Endotracheal and Gastric Tube Fixation

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**Executive Summary**

In neonatal intensive care units there is a need for a fixation device that will hold both endotracheal and oral-gastric tubes in the proper position in patients. Endotracheal and gastric tubes are often required in neonatal intensive care patients who are unable to breathe or eat on their own. These tubes, while necessary, can also be harmful to a newborn baby.

The current technology used involves using tape to fix endotracheal tubes to a patient's face in order to hopefully secure the tube in the correct location. For gastric tubes it is common for nasal-gastric tubes, rather than oral-gastric tubes, to be paced in patients due to the ease of fixation through the nose. Nasal-gastric tubes are unfavorable, especially for infants who are nasal breathers during their early months, but also because the nasal cavity was not designed to support a tube. Patients have also been known to remove endotracheal and gastric tubes, causing major health issues.

A fixation device, or devices, will be designed to hold endotracheal and oral-gastric tubes in proper locations as well as prevent patients from removing the tubes. The fixation device will replace nasal-gastric tubes, which will prevent many infections and unneeded pain for neonatal intensive care patients.

**1.0 Introduction**

**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.

1.2 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.

1.3 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.

1.3.1/1.3.2 Products and Patent Search Results.

Currently the patents present remain for an endotracheal tube support that works via the use of a mouth guard that the tubes can also be secured to. The clip is utilizes a resilient material in a U-shape that measures the length of the infants cheek in order to prevent the possibility of the tube snapping. The current inventor is Roland Roopchand, and the product was examined by Joseph F. Weiss, Jr. The patent number of 5941246 corresponds to the endotracheal tube support that was filed on October 31, 1997 and issued on August 24, 1999. Currently the latest update to the patent was on June 26, 2012 when Shield Manufacturing, Inc. incorporated the idea of a mouth guard into the original design.

2.0 Project Description

2.1 Objective

Using medical grade plastics and oral fixation gels a fixation device will be designed to hold endotracheal and oral-gastric tubes in the proper locations in neonatal intensive care patients. The fixation device will be held to the side of the mouth with the use of pressure and oral fixation gels. The device will prevent patients from removing tubes that are helping them breathe and receive nourishment.
The device will be shaped in a clip formation in order to use slight pressure to hold the tubes in place inside of the mouth. There will also be an oral gel used on the inside of the cheek to hold the device in place. If needed, another gel will be used to fixate the device on the outside of the patient’s cheek. It will be easily removable in order to allow adjustments to position or medical providers access to the mouth when needed. The clip will also have to be made from a soft and comfortable plastic in order to minimize the patient’s discomfort.

The device will be shaped in a specific way in order to hold the endotracheal and oral-gastric tubes in at the correct angles in the mouth. If need be the clip will have two separate holes for each tube in order to correctly align both the endotracheal and gastric tubes. The device will also be adjustable in order to fit both premature patients as well as full term patients.

2.2. Methods/Materials

The endotracheal and oral gastric tube fixation device will be made of HDPE (High Density Polyethylene) Plastic. The reason for this choice is based on investigation comparing metals, ceramics and plastics as potential device materials.

Metals were not used because they irritate the skin, may cause inner mouth injury and succumb to corrosion. Skin irritation is a primary concern for the neonatal caregivers because rashes and other epidermal disorders may drastically affect neonatal immunological health and may cause other severe allergic reactions. Metal is known to irritate skin (especially in sensitive baby skins) and is linked to the development of dermatitis (fungal skin disorder). Apart from this, metal conducts heat easily and may heat the infants face to an uncomfortable temperature. This is because the infant in neonatal care is sometimes in thermoregulatory chambers which are sometimes at high temperatures to maintain infant body temperature. Inner mouth injury is highly probable as metals are hard and any
unusual movement to place the device or by the infant can result in injury. Also, metal device cannot efficiently cling to the cheek of the infant unless it is specifically created for the cheek of that infant. However, the most pressing concern, from a development and engineering standpoint is the corrosion that a metallic device will face. At least some part of the device will have to directly interact with the saliva, fluid and food particles contained within the mouth. Metal is extremely prone to galvanic corrosion, a process where microscopic metallic particles disengage from the main device and are potentially (most probably) ingested by the infant, causing poisoning and other health issues.

Ceramics were not used because they have limited biocompatibility, again may cause inner mouth injury and are brittle. Since this device is directly interacting with the biological environment, it must be biocompatible and easily integrated. Although ceramics are used in bone scaffolds inside the body, they are usually part of a composite containing some polymer. Ceramics alone would cause an inflammatory response due to the weak shear strength and tendency for pieces of the ceramic to sear off. Along with this, ceramics are glassy and very brittle, leading to rampant injury. As with metals, ceramics can only be polished to a certain point to remove sharp edges. The hardness and gloss of manufactured ceramics will also cause irritation in general inside the mouth. Most importantly, ceramics are very expensive to produce and are very poor in mechanical properties. The machine workability of ceramics is very poor as it takes very special machinery and high temperatures to produce the desired product.

Plastics such as HDPE are the best choice as they are already used in the market for direct human applications and are very easy to manufacture and obtain. The FDA, NSF and USDA all approve HDPE for full human contact applications. HDPE
can be found in milk cartons, shampoo bottles and toys. Moreover, HDPE is one of the few plastics which does not cause skin irritation and is not a known carcinogen when extensively exposed to fluids. Its light weight is an added plus, as other materials would have weighed down the cheek of the infant causing potential long term health problems (tensed facial muscles or early wrinkling). HDPE is excellent in the machine shop and is easily workable, flexible and strong. The chance of inner mouth injury or any other hazardous situation is very small.

**Device structure**

The design of the device was initially generated by Dr. Leonard Eisenfeld of the UCONN Health Center and Hartford Hospital NICU, (a specialist in Perinatal Medicine & Neonatal medicine). There are multiple ideas the doctor proposed, the presented design of the doctor was not particularly favored by the doctor but was the choice of the team for further discussion. The proposed design consists of a clip with the tube holder inbuilt. The clip will slip onto the infant’s cheek with the tube holder inside the mouth. There are two sockets (holes) through which the tube will travel within the device in order to stabilize the tube in place (see Fig 1):

![Fig1: The drawing sent by the doctor, not drawn by any team member](image)
Although the design is very innovative and gives the team a strong idea of what the doctor wants, there are some flaws with the intricacies of the design. Primarily, the structure is overly thin to be stable once the tube is put in, unless a “squeeze” clip is designed (which will overcomplicate the project). Also, the two distinct holes will make fitting the tube through them more complicated than has to be. The tube may come out of one hole but stay in the other, or one hole may become damaged, compromising the stability of the tube. However, it is important to acknowledge that this initial design is the basis for the team’s design, and that the team will consistently work with the doctor to make sure every need is met.

In order to solve the hole problem, the team decided to construct a uniform hole through the device, allowing nurses to slip the tube through the device without having to aim for the second hole. Also having the tube within the device allows both the tong and inside of the cheek to not contact the tube, decreasing irritation. The device is also very compact and easy to operate (see Fig. 2-3)

![Diagram](image)

Fig 2: An isometric view of the device constructed in SolidWorks: Frontal view (looking into mouth). The hole is where tube will slide through, opening will fit snugly onto the cheek
Fig 3: The view from inside the mouth. Hole is continuous through the device. It is important to note that the diagram is somewhat misleading because it appears like a solid, sharp object. Realistically, the device will be smooth on all the edges and will be plastic (as stated). Also, the exact diameters of the device are still not decided upon, further meeting with the doctor will confirm the exact measurements (thus the official measurements of the device are not included).

3.0 Budget

The total budget available for us is 1000 US Dollars. The following table breaks down the materials and components required for the oral fixation device project.

<table>
<thead>
<tr>
<th>Components</th>
<th>Pricing in USD</th>
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<tr>
<td>Material HDPE (4 Natural Sheets of 0.125&quot;x24&quot;x96&quot;)</td>
<td>$120</td>
</tr>
<tr>
<td>Endotracheal Tube</td>
<td>Free</td>
</tr>
<tr>
<td>Gastric Tube</td>
<td>Free</td>
</tr>
<tr>
<td>Denture Cream</td>
<td>$10</td>
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<tr>
<td>Hydrogel Dressing</td>
<td>$30</td>
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<td>Salivart Oral Moisturizer</td>
<td>$12</td>
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<td>Software Solid Works</td>
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Total: $172
4.0 Conclusion

A senior design project will be created for Dr. Leonard Eisenfeld and the Neonatal Care Unit at the Connecticut Children’s Hospital. The project will be designing and building a fixation device for endotracheal and oral-gastric tubes in the oral cavity for NICU patients. The device will be used to hold tubes in the correct positions within the patients’ mouth as well as preventing patients from removing the vital tubes. Using this device will also allow medical providers to stop using the nasal cavity for gastric tubes, in turn preventing unneeded patient discomfort and potential infections. The fixation device will be made from a medically safe plastic and fixed to the patients’ cheek using pressure and an adherent gel. The clip will be adjustable in order to accommodate both premature and full term NICU patients. Creation of the endotracheal and oral-gastric fixation clip will increase patient comfort, decrease tube movement, and decrease risks of infections.