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Sensor system for early detection of heart valve bioprostheses failure☆

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Abstract

Heart valve bioprostheses usually do not need anticoagulation; however, they are threatened by an increasing 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: Bioprosthesis; Microwire; Magnetic sensor

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 should not 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 are not, 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 is not 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

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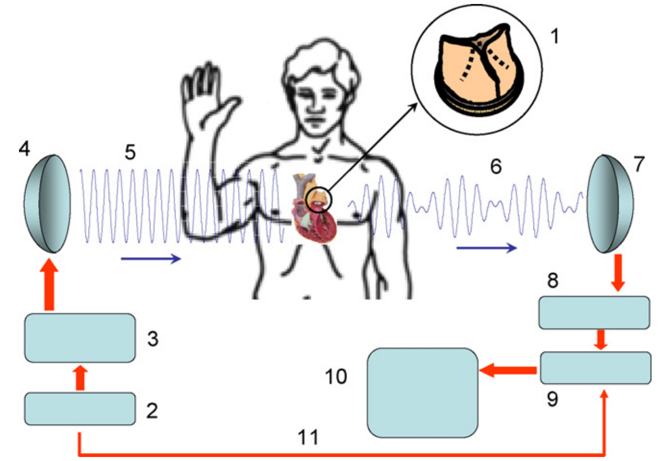

Fig. 1. Scheme of sensor operation: (1) biological valve, (2) wave generator, (3) power amplifier, (4) emitter, (5) carrier, (6) carrier modulated by the cusps movements, (7) receptor, (8) signal amplifier, (9) synchronous demodulator, (10) data acquisition and (11) synchronization generator-demodulator.

of valve prostheses implanted was 9269, 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.

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 that the patient needs not 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 10 years by average) and, which is more troublesome, with an important dispersion around the average that may be estimated in plus/minus 3 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 linear 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.

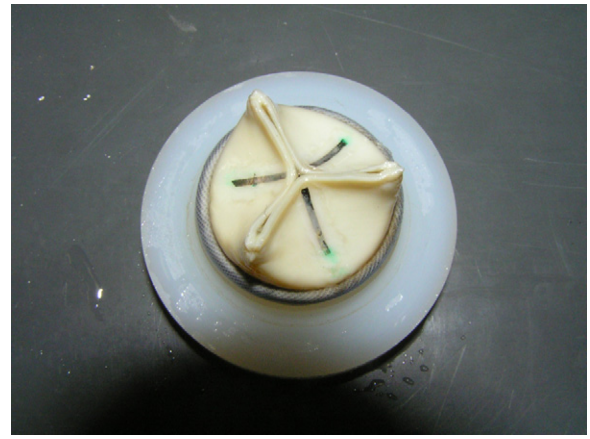

Fig. 2. Arrangement of magnetic elements.

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 soft magnetic materials [5] have been assayed: amorphous ribbons and wires made by melt spinning and amorphous microwires made by rapid quenching.

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

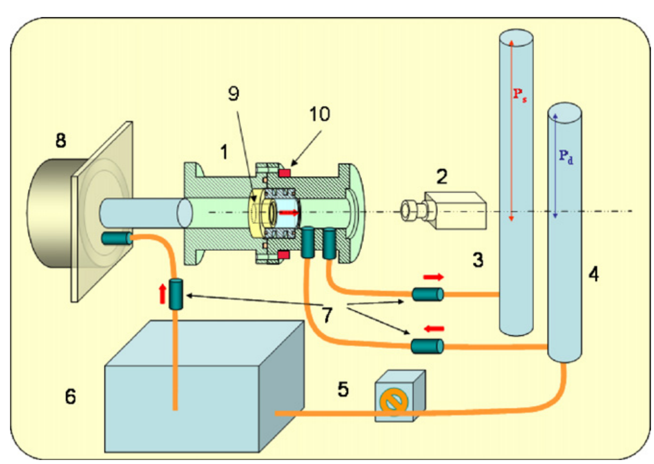

Fig. 3. Experimental setup: (1) valve seat, (2) digital camera, (3) systolic pressure control, (4) diastolic pressure control, (5) peristaltic pump, (6) saline solution, (7) one-way valves, (8) pneumatic cylinder, (9) assessment of valve and (10) exciting and detection coils.