Chapter

Catheter Robots in the Cardiovascular System

Marton Berczeli, Peter Legeza and Alan Lumsden

Abstract

Robotic-assisted endovascular therapy is a novel approach to augment precise skill requirements while simultaneously reducing radiation exposure. The CorPath system enhances the scope of minimally invasive procedures and facilitates the interventionalists to perform procedures in the field of vascular surgery, neuro-surgery and interventional cardiology. The reason for increasing interest in the CorPath system is the ability to control these robots through wireless connection, raising the possibility for remote interventions. CorPath is currently the only commercially available endovascular robotic system. Robotic-assisted approach has a high technical success rate in the field of peripheral vascular and coronary interventions and has encouraging results regarding neurointerventions. Remote endovascular procedures may transform the future of stroke treatment in areas where distance-related time loss can affect procedural outcome.

Keywords: Robotic-surgery, endovascular robotics, radiation protection, CorPath system, remote surgery, tele-robotic

1. Introduction

Our group has a long-standing interest in catheter robotics. This began with the initial launch of Hansen robotic platform for left atrial ablation then followed the evolution of the Hansen system for peripheral interventions [1, 2]. These early studies clearly demonstrated the feasibility of navigating inside the vascular system safely and effectively and outlined some of the future directions for robotic catheter evolution: integrating into imaging, remote control, fluoro-less navigation using electromagnetic fields and autonomous movement [3]. The development of endovascular robotic catheters was seriously interrupted, when Hansen was acquired Auris, who recognized the importance of being able to navigate robotically through long thin tubes, in their case, bronchi. One real challenge of these high-tech start-up companies is the prodigious amount of capital required to develop these technologies. The Auris endobronchial navigation platform (Monarch, Auris Health Inc., Redwood, CA, USA) recently acquired by Johnson & Johnson (New Brunswick, NJ, USA) for 4 billion dollars emphasizes the promise and value which this technology can bring to the clinical area. Currently the only endovascular robot available is from Corindus (Corindus, Siemens-Healthineers Company, Waltham, MA, USA). This will therefore be extensively described in the manuscript. Corindus was recently acquired by Siemens (Siemens-Healthineers, Erlangen, Germany), heralding the real possibility that "preflight" of a robot integrated into a fused image may at last move from fantasy to reality.

2. Robotic assistance and radiation protection

The demand for minimally invasive procedures is rapidly increasing. In an endovascular era, the radiation exposure is a crucial factor while performing these procedures on a day-by-day basis. There are several techniques currently available to reduce radiation, but robotic-assisted procedures are considered a different approach. The technique's advantage is that the operator does not have to be next to the patient [4]. The operator can sit behind radiation-shielded platform or away from the operating room by wireless connection (**Figure 1**) without the need of wearing a lead apron [6]. The greatest reduction of radiation is therefore on the primary physician, but the assistants can also keep more distance from the radiation source receiving smaller amount of dose levels [7].

Figure 1.
Robotic console workstation with radiation shielding. The monitors show live fluoroscopy images and patient vitals (© Corindus Inc., used with permission) [5] .

3. Robotic systems

Table 1 demonstrates characteristics of the below presented endovascular robotic systems (**Table 1**).

3.1 Magellan system

The first endovascular robotic system was the Magellan Robotic Catheter system (Hansen Medical, Mountain View, California, USA). It was designed for cardiac ablations. It consists a remote wire and catheter manipulator with two available steerable catheter systems. One with a 6 Fr inner leader catheter with a 180-degree multidirectional articulation and a 9 Fr outer sheath with a 90-degree multidirectional manipulation. The other is a 6 Fr low-profile system with two bending sections created for navigating in smaller vessels. The manipulation is done with different tightening of wires integrated into the catheters. The manipulator is mounted on the operating table and allows advancement, retraction, catheter

Robotic system	Compatible wires	Compatible catheters	Therapeutic device delivery	Navigation	Remote capability
Magellan	0.014, 0.018, 0.035	6 Fr or 9 Fr Magellan Robotic catheter system	Robotically stabilized manual delivery	Wire and catheter advancement-retraction; 6Fr catheter 180° multidirectional angulation; 9Fr catheter 90° multidirectional angulation	No
CorPath 200	0.014	Any commercially available 5–7 Fr catheter	Robotic Rx device delivery	Rx-device advancement, retraction; Wire advancement retraction, rotation	Yes
CorPath GRX	0.014	Any commercially available 5–7 Fr catheter	Robotic Rx device delivery	Rx-device advancement, retraction; Wire advancement retraction, rotation; Guide-catheter advancement retraction, rotation	Yes

Table 1.
Technical summary of endovascular robotic systems.

bending and rotation of the system also. The control panel is located outside of the operating room. It had a console and monitors to show the real-time fluoroscopic images and the catheter orientation as well. The disadvantage of the system is that the therapeutic devices cannot be delivered remotely it has to be done manually with robotic support. The system is approved by the FDA and CE marked, but it is not widely adopted and also not available commercially [8], later the technology was acquired by Auris Health Inc.

3.2 CorPath 200

The CorPath 200 robotic system is an endovascular, remotely guided system primarily developed for percutaneous coronary intervention purposes. The first publication appeared in 2011 using it for a coronary angioplasty. The system has two major components: a bedside unit and the interventional cockpit. The cockpit is a mobile radiation-shielded station to perform the intervention. It has two joysticks for device manipulation and monitors for real-time information about the patient's vitals and the actual procedural field (fluoroscopic and subtracted images). This allows an operator to perform an intervention remotely from the cockpit. The robotic arm is mounted to the table and contains the robotic drive and the attached single-use cassette (**Figure 2**). The arm is flexible, so an optimal angle positioning to the access site is achievable. The single-use cassette holds the wire, stent or balloon if loaded into the system and it is connected to a guiding catheter. In order to establish a stable connection with the guide catheter, it has a support track that prevents bending or bleeding while manipulating with the catheter. The cockpit and the robotic drive are connected via communication cables. The system is compatible with 0.014-inch guidewires, rapid exchange (RX) catheter, balloon

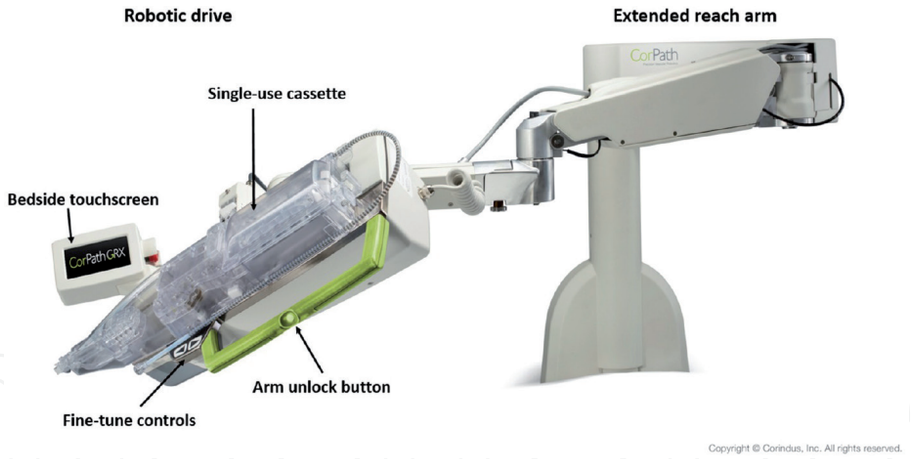

Figure 2.
The CorPath system's robotic arm loaded with a single-use cassette. The whole set-up is mounted to the surgical table (© Corindus Inc., used with permission) [5].

and stent systems. Additional feature is to measure lesion length by passing the balloon through it then retracting it. The advance and retract functions operate with a 1 mm increment. Through the joysticks the operator can manipulate with the wire and the rapid exchange devices, but the guide catheter control is not available in the CorPath 200. Therefore, a target vessel has to be approached manually. For the wire rotate, advance and retract functions are available, but for the RX devices rotate is not.

3.3 CorPath GRX

The next generation Corindus robotic system is the GRX. The major advantage is that it includes an active control on a guide catheter. Thus, the catheter has similar features as a wire in the CorPath 200 system, which is advance retract and rotate. This addition involves an extra joystick inserted into the control panel (**Figure 3**). The extent of guide catheter remote movement is 20 cm, therefor the target lesion has to be approached manually by the operator, but crossing the lesion and device delivery can be completed with the robot.

Another feature is the bedside touchscreen on the robotic drive that allows device exchange. This generation of CorPath robots have a turbo button which facilitates faster device movement and also a rotate-on-retract (RoR) function [9, 10]. RoR if turned on is an automated movement of the wire that provides a 270-degree rotation of the wire every time its retracted, which facilitates target vessel/side-branch cannulation mimicking manual rotation of the guidewire.

The newest features of the GRX are the wiggle, spin and dotter options. All of these were implemented based on experts' different lesion crossing techniques. The wiggle oscillates the guidewire upon advance to prevent prolapse in tortuous anatomy. The spin utilizes clockwise and counterclockwise rotation of the guidewire, while the dotter can be used for narrow or calcified lesions based on its small, rapid back-and-forth movements during advance.

Every generation of Corindus robotics are platform independent, which means that they are compatible with every type of operating room or catheter lab suite. The robotic drive is draped to preserve sterility in an approximately 2 minutes. The GRX system has FDA approval and CE marked, currently available to use for percutaneous coronary angioplasties and peripheral vascular interventions. It is commercially available and costs in between 500 and 650 000 USD, plus additional single-use cassette and device costs [11].

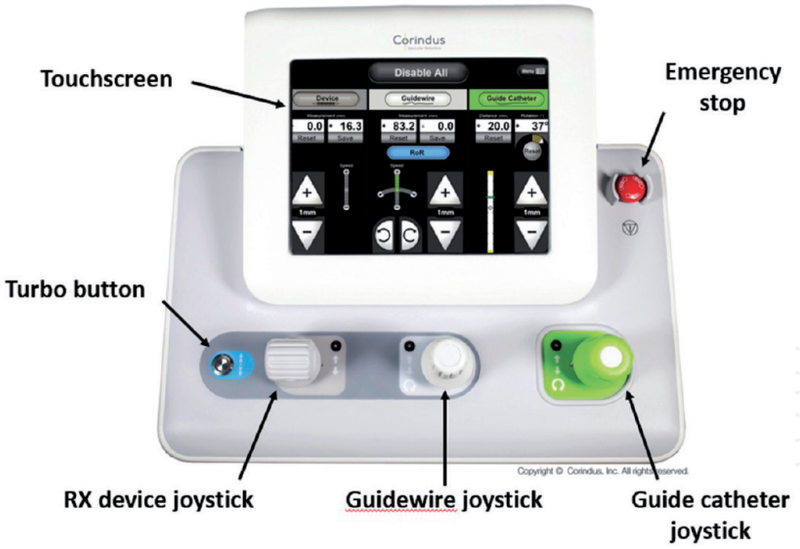

Figure 3.
The new console panel of the GRX system. The three joysticks control the wire, guide catheter and the stent/balloon. The panel consist a touchscreen that also allows manipulation of the devices (© Corindus Inc., used with permission) [5].

4. Clinical experience

4.1 Percutaneous coronary interventions

The first-in-human study regarding coronary angioplasty was published in 2011. Granada and colleagues reported 8 patients, who underwent PCI with the CorPath 200 system. Their data showed a 97% decrease in radiation exposure to the operator with a 97.9% procedural success rate [4]. The first multicenter study with robotic-assisted coronary interventions was the PRECISE study (percutaneous robotically-enhanced coronary intervention) [12]. The study was conducted with the CorPath 200 system and enrolled 164 patients with simple coronary lesions. The inclusion criteria were coronary artery stenosis above 50%, with the diameter in between 2.5–4 mm and with a length that could be covered by one stent. This prospective trial reported a 95.2% decrease in radiation level and a 97.6% success rate. The improvement of the newer generation devices allowed a wider potential application for the robotic assisted therapy as well. The CORA-PCI (Complex Robotically Assisted Percutaneous Coronary Intervention) trial focused on patients with complex coronary artery lesions. Patients were treated by a single operator and a total of 334 PCI-s were analyzed [13]. The results reported a 91.7% technical success and a 99.1% clinical success with robotic-assisted PCI. The study showed that the approach is a viable alternative to manually conducted PCI-s. Regarding postintervention outcomes [14] Walters and colleagues reported non-inferior results in major adverse (cardiac) events at 6 and 12 months also [15]. In 2020, Patel et all. Published their data showing a significant reduction in radiation exposure to patients and medical staff also [16].

4.2 Peripheral vascular interventions

The first-in-man study evaluating efficacy of robotic-assisted peripheral arterial lesion cannulation was a prospective, single-armed study by Bismuth et al. [17]. The trial focused on navigating successfully and safely through lesions ranging from simple to complex. The results showed a 100% successful navigation rate

and 19 of the 20 lesions were able to be treated by robotic-assisted means using the Magellan system. This study concluded that the robotic-assisted cannulation and treatment are feasible options even for complex peripheral arterial lesions. **Table 2** summarizes the clinical studies completed with the CorPath 200 system (**Table 2**).

The RAPID (Robotic-Assisted Peripheral Intervention for peripheral arterial Disease) trial was a single-arm prospective non-randomized study with symptomatic PAD patients [18]. The inclusion criteria were life-limiting femoro-popliteal stenoses above 50% or occlusion. Total of 20 patients with 29 lesions were treated, primary endpoints were technical success and safety, secondary endpoints included clinical procedural success, fluoroscopy time, contrast volume, procedure time, and adverse events. The procedures were performed from an antegrade femoral punctures, balloon angioplasty alone was performed in 65.5% and in the rest of the cases manually deployed stenting was required. The study reported 100% technical and clinical success without any significant major adverse event. The study's secondary outcome also demonstrated a reduced fluoroscopy time compared to studies treating similar lesions in a conventional manner. These favourable results provided the CorPath system F.D.A. approval for peripheral vascular interventions.

In 2020, the results of the RAPID II trial were published. This study focused on robotic-assisted drug-eluting balloon deployment in the peripheral vascular system [19]. The data of 20 patients reported technical success in all cases, without any major adverse events associated with the device.

The robotic system was used in the below the knee region also. Successful treatments were presented in the posterior tibial artery, tibio-peroneal trunk and in the proximal peroneal artery also [20].

A case-series of robotic-assisted percutaneous renal artery stenting has also been published with promising results and no major adverse events reported [21, 22].

4.3 Endovascular aneurysm repair (EVAR) and robotic assistance

Complex aneurysm treatments are technically challenging and more time consuming, therefore both the patient and the medical staff are exposed to higher radiation. The optimistic results from robotic-assisted target lesion/vessel cannulations pioneered the use of the system in endovascular aneurysm repairs also [23]. A feasibility study on an aortic model with the Magellan system showed lesser cannulation time, reduced radiation exposure and reduced number of catheter movements [24]. They highlighted also that with the assistance of the robot to overcome complex cannulations it is not necessarily required to have a well-experienced operator. In another arch model they concluded that robotic

Clinical trial	Year of publication	Intervention	Treated lesions	Technical success rate (%)	Clinical success rates (%)
Peripheral vascular					
RAPID [18]	2016	R-PVI	20	100	100
RAPID II [19]	2018	R-PVI	24	100	100
Coronary					
PRECISE [12]	2013	R-PCI	164	97.6	98.8
CORA-PCI [13]	2016	R-PCI	157	91.7	99.1
REMOTE PCI [16]	2017	Tele-PCI	22	86.4	N/A

Table 2.
Robotic-assisted clinical studies.

assistance reduced vessel wall contact and reduced navigational time [25]. More precise navigation was seen in human subjects as well. Comparing conventional and robotic catheter placement and retraction in patients undergoing TEVAR [26]. They recorded a significantly reduced cerebral embolization with the system, which was associated with the lesser number of catheter-vessel wall contacts during the procedure. There is no data currently available with the use of Corindus robotics in EVAR.

4.4 Carotid and neurointerventions

Robotic-assisted carotid artery stenting is the boundary of peripheral and neurointerventions. A recently published prospective feasibility study enrolled 13 patients who underwent this procedure. They reported technical success in all of the 13 cases, without postoperative neurological complications using the Magellan system [27].

The CorPath system underwent several modifications to become applicable in the field of neurointerventions. One of these modifications is the additional Y-adapter that enables the use of additional microcatheters, another modification is the active device fixation, which allows the operator to maintain guidewire position during catheter movements. Active guide catheter control also supports vessel cannulation [28]. A preclinical feasibility study on a porcine model was conducted to prove safe robotic navigation in neurovasculature sized vessels of the pig [29]. Based on this trial the use of the CorPath GRX system was authorized in New-Zealand, Australia and the European Union. Although the first-in-human use of the robotic system happened in Canada, when a basilar aneurysm was treated with robotic support [30]. Britz et al. used the GRX system to treat arterio-venous malformation by embolization in a pig model [31].

4.5 Robotic-assisted remote interventions

The upgrade on the CorPath system allowed the GRX model to be controlled remotely. Hence tele-stenting become a possible treatment option and a new aspect of robotic-assisted therapies become available. This approach does not require the operator to be in the operating room or next to the patient, the whole system is capable of being controlled from another hospital or office through telecommunication. The setup is provided by local area network and the two sites are using telepresence systems. This includes patient's vital parameters, live or stored fluoroscopy data displayed on monitors and an additional monitor with an overall view of the suite. Communication between the medical staff can be enhanced through wireless headsets [32]. There are multiple studies discussing the safety and feasibility of remote PCI [33–35]. Key factors of the procedure are the network stability and the communication of the medical team. Studies on simulators and on in-vivo models focusing on network latency reported that signal transmission should be below 250 ms not to influence the procedure outcome. The tele-stenting involved five in-human PCIs with a 53 ms mean command delay from a 20 miles distance [36].

5. Limitation of the CorPath system

Currently both the CorPath 200 and the GRX model are only compatible with 0.014-inch wires and rapid exchange delivery systems. The upcoming generations of the CorPath systems will be able to manipulate 0.035-inch wires also, which will

provide better support for more challenging procedures and could broaden the area of robotic-assisted procedures.

Results of robotic-assisted peripheral vascular interventions have been presented in several regions, but the utility of this approach remains unclear in complex and different scenarios such as chronic total occlusions, severely calcified lesions or obliterative diseases affecting bifurcations. Currently there is no data available in the use of mesenteric or celiac interventions and also the system was not yet used for EVAR. Although there is a demand to perform parts of complex aneurysm procedures to reduce radiation exposure and to reduce manipulation and the number of wire-vessel wall contacts. Active control of the guiding catheters may provide a possible solution to this problem [31].

It is important to emphasize that the published trials and studies reported excellent outcomes and good intravascular navigation, the absence of haptic feedbacks may have an effect on procedural outcomes [23]. This could be an important factor, when maneuvering in smaller vessels like coronary, cerebral and visceral vessels. For this reason, the precise control over the endovascular devices is mandatory and a crucial factor of procedural success [5].

6. Future prospects

Robot-assisted endovascular therapy has its benefits and limitations, but it is relatively a new option in the armamentarium of endovascular specialists. The persistent improvements and expanding indication fields provide a faster evolution and modifications of the toolset used for endovascular procedures. Many of these new techniques might not be implemented into robotic-assisted interventions, but basic procedures like vessel cannulation, angioplasty, stenting, angiography or coil delivery become possible to accomplish by robotic assistance.

The advancement of robotic techniques could provide better intravascular navigation and result in significant radiation time decrease for procedures requiring advanced endovascular techniques. One of the advantages of robotic-assisted device control is the stable and reliable manipulation compared to manual manipulation.

The first studies regarding tele-stenting were a milestone for robotic assisted endovascular therapies. This feature can overcome the burden of patient transportation in diseases where time window dictates patient outcome like stroke management.

The interest in remote stroke interventions is especially high as it shows an increasing trend in overall US population and recent thrombectomy interventions provided significant improvement in stroke outcomes. These procedures require experienced staff and immediate action, the treatment option is currently not available for great portion of the residents because of geographical difficulties. The use of tele-robotic systems in stroke management has the capability to offer a potential solution for disseminating acute thrombectomy care to smaller regions as well.

A key factor for remote endovascular procedure is the high-speed connection in between the local and remote site this provides better communication in the medical team and also an improved endovascular robotic-assisted navigation. Performing remote robotic-assisted operation in hospitals, does not equal improvement in postoperative patient care, to be able to maintain a well-functioning center sufficient cardiovascular and neurology intensive care units are mandatory. Therefore, the widespread of remote endovascular interventions in acute patient care is theoretical.

The future generation of endovascular robotics will include broader device compatibility like 0.035-inch wires, wider-range options for guide catheters, balloons

or stents. These would support the application of robotic-assisted endovascular intervention in more time-consuming procedures like contralateral gate cannulation during EVAR, target vessel catheterization and stenting in FEVAR or crossing the aortic bifurcation with the up-and-over technique.

7. Conclusion

CorPath system allows to perform remote endovascular procedures, promotes precise device navigation and reduces occupational hazards for the operator. Based on currently available experience the system has high procedural success rate in peripheral vascular, neurovascular and coronary interventions.

Conflict of interest

None.

Author details

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