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Impact of nasalis muscle repair in unilateral cleft lip patients

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ABSTRACT

Background: Although the role of nasalis muscle in the establishment of nasal deformity is well recognized; its abnormal anatomy and role in the correction of alar deformity in cleft lip patients have not been adequately studied. This work aimed to study the effect of nasalis muscle repair on the post-operative nasal symmetry.

Patients and methods: A controlled prospective randomized study was conducted on 45 cases of unilateral complete pre-alveolar cleft. Patients were divided into two groups; Group 1 (repair of the Orbicularis muscle only), Group 2 was further divided into 2 subgroups: Subgroup A (repair of the orbicularis oris muscle and dissection and repair the origin of the nasalis muscle). Subgroup B (repair of the orbicularis oris muscle and dissection of both origin and abnormal insertion of the nasalis and repair of the origin). Evaluation was conducted both subjectively and objectively through cleft lip evaluation profile and nostril angles measurement.

Results: Group 2B patients showed significantly better shape and symmetry of nasal tip, size and symmetry of nostrils and size, form and lateral displacement of the ala. Objective evaluation showed that group 2B had the closest results to the non-cleft side, with statistically significant difference, when compared to other groups.

Conclusion: Dissection and repair of both origin and insertion of nasalis muscle produced a nasal width, columellar height, and nasal tip projection close to the normal population of the same age.

1. Introduction

Anatomical abnormalities contributing to cleft lip nasal deformity include disfigurement and displacement of the lower lateral cartilage, a short columella, and mal-positioning of the lesser maxillary segment (Bagatain et al., 1999).

When the muscles are intact, growth stimulants from the nasal septum are transmitted to the sutures, and the nasal and maxillary periosteum, which positively influence development of the mid-face. In a cleft patient, the earliest points of ossification appear 2 weeks after the muscle precursors are first present. As a result, bone formation occurs at the direction, and under the influence, of asymmetrical muscular forces (Breitsprecher et al., 1999).

Since the early 1970s, surgeons have paid greater attention to correct anatomical reconstruction of the facial muscles to prevent secondary nose deformities and changes in mid-facial growth rather than focusing solely on skin incision alignment procedures (Randall et al., 1974; Fara, 1975; Millard, 1977; Delaire, 1987; Kernahan, 1978; Kernahan and Bauer, 1983; Joos, 1989; Breitsprecher et al., 2002).

The value of reconstructing normal anatomy and function of the orbicularis oris muscle is now well recognized. (Bagatain et al., 1999). The importance of restoring the nasalis muscle in both primary and secondary repairs has been noted by several authors. Delaire (1987); Joos (1989); Talmant (2006).

In Delaire (1975) was the first to study the nasalis muscle in cleft lip patients, reporting that this muscle inserts into the nasal spine and septum, not into the lateral nose. In a subsequent paper in Joos and Friedburg (1987) supported Delaire's finding with magnetic resonance imaging, observing that unopposed pull on the septum by the nasalis muscle in a patient with unilateral cleft lip caused the nasal septum to deviate to the non-cleft side.

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In Zide (1985) stated that the nasalis muscle has two parts, an alar and a transverse part. The alar part arises inferior to the edge of the pyriform aperture and inserts in the alar cartilage and assists in dilatation of the nares. The transverse part arises from the most lateral section of the sub-pyriform crescent and joins with the procerus muscle on midline as well as its opposite transversus, forming the nasalis-procerus aponeurosis, which is shaped like an inverted Y.

In Talmant (1993) elaborated further on these observations by describing the functional importance of the two fixed insertions of the nasal muscle. Zheng et al. (1999) located the nasalis muscle along the edge of the anterior nasal aperture with clear boundaries and divided it into four parts: transverse nasalis, alar, basis nasi, and columella nasi.

In fact, the nasalis muscle is now considered the strongest anterior anchorage point of the facial envelope on the cleft side, a role first described by Veau more than 80 years ago (Talmant, 2006).

Early attempts at restoring nostril and alar symmetry used techniques such as excising skin at the nostril sill and closing the defect with an alar flap (Sherif, 2014), or augmenting the region with bone or cartilage. However, it appears that reconstructing the nasalis muscular ring during cleft lip nasal surgery helps reduce alar flaring, narrows the nostril, elevates the nasal sill, and improves contralateral caudal septal deviation (Jonnalagadda et al., 2016).

There are no comparative studies to demonstrate its role in the correction of the alar deformity, thus we aimed in this work to study the effect of nasalis muscle repair in unilateral cleft lip patients on the postoperative nasal symmetry following its reconstruction.

2. Patients and methods

2.1. Patients

This randomized prospective study included 45 patients born with unilateral complete pre-alveolar cleft without post-alveolar cleft. Patients' age ranged from 3 months to 1 year. We recruited patients over a 2-year period from October 2014 to September 2016, after obtaining signed informed consent from each patient's legal guardian after full explanation of the procedure. The study was conducted according to the Declaration of Helsinki Principles and was approved by Faculty of Medicine Research Ethics Committee (FMASU 1317/2012).

There was no sex preference when including patients, although we excluded syndromic patients, those with congenital anomalies, patients with secondary cleft, and those undergoing pre-surgical interventions including lip adhesion correction.

2.2. Methods

We randomly divided patients into two main surgical groups: group 1 (12 patients) underwent repair of the orbicularis muscle only (control group); group 2 underwent repair of both the orbicularis oris and nasalis muscles, and this group was further divided into two sub-groups. Sub-group A (16 patients, group 2A) underwent repair of the orbicularis oris muscle and dissection and repair of the origin of the nasalis muscle. Sub-group B (17 patients, group 2B) underwent repair of the orbicularis oris muscle and dissection of both the origin and abnormal insertion of the nasalis muscle, and repair of the origin (Fig. 1).

All surgeries were performed by the second and third authors (who are board certified, having ten years of experience), and all patients underwent lip repair using the modified Millard rotation advancement flap (Millard, 1957). Two additional flaps that refine the repair are often also used: the white roll flap and the vermilion triangular flap to allow for a smoother transition at the vermilion cutaneous junction and at the vermilion contour according to Noordhoff, 1997 modification.

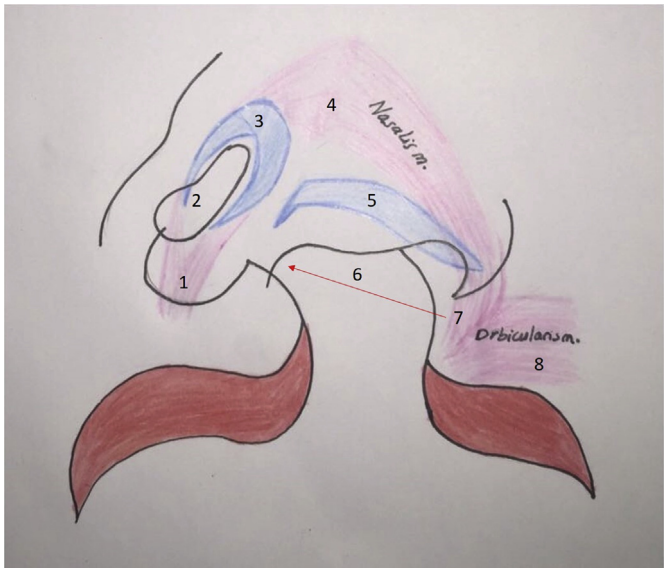

Fig. 1. Muscle anatomy and Deformities in patients. (1) Nasalis muscle at the non-cleft side. (2) Nasal sill at the non-cleft side. (3) Well-formed lower lateral cartilage of the non-cleft side. (4) Insertion of the nasalis muscle at the nasalis-procerus aponeurosis which is dissected from the nasal skin in group 2B patients. (5) Distorted lower lateral alar cartilage of the cleft side. (6) Nasal sill at the cleft side. (7) Nasalis muscle at the cleft side which is dissected, traverse the cleft and repaired to the anterior nasal spine (red arrow) in group 2 patients. (8) Orbicularis oris muscle which is repaired in all groups.

The repair procedure begins by identifying the nasalis muscle: muscle fibers of both the nasalis and orbicularis are joined at the edge of the cleft (See Video, Supplemental Digital Content 1). The transverse direction of the orbicularis oris muscle fibers distinguishes it from the nasalis' oblique fibers (Fig. 2). On inspection of the lower limit of the piriform margin, the muscle bundle is identified running up to the ala. Caudal pull on this muscle accentuates deformity of the ala and deepens the alar crease (Fig. 3).

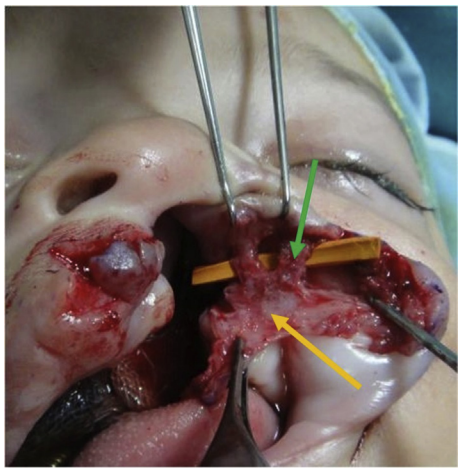

Fig. 2. Identification of nasalis muscle (green arrow). It runs subcutaneously just cephalic to the orbicularis muscle (yellow arrow) in an oblique manner up to the lower lateral alar cartilage.

Fig. 3. Confirmation of nasalis muscle. Pull on the nasalis muscle (held by the forceps) accentuates the deformity and deepens the alar groove (black arrow).

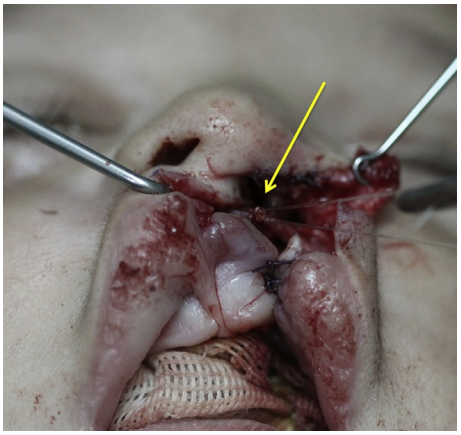

Fig. 5. Suturing of nasalis muscle to the anterior nasal spine (yellow arrow) after being dissected from the alar skin in group 2B.

Supplementary video related to this article can be found at https://doi.org/10.1016/j.jcms.2018.11.030.

In both subgroups A and B, this bundle was partially dissected from the orbicularis oris a sufficient distance to place a suture without over-dissection, to preserve blood supply (Fig. 4).

In subgroup B, we also dissected the nasalis insertion from the alar skin. Dissection of the orbicularis muscle from the skin is performed at the region of the vermilion-cutaneous junction, and the muscle is incised for approximately 2–3 mm on either side of the cleft paralleling the vermilion border to allow development of vermilion-cutaneous muscular flaps for final alignment.

The nasalis muscle is then sutured to the periosteum of the anterior nasal spine using 1.5 metric (4/0) Ethicon-coated Vicryl suture on a 17.5-mm cutting needle (Johnson & Johnson, New Brunswick, NJ, USA) (Fig. 5). The nasolabial group of the orbicularis muscles is repaired with the contralateral side and sutured into the nasal spine. This is followed by approximating the remainder of the orbicularis, interdigitated with its opposing element along the full length of the vertical lip.

We photographed all patients using a Canon EOS digital camera (Canon Inc., Tokyo, Japan) with both 50-mm and 18–135-mm lenses. Three different views were taken: anteroposterior, lateral (profile), and basal views 6 and 12 months postoperatively.

Subjective evaluation: All photos were shown to the parents who assessed the results using the cleft lip evaluation profile according to Ohannessian et al. (2011). Seven categories were assessed: symmetry of the tip of the nose, symmetry of the nostrils (form and position), size of the nostrils on the cleft compared with the non-cleft side, lateral displacement of the ala comparing the cleft with the non-cleft side (nasal wing symmetry), tip of the nose viewed from the cleft side, size and form of the ala comparing cleft with the non-cleft side, and position of the caudal septum. Every assessment category was illustrated by three images with increasing degrees of residual cleft-related disfigurement combined with a numerical rating of 0, 1, or 2, with 2 being poor and indicating most asymmetrical.

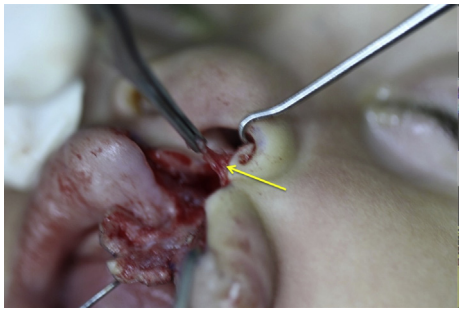

Fig. 4. Dissection of nasalis muscle origin (yellow arrow) in group 2 patients.

Objective evaluation was performed by assessing nostril symmetry using two angular measurements to assess nostril direction and symmetry on base view photos according to Brussé et al. (1999). Three plastic surgeons evaluated the patients and none of the surgeons were involved in the primary surgical treatment. All three evaluating surgeons had at least 20 years' experience in cleft surgery. Evaluating surgeons used the following method to evaluate nostril asymmetries between the nostrils and nostril direction on the cleft and non-cleft sides of the same patient: angle A was defined as the angle between the line connecting the highest and lowest points on the nostril outline and the horizontal plane, and angle B was defined as the angle between the longest axis of the nostril outline and the horizontal plane.

The level of agreement between evaluators (Inter-rater reliability) for both subjective and objective evaluation was calculated using the percent agreement method.

2.3. Statistical methodology

Analysis of data was done by IBM computer using SPSS (statistical program for social science version 16) as follows: Description of quantitative variables as mean, SD and range. Description of qualitative variables as number and percentage. Unpaired t-test was used to compare quantitative variables, in parametric data (SD < 50% mean). Paired t-test was used to compare quantitative variables in the same group before and after treatment. Comparison between groups as regards qualitative variables was done by using chi-square test or univariate analysis of variance test with post hoc Tukey's test (ANOVA). P value > 0.05 insignificant, P < 0.05 significant and P < 0.001 highly significant.

3. Results

This study included 37 male and 8 female children aged 3 months–12 months. Thirty-three patients had a left-sided cleft while 12 patients had a right-sided cleft. Forty-one patients had unilateral cleft lip and palate, and four patients had unilateral cleft lip without palate deformity. Patients' data are shown in Table 1.

Subjective Evaluation: The inter-rater reliability for the study was 55%.

Table 1
Comparison between the studied groups as regards patient data.

Variables	2A N = 16	2B N = 17	Control N = 12	P-value
Age (years)	5.1 + 1.8	4.8 + 1	6.1 + 0.9	0.12 NS
Gender				
Male	16 (100%)	15 (88.2%)	6 (50%)	0.0001
Female	0	2 (11.8%)	6 (50%)	HS
Laterality				
Left	12 (75%)	11 (64.7%)	10 (83.3%)	0.11
Right	4 (25%)	6 (35.2%)	2 (16.6%)	NS

NS: non-significant, HS: highly significant.

1 **Symmetry of the tip of the nose**: the control group (group 1) scored lowest compared with results in the nasalis group, while group 2B scored the best. Table 2 shows that the control group had the poorest results with a statistically significant difference from those of group 2B, by chi-square test (Fig. 6).
2 **Symmetry of the nostrils**: We found similar results as for symmetry of the tip of the nose, and Table 2 shows that the control group had the poorest results for nostril symmetry while group 2B had the best results. Results were statistically significantly different, by chi-square test (Fig. 7).
3 **Size of the nostrils**: The three groups showed close results when comparing nostril size, likely because good care was taken when measuring the base of the nostril before repair. Table 2 shows no statistically significant difference between the three groups for nostril size, by chi-square test.
4 **Lateral displacement of the ala**: The three groups showed similar results, and Table 2 shows no statistically significant difference between groups, by chi-square test.
5 **Nasal tip**: When viewed from the cleft side, the nasal tip was most appealing to the parents when the nasalis muscle was repaired (Fig. 8). Table 2 shows a statistically significant difference for the nasal tip results between the three groups by chi-square test, and group 2B showed the best results.
6 **Size and form of the ala**: Results were similar to those for nostril symmetry. Group 2B showed the best results, followed by group 2A, then the control group. Table 2 shows a statistically significant difference between the three groups for alar size and form, and results were best in group 2B, by chi-square test.
7 **Caudal septum**: When deprived of its muscular attachments, the caudal septum deviates to the cleft side. In our study, we saw similar results between the three groups. Table 2 shows no statistically significant difference between the three groups for position of the caudal septum, by chi-square test.

Table 2
Comparison between the studied groups as regards subjective evaluation.

Variables	2A N = 16	2B N = 17	Control N = 12	X^2	P-value
Tip of Nose					
Poor	0	1 (5.9%)	4 (33.3%)	10	0.04 S
Good	8 (50%)	7 (41.2%)	6 (50%)		
Very good	8 (50%)	9 (52.9%)	2 (16.7%)		
Symmetry of Nostrils					
Poor	2 (12.5%)	0	6 (50%)	14	0.006 S
Good	10 (62.5%)	11 (64.7%)	6 (50%)		
Very good	4 (25%)	6 (35.3%)	0		
Size of Nostril					
Poor	2 (12.5%)	2 (11.8%)	4 (33.3%)	5.1	0.27 NS
Good	10 (62.5%)	11 (64.7%)	8 (66.7%)		
Very good	4 (25%)	4 (23.5%)	0		
Lateral displacement of the ala					
Poor	3 (21.4%)	0 (0%)	8 (50%)	6.6	0.01 NS
Good	3 (21.4%)	5 (35.7%)	6 (37.5%)		
Very good	8 (57.1%)	9 (64.3%)	2 (12.5%)		
Tip of the nose viewed from the cleft side					
Poor	2 (12.5%)	0	2 (16.7%)	12.6	0.01 S
Good	6 (37.5%)	7 (41.2%)	10 (83.3%)		
Very good	8 (50%)	10 (58.8%)	0		
Size and Form of the ala					
Poor	2 (12.5%)	0	6 (50%)	17	0.0001 HS
Good	6 (37.5%)	7 (41.2%)	6 (50%)		
Very good	8 (50%)	10 (58.8%)	0		
Position of the caudal septum					
Poor	2 (12.5%)	0	2 (16.7%)	5.5	0.23 NS
Good	4 (25%)	9 (52.9%)	6 (50%)		
Very good	10 (62.5%)	8 (47.1%)	4 (33.3%)		

NS: non-significant, S: significant, HS: highly significant.

Objective evaluation: The inter-rater reliability for the study was 57%.

i) **Angle A**: Results reflected to what extent the cleft side resembled the normal side. The results in group 2A resembled the normal side more than those in the control group. Table 3 shows a statistically significant difference with group 2B having the closest results to the non-cleft side when compared with the other groups. Comparing controls and group 2A patients showed no statistical difference by analysis of variance test. Table 4 shows a statistically significant decline in the angle size among group B patients, by paired *t*-test.
ii) **Angle B**: Results in group 2B were superior to those in the other groups. Table 3 shows that group 2B had results closest to the non-cleft side with a statistically significant difference compared with the other groups. When comparing the control group with group 2A, the latter showed statistically significantly better results compared with group 2A, by analysis of variance test. Table 4 shows a statistically significant decline in the angle among groups 2A and 2B and no significant difference in the control group, by paired *t*-test.

4. Discussion

Patients with clefts are more often affected by social marginalization, and have more problems finding a life partner. Therefore, esthetic rehabilitation and normalization of the facial appearance is a major treatment goal (Krimmel et al., 2015).

There are two opposing views regarding surgery to correct cleft lip and palate deformities. One is a static approach that involves simply bringing together apparently inert elements to provide a corrected appearance; this concept is supported by Mooney et al. (1988). In contrast, Joos (1995) and Bagatain et al. (1999) support a dynamic approach that establishes vital function by reconstructing structures inhibited by their malposition through redeploying involved muscles.

Logically, the dynamic approach to correct the cleft re-establishes normal oral-facial muscular balance, lip competency, and good nasal breathing. Consequently, when these functional bases are achieved, the best possible esthetic result can always be obtained (Precious, 2009).

In the cleft, the two parts of the nasalis are shifted downward and laterally to the anterior surface of the maxilla from the dorsum nasi and are mixed with the muscles of facial expression on the same side. These disordered muscle fibers terminate at the nare skin and nasal alar cartilage beneath the skin, and pull the ala nasi and nasal alar cartilage laterally (Wu and Yin, 2014).

Restoring the normal anatomical position of the nasalis muscle elevates the nostril sill and floor, narrows the nostril, and decreases alar flare, normalizing its contour (Nicksic et al., 2018).

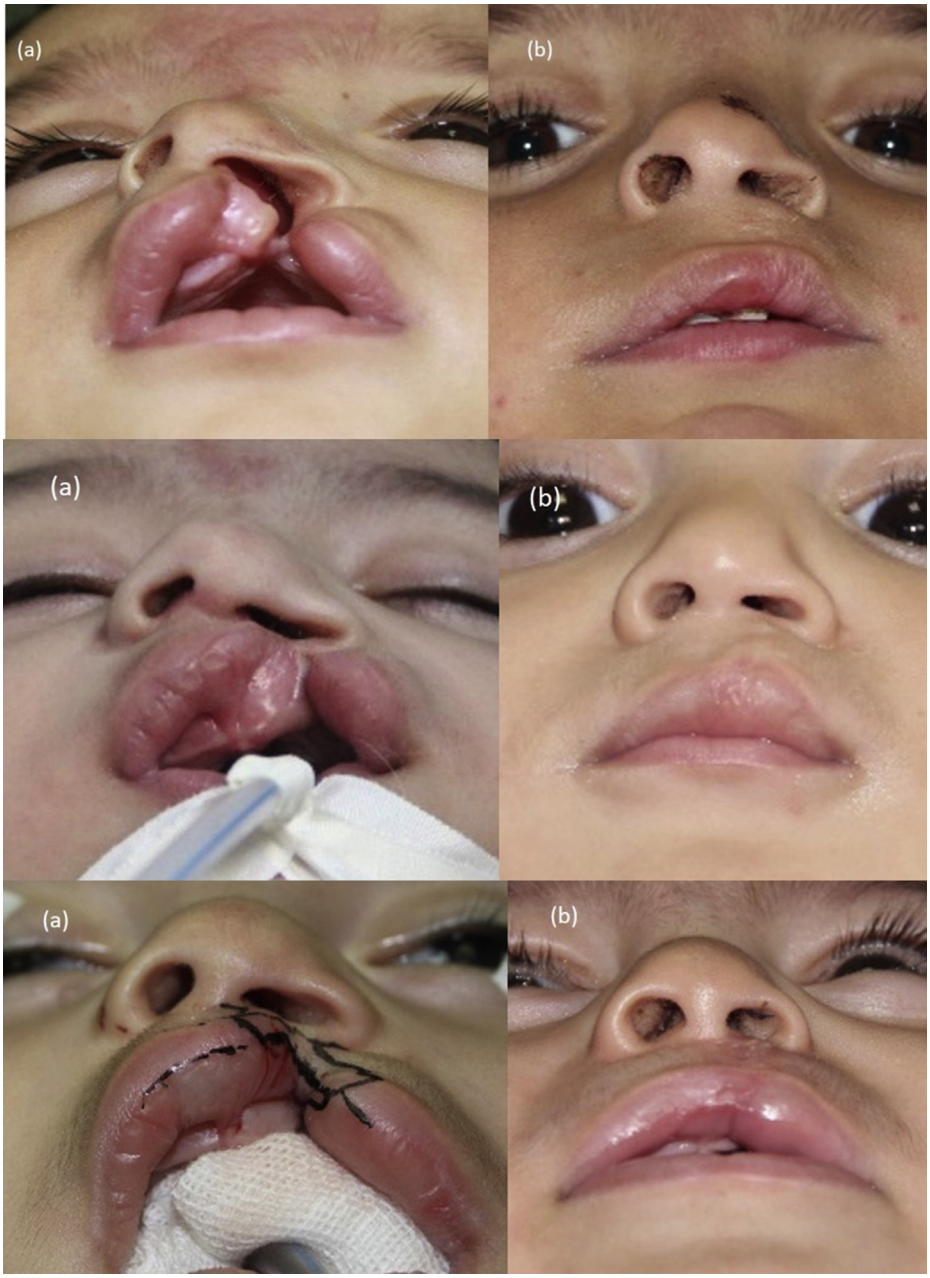

Fig. 6. (top) Case from the control group; (a) pre-operative (b) 1 year and 2 months post-operative, (middle) Case from group 2A; (a) pre-operative (b) 1 year post-operative, (bottom) Case from group 2B; (a) Pre-operative (b) 1 year post-operative.

Along with the orbicularis muscle, the two parts of the nasalis provide support for the corresponding half of the upper lip and, indirectly, the labial commissure (Precious, 2009).

In the present study, we dissected the nasalis muscle, then anatomically realigned and repaired the nasalis and used different evaluation methods to evaluate the results of this repair method on facial symmetry.

Tajima (1983) freed the nasalis muscle from the maxilla except for a section at the lower limit of the piriform margin. No attempt was made to dissect the muscle from the alar base; thus, the nasalis muscle was repaired without severing its insertion into the ala to retain its function, to form as wide a vestibule as possible. Joos (1995) compared two groups: group 1 underwent reconstruction of the perioral and perinasal muscles, and group 2 underwent only orbicularis repair. Analyses of both dental casts and lateral cephalometric radiographs showed that skeletal development in group 1 was better than in group 2.

In our study, when comparing groups regarding nostril size, we found no statistically significant difference between our three groups; however the inter-alar distance decreased in groups 2A and 2B, which did include dissection of the nasalis muscle from the alar cartilage. However, long-term follow-up is mandatory, as we expect that with facial growth, patients undergoing nasalis repair will maintain alar position and a more central position of the caudal septum, while the control group might develop displacement. We consider this lack of long-term follow-up a limitation in our study. Another limitation was the unequal number of patients in each subgroup.

Horswell and Pospisil (1995) retrospectively studied 33 patients with some receiving only orbicularis oris muscle repair, and the

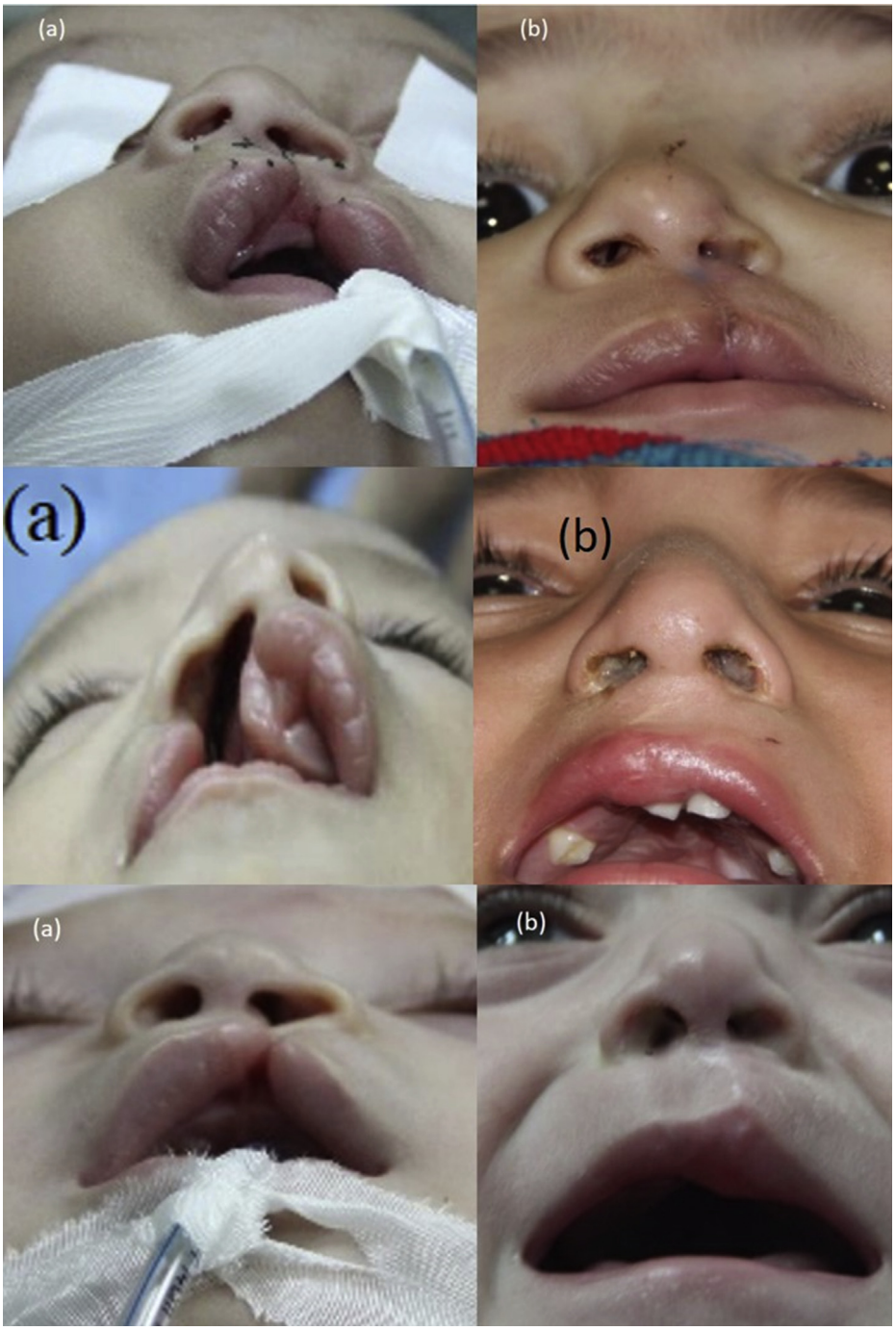

Fig. 7. (top) Nostril symmetry in control group; (a) preoperative (b) 3 months postoperative, (middle). Nostril symmetry in group 2A; (a) preoperative (b) 1 year postoperative, (bottom). Nostril symmetry in group 2B; (a) preoperative (b) 1 year postoperative.

remainder receiving peri-nasal muscle repair as well as orbicularis oris muscle repair. Results suggest that the orbicularis-only group had more tip deviation, less nasal protrusion, and more asymmetry in alar dimensions than did the combined-repair group, although there was no significant difference between groups. We found similar results in our study in that nasal tip symmetry was significantly better in groups 2A and 2B than in the control group ($p = 0.04$). Nasal symmetry was also significantly better in groups 2A and 2B ($p = 0.006$), although lateral alar displacement was not statistically significantly different.

Bagatain et al. (1999) retrospectively studied more than 100 patients undergoing nasalis muscle repair, and results in patients where this procedure was used as an isolated procedure demonstrated the procedure's effectiveness in reducing alar flaring, narrowing the nostril, and elevating the nasal sill. In our study, both groups with repaired nasalis muscles showed statistically significantly better nostril symmetry ($p = 0.006$) and alar size and form ($p = 0.001$).

Yoshimura et al. (2015) suggested that performing nasal repair at the time of primary cleft lip surgery has an adverse influence on

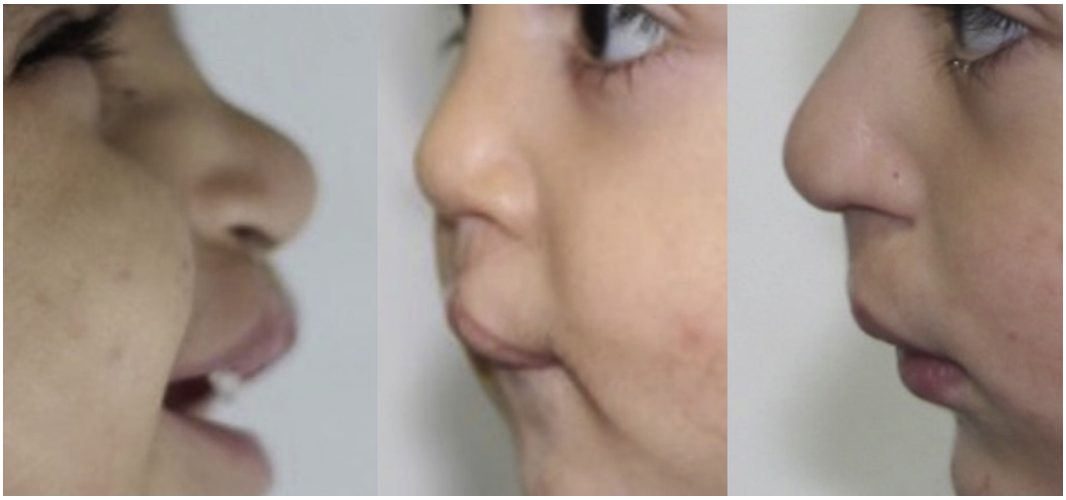

Fig. 8. (left) Tip of the nose from the cleft side 1 year postoperative in a control case, (middle) Tip of the nose from the cleft side 1 year postoperative in a case from group 2A, (right) Tip of the nose from the cleft side 1 year postoperative in a case from group 2B.

Table 3
Comparison between the studied groups as regards angles A and angle B measurements.

Variables	2A N = 16	2B N = 17	Control N = 12	P-value	LSD
Angle A					
Normal	43.2 + 11	46 + 6.8	42.3 + 6	0.43NS	
Cleft	30.1 + 12	40.4 + 9	29.7 + 10	0.01S	- Control versus A (p = 0.34NS) - control versus B (p = 0.002S) - A versus B (p = 0.01S)
Angle					
Normal	28.9 + 6	28.5 + 6	24.7 + 10	0.50NS	
Cleft	21 + 8	23 + 8.6	16 + 3.8	0.02S	- control versus A (p = 0.04S) - control versus B (p = 0.02S) - A versus B (p = 0.22 NS)

LSD: least significant difference, NS: non-significant, S: significant.

subsequent growth of the nose after 10 years of follow-up. Therefore, although our findings provide further evidence that the nasalis muscle technique helps produce a more symmetrical nose in cleft patients, we believe that these patients should be followed up regularly up to 10 years to evaluate the stability of the current results, determine changes occurring after growth and maturation of the face and lastly confirm long-term effectiveness of this technique.

Deepening the alar facial groove was a finding in the groups with repaired nasalis muscles and produced better esthetic results, in our study. However, nasalis muscle repair should be evaluated further because alar facial groove deepening is not reported in previous studies.

Table 4
Comparison between cleft versus normal sides as regards angles A and angle B.

Variables	2A N = 16	2B N = 17	Control N = 12
Angle A			
Normal	43.2 + 11	46 + 6.8	42.3 + 6
Cleft	30.1 + 12	40.4 + 9	29.7 + 10
% of change	29.8%	13%	31%
t	4.7	2.2	3.6
P	0.000HS	0.05S	0.000HS
Angle B			
Normal	28.9 + 6	28.5 + 6	24.7 + 10
Cleft	21 + 8	23 + 8.6	16 + 3.8
% of change	12.1%	17.8%	41%
t	0.9	2.6	4.9
P	0.37NS	0.02S	0.000HS

NS: non-significant, S: significant, HS: highly significant.

5. Conclusion

Our study showed better nasal symmetry with dissection of both origin and abnormal insertion of the nasalis muscle and repair of the origin, and patients showed nasal width, columella height, and nasal tip projection closer to the appearance of members of the non-cleft population of the same age.

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