Towards Wireless Implantable Pressure Sensor to Monitor Compartment Syndrome in Trauma Victims

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ABSTRACT

We present a miniature, implantable, wirelessly powered sensor system that is suitable for accurately measuring pressure fluctuations in the limb compartments of patients at risk of developing Acute Compartment Syndrome (ACS). The sensor system consists of a Micro-Electro-Mechanical-Systems (MEMS) capacitive pressure sensor and an Application Specific Integrated Circuit (ASIC) capacitance readout chip designed on a battery-less Radio Frequency Identification Device (RFID) platform that is powered with a standard RFID reader. The pressure sensor and ASIC circuitry are packaged into a polytetrafluoroethylene (PTFE) tube for sturdy protection and easy implantation using a syringe delivery procedure. The sensor system is undergoing *in-vivo* testing and preliminary calibration test results show that the system functions well with good linearity.

Keywords: Implantable pressure sensor, RFID, CMOS ASIC, MEMS, Acute Compartment Syndrome

1 INTRODUCTION

The muscles of the lower limb are bundled into "compartments" surrounded by inelastic connective tissue called fascia. High-energy impact causes swelling and increased pressure within the muscle compartments that reduces blood flow and results in the condition called Acute Compartment Syndrome (ACS) [1, 2], which is a well-recognized and common emergency. This intra-compartmental swelling is the result of increased size of the damaged tissues themselves following acute crush injury or from reperfusion of ischemic areas. It is usually not from a collection of free blood or fluid in the compartments. Presently, there is no reliable and reproducible test that confirms the diagnosis of ACS. A missed diagnosis or failure to cut the fascia to release pressure within reasonable time can result in severe intractable pain, paralysis, and sensory deficits.

Currently, the diagnosis of ACS is made on the basis of physical exam and repeated needle sticks over a short time period to measure intra-compartmental pressures [3, 4]. Missed diagnosis of compartment syndrome continues to be one of most common causes of malpractice lawsuits in USA/Canada. Existing technology for continuous pressure measurements are insensitive, particularly in the deep tissues and compartments, and its use is restricted to highly trained personnel. A method for the accurate and reproducible diagnosis of ACS, especially in the obtunded, poly-trauma or distracted patient is yet to be developed. Consequently, a large number of trauma surgeons face this diagnosis conundrum on an almost daily basis. Resolution or clarification of the diagnosis of ACS would be a great asset for the trauma patient population. In today's clinical scenario, pressure measurements through the use of repeated needle sticks are the best means of determining the need for a fasciotomy. Although newer technologies, such as ultrasound [5, 6] and near infrared [7] monitoring are being tested, but they all seem to have major problems with missing compartments and interfering with complete care of the patient.

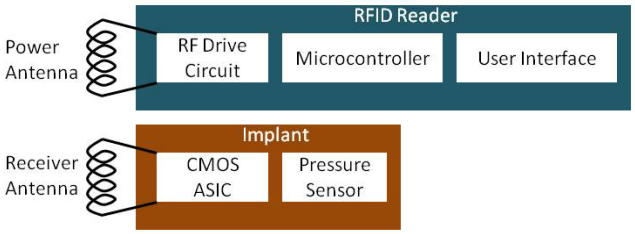

Figure 1: Block diagram of the implantable pressure sensor system

Here, we aim to develop a simple, miniature, wireless device that can accurately measure pressure fluctuations in the limb compartments of patients at risk of developing ACS. As shown in Figure 1, we use temporary indwelling, direct pressure monitors consisting of a Complimentary Metal-Oxide Semiconductor (CMOS) Application Specific Integrated Circuit (ASIC) designed on a battery-less Radio Frequency Identification Device (RFID) platform that is powered with wireless transfer of radio frequency electromagnetic energy and integrated with Micro-Electro-Mechanical-Systems (MEMS) capacitive pressure sensors. This small implantable silicon-based sensor microsystem

would be capable of measuring pressures under diverse conditions and can be easily used by nurses in hospital settings or by paramedical personnel in cases of accidents, natural disasters, and wartime situations. The proposed sensor microsystem will not interfere with movement of the patient during stabilization, surgery or intensive care stay, and will ultimately, revolutionize the management of trauma victims and minimize the devastating outcomes of compartment syndrome.

2 COMPONENTS OF THE SENSOR SYSTEM

The capacitive MEMS pressure sensor and the CMOS ASIC components are developed and provided by Tronics Medical Solutions, Inc. San Jose, California, USA. Figure 2 shows the micrograph integrated pressure sensor microsystem.

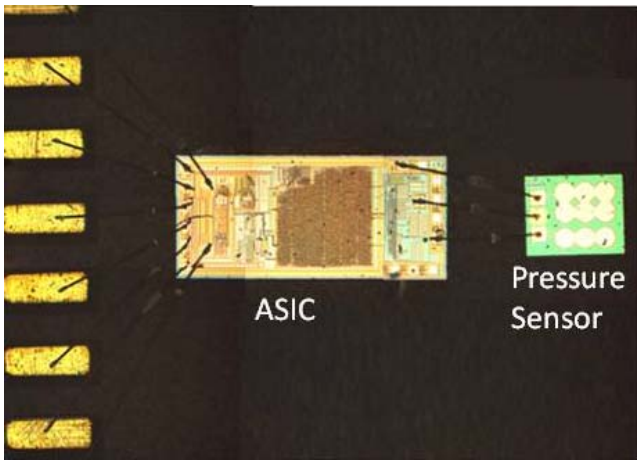

Figure 2: Microphotograph of the pressure sensor microsystem

2.1 Capacitive MEMS Pressure Sensor

A miniature absolute MEMS capacitive pressure sensor is used to measure the pressure. This pressure sensor is designed for various applications such as invasive/noninvasive medical pressure monitoring, industrial, and automotive applications. Figure 3 shows the pressure sensor and its electrical model, respectively. The dimensions of the pressure sensor are 1100µm×900µm×450µm(thickness). The dimensions of the bonding pads are 150µm×150µm. The absolute capacitive MEMS pressure sensor consists of several single crystal silicon membranes which are defined by single crystal silicon (Silicon-on-Insulator (SOI) device layer). The single crystal silicon layer offers ultra-low stress membranes, high reproducibility, good mechanical properties and excellent matching capabilities in mass-production. The silicon membranes transform external applied pressure into a proportional capacitance change.

The electrical model of the pressure sensor consists of two capacitors, C_{sens} and C_{ref}, and parasitic resistors, R_{s1} R_{s2}, R_{s3}, R_{p12} and R_{p23}. Only C_{sens} varies with the external applied pressure. C_{ref} is constant regardless of applied pressure, and is designed to be equal to C_{sens} at a pressure of 1 atmosphere. Both C_{sens} and C_{ref} vary with temperature change. Two types of measurement methods can be used to measure the capacitance of the pressure sensor: (a) excitation can be applied on Pad 2, with differential measurement on Pad 1 and 3; or (b) two excitations in counter-phase can be applied on Pad 1 and 3, with measurement on Pad 2. In either method, the capacitance difference C_{sens}-C_{ref} is a function of the applied pressure. The pressure sensor can operate under pressure range 0-1875 mmHg and temperature range 0-125°C with typical sensitivity of 0.4fF/mmHg.

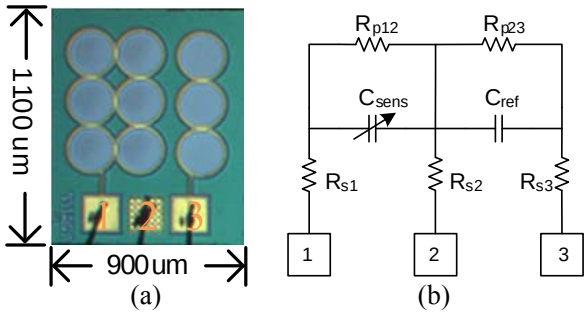

Figure 3: (a) pressure sensor, (b) electrical model of the pressure sensor

2.2 Capacitance Readout ASIC Circuitry

A high resolution, low power, and 16-bit resolution capacitance readout ASIC circuitry is used to directly transform the capacitance difference between C_{sens} and C_{ref} of the pressure sensor to a digital value. Figure 2 shows the microphotograph of the ASIC circuitry. The dimensions of the ASIC circuitry are about 3000µm×1100µm×450µm (thickness). The three pads of the pressure sensor are connected to the capacitance readout ASIC circuitry, where a Capacitance to Digital (C/D) converter directly converts the capacitance difference C_{sens}-C_{ref} into a digital output signal. There is an on-chip temperature sensor on the ASIC circuitry. The nonlinearity and temperature errors of the pressure sensor are compensated with a multi-order polynomial compensation which is based on temperature measurement and correction parameters stored in the EEPROM memory block of the ASIC circuitry.

Using a wireless connection (an RF link at 13.56MHz), the capacitance readout ASIC circuitry can be both powered and the output data be transmitted. The ASIC circuitry is connected to a RF antenna, the power is harnessed through the antenna from a standard RFID reader and the internal signal clock is extracted from external RF signal. The ASIC circuitry stores identification information in the EEPROM memory, so that it can be inventoried and identified by the

RF reader as a RFID tag. The ASIC circuitry is optimized for 600-1875 mmHg pressure range and 20-45°C temperature range with typical resolution of 0.75 mmHg and nonlinearity below 2%.

2.3 RF Reader and Antenna

An EM4094 RFID reader (EM Microelectronic-Marin SA) is used to power the ASIC chip and read-out the pressure data wirelessly through a SMA antenna (DLP-FANT, DLP Design Inc.). It supports all the Mandatory, Optional, Custom and Proprietary ISO15693 commands of 13.56MHz EM Microelectronic Marin transponder ICs. A mandatory command set of ISO14443-3 Type A and Type B is also implemented [8]. Several modifications have been made to the application software to suit it specifically for the capacitance readout ASIC circuitry. The software takes care of all communication between the ASIC circuitry, including: (1) send inventory command to identify if an ASIC circuitry/pressure sensor is available; (2) start temperature measurement and store the temperature value; (3) start pressure measurement and store the pressure value; (4) read, write and lock data inside the EEPROM of the ASIC circuitry.

A typical pressure measurement sequence is as follows: first, the RF reader sends inventory command to check if there is an available ASIC circuitry/pressure sensor. If the sensor is powered up by the RF reader, it responds with its unit identification number and a check-sum. By this time, all the configuration and calibration data has been loaded from the non-volatile memory to the registers inside the ASIC circuitry. A temperature measurement is then performed at least one time before the pressure measurement. The calibration coefficients are calculated based on temperature data and on the coefficients stored within the EEPROM. A pressure measurement is then performed and the pressure value is calculated based on the calibration coefficients. These calibration coefficients are stored in registers and are used for each pressure measurement. They are updated following each temperature measurement. The temperature and pressure values are shown in hexadecimal format in the RFID reader software user interface.

3 SYSTEM PACKAGING

The pressure sensor and the ASIC circuitry are glued on top of a Printed Circuit board (PCB) substrate using standard epoxy, as shown in Figure 4. The dimensions of the PCB substrate are 9mm×2mm×1.3mm(thickness). There are several copper pads and wires on the PCB board, which are used to make connection between the ASIC circuitry and the external RF antenna. Aluminum wedge bonding (with aluminum wire of 25μm diameter) is used to make connection between the pressure sensor, ASIC circuitry and the PCB board.

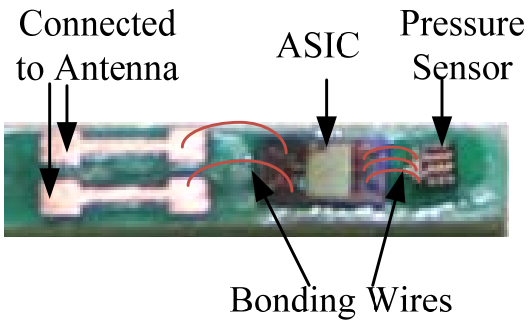

Figure 4: Schematic of the sensor packaging

The PCB with pressure sensor and ASIC is packaged inside a hollow polytetrafluoroethylene (PTFE) tube that is implanted into limb compartments. PTFE is a biocompatible material [9], which will mitigate the body reactions induced by the implantation of the sensor system. The RF antenna is connected to the readout ASIC circuitry and is located *in-vitro* for the current prototype demonstration. Two wires are soldered to the pads on the left hand side of the PCB board as shown in Figure 4. The other end of these wires are connected to a SMA RF antenna. A layer of "5 minute epoxy" glue is applied all over the PCB board, the ASIC circuitry and the bonding pads of the pressure sensor. This glue cures in 5 minutes and it forms a solid protection layer to protect the bonding wires and ASIC circuitry from damage during implantation and sensor use. Subsequently, part A and part B of a silicone gel (MED-6640, Nusil Technology LLC) are mixed with 1:1 ratio in volume and applied all over the PCB board, including the ASIC chip and the pressure sensor. The silicone gel cures in 30 minutes at ambient temperature and humidity. Application of the silicone gel is repeated for several times until the ASIC circuitry, pressure sensor and PCB board are completely covered by the silicone gel. The purpose of applying silicone gel is to make the sensor system biocompatible.

Figure 5: Packaged pressure sensor system next to Canadian 10-cent coin diameter of 18.03 mm)

Finally, the gel-coated PCB board with the ASIC chip and the MEMS pressure sensor is inserted into the PTFE tube for facilitating syringe delivery. The assembled

pressure sensor system after packaging is shown in Figure 5. The length and diameter of the final packaged sensor are 22mm and 4mm, respectively.

4 EXPERIMENTAL RESULTS

The packaged pressure sensor system is placed into an airtight vessel where a blood pressure monitor (R1 shock-proof, Rudolf Riester GmbH) is used to pump air into the vessel to vary the pressure inside the vessel. The blood pressure monitor is also used as a pressure gauge to measure the actual pressure value. The vessel is immersed in a 37°C water bath to mimic human body temperature. The sensor reading from the RF reader software interface for different pressures is recorded as shown in Figure 6. From Figure 6, the reading shows good linearity between the sensor output and the applied pressure. The reading changes only 0.03 for pressure range of 220 mmHg, this is because the sensing elements of the pressure sensor (the circular membranes as shown in Figure 3(a)) are covered by a thick silicone gel, which makes the pressure sensor less sensitive to the applied pressure. We are working on improving the packaging method by applying a thinner layer of silicone gel onto the pressure sensor membrane. We are also working on examining the *in-vivo* performance of the pressure sensor system by inducing ACS condition in the hind legs of a rat as shown in Figure 7.

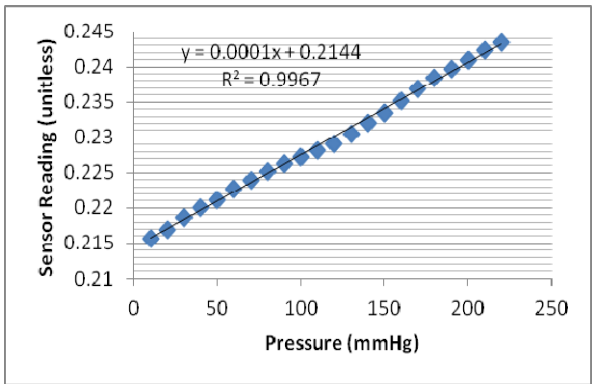

Figure 6: Sensor reading as a function different applied pressure

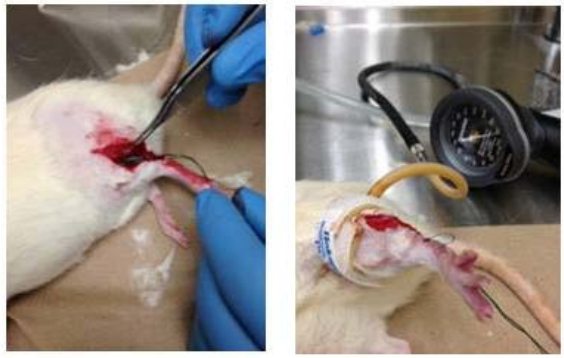

Figure 7: Sensor testing in rat hind legs

5 CONCLUSIONS

We described a simple, miniature, wireless sensor system that is suited to measure pressure fluctuations in the limb compartments of patients at risk of developing Acute Compartment Syndrome. The pressure sensor system consists of a MEMS capacitive pressure sensor and a CMOS ASIC designed on a battery-less RFID platform that is powered with wireless transfer of RF energy. The pressure sensor microsystem is packaged in a plastic tube for facilitating syringe based delivery. The proposed sensor microsystem has the potential to improve the management of trauma victims and minimize the devastating outcomes of ACS.

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