BEHAVIOURAL ANALYSIS OF AN IMPLANTABLE FLOW AND PRESSURE SENSING DEVICE

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Abstract: This paper presents a simplified MatLab model of an implantable device for pulmonary artery blood flow velocity measurement. A comparative review of the most popular blood flow measurement techniques has been carried out, showing the better suitability of pressure-sensing approaches to provide useful information to cardiovascular diseases monitorization. Different possible grades of stenosis in the pulmonary artery have been simulated in order to obtain an early estimation of the device behavior under real conditions.

1 INTRODUCTION

The development of micro-electro-mechanical systems (MEMS), the continuous evolution in the miniaturization and integration of sensor structures and electronic circuits in the same chip, together with recent advances in the field of biocompatible materials have boosted the development of wearable implantable medical devices .

Blood flow measurement represents one of the most common procedures performed in hospitals for the monitorization of cardiovascular diseases. Recently, several implantable electronic devices with both flow sensing and wireless communication capabilities have been developed and tested, but their power consumption, dimensions and long-term reliability remain as unsolved constraints.

In this article, an initial model of a proposed pulmonary artery flow sensing device is carried out under several stenosed conditions. Section 1 presents the definition of intelligent stent (e-stent) and its impact on cardiovascular treatments. In Section 2, different methods for blood flow measurement, compatible with an implantable intelligent stent design, are described. A simplified model of an implantable device for pulmonary artery blood flow measurement, based on pressure sensing, is described in section 3. Different possible grades of stenosis in the artery are simulated and presented in order to obtain a first approximation of the device behaviour under real conditions.

2 INTELLIGENT STENT

A stent is a bio-compatible flexible tube, made of plastic or metal mesh, and designed to be implanted in the human body during an angioplasty procedure. A collapsed stent is mounted at the tip of the catheter and then expanded in the site of an arterial or venous blockage to push the vessel wall.

The impact of stents in modern cardiovascular medicine has been enormous, reaching about 70% to 80% of all percutaneous coronary interventions (PCI) (Lau, Johan, Sigwart and Hung, 2004), significantly decreasing the total number of acute complications in patients.

Unfortunately, the pressure applied by the inflated balloon during an angioplasty procedure can damage the vessel walls. Besides that, the patients' body can respond using physiological repair mechanisms, such as spasms, plaque deposition and smooth muscle cells proliferation. In-stent restenosis (ISR), defined as blood vessels narrowing due to neointimal tissue growth inside an implanted stent, keeps on being the major drawback in stent implantation, seriously compromising its long-term results. ISR has ratios from 10% to 70%, regarding the nature of the disease (Hoffmann and Mintz, 2000). The introduction a drug-eluting stents, coated with anti-proliferative drugs, has lowered the ISR ratio to nearly 10% at the expense of higher cost and long term reliability issues.

An intelligent stent (e-stent) that incorporates a sensor capable of monitoring and transmitting real-

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time measurements of biological related parameters for its clinical consultation can help to detect ISR. The monitoring function is carried out through an implantable sensor, which must fulfil certain characteristics, like reduced dimensions, output stability and reliability over an extended period of time without recalibration, minimal invasiveness and low power consumption and cost.

3 MEASUREMENT METHODS

Blood flow measurement is one of the most usual techniques for monitoring various types of cardiovascular diseases. There are three typical flow measurement approaches compatible with intelligent stent design, such as electromagnetic, ultrasonic and pressure-based measurements.

3.1 Electromagnetic Flow

The stents with electromagnetic flow measurement capability are based on a direct application of Hall-effect. This effect is produced when an electrically conductive fluid passes through an externally applied magnetic field with a certain angle. Then, the magnetic field exerts a transverse force on the charge carriers in the flow, creating a voltage difference perpendicular to the flow and to the magnetic field itself. The magnitude of the voltage measured by two diametrically opposed electrodes attached to the vessel walls, is given by (Webster, 1999),

$$V_{EM\_MAX} = D \cdot B \cdot v \cdot \cos\varphi \cdot \cos\theta \quad (1)$$

Where D is the diameter of the blood vessel, B is the magnetic flux density and v is the blood flow cross-sectional mean velocity. The angles θ and φ, represents the magnetic field alignment with the flow and the generated electric field.

Electromagnetic flow-meters must overcome some major drawbacks. First, a shift between the actual positioning of the electrodes and the desired diametrical line, due to a non-uniform expansion of the angioplasty balloon, produces significant deviations in blood flow measurements. Second, these architectures present a strong dependence upon the magnetic field orientation, so an efficient correction method is needed (Takahata and Gianchandani, 2006).

3.2 Ultrasound

Ultrasound flow measurement techniques are based on a direct application of Doppler Effect. This principle postulates that the frequency change between an emitted sound wave and the received one is proportional to the relative velocity between the sound source and the observer. Doppler equation can be applied to hemodynamic variables, like blood flow, using the following expression (Webster, 1999),

$$\Delta f = \frac{2 \cdot v \cdot f_T}{c} \cos\theta \quad (2)$$

Where v is the blood flow velocity, c is the propagation velocity of the sound waves through human body tissues, Δf is the Doppler frequency shift, f_T is the transmitted sound wave frequency and θ is the angle between the axis of the emitted sound wave and the direction of the blood flow.

This approach is the base for thoracic and esophageal Ecocardiogram, commonly used nowadays in hospital procedures.

Low frequency ultrasound waves present high tissue penetration and low measurement resolution, while high frequency ultrasonic waves have a better resolution but are only able to scan the surface of the tissue. This is why external ultrasound Doppler blood-flow meters are incapable to reach deep inside patient's body without sacrificing the degree of resolution in the measurements.

Devices bringing the ultrasound transmitter and receiver closer to the blood vessel can avoid the previous limitations, using an ultrasound frequency high enough to allow good resolution (Wang and Chen, 2011). However, it is necessary to overcome important physical constraints to make this device implantable. Among them we can point out the determination of the angle between the probe and the vessel and the amount of energy needed to generate the ultrasound waveform and to process the received signal.

3.3 Pressure

Blood flow velocity in an obstructed vessel can be expressed as a function of the pressure gradient between both sides of the stenosis. The general expression can be written as (Young, 1983),

$$\Delta P = R_1 \cdot v + R_2 \cdot v^2 + R_3 \cdot \frac{dv}{dt} \quad (3)$$

Where ΔP is the pressure gradient between two separate locations in a stented vessel, v is the mean

cross-sectional flow velocity in the unobstructed vessel and R_1, R_2 and R_3 are coefficients that depend on fluid properties and the geometry of the obstruction. R_1 represents losses due to fluid viscosity and it is directly related to the length of the stenosis. R_2 represents nonlinear losses due to the flow difference between downstream and upstream locations and it is determined by the relationship between the transversal un-stented area of the obstructed vessel and its total area. R_3 is related to fluid inertial effects, and can be neglected under circumstances of severe stenosis (Young, 1983).

The simplest implantable version of the pressure sensor is made of a capacitive MEMS to measure blood pressure, and an inductance to form the LC tank that transmits the information by proximity coupling (Takahata, Gianchandani and Wise, 2006). More elaborated systems incorporate electronic circuits to process the information within the chip to enhance the system performance (Chow, Chlebowsky, Chakraborty, Chappell and Irazoki, 2010).

A pressure-based measurement allows the integration of the sensor and the electronic circuits in the same silicon substrate, decreasing the overall cost of the system. The low energy requirements of its components help to reduce the system size since it can be powered by a wireless link. Moreover, this approach provides the absolute pressure in the vessel, providing additional information to carry out the ISR monitorization.

4 ELECTRONIC SYSTEM

A simplified model of an implantable device for pulmonary artery blood flow measurement based on pressure sensing is described throughout this section. Figure 1 shows the aforementioned model description, to be implemented in the mathematical program MatLab. Different possible grades of stenosis in the artery will be simulated, by varying R_1 and R_2 parameters, in order to obtain a first approximation of the device behavior under real conditions.

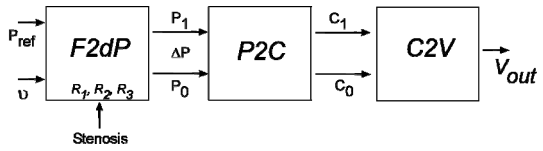

Figure 1: Simplified model of the electronic system.

The F2dP block performs the conversion from blood flow to differential blood pressure in the pulmonary artery using R_1 and R_2 parameters of eq. 3 to reflect the geometry of the stenosis. The parameter's values, as seen in Table 1, have been taken from medical research publications regarding the relationship between blood flow velocity and pressure gradient in stenosed coronary arteries (Marques, 2001). These values have been estimated in an indirect way, by applying the arteries pressure and blood flow measurements in the formula described in eq. 3. However, stenosis shape can also be correctly estimated with additional direct procedures, such as angiographies and intravascular ultrasonographies.

Table 1: Characteristics of the instantaneous flow velocity and pressure gradient relationship (Marques, 2001).

	R1	R2
Normal artery	0.032±0.018	0.00030±0.0049
Intermediate stenosis	0.15±0.11	0.0021±0.0014
Severe stenosis	2.67±1.58	0.0014±0.010

The F2dP block also takes into account the absolute pressure in the heart side of the stent, in order to provide two pressure waveforms whose values represent the magnitudes to be measured by the sensors placed at both sides of the stent. Figure 2 shows a simplified model of the device, focusing on sensor placement inside the stented artery; where P_o is the pressure in to the heart side of the stent and ΔP is the difference of pressure measured between both sensors.

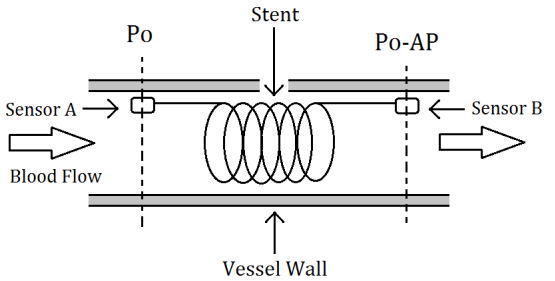

Figure 2: Sensor placement and measures.

The P2C module emulates the behavior of a capacitive MEM sensor, where the applied pressure produces a deformation in a diaphragm that reduces the chamber size, increasing the capacitance between the two-plate structure. Figure 3 shows a simplified cross-section of a MEMS capacitive sensor, based on a deflecting diaphragm and a fixed backplate; where P is the uniformly distributed pressure applied, w_o is the deflection of the diaphragm center, t_g is the undeflected gap between

the diaphragm and the backplate and t_m is the thickness of the diaphragm.

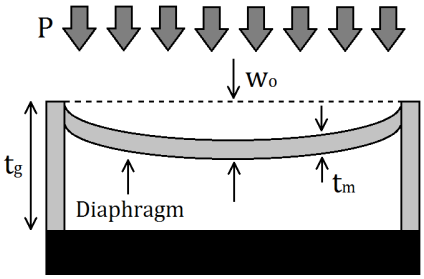

Figure 3: MEMS pressure to capacitance transfer function.

The general expression regarding the relationship between pressure and capacitance of a circular diaphragm-based MEMS capacitive pressure sensor can be written as (Chang, Lee and Allen, 2002),

$$C = \varepsilon_0 \frac{\pi a^2}{t_g}\left(1+\frac{Pa^4(1-\mu^2)}{16Et_m^{\,3}t_g}+\frac{9P^2a^8(1-\mu^2)^2}{1280E^2t_m^{\,6}t_g^{\,2}}\right) \quad (4)$$

Where ε_0 is the dielectric permittivity of free space and a, μ and E are the radius, the Poisson ratio and the elasticity modulus of the diaphragm, respectively.

The relationship between pressure and capacitance of the actual pressure sensor, with an average sensitivity of 9.1 fF/mmHg, is shown in Figure 4. It can be seen that its pressure range has been selected to fit the regular pulmonary artery pressures, which ranges between 15 to 30 mmHg during systole and 8 to 15 mmHg during diastole. Moreover, the sensor must be able to measure even higher pressure values, in order to be capable of detecting pulmonary artery hypertension caused by in-stent restenosis.

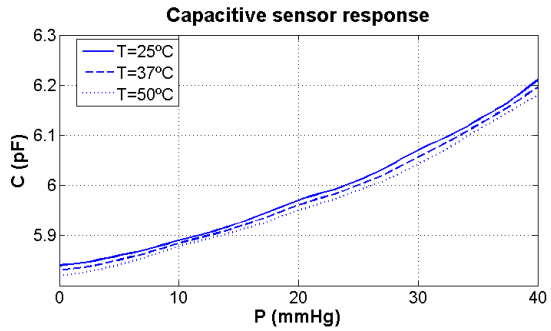

Figure 4: MEMS pressure to capacitance transfer function.

The last block C2V performs the conversion from MEMS' capacitance to an electric voltage, reflecting the difference between the two measured pressures and their absolute values. By this way, it is possible to monitorize both the artery pressure and the blood flow velocity, providing enough information to make an early restenosis diagnosis. The converter parameters have been selected to be similar to the ones common to this class of electronic circuits (Arfah, Alam and Khan, 2011), and its response can be seen in Figure 5.

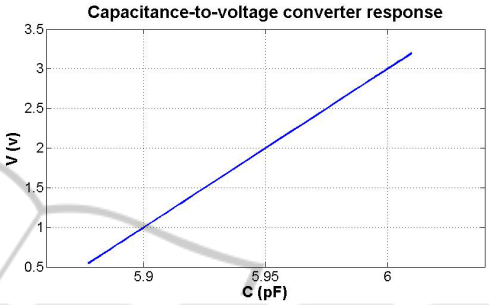

Figure 5: MEMS pressure to capacitance transfer function.

In this way, we can obtain a first approach to the behavior of the electronic system. Figure 6 shows the output voltage of the system (lower graph), reflecting the differential pressure at both sides of the stent when a blood flow signal (upper graph) and a blood pressure signal (center graph) are applied to a healthy artery (R_1=0.032 and R_2=0.0003).

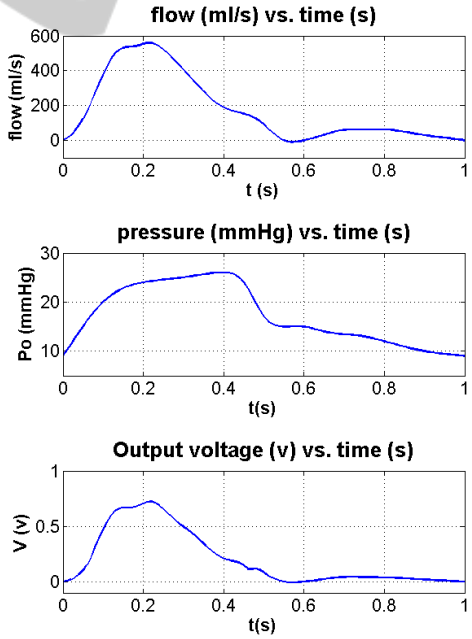

Figure 6: Output voltage reflecting the measured differential pressure under normal artery conditions.

This simplified model also allows to display the mean value of the output voltage of the system for different conditions of stenosis (R_1 and R_2 sweep)

when reference waveforms of blood flow and pressure are considered (Figure 7). As can be seen, higher R_1 and R_2 magnitudes produce higher pressure gradient along the stenosis, reflected in an increased output voltage. In a similar way, as expressed in eq. 3 formula, worse obstruction conditions produce higher pulmonary artery pressures, as expected according to medical reports about stenosed arteries (Rothman, Perry, Keane and Lock, 1990).

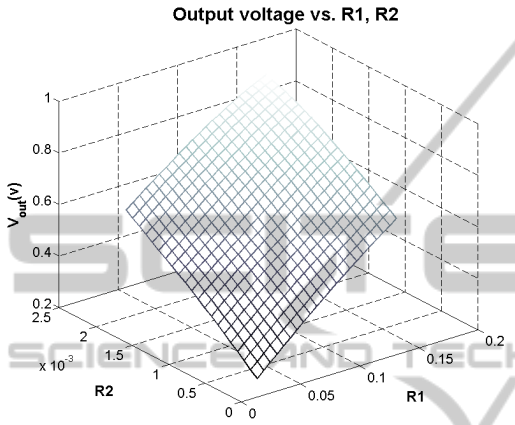

Figure 7: Output mean value of the system for R_1 and R_2 parameter sweep.

5 CONCLUSIONS

For the last forty years, several implantable electronic devices with flow sensing and wireless communication capabilities have been developed and tested, but their power consumption, dimensions and long-term reliability in such a hostile environment as human body remain as unsolved drawbacks. For this reason, a simplified model of an implantable device for pulmonary artery blood flow measurement based on pressure sensing has been developed. This kind of devices present some important advantages, such as its dual pressure and blood flow velocity sensing capabilities, together with an improved robustness and reliability compared with the rest of the analyzed measurement methodologies. Finally, different possible grades of stenosis in the artery have been simulated, by varying the obstruction geometry parameters between ranges reported by medical studies, in order to obtain a first approximation of the device behaviour under real conditions.

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