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Device to Secure Endotracheal Tube in Prone Patient

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Abstract:
The goal of this project is to develop an endotracheal tube securing device. The device proposed would attach to the mouth and hold varying sizes of tubes. While an endotracheal tube is in the airway during surgery, internal forces from the airway and external forces from surgical environment can move the tube in and out or side to side in the mouth. This device would prevent any unexpected movement of this kind and allow for control of movement that is required for adjustment. The device would function adequately even when the patient is in the prone position.

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1.0 Introduction

1.1 Problem Statement

Our project's goal is to develop an easy to use endotracheal tube securing device. The device fixes the tube in place within the mouth. Before surgery, an endotracheal tube can be inserted into the trachea to administer anesthetics or improve airflow to the lungs. During surgery, internal forces from the airway and external forces from the surgical environment can move the tube in and out or side to side in the mouth. This device would prevent any unexpected movement of this kind and allow for control of movement that is required for adjustment. The device must be versatile enough to function even if the patient is on their side or face-down and must function with a variety of tube diameters.

1.2 Background Information

Every year in the United States, over 27 million surgeries are performed on patients in hospitals[1]. Many times, the use of an endotracheal tube is required for these surgeries. An endotracheal tube is a tube inserted down the trachea to keeps the patient's airway open[2]. The tube, made of rubber or plastic, can be either inserted through the nose or through the mouth (Figure 1). When the tube is placed inside the mouth, the patient's chin is lifted to open their airway. A laryngoscope is then used to expose the larynx and vocal cords. The endotracheal tube is passed through the vocal cords and is inserted into the trachea. It is then slipped down to the lungs[3].

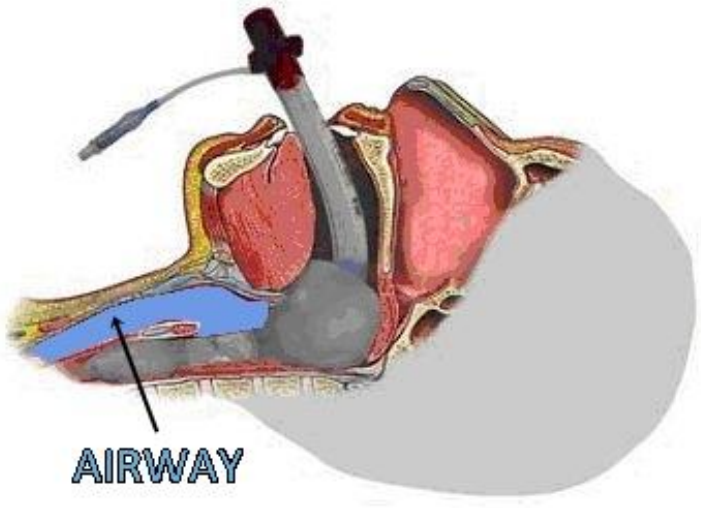

Figure 1: Depiction of the intubation of the endotracheal tube[2]

The tube delivers a steady flow of oxygen to the patient. The tube can also be hooked up to an artificial ventilation machine when the patient is not able to breath steadily on their own or when the tube alone is not capable of delivering a sufficient amount of air to the lungs. However, the patient is not capable of eating, drinking, or speaking when the tube

is inserted down the trachea[2]. The size of the tube depends on the size of the patient. The internal diameter of the tube is generally between 2.00-9.00 millimeters, while the length of the tube can be from 9.0-26.0 centimeters long. This length depends on the age and size of the patient[4].

Not only is it just oxygen that can be passed down the tube, but anesthesia gasses as well. 80% of anesthesia cases today involve endotracheal intubation. This is when the anesthesiologist administers the anesthesia through the endotracheal tube. This leaves patients unconscious and insensitive to pain[2].

Our client wishes to have an endotracheal tube holder small enough to fit inside the mouth while at the same time can hold the endotracheal tube in place when the patient is on his or her side or face down. Currently, the holders for the endotracheal tubes take up too much space on the face and do not adequately hold the tube in place while the patient is lying in positions other than flat on his or her back.

1.3 Motivation

It is essential for the endotracheal tube to stay in place from the entire duration of a surgery. During surgery, patients can be laying on their sides or in the prone position, which is when a patient is laying on their stomach. Currently, tape or a plastic device is used to hold the tube in place. These devices are attached to the endotracheal tube and then wrapped around the face via the cheeks and the back side of the neck. The tape holder does not give sufficient support to the endotracheal tube and movement is possible during surgeries, especially when the patient is in the prone position. With a plastic tube holder, the device takes up a great amount of space on the face and the doctors do not have access to the inside of the mouth or to certain areas on the face like the cheeks and lips. These methods to hold the tube in place generally are sold from $5.00-$25.00. However, these methods are inaccurate because they do not do an ample job of holding the tube in place and occupy too much space on the face. An inexpensive, sturdy, and small device will lead to more efficient surgeries when the surgeons are trying to work exclusively on the face or inside of the mouth, yet when they still need the endotracheal tube to stay firmly in place.

2.0 Design Specifications

The device must be able to perform for the entire length of the surgery and remain in the correct position the whole time. In order to account for the varying endotracheal tube sizes, the device needs to be adjustable to accommodate and accurately hold the different diameters, usually between 2mm-9mm, of endotracheal tubes. The size of this device is very important. This means that the device must fit inside of the mouth and not restrict access to the mouth or face. Chemicals and gasses are usually inserted into the endotracheal tube during surgery for anesthesia, so the tube holder cannot react chemically with these compounds. The operating environment of this device will be

inside of the mouth, so it needs to be able to withstand forces from the jaw and from the weight of the endotracheal tube. Safety is an important characteristic of the device because in will be inside the human mouth. The tube holder needs to be made of a non-toxic and sterile material for safe patient use. The device can not cause asphyxiation or any damage to the airway or the inside of the mouth, and it needs to comply with the FDA regulations. No sharp edges can be openly exposed inside of the mouth and when the device is done being used; it must be made of biocompatible materials.

3.0 Design Alternatives

In order to meet our product design specifications, three design alternatives were created. Each device has a unique way of attaching inside of the mouth as well as securing the endotracheal tube. Two of the designs use the similar attachment idea of a mouth guard, applying pressure around the teeth, while the other utilizes applying pressure against the roof of the mouth. The three designs are described below.

3.1 Spring-Loaded

The first design is a device that fits into the roof of the mouth and stays in place through the outward pressing forces from the device walls against the top row of teeth (Figure 2).

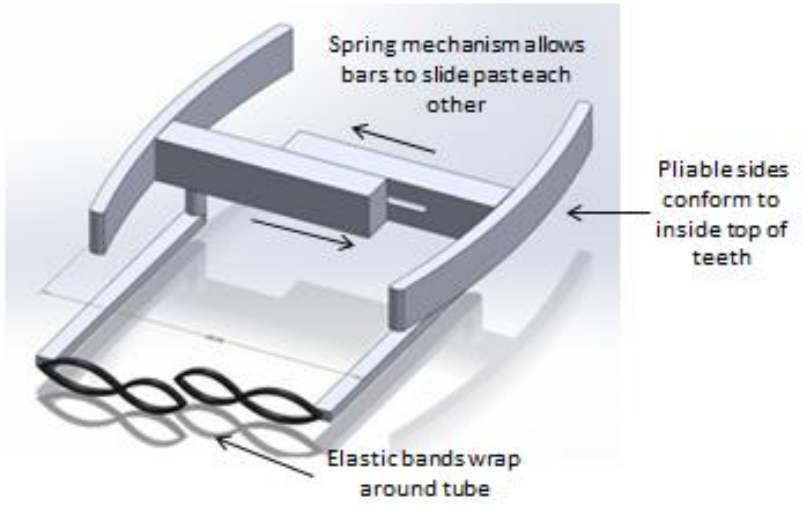

Figure 2: Device fits into the roof of the mouth, applying outward force to keep in place. Elastic bands wrap around endotracheal tube to secure them to the device

This device has a compressible spring mechanism located in the center which allows for expansion and compression of the entire device. The spring mechanism consists of two bars sliding past one another while compressing springs within the opposite bar. This motion allows for the device to compress in order for it to fit into the roof of the mouth

and then expand applying a strong force against the teeth fixing the device inside the mouth (Figure 3). Connected to the center bars are two pegs which allow for easy handling of the device. The pegs then connect to two arms which stretch out passing the front teeth (when the device is inside the mouth). These stick out approximately a few millimeters from the front teeth and connect to two elastic bands in the shapes of figure eights. These bands secure the endotracheal tube to the device by wrapping each around the tube and then allowing the expansion of the device to pull on the bands and tighten around the tube. Since these bands are so flexible, they should be able to attach to a variety of tube sizes.

This device is reusable and autoclaved between each use. Attached to the sides of the device are disposable padded covers that are replaced after each use. These add more comfort to the patient, add friction between the teeth and the device to prevent slipping, and prevent the device from directly coming in contact with the patient. The sides of the device are made from a strong but pliable material that allows them to conform to the sides of the teeth. The center bars and the arms which reach out are made from a strong metal such as stainless steel in order for the device to withstand strong forces and last repeated use. The elastic bands which attach the tube to the device will be made from a material similar to a rubber band but much stronger. This device comes in two different sizes, an adult's size as well as a child's size. The device should be able to fit a wide variety of patients and many different mouth widths.

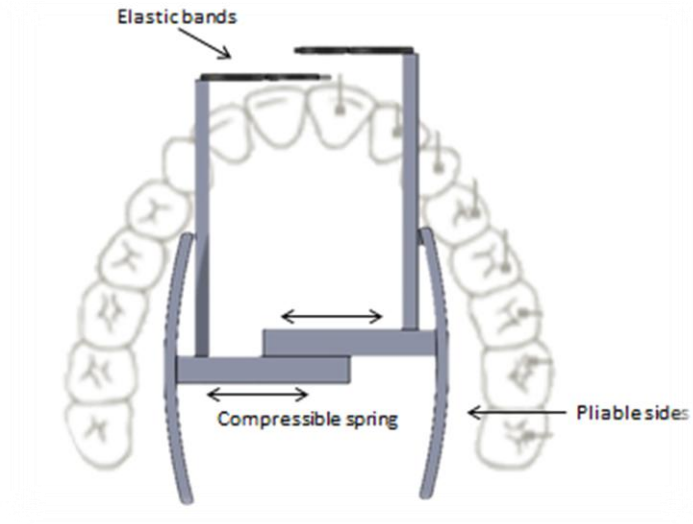

Figure 3: Device secured within the roof of the mouth, applying an outward force against the top of the teeth.

3.2 Fitted Mouthpiece

The second design takes a slightly different approach than the first design option. This design would still use the teeth as a point of attachment for the device; however, the device would be kept in place by force on the outside of the teeth, as well as force on the

inside (Figure 4). These forces would come from small pegs on the inside of the mouthpiece, which would provide points of pressure. These pegs would be placed all around both sides of the mouthpiece rim. The mouthpiece would be made out of a slightly pliable rubber to allow for a bit of elasticity when actually being used in the mouth. However, because there is such a variance in mouth sizes, there would most likely be a need for multiple different sizes of the mouthpiece.

A simple mechanism would be used to hold the tube in place on the mouthpiece. Small metal brackets would be used to hold a U-piece in place on the front of the mouthpiece. This U-piece would be made out of a similar material as the mouthpiece, but it would need to be a bit more flexible. The endotracheal tube would be held in place by looping the U-piece under it and pulling the ends of the U-piece until the tube stays snugly in place. In order for this mechanism to work, both rubbers being used would have to be able to produce enough friction to hold the tube in this position. The entire device would most likely be used multiple times, so it would need to be cleaned and sterilized between uses.

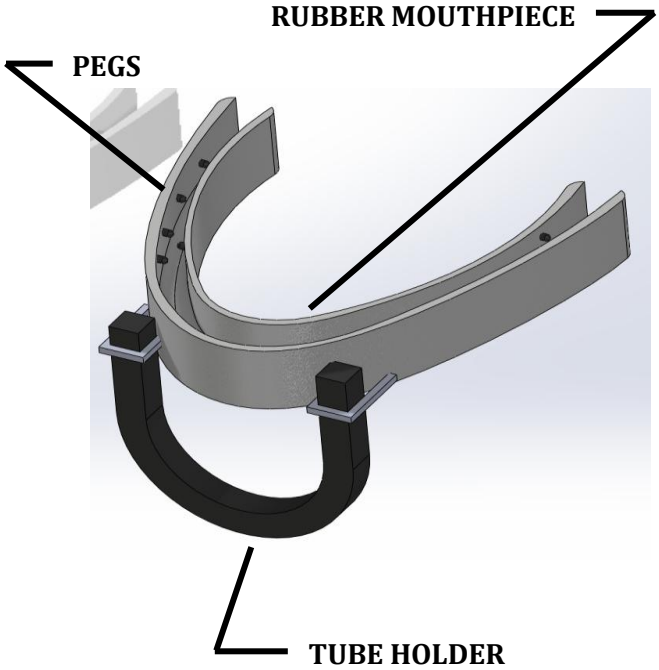

Figure 4: Solidworks model of the fitted mouthpiece design depicting the pressure points in the mouthpiece and "U-shape" tube holder.

3.3 Moldable Mouthguard

The final design alternative would use two distinct parts. The first piece of the design would consist of a "boil-and-bite" mouthguard. These mouthguards are commonly available in sporting goods stores and provide the user with a personalized fit. The mouthguard's material, usually ethylene-vinyl acetate (EVA)[5], is heated in boiling water and then formed around the teeth to create a secure hold. The mouthguard is allowed to

cool and it retains the shape of the patient's mouth[6]. The front of the mouthguard would then be attached to the second part of the design, the tube clamp (Figure 5). This piece would be a small disk with a spring mechanism that applies a force to the tube, keeping it in place. The disk would snap in place into the bottom of the mouthguard, interfacing with the attachment mechanism normally used for the mouthguard strap. The clamp's mechanism would have a spring constant such that it could accommodate the required variety of tube diameters (2 – 9mm), while still applying a satisfactory stabilizing force.

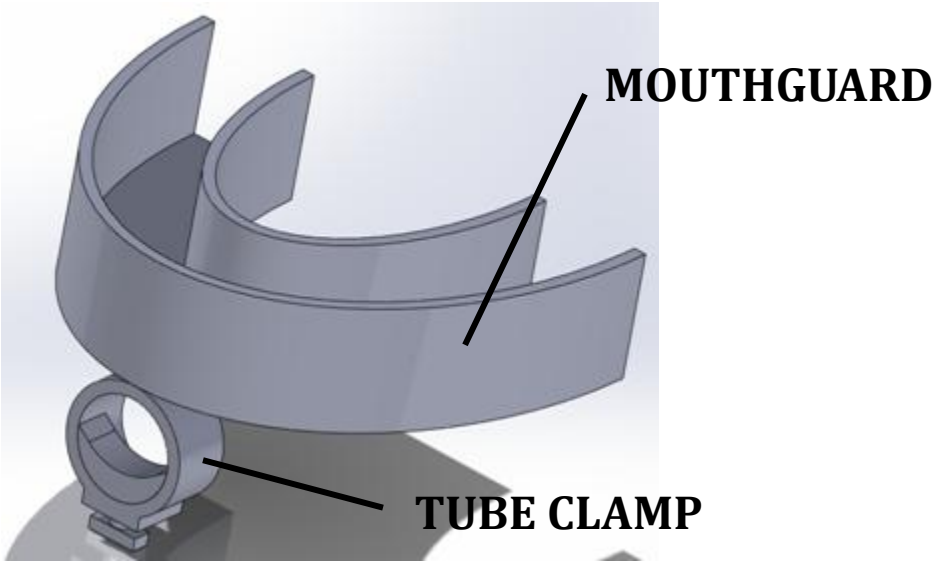

Figure 5: Moldable mouthguard design alternative, showing an idealized attachment of the mouthguard to the clamping mechanism

4.0 Design Matrix

In order to choose a final design, a design matrix was created (Table 1). The following categories were chosen for the design matrix (in order from most important to least important): Effectiveness, Feasibility, Safety, Ease of Use, Cost, Patient Comfort, and Maintenance. Effectiveness was determined to be the most important part of the design. The effectiveness was defined as the ability of the design to securely hold onto varying diameters of tube, as well as stay attached to the mouth for extended amounts of time. The fitted mouthpiece design received the highest point value in this category because the pressure points in the mouthpiece provided the most stabilizing force, while the "U-shaped" tube attachment piece held the tube adequately. The moldable mouthguard design also scored high because the spring-loaded tube attachment mechanism was considered the most robust solution for holding the endotracheal tubes.

Feasibility and Safety were the next two most important categories. Our client would like the device to be feasible to create so that it can be eventually produced in a larger quantity. The moldable mouthguard design had the best feasibility rating because it would made from parts that are either bought or simply machined from raw materials. The other two designs scored lower because the pressure points in the fitted mouthpiece and the spring-loaded mouth

attachment mechanism would be difficult to create. Safety was also a priority to our client. The designs must ensure patient safety regardless of body orientation, surgery duration, and unforeseen external pressures or forces. Since the spring-loaded design would contain a strong force generating mechanism as well as rigid or sharp pieces, it scored low in this category. The moldable mouthguard design scored the highest. The mouthguard portion would be safer for the patient than the other two attachment devices because it would be made of softer, more pliable material. Similarly to the category of safety, patient comfort was important to our design. The moldable mouthguard was the best for this design consideration because it would be the most personalized design. The mouthguard piece would be made of comfortable material that would not exert any excessively unnatural pressures on the mouth.

Ease of use, cost and maintenance of the device were the next most important categories. The device should be simple enough to use such that a person with little training on the device would be able to use it. Fitted mouthpiece design got a relatively high score compared to the spring-loaded device because it only requires the user to place the device over the teeth and wrap the "U-shape" attachment around the tube. The spring-loaded design would require manipulation of the elastic bands around the tube and may be difficult to place in the mouth. The moldable mouthguard would be more difficult to use because it requires an additional procedure prior to the surgery to boil and mold the mouthguard. Cost is another important consideration for this project. Each device scored similarly because the parts and materials needed would be similar for each design. The moldable mouthguard scored slightly higher because the majority of the cost would be the purchasing of the boil-and-bite mouthguard. Next, the device will be used in a hospital setting so it must be easy to clean and sterilize. Since the moldable mouthguard piece would be disposed of after use, and the tube clamp easily sterilized, the moldable mouthguard design scored the highest. The fitted mouthpiece and spring-loaded designs would be reused completely and therefore would need more difficult methods of sterilization.

Design Aspects	Spring-Loaded	Fitted Mouthpiece	Moldable Mouthguard
Effectiveness (25)	15	22	18
Feasibility (20)	12	14	18
Safety (20)	12	18	19
Ease of Use (15)	10	13	11
Cost (10)	7	7	8
Patient Comfort (5)	2	4	5
Maintenance (5)	4	2	4
Total (100)	**62**	**80**	**83**

Figure 5: Design matrix for the different designs to secure the endotracheal tube.

5.0 Final Design

The design that was chosen to pursue was the moldable mouthguard design. This design scored the highest in the design matrix with a total score of 83 out of 100 (Table 1). This was because of the design's effectiveness and feasibility, high level of safety, and relative low cost compared to the other design alternatives. The spring-loaded design was dismissed from final design

consideration, as it received a low score of 62. This was mainly because of a low feasibility and safety rating. The fitted mouthpiece design was also dismissed, after receiving a slightly lower score of 80. The major factor in this decision was the design's low feasibility score.

The design team concluded that the moldable mouthguard design was indeed the best alternative of the three. The cost is under budget, it is predicted to be highly effective, it is feasible to create, and the design is expected to maintain an acceptable level of safety and ease of use.

6.0 Future Work

Before any effort will be committed to fabrication of the final design, there is some research that needs to be done. In order to make a device that fits the widest range of potential patients, average mouth sizes in the population must be examined. It is also important to find information regarding the materials that may be used; any materials being utilized in the final product must be safe for use in a surgical environment. There are also some decisions that need to be made regarding the connection of the tube holder to the mouthguard.

Once this work has been done, materials will be ordered and fabrication will begin. It is important that tests be done on the fabricated device to see its effectiveness in holding the tube in place as well as the length of time that the device functions. Using the information gained from this testing, adjustments will be made to the prototype, and modifications will be made to the fabrication process as well. These steps of testing and adjusting will be repeated until the best possible final design is made. This design will then be delivered to the client, Dr. Scott Springman.

7.0 References

[1] American Hospital Association. 2012. *Research and Trends*. Accessed at http://www.aha.org/research/index.shtml

[2] Suro International. 2012. *Endotracheal Tube*. Accessed at http://www.suru.com/endo1.htm

[3] Patent Storm. 2000. *Laryngoscope*. Accessed at http://www.patentstorm.us/patents/6095972/description.html

[4] Smith Medical. 2009. *Tracheal Tubes-A guide to size and length.* Accessed at http://www.smiths-medical.com/userfiles/trachealtubechart.pdf

[5] Kittelsen, J.D. and Belvedere, P.C. (1993). "Thermoplastic mouthguard with integral shock absorbing framework" U.S. Patent No. 5339832. Fridley, MN: US.

[6] Jacobs, A.G. (1977). "Athletic mouthguard" U.S. Patent No. 4044762. Madison, WI: US.

8.0 Appendix

8.1 Product Design Specifications (PDS)

Problem Statement:
Our project's goal is to develop an easy to use endotracheal tube securing device. The device fixes the tube in place in the mouth. Before surgery, an endotracheal tube can be inserted into the trachea to administer anesthetics or improve airflow to the lungs. During surgery, internal forces from the airway and external forces from surgical environment can move the tube in and out or side to side in the mouth. This device would prevent any unexpected movement of this kind and allow for control of movement that is required for adjustment. The device must be versatile enough to function even if the patient is on their side or face-down.

Client requirements:

- Must be compatible with all current types of endotracheal tubes of varying diameters.
- Must not restrict accessibility to the mouth or face.
- Must be sterile.
- Must apply adequate force to maintain position of endotracheal tube.
- Must be made of biocompatible materials.
- Must be easily manufactured in large quantities.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: This device will have to be able to perform throughout the full length of a surgery and remain in the correct position the entire time. The device must apply adequate force towards the trachea and a stabilizing force to keep the tube in the sagittal plane. The device will also be able to hold all endotracheal tubes of 2mm-9mm inner diameters.

b. *Safety*: The device must be made of biocompatible, non-toxic materials. It is also important to make sure that the device will not cause asphyxiation or any damage to the airway. The device must comply with current FDA standards for Class 1 medical devices. It must also be able to resist chemical and physical degradation.

c. *Accuracy and Reliability*: Once in place, the device must not move more than 5 mm in or out of the airway and not more than 1.5 cm from side to side. The device will consistently hold the endotracheal tube in place for the duration of the surgery.

d. *Life in Service*: The device will be single-use and disposed of afterwards. It will function for a maximum of ten hours.

e. *Shelf Life*: Sterile packaging will be used for storage of this device. It will be stored in a hospital environment at room temperature (21˚C), normal atmospheric pressure (1 atm), and normal humidity (30-50%). The device should be able to maintain its sterility and stability in storage for five years.

f. *Operating Environment*: The device must be able to function at 37˚C and at 90% humidity in the mouth of the patient. It must be able to withstand the force applied to keep the endotracheal tube in place and must also be adjustable to be moved slightly by the surgeon for proper access to the mouth. In the case of possible jaw movement, the device must withstand 700 N of bite force. It must be compatible with water and sterilizing liquids, such as ethyl alcohol and chlorhexidine.

g. *Ergonomics*: The device must not interfere with surgery and must be easily adjustable. The set-up of the device with the endotracheal tube must be user-friendly and not require longer than five minutes.

h. *Size*: The device must be large enough to hold endotracheal tubes with inner diameters of 2mm-9mm, yet small enough to fit easily within a mouth.

i. *Weight*: The device should not weigh more than 2 ounces.

j. *Materials*: Materials used must be hypoallergenic and non-toxic.

k. *Aesthetics, Appearance, and Finish*: The shape must be cohesive with the shape of the mouth. The material should be smooth to ensure comfort for the patient and easy maneuverability.

2. Production Characteristics

a. *Quantity*: One prototype delivered, with the possibility of mass manufacturing.

b. *Target Product Cost*: The budget for this project is $100, but the target cost for the individual product is under $20.

3. Miscellaneous

a. *Standards and Specifications*: FDA Class 1 approval is required. The materials used must comply with the international ASTM plastic standards for the environment(s) described above.

b. *Customer*: The client would like the device to take up as little space as possible and fit in the mouth, allowing the face to be completely accessible.

c. *Patient-related concerns*: The device must be completely sterile upon introduction to the patient's mouth, but may be disposed of after use. Ideally, the device will cause the patient no physical discomfort and will keep the endotracheal tube in a safe position.

d. *Competition*: There are several devices currently on the market that perform a similar function. However, the facial attachment methods currently used are not ideal for our client's needs. These devices restrict access to the face and/or mouth during surgery and may not properly hold the endotracheal tube in place in the range of positions specified by our client.