Reduced Radiation and 3D Navigation: A Phantom Study on Aortic Side Branch Cannulation Using a Shape-Sensed Guidewire

This study evaluates a shape-sensed guidewire system that enables three-dimensional vascular navigation while minimizing radiation exposure during interventional procedures. Using an anatomically accurate aortic phantom model, we compared the performance of a prototype shape-sensed guidewire (0.035" diameter) system against traditional fluoroscopy-guided navigation. The system achieved successful vessel cannulation with zero radiation exposure beyond initial registration, compared to continuous fluoroscopy requirements in conventional approaches. Cannulation times were on average longer than under traditional two-dimensional guidance, however, this is attributed to the anatomy being clearly and continuously visible in the x-ray images without the use of contrast dye. The notable reduction of radiation exposure during navigation, combined with precise 3D visualization demonstrates this technology's potential for improving procedural safety in minimally invasive procedures.

Introduction

Interventional radiology has revolutionized the treatment of vascular pathologies through minimally invasive procedures that reduce patient recovery times. However, traditional methods rely heavily on fluoroscopy, which poses significant challenges due to radiation exposure risks and the limitations of two-dimensional (2D) imaging. These challenges are particularly pronounced in procedures involving complex vascular structures, where 2D projection views can limit the level of detail required for precise guidance.

In conventional interventional procedures, clinicians inject contrast dye to visualize anatomical landmarks during live fluoroscopy, aiding in device navigation. However, because contrast dye is flushed out with the blood flow, clinicians must inject repeatedly to maintain anatomical visualization, interrupting procedural flow and exposing patients to additional risks. Additionally, repeated exposure to x-ray radiation poses significant health risks to medical staff, particularly during complex, lengthy procedures like fenestrated or branched endovascular aneurysm repairs (FEVAR or BEVAR). Addressing these limitations requires developing a navigation technology that provides continuous, radiation-free anatomical visualization while maintaining precise guidance.

This study demonstrates the feasibility and clinical advantages of using a shape-sensed guidewire integrated with a 3D guidance system, addressing the limitations of fluoroscopy by providing real-time, three-dimensional visualization with decreased radiation exposure and use of contrast dye. Compared to commercially-available vascular 3D guidance solutions, the system presented in this work offers advantages: universal compatibility with existing fluoroscopy suites, cost-effective disposable guidewires through low-cost shape sensors, and immunity to electromagnetic (EM) interference. Additionally, while EM-based sensors are limited to device tip position and orientation data, our system provides visualization of the entire device shape. This advancement not only enhances patient safety but also safeguards clinicians from the cumulative effects of radiation exposure.

Study Overview

To ensure clinical relevance and to accurately simulate conditions encountered in abdominal aortic aneurysm (AAA) repair or thoracoabdominal aortic aneurysm (TAAA) repair procedures, this study was conducted in collaboration with Dr. Pedro Teixeira, Division Chief of Vascular Surgery at UT-Austin, Dell Medical School, a vascular surgeon advisor to TSSC. A flexible aorta phantom model (fig. 1) derived from a patient CT scan

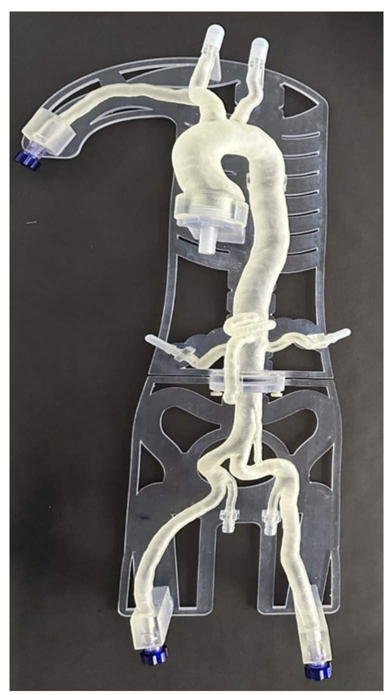

Fig. 1. Phantom model used in the study.

was used for the study. The model provides femoral access points using Tuohy-Borst valves and includes key branching arteries, such as the renal, mesenteric, and celiac arteries. Constructed from a compliant polyjet Agilus blend material, the model offers realistic vascular flexibility. A non-pulsatile pump circulated a solution of soap and water through the model to achieve accurate simulation of device maneuverability and to replicate vessel geometry changes due to vascular compliance.

The study utilized a prototype guidewire (0.035" diameter, 120cm length, 7cm flexible tip length) with an integrated multi-fiber bundle-based (MFB) shape sensor. This sensor, combined with optical frequency domain reflectometry (OFDR), provides real-time, three-dimensional shape measurements of the entire length of the sensor.

Methods

The primary objective of this phantom study was to assess the feasibility, efficiency, and clinical value of using a shape-sensed guidewire with real-time 3D guidance for navigating vascular anatomy and performing branch vessel cannulation. Specifically, the study aimed to minimize the use of x-ray imaging while evaluating the system's ability to facilitate accurate, efficient cannulation of target branches.

The procedure began with right femoral access via a Tuohy-Borst valve, enabling entry into the phantom model. Using fluoroscopy, Dr. Teixeira navigated the guidewire to the aortic bifurcation, followed by x-ray registration to the 3D aortic phantom. Once the guidewire was advanced past the bifurcation, the procedure transitioned entirely to 3D guidance, eliminating further radiation exposure. The semi-translucent material of the phantom did not allow for direct visualization of the guidewire during navigation, requiring Dr. Teixeira to rely solely on 3D guidance.

Dr. Teixeira cannulated the celiac, superior mesenteric, and renal arteries, identified as target vessels. The model's material enabled visual confirmation of the guidewire reaching the distal end of each vessel, confirming successful cannulation. The guidewire was advanced through each branch vessel solely using 3D guidance, demonstrating the feasibility of radiation-free navigation after initial registration.

For control purposes, a Terumo Glidewire (GR3501) was used under traditional guidance with continuous x-ray imaging. The Aptus 6.5Fr deflectable sheath (TG0655509) was employed in all interventions to provide enhanced control of the guidewire during vessel access.

Data collection focused on evaluating the efficiency and x-ray requirements of the 3D guidance system compared to traditional methods. For each target branch, we recorded cannulation time (measured from the aortic bifurcation to successful branch cannulation) and fluoroscopy time (total duration of fluoroscopy use during navigation).

Results

The study demonstrated successful cannulation of all target vessels with significantly reduced fluoroscopy when using the shape-sensed guidewire system. With 3D guidance, the average cannulation time (navigation from the aortic bifurcation to target branch cannulation) was 54 seconds, compared to 24 seconds using traditional x-ray guidance. Notably, radiation exposure was greatly minimized in the 3D guidance method, which required fluoroscopy only for initial navigation to the aortic bifurcation and registration—eliminating fluoroscopy use entirely during cannulation. In contrast, the traditional x-ray method relied on an average of 24 seconds of continuous fluoroscopy for this stage of the procedure.

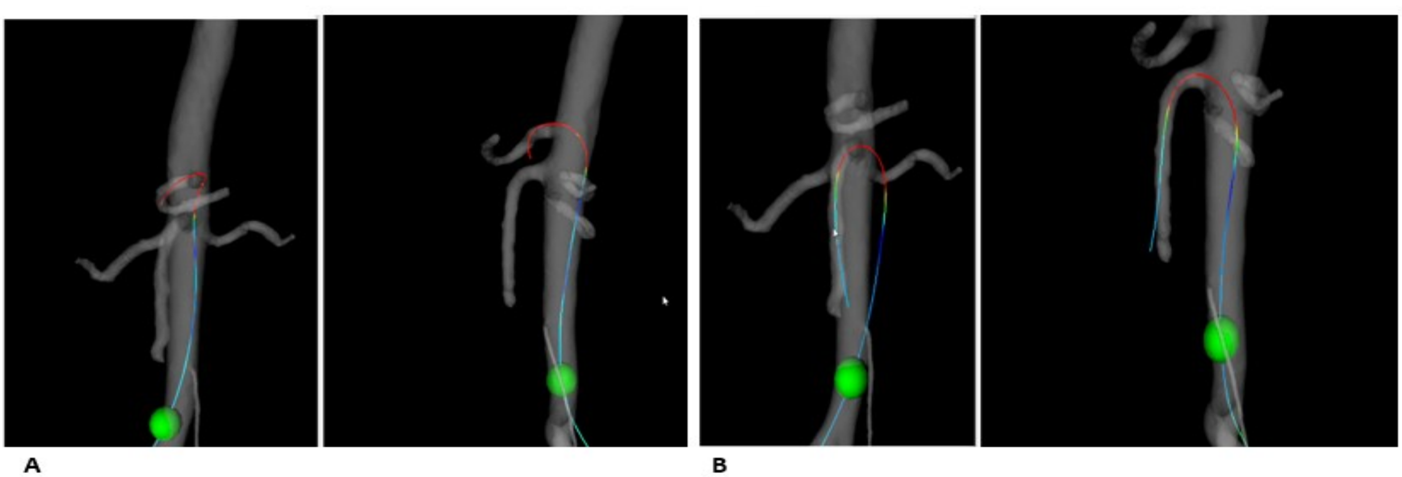

Fig. 2. (A) Successful cannulation of the celiac branch. (B) Successful cannulation of the superior mesenteric branch.

Discussion

The shape-sensed guidewire system demonstrated clear advantages over traditional methods, particularly in reducing radiation exposure while enhancing visual navigation feedback. Unlike conventional 2D fluoroscopy which provides only projection views, the 3D guidance system enables comprehensive spatial awareness of the guidewire's position and orientation. This capability not only reduces the need for continuous x-ray imaging but also provides clinicians with a more intuitive and precise navigational tool.

A key consideration is the phantom model used in this study. Unlike real anatomy, where contrast dye is typically required to visualize vessels under fluoroscopy, the phantom model allowed vessels to be clearly visible without dye. This difference simplified navigation in the traditional x-ray method, providing an unrealistic ease of visualization compared to real-world clinical scenarios. Figure 3 illustrates these differences in vessel visibility.

The system's compatibility with existing imaging platforms further enhances its practical value, enabling seamless integration into various clinical workflows, further promoting its practical adoption in endovascular procedures. The results of this study underscore the potential of 3D guidance to transform traditional x-ray dependent procedures.

Minimizing radiation exposure is especially significant for both patients and clinical staff. Interventional radiologists, who perform multiple procedures daily, are consistently exposed to ionizing radiation, with cumulative doses reaching dangerous levels over time. Studies have shown increased risks of radiation-induced cancers, cataracts, and other health complications among interventional radiologists due to long-term exposure. The 3D guidance system offers a viable solution by reducing fluoroscopy use, allowing for safer procedures while at the same time offering enhanced, more intuitive navigation capabilities.

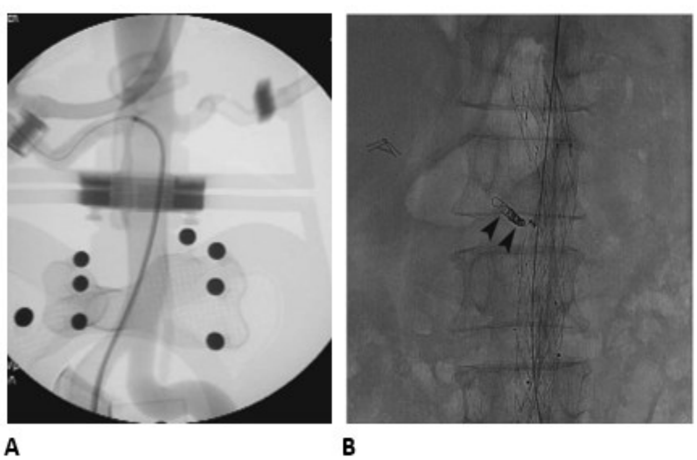

Fig. 3. (A) Radiopacity of the phantom model used in this study. (B) Radiograph obtained after EVAR, without contrast dye.[1]

Several limitations must be acknowledged. First, the limited number of participants limits the generalizability of the study. The phantom model's healthy anatomy does not fully replicate the complexity of real patient anatomy, potentially affecting the translation of these navigation results to clinical settings. The slight radiopacity of the model eased visualization for the traditional x-ray approach, creating conditions that may not reflect typical fluoroscopy challenges.

Technical limitations included the inability to back-load the shape-sensed guidewire and the lack of catheter tip visualization relative to the guidewire in the 3D system. These aspects present clear opportunities for improvement in future iterations of the technology.

Conclusion

This study demonstrates the feasibility and clinical potential of TSSC's shape-sensed guidewire system, highlighting its key advantages over traditional methods in reducing radiation exposure and providing enhanced 3D navigation. The ability to achieve successful vessel cannulation with minimal x-ray exposure represents a significant advancement over traditional methods requiring continuous fluoroscopy. Moreover, the system's compatibility with existing imaging platforms suggests that it could be seamlessly integrated into a range of clinical settings.

Dr. Teixeira commented after the study, "The shape sensing device was highly usable, with low latency and accurate position identification, performing well for branch cannulation in an aortic model."

Future research includes expanding these findings through larger studies involving varied anatomical models, including those with pathological features and more complex vascular structures. Additional focus areas include refining catheter tip visualization, improving back-loading capabilities, and addressing current model limitations. Furthermore, the progression to in vivo trials will be essential to evaluate the system's real-world impact on procedure time, radiation exposure, and overall clinical outcomes. These developments will be critical in establishing the shape-sensed guidewire as a transformative tool in 3D guided interventional radiology and endovascular procedures, potentially setting new standards for procedural safety and efficiency in vascular interventions.

[1] *Endovascular Aneurysm Repair for Abdominal Aortic Aneurysm: A Comprehensive Review. Korean J Radiol. 2019*