MEDICAL SCHOOL
UNIVERSITY OF MICHIGAN

Capstone for Impact Submission | GY2020

Project Title: The Vortex Catheter: A new Mechanical Thrombectomy Device for Acute Ischemic Stroke.

Student Name(s): Miranda Ajulufoh

Advisor Names(s): Dr. Luis Savastano and Yang Liu

Branch: Diagnostics and Therapeutics

Path of Excellence: Innovation and Entrepreneurship

If this project can be continued by another UMMS student, please include your contact information or any other details you would like to share here:

Summary:

I participated in an interdisciplinary research project with neurosurgeons (Dr. Savastano, Dr. Pandey) and mechanical engineers (Dr. Albert Shih, Yihao Zheng, Jeff Plott and Yang Liu) who recognized that acute ischemic stroke is one of the leading causes of long-term disability. While aspiration and stent-based mechanical thrombectomy devices have been used for interventional treatments, many of these devices require multiple passes, have low recanalization rates, difficulties maneuvering through tortuous anatomy or retrieving large, stiff emboli, and complications such as catheter jamming, vessel damage, and distal embolization. Therefore, they designed a mechanical thrombectomy device called "The Vortex Catheter," that has an aspirating catheter with a rotating wire shaft in the middle that fragments the embolus as it is being sucked into the catheter. The idea is that the device would be able to effectively remove large, stiff emboli without the complications associated with our current interventional options.

Given that emboli undergo significant tensile deformations during mechanical thrombectomy, the tensile strength of emboli affects their ability to fragment and thus the success of mechanical thrombectomy. Thus, it is important to fabricate embolus analogs with histologic compositions and mechanical tensile properties similar to real patient emboli in order to test the new device. However, research is lacking in this area.

I assisted the researchers' pursuit of testing the performance of their new device by helping them fabricate human embolus analogs with different amounts of blood components and subsequently performed mechanical tensile testing and histologic analysis. The results were compared with real patient emboli. The goal was to start the process of creating a standardized protocol for developing human embolus analogs that mimic the broad range of emboli retrieved in large vessel occlusion strokes. This protocol could be used as a platform for translational research in stroke and further advance the development of next-generation thrombectomy devices.

Methodology:

Ten different dog-bone shaped embolus analogs were molded with different ratios of red blood cells,

fresh frozen plasma and pooled packet platelets from the U of M blood bank. Five samples from each type of embolus analog underwent uniaxial mechanical tensile testing followed by histologic analysis to determine the exact percentages of blood components.

- Mechanical tensile testing: Embolus analog samples were gripped by two hemostats. One hemostat was fixed to a linear stage and pulled at a speed of 0.3mm/s until the embolus fragmented. The other hemostat was fixed to a stationary force transducer in order to quantify stiffness (resistance of the analog to elongate under pulling) and strength (stress/strain or the maximum force and maximum elongation the analog can withstand before fracture)
- Histologic Analysis: Samples were stained with H&E to show red blood cells in pink and CD61 to show platelets in dark brown

Information regarding the tensile strengths and histologic compositions of a cohort of emboli obtained during mechanical thrombectomy in patients with large vessel occlusion strokes was previously obtained as groundwork and ultimately correlated with the histologic characteristics and mechanical strengths of each embolus analog created.

Results:

Tensile properties, such as stiffness and strength, were negatively correlated with red blood cell percentage and positively correlated with fibrin and platelet percentage. This accurately represented results from emboli extracted from patients with large vessel occlusion strokes.

Conclusion:

Similar to real patient emboli, embolus analogs with a lower red blood cell and higher fibrin content are stiffer and can withstand higher tensile stress before fracturing. Results offer a method for fabricating embolus analogs that mimic the broad range of emboli retrieved in large vessel occlusion strokes, both histologically and mechanically. Results can be used as a platform for translational research in stroke and mechanical thrombectomy technologies.

Reflection/Impact Statement:

You may use the following questions to guide your reflection:

1. How did the process of conducting this research confront any limitations of your prior thinking?
    - Patient emboli are often non-homogeneous due to calcifications and necrotic core material. Harder and weaker parts within a single embolus have different mechanical properties. However, the embolus analogs created in our research were homogenous.
    - Patient emboli may be hours-months old before the onset of symptoms. This aging process has effects on mechanical properties. The embolus analogs created in our research did not age.
    - Patient emboli often have white blood cells. The embolus analogs created in our research did not have white blood cells.
    - Coagulation to create the embolus analogs in our research were induced with calcium-chloride. This may differ from the natural coagulation process in real patients.

2. Who could potentially benefit from this CFI project over different timescales and how?
    - *Students* → Students interested in neurology, neurosurgery, innovation/device development, or engineering would benefit from this project as it is very helpful for learning the process behind taking a medical device from the developmental stage to a potentially marketable product for a neuro-related patient population.

- *Engineers* → A standardized protocal for realistic embolus analogs would be beneficial to engineers who are in pursuit of relaibly testing how well next generation thrombectomy devices can extract emboli of diverse compositions.
- *Physicians* → Neurosurgeons could benefit from this project because it could help create a new market of mechanical thrombectomy devices with less complication rates and reduce the common challenges proceduralists face with current interventional options.
- *Patients* → Patients could benefit from this project because it could help create a new market of mechanical thrombectomy devices that offer better clinical outcomes.

3. <u>What actions will you take afterwards to continue the momentum of this project, and maximise the likelihood of the identified benefits being achieved?</u>
   - To continue the momentum of this project, I will stay up to date on current literature reguarding creating embolus analogs and testing mechanical thrombectomy devices.

4. <u>What advice would you give to another student completeing their CFI?</u>
   - *Think outside of the box* → If your initial plans are unsuccessful, try to think of creative alternatives. At one particular point, our team was testing mechanical properties of the embolus analogs by stretching the emboli vertically. After realizing we were getting unsuccessful results, we quickly switched to horizontal testing, allowing us to more accurately measure tensile properties.
   - *Don't be afraid to join a project you have no experience in* → I went into this project without any engineering, entrepreneurship or business background. I simply wanted to learn the ins and outs of medical device development. But, I was able to learn how I could effectively contribute to such a collaborative and interdisciplinary team. And, I can use the skillsets I learned to move my own future innovative ideas to the forefront.
   - *Connect your CFI project to your specialty of interest* → Although I do not plan on practicing neurosurgery, and thus will not be using devices of this nature, I think having experience with the mechanical side of thrombectomy devices will help me throughout my career in PM&R to better understand the benefits and challenges patients face with these devices after a stroke. I believe the device will be successful in the future and I look forward to one-day treating patients from a rehab standpoint who have benefited from this device.