A novel cervical esophagogastric anastomosis simulator

Mark B. Orringer, MD,[a] Doug Hennigar, BSME,[b] Jules Lin, MD,[a] and Deborah M. Rooney, PhD[c]

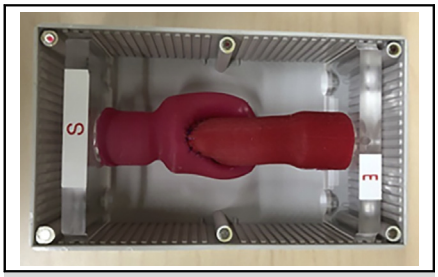
ABSTRACT

Objectives: At least partially technically related, a cervical esophagogastric anastomosis has a 12% to 14% leak rate, which is theoretically reducible with simulator practice. Preliminary development and testing of a cervical esophagogastric anastomosis simulator are described.

Methods: A portable, low-cost, scale reproduction of the cervical esophagogastric anastomosis operative site was engineered around a 19 × 11 × 6-cm plastic box. Silicone "esophageal" and "gastric tip" castings permitted construction of a stapled side-to-side cervical esophagogastric anastomosis guided by an illustrated curriculum. In a 2-phase pilot study, the simulator and curriculum were evaluated. Phase 1: Seven faculty evaluated fidelity using a 5-point, 24-item survey of (1) physical attributes, (2) realism of materials, (3) realism of experience, (4) value, and (5) relevance, and (6) ability to perform tasks. Overall impression of the simulator was also measured. Phase 2: Eight thoracic surgical trainees similarly evaluated the simulator and the quality of the curriculum. Faculty and trainee ratings were compared using a Rasch model, and inter-rater agreement was estimated.

Results: There were no overall fidelity differences across faculty and resident ratings. Combined observed averages ranged from 4.52 (Realism of Materials) to 5.00 (Relevance). Lifelike feel of esophagus had the lowest ratings (observed average = 4.40). Residents rated interrupted outer layer of anterior closure to be more difficult (observed average = 4.13) than faculty (observed average = 4.86; $P = .016$, d = 1.99). Global ratings (observed average = 3.33/4.00) indicated participants believed the simulator could be used for cervical esophagogastric anastomosis training now, but could be improved slightly.

Conclusions: Preliminary evidence suggests the novel cervical esophagogastric anastomosis simulator is valuable as a surgical training tool. (J Thorac Cardiovasc Surg 2020;160:1598-607)



Completed esophagogastric anastomosis in simulator box. *S*, Stomach; *E*, esophagus.

CENTRAL MESSAGE

The development and initial evidence supporting validity of a CEGA simulator are described.

PERSPECTIVE

Partially related to technique, a CEGA leak may lead to a poor functional result after esophagectomy. This is a pilot study of the development and evaluation of a novel CEGA simulator that offers standardized learning *before* coming to the operating room. Rating analysis of faculty and trainees suggests value in surgical training.

See Commentaries on pages 1608, 1610, and 1611.

"Blunt" transhiatal esophagectomy was resurrected in 1978,[1] and the feasibility of a cervical esophagogastric anastomosis (CEGA) in most patients was emphasized. Since then, the operative technique has been refined, the relative safety and efficacy of the procedure have been documented,[2] and many esophagectomies are now performed using the transhiatal approach worldwide, both "open" and with video-assisted techniques. The side-to-side stapled CEGA we reported in 2000[3] substantially reduced the anastomotic leak rate and has been our standard technique since.

Relatively contemporary reports document CEGA leak rates in the range of 12% to 30%,[4-10] higher than generally encountered with intrathoracic anastomoses. Although usually easily managed acutely, an anastomotic leak frequently results in a chronic stricture, and an operation intended to provide comfortable swallowing but resulting in the need for chronic dilations represents a functional failure. Although the CEGA may be regarded

Scanning this QR code will take you to the article title page to access supplementary information.

From the [a]Section of Thoracic Surgery, Departments of Surgery and [c]Learning Health Sciences, University of Michigan Medical School, Ann Arbor, Mich; and [b]Product Design Engineer, Ann Arbor, Mich.

Start-up cost for simulator was provided by the University of Michigan Section of Thoracic Surgery.

Institutional Review Board: January 9, 2017, exempt determination, HUM00123511.

Received for publication Nov 15, 2019; revisions received Feb 10, 2020; accepted for publication Feb 29, 2020; available ahead of print March 13, 2020.

Address for reprints: Mark B. Orringer, MD, Section of Thoracic Surgery University of Michigan, 2120 Taubman Center, 1500 E. Medical Center Dr, SPC 5344, Ann Arbor, MI 48109 (E-mail: morrin@med.umich.edu).

0022-5223/$36.00

https://doi.org/10.1016/j.jtcvs.2020.02.099

Abbreviations and Acronyms
CEGA = cervical esophagogastric anastomosis
ICC = intra-class correlation
MS = mean square
OA = observed average

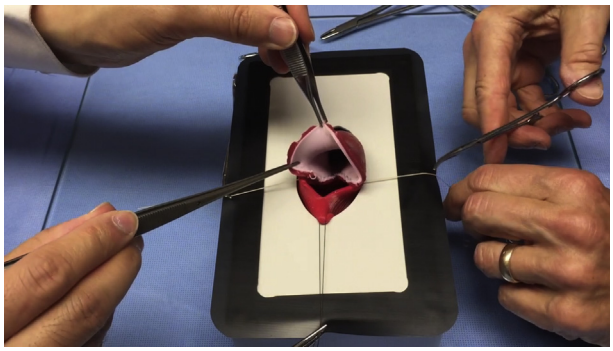
as the "easy" part of a transhiatal esophagectomy, the 15 to 20 minutes needed for anastomosis construction is the most important part of the operation because it has the greatest long-term impact on future comfortable swallowing. Multiple factors (operative technique, anastomotic tension, gastric conduit vascularity and trauma during mobilization, neoadjuvant chemoradiation, and poor nutrition) contribute to anastomotic leaks to varying degrees.

Focusing on operative technique, simulation in surgical education has become increasingly valued,[11-17] offering the potential for learning and practicing repetitively the steps of an operation *before* coming to the operating room, thereby reducing technical error and associated morbidity. Driven by the relatively high reported CEGA leak rates and a desire to impact this by achieving greater standardization, this study was undertaken with the goals of (1) creating a low-cost, realistic CEGA simulator (Video 1) and (2) assessing preliminary validity evidence of fidelity from faculty experts and residents evaluating its suitability for use in our thoracic surgery residency training program. This is a proof-of-concept study.

MATERIALS AND METHODS

Cervical Esophagogastric Anastomosis Simulator

A portable, low-cost scale reproduction of the CEGA operative site was engineered after 3 generations of prototypes. A mass-produced commercially available 19 × 11 × 6-cm plastic box (Hammond Manufacturing, Guelph, Ontario) replaced a 3-dimensional printed version to reduce cost (Figure 1, *A*). The intent of the simulator is to allow construction of a CEGA anastomosis beginning at the point in the operation at which the esophagus has been resected, the stomach manipulated through the posterior mediastinum, and the gastric tip mobilized into the cervical surgical field. The box lid has an obliquely oriented elliptical opening, simulating the left cervical incision. The opposite polarity of small magnets built into the box lid and base ensures proper alignment of the lid with the base so that the oblique "incision" is oriented because it would be anterior to the left sternocleidomastoid muscle with the esophageal casting toward the head (Figure 1, *B*). Suction cups fix the box base to the work surface. There are 2 removable plastic supports upon which the esophageal and gastric tip (stomach) castings are mounted (Figure 2). The "loaded" plastic supports are then returned to the box and secured in place with tongue-in-groove fittings between the inside walls of the base and the sides of the supports. The greater depth of the mounted gastric casting relative to the esophagus replicates the in vivo situation. The insertable single use "esophageal" and "gastric tip" castings were constructed using 3-dimensional printing technology and 3 different durometer silicone materials and pigments (Smooth-On Inc, Macungie, Pa) (Figure 3, *A*) to the specifications of the thoracic surgeon (M.B.O.), who iteratively assessed the realism of the materials. Their degree of softness and tensile strength mimic those of the normal stomach and esophagus. The esophageal casting has 2 incompletely fused layers that simulate the mobility of the inner mucosal layer (Figure 3, *B*). The 4 overhanging rubber edges of the box lid simulate drapes to which hemostats can be "clipped" during the procedure to secure sutures (Figure 3, *C*).



VIDEO 1. Use of the CEGA simulator is demonstrated. Video available at: https://www.jtcvs.org/article/S0022-5223(20)30547-X/fulltext.

Cervical Esophagogastric Anastomosis Curriculum

An illustrated step-by-step manual depicting the individual steps of the stapled CEGA[3] was distributed to all participants with instructions to review it before the simulation exercise. Users of the simulator can practice and master the CEGA using the same instruments, staplers, and sutures as in the operating room during the actual procedure. To perform an esophageal anastomosis correctly, the user must purposely suture the mobile inner mucosal layer with each "bite" of the needle through the esophageal wall, as emphasized in the illustrated curriculum.

Study

This 2-phase study followed review and exempt determination by the University of Michigan Institutional Review Board. In phase 1, 7 University of Michigan general thoracic surgery faculty not associated with the design or implementation of this study and each experienced with esophagectomy and CEGA were recruited by e-mail to perform the simulated procedure on the novel medium-fidelity CEGA simulator; all 7 participated in this assessment. In phase 2, 8 University of Michigan thoracic surgery trainees, including 1 first-year fellow and 3 second-year fellows, and 4 residents in our Integrated (I-6) program, all experienced with performing a CEGA as the surgeon or first assistant, were similarly recruited by e-mail to perform the simulated procedure. In both phases, the primary author (M.B.O.) served as a passive first assistant, also known as "dumb help" as defined by the Zwisch scale,[18] providing no prompting and little advice for each of the participant's CEGA procedures. After their experience with the simulator, all participants independently completed a paper evaluation survey with an option for anonymity, and the completed forms were forwarded directly to the senior author (D.M.R.) for analysis. When faculty provided their names on the evaluations, these were recoded by number to maintain anonymity.

Survey and Rating Procedures

The perceived value of the simulator was assessed with a 24-item survey (Figure 4, *A* and *B*) that was developed using cognitive task analysis and agreement by consensus, a method previously established as best practice for ensuring content validity for this purpose.[19,20] Perceived value was measured across 5 *fidelity* domains (18 items)—(1) physical attributes, (2) realism of materials, (3) realism of experience, (4) value, and (5) relevance, and (6) ability to perform tasks (5 items), using 5-point rating scales, with 5 being the highest rating. The 5 "tasks" specified in the sixth domain were the key technical tasks thought to be essential

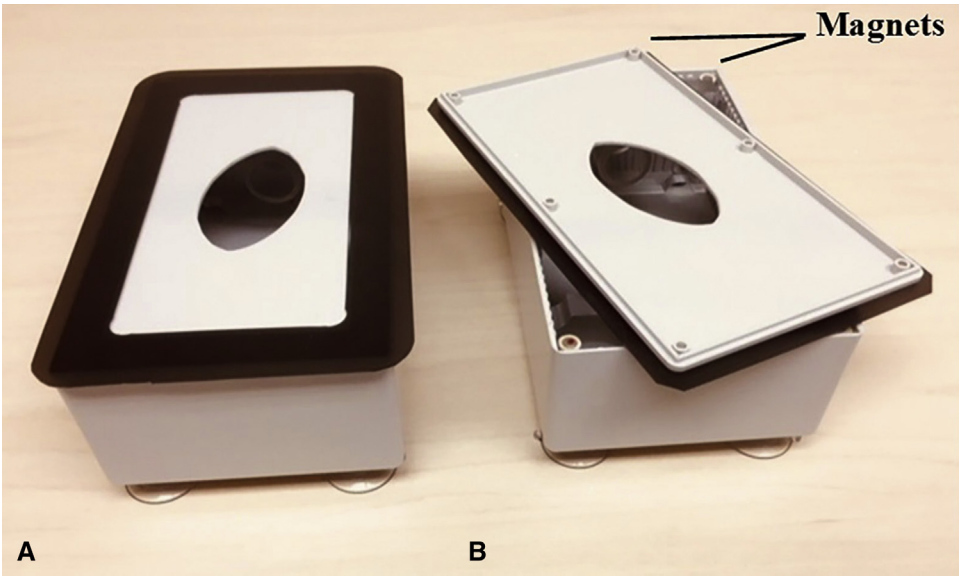


FIGURE 1. CEGA simulator box. A, 19 × 11 × 6-cm plastic box with removable lid (Hammond Manufacturing, Guelph, Ontario), modified to include an obliquely oriented elliptical "incision," overhanging rubber edges, and suction cups on the base. B, Six small magnets built into both the box lid and the base ensure proper alignment of the lid with the base so that the oblique incision is oriented so it would be anterior to the left sternocleidomastoid muscle.

components of competence in performing this procedure. A final global item was used to measure respondents' overall impression of the simulator and was scored on a 4-point rating scale ranging from 1 (This simulator requires major improvements before it can be used in CEGA training) to 4 (This simulator can be used as is for CEGA training without any further improvements).

Analyses

By using modern and classic theories and consistent with other simulator validation studies,[21,22] preliminary validity evidence relevant to test content and internal structure was evaluated using best practices defined by the American Educational Research Association, National Council on Measurement in Education, American Psychological Association, and National Council on Measurement in Education (Standards),[23] and applied to simulation-based studies.[24]

Evidence of Test Content

To evaluate evidence of test content (formerly referred to as "face validity"), a many-faceted Rasch model[25] was used. This is part of a family of modern psychometric measurement models known as item response theory and is commonly used for analyzing rating scale data at the item-level using statistical indices that are not accessible via classical methods. For this study, 2 Rasch indices were examined to evaluate content validity: observed averages (OAs) and item outfit statistics.[26]

Observed Average

Simulator fidelity ratings reflect participant perceived quality. To measure this, we used Rasch OA for each of the relevant domain and items. A higher OA indicated higher perceived quality, and lower OA indicated lower participant perceived quality. For the purpose of this study, an OA 4.00 or greater, aligning with "Adequate realism, but could be improved," was considered minimally adequate fidelity. Likewise, a higher OA for each of the 5 items in domain 6 associated with ability to perform technical tasks suggested high self-reported ability to perform each task, whereas a lower OA suggested lower self-reported ability to perform a particular task. For the purpose of this study, an OA of 3.00 or greater, aligning with "Difficult to perform," was considered the minimal ability standard for our participants to ensure that trainees could perform critical technical tasks on the simulator.

Item Outfit Statistics

To evaluate deeper evidence of content validity, another Rasch index, item outfit mean square (MS) statistics, was reviewed. Outfit MS values greater than 2.0 suggest that responses had extremely high variability and lack of agreement in ratings. In this study, item outfit MS values higher than 2.0 were considered a potential threat to content validity. Statistical analyses associated with evidence relevant to test content were performed using the Facets software v. 3.80 (Linacre, 2017).[27]

Evidence of Internal Structure

To evaluate validity evidence relevant to internal structure, an application from classic test theory, inter-rater reliability, was estimated using a 2-way random, average measures intra-class correlation (ICC) of faculty and resident groups for each of the domains—(1) physical attributes, (2) realism of materials, (3) realism of experience, (4) value, and (5) ability to perform tasks, and for each of the items. With typical values ranging from 0.00 to more than 1.00, an ICC value more than 0.60 was considered good, and values more than 0.75 considered excellent rater agreement. Statistical analysis was performed using IBM SPSS statistical software (version 24.00; IBM Corp, Armonk, NY). Written comments, when supplied, were reviewed for trends and alignment with rating patterns.

RESULTS

Evidence of Test Content Fidelity

Observed averages. There were no overall *fidelity* rating differences across faculty and trainees, chi-square = (1, N = 15) (P = .79). Because of this, faculty and trainee ratings were combined in this analysis. Combined OAs of the domains relevant to the simulator's fidelity were 4.52

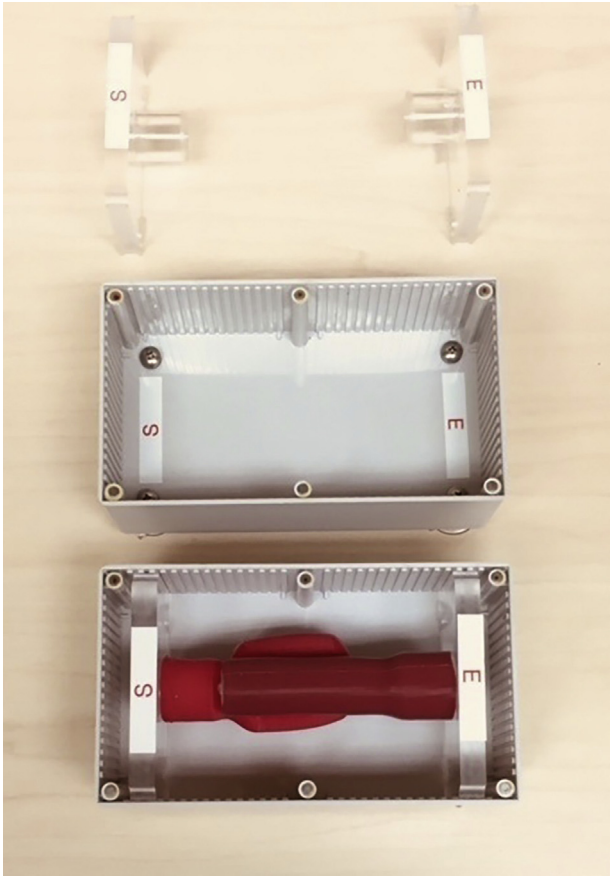


FIGURE 2. CEGA simulator box with removable plastic supports upon which silicone castings of both the gastric tip (stomach) and divided esophagus are mounted. Once the supports (*top*) have been "loaded" with gastric tip or esophageal castings, they are returned to the box base (*bottom*) and secured in place with tongue-and-groove fittings along the inside walls (*middle*) of the box and the sides of the plastic supports. *S,* Stomach; *E*, esophagus.

(*Realism of materials*), 4.82 (*Realism of experience*), 4.82 (*Value*), 4.83 (*Physical attributes*), and 5.00 (*Relevance*). Item-level analysis revealed that all items' OAs ranged between 4.40 and 5.00, indicating participants' perceived value was well over the minimum cutoff of 4.00 or more (Figure 5). The highest-rated items relevant to the simulator's fidelity were *Realism of CEGA anatomy* and *Realism of stapling* (both OA = 4.93). The lowest-rated items relevant to the simulator's fidelity were *Lifelike feel of esophagus* and Lifelike feel of stomach, with OAs of 4.40 and 4.47, respectively, aligning with "Adequate realism, but could be improved slightly," suggesting that minor modifications might improve the simulator. Specific feedback included "Suture tears through occasionally, but overall feels good," "tears a little too easily while tying," and "… second layer of anastomosis is difficult because the 'tissue' does not stretch well, especially when trying to tie down knots."

The *Global* OA was 3.33 of 4.00, indicating that overall, participants believed the new simulator could be used for CEGA training now but with minor improvements. This scoring aligned with comments such as "Realistic. Makes practical learning of sequence, exposure, [and] tissue handling" and "Valuable for surgeon, as well as assistant."

Item Outfit Mean Square Statistics

Fidelity. Review of item outfit statistics revealed that for 2 (11.1%) *fidelity* items, raters agreed 100%, resulting in standard deviations of 0.00, and thus incalculable fit statistics. The remaining 16 items had Outfit MS values ranging between 0.42 and 1.90, below the maximum 2.0 threshold. This suggested that there was a reasonable amount of variability in ratings for these items, and there were no extreme rating variations that would suggest potentially problematic aspects associated with the simulator's fidelity.

Ability to perform tasks. The sixth domain, *ability to perform tasks*, evaluated 5 technical tasks thought to be most important in demonstrating competence in performing this procedure:

- *Item Number 1*—"Setting up" the CEGA with the 3 key sutures
- *Item Number 2*—Positioning the stapler in the esophagus and stomach
- *Item Number 3*—Placement of bilateral "suspension" sutures (between the esophagus and stomach)
- *Item Number 4*—Placement of the running inner layer of the anterior closure
- *Item Number 5*—Placement of the interrupted outer layer of the anterior closure.

All OAs for the 5 tasks were over the 3.00 minimum threshold and ranged from 3.93 to 4.87. Item 5 (*Interrupted outer layer of anterior closure*) was associated with the lowest OA (OA = 3.93), but was well over the 3.00 difficulty threshold), Placing i*nterrupted outer layer of anterior closure* was also associated with extreme variability (Outfit MS = 2.19), which seemed to reflect participants' opposing comments, including "Sutures tear through occasionally" and "It is very good in being able to hold sutures."

Evidence of internal structure. Inter-rater agreement across faculty and resident groups was found to be good for *Physical attributes* (ICC[2,k]$\alpha = 0.67$) and excellent for *Realism of materials* ($\alpha = 0.96$), *Realism of experience* ($\alpha = 0.98$), *Value* ($\alpha = 0.99$), and *Ability to perform tasks* ($\alpha = 0.99$). At the item level, for all but 1 item, ICC estimates were moderate ($\alpha = 0.62$) to excellent (1.00). One item, *Thickness of stomach*, had poor rater agreement ($\alpha = 0.29$) across faculty and trainees.

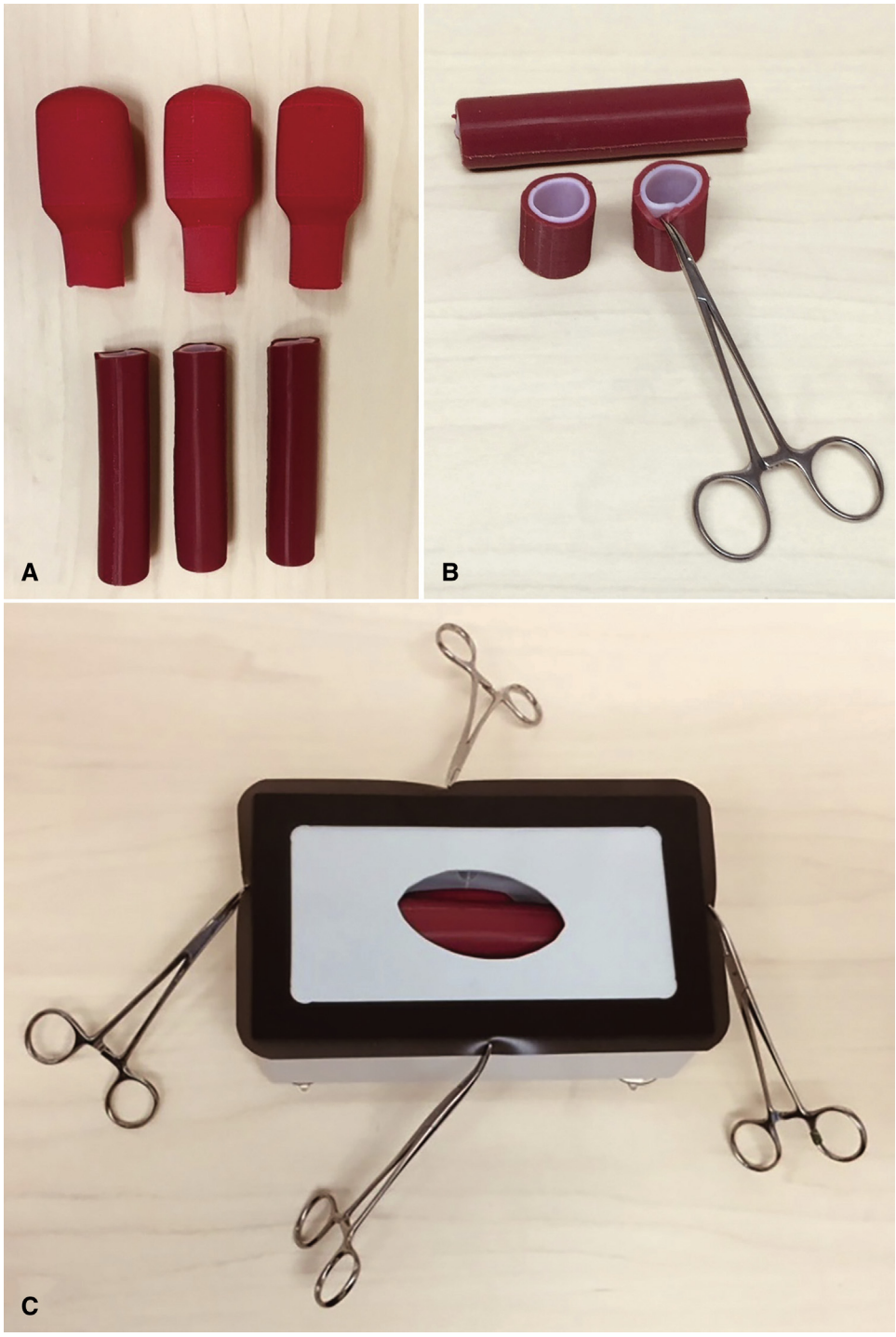


FIGURE 3. CEGA simulator box with the esophageal and gastric tip castings and simulated "drapes" (black rubber edging). A, The silicone esophageal (*bottom*) and gastric tip (stomach) (*top*) castings have been manufactured to mimic as closely as possible the softness and tensile strength of the human stomach and esophagus. B, The esophageal casting has 2 incompletely fused layers to permit some mobility between them simulating an inner mucosal layer that must be carefully sutured with each "bite" of the needle in construction of the anastomosis. C, Thin rubber overhanging edges simulate "drapes" to which hemostats may be clamped to secure sutures during construction of the anastomosis.

A-First page-EVALUATION FORM FOR CERVICAL ESOPHAGOGASTRIC ANASTOMOSIS (CEGA) SIMULATOR

Evaluator Name _____ **Date** _____

Please complete the rating below. Feedback on this model may be used to guide improvements of the simulator.

	Not at all realistic (1)	Not very realistic (2)	Don't know (3)	Adequate realism, but could be improved (4)	Highly realistic, no changes needed (5)
Physical attributes					
Size of "incision"/field					
Length of gastric tip					
Length of divided esophagus					
Depth of gastric tip					
Depth of divided esophagus					
Overall scale of model					
Comments (Please leave comments/suggestions for improvements in the *physical attributes* of the model.)					
Realism of materials					
Life-like feel of stomach					
Life-like feel of esophagus					
Thickness of stomach					
Thickness of esophagus					
Comments (Please leave comments/suggestions for improvements in the *realism of materials* for this model.)					
Realism of experience					
Realism of CEGA anatomy					
Realism of stapling					
Realism of suturing					
Does this simulator represent the expected experience during a CEGA?					
Comments: (Please leave comments/suggestions for improvement s in the *realism of experience* for this model.)					
Rate the value of	No value (1)	Little value (2)	Don't Know (3)	Some Value (4)	High value (5)
the simulator as a training tool					
the simulator as a testing tool					
being able to see the completed anastomosis from the "inside" in understanding the geometry of the stapled CEGA					
Comments: (Please leave comments regarding the *value* of this model.)					

Please continue on the next page →

FIGURE 4. Evaluation form for CEGA simulator. A, Page 1. B, Page 2. *CEGA,* Cervical esophagogastric anastomosis.

DISCUSSION

Since our initial 1978 report, the University of Michigan thoracic surgery service has performed more than 3000 transhiatal esophagectomies and cervical esophagogastric anastomoses and has described the procedure in both textbooks and published articles.[28-31] However, a CEGA may not easily be learned from 2-dimensional illustrations and text. Potential technical pitfalls and poor results may be related to the length of the remaining cervical esophagus, the orientation of the gastrotomy, the proximity of the anastomosis to the gastric staple suture- line, and the adequacy of the suturing technique to close the "hood" of the anastomosis at the end. Simulation-based training was thought by the primary author (M.B.O.) to be a logical "next step" in improving anastomotic outcomes, and this high-volume esophageal surgery service, well acquainted with the

B- Second page-EVALUATION FORM FOR CERVICAL ESOPHAGOGASTRIC ANASTOMOSIS (CEGA) SIMULATOR

Rate the relevance of this simulator to your practice	No relevance (1)	Little relevance (2)	Don't Know (3)	Some relevance (4)	Great deal of relevance (5)

Rate your ability to perform the below tasks	Too difficult to perform (1)	Very difficult to perform (2)	Difficult to perform (3)	Somewhat easy to perform (4)	Very easy to perform (5)
"Setting up" the CEGA with the 3 key sutures					
Positioning of stapler in esophagus and stomach					
Placement of bilateral suspension sutures					
Running inner layer of anterior closure					
Interrupted outer layer of anterior closure					
Comments: (Please leave comments regarding your *ability to perform the tasks* on this model.)					

Global: Check the one statement below with which you most agree:

- ☐ This simulator requires major improvements before it can be used in CEGA training.
- ☐ This simulator requires minor improvements before it can be used in CEGA training.
- ☐ This simulator could use minor improvements but can be used in CEGA training now.
- ☐ This simulator can be used as is for CEGA training now without any further improvements.

What changes, if any, would you suggest to improve the CEGA simulator?

FIGURE 4. *(Continued).*

CEGA, seemed appropriate for launching this effort. The faculty were charged with evaluating the suitability of the CEGA simulator as an educational tool. Although there is inherent bias in such a single institution study, these experienced surgical educators were qualified to make a reasonable judgment in this regard. The intent from the outset was to validate the simulator "internally" by faculty and trainee assessment, and *then* proceed with a multi-institutional trial among several thoracic surgery residency programs.

There are a number of limitations related to the interpretation and applications of the findings of this study. First is the relatively small sample size, although the participants included the entire University of Michigan General Thoracic Surgery faculty (excluding the primary author) and trainees experienced with this procedure. Although the homogeneity of this single-institution study may have led to overestimated ratings and limited generalizability, this concern is at least partially offset by the fact that more than half of the faculty received their thoracic surgery training and 2 of the 8 trainees received their general surgery training at outside institutions. With their variety of training backgrounds, the participants were able to draw upon other institutional experiences in performing a CEGA, potentially lessening bias in assessing the simulator and its components. Second, although this early study deliberately targeted validity evidence relevant to test content and some evidence of internal structure, the full breadth of evidence relevant to response processes, relationships to other variables, and consequence of testing were not evaluated.

Despite these limitations, results of the preliminary validation research were informative. First, we considered the rating differences across faculty and trainees for the one particular issue, the thickness of the gastric castings. Poor rater agreement (ICC[2,k]$\alpha = 0.29$) for that item compelled deeper review of faculty and trainee rating differences. The

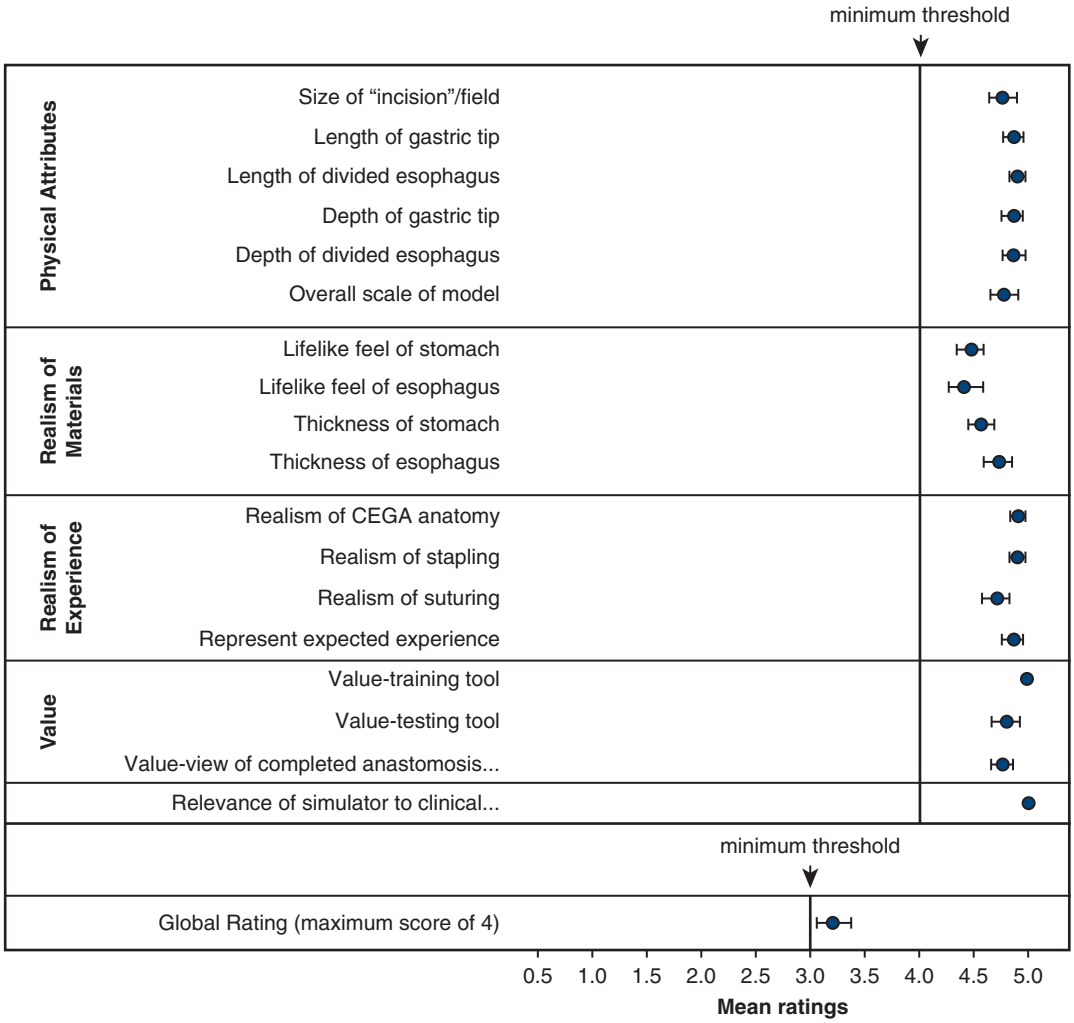


FIGURE 5. Participant (n = 15) OAs of CEGA simulator *fidelity* measured by the evaluation form for CEGA simulator. There was a "minimum adequate threshold" of 4.0 for all items, with the exception of the Global item, which had a "minimum adequate threshold" of 3.0. *CEGA,* Cervical esophagogastric anastomosis.

faculty had a significantly higher OA (OA = 4.86) when compared with trainees (OA = 4.25; $P = .05$, $d = 1.33$). This could be due to faculty having more gastric surgery experience, whereas trainees were less certain about normal stomach thickness resulting in more conservative ratings.

Second, average self-reported "ability" rating for "Interrupted outer layer of anterior closure" was the lowest (OA = 4.14). High associated variability (item outfit MS = 1.98) for this item may have suggested manufacturing inconsistency in "tissue" properties. This was unlikely given the degree of production uniformity of the castings. Alternatively, the "tissue" could not withstand the range of tension or traction the various participants applied during knot-tying, which seemed to align with one expert participant's comment, "the tissue holds sutures well, but tears a little too easily while tying." These findings have guided modifications to the CEGA simulator. Specifically, to address "tissue" limitations, the durometer (hardness) of the esophageal silicone castings has been increased from Shore 00-20 to 00-30 to better hold sutures.

As validation research continues, our focus has shifted to use of the simulator as a teaching tool in our residency program with utility not only for *training,* that is, teaching the technical steps, but also for *assessment (testing)*, that is, documenting proficiency before performing the procedure in patients. Data are now being collected on the time required for a trainee to complete the anastomosis with successive uses of the simulator. The *quality of the anastomosis* is being assessed by "bubble-testing" the submerged completed anastomosis while insufflating air to document an air-tight construction and direct inspection "from the inside" of the geometry of the completed anastomosis as viewed through the opened posterior aspect of the gastric tip casting (Figure 6, *A* and *B*). A multi-institutional trial of the effectiveness of this simulator in 5 thoracic surgery residency programs is being planned and will ensure

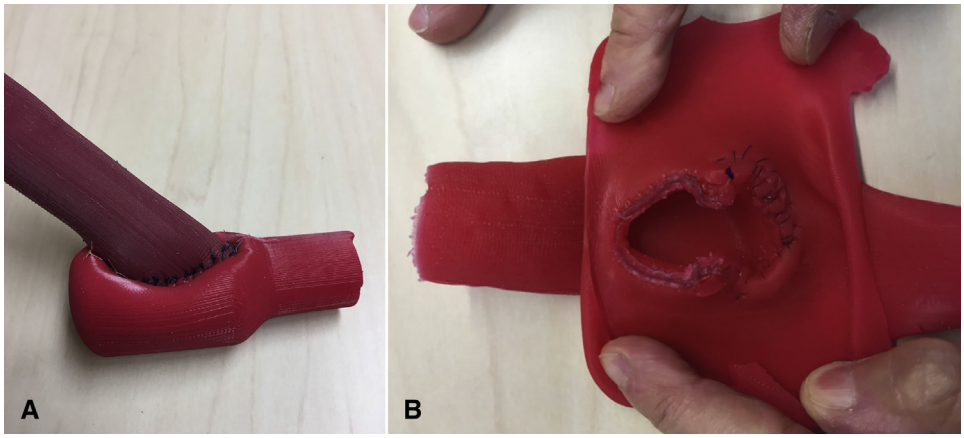


FIGURE 6. Completed simulated CEGA. A, Anastomosed castings removed from the simulator box. B, Anastomosis viewed from opened posterior aspect of gastric casting, side-to-side stapled anastomosis on the left, and manually sewn anterior closure on the right.

objective evaluation in a larger cohort of trainees and quantify residents' prior CEGA operative experience and the effect of deliberate practice with the simulator on operative time, and the quality of the anastomosis (eg, suture placement, bubble testing). If the multi-institutional study confirms the usefulness of the simulator in training, we intend to expand this research to include additional thoracic surgery and interested general surgery residency programs. The ultimate test of value, however, will be to demonstrate that use of the simulator by trainees, faculty, and practicing surgeons results in greater technical proficiency and decreased anastomotic leak rates in patients. It is conceivable that future iterations of the simulator could also be used as a teaching tool for intrathoracic esophagogastric anastomoses.

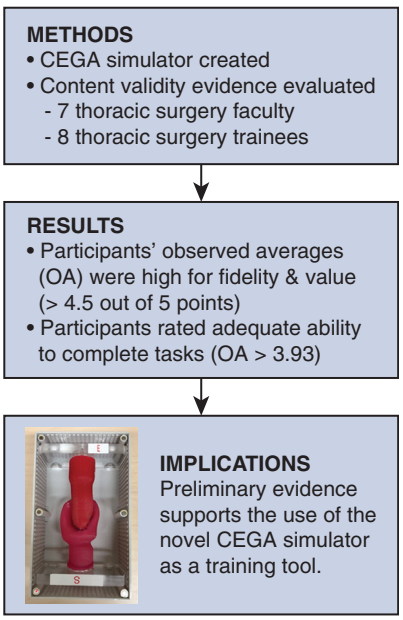


FIGURE 7. Early validation of a novel CEGA simulator. *CEGA,* Cervical esophagogastric anastomosis; *OA,* observed average.

This entire project was undertaken as a not-for-profit endeavor, with a current development cost estimate, including materials and effort that have been largely pro bono in excess of $100,000. It is anticipated that the simulator will be available for purchase during the coming year. The projected cost to users of approximately $500 will include the reusable simulator box and internal plastic supports, 6 pairs of single-use esophageal and gastric castings, and a small automatic air pump for planned "bubble testing" of the integrity of the anastomosis. Also included is on-line access to a narrated instructional video and an evaluation survey to be completed after using the simulator. Additional packs of 6 pairs of castings will cost approximately $175, a unit price of $29.17, which is comparable to other commercially available single-use "tissue" models, for example, for chest tube insertion "skins,"[32] "gallbladders" for practicing laparoscopic cholecystectomy,[33] and "bowel" for practicing anastomoses.[34] The silicone esophageal and gastric castings offer advantages over porcine or bovine tissue of permitting the procedure to be performed in a conference room, classroom, or home setting without the cost, complexity, ethical considerations, and regulations associated with use of biologic material. The projected cost of the proprietary simulator and castings is relatively low and affordable by most training programs. It is our intent to reduce these costs further through design and manufacturing continuous improvement and economies of scale.

CONCLUSIONS

A collaborative effort among the disciplines of thoracic surgery, engineering, and simulation education has resulted in the development of a medium fidelity CEGA simulator and its potential value as a training tool in surgical education supported through expert assessment (Figure 7).

Conflict of Interest Statement

Dr Lin is a Surgical Site Mentor and Proctor for Intuitive. All other authors have nothing to disclose with regard to commercial support.

The authors thank Alexander Price, University of Michigan Biomedical Engineering graduate student at the time, for his efforts in developing an early prototype of the simulator; Gurjit Sandhu, PhD, Assistant Professor, Education Research Sciences Collaborative, Departments of Surgery and Learning Health Sciences, University of Michigan, for her encouragement and suggestions during development and preliminary testing of the simulator; and Richard Sarns, former President and CEO of NuStep Inc, in Ann Arbor, for facilitating the thoracic surgical-engineering partnership in this project.

References

1. Orringer MB, Sloan H. Esophagectomy without thoracotomy. *J Thorac Cardiovasc Surg*. 1978;76:643-54.
2. Hulscher JBF, Tijssen JGP, Obertop H, van Lanschot JJB. Transthoracic versus transhiatal resection for carcinoma of the esophagus: a meta-analysis. *Ann Thorac Surg*. 2001;72:306-13.
3. Orringer MB, Marshall B, Iannettoni MD. Eliminating the cervical esophagogastric anastomotic leak with a side-to-side stapled anastomosis. *J Thorac Cardiovasc Surg*. 2000;119:277-8.
4. Orringer MB, Marshall B, Chang A, Lee J, Pickens A, Lau C. Two thousand transhiatal esophagectomies—changing trends, lessons learned. *Ann Surg*. 2007;246:363-74.
5. Collard JM, Romagnoli R, Goncette L, Otte JB, Kestens PJ. Terminalized semimechanical side-to-side suture technique for cervical esophagogastrostomy. *Ann Thorac Surg*. 1998;65:814-7.
6. Schuchert MJ, Abbas G, Nason KS, Pennathur A, Awais O, Santana M, et al. Impact of anastomotic leak on outcome after transhiatal esophagectomy. *Surgery*. 2010;148:831-8.
7. Sokouti M, Golzan SEJ, Pezeshkian M, Farahnak M. The role of esophagogastric anastomotic technique in decreasing benign structure formation in the surgery of esophageal carcinoma. *J Cardiovasc Thorac Res*. 2013;5:11-6.
8. Mishra PK, Shah H, Gupta N, Varshney V, Patil NS, Jain A, et al. Stapled versus hand-sewn cervical esophagogastric anastomosis in patients undergoing esophagectomy: a retrospective cohort study. *Ann Med Surg (Lond)*. 2016;5:118-24.
9. Bardini R, Bonavina L, Asolati M, Ruol A, Castoro C, Tiso E. Single-layered cervical esophageal anastomoses: a prospective study of suturing techniques. *Ann Thorac Surg*. 1994;58:1087-9.
10. Laterza E, de Manzoni G, Veraldi GF, Guglielmi A, Tedesco P, Cordiano C. Manual compared with mechanical cervical esophagogastric anastomosis: a randomized trial. *Eur J Surg*. 1999;165:1051-4.
11. Fann JI, Cafferelli AD, Georgette G, Howard SK, Gaba DM, Youngblood P, et al. Improvement in coronary anastomosis with cardiac surgery simulation. *J Thorac Cardiovasc Surg*. 2008;136:1486-91.
12. Tan SS, Sarker SK. Simulation in surgery: a review. *Scott Med J*. 2011;56:104-9.
13. Milburn JA, Khera G, Hornby ST, Malone PSC, Fitzgerald JEF. Introduction, availability and role of simulation in surgical education and training: review of current evidence and recommendations from the Association of Surgeons in Training. *Int J Surg*. 2012;10:393-8.
14. Davies J, Khatib M, Bello F. Open surgical simulation-A review. *J Surg Ed*. 2013;70:618-27.
15. Trehan K, Kemp CD, Yang S. Simulation in cardiothoracic surgical training: where do we stand? *J Thorac Cardiovasc Surg*. 2014;147:18-24.
16. ACGME Program Requirements for Graduate Medical Education in General Surgery. ACGME. Available at: https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/440_GeneralSurgery_2019.pdf?ver=2019-06-19-092818-273. Accessed November 7, 2019.
17. Hanks JB. Simulation in surgical education: influence of and opportunities for the Southern Surgical Association. *J Am Coll Surg*. 2019;228:317-28.
18. DaRosa DA, Zwischenberger JB, Meyerson SL, George BC, Teitelbaum EN, Soper NJ, et al. A theory-based model for teaching and assessing residents in the operating room. *J Surg Educ*. 2013;70:24-30.
19. Seagull FJ, Rooney D. Filling a void: developing a standard subjective assessment tool for surgical simulation through a focused review of current practices. *Surgery*. 2014;156:718-22.
20. Barsness KA, Rooney DM, Davis LM, O'Brien E. Preliminary evaluation of a novel thoracoscopic infant lobectomy simulator. *J Laparoendosc Adv Surg Tech A*. 2015;25:429-34.
21. Hsiung GE, Schwab B, O'Brien EK, Gause CD, Hebal F, Barsness KA, et al. Preliminary evaluation of a novel rigid bronchoscopy simulator. *J Laparoendosc Adv Surg Tech A*. 2017;27737-43.
22. Rooney DM, Tai BL, Sagher O, Shih AJ, Savastano L. Simulator and two tools: validation of performance measures from a novel neurosurgery simulator using the current Standards framework. *Surgery*. 2016;160:571-9.
23. American Educational Research Association, American Psychological Association, & National Council on Measurement in Education. *Standards for Educational and Psychological Testing*. Washington, DC: American Educational Research; 2014.
24. Cook DA, Zendejas B, Hamstra SJ, Hatala R, Brydges R. What counts as validity evidence? Examples and prevalence in a systematic review of simulation-based assessment. *Adv Health Sci Educ Theory Pract*. 2014;19:233-50.
25. Rasch G. *Probabilistic Models for Some Intelligence and Attainment Tests*. Copenhagen, Denmark: Danmarks Paedogigiske Institute; 1980.
26. Wolfe EW, Smith EV Jr. Instrument development tools and activities for measure validation using Rasch models: Part II-validation activities. *J App Meas*. 2007;8:204-34.
27. Linacre J. *Facets Many-Facet Rasch Measurement Software*. Chicago, IL: MESA Press; 2014.
28. Orringer MB. Transhiatal esophagectomy. In: Patterson GA, Cooper JD, Deslauriers J, Lerut AEMR, Luketich J, Rice TW, eds. *Pearson's Thoracic and Esophageal Surgery*. 3rd ed. Philadelphia, PA: Churchill, Livingstone, Elsevier; 2008:563-83.
29. Orringer MB. Transhiatal esophagectomy without thoracotomy. In: Shields TW, Locicero J III, Reed CE, Feins RH, eds. *General Thoracic Surgery*. 7th ed. Philadelphia, PA: Lippincott, Williams and Wilkins; 2009:1771-94.
30. Orringer MB. Transhiatal esophagectomy. In: Fischer JE, ed. *Mastery of Surgery*. 7th ed. Philadelphia, PA: Wolters Kluwer; 2018:1000-19.
31. Orringer MB. Transhiatal esophagectomy: how I teach it. *Ann Thorac Surg*. 2016;102:1432-7.
32. TraumaMan Surgical Simulator. Simulab website. Available at: https://www.simulab.com/products/traumaman-surgical-simulator. Accessed February 2, 2020.
33. Replaceable Gallbladder (10-pack). Simulab website. Available at: https://www.simulab.com/products/replaceable-gallbladder-10-pack. Accessed February 2, 2020.
34. Double Layer Bowel 20 mm Outside Diameter. Limbs & Things. Available at: https://limbsandthings.com/us/products/50065/50065-double-layer-bowel-20mm-outside-diameter. Accessed February 2, 2020.

Key Words: esophageal surgery, esophageal anastomosis simulator, esophagogastric anastomosis simulator, surgery education, thoracic surgery education, surgical simulation training, thoracic surgery simulation training