Optimal Design Report:
Endotracheal and Gastric Tube Fixation

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1. Optimal Design Project 30

1.1 Introduction

1.1.1 Background

Dr. Leonard Eisenfeld in conjunction with the Neonatal Care Unit at The Connecticut Children’s Hospital, request assistance in the development of a product that will provide a safer more practical care in the fixation of endotracheal and oral gastric intubation. Currently the intubation of the neonatal patients and infants in general, poses multiple problems in the care and comfort of the patients. Intubations currently occur through the trachea and the stomach. The tubes that are placed in order to increase breathing prospects for the infants are inserted through the mouth and put an overt amount of pressure on the hard plate, causing immense discomfort. Often infants will try to remove the tube with a thrashing of their tongue as it views the pain and presence of the tube as a foreign object that in some cases even provokes a choking, or gag reflex in the child. The other option for gastric intubation, in order to promote nutrition and encourage feeding in a neonatal patient, is to enter through the mouth. The problem with intubation through the mouth is that there is an increased difficulty to fix and secure the tubes to properly sit in the mouth of the patient. Due to the increased moisture found in the oral cavity there are few materials that can fixate to the inner side of the cheek and properly hold the tube in a secure location and allow it sit in the trachea at the correct angle. Another common problem is the issue of nasal intubation, where the tube is placed through the nasal cavity in order to promote a secure environment, and reduce the possibility of tube movement. While the idea of the nasal intubation is promising in theory, in reality it blocks an involuntary breathing passage increasing the infant’s discomfort, and essentially preventing the infant from breathing properly on its own. These current methods prove to be troublesome in establishing the optimal care for both neonatal and full term infants at the children’s hospital.

1.1.2 Purpose of the Project

The device in theory would be made of a material that securely fastens the tube to the inside and outside of the cheek, providing a proper placement of the tube to perform optimally. The product would allow for the intubation to create minimal discomfort for the patient, while providing them at the same time with the best possible care. The fixation device in theory would be a type of clip that uses minimal amounts of tension in the material to provide a place for the tube to sit and be properly located on the inside of the patient’s cheek. The angle at which the clip sits in the patient’s mouth allows for easy airflow and increased nutrition for both endotracheal and gastric intubation. Unlike other current devices, this one will be made of materials that do not irritate or inflame the area inside the patient’s mouth. The clip will provide the optimal amount of tension, while also remaining comfortable; to keep the tube in place and prevent any motion of the tube from occurring and causing unwanted extubation prior to the patient being ready. It will also provide a safer and more practical option of intubation through the mouth, rather than intubation through the nasal cavity where intubation is not meant to occur. The end goal is to provide patients with safer and more practical care, with increased nutrition and
breathing efficiency, by using the mouth as well as the cheeks to enhance the fixation site.

1.1.3 Previous Work Done by Others

Currently on the market there are a few clips that are trying to accomplish the same overall goal of increased stability for tubing. The current clips are struggling to reach a large market as some continue to utilize the nose as a holding point, but as this is the most impressing point, many physicians are against their use. Many of the devices are not considered clips, but rather support for tube to remain in place. Some devices use a ballooning device, where a cuff is inserted to retain the position of the tube while placed in vivo. There are also devices that use a suctioning mechanism to increase stability during intubation; however, the suctioning function can become an obstacle within the oral cavity, preventing optimal care in certain circumstances. While there are multiple options to maintain stability via clip or fixation device, they all have been currently proven in effective in the area of inflammation and irritation when placed in vivo. The inner side of an infant’s cheek is so delicate and is easily irritated by the long term presence of a material, it is hard to find the correct biomaterial to retain stability and remain fixated in the wet oral cavity. The current devices are in able to accomplish this overall goal, and therefore the need still remains.

1.1.4 Optimal Design

In order to accomplish the goal of providing a patient with optimal care when the need to intubate arises, the optimal design of the fixation device is a clip. The clip will be situated on the side of the mouth and will have two portions, both inside and outside of the oral cavity. The design of the “clothespin clip” will provide the sturdiest and most stable environment for the correct placement of both the endotracheal and gastric tubes. The material that comprises the clip will be high density polyethylene (HDPE), which is a rigid material that will provide low grades of tension to keep the clip in place when in vivo. The outside portion will also present a win that will run perpendicular to the clip, and this wing is used to provide extra stability on the child cheek, preventing the clip from slipping or moving when a patient is intubated. The other portion of the clip will be lined so that the portion that is touching the cheek is lined with a silicone fabrication to decrease the opportunity for the clip to slip along the cheek when in vivo.

The inner segment of the clip is designed to stabilize both endotracheal and gastric tubes by the placement of two holes, which will be developed to accommodate multiple sizes of tubes. This portion will be outlined in a silicone like material in order to prevent irritation on the inner side of a patient’s cheek. In order to accommodate for the basal mucosa that is present on the inner layer, the inner segment, while being outlined with a rubberized material, will have a body that is composed of a mesh HDPE to prevent the fluid flow for the mucosa when placed in vivo.

Also to be accounted for is the fact that the endotracheal tube needs to be angled between vocal chords and often this means that a ballooning device needs to be put in place to prevent any permanent damage onto the chords. Due to the implementation of this device, the endotracheal tube is comprised of a tube that is sturdier and less flexible, as it
has to maintain the ballooning device. The endotracheal tube curves first, to account for the angling thru the trachea and then straightens out so that when placed in vivo it will fit in between the vocal chords and provide the optimal care for the infant. However, the gastric tube is comprised of a more flexible material, and can be arranged in any way as long the patient is provided with whatever medication or nourishment they require. The “clothespin clip” is the most advantageous design because it provides the patient with optimal care and in doing so also eases the caretaker’s stresses when in high risk scenarios.

1.2 Subunits

Part 1: Tube Fixation Device

The tube fixation device will be described in three parts: the inner mouth component, outer mouth component and materials used in device construction. It is important to note that the dimensions of the features will not be given as they still need to be determined accurately. The discussed design is the accurate model without accurate measurements (refer to “Device Testing” section for more information about future studies for accurate dimensions).

The inner mouth component refers to that part of the device which will be inside the mouth and attached to the inner cheek tissue. The design of this part includes a smoothed rectangular geometry, skewed holes to allow correct orientation of the gastric and endotracheal tubes and houses the tubes within a solid block (Fig 1).
The reason why the tubes are enclosed in the block geometry is to protect the tubes from infant saliva and vice versa (the baby will not be interacting with tubes). This is important because the instability of the current tube fixation methods derives from the tubes bathing in slippery saliva. The saliva causes the tubes to move more freely and potentially disrupt correct orientation of the tubes. As for the baby, tonguing is a major problem in current tube configurations and housing the tubes will alleviate this problem. It is natural for the tong to explore new items in the mouth, and the tube is the primary target for this response. Without any tubes affecting the tong region, the infant will also be less stressed and will more easily intake the necessary food and oxygen (via the gastric and endotracheal tubes respectively). An added benefit of this design is the ease of use for nurses and other healthcare providers. The current method of free tube fixation involves the nurse having to properly position the tube and potentially tape or keep the tube in place using inefficient methods. Then, very often, the nurse must readjust as the infant moves. This problem was initially solved by creating two guiding "rings" for the tubes to pass through (this was part of the initial design proposed by the doctor) (Fig 2)

Fig 2: Alternate Design of tube fixation.(citation at the end)

However, one can easily see the problem with this solution. A health care provider has to aim the tube through both rings and properly fit the ring. With the optimal design, the ring is only inserted through the hole, and gently pushed. The walls of the hole guide the tube 100% to desired destination. Finally, since the tubes are enclosed, if anyone inserts the tubes too hard or quickly draws the tubes out, there is little chance of injury to the tong or cheek tissue.

Another feature of the inner mouth component is its smooth rectangular geometry. The reason for this design is to take up the smallest amount of oral volume while having a rigid enough base for the tubes. Any other geometry, such as cylindrical or angular rectangular would potentially harm the gums, tong and upper palette. Also, the goal was to have the device as close with the cheek and far away from the gums as possible and this geometry achieves the goal. Moreover, if there is a large implant which does contact the gums, it
could potentially slow dentin growth and cause the jaw muscles to remain tensed for extended periods of time.

This discussion ends with describing the skewed hole design. Unlike the other components of the design, the holes were measured in an accurate manner (the team was directly given the gastric and endotracheal tubes). The feeding tube is the larger (2.667mm) and the endotracheal tube is the smaller (1.33mm). The reason why the endotracheal tube is more towards the center of the mouth is because the tracheal tube must pass through the vocal cords. To not injure the vocal cords, the tube must be directed towards the center of the mouth and aimed straight down the throat (Fig 3):

![Diagram of vocal cord location](image_url)

**Fig 3: Diagram indicating vocal cord location for readers understanding of endotracheal tube weaving route (citation at the end).**

Another meticulous feature is the rounded edges of the holes to allow for easy penetration of the tubes through the device (Fig 4)
Now, moving to the outer mouth component of the clip there are two major features to note: the length of this outer component compared to the inner component and the parallel relationship between the inner and outer component edges.

This outer component is longer than the inner component to provide extra grip and stability. This design also prevents the clip from falling off from sudden movements and supports the infant’s cheek in a proper manner. The reason why there is a “straight line” parallel relationship between the inner and outer component is because this is just the “skeleton” of the device. The outer component will actually support the “Cheek Sheet” which is a rubbery material (much like the i-pod cover; for details about the material refer to the “Part 4: Cheek Sheet” section) which will further stabilize the device against the cheek (Fig 5):
The majority of the design lies in the materials used in this device. First, the discussion will be directed towards PVC, which is the bulk material used, and then further analysis will be directed towards the muco-adhesives that will be interacting with the inner cheek.

PVC specifically makes up the entire outer component of the clip along with the inner component directed toward the tong. The material adhering to the inner cheek is a muco-adhesive (Fig 6).
Fig 6: Outline of the material components of the device

Since PVC is already widely used in the medical industry, it will be in part used in this device. The interesting character of PVC is its ability to become softer or harder based on the addition of plasticizers. Furthermore, PVC can be manufactured into a variety of shapes using compression molding, calendaring, blow molding or injection molding. Also, unlike
other plastics, PVC has been proven not to have harmful biological effects when wet or in contact with skin.

There are multiple options for the muco-adhesive material. Out of the many researched, three were deemed appropriate. Chitosan is one option because it is a naturally derived substance with superior biocompatibility and zero toxicity. This material is usually used for clotting and wound healing applications, but it also has amazing adhesive properties. If Chitosan is cross-linked its stiffness increases by a factor of 10 while its enzymatic degradation susceptibility decreases. Unfortunately, a major drawback is its biodegradability. In fact Chitosan can undergo bulk degradation, if it’s not added with other materials. Sodium Carboxymethylcellulose is another safe and effective muco-adhesive. It is largely used in the food industry as a thickener and has been used like a sticky gum adhesive. The most promising evidence for this material lies in studies done by British dentists who successfully applied the material in mucal drug delivery applications. However, here again, the adhesive duration is a problem, as the longest time this can remain adhesive was 7-8hrs. Finally, Potassium Alginate is a water based adhesive. This means that it absorbs water to become adhesive. This is of huge advantage especially in a region 99% water. Yet, this application has two major problems. First, it could dehydrate the infant by absorbing large amounts of saliva. Although Potassium Alginate did show promise in adult patients, neonatal have under developed saliva, and most of the patients are already under hydrated (Potassium Alginate is also not really used in older patients, especially those who have diabetes). Thus, at the current stage of the design process, an adhesive suitable for the infants still need to be discovered. Suggestion has also been made to negate the adhesive as it may increase cost of device unnecessarily.

Part 2: Testing and Analysis of Tube fixation Device

The testing of the device can be broken down into two main categories: physical testing and materials testing. Within the physical testing, ergonomic and measurement accuracy experiments will be conducted to ensure proper fitting of the device before delivery. For the materials testing, it is more confirmatory than experimental since PVC has shown its use in the medical field already. However special tests will be conducted for the muco-adhesives (if it is decided to use them, taking into account cost).

In order to obtain a better understanding of average infant size, the team will meet with UConn Health Center NICU specialists and potentially burrow an infant manikin from the medical school. The manikin’s cheek curvature, cheek length and inner mouth volume will be measured. Potentially, an adult manikin from the anesthesiology department may be used because they can give a more accurate mouth opening representation. Ergonomic and comfort testing must be done, however it is unclear the exact method. One potential way is to continue modeling on the manikin and asking the client their expert opinion. However, real tests may have to be done on team members themselves in order to really understand the sensory reaction to the device. Advanced software modeling with SolidWorks can also be used to identify weak regions and even extrapolate ergonomic data.

The PVC testing will focus on mucosal testing, tong testing and UV light/Heat testing. The least expensive stock PVC will be set in a highly watery and sticky mucosal...
solution for approximately one to two days. These will mico-model the conditions in which PVC will be subject to. Although this will not be highly accurate, it will give some sense of its response (again, PVC is already used in gastric tubes, which must travel through and stay in highly mucous filled regions). In order to test PVC’s abrasive strength in liquid environment, SolidWorks friction analysis can be used. The frictional force will account for both tong abrasion and liquid abrasion. Again, the accuracy will not be as good as in physical experimentation, but this method is much more time efficient. Finally, to test the PVC in NICU heated/UV environment, the material will be placed in one of the infant incubation systems for almost a week (in between the team’s meetings with the client). Data will be taken on any heat transmittance, particulate debris and mechanical properties. Most of the experimentation will be done via observation and qualitative analysis such as using touch to determine degree of heat transmittance or visual inspection for particulate accumulation. The mechanical properties will be tested in the UConn Bronwell labs using the TINIUS machines. The compressive force and tensile test will be done to ensure that PVC has the proper mechanical properties for the application. The compressive force is necessary because the clip (especially the inner component) will be subject to random pressure from the tong and maybe even the guns at some point. Also, testing will be done to ensure that the hole diameter is of accurate size (the current displayed device has the diameter exactly the diameter of the tube, this is done because the tolerances of the tube sizes have not been researched). For this test, SolidWorks or ABAQUS will be used to computationally analyze “fluid flow” in the tubes. This fluid flow will model the frictional force of the tube as it is inserted and taken out. Dermatological test methods will be used to understand the skin compatibility of PVC for extended periods of time. The exact methods have not been devised, as animal testing is prohibited and obtaining skin grafts may be difficult. However, the team will work with dermatologists to device a unique skin test for PVC.

Muco-adhesive testing will cost more money and will be difficult to perform because of the materials for the experiments. Primarily, the muco-adhesive materials are in their infancy with regard to clinical use and research. Artificial mucous and saliva like liquids are also very expensive and hard to obtain. Thus it is still debatable if the team will actually even have the muco-adhesive, much less test the materials. However, if hypothetical testing were to take place the procedure would be relatively simple. First, the inner cheek would be modeled using skin grafts (obtained from the UConn Medical School) and artificial mucous mixed with water. The muco-adhesive material will be pasted onto this inner cheek model and a device will be stuck to the model via the muco-adhesive (Fig 7):
Part 3: SolidWorks Analysis: Prove of Tube Fixation device concept

3A) Mass/Mechanical properties

The main reason for performing the following analysis is to determine the mass, volume and surface area as these are essential for the device. The mass was calculated to be approximately .43 grams, the volume 433 cubic millimeters and the surface area 1103 square millimeters. From this initial reading it is apparent that the device will not weigh down the cheek and will not cause discomfort for the infant. Research still needs to be done on what mass tolerance is appropriate for the infant. Also, the exact dimensions and material characterization will improve the reading to a more accurate measure. The volume measure is also inaccurate because it takes into account the outer component of the device not interacting with the mouth. The volume is only important for the inner portion. Again the dimensions are not accurate which directly impacts the volume measure. Nevertheless, the total volume of the device is only .433ml whereas the average child’s mouth has volume 37.5ml (this is an older child, not neonatal). Until an accurate volume for neonatal mouths is not obtained, true accuracy cannot be achieved about how the device will interact with the infant (Fig 8)

Fig 7: A general experimental setup for inner cheek experiment: Not exact, more an algorithmic image.
Fig 8: Print screen of the mass properties data. Boxed region includes important data.

**Part 4: Cheek Sheet**

The “Cheek Sheet” is a rubbery material which will be attached to the outer tube fixation device. The material will be a silicone rubber (the same material used in i-pod cases). The reason for picking this material is because it is biocompatible, has excellent tensile strength and can be molded to the desired check curvature. Another purpose of the
device is to provide comfort to the infant’s outer cheek and dampen the pressure the clip may induce on the cheek.

To test the material, it will be subject to differently curved surfaces (which mimic cheek curvature) and the adherence of the material will be noted. Specifically, the team will obtain a manikin from the Health center and attach this material to the outer “cheek”, applying pressure similar to what the tube fixation device will apply. General tensile and compressive testing will also be done to understand exactly the material properties and applicability of the material to skin. Advanced testing can be done with SolidWorks to determine stresses in the material and potential for tear, as well as how flexible the material is.

**Part 5: System Integration**

The two components of the tube fixation system will be mated as in figure 5 above. There are various methods to achieve this goal. First the “Cheek sheet” can be attached via liquid cement to the outer component of tube fixation device. The liquid cement material is the same that is used in dentistry for crowning and tooth filling. Another, potentially less expensive method is to simply glue the material to the device using superglue (dental grade) or staple it to the device. Other ideas are also plausible and further discussion still needs to occur with the client and other health care specialists about best practices.

The reason why there are no hole fixtures or screws is because it leads to increased expense and may be dangerous for the infant. The current tube fixation method is actually relatively cheap, and with optimal costs in mind, hospitals will not pay more for the same process. Adding holes and screws will lead to more potential for failure and added stress regions in the outer portion of the device (this will be confirmed using SolidWorks and will be included in newer versions of the optimal design). Also is a screw is used, it will have to penetrate the “Cheek sheet” and the metallic screw head will be in contact with the infant’s cheek causing irritation. Moreover, any crevice within the outer regions will cause potential bacterial build up and lead to infections.

Total tube fixation system will be tested by the clinician on real infants. This is the only way to truly know if the system works. Testing the full device on a manikin will give very inaccurate results. Potential testing in SolidWorks can occur, but the complexity of the biological environment number of variables to consider may cause this testing option to be negated.

This design was chosen out of other alternative designs as the most practical, safe and effective design. However, the meticulous details of the design still need to be fine-tuned. Updates will occur frequently as more information is obtained and the design process continues to actual prototype design.
2 Realistic Constraints

In order to provide the most accurate detailed description of the product in design, it is important to take note of the specifications that are constraining the product. When dealing with neonatal infants there are a plethora of constraints that prevent some design aspects to be implemented. When dealing with infants in general their safety and well-being are of utmost importance and must remain the constant focus of the design process. In order to ensure that the infant’s safety is not compromised, the constraints must be accounted for and develop a plan to simultaneously provide the patient with the highest level of caretaking. One of the most important aspects is to ensure that the pieces of the “clothespin clip” are scaled to size to fit inside the infant’s mouth, but that the pieces are not small enough to cause the child to choke. The shape of the clip must not promote the possibility of choking either, and must be conducive to providing the correct placement of the tubing once placed in vivo. The clip must also adhere to scaling issues; it needs to provide the correct care, without impeding the patient in anyway. If the child is premature, the clip will need to be created to accommodate for its smaller stature, as you cannot have clip that was meant for a full term baby placed on the cheek of a baby that is seventeen weeks early. At the same time, a full term baby cannot have a clip that is meant for a premature baby, as more than likely it will be too small and could possibly promote choking. When the scaling does not match up, it could provide less than optimal care for the patient, or in certain cases it could prove detrimental to the patient’s health.

The “clothespin clip” is composed of both High Density Polyethylene (HDPE) and silicone, which are a rigid polymer and rubberized material, respectively. The material was chosen because of its advantageous material properties, but it is also extremely cost effective. The combination of the two projects, the Tube Fixation Device and the Continuous Urinary Output Monitor, carries a total budget of one thousand US dollars. The small budget led us to the use of HDPE and silicone as they provided the correct mechanical strength as well as material properties to compose a functional device. If granted a larger budget other materials could have been considered and could have possibly provided a more beneficial product leading to better patient care. However, the implementation of cost effective material ensures that it is marketable to a large range of socioeconomic backgrounds. Due to this, it will reach more people and increase patient care globally.

Environmentally this product will be a reused and recycled material that can be either sterilized for reuse, if not damaged. However, if damage is presented, it can be recast to form the desired shape of the original clip. In order to be manufactured the design will have to be developed in Solidworks, the HDPE needs to be meshed and the outer layer of the inner portion of the clip needs to be coated in silicone to promote a lack of inflammation in the baby’s mouth. The manufacturability of the clip is promising as it requires very few materials, but the machining process seems as though it could become problematic if the Solidworks drawing was incomplete or incorrect. The design needs to be tested using Solidworks and then the thickness of the clip can be designed so as to provide the exact amount of tension of the cheek. The tension remains a mechanical constraint that determines the thickness and the ultimate shape that the clip will take. Once these speci
dimensions are determined, the manufacturing of the product will be simple once inputting the design via solid works. By using Solidworks, the product will be able to be manufactured on the large scale.

In terms of its sustainability, the product must remain in vivo for extensive amounts of time, for as long as the patient requires assistance breathing, or eating. The clip must sustain the jaw movements that the infant produces, as to ensure that the clip is of the correct composition so that it is biomechanically compatible to the movements of the patient. The inner layer will be composed of a mesh material that will sustain the basal mucosa on the inside of the patient’s cheek, which will decrease the possibility of inflammation if the mucous environment is dried out. If both of those biocompatibility issues are determined the product will provide the infant with the best care.

Ethically this product produces a grey area, as primarily the patients that require the use of both an endotracheal and gastric tube, are the patients that have already suffered from some type of oxygen loss or nourishment issue. In certain cases, not all, these patients have previously suffered from a loss of nourishment that has predisposed them to a disease. By allowing for an easier method of caretaking, the possibility of saving more children arises and this means that more children will survive following these traumatic experiences where they are rendered disabled. The intubation of these patients can be controversial because the addition of products that save lives of patients that have already be labeled disabled increases the disabled population. In many cases some of the disabilities are minor and can be treated through therapy, and the patients can be fully submerged into the “mainstream”. However, the loss of oxygen to the brain can result in permanent loss of brain function, or it can lead to diseases that are extremely care intensive. The introduction of the product would mean that infant’s that present these disabilities following a loss of oxygen or nourishment would be faced with living a life that might not be as fulfilling. However, this is a highly controversial topic being consistently dealt with all throughout the medical field. Many say that a doctor’s first priority is to “first do no harm”. On the other side of the argument, the fact that there are an increasing amount of disabilities apparent throughout the population raises the question if it is the right thing to increase a person’s chance of a life time struggle with a disability. Politically this can tie into the constant debate of pro-life and pro-choice. However, for this design the implementation of the clips will help to provide the patient with the optimal care, and therefore it is the responsibility of the team to develop a product for that reason.

The engineering standards of this product directly relate to the specifications that were previously developed in order to form an outline, or guidelines for the creation of the “clothespin clip”. The HDPE must remain in place in vivo, when placed snuggly on the inner side of the cheek. The sizes of endotracheal and gastric tubes range, but in general the most commonly used sizes for the endotracheal tube are 2.0, 2.5, 3.0, 3.5, and 4.0 mm French. However, the only two common sizes for an infant’s endotracheal tube are 5 and 8 mm French. In order to mass produce multiple sizes will have to be designed so that all sizes of tubing are accounted for and all patients can receive the proper sized intubation that they require. The clip will normally be stored at 20 to 25 °C; while in vivo it will be placed in the oral cavity which is typically 36-37 °C. The environment in the oral cavity is a wet one,
where the clip will interact with the mucous, the basal mucosa, and the patient's saliva. By adhering to the constraints that are presented in all aspects of design, the “clothespin clip” will be developed to successfully provide increased care to NICU patient’s globally.

3 Safety Issues

Dealing with infants creates the need for a heightened sense of safety when it comes to the design of a product that will be used to care for them. The implementation of a tube on the infant’s cheek calls for the recognition of the delicacy that is associated with this surrounding tissue at such an early stage of life. When implementing the “clothespin clip” design the tension that is placed on the cheek is also called into question. The pressure that is exerted from the clip onto the cheek is something that needs to be called into question, in order to prevent the infant from experienced any unnecessary pain. The tension should be calculated to exert a very minimal amount of tension on the cheek, while holding the clip in place and promoting stability. The clip’s design will be tested to calculate the amount of tension will be exerted when the clip is put in place on the child’s cheek, this data will be taken into account to ensure that the patient is not exposed to any pressure that will encourage deformation or inflammation.

The added feature of the wing is implemented ensure stability, and will have to be made into a rounded piece of the clip, that will refrain from exposing the patient to hardened edges that will scratch or damage the outer portion of the patient’s cheek. It will have an inner layer of a silicone like substance that promotes an increased friction like property to keep the clip in place in vivo. The material will be soft enough that it will not cause any damage to the baby's cheek, while at the same time promoting increased stability. The silicone is biocompatible and will not cause any inflammation or irritation at the site of use.

The inner layer of the clip will be composed of a mesh HDPE material. The meshed portion is implemented to ensure that the inner layer of the basal mucosa is taken into account. By using a meshed material it will promote fluid flow against the inner layer, keeping the basal mucosa from drying out. If the basal mucosa is dried out it will increase irritation at the site of the clip. The meshed portion of the clip will be outlined, or encompassed, by a silicone material to promote a softer integration of the clip. The use of silicone will ensure that the meshed HDPE will not scratch the inner layer of the cheek. Both HDPE and silicone are biocompatible materials that have been tested in vivo, and when implemented in the correct way will ensure the most advantageous care.

Oral intubation and intubation in general, requires the analysis of how to best provide the patient with the best care, while also taking into account the harm that the tubing could cause when placed in vivo. The placement of the tubes needs to take into consideration the sensitivity of the vocal cords, and the ballooning device used to prevent the vocal cords from experiencing any damage. The tubes placement is critical in providing optimal care for patients, especially for infants in the NICU. The oral and gastric tubes fixation points on the device, or the holes through which the tubes will be placed, must ensure that the infant will get the most advantageous care from the intubation, and also prevents any type of choking from occurring. Any device that is placed in vivo in and infant
must ensure that the patient is fully able to breathe, as choking is extremely common in infant patients. The use of the holes in the front ensure that the tubes will be kept under the inner layer of the mesh clip, which will prevent the infant from thrashing its tongue and displacing the tubing, which would cause multiple problems for the caretakers both immediately and in the future of the patient. The “clothespin clip” will ensure a safe delivery of optimal care for infant patients in the NICU.

4 Impact of Engineering Solutions

The design of a product that ensures the optimal care of a neonatal patient that requires intubation, could severely impact the stress of giving care in neonatal units. When treating infants that require intubation, the placement and position of the tubes is critically analyzed. Through the implementation of the oral “clothespin clip” the placement will not require such intense scrutinizing as the use of the clip will ensure proper placement of the tubing. The clips use will create an easy routine when intubation is required.

The clips design and development are extremely cost effective. The use of silicone and HDPE ensures the use of materials that will provide advantageous care, while also remaining available for all socioeconomic areas throughout the country, and the world. The fact that the clip is cost effective makes it marketable to many lesser developed areas; this will help to promote safer and optimal care for infants. Its use could possibly work to help less experienced or trained caretakers in the intubation of a patient. In the case of emergencies its low cost and easy to use manner promotes its use and encourages a less stressful implementation of care during a more intense scenario.

Following their use the clips can be sterilized and reused as long as no deformation has occurred. The implementation of HDPE as a plastic material that comprises most of the fixation device makes it slightly less advantageous to the environment. However, its possible reuse will encourage both an environmentally friendly tactic, as well as a cost saving mechanism. The reuse may not be plausible in all scenarios, and because of this the use of HDPE as a thermoplastic material which allows for the reheating of the material multiple times, and the resetting of the shape. By recycling the material the product becomes increasingly more cost effective, as long as the product is sterilized.

The clip will be used to provide better care for babies that are having difficulties both eating and breathing on their own. These babies often suffer a great deal, and in some cases their sufferings cannot be changed once the damage is done. When a baby goes without oxygen or food for extended periods of time, the damage can be irreversible and even though the baby remains alive, their brain function or other bodily functions will be severely compromised. This device, along with any device that is used to promote the health of neonatal care unit infants, will therefore elongate the life of a baby that may have a life changing disability. This is something that brings up a very moral based debate, that comes into the spotlight more and more as extreme measures are being developed to help keep infants alive even following the introduction of life altering disabilities. The current situation is that due to the increase in extraordinary measures being taken to keep these children alive, there is an increase in the amount of disabilities presenting themselves within the population. The treatment of these disabilities is also changing helping to
integrate people with disabilities into the “mainstream” way of life. However, with regards to diseases such as mental retardation and cerebral palsy the children remain effected for the entirety of their life and while it is a positive that they remain alive, the struggles associated with these diseases are profound and require constant care.

5 Life-Long Learning

In any design process one of the most important aspects is the development of a new and useful product that will better the quality of care any nurse, doctor, or physician can provide to a patient. However, it is also important to note that while researching and designing a product, many new pieces of information present themselves and prove to be useful not only in implementation of the design but may provide a lifelong lesson.

Working in conjunction with a neonatal care unit doctor, it is very eye opening to see just the severity of being placed in an intensive care unit at such an early stage in life. Many of the patient’s in this unit are facing life threatening issues, and while the doctors will work to provide the best care, in certain cases the patients undergo problems that are irreversible and will face difficulties for the remainder of their lives. When these infants are subject to a loss of air or of nourishment they are experiencing a lack of brain activity or of specific organ function. The realization of what it means for a baby to be delivered seventeen weeks early was brought into focus, when it is said that the baby will undergo as much gestation, if not more, outside of its mother’s womb than inside.

When working with patients that are of such a smaller stature, it is important to try and scale everything down to a level that will still function while also providing its proper function. Working with neonatal infants requires the analysis of how to get things onto this desired level. It is important to take into account that working with infants is a lot different than working with a normal sized person. Not only are an infant’s dimensions of critical importance, but because they are at such an early stage in life they are not as exposed as a normal patient. They are very delicate and require delicacy when implementing a device onto or into their body. The fact that their skin is extremely fresh is something that is taken into account so that the material they are exposed to does not cause any irritation or inflammation when placed in vivo. Their dermal skin is extremely important to take into consideration, but using this clip requires the interaction of the device with the inner side of the infant’s cheek. The inner side layer is comprised of basal mucosa which requires exposure to fluid in order to prevent irritation. Placing any object in vivo in an infant requires added analysis, in order to ensure the heightened sense of safety associated with working with neonatal care units.

The exposure to the way in which a hospital works is an invaluable lesson, as working with a doctor helps to see how time is managed between patients. In particular seeing the difference between a neonatal doctor and a normal physician is extremely interesting. Dr. Eisenfeld has patients at multiple hospitals around New England, and so far has exposed Team 17 to two very different NICUs. After seeing the NICUs and discussing the products with physicians it was clear that the cost of the product being implemented in hospitals was a key component to the design. If the design calls for an increased cost, it will in many cases remain too expensive to mass produce and implement in hospitals. Exposure to a hospital’s budget helps to increase awareness of keeping to the project budget.
6 References


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