Evaluation of 3D Printing Modalities for Fabrication of Biliary Stents

Amanda Cimino[1,2], Claire Flippin[1], and Joanna Thomas[1]
[1]Biomedical Engineering Department, Mercer University School of Engineering, Macon, GA, USA
[2]Chemistry Department, Mercer University College of Liberal Arts, Macon, GA, USA

Introduction

The purpose of pancreatic and biliary stents is to alleviate obstructed ducts in the hepatobiliary system, shown in Fig. 1. Stents are often required to treat biliary or pancreatic leaks, decrease the risk of post-ERCP pancreatitis (Pfau, 2013), or mitigate strictures due to inflammatory diseases of the ducts such as primary sclerosing cholangitis. It is crucial to ensure that bile, the secreted fluid in the hepatobiliary system, is able to flow efficiently, since it plays roles in digestion, circulation, and elimination within the bile ducts (Banales, 2019). Current pancreatic and biliary stents are commonly constructed from plastic (PSs, composed of plastic polymers) or metal (self-expandable metallic stents, or SEMS), shown in Fig. 2. Characteristics of these materials and stent design stipulate the properties of the stents, including diameter, length, flexibility, and biocompatibility.

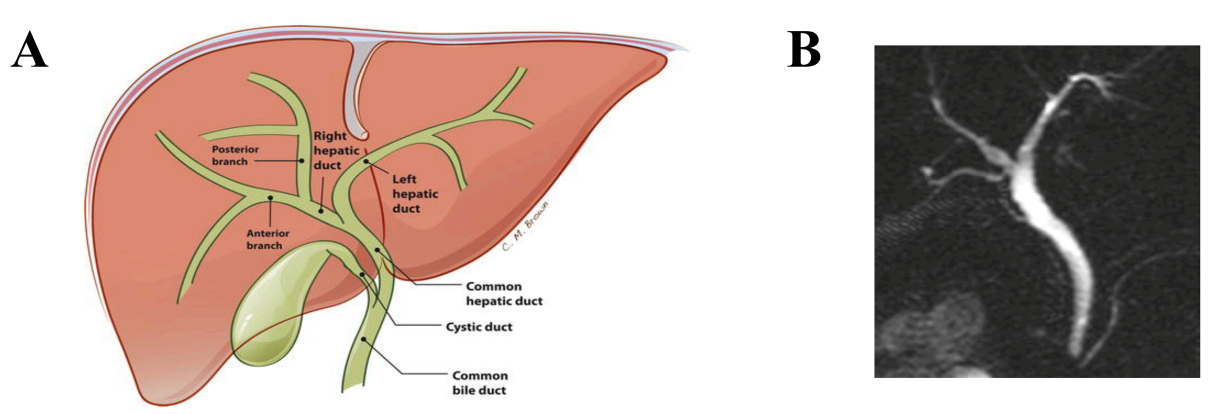


Figure 1. Hepatobiliary system. (A) Diagram of the liver and ducts, in: Hamm B., Ros P.R. (eds) Abdominal Imaging. Springer, Berlin, Heidelberg; (B) magnetic resonance cholangiopancreatography (MRCP) of the bile ducts (Ilhan, 2017).

A substantial barrier to bringing new biliary stents to market is pre-clinical R & D costs. Fig. 3 outlines the pathway from development through FDA approval. Minimizing the time spent on research and development can yield savings that could be passed on to patients. With the increased availability and reduction in purchase price for 3D printers, we believe fabricating stent prototypes with 3D printers could reduce the time needed to evaluate stent designs. For this study, we established the capabilities of two types of 3D printing, fused deposition manufacturing (FDM) and stereolithography (SLA), to achieve the resolution needed with appropriate material(s) for a biliary stent.

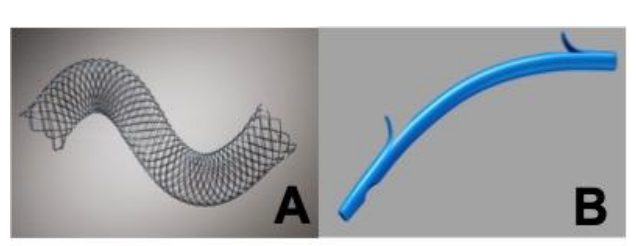


Figure 2. Commercially available biliary stents. (A) Uncovered SEM (Boston Scientific, 2011) (B) Plastic Stent (Cook Medical).

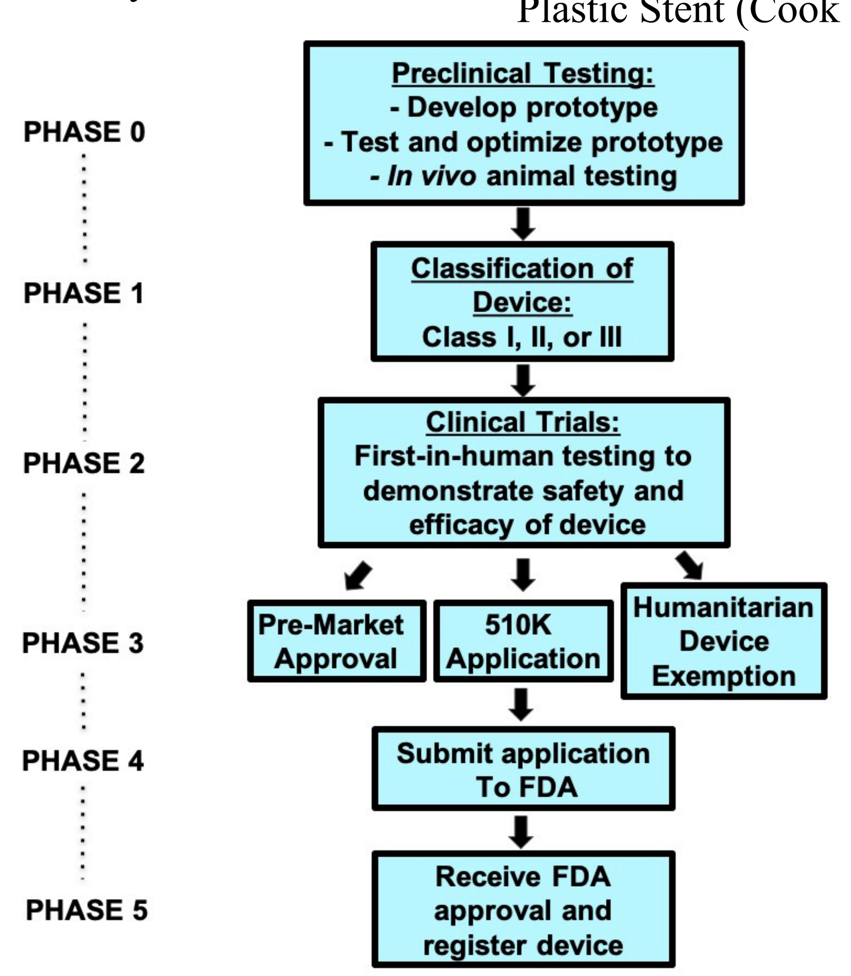


Figure 3. Medical Device Development Process (Norman, 2016).

Methods

For this study we first tested the abilities of two types of 3D printers to achieve the resolution needed with appropriate material(s) for a biliary stent.

FDM Printer: A Prusa iK3 MK3 with 1.75 mm polylactic acid (PLA) filament was utilized for the prints with a .4 mm nozzle. A flat, diamond lattice (28.6 mm x 50.1 mm) was printed with one layer of material or two layers of material. Both prints were attempted at print speeds of 100 mm/s and 20 mm/s.

SLA Printers: We utilized a Peopoly Moai (with standard Moai resin), a PhotonS (with standard PhotonS resin), and a Formlabs Form2 (with Durable resin). Again, the first test prints were the flat diamond lattice. On the Moai, prints with were run with layer thicknesses starting at 1mm decreasing to .1 mm in .02 mm increments.

Next, three basic stent designs were created in Autodesk Fusion. The stents were all externally dimensioned to mimic commercially available SEMs. We printed stent prototypes with polymers with varying elasticity and tensile strength targeting a highly compressible, yet resilient design. Stents printed with the Moai and Form2 were cured under 495nm light for 30 min. The dimensions of the printed stents were compared to the CAD models.

Results

- The single layer test ran on the FDM type printer did not form a contiguous flat diamond lattice at either print speed. During the two layer test print the filament stuck to the nozzle causing the print to lift off the print bed. Due to these results the FDM was deemed not suitable for this application and no additional tests were run.
- All SLA printers successfully printed the flat lattice.
- The three basic stent designs created in Fusion, a diamond lattice, a linked ring lattice, and center point lattice are shown in Figure 4.
- Biliary stents placed via endoscopy must be ≤ 5 mm in diameter when compressed. Results from the prototypes are listed in Table 1. Pictures of the printed stents are shown in Figure 5.

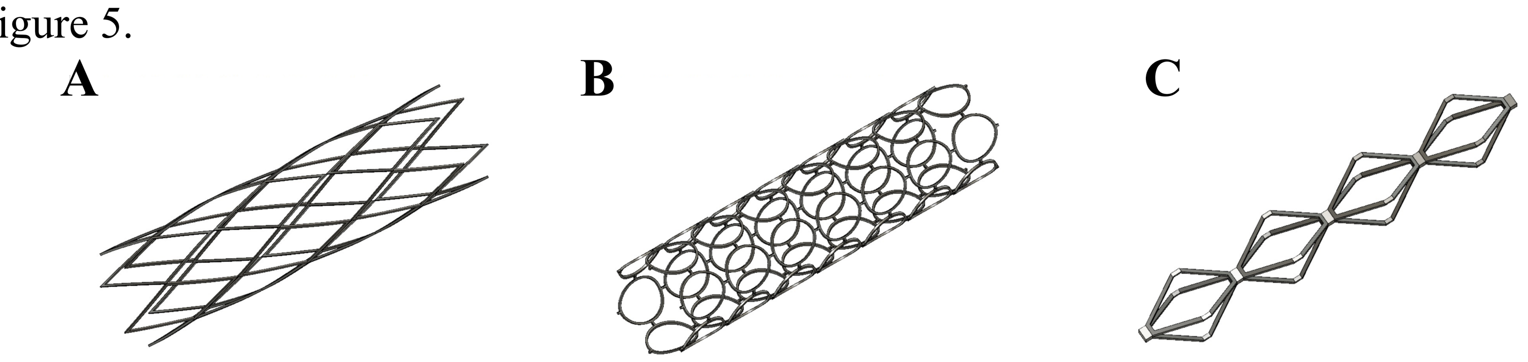
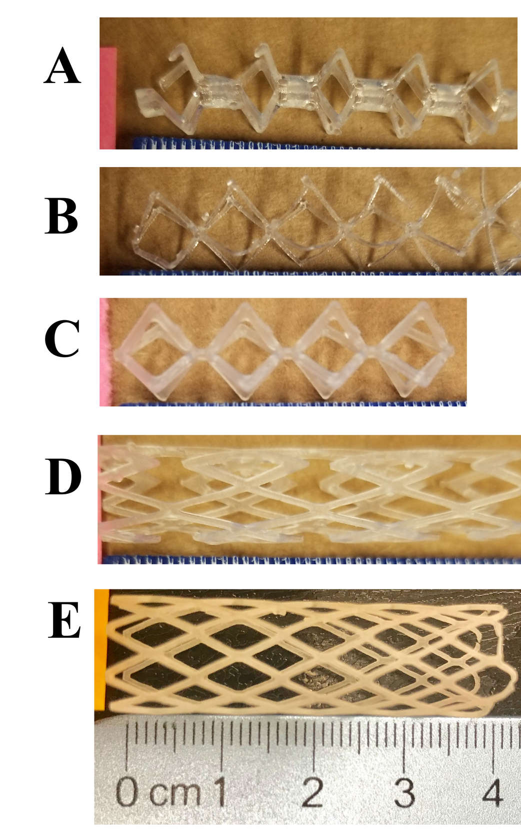


Figure 4. CAD prototype designs (A) diamond lattice (B) round lattice (C) center-point

Table 1. Expected and 3D-printed dimensions of prototype stents.

	Expanded Diameter (mm)	Expanded Length (mm)	Compressed Diameter (mm)	Compressed Length (mm)	Lattice Thickness (mm)	Lattice Width (mm)
Expected: Center Point 1	10.35	40.49	< 4	N/A	1.00	1.00
Printed: Center Point 1 (Fig 5A)	10.55	41.24	5.24	60.3	0.54	1.18
Expected: Center Point 2	12.13	35.80	< 4	N/A	1.00	1.00
Printed: Center Point 2 (Fig 5C)	11.85	36.18	4.80	49.93	0.91	0.98
Expected: Diamond Lattice 1	10.00	40.00	< 4	N/A	0.75	0.75
Printed: Diamond Lattice 1 (Fig 5E)	10.53	39.17	N/A, fractured	N/A	0.51	0.55
Expected: Diamond Lattice 2	9.54	39.00	< 4	N/A	.75	.75
Printed: Diamond Lattice 2 (Fig 5D)	9.19	38.57	3.75	40.56	.38	.58
Expected: Round Lattice	9.97	42.00	---	---	---	---

Results



When tension was applied to the center point 1 prototype connection points between strut and the post were broken. The initial diamond lattice print (Fig. 5B) also lacked the durability to withstand strong tension force. The second iteration of the center point design included an increase in the thickness and width of the struts (Fig 5C).

Initial prints of the diamond lattice 1 with standard Moai resin were successful; however, the standard resin fractured at the lattice joints when we attempted to radially compress the stent (Fig 5E). A modified diamond lattice (Fig 5D) printed successfully, but had poor resilience following compression.

Figure 5. Stent prototypes (A-C) alternative version of center-point design (D-E) diamond lattice designs. A-D printed with a Form2; E printed with a Moai.

Conclusions & Future Work

Three prototype stents were proposed and are being optimized for 3D printing. We hope to provide insight into the 3D printing capabilities for potentially using them to test commercial stents and decrease the time and money required for the R&D process.

Future work for the project includes optimizing stent prototypes, performing FEA on stent designs to assess the pre- and post-compression behavior of the polymers (Fig. 6), and *in vitro* testing of our stents (Fig. 7).

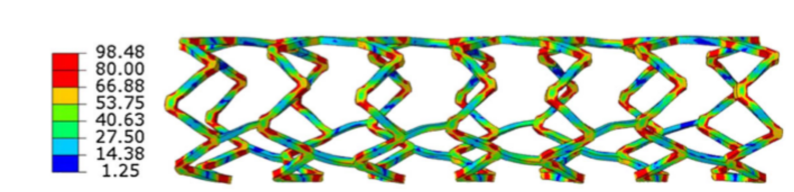


Figure 6. Sample of FEA analysis that will be conducted for stent types Image depicts pressure in Mpa (Qiu, 2018).

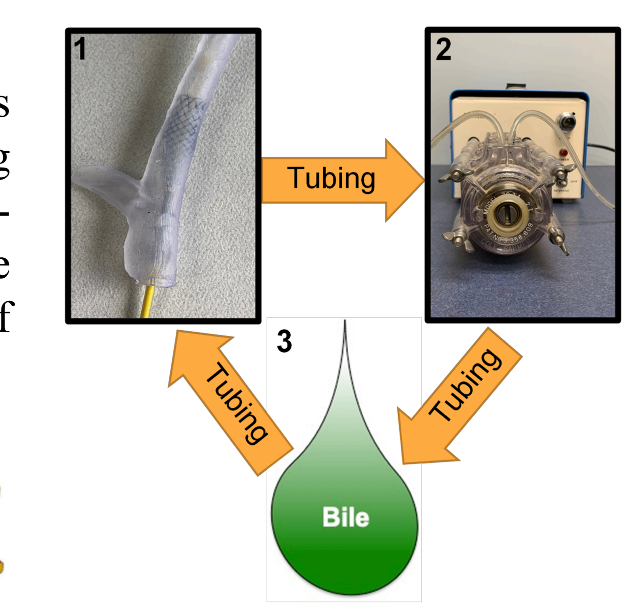


Figure 7. *In Vitro* Stent Testing System (1) stent placed in our *in vitro* model (2) peristaltic pump (3) bile reservoir at 37C

Acknowledgements

This research was funded by a Mercer University Provost Seed Grant, the Mercer University School of Engineering and Mercer Undergraduate Biomedical Scholars Program.

References

Pfau, P. R., et al (2013). Pancreatic and biliary stents. *Gastrointestinal Endoscopy, 77*(3), 319–327. https://doi.org/10.1016/j.gie.2012.09.026
Banales, J. M., et al (2019). Cholangiocyte pathobiology. *Nature Reviews. Gastroenterology & Hepatology, 16*(5), 269–281. https://doi.org/10.1038/s41575-019-0125-y
Ilhan, M et al (2017). Is Cholecystectomy Alone Enough To Prevent Acute Biliary Pancreatitis Attack? *J Pancreas, 18*(3), 272-276.
Boston Scientific Coorporation. "Biliary Metal Stent Images." *Biliary Metal Stent Images - Boston Scientific*, 2011.
"Cotton-Leung® Biliary Stent Only." *Cotton-Leung® Biliary Stent Only | Cook Medical*, www.cookmedical.com/products/esc_clso_webds/.
Norman, Gail A. Van. "Drugs, Devices, and the FDA: Part 2." *JACC: Basic to Translational Science*, vol. 1, no. 4, 2016, pp. 277–287., doi:10.1016/j.jacbts.2016.03.009.
Qiu, T. Y. et al. (2018). A computational study of crimping and expansion of bioresorbable polymeric stents. *Mech Time-Depend Mater, 22*, 273–290.