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

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ABSTRACT

Study Objective: Devices used to perform an emergency cricothyroidotomy often include multiple tools and can be too intricate to use without training. The device proposed will help alleviate the current issues by simplifying the process and acting as a multi-functional device to create an emergency airway without requiring multiple tools.

Methods: The proposed device was designed in SOLIDWORKS and fabricated out of aluminum. Excised porcine skin, larynx and trachea were isolated for testing of the device. The device was evaluated by puncturing the anatomical samples at a 45° angle of insertion. The prototype was held in one hand of the participant while the sample was held stable with the remaining hand. After preparation of the samples, four individuals participated in initial testing of the porcine trachea and larynx.

Results: The first attempt at puncturing the porcine trachea was 75%. The success rate increased to 100% after two attempts at tracheal puncture for all participants. One participant located the cricothyroid membrane on the porcine larynx and successfully punctured the membrane after three attempts. After thawing the porcine skin, many mechanical properties such as elasticity were lost. The participants failed to puncture the porcine skin with the completed device.

Conclusions: This device shows potential promise in creating an emergency airway as it can puncture through the necessary layers. Future directions include incorporation of more quantitative testing as well as testing on the skin layered on the porcine larynx to mimic the patient better.

INTRODUCTION

The cricothyroid membrane lies between the cricoid and thyroid cartilage in the larynx [1]. 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 [2]. However, its small size of 10.16 ± 1.48 mm for males and 8.72 ± 1.19 mm in females, makes it more difficult to locate and puncture [3]. Success rates of identification upon palpation are around 70% in non-obese patients and 39% in obese patients [4].

The Advanced Trauma Life Support manual recommends surgical cricothyrotomy as the preferred emergency airway procedure [2]. Various techniques exist, ranging from three to seven steps, with the three-step method being the quickest and most accurate [5]. This approach involves making a vertical incision over the cricothyroid membrane, followed by a horizontal incision and placement of an elastic bougie to guide the insertion of an endotracheal tube into the trachea. Once the airway is secured, a bag-valve mask is connected to deliver oxygen until chest rise is observed, minimizing the risk of barotrauma [6].

Importance

Each year, over 5000 individuals die from choking-related accidents in the United States alone[9]. The first immediate response to a choking person is to perform the Heimlich maneuver [10]. This technique employs a combination of abdominal thrusts and back blows [11]. Should the individual fall unconscious, chest compressions are the only solution[12]. Despite these treatments, their efficacy is not guaranteed, and victims often rely on timely assistance from emergency medical services (EMS) [13]. Clearing of the airway is imperative in order to avoid hypoxia and permanent brain damage [14]. However, the average EMS response time of 7 minutes exceeds the critical window for preventing permanent brain damage in choking incidents [15].

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 choking victims. By providing a user-friendly device, the proposed solution aims to enhance the efficiency of emergency response and reduce the incidence of choking-related fatalities.

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. 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 design will prioritize simplicity and adaptability, 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, orcine skin, tracheas, and larynxes were selected as anatomical models. We aimed to assess the device's ability to penetrate tissues effectively without causing excessive trauma or complications.

METHODS:

Study Overview and Design

The novel device 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 one animal subject.

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.

1 excised porcine larynx was included in the study. The porcine was ethically euthanized for purposes unrelated to this study and their larynges were purchased from the University of Wisconsin Meat Market (Madison, WI). All guidelines provided by the University of Wisconsin-Madison Institutional Animal Care and Use Committee were followed. Excess tissue was trimmed to isolate the cartilaginous skeleton, the cricothyroid membrane and approximately 4 cm of the trachea. The larynges were inspected for signs of trauma or other abnormalities. The excised larynx was placed in 0.9% saline solution and stored in a refrigerator.

Novel Device

The novel device was first sketched in SOLIDWORKS Version 2023 (Dassault Systemes) and subsequently fabricated from an aluminum rod. A STL file of the device is supplied in the Supplementary Materials. Aluminum was chosen due to its biocompatibility and ability to withstand the heat and pressure of autoclave sterilization. A more detailed protocol is supplied in the Supplementary Materials**.** During the development process, the dimensions of the novel device were strategically selected to remain inclusive of the neck size of multiple populations.

On the user end, it is compatible with bag valve masks (BVM). On the distal end, there is an additional hole for additional air flow, in the instance that the shank gets occluded by tissue upon puncture. The shank is 2 cm, for gender and age considerations, in order to increase its universality to a larger population. The dimensions of the device are outlined in Figure 1.

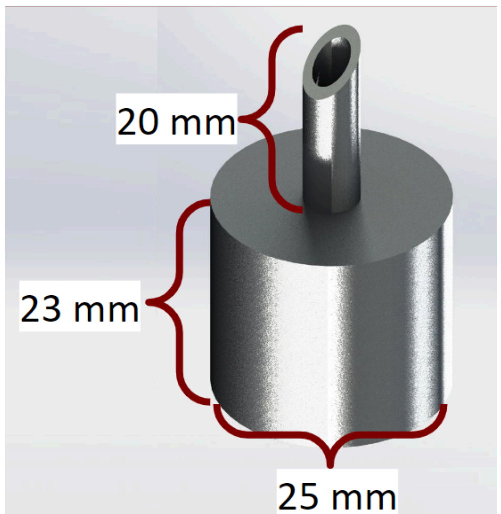


Figure 1: The device with dimensions outlined

Experimental Procedures

Roughly a section of 10cm x 4cm section of porcine skin was sectioned and fixed to a test tube rack. Fixation was performed by cutting small holes in the skin near the edges on both sides and using a stir rod that would go through the hole, through the test tube rack, and through the corresponding hole of the other side of the skin (Figure 2).

Figure 2: Affixation of porcine skin apparatus

10 cm in length of trachea was isolated from the porcine larynx tissue extraction and placed in a weight boat. The porcine larynx was put in a separate weight boat.

The device is designed to be inserted at a 45° angle relative to the patient caudally. The device is designed to be inserted where the beveled hole faces the patient. Once the user correctly places the device on the patient, a compressive force is applied to push the shank through the skin and cricothyroid membrane, into the airway.

Outcomes

Success of a trial was defined as a complete puncture through the tissue, where the BVM end rested on the surface of the porcine tissue. If the shank could puncture but not fully insert, this was considered an unsuccessful trial.

RESULTS

Characteristics of Study Subjects

A total of 4 individuals participated in initial testing of the porcine trachea and larynx. The participants consisted of two females and two males with an average age of 21.25 ± 0.43 years. None of the participants had previously performed a cricothyroidotomy.

Porcine Trachea

First attempt success at puncturing the porcine trachea was 75% for the fabricated aluminum prototype. The success rate increased to 100% success after two attempts at tracheal puncture for all participants. All participants applied grip pressure to 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.

Porcine Larynx

One participant completed a trial on the porcine larynx. The participant successfully identified the cricothyroid membrane and punctured the membrane after three attempts. 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. The third attempt at puncture was completed successfully with the beveled edge facing up.

Porcine Skin

Two participants attempted to puncture the skin with the aluminum device but failed to make a complete puncture. Multiple indents were observed where the sharp tip of the prototype had contacted the skin.

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.

DISCUSSION

Successful preliminary testing of the emergency cricothyroidotomy device shows potential for more rigorous testing, with larger statistical power. Preliminary testing was particularly useful for determining proper usage of the device and testing procedures. The participants discovered that the device was much sharper when used with the bevel facing up. Additionally, it was possible to test the device on each component of the upper airway anatomy on its own.

After thawing the porcine skin many of the mechanical properties of the skin were lost. The participants found the skin to have lost all elasticity. Additionally, the porcine skin had taken on a sticky quality after thawing. Future investigations should account for proper storage of tissues.

Many amendments will need to be made from the preliminary testing protocol to produce realistic and relevant results. Primarily, according to prior literature, many cricothyroidotomy devices have been tested on porcine tracheas and skin, affixed in a cricothyroidotomy trainer. These testing setups allow for proper fixation of the tissue, and a presentation closer to what would be experienced clinically. A more realistic testing setup would allow for the evaluation of the usage of the device, not just the efficacy. For example, qualitative data regarding ease of use, ergonomics, and safety can be assessed. In using a cricothyroidotomy trainer, porcine trachea and skin could be sourced just as it was in preliminary testing.

Finally, the scale of testing as a whole must be increased. From reviewing literature of other novel cricothyroidotomy devices, a sample size around n=40 must be tested. This is dependent on quantitative and qualitative measurements studied.

As the transition is made from preliminary to final testing, both the preliminary testing outcomes and literature review will be used to create an accurate and significant study. The viability of this device in a controlled setting will be a key indicator of its success in the unpredictable situations it aims to be used in. A novel device like this has the potential to save thousands of lives per year, and satisfies a niche not yet explored in emergency medicine.

In conclusion, this study presents preliminary outcomes of success of a novel device that performs a cricothyroidotomy without any accessory tools. Further directions include creating an animal model that includes all layers of the neck needed to puncture as well as a larger sample size to create statistical power. Considerations will also need to be made on the set up of the animal models to include for adequate physiological tension of the larynx in the superior-inferior direction and ipsilateral-contralateral direction.

ACKNOWLEDGEMENTS

No competing interests declared.

REFERENCES

1. Souza DP de. Cricothyroid Ligament. AnatomyZone. Published November 12, 2022. Accessed October 11, 2023. https://anatomyzone.com/articles/cricothyroid-ligament/
2. ATLS Subcommittee, American College of Surgeons' Committee on Trauma, International ATLS working group. Advanced trauma life support (ATLS®): the ninth edition. *J Trauma Acute Care Surg*. 2013;74(5):1363-1366. doi:10.1097/TA.0b013e31828b82f5
3. Kokulu K, Alkan E, Sert ET, Mutlu H, Turkucu C, Akar EH. Determination of the Cricothyroid Membrane Height by Age and Sex and Optimal Tracheal Tube Size. *The Laryngoscope*. Published online October 10, 2023. doi:10.1002/lary.31102
4. Lamb A, Zhang J, Hung O, et al. Accuracy of identifying the cricothyroid membrane by anesthesia trainees and staff in a Canadian institution. *Can J Anaesth J Can Anesth*. 2015;62(5):495-503. doi:10.1007/s12630-015-0326-y
5. McKenna P, Desai NM, Tariq A, Morley EJ. Cricothyrotomy. In: *StatPearls [Internet]*. StatPearls Publishing; 2023. Accessed September 18, 2023. https://www.ncbi.nlm.nih.gov/books/NBK537350/
6. MacIntyre A, Markarian MK, Carrison D, Coates J, Kuhls D, Fildes JJ. Three-Step Emergency Cricothyroidotomy. *Mil Med*. 2007;172(12):1228-1230. doi:10.7205/MILMED.172.12.1228
7. STATForce Adult Deluxe Field Cric Kit. QuadMed, Inc. Accessed September 19, 2023. https://quadmed.com/statforce-adult-deluxe-field-cric-kit/
8. Melker RJ. SYSTEMAND CRICOTHYROTOMY KIT.
9. Duckett SA, Bartman M, Roten RA. Choking. In: *StatPearls*. StatPearls Publishing; 2023. Accessed September 19, 2023. http://www.ncbi.nlm.nih.gov/books/NBK499941/
10. Hasan SS, Saeed AA, Mustafa IH. KNOWLEDGE AND ATTITUDE OF PRIMARY SCHOOL TEACHERS REGARDING CHOKING'S FIRST AID IN ERBIL CITY- KURDISTAN REGION - IRAQ. *Malays J Nurs MJN*. 2016;8(2):36-42.
11. Maalim Issack A, Jiru T, Wubetie Aniley A. Assessment of knowledge, attitude and practice on first aid management of choking and associated factors among kindergarten teachers in Addis Ababa governmental schools, Addis Ababa, Ethiopia. A cross-sectional institution-based study. *PLoS ONE*. 2021;16(7):e0255331. doi:10.1371/journal.pone.0255331
12. Zhou X, Wang L, Zhang Y, Wu Q, Cao Y. The Heimlich maneuver and chest compression relieve mask ventilation difficulties caused by asymptomatic laryngeal mass: A case report and review of

literature. *Medicine (Baltimore)*. 2023;102(48):e36362. doi:10.1097/MD.0000000000036362
13. Ojeda Rodriguez JA, Ladd M, Brandis D. Abdominal Thrust Maneuver. In: *StatPearls*. StatPearls Publishing; 2023. Accessed October 11, 2023. http://www.ncbi.nlm.nih.gov/books/NBK531467/
14. Mayahara T, Katayama T, Higashi Y, Asano J, Sugimoto T. Position-Dependent Symptoms of Pneumothorax During Mechanical Ventilation: A Case Report. *Cureus*. 2023;15(12):e50820. doi:10.7759/cureus.50820
15. Mell HK, Mumma SN, Hiestand B, Carr BG, Holland T, Stopyra J. Emergency Medical Services Response Times in Rural, Suburban, and Urban Areas. *JAMA Surg*. 2017;152(10):983. doi:10.1001/jamasurg.2017.2230

SUPPLEMENTARY MATERIALS

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

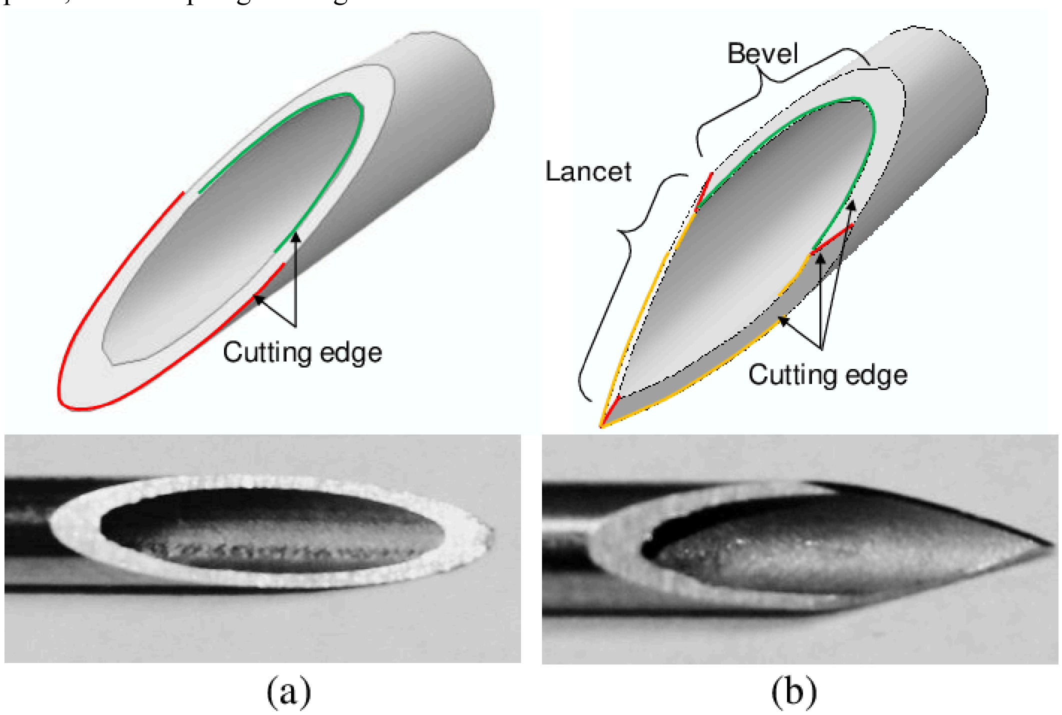
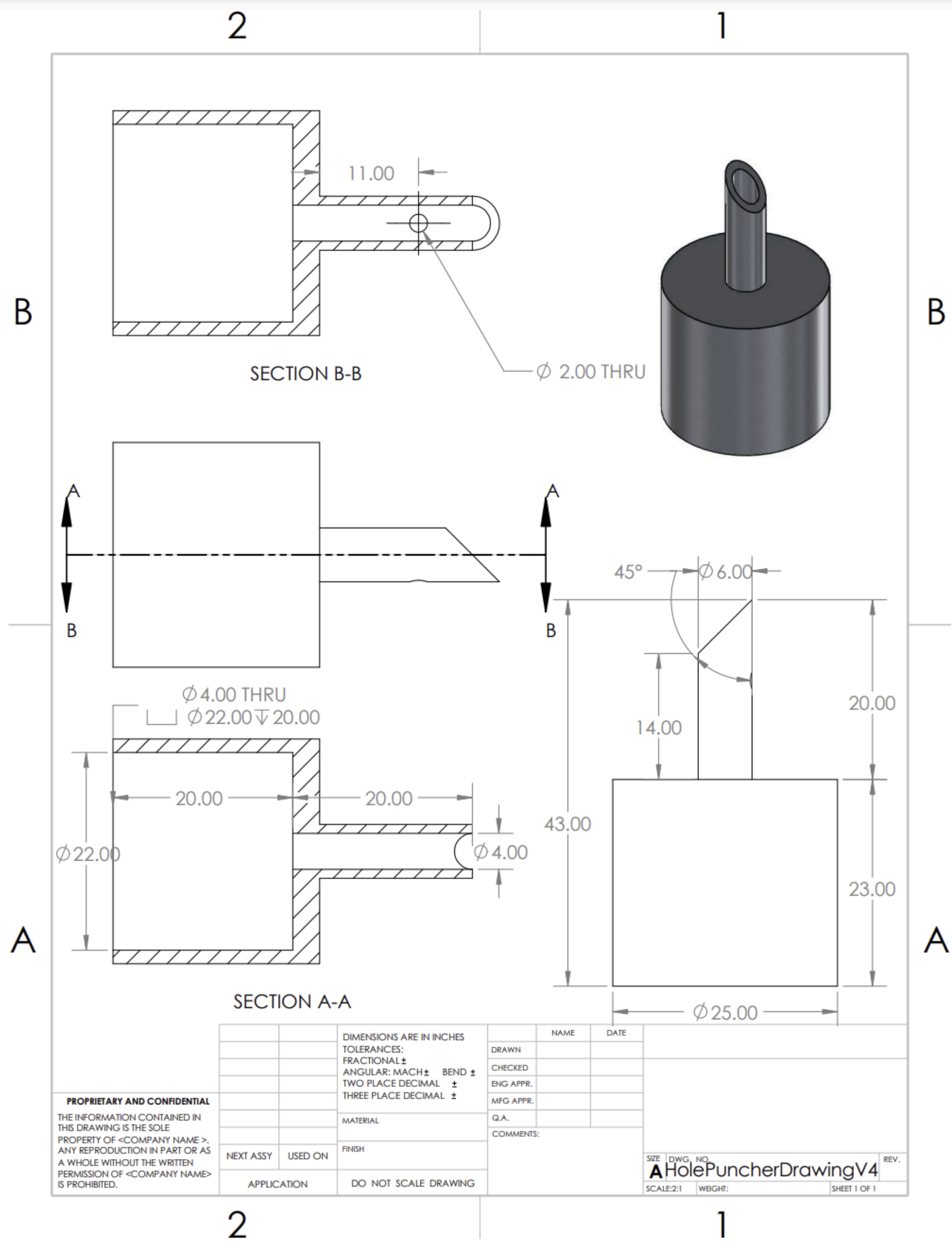


Figure 1 CAD and actual models of (a) bias bevel and (b) lancet tip needle

Fabrication References:

[1] B. L. Tai, Y. Wang, and A. J. Shih, "Cutting Force of Hollow Needle Insertion in Soft Tissue," in Volume 1: Processing, Madison, Wisconsin, USA: American Society of Mechanical Engineers, Jun. 2013, p. V001T01A007. doi: 10.1115/MSEC2013-1124.

DEVICE DRAWING



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