Experimental Investigation

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A Steerable and Electromagnetically Tracked Catheter: Navigation Performance Compared With Image Fusion in a Swine Model

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Abstract

Purpose: Cannulation of visceral vessels is necessary during fenestrated and branched endovascular aortic repair. In an attempt to reduce the associated radiation and contrast dose, an electromagnetically (EM) trackable and manually steerable catheter has been developed. The purpose of this preclinical swine study was to evaluate the cannulation performance and compare the cannulation performance using either EM tracking or image fusion as navigation tools. **Materials and Methods:** Both renal arteries, the superior mesenteric artery, and the celiac trunk were attempted to be cannulated using a 7F steerable, EM trackable catheter in 3 pigs. Seven operators attempted cannulation using first 3-dimensional (3D) image navigation with EM tracking and then conventional image fusion guidance. The rate of successful cannulation was recorded, as well as procedure time and radiation exposure. Due to the lack of an EM trackable guidewire, cannulations that required more than 1 attempt were attempted only with image fusion. The EM tracking position data were registered to preoperative 3D images using a vessel-based registration algorithm. **Results:** A total of 72 cannulations were attempted with both methods, and 79% (57) were successful on the first attempt for both techniques. There was no difference in cannulation rate (p=1), and time-use was similar. Successful cannulation with image fusion was achieved in 97% of cases when multiple attempts were allowed. **Conclusion:** This study demonstrated the feasibility of a steerable and EM trackable catheter with 3D image navigation. Navigation performance with EM tracking was similar to image fusion, without statistically significant differences in cannulation rates and procedure times. Further studies are needed to demonstrate this utility in patients with aortic disease.

Clinical Impact

Electromagnetic tracking in combination with a novel steerable catheter reduces radiation and contrast media doses while providing three-dimensional visualization and agile navigation during endovascular aortic procedures.

Keywords

electromagnetic, tracking, image fusion, steerable, catheter, endovascular, EVAR

Introduction

Fenestrated or branched endovascular aortic repair (F/BEVAR) is used to treat complex aortic aneurysms involving visceral vessels. Cannulation of branch vessels may be challenging and result in increased procedure time and use of ionizing radiation and nephrotoxic contrast media. Although improvements have been seen with the use of preloaded wires, image fusion, steerable instruments, and operator experience, the radiation dose is still considerable with F/BEVAR, potentially posing a risk to patients and personnel.[1–3] Electromagnetic (EM) tracking enables navigation without the use of radiographs and contrast media

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Figure 1. Steerable catheter. The distal tip can be bent to approximately 90° and rotated 360° by push/pull and rotation manipulation of the blue part of handle.

and provides accurate 3-dimensional (3D) visualization of anatomy and tracked instruments. While proposed and demonstrated in the research literature, commercial alternatives for endovascular use are lacking.[4] Recently, the combination of EM tracking with steerable catheters or sheaths has been proposed for complex cannulation tasks.[5,6] In a further attempt to combine the agility of a steerable catheter with the 3D visualization provided with EM tracking, a steerable catheter with an embedded EM sensor was developed.[7] The aim of this swine model study was 2-fold. First, we compared the cannulation rate and time-use when using either 3D navigation with EM tracking or image fusion as a navigation tool. Due to a lack of an EM trackable guidewire, only 1 cannulation attempt was allowed. Our hypothesis was that performance would be similar in the 2 groups. Furthermore, we wanted to demonstrate that the steerable catheter was able to achieve cannulation success when more than 1 attempt was required, with the guidance of image fusion.

Materials and Methods

Steerable Catheter

The prototype catheter was designed and produced by DEAM (Amsterdam, The Netherlands) in collaboration with the authors. The catheter had a relatively stiff body with a diameter of 7F and a 0.035 inch and 90 cm long working channel. The distal end of the catheter had a stiff part with a length of 1.5 cm, followed by a flexible joint section. The tip could be bent to an angle of approximately 90° and rotated 360° independent of each other by using push/pull and rotation manipulators in the handle (Figure 1). Movement of the tip was tendon-driven and could be rotated freely without having to rotate the entire catheter. A 6-degrees-of-freedom (DOF) EM sensor (Aurora Micro 6DOF sensor tool, part. no. 610059; Northern Digital Inc., Ontario, Canada) was embedded in the tip for position tracking capabilities.

Setup in the OR

The animals were treated according to the Guide for the Care and Use of Laboratory Animals. The Norwegian Food Safety Authority approved the study protocol after ethical consideration (FOTS ID 10682). Anesthesia followed a standardized protocol. After completion of the experiment, the animals were euthanized.

Preoperative computed tomography (CT) angiography of the entire aorta was acquired with the swine in the supine position with an intravenous injection of 80 mL of contrast media (Omnipaque 350 mg I/mL; GE Healthcare, Chicago, IL, USA). In the hybrid operating room (OR), the animal was placed in the same position, and percutaneous bilateral vascular access was established through the femoral arteries. After draping, cone beam computed tomography (CBCT) was acquired and registered to the preoperative CT for image fusion using the iPilot functionality on the Siemens syngo Multimodality Workplace (Siemens Healthcare, Forchheim, Germany). The ostia of the renal arteries, superior mesenteric artery (SMA), and celiac trunk were highlighted and shown on the live fluoroscopy screen after registration.

The EM tracking system consisted of an EM planar field generator (Aurora Planar 20-20 Field Generator; Northern Digital Inc.) located underneath the operating table, a sensor interface unit, and a system control unit that was connected to a workstation running CustusX, an open-source research platform for visualization and navigation during image-guided procedures.[8]

Vessel-Based Registration Method for EM Navigation

We used a registration algorithm that registers the EM tracked positions of a catheter tip to the extracted vascular centerline from the preoperative CT imaging. First, the contrast-filled aorta with side-branches was segmented with the semiautomatic active contour functionality of ITK-SNAP (itksnap.org).[9] Then, the centerlines of the 3D aorta model were extracted using the Vascular Modeling Toolkit (vmtk.org).[10] The tracked positions were gathered using a modified Ultra Flush catheter with an embedded 5-DOF sensor in the distal tip. The Ultra Flush catheter was advanced to the suprarenal aorta and withdrawn with a rotating motion, generating a point cloud of position sensor data along the vessel length. The procedure was repeated from the contralateral access. The registration algorithm (iterative closest point) minimizes the distance between this point cloud and the centerline extracted from the preoperative CT. This algorithm is implemented as a software plug-in in CustusX and previously described in more detail.[11] After automatic registration, the registration result was visually assessed based on the catheter position in CustusX and manually corrected as necessary. The navigation user interface in CustusX is shown in Figure 2.

Experiment

Three swine were included with a weight of 42 to 58 kg. Four arterial branches were chosen for cannulation: the left

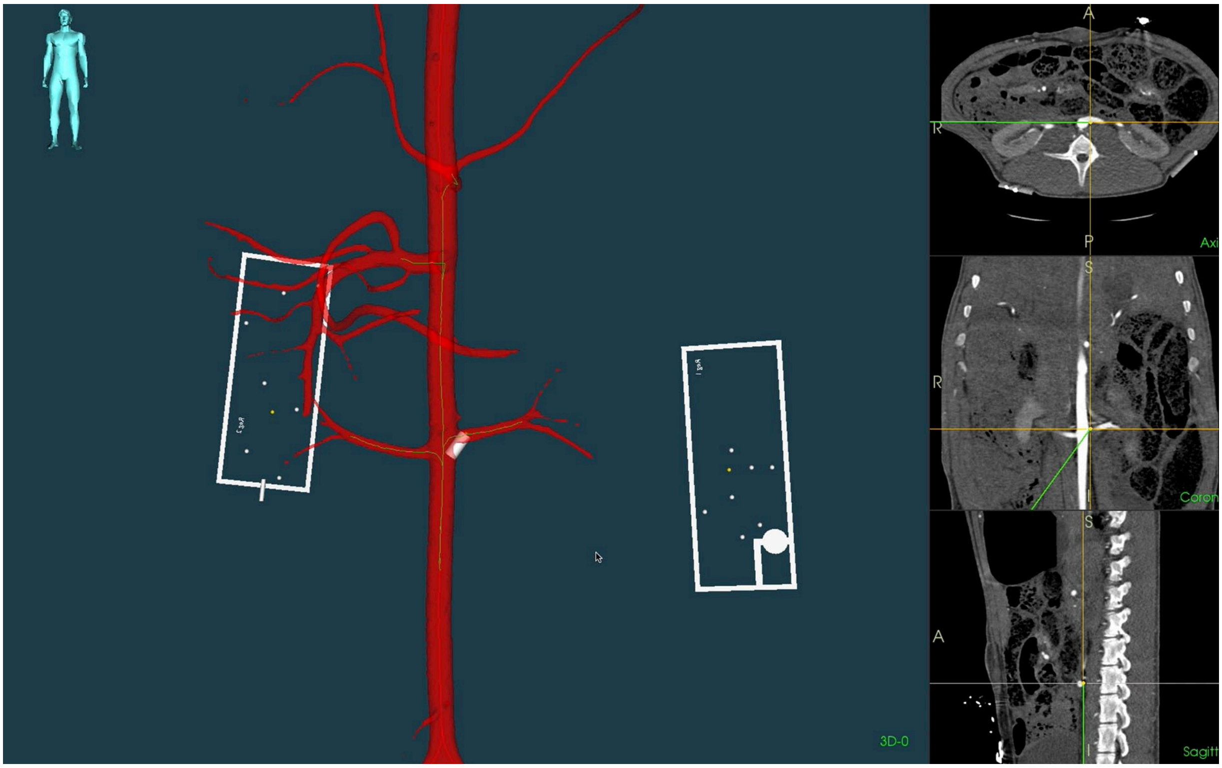

Figure 2. Screenshot from the CustusX navigation system. Reconstructed 3-dimensional (3D) model on the left. Axial, coronal, and sagittal planes are shown on the right. Position of the catheter is shown with a marker in the 3D model and a yellow cross in the reconstructed planes. The green line indicates the rotation of the sensor.

and right renal arteries, the SMA, and the celiac trunk. The experiment was conducted by 7 operators with each navigation alternative (EM tracking and image fusion). The operators were instructed briefly on the use of the catheter before use, demonstrating the pull/push motion for bending the tip and rotating the handle for rotation. The steerable catheter was then positioned in the distal abdominal aorta just cranial to the aortic bifurcation with access through the right femoral artery. The operators were instructed to cannulate the arteries in order, from the left renal artery, right renal artery, SMA, and celiac trunk. A nontrackable guidewire was advanced as distally as possible in the catheter, and all navigation took place using the catheter. Each operator started navigation with EM tracking followed by image fusion to minimize the learning effect in advantage of the experimental technology. Cannulation was confirmed by fluoroscopy and was considered successful if the guidewire was clearly and steadily positioned in the desired vessel. The operators had only 1 attempt at cannulation as we did not have a trackable guidewire available. For image fusion, the C-arm was positioned in the anterior-posterior direction before the start of each cannulation. In addition, for image fusion, if the first cannulation was unsuccessful, further attempts were made until successful cannulation or until the operator deemed further attempts futile. Successful cannulation, time-use, and radiation dose were recorded. Operators were allowed to repeat the experiment on the same animal but always with a break of a minimum of 30 minutes to minimize the learning effect.

Statistical Analysis

Statistical analysis was conducted in SPSS 25 (Mac OS, IBM). Time-use and radiation were displayed as medians with interquartile ranges, whereas cannulation success was displayed as a percentage. The Wilcoxon signed-rank test was used to compare time-use, and the McNemar test was used to compare cannulation rates. The significance level was set at 0.05.

Results

Among a total of 72 attempted cannulations of designated branch arteries, successful cannulation on the first attempt was achieved for 79% (n=57) with any of the navigation systems, with no significant difference (p=1). In more

Table 1. Percentage (and Number) of Successful Cannulations.

	EM tracking	Image fusion	p value
Cannulation	79% (57)	79% (57)	1
Time-use all, s (IQR)	34.0 (26.0–49.0)	31.0 (21.25–48.0)	0.291
Radiation, mGy (IQR)	NA	2 (1.0–4.0)	NA

Median values with IQRs for time-use and radiation.
Abbreviations: EM, electromagnetic; IQR, interquartile range.

Table 2. Percentage (and Number) of Successful Cannulations by Artery.

	EM tracking	Image fusion	p value
Left renal	83% (15)	100% (18)	0.250
Right renal	89% (16)	78% (14)	0.625
SMA	72% (13)	50% (9)	0.625
Celiac trunk	72% (13)	89% (16)	0.219

Abbreviations: EM, electromagnetic; SMA, superior mesenteric artery.

detail, for 67% (n=48), success was achieved on the first attempt for the same cannulations both with EM tracking and with image fusion, whereas cannulation on the first attempt was achieved in 12.5% (n=9) with only EM tracking and for another 12.5% (n=9) only with image fusion. For the remaining 8% (n=6), cannulation did not succeed on the first attempt with any of the navigation systems. The median time-use for cannulation was 34 seconds for EM tracking and 31 seconds for image fusion and did not differ significantly (p=0.291). The median radiation dose for image fusion was 2 mGy not including CBCT. The results are summarized in Tables 1 and 2, and Figure 3. When using multiple attempts with image fusion, successful cannulation was achieved in 97% of cases.

Discussion

This study evaluated a novel manually steerable catheter with EM tracking for aortic navigation in healthy swine models. We found that navigation was comparable for EM tracking and image fusion with similar cannulation performance in terms of both primary success rates and procedure times. Cannulation was possible in almost all cases when multiple attempts were allowed.

Our results are in line with previous studies comparing EM tracking with fluoroscopic navigation, where most have reported similar time-use with EM compared with fluoroscopy.[12–17] Four of these studies used nonsteerable (conventional) equipment and the others robotic catheter systems. No one implemented the use of image fusion, and all were performed ex vivo. Only 1 study reported longer time-use for EM; however, fluoroscopy use was less common when EM and fluoroscopy were used in combination.[17] One study found shorter cannulation times with complex tasks using EM, but not for simple tasks.[13] Penzkofer et al[5] demonstrated an EM trackable steerable catheter by performing in situ fenestration in a healthy animal model with good technical success. The catheter they used was a modified commercial catheter and performed satisfactorily. Recently, another group has demonstrated the use of a de novo trackable and steerable catheter for in situ fenestration.[6] The catheter had a bendable catheter tip allowing for 90° bend to allow for perpendicular positioning to the stent graft. The catheter was tested in a rigid model with good technical success. As there were differences in the study setup, direct comparison of outcomes was difficult. However, the catheter in the present study shares most of the characteristics of these 2 catheters; in addition, it offers a 360° rotatable catheter tip.

The need for steerable equipment is demonstrated in patients undergoing F/BEVAR where a steerable sheath facilitates cannulation when conventional equipment fails or a difficult cannulation is anticipated.[18] Complex EVAR is a radiation-intensive procedure that benefits from navigational 3D support. Electromagnetic tracking offers navigational 3D support with no additional ionizing radiation. In this study, the tracked catheter tip was visualized in 3D reconstruction and in the axial, coronal, and sagittal planes, with rotation depicted in all planes. The orientation in the axial plane was especially useful, as it easily displayed the rotation of the catheter tip perpendicular to the aortic wall, which in combination with the independent rotation of the catheter tip allowed for precise positioning before attempting cannulation. A disadvantage compared with fluoroscopy is the lack of catheter shape visualization. Shape estimation, either with 2 or more EM sensors or using a fiber Bragg grating,[19–21] may therefore be of interest in future implementations. Robotic catheter systems, such as the Magellan robotic catheter system (Hansen Medical, Mountain View, CA, USA), are an alternative to manually

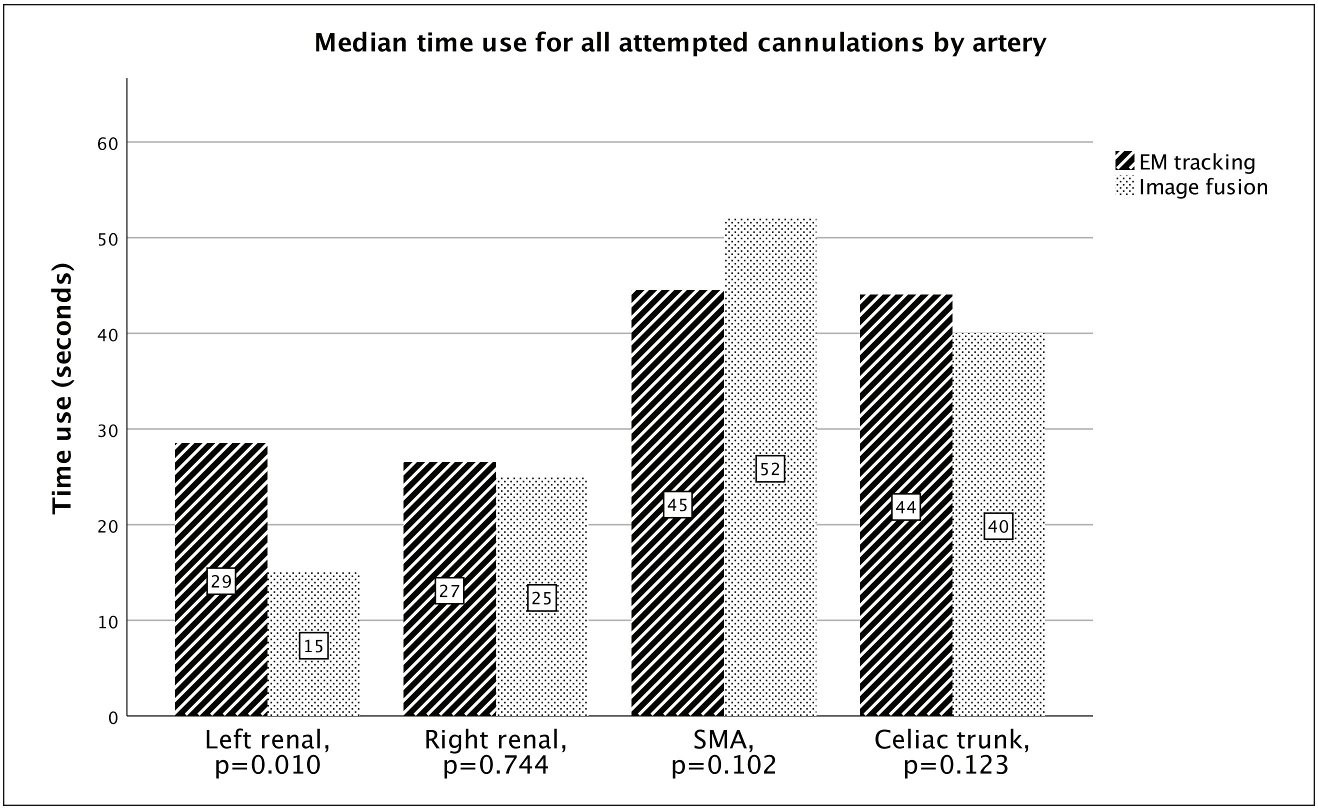

Figure 3. Median time-use for all attempted cannulations by artery. EM, electromagnetic; SMA, superior mesenteric artery.

steerable equipment and have also been trialed for F/BEVAR.[22] Current drawbacks with robotic systems include high cost, prolonged setup times, and no clinically proven benefit. In contrast, a manually steerable catheter may be used with minimal setup time, easier integration into existing ORs and interventional suits, and lower cost.

Cannulation was possible in almost all instances (97%) with repeated attempts, demonstrating the good maneuverability of the catheter. As we lacked an EM trackable guidewire, we were able to demonstrate this only with image fusion. Both the unsuccessful cannulations were with the SMA in the smallest animal. It was our experience that the diameter of the aorta of this animal was too small to accommodate a full bend of the tip of the catheter due to an aortic diameter just above 1 cm, which combined with the steep angle of the SMA made cannulation difficult. This issue would be mitigated in the human aorta, although it could potentially be a problem in patients with tortuous anatomy and navigation in smaller vessels.

Future work should explore the technology in patients undergoing relevant procedures where cannulation of abdominal vessels is necessary, such as F/BEVAR or angioplasty of renal artery stenosis. For such studies, clinically approved instrumentation is needed. Together with the catheter vendor, we have started investigating the requirements and funding for this. Improvements in instrumentation for future studies include increasing the maneuverability of the catheter by decreasing the length of the distal stiff part of the instrument. Adding a guidewire with a position-tracking sensor also will improve the navigation capabilities of the system.

Limitations

The study was carried out in a healthy animal model with simple anatomical features compared with the intended use case. In addition, the procedure itself was relatively simple. Furthermore, a low number of animals and therefore few different anatomies were used in this study, which may limit the validity of the results. The lack of a trackable guidewire limited navigation to only catheter movement. Further research should include a trackable guidewire to better represent real-world use. However, the results of the current study motivate further development of the navigation technology.

Conclusion

Navigation performance with EM tracking is comparable to image fusion, with statistically nonsignificant differences in cannulation rates and procedure times.

Cannulation is almost always feasible with multiple cannulation attempts.

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Declaration of Conflicting Interests

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