount of change in the nasolabial angle, and patient's satisfaction.

Who can participate?
Females aged 18 - 45 years old with thin upper lip

What does the study involve?
Participants will be randomly divided into two groups to be treated with a surgical technique (V-Y in V-Y) and a filler technique (autogenous micro-fat injections).

What are the possible benefits and risks of participating?
The anticipated benefits of this study include improving the aesthetic appearance of women with a thin upper lip. The potential risks involve asymmetrical enlargement of the upper lip; however, these risks can be managed subsequently through various corrective measures.

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

When is the study starting and how long is it expected to run for?
November 2021 to July 2023

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UDDS-585/22042021/SRC-574

Study information

Scientific Title
Evaluation of Two Methods for Upper Lip Augmentation: V-Y in V-Y Technique Compared to Autogenous Micro-fat Injection: A Randomized Clinical Study

Study objectives
This study was designed to test the hypothesis that the surgical technique using V-Y in V-Y may outperform the micro-fat injection filler technique in upper lip augmentation, in terms of the changes in the linear height of the upper lip, changes in the nasolabial angle, stability of lip dimensions, and patient satisfaction, over a follow-up period of 6 months.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/11/2021, Damascus University (Almazzeh ST, Damascus, 20872, Syria; +963 90404840; president@damasuniv.edu.sy), ref: 574

Study design
Single-center parallel designed interventional single-blinded randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Thin upper lip with the linear height ratio of the upper to lower lip is 1:2.

Interventions
Forty female healthy patients aged between 18-45 years will be randomly divided into two groups using http://www.randomization.com:
Group A: Upper lip augmentation using the V-Y in V-Y surgical technique.
Group B : Upper lip augmentation using autogenous micro-fat injection filler technique.
Augmentation using the V-Y in V-Y technique group:
Patients are prepared by rinsing with 0.12% chlorhexidine for one minute. The external skin around the mouth is sterilized using povidone-iodine, and surgical drapes are applied. The procedure is performed on the mucosal surface of the upper lip. Before administering

anesthesia, to avoid distortion from anesthetic fluid infiltration, the upper lip is divided externally into three equal sections, maintaining a 4-5 mm distance from the commissures on both sides. The incision sites are marked using methylene blue.
An infraorbital nerve block is administered bilaterally with 2% lidocaine containing 1:80,000 epinephrine, followed by local infiltration at the incision sites beneath the mucosa to minimize bleeding. The work is focused on the mucosal surface of the upper lip. The first incision is made in a large V-shape, starting at the wet-dry junction and covering most of the upper lip, with its apex at the frenulum. The second incision, a smaller V-shape, also starts at the wet-dry junction and involves the middle third of the lip, with its arms parallel to the larger V. The incisions are carefully and symmetrically marked to ensure optimal, even results.
With the "V in V" positioning, two separate flaps are created: the first is a bipedicled flap supported by the lateral portions of the lip, while the second is a smaller unipedicled flap supported by the middle third of the lip. The incisions are made through the mucosal and submucosal layers, extending down to the muscular layer without involving it, using an 11-blade scalpel. During the large V incision, the frenulum of the lip is transected.

The flaps are dissected from the orbicularis oris muscle, with the dissection plane extending slightly above the wet-dry junction of the lip. After hemostasis is achieved, each incision is closed in a Y-shape rather than the original V. The large incision is approximated at its apex with simple interrupted sutures, followed by the same technique for the small incision, ensuring equal numbers of sutures and spacing. This creates the lower limb (tail) of the Y. The remaining portions of the incisions are closed with continuous sutures using 4/0 nylon with a round-bodied needle.

Augmentation using autogenous micro-fat injection technique group:
The perioral area is disinfected with povidone, and anesthesia is administered using an infraorbital injection on each side with a local anesthetic (2% lidocaine with 1:80,000 epinephrine). A 16-gauge needle is used to puncture the lip, 3-4 mm away from the corner of the mouth, followed by the insertion of an 18-gauge blunt-tip injection cannula with a side port.

The injection is performed using a combination of the retrograde linear technique and serial puncture technique, with approximately 1 cc of fat injected into the lip. The fat is then massaged to ensure symmetrical distribution, and post-procedure instructions are provided. Occasionally, the needle may clog with fat, making the injection difficult. This issue is resolved by passing the fat through the needle into an empty syringe, after which the injection process becomes smoother with more consistent fat application.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. The amount of change in the linear height of the upper lip (apparent) which is estimated based on the following axes:
Axis (1): A reference line at the base of the nose.
A. The distance between the commissures Ch-Ch' (denoted as 2).
B. The linear height of the white upper lip in the middle Sn-Bc (denoted as 3).
C. The linear height of the red upper lip in the middle sto-Bc (denoted as 4).
D. The linear height of the lateral white upper lip from point Tc to the lower edge of the nasal base, parallel to axis 3 (denoted as 5).
E. The linear height of the lateral red upper lip from point Tc, parallel to the line sto-Bc, extending to the oral commissure (denoted as 6).

F. The linear height of the lateral white upper lip on the corresponding side of axis 5 (denoted as 5').
G. The linear height of the lateral red upper lip on the corresponding side of axis 6 (denoted as 6').
2. The amount of change in the nasolabial angle using lateral photographs analysis

This outcomes were assessed by a blinded committee that was unaware of the specific surgical procedure performed. This assessment was conducted one month and six months after the procedure.

Secondary outcome measures
Patient satisfaction is evaluated and compared between the two groups at two time points: one month and six months after the procedure. A Visual Analog Scale (VAS) was used for this purpose. The VAS consists of a horizontal 10 cm line with descriptors at each end representing the extremes of satisfaction (i.e., complete dissatisfaction and extreme satisfaction). Patients indicate their level of satisfaction by marking this line. Measurements were converted into a score ranging from 0 to 10 points. The primary question was: "How satisfied are you with the technique applied to you?". The question was posed by a blinded committee that was unaware of the specific surgical procedure performed. This assessment was conducted both one month, three months, and six months after the procedure.

Overall study start date
08/11/2021

Completion date
01/07/2023

Eligibility

Key inclusion criteria
1. Healthy individuals with the linear height ratio of the upper to lower lip is 1:2
2. Lip fullness grade of 0 to 2 according to the Merz scale

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. Patient had undergone lip augmentation procedures before or during the study period
2. Patient had undergone orthodontic treatment that was not yet completed
3. Patient scheduled for facial surgery during the study period that could impact the final lip augmentation results were excluded

Date of first enrolment
07/01/2022

Date of final enrolment
01/07/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University, Faculty of Dentistry, Department of Oral and Maxillofacial Surgery
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Funder(s)

Funder type
Not defined

Funder Name
Damascus University

Results and Publications

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

Intention to publish date
15/09/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication