

Device to Secure Endotracheal Tube in Prone Patient

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1.0 Abstract

The goal of this project was to develop an endotracheal tube securing device. The device proposed attached to the mouth and held 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 prevented any unexpected or undesired movement of this kind and allowed for control of movement that was required for adjustment. The device was expected to function adequately even when the patient was in the prone position. The final design incorporated a ‘boil and bite’ mouth guard in order to secure the device to the upper teeth. Tests were performed to analyze the length of time the device stayed securely inside the mouth, as well as the amount of weight required to pull the device or tube from the mouth. The tests revealed that the design was capable of withstanding the forces applied from a standard breathing circuit.

2.0 Introduction

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 keep the patient's airway open^[2]. Although these tubes may seem quite trivial in comparison to the rest of the surgery, many surgeries would not be accomplished without using them. The tube needs to be held in place during the surgery to prevent complications or harm to the patient. The methods currently used to keep the tube in place are straps made from various materials (Figure 1). These straps function



Figure 1: Various straps for holding tube in place: tape, cloth, & plastic.

properly in many surgical procedures, but there are times when their use can cause complications. For example, when patients are lying face-down in the prone position during surgery, some of the current methods do not provide quite enough stability to keep the tube properly in place. The bulky straps can also cause difficulties when a surgeon needs access to the face or mouth. Therefore, there is a need for a device that can hold the endotracheal tube in place, has a smaller mouth, and fits in the mouth.

2.1 Background Information

The endotracheal tube, made of rubber or plastic, can be either inserted through the nose or through the mouth (Figure 2). When the tube is placed inside the mouth, the patient's

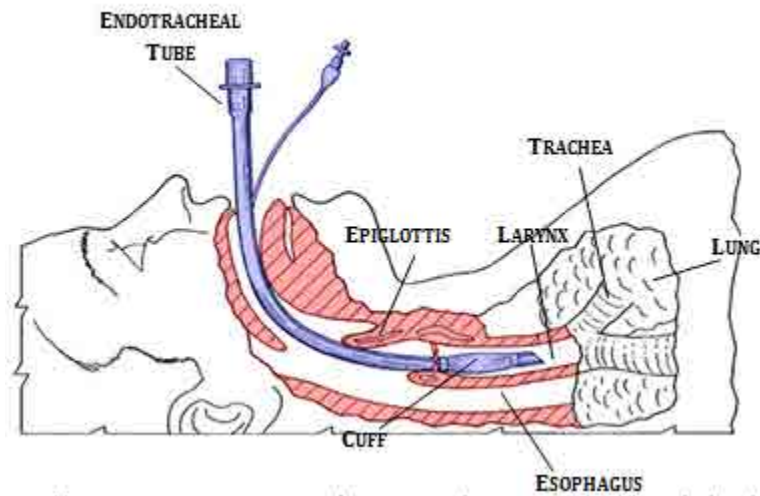


Figure 2: Depiction of the intubation of the endotracheal tube.

chin is lifted to open their airway. Then, a device known as a laryngoscope is inserted into the mouth and down the throat. A laryngoscope consists of a handle and a blade with a light source. This opens up the throat and lets the anesthesiologist see clearly down the trachea. After the insertion of the laryngoscope, the endotracheal tube is passed through the vocal cords and is inserted into the trachea, where it is then slipped down to the lungs^[3].

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 breathe 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 in 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].

Oxygen is not the only gas that can be passed down the tube; in surgeries, anesthetic is commonly administered through the endotracheal tube. Eighty percent of anesthesia cases today involve endotracheal intubation, which is the process of administering the anesthetic through the endotracheal tube. This leaves patients unconscious and insensitive to pain^[2].

During surgery it's important to keep the endotracheal tube in place within the patient. It's common for the tube to make slight movements out of the mouth and trachea after intubation. This can lead to accidental extubation where the endotracheal tube is unpredictably removed from the trachea through factors such as movement of the body,

tube size or type, and fixation method. Outside forces from the breathing circuit to which the endotracheal tube is attached can pull the tube out of the mouth or remove it from its correct position in the trachea. Accidental extubation can lead to serious consequences such as morbidity and mortality which is why tube fixation is vital to a patient during surgery^[5].

On average, a general surgeon spends 270 minutes per operation while a neurosurgeon spends the most time in surgery with an average of 332 minutes^[6]. With this information in mind, it's important for the endotracheal tube to stay in place for that allotted amount of time.

2.2 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 harness 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 still 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 cost \$5.00-\$25.00. However, these methods are inadequate 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, reliable 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.

2.3 Problem Statement

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, do not adequately hold the tube in place while the patient is lying in positions other than flat on his or her back., and require several support mechanisms to ensure stability.

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 or undesired 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.

3.0 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 sizes of endotracheal tubes, usually between 2mm-9mm diameter. 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 it will be inside the human mouth. The tube holder needs to be made of a non-toxic and sterile material for safe patient use as well as comply with the FDA regulations. For safety reasons, sharp edges cannot be exposed, the device must not cause asphyxiation, and should not cause damage to the inside of the mouth.

4.0 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.

4.1 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). 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 may be autoclaved. Attached to the sides of the device are disposable padded covers that are replaced after each use. These provide more

comfort to the patient, add friction between the teeth and the device to prevent slipping, and prevent the metal frame of 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 through repeated use. The elastic bands that 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.

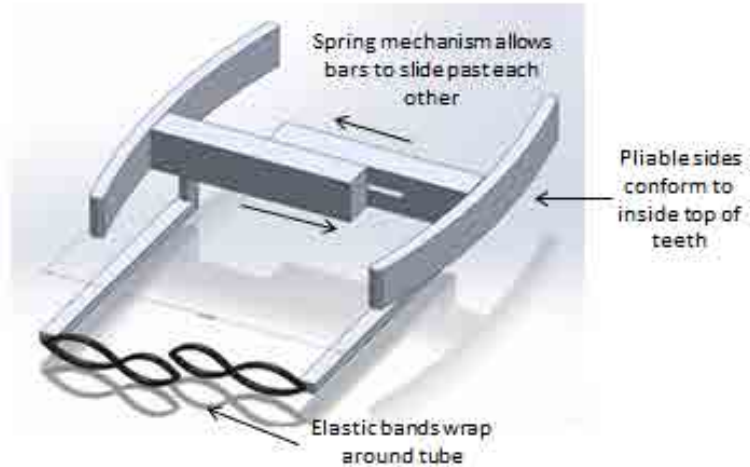


Figure 3: Device fits into the roof of the mouth, applying outward force to keep in place. Elastic bands wrap around endotracheal tube to secure them to the device.

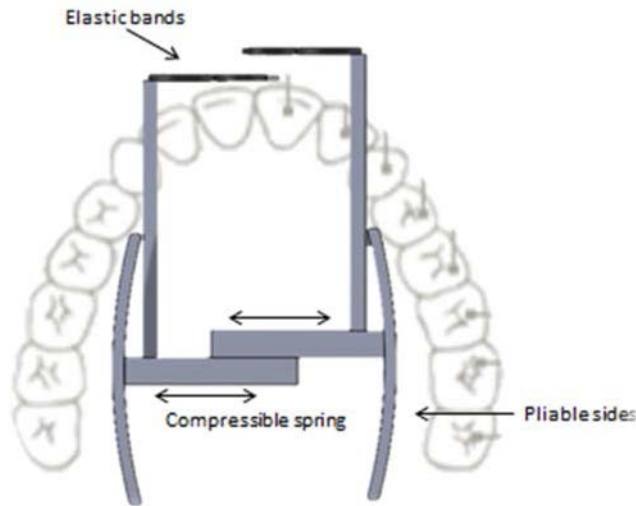


Figure 4: Device secured within the roof of the mouth, applying an outward force against the top of the teeth.

4.2 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



Figure 5: SolidWorks model of the fitted mouthpiece design depicting the pressure points in the mouthpiece and "U-shape" tube holder.

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 passing through the U-piece, then pressing on 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 be used multiple times, so it would need to be cleaned and sterilized between uses.

4.3 Moldable Mouthguard

The final design alternative would have two distinct parts. The first piece of the design would consist of a "boil-and-bite" mouthguard. These mouthguards are commonly used in contact sports and provide the user with a personalized fit. The mouthguard's material, usually ethylene-vinyl acetate (EVA)^[7], 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^[8]. The front of the mouthguard would

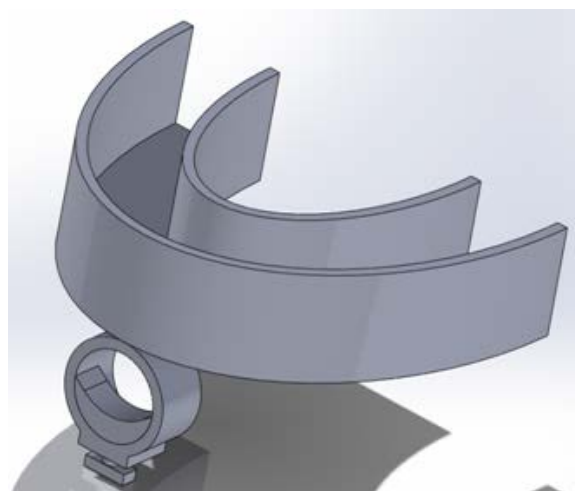


Figure 6: Moldable mouthguard design alternative, showing an idealized attachment of the mouthguard to the clamping mechanism.

then be attached to the second part of the design, the tube clamp (Figure 5). This piece would be a small ring, just big enough to fit the variety of endotracheal tube diameters, with a spring-loaded clamping mechanism that applies a force to the tube, keeping it in place. The ring 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.

5.0 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 because the specifications require the device to be effective enough to replace the inexpensive but usually ineffective tape securing method during surgery. 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. Safety was highly rated because avoiding harm and complications are the main goals of this project. The reasoning behind rating feasibility so high was due to the fact that we have only a short period of time to construct a prototype. 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 be made from parts that can be purchased 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 unnatural forces, unlike the spring-loaded design, 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. It scored lower in importance than other categories because as long as cost was not overwhelmingly high, effectiveness and safety was a much higher concern. 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. Maintenance was rated lowest because according to our client, factors such as sterilization were easy to work around. 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 7: Design matrix for the different designs to secure the endotracheal tube.

6.0 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.

It was concluded that the moldable mouthguard design was indeed the best alternative of the three. The mouthguard found to work best for the design was the Shock Doctor Gel Max Strapped Mouthguard (see Figure 8). It created the best fit to the teeth when compared to the Nike Intake Convertible Mouthguard. Its material is ethylene-vinyl acetate which allows for the conforming fit around the top teeth and should fit the majority of adult mouth sizes (also available in a youth size). The mouthguard came with a removable strap that connects to the

mouthguard by protruding arms from the front. These arms were easily altered to attach the tube clamping device.

The final tube attachment was constructed from D-Wings™ made by UTWire®. These are simple cord organizers designed for home and office use but adjusted perfectly to fit the 7.5mm diameter tubes and larger. Their flexible foam material fit allows for the endotracheal tube to easily pass through. One was super-glued to the protruding arms of the mouthguard therefore an endotracheal tube is able to pass out of the mouth and slide snugly through the D-Wing®, keeping the tube in place.

The product designed will need to be fit before surgery ideally during a pre-surgical consultation. This is where the boil and biting of the mouthguard will take place. During surgery, the endotracheal tube will first be inserted into the trachea of the patient and then the mouthguard will be pressed into the top of the mouth. The tube attachment will form around the tube and the device should keep the endotracheal tube in place within the mouth.

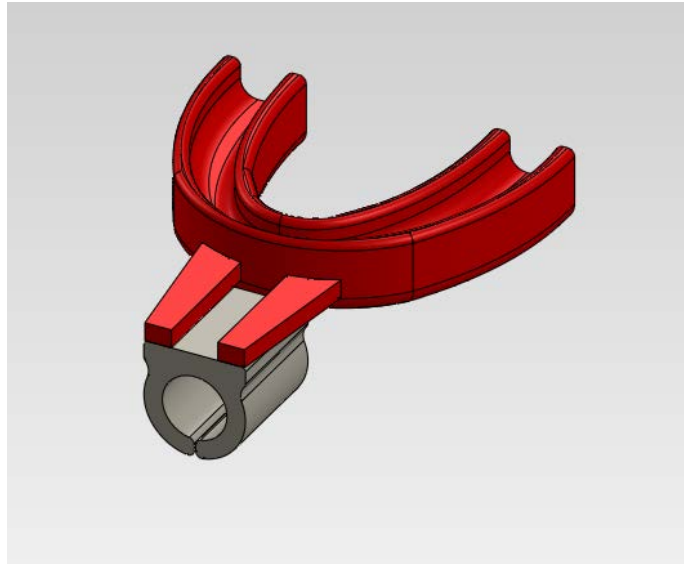


Figure 8: SolidWorks model of the final design, including the Shock Doctor mouth guard and the foam D-Wing.

7.0 Testing

Two different methods were set up in order to test our device: one that tests if the device can perform for up to ten hours and another that evaluates the amount of weight that causes the mouth guard design to fail. In order to conduct these tests, conditions similar to the human mouth were created. Two mouth models (see Figure 9), obtained from a dentist's office, were used as the teeth for our testing procedure. One of the mouth models had a full set of teeth while the other was missing a few, which allowed us to observe whether our device would work on a range of teeth conditions. A mouth guard was then boiled and formed to fit each set of teeth, and the tube holder was added on to the mouth guard.



Figure 9: Two human mouth models borrowed from a dentist's office for use in testing.

The conditions of the mouth such as humidity and temperature were also necessary to have more accurate testing results. A partially enclosed box made from plastic window seals and a metal frame was created to keep a humid and moist environment (see Figure 9). Moisture was simulated using a water boiler that would add just enough steam to keep the inside of our box at around 39 degrees Celsius (two degrees off from our actual mouth temperature of 37 degrees Celsius.) From the wire frame, the mouth model (with our device attached) was hung in a position that mimics where the mouth would be while a patient is in the prone position.

Using this simulated mouth environment, an endotracheal tube was inserted through our device and out the back of the “mouth”. This tube was connected to another plastic tube that was used to simulate the breathing circuit. At this connection point, the plastic tube fit into the end of the endotracheal tube quite snugly, but it was not completely stable. The plastic tube that we used was about 274 centimeters long and weighed about 118 grams. This tube was then connected to a metal stand at the same height as the mouth model. This was to simulate the connection of the breathing circuit to the ventilator that would be used in the surgery. This setup of the mouth environment and tubing was used for both testing methods.

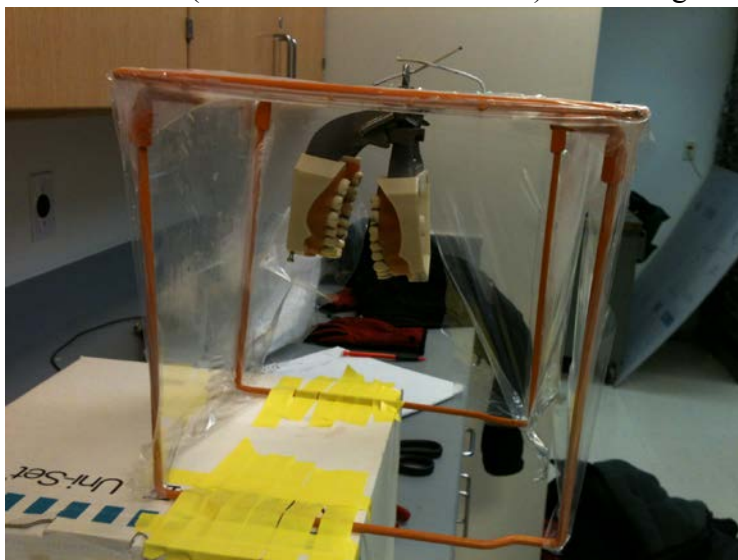


Figure 10: The set-up of the mouth model within the enclosed box. (Water boiler not shown.)



Figure 11: Overnight set-up of the mouth environment being filmed by a webcam.

The first type of testing, the long-term loading testing, was conducted overnight three times. The testing environment was set up as usual, with 300 grams of weight added on to the tube to reproduce the weight of an actual breathing circuit. The tubing reached to the metal stand at a distance of 2.4 meters away from the mouth model. After the device was situated in the mouth environment with the endotracheal tube and its attachments in place, a camera was used to record the device for the duration of the testing (see

Figure 10). Overnight the camera recorded our enclosure to see if the device could withstand long surgical procedures, and if it didn't last a full ten hours, to see at what time the device failed. The same was repeated for two trials using the model of healthy teeth.

Using the same enclosure, mouth guard prototypes and both mouth models, the device's maximum allowable loading was measured (see Figures 11 & 12). Once again, we attached the simulated breathing circuit to the endotracheal tube, but this time, we varied the extra weight that we added. Our independent variables included whether the environment was moist or dry, the distance that the ventilator was from the "patient," the set of teeth used, and whether or not the plastic tubing was taped into place in the endotracheal tube for stability. We decided to test the difference between a moist and dry environment because there are some drugs used in surgery that cause dry mouth^[9]. The distance between the ventilator and the mouth model are important and

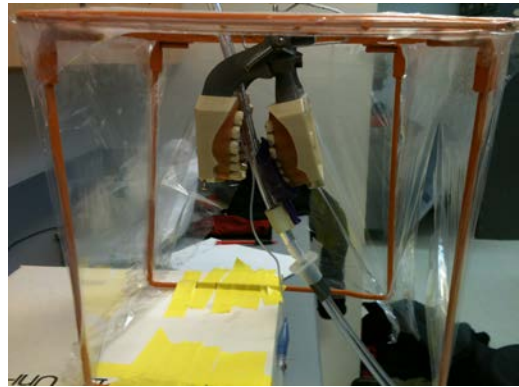


Figure 12: The mouth environment with endotracheal tube inserted.



Figure 13: The set-up of the "breathing circuit" with the mouth environment to the far right.

were varied because the angle of the force acting on our device depends on this distance; we tested at distances of 2.4 meters, 2.0 meters, and 1.6 meters. We examined the effects of using different sets of teeth to see if our device would function with lower quality teeth. The variance of having the tube taped into place within the endotracheal tube was added when we saw that testing could be affected by these tubes slipping away from each other, resulting in failure that was not related to our device.

The testing began 218 grams of weight, which consisted of the tube's 118 grams and an additional 100 gram weight. Each increment was tested for thirty seconds, and if failure had not occurred, an additional 100 grams was added. Failure constituted either the tube falling from our device or the entire device falling from the mouth model.

8.0 Results & Discussion

See Appendix 11.3 for the data collected during testing. The derived formula for force applied on the device as a function of angle and weight of the tubing was used to calculate the allowable force before failure (see Appendix 11.2). The formula was determined from the geometric conditions in Figure 13.

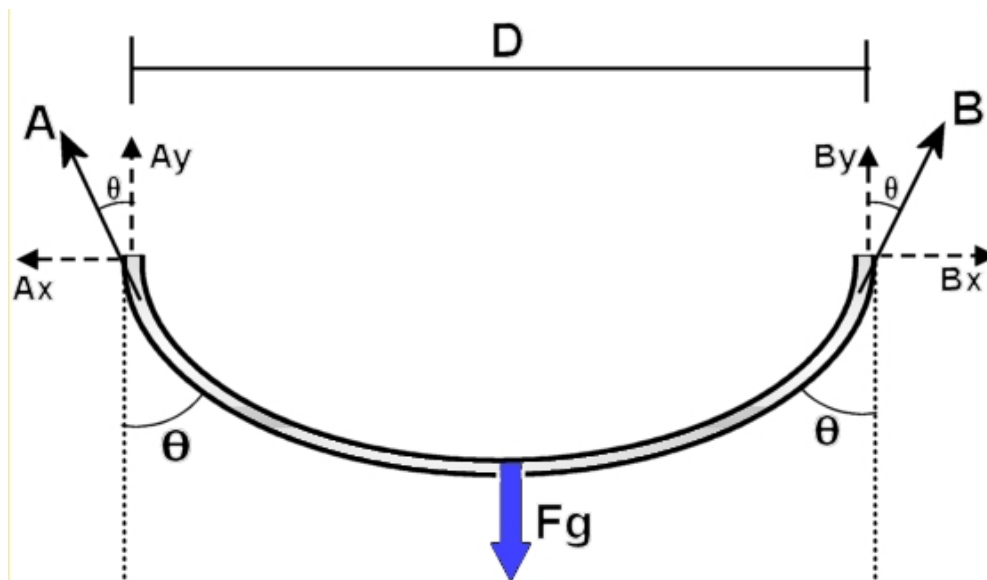


Figure 14: Free body diagram of breathing circuit tubing. The tubing is approximated as pinned at A (the patient's mouth) and B (the anesthesia ventilator). The weight of the breathing circuit is F_g and the angle of insertion is θ .

Failure consisted of either the mouth guard falling out of the mouth or the tube falling from the tube holder. For the long-term loading testing, the device withstood the average force of the breathing circuit weight for 10 hours. This trial was repeated twice, and it could be concluded that a standard breathing circuit would not remove the device from the mouth or dislodge the endotracheal tube during the duration of a surgery. The average surgery duration was shorter than the 10 hours in which the endotracheal tube holder stayed securely in the mouth.

The second test was conducted as described earlier and the resulting data is shown in Appendix 11.3. Using the formula described in Appendix 11.2, the maximum force allowed was calculated. Below is a visualization of the maximum allowable force versus angle under the variety of conditions previously mentioned.

Regardless of conditions, the device had a higher maximum allowable loading force than would be applied by widely-used breathing circuits.^[1] We calculated that force to be 1.61 N based on our free body diagram calculations (Figure 13 and Appendix 11.2). Other trends were observed in the data. Generally, allowable force increased as angle decreased. This suggested that the device functioned better when the distance between the patient and the ventilation machine was decreased. Humidity decreased the maximum allowable loading compared to the dry condition. This verified the prediction that the higher temperature and humidity of the mouth would cause the device to fail at lower applied forces. No difference could be observed, based upon the data collected, in the performance of the device for the two sets of prosthetic teeth. However, it was observed qualitatively that the model missing teeth actually better withstood unaccounted forces such as swaying in the tube or removal/insertion of the tube. Other stress testing in different orientations and locations could be performed in order to determine quantitatively whether this assertion was accurate. Finally, in the taped condition, the device withstood more force. This led to the conclusion that the mouth guard portion of the design was successful in withstanding any normal gravitational forces from the surrounding equipment. Many failures in all of the non-taped (normal) conditions were tube holder malfunctions, also suggesting that the mouth guard portion of the design was successful, while the tube holder portion needed improvement.

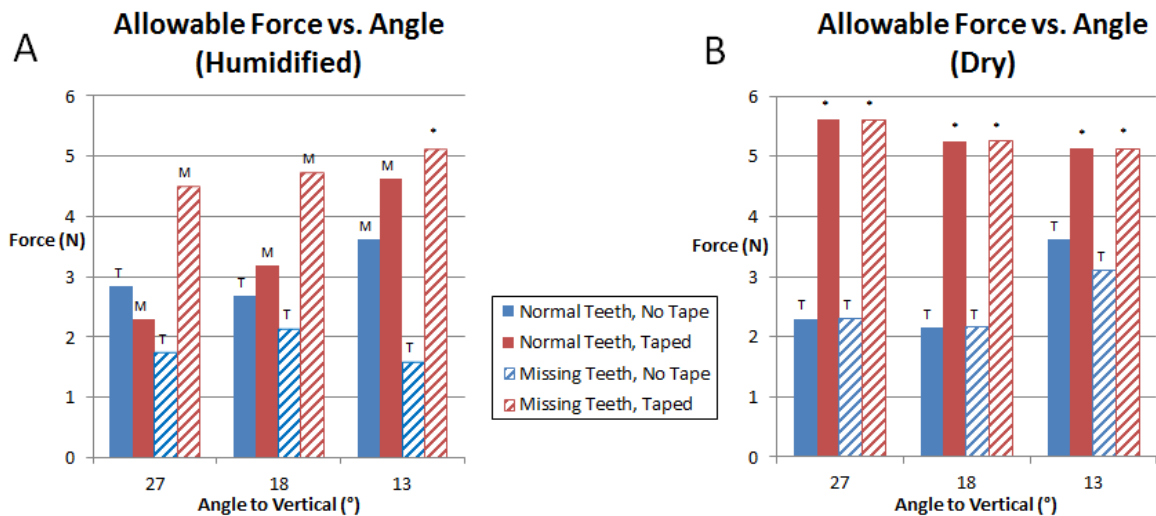


Figure 15: Maximum force allowed before failure. (A) In a humidified chamber, maximum force allowed versus angle between endotracheal tube trajectory and the vertical (see Figure 8) is shown. Force was applied as added weight to center of the simulated breathing circuit. One standard prosthetic mouth model (solid bars) and one model with missing teeth (striped bars) were tested. To determine the force required to cause the mouth guard to dislodge, separately from the force required to displace the tube from the tube holder, the tube was secured to the holder with tape in one condition (red). It remained unsecured in the other condition (blue). M denotes a failure in which the mouth guard was dislodged. T denotes a failure in which the tube was dislodged from the tube holder. * denotes a trial in which the device withstood an excessively high force and did not fail. (B) In a dry chamber, the same experimental conditions as (A) were applied.

9.0 Future Work

After the production and testing of multiple prototypes, it was discovered that certain design aspects could be improved with further undertakings of this project. One problem encountered during the testing process was the material used for the tube clamp. Too much liquid coming in contact with the clamp caused a slicker surface and made it difficult for the tube to stay in place. Looking into better materials as well as a tighter fit for the clamp is necessary for the future. The clamping device could be made from a similar if not identical material to the mouthguard to allow for easy boiling and water-resistance. The clamp and mouthguard should be connected as one product. The tube clamp used for the prototypes came in one size which fit the 7mm inner diameter and larger tubes very well. Adjustments to the size of the clamp to fit smaller tubes will be an important factor with moving forward as well.

Since the product created is personalized to each patient, mass production would be necessary to successfully use the device on many patients during surgery. Formulating a mass production plan would be critical to the usage of multiple devices and is something that can be looked at in the future.

In order to deem the device safe for patient use during surgery, testing protocols should be extended to human use. Testing the device's effectiveness on an actual patient was not possible with the restraints of a semester but is important when thinking about moving forward with the use of the device in a hospital setting.

Although the final design did prove to work on patients missing a few teeth, the design has the inability to properly fit patients with minimal teeth or no teeth at all. Adjusting the materials used in the boil and bite mouthguard is a possible solution to this dilemma. Having materials that

better conform to the upper gums of the mouth would allow the device to work on a wider variety of patients ranging from infants to the elderly.

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11.0 Appendix

11.1 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.

11.2 FBD Calculations

Sum of forces in the x direction:

$$\begin{aligned}\sum F_x = 0 &= -A_x + B_x \\ \Rightarrow A_x &= B_x\end{aligned}$$

Sum of forces in the y direction:

$$\begin{aligned}\sum F_y = 0 &= A_y + B_y - Fg \\ \Rightarrow Fg &= A_y + B_y\end{aligned}$$

Sum of moment forces:

$$\begin{aligned}\sum M_A = 0 &= -Fg\left(\frac{D}{2}\right) + B_y(D) \\ \Rightarrow B_y &= \frac{Fg}{2} \\ \Rightarrow A_y &= \frac{Fg}{2}\end{aligned}$$

Angle method:

$$\begin{aligned}A_y &= A\cos\theta \\ \Rightarrow A &= \frac{A_y}{\cos\theta} = \frac{Fg}{2\cos\theta}\end{aligned}$$

11.3 Testing Results

Time Applied (s)	Tape (Y/N)	Humidity	Distance (m)	Length (m)	Angle from Vertical (°)	Angle from Vertical (rad)	Max Weight Withstood (kg)	Max Total Weight (kg)	Max Force (N)	Failure Description
Good Teeth										
30	N	Moist	2.4	2.74	27	0.4712388	0.4	0.518	2.8516	Tube holder failure
30	N	Moist	2	2.74	18	0.3141592	0.4	0.518	2.6715	Tube holder failure
30	N	Moist	1.6	2.74	13	0.2268928	0.6	0.718	3.6144	Mouthguard failure
30	Y	Moist	2.4	2.74	27	0.4712388	0.3	0.418	2.3011	Mouthguard failure
30	Y	Moist	2	2.74	18	0.3141592	0.5	0.618	3.1873	Mouthguard failure
30	Y	Moist	1.6	2.74	13	0.2268928	0.8	0.918	4.6212	Mouthguard failure
30	N	Dry	2.4	2.74	27	0.4712388	0.3	0.418	2.3011	Tube holder failure
30	N	Dry	2	2.74	18	0.3141592	0.3	0.418	2.1558	Tube holder failure
30	N	Dry	1.6	2.74	13	0.2268928	0.6	0.718	3.6144	Tube holder failure
30	Y	Dry	2.4	2.74	27	0.4712388	0.9	1.018	5.6041	*No failure
30	Y	Dry	2	2.74	18	0.3141592	0.9	1.018	5.2503	*No failure
30	Y	Dry	1.6	2.74	13	0.2268928	0.9	1.018	5.1246	*No failure

Time Applied (s)	Tape (Y/N)	Humidity	Distance (m)	Length (m)	Angle from Vertical (°)	Angle from Vertical (rad)	Max Weight Withstood (kg)	Max Total Weight (kg)	Max Force (N)	Failure Description											
Bad Teeth											30	N	Moist	2.4	2.74	27	0.4712388	0.2	0.318	1.7506	Tube holder failure
											30	N	Moist	2	2.74	18	0.3141592	0.3	0.418	2.1558	Tube holder failure
											30	N	Moist	1.6	2.74	13	0.2268928	0.2	0.318	1.6008	Tube holder failure
											30	Y	Moist	2.4	2.74	27	0.4712388	0.7	0.818	4.5031	Mouthguard Failure
											30	Y	Moist	2	2.74	18	0.3141592	0.8	0.918	4.7345	Mouthguard Failure
											30	Y	Moist	1.6	2.74	13	0.2268928	0.9	1.018	5.1246	*No Failure
											30	N	Dry	2.4	2.74	27	0.4712388	0.3	0.418	2.3011	Tube holder failure
											30	N	Dry	2	2.74	18	0.3141592	0.3	0.418	2.1558	Tube holder failure
											30	N	Dry	1.6	2.74	13	0.2268928	0.5	0.618	3.1110	Tube holder failure
											30	Y	Dry	2.4	2.74	27	0.4712388	0.9	1.018	5.6041	*No Failure
											30	Y	Dry	2	2.74	18	0.3141592	0.9	1.018	5.2503	*No Failure
											30	Y	Dry	1.6	2.74	13	0.2268928	0.9	1.018	5.1246	*No Failure