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SYSTEMS-LEVEL QUALITY IMPROVEMENT

Wireless Endocardial Atrial (and Ventricular) Sensing with no Implanted Power Source: a Proposal

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Abstract

Cardiac electrical activity is mainly evaluated by monitoring the electrical biosignals. This requires a long-lasting power supply to make implantable devices cost-effective and efficient. Since the current trend is to implant catheter-free stand-alone electrodes (implantable cardiac monitors), the need for smaller devices is at odds with the need for long-life batteries. To avoid these problems, we propose a passive endocardial sensor able to monitor the movement of the considered chamber based on a permanent magnet shaped for implantation in the internal chamber of the heart (i.e. the right atrium) and an external gauss meter unit to measure sensor-induced magnetic field variations. Since the magnet is permanent, no replacement is needed after the first implant, thereby reducing the risks linked to invasive procedures, and the battery in the external device can be substituted more easily. To test our idea we used a permanent magnet mounted on the tip of a commercial catheter for heart mapping together with a dedicated gauss meter built in our laboratory. The device was tested in vitro and the magnetic field variations were acquired and measured in different conditions of movement and distances. The results demonstrate the feasibility of our approach and open an interesting new scenario where permanent magnets can be used to monitor the mechanical behaviour of the heart.

Keywords Atrial activities · Endocardial wireless sensors · Magnetic sensor · Gauss meter

Introduction

Currently, cardiac electrical activity (ventricles and atria) is mainly evaluated by monitoring the electrical activities of cardiac muscle tissue. Endocardial biosignal analysis discriminates between normal and pathological behaviour so that implantable devices (i.e. pacemakers, defibrillators) can supply the appropriate therapy (i.e. pacing and defibrillation) [1, 2]. Traditional implantable devices consist of a small box containing the power supply and a central processing unit (CPU) connected through catheters to different electrodes placed in the heart chambers.

The main problems related to this technology are the risks linked to the invasive procedure required for implant placement, the difficulties of inserting the endocardial electrodes, the mechanical stress acting on the catheters and the duration of the battery [3–6]. When the power supply falls below a threshold value, the device must be replaced, often with replacement of the electrodes and catheters. These procedures are invasive and can be dangerous since the electrodes are commonly covered by fibrous tissue and their extraction can seriously damage the muscle walls [4, 7, 8]. To solve these problems, major technological improvements have led to the development of ever-smaller implantable devices with shorter (or absent) catheters and a more capacious power supply [9, 10]. In recent years, implantable device manufacturers have marketed systems that can be placed externally to the heart to avoid the insertion of catheters on the atria and ventricles and allow electrical monitoring and stimulation from outside the cardiac walls. Despite these improvements, atrial sensing remains an unresolved issue

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since atrial signals are low and can be confused with other electrical activities (noise, ventricular, movements, etc.) [9, 11–13], while the atrial chambers are small and cannot house even a small implantable device [14].

To solve these problems, our proposal presents two main innovations: (a) the possibility to evaluate atrial activities measuring not the electrical activities of the tissues but their mechanical behaviour; (b) the use of a wireless implantable passive sensor that does not require any wire or power supply and does not need to be replaced. The reader device and CPU with its battery can be placed in a subcutaneous position outside the heart allowing easy replacement. The sensor we used to obtain this result is a permanent implantable magnet (PIM) and the reader device connected with the CPU is a Hall effect sensor (HES). Since the PIM is linked to the atrium, it moves with the wall contractions resulting in a variable distance between the PIM so the HES can measure the magnetic field variations.

Materials and methods

As a preliminary validation of our approach, we used a permanent magnet placed in the tip of a Carto Mapping catheter (Biosense Webster Inc., Irvine, CA, USA) since it has the right shape and size to be placed inside an atrium.

Our evaluation was divided into two steps:

1) Magnetic field characterization around the PIM. A Namicon MPU-ST Gaussmeter (Namicon Testing Srl, Otopeni, Romania) with a resolution of 0.1G was used to draw a cylindrical map. The distance of the points of interest from the magnet was chosen since it is similar to the distance between an electrode implanted in the atrium and an external sensor [1, 9]. Since the Gaussmeter measures the field along its probe's axis, to calculate the total module of B, three measurements were taken to calculate the components in an xyz-space. The measurements were made both in air and water.
2) Mechanical simulation of simple physiological situations: PIM was fixed to two different mocks of the ventricles [15–18] to create two different movements (linear and radial) as described in Fig. 1. An HES (UGN3503U) was mounted on a dedicated amplification circuit to measure the magnetic field. The HES was then positioned at different distances from the magnet's initial position and the corresponding amplified signals were then acquired with a digital oscilloscope (Tektronix, TDS 1001 B) and data were exported to be represented with MS Excel. The only component of the B module along the HES axis was evaluated.

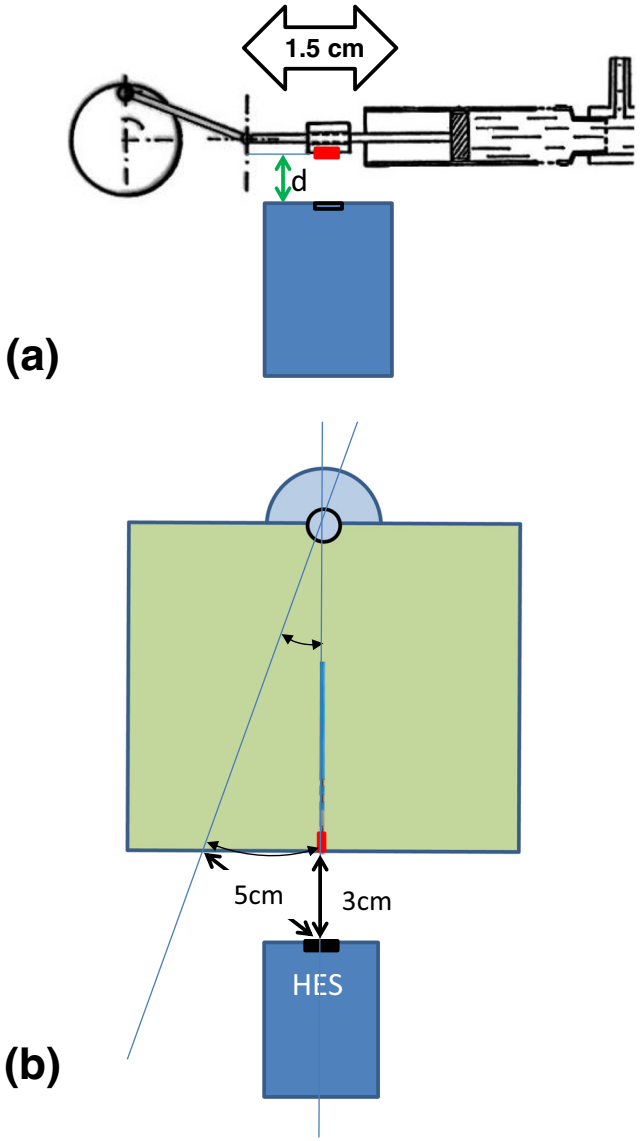

Fig. 1 (a) PIM is connected to a syringe-based pumping system. The HEF sensor was fixed at a distance d = 2 cm and 5 cm. The elongation of the pump is 1.5 cm. (b) Rotatory system: HEF is positioned at a fixed distance of 3 cm. Maximal distance between the HES and the PIM is about 5 cm

Results

The magnetic field modules generated by the permanent magnet were performed both in air and water and they yielded the same results (Fig. 2).

The magnetic field modules on a plane at the same height as the PIM show higher values near the magnet (greater than 30G). These values rapidly decrease under 0.1G of the instrumental resolution at a distance of 4–5 cm depending on the angles. The values of B module along the vertical line range between 43G and 0.4G at a distance of 6 cm.

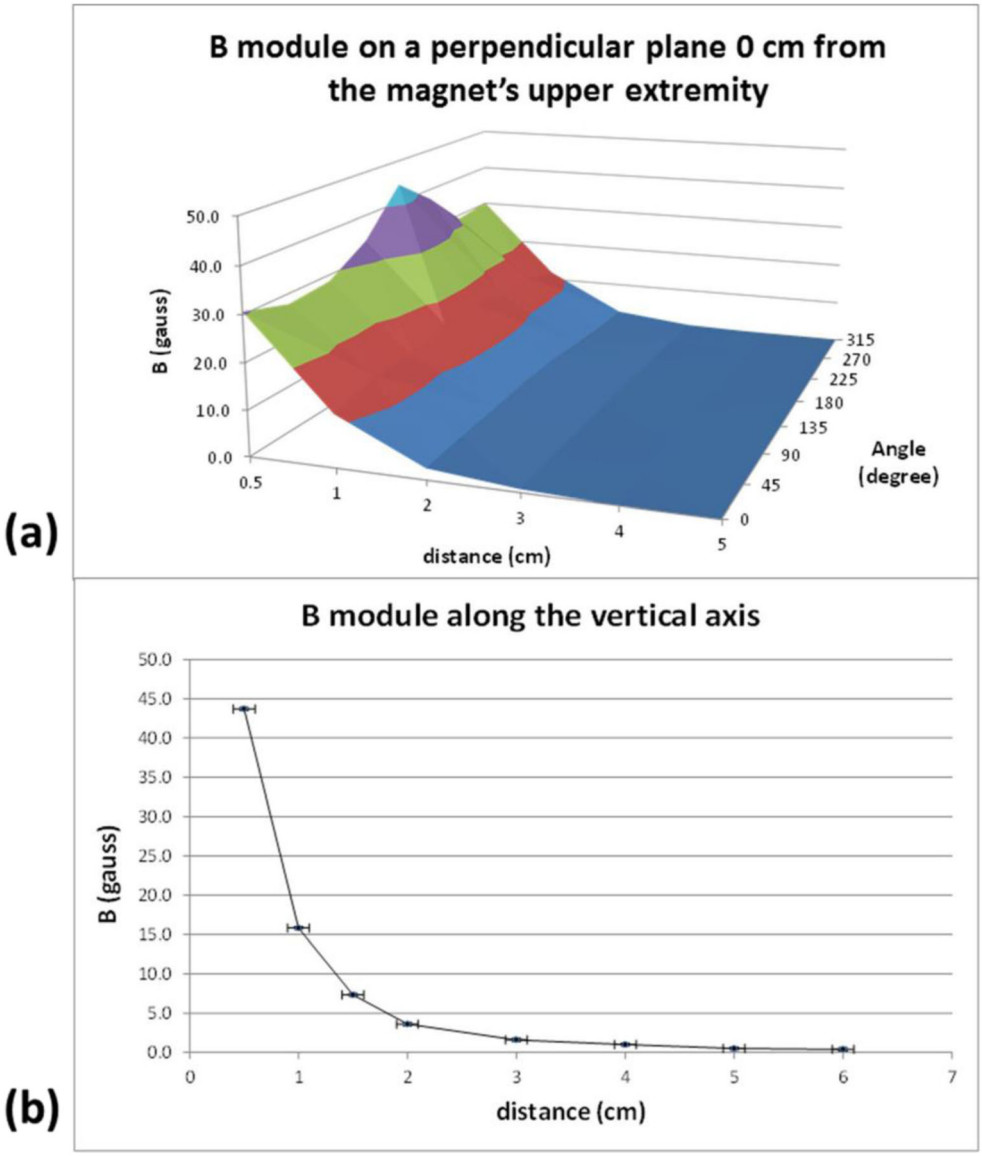

Fig. 2 (a) Magnetic field module distribution on a plane at the same height as the magnet, perpendicular to the magnet axis, at different angles and distances; (b) B module along the vertical axis

Simulation of the two kinds of movements yielded the results shown in Table 1.

Discussion

The problem of atrial sensing for cardiac stimulation has been an open issue since the first pacemakers were implanted [13, 19]. The traditional approach provides electrical sensing as the reference technique to evaluate if the atrium is activated, if the activation is regular or some atrial arrhythmias are present. Since atrial signals are quite low, this technique can lose sensitivity in case of atrial fibrillation or abnormal impedance increases due to the fibrotic tissue around the electrode. Moreover, traditional electrical sensing requires an implanted battery to amplify and condition the acquired signals with a power consumption inversely proportional to the original biosignal amplitudes. Technological trends are mainly focused on designing and building ever-smaller and more powerful batteries and using specifically shaped electrodes to reduce the contact impedances.

Magnetic sensing inside a heart chamber is not a new proposal since all the mapping systems (i.e. Carto, EnSite, RhythmiaHDx, etc.) use this technology to create an virtual map of the cavities [20–24]. What is new in our proposal is the use of a magnet to evaluate if the muscular wall of the atrium moves or not, so as to obtain a feasible indication of the atrial activation with a mechanical approach. This idea is a sort of "backward revolution": to date, electrical monitoring of the heart has been used to study and evaluate the mechanical behaviour of both atria

Table 1 Maximal variations of B field for the different simulated movements

Kind of movement	Max B variation (Gauss)	Distance range (cm)
Linear – initial d = 2 cm	2.00	2.0–2.5
Linear – initial d = 5 cm	0.12	5.0–5.2
Circular –initial d = 3 cm	1.12	3.0–5.8

and ventricles. Directly monitoring the movements with a magnet moving with the chamber wall avoids all the problems related to electrode sensitivity. Our proposal is only at an initial stage and this work demonstrates its feasibility. A permanent magnet requires only one endocardial implantation and solves all the problems related to contact impedance that are negligible for a magnetic field sensing.

The results we obtained both in air and water support this hypothesis. The technology we used is currently available and very little preliminary work is required to pass from an in vitro validation to animal experimentation. One major problem remains open: the interference of a PIM with an external high magnetic field like the one used in a nuclear magnetic resonance (NMR). This limitation should be properly evaluated, but since cardiac NMR is not always mandatory to study heart behaviour, we are confident that a good compromise can be reached. Last but not least, we propose a passive approach for atrial sensing but our idea can be applied to the ventricles too. If the magnet is properly implanted, an external sensor can directly evaluate the mechanical behaviour of the cardiac chambers, providing useful information for a wide range of pathologies, such as ventricular dilatation, heart failure, ischaemic disease, etc. Obviously, more than one magnet can be implanted to better characterize the chamber contraction, but the interactions between the generated magnetic fields should be studied in depth.

Compliance with Ethical Standards

We certify that:

1) there is no conflict of interest with any financial organization regarding the material discussed in the manuscript;

2) this article does not contain any studies with human participants or animals performed by any of the authors;

3) no funds were received for this study.

Regards,

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