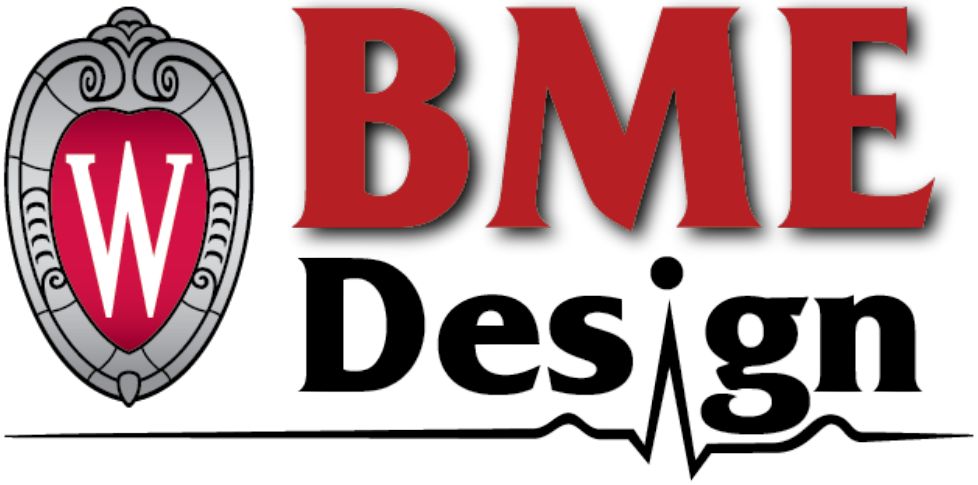


Emergency Cricothyroidotomy

Preliminary Report

Biomedical Engineering Design 400
Department of Biomedical Engineering
University of Wisconsin – Madison
Oct 13, 2023

Team Members:
Zac Mayhew – Leader
Annika Rossebo – BSAC
Mateo Silver – BWIG
Katerina Smereka – Communicator
Megan Finell – BPAG

Client:
Dr. Lenard Markman
Private Client

Advisor:
Dr. Darilis Saurez-Gonzalez
Department of Biomedical Engineering
University of Wisconsin – Madison

Abstract

Each year thousands of people die from choking related accidents. A majority of these deaths are elderly and children who are already more vulnerable than the rest of the population. 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 would help alleviate the current issues by simplifying the process by creating 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 should create and maintain the airway without needing multiple tools. It would also be made out of a non ferrous material so it will be affordable and able to be brought anywhere such as an airport. Testing will be conducted using non-biological laryngeal replicas to ensure its accuracy. Strength testing will also be performed to ensure the material will be able to withstand the force needed to penetrate the skin and cricothyroid membrane.

Introduction

Motivation:

Each year over 5000 people die from choking related accidents. Of those 5000 people, a majority are the most vulnerable ages of one to three and sixty years old 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 falls unconscious [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 is made 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’’x8’’). It retails for $60.95. A pediatric version of this kit includes only a 1.25’’ large bore IV catheter, syringe, and 15mm 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.

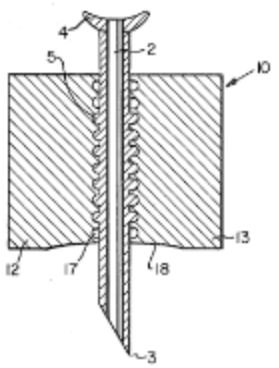


Figure 3: Emergency Cricothyroidotomy Instrument Assembled [13]

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 cmH_2O, whereas the pressure in the stomach typically measures to be 57 ± 17cmH_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 cricothyroid membrane is an intrinsic ligament located in the larynx, supporting the cartilaginous skeleton. It connects the thyroid cartilage with the cricoid cartilage [22]. 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 [23].

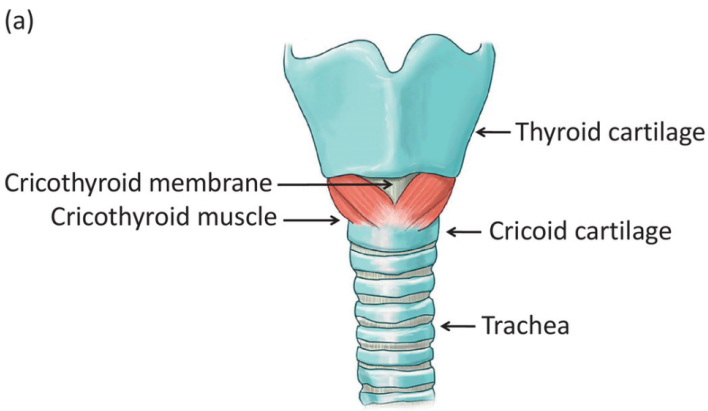


Figure 5: Anatomy of the larynx [24, p. 2]

In the average male, in the neutral position, the mean height of the cricothyroid membrane is 7.71 ± 1.38mm and 6.41 ± 1.28mm in females. When the cricothyroid membrane is fully extended, the average height for males is measured to be 10.16 ± 1.48mm and 8.72 ± 1.19mm in females [25]. In the pediatric population, the average height of a cricothyroid membrane for a patient less than 2 years old is 1.7 ± 0.3mm, for a patient in the 2 year old to 6 year old age range, the cricothyroid membrane height is 1.4 ± 0.3mm and for a patient above the age of 6, the cricothyroid membrane is 1.5 ± 0.2mm [26]. The average diameter for the cricothyroid membrane in adults is 0.94 ± 0.32cm, with no gender differences observed [27]. The depth of the cricothyroid membrane measures to be 10.6mm in adults with a normal weight (BMI $\leq 25\ kg \cdot m^{-2}$) and 18.0mm in adults with severe obesity (BMI $>45\ kg \cdot m^{-2}$) [28].

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 3mm in thickness [29]. In adolescent subjects, the average coronal tracheal diameter is 15.5 ± 2.8mm for males and 14.4 ± 1.6mm for females. For the 20-29 year old population, the average coronal tracheal diameter is 18.7 ± 2.0mm in males and 15.7 ± 1.6mm 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 [30].

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 [31]. 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 [32]. 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 [33]. 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 5mm 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 [34]. 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 [35].

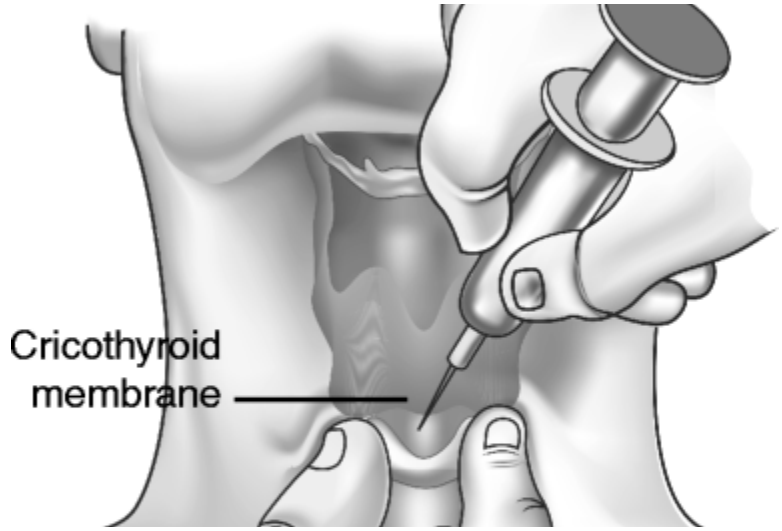


Figure 6: Schematic of an cricothyroidotomy puncture [36]

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% [37]. 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 [38]. Survival rate of cricothyroidotomy is 66.6% and of patients of failed cricothyroidotomy, 33% survive, where other methods of securing an airway were used [37].

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 [39]. For females, the average success rate of correct identification of the cricothyroid membrane is 71% in non-obese subjects and 39% in obese subjects [27]. Success rate significantly increases with the addition of ultrasonography, roughly 95% success rate, regardless of patient age, gender or weight [40].

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 [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: PDS.**

Preliminary Designs

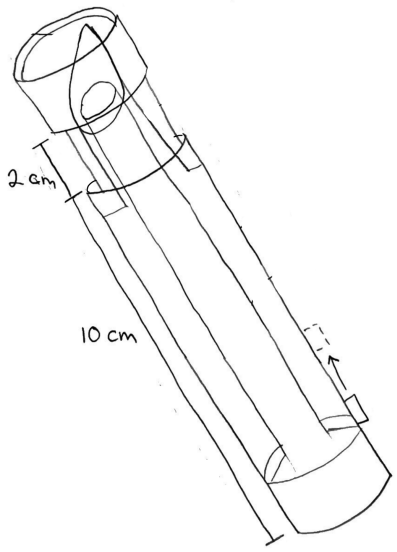


Figure 7: Preliminary Design #1, The Lancet

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.

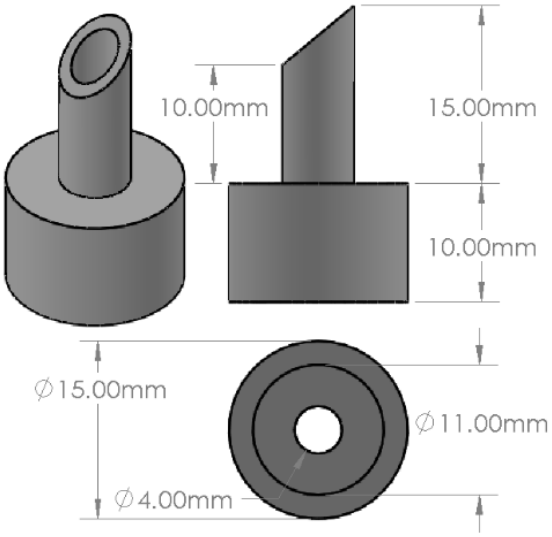


Figure 8: Preliminary Design #2, The Hole Puncher

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 15mm 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.

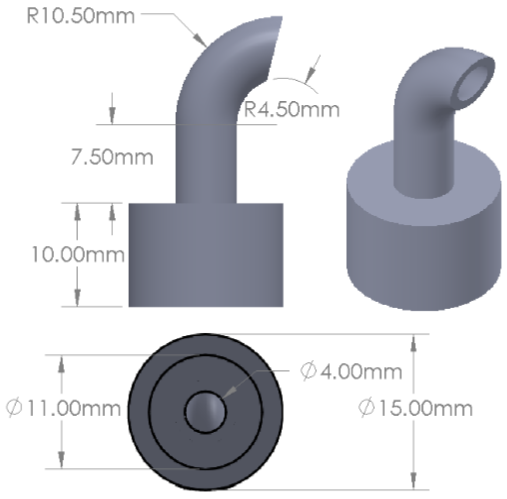


Figure 9: Preliminary Design #3, Captain Hook

Captain Hook

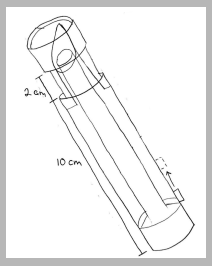
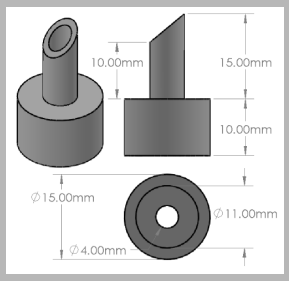
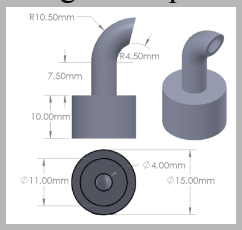
This design is an iteration on the Hole Puncher, with a greater emphasis on ergonomics and device usage. This device features the same sharp beveled edge for puncturing, a flange to avoid injury during placement, and a point to attach a BVM. The addition of a curve helps guide

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.

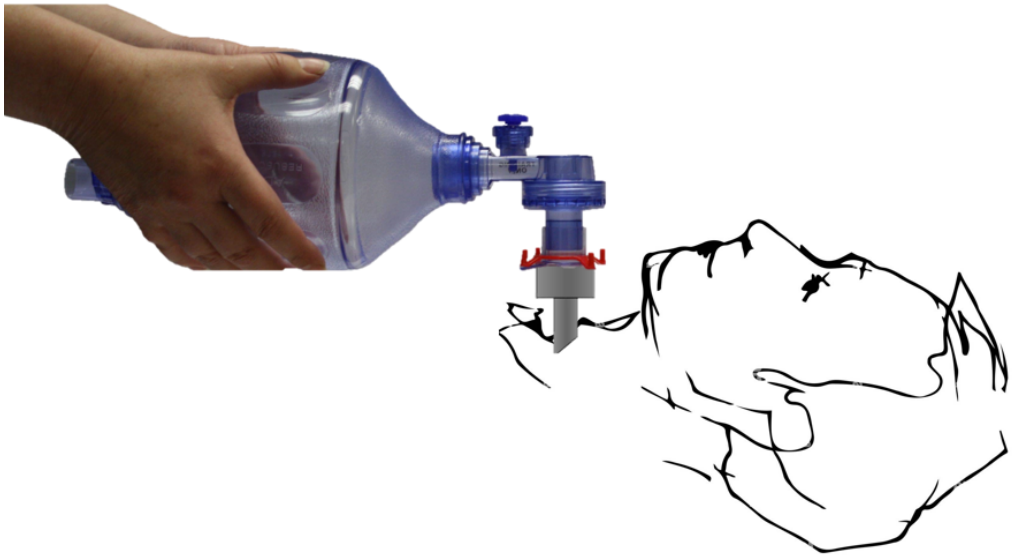


Figure 10: A schematic of how the proposed final design (gray) will interface with a bag valve mask and human anatomy [44], [45].

Fabrication

Materials:

The device must create the emergency airway in one motion and rest in a patient's airway. Therefore, it is important to have a homogenous device possessing material properties that withstand the forces applied to create the airway and have a high durability. In addition, the

plastic chosen should be sharp, strong, and rigid. Multiple materials have been selected as candidate materials, and will be evaluated through 3D printing and testing. The first is polyvinyl chloride (PVC), which is a material commonly used in endotracheal breathing tubes [46]. It is latex-free and easily sterilized. It also is quite transparent, allowing for visual contact with flow, upon insertion [47]. It has a tensile strength of 7500 psi and a flexural modulus of 481 kpsi. Its density measures to be 1.41 g/cm^3 [48]. Research suggests that PLA is the most eco-friendly, cost effective, and commonly used plastic for 3D printing [49]. It has high strength, density, and stiffness which makes it a suitable plastic for the application. Another material of interest for fabrication is medical grade polypropylene. This material is commonly used in disposable plastic syringes [50]. It has a density of 0.930g/cc and has an average thickness of 88.9μm. Its yield tensile strength is an average of 31.6 MPa and has a modulus of elasticity of 1.67 GPa. Its flexural modulus measures 1.43GPa [51].

Additional printing materials could include acetal, which is a strong and rigid plastic with excellent machinability, or teflon, which can have precise components with sharp edges [52]. In addition to the puncturing device, the final design will require a cap to place over the blade. This should also be made of a similar material and be non-ferrous. To properly test the design, the team may also need to acquire a bag valve mask through purchase. The final design and manufacturing process will require sterile packaging.

Methods:

Before developing the chosen design, the team will first begin rapid prototyping to evaluate the efficacy of the initial design. This will involve using household items or materials such as plastic straws to loosely represent the device and plastic wrap pulled tight to simulate biological membrane. Next, a SolidWorks model of the device with proper dimensioning will allow for 3D-printing of the design. After 3D-printing, the team will make improvements to the CAD model and finalize drawings for preliminary prototyping. Once design modifications are made, holes will be cut in the beveled side of the device using a milling machine. Next, the use of a sander will allow for sharpening of the beveled plastic blade and smoothing of other surfaces. Several rounds of prototyping will occur to ensure modifications can be made throughout each iteration. This will guarantee the most effective and functional final product as a solution.

Testing:

An in-depth testing protocol will need to be developed to ensure that the device has been tested under several forces, depths, angles of insertion, environments, and conditions before being used with human subjects. Basic grip tests will be performed to determine the strength of the plastic and that the device will not be crushed by the user. In addition, deformation tests will be necessary to evaluate how the strength of the blade holds up against skin and tracheal interactions when puncturing. Initial testing will include stabbing the device into a non-biological replica of a trachea. This movement will be repeated many times to measure the

accuracy and replicability of the procedure. Lastly, static testing will be conducted on the airway that the device makes. Comparing the volume of air flowing through the device is important to evaluate its efficacy in mimicking normal lung volume in a healthy individual.

Once the device has passed initial testing in non-biological models, it will be tested with porcine tracheas. These models will include securing the trachea and wrapping it with artificial human skin to best represent an authentic situation. A similar procedure of puncturing the skin and trachea with the device will be performed as was with the non-biological model to determine the effectiveness. Ideally, future testing will also be performed on cadavers or intact skin-tracheal complexes to determine any limitations of the device.

Discussion

It is important to note that this device will need to be used in emergency situations where use of this device could mean life or death for the choking person. The packaging and design should be fairly intuitive for the lay-person, even if the person utilizing the device does not speak english. Universal drawings or symbols should be utilized for directions, similar to how automated external defibrillators (AEDs) feature universal symbols to demonstrate the steps of usage [53].

The novelty of this design is the non-ferrous competition. Current market devices contain ferrous metal of some sort, whether that be a metallic tip used to puncture skin, or a scalpel used to create an initial incision. Additionally, this device will be able to articulate with a bag valve mask which is commonly carried by first responders.

Testing has not yet been completed, so no sources of error for testing could be identified. One possible source of error in the initial design was the size and measurements of the designs. After meeting with the client to present the initial design, he stated that if the shaft of the device was longer, the device could also be used in an emergency in the case of a tension pneumothorax. The client stated that even though being used for a tension pneumothorax is not a requirement, it would be beneficial.

The client envisions any lay-person being able to use this device in the case that the Heimlich maneuver is unsuccessful at dislodging the foreign body, or in the case of other tracheal trauma. In Wisconsin, if the device were used by a lay-person and the lay-person causes undue injury to the choking victim, the lay-person could not legally be charged with injuring the victim. Wisconsin Law 895.48(1) states that any person who in good faith renders emergency care to another individual cannot be held civilly liable for any actions or omissions while rendering that care [54].

This device has potential to have a global impact because, while it would be used in day to day life, it also has potential to be carried by those with severe allergies and also those in

military conflict. The client envisioned this device being carried by those who are at risk for anaphylaxis, which would close the airway [14]. Ideally, the device would be small enough to carry beside an EpiPen. Multiple cricothyroidotomy devices are used in the military and having a small, intuitive device has the potential to save lives around the world [13], [55].

Conclusion

The purpose of this device is to create a single use, simply-designed, non-ferrous device to be used to create an emergency airway in the cricothyroid membrane in cases of tracheal blockage. Blockage could be due to a foreign body, anaphylaxis, or other tracheal trauma. This device will be able to articulate with a bag valve mask that is carried by EMS personnel. The proposed final 'hole puncher' design is a straight, hollow, plastic tube that features a sharp bevel with which the skin and trachea are punctured.

Initial prototyping will be completed using 3D printing. The 'hole puncher' design will be 3D printed and shown to the client. From there, the client and team will decide which changes or modifications to make to the design. Likely, a second 3D printed prototype will be fabricated following these modifications.

Once an initial prototype has been established, testing will begin. Porcine tissue will be acquired to test the ability of the device to puncture the skin and tracheal tissue. Ease of use will be qualitatively evaluated. In addition, a skin mimetic device may be purchased to further test ease of use and efficacy of the device. A design requirement set by the client states that 500mL of air needs to be able to be exchanged by the device every 3 seconds. A testing plan will be established to quantitatively measure the airflow into the device to determine if the device meets the design criteria. Lastly, a bag valve mask will be acquired to test how well the device will be able to articulate with it.

It is important to consider the end user when testing and remodeling the device. A qualitative survey will be written and distributed to 'lay-people' who have no medical experience, as well as first responders who have lengthy emergency medical experience. This device should be intuitive for lay person usage and be able to safely and efficiently articulate with other emergency devices, such as the bag valve mask. The survey would aim to find if the user understands when and how the device would be used, as well as if they would be likely to use this device in a true emergency situation.

References

[1] S. A. Duckett, M. Bartman, and R. A. Roten, "Choking," in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2023. Accessed: Sep. 19, 2023. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK499941/

[2] J. A. Ojeda Rodriguez, M. Ladd, and D. Brandis, "Abdominal Thrust Maneuver," in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2023. Accessed: Oct. 11, 2023. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK531467/

[3] "Choking - unconscious adult or child over 1 year: MedlinePlus Medical Encyclopedia." Accessed: Oct. 11, 2023. [Online]. Available: https://medlineplus.gov/ency/article/000051.htm

[4] "Emergency Medical Services Response Times in Rural, Suburban, and Urban Areas - PMC." Accessed: Sep. 19, 2023. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5831456/

[5] "CPR - adult and child after onset of puberty: MedlinePlus Medical Encyclopedia." Accessed: Sep. 30, 2023. [Online]. Available: https://medlineplus.gov/ency/article/000013.htm

[6] J. Borke, "Emergency airway puncture - series - Normal anatomy: MedlinePlus Medical Encyclopedia," MedlinePlus. Accessed: Sep. 19, 2023. [Online]. Available: https://medlineplus.gov/ency/presentations/100113_1.htm

[7] "STATForce Adult Deluxe Field Cric Kit," QuadMed, Inc. Accessed: Sep. 19, 2023. [Online]. Available: https://quadmed.com/statforce-adult-deluxe-field-cric-kit/

[8] R. J. Melker, "SYSTEMAND CRICOTHYROTOMY KIT"

[9] "Rusch QuickTrach Cricothyrotomy Kit," QuadMed, Inc. Accessed: Sep. 19, 2023. [Online]. Available: https://quadmed.com/rusch-quicktrach-cricothyrotomy-kit/

[10] "STATForce Pediatric Field Cric Kit," QuadMed, Inc. Accessed: Sep. 19, 2023. [Online]. Available: https://quadmed.com/statforce-pediatric-field-cric-kit/

[11] "The Quick Fix Adult Cric Kit," QuadMed, Inc. Accessed: Sep. 19, 2023. [Online]. Available: https://quadmed.com/the-quick-fix-adult-cric-kit/

[12] "The Quick Fix Jr.," QuadMed, Inc. Accessed: Sep. 19, 2023. [Online]. Available: https://quadmed.com/the-quick-fix-jr/

[13] R. W. Barrickman, "Emergency cricothyroidotomy instrument," US4438768A, Mar. 27, 1984 Accessed: Sep. 19, 2023. [Online]. Available: https://patents.google.com/patent/US4438768/en

[14] E. O Cathain and M. M. Gaffey, "Upper Airway Obstruction," in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2022. Accessed: Oct. 12, 2023. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK564399/

[15] C. Wang, Z. Wang, and T. Wang, "Blunt myocardial injury and gastrointestinal hemorrhage following Heimlich maneuver: A case report and literature review," *World J. Emerg. Med.*, vol. 13, no. 3, pp. 248–250, 2022, doi: 10.5847/wjem.j.1920-8642.2022.038.

[16] C.-M. Chao, C.-C. Lai, and C.-K. Tan, "Gastric Perforation after Heimlich Maneuver," *Am. J. Med.*, vol. 125, no. 6, pp. e7–e8, Jun. 2012, doi: 10.1016/j.amjmed.2012.02.008.

[17] A. Langhelle, K. Sunde, L. Wik, and P. A. Steen, "Airway pressure with chest compressions versus Heimlich manoeuvre in recently dead adults with complete airway obstruction," *Resuscitation*, vol. 44, no. 2, pp. 105–108, Apr. 2000, doi: 10.1016/s0300-9572(00)00161-1.

[18] M. J. Pavitt *et al.*, "Choking on a foreign body: a physiological study of the effectiveness of abdominal thrust manoeuvres to increase thoracic pressure," *Thorax*, vol. 72, no. 6, pp. 576–578, Jun. 2017, doi: 10.1136/thoraxjnl-2016-209540.
[19] M. Bintz and T. H. Cogbill, "Gastric rupture after the Heimlich maneuver," *J. Trauma*, vol. 40, no. 1, pp. 159–160, Jan. 1996, doi: 10.1097/00005373-199601000-00036.
[20] L. Scouter, "The Heimlich Maneuver," ScouterLife. Accessed: Oct. 13, 2023. [Online]. Available: https://www.scouterlife.com/blog//2014/12/the-heimlich-maneuver.html
[21] A. Goodarzi, A. Jalali, A. Almasi, A. Naderipour, R. P. Kalhori, and A. Khodadadi, "Study of Survival Rate After Cardiopulmonary Resuscitation (CPR) in Hospitals of Kermanshah in 2013," *Glob. J. Health Sci.*, vol. 7, no. 1, pp. 52–58, Jan. 2015, doi: 10.5539/gjhs.v7n1p52.
[22] D. P. de Souza, "Cricothyroid Ligament," AnatomyZone. Accessed: Oct. 11, 2023. [Online]. Available: https://anatomyzone.com/articles/cricothyroid-ligament/
[23] "Cricothyroid Ligament Anatomy, Function & Diagram | Body Maps." Accessed: Oct. 11, 2023. [Online]. Available: https://www.healthline.com/human-body-maps/cricothyroid-ligament#2
[24] U. F. O. Themes, "Chapter 2 – Cricothyroidotomy," Anesthesia Key. Accessed: Sep. 30, 2023. [Online]. Available: https://aneskey.com/chapter-2-cricothyroidotomy/
[25] K. Kokulu, E. Alkan, E. T. Sert, H. Mutlu, C. Turkucu, and E. H. Akar, "Determination of the Cricothyroid Membrane Height by Age and Sex and Optimal Tracheal Tube Size," *The Laryngoscope*, Oct. 2023, doi: 10.1002/lary.31102.
[26] S.-A. Cho *et al.*, "Performance time of anesthesiology trainees for cricothyroid membrane identification and characteristics of cricothyroid membrane in pediatric patients using ultrasonography," *Pediatr. Anesth.*, vol. 32, no. 7, pp. 834–842, 2022, doi: 10.1111/pan.14451.
[27] L. Gómez-López, B. Torres, R. Bergé, O. Aguirre, M. Luis, and X. Sala-Blanch, "Ultrasound measurement of anatomical parameters of the upper airway in adults," *Rev. Esp. Anestesiol. Reanim.*, vol. 65, no. 9, pp. 495–503, Nov. 2018, doi: 10.1016/j.redar.2018.05.007.
[28] K. Gadd, K. Wills, R. Harle, and N. Terblanche, "Relationship between severe obesity and depth to the cricothyroid membrane in third-trimester non-labouring parturients: a prospective observational study," *Br. J. Anaesth.*, vol. 120, no. 5, pp. 1033–1039, May 2018, doi: 10.1016/j.bja.2018.02.010.
[29] P. W. Furlow and D. J. Mathisen, "Surgical anatomy of the trachea," *Ann. Cardiothorac. Surg.*, vol. 7, no. 2, p. 255, Mar. 2018, doi: 10.21037/acs.2018.03.01.
[30] E. Breatnach, G. C. Abbott, and R. G. Fraser, "Dimensions of the normal human trachea," *AJR Am. J. Roentgenol.*, vol. 142, no. 5, pp. 903–906, May 1984, doi: 10.2214/ajr.142.5.903.
[31] ATLS Subcommittee, American College of Surgeons' Committee on Trauma, and International ATLS working group, "Advanced trauma life support (ATLS®): the ninth edition," *J. Trauma Acute Care Surg.*, vol. 74, no. 5, pp. 1363–1366, May 2013, doi: 10.1097/TA.0b013e31828b82f5.
[32] P. McKenna, N. M. Desai, A. Tariq, and E. J. Morley, "Cricothyrotomy," in *StatPearls [Internet]*, StatPearls Publishing, 2023. Accessed: Sep. 18, 2023. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK537350/
[33] J. A. Quick, A. D. MacIntyre, and S. L. Barnes, "Emergent Surgical Airway: Comparison

of the Three-Step Method and Conventional Cricothyroidotomy Utilizing High-Fidelity Simulation," *J. Emerg. Med.*, vol. 46, no. 2, pp. 304–307, Feb. 2014, doi: 10.1016/j.jemermed.2013.08.065.

[34] A. MacIntyre, M. K. Markarian, D. Carrison, J. Coates, D. Kuhls, and J. J. Fildes, "Three-Step Emergency Cricothyroidotomy," *Mil. Med.*, vol. 172, no. 12, pp. 1228–1230, Dec. 2007, doi: 10.7205/MILMED.172.12.1228.

[35] J. T. Bucher, R. Vashisht, M. Ladd, and J. S. Cooper, "Bag-Valve-Mask Ventilation," in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2023. Accessed: Oct. 13, 2023. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK441924/

[36] U. F. O. Themes, "Cricothyroidotomy," Radiology Key. Accessed: Oct. 13, 2023. [Online]. Available: https://radiologykey.com/cricothyroidotomy/

[37] Y. S. Kwon, C. A. Lee, S. Park, S. O. Ha, Y. S. Sim, and M. S. Baek, "Incidence and outcomes of cricothyrotomy in the 'cannot intubate, cannot oxygenate' situation," *Medicine (Baltimore)*, vol. 98, no. 42, p. e17713, Oct. 2019, doi: 10.1097/MD.0000000000017713.

[38] E. B. Ner, A. M. Tsur, R. Nadler, E. Glassberg, A. Benov, and J. Chen, "High Success Rate of Prehospital and En Route Cricothyroidotomy Performed in the Israel Defense Forces: 20 Years of Experience," *Prehospital Disaster Med.*, vol. 36, no. 6, pp. 713–718, Dec. 2021, doi: 10.1017/S1049023X21001199.

[39] A. Lamb *et al.*, "Accuracy of identifying the cricothyroid membrane by anesthesia trainees and staff in a Canadian institution," *Can. J. Anaesth. J. Can. Anesth.*, vol. 62, no. 5, pp. 495–503, May 2015, doi: 10.1007/s12630-015-0326-y.

[40] S. E. Nicholls, T. W. Sweeney, R. M. Ferre, and T. D. Strout, "Bedside sonography by emergency physicians for the rapid identification of landmarks relevant to cricothyrotomy," *Am. J. Emerg. Med.*, vol. 26, no. 8, pp. 852–856, Oct. 2008, doi: 10.1016/j.ajem.2007.11.022.

[41] "Cricothyroidotomy | NEJM." Accessed: Oct. 11, 2023. [Online]. Available: https://www.nejm.org/doi/full/10.1056/nejmvcm0706755

[42] M. A. Qawee, "Stevens Point holds anaphylaxis training course to help raise awareness," WJFW. Accessed: Oct. 11, 2023. [Online]. Available: https://www.wjfw.com/news/local/stevens-point-holds-anaphylaxis-training-course-to-help-raise-awareness/article_b935dea0-3874-11ed-997e-83ef23ee04ac.html

[43] "Client Meeting 1 - 09/14/2023," Google Docs. Accessed: Oct. 11, 2023. [Online]. Available: https://docs.google.com/document/d/1r-ZxB_PZNDX3CZJqmqD_8F3GGGyVcJ_eNhJ-PzN-0hA/edit?usp=drive_web&ouid=102138681681923116800&usp=embed_facebook

[44] A. Limited, "black and white vector sketch for a portrait of a young man's profile Stock Photo - Alamy." Accessed: Oct. 12, 2023. [Online]. Available: https://www.alamy.com/black-and-white-vector-sketch-for-a-portrait-of-a-young-mans-profile-image459485225.html

[45] "Amazon.com: CPR Training Bag Valve Mask (BVM) ADULT/CHILD in Mesh Bag, BVM-3081-001 : Industrial & Scientific." Accessed: Oct. 12, 2023. [Online]. Available: https://www.amazon.com/Training-Plastic-MCR-Medical-BVM-3081-001/dp/B00GABWX8K

[46] R. A. Ahmed and T. J. Boyer, "Endotracheal Tube," in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2023. Accessed: Oct. 13, 2023. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK539747/

[47] K. Elastomer, “Medical Grade PVC Tubing - PVC Compound,” Kent Elastomer Products. Accessed: Oct. 13, 2023. [Online]. Available: https://www.kentelastomer.com/pvc-benefits-uses/
[48] “Overview of materials for PVC, Extruded.” Accessed: Oct. 13, 2023. [Online]. Available: https://www.matweb.com/search/datasheet_print.aspx?matguid=bb6e739c553d4a34b199f0185e92f6f7
[49] J. Flynt, “Sanding your PLA Prints: How to Get the Best Results,” 3D Insider. Accessed: Oct. 13, 2023. [Online]. Available: https://3dinsider.com/sanding-pla-prints/
[50] “Disposable Plastic Storage Syringes.” Accessed: Oct. 13, 2023. [Online]. Available: https://www.tedpella.com/Embedding_html/Disposable_Syringes.aspx
[51] “Overview of materials for Polypropylene, Molded.” Accessed: Oct. 13, 2023. [Online]. Available: https://www.matweb.com/search/DataSheet.aspx?MatGUID=08fb0f47ef7e454fbf7092517b2264b2&ckck=1
[52] “POM 3D Printing (Acetal/Delrin) – All You Need to Know,” All3DP. Accessed: Oct. 13, 2023. [Online]. Available: https://all3dp.com/2/pom-acetal-delrin-3d-printing/
[53] “AED Defibrillator for Business | Office | Workplace,” American AED. Accessed: Oct. 12, 2023. [Online]. Available: https://americanaed.com/aed-solutions/business-aed-package/
[54] “Wisconsin Legislature: 895.48(1).” Accessed: Oct. 12, 2023. [Online]. Available: https://docs.legis.wisconsin.gov/statutes/statutes/895/ii/48/1
[55] W. S. Krimsky, C. S. Kothera, A. N. Shah, and G. J. Hiemenz, “Assist device for medical procedures,” US20160220772A1, Aug. 04, 2016 Accessed: Oct. 13, 2023. [Online]. Available: https://patents.google.com/patent/US20160220772A1/en?q=(emergency+cricothyroidotomy+device)&oq=emergency+cricothyroidotomy+device

Appendix

A. PDS

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.
- The device should be 3.25 inches in length.
- 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. A bag valve mask has a diameter of 15mm.
- Once the airway is created, the device should be capable of exchanging 500mL of air every 3 seconds.
- The device should be marked to indicate the depth inserted.
- The overall cost of the device must remain under $30.00

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 20mm 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.

2. 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.

3. 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 demarcation to illustrate where the device should meet the patient's skin. This line of demarcation 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 15mm 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.

References:

[1] S. A. Duckett, M. Bartman, and R. A. Roten, "Choking," in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2023. Accessed: Sep. 19, 2023. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK499941/

[2] "What happens after you choke?," *texasspecialtyclinic*. https://texasspecialtyclinic.com/blogs/what-happens-after-you-choke/ (accessed Sep. 20, 2023).

[3] "Choking: First aid - Mayo Clinic." https://www.mayoclinic.org/first-aid/first-aid-choking/basics/art-20056637 (accessed Sep. 20, 2023).

[4] J. Borke, "Emergency airway puncture - series - Normal anatomy: MedlinePlus Medical Encyclopedia," *MedlinePlus*, Oct. 06, 2022. https://medlineplus.gov/ency/presentations/100113_1.htm (accessed Sep. 19, 2023).

[5] J. Borke, "CPR - adult and child after onset of puberty: MedlinePlus Medical Encyclopedia," Jan. 02, 2023. https://medlineplus.gov/ency/article/000013.htm (accessed Sep. 19, 2023).

[6] "Surgical anatomy of cricothyroid membrane with reference to airway surgeries in North Indian population: a cadaveric study' | International Journal of Otorhinolaryngology and Head and Neck Surgery." https://www.ijorl.com/index.php/ijorl/article/view/1038 (accessed Sep. 19, 2023).

[7] "Cricothyroidotomy: Overview, Periprocedural Care, Technique," Dec. 2022, Accessed: Sep. 18, 2023. [Online]. Available: https://emedicine.medscape.com/article/1830008-overview#showall

[8] "Emergency Medical Services Response Times in Rural, Suburban, and Urban Areas - PMC." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5831456/ (accessed Sep. 19, 2023).

[9] N. P. Ashburn *et al.*, "Prehospital Trauma Scene and Transport Times for Pediatric and Adult Patients," *West. J. Emerg. Med.*, vol. 21, no. 2, pp. 455–462, Mar. 2020, doi: 10.5811/westjem.2019.11.44597.

[10] "How High Do Planes Fly and Who Makes the Call?," *Travel + Leisure*. https://www.travelandleisure.com/airlines-airports/why-do-planes-fly-at-36000-feet-cruising-altitude (accessed Sep. 19, 2023).

[11] "Temperature and Humidity Requirements – Guidance for Storage of Sterile Supplies | Ambulatory | Environment of Care EC | The Joint Commission." https://www.jointcommission.org/standards/standard-faqs/ambulatory/environment-of-care-ec/00001275/ (accessed Sep. 19, 2023).

[12] "Barometric Pressure Forecast and History." http://barometricpressure.app/ (accessed Sep. 19, 2023).

[13] "Outdoor Temperatures and Relative Humidity - US Winter and Summer Conditions." https://www.engineeringtoolbox.com/us-outdoor-design-temperature-humidity-d_296.html (accessed Sep. 19, 2023).

[14] J. Fagan, Ed., "1.27: Cricothyroidotomy and Needle Cricothyrotomy," in *Open Access Atlas of Otolaryngology, Head and Neck Operative Surgery: Volume 1 - Head and Neck*, University of Cape Town Libraries, 2017. doi: 10.15641/0-7992-2534-1.

[15] A. Katayama *et al.*, "Cricothyroidotomy needle length is associated with posterior tracheal wall injury: A randomized crossover simulation study (CONSORT)," *Medicine (Baltimore)*, vol. 99, no. 9, p. e19331, Feb. 2020, doi: 10.1097/MD.0000000000019331.

[16] "Syringe,disp,10ml,w/ndl,21G/BOX-100." https://supply.unicef.org/s0782112.html (accessed Sep. 22, 2023).

[17] "The Quick Fix Jr.," *QuadMed, Inc*. https://quadmed.com/the-quick-fix-jr/ (accessed Sep. 19, 2023).

[18] "STATForce Pediatric Field Cric Kit," *QuadMed, Inc*. https://quadmed.com/statforce-pediatric-field-cric-kit/ (accessed Sep. 19, 2023).

[19] "STATForce Adult Deluxe Field Cric Kit," *QuadMed, Inc*.

https://quadmed.com/statforce-adult-deluxe-field-cric-kit/ (accessed Sep. 19, 2023).
[20] "The Quick Fix Adult Cric Kit," *QuadMed, Inc*. https://quadmed.com/the-quick-fix-adult-cric-kit/ (accessed Sep. 19, 2023).
[21] "Rusch QuickTrach Cricothyrotomy Kit," *QuadMed, Inc*. https://quadmed.com/rusch-quicktrach-cricothyrotomy-kit/ (accessed Sep. 19, 2023).
[22] "CFR - Code of Federal Regulations Title 21." https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=868.5090 (accessed Sep. 19, 2023).
[23] "CFR - Code of Federal Regulations Title 21." https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=868.5095 (accessed Sep. 19, 2023).
[24] C. for D. and R. Health, "Premarket Notification 510(k)," *FDA*, Aug. 15, 2023. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k (accessed Sep. 19, 2023).
[25] "ISO 10993," *Wikipedia*. Sep. 11, 2023. Accessed: Sep. 19, 2023. [Online]. Available: https://en.wikipedia.org/w/index.php?title=ISO_10993&oldid=1174864073
[26] 14:00-17:00, "ISO 4135:2022," *ISO*. https://www.iso.org/standard/75315.html (accessed Sep. 19, 2023).
[27] 14:00-17:00, "ISO 5366:2016," *ISO*. https://www.iso.org/standard/62242.html (accessed Sep. 19, 2023).
[28] 14:00-17:00, "ISO 18190:2016," *ISO*. https://www.iso.org/standard/61728.html (accessed Sep. 19, 2023).
[29] 14:00-17:00, "ISO 11607-1:2019," *ISO*. https://www.iso.org/standard/70799.html (accessed Sep. 19, 2023).
[30] "Tracheostomy-Tubes_IFU.pdf." Accessed: Sep. 19, 2023. [Online]. Available: https://www.premiermedicalco.com/wp-content/uploads/2021/04/Tracheostomy-Tubes_IFU.pdf
[31] R. J. Melker, "SYSTEMAND CRICOTHYROTOMY KIT"
[32] R. W. Barrickman, "Emergency cricothyroidotomy instrument," US4438768A, Mar. 27, 1984 Accessed: Sep. 19, 2023. [Online]. Available: https://patents.google.com/patent/US4438768/en
[33] J. W. Jessen, "Means for performing an emergency cricothyrotomy," US4291690A, Sep. 29, 1981 Accessed: Sep. 19, 2023. [Online]. Available: https://patents.google.com/patent/US4291690/en

B. Material Expenses

Currently, no materials have been purchased for fabrication or testing of the device.

Table 2: An expense table to be filled out following purchases for the device.

Item	Description	Quantity	Cost
Porcine Larynx		1	TBD
Artificial Skin		1	TBD

3D printing prototype	Initial prototype of device made of tough PLA	1	$0.12
			Total cost: $0.12