SENSOR LETTERS
Vol. 5, 1–4, 2007

Magnetic Sensor for Early Detection of Heart Valve Bioprostheses Failure

G. Rivero[1,*], J. M. García-Páez[2], L. Alvarez[2], M. Multigner[1], J. Valdés[1], I. Carabias[1], J. Spottorno[1], and A. Hernando[1]

[1] *Instituto de Magnetismo Aplicado (RENFE-UCM-CSIC), P. O. Box 155, Las Rozas, Madrid 28230, Spain and Departamento de Física de Materiales, UCM, Ciudad Universitaria, Madrid, Spain*
[2] *Hospital Universitario Puerta de Hierro, San Martín de Porres 4, 28035 Madrid, Spain*

(Received: xx Xxxx xxxx. Accepted: xx Xxxx xxxx)

Heart valve bioprostheses usually do not need anticoagulation; however they are threatened by an increasing with time risk of degeneration. The aim of this work is to find a magnetic sensor, which could be integrated in a bioprosthesis, monitoring the prosthesis in such a way that allows to confidently forecast the failure. Several models of magnetic sensors have been tested in a hydrodynamic setup specifically manufactured, where the heart pressure, frequency, and cardiac flow were simulated. Small pieces of amorphous soft magnetic material were stuck to the cusps of a bioprosthesis, and through a carefully designed electronic system, the movement of the cusps is detected at the same time that the image of the working valve is captured by a digital camera. The small pieces placed in the valve are under an external applied field of few Khz, and the magnetization signal of the pieces is acquired by means of two series connected coils. The movement of the pieces, at a cardiac simulated rhythm, induces a modulation in the amplitude of the signal detected in the secondary coils, with the same frequency as the valve movement. The modulated signal is analysed with a system consisting of an amplifier and a synchronous demodulator. The analysis of the electronic signal together with the image allows characterizing the signal changes when the valve begins to fail, preventing the bioprosthesis functional failure.

Keywords:

RESEARCH ARTICLE

1. INTRODUCTION

During the last century, life expectancy in our planet has experienced a remarkable increase, if we exclude those regions ravaged by war conflicts and those others in which the population lives (more likely survives) under conditions that we shouldn't tolerate. In Europe this increment has been spectacular, with an average life expectancy that reaches 80 years old among men population and some more for the women population and with a tendency to grow.

This increase of the life expectancy presents an important sanitary problem: our bodies aren't, in average, ready to work for such a long time without reparations and/or replacements.

As a consequence, the so called substitution surgery takes an increasing percentage of the total interventions in current hospitals: bone prostheses for the hip, knee and teeth, eye and ear implants, artificial sphincters and penis, and the one that has given birth to the work that we present here: Artificial heart valves.

A native heart valve is submitted during its "*in vivo*" working to millions of opening and closing cycles, in order to provide the organism the cardiac performance needed for its survival. So it isn't rare that an always increasing percentage of the population needs to replace one or more valves with a mechanical or biological prosthesis, and, in some cases more than once.

For instance, in the Spanish Society of Cardiovascular Surgery Registry for the year 2002 which includes data from 56 hospitals, a total of 30,700 patients are portrayed. The number of valve prostheses implanted was 9,269, almost 35% of which were biological ones. In contrast, during the same period of time, in Spain, a pioneer country in transplant surgery, only 310 heart transplants were registered, which means a 1.5% of the total amount of cardiac interventions.[1] These percentages are similar to those of other European countries.

*Corresponding author; E-mail: grivero@adif.es

1546-198X/2007/5/001/004
doi:10.1166/sl.2007.086

Biological heart valves, currently made with calf pericardium, have a similar shape to that of the native ones and better hemodynamic conditions than the mechanical ones. Moreover they have the advantage of not needing the patient to be submitted to a life-long treatment with anticoagulants, as happens with the mechanical valves. This treatment is practically impossible to carry out in underdeveloped countries and, in any case, entails a permanent risk for the patients. Nevertheless, biological cardiac valves, or bioprostheses, carry the inconvenience of its limited durability (about ten years by average) and, which is more troublesome, with an important dispersion around the average that may be estimated in plus/minus three years.[2–4]

These bioprostheses present several failure causes, in a similar way to the native ones and many are the factors that can contribute to its deterioration. The most important ones are the biochemical degradation and the mechanical damage of the tissue. The mechanical fatigue is generated due to the great number of opening and closing cycles (approximately 30 millions a year) the valve is submitted to. Their effects are cumulative, and are expressed by lineal ruptures and/or perforations.[2]

Other common causes of failure are the calcium, cholesterol and/or amyloidal sediments. The calcium sediments are the most important ones and are developed in an especially fast way in kids and young adults. These sediments increase the cusps stiffness even getting to join in some cases its commissures, restraining the movement of the valve opening and closing.[2]

This means an important uncertainty about the time when it is convenient to make the replacement of the valve, being established an undesirable competition between the risk for the user of getting it done too late and the economic pain for the Social Services if it is carried out unnecessarily early.

Some time ago we thought that this problem could be solved by the implantation in the bioprostheses of a magnetic sensor, that allowed to carry out a continuous test, non invasively, of the movement of the valve cusps, so detecting their progressive damaging and providing the physicians objective data for proceeding to the substitution of the valve at the right time.

2. PRINCIPLES OF SENSOR OPERATION

The sensor that has been developed is based on the detection of the movement of small samples of soft magnetic material, joined to the valve cusps.

The valve is submitted to an excitation electromagnetic field of a frequency ranging from a few tens of Hz to tens of MHz, depending on the magnetic material used and its morphology (Fig. 1).

Different magnetic materials have been assayed: amorphous ribbons and wires made by melt spinning and amorphous microwires made by rapid quenching.

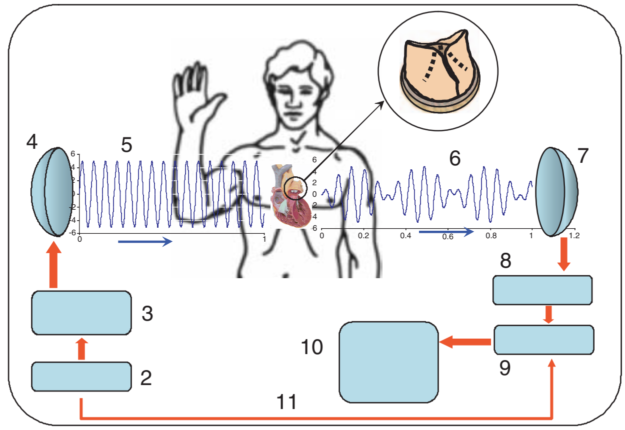

Fig. 1. Scheme of sensor operation: (1) biological valve, (2) wave generator, (3) power amplifier, (4) emitter, (5) carrier, (6) carrier modulated by the cusps movements, (7) receptor, (8) signal amplifier, (9) synchronous demodulator, (10) data acquisition, (11) synchronization generator—demodulator.

In Figure 2 we show, as an example, an image of the magnetic ribbons integrated in the valve.

The movement of the cusps, and of the magnetic elements joined to them, brings a signal of the frequency of the exciting magnetic field, modulated by the magnetization and the ensuing energy absorption of these magnetic elements, as it is sketched in Figure 1.

A very important point is that the magnetic elements integrated in the cusps don't interfere in the normal working of the valve. The performed tests show that to ensure this topic each element's mass shouldn't be higher than a few micrograms and its section must be of 10^{-8} m^2 or lower.

On the other hand the material must be biocompatible or be coated by a biocompatible material.

The best results have been obtained using as magnetic element an amorphous Fe based microwire, made by the Micromag firm. This microwire has a diameter of 20 μm and is coated in the same fabrication process by a glass layer to a total diameter of 45 microns and presents

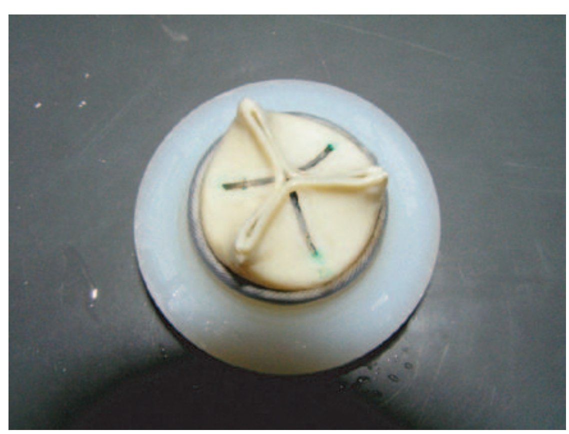

Fig. 2. Arrangement of magnetic elements.

remarkable advantages against other materials:[5]
(a) They can be integrated in the cusps without the usage of biological glues.
(b) They don't diminish the cusps flexibility, nor do they change its mass in an appreciable way due to its minimum size.
(c) They are coated, during the process of fabrication itself, by a biocompatible glass, so facilitating its integration.
(d) Despite its reduced size the magnetic signal obtained is comparable to that obtained with the other models.
(e) Its high shape anisotropy (10 mm × 45 microns) together with its high magnetic susceptibility allows to remarkably reduce the energy expense needed for the sensor working.

The dysfunctions produced in the movement of the cusps during the opening and closing of the valve, due to degradation, hardening or rupture processes, provoke a change in the modulated signal, which is monitored versus the signal obtained in the standard working conditions. The comparison between both signals may allow the medical services to establish precisely the moment when the valve must be replaced. All that may be done wireless, without needing to implant in the patient any electrical or electronic device of detection or transmission, or to establish any type of material bonding of the valve to the patient.

3. EXPERIMENTAL TECHNIQUES

In order to check *in vitro* this idea, a hydrodynamic setup (Fig. 3) was designed and developed that allowed us to submit the valves to similar flux and pressure regimes, as far as possible, to the ones they suffer *in vivo*. The flux through the valve has been simulated by a DC motor and a programmable controller which is forced to follow the real curve of flux of a standard heart. The maximum systolic and diastolic pressure have been fixed around the typical values (14 and 8 cm Hg, respectively) adjusting the impedance and the pressure of the input and output circuits of the hydrodynamic setup. The assays have been made using cardiac rhythms ranging from 60 to 80 pulses by minute.

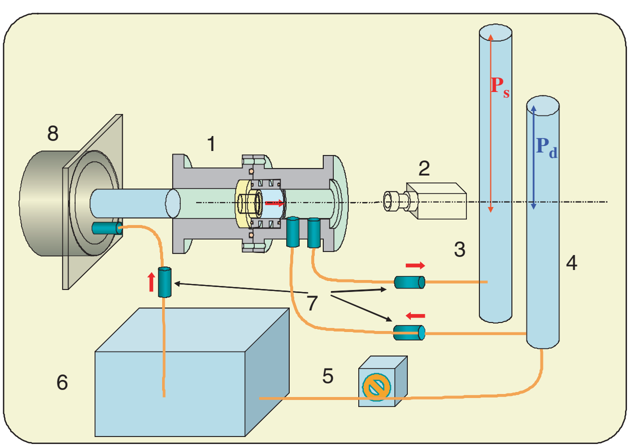

Fig. 3. Experimental set-up: (1) valve seat, (2) digital camera, (3) systolic pressure control, (4) diastolic pressure control, (5) peristaltic pump, (6) saline solution, (7) one way valves, (8) pneumatic cylinder.

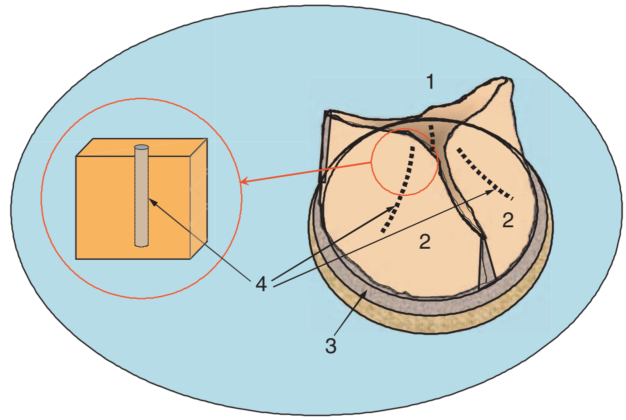

Fig. 4. Detail of microwire arrangement. (1) Valve, (2) cusps, (3) elastic structure, (4) microwires.

A commercial model of mitral valve (made of calf pericardium as biological tissue) from Mitroflow has been used. In each one of the cusps of this valve prosthesis a magnetic microwire was inserted parallel to the cusps surface and in a position close to the flexion neutral fibber of these cusps, so that the magnetic microwire stays completely inside of the biological tissue, as is represented in Figure 4. This system eliminates the necessity of using fixing elements such as glues or sutures that negatively affect the movement of the cusps.

For the tests we used an electromagnetic wave of frequency 2 KHz generated in a conventional way by the combination of a wave generator, a power amplifier and an exciting coil. The detection of the modulated transmitted signal was made using two series connected coils, an amplifier and a synchronous demodulator for extracting the information (Fig. 1).

The setup has a digital camera that enables us to take images of the movement of the cusps synchronised with the acquired electromagnetic signal, so letting us to correlate the amplitude and shape of the signal with the movement of the cusps.

The electronic system is a complete measurement acquisition and control system customized by SEEK Image & Motion S.L. The system, built to meet the specific requirements of the experiments, consists of different subsystems, DDS (Direct Digital Synthesis) Carrier generator with programmable phase reference signal, a low noise 4 nV/sqrt (Hz) input stage with 120 dB CMRD (Common Mode Rejection Ratio), a commutating synchronous demodulator, a 12 bit 100 Ksps ADC (Analog to Digital Converter) and a DSP (Digital Signal Processor) to perform the oversamplig and filtering of the input signal.

RESEARCH ARTICLE

These subsystems has been linked together through a CAN (Controller Area Network) 2.0 Network. This allows for an easy and fast addressing of the different modules for configuration from a host computer, which is used as an experimenter console and as the main storage device. Image capturing and camera control runs on a separate IEE1394 communication channel allowing full 640×480 RGB frame acquisition at rates up to 30 frames per second.

4. EXPERIMENTAL RESULTS

The assays with each valve begin normally with the following sequence: recording of the working of the untouched valve, registration of the electromagnetic signal and simultaneous recording of the working of the valve with a microwire integrated in one of the cusps, the same with two and three microwires integrated in two or three different cusps, simulation of different damage stages of the valve and registration of the electromagnetic signal together with simultaneous recording of the working of the valve in each stage.

The experimental results obtained in these tests have fully confirmed the initial hypotheses, about the detection of the movement of the cusps of the bioprostheses in the cyclic process of opening and closing. The signals, simultaneously registered to the image of the valves during its working, lets us to perfectly distinguish the changes in the movement of the cusps, due to the artificially introduced defects.

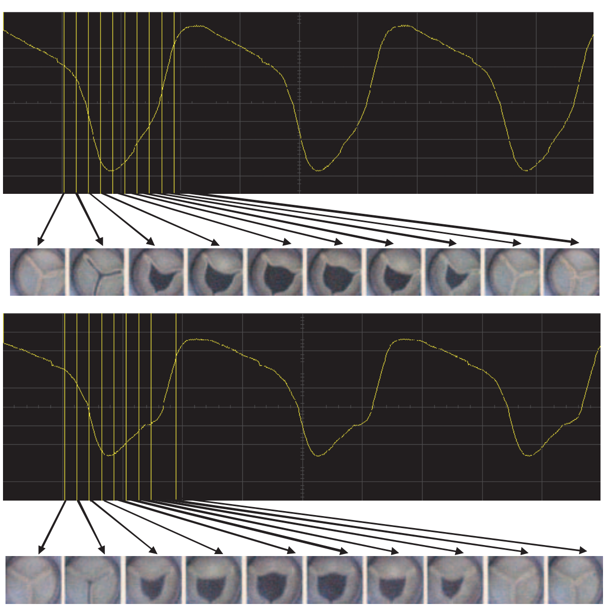

Fig. 5. Electrical signal (2 μV/div) and corresponding synchronous images registered from the valve undamaged (top) and with a slightly glued commissure (bottom).

Figure 5 shows the signal and synchronous images registered from the valve undamaged with three microwires, versus the same valve with a typical damage made by joining slightly the commissures between two cusps using biological glue. A change both in the amplitude and in the slope of the curve can be appreciated.

5. CONCLUSIONS

A high sensibility system has been developed for noninvasively detect the dysfunctions that occur in a biological prosthesis of a heart valve. The detection is carried out registering the changes in the movement of very small pieces of magnetic material (glass coated Fe-based microwire) integrated in the cusps of the valve, without modifying the normal operation of the valve. The emissor/receptor system of the electromagnetic signal allows a wireless detection of the movement of the magnetic elements, external to the patient's body.

An experimental setup has been built for simulating the pressure and flux conditions in a heart valve, that in addition allows us to simultaneously and synchronously register the movement of the heart valve and the electromagnetic signal linked to that movement.

The assays show that the developed sensor is able to detect progresive damaging in the bioprosthesis of the valve. The experimental setup together with the sensor could be a useful tool for the research of the causes that provoke the chemical and mechanical degradation of the bioprosthesis.

Furthermore, these results lead us to think of a future development in order to get a sensor that could be used for patient monitoring both at hospital and home environments.

Acknowledgments: This work has been supported by Consejería de Educación of Comunidad Autónoma de Madrid by the project CAM/GR/MAT/0492.

References and Notes

1. A. Igual and E. Saura, Registro de Intervenciones de la Sociedad Española de Cirugía Cardiovascular, *Cir. Cardiov* 11, 97 (**2004**).
2. N. T. Kouchoukos, E. H. Blackstone, D. B. Doty, F. L. Hanley, and R. B. Karp, Kirklin/Barratt-Boyes Cardiac Surgery, 3rd edn., Churchil Livingstone, Philadelphia (**2003**), pp. 554–656.
3. A. Nötzold, M. Hüppe, C. Schmidtke, P. Blomer, T. Uhlig, and H. H. Sievers, *J. Am. Coll. Cardiol.* 37, 1963 (**2001**).
4. W. R. E. Jamieson, O. von Lipinski, R. T. Miyagishima, L. H. Burr, M. T. Janusz, H. Ling, G. J. Fradet, F. Chan, and E. Germann, *J. Thorac. Cardiovasc. Surg* 129, 1032 (**2005**).
5. P. Marín and A. Hernando, Enciclopedia of Materials: Science and Technology, edited by K. H. J. Buschow, R. W. Cahn, M. C. Flemings, B. Ilschner, E. J. Kramer, S. Mahajan, and P. Veyssière, Elsevier, Oxford (**2004**), pp. 1–9.