

# Manual for the pre-and post-surgical treatment of the cleft patient



Martha L Mejía, DDS



**Nicklaus  
Children's  
Hospital**

Where Your Child Matters Most



Dr. Anthony Wolfe

His influence on my life was immeasurable, and I will forever carry his memory in my heart. I am profoundly grateful for working alongside with him throughout these years. He always believed in me and constantly encouraged my growth as a professional. His guidance and unwavering support have been invaluable in shaping my journey.

Rest in peace, dear Dr. Wolfe you will forever be in my heart.

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The purpose of this manual is to provide tools for professionals—orthodontists, pediatric dentists, and maxillofacial orthopedists—so that they can provide the highest quality treatment for their cleft patients.

A photograph of two young girls with blonde hair, laughing joyfully. The image is overlaid with a semi-transparent pink filter. The girl in the foreground is laughing with her mouth wide open, while the girl behind her is also laughing and looking upwards. The text is overlaid on the left side of the image.

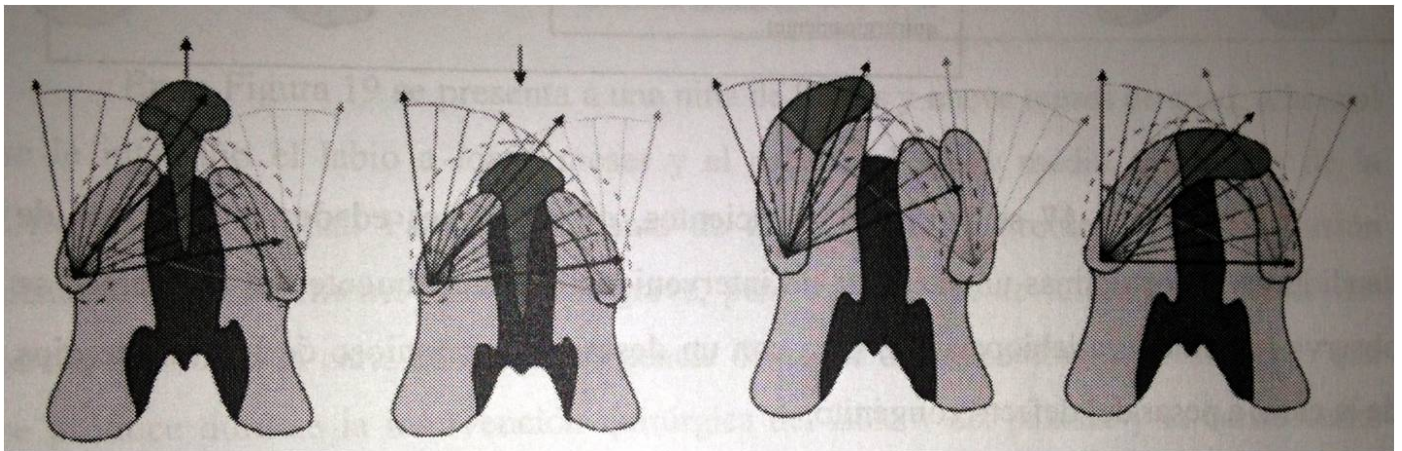
**Section I.**

**General aspects  
of clefts**

We created this manual describing the pre- and post-surgical management of cleft patients based on our knowledge and experience of more than 20 years of treating different cleft lip and palate types. After researching different kinds of pre-surgical orthopedics treatments used in the past (obturators, orthopedics appliances, Latham appliances, and Nam appliances), we want to share our experience, technique, and results in facial and maxillary development. Show cleft patient's results in temporary dentition and mixed dentition.

The facial growth of the cleft patient will determine each patient's treatment approach. When the cleft patient is born, all physiological oral and respiratory functions are altered: sucking, swallowing, breathing, and condylar growth.

In order to provide the best treatment, we must utilize pre-surgical treatment to return all structures to the best possible physiological position, thus allowing the best facial development. Patients who are operated on without pre-surgical assistance will most likely not return to functional physiology. In unilateral clefts, the force of the scar after repair collapses the cleft segments, producing a shorter and narrower maxilla and altering the growth of the middle third of the face. In bilateral clefts, scarring will cause rotation of the pre-maxilla down and tilted back, creating a shorter jaw and causing a collapse of the midface. (Fig.1)

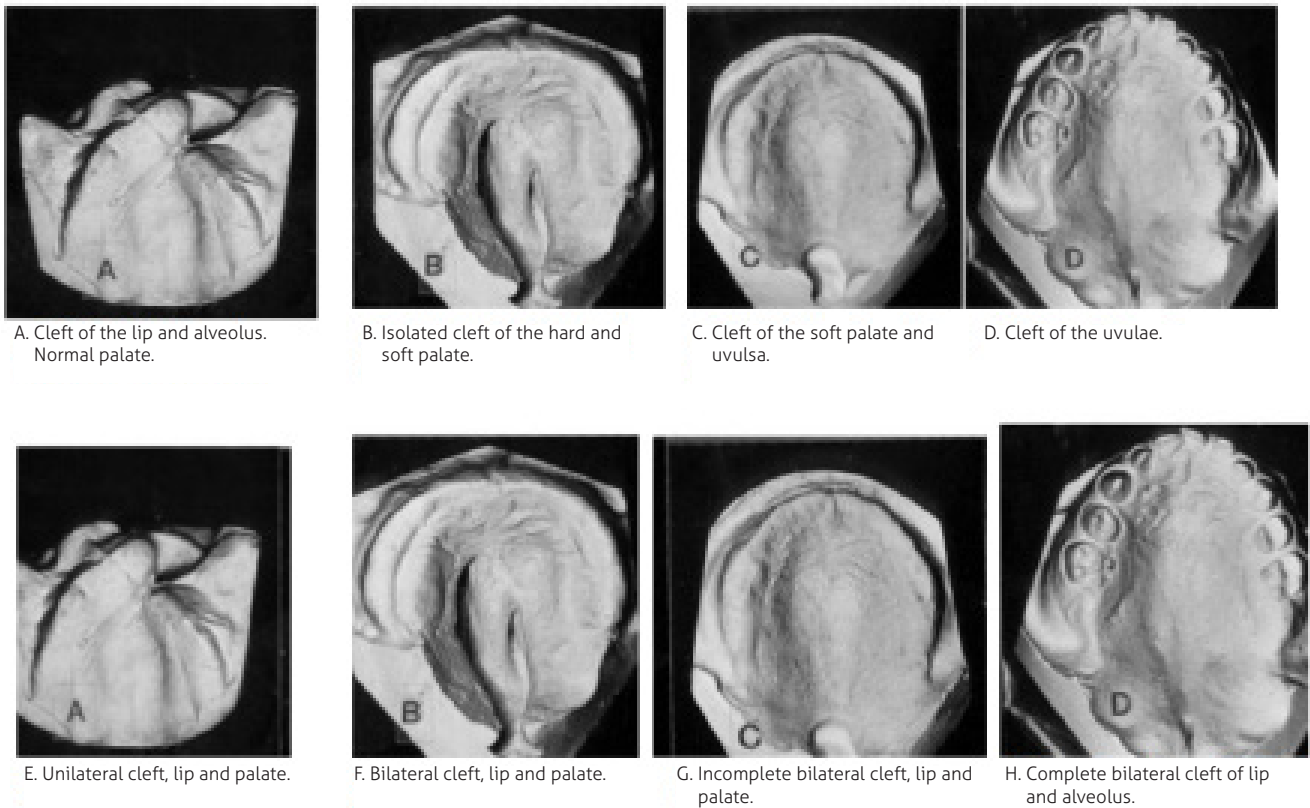


*Fig.1 Diagram illustrating the movement and collapse of the cleft segments after operative repair in bilateral (left) and unilateral (right) cleft lip repair without pre-surgical treatment.*

*Courtesy of Dr Doreen Mercedes Araque. D.D.S book Celulas Madre, Ortopedia Funcional y El Organo Bucal. (2006)*

With pre-surgical orthopedics, we can return the maxilla, muscles, and soft tissues to a more physiological position, creating a smaller scar and, thus, reducing the impact on facial growth. In the cleft patient, it is essential to begin pre-surgical orthopedic treatment as soon as possible, preferably in the first week of life, allowing better sucking, swallowing, and jaw movements in the newborn. The orthopedic device causes the tongue to descend, placing it in a position to allow for normal sucking and swallowing. The primary objective of pre-surgical treatment is to reduce the severity of the deformity caused by the cleft. Other purposes include bringing the segments closer together to allow repair of the alveolus, leveling the segments into the correct occlusal plane, achieving symmetry of the nasal septum and the lower lateral cartilage of the affected nostril, and placing the lip components, nasal mucosa, and nasal tip in positions that are as close to normal as possible.

The anatomic classification system on the location, completeness and extent of the cleft deformity. Because the lip, alveolous, and hard palate develop from different embryologic sources, combination of clefing can exist.



Courtesy of Wolfe SA, Beckowitz S. eds. Plastic Surgery of the Facial Skeleton. Boston: Little, Brown and Co; 1989:292.

Fig.2 Classification.

Pre-surgical orthopedics is a treatment that can't be generalized. Each cleft baby is unique. There are narrow clefts, and in other cases, there are large deficiencies of the maxilla. Therefore, it is very important to formulate a treatment plan, determine the arch we want to create, and, if possible, closely approximate the segments or leave them a little separate (Figure 2). This is determined by evaluating the occlusion of the alveolar ridges of the baby, avoiding at all costs the development of a class III occlusion in the newborn, which has a poor prognosis for facial development. Functional pre-surgical treatment is ideal because we can utilize the excellent elasticity of the bony structure of the baby's face. This is because the cartilage has high hyaluronic acid and maternal estrogen. We can reduce the deformity and allow better facial development by using functional orthopedics with adequate pressure on the nasal cartilages and columella and re-positioning the maxillary segments. Pre-surgical treatment should be started as soon as possible in the first week of life. To perform pre-surgical treatment, one must have experience in orthopedic appliances and be a practicing dental care professional (orthodontist, maxillofacial orthopedist, or pediatric dentist). Whatever changes are made in the bony structure of the baby will affect future craniofacial growth. The treatment must be planned and performed responsibly.

First, we will explain the steps for pre-surgical treatment with the apparatus that we use: modified Naso-alveolar molding (NAM). This is a pre-surgical maxillary orthopedics appliance (POA). The steps include making an impression, treatment planning, evaluation of the segments, construction of the appliance, making the adhesive tape and elastic to maintain the device and activation.

Then, we will describe the pre-surgical treatment for each type of cleft, including isolated cleft lip, incomplete and complete cleft lip and palate, cleft palate, and Pierre-Robin sequence.



## **Section II.**

**Steps on how  
to make the  
orthopedic device  
and how to perform  
pre-surgical  
treatment.**



## a. Taking the impression

Previously, we had a kit of pre-made acrylic template trays in different sizes. To make the impression, we have to use a material that is easy to manipulate but, above all, safe for the patient. We use "Vinylpolysiloxane Impression Material Fast-Set" (Fig. 3). This material is safe and fast and does not leave residue in the baby's mouth. It can be removed easily if the baby vomits or has difficulty breathing, minimizing the possibility of complications. The baby doesn't need to be under anesthesia or sedated, assuming the baby is healthy and has no other comorbidities conditions. The impression is taken of the child. When placing the template with the impression material, put the baby's head down slightly to prevent the material from getting into the airway.

Complications infrequently occur, but regardless, one should always take impressions in a setting where one can obtain help rapidly if problems arise. When you have removed the impression from the baby's mouth, examining and cleaning the mouth with gauze is important to ensure no residue remains. In Figure 4, one can appreciate the quality of the impression that can be obtained.



Fig.3 Templates of trays and material used for obtaining impressions.

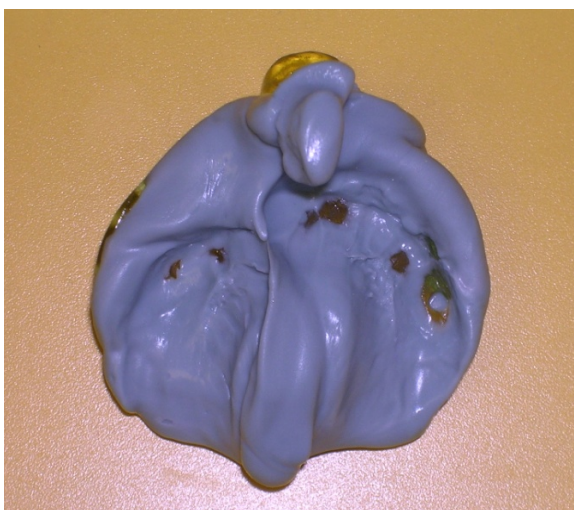


Fig.4 Quality of impression.

## b. Planning the treatment

After obtaining the plaster model, treatment can be planned. By evaluating the position of the segments and knowing the maxillary form in a typical newborn, the plan is to create a movement of the segments to make the most physiologic maxilla.

In unilateral patients, the greater segment is generally displaced laterally and forms the opposite side of the cleft. The lesser segment is generally farther back. In bilateral patients, the pre-maxilla is the most deformed and rotated most of the rotated.

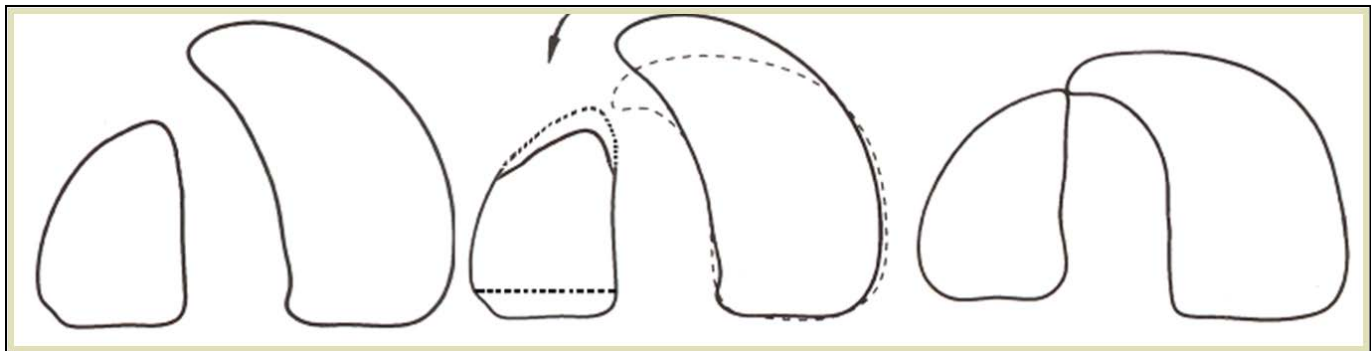


Fig.5 allows the lesser segment to grow forward and brings the greater segment to the midline without reducing the maxilla longitudinally.

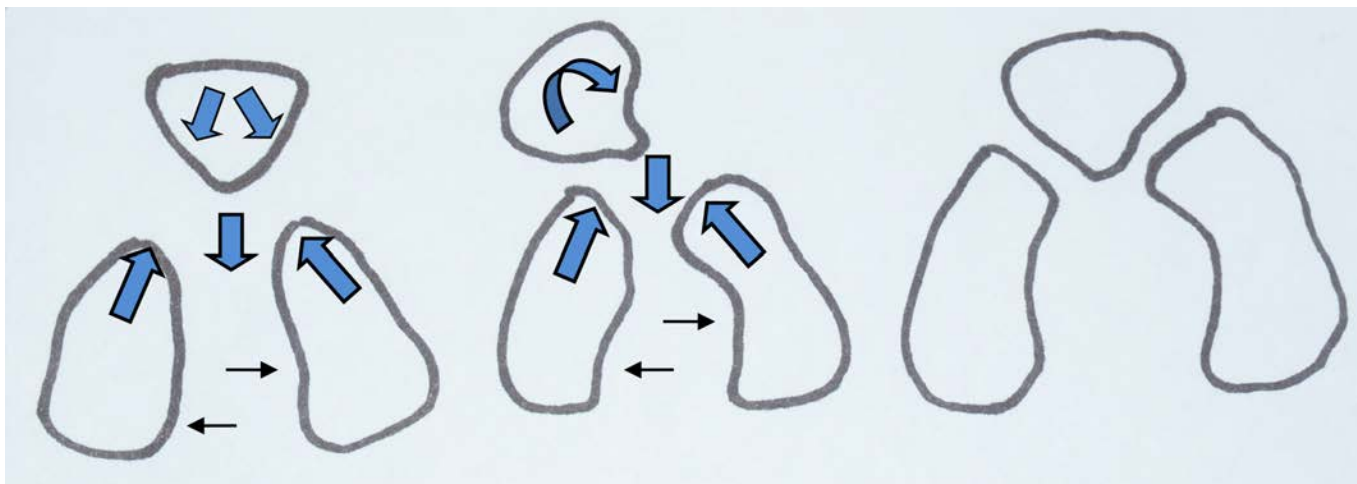


Fig.6 Diagram illustrating the movement of the segments and pre-maxilla in two different situations in bilateral cleft palatal. In the left figure, the lateral segments have a reasonable transversal distance, the middle figure has a small transversal, and the correct figure shows where we will bring the segments and pre-maxilla.

### c. Evaluation of the segments

We need a measurement of the shape and size of the maxilla using an orthometer, using previously determined measurements in both the transverse and longitudinal sense, using recent newborns with small soft palate cleft only as our controls (fig.7-8). This model will give us a clearer idea of where we should direct the segments. That way, we can determine which points of these segments require pressure to remodel and which areas we allow to grow physiologically. With an understanding of this, we can shave down small areas of the plaster model in the area of the tuberosity and over the incisal papilla, where proprioceptors in the maxilla send information to the brain. (Fig 9).

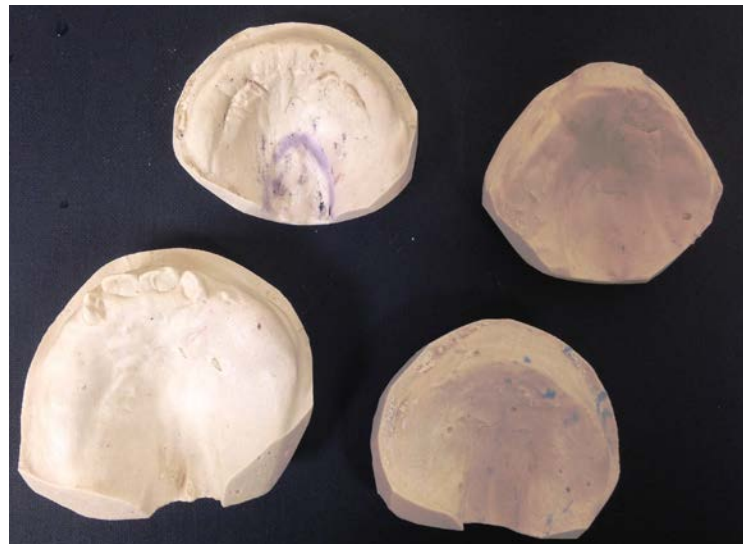
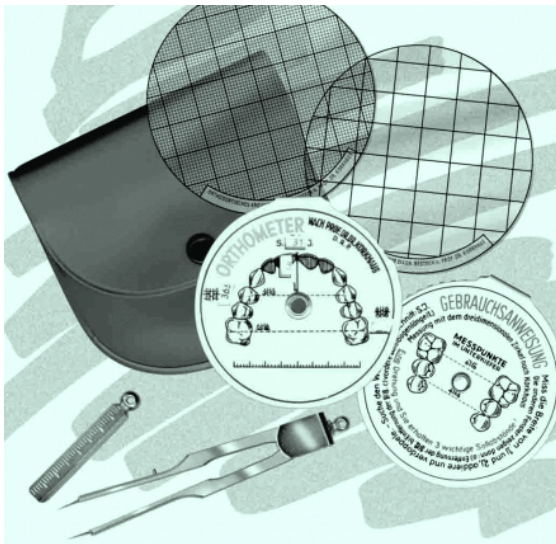


Fig.7 With the orthometer as a tool and using previous records from newborns with soft palates, we designed a plan where we need to direct the segments.

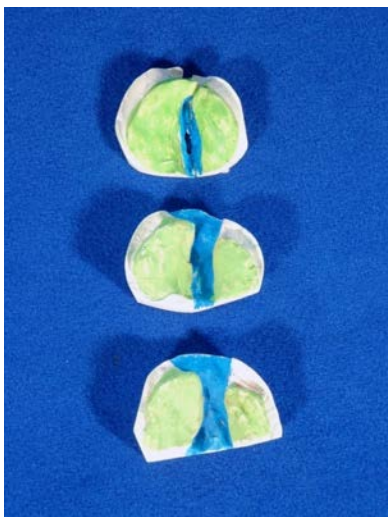
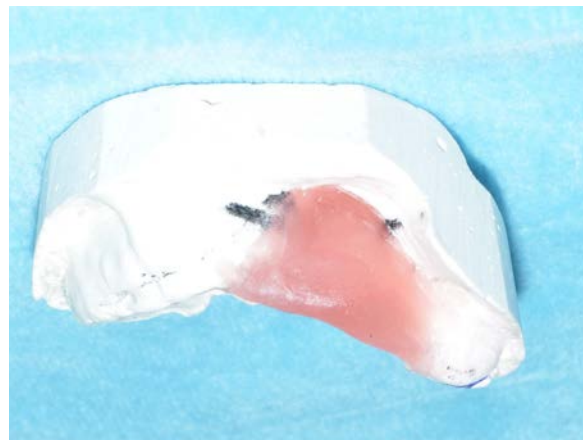


Fig.8 Examples of segment direction and growth.

#### **d. Construction of the appliance**

The first thing that should be done before making the appliance is to fill the cleft space with wax. Filling this space with wax is done to help direct the segments into the desired position, always considering the three-dimensional aspects of the maxilla. For example, if the lesser segment in unilateral patients is very retruded, we should fill the space in front of it with wax, leaving a space so that it can grow into the desired position. We should also consider if there will be any descent of the occlusal plane (Fig. 9). We must consider what the maxilla will look like when it is complete and physiologic. It is essential to grind down the area over the tuberosity a little bit since this is the area containing the growth center of the maxilla, and there are many terminal sensory nerves sending signals to the brain in response to our treatment. The device is made of hard acrylic with soft borders to protect the gentle oral tissues of the newborn. The plate should be made as physiological as possible to imitate the rugae of the palate and help with tongue position and swallowing. The nasal appliance is used when the cleft size is 7 mm or less. The acrylic part is placed and held onto the greater segment, so we plan to rotate this segment to the side of the lesser segment in unilateral clefts. Suppose the lesser segment is found to be very retruded. In that case, we can make the appliance on that side as deep as the gingival sulcus allows, creating a shield effect in that zone, trying to create traction towards the front (philosophy of shielding by Frankel), without extending the acrylic to the back portion of the tuberosity of the lesser segment. The device is rotated towards the back of the lesser segment, and we take care not to lacerate the mucosa in this location. Fig. 10

In making an appliance for bilateral cases, fill the cleft space with wax but leave a little retention in the back to maintain the posterior transversal dimension in the anterior part-filled space to move the pre-maxilla to the middle and back. Fig.11



*Fig.9 Examples of points to grind down.*

**Types of cleft**

A) Unilateral cleft lip



B) Bilateral cleft lip



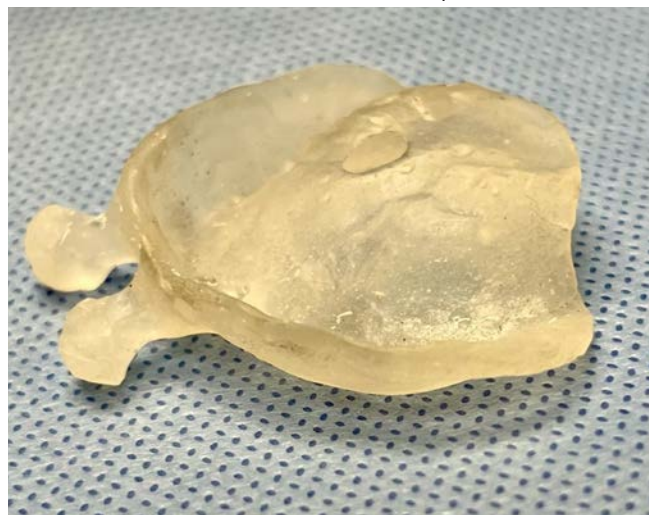
*Fig. 10 Preparation before you make the maxillary appliance.*

**Types of cleft**

A) Unilateral cleft lip



B) Bilateral cleft lip



*Fig. 11 Appliance for unilateral and bilateral clefts*

### e) Preparation of the tape and elastic to hold the appliance

The first point to consider is protecting and being careful with the newborn's skin. We place DuoDERM® in direct contact with the newborn's skin to do so. STERI-Strips™ are placed over the DuoDERM®, attached to the elastics, as seen in Figure 12-13. That way, when the elastics are loosened, only the STERI-Strips™ need to be changed. The DuoDERM® can remain on the baby's skin for 1 or 2 weeks as long as it stays dry. To remove the DuoDERM®, do it gradually with a cotton swab moistened in baby oil, then wash and dry the surface to remove any oil before placing a new DuoDERM®. Fig 12-13



Fig.12 Tape is used to hold the device in position.

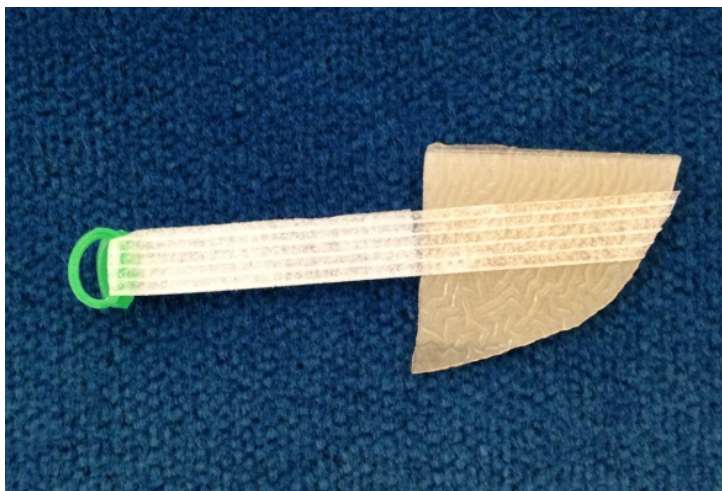


Fig.13 Examples of tapes with elastics

## f) Placing the orthopedic device.

On the day treatment is initiated, scheduling the appointment 30 minutes before the baby's next feeding is crucial. This timing helps the baby adapt more readily to the new treatment. When introducing the device into the newborn's mouth for the first time, significant changes in oronasal physiology occur, including the descent and repositioning of the tongue. Oxygen saturation may decrease, particularly in babies with a wide cleft palate, and insufficient space in the mouth for tongue descent may be a challenge. This makes the initial treatment day highly significant and demands responsibility.

If there is an issue with oxygen saturation, treatment should be postponed until the child is a bit older. The initial insertion of the device may cause discomfort for the baby as its physiology is modified, leading to increased saliva production in response to the foreign object. Adjustments to the device may be necessary, such as reducing the length of the posterior part to prevent the baby from pushing it out with its tongue.

The baby should be hungry during the procedure to facilitate feeding with the apparatus. Teaching the baby to suck and drink milk from a bottle with the apparatus involves pressing the nipple between the tongue and the device. Special bottles that can be squeezed to express milk are used, and stimulation of the baby's chin and circular movements on the cheeks aid in initial suctioning.

After bottle-feeding, parents are taught how to insert and remove the device, and close monitoring is recommended for the first 24 to 48 hours until the baby fully adapts to the device and can control secretions to prevent aspiration.

Emphasizing the importance of initial monitoring, the baby is expected to become comfortable with the new device within 48 hours. A potential complication is erosion of the oral mucosa, which requires adjustments by removing some hard acrylics, covering them with a softer acrylic, and applying oral gel with an applicator. The next appointment is scheduled for a week, and I will make the necessary adjustments. Fig.14



Fig.14 Appliance insertion and feeding stimulation.

### g) Different adjustments according to the treatment plan.

To describe all the possible adjustments and settings is impossible, but for those who have had experience with orthopedic devices, we can describe general guidelines for treatment. We can begin the treatment with pressure points and stretching, depending on what is needed. An important thing to remember when progressing with treatment is the type of arch we are creating, and we want to avoid making a small, collapsed maxilla. It's essential to understand clearly what the arch should be. There will be cases where we may have to expand a segment, and to make the adjustment in this case; we should put the pressure point on the palatal side to move it, thus creating free space in the vestibule into which the segment can be moved. Fig.15

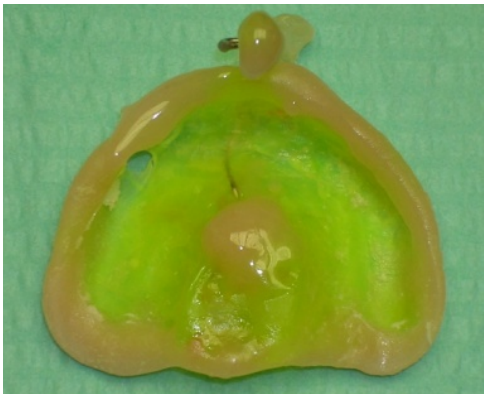


Fig. 15 Adjusting the shape of the maxilla by placing pressure on a segment from the palatal side.

In cases where the greater segment is canted, and we need to level the occlusal plane, we can make an extended flange that covers the segment from above and creates a space below so that the segment can descend. Fig.16

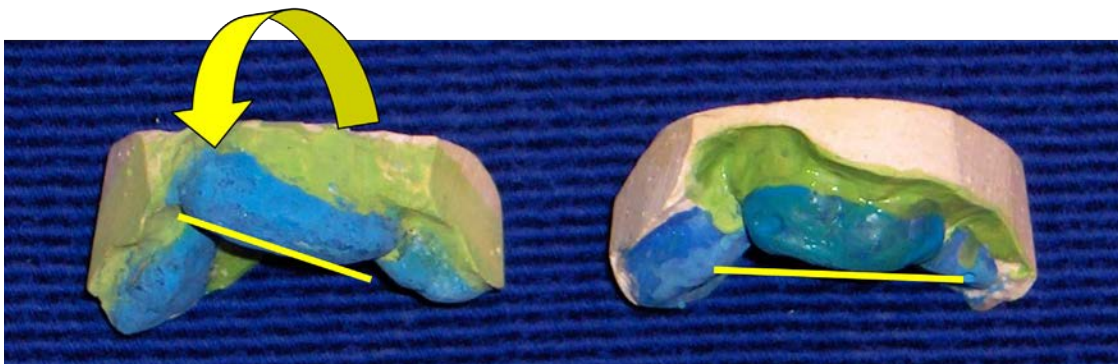


Fig.16 Adjusting by leveling an inclined segment and placing it into a normal occlusal plane



In cases where the cleft is very wide, it is possible to reduce it transversely without touching the anterior part; a subsequent device can be made with a more adequate arch. Fig.17



*Fig.17 Initial adjustment to reduce the transverse plane.*

We have described some of the possible adjustments. To achieve adequate treatment, it is necessary to make different devices during the process, according to what is needed in each case.

To help with the treatment and to maintain activity, we can get the baby accustomed to using a pacifier most of the time. A pacifier is beneficial for treating a baby with a cleft lip and palate. The babies will use the pacifiers to stimulate movement of the mandible. If the pacifier is used with attachments, it should always be under the constant supervision of an adult. Fig.18



*Fig.18 A baby with a pacifier fastened with elastic.*



# Section III.

**Descriptions of  
treatment based on  
the type of cleft.**

We will now describe pre-surgical treatment for each type of cleft, including isolated cleft lip; cleft lip and palate, unilateral or bilateral, complete or incomplete; isolated cleft palate; and Pierre-Robin sequence.

## a) Unilateral cleft lip

### Unilateral

Isolated cleft lip is usually accompanied by deviation of the nasal septum, with some inclination and rotation of the lip. In this case, pre-surgical treatment requires using a tape (stereo-strip) on the lip, effectively rotating it down, and simulating the closure of the cleft. The tape needs to be used one centimeter before the lateral alar base on the non-cleft side, using a little pressure to move the tissue to the midline and tape it on the check cleft side. If the newborn has septal deviation, a nasal RAS device can straighten the septum and align the nostril to a more symmetrical position. This treatment can be done in the first few months of life until the baby has his surgical cleft lip repaired. Fig.19-20

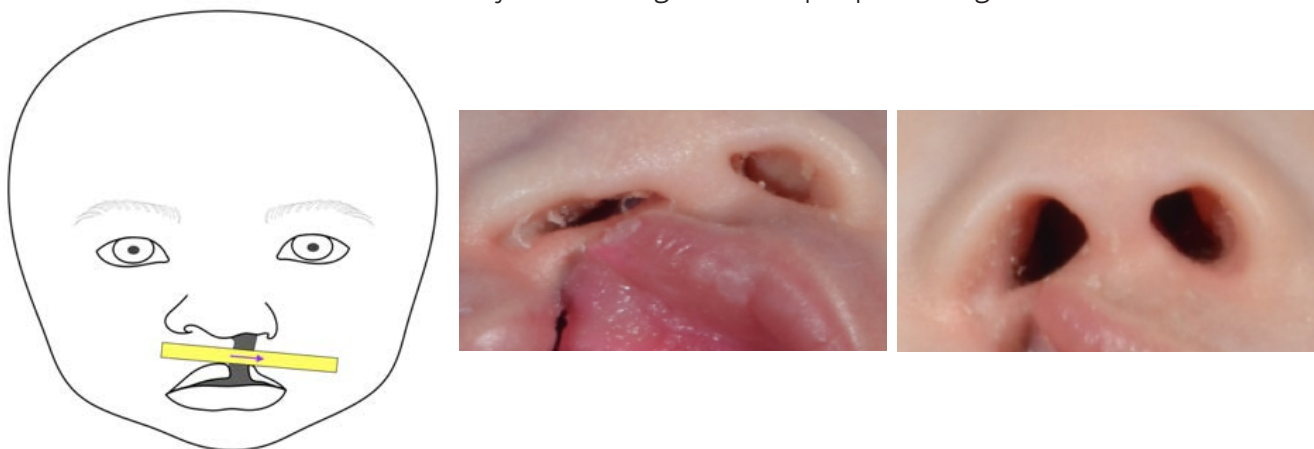


Fig.19 Pre-surgical treatment before and after with labial tape and RAS device.

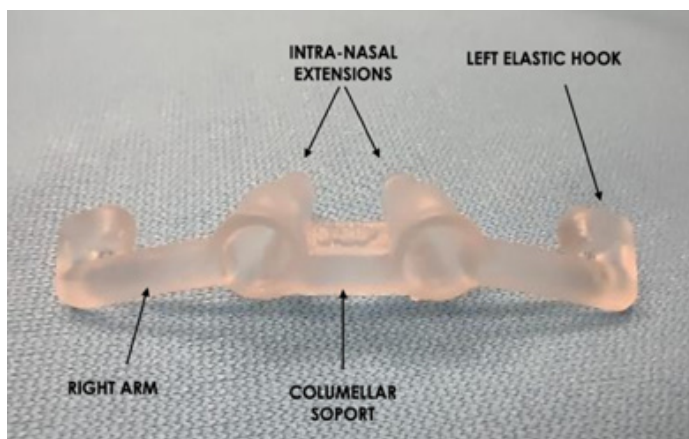


Fig.20 RAS Orthopedic device elevates the nostrils and straightens the nasal septum.

### Unilateral Incomplete cleft lip-palate

In the unilateral incomplete cleft lip and palate, various things must be considered before beginning the treatment, such as the size of the cleft and whether the nasal septum is affected. Assessing these factors is essential to determine if a fabricated orthopedic device is needed or if taping over the lip will suffice. But if the cleft is incomplete and involves the alveolus, hard palate, and soft palate, we will treat it as described below for unilateral complete cleft lip and palate.

## b) Bilateral cleft lip

Pre-surgical treatment in incomplete bilateral clefts can reduce deformity and improve facial development. Bilateral cases usually have a short columella and pro labium. Fig.21 In bilateral cases, the pre-surgical treatment can lengthen the columella's size and improve the nose's projection. We used Rhinoplasty appliances for 3-4 months to get this proposal. Fig.22



Fig. 21 Before the Rhinoplasty appliance



Fig. 22 After four months of treatment

### c) Unilateral complete cleft lip-palate

Several considerations should be made in the unilateral cleft lip-palate before beginning treatment: the size and location of the cleft and if the greater segment is inclined and affects the occlusal plane. After completing our analysis and treatment plan, we can begin with a simple orthopedic plate to adapt to the baby. We will modify the physiology once the device is placed on the newborn. After covering the palate, breathing, swallowing, and suction are affected. The intra-oral apparatus increases salivary production. Given these reasons, it can be difficult for the baby the first time the orthopedic apparatus is placed. It is very important that the professional placing the device remains calm and has complete control of the situation. It is usual for the baby to have difficulty controlling his saliva and to suck. Sometimes, shortening the device from behind is necessary, which helps the baby adapt more quickly.

Once the device is inserted and appropriately fastened with the bands and tape, it is okay to proceed with feeding. A special nipple is used to help babies with cleft lips and palates, which allows them to extract milk and teaches them to suck. We can use speech therapists' techniques, such as pressing the baby's cheeks and stimulating under the chin to help promote suction. When the baby has been fed and the mother feels comfortable with the instructions, it is okay to end the first treatment. Parents must closely monitor the child during the first 48 hours until the baby has learned to control his saliva and adapted to the device. The baby should never be without supervision during the first several hours when an accident could occur, especially if the baby vomits and potentially aspirates. The patient must return every 8 to 15 days to follow the cleft's changing size and monitor how the parents are doing. When the cleft is between 15 – 25 mm, it is essential to adjust weekly, and if the size is between 5 -15 mm, the changes can be made every 15 days. Typically, we use soft resin in the areas where we need to use pressure to direct our segments into the correct position to obtain a physiological maxilla. When the greater segment is inclined upwards, a device that covers the superior part of the segment creates a free space so that the segment can descend. We use the nasal device when the cleft size is 7 mm or less. During treatment, some devices may need to be used to obtain the objectives of the patient's particular treatment plan. Fig.23 It is essential to feed the baby with the bottle on the greater segment and before the acrylic pin to help with the greater segment rotation. Fig. 24



Fig. 23 Unilateral complete cleft lip (before and after pre-surgical treatment)



Fig. 24 Feeding with the bottle before the acrylic pin on the greater segment side

## d) Bilateral incomplete cleft lip-palate

In bilateral incomplete cleft lip and palate, we should have the same considerations that we previously described, with additional evaluation of the size of the columella. In some cases, patients may have a very small columella, and it will be necessary to elongate it. For this reason, we use an RAS orthopedic device to lengthen the columella and improve nasal projection and nostril symmetry. This is below in Fig. 25a. The initial occlusal plane is inclined upwards. The device is made to help bring the segment down, and it is also important to perform pressure exercises to allow it to descend and correct the occlusal plane appropriately.

To accomplish this objective, the use of a pacifier is helpful. With the pacifier, the baby is sucking, and that maintains an active form of treatment, applying pressure to keep an active treatment. Fig.25b-26



Before



After

Fig. 25 Pre-surgical treatment before & after treatment



Before



After

Fig. 25a Before and After If you have a case with the initial occlusal plane inclined upwards. The device is made to help bring the segment down and it is also important to perform pressure exercises to allow it to appropriately descend and correct the occlusal plane

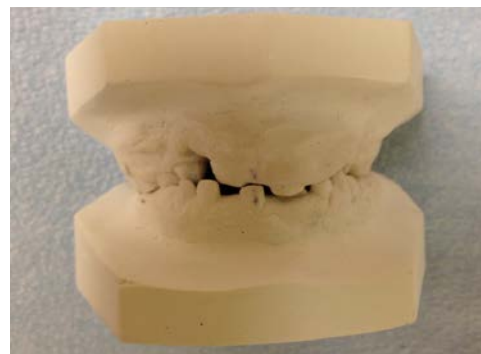


Fig. 26 Pre- and post-surgical models of sequential treatment.

### e). Bilateral complete cleft lip-palate

In the bilateral cleft lip and palate, it is essential to consider the following: the position of the pre-maxilla, the size of the cleft, the length and location of the segments, and the inclination and rotation of the pre-maxilla affecting the occlusal plane. After completing our analysis and treatment plan, we can start with a simple maxillary orthopedic appliance to allow the baby to adapt to the process quickly.

When the baby has adapted to the process and tolerates the appliance, weekly appointments begin for adjustments. Depending on the defect severity, the appliance is used for one to four weeks, placing the pre-maxilla in the center and preparing it for backward movement. Once the pre-maxilla is centered and the cleft measure between the lateral segments and premaxilla is 7 mm or less, we can start with the nasal device to begin the elongation of the columella.

As we can see in the following figure, with upward force on the nostrils and downward pressure on the pro labium, we will lengthen the columella (Fig27-28). To obtain the best results, we recommend using the pacifier as much as possible to maintain the activation of the apparatus. In the subsequent figures, you can observe the initial apparatus and the facial profile before and after the columella lengthening and after surgery and the sequence of models during the treatment. Fig. 28-29-30



Fig. 27 Lengthening of the columella



Fig.28 - 29 Orthopedic appliance initially and profile pictures before and after lengthening of the columella.

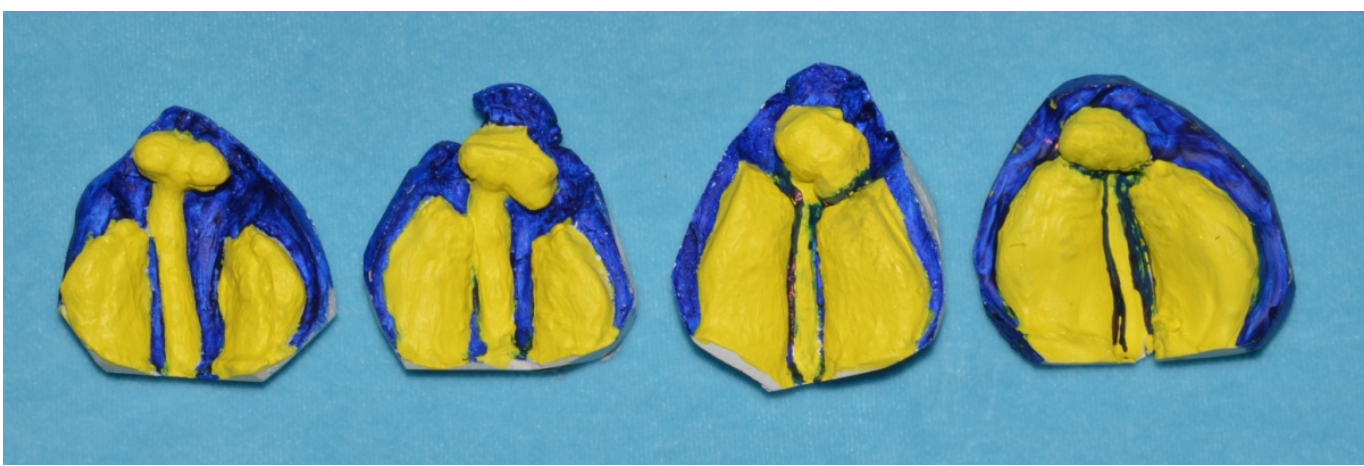


Fig.30 Sequence of models during the pre-surgical treatment of bilateral cleft.



## f). Pierre-Robin sequence and cleft palate

Our treatment of patients with a cleft palate is slightly different than previously described. The orthopedic plate is intra-oral, there is no external retention, and it is used for much longer, anywhere between 8 to 15 months, depending on the size of the cleft palate. The plate should be changed every five weeks to allow adequate growth of the maxilla. An impression is made between 0 and 1 month of age with fast Putty (the safest material to use). Then, the model is made in the following fashion: wear down the plaster on the tuberosity and incisive papilla, then use wax to cover the cleft palate up to the border of the cleft. The orthopedic obturator is made with hard acrylic, with the obturator having no direct retention in the cleft. When creating the plate that covers the palate, it is essential to simulate the palatal rugae, and posteriorly, it shouldn't go beyond the line of the tuberosity (the obturator can be made of acrylic or silicone. Usually, it is easier to adapt when the first obturator is soft). The borders of the obturator should be covered with soft acrylic to protect the mucosa of the child. We place a black suture on the front of the obturator for easy and rapid removal during the adaptation process. Fig.31. Monitoring the baby when inserting the obturator is essential. The oxygen saturation should be evaluated to determine if the patient can safely use it. If the baby cannot tolerate treatment, try again a week later when the baby is older. This is a common scenario in children with the Pierre-Robin sequence. The parents should monitor the baby during the first 48 hours. The baby should be supervised when eating and observed to see how long it takes to bottle feed and how he breathes during feeding. One can help with feeding by pressing the cheeks and stimulating the chin during the first few times the baby is being bottle-fed to help teach him how to suck. The baby should have adapted to the obturator by 24 to 48 hours (Fixodent®), which can be used to maintain it in position and to assist with adaptation).

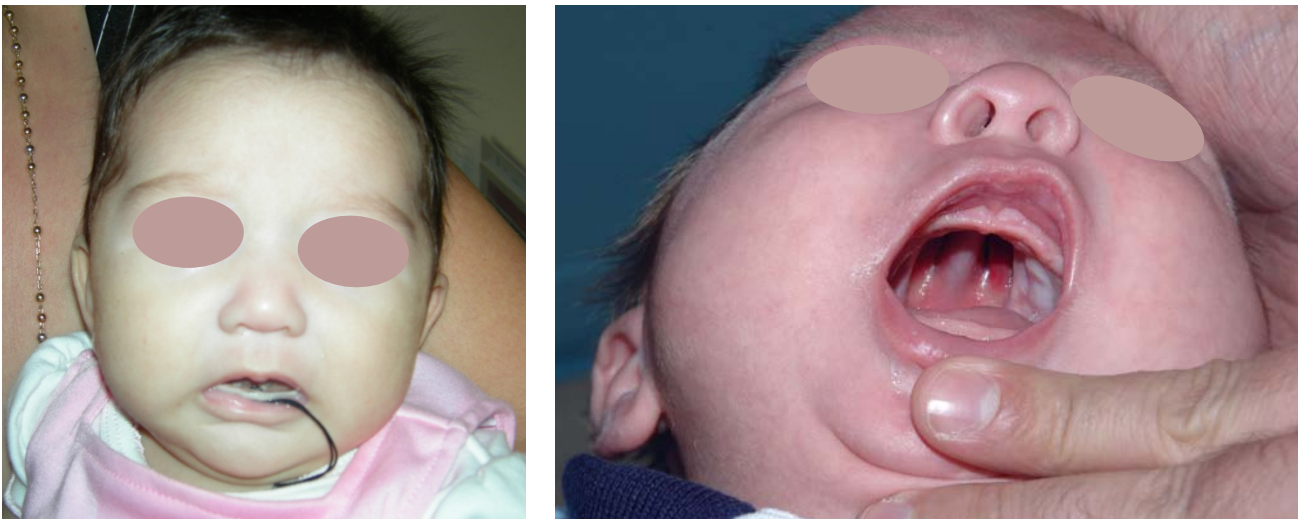


Fig.31 Example of the black suture on the front of the obturator

A new obturator can be made every five weeks with a space of 1 or 2 millimeters around the maxilla to allow its growth. With this treatment, throughout 8 to 15 months, a 50 percent reduction in the size of the cleft can be achieved, depending on its original length, as seen in Fig. 32- 34.



Fig.32-34 Pressure points on the maxilla, palatine rugae, and the cleft's size reduction.



A young girl with a cleft lip and palate is smiling and resting her chin on her hands. The image is overlaid with a semi-transparent red filter. The text is white and positioned on the left side of the image.

# Section IV.

# Post-surgical Treatment of Clefts.

The post-surgical treatment of cleft patients requires time and is essential for the overall success of the facial growth and appearance of the patient. During the first four months after the operation, it is necessary to massage the scar correctly. In our treatment protocol, an initial appointment is made with the parents three weeks after the operation to train them on performing the massages.

The massaging should be performed as follows: the index finger should be placed inside the lip and the thumb on the outside. Use the tips of these digits to squeeze and massage the scar internally and externally while also putting traction on the lip to create space in the vestibule of the lip.

The massaging should initially begin as indicated in Figure 35. Later, vibration or circular movements can be used, as shown in Fig.36. Finally, traction on the lip is used to pull it down, as seen in Fig. 37.



Fig.35



Fig.36



Fig.37

Post-surgical, we also use the RAS devices 4 to 6 months after surgery to preserve the nasal correction and avoid collapse. Fig.38.39 In all cleft cases, the nasal device is started three weeks after the operation. This "Rhinoplasty Appliance," as we call it, is pretty easy to clean and use.



Fig. 38-39 Unilateral patient with nasal (RAS) device being used after surgery.

We can also use a unilateral appliance to obtain symmetry of the nostrils in older patients. In this case, we refer to it as an orthonostric appliance (Figure 40), custom-made for each patient. It has a small screw.

In Figure 41, you can see a case.



*Fig.40 Orthonostric appliance*



*Fig.41 Constricted left nostril before and after treatment.*





**Section V.**

**Presentation of  
Cleft Cases**

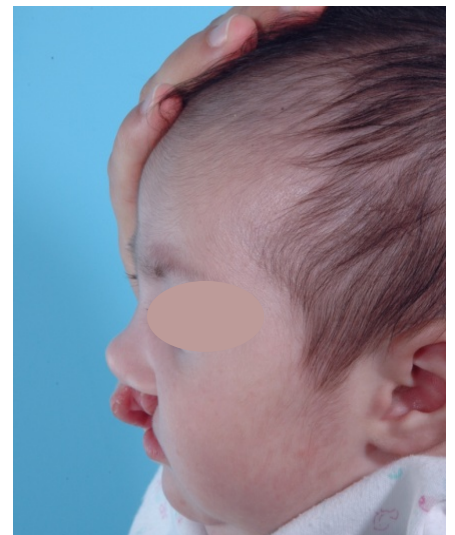


## Unilateral Case

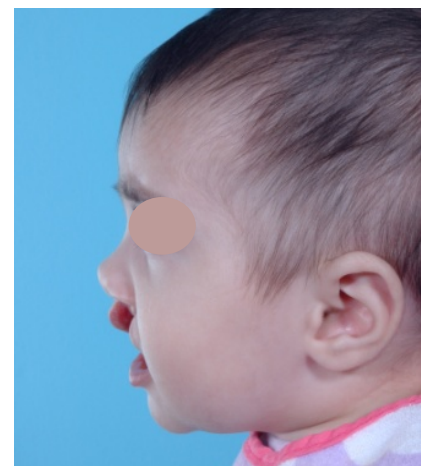
We will describe a unilateral case that illustrates development until permanent dentition, where one can appreciate the growth of the maxilla, the occlusion, the occlusal plane, and the development of the middle third of the face.

### 1) Patient with complete unilateral cleft lip and palate

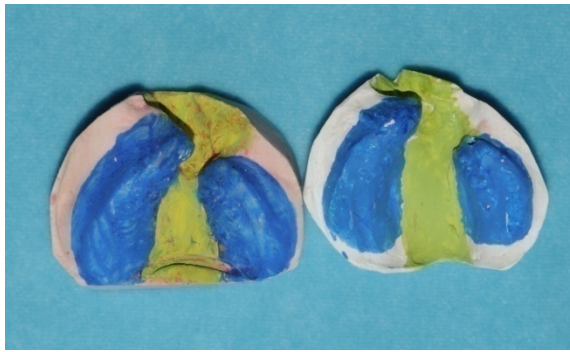
This is a patient with complete unilateral cleft lip and palate who was born in Trinidad and started pre-surgical treatment at six weeks of age, with a total treatment of 20 weeks. The first surgery was performed at six months of age, involving closure of cleft lip, gingivoperiosteoplasty, and cleft nasal correction. The closure of the cleft palate was performed at 18 months.



Newborn six weeks old



After presurgical treatment



Pre-Surgical records: Six months old before the first surgery



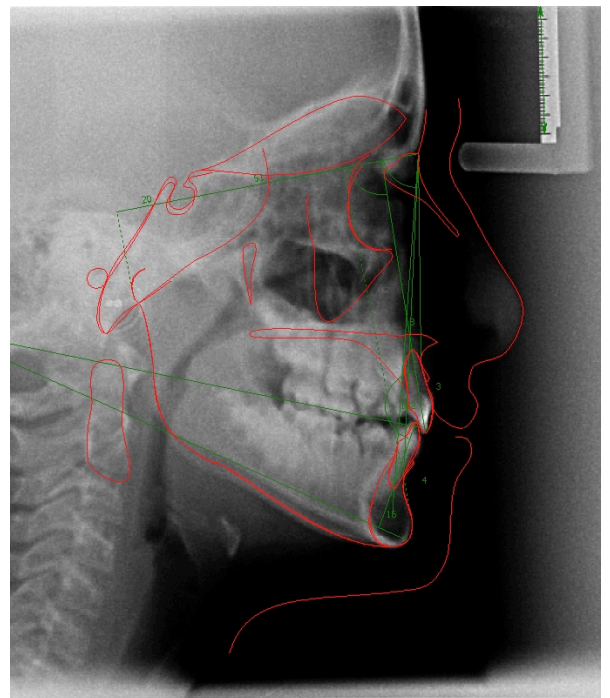
Temporary dentition Maxillary and mandible arch

Temporary Dentition Mix Dentition





Final occlusion 18 years of age



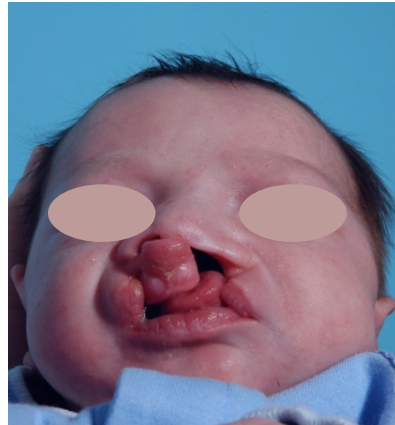
Cephalometric Rx before orthodontics treatment

## Bilateral Case:

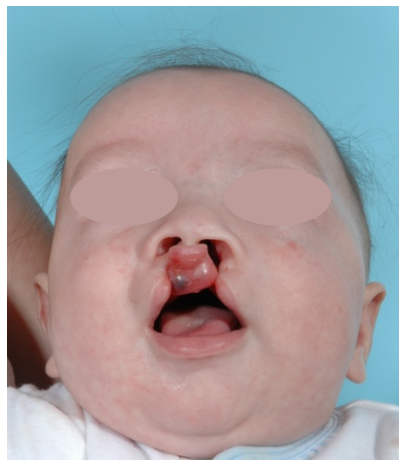
The case below illustrates the results of bilateral patients up to the time of mixed and permanent dentition, where one can appreciate the average growth of the maxilla, the normal occlusion and occlusal plane, and the normal development of the middle third of the face

## 2. Patient with bilateral incomplete cleft

Born in the US, this patient began pre-surgical treatment at two months of age, with the treatment performed for 18 weeks initially on both sides, then ten weeks on the left. The right side was closed first at six months, then the left at nine months, with pre-surgical treatment maintained between these two operations. The palate was closed at 18 months, along with a dermal graft to the prolabium.



Newborn eight weeks old



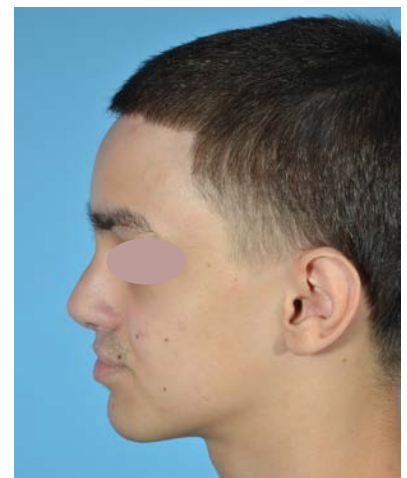
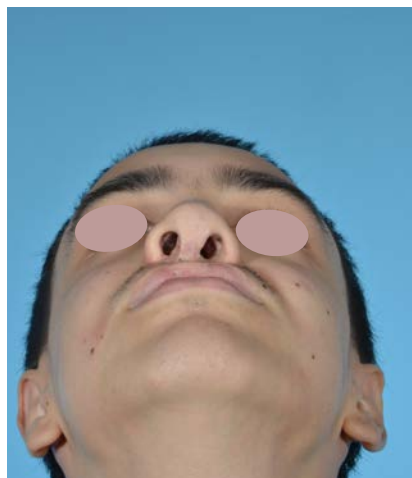
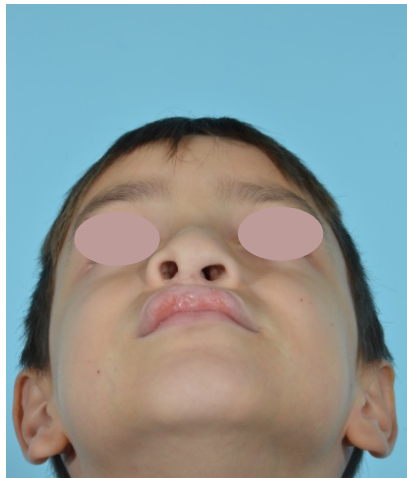
Six months old before the first surgery



Pre-surgical records



After surgery ( two-stage)





Temporary dentition



Temporary dentition



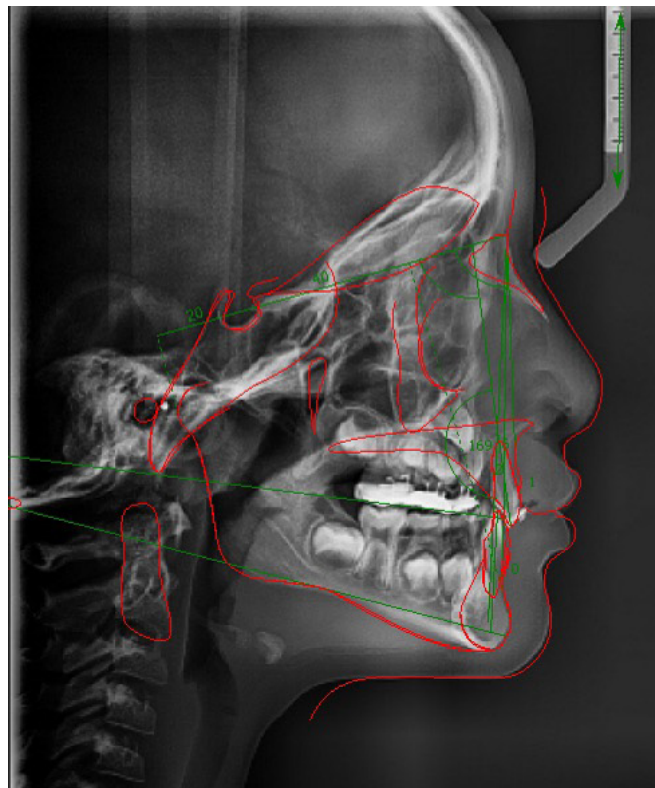
Maxillary and mandible arch



Mix-dentition



Permanent dentition at 17 years of age.



Cephalometric RX before orthodontics treatment

A close-up photograph of two young girls smiling and hugging. The image is overlaid with a semi-transparent purple filter. The girl on the left has long blonde hair and is smiling warmly. The girl on the right has curly brown hair and is also smiling broadly, showing her teeth. They are both wearing light-colored clothing.

**Section VI.**

**Conclusions and  
Bibliography**



## Conclusions

- The treatment of the cleft patient requires an interdisciplinary and stepwise approach.
- Pre-surgical treatment is an integral component of the management of this patient. Each patient is unique, and careful analyses, planning, cooperation, and dedication are needed.
- Overall, the use of pre-surgical treatment can significantly improve the results in the repair of cleft lips and palates and enhance the quality of life of our patients.
- Our goals as an interdisciplinary team are to maximize facial esthetics, optimize the development and growth of the face, and minimize physical, emotional, and surgical impacts.
- Development of good self-esteem is significant and will depend on facial esthetics and speech during mixed dentition.
- The results of an integral treatment will be seen in the long term.
- Working as a part of an interdisciplinary team in an institution, we can find better treatments to improve our patients' quality of life.
- Our pre-surgical treatment and alignment of the alveolar cleft and the anterior palate do not interfere with maxillary growth nor cause a Class III malocclusion. We should write that we are performing a "supra-periosteal" gingivoperiosteoplasty rather than a true sub-periosteal gingivoperiosteoplasty, thus having a less impact on maxillary growth and permitting better development on it. Meso and Brachycephalic biotypes were found on the cephalometric analysis: average sagittal maxillary growth.

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## About Nicklaus Children's Hospital, Where Children Matter Most

Founded in 1950 by Variety Clubs International, Nicklaus Children's Hospital is South Florida's only licensed specialty hospital exclusively for children, with approximately 850 attending physicians, including more than 500 pediatric subspecialists. The 309-bed hospital, known as Miami Children's Hospital from 1983 through 2014, is renowned for excellence in all aspects of pediatric medicine with many specialty programs routinely ranked among the best in the nation by *U.S. News & World Report* since 2008. The hospital is also home to the largest pediatric teaching program in the southeastern United States and since 2003 has been designated an American Nurses Credentialing Center (ANCC) Magnet facility, the nursing profession's most prestigious institutional honor. For more information, please visit [www.nicklauschildrens.org](http://www.nicklauschildrens.org)



Martha L Mejía, DDS

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# PART II

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**Manual for the Rhinoplasty  
Appliance System (RAS)  
Pre- and post-surgical management**



**Special thanks to:**

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# 1. Introduction

The birth of a child with cleft lip and palate significantly impacts the individual's development. The complexity of this condition generates psychological, aesthetic, functional, and anatomical alterations that can affect breathing, feeding, hearing, chewing, craniofacial development, and speech. This involves them, as well as, their social, school, and family environment. Patients with this condition require interdisciplinary management, excellent coordination and, treatment planning. Over the past few years, many pre-surgical treatments have emerged to try to direct growth and reduce the defect before the first surgery. This would reduce the number of surgical interventions and the impact on the craniofacial and psychological development of the patient. The Rhinoplasty appliance is a nasal appliance that allows the nasal septum and nostrils to be aligned. This has an impact on the entire craniofacial growth, in particular the airway. Breathing is the most vital function of humans, and proper breathing influences the development of all human body organs. Breathing also affects phonation, an important aspect where patients with cleft lip and palate have been stigmatized.

Presurgical orthopedics (PSO) is a powerful tool for modifying cleft structures during the first months of life, allowing and restoring essential functions. Breathing is vital for craniofacial growth and the functional development of newborns. Patients with cleft lip and palate have problems with sleep apnea, oral breathing, attention deficit disorders, allergies, and lack of development of maxillary sinuses that affect their entire lives. For this reason, nasal molding is an essential part of treatment.

## 2. General Aspects

The purpose of this manual is to standardize a method and appliances for the pre- and post-surgical management of the nose in patients with cleft lip and palate. This tool helps clinicians improve their results and reduce the number of surgeries in these patients. The main objective is to create a protocol and method of using the Rhinoplasty Appliance system clear enough to be widely used.

This technique is possible due to the malleability of nasal cartilage during the first months of life, as described by Matsuo and Nakajima in 1984. Several authors have attributed the nasal deformity in patients with cleft lip and palate to the adjacent facial musculature as an extrinsic agent. Another cause of the deformation of the nasal ala of the nose is attributed to the failure in the union of the piriform foramen due to hypoplasia of the maxilla. The nose of children with cleft lip after surgery is prone to developing local collapses (Mori et al., 2005; MOs Muller et al., 2017) The nasal devices are commonly used pre-surgically in patients with cleft lip and palate to improve the shape of the nose; when used post-surgically, nasal conformers enhance the therapeutic effect, maintaining repair, projecting the tip of the nose and preventing collapse (Cobley et al, 2000). Postoperative management requires adequate follow-up after cleft lip and palate surgery. The incisions inside the nostrils can contract, causing a relapse of nasal reconstruction; therefore, it is essential to support in the first healing period to avoid tissue contraction and maintain the size and shape of the nasal cartilage while having an adequate airway.



Studies have indicated that the long-term goals in treating cleft lip and palate are to reduce scar tissue formation, establish the shape of the nose, and improve lip and nasal aesthetics. While reducing the number of surgical revisions. With nasal conformers, we can preserve the nasal reconstruction performed by the surgeon, maintain the elongation of the columella, and prevent the collapse of the nostrils.



*Fig. 1 One of the most notable features in newborns with cleft lip and palate is nasal deformity.*

### 3. Description of the Rhinoplasty Appliance System

The Rhinoplasty Appliance System is a nasal prosthesis system consisting of nasal stents that are inserted into the nostrils, a middle component that joins the stents, and two lateral parts that finish in hooks and allow the device to be held in position and simultaneously manipulate the nasal septum and the height of the nostrils horizontally and vertically. The device is held in place with adhesive tapes over the cheeks.

#### **Principles of operation of the device:**

This device has been designed to treat pre-and post-surgical patients with cleft lip and palate, by molding the nostrils, correcting the nasal septum, and elongating the columella before surgical repair also allow for maintaining the correct height of the nostrils and the proper position of the septum, which is also used in post-surgical treatments.

With its intranasal retention, the device has greater lateral control over the nasal septum in an infant with cleft lip and palate (CLP). The system allows for the nose to be corrected, since the appliance has a lateral component with hooks drawn by an elastic module taped to the infant's cheeks.

The advantages of the Rhinoplastic Appliance are that it is biocompatible, durable, and easy to clean, remove, and insert.

#### **Type and amount of energy to be used in the appliance:**

The device uses a slight pressure to stretch the soft tissue and cartilage. (The force is exerted on the tissue using different sizes of the appliance with the adhesive tapes regulating the height of the nostrils and straightening the nasal septum). As it is difficult to quantify the pressure on the soft tissue, we will base it on the amount of ischemia that occurs at the time of placement and the disappearance of this in the first 5 minutes after insertion.

**Uses of the device:**

- To improve the size and shape of the nasal nostrils, lengthen the columella and straighten the nasal septum in presurgical treatment in patients with cleft lip and palate.
- To maintain and improve the appearance of the nasal alae and prevent scar tissue growth after cleft lip and palate surgery.
- Connect oxygen cannulas in newborns and prevent columella damage.
- Correction of the nasal septum deviation in newborns without any abnormality or other conditions.

**Part of the body or type of tissue in which it is applied or interacted with:**

Direct: Nostrils, lateral aspect of the nose, septum, and cheeks.

It also impacts the alveolar segments that interact with the nasal septum.

**Frequency of use:** The device should be used 24 hours per day, in pre- and post-surgical treatment. The duration of each treatment is described in the protocol.

## 4. Protocol of photos and measurements

At the beginning of the treatment, they must have completed the general information required (complete medical history), protocol of photographs, location of anatomical points, and facial scan (if possible). The photos, anatomical points, and facial scanning protocol should be performed at the treatment's beginning, middle, and end.

- Clinical History
- Photographs (Single color background, preferably blue or white)
- Anthropometric measurements

**A. PHOTO PROTOCOL:** A uniformed colored background should be ideally used for ALL clinical photographs.

**1. FRONTAL PHOTO**

Frontal view of patient's face



Fig.2 (frontal photo)

## 2. RIGHT AND LEFT PROFILE PICTURE

The patient's right and left profile.



*Fig.3 right and left profile*

## 3. SUBMENTAL or BASAL PHOTO

Submental or basal view of the patient's face.



*Fig.4 Photo submental o basal*

## 4. FRONTAL PHOTO OF THE CLEFT



*Fig.5 Frontal photo of the cleft*

**5. BASAL PHOTO OF THE NOSE IN UNILATERAL**



*Fig.6 Photo submental o basal*

**BASAL PHOTO OF THE NOSE AND PREMAXILLA IN BILATERAL**



*Fig.7 Submental photo of a basal*

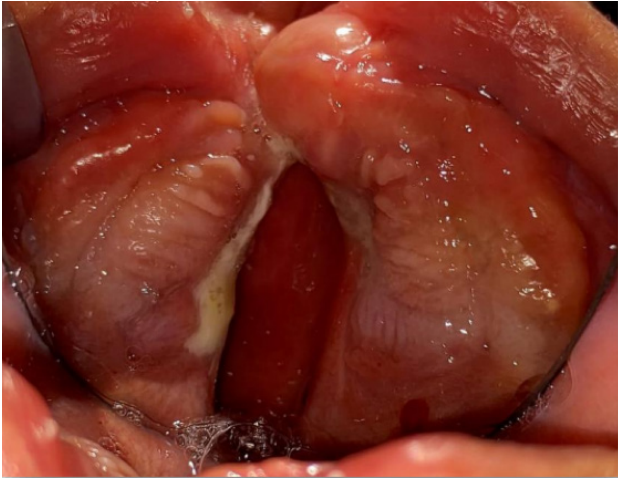


**FRONTAL PHOTO WITH LIP TAPE**



*Fig. 8 Frontal photo with tape*

**PHOTO OF THE CLEFT AND ALVEOLAR SEGMENTS**



*Fig.9 Intraoral upper occlusal (palatal) view.*

**PHOTO OF THE FRONT PREMAXILLA, LEFT AND RIGHT SIDE**



*Fig.10 Photo of the front and side premaxilla right and left.*

**BASAL PHOTO OF THE NOSE WITH THE LIP TAPE AND WITH THE DEVICE**



*Fig.11 Submental or basal photo with tape and device*

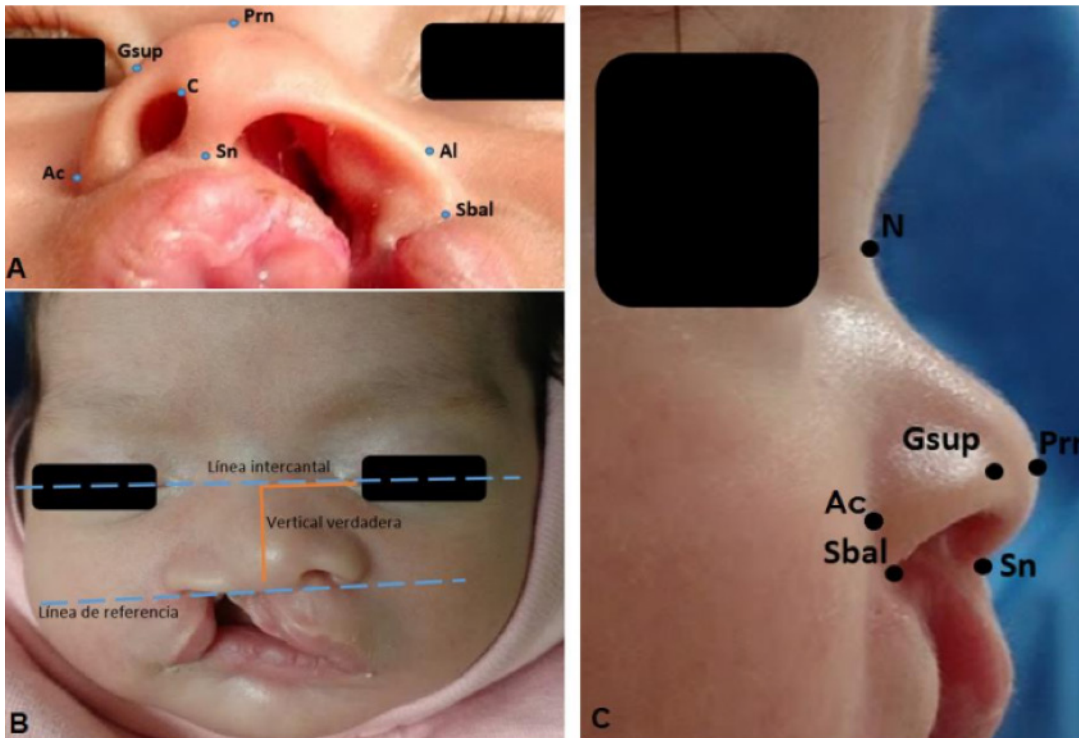
**FRONTAL PHOTO WITH NASAL DEVICE**



*Fig.12. Frontal photo with THE DEVICE*

## B. PROTOCOL OF MEASURES

Locating anthropometric points and reference lines

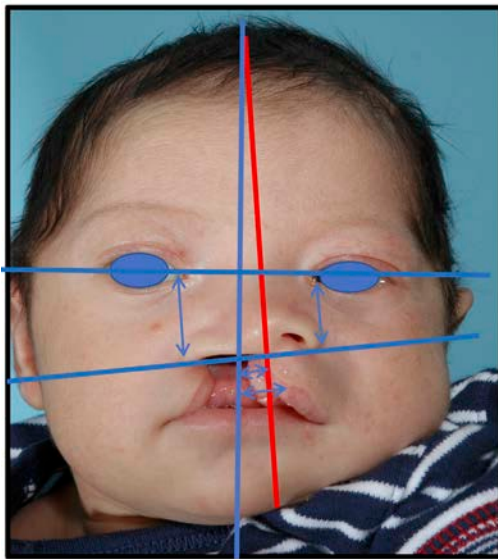


(Photo courtesy of Dr. Tatiana Castillo)

Fig 13. Location of anthropometric points and reference lines. A. Basal view; Pronasal (Prn), Upper point of the nasal dome (Gsup), Columella (C), Wing curvature (Ac), Subnasal (Sn), Alar (Al), Subwing (Sbal) B. Front view; Intercantal line, True Vertical and Reference line. C. Side view; Nasion (N), Pronasal (Prn), Upper point of the nasal dome (Gsup), Subalar (Sbal), Wing curvature (Ac), Subnasal (Sn).

## 5. Facial analysis

The following facial planes are critical to the adequate installation and adjustment of the Rhinoplasty Appliance: **A.** The facial midline. **B.** A vertical line over the tip of the nasal septum. **C.** Horizontally, the intercanthal line that goes through the middle of the pupils. **D.** Another horizontal line that would pass at the height of the nose by the edge of the lateral wings of the nostrils. Based on these planes, we will measure the horizontal line far from the midline, the nasal tip (tip of the septum), and the lip. And in the horizontal lines, we will measure the nostrils' height relative to the intercanthal plane.



- A.** The facial midline plane
- B.** The septal plane
- C.** The intercanthal plane
- D.** The nasal alae plane

*Fig. 14. Location of vertical and horizontal planes. A. Middle Line. B. Line on nasal septum C. Interpupillary plane. D. Plane by the lateral wing base*

It is also essential to have located the patient's midline before and after putting the lip tape since it is necessary to exert pressure with the tape and elongate the lip on the side of the greater segment, impacting the septum and lip.



*Fig. 15. Midline before and after the lip tape.*



## 6. Presurgical treatment with the Rhinoplasty Appliance

The first step to start treatment with RAS is to make parents aware of the importance of their use (small presentation in PowerPoint or booklet), showing the benefits of nasal molding, the impact of straightening or maintaining the nasal septum, and the opening of the nostrils for breathing and future facial growth—improvement: Feeding, breathing (effect on all development), facial growth and appearance, facilitating surgery. Show before and after images.



*Fig. 16. Before and after treatment in unilateral and bilateral patients*

### **Determine the number of the device.**

The measurement of the columella and nostrils will be taken in millimeters to determine which number of conformers we will use. The conformer you choose will cause a small ischemia at the top of the nostril (a white area at the top of the nostril).

The health professionals in charge of the placement and monitoring of the RAS must have clear information about the selection of the size of the device and the proper insertion and pressure when applying it.

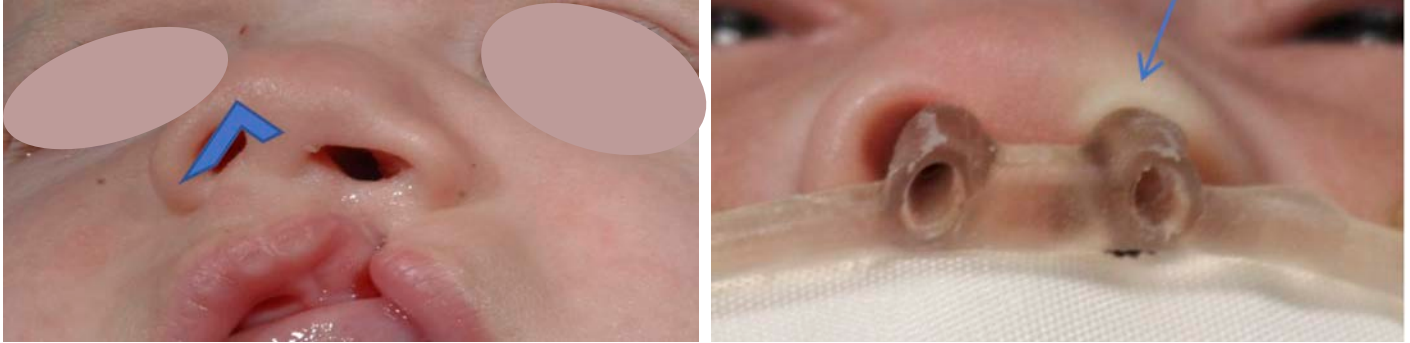


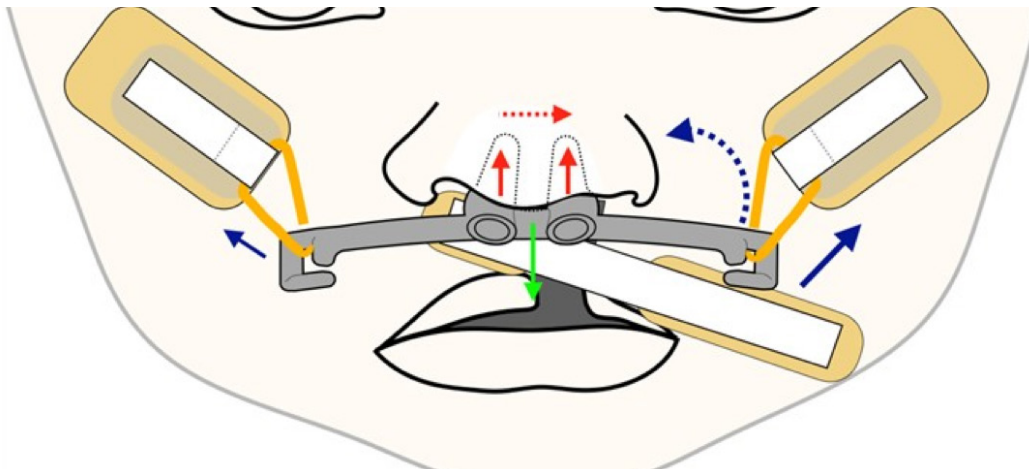
Fig. 17. Measurement of nostril and appliance pressure Ischemia when you elevate the lateral alar on the cleft side.

**Lip tapes:**

The principal objective of labial tape is a little different for unilateral cleft patients than for bilateral cleft patients. In unilateral cleft patients, the tape is used from the lateral part of the nasal alar base on the noncleft side to the cleft side, stretching the tissue to the midline and putting a little pressure down on the lip to elongate the lip tissue. With this lip elongation, we can better manipulate, straighten the septum, and mold the nose. In bilateral patients with the premaxilla on the occlusal plane, the labial tape is used to assemble the prolabium with the lateral lip structures. The proposal is to add a slight pressure on the prolabium that elongates the tissue there and helps to bring the premaxilla backwards.



Fig. 18. Pictures with the tape in position in bilateral and unilateral patient



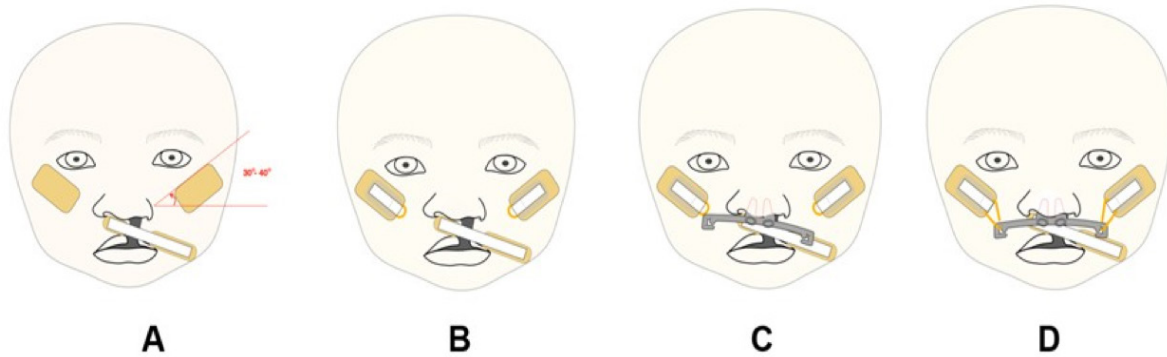
(Illustrations courtesy of Dr. Juan Pablo Gómez)

Fig. 19. Pressure and direction diagram when placing the RAS.

### Insertion of the RAS:

Before insertion, the elastics are made with tapes to put them immediately after the device is inserted and be able to align it in the appropriate position.

Before inserting, petroleum jelly should be used around the back of the stents to make it easier to slide them in. When the conformers enter, the most important thing is to know the location in the vertical and horizontal plane and the tension that must be put in to locate them correctly. Also, the vertical plane should be centered about the middle line. This position is achieved with the tapes and elastics that are laterally attached to the cheeks of the baby with an angulation of 45 degrees inclined towards the top.



Sequence of RAS: A. lip and protector tape on the cheeks 45 degrees inclination, B. rubber bands w/tapes, C. appliance insertion, D. appliance activation with rubber bands and tapes. (Illustrations courtesy of Dr. Juan Pablo Gómez)

Fig. 20 Position of the device aligning the lateral alar base of the nose of both sides in the horizontal plane.

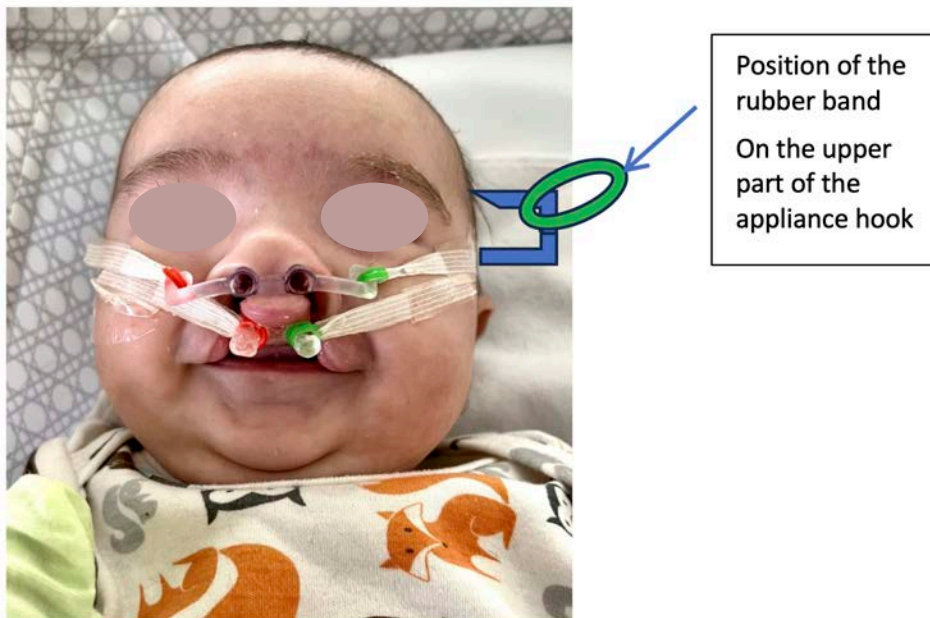


Fig. 21. Position of the device to avoid its rotation

## **Description and materials for pre-surgical treatment with RAS:**

### **Bilateral cleft lip (with or without cleft palate) Presurgical treatment:**

#### **Materials:**

- The nasal appliance (rhinoplasty) is printed on a 3D printer in 4 sizes for bilateral.
- 4 orthodontic elastics of 3/16 or 4.7mm (half 3 ounces)
- Adhesive tapes: Extra-thin DuoDERM® and Steri-Strip®. (Something similar can be used.)
- Alcohol to remove excess grease from the skin, gauze to dry.

#### **Procedure:**

- Excess grease is removed in the cheeks, the baby's lips, and prolabio.
- 2 rectangles of 0.7 millimeters wide by 2 centimeters long are cut into extra thin DuoDERM® for use in the cheeks. The Steri-Strip® is put to exert pressure on the prolabio, thus lengthening the tissue. (Should be changed as many times as necessary.)
- Then, With two elastics on each side with lateral Steri-Strip® adhesive tapes (5 cm long)
- The nasal apparatus is inserted, placing it on the cheeks higher than the lip. (45-degree upwards) Fig.21
- The use of the device will be 24 hours for the time required (varies from 2-5 months depending on the severity of the condition)
- The device will be changed by the following measure every 2 or 3 weeks as the tissue elongation progresses.
- The appliance will be removed twice daily to clean it with an interdental brush with regular soap and water and to clean the baby's nostrils.

### **Unilateral cleft lip (with or without cleft palate) Presurgical treatment:**

#### **Materials:**

- The nasal apparatus (RAS) in 4 measures printed on a 3D laser printer
- 4 orthodontic elastics of 3/16 or 4.7mm (half 3 ounces)
- Adhesive tapes: Extra-thin DuoDERM® and Steri-Strip® (something similar can be used)
- Alcohol and gauze.

#### **Procedure:**

- Excess grease is removed from the cheek of the minor segment, the prolabio, and the lateral part of the alar base of the nose on the side of the greater segment with a bit of alcohol.
- A rectangle of DuoDERM® of 0.7 millimeters wide and 2 centimeters long is cut that will be placed from the lateral alar and above the prolabio in the greater segment; on this will be put the Steri-Strip® and pressure is exerted to straighten the nasal septum towards the cheek on the other side. (They should be changed as many times as necessary.)
- The nasal apparatus is inserted by placing it in position with two elastics attached to the lateral Steri-Strip® adhesive tape (5 cm long) on each side of the cheeks in a position higher than 45 degrees to the lip straps.
- The use of the device will be 24 hours for the time required (varies from 2-5 months depending on the severity of the condition)
- The appliance will be removed two times a day to clean it with interdental brush soap and water and to clean the baby's nostrils.

## 7. Protocol: The Rhinoplasty Appliance

**Presurgical treatment in unilateral:** It should be used when.

Alveolar segments measure about 7mm or less. A tape should first be on the lip, straightening the nasal septum, and then the appliance should be inserted.

The appliance should be changed to the following number every 2-3 or 4 weeks, depending on the severity of the nasal deviation.

Use it 24 hours for 2-4 months as the deformity requires. It should only be removed for cleaning in the morning and evening. (With regular water and soap)

**Presurgical treatment in bilateral:**

It should be started when the premaxilla is centered and the space between the pre-maxilla and the lateral segments is less than 7 mm. Initially, a tape is used by joining the prolabio and the lateral parts of the fissured lip.

Depending on the severity, the appliance should be changed to the following number every 2-3 or 4 weeks.

The evolution will use the apparatus that increases the size to elongate the columella.

The columella and nostrils thus improve the projection of the nose. The appliance uses 24 hours for 2-4 months as the deformity requires. You must

Remove to clean in the morning and evening. (With regular water and soap)

**Post-surgical treatment:**

It should be used during the first two or three weeks after surgery, 24 hours.

For six months during the first healing period, 24 hours or more will be needed according to clinical evaluation as retention. It should only be removed for cleaning in the morning and evening. (With regular water and soap)

**Physiological purpose:**

Maintain and reshape nasal structures that have been modified.

Either from a birth defect or scar tissue growth.

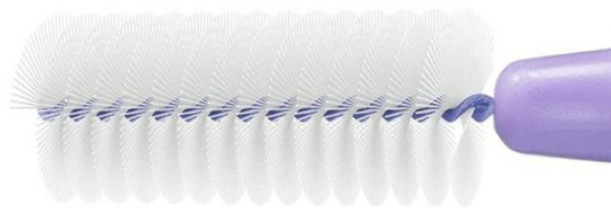
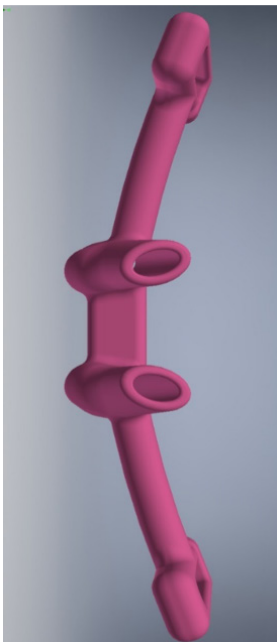
After surgery, it is essential to keep nasal structures in the correct position to prevent the relapse of nasal asymmetry and avoid cicatricial stenosis that can occur in the caudal-most portion of the nasal cavity of CLP patients, resulting in a micro nostril. For this purpose, we use a silicone Porex Stent® for three weeks. After surgery. Immediately after removal, we use a Rhinoplasty Appliance System (RAS) for six months, 24 hours daily. In post-surgical treatments, experience has shown that applying a dynamic nasal splint can effectively maintain the surgical results by opposing the contractive forces of scar tissues.



*Fig.22 Rhinoplastic Appliance System RAS*

**Instructions to Parents:** How to remove facial tapes and clean the device. To remove the facial tape, we must use a Q-tip with coconut or baby oil and gently lift it without pulling it to avoid damaging the skin.

The Rhinoplasty appliance will be cleaned with regular water and liquid soap. An interdental brush will remove any mucus or secretion obstructing it from cleaning inside the device.



*Fig.23. Interdental brush to clean the conformers internally.*

## 8. Postsurgical treatment

Post-surgical treatment is essential to maintain the proper shape and size of the nostrils. Maintaining the position of the nasal septum and nostrils is also essential since cartilage has memory and tends to return.

### Unilateral and bilateral post-surgical treatment:

#### Materials:

- The nasal appliance in a measure printed on a 3D laser printer, usually symmetrical appliance # 2 or 3
- 4 orthodontic elastics of 3/16 or 4.7mm (half 3 ounces)
- Steri-strip® adhesive tape or similar
- Alcohol and gauze

#### Procedure:

- Remove grease excess in cheeks at the height of the nose with alcohol and dry
- The nasal apparatus is inserted with the elastics attached to the side straps of the steri-strip® (5 cm long) and rubber bands to the side of the lateral alar of the nose.
- The appliance will be used 24 hours for the first six months after surgery and then in the evenings for a 4-6 months retention.
- The device is removed two times a day to clean it with soap and water and to clean the baby's nostrils.

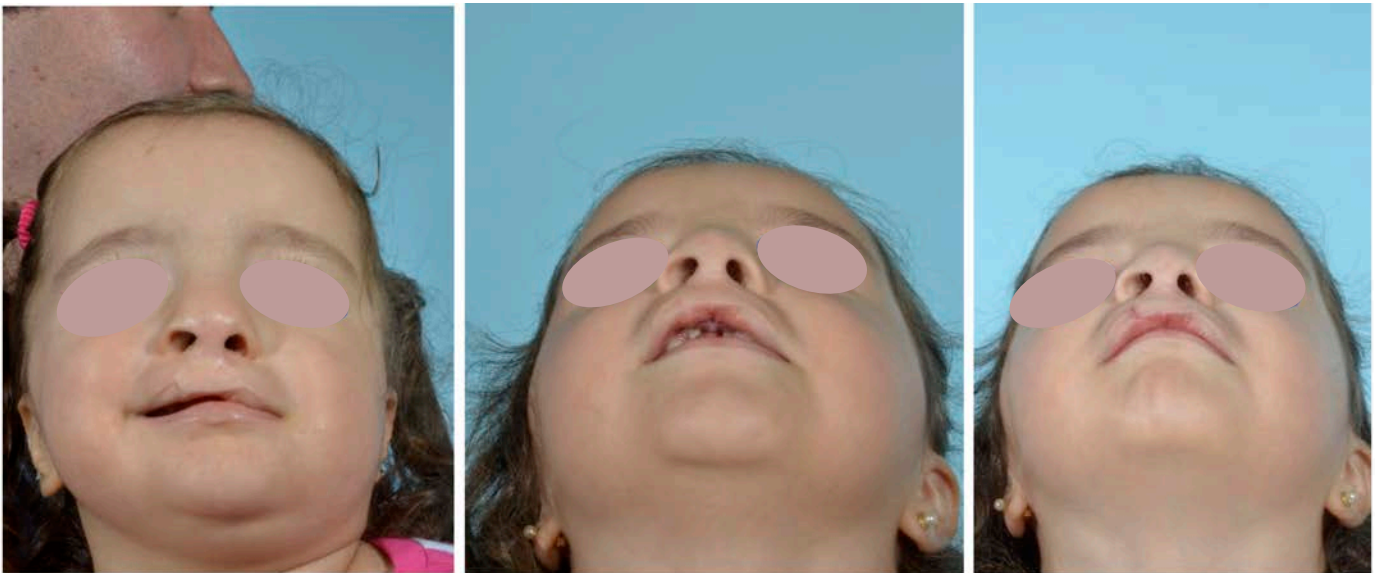


Fig.24. Sequence of the effectiveness of long-term postoperative treatment.

## 9. Description of the procedure

### PHASE I PRESURGICAL

**1. FIRST VISIT (V1):** The first approach of the patient and family is to inform and explain the importance of nasal molding; data are captured in the patient's single file, clinical, photographic record, baseline anthropometric measurements (scanner, and dental model taking), and administration processes, consent)—maxillary impression if it's necessary to use before the nasal molding system. If you start with the RAS system, you can initiate the treatment with size number 1 or 2, depending on the nasal size and deformity.

#### **1. FOLLOWING VISITS:**

A follow-up of the patient can be 1 to 2 weeks after you start the treatment; if the deformity is not severe, you see if applying the following size change to the device is possible. To determine if the nose is ready for the next size, you evaluate if the device produces minor ischemia and activation of the soft tissue. Depending on the severity, you can use the following size on the system every 2/3 or 4 weeks. When you finish the system, the presurgical treatment is completed, and the patient can be scheduled for surgery.

### B. POST-SURGICAL PHASE II

- 1. FIRST VISIT (V1):** postoperative clinical review. Usually, after surgery, surgeons keep silicone stents in place for three weeks. On the same day it is removed, you can use the RAS appliance number 2 or 3, depending on the nostril size.
- 2. SECOND VISIT (V2):** clinical review at four weeks. Review of the device, technical advice, and revision of surgery by the surgical team.
- 3. THIRD VISIT (V3):** clinical review in the third month. Review of the device, technical advice, and revision of surgery by the surgical team. Clinical measurements, photographic record, baseline anthropometric measurements, scanner.
- 4. FOURTH VISIT (V4):** clinical review in the sixth month. Review of the device, technical advice, and revision of surgery by the surgical team. Clinical measurements, photographic record, baseline anthropometric measurements, scanner.



## 10. Complications

1-The location of the Rhinoplasty appliance with the tension of the elastics and tapes. It is a frequent complication. For this reason, it is necessary to explain to the parents how to put the device and the tension of the elastics.



*Appliance is totally inverted*



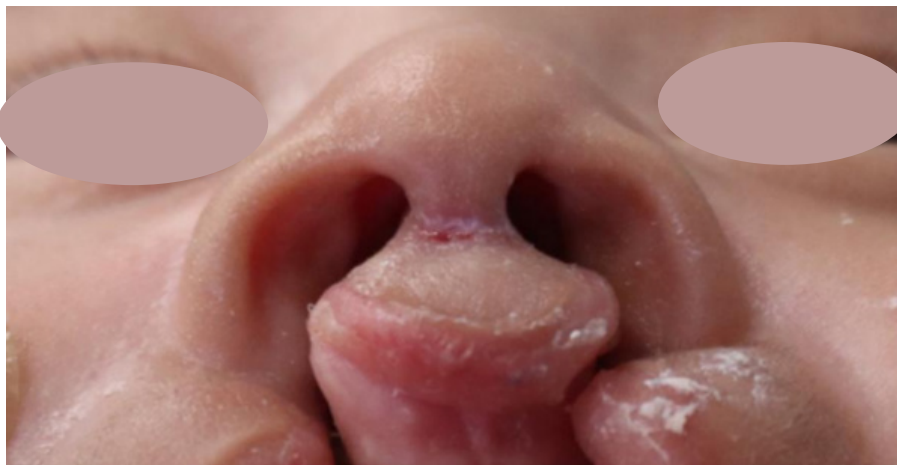
*Inclination of the tapes should be 45 degrees*



*Put attention in the way you insert the rubber bands. Don't twist the tape.*

*Fig.25. Complications*

### **Soft tissue complication:**



2-It is very important to properly insert the device and lubricate it with petroleum jelly so as not to cause irritation and subsequent wounds in the tissue. Also, there is special care in cleaning the tissue free of accumulated secretions. These can be the first complications; to manage them, if there is a wound in the tissue, a small portion of triple antibiotic cream is used. For a week until the wound heals. But continuing with the device and only removing two days if strictly necessary for the damage. Secretions adhering to the skin or accumulated should be cleaned with a swab (Q-tip®) 2 times a day.

3-Irritation or redness of the insertion area or the area where the tapes are used to hold the device. A mixture of Desitin® or a similar cream containing zinc and hydrocortisone should be made. This mixture is used for about 5 hours, then cleaned and put back on the device.

4-Allergy to tapes. This complication is rare, but the same mixture described above is used if it happens. Also, you can try other tapes.

**REASON FOR NOT USING THE APPLIANCE:**

The primary reason for not using the device is if the patient has any respiratory problems (asthma, low oxygen saturation) or any condition or disease that produces excess secretions.

The other reasons are the time it is used (if it is not enough, the treatment is discontinued and, finally, the cleaning (infection)

## 11. Adherence to the treatment

The total number of weeks used depends on when treatment starts and the severity of the craniofacial anomaly. It takes about 10 to 20 weeks, depending on severity.

It is essential to train and follow up with parents on the importance of using it, how to insert the device, hold it, and clean it. Take care of how to change and remove the tapes of the skin to avoid irritation of the tissue.

If the baby is over three months old, you must prevent the parent from using something on the baby's hand to avoid the possibility of removing the device; therefore, in the first days, you should put some pads on the baby's elbows to prevent their hand from pulling the device.

It is also important to emphasize that if they remove the device during the bath or at any time, keep it in the container or box that is given to them with the device. Since these devices are attractive to pets, they bite and damage quickly.

## 12. Conclusion

There is a long way to go to take it to another level in treating cleft lip and palate.

Continue to identify the external and environmental factors that influence this condition to carry out more interventions in prevention.

Continue advancing with the design of treatments with computerized digital technology and 3D printers to perform pre-surgical and post-surgical treatments with greater precision and coverage nationally and worldwide.

## 13. Bibliography

3D Infant Orthopedic Nasal Molding System for Improved Outcomes in Cleft Nasal Deformity Martha L. Mejia<sup>1</sup>, Juan Pablo Gomez<sup>2</sup>, Savannah L. Moon<sup>1</sup>, Erin M. Wolfe<sup>1</sup>, Chad A. Perlyn<sup>1</sup>, S. Anthony Wolfe<sup>1</sup>, and Jordan P. Steinberg<sup>1</sup>

**Contact for technical questions:**

Martha Mejia

Email: [Marteja@gmail.com](mailto:Marteja@gmail.com)

WhatsApp. Phone +1(305) 606-4951





Where Your Child Matters Most

3100 SW 62 Avenue  
Miami, FL 33155  
305-666-6511

[nicklauschildrens.org](http://nicklauschildrens.org)