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COMPARISON OF ROTATION-ADVANCEMENT AND STRAIGHT-LINE METHODS FOR REPAIRING OF UNILATERAL CLEFT LIP (A RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

INTRODUCTION: A cleft is a universal and non-standardized defect. To overcome stigmatization; cleft repair is essential to normalize the facial appearance. Thus, different surgical techniques and modifications have been developed. These techniques are based on three surgical approaches: The straight-line (Rose-Thompson), rotation-advancement (upper lip Z-plasty), and the triangular flap (lower lip Z-plasty).

OBJECTIVES: Comparing the effectiveness of rotation-advancement approach to the straight-line approach in repairing unilateral cleft lip.

METHODOLOGY: A prospective control clinical trial of twelve patients with unilateral cleft lip (aged between 1- and 24 months) was conducted. These patients were randomly selected and equally divided into two groups of 6 participants, each group was operated on with Millard or Fisher incisions. Caliper measurements of the lip and nose were recorded preoperatively. The analysis was based on a quantitative and qualitative comparison of the cleft side versus the non-cleft side for 3 outcomes (the constructed philtral ridge, the degree of labial scar, and degree of nasal symmetry) which were all used to assess the aesthetic difference between the two incisions. These outcomes were measured postoperatively at 6 months. Both Chi-square and Mann Whitney tests were used for statistical comparison of outcomes.

RESULTS: The nasal asymmetry improved in both groups with a better result in cases operated on with Fisher; which was statistically significant at (2.201* (0.028*). Medial lip height was increased in both groups with no statistical significance. The difference was statistically significant for the increase of lateral lip height of both groups at a P-value of <0.05.

CONCLUSION: Nasolabial appearance in both incisions was satisfactory. Lip dimensions were improved in both groups. Due to the ''BACK CUT'' use; the lateral lip height was better with the Millard. Meanwhile, the nasal symmetry showed better results with the Fisher due to the definite preoperative measurements. Therefore, neither Fisher nor Millard incision was predominantly better than the other.

KEYWORDS: Cleft lip, Straight-line, Rotation-advancement, Clinical trial, Fisher, Millard.

RUNNING TITLE: Methods for repairing unilateral cleft lip.

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INTRODUCTION

A cleft is an abnormal vertical gap or crack in normally closed anatomical structures. It is usually noted at birth, and follows the path of the normal embryological suture lines. As a result of this suture course, clefts vary in type and severity [(1)]. Clefts do not occur within the course of the main blood vessel nor cause an absence of the main vessel or nerve [(2,3)].

Cleft lips are arising in 1 in 500 to 1,000 live births. If a cleft child is born, the risk for the second child is 4%. However, the risk for the second child has increased to 15.3% if a mother and child have a cleft [(1)]. The unilateral cleft lip is more common in males with high prevalence on the left side [(4)].

The cleft lip can be unilateral or bilateral. It can also be complete or incomplete according to the anatomical involvement level. Moreover, clefts may occur as an isolated defect or as a part of a congenital syndrome. The orofacial clefts (OFC) are a multifactorial inheritance condition with both genetic and environmental inputs [(5)]. The genetic factors are a sequence mutation of specific genes e.g. (TGFa, MSX1, IRF6, TBX22, RAR), or gene to gene interaction e.g. (MSX1 and TGFB) [(6-8)]. Meanwhile, the environmental factors include maternal use of certain medications, nutrient deficiency, viral infections, maternal smoking, alcohol intake and toxins, maternal obesity, increased parent's age more than 40 years, and the low socioeconomic status [(9, 10)]. Physical interference can also cause a cleft as a result of blood disruption to the affected

part, these physical interferences include fetal positioning or crowding, micrognathia, and amniotic bands [3, 11, 12].
Unilateral cleft lip occurs because of the failure in the fusion between the medial nasal process and the maxillary process on one side [7, 13]. It can result from hypoplastic and displaced tissues in the orofacial region [14]. The continuity and normal insertion of the orbicularis oris in the midline is distorted by the cleft [15], where the pars superficialis run vertically along cleft margins, and become attached to the lateral side of the alar base and nasolabial fold, causing nasal deformity [8], and creating a lateral bulge, in addition to a step-off between the cleft segments [10,16,17]. Aesthetics are the initial step and a potent factor in the formation and integration in the social life. Hence, to improve possible aesthetic outcomes; many surgical methods have been developed and modified by the surgeons [7].

The Rotation-Advancement technique has been introduced by Dr. D. Ralph Millard, Jr. in Korea (1958) as an incision with two side flaps; rotation flap on medial lip element and advancement flap on lateral lip element. Millard incision was considered as the most commonly used technique by cleft surgeons because of its versatility with the different types of clefts. However, a transverse scar has been developed with this technique as a side effect [18].

An Anatomical Subunit Approximation Technique is a new surgical technique introduced by DR. David M. Fisher in Canada (2005), it's based on previously mentioned techniques (Rose-Thompson and Noordhoff's flap) [7,19]. Fisher's outcomes are prospective due to the precise surgical landmarks and measurements, in addition to the more anatomical position of the scar.

The aim of this study is to compare between Millard and Fisher's techniques for unilateral cleft lip repair. The null hypothesis states that there is no significant difference between Rotation-advancement (Millard) and straight-line (Fisher) for unilateral cleft lip repair.

MATERIAL AND METHODS

Study design: Ethical approval was granted by the Ethics Committee in the Faculty of Dentistry, Alexandria University. The study is following the CONSORT guidelines (A randomized control clinical trial) and written informed consents have been obtained from the patient's parents and all patients whose photographs were included in this study.

Source of data: Patients who presented to the Oral and Maxillofacial Department, Faculty of Dentistry, Alexandria University participated in this study. All the patients were in the age group of 1-24 months with unilateral cleft lips.

Method of collection: Twelve children with unilateral cleft lip (age between 1-24 months) were randomly selected and equally divided into two groups: The control group (n=6) were operated on with Millard's incision, and the test group (n=6) were operated on with Fisher's incision. Before the surgical repair of the cleft, the study protocol (surgical, postoperative care, and possible complications) was explained to each participant in detail. All the patients were treated by the same surgical team under general anesthesia.

Method of randomization: Random allocation using an online randomizer (www.random.org)

Simple size calculation

A minimal total hypothesized sample size of twelve children (six per group) is required to detect the average proportional difference in cleft repair using Millard and Fisher techniques. By using the chi-square- test, the confidence level was 95% and the power of the study was 80%. (PASS program version 20).

Inclusion criteria

Have a unilateral cleft lip.

Child (age from birth to 4 years).

Exclusion criteria

Syndromic cleft.

Pre-surgical assessment and examination

All patients were subjected to a medical consultation to confirm that the child is medically fit to undergo the surgery. Investigations including: blood tests (CBC), bilirubin (direct, indirect, total), and coagulation profile were all performed, in addition to the photographic documentation.

Pre-surgical preparation

All patients were fasting for at least 6-8 hours before the surgery. The anthropometric measurements of the study (nasal width, cleft nostril width, non-cleft nostril width, lip width, medial lip height, lateral lip height, and central lip height) in millimeters were collected preoperatively on patients directly, and postoperatively indirectly on the 2D photograph after 6 months of the surgery (Figure.1).

Surgical phase

After General anesthesia induction and conformed central oral endotracheal tube fixed on the chin, all the patients went through the same surgical steps. The patient was placed in the supine position with a slightly extended neck using a small head roll to prevent head movement. The face is then prepared using betadine solution and draped, the patient's eyes were closed and a thin coat of Vaseline was applied, then protected and covered with clear sterile surgical adhesive tapes. Methylene blue tattooing and 30-gauge needle were used to outline the flap design as a preliminary step. A superior labial artery pressure was applied to decrease the bleeding during the incision. A surgical blade No. (15) on scalpel No. (3) were used to open the flap. The surgical flap performed was either according to Millard's outline in group I (control group), or Fisher's outline in group II (test group).

Group I (Millard group(n=6))

Surgical marking and measurements [8,14,15,20,21]

Are shown in (Figure.2)

Flap Measurements and calculations

These measurements are used to enhance the cupid's bow and nasal symmetry:

Points [2-1] = [3-1] =2-4mm.

Points [2-4] = [5-6] = 20mm.

Points [2-7] = [6-8] = 9-11mm.

Distance between points [11-3] + distance of back-cut needed (length of rotation flap) = distance between points [6-9] (length of advancement flap) = 8-9mm [15,22].

Millard's design is based on the idea of "cut as -you- go" and is not based on precise measurements, these

measurements are used as a guide with the arbitrary judgment for the newly trained surgeon [23,24].

Surgical Incisions

Marking rotation flap (A) is 1st; which extends from point 3 (peak of cleft cupid's bow) to lip-columellar base as far as non-cleft philtral column but not crossing to another side.

Advancement flap (B) starts from Noordhoff's point to mid-point at the nasal sill and extends to include circumalar incision (flap D); which depends on the amount of rotation needed to make both sides symmetrical.

C-flap is a bonded flap between the incision marks of the rotation flap and cleft margin (could include Simonart's band in incomplete cases) [5,25].

Group II (Fisher group)

Surgical marking and measurements

Are shown in (Figure.3)

Surgical incision

Lines between points [3-8] and between [2-7] should mirror each other.

The straight line between [8,6,12] is drawn perpendicular to the free lip margin.

The length between [19,21] is equal to the length between [3,16] and represents third lip height.

The length between [21-20] is equal to the length between [3,8].

Line's length between [18,22] and [20,22] should be equal to the length between [8,9].

After drawing anatomical landmarks on medial and lateral lip elements, the surgical incision design will connect these landmarks to create a Fisher flap.

Flap Measurements and calculations [7,19,26]

Distance between points [2,7] represents total lip height at rest.

Distance between points [3,8] represents greater lip height with little downward lip traction a Fisher design.

Lesser lip height= total lip height - great lip height - 1mm.

Lesser lip height is commonly (1 to 1.5mm) and never pass 2mm.

Lesser lip = Base width of the small inferior triangle.

Then both incisions continue with the same steps as the soft tissue dissection (layer dissection) by using a surgical blade and scissors to free muscle layers from skin and mucosa. The orbicularis oris muscle is freed from its abnormal insertion. Skin dissection from muscle on medial lip element should not cross the philtral column to preserve philtral dimple, in contrast to lateral lip element which should be extensive and extending to the alar base to free muscle bulge. The marginal tissue of the cleft is removed and discarded by blade No.11 or surgical scissors. Evaluation of tissue tension is performed by approximating the flap edges before final lip closure. Primary wound closure performed in layering technique; muscle layer closed using horizontal matters technique with 5-0 vicryl suture, and then close the skin using simple interrupted technique and 6-0 prolene suture with non-cutting end needle. Adhesive tapes (Steri-Strips) were used to cover the surgical site.

Post-operative care and follow up

Antibiotic ointment (Fucidin cream) was prescribed for 10 days.

Instruction of no breast feeding for two weeks.

Scaro gel was prescribed for 3 months.

Postoperative Evaluation

Patients were recalled after 7-14 days postoperatively.

The suture was removed after 14 days.

Patients were recalled at 3 and 6 months for scar evaluation and photographic documentation.

Statistical analysis

The recorded data were entered into soft Excel (Microsoft Corp., Redmond, Wash.), then exported to IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) for statistical analysis.

The data were summarized by using: percent, range, mean, standard deviation, and median (IQR). Tests used to compare data between two groups were:

Chi-square test.

Mann Whitney test.

The test used to compare data in the same group was:

Wilcoxon signed ranks test.

Kolmogorov-Smirnov test was used to assess the normality of the continuous variables.

An alpha level was set to 5% with a significance level of 95%, and a beta error accepted up to 20% with a power of study of 80%.

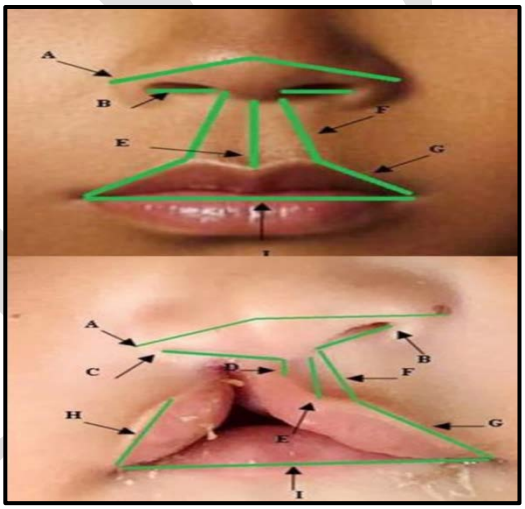

Fig. 1: Anthropometric measurements. A: Nasal width, B: Non-cleft nostril, C: Cleft nostril, D: Cleft philtral ridge, E: Center of the philtrum, F: Non-cleft philtral ridge, G: Medial lip height, H: Lateral lip height, I: Lip width.

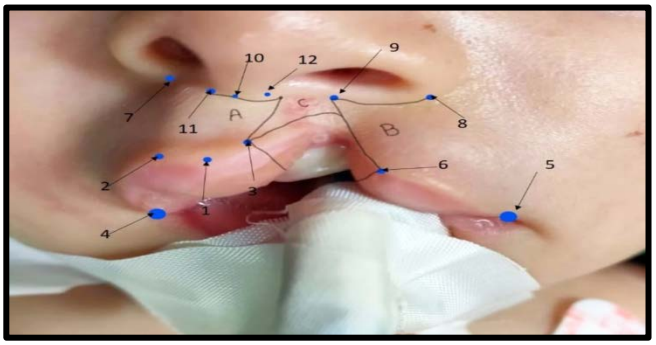

Fig. 2: 1: Midline point of cupid's bow; 2: Non-cleft Peak of Cupid's bow(lateral); 3: Cleft Peak of Cupid's bow (medial); 4: Commissure on the non-cleft side;5:

Commissure on the cleft side; 6:Noordhoff's point (Peak of Cupid's bow);7: Non -cleft Alar base (medial);8: Cleft alar base(lateral);9: Medial tip of advancement flap;10: Center of Columellar base;11: Non -cleft philtral column at the columnal-lip junction;12: Cleft philtral column at the columnal-lip junction.

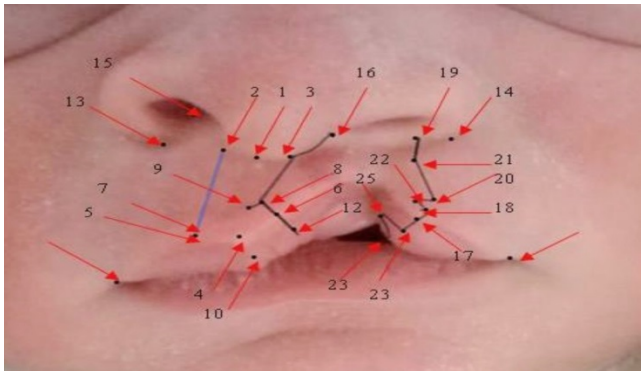

Fig. 3: Fisher landmarks: Medial lip element landmark: At lip-columellar crease (1) midline, (2) height of the non-cleft philtral column, (3) height of the cleft philtral column. At vermilion-cutaneous junction (4) lip midline, (5) non-cleft cupid's peak,(6) represents cleft cupid's peak; At the junction between white roll and flat lip area just above white roll (7,8); At the flat lip area; (9) is marked just above point (4); on vermilion, (10) is marked below point (4) At the lip-alar junction, (13,14) are alar bases. At nasal sill, (16) is marked and represent lip height at the site of closure. (16,15) are identical and on the nasal sill and they are arbitrary**. Lateral lip element landmark**: (17) is at Noordhoff's point; on the cutaneous roll (18) is marked just above point (17); (19) is superomedial to (14) and on the site of nasal sill closure. By using caliper; (20,21,22) are marked; as points (20,21) are equal to greater lip height, (22) placed to form a small inferior triangle with points (18,20). On the red line;(23) is marked just above point (17). On vermilion, 24 is marked between points (17,23); (25) is marked based line length between (5,11) minus line length between (6,12) and is equal to the amount of vertical lip height required during the repair.

RESULTS

Demographic data, side, and type of cleft: (Table 1) shows sample distribution details of demographic data, side, and type of cleft between the two groups of the side.

The nasal dimensions: (Total nasal width, cleft nostril width, non-cleft nostril width) (Table 2) shows a decrease in all nasal dimensions with statistical significance concerning cleft nostril width for the Fisher group as shown in Figure. (4-5).

The lip measurements: (Lip width, medial lip height, lateral lip height, central lip height) (Table 3) shows an increase in all lip dimensions with the exception of lip width; which is decreased as a result of cleft repair as shown in Figure. (4-6). Mann Whitney test showed a statistically significant increase in the lateral lip height by (0.046) for the Millard group, and by (0.028) for the Fisher group.

Fig. 4: Fisher Case. **A:** Preoperative, **B:** Anthropometric, **C:** Drawing flap design, **D:** Surgical incision by a blade, **E:** Surgical suturing, **F:** Surgical suturing with a nasal stent, **G, H, I:** Postoperative and follow up.

Fig. 5: Millard Case. **A:** Preoperative, **B:** Anthropometric, **C:** Drawing flap design, **D:** Surgical incision by a blade, **E:** Tissue tension test, **F:** Surgical suturing, **G:** Surgical suturing with a nasal stent, **H:** postoperative at 1 month, **I:** Postoperative at 6 months.

Fig 6: preoperative and postoperative clinical cases: A, B: Fisher incision. C, D: Millard incision

Table (1): Comparison between the two studied groups according to demographic data, side, and type of cleft.

	Millard Group (n = 6)		Fisher Group (n = 6)	
	No.	(%)	No.	(%)
Gander				
Male	3	(50.0)	4	(66.7)
Female	3	(50.0)	2	(33.3)
Mean ± SD.	4.0 ± 2.76		9.50 ± 7.71	
Cleft side				
Right	1	(16.7)	2	(33.3)
Left	5	(83.3)	4	(66.7)
Cleft type				
Complete	2	(33.3)	2	(33.3)
Complete with simonart's band	1	(16.7)	0	(0.0)
Complete +palate	0	(0.0)	2	(33.3)
Incomplete	3	(50.0)	2	(33.3)

Table (2): Comparison between the two studied groups according to the nose.

	Group I (n = 6)	Group II (n = 6)	U	p
Nasal width (mm)				
Pre-operation				
Min. – Max.	18.25 – 59.24	13.73 – 34.46	9.000	0.180
Mean ± SD.	32.90 ± 20.0	20.34 ± 7.75		
Median (IQR)	20.84 (20.1 – 58.1)	17.65 (14.8 – 23.7)		
Post-operation				
Min. – Max.	11.25 – 29.19	10.75 – 24.09	9.000	0.180
Mean ± SD.	22.0 ± 7.52	16.50 ± 5.28		
Median (IQR)	23.94 (15.5 – 28.2)	15.94 (12.3 – 20.0)		
Z (p_0)	1.363 (0.173)	1.572 (0.116)		
Decrease	**10.91 ± 16.43**	**3.84 ± 5.53**	12.000	0.394
Cleft nostril width (mm)				
Pre-operation				
Min. – Max.	5.21 – 16.06	3.22 – 12.18	10.0	0.240
Mean ± SD.	9.11 ± 4.48	6.34 ± 3.21		
Median (IQR)	7.05 (6.0 – 13.4)	6.05 (3.7 – 6.9)		
Post-operation				
Min. – Max.	3.11 – 9.32	1.92 – 6.85	11.0	0.310
Mean ± SD.	5.70 ± 2.27	4.13 ± 1.87		
Median (IQR)	5.35 (3.9 – 7.2)	4.02 (2.4 – 5.6)		
Z (p_0)	1.782 (0.075)	2.201* (0.028*)		
Decrease	**3.41 ± 3.52**	**2.21 ± 1.77**	14.0	0.589
Non-cleft nostril width (mm)				
Pre-operation				
Min. – Max.	3.66 – 10.38	2.68 – 6.56	4.0*	0.026*
Mean ± SD.	6.15 ± 3.0	3.69 ± 1.47		
Median (IQR)	4.62 (4.1 – 9.5)	3.28 (2.7 – 3.6)		
Post-operation				
Min. – Max.	2.51 – 5.05	1.53 – 5.32	17.0	0.937
Mean ± SD.	3.70 ± 0.87	3.55 ± 1.51		
Median (IQR)	3.83 (3.0 – 4.0)	3.62 (2.4 – 4.8)		
Z (p_0)	1.572 (0.116)	0.314 (0.753)		
Decrease	**2.44 ± 3.42**	**0.14 ± 1.33**	11.0	0.310

Table (3): Comparison between the two studied groups according to the lip.

	Group I (n = 6)	Group II (n = 6)	U	p
Lip width (mm)				
Pre-operation				
Min. – Max.	20.18 – 61.95	12.79 – 42.65	7.0	0.093
Mean ± SD.	34.36 ± 20.17	21.30 ± 10.88		
Median (IQR)	22.41 (20.6 – 58.7)	18.24 (15.2 – 20.7)		
Post-operation				
Min. – Max.	14.84 – 34.07	9.76 – 25.82	8.0	0.132
Mean ± SD.	24.68 ± 8.10	17.82 ± 7.08		
Median (IQR)	26.24 (15.5 – 31.2)	16.81 (12.3 – 25.4)		
Z (p_0)	1.363 (0.173)	0.943 (0.345)		
Decrease	**9.68 ± 14.86**	**3.48 ± 7.52**	12.0	0.394
Medial lip height (mm)				
Pre-operation				
Min. – Max.	5.28 – 18.58	3.92 – 9.39	9.0	0.180
Mean ± SD.	8.70 ± 5.14	6.08 ± 2.59		
Median (IQR)	6.30 (5.7 – 10.1)	4.80 (4.2 – 9.4)		
Post-operation				
Min. – Max.	3.30 – 17.99	3.98 – 6.62	9.0	0.180
Mean ± SD.	9.43 ± 5.33	5.43 ± 1.11		
Median (IQR)	8.49 (5.7 – 12.6)	5.57 (4.4 – 6.4)		
Z (p_0)	0.314 (0.753)	0.314 (0.753)		
Decrease	**-0.73 ± 5.14**	**0.65 ± 1.73**	15.0	0.699
Lateral lip height (mm)				
Pre-operation				
Min. – Max.	1.92 – 11.23	1.94 – 5.24	13.0	0.485
Mean ± SD.	4.53 ± 3.36	3.12 ± 1.18		
Median (IQR)	3.42 (3.1 – 4.1)	2.82 (2.4 – 3.5)		
Post-operation				
Min. – Max.	2.79 – 17.65	3.59 – 6.17	10.0	0.240
Mean ± SD.	8.97 ± 5.46	5.04 ± 1.05		
Median (IQR)	7.66 (5.3 – 12.7)	5.33 (3.9 – 5.9)		
Z (p_0)	1.992* (0.046*)	2.201* (0.028*)		
Increase	**4.43 ± 5.18**	**1.93 ± 0.94**	12.0	0.394
Central lip height (mm)				
Pre-operation				
Min. – Max.	3.09 – 14.06	3.01 – 7.09	11.0	0.310
Mean ± SD.	6.98 ± 3.99	4.71 ± 1.74		
Median (IQR)	5.21 (5.2 – 9.2)	3.98 (3.5 – 6.7)		
Post-operation				
Min. – Max.	3.42 – 17.68	3.50 – 6.33	7.0	0.093
Mean ± SD.	9.87 ± 5.67	4.85 ± 1.17		
Median (IQR)	7.99 (6.3 – 15.8)	4.62 (3.9 – 6.1)		
Z (p_0)	1.572 (0.116)	0.734 (0.463)		
Increase	**2.89 ± 3.72**	**0.13 ± 0.72**	6.0	0.065

DISCUSSION

A cleft lip is the most predominant facial congenital defect with a low morbidity and mortality rate. It has serious effects on the patient's appearance and functions (sucking, speech, breathing, etc.). Furthermore, it causes an effect on facial growth of the new-born [1,27].

Surgical repair of the oral cleft is fundamental to improve physiologic functions, aesthetics, and to establish social and psychological health in children with orofacial clefts. Nowadays, multidisciplinary teamwork is considered as a recent route in the treatment of orofacial clefts to improve therapeutic outcomes [7,9].

Over several years, many surgical techniques have been developed to normalized patient's aesthetics and functions. Despite cleft lip types (unilateral or bilateral cleft) and severity (mini\microform, incomplete/complete); different surgical techniques and modifications were developed to repair this defect. All of these techniques were based on 3 principal ideas: Straight-line, rotation-advancement, geometric [17]. There is a special concern about micro\mini-form unilateral cleft lip with little nasal asymmetry; where some surgeons preferred to use a double Z-plasty method to repair this type of cleft [14].

The primary goals of oral cleft treatment include: Closing of lip defect, reconstructing Orbicularis oris muscle with the establishment of muscle continuity,

reconstructing aesthetic lip components (e.g. median tubercle, cupid's bow, white roll, lip height vertical/ horizontal, vermillion volume beneath the cleft), creating a philtral ridge which mimics the non-cleft philtral ridge, developing the labial sulcus, correcting nasal asymmetry, closing the nasal floor, repositioning alar rim, elongating shorted columella, creating a Medline positioned columellar base, and finally improving psychosocial development [7,8].

The unrepaired or badly repaired orofacial cleft has serious social and psychological implications as it may cause social stigma and prevent the cleft-holder from good integration into society. Therefore, comparative studies about surgical techniques for cleft lip repair provide more evidence on advantages, disadvantages, and limitations of these techniques. Moreover, these researches suggest awareness and compare aesthetic outcomes of each technique [7].

Rotation- advancement method is the most commonly used technique by the cleft surgeon with very reproducible aesthetic results. Furthermore, it is an easy and uncomplicated method with minimal surgical landmarks and measurements [15,23]. Millard design is considered as a manageable technique (Cut as-you-go) with less tissue discarded, better nasal access, and the preservation of the philtral dimple and cupid's bow. This technique was investigated in many comparable studies, as most of the cleft surgeons use Millard's flap or one of its modifications as a standard to compare with [28,29].

Anatomical Subunit Approximation Technique (Fisher technique): It's a new technique developed by Dr. Fisher in 2005 as a modification of the straight-line method. Despite Fisher's successful clinical results; it's considered recent and wasn't involved in comparable research studies of unilateral cleft lip repair [19,30]. The Fisher's design divides the cleft into two anatomical separated units: nasal (nasal base, alar rim), and lip (white roll, vermillion and philtral ridge), with precise measurements and a larger number of possible equivalent dimensions of anatomical subunits pre- and intra-operatively. Therefore, Fisher's postoperative nasolabial results are predictive in almost all cases, as it creates a scar in a more anatomical position from the peak of the cupid's bow to the nasal base; hence hidden under the base of the columella and within the white roll. However, Fisher's design is considered as a time-consuming and a complex technique due to the use of 25 landmarks and the guided lip repair [7].

In the present study; A total of 12 cleft children (aged between 1 - 24 months) participated in the study. They were divided into two groups, and randomly assigned to these groups to minimize selection bias. The control group was operated on with the rotation-advancement (Millard) technique, and the test group was operated on with Anatomical Subunit Approximation (Fisher) technique by the same surgical team.

It was found that both surgical techniques improve the nasolabial appearance by decreasing the nasal dimensions (total nasal width, cleft nostril width, and non-cleft nostril width). The comparison between pre-operative and post-operative nasal cleft values in the same group showed a positive change in the values of nasal dimensions in both groups. The Fisher incision has shown a better statistical significance (Z (p_0) =2.201* (0.028*) compared to Millard incision in terms of cleft nostril width [13,31]. This difference was statistically significant at $P > 0.05$. In 2016, A prospective study by Kuna et al; compared the outcomes of Millard and Delaire functional method techniques and found that Millard incision has a better improvement of the lip length, whereas the Delaire method improved nasal symmetry [32]. In 2010; Reddy et al; compared and evaluated nasolabial outcomes (The white roll, vermilion border, scar, Cupid's bow, lip length, nostril symmetry, and appearance of the alar dome and nasal base) between a rotation-advancement repair, Pfeifer wave line incision, and Afroze incision on 1200 patients [22,33]; where they found that the labial improvement was better with Millard, whereas nasal symmetry was better with Pfeifer incision, and better labial and nasal results with Afroze incision (companion of Millard and Pfeifer) as it improves nasal symmetry, white roll approximation, vermilion repair, scar quality, lip length, and Cupid's bow symmetry by using Millard on medial lip side and Pfeifer on lateral lip side. Besides, both Millard and Fisher are statistically significant in the increase and improvement of the lateral lip height with better results with Millard technique. Clinically, the lateral lip lengthening of the cleft side was better achieved by Millard's incision because of the use of ''BACK CUT'' which helps in more rotation of flap and overcome vertical lip shortness [32]. In 2017; Mbuyi-Musanzayi et al; evaluated the surgical outcomes of 101 cases using the Fisher technique, the study showed that it increases the length of the medial and lateral lips with a fair scar [34]. In 2007, Funayama et al; changed their cleft treatment protocol to use the Fisher technique instead of Millard, a scar improvement was found with the Fisher technique [13].

Our statistical analysis for the surgical outcomes supports the results of previous studies which reported improvement of nasolabial appearance with both incisions, with a better scar and nasal symmetry with Fisher's in comparison to Millard's.

The Millard technique has better lip continuity, it is easy for clinical use and can be modified (cut-as you-go) according to: The clinical case presentation, type of the cleft, and surgeon experience [23]. According to literature, Millard technique can be used in each cleft type with excellent results in micro-form and incomplete cleft [34]. Millard's method increases lateral lip length and achieves white roll continuity with improvement in vermillion height if "BACK CUT" is used. Nasal asymmetry with Millard in severe complete cleft showed improvement, however a secondary rhinoplasty was needed [32,33]. The Fisher technique is based on precise measurements and equivalent dimensions of anatomical subunits preoperatively and intra operatively. For this reason, Fisher's postoperative nasolabial results are predictive in almost all cases [30,31]. The nasal dimensions (total nasal width, cleft nostril width, non-cleft nostril width) are improved with the Fisher method because it improves alar rim position and nostril width. Furthermore, it increases

lateral lip height to produce an acceptable scar in an anatomical mirror to non-cleft philtral ridge [13].

LIMITATIONS

The small sample size of our study (n=12) limits the power of statistical analysis tests, and postoperative photographs were not standardized (different time and angulation); which may cause bias in the evaluation of outcomes especially the nasal form and scar quality in each patient.

CONCLUSION

The overall clinical appearance of the nasolabial region (white roll, vermilion height, cupid's bow symmetry, philtral ridge, nasal width, and alar rim position) in case of both incisions (Millard and Fisher) was satisfactory. There was lateral and medial Lip length improvement in both groups. Lateral lip length was better in the case of Millard because of ''BACK CUT'' use. Both incisions improved nasal symmetry with better outcomes in the case of the Fisher technique as it is based on definite preoperative measurements. Thus, we found that Fisher's technique was essentially as good as the Millard's technique.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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REGISTRATION

This randomized controlled clinical trial was registered at a clinical trial. Gov under the number NCT04607213 with the study name: effectiveness of Rotation-advancement and Straight-line surgical approaches in repairing unilateral cleft lip defect. This clinical trial was approved by the ethics committee in the Faculty of Dentistry, Alexandria University. Under the serial number IRB, NO:00010556-IORG0008839.

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