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Telerobotic Endovascular Interventions and Their Potential for Cerebrovascular Treatment

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After the introduction of the first robotic-assisted surgical procedures, the technology soon reached the world of endovascular specialists, giving rise to several publications about robotic-assisted endovascular therapy. Compared with conventional procedures, robotic-assisted procedures can be more accurate and reduce radiation exposure. The latest commercially available endovascular robotic system is the CorPath GRX, which can be operated remotely. Robotic-assisted approaches have proved applicable in the fields of coronary and peripheral vascular intervention and neurointervention. Remote intervention has already proved feasible in the coronary and peripheral vascular systems and, according to expert opinion, could revolutionize acute stroke management as well. We review current knowledge about robotic-assisted therapies and remote interventions, and the future prospects and pitfalls. ***(Tex Heart Inst J 2022;49(2):e217608)***

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Robotic-assisted endovascular intervention was first introduced in the field of cardiology.[1] Since then, the technique has evolved substantially. Currently, the only available robotic system for endovascular procedures is from Corindus (a Siemens Healthineers company). The greatest advantages of this system are enhanced dexterity for precise navigation and device delivery, less radiation exposure for the operating physician, and remote control.[2]

The term "telestenting" refers to remotely performed endovascular stenting. This technique has been used successfully in preclinical tests[3-5] and in a first-in-human study, which focused on percutaneous coronary intervention (PCI).[6]

According to an American Heart Association/American Stroke Association policy statement,[7] by 2030 almost 4% of the United States (US) population is expected to have had a stroke. The evolution of acute cerebrovascular management and the introduction of endovascular thrombectomy (ET) have created the potential for remote stroke treatment.[8,9]

Description of the CorPath GRX System

Corindus's first commercially available endovascular system was the CorPath 200. This system was designed primarily for PCI, but it was used in peripheral vascular interventions as well. The latest version, currently in widespread use, is the CorPath GRX. It has 2 major components: a bedside unit that can be mounted on the operating table, and the interventional cockpit—a mobile station that has a radiation shield, a console panel, and monitors (Fig. 1).

The console panel has a touchscreen; a turbo button for faster tool movement; and 3 joysticks, which are used to control the guidewire, a guide catheter, and the device being inserted (for example, a balloon or stent). Monitors show real-time fluoroscopic images, saved angiographic images, and the patient's vital signs. The bedside unit consists of a flexible robotic arm that can be positioned at the optimal angle to

maintain easy transition to the access site. The other element of the unit is a single-use cassette that holds the guidewire, the guiding catheter, and a stent or balloon catheter (Fig. 1B). To prevent access site complications, the cassette has a support track to keep it firmly connected during manipulation. The connection between the 2 major components is maintained through communication cables.

Currently, the system is compatible only with 0.014-in guidewires and rapid-exchange (RX) or monorail balloons and stents. These devices are maneuvered with use of the joystick or the console panel's touchscreen. It is important to emphasize that the guide catheter's range of motion is only approximately 20 cm. Therefore, the target lesion must be approached manually. Once the lesion is reached, lesion measurement and device delivery can be done by the robot.

The GRX model can perform several lesion-crossing techniques, each of which is based on existing manual techniques. The rotate-on-retract function is a 270° rotation of the wire achieved upon retraction.[10,11] The wiggle function causes the wire to oscillate, to prevent prolapse in tortuous vessels. The spin function rotates the wire clockwise and counterclockwise. The dotter function, used to cross calcified lesions, moves the wire rapidly back and forth while the device is advanced. Lesions can be measured during device crossing and retraction.

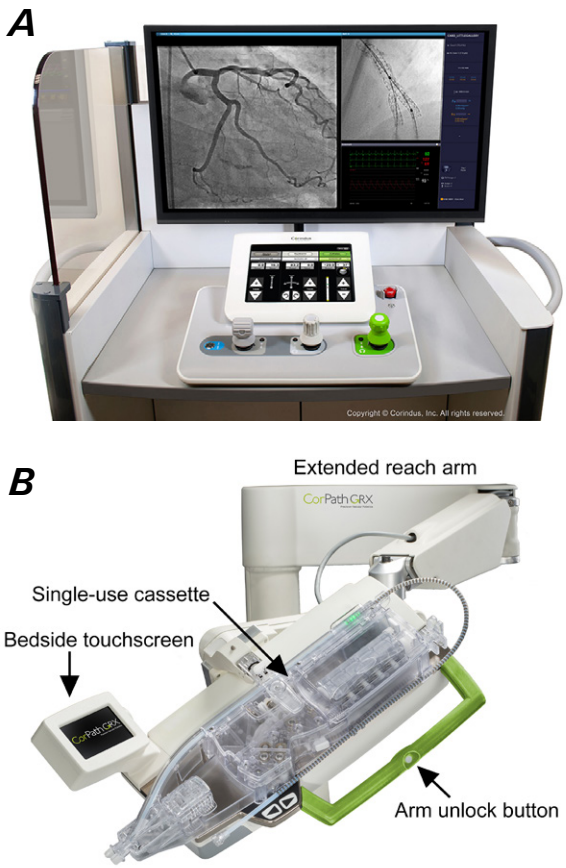

Fig. 1 *Photographs of the CorPath GRX system show* ***A****) the interventional cockpit, with console panel, radiation shield, and monitors, and* ***B****) the bedside unit.*

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Figure 2 illustrates a regular setup for a robotic-assisted coronary angioplasty procedure. Every generation of the Corindus system is compatible with every type of catheterization laboratory and operating table. The drive can be draped and prepared for intervention in approximately 2 minutes. The system's estimated cost is between $500,000 and $650,000, plus the cost of extra single-use cassettes and devices. The GRX system is approved by the US Food and Drug Administration (FDA) and has a Conformité Européenne (CE) mark for coronary angioplasty and peripheral vascular interventions.

Robotic-Assisted Therapy

Coronary and Peripheral Vascular Interventions

The earliest report of robotic-assisted PCI was published in 2011. Granada and associates reported on 8 patients who underwent the procedure, with a 97.9% success rate and a 97% decrease in radiation exposure.[12] The next milestone was the Percutaneous Robotically-Enhanced Coronary Intervention (PRECISE) study,[13] a multicenter study that enrolled 164 patients with simple coronary lesions short enough to be covered by one stent. The results were promising: a 97.6% success rate and a 95% decrease in radiation exposure.[13] The Complex Robotically Assisted Percutaneous Coronary Intervention (CORA-PCI) study involved patients with complex lesions.[14] In that prospective trial, 334 PCIs were performed by a single operator. The investigators reported a 91.7% technical and a 99.1% clinical success rate, and they concluded that the robotic approach is a viable alternative to conventional PCI.

Bismuth and colleagues published results of a prospective first-in-human study of robotic-assisted peripheral arterial lesion cannulation.[15] The trial focused on safe and successful cannulation of simple and complex lesions. The investigators used the Magellan system (currently not commercially available), which was initially invented for cardiac ablation procedures. The group reported 100% success in navigation and was able to treat 19 of 20 lesions by using the robotic-assisted method.

The first trial of the CorPath robotic system for treating peripheral vascular disease was the Robotic-Assisted Peripheral Intervention for Peripheral Arterial Disease (RAPID) trial.[16] It involved patients with critical limb ischemia or claudication and at least 50% stenosis in the femoropopliteal arteries. The results showed 100% technical and clinical success rates for the 20 patients treated. Balloon angioplasty alone was performed in 19 (65.5%) of the 29 vessels treated, and stenting was required in 10

(34.5%). The results also showed that fluoroscopy time was shorter for the robotic procedures than for procedures performed manually to treat similar lesions. These promising results secured FDA approval for use of the CorPath system in peripheral vascular interventions. The success of the RAPID trial continued with the RAPID II trial,[17] in which drug-eluting balloon therapy was done with robotic assistance. The investigators reported 100% technical and clinical success rates in the 20 treated patients, with no major adverse events.

On the border between peripheral intervention and neurointervention is robotic-assisted carotid artery stenting. In a prospective feasibility study including 13 patients, robotic-assisted therapy with use of the Magellan system had a 100% technical success rate and resulted in no neurologic adverse events postoperatively.[18]

Neurointervention

Robotic-assisted neurointervention is attracting research interest. Currently, the CorPath GRX system—the only available robotic system designed for this use—is not approved for neurointervention in the US, but approval in the future is possible. To facilitate this, several additional features (hardware and software) were added to the system. Britz and colleagues published the results of using the new features in a pig model.[19] They manipulated the porcine external carotid artery, which is similar in size to intracranial human vessels. One of the added features is active device fixation, which enables microcatheter movement without changing the position of the guidewire. The investigators concluded that the added attributes contribute to safe navigation in vessels similar in size to human vessels. This trial resulted in the system's approval in Australia, New Zealand, and the European Union for neurovascular applications. Britz's group also successfully simulated an arteriovenous malformation embolization in pigs. The first-in-human robot-assisted neurointervention was performed in Canada,[20] to treat a basilar aneurysm. In 2020, Desai and colleagues published the results of a feasibility study of robotic-assisted extracranial carotid intervention.[21]

Fig. 2 *Photograph shows the setup for a conventional robotic-assisted percutaneous coronary intervention.*

Remote Control

The second-generation CorPath GRX can be controlled remotely—a totally new aspect of robotic-assisted therapies. The operator does not need to be in the operating room or even in the same building; rather, the entire system can be controlled from a geographically remote site.

Setup

For remote procedures, the local and remote sites must be connected (Fig. 3). Various options are available, depending on the location of the systems. The operator console must have a local area network, a wide area network, and a metropolitan area network. If the 2 workstations are in the same institution, the network connection between them can be used if it is reliable. The connection requires a computer that can synchronize the remote site's console panel with the local site's bedside unit and transmit the input. At the remote workstation, regular monitors are required for displaying real-time fluoroscopic images, patients' vital signs, stored images, and output from an additional audiovisual telecommunication system. The computer can also measure the latency time between the 2 workstations (that is, the interval between the movement of the remote-site joystick and the movement of the local device). Additional wireless headsets can be used for communication among all necessary staff members.

Remote Interventions

Multiple studies have demonstrated the feasibility of remote interventions.[3-5,22] Madder and associates created ex vivo and in vivo models to test connection reliability by measuring network latency and its effect on robotic-assisted manipulation in a coronary artery.[3,23] The investigators reported a threshold of 400 ms for perceivable latency between 2 sites 103 miles apart; and they

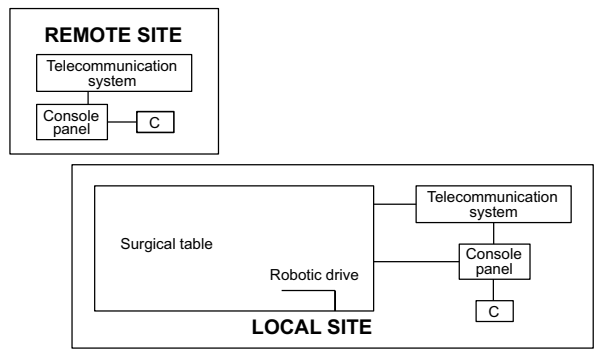

Fig. 3 *Schematic diagram shows a setup for remote control. The console panel (interventional cockpit) is used by the operating specialist and includes monitors and computers. The telecommunication system represents the constant audiovisual connection and also the view of the local site that it provides during intervention.*

C = connection between sites

suggested 250 ms as a threshold for performing remote interventions. Legeza and colleagues also identified 400 ms as the perceivable latency threshold in simulated femoral, carotid, and coronary interventions.[4] The same group focused on identifying contributing factors for a successful remote peripheral vascular intervention and reported that a stable network connection and a good communication protocol are crucial to achieving a high success rate.[5]

The first-in-human remote PCI procedure, reported in *Lancet*,[6] assessed the feasibility of remote robotic-assisted PCI with the treating cardiologist 20 miles away from the patient. The intervention was successful and represents a milestone in the field of telerobotic-assisted intervention.

Remote Stroke Treatment

A major factor stimulating interest in remote intervention is the public health need to increase access to acute ischemic cerebrovascular treatment.[8] Endovascular thrombectomy has become the standard of care for treating large-vessel occlusions.[8] The success of this therapeutic option and the expected increase in stroke incidence highlight the need to expand the infrastructure for stroke treatment.[7,9]

This expansion has several controversial aspects and limitations. An important factor is the window of time that dictates the outcome of treatments. Approximately 50% of the US population lives farther than a 60-minute drive from a tertiary center where all of the services required to perform ET are available.[24] Another factor determining stroke treatment outcome is the number of ET procedures performed annually[25]; geographically isolated centers with low case volumes cannot maintain proficiency in ET.[26]

Successes in the field of remote PCI inspired the idea of remote stroke treatment. The CorPath GRX system has already been used in the cerebrovascular system, and it is hoped that the next-generation robot will overcome current limitations. The future system would display intraprocedural 2D fluoroscopic images along with the normally required patient vital signs; conducting the procedure itself could be similar to performing it on-site, apart from gaining vascular access.

Panesar and colleagues[19] created a flow chart showing their proposed model for teleoperated ET services. They stated that nonremote intervention is preferable if it can be done within a reasonable time frame. If the patient is at a nontertiary center that has the infrastructure for performing remote ET, the diagnosis can be made on-site by using a telecommunication system to consult with experts at a tertiary center.[27,28] Depending on the treatment decision, tissue plasminogen activator therapy could be initiated by the local staff. If ET is the choice of treatment, vascular access for the robotic procedure must be obtained by local medical staff (for example, vascular surgeon, general surgeon, interventional radiologist, cardiologist). Then, the ET would be performed remotely by an experienced interventional neurologist at the tertiary center. This method could make it possible to perform ET within a suitable time frame, after which the patient could be transferred to a higher-level stroke center if necessary.

Limitations. Currently, remote stroke treatment has some limitations. The CorPath GRX system has never been used for ET in humans. Before it can be used routinely for that, feasibility studies and clinical trials must be conducted to ensure the system's safety and efficacy.[29,30] To perform remote interventions, several technical considerations have to be addressed. One crucial factor is maintaining a secure connection between local and remote sites to share patient data and allow remote consultation. This connection must be high-speed to avoid perceivable latency between sites that could affect treatment outcome. In addition, performing the ET requires vascular access, which would need to be obtained by an on-call vascular surgeon or other interventionalist. Furthermore, although the robotic systems enable precise device handling, they do not provide tactile feedback during interventions. Treating patients remotely would also require creating contingency protocols for potential periprocedural complications such as dissection, air embolism, and access site bleeding. Furthermore, maintaining good procedural outcomes also requires that a local expert be present during procedures and that local medical personnel be trained in gaining vascular access and in handling robots.

Another consideration is the infrastructure available for acute stroke management. Patients treated with telerobotic ET may need aftercare in postoperative neurologic intensive care units, necessitating their transfer to a high-volume center. Financially, the approximate cost of the system is around $500,000 to $650,000, plus the cost of the single-use cassettes ($650–750 each). The cost of hiring additional qualified medical staff may also create a barrier to implementing telerobotic treatment. If the technique does become available, medical-legal issues also have to be clarified.

Conclusion

Robotic-assisted endovascular procedures have had substantial technical and clinical success in the field of percutaneous coronary and peripheral vascular interventions. The CorPath GRX system can perform remote interventions, as proved in several ex vivo studies and one in vivo study. This capability could provide the basis for remote treatment of acute stroke and may change the future treatment of acute cerebrovascular events.

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