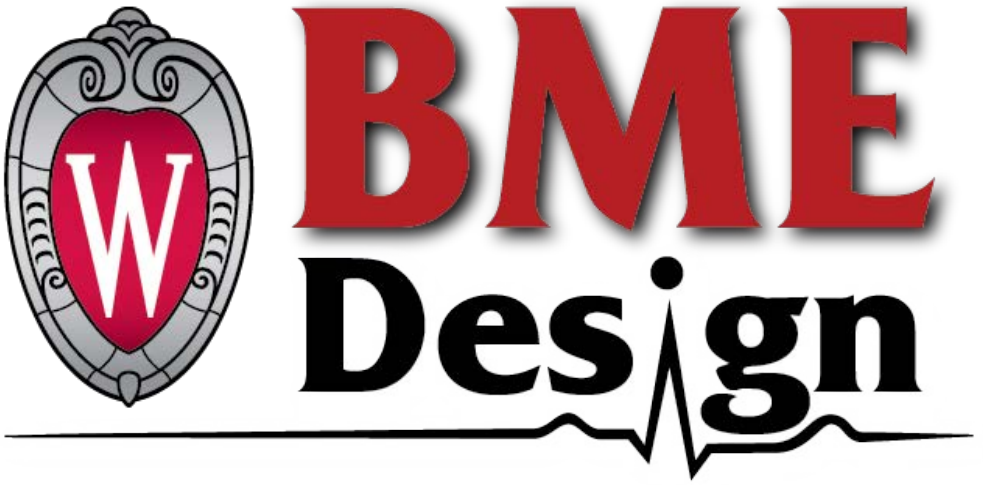

Emergency Cricothyroidotomy

Final Report

Biomedical Engineering Design 400
Department of Biomedical Engineering
University of Wisconsin – Madison
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Abstract

Each year over 5000 people die from choking related accidents [1]. While interventions such as the Heimlich maneuver and cardiopulmonary resuscitation (CPR) exist, they are not always effective. Advanced interventions such as an emergency cricothyroidotomy exist to create an emergency airway but they require trained emergency responders. The response time of emergency medical services (EMS) is on average too slow to prevent serious permanent damage from occurring in a choking scenario. Devices used to perform an emergency cricothyroidotomy often include multiple tools and can be too intricate to be used without strenuous training. The device being proposed will help alleviate the current issues by simplifying the process by being a multi-functional device to create an emergency airway with a simple mechanism where only simple training would be sufficient to use it accurately. The device is able to create and maintain the airway without needing multiple tools. Two initial devices were fabricated from polylactic acid (PLA) and aluminum. The PLA device was 3D printed, while the aluminum device was fabricated with a mill and lathe. Testing was done in 4 stages: Solidworks simulation testing, force testing with rubber faux skin, force testing with porcine larynx and a survey to gauge public opinion. Force testing with the skin yielding a force less than the predicted 603 kPa pressure from Solidworks. The porcine force testing was not properly completed, as errors in affixation of the porcine larynx did not allow any puncturing of the MTS machine. Future work includes refining testing protocols and replicating force testing. To increase gender inclusivity, a mechanism to control the length of the puncture shaft will be designed. Before major design alterations occur, the device should be properly tested for performance to indicate any flaws in the design.

Introduction

Motivation:

Each year over 5000 people die from choking related accidents [1]. Of those 5000 people, a majority are the most vulnerable ages of one to three and sixty and older. Choking is the leading cause of infantile death and the fourth leading cause of unintentional death [1]. Methods exist to assist someone who is choking such as the Heimlich maneuver, and CPR if the subject becomes pulseless [2], [3]. However, these methods are not always effective and without a secure airway, subjects are left helpless until EMS arrives. The average response time for EMS in the United States is 7 minutes and within 4 minutes of the onset of choking, permanent brain damage is likely to occur [4], [5]. In hospital and advanced life support settings, emergency cricothyroidotomy procedure is done through the cricothyroid membrane to create an airway [6]. However, there is no suitable device on the market that creates an emergency airway, as an alternative rescue measure, that is accessible to the general public.

Current Devices:

At a minimum, most emergency cricothyroidotomy devices on the market are sold as a sterile kit containing a scalpel to create an incision, a cuffed endotracheal tube, and tape or a strap to hold the device in place. Some devices require a system of tool insertions, such as a guide-wire and air catheter [7], [8]. All of the commercially available kits feature a metal tool to create the stoma. This commonly leads to the high prices per device. Listed below are devices commonly sold for emergency responders as well as some of the patents that exist surrounding similar devices.

Rusch QuickTrach Cricothyroidotomy Kit

This product is a pre-assembled emergency cricothyroidotomy device that features a 10 mm syringe with a stainless steel needle attached to a flexible tube and tube holder [9]. Notably, this product features a ‘safety stop’ feature on the tube holder that aims at preventing puncture of the back of the trachea. It retails for $212.95.

Figure 1: Rusch QuickTrach Cricothyroidotomy Kit [9]

STATForce Adult Deluxe and Pediatric Field Cric Kit

This commercially available kit features a #10 sterile scalpel, as opposed to a needle, and a trach tube holder [7]. It also contains a 6.0 cuffed endotracheal tube and syringe to inflate the endotracheal tube balloon. Notably, this kit includes an iodine prep pad, face shield for the provider performing the procedure, and a trach hook. It is sold for $29.95. A pediatric version of this kit is available with a 2.5 cuffed endotracheal tube and retails for the same price of $29.95 [10].

The Quick Fix Adult Cric Kit and The Quick Fix Jr.

This kit includes a scalpel, cuffed tube, syringe, forceps, and tape [11]. Notably, the kit contains photo directions for easy review and states the kit comes in a sterile package that takes up “very little space” (5’’ x 8’’). It retails for $60.95. A pediatric version of this kit includes only a 1.25’’ large bore IV catheter, syringe, and 15 mm endotracheal tube adapter. The pediatric Quick Fix Jr. is sold for $23.95 [12].

Figure 2: Quick Fix Adult Cric Kit [11]

US Patent US4677978A- Emergency Cricothyrotomy System and Cricothyrotomy Kit

This patent describes a device that can be inserted into the trachea through an incision. It does not include a method by which to create an incision . This patent features an over-the-needle catheter that is removed after insertion of a guide-wire [8]. From there, the cricothyroid membrane is dilated and an air passage catheter is inserted along the guide-wire. The guide-wire is then removed and the air passage catheter is secured.

US Patent US4438768A- Emergency Cricothyroidotomy Instrument

This patent is a single elongated needle with a sharp point and an accompanying needle holder [13]. The needle features an adapted outer shaft designed to abut the needle holder. The needle holder features ridges designed to hold the device in place. The needle and needle holder are connected by a hinge that allows for pivotal movement of each section to open and close the needle holder.

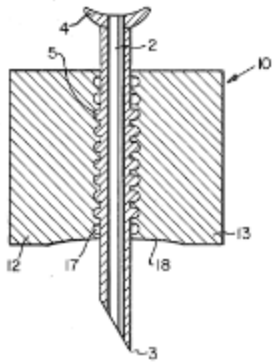


Figure 3: Emergency Cricothyroidotomy Instrument Assembled [13]

Problem Statement:

Current devices used to create an emergency airway through the cricothyroid membrane contain multiple moving parts and require specialized EMS training to be able to operate. In situations where choking victims are without oxygen, time is everything and if conventional treatments fail, victims' lives rest on the response time of the EMS service in their area. The need for a device that could be used by a bystander witnessing a choking episode is clearly prevalent. The device aims to be easy to use and incorporate multiple parts into one such as creating the stoma as well as being the airway adjunct. The device will also need to be adaptable to EMS tools such as a bag valve mask so it can continue to be used when EMS arrives on the scene.

Background

Design Research:

An upper airway obstruction, colloquially known as choking, occurs when an object, illness, such as cancer, or severe trauma blocks transfer of oxygen between the upper airway and the lungs [14]. This prevents oxygen from traveling to the brain. A complete airway obstruction occurs when the foreign body becomes lodged in the larynx or trachea, however, foreign bodies may become stuck in a bronchus [1]. Permanent brain damage onsets after 4 minutes without oxygen and death ensues roughly 6 minutes later [5].

The primary treatment for an airway obstruction is the Heimlich maneuver. In order to perform this maneuver, a person places their arms around the upper abdominal region of a choking victim, approximately two inches above the belly button. The person should make a fist with one hand and wrap the other hand around it and deliver five crisp midline thrusts inward

and upward. If the patient is pregnant, the thrusts should be applied over the sternum. This technique increases intrathoracic pressure affecting the airway, stomach and esophagus produced by diaphragmatic thrusts [2]**.** The success rate of the Heimlich maneuver is 86.5%, considering it an effective and reliable method [15]. However, some risks are associated with this treatment. Primarily, rib fracture, diaphragm rupture and mesenteric laceration [16]. During the maneuver, the mean peak airway pressure measures to be 26.4 ± 19.8 cm H_2O, whereas the pressure in the stomach typically measures to be 57 ± 17cm H_2O [17], [18]. This difference in pressure results in gastric rupture, the most common complication of the Heimlich maneuver [19].

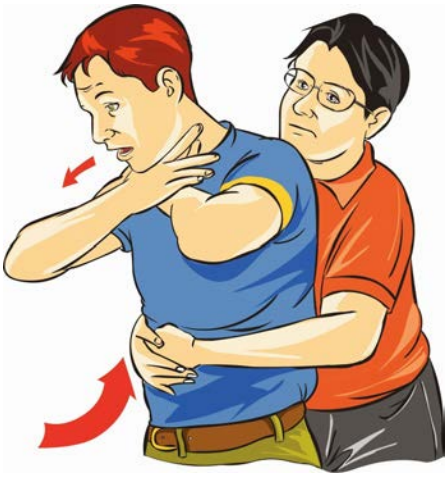


Figure 4: A person performing the Heimlich, with arrows on the motion of the thrusts [20]

Should the Heimlich maneuver not be successful and the victim falls unconscious, the next treatment would be to perform CPR [3, p.]. The initial success rate of CPR is estimated to be 15.3% and the success rate of patients who are discharged alive from the hospital after CPR was performed was 10.6%. Studies have found that there are no statistically significant differences between age group success for initial success rate of resuscitation [21].

The Advanced Trauma Life Support manual specifies that in the event that an emergency surgical airway is needed, a surgical cricothyrotomy is the recommended procedure. This is preferred over a tracheotomy because of the easiness and safety of the cricothyrotomy: it leads to less bleeding and less surgical time [22]. The literature discusses several techniques, where some procedures are reduced to three steps, whereas others range from four to seven steps, varying in equipment and tools used to obtain tracheal access [23]. The quickest and most accurate procedure is the three-step method. It resulted in faster airway placement and more correctly placed airways on the first attempt. It also can easily be taught using a high-fidelity simulator and a brief lecture [24]. It requires a size 10 scalpel, an elastic bougie and a cuffed endotracheal tube. After sterilizing the neck, it is necessary to grasp the larynx with the nondominant hand to secure it. It is imperative to identify necessary anatomical landmarks: the thyroid cartilage, cricothyroid membrane and cricoid ring. Then, a vertical incision is created over the cricothyroid membrane. Immediately, a 5 mm horizontal incision is made through the cricothyroid membrane

and the elastic bougie is placed and advanced until it reaches the bronchus. The final step is to insert the endotracheal tube over the elastic bougie and advance it through the puncture and enter the trachea [25]. Once an airway is secure, the endotracheal tube is connected to a bag-valve mask (BVM). It supplies a minimum of 15 liters of oxygen per minute. It should deliver oxygen until the chest begins to rise, in order to reduce the risk of barotrauma from overdistention [26].

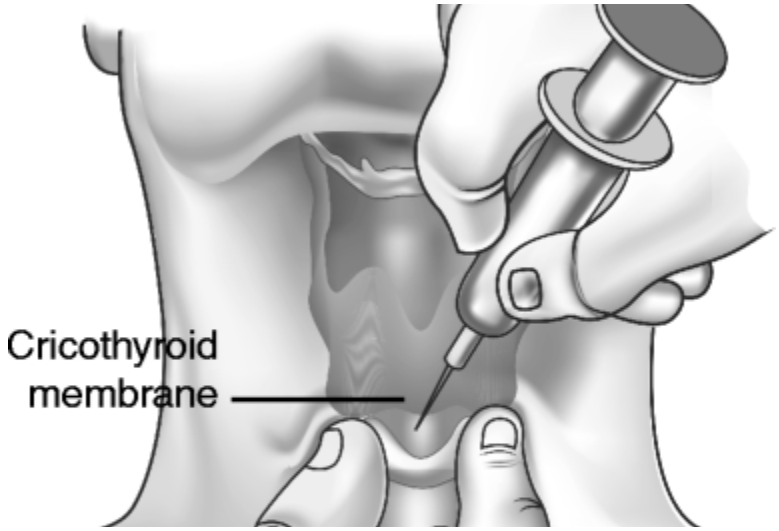


Figure 5: Schematic of an cricothyroidotomy puncture [27]

Very few data are available regarding the occurrence of the cricothyroidotomy procedure in a choking event. In a study regarding tracheal intubations, it is estimated that 0.23% of patients underwent cricothyroidotomy, hospital wide. In the emergency department alone, the prevalence of cricothyroidotomy is roughly 0.39% [28]. This procedure is quite successful, estimated to have a 94% success rate in establishing a patient airway. The mortality rate of this procedure is 33% and increases to 48% for two or more cricothyroidotomy attempts [29]. Survival rate of cricothyroidotomy is 66.6% and of patients of failed cricothyroidotomy, 33% survive, where other methods of securing an airway were used [28].

Common complications of the procedure include, but are not limited to, esophageal perforation, subcutaneous emphysema and excessive bleeding. Esophageal perforation typically occurs when the blade penetrates too deeply. If the horizontal incision is too wide, this results in trapping of air in the subcutaneous tissue, leading to subcutaneous emphysema. Moreover, if a blood vessel is ruptured, most likely the carotid artery or internal jugular vein, hemorrhage can occur [30].

The cricothyroid membrane is an intrinsic ligament located in the larynx, supporting the cartilaginous skeleton. It connects the thyroid cartilage with the cricoid cartilage [31]. It supports articulation, with the addition of synovial joints, which are also moved by the cricothyroid ligament. The cricothyroid artery is located in the middle of the cricothyroid ligament [32].

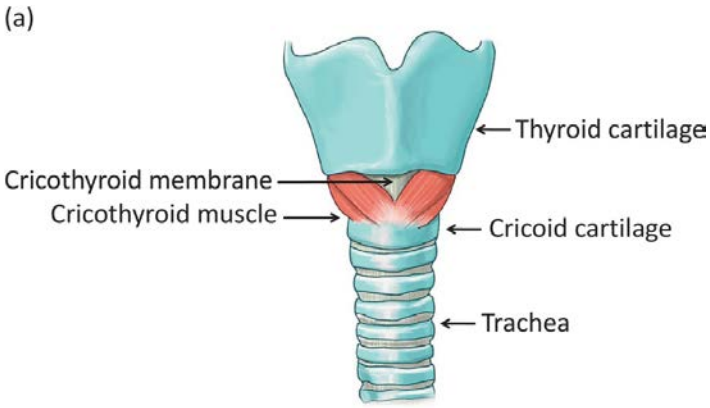


Figure 6: Anatomy of the larynx [33, p. 2]

In the average male, in the neutral position, the mean height of the cricothyroid membrane is 7.71 ± 1.38 mm and 6.41 ± 1.28 mm in females. When the cricothyroid membrane is fully extended, the average height for males is measured to be 10.16 ± 1.48 mm and 8.72 ± 1.19 mm in females [34]. In the pediatric population, the average height of a cricothyroid membrane for a patient less than 2 years old is 1.7 ± 0.3 mm, for a patient in the 2 year old to 6 year old age range, the cricothyroid membrane height is 1.4 ± 0.3 mm and for a patient above the age of 6, the cricothyroid membrane is 1.5 ± 0.2 mm [35]. The average diameter for the cricothyroid membrane in adults is 0.94 ± 0.32cm, with no gender differences observed [36]. The depth of the cricothyroid membrane measures to be 10.6 mm in adults with a normal weight (BMI $\leq 25\ kg \cdot m^{-2}$) and 18.0 mm in adults with severe obesity (BMI $>45\ kg \cdot m^{-2}$) [37].

The trachea is composed of 18 to 22 rings with anterior and lateral walls made of C-shaped cartilage. The trachealis muscle lies longitudinally on the posterior aspect of this wall. Each tracheal ring is approximately 4 mm in height. The wall of the trachea is on average 3 mm in thickness [38]. In adolescent subjects, the average coronal tracheal diameter is 15.5 ± 2.8 mm for males and 14.4 ± 1.6 mm for females. For the 20-29 year old population, the average coronal tracheal diameter is 18.7 ± 2.0 mm in males and 15.7 ± 1.6 mm in females. There are growth differences between genders, where there is a sharp increase in growth for males observed in the 20-29 and 30-39 age groups and then more slowly in the 40-49 population. Whereas in women, the growth is more gradual for the 20-29, 30-39 and 40-49 age groups. There is no statistical growth beyond age 49 in females [39].

Success rates of identification of the cricothyroid membrane by palpitation typically varies by sex and body positioning of the patient. In males, identification of the cricothyroid membrane is successful in 72% of non-obese patients and 39% of obese patients [40]. For females, the average success rate of correct identification of the cricothyroid membrane is 71% in non-obese subjects and 39% in obese subjects [36]. Success rate significantly increases with the addition of ultrasonography, roughly 95% success rate, regardless of patient age, gender or weight [41].

Client Information:

Dr. Lenard Markman is a family physician, practicing in Amherst, WI [42]. He previously practiced in rural medicine. Currently, he advocates for epinephrine legislation for the state of Wisconsin [43]. His motivation for the device follows the tragic death of his friend's child when the Heimlich maneuver did not dislodge a tracheal foreign body and an airway was not established.

Design Specifications:

In order to reduce mortality rates in choking incidents and increase accessibility of emergency medicine procedures to the general public, the design process involves creating a emergency cricothyroid device that reduces the amount of tools and can pierce through the skin and cricothyroid membrane in one action to obtain immediate access to the trachea. This single-use device will be used in emergency choking situations that arise outside the hospital. Made from a non-ferrous material, this device should be able to create an airway for the general population, inclusive of age, gender, height and weight. The device should cost at a price that is competitive on the market. Current devices retail roughly between the range of $30.00 USD - $200.00 USD [7], [9]–[12]. The user end should be adaptable to a bag valve mask and allow for an exchange of 500mL of air every 3 seconds. The final design should be at a size small enough to be included in first aid kits and carried easily in people's belongings. More detailed information is outlined in *Appendix A*.

Preliminary Designs

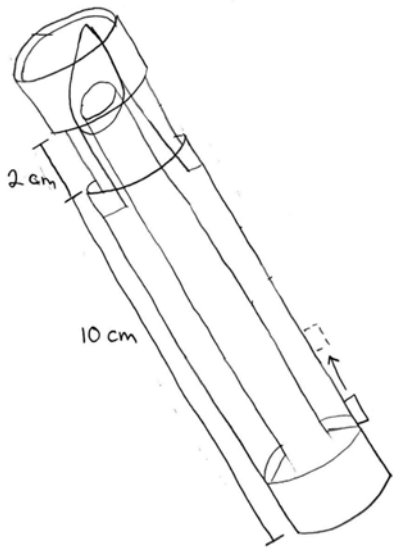


Figure 7: Preliminary Design #1, The Lancet

The Lancet

This device operates similarly to a lancet, and focuses on safety for the user. It was designed to be an approachable device, usable by anyone. The design consists of an outside shell, a sharp beveled blade, and a flexible inner tube to maintain the airway. When pressed against the skin, the cap is pushed back and the blade punctures the skin and the cricothyroid membrane. The slide lever at the opposite end of the device is pushed with the user's thumb. When pushed, the innermost tube extends forward, locking it into place. This ensures that the airway remains open throughout the procedure. After locking the inner tube into place, pressure is removed until the outer shell is at its original length and only resting on the outside skin. In doing so, the blade is removed from the trachea, preventing further damage. The end of this device can also be attached to a bag valve mask when first responders arrive. This design prioritizes safety, ease of use, and approachability.

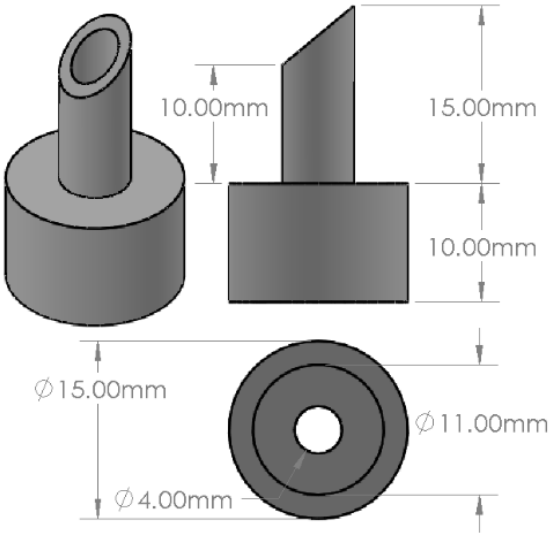


Figure 8: Preliminary Design #2, The Hole Puncher

Hole Puncher

This design is most closely based off of the client's prototype for an emergency cricothyroidotomy device. It is made of a straight, hollow, plastic tube that features a sharp bevel with which the skin and trachea are punctured. The sharp beveled edge allows for a clean insertion. At the other end, the opening widens so it can easily be connected to the end of a bag valve mask (BVM). The flange created by the bag valve mask attachment is located 15 mm from the tip of the bevel. This prevents the device from being inserted too far and puncturing the back of the trachea. This design is meant to be the most simple, portable, and cost-effective of the three designs.

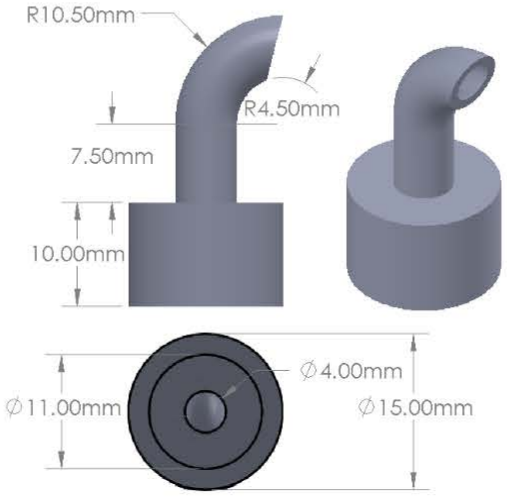


Figure 9: Preliminary Design #3, Captain Hook

Captain Hook

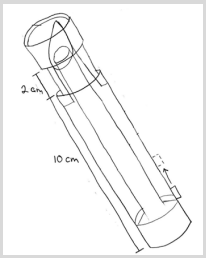
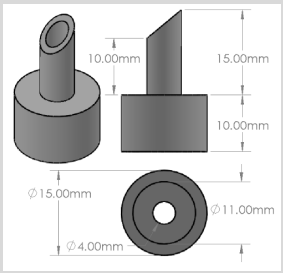
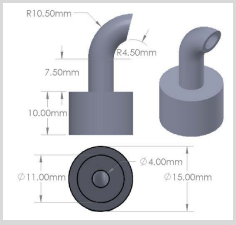
This design is an iteration on the Hole Puncher, with a greater emphasis on ergonomics and device usage. This device features the same sharp beveled edge for puncturing, a flange to

avoid injury during placement, and a point to attach a BVM. The addition of a curve helps guide the user in inserting the device properly. When a cricothyroidotomy tube is placed, it must be inserted into the skin at a 45° caudal angle, then straightened out to 90° as it is advanced into the trachea. While being placed, the user must only follow the angle of the blade, keeping the needle perpendicular to the skin as it is inserted. This balance between being user-friendly while maintaining a low-cost is unique to this design.

Preliminary Design Evaluation

Design Matrix

Table 1: Design Matrix, featuring rankings for each design criteria and each design.

Criteria	Weight	Design 1: The Lancet 	Design 2: The Hole Puncher 	Design 3: Captain Hook 
Ease of Use	25	**5/5 (25)**	4/5 (20)	3/5 (20)
Portability	25	4/5 (20)	**5/5 (25)**	3/5 (15)
Cost	20	2/5 (8)	**5/5 (20)**	4/5 (16)
Ease of Fabrication	15	3/5 (9)	**5/5 (15)**	4/5 (12)
Ergonomics	10	**5/5 (10)**	3/5 (6)	4/5 (8)
Safety	5	**5/5 (5)**	3/5 (3)	2/5 (2)
Total:	100	77	**89**	73

Ease of Use (25%):

Ease of use refers to how easily a member of the general public could use the device without elaborate training. A higher score indicates that someone could use the device without needing strenuous training. This was weighted the highest because the device should be inclusive of the general population, and should not need proper training to use. The Lancet design won this category because the device works similarly to a lancet and would be set so people could not

puncture the hole too deep. Also, the device's mechanics allow for easy puncturing without too much force, which is compatible with people who do not have much strength or practice.

Portability (25%):

Portability refers to if the design is able to be packaged and transported without taking up a lot of space. The device should be small enough to be an addition to a general first aid kit and could be small enough to rest in a person's pocket. For those reasons, this category was weighted the highest. The Hole Puncher design won this category because it takes up the least amount of space and could easily be put into any first aid kit because it is compact and narrow.

Cost (20%):

Cost refers to the price it would take to develop and fabricate the product. Other products already exist that can be used for an emergency cricothyroidotomy. However, these devices are $30 at a minimum and the client aims to create an affordable and mass producible product. Cost was weighted third highest because without making a more cost effective device, the product wouldn't be able to compete with other products that already exist on the market. The Hole Puncher design won this category because it is the smallest and most simple to make device. That means it would cost less to fabricate and manufacture because it would use less material and be easier to produce on a large scale.

Ease of Fabrication (15%):

Ease of fabrication refers to how manageable the design is to prototype. A design with a higher score indicates that the design is relatively easy to fabricate, not requiring a lot of components. The rationale behind judging based on fabrication of the prototype is that creating the initial prototype will require more fabrication steps than when the device hits the market and will be commercialized, the fabrication process will be streamlined. To judge based on the hardest steps first provides more accuracy in fabrication clarity. The Hole Puncher was ranked the highest because of the simplicity of the device. Because of its simple design, consisting of only a beveled edge, flange, and BVM attachment point, it will take less steps compared to the other designs. The Lancet was ranked the lowest because of the amount of components needed, meaning fabrication will be more extensive in order to fabricate each component and then assemble.

Ergonomics (10%):

Ergonomics refers to the universality and inclusivity of the device as it interacts with the general public. Because this device is not catered to a specific population, it must be adaptable to everyone. It should cater to ambidexterity, age of user, etc. A higher score indicates that the device is adaptable to all populations. The Lancet is ranked the highest because the mechanism required to use could be accommodated to both right and left handed-users and is simple enough to be used by any user, regardless of age.

Safety (5%):

Safety refers to the condition of how the user will be protected from harm from the device. This evaluates if the user will be injured from using this device or any unintentional harms associated with the device. A higher score indicates that the device has minimal risk, whilst a lower score indicates that the device has some risks involved with usability. The Lancet was ranked the highest because the sharp tip used to puncture the patient is retractable and in the resting state, is covered by the outer shell. It is anticipated that there is a low chance of accidental puncture through the packaging and to the user. The Hole Puncher was ranked the lowest because the tip is exposed and accidental movement could lead the device to break the packaging and injuring the user

Proposed Final Design

Based on the design matrix and input from the client, the team is planning on pursuing a design similar to the Hole Puncher. The straightforward design allows for easy prototyping and manufacturing of the device. Additionally, features from the other designs may be adapted depending on testing results and client feedback. This device will be able to articulate with a BVM.

Figure 10: A schematic of how the proposed final design (gray) will interface with a bag valve mask and human anatomy [44], [45].

Fabrication

Below is a summary of the methods used to fabricate the final prototype. A full fabrication protocol is available in Appendix B. Note that the dimensions are provided in imperial units in the full fabrication protocol to aid with machining in the TEAM Lab.

Materials:

- 26 mm aluminum rod stock, at least 8 cm long

Tools:

- Manual lathe
- Drop saw
- Vertical milling machine
- Bench grinder

Methods:

A. Machining on Lathe

1. **Setting up the lathe:** The stock material is measured and the lathe is turned on at the correct RPM.
2. **Zeroing the Z-axis:** The end of the material is shaved off to set the origin in the Z-axis.
3. **Setting the X-axis diameter:** The cutting tool makes contact with the diameter of the part. The part is measured and the X-axis origin is set.
4. **Cutting the major diameter:** The diameter of the larger portion of the part is cut. The final diameter is 25 mm.
5. **Cutting the minor diameter:** The smaller end of the device is turned down to size. The end is 20 mm long with an outer diameter of 6 mm.

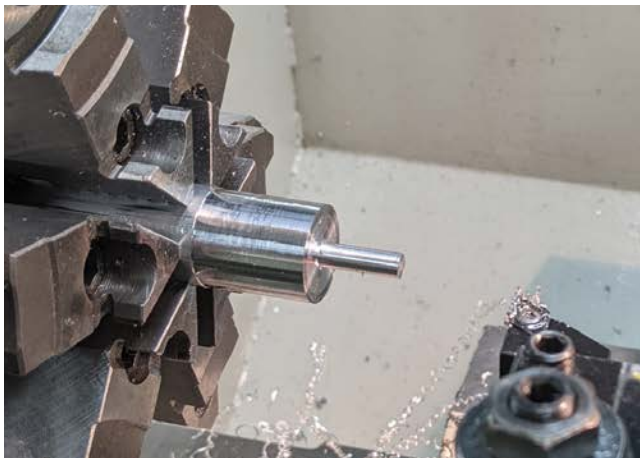


Figure 11: Turning the minor diameter (smaller end) of the device on the lathe.

6. **Drilling the minor diameter channel:** The hole in the smaller end of the device is drilled out.

Figure 12: Drilling out the channel in the minor diameter of the device.

7. **Cutting off excess stock:** The workpiece is cut off from the stock material so the other end can be machined.
8. **Cutting the part to its final length:** The piece is placed back on the lathe and cut to its final length of 43 mm.
9. **Drilling the major diameter channel:** The larger hole, in the wide end of the device, is cut out. A flat drill bit is used to create perpendicular walls in the interior.

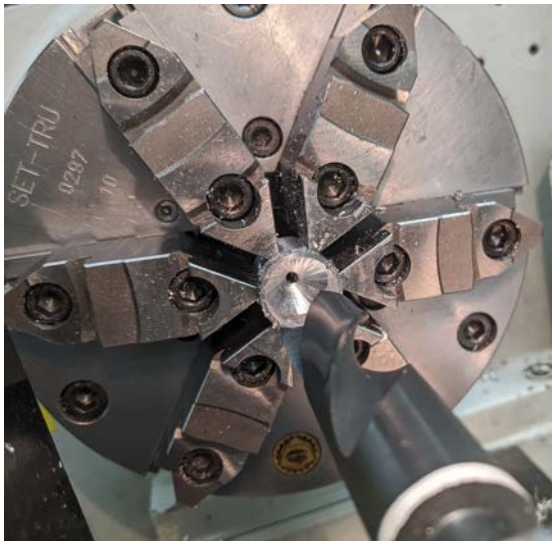


Figure 13: Drilling out the channel in the major diameter of the device.

10. **Part Deburring:** The part is deburred to remove sharp edges.

B. Machining on Mill

1. **Setting up the Mill:** The piece is secured in the mill, at a 45° angle.
2. **Zeroing the z-axis:** The cutting tool of the mill makes contact with the top of the part and the z-axis origin is set.

3. **Creating angled edge:** The tip of the device is cut off to create the sharp beveled edge.

Figure 14: Using the mill to create the sharp angled edge of the device.

4. **Zeroing the y-axis:** An edge-finder is used to find the center of the piece. The y-axis origin is set.
5. **Zeroing the x-axis:** An edge-finder is used to find the location of the tip of the device. The x-axis origin is set.
6. **Drilling the supplementary airflow channel:** The supplementary airflow channel hole is cut opposite the sharp end of the device.

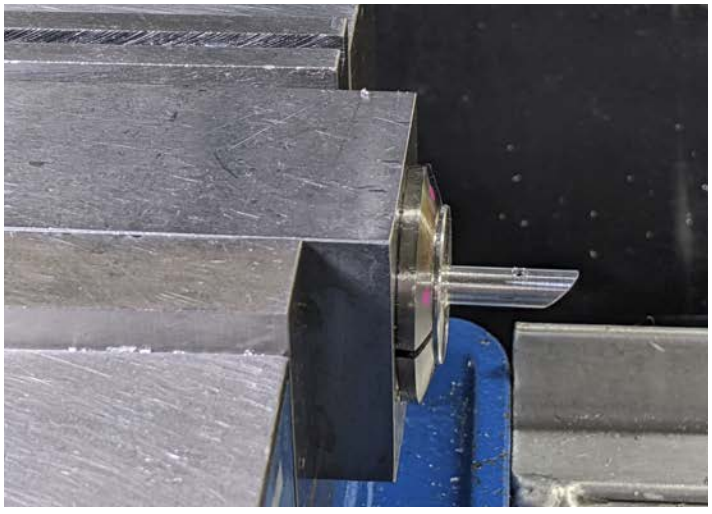


Figure 15: Drilling the supplementary airflow channel using the mill.

7. **Part Deburring:** The part is deburred to remove sharp edges.

C. Sharpening on Bench Grinder

1. **Creating a Beveled Edge:** The tip of the device is ground down to a point, similar to that of a hypodermic needle.

Testing:

Feedback Survey

A five question survey was created to assess user comfort with the emergency cricothyrotomy device. Questions for the survey can be seen in *Appendix C*. Each question asked the survey participant to rank their feelings on the device in different ways on a scale of 1-5. Before taking the survey, participants were given a 1-2 minute explanation of when the device would be used and how to locate the cricothyroid membrane on their own neck or an anatomic model (Figure 16). Instructions for palpating the cricothyroid membrane were created for this survey that participants could use to learn (Figure 17). Participants then completed the survey. Responses remained anonymous. The data is available in *Appendix F* statistical results are available in *Appendix G*.

Figure 16: The cricothyroidotomy device (right) and the upper airway training device (left), used to explain the anatomy and use of the device.

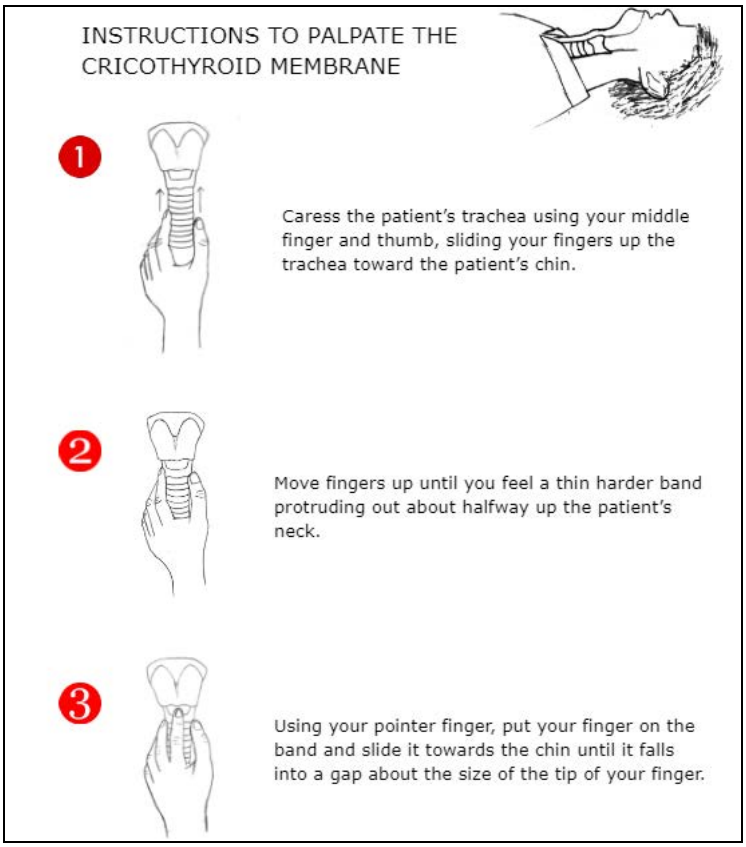


Figure 17: A diagram shown to survey participants to teach them how to palpate the cricothyroid membrane before completing the user feedback survey.

Solidworks Testing

Preliminary material testing was performed using simulations in Solidworks to compare stress and strain in aluminum and PLA models of the final design. The simulation was run using a peak compressive force of 2.75 N (Figure 18) on the tip of the device to mimic the average force required for a needle to puncture human skin [46]. After finishing the simulation, the maximum stress and strain values were compared to determine which material would be ideal for creating the final prototype. Factor of safety was also measured, however, both values were significantly larger than the minimum required so it wasn't considered.

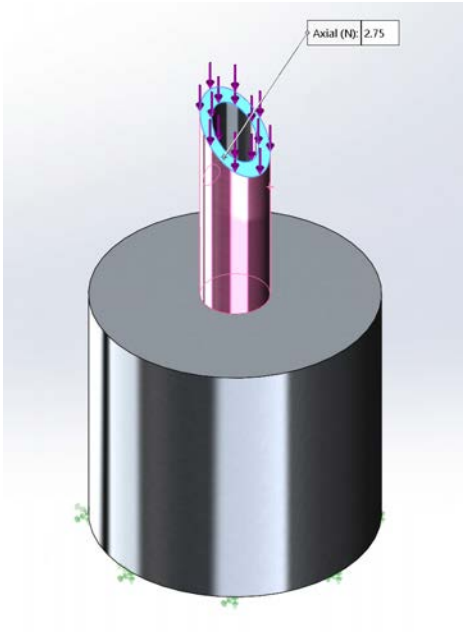


Figure 18: Solidworks simulation was used to test the force needed to puncture skin with our device. In the simulation, the device was inserted perpendicular to the skin. The force was loaded against the beveled edge as shown above. Both the aluminum and PLA materials were modeled.

Puncture Testing

Preliminary force testing was completed to measure how much force was required for the second prototype to puncture a skin mimetic. Protocol for this testing can be found in *Appendix D*. A Dr. Meter ES-PS01 Force Gauge was secured to a surface and pulled perpendicular to the skin mimetic which was also clamped taught between two surfaces (Figure 19). The cricothyroidotomy device was secured to the force gauge and held perpendicular to the skin mimetic. The force gauge was zeroed and then the prototype was pushed by hand through the skin mimetic. The maximum force applied to the prototype was recorded as the skin mimetic was punctured.

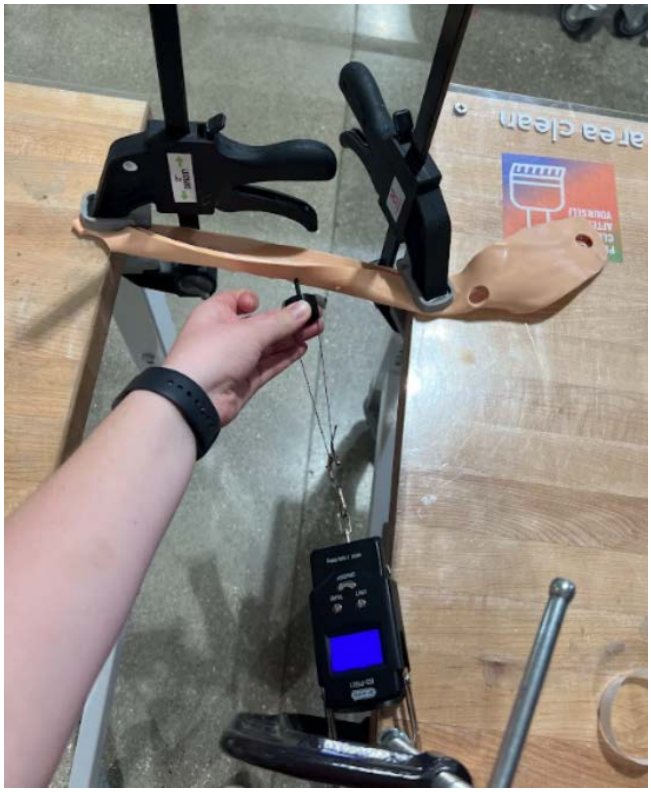


Figure 19: The puncture testing setup. Note that the force gauge and prototype were held perpendicular to the skin mimetic.

MTS Testing

A porcine larynx was acquired for anatomically relevant force testing. The porcine larynx was prepared using the protocol in *Appendix E*. Porcine tissue was chosen because the large animal has similar anatomy to a human and was easier to acquire compared to other animal tissue types, such as bovine, canine, or human. The larynx was affixed to a petri dish and used for puncture testing on the MTS Inspiron machine (Figure 20). The final metal prototype was attached to the MTS grips using a custom 3D printed adaptor. The cricothyroid membrane was aligned directly underneath the cricothyroidotomy device. A test rate of 3.0 mm/s with a 50 N load cell were utilized.

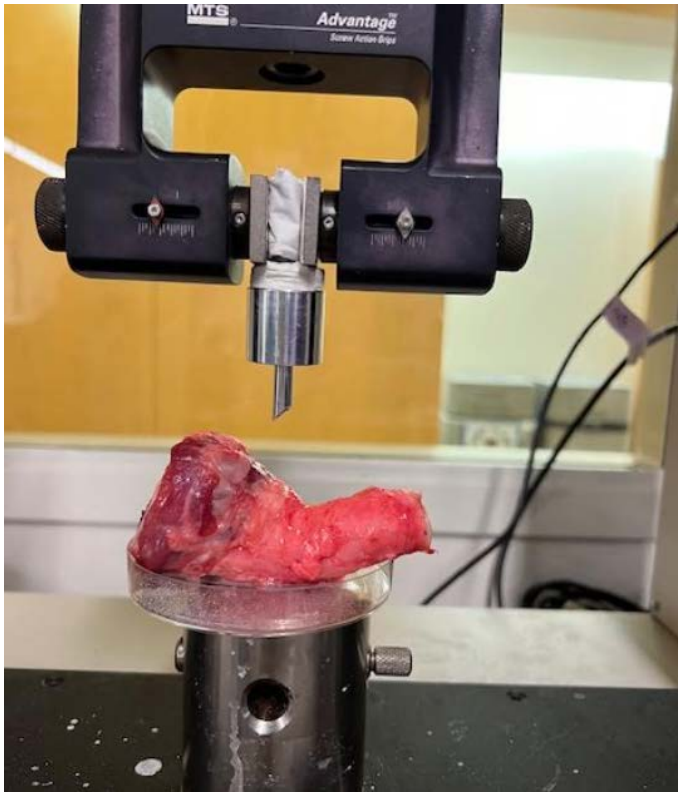


Figure 20: MTS Inspiron testing setup with a porcine larynx. Note the custom white grip binding the metal prototype to the MTS grips. The grip appears wrinkled because it is wrapped in tissue to create less slip.

Final Prototype:

The final design consists of an updated version of the Hole Puncher design (Figure 22). Dimensions were updated to be as seen in Figure 21. The final dimensions allowed a bag valve mask to be attached to the device when EMS arrives. The dimensions of the tip were altered to better align with the average anatomical dimensions of an adult, allowing for adequate depth to be reached upon insertion. A supplementary airflow channel was added to the shaft based on the client's later request for multiple airflow channels in case one was to get clogged while puncturing. Protocol for fabricating the metal prototype can be found in *Appendix B*.

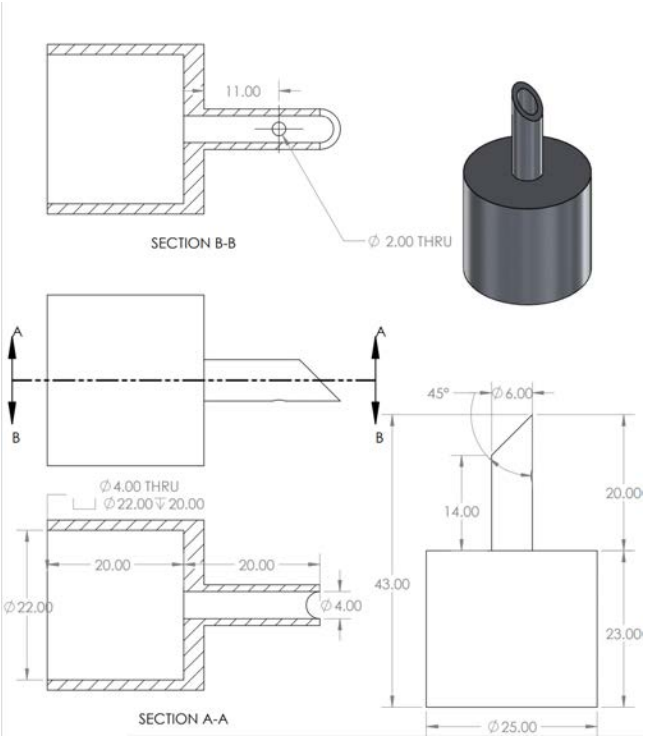


Figure 21: Solidworks drawing of final design in millimeters.

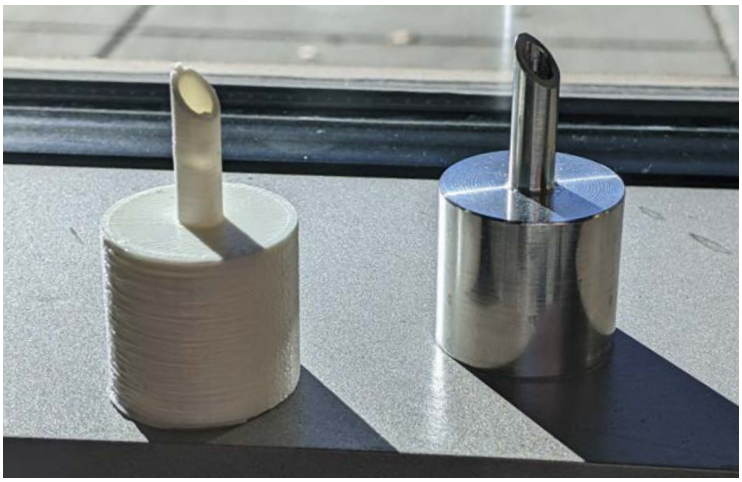


Figure 22: PLA (left) and aluminum (right) final prototypes.

Results

Feedback Survey

A survey was conducted to gauge the approachability of the device as well as the confidence of the general public to identify the cricothyroid membrane. These aims were established as there is a heavy emphasis during the design process of universality and inclusivity. The client intends that the device should be used by anyone, not limited to age, gender, or location of emergency. The survey questions are underscored in *Appendix C*. The specific

question, “How prepared do you feel to use this device on a scale from 1-5” yielded an average response of 2.75 and a median response of 3. The specific question, “How long do you think it would take you to identify the cricothyroid membrane (minutes)” yielded an average response of 1.479 minutes and a median response of 1.25 minutes. Results are shown in Figure 23 and further statistical analysis and data are in *Appendix G*.

One source of error in this testing is that the survey participants are all college educated biomedical engineering students. This population likely skewed the results of the survey for users to seem more confident locating the cricothyroid membrane. In order to acquire more accurate data from the general public, a second survey will be distributed next semester to gain a better understanding of the layman’s opinions on usage of this device.

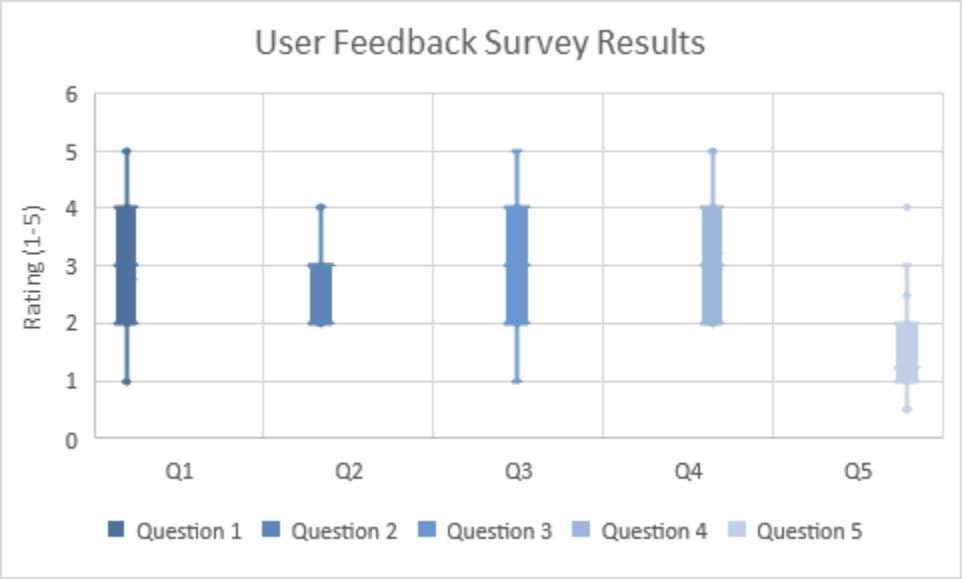


Figure 23: User Feedback Survey Results. This box and whisker plot shows the mean value and quartiles of the responses.

Solidworks Testing

The test performed in Solidworks to quantify the force needed of the device to puncture skin is outlined in *Testing* above. This allowed the comparison of the aluminum device against a device fabricated with PLA. It was calculated that 603 kPa of stress would be needed to puncture skin with the aluminum device, whereas 654 kPa of stress is required for the PLA device. This data confirmed that future prototypes will be made with aluminum because it endures less stress when compared to PLA.

Puncture Testing

This simulation was recreated with a force gauge using a skin mimetic. The overall protocol is outlined in *Appendix D*. From 5 trials, on average it required a force of 2.174 ± 0.336 lbs, translating to roughly 43.5 kPa of pressure. Comparing the Solidworks computer simulation

to the manual testing, there is a difference of 610.5 kPa of pressure, as the PLA device was used for the faux skin testing.

There are two main limitations of this testing. The first important limitation is that the Dr. Meter ES-PS01 force gauge can only measure pulling force, not pushing force. Ideally, the pushing force would be measured for this device. The current testing setup was designed to measure the force as accurately as possible without having a device that can measure pushing force. The second important limitation of this test is that the device is accurate to 5-10 grams which may introduce minor sources of error into the data.

Table 2: Puncture testing data with the second prototype device.

Test Run	**Force (lbs)**
1	2.02
2	1.99
3	1.84
4	2.80
5	2.22

MTS Testing

The porcine MTS testing yielded no viable results. The strain rate of the MTS machine was originally set at 0.02 mm/second, which was too slow to puncture the larynx, as it would rather fold under the force applied. The strain rate was incrementally increased to 0.5 mm/second, and thereafter increased by 0.5 mm/second until 3.0 mm/second. At each frame rate, the larynx did not puncture. The larynx was supported as to avoid movement during testing. However, the supports did not adequately fixate the larynx, leading to inaccurate results.

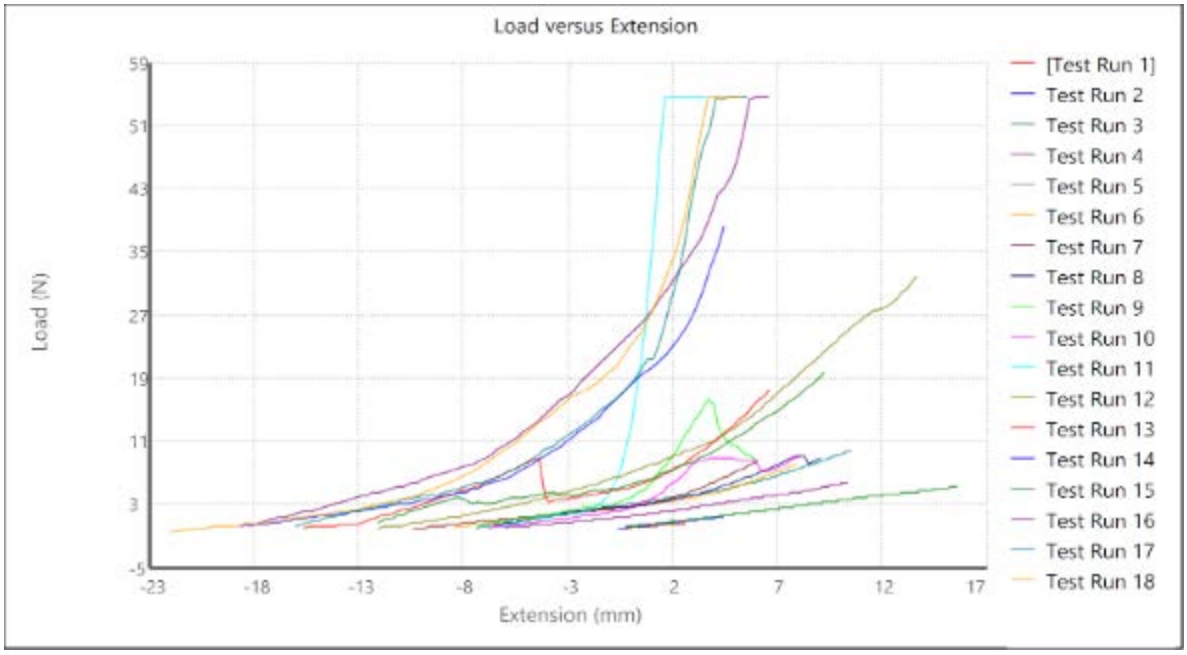


Figure 24: MTS stress-strain curves of the 18 tests.

Discussion

In the final design, material choice was an important consideration. The device should be simple to manufacture and cost effective. Another important design criteria was the portability of the final design. When initially considering materials, metal was ruled out entirely and polymer options were mainly considered. As the semester continued, nonferrous metals came into consideration and a prototype was machined out of aluminum stock. The CAD simulations performed in Solidworks evaluated the puncture force needed with the final prototype in PLA and in aluminum. Due to the difference in simulated pressure needed to puncture skin, aluminum was chosen as the material for the prototype moving forward. With aluminum needing less pressure to puncture, a cleaner and easier cut will be obtained by the user. This ensures greater safety and accuracy with the device for both the patient and the user.

One goal that the team had this semester was to evaluate the approachability of the device. This is an important consideration in the final design and necessary to fully understand before moving further. The survey conducted to gauge the approachability resulted in a median response not fully in favor of the device but also not completely opposed. Design modifications should be made to maximize the approachability, hopefully widening the range of participants willing to use it in case of an emergency. This could be as an addition of a handle to make it more ergonomic, or present the final device in the packaging, without the tip exposed. Fine tuning the ergonomics could increase approachability of the device. The second part of the survey included the evaluation of how long it took for participants to find the cricothyroid membrane on themselves with provided instructions. The results of the survey suggest that the device could be used quickly enough to avoid permanent brain damage. This means that with the

drawings and written instructions provided, the user should be able to locate the cricothyroid membrane and use the device to create an emergency airway before further injury occurs.

The only participants of this survey included other biomedical engineering students on other senior BME teams. Because BME students generally understand basic anatomy and the use of medical devices, it is likely that these results are biased. Participants across diverse demographics should be surveyed as well to fully understand how users would respond to this device and understand the anatomy involved.

Failure of viable testing of the porcine MTS testing could have resulted from a couple of factors. The primary factor is the strain rate of the MTS machine, originally programmed to 0.2 mm/second. The descent of the head down to the larynx did not generate enough energy to puncture the larynx. With no proper supervision to indicate how much to increase the strain rate, the head was programmed with a higher strain rate, however these speeds still did not generate enough force to puncture through the larynx. Further testing should recruit professional supervision to properly advise and program the MTS machine to the proper strain rate comparable to the speed at which the device would be used in an emergency scenario. The other main complication resulted from incomplete fixing of the tissue. As the larynx and trachea is relatively pliable *in vitro* with no cartridge or ligaments to secure it in place, as the force was applied, there was some displacement of the tissue. While the tissue was fixed on the external posterior side, there were no supports employed inferiorly, superiorly, or laterally. This could have caused malfunctioning in MTS testing, as the cricothyroid membrane, while properly secured to the larynx, was not properly secured in the system, causing collapse of the organ itself. Future investigations should employ increased support of the larynx. This could be from increased adhesion of the tissue to the petri dish, 3D printed supports that are affixed to the petri dish, preventing lateral collapse. Future work should also look at trimming less excess tissue in the porcine preparation protocol (*Appendix E***)**.

Due to this project involving the development of an emergency device, ethical and legal considerations throughout the design are paramount to its success. The user will not be able to obtain informed consent from the patient because the device is only used while the patient is unconscious. Therefore, it is important that the capabilities, potential risks, and expected outcomes are clearly stated on the device packaging. Legally, the responsibilities undertaken when the device is put in use should be clearly defined for manufacturers, healthcare providers, and end-users. Proper training and instructions need to be provided as well to prevent possible legal issues. This device is only to be used when the patient is already at risk of dying and the airway is completely blocked. The purpose of the device is to create an emergency airway as a last-resort option when oxygen is not getting to the brain.

Conclusion and Future Works

The goal of this project is to design a device that effectively creates an emergency airway during a cricothyroidotomy when a patient is choking and falls unconscious. This semester, the team aimed to create a device that incorporated multiple tools into one while being approachable to many users. Three designs were developed and evaluated against six design criteria, which were created and weighted based on conversations with the client for the project. The design that was deemed the best based on the established criteria was the Hole Puncher Device. Initial prototypes were printed out of PLA plastic and design modifications were made after every new iteration. A final design was fabricated on a lathe and mill from aluminum stock material.

The testing process involved four unique methods of testing, evaluating multiple aspects of the design and user interaction. First, qualitative surveys were conducted on other BME design students to gauge the approachability of the final metal prototype, as well as the participants' ability to locate the cricothyroid membrane. The second testing process used a CAD simulation on Solidworks to evaluate the maximum and minimum loads imposed on the aluminum design during applied compression on the beveled edge. The next testing method involved rudimentary functionality testing with the final prototype and a skin mimic. Lastly, testing was conducted on the MTS machine with a porcine larynx, which yielded no viable results due to the porcine tissue not being affixed properly. The CAD simulation and skin puncture testing indicate that the device is strong enough to withstand puncture forces during a cricothyroidotomy.

Moving forward, the team would like to formulate a reliable testing protocol and process. This involves considering ways to secure the trachea and larynx while testing with the MTS machine to prevent slip. Additionally, the procedural relevance of the force application should be evaluated, which will most likely result in increasing the strain rate of the MTS machine to mimic a stabbing motion. Materials such as porcine skin will be obtained to improve the physiological representation of human skin compared to the rubber skin mimic used in puncture data collection. The team also plans to measure airflow through the device with a BVM bag and air flow meter to determine if the air delivery rate of the device matches at least 500 mL every 3 seconds.

Additional testing will include performing another qualitative survey to evaluate the ergonomics of the device and how the user will grip it. It is essential to survey people across broad and diverse demographics to understand the extent of the universality of the current design. Lastly, necessary design modifications will be made based on not only this testing data, but also the anatomical differences in trachea depth across genders. These design modifications will ensure the most universal device and the highest success rates when performing a cricothyrotomy. After performing testing on the modified device and evaluating its efficacy,

steps can be taken to develop a manufacturing and marketing strategy as well as meeting with the Wisconsin Alumni Research Foundation (WARF) to discuss obtaining a patent for the design.

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Appendix

A. *Product Design Specifications*

Function:

Each year over 5,000 deaths occur in the United States related to choking. Choking is the leading cause of death for infants and fourth leading cause of unintentional death [1]. Severe damage from upper airway obstruction, leading to no proper oxygen flow, can cause brain damage within 4 to 6 minutes [2]. In a choking emergency, the first response is to deliver a repeated cycle of 5 back blows and 5 abdominal thrusts. If the person falls unconscious, cardiopulmonary resuscitation should be performed immediately [3]. In hospital settings, emergency airway puncture can be performed to place an airway below the obstruction through the cricothyroid membrane [4]. However, there is no suitable device on the market that creates an emergency airway, as an alternative rescue measure, that is accessible to the general public. Death can occur in situations if oxygen flow is not restored in time [5]. This device aims to be a novel choking rescue tool to create an emergency airway to replenish oxygen for an unconscious choking victim.

Client requirements:

- The device must be made out of a non-ferrous material.
- It should not be bulky, it should be easy to carry with someone.
- The tip of the device should be fabricated with plastic or ceramic material.
- The device must come sterile upon first use.
- It should be a single-use device.
- The tip must be sharp enough to piece the skin and the cricothyroid membrane.
- The width of the tip should be more than 14 gauges thick.
- The handle end of the device should be adaptable to a bag valve mask and/or facilitate a person breathing into it.
- Once the airway is created, the device should be capable of exchanging 5000mL of air every 3 seconds.
- The device should be marked to indicate the depth inserted.
- The overall cost of the device must remain inexpensive.
- The device should be 3.25 inch in length.

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements:

This device must be able to puncture through the skin and the cricothyroid membrane in a single attempt. The handle end of the device must be adaptable to a bag-valve mask or facilitate rescue breaths delivered by the user. There must be marks indicating the relative depth on the device. For the average male, the device should puncture at a depth of 4.53 ± 0.92 mm in order to successfully go through the cricothyroid membrane. For females, this depth should be 2.89 ± 0.22 mm [6].

The device is single use and should be discarded upon usage. It also should come with instructions in order to make it accessible to a wider population, regardless of medical training.

b. Safety:

This device should be sterile upon initial use. It should be immediately discarded once removed from a patient. It will not be used in conjunction with any anesthetics. If the device is incorrectly inserted, it could lead to a false passage or potentially pneumothorax. Further damage to the trachea and larynx could possibly occur, such as esophageal perforation, aspiration, vocal cord injury. Long term complications include but are not limited to airway stenosis, dysphonia, infections, hematoma, scarring, tracheoesophageal fistula [7].

c. Accuracy and Reliability:

This device should be able to puncture swiftly through the skin and the cricothyroid membrane. As this device will be used for a diverse population, it is expected for the device to puncture at various depths. For the average adult, the device is expected to puncture at a depth of 4.53 ± 0.92 mm for males and 2.89 ± 0.22 mm for females [6]. Upon successful creation of the airway, it should maintain an airway until first responders are on the scene and during the evaluation and care provided by emergency medical services. It should at least maintain an airway for 7 ± 4 minutes for first responders to respond in urban settings and 30 ± 10 minutes for rural areas [8]. As the average scene time for first responders is 14.2 minutes and transport time is 17.5 minutes, the device should maintain an airway for an estimated total time of 38.7 ± 4 minutes in urban areas and 61.7 ± 10 minutes in rural areas [9].

d. Life in Service:

This device will be single use and therefore not require resterilization. It will be in use for up to ten minutes while in interaction with bodily fluids such as blood, saliva, mucus, and acid. The device should be able to undergo travel without concerns of compromising mechanics and

material properties, including reaching up to an elevation of 42,000 feet, as planes often fly between 36,000 and 42,000 feet [10]. In addition, the device needs to withstand these conditions for up to 10,000 miles whilst being delivered worldwide [10].

e. Shelf Life:

The device must remain fully functional in storage for 5 years without any deterioration in accordance with the shelf life of a first aid kit. It should be packaged and kept in a sterile and hygienic environment. In addition, the packaging needs to be dust and moisture resistant. Storage conditions include temperatures from 65℉ to 80℉ to comply with standard room temperatures between 68℉ and 77℉ [11]. The device must withstand a humidity of up to 65% in storage [11]. Appropriate storage pressures range from 740-780 mmHg [12].

f. Operating Environment:

The device will need to withstand the force used to puncture the skin, which is dependent on the surface area, the velocity, and the sharpness of the object making contact. In addition, the force of blowing through the device must not cause any damage to the mechanical integrity. The device must withstand humidity levels from 10% to 95% as well as temperature levels between -20℉ to 110℉ [13]. It will be used primarily by physicians and trained medical personnel, but should be adaptable to be used by the general public as well. If the device is placed in a first aid kit, friction against other tools should not jeopardize the integrity of the device.

g. Ergonomics:

The device must be comfortably used in one hand by an average adult. In addition, the grip area on the device should allow for comfortable wrist placement for the user. To ensure no misalignment of the cut, the grip should have an anti-slip surface for contact with the hand.

h. Size:

The device should be as compact as possible, while not compromising on providing adequate ventilation. The size of the airway created should allow for 500mL of air to pass every 3 seconds. Current procedures for a needle cricothyroidotomy call for the usage of a 12-14 gauge needle [14]. Competing devices have a penetrating depth of approximately 15 to 20 mm into the trachea [15]. Based on images of competing designs, the dimensions of the entire device can be approximated to 12.5 cm x 5 cm x 2.5 cm [15]. This device is intended to be carried by medical personnel and civilians who aim to be prepared in emergency situations. Therefore, it is important that the device be portable and easy to store. Additionally, the device should be small and light enough to be added to a first aid kit easily.

i. Weight:

The device should weigh as little as possible, for portability and material cost reasons. However, it should not be too light as to reduce the durability of the product. Based on the weight of a 10mL syringe often used in competing designs, the device will weigh approximately 25 g [16]. The weight distribution is an important consideration, as deliberate design could make the placement of the device more natural for an inexperienced user. A lighter weight would also facilitate the addition of the device into first aid kits.

j. Materials:

The material used must be biocompatible, and cause no adverse effects during extended contact with the body. As the device is single use, it does not need to be sterilized in between uses, just when produced. The client prefers a ceramic or plastic material, as opposed to metal construction, to aid in portability. The device should not set off a metal detector, for example, in an airport. The tip of the device should be able to hold a sharp point for the shelf life of the device.

k. Aesthetics, Appearance, and Finish:

The device should have a function-focused appearance, with markings to facilitate proper usage and placement of the device. The proper depth of insertion will be marked obviously on the device. An anti-slip texture should be used on the areas of the device in contact with the user's hand, to aid in placement.

1. Production Characteristics

a. Quantity:

This device would be used once per patient. Once it has been touched or taken outside of the sterile wrapping, it can no longer be used. One unit of this product consists of one device. One unit would be placed in every first-aid kit.

b. Target Product Cost:

The client expressed that the target cost to sell this device would be less than $60.00. Pediatric emergency cricothyroidotomy devices retail for roughly $30.00 [17], [18]. Adult emergency cricothyroidotomy devices retail anywhere from $30.00 to over $200.00 [19]–[21]. If the present device were to retail for less than $60.00, it should cost roughly $20.00 to manufacture to ensure profit.

2. Miscellaneous

a. Standards and Specifications:

This device falls under two categories in the Code of Federal Regulations Title 21 set by the U.S Food and Drug Administration (FDA): Emergency airway needle and Retrograde intubation device [22]. Both regulations state that this device is classified as a Class II medical device. In addition, the Retrograde intubation device controls disclose that this device must pass special controls set by the FDA. This device must have valid testing that proves that the device functions as predicted under foreseeable conditions**,** such as compatibility of components that interact, accuracy testing of markings, validation of the maximum airway pressure. This device must also prove its shelf life, ability to remain sterile and functional over the specified shelf life and clear labeling [23].

As this device does not fall under any exemptions set by the FDA, a 510(k) must be filed before the device reaches the market. A 510(k) illustrates that the device is safe, effective and must compare the novel device with a current, legal device on the market in order to substantiate the claims made [24].

In terms of standards needed to acquire for the device, there are several necessary. ISO 10993 is an important standard needed for this device. This standard evaluates the biocompatibility of the device in order to determine and manage the biological harms. There are 24 parts to this standard, but only 10 parts are needed. ISO 10993-1, 3, 4, 5, 11, 13, 18, 19, 20 and 23 are the main parts of the overall standard required for this device [25, p. 10]. ISO 4135:2022 is another prominent standard expected of the device. This standard discloses the vocabulary and the meanings used for respiratory equipment and related devices [26]. Because this device is considered an intubation device, ISO 5366:2016 is necessary. Typically for tracheostomy tubes, this standard specifies the requirements for tracheostomy tubes and other devices that create artificial ventilation or assist ventilation in other ways [27]. Another standard in relation to general airway equipment that is necessary is the ISO 18190:2016, which discloses the requirements of airway and respiratory equipment [28].

In relation to the sterilization and shelf life of the product, the ISO 11607 must be held. There, specifications for requirements and testing methods for sterile materials and their packaging systems [29].

b. Customer:

As this device should be designed with accessibility and inclusivity, the customer should not only be limited to medical professionals, but the average population. Therefore, it is imperative to include clear, concise directions with the device in order to encourage a normal civilian to use this device in an emergency. Because this should be used with one hand, it should accommodate both left and right handed people. As the client would like the device to be sterile upon initial use, it should be able to withstand an autoclave, carried out at 134°C for 5 minutes [30]. Since this device not only creates an emergency airway but is adaptable to deliver manual or bag-valve rescue breaths, the handle must be adaptable to external attachments.

c. Patient-related concerns:

This device must be sterilized after the manufacturing process. Sterilization ensures that no infection will be conferred to the patient due to the device itself. In order to perform an emergency cricothyroidotomy, an incision must be made in the patient's neck. Any time the skin barrier is broken, the chance of infection increases. Ideally, the skin could be sanitized with an alcohol prep pad or sterilized with chloraprep before any incision is made. However, the client expressed that this device will be quick to use and would only be sold as a single device.

This device has the potential to puncture the dorsal side of the trachea and even puncture into the esophagus. Puncturing the esophagus can lead to aspiration of stomach contents into the respiratory system. This can be fatal. The device should include a clear line of demarkation to illustrate where the device should meet the patient's skin. This line of demarkation will show the provider where to not insert the device past to mediate chances of puncturing the dorsal side of the trachea.

d. Competition:

At a minimum, most emergency cricothyroidotomy devices on the market are sold as a sterile kit containing a scalpel to create an incision, a cuffed endotracheal tube, and tape or a strap to hold the emergency cricothyroidotomy device in place. Some devices require a system of tool insertions, such as a guide-wire and air catheter. All of the commercially available kits feature a metal tool (scalpel or catheter) to create the stoma. This likely leads to the high prices per device. Listed below are devices commonly sold for emergency responders.

Rusch QuickTrach Cricothyroidotomy Kit

This product is a pre-assembled emergency cricothyroidotomy device that features a 10 mm syringe with a stainless steel needle attached to a flexible tube and tube holder [21]. Notably, this product features a 'safety stop' feature on the tube holder that aims at preventing puncture of the back of the trachea. It retails for $212.95.

STATForce Adult Deluxe and Pediatric Field Cric Kit

This commercially available kit features a #10 sterile scalpel, as opposed to a needle, and a trach tube holder [19]. It also contains a 6.0 cuffed endotracheal tube and syringe to inflate the endotracheal tube balloon. Notably, this kit includes an iodine prep pad, face shield for the provider performing the procedure, and a trach hook. It is sold for $29.95. A pediatric version of this kit is available with a 2.5 cuffed endotracheal tube and retails for the same price of $29.95 [18].

The Quick Fix Adult Cric Kit and The Quick Fix Jr.

This kit includes a scalpel, cuffed tube, syringe, forceps, and tape [20]. Notably, the kit contains photo directions for easy review and states the kit comes in a sterile package that takes up “very little space” (5’’x8’’). It retails for $60.95. A pediatric version of this kit includes only a 1.25’’ large bore IV catheter, syringe, and 15 mm endotracheal tube adapter. The pediatric Quick Fix Jr. is sold for $23.95 [17].

US Patent US4677978A- Emergency Cricothyrotomy System and Cricothyrotomy Kit

This patent describes a device that can be inserted into the trachea through an incision. It does not include a method by which to create an incision . This patent features an over-the-needle catheter that is removed after insertion of a guide-wire [31]. From there, the cricothyroid membrane is dilated and an air passage catheter is inserted along the guide-wire. The guide-wire is then removed and the air passage catheter is secured.

US Patent US4438768A- Emergency Cricothyroidotomy Instrument

This patent is a single elongated needle with a sharp point and an accompanying needle holder [32]. The needle features an adapted outer shaft designed to abut the needle holder. The needle holder features ridges designed to hold the device in place. The needle and needle holder are connected by a hinge that allows for pivotal movement of each section to open and close the needle holder.

US Patent US4291690A- Means for Performing an Emergency Cricothyrotomy

This device is a trocar assembly featuring an outer cannula and cutting stylet [33]. Once inserted, it is designed to be inserted two-thirds of the length of the cannula. The device maintains its position in the neck by the flaring distal end of the device.

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B. Fabrication Protocol

The full fabrication protocol is written in inches, to aid with fabrication in the TEAM Lab.

Materials:

- 1” aluminum rod stock, at least 3” long

Tools:

- Manual lathe
- Drop saw
- Vertical milling machine
- Bench grinder

Methods:

A. Machining on Lathe

11. **Setting up the lathe:** Measure the diameter of the aluminum stock. Place the aluminum stock in the chuck with approximately 2 inches hanging out. Insert the cutting tool into the tool post, and set the machine into high gear. Make sure to rotate the chuck while changing gears to allow them to mesh. Pull the spindle lever upwards to start the lathe. Adjust the RPM of the machine to approximately 1000 RPM. If machining the part out of a different material, consult the RPM tool to determine the correct RPM. The chuck should be spinning counterclockwise.
12. **Zeroing the Z-axis:** Do this by moving the tip of the cutting tool towards the face of the part. Once light contact is made, use the x-axis handwheel to move the tool off the face of the part. Stop the machine and zero the z-axis on the DRO. Turn the z-axis handwheel until the DRO reads -0.015”. Zero the DRO again, and face off the part. Make sure to only move the x-axis handwheel when facing off.
13. **Setting the X-axis diameter:** Move the cutting tool along the z-axis until it is along the edge of the part. Slowly turn the x-axis handwheel clockwise until light contact is made against the diameter of the part. Turn the z-axis handwheel clockwise to move off of the part. Make sure not to move the x-axis handwheel at this time. Turn the machine off, and set the x-axis measurement on the DRO to the measured diameter of the stock.
14. **Cutting the major diameter:** Set the x-axis on the DRO to the outer diameter of the part, 0.990”. Moving only the z-handwheel, take the cutting tool down the length of the part, stopping about 0.2” before the spindle. Stop the spindle and measure the diameter of the part. Update the DRO diameter reading if the numbers do not match. Make a final pass to create the actual outer diameter of 0.9843”. Move slowly to ensure a good surface finish.
15. **Cutting the minor diameter:** While taking 0.03” cuts, move the cutting tool to -0.7800 in the z-axis. Continue cutting until a diameter of 0.25” in reached. This should take about 26 cuts. Now do the final pass. Set the x-axis to the final part

diameter, 0.2362. Move the cutting tool down the length of the part until the final length is reached, -0.7874”. Slowly turn the x-handwheel counterclockwise to remove the cutting tool from the face.

Figure B1: Turning the minor diameter (smaller end) of the device on the lathe.

16. **Spot drilling the minor diameter channel**: Remove the cutting tool from the tool post. Place the keyless chuck into the tailstock. Secure the spot drill into the chuck. Move the tailstock towards the part, lock it in place. Touch the spot drill to the face of the part and zero the digital readout. Retract the chuck away from the material and turn the spindle on at approximately 800 RPM. Spot drill until a readout of -0.04” is reached.
17. **Drilling the minor diameter channel:** Next, the 0.1572” diameter channel will be drilled out. Use a 5/32” bit, or a more accurate drill bit if available. Turn the spindle on at 1000 RPM. Peck drill until a depth of approximately 1.000”. Make sure to completely remove the bit out of the hole while drilling to remove debris.

Figure B2: Drilling out the channel in the minor diameter of the device.

18. **Cutting off excess stock:** Using the drop saw, cut the excess stock off of the part. For aluminum, the drop saw should run at 200 RPM. Leave an extra 0.1” or so the

part can be machined to it's final length. For example, the final part length is 1.6929", so make the cut at 1.8"

19. **Cutting the part to its final length:** Measure the length of the major diameter section. Place the part back in the lathe chuck, with the major diameter facing outwards. Set the cutting tool into the tool post, and face off the part. Set the z-axis DRO to the measured length. Taking 0.03" cuts, cut the length of the part down to 0.92". On the final pass, take a cut at 0.9055", moving the x-handwheel slowly to ensure a good surface finish.
20. **Spot drilling the major diameter channel:** Remove the cutting tool and place the spot drill into the keyless chuck. As before, zero the spot drill against the face of the material. At 800 RPM, spot drill until a depth of -0.04".
21. **Drilling the major diameter channel:** Finally, the 0.8661" diameter channel will be drilled. Use a 55/64" bit, or a more accurate drill bit if available. Turn the spindle on at 275 RPM. Peck drill until a depth of approximately 0.7874". Make sure to completely remove the bit out of the hole while drilling to remove debris. Next, replace the bit with an flat end mill of the same diameter. At as slow an RPM as possible (~237 RPM), drill down to the same length as before. This creates the flat bottom of the channel

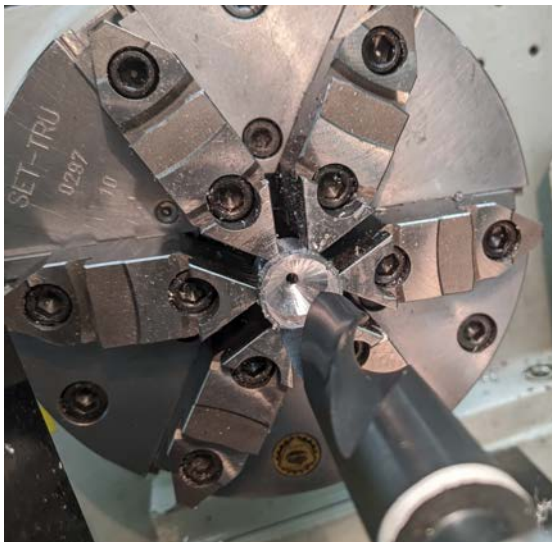

Figure B3: Drilling out the channel in the major diameter of the device.

22. **Part Deburring:** Move the carriage away from the chuck. Then, at 300 RPM, use a file to knock off the sharp edges. File down all sharp edges, on both sides of the part. Use swivel head deburring tools to clean up the inside of the minor diameter channel.

B. Machining on Mill

8. **Setting up the Mill:** Place the piece in a 63/64" collet block to secure it. Using a 45° angle block, clamp the piece down at an angle. Place a ½" 2-flute aluminum endmill in the collet, and load the collet into the spindle.

9. **Zeroing the z-axis:** Align the tip of the part with the drill bit. Turn the mill on at 1000 RPM. Raise the z-axis upwards until contact is made with the part. Zero the z-axis on the DRO.
10. **Creating angled edge:** Removing ten thousandths of material in each pass (0.01”), begin taking material off the end of the tip. Make sure to use cutting oil for lubrication and cooling. One may need to move the part in the x and y axes to ensure the entire tip is machined. Move more slowly as you begin taking off more material with each pass. Stop when a z depth of -0.167” is reached.

Figure B4: Using the mill to create the sharp angled edge of the device.

11. **Removing the endmill:** Remove the part from the clamp and turn it over so that the longer end of the needle is facing upwards. Reclamp the piece and lower the table. Ensure that the quill is all the way up and locked, then remove the collet and endmill. Load the keyless chuck into the spindle and place the edge finder into the chuck.
12. **Zeroing the y-axis:** Maneuver the table and quill until the edge finder is along the side of the shaft. Turn the mill on at 800 RPM. Slowly move the edge finder until it makes contact with the side of the shaft closest to you. Keep going until the edge finder begins to break the other way. Raise the quill and zero the y-axis on the DRO. Compensate for the radius of the edge-finder by setting the y-readout to 0.250”, then zero again. Next, use the edge finder to locate the edge of the other side of the shaft. Make sure to compensate for the radius of the edge finder. Note the diameter of the shaft you just found. Zero the y-axis again, so that it it zero at the edge of the shaft. Move the y-axis the distance of the radius of the shaft and zero it one last time.
13. **Zeroing the x-axis:** Place the edge finder near the tip of the shaft, where the y-axis DRO reads 0.0000. Gradually turn the x-handwheel until the edge finder

makes contact, then breaks the other way. Zero the x-axis on the DRO. Remove the edge finder from the keyless chuck.

14. **Spot drilling supplementary airflow channel:** Place the spot drill into the keyless chuck. Move the part until the DRO reads 0 in the y-axis and -0.345 in the x-axis. Bring the quill down until it touches the part, then zero the quill readout. Turn on the spindle at a speed of 1000 RPM. Tap the spot drill until it just makes contact. Make sure not to drill too far as to make a spot drill hole which is larger than the drilled hole. Remove the spot drill from the keyless chuck.
15. **Drilling the supplementary airflow channel:** To create the supplementary hole, which has a 0.0787” diameter, use a 5/64” bit , or a more accurate drill bit if available. Lower the quill until the bit touches the part and zero the quill readout. At 1500 RPM, drill through only one side of the shaft, approximately a depth of 0.03935”.

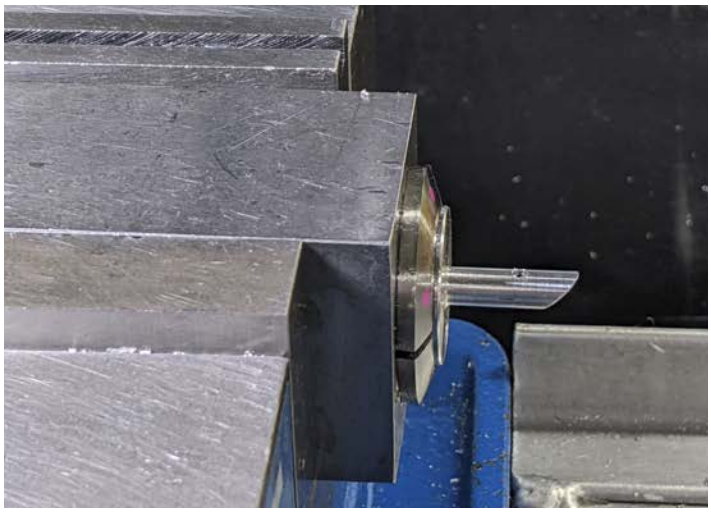

Figure B5: Drilling the supplementary airflow channel using the mill.

16. **Part Deburring:** Use a file to deburr the angled edge created. Use a swivel head deburring tool to reach the inner portion of the angled edge. Finally, use a countersink deburring tool to clean up the supplementary hole.

C. Sharpening on Bench Grinder

2. **Creating a Beveled Edge:** Using a bench grinder or other sharpening tool, grind each side of the tip of the device to a 45° angle. This creates a sharp point similar to that of a hypodermic needle.

C. <u>Feedback Survey</u>

A. On a scale of 1 to 5, how approachable is this device? (1 being completely intimidated by this device, 5 being able to slip into pocket and use comfortably)

B. On a scale of 1 to 5, how prepared do you feel to use this device? (1 being needing extensive/higher level education training, 5 being able to use this device within a minute's notice)
C. On a scale of 1 to 5, how much force do you imagine you would need to apply to use this device? (1 being immense force, needing to rely on a strong, muscular user, 5 being as much force to push a fluid out of a syringe)
D. On a scale of 1 to 5, how confident are you that you could identify the cricothyroid membrane using the directions provided (1 being extremely unconfident, 5 being extremely confident)
E. Using the directions provided, how long do you think it would take you to identify the cricothyroid membrane (please provide in minutes)

D. Puncture Testing Protocol

Materials

- Dr. Meter ES-PS01 Force Gauge
- 3 clamps
- Plastic skin mimetic
- Cricothyroidotomy device(s)
- Embroidery floss

Protocol

1. Clamp skin mimetic between 2 tables using clamps, pull taught
2. Clamp force gauge onto the table
3. Create a loop of embroidery floss, double knotted
4. Connect the cricothyroidotomy device and the hook on the force gauge using the embroidery floss loop
5. Place the tip of the cricothyroidotomy device onto the surface of the skin memetic and pull taught
6. Zero force gauge
7. Cricothyroidotomy device pushed fully through the skin memetic, simultaneously record the max force needed to push the device through
8. Reset the cricothyroidotomy device at a different part of the skin mimetic for a new piercing
9. Repeat steps 5-8 for all trials

10. Convert lbs of force from force gauge to newtons

E. MTS Testing Protocol

Porcine Tissue Prepping protocol:

1. Acquire porcine larynx tissue, with external adipose tissue
2. Remove excess tissue from larynx with a scalpel
    a. Ensure that the cricothyroid membrane is intact and undamaged
3. Trim the trachea to 4 inches
4. Place larynx in a bag and soak tissue in 0.9% saline solution
5. Freeze sample at -80℃
6. Thaw sample in heat bath, heated to 23℃ 1 hour before MTS testing
7. Remove sample from bag and pat dry to remove excess solution
8. Trim sample to fit in a petri dish with the cricothyroid membrane in the middle
9. Adhere with Loctite 401 glue
10. Hydrate the larynx every 5 minutes with 0.9% saline spray

MTS test protocol for use with the MTS Inspiron machine:

1. Attach the 50 N load cell
2. Attach the custom 3D printed grip to the metal prototype and the MTS grips
3. Place the porcine tissue on a petri dish
4. Set up the petri dish under the load cell with the cricothyroid membrane directly beneath the prototype
5. Open the compression test file on TW Elite
6. Set the test rate to 3.00 mm/s, strain end point to 6.000 mm/mm, and the data acquisition rate to 10.0 Hz
7. Lower the prototype and load cell to just touch the porcine larynx
8. Zero the system
9. Click play on the TW Elite software
10. Watch for a spike of force on the graph or for a puncture in the larynx

F. User Feedback Survey Data

Table F1: Data from the User Feedback Survey.

Student	Q1: How approachable is this device?	Q2: How prepared do you feel to use this device?	Q3: How much force do you imagine you would need to use the device?	Q4: How confident are you that you could identify the cricothyroid membrane?	Q5: How long do you think it would take you to identify the cricothyroid membrane? (minutes)
1	3	3	2	3	2
2	4	3	3	2	1.5
3	5	3	2	2	1
4	5	3	3	4	1.5
5	4	3	4	5	1
6	3	3	4	4	0.5
7	5	2	2	3	1
8	2	2	3	2	0.5
9	2	3	3	3	1.5
10	2	4	4	2	0.5
11	3	2	2	3	1
12	3	4	4	3	1.5
13	3	2	3	3	1
14	4	2	3	5	1
15	3	3	2	4	1
16	3	2	3	4	2
17	2	2	2	3	1
18	1	4	2.5	5	1
19	1	2	4	2	2
20	2	2	4	2	2
21	4	3	5	3	3
22	2	3	2.5	2	2.5
23	2	3	4	2	4
24	2	3	1	2.5	1.5

G. <u>User Feedback Survey Statistics</u>

Table G1: Statistics for each question of the user feedback survey.

	Question 1	Question 2	Question 3	Question 4	Question 6
Median	3	3	3	3	1.25
Mean	2.916666667	2.75	3	3.0625	1.479166667
SD	1.176459932	0.6756639247	0.9539474039	1.024827663	0.8272422318
Min	1	2	1	2	0.5
Q1	2	2	2	2	1
Q3	4	3	4	4	2
Nax	5	4	5	5	4

H. Material Expenses

Table H1: Material expenses for prototype development.

Item	Description	Supplier	Part/ Model #	Date	QTY	Cost Each	Total	Link
PLA Print of Design	3D printed prototype that will be utilized in initial testing.	UW-Maker space		10/16	1	$0.16	$0.16	Link
3D Print of Trachea	3D printed representation of trachea for modeling purposes.	UW-Maker space		10/27	1	$6.24	$6.24	Link
3D Print of Larynx	3D printed representation of larynx for modeling purposes.	UW-Maker space		10/27	1	$10.41	$10.41	Link
PLA Print of Prototype	3D printed re-dimensioned prototype to be used in testing.	UW-Maker space		11/8	1	$0.38	$0.38	Link

PLA Print of Prototype	3D printed re-dimensioned prototype to be used in testing.	UW-Maker space		11/17	1	$0.48	$0.48	Link
Porcine Larynx	Fresh porcine larynx used in testing on the MTS machine.	USDA Meat Plant		11/28	1	$10	$10	Link
3D printed grips for the MTS machine	3D printed grips to be used in testing on the MTS machine.	UW-Maker space		12/1	3	$0.67	$2	Link
TOTAL:								**$29.67**