Review Article

Robotics for Neuroendovascular Therapy

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In the field of abdominal and pelvic surgery, endoscopic procedures have increasingly utilized robotic surgery, including the da Vinci system (Intuitive Surgical, Sunnyvale, CA, USA). Unlike robotic surgery in these fields, endovascular treatment involves simple movements such as pushing and pulling or twisting catheters and wires, allowing for the creation of relatively straightforward robotic systems that can replicate these endovascular procedures. Recently, there have been clinical applications of this technology in coronary arteries. However, when applying it to cerebral vessels, which have significant curvature and fragility, it is essential to develop a system that can adequately assess and reflect the physical stress on the vessel wall. Furthermore, remote surgery (telesurgery) performed by specialists is one of the most sought-after applications of robotics, but issues remain due to poor communication environments, leading to delays in operation and control difficulties. Additionally, there are ethical concerns regarding the responsibility for adverse events related to robotic surgery, highlighting the urgent need for the establishment of guidelines.

Keywords ▶ neuroendovascular therapy, robotics, remote control

Background of Robotics

In surgical treatment, including neurosurgery, traditional invasive methods that involve making incisions in the body to expose lesions have been predominant. However, there has been a growing spotlight on minimally invasive techniques, such as endoscopic surgery, and the demand for these methods is rapidly increasing. Endovascular treatment of cerebral vessels is an extremely minimally invasive approach that treats diseases from within the vessels using catheters. The manipulation of catheters primarily involves simple movements of pushing, pulling, and twisting, which does not require the complex motions needed in surgical robotic systems like the da Vinci (Intuitive Surgical, Sunnyvale, CA, USA). This makes mimicking the movements relatively easier.[1,2)]

However, unlike endovascular treatments in other areas, cerebral arteries have thin and fragile walls, and any damage can lead to severe, potentially fatal complications. Therefore, procedures within the brain require a system capable of replicating gentle and fine movements that do not impose stress on the vessels.

On the other hand, in the event that patients requiring emergency endovascular treatment may arise, if the transporting hospital has no highly experienced interventionalists, they may have to undergo insufficient treatments. In such cases, if a supportive robot is available, it could facilitate treatment through remote operation by a specialist (telesurgery) even in the absence of the treating physician.

Moreover, in endovascular procedures performed under fluoroscopy, there is an unavoidable issue of cumulative radiation exposure for the operator. However, this robotic system allows for operation in a separate room without X-ray exposure, thus addressing this concern.

This paper provides an overview of the history and current status of robotic surgery in endovascular treatment, supplemented by a review of the literature.

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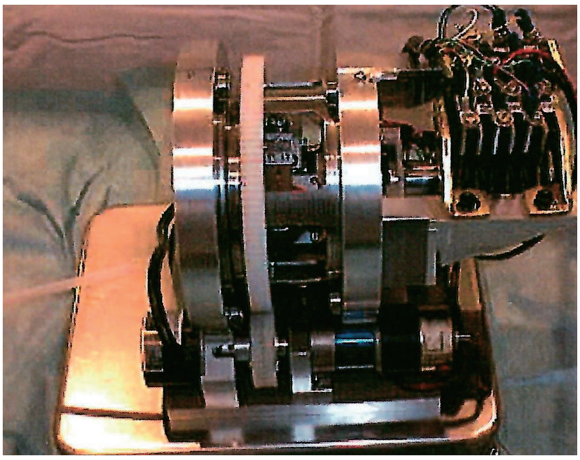

Fig. 1 Robotic controlled catheter system developed in 2001.

History

Development

Since the 1980s, attempts have been made to control catheters using robotic technology, and prototypes using roller systems were developed in the 2000s[1,3] (**Fig. 1**). The development of endovascular treatment robots rapidly progressed in the field of cardiology, with reports of clinical applications in 8 cases of coronary intervention by 2011.[4] Subsequently, the implementation of automated maneuvers led to further development of equipment, and large-scale clinical trials were conducted at multiple institutions for percutaneous coronary intervention (PCI).[5,6] Recent advancements in internet and wireless communication technologies have made remote surgery feasible.[7,8]

Clinical applications

The first practical robotic-assisted surgeries were performed by Harrison et al.[9] using the CorPath 200 (launched in 2012 by Corindus, a company of Siemens Healthineers [Erlangen, Germany]) on 108 patients. In 88 of these cases (81.5%), full robot operation was possible without the need to switch to manual operation. The second-generation CorPath GRX (**Fig. 2**) received Food and Drug Administration approval for PCI in 2016 and then was approved for peripheral vascular interventions in 2018. In the neurovascular field, the application began with angiography. In 2017, Vuong et al.[10] reported their experience using the Magellan Robotic Catheter System (Hansen Medical, Mountain View, CA, USA) for 9 robot-assisted cerebral angiograms and 18 robot-assisted intracranial interventions. In 2020, Sajja et al.[11] used the CorPath GRX Robotic System (Corindus, Waltham, MA, USA) for 7 transradial cerebral angiograms and 3 cases of carotid artery angioplasty and stent placement, although 3 cases required conversion to manual operation due to difficulties in approach. Britz et al.[12] pointed out that the CorPath GRX, designed for PCI, faced challenges with the micro-guidewire used in neuroendovascular therapy, as the guidewire track was too short, complicating the delivery of small devices like coils and sometimes causing them to go off track. Then, improvements have been made to the CorPath GRX for neuroendovascular treatments.[13] Nogueira et al.[14] successfully performed carotid stenting in 4 cases of severe symptomatic carotid stenosis, while Mendes Pereira et al.[15] successfully conducted a stent-assisted coiling procedure for a 12-mm basilar trunk aneurysm using robotic operation. The effectiveness and safety of the CorPath GRX System for endovascular embolization of cerebral aneurysm procedures were recently reported based on the results of a prospective, international, multicenter study.[16]

Current development status in Japan

In Japan, researchers such as Negoro et al.[1,17] have developed catheter robots using a motorized roller feeding mechanism (**Fig. 1**). However, this system was quite large and only allowed for simple forward and backward movements, preventing its practical application. Matsubara et al.[18,19] have been developing a guidewire and coil insertion force measurement device since 2009, along with an automated coil delivery system,[20] and in 2014 created a robotic system to assist in neuroendovascular treatments, confirming its operational accuracy in experimental aneurysm models[21] (**Fig. 3**).

Unlike commercially available products like the CorPath system, this innovative model visually and audibly communicates the insertion resistance to the operator, providing unprecedented feedback (**Fig. 4**). Initially, a large driving mechanism was required, and there were issues such as roller slippage and operational failures. However, recent advancements in small motor development and compact, precise designs using 3D printing have led to the creation of a slave robot with accurate motion reproduction capabilities, facilitating smooth control such as automatic coil insertion. Challenges related to slippage during insertion have been addressed through features like slip prevention and enhanced motor output.

Mechanism of Endovascular Treatment Robots

Essentially, robotic surgery involves remotely controlling catheters and guidewires inserted into the patient from a

Fig. 2 Image of the CorPath GRX system (Siemens Healthineers, Erlangen, Germany) © Simens Healthineers Inc. Used with permission (press release: 2021.11.2).

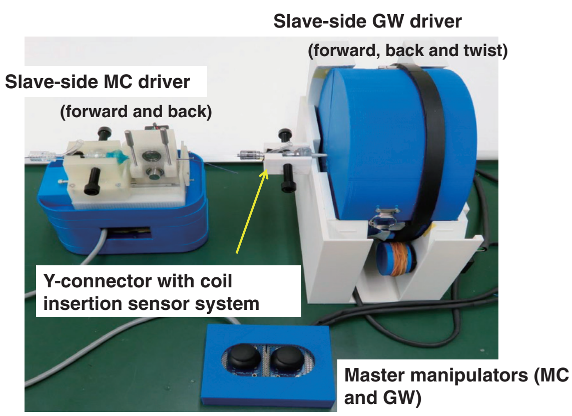

Fig. 3 Neuroendovascular intervention support robot system. GW, guidewire; MC, microcatheter

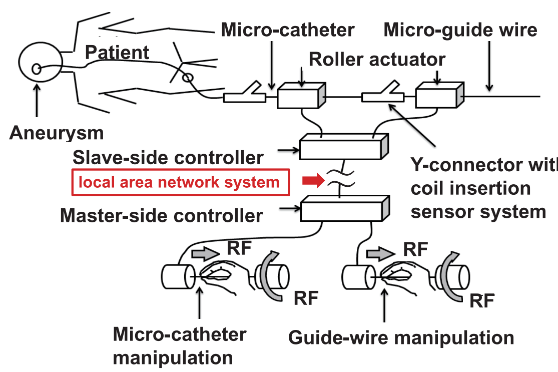

Fig. 4 Scheme of control mechanism of neuroendovascular intervention support robot system. RF, reaction force

control room. In neuroendovascular treatment, catheters are carefully advanced to the lesion site through collaborative work with the guidewire, necessitating a master-slave system comprising 2 feeding mechanisms that can operate independently. These 2 systems are connected via cables or wireless telecommunication for task transmission. The console features 2 joysticks for operating the catheter and guidewire, as well as a high-resolution display monitor.

In the CorPath system (Corindus), the driving side and slave side are connected via cables, with the procedure conducted in a radiation-shielded cockpit equipped with computer monitors, various sensors, and joysticks for guiding the wire and catheters.[2,7] Our developed robotic system is similarly designed to replicate standard endovascular procedures.[22,23] For the forward and backward movement of the catheter, guidewire, and devices, clamping devices that prevent slippage and provide sufficient pinching force are essential.[12, 24,25] The feeding mechanism on the guidewire side achieves both axial drive for advancement and rotational drive for twisting through its rotation.

Operations are performed using 2 joysticks for simultaneous control of the catheter and wire, allowing for not only simple insertion and retraction movements but also adjustment of insertion speed based on the tilt angle of the joystick. Monitors in the operating room display images at the same resolution as in the angiography room, allowing for real-time imaging, patient hemodynamics, fractional flow reserve, intravascular ultrasound, and other adjunct technologies to be presented as usual.

In the clinically applied CorPath system, the table-side slave unit connected to the control console via cables is fixed to an arm on the imaging table, integrating the robotic drive system and a sterile, single-use cassette for patient access. The workstation interface, software, robotic drive motors, and cassette work together to translate the interventionalist's directions into precise and controlled linear, rotational, and pinch micromovements in the guide or microcatheter, guidewire, and rapid-exchange balloons, stents, coils, or other working devices during navigation and intervention.[7,12]

Usefulness of Robotics

Reduction of operator radiation exposure and orthopedic strain

One of the advantages of robotic surgery is the ability to perform procedures away from the fluoroscopy unit, thereby reducing radiation exposure to the operator.[5,26] For instance, the prospective Percutaneous Robotically Enhanced Coronary Intervention (PRECISE) study by Weisz et al.[5] reported a 95% reduction in median radiation exposure to operators. Further, robotic operation can be performed while sitting at the console, so there is no need to wear heavy protective gear, which helps reduce orthopedic strain on the waist and other areas.

Lower infection risk in treating infected patients

When treating patients with severe infections, the operator and assistants closest to the patient face a risk of viral exposure. Conducting procedures in a cockpit in a segregated room can reduce this risk and ensure the safety of healthcare workers, a benefit particularly evident during the coronavirus disease 2019 pandemic.[27]

Remote surgery by specialists in underserved areas

The application of robots in remote surgery (telesurgery), especially in cases of telestroke, demonstrates its value in treating urgent conditions when specialists are unavailable.[7] In cases of cerebral embolism, prompt revascularization treatment is critical to prevent irreversible brain damage, making emergency mechanical thrombectomy an essential procedure. However, transporting patients to facilities with endovascular treatment capabilities or waiting for a specialist to arrive can be time-consuming, particularly in remote hospitals. Therefore, employing a telesurgery system for urgent interventions by specialists proves to be extremely useful. Successful experiments in teleangiography were reported by Lu et al.[28] in 2017 between Japan and China, with stent placements in the coronary artery reported by Madder et al.[29] in 2017 and Patel et al.[30] in 2019. Miyachi et al.[23] succeeded in the experimental verification of remote surgery between completely separated rooms using a neuroendovascular intervention support robot for the embolization of an aneurysm model (**Fig. 5**).

Limitations of Robotics

Installation issues

The installation and replacement of devices must be performed by on-site staff, which can take time if they are not accustomed to the procedures. Incomplete setups can lead to malfunctions. Additionally, since the work must be performed in a sterile environment, staff may sometimes need to remain close to the table in the imaging room to monitor the robot's movements, which does not entirely resolve the issue of staff radiation exposure.

Control issues

The movements of devices used in endovascular treatment are very delicate and require extreme precision.[23] Unlike the heart and peripheral arteries, the cerebral arteries are narrow, often have 3D curves, and are fragile and delicate; damage can lead to fatal complications.[31] The endovascular operation is mainly composed of only 4 patterns: "spin," "wiggle," "dotter," and "constant speed."[7] While these movements can be compensated by manipulating the joysticks, there are concerns that unexpected or counterintuitive motion of the catheter-device-guidewire assembly could increase the risk of perforating delicate neurovascular structures during navigation.[13] Furthermore, these precise movements are driven by motors activated by electrical signals, which raises the potential for accidental malfunction or loss of braking control due to poor communication or control.

Time lag issues

Britz et al.[13] found inadvertent forward movement of the wire when delivering the microcatheter, which poses a risk of perforation. Although satisfactory verification was achieved using a wired operation model at close range, handling the time lag during remote operation is problematic for a complete wireless implementation. There are already delays of several hundred milliseconds observed in image processing and reconstruction during standard endovascular procedures, and this time is expected to increase further with remote surgery, including round-trip transmission

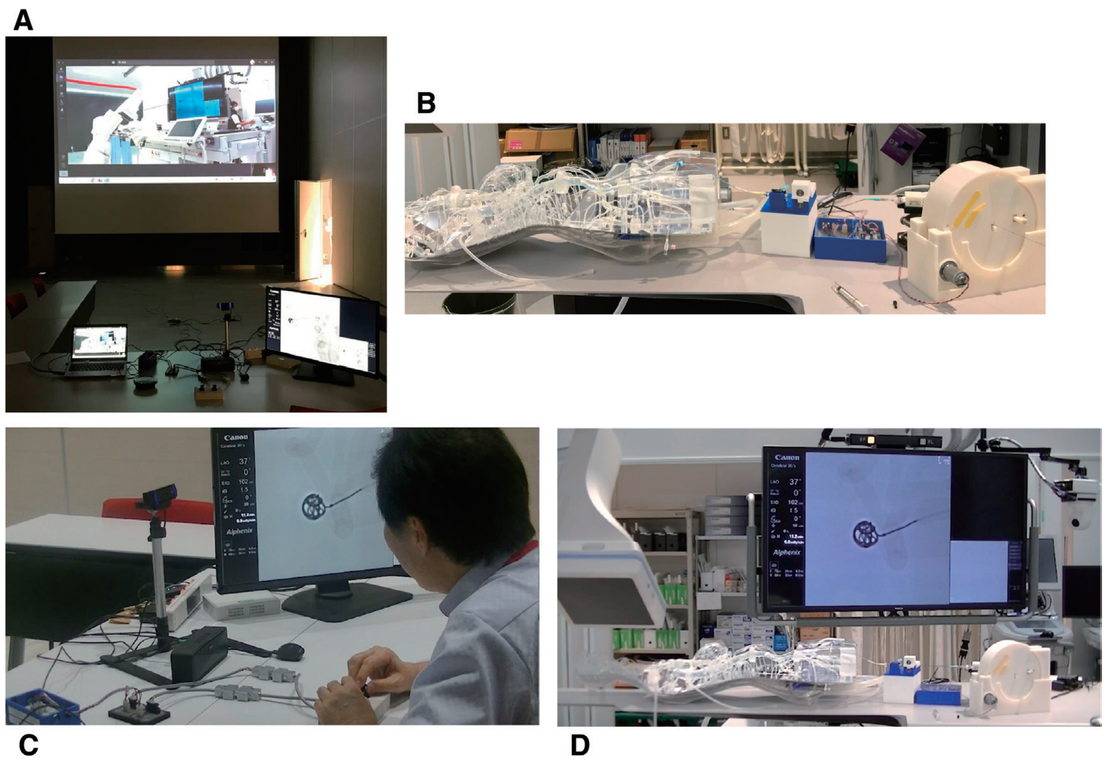

Fig. 5 Remote experimental telesurgery of aneurysm embolization. Master control room (**A**) is located 50 m from the angiography room (**B**), where the vascular model and slave robot are set on the table. The coiling operation on the master side (**C**) corresponded exactly with the operation on the slave side (**D**).

time.[23] Therefore, due to the delay in recognizing the position of the guidewire on the images compared to its actual position, there is a risk of complications such as inadvertent forward movement of the wire.[13] The Japan Surgical Society's guidelines for remote surgery[32] also require that serious communication delays, jitter, and packet loss be confirmed, and the total round-trip communication delay and information delay must be kept to a maximum of 100 ms.

Sensor issues

One major limitation of current robotic endovascular systems is the loss of tactile feedback during manual procedures. Tactile feedback provides additional sensory input that enhances the physician's situational awareness beyond what is conveyed by 2D or 3D visual imaging.[7] Anticipating the release of potential energy in catheter systems is crucial to prevent wire advancement, vessel dissection, or perforation. In neuroendovascular treatment, the operator's finger sensation is critical; if there is abnormal resistance, it may indicate excessive load on the vessel wall or some malfunction along the catheter's path. However, relying solely on visual cues from the screen does not provide an accurate sense of force, which can lead to perforation if the procedure continues without awareness of the actual force being applied. Current robotic techniques without sensing feedback only allow the operator to recognize abnormal or excessive behavior by observing wire deflection or deformation on the monitor. In contrast, our system includes an insertion force sensor system designed to visualize fingertip resistance.[22,23] We have improved a Y-connector, a medical device used for inserting a guidewire and irrigating with heparinized saline, incorporating an insertion force sensor that measures the magnitude of the force using a non-lamp gauge and sound scale. Such a sensing feedback system that can provide information about resistance and friction is crucial for managing risks during treatment and will be necessary for procedures requiring delicate and nuanced movements in the future. Guo et al.[33] also developed a force-sensing catheter with a fiber pressure sensor and an early safety warning system with a real-time adjustable pressure threshold. Future research may allow interventionalists to physically sense the pressure in the guidewire or catheter, a technology known as haptics, similar to haptic technology found in commercial game controllers. Adding force-sensing and haptic technology to robotic endovascular systems will likely be key areas for future research.

Adaptation to adjunctive techniques

The traditional CorPath system (Corindus) employs a single delivery device, making it unsuitable for implementing the multiaxial approach (guiding catheter, distal access catheter, and microcatheter) required for many neurovascular cases.[7,13] Additionally, the balloon guide catheter cannot fit into the disposable cassette. Furthermore, the range of motion of the CorPath GRX robotic arm is limited and too short for neuroendovascular procedures, necessitating reliance on manual operation.[13]

Waterproofing, sterilization, and disposable kit for slave robot

The most significant challenges are waterproofing and sterilization. To achieve waterproofing, it is necessary to minimize metal components and create a disposable kit that allows for easy removal, which would result in a relatively high cost.

Operating environment for master robot

Currently, the operation is controlled through a joystick interface, resembling a game panel, which is far removed from real-life catheter procedures where operators typically manipulate catheters and guidewires with their fingers. Ideally, the operation should simulate actual endovascular treatment techniques.[23]

Training issues

As mentioned, mastering joystick operation requires specialized training, and a standardized training curriculum is needed to optimize physician interaction with robotic systems. Rapid adaptation and updates are essential due to the fast pace of advancements in device technology.

Time-saving issues

As mentioned, the installation and replacement of devices must be done manually, and reports indicate that these tasks can take more time compared to manual operations.[34] Moreover, the wire rotation speed is slower than in typical manual operations, and due to communication time lags, rapid movements are difficult to execute, leading to a cautious approach that results in slower operations compared to actual clinical procedures, creating a gap in usability.[23]

Cost-performance issues

Although there are costs associated with equipment and communication in telesurgery for mechanical thrombectomy, it has been reported to be cost-effective.[35] Sanmartin et al.[35] reported that remote robotic endovascular thrombectomy could extend access to care in underserved communities and rural areas and improve care for socioeconomically disadvantaged populations affected by health inequities.

Manual rescue in accidents

While remote surgery is highly sought after, a physician must be on-site to obtain manual vascular access, place the sheath, and guide the catheter into the arch. Additionally, any complications must be handled on-site, as there may be no available physician to convert to manual operation in the event of a serious adverse event. Such manual rescue systems and teams should always be on standby to respond to any intraoperative accidents.

Communication environment for remote surgery

Commodity internet is widely available, and its use would greatly enhance telerobotic adaptation, but special-purpose restricted networks may offer greater reliability.[35] However, the instability of wireless communication can introduce delays, interruptions, and risks such as interference and redundancy, posing significant hurdles for practical implementation.[23] Furthermore, the lack of data confidentiality and security on public lines necessitates end-to-end encryption to ensure patient confidentiality and safety. Further technical investigations into network performance are essential for the widespread expansion of telerobotics.[36]

Ethical issues

One major concern is the question of operator responsibility in the event of complications. While medical licensing boards permit interstate teleoperation, determining where the responsibility lies in the event of complications arising from robotic or communication failures is an unresolved issue.[23,35]

Future Prospects

Advancement of robotics using artificial intelligence (AI)

Currently, AI-assisted diagnosis is rapidly advancing in the diagnostic field, but the use of robots for surgical treatment is still a long way off. Particularly, neuroendovascular treatment requires extremely careful and precise techniques for just a few millimeter lesions, but current machines cannot replicate the necessary movements. While robots excel at selecting correct responses from vast datasets and performing repetitive tasks, human vascular structures, types of lesions, and procedural difficulty vary from one individual to another, making flexible adaptation difficult. Presently, robots are puppets that replicate human operators accurately, but in the future, incorporating automated maneuvers and machine learning could eliminate redundancies, reduce procedure times, and greatly enhance safety. AI's innate or autonomous "intelligence" will be essential, and in the future, AI and its subsets, such as machine learning and deep learning, may be fully integrated into robotic systems.[13] Furthermore, risk management could benefit from sensory input and sensor-motor feedback, ultimately assisting human decision-making during critical situations, such as detecting dangerous situations or initiating spontaneous retraction when insertion becomes difficult.[23,37] Other anticipated upgrades include improved sensors, tactile feedback, machine learning algorithms, and autonomous functions to enhance precision and reduce (or eliminate) human error.[7]

Magnetic guidance methods

On the other hand, an alternative guidance method involves magnetic navigation. This method utilizes large, strong externally generated magnetic fields, altering the direction of magnetic lines to facilitate the guidance of a passive ferromagnetic catheter through traction.[38] Its usefulness has been confirmed in vitro, and there are ongoing attempts to apply it to neuroendovascular procedures.[39] Currently, it is primarily utilized in treatments for atrial fibrillation.[40] Combining these new external guidance technologies with direct catheter and wire control could further enhance the reproducibility of navigation.

Conclusion

With the rapid advancements in AI, virtual reality, the Internet of Things, and other technologies, the development of highly intelligent robots with judgment capabilities is expected to become possible. For younger generations who are familiar with 3D imagery and accustomed to robot operations in e-sports, new ideas will continue to emerge. These technologies are anticipated to advance further through collaborative development with engineering technologies.

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