Development of robotic patch-stabilizer using wire driven mechanism for minimally invasive fetal surgery

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Abstract: The clinical target of this study is intrauterine patch coverage of fetal myelomeningocele. The collagen patch is supposed to be stabilized onto the fragile fetal tissue during the laser fixation process. This paper shows the development of robotic patch-stabilizer using wire driven mechanism (2 D.O.F, Max bending angle is 45[deg]). The diameter of the stabilizer's shaft is 2.4[mm] and the length of the stabilizing part is 60[mm]. The stabilizer is driven by the wire and the tension of wires is measured by the drive unit outside of the body to estimate the force on the tip. The force on the tip was estimated by the wire tension with 3.5 % error between the estimated value and the measured value. In addition, the design of new drive unit realizing the precise motion is shown in this paper.

Introduction

In recent years,.the fetal disorders have been discovered extremely early by the progress of therapeutic apparatus such as an ultrasound and MRI diagnosis apparatus. After that, a minimally invasive fetal surgery has been used to treat some disorders in recent years. The tools are required to insert into the uterine wall from the small incision in this kind of surgery. The virtual applications and the results of the surgery have been shown [1].

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

The fetal patch surgery system

For the fetal patch surgery, we propose the system, which is shown in Fig. 1. The endoscope, the stabilizer and the laser manipulator are inserted into uterus. The patch is pressed by the robotic patch-stabilizer on the surface of the lesion that cropped out into liquor amnii. Then, the patch protecting lesion temporarily is fixed in fetal cutis by the laser manipulator.

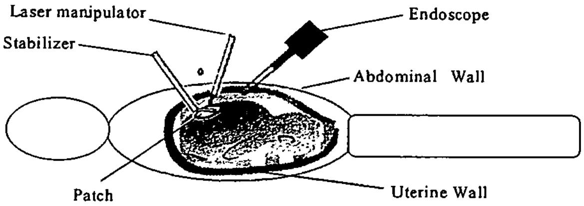

Fig.1 Patch Surgery System

This study is aimed to the development of a stabilizer, which holds a collagen patch with appropriate stabilizing force. The technical problem is the method of controlling the force of a stabilizing patch onto the fragile fetal skin.

After the previous descriptions, the stabilizer is required to estimate the force on the tip part. However, the direct measurement on the tip part is very difficult as it is not preferable to use a sensor in the body for security reasons. As a solution, the stabilizer is driven by the wire and the tension of wires is measured by the drive unit outside of the body to estimate the force on the tip.

This paper shows the development a prototype of the stabilizer which has been developed into two degree of freedom from the required specifications. The relation of the force sensor and the wire which we installed in the tip has been measured in the static state and inspected the precision.

The Specification of Stabilizer

The specifications of the robotic patch-stabilizer could be conclude 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] , because that the amniotic cavity breakdown raises the danger of abortion. (2) The length 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 that is needed, because of the limited movement space taken by the placenta. (4)The precise force control stabilized the patch, which is required in order to avoid any damages on fetal tissue.

Mechanism of the patch-stabilizer

Figure.2 shows the developed robotic patch-stabilizer.

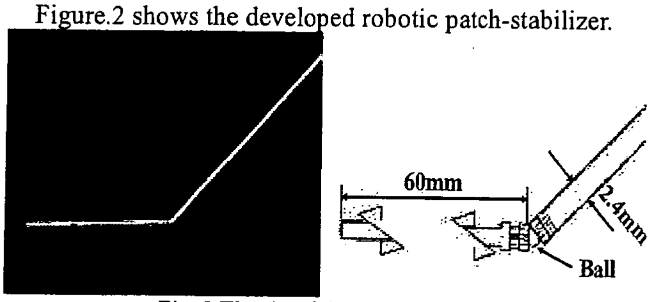

Fig. 2 The tip of the Patch-stabilizer

The developed patch-stabilizer uses a wire driven mechanism that achieves two bending degrees of freedom with the use of one ball joint-shaped arthrosis. The same mechanism introduced in [1] is used for joint part.

As shaft diameter required, which is to be inserted into the trocar for the fetal, the diameter of the stabilizer's shaft is 2.4[mm], the maximum width is 2.4[mm], and the thickness is 1.5[mm]. The length of the stabilizing part has been designed as 60[mm], because that the diameter of the lesion is 40[mm]～60[mm].

The force sensing

The aim of this study is to control the force sensing of less than 500[Pa] because it has been reported from a preliminary research[2] that the fetal cutis will not be damaged under the force of 500[Pa]. In this paper, the accuracy of estimated force has been confirmed by using one degree of freedom.

The distributed force is loaded on stabilizer in clinical application. Therefore, the stabilizing force should be evaluated by the pressure. However, as a first approximation, a piece of concentration load was measured in a static state in this paper.

Fig.3 shows the experiment installation of the force sensing experiment. A force sensor was set the tip to measure the stabilizing force. The force of around 2-20% for 500[Pa] of preliminary research [2] inspected by this experiment was measured with seven times. Therefore the relation of force that was obtained between the force senor and tension sensor, and also the accuracy of estimated force has been measured.

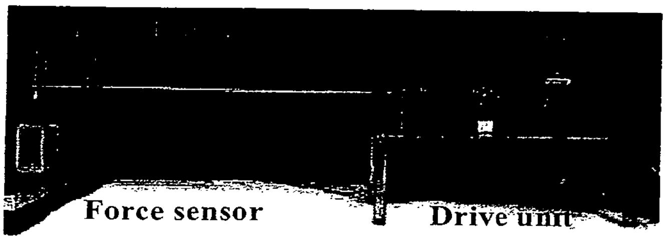

Fig. 3 The experimental overview of Stabilizer prototype

Figure.4 shows the results of experiment. The certain relation has been shown between the obtained force through the sensor, which contacted at the tip of stabilized part and the measured force from the tension's sensor. An error is occurred at 33.2% when the value of a wire's tension is small, and an error decreases into 3.5% when tension of a wire increases. The interference between wires is considered as an error.

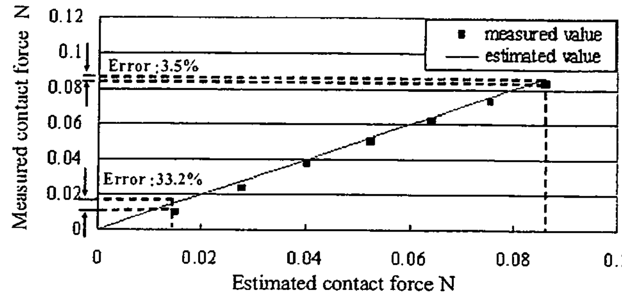

Fig.4 The relation between force calculated from the tension sensor (X axis) and force measured from force sensor (Y axis).

In addition, influence of a noise of a sensor is large when the measured tension value is small.

New drive unit

In order to control the force of pressing the patch more precisely, a new drive unit is currently developed, which is designed with the length of 85mm, the width of 70.4mm and the height of 50mm. In the new drive unit, the precise movement will be realized. This is because that two AC motors with large reduction ratio is used to control stabilizer. *in.vivo* experiment will be carried out using the new drive unit.

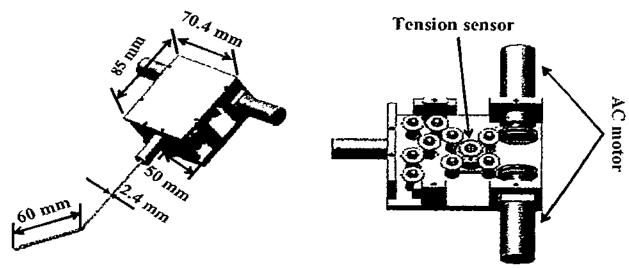

Fig.5 The new Drive Unit

Conclusion

In this paper, a robotic patch-stabilizer using wire driven mechanism has been developed to hold the patch with the precise stabilizing force. Additionally, using the developed stabilizer, the accuracy of estimated force has been confirmed by using one degree of freedom. The designed new drive unit is introduced. In further work, the new drive unit will be developed and *in. vivo* experiment will be carried out.

Acknowledgement

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Sound Navigation System for Collision Avoidance Using 3D Ultrasound Imaging in Endoscopic Fetal Surgery

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Introduction

The major hindrances in establishing a safer endoscopic fetal surgery are the limited surgical field and view and the fact that placenta is an extremely soft and weak tissue. For example, endoscopic laser coagulation of placental vessels for twin-twin transfusion syndrome (TTTS) requires a highly advanced technique and surgical experience in order to avoid collision with the placenta and other surrounding weak tissues. We have developed a new navigation system using 3D ultrasound images to avoid damage to placenta etc. This system informs the surgeons about the distance between the endoscope and the placenta by producing an alarm sound. (Fig.1)

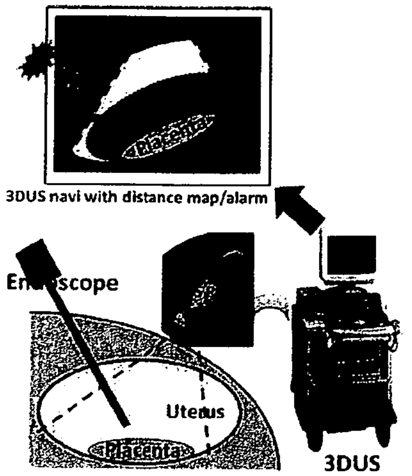
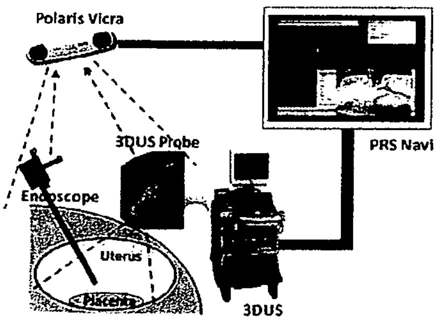


Fig.1 Concept of sound navigation system for collision avoidance. A colored distance map is generated for the region around the placenta, and this system informs the surgeon about collision risk by using this map and an alarm sound.

Methods

Configuration of the 3D ultrasound navigation system and registration

This system comprises 3D ultrasonography system (3DUS; Prosound™ α10; Aloka Co., Ltd) and a navigation system (PRS Navi, TWMU; Toshiba Medical Systems, Infocom). In the navigation system, the location of surgical instruments such as an endoscope is measured using an optical tracker (Polaris Vicra™, NDI) and displayed on 3D ultrasound images after registration between the optical tracker field and the images field. (Fig.2)



We constructed a calibration jig for registration between the locations of surgical instruments (optical tracker field) and the image. The locations of the tip of 4 steel balls were used for registration between the 3DUS probe location and image. The location of the endoscope was displayed on the 3DUS images by using the registration information and the location data of the endoscope and 3DUS probe measured by Polaris Vicra. (Fig.3)

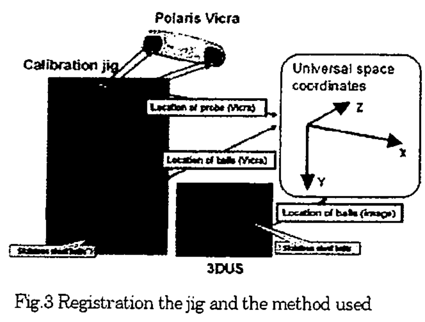
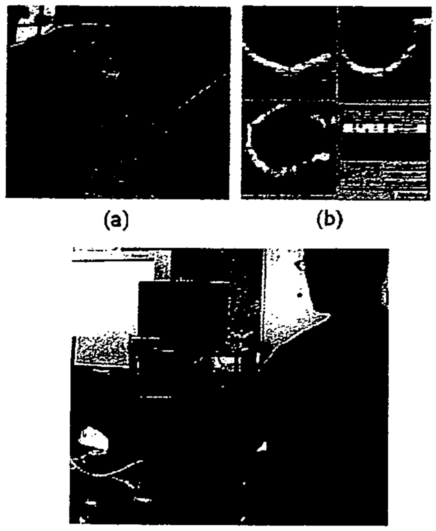


Fig.3 Registration the jig and the method used

Generation of a distance map for collision avoidance alarm

To generate a quantitative map denoting the distance between the placenta and endoscope, a 3D model of uterus was defined in order to decide the border between the tissues and amniotic fluid. The 3D amniotic fluid region was automatically divided into several regions by using the information about the distance between the contour of the placenta and the tip of the endoscope. However, during treatment, surgeons have to concentrate their attention on the endoscopic view. Therefore, the information displayed on the 3DUS navigation screen cannot be noted continuously by the surgeon. Hence, we employed sounds that vary with the distance to inform surgeons about the distance.



(a) (b)

(c)

Fig.4 Phantom Experiment. (a): Uterus phantom (silicon rubber phantom and water tank). (b): Distance map generated from the 3DUS phantom data. The red region is closer to and the green region is away from the endoscope. (c): Overview of the experiment. The surgeon saw only through the endoscope and was aware of the distance information by means of the alarm sound.

Results

We attempted basic experiments using the placenta phantom and the sound navigation system. A silicon rubber phantom (placenta phantom) was placed in a water tank (uterus phantom). Surgeons were instructed to follow a red line on the placenta phantom by viewing through the endoscope with/without the support of the sound navigation system. The distance map was set to 4 regions based on the distance of the endoscope from the placenta phantom surface: for regions 1 to 4, this distance was 0~5, 5~10, 10~20, and >20 mm, respectively. Surgeons could realize the distance between the placenta phantom surface and the tip of the endoscope quantitatively and intuitively when using the sound navigation system.

Conclusion

We have thus developed a surgical navigation system for collision avoidance to be applied for weak organs. The 3DUS system, distance map generator, and sound alarming module can provide quantitative and intuitive information regarding the damage risk to the surgeon. This system can help improve the surgical safety of endoscopic fetal surgery.

Acknowledgement

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Image mapping system of placenta using endoscopic image mosaics for intra-uterine Twin-to-Twin Transfusion Syndrome (TTTS) treatment

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Introduction

Twin-to-Twin Transfusion Syndrome (TTTS) is a disease of the placenta that affects identical twins who share a single placenta. The syndrome occurred in the vascular communications between the fetuses in a monochorionic gestation. This serious condition occurs when the shared placenta contains abnormal blood vessels which connect the twins, resulting in an imbalanced flow of one twin to another. Nowadays, several types of technique including amniotic septostomy, amnio reduction and laser photocoagulation are developed for the syndrome's treatment. Laser photocoagulation is one of useful method, which gives a good survival and a low complication rate to the twins. In this method, a laser fiber and an endoscope are inserted into the uterus. With the guidance of ultrasound and direct video, specific vessels that cause the blood-sharing problem are coagulated using a laser fiber to stop the imbalanced flow of blood between the twins. Thus precision laser treatment requires the accurate position information of the vessels.

In current laser photocoagulation treatment, the connecting vessels are identified by visual measurement based on endoscope image. However, the narrow viewing area of endoscope makes the surgeon difficult to grasp the whole picture of placenta and decide whether the blood vessels that being observed is one of the connecting vessels or not. As a result, the surgical success relies on the surgeon's ability in memorizing the blood vasculatory system on the placenta surface, leaving a risk of missing some connecting vessels.

System and Method

To improve the safety and accuracy of laser photocoagulation treatment for TTTS, we have been developing an image mapping system for mapping the endoscope image to a 3D model of the placenta. This system will provide the overall image of placenta and enable the surgeon to perform identification of the connecting vessels.

Our system consists of an endoscope, an ultrasound device, a 3D position tracking system and a computer. The endoscope is used to capture images of placenta surface, and the ultrasound is used to obtain the whole information of the placenta (Fig.1). We use the 3D position tracking system to obtain the position and orientation of the endoscope and the probe of ultrasound. These position and orientation of the probe will be used in estimating the position and orientation of placenta. The computer is used to integrate the position information, the captured image of the endoscope, and the 3D ultrasound data of the placenta. The images of placenta surface are captured by endoscope and the 3D model of placenta is created by the reconstruction of ultrasound image. The captured endoscope

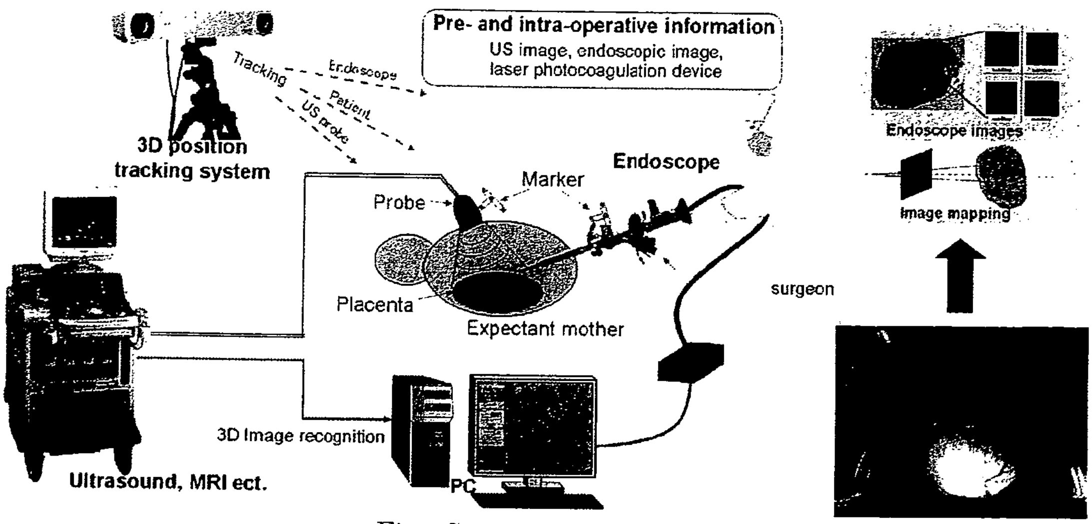

Fig. 1 System configuration.

images are projected on the 3D ultrasound model and the combined results of the placenta is displayed in three-dimensionally.

Since the fish-eye lens of the endoscope camera make a barrel type spatial distortion, compensation for the distortion of the image is required in the image mapping to enable accurate measurement and registration. The image correction is performed only to the image area of a circle shape. Active contour method is used to extract the image. We calculate the corresponding positions of points on image data and placenta model to map the images onto the placenta. After obtaining the corresponding positions, we map the images onto the placenta model and display the results in three-dimension. The endoscope is assumed as a pinhole camera model. Each pixel on the images data are mapped onto the triangle patches through the focal point of the endoscope.

Experiment and results

We used a placenta model with red and blue vessels simulated to vein and artery, as the object in performing experiment to test our placenta mapping system. The placenta model was inserted into a container which illustrated the uterus. We modeled the placenta surface using 3D-Slicer from ultrasound image data, and converted the surface configuration to triangle patches using VTK. Furthermore, we mapped the corrected endoscope images to the surface model. The result of mapped images in three-dimensional image was generated using OpenGL. From these results, we found that this mapping system will be effective enough in providing a large-scale image of the placenta and enabling a surgeon to get the information in convenient way.

Experimental results show that the system could provide the overall image of placenta and give a promising support to surgeon for performing identification of connecting vessels and executing the laser photocoagulation treatment. The image mapping system can provide three-dimensional large-scale image of placenta surface, which enables surgeon to observe the vessels of the twins without any need of memorizing. Our future works include improving the accuracy of the image mapping to smoothen the mapped image results. Furthermore, we are going to improve the speed of the image mapping and test the system in an in vivo experiment.

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第7回日本VR医学会学術大会
プログラム・抄録集

「VR医学のHapticsへの展開」

会　期：平成19年9月1日（土）
（8月31日（金）夜に、懇親会並びに学術展示・企業展示を開催）

会　場：慶應義塾大学三田キャンパス　北館ホール

大会長：森川　康英　（慶應義塾大学医学部小児外科）

双胎間輸血症候群の子宮内治療における胎盤表面のマッピングシステムの開発

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双胎間輸血症候群は，一卵性双胎に起こる疾病であり，双胎児の胎盤血管が吻合することにより双子の間で血液の不均衡が生じることで発症する．現在，この疾患に対する低侵襲な治療法の一つとしてレーザ焼灼療法が注目されている．この治療法では，医師が内視鏡で胎盤表面をたどり，目視で吻合血管の同定を行う．吻合血管と判断された部位は，レーザで焼灼して不均衡な血流を遮断させる．ここで，内視鏡の視野は狭く，吻合血管の同定に必要とする全体的な胎盤上の血管系を把握するには，医師の記憶に頼らざるを得ない．これでは，医師の負担も大きく，吻合血管を見落とす可能性を無視できない．そこで我々は，双胎間輸血症候群の治療法であるレーザ焼灼術の効率・安全性を向上させるために，内視鏡画像を胎盤モデルにマッピングする，胎盤表面マッピングシステムを開発してきた．このシステムにより，胎盤の全体像が把握でき，医師の吻合血管同定が容易になる．本システムは，内視鏡，超音波診断装置，光学式三次元位置計測装置とコンピュータから成る（図１）．胎盤表面画像は内視鏡で取得する．超音波診断装置で術中の胎盤の三次元形状を取得する．光学式三次元位置計測装置では内視鏡及び超音波プローブの位置・姿勢を得られる．この位置データがあれば，超音波で取得した胎盤モデルの位置と姿勢が求められる．得られた全てのデータはコンピュータに転送し処理する．コンピュータではまず内視鏡画像の歪みを補正し，マッピング可能な画像にする．続いて画像から内視鏡視野の円形領域を抽出する．これには active contour 法を用いる．

マッピングを行うためには，まず三角形状のパッチで構成された胎盤のサーフェスモデルが必要である．今回の実験では，胎盤モデルを得るのに，超音波診断装置の代わりにMRIを用いた．内視鏡はピンホールカメラモデルであると仮定して，画像上の全ての点に対応する胎盤モデル上の点を求め，マッピングを行い，結果を三次元で表示した．結果を図２に示す．本マッピングシステムにより，大規模な胎盤表面画像を十分効果的に提示でき，医師にとっても簡単に情報が得やすい画像を表示することが可能であった．今後は，精度の良い内視鏡の使用，照明むらの補正等によりマッピング画像の質を改善し，更には，マッピングの精度，速度を向上させ in vivo の実験を行う予定である．

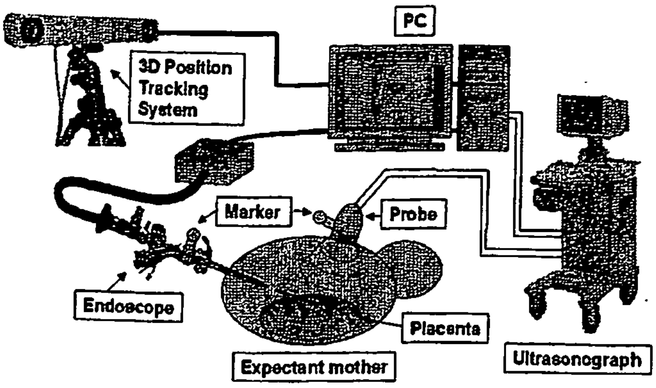

図 1．胎盤マッピングシステムの構成

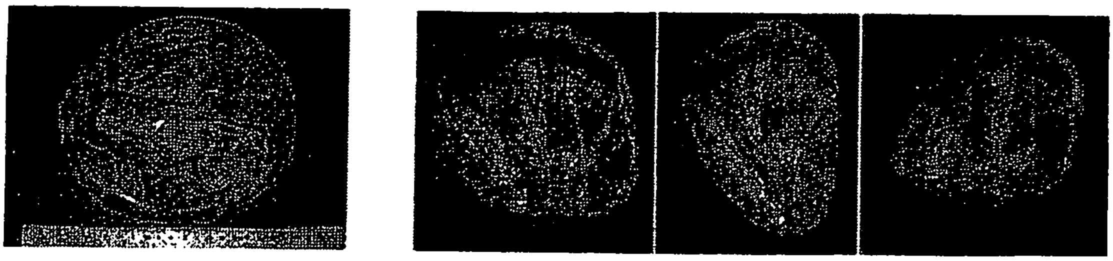

図 2．胎盤モデル(a)とマッピングの結果(b)

第３回３次元超音波研究会
抄 録 集

２００７年９月２９日（土）

会場：国立成育医療センター　１Ｆ講堂

主催：３次元超音波研究会

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双胎間輸血症候群の治療における３次元超音波画像を用いた胎盤表面のマッピングシステムの開発

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双胎間輸血症候群(TTTS)は、一卵性双胎で、双胎児の胎盤血管が吻合し双胎間で血液の不均衡が生じる疾病である。この治療法の一つにレーザ焼灼療法がある。
この方法は、医師が内視鏡で胎盤表面を辿り、目視で吻合血管の同定を行い、レーザで焼灼し血流を遮断する。一方、内視鏡の視野は狭く、吻合血管の同定に必要な胎盤上の全体的な血管系を把握するのは難しい。そこで我々は、３次元超音波診断装置を用いた胎盤表面マッピングシステムを開発した。このシステムにより胎盤の全体像が把握でき、医師の吻合血管同定が容易になる。本システムは、内視鏡、超音波診断装置、光学式三次元位置計測装置とコンピュータから成る。内視鏡及び超音波プローブの位置・姿勢を光学式三次元位置計測装置で計測する。術中の胎盤の三次元形状は３次元超音波で取得する。超音波プローブの位置情報から、超音波で取得した胎盤形状モデルの位置と姿勢が求まる。続いて胎盤表面画像を内視鏡で撮影する。内視鏡画像は歪み等を補正し、胎盤モデルにマッピングする。
胎盤ファントムを用いてマッピングを行ったところ、このシステムにより、大規模な胎盤表面画像を十分効果的に提示でき、医師が簡単に情報を得やすい画像を表示できた。同時に、寒天で作ったファントムでマッピング位置の精度を評価したところ、平均7.5㎜の誤差を認めた。今後、マッピング画像の質の改善、及び精度の向上を検討する必要がある。

内視鏡下胎児外科手術における３次元超音波画像を用いた組織近接覚提示法

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はじめに：内視鏡下での胎児外科手術を実現するための術式安全性向上には、狭視野・脆弱な奥行感覚に起因する不意の術具接触による胎盤等子宮内組織損傷を避けるための支援システムが重要である。本報では、３次元超音波画像情報を元に、術具の子宮内組織への接近度合(近接覚)を提示する技術について報告する。
方法：近接覚提示システムは３次元超音波画像診断装置(prosound α10, ALOKA)と手術ナビゲーションシステム(東京女子医大・東芝・Infocom)により構成される。術中に取得した３次元超音波画像から羊水領域を抽出し、この領域を胎盤表面からの距離により細分化した距離マップを作成し、ナビゲーション画面上にカラーマップ重畳表示することで直感的な胎盤からの距離確認を可能にした。さらに、術中に医師は内視鏡画面に注視し距離を継続的にナビゲーション画面で確認することは不可能であるので、距離マップの各エリアに応じた警告音を発することで胎盤までの距離を音声で認識可能にした。
結果：シリコンゴムファントムを胎盤に見立て水槽内に設置し、ファントム上に描かれたラインを内視鏡で追尾するタスクを、ナビゲーション併用と非併用の条件で行った。ナビゲーション併用時、医師は内視鏡画面を注視しながらファントムまでの距離を音により定量的に理解することが可能だった。

第5回

日本胎児治療学会

会期

2007年10月19日（金）20日（土）

会場

大阪国際会議場

大阪市北区中之島5-3-51

会長

窪田昭男

大阪府立母子保健総合医療センター
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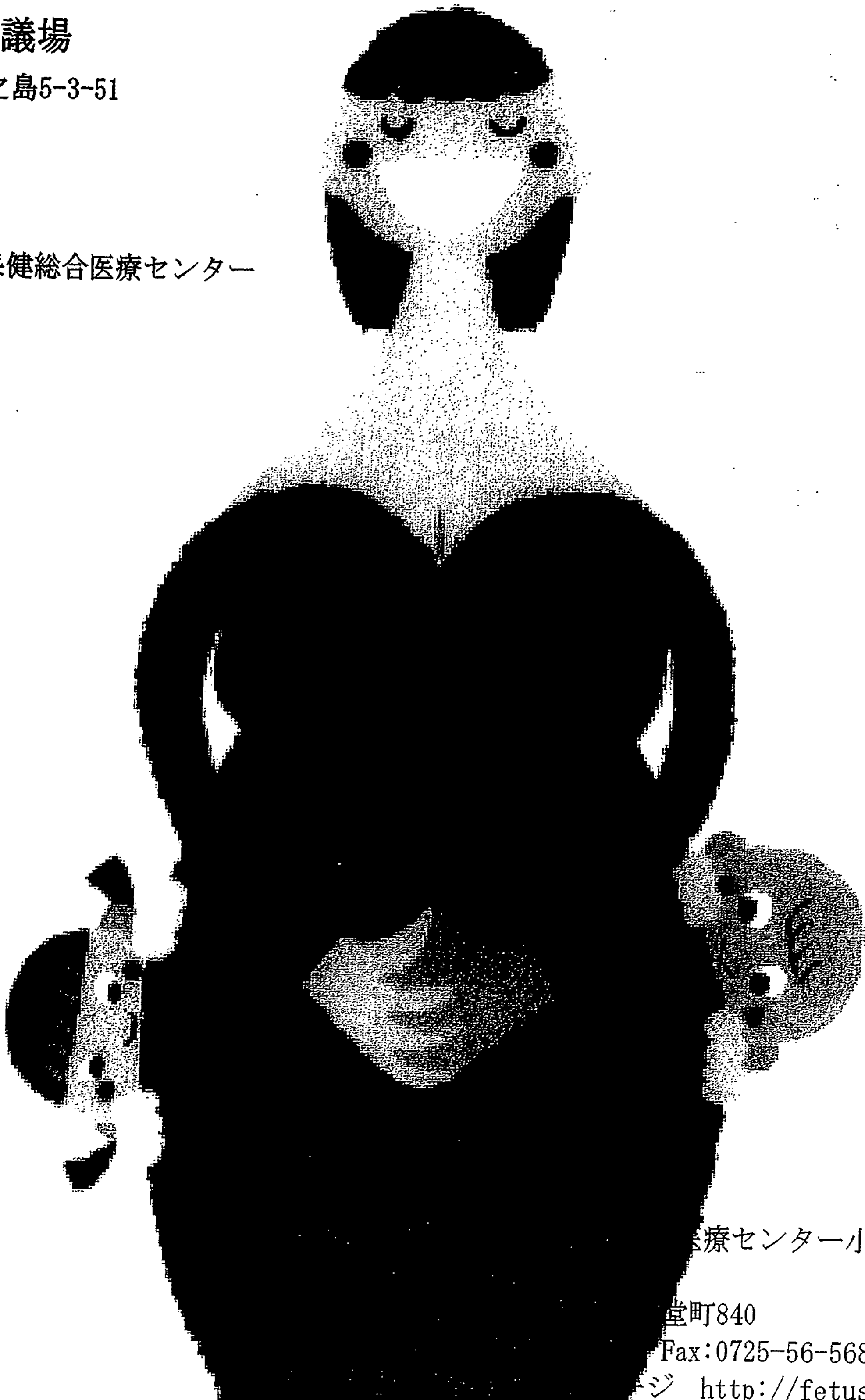

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セッションⅡ　新技術

6. TTTSに対するFLPCのためのレーザー内視鏡の高機能化

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【背景】双胎間輸血症候群(TTTS)に対し、我々は胎盤付着位置にかかわらず、低侵襲で安全・確実な胎児鏡下胎盤吻合血管レーザー凝固術(FLPC)を可能とするため、胎児外科治療用レーザー内視鏡装置（複合型光ファイバスコープ）の開発を行っている。
【目的】本件では、これまでに製作した複合型光ファイバスコープシステムに、1)対象までの距離計測機能、2)標的血管の血流計測機能を付加する方法について検討し、in vivo実験にてその有効性を確認した。
【方法】リアルタイムの距離計測及び血流計測を行うため、半導体レーザー光による非観血式のレーザー微小循環血流計測方法を原理とする市販の血流計測装置を本システムへ組み込んだ。これにより、組織血流量，組織血液量，血流速度，全受光量の計測を可能とした。また、この受光量値を用いることで対象までの距離を計測した。
【結果】in vivoにて豚の腸間膜を36℃近傍の水中に浸し、腸間膜の血管に30Wのレーザー光を3秒間照射した。その結果、レーザー照射中に画像観察を行いながらリアルタイムに焼灼度を調節することが可能であった。本試験後、焼灼した血管をマイクロスコープで観察し、レーザー焼灼により血管径が約1mmから0.28mm（1/3以下)に収縮し、血流の停止していることを確認した。また、焼灼部位の血管近位側において、収縮後の血管内に血液が溜まり、約3倍の太さの約0.94mmにまで膨張することも明らかとなった。一方、レーザー焼灼とは別の波長のレーザー光を照射・受光することにより、5～20mmの範囲で腸間膜までの距離計測がリアルタイムに可能となることを確認した。さらに、血流の減少及び停滞の様子も定量的に把握できた。以上より、複合型光ファイバスコープシステムの応用により、①画像観察、②距離計測、③血流計測、④レーザー照射をシームレスに行い、安定した治療が可能になると期待される。

セッションⅡ　新技術

7. 双胎間輸血症候群における胎盤損傷を回避するための接近警報提示ナビゲーションシステム

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はじめに：双胎間輸血症候群のレーザ治療においては、狭く奥行感覚の薄い内視鏡視野の中で、胎盤損傷や出血を回避するために胎盤への手術器具の接触を防止することが要求される。本研究では、子宮内での術具位置に応じて接近危険度を術者に提示し、胎盤損傷回避をサポートするための新しいナビゲーションシステムの開発を行った。
方法：本システムは3次元超音波画像診断装置(prosound α10, ALOKA)と手術ナビゲーションシステム(東京女子医大・東芝・Infocom)により構成される。手術ナビゲーションシステムは光学式3次元位置計測装置(PolarisVicra、NDI)により実空間の術具位置を計測し、画像と実空間での術具の位置の統合を行い画像上に術具位置を表示する。術具先端から胎盤までの距離を定量的かつ直感的に提示するために、術中に取得した3次元超音波画像から羊水領域を抽出し、この領域を胎盤表面からの距離により細分化した距離マップを作成し、ナビゲーション画面上にカラーマップ重畳表示することで直感的な胎盤からの距離確認を可能にした。さらに、術中に医師は内視鏡画面に注視し距離を継続的にナビゲーション画面で確認することは不可能であるので、距離マップの各エリアに応じた警告音を発することで胎盤までの距離を音声で認識可能にした。
結果：シリコンゴムファントムを胎盤に見立て水槽内に設置し、ファントム上に描かれたラインを内視鏡で追尾するタスクを、ナビゲーション併用と非併用の条件で行った。ナビゲーション併用時、医師は内視鏡画面を注視しながらファントムまでの距離を音により定量的に理解することが可能だった。
結論：手術機器と脆弱な胎盤との接触を回避し、安全な内視鏡下胎盤レーザ手術の実現を支援するナビゲーションシステムを開発した。ファントム実験では良好な距離認識補助能力を有していることが示唆された。

低侵襲胎児手術を目的としたパッチスタビライザに関する基礎研究
～ワイヤ駆動による試作機とパッチを押さえる力制御の提案～
Basic research on a robotic patch-stabilizer for minimally invasive fetal surgery
～Experimental force control of a prototype using wire driven mechanism～

○ 張 博（早大） 原田 香奈子（早大） 柳原 勝（早大） 岡本 淳（早大）
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The clinical target of this study is intrauterine patch coverage of fetal myelomeningocele. The collagen patch is supposed to be stabilized onto the fragile fetal tissue during the laser fixation process. In this paper, a robotic patch stabilizer using wire driven mechanism(2 D.O.F, Max bending angle is 45[deg]) has been developed for precise force control on the patch without damaging fetal tissue. The diameter of the stabilizer's shaft is 2.4[mm] and the length of the stabilizing part is 60[mm].The driving wires are moved using an ultrasonic motor while the tension of the wires is measured using a force sensor. The stabilizing force was estimated by the wire tension with 3.5 % error between the estimated value and the measured value. The future work is to control the stabilizing force using a phantom of fetal fragility.

Key word: Minimally invasive surgery, Wire driven robot, Fetal surgery

1．緒言

近年，超音波やMRI診断機器と内視鏡などの治療機器の進歩により，極めて早期に胎児異常が発見されるようになった。そのうちいくつかの疾患に対しては，子宮壁にあけた小さな切開部から術具を挿入して外科治療を行う低侵襲胎児手術が行われ，効果が示されている[1].

本研究にて対象としている脊髄髄膜瘤では，胎児の背骨と脊柱管の形成不全により神経が露出しており，生後の脳や下半身の障害の原因となる．治療方法としては，出産までの間，患部を一時的に保護ために，パッチ（患部を保護するシート）を貼付する手術方法がある．脆弱でゼラチン状の胎児組織に、適切な力でパッチを押えつけ，レーザ等で固定化する手術システムが構想されている[2].

本研究は，微弱な力制御を行い，パッチを押さえるワイヤ駆動方式のスタビライザの開発を目的としている．技術的課題は，脆弱な胎児皮膚上にパッチを押さえる力の設定や制御法である．体内でセンサを使用することは安全上好ましくないため、先端部の力を直接測定はできない．そこで，体外に置かれる駆動用ワイヤの張力を測定することにより，先端部が胎児を押さえる力を推定できるスタビライザの開発を行った．

まず要求仕様から２自由度の試作機を製作し、そのうち１自由度について評価を行った．次に，先端部に設置した力センサとワイヤの張力の関係を静的な状態で測定し，その精度を検証した．

2. スタビライザの要求仕様

(1) 羊膜の損傷が早産の危険性を高めるため，胎児用の直径3[mm]のトロカールに挿入可能であること，つまりシャフト径が直径2.4[mm]

(2) 手術対象とした妊娠20～25週の胎児における脊髄髄膜瘤の患部（直径40[mm]~60[mm]）を押さえることを可能とするため，先端の長さは60[mm]以上

(3) 胎盤の位置によりスタビライザ挿入ポートが限定されるため，胎児にアプローチ可能な自由度を有すること

(4) 羊水中に浮遊する胎児を動かさず，かつ胎児皮膚を損傷しない力でパッチを押さえる制御

3. スタビライザの機構

試作したスタビライザを図１，図２に示す．

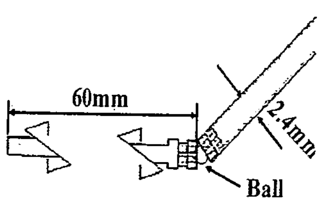

Fig. 1 The tip of the Stabilizer

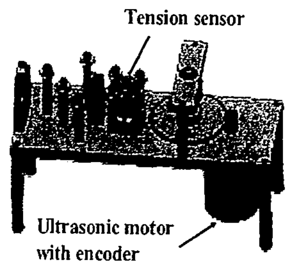

Fig.2 Drive Unit

試作したスタビライザは，プーリを用いたワイヤ駆動方式を選択し，ボールジョイント型の１関節を設けることで，屈曲２自由度を実現できる．先端でパッチを押さえる力を推定するため，１自由度について評価を行った．直径3[mm]の胎児用トロカールに収まるように，スタビライザのシャフトの直径を2.4[mm]，胎児と接触するスタビライザ先端部は最大幅2.4[mm]，厚さ1.5[mm]とした．患部直径は約40-60[mm]と考えられるため，スタビライザ先端の長さは60[mm]に設計した．また，先行研究[3]より，500[Pa]以下の力で押さえつけるならば，胎児皮膚を損傷しないことが報告されているので，

本研究では，500[Pa]以下の力をセンシングすることを目標とした．

4. 力の推定評価実験

4.1 評価方法

パッチを押さえる力の評価は圧力にて行うべきであるが，本論文では初期検討として，一点に集中荷重させた先端の力と張力センサの値を比較する．先端部を図 3 に示すように，機構をモデル化する．先端の押す力を f とし，ワイヤ張力を T とすると，

押す力によるモーメント M_1 は，l を押す力のモーメントアームとすると，

$$M_1 = f \times l \qquad (4.1)$$

と表される．

また，ワイヤのモーメントアームを R とすると，ワイヤの張力による発生するモーメント M_2 は，

$$M_2 = T \times R \qquad (4.2)$$

となる．

したがって，式(4.1)および式(4.2)より，モーメントの釣り合いを考えると，押す力 f と T の関係は摩擦などの外乱を考慮しない理想状態において，次式のように与えられる．

$$f = \frac{R}{l} \cdot T \qquad (4.3)$$

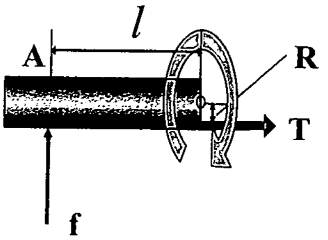

Fig.3 Stabilizer joint model

先端部の点 A において力センサを設置し，ワイヤを一定距離引っ張ったときの張力の値を(4.3)式に代入して算出した先端の力と，力センサで実測した力の比較を行う．これにより張力センサから推定した先端の力の精度を評価する．

4.2 計測実験

計測実験は図 4 に示すような環境で行った．

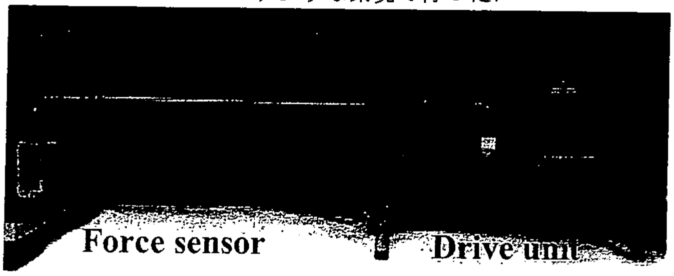

Fig. 4 The experimental overview of Stabilizer prototype

本実験では，マニピュレータ先端部で患部を押さえると想定し，押す力のモーメントアーム l=50[mm]におけるスタビライザ先端押す力とワイヤ張力の関係を測定した．（本試作機において R は 0.9 [mm]である．）本実験で検証する範囲としては，先行研究の 500[Pa]に対して，2～20%程度の力とし，7 回に分けて測定を行った．

実験結果を図 5 に示す．先端に置いた力センサで測定した値と，張力センサの値を理論計算に代入して得られた値はほぼ一定の比列関係になった．ワイヤの張力が小さい範囲では，理論値に対して誤差が 33.2%であったが，ワイヤの張力が徐々に大きくなると，誤差が 3.5%に収まることがわかった．誤差の原因としては，ワイヤ同士の干渉が考えられる．また，値が小さいほどセンサのノイズの影響が大きいためのと考えられる．これにより，小さい力ほど，精度が悪くなることが分かった．この精度が許容範囲か否かは，ファントム等を用いて今後検討を行っていく予定である．

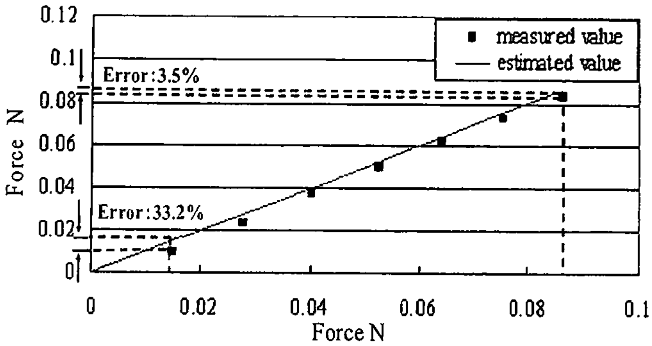

Fig.5 The relation between force calculated from the tension sensor (X axis) and force measured from force sensor.

5. 結言

本研究では，脊髄髄膜瘤の治療において羊水中に露出した神経組織をふさぐことを目的としたワイヤ駆動式スタビライザの試作を行った．パッチを胎児の皮膚に固定する力のセンシングが難しいことから，先端の力を駆動部で推定できるように張力センサを設置した駆動部を試作した．試作したスタビライザを用いて，微小な力を駆動部からセンシングできることがわかった．

今後は，胎児のファントムを製作し，実際にパッチが押さえられるかの検証実験を行う予定である．

6. 謝辞

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Bending Laser Manipulator for Intrauterine Surgery and Viscoelastic Model of Fetal Rat Tissue

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***Abstract*— A bending laser manipulator of 2.4 mm in diameter has been developed for intrauterine fetal surgery. This manipulator deflects a laser fiber in any direction thorough 90 degrees. The results of a positioning test and *in vitro / in vivo* tests are reported. Meanwhile, creep tests for fetal rat tissue of 16 to 20 days in gestation were performed to evaluate fetal tissue fragility. Unique features of fetal rat tissue compared to other soft organs are discussed and a viscoelastic model of the fetal rat tissue was proposed. The result of the modeling will be used not only for fabricating fetal tissue phantom but also for the force control of robotic application for fetal surgery.**

I. Introduction

Recent progresses in prenatal diagnosis have enabled accurate identification of fetus with treatable congenital malformation. Fetal intervention has been developed over 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 occasionally causes critical problems; preterm labor or premature rupture of the chorioamniotic membrane. Meanwhile, minimal access fetal surgery has been introduced in the hope that less invasive surgery will result in better therapeutic outcomes with shorter hospital stay and smaller expenses [1].

Minimal access fetal surgery now achieves better therapeutic results, however, the access to the surgical target in the uterus using the conventional rigid tools through both abdominal and uterine walls is difficult for surgeons. Besides, the technical difficulty for handling a fetus of fragile tissue in amniotic fluid prevents further expansion of minimal access fetal surgery. For these reasons, robotic fetal surgery is expected to overcome the technical difficulties and provide safer operative techniques.

In this paper, a bending laser manipulator of 2.4mm in diameter has been developed to deflect a laser fiber freely *in utero*. The results of its positioning test and *in vitro /in vivo* tests are reported. For handling fragile fetal tissue with robotic tools, the fetal tissue fragility was evaluated as a first step. Shear creep tests for fetal rat tissue at 16 to 20 days gestation were performed to measure its properties. Other soft organs (brain, lung and liver of an adult rat) were also tested in the same condition to illustrate the unique features of fetal tissues. Finally, the prototype of a robotic patch stabilizer and future works are discussed.

II. Fetal Surgery

A. Clinical Targets

Our target surgical procedures are laser photocoagulation of placental vessels in twin-twin transfusion syndrome (TTTS) [2] and intrauterine repair of fetal myelomeningocele (MMC) [3]. TTTS is seen in 10 to 15 % of monochorionic diamniotic twin pregnancies (single placenta and two amniotic sacs). In TTTS, one twin (donor) and the other (recipient) have imbalanced blood flow through anastomotic vessels in the shared placenta. The donor is accompanied by significantly less blood supply resulting in definitely decreased amniotic fluid, whereas the recipient with much increased blood flow presents with a large amniotic fluid volume. Without any prenatal treatment, both twins are likely to die or have irreversible brain damages. Currently, intrauterine laser photocoagulation of placental anastomotic vessels has been performed to interrupt responsible blood flow using a Nd:YAG laser fiber mounted on a fetoscope. When the placenta is located anteriorly (anterior placenta, 40 % of the whole pregnancy), an available window on the maternal abdominal wall is occasionally quite limited to avoid intraoperative placental injury. Therefore, we have proposed a bending laser manipulator that deflects a laser fiber freely *in utero* to treat TTTS with an anterior placenta (Fig.1) [4].

The other 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

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coverage of the spinal defects has been reported as a temporal protection method of the diseased part before birth[5]. Although a patch is sutured on the defect area in the technique, we proposed less invasive procedure to attach a collagen patch onto the fetus using laser [6]. In the proposed procedures, A collagen patch is stabilized on to the fetus using a robotic patch stabilizer while the laser from the bending laser manipulator welds the patch to the fetal tissue (Fig.2).This robotic surgery is expected to enable easier manipulation and shorter operation time.

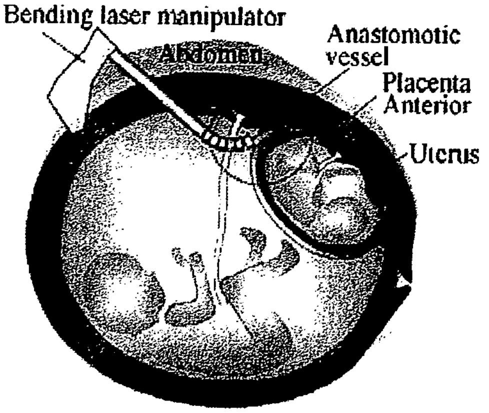

Fig. 1. Proposed TTTS surgery with a bending laser manipulator

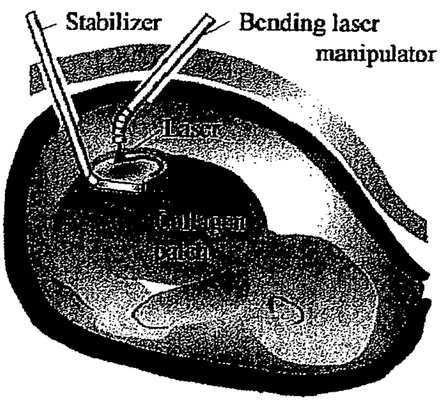

Fig. 2. Proposed MMC patch coverage procedure with a bending laser manipulator and a robotic patch stabilizer.

B. Surgical Robots for Fetal Surgery

Many studies have conducted to enhance the endoscopic operability and some commercial surgical robots [7] are used in clinical cases. These robotic techniques are expected to be introduced also in minimally invasive fetal surgery. However, experiments applying commercial surgical robots to fetal animal surgery [8-10] reported many problems. Commercial surgical robots of 5 mm or more were too big for the allowable surgical incision. Moreover, one report found that although the surgical robot is costly and required long setup time, 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 [11], a forceps manipulator [12], laser device [13], a microfabricated instrument for haptic tissue recognition [14] and a three components force sensorized tip [15].

Our approach is to develop inexpensive, simple, thin robotic manipulators available for fetal surgery. The evaluation of fetal tissue fragility is also studied for the force control of the robots. The developed manipulators are expected to be useful not only in fetal surgery but also in other kinds of minimally invasive surgery.

III. Bending Laser Manipulator

A. Bending mechanism

Many kinds of bending mechanism have been studied for surgical manipulators or catheters of small diameter. Such devices includes a SMA actuated catheter [16], wire-actuated manipulators [17-19], hydrodynamic active catheter [20], manipulators with a linkage design [12, 21], and snake-like units using flexible backbones [23].

The bending mechanism of our bending laser manipulator is shown in Fig.3 and its photos are shown in Fig.4 and Fig.5. The diameter was 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 risk of premature rupture of chorioamniotic membrane is small. The premature rupture of chorioamniotic membrane must be avoided since the fetus at the surgical period cannot survive outside the uterus. Besides, the incision less than 3mm need not sutured since the contractive force of the uterus itself closes the small hole unaided. This unaided incision closure results in faster operation and less chance of amniotic fluid leakage.

The developed bending mechanism is composed of cylindrical parts having four holes and spheres with a hole, and it is assembled without any small gear and pin. These parts are easily assembled just inserting four wires and a central tool. The number of joints can be changed according to the stiffness of the centrally inserted tool. This mechanism enables maximum curvature without adding the breading force to the centrally inserted tool. The maximum curvature is also preferable for the bending motion in a small surgical space. Four wires are moved using two ultrasound motors to control the bending angle through 90 degrees in any direction (up to 180 degrees bending is possible when the centrally inserted tool is soft). The bending angle was commanded either with a handheld 4-directional switch or executing pre-programmed motion.

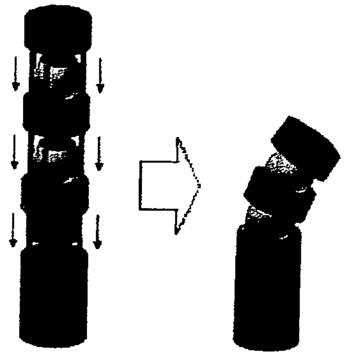

Fig. 3. Bending mechanism (without any gear and pin)

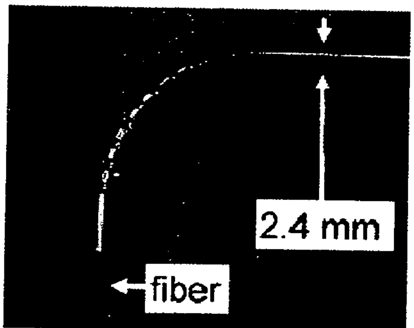

Fig. 4. The bending laser manipulator (2.4 mm in diameter, 2 D.O.F) with a centrally inserted laser fiber (0.7 mm in diameter whose central core is silica glass of 0.4 mm in diameter)

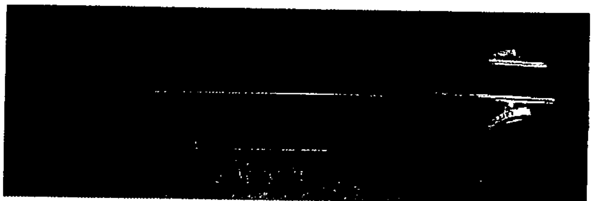

Fig. 5. Bending laser manipulator

B. Kinematics

The kinematics of the bending laser manipulator approximates that of a continuum robot with a backbone [23]. In this paper, the bending curvature was supposed to be constant.

The static deformation of the bending laser manipulator (Fig.6) is described with (1) and (2), where κ is curvature, F is wire tension, a is the distance from the fiber's center to the hole for the wires, E is the fiber's Young's modulus, I is the fiber's cross-sectional moments of inertia, and s is a parameter of bending arc length ($s=L$ at the distal end when the length of the bending part is L).

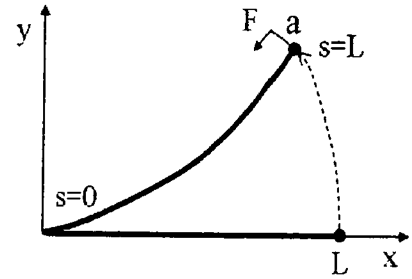

Fig.6 Defined coordinate for a manipulator deflection

$$\kappa = \frac{F \cdot a}{E \cdot I} \quad (1)$$

$$x(s) = \frac{1}{\kappa} \cdot \sin(\kappa \cdot s) \qquad y(s) = \frac{1}{\kappa}\{1 - \cos(\kappa \cdot s)\} \quad (2)$$

Since the designed length of the bending part in the 10-joint prototype in Fig.4 is 19.9mm, the curvature κ is 78.7 m^{-1}. The measured F necessary to bend the manipulator to 90 degrees was about 14.7 N. The designed a is $0.9\cdot10^{-3}$ m, then EI is $1.8\cdot10^{-4}$ $N\cdot m^2$.

Although the fiber's Young's modulus is unknown (fiber core: silica glass, 0.4 mm in diameter, E is $73.5\cdot10^5$ N/m^2; fiber coat: polymer, 0.15 mm in thickness), its Young's modulus is equivalent to the silica glass fiber of 0.47 mm in diameter calculated back using (1). This equivalence is reasonable and suggests that precise positioning is possible with wire tension sensing and this deformation model.

C. Positioning test

Sequential bending motions through ± 90 degrees were commanded to evaluate the repeatability of the motion. Two markers were attached to the fiber tip and their positions were tracked using a matching technique of image processing to figure out the bending angle (Fig.7). The result is shown in Fig. 8 and high repeatability was 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 change around 0 degree is due to insufficient initial wire tension and small gaps between the fiber and holes in the joint spheres. Although the precise setting of the initial wire tension is important, this high reparability is sufficient for controlling the bending angle with the handheld 4-directional switch under direct vision.