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An Early Comparative Analysis of Presurgical Lip, Alveolus and Nose Approximation (PLANA) and Nasoalveolar Molding (NAM)

Neha Multani, BDS MS[1]

Natalie M. Plana, MD[1]

David A. Staffenberg, MD[1]

Roberto L. Flores, MD[1]

Pradip R. Shetye, DDS[1]

[1]NYU Langone Medical Center, Hansjörg Wyss Department of Plastic and Reconstructive Surgery

Corresponding Author: Pradip R. Shetye, DDS, BDS, MDS NYU Langone Health 222 E 41st Street, 22nd Floor New York, NY 10017 Office: (212) 263-3704 Fax: (212) 263-8492 Email: Pradip.Shetye@nyulangone.org

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Ethics Statement: Institutional Review Board (IRB) approval was obtained from our institution for the conduct of this study.

Consent Statement: Not applicable

Running Title: *Comparative Analysis of PLANA vs NAM*

Abstract:

Background: This study evaluates the Presurgical Lip, Alveolus, and Nose Approximation (PLANA) technique as a novel alternative to NasoAlveolar molding (NAM). The study hypothesizes that PLANA can achieve comparable Nasolabial outcomes to NAM while addressing its limitations, particularly by reducing the burden of care.

Methods: A retrospective review was conducted on 50 patients with non-syndromic unilateral or bilateral cleft lip and palate (CLP) treated with either NAM (n=28, including 2 treatment discontinuations) or PLANA (n=22). The overall physical burden of care was assessed in the full cohort. A subset of 25 patients with complete unilateral CLP (PLANA n=12; NAM n=13) was further analyzed to assess changes in nasolabial anthropometric ratios between cleft and non-cleft side using standardized 2D photographs taken pre-treatment (T1) and post-treatment (T2).

Results: The physical burden of care was significantly lower in the PLANA group, with 61.2 % fewer total office visits (5.2 vs. 13.4; $p<0.001$). The PLANA group also showed 72.19 % reduction in transient reversible side effects, such as oral, nasal, and cheek irritations (18.18% [n=4] vs. 65.38% [n=17]; $p<0.001$). PLANA achieved a significantly greater improvement in the columellar length ratio (0.53 vs. 0.37; $p = 0.026$), while NAM demonstrated a greater increase in the nostril height ratio (0.29 vs. 0.39; $p = 0.04$). No significant differences were observed in nostril width and alar base width ratios, or columellar deviation angle between the groups.

Conclusion: These findings suggest that PLANA significantly reduces the burden of care for patients with cleft lip and palate and may offer comparable nasolabial outcomes to NAM.

Keywords: Cleft Lip, Presurgical Infant Orthopedics, Nasoalveolar Molding, Presurgical Lip Alveolus Nose and Approximation, NoseAlign, The Burden of Care, PSIO, NAM, PLANA

Introduction:

Presurgical Infant Orthopedics (PSIO) plays a pivotal role in reducing cleft deformity, facilitating surgical repair, and enhancing both aesthetic and functional outcomes. Currently, several different types of PSIO therapies are used, including lip taping, passive and active oral plates, nasal elevators, nasoalveolar molding appliances (NAM), and lip adhesion surgery[1]. NAM remains the most widely used PSIO technique in North America; however, challenges such as high costs, frequent adjustment visits, reversible side effects (oral, nasal, and cheek irritation), and limited trained provider availability continue to contribute to its burden of care [2-6].

Presurgical Lip Alveolus Nose Approximation (PLANA) is an innovative advancement within the PSIO domain[7] **(Figure 1)**. PLANA therapy is based upon Matsuo's foundational concept of presurgical nasal molding using nostril retainers in infants with incomplete unilateral clefts and intact nasal floors.[8-10] In addition, PLANA employs the technique of external lip taping to gradually approximate the displaced cleft lip and alveolar segements[11,12].

PLANA therapy utilizes a series of three different sizes of NoseAlign devices and LipAlign adhesive tapes to approximate displaced nasolabial structures, without the need for an intraoral plate, offering a potential alternative to NAM **(Figure 2).** The NoseAlign device, made of medical-grade silicone, resembles nasal conformers and features an innovative angulated horizontal lip band with elastic clasps. Each NoseAlign device is worn daily for 20 to 22 hours for 2 to 4 weeks and the device size is changed as the infant's face grows[7]. The LipAlign tapes, made of hydrocolloid medical adhesive, are used for 20 to 22 hours daily and replaced each day, starting with a larger size and transitioning to smaller sizes as the cleft narrows during the course of the therapy.

The goals of PLANA and NAM therapies include improved nasal symmetry, approximation of the alveolar and lip segments, and reduce the complexity of the primary surgical repair[7,13]. However, PLANA and NAM differ significantly in achieving presurgical goals for primary cleft reconstructive surgery (Table 1). This study compares the burden of care and nasolabial outcomes between PLANA and NAM therapy.

Methods:

A retrospective review was conducted on patients treated with PSIO therapy by the senior author at NYU Department of Plastic Surgery during 2018–2019 (NAM) and 2023–2024 (PLANA). During the study period consecutively treated patients with unilateral and bilateral clefts (with or without cleft palate) were eligible for inclusion, while those with syndromic diagnoses were excluded from the study. The above criteria resulted in a total of 50 patients, of which 28 were treated with NAM and 22 with PLANA therapy.

Demographic variables collected included age, sex, race, and distance traveled to the treatment center. PSIO related variables included type of PSIO intervention, age at PSIO initiation, age at the start of nasal molding, total office visits, treatment duration, type and incidence of reversible transient side effects.

A subset of 25 patients with complete unilateral CLP (13 NAM, 12 PLANA) was selected for further analysis of anthropometric ratio changes related to nasal symmetry. Measurements were made on standardized 2D photographs following previously established protocols [14-17]. These measurements included changes in the ratios of nostril height, nostril width, alar base width, columellar length, and columellar angle deviation, comparing cleft to non-cleft sides at two defined time points (**Figure 3).** Time points were as follows: T1 at the initiation of PSIO; and T2 at the

completion of PSIO therapy. For the NAM group, T1 was calculated starting from appliance insertion, typically 7 days after the initial visit to allow for NAM device fabrication.

PLANA and NAM cohorts were comparable in pretreatment (T1) cleft deformity, as confirmed by statistical analysis of anthropometric measures with no significant differences observed between groups ($p > 0.05$). Paired t-tests evaluated intra-group changes and inter-group differences in ratios of the anthropometric measurements from T1 to T2. Prior to performing these tests, normality of the continuous variables was confirmed using the Shapiro-Wilk test ($p>0.05$ for all variables), justifying the use of parametric testing. Statistical comparison was not performed for variables where distributions were identical or clinically insignificant across groups. Reversible side effects were analyzed using Fisher's exact test due to small sample sizes. Two blinded raters independently conducted all measurements, with inter-rater reliability calculated to ensure consistency. Statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 27.0 (IBM Corp., Armonk, NY) and Microsoft Excel. Although some care-related variables differed between groups (e.g., age at nasal molding initiation), baseline cleft severity as measured by T1 anthropometric ratios was comparable. Given the small sample size, multivariable adjustment was not feasible. These baseline differences are acknowledged as limitations and highlight the need for future studies with larger cohorts and adjusted analyses.

Results:

A total of 50 patients were analyzed, of which 28 underwent NAM treatment while 22 underwent PLANA therapy **(Table 2).** Two (7.14%) patients in the NAM group discontinued treatment, whereas no discontinuation occurred in the PLANA group. The PLANA group began nasal molding (NoseAlign device) at a significantly younger average age (23.3 days) compared to the NAM (addition of nasal stent to the NAM oral plate) (48.5 days; $p<0.001$). Other variables

such as age at PSIO initiation (p=0.09), treatment duration (p=0.22), and travel distance (p=0.25) were comparable between groups.

The PLANA cohort reported a 61.2 % reduction in total visits (5.2 vs. 13.4, p<0.001) and showed a 72.19 % reduction in reversible transient side effects (18.18% vs. 65.38%, p<0.001). Specific side effects, including mucosal lesions (n=10, 38.46%) and oral thrush (n=4, 15.38%) were reported only in the NAM group. Additionally, no significant difference was observed for unscheduled visits between the two groups (PLANA =0.30 vs NAM =0.38, p=0.62)

Anthropometric analysis of 25 patients with complete unilateral CLP (PLANA=12, NAM=13) using 2D photographs showed statistically significant improvements in cleft-to-noncleft side ratios for nostril height, nostril width, alar base width, columellar length, and columellar angle post-PSIO in both groups **(Table 3).** Comparisons between the two groups indicated that PLANA achieved a significantly greater increase in the columellar length ratio (0.53 vs. 0.37; p = 0.026), while NAM demonstrated a greater increase in the nostril height ratio (0.29 vs. 0.39; p = 0.04). No significant differences were observed in nostril width and alar base width ratios, or columellar deviation angle between the PLANA and NAM groups.

Discussion:

This study assesses if PLANA, a novel technique, can achieve comparable Nasolabial outcomes to NAM with a reduced burden of care. Treatment adherence is the most critical factor in determining PSIO success[18,19]. This study reports a NAM discontinuation rate of 7.14%. Specifically, two patients discontinued NAM due to caregivers finding the NAM device difficult to manage, along with the infant experiencing feeding difficulties and discomfort—highlighting the challenges that can impact treatment adherence. Reported noncompletion rates for NAM therapy in the literature range from 13% to 25% [18-23]. Reasons reported for non-completion with

NAM therapy include intraoral sore spots, feeding difficulties, improper fitting of the oral plate, incorrect appliance usage, and an increased number of clinical visits[18,19,23]. In contrast, all PLANA treated patients completed their full course of care. NoseAlign, a pre-fabricated medical-grade silicone device used in PLANA therapy, is placed directly in the nostril and supported externally on the lip and cheeks, eliminating the need for the intraoral plate required to support the nasal stent in NAM therapy.

Although there was no statistically significant difference in the initiation of PSIO therapy between the PLANA and NAM groups (18.5 vs. 24.42 days, $p<0.09$), a significant difference was observed in the timing of nasal correction. The nasal cartilage deformity correction for the PLANA therapy group was initiated at a significantly earlier age at 3.3 weeks compared to the NAM patient cohort at 6.9 weeks ($p<0.001$). This early nasal intervention with PLANA therapy capitalizes on the increased plasticity of neonatal cartilage[9,10]. By initiating nasal molding at an earlier age, PLANA may more efficiently reduce the severity of nasal deformity. To optimize these benefits, it is recommended to begin PLANA therapy within the first 2 weeks after birth. The delay in initiating nasal deformity correction with NAM therapy is due to the primary focus on alveolar molding during the first few weeks of treatment. With NAM therapy the nasal stents are typically added only after the cleft alveolus is reduced to 5 mm or less[24]. Introducing nasal stents too early with NAM may lead to overexpansion of the nostrils[25,26].

Any PSIO therapy can impose an increased burden of care due to the prolonged treatment protocols [3,5,23,27]. In this analysis, the burden of care, assessed by comparing appointment frequency, reversible side effects, and travel distances demonstrated a 61.2% reduction in appointments with PLANA, consistent across both patients with unilateral (5.06 vs. 13.04, $p<0.001$) and bilateral (5.8 vs. 15.5, $p<0.001$) clefts. Additionally, PLANA therapy demonstrated

a 72.19 % reduction in reversible side effects (18.18% vs. 65.38%). The majority of the reversible transient side effects associated with NAM (53.84%) were related to the oral plate causing mucosal lesions and oral thrush (Table 2). This frequency of reversible side effects of NAM is consistent with previous reports[21,28-30]. While travel distances were comparable between groups, the significant reduction in appointment frequency and reversible side effect incidence with PLANA highlights the potential benefit of substantially reducing the burden of care using this form of treatment.

In patients with unilateral cleft lip, both PLANA and NAM independently demonstrated comparable efficacy in improving nasal symmetry, with statistically significant gains in cleft-to-noncleft side ratios for nostril height, nostril width, alar base width, columellar length, and columellar angle post-treatment. PLANA achieved a greater increase in the columellar length ratio ($p=0.026$). Conversely, NAM demonstrated a greater increase in the nostril height ratio ($p=0.04$) compared to PLANA. This difference may be explained by the unilateral approach of acrylic nasal stenting in NAM, where the stent is placed exclusively on the cleft side **(Figure 4a-b).** The targeted support provided by the NAM nasal stent on the cleft side only promotes elongation of the cleft nostril, resulting in a more significant change in the cleft-to-noncleft nostril height ratio **(Figure 5a-b).** In contrast, PLANA utilizes bilateral support through the NoseAlign device, which applies uniform molding forces to both nostrils. This symmetrical approach leads to more even changes in both the cleft and noncleft sides. As a result, the relative difference in nostril height ratio between the cleft and noncleft sides may be less pronounced with PLANA, as both sides undergo reshaping. Recent three-dimensional imaging studies have revealed that the non-cleft side of the nose is also distorted in infants with unilateral cleft lip[31-33]. Nasal deformities on the non-cleft side include narrowing of the nostril, shortened columella, and deviation of the alar base and subnasale

toward the non-cleft side. The bilateral nostril support provided by the NoseAlign device offers a significant advantage of PLANA therapy in addressing these distortions on the non-cleft side for infants with unilateral cleft lip (**Figure 6a-b).** Additionally, the NoseAlign device transitions to a passive role upon achieving the desired molding of the nasal cartilages, ensuring that the nasolabial structures maintain their corrected morphology without additional active intervention. This design minimizes the risk of overexpansion of nostrils, complications occasionally observed with the extended use of NAM devices[28,29].

Prior to the implementation of PLANA therapy, nasoalveolar molding (NAM) represented the sole presurgical infant orthopedic (PSIO) modality employed at the author's institution. Following the introduction of PLANA, a progressive transition in clinical practice was initiated in response to observed therapeutic benefits and favorable caregiver feedback. Caregivers consistently reported reduced stress and improved ease of use when managing PLANA at home, suggesting enhanced feasibility and adherence compared to NAM. These findings informed a strategic shift in institutional protocols, culminating in the complete replacement of NAM with PLANA as the standard PSIO approach for all eligible patients.

Although a comprehensive cost-benefit analysis was beyond the scope of this study, preliminary observations suggest that PLANA therapy may offer a more cost-effective alternative to traditional presurgical infant orthopedics. The reduced need for frequent in-person follow-up visits, along with the elimination of labor-intensive appliance fabrication, insertion and adjustments, has the potential to significantly decrease both institutional healthcare costs and the financial burden on families related to travel and time away from work[34,35]. These initial findings support the hypothesis that PLANA therapy could lead to substantial savings while maintaining or improving clinical outcomes. To rigorously evaluate this potential, we are

planning a prospective, comparative study to assess the cost-effectiveness of PLANA therapy in relation to nasoalveolar molding (NAM), the Latham appliance, and lip adhesion surgery. This future research will include a detailed analysis of direct and indirect costs, treatment timelines, and outcomes, providing a more definitive understanding of PLANA's economic and clinical value.

This early study is limited by its retrospective design, small sample size, and reliance on 2D photographic measurements, which may impact the generalizability of the findings. PLANA therapy does not require maxillary dental impressions. As a result, a direct quantitative comparison of alveolar changes using dental casts was not possible in this study. Future comparative prospective studies with larger cohorts and comprehensive evaluation of surgical and long-term outcomes are necessary to validate these results.

Conclusion

PLANA may offer an efficient and effective approach to presurgical infant orthopedics, with a significantly reduced burden of care compared to NAM. It minimizes the frequency of office visits and decreases reversible side effects while achieving nasolabial improvements comparable to NAM. Additionally, PLANA offers the unique advantage of enhancing the ala and columella on the non-cleft side in infants with unilateral cleft lip.

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Legends

Figure 1. Infant with unilateral cleft lip and palate with NoseAlign device size # 3 supported with 3M Steri-strip and 3/16 inch diameter, 3.5 oz orthodontic elastics. Note the bilateral support of the nasal cartilages and uprighting of the columella. The cleft lip is approximated with LipAlign medium-size, 3-inch wide medical adhesive tape.

Figure 2. An infant with bilateral cleft lip and palate treated with PLANA therapy; a) Pre-treatment presentation demonstrates, distorted nasal cartilage, a protruded premaxilla, a short columella, a small prolabium, and an increased alar base width. b) The same infant after completing 10 weeks of PLANA therapy using the NoseAlign devices sizes # 1 (for 2 weeks), #2 (for 4 weeks), and # 3 (for 4 weeks) along with LipAlign adhesive tapes. Note the retraction of the premaxilla, approximation of the lips, narrowing of the alar base width, reshaping of the nostrils, and the elongation of the columella. c) Two months post-surgery presentation; This infant used the NoseAlign device size #1 as a retainer starting three weeks after surgery

Figure 3. The figure illustrates the anatomical landmarks identified on 2D photographs of infants with unilateral cleft lip. The ratio for nostril height, columella length, alar base width, and nostril width was calculated for both the cleft and non-cleft sides, pre-PSIO and post-PSIO, for comparison between the PLANA and NAM groups.

Figure 4. Comparison of nasal stenting approaches in infants with unilateral cleft lip using PLANA and NAM therapies. (a) NoseAlign device (Size #3) used in PLANA therapy, providing bilateral support to both the cleft and non-cleft alar cartilages. (b) NAM device with a unilateral nasal stent, supporting only the cleft side alar cartilage. Note the lack of correction on the non-cleft side.

Figure 5. An infant with unilateral cleft lip and palate treated with NAM therapy. a) Pre-treatment: Note the wide cleft, distorted nasal cartilage, deviated nasal septum, and wide alar base width. b) Post-NAM: In the same infant after completion of the NAM therapy there is a notable reduction of the cleft width, narrowing of the alar base width, and molding of the alar cartilage on the affected side.

Figure 6. An infant with unilateral cleft lip and palate treated with PLANA therapy. a) Pre-treatment: Note the wide alveolar cleft, distorted nasal cartilage, deviated nasal septum, wide alar base width, and narrowing of the nostril, and shorten columella on the non-cleft side. b) Post-PLANA: There is a significant reduction in cleft width, improved lip approximation, narrowing of the alar base, and molding of the alar on the cleft side. Additionally, molding of the alar cartilage and an increase in columella length on the non-cleft side are observed, attributed to the bilateral nostril support provided by the NoseAlign device.

Table 1: Comparison of PLANA and NAM therapy for infants with Cleft Lip and Palate

Table 2: This table presents a comparison of the key characteristics between the PLANA and NAM treatment groups, including demographic information, details of clinic visits, and any reversible side effects observed during treatment.

Table 3: Measurements of nasal anthropometric variables calculated as a ratio of the cleft side compared to the non-cleft side in patients with unilateral cleft lip for PLANA and NAM treatment groups

Table 1

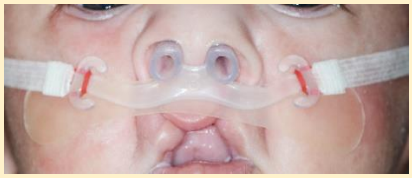
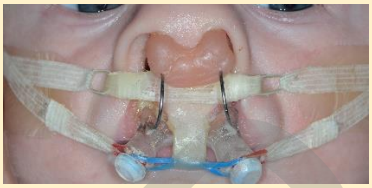
Features	PLANA Therapy	NAM Therapy
Image		
Device Components	Nasal and labial components	Nasal and oral components
Device Application	Extraoral	Extraoral and Intraoral
Device Fabrication	Prefabricated	Custom fabricated
Device Availability	Universal for infants with UCLP and BCLP	Custom for infants with UCLP and BCLP
Intra-oral Impression	Not required	Required (Polyvinyl siloxane or Digital impression)
Device Material	Medical Grade Silicone	Acrylic resin-Polymethyl methacrylate
Provider Training	Easy adoption; minimal training required	Specialized training required; significant learning curve
Facility	No dental laboratory required	Requires a dental laboratory for device adjustments
Device adjustments for therapy progress	Simple -swap NoseAlign device size.	Complex addition and removal of acrylic to the oral plate and nasal stents
Appointments	Every 2-4 weeks	Weekly visits required
Patient leaving far from Cleft center	Advantage -fewer office visits	Disadvantage – frequent in-person office visits
Remote monitoring	Option	Not an option
Infants adjust to the device	Easier - no oral component	Slower - baby must adapt to oral plate
Impact on oral tissue	No intraoral contact	Risks of oral mucosal ulcers
Parental involvement at home	Simple NoseAlign insertion and taping	Requires training for oral plate handling and taping
Effect on the Nose	Immediate – NoseAlign functions immediately after insertion	Delayed – nasal stents added to the oral plate 4-6 weeks after alveolar molding

Table 2:

	PLANA (n=22)	NAM (N=26)	P-value
Cleft type and severity			
Unilateral Complete	12 (54.55%)	13 (50.0%)	NA
Unilateral Incomplete	5 (23.0%)	9 (34.6%)	
Bilateral Complete	4 (18.18%)	3 (11.5%)	
Bilateral Incomplete	1 (4.54%)	1 (3.8%)	
Sex			
Male	16 (72.73%)	19 (73.0%)	NA
Female	6 (27.27%)	7 (26.9%)	
Race			
White	10 (45.45%)	11(42.3%)	NA
Asian	6 (27.27 %)	5 (19.2%)	
Hispanic	3 (13.64%)	6 (23.0%)	
Black	1 (4.54%)	4 (15.3%)	
Not specified	2 (9.09%)	0 (0.00%)	
Distance Traveled			
Average miles	15.35	22.64	0.254
Total number of visits (average)			
Overall	5.2	13.4	<0.001
Unilateral	5.06	13.04	<0.001
Bilateral	5.80	15.50	<0.001
Unscheduled	0.30	0.38	0.62
Average age at start of PSIO			
Days	18.15	25.42	0.09
Average age at start of Nasal Stenting			
Days	23.3	48.5	<0.001
Total duration of PSIO (weeks)			
Overall	12.4	13.45	0.22
Unilateral	12.2	12.18	
Bilateral	12.7	14.7	
Reversible Side Effects*			
Type [incidence (%), frequency]			
Oral mucosal lesions/sores	0	10 (38.46%), (15)	<0.001
Oral thrush	0	4 (15.38 %), (4)	
Facial skin/cheek irritation	2 (9.09%) (2)	5 (19.23%), (6)	
Nasal mucosa irritation/erythema	2 (9.09%) (2)	2 (7.69%) (2)	
Overall Total	4(18.18%)	17(65.38%)	

*Fisher's exact test

Table 3:

		PLANA group (n=12)	P-value (PLANA pre v. post)	NAM group (n=13)	P-value (NAM pre v. post)	P-value (PLANA v. NAM)
Nostril Height Ratio	Initial(T1)	0.41	<0.001	0.43	<0.001	
	Post(T2)	0.70		0.82		
	T2-T1	0.29		0.39		0.04
Nostril Width Ratio	Initial	4.13	0.028	3.68	0.027	
	Post	2.09		2.52		
	T2-T1	-2.04		-1.16		0.117
Alar Base Width Ratio	Initial	3.63	<0.001	3.64	0.007	
	Post	2.56		2.66		
	T2-T1	-1.07		-0.98		0.683
Columellar length Ratio	Initial	0.31	<0.001	0.20	<0.001	
	Post	0.84		0.57		
	T2-T1	0.53		0.37		0.026
Columellar Angle	Initial	42.92	<0.001	37.08	<0.001	
	Post	58.64		58.54		
	T2-T1	15.72		21.46		0.982

Figure 1

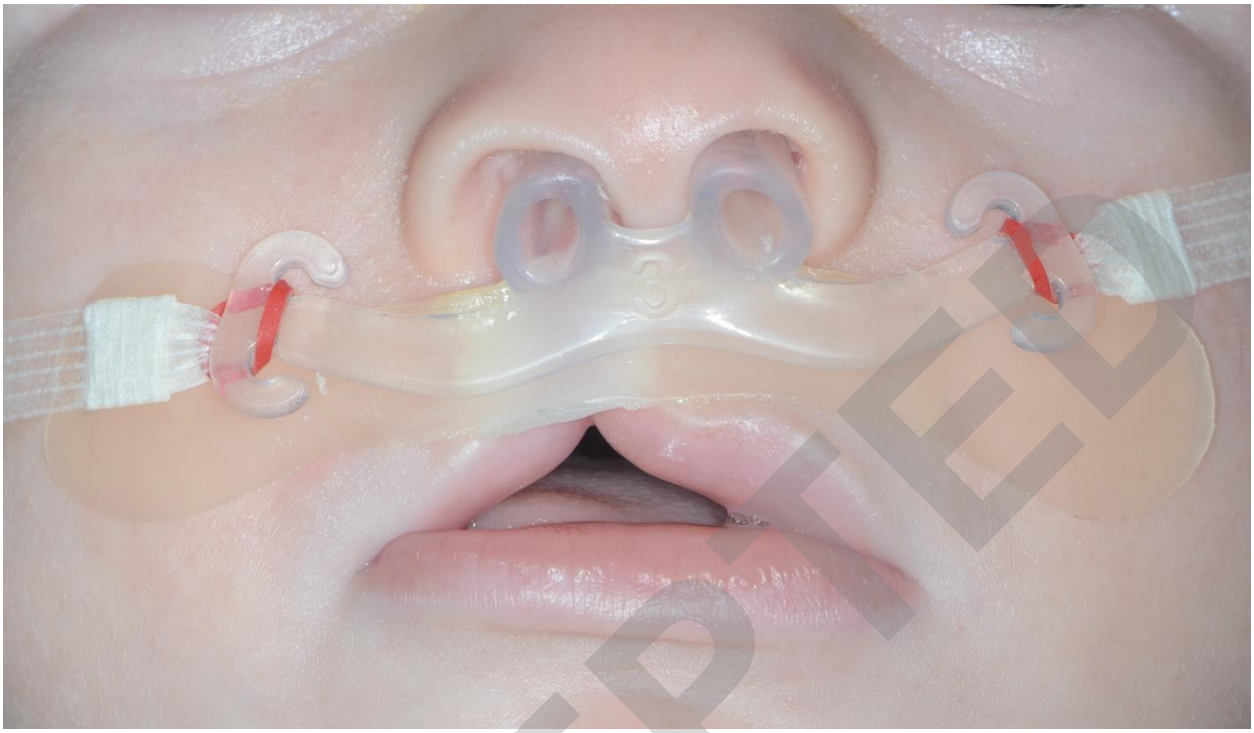


Figure 2a

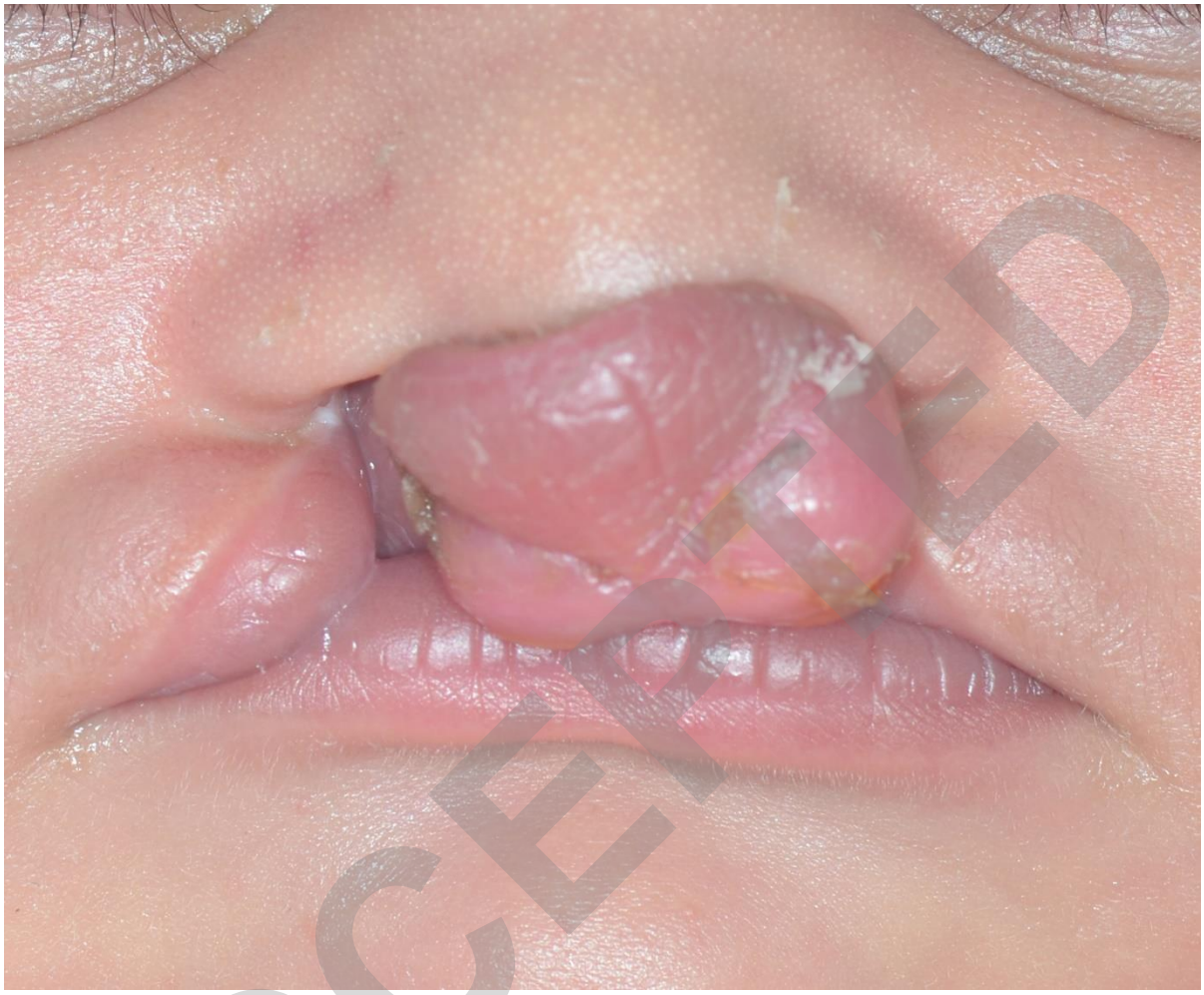


Figure 2b

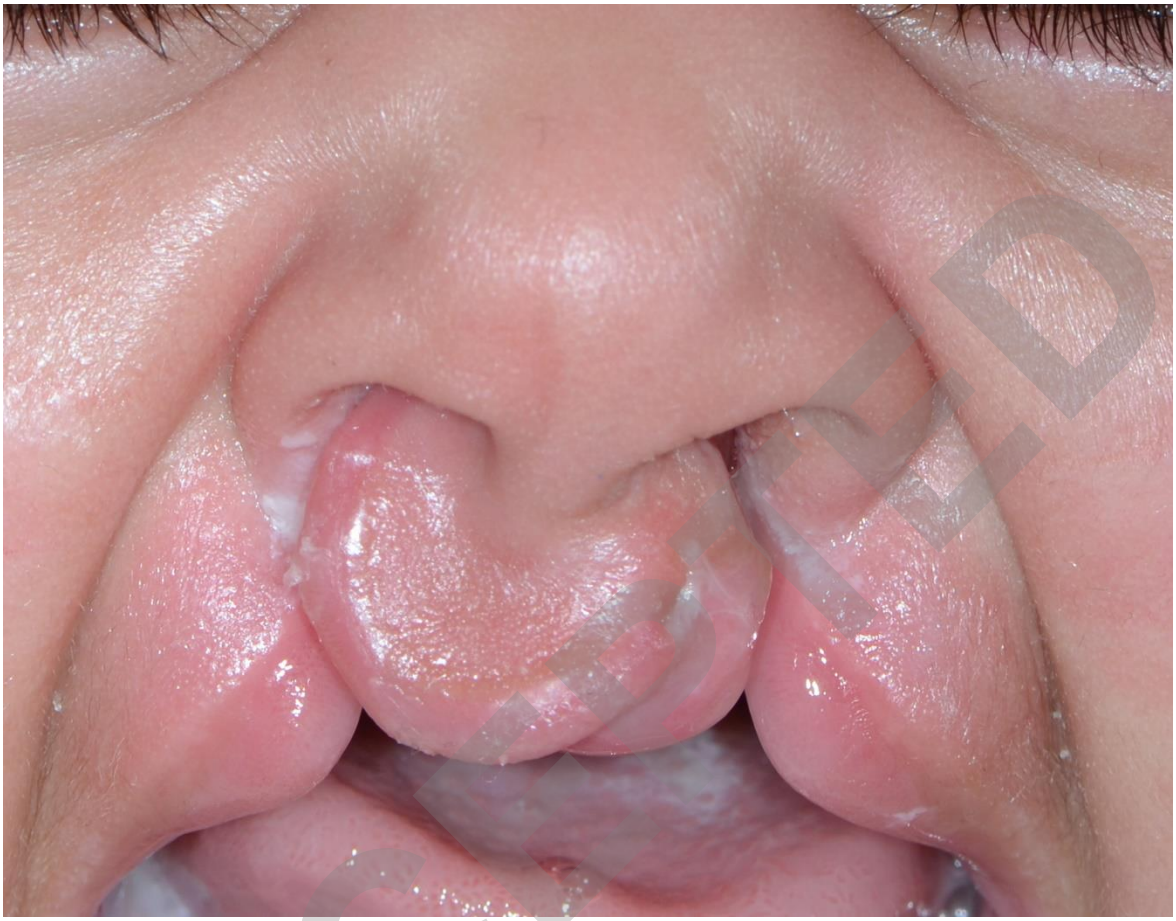


Figure 2c

Figure 3

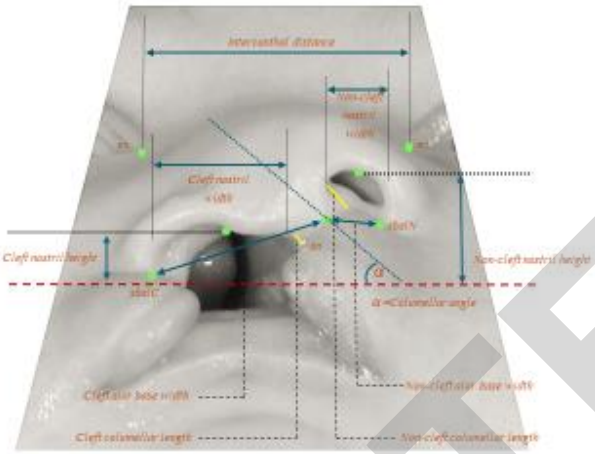


Figure 4a

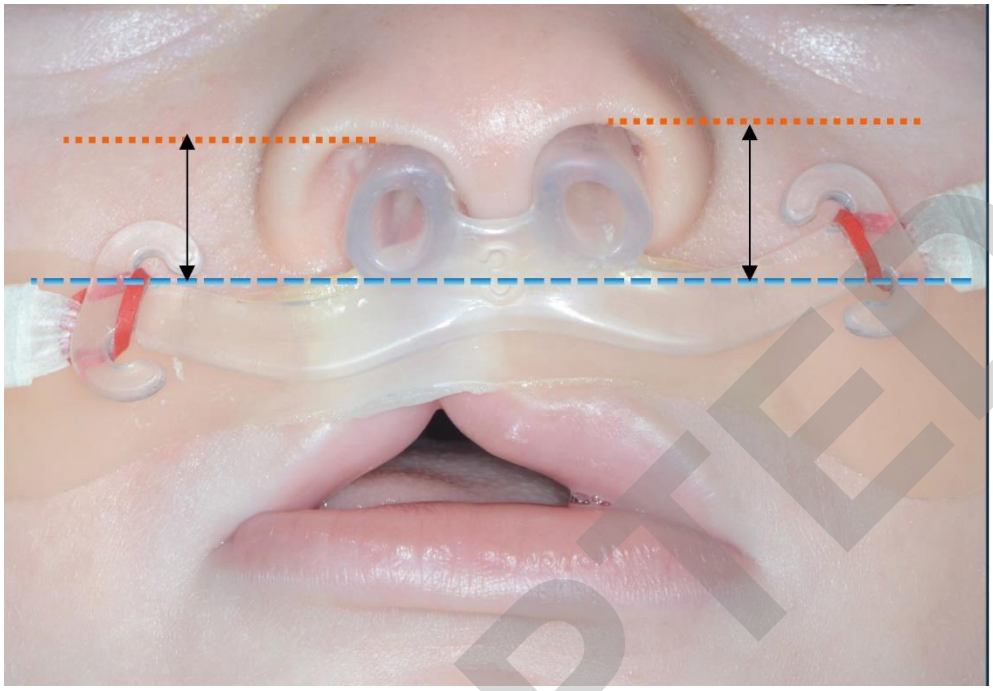


Figure 4b

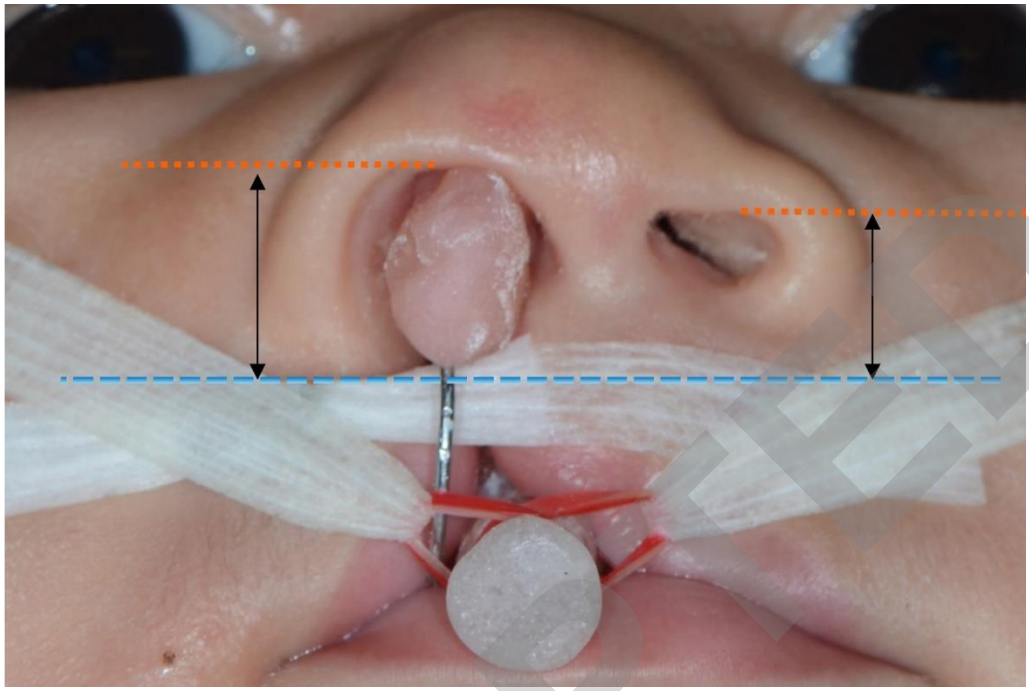


Figure 5a

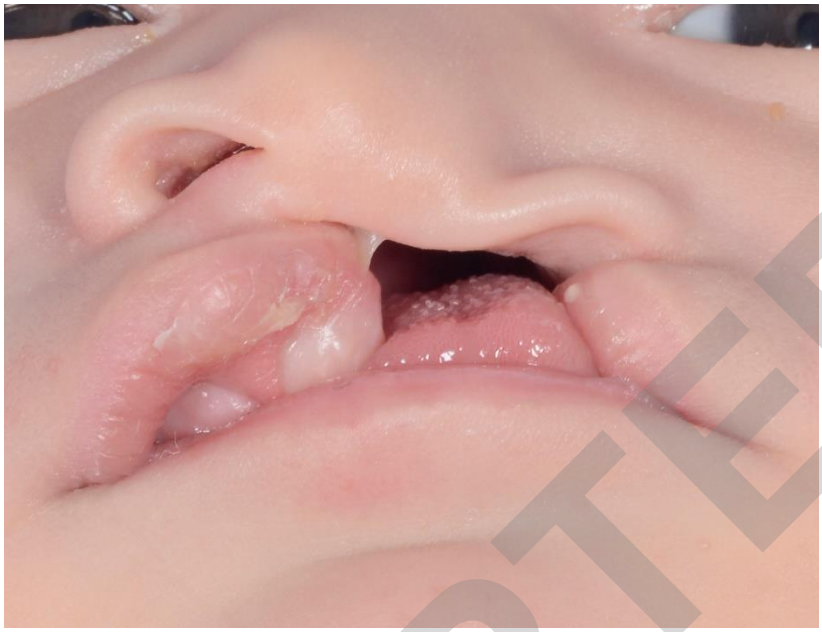


Figure 5b

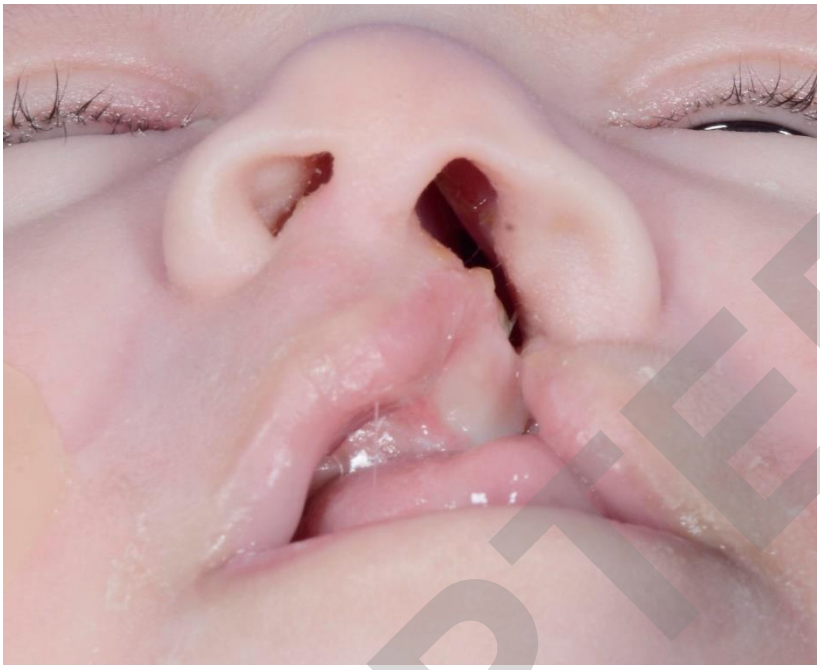


Figure 6a

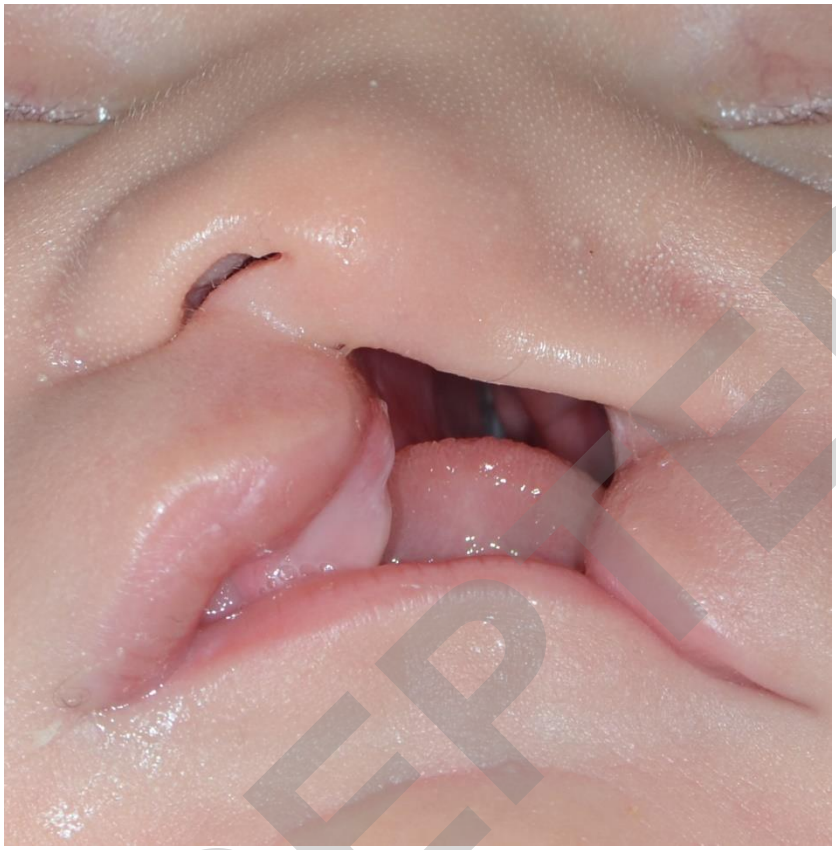


Figure 6b