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Biocompatible packaging of an epicardial accelerometer for real-time assessment of cardiac motion

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Abstract

An implantable accelerometer has been developed to monitor the cardiac function and the heart wall motion. The device, to be stitched on the pericardium, can also provide an insight on amplitude and frequency components of the acceleration on different locations on the heart. A commercially available three-axis accelerometer was mounted on a miniature PCB and coated with Parylene-C. The PCB was glued on a laser-cut Teflon structure and then embedded in PDMS. The structural flexibility of the assembly allows the device to adapt to the natural curvature of the muscle and to stretch, therefore not limiting the natural movement of the underlying tissue. The device was tested in-vitro for current leakage and water diffusion. The in-vivo performance was evaluated by recording acceleration signals from the heart of a sheep.

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Keywords: Epicardial; Accelerometer; Heart motion; Biocompatible packaging, Parylene.

1. Introduction

Monitoring of the cardiac contractions is desired in a number of applications. Observation of the epicardial acceleration signal during and after coronary bypass can allow early detection of graft occlusion and myocardial ischemia [1]. Advanced heart failure patients with a ventricle assist device (VAD) can sometimes recover sufficiently to allow explantation of the pump. In those patients, continuously monitoring acceleration can provide information on

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the recovery of cardiac function and contractility [2]. The information on the intrinsic cardiac activity can also be used in rate-responsive pacemakers to modulate the pacing rate, based on the effective requirement of the patient [3-4]. Moreover, in pacemaker technology, the acceleration data can also provide a feedback on the motion of the heart in response to the electrical pacing stimulus. And finally, the detailed mapping of the acceleration on the heart muscle is of paramount importance for efficient placement of mechanical harvesters that collect energy from rhythmic vibrations of the heart to power small implants.

We have previously presented a device for acquisition of acceleration signals from the inner cardiac wall [5], this work proposes the assembly and packaging of an epicardial accelerometer to retrieve acceleration signals from the outer heart wall.

2. Biocompatible packaging strategy

A commercially available 3-axes digital accelerometer from Bosh Sensortec (BMA-280) was mounted on a circular PCB with a diameter of 3.2 mm and four wires were soldered on the back of the board. The device was then coated with 5 µm of parylene-C. Thanks to a chemical vapor deposition process, and its low permeability to water, Parylene provides a conformal insulation layer that protects the electronic from the aggressive body fluids. The PCB was fixed on a 1 mm thick laser-cut Teflon support using the biocompatible epoxy EPOTEK 302-3M. (Fig. 1).

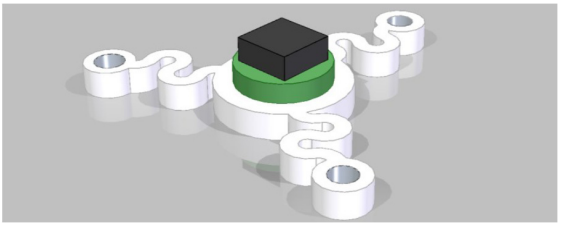

Fig. 1. Artist view of the sensor, with the Teflon support, before packaging. 3 suture holes are provided

The same adhesive was used to globe-top the sensor, offering additional protection from water diffusion. Finally, a soft encapsulation in medical grade PDMS (NUSIL MED-6015) was fabricated around the device. Three Teflon rings allow stitching of the sensor on the cardiac wall. The stitching offers a trustworthy fixation that minimizes self-motion of the sensor, while the wavy profile of the Teflon ‘legs’ allows the device to adapt to the natural curvature of the heart and to stretch during the filling phase, without hindering the natural movement of the underlying tissue. An alignment mark on the Teflon ring indicates the positive y-axis and, during surgery, allows the physician to position the accelerometer according to the relevant cardiac coordinate system. Fig. 2 illustrates the sensor assembly with its different packaging layers.

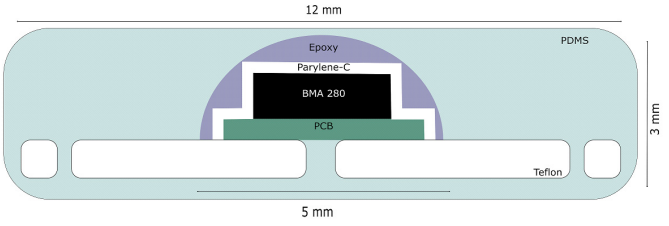

Fig. 2. Transversal section of the sensor, illustrating the different packaging layers.

3. Device testing and validation

The epicardial accelerometer is specifically designed to be used in conjunction with an endocardial sensor described elsewhere [5]. Fig. 3 gives a top level schematic of the electronic system used to readout both devices. The digital data collected from a maximum of four different accelerometers is simultaneously recorded, through wired connections,