A Cricothyrotomy Training Device

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EXECUTIVE SUMMARY

We found that within the realm of surgical training, a cricothyrotomy is a somewhat neglected procedure simply because it is rarely performed; residents admit not having trained on a simulation device more than a few times. In addition, the industry seems to have halted development of their training devices because a very basic one has been deemed adequate. But we recognized the extreme importance of cricothyrotomy training and the significant shortcomings of existing devices.

We believe that simulation design does not mean replicating procedures with the most accuracy and precision, but critically analyzing tasks and focusing on the most critical aspects and failure points. Our devices are created with the aim to educate; we identified two basic needs of a simulation: a cognitive and dexterity training component. We found that current day simulation devices are designed within the wrong reference frame and are not considering the necessary educational learning aspects of clinical procedures before all else.

Looking at the scenarios for cricothyrotomy procedures, our device did not neglect to design for suboptimal environments associated with this procedure; we identified it as the cause for the most failures. We found that errors generally lie in two categories: decision making errors, and surgery dexterity errors. Since a cricothyrotomy is relatively low in complexity compared with other procedures, teaching dexterity was not a top priority. Instead, our main solution became recreating a stressful environment, while providing pathways to mitigate the failure under pressure. We harnessed the forces of teamwork and collaboration, which helps in these stressful situations as competition intensifies focus.

In our design, we included components that not only improve upon the current "state of the art" but offer a novel approach to surgical training. We designed CoLeS (Collaborative Learning Simulator) that provides a framework which promotes discussion and interaction while training. This system allows for the simultaneous training on three bases, where cricothyrotomy modules will be placed. These three modules simulate the anatomy associated with a cricothyrotomy and allow the trainee to locate the incision site via palpation, make two incisions through the skin and cricothyroid membrane, respectively, and insert a tracheostomy tube. We included a variety of anatomical variations in these three modules, including a layer of subcutaneous fat, differing cartilage sizes, and a tracheal shift. Furthermore, we included a line that pumped fake blood (from the center of CoLes) to one of the modules. Finally, in order to heighten the sense of urgency and stress level in the trainee, we included an accelerating beeper, acting as a stress-inducing timer. Overall, we firmly believe that the system presented here has the ability to effectively train surgeons and help maintain the skills associated with performing a cricothyrotomy.

INTRODUCTION

A Cricothyrotomy is an emergency procedure that is performed when a patient's airway is completely obstructed and a new airway needs to be established in order to oxygenate the blood. The procedure is a "last-resort" when mask ventilation and tracheal intubation (insertion of a tube down the trachea) fail, usually due to excessive trauma to the neck (leading to a deformed trachea and/or swelling).

CRICOTHYROTOMY PROCEDURE

In brief, the procedure consists of the following five steps:[1]

1) Locating the cricothyroid membrane (CTM) by palpation.
2) Making a 1-1.5cm horizontal incision through the skin, subcutaneous tissue and CTM (without puncturing the posterior end of the trachea).
3) Dilating the incision with a hemostat or Trousseau dilator.
4) Inserting the tracheostomy or endotracheal tube into the trachea while rotating it in the caudad direction.
5) Superficially securing the tube using tape and/or sutures.

Note that while the procedure is life-saving in extreme circumstances, this technique is only intended to be a temporizing measure until a definitive airway can be established.[2]

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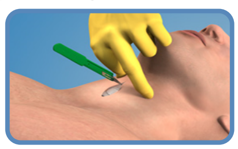

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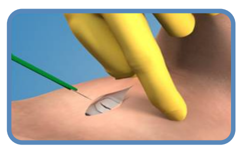

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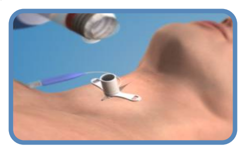

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CURRENT TECHNOLOGIES AND "STATE OF THE ART"

There are a very limited number of training devices for Cricothyrotomy in the market. Most of the available simulators have very similar features. Two such devices in the market are the Trauma Man[3] and the Life/Form Cricothyrotomy Simulator.[4] The Trauma Man is an anatomical human body representation, which is designed for students to practice advanced surgical procedures including Cricothyrotomy. The Life/Form Cricothyrotomy Simulator is a device designed specifically for the instruction of the Cricothyrotomy procedure. Both devices are similar in that they have a realistic appearance and representation of bodily tissues. However, after our assessment of the devices, we feel as though improvements can be made in cost, feedback, etc.

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[1] Orebaugh, Stephen L. *Atlas of Airway Management: Techniques and Tools.* Lippincott Williams and Wilson, 2007.

[2] M. Gregory Katos and David Goldenberg (June 2007). "Emergency cricothyrotomy". *Operative Techniques in Otolaryngology* **18** (2): 110–114. (2007).

[3] TraumaMan System, Simulab Corporation. <http://www.simulab.com/product/surgery/ open/traumaman-system?gclid=CLve99bd_aQCFQUSbAodwEYfhg> 1 Nov 2010.

[4] Life/Form Cricothyrotomy Simulator, Simulaids. <http://www.simulaids.com/LF01082U.htm> 1 Nov 2010.

Pros:

- ○ Realistic Appearance
- ○ Anatomically Accurate
- ○ Replaceable Skin Tissue/Parts
- ○ High Quality Materials
- ○ Modular Anatomy (TraumaMan)

Cons:

- ○ Expensive
  - TraumaMan costs ~$18,000 for the full kit and ~$60 for neck skin replacement
  - Life/Form Cricothyrotomy simulation kit costs $650 for a kit and $170 for a set of three replacement skins
- ○ The cricothyrotomy procedure with TraumaMan is coupled with three other procedure trainings, driving up the cost in a potentially unnecessary way.

USERS AND THEIR NEEDS

There are a wide range of potential users for this system. The largest user base will clearly be surgical residents who need to undergo training for a cricothyrotomy and will be most likely to perform this procedure on a real patient. This group extends to trainees of Advanced Trauma Life Support (ATLS), a required training program for doctors and paramedics that is implemented in over 40 countries.[5] In addition, this tool could be particularly useful for Emergency Room physicians who may need to perform a cricothyrotomy if a surgeon is not available or cannot be called in time. More rarely, anesthesiologists (including their residents) may also want to train to learn how to do a cricothyrotomy if a surgeon is not available. A final significant user base could be military medics who may not have the option of intubation in the field, and where a cricothyrotomy may be one of their only options to create an airway and oxygenate a patient.

User Needs

To successfully train medical personnel in the cricothyrotomy procedure

- ○ Complete representation of cricothyrotomy procedure and it's anatomy
- ○ Tactile feedback (the most important surgical dexterity skill in this procedure)
- ○ Varying anatomical scenarios that mimic the diverse nature of patients' anatomy
- ○ Some level of stress simulation
- ○ A relatively low-cost device that could be potentially made available to wider user base
- ○ A system that allows for an optimal learning environment through collaboration and trainee interaction.

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[5] Bouillon, B., Kanz, K.G., Lackner, C.K., Mutschler, W., & Sturm, J. The importance of Advanced Trauma Life Support (ATLS) in the emergency room [Article in German]. Unfallchirurg, 107, 844-850.

PROBLEM STATEMENT

A cricothyrotomy is a simple, but life-saving procedure. Yet medical personnel rarely practice or have frequent exposure to this operation. They need a simulation that helps them refine the critical dexterity skills for a cricothyrotomy within a learning environment that mimics the stress of this rare, but crucial emergency.

DESIGN INSIGHTS THROUGH INTERVIEWS

Clinical Need

In order to assess the general needs associated with designing a cricothyrotomy training device, we interviewed a senior surgical resident at Stanford University, Dr. Yulia Zak. Dr. Zak offered much insight into the typical training procedures and how they differ from an actual surgery. She outlined that the most important part of performing a successful cricothyrotomy was correctly identifying the incision site via palpation where one could effectively "bypass" cutting cartilage and only have to cut through a thin layer of cricothyroid membrane and trachea. In effect, a training device would have to simulate the neck anatomy and require the trainee to locate the incision site via palpation. We also learned that while incisions and tracheostomy tube insertion are not particularly difficult surgical procedures, it is crucial that a surgeon feels comfortable in performing them. Our device would therefore need to simulate these aspects of a cricothyrotomy as well.

Collaborative Learning

To understand first-time users' learning process on simulation devices, we observed a didactic training session in the Stanford Goodman Simulation Center. Watching the dynamics amongst residents and the facilitator, who is an experienced surgeon, we found that skill building required constant engagement between mental stimulation and hands-on interaction. The best learning was achieved by individuals who seemed to "switch off" between thinking, discussing, and then thinking with their hands. Having multiple levels of interaction was essential for efficient learning. However, the set-ups in these short sessions did not promote collaboration. We believed that our device should encorporate a system that lowers the amount of "standing around", where surgical tasks could be done in parallel. By experiencing the critical operations and decisions at the same time, the residents would be able to articulate the possible variations in their scenarios and also track their progress relative to other students.

Training Under Stressful Conditions

In order to gain insight from the perspective of another senior resident from a different hospital, we spoke with Dr. Victor McCray, a BioDesign fellow and surgeon at University of California, San Francisco - Fresno. He reiterated many of the concerns that Dr. Zak previously outlined, but emphasized that the main difficulty in performing a cricothyrotomy comes from the stressful environment under which this procedure is always performed. He believed that a successful simulation device would have to somehow discomfort the trainee, disturbing the usually calm training conditions. After further discussions, we decided that this feature would have to be included in our design.

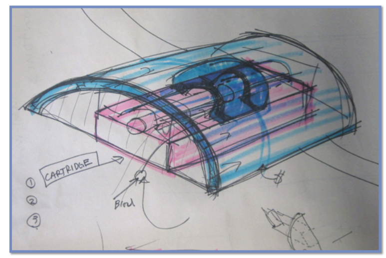
Experience in Emergency Trauma Situations

To understand the expert needs for a training device, we talked to Dr. Garett Lee, an experienced ER doctor of 17 years. Immediately, he verified the need for a simulation device to train for rare emergencies like the cricothyrotomy procedure in emergency care units. In his experience, a cricothrotomy has been an avoided procedure for lack of comfort in emergency care scenarios. This discussion illustrated the difference between ER doctors and surgeons with the operation, and verified the scope of user group.

REJECTED ITERATIVE DESIGNS

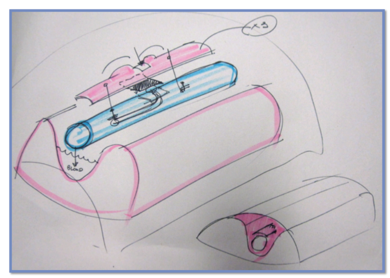
During our design process, we iterated through many designs and ideas. While we eventually rejected these overall ideas, we found them to be crucial steps in our brainstorming process. Our final design also included some features that originated as part of these rejected designs.

Cartridge design



We envisioned a system where a set "cartridge" could be inserted and removed from a single cricothyrotomy device. This would allow the user to easily modulate the simulated anatomical features and have different user experiences within a single device. We eventually rejected this design on the basis of unnecessary complexity once we decided that we needed to create a collaborative learning environment.

"Blood Pool" Design



A second rejected design was one where all of the subcutaneous anatomical structures were submerged in a pool of fake blood. We eventually decided that static liquid provides for a less-than-optimal simulation of the complexities associated with bleeding during a cricothyrotomy. Nevertheless, our overall device structure (trachea, cartilage, membrane) stemmed from this iteration.

FINAL DESIGN

Our final design consists of two main parts: a collaborative framework dubbed "CoLeS" and cricothyrotomy simulation modules that are places on each of the three CoLeS bases.

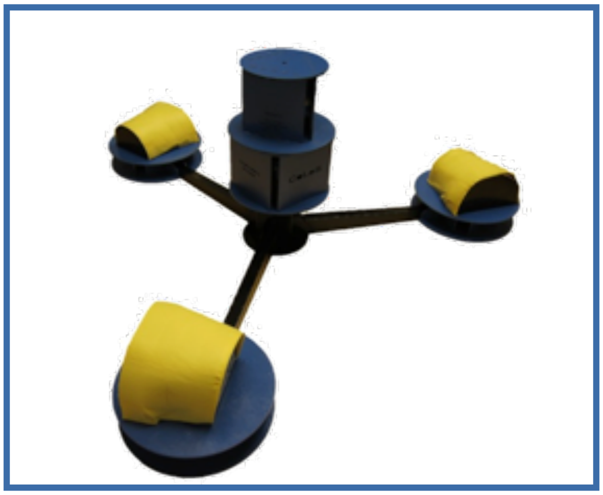
CoLeS

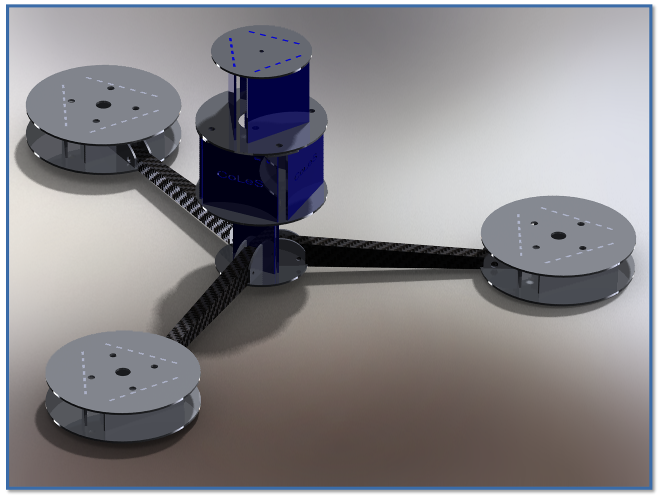
The Collaborative Learning Simulator, "CoLeS", is the culmination of our design innovation process. This device is a combination of the most promising aspects of several prototypes and design iterations; it provides a medium through which our user can benefit from a unique and effective learning experience.

The CoLeS device is designed as a framework with which to present users with several practice procedures. The device comes equipped with a central processing unit as well as control pipelines to provide a structured but dynamic learning experience for all users. CoLeS adheres to the specific constraints for our target solution - our device provides:

- a realistic representation of the cricothyrotomy procedure
- provides adequate tactile feedback
- provides varying neck anatomies
- provides stress simulation
- provides a collaborative structure

CoLeS design blueprint was developed using SolidWorks 3D design software. Our device was manufactured from medium-density fiberboard using Lasercamm™ technology. CoLeS was assembled manually.

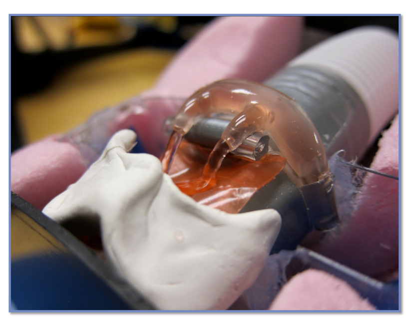




Central Hub

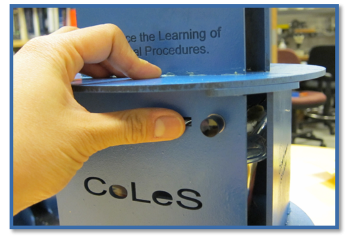
A critical component of our device is the control hub which contains a central processing unit. This processing unit includes a blood pump to regulate blood flow simulation as well as a timing mechanism to simulate decreasing oxygen levels in a cricothyrotomy patient. This device can control the length and frequency of the bleeding that will occur in each module. Further development may also include a series of events that the trainee needs to complete before proceeding to the next step or module. In our prototype, we implemented a PIC16F690 microcontroller for this unit due to its small form factor, inexpensiveness, and relatively high performance. For the circuit diagram, please see Appendix.

Blood Pump



In order to simulate a real-life situation where unexpected obscured views may occur, we simulate bleeding using a computer controlled bilge pump. This allows us to either give an unexpected (random in time) bleeding or be manually controlled by a moderator with a touch button at the central hub of CoLeS. We also added an ability to control to the bleeding using a cellphone via Bluetooth communication.

Beeper for Stress Simulation

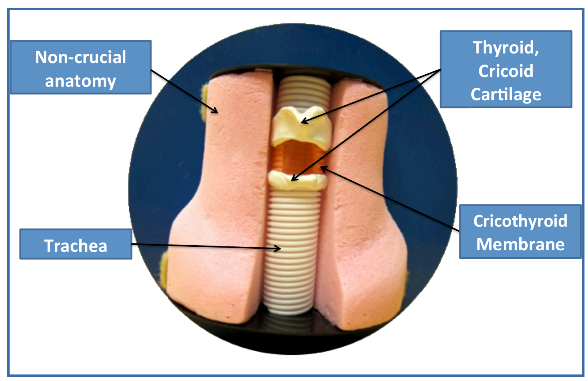


Many medical procedures are usually performed under stressful conditions. We simulate this condition simply through an accelerated beeping, mimicking a pulse oximeter sound. When the time passes, the beeping increases in frequency, simulating decreasing oxygen levels. When the time limit is reached, the user hears a flat beep - replicating zero oxygen level. The beeper is turned on via a switch right next to the button that controls blood flow.

Control Pipelines

At the base of this central processing unit are three control pipelines. The pipeline allows the system to route both electronics and mechanical components through each simulator module while maintaining its modular design and portability. In our current prototype, these pipelines are responsible for channeling the flow of blood to the cricothyrotomy simulator module. This can be expanded to connect other types of sensors and actuators as well. CoLeS is designed for optimum portability – the control pipelines are foldable and the cricothyrotomy simulator modules are detachable.

Cricothyrotomy Simulation Modules

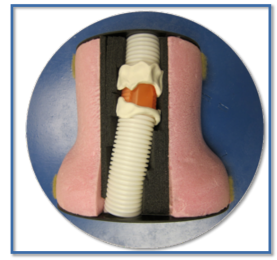


In our simulator modules, we focused on the cricothyrotomy procedure. It essentially mimics the anatomical structures that are involved in an actual cricothyrotomy. The outermost layer wraps around the device offers a realistic skin texture. Just underneath the skin are two stiff structures that are shaped as thyroid and cricoid cartilages, which can be palpated through the outer layer of skin. These structures are placed on a semi-stiff tube that emulates the trachea. Based on palpation of the trachea and cartilage, the incision site can be located in an anatomically-accurate fashion. A thin film between the two cartilages represents the cricothyroid membrane, the site of the second incision. Finally, the hollow tube allows for the insertion of an actual tracheostomy or endotracheal tube. These modules attach and detach to the CoLeS base with strong magnets.

Anatomical Variations

Due to the emergent nature of a cricothyrotomy, surgeons do not have time to plan for many kinds of anatomical variations that may arise in any given patient. As such, we chose to implement some basic variations in our design (in addition to the previously mentioned blood) that would increase the difficulty in performing a cricothyrotomy. This would further prepare a surgeon for unusual anatomy structures that may exist in an actual patient. The most simple anatomical variation that we implemented was differing sizes and shapes of the cartilages, since they do indeed vary with gender,age, and size.

Perhaps the two most common variations that would increase the procedure's complexity is the abnormal case of subcutaneous edema or emphysema in the neck due to trauma or the “normal” case of obesity. In both cases, the cricoid cartilage becomes more difficult to palpate and the incision site becomes more difficult to locate. To simulate this, we included a “subcutaneous” layer of foam that the trainee would also have to cut through in two of the models.

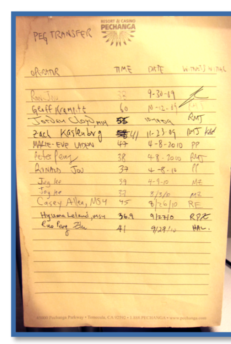


Next, we simulate a tracheal shift from the midline, which further increases the difficulty and confusion associated with palpating the cricoid cartilage in an emergent situation. Potential causes for such a tracheal deviation include natural anatomy variation and trauma to the neck. Note that a tracheal deviation makes it difficult to intubate a patient, making a cricothyrotomy more likely. We simulated such a shift in one of the models by shifting the trachea by about 1cm.

PRODUCT FEEDBACK

Once a near-final prototype was constructed, we received feedback from six junior and senior surgery residents who were in the midst of surgical training through simulation devices. The reception was generally positive as they realized that this device included features that previous cricothyrotomy training devices did not, and is a near-complete simulation of the procedure: “we usually train until we hit the ‘I-got-it point’. For example, we found the airway, yet we forget we have to suture onto the skin, hook up the line, and make sure everything else is stable. It’s hard to focus on all of the details. This is good, it walks through all of the motions.”

At least one resident noted that surgeons “are set up to fail in a cric” where morale is low, confidence is shook and the probability of patient death is high. Another resident stressed the necessity of confidence in successfully performing the procedure, where he found that the importance was grounded “the leadership ability. Only people with this skill set have the comfort to make the decision and say ‘let’s cric them!’” Both these residents appreciated the ability to increase simulation difficulty, through anatomical variations. To them, it was almost impossible to make our design and device too difficult.



Perhaps the most positive reception was in regards to our CoLeS system. All of the residents reviewed it positively, but most interpreted “collaborative learning” through discussion as “competition”, which they found extremely exciting. We learned that the atmosphere in these types of surgical trainings are (playfully) competitive, and a device that promotes would be well-received by trainees. In fact, there was a posted sheet outlining the resident’s times to complete a laproscopic peg transfer. One resident noted that while this is indeed a simulation, the competitive aspect and beeper helps mock the stressful environment of the emergency room: “Yes, you’re acting, but let’s play on that. We get more into (the scenario), and take more away from it. This competition gives us adrenaline, and adrenaline is adrenaline, so it helps.”

Some residents also had some suggestions for improvements. They noted that the system necessitated a facilitator who would organize the competition, start the buzzer and induce blood flow. Streamlining and automating this could be useful for the purpose of individual training. Other suggested features included a sensor that would notify the user when he or she makes a poor incision. One resident also suggested that there be a real-time indicator to inform the trainee (and their competition) how well they are performing the cricothyrotomy.

FUTURE DIRECTIONS

Material improvements (Trachea, Cricothyroid Membrane, Skin)

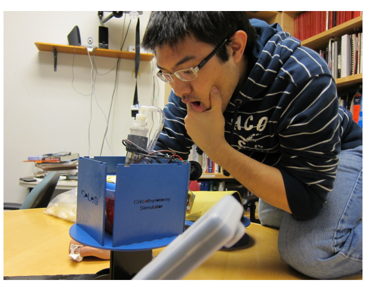
Material improvements will be vital to the future development of CoLeS' cricothyrotomy simulation module. Our team's goal is to create a learning tool which accurately represents "real-life" activity. Improvements in the texture & functionality of the trachea, cricothyroid membrane, and skin will certainly move CoLeS in the right direction.

Anatomical Variations

The inclusion of mutliple simulator modules with additional anatomical variation will also be essential. The cricothyrotomy procedure is a procedure that becomes exponentially more challenging when a doctor is faced with extreme variations in anatomy. The optimum training procedure will provide training with both "normal" and "extreme" anatomical variations to better prepare doctors to face these challenges.

Additional Surgical Simulation Procedures

The future of CoLeS is as a framework for a variety of medical training procedures. The medical practice environment is a collaborative one - success in the field requires a combined effort from a wide range of medical personnel. Thus, it is logical to create an atmosphere, during training procedures, which encourages collaboration and builds on the teamwork/cooperation aspect that is so valuable in medical practice. CoLeS can be expanded to include a variety of training procedures involving time sensitivity, precision, and collaboration - surgery, first aid application, and other medical procedures. With CoLeS, we have laid a foundation for future innovation in the training of medical personnel.



APPENDIX