3D-PRINTABLE SELF-POWERED PIEZOELECTRIC SMART STENT FOR WIRELESS ENDOLEAKS SENSING

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2024 IEEE 37th International Conference on Micro Electro Mechanical Systems (MEMS) | 979-8-3503-5792-9/24/$31.00 ©2024 IEEE | DOI: 10.1109/MEMS58180.2024.10439508

ABSTRACT

In this paper, we present a 3D-printable self-energized smart stent capable of in-situ continuous wireless monitoring of blood flow and pressure in the endovascular aneurysm. We demonstrated the 3D-printing technique to create such a piezoelectric smart stent. The smart stent is made of piezoelectric polymer, polyvinylidene fluoride-co-trifluoroethylene, which produces charge in response to stress created by mechanical stimuli, such as blood pressure or flow. Here, we evaluated the sensing response due to the change in pressure and flow rate, demonstrating its functionality as a self-powered smart stent. Additionally, a wireless monitoring scheme for detecting endoleaks was demonstrated via an electromagnetic (LC resonator) readout system to retrieve blood pressure information.

KEYWORDS

Smart Stent, 3D printing, piezoelectric, pressure, flow, sensing, wireless sensor, implantable medical device.

INTRODUCTION

Endovascular aneurysm refers to an abnormal bulge in blood vessels weakening the artery walls, often leading to life-threatening rapture or bursting. Incidents like this may require immediate surgical interventions. There are mainly two types of such surgical procedures; one is open surgery for aneurysm repair and another is endovascular repair [1]. An open aneurysm repair requires an incision on the patient's abdomen or side, where the endovascular repair is comparatively a minimally invasive procedure [2]. It involves placing a metal or combination of metal-fabric stent-graft through a catheter in the affected area to bypass blood flow and relieve pressure on the artery walls [3]. Delayed treatments could be catastrophic due to several complications, such as rapture, aortic dissection, and ischemia, among others. Therefore, placing a stent using Endovascular Aneurysm Repair (EVAR) surgery is the most suitable treatment plan to prevent complications. EVAR is not only a popular method of treating AAA, but according to NIH, the success rate of EVAR exceeded 90% in all cases and showed significantly reduced morbidity and mortality against open repair [4].

Nonetheless, even after a successful EVAR surgery, complications may occur (e.g., endoleaks, endograft infection, occlusion, ischemia, etc.). There are also five different kinds of endoleaks (leaking of blood outside the stent graft within the aneurysm sac). Therefore, regular and periodic monitoring is obligatory to prevent such occurrences [5]. Post-EVAR monitoring is commonly performed using different imaging techniques such as radiography (X-ray), computed tomography, magnetic resonance imaging, ultrasound, etc. These methods are often expensive, have limited availability, are invasive, or are sometimes unable to detect endoleaks. Moreover, many patients are often lost to follow-up, missing a golden time for treatment [6].

In recent works, Ahmadpour et al. reported piezoelectric metamaterial (PVDF) based skin adherent blood pressure sensors where different structures of piezoelectric metamaterials were analyzed for improving the sensitivity [7]. Additionally, we also previously reported piezoelectric smart stents, and their design optimizations to work as implantable blood pressure sensors in the aneurysm sac [8, 9]. In this work, we focused on the 3D print manufacturing technique for such piezoelectric smart stents with a wireless sensing scheme. The 3D printing technique offers several advantages, for example, design customization, the ability to manufacture complex geometries, reducing waste, rapid prototyping, and patient-friendly designs. There are also several researchers working on 3D printable stents. For example, Luo et al. used the stereolithography technique to create a stent for nasal passage after cleft lip surgery [10], Zhao et al. reported the use of fused deposition modeling to experimentally evaluate the performance of different designs of 3D printable stents [11]. Geng et al. reported the use of selective laser sintering for creating 3D printable stents [12]. However, the focus of those 3D printing stents is to replicate the traditional stent fabrication and omit sensing functions. In this work, we present novel features of wireless blood pressure sensing capabilities while also working as a 3D-printed stent.

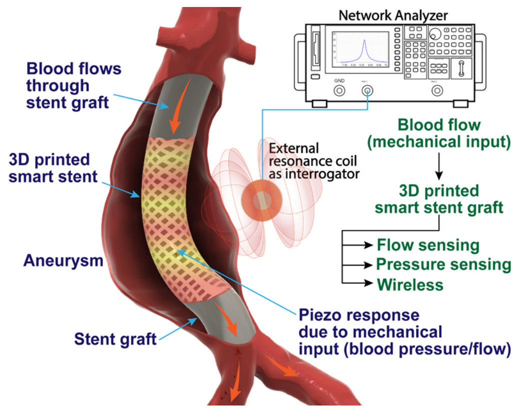

Figure 1: 3D printed self-energized smart stent incorporated with a traditional stent graft working as an in-situ wireless blood flow and pressure sensor.

Fig. 1 represents the schematic of the proposed 3D-printed Smart Stent. The smart stent not only bypasses the blood circulation around the aneurysm but also enables wireless pressure sensing to identify post-EVAR complications such as endoleaks or significant blood pressure loss. As the blood circulation passes through the Smart Stent, the mechanical oscillation will induce electrical energy generation, which charges the inductor-capacitor (LC) tank. The charged LC tank resonates and emits an electromagnetic field that contains pressure information. Such electromagnetic field can be captured wirelessly from outside of the body with a readout system, e.g., a vector network analyzer. The Smart Stent is expected to lower post-surgery monitoring costs, increase monitoring frequency, and enhance the overall quality of life.

MATERIALS AND METHOD

Fig. 2 shows the fabrication procedure. The Smart Stent is fabricated using 3D-printed PVDF-TrFE (polyvinylidene fluoride-co-trifluoroethylene) 70/30 mol copolymer filament (PolyK Tech.), which has a Curie temperature of 95°C. The copolymer was selected because it is relatively easier to pole for piezoelectricity during 3D printing [13]. Fig. 2(a) shows 3D printing and in-situ high-voltage (37.5 kV/mm) poling technique [13]. The printing bed was prepared with two layers of polyimide tape for insulation, then a single layer of copper tape for high voltage source connection, and another two layers of polyimide tape on top of it for proper insulation. An additional layer of painter's tape was applied, which helped promote 3D printing adhesion. The printing nozzle was connected to high voltage ground. The PVDF-TrFE film was printed directly onto the build platform using a customized 3D printer (MK3S+, Prusa). A 220°C nozzle temperature with a 100°C print bed temperature produced the best quality PVDF-TrFE film without any printing artifacts. The total printed film height (stent wall thickness) was 0.4 mm. A thin (50 ± 5 µm) and uniform electrode layer was applied on both sides using conductive silver epoxy, followed by curing process at 60 °C for an hour (Fig. 2b). Then, the printed PVDF-TrFE sheet was rolled and joined using a heat press to complete the proposed smart stent (Fig. 2c). A thin layer of biocompatible resin (Formlabs) coating was applied to the surface for insulation. The diameter and length were 22 mm and 30 mm, respectively (Fig. 2d).

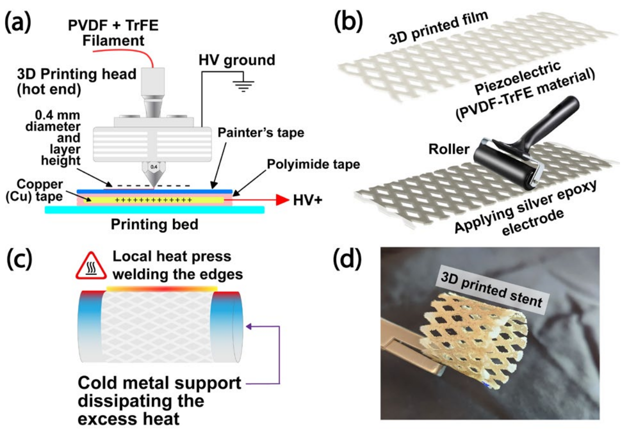

Figure 2: (a) 3D printing PVDF-TrFE material with in-situ high voltage poling at 15 kV to create a piezoelectric stent; (b) applying electrode layers; (c) rolling and joining the edges using heat press method; (d) fabricated smart stent.

EXPERIMENT SETUP

Piezoelectric response test

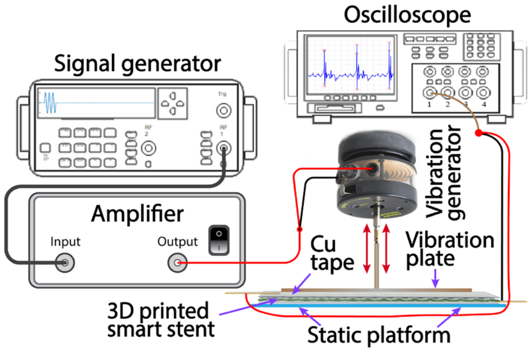

Figure 3: Experiment setup for piezoelectric response test.

First, we conducted a test on piezoelectric behavior. An external mechanical force at various frequencies was applied on flat 3D-printed PVDF-TrFEs using a vibration generator (VBGN, Eisco Labs). The vibration generator was driven using 5 to 30 Hz sinewave signals via an amplifier (OPA541, Texas Instruments). The mechanical force applied to the material was converted to electrical energy due to PVDF-TrFE's piezoelectric effect. The output voltage was recorded using an oscilloscope (DSOX3034G, Keysight). The experiment setup is shown in Fig. 3. Additionally, we also measured the piezoelectric coefficient (d_{33}) using a Berlincourt piezoelectric meter (PKD3-2000-F10N, PolyK Tech.) to confirm the piezoelectricity. The PVDF-TrFE membrane with 0.4 mm thickness and 15 kV (37.5 kV/mm) poling voltage showed an average piezoelectric coefficient (d_{33}) around 9.967 ± 0.306 pC/N when tested with a force of 250 mN at 110 Hz.

Simulated blood circulation test

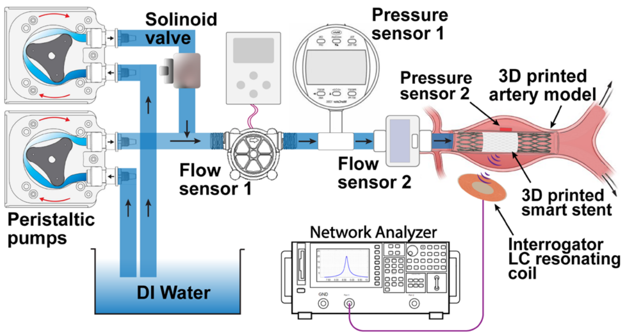

Figure 4: Experiment setup with realistic aneurysm model.

Fig. 4 describes the experiment setup precisely mimicking an abdominal aortic aneurysm. Two peristaltic pumps (AIP, Kamoer) delivered pulsating deionized (DI) water mimicking actual blood flow at a resting heart rate of 80 beats per minute (BPM) into the flow system controlled by a digitally programmed solenoid valve. Two commercial flow meters and one pressure transducer (DPG210-005G, Omega) were attached in line with a realistic 3D-printed (Elastic resin-50A, Formlabs) aneurysm model. An additional pressure transducer (BP0001, Merit Sensor) was placed in the aneurysm site to capture the internal pressure during the experiment. The 3D-printed stent was placed inside the aneurysm model with a 3D-printed graft.

Two experiments were conducted using this setup. First, the output voltage of the smart stent was measured due to the change in flow rate between 500 to 1400 mL/min, and pressure change in the aneurysm sac between the range of 25 to 85 mmHg using an oscilloscope (DSOX3034G, Keysight). Second, we placed a planner LC coil (L = 6.76μH, C = 50pF) next to the aneurysm connected to a vector network analyzer (E5061B, Keysight) to wirelessly observe the changes in self-resonance frequency. We hypothesized that a shift in the resonant frequency of the LC coil reflects the change in the inductive coupling with the smart stent, which can represent the change in pressure and flow.

RESULTS AND DISCUSSION

Piezoelectric response results

The piezoelectric response due to mechanical excitation at 5, 10, 20, and 30 Hz was tested using an experimental setup in Fig. 3. Piezoelectric responses from four different excitation frequencies are shown in Fig. 5(a-d). The output voltage ranged between 1.1 to 1.4 volts. There was a slight rise in the output voltage in relation to the excitation frequency increase, which suggests that the 3D-printed PVDF-TrFE could be used for higher frequency energy harvesting. Nevertheless, the overall performance was suitable for sensing applications.

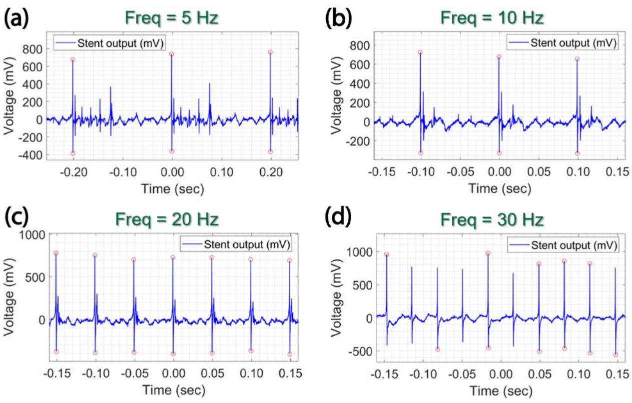

Figure 5: Piezoelectric response due to (a) 5 Hz, (b) 10 Hz, (c) 20 Hz, and (d) 30 Hz sinusoidal mechanical loading.

Simulated blood circulation (in vitro test) results

As mentioned in the experiment setup, DI water was used with pulsating pump systems to mimic realistic blood flow dynamics in the aneurysm sac. The pressure in the aneurysm sac varied between 25 to 85 mmHg. The change in pressure showed a linear response of the piezoelectric stent output with a $V_{peak\text{-}to\text{-}peak}$ of 0.943 mV/mmHg with an R^2 value of 0.83. The responses are shown in Fig. 6. The subset figure shows an example voltage output captured for an individual pressure point (e.g., 56 mmHg).

Similarly, the flow rate through the aneurysm system was varied between 500 to 1400 mL/min using the peristaltic pumps. The voltage output of the smart stent also showed a linear relationship for the change in flow rate with a sensitivity of 59.1 μV/mL/min with an R^2 value of 0.86. Fig. 7 shows the voltage outputs ranging from ~70 mV to ~130 mV for the change in flow rate from 500 to 1400 mL/min. The subset figure shows an example response signal for a flow rate of 1000 mL/min.

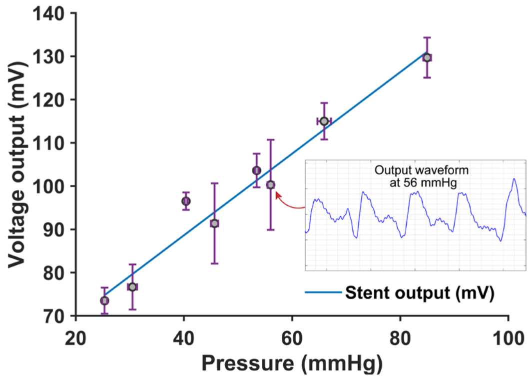

Figure 6: Voltage output of the piezoelectric smart stent changes based on the pressure inside the aneurysm sac.

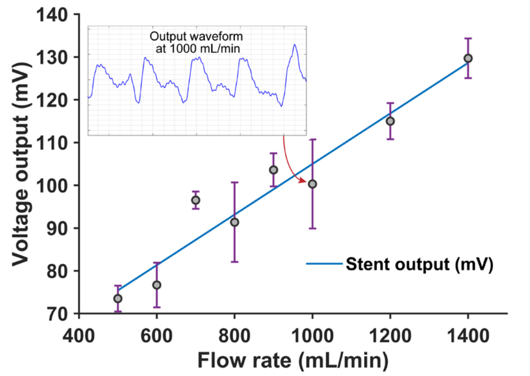

Figure 7: Voltage output of the piezoelectric stent changes based on the flow rate inside the aneurysm sac.

Since the smart stent is also a coil-like shape with front and back electrodes, it is also presented as a pair of a capacitor and an inductor. We utilized such an LC tank with an inductive coupling with an external coil. The change in the resonance frequency of the external coil was subject to the change in the mutual coupling between the smart stent, which could be captured using a vector network analyzer. When the smart stent was exposed to varying pressure and flow rates, its physical dimensions caused a change and induced a shift in resonant frequency due to the mutual coupling. The external coil had an inductance of 6.76 μH, and a capacitance of 50 pF resulting in a resonance frequency of 8.657 MHz. The results are shown in Fig. 8. As expected, the wireless measurement due to the change in aneurysm pressure demonstrated a linear response with a sensitivity of -2.2 kHz/mmHg, with an R^2 value of 0.91.

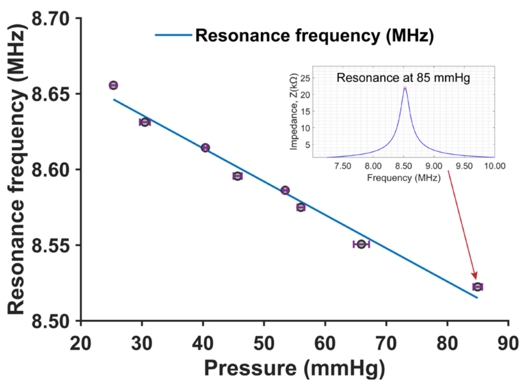

Figure 8: Change in resonance frequency of the LC interrogator coil due to change in aneurysm pressure.

CONCLUSIONS

The proposed smart stent demonstrates that traditional stents can be created using a 3D printer and piezoelectric PVDF-TrFE filaments. Combined, pressure sensing results show that a change in aneurysm pressure could be wirelessly detected, allowing early detection of post-EVAR complications. Moreover, it has the ability to extract energy from blood flow in the human body in addition to being utilized to detect changes in blood flow rate or pressure. Therefore, it will be able to energize onboard electronics to transmit that information. In future research, we will also aggregate sufficient data to associate the type of endoleaks with flow and pressure information and apply machine learning techniques to analyze the collected data in an effort to identify and forecast as a kind of early warning system. Overall, the proposed smart stent demonstrated that traditional stents can be sensorized with 3D-printed piezoelectric PVDF-TrFE and have the potential to harvest energy from blood flow in the human body, which may energize onboard electronics to transmit that information in the future.

ACKNOWLEDGEMENTS

The authors would like to acknowledge Alex Lapointe (University of South Florida) for his help with the experiments and National Science Foundation (NSF) Award # 2306330, 2029086, and NSF CAREER award # 2245090 for funding the research.

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