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

INTRODUCTION

A cleft lip is a congenital abnormality that affects the orofacial region and manifests as a gap or fissure in the upper lip. It is considered one of the most common congenital abnormalities. Out of every 700 natural births, one newborn has an orofacial cleft. An orofacial cleft significantly impacts the oral health-related quality of life, functional well-being, and social-emotional well-being in children and teenagers.

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. Oral and maxillofacial surgery is moving towards a new era. However, to date, secondary reconstruction has not been eliminated. Choosing the optimal surgical technique and reconstruction time is one of the challenges facing the surgeon, given that the patient undergoes many surgical procedures in the early stage of life. The appropriate technique aims to obtain optimal results and reduce the number of interventions. Short lip length, lack of thickness, and lip distortion, especially the vermilion mucosal layer, are the challenges facing surgeons during secondary reconstruction.

A rotation flap is a curved flap of skin and underlying tissue that pivots around a specific point to fill a defect. Each nasal sidewall provides rotation flaps that can be used to cover the defect by rotating them towards the midline. If the defect is not centrally located, this flap may distort the symmetry of the nose. In 1970, Pfeifer introduced the wave-line incision method. The Pfeifer's incision is short, curved waves that are then brought together in a straight line, aiding in the expansion of the tissue's length and width. The dimensions of the cleft vary between individuals, which leads to variation and differences in the surgical procedure. The wave-line incision method allows for various modifications in the shape of the surgical incision to suit the variety of clefts of the lip. Therefore, surgical techniques aim to increase the lip length and thickness and to reduce the scar size. 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. The null hypothesis is that Pfeifer's wave-line incision method would not outperform the rotational flap method in enhancing the facial anthropometry measurements. To the authors' knowledge, no study has ever compared the previous two surgical methods in the secondary reconstruction of unilateral lip clefts in patients with unilateral cleft lip and ala nasi. Such trials provide surgical techniques for enhancing aesthetic and functional treatment outcomes, improving the oral health-related quality of life of unilateral cleft lip and ala nasi patients.

MATERIALS AND METHODS

Study design and ethical considerations

It was a double-blinded, randomized, parallel-group, active-controlled trial with two arms. The study took place at the Oral and Maxillofacial Surgery Hospital, Faculty of Dentistry, Damascus University, Syria, from August 2022 to March 2024. Informed consent was obtained from the participant or the participant's legal guardian under eighteen years old, and the participant's anonymity was preserved. The research was conducted in strict compliance with the CONSORT guidelines and the World Medical Association Declaration of Helsinki concerning experiments with human subjects, as updated in 2013. Approval for the study was granted by the Ethics Committee of Damascus University (N4070).

Sample size calculation

The sample size was calculated utilizing G*Power version 3.1.9.4 (Heinrich Hein Universität Düsseldorf, Germany). A sample size of 24 patients achieved an effect size d of (1.19), 80% power (1 − β error probability), and a significance level (α error probability) of 0.05. The effect size was estimated based on a pilot study for four samples.

Eligibility criteria and grouping

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.

Exclusion criteria

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

Randomization and blinding

Participants were randomly divided into two groups utilizing a simple randomization method by flipping a coin. This was a double-blind trial where both participants and outcome assessors were kept unaware of group assignments and the study's purpose. However, blinding the surgeon was not feasible.

Grouping and intervention

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) (Figure 1).

The following landmarks were considered (Figure 2):

(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) (Figure 3).

Outcome measure and follow-ups

The following anthropometric measurements were considered utilizing AutoCAD software (Autodesk AutoCAD 2012, Autodesk Inc., San Francisco, United States) (Table 1 and Figure 4):

- Lb(X):En-En: The horizontal position of the center of the cupid's bow.
- Ch-Lt(l:r): The distance between the cheilion and the tip of the cupid's bow.
- Lt-Lb(l:r): The length of the cupid's bow.
- Lt(Y)(l:r): The length of the upper lip.
- Lt-Lt'(l:r): The height of the vermilion at the tip of the cupid's bow.

The interpretation of anthropometric measurement values is presented in Table 2. Photographs were performed at successive intervals according to the follow-up periods:

- At the baseline, before surgery (t_0).
- Immediately after surgery (t_1).
- Two weeks after surgery (t_2).
- Six months after surgery (t_3).

Statistical analysis

Data analysis was conducted using IBM SPSS software version 24 (IBM SPSS Statistics® version 24, IBM Corp., New York, USA). Participants' characteristics were summarized with descriptive statistics, shown as frequency, percentage, mean, and standard deviation (SD). The anthropometric measurements were also presented using descriptive statistics, including mean, SD, minimum (Min), and maximum (Max). The Kolmogorov–Smirnov test was used to assess the normality of the data. An Independent sample t-test was utilized to compare unpaired data, while a paired sample t-test was used for paired data. The significance level was set at 0.05 ($p < 0.05$).