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RESEARCH LETTER

Preclinical Feasibility of Robotic Peripheral Endovascular Interventions: A Cadaveric Study

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Recent studies have suggested a potential increased carcinogenic risk associated with chronic low dose radiation exposure, prompting calls to further reduce radiation exposure among endovascular interventionists.[1,2] Previous endovascular robotic systems have demonstrated a successful reduction of operator radiation exposure.[3,4] The SENTANTE endovascular robotic system (UAB Inovatyvi Medicina, Kaunas, Lithuania) is a new robotic system, designed to perform endovascular procedures robotically, including the placement of interventional devices (https://sentante.com/).

The system's bedside unit can manipulate three conventional endovascular devices simultaneously, including 2 — 8 F catheter based devices and one 0.014", 0.018", or 0.035" guidewire. The bedside unit is controlled by the operator at the remote workstation, with two conventional catheters and a guidewire as the user interface that provides haptic feedback. The movements with the interface devices made by the physician are replicated by the bedside unit to the devices inside the vessels. The force applied by the bedside unit depends on the force delivered at the workstation.

A preclinical cadaveric study was conducted to evaluate the system in performing peripheral endovascular interventions across various anatomic locations. Donors had provided their consent, and the study was performed in accordance with the Anatomy Act (Scotland/UK) (1987) and the Human Tissue Act (Scotland) (2006).

Three Thiel embalmed human cadaveric models (two men and one woman; aged 51, 63, and 66 years) were used, with vascular perfusion to enable angiography and maintain lifelike tissue consistency. In two models, procedures were performed via right femoral antegrade access, including popliteal artery percutaneous transluminal angioplasty (PTA), below knee PTA, and below knee artery stenting. In two models (one model underwent six procedures), procedures were performed via left femoral retrograde access, including left iliac artery stenting, left renal artery stenting, and right renal artery upper branch embolisation. Procedures were performed using a mobile C arm and a floating table. All procedures were performed twice (once by a vascular surgeon and once by an interventional radiologist, on two different models), with the operator seated at a workstation positioned behind a lead shield, after 30 minutes of onsite training. A range of standard endovascular devices was used, including 0.014", 0.018", and 0.035" guidewires, and 2.9 to 8 F catheters.

Technical success (balloon catheter or balloon expandable stent placement in the intended vessel and effective expansion up to nominal pressure, or implantation of embolisation materials in the intended vessel) was achieved for all 12 treatment procedures. All procedures were performed robotically without manual assistance, including PTA, stenting, embolisation, and angiography pre- and post-procedure, resulting in 0.0 mGy operator radiation exposure (Table 1). No procedural complications were observed by the operators or on subsequent core laboratory analysis, besides perforation of a small blood vessel due to inadvertent guidewire advance into a smaller branch instead of the popliteal artery, without contrast extravasation on subsequent angiography. After each procedure, both operators evaluated the systems' haptic feedback using a non-validated four point qualitative rating scale (1 = very good to 4 = inadequate). Haptic feedback was consistently rated as very good (score 1).

Previous experience with peripheral endovascular robotic interventions has been reported primarily with the Magellan system (Hansen Medical, Mountain View, CA, USA) and CorPath system (Siemens Healthineers, Erlangen, Germany).[4] These systems allowed for remote control of two endovascular devices from a control console. The Magellan demonstrated high precision and stability in a large number of cases but was ultimately discontinued. The CorPath showed clinical feasibility in peripheral and visceral interventions, and compatibility with third party endovascular devices.[5,6] Although multifactorial, broader adoption of previous endovascular robotic systems may have been influenced by the need for dedicated catheters, associated costs, absence of tactile feedback, and the need for partial manual device deployment.[3—6]

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Table 1. Procedure details and outcomes of robotic peripheral endovascular interventions in human cadaveric models.

Procedure description	Procedures − *n*	Fluoroscopy time	Operating time*	Access site	Access route
PTA popliteal artery	2	2 min 46 sec, 5 min 24 sec	16 min, 28 min	Right femoral artery	Antegrade
PTA below knee artery	2	2 min 18 sec, 3 min 55 sec	15 min, 19 min	Right femoral artery	Antegrade
Below knee artery stenting	2	2 min 34 sec, 7 min 38 sec	9 min, 15 min	Right femoral artery	Antegrade
Iliac artery stenting	2	2 min 19 sec, 10 min 39 sec	19 min, 41 min	Left femoral artery	Retrograde
Renal artery stenting	2	10 min 22 sec, 22 min 21 sec	40 min, 73 min	Left femoral artery	Retrograde
Renal artery upper branch embolisation	2	10 min 55 sec, 15 min 2 sec	39 min, 48 min	Left femoral artery	Retrograde

PTA = percutaneous transluminal angioplasty.
* Operating time was recorded from the start of the robotic procedure, after access had been gained manually.

The SENTANTE system is compatible with standard endovascular devices and allows simultaneous manipulation of three devices. Its interface uses conventional wires and catheters as input tools, which provide haptic feedback. After manual vascular access has been obtained, the endovascular procedures can be performed fully robotically. The current system is not compatible with complex endovascular devices and self expandable stents, which require manual deployment. In addition, the maximum supported catheter size of 8 F limits its applicability in aortic procedures. Potential practical limitations to implementation include system related costs, setup time, and personnel training requirements. Importantly, at present, comparative data with other robotic systems or conventional manual interventions are not available.

Limitations of cadaveric models include changes in vascular properties, and a lack of various biologically active phenomena. Future studies should assess access site related complications and further evaluate the clinical trade offs between procedural benefits, costs, and system setup time.

The endovascular robotic system demonstrated early feasibility across a range of elective peripheral endovascular procedures in a cadaveric model, including PTA, stenting, and coiling. These results support progression to clinical evaluation.

CONFLICT OF INTEREST

Authors L.D. and T.o.B. are employed by Inovatyvi medicina UAB. T.o.B. holds shares in Inovatyvi medicina UAB. C.Z. has served as a Consultant and has received research support, honoraria, and travel support from W.L. Gore & Associates, LeMaitre Vascular, Atrium Maquet Getinge Group, Artivion, and Terumo (Vascutek and Bolton). The remaining authors have no conflicts of interest to declare.

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