Simultaneous Tracking of Catheters and Guidewires: Comparison to Standard Fluoroscopic Guidance for Arterial Cannulation

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WHAT THIS PAPER ADDS

In vitro evaluation of an innovative three-dimensional electromagnetic navigation platform, the principal peculiarity of which is the real-time tracking of both guidewires and catheters to guide endovascular procedures with a reduced X-ray dose and contrast medium injection.

Objectives: The purpose of this in vitro study was to clinically assess the feasibility of a three-dimensional (3D) electromagnetic (EM) navigator, including sensorized catheters and guidewires, to determine any reduction in radiation dose and contrast medium injection.

Methods: The study was performed using a navigator prototype developed at the EndoCAS center. The system includes catheters and guidewires simultaneously tracked with an EM localizer (Aurora, Northern Digital, Waterloo, Canada). Tests were performed on a commercial abdominal aortic aneurysm model. Fifteen operators were asked to cannulate renal arteries using the conventional fluoroscopic guidance and the EM navigator without fluoroscopic support. Each trial was video-recorded and analyzed for timing and success of completing the cannulation task by two blinded and independent observers. Performances were also qualitatively evaluated using the Imperial College Endovascular Cannulation Scoring Tool (IC3ST). Moreover, a questionnaire was administered to participants to evaluate the navigator potentialities.

Results: Quantitative analysis results show no significant difference between the fluoroscopic and EM guidance regarding the total procedure time (median 2.36 minutes [interquartile range {IQR} = 1.26–4.7) vs. 2.95 min [IQR = 1.35–5.38], respectively; $p = .93$); number of total hits with catheter/guidewire tip to vessels wall (median 5.50 [IQR = 2.00–10.00] vs. 3.50 [IQR = 2.50–7.00], respectively; $p = .65$); and number of attempts at cannulation (median 4.0 [IQR = 2.00–5.00] vs. 4.0 [IQR = 2.00–5.00], respectively; $p = .72$). Moreover, there was no significant difference between the IC3ST score obtained using the EM navigator and the traditional method (average 22.37 [STD = 7.95] vs. 21.58 [STD = 6.86]; $p = .92$). Finally, questionnaire results indicate a general agreement concerning the navigator usefulness, which clearly shows the positions of instruments inside the 3D model of the patient's anatomy. Participants also agreed that the navigator can reduce the amount of contrast media delivered to the patient, as well as fluoroscopy time.

Conclusions: This work provides proof of concept that simultaneous EM navigation of guidewires and catheters is feasible without the use of live fluoroscopic images.

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INTRODUCTION

Traditional fluoroscopy-guided endovascular procedures have several limitations, including exposure of the patient and clinical staff to ionizing radiation and the use of nephrotoxic contrast medium. Moreover, convectional C-arms provide only bi-dimensional images and the consequent lack of depth perception makes it difficult for the surgeon to estimate the spatial relationships between the endovascular instruments (e.g., catheters and guidewires) and the patient's anatomy. As a result, in cases of difficult angulations and tortuous anatomies, even a conceptually simple task, such as vessel cannulation, can become challenging and time-consuming, thus requiring prolonged fluoroscopic exposure time and the injection of large volumes of contrast medium.

In an attempt to overcome some of the aforementioned limitations and reduce the perceptual difficulties due to the

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lack of depth perception, multimodal imaging strategies have been developed. For example, live fluoroscopic images containing the real-time information on interventional devices position can be registered with a three-dimensional (3D) model of the patient anatomy, acquired intraoperatively (with a 3D rotational angiography [3DRA] or an X-ray/magnetic resonance (XMR) system) or from a previous scan.[1–4] The resulting fused images provide detailed 3D information regarding the vascular morphology and pathology; moreover, the amount of contrast agent can be potentially reduced, as vascular structures can be visualized thanks to the initial 3D model, without injecting additional contrast medium. Despite these advantages, during the procedure surgeons still have to rely on fluoroscopic images to guide the instruments.

Recent studies have attempted to reduce also the intraprocedural radiation exposure by monitoring the instruments position without an X-ray imaging system. For example, methods have been studied to track catheters and guidewires in the MR environment;[5] but, besides the technical difficulties related to the instrument tracking, these MR-guided techniques are limited by the lack of a MR-compatible instrumentation with proper mechanical characteristics.

Finally, new techniques have been developed to partially replace fluoroscopic guidance with systems based on the integration of preoperative radiological images and electromagnetic (EM) tracking technology. For example, in 2004, Pujol et al.[6] developed a navigator based on the registration of preoperative computed tomography (CT) images, two-dimensional US data, and the EM tracking of a modified catheter. In another major study, Sidhu et al.[7] evaluated the feasibility of an EM-based approach to arterial cannulation using the StealthStation Guidance System (Medtronic, Louisville, CO, USA) to display the position of the tip of a sensorized guidewire within a 3D model of the vascular anatomy. This latter study confirmed previous findings and contributed additional evidence suggesting how the EM technology might offer potential benefits in the execution of surgical tasks and reducing the fluoroscopic dose. Despite these promising results, all the existing systems manage to track either the guidewire distal part or the catheter tip; thus, they still rely on fluoroscopy.

Results obtained by Cochennec et al.,[8] for example, suggest that relying solely on the StealthStation Guidance System to track the guidewire, the performance of operator is lower than with the traditional fluoroscopic guidance. The simultaneous tracking of both the guidewire and the catheter is, in fact, paramount for an optimal and safe execution of endovascular tasks and thus to achieve better outcomes.

For this reason, we developed, in 2012, an EM system that allows the operator to track, in real time, the guidewire and the catheter, and to reconstruct the distal curvature of the latter.[9] The system was evaluated in vitro during 70 targeting trials and obtained an overall accuracy of 1.2 ± 0.3 mm. The aim of this study is to further prove the in vitro efficacy of the developed navigator by comparing EM navigation with standard fluoroscopy for arterial cannulation, a typical endovascular task.

MATERIALS AND METHODS

EM navigator prototype

The navigator prototype includes sensorized catheters and guidewires simultaneously tracked with the NDI Aurora (Northern Digital, Waterloo, Canada) EM localizer and allows the operator to follow their movements inside a 3D map of the patient's anatomy extracted from 3D radiological images (e.g., preoperative CT or intraoperative 3DRA).

In particular, two NDI Aurora sensor coils (5 degrees of freedom [DOF], 0.5 mm diameter $\times$ 8 mm length) are used to track 5-F cobra-shaped catheters (Fig. 1), while a single coil (5 DOF, 0.3 mm diameter $\times$ 12 mm length) is employed to sensorize ad hoc-made 0.035-inch guidewires (Fig. 2).

Thanks to a calibration procedure detailed in a previous publication,[9] the two sensors embedded in the catheter enable the calculation of the catheter tip position, orientation of the tip axis (A1), and, finally, orientation of the catheter axis (A2) in correspondence to the second sensor. Moreover, from A1 and A2, it is possible to infer the deformation of the catheter distal part (the tract between the two sensors).

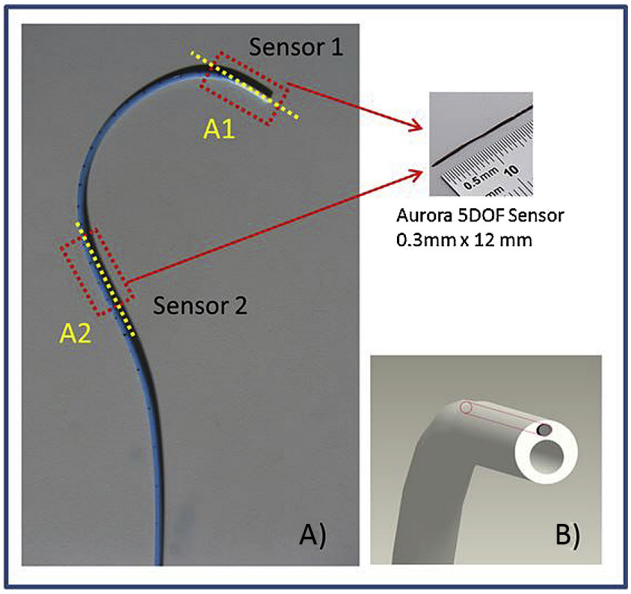

Figure 1. A sensorized 5-F cobra catheter. The catheter is made modifying a steerable angiographic catheter, the Orienter from Angiologica (S. Martino Siccomario, Pavia, Italy). The Orienter has two lumens: one operative and the other for the steering cable. For our particular application, the catheter distal portion is thermoformed to have a cobra-shaped tip, the steering cable is removed and two Aurora sensors are inserted within its lumen (A). Sensors positions are highlighted in red: the axes of the coils are aligned with that of the catheter operative lumen. More particularly, one sensor is positioned at the catheter tip (B), while the other, which provides the sixth degree of freedom, is positioned few centimeters below the first coil to acquire information about the curvature of the catheter distal part.