Remote Surgery Using a Neuroendovascular Intervention Support Robot Equipped with a Sensing Function: Experimental Verification

Abstract

Purpose: Expectations for remote surgery in endovascular treatments are increasing. We conducted the world's first remote catheter surgery experiment using an endovascular treatment-supported robot. We considered the results, examined the issues, and suggested countermeasures for practical use. Methods: The slave robot in the angiography room is an original machine that enables sensing feedback by using an originally developed insertion force-measuring device, which detects the pressure stress on the vessel wall and alerts the operator using an audible scale. The master side was set in a separate room. They were connected via HTTP communication using local area network system. The surgeon operated by looking at a personal computer monitor that shared an angiography monitor. The slave robot catheterized and inserted a coil for an aneurysm in the silicon blood vessel model in the angiography room. Results: Our robot responded to the surgeon's operations promptly and to the joystick's swift movements quite accurately. The surgeon could control the stress to the model vessels using various actions, because the operator could hear the sound from the insertion force. However, the robot required a time gradient to reach a stable advanced speed at the time of the initial movement, and experienced a slight time lag. Conclusion: Our remote operation appeared to be sufficiently feasible to perform the surgery safely. This system seems extremely promising for preventing viral infection and radiation exposure to medical staff. It will also enable medical professionals to operate in remote areas and create a ubiquitous medical environment.

Keywords: Neuroendovascular intervention, remote surgery, robotics, sensor feedback

Introduction

With coronavirus disease (COVID-19) infections becoming a global problem, the risk of infection by patients to the medical staff, especially surgeons, is exceptionally high; some deaths have even been reported. Under these circumstances, a surgical support robot that reproduces the procedure in real time without touching the patient is currently the most sought-after device, as an alternative to ensure medical professionals' safety. An endovascular procedure is performed with fluoroscopy and even if a radiation protector is attached, exposure is unavoidable. Robots are the only solutions to this risk.^[1,2]

In the cardiovascular field, a simple device for coronary catheterization has already been put into practical use by the Corindus robot system (CorPath GRXTM).^[3-5] Although it has been introduced in Japan and used clinically,^[6] this device is limited to wired control from a neighboring

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separate room because it does not have a wireless operation function. Last year, this system was reportedly applied to neuroendovascular treatment in humans;^[7-9] however, it has not been in the practical stage yet.

We completed a prototype of an endovascular operation support robot, with a sensing function developed over 10 years, [10] and conducted the world's first wireless remote catheter surgery. After presenting the results, we describe the issues and suggest countermeasures for practical use.

Materials

The robot has the same specifications as the models we have announced thus far,^[10] and can operate the catheter and the guidewire separately and simultaneously. It is combined with the insertion force-measuring device that we

How to cite this article: Miyachi S, Nagano Y, Kawaguchi R, Ohshima T, Tadauchi H. Remote surgery using a neuroendovascular intervention support robot equipped with a sensing function: Experimental verification. Asian J Neurosurg 2021:16:363-6.

Submitted: 22-Feb-2021 Accepted: 26-Mar-2021

Published: 28-May-2021

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Access this article online

Website: www.asianjns.org

DOI: 10.4103/ajns.AJNS_77_21

Quick Response Code:



have been working on for many years^[11,12] [Figure 1]. We also succeeded in miniaturizing the robot to some extent, allowing it to be easily installed and moved on the angiography room's operating table. Specifically, with the catheter attachment/detachment part, we can attach/detach the Y-connector with a single touch, using an eccentric cam.

For insertion force detection, the insertion force that is applied to the wire passes through the curved through-hole of the sensor head in the wire drive robot and is measured by the sensor load cell. This is converted into the wire insertion force using a result measured in advance by the calibration load cell. In the previous design, this was a complicated structure incorporated into the drive unit inside the rotating body; however, it has been improved to make it easier to attach and detach, as a sensor that can be separated from the wire drive unit [Figure 2].

Methods

We rented a company's experimental angiography room and conducted a remote control experiment using a blood vessel model from a remote environment in a separate room (a distance of approximately 50 m) [Figure 3]. The slave robot on the operating side was an original machine that enabled sensing feedback using our originally developed insertion force-measuring device.^[2] The master side used joysticks. The operation unit transfers the two joysticks' tilt data to the robot, and the robot drives the catheter and wire according to the tilt data.

When the robot transfers the sensor data of the mounted wire insertion force to the operation unit, the operation unit informs the operator of the insertion force by varying the pitch of a sound emitted from the control device connected to the controller. Thus, the operator in the separate room can grasp the degree of pressure stress applied to the blood vessel wall in real time.

The slave robot was placed at the foot of the blood vessel model on the procedure table of the angiography room. The master side was set in a separate room, at least 50 m away, and they were connected by HTTP communication using a local area network. The surgeon operated by looking at a personal computer (PC) monitor that shared a screen with the monitor of the angiography equipment (AlphenixTM: Cannon Medical System) in the angiography room. In the angiography room, the slave robot catheterized and inserted the coil into the aneurysm in the silicon blood vessel model [Figure 4].

Results

Verification of operating environment

Delay time analysis

The robot required a time gradient to reach a stable advanced speed at the time of initial movement, and

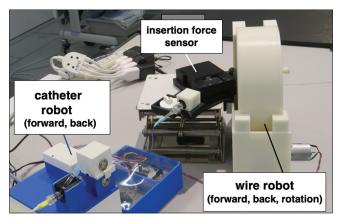


Figure 1: Slave robot system with a catheter and a wire robot and an insertion force sensor

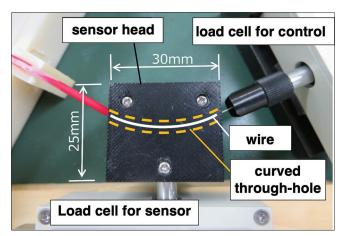


Figure 2: Inner structure of the insertion force sensor

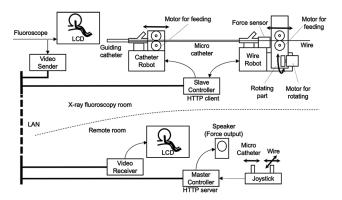


Figure 3: The scheme of remote control and transmission system

experienced a slight time lag when braking to a complete stop, when the surgeon stopped advancing. On measuring the robot operation's delay time, we found delays in both the catheter and the coil. On the catheter side, the motor experienced a 0.1-s delay, before stopping from the maximum speed. The wire side experienced delays in the wireless transmission of the control signal, by Bluetooth, to the motor in the rotating body and the motor section, resulting in a total delay of approximately 0.1 s. There was no delay due to the return of the joystick. On the

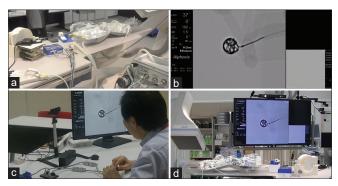


Figure 4: The whole view of the slave robot (a) and the monitor of angiography room (b), The operation of coiling in the master side (c) was exactly corresponding with the slave side (d)

other hand, because the video was captured by a PC and then sent and received via network transfer, the delay due to this image transmission mechanism was approximately 0.1 s. Moreover, the delay of the network itself was approximately 0.1 s or less.

Remote operation feasibility

Compared to the conventional wired experiment, the delay was significantly improved, as described above, and it responded to the joystick's swift movement with some accuracy. In addition, the surgeon could control the stress on the blood vessels during the operation, for example, by stopping the operation and reinserting the device, by listening to the pitch indicating the insertion force, which was picked up by the microphone in the angiography room in real time.

Discussion

Significance of this robot

Endovascular treatment robots make simple two-dimensional movements, for example, pushing, pulling, and twisting devices such as catheters, as opposed to complicated three-dimensional conventional surgeries. The range of movement is small and stable. Therefore the road to robotization is very close. Currently, remote surgery is sought after in various fields to ensure the safety of medical staff in the surgical treatment of COVID-19-positive patients, and to avoid direct contact with the patients as much as possible. As the da Vinci surgical system is used widely in abdominal surgery, it is necessary to develop similar devices in the cerebrovascular field.

In a cerebral embolism, in which a large thrombus clogs the main trunk of cerebral artery, the brain will suffer an irreversible cerebral infarction if the treatment is delayed, so a maximally rapid recanalization is required. Acute mechanical thrombectomy treatment has achieved excellent results in this case, so the spread of this method has been recognized as essential. In this meaning, a remote emergency surgery by a specialist using the remote surgery system can be beneficial; for example, when transporting patients in need of thrombectomy to a far stroke center with neuroendovascular physicians, or in remote hospitals where it takes time for the arrival of the specialists. There is a report of the feasibility of long-distance tele-robotic-intervention in coronary intervention, [12] but it may be still a preliminary trial.

Although endovascular treatment is a minimally invasive treatment, the surgeon's and the staff's cumulative radiation exposure is problematic; thus, if it becomes possible to operate in a separate room without exposure, it can also contribute to the medical staff's safety and health.

Items to be improved for practical use

Although the insertion and procedure do not leave a permanent indwelling device in the human body, it is necessary to ensure operational certainty, as in automatic driving. The above-mentioned Corindus robot system (GRX) has already been introduced in Japan, and clinically used in the cardiovascular field.[6] We must compare and verify our device with this; however, we suppose that having a sensing function is more practical in terms of safety. Previous reports did not address the importance of tactile feedback, because the friction is noted visually by watching for subtle changes in the shape and motion of devices as a compensation for the sensory profile.^[7] However, we may not avoid the penetration of the vessel or aneurysm because it is too late to stop the robot handling to advance, if we make the decision only by watching the visual information. That is why we are particular about the equipment of sensory motor feedback system.

The following improvements and countermeasures are necessary for the practical clinical use of our system.

Unified, integrated system design

Because these devices are now entirely separate, it is necessary to create a more compact and elaborate integrated drive and sensing system, for practical use in future. Therefore, comprehensive development by multiple industries, including hardware design, is required.

High-performance transmission control system

The system currently requires a time gradient to reach a stable advanced speed at the time of initial movement, and experiences a slight time lag when braking to a complete stop when the surgeon stops advancing. In addition, a high-speed wide area network line and motor improvement are required. In addition, it is essential to prepare for robot malfunctions or unforeseen complications by adding safety functions, for example, emergency stop devices and manual intervention methods. Moreover, we should consider how to rescue patients in these cases.

As a solution to the delay in image transmission, we should improve the current transmission system:

fluoroscope \rightarrow network transmission \rightarrow PC network reception \rightarrow PC display. By devising a transfer method that avoids the PC, we can expect to shorten the delay by 0.05–0.08 s. We believe that the mechanical section's delay can be shortened to 0.02 s by improving the motor's performance and changing to infrared communication, instead of Bluetooth. In addition, a network environment considerably influences the transmission speed when congested; hence, it is necessary to strengthen the network as a countermeasure against delays.

As a technical measure, we should set in advance a maximum limit between the master and the slave, and take measures, for example, pausing the robot or issuing a warning, when the time lag becomes large.

Confirmation of the safety and operational impact of sterilization

This is related to the equipment design. The device should have a compact design that is waterproof and sealed. It must also use parts made of materials that do not affect the human body, and have a structure that withstands the sterilization process. We will also develop a disposable device insertion kit for each patient, which is attachable and detachable from the drive unit.

Ethical issues

It is necessary to clarify the ethical issues regarding responsibility, in the event of complications during the procedure.

Conclusion

In future, when we complete our system, we can apply it to endovascular treatments other than the brain, and to endoscopic surgery robots equipped with sensing functions.

In the world's first remote experiment using an endovascular treatment robot equipped with our sensing function, the performance appeared to be sufficiently feasible to perform the surgery safely. It seems to be clinically applicable in future, if we make further improvements for long-distance experiments, safety, accuracy, sterilization, etc., This system seems extremely promising for preventing COVID-19 infection and radiation exposure to medical staff and increasing safety. It will also enable medical professionals to operate in remote areas and create a ubiquitous medical environment.

The robotic system was successful at navigating and deploying small-gauge devices specific to neurovascular procedures. Given the potential benefits of robotic-assisted surgery for the patient and the surgeon, further investigation is warranted for this indication.

Financial support and sponsorship

This work was supported by JSPS KAKENHI Grant Number JP 18K08954.

Conflicts of interest

There are no conflicts of interest.

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