

Cassio Eduardo Raposo-Amaral  
and Cesar Augusto Raposo-Amaral

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## 9.1 Introduction

### 9.1.1 Concept

Bilateral cleft lip has some unique embryological and anatomical characteristics and therefore requires a different therapeutic approach. The deformity is a consequence of fusion failure or lack of mesodermal migration that generates a discontinuation between the nasomedial process and the lateral maxillary process that separate the lip and alveolar arch into three pieces (Pruzansky 1971; Heidbuchel et al. 1998).

The bilateral cleft presents a wide phenotypical spectrum that can be shown as an asymmetric form evolving the lip and maxillary arch in different degrees. Possible manifestations involve the presence of Keith scar, preforamen incisive incomplete or complete, and transforamen incisive, with presence or absence of Simonart band (Spina et al. 1972). The involvement of the lip may similarly occur on cleft sides or be totally uneven, requiring an individualized treatment for each case. The prolabium and premaxilla are shown in the preforamen and transforamen incisive forms.

The prolabium contains the portion corresponding to the philtrum with absence of the *orbicularis muscle* (Khosla et al. 2012). The premaxilla remains connected to the vomer and projected in relation to the maxillary arch. Common nasal alterations seen in the bilateral clefts are the wide alar base with laterally flared nasal valve with malpositioning of the lower lateral cartilage, wide nasal base, short columella, malpositioning of the domes, and bifid nasal tip.

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C.E. Raposo-Amaral, M.D., Ph.D. (✉)  
Institute of Plastic and Craniofacial Surgery, SOBRAPAR Hospital,  
Campinas, São Paulo 13084-880, Brazil

Universidade de São Paulo, São Paulo, Brazil  
e-mail: [cassioraposo@hotmail.com](mailto:cassioraposo@hotmail.com)

C.A. Raposo-Amaral, M.D.  
Institute of Plastic and Craniofacial Surgery, SOBRAPAR Hospital, Campinas, São Paulo, Brazil

A particularity of the bilateral clefts that should be emphasized is the symmetry of the deformities and the similarity between the sides of the affected nose. Generally, there is a symmetrical involvement of the alar base. As the lower lateral cartilage is malpositioned and anatomically lower compared to the normal position, it results in reduction of the projection of the nasal tip and columella height. However, the nasal base often remains symmetrical.

The palatine cleft tends to be wider in bilaterals with the narrow palatal shelves and centered vomer. All these characteristics make the rehabilitation of the bilateral cleft lip and palate a major challenge for the cleft team. The plastic surgeon should be aware of the three main variables that are the keystones of the rehabilitation: speech, nasolabial aesthetics, and facial growth.

Aiming to overcome the difficulties and limitations of surgery in a bilateral cleft, a delicate and atraumatic technique, the development of principles to maintain the long-term satisfactory outcome and avoid recurrence as well as the ability to deal with complications are critical (Cutting et al. 1998).

### 9.1.2 Principles

The modern principles of the bilateral cleft lip repair can be summarized below which description is credited to Mulliken (Mulliken et al. 2003):

- Try to establish symmetry or decrease the asymmetry.
- Realign the alveolar arch especially for those with severely protruding premaxilla using presurgical orthopedics or premaxilla setback.
- Insert the vertical lip scar into the aesthetic lip subunits lines that can possibly mirror a natural philtral column.
- Construct the median tubercle and Cupid's bow using lateral labial elements and mobilize the *orbicularis oris* muscle to the middle, whenever possible.
- Reposition the lower lateral cartilage and refine nasal tip and columella.

Ideally, a successful protocol is based on intelligible speech, satisfactory functional and aesthetic outcome, absence of sequels, and facilitation of the orthodontic treatment with inhibition of major facial growth disturbance. In most cases a minor degree of maxillary retrusion is expectable as a consequence of scar tissue produced by the closure of the lip and palate or both. Some of the trends and techniques used in the bilateral are not a consensus among the cleft teams worldwide, such as whether or not to use a presurgical orthopedics, or surgically manipulate the severely protruded and deviated premaxilla and finally to perform the lip repair in one or two stages. It is important to emphasize our understanding as a craniofacial plastic surgeons that the maxillary retrusion can be predictably corrected by orthognathic surgery either using distraction osteogenesis in younger patients with severe discrepancy between the jaws or by immediate movements at an adult age. Thus, the keystone for patient rehabilitation should be based on the normal speech first, satisfactory nasolabial appearance without the bilateral cleft stigmata, and second and normal facial growth third.

### 9.1.3 Infant Presurgical Orthopedics

The concept and philosophy of presurgical orthopedics was initially proposed by McNeil in 1954, who developed a device for premaxillary repositioning before surgery (Winters and Hurwitz 1995). Since then there were several modifications as done by the Brazilians Spina and Lapa that utilized elastics to set back the premaxilla in the severe bilateral patients (Lapa and Spina 1969).

During the last five decades of evolution and progress, the infant preoperative orthopedics has significantly changed with the development of molding of the nasoalveolar region and the premaxillary segment. One of these devices of premaxilla setback was developed by Georgidane (Georgiade et al. 1989) and modified by Millard and Latham (Millard and Latham 1990). It consists of acrylic plates fixed to the maxillary shelves and through an elastic system daily activated that can bring the premaxilla back and expand the anterior palatal segments (Millard and Latham 1990).

Cutting and Grayson described a nasoalveolar molding apparatus that consists of a passive plate to reduce the width of cleft and reshape the nasal contour by elevating the nostril and can be adapted to elongate the columella (Grayson and Cutting 2001). Weekly changes and adaptations are necessary to maximize the potential benefits of this passive device.

Bennun and Figueroa proposed a more loosely intraoral plate that takes advantage of the force of the tongue during movements to push upward the nasal nostril through a flexible spring connected to the acrylic plate (Bennun and Figueroa 2006; Bennun and Langsam 2009).

The major advantages of infant presurgical orthopedics has been the alignment of the alveolar arch, facilitation of feeding, improvement of the speech, and modification of nasolabial morphology (Ross and MacNamera 1994; Uzel and Alparslan 2011). In addition, it may have reduced the number of secondary surgeries by generating longitudinal nasal symmetry.

A recent study showed that surgeons rated the severity of the cleft as minimal in patients prepared with NAM in comparison to their controls without NAM preparation, and pointed out that less cleft severity yields the better outcomes (Rubin et al. 2015).

NAM and Latham devices reduced the width of the cleft by bringing back the premaxillary segment and promoting similar objectives. Thus, the NAM could facilitate the closing of the palate shelves and alveolar gaps and allow maxillary stability, absence of oronasal fistulas, and better nasal positioning and labial philtrum format. However, Uzel and Alparslan (Uzel and Alparslan 2011) have found in a systematic review that only 09 studies with high-level evidence showed changes on nasal symmetry after PSO and NAM and only one had a control group. One study by Ross and MacNamera in a bilateral cleft did not identify differences in aesthetics scores between groups with and without PSO (Uzel and Alparslan 2011). Opponents of NAM have implicated its use to additional cost and labor intensiveness (Xu et al. 2009), lack of expansion of the maxillary segment, and inability to align the protruded premaxillary segment to alveolar arch and its complication associated to

inflammation of the mucosa and ulceration of the skin when the prolabial band is tight, and eventual airway obstruction. It has been postulated that the NAM therapy does not have any influence on facial growth as other type of active apparatus that may cause facial growth disturbance, maxillary retrusion, and crossbite owing to pressure at an infant age (Ross and MacNamera 1994; Uzel and Alparslan 2011). In addition, the treatment of bilateral cleft has its inherent implication on facial growth, restricting the vertical and anterior dimension of the maxilla. Thus, it can be difficult to determine if the NAM or the surgeries that are responsible for the restriction of facial growth.

As stated by Meara and Abbot, NAM appears to be a promising technique that still requires a high-level evidence to demonstrate its efficacy (Abbott and Meara 2012). The group of Chang Gung University has shown in a controlled clinical trial comparing different groups with or without NAM therapy that the association of NAM and primary surgical therapy yielded the optimal result by approximating the operated anatomy to normal (Chang et al. 2014).

In Brazil very few centers adopted infant presurgical orthopedics technique as it is not covered by our unified health insurance (SUS); on the other hand a majority of centers of North America use some type of presurgical orthopedics (Sitzman et al. 2008).

Thus, further studies may identify the role of facial orthopedics on decreasing the tension of the final cutaneous suture, scar contraction, and lip height deficiency, especially in severe patients with wide clefts. These population are best candidates for NAM therapy or any other type of IPSO.

## 9.1.4 Surgical Technique

### 9.1.4.1 Surgical Goals

One of the greatest challenges in correcting a bilateral cleft is to construct a well-defined curvilinear Cupid's bow with emphasis on the midline white roll that is absent in bilateral prolabium. Construction of a philtral dimple and elevated ridges as previously pointed out "can be beyond one's surgical skills" and it may be highly depended on individuals' response to scar formation and contraction (Rogers et al. 2014). The final scar should be symmetrical and simulate the philtrum column bilaterally. The transition of the dry and wet lip vermilion on the lateral side toward the medial side should be smooth with an inconspicuous scar in the midline and without a color or volume mismatch in the midline tubercle. The static and dynamic lip anatomy should look equally satisfactory as the *orbicularis oris muscle* adequately healing determines the ability to move the lips without compromise of pickling and whistling.

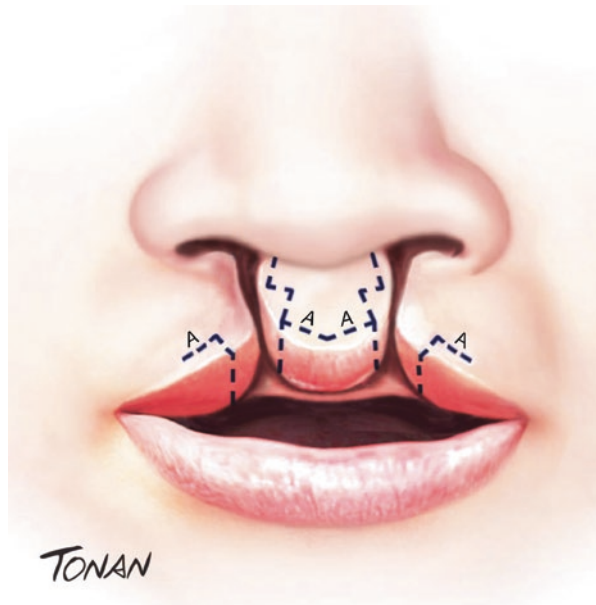
The nose should be symmetrical and as close to normal as possible. Common postoperative deformities have been a consequence of severely intrinsic anomaly

or mistaken preoperative markings (Losee et al. 2003) or might be a lack of full understanding of the bilateral deformity and current philosophy and principles to be followed as most of the poor results in Brazil come from the nonspecialized centers.

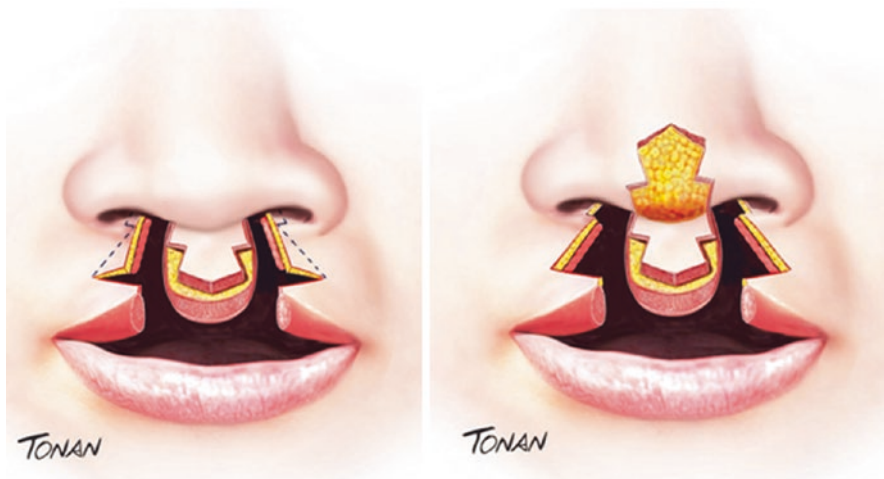
#### 9.1.4.2 Markings

The peak of the Cupid's bow is initially marked, and then two points are marked laterally 3 mm from the first one; thus the width of the philtrum is usually 6–7 mm. The vertical line that simulates the philtrum column is slightly angulated toward 1–2 mm below the columellar line. The base of the prolabium flap is usually narrow to 5 mm of measurement in its width (Fig. 9.1).

The peak of the Cupid's bow is marked laterally, placing the lateral point at the attenuation of the white roll as previously emphasized. Then we marked also a 3 mm straight line (similar distance of half dimension of the philtrum width) in the lateral skin component at 01 mm above the white roll (distance named in our drawing as distance A). This incision will facilitate rotation of the lip vermilion as it will not efface the white roll. If the incision is placed in the white roll there is a tendency to efface the natural curvature of the bow and the continuation of the tiny roll. The lateral prolabium tissue is used for the nasal floor if needed. A small triangular region of skin is deepithelialized as marked in Fig. 9.2.



**Fig. 9.1** Illustration of the preoperative markings. Note the strip of skin above the white roll marked in a dotted line (letter A). The lateral segments are designed to build the median lip tubercle



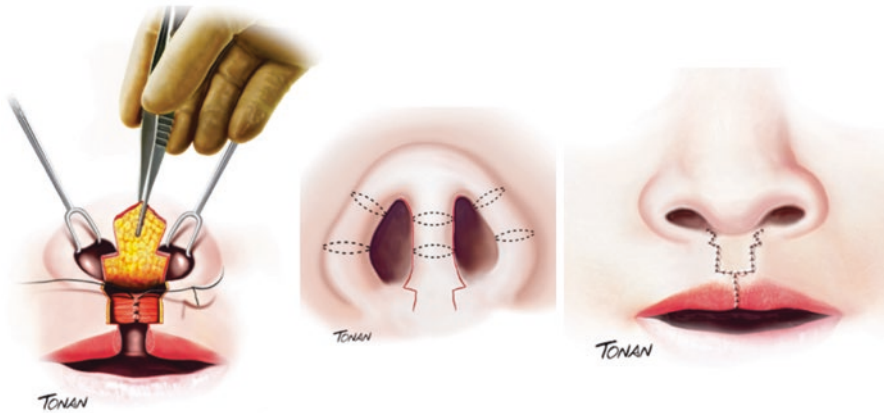
**Fig. 9.2** Illustration of the surgical sequence. *Left*: The lateral segments are incised and rotated medially and then the area formed by the most caudal point on the lateral segment and the upper point on the cleft edge (bilateral triangular area) is deepithelialized. This area allows sagittal projection of the philtrum column. *Right*: The philtral flap is elevated toward the columella, and the septal columellar incision is performed

### 9.1.4.3 Operative Technique

The Cupid's bow peak is initially marked, and then two points are marked laterally, 3 mm from the first one; thus, the width of the philtrum is usually 6 mm. The vertical lines that simulate the philtrum column are slightly angulated toward 1 to 2 mm below the columellar line. The base of the prolabium flap is usually narrow, measuring 4 mm in its width.

The peak of Cupid's bow is marked laterally, placing the lateral point at the attenuation of the white roll, as previously emphasized. Then we also marked a 3 mm straight line (similar distance of one-half the dimension of the prolabium width) in the lateral skin component at 1 mm above the white roll (named distance A in our drawing). This incision will facilitate rotation of the lip vermilion, as it will not efface the white roll. The lateral prolabium tissue is used for the nasal floor, if needed.

The first maneuver usually elevates the prolabium and goes in the direction of the septum-columellar junction that is also cut. This incision is extended to the tip mucosa, as the nasal tip can be exposed for suturing of the medial crura of the alar cartilages after elevation of the prolabium-columellar flap. The remaining prolabium vermilion is used to offer tissue to the gingivobuccal sulcus; therefore, little tissue is trimmed. The lateral incision starts at the transverse incision determined as letter A (Fig. 9.2). This 3 mm incision in the lateral segment (A incision) is performed 1 mm above and parallel to the white roll and rotates it down, toward the midline at the central portion of the lip vermilion. The lateral skin tissue within the lateral vermilion-mucosal flaps is dissected and prepared for a latter rotation forming the central lip bow. The lateral incisions are performed in a triangular fashion



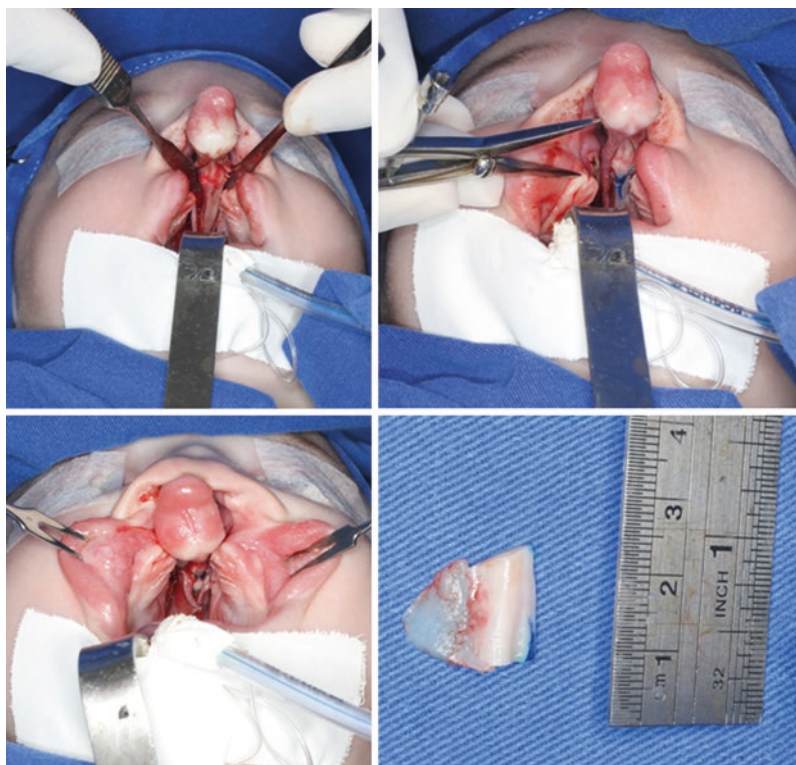
**Fig. 9.3** *Left:* The *orbicularis oris* muscle is isolated from the lateral labial segments, and the muscle fibers are directed to the midline to form the central lip. *Center:* Details of the suturing of the medial alar crus and alar cartilage that prevent vestibular webbing. *Right:* Final aspect of the lip repair with well-defined curvilinear Cupid's bow. The strip of skin avoids the scar into the white roll

from the most caudal point on the lateral segment to the upper point on the cleft edge. This area of skin is deepithelialized (Fig. 9.2). The supra-periosteum dissection is accomplished by a gingivobuccal incision. The extension of the dissection is usually dictated by the severity of the cleft, as the most severe clefts require the widest dissection. The floor of the nose can be constructed using the L flap (lateral flap) sutured to the vestibular mucosa and the S flap (nasal septum flap), as previously described for unilateral cleft lip repair (Cutting and Dayan 2003). The two lateral segments are brought together. The *orbicularis oris* muscle is isolated and sutured in the midline. The skin is gently sutured with nylon thread and an atraumatic needle, as we previously described for unilateral clefts, and removed 7 days after surgery under sedation (Raposo-Amaral et al. 2012, 2014) (Fig. 9.3).

#### 9.1.4.4 Premaxillary Setback and Lip Adhesion

Premaxillary setback combined with lip adhesion was performed in all patients with protruded and deviated premaxilla (over 10 mm). The projection of the premaxilla is measured from the lateral segments, alveolar arch and the premaxillary arch. This distance determines the length of bone resection to be performed. The mucosa is incised and undermined toward the septum. The maxillary growth center bulb is identified, and the osteotomy is performed 2 mm caudally of this bulb with a long and small reciprocating saw (Aesculap®). The triangular resection of the cartilaginous septum is performed either with a scissor or a number 11 blade. The bone and septal cartilage are removed (Fig. 9.4, below), and two bony segments are brought together and fixed with one number 0-wire (Ethicon®). This wire is twisted and trimmed and covered by the mucosa sutured with a 4-0 polyglactin suture (Vicryl, Ethicon®) that can be removed during the palatoplasty if needed. The basis of the premaxillary setback was described by Millard (1977). The final lip repair is performed after palate repair and 12–13 months after premaxillary setback and lip adhesion (Fig. 9.5–9.13).





**Fig. 9.4** *Left and above:* Photograph of a bilateral patient showing a premaxillary projection of 25 mm. The *methylene blue* marked the amount of resection to be performed to set back the central segment and to fit it into the alveolar arch. *Right and above:* The caliper was used to measure the amount of premaxillary projection. *Left and below:* Photograph of the same patient after the premaxillary setback. The alveolar arch is aligned. Lip adhesion is performed in conjunction with the premaxillary setback and the final lip repair after palate repair. *Right and below:* The osseous cartilaginous resection in a triangular fashion of the vomerine-septal region



**Fig. 9.5** *Left:* Preoperative photograph of a bilateral complete cleft lip and palate patient. *Center:* Postoperative photograph of the same patient at 3 months after surgery. *Right:* Postoperative photograph of the same patient at 2 years after surgery





**Fig. 9.6** *Left:* Postoperative basal view of the same patient and *Right,* lateral view



**Fig. 9.7** *Left:* Preoperative photograph of an asymmetric bilateral cleft lip and palate patient. *Center:* Postoperative photograph of the same patient at 3 months after surgery. *Right:* Postoperative photograph of the same patient at 2 years after surgery



**Fig. 9.8** *Left:* Preoperative basal view of the same patient, and *right,* postoperative basal view



**Fig. 9.9** *Left:* Preoperative photograph of a 4-year-old bilateral complete cleft lip and palate patient showing a protruded and deviated premaxilla. *Center:* Postoperative photograph of the same patient at 3 months after surgery. *Right:* Postoperative photograph of the same patient at 2 years after surgery



**Fig. 9.10** *Left:* Preoperative basal view of the same patient, and *right,* postoperative basal view



**Fig. 9.11** *Left:* Profile view of the same patient, and *right,* postoperative profile view



**Fig. 9.12** *Left:* Preoperative frontal photograph of a patient with a severely deviated and protruded premaxilla. *Right:* Postoperative frontal photograph after premaxillary setback and lip adhesion and final lip repair



**Fig. 9.13** *Left:* Preoperative basal view of the same patient, and *right,* postoperative basal view



#### 9.1.4.5 Controversies

The bilateral cleft lip repair carries controversies. Among the highly important ones are whether to repair the lip in one or two stages or surgically primarily retrude the premaxilla.

Historically, the treatment of the bilateral lip repair was performed in two stages by operating the most severe side first.

Victor Spina in 1964 proposed the method of staging the operations in patients with protruded premaxilla to avoid maxillary growth restriction, probably one of the most used techniques in Brazil to date (Spina 1964). He performed adhesion of one side first, then the other one, and at 3 years of age the definitive repair by using the philtrum mucosa to construct the median tubercle with the lateral segments. Similar principles became popularized worldwide by Manchester (1970). In fact, Spina's main concern was the facial growth by avoiding a tight lip. In this technique the *orbicularis oris* muscle is rarely sutured in the midline and the philtrum width tends to be wider in comparison to lips treated by the modern current techniques. Current trends construct a lip surrounded by a straight-line bilateral scar (one in each side). In addition, old techniques that advocate using the philtrum mucosa to recreate the median tubercle often end up with a color mismatch between the lateral mucosa and philtrum mucosa as well as lip volume discrepancy in the midline known as whistle deformity, a striking stigmata of bilateral cleft. The wide philtrum created by these principles is very difficult to correct in a later stage and has been a wish among patients of our clinic. In addition, Nagase (Nagase et al. 1998) has shown no growth disturbance after *orbicularis oris* muscle repositioning. However, it is our belief that it is dependable on the degree of protrusion of the premaxillary segment.

Millard also described a staged method in which a forked skin flap was primarily banked to improve columella height in a second stage in addition to nasal suspension (Millard 1971). The banked flap has been no longer used by cleft surgeons around the globe as it effaces the natural columellar-lip junction. There is a continuous debate over performing the lip correction in one or two stages. We believe that performing it into a single stage is easier to achieve the final symmetry. Exception to this rule is when the premaxilla is highly protruded and deviated, and then we perform the premaxilla setback and lip adhesion first and then in a second stage perform the lip repair simultaneously addressing the both sides. The setback is reserved either for patients with severely protruded or a deviated premaxilla in 3-month-old child or for primary patients with late presentation.

The key element to achieve the proper fullness of the tubercle is the preoperative markings of the peak of the Cupid's bow. This point should be marked at the point where the white roll started to be attenuated (Xu et al. 2009) that usually coincides with the point proposed by Losee "before the beginning of the vertical attenuation of the lip fullness" (Losee et al. 2003). The long-lasting lip fullness depends on where one places the incision. Two incisions in the lateral segment are critical. The first one is the top of nasal labial junction and at lower margin of the alar base and

the second incision should be at 01 mm above the transition toward the lateral segment and allowing skin to be rotated with musculocutaneous flap and allowing the tubercle to be filled by lateral tissue. Considering that the tubercle white roll is missing in the bilateral clefts, it is important that the lateral well-defined white roll rotates downward to be sutured together in the midline. If the incision is placed in the immediate transition of white roll and dry mucosa, the postoperative scar tends to obliterate the natural white roll curvature as it might lose its natural design. However, to accomplish such a maneuver one has to be able to make sure that the premaxilla is aligned into the alveolar arch and not overprotruded. As we in our center do not offer NAM or any type of infant orthopedics, we plan the premaxillary setback in severe patients with protruded and deviated premaxilla, cleft patients with a very short columella (less than 2 mm). This maneuver is done in conjunction with the lip adhesion. The final lip repair is done after the palate repair. The *orbicularis oris* muscle is sutured in the midline whenever possible. The osteotomy is performed behind the growth center bulb to avoid premaxillary growth disturbance. The segments are fixed with wires and enough stability is guaranteed. We understand that the setback is easier to perform when the palate is still open because once it is close the osteotomy lines needed to be done anteriorly, close to the septum jeopardizing the growth center bulb and vascularity of the premaxillary segment.

The muscle dissection on the maxilla can be accomplished subperiosteally or supraperiosteally. There is no evidence for which type of dissection promotes less facial growth disturbance. It is our belief that dissecting over the periosteal plane is easier to mobilize the lateral segments medially.

With regard to nasal approach, we do believe that the tip exposure can be achieved by a minimal extension of the septum columellar incision on the tip mucosa similarly as described by Cutting as a retrograde method (Cutting et al. 1998). The Tajima incision may be an option, but the skin incision and subsequent healing may be subject to parent's complaints. The idea is offering enough room for alar crus harvesting and suturing, allowing tip projection either by a Tajima incision or a retrograde method as described by Cutting. The blood supply of the prolabium is derived from the external branches of the anterior ethmoid arteries as it allows retrograde elevation of the prolabial flap and exposure of the nasal cartilages.

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## 9.2 Summary

We review our approaches to bilateral cleft patients. Based on our national characteristics of our unified health system, we do not work with infant presurgical orthopedics and we tend to approach the lip in one stage following the current modern trends of bilateral cleft lip repair. We use a premaxilla setback in severely deviated and protruded premaxilla. This maneuver facilitates lip closure without tension. We have been using our own SOBRAPAR modification of bilateral cleft lip repair shown in our sequencing drawings. We have been able to avoid the current cleft stigmata often seen in patients whose surgery was not performed in Brazilian cleft centers.

**Acknowledgments** The authors thank the artist Rodrigo Tonan for the drawings.



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