31st Annual International Conference of the IEEE EMBS
Minneapolis, Minnesota, USA, September 2-6, 2009

Robotic patch-stabilizer using wire driven mechanism for minimally invasive fetal surgery

Bo Zhang, Yo Kobayashi, Toshio Chiba, and Masakatsu G. Fujie, *Member, IEEE*

***Abstract*—The clinical target of this study is intrauterine patch coverage of fetal myelomeningocele. We propose a new surgical robotic system for intrauterine fetal surgery with patch-stabilizer and laser manipulator. The target disease of the fetal surgery is spina bifida or myelomeningocele, which is incomplete closure in the spinal column and one of the common fetal diseases. In the fetal surgery, the collagen patch is supposed to be stabilized onto the fragile fetal tissue during the laser fixation process. In this study, a prototype of the patch-stabilizer using wire driven mechanism has been developed for precise force control on the patch without damaging fetal tissue. The diameter of the patch-stabilizer's shaft is 2.4 mm. The patch-stabilizer including one ball joint and wire driven mechanism is able to bend through 40 degrees. The stabilizing part holds collagen patch with diamond shape mechanism using wire driven. In this paper, we showed that the patch-stabilizer is developed with the stabilizing force control using the tension control of wires. Results of the experiment showed that the tension of driven wires was controlled at 0.3 N to stabilize the collagen patch onto the lesion surface without the damages of fetal tissues and the influence by the amnion liquid.**

I. Introduction

In recent years, fetal disorders have been discovered extremely early by the progress of therapeutic apparatus such as ultrasound and MRI diagnosis apparatus. Fetal intervention has been developed over the last two decades to provide better perinatal prognosis for the fetus with the diseases which deteriorate before birth. Open fetal surgery has successfully treated a number of fetuses, but its invasive technique including maternal laparotomy followed by hysterotomy could cause preterm labor or premature rupture of chorioamniotic membrane. Meanwhile, minimal access fetal surgery or fetoscopic surgery has been introduced in the hope that less invasive surgery might result in better therapeutic outcomes with shorter hospital stay and less expenses [1].

Myelomeningocele is a kind of disorder in which the nerve gets into the liqur amnii from the dysplasia of the fetal backbone and the spinal canal. This affection could cause damages to the postnatal brain and the lower part of the body. A patch protects the effected part to avoid any irritations of the nerve, which is attached as the temporarily treating method used before childbirth. It is required to stabilize the collagen patch onto the fragile fetal skin tissue with appropriate force and to fix patch by using laser.

However, conventional endoscopic tools are inadequate for intrauterine operations, especially for operating a fetus with fragile tissue. Our research strategy is to develop a surgical robot for minimal access intrauterine surgery and then quantitatively evaluate fetal tissue fragility to improve the robot for more complicated tasks. In this paper, a prototype of the patch-stabilizer using wire driven mechanism has been developed for precise force control on the patch without damaging fetal tissue because it is described by surgeons as soft, fragile, gelatinous, and difficult to handle.

II. Fetal Surgery

A. Clinical Target

Our target disease, myelomeningocele (MMC), is congenital anomaly having spinal bone defects with open spinal canal. MMC is not life-threatening, but mechanical and chemical stimulus to the exposed spinal code and spinal fluid leakage worsens postnatal infant's neurologic function with resultant life-long disabilities. Recently, intrauterine patch coverage of the spinal defects has been performed [2] and we proposed much less invasive procedure to attach a collagen patch onto the fetal ski n using a laser [3]. For the fetal patch surgery, we propose the system, which is shown in Fig. 1. The

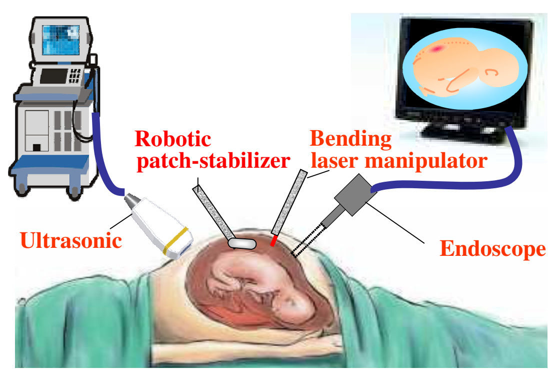

Fig.1 Patch fetal surgery system

Manuscript received April 7, 2009. This work was supported in part by the Global COE (Centers of Excellence) Program "Global Robot Academia", Waseda University, Tokyo, Japan and in part by "High-Tech Research Center" Project for Private Universities: matching fund subsidy from MEXT(Ministry of Education, Culture, Sports, Science and Technology).

Bo Zhang is with the Graduate School of Science and Engineering, Waseda University, Tokyo 169-8555, Japan (email: zhangbo@suou.waseda.jp).

Yo Kobayashi is with the Faculty of Science and Engineering, Waseda University, Japan(e-mail: you-k@aoni.waseda.jp)

Toshio Chiba is with National Center for Child Health and Development (NCCHD), Tokyo, Japan(e-mail: chiba-t@sea.plala.ne.jp).

Masakatsu G. Fujie is with the Faculty of Science and Engineering, and the Consolidated Research Institute for Advanced Science and Medical Care, Waseda University, Tokyo, Japan (e-mail: mgfujie@waseda.jp).

978-1-4244-3296-7/09/$25.00 ©2009 IEEE

endoscope, the patch-stabilizer and the laser manipulator are inserted into uterus. The collagen patch is pressed by the robotic patch-stabilizer on the surface of the lesion that cropped out into liquor amnii. Then, the collagen patch protecting lesion temporarily is fixed in fetal skin tissue by the laser manipulator.

B. Surgical Robots for Fetal Surgery

Many studies have been conducted to enhance the endoscopic operability and some commercial surgical robots [4] are used in the clinical cases. These robotic techniques are expected to be introduced in minimally invasive fetal surgery. However, experiments applying commercial surgical robots to fetal animal surgery [5-7] have reported many problems. Commercial surgical robots of 5 [mm] or more are too big for the fetal size and allowable surgical space. Moreover, one report found that not only the surgical robot is costly and requires long setup time, but also clinical outcomes differed little. In the meantime, researchers have studied to develop surgical devices specially designed for fetal surgery including a fetal blood sampling robot [8], a forceps manipulator [9], laser forceps [10], a microfabricated instrument for haptic tissue recognition [11] and high-intensity focused ultrasound (HIFU) system [12]. Our approach is to develop an inexpensive, simple and thin manipulator for easier and faster introduce in clinical case. The developed patch-stabilizer is expected to be useful not only in fetal surgery but also in other kinds of minimally invasive surgeries.

III. PATCH-STABILIZER

A. Specification of Patch-stabilizer

The specifications of the robotic patch-stabilizer could be concluded as: (1) The shaft diameter is required to be under 3[mm] that is able to insert a trocar with a diameter of 3 mm, as the amniotic cavity breakdown raises the danger of abortion. (2) The diameter of the stabilizing part is more than 60 mm in order to stabilize the collagen patch onto the lesion (ϕ40 mm~ 60 mm) of myelomeningocele in an embryo of pregnancy of 20-25 weeks. (3) Bending and moving the angle is needed, because of the limited movement space taken by the placenta. (4)The precise force control stabilized the collagen patch, which is required in order to avoid any damages on fetal tissue.

B. Mechanism of Patch-stabilizer

Fig. 2 shows the developed robotic patch-stabilizer. The developed patch-stabilizer uses a wire driven mechanism to achieve two bending degrees of freedom with the use of one ball joint-shaped arthrosis. The same mechanism introduced in [13] is used for joint part.

The diameter of the stabilizer's shaft is designed to be 2.4 mm so that the manipulator can be inserted into a 3 mm trocar. When the size of incision in the uterus is less than 3 mm, the incision does not need to be sutured since the contractive force of the uterus itself closes the small hole unaided.

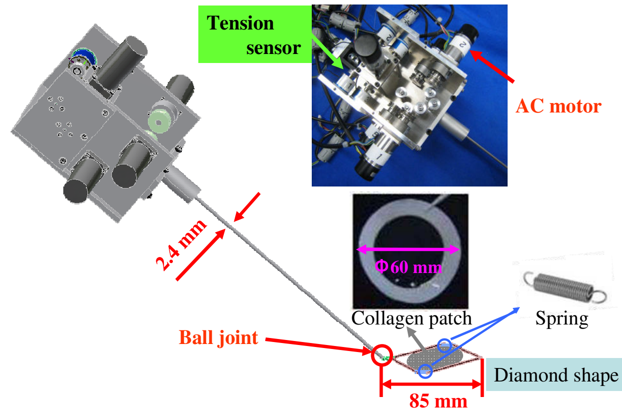

Fig.2 The Patch-stabilizer

Besides, the smaller incision is necessary to avoid premature rupture of chorioamniotic membrane since the membrane has poor wound healing ability.

The stabilizing part has been designed as a diamond shape with wires driven and the mechanism of springs. The wires are driven to open the stabilizing part and the springs are used to close by the power of restitution. The length of the opening stabilizing part is designed as 85 mm. The reason of doing this design is to hold the collagen patch with the diameter of 60 mm.

In order to hold the collagen patch onto the lesion surface, the drive unit is moved by a ball screw in translation with the stabilizing force control using the tension control of wires.

C. Positioning experiment of bending

Sequential bending motions through ± 40 degrees(0.6 rad) were commanded to evaluate the repeatability of the motion. With the same experimental condition of patch containment, two markers were attached to the stabilizer tip and their positions were tracked using the matching technique to figure out the bending angle. The result was shown in Fig. 3 and the high repeatability is confirmed. The asymmetric motion depending on the direction is due to the difference of initial tension of wires since the initial tension was manually set. The gradual angle changes around ± 40 degree is due to insufficient initial wire tension and small gaps between the fiber and holes in the joint spheres, not due to the kinematics' features of this bending mechanism. This is because that the minimum step angle and the stiffness of the manipulator itself depends on the initial wire tension.

D. Positioning experiment of patch containment

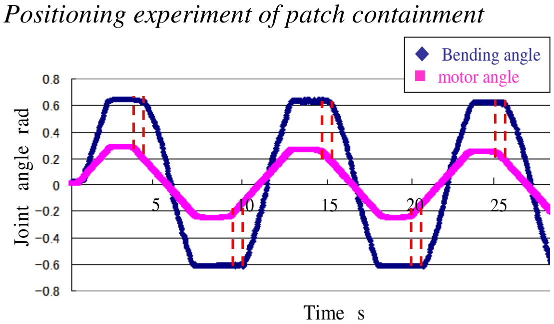

Fig.3 The result of the bending

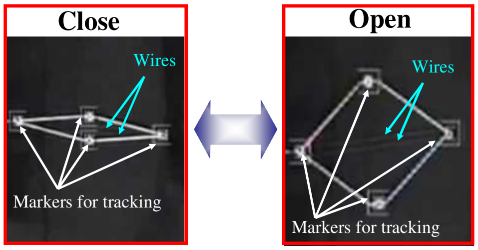

Fig.4 The tip of the Patch-stabilizer

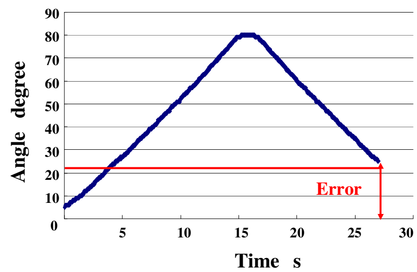

Fig.5 The result of the opening and shutting movement

By using the mechanism of diamond shape, opening and shutting movement of the stabilizing part was evaluated by the image processing. Four markers were attached to the stabilizer tip and the positions of patch containment were tracked using a matching technique of image processing to figure out the opening and shutting angle(Fig.4). The result was shown in Fig.5. The patch-stabilizer was opened to 80 degrees and an error of 20 degrees was measured in movement to close. The reason for this was the interference between the driving wires and the friction of the ball joint arthrosis part with the driving wires. The friction improvement methods are being reviewed to change thin wires and strong springs in the future.

IV. STABILIZING FORCE CONTROL

A. Measurement of pressure distribution

Measuring the distribution of the pressure is essential, as the pressure hold the collagen patch onto the lesion surface on the stabilizing part is distributed unevenly. In this study, the patch-stabilizer was pushed onto the fetal phantom(Oil 200) in translation with the ball screw to estimate the pressure distribution by pressure measurement film(Fig.6). Because that the cutaneous mechanical characteristics of rat fetal tissues are reported [14] to be similar in character of silicone which the oil quantity is 200 g.

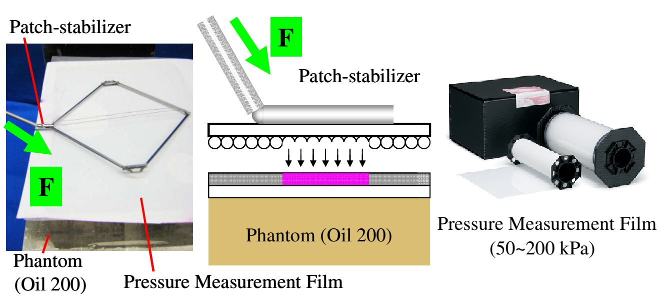

Fig.6 The measurement system of pressure distribution

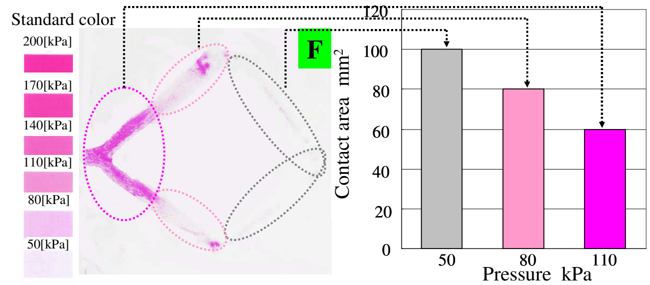

Fig.7 The result of the pressure distribution

Fig.7 showed the relation between contact area and pressure. The pressure is the largest at the ball joint arthrosis, and the pressure weakened further from the ball joint arthrosis. The aim of this study is to control the stabilizing force less than 0.3 kPa as it has been reported from a preliminary research[14] which the fetal tissues will not be damaged under the force of 0.3 kPa. As the result shown in the experiment, if the largest pressure acted on the contact area of 60 mm2 is 0.3 kPa, then the stabilizing force could be controlled under 0.3 kPa on the stabilizing part.

B. Experiment under water

The developed patch-stabilizer is designed to stabilize the collagen patch with a precise stabilizing force using the tension control of driven wires. With the initial study [15], we measured the relation between the stabilizing force and the tension of driven wires. In this paper, the precise stabilizing force was evaluated by the tension control of driven wires using the fetal model under water that is similar to intrauterine environment as shown in Fig.8.

The ball joint moment of distribution load is described with (1), where f_0 is distribution load, L is the length of the contact area, B is the width of the contact area.

$$M_1 = \frac{f_0 L^2 B}{2} \tag{1}$$

The ball joint moment of wires tension is described with (2), where T is tension of driven wires, R is the radius of the ball as moment arm.

$$M_2 = T \times R \tag{2}$$

By combining (1) and (2), the relation between distribution load and tension of driven wires is described with (3).

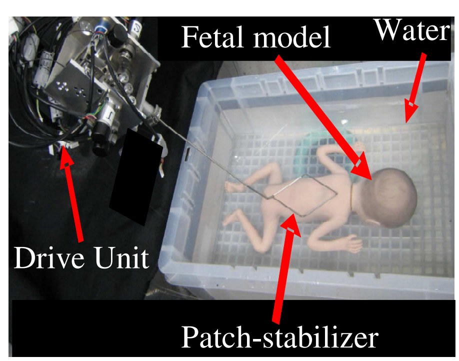

Fig.8 The experimental system(Under-water)

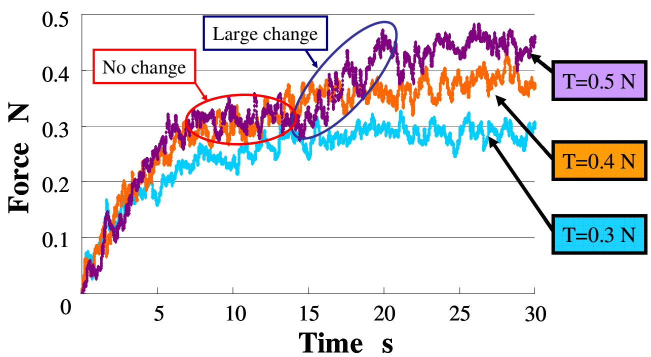

Fig.9 The result of the wires tension(Under-water)

$$T = \frac{f_0 L^2 B}{2R} \tag{3}$$

As the stabilizing force is required to be under 0.3 kPa, the target tension of driven wires is calculated under 0.5 N by using (3) (L , B were showed in Fig.7 with the contact area of the largest pressure).

In this experiment, the tension of driven wires was controlled at 0.3, 0.4, 0.5 N for controlling the stabilizing force under 0.3 kPa. The tension of wires was measured by the tension sensors which were set on the drive unit.

Fig.9 showed the force control of the wires tension. The result showed a change too suddenly at the wires tension of 0.4 and 0.5 N. The reason is that the stabilizing force is so large that the attitude of the fetal model was changed in the water. Therefore, the tension of driven wires was controlled less than 0.3 N, the collagen patch could be stabilized onto the lesion surface without the damages of fetal tissues and the influence by the amnion liquid.

V. Conclusion

In this study, a robotic patch-stabilizer using wire driven mechanism has been developed to hold the collagen patch with a precise stabilizing force. The developed patch-stabilizer could hold a collagen patch with diamond shape mechanism and bend though ± 40 degrees. Additionally, by the tension control of driven wires, the precise stabilizing force was evaluated using the fetal model under water that is similar to intrauterine environment. As a result, the tension of driven wires was controlled less than 0.3 N, the collagen patch could be stabilized onto the lesion surface without the damages of fetal tissues and the influence by the amnion liquid. In further work, the fetal surgery system will be developed and *in.vivo* experiment will be carried out.

References

[1] Danzer E, Sydorak RM, Harrison MR, Albanese CT. , “Minimal access fetal surgery”,Eur J Obstet Gynecol Reprod Biol,2003 May 1, 108(1), pp. 3-13

[2] Kohl T, Hering R, Heep A, Schaller C, Meyer B, Greive C, Bizjak G, Buller T, Van de Vondel P, Gogarten W, Bartmann P, Knopfle G, Gembruch U. ,“Percutaneous fetoscopic patch coverage of spina bifida aperta in the human--early clinical experience and potential”, Fetal Diagn Ther., 2006, 21(2), pp. 185-93

[3] Enosawa S, Tanemoto T, Harada K, Ide A, Tsubouchi K, Fujie M, Takezawa T, Chiba T.,”Vitrified collagen sheet, Vitrigel, a novel biophilic sealant for fetal surgery”,The 25th Annual Meeting of International Fetal Medicine and Surgery Society (IFMSS2006)

[4] Kevin Cleary, Charles Nguyen, “State of the Art in Surgical Robotics: Clinical Applications and Technology Challenges”, Comput Aided Surg. 2001, 6(6), pp. 312-28

[5] O. S. Aaronson, N. B. Tulipan, R. Cywes, H. W. Sundell, G.H. Davis, J. P. Bruner, and W. O. Richards, “Robot-Assisted Endoscopic Intrauterine Myelomeningocele Repair: A Feasibility Study,” Pediatric Neurosurgery, 2002, Vol.36, pp. 85-89

[6] T. Kohl et al., “Percutaneous fetoscopic patch coverage of experimental lumbosacral full-thickness skin lesions in sheep,” Surgical Endoscopy, Vol.17, 2003, pp. 1218-1223

[7] Knight CG, Lorincz A, Johnson A, Gidell K, Rabah R, Klein MD, Langenburg SE,” Robot-enhanced fetoscopic surgery”, J Pediatr Surg. 2004 Oct, 39(10),pp. 1463-5

[8] J. Furusho, T. Katsuragi, T. Kikuchi, T. Suzuki, H. Tanaka, Y. Chiba, H. Horio,“Curved multi-tube systems for fetal blood sampling and treatments of organs like brain and breast”, International Journal of Computer Assisted Radiology and Surgery, Vol.1, Supplement.1, June 2006, pp. 223-226

[9] H. Yamashita, K. Matsumiya, K. Masamune, H. Liao, T. Dohi, T. Chiba, “Two-DOFs bending forceps manipulator of 3.5-mm diameter for intrauterine fetus surgery: feasibility evaluation”, International Journal of Computer Assisted Radiology and Surgery, Vol.1, Supplement.1, June 2006, pp. 218-220

[10] K.Oka,T.Nakamura,K.Harada,Y.Ohkawa,T.Hidaka,T.Chiba,"Develop ment of laser forceps for fetal surgical treatment", Proc. of IFMBE World Congress on Medical Physics and Biomedical Engineering (WC2006), pp. 2976-2979

[11] Anna Eisinberg, Oliver Tonet, PaoroDario, Giovanna Macri, Maria Chiara Carrozza, “Microfabricated instrument for haptic tissue International Conference on Biomedical Robotics and Biomechatronics (BioRob 2006), pp. 1183 - 1188

[12] Fujisaki M, Harada K, Enosawa S, Sasaki K, Azuma T, Takamoto S, Dohi T, Chiba T. ”Creation of an atrial septal defect in beating hearts using high-intensity focused ultrasound(HIFU): Is it useful for minimally invasive fetal cardiac interventions ?”, The 25th Annual Meeting of International Fetal Medicine and Surgery Society (IFMSS2006)

[13] Kanako Harada, Bo Zhang, Shin Enosawa, Toshio Chiba, Masakatsu G.Fujie, “Bending Laser Manipulator for Intrauterine Surgery and Viscoelastic Model of Fetal Rat Tissus”, ICRA2007, pp.611-616

[14] Kanako Harada, “Surgical Robotics for Minimally Invasive Fetal Surgery”, 2007, pp.40-63

[15] B. Zhang, K. Harada, M.Yanagihara , Y. Kobayashi , J. Okamoto , T. Chiba , S. Enozawa Masakatsu G.Fujie, “Development of robotic patch-stabilizer using wire driven mechanism for minimally invasive fetal surgery”, ACCAS2007

[16] Makoto Jinno, Takamitsu Sunaoshi, Toyomi Miyagawa, Takehiro Hato, Nobuto Matsuhira, Yasuhide Morikawa, Soji Ozawa, Masaki Kitajima, “Development of Robotic Forceps for Laparoscopic Surgery”, Journal of Robotics and Mechatronics, Vol.18, No.3, 2006, pp.249-256

[17] Kanako Harada, Kentaro Iwase, Kota Tsubouchi, Kousuke Kishi, Tetsuya Nakamura, Toshio Chiba, Masakatsu G.Fujie, “Micro manipulator and Forceps Navigation for Endoscopic Fetal Surgery”, J of Robotics and Mechatronics, Vol.18, No.3, 2006, pp.257-263

[18] Wataru Makishi,Tadao Matunaga, Yoichi Haga, Masayoshi Esashi, “Active Bending Electric Endoscope Using Shape Memory Alloy Coil Actuators” , Proc. of the 1st IEEE/RAS-EMBS 2006 International conference on Biomedical Robotics and Biomechatronics (Biorob2006), pp.217-219

[19] Koji Ikuta, Daisuke Yajima, Hironobu Ichikawa, Katsuya Suzuki,”Hydrodynamic Active Catheter with Multi Degrees of Freedom Motions”, Proc. of IFMBE World Congress on Medical Physics and Biomedical Engineering (WC2006),pp.2968-2971

[20] Yoriko Iwamori,Jun Okamoto,Masakatu G.Fujie, “Multi-DOF Forceps Manipulator for an Approach to the Dorsal Aspect of an Organ”, Proc. of IFMBE World Congress on Medical Physics and Biomedical Engineering (WC2006), pp. 4022-2026