Multi-institutional beta testing of a novel cervical esophagogastric anastomosis simulator

Jules Lin, MD, Deborah M. Rooney, PhD, Stephen C. Yang, MD, MAMSE, Mara Antonoff, MD, Michael T. Jaklitsch, MD, Allan Pickens, MD, Jinny S. Ha, MD, MHS, Monisha Sudarshan, MD, Alejandro Bribiesco, MD, David Zapata, MD, Kathleen Weiss, MD, Christopher Johnson, MD, Doug Hennigar, BSME, Mark B. Orringer, MD

PII: S2666-2507(24)00063-4
DOI: https://doi.org/10.1016/j.xjtc.2024.01.028
Reference: XJTC 1623

To appear in: JTCVS Techniques

Received Date: 8 May 2023
Revised Date: 21 November 2023
Accepted Date: 10 December 2023


This is a PDF file of an article that has undergone enhancements after acceptance, such as the addition of a cover page and metadata, and formatting for readability, but it is not yet the definitive version of record. This version will undergo additional copyediting, typesetting and review before it is published in its final form, but we are providing this version to give early visibility of the article. Please note that, during the production process, errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Copyright © 2024 The Authors. Published by Elsevier Inc. on behalf of The American Association for Thoracic Surgery
Multi-institutional Beta Testing of a Novel Cervical Esophagogastric Anastomosis (CEGA) Simulator

Following single center study supporting its value in surgical education, simulator distributed to 6 thoracic residencies for validation testing.

63 residents, fellows, and junior faculty completed simulation.

Assessment of completed anastomosis by time, direct inspection, and bubble test.

- Majority of mean ratings for physical attributes, realism, and value ≥ 4.00 minimum threshold
- 90.5% felt simulator could be used in training now with only minor improvements supporting its potential value in surgical education.

Further research needed to determine its value in assessing competence for independent operating and association between performance and outcomes.
Title:

Multi-institutional beta testing of a novel cervical esophagogastric anastomosis simulator

Running Head: Beta testing a cervical esophagogastric anastomosis simulator

Authors: Jules Lin, MD¹; Deborah M. Rooney, PhD²; Stephen C. Yang, MD, MAMSE³; Mara Antonoff, MD⁴; Michael T. Jaklitsch MD⁵; Allan Pickens, MD⁶; Jinny S. Ha, MD, MHS³; Monisha Sudarshan, MD⁷; Alejandro Bribriesco, MD⁷; David Zapata, MD⁸; Kathleen Weiss, MD⁵; Christopher Johnson, MD³; Doug Hennigar, BSME⁹; Mark B. Orringer, MD¹

Institutions/Affiliations:

¹ Section of Thoracic Surgery, University of Michigan Medical School, Ann Arbor, MI

² Department of Learning Health Sciences, University of Michigan Medical School, Ann Arbor, MI

³ Division of Thoracic Surgery, Department of Surgery, The Johns Hopkins Medical Institutions, Baltimore, MD

⁴ Department of Thoracic and Cardiovascular Surgery, MD Anderson Cancer Center, Houston, TX

⁵ Division of Thoracic Surgery, Brigham and Women's Hospital, Boston, MA

⁶ Department of Thoracic Surgery, Vanderbilt University Hospital, Nashville, TN

⁷ Section of Thoracic Surgery, Cleveland Clinic, Cleveland, OH

⁸ Division of Cardiothoracic Surgery, University of Maryland, Baltimore, MD

⁹ NuStep LLC, Product Design Engineer, 1721 Dunmore Road, Ann Arbor, MI
Conflict of Interest: All authors confirm that they have no relevant conflicts of interest to disclose.

Source of Funding: Funding was provided through the Donald B. Doty Educational Award from the Western Thoracic Surgical Association.

AATS Meeting: This abstract was accepted for poster presentation at the 2023 AATS Annual Meeting.

Corresponding Author:

Jules Lin, MD
Section of Thoracic Surgery
University of Michigan, 2120 Taubman Center, 1500 E. Medical Center Dr., SPC 5344
Ann Arbor, MI 48109
Phone: 734-936-0470
Fax: 734-615-2656
juleslin@med.umich.edu

Word count: 3468

Keywords: Esophageal anastomosis simulator; esophageal surgery; esophagogastric anastomosis simulator; surgery education; surgical simulation training; thoracic surgery education; thoracic surgery simulation training

IRB: Reviewed by IRB and granted an educational exemption (45 CFR 46.104(d)).
Glossary of Abbreviations

CEGA, Cervical Esophagogastric Anastomosis; PG, postgraduate year; SD, Standard Deviation; TECoG, Thoracic Education Collaborative Group; THE, Transhiatal Esophagectomy

CENTRAL PICTURE

Bubble testing the submerged completed esophagogastric anastomosis by air insufflation.

CENTRAL MESSAGE

This multi-institutional study supports the potential value of this cervical esophagogastric anastomosis simulator in surgical education.

PERSPECTIVE STATEMENT

Anastomotic leaks lead to poor functional results after esophagectomy. Results from this multi-institutional study support the potential value of the cervical esophagogastric anastomosis simulator in surgical education. Further research is needed to determine its value in assessing competence for independent operating and associations between improved measured performance and clinical outcomes.
ABSTRACT

Objective: A novel simulator developed to offer hands-on practice for the stapled side-to-side cervical esophagogastric anastomosis (CEGA) was tested previously in a single center study which supported its value in surgical education. This multi-institutional trial was undertaken to evaluate validity evidence from six independent thoracic surgery residency programs.

Methods: After a virtual session for simulation leaders, learners viewed a narrated video of the procedure and then alternated as surgeon or first assistant. Using an online survey, perceived value was measured across fidelity domains: physical attributes, realism of materials, realism of experience, value, and relevance. Objective assessment included time, number of sutures tearing, bubble test, and direct inspection. Comparison across programs was performed using the Kruskal-Wallis test.

Results: Surveys were completed by 63 participants as surgeons (17 junior and 20 senior residents, 18 fellows, and 8 faculty). For 3 of 5 tasks, mean ratings of 4.35-4.44 correlated with "somewhat easy" to "very easy" to perform. The interrupted outer layer of the anastomosis rated lowest, suggesting this task was the most difficult. The simulator was rated as a highly valuable training tool. For the objective measurements of performance, "direct inspection" rated highest followed by "time." 90.5% of participants rated the simulator as ready for use with only minor improvements.

Conclusions: Results from this multi-institutional study suggest the CEGA simulator is a useful adjunct for training and assessment. Further research is needed to determine its value in assessing competence for independent operating and associations between improved measured performance and clinical outcomes.
Introduction

In 1978, the transhiatal esophagectomy (THE) was re-introduced, and a cervical esophagogastric anastomosis (CEGA) was found to be feasible in most patients. The operative technique has been continually refined, and relative safety and efficacy has been reported by our group and others. Many esophagectomies world-wide are being performed using open and minimally-invasive transhiatal approaches. The side-to-side stapled CEGA we reported in 2000 substantially reduced our anastomotic leak rate and has been our standard technique since.

Other contemporary reports show CEGA leak rates of 12-30%, which is higher than generally encountered with an intrathoracic anastomosis. While CEGA leaks are usually easily managed with wound packing, leaks often result in chronic strictures—a functional failure for an operation intended to provide comfortable swallowing. While the CEGA is often considered the “easy” portion of a THE, the 15-20 minutes needed are an important part of the operation and have the greatest long-term impact on comfortable swallowing. Multiple factors contribute to the risk of anastomotic leak including operative technique, anastomotic tension, gastric conduit vascularity and trauma during mobilization, neoadjuvant chemoradiation, and poor nutrition.

Focusing on operative technique using simulation in surgical education has become increasingly valued, offering trainees the opportunity for learning and practicing the steps of an operation before coming to the operating room, potentially reducing technical errors and associated morbidity. Driven by relatively high reported CEGA leak rates and a desire to impact this by achieving greater standardization, the thoracic surgery group at University of Michigan created a low-cost, realistic CEGA simulator and performed a pilot study assessing validity evidence of fidelity from faculty and residents evaluating suitability for use in residency education. Analyses of their standardized ratings supported the simulator’s value in surgical education.
This multi-institutional trial assessed the University of Michigan CEGA simulator-based training program through validity evidence from six independent, well-established thoracic surgery residency programs. The results of this study will facilitate further refinements of the CEGA simulator and potentially identify objective measures to assess trainees’ CEGA skills proficiency before offering the simulator more broadly to thoracic surgery residencies.

**Materials and Methods**

**CEGA Simulator**

Our development of a portable, low-cost reproduction of the CEGA operative site has been described previously.\(^{16}\) The simulation begins at the point when 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 oblique elliptical opening, simulating the left cervical incision. Polarized magnets in the lid and base ensure proper alignment while suction cups secure the simulator to the work surface. Silicone esophageal and gastric tip castings are mounted on two removable plastic supports secured in place with tongue-in-groove fittings. The esophageal support has an air-insufflation port for bubble testing of the completed anastomosis. The single use silicone castings (Smooth-On Inc, Macungie, PA) were constructed using 3-D printing to the specifications of the senior author (MBO) who assessed the softness and tensile strength relative to normal stomach and esophagus. The esophageal casting was designed with two incompletely fused layers, the inner simulating the mucosal layer. The overhanging rubber edges of the box lid simulate drapes to which traction sutures can be secured.

Based on feedback from our pilot study, the durometer of the gastric tip casting was adjusted to make the material firmer. Additional refinements included a “staple line” imprinted
into the gastric conduit and the corresponding plastic support to facilitate proper alignment and as
a teaching point to keep the anastomosis away from the gastric staple line to prevent ischemia of
the intervening tissue. QR codes were added to the undersurface of the box lid linking the user to
the: (1) detailed narrated video describing the simulator and procedure; (2) step-by-step video to
be played and paused during performance of the anastomosis; and (3) web-based survey (Qualtrics,
LLC; Provo, UT) which every surgeon was to complete evaluating the simulator. A list of all
instruments and sutures was also included on the undersurface of the box. Each site received 2
simulator boxes, 12 sets of silicone gastric tip and esophageal castings, and a standardized air
pump for bubble testing.

Participants

There was enthusiasm for a potential multi-institutional validation study of the CEGA simulator discussed at a meeting of the Thoracic Education Collaborative Group (TECoG). The six institutions involved in the study included University of Michigan, Johns Hopkins, MD Anderson Cancer Center, Brigham and Women's Hospital, Cleveland Clinic, and Emory University, all chosen because of their well-established thoracic surgery residencies and experience with esophagectomies incorporating a CEGA. Study participants were residents, fellows, and junior faculty with previous operative experience with the CEGA. The participants at University of Michigan were not included in the initial pilot study. All participants consented to be included in the study, which was reviewed by each institution’s IRB and granted an educational exemption (45 CFR 46.104(d)).
Site principal investigators attended a virtual session providing an overview of the CEGA simulator, instruments needed, and the survey. Prior to the simulation session, participants were required to watch a 20-minute video demonstrating the procedure. To better standardize the simulation session across institutions and create a more focused learning experience, an 8-minute step-by-step video was played and paused during performance of the anastomosis (Video 1). Participants worked in pairs under the supervision of a faculty member and were assigned alternatively as either “surgeon” or “first assistant” (Figure 1). Following the simulation, the “surgeon” completed an online survey evaluating the simulator and noted the procedure time, quality of suturing (uniformity in spacing and depth of sutures), number of sutures breaking or tearing during tying, and rating of a bubble test of anastomotic integrity (Figure 2). Surveys were completed anonymously immediately following the simulation to ensure no random degradation in knowledge, confidence, and skills prior to assessment.

Survey and Rating Procedures

Perceived value was assessed with a 44-item survey (Supplemental Figure 1) developed using cognitive task analysis and consensus, a method previously established as best practice for ensuring content validity.\textsuperscript{17, 18} Perceived value was measured across five fidelity domains (18 items): a) physical attributes, b) realism of materials, c) realism of experience, d) value, and e) relevance, and a sixth domain f) ability to perform tasks (5 items), using a 5-point rating scale with 5 being the highest. The five “tasks” in the sixth domain were key technical tasks felt to be essential components of competence in performing a CEGA. A final global item measured respondents’ overall impression of the simulator and was scored on a 4-point 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"). An objective
assessment of the quality of the anastomosis was also performed in conjunction with the faculty member and included time to complete the anastomosis, number of sutures tearing through or breaking, air-tight construction ("bubble test"), and direct inspection from "inside."

**Analyses**

Employing methods consistent with exemplar simulator validation studies, preliminary validity evidence was evaluated using best practices defined by the American Educational Research Association, National Council on Measurement in Education, American Psychological Association and the National Council on Measurement in Education (Standards) and applied to simulation-based studies.

**Evidence of Test Content**

*Mean ratings.* Simulator fidelity ratings reflect participant perceived quality. To measure this, we used mean ratings for each of the relevant domains and items. Higher mean ratings indicated higher perceived quality. A mean rating ≥ 4.00 aligning with “Adequate realism, but could be improved,” was considered minimally adequate fidelity. Similarly, a higher mean rating 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. A mean rating ≥ 3.00, aligning with “Difficult to perform,” was considered the minimal ability standard to ensure that trainees could perform critical technical tasks on the simulator.

**Evidence Relevant to Relationship to Other Variables**

Comparison of objective measures including time to complete the anastomosis and rating the quality of the anastomosis by counting the number of sutures tearing through or breaking, scored as 1 (> 3: Novice), 2 (2-3: Competent), and 3 (0–1: Expert); bubbles produced during the underwater
bubble test, scored as 1 (Gross bubbling: Novice), 2 (Moderate bubbling: Competent), and 3 (None to few pinhole bubbles: Expert); and direct inspection from inside the anastomosis, scored as 1 (Poor: Suture placement and depth inconsistent or mucosa not inverted) or 2 (Good: suture placement uniform, and depth consistent and mucosa inverted), was performed across programs using the Kruskal-Wallis test. Statistical analysis was performed using SPSS (version 24.00; Armonk, NY: IBM Corp.). Written comments were reviewed for trends and alignment with rating patterns.

Results

Surveys were completed by 63 participants as surgeons including 17 junior (6 integrated and 11 general surgery) and 20 senior (14 integrated and 6 general surgery) residents, 18 fellows, and 8 junior faculty (Table 1). The mean time to complete the procedure was 50.62 (SD 13.64) minutes. The mean rating for sutures tearing through or breaking was 2.32 (SD 0.70) (Competent) and for bubble testing was 2.13 (SD 0.60) (moderate bubbling). The mean score on direct inspection was 1.87 (SD 0.34) out of 2 (suture placement uniform and depth consistent and mucosa inverted). There were statistical differences in procedure time (36.25-54.85 minutes; p<0.001) and the rating for number of sutures tearing between training sites (1.75-2.64; p=0.001) (Supplemental Table 1). The 3 sites with the shortest times had a higher faculty:junior resident ratio while the 3 with the longest times had a lower faculty:junior resident ratio. The site with the shortest time had only 2 junior residents, while the 2 with the longest times had either no faculty participants or the highest percentage of junior residents (n=5; 50%). There were no significant differences between training levels.

Evidence of Test Content-Fidelity
Mean ratings. One-way ANOVA indicated no overall fidelity rating differences across faculty and trainees. Because of this, faculty and trainee ratings were combined in this analysis (Figure 3). Mean ratings for the domains relevant to the simulator’s fidelity were 3.80 (Realism of materials), 4.32 (Realism of experience), and 4.19 (Physical attributes). Item-level analysis revealed that all items had mean ratings over the minimum cut-off of ≥ 4.00 except for Lifelike feel of stomach (3.63), Lifelike feel of esophagus (3.77), and Thickness of stomach (3.79), aligning with “Adequate realism, but could be improved slightly,” and suggesting that minor modifications might improve the simulator. Specific feedback included “Stomach could be a little stronger, but esophagus is nice with a mucosal layer” and “Overall model is quite realistic, [but] sometimes suture tears in model tissue felt different from what would tear in real tissue.” The highest-rated item was Realism of stapling (4.76).

Mean ratings of domains relevant to the simulator’s value were 4.62 (Value) and 3.73 (Relevance) (Figure 3) and 4.20 for Value of Performance Measures (Table 2). Participants rated the simulator as highly valuable for both training and testing, with no statistical differences across groups. When reviewing the objective measurements for performance assessment, participants rated “direct inspection” the highest, followed by “time.” “Numbers of sutures tearing/breaking” and “bubble test” were rated lower. Feedback on the step-by-step narrated video was generally positive with suggestions on length, speed, and additional details on suture placement.

Ability to Perform Tasks

All mean ratings for the five tasks felt to be most important in demonstrating competence in the sixth domain, ability to perform tasks, were over the 3.00 minimum threshold (Table 3). Three out of five tasks’ mean ratings fell between 4.35-4.44, indicating that overall, participants felt these tasks were “somewhat easy” to “very easy” to perform. The lowest rated task was
Interrupted outer layer of anterior closure, suggesting that this task was overall the most difficult. There were no statistical differences in ratings across types of residency programs or sites indicating that there were no potential biases across programs.

A Global rating of the CEGA simulator showed that 90.5% of participants felt that the simulator could be used in training now (31.8% with no further changes and 58.7% with minor improvements) (Table 4). This aligned with comments such as “This is an incredible educational tool, and I think it will truly improve not only education but also leak rates and patient outcomes.”

Comment

Duty-hour restrictions can impact the operative exposure of residents and their ability to achieve mandated esophagectomy case numbers. Simulation can provide trainees the opportunity to learn and practice the steps of an operation in a safe environment without patient risk. Simulation has been used in cardiothoracic surgery training through an annual resident boot camp organized by the Society of Thoracic Surgeons with high-fidelity simulators for coronary anastomoses, aortic and mitral valve surgery, and open and robotic lobectomy. Fann et al. reported that the ability to perform coronary anastomoses improved after using a porcine model, and Macfie et al. found improvement in all graded components after using a porcine lung model of hilar dissection. Chan et al. reported increased confidence in residents transitioning to cardiothoracic residency after a simulation course. Additionally, the American Board of Thoracic Surgery has mandated at least 20 hours of simulation training during residency.

Available models simulate the mediastinal dissection during esophagectomy. THE GooseMan, developed at Johns Hopkins, uses a porcine organ block to practice esophageal mobilization, gastric tubularization, and management of complications like bleeding from the
azygous vein. Fabian et al. described a porcine model for a thoracoscopic intrathoracic esophagogastric anastomosis and showed improvements in the time and quality of the anastomosis with successive attempts.

Currently, no commercially available simulator models elicit the nuanced skills required in constructing a side-to-side stapled CEGA. Our group at University of Michigan has developed a novel simulator which approximates the operative field and relevant anatomy providing trainees the opportunity to learn, practice, and master proper CEGA skills. This medium-fidelity simulator using synthetic materials offers certain advantages over using organ blocks in terms of costs, standardization of materials, and logistical issues with inherent limitations with using biological materials.

Since our initial 1978 report, over 3,000 transhiatal esophagectomies have been performed at the University of Michigan. Our technique and continuous refinements have been published in detail. Many esophagectomies world-wide are being performed with a CEGA, and 44% of 4321 esophagectomies performed between 2012 and 2014 in the Society of Thoracic Surgeons Database were completed using an approach that required a CEGA. However, the nuanced details of a CEGA can have a substantial effect on anastomotic leaks and subsequent strictures and may not be easily learned from 2-dimensional illustrations and text. Potential technical pitfalls and poor results may be related to the length of the remaining cervical esophagus, orientation of the gastrotomy, proximity of the anastomosis to the gastric staple line, and adequacy of the suturing technique to close the “hood” of the anastomosis.

Simulation-based training was felt by the senior author (MBO) to be a logical “next step” in improving anastomotic outcomes, and the high-volume esophageal surgery service at University of Michigan, well-acquainted with the CEGA, seemed appropriate for launching this effort. A
single center pilot study provided preliminary validity evidence of fidelity from faculty and residents supporting the simulator’s value in thoracic surgery education. To address the issue of potential institutional bias, this multi-institutional study was undertaken.

There are some limitations related to the interpretation and application of the findings of this current study. First, this validation study was conducted at six well-established residency programs with extensive experience with esophagectomies including a CEGA. Whether these results will be reproducible at smaller, low volume esophagectomy residency programs remains to be seen. Second, this early study deliberately focused on validity evidence evaluating the fidelity and perceived value of the CEGA simulator, and the effect of serial practice and the relationship to other variables like clinical outcomes were not assessed.

Some targeted objective measures which act as proxy measures for clinical outcomes were considered, and preliminary findings indicated no statistical differences when comparing trainees and faculty. Since the primary objective was to evaluate perceived value measured across fidelity domains, study participants were limited to (1) trainees with previous intraoperative exposure performing a CEGA to allow adequate evaluation of the simulator’s nuanced characteristics and (2) junior faculty to provide similar study groups. This likely decreased differences in objective measures among junior residents, senior residents, and faculty. Future studies with deeper analysis of objective measures will expand to also include junior residents and students with no previous intraoperative CEGA experience, as well as experienced faculty (>20 CEGA/year), to evaluate the value of deliberate practice using the simulator on these objective measures.

Despite these limitations, results of the current multi-institutional validation study are encouraging and support broader distribution of the CEGA simulator to other surgical programs. Virtual online orientation sessions for faculty and narrated step-by-step videos watched before and
during the simulation helped to standardize the experience across sites. The list of instruments and QR code links to the videos printed directly on the box enhance the “completeness” of the simulator. There were no significant differences in perceived value across training levels or programs suggesting that the CEGA simulator could be a more broadly useful training tool.

This study provides multi-institutional validity evidence of the fidelity of the CEGA simulator with the majority of mean scores greater than the minimum threshold of 4.00 out of 5. The lowest-rated item relevant to the simulator’s fidelity was *Lifelike feel of stomach* with comments on strength of the material and sutures tearing. This was consistent with ratings for the ability to perform tasks domain with the lowest rated task being *Interrupted outer layer of the anterior closure*, suggesting that this task was overall the most difficult. These findings have guided modifications in the durometer (hardness) of the silicone castings, which has been further increased to better hold sutures. Similar to the findings of our initial study, the global rating scores showed that 90.5% of participants felt that the simulator could be used in training now with comments such as “This is an incredible educational tool, and I think it will truly improve not only education but also leak rates and patient outcomes.” Based upon this validation study, our focus will shift to use of the simulator as a teaching tool in residency, not only for *training* (learning the technical steps), but also for *assessing competence* (documenting proficiency) before performing the procedure in patients. When reviewing the different objective measurements of performance assessment, participants in the current study rated “direct inspection” of the completed anastomosis the highest followed by “time.”

Despite efforts to standardize the outcome measures across sites with a step-by-step narrated video for timing and a pressure-regulated pump for the bubble test, there were significant differences in procedure time and the number of sutures tearing between training sites. One
possible contributing factor could be differences in experience and training level between sites. The 3 sites with the shortest times had a higher faculty:junior resident ratio while the 3 with the longest times had a lower faculty:junior resident ratio. Due to the small size of thoracic surgery residency programs and the variety of program types available (fellowship, I-6, and general surgery), it was difficult to mandate prior operative experience for each training level at each site.

Other possible factors included the use of 2nd assistants which was not uniform across sites and the variable experience of both 1st and 2nd assistants (ranging from medical students to senior faculty). One reason for this variability and a limitation of the study was the evolving and varied coronavirus pandemic restrictions on group gatherings during the study period. There were also likely differences in the degree of coaching faculty mentors did during the procedure which could affect procedure time. While there was a step-by-step video, some participants paused to watch the video between steps while others started the next step while watching the video. Variation in the number of sutures tearing could also be due to institutional differences in training levels. There was also likely variability in faculty mentors’ definition of a “tear” (small needle tears versus sutures tearing through the material).

Additional multi-institutional collaborations are planned to evaluate the effect of deliberate practice with the simulator on operative time and the quality of the anastomosis. The ultimate test of value, however, will be the demonstration that use of the simulator by trainees, faculty, and practicing surgeons results in greater intraoperative proficiency and decreased anastomotic leak rates.

In conclusion, a collaborative effort among the disciplines of thoracic surgery, engineering, and simulation education has resulted in the development of a novel, medium-fidelity CEGA simulator. The results of this multi-institutional study provide validity evidence of fidelity
supporting its potential value in surgical education (Figure 4). Further research will be needed to determine the value of the simulator in assessing competence for independent operating and an association between improved measured performance and clinical outcomes.
Acknowledgements

The authors wish to acknowledge 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, Associate 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 Mr. Richard Sarns, former President and CEO of NuStep Inc in Ann Arbor, for facilitating the thoracic surgical-engineering partnership in this project.
References


Table 1 Participating Thoracic Surgery Residency Programs

<table>
<thead>
<tr>
<th>Institutions</th>
<th>Total Sample (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brigham and Women’s Hospital</td>
<td>10 (15.9%)</td>
</tr>
<tr>
<td>Cleveland Clinic</td>
<td>11 (17.5%)</td>
</tr>
<tr>
<td>Emory University</td>
<td>8 (12.7%)</td>
</tr>
<tr>
<td>Johns Hopkins University</td>
<td>8 (12.7%)</td>
</tr>
<tr>
<td>MD Anderson Cancer Center</td>
<td>12 (19.0%)</td>
</tr>
<tr>
<td>University of Michigan</td>
<td>14 (22.2%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>63</strong></td>
</tr>
</tbody>
</table>
Table 2. Summary of All Participants’ Mean Ratings of Value of Performance Measures, n=63.

<table>
<thead>
<tr>
<th>No.</th>
<th>Performance Measure</th>
<th>Mean (SD)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Time to complete the anastomosis</td>
<td>4.40 (1.66)</td>
<td>4.24 – 4.56</td>
</tr>
<tr>
<td>2.</td>
<td>Number of sutures tearing through or breaking</td>
<td>3.81 (1.20)</td>
<td>3.51 – 4.11</td>
</tr>
<tr>
<td>3.</td>
<td>Air-tight construction (&quot;bubble test&quot;)</td>
<td>4.11 (1.05)</td>
<td>3.85 – 4.38</td>
</tr>
<tr>
<td>4.</td>
<td>Direct inspection from &quot;inside&quot; to better understand the geometry of the CEGA and adequacy of suture placement</td>
<td>4.48 (1.67)</td>
<td>4.31 – 4.64</td>
</tr>
</tbody>
</table>

* CEGA, cervical esophagogastric anastomosis
Table 3. Summary of All Participants’ Mean Ratings of Their Personal Ability to Perform CEGA Tasks, n=63

<table>
<thead>
<tr>
<th>No.</th>
<th>Item (Task)</th>
<th>Mean (SD)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>“Setting up” the CEGA with the key sutures</td>
<td>4.44 (0.62)</td>
<td>4.29 – 4.59</td>
</tr>
<tr>
<td>2.</td>
<td>Positioning of the stapler in esophagus and stomach</td>
<td>4.35 (0.65)</td>
<td>4.19 – 4.51</td>
</tr>
<tr>
<td>3.</td>
<td>Placement of bilateral suspension sutures</td>
<td>4.44 (0.62)</td>
<td>4.29 – 4.59</td>
</tr>
<tr>
<td>4.</td>
<td>Running inner layer of the anterior closure</td>
<td>3.98 (0.80)</td>
<td>3.78 – 4.18</td>
</tr>
<tr>
<td>5.</td>
<td>Interrupted outer layer of anterior closure</td>
<td>3.58 (0.93)</td>
<td>3.35 – 3.81</td>
</tr>
</tbody>
</table>

* CEGA, cervical esophagogastric anastomosis
Table 4. Distribution of All Participants’ Global Ratings of Current CEGA Simulator by Percent, n=63

<table>
<thead>
<tr>
<th>No.</th>
<th>Item</th>
<th>Raw (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>This simulator requires <em>major</em> improvements before it can be used in CEGA training.</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>2.</td>
<td>This simulator requires <em>minor</em> improvements before it can be used in CEGA training.</td>
<td>6 (9.5%)</td>
</tr>
<tr>
<td>3.</td>
<td>This simulator can use minor improvements, but it can be used in CEGA training now.</td>
<td>37 (58.7%)</td>
</tr>
<tr>
<td>4.</td>
<td>This simulator can be used as is for CEGA training without any further improvements.</td>
<td>20 (31.8%)</td>
</tr>
</tbody>
</table>
Figure Legends

Central picture. Bubble testing the submerged completed esophagogastric anastomosis by air insufflation.

Figure 1. The inner running suture of the cervical esophagogastric anastomosis is performed by the surgeon while watching a step-by-step narrated video to help standardize the simulation experience across training sites.

Figure 2. Assessment of the completed esophagogastric anastomosis was performed by: A. Direct inspection from the opened posterior aspect of the gastric casting (side-to-side stapled anastomosis on the left and manually sewn anterior closure on the right) and B. Using air insufflation into the submerged anastomosis for a bubble test of anastomotic integrity. The esophageal support has a port (arrow) for air insufflation using a low-volume standardized pump.

Figure 3. Participant (n=63) mean ratings of the fidelity, value, and relevance of the cervical esophagogastric anastomosis simulator. The “minimum adequate threshold” was set at 4.00 out of 5.00 aligning with “Adequate realism but could be improved.” For the global rating, the minimum threshold was set at 3.00 out of 4.00. The ratings showed that 90.5% of participants felt that the simulator could be used in training now.

Figure 4. Multi-institutional beta testing of a novel cervical esophagogastric anastomosis simulator suggest the cervical esophagogastric anastomosis simulator may be a useful adjunct in surgical education.
**Video 1.** To better standardize the simulation session across institutions and create a more focused learning experience, a step-by-step video was played and paused during performance of the anastomosis.

https://www.dropbox.com/s/5ej9pmzxyj3je0d/CEGA%20Simulator%20Steps%204-23-21.mp4?dl=0

**Supplemental Figure 1.** Online survey accessible by QR code evaluating the fidelity and value of the simulator in thoracic surgical education as well as noting the time to complete the task, the quality of suturing, the number of sutures either breaking or tearing during tying, and rating of bubble testing of anastomotic integrity.
<table>
<thead>
<tr>
<th>Physical Attributes</th>
<th>( \text{Size of &quot;incision&quot;/field} )</th>
<th>( \text{Length of gastric tip} )</th>
<th>( \text{Depth of divided esophagus} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \text{Relation of Material} )</td>
<td>( \text{Lifelike feel of stomach} )</td>
<td>( \text{Lifelike feel of esophagus} )</td>
<td>( \text{Thickness of stomach} )</td>
</tr>
<tr>
<td></td>
<td>( \text{Thickness of esophagus} )</td>
<td>( \text{Realism of CEGA anatomy} )</td>
<td>( \text{Realism of stapling} )</td>
</tr>
<tr>
<td></td>
<td>( \text{Realism of suturing} )</td>
<td>( \text{Represent expected experience} )</td>
<td>( \text{Value-training tool} )</td>
</tr>
<tr>
<td></td>
<td>( \text{Value-testing tool} )</td>
<td>( \text{Value-view of completed anastomosis...} )</td>
<td>( \text{Relevance of simulator to clinical...} )</td>
</tr>
</tbody>
</table>

| Global Rating (maximum score of 4) | 0.5 | 1.0 | 1.5 | 2.0 | 2.5 | 3.0 | 3.5 | 4.0 |

Mean ratings
Multi-institutional Beta Testing of a Novel Cervical Esophagogastric Anastomosis (CEGA) Simulator

Following single center study supporting its value in surgical education, simulator distributed to 6 thoracic residencies for validation testing

63 residents, fellows, and junior faculty completed simulation

Assessment of completed anastomosis by time, direct inspection, and bubble test

- Majority of mean ratings for physical attributes, realism, and value ≥ 4.00 minimum threshold
- 90.5% felt simulator could be used in training now with only minor improvements supporting its potential value in surgical education

Further research needed to determine its value in assessing competence for independent operating and association between performance and outcomes
Orringer CEGA Simulator

Block: Default Question Block

CEGA Simulator Evaluation

Please complete this evaluation of this simulator experience. Your input will guide necessary improvements.

I attest that I completed viewing of the CEGA audio-video presentation prior to performing the simulated anastomosis.

☐ Yes
☐ No

DEMOGRAPHICS

Level of Training

☐ Thoracic Surgeon
☐ General Surgeon
☐ Thoracic Surgery Fellow
☐ I-6 Resident
☐ General Surgery Resident
☐ Other

Venue of Practice

☐ Academic
☐ Private Practice
Years in Practice

1 - 4 years
5 - 10 years
11 + years

Current year of training:

1 2 3 4 5 6 7 8 9

Residency Program:

Experience

How many stapled side-to-side cervical esophagogastric anastomoses (CEGA) in patients have you performed to date as the surgeon, i.e., standing to the left of the patient's head?

0 - 4
5 - 10
> 10

How many stapled side-to-side cervical esophagogastric anastomoses (CEGA) in patients have you performed to date as first assistant, i.e., standing to the right of the patient's head?

0 - 4
5 - 10
> 10

Have you already performed a stapled side-to-side cervical esophagogastric anastomoses (CEGA) using the simulator?

No
Yes

How many times have you performed a stapled side-to-side CEGA using the simulator?

1 2 3 4 5 or more
What was your role in today's CEGA simulation?

- [ ] Surgeon
- [ ] First-Assistant

**Block: CEGA Simulator Feedback**

**OBJECTIVE ASSESSMENT OF ANASTOMOSIS**

Procedure Time:

- Procedure Start Time: 
- Procedure End Time: 
- Total Procedure Time (min): 

Did you have a second assistant for today's simulated CEGA to load needle holders and pass sutures?

- [ ] No
- [x] Yes

Number of sutures broken or tearing through during sewing or tying:

- [ ] 0 - 1 (Expert)
- [ ] 2 - 3 (Competent)
- [ ] > 3 (Novice)

Bubble Test:

- [ ] None to few pinhole bubbles (Expert)
- [ ] Moderate bubbling (Competent)
- [ ] Gross bubbling (Novice)

Direct Inspection (from both outside and inside the open stomach):

- [ ] Poor (suture placement and depth inconsistent or mucosa not inverted)
ASSESSMENT OF THE COMPONENTS OF THE CEGA SIMULATOR EXPERIENCE

The narrated instructional video (i.e., the "curriculum")

<table>
<thead>
<tr>
<th>Value</th>
<th>No value</th>
<th>Little value</th>
<th>Don't know</th>
<th>Some value</th>
<th>Great deal of value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments/suggestions for improvements in the video

Block: Evaluation of the Simulator

Physical attributes of the simulator

<table>
<thead>
<tr>
<th></th>
<th>Not at all realistic</th>
<th>Not very realistic</th>
<th>Don't know</th>
<th>Adequate realism, but could be improved</th>
<th>Highly realistic, no changes needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size of &quot;incision&quot;/field</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Length of gastric tip</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Length of divided esophagus</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Depth of gastric tip</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Depth of divided esophagus</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Comments/Feedback for improvements in the physical attributes of the model

Realism of the materials
Comments/Feedback for improvements in the *realism of materials* for this model

Realism of the experience

Comments/Feedback for improvements in the *realism of experience* for this model

**ABILITY TO PERFORM CEGA TASKS**

Please rate your ability to perform the below tasks on the simulator:
<table>
<thead>
<tr>
<th>&quot;Setting up&quot; the CEGA with the 3 key sutures</th>
<th>Too difficult to perform</th>
<th>Very difficult to perform</th>
<th>Difficult to perform</th>
<th>Somewhat easy to perform</th>
<th>Very easy to perform</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positioning of stapler in esophagus and stomach</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Placement of bilateral suspension sutures</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Running inner layer of anterior closure</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Interrupted outer layer of anterior closure</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

**OVERALL VALUE OF THE SIMULATOR**

<table>
<thead>
<tr>
<th>Rate the value of the simulator as a training tool (i.e., for practice with technique)</th>
<th>No value</th>
<th>Little value</th>
<th>Don't know</th>
<th>Some value</th>
<th>Great deal of value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate the value of the simulator as a testing tool (i.e., required proficiency before operating)</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

**VALUE OF BEING ABLE TO OBJECTIVELY ASSESS THE QUALITY OF THE ANASTOMOSIS**

<table>
<thead>
<tr>
<th>Time to complete the anastomosis</th>
<th>No value</th>
<th>Little value</th>
<th>Don't know</th>
<th>Some value</th>
<th>Great deal of value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of sutures tearing through or breaking</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Air-tight construction (&quot;bubble test&quot;)</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Direct inspection from &quot;inside&quot; to better understand the geometry of the CEGA and adequacy of suture placement</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

What changes, if any, would you suggest to improve the CEGA simulator?
Block: Ability to perform tasks

RELEVANCE OF THE SIMULATOR

Rate the relevance of this simulator to your practice/residency education

<table>
<thead>
<tr>
<th>No relevance</th>
<th>Little relevance</th>
<th>Some relevance</th>
<th>Great deal of relevance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Check the 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 it can be used in CEGA training now.
- This simulator can be used as is for CEGA training without any further improvements.

Powered by Qualtrics
<table>
<thead>
<tr>
<th>Objective Measures</th>
<th>Site 1 (n=10)</th>
<th>Site 2 (n=11)</th>
<th>Site 3 (n=8)</th>
<th>Site 4 (n=8)</th>
<th>Site 5 (n=12)</th>
<th>Site 6 (n=14)</th>
<th>p-Value</th>
<th>Effect size ε²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure Time (minutes)</td>
<td>58.33 (10.71)</td>
<td>40.90 (5.49)</td>
<td>63.88 (19.42)</td>
<td>36.25 (7.83)</td>
<td>46.18 (10.44)</td>
<td>54.85 (9.12)</td>
<td>&lt;.001</td>
<td>.71</td>
</tr>
<tr>
<td>Number of sutures tearing/breaking</td>
<td>2.50 (0.71)</td>
<td>1.91 (0.54)</td>
<td>1.75 (0.71)</td>
<td>2.25 (0.89)</td>
<td>2.82 (0.41)</td>
<td>2.64 (0.50)</td>
<td>.001</td>
<td>.23</td>
</tr>
<tr>
<td>&quot;Bubble test&quot;</td>
<td>2.30 (0.68)</td>
<td>2.09 (0.70)</td>
<td>2.25 (0.46)</td>
<td>2.00 (0.76)</td>
<td>2.55 (0.52)</td>
<td>2.00 (0.39)</td>
<td>.23</td>
<td>—</td>
</tr>
<tr>
<td>Direct inspection</td>
<td>1.90 (0.32)</td>
<td>1.82 (0.41)</td>
<td>2.00 (0.00)</td>
<td>1.75 (0.46)</td>
<td>1.82 (0.41)</td>
<td>1.93 (0.27)</td>
<td>.68</td>
<td>—</td>
</tr>
<tr>
<td>Training Level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Junior Residents, n (%)</td>
<td>5 (50)</td>
<td>2 (18.2)</td>
<td>2 (25)</td>
<td>2 (25)</td>
<td>2 (16.7)</td>
<td>4 (28.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Senior Residents, n (%)</td>
<td>1 (10)</td>
<td>5 (45.5)</td>
<td>3 (37.5)</td>
<td>2 (25)</td>
<td>1 (8.3)</td>
<td>8 (57.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fellows, n (%)</td>
<td>2 (20)</td>
<td>2 (18.2)</td>
<td>3 (37.5)</td>
<td>2 (25)</td>
<td>8 (66.7)</td>
<td>1 (7.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Faculty, n (%)</td>
<td>2 (20)</td>
<td>2 (18.2)</td>
<td>0</td>
<td>2 (25)</td>
<td>1 (8.3)</td>
<td>1 (7.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Faculty:Junior Resident Ratio</td>
<td>0.4</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>.5</td>
<td>0.25</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*SD, Standard Deviation