Designing a Self-Swelling Pancreatic Stent to Improve Whipple Surgery Outcomes

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Introduction

Whipple surgery is a complex operation that involves the removal of the head of the pancreas, the first part of the small intestine, the gallbladder, and the bile duct. Whipple surgeries are used to treat tumors and other disorders of the pancreas, intestine and bile duct. Although it is often lifesaving, it comes with significant risks.

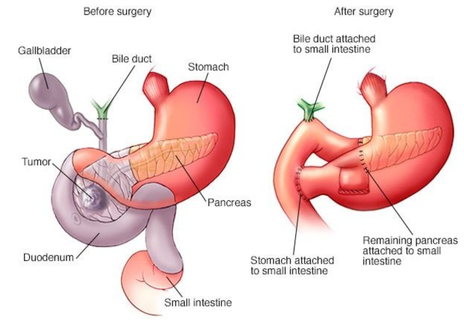


Figure 1 — Whipple Surgery Diagram

A key challenge of operating on a non-cancerous pancreas is its soft butter-like consistency. Specifically, soft pancreatic consistency and low fibrosis ratio are key risk factors for postoperative pancreatic fistula (POPF), which develops from pancreatic juice leakage and can cause lethal hemorrhage.

Objectives

To address these postoperative complications, we aim to imitate a phenomenon observed in pancreatic cancer patients, in which blockage of the pancreatic duct causes the pancreas to stiffen, making surgery easier and safer to perform.

We are proposing the use of polyacrylamide (PAAm) gel as the stent material, which will expand and internally occlude with time in the pancreatic duct to restrict flow to the pancreas.

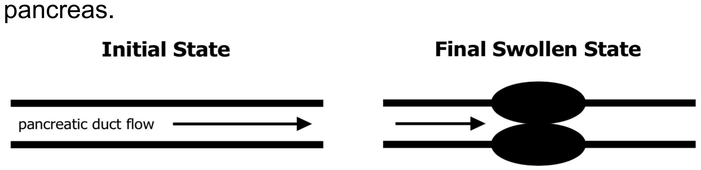


Figure 2 — Self-Swelling Stent Mechanism

Stent Design Criteria

- Occlusion should occur over ~ 6 weeks to 3 months
- Biocompatible and nonmagnetic
- Tough, strong, and flexible
- Outer diameter increases from 2-3 mm to 10 mm
- Inner diameter decreases from ~2 mm to 0 mm
- Length of 5 - 10 cm

Results

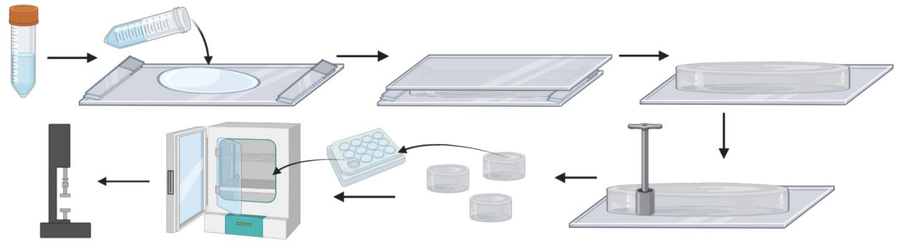


Figure 3 — Workflow Diagram of Gelation Protocol

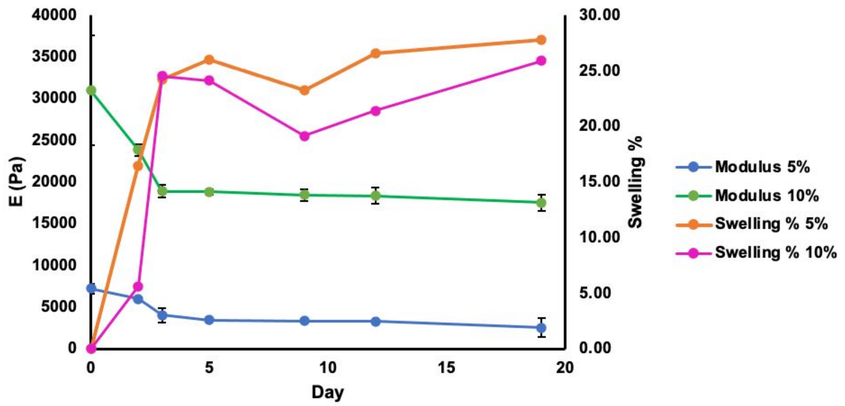
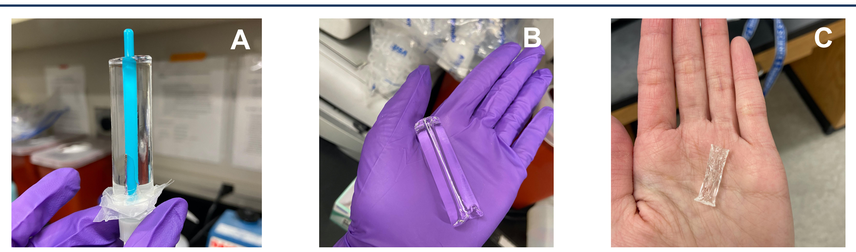


Figure 4 — Graph of Swelling Test Data

Swelling Time (Days)	Thickness (mm)		Swelling %		E (Pa)	
	5%	10%	5%	10%	5%	10%
0	2.01	2.05	0.00	0.00	7246.49±8.35%	31010.57±21.34%
2	2.34	2.16	16.43	5.65	6010.46±2.92%	23841.35±2.86%
3	2.49	2.55	24.23	24.53	4050.75±21.45%	18898.44±3.9%
5	2.53	2.54	26.04	24.13	3478.2±1.49%	18832.28±1.65%
9	2.47	2.44	23.25	19.14	3374.74±2.01%	18456.26±3.61%
12	2.54	2.49	26.55	21.41	3301.61±1.39%	18367.47±5.3%
19	2.56	2.58	27.81	25.90	2572.07±43.24%	17532.03±5.31%

Figure 5 — Table of Swelling Test Data



Figures 6A, 6B, & 6C — Hydrogel Stent Prototype
A. Gel formation, B. Swollen gel, C. Dehydrated gel

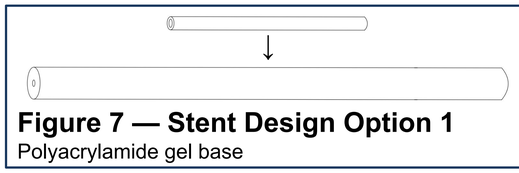


Figure 7 — Stent Design Option 1
Polyacrylamide gel base

Inner Diameter
2 mm → ~1 - 1.5 mm
Outer Diameter
3 mm → 7.5 mm
Length
4.5 cm → 11.25 cm

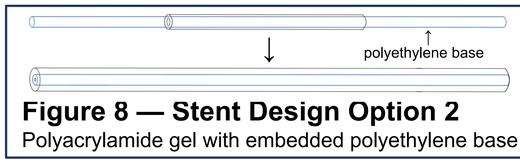


Figure 8 — Stent Design Option 2
Polyacrylamide gel with embedded polyethylene base

Inner Diameter
1.9 mm → ~0.3 mm
Outer Diameter
3.2 mm → 5.2 mm
Length
4.5 cm → 11.25 cm

Conclusions

- Swelling
  - PAAm gels swelled quickly to upwards of 25% at Day 19
  - 10% Am PAAm gel was sturdier than 5% Am both in the dried and swollen state, without becoming brittle
  - Volume of dried 10% PAAm gel doubled during initial swelling state (Days 1-2)
- Degradation
  - PAAm gels showed no outward qualitative signs of degradation to Day 19
- Geometry and Preparation
  - Prototype drying for packaging had no significant effect on reswelling volume and was able to withstand relevant shear stresses (placement)

Future Directions

Packaging & Rheology for Placement

- Organic based design
- Planned shear modulus and viscosity profile characterization
- Materials and coatings (i.e. PTFE)

Studies *in vitro*

- Human pancreatic duct epithelial cells (H6c7)
- LIVE/DEAD assays, ELISA Duo-Sets

Adhesion

- Interfacial IPN adhesive (PAA)
- Peeling adhesion test: bilayer edge crack model

Slowing the Hydrogel Swelling Process

- Polymer coatings (ex. PEGTMO)
- Reduce surface area for absorption

Acknowledgements

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Works Cited

[1] Li, J et al. (2017). *Science.* [2] Tse, JR & Engler, AJ et al. (2010). *Current Protocols in Cell Biology*