The Laryngoscope

Synthetic Simulator for Surgical Training in Tracheostomy and Open Airway Surgery

Ashley R. Deonarain, BASc, MHSc; Robert V. Harrison, PhD, DSc; Karen A. Gordon, PhD; Thomas Looi, PhD; Anne M.R. Agur, PhD; Marvin Estrada, BSc; Nikolaus E. Wolter, MD, MSc, FRCSC; Evan J. Propst, MD, MSc, FRCSC

Objective(s): To create and validate a synthetic simulator for teaching tracheostomy and laryngotracheal reconstruction (LTR) using anterior costal cartilage and thyroid ala cartilage grafts.

Methods: A late adolescent/adult neck and airway simulator was constructed based on CT scans from a cadaver and a live patient. Images were segmented to create three-dimensional printed molds from which anatomical parts were casted. To evaluate the simulator, expert otolaryngologists - head and neck surgeons performed tracheostomy and LTR using anterior costal cartilage and thyroid ala cartilage grafts on a live anesthetized porcine model (gold standard) followed by the synthetic simulator. They evaluated each model for face validity (realism and anatomical accuracy) and content validity (perceived effectiveness as a training tool) using a five-point Likert scale. For each expert, differences for each item on each simulator were compared using Wilcoxon Signed-Rank tests with Sidak correction.

Results: Nine expert faculty surgeons completed the study. Experts rated face and content validity of the synthetic simulator an overall median of 4 and 5, respectively. There was no difference in scores between the synthetic model and the live porcine model for any of the steps of any of the surgical procedures.

Conclusion: The synthetic simulator created for this study has high face and content validity for tracheostomy and LTR with anterior costal cartilage and thyroid ala cartilage grafts and was not found to be different than the live porcine model for these procedures.

Key Words: Simulator, simulation, tracheotomy, tracheostomy, airway, open, laryngotracheoplasty, laryngotracheal reconstruction, cricoid split, graft, pediatric, children, adult, adolescent, Awsim.

Level of Evidence: 5

***Laryngoscope*, 00:1–9, 2021**

INTRODUCTION

Tracheostomy and open airway surgical procedures such as laryngotracheal reconstruction (LTR) are complex, low-frequency procedures that require advanced training. Tracheostomy involves creating a surgical opening through the neck into the trachea, most commonly performed to bypass an upper airway obstruction or for prolonged mechanical ventilation. Tracheostomy is an essential surgical skill for otolaryngologists-head and neck surgeons, anesthesiologists, general surgeons, trauma surgeons, emergency and critical care physicians, emergency medical support workers, and military personnel.[1] LTR is a surgery for expanding the airway in patients with subglottic or tracheal stenosis, where the stenosed airway segment is divided and expanded with an autologous cartilage graft. The graft is commonly harvested from costal cartilage in older children and adolescents, and thyroid cartilage in neonates. Challenges of resident work-hour restrictions, low case volumes, and pressure for increased operating room efficiency limit opportunities for surgical trainees to learn these procedures in the operating room.[2-4]

Surgical simulation is a growing area of research as it can provide valuable opportunities for residents and fellows to learn and refine technical skills without risk to patient safety. In 2014, the senior author published a surgical dissection manual teaching tracheostomy and open airway surgery in a porcine model.[5] The live porcine model has been the gold standard for teaching these procedures for many years.[6] We subsequently demonstrated

From the Department of Otolaryngology—Head & Neck Surgery, The Hospital for Sick Children (A.R.D., R.V.H., K.A.G., N.E.W., E.J.P.), University of Toronto, Toronto, Canada; Institute of Biomaterials and Biomedical Engineering (A.R.D., R.V.H., T.L.), University of Toronto, Toronto, Canada; Centre for Image Guided Innovation and Therapeutic Intervention (CIGITI), The Hospital for Sick Children (A.R.D., T.L., E.J.P.), University of Toronto, Toronto, Canada; Division of Anatomy, Department of Surgery, Faculty of Medicine (A.M.R.A.), University of Toronto, Toronto, Canada; and the Laboratory Animal Services (M.E.), The Hospital for Sick Children, Toronto, Canada.

Additional supporting information may be found in the online version of this article.

Editor's Note: This Manuscript was accepted for publication on December 15, 2020. This work was funded by the Gnat and Bastable-Potts Chair in Otolaryngology, The Hospital for Sick Children Restracomp Scholarship, and the Choi, Lo, Stronach and Paris families.

EJP, ARD, TL have a patent pending for the simulator used in this study.

This work was presented at the Society for Ear Nose and Throat Advances in Children (SENTAC) Annual Meeting December 6, 2019, San Diego, California.

Send correspondence to Evan J. Propst, MD, Department of Otolaryngology-Head and Neck Surgery, 6th Floor, Burton Wing, The Hospital for Sick Children, 555 University Avenue, Toronto, Ontario, M5G 1X8, Canada. E-mail: evan.propst@utoronto.ca

DOI: 10.1002/lary.29359

that the live porcine model has high face and content validity as a training tool for tracheostomy and LTR using costal cartilage and thyroid ala cartilage grafts.[7] Use of animals for training, however, can be limited due to anatomical differences from humans, cost, availability, ethics, and a need for specialized facilities and personnel.[5,7] Animal parts also need to be disposed of after use, limiting the ability to archive work or preserve progress.[8]

A synthetic three-dimensionally-printed trachea has been validated for needle cricothyroidotomy and LTR using anterior costal cartilage graft.[8,9] Although the three experts in their study felt the model realistically simulated the key portions of LTR with anterior costal cartilage graft, they suggested improvements to the vocal cords, cricoid and thyroid cartilages, and adding a mucosal layer to allow for improved suturing practice.[8] Because their model was casted out of silicone using a single mold, it is difficult to recreate the various tissue layers encountered during these complex surgeries.

The purposes of our study were to: 1) create a multi-layered synthetic neck and airway simulator to more closely resemble human tissue; 2) investigate face and content validity for tracheostomy and LTR using costal cartilage and thyroid ala cartilage grafts; 3) compare our synthetic model with the live porcine model for performing these surgical procedures.

MATERIALS AND METHODS

Simulation Session

Ethics approval was obtained from the Hospital for Sick Children Research Ethics Board (REB 1000061271). Experienced pediatric Otolaryngologists—Head and Neck Surgeons who attended as faculty at the 5th Toronto International Pediatric Open Airway Surgery Workshop were recruited (n = 9). Experts performed a tracheostomy, LTR using anterior costal cartilage graft and LTR using anterior thyroid ala cartilage graft on a live porcine model and completed a questionnaire about their experience. The experts then performed the same procedures on the synthetic model and completed the same questionnaire. Experts were asked to anonymously rate the realism/anatomical accuracy (face validity) and effectiveness as a training tool (content validity) of both models using statements specific to the three simulated surgical tasks. Participants were asked to rate their level of agreement with each statement on a five-point Likert scale (1, strongly disagree; 2, disagree; 3, neutral; 4, agree; 5, strongly agree). The questionnaire also included demographic and surgical experience questions, as well as a comment section for open-ended feedback. Participants were asked how much they would be willing to pay for each model to train students as a proxy for their perceived value of the model. Ordinal categorical Likert data for each question were analyzed and the distribution of

TABLE I.
Demographics and Surgical Experience of Participants.

No. of participants	9
Median age, yr (IQR)	45 (42–56)
Male, %	89%
Right handed, %	100%
Median years as an attending surgeon (IQR)	13 (7–23)
Country of practice	
Canada, %	44%
USA, %	56%
Median estimated no. procedures performed as primary surgeon (IQR)	
Tracheostomy	200 (150–275)
Laryngotracheal reconstruction using anterior costal cartilage graft	40 (18–150)
Laryngotracheal reconstruction using anterior thyroid ala cartilage graft	7.5 (5–25)

IQR = interquartile range.

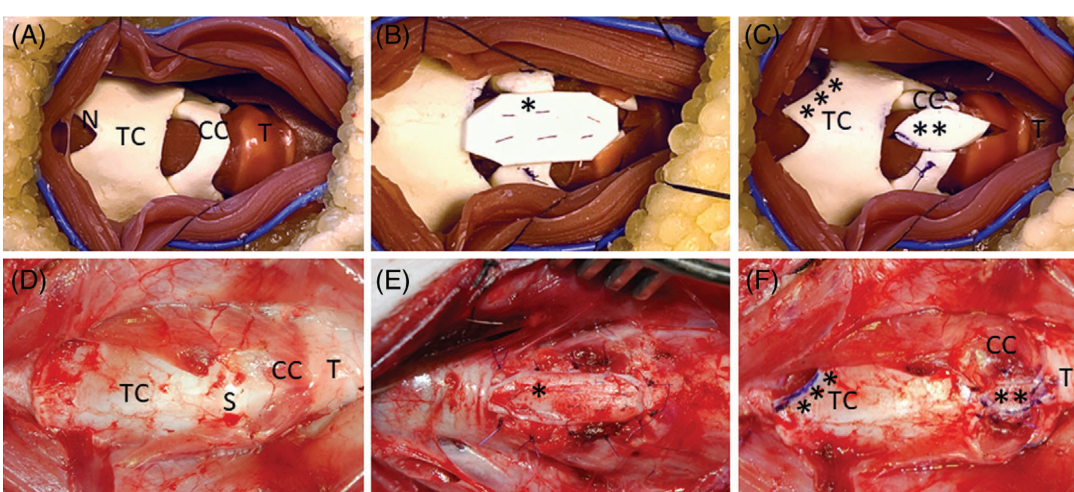

Fig. 1. (A–C) Synthetic simulator, (D–F) porcine airway: normal anatomy (A,D), anterior costal cartilage graft (B,E), anterior thyroid ala cartilage graft (C,F). Synthetic simulator (A) and porcine airway (D) have thyroid cartilage (TC), cricoid cartilage (CC), and trachea (T), but only the synthetic simulator (A) has a thyroid notch (N) as seen in humans, and the porcine thyroid cartilage (D) has a cartilaginous spike (S). Anterior costal cartilage graft (*) in synthetic simulator (B) and porcine (E) model. Anterior thyroid ala cartilage graft (**) in synthetic simulator (C) and porcine (F) model harvested from thyroid ala cartilage (***). [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.] [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

responses, median, and interquartile range were calculated. The scores for each item rated by each expert for the two simulators were compared using a Wilcoxon Signed Rank test with Sidak correction for multiple comparisons ($p < 0.05$). Statistical analysis was performed using JMP® statistical analysis software (JMP®, Version 14, SAS Institute Inc., Cary, NC).

Animal Model

The live animal workshop was approved by the Animal Care Committee at the Hospital for Sick Children. Participants performed the simulated surgical procedures on Yorkshire piglets weighing 10 to 15 kg. Animals were sedated with an intramuscular injection of Akmezine (0.2 mL/kg) and were placed under anesthesia using Isoflurane (5%) delivered by facemask. Animals were intubated with a 6.0 or 6.5 mm internal diameter cuffed Sheridan endotracheal tube (ETT; Teleflex Medical, Research Triangle Park, NC) and anesthesia was maintained using Isoflurane 3%. ETT cuff pressure was maintained at 20 cm H_2O using a Magnehelic manometer (Dwyer Instruments, Michigan City, IN). Heart rate, respiratory rate, oxygen saturation, and carbon dioxide levels were monitored throughout the surgical procedures by experienced animal care facility technicians.

Synthetic Model

The simulator represents the neck from the inferior border of the mandible to the clavicles. It was created to fit seamlessly onto the neck of mannequins already on the market (i.e. Laerdal SimMan and others) so it can become part of a high-fidelity patient simulation. The model consists of a protective base and soft-tissue neck contents designed from patient images and created using carefully selected materials.

Base. The base was designed to protect the mannequin from inadvertent injury (Fig. S1). On the base, the following anatomical structures and tissue layers were assembled (Table SI).

Hyoid bone, thyroid cartilage, cricoid cartilage, trachea, epiglottis, and arytenoids. One soft-embalmed adult cadaveric specimen from the Division of Anatomy at the University of Toronto was dissected and scanned using CT imaging with slice thickness of 0.1 mm. Ethics approval for this procedure was obtained from the University of Toronto Health Sciences Research Ethics Board (REB 34613).

Soft tissue. The soft tissue layers for the remainder of the neck were based on live patient scans rather than cadaveric soft tissue to avoid alterations caused by embalming. The Picture Archiving and Communication System (PACS) at The Hospital for Sick Children was searched and Digital Imaging and Communications in Medicine (DICOM) format images were obtained. Images were de-identified and rendered unrecognizable by removing data down to the inferior border of the orbital rim bilaterally. Ethics approval for these procedures was received from the Hospital for Sick Children Research Ethics Board (REB 1000059925).

Image segmentation and three-dimensional computer modeling. All tissues listed in Table SI were segmented from CT images using Mimics® (Materialise, Leuven, Belgium). Segmentation involves delineating anatomical structures on two-dimensional planes (i.e. axial, coronal and sagittal) based on Hounsfield units (Fig. S1). A thresholding technique was used to group pixels within a certain gray value range into a 'mask'. Manual post-processing was employed to clean up anatomical structures. Cadaveric and live scans were merged by overlaying anatomical landmarks. Tissues that were difficult to identify were verified by an otolaryngologist—head and neck surgeon (EJP). A synthetic cartilage block with dimensions 4 (length) x 1 (width) x 1 (height) cm was modeled to approximate harvested costal cartilage used for LTR with costal cartilage graft.

Material selection. All anatomical structures were cast individually using molds for silicone or urethane because three-dimensionally printed structures did not realistically simulate the tissues we were striving to duplicate. The material for each tissue type was selected based on iterative testing by an expert otolaryngologist—head and neck surgeon with surgical neck and airway experience (EJP). Samples were created using the techniques provided by the material manufacturer (Smooth-On Inc., Macungie, PA). Briefly, the silicone or urethane constituent parts

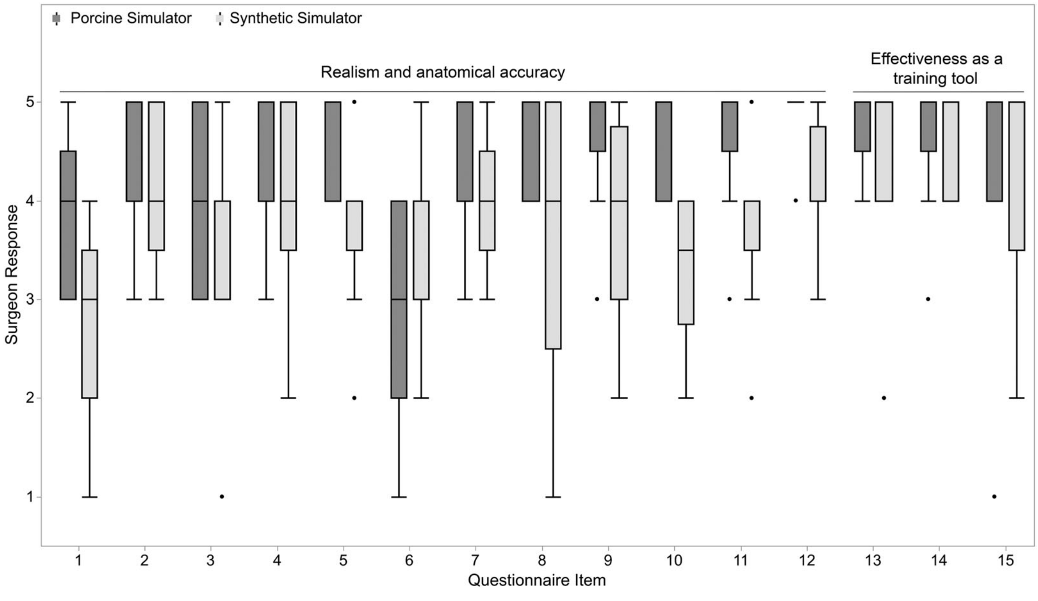

Fig. 2. Comparison of porcine and synthetic simulator scores for tracheostomy. Questionnaire items are listed in Table II.

were mixed manually in the appropriate volume/weight ratio. Color pigments for silicone (Silc Pig®) and urethane (SO-Strong®), and any starch additives were manually mixed into the formulation. Each tissue was color-matched intra-operatively using a Pantone® color guide (Pantone LLC, Carlstadt, NJ). The liquid silicone/urethane formulation was then degassed in a vacuum chamber to eliminate entrapped air prior to dispensing the formulation in the negative molds. The silicone/urethane material cured at room temperature for the manufacturer's prescribed time. Samples measured 10 cm x 10 cm, with appropriate tissue thickness determined from imaging. During each iteration, the expert surgeon (EJP) who was blinded to tissue composition assessed and ranked the realism of 3 to 6 samples based on the following factors: tissue handling, incision with a scalpel, retraction, and suturing. The highest-ranking sample was refined in the following iteration by adjusting the composition of ingredients around the sample and using the same protocol to select the optimal specimen.

Casting. Molds for casting anatomical structures were three-dimensionally printed from computer-aided design (CAD) files in stereolithography (STL) format. Objet500 Connex3 and Objet260 Connex3 polyjet printers (Stratasys, Rehovot, Israel) were used because of their speed and accuracy and because they did not inhibit the silicone curing process. Casting molds were printed in VeriWhitePlus material (Statasys, Rehovot, Israel) with a matte finish. Cartilaginous structures, membranes, fat, and lymph node layers were cast in silicone molds made from EcoFlex™ 00–20 (Smooth-On Inc., Macungie, PA) to facilitate easy demolding.

RESULTS

Demographics and Surgical Experience

Nine experienced Otolaryngologists - Head and Neck Surgeons from major airway centers across Canada and the United States completed the study (Fig. 1). Demographic information and surgical experience of participants are summarized in Table I. The median (IQR) number of years as an attending surgeon was 13 (7–23). Participants had

TABLE II.
Summary of Questionnaire Results for the Synthetic Simulator for Tracheostomy (N = 9).

Questionnaire Item	Likert Score: 1 Strongly Disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly Agree	Median	IQR	Range	Mode	Mean	SD
Realism/anatomical accuracy											
1. The surface anatomy is realistic on palpation for planning the skin incision.	1 (11%)	3 (33%)	3 (33%)	2 (22%)	0 (0%)	3.0	2.0–3.5	1.0–4.0	3.0	2.7	1.0
2. Incising the skin feels realistic.	0 (0%)	0 (0%)	2 (22%)	4 (44%)	3 (33%)	4.0	3.5–5.0	3.0–5.0	4.0	4.1	0.8
3. Incising, retracting and/or removing the fat feels realistic.	1 (11%)	0 (0%)	3 (33%)	4 (44%)	1 (11%)	4.0	3.0–4.0	1.0–5.0	4.0	3.4	1.1
4. The musculature appears anatomically accurate.	0 (0%)	1 (11%)	1 (11%)	4 (44%)	3 (33%)	4.0	3.5–5.0	2.0–5.0	4.0	4.0	1.0
5. Dividing and retracting the sternohyoid and sternothyroid muscles feels realistic.	0 (0%)	1 (11%)	1 (11%)	6 (67%)	1 (11%)	4.0	3.5–4.0	2.0–5.0	4.0	3.8	0.8
6. The thyroid gland appears anatomically accurate.	0 (0%)	1 (14%)	3 (43%)	2 (29%)	1 (14%)	3.0	3.0–4.0	2.0–5.0	3.0	3.4	1.0
7. The trachea appears anatomically accurate.	0 (0%)	0 (0%)	2 (22%)	5 (56%)	2 (22%)	4.0	3.5–4.5	3.0–5.0	4.0	4.0	0.7
8. Incising the trachea feels realistic.	1 (11%)	1 (11%)	1 (11%)	3 (33%)	3 (33%)	4.0	2.5–5.0	1.0–5.0	4.0	3.7	1.4
9. Placing retention/stay sutures in the cut edges of the trachea feels realistic.	0 (0%)	1 (13%)	2 (25%)	3 (38%)	2 (25%)	4.0	3.0–4.8	2.0–5.0	4.0	3.8	1.0
10. Maturing the stoma by suturing the skin to the tracheal cartilage feels realistic.	0 (0%)	1 (17%)	2 (33%)	3 (50%)	0 (0%)	3.5	2.8–4.0	2.0–4.0	4.0	3.3	0.8
11. Inserting the tracheostomy tube feels realistic.	0 (0%)	1 (11%)	1 (11%)	6 (67%)	1 (11%)	4.0	3.5–4.0	2.0–5.0	4.0	3.8	0.8
12. Suturing the flanges of the tracheostomy tube to the skin feels realistic.	0 (0%)	0 (0%)	1 (13%)	5 (63%)	2 (25%)	4.0	4.0–4.8	3.0–5.0	4.0	4.1	0.6
Effectiveness as a training tool											
13. The simulator is a valuable training tool for tracheostomy.	0 (0%)	1 (11%)	0 (0%)	3 (33%)	5 (56%)	5.0	4.0–5.0	2.0–5.0	5.0	4.3	1.0
14. Use of this model will increase trainee competency when performing a tracheostomy.	0 (0%)	0 (0%)	0 (0%)	3 (33%)	6 (67%)	5.0	4.0–5.0	4.0–5.0	5.0	4.7	0.5
15. I would use this simulator for teaching my trainees.	0 (0%)	1 (11%)	1 (11%)	2 (22%)	5 (56%)	5.0	3.5–5.0	2.0–5.0	5.0	4.2	1.1

Items 6 (n = 7), 9 (n = 8), 10 (n = 6) and 12 (n = 8).

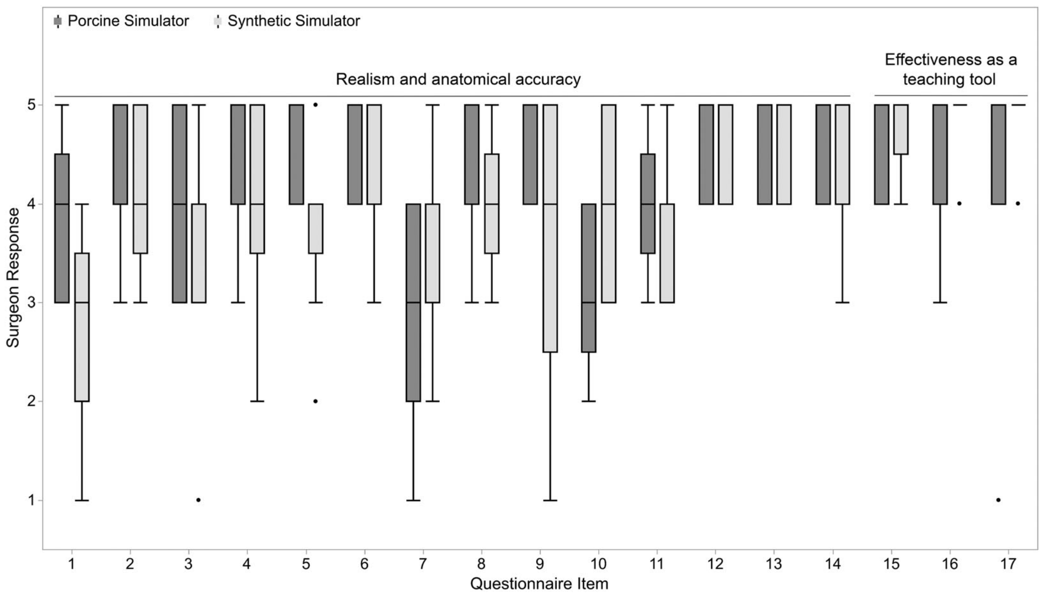

Fig. 3. Comparison of porcine and synthetic simulator scores for laryngotracheal reconstruction using anterior costal cartilage graft. Questionnaire items are listed in Table III.

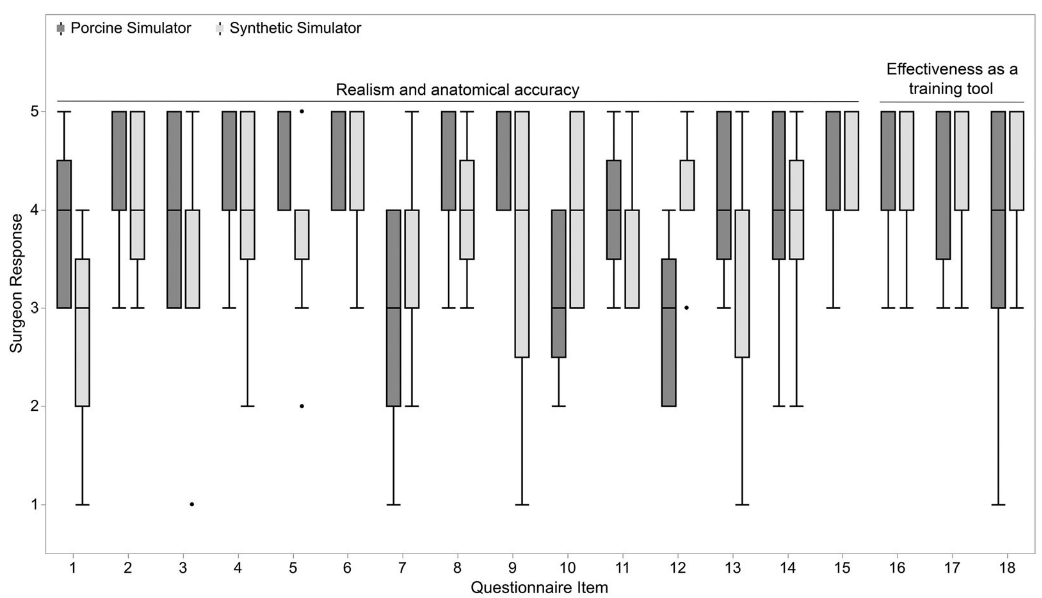

Fig. 4. Comparison of porcine and synthetic simulator scores for laryngotracheal reconstruction using anterior thyroid ala cartilage graft. Questionnaire items are listed in Table IV.

performed a median (IQR) of 200 (150–275) tracheostomies, 40 (18–150) LTRs using costal cartilage graft, and 7.5 (5–25) LTRs using thyroid ala cartilage graft as primary surgeon.

Face and Content Validity for Synthetic Simulator

Questionnaire results for the live porcine model have been published previously.[7] Results for the synthetic simulator are summarized in Tables II–IV. For tracheostomy, realism/anatomical accuracy (face validity) achieved an overall median (IQR) score of 4.0 (3.0–4.0). The lowest-scoring items related to palpation of surface anatomy, anatomical accuracy of the thyroid gland, and maturing the stoma. Experts rated the effectiveness of the model as a training tool (content validity) an overall median (IQR) score of 5.0 (4.0–5.0).

For LTR with anterior costal cartilage graft, realism/anatomical accuracy (face validity) achieved an overall median (IQR) score of 4.0 (3.0–5.0). The lowest-scoring items related to palpation of surface anatomy and anatomical accuracy of the thyroid gland. Experts rated the effectiveness of the model as a training tool (content validity) an overall median (IQR) score of 5.0 (5.0–5.0).

TABLE III.
Summary of Questionnaire Results for the Synthetic Simulator for Laryngotracheal Reconstruction Using Anterior Costal Cartilage Graft (N = 9).

Questionnaire Item	Likert Score					Median	IQR	Range	Mode	Mean	SD
	1 Strongly Disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly Agree						
Realism/anatomical accuracy											
1. The surface anatomy is realistic on palpation for planning the skin incision.	1 (11%)	3 (33%)	3 (33%)	2 (22%)	0 (0%)	3.0	2.0–3.5	1.0–4.0	3.0	2.7	1.0
2. Incising the skin feels realistic.	0 (0%)	0 (0%)	2 (22%)	4 (44%)	3 (33%)	4.0	3.5–5.0	3.0–5.0	4.0	4.1	0.8
3. Incising, retracting and/or removing the fat feels realistic.	1 (11%)	0 (0%)	3 (33%)	4 (44%)	1 (11%)	4.0	3.0–4.0	1.0–5.0	4.0	3.4	1.1
4. The musculature appears anatomically accurate.	0 (0%)	1 (11%)	1 (11%)	4 (44%)	3 (33%)	4.0	3.5–5.0	2.0–5.0	4.0	4.0	1.0
5. Dividing and retracting the sternohyoid and sternothyroid muscles feels realistic.	0 (0%)	1 (11%)	1 (11%)	6 (67%)	1 (11%)	4.0	3.5–4.0	2.0–5.0	4.0	3.8	0.8
6. Suturing the sternohyoid and sternothyroid muscles to the skin laterally feels realistic.	0 (0%)	0 (0%)	1 (14%)	4 (57%)	2 (29%)	4.0	4.0–5.0	3.0–5.0	4.0	4.1	0.7
7. The thyroid gland appears anatomically accurate.	0 (0%)	1 (14%)	3 (43%)	2 (29%)	1 (14%)	3.0	3.0–4.0	2.0–5.0	3.0	3.4	1.0
8. The trachea appears anatomically accurate.	0 (0%)	0 (0%)	2 (22%)	5 (56%)	2 (22%)	4.0	3.5–4.5	3.0–5.0	4.0	4.0	0.7
9. Incising the trachea feels realistic.	1 (11%)	1 (11%)	1 (11%)	3 (33%)	3 (33%)	4.0	2.5–5.0	1.0–5.0	4.0	3.7	1.4
10. The cricoid cartilage appears anatomically accurate.	0 (0%)	0 (0%)	3 (33%)	3 (33%)	3 (33%)	4.0	3.0–5.0	3.0–5.0	3.0	4.0	0.9
11. Incising the cricoid cartilage feels realistic.	0 (0%)	0 (0%)	3 (33%)	5 (56%)	1 (11%)	4.0	3.0–4.0	3.0–5.0	4.0	3.8	0.7
12. Carving the simulated costal cartilage graft feels realistic.	0 (0%)	0 (0%)	0 (0%)	5 (56%)	4 (44%)	4.0	4.0–5.0	4.0–5.0	4.0	4.4	0.5
13. Suturing through the costal cartilage graft and the cricoid/ tracheal cartilage feels realistic.	0 (0%)	0 (0%)	0 (0%)	3 (33%)	6 (67%)	5.0	4.0–5.0	4.0–5.0	5.0	4.7	0.5
14. “Parachuting” the costal cartilage graft into the defect feels realistic.	0 (0%)	0 (0%)	1 (11%)	2 (22%)	6 (67%)	5.0	4.0–5.0	3.0–5.0	5.0	4.6	0.7
Effectiveness as a training tool											
15. The simulator is a valuable training tool for laryngotracheal reconstruction using anterior costal cartilage graft.	0 (0%)	0 (0%)	0 (0%)	2 (22%)	7 (78%)	5.0	4.5–5.0	4.0–5.0	5.0	4.8	0.4
16. Use of this model will increase trainee competency when performing laryngotracheal reconstruction using anterior costal cartilage graft.	0 (0%)	0 (0%)	0 (0%)	1 (11%)	8 (89%)	5.0	5.0–5.0	4.0–5.0	5.0	4.9	0.3
17. I would use this simulator for teaching my trainees.	0 (0%)	0 (0%)	0 (0%)	1 (11%)	8 (89%)	5.0	5.0–5.0	4.0–5.0	5.0	4.9	0.3

For items 6 and 7, n = 7.

For LTR with anterior thyroid ala cartilage graft, realism/anatomical accuracy (face validity) achieved an overall median (IQR) score of 4.0 (3.0–4.0). The lowest-scoring items related to palpation of surface anatomy and anatomical accuracy of the thyroid gland. Experts rated the effectiveness of the model as a training tool (content validity) an overall median (IQR) score of 5.0 (4.0–5.0).

Comments from experts were extremely positive with respect to the overall anatomical accuracy of the model and carving of the simulated costal cartilage graft. One expert wrote: “overall representation was almost eerily representative. Nice!”. Experts were willing to pay a median (IQR) of $265 ($60–$449) for one synthetic airway simulator.

Comparison of Synthetic and Porcine Simulators

Data for synthetic and porcine simulators are plotted in Figs. 2–4. Wilcoxon Signed-Rank tests with Sidak correction for multiple comparisons demonstrated no significant differences between the synthetic simulator and the gold standard porcine simulator for

TABLE IV.
Summary of Questionnaire Results for the Synthetic Simulator for Laryngotracheal Reconstruction Using Anterior Thyroid Ala Cartilage Graft (N = 9).

Questionnaire Item	Likert Score: 1 Strongly Disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly Agree	Median	IQR	Range	Mode	Mean	SD
Realism/anatomical accuracy											
1. The surface anatomy is realistic on palpation for planning the skin incision.	1 (11%)	3 (33%)	3 (33%)	2 (22%)	0 (0%)	3.0	2.0–3.5	1.0–4.0	3.0	2.7	1.0
2. Incising the skin feels realistic.	0 (0%)	0 (0%)	2 (22%)	4 (44%)	3 (33%)	4.0	3.5–5.0	3.0–5.0	4.0	4.1	0.8
3. Incising, retracting and/or removing the fat feels realistic.	1 (11%)	0 (0%)	3 (33%)	4 (44%)	1 (11%)	4.0	3.0–4.0	1.0–5.0	4.0	3.4	1.1
4. The musculature appears anatomically accurate.	0 (0%)	1 (11%)	1 (11%)	4 (44%)	3 (33%)	4.0	3.5–5.0	2.0–5.0	4.0	4.0	1.0
5. Dividing and retracting the sternohyoid and sternothyroid muscles feels realistic.	0 (0%)	1 (11%)	1 (11%)	6 (67%)	1 (11%)	4.0	3.5–4.0	2.0–5.0	4.0	3.8	0.8
6. Suturing the sternohyoid and sternothyroid muscles to the skin laterally feels realistic.	0 (0%)	0 (0%)	1 (14%)	4 (57%)	2 (29%)	4.0	4.0–5.0	3.0–5.0	4.0	4.1	0.7
7. The thyroid gland appears anatomically accurate.	0 (0%)	1 (14%)	3 (43%)	2 (29%)	1 (14%)	3.0	3.0–4.0	2.0–5.0	3.0	3.4	1.0
8. The trachea appears anatomically accurate.	0 (0%)	0 (0%)	2 (22%)	5 (56%)	2 (22%)	4.0	3.5–4.5	3.0–5.0	4.0	4.0	0.7
9. Incising the trachea feels realistic.	1 (11%)	1 (11%)	1 (11%)	3 (33%)	3 (33%)	4.0	2.5–5.0	1.0–5.0	4.0	3.7	1.4
10. The cricoid cartilage appears anatomically accurate.	0 (0%)	0 (0%)	3 (33%)	3 (33%)	3 (33%)	4.0	3.0–5.0	3.0–5.0	3.0	4.0	0.9
11. Incising the cricoid cartilage feels realistic.	0 (0%)	0 (0%)	3 (33%)	5 (56%)	1 (11%)	4.0	3.0–4.0	3.0–5.0	4.0	3.8	0.7
12. The thyroid cartilage appears anatomically accurate.	0 (0%)	0 (0%)	1 (11%)	6 (67%)	2 (22%)	4.0	4.0–4.5	3.0–5.0	4.0	4.1	0.6
13. Incising the thyroid cartilage feels realistic.	1 (11%)	1 (11%)	2 (22%)	4 (44%)	1 (11%)	4.0	2.5–4.0	1.0–5.0	4.0	3.3	1.2
14. Suturing through the thyroid ala graft and the cricoid/tracheal cartilage feels realistic.	0 (0%)	1 (11%)	1 (11%)	5 (56%)	2 (22%)	4.0	3.5–4.5	2.0–5.0	4.0	3.9	0.9
15. "Parachuting" the thyroid ala graft into the defect feels realistic.	0 (0%)	0 (0%)	0 (0%)	6 (67%)	3 (33%)	4.0	4.0–5.0	4.0–5.0	4.0	4.3	0.5
Effectiveness as a training tool											
16. The simulator is a valuable training tool for laryngotracheal reconstruction using anterior thyroid ala cartilage graft.	0 (0%)	0 (0%)	1 (11%)	3 (33%)	5 (56%)	5.0	4.0–5.0	3.0–5.0	5.0	4.4	0.7
17. Use of this model will increase trainee competency when performing laryngotracheal reconstruction using anterior thyroid ala cartilage graft.	0 (0%)	0 (0%)	1 (11%)	3 (33%)	5 (56%)	5.0	4.0–5.0	3.0–5.0	5.0	4.4	0.7
18. I would use this simulator for teaching my trainees.	0 (0%)	0 (0%)	1 (11%)	3 (33%)	5 (56%)	5.0	4.0–5.0	3.0–5.0	5.0	4.4	0.7

For items 6 and 7, n = 7.

any of the questionnaire items across the three surgical procedures.

DISCUSSION

The challenges of resident work-hour restrictions, low case volumes, and pressure for increased operating room efficiency limit learning opportunities for surgical trainees in the operating room.[2–4] Although we previously demonstrated that the live porcine model has high face and content validity as a training tool for tracheostomy and LTR, use of animals for training can be limited due to anatomical differences from humans, cost, availability, ethics, a need for specialized facilities and personnel, and a limited ability to archive specimens or preserve progress.[5,7,8] Many synthetic anatomical models produced to date lack the interplay of tissue layers and relative constraints of the human neck that may confound a learner's progress intraoperatively.[10] We therefore created a multilayered synthetic neck and airway simulator to closely resemble human tissue and investigated face and content validity for tracheostomy and LTR with costal cartilage and thyroid ala cartilage grafts.

Expert airway surgeons rated the synthetic simulator as being realistic and anatomically accurate (face validity) for tracheostomy and LTR using anterior costal cartilage and thyroid ala cartilage grafts, with all three procedures attaining a median score 4 out of 5. This was complemented by a belief that the synthetic simulator would be an effective training tool (content validity), with all three procedures attaining a median score of 5 out of 5. Similar results have been reported using a five-point Likert scale to evaluate face and content validity for surgical simulators. Podolsky et al.[11] achieved median scores of 4 (face validity) and 5 (content validity) when validating a cleft palate simulator. Breimer et al.[12] achieved similar median scores for face and content validity for a brain simulator for endoscopic third ventriculostomy procedures. Eastwood et al.[13] reported an overall median score of 4 for face validity of their craniosynostosis model. Our simulator achieved higher scores for face and content validity than several other published models. Varaday et al.[10] described a cricothyrotomy model whose realism was rated a median score of 3 and therefore did not adequately establish face validity. Sinceri et al.[14] created a simulator for endovascular procedures and Eastwood et al.[13] created a craniosynostosis model, both achieving a median score of 4 for content validity. Overall, our airway simulator was rated as highly or better than other simulators in the literature.

The synthetic simulator had comparable realism, anatomical accuracy, and perceived effectiveness as a training tool to the live porcine model, with none of the items being scored significantly differently across the two models. Participants noted the superior anatomical accuracy of the thyroid cartilage in the synthetic simulator compared to the porcine simulator, because the thyroid cartilage in the pig does not have a notch, it is more anterior than the trachea, and it has an inferior spike, all of which are not present in humans.[7] Anatomical differences can be confusing for trainees learning how to perform open airway procedures that involve the thyroid cartilage such as LTR. One expert noted that they would not use a porcine model if thyroid ala cartilage graft simulation was the only role for the model.

Some participants felt it was difficult to palpate landmarks on the synthetic simulator, but this was not different from that in the live porcine model. Because experts reported that incising the skin on the synthetic simulator felt realistic, difficulty palpating landmarks may have been due to the thickness of the subcutaneous fat and lymph nodes. Basing these structures on a leaner person may help to improve palpation of landmarks. Nevertheless, being comfortable performing surgery on a neck with more adipose tissue should translate to greater ease performing the same procedures on a thinner neck. The anatomical accuracy of the thyroid gland was rated lower in both the synthetic and porcine models. For this study, the synthetic thyroid gland was not glued circumferentially around the trachea, but will be in future models. This may render the synthetic thyroid gland more realistic than in the porcine model, where the thyroid gland is a single lobe in the midline.[7] Maturing the stoma in the synthetic model was rated a median of 3.5, which was not different from that in the live porcine model. Because experts rated incising the skin and placing retention sutures as realistic in the synthetic model, difficulty maturing the stoma may have been due to the thickness of the subcutaneous fat and lymph nodes. Reducing the thickness of these structures may render the synthetic model more realistic than the porcine model for this step, because the porcine model has thick skin that is difficult to suture. Interestingly, stoma maturation did not achieve consensus as an important surgical step in a recently created competency-based assessment tool for pediatric tracheostomy.[15] Two experts commented that it was difficult to incise the trachea in the synthetic simulator, despite this item achieving a median score of 4.0 and not being different than the live porcine model. Because the synthetic cartilage was synthesized several weeks prior to the study and exposed to sunlight and air, the starch constituent in the material stiffened. Subsequent testing, whereby models were assembled immediately and not exposed to sunlight and/or were vacuum sealed, did not encounter stiffening over time.

Experts were willing to pay a median (IQR) of $265 ($60–$449) for one synthetic airway simulator and a median (IQR) of $500 ($240–$1,409) for one live porcine model.[7] The cost of one live porcine model plus facility rental at the animal facility used in this study is approximately $2146. Additional financial hurdles when using animals include costs for dedicated surgical instruments, headlights, telescopes, towers, and sutures. In contrast, synthetic simulators can be used anywhere, including an operating theater traditionally used for human patients. Specialized surgical instruments meant for humans, headlights, telescopes, and video towers can all be used on synthetic simulators and cleaned using traditional hospital methods thereafter. These cost savings, plus the enhanced surgical experience of using anatomically correct specimens with the ability to incorporate variations and archive specimens makes use of high-fidelity synthetic simulators enticing when teaching tracheostomy and open airway surgical procedures. The ethics of animal use for surgical education may need to be re-evaluated where equal alternative synthetic models are available.

Future research is needed to assess the synthetic simulator's ability to distinguish between different levels of surgical expertise (construct validity) and to demonstrate improvement in surgical performance over time. Competency-based assessment tools for pediatric tracheostomy and LTR could be used to evaluate construct validity.[15] This study did not evaluate this model for LTR with posterior costal cartilage graft, cricotracheal resection, tracheal resection, slide tracheoplasty, cricothyroidotomy, thyroplasty, endoscopic balloon dilatation of subglottic stenosis, and laryngeal cleft repair. However, because the synthetic model comprises all anatomical structures of the human neck and airway, it should be capable of being used for these procedures. This model also has the potential to be used for specialty certification or recertification, or by a surgeon wishing to practice a procedure after having not performed it for a period of time. Each of these procedures would require validity testing.

CONCLUSION

The synthetic neck and airway model described in this study was rated by expert surgeons as having high face and content validity as a training tool for tracheostomy and LTR using anterior costal cartilage and thyroid ala cartilage grafts. Experts did not rate the synthetic simulator differently from the gold standard live anesthetized porcine model. This synthetic training model can therefore help surgical trainees practice these complex, low frequency procedures, and implementation into the training curriculum has the potential to enhance education of tracheostomy and open airway surgical procedures while decreasing the number of live pigs being used.

ACKNOWLEDGMENTS

This work has not been published elsewhere. The authors would like to thank Deborah Scollard, Teesha Komal and James Stewart for their assistance with this study.

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