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**Research Article**

# SOFT BIO-IMPLANTABLE SENSOR TECHNOLOGY FOR CARDIAC DISEASE DETECTION

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## Abstract

For many years. cardiac diseases continue to be a significant global health concern, necessitating innovative approaches to early detection and continuous monitoring. Currently cardiac devices are formed in bulky and rigid form, which consists of battery, electrode, and circuits, causing many limitations for long-term use. Soft bio-implantable sensor technology has emerged as a promising solution, offering unique capabilities to revolutionize cardiac disease detection and management. To detect and early treatment of the cardiac disease, electric sensor and pace-maker could be integrated in cardiac devices. All these components, constructed from biocompatible materials and designed to conform to biological tissues, offer a paradigm shift in cardiovascular healthcare. Data collected by these sensors can be wirelessly transmitted to external devices or cloud-based platforms, enabling remote monitoring by healthcare professionals. Their soft, biocompatible nature reduces the risk of adverse tissue reactions, making them suitable for long-term implantation. In this review we address the importance of biocompatible soft cardiac sensor technology. Moreover, we focused on what kinds of sensors could be integrated in future soft cardiac disease detection system.

**Keywords:**Cardiac Device, Bio-implantable, Biocompatible, Elastic, Conductible, Stretchable.

## INTRODUCTION

Implantable cardiac sensor technology in the ever-evolving landscape of healthcare, the integration of cutting-edge technology with medical science has led to remarkable innovations. Cardiovascular diseases stand as a leading global health challenge, with early detection being a key determinant of effective treatment and improved patient outcomes. Traditional diagnostic methods often lack the continuous, real-time monitoring required to detect subtle changes in cardiac health. Recently, soft bio-implantable sensors have emerged as a revolutionary paradigm in the early detection and monitoring of cardiac diseases (1, 2). These extraordinary systems, integrated seamlessly to internal organ or human body, show a groundbreaking advancement in the realm of cardiology. Soft bio-implantable sensors, with their ability to intimately interact with the heart's dynamic environment, offer a novel solution. The ideal bioelectronic device should mimic the mechanical properties of cardiac tissue, possess deformability, and offer various sensing functionalities (3). It should seamlessly interface with the epicardium while accommodating the heart's beating motion. Additionally, it should provide spatiotemporal mapping capabilities for cardiac conduction characteristics and other physical parameters. Recent advancements in materials, mechanical design, and bioelectronic technologies have led to the development of deformable epicardial bioelectronics. Strategies include engineering rigid materials to achieve mechanical softness. For example, thin-film flexible electronics, based on ultrathin silicon on a polymer film, have been employed to map electrophysiological activities spatially. Additionally, open-mesh structural designs in epicardial patches with rigid materials offer overall mechanical stretchability and deformability (4), allowing them to conform to the heart's motion. However, these devices face challenges in effectively interfacing with cardiomyocytes, and flexible silicon electronics for cardiac mapping do not concurrently deform with the beating heart.

To overcome these limitations, there have many research progresses in terms of soft materials and sensor technology. We will review the importance of soft materials in mechanical aspects followed by address of principle of cardiac devices.

### Soft materials and biocompatibility for Bio-implantable system

Recently, various kinds of bio-compatible system have been developed for accurate diagnosis. Softness and biocompatibility are critical considerations in the development and deployment of bio-implantable systems. These systems, which encompass a wide range of medical devices such as artificial joints, cardiac pacemakers, and drug-eluting stents, rely on carefully selected materials to ensure they function effectively within the human body. Specifically for the heart diagnosis system, current pacemaker system still has challenges in terms of wearing-comfort, which originates from rigidity and possibility of disconnection of wiring from device to heart. To detect the direct signal from the heart, stretchability and soft devices have been required to diminish the modulus mismatch between device and biological tissue during dynamic environments. The choice of materials, whether they be metals, polymers, ceramics, or even biologically derived substances, holds the key to the success of these medical approaches. This demands rigorous biocompatibility testing, evaluating how these materials interact with our physiology. There have many progresses in soft conductive materials for soft sensor system. Conductive composite materials, consisting of soft elastomer matrix and conductive fillers, are the novel materials, which have both electrical conductivity and mechanical stretchability. The key of conductive composite is percolative structure formed inside of the elastomer matrix. As the percolated nanomaterial networks form the electrical conduction pathways inside a nanocomposite, high conductivity can be produced by effective usage of physical and chemical properties. One of the most common strategies to minimize the contact resistance in nanomaterials percolation network is to manipulate the size of

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the filler material. Among nanomaterials of various sizes, such as 0-D nanoparticles (NPs), 1-D nanowires (NWs), and 2-D flakes/plates, the 1D NW structure is most useful to achieve the high electrical conductivity due to their high aspect ratio, which allowed them to form the percolation network easily with the lower concentrations than the nanomaterials. These advantages have promoted the metallic NWs as an attractive filler for stretchable nanocomposites (5). For this reason, nanocomposites based on metallic NWs, such as copper NWs, Ag NWs, and Au NWs, have been developed as stretchable composite conductor.

In order to keep the stable performance of the device, the device should be able to maintain high conductivity even after being stretched. However, metallic nanomaterial is more rigid and brittle so that it cannot be deformed easily. Despite such mechanical characteristics, nanocomposite can preserve its conductivity under the applied strain through its rearrangement of nanomaterials inside the elastomer matrix. When the nanocomposite is elongated, the percolation network of nanomaterials rearranges in response to the applied strain, which deforms the shape of the network and protects the connection of the network from breaking up. These characteristics enable stable percolation of nanomaterials even under highly stretched conditions. After this study, many researchers have developed highly stretchable nanocomposites using self-rearrangement of nanoparticles. Figure 1 shows a highly elastic nanocomposite consisting of Ag flakes in rubber. During the fabrication of nanocomposite, Ag NPs were produced in situ from Ag ions diffused from Ag flakes. The fluorine rubber around Ag flakes and added heat have facilitated the reduction of Ag ions released from Ag flakes to form Ag NPs inside the composite. The strain-induced rearrangement of in situ formation Ag NPs made electrical bridges between Ag flakes and allowed high stretchability over 300%, also maintaining the conductivity (6)

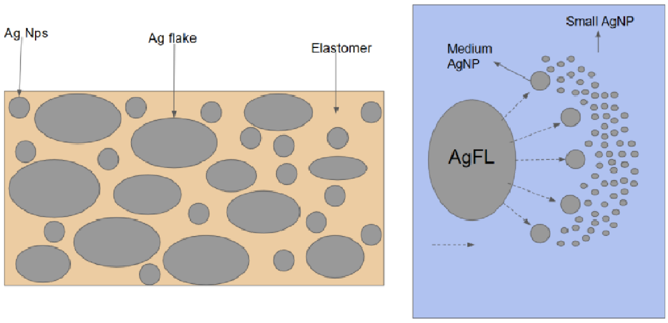

**Figure 1. Conductive composite based on Ag flakes and Ag NPs embedded in elastomer**

To improve electrical and mechanical properties of metallic nanocomposites, more than two conducting nanomaterials can be used to produce one nanocomposite. For such a nanocomposite, strain-induced rearrangement of the nanomaterials is also required to enhance its stretchability. When more than two nanomaterials are used as conducting fillers, one can serve as the main conducting percolation network, while the other can be rearranged under external strains to maintain the connection of the main percolation network.

## Soft, biocompatible sensors for epicardial patch

Soft device technology could provide detection and treatment of cardiac disease earlier. Currently, there are various kinds of devices to monitor the vital signal of heart and treat appropriately, including electrocardiogram (ECG), pressure sensor and pace-maker (Figure 2). Firstly, bio-implantable ECG devices are specialized medical implants designed to continuously monitor and record the electrical activity of the heart from within the body. These devices are typically used for long-term monitoring of patients with specific cardiac conditions or those at risk of arrhythmias or other heart-related issues. Bio-implantable ECG devices are particularly beneficial for patients who experience intermittent or asymptomatic arrhythmias, as they can capture data that may be missed during short-term monitoring. Additionally, they are valuable for long-term management of chronic cardiac conditions, allowing healthcare providers to make informed treatment decisions based on continuous, real-time data. Second, the pressure sensor is essential parts of system for the detection of volumetric change of chambers of heart. Specifically, pressure sensors can be used to monitor pressure changes within the ventricles, which is very important of heart activity. This data can be valuable in assessing heart function, diagnosing conditions like heart failure, or optimizing treatment regimens. Implanting pressure sensors in the heart could provide real-time, accurate pressure measurements. Lastly, the soft pace-maker is a novel concept of implantable cardiac device system in terms of cardiac rhythm management. Traditional pacemakers are implantable medical devices with rigid components, including leads and a pulse generator. Soft pacemakers, on the other hand, are designed to have flexible and biocompatible materials, potentially offering several advantages. Important advantage is minimization of discomfort to patient. Soft pacemakers aim to reduce patient discomfort by being more flexible and conforming to the natural contours of the heart and surrounding tissues. This could result in fewer sensations or discomfort at the implantation site. Moreover, this characteristic may have less potential to cause irritation, inflammation, or damage to the tissues surrounding the implantation site.

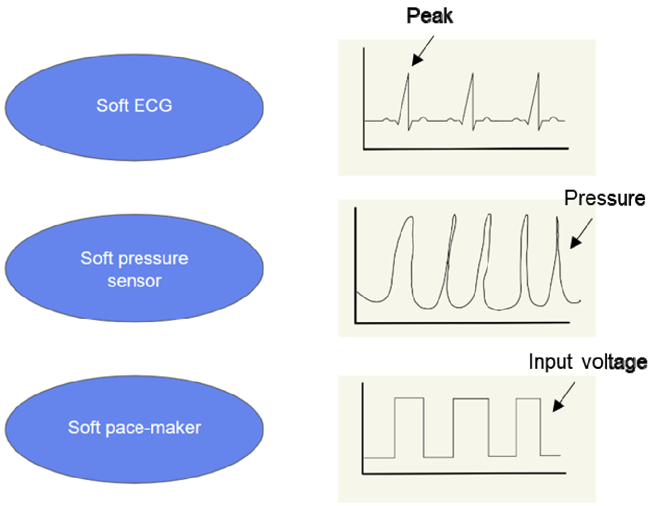

**Figure2. Various kinds of sensor for heart signal monitoring**

## Application of soft sensor system for detection of cardiac function

Soft cardiac interfacing devices have made notable progress in facilitating electrophysiological recording and electromechanical treatment within living organisms. However, their potential application in clinical trials necessitates further exploration. Unlike brain-machine interfaces, cardiac-machine interfaces demand unique designs and material choices to fulfill the demands of superior stretchability and dependable electrical and mechanical performance, particularly when subjected to substantial deformations caused by the heart's volumetric expansion and contraction. Recent research on cardiac devices has primarily concentrated on innovating soft electronic materials and devices capable of recording and controlling cardiac activities while adapting to the dynamic motions of the heart. Xu and colleagues devised three-dimensional (3-D) flexible membranes designed to fully encase the heart (7). These 3D integumentary membranes were equipped with stretchable electronics featuring a serpentine design that mimicked the horseshoe shape, the membrane surrounding the heart. As a result, they formed seamless connections with the heart at all contact points, creating a conformal interface between biological tissue and soft device elements. Importantly, these 3-D membranes maintained their conformal attachment even when subjected to the heart's dynamic cycles (contraction/relaxation) and exposure to fluids. Using standard photolithography techniques widely used in semiconductor process, they fabricated and integrated various electrical and optoelectrical components onto the membrane, including light-emitting diodes, strain gauges, electrophysiological recording electrodes, stimulators, pH sensors, temperature sensors, and heaters. This multifunctional integration enabled high-density multiparametric epicardial mapping and stimulation.

To maintain the electrical and mechanical functions of soft cardiac implants during the dynamic micro-motions of cardiac tissues, it is crucial to employ stretchable designs and conductive materials. These innovations aim to prevent congestive heart failure. One effective approach involved the development of an epicardial mesh using conductive rubber and a stretchable filamentary design. This mesh was designed with cross-linked conductive silver nanowires (AgNWs) combined with mechanically elastic styrene-butadiene-styrene rubber (8). The use of stretchable design and elastic materials allowed the cardiac mesh to closely match the elasticity of cardiac tissue. This soft device could seamlessly and mechanically integrate with the heart, wrapping around the entire ventricle to globally pace the cardiac chambers. This stable integration allowed for the detection and activation of electrophysiological signals from the rat heart for a duration of 8 weeks without compromising diastolic function. To enhance the stability and biocompatibility of the epicardial mesh, coating of inert metal is widely used strategy for inflammation from our organs. The addition of these Au shells improved biocompatibility by protecting the AgNWs from oxidation and Ag ion leakage, while also enhancing electrical conductivity for improved performance. Additionally, the authors optimized the hexylamine during the nanocomposite formation process, inducing phase separation and forming a cushioned microstructure for high stretchability. This stretchability was further enhanced through heat rolling-press treatment. When conformally integrated onto a live swine heart, the epicardial mesh demonstrated continuous electrophysiological recording, successfully detecting high-voltage changes in local intracardiac electrograms during ischemia.

## Conclusion

Conventional medical devices, especially an electrocardiogram (ECG) have been used to check the current status of patient and prevent additional shock. However, the system has challenging to detect cardiac disease earlier due to relative low accuracy. Heart disease should be treated in golden time, which is below 5 minutes. In this respect, early detection of heart disease and direct treatment is vital in medical system. To detect the accurate signal from the heart for diagnosis, direct interaction with intimate contact is promising solution and it could be realized by soft cardiac devices. By using the soft conductive materials, low modulus and deformability of materials relax the external stress applied to cardiac devices during repetitive expansion and contraction of ventricles. From this approach, bio-implantable cardiac devices could have a further step to next generation epicardial patch.

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