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Original Research

A Novel Approach to Emergency Airway Simulation Using a 3D-printed Cricothyrotomy Task Trainer

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Introduction

Cricothyrotomy is an invasive airway access technique on the emergency pathway of the difficult airway algorithm published by the American Society of Anesthesiologists[1] and the Difficult Airway Society.[2] Attaining competency with this technique is challenging due to the low incidence (1 in 22 000) of emergency airway events during elective procedures.[3] The Fourth National Audit Project, the largest study of major airway complications, identified that 60% of anesthesiologists failed to appropriately cannulate patients that required an emergency cricothyrotomy.[3] It is essential to design curricula to improve proficiency in this life-saving skill. Cricothyrotomy simulation has been described with mannequin, cadaver, and animal anatomic models. Model fidelity, which refers to the degree of realism, varies across various models. Mannequin and cadaver models are hampered by high cost and donation limitations.[4–6] Animal models pose logistical limitations with storage, handling, disposal, and ethical concerns.[4,7–9] Due to the high cost of anatomic models, and because prior research has demonstrated that high-fidelity models are not superior to low-fidelity models, low-cost airway models have been developed as a viable substitute.[10] These specialized devices, known as task trainers, have been successful in improving competency in residents and medical students learning surgical cricothyrotomy. Rudimentary yet effective task trainers have been developed using inexpensive household supplies.[11] Three-dimensional (3D) printing has garnered significant attention in the field of surgery and has been a key component in planning and facilitating complex operations.[12] Advances and cost reductions in 3D-printing technology bring to light a new era of medical applications for inexpensive simulation training. Limited data exist for the utility of 3D-printed models as a substitute for high-fidelity, high-cost cricothyrotomy models.

Our program developed a novel 3D-printed task trainer to provide cricothyrotomy training for a difficult airway to anesthesiology residents. We developed a simulation course to improve competency among anesthesiology residents using both a porcine animal model and the novel task trainer. Our primary aim was to determine if the task trainer was noninferior to the porcine model for teaching surgical cricothyrotomy to anesthesiology trainees.

Materials and Methods

This unblinded, randomized, controlled, single-institution, non-inferiority trial was deemed exempt by our program's Institutional Review Board, and the Institutional Review Board waived the requirement for written informed consent. The study was performed as an elective workshop for the anesthesiology residency program at Mayo Clinic in Rochester, Minnesota. Study participants were recruited by email invitation, which explained the rationale, aims, and structure of the workshop. Verbal consent was obtained from study participants. Those who did not wish to participate in the simulation or the study were free to opt out and were excluded from analysis. Participants were randomized into the porcine anatomic model group or the 3D task trainer group.

Airway Models

For the porcine group, pig tracheas (Hormel Foods, Austin, MN) were obtained by our institution's simulation center, stored, and used in compliance with institutional safe practices. The novel 3D task trainer was designed using schematics for the 3D-printed surgical cricothyrotomy task trainer (3D Cric Trainer) downloaded from The Airway App website and printed by our institution's Anatomic Modeling Lab.[13,14] Models were printed with white resin (Formlabs.com) (Figure 1, upper panel). Silicone "skin" pads were formed from a layer of Ecoflex 00-20 (Smooth-On, Inc) mixed with peach acrylic paint, a layer of power mesh fabric, and a layer of Ecoflex gel (Smooth-On, Inc) mixed with yellow acrylic paint (Figure 1, middle panel). For complete details on how to make the silicone skin pads and assemble the task trainer, please reference Appendix 1. Each participant received a porcine trachea. Standardized sets of cricothyrotomy supplies were assembled for study participants, including an airway model, scalpel, syringe, endotracheal tube, and intubating stylet (Figure 1, lower panel).

Three identical workshop sessions were held in January 2020 at Mayo Clinic (Rochester, MN) in an audio/video-equipped conference hall reserved for educational activities. Anesthesiology residents who

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attended one of the workshops were eligible for study inclusion. All participants received educational training on the scalpel-finger-bougie technique via an instructor-led slide presentation and several videos from EMCrit Podcast 131.[15] Participants then observed instructor-led demonstrations on each of the simulation models. Details of the workshop didactics are provided in Appendix 2. The workshop PowerPoint presentation is provided as Appendix 3.

Participants first performed a complete surgical cricothyrotomy on a pig trachea; the time to completion (termed prepractice) was measured by one of the study authors. To ensure consistency, participants were asked to begin by placing both hands on the table. All necessary materials were placed next to the participant. The timer was started when they lifted their hands from the table and was stopped once the endotracheal tube balloon was inflated and the bougie was completely removed from the endotracheal tube. Participants were then randomized into either the pig trachea arm or the 3D model arm and asked to practice 5 repetitions on their own. The study authors were available to assist individuals and answer questions during this practice time. Following practice, all participants were then reassessed on a pig trachea for time to cricothyrotomy completion (termed postpractice).

Statistical Analysis

Using the calculator on the Sealed Envelope website, we established that a sample size of 32 (16 per arm) provided 80% power to detect noninferiority based on a 2-sample *t* test with a 1-sided noninferiority α level of .025.[16] The reporting of this study complies with the Consolidated Standards of Reporting Trials extension for reporting noninferiority and equivalence trials.[17]

Statistical analysis was performed using BlueSky Statistics software version 7.20. Prepractice and postpractice times to cricothyrotomy completion of each trainee were compared using paired Student *t* tests. Parametric means were compared with unpaired Student *t* tests. Postpractice times were compared between groups using analysis of covariance to adjust for prepractice times. The noninferiority test was conducted with a margin of 10 seconds. Trainee comfort with surgical cricothyrotomy before and after training was assessed with a 5-point Likert scale and compared with a Wilcoxon signed rank test.

Results

Twenty-five residents participated in the study. Thirteen residents were randomized to the 3D model arm, and 12 were randomized to the pig trachea arm. Demographic characteristics were similar between study arms (Table 1). All residents had previously undergone a single standardized 2-hour surgical airway workshop during their first year in clinical anesthesiology. No participants had previously performed a surgical airway on a patient. In the 3D model arm, two residents had witnessed a cricothyrotomy (once and three times, respectively). In the pig trachea arm, one resident had witnessed a cricothyrotomy (once).

All participants successfully completed a cricothyrotomy on their first attempt both prepractice and postpractice. For the overall cohort, the mean (SD) prepractice cricothyrotomy completion time was 39 (10) seconds, and the postpractice time was 30 (11) seconds. Cricothyrotomy completion times by study arm are depicted in Table 2. Participants showed significantly faster postpractice times (mean [SD] improvement for the 3D model group, 8 [11] seconds, $P = .017$; pig trachea group, 10 [14] seconds, $P = .035$). The mean (SD) improvement for the entire cohort was 9 (12) seconds ($P = .001$). Postpractice times were similar between groups; analysis of covariance estimated that the pig trachea group was 0.1 seconds slower (95% confidence interval, −9.4 to 9.2; $P = .98$). The 3D model was noninferior to the pig trachea at the prespecified noninferiority margin of 10 seconds ($P = .017$). The number of participants who agreed or strongly agreed that they were confident in their ability to perform a surgical cricothyrotomy increased from 4/25 prepractice to 23/25 postpractice ($P = .002$).

Discussion

Cricothyrotomy performance is a key skill for anesthesiologists, but competency can be challenging due to a low incidence of emergency airway events during elective procedures.[3] Prior literature has shown that a majority of anesthesiologists fail to cannulate patients appropriately in those requiring an emergency cricothyrotomy.[3] Given these findings, it is crucial to design a curriculum to improve proficiency in this life-saving skill. Current options for airway skill simulation include mannequin, cadaver, and animal anatomic models.[4–9] Pig tracheas are commonly used for teaching surgical cricothyrotomy technique.[4–6] Three-dimensional-printing technology has emerged as a new alternative that can reduce cost and improve ease of use.[12] This study demonstrates that 3D models are noninferior to pig tracheas for teaching surgical cricothyrotomy to anesthesia trainees.

The definition of a successful cricothyrotomy has varied in the literature, with different a priori time cutoffs used to define success. In clinical practice, the time threshold that defines a successful cricothyrotomy varies based on multiple factors, including underlying patient comorbidities and duration of hypoxemia before the emergency airway attempt. We thus chose to analyze time to cricothyrotomy completion rather than a binary outcome of success or failure. In the literature, improvement in percutaneous cricothyrotomy performance plateaus by the fourth to fifth repetition, with a mean (SD) time of 28 (9) seconds at the fifth repetition among anesthesiologists who had finished their training in the past 0 to 4 years.[18] Conservatively, we rounded up to a SD of 10 seconds for our sample size calculation. A clinically relevant noninferiority margin of 10 seconds was selected a priori, and we hypothesized that after 5 practice repetitions, trainees who practiced on the 3D model would not be 10 or more seconds slower than trainees who practiced on the pig trachea. The relatively large noninferiority margin was chosen because even if the 3D model resulted in a 10-second slower performance than the pig trachea, the 3D model still offers improved reproducibility and ease of use.

The speed of cricothyrotomy performance before and after practice in our overall cohort (39 [10] improving to 30 [11] seconds) was comparable to procedural speeds reported elsewhere in the literature (37 [11] improving to 28 [9] seconds in anesthesiologists who were between

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0 and 4 years into practice), suggesting strong external validity.[18] We found that after 5 practice repetitions, the 3D model group was 0.1 seconds faster than the pig trachea group (a clinically and statistically insignificant difference). Trainees were intentionally assessed only on pig tracheas (prepractice and postpractice) regardless of the study arm assignment, which would be expected to advantage the pig trachea arm and make it more challenging to demonstrate noninferiority. Our results provided strong evidence that despite the lower fidelity of the 3D model, the skills acquired from practicing on the 3D model translated well to skill performance on actual tissue. Of note, residents of all training years were included in the workshop due to the critical nature of learning to perform a cricothyrotomy. We recommend that programs seeking to replicate this workshop for all years of resident training should schedule the workshop in the latter half of the year to avoid overwhelming first year clinical anesthesiology residents while they are acquiring basic skills of the specialty.

Regarding surgical versus percutaneous cricothyrotomy technique, the evidence in the literature does not clearly support the superiority of one technique over the other.[19] We chose to teach surgical cricothyrotomy in this workshop owing to the availability of supplies for simulation and prior literature that suggested improved success rates with the surgical approach among inexperienced trainees.[20,21]

Existing airway simulation modalities, such as pig tracheas, cadavers, and mannequins, require dedicated educational space and resources. The 3D-printed model holds several advantages over these traditional training models. It avoids use of biohazardous material and is inexpensive, reusable, and highly portable. Pig tracheas are inexpensive but are single use and require storage and handling of raw animal products; ethical concerns may also be present depending on the source of the animal product. Cadavers are high fidelity but are expensive, single use, and limited by donations. Mannequins are reusable but expensive. Cardboard models are inexpensive but are limited in their ability to simulate dissection of subcutaneous tissue. The novel silicone skin pad that we developed provides a higher degree of fidelity for the dissection process without significantly increasing overall costs. Limitations of the 3D model include the inability to simulate complications, such as a false passage, fracture of cartilage, and posterior wall perforation. Three-dimensional-printed models avoid the storage and handling challenges of a pig trachea and are far less expensive than a mannequin or cadaver model. Inexpensive practice kits (Figure 1C) can be readily produced in large batches as described in Appendix 1 and can be reused over multiple teaching sessions. The portability of this model provides flexibility to trainees who can subsequently take these kits home and practice at their convenience, thus promoting spaced repetition. We believe that these advantages make 3D models highly suitable for airway education.

The resin used for 3D printing of the model costs approximately $5 per model (all costs in US dollars). Entry-level 3D printers are more than sufficient for printing these models; these printers can be purchased for between $200 and $500 and can be reused for many years. Commercial 3D printing costs approximately between $30 and $35 per model. The silicone skin pads cost approximately $2 to $5 per pad; most of this cost comes from the silicone rubber gel, with the cloth fabric and acrylic paint amounting to pennies each. We purchased 3.8 liter (7.8 kg) of each of the 2 silicone gels (Smooth-On Ecoflex 00-20 and Smooth-On Ecoflex Gel), which cost approximately $200 each, and were able to make more than 200 3-inch by 2-inch pads from this amount. The silicone gel is available for purchase in smaller trial sizes costing $30 to $35 for 2 lb and would be sufficient to make several dozen pads. The cost could be further decreased by omitting the Ecoflex Gel and using only the Ecoflex 00-20 for both layers. Commercial skin pads can be purchased for approximately $50 each. Each silicone skin pad can be cut multiple times. In comparison, cadavers can cost several thousand dollars each and can only be cut once. Mannequins can range from hundreds of dollars to over a thousand dollars, with a recurring cost of hundreds of dollars to replace the skin/subcutaneous tissue after being cut. Pig tracheas cost approximately $1 to $2 dollars each. Cardboard task trainers cost under $1 each. Please refer to Table 3 for a comparison of models.

Strengths of this study include the randomization of study participants and the standardized assessment of time to cricothyrotomy completion. The educational goals of the workshop were enhanced using multiple audiovisual modalities, including a PowerPoint presentation, videos, and live demonstrations.

Study limitations include the single-institution source of the study participants, lack of objective assessment of technical skill quality, large noninferiority margin, failure to achieve the target sample size, and the work necessary to manufacture the silicone skin pads. While all participants satisfactorily placed the endotracheal tube into the pig trachea during the postpractice assessment, we did not assess outcomes such as the size of the vertical incision, the severity of the injury, or creation of a false lumen. These are clinically relevant complications that should be assessed in future studies. A relatively large noninferiority margin of 10 seconds was used for our analyses. The rationale was detailed above, although an argument could be made that a smaller noninferiority margin should be used given the emergent nature of the procedure. The sample size was 7 participants short of the target recruitment, although we were still able to demonstrate statistical noninferiority. The silicone skin pads were universally appreciated by workshop participants, but they were the most expensive component of the model and considerable effort was needed to manufacture them as described above in the Materials and Methods and in Appendix 1. Possible solutions include producing the skin pads in large batches or using a low-cost alternative as described in prior literature, such as cloth fabric and foam pipe insulation.[11]

This work provides a foundation to improve the teaching of emergency airway access to anesthesiology trainees and other care providers involved in airway management. Future areas for research could include assessing the effectiveness of this task trainer for emergency airway

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training in nonanesthesia personnel, such as first responders. While only a surgical cricothyrotomy technique was tested in this project, the 3D model is likely suitable for simulation training of needle (percutaneous) cricothyrotomy technique. Furthermore, the 3D model could be customized to simulate other challenging airways, including distorted airway anatomy (eg, torticollis and tracheal deviation from injury), obesity (thicker silicone skin pad), or bleeding (artificial blood vessels in the skin pad).

Conclusion

This study demonstrated that the 3D model is noninferior to pig tracheas for teaching surgical cricothyrotomy to anesthesia trainees. Three-dimensional printing offers exciting potential for emergency airway simulation, and we look forward to future developments in this field.

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Abstract

Background: Cricothyrotomy is a final recourse for salvaging a difficult airway, yet most anesthesiology providers have little training, exposure, or comfort with the procedure. Pig tracheas are frequently used for training, but are single use and require special handling and storage. Other simulation models, such as mannequins and cadavers, are costly. Advances in 3dimensional (3D) printing have improved accessibility and decreased costs. This research project sought to determine whether an inexpensive 3D-printed task trainer was noninferior to pig tracheas for teaching surgical cricothyrotomy skills.

Methods: Anesthesiology residents were enrolled in an institutional review board-exempted, unblinded, randomized, controlled, single-institution, noninferiority trial. Participants were trained in the scalpel-finger-bougie technique for surgical cricothyrotomy. Participants were randomized to practice 5 repetitions on either a pig trachea or the 3D model and were assessed on time to cricothyrotomy completion on a pig trachea before and after practice.

Results: Demographic characteristics of the 25 workshop attendees were similar between study arms. Overall mean (SD) improvement in speed was 9 (12) seconds ($P = .001$). Postpractice times were similar between groups (analysis of covariance estimated difference of −0.1 seconds [95% confidence interval, −9.4 to 9.2]; $P = .55$). The 3D model was noninferior to the pig trachea at the prespecified noninferiority margin of 10 seconds ($P = .017$).

Conclusions: The 3D model was noninferior to pig tracheas for improving the time to completion of a surgical cricothyrotomy. A 3D-printed model offers a viable alternative to pig tracheas for emergency airway simulation that is inexpensive, reusable, and readily modified to simulate challenging airway anatomy.

Keywords: Anesthesia, anesthesiology, airway, simulation, education, residency, trachea

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Tables

Table 1. *Demographic Characteristics and Time to Cricothyrotomy Completion*

Outcome	3D Cricothyrotomy Trainer (n = 13)	Pig Trachea (n = 12)
Age, mean (SD), y	31 (3)	30 (2)
Sex		
Female, n (%)	3 (23)	5 (42)
Male, n (%)	10 (77)	7 (58)
Trainee		
CA1, n (%)	6 (46)	5 (42)
CA2, n (%)	3 (23)	5 (42)
CA3, n (%)	4 (31)	2 (17)

Abbreviations: 3D, 3-dimensional; CA1-3, clinical anesthesiology resident (year 1, 2, or 3).

Table 2. *Time to Completion Data*

Outcome	3D Cricothyrotomy Trainer (n = 13)	Pig Trachea (n = 12)	*P* Value
Prepractice speed, mean (SD), s	38 (10)	41 (10)	.82
Postpractice speed, mean (SD), s	30 (11)	31 (11)	.51
Improvement in speed of cricothyrotomy after practice, mean (SD), s	8 (11)	10 (14)	.75

Abbreviation: 3D, 3-dimensional.

Table 3. *Comparison of Airway Simulation Models*

Model	Fidelity	Reusable	Cost	Comments
Cadaver	High	No	Very high (several thousand dollars each)	Requires precautions and preparation for human tissue.
Pig trachea	High	No	Low ($1 each)	Requires precautions and preparation for raw animal product.
Mannequin	Moderate	Yes	High (several hundred dollars per mannequin, plus additional hundreds of dollars for replacement skin pads)	Simulated skin and cricothyroid membrane may be proprietary and expensive.
3D-printed model	Low to moderate	Yes	Low ($5 for each 3D model, $3 to $5 for each silicone skin pad depending on size)	3D printing is inexpensive, although there is a significant up-front cost for the 3D printer.
Cardboard	Very low	No	Low (less than $1 each)	Requires manual assembly.

Abbreviation: 3D, 3-dimensional.

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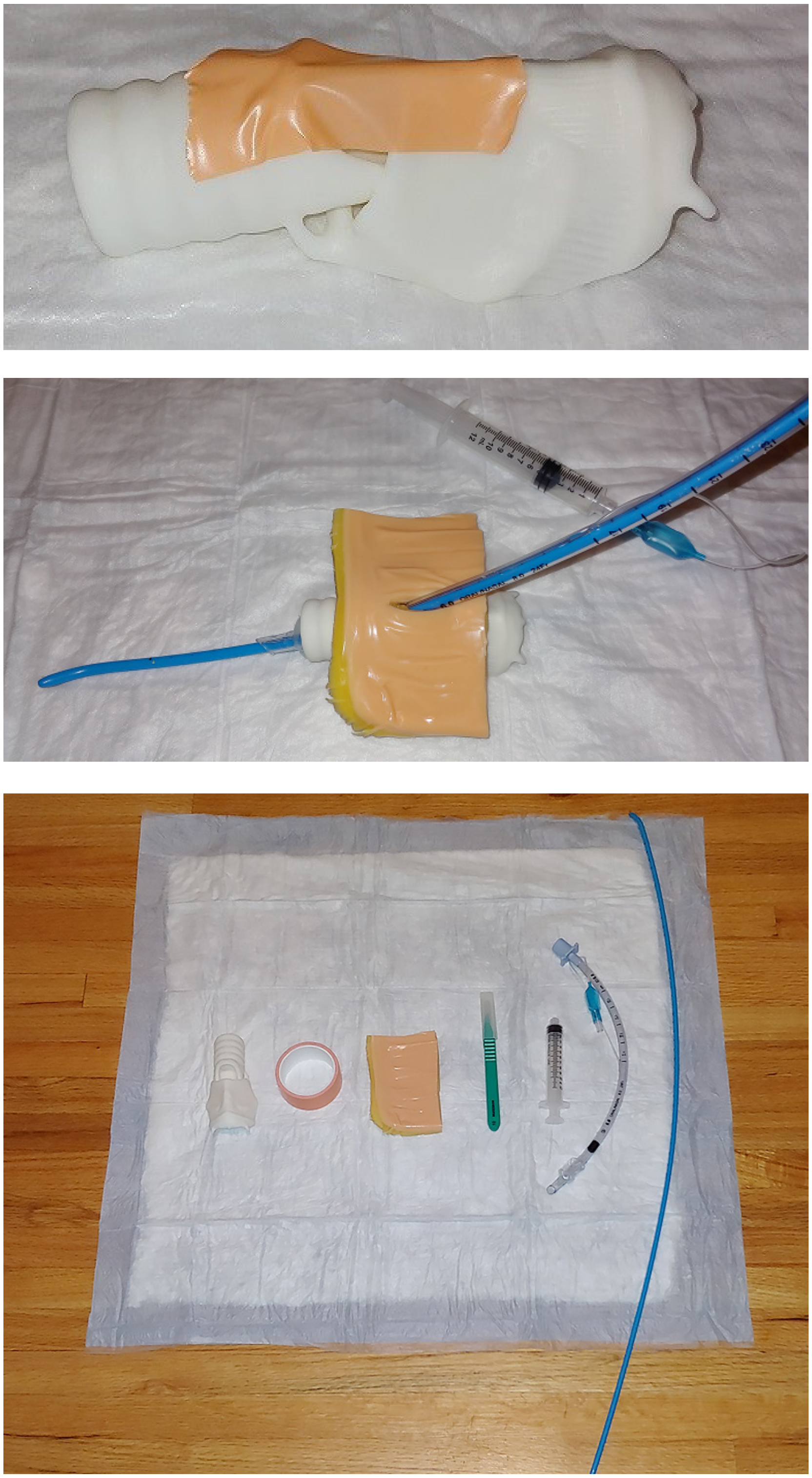
Figures

Figure 1. *Training supplies. (upper panel) Three-dimensional printed model (3D Cric Trainer; The Airway App) with zinc oxide tape (Hy-Tape International) applied to simulate the cricothyroid membrane. (middle panel) Model is overlaid with a silicone "skin" pad and shows the completed surgical cricothyrotomy. (lower panel) Materials for practicing a surgical cricothyrotomy.*



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Appendices

Appendix 1. Workshop Materials

3D Model

The STL file for the 3D Cric Trainer was downloaded from The Airway App website (http://www.airwaycollaboration.org/3d-cric-trainer-1) and 3D printed using Formlabs white resin (https://formlabs.com/store/materials/white-resin/). Rolls of zinc oxide tape (Hy-Tape International; 2.54-cm width) were obtained through an institutional supplier to simulate the cricothyroid membrane. See Figure 1 (upper panel) for a photograph of the 3D Cric Trainer with zinc oxide tape applied.

Silicone Pads to Simulate Skin

Silicone pads were constructed using two separate layers of silicone with an intervening layer of fabric. The dermis layer was constructed by mixing the Smooth-On Ecoflex 00-20 with several drops of generic peach-colored acrylic paint and pouring the resulting mix into disposable aluminum broiler pans (34- × 23- × 2.2-cm) to create a layer approximately 0.5-cm deep. Once the dermis layer had solidified, a single layer of power mesh fabric purchased from Joann Fabrics was layered on top of the dermis layer to improve the texture of the final product and increase the fidelity when cutting with a scalpel. The subcutaneous layer was constructed by mixing the Smooth-On Ecoflex Gel with several drops of generic yellow acrylic paint and pouring the resulting mix over the dermis layer and fabric. Once the subcutaneous layer had solidified, the entire construct was removed from each aluminum broiler pan and cut into approximately 5- × 7.6-cm rectangles using a pair of office scissors.

This photograph (Appendix Figure 1) depicts the two components of Smooth-On Ecoflex Gel on the left side in the yellow and blue buckets. Mixing bowls can be seen between the buckets. A small bottle of yellow acrylic paint sits next to the bowls. Three rows of aluminum broiler pans can be seen. The top row depicts solidified fully constructed skin pads. The lower two rows only have the initial peach dermis layer and are awaiting application of the fabric layer followed by the yellow subcutaneous layer.

Cricothyrotomy Tools

Bound Tree Curaplex 6.0-mm endotracheal tubes, McKesson 10-mL general purpose Luer lock syringes, McKesson disposable scalpels, and Tiger Medical 15 French Dynarex 4583 Endotracheal Tube Introducers (bougies) were obtained from institutional suppliers.

Pig Tracheas

Pig tracheas were purchased from Hormel Foods (Austin, MN) by the Mayo Simulation Center. The pig tracheas were frozen before shipment, delivered frozen, and stored in a designated freezer in a locked room accessible only to management staff. The workshop was conducted in a room designated for education and distant from areas used for patient care. No food or drink was allowed in the above room.

Other Supplies

Chux pads, nitrile gloves of varying sizes, and gallon-size freezer bags were obtained from institutional suppliers.

Appendix Figure 1. *Two components of Smooth-On Ecoflex Gel on the left side in the yellow and blue buckets.*

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Appendices *continued*

Appendix 2. Workshop Didactics

Workshop participants received a series of didactics, including a PowerPoint presentation, videos, and live demonstrations on the simulation models. After the baseline assessment on a pig trachea, participants then practiced several repetitions on their assigned model (3D-printed task trainer or pig trachea). Instructors were available to provide personalized feedback during individual practice time.

PowerPoint Presentation

The PowerPoint presentation included a review of the American Society of Anesthesiologists Difficult Airway algorithm, a review of pertinent anatomy, comparison of needle versus surgical cricothyrotomy techniques, and a walkthrough of the scalpel-finger-bougie technique. A compilation of clinical pearls from experienced anesthesiologists was included at the end of the presentation. The PowerPoint file is available upon request.

Videos

Three short videos from EMCrit Podcast 131 "Cricothyrotomy–Cut to Air: Emergency Surgical Airway" (https://emcrit.org/emcrit/surgical-airway/) were played for the audience.

Specifically, the following three videos were played during this workshop: "Scalpel Finger Bougie II", "Scalpel Finger Bougie I", and "Idealized Cric on Actual Patient".

Instructor-led Live Demonstrations

The scalpel-finger-bougie technique was demonstrated on both a 3D-printed task trainer as well as on a pig trachea.

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Appendices *continued*

Appendix 3. Workshop PowerPoint

Surgical Cricothyrotomy
"Scalpel-Finger-Bougie"

Jeffrey Huang, MD
January 2020

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Goals

- By the end of this workshop, participants should be proficient with the Scalpel-Finger-Bougie technique for emergency cricothyrotomy

2

Cricothyrotomy

- Cricothyrotomy is a life-saving emergency intervention located at the end of the difficult airway algorithms published by the American Society of Anesthesiologists and the Difficult Airway Society
- Most providers have little to no experience performing a cricothyrotomy
- Two approaches
  - Needle (Percutaneous)
  - Surgical

3

Needle vs Surgical Cric

- Multiple different commercial cric kits available
- Low quality evidence on which technique is superior
  - Systematic review inconclusive, though trend towards surgical cric being superior
- Heyman et al found that trainees inexperienced in either approach were more successful with the surgical approach.

4

Needle Cric

- More familiar for anesthesia providers (Seldinger technique)
- Less risk of injury to nearby structures
- Downsides:
  - Guidewire may kink and prevent advancement of dilator
  - Needle or guidewire may end up in a false passage (i.e. not in the trachea)
  - Slower
  - Lower success rate

5

Surgical Cric

- Faster
- Higher success rate
- Downsides:
  - Less familiar for anesthesia providers
  - Higher risk of injury to nearby structures

Langvad S, Hyldmo PK, Nakstad AR, Vist GE, Sandberg M. Emergency cricothyrotomy - a systematic review. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine 2013, 21:43.

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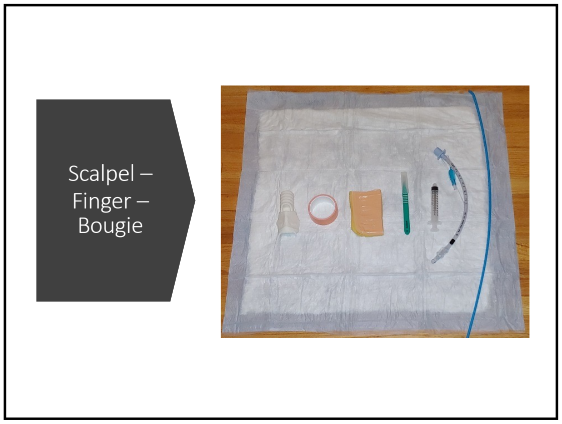
Appendices *continued*



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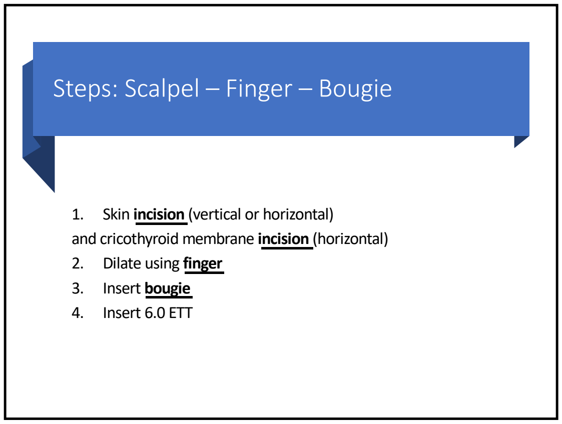

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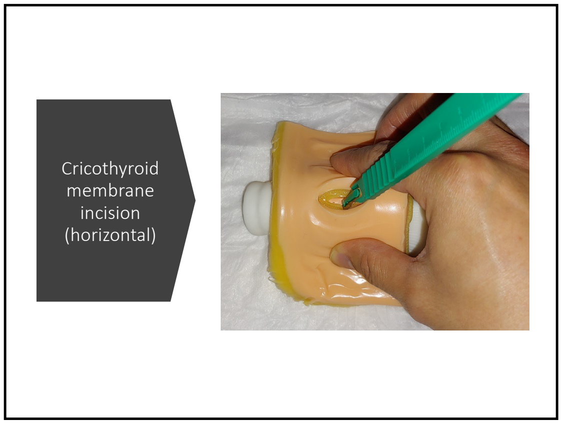

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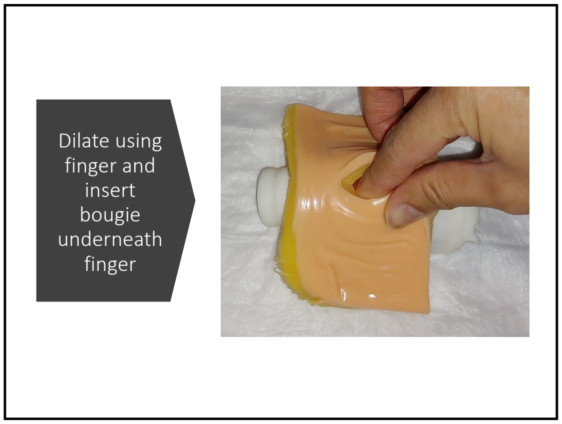

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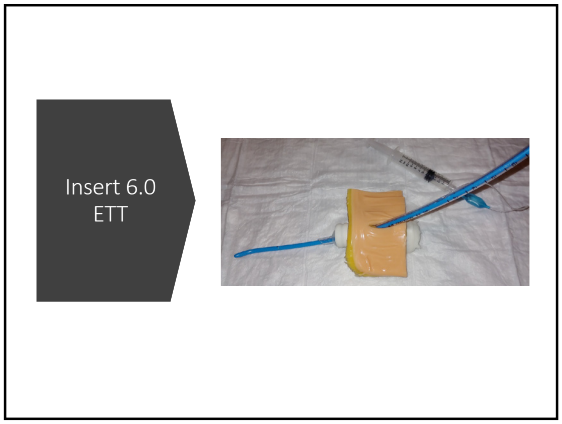

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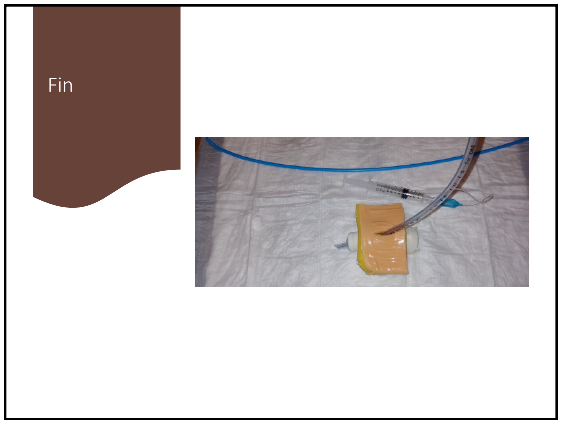

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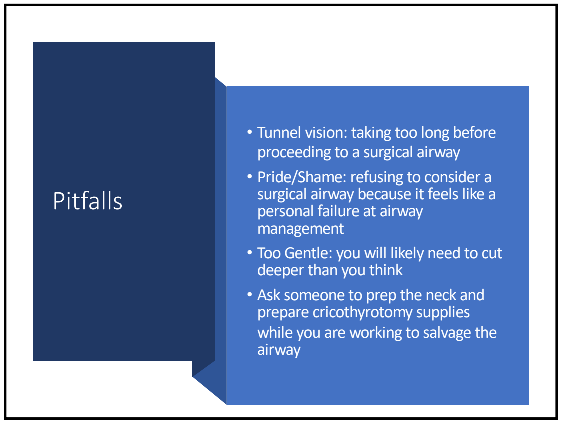

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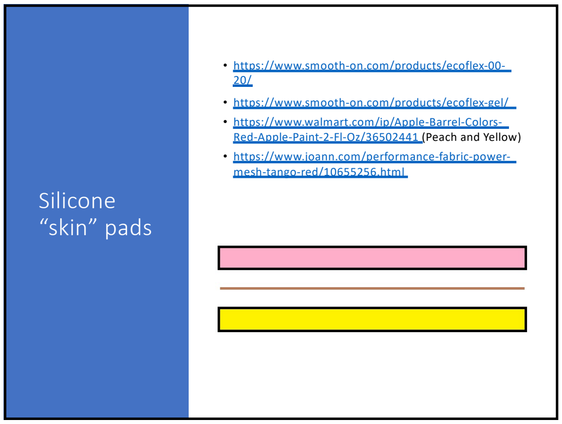

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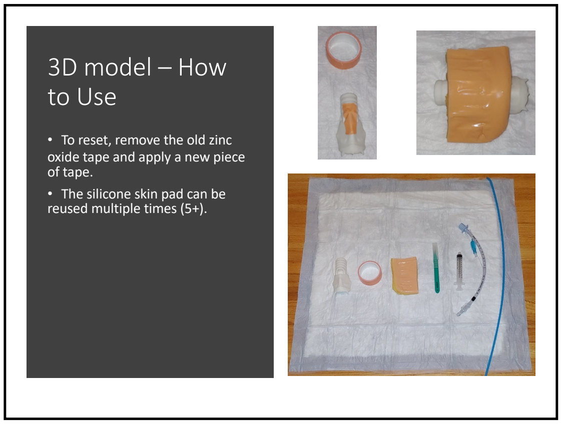

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