ORIGINAL ARTICLE

Less is more: creation and validation of a novel, affordable suturing simulator for anorectal surgery

S. J. Langenfeld[1] · M. A. Fuglestad[1] · K. G. Cologne[2] · J. S. Thompson[1] · C. Are[1] · S. R. Steele[3]

Abstract

Background Duty hour restrictions have increased the role of simulation in surgical education. A simulation that recreates the unique visual, anatomic, and ergonomic challenges of anorectal surgery has yet to be described. The aim of this study was to develop a low-cost, low-fidelity anorectal surgery simulator and provide validity evidence for the model.

Methods A novel, low-fidelity simulator was constructed, and anorectal surgery workshops were implemented for general surgery interns at a single institution. Face and content validity were assessed with separate questionnaires using a 5-point Likert scale. Participants performed a simulated hemorrhoid excision with longitudinal wound closure, and transverse wound closure. Time-to-task completion and quality of suturing/knot tying were evaluated by a blinded observer to assess construct validity.

Results Material cost was US $11 per simulator. We recruited 20 first-year surgery residents (novices) and 4 practicing colorectal surgeons (experts), and conducted 3 workshops in 2014–2016. All face and content validity measures achieved a median score greater than 4 (range 4.0–5.0). Time-to-task completion was significantly lower in the expert cohort (hemorrhoid excision with longitudinal wound closure: 195 vs. 477 s and transverse closure: 79 vs. 192 s, $p < 0.001$ for both). Suturing and knot-tying scores were significantly higher in the expert cohort for both tasks ($p < 0.05$ for all comparisons).

Conclusions Our low-fidelity, low-cost anorectal surgery model demonstrated evidence of face, content, and construct validity. We believe that this simulator could be a useful instrument in the education of junior surgical trainees and will allow residents to obtain proficiency in anorectal suturing tasks in conjunction with traditional surgical training.

Keywords Simulation-based education · Anorectal surgery · Colorectal surgery · Hemorrhoidectomy simulation

Introduction

With the intent of improving patient safety and resident well-being, there has been an international effort to define the optimal working hours for medical trainees. In the United States, the Accreditation Council for Graduate Medical Education (ACGME) outlined limitations on resident work hours in 2003, and then updated these rules in 2011 placing additional restrictions on the "80-hour work week" [1]. Similarly, under the European Working Time Regulation (EWTR), resident duty hours were gradually reduced to 48 h per week [2, 3]. As a result, surgery residents are spending less time in the hospital than they did in years past. These duty hour restrictions have been implemented hesitantly with concern that they have a deleterious impact on surgical education, operative experience, and resident autonomy [4]. While 5-year major case totals have not significantly changed for United States surgical residents, the scope of operative experience is narrowing, and case volumes of first-year residents have decreased by up to 25% since the adoption of duty hour restrictions [1, 5–7]. However, under the more restrictive EWTD, operative volume has been affected with significantly fewer cases logged as the primary operator [2, 3].

✉ S. J. Langenfeld
sean.langenfeld@unmc.edu

1 Department of Surgery, University of Nebraska Medical Center, 620 S 42nd St and Emile St, Omaha, NE 68198, USA

2 Department of Surgery, Keck School of Medicine, University of Southern California, 1975 Zonal Ave, Los Angeles, CA 90033, USA

3 Department of Colorectal Surgery, Department of Surgery, Cleveland Clinic, 9500 Euclid Ave, Cleveland, OH 44195, USA

Whether it is work hour restrictions, increased surgical sub-specialization, or workflow changes that limit resident autonomy, the result is that the technical skills of graduating general surgery residents have been called into question [8, 9]. A widely quoted 2013 survey highlighted that Fellowship Council program directors often lacked confidence in the technical abilities of their new fellows, who were frequently unable to complete fundamental laparoscopic procedures without direct supervision [9].

In response to the challenges of duty hour restrictions, educators have changed the construct of surgical training to ensure that graduates are both technically competent and sufficiently confident in their technical abilities [10–12]. To accomplish this, the time that residents spend in the hospital must be high yield. One avenue for increasing the yield of resident operative experience is the employment of surgical simulation.

High- and low-fidelity simulation-based education has become increasingly prevalent in the curriculum of surgical residents and now represents an ACGME program requirement [13]. Typically, simulations aim to orient the learner to surgical techniques and operative anatomy prior to the bulk of their experience with live patients. Simulation allows learners to work at their own pace to obtain proficiency in basic surgical tasks [14]. Mobile simulators also allow them to practice their skills outside the confines of the hospital and work hour restrictions [15]. This has potential to bridge the gap in technical skills created by duty hour restrictions, reduce cognitive overload in the operating room (OR), and allow the resident to gain more from their OR experience. Required curricula such as the Fundamentals of Laparoscopic and Endoscopic Surgery have been developed to accomplish these goals [10, 11].

Anorectal surgery is a fundamental component of both general and colorectal surgery resident education. Due to the confined space, difficult angles, and limited exposure within the anal canal, anorectal surgery presents many technical challenges to the surgical resident and teacher alike. Despite the high prevalence of simulation for laparoscopic and endoscopic surgery, anorectal surgical simulation has not been described in the literature, and its role in resident education remains unclear.

The purpose of our study was to design a novel, affordable, and reproducible low-fidelity anorectal surgery simulator that could assist in the education of junior surgical residents. We also sought to evaluate the model for evidence of face, content, and construct validity. Our hypothesis was that this model would accurately recreate the technical challenges of anorectal surgery and be well received by both experts and novices.

Materials and methods

In July 2014, a simulator for anorectal surgery was constructed with the goal of establishing a low-fidelity model that could be utilized by surgical residents. Priorities of model construction included cost containment, high reproducibility, and adequate versatility to simulate the unique challenges of anorectal surgery.

Workshop design

University of Nebraska Medical Center (UNMC) Institutional Review Board approval was obtained for a simulation workshop and model validation. Three separate workshops on anorectal surgery were then conducted at UNMC from August 2014 to July 2016. The instructors were two practicing colorectal surgeons from UNMC (defined as experts), and the students were first-year general surgery residents at UNMC (defined as novices). The workshops featured a 30-min tutorial in anorectal surgery, which included a description of technical challenges and expert tips and tricks. During the tutorial, residents were allowed to practice transverse and horizontal suturing on the simulator with expert guidance and feedback, after which they completed a formal assessment on two separate timed tasks, detailed below. They then completed an anonymous questionnaire regarding their experience with the workshop and their opinions about the simulator (Fig. 1). Experts also completed the tasks and were then asked to fill out an extended version of the novice questionnaire (Fig. 2). Two additional experts were recruited from outside institutions for task and questionnaire completion. Experts were eligible for recruitment if they had been fellowship trained in colorectal surgery and maintained a robust anorectal practice. Expert surgeons were not given time to practice or warm up prior to the formal assessment.

Anorectal surgery simulator

The cylindrical nature of the anal canal was reproduced using disposable 16-ounce plastic cups. After testing several options for simulation of the anoderm and rectal mucosa, commercially available suture pads (Limbs & Things, Savannah, GA, USA) were chosen for inside the plastic cup, and a marker was used to recreate the dentate line as well as several suturing tasks (Fig. 3). These pads were the most costly component at $47 for a pack of 6, with each pad being used for 2 simulators ($3.92/simulator).

A three-ring binder was used to recreate angled visualization into the anal canal, and the cup was secured to the binder using a Velcro (Velcro USA, Manchester, NH, USA) strap. The binders and straps could be adjusted to simulate

Anorectal Surgery Model Evaluation (Novice Form)

Face Validity Evaluation	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
(1) This model has value as a training tool for anorectal surgery.	1	2	3	4	5
(2) The anorectal surgery simulation model is relevant to resident education.	1	2	3	4	5
(3) This model should be a part of surgical resident education in the future.	1	2	3	4	5
(4) This model can be used to test subjects and determine proficiency in anorectal surgery.	1	2	3	4	5

Fig. 1 Novice evaluation form

Anorectal Surgery Model Evaluation (Expert Form)

Face Validity Evaluation	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
(1) This model has value as a training tool for anorectal surgery.	1	2	3	4	5
(2) The anorectal surgery simulation model is relevant to resident education.	1	2	3	4	5
(3) This model should be a part of surgical resident education in the future.	1	2	3	4	5
(4) This model can be used to test subjects and determine proficiency in anorectal surgery.	1	2	3	4	5

Content Validity Evaluation	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
(5) The anorectal simulator was realistic in angles and spatial orientation.	1	2	3	4	5
(6) Instrument and tissue feel was similar to actual anorectal surgery.	1	2	3	4	5
(7) The tasks were appropriate simulations of actual anorectal procedures.	1	2	3	4	5
(8) The hemorrhoid excision with longitudinal wound closure task has value in anorectal surgery simulation.	1	2	3	4	5
(9) The transverse wound closure task has value in anorectal surgery simulation.	1	2	3	4	5
(10) The circumferential directed suturing task has value in anorectal surgery.	1	2	3	4	5

Fig. 2 Expert evaluation form

suturing in different areas of the anal canal (anterior, posterior, and lateral, Fig. 3). Sutures and surgical instruments were obtained from UNMC's Michael F. Sorrell Clinical Simulation Lab.

Model validation

The model was tested for face, content, and construct validity. Face validity is defined as the extent to which a test is subjectively viewed as covering the concept it purports to measure [16, 17]. The first questionnaire (Fig. 1), completed by both novices and experts, evaluated face validity of the model using a 5-point Likert scale (1, strongly disagree; 2, disagree; 3, neutral; 4, agree; 5, strongly agree). Based on previous validation literature, a score of 4/5 was determined to be adequate to demonstrate face validity [17].

Content validity is obtained when the model's tasks are felt by experts to be appropriate recreations of the actual surgical task. In our study, this was assessed by a supplemental questionnaire with six additional 5-point Likert scale questions posed to the study's experts (Fig. 2). Again, a score of 4/5 was set for validation [17].
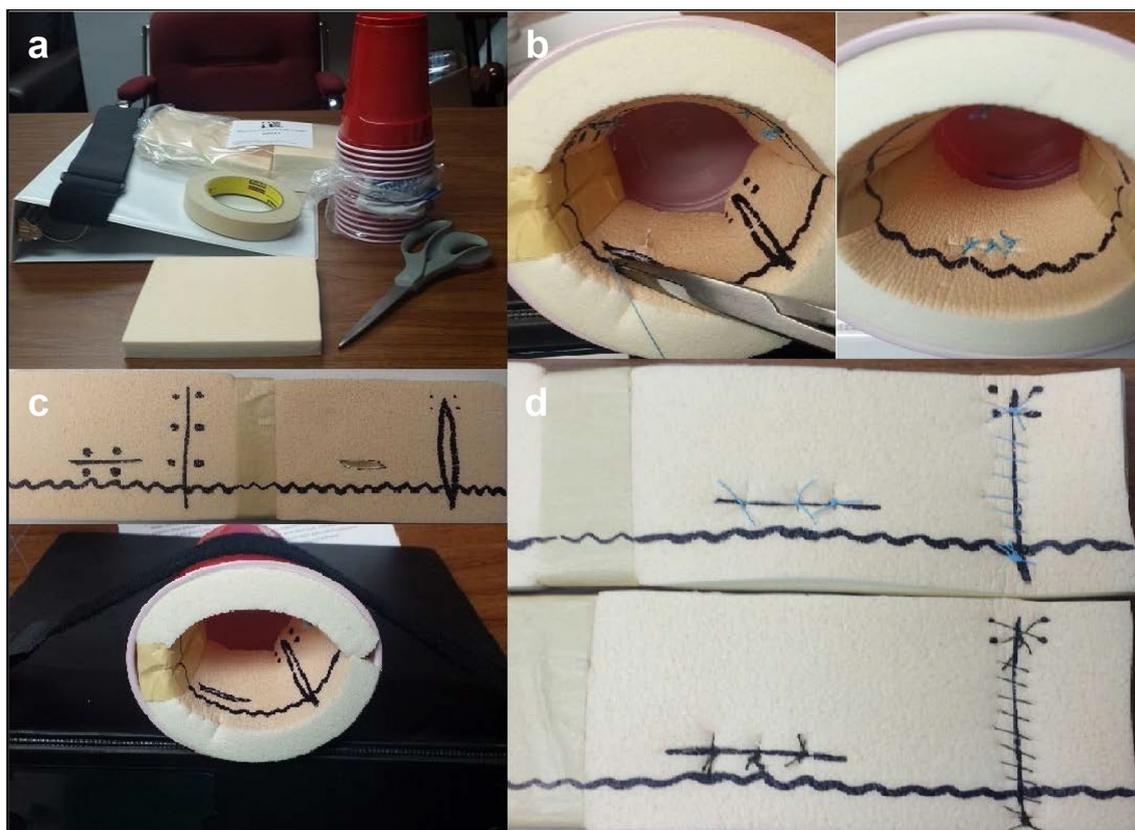
Fig. 3 Anorectal surgery simulator. **a** Materials for construction—Velcro strap, suture pad, tape, 16-oz plastic cup, 3-ring binder, and scissors. **b** Transverse wound closure task. **c** Assembled surgical model with timed tasks—Hemorrhoid excision with longitudinal wound closure (right) and transverse wound closure (left). Task orientation can be altered to recreate wound closure in varied anatomic positions. **d** Completed timed tasks—Novice (top) and Expert (bottom)

Construct validity is evidenced when a model can accurately differentiate a novice from an expert [15]. We started our assessment of construct validity by defining novices as first-year surgical residents and experts as attending surgeons in colorectal surgery. Two separate tasks specific to anorectal surgery were then created with the simulator: (1) transverse wound closure using interrupted sutures (TC), and (2) hemorrhoid excision followed by a longitudinal running closure (LC). Time-to-task completion was measured and recorded. Next, the suture pads were numbered, and the participant's identity removed. The quality of the knot tying and suturing were then graded on a 5-point Likert scale by a blinded observer (1, poor; 2, fair; 3, good; 4, very good; 5, excellent). This observer was a board-certified surgeon who did not participate in the workshop.

Statistical analysis

Statistical analysis was performed using SPSS Statistical Software (IBM Corp. IBM SPSS Statistics for Macintosh, Version 25.0. Armonk, NY, USA). Standard descriptive statistics were performed for all continuous variables. Time to completion of the two simulated tasks was compared by two-way ANOVAs. Likert scale data were compared with Fisher's exact tests. A p value of < 0.05 was considered statistically significant.

Power calculation

After an initial group of six novices and two experts completed the workshop, our pilot results were presented at the 2015 American Society of Colon and Rectal Surgeons (ASCRS) annual scientific meeting. Preliminary analysis suggested that the model was viewed favorably by the expert and novice cohort, and that the simulated tasks appropriately differentiated the two skill levels. At the time of presentation, the time to expert task completion was roughly half of the novice time for both tasks. Based on these results, we predicted a 35% reduction in time to complete tasks among experts, with a novice to expert enrollment ratio of 5:1. For 80% power with an alpha = 0.05, we calculated that the study would require 4 experts and 18 novices. We proceeded with two additional workshops in 2015 and 2016, at which point we had accumulated 20 novices and 4 experts. Post hoc

power analysis was then done for the time to task completion as well as the suturing and knot-tying scores of these 24 subjects, showing 100% power for our study.

Results

The workshops were conducted from August 2014 to July 2016. A total of 4 experts and 20 novices were recruited for this study. All participants provided written consent and completed the timed tasks and questionnaires. No participants were excluded. The cost of production was US $11 per simulator, which included the suture pads, cups, Velcro straps, binders, and sutures.

The model achieved a median Likert score of 5 for the first 3 questions (mean 4.6–4.7) and 4 for the fourth question (mean 4.2) in the face validity questionnaire (Table 1). Median and mean values of 4 or greater for all six content validity questions were reported by the expert cohort. Experts accomplished both TC and LC faster with a greater than 50% reduction in time-to-task completion ($p < 0.001$, Table 2). Blinded suturing and knot-tying scores were significantly higher in the expert cohort despite faster time-to-task completion ($p < 0.05$ for all, Table 2).

Discussion

Anorectal surgery presents unique anatomic and technical challenges to the surgical trainee. While anorectal models exist for teaching anatomy and repairing obstetric-related injuries, there has yet to be a report of a model that recapitulates the visual, spatial, and ergonomic demands of operating within the anal canal [18–20]. With the changing landscape

of surgical residency, development of effective simulation in all surgical disciplines is needed to enhance resident education, and bridge any gaps in operative experience related to reduced work hours.

Simulation has been widely implemented across a range of operative platforms [21–23]. Both low- and high-fidelity models allow residents to refine and maintain their operative skills outside the confines of duty hour restrictions. While it is desirable to create high-fidelity simulations for the purpose of formal assessment, the strengths of low-fidelity modeling should not be overlooked. Many learners become proficient in knot tying and basic suturing using the back of chairs and suture pads. The simple nature of low-fidelity simulators makes them more

Table 2 Results of construct validity testing

Task performance	Novice ($N=20$)	Expert ($N=4$)	p
Time to task completion, mean, (range), s			
Transverse wound closure	192 (122–310)	79 (72–85)	< 0.001*
Hemorrhoid excision and longitudinal wound closure	477 (249–700)	195 (180–220)	< 0.001*
Quality of completed ask, mean, (range), Likert score[a]			
Transverse sutures	3.0 (1.0–5.0)	5.0	0.019*
Transverse knot tying	3.3 (1.0–5.0)	5.0	0.037*
Longitudinal sutures	3.2 (1.0–5.0)	5.0	0.001*
Longitudinal knot tying	3.0 (1.0–4.0)	5.0	< 0.001*

*$p < 0.05$ considered statistically significant

[a]All expert participants scored 5/5 for each quality measure

Table 1 Results of face and content validity questionnaires

Validity measures	Median score ($N=24$)	Mean score ($N=24$)	SD
Face validity, Likert score			
(1) Valuable training tool	5.0	4.6	0.49
(2) Relevant to resident education	5.0	4.7	0.48
(3) Should be included in curriculum	5.0	4.6	0.58
(4) Can be used to determine proficiency	4.0	4.2	0.76
Content validity, Likert score	Median score ($N=4$)	Mean score ($N=4$)	SD
(5) Accurate simulation	5.0	4.8	0.50
(6) Instrument and tissue feel	4.0	4.0	0.00
(7) Appropriateness of simulation	4.5	4.5	0.58
(8) Longitudinal wound closure	4.0	4.0	0.00
(9) Transverse wound closure	5.0	4.8	0.50
(10) Directed suturing tasks	5.0	4.8	0.50

SD standard deviation

available to trainees. When difficulties with the model arise, low-fidelity simulators are also easier to troubleshoot. Furthermore, low-fidelity simulation often utilizes instruments identical to those used in the operating room. This familiarizes learners with the actual look and feel of surgical instruments while providing realistic tactile feedback, which is difficult to replicate in high-fidelity models. The benefits of low-fidelity simulation explain its continued use in surgical education despite the availability of high-fidelity models. However, as the evidence in support of simulation-based learning continues to grow, a balance of high- and low-fidelity models will be needed to meet the new demands of educating future surgeons [22, 23].

Recently, competency and milestone-based education have entered the forefront of surgical education. Within this educational framework, surgical simulation has, in part, taken on the important role of assessing residents for technical competence [10, 11]. Currently, surgical residents must complete two simulation-based curricula in laparoscopy and endoscopy prior to board eligibility: Fundamentals of Laparoscopic Surgery and Fundamentals of Endoscopic Surgery [10, 11]. A similar desire to demonstrate competence in colon and rectal surgery residency graduates prompted the creation of the Colorectal Objective Structured Assessment of Technical Skill (COSATS) [12]. These high-stakes examinations will likely play an increasing role in assessing preparedness for independent practice, and should be rigorously evaluated for validity. However, the development and use of simulators as a method to gain technical proficiency in basic surgical skills should continue to be pursued.

We created a low-fidelity anorectal surgery simulation using readily purchased materials for the purpose of developing proficiency in basic anorectal surgery technique. A primary focus in development was cost containment and reproducibility. The model is economically produced at a cost of US $11 per simulator, has straightforward assembly, and has the versatility to be utilized across several levels of training. Students and junior residents can use it to gain initial familiarity with anorectal suturing, while more advanced learners can use it to hone their skills in more complicated tasks. In addition, the lightweight design and benchtop nature of the model makes for easy portability. This allows practice to occur in a variety of environments and promotes consistent use, which is an important component of technical improvement [24].

We evaluated the model using a traditional framework [17]. All study participants reported high face validity scores. Similarly, the expert cohort of practicing colorectal surgeons scored the simulation as accurately recreating the visual, spatial, and ergonomic challenges encountered in anorectal surgery practice suggesting content validity. Finally, our results also provide evidence for construct validity as the simulation readily differentiated expert from novice both in time-to-task completion and quality-of-task performance.

There are certain limitations to our study. We recruited first-year surgical residents as novices to evaluate the model, and did not test it in more senior residents. This prevents us from commenting on the simulator's ability to distinguish between residents of different post-graduate years. Similarly, we did not repeat testing in the novice cohort to see if the skills learned during the workshop were retained over time. Rather, we focused on evaluating the model's ability to recreate the challenges of anorectal surgery and provide early evidence for validity of the model. We were pleased with the results of the anorectal surgery workshops and are currently in the process of developing a curriculum aimed at preparing medical students and residents of all levels for their colorectal rotations. We envision an anorectal surgery workshop would be initially offered to incoming surgical interns rotating through our colorectal surgery service. After the initial training session, a simulator would be given to each of them for independent use. Residents would be sent with pictures demonstrating appropriately spaced sutures, properly secured knots, high-quality wound closure, and be given a goal time to task completion which demonstrates basic proficiency allowing for self-evaluation. Additional supervision of simulator use would be on an as needed basis if trainees had additional questions or needed further instruction. Feedback from attending surgeons would largely come through evaluation of residents' ability to progress through and independently complete anorectal cases in the operating room. The end goal would be increasing resident comfort with anorectal surgery, so they can maximally learn from and participate in anorectal surgery cases throughout their training.

This study is also limited by the low-fidelity nature of the model. While the simulator effectively models suturing within the anal canal, the hemorrhoidectomy task does not assess the resident's ability to operate in the presence of a retractor, or evaluate their understanding of key steps of the operation including preservation of the internal sphincter. With simple modifications to the simulation, these aspects of a hemorrhoidectomy could be modeled providing a more robust experience.

While the study is appropriately powered to compare the novice and task performance, the overall size of the cohort is modest. We aimed to assess the simulator's utility within a formal training program, and thus were limited by the number of residents at our institution. We extended our study over 3 years to obtain adequate numbers, and felt that further extension to achieve a larger cohort would not add significant value to the study, and could delay our introduction of the model to a larger group of surgical educators.

Another limitation is variability in the baseline level of experience among interns in anorectal surgery. We did not

review case logs or inquire about previous surgical rotations. Therefore, it is possible novices with significant previous experience may have participated. In addition, prior to completion of the two timed tasks, all novices underwent a tutorial that may have improved their baseline performance. This design may have lowered the time to complete the individual tasks while simultaneously increasing the task score of the novice cohort, diminishing the distinction between novice and expert. Nevertheless, the expert cohort performed both tasks significantly faster and with higher performance scores. If previous anorectal surgery experience or the tutorial did improve novice performance, it had minimal influence over the results of the study.

Finally, our study utilized a traditional method of model validation [17]. While there has been movement towards new standards for validity evidence, this framework for model validation continues to be present in the literature and aims to justify a model's use in trainees [17, 21, 25]. Medical education experts have justifiably reduced their focus on model validation, and instead focused on the results of model implementation, e.g., the ability to improve anorectal surgical skills using our simulator. We agree that this refocusing is appropriate, and our simulator's value lies more in its versatility and reproducibility than it does in the ability to discriminate experts from novices. Future work with this simulation will incorporate consensus standards for educational modeling to provide additional evidence of validity [25]. Nonetheless, these results demonstrate evidence that our model accurately recreated the challenges of anorectal surgery, and that it represents a useful tool for the education of surgical residents as surgical education moves to include more simulation-based education platforms.

Conclusions

Our low-fidelity, low-cost anorectal surgery model demonstrated evidence of face, content, and construct validity. We believe that this simulator could be a useful instrument in the education of junior surgical trainees and will allow residents to obtain proficiency in anorectal suturing tasks in conjunction with traditional surgical training.

Compliance with ethical standards

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