

Fig. 5 Structure of thin bundle system

using the nesting of drive mechanisms for different motions ensures freedom from interference between different motions, thereby improving the stability and reliability of movement.

Thin-bundle System Combining Multiple Manipulators

To be able to operate multiple manipulators as a bundle in the inserted part, interference between manipulator drive mechanisms, as well as that between them and the camera unit of the endoscope, needs to be avoided. A mechanism allowing smooth rotation and translation in the bundle of multiple manipulators is also needed.

In this system, one end segment of the hollow pipe shown in Fig. 4 is made of a hollow flexible torque tube, which is curved and fitted in an adapter so that the drive mechanisms of the multiple manipulators are kept in place without causing mutual interference. Fig. 5 illustrates the system with an endoscope and two HUMAN manipulators installed. This structure solves the problem of interference between mechanical elements. While avoiding interference, the flexible torque tube transmits the torque and thrust for rotation and translation movements along the curved path. When the drive mechanism (shown in Fig. 4; located in an area of the drive

mechanism of the HUMAN manipulator in Fig. 5) exerts the torque and thrust for rotation and translation movements, the action is efficiently transmitted to the joint at the tip of the manipulator.

Mechanism for Changing Surgical Tools

A surgical manipulator must have a mechanism for changing surgical tools without replacing the manipulator itself so that the development of surgical tools may be facilitated and a variety of surgical tools can be used during an operation.

To create this mechanism for changing surgical tools, we designed the HUMAN system is designed to have a hollow structure as shown in Fig. 4. We developed a surgical-tool unit that enables various surgical tools to be attached to and removed from the tip joint by means of insertion and withdrawal through the bore. We also developed various tools that can be attached and removed in this way; including those with driving mechanisms, such as tweezers, biopsy forceps, scissors, and bipolar forceps,⁹ and those without driving mechanisms, such as monopolar tools, S-shaped hooks, spatulas, and needles.

The surgical-tool unit consists of a power-transmission part, with an outside diameter of

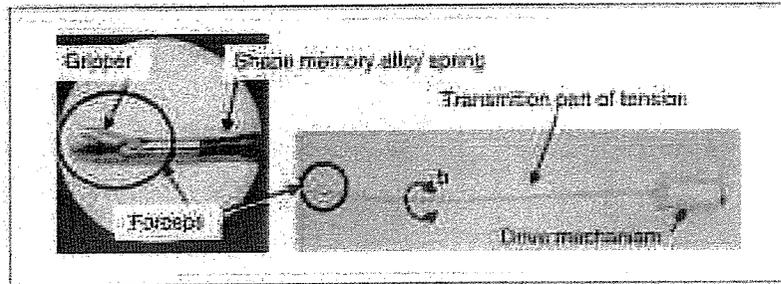


Fig. 6 Surgical-tool unit

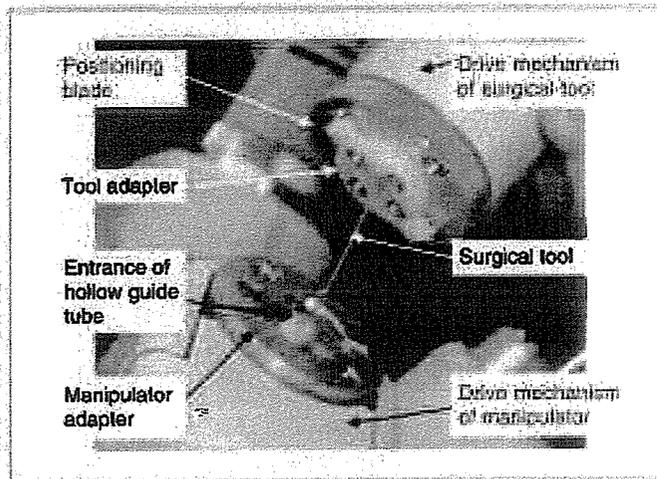


Fig. 7 Usage of exchangeable adapter module

1 mm, which extends from the drive mechanism and has a pair of forceps at the tip (Fig. 6). The opening and closing motions of the gripper part are controlled by transmission of the power produced by the drive mechanism via the drive wire located in the tension-transmission part. A torque tube with high torque-transmission efficiency is used in the tension-transmission part. With this mechanism, the tool inserted in the joint can be rotated (motion labeled "b" in Fig. 2 and Fig. 6) by the twisting motion of the power-transmission part applied to the drive mechanism, and the tool can be inserted and withdrawn freely even when the path in the hollow tube is curved as in Fig. 5. The ability to rotate the surgical tool enables the direction of the opening and closing of the tool to be changed relative to the direction of joint bending (α in Fig. 2), thereby improving the maneuverability

of treatment operation.

To achieve this rotation capability, the forceps must be able to be bent toward in direction and follow the bending of the joint. To this end, the part corresponding to the movable part of the micro-joint on a neck of the forceps has been designed with a super-elastic shape-memory-alloy spring (Fig. 6). This super-elastic material has the advantage of high flexibility combined with the resistance to plastic deformation. Irrespective of the direction of the opening and closing of the tool relative to the bending direction of the joint, this structure of forceps enables the surgical tool unit to follow the bending motion of the manipulator without interference. At the same time, this structure with a shape-memory-alloy spring prevents permanent curling of the device in a certain direction, realizing a durable system suitable for practical use.

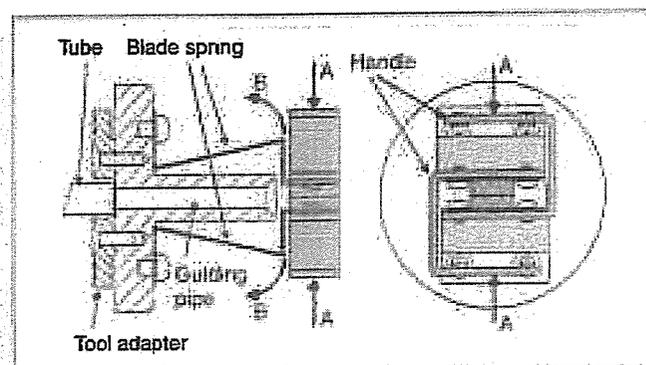


Fig. 8 Tool holder

Fig. 7 illustrates how the surgical unit is installed. The surgical tool is fixed to the manipulator by a newly developed adapter module consisting of a tool adapter and a manipulator adapter complementing it. The tool adapter is fixed to the end of the surgical-tool drive mechanism (Fig. 7). The manipulator adapter is fixed to the bending unit (to the extreme right in Fig. 4 and in Fig. 7). At the center of this adapter, there is an entrance leading to the bore of the manipulator. The surgical tool is inserted from here and is led through the hollow path to the joint tip. The tool adapter is then connected to the manipulator adapter using a rotating motion, which integrates the tool and manipulator drive mechanisms. This connection also integrates the inserted tool with the micro-joint as shown in Fig. 2. Similarly to the structure shown in Fig. 4, this structure avoids mutual interference between different motions of the manipulator and the surgical tool, realizing good stability and reliability of motions during use of the manipulator with surgical tools attached.

Fig. 8 schematically shows the surgical-tool holder, which is used for attaching monopolar forceps and other dedicated tools with no drive mechanism, as well as third-party flexible surgical tools, to the manipulator. Also attached to this holder is a tool adapter that can be attached to the manipulator drive mechanism in place of the tool drive mechanism. The surgical tool is inserted into the guiding pipe connected to the bore of the manipulator, and this tool is held by handles. As an example, we experimentally confirmed the feasibility of this holder in using third-party optical fibers for laser knives.¹⁰

Safety Control

Because conventional systems are targeted at use in the abdominal cavity, they are designed to move the manipulator over a wide area with a spatial resolution of several millimeters. In the position-control systems developed for such applications, the position of the operating lever responding to the surgeon's maneuver is sampled at a frequency of 1,000 times per second and feedback to the manipulator.

In contrast, because our system is intended for neurosurgery, it can perform fine movements at steps smaller than $10\ \mu\text{m}$ in volumes as small as $1\ \text{cm}^3$, as shown in Table 1. It detects the input force applied by the surgeon at a frequency of 250 times per second and with a resolving power of 7.8 mN. According to the detected amount of input movement, the position after the execution of movement is calculated and actual movement is performed only when the calculated result falls within the prescribed range of allowed movement. This method of control, developed for this system to ensure safety, is called "prior-confirmation-based safety control". Compared with frequency of position detection of conventional systems, that of our system is lower, but a higher degree of safety is realized, because safety is confirmed before actual movement and the resolving power is finer than that of conventional systems by a factor of 100. In this way, our system prevents any movement of the manipulator beyond the predetermined range in the field of neurosurgery, where the safety of the surrounding normal tissues is crit-

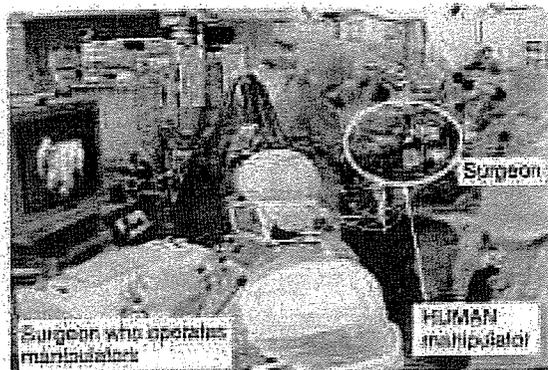


Fig. 9 Clinical use of the HUMAN system (overall view)

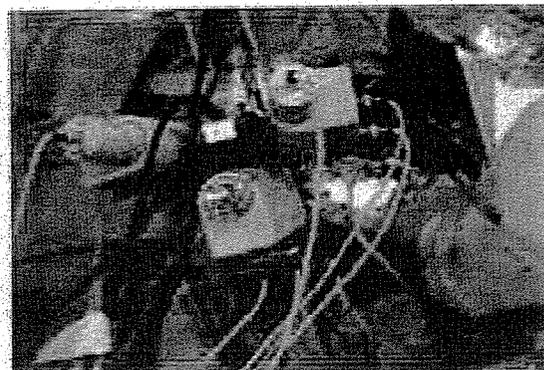


Fig. 10 Clinical use of the HUMAN system (close-up)

ical. In this system, the check and control for ensuring the safety of manipulation in the background of operation is performed in a triplicate manner.

Clinical Use

In addition to the mechanical development described above, we have repeated manipulation experiments,¹⁰⁻¹² confirmed sterilization properties,¹³ and simulated surgical operations¹⁴ in cooperation with surgeons.

This system was designed as a unit-based structure that can be disassembled and assembled by medical staff, and all parts were sized to fit in sterilization containers, ensuring the ease of sterilization and scrubbing. In the sterilization experiments, all separable units of the manipulator system were treated with ethylene oxide gas (EOG) sterilization, and we confirmed that the number of viable bacterial cells was 10^6 times lower than the level needed to guarantee sterility. In the manipulation experiments and the simulated surgical operations using our system, presuming actual surgical operations, we repeatedly evaluated the methods of system operation and confirmed the surgical procedures.

After these experiments, we obtained the approval of the ethics committee of Shinshu University and the informed consent from patients and their families. Following these steps, we have so far been able to use this system in the treatment of four patients.

The first clinical use of this system was as represented in Fig. 9 to Fig. 11. The patient was a



Fig. 11 Endoscopic view of manipulators performing enucleation of a tumor

54-year-old male. The target lesion was a recurrent meningioma in the left middle cranial fossa.⁶ In this clinical case, conventional craniotomy was performed, and the manipulator was set up at the side of the surgeon performing the operation with his own hands. Another surgeon operated the manipulator, while observing the field of operation in the endoscopic image, as shown in Fig. 11. Procedures performed using the manipulator started with the separation of normal brain tissues and tumor by using a spatula and an S-shaped hook. Detachment was performed by grasping the tissues with forceps. Next, bipolar forceps were used to coagulate blood vessels on the tumor surface, and the tumor was exposed and then enucleated using a laser knife and forceps. The time required for tool exchange and resuming the operation was

about 1 min per exchange.

During the operation, smoke resulting from the use of the laser knife and bipolar forceps, as well as fogging and staining of the endoscope lens, was generated. However, a clear field of view could be maintained throughout the operation by smoke suction and dripping via the irrigation tubes installed in the insertion part.

As shown in Fig. 11, the system can safely remove a tumor as small as about 1 mm using the finely controlled movement of the manipulator. According to the system warning, input operations exceeding the prescribed limits of motion occurred during the operation, but the prior confirmation-based safety control worked and the manipulator did not move beyond the range of permitted motion.

Discussion

Conventional systems are designed to work in wide spaces in the peritoneal cavity, and treatment using such systems is set up with two manipulators (10 mm in diameter) and an endoscope inserted through three incisions. In this case, the manipulators move widely to cover the wide area to be treated. Collision between the arms holding the manipulators, as well as collision between a manipulator and a medical staff nearby, occasionally takes place, so medical staffs have to pay great attention to manipulators when supporting treatment around them.

In contrast, our system (with a thin bundle system structure) enables three manipulators (3 mm in diameter) and an endoscope to approach the lesion through a single insertion part (10 mm in diameter). In addition, it can perform fine movement of manipulators without moving the insertion part. As a result, this system also opens up the possibility of cooperative treatment in which a manipulator system is set up next to a surgeon performing delicate treatment. In these respects, our system is considered safer and more convenient than conventional systems using large motions.

Conventional systems have already been provided with interchangeable dedicated surgical tools. However, it has been demonstrated in clinical tests that the HUMAN system can be used with third-party surgical tools, such as optical fibers for laser knives, in addition to dedicated tools. The ability to accept third-party surgical

tools means wider choices of surgical tools to meet various clinical situations. In addition, the HUMAN system accepts almost any surgical tool that has an outside diameter of no more than 1 mm and is flexible. This advantage encourages the development of surgical tools in response to the needs in clinical practice and, thus, helps increase system expandability. Through the training effect, it is considered possible to shorten the time required for changing surgical tools and resuming the operation procedure.

The use of fine movements smaller than 10 μm was infrequent, but the movements were effective in situations requiring careful manipulation, such as manipulation around a tumor. Since movement beyond the range of permitted motion was successfully prevented in clinical use, the ability to achieve fine movement and the prior-confirmation-based safety control contributed synergistically to the improvement of safety.

As discussed above, the practical feasibility of the basic functions of the HUMAN system has been confirmed in clinical settings.

Conclusion

We developed a surgical manipulator system—called HUMAN—to enable minimally invasive surgery in the field of neurosurgery. This system is characterized by the concept of performing minute and accurate surgical manipulation using an endoscope and three surgical tools inserted through a single small cranial opening. As a world's first, we succeeded in the clinical application of a manipulator system to the field of neurosurgery and confirmed the practical feasibility and safety of this system.

As a characteristic feature of this system, a manipulator incorporating a flexible-torque-tube structure, which consists of three surgical tools and an endoscope contained in the insertion part with a diameter of 10 mm, was first developed. Next, stable movement of this system with surgical tools installed in the insertion part was achieved. This made it possible to perform minimally invasive surgery via a single insertion part. We conducted clinical tests using the manipulator system at the side of a surgeon. These tests demonstrated that the surgeon and the manipulator system can cooperate and safely perform therapeutic operations.

Second, a mechanism for easy replacement

of surgical tools, as well as a large variety of surgical tools that can be attached to the manipulator, was developed. We demonstrated the convenience and practical effectiveness of this mechanism in clinical tests, where we were able to use and replace multiple surgical tools (including forceps and laser knives) as needed during a surgical procedure.

With respect to system safety, we developed a drive mechanism to avoid interference between different motions of a manipulator. As a result of this mechanism, high performance, namely, minute therapeutic manipulation smaller than 10 μm , was achieved. We also developed a method called "prior-confirmation-based safety control", in which actual movement of the manipulator takes place only after prior calculation of the position that would result from the input manipulation. These two mechanisms realized a high degree of safety in a field of application,

such as the field of neurosurgery, where ensuring the safety of the surrounding normal tissues is critically important. At the same time, the results of our clinical trial demonstrated the ability of these mechanisms to support the safe operation of the system in clinical use. In future development of the HUMAN system, we plan to expand its applicability to a larger variety of cases and more fields of practice.

Acknowledgements

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A Novel Robotic Laser Ablation System for Precision Neurosurgery with Intraoperative 5-ALA-Induced PpIX Fluorescence Detection

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Abstract. We developed a combined system of tumor detection by 5-ALA-induced PpIX fluorescence and precise ablation by micro laser for the first time, with an automatic focusing and robotic scanning mechanism for the brain surface. 5-ALA accumulates on tumors to be metabolized to become PpIX that is a fluorescent. Intra-operative detection of 5-ALA induced PpIX fluorescence provides useful information for tumor detection. The wavelength of the micro laser is 2.8 μm close to the absorption band of water. This laser is effective only on the surface of brain tissue, enabling precise ablation at the boundary between tumor and normal tissue identified by intra-operative 5-ALA induced fluorescence. Combination tests of the fluorescence measurement and the laser ablation were performed, and it was possible to extract the area with fluorescence appropriately from the measurement data, and the micro laser with automatically scanning selectively ablated the extracted area.

1 Introduction

In current neurosurgical practice, surgeons can remove most of a tumor with an accuracy of a few millimeters by using a combination of conventional surgical instruments, such as an electric cautery, and a computer-aided navigation system based on diagnostic images, such as MR and CT images. Residual tumor, especially if the malignant tumor like glioma, may impair the prognosis of the patients and it is necessary to remove as much of the tumor as possible while keeping the normal tissue

intact. However, it is difficult to know the exact boundary between tumor and normal tissue, and excessive ablation of the normal brain tissue will damage its function.

In craniotomy procedure, deformation of the brain tissue, called "brain shift", occurs due to cerebrospinal fluid leakage and surgical interventions. In some cases, brain shift reaches to several tens of millimeters and continuously increases during the procedure [1]. This requires navigation based on intraoperative MR images. This navigation, however, contains a few millimeters of errors at a maximum caused by a registration of preoperative diagnosis images [1] and intraoperative images and an accuracy of the position tracking using such as an optical marker. Furthermore, there is a tradeoff between high frequency of image acquisition for more accurate navigation and not time-consuming imaging.

Similarly, the accuracy of conventional surgical procedures is a few millimeters for removal of residual tumors. Therefore, we desired to achieve a more precise operation with an accuracy of sub-millimeters. To that end, each of a measurement and removal of residual tumors has to realize this accuracy.

To solve these problems, we have proposed a novel approach to therapy using 5-aminolevulinic acid (5-ALA) [2][3] and a micro-laser ablation system [4], with the boundary between the tumor and the normal tissue distinguished by the 5-ALA-induced protoporphyrin IX (PpIX) fluorescence in the tumor and with accurate ablation of the tumor with the micro laser. 5-ALA, which is orally administrated to a patient, accumulates on tumors to be metabolized to become PpIX that is a fluorescent substance [5]. The wavelength of the micro laser is 2.8 μm . Light with this wavelength is mostly absorbed by water, and therefore this laser is effective only on the surface of brain tissue, enabling precise ablation at the boundary between tumor and normal tissue [4].

In this paper, we developed a combined system of tumor detection using 5-ALA and precise ablation by micro laser, with an automatic focusing (AF) and robotic scanning mechanism for the brain surface. This system is designed for possible localized pinpoint detection of the tumor, then ablating the fluorescent area with stepping driven precise position control in the whole system. This is first attempt to integrate intraoperative fluorescence detection and high precision laser ablation system. In addition, each of the measurement and ablation is performed under the robotic position controlling.

2 Materials and Methods

In this chapter, the tumor detection using 5-ALA-induced PpIX fluorescence, the micro laser module, the automatic focusing and robotic scanning system, and the whole system integration are described. Finally we proposed the experimental procedure for combining these surgical processes.

2.1 Intraoperative Detection System for Brain Tumor Using 5-ALA

Fluorescence of PpIX is fully observed a few hours after orally administrated 5-ALA. Irradiating near-ultraviolet light of around 400 nm, PpIX emits the fluorescence of the wavelength of 635 nm at peak intensity from the brain tissue.

Applying a highly sensitive camera is one of the reasonable ways for intraoperative detection of PpIX fluorescence. Although it is possible to acquire a wide-area 2-dimensional data at one time, obtained data contains only light intensity and simple color information. As PpIX fluorescence is so much weaker than the excitation light and a guide laser of the AF system, it requires the optical narrow-band-pass filter to cut off the other light sources. Nevertheless, it is difficult to separate the fluorescent component from the intensity and the color information of the image signal. Therefore, we chose the use of a spectral photometer, easily extracting the peak intensity of the fluorescence. The spectral data contains important information about tumors; for example, a spectral shape and a peak wavelength possibly vary with a density of tumor cells, a class of tumors, and other conditions of tissues. In the future task, we consider acquisitions of the functional information of tumors by spectral analysis.

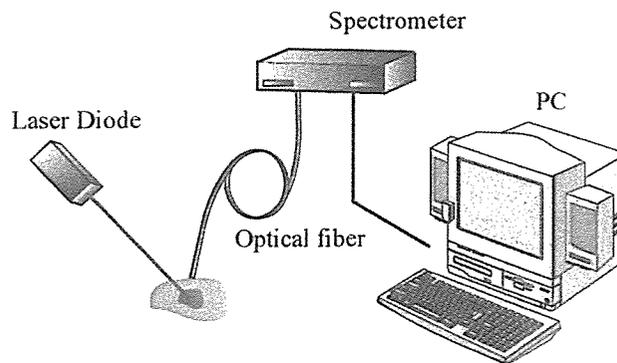


Fig. 1. Tumor detection system using 5-ALA-induced PpIX fluorescence

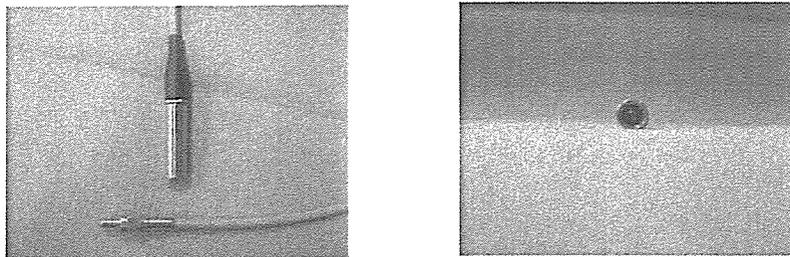


Fig. 2. Fluorescence detection probe

PpIX fluorescence was collected by a detection probe and guided into a spectrophotometer through an optical single-mode fiber, then performed spectral analysis (Fig. 1). The detector has a diameter of 8 mm, using aspheric lenses to correct aberrations. The detection resolution is set to 0.6 mm, considering a tradeoff between not decreasing of the acquired light intensity in proportion to the square of the resolution diameter and improving the accuracy of the measurement (Fig.2). A band-pass filter, which transmits over 60 % at 635 nm and up to 5 % at 670 nm, was

fixed on the tip of the detector, cutting off the excitation light and the guide laser (peak at 670 nm) of the AF system. The working distance of the detector is 16 mm to a tolerance of plus or minus 0.5 mm.

2.2 Micro Ablation Laser Module

For ablation of tumor tissues, we used a mid-infrared continuous-wave laser with a wavelength of 2.8 μm , being output by a microchip solid-state laser on the tip of a laser probe [4]. The pumping light source for the solid-state laser is a near-infrared diode laser with a wavelength of 970 nm, guided through a quartz optical fiber to the laser probe.

As the light wavelength around 3 μm has strong absorption feature by water, this laser is effective only on the surface of the living tissue, and it can make a precise ablation with a low output of 0.2 W or less. The laser beam is focused to a diameter of 0.1 to 0.15 mm with a lens, and an ablation groove is formed equivalent to the spot diameter in the soft vital tissue. The working distance of the laser probe is 15 mm \pm 1 mm.

2.3 Automatic Focusing and Robotic Scanning System

Both the fluorescence detection probe and the micro laser probe have each working distance, and this requires an AF mechanism, constantly maintaining the distance from the brain surface. In this practice, we used an AF system designed based on the three-dimensional measurement system (Mitaka Ko-ki Co., Ltd.) (Fig. 3). In this system, position measurement was performed using a confocal optical mechanism and the guide laser was picked up with a split photodiode, enabling a focusing with an accuracy of micrometers. The wavelength of the guide laser is 670 nm. This system was coupled with 2-axial automatic stepping drive stage and can make a robotic scanning on the surface of the brain.

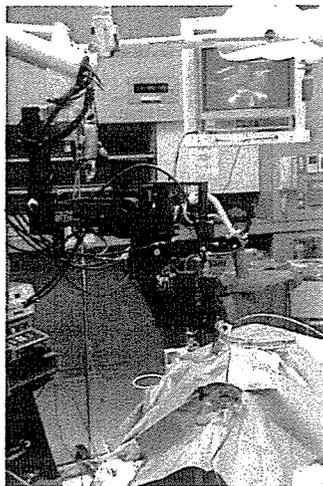


Fig. 3. Automatic focusing and robotic scanning system

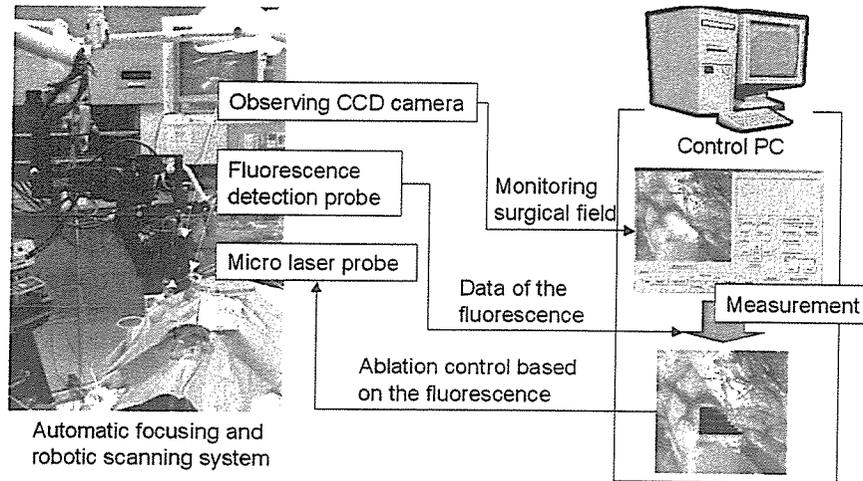


Fig. 4. System configuration

2.4 System Integration

Fig. 4 shows the system configuration in this paper. The fluorescence detection probe and the micro laser probe were attached to the AF system. The data from the spectral photometer was stored into a personal computer (PC). Switching of the micro laser and scanning with the stepping drive were both controlled by the PC. We can observe surgical field view by a CCD camera in the AF system. This image was used to control electric motors to position the fluorescence measurement system and the laser ablation system.

2.5 Experimental Procedure

Measurement of Fluorescence Signal

Measurement area was defined on a CCD camera view of the AF system and sectioned in a grid pattern. Measurement was performed on each grid point with raster

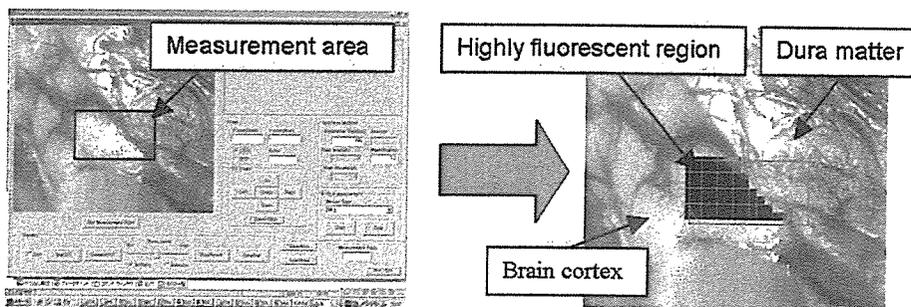


Fig. 5. An example of the measurement procedure of the fluorescence on a porcine brain

scanning. A point in the measurement area was regarded to have same fluorescent property with nearest grid point. A grid interval was determined to 0.4 mm, considering that the grid square was included in the circle of the measurement resolution of 0.6 mm. As a measurement required more than a few hundred of milliseconds, it took several tens of seconds or more to measure a few millimeters square. Fig. 5 shows an example of the fluorescence measurement procedure.

Ablation of the Target Area

A threshold was set for the intensity level of measured fluorescence. In this paper, a surgeon or an experimenter determined the threshold, viewing the measurement area on the CCD camera image. Then scanning was started, and the micro laser was automatically irradiated on the region over the threshold.

3 Results

Combination tests of the tumor detection system and the micro ablation laser module were performed for a biomedical simulant material (phantom) and a porcine brain.

3.1 Phantom Experiment

The phantom was composed of agar plate containing Intralipid-10% that is intravenous lipid emulsion and used for scattering medium [6]. The concentration of Intralipid-10% was adjusted so that the scattering coefficient became 3 cm^{-1} , which is similar to that of Glioma [6][7]. A half part of the phantom contained PpIX to emit fluorescence and the other half part did not contain PpIX.

Fig. 6(a) shows one of the results of experiments. Black rectangular area stands for the scanned area by the system. The system could identify the boundary between the area with fluorescence and without fluorescence, and could precisely ablate the fluorescent area with automatically scanning.

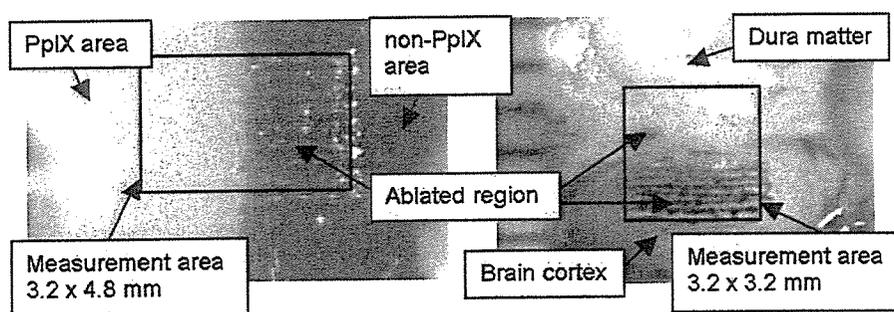


Fig. 6. Result of the combination tests of the tumor detection system and the micro ablation laser module

3.2 Porcine Brain Experiment

The target was the surface of a porcine brain exposed by craniotomy under anesthesia. Before the experiment, 5-ALA was administered in sufficient quantities to accumulate on a normal brain tissue and metabolize to become PpIX. A half of the measurement area was covered with dura matter, where the fluorescence was not observed, and the other half was exposing brain cortex.

Fig. 6(b) shows one of the results of experiments. Black rectangular area stands for the scanned area by the system. The dura matter covering the porcine brain could not completely block the fluorescence. We could identify weak signal of fluorescence from some part of the dura matter. As shown in Fig. 6(b), ablation laser was irradiated to such area on the covered region. We could successfully identify and ablate the fluorescent area of the porcine brain based on the fluorescence data. The AF system functioned properly even for porcine brain and was effective to stabilize both of the conditions of the measurement and the laser ablation.

4 Discussion and Conclusions

We developed a combined system of tumor detection by 5-ALA-induced PpIX fluorescence and precise ablation by micro laser for the first time, with an automatic focusing and robotic scanning mechanism for the brain surface. In this system, ablation was performed based on the fluorescent information under the robotic position controlling.

Combination tests of the fluorescence measurement and the laser ablation were performed for a biomedical simulant material (phantom) and a porcine brain. Measurement areas of the phantom and the porcine brain were both separated into fluorescent part and non-fluorescent part. In each test, it was possible to extract the area with fluorescence appropriately from the measurement data, and the extracted area was selectively ablated by the micro laser with automatically scanning.

In this practice, the experimental targets were clearly separated into the area with fluorescence and without fluorescence. In clinical cases, the boundaries between tumors and normal tissues are often unclear, and tumors invade normal tissues. Therefore, thresholding of a fluorescence data and an extraction of the area for ablation will have problems, and are considered making some automation process. Solutions for these problems are desired in the future work. To automatically discriminate the tumor region by fluorescence data, a multiple classification analysis based on another spectral features not only peak intensity of the fluorescence will be investigated.

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Feasibility Analysis of Bipolar Electric Scalpel Forceps Manipulator with 2-DOFs Bending Mechanisms

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Abstract— This paper proposes multi-functionalization of the previously reported laparoscopic forceps manipulator with multi-slider linkage mechanism which enables 2-DOFs horizontal and vertical bending of ± 90 degrees and 1-DOF grasping manipulation. Specifically we added a bipolar electric scalpel function on the forceps blades for more safe, speedy and efficient surgical operation with coagulation of tissues and occlusion of blood vessels from various directions in abdominal cavity. This functionalization can lead cutting down the number of surgical instruments and insert ports, and saving troubles of changing tools. For the scalpel function, we mounted a pair of electrodes measuring $1.0 \times 5.0 \times 0.1$ mm \times 2 lines aligned with a 0.5-mm space, to generate high current density between two forceps blades. In animal experiment using swine (39 kg, male), we evaluated the ability of occluding blood vessels on mesenteric surface tissues through various directional approach paths using 2-DOFs bending manipulation effectively. We coagulated blood vessels 2-3 times with setting of 20 W and 2-3 seconds energization. And in order to confirm whether the blood vessels were completely occluded or not, we attempted a cut of ablated parts with scissors and checked blood leak. In this experiment we tried to occlude 6 vessels. Four vessels were occluded successfully, while other two vessel occlusions were incomplete. A little leak was shown in these vessels, however, some repeated coagulation made complete seals. These incomplete coagulations resulted from ablated tissues on the electrodes surface for something of a shield to interrupt effective energization. For the solution of this trouble, it can be effective to improve the electrode and forceps blade shapes. In conclusion, we are sure of feasibility of the bipolar electrode scalpel function with multi-DOFs bending manipulator to ablate tissues and seal blood vessels for laparoscopic clinical applications.

Keywords— Bipolar electric scalpel, Laparoscopic forceps manipulator, Occlusion of blood vessels

I. INTRODUCTION

Laparoscopic surgery enables the incision on abdominal wall smaller and makes invasion to patients minimal. For this advantage this surgery is taken in almost all surgery,

such as abdominal surgery, chest surgery, orthopedic surgery, brain surgery, obstetrics and gynecology. Surgical instruments such as forceps and electric scalpel are, however, straight-shape thus surgical approaches and manipulations are restricted due to low degree-of-freedom (DOF) instruments through trocars. This inflexibility causes one of the surgeons' mental and physical stress. In order to overcome this issue on limited maneuverability, several robotized devices have been developed to add additional DOFs at the manipulators tip [1]-[3]. Our group developed laparoscopic bending forceps manipulator with multi-slider linkage mechanisms to achieve wide-range 2-DOFs motion at the tip of the forceps in the abdominal wall [4][5]. The linkage-driven approach, unlike recently reported wire-driven mechanisms, enabled sufficient bending power of up to 0.85 kgf, high accurate manipulation of less 1.0 mm, high stiffness and durability. This manipulator performed laparoscopic surgical tasks, such as raising the liver and stomach, stitching and suturing the surface tissues in vivo experiments using swine. However the manipulator had only a forceps function for the end-effector so it was not adaptable enough for a variety of operations.

Therefore we will propose in this paper multi-functionalization of the laparoscopic forceps manipulator to cut down the number of surgical instruments and insertion ports and to save troubles of changing tools so as to improve safety and efficiency of surgical operations for more minimal invasive surgery. In laparoscopic surgery it is significant to do vessel manipulations around the affected area safely and speedy. Current standard electric scalpels are often used for vessel manipulations so it is expected to be useful to combine electric scalpel function and multi-DOF bending mechanism for highly efficient coagulation, exfoliation and occlusion of blood vessels.

This paper reports 1) the addition of a bipolar electric scalpel function on the previously reported laparoscopic forceps manipulator with 2-DOFs bending mechanism, 2) feasibility analysis of this manipulator in vivo experiments to evaluate it for laparoscopic clinical applications.

II. MATERIALS AND METHODS

A. Bipolar Electrode Specification

We mounted a pair of electrodes on the stainless-steel forceps blades surface of the laparoscopic 2-DOFs bending manipulator in order to add a bipolar electric scalpel function. Current standard electric scalpels are for dissection or coagulation, for the former function fine tweezers-type instruments are mainly used in microsurgery. In the meanwhile for the latter function, general forceps-type instruments with properly designed electrodes are often used. Our purpose in this study is to enable dexterous vessel manipulations with multi-DOFs bending motion, therefore we determined the electrodes dimension referring to recently reported studies, such as LigaSure™ (Valleylab, USA) for vessel sealing application [6][7] and the bending forceps manipulator with an electric-cautery function for cystic duct obstruction [8].

Electrodes measurement was 1.0 x 5.0 x 0.1 mm x 2 lines aligned with a 0.5-mm space (Figure 1). Material of electrodes was nickel-based gold, and between electrodes and blades, the insulating resin sheets (glass epoxy) were layered to insulate the electrodes from other components of forceps bending mechanisms. Our manipulator had sufficient grasping power up to 0.85 kgf, thus in case grasping blood vessels and surrounding connective tissues, the gap between electrodes could be so narrow that current efficiency through tissues would be very high.

B. System Configurations

The system configuration of the bipolar electric scalpel manipulator consisted of mainly five parts (Figure 2). First part was the multi-DOFs end-effector with 2-DOFs bending mechanism and 1-DOF grasping forceps blades with a pair of bipolar electrodes. Second part was the linear-drive unit consisted of three sets of brushless DC-servomotors

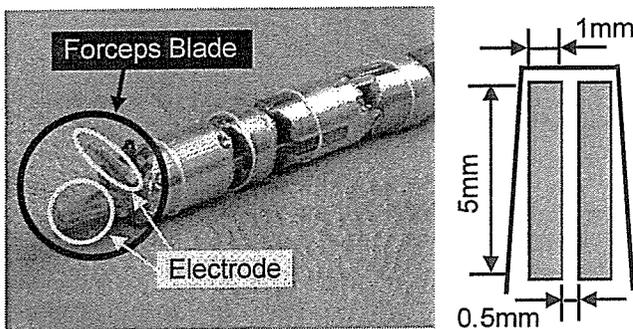


Fig. 1 Shape of bipolar electrode on the multi-DOFs forceps blades.

(FAULHABER GROUP MINIMOTOR SA, 1628 024 B), linear sensors detecting linkage displacements (ALPS ELECTRIC CO., LTD., RDC1014A09), linear-guides (THK Co., Ltd., RSR3WNUU+36L+) and ball-screws (NSK Ltd., M3 x 0.5). Third part was the dial-type interface with three spindle operated potentiometers (Meggitt Electronic Components Ltd., TYPE 51 SERIES), that had two dials for the horizontal and vertical bending operation, a trigger lever for grasping operation and a button for straightening the bending mechanisms in case of getting through a trocar. Fourth part was the computer-based control unit that consisted of a laptop computer (CPU: Intel Pentium M 1.0GHz, RAM: 1GB, OS: Fedora Core 1), a bus bridge including a DIO board (Interface Corporation, PCI-2727) and AD/DA board (Interface Corporation, PCI-3521), and three servo amplifiers (FAULHABER GROUP MINIMOTOR SA, BLD 3502) calculating displacements of sliding two linkages and one stainless-steel wire by inputted target angles from the dial-type interface. And last part was the bipolar coagulator (MIZUHO Co., Ltd., SS-2100) with a foot switch to turn on electricity to the electrodes.

Between the multi-DOFs end-effector and the linear-drive unit we equipped easy linkage connector for cleaning, sterilization before and after operation. At this connector the multi-DOFs end-effector, the linear-drive unit and the dial-type interface were isolated completely so as to protect patients and surgeons from any electric shock.

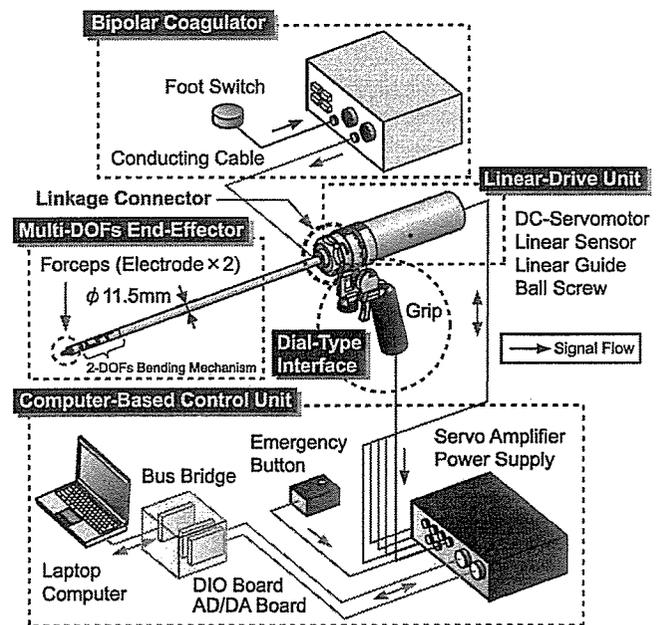


Fig. 2 System configuration of the bipolar electric scalpel manipulator.

III. RESULTS

We did feasibility analysis of the bipolar electric scalpel forceps manipulator in vivo experiment using animal (swine, 39 kg, male) (Figure 3). We evaluated the ability of vessel manipulations, especially occluding blood vessels in laparoscopic surgery. Target area was around mesenteric surface tissues including large and small vessels. We had surgeons to approach safely from various direction without too much tension for blood vessels using 2-DOFs bending manipulation effectively. Bipolar coagulator's setting was that frequency was 450 kHz, cycle period was 40 μ s, duty cycle was 50% and output power was 20 W using burst waves.

Experiment procedure was following: (1) Approach to the blood vessel surrounded by connective tissues from as vertical as possible direction with 2-DOFs bending manipulation. (2) Grasping the vessel and 2-3 seconds energization between forceps blades. This action was repeated at 2-3 places around the targeted area. (3) After heat denaturation of collagen and elastin, cutting the ablated area by shears. (4) At last check blood leakage from the relevant area to confirm whether coagulated blood vessels were completely occluded or not (Figure 4).

In this experiment we tried to occlude six vessels of which diameter were 1.0 mm or less. At four vessels, that were veins, complete occlusions were done successfully. On the other hand at other two vessels, efficient occlusions were not succeeded. A little leakage was shown after cutting in these vessels, one was an artery and another was a vein, so we did another coagulation cutting surface of blood leakage again, and at last completed their occlusions. These incomplete coagulations resulted from ablated tissues (heat denaturalized protein) that were adhered on the electrodes surface after repeated ablations. This adhesion became something of insulation shields and interrupted effective energization between electrodes.

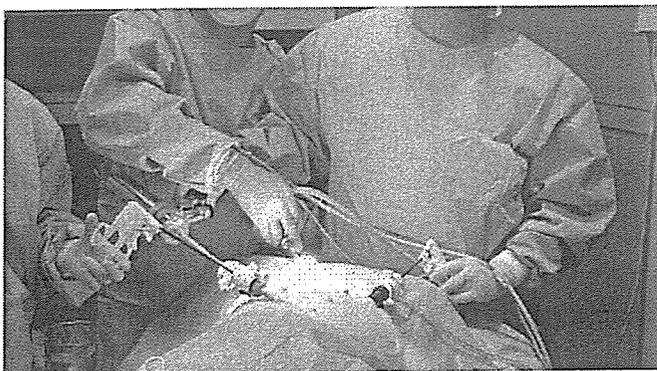


Fig. 3 Scene of in vivo experiment by surgeons for feasibility evaluation of the bipolar electric scalpel forceps manipulator.

IV. DISCUSSIONS

We confirmed that the combination of bipolar electric scalpel function and 2-DOFs bending forceps enabled safely and speedy vessel manipulations with highly dexterous and effective approach toward affected areas without too much invasion for perilesional tissues and organs. Grasping with its forceps blades from near-vertical direction toward targeted tissues made efficient energization through forceps blades possible. Therefore additional DOF of rotation at the end-effector around long axis of the manipulator's frame would be expected to realize more delicate and finer vessel manipulations. And in the forceps function only grasping drive was available, therefore an addition of the driving mechanism to open forceps blades would be able to exfoliate coagulated tissues reliably.

Bipolar electric scalpel function could almost make effective vessel occlusions, however there was an issue that energization efficiency dropped drastically by ablated tissue's adherence on the electrodes. Major cause of this adherence was that the electrodes were very flat and boundaries between electrodes and insulating part were blurred, so whole electrodes were covered over occasionally. In vivo experiments we dealt with this issue by wiping out with alcohol, however in clinical use to avoid this trouble, improvement of electrodes shape and alignment would be required. In particular we will make electrodes' surface convexo-concave and make a sharp distinction between these electrodes and insulating parts on the forceps blades.

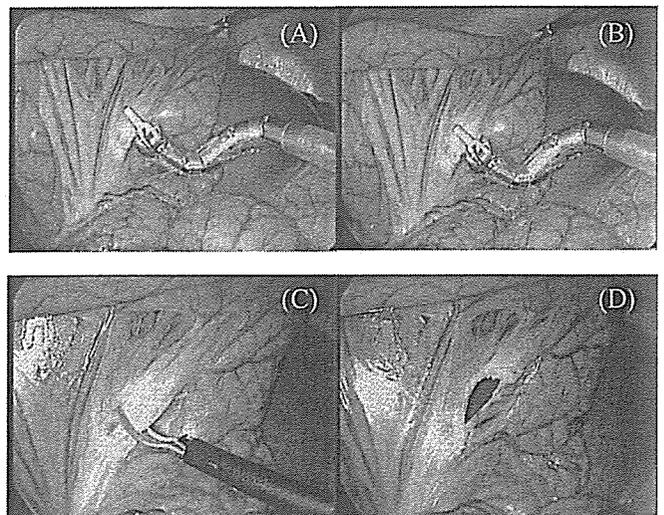


Fig. 4 Sealing mesenteric blood vessels safely with 2-DOFs bending manipulation. (A): Approach from near-vertical direction to running vessels. (B): Turning on electricity 2-3 times around targeted area. After heat denaturation of protein (C): cutting ablated area and (D): confirming vascular occlusion by observation of bleeding.

V. CONCLUSIONS

From the results of in vivo experiments we are sure of the feasibility of synergy effect between the bipolar electric scalpel function and the multi-DOFs bending forceps function to perform blood vessels manipulations safely and speedy. In order to solve remaining issues we will redesign electrodes dimension for more reliable clinical applications.

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Rigid-flexible outer sheath model using shape lock mechanism by air pressure and wire driven curving mechanism

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Abstract— Laparoscopic surgery has many merits for patients. However, it requires wide space in human body and it is difficult to approach the target in deep narrow area, because instruments are long rigid stick. To overcome this problem, we propose an outer sheath to make a curved instrumental to the target avoiding the critical organs or tissues. This sheath is able to change its flexibility. A surgeon inserts the sheath in human body when it is flexible, and locks the shape to rigid mode. Then flexible instruments are able to reach the target easily without damaging critical tissues by going through the sheath. The outer sheath consists of many short sheath units connected serially. Each joint is able to rotate freely, and has slider that moves the adjacent unit in conjunction with the unit rotation by link connection. The slider has gear rack. Air pressure moves up a stopper that fixes the slider by meshing with the gear rack, and then all units are fixed the rotation and the shape of the sheath is locked. We made a prototype whose outer diameter is 16mm and inner diameter is about 6mm. The length is 290mm and this sheath has 7 joints. This sheath is able to curve itself by tendon driven mechanism in addition of external forces when it is flexible. We examined the insertion force when some flexible devices are inserted through the sheath. When the shape of sheath is the 90 degrees arc, the maximum insertion force is 346.9 gf. And we tested the insertion property in gelatin phantom. Then we confirmed that flexible devices could pass through the narrow space in the body using this outer sheath.

Keywords— Rigid-Flexible outer sheath, slider-linkage mechanism, laparoscopic surgery.

I. INTRODUCTION

Laparoscopic surgery enables minimal invasion to patients with the assistance of a video camera and several small instruments. Laparoscopic surgery has been widely performed in abdominal surgery. Surgeon can insert special instruments from small holes on the abdominal wall and perform operation after lifting the abdominal wall. Many researchers and engineers developed various instruments to improve the performance, and reduce the risks and the complexities in taking laparoscopic surgery. For example, dexterous robotic manipulator [1][2] added multi degree-of-freedom (DOFs) motion to instruments and improved performance of surgery. Master-Slave type robotic manipulators, such as da Vinci, enable greater precision and better visualization compared to standard laparoscopic surgery,

However, some problems remain unsolved. First, laparoscopic surgery requires wide space below the abdominal wall. Pneumoperitoneum is commonly used in lifting the abdominal wall, but some complications caused by this method are reported. Second, although the laparoscopic surgery can approach the target in anterior area of the body, it is difficult to approach the target in deep, narrow area.

To address these problems, instruments are required to be inserted into the body avoiding the critical areas. Several groups developed different flexible manipulators with wide curve. Ikuta et al. developed a micromanipulator [3] to reach difficult area. Moreover, other flexible manipulators using shape memory alloy (SMA) [4], or wire-driven mechanism [5] were also developed. However, flexible instruments can not be inserted easily in narrow space between the tissues or organs, and can not be stabilized completely when approaching target. In order to solve problem of flexible instruments, it is required to manage rigid path to insert flexible instruments in advance.

The purpose of this study is to develop an outer sheath to make an instrumental path in human body. This sheath is able to be changed to any given shape, and to be locked from external force. Before inserting flexible instruments, the surgeon inserts the outer sheath through the narrow gap between the safety areas. When the sheath reaches the target, the surgeon locks the shape of the sheath. So the surgeon is able to insert flexible instruments easily through the planned path.

In order to realize the switch of two modes: flexible mode and rigid mode, we used multi-joint model for flexibility and slider-linkage mechanism and air pressure locking mechanism for rigidity.

This paper reports 1) a mechanism that enables to switch flexible mode and rigid mode, 2) a prototype of outer sheath using above mechanism, and 3) evaluation experimental results about the stiffness and the property of inserting the sheath into the human body by gelatin phantom.

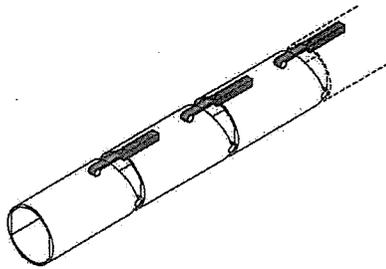


Fig. 1 Overview of the outer sheath mechanism

II. RIGID-FLEXIBLE OUTER SHEATH

A. Rigid-Flexible Mechanism

The outer sheath consists of several pieces of short sheath (Fig. 1). These sheath units are connected serially to make a long sheath. Each unit is able to be rotated several degrees around the joint independently of the rotation of other joint. So this kind of outer sheath is possible to be changed to different shape, such as a complex shape of letter 'S'.

To lock the shape and keep from the external force, we proposed a slide-linkage mechanism. Each unit has a link, a slider, a stopper, and an air channel inside the instrument. The unit and the slider are connected by a link with pin joints. The slider moves in the slider channel of the adjacent unit in conjunction with the rotation of the unit.

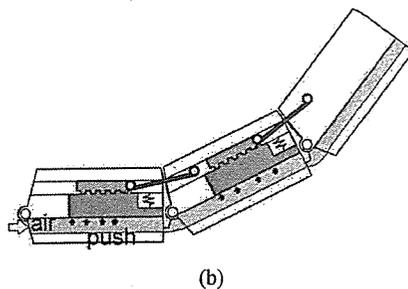
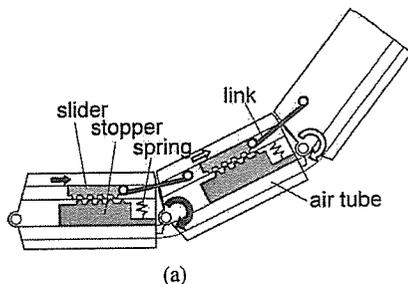


Fig. 2 Rigid-Flexible mechanism: (a) Flexible mode. (b) Rigid mode

Since the sliders and the stoppers have gear racks, when the air pressure pushes the stopper, the stopper moves and meshes the gear tooth of the slider. The rotation of the unit is locked after locking the slider, so the sheath can be switched to the rigid mode. When the air pressure is off, the spring attached to the stopper push the stopper back, and then the sheath is switched to the flexible mode (Fig. 2).

There are two merits of this rigid mechanism. First, air pressure is possible to transmit force to every joint, so only one actuator is required in our mechanism, compared with the common multi-joint type manipulator that requires actuator as the same number of joints and results big and complex system. Using fluid pressure, the manipulator system becomes simple and small. Second, the fluid pressure is possible to be pressed everywhere independence of the shape. The outer sheath can keep its shape at the same stiffness, including straight, curve like the letter 'S', and other complex shapes.

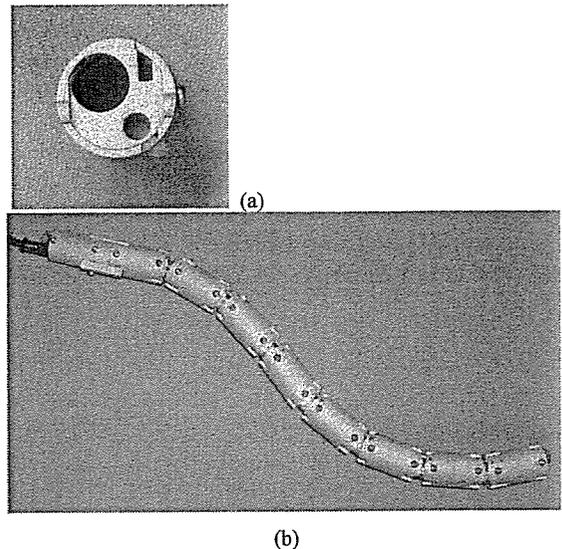


Fig. 3 Prototype of outer sheath : (a) cross section image. (b) the outer sheath when it curve.

B. Prototype

We made a prototype based on the concept mentioned above (Fig .3). The cross section of this sheath is circle diameter of 16mm. This sheath has two holes. One is instrumental path diameter of 8mm. Polyvinyl chloride tube is attached in the inner guide tube of this hole, so the sheath enables instruments to go through the device with a diameter of less than 6 mm. Another hole is for air channel diameter of 3.6 mm. The natural rubber tube is attached to transmit air pressure to the stopper. The length of each unit is 30