Biodegradable Coating to Improve Administration of Endoscopic Negative Pressure Therapy

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MOTIVATION & BACKGROUND

- Anastomotic leaks are gaps in the esophagus walls after surgery
- Leaks are reported in up to 40% of esophagectomies and contribute to high mortality and morbidity [1]
- Traditional treatment involves sealing off the cavity and invasive surgery
- Endoluminal Vacuum Assisted Closure, EndoVAC, involves placing a sponge in the cavity and connecting it to negative pressure

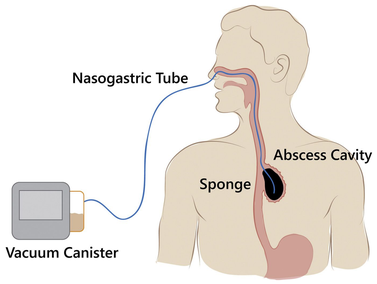

Figure 1. Use of EndoVAC to close cavity in esophagus [2]

- Only commercially available competing design is Eso-SPONGE by Boston Scientific
- Surgeons improvise by hand trimming sponge and suturing it to nasogastric tube
- EndoVAC therapy achieves a 95% healing success rate [3]

PROBLEM STATEMENT

Utilization of EndoVAC devices can be labor intensive and require skill in manipulating an endoscope. Therefore, the team is tasked with developing a device that can easily deliver a sponge within the gastrointestinal tract to promote accessibility to surgeons and simplify the procedure.

DESIGN CRITERIA

Size: diameter must be less than 2.0 cm to fit inside esophagus
Procedure: be stable in pH 7 and 37° C for 15 minutes
Standards:

- ISO 10993-1: biocompatibility
- ISO 8600-4: compatibility with anatomy and other devices

BIOMATERIALS

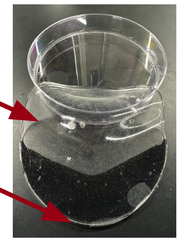

Figure 2. Gelatin hydrogel sheet

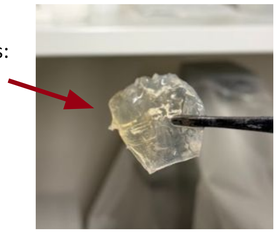

Figure 3. CaCl2 crosslinked sodium alginate

FINAL DESIGN

Sponge is cut to 3.0 cm diameter and sutured to nasogastric tube

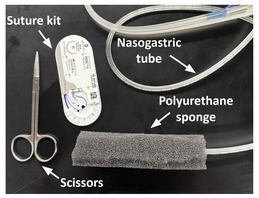

Figure 4. Supplies for sponge compression fabrication

Sponge is wrapped in gelatin and placed in compression mold

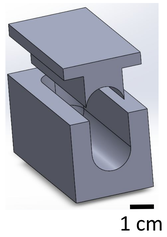

Figure 5. 1.5 cm diameter sponge compression mold

Mold is heated at 50°C and cooled at 3°C to set coating

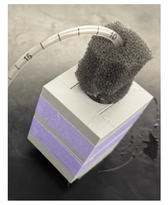

Figure 6. Sponge being compressed by 1.5 cm mold

Figure 7. Biodegradable gelatin film compressing polyurethane sponge

Figure 8. Polyurethane sponge after degradation

DEGRADATION TESTING & RESULTS

Methods:

- 6 samples of gelatin hydrogel, gelatin film, and crosslinked sodium alginate were prepared
- Samples immersed in PBS solution simulating esophageal conditions (pH 7.4, 37°C)
- Mass recorded over 100 minute interval
- Samples dried prior to weighing

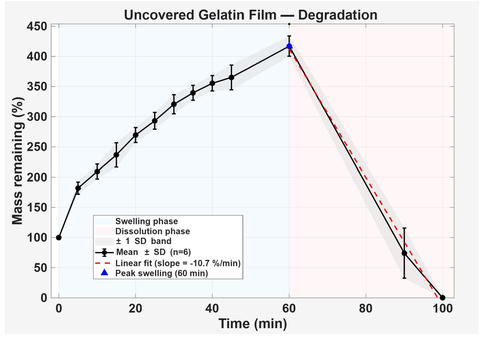

Figure 9. Degradation graph for gelatin film

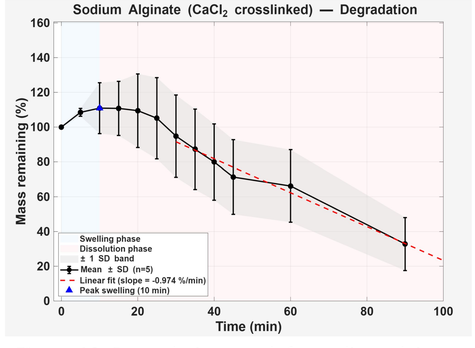

Figure 10. Degradation graph for sodium alginate

Results:

- Gelatin hydrogel
  - Dissolved within 1 minute
- Gelatin film
  - 4.17x increase in mass by 60 minutes
  - Dissolved within 100 minutes
- Sodium alginate
  - 1.11x increase in mass by 10 minutes
  - 42.5% mass remaining at 90 minutes

SPONGE EXPANSION TESTING & RESULTS

Methods:

- Gelatin coated sponges were compressed using 1.5 cm mold
- Samples were immersed in PBS (pH 7.4, 37°C)
- ImageJ was used to capture measurements every minute based on video

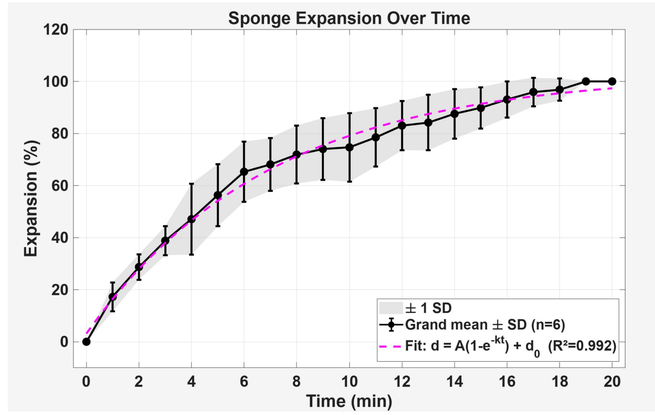

Figure 11. Average sponge expansion for gelatin film

DISCUSSION

- Fabrication yielded irregular gelatin coating on sponge, leading to wide range of results during expansion testing
- Hot plate heating for expansion testing, used in the absence of an incubator, may have introduced temperature inconsistencies between samples
- Optical measurements through water may have introduced refraction error, affecting diameter accuracy

FUTURE WORK

- Test sponge expansion with sodium alginate
- Standardize fabrication of sponge and coating to ensure predictable degradation
- Compare degradation rate and mechanical properties of crosslinked and uncrosslinked sodium alginate coatings
- Conduct testing in an esophageal model

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- Dr. John Puccinelli, Advisor and Isabelle Peters, TA

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.
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[3] S. G. Leeds, M. Mencio, E. Ontiveros, and M. A. Ward, "Endoluminal Vacuum Therapy: How I Do It," *J. Gastrointest. Surg. Off. J. Soc. Surg. Aliment. Tract*, vol. 23, no. 5, pp. 1037–1043, May 2019, doi: 10.1007/s11605-018-04082-z.
[4] Biological evaluation of medical devices — Part 1, ISO Standard 10993-1:2018, 2018.
[5] Endoscopes - Medical endoscopes and endotherapy devices - Part 4, ISO Standard 8600-4:2023, Jan. 2023.