H. Yamashita, K. Matsumiya, K. Masamune, H. Liao, T. Chiba, T. Dohi:
Two-DOFs Bending Forceps Manipulator of 3.5-mm diameter for Intrauterine Fetus Surgery: Feasibility Evaluation,
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A B C

Fig. 6 A is manipulator with Nd:YAG laser fiber bended toward 66 degrees. B is laser photocoagulation of phantom model of placenta (boneless chicken leg) with bending motion of the miniature manipulator. C is macro view of laser ablated scars.

about 200 gf at the manipulator tip's part, enabled to bend a laser fiver with bending radius of 3.82 mm without fiber breakage failure. On the other hand at tip-side DOF bending mechanism, bending radius was too small against allowable curvature radius of solid quartz fiber to give much bending angle. For this issue about insufficient bending angle, it can be solved by adjusting bending radius to adequate length, by turning up bending torque, and by selecting more flexible laser fiber without photocoagulation efficiency reduction.

4. Conclusion

Newly designed 2-DOFs bending mechanism was suitable to fabricate forceps manipulator of 3.5-mm diameter which has sufficient durability and rigidity owing to stainless-steel linkage mechanism and slip-less wiring guide mechanism. This manipulator is also equipped with an adequately spaced central channel to pass various end-effectors. Based on our feasibility evaluation, we are sure that the manipulator which has a maximum bending angle of 66 degrees enables us much less invasive laser therapy for TTTS.

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References

[1] Ville Y, Hyett J, Hecher K, Nicolaides K, Preliminary Experience with Endoscopic Laser Surgery for Severe Twin-Twin Transfusion Syndrome. N Engl J Med. 1995 Jan 26; 332:224-7.

[2] Senat MV, Deprest J, M Boulvain, et al. Endoscopic Laser Surgery ersus Serial Amnioreduction for Severe Twin-to-Twin Transfusion Syndrome. N Engl J Med. 2004 Jul 8; 351(2):136-44.

[3] Yamashita H, Kim D, Hata N, Dohi T, Multi-Slider Linkage Mechanism for Endoscopic Forceps Manipulator, Proceedings of the 2003 IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS 2003); 2003 Oct 27-31; Las Vegas, Nevada, U.S.A; Vol.3, p. 2577-82.

[4] Yamashita H, Hata N, Hashizume M, Dohi T, Handheld Laparoscopic Forceps Manipulator Using Multi-slider Linkage Mechanisms, Proceedings of the 7th International Conference on Medical Image Computing and Computer-Assisted Intervention (MICCAI 2004); 2004 Sep 26-29; Saint-Malo, France; Lecture Notes in Computer Science (LNCS) 3217 Springer, p. 121-8.

Design and evaluation of a flexible manipulator for endoscope intrauterine surgery

Hongen Liao[1], Hirokazu Suzuki[2], Kiyoshi Matsumiya[2], Ken Masamune[2], Takeyoshi Dohi[2], Toshio Chiba[3]

[1] Graduate School of Engineering, the University of Tokyo, Tokyo, Japan
[2] Graduate School of Information Science and Technology, the University of Tokyo, Tokyo, Japan
[3] Department of Strategic Medicine, National Center for Child Health and Development, Tokyo, Japan

Abstract—**We designed and fabricated a prototype of the fetus supporting manipulator with a flexible mechanism and a soft balloon-based stabilizer for endoscopic intrauterine surgery. The flexible bending and curving mechanism enables the stabilizer to reach the required position in the uterus under the guidance of ultrasound. The balloon-based stabilizer could be inserted into the uterus from a small incision. The experimental findings demonstrated feasibility of the developed manipulator. The developed flexible manipulator could be controlled to reach an optimal position in the uterus and the balloon-based device could stabilize the fetus softly. The manipulator has the potential to be used in minimally invasive intrauterine surgery, though further improvements and experiments remain to be carried out.**

Keywords— **Enter up to five keywords and separate them by commas**

I. Introduction

Myelomeningocele is one of the most common congenital defects of the central nervous system. It is a neural tube defect in which the bones of the spine do not completely form, and the spinal canal is incomplete. This can result in the spinal cord and its covering membranes protruding from the infant's back. Myelonmeningocele accounts for about 75% of all cases of spina bifida and may occur in 1 per 1000 infants.

Previous studies showed that the intrauterine environment may cause secondary injury to the spinal cord that is already dysplastic [1]. This suggested that early closure of the myelomeningocele sac could prevent the secondary injury and then improve neurologic outcome [2].

The surgical treatment to the myelomeningocele or spina bifida at 19-25 weeks of gestation can improve the obstacle of central nerves and hydrocephalus within the uterus. This resulted normalizing the development of a fetus brain. Both animal and human studies have shown that the ability of the body to repair damaged nervous tissue is best in young individuals [3]. Because of these considerations, doctors have been working on ways to close spina bifida defects as early as possible.

In recent year, endoscope has provided a technological advances and a minimally invasive approach to surgical treatment. Minimally invasive endoscopic fetal surgery enables intrauterine intervention with reduced risk to the mother and the fetus [4]. The treatment required the mother to undergo surgery under the guidance of endoscope. Neurosurgeon will close the lesion on the baby's back. The problem is that the fetus is floating in the amniotic fluid and the movement will affect the implementation of surgical treatment. It is necessary to develop a device to prevent the fetus from moving. A previous research was to develop a stainless steel fetal stabilizer [5]. The fetus is fixed completely by the device, which has a bad influence on the fetus. Other device included suction type stabilizer using suction holes in a silicone tube to aspirate the skin of the fetus [6]. The suction part of the fetus will be made congested during the long time operation.

Our proposal to overcome these issues is to develop of a manipulator with a flexible mechanism and a balloon-based soft support stabilizer. In this study, we summarize the mechanism and design criteria of the fetal supporting manipulator for endoscope intrauterine surgery, followed by evaluation studies from mechanism performance experiments and fetus model test experiment with ultrasonic guidance.

II. Methods

A. Requirements of fetal surgery

The gestational age selected for myelomeningocele treatment is at 19-25 weeks corresponding to the characteristics of the fetus. The fetus in the target gestation is very small with a length of about 30 cm and weight of about 500 g. The volume of the amniotic fluid is about 500 ml.

The fetal surgery is different from the other forms of surgery as follows. First, the fetus is fragile; the surgical instrument needs to be made small and flexible enough from hurting the fetus and the placenta. Second, the insertion sites for the surgical instrument into the uterus depend on

the position of the placenta and the umbilical cord. Third, the operation space for instrument within the uterus is limited and the quality of endoscope image falls off due to the cloudy amniotic fluid. Those conditions limit the design of fetal surgical instrument.

B. Fetus stabilizing mechanism

During the myelomeningocele surgical repair, the forces pushed or pulled to the fetus will change the position and the posture of the fetus. In order to prevent the fetus from moving or rotating, the points supported to the abdomen side corresponding to the back of the fetus are required. Furthermore, it is necessary to support the breast of the fetus since the head is heavy. Considering of above two requirements, the designed fetal stabilizer should be enable supporting the abdomen side of the fetus from breast to the abdomen softly.

To meet the requirements mentioned above, we developed a fetal stabilizing mechanism with a balloon that swells into a circle shape to support the fetus (Fig.1). This balloon-based stabilizer is possible to support the fetus softly without any physical damage. We can fold the balloon and insert it into the uterus from a small incision. Furthermore, we use inject physiological saline from a syringe to swell the balloon. The injected amount and the pressure are controlled by PC. Even the balloon is broken during the operation it will not influence the fetus. The inserted part of the bending mechanism is covered by silicon so that the fetus and the placenta will not be injured.

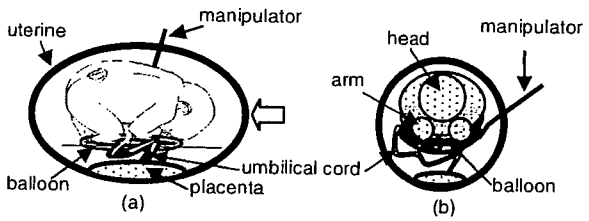

Fig.1 Fetus supported by a balloon-based flexible manipulator. (a) Viewed from left side. (b) Viewed from head side.

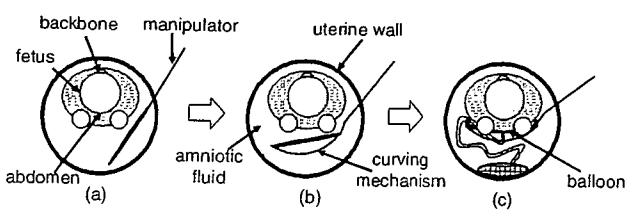

Fig.2 Manipulator insertion procedure: (a) insert the manipulator straightly. (b) bend and adjust the curving mechanism to a optimal position. (c) pump the balloon by injecting physiological saline and stabilize the fetus.

C. Procedure of inserting the balloon-based stabilizer

The procedure of inserting the balloon-based stabilizer to the uterus and stabilizing the fetus with the ultrasound guidance is shown in Figure 2.

1) We insert the instrument with a shrunk balloon according to the position of the fetus. The spatial relationship of the fetus, the uterine wall and the instrument is observed using an ultrasonic diagnosis device.
2) The bending angle of the link part and the curving part of the manipulator are controlled by a PC according to position of the fetus. The bending and curving mechanisms are crooked and inserted into the required position with the guidance of intra-operative ultrasonic image.
3) When the silicon covered curving part arrive the abdomen of the fetus, we inject the physiological saline into the balloon and adjust the balloon to optimal position for stabilizing the fetus.

The circle-shape balloon supports the fetus near the hand and the foot. The umbilical cord passes by the balloon as shown in Fig.2c.

D. System overview

The prototype of the fetal support manipulator is comprised of three units: the flexible manipulator unit with a balloon-based stabilizer and a curving mechanism; the PC for controlling the bending mechanism and the syringe; the ultrasonic device for viewing the intra-operative situation of the fetus and the instrument (Fig.3).

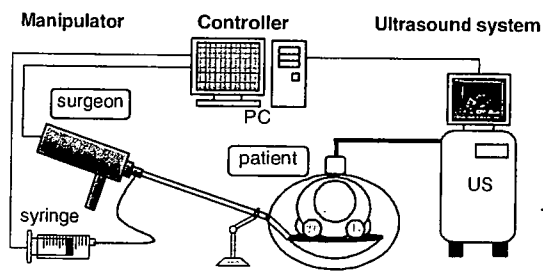

Fig.3 Fetus support manipulator system for intrauterine surgery. Mechanism of the manipulator

Our linkage mechanism includes a tube to transmit the saline to the balloon. The linkage mechanism made of stainless steel 6 mm in diameter. The length of the curving mechanism is determined by the size of balloon. Since the circumference of the fetus's body is about 15~20 cm and the diameter of the corresponding balloon is about 10 cm, we developed a curving mechanism with 15cm length which is suitable for enlarging the balloon.

The balloon is connected with a syringe. The pressure is generated by an electric linear slider with a syringe (60 ml) similar to a syringe pump. The manipulator is held by the surgeon and controlled by the PC. The manipulator is performed under the guide of the ultrasonic image.

In order to minimize the size of the incision, we developed a curving mechanism that is comprised of a plate spring and a wire mechanism (Fig.4c). The balloon could be stored between the curving mechanism and the linkage part.

To the bending mechanism, we adopt a linkage-driven approach so that the manipulator enables a high stiffness, durability and accurate performance than a wire-driven approach. Since the latex may trigger the fetus allergic reaction, they will not be considered as material for the supporting device. The balloon is made of polyethylene so that fetus could be supported almost without pressure. The area in contact with the fetus becomes larger and the pressure to the fetus becomes smaller when the balloon is made bigger. However, the incision to the patient would be large. As shown in Fig. 4c, the diameter of the curving mechanism is 6 mm.

The tip part of the manipulator is sterilized by the autoclave (high-pressure steam), and connected with the actuator by draping mechanism.

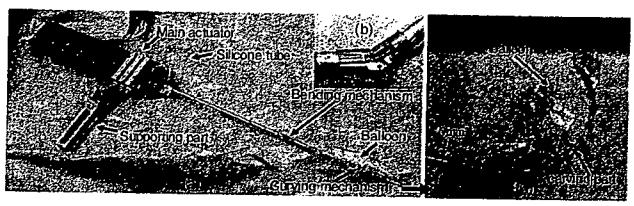

Fig.4 Linkage bending mechanism, carving mechanism and balloon-based stabilizer.

III. Experimental results

A. Accuracy evaluation of stabilizer curving mechanism

We carried out experiment to evaluate the mechanical performance of the stabilizer bending mechanism. For supporting the fetus with required shape of the balloon, it is necessary to shorten the distance between the root and the tip part of the curving mechanism. Furthermore, even the curving mechanism was not contacted the womb during the curving process, it is possible to touch the womb when the curving mechanism is elongated if the hysteresis existed. The first set of tests aimed to measure the distance change from the root point to the tip end point of the curving linkage. We use a camera (QV-R51, CANON) to capture the situation of the curving process and measure the position of the tip end point.The hysteresis was existed and the error was a maximum of 7 mm (Fig.5). This result showed the accuracy of curving mechanism is sufficient in stabilizing the fetus.

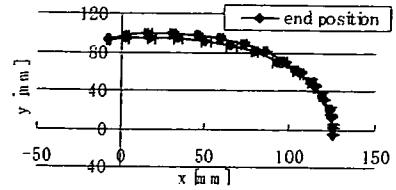

Fig.5 Tip end point positions of the manipulator.

B. Accuracy evaluation of linkage bending performance

The second set of tests assessed the performance of the linkage bending mechanism. We inserted and adjusted the stabilizer corresponding to the position of the placenta using the bending mechanism. It is necessary to ensure the bending range of the linkage mechanism. We evaluated the accuracy of the bending angle from -45° to 45° and compared the results with the theoretical values. It was found that the measured values were satisfied with the theoretical value. The maximum error of the bending angle was 5° and the standard deviation was 1.6°.

C. Accuracy evaluation of linkage bending performance

The flexible fetal supporting manipulator was applied to a fetus model stabilizing experiment. The fetus model weighs 600g with volume of about 600 cm^3 and length of 30cm. The long radius of the abdomen is about 6 cm. The fetus model was suspended in a water tank. We inserted the manipulator from the side of the fetus, bending the linkage mechanism and crooking the stabilizing mechanism. The balloon was swelled and adjusted to support the fetus from the abdomen side. Figure 6 showed that the developed manipulator could support the fetus model and stabilize the posture. The picture also showed that only the balloon contacted with the fetus and the metal curving mechanism was not in contact with the fetus. The balloon could stabilize the fetus and prevent it from moving or rotating. The experiment showed that the fetus model could be supported and lifted up sufficiently using the manipulator.

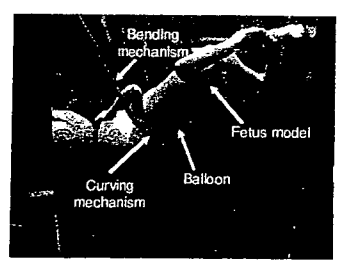

Fig.6 Manipulator stabilizes the fetus model softly.

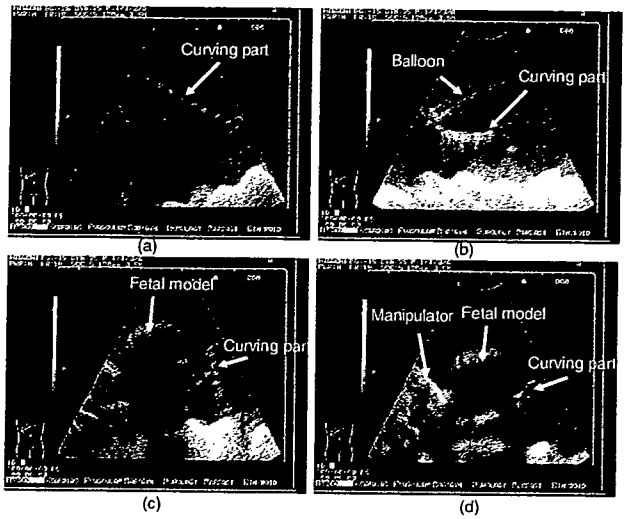

Fig.7 Ultrasound guided manipulator insertion in stabilizing the fetus model (a) the curving mechanism was observed clearly. (b) both of the curving mechanism and the swollen balloon were observed. (c) the fetus model and the manipulator is observed . (d) The manipulator and the curving mechanism could be observed under the fetus model.

D. Ultrasound guided manipulator insertion

We carried out experiments to evaluate the feasibility of the ultrasonic image guidance to the insertion of the manipulator. The situation of the fetus model in the action of the manipulator is also identified using the ultrasonic device.

The first set of tests is to evaluate the ultrasonic image of the manipulator without placing the fetus model. Figure 7a showed the situation when the balloon was shrunk. The curving mechanism was observed clearly. Figure 7b showed that both of the mechanism and the balloon were observed clearly after the balloon was swollen up.

The second set of tests is to use fetus model to similar an implementation of fetal surgery with the developed manipulator. Figure 7c showed that the fetus model and the manipulator could be observed. We adjusted the stabilizer to the optimal position to support the fetus (Fig.7d). The manipulator and the curving mechanism could be observed under the fetus model clearly.

IV. Discussions and Conclusions

The prototype manipulator has the potential to successfully insert the uterus in endoscope intrauterine surgery, while the balloon-based stabilizer has the potential to support the fetus softly. The experimental findings demonstrated feasibility of the developed manipulator. First, the hysteresis evaluation experiment of the curving mechanism showed that the error was 7 mm and the accuracy evaluation of the linkage bending mechanism showed the standard deviation of bending angle was 1.6°, which is satisfactory for the endoscope intrauterine surgery. Second, the fetus model could be supported and lifted up by the balloon based stabilizer. Third, the manipulator could be controlled under the guidance of ultrasound and the curving mechanism with balloon in the stabilizer could be observed clearly.

The results of ultrasonic image showed that although the manipulator could be observed clearly with fetus model, some information below the fetus model could not be identified as shown in Fig. 7c. Actually, we can move the ultrasonic probe and identify the situation of the fetus and the manipulator from different directions. The endoscope could also be used to achieve the intra-operative information.

In conclusion, we reported the development of a new method of supporting fetus in endoscope intrauterine surgery. The developed flexible manipulator could be controlled to reach the optimal position in the uterus and the balloon-based device could stabilize the fetus softly. The manipulator has the potential to be used in minimally invasive intrauterine surgery, though further improvements and experiments remain to be carried out.

Acknowledgment

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References

1. D.S. Heffez, et al., "The paralysis associated with myslomeningocele: Clinical and experimental data implicating a preventable spinal cord injury," Neurosurgery Vol. 26, pp.987-992, 1990.
2. O.S. Aaronson, et al. "Robot-assisted endoscopic intrauterine myelomeningocele repair: A feasibility study," Pediatric Neurosurgery, Vol.36 No.2, pp.85-89, 2002.
3. http://www.spinabifidamoms.com/english/overview.html
4. K.C. Oberg, A.E. Robles, et al. "Endocsopic intrauterine surgery in primates," Surgical Endoscopy, Vol.13, pp420-426, 1999.
5. M. Dinh, J. Bruner, "Fetal Stabilizer for Intrauterine Surgery", Report of Vanderbilt University, http://vubme.vuse.vanderbilt.edu/.
6. Tsubouchi et al. "Development of the drawn-in type stabilizer for a fetus operation," The 14th conference of JSCAS, pp.45-46, 2005.

Address of the corresponding author:

Author: Hongen Liao
Institute: The University of Tokyo
Address: 7-3-1 Hongo, Bunkyo, Tokyo 113-8656, Japan
Email: liao@miki.pe.u-tokyo.ac.jp

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Development of laser forceps for fetal surgical treatment

K. Oka[1], T. Nakamura[2], K. Harada[3], Y. Ohkawa[1], T. Hidaka[2] and T. Chiba[3]
[1] Japan Atomic Energy Agency, 2-4 Shirane, Shirakata, Tokai-mura, Naka-gun, Ibaraki, Japan
[2] PENTAX Corporation, 1-9-30 Shirako, Wako-shi, Saitama, Japan
[3] National Center for Child Health and Development, 2-10-1 Okura, Setagaya-ku, Tokyo, Japan

Abstract— **In this report, we present feasibility of our newly developed laser device for prospective human fetoplacental surgery. Fetuses having congenital fetoplacental anomalies, if untreated before birth, occasionally deteriorate in utero with high perinatal mortality and/or morbidity. If this is the case, outcomes of conventional postnatal care might be quite unrewarding medically as well as economically. Although the advent of minimally invasive fetal endoscopic laser treatment (fetoscopic laser photocoagulation, FLPC) has strikingly improved the natural history of fetuses with twin-twin transfusion syndrome (TTTS), this underwater unique surgery is still technically demanding depending on placental location, position of floating twins, gestational age, and fetomaternal obstetrical conditions. In an attempt to resolve most of these difficulties associated with FLPC, we developed a composite-type optical fiber scope that enables transmission of laser light and endoscopic images concurrently. This technology is a spin-off of our research works on the International Thermonuclear Experimental Reactor (ITER) at Japan Atomic Energy Agency and the device is an integrated system consisting of a composite-type optical fiber scope (2 mm in OD), a coupling device for transmission/distribution of laser light along with object images, a laser light source and a magnified image monitoring system. A lens made by quartz is installed on the tip of composite-type optical fiber scope. It has the resolution of about 9,000 pixels and the angle of view of 54 degrees. In addition, it can transmit the 40W laser energy with a focal length of 10 mm. Clinically, the composite-type optical fiber scope, if mounted on our multi-DOF robotic manipulator, is supposed feasible for much more accurate identification and coagulation of the target placental vessels responsible for TTTS pathophysiology. Our current state of the art will be presented in detail along with basic test results.**

Keywords— **Laser forceps, Fetal surgical treatment, Composite-type optical fiberscope**

I. Introduction

Treatment of fetal abnormalities such as twin-twin transfusion syndrome (TTTS) and fetal myelomeningocele is difficult and has limited effects after birth. Some cases require fetal treatment, by fetoscopic surgical intervention. However, as this treatment targets fetuses floating in the small amniotic cavity, dramatic technological advancements are necessary to functionally enhance current endoscopic surgical devices.

The following issues are given concretely; (1) Collimation of a laser are not always enough to hit the targets precisely, because the fetal endoscopic scanning axis is different from that of optical fiber for laser irradiation, (2) It is difficult for the laser focus to agree with the targets well, because we do not measure a distance between the laser tip and the object definitely. (3) Excessive cauterization is always the risk because the laser energy required for sufficient cauterization are not accurately measured in advance. and (4) occasionally we cannot access some placental surface areas, because our straight and rigid fetoscope cannot be mechanically bent.

On the other hand, technological developments have been achieved at the Japan Atomic Energy Agency (JAEA) for remote maintenance as required by International Thermonuclear Experimental Reactor (ITER)[1]. Based on our accomplishments, the composite-type optical fiber technology was developed, which could transmit laser energy and images for observation in parallel. Now, using the composite-type optical fiber, we are aiming to develop a new device for TTTS laser surgery that is "flexible and extra-fine-diameter endoscope equipped with a laser transmitting function".

This paper presents its design and feasibility test results.

II. Composite-type optical fiber

JAEA has developed a tool used in the cooling pipes attached to major structures inside the ITER[2]. This tool can access the pipe wall (internal diameter of 100 mm) from inside, then it bends to weld, cut, and inspect inside branch pipes (internal diameter of 50 mm). Because the tool for welding and cutting needs to access inside the pipe to carry out inspection and repair at any location, sufficient power must be transmitted to the target site. A confirmation process is also necessary before and after welding and cutting as well as during the process. Since the processes of welding and cutting are performed on the inner surface of the pipes, visual inspection is extremely difficult. To observe the status of the welding and cutting processes before, during and after the processes inside the small pipes with limited space, JAEA has developed a composite-type optical fiber system shown in Fig.1. This system performs the processes of welding, cutting, and observation using a multi-functional optical fiber and lens optics system, while enabling parallel transmission of the observation images and a 1 kW YAG laser beam[3]. Characteristics of this system are as follows; (1) Fibers for laser induction and image transmission are integrated into the same axis, (2) Separation and integration of laser light (wavelength of 1064 nm) and images (wavelength of 400~780 nm) are capable.

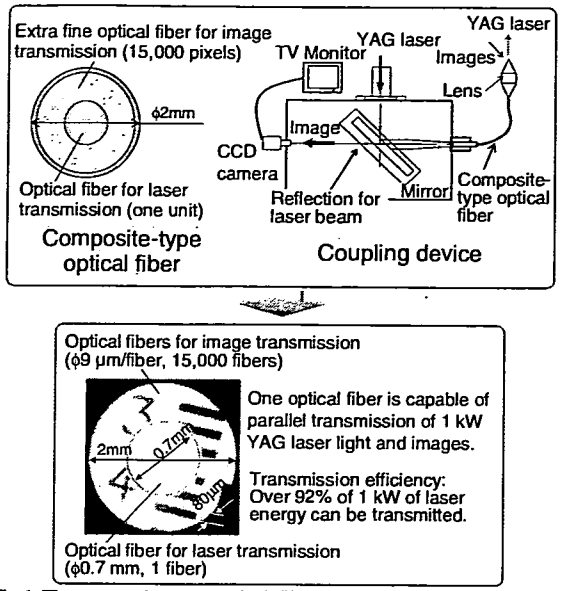


Fig.1 The composite-type optical fiber system (patented) capable of parallel transmission of laser light and image (A large lens was attached to the tip of the composite-type optical fiber, and an image was taken under external illumination.)

This composite-type optical fiber is capable for processes other than remote maintenance of ITER, and possible applications in diverse fields have been studied.

In this paper, we are hoping to contribute for the fetal treatment by developing the new device with using this technology.

III. New Device for Fetal Treatment

In this study, we utilized our experiences and technologies, and have developed a flexible and extra-fine-diameter endoscopic device having a laser irradiation function. To develop the device, there were following issues; (1) Development of a composite-type optical fiber scope of the allowable diameter for the use in utero, (2) Development of a device which can transmit laser beam with a narrow spot diameter, (3) Development of a coupling device for transmission / distribution of laser light and object images.

(1) Composite-type optical fiberscope

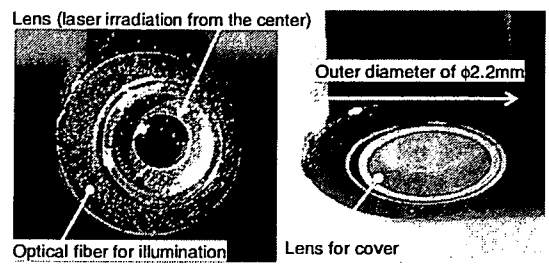
Based on our experiences of welding / cutting by the YAG laser light, the diameter of an optical fiber core to transmit high output laser of several kW needs to be around ϕ0.7mm to transmit the collected lasers from a laser oscillator to an optical fiber. In addition, the optical fiberscope for observation should have around 2,000-20,000 pixels to ensure a field of vision. In consideration of these conditions, we designed and developed the fiberscope as follows.

An optical fiber for laser transmission was designed as thin as ϕ0.1mm, because minimum laser output of around 40W is necessary for treatment in utero. About a lens attached to a tip of optical fiber, we developed a small lens which can collect laser beam and obtain an image at the same time. Furthermore, optical fibers for illumination were placed surrounding the optic fiber for laser transmission. The total outer diameter was designed for the use in utero.

The specifications of the newly developed composite-type optical fiberscope are shown in Table 1 and Fig.2.

Table 1 Specifications of the composite-type optical fiberscope

Item	Specification
Core diameter for laser	About 100μm
Cladding surface diameter for laser	About 120μm
Core materials	A quartz glass
Cladding materials	A quartz glass
The number of the picture element	About 9,000
An angle of view	About 54 degrees
Materials of an object lens	A quartz glass
A total external diameter of a scope (a flexible part)	ϕ2.2mm
Full length of a scope	3m
Flexibility of a scope (a flexible part)	Smallest bending radius of 45mm
Waterproofing	A tip is a waterproofing structure
Disinfection processing	EOG sterilization is capable



(a) Front view (b) Side view

Fig.2 The tip of the composite-type optical fiberscope

(2) Laser source

A laser spot produced by a laser oscillator cannot be condensed to a smaller spot. Therefore, a laser source with a good condensing performance is necessary as to condense a laser beam to the laser fiber of the composite-type optical fiberscope mentioned above. In other words, a laser source is necessary with a laser spot diameter smaller than the optical fiber diameter of ϕ0.1mm for laser transmission of composite-type optical fiberscope. For this reason, we selected a fiber-laser having a wavelength of 1,075nm, not a conventional Nd:YAG laser oscillator having a wavelength of 1,064nm. The selected fiber-laser can collect the laser beam to the diameter of the optical fiber of ϕ0.1mm, because the minimum diameter of the laser spot condensed with the fiber-laser is ϕ0.05mm. In addition, a power supply is 100V-20A and laser output of 50W is capable, which is sufficient under normal operation environment.

(3) Coupling device

In order to collect the laser beam from the laser source and transmit a laser to a composite-type optical fiberscope, a coupling device was developed. This coupling device is composed of a beam splitter which can transmit a visible

light of wavelength 400-780nm and reflect the fiber-laser of wavelength 1,075nm. Fine adjustment mechanisms were installed in each optical system to maintain precise connections in its interface. The imaging system was composed with a condenser system, a dielectric multi-layer coated mirror, and an imaging lens. Each optical component has an anti-reflection (AR) coat. A CCD camera for imaging was 1/4 inches digital color camera. Its image signal is NTSC signal output with a BNC connector.

IV. Performance tests

The devices mentioned above were installed in a 19 inches rack of Japanese Industrial Standards. Fig.3 shows the whole setup with all devices necessary for composite-type optical fiberscope. A prototype of the composite-type optical fiberscope (named Tainai-LaMiel) was successfully developed for prenatal surgical treatment and we carried out feasibility tests.

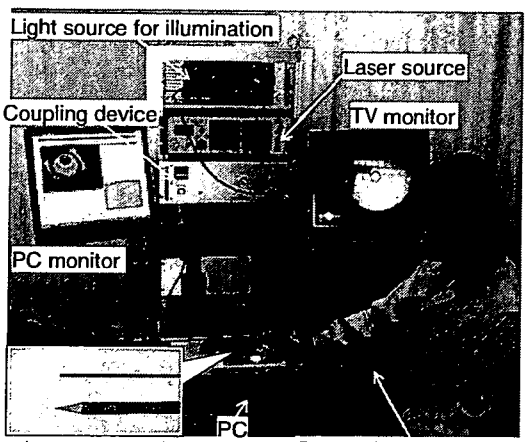


Fig.3 Newly developed composite-type optical fiberscope system (named Tainai-LaMiel)

(1) Laser irradiation test

The laser beam was transmitted to the composite-type optical fiber scope and the phases of cauterization is shown in Fig.4. The test conditions were that the scope's tip was kept 10mm away from a color chart paper in the air and the laser beam of 3W at the scope's tip was irradiated for two seconds. The tests demonstrated that the device can perform observation and cauterization of an object simultaneously.

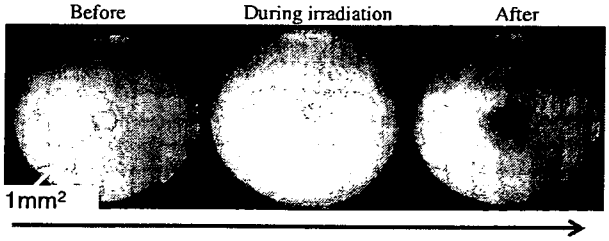


Fig.4 Laser irradiation test on a color chart paper

(2) Laser transmission efficiency test

Laser beam was transmitted to the composite-type optical fiberscope through the coupling device, and then the power efficiency of the laser transmission was measured between the laser source and the composite-type optical fiberscope when the laser source output was set at a range of 10-90%. A power sensor (LM-100HTD ,COHERENT JAPAN Inc.) and an energy meter (Field Master-GS, COHERENT JAPAN Inc.) were used for measurement of laser output. Table 2 shows the test results.

When the output of the laser source was set at 55W (setting point of 90%) and the laser was transmitted to the composite-type optical fiberscope through the coupling device, the laser output of 46W was confirmed at the tip of the composite-type optical fiberscope. The transmission efficiency was therefore 83.6%. For the output setting points of 10-90% at the laser source, the average of 84.7% transmission efficiency was obtained.

Table 2 Laser transmission efficiency of the composite-type optical fiberscope

Output from laser source		Output from the composite-type optical fiberscope tip	
Set-point (%)	Power (W)	Power (W)	Efficiency (%)
10	0.72	0.60	83.3
20	7.07	6.0	85.3
30	13.7	11.8	86.1
40	20.6	17.6	85.4
50	27.4	23.4	85.4
60	34.2	29.1	85.1
70	41.2	34.9	84.7
80	48.0	40.1	83.5
90	55.0	46.0	83.6

(3) Comparison test

We carried out the cauterization performance test to compare the composite-type optical fiberscope (a quartz lens at the tip) to a normal laser fiber usually used in fetal surgical operations (diameter of ϕ0.6mm, without a lens at the tip). We used a resected liver of a pig as an irradiation object. The laser power at the laser fiber tip was changed at the range of 10, 20, 30, 40W, and distance between the tip and the object was changed at the range of 5, 10, 15, 20mm, and then the burnt areas were observed. We carried out the tests in the water tank filled with physiological saline kept at a temperature of 37 degrees to simulate intrauterine environment.

Fig.5 shows the relations between the distance from fiber tip to the target and the diameter of the burnt area of pig liver using the normal laser fiber at several conditions of laser output. The burnt size was measured with a microscope.

From the measurement results, we found that a cauterized area greatly changes according to the laser output. The burnt depth, not described in the figure, showed the same tendency. Since the surface of the pig liver intensely burst in the case of 40W output at the distance of 5mm, careful setting of the laser output parameter is necessary in a real operation.

Fig.6 shows the relations between the distance from fiber tip to the target and the diameter of the burnt area of pig liver using the composite-type optical fiberscope at several conditions of laser output. The test results showed that the diameter of the cauterized area at the distance of 10mm, did not change according to the laser output change, and the stable cauterization was always achieved. In addition, it became clear that the cauterization performance extremely decreased when distance was over 10mm. Because the focal length of the lens attached to the tip was designed 10mm, the laser beam is spread when the distance to the object is over the laser focal length. In other words, we can secure safety for inadequate positioning of the fiberscope.

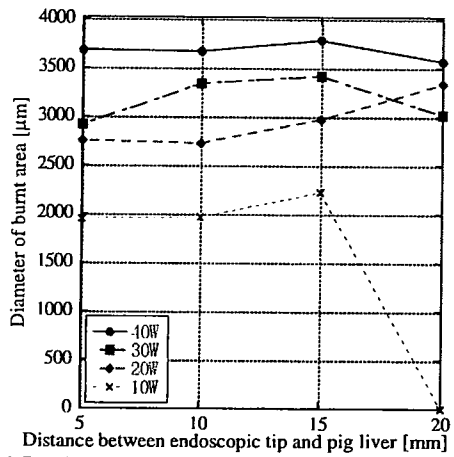


Fig.5 Result of laser cauterization test by the normal optical fiber (ϕ0.6mm).

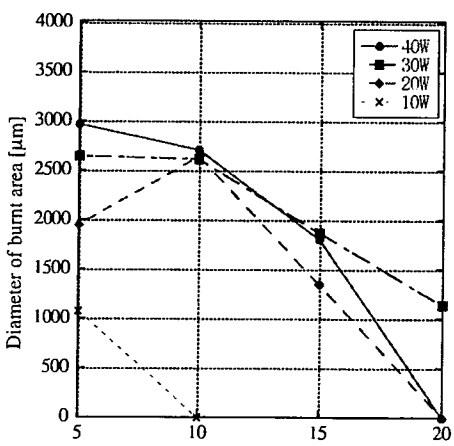


Fig.6 Result of laser cauterization test by the composite-type optical fiberscope.

V. Conclusions

We successfully developed a composite-type optical fiberscope with outer diameter of ϕ2.2mm. A quartz lens was installed at the tip of this fiberscope. The fiberscope has the image resolution of about 9,000 pixels and the angle of view is 54 degrees. In addition, the fiberscope can transmit laser energy of more than 40W at the focal length of 10mm. As the results of fundamental feasibility tests, the laser beam collection was sufficient and the depth of focus was kept constant. On the other hand, the cauterization showed best performance at the focal area (focal length = 10mm). In addition, cauterization performance decreased at those points off the focus resulting in safe and efficient operation.

In the future, the composite-type optical fiberscope will be mounted on a freely-bending robotic manipulator[4] in order to move the fiberscope freely in the uterus.

Acknowledgment

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References

1. Shibanuma K, Honda T (2001) ITER R&D: Remote handling systems: Blanket remote handling systems, Fusion Engineering and Design, Volume 55, Issues 2-3, pp.249-257
2. Oka K, Itou A, Takiguchi Y (1999) Development of bore tools for pipe welding and cutting, Journal of Robotics and Mechatronics, Vol.10, No.2, pp.104-109
3. Oka K, (2003) A new optical fiber system with hybrid functions of power delivery and real-time remote observation for YAG laser welding, The Review of Laser Engineering, Vol.31, No.9, pp.612-617
4. Harada K, Nakamura T, Chiba T, Fujie M, Bending Laser Manipulator for Intrauterine Surgery, IEEE / RAS-EMBS International Conference on Biomedical Robotics and Biomechatronics, 2006 (In Press)

Address of the corresponding author:

Author: Kiyoshi Oka
Institute: Japan Atomic Energy Agency
Street: 2-4 Shirane, Shirakata, Tokai-mura, Naka-gun
City: Ibaraki
Country: Japan
Email: oka.kiyoshi@jaea.go.jp

The 45th Annual Meeting of Japanese Society of Gastroenterological Cancer Screening

第45回
日本消化器がん検診学会総会

集団検診から
新たなる飛

プログラム・抄録集

会期：2006年6月1日（木）～3日（土）

会場：名古屋市中小企業振興会館（吹上ホール）

会長：芳野　純治（藤田保健衛生大学第二教育病院内科）

指定講演

「産学連携による医療機器の開発」

岡　　潔（(独)日本原子力研究開発機構産学連携推進部）

原子力に替わる次世代のエネルギー源として，核融合エネルギーシステムの実現を目指し，現在，日本・ロシア・欧州・中国及び韓国等が協力し，国際熱核融合実験炉(ITER)の開発を進めている。

このような背景の下，日本原子力研究開発機構では，ITER炉内の主な構造物に付属している冷却配管を対象として，各冷却配管の内側からアクセスし，曲がり部を通って任意の枝管・母管を溶接・切断する配管加工ロボットの開発を進めてきた。この配管内アクセスによる溶接・切断ロボットが任意の場所で配管の加工を行うためには，目的の場所まで配管加工用のパワーを伝送する必要がある。また，溶接・切断前後の加工状態の確認作業も必要である。このため，配管内という狭隘な空間において，溶接・切断加工の状況や加工前後の観察を行うことを目的に，1系統の光ファイバとレンズ光学系で溶接・切断・観察作業を可能とする複合型光ファイバシステムの開発を行った。開発した複合型光ファイバは，2kWのNd:YAGレーザー光と画像を並列伝送可能とした。今後，本技術はITERの配管加工ロボットに適用される予定である。

一方，このような核融合炉の実現に向けて研究開発した成果を広く一般に適用し，世の中のニーズにマッチングさせるべく，産学官連携による新しい価値の創出を推進している。現在，医療分野への技術応用に着目し，開発した複合型光ファイバ技術を適用することで，体内におけるレーザー治療と観察を1つの器具で実現することが可能な新しい内視鏡及び手術器具の研究開発を進めている。

本報告では，先天性疾患を有する胎児に対する外科治療器具の開発に関して，双胎間輸血症候群・胎児脊髄髄膜瘤の低侵襲胎児内視鏡手術手技改善・完遂のため，あらゆる胎盤・胎位での安全な胎盤手術及び胎児外科手術が可能で，対象物への正確なレーザー光の照射が可能な内視鏡を完成させることを目的とし，外径2mm程度の複合型光ファイバスコープ，レーザー光を導光し対象物からの画像を取得するためのカップリング装置，視野の狭い光ファイバスコープの画面を拡大表示する画像処理システム，レーザー照射治療用のレーザー光源などを一体化した胎児外科治療器具を開発したので，その基本性能及び基礎試験結果等を述べる。また，腸に閉塞及び癒着を有する患者に対して，その治療を目的として使用可能なイレウスチューブにそのまま挿入可能で，挿入からわずか数分で閉塞・癒着部位の状況を観察可能なイレウスチューブ型光ファイバスコープを開発したので，その基本性能及び基礎試験結果等を述べる。本光ファイバスコープは，今後，レーザー導光可能な内視鏡として開発を進めることで，診療行為から治療行為への円滑な移行を目指している。

内視鏡下胎児手術における柔支持マニピュレータの研究

廖　洪恩・鈴木　宏和・松宮　潔
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研究

内視鏡下胎児手術における柔支持マニピュレータの研究

廖　洪恩*・鈴木　宏和**・松宮　潔**
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Fetus Supporting Flexible Manipulator for Endoscopic Fetal Surgery

Hongen LIAO,* Hirokazu SUZUKI,** Kiyoshi MATSUMIYA**
Ken MASAMUNE,** Takeyoshi DOHI,** Toshio CHIBA***

Abstract Minimally invasive endoscopic fetal surgery enables intrauterine intervention with smaller risk to the mother and fetus. We designed and fabricated a prototype of a fetus-supporting manipulator equipped with flexible bending/curving mechanisms and a soft balloon-based stabilizer to prevent the fetus from free-floating during endoscopic intrauterine surgery. The manipulator enables the stabilizer to reach the target sites within the uterus under ultrasound guidance. The balloon-based stabilizer can be inserted into the uterus from a small incision. The experiments using a fetus model show that the manipulator is well controlled using ultrasound guidance, and its curving mechanism and balloon-based stabilizer are clearly visible when implementing fetus support.

Keywords: Fetal surgery, stabilizer, manipulator, ultrasound guidance.

1. はじめに

胎児期に発症する疾患の一つに，脊髄髄膜瘤があげられる．脊髄髄膜瘤は先天性の中枢神経の奇形で，腰背部で神経管が閉鎖せずに開放されて脊髄が背中の表面に露出する症患である．日本では，約3000人に1人の頻度で発症するが[1]，感染を予防する目的で，生後早期に閉鎖術が行われているのが一般的である[2-3]．

新生児に対して手術が行われるのは，神経障害および脳脊髄液（CSF: Cerebrospinal fluid）の循環・産生・吸収の障害が既に不可逆的に進行している時期であり，この手術は，中枢神経障害の改善というよりは，感染予防および残存神経機能の温存を目的としたものである．結果として，この手術では，CSF循環の閉塞による水頭症が髄膜瘤閉鎖術後に顕在化し，脳室腹腔シャント術の必要性が増加する．

これとは対照的に，現在行われている胎児期の脊髄髄膜瘤の修復術は，妊娠19～25週の胎児が対象となっているため，中枢神経障害や水頭症を分娩前に改善できる．その理由として考えられることは，胎児脳の発達過程が正常化されることにある．また，妊娠早期は神経組織ミエリン化が進行してはいないため，胎児神経組織のコンプライアンス・可塑性が高く，脳組織の位置や形態の復元力ないし神経細胞自体の再生能が維持されていると考えられる[4]．

従来の胎児手術法は，母体開腹と子宮切開にて行われるため，母児への侵襲性が高い手技であり，また再縫合するのが困難であり問題となっている[4]．

そこで近年，胎児内視鏡下の低侵襲性手術が望まれているが，子宮切開下の手術同様にその手技は極めて困難である[5]．その問題のひとつに，水中に胎児が浮遊しているという点が挙げられる．その解決策として，胎児を手術中に保定し支える器具の開発が考えられる．先行研究としては，ステンレス製のFetal Stabilizerがあげられる[6]．この器具は，胎児を支持する際に，胎児を完全に固定しているため，胎児に悪影響を与えると考えられる．また，近年では，胎児手術用吸引型スタビライザも開発されているが[7]，胎児体表での陰圧固定のリスクも考えられる．そこで本研究では，内視鏡下手術を行う際に胎児を柔軟に支持

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* 東京大学大学院工学系研究科
Graduate School of Engineering, the University of Tokyo
** 東京大学大学院情報理工学系研究科
Graduate School of Information Science and Technology, the University of Tokyo
*** 国立成育医療センター特殊診療部
Department of Strategic Medicine, National Center for Child Health and Development

しうるマニピュレータを開発し，その有効性を評価する．

2. 胎児柔支持法

2·1 胎児支持法

胎児を支持する目的は，内視鏡下に脊髄髄膜瘤を手術する際に，胎児の浮遊性移動防ぎ，手術を円滑に進めることにある．その際に，胎児への圧迫や臍帯損傷を防ぐ機構が求められる．

胎児の柔支持を考えるにあたり，まずは，手術時における胎児の特徴を考える必要がある．胎児を実際に手術するのは，妊娠19～25週が適切とされている．胎児の体重は約500 g，身長は約30 cm，そして，羊水量は約500 mlである．しかし胎児には，個体差がかなりあると同時に，疾患を有する胎児には，成長上のばらつきが見られる．有病胎児の羊水量は多くの場合，平均値を上回っているが，ある程度の範囲で調整が可能である．羊水過少例では，子宮内に生理食塩水を加えるなどして，手術に適切な量に調整することが可能である[8]．

2·2 胎児柔支持における要求仕様

胎児の脊髄髄膜瘤修復手術を行う際には，胎児に対し圧迫ないし牽引力を少なからず与える．従ってこのような作業を行っても，胎児が回転ないし移動しないように動きを制限しうることが条件となる．

回転させないためには，胎児腰背部に対して，腹部を支え，胎児が保持・固定されていなければならない．そのためには，胎児の頭部重量を考慮し，胎児胸部周囲を支える必要がある．

これら2点を考慮すると，胎児の胸部から腹部にかけて，腹側から柔軟に支持することが求められる（図1）．

2·3 胎児柔支持機構

上述の条件を満たす機構として，ドーナツ型に膨らむバルーンを採用した．先端部を湾曲させる事で，バルーンが下降してもその硬性部への接触による胎児損傷を防ぎつつ，柔軟な支持が可能となる．

バルーン方式の採用は，小さい挿入口から子宮内へ挿入しても，胎児への接触面積を有意に増加できることが大きな利点である．また，バルーンに生理食塩水を注入して膨らませるのであれば，バルーンが破損しても胎児への影響は少ないと考えられる．

このドーナツ形状バルーンにより胎児を支持する方法を実現するためには，バルーンの配置法およびバルーンの挿入法を工夫する必要がある．そこで，湾曲部と屈曲部を併せ持つマニピュレータを考案した．具体的には，図2に示すように，ドーナツ形状バルーンの両端が湾曲部に接続している機構である．

この機構が実際に胎児を支えている様子を図3に示す．

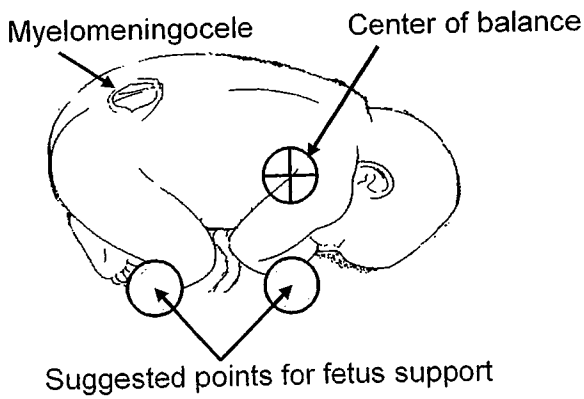

図1　胎児の柔支持点
Fig. 1　Points for fetus non-compressing support.

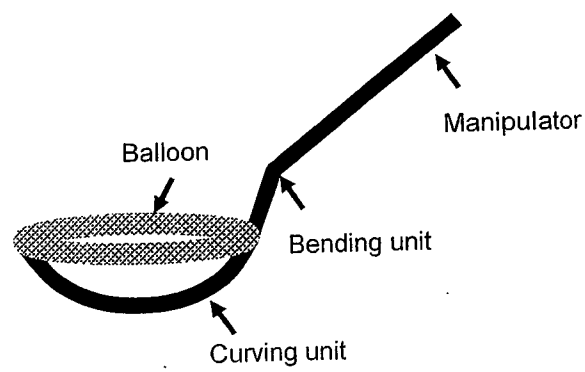

図2　円形状のバルーンを実現する胎児支持機構
Fig. 2　Round-shaped balloon for fetus support.

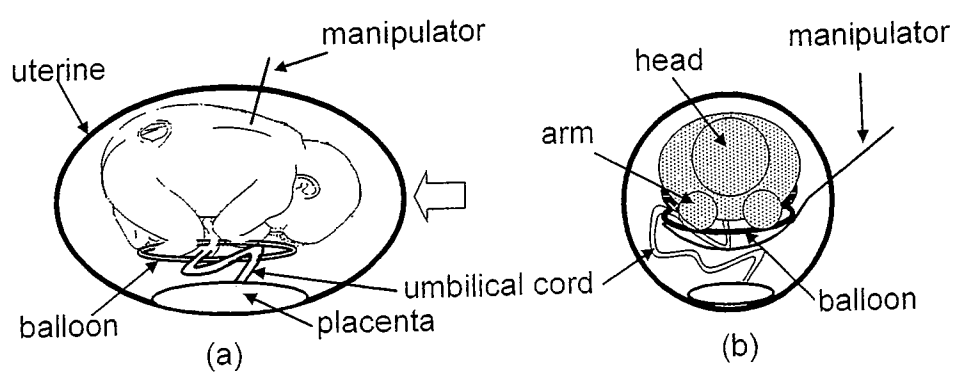

図3　胎児をバルーンにて下方より支える想定図．（a）胎児を側方より見た図．（b）胎児を頭側から見た図
Fig. 3　Fetus supported by a balloon-based flexible manipulator. (a) Viewed from left side. (b) Viewed from the head.

胎児の肘関節および膝関節付近をバルーンが支持する形となっており，臍帯はバルーンによる圧迫を受けない構造であるる．

2·4　胎児の柔支持手順

図3に示したとおり，胎児の肘関節および膝関節付近をバルーンが支持する形となっており，臍帯はバルーンの横を走行し圧迫を受けない構造になる．この機構の挿入手順を以下の図4に示す．

全ての段階において，超音波ガイドが用いられる．最初に，子宮壁からマニピュレータを直線的に挿入する（図4a）．その際，胎盤や臍帯への接近を避けながら挿入する．対側の子宮壁への接触を避けるべく湾曲部分を屈曲させる（図4b）．そして，胎児を支持しうる位置にマニピュレータを移動させるが，その際は屈曲部を操作しつつ胎児を下方から支える位置まで先端部を制動していく．その後，適切な位置でバルーンを膨らませ，胎児の支持を行う（図4c）．

3.　柔支持マニピュレータ

3·1　システム全体像

胎児柔支持システム全体像を図5に示す．システムは，柔支持マニピュレータ，制御用コントローラ，超音波診断装置の3つからなる．マニピュレータを，母体の腹部より挿入し，超音波ガイド下で適切な位置に先端部を配置，屈曲させ，バルーンを膨らまして胎児を支持する．

胎児手術に使われている器具は，通常直径5 mm以下である．しかしながら，本研究では低侵襲の低減以上に安全性を重視し，バルーンを膨らませるためのチューブを通すチャネルを有する直径6 mmのリング機構実現をまず目指す．

また，マニピュレータの湾曲部は，胎児の躯幹周囲長(15～20 cm）に対応し，直径10 cm程度のバルーンとなる15 cm前後の長さが適切と考える．

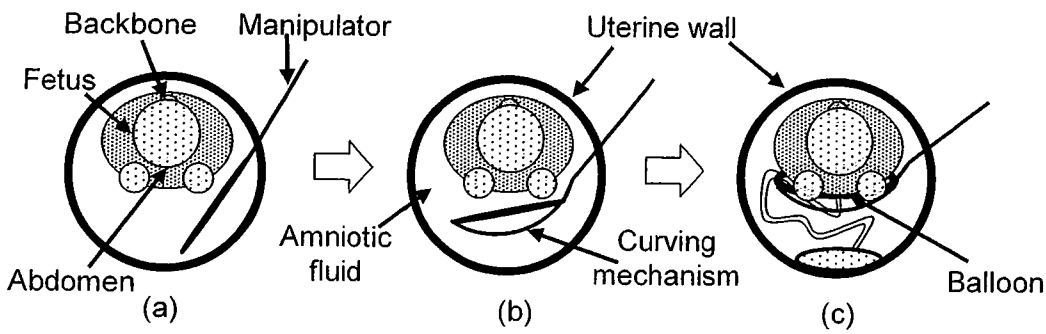

図4　柔支持マニピュレータの挿入手順．超音波ガイド下で子宮内への挿入を行う．(a)マニピュレータを直線的に挿入する．(b)マニピュレータの湾曲部分と屈曲部分をコントロールしながら，胎児を支えうる形状に変化させる．(c)胎児の下部にうまく配置できた時点で，バルーンを膨らませる胎児支持を実現する

Fig. 4　Fetus supported by a balloon-based flexible manipulator using ultrasound guidance. The insertion procedures shown in (a)-(c): (a) Insert the manipulator straightly. (b) Bend and adjust the curving mechanism to an optimal position. (c) Inflate the balloon and optimally stabilize the fetus from underneath.

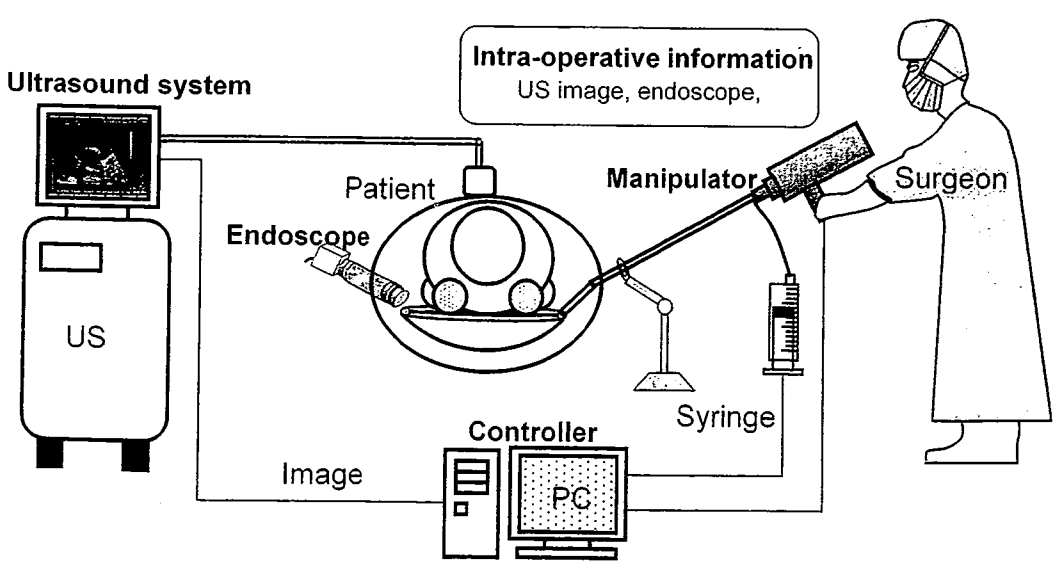

図5　内視鏡下胎児手術におけるマニピュレータシステム構成図

Fig. 5　Fetus support manipulator system for intrauterine surgery.

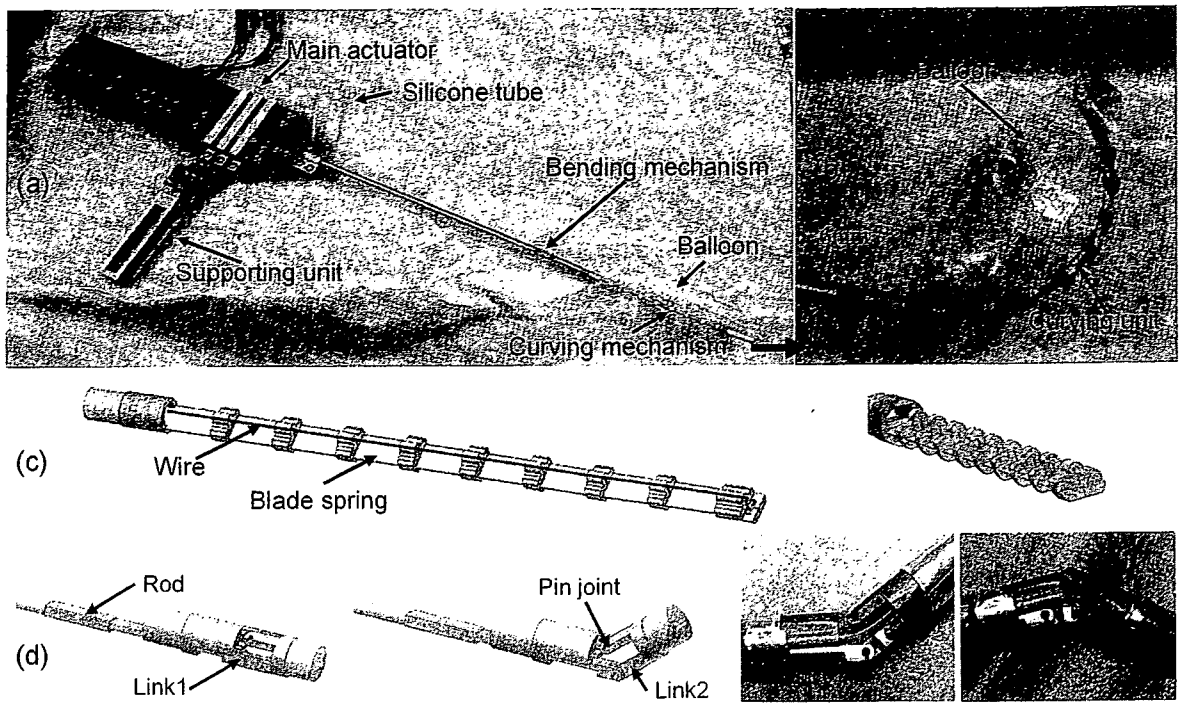

図6　マニピュレータ全体図（湾曲機構，リンク機構，バルーン）
Fig. 6　Manipulator with curving mechanism, linkage bending mechanism and balloon-based stabilizer.

3・2　マニピュレータの詳細

マニピュレータは，屈曲部，湾曲部，柔支持部と，モータ系統が含まれる本体の駆動部と，操作部とに分かれる．製作したマニピュレータ全体像を図6aに示す．

湾曲部は，挿入口を出来るだけ小さくするため，湾曲機構にはリング状バルーンを収める板バネおよびワイヤー機構を考える．湾曲機構の実現方法としては，板バネとワイヤー機構を組み合わせた方法の他，形状記憶合金を用いる方法，膨張率の異なる2つの金属板を重ね合わせ片方を加熱して湾曲させる方法なども考えられるが，生体に対する安全性や，バルーンサイズ確保のため，断面積が少ない単板バネおよびワイヤー機構を採用する（図6c）．

本マニピュレータの屈曲部にはスライダリンク機構を採用する[9]．これはリンク駆動にはワイヤー駆動に比べて剛性を高く，屈曲と伸張のストロークが等しいという利点があるためである．屈曲機構の構造詳細を図6dに示す．屈曲機構は，ピンジョイントによってリンク結合されている．

柔支持部であるバルーンは，圧迫を与えずに胎児を支えうるよう，ポリエチレン製バルーンを採用する（図6b）．ラテックス製品は胎児の皮膚反応を引き起こす可能性もありその使用を避けられる．また，低侵襲性実現のため，バルーン径と挿入口のサイズのバランスを検討し設定する．

以上を考慮して，図6bに示すように，直径6 mmに収めるべく設計を行う．なお本研究では，先端部と駆動部取り外しが可能な機構を採用する．これは先端部をオートクレーブ（高圧蒸気法）滅菌し，ドレーピングした駆動部に接続することを想定したためである．

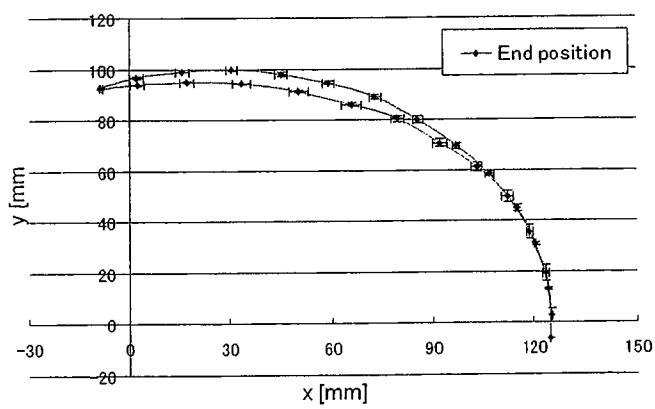

図7　湾曲部先端の座標変化（1秒間隔）
Fig. 7　Tip end positions of the curving mechanism of the manipulator (1-sec interval).

3・3　超音波画像誘導

胎児内視鏡手術においては，超音波画像誘導が一般的に用いられている．本システムでも超音波断層像による誘導と，マニピュレータに対する胎児や臍帯等との位置関係の把握が可能である．

超音波診断装置は，胎児に対する安全性が高く，胎児の観察に一般的に使用される．そこで，本研究においても，超音波画像で観察を行いながら手術が行うために，超音波診断装置による術中情報の提示を想定する．

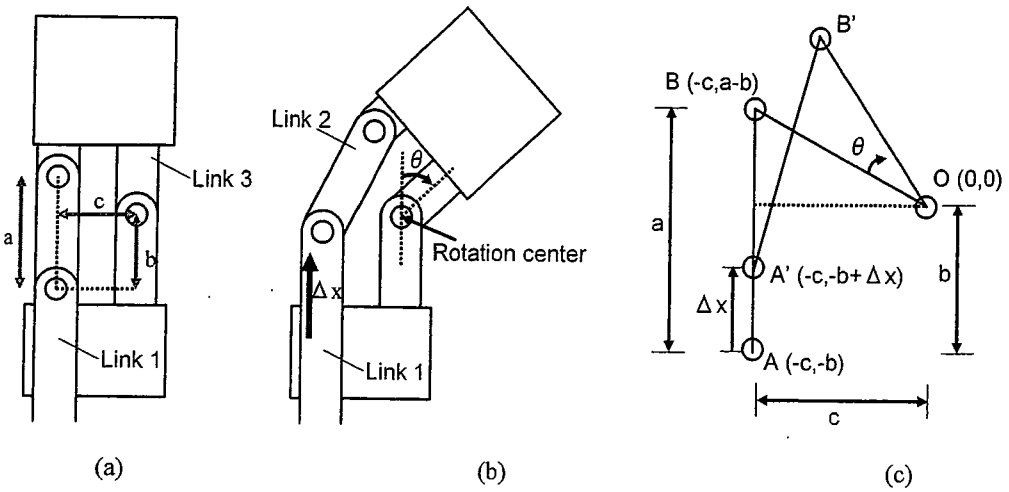

図 8　リンク機構．(a)直線状リンク．(b)リンクを Δx 変化させたときに θ 角だけ屈曲した場合．(c)ピンジョイント部の座標関係
Fig. 8　Linkage mechanism. (a) Initial position of the linkage. (b) Δx movement of Link 1 results in the bending angle θ of Link 3. (c) Coordination of each pin joint of the linkage mechanism.

4. 評 価 実 験

4·1　湾曲部の精度評価

湾曲部根元から先端までの距離変化を測定し，精度評価を行った．この実験では，湾曲部評価のために，リンク機構を付与しない状態での測定を行った．その結果，**図 7** に示すようなヒステリシスを持つことが判明した．その差分は最大約 7 mm であった．この誤差は，子宮内での制御に際し，子宮壁や臍帯，胎盤などに大きな影響を及ぼすほどの数値ではないと考えられる．

4·2　屈曲部の精度評価

屈曲部リンク機構の並進距離に対する屈曲角度の精度評価を行い，理論値と実際の値とを比較した．機構の並進距離とリンクの屈曲角度との関係は**図 8** に示した．リンクの屈曲角度とストローク変位量の関係は以下の式で表される．

$$\Delta x = c\sin\theta + a\cos\theta + b(1-\cos\theta) - \sqrt{a^2 - \{c(1-\cos\theta)+(a-b)\sin\theta\}^2}$$

評価実験の結果，**図 9** に示すように，理論値とかなり一致する結果となった．屈曲角度の最大誤差は図 9 に示す範囲では約 5° であるが，標準偏差の最大値が 1.6° であるため，十分な再現性が確認された．

4·3　胎児モデルを用いた胎児支持の実験

胎児モデルを用いて胎児支持実験を行った．実際に手術を行うのは妊娠 19 ～ 25 週の胎児であるが，胎児モデルには，体重約 500 g，比重約 1 g/cm³，全長約 30 cm のものを使用した．その結果，**図 10** に示すように，胎児モデルの姿勢支持の可能であることが確認され，本バルーンにより胎児の子宮内回転および移動を抑えることができた．これに加え，胎児を挙上することも可能であった．実際の手術に際し，胎児に対する圧迫やモーメントを発生させるポイ

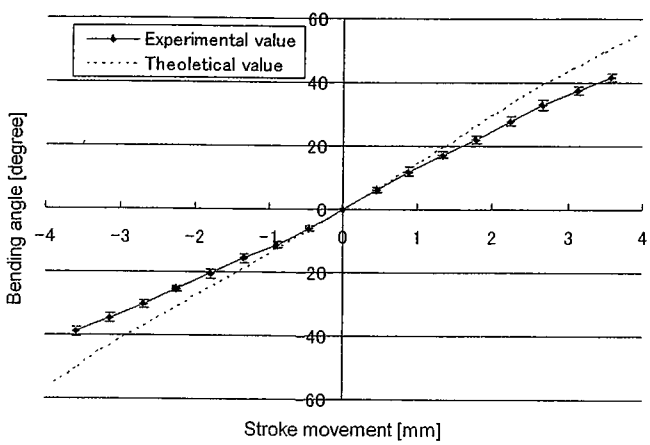

図 9　屈曲部のストローク距離と角度変化
Fig. 9　Relationship between the translation movement and the bending angle of the bending mechanism.

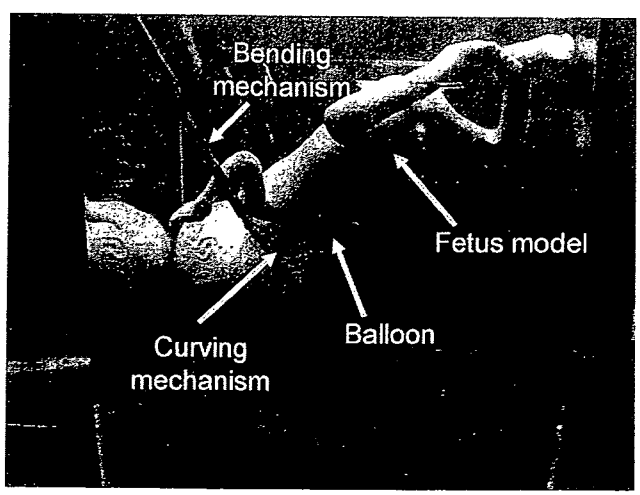

図 10　胎児モデルを支持している様子
Fig.10　Manipulator stabilizes the fetus model non-compressively.

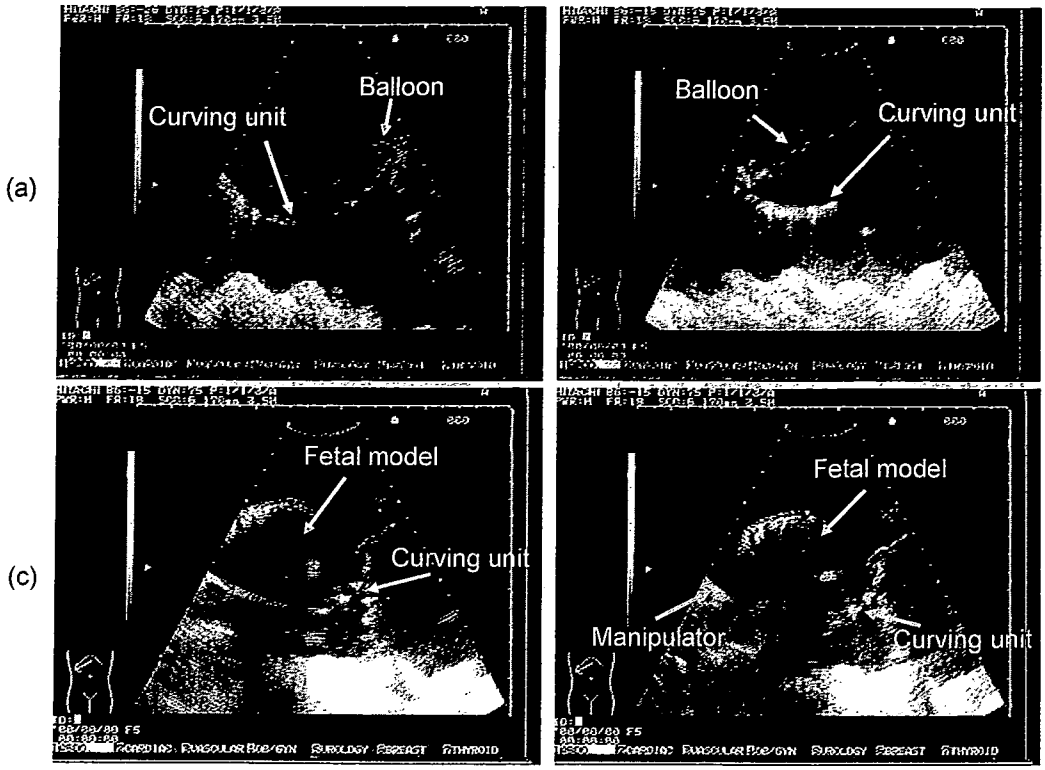

図11　超音波ガイド下マニピュレータの操作：(a)マニピュレータの湾曲部ははっきりと確認できる．(b)バルーンを水で膨らませている状態．バルーンと湾曲部がはっきりと観察される；胎児モデルを投入し，湾曲させつつバルーンを膨らませた状態での超音波画像：(c)胎児モデルと湾曲部をはっきりと確認できる．(d)胎児モデルの存在下，マニピュレータと湾曲部を確認する事が出来る

Fig. 11　Ultrasound-guided manipulator insertion for stabilizing the fetus model. (a)Curving mechanism of the manipulator clearly visible. (b)Both the curving mechanism and the inflated balloon; fetus model for simulating fetal surgery using the bending manipulator and inflated balloon. (c)Fetus model and manipulator. (d)The manipulator and curving mechanism observed underneath the fetus model.

ントを考慮し，適切な場所にバルーンが配置できれば，胎児の回転や並進を抑えることは可能と考えられる．

4・4　超音波装置を用いた撮像実験

実際に水中にマニピュレータを挿入し，マニピュレータが超音波診断装置にて視覚的に観察できることを確認した．また，胎児モデルの存在により画像がどのように変化するかを評価した．

画像から明らかなように，マニピュレータのバルーン部，湾曲部などを含めた先端部は，明確には描出されなかった．胎児モデル内部も基本的に描出しえなかった．しかし，胎児モデルを配置しない場合に比べ画質は低下するものの，胎児モデルの両脇の下方では，バルーンやマニピュレータの外筒部分が確認しえた（図11）．

また，胎児モデルはその表層のみが描出され，その下方は何も観察できなかった．

5. 考　　察

湾曲部のヒステリシス評価実験より，湾曲部は最大約7 mmの誤差を持つことがわかった．また，屈曲部の精度評価実験より，屈曲角の標準偏差は最大5°である事が判明した．しかし，その精度は身長が30 cmの胎児を支持するためには十分な精度と考えられ，駆動範囲も十分に要求仕様を満たすものと考えられた．この事から，マニピュレータは様々な胎盤付着部位に対応可能と考えられる．ただ，臨床への応用を考慮すると，ヒステリシスを低減するための機構改良が必要と考えられる．また，ワイヤーの牽引距離に対し，湾曲部先端から根元までの距離変化量（バルーンの長半径の距離）が線形性を有しないため，適正な位置でバルーンを膨らませうるよう根元から先端部までの距離を表示できる仕組みも必要である．

胎児の支持には，出来るだけ大きなバルーンサイズが望まれるが，低侵襲性手術とするためには挿入口サイズを抑えなくてはならない．これら相反する二つの仕様要求を満たすためには，より適切なバルーンの折りたたみ方式の開発も必要と考えられる．

胎児の下方の死角部については，他の機器と同様に，マニピュレータが超音波にて描出できなかったが，超音波の原理上ある程度避けえないものと考えられる．実際の手術に際しては，様々な角度からの超音波観察によるマニピュレータの位置を把握するか，あるいは，内視鏡を挿入している場合には，内視鏡にて確認することが望まれる．

6. ま　と　め

本研究では，胎児脊髄髄膜瘤の内視鏡下修復に際して使用できる適切な胎児柔支持マニピュレータの開発を試した．胎児に加える圧迫を低減するバルーン機構と，湾曲機構の採用によりハード部分の胎児への接触を避け，同時に屈曲機構の採用により胎盤の付着部位に制限されない挿入口の選択が可能となった．また実際に，胎児モデルに対して柔支持を実現しえた．

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文　献

1. 住吉好雄, 平原史樹, 田中政信, 清川尚, 本田洋, 坂元正一, 竹下研三, 中川秀昭, 黒木良和：わが国の先天形態異常. 産科と婦人科. **66**(7): 871–881, 1999.
2. Meuli M, MeuliSimmen C, Yingling CD, *et al.*: In utero repair of experimental myelomeningocele saves neurological function at birth. Journal of Pediatric Surgery. **31**(3): 397–402, 1996.
3. Johnson MP, Sutton LN, Rintoul N, *et al.*: Fetal myelomeningocele repair: Short-term clinical outcomes. American Journal of Obstetrics and Gynecology. **189**(2): 482–487, 2003.
4. 千葉敏雄, 師田信人：胎児脳神経外科(2)—胎児脊髄髄膜瘤—. 産科と婦人科, **71**(9): 1219–1225, 2004.
5. Aaronson OS, et al.: Robot-assisted endoscopic intrauterine myelomeningocele repair: A feasibility study. Pediatric Neurosurgery. **36**(2): 85–89, 2002.
6. Michael Dinh, Joseph Bruner: Fetal Stabilizer for Intrauterine Surgery. BME.
7. 坪内広太, 原田香奈子, 千葉敏雄, 絵野沢伸, 藤江正克：胎児手術用吸引型スタビライザの開発. 第14回日本コンピュータ外科学会抄録, pp. 45–46, 2005.
8. 福家信二, 石川睦男：羊水還流と胎児の代謝・発育. 周産期医学, **31**(8): 1015–1019, 2001.
9. H. Yamashita, D. Kim, N. Hata, T. Dohi: Multi-Slider Linkage Mechanism for Endoscopic Forceps Manipulator, in Proceedings of the 2003 IEEE/RSJ International Conference on Intelligent Robots and Systems(IROS 2003). Vol. 3, pp. 2577–2582, 2003.

廖　洪恩（リョウ　コウオン）

2003年東京大学大学院工学系研究科博士課程修了，博士（工学）．日本学術振興会特別研究員を経て，2004年東京大学大学院工学系研究科特任教員，現在に至る．2006年ハーバード大学医学部客員研究員．

医用工学，三次元医用画像，医用ロボット，立体ディスプレイの研究に従事．

日本生体医工学会，日本コンピュータ外科学会，IEEE，OSA，SPIE，MICCAIなどに所属．

鈴木　宏和（スズキ　ヒロカズ）

2004年東京大学機械情報工学系卒業．2006年東京大学大学院情報理工学研究科修士課程修了．

コンピュータ外科，医用ロボットの研究に従事．

日本コンピュータ外科学会の学生会員．

松宮　潔（マツミヤ　キヨシ）

2004年3月，東京大学大学院工学系研究科精密機械工学専攻博士課程修了．2004年4月，東京大学大学院情報理工学系研究科知能機械情報学専攻助手．

医用工学，コンピュータ外科において主に低侵襲外科手術支援技術に関する研究に従事．

日本機械学会，日本コンピュータ外科学会に所属．

正宗　賢（マサムネ　ケン）

東京大学大学院工学系研究科修士課程卒業，1995年より同大学助手，2000年より東京電機大学理工学部講師，2004年に同大学助教授となり，2005年に東京大学大学院情報理工学系研究科知能機械情報学専攻助教授となり現在に至る．博士（工学）．

専門は医用精密工学で，医用システム，医療用ロボットの研究に従事．

日本コンピュータ外科学会，ライフサポート学会，日本生体医工学会，日本機械学会などに所属．

土肥　健純（ドヒ　タケヨシ）

1977年東京大学工学系研究科博士課程修了，工学博士．東京大学工学部精密機械工学科助教授を経て，1988年同教授，1995年東京大学大学院工学系研究科教授，1999年同新領域創成科学研究科教授，2001年同情報理工学系研究科教授，現在に至る．

コンピュータ外科，福祉工学等医用精密工学に関する研究に従事．

日本生体医工学会，ライフサポート学会，日本コンピュータ外科学会，国際コンピュータ外科学会などに所属．

千葉　敏雄（チバ　トシオ）

昭和50年東北大学医学部卒業．東北大学小児外科講師，ピッツバーグ大学小児外科，UCSF胎児治療センター（客員教授）などを経て，平成13年国立成育医療センター特殊診療部部長，現在に至る．

小児外科と胎児治療に関する研究に従事．

IFMSS, Pacific Association of Pediatric Surgeons, Asian Association of Pediatric Surgerons, 日本外科学会，日本産婦人科学会，日本小児外科学会，日本内視鏡外科学会，日本周産期・新生児学会，日本コンピュータ外科学会，日本機械学会などに所属．