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Treatment outcomes of two surgical techniques in secondary reconstruction of unilateral cleft lip and ala nasi

Submission date
05/11/2024

Recruitment status
No longer recruiting

Registration date
06/11/2024

Overall study status
Completed

Last Edited
07/01/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
The study aimed to evaluate utilizing Pfeifer's wave-line incision method and the rotational flap method in the secondary reconstruction of unilateral lip clefts in patients with unilateral cleft lip and ala nasi aged 5-25 years utilizing anthropometry assessment. Although surgeons try to achieve optimal results in primary lip reconstruction in patients with cleft lip and palate, many cases require secondary reconstruction to improve the functional and aesthetic outcomes. The secondary reconstruction is a more complex procedure due to tissue deficiency and scarring resulting from complications in wound healing and lack of surgeon experience.

Who can participate?
1. Patients have unilateral cleft lip with/or without cleft palate.
2. Patients aged 5-25 years.
3. Patients have previously undergone primary reconstruction of unilateral cleft lip.
4. Patients have a non-aesthetic scar.
5. Patients have a deficiency in the length of the upper lip.
6. Patients have a defect in the vermilion mucosal layer of the lip.

What does the study involve?
The philtrum was marked utilizing a metal wire and measured from the oral commissure on the unaffected side up to the peak of Cupid's bow on the same side. The metal wire was placed on the affected side to mark the virtual peak of Cupid's bow on the affected side. To determine the number and shape of the waves, the distance (2-4) was measured using an adaptable wire, then it was adjusted in the form of waves between the two points (3-5) and (3' 5'), and the last wave went towards the vermilion at a right angle, and the waves intersect at the nostril. Local anesthetic 2% lidocaine with epinephrine 1:80,000 solution (2% Lidocaine HCL Injection, Huons Co., Ltd, Seongnam) was injected. The incision was made with a Surgical Scalpel Blade No.11. (No. 11, Swann-Morton® Ltd., Sheffield, England), reaching the muscle layer to remove the scar. The muscles were released to 4-6 mm under the skin, and several transverse incisions were performed. Suturing was initiated with a stitch guide on the vermilion and pulled down to evaluate the position of the waves. The oral mucosa was sutured from the nose towards the red

lip, then the orbicularis oris muscle from the vermilion towards the nose with 4-0 Vicryl suture, then suturing subcutaneous layer with 5-0 Vicryl suture (Vicryl suture 5-0, V391H, FS-2 needle, 45 cm purple, Ethicon Inc., New Jersey, United States), and the skin with 5-0 nylon suture (Ethilon suture 5-0, 698H, P-3 needle, 45 cm black, Ethicon Inc., New Jersey, United States).

What are the possible benefits and risks of participating?
- Benefits: Participants will receive a secondary reconstruction of unilateral cleft lip and ala nasi.
- Risks: There is a risk of the aesthetic outcomes.

Where is the study run from?
The study is conducted at Damascus University in Syria.

When is the study starting and how long is it expected to run for?
August 2022 to March 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr. Mawia Karkoutly, mawia95.karkoutly@damascusuniversity.edu.sy

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
Nil known

Study information

Scientific Title
Treatment outcomes of two surgical techniques in secondary reconstruction of unilateral cleft lip and ala nasi utilizing anthropometry assessment: a randomized controlled trial

Study objectives
The null hypothesis is that Pfeifer's wave-line incision method would not outperform the rotational flap method in enhancing the facial anthropometry measurements in the secondary reconstruction of unilateral lip clefts in patients with unilateral cleft lip and ala nasi aged 5-25 years.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/08/2022, The Biomedical Research Ethics Committee (BMREC) of Damascus University (Mezzeh highway, Damascus, -, Syria; +963 (11) 33923223; dean.dent@damascusuniversity.edu.sy), ref: N4070

Study design
Double-blinded randomized parallel-group active-controlled trial with two arms

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Unilateral cleft lip and ala nasi

Interventions
All participants underwent clinical and laboratory examinations. Photographs were taken according to the Frankfurt horizontal plane. Individuals referred to the Oral and Maxillofacial Surgery Hospital underwent an assessment for eligibility. Out of 31 patients, 24 patients were randomly divided into two groups:
• Group 1: Rotational flap method (n = 12).
• Group 2: Control group, Pfeifer's wave-line incision method (n = 12).

Group 1
The surgical incision was made on the edges of the scar after marking the incision with methylene blue (Terry's Polychrome Methylene Blue 2% Aqueous, Polysciences Inc., Warrington, United States). The scar was then removed. The incision was bound to the muscles and the mucous membrane, after which the nasal labial muscles were dissected from the skin and mucous membrane, resulting in two muscle sections, a middle section, and a lateral section. The median part was divided into two muscle flaps, the first containing the depressor septi nasi muscle and the second containing the orbicularis oris muscle, and the lateral part into two muscle flaps, the first containing the levator labii superioris alaeque nasi muscle and the second containing the orbicularis oris muscle. Four muscle flaps were obtained. The muscle flap containing the levator labii superioris alaeque nasi muscle was sutured to the periosteum of the anterior nasal spine. The depressor septi nasi muscle flap was used to cover the previous flap and was sutured superficially. The lateral part of the orbicularis oris muscle was sutured to the periosteum of the anterior nasal spine and the levator labii superioris alaeque nasi muscle. Then, the free edges of the two orbicularis oris muscle flaps were sutured with a horizontal mattress suture to form the philtrum with a 4-0 Vicryl suture (Vicryl suture 4-0, V304H, RB-1 needle, 70 cm purple, Ethicon Inc., New Jersey, United States).
The following landmarks were considered:
(1): The center of the upper lip at the vermilion border.
(2): The peak of Cupid’s bow on the unaffected side.
(3): The virtual peak of Cupid's bow on the affected side, which is a distance from point (1) equal to the distance between points (1) and (2).
(4): A point on the nasal floor distal to the columella base by 2 mm on the unaffected side.
(5): A point on the nasal floor located 2 mm distal to the columella base on the affected side.
(6): The oral commissure on the unaffected side.
(7): The oral commissure on the affected side.
(3'): A point on Cupid's bow and the scar corresponding to the end (3) at a distance from (7) equal to the distance (2) from (6).
(5'): A point opposite to point (5), which is the same distance from the base of the ala nasi as point (4), is from ala nasi on the unaffected side.

Group 2
The philtrum was marked utilizing a metal wire and measured from the oral commissure on the unaffected side up to the peak of Cupid's bow on the same side. The metal wire was placed on the affected side to mark the virtual peak of Cupid's bow on the affected side. To determine the number and shape of the waves, the distance (2-4) was measured using an adaptable wire, then it was adjusted in the form of waves between the two points (3-5) and (3' 5'), and the last wave went towards the vermilion at a right angle, and the waves intersect at the nostril. Local anesthetic 2% lidocaine with epinephrine 1:80,000 solution (2% Lidocaine HCL Injection, Huons Co., Ltd, Seongnam) was injected. The incision was made with a Surgical Scalpel Blade No.11. (No. 11, Swann-Morton® Ltd., Sheffield, England), reaching the muscle layer to remove the scar. The muscles were released to 4-6 mm under the skin, and several transverse incisions were performed. Suturing was initiated with a stitch guide on the vermilion and pulled down to evaluate the position of the waves. The oral mucosa was sutured from the nose towards the red lip, then the orbicularis oris muscle from the vermilion towards the nose with 4-0 Vicryl suture, then suturing subcutaneous layer with 5-0 Vicryl suture (Vicryl suture 5-0, V391H, FS-2 needle, 45 cm purple, Ethicon Inc., New Jersey, United States), and the skin with 5-0 nylon suture (Ethilon suture 5-0, 698H, P-3 needle, 45 cm black, Ethicon Inc., New Jersey, United States).

Intervention Type
Procedure/Surgery

Primary outcome measure
The following anthropometric measurements were considered utilizing AutoCAD software (Autodesk AutoCAD 2012, Autodesk Inc., San Francisco, United States) after the surgery:
1. Lb(X):En-En: The horizontal position of the center of the cupid's bow.
2. Ch-Lt(l:r): The distance between the cheilion and the tip of the cupid’s bow.
3. Lt-Lb(l:r): The length of the cupid’s bow.
4. Lt(Y)(l:r): The length of the upper lip.
5. Lt-Lt'(l:r): The height of the vermilion at the tip of the cupid's bow.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/08/2022

Completion date
25/03/2024

Eligibility

Key inclusion criteria
1. Patients have unilateral cleft lip with/or without cleft palate.
2. Patients aged 5-25 years.
3. Patients have previously undergone primary reconstruction of unilateral cleft lip.
4. Patients have a non-aesthetic scar.
5. Patients have a deficiency in the length of the upper lip.
6. Patients have a defect in the vermilion mucosal layer of the lip.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
5 Years

Upper age limit
25 Years

Sex
Both

Target number of participants
24

Total final enrolment
24

Key exclusion criteria

1. Patients who have any systemic condition are contraindications for surgery and general anesthesia.
2. Patients have undergone corrective scar treatment.

Date of first enrolment
25/08/2022

Date of final enrolment
02/09/2024

Locations

Countries of recruitment
Syria

Study participating centre
Oral and Maxillofacial Surgery Hospital, Faculty of Dentistry, Damascus University, Syria
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Nill

Sponsor information

Organisation
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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 peer-reviewed journal

Intention to publish date
01/02/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Mawia Karkoutly, Mawiamaherkarkoutly@hotmail.com. The type of data that will be shared includes anonymised demographic information that will be available after publication. Consent from participants was required and obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			06/11/2024	No	No
Results article		02/01/2025	07/01/2025	Yes	No