

# **Presurgical Maxillary Orthopedic**

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**Abstract**

It is estimated that one in every 800 infants is affected by a cleft lip and palate. There are various ways physicians go about rectifying this malformation, including surgery and presurgical orthopedics. The latter will be the focus of this project. Benefits such as post-operative decrease in tissue tension and a more normal palatal configuration are a result of repositioning the palate with a presurgical orthopedic. When the cleft is unusually large or misshapen (as deemed by the physician) it is particularly beneficial to use a presurgical orthopedic. Although no mass-produced or patented presurgical orthopedics could be found, they are used widely throughout the medical population when dealing with the problem of clefts. These devices vary widely from active implants with springs and/or screws, to passive acrylic molds and simple medical tape. The problems with current devices include being solely designed for a specific cleft deformation, i.e. bilateral or unilateral clefts, and their inability to hold one portion of the oral cavity static while translating the other into a predetermined position. Therefore, the goal of this project is to design a pre-surgical orthopedic device with a universal mechanism, which encompasses the benefits of current devices, allows movement in two dimensions, and is easily adjustable.

**Design Problem**

A cleft palate is a deformity in which the palate is not completely formed, and the nasal cavity opens into the mouth. This deformity occurs in approximately one out of every 800 infants (4). There is often a need for pre-surgical manipulation of the palate; this is currently done through the use of an orthopedic. The current devices being used all have limitations, including: restricted movement, non-universal application, and inefficiency (3). Current devices are inefficient because they require multiple clinical visits to readjust the device, which requires a considerable time commitment from the family and the physicians. The project goal is to design an orthopedic device with a universal mechanism, which encompasses the benefits of current devices, allows movement in two dimensions, and is easily adjustable.

## Background

A cleft palate is a fairly common congenital deformity. It is a posterior-anterior separation of the roof of the mouth that creates an opening between the oral and nasal cavities. It occurs when the palatal plates fail to close during the second month of embryogenesis. The resulting fissure may occur on the soft palate only, or it may extend forward through the hard palate. Cleft palates may be unilateral or bilateral (see Figure 1) and may occur alone or in conjunction with a cleft lip, a fissure through the lip beneath or extending into the nostril. Cleft palates can cause various health problems in afflicted infants (4). For more information on cleft palates see Appendix A.

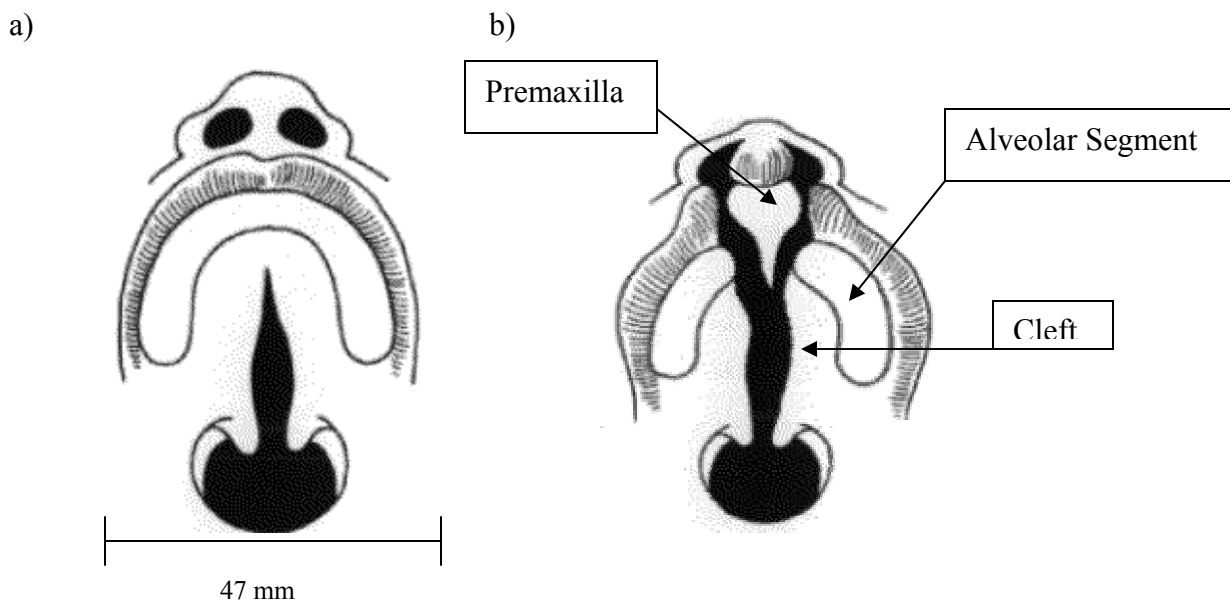


Figure 1: a) A unilateral cleft palate. b) A bilateral cleft palate and lip, also demonstrating the anatomy of the mouth (4). 1 mm in picture = 1.234 mm actual.

Surgical closure of the cleft is usually administered between 7 and 9 weeks of age. This surgery holds the cleft static (does not allow for cleft expansion or distortion). Surgical closure of the cleft palate is usually administered between 6 and 18 months of age. In addition to closure, surgery restores normal eating and drinking function, improves appearance, and helps the development of normal speech. It is a complex surgery, usually requiring a team of dentists, orthodontists, craniofacial surgeons, and plastic surgeons for postoperative care (4).

Although surgery has made a great impact on the treatment of cleft lips, surgical repair alone cannot solve all the problems encountered with the cleft palate. It is often necessary to decrease the width of the cleft or keep it from expanding prior to surgery. Reducing the size of the cleft results in a post-operative decrease in tissue tension as well as a more normal palate configuration. In addition, it is essential to restore the maxillary arch contour. To accomplish all of these tasks, pre-surgical maxillary orthopedics are employed (4).

There are two major styles of presurgical orthopedic devices being employed currently. One style is an active device, which places forces on the alveolar segments (Figure 1b) and moves them into alignment. The size of the cleft can be significantly diminished using these sorts of devices. The other style acts as a passive device that simply holds the palate in a static conformation. There are no moving parts and the cleft is maintained at a constant width. Each style has many individual types of devices. For a more in-depth description of some of the current devices, see Appendix B.

The use of presurgical orthopedics has many beneficial effects. The constraint or adjustment of the configuration of the palate results in a much less traumatic surgery for the infant. Also, during the presurgical period, the device supplies a “false palate” for the infant, which keeps the tongue out of the cleft, thus reducing the possibility of the tongue widening the cleft. The false palate prevents gastric contents from invading the nasal cavity, causing infarction. The false palate also assists in feeding by providing a place for the tongue to press the nipple against to squeeze out milk.

In order to design a proper device for use in the mouth, the fluids that will come in contact with the device in the mouth need to be considered. The most common fluids that will be regularly present in an infant’s mouth are milk, saliva, and vomit. The contents of these fluids are detailed in Appendix C.

In order to more completely define the problem of moving the alveolar segments into better alignment, free body diagrams were made with first order approximations. The values for tissue properties were initially approximated as the properties of soft cartilage. The range for Young’s Modulus of Cartilage: 0.69-5.8 MPa (9). During a meeting with Professor Lakes (7) the force diagrams were discussed and he stated that the modulus and other tissue property values for infant alveolar segments would be very

difficult, if not impossible to find due to the lack of cadaverous tissue donated from this population. From a specific study, values for the time-dependent mechanical behavior of the periodontal ligament (a layer of soft connective tissue that mechanical force is transmitted through to the alveolar bone) were found for beagle dogs. The estimated tissue elastic modulus was found to be 15 +/- 1 KPa (10). Refer to Appendix G for free body diagrams of alveolar segments and final design interactions. Also, calculations for force and torque on device and alveolar segments were performed (Appendix G).

### **Design Constraints**

In order to produce a functioning device that meets the clients' needs, certain design constraints must be considered. To properly realign the cleft, translation and rotation in two dimensions needs to occur. This is because the alveolar segments may need to be moved or rotated independently in order to close the cleft. The device should accommodate both unilateral and bilateral clefts. This feature allows the device to be more universal, which is an improvement over existing orthopedics. Current devices require many clinical visits to manipulate the orthopedic or to replace jackscrews (Figure 2). For this reason, it is desirable to design a device that can be easily adjusted at home and does not require the regular replacement of screws or other mechanisms. The device should also not be bulky, because an infant's mouth is very small, and a large device would inhibit movement of the tongue and could make feeding more difficult. On the other hand, the device must not include small parts that could break off and create a choking hazard. Finally, the choice of material is important. It must be non-toxic, strong enough to withstand applied forces, and resistant to acid contained in stomach bile. For a complete list of product design specifications see Appendix D.

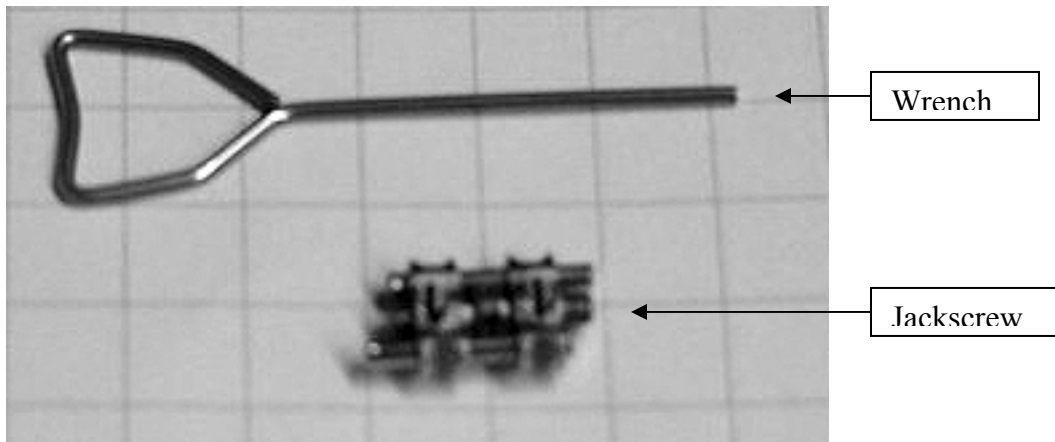


Figure 2: Jackscrew and adjustment wrench. The wrench can be used to turn a nut in the center of the jackscrew which controls expansion or retraction of the two outer bars. The bars can each extend out about 2 mm. 1 mm in picture = 0.275 mm actual.

After several brainstorming sessions, many possible design ideas were formulated. Five major designs were created, and many slight alterations were suggested. All of the designs use acrylic pieces that are premolded to the patient's gums. The acrylic pieces will be held in place with denture adhesive. Some of the designs utilize expansion-retraction screws for movement of the alveolus, and one design uses rubber bands. For individuals with a cleft lip, all of these designs can include the application of medical tape across the cleft lip. This is a common practice that aids in closing the cleft lip and also positions the premaxilla (Figure 1b) in the case of the bilateral cleft.

Previous designs used jackscrews, but they need to be reset multiple times and make inefficient use of space. The expansion-retraction screw was designed to allow pushing and pulling and to minimize space so that more than one could be used. In addition, it can be constructed and adjusted easily, and can double or halve its length. It has three parts: a screw, a nut, and a hollow tube with a nut lock arm (Figure 3). To expand or retract the screw, one just turns the nut in a given direction. The required direction of rotation will be clearly marked on the nut with an arrow. This direction depends upon the patient, but will remain constant during the course of treatment. The initial setting of the screw is fundamental to its action. If expansion is required then the screw should lie mostly within the hollow tube. Likewise, if retraction is the goal the screw should be fully extended.

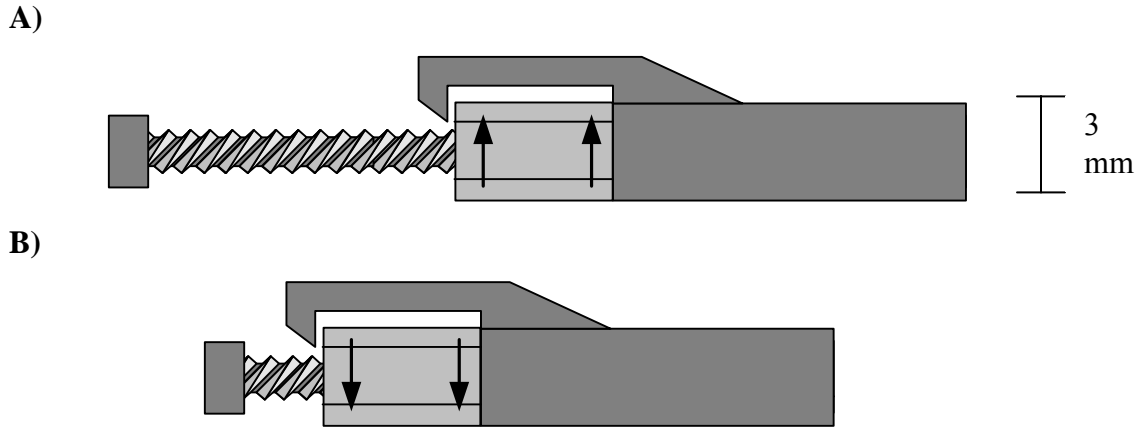


Figure 3: The expansion-retraction screw in the retraction, fully extended screw will be 30mm long (A) and expansion (B) settings. 1 mm in picture = 0.24 mm actual.

The first two designs are very similar and differ only in the method used to create the vertical force on the palate (Figure 4 A & B). The primary mechanism consists of three expansion-retraction screws, each with their own axis to rotate about. This allows for a wide variety of motion. For bilateral cases, one of the screws will attach to an acrylic piece molded to the premaxilla (anterior alveolar segment). If there is a significant vertical disparity between the alveolar segments (the alveolar segments do not lie in the same horizontal plane), vertical forces could be applied to the alveolar segments to correct this. One of the designs uses a passive force applied to an acrylic plate molded to the roof of the mouth. This design was quickly eliminated because if a force great enough to move the palate were applied vertically it could pop the device off of the gums. The other design uses repulsive magnets. One magnet would be mounted in each of the acrylic pieces applied to the roof of the mouth. An additional magnet, directed to repel the magnets on the roof of the mouth would be mounted on an acrylic piece applied to the lower gums. With this design, the device would not become dislodged due to the vertical pressure. However, designing a successful and safe magnetic device would be nearly impossible because of the controversy of the effects of magnetic fields on the body, and the force changes that would occur with changing orientation and dimensions of the device. Furthermore, both of these designs are severely flawed, because if two screws are mounted on the same acrylic piece, any adjustment after the screws have been initially set would put stress on the acrylic and the screws themselves, and could lead to breakage of the device.

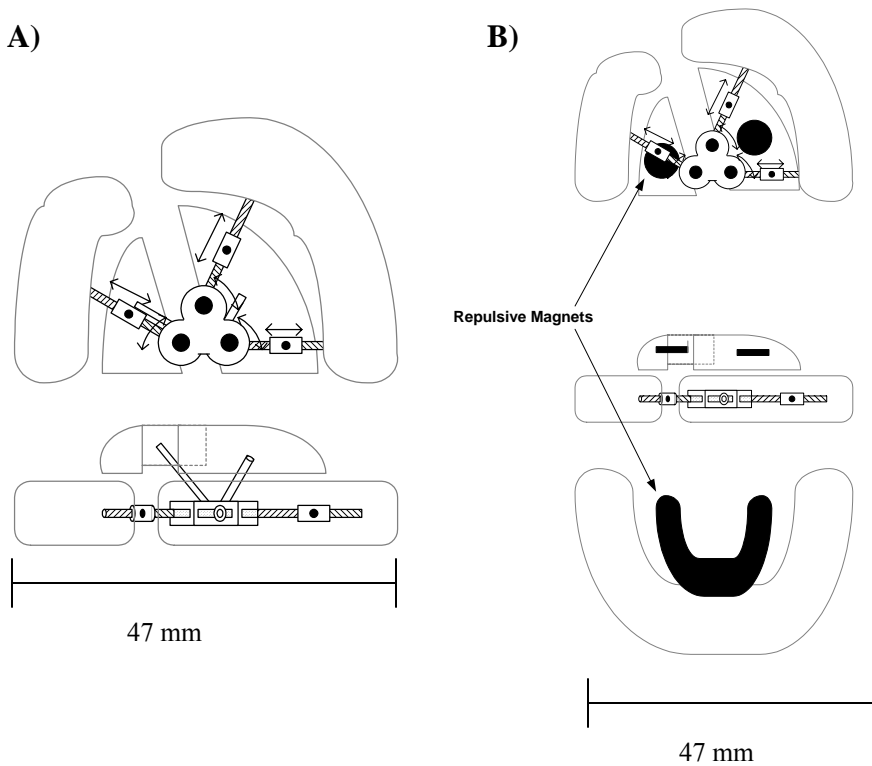


Figure 4: A) This device applied the passive force to roof of the mouth and is viewed from the bottom-up and from the front. For A: 1 mm in picture = 0.925 mm actual. B) This device uses magnets and an acrylic piece mounted on the lower gums to hold a repulsive magnet. For B: 1 mm in picture = 1.23 mm actual.

The third major design was very similar to the Latham Device (information on this device in Appendix B), with a few alterations. The Updated Latham Device would have a metal bar across the back (posterior portion) of the two acrylic pieces (Figure 5). This bar would be separated by an expansion-retraction screw, which would allow for the posterior portion of the alveolus to be moved in or out independent of the rotation of the anterior portions. The metal bar would be attached to metal rods extending into the acrylic pieces by hinges. The hinges would allow each acrylic piece to rotate individually to move the alveolar segments (separated portions of the palate) closer together, closing the cleft. Since each hinge can be adjusted independently, this design allows for independent movement of each of the alveolar segments. If only one segment needs to be moved, the other can be held static. Each of the metal bars extending into the acrylic pieces would contain a spring (similar to the springs in the arms of eye glasses) that could be adjusted to create an upward force on each alveolar segment. The springs would be able to put force on each alveolar segment independently to adjust for the

possibility of vertical disparity between the two. The springs and hinges are all independently adjustable to allow for vertical and/or horizontal movement of each alveolar segment independently.

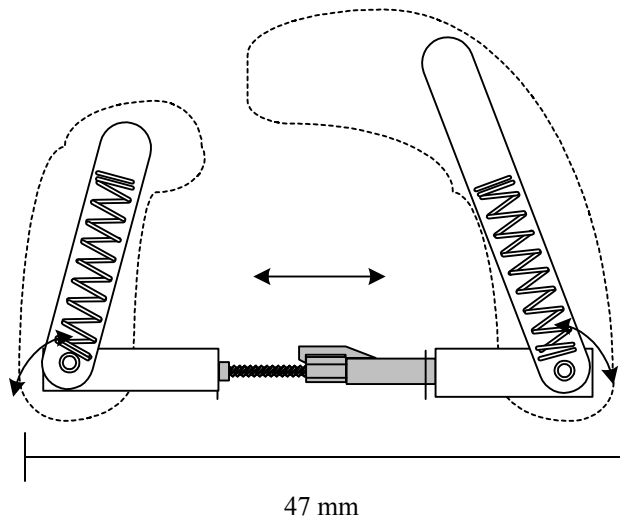


Figure 5: Updated Latham Device. Range of posterior length is approximately +/- 10 mm.  
1 mm in picture = 0.597 mm actual

Although the fourth major design will also consist of two pieces of acrylic molded to the patient's mouth, this design (Acrylic/Rubber Band device) does not include the use of screws, hinges, or springs for active force creation. Rubber bands are used to achieve the force required to move the alveolar segments (See Figure 6 A-D for details). One piece of acrylic will contain a thin male protrusion and the other will have a female extension on the interior that spans across the roof of the mouth, but leaving enough room between the two pieces of acrylic for ample movement of the cleft. The male protrusions will be attached via a pivot to one acrylic segment and also have a series of stainless steel hooks at their ends. Corresponding hooks will be placed just above the female extension on the other acrylic segment. The female extension will also have a series of hooks on its end with corresponding hooks attached to the male acrylic segment just below the protrusions. The female extension will also have a series of hollow tubes pivot mounted

on the top side for the male protrusions to fit through. A small acrylic extension will also be on the male side below the hooks to protect the tongue from the hooks and the rubber bands from the tongue. Once the male segment is inserted through the female, rubber bands will be placed across the corresponding hooks to produce force, and the device can then be secured in the mouth with denture adhesive. The pivoting action of the male protrusions and hollow tubes allow for applications in which there is a vertical and horizontal disparity. The device can also be used to move only the posterior or anterior alveolar segments, while keeping the other static, by incorporation of a stiff bar spanning the mouth and/or, varying the rubber band strengths and sizes from posterior to anterior. This device will also create a “false palate”.

This device would be adequate for closure of the cleft, but has limited use for expansion of the cleft. Other problems with this device include a limited range of rubber band strengths and sizes and difficulties could arise with the rubber bands falling off when trying to position the device in the mouth. Placing the rubber bands on their hooks could also become difficult due to the small scale of the device. Schematic diagrams of the device are presented in Figure 6.

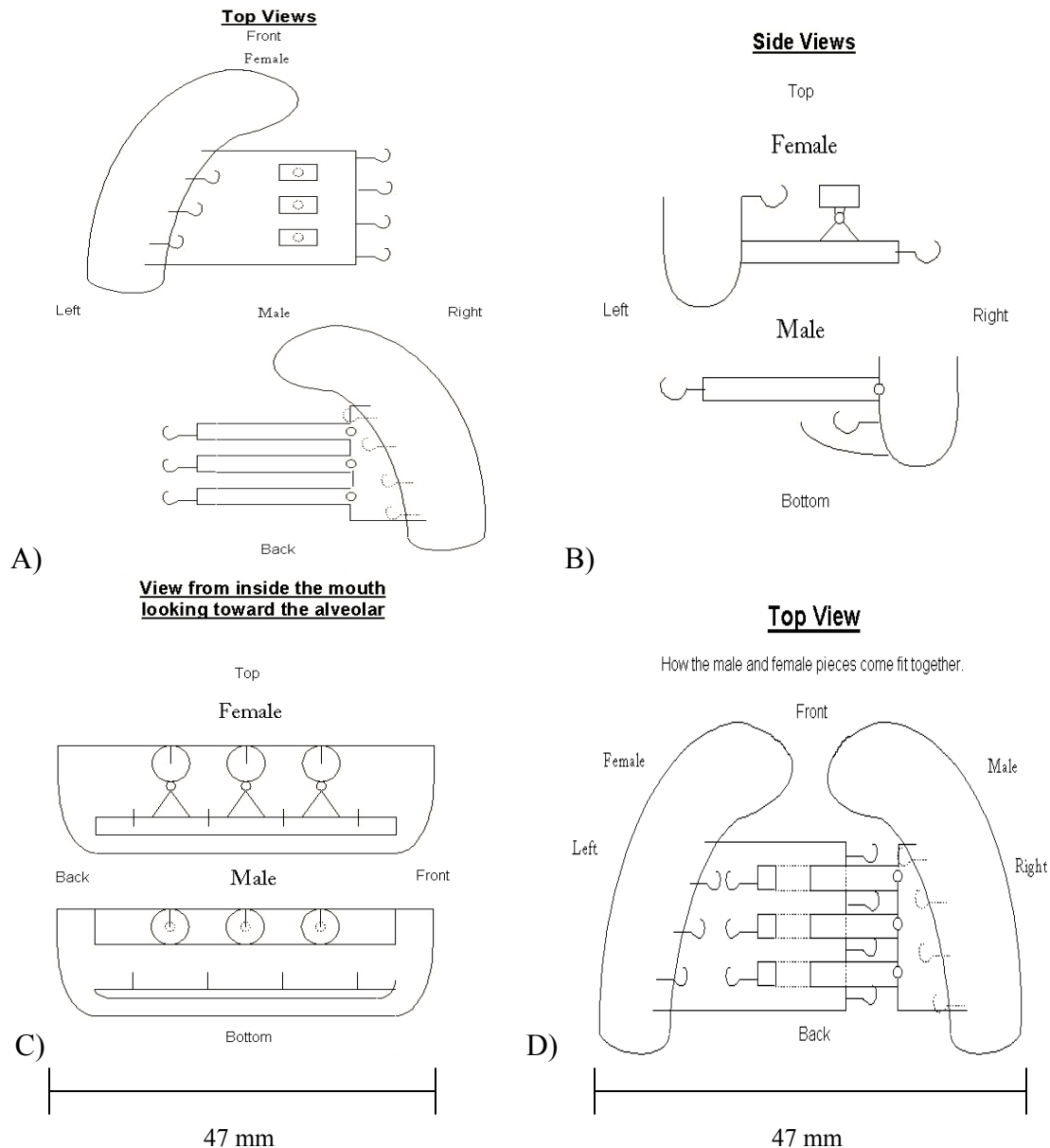


Figure 6: Schematics of the acrylic with rubber bands device. A) This is a top view if the device with the anterior portion directed upward. 1 mm in picture = 1.38 mm actual. B) This is a cross-sectional view of the device looking from posterior to the anterior. 1 mm in picture = 1.38 mm actual C) This view is looking at the device segments from the inside of the oral cavity towards the alveolar segments. 1 mm in picture = 0.88 mm actual. D) A top view of the device, anterior portion directed upward, of how the male and female segments fit together in the mouth. 1 mm in picture = 0.77 mm actual. The range of the width of the device is +/- 12 mm.

The fifth design, nicknamed the Baby Beautiful 2002, uses one expansion-retraction screw and two hinges (Figure 7). Retracting the screw brings the two segments together and effectively closes the cleft. In addition, it allows for the anterior portions of the alveolar segments to be rotated together while the posterior portion remains static.

For bilateral cases, the alveolar segments can be pushed apart, and tape can be applied from cheek to cheek to pull the premaxilla posteriorly. The expansion-retraction part of the design is moved anterior to avoid gagging the infant. This positioning also keeps the infant's tongue from entering the cleft, and provides a barrier, against which the tongue can use to press the nipple to aid in feeding (false palate). This device has several moving parts, which adds to the complexity of the device. However, in certain cases, some of these parts can be eliminated without changing the basic concept of the design to allow for easier adjustment. For example, if one simply wants to close the cleft, the hinges could be eliminated, and only one type of adjustment would be necessary.

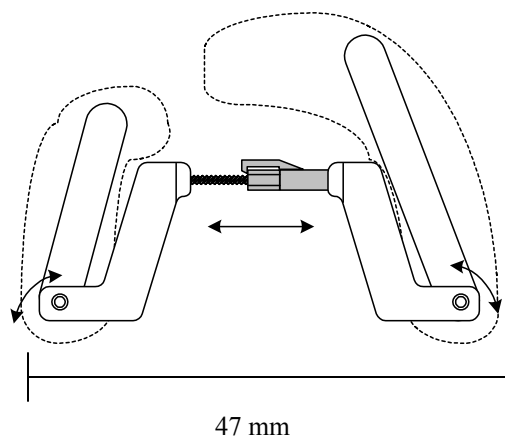


Figure 7: This is a view from the bottom. There is freedom to move in several directions. The screw is mounted anterior to avoid gagging the infant. The range of the width of the device is +/- 12 mm. 1 mm in picture = 0.74 mm actual.

To correct a vertical disparity between the alveolar segments with the fifth device (Baby Beautiful 2002), an additional piece can be used. It is an acrylic piece for the lower gums, which has an attachment for applying the vertical force. A coil that becomes compressed when deviated from rest is placed at the axis of a lever arm. At the end of the lever arm is a miniature rolling pin. With this design there is a vertical force applied when the mouth is open and closed. The force acts on the lowest alveolar segment and pushes them into alignment (Figure 8 A-C). Although the force will be greater when the mouth is closed, the device will apply a force great enough to move the palate but not significantly affect opening and closing of the mouth. In addition, it may be desirable to wrap the lever arms in a cushiony material to protect the tongue and cheek from a pain-inducing pinch.

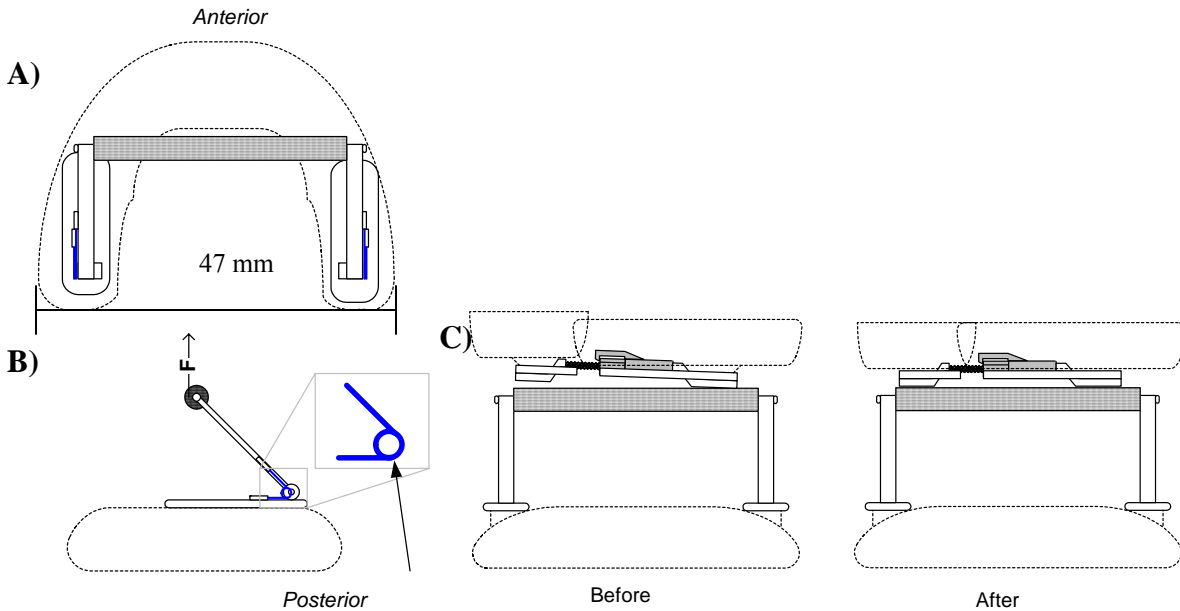


Figure 8: A) A top view of the bottom piece mounted on the lower gums. B) A side view of the device, the enlarged image is the coil. C) A before and after frontal view, notice how the vertical disparity no longer exists and how the force is only applied to the lowest portion of the upper device. The height of the roller-bar is variable depending upon how far open the infant's mouth is. 1 mm in picture = 0.97 mm actual.

## Final Design

From a decision matrix (Appendix E, table 1) and consultations with clients and advisors, it was concluded that the Baby Beautiful design is the best-suited device. Some modifications have been made to this device, such as an additional screw on the anterior section and all screws mounted on free pivots (Figure 9 A & B). The additional screw will allow the posterior and anterior portions to move independently of one another, while the free pivots will allow rotation, aiding in the independent movement of the posterior and anterior segments.

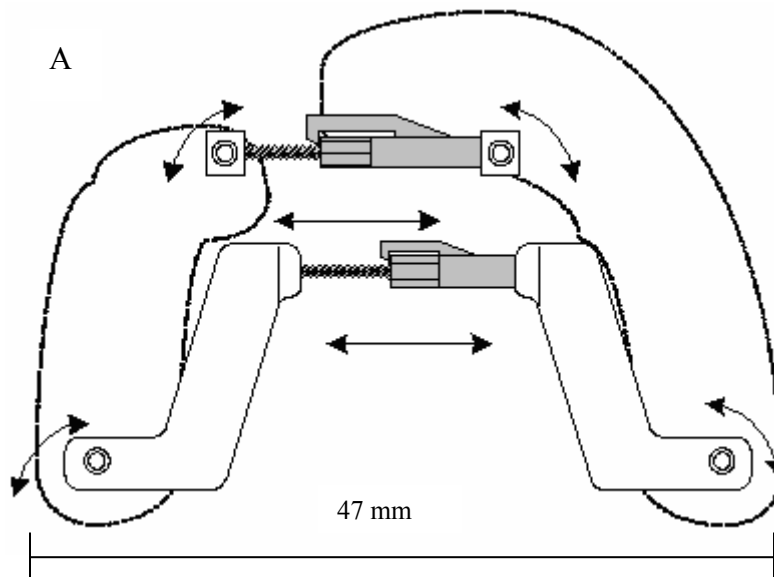
The universal application of the final design relies on the manipulation of each expansion/retraction screw independently. To rotate the anterior portion together, one just retracts the anterior screw. This also keeps the posterior width constant. To expand the cleft, an action necessary for some bilateral cases, one must expand both posterior and anterior screws. Likewise, to close the cleft one must retract both screws.

One benefit of this device that is not seen in previous designs is its ability to fine tune the palate. For instance, after the cleft has been closed a physician might want to expand the posterior region slightly. Similarly, in a bilateral case after the alveolar

segments are expanded and the premaxilla has been pulled in, it may be beneficial to rotate the anterior in for a closer fit. This device could accommodate for both of these scenarios while previous devices are limited to movement in one direction.

Upon further consultation with the clients, it was determined that the bottom piece with the roll bar will not be used. This piece would not work efficiently due to variability in the distance between the bottom and top portions of the mouth. Additionally, it might be a choking hazard as well as cause painful pinching of the cheek and tongue.

A prototype of this device has been produced. It is approximately three times actual size and made from aluminum sheet metal and stock screws. A fake cleft palate and set of acrylic molds were also made from a plastic compound called SculpeyIII. SculpeyIII is moldable clay that when baked in an oven becomes rigid. The metal portion of the design was embedded into the SculpeyIII before baking. Preliminary tests have begun. It appears that the device expands, contracts, and rotates as desired. Further more quantified testing will be completed next semester.



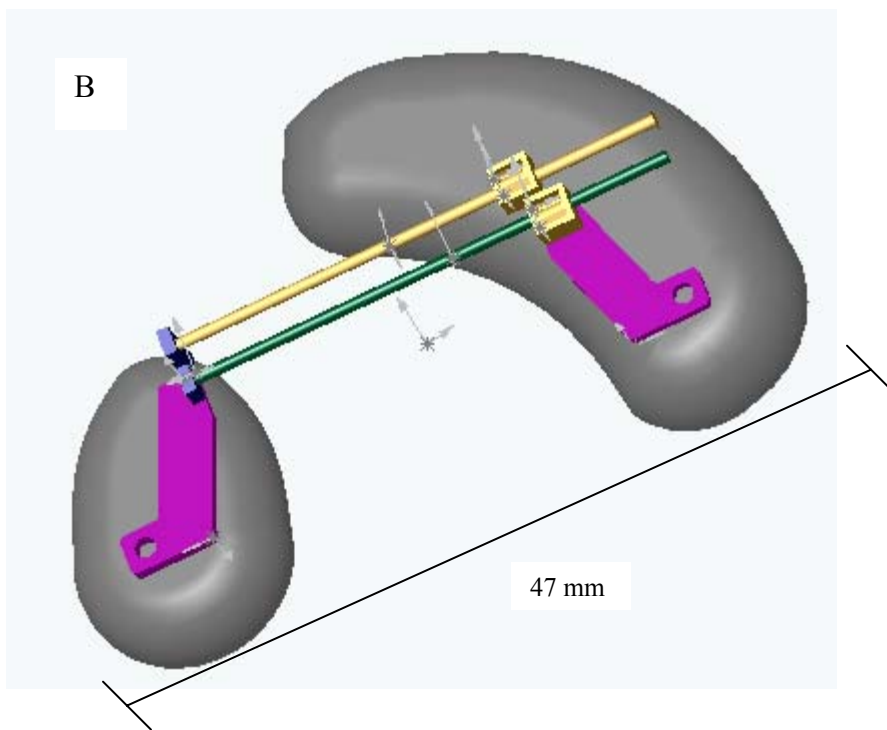


Figure 9: Final design of the Baby Beautiful 2002. The design contains two screws mounted around free rotating pivots in the acrylic. A) Two-dimensional drawing. B) Three-dimensional drawing. For all of figure 9: 1 mm in picture = 0.48 mm actual.

## Conclusion

In the future, additional testing of the three-times scale prototype of the Baby Beautiful will be performed. Testing will aid in determining if the design is feasible and will perform the functions intended in the design. From these tests, more modifications can be made, if needed, and eventually a “to-scale” prototype will be built and tested.

One additional design alternative will also be inquired upon. This design will include the use of either one or two springs or metal alloys with “memory.” The springs will be mounted to the acrylic segments and either have an original extended shape, for expansion of the palate, or a compressed shape, for closure of the palate. Thus, different springs can be used for different clefts, while maintaining independent movement of posterior and anterior segments. The “memory” metal works on the same principal as the springs, but would be much easier to use than the springs, but more expensive (Appendix F).

Both of these technologies, the springs and “memory” metals are widely available and relatively inexpensive to obtain. They will both provide a constant force over a

desired range of movements to give a persistent deformation of the palate. Although, before either of these two design alternatives can be seriously pursued, tissue mechanics of infant bone must be studied, and measured accurately, to prevent injury to the patients.

There are some ethical considerations that need to be accounted for in the design of this project. First of all, the cost of the device may be prohibitive to some patients because insurance may not cover the expense. For this reason, overall cost of the device should be kept to a minimum without compromising device quality. Also, safety is an ethical concern because it is possible that the device could cause injuries that could result in death (choking hazards) or increased facial abnormalities. So, the device should be designed with safety as a paramount concern so as to improve the patients' situations and minimize the possibility of injuries.

## Appendix A

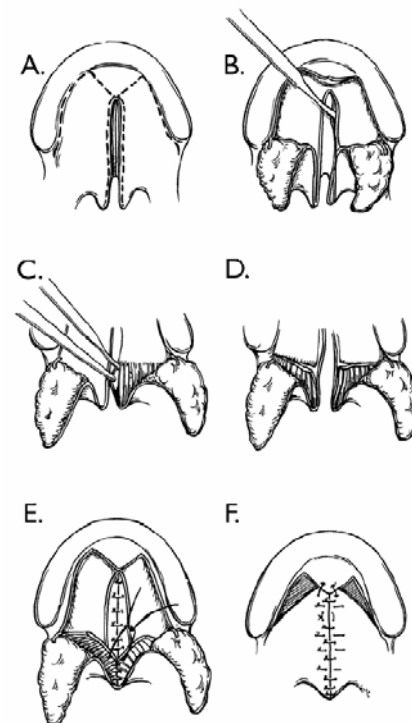
### Cleft Palate Information

The palate (roof of the mouth) is a wall of tissue, partitioning the nasal and oral cavities. This partition is made up of two parts: the hard palate and the soft palate. The hard palate forms the front portion of this partition and is made up of two bony plates that are normally fused together at their midline juncture. This fusion normally takes place during fetal development. The soft palate forms the rear portion of the palate wall and consists of muscle. Both palates are covered with a mucous membrane. A cleft palate is a fairly common congenital deformity that occurs in about one of every 800 infants. In these cases, as the fetus develops the palatal plates or facial processes fail to close during the second month of embryogenesis. The resulting fissure may occur on the soft palate only, or it may extend forward through the hard palate, in which case the nasal cavity opens directly into the mouth. Cleft palate may be unilateral or bilateral and may occur alone or in conjunction with cleft lip, a fissure through the lip beneath or including the nostril. The width of the cleft can be up to 10-12 mm or larger (2). Cleft palate limits an infant's ability to suckle and may lead to malnutrition, ear and sinus infections, and intestinal disorders. Later, speech difficulties may develop (4).

If the cleft is only through a child's lip, surgery to repair the lip is usually performed when the child is 12 weeks of age, after the labial muscles have matured and strengthened. If the child has a cleft palate it may be surgically closed between 6 and 18 months of life, generally at 12 months (4).

The objective of the cleft palate surgery is to close the palate to restore normal eating and drinking, to improve appearance, and prevent speech difficulties. It is a complex surgery, usually requiring a team of dentists, orthodontists, craniofacial surgeons, and plastic surgeons for postoperative care (4). A diagram of a typical cleft palate surgery can be seen in figure A-1.

Figure A-1: The cleft palate is surgically closed by elevating two mucoperiosteal flaps of the hard palate (A-B). The abnormal levator muscle insertion is then identified and cut free (C-D). The muscles are then elevated, redirected, and repaired. After the nasal mucosa, levator muscles, and oral mucosa have been separated from each other, the three sets of corresponding tissue are separately united across the cleft (E-F) (4). 1 mm in picture = 2.31 mm actual.



Cleft palates are more common in males, at a 3:2 ratio to females. In unilateral clefts, the left side of the palate is affected twice as much as the right side. Among infants with cleft deformities, 32% are only the cleft palate, 28% are only the cleft lip, and 40% are both cleft lip and palate. Cleft palates are more common among Asian populations and less common among Black populations. The incidence of clefts is increasing, and is believed to be due to more women having children later in life. Women over 39 years of age have triple the risk of having an infant with a cleft than women from the ages of 25 to 29 (1).

## Appendix B

### Existing Devices

1. **Passive Plates:** These devices consist of a piece of acrylic that simulates a normal palate. Often used in conjunction with tape across a cleft lip, to help bring the lip segments closer together (Figure B-1) (4).

**Pros:**

- Provides a false palate.
- Prevents worsening of the cleft.

**Cons:**

- Does not allow for any adjustment of cleft.

2. **Molding Plates:** These devices also consist of a piece of acrylic formed to fit the individual palate. Acrylic is gradually added or removed in order to realign the palate to a more normal configuration (6).

**Pros:**

- Provides a false palate.
- Has the option of using nasal stints, which help to reshape any nasal deformities that may accompany a cleft lip.
- Allows manipulation of palatal segments to desired locations.

**Cons:**

- Requires multiple clinical visits to modify the orthopedic.
- Some are aesthetically unpleasing.

3. **Latham:** This device consists of two acrylic pieces that fit over the alveolar segments. These pieces are connected in the posterior by way of a hinged bar. The palate is manipulated by rotating the hinged pieces. This is a type of “fixed” appliance, which means that it is attached to the mouth in such a way that it is not removed until the manipulation has been completed (Figure B-2) (4).

**Pros:**

- Easily adjustable, thus reducing required clinical visits.
- Allows manipulation of palatal segments to desired locations.

**Cons:**

- Does not provide a false palate.
- Cannot adjust width in the posterior.
- Cannot adjust front to back and left to right independently.

4. **Nordin Device:** This device is used for bilateral clefts. Like the Latham device, pieces of acrylic hold the alveolar segments. A ring of plastic encircles the premaxilla. This device expands the alveolar and pulls the premaxilla into position (Figure B-3) (4).

**Pros:**

- Allows manipulation of palatal segments to desired locations.

**Cons:**

- Does not provide a false palate.
- Not aesthetically pleasing.
- Does not allow rotation of the alveolar segments.

5. **Jackscrew Device:** This device consists of two acrylic pieces that fit over the alveolar segments. The acrylic pieces are manipulated by single or multiple jackscrews to adjust the position of the alveolar segments (Figure B-4) (3).

**Pros:**

- Allows manipulation of palatal segments to desired locations.
- Screws keep tongue out of cleft.

**Cons:**

- Multiple clinical visits are required to manipulate the device and replace jackscrews.
- Does not allow rotation of the alveolar segments.



47 mm

Figure B-1: Passive Plate (4)\*



Figure B-2: Latham Device (4)\*

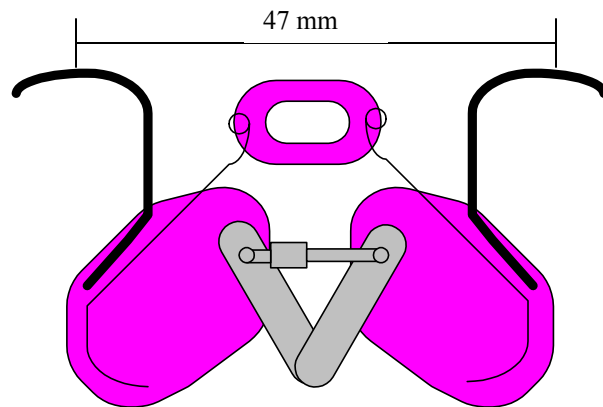


Figure B-3: Nordin Device\*

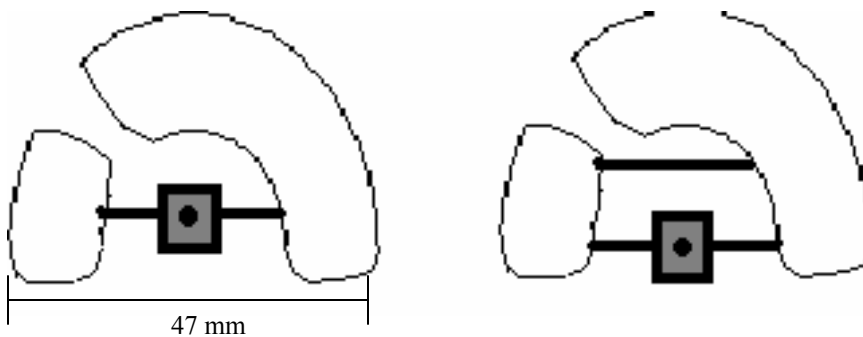


Figure B-4: Jackscrew devices. The device on the left contains a single jackscrew, which pulls the two acrylic pieces together. The device on the right contains a jackscrew that expands the posterior palate, while the anterior distance is maintained.\*

\*For all of Figure B, the anterior of the device points to the top of the picture, the posterior of the device toward the bottom of the picture. The approximate scale for B is 1 mm (actual) = 1.25 mm (in figure).

## Appendix C

### **Background Information on Saliva (5):**

- Salivary glands produce about 1 Liter of saliva a day
- Saliva lubricates food
- Contains mucins, glycoproteins, and amylase
- Amylase is an enzyme that reduces starch to oligosaccharide molecules
- Optimum pH is 7

### **Background Information on Breast Milk (5):**

- Contents:
  - 1% protein (largely casein, lactalbumin, and lactoglobulin)
  - 7% lactose
  - 3.5% fat
  - Calcium
  - Phosphorous
  - Immunoglobins
  - Also hormones and growth factors

### **Background Information on Bile (5):**

- Contains:
  - Bile acids
  - Cholesterol
  - Lecithins
  - Bile pigments
- Bile acids compose 50% of the dry weight of bile
- Contents of bile acids
  - Cholic acid
  - Chenodeoxycholic acid
  - Deoxycholic acid
  - Lithocholic acid

## Appendix D

**Product Design Specifications Version 2.1**

Last updated: 12/4/01

**Title:** Presurgical Maxillary Orthopedic for Cleft Palate Infants.**Team members:**

Elan Bomsztyk, Alissa Garman, Shannon Kane, Aaron Kroner, and Sarah Schram

**Function:**

A cleft palate is a deformity in which the palate is not completely formed and the nasal cavity opens into the mouth. This deformity occurs in approximately one out of every 800 infants. Often times there is a need for pre-surgical manipulation of the palate; this is currently done through the use of an orthopedic. The current devices being used all have limitations, including: restricted movement, non-universal applications, and inefficiency. The inefficiency results from the requirement for many clinical visits for replacement of jackscrews or other manipulations of the orthopedic. Our goal is to design an orthopedic device with a universal mechanism, which encompasses the benefits of current devices, allows movement in two dimensions, and is easily adjustable.

**Client requirements:**

- Translation and rotation in 2 dimensions
- Can accommodate both uni- and bi-lateral clefts
- Can't be too bulky
- Reduce the need for replacement of screws

**Design requirements:****1. Physical and Operational Characteristics***a. Performance requirements*

- Continuous usage 24 hours a day for 7-9 weeks (at 7-9 weeks the cleft lip is surgically closed, this holds the palate in place until the surgery is performed to close the cleft palate at 6-18 months)
- Will not be out of mouth for more than 4-6 hours at a time
- Must be fastened to gums—remain stationary

- Will be loaded with force required to move palate approximately 1 mm per day (this force has not been quantified)
- a. *Safety*
- Must not be a choking hazard
  - Non-toxic materials
  - No sharp objects—must be smooth so as not to be a cutting hazard
  - Easily sterilized to prevent bacterial growth
- b. *Accuracy and Reliability*
- Adjustments need to be repeatable
  - Precision is not critically important. The main goal is to reduce the amount of realignment that must be done during surgery.
- c. *Life in Service*
- Used for 7-9 weeks
  - Used 24 hours a day
- d. *Operating Environment*
- Infant mouth with no teeth
  - Come in contact mostly with saliva, milk, and vomit
- e. *Ergonomics*
- Limitation of forces on infants mouth (this has not been quantified, but it must not cause soft tissue breakdown)
  - Easy to put in, take out and adjust at home by the guardians
  - As unobtrusive to infant as possible
  - Needs to be able to be easily cleaned
- f. *Size*
- Small enough so infant can move tongue

- Dimensions will be custom fitted to infant's mouth. No documentation can be found concerning ranges of oral cavity dimensions

g. *Weight*

- As light as possible, current devices weigh between 3 and 4 grams

a. *Materials*

- Non-toxic
- Non-porous
- Strong enough to withstand forces of device and counter forces of tissue
- Operational temperature: needs to be functional from: 50-120 degrees F
- Resistant to acid in stomach bile

b. *Aesthetics*

- Smooth texture
- Keep as concealed as possible
- Neutral color

## **2. Production Characteristics**

a. *Quantity*

- Custom molded to each individual palate
- Client uses 6 per year

b. *Target product cost*

- \$500-600
- Some leeway because insurance usually covers cost of device

## **3. Miscellaneous**

a. *Standards and Specification*

- No patents exist on current devices, therefore there are no existing standards or specifications

b. *Customer*

- Not bulky
- Somewhat concealed as to not alarm parents

*c. Patient-related concerns*

- Sterile when first used and easily cleanable between adjustments

*a. Competition*

- No patents have been found.
- There are many devices currently used, but none appear to be mass produced – all are custom fabricated

## Appendix E: Decision Matrix

Design Specifications	Design Alternatives		
	Acrylic/Rubber Bands	Updated Latham	Baby Beautiful 2002
Translation in 2D	0	+	+
Accommodate both Uni and Bi-Lateral	+	+	+
Provides False Palate	+	-	0
Simplicity of Adjustment	-	0	0
Minimizes Clinical Visits	0	0	0
Not a Choking Hazard	-	-	0
Rotation	-	+	+
Upward Force	-	+	-
Feasibility	-	-	0
Totals	-2	+1	+2

**Table 1:** Decision matrix for possible solutions. A + indicates that the design provides this feature well. A 0 indicates that the design may provide the feature, but not as well relative to a +. A - indicates that the design does not provide the feature. A + scores one, 0 scores nothing, - scores a negative one.

**Appendix F:**

“Memory metal” is a metal alloy that can be preformed into a desired shape, deformed from this shape, and will then return to its initial configuration upon heating above its transformation temperature (11). In addition to direct heating of the element, the resistive properties of the alloy also allow a current to be passed through the metal, which creates heat itself and causes the deformation. The most common alloy used for this is Nitinol, a nickel and titanium alloy. This material is available in many shapes, tubing, wire, sheets, and ribbon for example, which are all available in various sizes and strengths.

The exact properties of these alloys can be varied by differing how the alloy is created. These processes include changing the alloy composition, mechanical working, and heat treatment. The properties that can be manipulated included the transformational temperature (-200 °C -110 °C), original conformation, stresses and strains over varying amount of cycles of use, resistivity (50  $\mu\Omega$  -110  $\mu\Omega$ ), and the strengths (12). An example of forces these alloys are able to produce are a 4 mm Nitinol wire can lift up to a 1 ton load for one cycle and a 0.51 mm wire can lift a mass of 150 kg consistently, although most applications for this size wire use loads of up to 10 N (12). Nitinol can also be configured to apply considerably smaller loads and also varying loads at different lengths along a single piece of alloy.

Nitinol is also highly biocompatible, has a high corrosive resistance, and has an excellent cytocompatibility, which all allow it to be used in medical devices and applications. Some current uses in the medical field include the Simon Nitinol Filter, which keeps blood vessels open and traps clots present in the blood stream, and the Mitek suture anchor, which provides a stable attachment of soft tissues to bone.

## Appendix G: Free Body Diagrams and Force Calculations for Compression of the Cleft

### Abbreviations:

$F_A$  = Force of the alveolar segment

$F_{SA}$  = Force of the anterior screw

$F_{SP}$  = Force of the posterior screw

### Assumptions:

- 1) For purposes of calculation it is assumed that the alveolar segments have the same dimensions. The data from the larger segment on the unilateral cleft mold from the client will be used. This is a reasonable assumption because no two clefts will look the same and the force required to move the segments will have to be at least as large as that produced by the largest alveolar segment.
- 2) It is assumed that the force of the alveolar segments is evenly distributed over the screws during compression.
- 3) It is assumed that the forces acting on the right alveolar segment (shown in the diagram) will be equal and opposite those for the left alveolar segment.
- 4) It can also be assumed that the forces on the right alveolar segment will be equal and opposite of the forces acting on the right acrylic piece (replacing the acrylic force with the force of the alveolar segment). This assumption also applies to the left acrylic piece.

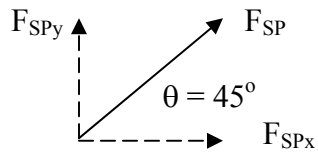
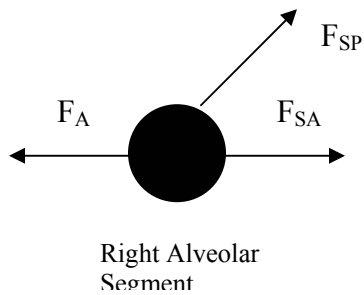
### Estimations:

- 1) The cleft will be closed at a rate of 1mm a day. This means that each segment will move approximately 0.5mm.
- 5)  $E$  (Young's modulus) = 15 KPa  $\pm$  1 KPa. This is the value for canine periodontal ligament. This is reasonable because this is the closest value we could find for the alveolar segments. This type of tissue is also weaker than cartilage, which is to be expected for infant alveolar tissue.
- 2) A rectangular segment will approximate the area of the side of the alveolar segment. The area of this rectangular segment corresponds to the cross-sectional area of the connective tissue at the median and transverse palatine sutures of the palatine process of the maxilla. Since these sutures are incomplete (resulting in the presence of a cleft) the alveolar segments can be translated and rotated.

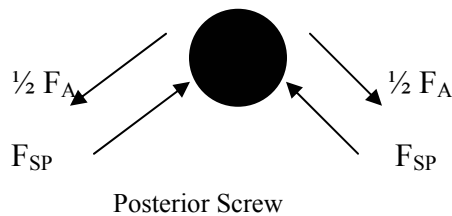
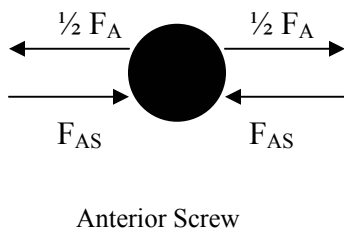
### Note:

For a better understanding of the parts outlined in the free body diagrams, see the 2-D figure of the device with labels (beneath free body diagrams).

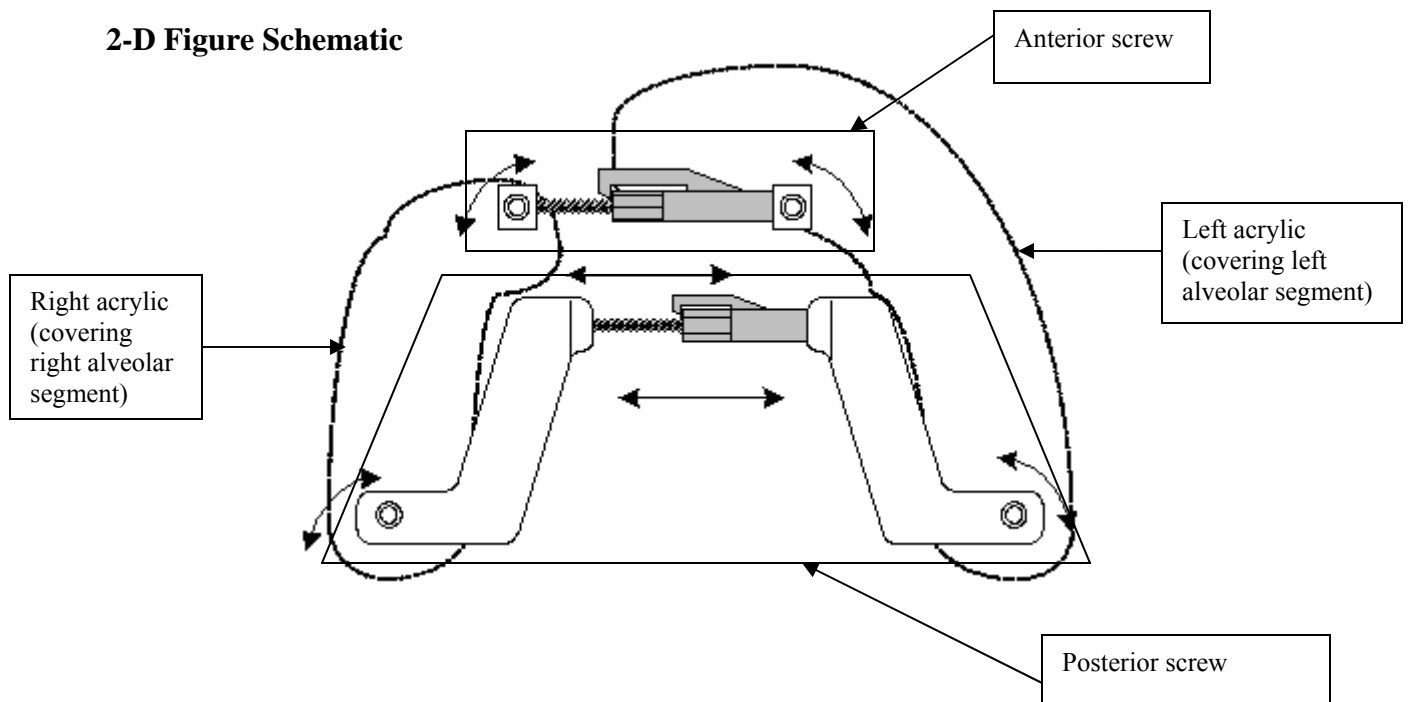
**Free Body Diagrams: (for compression of cleft)**



\*NOTE. The positive y points toward the anterior of the mouth. The positive x points medial-laterally.



**2-D Figure Schematic**



$$E = \sigma/\epsilon = (\text{Force} \times \text{Length})/(\Delta\text{Length} \times \text{Area})$$

$$\text{Force} = (E \times \Delta L \times A)/L$$

$$\Delta L = 0.5\text{mm}$$

$$L = 13\text{mm (from mold of cleft palate)}$$

$$A = 4.5\text{mm tall} \times 30\text{mm long} = 135\text{mm}^2$$

$$F_A = (0.015\text{MPa} \times 0.5\text{mm} \times 135\text{mm}^2)/(13\text{mm}) = \mathbf{0.07789\text{Newtons} \sim 780 \text{ Dyne}}$$

At equilibrium:

$$F_A = F_{SA} + F_{SPx}$$

\*use assumption that alveolar force evenly distributed over the screws.

$$F_{SA} = \frac{1}{2} F_A = 0.07789/2 = \mathbf{0.038942N}$$

$$F_{SPx} = \frac{1}{2} F_A = \mathbf{0.038942N}$$

$$F_{SP} = F_{SPx}/\cos 45^\circ = \mathbf{0.05507N}$$

$$F_{S_{py}} = F_{SP} \times \cos 45^\circ = 0.05507 \times \cos 45^\circ = \mathbf{0.038942N}$$

#### **Moment Calculations:**

\*the length of the  $45^\circ$  bar is  $\sim 10\text{mm}$ .

$$\mathbf{\text{Moment in the x direction}} = F_{SPx} \times \text{moment arm} = 0.038942 \times 10\text{mm} \times \sin 45^\circ = \mathbf{0.275\text{Nmm}}$$

$$\mathbf{\text{Moment in the y direction}} = F_{S_{py}} \times 10\text{mm} \times \sin 45^\circ = \mathbf{0.275\text{Nmm}}$$

#### **Comparisons to ultimate strength of materials used:**

Prototype made out of aluminum:

$$\sigma^{\text{ult}} \text{ aluminum} = 110\text{MPa}$$

Stainless steel will be used for final model:

Ultimate strength was not found, but is stronger than aluminum. Its elastic modulus is 29MPa.

\*Comparing these values to the forces that the material will undergo clearly shows that, at least on paper, the material should not fail.

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