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Chonnam National University, KOREA

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TISSUE ACTUATORS**Xinzhu Ren¹, Yuya Morimoto^{1,2}, and Shoji Takeuchi¹¹University of Tokyo, JAPAN and ²Waseda University, JAPAN**W08-a ASIC INTEGRATION VIA POLYMER ULTRASONIC BUMP BONDING TO
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CARBON NANO TUBES-INCORPORATED SMART STENTS TO IMPROVE MECHANICAL STRENGTH AND SENSOR RELIABILITY

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ABSTRACT

Atherosclerosis, a primary manifestation, involves the accumulation of plaques within artery walls, gradually constricting them. To address such constriction, a common intervention involves the insertion of various stent into the affected blood vessels. In addition, the material properties of the stent are very important because the stent inserted into the human body is a foreign substance. Ideally, substances that are absorbed into the body over time are desirable. However, the bioabsorbable polymer stents developed to date have limitations due to their low mechanical elasticity of the materials. Furthermore, if the stents inserted into the blood vessel have a function to detect the restenosis at an early stage, a simple drug treatment can solve the blockage. In this paper, we propose a 3D-printed polymer stent with high radial strength integrated with an LC-type sensor to monitor pressure changes in blood vessels in real time. The wireless pressure sensor is fabricated using the photosensitive polymer SU-8, with a supporting micro-pillar at the center of the capacitor to improve sensor performance, while the 3D-printed stent is mixed with CNT to enhance mechanical strength. The connection and operational principles of the wireless pressure sensor are assessed through an inductance-capacitance coupling circuit. This method aims to enhance early detection of restenosis, offering a promising solution in cardiovascular care.

KEYWORDS

Polymer stent, wireless sensor, LC type pressure sensor, 3D prints, Carbon nano tube (CNT)

INTRODUCTION

Coronary artery disease (CAD) stands as the prevailing form of heart disease, claiming the lives of approximately 375,476 individuals in the year 2021 alone [1]. This condition affects a significant portion of the population, with an estimated prevalence of approximately 5% among adults aged 20 and older. Disturbingly, the impact of CAD extends beyond the elderly, as statistics reveal that in 2021, around 2 out of 10 deaths resulting from CAD occurred in individuals younger than 65 years old. These figures underscore the urgent need for preventive measures, early detection, and improved management strategies to combat this pervasive and potentially fatal disease [2]. The stenting method has been extensively employed for reopening blocked blood vessels, with a history spanning several decades. While stents have proven to be effective in restoring blood flow, it is important to consider that the long-term impact on blood vessels can

vary depending on the type of stent material used [3-4]. Metal stents, often referred to as bare-metal stents (BMS), have been widely used for many years [5]. While they provide immediate relief by opening up the blocked vessel, they can have potential drawbacks. Over time, the presence of metal stents within the blood vessel can lead to complications such as inflammation and scar tissue formation. In the context of angioplasty and stent placement, the pressure applied during the procedure is a critical consideration for preventing late thrombosis (blood clot formation) and ensuring optimal outcomes [6,7]. The magnitude of the pressure exerted can have significant effects on the blood vessels, including the potential for necrosis (cell death) within the vessel walls. When the pressure exceeds approximately 16 atm or surpasses 20 atm, there is a significant difference in the response of the blood vessels [8]. Higher pressures can cause mechanical injury to the vessel walls, leading to cell damage or necrosis. This damage can trigger an inflammatory response and increase the risk of thrombosis or restenosis (re-narrowing of the vessel), resulting in a process called in-stent restenosis, where the blood vessel becomes narrowed again due to the body's reaction to the stent. To address the issue of in-stent restenosis, drug-eluting stents (DES) were developed [9-11]. These stents are coated with medications that are slowly released into the surrounding tissue, helping to inhibit the growth of scar tissue and reduce the risk of vessel re-blockage. However, even with DES, there is a possibility of late adverse effects, including delayed healing or hypersensitivity reactions to the medication. In addition, reducing the strut thickness of bare metal stents has been found to have a significant impact on reducing complications associated with blood vessels. Thinner struts exert less mechanical stress on the vessel, promoting better endothelialization (recovery of the vessel lining) and reducing the risk of complications such as in-stent restenosis or thrombosis [12]. However, it is important to note that metal stents, which are permanent implants, can be associated with complications, particularly in cases of in-stent restenosis. The use of bioresorbable polymer stents (BRS) has gained significant attention as a desirable alternative to permanent stents. These innovative devices are specifically engineered to degrade gradually after the blood vessel has healed, offering the potential for a regenerated artery. The advantage of biodegradable stents lies in their potential to eliminate the long-term complications associated with permanent stents. By allowing the blood vessels to regenerate and adapt naturally, these stents offer the possibility of improved long-term outcomes. However, one of the challenges associated with BRS is their mechanical

integrity, which is crucial for ensuring optimal treatment outcomes. In order to enhance the mechanical properties of bioresorbable polymer stents, various additive materials have been incorporated to improve their performance. Examples of such additives include graphene oxide, single-walled carbon nanotubes (SWCNTs), and multi-walled carbon nanotubes (MWCNTs) [13]. Graphene oxide is a two-dimensional material derived from graphite. Its unique properties, such as high mechanical strength and excellent conductivity, make it an attractive additive for bioresorbable stents. By incorporating graphene oxide into the polymer matrix, the stent's mechanical strength can be significantly improved, enhancing its ability to withstand external forces and maintain structural integrity. Carbon nanotubes, both single-walled and multi-walled, are cylindrical structures composed of carbon atoms. They possess exceptional mechanical properties, including high tensile strength and stiffness. Incorporating carbon nanotubes into the polymer stent can reinforce the material and enhance its mechanical performance. These nanotubes act as fillers within the polymer matrix, improving its strength, toughness, and resistance to deformation.

The integration of an LC type pressure sensor with a polymer stent is a highly intriguing aspect of this research, as it offers the potential for non-invasive blood pressure control [14-18]. By incorporating the LC type pressure sensor directly into the polymer stent, we have established a means to monitor blood pressure without the need for invasive procedures. However, the MEMS-based fabrication of LC type pressure sensors often exhibits lower reliability and sensitivity due to the non-uniform flexible capacitor surface.

To enhance the reliability of the sensor, a specific micro pillar design was implemented and patterned at the center of the two capacitor plates. This design aimed to support a uniform surface between the pair of capacitor plates, addressing the issue of non-uniformity. In addition, we have successfully developed an additive bioresorbable polymer stent mixed with CNT to further increase mechanical strength. This design combines the benefits of bioresorbable polymers with the functionality of a pressure sensor, enabling real-time monitoring of pressure changes within the blood vessel and providing valuable information on hemodynamic conditions to ensure optimal treatment outcomes. The schematic image of the proposed smart stent was shown in Figure 1. This development represents a significant advancement in the field of stent technology and holds great promise for improving patient care and overall cardiovascular health.

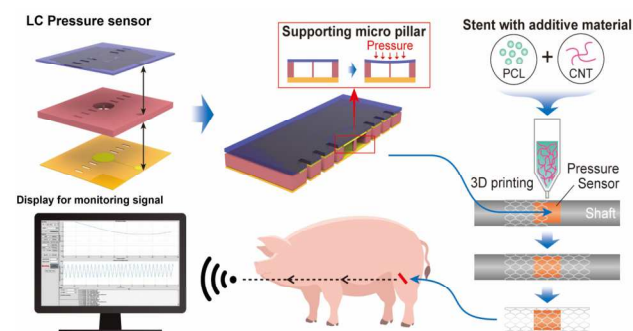


Figure 1. Concept of the additive bioresorbable polymer stent integrated with LC type pressure sensor for sensing signal wirelessly to convert portable device.

FABRICATION OF SENSOR AND MEASUREMENT METHODS

Design and fabrication of stent

The fabrication process begins with a 300 nm thick oxide layer on a 4-inch wafer, which serves as a sacrificial layer for separating the wireless pressure sensor from the wafer. Next, SU-8 3010 photoresist is applied on a silicon wafer, and Ti/Au is deposited using an e-beam with a thickness of 10/100 nm. Capacitors of different types are patterned (400 μm , 600 μm , 800 μm , 1000 μm , 1200 μm , and 1300 μm) on the SU-8 layer using a metal wet etching technique. Following this, a 10 μm thick layer of Perminex is applied to create an insulating layer that only opens the capacitor area, allowing for the creation of a cavity between the top plate and the bottom plate capacitor (Figure 2a).

The bottom layer of the sensor is patterned using a thin layer of SU-8 (SU-8 2002) coated on the silicon dioxide substrate (SiO_2) to support the sensor base layer. Ti/Au is then deposited using an e-beam with $\sim 10/200$ nm, respectively, to fabricate a seed layer for a thick inductor. The inductor coil pattern is formed using a thick AZ4620 photosensitive resist masking with a thickness of 12 μm , and an electroplating process is used to form an Au coil with a thickness of about 10 μm . The SU-8 layer is then coated on the inductor coil and patterned to complete the top layer of the pressure sensor (Figure 2b). Subsequently, an LC resonance-type wireless pressure sensor is combined between the top and bottom layers using the hot-pressing technique, with parameters set at 150°C for 1 minute. The area of the pressure sensor is about 6.5 x 6.5 mm.

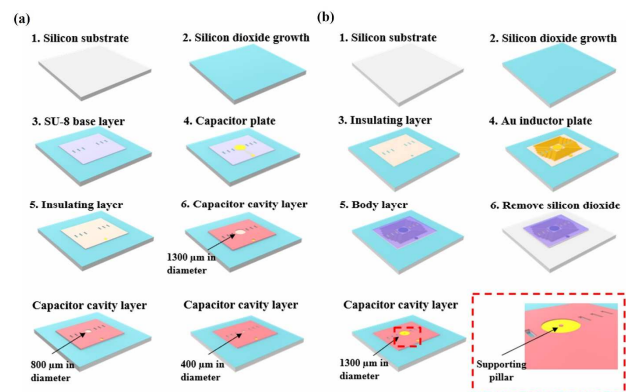


Figure 2. The fabrication process flow of LC pressure sensor. (a) fabrication process flow of the top layer, (b) The fabrication process flow of the LC wireless pressure sensor bottom layer

Measurement system and theoretical description

The electromagnetic coupling effect facilitated the detection of the response from the LC-type pressure sensor by wirelessly coupling it with an external loop antenna. Initially, the inductance and capacitance of the LC pressure sensor were assessed using an LCR meter (E4980AL, Keysight, USA). Subsequently, the portable network analyzer (Field Fox RF Analyzer N19913B, Keysight,

USA) was employed, with the external antenna connected, to capture the variations in the resonance frequency of the LC circuit corresponding to changes in capacitance.

RESULT AND DISCUSSION

The fabrication process was executed using MEMS techniques, enabling the production of very small sensors as well as mass manufacturing. Figure 3(a) presents an optical image of both the top and bottom layers on the silicon substrate. Figure 3(b) displays a photograph of the LC pressure sensor after the removal of the silicon dioxide sacrificial layer using the BHF solution.

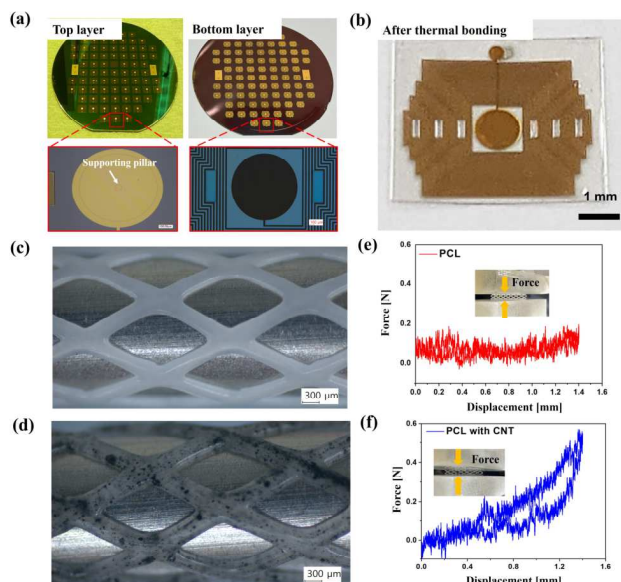


Figure 3. (a)-(b) Optical images of the fabricated pressure sensor; 3D printed PCL and PCL/CNT stent on the 3D printing shaft; (d)-(e) The graph of radial force for the PCL and PCL/CNT stents.

The 100 μm diameter of the micro-supporting pillar was positioned at the center of the capacitor plates, enabling control over the movement of the capacitor plate, and ensuring stable capacitance changes. The diameter of the micro-pillar was set at 10% of the capacitor diameter. After fabricating the absence and presence of the micro-supporting pillar on the pressure sensor's capacitor, the surface was examined using a 3D surface profiler to detect the initial deformation of the capacitor. The absence of the supporter mainly resulted in excessive deflection in both upward and downward directions, indicating reduced reliability of the pressure sensor, while the presence of the supporter showed a uniform surface.

To test the mechanical properties of the polymer stent, both stents with and without CNT mixed into the PCL were 3D printed. The printed PCL and PCL/CNT stents were shown in Figure 3 (c) and (d), respectively. The polymer stent, consisting of a 0.2w% CNT mixed PCL polymer, was then 3D printed to form the stent. The radial force was checked by applying a uniform force distribution across the entire stent structure and measuring the related deflection. The experimental result showed that the pure PCL stent exhibited 0.01 N/mm radial force, while the stent made with the PCL/CNT mixture showed 0.05 N/mm in radial

force (Figure (e-f)). After conducting the mechanical test, we performed the connection between the polymer stent and the LC pressure sensor. For this, the pressure sensor was first fixed on a 3D printing shaft using polyvinyl alcohol (PVA) water-soluble solution. Then, the stent was 3D printed onto the pressure sensor and removed from the printing shaft using a PVA water-soluble solution. The 3D printing was carried out with a 300 nm nozzle on a 300 μm shaft. After applying pressure to both PCL and PCL/CNT, the resonance frequency was examined. The experimental findings indicated that the initial resonance frequency was 32 MHz, aligning with the theoretical value (Figure 4 (a)). The decrease in S_{11} amplitude was attributed to the presence of CNT. The sensitivity of the proposed sensor was determined to be 26 kHz/mmHg (Figure 4(b)).

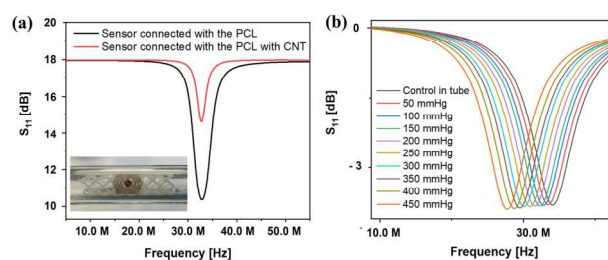


Figure 4. (a) The resonance frequency of the sensor measured with different stents (PCL and PCL/CNT); (b) Changes in resonance frequency under different applied pressure.

CONCLUSION

This paper presents a polymer stent integrated with an LC-type wireless pressure sensor. The proposed smart stent offers advantages in enhancing reliability with a supporting micro pillar, while simultaneously improving mechanical strength by incorporating CNT into PCL. The micro-supporting pillar notably ameliorated undesired deflection of the flexible membrane. In the case of the 3D-printed polymer stent, the radial force of the PCL/CNT increased fourfold compared to the pure 3D-printed PCL stent.

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CARBON NANO TUBES-INCORPORATED SMART STENTS TO IMPROVE MECHANICAL STRENGTH AND SENSOR RELIABILITY

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Atherosclerosis, a primary manifestation, involves the accumulation of plaques within artery walls, gradually constricting them. To address such constriction, a common intervention involves the insertion of various stent into the affected blood vessels. In addition, the material properties of the stent are very important because the stent inserted into the human body is a foreign substance. Ideally, substances that are absorbed into the body over time are desirable. However, the bioabsorbable polymer stents developed to date have limitations due to their low mechanical elasticity of the materials. Furthermore, if the stents inserted into the blood vessel have a function to detect the restenosis at an early stage, a simple drug treatment can solve the blockage. In this paper, we propose a 3D-printed polymer stent with high radial strength integrated with an LC-type sensor to monitor pressure changes in blood vessels in real time. The wireless pressure sensor is fabricated using the photosensitive polymer SU-8, with a supporting micro-pillar at the center of the capacitor to improve sensor performance, while the 3D-printed stent is mixed with CNT to enhance mechanical strength. The connection and operational principles of the wireless pressure sensor are assessed through an inductance-capacitance coupling circuit. This method aims to enhance early detection of restenosis, offering a promising solution in cardiovascular care.

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