Development of Minimally Invasive Surgery Systems

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OVERVIEW: In responding to the health and medical needs of Japan's rapidly aging society, the early detection of diseases and the ability to treat health conditions without imposing an inordinate burden on the patient have emerged as critically important issues. These factors have fueled a demand for minimally invasive surgery systems that minimize the pain and trauma of surgery and promote faster recovery and return to work. Hitachi Group has been an industry leader in the development and deployment of minimally invasive surgery systems including the intraoperative MRI operating room system that was deployed at Tokyo Women's Medical University in 2000. This system has proved effective in performing malignant brain tumor operations, and has shown an exceptionally high malignant tissue removal rate. In another development, approval was obtained from the Medical Ethics Committee of Shinshu University School of Medicine for a micromanipulator built around a robotics system designed to aid in brain surgeries, and the system's functional capabilities were verified through clinical trials conducted in August 2002. Finally, the endoscopic manipulator was developed in a joint project with The University of Tokyo, and this system's effectiveness and performance was verified through clinical trials carried out with the cooperation of Kyushu University. These R&D initiatives to develop minimally invasive surgery systems are finally being brought into practical use in the operating room.

INTRODUCTION

WITH one of the lowest birth rates and fastest growing elderly population in the advanced industrial world, there is great concern in Japan over raising health costs in the years ahead. To deal with this emerging situation, every effort must be made to prevent disease in the first place, but when medical conditions do arise, it is of course desirable that patients recover and return to work as quickly as possible. This makes it all the more urgent to establish medical procedures that minimize pain and trauma to patients, and to develop advanced clinical systems that support those ends.

The medical equipment industry has seen rapid development of sophisticated diagnostic systems that exploit the rapid advances of information technology (IT). Therapeutic systems have also benefited and shown enormous progress over the last few years by leveraging the advances in imaging and robotics technologies. By making the best use of an array of cutting-edge technologies, Hitachi Group has focused its R&D resources on developing and deploying minimally invasive surgery systems that offer improved accuracy and safety while minimizing the pain and trauma experienced by patients.

This paper will highlight three key initiatives illustrating the Hitachi Group's commitment to

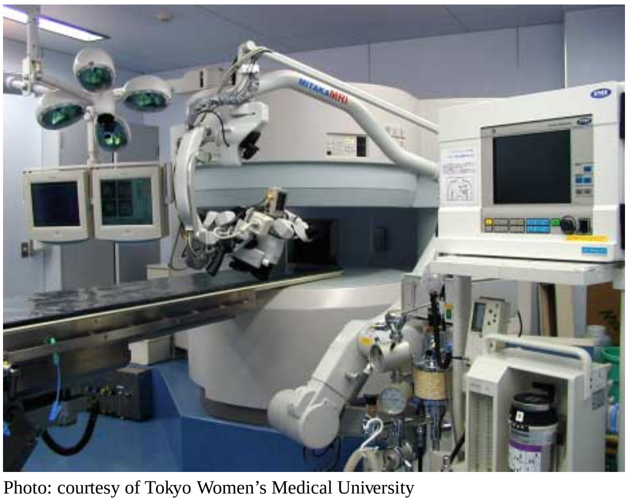

Photo: courtesy of Tokyo Women's Medical University

Fig. 1—Intraoperative MRI Operating Room System.
Hitachi's intelligent operating room system, now deployed at Tokyo Women's Medical University, consists of the open-configuration MRI system AIRIS II, an operation support microscope, an operating table, an anesthesia machine, a non-glare lamp, and other peripheral equipment.

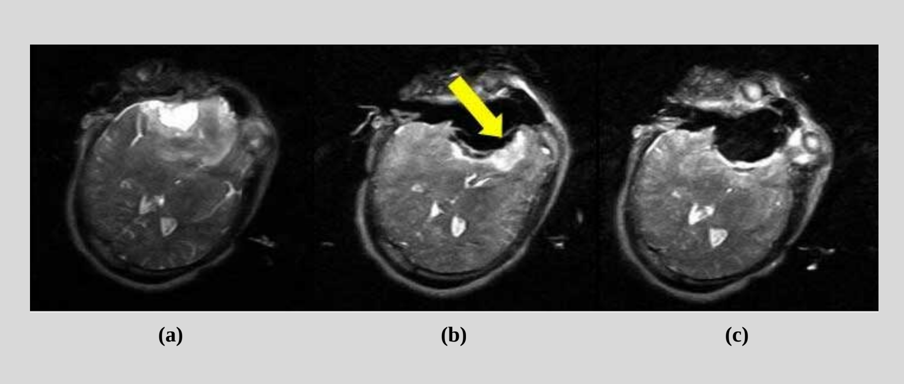

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Fig. 2—MRI Images Taken with Intraoperative MRI Operating Room System.
Images taken (a) before, (b) during, and (c) after surgery. The image just prior to the surgery (a) enables the doctor to pinpoint the exact location of the tumor. The image taken during the surgery (b) allows the surgeon to see how much of the tumor is left (the arrow). And the image after the surgery (c) verifies that the tumor has been completely removed.

minimally invasive surgery: the intraoperative MRI (magnetic resonance imaging) operating room system, a micromanipulator system that supports surgical procedures, and the endoscopic manipulator.

INTRAOPERATIVE MRI OPERATING ROOM SYSTEM

Overview

By exploiting the recent advances in image processing technology for medical applications, dramatic progress has been made in surgery support systems harnessing the power of computers. And this involves not just pre-operative imaging capabilities, for we have also seen very rapid and ongoing development of CT (computerized tomography), MRI, and other technologies for acquiring imaging data even while surgery is in progress. In the year 2000, Hitachi Group installed the diagnostic open-configuration MRI operating room system at Tokyo Women's Medical University, a system supporting safe and highly accurate surgical support providing major benefits to patients and surgical staff alike (see Fig. 1). Although MRI imaging data has been available before and after surgery for some time, now, with the deployment of MRI equipment in the operating room, MRI image data can be obtained even while surgery is in progress. This permits the surgeon to verify shifting and movement of organs in area being operated on and maintains vital functions during the course of the operation. This system has been used with great success in the clean removal of malignant brain tumors that removed virtually all malignant tissue (see Fig. 2).

Configuration

For this implementation we used the open-configuration MRI AIRIS II system (manufactured by Hitachi Medical Corporation) to bring MRI capabilities into the operating room. It is a hamburger-shaped device that uses vertical-field permanent magnets [with static field intensity of 0.3 T (tesla)], and the height of the aperture is 43 cm. A notable feature of the system is that the 5-gauss (500 μT) line range (an indicator of magnetic flux leakage) is quite narrow at only about 1 meter from the MRI gantry edge. Since there are few limitations on the surgical implements that can be used outside this 5-gauss line, it means that ordinary surgical implements and tools can be freely used (see Fig. 3).

It is desirable that the implements likely to be used within the 5-gauss line do not become a source of noise in MRI images or adversely affect the MRI field, which could diminish the performance of the equipment. We therefore teamed up with a number of specialized equipment manufacturers and developing MRI-

Photo: courtesy of Tokyo Women's Medical University

Fig. 3—System at Work in a Clinical Setting.
A key feature of the open-configuration MRI AIRIS II system is that the 5-gauss line range is exceptionally narrow as a result of having minimized the magnetic flux leakage. This permits ordinary surgical techniques to be used right up next to the gantry.

compatible equipment made of nonmagnetic materials. Working out all the technical details, we worked together with these manufacturers to develop enhanced peripheral equipment, which was then incorporated in the intraoperative MRI operating room system including a nitrogen gas-driven MRI-compatible operating microscope (Mitaka Kohki Co., Ltd.), an MRI-compatible operating light (Yamada Shadowless Lamp Co., Ltd.), and an MRI-compatible operating table (Mizuho Co., Ltd.). The one thing that these new peripherals all have in common is that they can be used without ill effect in an MRI environment.

Working outside the 5-gauss line, ordinary surgical techniques and procedures are perfectly compatible with the intraoperative MRI operating room system. When an MRI image is taken, the patient is moved onto the MRI gantry. For moving the patient onto the gantry, the electric motor-driven top plate of an MRI-compatible operating bed is used. It takes about 20 minutes to perform an MRI scan.

Navigation Based on Images Taken During Surgery

It is difficult to differentiate tumor from healthy tissue with the naked eye, so image-based navigation can be an effective tool for assisting the surgeon in removing malignant brain tumors. In navigational surgery, the surgeon sees the area right around the tip of the implement he is holding using an MRI or some other kind of image data, and he performs the operation based on the image data. This allows the surgeon to proceed while constantly checking to see if the tissue is malignant or normal. In traditional navigation-based surgery, the surgeon typically only had access to images taken before the operation. However, one of the challenges of performing craniotomies to remove brain tumors is that the brain tends to subside slightly (brain shift) when the skull is opened due to the outflow of cerebrospinal fluid. In this kind of navigation surgery based on images taken before the procedure, there are sometimes major differences in what the image shows and the actual site of the operation as a result of this brain shift phenomenon.

One of the key advantages of the intraoperative MRI operating room system is that MRI data is collected after the skull is opened during the operation, thus permitting much more accurate navigation surgery that takes the brain shift into account. The system permits as many MRIs to be taken as necessary to provide the navigation system with constantly undated imaged data and support safer, more precise surgical procedures. By checking the progress of procedures against a succession of MRIs, the surgeon can see immediately if it is necessary to continue or if the tumor has been completely removed. This approach permits a significantly higher removal rate than has been possible up to now.

Another key advantage of the intraoperative MRI operating room system is that the surgery is performed while retaining the functioning of the brain. This is important because overshooting and taking out too much is always a calculated risk in brain surgery. Needless to say, motor skills, speech, and other critical functions are localized in the brain, and one slip of the scalpel could result in paralysis, aphasia, or other serious consequences. With the system, the surgeon constantly checks against morphological and functional data revealed in the intraoperative images as he/she precedes, a procedure that minimizes the risk of post-operative complications and ensures a safe outcome.

Performance Assessment

The intraoperative MRI operating room system was used for the first time on March 13, 2000, and as of May 15, 2003, had been used to perform 166 surgeries. These cases included 84 male and 82 female patients, who ranged in age from 1 to 80, and whose average age was 40.5. A diverse range of conditions was treated including 89 malignant brain tumors, 31 pituitary tumors, 8 craniopharyngiomas, 8 cerebral

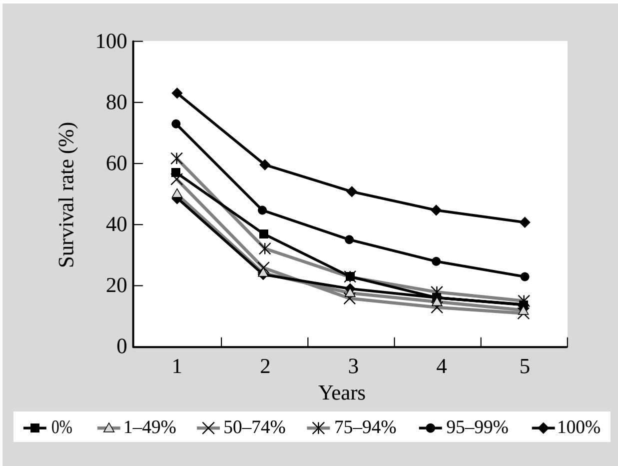

Fig. 4—Survival Rate as Function of Brain Tumor Removal Rate[3).]

A removal rate of less than 94% has little effect on the survival rate, but 20% of patients with 95–99% tumor removal survive longer than five years, and more than 40% of patients with 100% removal survive longer than five years. The importance to patients of a clean removal of tumor tissue is obvious.

arteriovenous malformations, 5 cavernous angiomas, 4 meningiomas, 3 hydrocephalus, and 18 other miscellaneous cases. There has been a clear and discernable improvement in the clean removal rate of malignant brain tumors at Tokyo Women's Medical University since the intraoperative MRI operating room system was introduced. The average removal rate reached as high as 91%, and the complete removal figure for the University has been remarkably improved to 39%, a figure that is extremely high compared to the national average of 8%. The improved removal rate translates directly to enhanced five-year survival life expectancy (see Fig. 4). The system thus makes an enormous contribution to improved QoL (quality of life) of patients since its use results in a better tumor removal rate and an enhanced five-year-survival rate.

Future Issues

Efforts are currently under way to develop an existing system-based operating room system for neurosurgery. We also plan to adapt the system for other surgical specialties including emergency applications, abdominal surgery, orthopedic surgery, gynecology, urology, and ENT (ear, nose, and throat).

MICROMANIPULATOR SYSTEM FOR BRAIN OUTPATIENT SURGERY

Minimally invasive surgery systems for performing malignant brain tumor operations are broadly divided into visualization systems and operation support systems. In this section we will focus on the operation support system approach.

System Configuration

At the core of operation support systems is the micromanipulator. Fig. 5 is a schematic showing the configuration of a micromanipulator. Basically it consists of an endoscope for vision and several micromanipulators that can perform a variety of tasks housed in tip of a long narrow instrument that measures only 10 mm in diameter. The micromanipulator is then inserted through a tiny incision, and minimally invasive procedures are performed from outside the body.

Fig. 5 shows a prototype system that we developed. The tip of the micromanipulator is maneuvered from the control panel shown on the right in the figure. The endoscopic image monitor is shown in the center of the figure, and the holding fixture that holds and fixes the position of the micromanipulator in on the left. An enlarged view of the tip of the micromanipulator is shown in the inset in the lower left.

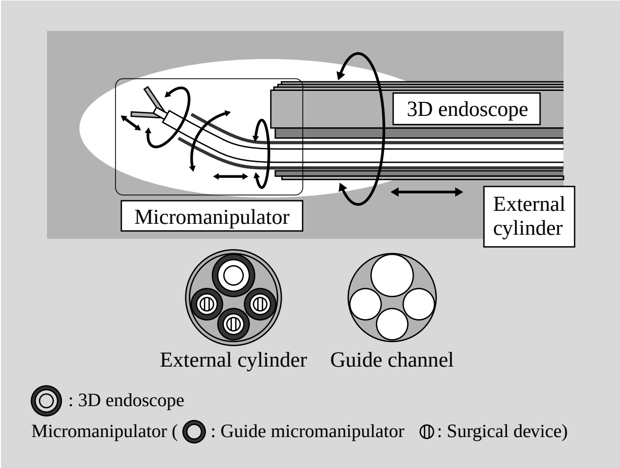

Fig. 5—Structure of Manipulator Tip.
The 10-mm-diameter tip is a narrow converging structure in which three manipulators and an endoscope are bundled. Having three degrees of movement, the manipulators can perform minute actions down to a scale of 10 µm.

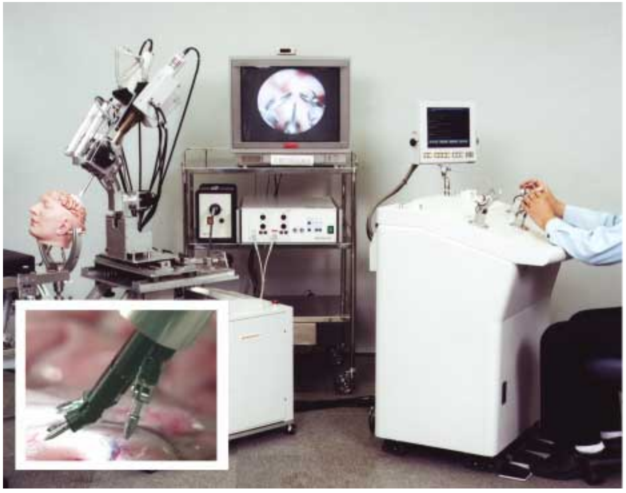

Fig. 6—Configuration of Micromanipulator System.
The control panel is on the right, the endoscope screen monitor is in the middle, and the holding fixture is on the left. The inset shows the tip of the micromanipulator.

A set of three micromanipulators is integrated in the tip that functions as a set of forceps measuring no more than 1 mm in diameter. The tips of all micromanipulators are freely capable of three kinds of movement—swing, rotation, and translation—and a high degree of relative positioning accuracy of less than 20 µm.

As one can see in Fig. 6, the tips of the micromanipulators have a hollow structure with three degrees of freedom, and allow micro surgical tools to pass through the hollow part. The micro surgical tools

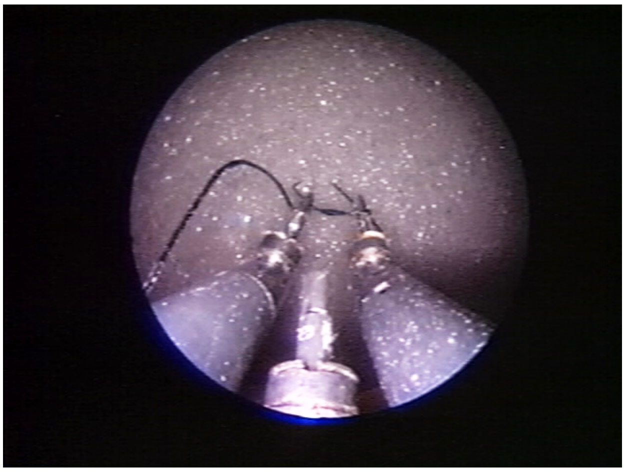

Fig. 7—Tying a Knot.
A clinician attempts to tie a knot based solely on endoscopic images. He found that, with a little practice, he could do it.

Fig. 8—A Clinician Tests the System's Capabilities.
Clinical trials revealed that washing and sterilization procedures presented particular problems for surgical robotics, an issue that has to be assessed from a medical standpoint for the system as a whole.

are interchangeable, and various useful things can be passed through the hollow micromanipulator including fibers, tubes, needles, scoop-like implements, etc. The micromanipulators thus have multifunctional capabilities.

Operating Trials

Fig. 7 demonstrates the system's ability to tie a knot, one task in the operating trials. The trials demonstrated that, with minimal training, a clinician could easily learn to tie a knot with the system. Based on feedback from the clinicians during these trials, the operation of the holding fixture was modified to make it easier to use.

Fig. 8 shows the trial set up with a clinician operating the equipment. To verify the micromanipulator's functionality, we collected basic data using a rat and performed simulated operations on donated cadavers. Problems arose over clinical procedures for washing and sterilizing the subjects. The micromanipulator itself is sterilized by gaseous sterilization. It was verified through repeated use that no complications or abnormalities arose that could be attributed to the sterilization procedures. Bacterial assessments were conducted by the clinician after sterilization, and it was confirmed that required conditions were fully satisfied. The equipment cover was also modified to make it better fit the irregular shapes of the holding fixture and other equipment.

After obtaining approval for the micromanipulator system from the Medical Ethics Committee of Shinshu University School of Medicine, we obtained permission (informed consent) from a patient, used the system on a trial basis for the first time in August 2002, and verified its general effectiveness and performance.

ENDOSCOPIC MANIPULATOR

Overview

Performing surgery using an endoscope has significant advantages for the patient:
(1) small incisions result in faster recovery and return to work (patients can sometimes go home the same day as the operation),
(2) less post-operative pain and trauma, and
(3) less scarring and improved appearance.

The number of hospitals and clinics using endoscopic procedures is steadily increasing. Working together with the University of Tokyo and Kyushu

Fig. 9—Overview of Endoscopic Manipulator System.
The manipulator portion is attached near the center of the bed. The main unit and other peripheral modules are on the left in the photo.

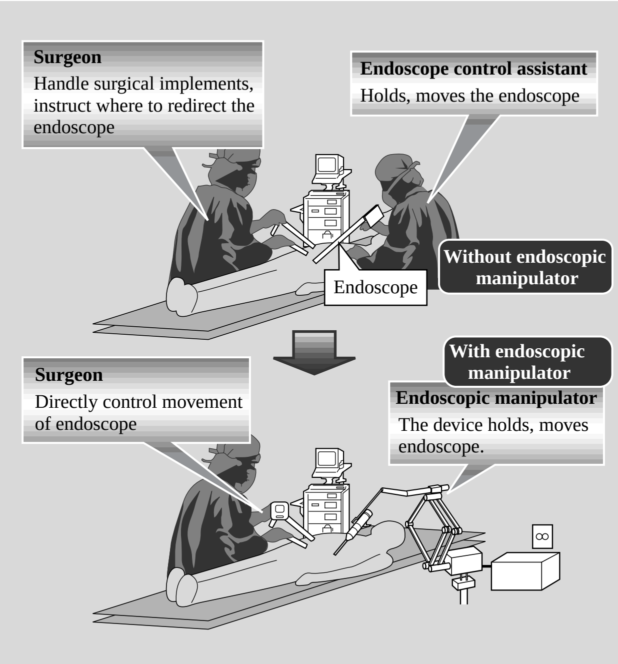

Fig. 10—Operating without Endoscopic Manipulator (above) and with Endoscopic Manipulator (below).
In laparoscopic surgery an assistant holds and moves the endoscope on the command of the doctor, so mutual understanding between the doctor and assistance is critically important. The primary advantage of the endoscopic manipulator is that the doctor himself directly repositions and points the endoscope.

Photo: courtesy of Kyushu University

Fig. 11—Clinical Trials Conducted at Kyushu University Hospital.
The performance and utility of the endoscopic manipulator was demonstrated in clinical trials carried out in cooperation with Kyushu University. The deployment and acceptance of the system has gone smoothly, and there have been no infections or accidents so far that are attributed to the use.

University, Hitachi Group developed an endoscopic manipulator, a system permitting the surgeon himself to control the endoscope while performing laparoscopic surgeries [4, 5], the first operation support system to be commercialized in Japan (see Fig. 9).

Generally when a laparoscopic surgery is performed, an assistant holds the endoscope, and repositions it as directed by the surgeon. In the system, the endoscope is held by the device, and the doctor controls the endoscope using a control switch attached to his surgical tool (see Fig. 10). This permits the surgeon to immediately see exactly the spot he wants to see without the stress of interacting with another person, and contributes to safer, more certain surgical outcomes.

Essentially, the endoscopic manipulator gives surgeons the ability to point the endoscope anywhere they want, utilizing recent advances in manipulation technology developed by Hitachi in collaboration with the University of Tokyo. With safety being the number one priority, the system was carefully engineered so that shifting or repositioning the endoscope could not in any way damage other organs, interfere with surgical implements, or malfunction, and mechanics that are highly resistant to failure were adopted. The effectiveness of the system was verified and the system was fine-tuned to make it more practical through clinical trials carried out in cooperation with Kyushu University.

Fig. 11 shows the clinical setting at Kyushu University. By the end of June 2003, Naviot had been deployed in 16 hospitals and used in 51 cases. The system was mainly used to perform cholecystectomies, but we believe the system could be readily adapted to a number of new areas including obstetrics and gynecology.

Features

Now let us highlight the principle features of the endoscopic manipulator:

(1) Surgeon freely points the endoscope

By pressing a switch that is attached to forceps or other implement, the surgeon controls the attitude and orientation of the endoscope, and the field of view illuminated by the endoscope shifts in the direction indicated.

(2) Ensured mechanical safety

The endoscope is anchored by the puncture incision or port into the abdominal cavity, and because the endoscope can rotate in the port, there is no danger that the port will cause an internal wound. And by incorporating an optical zooming mechanism, the need for the endoscope to physically move forward into the abdominal cavity and the risk of interfering with other organs has been eliminated. The endoscope has also been designed to make it easy to remove the instrument from the port in the abdominal cavity. Finally, the mechanism limiting the degree of freedom movement has been simplified making it far less likely that the device will malfunction or fail.

CONCLUSIONS

This article describes a number of minimally invasive surgical systems, part of a broad initiative by the Hitachi Group to help cope with the growing elderly population and medical problems associated with the aging of society.

The intraoperative MRI operating room system was originally developed as an operating room support system for neurosurgery, but subsequently migrated to other surgical specialties including emergency response, abdominal surgery, orthopedic surgery, gynecology, urology, and ENT. We anticipate that the micromanipulator system developed for brain surgery and the endoscopic manipulator will also see significant functional enhancement and application to a wide range of areas.

In addition to the systems surveyed in the paper, Hitachi Group has other systems under development including a laser guidance system that supports surgical navigation and an MRI surgery support system targeting heart and abdominal diseases. It is also clear that, before surgical robotics can take hold and become widely adopted, approved standards making procedures and system education must be put in place. Working closely with many who are in positions of leadership in the medical field, Hitachi Group is committed to continue its efforts to develop this field.

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