3D Visualization in Vascular Navigation: A Breakthrough with Fiber Optic Shape Sensing

Endovascular interventions have emerged as a preferred alternative to traditional open surgery for treating many vascular diseases. However, heavy reliance on fluoroscopy and variable, complex anatomy frequently present navigational challenges for minimally invasive techniques. These challenges often result in reduced precision, prolonged procedure times, increased radiation exposure, post-procedural complications, and in the worst cases, a continued reliance on open surgery. For example, it is often challenging to cannulate the visceral vessels during Abdominal Aortic Aneurysm (AAA) repairs. It can require multiple attempts, heavy radiation exposure, excessive switching of sheaths and guidewires, ultimately resulting in higher risks and suboptimal patient outcomes. These challenges highlight the need for significant advancement in surgical navigation to enable surgeons to efficiently and reliably navigate even the most tortuous anatomy with ease and minimal reliance on X-ray imaging.

Fiber optic shape sensing (FOSS) technology presents a promising solution to these challenges. By providing real-time, 3D visualization of device shape, orientation, and position within vascular anatomy, it can simplify the navigation and placement of endovascular devices. This whitepaper provides an introductory example and examination of how FOSS can address the current challenges in endovascular navigation, potentially reducing procedure times, minimizing radiation exposure, and improving overall outcomes.

The Shape Sensing Company's (TSSC) FOSS solution utilizes a disposable bundled fiber sensor and a system which performs Optical Frequency Domain Reflectometry (OFDR) measurements. The system processes signals generated by reflected light from the sensor and produces real-time, three-dimensional measurements of sensor shape. This further enables visualization of the entire length of the device in which the fiber sensor is integrated. The unique properties of fiber optic sensors offer several advantages in medical applications - they are compact and flexible, allowing for integration into various medical devices without compromising their size or maneuverability. Unlike traditional navigation methods, FOSS does not require direct line-of-sight and is immune to electromagnetic interference, making it ideal for navigating complex anatomies and ensuring reliable performance in surgical environments. Furthermore, it provides continuous real-time shape information along the entire length of the sensor, enhancing visual feedback and precision of device manipulation.

While the fundamental concept of fiber optic shape sensing has existed for some time, its widespread adoption in medical settings has been hindered by several factors. These include challenges in accurately sensing twist, limitations in spatial resolution, and prohibitive costs associated with its use in disposable medical devices. However, TSSC has overcome these limitations as previously demonstrated in our shape and orientation accuracy whitepapers. To further validate TSSC's FOSS technology, this whitepaper demonstrates precise and repeatable cannulation of the celiac trunk in a rigid anatomical model. This study demonstrates the technology's value in one of the more challenging and fluoroscopy-heavy vascular procedures, and paves the way for broader implementation of FOSS in complex surgical interventions.

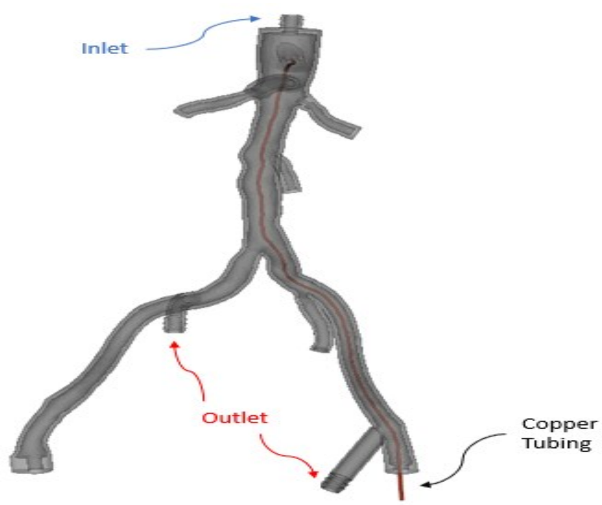

Figure 1: Anatomical model with copper tubing simulating the vascular path to the celiac trunk

In this study, TSSC demonstrates the successful cannulation of the celiac trunk in a rigid anatomical model using FOSS as a navigation and visualization tool. The model, derived from a CT scan and modified to enable fluid flow at body temperature (99 °F), was manufactured using 3D printing (Figure 1). The test setup (Figure 2) incorporates circulating and temperature controlled flow, and a thermocouple at the outlet pipe. Copper tubing was inserted into the model providing a controlled, repeatable path from the left femoral artery to the celiac trunk. A distributed fiber optic temperature sensor was inserted into the copper tubing to validate uniform body temperature distribution along the entire path. The mean and standard deviation of temperature along this path was approximately 99.8 °F and 2 °F, respectively. Testing included inserting TSSC's shape sensor into the copper tubing, following a path of approximately 32 cm through the anatomy. This setup allows for a benchtop simulation of the cannulation process, enabling the evaluation of FOSS as a navigation and visualization tool in a controlled environment.

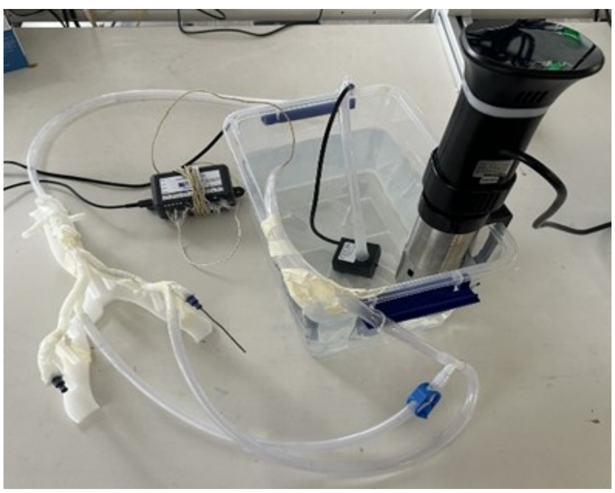

Figure 2: Experimental setup

Successful cannulation of the celiac branch was determined using a qualitative, visual verification method. Since the copper tubing forces the sensor along a path which is known to take the distal end into the celiac trunk, a trial was deemed successful when the measured and visualized distal part of the fiber optic sensor intersected the celiac trunk ostium, as confirmed from visualizing both Posterior-Anterior (PA) and Lateral (LAT) views. Figure 3 provides a visual representation of a successful trial. As seen in the figure, the sensor passes through the ostium in both the PA and LAT views. This test process was repeated over 30 consecutive trials. Of these, 29 were classified as successful, yielding a success rate of 96.67%. These results demonstrate the TSSC system's reliability in being used as a navigation tool for cannulating the abdominal aortic side branches without fluoroscopy. The technology enables surgeons to clearly visualize their devices entering target branches in real-time, in 3D, and without the use of fluoroscopy.

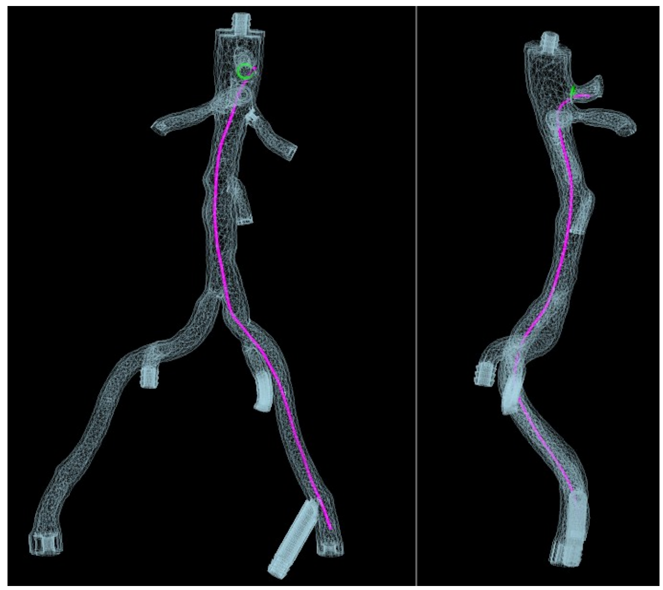

Figure 3: Visualization showing successful cannulation of the celiac trunk

Successful visualization of celiac trunk cannulation in a rigid anatomical model using TSSC's FOSS technology demonstrates its ability to address the longstanding challenges associated with vascular navigation. These procedures are hindered by the limits of 2D fluoroscopy and complex, tortuous anatomies. Building upon our previous demonstrations of sub-millimeter shape accuracy and precise orientation measurements, these results further highlight the potential of TSSC's fiber optic shape sensing technology to minimize radiation exposure and improve overall patient outcomes in endovascular interventions. Next steps include conducting a flexible phantom study and in vivo animal studies. This future work will further demonstrate shape sensing's advantages over current navigation technologies and techniques, and propel it toward adoption in vascular and many more minimally invasive procedures. The Shape Sensing Company is positioned to make a meaningful impact in endovascular interventions and surgical navigation.