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TITLE:

Manufacture of a Multi-Purpose Low-Cost Animal Bench-Model for Teaching Tracheostomy

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KEYWORDS:

Manufacture; low-cost; bench-model; tracheostomy; percutaneous; cricothyrotomy; simulation; anesthesiology; otorhinolaryngology; surgery; education; medical education.

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SUMMARY:

This article illustrates every step of the manufacture of a new multi-purpose low-cost animal bench-model for subglottic airway access management. All the procedures are shown in the video. The model's realism and its suitability for training the given clinical maneuvers were assessed by independent senior otolaryngologists and anesthesiologists.

40 41 42

ABSTRACT:

- 43 Tracheostomy is one of the most frequent procedures, performed through various techniques
- in the intensive care unit and emergency situations. Despite this, there is a lack of training on
- 45 this procedure that affects its outcome, which is also dependent on operator's dexterity.
- 46 Here, we take the specific training and simulation into consideration. This article aims to
- 47 describe every step of the manufacture of a new multi-purpose low-cost animal bench-model,

with the support of video and images, and to obtain an opinion about the quality of this model by administering a questionnaire to professionals with experience in the procedures.

Ten experts in the technique were enrolled. The model scored an average of 3.45/5 for its anatomical realism; 4.75/5 for its usefulness as a training tool for simulation courses and assessments. The time necessary to build the model was 15 minutes, and the cost amounted to 10€. The animal bench-model was considered a very useful simulator for tracheostomy training and assessments. Therefore, it could be used as a tool for medical courses and residencies.

INTRODUCTION

Difficult airway management is a critical skill for every physician dealing with critical, ill, and emergency patients. A review published in 2013 estimates that the incidence numbers of 'cannot ventilate, cannot intubate' situations with the use of surgical airway techniques vary from 0 to 18.5%¹.

Tracheostomy is one of the oldest surgical procedures and is extensively used as the method of choice for subglottic airway access for patients requiring prolonged artificial ventilation. Originally performed in the operating theater, it has become a routine practice bedside at many hospitals, especially in the intensive care unit (ICU)². Several types of techniques have been described, including surgical (ST) and percutaneous tracheostomy (PCT). Tracheostomy has been widely reported to have high complication rates. A national audit reports that 50% of airway-related deaths or brain damage in critical care are caused by tracheostomy complications³. Often, the high complication rates reflect lack of familiarity with the technique and inadequate training.

Another way to subglottically access the airways is to perform a cricothyrotomy (CT), which has been broadly recommended as a strategy to deal with 'cannot ventilate, cannot intubate' situations in both prehospital and intra-hospital care⁴. Being a fast and potentially lifesaving fallback maneuver in the patients with a failed airway, clinicians responsible for airway management must be familiar with the technique. Practice and training therefore play a pivotal role since its success is dependent on the operator's dexterity⁵. However, due to improvements in airway management in the past decades, a decline in the need for tracheotomy and emergency surgical airways was observed. This has resulted in a lack of clinical experience and decreased exposure to this life-saving technique, which may negatively affect the quality of procedures and ultimately the safety of patients^{6,7}.

 Nowadays, simulation is a common and effective teaching method to train medical and surgical skills, especially for novices who are learning new abilities^{8,9}. Simulation allows to recreate a clinical procedure or situation, providing trainees with first-hand exposure to clinical scenario and complex techniques while eliminating the risk for patients¹⁰.

A broad variety of simulators, from virtual reality to animal models, have been used in training surgical airway management¹¹⁻¹⁴. Practice on models and mannequins is reported to be the most common form of instruction for Anesthesiology and Emergency Medicine residents^{15,16}. Cadavers have also been used to teach neck anatomy and the procedural skills¹⁷. However, the cost of all these options are sometimes prohibitive and can pose ethical and moral

constrains and challenges. Low cost simulators have also been described and suggested for educational purposes but have not been used to train all the subglottic airway access procedures.

In this manuscript, we describe how to manufacture an easily-made, low-cost and high-fidelity bench-model that simulates the human neck to perform cricothyrotomy, percutaneous and surgical tracheostomy and its evaluation. The main aim was to design an easy-to-make model with readily and regularly available materials so that anyone can simply emulate and reproduce it. The overall time to assemble the model was about 15 minutes and the cost estimate was approximately of 10€ including resources and manufacturing (20€/h).

PROTOCOL:

The animal anatomic segments, normally intended for human consumption, were purchased at a local butcher's shop (**Figure 1**). Therefore, they could be easily transported and stored with no specific restrictions or sanitary regulations.

112 1. Cleaning the swine upper airways

1.1. With the help of a dissecting scalpel, Adson forceps and Metzembaum scissors, clean
 the trachea and larynx from excess surrounding tissues (lateral muscles, excess of tongue),
 by cutting and dissecting.

1.2. Remove tissue until the larynx cartilages are almost exposed and the tracheal ringsare easy to palpate.

1.3. Remove the hyoid bone and surrounding soft tissues: find the eminence of the greater horn and follow the horn with the blade, then pass to the contralateral one and repeat the same operation until the whole part is removed.

125 1.4. Cut the trachea at its distal side approximatively at 15 cm from the larynx using a dissecting knife.

NOTE: The removed part, composed by mediastinal organs, will be used for the next step in the procedure.

2. Preparing the thyroid

133 2.1. Take the previously discarded mediastinal organs and search for the thymus.

NOTE: The thymus is usually located on the frontal portion of the mediastinum right over the right atrium. Adult pigs may have a very small thymus.

138 2.2. With dissecting forceps, detach the thymus from the surrounding tissue. 139 140 2.3. Carve the just obtained pig thymus into a butterfly shape to recreate a simulated 141 thyroid. 142 143 2.3.1. With a dissecting knife, cut a flat slice of thymus 1.5 cm thick. 144 145 2.3.2. With Metzembaum scissors, cut the slice in a butterfly shape with two 3 cm x 2 cm 146 lobes connected by a hystmus. 147 148 NOTE: The overall dimensions of the thyroid should be 3 cm long, 6 cm large and 1.5cm 149 thick. 150 151 3. Suturing the thyroid to the tracheal wall. 152 153 NOTE: For the next step, use the previously prepared upper airways and the simulated 154 thyroid. 155 156 3.1. Place the simulated thyroid between the first and third tracheal ring. 157 158 3.2. Take a needle holder and surgical forceps. Grab a 2/0 silk suture. 159 160 Suture the thyroid with two lateral horizontal mattress stitches passing in each lobe 3.3. 161 and in the lateral portion of the trachea. 162 163 NOTE: The horizontal mattress stitch wraps more tissue than the normal stitch. This is 164 important when suturing soft tissues, as pig thymus, that tends to tear up. 165 166 3.4. Pass the needle only in the superficial part of the trachea to prevent the possibility of 167 seeing the thread in the tracheal lumen if performing fibroscopy. 168 169 NOTE: Identification and preservation of the thyroid gland avoiding postoperative bleeding 170 represent crucial surgical steps during tracheotomy procedure. 171 172 4. Preparing the esophagus 173

174 4.1. Use the esophagus, which is located on the backside of the trachea, to simulate the 175 neck fascia and muscles.

176

4.2. Remove the esophagus from its larynx connection by cutting it with a scalpel or withsurgical scissors.

179 180 4.3. Cut and open the esophagus on its length with surgical scissors. 181 182 4.4. Hold the muscle and mucosa with toothed forceps to help the cutting procedure. 183 The result of this operation will be a rectangle of muscle covered by esophagus mucosa. 184 185 5. Suturing the esophagus to the trachea 186 187 Place the just obtained layer of muscles on top of the trachea and larynx with the 5.1. 188 mucous membrane face up. The aim is to cover the larynx: from the thyroid cartilage 189 summit to the last tracheal rings. 190 191 Suture the opened esophagus with at least 6 simple stitches: 5.2. 192 One on the proximal side of the model, on the summit of the Thyroid cartilage. 193 One on the distal side of the preparation, on the frontal portion of the last tracheal ring. 194 At least one on each side of the trachea. 195 One on each side of the lower lateral portion of the thyroid cartilage where cricothyroid 196 muscles are. 197 198 5.3. 5.3. Mark a line on the esophagus mucosa with white India ink to simulate the linea 199 alba. 200 201 NOTE: Identification and proper dissection through the *linea alba* is an important step 202 during tracheotomy procedure (Figure 2). 203 204 5.3.1. To do so, use white India ink and an insulin syringe. 205 206 5.3.2. Withdraw some ink and then track a line on the simulated fascia by scratching it with 207 the needle while spilling little drops of ink. 208 209 5.3.3. Remove the excess of ink gently with a small swab. 210 211 6. Preparing the foam base for the model 212 213 6.1. Cut a square of foam of 3 cm x 10 cm x 15 cm. 214 215 6.2. Shape a furrow 2.5 cm large and 10 cm long in the center of the foam. 216 217 6.2.1. To do this, fold half of the square of foam so that it creates a longitudinal hump on one side. 218 219

6.2.2. Cut 1 cm of the hump off all its length with scissors.

220

221		
222	6.2.3.	Unfold the foam square and trim the just formed furrow smoothly.
223		
224	7.	Stapling the model to the wooden tablet
225		
226	7.1.	Take a wooden tablet of the same dimensions of the foam.
227		
228	7.2.	Place the foam square on the wooden tablet and insert the model in the foam
229	furrow	

230

7.3. With a wood stapler, place a clip on the end of the trachea, on the remaining lateral muscles of the thyroid cartilage and on the epiglottis.

233

8. Preparing the skin

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236 8.1. Take the pig skin collected from the butcher shop and cut it in a square shape big enough to cover the whole model. Usually, a square of 25 cm x 20 cm is sufficient.

238

239 8.2. Cut the skin with a dissecting knife and cover the model with it.

240

241 9. Stapling the skin to the wooden tablet

242

243 9.1. Take the stapler and fix the skin to the tablet with about 10-15 clips. Place them on the vertical sides of the tablet

245

246 9.2. Trim the excess skin on each side of the tablet with the help of a knife.

247

248 9.3. Use cocker forceps to firmly hold the skin to allow a safer cutting.

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REPRESENTATIVE RESULTS

- We assessed the feasibility and acceptability of the easily-made, low-cost and high-fidelity bench-model that simulates the human neck as a tool for cricothyrotomy, percutaneous and surgical tracheostomy training. After a review of current literature about simulation in surgical education, a survey instrument was designed. The questionnaire consisted of the following content sessions:
- 256 a. general data and demographics of the participants;
 - b. fidelity of the bench-model;
- c. suitability of cricothyrotomy, percutaneous and surgical tracheostomy for training by the manufactured model.

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- Participants were asked to rate statements with a five-point Likert scale (1: strongly disagree, 5: strongly agree). All participants were also given the opportunity to add positive and
- 263 negative aspects of the bench model as well as to recommend improvements. A detailed

description of the survey instrument is provided in **Table 1**. A panel of experts composed of simulation educationalists, Ear, Nose and Throat (ENT) physicians, anesthesiologists and surgical education tutors reviewed the survey instrument content for accuracy and provided appropriate modifications to ensure validity of the study.

Participation to the study was voluntary, anonymous, and independent. Confidentiality of information was ensured and no financial incentive to participate in the study was offered. The study was conducted in accordance with the principles of the Declaration of Helsinki. Data were analyzed using a spreadsheet and are presented as mean and interquartile range (IQR). Qualitative data from the open-ended question were interpreted using content analysis.

Ten independent senior ENT physicians and anesthesiologists with experience in cricothyrotomy, percutaneous and surgical tracheostomy were enrolled. The mean age and the mean seniority were 31 years and 7 years, respectively. The overall mean rating for realism of the model, including anatomy, tactile feedback, reaction of the tissues to palpation, perception of landmarks, was 3.45/5. Suitability of model training for the given subglottic airway access procedures was highly rated with an overall mean of 4.75/5. All responders listed positive and negative aspects in the open-ended part of the survey. A total of 24 suggestions were collected. Three positive and 3 negative aspects were identified (**Table 1**). Among the positive ones, the most often suggested was the tactile feedback of the model compared to the synthetic alternatives. Whilst the sliding of the layers of the model was the negative aspect most often found. Four participants suggested possible improvements, which are reported in **Table 1**.

FIGURES AND TABLE LEGENDS:

Figure 1: **Different animal segments needed to make the model.** From the top-left: Swine upper airways, pig thymus cut in a butterfly shape, swine esophagus opened longitudinally, pig skin.

Figure 2: Fascial dissection. In this picture, the finished model during the surgical open tracheostomy procedure is shown. In the center, the blunt dissection of the simulated neck fascia and muscles with Metzembaum scissors are shown.

Table 1: Description of the survey instrument and results.

DISCUSSION:

The manufactured low-cost and high-fidelity bench-model simulated the human neck and enabled practice of cricothyrotomy, percutaneous and surgical tracheostomy. The designed survey filled by senior ENT physicians and anesthesiologists evaluated the extent to which the model replicates the physical characteristics of the neck and its suitability for training the given subglottic airway access procedures.

Several home-made models or simulators have been reported and we tried to overcome their limitations. The porcine model presented by Netto et al.¹⁸ lacks anatomical structures between the skin and trachea, making it suitable for cricothyrotomy only. Two studies describe synthetic models assembled with candies and anesthesia room materials (tubes, gauzes) compromising the fidelity and excluding the model for ST training^{19,20}. To our

knowledge, our bench model is the first multipurpose model suitable for the three main tracheostomy procedures (CT, PDT, ST).

Porcine trachea with all the annexes (muscles, cervical fascia, thyroid gland) and skin are relatively similar to human tissue²¹. Nevertheless, it is hard to find the whole animal piece since the neck is usually cut through all its length and many structures are lost in the pig slaughter procedures. For this reason, we assembled a simulated thyroid to allow interisthmic tracheotomy. The pig thymus was chosen as the most suitable organ for this purpose due to its texture.

The pig skin was sometimes too thick, making the trachea prone to collapse when putting force on the neck to penetrate it with needles and dilators in the percutaneous approach. The anatomical difference among the assembled models due to the variety of animal tissues could pose some challenges in terms of reproducibility and quality of the models. However, this could equate to the anatomic variability of human necks. The lack of bleeding and tissue secretion is another limit of ex vivo models. Simulation of bleeding remains a challenging problem because of the complexities of the circulatory system and the physics of viscous fluid flow. Due to this limitation, the reported model could be considered as a middle-fidelity simulator.

Traditionally, mannequins, live, and anaesthetized animals are used in cricothyrotomy and tracheotomy teaching. Nevertheless, mannequins are not similar enough to the human anatomy and do not provide a realistic model to learn this technique. Animals would be ideal but the cost is prohibitive and only a limited number of residents may have this opportunity²².

The lack of funds is considered a barrier to medical training. The cost of commercial mannequins and synthetic devices ranges from 1000\$ to 3000\$ and replacement pieces are expensive too. We tried a synthetic simulator²³ that can be reused no more than 10 times. In addition, after the first incision, only the dilation and insertion of the tube can be performed several times, making the educational procedure incomplete. On the contrary, a cheap, disposable model such as the one described here can be assembled and used in a few minutes with no expensive components. The model can be reused up to three times, reducing the cost of the model per number of attempts. The 3 different techniques can be performed consequently, since they are executed in different portions of the model: (1) emergency cricothyrotomy, (2) percutaneous dilatational tracheostomy, and (3) surgical open tracheostomy.

Difficult airway management is a critical skill and it is still associated to a high complication rate. Since its success is dependent on operator's experience and dexterity, practice and training play a key role. Generally, the training is still limited to explanation and seeing the technique. Most of the residents have the opportunity to see the procedure only a few times before performing it in a clinical setting. This article presents step-by-step instructions to manufacture an experimental airway bench-model based on low technology and cost for teaching the three main tracheostomy procedures (CT, PDT, ST). However, the evaluation survey showed that the model, although realistic, should be perfectioned.

- 358 In the future, we would like to compare skins from different animals (e.g., a calf, a turkey, and
- a rabbit) to find the best choice and how much this can affect procedure quality and ultimate
- 360 learning. Finally, we would like to adopt and improve the idea by Fiorellia et al.²² to mix
- 361 synthetic simulators and animal tissues. We will build a synthetic shell scaffold representing
- 362 the head, neck and upper thorax, where a pig trachea can be inserted. This might help to tear
- 363 down the manufacture time and reach higher fidelity, reproducibility and cost efficiency.
- 364 Further studies should be carried out to compare this model to other animal models and other
- 365 synthetic task trainers in terms of fidelity and training effectiveness.

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DISCLOSURES:

The authors have nothing to disclose.

372 373 374

REFERENCES

- 375 1. Langvad, S., Hyldmo, P. K., Nakstad, A. R., Vist, G. E., Sandberg, M. Emergency
- 376 cricothyrotomy--a systematic review. Scandinavian Journal of Trauma, Resuscitation And
- 377 Emergency Medicine. **21**, 43 (2013).
- 378 2. Ben-Nun, A., Altman, E., Best, L.A. Emergency percutaneous tracheostomy in trauma
- patients: an early experience. *Annals of Thoracic Surgery*. **77** (3), 1045-7 (2004).
- 380 3. Cook, T.M., Woodall, N., Harper, J. Major complications of airway management in the UK:
- 381 results of the Fourth National Audit. Project of The Royal College of Anaesthetists and the
- 382 Difficult Airway Society. *British Journal of Anaesthesia*. **106**, 632–642 (2011).
- 383 4.Das, B., Nasreen, F., Haleem, S. A "cannot ventilate, cannot intubate" situation in a patient
- 384 posted for emergency surgery for acute intestinal obstruction. Anesthesia Essays and
- 385 Research. **7** (1), 140-141 (2013).
- 386 5. Bann, S., Khan, M.S., Datta, V.K., Darzi, A.W. Technical performance: relation between
- surgical dexterity and technical knowledge. World Journal of Surgery. 28 (2), 142-146 (2004).
- 388 6. Lesko, D., Showmaker, J., Ukatu, C. Declining Otolaryngology Resident Training Experience
- in Tracheostomies: Case Log Trends from 2005 to 2015. Otolaryngology Head and Neck
- 390 Surgery. **156** (6), 1067-1071 (2017).
- 391 7. Patel, H.H., Siltumens, A., Bess, L. The decline of tracheotomy among otolaryngologists: a
- 392 14-year review. *Otolaryngology Head and Neck Surgery.* **152**, 465-9 (2015).
- 393 8. Maran, N.J., Glavin, R.J. Low-to high-fidelity simulation a continuum of medical education?
- 394 *Medical Education.* **37** (1), 22-8 (2003).
- 395 9. Lippert, A., Dieckmann, P.G., Oestergaard, D. Simulation in medicine. Notfall
- 396 Rettungsmedizin. 12 (2), 49 (2009).
- 397 10. Beaubien, J.M., Baker, D.P. The use of simulation for training teamwork skills in health
- 398 care: how low can you go? Quality & Safety in Health Care. 13 (1), 51-6 (2004).
- 399 11. Terragni, P., Mascia, L., Faggiano, C. A new training approach in endoscopic
- 400 percutaneous tracheostomy using a simulation model based on biological tissue. Minerva
- 401 Anestesiologica. **82** (2), 196-201 (2016).
- 402 12. Jayaraman, V., Feeney, J.M., Brautigam, R.T. The use of simulation procedural training to
- 403 improve self-efficacy, knowledge, and skill to perform cricothyroidotomy. The American
- 404 Journal of Surgery. **80** (4), 377-81 (2014).

- 405 13. Takayesu, J.K., Peak, D., Stearns, D. Cadaver-based training is superior
- 406 to simulation training for cricothyrotomy and tube thoracostomy. 12 (1), 99-102 (2017).
- 407 14. Aho, J.M. et al. Every surgical resident should know how to perform a cricothyrotomy: an
- 408 inexpensive cricothyrotomy task trainer for teaching and assessing surgical trainees. Journal
- 409 of Surgical Education. **72** (4), 658-61 (2015).
- 410 15. Holak, E.J., Kaslow, O., Pagel, P.S. Who teaches surgical airway management and how do
- 411 they teach it? A survey of United States anesthesiology training programme. Journal of Clinical
- 412 *Anesthesia*. **23** (4), 275-9 (2011).
- 413 16. Makowski, A.L. A Survey of Graduating Emergency Medicine Residents' Experience with
- 414 Cricothyrotomy. The Western Journal of Emergency Medicine. 14 (6), 654-661 (2013).
- 415 17. Tonui, P.M., Nish, A.D., Smith, H.L., Letendre, P.V., Portela, D.R. Ultrasound Imaging for
- 416 Endotracheal Tube Repositioning During Percutaneous Tracheostomy in a Cadaver Model: A
- 417 Potential Teaching Modality. *Ochsner Journal.* **14** (3), 335-338 (2014).
- 418 18. Netto, F.A. et al. A porcine model for teaching surgical cricothyridootomy. *The journal of*
- 419 the Brasilian College of Surgeons. **42** (3), 193-196 (2015).
- 420 19. Varaday, S.S., Yentis, S.M., Clarke, S. A homemade model for training in cricothyrotomy.
- 421 Anaesthesia. **59,** 1012–1015 (2004).
- 422 20. Bryant, R.J., Morgan, M.H., Youngquist, S.T., Fix, M.L. Edible Cricothyrotomy Model: A
- Low-Cost Alternative to Pig Tracheas and Plastic Models for Teaching Cricothyrotomy. *Journal*
- 424 of Education and Teaching Emergency Medicine. **2** (1) (2017).
- 425 21. Fikkers, B.G., van Vugt, S., van der Hoeven, J.G., van den Hoogen, F.J., Marres, H.A.
- 426 Emergency cricothyrotomy: a randomised crossover trial comparing the wire-guided and
- 427 catheter-over-needle techniques. Anaesthesia. 59 (10), 1008-11 (2004).
- 428 22. Fiorelli, A. et al. A home-made animal model in comparison with a standard manikin for
- 429 teaching percutaneous dilatational tracheostomy. Interactive Cardiovascular and Thoracic
- 430 Surgery. 20, 248-253 (2015).
- 431 23. Cricotracheotomy Trainer Manikin Global Technologies "Simulators for Education" -
- 432 Parmabotics LTD. Authorized Dealer (2019).





	Mean (IQR)
Session 1: Demographics	31,3 (6)
1 Age	
2 Gender	
3 Professional seniority (in years)	6,6 (7)
Session 2: Fidelity of the bench-model	
4 The model represents accurately human neck anatomy (for what concert the performed procedure)	rns 3,2 (0,25)
5 The model tissues reacts to my movements in a realistic way and give a realistic tactile feedback	me 3,6 (1)
Session 3: Suitability of cricothyrotomy, percutaneous and surgical tracheostomy training by the manufactured model	for
6 The model is a useful instrument to simulate the procedure	4,8 (0,25)
7 The model enables to train on all the essential technical skills needed the procedure (excluding communication with patient or clinical decisi making)	, ()
8 The simulator could be used for training purpose	4,8 (0,25)
9 The simulator could be used as a test/assessment in surgery school	4,8 (0,25)

Positive aspects of the bench model

Better tactile feedback than the synthetic simulator Possibility to enhance manuality and technical skills of students/residents Could allow students to better understand the steps of the procedure

Negative aspects of the bench model

Skin is too thick and hard to penetrate Skin slides over deeper layers Difficult to find landmark

Recommended improvements

Prevent the sliding movements by suturing the layers together Experiment skin of different animals (turkey, rabbit)

Table 1. Description of the survey instrument and results

Name of Material/ Equipment	Company	Catalog Nur	mber
Foam	BRICOSELF ITALIA, vercelli	na	
Insuline Syringe	na	na	
Pig Esophagus	Butcher shop (Il mercato carni, di Dutto Srl 28100, Novara (Italy)	na	
Pig skin	Butcher shop (Il mercato carni, di Dutto Srl 28100, Novara (Italy)	na	
Pig thymus	Butcher shop (Il mercato carni, di Dutto Srl 28100, Novara (Italy)	na	
SILK suture - Vetsuture SILK 2/0			
(Metric 3) Ago 3/8 30mm Reverse			
Cutting (12 pz)	Sanitalia Care Srl	SILK2CN	
Surgical instruments scissors,			
forceps, knife, needle holder	na	na	
Swine upper airways	Butcher shop (Il mercato carni, di Dutto Srl 28100, Novara (Italy)	na	
white india ink - pelikan 10ml	Cartoleria Manzoni di Lo Monaco Rosaria s.a.s. 97019 Vittoria, Italy		36340
Wood stapler	BRICOSELF ITALIA, vercelli	na	
Wooden tablet	BRICOSELF ITALIA, vercelli	na	

Comments/Description

Used to stabilyze the model on the wooden tablet
Used to draw linea alba with india ink
Wet material used to build the simulated muscular layers and fascia
Wet material used to obtain the simulated skin
Wet material used to build the simulated thyroid

Sutures to tight all the parts of the model

na

Wet material used to build the model
Ink used to mark the linea alba on the esophagus
Used to staple on the model
Used to stabilyze the model with the stapler



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Editorial and production comments:

Changes to be made by the Author(s) regarding the written manuscript:

1. Please take this opportunity to thoroughly proofread the manuscript to ensure that there are no spelling or grammar issues. The JoVE editor will not copy-edit your manuscript and any errors in the submitted revision may be present in the published version.

Grammar revised by an external English speaking expert and autors.

2. Please submit the figures as a vector image file to ensure high resolution throughout production: (.svg, .eps, .ai). If submitting as a .tif or .psd, please ensure that the image is 1920 pixels x 1080 pixels or 300dpi.

Pictures submitted as Tif 1920x1080

3. Please shorten the title for conciseness. Please ensure that the title matches the manuscript and the video.

The Title was shortened.

4. Please add more details to your protocol steps. Please ensure you answer the "how" question, i.e., how is the step performed? Alternatively, add references to published material specifying how to perform the protocol action.

More details were added in the new protocol and video.

5. How is the trachea cleaned? Can more surgical coordinates be provided on the cutting: how much is cut and where, etc.

More details were added on how the trachea is cleaned (see step 1 of the protocol)

6. Please provide as much directions and parameters for the experiment: How small are the pieces cut to? Etc.

Measures and parameters were included where appropriate.

7. What instruments are used throughout?

Type of used Instruments were included in every step.

8. Please include this information in the video narration as well.

Instruments' names were also added in video description.

9. Please ensure all figures are referenced in the text: Figure 4.

References were correctly included.

10. Please do not abbreviate journal titles.

Journal titles corrected

11. Where is Table 1?

Table 1 is included in the submission

Changes to be made by the Author(s) regarding the video:

Due to all comments, we opted to record again the video.

1. Please increase the homogeneity between the video and the written manuscript. Ideally, the video narration is a word for word reading of the written protocol text.

Video and text were modified and are now very similar.

2. Can the video be made less bloody? One example is 4:04; the surface they are going to place the trachea on is already dirty with blood and animal debris. This issue is present throughout the video, and while we understand that the subject material is somewhat graphic it does seem that surfaces are left quite bloody when they could be cleaned to present a less gruesome visual.

During the new video recording, the table was cleaned after every steps to make the image clearer.

3. The video cannot exceed 15 minutes in total length. The video length must be reduced to be below 15 min.

Video has been shortened.

4. Please include title cards for each section: Introduction, Protocol, Representative Results, Conclusion

Title cards were added.

5. Please include a short introduction before the protocol itself. Typically, this involves an on screen interview or statement.

Short introduction was added with screen interview.

6. Please include a short conclusion session. Typically, this involves an on screen interview or statement.

Short conclusion with screen interview was added.

7. The video must have a representative results section following the protocol. This section must have voice-over describing the results being shown.

Section was added with voice-over

8. The video must have a concluding statement after the results section. This section must have both audio and video.

Conclusion section was added with on screen interview

9. The video must have title cards at beginning and end. These title cards should include the authors' names and their affiliations.

Title cards with names and affiliation were added

10. The music should be lowered by about 6 dB, as it competes with the narrator's voice. The narration volume should be peaking between -6 and -12 dB.

Audio was optimized

11. 0:04-0:34 - This materials section of the video could be removed to help get the video under the length limit. The materials will be covered in the text protocol.

Material section was removed.

12. Fast motion is used throughout the video. Fast motion should be used minimally and should not be used where animals or animal materials are involved. Instead, the steps should be edited for length. If fast motion absolutely must be used, text should be added indicating how fast the footage was sped up.

All the fast motion were eliminated

13. 3:05, 4:57, 5:02, 5:37, 6:31, 8:18, 8:29, 8:37, 8:43, 9:25, 9:27, 9:35, 9:48, 10:29, 11:38, 12:25, 12:29, 12:44, 12:52, 13:13, 13:29, 14:00, 14:16, 14:53, 15:00, 15:03 - The edits here are jump cuts, which tend to have a jarring effect on the viewer. They should be smoothed out with crossfades instead.

Jarring effect was lowered at minimum. Crossfades were used in beginning and end of the scenes, while during the middle cuts we tried to smooth them as much as we could.

14. 4:35-4:37 - The audio at the beginning of this sentence sounds like it slowly fades up while the narrator is talking. The audio level should be consistent throughout.

Audio was optimized

15. 8:08-8:47 - This amount of time is too long to go with no narration. Additional narration should be added and/or this section should be edited for length.

No narration parts (>5 sec) were eliminated.

16. 14:31 - The edit here seems to flicker. This should be corrected.

17. 15:37, 15:40 - These images should fill the frame.

New video with optimized quality was made.

Please upload a revised high-resolution video

here: https://www.dropbox.com/request/Vw51OF0riHy35n9ZaJUC

Reviewers' comments:

Please note that the reviewers raised some significant concerns regarding your method and your manuscript. Please revise the manuscript to thoroughly address these concerns. Additionally, please describe the changes that have been made or provide explanations if the comment is not addressed in a rebuttal letter. We may send the revised manuscript and the rebuttal letter back to peer review.

Reviewer #1:

Manuscript Summary:

-Needs copy editing for multiple grammatical errors throughout manuscript

A grammatical revision was conducted.

Major Concerns:

- -Clarify Step 3.2-3.3 (esophagus) and add Note for why it is important to suture the way specified step 3.2, 3.3 were specified and notes added
- -Tongue stitch shown in video is not mentioned in the procedure protocol; please make sure all critical steps of the protocol are written.

Tongue stitch was eliminated in the new perfected procedure.

-Table 1 does not appear attached to the manuscript; need to see survey attached and results as shown in the Legend for Table 1

Table 1 was included in the submission

-Was the survey validated prior to use in this study?

A panel of experts (simulation educationalists, ENT physicians, anesthesiologists and surgical education tutors) reviewed the survey instrument content for accuracy and provided appropriate modifications to ensure validity of the study. A statement was added in the Discussion

Minor Concerns:

- -Step 5.2: be more specific in "hidden sutures" what is the best way to anchor the overlying skin? **Hidden sutures were eliminated in the new perfected procedure.**
- -How did you arrive at the reuse number quoted in the discussion (three times)? After the incision is made, is the fidelity similar for the subsequent uses?

The number of three for reuse is due to the three different techniques that can be, consequently, performed with this model: (1) cricotirotomy (small pierce in the intercricothyroid space), (2) percutaneous dilatational tracheostomy (small horizontal incision in the first tracheal ring), and (3) open surgical tracheostomy (large incision super-hystmic or inter histmyc or sub-hystmic). A statement was added in the revised manuscript. (line 295)

-What supports your claim that rabbit skin is better than calf foot skin? Why? Keep consistent throughout the manuscript what type of overlying skin tissue you utilized.

Since no evidence supported the claim but our personal experience, the given statement was removed from the manuscript.

-Add frequency or prevalence of surgical airway management to your introduction for context

Incidence of difficult airway management situations with the use of surgical airway techniques was included in the Introduction (line 68)

-Add materials to list for the "V shaped cradle" holder for the model

We took the advantage of this revision to report a simpler way to hold the model (Staple the skin to the wooden tablet)

-In protocol, change "windpipe" to "trachea"

The changes were done

-Video does not demonstrate securing model to the cradle.

Cradle eliminated in new perfected procedure and substituted with a wooden tabled

Reviewer #2:

The authors propose an ex-vivo animal model to improve the skill for performing tracheostomy and give information how to create it

The topic is interesting

Only few comments:

1) The main limitation of this ex-vivo model is the lack of bleeding and or secretion. The authors should comment this limit in the discussion

The limitation was included in the discussion (line 292)

2) In addition, the use of head and neck in the model could improve the skill of intubation with bronchoscopy

Very interesting hint. However, the human neck and larynx unfortunately, after our experiments seemed to be very different to those of most lab animals. In fact, the human upright position lead, during the evolution of our species, to a rotation of the larynx and pharynx to 90 degrees, a characteristic that is not found in most mammals. We tried to add a plastic shell over the model to better represent the head and neck relative proportions and positions and it well worked. It might be the best realistic improvement in this direction. We did not comment it in the manuscript because it is out of its originally scope.

3) How many attempts are needing for each participant in order to acquire the skill for performing tracheostomy in live patients?

The question is challenging. However, the aim of the study was to describe how to manufacture an easily-made, low-cost and high-fidelity bench-model that simulates the

human neck to perform cricothyrotomy, percutaneous and surgical tracheostomy and to evaluate it in terms of model realism and its suitability for training the given clinical maneuvers.

Further studies, with wider cohort of participants and with a reliable skills evaluation system, are needed to address the issue.