

Robotics in Interventional Radiology: Past, Present, and Future

Abstract

Robotic endovascular systems have been successfully used to treat a wide range of pathologies including endovascular aneurysm repairs, uterine artery embolizations, and cardiac electrophysiology ablations. Limited research suggests that the use of robotic systems may help to achieve a more accurate manipulation and increased steerability of the catheter during endovascular procedures. In addition, robotic systems have also been designed to enhance image-guided percutaneous procedures, demonstrating a potential to facilitate needle placements and guidance and diminish radiation exposure risk. There are still many limitations for the widespread of this emerging technology. More studies are needed to validate the use of robotic systems and to show meaningful clinical advantages over traditional methods as well as assessing cost-effectiveness.

Keywords: Image-guided robotic systems, interventional radiology, robotic endovascular systems, robotics

Introduction

Interventional radiology (IR) is a relatively new field with <100 years since its foundations. Although there is a previous documentation of interventional procedures, IR is born on the basis of Charles Dotter work in 1963.^[1] His pioneer labor in angioplasty and vascular radiology sets ground for the creation of a new medical specialty, IR.^[2] Since then, IR has grown rapidly and now covers a broad spectrum of procedures. An escalating role of IR has been noticeable by the increased complexity of the procedures and the enlarged range of conditions it now covers.

In contrast to open surgery, IR depends on minimally invasive approaches and therefore relies on multimodal radiological image guidance and patient anatomy for precise targeting and therapy.^[3] Improved imaging of internal structures with better and safer contrast agents has given IR a protagonist role and more demand on percutaneous peripheral vascular interventions.^[4] Compared to more invasive surgeries, IR procedures have shown to be safe and cost-effective with less complication rates, duration of hospital stays, and less recovery periods.^[5]

The adoption of novel techniques is particularly inherent to IR. Medical

robotics has produced a paradigm shift in therapy of various pathologies since the introduction of the Vinci system, the first robotic system approved by the Food and Drug Administration (FDA) in 2000, now used in general laparoscopic surgeries and minimally invasive prostatectomies.^[6] The greatest impact of robotic surgery is the increased precision and accuracy during tissue manipulation.^[7] This principle inspired research to extend the use of robotic assistance for image-guided percutaneous interventions and endovascular procedures. This paper provides an overview of the use and impact of robots in multiple domains of IR as well as a brief outline on the latest mayor technological innovations in the field.

Steerable Robotic Catheter Systems

Hansen Medical (Mountain View, California) developed two generations of robotic endovascular systems. The first one, the Sensei X robotic catheter system, is a robot with FDA approval since 2007 designed to achieve more accurate manipulation and increased steerability of the catheter during cardiovascular procedures. The Artisan Extend Control Catheter is a robotically steerable sheath manufactured to work with this system. The catheter consists of a flexible, multidirectional inner guide 11-F outer

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diameter and 8.5-F inner diameter, within a unidirectional outer guide sheath 14-F outer diameter and 11-F inner diameter.^[8] They have been used in numerous endovascular procedures. Initially, its main use was focused on cardiac electrophysiology ablation. Dello Russo *et al.* used the Sensei X™ robotic navigation system and the Artisan Extend Catheter to increase contact force during atrial fibrillation ablation with good results.^[9] Other applications have been explored for this robotic system and catheter. Technical feasibility has been demonstrated in other procedures such as endovascular aneurysm repair (EVAR), treatment of pulmonary stenosis following single-lung transplant, and stenting of right renal branch during fenestrated stent graft.^[10-12]

The next generation system developed by Hansen Medical is called The Magellan robotic system. Unlike the previous system, The Magellan robotic system was designed specifically to navigate peripheral arteries. It consists of a workstation with a control screen and the controller device where the physician has access to parameters such as torque position, catheter angulation, and rotational position.^[13] It also counts with an electromagnetic catheter manipulator and a number of steerable guide catheters. The system counts with three FDA-approved specialized catheters. They range from 50 to 102 cm in length and have outer diameters of 10, 9, and 6 Fr.^[14,15]

Stent grafting of aneurysms through endovascular approach is becoming a more frequent procedure for interventional radiologists. In the presence of challenging anatomy with tortuous iliac arteries, atherosclerosis and angulated visceral aortic segment technical difficulties may arise making the procedure more time-consuming. Available catheters have pre-made shapes and intrinsic curve design that limit maneuverability, tip control, and target access.^[16] Imperial College Endovascular Team have adapted the use of the Magellan robotic catheter steering system in phantom and porcine models.^[17,18] Later, they published a case report of a robot-assisted fenestrated EVAR procedure, demonstrating its safety and achievability.^[19] All of these works showed reduction in vessel cannulation times and instrumentation, precise positioning, and significant reduction of radiation exposure when using the robotic systems. At the moment, there are no randomized clinical trials that can corroborate any further these early findings.^[20]

The Hansen Medical Vascular Catheter Control System has been successfully used to treat a wide range of other pathologies. For example, Bismuth *et al.* used it to successfully treat iliac and femoral artery lesions. Interestingly, they also found that although the system could be used by all interventionalists regardless of their experience, a statistically significant difference in navigation time and total fluoroscopy times between experienced and unexperienced interventionalists was observed.^[21] Figures 1 and 2 show an example of an embolization of left internal

iliac artery aneurysm. Rolls *et al.* published the first in woman safety evaluation of the Magellan system with the NorthStar catheter. They successfully performed bilateral uterine artery embolization in five women noticing the robotic system may facilitate catheterization of small iliac artery divisions specially in complex anatomy.^[14] Finally, Bagla *et al.* performed 40 prostatic artery embolizations, showing that a wider range of pelvic pathologies in both men and woman can be addressed successfully and safely with robotic systems, Figure 3 shows an example of a successful robotic-assisted prostate artery embolization.

There are other commercially available remote catheter navigation systems with electromechanical technology intended for percutaneous coronary interventions and radiofrequency (RF) ablations. The Amigo remote catheter system (Catheter Precision Inc., NJ, USA) is a robotic arm with three degrees of freedom (DOF) that attaches to the electrophysiology table. Amigo is designed to adapt many commercially available catheters that are manipulated remotely, up to 30 m away from the patient. Catheters are visualized using conventional fluoroscopic techniques. The operator can produce three types of catheter movements while monitoring using standard fluoroscopic techniques: deflection, rotation, and linear motion. Khan *et al.* published a nonrandomized prospective clinical trial validating the safe and effective use of the Amigo remote catheter system for positioning a mapping catheter within the right atrium and ventricle.^[22]

The CorPath 200 and its second generation CorPath GRX (Corindus Vascular Robotics, MA, USA) are intended to assist in percutaneous coronary interventions. This complex robot is composed of a control console for the physician to control the catheter remotely and a cassette mounted on a robotic drive in the robotic arm at bedside.^[23] Weisz *et al.* published a pivot multicenter study where 164 patients underwent percutaneous intervention with the CorPath 200. The study showed technical success of 98.8% and clinical success of 97.6%. In addition, radiation exposure to the operator was reduced in 95.2% compared to traditional methods.^[24] The CathROB is also an electromechanical robotic device made to manipulate steerable electrophysiology catheters. It has a compact and lightweight design comprising a motion unit, a central unit, and a remote user interface. The system has been used by Cerenelli *et al.* in *in vitro* and *in vivo* animal evaluations with good accuracy and adequate tissue contact.^[25]

The Niobe remote magnetic navigation system and the Vdrive robotic navigation system (Stereotaxis Inc., MO, USA) are electromagnetically driven systems used to navigate especially designed catheters. Two external magnets are positioned on each side of the patient allowing movement of the catheter within three DOF. Due to these external magnets, the system is inherently incompatible with real-time use of magnetic resonance imaging (MRI)

in procedure guidance.^[26] A newer version the Niobe ES was used for catheter ablation of atrial fibrillation reducing operating and fluoroscopy times.^[27]

All of these studies suggest that robotic catheterization can provide superior maneuverability compared to traditional techniques, especially in angulated vessel segments and in unfavorable artery access. In addition, robotic systems such as the Magellan robot could avoid complications such as dissection or rupture and may expand the pathologies and patients suitable for endovascular treatment.^[28] Finally, one of the biggest benefits of the robotic-assisted systems is the ability to perform safer procedures outside the radiation zone. Rao published seven cases of transarterial chemoembolization using the Magellan robot, showing an average reduction of over 80% in radiation exposure

to the operator.^[29] Definite downsides of these systems that have not allowed their commercial availability are the increased cost with this technology. Fitting Riga *et al.* calculations, \$600,000, are needed as an initial capital to acquire Magellan robotic system. In addition, maintenance costs are around \$80,000, and each disposable robotic catheter can cost a minimum of \$1500 per catheter.^[30] This was perhaps one of the main reasons that prohibited wide adoption in the clinical community and led eventually to discontinue production of those particular robot type. The newer systems, such as CorPath GRX (Corindus Vascular Robotics, MA, USA), is yet to be evaluated both clinically and commercially. At present, there are no large cohort studies, randomized trials, or cost-effectiveness analysis that can encourage to greatly adopt this technology.

Computed Tomography-Guided Robotic Systems

Image-guided percutaneous puncturing techniques entail meticulous path planning and navigation. Adequate visualization of target by means of different image-guiding modalities such as fluoroscopy, ultrasound (US), computed tomography (CT), and MRI is crucial for the success of the intervention.^[31] In clinical practice, the interventional radiologist has to assess inherent advantages and disadvantages of each modality for correct selection and application and even consider multi-image techniques.

Percutaneous CT-guided needle interventions are common in medical practice given that they are minimally invasive procedures that can be very effective for image-guided biopsies and for therapies such as tumor ablations and infiltrations.^[32] CT-guided procedures have great benefits in terms of costs, availability, and visibility of anatomical structures specially when visualizing deep tissues.^[32,33] The success of CT and CT fluoroscopy-guided biopsies varies from 90% to 100% and 83% to 100%, respectively.^[34] Diagnostic yield and procedure outcome is dependent upon physicians' experience but also upon lesion site and anatomy. When the location of the target prompts a risk of damage to neighbor structures, there is low tolerance in needle placement errors. In cases where there is limited entry site and when access is restricted due to angulations and anatomy, an increase in patients

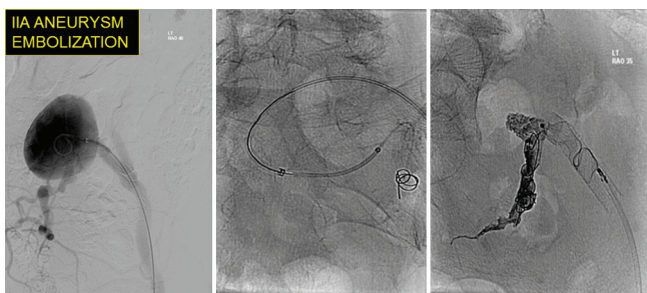


Figure 1: Embolization of left internal iliac artery aneurysm using Onyx and occlusion Amplatzer device

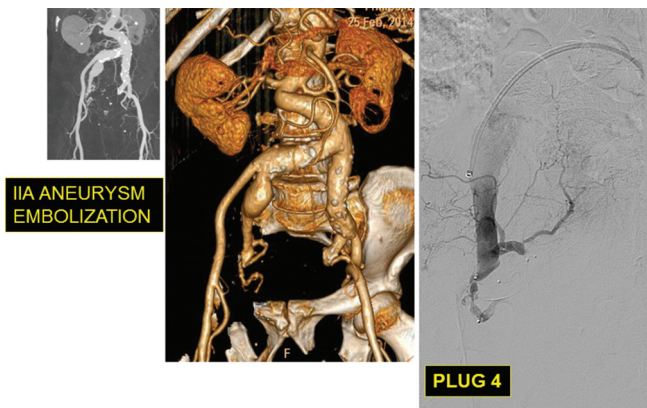


Figure 2: Embolization of right internal iliac artery using Amplatzer occlusion device

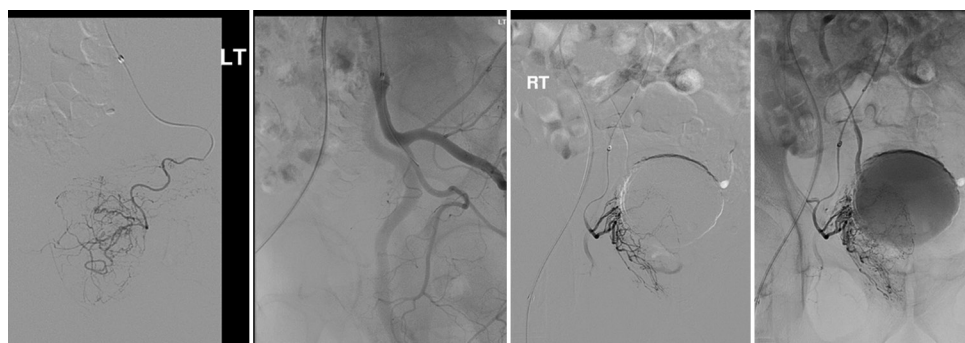


Figure 3: Robotic cannulation and embolization of bilateral prostatic arteries

and physicians' radiation exposure is a risk due to longer procedure times because of needle adjustments.^[32] CT fluoroscopy has allowed for shorter procedure times and more success rates compared to conventional CT. In both of their studies, Gianfelice *et al.* and Silverman *et al.* showed statistically significant decreased needle placement times using CT fluoroscopy.^[35,36] The setback is that CT fluoroscopy implies much higher radiation both to the patient and to the physician. Kato *et al.* calculated that a physician with continuous hand exposure could only perform four CT fluoroscopic procedures each year on the basis of an annual dose limit of 500 mSv.^[37] Although there are a number of techniques to minimize radiation exposure, robotic assistance offers to address this matters by facilitating needle placements and guidance and diminishing the radiation exposure risk.

There have been several robotic systems designed to work with CT. The AcuBot robot was one of the first, developed in the URobotics Laboratory at Johns Hopkins Medical Institutions (Baltimore, USA). The AcuBot has six DOF and it includes three previous robotic modules developed by the company: (1) the percutaneous access to the kidney (PAKY) radiolucent needle driver where the instrument would be loaded, (2) a remote center of motion that holds PAKY and is capable of needle orientation, and (3) a passive position S-arm mounted on a bridge frame. In addition, the robot is composed of (4) An XYZ Cartesian stage for positioning and (5) a user interface with controls and a two-axis joystick.^[38,39]

This robotic system was tested in a cadaveric study by Stoianovici *et al.* proving its feasibility in perispinal and facet blocks.^[38,40] The PAKY and the RCM (Remote Center of Motion) robot was tested in a phantom study showing that the angular error between the ideal trajectory to target and the actual robot's trajectory was 0.61°. Subsequently, they successfully used the robot in numerous clinical cases including several core needle biopsies, radiofrequency ablations (RF), nephrostomy tube placements and neobladder access. Although no statistical data was generated, the value of this studies is, they showed radiation exposure to the physician could be reduced and in fact it can be completely avoided. Moreover, radiation to the patient can also be diminished by avoiding continuous imaging when advancing the needle given the reliability of the robot when respiration is controlled. There is still much research to be done; the robot showed mayor limitations such as extra preparation time, issues with the RF probes, and absence of tactile feel and force feedback when handling the joystick.^[41,42]

The B-Rob I is another robotic system developed by Austrian Research Center (ARC) - Seibersdorf, Austria. together with the Departments of Diagnostic Radiology and Biomedical Engineering and Physics, Vienna Medical University. The system was developed, so it can work

with both CT scanners and US systems. This seven DOF robot is integrated to a mobile rack with a four DOF needle positioning system in a three Cartesian plane plus a rotational link component for needle orientation. The system includes an optical tracker system (Polaris, Northern Digital, Bakersfield, CA, USA) as well as the planning and monitoring software.^[39] The robot uses active joints to position the instrument, but the insertion of the needle has to be performed manually by the physician. This system was used in several phantom studies^[43,44] showing its feasibility. Nonetheless, given it was difficult to integrate in the clinic and it was not practical, a second prototype B-Rob II was designed. Martinez *et al.* used this latest prototype in a phantom model performing 21 biopsies. He attained an average needle placement accuracy of 1.8 mm (± 1.1 mm) using robotic assistance with average of 2 min 21 s per procedure.^[45]

Maurin *et al.* presented in 2008 a novel robotic system called the CT-Bot. It consists of a patient-mounted parallel structure with three DOF for position, two DOF for orientation, and an extra DOF for needle self-rotation. It has an accuracy of 5-mm position error at the tip of a 200-mm long needle.^[46] The system counts with haptic interface and ultrasonic motors that allow the needle to be held firmly throughout the procedure. Although some experiments have been conducted to show its feasibility and accuracy at object targeting, this prototype is not available commercially and had not been explored further.

The Robopsy system, introduced by Walsh *et al.* is a patient-mounted, telerobotic needle guidance and insertion system for more accurate targeting during CT-guided biopsies. Robopsy was originally designed to perform percutaneous lung biopsies. The needle is intended to be guided by the interventionist remotely while allowing simultaneous imaging. The robot counts with four DOF, two for needle orientation, one for needle gripping, and one for needle insertion and retraction.^[47] Furthermore, Seitel *et al.* developed an interface for the Robopsy that is directly integrated with the medical imaging data to provide specificity in trajectory and automatically calculate insertion parameters.^[48]

There have been other robotic systems developed, for example, the robotic IR assistance platform (MAXIO; Perfint Healthcare, Chennai, India) described by Koethe *et al.* in 2014.^[32] The iSYS Medizintechnik and its newer version the iSYS1 have been tested in phantom studies with good results.^[49] Perfint Healthcare Pvt. Ltd. holds two commercially available robotic systems. The ROBIO EX which is a CT and positron emission tomography-CT robotic positioning systems for assisted thoracoabdominal interventions and the ROBIO EZ a robotic system with 5 DOF used for needle placement during CT procedures.^[50] Zhou *et al.* used a Mitsubishi RV-E2 6 DOF (developed in the Stony Brook University, NY, USA) articulated robot

with a respiratory phase tracking to propose a robotic needle placement technique for accurately biopsying lung nodules during respiratory motion.^[51] Finally, the Institute of Robotics and Mechatronics at the German Aerospace Center in collaboration with KUKA roboter setup a third generation of torque-controlled robot called the Light Weight Robot III. It is a seven DOF robot counting with a tracking system for needle guide and registering with an angiographic C-arm.^[52]

Magnetic Resonance Imaging-Guided Robotic Systems

INNOMOTION (Innomedic, Herxheim and FZK Karlsruhe Germany and TH Gelsenkir) is a pneumatic robotic assistance platform consisting of a six DOF robot arm attached to an arch that is mounted to the patient table. The arm can be positioned according to the area of interest within the body.^[39,53] The INNOMOTION has been assessed in the clinic by Zangos *et al.* when they used this robotic system and a 1.5-T MR system to perform image-guided biopsies using a transgluteal approach in patients with suspicious prostate lesions.^[54] Kettenbach *et al.* also evaluated its feasibility when performing percutaneous biopsy, drainage, and tumor ablation within the chest, abdomen, and retroperitoneum.^[55] Since the INNOMOTION is also compatible with CT, it has been compared with other systems, finding that it is less flexible in selecting entry points compared to other robotic systems such as AcuBot or iSYS1 system. In addition, a mayor disadvantage is that it is very large, and especially for breast interventions, it is difficult to use with breast coils because of the patient's position. Yang *et al.* developed a six DOF slave robotic platform and a one DOF needle driver designed for MRI-guided breast biopsies.^[56] Park *et al.* also described an image-guided intervention robot system designed for use with the General Electric (GE) Signa HDxt 3.0 Tesla MRI system (GE Healthcare, Waukesha, Wisconsin, USA) for breast cancer patients that overcomes the space limitations in the MRI gantry.^[57]

MrBot is a six DOF robot for image-guided transperineal prostate percutaneous access. It is compatible with all MRI scanners, even the ones with the highest field strength. It is made up of electrically nonconductive and nonmagnetic materials such as plastics, ceramics, and rubbers and has especially designed motor with all electric components outside the imager room.^[58] MrBot has FDA approval for a biopsy trial that has been successfully performed in five patients with a needle target accuracy of 2.55 mm.^[59] Another robot for percutaneous interventions is The Light Puncture Robot (LPR) being developed in Grenoble. This robotic system has 5 DOF, dimensions of 15 × 23 cm and only weights 1 kg. It is compatible with both CT and MRI; therefore, it is made out of plastic and uses pneumatic actuators powered by compressed

air.^[60] Initial phantom and animal experiments have been conducted with this robotic device apparently with good reproducibility. Nonetheless, translation accuracy of the robot over the patient's body surface is only satisfactory over distances <30 mm, having an inaccurate displacement above this limit.^[61]

Ultrasound-Guided Robotic Systems

US is an inexpensive widely available technique with frequent use in clinical diagnosis and intervention. Due to the extreme operator-dependent nature of US imaging, robotic application and research in this area have been slow. Nonetheless, it is precisely because of the need of a skilled sonographer that robotic-assisted US could aid to standardize its use and make it more widely available in remote rural areas. Autonomous US imaging systems need a tracking system to measure the position of the probe. This information can be obtained through optical tracking, electromagnetic tracking, and passive encoded mechanical systems.^[62]

Boctor *et al.* used an LBM/JHU LARS 6 DOF dual-arm robot with electromagnetic tracking system equipped with torque and force sensor. This autonomous US imaging robot was tested in animal phantom to perform needle placements with a 3-mm error reported; nonetheless, no further work has been performed.^[63] Liang *et al.* proposed a real-time three-dimensional (3D) US-guided multiple core biopsy to be autonomously conducted by a 6 + 1 DOF robotic arm with a success rate of 93% in a phantom study with turkey breasts.^[64] Other autonomous robotic US imaging systems are being developed like the one by Mebarki *et al.*, a six DOF robot intended to guide 2D US probe accurately with respect to an observed object.^[65] Janvier *et al.*^[66] developed a robot prototype to provide accurate 3D US scanning of lower limb vessels.

Teleoperated US imaging has been developed to allow a skilled radiologist to remotely operate the device. The radiologist at the master site can control through a joystick or a haptic device the robot at the slave site.^[62] Real-time US image is provided for the radiologist to use for diagnostic purposes. Many ongoing projects have encouraged the development of these devices, for example, the Advanced Robotised Tele-sonography Integrated Service project by the European Space Agency.^[62,67] Other similar projects include the TERESA project to bring astronaut quality US examinations^[68] and the ESTELE^[69] and PROSIT^[70] projects for abdominal and fetal echography.

Conclusions

Although initial case studies and case reports have shown that robotic assistance has superior maneuverability in endovascular procedures, it is important to acknowledge that it will not eliminate the need for a learning curve and for an experienced interventional radiologist. Great

advances in imaging techniques and its fusion with robotic systems seem to have great promise for image-guided percutaneous procedures specially to reduce radiation exposure risk. Main limitations include lack of haptic feedback, robotic catheter compatibility with various stents and balloons, lack of smooth workflow within the angiography suite setting, and high capital and/or consumable cost. Technological refinement led by interventional radiologists in collaboration with industry, and more studies are needed to advance technological maturity and to show meaningful clinical advantages over traditional methods as well as assessing cost-effectiveness.

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Conflicts of interest

There are no conflicts of interest.

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