Evaluation of Aesthetic Outcomes of Two-Stage Cleft Lip Repair versus Pre-Operative Nasoalveolar Molding Prior to Single Stage Repair in Unilateral Cleft Lip Patients: A Randomized Controlled Trial

Original Article

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ABSTRACT

Background: Cleft lip with or without cleft palate is the most common congenital craniofacial anomaly. Presurgical nasoalveolar molding (PNAM) is a development in cleft care that allows for shaping and contouring of the lip and nose for easier closure. We aimed to evaluate the aesthetic outcomes and nasal symmetry after lip repair without nasoalveolar molding (NAM) in comparison with using PNAM prior to lip repair in unilateral cleft lip patients.
Methods: This randomized controlled trial was carried out on 20 patients with unilateral cleft lip, from 6 weeks to 2 years, non-syndromic patients. Using two stage surgery without NAM in a group of patients with unilateral cleft lip repair. Another group with presurgical NAM with single stage repair of unilateral cleft lip patients.
Results: Ratio nasal width, height measurements and alveolar gap measurements at S1, S2 and S3 were insignificantly different between both groups. Relapse occurred in 3 (30%) patients and not in 7 (70%) patients in the two-stage surgery group.
Conclusions: The study showed no difference in the aesthetic outcomes (Ratio nasal width and height measurements and alveolar gap measurements) between lip repair without NAM in comparison with using PNAM prior to lip repair in unilateral cleft lip patients.

Key Words: Aesthetic, Two-Stage Cleft Lip Repair, Naso-alveolar Molding, Unilateral Cleft Lip .

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INTRODUCTION

Cleft lip with or without cleft palate is the most common congenital craniofacial anomaly. Embryologically, cleft lip results from a failed fusion of the maxillary and medial nasal processes. This defect results in a deformity of the nasolabial complex, with a complete cleft exhibiting the most significant structural displacement. [1]

Major advances have been made in cleft care in the past 50 years. The cleft lip and nose deformity can be transformed to a minimal variation of normal. Despite careful planning to achieve the best result in the primary cleft repair, secondary cleft deformities are common. [2]

Unilateral cleft lip repair is a challenge to the surgeon. Millard repair remains very popular and around 10 to 12 weeks of age is still the most common timing of lip repair. The repair includes many of the deficiencies of the cleft lip deformity and leaves a relatively anatomic lip scar mimicking the philtral ridge.[3]

Many problems have been discussed at the repair over the years. Prominent among these are the width of the cleft, scar shortening, and the demand to reposition the nasal ala of the cleft-side. To reduce these problems, lip adhesions on wider clefts is suggested. If available, presurgical nasoalveolar molding (PNAM) can also reduce these problems. Although the width of the cleft does determine how far both cleft margins must be advanced horizontally in the Millard repair, the vertical discrepancy between the cleft and noncleft peaks of Cupid's bow determines the amount of advancement flap necessary to fill in the defect above the rotation flap. [4]

PNAM is a development in cleft care that allows for shaping and contouring of the lip and nose for easier closure. Advocates of PNAM also claim better results than with traditional single stage cleft repair. However, PNAM is time intensive, expensive and requires frequent visits to clinic for adjustments, which is often less feasible depending on patient demographics. [5]

So, Tatum et al,. [6] described the two-stage unilateral repair technique as an alternative to PNAM.

The aim of this work was to evaluate the aesthetic

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outcomes and nasal symmetry after lip repair without nasoalveolar molding (NAM) in comparison with using PNAM prior to lip repair in unilateral cleft lip patients.

MATERIALS AND METHODS:

This randomized controlled trial was carried out on 20 patients aged from 6 weeks to 2 years, both sexes, with until lateral cleft lip and non-syndromic patients. The study was done from February 2020 to December 2022 after approval from the Ethical Committee of Cairo University Hospitals, Faculty of dentistry, Egypt. An informed written consent was obtained from the relatives of the patients.
Exclusion criteria were facial cleft cases, ages above 2 years, syndromic patients, and emotional instability.

The patients were divided into two equal groups: control group and two stage surgery group. Two stage surgery in unilateral cleft lip versus presurgical NAM and single stage cleft lip repair.

In two stage surgery: Stage 1: It is a lip repair performed in 3 layers. The lip landmarks are marked for Modified Millard repair. The patient is placed in reverse Trendelenburg position with the head section of the bed extended and prepped and draped in a standard fashion. Local anesthesia infiltration points (approximately 3 ml of 2% lidocaine with 1:200,000 epinephrine) for hemostasis, governed by heart rate of the patient.

Markings of modified Millard technique

Peaks of the Cupid's bow, alar base bilaterally and mid columellar point. Bilateral vestibular incisions with supraperiosteal dissection. Depending on cleft width, the lateral extension is done, if necessary. Separation of the skin from the underlying muscle is done with sharp dissection using Metzenbaum scissor. If the alar rim remains flattened with a tendency toward concavity on the external surface and the nostril remains horizontally oriented, then dissection with tenotomy scissors is performed through the cleft margin incisions to free the cleft-side lower lateral cartilage. After the nose has been addressed, the labial vestibular mucosa is then advanced medially, increasing the vertical length of mucosa in the cleft margin. The first vicryl 40- suture of the mucosal closure is anchored to the anterior nasal spine, and one or two sutures are then placed in the vestibular incisions bilaterally, elevating the apex of the vestibule to the level of the nasal spine leaving the alveolar side of the vestibule to heal secondarily. Muscle closure is performed with 4–0 vicryl sutures. Straight line repair of the skin was done using 60- vicryl suture.

Postoperative Management: The patients are typically observed overnight because of their young age. Feeding is accomplished with small soft catheters on a syringe or pigeon-type feeder to reduce stress on the lip repair for 7 to 10 days after surgery. The parents are instructed to keep the suture line covered with antibiotic ointment.

Stage 2: The skin scar is excised and repair according to Modified Millard technique will be performed. It is typically performed around 6 months of age under general anesthesia with similar positioning, prepping, and draping. The lip scar is excised with a scalpel down to the muscle layer. If muscle shortening or contracture was found, so muscle revision was done and re-sutured using 4-0 vicryl. On the cleft side, the undermining is extended out to the ala and then straight down to and around the vermilion.

An incision on the cleft side was done extended to the ala in curvilinear manner to create an advancement flap. On non-cleft side the incision extended from the peak of vermillion border up to the mid-columellar point with back cut incision (about 2 mm). Creation of c- flap for nasal closure .skin was sutured using 6-0 vicryl obtaining three layers closure (mucosa, muscle, and skin).

4-0 vicryl suture was used for muscle and mucosa closure, while the dermis was closed using 6-0 vicryl suture and covered by steri strips.

In single stage repair: Pre surgical NAM then the surgery done at about 3 to 4 months of age using Modified Millard repair technique. An alginate impression of maxilla is taken in first visit then delivery of molding plate occurs within 1-week acrylic bulb at the end of a wire which is extended from the buccal flange and embedded in the plate. the inner side of the plate will be relieved for alveolar segment approximation. Modified Millard technique was performed for both groups as final repair. 2D photos using professional camera will be obtained preoperatively, 1month postoperatively and at 1 year of age. postoperatively.

Height of nostril: the heighest point of the nostril perpendicular to the reference line.

Width of nostril: the distance from the point farthest right to the point farthest left of the nostril on each side. (Symmetry of the nose after PNAM in infants with unilateral cleft lip and palate).

Measurements also were analyzed using image j software [7]. Regarding photographs, a standard ruler was used as a reference on the lower lip. The scar width was measured at 2 different points with the ImageJ program. The first point was represented by 1 mm above the white roll, whereas the second one was 1 mm below the C-flap suture line.

Postoperative care: A minimal compression bandage was applied to the donor site: all the patients were kept in the hospital overnight until adequate oral intake was attained.

The parents were instructed to apply cold packs over the lip to prevent hematoma formation.

No nipples were allowed. The parents were instructed to clean the wound and apply topical antibiotic cream twice daily. Postoperative massage of the scar, 2 weeks after operation continued for 8 weeks to soften the scar. Amoxicillin /clavilunic acid oral according to the weight of the patients every 12 hours for 5 days. Oral Non-steroidal anti-inflammatory drugs every 12 hours for three days post operative. Topical antibiotic ointment applied to the lip wound and to the whole lip for softening every 8 hours. Antiedematous medication (maxilase in pediatric and alphintern in adolescent) every 12 hours for 5 days.

Dehiscence: one patient in each group, allowed to heal using tension bandage with steri-strips and hyalo 4 control cream [8].

Follow-up visits: 1st visit: 1 week postoperative to assess any lip hematoma or infection. 2nd visit: 1 month postoperative to assess the patient with VSS clinically(S2). 3rd visit: 1 year postoperative to assess the patient with VSS clinically, assess scar dimension, and lip thickness (S3) by ultrasound and computer image J program.

Statistical analysis

Statistical analysis was done by SPSS v26 (IBM Inc., Chicago, IL, USA). Quantitative variables were presented as mean and standard deviation (SD) and compared between the two groups utilizing unpaired Student's t- test. Qualitative variables were presented as frequency and percentage (%) and were analyzed utilizing the Chi-square test or Fisher's exact test when appropriate. A two tailed P value < 0.05 was considered statistically significant.

RESULTS:

Patient characteristics and duration of operation were insignificantly different between both groups. Table 1

Table 1: Patient characteristics and duration of operation of the studied groups

		Control group (n=10)	Two stage surgery group (n=10)	P
Age (months)				
sex	male	15.1 ± 7.03 3 (30 %)	12.2 ±6.92 4 (40 %)	0.365
	female	7 (70 %)	6 (60 %)	0.639
type of clef	complete clef	10(100%)	10 (100 %)	
Duration of operation (min)		102.5 ±11.84	101.5 ± 9.44	0.837

Data are presented as mean ± SD or frequency (%). *Significant p value<0.05

Ratio of nasal width, height measurements at S1, S2 and S3 were insignificantly different between both groups. Figure 1

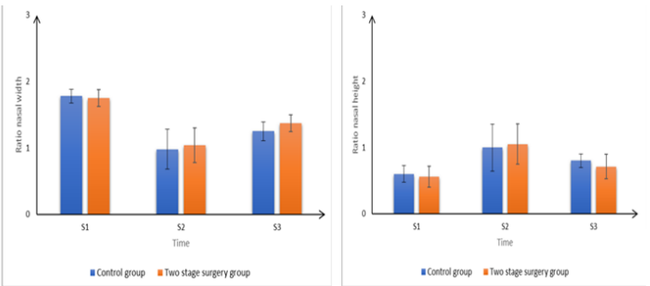

Figure 1: Ratio nasal (A) width, (B) height measurements of the studied groups

Alveolar gap measurements at S1, S2 and S3 were insignificantly different between both groups. Table 2

Table 2: Alveolar gap (mm) measurements of the studied groups

	Control group (n=10)	Two stage surgery group (n=10)	P
S1	11.5±2.8	11.1±3.84	0.793
S2	8.3±3.4	9.3±3.37	0.517
S3	3.1±0.88	4.2±1.62	0.075

Data are presented as mean ± SD. *Significant p value <0.05.S1: Presurgical measurement, S2: 1 month after surgery measurement, S3: At the age one year measurement.

Naso alveolar molding single stage group photos were shown in Figures 2,3 and 4. Two stage surgery group photos were shown in Figures 5,6 and 7.

Figure 2: preoperative photo of Naso alveolar molding single stage group

Figure3: Post operative photo after 1 month of Naso alveolar molding single stage group

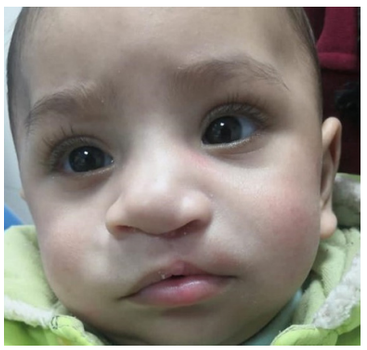

Figure 4: Post operative photo after 1 year of Naso alveolar molding single stage group

Figure 5: preoperative photo of 2 stage group

Figure 6: Post operative photo after 1 month of 2 stage group

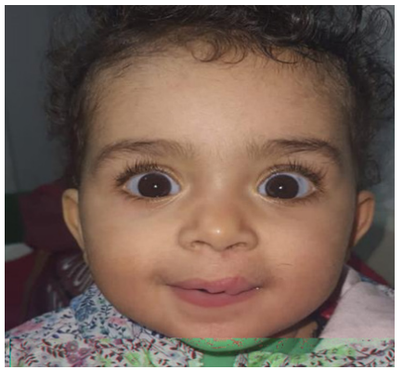

Figure 7: Post operative photo after 1 year of 2 stage group

DISCUSSION

The reconstructive surgeon continues to struggle with unilateral cleft lip repair. Between the ages of 10 and 12 weeks, the Millard repair is still used as the most prevalent type of lip closure. A lip scar that is adequately anatomical and resembles the philtral ridge is left behind after the treatment, which corrects many of the problems with cleft lips. [9]

The present study showed that there was no statistically significant difference between both groups regarding aesthetic outcomes (Ratio nasal width and height measurements and alveolar gap measurements). Similar to our study, a study was conducted by **Nayak et al.** [10]

reported that at 5-year postoperative follow-up, nasoalveolar molding group patients had better mean values on the objective scores; however, these were not statically significant. The nasoalveolar molding group of patients had a statistically significant improvement in the subjective evaluation in comparison to the non-nasoalveolar molding-treated patients. The number of lip revisions was also statistically higher in the non-nasoalveolar molding-treated group of patients. **El-Bestar et al.** [11]

reported that the ratio of the hemi-columellar height between the cleft side/normal side was more symmetrical in the NAM group than in the control group. The difference was statistically significant. **Ellithy et al.** [12]

reported that there were significant improvement of nasal symmetry and reduction of alveolar gap width (AGW) after use of NAM.

Another study was conducted by **Pai et al.** [13] reported that Effects of nasal symmetry after presurgical nasoalveolar molding were compared between the affected and nonaffected side. The nostril width ratio was 1.7, 1.2, 1.0, and 1.2 for S1 to S3.

The nostril height ratio was 0.5, 0.8, 1.0, and 0.9 for S1 to S3. The angle of the columella was 53.3 degrees, 69.9 degrees, 91.2 degrees, and 86.9 degrees for S1 to S3.

The concept of a two-stage lip repair is not new, and there are many criticisms. The two-stage repair adds a second anesthetic session with the inherent risks, Two-stage protocols have been additionally criticized for having to perform the second stage through the scar formed by the first stage, creating greater difficulties with tissue handling. About anesthesia safety, we have been fortunate to have no untoward anesthetic events in our cleft population related to this early age for surgery. With the increase in experience and availability of pediatric anesthesiology specialists, surgery in the first 4 to 6 weeks of life seems to be safe and reasonable. Children with cleft lip and palate typically undergo from two to five procedures depending on the protocol and the need for revisions. About the scar, the wide undermining provides less tension on the closure and may be why we do not experience significant scarring after our first stage The alveolar arch molding occurs from the relatively gentle constant pressure of the repaired orbicularis muscle. Early second intervention preventing children bullying at the school age in case of delayed cheiloplasty.

Also, the availability of NAM was a problem especially in case of pandemic diseases as noticed in COVID-19 era, regular parents' visits and coming from outside Cairo government for follow up.

Limitations of our study included that bring a single-center study, and the results may differ elsewhere, small sample size and short follow up. So, we recommended that clinical studies are needed with multicenter cooperation to validate our findings. We considered that further studies should be carried out with larger sample size and longer periods of follow up.

CONCLUSION:

The study showed no difference in the aesthetic outcomes (Ratio nasal width and height measurements and alveolar gap measurements) between lip repair without NAM in comparison with using PNAM prior to lip repair in unilateral cleft lip patients.

CONFLICT OF INTEREST

This clinical study was self-funded by the authors, with no conflict of interest.

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