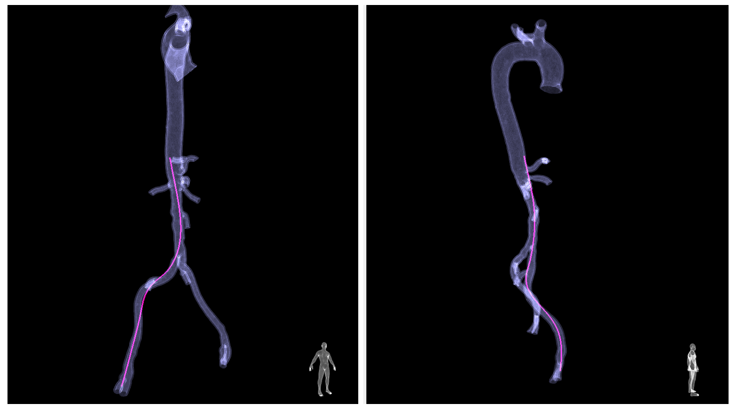
Submillimeter Shape Accuracy Using Fiber Optic Shape Sensing in Surgical Applications

In the world of surgical device navigation, the historical reliance on X-ray technology is undergoing a transformative shift fueled by the emergence of alternative navigation methods such as vision-based approaches, electromagnetic tracking, mechanical end effector tracking, and ultrasonic systems. These alternatives offer increased accuracy, improvements in real-time imaging, improved costs, size advantages, and reduced radiation exposure. While the emergence of alternative navigation methods has proven disruptive in medicine and various industries, significant limitations such as line of sight requirements, electromagnetic interference, and cumbersome workflows continue to be problematic in meeting the requirements for further adoption in operating rooms. Amidst these challenges, fiber optic shape sensing (FOSS) has emerged as an innovative technology that introduces solutions to many of the established limitations of conventional surgical navigation methods. The Shape Sensing Company's (TSSC) shape sensing and navigation technology, leveraging the distinctive advantages of fiber optics, is poised to change the landscape of device guidance. Today, we aim to demonstrate that our shape sensing and navigation technology not only addresses the drawbacks of existing systems but also meets the strict accuracy requirements essential for a surgical device navigation system.

Fiber optic shape sensing involves a sensor consisting of either a multi-core fiber or a configuration of multiple single-core fibers, and an interrogation technique called Optical Frequency Domain Reflectometry (OFDR). These elements, in combination with TSSC's processing algorithms, enable the 3D shape of the sensor to be measured and visualized. Fiber-based shape sensors are compact and flexible, they do not require line-of-sight, they provide real-time visualization of the entire sensor length, and are immune to electromagnetic interference. The concept of fiber optic shape sensing has been around for quite some time, however, limitations in sensing twist, spatial resolution, and cost have limited accuracy and adoption. Recent studies demonstrate attempts in artificial twist compensation, yielding average shape accuracy results in the range of approximately 1 mm, with some publications displaying submillimeter accuracy. However, these studies do not indicate realistic results that may be

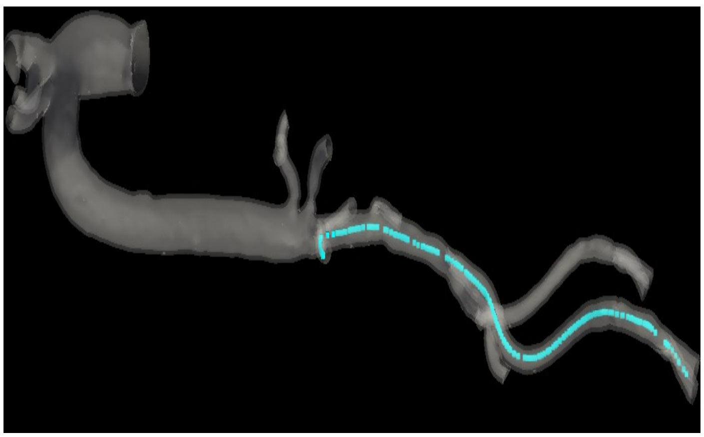


Visualization of a fiber optic shape sensor in an anatomical model.

achieved outside of a tightly controlled laboratory setting, let alone in a device in the operating room. Current studies also illustrate the absence of standardized testing methods and error metrics, making comparison of different shape sensing solutions difficult or impossible.

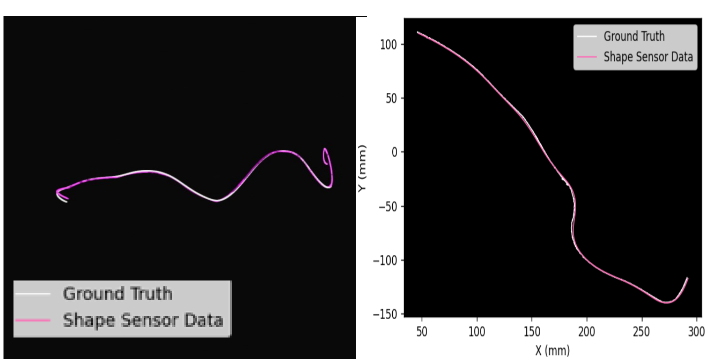
TSSC's technology overcomes the limitations of existing shape sensing solutions. In contrast to these alternatives, it provides spatially continuous measurements along the entire sensor length with resolution down to a few 10s of microns, provides accurate, distributed twist sensing, and is on a path toward consumable pricing. Twist sensing has proven to be absolutely essential for shape sensing technology to maintain accuracy when used within devices such as endoscopes, catheters, and guidewires. TSSC's technology has been rigorously tested under conditions that mirror its intended use in surgical environments, ensuring relevance and applicability.

In this study, TSSC is demonstrating 3D shape accuracy when our fiber sensor is inserted into a tortuous anatomical path. The test process includes inserting the sensor into the path just as a surgeon would deploy a guidewire or catheter within a patient, and no effort is made to restrict or minimize twist. The path selected for this study represents a typical anatomy surgeons must navigate during abdominal aortic aneurysm (AAA) treatment. It was derived using the centerline of the vasculature contained in a CT scan of a normal and healthy adult female. The in-patient portion of the path is approximately 43.5 cm, and TSSC added 68.0 cm of nontortuous path length proximal to the anatomical portion. This was done to extend the test length to over 1 m. A test fixture to hold the sensor in the target shape was built by 3D printing a static, tubular structure that incorporates a central lumen to accommodate the sensor, as well as an external groove which follows the same path as the lumen. The groove was included to allow for experimental reconstruction and verification of the path using infrared (IR) cameras and markers. The test process involved inserting the sensor into the entire path length and then recording the output shape. The recorded shape is then compared to the IR-measured path using iterative closest point (ICP) analysis.

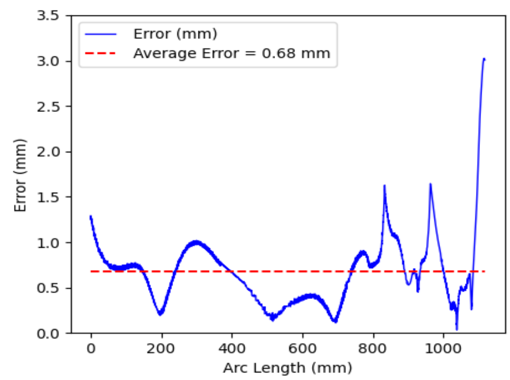


Visualization of the medically relevant portion (cyan) of the path used in this study

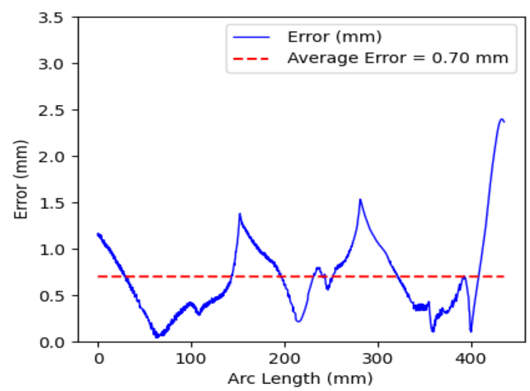
The metric used for calculating shape accuracy is the average distance error between all corresponding points on the ICP-registered shape sensor set and the ground truth set (the IR-measured path data). Over the entire path length, the average shape error is approximately 0.68 mm with a deviation of ± 0.40 mm, reaching a maximum error of ≈ 3.00 mm at the distal end. When focusing solely on the medically relevant (in-patient) region, the average shape error is approximately 0.70 mm with a deviation of ± 0.44 mm and a maximum error of ≈ 2.40 mm at the distal end. Current inaccuracies stem from known calibration limitations, and these metrics are expected to improve as TSSC continues development of the technology.



3D visualization of the entire shape's registration results (left) 2D projection visualization of the medically relevant region's registration results (right)



Error as a function of arc length when considering the entire path



Error as a function of arc length when considering only the medically relevant (in-patient) portion

In light of these submillimeter shape accuracy results, TSSC's FOSS and navigation technology is a strong candidate for use in endovascular procedures. The highlight of TSSC's technology lies in maintaining high accuracy in a tortuous path and under arbitrary twist, areas where FOSS accuracy has historically diminished. The Shape Sensing Company is excited to share these submillimeter shape accuracy results, and we look forward to discussing how the technology may be deployed in any number of medical devices in need of improved navigation.