Endovascular robotics

The current state and the future direction

Alexander Rolls Specialist Registrar in Vascular Surgery, London Deanery

Celia Riga Consultant Vascular Surgeon and Clinical Senior Lecturer, Imperial Vascular Unit, Imperial Healthcare NHS Trust, London

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The use of endovascular robotic technology has attracted physician interest internationally, with more than 15 centres worldwide using the commercially available Magellan™ (Auris Surgical Robotics, San Carlos, CA, US) system. This article provides a brief description of the system and outlines its trajectory from pre-clinical stages to translation into clinical application and examines some of the challenges of this process.

In essence, the Magellan™ is a remotely steerable catheter system that is based largely on the original Sensei™ platform but with significant modifications. Its key components are a 6-F leader catheter, which affords enhanced manoeuvrability by means of 180-degree multidirectional articulation, and 9.5-F outer sheath that confers an additional 90-degree multidirectional articulation. Both of these components form the Northstar™ catheter (Auris Surgical Robotics, San Carlos, CA, US), which is controlled by the operator from a remote workstation situated outside the operating room, and away from the radiation source (Fig 1). Catheter-shaping and manipulation is

achieved by orthogonal pull-wires controlled by the remote catheter manipulator, which in turn receives input from the physician workstation. The workstation itself displays active fluoroscopic imaging with virtual overlay of the catheter. The system offers full rotational capability and independent torque control at the tip. Additionally, the remote manipulator permits automated insertion, retraction and rotation of conventional 0.018 and 0.035 hydrophilic wires.

The first clinical application of the Sensei™ system in the peripheral vascular setting was reported in 2009,¹ for contralateral gate cannulation in infra-renal endovascular aneurysm repair (EVAR). Prior to this, a series of robust pre-clinical studies on high-fidelity pulsatile phantoms involving more than 30 experienced interventionalists demonstrated enhanced navigational features. These include overall reductions in target vessel cannulation times, reduced contact with the arterial wall, reduced overall catheter tip motion with economy of movement, and improved catheter stability within target vessels for efficient wire and device exchange.²⁻⁴ Furthermore, at least in

Figure 1 Robotic workstation **Figure 2** Robotic right renal artery cannulation during fenestrated endovascular aneurysm repair (FEVAR).

the pre-clinical setting, robotic technology appears to flatten the learning curve for complex cannulations.⁵ In practice, it is evident that the technology confers advantages to the surgical team. With the workstation situated outside the operating theatre, radiation exposure is negligible during phases of the procedure that involve robotic manipulation. The current literature describes the use of endovascular robotic technology across an impressively diverse range of clinical applications in various vascular beds, while at the same time documenting the safety of this technology.

Following on from the initial report of its use in infra-renal EVAR, the Vascular Unit at Imperial College used the Magellan™ system for complex fenestrated endovascular aneurysm repair (FEVAR).⁶ Conventionally, target vessel cannulation and stenting during FEVAR requires advanced endovascular skills and can be time-consuming, particularly if there is misalignment of the graft fenestration with the target vessel ostium or partial obstruction of the fenestration by metal struts. Furthermore, stability of the catheter within the target vessel is crucial for wire exchanges and bridging stent deployment. Failure to successfully cannulate the target vessels can have catastrophic consequences.⁷ In the case described by Riga and colleagues,⁶ target vessel catheterisation was achieved within 3 minutes, and the stability of the robotic catheter facilitated rapid wire exchange (Fig 2). Cochenne and colleagues describe a larger series of 37 attempted renal and visceral target vessels in 15 patients undergoing FEVAR using the robotic technique and report a success rate of 81%, with a mean cannulation time of 4.3 minutes and no robot-related complications.⁸

On the other end of the clinical spectrum, the robotic system has been used to successfully access small and tortuous target vessels during uterine artery embolisation. Failure to achieve target vessel cannulation in this procedure is frequently due to challenging anatomy.^{9,10} Specifically, the leader catheter's ability to bend up to 180 degrees, while maintaining relative stability, allows for ipsilateral puncture of the common femoral artery and navigation into the acutely angled origin of the internal iliac artery. Fine

adjustments of the leader catheter's tip were used to direct and deliver micro-catheters into the uterine arteries.

The system's versatility was further demonstrated by Bismuth and colleagues, who conducted a study that focused on the use of the catheter for navigation of the iliac and superficial femoral arterial systems.¹¹ Using conventional techniques, accessing the superficial femoral artery via the contralateral groin can be challenging if the aortic bifurcation is more acutely angled. Furthermore, trackability of conventional endovascular tools when crossing contralateral distal or heavily calcified superficial femoral lesions can be limited owing to angulation of the catheters as they cross over the bifurcation.

In the study mentioned above, inherent robotic catheter stability facilitated successful crossing of all contralateral target lesions. Catheter stability, in endovascular terms, refers to the ability of a guiding catheter to remain in position within a target vessel during wire exchanges, and is particularly relevant during stiff wire advancement, because the tensile strength of the wire can force the catheter out of the target. It also refers to the ability of the catheter to push past tight stenotic lesions without deforming or kinking. Two case reports highlight this particular feature of the robotic platform. In the first report, the authors describe its use to cross a kinked renal bridging stent following complex aortic repair, which was not achievable using conventional techniques.¹² In another report, Schwein and colleagues describe the use of the robotic catheter to enter the space between the iliac limb of

an EVAR stent-graft and the arterial wall to access the aortic sac and embolise a back-bleeding vessel.¹³ This would have been hard to achieve with a conventional catheter owing to limited stability and trackability. Other reports describe the use of the system in vena cava filter retrieval,¹⁴ stenting of a tight pulmonary artery stenosis,¹⁵ retrieval of a foreign body within the pulmonary arterial tree,¹⁶ and coil embolisation of an ascending aortic pseudoaneurysm.¹⁷

Although these clinical reports certainly illustrate the feasibility and potential advantages of robotic navigation platforms across a range of clinical scenarios, clinical trial data is lacking

clear potential to translate into clinical benefit. Duran and colleagues conducted a randomised controlled trial of conventional versus robotic visceral, renal, and lower extremity cannulations and found significantly reduced traumatic lesions in the robotic arm of the trial on histopathological evaluation. Embolisation of atheromatous debris during endovascular intervention is a well-recognised phenomenon and is caused by plaque disruption during wire manipulation or stent deployment. The use of robotic catheters in the aortic arch during thoracic endovascular aneurysm repair (TEVAR) has been shown to produce fewer embolic events in the brain when compared with conventional tech-

numbers of endovascular cases during the course of a professional lifetime. However, the patient is still exposed to radiation and contrast media, and further work is required to integrate novel imaging strategies with the robotic platform. Image fusion typically involves combining preoperative CT volumes with intra-operative cone-beam CT (CBCT) to provide an intra-operative 3D image overlay on the fluoroscopy.²¹

Tystad Lund and colleagues have shown, using CBCT fusion techniques on a silicone aortic phantom, that it is possible to use electromagnetic tracking (EM) to localise catheters within the 3D phantom overlay, negating the need for intra-operative fluoroscopy.²² A further report has shown that it is possible to use EM techniques to track the robotic catheter both in bi-plane fluoroscopic imaging and in 3D reconstructions.²³ Modification of the catheter tip with an electromagnetic sensor allowed for EM-derived catheter positions to be superimposed on the fluoroscopic imaging in real-time. Another paper by the same group has shown that it is feasible to simultaneously combine the robotic system with a standard fusion imaging system (syngo DynaCT, Siemens Medical Solutions USA Inc).²⁴ Given the findings described above, it would appear feasible to combine the robotic platform with electromagnetic tracking and fusion imaging to completely obviate the need for active fluoroscopy. However, clearly further work is required to optimise the accuracy of the fusion overlay²⁵ and integrate the systems into a user-friendly package. Furthermore, depending on the case performed, the radiation burden incurred by the CBCT acquisition ranges between

The potential for zero-radiation procedures with the aid of robotic technology is certainly an attractive proposition for surgeons who will be performing increasing numbers of endovascular cases during the course of a professional lifetime

and this may be in part because of the recognition by clinicians that the routine use of the robotic platform in straightforward index cases may not be cost-effective. Further research to understand the merits of robotic catheter technology has focused on the potential for 'minimal footprint' intervention. Rafii-Tari have shown, using a high-fidelity flow model mounted onto a force sensor, that contact forces applied to the walls of the aortic model are significantly reduced with robotic technology.¹⁸ Subsequent *in vivo* studies have shown that this has

techniques, as measured by trans-cranial Doppler (TCD) in a recently published clinical series.¹⁹

Currently, robotic navigation is still performed using standard fluoroscopic imaging. A recent report demonstrates that even small amounts of radiation are sufficient to induce DNA damage in surgeons who perform endovascular aneurysm surgery.²⁰ The potential for zero-radiation procedures with the aid of robotic technology is certainly an attractive proposition for surgeons who will be performing increasing

4% and 32% of the total effective dose in complex cases.²¹

There is an ongoing need to develop and validate methods for the assessment of technology benefit that are more refined than traditional outcome measures in surgery. Although clinical evaluation of this technology is still at its early stage, an increasing number of reports highlight its use and benefit where conventional techniques have been attempted and failed as a result of anatomical complexity.^{12,15,16} Imperial College has used the system across a variety of procedures, including lower-limb and iliac intervention, EVAR, FEVAR, TEVAR, carotid intervention and management of complex endoleaks. This constitutes a total of 111 patients and 145 peripheral arterial targets, with a technical success rate of 97%, and 100% success in terms of device or embolic agent delivery. Thirty-day mortality was 1.8% across all patients and was unrelated to the use of robotic technology; one patient died from sepsis whereas another from a myocardial infarction. Most importantly, 16% of cases consisted of conversions from manual to robotic techniques, due to difficulties with

standard endovascular cannulations, and a further 15% were performed robotically as they were deemed too high-risk for a conventional approach.

To conclude, since the pre-clinical studies first investigated the use of catheter technology for endovascular interventions, clinical applications have expanded and diversified significantly. Despite the lack of trial data, both pre-clinical and clinical studies demonstrate clear improvements in efficiency and accuracy of intraluminal navigation. Additionally, recent experimental work suggests that robotic technology can be integrated with advanced localisation and imaging techniques, although further work in this area is required to deliver zero-radiation procedures. It is expected that reductions in market price and further industry-supported research and development, coupled with robust registry data will lead to wider adoption and improved outcomes.

The Commission on the Future of Surgery will be publishing its findings in autumn. Look out for updates on the RCS website to see what innovations will change surgical care in the next twenty years.

<http://bit.ly/2KWqiyz>

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