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HYBRID BIODEGRADABLE POLYMER STENT FABRICATION USING 3D PRINTERS AND INTEGRATION WITH WIRELESS SENSORS FOR REAL-TIME PRESSURE MONITORING IN BLOOD VESSELS

Jin-liang Wei¹, Nomin-Erdene Oyunbaatar¹, Dong-Su Kim¹ and Dong-Weon Lee^{1,2,3}*

¹Department of Mechanical Engineering, Chonnam National University, Gwangju, SOUTH KOREA

²Center for Next-generation Sensor Research and development, Chonnam National University, Gwangju, SOUTH KOREA

³Advanced Medical Device Research Center for Cardiovascular Disease, Chonnam National University, Gwangju, SOUTH KOREA

ABSTRACT

Cardiovascular diseases (CVD) continue to be a major cause of mortality worldwide. Although traditional treatment using stents has been effective in managing these diseases, it can lead to several adverse effects, including in-stent restenosis. To address this issue, we present the development of a novel hybrid polymer stent composed of polycaprolactone (PCL) and polylactic acid (PLA) that exhibits improved bending flexibility and radial force. The hybrid stent is integrated with a wireless sensor to enable real-time monitoring of pressure changes in the blood vessel. A MEMS-based LC-type wireless pressure sensor is fabricated, with unique microstructures incorporated into the stent to enhance the binding strength between the sensor and the stent. This approach holds promise for improving the clinical outcomes of CVD patients by providing accurate and timely detection of restenosis.

KEYWORDS

Hybrid biodegradable stent; Wireless pressure sensor; Smart stent; In stent restenosis

INTRODUCTION

Cardiovascular disease (CVD) constitutes a major global health burden, as it remains the foremost cause of mortality worldwide [1]. A primary contributor to CVD is atherosclerosis, which is characterized by the progressive thickening of arterial walls due to the accumulation of lipids, cholesterol, and other substances. Traditional treatments for CVD include the use of stents, which mechanically dilate the affected vessels to restore blood flow. Nonetheless, this mechanical dilation method frequently results in vascular trauma and subsequent human tissue proliferation on the stent, culminating in the re-narrowing of the vessel called in stent restenosis. The drug eluting stents have received considerable attention owing to their significantly better performance compared to the bare metal stents. The surface of the drug eluting stents coated with the cell growth-inhibiting agents, which effectively mitigate the proliferation of human tissue on the stent and subsequently decrease the likelihood of restenosis. However, given that drug-eluting stents are fundamentally metal-based, they persist within the human body post-implantation. As the surface-coated drugs are progressively depleted over time, the probability of vascular re-narrowing incrementally increases. Statistical analysis

reveals that approximately 50% of patients experience restenosis in the latter stages of implantation [2].

The development of a third-generation biodegradable stent, composed of materials capable of being absorbed or metabolized by the human body, has been proposed. This approach aims to resolve the issue of permanent stent retention within the body [3]. Nevertheless, due to the inferior mechanical properties of polymeric materials in comparison to metals, practical implementation of such stents remains a significant challenge. Recently, the integration of pressure sensors into stents, commonly referred to as "smart stents," has gained considerable attention in biomedical applications. Such stents are capable of detecting changes in blood flow and pressure within the coronary arteries and transmitting this information wirelessly to a receiver located outside the body [4]. For example, Takahata et al. proposed a smart stent featuring a capacitive pressure sensor and an inductive stent antenna. However, the initial planar shape of the stent made it unsuitable for insertion into blood vessels using standard stenting procedures [5]. Chen et al. utilized modern processing technology to produce inductance coils with exceptional mechanical properties and inductive functions. The capacitive pressure sensors are integrated at both ends of the metal stent using a conductive epoxy. However, the authors realized that the inductor and capacitor closed loop configuration by connecting the sensor membrane with an external gold wire limited its real-time practical feasibility [6, 7]. Park et al. used MEMS technology to fabricate a wireless pressure sensor consisting of SU-8 and copper. This sensor can independently detect pressure and transmit data wirelessly. They combined this sensor with a biodegradable polymer stent using conductive epoxy. However, the platform presented difficulties in implanting the polymer stent into the human body because it could not perform crimping like the stent [8, 9]. Although there has been considerable progress in developing self-reporting stents, there are still technical challenges that need to be overcome to improve the feasibility and reliability of these devices for use in clinical studies. Further research is needed to find more reliable and convenient ways to integrate the wireless pressure sensors and polymer stents, and to develop stent designs that can be easily inserted into blood vessels using standard stenting procedures.

Herein, we present a novel smart stent design based on a hybrid polymer composed of PCL and PLA for the real-time detection of blood pressure in the coronary arteries

and other functional dynamics of the heart. A custom-designed 3D printer was employed to fabricate the biodegradable stent, and we utilized detailed optimization strategies to achieve uniform thickness and width, as well as improved bending flexibility and radial force of the hybrid biodegradable polymer stent. The MEMS-based LC-type wires sensor was integrated into the hybrid biodegradable stent using SU-8 photoresist, and unique microstructures were formed in the sensor to enhance the binding strength between the sensor and the stent. The resulting wireless pressure sensor and hybrid biodegradable stent, as well as the integrated smart stent, are schematically depicted in Figure 1. Based on the results obtained from our study, we firmly believe that the proposed smart stent can serve as a next-generation ubiquitous health (U-health) platform, allowing patients to access healthcare services anywhere and at any time.

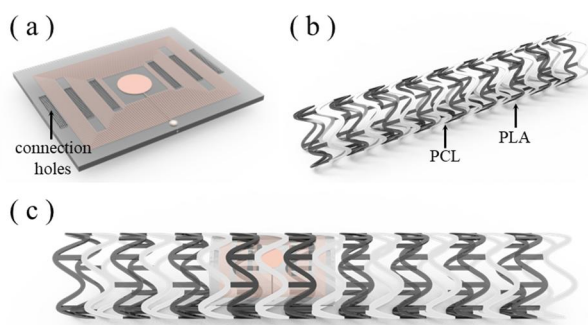


Figure 1: (a-c) Conceptual representation of the wireless pressure sensor integrated with a hybrid polymer stent.

MATERIALS AND METHODS

Fabrication of wireless pressure sensor

Figure 2 schematically illustrates the fabrication process flow of the wireless pressure sensor. The wireless pressure sensor was fabricated using modified photolithography, which follows three important steps: preparation of the top capacitor plate with the inductor coil, fabrication of the bottom capacitor plate, and thermal bonding process. Two four-inch wafers were typically used in the fabrication process, where a 300 nm silicon dioxide (SiO_2) sacrificial layer was formed on the silicon wafer through a wet oxidization method. To prepare the top capacitor plate with the inductor coil, a 2 μm thick SU8-6002 layer was spin-coated on the SiO_2 sacrificial layer. Then, a 20/200 nm thick chromium (Cr) and gold (Au) layer was formed on the SU-8 layer using E-beam technique. Subsequently, a 12 μm thick AZ 4620 layer was formed to define the shape of the plated area. After that, a 10 μm thick gold (Au) inductor coil was patterned using electroplating technique at a current density of $0.8\text{A}/\text{cm}^2$ for 40 min. The AZ4620 photoresist and metal seed layer were removed using acetone and metal etchant, respectively. Finally, a 15 μm thick SU8-3010 layer was spin-coated to realize the top capacitor plate with the inductor coil, as shown in Figure 2(i-iii).

The bottom capacitor plate was fabricated by spin-coating a 10 μm thick SU8-3010 layer on the SiO_2 sacrificial layer. Then, a 20/200 nm thick Cr and Au seed layer was formed on the SU8-3010 layer using E-beam

technique. Next, a 2 μm thick GXR-601 layer was used to define the shape of the capacitor plate. The metal etchant was used to remove the metal seed layers, followed by the formation of a 2 μm thick SU8-6002 layer on top as an insulating layer, as shown in Figure 2(iv-vi). The thermal bonding process was employed to realize the wireless pressure sensor. The top capacitor plate with the inductor coil and the bottom capacitor plate were precisely aligned under the microscope using PermiNex 1010 and placed on a preheated hotplate at 150 $^\circ\text{C}$. A pressure of approximately 10kN was applied for 30 s. After the thermal bonding process, a BHF solution was used to release the wireless pressure sensor from the silicon wafer by removing the SiO_2 sacrificial layer, as shown in Figure 2(vii-ix).

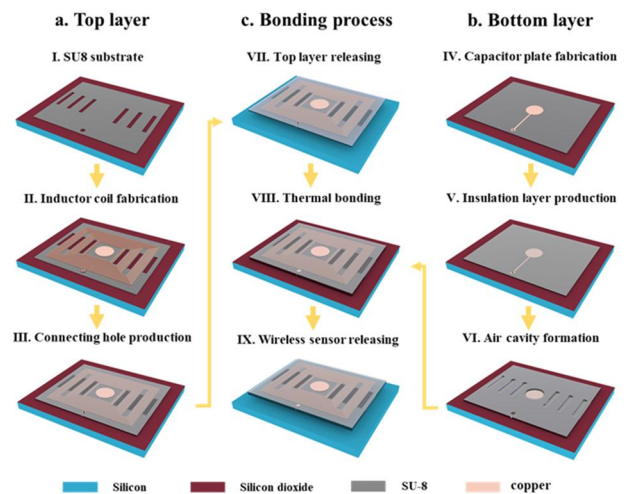


Figure 2: Fabrication process flow of the MEMS-based wireless sensor. Schematic illustrate the fabrication process flow top capacitor plate with the inductor coils, bottom capacitor plate, and thermal bonding process.

Fabrication of hybrid biodegradable stent

The hybrid biodegradable stents were fabricated using a combination of two polymer materials, namely PCL and PLA. This approach was expected to enhance the mechanical properties of the hybrid biodegradable stent as compared to bare biodegradable stents. The custom designed 3D printer facilitated the fabrication process by enabling the definition of the printing path and the splitting of the polymer bracket into PCL and PLA parts. The use of different temperatures of the two materials facilitated their combination into a fused state. To fabricate the hybrid biodegradable polymer stent, the PCL material, which has a lower melting point, was printed first, followed by the PLA material, which has a higher melting point. Since the printing paths of the two materials have numerous intersections, the higher melting PLA material melts the PCL material during printing. The thermal motion enables the two materials to bond at the intersection point, resulting in the formation of a hybrid biodegradable stent.

Fabrication of wireless pressure sensor integrated biodegradable stent

The smart stent was fabricated by integrating the previously fabricated wireless pressure sensor and hybrid

biodegradable stent. A rotating shaft with a diameter of 4 mm was coated with a sacrificial layer of polyvinyl alcohol (PVA) on its surface. The fabricated wireless pressure sensor was then attached to the PVA sacrificial layer. Subsequently, the hybrid biodegradable stent was 3D printed on the rotating shaft, with the wireless pressure sensor attached to it. During the printing process, the molten polymer materials such as PCL and PLA flowed into the connection hole of the wireless sensor, and the two components formed a mechanical connection after cooling and solidification. Finally, the PVA sacrificial layer was removed, resulting in the realization of the wireless pressure sensor-integrated hybrid biodegradable stent.

RESULT AND DISCUSSION

The structure and size of the fabricated wireless pressure sensor were investigated by optical and scanning electron microscopy (SEM) analysis, as shown in Figure 3. Optical image shows the fabricated wireless pressure sensor after releasing from the silicon wafer is shown in Figure 3a. The dimensions of the wireless pressure sensor were 6 mm in width and 7.4 mm in length, respectively. SEM image shows the cross-sectional view of the fabricated wireless pressure sensor (Figure 3b). The thickness of the inductor coil in the wireless pressure sensor was found to be $\sim 10 \mu\text{m}$.

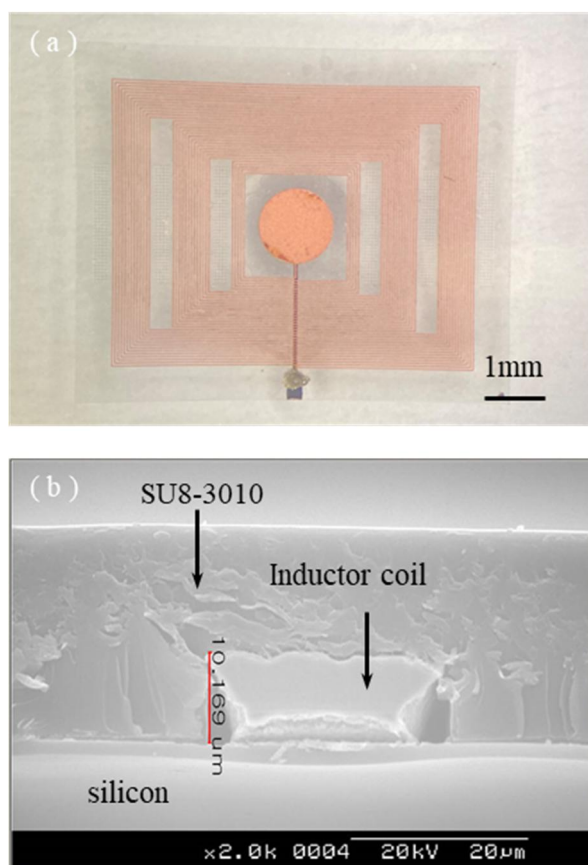


Figure 3. The photograph and SEM image of the fabricated wireless pressure sensor. (a) wireless pressure sensor after releasing from the wafer and (b) SEM image shows the thickness of inductor coil.

The wireless sensor has been designed with an air cavity located at the central position of the device. As a

result of this design, when an external pressure is applied, only the membrane at the central position will deform, leading to a change in the capacitance of the wireless pressure sensor. This change in capacitance value will subsequently cause a shift in the resonance frequency of the wireless pressure sensor. Therefore, this design approach ensures that the pressure sensitivity of the LC wireless sensor is focused only on the central region of the device, resulting in a more accurate and precise measurement of the applied pressure. The effect of applied pressure on the displacement of the capacitor plate was investigated, as shown in Figure 4a. Different applied pressures, ranging from 0-200 mmHg, were applied to the variable capacitor plates. The displacement of the capacitor plate caused by external applied pressure was monitored using a laser vibrometer (OFV-5000, Polytech, USA) with a high degree of precision at the nanoscale level. The results indicated that the displacement of the capacitor plate increased with an increase in the applied pressure, exhibiting a maximum displacement of $5.2 \mu\text{m}$ at an applied pressure of 200 mmHg. Furthermore, once the applied pressure was withdrawn, the capacitor plate retained its initial position without any hysteresis, indicating the high reliability and flexibility of the fabricated capacitor plates. Theoretical calculations were carried out based on the deformation theory of a pressure sensor with a sealed cavity under pressure. The results of the calculations showed that when an applied pressure of 200 mmHg was exerted, the deformation of the center of the membrane was found to be approximately 6 mm, as previously proposed by V. Rochus et al. [10]. The experimental value obtained in this study was found to be close to the theoretical calculation value. The observed discrepancy between the theoretical calculations and the experimental results may be attributed to the slight deformation of the capacitor plates after its release from the wafer.

The resonance frequency of the fabricated wireless pressure sensor was investigated at different applied pressures ranging from 16-280 mmHg with the ramp of 30 mmHg as shown in Figure 4b. To measure the resonance frequency of the wireless pressure sensor, the device was placed inside a vacuum chamber comprising two channels. One end of the channel was connected to an external syringe pump, while the other end was connected to a commercial pressure gauge. The desired external pressure was then applied to the LC-pressure sensor using a syringe pump (LEGATO210, kdScientific, USA). To ensure accurate pressure measurement, the force applied by the external syringe pump was closely monitored using a commercial pressure gauge (PSCH0230HGPG, Sensys, South Korea). The resonance frequency of the wireless pressure sensor exhibited a decreasing trend with increasing applied pressure, ranging from 16 to 280 mmHg. Specifically, the resonance frequency decreased from 91.54 MHz to 87.53 MHz as the applied pressure was increased from 16 to 280 mmHg, respectively, as shown in Figure 4b. The sensitivity of the fabricated wireless pressure sensor was determined to be $19.66 \text{ kHz mmHg}^{-1}$. The fabricated hybrid biodegradable smart stent exhibits the uniform strut width and thickness of $300 \mu\text{m}$ and $200 \mu\text{m}$ (Figure 5). The radial force of the hybrid polymer stent was 0.1 N/m .

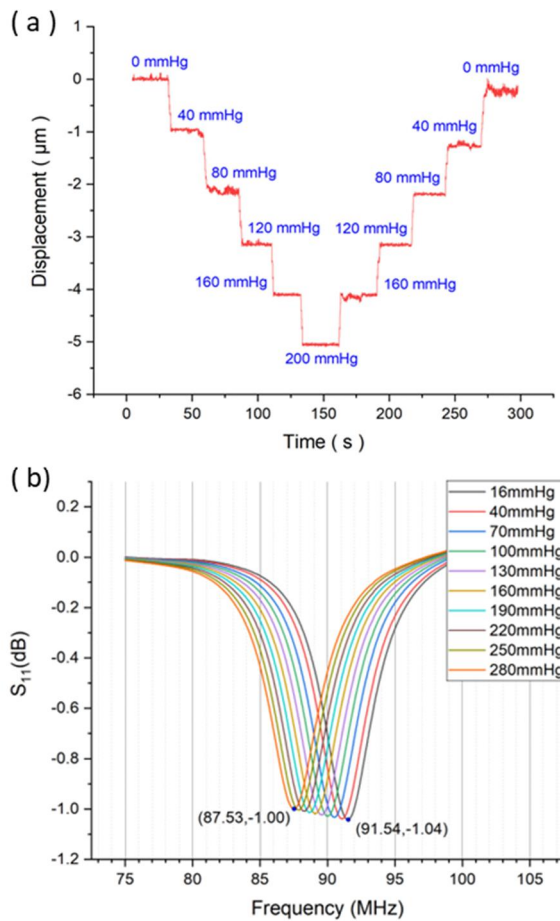


Figure 4: Preliminary characteristics of the fabricated wireless pressure sensor. (a) Displacement of capacitor plates according to the different applied pressures. (b) Resonance frequency of the wireless pressure sensor at different applied pressures.

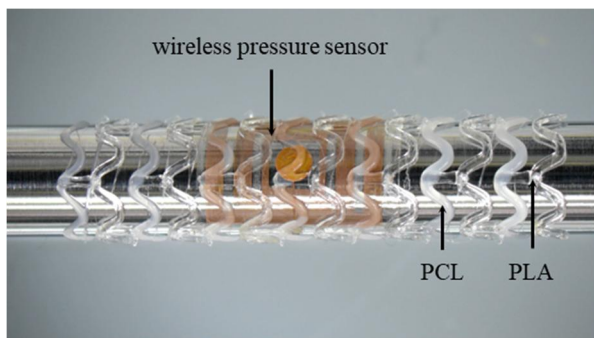


Figure 5: Photograph shows the wireless pressure sensor integrated hybrid biodegradable smart stent.

CONCLUSION

In summary, we proposed a novel hybrid smart stent for potential cardiovascular applications. The combination of hybrid biodegradable stent exhibiting better mechanical characteristics than a single-material stent. Moreover, the use of hybrid materials in combination for printing the stent overcomes the limitations of a single material and enhances its bending flexibility while ensuring radial force. The basic experiment conducted with the fabricated smart stent demonstrated that the change in the resonant frequency according to pressure was highly consistent with the design

value. The excellent performance of the proposed smart stent highlights its potential for medical purposes.

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CONTACT

*D. W. Lee, Email: mems@jnu.ac.kr