

REVIEW

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A review: flexible, stretchable multifunctional sensors and actuators for heart arrhythmia therapy

Seung-Jo Kang and James Jungho Pak*

Abstract

Cardiovascular disease is a very serious disease which results in about 30% of all global mortality. Atrial fibrillation (AF) causes rapid and irregular contractions resulting in stroke and cardiac arrest. AF is caused by abnormality of the heartbeat controlling electrical signal. Catheter ablation (CA) is often used to treat and remove the abnormal electrical source from the heart but it has limitations in sensing capability and spatial coverage. To overcome the limitations of the CA, new devices for improving the spatial capability have been reported. One of the most impressive methods is wrapping the heart surface with a flexible/stretchable film with an array of high-density multifunctional micro-sensors and actuators. With this technique, the overall heart surface may be diagnosed in real time and the AF may be treated much more effectively. The data acquisition from the array of multifunctional sensors is also very important for making the new devices useful. To operate the implanted device system, a battery is mostly used and it should be avoided to replace the battery by surgery. Therefore, various energy harvesting techniques or wireless energy transfer techniques to continuously feed the power to the system are under investigation. The development of these technologies was reviewed, and the current level of technology was reviewed and summarized.

Keywords: Cardiac ablation (ca), Atrial fibrillation (af), Radiofrequency (RF) catheter, Balloon catheter, 3D multifunctional integumentary membranes (3D-MIM), Implantable device, Chronic implant device

Background

Arrhythmia describes an irregular heartbeat and the arrhythmia may make heartbeat rate too fast, too slow, or with an irregular rhythm [1]. There are four main types of arrhythmia: premature (extra) beats, supraventricular arrhythmias, ventricular arrhythmias, and bradyarrhythmia. Among them, the supraventricular arrhythmias are tachycardia (fast heart rates) that start in the atria or atrioventricular (AV) node and this includes atrial fibrillation, which is the most typical type of serious arrhythmia, which causes rapid and irregular atrial contractions resulting in stroke and cardiac arrest. This atrial fibrillation is caused by abnormality of the electrical signals that control the heartbeat in normal conditions [2]. By the nineteenth century, physicians had little knowledge

of coronary artery disease, valvular heart disease, cardiac arrhythmias, and cardiomyopathy, although the deaths from cardiovascular disease, including arrhythmia, accounted for about 30% of all global mortality [3, 4]. In the twentieth century, they were able to diagnose and treat heart disease using new techniques including the radiograph, electrocardiograph (ECG), and cardiac catheter, etc. [3].

With better understanding of the mechanisms of AF, the cardiac ablation (CA) treatment has been more popular for the treatment of various types of AF [5]. CA removes arrhythmogenic tissue by either RF (radiofrequency) heating or cryotherapy cooling with treatment by other energy sources such as laser energy, which is under clinical trials [5–15]. CA procedures mostly rely on a point ablation and, while it is good for treating simple arrhythmias, it is not suitable for treating complex arrhythmias that occur continuously at multiple sites due to limited sensing functionalities and single point

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ablation source [16]. Also, since arrhythmias can occur in all component structures and 3D regions of the heart, it is quite challenging to diagnose and treat the precise anatomic locations, especially when you want to cover a large area [6, 9]. In order to overcome this limited sensing functionality or limited spatial coverage, the catheter was designed to be inflated like a balloon as shown in Fig. 1. An advanced balloon catheter design with multiple sensors on the outside surface was reported for enabling the catheter to obtain temperature, flow characteristics, tactile, optical, and electrophysiological data from the tissue-balloon interface [17–28]. While the CA is considered as one of the best methods for diagnosing and treating AF, there is a higher risk of procedural complications due to the complexity of technique and the location of ablation sites [5]. It is reported that approximately 50,000 AF ablation procedures are being performed every year in the United States and a major complication rate of

approximately 5% have been reported after CA treatment in USA [5, 29–31]. In order to reduce the major complications associated with the CA while increasing the sensing functionalities and spatial coverage, various novel devices that can be attached on the outer wall of the heart have been reported in order to replace the catheter for the diagnosis and treatment of the CA. One of the most impressive devices is a flexible and stretchable membrane-type device which has multifunctional sensors and actuators that can provide electrical stimulation, enabling real-time mapping of many cardiac characteristics.

This paper briefly reviews a recent trend in the development of flexible, stretchable multifunctional sensors and actuators for heart arrhythmia therapy that can overcome various limitations of the traditional single-point source CA technique. This new technology becomes possible by achieving improvement in the following fields—realization of flexible and stretchable substrate, successful multifunction sensors and actuators on the flexible and stretchable substrate, energy harvesting method to avoid battery replacement surgery, and information and communication technology (ICT) for exchanging the data between the sensors and other systems. Each of these subjects will be addressed with some of the recent development reports.

Next generation devices for heart arrhythmia therapy

The next generation device was aimed to diagnose and treat the complex heart arrhythmias that occur continuously at multiple sites. This complex arrhythmia cannot be treated with a single-point source catheter, even though it is an approved and one of the most widely accepted methods for treating a single point cardiac ablation due to its limited sensing functionality or limited spatial coverage. Therefore, in order to overcome these limitations various new technologies have been developed and reported. This paper introduces a part of those technologies to inform the readers what have been developed recently in the heart arrhythmia therapy field. First, in order to improve the spatial coverage of the sensors, the sensors should be fabricated on a flexible and stretchable substrate which can then be tightly and conformally attached to the curvy organ surface, in this case the heart. By fabricating small sized, high density sensors on this flexible and stretchable substrate, the device multifunctionality for collecting various cardiac characteristics can be achieved. In addition to them, the ICT capability should be included into the device for data communication and finally the power should be provided or generated without the surgery for replacing the battery.

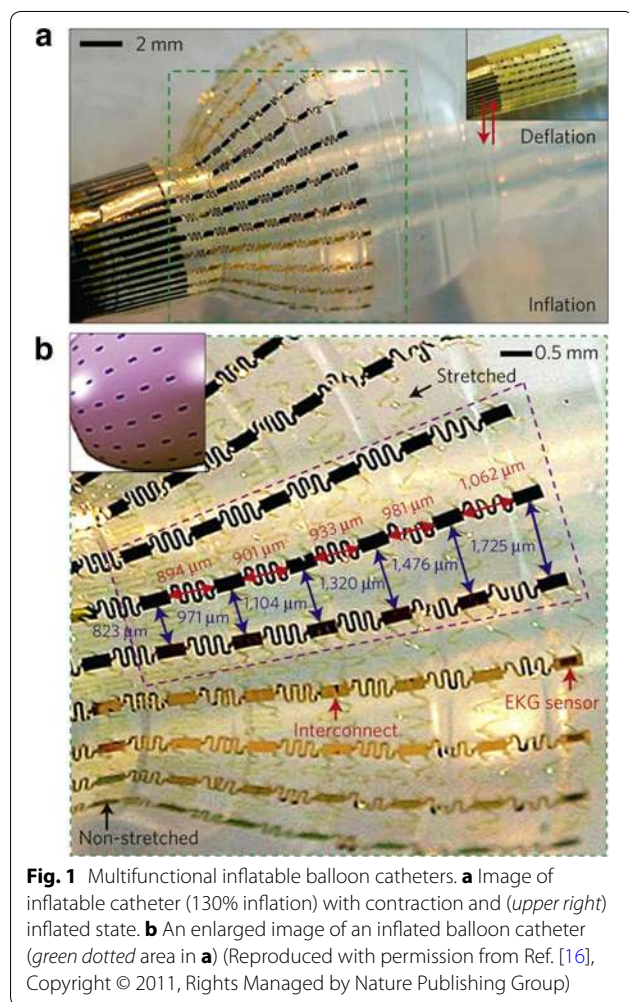


Fig. 1 Multifunctional inflatable balloon catheters. **a** Image of inflatable catheter (130% inflation) with contraction and (upper right) inflated state. **b** An enlarged image of an inflated balloon catheter (green dotted area in **a**) (Reproduced with permission from Ref. [16], Copyright © 2011, Rights Managed by Nature Publishing Group)

Flexibility and stretchability

Implantable devices quite often either cause a damage to the organs or plays a source of infection by the tissue immune reaction. The implantable devices usually need to be attached tightly to the organs as long as there is no immune reaction from the organ. It is particularly critical to attach the sensors or actuators very tightly on the heart surface because the heart expands and contracts as it beats, resulting in detaching of any sensors from the surface. This will cause the failure of the sensors and with rigid sensor body it is almost impossible to have a good contact with the curvy heart surface. Even if the soft sensor body makes a good contact with the heart surface, it will be detached from the heart surface after some heartbeats because the movement of the heart is quite strong. Therefore, it is necessary to make the sensor body with a flexible and stretchable material so that the sensor body may be able to follow the shape change of the heart when the heart beats. Polydimethylsiloxane (PDMS) is one of the polymers, which Whitesides et al. reported to deform up to 200% when heating and cooling it as a stretchable structure shown in Fig. 2 [17, 32–35]. Therefore, when the sensors are fabricated on the PDMS body, they can be stretched and deformed following the heart shape without being detached.

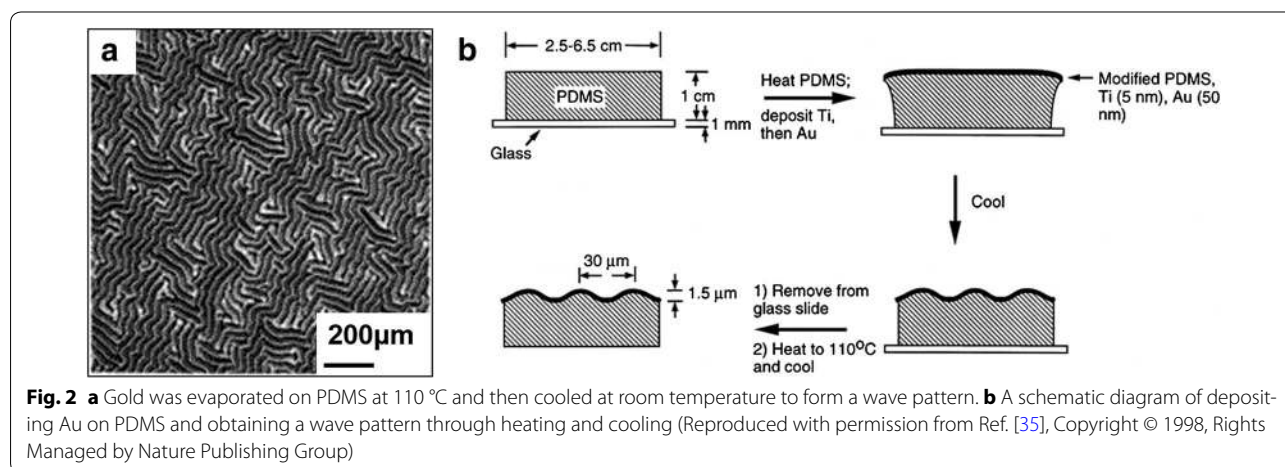
Multifunctional device

It is tendency to develop an array of sensors in the medical devices so that many physiological parameters can be examined at the same time from one location of the body. For example, the balloon catheter reported by Kim et al. is a multifunctional device that can measure various properties such as electrical properties, thermal properties, pH, temperature, and mechanical strain [36]. This device's electrodes consist of a fractal structure, which allows high density sensing over a large area and low impedance without compromising elasticity and

compliance [37]. Xu et al. [36] demonstrated a cardiac model with a 3D printer and created an elastic membrane called 3D multifunctional integumentary membranes (3D-MIM) as shown in Fig. 3. This device is able to diagnose various diseases of heart such as arrhythmia, ischemia, and heart failure spatially [36]. As shown in Fig. 4, Xu et al. [37] also reported an actuator capable of not only sensing but also electrical stimulation. This device has an array of 8 electrodes located around the heart circumference and it was able to deliver spatially and temporality programmed electrical stimulation onto the heart outside membrane [37].

Generator

In recent years, the importance of these medical implant devices has increased dramatically and the field of application has also expanded rapidly. However, most of these devices rely on internal batteries and the lifetime of the devices is limited by the battery life [38–40]. The implantable medical device usually employs a small high-capacity battery with low-power devices in order to increase the lifetime of the medical device to avoid the surgery for replacing the battery or medical device. However, with the current technology, the lifetime of battery-operated pacemakers, for example, is reported to be about 5–15 years and the device replacement must be done, normally by surgery [38, 41]. Research is underway to overcome these drawbacks by considering a generator with an energy harvesting method instead of a battery [38]. Energy harvesting may be done by various methods and all kinds of energy harvesting principles are studies by researchers. Some people are trying to obtain energy using a fuel cell by a chemical reaction between glucose and oxygen, and many people are trying to harvest substantial amount of energy from various mechanical body movements including a knee, body movement, and even a heart wall movement from the heartbeats [38, 42–48].



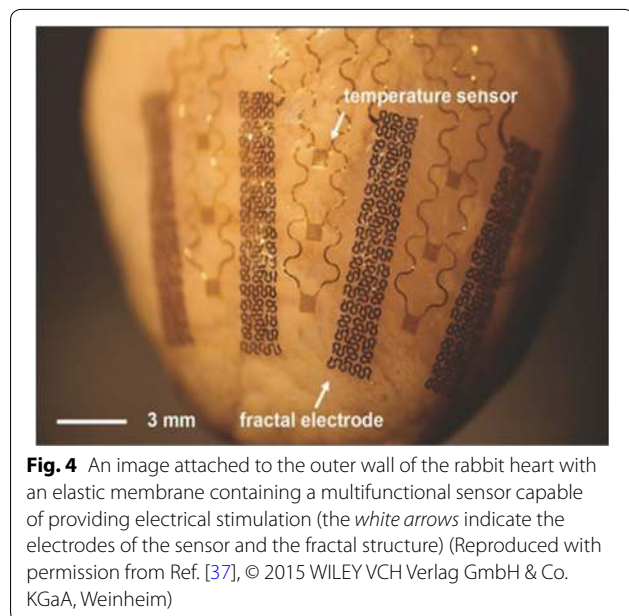
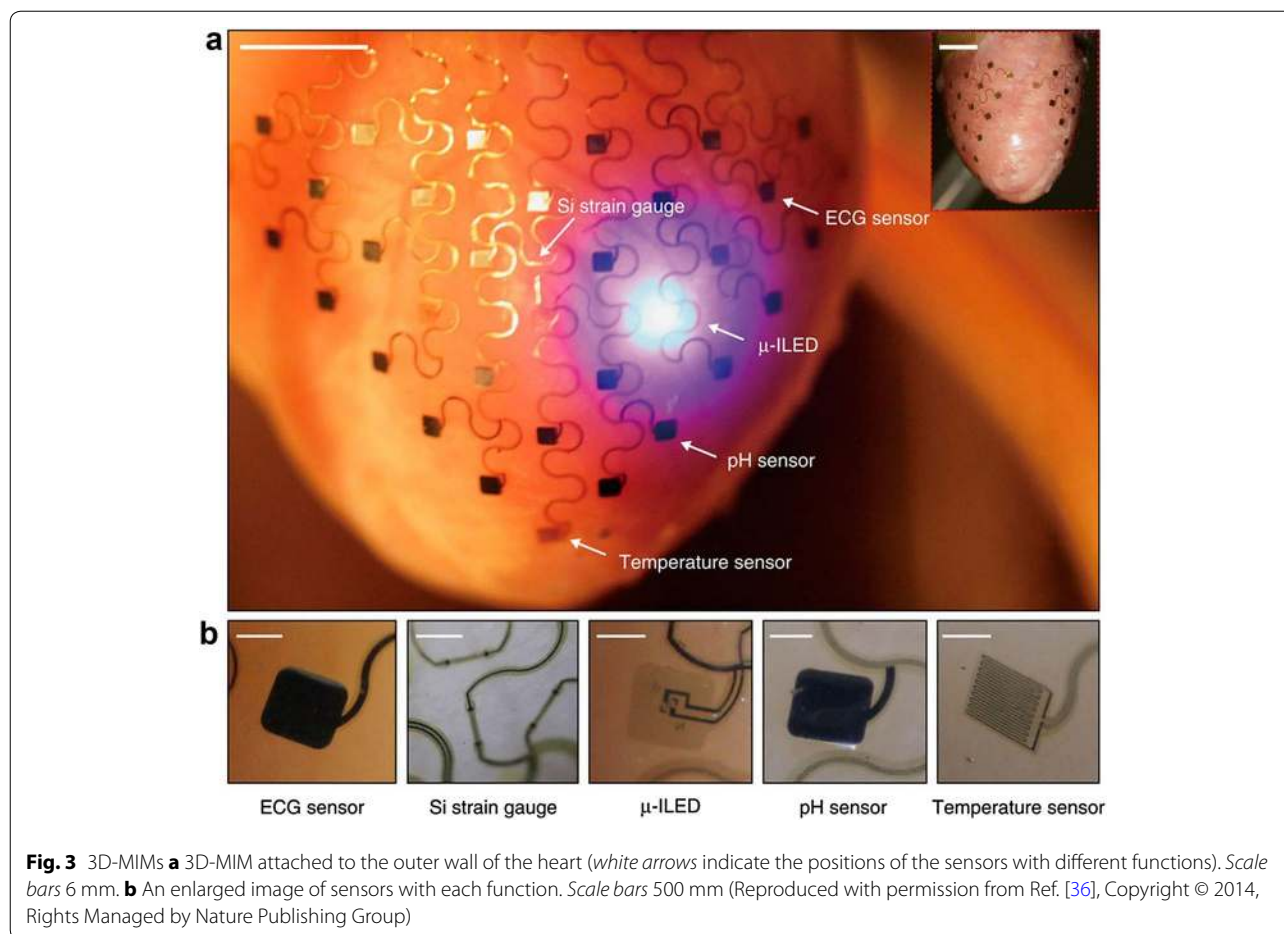


Figure 5 shows an example of obtaining energy by attaching mass imbalance oscillation generator (MIOG) to the left ventricle wall of Swiss alpine sheep. From this experiment, the heart was beating at an average of 90 bpm and the experiment lasted for a total of 18 min and 45 s, producing 11.1 μ J per heartbeat [38]. However, attaching the energy harvesting device directly on the heart may cause impairment or even damage to the heart chronically. The possibility of causing cardiac damage, such as bleeding, has been raised because of heart's vigorous contraction and vulnerability [49]. Figure 6 shows a flexible and implanted PVDF piezoelectric energy harvesting generator film wrapped on an ascending aorta for harvesting energy from the pulsation of the aorta to avoid the cardiac damage. Figure 6 shows before and after of PG injection in the pig's aorta. Figure 7 shows that the schematic illustration of the piezoelectric generator (PG) wrapped around the latex tube, its cross-sectional SEM image, and the photograph of the fabricated the PG by depositing Al on both sides of the PVDF. The reported results showed

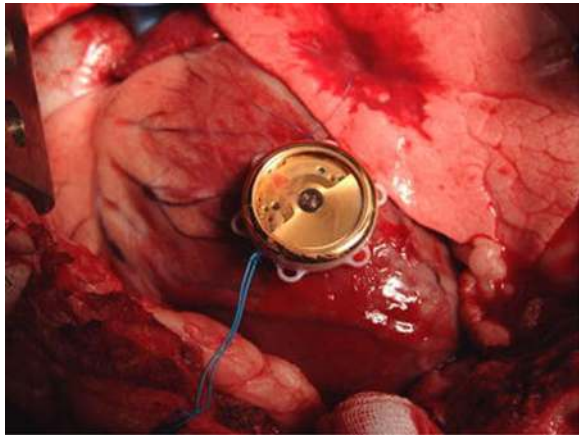


Fig. 5 Attachment of mass imbalance oscillation generator (MIOG) to the left ventricle of Swiss alpine (sheep Reproduced with permission from Ref. [38], © Biomedical Engineering Society 2012)

lasted for 700 ms and was charged to 1.0 V for 40 s for a 1 μ F capacitor in the charge test [49].

Information and communication technology

Even if there is a sensor that can map every part of the heart spatially and a generator that can operate the sensor indefinitely, it is meaningless if it cannot send the collected information to the outside. In order to monitor heart information in real time, the collected information should be transmitted to an information processing device outside the body [52]. Hammond et al. developed a device that transmits heart pressure data wirelessly and can monitor the information in real time in 2012 [53]. The device, as shown in Figs. 8 and 9, encapsulates pressure sensors made with MEMS technology and electronic components that provide signal conditioning, power management, and radio frequency transmission into glass capsules, which are then implanted into the left ventricular apex. Data from this device is passed through a proprietary transceiver unit and a handheld antenna. The transceiver can provide power to the device through electromagnetic induction, detect and process radio

that the average heart rate of pigs was 120 bpm and the aorta had a strain rate of about 10% due to heartbeat [49–51]. The instantaneous output of the PG was 30 nW and

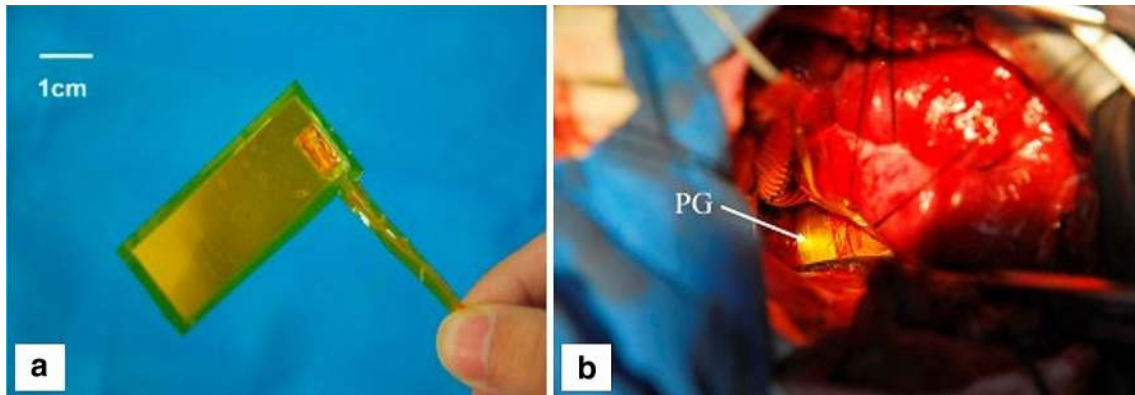


Fig. 6 **a** PG picture wrapped in PI tape. **b** PG implanted in the aorta (Reproduced with permission from Ref. [49], Copyright © 2015 Elsevier Ltd. All rights reserved)

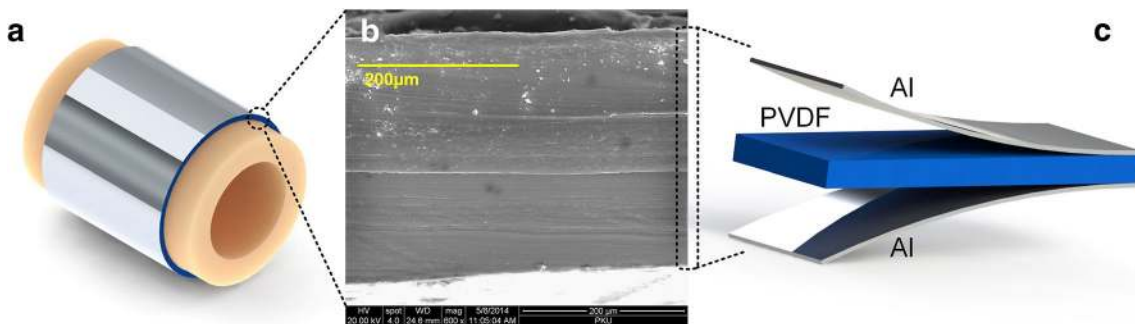


Fig. 7 **a** A schematic diagram of a piezoelectric generator (PG) surrounding the aorta. **b** cross-sectional SEM image of PG. **c** PG structure diagram (Reproduced with permission from Ref. [49], Copyright © 2015 Elsevier Ltd. All rights reserved)

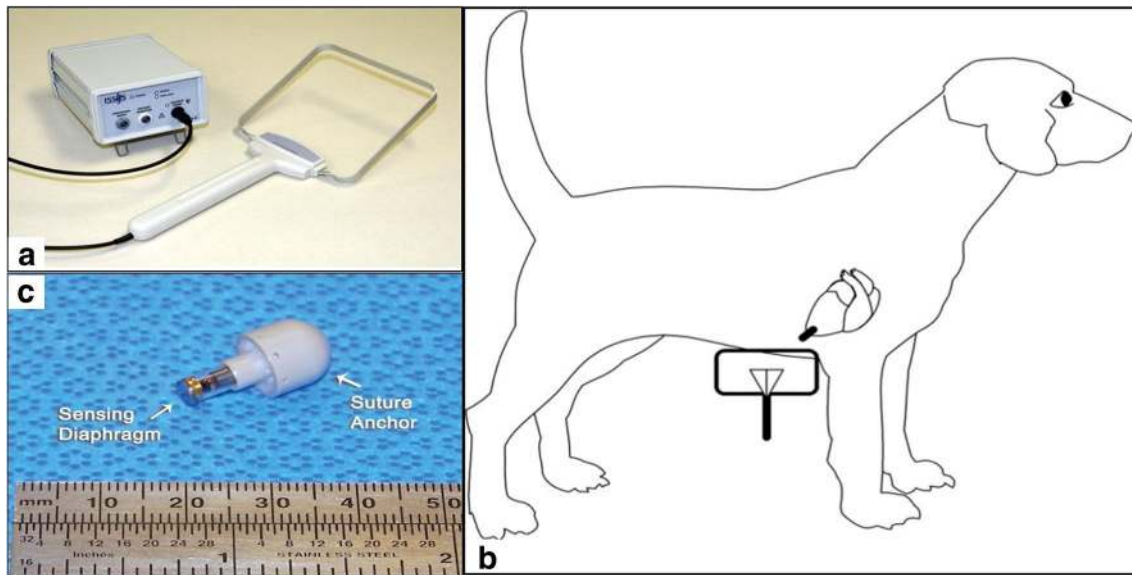


Fig. 8 **a** Proprietary transceiver unit and a handheld antenna. **b** Diagram implanted in apex of left ventricle. **c** Pressure sensors made with MEMS technology and electronic components providing signal conditioning, power management and radio frequency transmission are encapsulated in glass encapsulation devices (Reproduced with permission from Ref. [53], Copyright © 2012 by the American Society for Artificial Internal Organs)

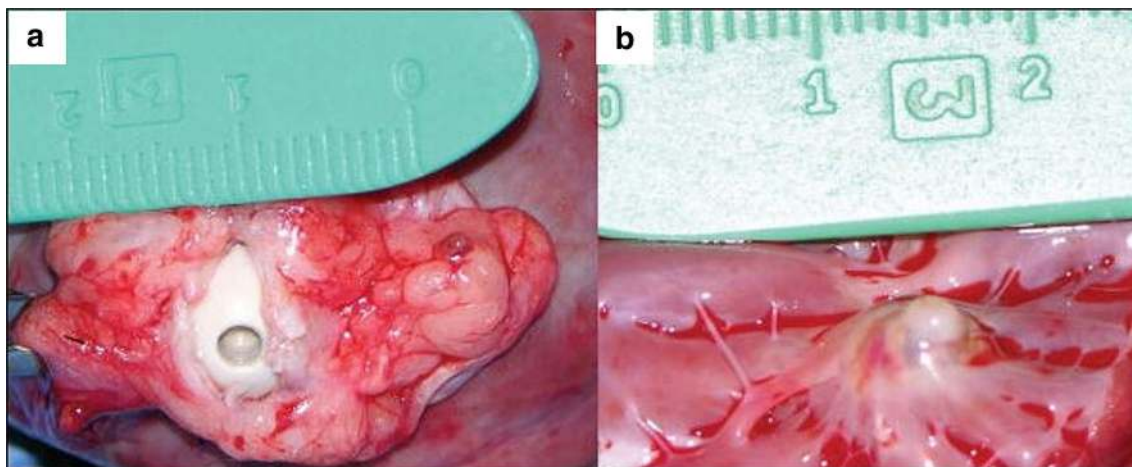


Fig. 9 **a** Pictures of devices implanted in the left ventricular apex. **b** Implant site (Reproduced with permission from Ref. [53], Copyright © 2012 by the American Society for Artificial Internal Organs)

frequency signals emitted by the device, and store the data in a computer via USB [53]. However, until now, the transmittable distance is short and only the data about the pressure can be collected and encoded and transmitted. Therefore, it is necessary to secure the data of the multi-function sensor to be able to process. Also, the connection to the sensor should be considered to process the data in the membrane type sensor which surrounds the whole heart.

Conclusions

Compared to a single point source CA, which is currently used to treat cardiac arrhythmia, a new implantable, flexible and stretchable membrane-type device with multifunctional sensors and actuators has been developed and reported in order to map in real-time, and large-area spatial cardiac characteristics. In order to operate such devices by attaching it on an organ in a live body for a long time, the battery replacement surgery

should be avoided. To overcome this difficulty, various energy generation/harvesting techniques have been reported, including a fuel cell using a chemical reaction between glucose and oxygen, energy harvesting from various mechanical body movements including a heart wall movement from the heartbeats. One of the energy harvesting experiment results is that 11.1 μJ energy per heartbeat was harvested from the 90 bpm heartbeats for 18 min and 45 s by attaching the generator to the heart outside wall of the sheep. In addition, there must be a communication device capable of sending the data collected by the sensors to an external device enabling real-time monitoring outside the body. Transmitting an electrical signal through a human body suffers significant signal, limiting a real-time data transmission only for a short distance. Therefore, some of the developments in those important issues were reviewed and reported in this paper to address what needs to be developed further to make successful flexible, stretchable multifunctional sensors and actuators for heart arrhythmia therapy.

Abbreviations

CA: cardiac ablation; AF: atrial fibrillation; RF: radiofrequency; 3D-MIM: 3D multifunctional integumentary membranes; AV: atrioventricular; ECG: electrocardiograph; ICT: information and communication technology; PDMS: polydimethylsiloxane; MIOG: mass imbalance oscillation generator; PG: piezoelectric generator; MEMS: microelectromechanical systems.

Authors' contributions

SJK and JJP wrote the manuscript. Both authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interests.

Availability of data and materials

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