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.

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 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.

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).

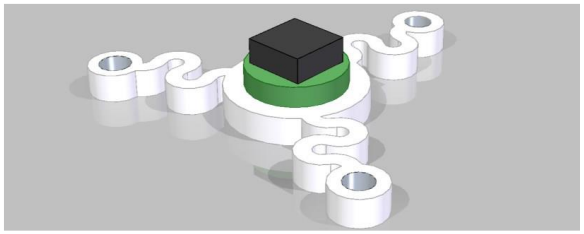

Fig. 1. Artist view of the sensor, with the Teflon support, before packaging. 3 suture holes are provided

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.

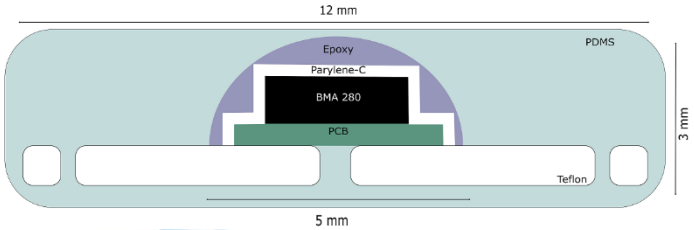

Fig. 2. Transversal section of the sensor, illustrating the different packaging layers.

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, from a microcontroller (Texas Instruments CC430F5137) on an extracorporeal battery powered test board. One ECG derivation is also recorded from a biopotential amplifier (Texas Instruments ADS1292), and allows to align the acceleration signals with hemodynamics data from other acquisition systems.

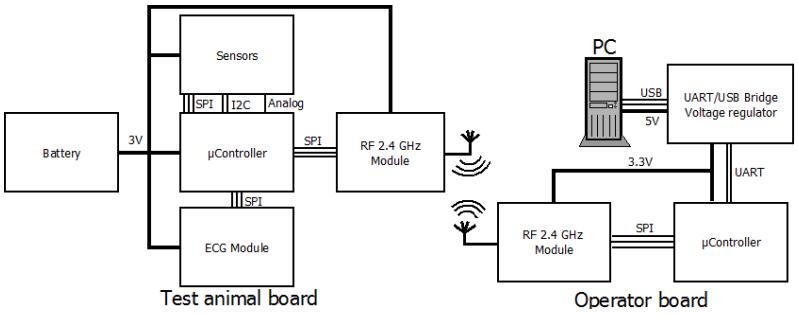

Fig. 3. Block diagram of the readout system

The acquired data is wirelessly transmitted over a bi-directional RF link functioning at 2.4 GHz (Nordic nRF24L01+). An operator board, powered by USB, receives the wireless data and transmits it, over a UART to USB bridge (FTDI FT232R), to a PC.

The functionality of the device was first tested in-vitro by soaking it for a week in saline solution 0.9% at 37°C to mimic the body environment. Using the readout board described above, data was continuously logged on a calculator.

At the same time the current leaking through the packaging layers was picked up by a graphite counter electrode submerged in the saline bath and measured by a sourcemeter (Keithley 2400). Over the measured time span the leakage current remained always lower than 1 µA, well within the limit imposed by European standards for direct cardiac application (10 µA).

The in-vivo functionality of the implantable accelerometer was tested by recording accelerations from the heart wall of a ewe. In order to compare the signals recorded from the epicardium and the endocardium, an endocardial accelerometer (Fig. 4a) was introduced through the heart wall, in close proximity of the epicardial.

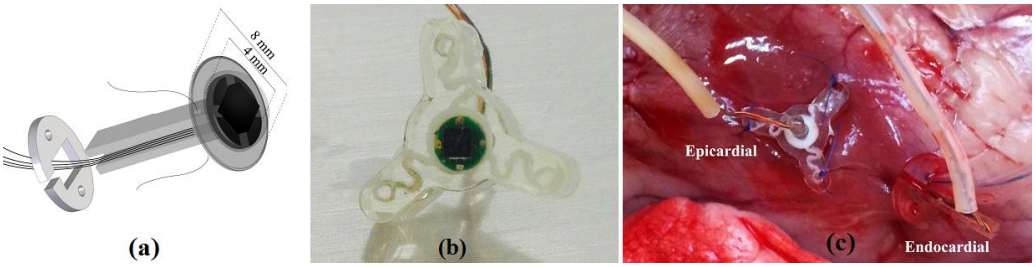

Fig. 4. Endocardial (a) and epicardial accelerometer before (b) and during (c) implantation on the cardiac wall of a sheep.

After sedation with intramuscular ketamine 15 mg/kg, anesthesia was induced and maintained with isoflurane. Several parameters were continuously monitored throughout the study: respiratory volume and frequency, ECG, heart rate and blood O2 saturation were measured, but also peripheral arterial, carotid arterial, central venous and right ventricular blood pressure together with pulmonary arterial flow and pressure. After positioning of all hemodynamical sensors, a sternotomy was performed. First, the endocardial accelerometer was implanted in the right ventricular free wall of the animal: a purse suture was performed, and the sensor was pushed through a hole pierced in the center of the suture. After securing of the endocardial, the epicardial accelerometer was fixed on the outer right ventricular free wall by means of three stitches. Fig.4b and Fig4c show the device before and during testing. Using the provided marks, both sensors were aligned with each other and to the cardiac axes. To validate the data acquired by the accelerometers, reference echocardiography records (Vivid 7, GE) were simultaneously recorded during testing. A plot of a four second window of acceleration data is given, after DC filtering, in Fig.5a for both endocardial and epicardial accelerometers. Fig. 5b shows the main components in the spectrum of frequencies of the acceleration signal obtained, in MATLAB, by Fast Fourier Transform computation (FFT).

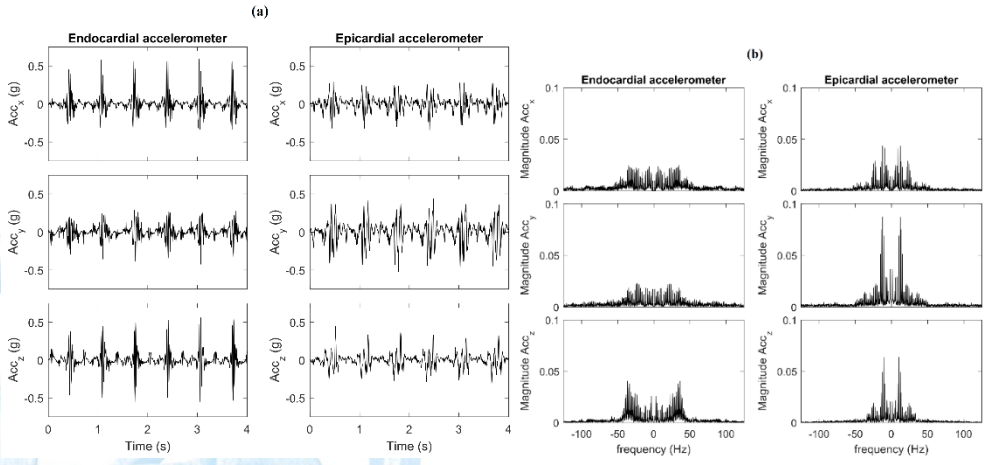

Fig. 5. Four seconds of the acceleration measured from the two accelerometer along the X, Y and Z axis in the (a) time and (b) frequency domain.

A comparison between the accelerations recorded simultaneously on corresponding locations on the inner and the outer heart wall shows significant differences in terms of amplitude and spectral energy.

Conclusion

An implantable sensor, intended to acquire acceleration signals from the epicardial wall, was fabricated. A multilayer packaging technique was proposed, that limits the leakage current and ensures excellent biocompatibility of the implant while protecting the delicate electronic components from the harsh body environment. The device functionality was tested in-vivo during animal experiments. The three components of the epicardial acceleration along the cardiac coordinate system were successfully acquired, and their frequency spectra were studied by means of FFT computation. The test proved the possibility of using the device for real-time monitoring of heart contractility during surgery. Furthermore, together with the endocardial sensor, the proposed device enables the physician to obtain a detailed and complete map of the cardiac motion in both time and frequency domains.

Acknowledgements

This research was performed within the ERC-2013-AG, MicroThalys, grant agreement No. 340931 and the MANPower project, EC co-financing programme (FP7-NMP-2013-SMALL-7) under the grant agreement No. A604360.

References

[1] P.S. Halvorsen, E.W. Remme, A. Espinoza, H. Skulstad et al. (2010): Automatic real-time detection of myocardial ischemia by epicardial accelerometer. J Thorac Surg 139, 1026-1032.

[2] P.S. Halvorsen, A. Espinoza, A.E. Fiane, E. Fosse (2013): Continuous Monitoring of Right Ventricular Function with a 3-Axis Accelerometer during Left Ventricular Assist Device Implantation. J Heart Lung Transplant 32, S161–S162.

[3] S. Dell'Orto, P. Valli, E. M. Greco (2004). Sensors for rate responsive pacing. Indian Pacing and Electrophysiology Journal, 4, 137–145.

[4] J. Brugada, J. Brachmann, P. P. Delnoy, L. Padeletti, et al. (2014): Automatic Optimization of Cardiac Resynchronization Therapy Using SonR—Rationale and Design of the Clinical Trial of the SonRtip Lead and Automatic AV-VV Optimization Algorithm in the Paradym RF SonR CRT-D (RESPOND CRT) Trial. Am Heart J, 167, 429-436.

[5] L. Brancato, T. Weydts, H. De Clercq, T. Dimiaux, P. Herijgers, R. Puers (2015): Biocompatible packaging and testing of an endocardial accelerometer for heart wall motion analysis. Procedia Eng 120, 840-4.