

# SENSORIZED MICROCATHETER

## *Smart Microinstrumentation Addressing Fetal Surgery – First Results*

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**Keywords:** Fetal surgery, Endoscopy, Fetoscopy, Pulmonary Atresia, Bio-impedance, Catheter.

**Abstract:** Pulmonary Atresia is a malfunction that is diagnosed in about 1 out of 20.000 fetus. The authors propose a novel surgical intervention where the fetal heart is accessed with an endoscopic intervention through the umbilical cord. The key for this innovative procedure is a novel micro-catheter that is equipped with sensor and actuators that allow active navigation inside the heart and also tissue characterisation. The present paper presents the first prototype.

## 1 INTRODUCTION

### 1.1 Fetal Surgery

Birth defects occur in 1/28 of births and are the leading cause of infant deaths. Costs for treatment after birth are sometimes higher than surgery costs. Surgical interventions on the fetus during pregnancy allow a higher intra-uterine survival rate and an improved postnatal outcome. Till now for a fetus with diagnosed congenital malformation abortion, continuation of the pregnancy until termination with a Cesarean delivery, change in timing mode or place of delivery were the only possibilities. Fetal surgery may now provide a solution in these cases.

Starting from the two main American centres (Harrison, M. R., 2003) that have been performing fetal surgery for more than twenty years - University of California, San Francisco Fetal Treatment Center and Children's Hospital of Philadelphia, Center for Fetal Diagnosis and Treatment - nowadays about a dozen worldwide centres provide prenatal surgical intervention and many others carry on research and experiments for specific fetal surgical applications. (Raul A. Cortes and Diana L. Farmer, 2004)

Fetal surgery is still intended for a restricted number of malformations that can not be successfully or efficaciously treated after birth. However, since 1981 many life-threatening fetal pathologies have been treated through in-utero surgical corrections, approaching prenatal

interventions as a valid alternative to neonatal therapy or induced abortion.

At the moment open fetal surgery is the standard procedure. It is similar to standard surgical interventions, but causes a high level of stress for both the fetus and the mother. An alternative can be performing a key-hole surgical intervention on the fetus with the help of endoscopic microtools. This procedure is commonly known as fetoscopy and allows an intervention on the fetus in its natural environment causing less uterine trauma, less fetal manipulation but preterm labor, damage to uterine membranes and manipulation difficulties. (Sydorak, R. M., Albanese, C.T., 2003; Danzer, E., Sydorak, R.M., Harrison M.R., Albanese C.T, 2003; Flake, A.W., 2003 ; Berris M., Shoham M., 2006; Papadopulos, N.A., Papadopoulos, M.A., Kovacs, L., Zeihofer, H.F., Henke, J., Boettcher, P., Biemer, E., 2005).

These procedures are performed through the use of small trocars and a combination of videofoscopic and sonographic visualization. Paediatric surgeons are trying to apply standard minimal invasive instruments, designed by medical engineers for different kind of surgery, to fetal surgery applications. These instruments may be suitable for some interventions, but are far too big for interventions in an early development stage of the fetus. Thus one of the main problems fetoscopy is facing is the lack of suitable micro instrumentation.

## 1.2 Pulmonary Atresia

During pregnancy the necessary oxygen is not supplied through the fetal lungs but by the placenta. The Foramen Ovale is an opening between the right and the left atrium that allows blood to pass by the pulmonary tract. After birth this opening is usually closed. Pulmonary Atresia (Daubeney, P.E.F., Wang, D., Delany, D.J., Keeton, B.R., Anderson, R.H., Slavik, Z., Flather, M., Webber, S.A., K., 2005; Litovsky, S., Choy, M., Park, J., Parrish, M., Waters, B., Nagashima, M., Praagh, R.V. & Praag, S.V., 2000) is a malfunction that may appear during pregnancy: it is an incorrectly developed pulmonary valve that is, instead of a valve there is just a membrane (compare Figure 1A and Figure 1B).

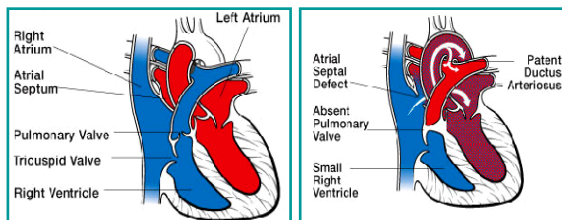


Figure 1A: Healthy heart 1B: Heart with absent pulmonary valve (<http://www.americanheart.org/>).

No blood supply to the lungs is possible in this case which usually causes the death of newborns when oxygen supply by the placenta is not given anymore. Furthermore anatomic obstruction to the right or left ventricular outflow tract may cause ventricular dysfunction, can divert fetal blood flow in the uterus and result in cardiac chamber hyperplasia. Thus severe aortic or pulmonary stenosis can result in a hypoplastic left or right ventricle with an inability for the ventricular chambers to support the systemic or pulmonary circulation. Theoretically early relief of the fetal aortic or pulmonary stenosis may prevent such occurrence and might preserve the right or left ventricular function. In the case of pulmonary atresia this can be achieved by a punctuation of the pulmonary membrane to enable a pulmonary blood flow and a further correct development of the valve. (Tworetzky, W., Wilkins-Haug, L., RW. Jennings, 2004; Kohl, T., Witteler, R., Strämper, D., Gogarten, W., Asfour, B., Reckers, J., Merschhoff, G., Marcus, A.E., Weyand, M., Van Aken, H., Vogt, J., Scheld, H.H., 2003)

Pulmonary atresia can be diagnosed in the 12-14th week of gestation. The surgical intervention should be performed as soon as possible. In the 14th week the fetus size is about 9-14cm and has a

weight in the range of 60 - 200g. In this development stage the pulmonary membrane has a diameter of approximately 1mm.

Pulmonary atresia occurs in about one out of every 20,000 live births. An early surgical intervention is the only alternative to abortion and could allow normal development of the pulmonary valve and the right ventricle.

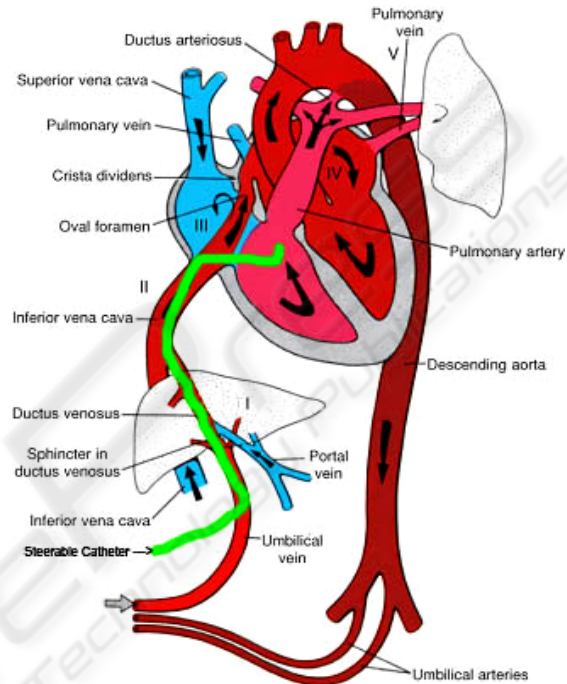


Figure 2: Fetoscopic approach to access the fetal right ventricular through the umbilical cord

## 2 METHODS

### 2.1 Fetoscopic Approach

We propose a minimally invasive surgical procedure in the case of pulmonary atresia which includes the following steps:

- (1) Externalisation of the uterus where the fetus remains in its own environment
- (2) Accessing the right ventricle with a flexible and steerable microcatheter through the umbilical cord (need for a microcatheter (outer diameter <1mm), steering mechanism (3 degrees of freedom), the catheter needs to be highly flexible, position feedback systems need to be available to track the catheters tip) (Figure 2)

- (3) guiding the catheters tip in front of the pulmonary membrane (need for a steerable catheter)
- (4) recognition of the tissue in front of the catheter: Due to the small dimensions of the pulmonary tissue and the surrounding tissue it is very difficult to distinguish between those just by vision on an ultrasound picture. Tissue characterisation and recognition sensors may then be the solution for a reliable tissue distinction.
- (5) once the pulmonary membrane is detected the perforation takes place (need for a cutting tool)

It is clearly visible that the development of suitable microinstrumentation is the key to this novel surgical technique. To proof the feasibility of the approach, we designed a first prototype for such a smart catheter that is equipped with tissue characterisation sensors and a steering mechanism.

## 2.2 Steering Mechanism

To be able to reach the right ventricle through the umbilical cord (figure 2), the catheter needs to be equipped with steering capabilities (Ascari, L., Stefanini, C., Menciassi, A., Sahoo, S., Rabischong, P., Dario, P., 2003). The multi-lumen catheter consists of a very flexible ending and a less flexible part. In the walls of the catheter 4 thin diameter lumen are integrated, each one for one steering wire. Pulling on these 4 wires and releasing at the same time the wire which is on the opposite side in the catheter will primarily result in a movement of the flexible end part of the catheter. Two microcontroller driven servo drives are used to pull and release the wires. This microcontroller is then connected to a personal computer, which, equipped with a haptic force feedback joystick, allows a precise control of the catheter. A third degree of freedom is realized by either manually or servo supported driving the catheter forward and backwards.

## 2.3 Electrical Impedance Sensor

Bio-impedance spectroscopy allows tissue classification and identification by recording and analyzing the electrical impedance at different frequencies (Rigaud, B., Hamzaoui, L., Chauveau, N., Martinez, E., Morucci, J., 1994; Cao, H., Tungjitkusolmun, S., Choy, Y. B., Tsai, J. Z., Vorperian, V. R., Webster, J. G., 2002). From the electrical point of view cell membranes appear as capacitors. In comparison to low frequency electrical

current where the current path is leading mainly through extra cellular fluid, high frequency electrical current is able to penetrate the cells. Different tissues can be distinguished by comparison of their characteristic impedance over frequency and phase over frequency plots. Principle Component Analysis can then be used to classify a tissue by a recorded data set.

For impedance spectroscopy two or four electrodes configuration are state of the art. Four electrodes impedance measurement allows higher accuracy, as two electrodes are used to drive in the electrical current and the other two, which are normally arranged in between the first two ones, are used the small sensing electrode.

It must be kept in mind that for tissue classification it is not necessary to record accurate impedance data from the electrical point of view. It is just important that the training data sets are recorded with the same electrode configuration to give comparable recordings.

## 2.4 Spectrophotometric Sensor

To enable a reliable tissue distinction a second sensor system based on a different principle is required. Tissues can be distinguished by their colour, so pulmonary valve tissue appears rather white in comparison to the surrounding more red endocardium. Integration of two optical fibres is the basis for the recording of optical reflectance spectrum in front of the catheters tip. One fibre is used for guiding the necessary light from a white LED to the point of interest. Reflected light is then received with a second fibre leading to an optical spectrophotometer working in the visible range. Unfortunately in normal condition the heart is filled with blood. Haemoglobin is a strong light absorber, where furthermore the wavelength dependent light absorption also is dependent on the oxygenation status of haemoglobin. Measuring tissue characteristics with a spectrophotometric method is therefore not possible in the presence of whole blood.

## 2.5 Washing System

To solve the above described problem we integrated another lumen in the catheter to provide washing solution with a small amount of physiological saline solution blood in front of the catheters tip can be washed away. Thus blood in the measuring zone is substituted with the washing solution, which enables



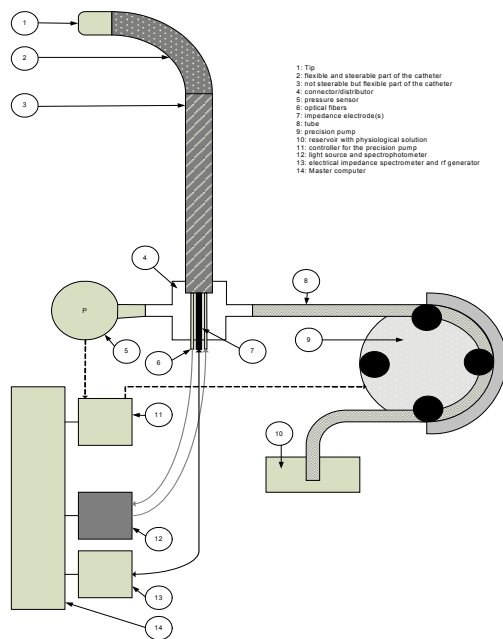


Figure 3: System setup.

spectrophotometric reflectance measurement (Sieber, A., 2007). In figure 3 the principle setup including the peristaltic pump for the physiological saline solution is shown.

### 2.6 Tissue Fixation

Impedance and photometric spectrum recording requires mechanically stable conditions – the tissue in front of the catheter should not move relatively to the catheter, which is difficult to realize in a moving environment like a beating heart. To solve this problem the washing system described above has a second functionality: After the blood in front of the catheter is substituted with a small amount of physiological saline solution (Figure 4, 1-3), the washing solution pump can be driven backwards, thus sucking in washing solution and creating suction in front of the catheter. Tissue in front of the catheter is sucked to the tip and a reliable electrical and mechanical connection is established (Sieber, A., 2007), and electrical impedance and optical spectroscopy are performed (Figure 4, 4-5). The maximum suction pressure used in this setup is -50 mbar.

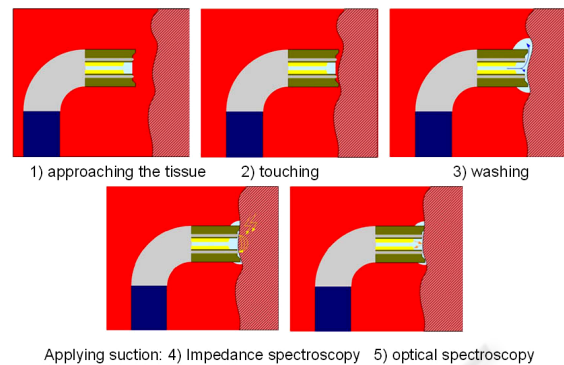


Figure 4: tissue characterisation scheme.

## 3 RESULTS

### 3.1 Catheter Prototype

To prove the feasibility of the concept a catheter was fabricated with the following specifications (Figure 5 and 6):

- diameter: 3,5 mm
- steerable tip, 2 DOF, servo actuated
- four electrodes for electrical impedance spectroscopy and radio frequency cutting
- two 500 µm optical fibers for optical reflectance spectroscopy
- housing micromachined from PEEK with 5 axis Kern CNC milling centre
- integrated washing / suction channel

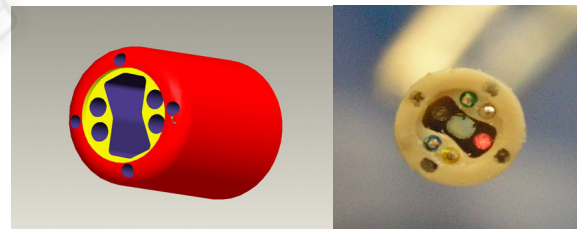


Figure 5: Catheter tip design (A) and first prototype (B).



Figure 6: Catheter prototype (A) and control with a joystick (B).

A joystick is deployed for the control of the bending of the catheter tip (Figure 6B).

### 3.2 System Setup

Figure 3 shows the principle setup. The catheter consists of the PEEK tip (1) with the integrated electrodes, the washing channel and the optical fibers, the steerable part (2) and the passive flexible part (3). It is connected to a distributor (4) where a pressure sensor (5) is mounted. Another port is connected to the pump providing the washing solution from a reservoir (10). The pump is connected to a microcontroller ATMEL Atmega 32 (11). This microcontroller also serves as a controller for two servos driving the Bowden cables of the catheter needed for active bending of the catheter tips (not displayed). The optical part (12) consists of a light source (white LED) and a microspectrometer [Microparts]. The electrodes are connected to a programmable precision LCR meter [TEGAM]. All the components 11, 12 and 13 are then connected to a PC. The software is written under National Instruments LabView.

### 3.3 Tissue Distinction

Several electrical impedance spectra of in total 10 dissected bovine pulmonary valves and surrounding endocardium were recorded (in the presence of saline solution).

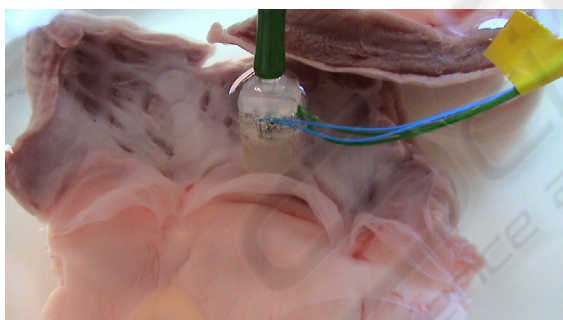


Figure 7: test setup: recording impedance spectra of pulmonary valve tissue.

Therefore a second slightly larger (5mm diameter) catheter tip was fabricated from peek again using the Kern CNC milling centre. During the recording the negative suction pressure was kept constant at -25 mbar.

The impedance spectra were recorded from 10kHz to 5 Mhz with a induced signal of 1V peak to peak. Pulmonary valve and endocardium tissue can be clearly distinguished by electrical impedance spectroscopy (see plots shown in Figure 8 and 9).

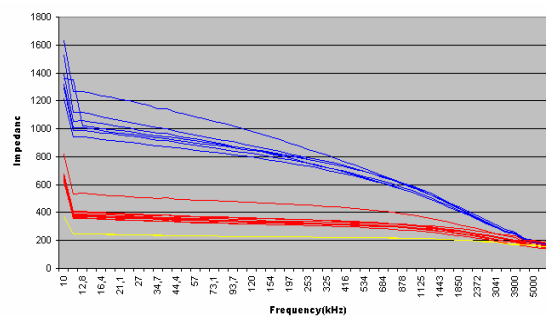


Figure 8: Impedance vs frequency endocardium: blue; pulmonary valve: red; saline solution: yellow.

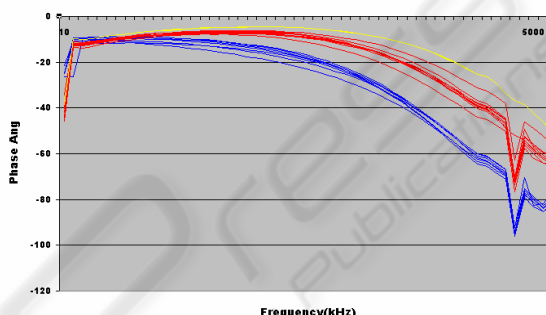


Figure 9: Phase vs frequency: endocardium: blue; pulmonary valve: red; saline solution: yellow. The negative peak at approximately 4 Mhz seems to be a result of resonance.

## 4 CONCLUSIONS

Pulmonary atresia is a malfunction that occurs in approximately 1 out of 20000 fetus. It can be diagnosed in the 15<sup>th</sup> week of pregnancy. A feasible approach to correct the malfunction is described, but it requires sophisticated instrumentation.

The fabrication of the first prototype is a major step towards the final catheter, which will be the key for a successful early treatment of pulmonary atresia thus offering an affected fetus a prospect to a future without handicaps.

## 5 FUTURE WORK

Next steps will be catheter insertion tests of the prototype on the animal model, enlargement of the impedance spectra database and in parallel the design of the miniaturized version. We envisage the substitution of the bowden wires (the actuation wires for bending of the catheters tip) by smart actuators such as Ion Polymer Metal Composites – which will enable a reduction of the overall

diameter of the catheter to 0.8 mm, or SMA actuators (Mineta, T., Mitsui, T., Watanabe, Y., Kobayashi, S., Haga, Y., Esashi, M., 2002). Additionally coils will be integrated, in order to give a position feedback (Salomon, O., Kosa, G., Shoham, M., Stefanini, C., Ascari, L., Dario, P., Zaaroor, M., 2006; Aurora NDI).

## ACKNOWLEDGEMENTS

The work described in this paper was supported by the Austrian Research Centers GmbH, by the Fondazione Cassa di Risparmio di Pisa in the framework of the "microSURF" project for the development of innovative tools and techniques in fetal surgery, and by the ASSEMIC project, a Marie Curie Research & Training Network (MRTN-CT-2003-504826).

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