

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

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<b>Registration date</b> 06/11/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/01/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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

### Contact name

Dr Mawia Karkoutly

### ORCID ID

<https://orcid.org/0000-0003-0227-1560>

### Contact details

Mazzeh highway

Damascus

Syria

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+963 (0)992 647 528

mawia95.karkoutly@damascusuniversity.edu.sy

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

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

## Study type(s)

Treatment

## 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(s)

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.

## Key secondary outcome(s)

There are no secondary outcome measures

**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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

5 years

**Upper age limit**

25 years

**Sex**

All

**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

Mazzeah highway

Damascus

Syria

Nil

## 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 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?
<a href="#">Results article</a>		02/01/2025	07/01/2025	Yes	No
<a href="#">Protocol file</a>			06/11/2024	No	No