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Philtrum reconstruction using autogenous fat injection versus a surgical repair with Orbicularis reconstruction, in secondary unilateral cleft lip revision (A randomized controlled clinical trial)

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ABSTRACT

Objective Our study's objective was to quantitatively assess the efficacy of autogenous fat injection in philtrum reconstruction and to compare it with the surgical revision and muscle reconstruction in secondary unilateral cleft lip repair.

Patients and Methods Philtral reconstruction was evaluated using both a subjective visual analogue scale and quantitative clinical measurements for the assessment. Fat injection is compared with a minimal invasive surgical revision technique which implies re-approximation of the Orbicularis oris muscle using two inverted horizontal mattress sutures after excision of the scar tissue.

Results Regarding clinically assessed philtral column projection and philtral ridge prominence scoring after one week, the difference between the fat injection and the surgical groups was not statistically significant. The only statistically significant difference found in the study between the surgical and fat injection groups, was at one year only, in philtral ridge prominence scoring, favoring the surgical revision group, where (p=0.004). This can be attributed to the expected fat resorption that occurs by time. However, patients were highly satisfied with fat injection probably due to its less invasiveness and lower morbidity as compared to surgery.

Conclusion Fat injection can be used in secondary cleft lip repair with results similar to those obtained with surgical revision. The technique is preferred by patients and produces satisfactory and patient pleasing results.

Keywords: *Cleft lip. Secondary repair. Philtrum reconstruction. Fat injection*

1. INTRODUCTION

Cleft lip and palate is one of the most common congenital deformities [1, 2]. Primary surgical repair should address upper lip abnormalities including discontinuity and abnormal attachments of the Orbicularis oris muscle [2, 3]. Cleft lip repair is mainly centered around reconstruction of symmetric cupid's bows, normal alar base width, normal projection of the nasal tip, as well as normal philtral contour [4]. The philtrum is an important aesthetic unit of the face as it is located centrally in the lip [1, 3, 5-10]. It has a role in speech and facial expressions due to its dynamic muscle components [3]. Philtrum reconstruction is one of the important factors signifying successful repair of cleft lip and has been emphasized by many authors [1, 3, 5-9].

Unsuccessful reconstruction during primary cleft lip repair results in secondary deformities that should be addressed during secondary repair [7, 8, 11]. Secondary Lip deformities typically include a flat or grooved philtral column, an excessively high or low cupid's bow, deviation of the philtrum, mucosal hypertrophy on the affected side and a vermillion defect causing a whistle deformity [9, 11-18]. Philtrum deformities range from excessive scar tissue formation to flattening or grooving of the philtral column that is accentuated with lip movement and requires lip revision [3, 6-8].

Strategies for superficial lip reconstruction in secondary repair include; local flap reconstruction, CO_2 laser treatment, silicone sheeting and grafts such as subcutaneous de-epithelialized dermis, de-epithelialized scar tissue flaps, tendon or auricular cartilage grafts [9, 10, 13, 19-27]. Fillers such as hyaluronic acid, silicone gel injection and fat injection have also been proposed [2, 12, 28-35]. Several methods have been described for muscular reconstruction in secondary cleft lip repair, including the traditional surgical revision with scar removal and re-orientation and approximation of the Orbicularis oris muscle [3, 4, 6, 8]. Muscle flaps such as pedicled pro-labial flap, Abbe flap and Orbicularis oris muscle flaps have also been described [3-8, 11, 20, 36-38].

All the previously mentioned surgical techniques of secondary cleft lip repair have their possible setbacks such as the accentuation of previously scared tissue and excessive tissue tension and oedema. Most of the revisional surgeries rely on tissues that are already deficient. Well-known drawbacks of grafts and muscle flaps are the donor site morbidity and tissue necrosis. Graft exposure was reported in several cases when using the palmaris longus tendon graft [5, 10]. Although dermal fat grafts yield durable results particularly with overcorrection, there is an increased risk of developing infection and a possibility of keratin cyst formation from the dermal element [9, 39]. Development of fat necrosis that can be palpable in areas is another complication reported when using dermal fat grafts [40]. In addition to this, in mild to moderate philtral deformities, surgical repair is unnecessarily invasive and time consuming thus vainly increasing the risk of postoperative complications such as: pain, swelling bleeding, wound infection, oedema, scaring and temporary smile stiffness.

Using autogenous fat transplantation in secondary cleft lip repair was found to be more convenient and safer with less tissue damage, operative duration and morbidity than the traditional surgical techniques. Autogenous fat grafting has been shown to improve the quality and color of skin, it softens and modulates scars and restores proper contour and function [28, 39, 40]. In contrast to temporary fillers such as collagen and hyaluronic acid that often require frequent reinjections, fat injection has the potential of providing long term results with a closer to normal shape and texture [28]. Being autogenous in nature, it is of good histocompatibility and avoids complications known with fillers such as hypersensitivity, foreign body reaction and host rejection [28]. It is convenient, easily accessed with abundant resources. Autogenous fat injection has been used by many authors for volume enhancement of the lip in secondary lip revision with successful results [2, 12, 28-31, 41].

Unfortunately, there is no objective data in the literature on the efficacy of the previously mentioned techniques for philtral reconstruction. Visual analogue scales have been widely used for the assessment but are considered subjective in nature. Quantitative methods such as 3-dimensional imaging, anthropometric measurements, or ultrasonography to assess depth of the philtral dimple and philtral ridge elevation, have not been used by researchers to assess the efficacy of the many techniques described in the literature to build philtral ridges and have been recommended by some authors [1, 42].

The aim of our study is to quantitatively assess the efficacy of autogenous fat injection on philtrum reconstruction and to compare it with surgical revision and muscle reconstruction. We focus on evaluation of philtrum reconstruction using both the subjective visual analogue scale and objective quantitative clinical measurements for the assessment. Fat injection is compared with a minimal invasive surgical revision technique which implies re-orientation and re-approximation of the Orbicularis oris muscle using two inverted horizontal mattress sutures after excision of the scar tissue.

2. PATIENTS AND METHODS

Study design, Recruitment and Eligibility Criteria

Twenty patients suffering from mild to moderate secondary cleft lip deformities including mild to moderate grooving and/or scarring of the philtral column after primary repair of unilateral cleft lip were enrolled in this study. They were selected from those attending the outpatient clinic of the Oral and Maxillofacial Surgery Department- Cairo University and Plastic Surgery Department at Abou-Elriesh Hospital - Kasr Eleini - Cairo University. Inclusion criteria comprised patients with repaired unilateral cleft lip deformity without an alveolar cleft defect or with a repaired alveolar cleft who required a secondary cleft lip repair, ages ranging between 4 and 16 years and the absence of any systemic disease that may affect normal tissue healing. Patients younger than 4 and older than 16 years old, those whose caregivers declined a revisionary operation, patients with any other craniofacial malformation and syndromic cleft patients were excluded from the study.

The study was a randomized controlled clinical trial. Patients in the intervention group underwent autogenous fat injection obtained from the abdominal region, through an incision in the vermillion into the philtrum. Fat injection into the vermillion, vertical component of the lip and alar base were also carried out if needed for volume enhancement. Patients in the comparator group underwent lip revision surgery with Orbicularis oris muscle reconstruction using inverted horizontal mattress sutures for enhancement of the philtral ridge. Patients were randomly divided into 2 equal groups using www.random.org with an allocation ratio (1:1) and simple randomization. Funded patient files in a dark sealed envelope were the method for allocation concealment. Patients, raters and statistician were blinded.

The current research was conducted in full conformity with the principles of the Declaration of Helsinki. Ethical approval was granted by Ethics Committee of Scientific Research – Faculty of Dentistry – Cairo University. ethics@dentistry.cu.edu.eg [with an Approval / Reference number: 10-9-20]. The study was registered in clinicaltrials.gov with a unique protocol ID: “NCT04735237”.

Sample size Calculation

The sample size was calculated in accordance with Chang 2014 [43]. The VAS score in the study group was significantly higher than in the control group. Entry 1was [6.1, SD 1.06.] & Entry 2 was [7.6 (clinically significant difference estimated by expert)]. Regarding the 1ry outcome, satisfactory esthetic results 'VAS score', 8 patients per group were deemed sufficient as a sample size for the study, with a total sample size of 16 patients (2 groups). The power was 80%, the α level of significance was ≤ 0.05, and the effect size used in calculation was 1.42. An increase in the number of patients was carried out from 16 to 20 patients (2 per group) to compensate for the predicted losses during follow-up. Thus, the total sample size is 20 patients divided into two groups (10 per group). The clinically important difference was 1.5. The sample size was calculated using the PS program (Power and Sample Size Calculation software; Vanderbilt University, Nashville, Tennessee).

Preoperative measures:

A thorough preoperative assessment of all patients was carried out including history taking, clinical examination and routine preoperative blood investigations. Preoperative clinical measurement of the philtral projection was carried out using a vernier caliper. Preoperative photographs of the face were captured at the last clinic visit before lip revision. Non-retouched photographs were obtained for each patient in the frontal, profile, and three-quarter plane.

Operative Techniques

For the fat injection group, lip revision was done under general anesthesia. For fat harvesting, the wet technique was used. Klein's solution "200 ml saline, 1 ml adrenaline 1:200,000 and 1.5 ml xylocaine 2%", was injected in the abdomen [28]. Fat was then manually aspirated using a 3mm blunt tipped catheter on a 20-mls syringe (figure 1). The lipoaspirate was then left for sedimentation after which the superior fat layer was further processed, and the inferior fluid layer was discarded. The obtained fat was then sheared into finer particles by passing it between two 10-mls syringes using a Leur-to-Leur connector. The processed fat was then loaded into a syringe and injected into the recipient site using a 0.2mls blunt tipped grafting needle (figure2). A small incision near the oral commissure was made through which the grafting needle was introduced. Fat was then injected in the subcutaneous, submucosal and muscular tissues in small aloquets according to the deficiency in the lip. The grafting needle was fanned out to varying depths during injection in the soft tissue to avoid excessive interstitial pressure and overcrowding of the grafted adipocytes (figure2) [41]. An average of (1-2mls) was injected under the ala of the nose, into the philtrum and vermillion according to the contour deficiency in the lip. A 30% overcorrection was done to compensate for fat resorption.

For the secondary surgical revision group, the operation was done under general anesthesia. The original scar was marked on the skin after which 0.5% lidocaine (containing 1:200,000 epinephrine) was injected into the operating area. Along the designed line, the skin was incised with removal of the scar tissue. A full- thickness incision was made through the skin down to the Orbicularis oris muscle and to the mucosa. Subcutaneous and sub-mucosal dissection was then carried out from the nostril sill to the lower border of the vermillion, for both the lateral and medial segments. Medially, dissection was not carried out past 5mms to avoid crossing the dimple and disruption of the philtral dimple anatomy. Laterally, the Orbicularis oris muscle was freed from the alar base by scissor dissection and abnormal attachment of the nasolabial fibers at the nostrils and alar base were cut. The dissected medial and lateral Orbicularis oris muscle segments were then approximated and sutured using two inverted horizontal mattress 4-0 vicryl sutures, thus causing eversion of the muscle edges to simulate the natural philtral ridge morphology (figure 3). Skin and vermillion suturing then followed the muscle approximation and was done using 5-0 vicryl interrupted sutures. Mucosal suturing was done using 4-0 vicryl interrupted sutures. The skin incision line was then covered by steri-strips.[1]

Postoperative measures and medication

Patients were instructed to apply cold compresses for 20 minutes every hour for the first eight postoperative hours to minimize oedema. They were also instructed to avoid direct sunlight till maturation of the scar. Steri strips were removed on the third postoperative day. The application of topical fucidin cream[2] was done over the wound after removal of steri strips. To avoid undue forces on the surgical site, patients were advised to stay on soft diet for 4 weeks.

Postoperative medications included (i) Amoxicillin/Clavulanic acid 457 mg/5 ml[3] . 45 mg amoxcillin/kg/day, twice daily for 10 days (ii) Ibuprofen 100 mg/5 ml[4] for pain control. 10 mg/kg/dose and (iii) Alpha-Amylase 200 U. CEIP/ml [5] for oedema. 10 ml 3 times per day.

[1] Steri-strips; 3M Deutschland GmbH Health Care Business, Carl-Schurz-Str.1, 41453 Neuss, Germany.
[2] Fucidin cream 2%, Minapharm Pharmaceuticals, 10th of Ramadan City, Egypt.
[3] Hibiotic, Amoun Pharmaceuticals, El Obour city, Cairo, Egypt.
[4] Brufen, Abbott Pharmaceuticals, Egypt
[5] Maxillase, Sanofi Pharmaceuticals, Egypt.

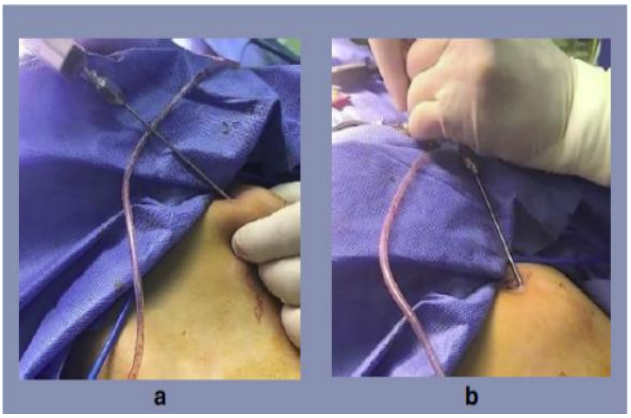

Fig.1 Fat harvesting & processing (a) Injection of Klien's solution (b) Fat aspiration

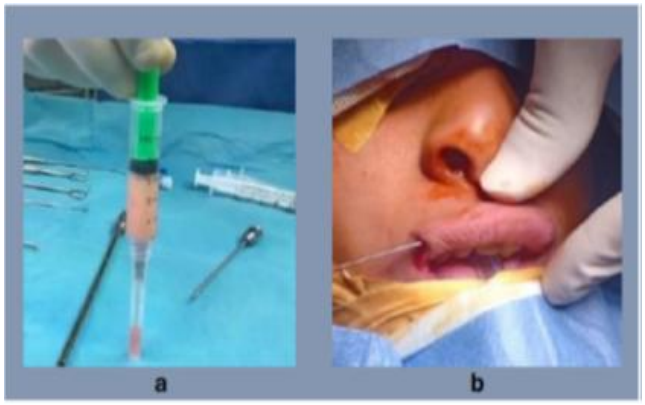

Fig.2 Aspirated fat that is injected in the lip (a) aspirated fat to be injected (b) fat injection into the lip

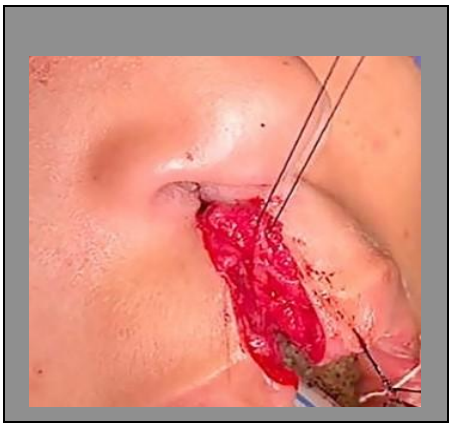

Fig.3 Horizontal mattress sutures for muscle approximation

Postoperative Assessment

The patients were seen and assessed after one week and after one year postoperatively. The sutures were removed after 4-7 days. Assessment of the efficacy of philtral column reconstruction in both groups (autogenous fat injection group and revision surgery group) was done by obtaining photographs that were taken preoperatively, after one week and after one year. Non-retouched photographs were obtained for each patient in the frontal, profile, and three-quarter plane. To avoid distraction of ratters by other face features, the photos were cropped to focus on the nasolabial area. Assessment of these photographs was done using a 5-point scoring scale (Table 1) [7, 8]. Two blind professional ratters assessed the photos according to the scale. Scores collected from photographs, after one postoperative week and after one year were the primary interest for analysis.

Clinical assessment of the philtral projection was also done preoperatively, after one postoperative week and after one year, using a vernier caliper (figure 4). Measurements in mms were taken for the cleft side philtral projection preoperatively

and postoperatively after one week and one year. Postoperative change in cleft side philtral projection was then calculated in mms by subtracting preoperative measurements from both postoperative one-week and one-year measurements and this was the primary interest for analysis.

Table 1 The visual analogue scales used in the study [7, 8]

SCORE	DESCRIPTION
PROMINENCE OF PHILTRAL RIDGE	
1	Same height as normal side
2	Less prominent than normal side
3	Flat ridge
4	Slightly grooved ridge
5	Prominently grooved ridge

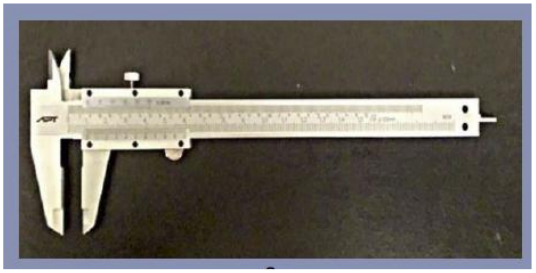

Fig.4 Vernier caliper for quantitative assessment

Statistical Analysis

The mean, standard deviation and median values were calculated for each group in each test. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests, quantitative measurements showed parametric (normal) distribution, while the rest of data showed non-parametric (not-normal) distribution. For parametric data, Independent-sample t-test was used to compare between two groups in nonrelated samples. Paired-sample t-test was used to compare between two groups in related samples. For non-parametric data, Mann Whitney test was used to compare between two groups in nonrelated samples. Wilcoxon test was used to compare between two groups in related samples. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

3. RESULTS

Twenty patients suffering from mild to moderate secondary cleft lip deformities including mild to moderate grooving and/or scarring of the philtral column were enrolled in the study. Eighteen patients, [ten patients in the study (fat injection) group and eight in the control (surgical) group] completed their follow-up assessments. Patients in the study (fat injection) group had a mean age of 9.4 ± 3.3 years, while those of the control (surgical) group had a mean age of 7.2 ± 2.3.

The patients were followed up for 1 year with assessment done at both I week and 1 year postoperatively. Satisfactory results were obtained after both fat injection and surgery with approximation of the Orbicularis oris muscle (figure 5 & 6). No postoperative complications were recorded except for an allergic reaction from the steri strips followed by keloid formation in one of the surgical control group cases which was managed by the application of anti-scarring cream and a corticosteroid ointment.

Regarding the clinical assessment of philtral projection, the mean clinical philtral projection in the study (fat injection) group was (1.4 ± 0.4) preoperatively which increased to (2.1 ± 0.4) one week postoperatively and to (2 ± 0.4) one year postoperatively. In the surgical revision (control) group, the mean clinical philtral projection was (1.7 ± 0.4) preoperatively which increased to (1.9 ± 0.6) one week postoperatively and to (1.9 ± 0.7) one year postoperatively. Postoperative change in cleft side philtral projection was then calculated in mms by subtracting preoperative measurements from both postoperative one-week and one-year measurements and this was the primary interests for analysis (Table 2). In both the study and the control groups, the difference between mean values found at both one week and one year, was not statistically significant. After both one week and one year, the difference between the mean values recorded in the study and the control groups was also not statistically significant (Table 2).

Table 2 The mean, standard deviation (SD) and median for the postoperative changes in the cleft side clinical philtral projection for the tested groups.

Variables	Clinical philtral projection (Postoperative changes in cleft side philtral projection in mms)								
	Pre-Op./ 1week				Pre-Op./ 1 year				p-value
	Mean	SD	Median	Range	Mean	SD	Median	Range	
Fat injection cases	0.650	0.076	0.500	0.500	0.667	0.083	0.500	0.500	**0.999 #**
Surgical cases	0.438	0.148	0.500	1.000	0.357	0.210	0.500	1.500	**0.356 #**
p-value	**0.194 #**				**0.157 #**				

#: non-significant

In both the study and the control groups, the difference in mean philtral ridge prominence scoring values that were recorded for both one postoperative week and one postoperative year, was not statistically significant. After one week postoperatively, the surgical revision group had the highest mean value (1.750 ± 0.250), while the fat injection group had the lowest mean value (1.200 ± 0.133) and the difference was not statistically significant, where (p=0.062). In addition, after one year, the highest mean value was found in the surgical revision group (2.143 ± 0.340), while the study fat injection group had the lowest mean value (1.111 ± 0.111) where the difference was (1.032), which is statistically significant (p=0.004), (table 3).

Table 3 The mean, standard deviation (SD) and median for prominence of philtral ridge scoring for tested groups.

Variables	Prominence of Philtral Ridge Scoring								
	1week				1 year				p-value
	Mean	SD	Median	Range	Mean	SD	Median	Range	
Fat injection cases	1.200	0.133	1.000	1.000	1.111	0.111	1.000	1.000	**0.998 #**
Surgical cases	1.750	0.250	2.000	2.000	2.143	0.340	2.000	3.000	**0.157 #**
p-value	**0.062 #**				**0.004***				

*; significant, #; non-significant

Fig. 5 Preoperative and one year postoperative photos of a Fat Injection case (a) Preoperative Frontal View (b) Preoperative 3-quarter View (c) 1 Year Postoperative Frontal View (d) 1 Year Postoperative 3-quarter View

Fig. 6 Preoperative and one year postoperative photos for a surgical case (a) Preoperative Frontal View (b) Preoperative 3-quarter View (c) 1 Year Postoperative Frontal View (d) 1 Year Postoperative 3-quarter View

4. DISCUSSION

The philtrum is an important central esthetic unit of the lip that requires special attention during cleft lip primary repair and revision. In secondary cleft lip revision, the main stay remains scar revision with approximation of the Orbicularis oris muscle and meticulous closure. Contour defects of the lip can be corrected by designing local flaps such as the Z-plasty, the V-Y closure or nearby flaps such as the Abbe flap. Yet less invasive techniques are gaining more popularity particularly when dealing with mild to moderate defects. These include dermal fat grafts, alloplastic fillers and autologous fat grafting. While alloplastic fillers are widely available and avoid the inconvenience of surgery and the risks of general anesthesia, their results are temporary, requiring frequent reinjections making them a less cost-effective modality. Although dermal fat grafts yield durable results particularly with overcorrection, there is also an increased risk of developing infection and a possibility of keratin cyst formation from the dermal element [9, 39]. Development of fat necrosis that can be palpable in areas is another complication reported when using dermal fat grafts [40].

Autologous fat grafting provides both the advantage of being a minimally invasive procedure similar to alloplastic fillers and the potential durable results of autogenous grafts. Applications of structural autogenous fat grafting in the field of plastic surgery include volume restoration, scar modulation and tissue regeneration. In contrast to temporary fillers such as collagen and hyaluronic acid that often require frequent reinjection, fat injection has the potential of providing long term results with a closer to normal shape and texture [30].

Regarding muscular reconstruction of the philtrum, most of the techniques described in the literature are unnecessarily invasive. Partial splitting and folding of the muscle can lead to distortion of the anatomy of the normal philtrum and dimple [7]. Muscle flaps can lead to increased scarring, muscle inter-digitation technique can be affected by early labial movement before wound healing, leading to loss of the muscle inter-digitation with scar formation and inacceptable results [5]. The muscle layering technique can lead to devascularization and denervation of the muscle edges with extensive splitting of the muscle causing poor wound healing and scaring [11]. Thus, in this study a simple, less invasive technique for philtral ridge reconstruction was used as a comparator to evaluate fat injection in secondary cleft lip revision. It involved the approximation of the dissected medial and lateral Orbicularis oris muscle stumps which were then sutured using two inverted horizontal mattress 4-0 vicryl sutures [6]. This suturing technique resulted in an outward eversion of the muscle under the deficient philtrum which supported the overlying sub-dermal and skin tissues thereby simulating the natural philtral column topography.

The present study showed that fat injection can be used as an alternative to surgical revision in secondary cleft lip repair. This is consistent with the results of most studies that were conducted to evaluate fat injection in secondary cleft lip repair which reported a statistically significant improvement in aesthetic lip appearance. Authors reported that autogenous fat was more convenient and safer than the traditional surgical methods with less tissue damage and postoperative morbidity [2, 12, 30, 31].

Jones CM et al used structural fat grafting in secondary cleft lip repair [12]. Scores given to grade all the four aspects according to the Asher Mcdade scale were lower preoperatively than postoperatively denoting a better appearance for all patients. Jones CM and Mackay DR used the Asher-McDade scale for the assessment of autogenous fat injection in secondary cleft lip repair and found statistically significant improvements in nasal form and vermillion border [29]. In the study conducted by Zheng D et al for assessment of lip aesthetics after autogenous fat injection in secondary cleft lip repair, esthetis

and symmetry were significantly improved postoperatively based on lip symmetry, lip profile and vermillion border shape [30]. The study conducted by Koonce SL et al for the treatment of volume asymmetry in cleft lip during secondary repair using autogenous fat injection showed that esthetics and symmetry improved after fat transplantation based on vermilion border shape, lip symmetry and nasal profile including upper lip [31]. Mean scale values significantly improved after fat grafting in comparison with preoperative scores. Vermilion border and nasal form showed statistically significant improvements. Alighieri C et al used fat injection for secondary cleft lip repair to assess functional and self-reported esthetic outcomes and found statistically significant improvement in profile postoperatively in self-evaluation of appearance [2].

In our study significant improvement in lip esthetics, lip symmetry, vermilion border shape and nasal lip profile were observed after fat injection as well as surgical repair. This is consistent with the results reported by Jones CM and Mackay DR, Zheng D et al, Koonce SL et al, Jones CM et al and Alighieri C et al [2, 12, 29-31]. In the study conducted by Zheng D et al, mean scale values for contour significantly improved after fat grafting [30]. Our study also showed significant improvement in lip contour after both fat injection and surgical repair. The only part observed to remain deficient after fat injection was the nasal sill, which was shown to acquire adequate fullness and contour after surgical repair. This was attributed to the effect of muscle re-approximation in this area which improved the alar base width and subsequently the contour at the nasal sill.

The current study is unique in that it compares fat injection with a simple surgical revision technique for secondary cleft lip repair, in an objective quantitative manner. The muscle roll technique used in our surgical revision (control) group is not a severely invasive surgical technique and was first described by Naidoo S and Butow K-W for accentuating the philtral column and capturing the natural normal looking anatomy of the philtral ridge and dimple. It implies utilizing inverted horizontal mattress sutures for eversion of the muscle. This suturing technique was reported to result in an outward rotation of the 2 muscle segments, supporting the overlying skin and resulting in the prominence of the philtral column thereby resembling the natural side [6]. The current study supported the results concluded in the studies conducted by Jones CM and Mackay DR, Zheng D et al, Koonce SL et al, Jones CM et al and Alighieri C et al that stated that fat injection can be used as a successful modality in secondary cleft lip repair [2, 12, 29-31]. The visual analogue scale used in the current study however, evaluated philtral ridge prominence and focused on the philtrum. Scales used in previous studies assessing fat injection in secondary cleft lip repair, evaluated the lip as a whole in terms of lip profile, symmetry and vermilion border shape. In their study Zheng D et al used a five-point grading scales for assessment of lip aesthetics and another 5-point scale to assess lip contour after autogenous fat injection [30]. Jones CM and Mackay DR, Koonce SL et al, Jones CM et al and Alighieri C et al used the Asher-McDade scale for the assessment of autogenous fat injection in secondary cleft lip repair [2, 12, 29, 31]. In this scale scores were given to assess nasal form, vermilion border shape, lip symmetry and nasal profile including upper lip. In contrast, our study used a five-point grading scale for evaluation of philtral ridge projection (table 1). The clinical philtral projection assessment used in our study is considered an objective quantitative methods that provides an even stronger evidence for the results obtained. In the study conducted by Zheng D et al, autogenous fat injection in secondary cleft lip repair was assessed at 6 months and for an average of 17 months [30]. Jones CM and Mackay DR reported stability of results at a postoperative follow up period of an average of 11 months in the assessment of autogenous fat injection in secondary cleft lip repair [29]. Koonce SL et al evaluated autogenous fat injection for the treatment of volume asymmetry in cleft lip during secondary repair for a period of 2 years and observed volume retention of the fat graft [31]. Jones CM et al reported long lasting results when structural fat grafting was used in secondary cleft lip repair, and only one patient required a repeated procedure of fat grafting [12]. In our study assessment was conducted at both one week and one year postoperatively. Results were shown to be stable with no statistically significant difference between one week and one year. No patients required repeated sessions of fat injection.

A statistically significant difference in philtral ridge prominence scoring between the study fat injection group and the control surgical group, favoring the surgical revision was found at one year only. The mean values were higher for the surgical group than for the fat injection group at both one week and one year. When clinical philtral column projection (difference between preoperative and postoperative phlitral column projections), between the study group and the control group, no statistically significant differences were found, neither at one week nor at one year.

According to our study, fat injection has been shown to provide results similar to that obtained with surgical revision. The statistically significant difference in philtral ridge prominence scoring, favoring the surgical revision found at one year only can be attributed to the expected fat resorption that occurs by time. Regarding clinically assessed philtral column projection and philtral ridge prominence scoring after one week, there were no statistically significant difference between the fat injection and the surgical groups.

The current study showed that fat injection was minimally invasive with less operative time than surgical repair. It led to volume restoration with long term results and a closer to normal shape and texture. Autogenous fat was easily accessed, and no complications resulted from the procedure. Patients were highly satisfied with the procedure and its outcomes. It is particularly beneficial in the cleft patients who have undergone many operations during childhood. Limitations however include deficiency in providing proper contour of the nasal sill and the possible fat resorption that can occur by time. Gentle handling, minimal processing and injection of small aloquets of fat in multiple planes are recommended to prevent fat

resorption. To prevent the need for further grafting, overcorrection of approximately 30% is required.

5. CONCLUSION

Fat injection can be used in secondary cleft lip repair with results similar to those obtained with the surgical revision in the mild to moderate deficient philtral ridges. It is particularly beneficial in the cleft patients who have undergone many operations during childhood. The technique is preferred by the patients and produces satisfactory and patient pleasing results. This is due to its minimal invasiveness and lower morbidity as compared to surgery.

Authors contribution (S IF, S MY and H A-G) contributed to the study conception and design. Material preparation and data collection were performed by (S IF). Data analysis and interpretation were done by (S IF and M AE). Operations were done by (D E and S IF). The first draft of the manuscript was written by (S IF) and all authors critically revised previous versions of the manuscript. All authors read and approved of the final manuscript.

Funding The authors declare that no funds, grants or other support were received during the conduction of this study.

Data Availability No datasets were generated during the current study.

Declarations

Ethics Approval The current research was conducted in full conformity with the principles of the Declaration of Helsinki. Ethical approval was granted by Ethics Committee of Scientific Research – Faculty of Dentistry – Cairo University. ethics@dentistry.cu.edu.eg [Approval / Reference number: 10-9-20].

Consent to participate Informed consent was obtained from the parents of all patients included in the study.

Consent to publish Parents of all human research participants provided informed consent for publication of the images in figures 1-6.

Competing interests The authors have no relevant financial or non-financial interests to declare.

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