Improving Negative Pressure Therapy for Gastrointestinal Leaks

Team Members:

Simon Fetherston (Leader)

Mariah Smeeding (Communicator)

Evelyn Mikkelson (BSAC)

Yeanne Hwang (BWIG & BPAG)

Client:

Dr. Amber Shada

UW Health General Surgery at The American Center

Division of Minimally Invasive Surgery

Advisors:

Prof. John Puccinelli

Department of Biomedical Engineering

Presentation Overview

- Problem Statement
- Background
- Product Design Specifications
- Design Considerations
- Final Design
- Planned Testing
- Future Work
- References and Acknowledgments

Background Information

Anastomotic leaks occur when surgically connected parts of the intestine fail and leak contents into the body.

- Serious postoperative complication
- Traditionally requires invasive reoperation
- Significant patient morbidity and mortality risk
- Anastomotic leaks are reported in in up to 40% of esophagectomies and up to 17% of gastrectomies [1]

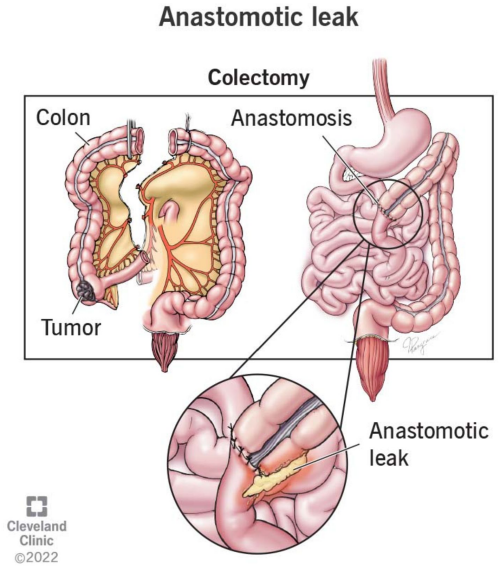


Figure 1. Anastomotic leak post colon resection surgery [2].

Problem Statement

- Anastomotic leaks following esophagectomy are a life-threatening complication often requiring surgical reintervention
- Endoluminal Vacuum Assisted Closure, VAC, therapy achieves a 95% healing success rate in esophageal leaks [3]
- Placement is labor-intensive requiring anywhere from 30 minutes to 3 hours under anesthesia
- Requires advanced endoscopic skill

Background - Client Description

Amber L. Shada, MD, FACS

Fellowship trained in advanced endoscopic and laparoscopic gastrointestinal surgery

Clinical Expertise

- Minimally invasive GI surgery
- Esophageal and gastric disorders
- Advanced Endoscopic techniques

Research Interests

- Endoscopic device development
- Clinical trials and outcomes of esophageal, foregut, and general surgery

Dr. Shada's goal is a simplified VAC deployment device that reduces procedural complexity and broadens surgical accessibility.

Background - Current Methods/Designs

Endoluminal VAC therapy

- Endoscopically placed sponge applies negative pressure to promote healing
- Commercially available products made by Boston Scientific include the Eso-SPONGE and Endo-SPONGE
- Surgeon-assembled sponge and vacuum tube which is not standardized

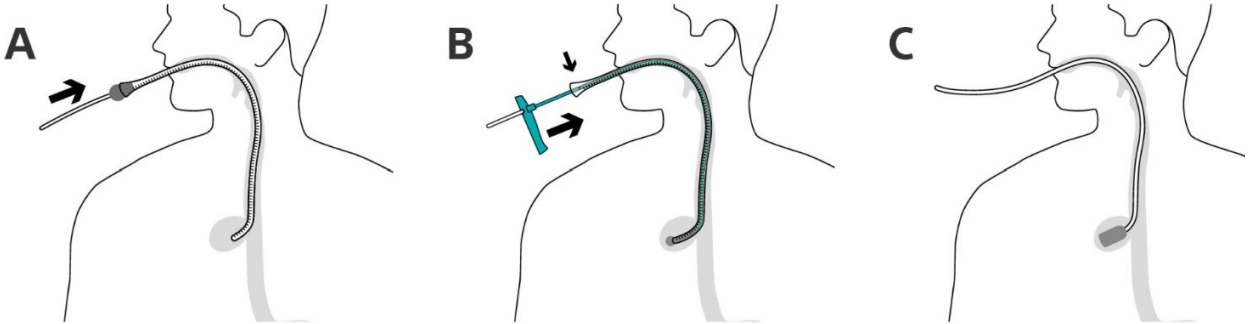


Figure 2. The Eso-SPONGE placement procedural flow [4]

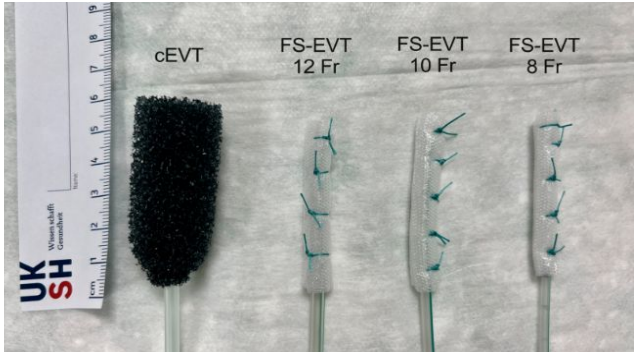


Figure 3. Comparison of surgeon assembled systems [5]

Product Design Specifications

Size

- Accommodate cavities (l=2-15cm)
- Device must be smaller than esophagus (d<2-3cm)

Standards and Specifications

- ISO 10993-1: biocompatibility [6]
- ISO 8600-4: compatibility with anatomy and other devices [7]
- Class 2 Medical Device: endoscopes and accessories pose moderate risk [8]

Patient Related Concerns

- Nasogastric tube discomfort [9]
- Multiple procedures [9]

Operational Performance

- Must be replaced every 3-7 days
- Withstand pressures of 125mmHg - 175mmHg [9]
- Deployment time <1 minute

Balloon Sponge-Stent

Three main components

- Polyurethane Sponge
- Expandable stent
- Inflatable balloon

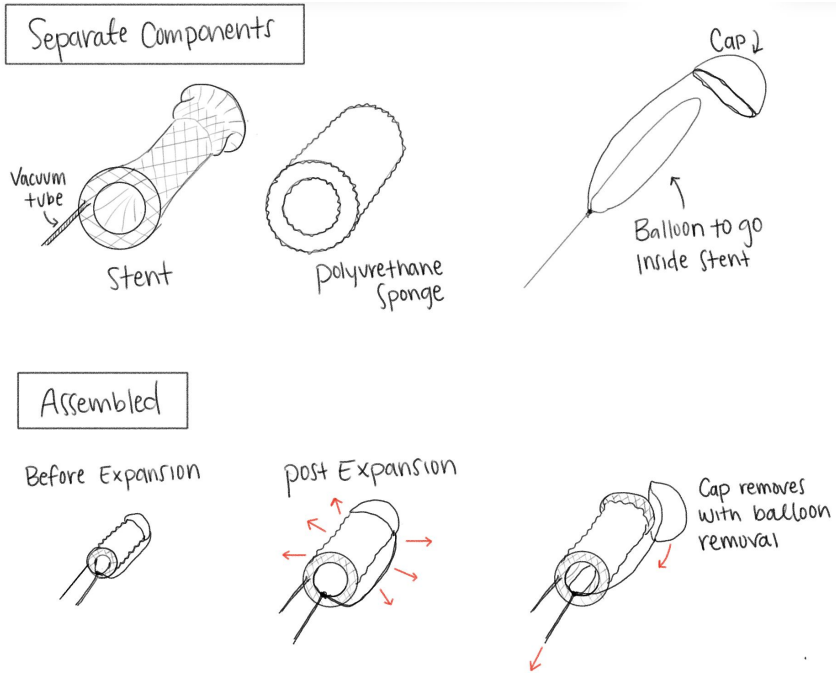


Figure 4. Drawing of Balloon Sponge-Stent Design

Degradable Coating

Coating

- Degrade after placement of sponge
- Expansion of sponge after degradation

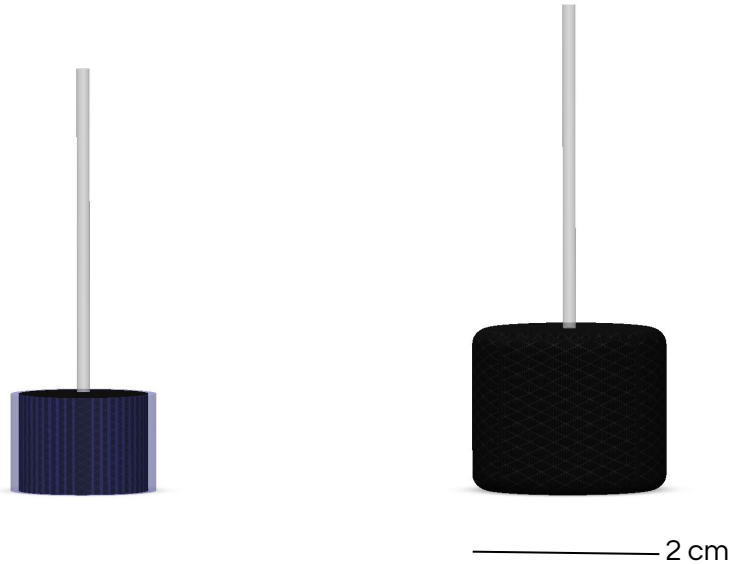


Figure 5. Degradable Coating Design Before (Left) and After (Right) Deployment

Cap Delivery

Cap Insertion

- Help with guiding sponge to cavity
- Smoother esophagus insertion
- Push sponge through cap to employ
- Cap stays with sponge until removal

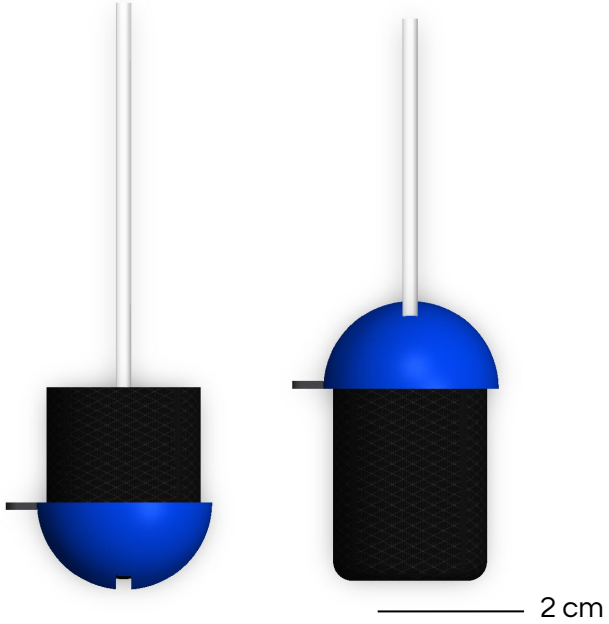


Figure 6. Cap Delivery Design Before (Top Left) and After (Bottom Right) Deployment

Design Matrix

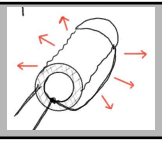
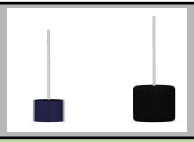
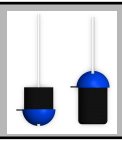
Criteria	Weight	Balloon Stent 		Degradable Coating 		Cap Delivery 	
Safety	**17.5**	3/5	10.5	**4/5**	**14**	3/5	10.5
Ease of Placement	**17.5**	3/5	10.5	**4/5**	**14**	3/5	10.5
Ease of Removal	**15**	2/5	6	**4/5**	**12**	3/5	9
Ease of Fabrication	**15**	2/5	6	3/5	9	**4/5**	**12**
Patient Comfort	**15**	**4/5**	**12**	3/5	9	2/5	6
Adjustability	**10**	2/5	4	**4/5**	**8**	3/5	6
Cost	**10**	2/5	4	3/5	6	**4/5**	**8**
Total (100)	**100**	53/100		**72/100**		**62/100**	

Table 1. Design Matrix

Final Design

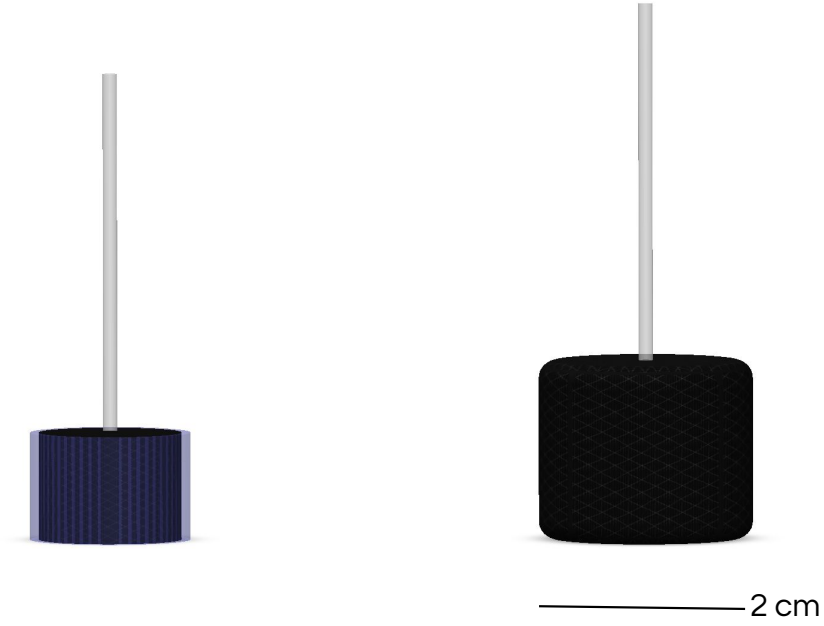


Figure 7. Degradable Coating Design

Planned Testing

Deployment testing

- Sponge deployment time ≤ 5 minutes
- Consistent placement position accuracy within cavity

Mechanical testing

- Force required to remove device
- Measure expansion of sponge from compressed state

Degradability testing

- Record degradation rate in esophageal models
- Record qualitative observations of device in 37° C saline bath over 3-day periods

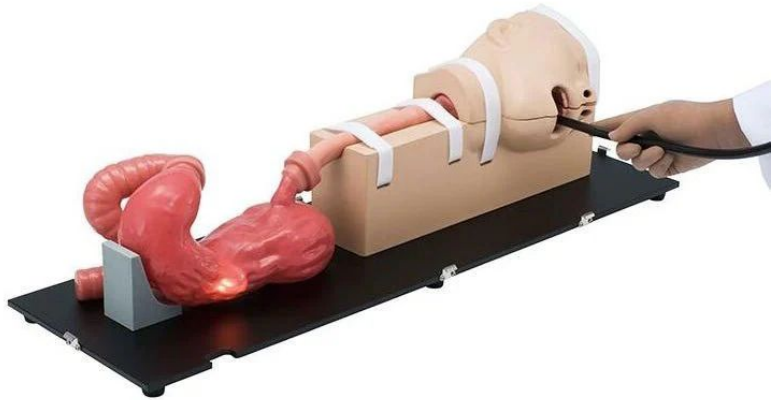


Figure 8. Koken EGD (Esophago-Gastro-Duodenoscopy) Simulator used to replicate endoscopic examination of the upper gastrointestinal tract [10].

Future Work

Prototype development

- Confirm material choices
- Generate SolidWorks model and conduct FEA analysis
- Create detailed instructions for use

Testing

- Develop testing protocols
- Construct endoscopy trainer model
- Design iteration based on preliminary results

References

[1] R. Hummel and D. Bausch, “Anastomotic Leakage after Upper Gastrointestinal Surgery: Surgical Treatment,” Visc Med, vol. 33, no. 3, pp. 207–211, Jun. 2017, doi: 10.1159/000470884.

[2] “Anastomotic Leak: Symptoms, Treatment & What It Is,” Cleveland Clinic. Accessed: Feb. 16, 2026. [Online]. Available: https://my.clevelandclinic.org/health/diseases/22324-anastomotic-leak

[3] S. G. Leeds, M. Mencio, E. Ontiveros, and M. A. Ward, “Endoluminal Vacuum Therapy: How I Do It,” Journal of Gastrointestinal Surgery, vol. 23, no. 5, pp. 1037–1043, May 2019, doi: 10.1007/s11605-018-04082-z.

[4] Boston Scientific, "Eso-SPONGE Endoluminal Vacuum Therapy," Marlborough, MA, USA. [Online]. Available: https://www.bostonscientific.com/en-EU/products/endoluminal-vacuum-therapy/eso-sponge.html. Accessed: Jan. 29, 2026.

[5] F. Richter et al., “Endoluminal Vacuum Therapy Using a New ‘Fistula Sponge’ in Treating Defects of the Upper Gastrointestinal Tract—A Comparative, Retrospective Cohort Study,” Medicina, vol. 60, no. 7, p. 1105, Jul. 2024, doi: 10.3390/medicina60071105.

[6]]“ISO 10993-1:2025,” ISO. Accessed: Feb. 03, 2026. [Online]. Available: https://www.iso.org/standard/10993-1

[7] “ISO 8600-1:2025,” ISO. Accessed: Feb. 03, 2026. [Online]. Available: https://www.iso.org/standard/84216.html

References

[8] "21 CFR 876.1500 -- Endoscope and accessories." Accessed: Feb. 03, 2026. [Online]. Available: https://www.ecfr.gov/current/title-21/part-876/section-876.1500

[9] D. T. H. de Moura et al., "Role of endoscopic vacuum therapy in the management of gastrointestinal transmural defects," World J Gastrointest Endosc, vol. 11, no. 5, pp. 329–344, May 2019, doi: 10.4253/wjge.v11.i5.329.

[10] "Koken EGD (Esophago-Gastro-Duodenoscopy) Simulator," GTSimulators.com. Accessed: Feb. 17, 2026. [Online]. Available: https://www.gtsimulators.com/products/koken-egd-esophago-gastro-duodenoscopy-simulator-lm-103

Acknowledgements

UW Health

- Dr. Amber Shada (Client)

University of Wisconsin - Madison

- Prof. John Puccinelli (Advisor)
- Isabelle Peters (TA)
- Design Faculty
- UW Makerspace and TEAMLab