SYNTHETIC BOWEL TISSUE DEVELOPMENT

School of Medicine and Public Health, University of Wisconsin-Madison

UW BME Design

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Abstract

Why? Residency programs use **cadaveric animal tissue** to teach and assess surgical ability, which is **costly, difficult to come by**, and most importantly **does not accurately replicate *human anatomy***.

How is this model different? Using the "**The Nesting Dolls Technique**," a **cotton fiber matrix provides scaffolding** for **Smooth-On silicone** and a **cellulose fiber sheet** mimics the mucosa. This model is **much cheaper** than current products on the market, can be **reused**, has a **long shelf-life**, and provides **real-time surgical skill teaching, assessment, and maintenance** over the life of the surgeon.

How was it tested? With **MTS testing** and through **surveys** done by surgical residents at UW Hospital following completion of an anastomosis simulation.

End evaluation: Improvements were made in this semester's second generation model, including **maximum stress and elongation at failure to better mimic human small bowel**. Qualitatively, the surgical residents supported the model's **accuracy in aesthetic and physical characteristics, surgical simulation, and marketability**.

Motivation

1.) Motivation

- **Gunshot wounds** are responsible for 64% of penetrating abdominal trauma [1]
- 50% of penetrating abdominal trauma results in perforation of the small intestine. [1]
- Funded by **Department of Defense: Medical Practice Initiative Procedural Skill Decay and Maintenance (MPI-PSD)** to develop training systems and assessment tools for the sustainment of "military medical readiness" [2]
- Other uses: Crohn's disease, removing malignancies, and correcting perforations [3]
- **Four times the risk of mortality** should an anastomosis leak occur [4]

2.) Current Method

Animal Tissue

- Expensive and short-lived
- Anatomically not to scale

Market Items

- Anatomical inaccuracy
  - No mesentery
  - Saturated fabric material
- Lack *in vivo* environment

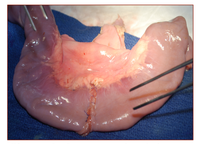


Figure 1: Current animal tissue used for practice and assessment [5].

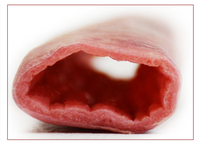


Figure 2: Cross-Sectional view of SynDaver synthetic small bowel [6].

Background

1.) Anatomy

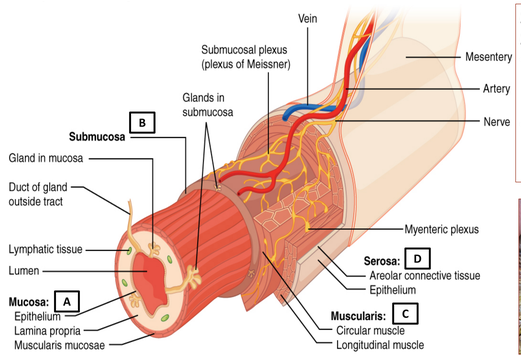


Figure 3: Tissue layers of the small intestine, including mucosa (A), submucosa (B), muscularis (C), and serosa (D) [7]

Mechanical Properties

- 0.9 MPa Maximal Stress
- Elongation at Failure (%): 162.8% [8]

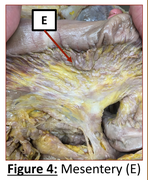


Figure 4: Mesentery (E) of the cadaveric small bowel [9]

2.) Procedure - Two-Layer, Hand-Sewn Anastomosis

Step 1

- Puncture all layers to lumen on one segment back through lumen out serosa on other segment
  - Pull knot tight to close gap of puncture
- Sew length of puncture or resection – 2mm apart

Step 2

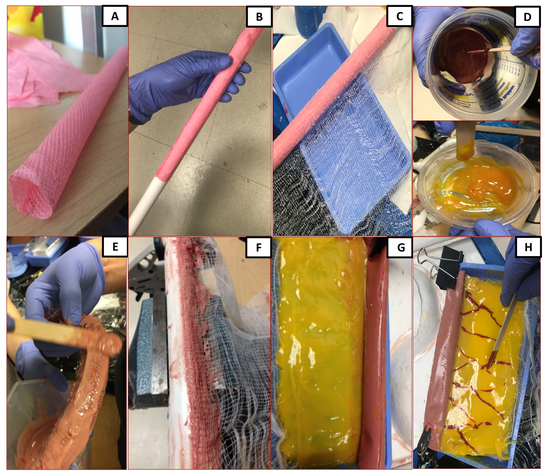
- Sew through the serosa and muscularis only (intentionally not penetrating through to lumen layer)

Design Specifications

- Accurately represent anatomical features of small bowel
  - Distinct muscularis and mucosa
- Accurately represent the mesentery, without blood vessels
- Mimic mechanical properties of small bowel
- Assessable resection and anastomosis
- Easily fabricated and reusable

Final Fabrication Method – Nesting Dolls

Fabrication



Figures 5A-H: A) Fabricating cellulose sheath B) Placing preformed sheath on inner PVC mold C) Wrapping inner tube from B in cotton matrix D) Coloring DragonSkin and EcoFlex Gel for small bowel and mesentery E) Spreading Smooth-On from step D onto wrapped pipe from C F) Securing pipe/cotton matrix/silicone complex in outer mold G) Pouring yellow EcoFlex Gel onto cotton matrix to form mesentery H) Adding vasculature to the mesentery

Materials

- DragonSkin Pro-FX + Slacker (1): Muscularis
- EcoFlex Gel (2): Mesentery
- SilcPig (3): Silicone dye
- Cotton fiber matrix (4): Connects small bowel & mesentery
- Organic cellulose fiber sheath (5): Mucosa
- PVC: Mold
- Surgical Lubricant: Peritoneal fluid

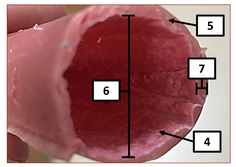


Figure 6: Inner lumen shows difference between mucosa and muscularis

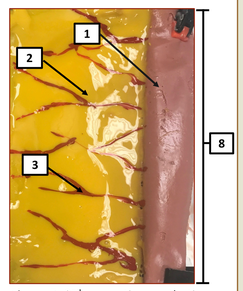


Figure 7: 2nd generation synthetic small bowel model

Dimensions:

- Hollow lumen (6): 2.54cm
- Thickness (7): 1.2mm
- Length (8): 30cm

Cost

Prototype: $5.03 **Hardware: $7.12**

Testing

Stress Analysis

Performed Mechanical Testing System (MTS) tensile testing on three samples per generation until failure

- Each sample was approximately 3.8cm in length
- Stretched uniformly at 10mm/min

Tensile properties of interest

- Elongation at Failure
- Stress and Strain

Raw data analyzed through online software, MATLAB, and Excel

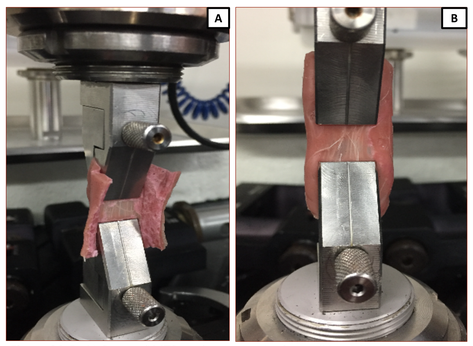


Figure 8A-B: A) Onset of MTS testing on synthetic small bowel sample B) Sample beginning to elongate

Survey Analysis

Residents performed a two-layer hand sewn anastomosis simulation utilizing the prototype

- A survey was administered to three surgical residents at UWSMPH to evaluate aesthetic and physical accuracy, surgical accuracy, and marketability
- Raw data transformed into a Likert scale and analyzed through Excel

Figure 9: A survey participant performing two-layer anastomosis on synthetic bowel tissue

Figure 10: Small bowel model post-simulation.

Results and Discussion

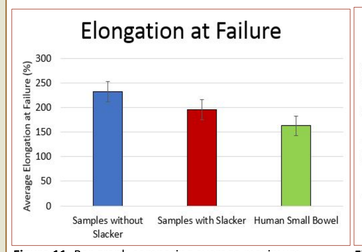


Figure 11: Bar graph comparing average maximum stress values for small bowel models made with and without Smooth-On Slacker.

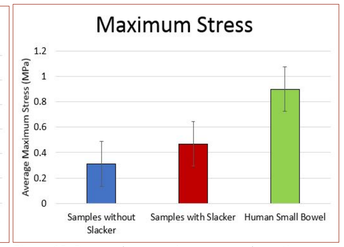


Figure 12: Bar graph comparing average elongation at failure for small bowel models made with and without Smooth-On Slacker.

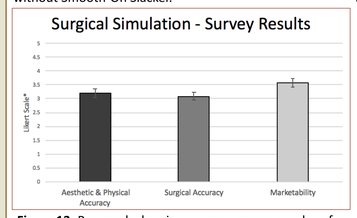


Figure 13: Bar graph showing average response values for each category: Aesthetic & Physical Accuracy, Surgical Accuracy, and Marketability

* (1= Highly Inaccurate, 3 = Average, 5= Highly Accurate)

"This simulation could be used to highlight strengths and weaknesses in my technical skills."

- Second generation of model (with Slacker) has a **reduced elongation at failure value of 196%** compared to that of actual human bowel at 163%.
- Second generation of model (with Slacker) has an **increased maximum stress value of ~0.5 MPa** compared to that of actual human bowel at 0.9 MPa.
- Analysis of survey results showed **the small bowel model scored in the average accuracy range across all categories**.
- The sample size of 3 residents makes this data **difficult to scale-up**, but provides a **good point of reference.**

"This small bowel model is a better substitute than other synthetic small bowel materials that I have used."

Market Opportunities

- Preventable death costs the United States an estimated **$735 to $980 billion annually** [10]
- **"Quality care is less expensive care. It is better, more efficient, less wasteful. It is the right care, at the right time, every time."** [10]
- In 2011, 83 of 90 medical schools used simulation during residency programs [11]
- The medical simulation market was valued at **$1.6 billion in 2016**, expected to reach **$3.1 billion by 2021** [12]
- **Our model is reusable** over dozens of iterations by removing the stitches from the previous simulation, with a **shelf-life of at least 2 years** when stored at 25°C

Acknowledgements

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References

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