Chronic Total Occlusion Plug

Andrea Quintero, Elizabeth Hernandez, Jessica Follis, Jonathan Shaw

Department of Biomedical Engineering, University of Texas at San Antonio, San Antonio, TX

NextGen Solutions

UTSA Klesse College of Engineering and Integrated Design

Clayton Biotechnologies | UT Health San Antonio

INTRODUCTION

Around 20-25% of the 18 million Americans living with some form of coronary heart disease will have a chronically occluded artery. The blockage of the artery compromises blood flow to the heart. However, the pathophysiology of Chronic Total Occlusion (CTO) remains poorly understood and current Chronic Total Occlusion animal models have a low success rate, with an expected 50% survival rate as a result of the artery being blocked too quickly, leading to fibrillation. Our team aims to innovate a successful CTO plug that will standardize this disease model while also being biocompatible, resorbable and can be deployed into an animal model's artery without causing fibrillation.

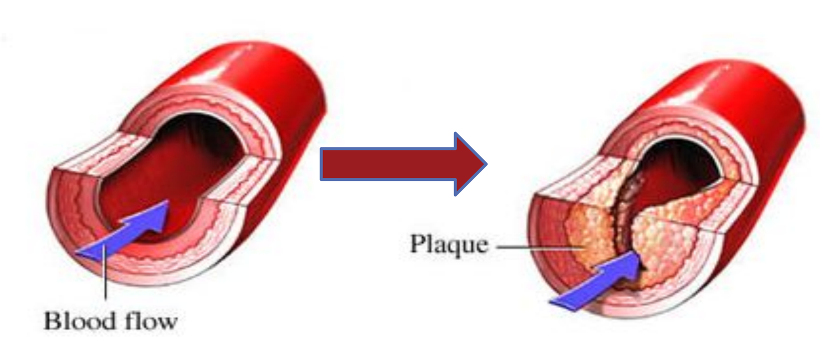

Figure 1: Clear coronary artery (left); occluded artery (right).

CUSTOMER STATEMENT

Develop a plug design that can be successfully deployed into an animal coronary artery and will not defibrillate the animal. Plug design must be resorbable, biocompatible and lead to CTO formation using poly(lactic-co-glycolic acid).

FUNCTIONAL SPECIFICATIONS

- ❑ **Dimensions: 3 - 4 mm diameter, max. 2 cm length**
- ❑ **Induces inflammatory response: Y/N**
- ❑ **Biodegradable: Y/N**
- ❑ **Permeability maintained upon deployment: Y/N**
- ❑ **Functional time period: 6 - 8 weeks**
- ❑ **Desired blood flow at 6 - 8 weeks: 0 ml/min**
- ❑ **Static: Y/N**
- ❑ **Plug restricted to lumen: Y/N**
- ❑ **Post insertion intervention: Y/N**

FINAL PRODUCT

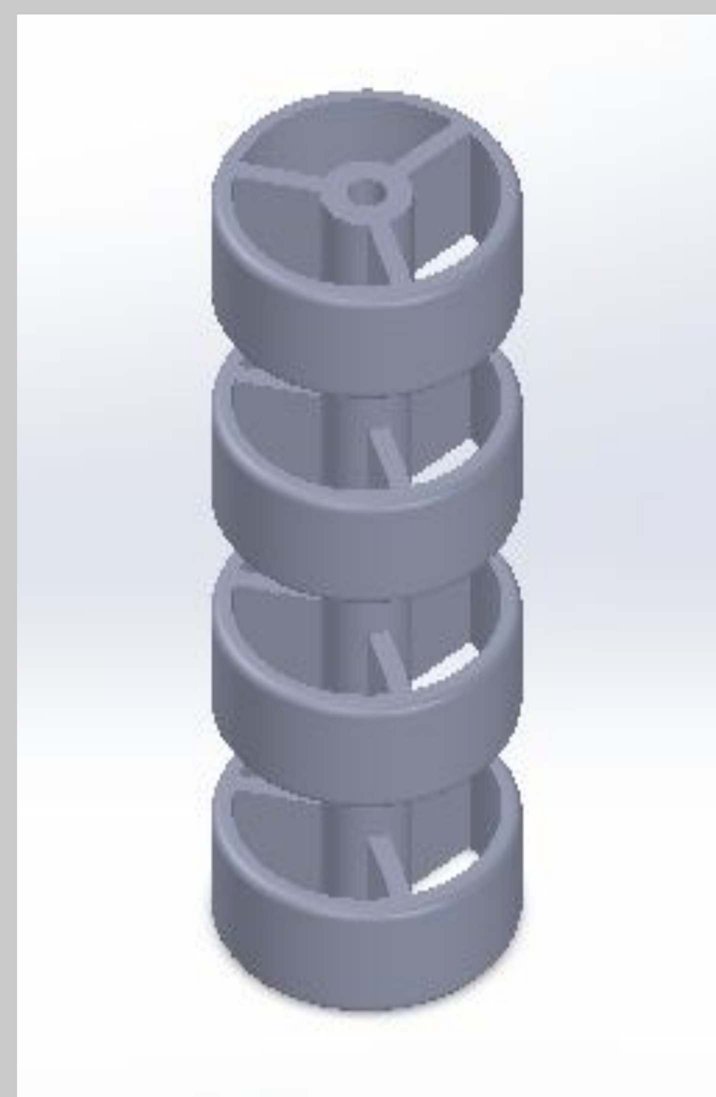

Figure 2: Rendered image of (a) exploded view of device and (b) sectioned view of the device

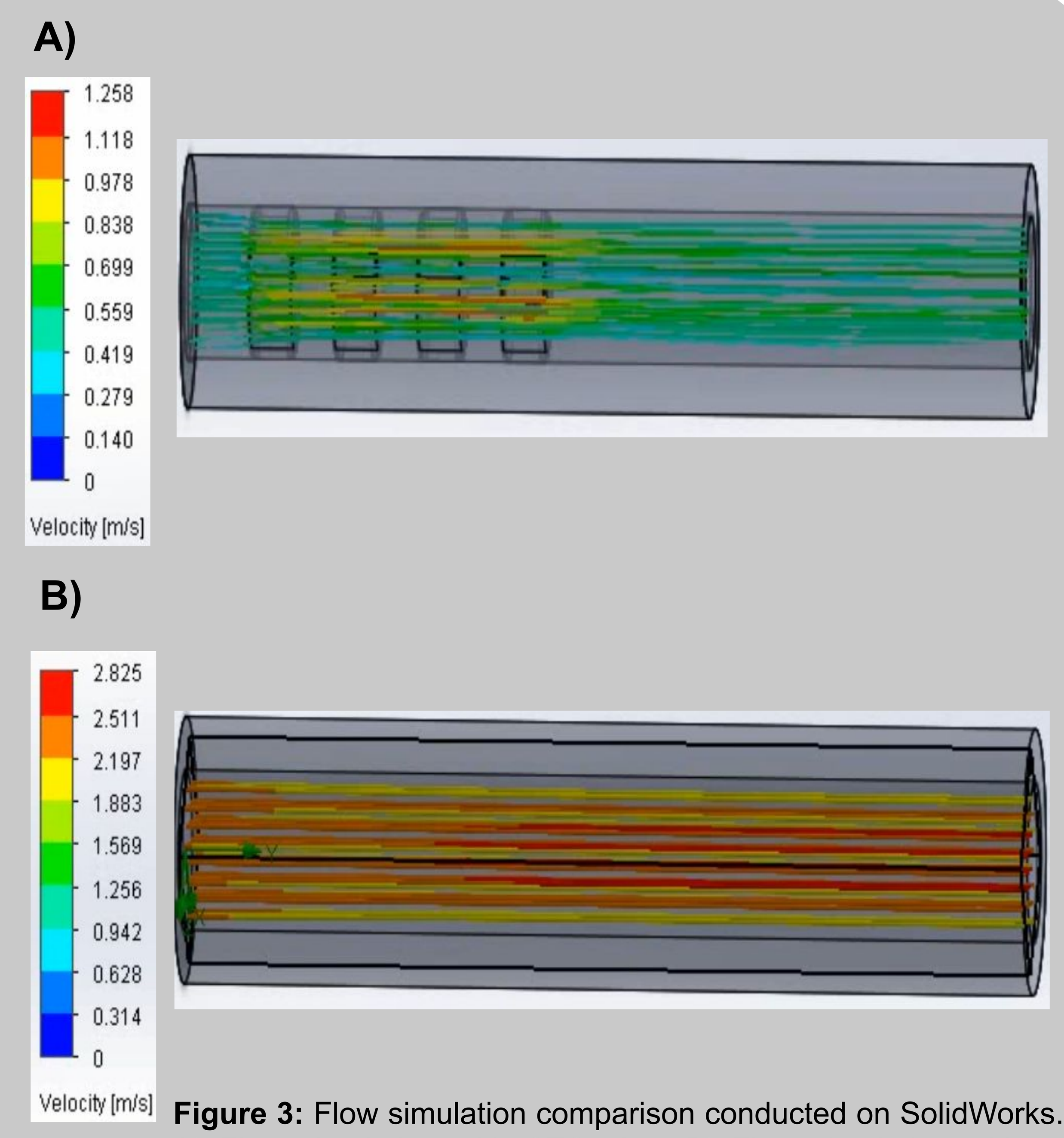

Figure 3: Flow simulation comparison conducted on SolidWorks. A) Flow simulation with CTO plug. B) Flow simulation without CTO plug. Flow is reduced by 30-45% with CTO plug. .

TRACEABILITY MATRIX

Design Criteria	Testing Plan	Biocompatibility Test	Flow Analysis Test	Material Degradation Test	Calcium Formation Test	Mechanical Test
Dimensions: 3 - 4 mm diameter, max. 2 cm length						
Inflammatory response		X				
Biodegradable				X		
Permeability maintained upon deployment			X			
Functional time period						
Desired blood flow reached					X	
Plug remains static			X			
Plug restricted to lumen						
Post insertion intervention				X		

Table 1: Traceability matrix of design criterias and proposed verification tests.

TESTING RESULTS

Test	Max Radial Force	Max Longitudinal Force	Stress (Radial)
1	33 N	27.9 N	141.9 Pa
2	34 N	17.8 N	146.2 Pa
3	32 N	13.6 N	137.6 Pa
Averages	33 N	19.77 N	141.9 Pa

Table 2: Results from mechanical test using device made of PLA.

PERSONNEL AND REPORTING

Labor Category	Total time (in hours)	Total Labor Cost
Senior Project Manager	11	$2,200
Senior Engineer	11	$1,375
Engineer	363	$36,300
Total	385	$39,875

Table 3: Calculated Personnel time and Reporting Costs over the Design Process

MANUFACTURING COSTS

Total Prototype Cost: $0.17 (Flexible Resin)

CLAIMS

- **The present device is designed to mimic CTO in the left anterior descending artery.**
- **CTO plug is carefully designed with PLGA polymer which has been proven to be biodegradable and biocompatible.**
- **Plug geometry and dimensions are compatible to that of the coronary artery.**
- **Adequate flow is maintained with the presence of the CTO plug.**

CONCLUSIONS

The CTO plug is designed in accordance to the main objective. The device is designed with the focus on mimicking a CTO in the left anterior descending coronary artery and carefully follows the technical specifications and customer requirements.

TEAM MEMBERS & MENTORS

Team Members:

- **Andrea Quintero**
- **Elizabeth Hernandez**
- **Jessica Follis**
- **Jonathan Shaw**

Mentor:

- **Hugo Giambini Ph.D.**
- **Settimio Pacelli Ph.D.**
- **Marc D. Feldman, MD**

ACKNOWLEDGEMENTS

We would like to thank our mentors and our sponsors, The Clayton foundation and UT Health medical device innovation lab members Drew Nolan and Dr.Gruslova.
We would also like to thank the Department of Biomedical Engineering as well as our Senior Design professor Dr. Laura Gaviria.

REFERENCES

1. Liu, Jian et al. "Mp-Pic Simulation of Blood Cell Movement through a Lad with High Stenosis." Powder Technology, vol. 361, 2020, pp. 448-454, doi:https://doi.org/10.1016/j.powtec.2019.05.076.
2. Darestani, Mariam et al. "Degradation of Poly(D,L-Lactide-Co-Glycolide) 50:50 Implant in Aqueous Medium." Iran Polym J, vol. 14, 2005.
3. Zhong, Liang et al. “Effects of stenosis on the porcine left anterior descending arterial tree.” Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Annual International Conference vol. 2013 (2013): 3869-72. doi:10.1109/EMBC.2013.6610389
4. Makadia, Hirenkumar K, and Steven J Siegel. “Poly Lactic-co-Glycolic Acid (PLGA) as Biodegradable Controlled Drug Delivery Carrier.” Polymers vol. 3,3 (2011): 1377-1397. doi:10.3390/polym3031377.