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Electromagnetic tracking of flexible robotic catheters enables "assisted navigation" and brings automation to endovascular navigation in an in vitro study

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ABSTRACT

Objective: Combining three-dimensional (3D) catheter control with electromagnetic (EM) tracking-based navigation significantly reduced fluoroscopy time and improved robotic catheter movement quality in a previous in vitro pilot study. The aim of this study was to expound on previous results and to expand the value of EM tracking with a novel feature, *assisted navigation*, allowing automatic catheter orientation and semiautomatic vessel cannulation.

Methods: Eighteen users navigated a robotic catheter in an aortic aneurysm phantom using an EM guidewire and a modified 9F robotic catheter with EM sensors at the tip of both leader and sheath. All users cannulated two targets, the left renal artery and posterior gate, using four visualization modes: (1) Standard fluoroscopy (control). (2) 2D biplane fluoroscopy showing real-time virtual catheter localization and orientation from EM tracking. (3) 2D biplane fluoroscopy with novel EM assisted navigation allowing the user to define the target vessel. The robotic catheter orients itself automatically toward the target; the user then only needs to advance the guidewire following this predefined optimized path to catheterize the vessel. Then, while advancing the catheter over the wire, the assisted navigation automatically modifies catheter bending and rotation in order to ensure smooth progression, avoiding loss of wire access. (4) Virtual 3D representation of the phantom showing real-time virtual catheter localization and orientation. Standard fluoroscopy was always available; cannulation and fluoroscopy times were noted for every mode and target cannulation. Quality of catheter movement was assessed by measuring the number of submovements of the catheter using the 3D coordinates of the EM sensors. A *t*-test was used to compare the standard fluoroscopy mode against EM tracking modes.

Results: EM tracking significantly reduced the mean fluoroscopy time ($P < .001$) and the number of submovements ($P < .02$) for both cannulation tasks. For the posterior gate, mean cannulation time was also significantly reduced when using EM tracking ($P < .001$). The use of novel EM assisted navigation feature (mode 3) showed further reduced cannulation time for the posterior gate ($P = .002$) and improved quality of catheter movement for the left renal artery cannulation ($P = .021$).

Conclusions: These results confirmed the findings of a prior study that highlighted the value of combining 3D robotic catheter control and 3D navigation to improve safety and efficiency of endovascular procedures. The novel EM assisted navigation feature augments the robotic master/slave concept with automated catheter orientation toward the target and shows promising results in reducing procedure time and improving catheter motion quality. (J Vasc Surg 2017;■:1-8.)

Clinical Relevance: We show in this study how the combination of robotic endovascular navigation and an electromagnetic tracking system has the potential to improve procedural safety and efficacy and to lead toward "fluoroscopy-free" endovascular surgery.

The endovascular approach has overcome the open surgical one for various vascular procedures, becoming the first line of treatment, mainly due to its minimally invasive nature and the recent availability of novel endovascular devices. Better control of the tip of the endovascular tools, such as catheters and wires, in relationship to

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the patient's vasculature, and better visualization with less radiation remain two areas that are in need of improvement in endovascular techniques.

Better control of endovascular tools has been improved by several shapeable and bendable catheters but mostly by the development of flexible robotics with the capability of being remotely steered with 6 degrees of freedom, thus allowing three-dimensional (3D) maneuverability of the catheter tip.[1-3] Telescoping triaxial configuration of flexible robotic catheters also enables higher support and is particularly advantageous while navigating in tortuous vascular anatomy.

Major drawbacks of current endovascular techniques include the need for real-time fluoroscopy and 2D angiography, meaning ionizing radiation, and repeated injection of a nephrotoxic contrast agent to visualize the endovascular tools and the vasculature.

The recent development of image fusion techniques has allowed for real-time 3D overlay of patient-specific vasculature from preoperative imaging data sets, such as computed tomography (CT) and magnetic resonance imaging, onto the real-time 2D fluoroscopic images to understand the relationship of endovascular tools to the vasculature.[4-7] The use of these image fusion techniques has resulted in a significant reduction in procedure length, radiation dose, and injected contrast agent volume.[5,8,9] Nevertheless, endovascular procedures still require real-time fluoroscopy to visualize and navigate the endovascular tools after understanding their relationship to complex 3D vasculature from 2D projection images.

Newer remote sensing and tracking technologies enable localization of endovascular tools and provide better 3D visualization without the need for real-time fluoroscopy. These novel tracking technologies have the future potential to enable fluoroscopy-free navigation and to improve the safety and efficiency of endovascular procedures.

Electromagnetic (EM) tracking is one such technology that enables real-time 3D localization of endovascular devices in a radiation-free environment and has been used in medical applications since the mid-2000s.[10-14] A pilot study assessed the feasibility and utility of combining EM tracking technologies and flexible robotics for endovascular navigation in an in vitro model.[15] After evaluating six users performing two endovascular cannulation tasks, the study showed that the EM-tracked robotic catheter allowed better real-time 3D orientation and facilitated navigation, with a significant reduction in cannulation and fluoroscopy times. The study also showed improvement in catheter movement consistency, efficiency, and smoothness using several kinematic metrics, especially for complex cannulation tasks.

The aim of this study was to expound on results of a previous study in a larger study population using an EM-tracked robotic catheter and to evaluate the effect of a new *assisted navigation* feature that allows automatic catheter orientation and semiautomatic cannulation of a predefined vascular target.

ARTICLE HIGHLIGHTS

- **Type of Research:** Endovascular simulation study
- **Take Home Message:** Using a silicon model of an aortic aneurysm, 18 users navigated robotic catheters with electromagnetic (EM) guidewire and sensor. Combining EM tracking and flexible robotics significantly reduced fluoroscopy and cannulation time and improved catheter's motion quality.
- **Recommendation:** The authors suggest that using EM tracking combined with flexible robotics might be the first step towards fluoroscopy-free endovascular procedures.

METHODS

Participants. This study asked 18 users with a range of endovascular and robotic catheter navigation expertise to perform a set of procedural tasks in an in vitro phantom study. The users were classified by their endovascular and robotic experience into beginner, intermediate, and expert categories.

In an attempt to characterize users, some a priori definitions were made, which were that a beginner was defined as a user who had neither used a standard endovascular nor a robotic catheter, an expert was defined as a user with experience in performing clinical cases using standard endovascular material or the endovascular robotic catheter, and an intermediate was a user in between those previous two categories.

The experiment was set up and conducted in two different facilities with the same study protocol and recorded parameters. This in vitro study did not require Institutional Review Board approval.

System. A standard 9F Magellan Robotic Catheter (MRC; Hansen Medical, Mountain View, Calif) was specifically modified for the purpose of the study:

- One EM sensor, composed of two sensing coils, was integrated into the wall of the MRC leader catheter at the proximal end of the articulation section.
- One EM sensor was embedded at the proximal end of the articulation section of the MRC sheath.

Both sensors measured and transmitted roll orientation and the forward motion of the leader and sheath tips. As a consequence of the integration of both sensors, the size of the system was increased by 1F. In addition, a standard J-tip 0.035-inch guidewire was modified with an integrated EM sensor located 11 mm proximal to its tip and was transmitting its forward motion. The current system thus involved three sets of EM tracking data,

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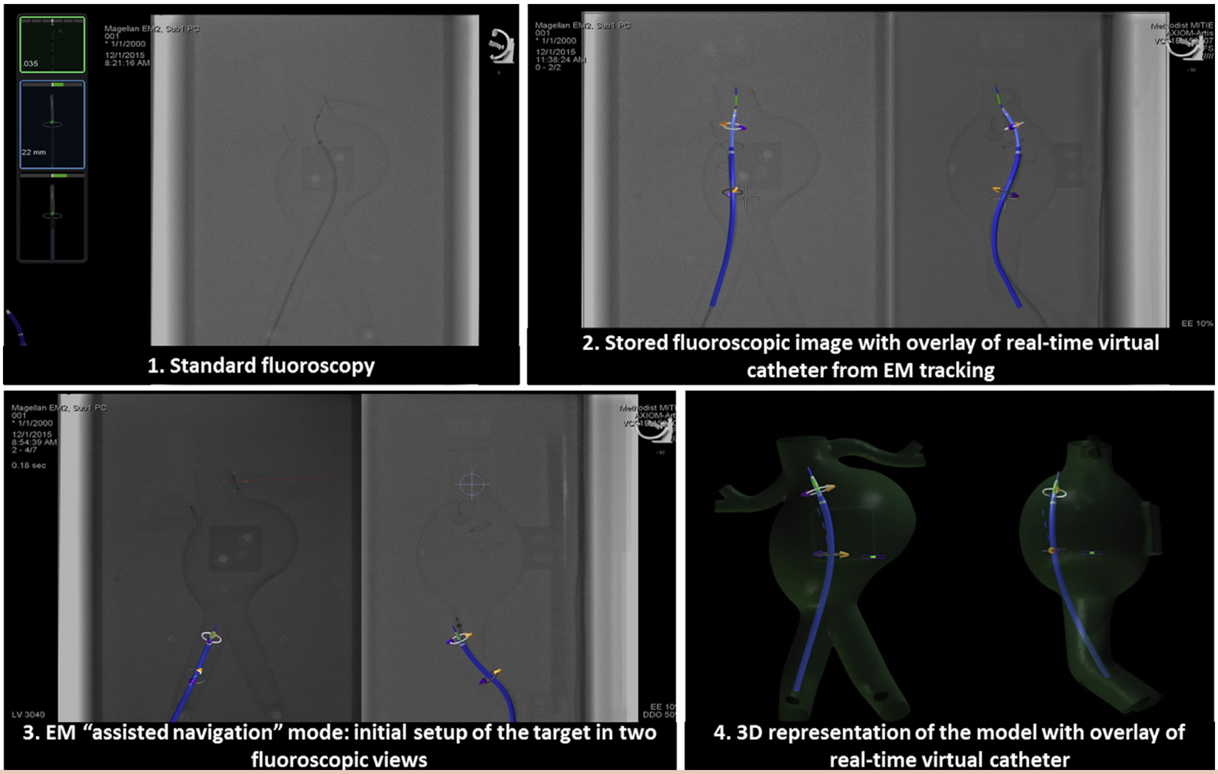

Fig 1. Four different visualization modes of the phantom: **1,** Mode 1: standard two-dimensional (2D) fluoroscopy mode (control mode). **2,** Mode 2: 2D fluoroscopy mode shows the real-time virtual catheter position and orientation from electromagnetic (*EM*) tracking in both a real-time fluoroscopic image (anteroposterior view) and a reference image at an orthogonal angulation (lateral view). **3,** Mode 3: 2D fluoroscopy mode shows real-time virtual catheter position and orientation from EM tracking in both anteroposterior and lateral views as well as an incorporated EM assisted navigation feature. **4,** Mode 4: Three-dimensional (*3D*) virtual model of the aneurysmal phantom (anteroposterior and lateral views) shows the virtual catheter position and orientation from EM tracking.

one for each part of the triaxial telescoping system: guidewire, MRC leader, and MRC sheath.

An EM field was generated by the Aurora Window Field Generator (NDI Northern Digital Inc, Waterloo, Ontario, Canada), which was placed under the angiography table. Meanwhile, a processor relayed the signals from the source and the sensors to track the sensors in the 3D space.

The current experiment used the same rigid fluid-filled aortic aneurysmal phantom that was used for our pilot study.[15] It consists of the aortoiliac bifurcation and the left and right renal arteries and also has a removable simulated gate oriented toward the posterior wall of the aneurysm model.

A 3D image of the phantom was generated from the cone-beam CT (CBCT) acquired using the Artis *zeego* VC21robotic angiography system (Siemens Medical Solutions USA Inc, Hoffman Estates, Ill). A virtual model of the phantom was created and sent to the EM system for coregistration. Image coregistration was achieved during the setup process by placing an EM sensor on a few known points in the phantom and manually aligning them to the virtual model obtained from the CBCT images.

Procedural tasks. Study participants were asked to navigate the MRC and cannulate two targets in the aortic aneurysm phantom: the left renal artery and the simulated posterior gate. The left renal artery was defined a priori as a simple cannulation target because its cannulation could be performed with catheter movements predominantly in a single anteroposterior plane, whereas the simulated posterior gate was defined as a complex cannulation target because its catheterization required catheter navigation in multiple planes requiring toggling between different fluoroscopic projections.

Four different visualization modes were used for each cannulation (Fig 1):

- Mode 1: Standard 2D fluoroscopy mode (control mode).
- Mode 2: 2D fluoroscopy mode showing real-time virtual catheter position and orientation from EM tracking in both a real-time fluoroscopic image (anteroposterior view) and a reference image at an orthogonal angulation (lateral view).

- Mode 3: 2D fluoroscopy mode showing real-time virtual catheter position and orientation from EM tracking in the anteroposterior and lateral views as well as an incorporated EM assisted navigation feature. This EM assisted navigation feature allows the user to define the target vessel in two orthogonal fluoroscopic views. The robotic catheter orients itself automatically toward the target; the user then only needs to advance the guidewire following this optimized predefined orientation. In addition, while advancing the robotic leader and sheath over the guidewire within the vessel ostium, the EM assisted navigation mode automatically modifies their bending and rotation according to the stress applied on them. This ensures smooth progression over the wire and avoids wire access loss (Fig 2).
- Mode 4: 3D virtual model of the aneurysmal phantom (anteroposterior and lateral view) showing the virtual catheter position and orientation from EM tracking. It was also possible to rotate the two virtual views in any 3D direction.

To minimize bias resulting from learning a process, we randomly assigned the order of visualization mode and cannulation for each user. Standard X-ray fluoroscopic imaging was always available during navigation, regardless of visualization mode.

Performance measure. Success was defined as positioning the distal tip of the robotic sheath beyond the origin of the target and was verified by fluoroscopic imaging.

The primary variable measured was the fluoroscopy time needed to successfully cannulate the target. The secondary variable was the time needed to perform the task, recorded as cannulation time. In addition, to assess the catheter movement consistency and efficiency, we used the EM tracking system to calculate the number of catheter submovements from recorded positions of the tip sensor in the distal catheter at a 30-Hz frequency. This metric evaluates the smoothness of the catheter motion.[12,13] Movements are thought to consist of a set of submovements that can be extracted from the movement speed profile. This kinematic metric is a count of the number of submovements that are required to complete the task. Fewer numbers of submovements indicate a smoother catheter movement.

Finally, we used the recorded positions of the tip sensor from EM tracking system to calculate the number of catheter turns: a turn was defined as change of $>150°$ between two velocity vectors within a catheter movement direction. The number of changes in direction can be interpreted as a measure of the difficulty of task completion.

Statistical analysis. For each cannulation task, fluoroscopy and cannulation times for the standard fluoroscopy mode (mode 1) were compared to the average of the three modes using EM tracking (modes 2, 3, and 4) using a Student *t*-test. To evaluate the new EM assisted navigation feature, a subgroup analysis was performed comparing the results of mode 3 to mode 2 using a Student *t*-test. A mixed-design analysis of variance was used for analyzing the between-subject effect of level of expertise.

To evaluate the quality of the endovascular navigation using number of submovements as a kinematic metric, the total cannulation task was subdivided into (1) wire cannulation only, using the 3D coordinates of the EM sensor located at the extremity of the guidewire, and (2) leader cannulation over the wire, using the 3D coordinates of the EM sensor located at the distal tip of the MRC leader. Comparisons between mode 1 and modes 2, 3, and 4 and between mode 2 and 3 were assessed using a Student *t*-test.

Finally, a Student *t*-test was used to compare the number of catheter turns for both cannulation tasks using the standard 2D fluoroscopy visualization mode to assess quantitatively the difference of complexity between left renal artery and simulated posterior gate cannulation.

RESULTS

The 18 users in this benchtop study successfully cannulated the two targets with the EM-tracked guidewire (100%) and robotic catheter (98.1%). Wire access established across the left renal artery target was lost in two instances while the robotic catheter was driven over the wire, during mode 2 and 3 each.

Cannulation and fluoroscopy times. Cannulation and fluoroscopy times for both targets across all four modes are summarized in Table I. For the left renal artery target, mean cannulation times were 2:41, 2:34, 2:15, and 2:04 (minutes:seconds) for modes 1, 2, 3, and 4, respectively, and mean fluoroscopy times were 133, 22, 15, and 5 seconds, respectively. For this simple cannulation target, the use of EM tracking modes (modes 2, 3, and 4) significantly reduced the fluoroscopy time ($P < .001$) but did not show any difference in the cannulation time ($P = .252$) compared with standard fluoroscopy (mode 1).

For the posterior gate target, mean cannulation times were 4:22, 2:35, 1:29, and 2:09 (minutes:seconds), respectively, for modes 1, 2, 3, and 4, and mean fluoroscopy times were 205, 6, 3, and 2 seconds, respectively. For this complex cannulation target, the use of EM tracking modes significantly reduced cannulation and fluoroscopy times compared with the standard fluoroscopy mode ($P < .001$ and $P < .001$, respectively).

Evaluation of EM assisted navigation feature. Results of a subgroup analysis comparing mode 2 to mode 3 showed that the use of the EM assisted navigation feature significantly reduced the cannulation time for

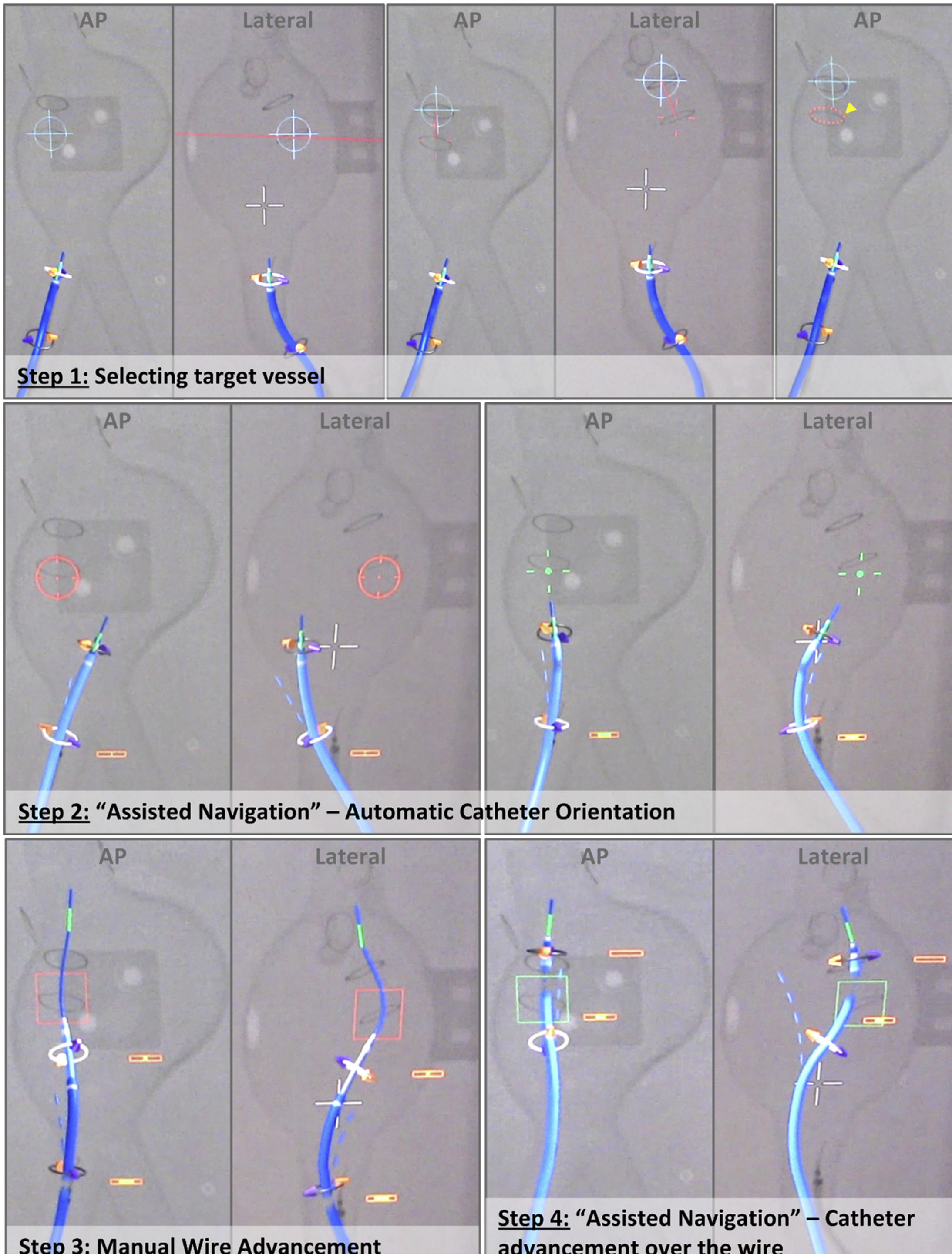

Fig 2. Detailed representation of the electromagnetic (EM) assisted navigation feature. Step 1: The user defines the location of the targeted ostium in an anteroposterior (*AP*) view and lateral view, the orientation of the vessel in AP and lateral views, and finally, the size of the ostium (*arrowhead*). Step 2: The *red target* on the vessel ostium indicates that the catheter's orientation is not optimal to catheterize the predefined ostium. While the user presses a button, the robotic catheter orients itself automatically toward the ostium (the *red target* becomes *green*). Step 3: The user only needs to advance the guidewire following this predefined optimized path to catheterize the vessel. The *red box* on the wire indicates that the catheter's bending and rotation are not optimal to advance it safely over the wire. Step 4: While advancing the catheter over the wire, the assisted navigation automatically modifies catheter bending and rotation to ensure smooth progression, avoiding loss of wire access (the *red box* becomes *green*).

Table I. Average fluoroscopy and cannulation times for both cannulation tasks and for each visualization mode

Variable	Mode 1	Mode 2	Mode 3	Mode 4	*P* values[a]: Mode 1 vs 2, 3, and 4	*P* values[a]: Mode 2 vs 3
Left renal artery						
Fluoroscopy time, seconds	133.4	21.7	14.8	4.7	<.001[b]	.400
Cannulation time, minutes:seconds	02:41	02:34	02:15	02:04	.252	.329
Posterior gate						
Fluoroscopy time, seconds	204.6	5.8	2.7	1.6	<.001[b]	.133
Cannulation time, minutes:seconds	04:22	02:35	01:29	02:09	<.001[b]	.002[b]

[a]Comparisons between mode 1 and the average of modes 2, 3, and 4, as well as between modes 2 and 3, were made using a Student *t*-test.
[b]Statistically significant ($P < .05$).

the complex target cannulation compared with the standard 2D EM mode (2:35 vs 1:29; $P = .002$) (Table I).

Catheter movement quality evaluation using kinematic metrics. Graphic representation of the catheter pathway, extracted from the coordinates of the EM sensor for one user while cannulating the complex posterior gate, is illustrated in Fig 3. Detailed kinematic metric results for each cannulation task and visualization mode are summarized in Table II.

For guidewire cannulation, the use of EM tracking significantly improved the number of submovements while cannulating both the left renal artery ($P = .019$) and the simulated posterior gate ($P < .001$). The assisted navigation feature (mode 3) also significantly reduced the number of submovements compared with the standard 2D EM mode (mode 2) for the left renal artery cannulation ($P = .021$).

For robotic catheter leader cannulation over the wire, there was no significant difference in number of submovements between the four visualization modes.

Comparison between the level of expertise in endovascular and robotic navigation. Among all cannulation tasks and visualization modes, there were no statistically significant differences between beginners, intermediates, and experts in standard endovascular skills. There was a significant difference between beginners, intermediates, and experts in robotic navigation with respect to fluoroscopy time ($P = .008$).

Assessment of complexity of both cannulation tasks. Irrespective of EM tracking, analyzing data from standard 2D fluoroscopy mode (mode 1), the number of catheter turns for the left renal artery cannulation and the simulated posterior gate cannulation were 67.7 and 171.2, respectively ($P < .001$), confirming that the posterior gate cannulation was significantly more complex than the left renal artery cannulation.

DISCUSSION

The results of this study confirmed the findings from a pilot study: incorporation of EM tracking on flexible robotic catheters provides better real-time 3D orientation and significantly reduces cannulation and fluoroscopy times during complex vascular target cannulation. In addition, the present in vitro study, including data collected at 30 Hz from a larger user sample (18 vs 6 users initially), showed that the use of EM tracking also significantly reduces fluoroscopy time when cannulating a simple target, without significant changes in cannulation time.

It is inarguable that exposure to ionizing radiation during endovascular procedures has both short- and long-term effects to patients and surgeons. Therefore, diligent efforts in favor for radiation awareness, radiation safety training, and adapting novel technologies to reduce radiation in the hybrid operating room are recommended.[16] Similar EM tracking technology has been shown to add clinical value in various other specialties[11-13,17,18] and has a potential capability of enabling remote catheter manipulation in a virtually radiation-free environment in the future. This can significantly reduce radiation usage during endovascular procedures.

In this study, we evaluated a newer feature: the EM assisted navigation feature (in mode 3), which offers a novel concept in flexible endovascular robotics enabled by EM tracking technology. As a first step, the user electronically identifies the target vessel ostium and size in two fluoroscopic orthogonal views. Then, the system transforms this information from the X-ray image coordinate space to the EM coordinate space, using manual registration of a virtual model of the phantom generated from CBCT images, as described earlier.[15] The assisted navigation feature automatically orients the catheter tip to the target vessel ostium defined in the fluoroscopic images, which ultimately enables wire cannulation. Furthermore, it semiautomatically maintains the robotic catheter position during navigation over the wire. This enables catheter advancement without the risk of losing wire access from the cannulated vessel. The EM assisted navigation feature takes the robotic navigation from a master/slave concept to real automation. The user still must advance the robotic catheter, which guarantees

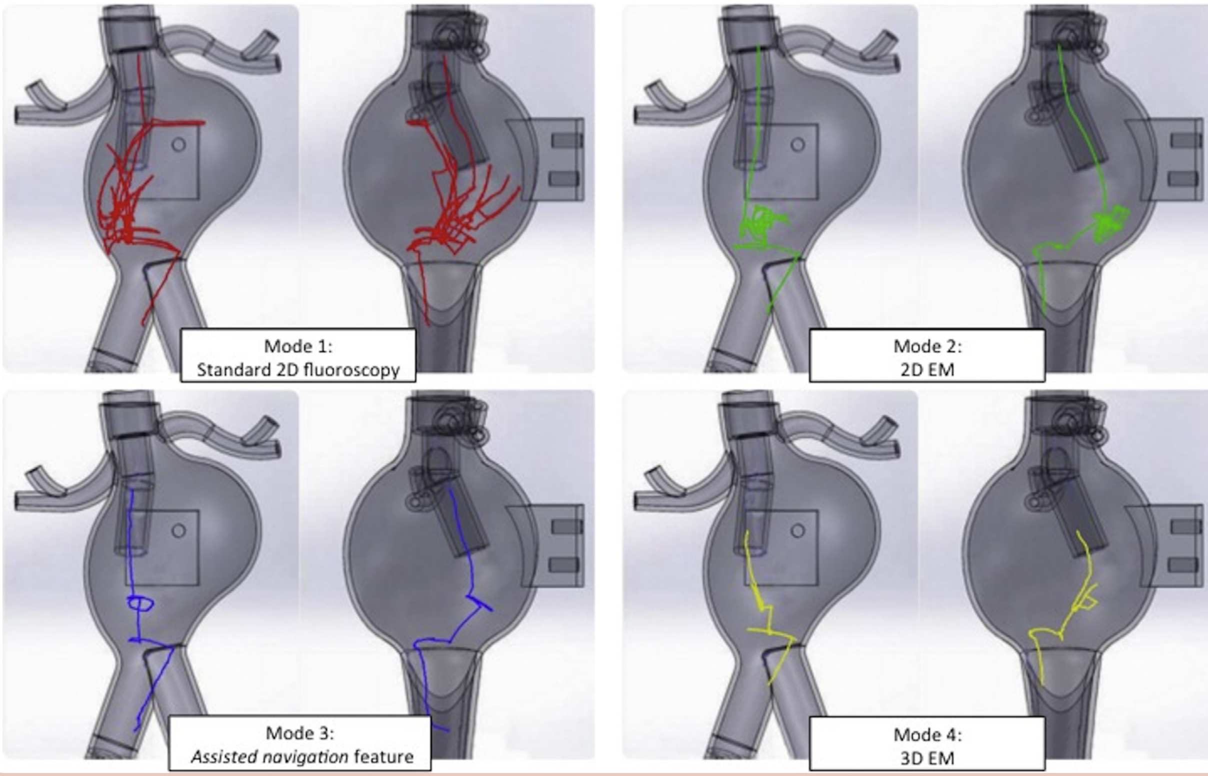

Fig 3. Representation of the trajectory of the luminal tip sensor in the model from electromagnetic (*EM*) tracking when one expert user is cannulating the simulated posterior gate. For each mode, the anteroposterior view is on the *left*, and lateral view is on the *right*. *2D*, Two-dimensional; *3D*, three-dimensional.

Table II. Mean kinematic metric results for each cannulation tasks and visualization modes

	Submovements				*P* values[a]	
Task	Mode 1	Mode 2	Mode 3	Mode 4	Mode 1 vs 2, 3, and 4	Mode 2 vs 3
Left renal artery						
Guidewire cannulation	24.056	19.222	13.444	16.222	.019[b]	.021[b]
MRC leader cannulation	5.034	5.463	4.509	5.065	.978	.267
Posterior gate						
Guidewire cannulation	37.500	14.889	9.206	12.389	<.001[b]	.069
MRC leader cannulation	5.943	8.511	4.940	4.400	.995	.143

MRC, Magellan Robotic Catheter (Hansen Medical, Mountain View, Calif).
[a]Comparisons between mode 1 and the average of modes 2, 3, and 4 as well as between modes 2 and 3 were made using a Student *t*-test.
[b]Statistically significant ($P < .05$).

the ability to keep manual control and verification during each procedural step.

The current experiment could overcome several limitations of our first pilot study. We used a modified 0.035-inch guidewire that allowed us not only to perform a more realistic cannulation procedure but also to monitor and study its precise trajectory and bending degree thanks to the incorporated EM sensor. We changed the 3D coordinates recording of all sensors from 5 Hz to 30 Hz, allowing more accurate and powerful analyses of their trajectories.

Finally, increasing the user number to 18 participants with different endovascular and robotic skills could increase the power of the statistical analysis and show an additional significant difference between the visualization modes regarding the simple cannulation task as well as allowing a better subgroup analysis between different skill levels.

Although our pilot study did not show any significant difference between beginners, intermediate, and expert users, the current experiment did highlight a significant difference in fluoroscopy time and catheter motion quality between different robotic skills. Interestingly, and as found in a previous work, there were no changes regarding the level of expertise in standard endovascular navigation.[19]

The in vitro nature of our study remains one major limitation. In the most recent animal study, the accuracy of EM registration reached a mean target registration error of 4.18 mm.[14] Our next step will be to conduct a similar cannulation experimentation in a porcine model to assess how this mean error will affect our results and also to evaluate the benefit of EM navigation with respect to contrast agent usage.

CONCLUSIONS

The results of this larger study confirm the value of combining 3D control and 3D navigation to improve safety and efficiency of endovascular procedures. This association between flexible robotics and EM guidance might be the first step toward fluoroscopy-free endovascular procedures. In addition, the assisted navigation feature turns the robotic master/slave concept into real automation and shows promising results in further reduction of procedure time and improvement of catheter motion quality.

AUTHOR CONTRIBUTIONS

Conception and design: AS, PC, MO, AL, JB
Analysis and interpretation: AS, BK, PC, MO, JB
Data collection: AS, BK, NV, SW
Writing the article: AS, PC, JB
Critical revision of the article: AS, BK, PC, NV, SW, MO, AL, JB
Final approval of the article: AS, BK, PC, NV, SW, MO, AL, JB
Statistical analysis: AS, BK, MO
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Overall responsibility: JB

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