Presurgical Management

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Introduction

There is a wide spectrum of cleft lip and palate and the degree of severity may vary significantly; these complex forms require an interdisciplinary, advanced, and lifelong management. The main limitation in complex cases is the skeletal deformity, specially bilateral cleft lip and palate cases. These patients may benefit from interdisciplinary treatment in advance of the cleft deformity to improve skeletal conditions via a process known as presurgical orthopedics. The term "orthopedic" comes from the Greek which means "straight" or "align" and the term "paideia" means "rearing of children." This word was initially used for the kind of treatment used for skeletal deformities in children. The presurgical techniques for cleft lip and palate management are classified as surgical or nonsurgical methods. Surgical method used for orthopedic treatment includes lip adhesion, and nonsurgical methods include tapes or elastic bandages and passive or active alveolar plates that can be used for the same purpose in combination with nasal stents.

These methods provide different treatments for repositioning of the maxillary segments and premaxilla (in bilateral) closer to each other, facilitating primary lip and nose surgery. In 1689, Hoffmann used a facial binding to narrow the cleft preventing postsurgical dehiscence, and later Desault used a similar method to retract the premaxilla segment in bilateral cleft lip and palate patients [1, 2].

Early intervention using presurgical treatments is extremely important, and these methods should be used during the first few weeks after birth prior to primary cleft lip and nose repair.

Reducing the severity of the anatomic defect as a means of facilitating corrective surgery has always been of interest to clinicians treating patients with nasoalveolar clefts. In the 1950s and 1960s, pioneers like McNeil and Burstone [3, 4] first published the idea that by stimulating the overlying soft tissues, using different acrylic appliances, the morphology of the maxillary structures could be modified, favoring growth, while reducing the width of the alveolar and palatal clefts. Within the same line of thought, Hotz et al used selective, periodic grinding (every 4–6 weeks) in specific areas of acrylic plates to modify the position of the greater and lesser maxillary segments and vomer [5].

Later, an important step in presurgical orthopedic method development was based on Matsuo's findings for treating congenital auricular deformities. He observed that during the first 3 months after birth, the elasticity and malleability of the auricular cartilage allowed him to correct it. Matsuo et al. offered a preliminary explanation for the mechanism behind the molding of the alar cartilages, claiming that during this short period, it was possible to presurgically modify these specific nasal structures, favoring results in shape and symmetry [6, 7]. The groundbreaking work done by Grayson and Cutting in the early 1990s provided the first thoroughly described nasoalveolar molding (NAM) protocol, accompanied by documented clinical results, demonstrating that alveolar and nasal structures could be rapidly and successfully modified toward their normal form and position, facilitating primary surgical correction [8, 9]. The use of this presurgical orthopedic method (in special the nasal molding) is a common debate in different cleft meetings actually, and some authors as Samuel Berkowitz believe that presurgical orthopedics may restrict the maxillary development after the molding process, creating a vomero-premaxillary synostosis and therefore affecting its growth and development [10, 11]. Finally, it looks like that the use of plates is not necessary for feeding or orthodontic reasons; therefore it may not improve feeding efficiency or child's growth [12]. All its described benefits are actually under scientific debate and questioning.

These challenges have motivated the advancement of novel alternatives, based on digitally devised strategies for designing and manufacturing NAM devices [13] increasing access to treatments by reducing the dependency on the proficiency of a small group of experts. This new generation of early treatment modalities is still often regarded primarily as a tool for facilitating initial cleft surgery. However, it serves a broader purpose, offering the opportunity to return the segments to a more physiological alignment without compromising the maxillary length, alignment of the occlusal plane, or straightening of the nasal septum, consequently enabling more normal functions such as breathing, swallowing, and feeding, with the potential benefits for future growth and development of the facial complex.

Another potential benefit of presurgical orthopedics is the gingivoperiosteoplasty (GPP), which requires alignment and approximation of the alveolar segments to narrow the alveolar cleft, reducing the need for concurrent dissections during primary repair [14, 15]. GPP is a contentious technique employed by some surgeons and developed to achieve bony fusion across the cleft at the time of primary lip repair. Originally, the aim was to raise flaps in the subperiosteal or supraperiosteal plane and close the alveolar defect to create sufficient bone stock for dental eruption, potentially obviating the need for secondary bone grafting and reducing the occurrence of anterior fistulas, which are complex complications, especially in bilateral cases. Uni- or bilateral GPP executed during primary lip repair address the anterior portion of the primary palate, nose, and lip during the same procedure, providing numerous advantages for bilateral cleft patients, particularly those with anterior fistulas [16]. Furthermore, this approach may reduce the need for a secondary alveolar bone graft or, if needed, enhance the success of such an intervention. In summary, the main objectives of these presurgical methods are to facilitate oral feeding, improving nasal deformity and maxillary growth, reposition the protruding premaxilla in bilateral clefts making easier the primary lip and nose surgeries and improve wound healing by reducing lip tension which benefits the quality of the lip scar. Importantly, all the described benefits are not supported by adequate scientific evidence, and many researchers question whether these short-term outcomes will have any beneficial long-term effects.

Despite of the lack of scientific support based on our experience, we believe that the use of presurgical orthopedics is essential for obtaining adequate outcomes after primary cleft rhinoplasty in patients with severe bilateral cleft lip and palate. This benefit is related to the skeleton remodeling and not necessarily to the nasal molding which is currently under discussion actually.

Types of Presurgical Orthopedics

Nonsurgical Orthopedics

Lip Taping

This is a widely used presurgical orthopedic method because of its low cost and availability. The use of lip taping was initially described by Hullihen in 1844 stressing the importance of the presurgical preparation of clefts using an adhesive tape binding [2]. In 1905, Brown described the method as follows: "production of narrowing effect stretching the lip muscles and skin on each side whenever the patient cries or laughs" reducing the need for soft tissue undermining and establishing a continuity of the orbicularis oris muscle [17].

In 1922, Federspiel reported that the use of adhesive tape after birth lessened the impact of the deformity on the parents and aided in reducing the maxillary cleft [18].

Later, the use of lip taping was well described and reported in the literature by Pool in 1994 as presurgical management for primary cleft lip repair [19]. His method was based on the use of tape strips across the cleft before the primary cleft lip repair. Like other presurgical orthopedic methods, the age of the start of the treatment is essential and should be done during the first week of life in order to achieve this objective. Its use at a later age is ineffective, especially for protruding premaxilla management. The main effect is over the maxillary segments, molding the alveolar segments and making the primary lip repair easier. The main limitation of the method is that it has little effect on nasal correction. Skeletal changes may help with primary cleft rhinoplasty making this procedure easier, but this has not yet been demonstrated.

Observed complications are skin reactions to the tapes and treatment failure. A recent modification of this method was described as Dynacleft and used in combination with nasal elevators to mold nasal cartilages. It is a self-adhesive tape that helps to align skeletal and soft tissues in patients with cleft lip and palate [20] (Fig. 4.1).

Dynacleft nasal elevators are plastic hooks that lift and support nasal tissues from a tether strip. A gentle adhesive placed against the child's forehead pulls it. The hook repositions the nasal structures; however, there is a lack of scientific evidence supporting this method. Different studies on its efficacy have been published; however, they have not yet demonstrated better lip and nose outcomes using this method and well-designed studies are needed. Monasterio et al. compared the Dynacleft with NAM and observed similar changes after using them but the outcome after primary surgery was not studied [21]. Most of the published studies regarding the efficacy of lip taping show skeletal changes after its use (preoperatory outcomes), but they do not present lip and nose outcomes.

Therefore, after surgery, there is no evidence of whether the outcome is the result of the surgery or the combination of both methods. A recent randomized controlled trial study published by Abd El-Ghafour et al. [22] studied the effect of using taping alone and reported good outcomes. The technique of presurgical orthopedic lip taping described by Pool is detailed here. Treatment starts during the first week of life

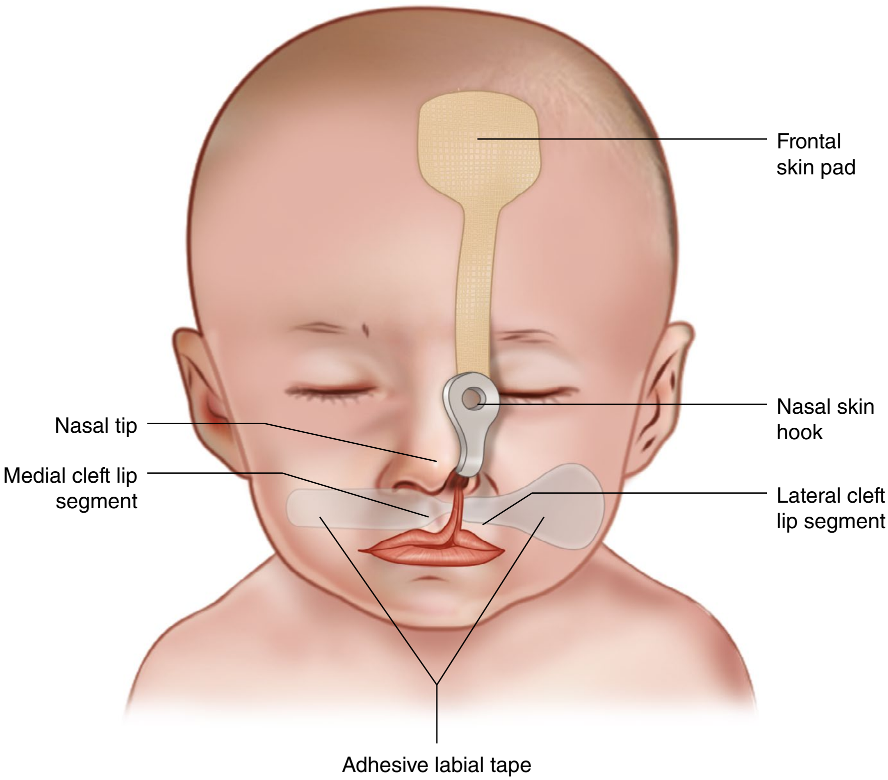


Fig. 4.1 Dynacleft system for presurgical orthopedic treatment of unilateral cleft lip and palate

(a key point of the success) when the use of presurgical orthopedics is indicated (mostly severe forms of bilateral cleft lip and palate) and is accomplished over a 6-week period, on average, and surgical repair of the lip is performed at an average age of 12 weeks.

During early phases, the tape must be reapplied daily; however, when skin irritation occurs, a recess of several days is mandatory. Adherent skin is applied, followed by three or four narrow strips of tape.

It is important that the parents should be instructed in applying the tapes to make them feel participatory in their child's treatment. Long strips of tape should be applied first to the cheek, and then after the alveolar gap is improved, shorter strips are applied to the lip on either side of the cleft.

The objective to be achieved is to move the alveolar segments within 5 mm to each other recontouring the lip and nose soft tissues.

The forces at work from lip taping have a functional effect on maxillary growth due to the action of the orbicularis muscle.

This is a simple and low-cost procedure that facilitates lip and nose repair and protects the maxillary growth molding maxillary arches and mobilizes lip and nose soft tissues. Finally, we must consider that this method requires compliance from the parents with regular and costly in-office visits.

A recent meta-analysis to evaluate its efficacy concluded that there are not enough studies to demonstrate its utility and more research is needed [23].

Elastic Bandages (Fig. 4.2)

Another widely used method for presurgical skeletal management in cleft lip and palate patients is the use of elastic bandages. Since the sixteenth century, bandages and mechanical compression devices have been used to mold the maxillary arch in these patients. Hoffman (1686), Louis (1768), Chaussier (1776), Desault (1790), and Von Esmarch (1892) used compression devices as presurgical treatments [2, 24].

In 1875, Thiersch reported the use of rubber bands over the premaxilla using an adhesive butterfly bandage over the cheeks. Later in 1954, Mc Neil [3] used a combined device including a wire head frame with elastic bands to apply pressure to the protruding premaxilla.

Brauer and Cronin in 1964 reported positive outcomes using a combination of elastic bandages and maxillary orthopedics in severe bilateral cleft lip and palate patients [25]. In 1966, Griswold reported the use of an elastic band system to apply compression for the protruding premaxilla correction from birth until 6–12 weeks of age in bilateral cleft lip and palate patients. He used a traction band made of a piece of elastic girdle.

Alveolar Molding Using Plates

Basically, there are two types of presurgical orthopedic plates: active and passive. Active maxillary devices produce controlled forces to move the alveolar segments in a predetermined manner.

Fig. 4.2 Presurgical orthopedics using elastic bandages in the bilateral cleft lip and palate

Passive orthopedic plates act as a fulcrum upon which the forces with the forces generated by surgical lip closure enhance the alveolar segment molding in a predictable position.

In 1954, starting in the modern school, Mc Neil, a Scottish prosthodontist, used active plate series to gradually mold the alveolar segments into the desired position. He assumed that each successive plate under worn pressure would stimulate growth of the underlying bone, thus reducing the width of the cleft palate. Interestingly, changes in the width of the cleft palate are observed after cleft lip closure, and the use of active plates is not necessary. This is the concept proposed by the author as the "surgical nasoalveolar molding" [26].

In 1975, Giorgiade and Latham used another active appliance to retract the premaxilla and expand the maxillary segments in bilaterals [27] (Figs. 4.3 and 4.4).

Later in 1987, Hotz in Zurich, Switzerland, described the use of a passive orthopedic plate to align cleft segments. They devised an alveolar molding plate made of acrylic [28]. The surface of the plates was gradually modified such that the alveolar segments were pressed to mold into the desired shape and position.

All of these devices failed to address the nose deformity associated with the cleft lip and palate.

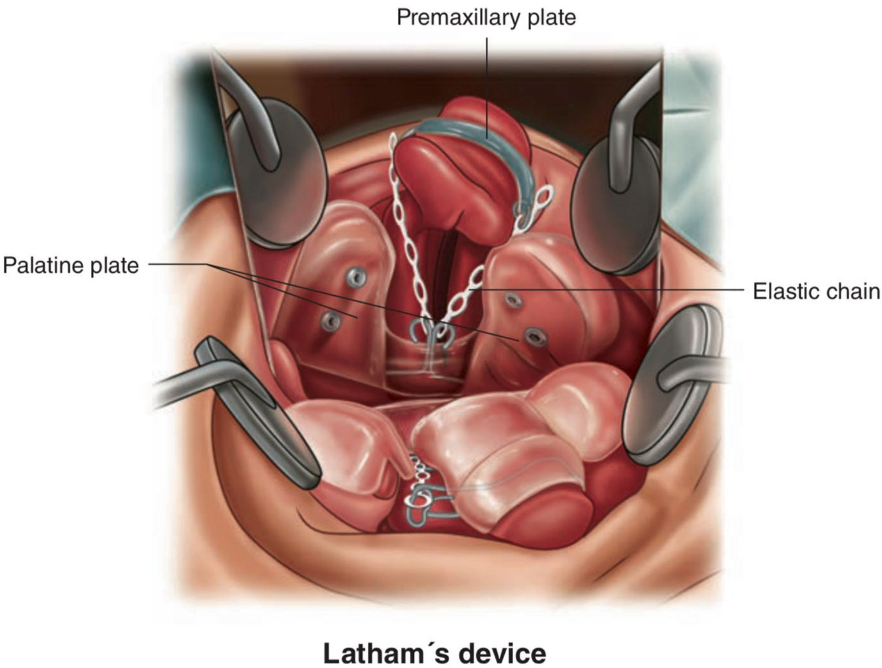
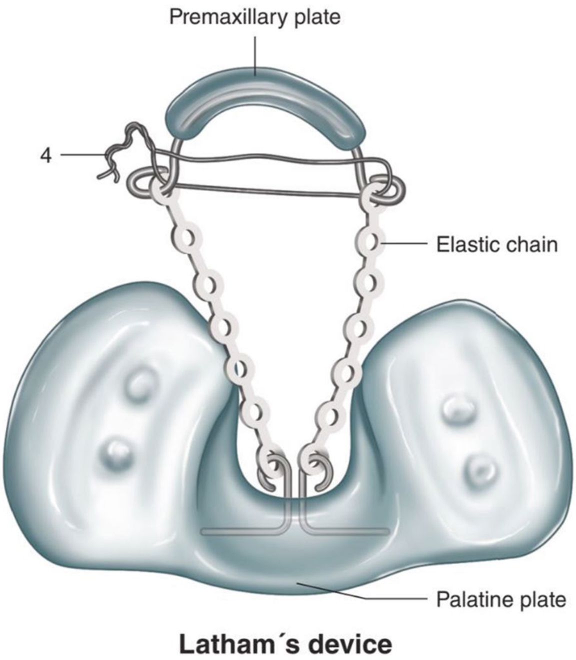


Fig. 4.3 Presurgical orthopedics based on the Latham device for bilateral cleft lip and palate treatment

Fig. 4.4 Latham's device



Surgical Orthopedics

In fact, this method is not a presurgical treatment; however, it should be considered for pre-primary surgical orthopedics. This preliminary procedure (when it is properly applied) reduces the cleft size allowing the primary repair with less undermining and a greater of growth disturbances. The effect of extensive soft tissue mobilization on maxillary growth can be deleterious; therefore, the use of presurgical orthopedics may prevent these potential complications. First, this technique was described in the literature by Johanson in 1961 and used for bilateral cleft lip repair by authors such as Millard in 1960 and Spina in 1964, and then Millard in the same year proposed a partial lip adhesion as presurgical treatment in order to facilitate definitive surgery achieving same outcomes as external elastic pressure or dental appliances [2].

In 1966, Peter Randall, a strong proponent of preliminary lip adhesion, used a full-length lip adhesion. This extra operation facilitates better definitive repair and prevents secondary revisions [29].

All of these authors reported narrowing of the alveolar gap and soft tissue expansion of the prolabium. Surgical lip adhesion reduces the need for soft tissue undermining and facilitates the repair in wide clefts; however, it has a minimal effect on nasal repair even when some authors have described nasal deformity treatment during lip adhesion ("lip nasal adhesion") which is not a conventional method [30, 31].

The main limitations of using this presurgical orthopedic method are the risk and cost of additional surgery.

To achieve optimal outcomes over the skeleton, an early lip adhesion is mandatory. Based on my personal experience, the lip adhesion should be performed before 3 months of age, and any adhesion later than this age produces minimal changes in the skeleton. Even when the soft tissues are expanded after surgical lip adhesion facilitating the primary lip closure and minimizing the risk of lip dehiscence, the premaxilla remains protruded and will require a premaxillary setback in combination with maxillary orthopedics later. The timing of primary lip repair after lip adhesion remains controversial and is recommended to be 3–6 months after adhesion. Personally, I recommend the following protocol for severe bilateral cleft lip and palate treatment (alveolar cleft wider than 1 cm):

Bilateral surgical lip adhesion (before 3 months of age)
One stage primary palatoplasty (9–12 months of age)
Primary cheilorhinoplasty (18–24 months of age)
Alveolar bone graft (mixed dentition period)

There is a risk of lip dehiscence after lip adhesion exists, and some authors have reported 24% for bilateral clefts [32]; however, other authors have reported 5% of total dehiscence [33].

Surgical Technique

The method described here is based on Randall's description.

Markings (Fig. 4.5)

Two flaps are designed at the central segment (prolabium and columellar base flaps), and three flaps are designed at the lateral segments (lateral mucosa, oral mucosa, and alar flaps). Flaps are elevated from the central and lateral segments, and then the upper lip muscles are freed from their abnormal insertion. Surgical repair starts with suturing of the prolabium flap to the oral mucosa via the oral mucosa flap from the lateral segment on both sides. Then, the muscles are attached to the subcutaneous tissue of the prolabium on both sides. Finally, the lateral mucosal flap is turned up medially and sutured to the skin of the prolabium; simultaneously the lateral alar flap is sutured to the medial columellar flaps. I like to add that a "cinch" suture of polypropylene is brought through the dermis of each alar base, which is passed beneath the nasal philtrum narrowing the interalar distance.

Premaxilla reposition and tissue expansion produced by the surgical lip adhesion help surgeons perform the primary bilateral cleft rhinoplasty under good conditions (Figs. 4.6 and 4.7).

The utility of primary premaxillary setbacks has been actualized recently; however, their safety and utility are under strong debate actually (Figs. 4.8, 4.9, 4.10 and 4.11).

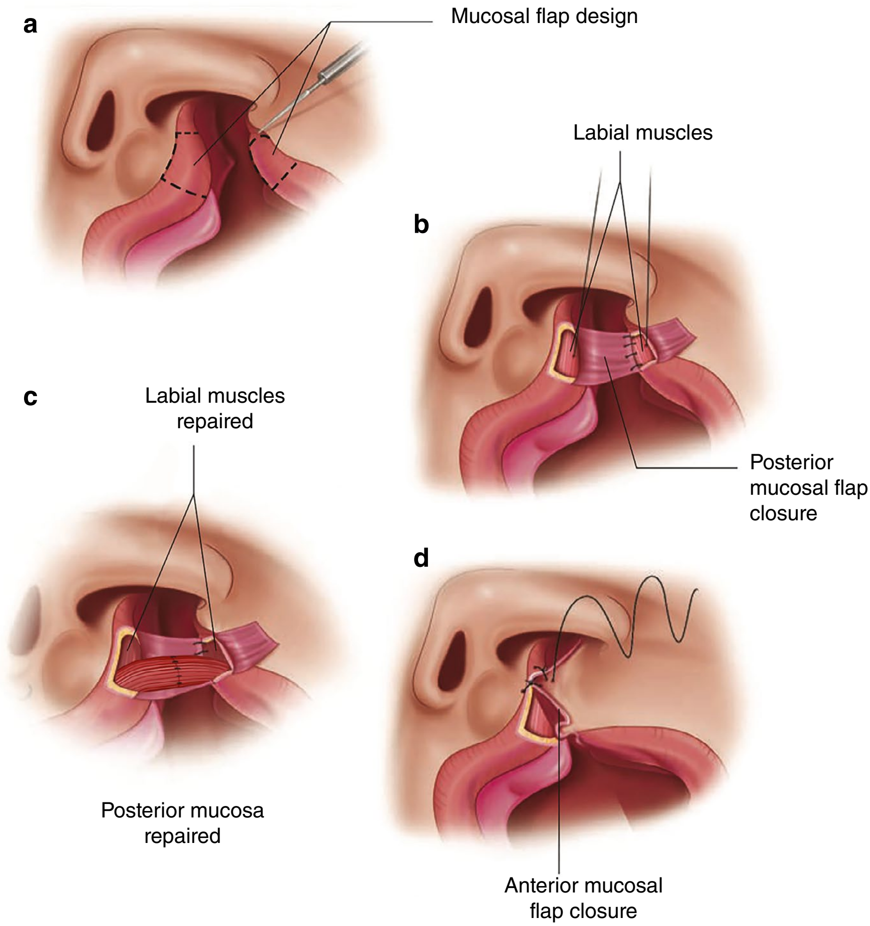


Fig. 4.5 Randall's technique for surgical lip adhesion

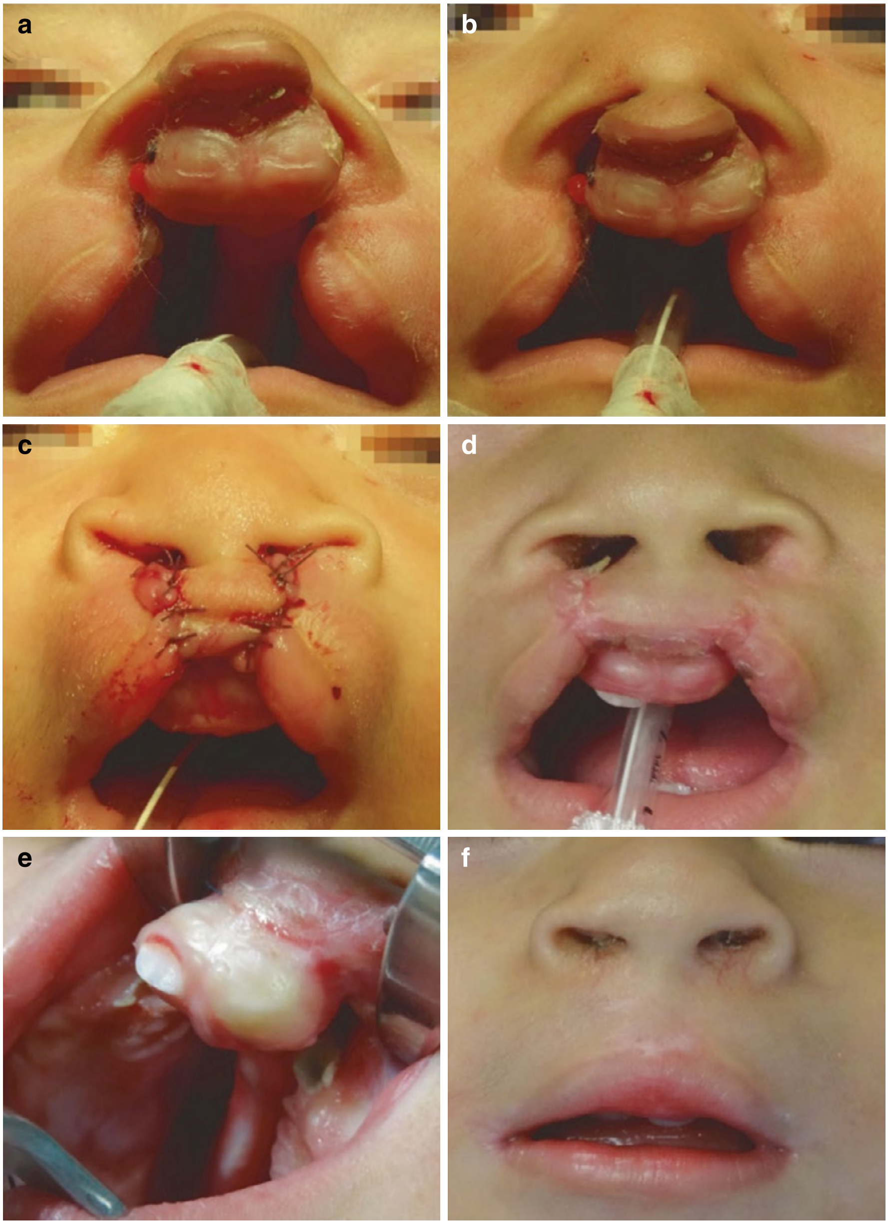


Fig. 4.6 Patients born with severe bilateral cleft lip and palate were treated using the surgical lip adhesion. (**a**) Worm eye view (alveolar gap 15 mm). (**b**) Frontal presurgical view. (**c**) Immediate postoperative view. (**d**) Postoperative view after 4 months. (**e**) New position of the premaxilla (alveolar gap 5 mm). (**f**) Postoperative view 1 year after primary cheiloplasty

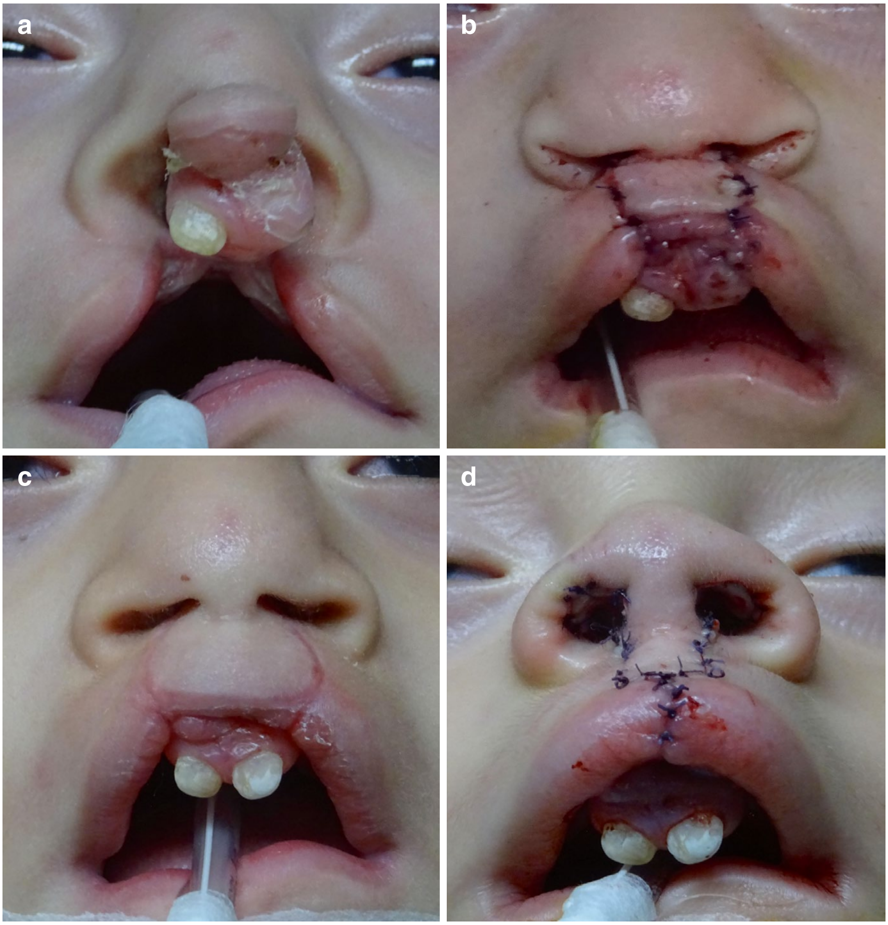


Fig. 4.7 Patients born with severe bilateral cleft lip and palate were treated using the surgical lip adhesion. (**a**) Worm eye view (alveolar gap 14 mm) (frontal presurgical view). (**b**) Immediate postoperative view. (**c**) Postoperative view after 6 months. (**d**) Immediate postoperative view after primary rhinoplasty using the rotational composite flap method

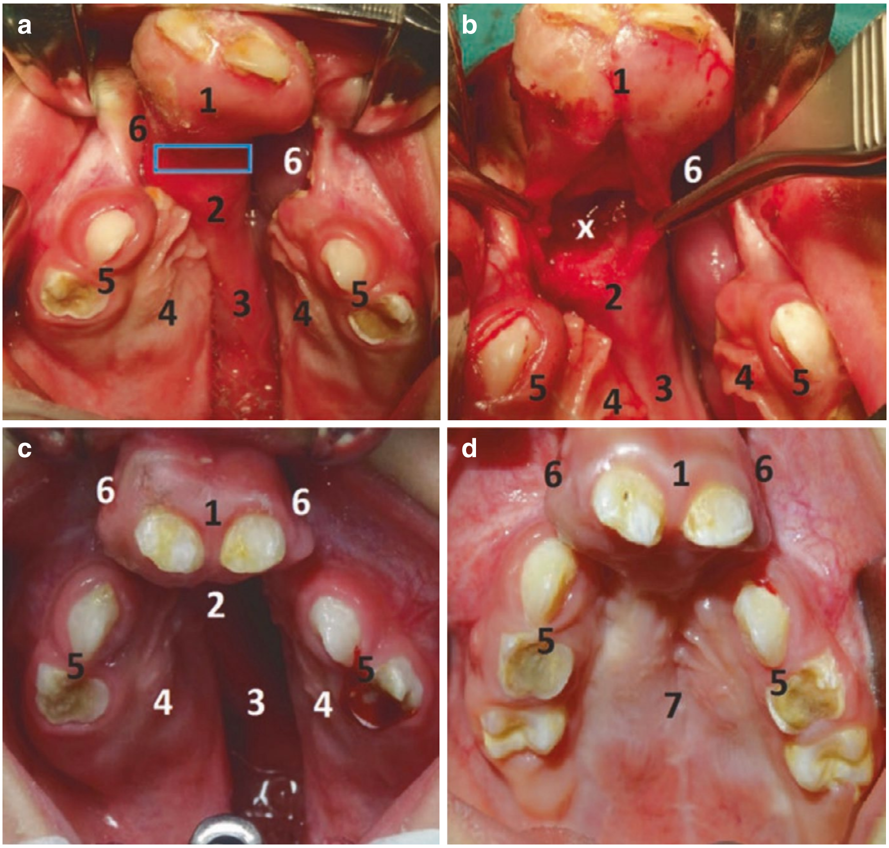


Fig. 4.8 Premaxillary setback surgical technique. (**a**) A 3-year-old patient with severe bilateral cleft lip and palate. (**b**) Vomer midline incision and ostectomy. (**c**) Premaxilla position after 6 months after surgical setback. (**d**) Premaxilla position 1 year after surgery. 1. Premaxilla. 2. Premaxillary-vomerine suture. 3. Vomer. 4. Cleft palate segments. 5. Maxillary arch. 6. Alveolar cleft. 7. Hard palate. x: Ostectomy

Fig. 4.9 A 1-year-old patient with cleft lip repair dehiscence due to protruded premaxilla

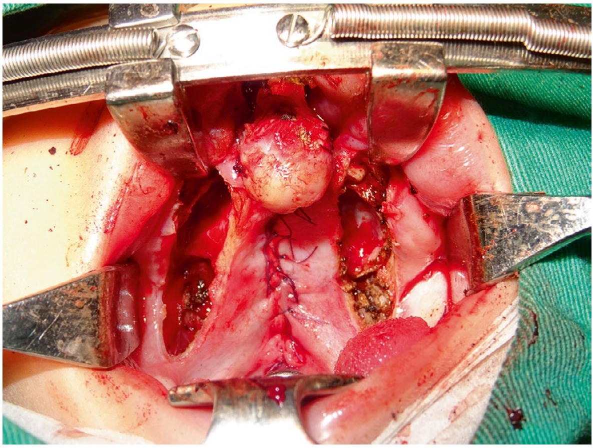


Fig. 4.10 Premaxilla setback combined with primary palatoplasty

Fig. 4.11 Secondary cleft lip closure after premaxilla reposition. Nose requires secondary correction later

The Nasoalveolar Molding (NAM)

This is a well-known presurgical orthopedic method based on the concepts of presurgical orthopedics developed since the 1950s and the contributions of Matsuo to modeling congenital ear deformities using splints. This innovative concept was introduced by Grayson in 1993 [6, 8]. The device used for maxillary alignment and nasal molding was named as nasoalveolar molding (its acronym is NAM) and designed to correct skeletal discrepancies and nose deformities to a normal form and position during the neonatal period in patients with cleft lip and palate (Figs. 4.12, 4.13, 4.14, 4.15 and 4.16).

The best time to begin using the nasoalveolar molding is 1–2 weeks after birth. This technique utilizes wire and acrylic nasal stents attached to an intraoral denture, and its objective is to reduce the lip and nasal severity before primary surgery. Weekly visits are required to modify the molding plate to guide the alveolar segments into the desired position. Nasal stent molding is added when the alveolar cleft is reduced to 5 mm or less, and the phase can last between 3 and 6 months depending on cleft's severity.

The different advantages described by authors such as improved feeding, easier surgical procedures, better aesthetic outcomes, and reduced number and cost of revision surgical procedures were not demonstrated scientifically at this time. This is why this method is alternative and not the standard of care, and maxillary

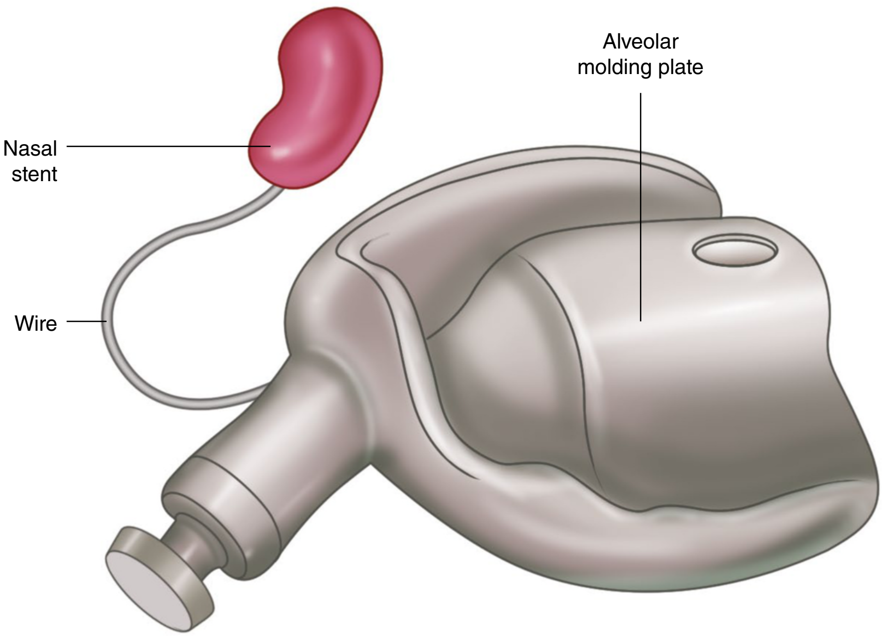


Fig. 4.12 Nasoalveolar molding device used for presurgical treatment of cleft lip and palate

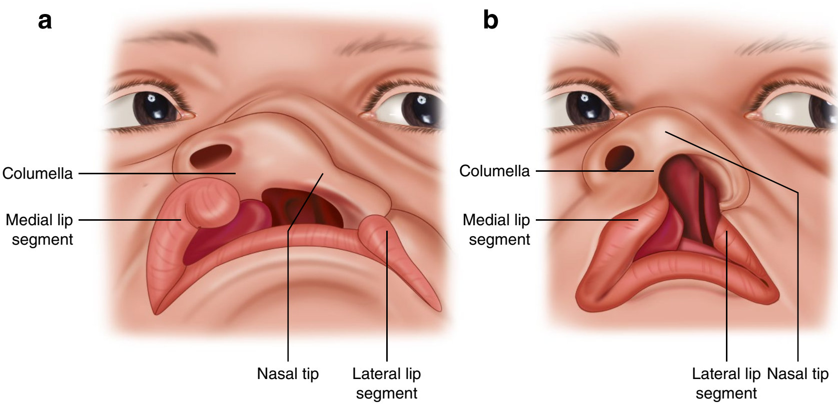


Fig. 4.13 Pre- and posttreatment condition of unilateral cleft lip and palate using NAM

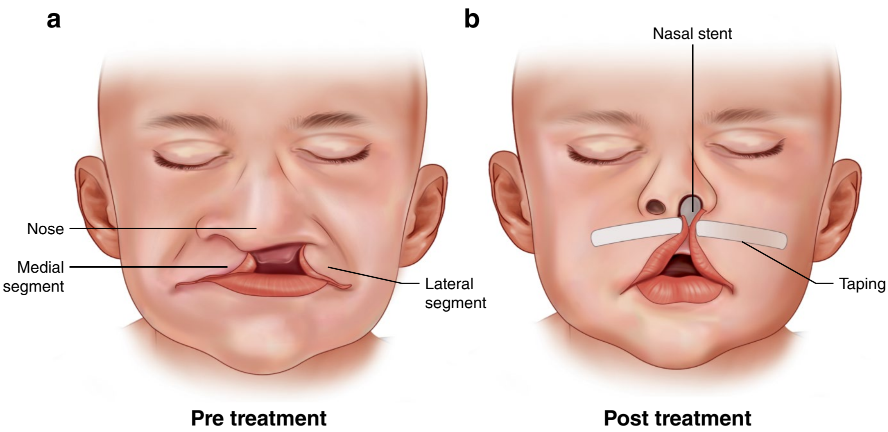


Fig. 4.14 Diagram illustrating a patient with unilateral cleft lip and palate using NAM device

alignment and nose symmetry can also be achieved properly by surgical techniques alone in unilateral cleft lip and palates [26].

At present, NAM is considered part of the presurgical treatment protocols for patients with bilateral and unilateral cleft lip and palate. According to previous studies, NAM has been shown to improve nasal symmetry and shape [34–36], reduce the size of the cleft gap [37, 38], improve the premaxilla-midline deviation [39], and may reduce the need for revision surgery and the associated costs [40, 41]. Nevertheless, the implementation of NAM therapy protocols requires the coordination of an interdisciplinary team of therapists and technicians with years of experience, as well as highly trained and motivated caregivers, along with other practical requirements that can make the technique difficult to implement.

Fig. 4.15 Patient with unilateral cleft lip and palate using NAM device

Fig. 4.16 Patient with bilateral cleft lip and palate using NAM device

The protruded premaxilla in the bilateral cleft lip and palate can also be corrected by any other presurgical orthopedics. A study published by Monasterio in 2013 compared NAM versus the lip taping method (specifically Dynacleft) and revealed no difference between these two techniques regarding cleft width and nasal symmetry [21].

The author (PR) developed an innovative concept based on nasal vestibule elongation (as a nasal stent of NAM produced) using the VYZ rhinoplasty and maxillary alignment as a result of muscular action after lip repair, this method has been named "the surgical nasoalveolar molding" [26, 42].

The Three-Dimensional CAD-CAM Presurgical Orthopedics

Computer-aided design (CAD) and computer-aided manufacturing (CAM) technologies have impacted all areas of medicine in which complex devices are needed, becoming safer, faster, less expensive, and easily accessible, allowing highly accurate fabrication of digitally designed appliances [43, 44]. The level of digitalization of current NAM protocols range from the implementation of direct intraoral scanning to the replacement of traditional impression techniques [45] progressing toward the digital manipulation of digital models that are subsequently three-dimensional printed and used for appliance manufacturing [46]. At present, the most advanced protocols start out with a digital model that is then modified to produce sequential treatment stages that are finally used to design and directly three-dimensionally print the actual devices [47].

The currently available literature offers studies that simultaneously support and discourage presurgical orthopedic intervention. This contradiction results from the unfortunate lack of high-quality randomized clinical trials, in which the efficacy of PSIO has not been sufficiently demonstrated. Heterogeneity of study designs and treatment methods, difficulty in the repeatable localization of anatomic landmarks, deficient data reporting, and the difficulty encountered in the standardization of the highly operator-dependent manual appliance adjustments required in most intervention protocols, especially in multicentered studies, are the main barriers to obtaining more reliable evidence-based results to validate clinical efficacy and guide further development.

This technology and its application involve the following steps:

1. Appliance manufacturing: Traditional PSIO techniques involve the labor-intensive fabrication of therapeutic devices, which rely on manual craftsmanship, years of experience, and a high degree of manual dexterity. This approach often results in significant interoperator variability. In contrast, digital appliance manufacturing workflows effectively eliminate this variability, facilitating standardization and reducing dependence on individual clinician expertise.
2. Treatment implementation: By utilizing sequentially delivered appliance kits as opposed to one consecutively modified device that requires manual adjustments, the clinical implementation of the treatment protocol becomes simpler. This approach relieves both patients and healthcare professionals of the burden of executing complex adjustments and activations that can be challenging for many.

The method designed by Dr. Juan Pablo Gomez and Dr. Martha Mejia proposes the development of a fully digitalized workflow for NAM, consisting of three independent interventions: Labial Taping, the Rhinoplasty Appliance System, and Sequential Alveolar Aligners System.

Labial Component (Lip Taping)

The clinical objectives of lip taping in patients with clefts are as follows:

1. The elongation of labial tissues reduces the width of the cleft, facilitating surgical correction.
2. Contributing to the elongation of the columella.
3. In unilateral cases, it contributes to correcting nasal and palatal asymmetries.
4. In bilateral cleft cases, it helps reposition the premaxilla and prolabium when they are displaced laterally and anteriorly. A downward force vector applied to the prolabium also contributes to the elongation of the columella (Fig. 4.17).

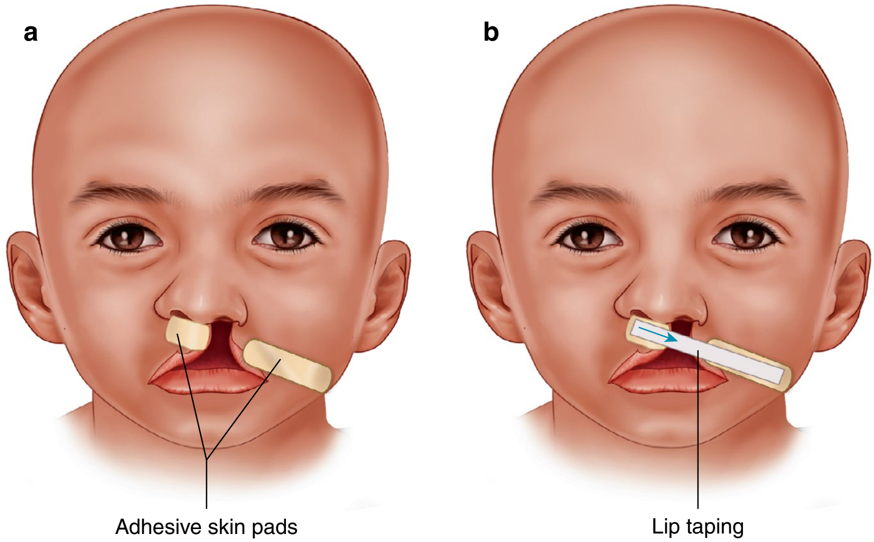


Fig. 4.17 The RAS labial component is composed of the following elements: protective pads on the lip and contralateral cheek (**a**). Adhesive tape, tensing the prolabium, and philtrum DOWNWARDS toward the cleft side, partially closing the cleft gap (**b**). To protect the delicate skin of the newborn patient from the repetitive removal and placement of tapes, protective pads are positioned on the surfaces that will accommodate the tapes. To apply the technique, first the short (2 cm approximately) end of the tape was adhered to the lip opposite to the cleft. The long end of the tape (6 cm approximately) was then pulled in a downward—lateral direction, approximating the labial structures—and adhered to the opposite cheek

Rhinoplasty Appliance System (RAS) Nasal Component

The clinical objectives of the Rhinoplasty Appliance System are as follows [48]:

1. The vertical and transverse asymmetries of the nose were corrected, the septum and nostrils were displaced to a more physiological and esthetic positions before surgery, and the nasal cartilage was subsequently corrected to avoid collapse after surgery.
2. This contributes to the elongation of the columella, facilitating surgical correction.

With its intranasal extensions (Fig. 4.18), the device must be controlled to displace the cartilaginous structure of the nasal septum laterally in infants with unilateral and bilateral clefts. The therapeutic force is produced by elastics anchored at the cheeks, pulling the device from the hook at the end of the arms, allowing the nose to be relocated to and maintained in a corrected position (Fig. 4.18). This contrasts with the traditional NAM appliance, which projects the nasal tip anterolaterally, with an extension stemming from the intraoral plate on the affected cleft side.

CAD CAM Workflow

Initially, the RAS devices were manufactured and adjusted manually, requiring high levels of training and expertise. In the proposed protocol, they are digitally designed and manufactured via CAD/CAM technology. They are sequentially delivered, allowing high precision and reducing the dependency on the expertise of highly specialized clinicians and technicians (Fig. 4.19).

Our system requires a kit of four nasal appliances that are sequentially exchanged at home by the caregiver, with the help of remote treatment progress monitoring,

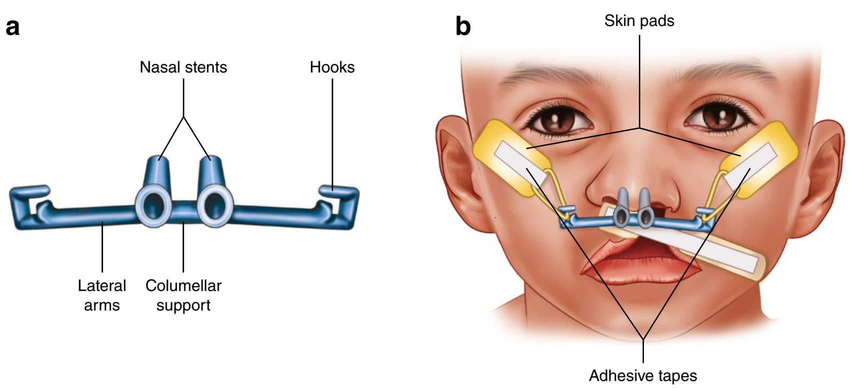


Fig. 4.18 The RAS nasal component is composed of the following elements: (**a**) nasal device consisting of intranasal extensions (stents) inserted into the nostrils, united by columellar support and two lateral arms ending in hooks (**a**). Two protective pads that avoid direct contact between the adhesive tapes that sustain the elastic elements of the patient's skin (**b**). Two adhesive tapes that sustain the elastic elements providing orthopedic forces (**b**)

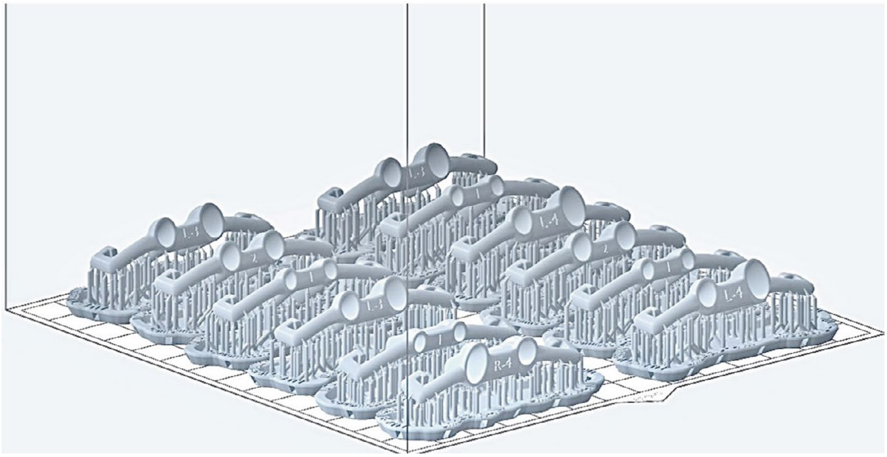


Fig. 4.19 RAS KIT digital manufacturing workflow. Digitally designed sets of appliances distributed on the virtual printing platform (**a**). Three-dimensional printed, four-step RAS kit for a bilateral cleft lip and palate patient (**b**)

during the active phase of treatment. The smallest appliance is initially fitted and activated. Then it should subsequently be changed periodically, increasing the size to modify the nasal structures in preparation for primary lip repair surgery. The kits are available for bilateral and right and left unilateral CLP and can be delivered at home by the caregiver, with the help of cellphone-based, remote treatment progress monitoring, in cases where travel to the treatment center constitutes a burden for patient and family.

For bilateral cleft lip and palate cases, each device presents a symmetrical sequential increase in the intranasal extensions to achieve the goal of elongating the columella and projecting the nasal tip. Each size is applied based on the degree of deformity. In typical cases, each sequential device should be used for 2 weeks, totaling 8 weeks of nasal molding. In more severe cases, in which the columella is markedly shortened, the appliances should be changed every 3–4 weeks, extending the nasal molding duration to 12–16 weeks. The kits for managing unilateral cleft lip and palate (right and left unilateral) are asymmetric, preserving the size of the healthy nostril while actively addressing the affected nostril. Progression to subsequent stages is implemented according to the severity of the defect. If the nasal deformity was minor, the conformer was switched every 2 weeks, and if it was more substantial, it was switched every 3–4 weeks. The overall nasal molding period ranged from 8 to 16 weeks.

Only after the labial component (lip tape) has been installed is the nasal component delivered, following the steps described in Fig. 4.20.

Once properly delivered and activated, the device produces a unique force system (Fig. 4.21) that is biomechanically independent of the alveolar molding device, favoring the resolution of the fundamental morphologic discrepancies found in newborn patients with CLP.

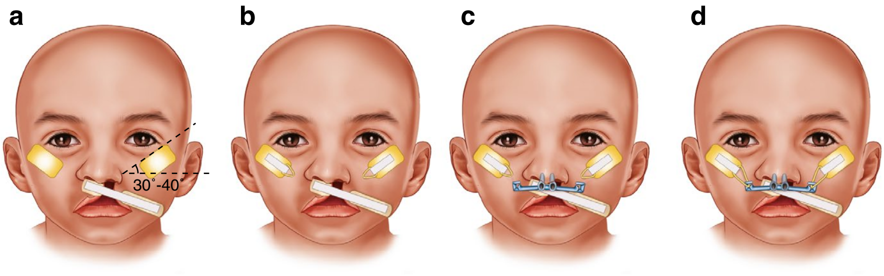


Fig. 4.20 Step-by-step RAS setup procedure: Protective pads placed at a 30–40-degree angle (**a**). Bilateral tapes with elastic elements, following the angulation of the protective pad (**b**). The passively inserted rhinoplastic device was slightly tilted, following the asymmetric disposition of the nasal structures (**c**). The device was activated in a more horizontal position, after the engagement of elastic elements in the hooks (**d**)

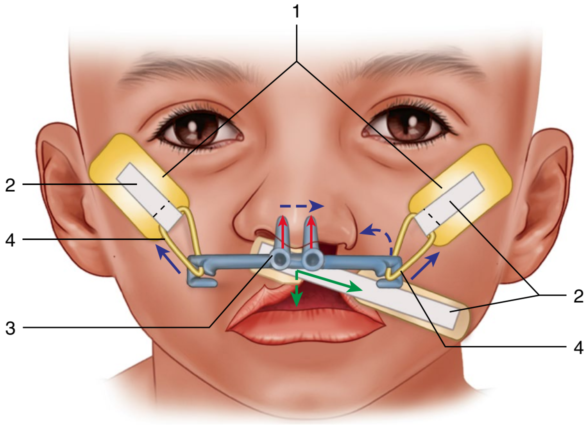
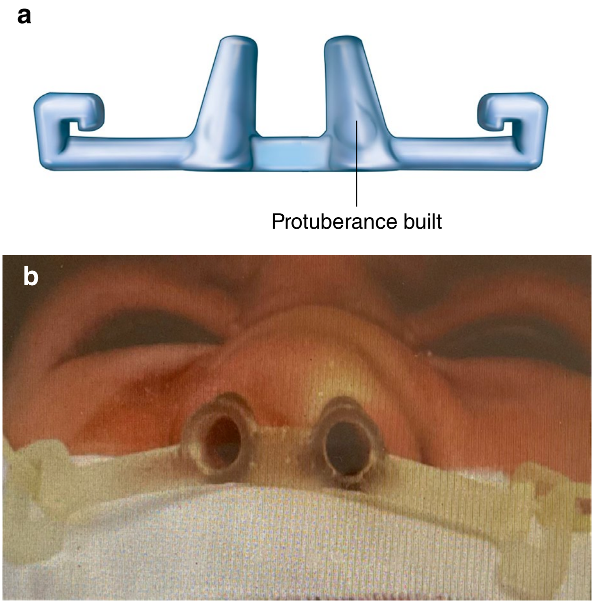


Fig. 4.21 The RAS force system (unilateral left CLP): Asymmetric upward-outward forces (continuous blue arrows) that displace the deviated nasal septum toward the midline (dotted red arrow). Counterclockwise rotation (dotted blue curved arrow) was used to elevate the nasal ala of the cleft side. The downward force component (dotted green arrow) of the diagonal traction force applied by the lip tape (continuous green arrow). Upward force produced by the elastic force at the columellar support (continuous red arrows)

When adequately installed, mild ischemia should appear on the nasal dome of the cleft side, resulting from the pressure applied by the prominence incorporated into the specific intranasal extension (Fig. 4.22), favoring the projection of the nasal tip and remodeling of the alar cartilage.

Fig. 4.22 The protuberance built into the appliance is intended to apply pressure in specific areas. (**a**) Nasal device. (**b**) Patient using the nasal device



Alveolar Component (SAAS)

The clinical objectives of modifying the morphology ("molding") of the alveolar segments using palatal plates in patients with clefts are as follows:

1. The approximation of the borders of the alveolar processes, facilitating surgical correction
2. Improvement of support for alar base
3. Restoration, to variable extent, the normal anatomy of the palate:
   - Allowing more normalized function, favoring growth
   - Avoiding early posterior crossbite
4. Avoiding the positioning of the tongue within the cleft
5. Facilitation of feeding and reduction of risk of aspiration
6. In bilateral cases, three-dimensional repositioning of the premaxilla

Our method proposes the development of a fully digitalized workflow for alveolar molding that includes the virtual modification of three-dimensional scanned models from bilateral and unilateral CLP newborn patients, generating a series of sequential, three-dimensional printed devices (alveolar aligners). By providing the patient with the complete set of aligners for at-home administration, coupled with the possibility of remotely monitoring treatment progress through a cellphone-based application, we can significantly reduce the burden of travel associated with conventional PSIO protocols.

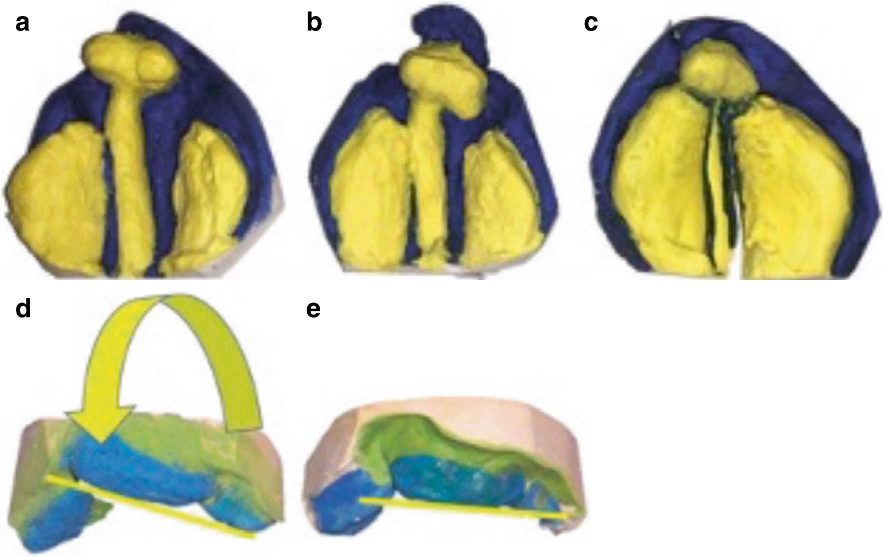


Fig. 4.23 Repositioning of the premaxilla in the transverse and sagittal planes, reconfiguring the palatal arch form (**a–c**). Counterclockwise rotation of the premaxilla improved the vertical discrepancy (**d**, **e**)

CAD Phase In the initial digital design phase (CAD), the patient digital model of the maxillary arch (Fig. 4.23a) is processed by a specialized software (AcuuCleft) (Fig. 4.23b), which delivers a series of sequential digital models (Fig. 4.23c) in the form of data sets that serve as the blueprint for designing successive devices (Fig. 4.23d) for the different stages of anatomical correction. In addition to its parametric alveolar molding algorithm, the software incorporates the normal three-dimensional growth of the newborn palate during the initial months during which the intervention is undertaken.

CAM Phase The resulting set of individual digital appliances is then used in the subsequent digital manufacturing phase (CAM) which relies on rapid additive prototyping (three-dimensional printing) to produce high-precision, sequential palatal molding devices, without the limitations that come with conventional handmade acrylic appliances which require highly trained clinicians and technicians for manufacturing and weekly adjustments (Figs. 4.24 and 4.25).

The parametric nature of the treatment software allows for adjustment in the incremental amount of alveolar modification applied by each individual device/stage. The number of sequential devices/stages employed in each individual case will depend on the severity (width) of the cleft defect, the frequency of aligner changes, and the amount of modification per stage defined by the clinician. A typical example of treatment planning possibilities for the closure of a 10 mm alveolar cleft could be as follows:

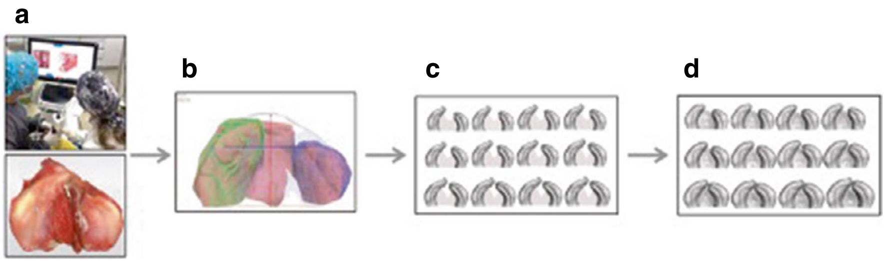


Fig. 4.24 The CAD phase of the digital workflow proposed for designing and manufacturing sequential alveolar aligners for presurgical infant orthopedics begins with the direct intraoral scanning of the infant's palate (**a**), followed by AccuCleft sequential treatment stage simulation (**b**), and the individualization of sequential treatment stages (**c**), which are used to design each individual sequential aligner (**d**)

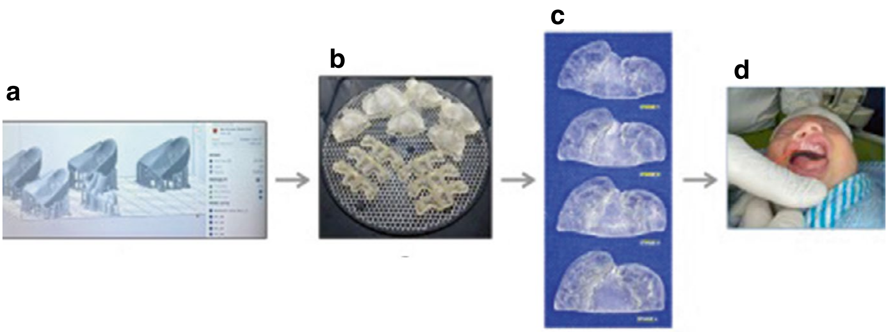


Fig. 4.25 The CAM phase of the digital workflow begins with the preparation of the digital aligner models on the virtual three-dimensional printing platform, with their corresponding supports (**a**). Once printed, they must undergo a strict washing and post curing protocol (**b**), and final removal of printing supports and finishing and sterilization (**c**), before being delivered to the patient's mouth (**d**)

#1: Ten alveolar aligners with 0.5 mm increments (at each alveolar border)
#2: Five alveolar aligners with 1 mm increments (at each alveolar border)

The fundamental implication of duplicating the extent of modification per stage (from 0.5 to 1.0 mm, in this case) is that the frequency of appliance change can be proportionately reduced (from 10 to 20 per stage, for example). This adaptability provided by the digital nature of the system offers clinicians the possibility of tailoring the biomechanical capabilities of the devices to different clinical circumstances, in a repeatable and precise manner.

Caregivers are instructed in the proper delivery and care of the devices, as well as the sequential appliance substitution regime, which is specifically formulated for each patient, usually ranging between 1 and 4 weeks per stage.

Clinical Cases RAS

Complete Unilateral Cleft Lip and Palate

Patient #1: A 2-week-old male patient with a complete unilateral-right cleft lip and palate in which a severe collapse of the right nasal ala and deviation of the nasal septum were observed. The initial interlabial gap measured 20 millimeters, with a 16-millimeter separation between alveolar segments (Fig. 4.26). PSIO was initiated with alveolar molding devices with the objective of descending the occlusal plane to a better position, rotating the greater process toward the midline, and approximating the alveolar segments. After 3 weeks of alveolar molding, the patient began with the RAS protocol to address nasolabial asymmetry and reduce the columellar dimension. After a total PSIO treatment of 16 weeks, substantial improvement was attained in nasal symmetry, columellar length and deviation, morphology of the nasal ala, width of intralabial gap, and projection of the nasal tip (Fig. 4.27).

Fig. 4.26 Case #1: Pretreatment photographs

Fig. 4.27 Case #1: Posttreatment photographs

Complete Bilateral Cleft Lip and Palate

Patient #2: A 3-week-old patient with a complete bilateral cleft, accompanied by a deviation of the nasal septum and premaxilla toward the left side (Fig. 4.28). The right-sided cleft lip and alveolus had an initial width of 18 mm, while the left side measured 17 mm. Treatment was initiated to align the premaxilla with the alveolar arch and bring the nasal septum to the midline. This initial treatment was carried out using alveolar aligners for 3 weeks, followed immediately by the bilateral RAS protocol. Correction of the premaxillary deviation was achieved, as well as elongation of the columella and elevation of the nasal tip and improvement of nasal al morphology (Fig. 4.29). At 5 months of age, upon completion of the presurgical treatment, the patient was able to undergo surgery, which included primary palate closure with gingivoperiosteoplasty, lip surgery, and nasal correction.

Fig. 4.28 Case #2: Pretreatment photographs

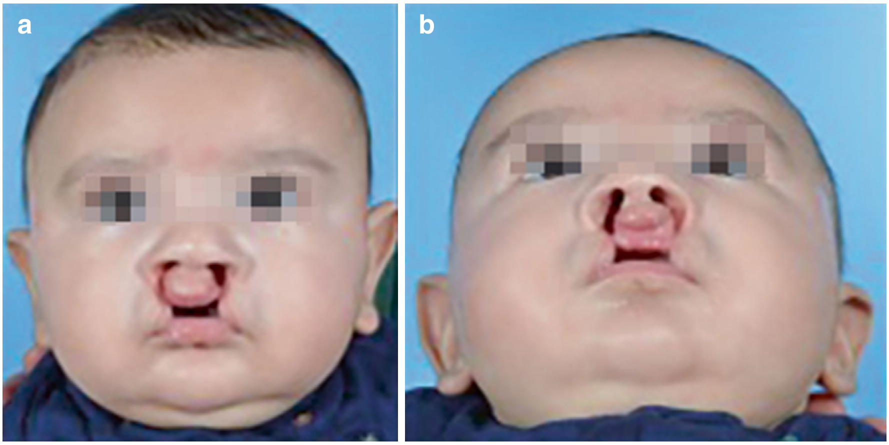


Fig. 4.29 Case #2: Posttreatment photographs

Complete Bilateral Cleft Lip and Palate

Patient #3: Premature male infant with a complete bilateral cleft lip and palate with a prominent premaxilla on the midline (Fig. 4.30). PSIO was initiated at 2 months of age with alveolar aligners, after which the RAS protocol was implemented for 16 weeks. Posterior repositioning of the premaxilla and its alignment with the alveolar arch were achieved. The columellar length, nasal tip projection, and improvement in alar curvature were significantly improved (Fig. 4.31). Corrective primary surgery was performed at 6 months of age.

Fig. 4.30 Case #3: Pretreatment photographs

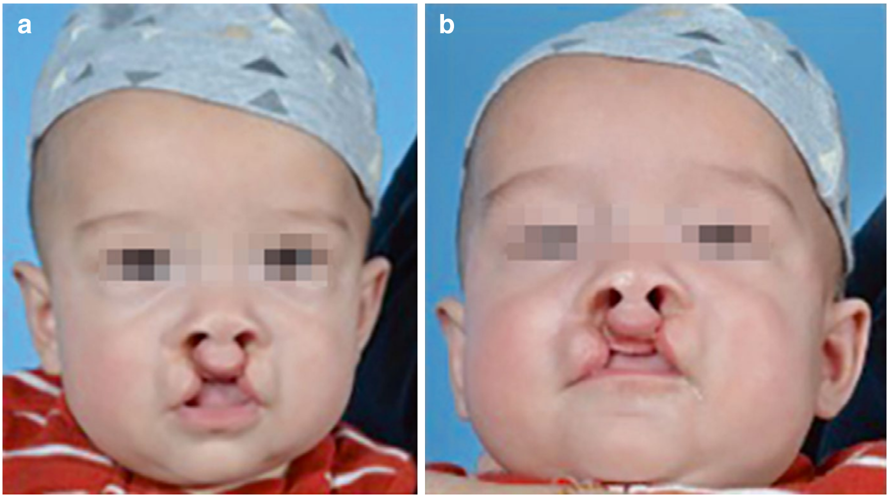


Fig. 4.31 Case #3: Posttreatment photographs

Complete Unilateral Cleft Lip and Palate (SAAS)

Patient #4: A 3-week-old patient with a complete unilateral left cleft, with significant deviation of the nasal septum and flattening of the left nasal ala. The initial anterior width of the cleft was 9.74 mm. Alveolar aligners were initiated simultaneously with the RAS at 4 weeks of age for a total of 12 weeks. A reduction in anterior and posterior cleft width was achieved, along with sagittal and transverse development of the alveolar arch (Figs. 4.32, 4.33, 4.34 and 4.35).

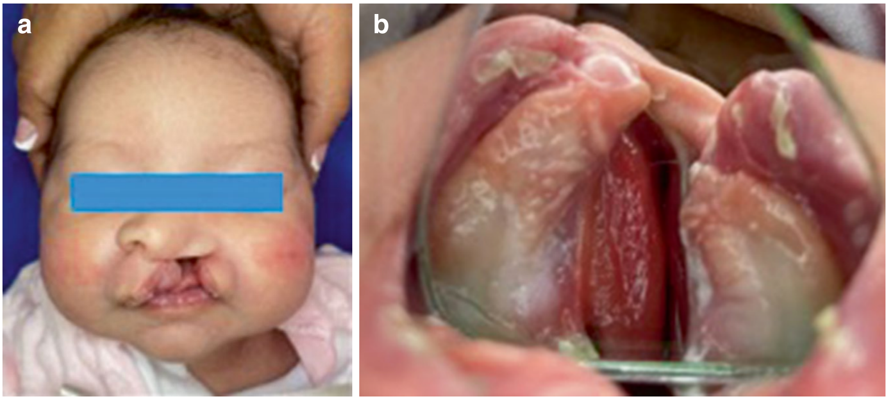


Fig. 4.32 Clinical case: Initial presurgical facial (**a**), and occlusal photographs of a patient with a unilateral complete left cleft (**b**)

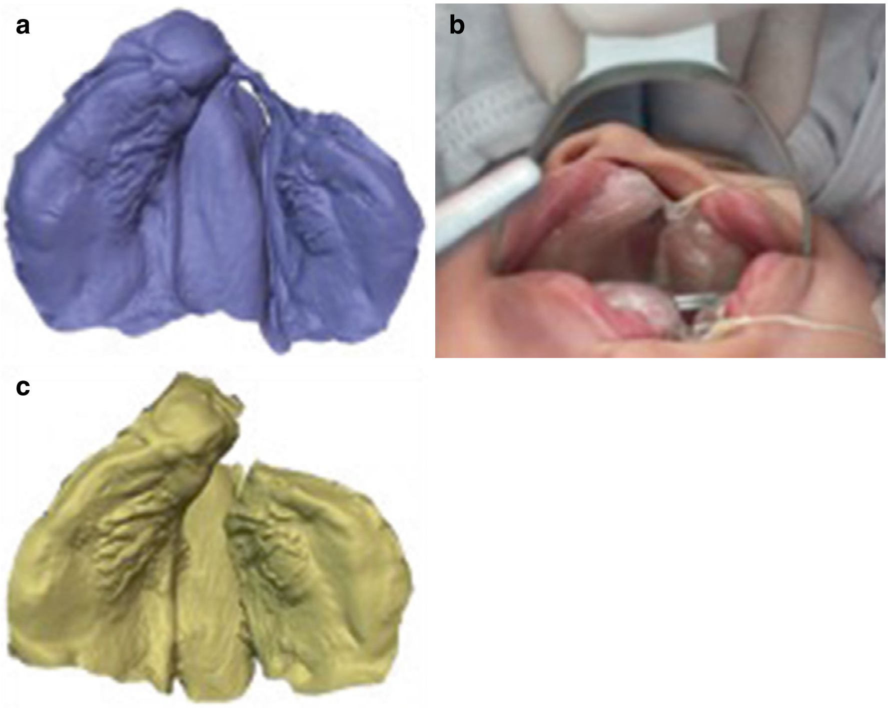


Fig. 4.33 Clinical case: The pretreatment digital model portrays the morphology of the left unilateral complete cleft (**a**). Intermediate occlusal image with the aligner properly inserted (**b**). Posttreatment digital model revealing the favorable change in palatal anatomy (**c**)

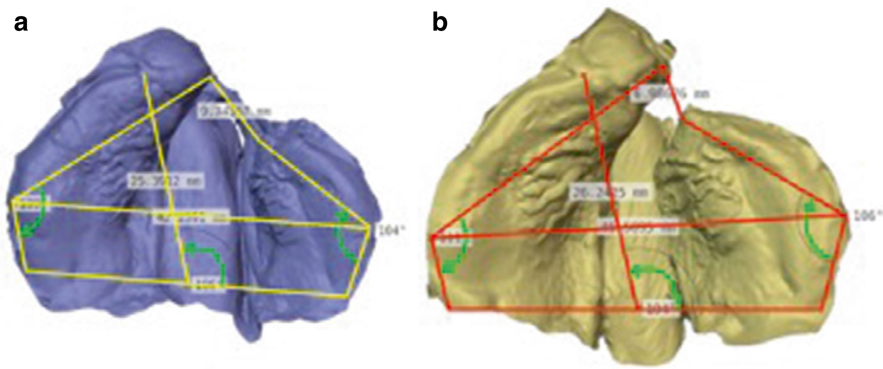


Fig. 4.34 Clinical case: Accurately scaled digital models of a unilateral left cleft of the palate, before (blue) and after (yellow) alveolar molding (**a**, **b**) with sagittal and transverse linear and angular measurements

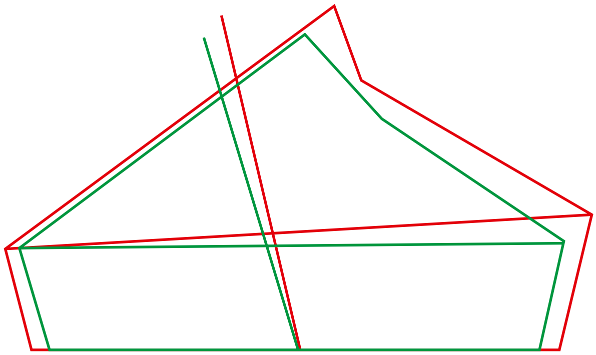


Fig. 4.35 Evaluation of treatment effect using superimposition of pretreatment (green) and posttreatment (red) polygons. A reduction of cleft width, improvement in sagittal/transverse dimensions, and midline deviation can be observed, as well as favorable clockwise rotation of the greater palatal segment

Associated Poor Outcomes and Complications

The main problem associated with the use of presurgical orthopedics is the compromise of the final aesthetic treatment outcome. Based on the Levy-Bercowski et al.'s study [49], we may consider two types of complications associated with presurgical orthopedics (specifically NAM): soft and hard tissue complications. These undesirable outcomes may be the result of inadequate use of the orthopedic device or individual reactions of the patients to the foreign material.

Soft Tissue Complications Soft tissues (skin and mucosa) may be affected by contact or pressure with the foreign material used for orthopedic purposes. It is not rare to observe skin and mucosa ulceration or irritation (reported in more than 10% of cases), bleeding, and infection during the use of these devices [49].

Fig. 4.36 Contact dermatitis produced by adhesives during nasoalveolar molding treatment in a cleft lip and palate patient

Skin irritation (contact dermatitis) is commonly observed in relation to the use of tapes and bandages which require temporal suspension of its use and local treatment. If the patient is hypersensitive to the material used, the treatment should be finished, and another alternative should be used (Fig. 4.36).

Ulceration is a more severe complication and may leave permanent scars with cosmetic and/or functional sequels. It is produced by contact of the acrylic material with the oral mucosa or skin.

Parents must identify these problems early in order to alert the healthcare provider and proceed with an adequate treatment. Any delay will worsen the complication resulting in permanent sequels that complicate surgical procedures later.

Infections (in special fungal infections) are mostly associated with *Candida albicans*. The molding plate should be removed and cleaned regularly in order to prevent this problem. They should be treated using Nystatin or Amphotericin ointment.

In relation to the nasal soft tissues, ulcers, bleeding, and irritation are also observed. Bleeding produced by a rough nasal stent may be avoided by deactivating the device for approximately 1 week to allow for tissue recovery, after which the stent can be reactivated with reduced force.

Personally, I observed nasal soft tissue thinning after molding; this condition affects the performance of surgical techniques involving cartilage dissection and may produce more poor outcomes and complications.

Hard Tissue Complications These complications are related mostly to incorrect mobilization of the cleft segments. Adequate approximation of the segments is crucial, to facilitate an adequate alignment of the maxilla.

Another important poor outcome is the secondary maxillary hypoplasia. This was described by Samuel Berkowitz, and it is related to vomeropremaxillary junction synostosis as a consequence of premaxilla retrusion by the action of an alveolar molding device [10]. Finally, another complication is the premature eruption of the premaxillary incisors as a result of the pressure exerted by the molding plate. Their extraction may be indicated if the erupting tooth is mobile or interferes with activation of the device.

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