

WIRELESS BLOOD PRESSURE MEASUREMENT IMPLANT ELECTRONICS FOR INTEGRATION IN A STENT GRAFT

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ABSTRACT

This paper describes the design, implementation and testing of a wireless blood pressure sensing implant. The implant is mounted on a stent graft. The implant along with the stent graft must fit into a 16F applicator stent delivery system. The implant is powered using the energy harvested from wireless power transmission. The measured pressure data is sent wirelessly to an external data reader hardware. The pressure measurement must have resolution of 1 mmHg.

KEY WORDS

Stent Graft, Blood Pressure Measurement, Wireless Power Transmission, Medical Implant

1 Introduction

Stent graft insertion is a commonly used procedure for abdominal and thoracic aortic aneurysm treatment [1]. The complication that may follow stent insertion for endovascular aneurysm repair (EVAR) is endoleakage, which is the leakage of blood around the stent graft. This can happen for up to 40% of the patients who underwent EVAR [2]. The shortcomings of currently used methods like contrast-enhanced computed tomography (CT) or ultrasound for detecting endoleak are lack of real-time measurement of intrasac aneurysm pressure and the inconvenience for the patients due to periodical hospital visits.

A new approach enabling patients to monitor changes in the blood pressure around the stent graft without regular checkups is described in this paper. This approach integrates pressure sensors into the existing stent graft used for EVAR. The pressure sensor together with other electronic components form the implant. This implant transmits pressure data wirelessly to an external reader hardware.

2 Implant Requirements

The stent graft is permanently implanted in the body of the patient. The implant can be powered using batteries, but small batteries have low capacity demanding periodic replacements. So powering the implant using wireless energy harvesting is chosen for this application. The implant consists of a pressure sensor mounted inside a stent graft that

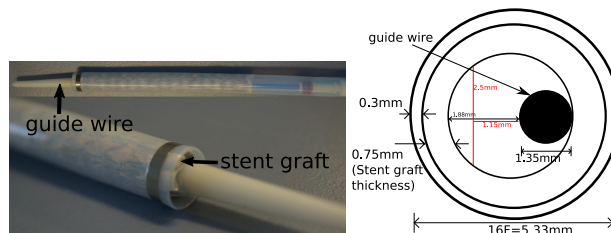


Figure 1. Stent graft inside an applicator delivery system and the cross section of a 16F applicator delivery system

measures the pressure with high resolution. The stent graft along with the implant must fit into the existing commercially available 16F applicator stent delivery systems.

Figure 1 shows the cross section of a 16F applicator delivery system. The outer diameter of the applicator is 5.33 mm with an inside wall thickness of 0.3 mm containing a guide wire of 1.35 mm diameter. The stent graft has a thickness of 0.75 mm and a length of 90 mm. From mathematical calculation, it has been found that an implant of width 2.5 mm and height 1.15 mm mounted on the stent graft will surely fit into the 16F applicator. The pressure sensor must have a resolution of 1 mmHg in the pressure measurement range from 760 mmHg to 850 mmHg.

3 Implant Design

The implant consists of four main modules: wireless power reception, pressure sensor and capacitance to digital converter (CDC), wireless data transmission and a low power microcontroller. The absolute dimensions of width 2.5 mm and height 1.15 mm limit the choice of electronic components to be used in the implant. The circuit diagram of the implant is shown in figure 2.

3.1 Pressure Sensor and CDC

The implant is powered using the energy harvested from wireless power transmission. So the power consumption of the electronic components in the implant must be as small as possible. Instead of state of the art resistive pressure sensor, a capacitive pressure sensor is used in order to reduce

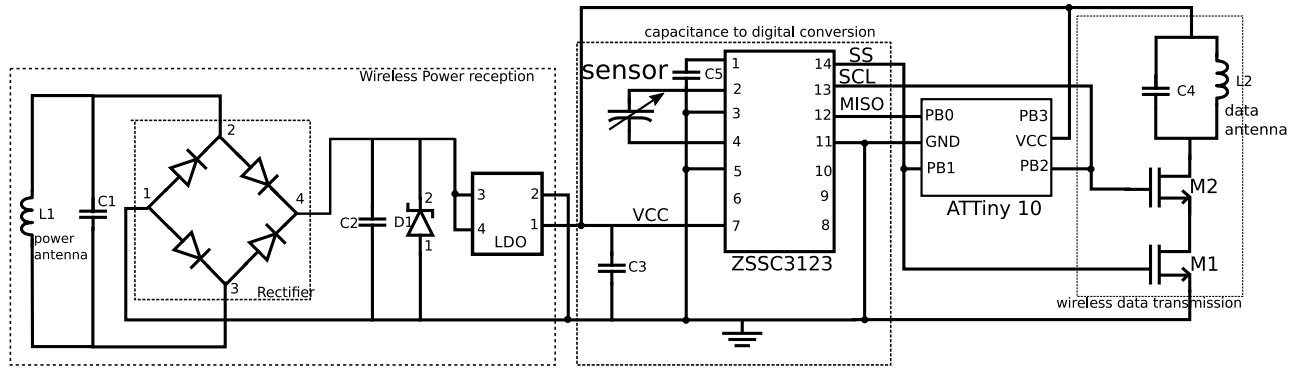


Figure 2. Circuit diagram of the implant

power consumption.

This implant utilises a commercially available capacitive pressure sensor E1.3N from microFAB Bremen GmbH [3]. The sensor die has dimension of 1.2 mm x 0.6 mm x 0.5 mm and the pressure window of measurement is from 1 bar to 1.3 bar (1 bar = 750 mmHg). The sensor has an offset capacitance of 6.026 pF at 750 mmHg.

The capacitor to digital converter, ZSSC3123 [4] has a resolution of 125 aF and wide capacitance range from 0 to 260 pF. The CDC can be calibrated using a computer software for the desired capacitance range, resolution and measurement frequency. Programmable capacitance range is used to offset the increased capacitance due to the parasitic capacitance of the PCB. The CDC chip die has dimensions of 1.6 mm x 1.5 mm.

3.2 Wireless Power Reception

The wireless power reception module consists of a resonant circuit (L1 and C1) tuned to the frequency of the external wireless power transmitter. The rectifier converts ac output of the resonant circuit to pulsating dc. The zener diode (D1) of 3.3 V is used for overvoltage protection of the implant. A Low-Dropout (LDO) regulator generates a regulated output voltage of 2.5 V. Capacitor C3 is used as energy storage.

3.3 Low Power Microcontroller

The microcontroller fetches pressure sensor data from the CDC and sends it to the wireless data transmission module. Atmel's AVR microcontroller, ATtiny 10 [5] is chosen for this implant because of its small package dimensions of 2 mm x 2 mm. The microcontroller communicates to the CDC using SPI interface. The pressure data packet output of the microcontroller is shown in figure 3. Cycle Redundancy Checksum (CRC) is used for identifying errors in the received data at the external reader hardware. The polynomial used for CRC is $p(x) = x^5 + x^2 + 1$.

The microcontroller has 6 pins, out of which only 3 pins are available for this application because PB3 is re-

START (2 bits)	Pressure value (14 bits)	CRC-5 (5 bits)	STOP (1 bit)
1 1	C0, C1, C2, ..., C12, C13	crc0,...crc4	1

Figure 3. Data packet output of the microcontroller

served for reset. So the pins PB1 and PB2 are shared for the communication of the microcontroller with CDC and the wireless data transmission module.

3.4 Wireless Data Transmission

The wireless data transmission module consists of two NMOS transistors and a resonance circuit load. Transistor M1 enables or disables the wireless data transmission module based on output of the pin PB1. During SPI communication, PB1 is LOW and transistor M1 is disabled. The data for transmission is fed to the transistor, M2 which is connected to the resonance circuit load. When PB2 is HIGH, M2 is turned ON and the inductor L2 starts storing energy until the transistor is off. When transistor M2 is off, L2 discharges through C4 generating a magnetic field. This magnetic field is detected by the external reader hardware.

4 Wireless Power Transfer

The wireless power transmission is realised by using an external power sender which is magnetically coupled to an RF energy harvesting module in the implant hardware. This system uses Near Field Coupling (NFC) where the energy from the transmitting antenna generates a magnetic field surrounding the antenna. The reactive near field can supply more energy compared to the radiating far field.

The received power, P_{RX} as function of the transmitted power, P_{TX} has been derived by using the following assumptions [6].

- Orientation: the wireless power transmitter coil and

the implant's receiver coil are aligned on common center axis;

- Coupling: the transmitter and receiver coils have poor coupling because both coils are far apart;
- Impedance matching: the perfect impedance matching between the receiver coil of the implant and the implant load will ensure maximum power transfer.

The result is

$$\frac{P_{RX}}{P_{TX}} = \frac{\mu_0^2 N_{TX}^2 a_{TX}^4}{16 R_{TX} (a_{TX}^2 + r^2)^3} \cdot \frac{N_{RX}^2 A_{RX}^2}{R_{RX}} \cdot \omega^2 \quad (1)$$

where N_{TX} , N_{RX} are the number of turns and R_{TX} , R_{RX} are the ac resistances at the power transmitter frequency ($\omega=2\pi f$) of the transmitter and receiver coils, respectively. a_{TX} is the radius of the transmitter coil, r is the distance between transmitter and receiver coils and A_{RX} is the cross-sectional area of the receiver coil.

4.1 Wireless Power Transmission Frequency

From (1) it can be concluded that as frequency increases, the efficiency ($\frac{P_{RX}}{P_{TX}}$) increases, provided that other parameters remain constant. The boundary condition between reactive near field and radiating far field regions determines the maximum frequency for wireless power transmission. The boundary between these two regions is at a distance, r from the antenna, where r is given by [6]

$$r = \frac{c}{2\pi \cdot f} \quad (2)$$

where c is the velocity of light and f is the frequency. So the frequency used for wireless power transmission is typically less than 50 MHz, which allows to achieve distances of at least 100 cm [7].

The frequency for wireless power transmission decides the size of the coil, most importantly the implant's receiver coil. Higher frequencies enable the design of smaller antenna for the implant [8]. The power conversion efficiency of the electronic components (like rectifier etc.) in the implant decreases as frequency increases. Moreover, human tissue absorption increases with frequency, reducing the amount of power received in the implant [9].

Frequencies between 100 kHz to 15 MHz are commonly used for medical implants. Based on previous in vivo testing experience, a wireless power transfer frequency of 4 MHz is chosen [10]. At this frequency there was no evident degradation in the performance of other electronic equipments like CT scanner, heart rate monitor etc. that were used in that animal experiment.

4.2 Wireless Power Transmitter Antenna

The parameters of the transmitter antenna influencing efficiency ($\frac{P_{RX}}{P_{TX}}$) of the power transmission are radius (a_{TX}),

number of turns (N_{TX}) and ac resistance (R_{TX}) of the transmitter coil. The optimal radius of the transmitter coil for a given distance (r) is calculated by minimising (1) with respect to a_{TX} , giving

$$a_{TX\text{optimal}} = \sqrt{2} \cdot r \quad (3)$$

Efficiency can be increased by reducing resistance of the transmitter coil (R_{TX}) and increasing number of turns (N_{TX}). Resistance decreases as the cross-sectional area increases ($R \propto \frac{1}{A}$), so a thicker copper wire can reduce the resistance of the coil. As the number of turns increases, the resistance increases proportionally. So the efficiency increase is proportional to the increase in the number of turns of the transmitter coil. The parameter limiting the increase in the number of turns is the quality factor (Q) of the antenna. As number of turns increases, the frequency at which highest Q is attainable reduces in addition to the decrease in the self resonance frequency of the coil [9]. For the distance of 5 cm between wireless power sender and the implant, antenna of 7cm radius is chosen. The sender antenna is produced using five turns of 2 mm thick laminated copper wire.

4.3 Implant Antennas

The inductance of a solenoid antenna is calculated according to the following equation [11]

$$L = \frac{\mu_0 \mu_{\text{Ferrite}} \cdot N_{RX}^2 A_{RX}}{l} \quad (4)$$

where l is the length of the core. Quality factor (Q) of an inductor is written as

$$Q = \frac{\omega L}{R_{RX}} = \frac{\mu_0 \mu_{\text{Ferrite}} \cdot N_{RX}^2 A_{RX} \omega}{l \cdot R_{RX}} \quad (5)$$

From (1) it can be written that

$$\frac{P_{RX}}{P_{TX}} \propto \mu_0 \frac{N_{RX}^2 A_{RX}^2}{R_{RX}} \cdot \omega^2 \quad (6)$$

Substituting (5) in (6) we get

$$\frac{P_{RX}}{P_{TX}} \propto Q \cdot A_{RX} \cdot l \quad (7)$$

From equation (7), the received power at the implant can be increased if the volume ($A_{RX} \cdot l$) or the quality factor of the implant antenna is increased. The size of the implant's receiver antenna is decided by the geometry of the system. For the stent the antenna can have a maximum width of 2.5 mm and height of 1.15 mm.

Self-made inductors are created using coils wound on a ferrite core. The ferrite core material is chosen based on the frequency of wireless power transmission and the geometry of the implant. We use ferrite core 61 from Fair-Rite Products Corp with a diameter of 0.75 mm [12]. Thin laminated copper wire of thickness 0.2 mm is wound over the ferrite core. In order to maximise the efficiency by increasing the volume, two or more ferrite cores are used in a coil and several coils are used on a single implant.

4.4 Wireless Power Transmitter Hardware

Figure 4 shows the wireless power transmitter used for powering the implant. It consists of a waveform generator generating 4 MHz sine wave which is fed into an 8 W power amplifier. The power amplifier has an output impedance of 10Ω . For maximum power transfer, the load impedance (transmitter antenna) must be equal to the output impedance of the power amplifier [13]. An L-network consisting of inductors and capacitors are used for impedance matching.

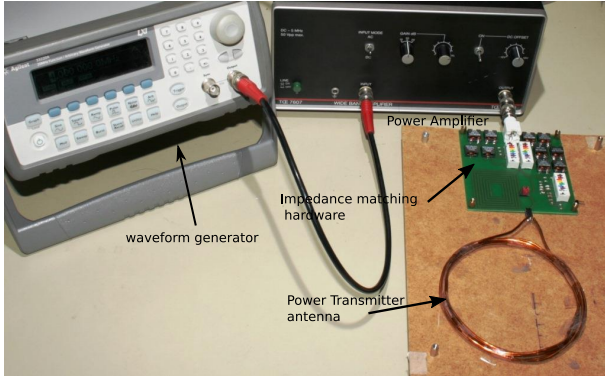


Figure 4. Wireless power transmitter hardware

5 Implant Test Results

5.1 Implant PCB

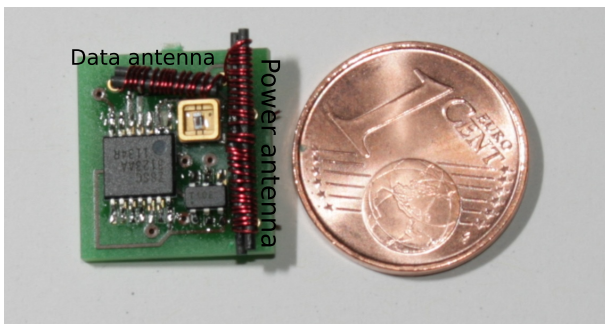


Figure 5. Test PCB of the implant

The implant circuit implemented on a PCB for testing is shown in figure 5. The power antenna is fabricated using four ferrite cores of $7.5 \text{ mm} \times 0.75 \text{ mm}$ and data antenna using two cores. The power antenna has an inductance of $3.18 \mu\text{H}$ with a Q-factor of 53 at wireless power transmission frequency of 4 MHz. Measured average power consumption of the implant is $600 \mu\text{W}$ and the peak power consumption is 1 mW .

When pin PB1=0 (SS=0), the wireless data transmission module is disabled and the microcontroller receives

pressure data from the CDC through SPI interface. For the time period when PB1=0, pin PB2 (SCL) generates the clock for SPI communication. When PB1=1, wireless data transmission module is enabled and PB2 acts as the data output of the microcontroller.

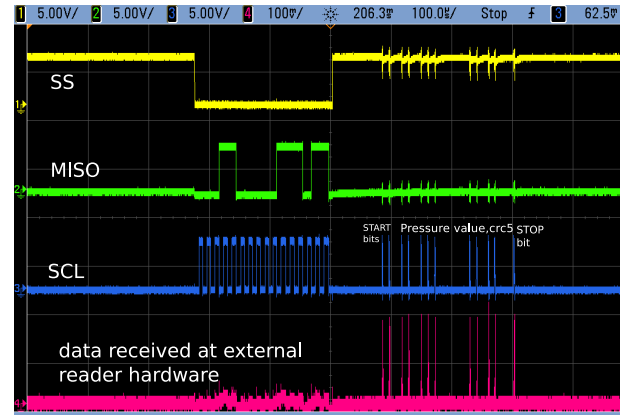


Figure 6. Data received at the external reader hardware, SPI interface, data packet output of the microcontroller

The SPI interface communication between microcontroller and CDC is shown in figure 6. The pin PB2 (SCL) is also used for transferring data packet from microcontroller to the wireless data transmission module. The pulse width of the data output of the microcontroller is chosen to be $1 \mu\text{s}$.

5.2 Wireless Data Transmission

When SCL is HIGH, transistor M2 is turned on and the inductor L2 starts storing energy until it is off. Since the resistance of the inductance is very low (around 0.1Ω), L2 draws high current, reducing the voltage level of the supply. The ON time of the transistor is chosen to be $1 \mu\text{s}$, so that L2 charging will not impact the proper working the implant. When M2 is turned OFF the inductor discharges, generating a spike of 20V (voltage at the drain of M2) as shown in figure 7. The external reader antenna is a loop antenna detecting these spikes to decode the transmitted data.

5.3 Pressure Sensor Test

The implant must have a pressure resolution of 1 mmHg for the given pressure range. In order to test the resolution of the pressure sensor, a wired test of the pressure sensor with CDC is conducted. During the test, the pressure sensor will measure variations in the pressure due to altitude. As altitude increases, atmospheric pressure decreases and vice versa. External influences on pressure measurement from other sources are prevented by placing the pressure sensor in an airtight chamber. The result of the test is shown in figure 8. The resolution of the sensor is approximately 0.5 mmHg which satisfies the application requirement.

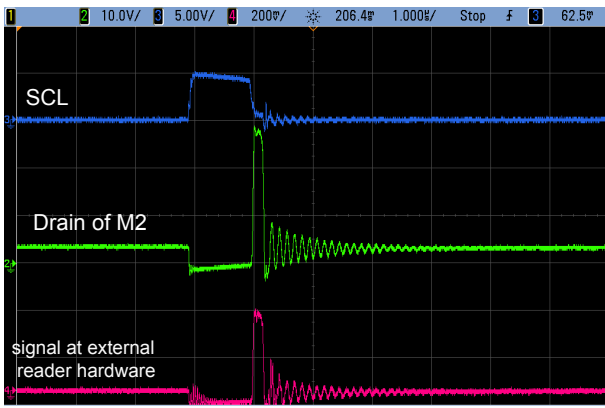


Figure 7. Data output, drain of transistor M2 and the signal received at the external hardware

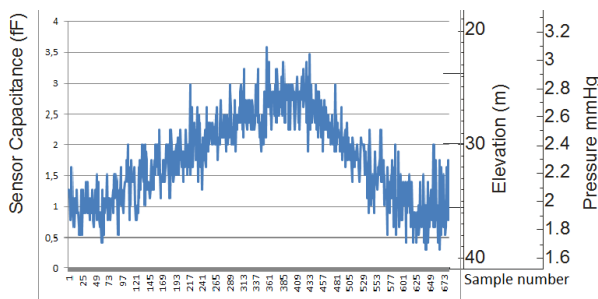


Figure 8. Measured results of the pressure sensor test

6 Conclusion

A blood pressure measuring implant has been implemented and tested to meet the requirements set for integration into a stent graft. The implant is programmed for transmitting 8 pressure samples per second while being powered using energy harvested through wireless power transmission. The power consumption of the implant is $600 \mu W$. The pressure sensor and the CDC have a resolution of 0.5 mmHg for the required pressure range. The implant is fabricated on a PCB and it is able to receive power for a distance of more than 5 cm. The designed implant meets the geometric dimension set by the system.

Acknowledgment

The authors acknowledge the support of this work by a grant from the Federal Ministry of Education and Research (BMBF, ESiMed [16 M3201D]).

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