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Wireless Accelerometers for Early Detection of Restenosis

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Abstract

The goal of this paper is to use accelerometers as an early detection of restenosis. Restenosis (re-narrowing of the blood vessel) typically occurs within 3-6 months after the implantation of a stent. Finite element modelling of an occluded blood vessel showed that eddies along with an increase in velocity occur around the occlusion. In this paper a wireless accelerometer device was used to detect an occlusion. A human phantom model was used to mimic the wireless transmission capabilities of the system through human muscle ex-vivo. Fast Fourier transform results from the accelerometer showed that a non-occluded blood vessel had significant peaks >15 Hz, whereas an occluded blood vessel had peaks <15 Hz, which provides a signature template for detecting restenosis. The results of the FEM and human phantom experiments show that an accelerometer sensor is capable of detecting restenosis.

Keywords: Accelerometers, Stent, Restenosis, Wireless, Human phantom, finite element modelling

1. Introduction

Every year nearly one million patients are implanted with a coronary stent to help restore blood flow to a narrowed blood vessel caused by plaque buildup. The process of widening the lumen often results in damage to the blood vessel walls, which leads to an immune response. The immune response forces protein and cell adhesion to the stent. The major failure mode of coronary stents is restenosis, which is a re-narrowing of the blood vessel due primarily to an immune response. Restenosis can occur in two stages. The first stage typically occurs within the first couple of weeks, and is typically avoided by using drug-eluting stents. The second stage typically occurs 3-6 months after surgery, and is the result of proliferation of the cells on the blood vessel wall. A fatal outcome can occur if restenosis is not detected early.

Researchers have tried to develop devices to detect restenosis using pressure sensors on stents [1,2] along with several companies such as CardioMEMS. These devices include passive pressure sensors, which can only detect pressure. The presented work tests the potential capability of using

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accelerometers to detect restenosis. The advantage of using accelerometers is that it has the potential to detect velocity, stiffness of artery wall, and heart rate in addition to detecting restenosis. Packaging of the accelerometer is also an advantage, as cell adhesion to the sensor should not significantly affect the measurements. The hypothesis is that blood that flows through an occluded blood vessel will have an increase in turbulence or eddies which can be detected via the accelerometer. This paper presents finite element modelling blood flow through an occluded vessel, along with ex-vivo testing of the wireless accelerometer sensor through a human phantom model.

2. Materials and Methods

A finite element model (FEM) was developed to determine optimal positioning of the accelerometers and as a proof of concept of the hypothesis. A 2D model of pulsed blood flowing through a blood vessel was developed using COMSOL. The blood vessel, plaque, and blood properties used in the simulation were taken from [3]. Figure 1 shows a schematic of the model and the ex-vivo setup with accelerometer placement. The simulation assumed blood flow was Newtonian, and the pulsed flow was simulated using equation (1). Where P is the pressure at the inlet and P_{dia} and P_{sys} are the diastolic and systolic pressures, respectively, and ω is the frequency.

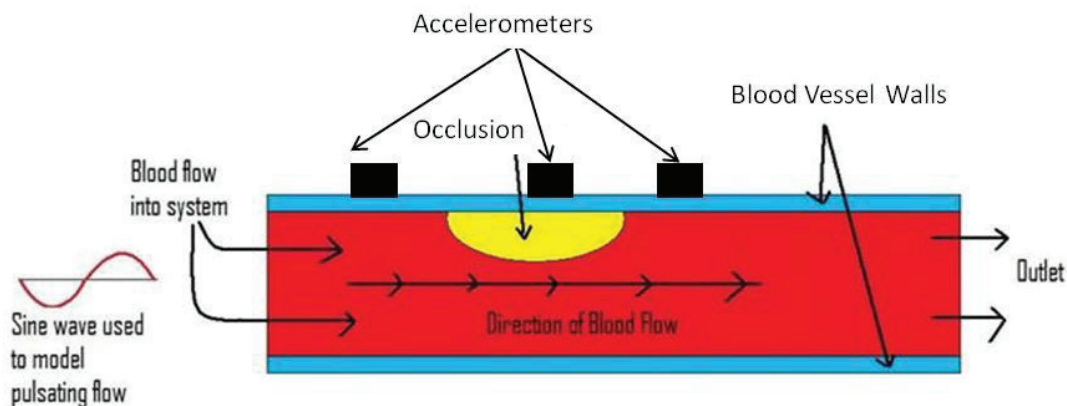$$P = P_{dia} + (P_{sys} - P_{dia}) * \sin(\omega t) \tag{1}$$

Figure 1- Schematic of the FEM simulation and ex-vivo setup. Blood flow is pumped through the artery walls with accelerometers placed before, on, and after the occlusion. The blood is simulated with a pulsed sine wave as shown in (eqn. 1).

The sensor and wireless system used in this paper consists of an ADXL330K (Analog Devices Inc) 3-axis accelerometer, along with a Tyndall Mote system [4]. The accelerometer is SMD bonded to a flexible cable, and the system is powered by Lithium-ion battery. All of the components used are off the shelf mounted on an FR-4 PCB. The current device is a proof of concept device and is not intended to be implanted, which will require minaturisation of the components, biocompatibility, and flexibility. The sensor and wireless system is shown in Fig 2(c).

The ex-vivo testing setup included a perfusion system shown in Fig (2a), which is used to circulate fluid through a tubing system. The perfusion system allows for varying pressure and beats per minute. The tubing used was soft silicone tubing with thin walls, and is typically used to mimic the mechanical properties of blood vessels in stent testing (Dynatek Dalta, MO USA). The tubing was filled

with artficial blood which has similiar viscosity, ion concentration, and particles to resemble RBC [5]. The occlusion was made of a rubber adhesive which adhered to the silicone tubing inner wall. The tubing went through a moulded silicone human torso (Fig 2b) with a cavity filled with modified ballistic gel (Gelita, Germany). The modified ballistic gel mimics the mechanical and electrical conductivity of human muscle (Fig 2d), and was used to determine if the data could be transmitted through the body. The accelerometer was placed on the tubing wall in three locations (before occlusion, on the occlusion, and after the occlusion). The data was wirelessly transmitted to a Labview program to be monitored and analyzed in real time.
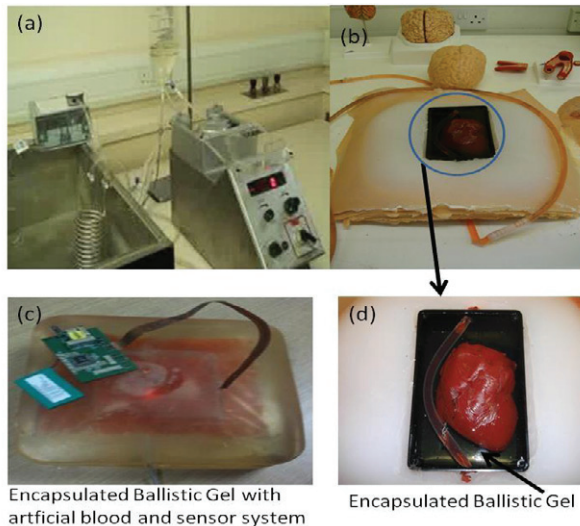

Figure 2- Micrographs of the testing setup. (a) shows the perfusion system, which circulates the artificial blood through the silicone tubes. (b) shows the human phantom, which includes the silicone tubing running through an open cavity of a moulded torso. (c) shows the receiving board encapsulated between ballistic gel and artificial blood, which is used test the ability of the system to transmit the data wirelessly through a human body. (d) shows a close up image of the tubing running through the ballistic gel.

3. Results and Discussion

The simulated FEM modelling results in Figure 3 show that during and after an occlusion there is an increase in velocity as well as an increase in turbulence as shown in Figure 3 (a and b) respectively. Figure 4 shows the results from the ex-vivo setup. Figure 4 (a) shows a sample of the raw data gathered from the accelerometer that was transmitted through the human phantom. The pulses are easily recognised, which allows for accurate heart beat monitoring. Fig 4(b) is the average pulse waveform detected before, on, and after the occlusion. Fig 4 (c) is the FFT of the the average pulsed waveform, which shows that on or after the occlusion have lower frequency peaks (<15 Hz) while accelerometers placed before an occlusion have peaks >15 Hz.

The results in this paper show that a wireless accelerometer is capable of early detection of restenosis. An ex-vivo test setup was successfully designed for future testing that includes implantable telemetry devices and fluid flow measurements. Future work will include minaturisation, powering mechanisms, biocompatibility testing, and in-vivo animal testing .
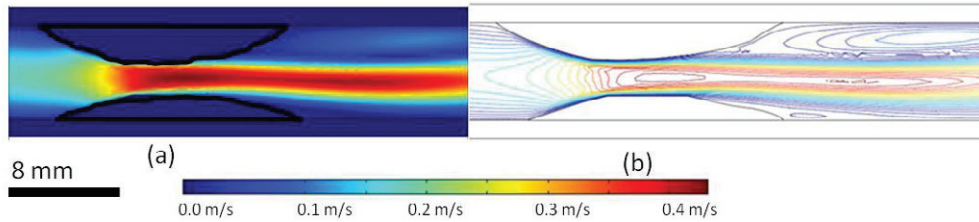
Figure 3- FEM simulation of pulsed blood flow through an artery. (a) shows the velocity of the blood before, during, and after an occlusion. (b) shows the eddies that are associated with blood flow through an occluded artery.
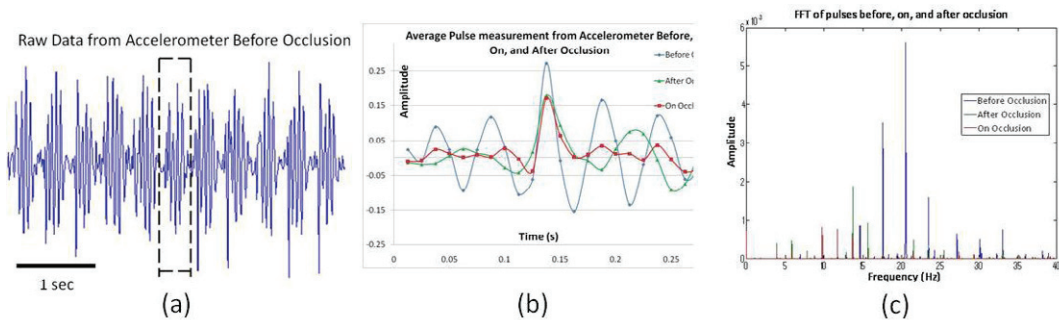

Figure 4- The results from ex-vivo accelerometer testing. (a) shows the raw data recieved by the accelerometer. (b) shows the average waveform of the pulses when the accelerometer is placed before, after, and on the occlusion. (c) shows the FFT graph of the average pulsed waveforms when the accelerometer is placed before, after, and on the occlusion.

Acknowledgements

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