Title: Evaluation of a Novel Cricothyroidotomy Device for Emergency Airway Creation in Unconscious Choking Patients

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Grants/Financial Support: Financial support provided by Department of Biomedical Engineering at the University of Wisconsin-Madison

Conflicts of Interest: No potential conflicts of interest to disclose

Author Contributions: KAS, MNS, MF, ZM conceived the study, designed the trial and obtained research funding. KAS, MNS, MF, ZM performed data collection. MF performed data analysis. DSG provided advice on study design. KAS, MNS, MF, ZM drafted manuscript.

ABSTRACT

Study Objective: Devices used for emergency cricothyroidotomy often involve multiple tools, complicating the procedure and requiring strenuous training. The Quic Cric aims to simplify this process by serving as a multifunctional device, eliminating the need for various tools and exhaustive training.

Methods: The Quic Cric was designed using SOLIDWORKS and fabricated from aluminum. Testing involved excised porcine tissue, simulating human anatomy. Samples included larynges, tracheas, and skin, layered and fixated to mimic anatomical structures. Four individuals, without prior experience in the procedure, participated in simulations replicating choking scenarios. A t-test was calculated to compare the timing to use the device versus the traditional procedure, and computer simulations assessed airflow capabilities.

Results: Qualitative testing showed high success rates, notably 88.9% for complete tracheal puncture and 100% for cricothyroid membrane identification and puncture on the first attempt. The fixation device improved success rates, especially for thicker tissues like skin. Puncture holes exhibited clean cuts, facilitating unobstructed airflow. The Quic Cric significantly reduced procedure time, averaging 13.062 seconds. CAD simulations confirmed adequate airflow rates of up to 1.5 L/sec ensuring patients would receive adequate airflow following puncture.

Conclusions: The Quic Cric simplifies emergency airway procedures by eliminating the need for additional tools. Future steps include clinician validation and increasing participant numbers for statistical validity.

INTRODUCTION

Background:

A cricothyroidotomy is an emergency medical procedure used when a surgical airway is needed and conventional methods, such as endotracheal intubation are not feasible or have failed. Incidents where a cricothyroidotomy would be performed include, but are not limited to, trauma causing blockage of the upper airway or choking patients that cannot otherwise be intubated[1]. The simplest procedure involves creating a vertical incision through the skin on the patient's neck after locating the cricothyroid membrane. Then a 5 mm horizontal incision is created through the cricothyroid membrane, using a size 10 scalpel for both. Once the incisions have been made, a bougie is advanced through them and into the trachea followed by an endotracheal tube to create a patent airway. Rescue breaths are then provided by a bag valve mask (BVM)[2]. In order to perform the procedure, the provider must have a minimum of a paramedics license[3]. Cricothyroidotomy is an invasive procedure requiring multiple tools and strenuous training to be able to complete.

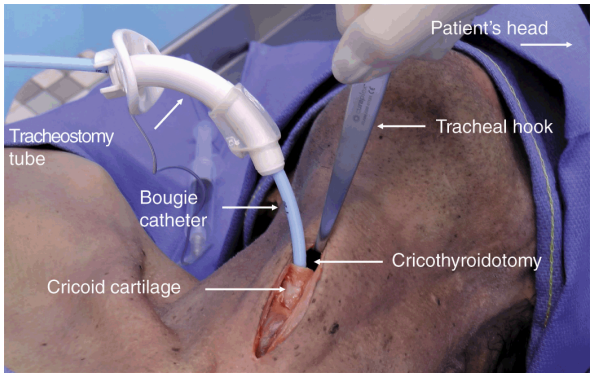

Figure 1: Traditional Cricothyrotomy Performed in a Hospital Setting[4]

Surgical cricothyroidotomy is rarely performed in prehospital settings, accounting for approximately 1% of all prehospital advanced airway management[3]. However, the success rate in prehospital settings is 90.5%, which is on the higher end when compared to other interventions[5]. Following a cricothyroidotomy, patients are given a tracheostomy in the hospital if there is a need for a prolonged use of a breathing tube. If the patient is stable, the breathing tubes are removed and the incision site is allowed to heal[6]

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[7].

The cricothyroid membrane lies between the cricoid and thyroid cartilage in the larynx[8]. Its material properties are much weaker compared to the tough surrounding cartilage, making it the prime target to puncture and create an airway adjunct in emergency situations where the upper airway is obstructed[9]. However, its small size of 10.16 ± 1.48 mm for males and 8.72 ± 1.19 mm in females, makes it difficult to locate and puncture[10]. Success rates of identification upon palpation are around 70% in non-obese patients and 39% in obese patients[11].

Importance

Each year, over 5000 individuals die from choking-related accidents in the United States alone[12]. The first immediate response to a choking person is to perform the Heimlich maneuver[13]. This technique employs a combination of abdominal thrusts and back blows[14]. Should the individual fall unconscious, chest compressions are the only solution[15]. Despite these treatments, their efficacy is not guaranteed, and victims often rely on timely assistance from emergency medical services (EMS)[16]. Clearing of the airway is imperative in order to avoid hypoxia and permanent brain damage[17]. However, the average EMS response time of 7 minutes exceeds the 4 minute window for preventing permanent brain damage in choking incidents[18].

The significance of this device lies in its potential to address a critical gap in emergency medical care by developing an innovative solution to improve outcomes for victims with upper airway obstructions. By providing a user-friendly device, the proposed solution aims to be used in situations where victims require surgical intubation prior to EMS arrival. The Quic Cric could be the difference between a patient suffering irreversible trauma, or even worse, death, due to the lack of oxygen.

Figure 2: Quic Cric attached to a BVM set up in a patient

Goal of This Investigation

The proposed solution involves the development of a streamlined emergency airway device that combines multiple functions into a single, easy-to-use apparatus, called the Quic Cric. This device will aim to create a secure airway through the cricothyroid membrane, serving as both a stoma creation tool and an airway adjunct. The Quic Cric will prioritize simplicity and adaptability, requiring less training to use and allowing for seamless integration with EMS tools like a bag valve mask for continuous patient care.

To evaluate the efficacy and safety of the proposed emergency airway device, porcine skin, tracheas, and larynxes were selected as anatomical models. We aimed to assess the device's ability to penetrate tissues effectively and efficiently without causing excessive trauma or complications.

METHODS:

Novel Device

The Quic Cric was carefully designed to remain inclusive of the neck size of multiple populations. The shank has a length of 20 mm, which was selected to fit the airways of both adult males and females. The average width of a male airway, on the anterior-posterior axis is 25-27mm and the average width of a female airway is 22-23mm[19]. The user end measures 25 mm in outer diameter, 22 mm in inner diameter, with a height of 23 mm. These dimensions were selected in order for the flange to secure to the output valve of a BVM. The final sharpened device is shown in Figure 3.

The Quic Cric was fabricated out of aluminum. Aluminum was chosen for the construction of the device due to its biocompatibility and ability to withstand the heat and pressure of autoclave sterilization[20]. Moreover, aluminum does not rust, making it ideal for a long shelf life and durability[21].

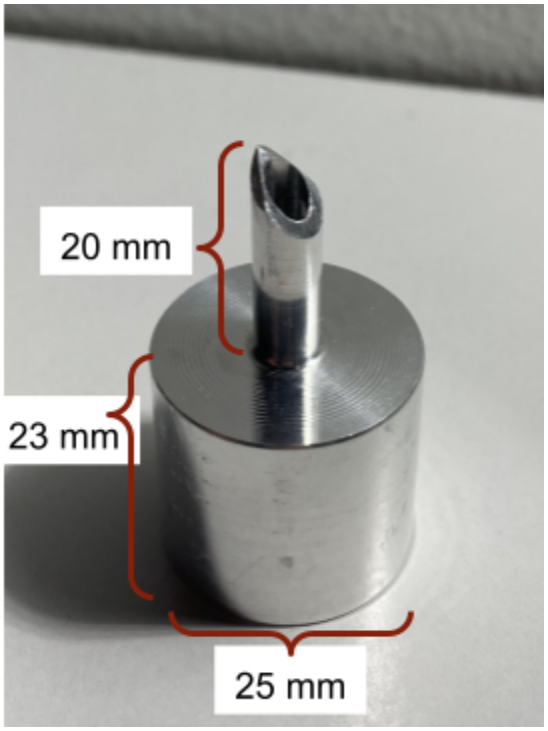

Figure 3: The final device with outlined dimensions

Study Design and Setting

The Quic Cric is designed to provide an alternative treatment to choking victims once they fall unconscious. Ethically, it would be far-fetched to simulate a choking victim in order to test the device in the ideal situation. In consideration, animal models were incorporated to mimic the anatomy of a human.

The investigation was conducted as a non-randomized, small, quasi experimental study including six animal subjects.

Animal Models

Fresh porcine skin purchased from a local butcher was used in this study. The skin was sealed in an airtight container and stored at -12°C. Upon use, the skin was thawed slowly in a refrigerator.

6 excised porcine larynges was included in the study. The porcines were ethically euthanized for purposes unrelated to this study and their larynges were purchased from the University of Wisconsin Meat Science Department (Madison, WI). All guidelines provided by the University of Wisconsin-Madison Institutional Animal Care and Use Committee were followed. The larynges were trimmed of excess tissue. The thyroid glands were removed as well. The trachea was trimmed to 4 cm in length. The larynges were inspected for signs of trauma or other abnormalities. The larynges were placed in 0.9% saline solution and stored in a refrigerator.

Animal Model Preparation

Testing of this device was performed on 1) porcine skin alone, 2) porcine trachea alone, 3) porcine cricothyroid membrane alone, 4) porcine skin on top of the porcine larynx and 5) porcine skin on top of the porcine trachea. Success was quantified as a clean puncture created by the Quic Cric through the tissues in one swift motion. If the device could only puncture through one of the layers or if a small slit was created, the trial was concluded as a failure. The distal end

has an inner diameter of 4mm, therefore, it is anticipated that the puncture wound will be 4 mm in diameter with a tolerance of ± 1mm.

Fixation Device

In order to mimic physiological tension created *in vivo*, a fixation device was created. It consists of a 180 mm by 205 mm base with a channel that runs along the length, with a width of 32 mm. It was created out of ⅛ in aluminum sheet metal. There are 6 screws, 3 on each end. The inner channel is designed to hold the trachea or larynx so that under pressure, the tissue does not flatten. The skin is layed on top and fastened with the screws to provide adequate lateral tension. Figure 4 displays the fixation device with the skin affixed.

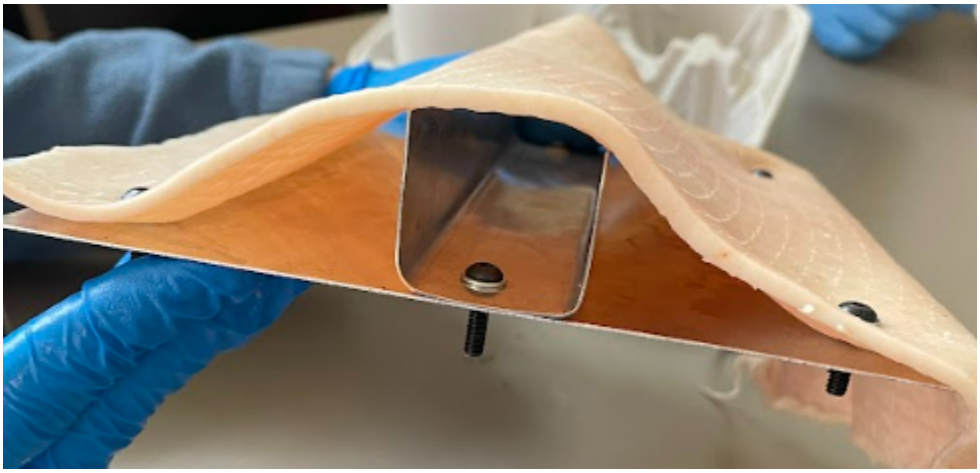

Figure 4: Fixation device with porcine skin attached

Characteristics of Study Subjects

A total of 4 individuals participated in testing of the porcine trachea, larynx, and skin. The participants consisted of two females and two males with an average age of 21.25 ± 0.43

years. One participant is a certified EMS member. None of the participants had previously performed a cricothyroidotomy.

Timing Testing

Participants were recruited to perform the Quic Cric procedure on the animal models. The fixation device was set up to secure the porcine larynx and affix the skin on top. The Quic Cric was bagged to mimic sterilized packaging that would be encountered in a real life application of this device. The subject was blinded to the set up. A study team-member would prompt the participant to begin. The participant had to unbag the Quic Cric, palpate the animal model for the cricothyroid membrane and use the device to create the emergency airway. The timer started once the participant reached for the bag with the device and the timer stopped when the participant was confident that the puncture was created. Validation of puncturing was performed by delivering air through the device and feeling the sides of the affixation device to determine if air was flowing. If a participant was unsuccessful, the trial was noted as a failure and the time was discarded.

Airflow Testing

Airflow testing was completed in SOLIDWORKS (Dassault Systems, Version 2023, Waltham, MA). The wide end fit for the BVM was classified as the inlet and the sharp distal end was designated as the outlet. The input velocity was entered as 12 m/s, which is equivalent to the average air velocity delivered from an adult blowing out of their mouth[22]. Exit velocity of air leaving the shank was estimated using the color key on solid works. After obtaining the exit velocity, flow rate was calculated using the equation $Q = AV$, where A is the cross-sectional

area of the shank and V is the average velocity. The calculated airflow ensured at least 500 mL of air was exchanged every 3 seconds.

Statistical Analysis

The puncture wound was captured and analyzed via ImageJ analysis (National Institutes of Health, Bethesda, MD). Literature values of traditional emergency cricothyroidotomy were synthesized and an average sample was formulated. A t-test was performed to compare the timing of the Quic Cric against traditional hospital values. All descriptive statistics and statistical tests were completed on R Studio (RStudio, Boston, MA). A significance level of $\alpha = 0.05$ was used. A bar graph was created to compare the relative times to complete the cricothyroidotomy. The error bar represents the standard deviation of a group.

RESULTS

Main Results

Puncture Testing

The Quic Cric was validated through qualitative puncture testing of porcine larynges, tracheas, and skin. The tissues were each tested individually and in conjunction with each other. First attempt success at puncturing the porcine trachea was 88.9% of trials, or 8 out of 9 attempts, with the sharpened Quic Cric. All participants stabilized the outer wall of the trachea with their left hand while successfully completing the procedure with the device in their right hand. The external pressure to the trachea minimized changes in the tracheal diameter due to puncture force.

Participants completed six trials on the cricothyroid membrane of porcine larynges. Each participant successfully identified the cricothyroid membrane and punctured the membrane on the first attempt, indicating success. During all attempts, the porcine larynx collapsed under the pressure of the aluminum prototype due to force applied while attempting pressure. The pressure caused displacement of the surrounding laryngeal anatomical structures near the cricothyroid membrane. Every attempt at puncture was completed successfully, according to the criteria above, with the beveled edge of the Quic Cric facing up. Two participants attempted to puncture the skin with the device but failed to make a complete puncture. Multiple indents were observed where the sharp tip of the prototype had contacted the skin. These tests were completed without the testing fixation device.

Next, qualitative puncture testing was performed with the testing fixation device. Each trial tested two types of tissue layered on top of one another. Complete puncture of the cricothyroid membrane and the skin was successful on the first attempt. The skin was difficult to puncture due to its thickness and toughness, as well as a lack of strong tension. The trachea and skin was tested next. The Quic Cric successfully punctured both tissues on the first attempt. Additionally, less force was necessary to puncture the trachea and skin compared to the test on the cricothyroid membrane and the skin. This is likely due to the skin being fixated in higher tension or differences in the thickness and location of the skin.

Size of Puncture Hole

Analysis was conducted on the resulting punctures from the device after procedure completion. The puncture hole size on five larynges had an average width of 3.96 ± 0.234 mm

and an average length of 4.18 ± 0.47 mm. The resulting hole in the cricothyroid membrane is seen in Figure 5.

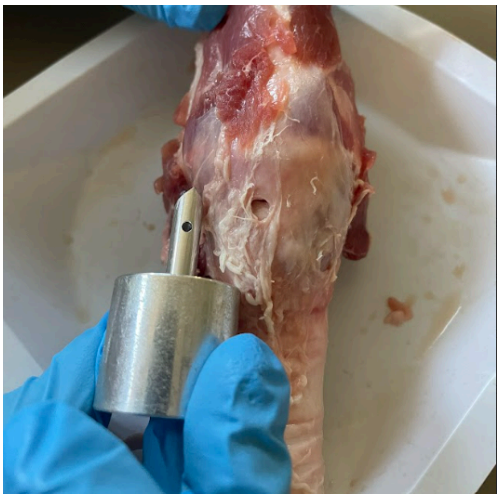

Figure 5: Puncture hole in the cricothyroid membrane

The outer diameter of the shank of the device is 6 mm and the inner diameter is 4 mm. As the diameter of the puncture is about 4 mm, it is likely that the porcine tissue was stretched while being punctured and then retracted as the device was removed. As seen in Figure 5, the Quic Cric made a clean cut with little to no tearing of surrounding tissue. Miniscule amounts of porcine tissue stuck to the inner diameter, indicating no risk of air delivery blockage through the device.

Timing Testing

Timing tests were performed to determine if the Quic Cric saves time in an emergency compared to existing cricothyroidotomy kits on the market. After five trials, results show that the average time to unpackage the Quic Cric, palpate the cricothyroid membrane, and puncture

through the skin and membrane is 13.062 ± 2.312 seconds. Current cricothyroidotomy kits have an average surgical procedure time of 64.83 ± 26.61 seconds, as seen in Figure 6 below.

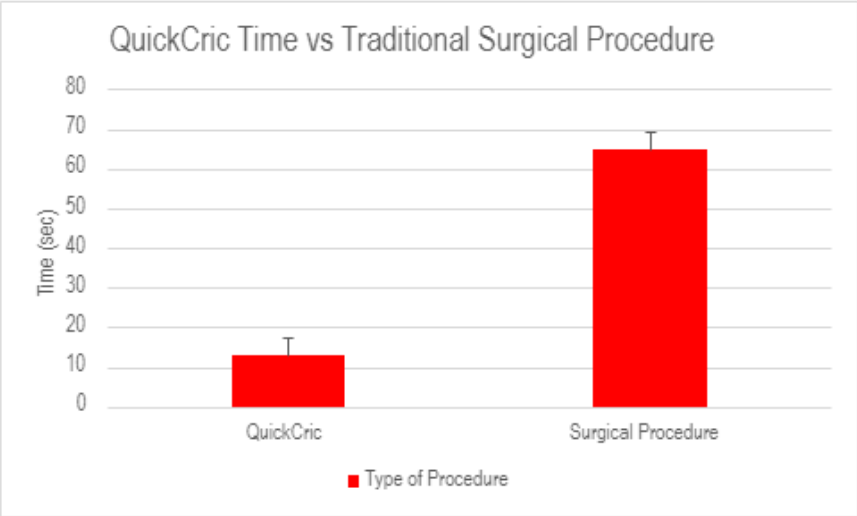

Figure 6: Average time to complete a cricothyroidotomy with the Quic Cric vs the traditional surgical technique

A t-test was performed against these literature values and resulted in a p-value of 0.0012, indicating the results are statistically significant.

Airflow Testing

Lastly, CAD simulation airflow modeling was performed in SOLIDWORKS to confirm an air delivery rate through the Quic Cric of at least 500 mL every 3 seconds. The output velocity was estimated to be at least 30 m/s. Using the inside area of the shank, flow rate was calculated to be approximately 1.5 L/sec. These results are shown through color analysis in Figure 7.

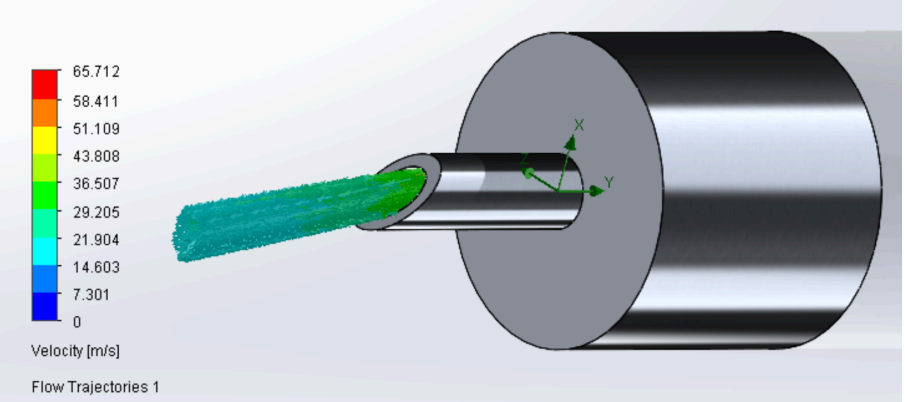

Figure 7: SOLIDWORKS Results of Airflow Testing

LIMITATIONS

The sample size was small and the original inclusion rate is somewhat low. Therefore, outcomes may provide an overestimate of the performance of the device. Moreover, the set up of the animal tissues was quite rudimentary. No considerations were made of accessory ligaments and structures that provide the adequate tension and support that is physiologically relevant.

After thawing the porcine skin many of the mechanical properties of the skin were lost. The participants found the skin to have lost nearly all elasticity. Additionally, the porcine skin had taken on a sticky quality after thawing. Additional tests were done on porcine skin that was purchased the same day with similar observations. Future investigations should account for proper storage of tissues.

Due to the inability to recreate an exact emergency situation, it is likely that some results would differ compared to the laboratory tests completed. Testing was not completed on human tissue. Mechanical properties such as the strength, toughness, Young's modulus, and friction

could produce different results. Additionally, situational components in an emergency would add to procedure time and create possible complications.

DISCUSSION

Preliminary testing of the Quic Cric device validates it as an effective and efficient device for emergency cricothyroidotomy. Puncture testing, timing testing, and airflow testing were all chosen to emphasize how this novel device satisfies the design requirements of an emergency cricothyroidotomy device.

Puncture testing was conducted to ensure that the device was sharp enough to pierce all tissues needed to access the airway. A key component of our design is the usage of a sharp beveled edge instead of the traditional method of using a scalpel to create the incision. By proving that the device could successfully pierce through the skin, trachea, and cricothyroid membrane, both separately and under anatomical conditions, its efficacy was validated. Qualitative analysis of the puncture created by the device was also performed. The small, clean incision made is comparable to the amount of tissue damage caused by the traditional surgical technique. Additionally, there were no signs of blockage of the shank of the device, further exemplifying the viability of a needle based device.

Timing testing of the device was conducted to compare the efficiency of the Quic Cric to the standard surgical procedure. The novel device was shown to be almost 5 times faster than the current scalpel based technique. As stated previously, accessing the airway as quickly as possible is the most important factor in preventing permanent brain damage. If used properly, the Quic Cric can save precious minutes in case of an emergency, with its novel single-component design.

Finally, airflow testing was conducted to quantify the amount of air exchange the device can accommodate. The 1.5 L/sec results from simulation testing exceed the 0.1 L/sec (500 mL per 3 seconds) requirement needed to sustain oxygenation. This proves that the device can effectively provide ventilation to the patient, while limiting the size of the needle used.

In conclusion, this study presents successful testing outcomes of a novel device used to perform a cricothyroidotomy without any accessory tools. A device like the Quic Cric has the potential to save thousands of lives per year, and satisfies a niche not yet explored in emergency medicine. Further directions include recruiting clinicians to test the ease of use and familiarity using a single-component device like the Quic Cric. Additionally, a larger sample size for device testing and physical airflow testing could be used to build more confidence in this tool.

ACKNOWLEDGEMENTS

The authors would like to extend their appreciation to Dr. Lenard Markman for guiding the development of this project. Additional thanks to Dr. Darilis Suarez-Gonzalez for her ongoing support. The team would also like to recognize the TEAM lab for their help with design consultations and the Meat Sciences department for sourcing porcine tissue for testing. This project would not be possible without the support of the UW Department of Biomedical Engineering.

No competing interests declared.

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SUPPLEMENTARY MATERIALS

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 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 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 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.

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SOLIDWORKS File

File would go here

FABRICATION PROTOCOL

A. Machining on Lathe

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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”
9. 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.

10. 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”.
11. 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
12. 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

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
7. Spot drilling the additional hole: 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.

8. Drilling the additional hole: To create the additional 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”.
9. 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 additional hole.

C. Sharpening on Belt Sander

1. Marking lancet cut: Using a permanent marker, mark out the shape of the lancet. Starting at the pointed end of the device, draw a line on the outer shaft of the needle. The line should follow the angled edge of the tip, about 3 mm from the edge, until halfway around the shaft. The figure below illustrates the shape of the needle before and after [1].
2. Sanding: Use a belt sander to create the lancet tip along the marked line. The tip should come to a point, with sharp edges along the side of the lancet

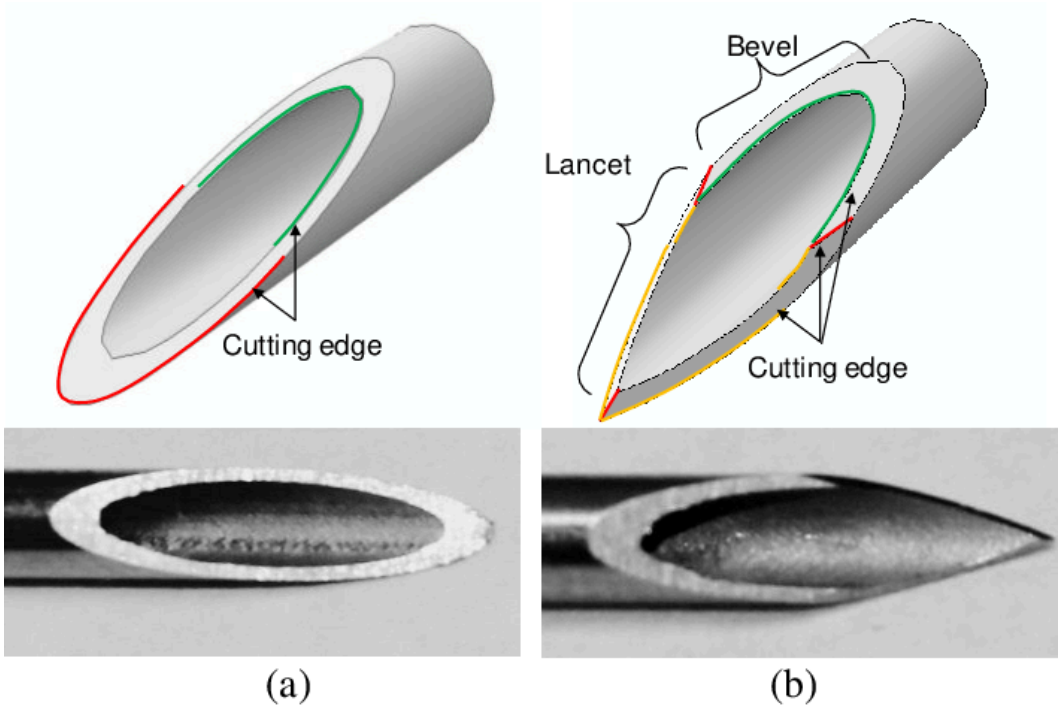

Figure 1 CAD and actual models of (a) bias bevel and (b) lancet tip needle

Figure 1: Lancet tip needle bevel shape [1].

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DEVICE DRAWING