Development of an Implantable Blood Flow and Pressure Monitor for Pulmonary Hypertension

SE Locke[1], TJ Gale[1], D Kilpatrick[2]

[1]School of Engineering, University of Tasmania, Hobart, Australia
[2]School of Medicine, University of Tasmania, Hobart, Australia

Abstract

We are developing an implantable blood flow and pressure monitor for pulmonary hypertension. Implantable haemodynamic monitors have been used to continuously measure pulmonary pressures in humans in a research setting. However there is currently no implantable haemodynamic monitoring device available that measures both blood pressure and flow. We aim to measure blood flow using the impedance technique from a catheter through the right ventricle. Initial experiments have been conducted in saline and blood to validate our experimental technique. Excellent agreement was found between theory and experimental results. A numerical model of the chest is being developed to develop an algorithm that calculates blood flow from impedance measurements. At a later stage we hope to use sheep to demonstrate the usefulness of the developed device.

1. Introduction

1.1. Pulmonary hypertension

The condition of pulmonary hypertension is the medical condition where there is unusually high blood pressure in the lungs and supplying artery (the pulmonary artery). This condition often leads to secondary conditions such as right heart failure and consequently has a very high mortality. Mechanisms involved include narrowing of the small blood vessels in the lungs, with obstruction of blood flow and the raising of pressures.

Current treatment is either with very expensive drugs or by lung or heart and lung transplantation. Treatment drugs aim to stop the increase in vascular resistance occurring in the small vessels in the lungs. To measure the vascular resistance accurately it is necessary to measure both the pressure in the pulmonary artery and the blood flow.

1.2. Implantable blood pressure and blood flow monitors

Implantable haemodynamic monitors have been developed to continuously measure pulmonary artery and right ventricular pressures in humans in a research setting. The pressure sensors, which are of piezo-resistive or capacitive type, are mounted on a catheter through the right side of the heart. The catheter is connected to a pacemaker-type control unit. The pressure sensors have been demonstrated to be reliable and accurate [1-5]. An external unit carried by the patient that monitors atmospheric pressure is needed to determine accurate pressure from implantable monitor data.

Pulmonary artery diastolic pressures may be monitored reasonably accurately from a right ventricle pressure transducer. The point of maximum rate of pressure development in each cardiac cycle has been found to coincide with the time that the right ventricle pressure is equal to the pulmonary artery diastolic pressure. This has been demonstrated in patients with heart failure [6, 7].

There is currently no implantable haemodynamic monitoring device available that measures blood flow. However implantable monitors (Medtronic) have been developed that incorporate a mixed venous oxygen sensor. These sensors have been demonstrated to be reliable and accurate [3-5,8]. These sensors are of limited use for blood flow monitoring since blood flow is also dependent on artery oxygen saturation and oxygen consumption. Implantable monitors cannot use injected indicator methods for measuring flow since indicator would have to be stored in the monitors. Implantable monitors have a small power source which ideally should last the rest of the patients life. This eliminates the potential to use heater thermodilution techniques for regular flow measurement by an implantable monitor.

Although a practical implantable blood flow sensor has not been developed, the technology for long term implantable monitors incorporating sensors on an

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attached catheter through the heart is mature. Heart pacing devices are used routinely in humans. It has been shown that catheterization has little effect on central haemodynamics [9].

1.3. Intracardiac impedance method for measuring blood flow

Impedance measurement is a technique routinely used in non-implantable systems monitoring the pressure-volume characteristics of the heart [10]. The impedance presented between electrodes on a catheter through the right ventricle is sensitive to the volume of the ventricle since blood is a better conductor than the surrounding tissue. Hence blood flow can be determined from changes in impedance between appropriately positioned electrodes [11-13].

1.4. Our approach

Since implantable pressure measuring technology is relatively mature, we are concentrating on the problem of measuring blood flow. The intracardiac impedance method potentially offers low power, low cost (simple catheter design and electronics) continuous measurement of blood flow. We aim to measure blood flow using the impedance technique from a catheter through the right ventricle.

2. Methods

2.1. Validation of experimental technique

Initial experiments have been conducted in saline and blood to validate our experimental technique of impedance measurement in blood. Electric potential measurements were made and compared with theory.

Within long square cross section perspex containers filled with saline and blood, a constant current was applied between two source electrodes and the potential difference was measured between two other electrodes. The geometry of the source and measuring electrode positions was varied. Saline, one of the main constituents of blood, was used in addition to blood since, unlike blood, its impedance may easily be calculated from literature. Detailed experimental method has been reported previously [14] .

The analytical solution for the electric potential inside an infinitely long, square cross section isotropic conductor containing a point current source and sink (electrodes) along the centre line as in Figure 1 was developed from first principles.

Let σ = conductivity of conductor and I_0 = current source/sink magnitude or electrode current. If the potential at the origin of the x, y, z axis is zero, then the electric potential V in the conductor can be shown to be given by,

$$V = \frac{I_0 z}{\sigma D^2}$$
$$+ \sum_{m=1}^{\infty} \frac{I_0}{2m\pi\sigma D} \cos\left(\frac{2m\pi y}{D}\right) \left(e^{-\frac{2\pi\left|z-\frac{L}{2}\right|}{D}m} - e^{-\frac{2\pi\left|z+\frac{L}{2}\right|}{D}m} \right)$$
$$+ \sum_{n=1}^{\infty} \frac{I_0}{2n\pi\sigma D} \cos\left(\frac{2n\pi x}{D}\right) \left(e^{-\frac{2\pi\left|z-\frac{L}{2}\right|}{D}n} - e^{-\frac{2\pi\left|z+\frac{L}{2}\right|}{D}n} \right)$$
$$+ \sum_{n=1}^{\infty}\sum_{m=1}^{\infty} \frac{I_0}{\sqrt{n^2+m^2}\pi\sigma D} \cos\left(\frac{2n\pi x}{D}\right) \cos\left(\frac{2m\pi y}{D}\right) \left(e^{-\frac{2\pi\left|z-\frac{L}{2}\right|}{D}\sqrt{n^2+m^2}} - e^{-\frac{2\pi\left|z+\frac{L}{2}\right|}{D}\sqrt{n^2+m^2}} \right)$$

for $-\frac{L}{2} < z < \frac{L}{2}$.

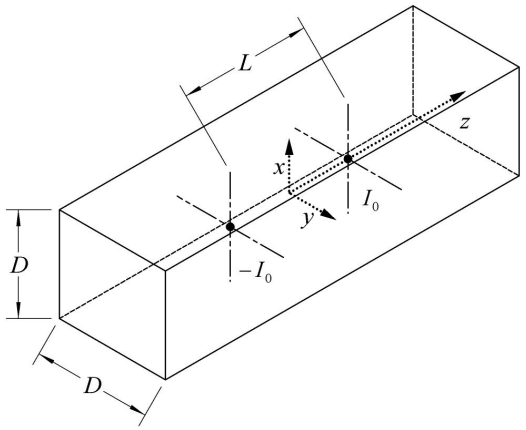

Figure 1. Infinitely long, square cross section isotropic conductor containing a point current source and sink (electrodes) along the centre line, used in the analytical model.

2.2. Device development methodology

Figure 2 shows how patient data is used in a finite element model to develop a database used to calculate flow from experimental measurements. Animal experiments have significant variability, are time consuming and costly. A numerical model allows fast, virtual experimentation in a controlled environment. Parameters (like blood impedance and catheter position) in the numerical model will be varied in coarse increments. Data (catheter electrode potential differences for different current source electrode combinations and current source frequencies, and stroke volume) will be interpolated between these coarse increments (at a density that corresponds to the probability of parameter variation) to create a database of measurement to stroke volume data. An algorithm will find the data in the database that is closest to the experimental input vector (input vector not further away from the experimental input vector in all variables than another input vector in the database) and determine an average stroke volume.

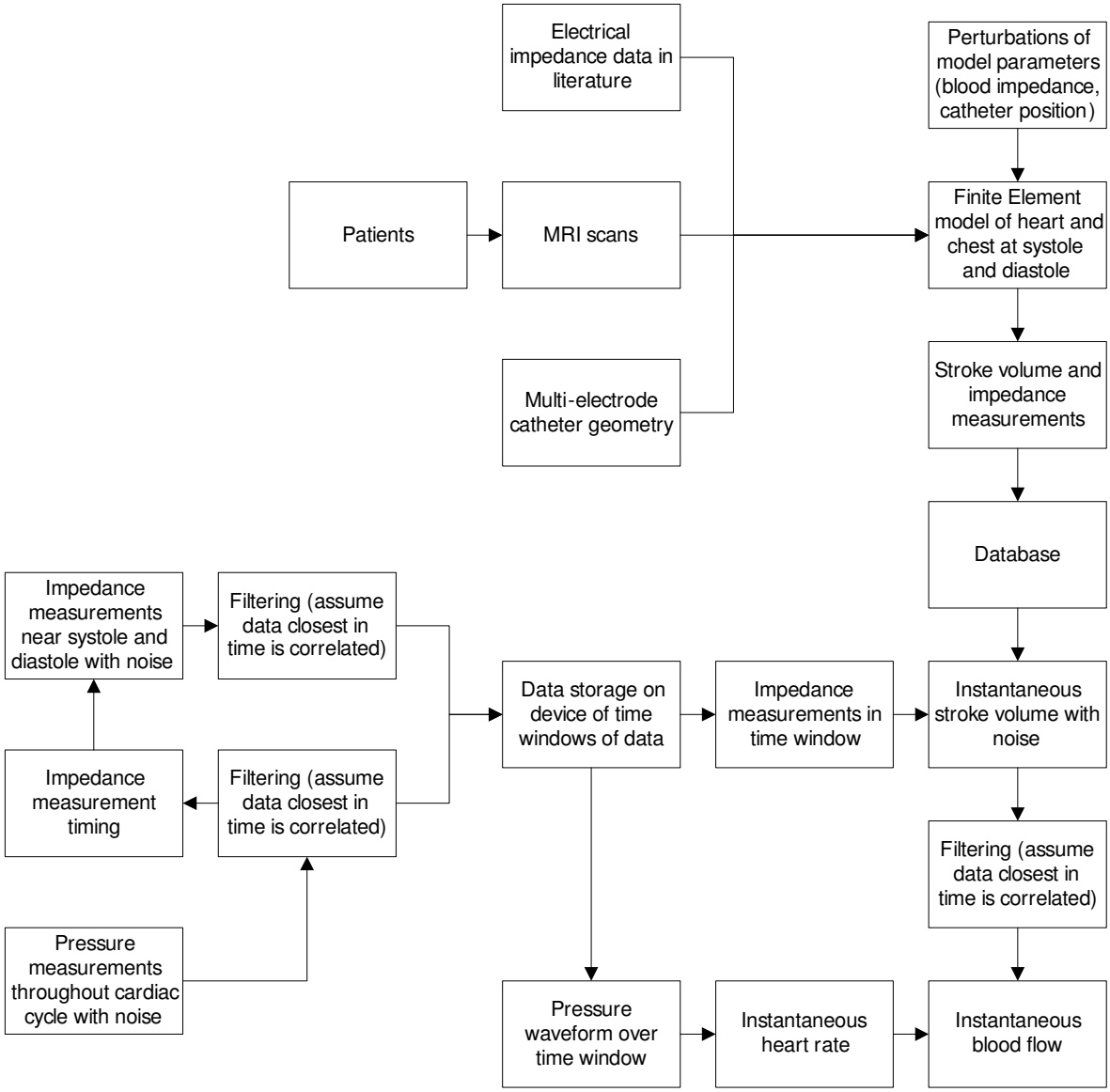

Figure 2. Device development methodology

3. Results

3.1. Validation of experimental technique

A plot of some of the results is shown in Figure 3. Notation is the same as that used previously. L = distance between source electrodes. L' = distance between measurement electrodes (which were symmetrically located between the source electrodes.) Detailed experimental results have been reported previously [14].

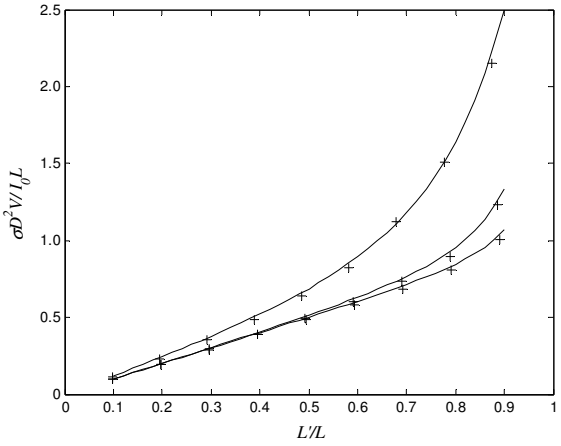

Figure 3. Non-dimensional experimental (cross) and theoretical (line) electric potential plotted against measurement electrode separation for saline in 100mm×100mm×550mm tube (from top to bottom: L = 103mm, L = 203mm, L = 303mm)

4. Discussion and conclusions

Excellent agreement was found between theory and experimental results and this confirms our ability to take accurate impedance measurements. This technique (using separate current source and measurement electrodes) will be used by our device to take impedance measurements.

Having established the methodology for developing the device the next stage is to complete the numerical model so we can apply our algorithm to determine blood flow from experimental measurements.

At a later stage we hope to use sheep to demonstrate the usefulness of the developed device. We have a model of the thorax of a sheep at one stage of the cardiac cycle to compare with our human models. We hope to compare measurements of flow using our algorithm to flow measured by ultrasonic transit time meters and thermodilution techniques.

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Address for correspondence

Simon Locke
School of Engineering, UTAS
GPO Box 252-65
Hobart, TAS 7001
Australia
slocke@utas.edu.au