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ORIGINAL ARTICLE

Bowel anastomosis training simulator: design and pilot testing

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Abstract

Background: Simulation in surgical training continues to evolve. As surgical trainees have limited opportunities to regularly practice hand-sewn bowel anastomoses, the aim of this pilot study was to design a low-cost simulation system, the bowel anastomosis training simulator (b-ATS), for teaching hand-sewn small bowel anastomoses and providing learners with real-time feedback via leak testing. **Methods:** The study consisted of three phases. Phase 1 was the initial design of the b-ATS. The b-ATS consists of a base, stand, fluid bags, tubing, and a novel silicone bowel (bowel A). Phase 2 consisted of data collection. Two PGY-1 residents and one bariatric surgeon created multiple anastomoses using bowel A, several commercially available synthetic bowels, and porcine small bowel. Leak pressures were compared to determine which synthetic bowel most closely resembled biologic tissue. Phase 3 implemented the findings from phase 2 to refine the b-ATS and select the optimal bowel for use in the simulator. **Results:** The synthetic bowel had the following average leak pressures with polydioxanone (PDS)/Vicryl (cmH_2O): bowel A, 39.2/37.1; bowel B, 11.4/17; bowel C; 30/36.2; bowel D, 68/65.1; bowel E, 38.2/38.1; and bowel F, 55.2/39.2. The average leak pressures for porcine bowel were 62.3/61.6 cmH_2O with PDS/Vicryl. The most common location of leaks was between the suture and suture holes, followed by the site of attachment to the circular stand. Porcine bowel had the lowest cost at US$0.10 per inch compared with the synthetic bowel tissues which ranged from US$1.66 to US$6.00 per inch. Based on these results, phase 3 consisted of refinements to the simulator structure to prevent the latter leaks and selection of bowel D for use in the final simulator model. **Conclusion:** The b-ATS is a functional simulator for teaching hand-sewn small bowel anastomosis. Bowel A had significantly lower leak pressures compared with porcine bowel. Bowel D had the closest leak pressure to porcine bowel, at low cost and with adequate durability. Further research is needed to validate the efficacy of this tool.

Keywords: *laparoscopic training tool; surgical training; small bowel anastomosis; surgical education; surgical resident; design and bench testing*

Introduction

Simulation training is an ever evolving and increasingly utilized tool for training surgical residents. With the implementation of restrictions on resident hours came concerns about decreased operative experience. Simulation training has arisen as one method to address these concerns. Although results have varied, several studies have reported decreased overall operative experience.[1–3] In 2008, Kairys and colleagues found a statistically significant reduction in case volume when evaluating Accreditation Council for Graduate Medical Education reports.[1] The need for educational supplementation has increased further with the COVID-19 pandemic, when social distancing was strictly enforced and elective operations were limited. Simulation not only provides learners with operative knowledge but also allows learners to gain confidence in a low-stakes environment.[4–6]

Many successful surgical simulations have been developed, but there are numerous surgical experiences that are not yet easily simulated.[6] With the advent of surgical staplers, hand-sewn bowel anastomoses are performed less frequently, resulting in fewer opportunities for residents to learn this skill. Developing a successful and sustainable bowel anastomosis simulation presents with its own set of challenges. One must first consider an alternative material to replicate living human tissue. Porcine bowel is thought to be most similar but has its limitations, including a short shelf life, making storage and interval repetition difficult. Alternately, synthetic bowel products have longer shelf lives but higher costs. Cost effectiveness and accessibility are essential in

planning a successful simulation. Between the short shelf life of porcine bowel and the high cost of synthetic bowel, these resources become poorly accessible to learners because many programs offer anastomotic training simulation annually. This prevents learners from the frequent repetition needed to refine technical skills.

Feedback and the ability to track progression is also a crucial part of any simulation. Testing an anastomosis for a leak is commonly performed in the operating room, and thus, using leak pressures as a marker of progression has been proposed.[5,7] This requires defining a clinically relevant benchmark pressure, which is a challenge because the pressure at which human bowel anastomoses leak is unknown. Several authors have compared the leak pressures of porcine bowel with synthetic products; synthetic products often leak at a lower pressure.[8–11] Furthermore, the density and elasticity of synthetic bowel products vary, which can have an impact on the seal formed by the tissue after creating an anastomosis. Products with low elasticity may leak at lower pressures despite an adequate anastomosis technique. Therefore, the clinically relevant leak pressure likely differs between products.

The aim of this pilot study was to design and test a low-fidelity, low-cost, durable, hand-sewn bowel anastomosis simulator that could be utilized by learners both in a simulation lab setting and at home for repeated anastomoses.

Methods

The bowel anastomosis training simulator (b-ATS) project had three phases: (1) simulator conceptualization, design, prototype fabrication; (2) prototype testing; and (3) prototype iteration to final design.

Phase 1 was performed in conjunction with an engineer who helped develop the model concept, 3D CAD models, and a 3D printed prototype. Essential requirements implemented in the initial prototype were portability, durability, ability to attach and retain synthetic bowel, and to test leak pressures using a gravity-based water pressure method. For the initial prototype, a single-layer silicone bowel was developed. The b-ATS consisted of a base, a stand for bowel attachment, a novel synthetic bowel, fluid bags, and tubing (Fig. 1).

In phase 2, we evaluated the overall functionality of the b-ATS for performing a single-layer hand-sewn side-to-side bowel anastomosis. During this phase, we evaluated various suture types and compared our silicone bowel material (bowel A) with five other currently available commercial synthetic bowel materials (bowels B–F). To test the b-ATS, we compared leak pressures and leak locations of bowels A–F with ex vivo porcine small bowel (bowel P) to determine which synthetic bowel most closely resembled biological tissue. The commercial bowel products were from the following companies: Simulab (bowel B/single layer/dry model), 3DMed (bowel C/double layer/dry model), SimVivo (bowel D/triple layer/dry model), Syndaver (bowel E/double layer/wet model), and Lifelike Bio Tissue (bowel F/double layer/wet model) (Fig. 2).

The b-ATS bowel simulator model was used to perform a hand-sewn anastomosis by three separate individuals: two general surgery interns and one fellowship trained minimally invasive surgeon. Two types of suture were utilized: 3-0 polydioxanone monofilament and 3-0 braided polyglycolic acid. Each suture type was used for three separate trials on each bowel type for a total of six trials on each bowel type. This resulted in six anastomoses for each bowel type. After each anastomosis was sewn, it was pressure tested for leaks using a gravity system measuring centimeters of water.

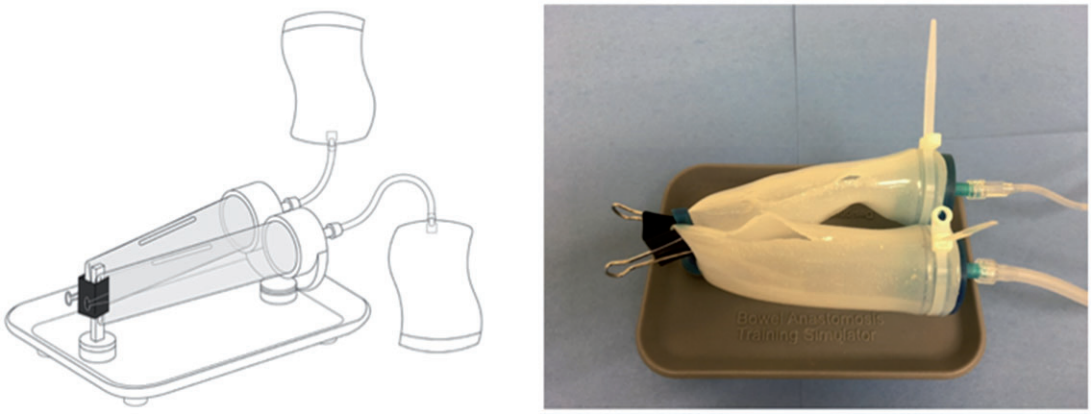


Figure 1. Bowel anastomosis training simulator technical drawing (left) and initial prototype (right).

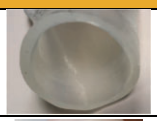
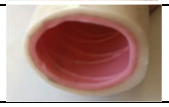
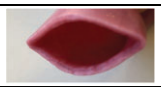
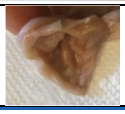
Bowel Type	Company	Layers	Wet/Dry	Photo - Length	Photo – Cross Section	Cost Per Inch
Synthetic	WVU Model (Bowel A)	One	Dry			$1.66
Synthetic	Simulab (Bowel B)	One	Dry			$3.91
Synthetic	3D-Med (Bowel C)	Two	Dry			$6.00
Synthetic	Sim Vivo (Bowel D)	Three	Dry			$2.49
Synthetic	Syndaver (Bowel E)	Two	Wet			$4.83
Synthetic	Lifelike Biotissue (Bowel F)	Two	Wet			$5.83
Biologic	Porcine (Bowel P)	Four	Wet			$0.10

Figure 2. Synthetic bowel types used in phase 2. Costs are in US dollars.

A leak was defined as the appearance of visible water droplets on the bowel, and it was noted whether the leak was coming from suture puncture sites, from the anastomosis itself, or at the connection points of the bowel to the simulator stand. Sutures were removed after each trial and the bowel model was reused with the same simulated enterotomy. Study participants provided subjective input regarding ease of working with wet versus dry bowel and the durability of each bowel model for subsequent trials. Cost per linear inch of each bowel type was also recorded.

In phase 3, we conducted prototype iteration using data from phase 2 to select the best synthetic bowel type to use for the final model, and to further refine the simulator base and stand to improve their functionality.

A mixed-effects model was used to compare groups in the presence of repeated measures, adjusting for different suture materials. This approach can handle fixed and random effect model parameters, as well as unbalanced designs and repeated measures with various correlation structures. Subject effect was treated as random to account for the dependence among repeated observations on the same individuals.

Results

Phase 1 of the project, performed in conjunction with an engineer, involved translating the b-ATS concept from idea to functional prototype by creating technical drawings, a 3D CAD model, and finally a 3D printed prototype. The technical drawings were created using Autodesk Fusion 360 and depict the following simulator elements: base, stand for bowel attachment, synthetic bowel, fluid bags, and tubing. The 3D CAD design was also created using Autodesk Fusion 360; a Formlabs Form 2 SLA 3D printer was used to produce the initial simulator prototype.

For the initial prototype, a single-layer silicone bowel was developed. The silicone bowel was created using a two-part silicone called Dragon Skin 10 from Smooth-On. To create the desired bowel shape for this project, a bowel mandrel was designed and 3D printed. The mandrel was fixed to a rotisserie and used as a core/mandrel for which to coat the silicone. The silicone was prepared according to the manufacturer's instructions and coated onto the bowel mandrel as the mandrel rotated. This rotation provided by the rotisserie allowed the liquid silicone to coat the mandrel evenly until it cured. After curing, the silicone was removed from the mandrel and was ready for testing. Essential requirements implemented in the initial prototype were portability, durability, ability to attach and retain synthetic bowel, and ability to test leak pressures using a gravity-based water pressure method (Fig. 1).

Phase 2 results included leak pressure data and subjective feedback regarding ease of use and durability of bowel types. The average leak pressure for porcine bowel was

Table 1. Average anastomotic leak pressures (cmH_2O) for different bowel and suture types

Researcher	Porcine PDS	Vicryl	A PDS	Vicryl	B PDS	Vicryl	C PDS	Vicryl	D PDS	Vicryl	E PDS	Vicryl	F PDS	Vicryl
1	55.8	56.5	45.2	35.4	11.4	27.1	45.5	46	68	68	42	37.6	51.1	30.5
2	68	68	40.8	38.1	9.7	7.5	17.8	34.4	68	59.2	34.9	43.1	59.4	29.8
3	63.1	60.4	31.5	37.7	13.1	16.3	26.8	28.1	68	68	37.6	37.6	55	57.3
Average	62.3	61.6	39.2	37.1	11.4	17	30	36.2	68	65.1	38.2	38.1	55.2	39.2
Range	55.8–68	56.5–68	31.5–45.2	35.4–38.1	9.7–13.1	7.5–27.1	17.8–45.5	28.1–46	68–68	59.2–68	34.9–42	37.6–43.1	51.1–59.4	29.8–57.3
Standard deviation	6.8	4.0	10.2	5.1	4.0	12.0	16.9	10.8	0.0	9.1	5.7	5.4	5.3	18.8

62 cmH_2O; synthetic bowel types had the following average leak pressures (cmH_2O): bowel A, 38.1; bowel B, 14.2; bowel C, 33.1; bowel D, 66.5; bowel E, 38.2; bowel F, 47.2 (Table 1). Results of the linear mixed model showed there was no difference in leak pressure between porcine tissue and bowel D. There was a significant difference in leak pressures between porcine bowel and the remaining bowel types (Fig. 3). There was no significant difference in leak pressure between suture types.

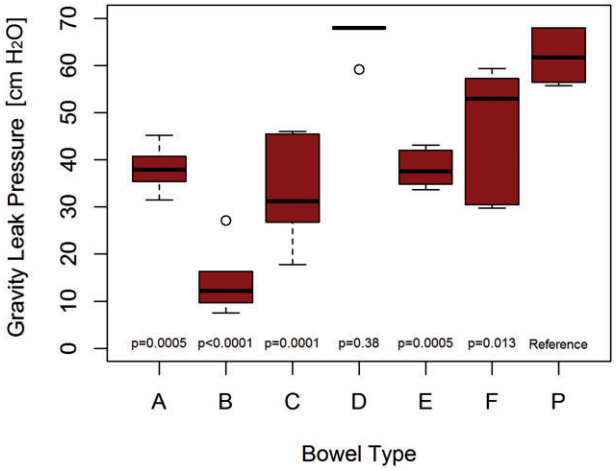


Figure 3. Bowel anastomoses leak pressures: p values were based on a mixed-effects model in which subject effect was treated as random to account for the dependence among repeated observations on the same individuals.

Leaking between the suture hole sites and the suture was the most common site of leaks for the model and occurred in synthetic bowel models A, C, D, and F. Once the suture was removed, there was minimal to no leaking from the pre-existing suture sites. The second most common site of leaks was at the connection point of the bowel to the circular stand, where bowel was secured to the stand with silicone ties, and occurred in bowel models B, E, and P. The cost for the seven tissues ranged from US$0.10 to US$6.00 per inch. The wet tissue models (porcine, bowel E, bowel F) began to deteriorate significantly with repeated use. Two of the dry models (bowels C and D) had adequate durability for repeat anastomoses, whereas bowels A and B had significant deterioration. Subjectively, the dry bowel types were easier to handle.

The results of phase 2 identified three areas of improvement for the simulator design. First, the site attaching the bowel to the simulator was too large to comfortably accommodate several bowel types. Second, the connectors for the tubing to conduct leak pressure testing were not compatible with our intravenous tubing. Third, the bowel required cross clamping to provide adequate water seal for leak testing, which interfered with sewing for anastomosis and contributed to bowel deterioration.

At the conclusion of the data collection and testing of our model, suggestions for improvements to the model were implemented in the overall design. In phase 3, we utilized our findings from phase 2 to develop a final version of the b-ATS. We selected bowel D (3-layer synthetic dry bowel) because it had the closest leak pressure to porcine bowel, the second lowest cost, as well as adequate durability. In addition, we worked with our engineer to make adjustments to the b-ATS. These refinements included a clamp at one end of the bowel that was tight enough to both retain the bowel and stop water from leaking during leak pressure testing. To facilitate universality, Luer lock compatible attachments were added to the bowel attachment sites to be compatible with standard medical intravenous tubing for leak pressure measurements. The diameter of the bowel attachment sites was decreased to allow the bowel to be attached more easily; specifically, the diameter of the mounting attachments was optimized for use with bowel D to facilitate easier installation of the bowel. The final prototype of the b-ATS is shown in Fig. 4.

Figure 4. Final prototype of the small bowel anastomosis training simulator.

Discussion

In modern surgical training, residents continue to face challenges getting adequate operative exposure and training; some of the constraints include a decrease in elective operations during the COVID-19 pandemic, work hour restrictions, a decreasing number of open operative procedures, and an increasing number of advanced laparoscopic, robotic and endovascular procedures. All of these issues hinder resident operative training within the surgical suite and drive a need for simulation training to fill these gaps in surgical education.[1–4,12]

The value of simulated surgical training has been emphasized in several studies to date. Rowse et al.[6] used a low-fidelity small bowel model to teach general surgery interns anastomosis creation. Those interns who were able to implement or observe these skills in the operating room showed greater retention on a test 3 months after the initial skills test. It is not unreasonable to assume that trainees who have access to a simulation at home might be able to retain these skills despite not having observed it in the operating room. Egle et al.[5] showed that training on cadaveric small bowel with formal instruction improved the residents' technical skills in several areas, including decreased operating time, increased leak pressures, and objective assessment scores. Furthermore, Boza et al.[4] showed that junior residents who completed a 16-session advanced laparoscopy training curriculum performed better on a stapled jejuno-jejunostomy in the operating room than general surgeons without simulation training. This highlights the importance of simulation training, and how adequately designed simulation training can prepare learners for safe performance in the operating room.

Our goal was to design, build, and perform pilot testing of a bowel anastomosis training simulator. Simulator fidelity, cost, durability, and the ability to track progression were all considered during this evaluation. The final b-ATS consisted of the base, stand, tubing, and bowel D. A simple gravity-based water pressure system was utilized to measure anastomotic leak pressures. Many studies investigating leak pressures utilize a transducer system, but this gravity-based system was chosen based on its simplicity and cost effectiveness.

One of the challenges in creating a simulated anastomosis practice tool includes the interpretation of leak pressures among different tissue types. With regard to leak pressure, as porcine bowel is thought to best resemble human bowel, it was used as the standard against which all synthetic bowels were compared. The average porcine leak pressure in this study of 62 cmH_2O was similar to reported leak pressures in previous porcine and canine models.[8–11] However, leak pressure can vary depending on the method of measurement as well as whether the bowel material has been processed; for example, Aeschlimann et al.[10] showed a statistically significant decrease in leak pressures when porcine bowel was frozen before use.[9]

Earlier work has suggested that leak testing of synthetic material may be less useful for leak testing biological tissue. Regier et al.[11] compared leak pressures of an enterotomy closure between canine bowel and one commercially available synthetic segment and concluded that leak testing should not be used to assess the accuracy or security of enterotomy suture lines in synthetic intestinal tissue. In the present study, we evaluated the same synthetic segment used by Regier et al.[11] (bowel E) and had similar findings of an anastomotic leak pressure significantly less than that of porcine bowel. However, the conclusion of Regier et al. that leak testing cannot be used for synthetic intestinal tissue is limited in that the study compared only one synthetic tissue type with canine bowel. The present study compared six synthetic small bowel tissues with porcine bowel and was able to identify one (bowel D) with similar leak pressure to biological tissue. This suggests that there may be value in leak testing appropriate synthetic tissues.

Nevertheless, the interpretation of leak pressures in relation to the quality of anastomosis and development of skills is difficult. For the present study, leak pressure was used as an indirect measure of fidelity, however this construct did not adequately consider how tissue characteristics such as elasticity and tissue density can affect leak pressure. For instance, products with low elasticity may leak at lower pressures despite an adequate anastomosis technique. This means the clinically relevant pressure at which a high-quality anastomosis would leak on different synthetic bowel types may differ. To address this, a separate examination of validity utilizing the Messick framework would be required for each bowel type.[13–16] Due to budget restraints, this was not feasible, and thus, the decision was made to complete initial optimization of the simulator including the selection of bowel type D before performing further studies.

In relation to cost, porcine bowel had the lowest cost at US$0.10 per inch compared with the synthetic models, which ranged from US$1.66 to US$6.00 per inch. Of the synthetic models, the novel silicone bowel (bowel A) was the most cost effective at US$1.66 per inch; the second most cost effective synthetic small bowel was bowel D at US$2.49 per inch. Bowel A performed poorly with regard to leak testing and handling, therefore bowel D was chosen for the simulator.

With regard to durability, porcine bowel and wet synthetic models were not robust and multiple tissue tears and leaking from previous suture sites occurred after repeated use. In addition, storage of these bowel types proved cumbersome, because each required refrigeration. Despite being cost effective and lifelike, subjectively the porcine bowel was less convenient to use at home compared with synthetic bowel. Although the b-ATS can accommodate porcine bowel for simulations in a simulation lab setting, the decision to use a synthetic bowel for the final simulator design was influenced by the objective of designing a simulator that was easy to set up and train on repeatedly, thus giving surgical learners a simulator they could use at home. The above findings contributed to the ultimate selection of bowel D, a dry synthetic intestinal tissue, for the final simulator because it had the closest leak pressures to porcine bowel, was cost effective, and could withstand repeated use.

The present study has some limitations. It represents the most primitive exploration of simulator function, in that one attending and two residents performed all the testing, making it difficult to determine how the simulator will perform when used to teach a cohort of residents in a residency program. Due to the cost and time of making the simulator prototypes, it was not practical to have a large number of residents use them until the simulator design had been finalized. The most significant limitation of the present investigation was the use of leak pressure as a surrogate for bowel fidelity. The affiliation of leak pressure to bowel fidelity is an oversimplification, because leak pressures are a function of multiple tissue characteristics, such as tissue elasticity, tissue density, and tissue thickness. Another limitation of this study was that the leak testing was performed using a gravity-based water pressure system, which lacked precision. A more precise but more expensive method of leak testing would be to use a digital manometer. An additional limitation was the unexpected sites of leaking between the suture holes and suture, as well as from the bowel at the connection with the simulator. This was likely caused by the synthetic bowel not conforming or sealing to the suture, resulting in a passageway for fluid to escape. Once sutures were removed, there was minimal to no leaking from the pre-existing suture sites. Nevertheless, the presence of unanticipated leaks from the site where the suture passed through the tissue did decrease the ability to use the model to evaluate leaking directly from the anastomosis and should be considered a limitation of the present study. Although the latter leaks were addressed in phase III when improving the simulator design, the former leaks suggest, in agreement with the literature, that leak testing has limitations when assessing the accuracy or security of enterotomy suture lines in synthetic material.

Conclusion

This pilot study on surgical biodesign created a low-fidelity, low-cost simulator that will allow surgical trainees to learn and practice hand-sewn small bowel anastomosis skills both in a simulation lab and in a home setting. Having established a functional b-ATS model and bowel type, future plans will focus on evaluating learner experience and skill acquisition using the model with a larger cohort of both surgical trainees and attending surgeons. Further research is needed to validate the efficacy of this tool.

Conflict of interest

Nova Szoka serves as a consultant for Johnson & Johnson and CMR Surgical. She also conducts industry-sponsored research via Digbi Health and is the founder of Endolumk Inc. All other authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

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