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Wireless Monitoring of Vascular Pressure Using CB-PDMS Based Flexible Strain Sensor

Hao Chong, Jason J. Lou, Christian A. Zorman, *Senior Member, IEEE*, and Steve J.A. Majerus, *Senior Member, IEEE*

***Abstract*—Rising pressure within a vascular graft can signal impending failure caused by stenosis or thrombosis, and early detection can improve surgical salvage outcomes. To enable regular graft pressure monitoring, we developed a thin flexible pulsation sensor (FPS) with wireless data readout. A conductive polymer sensing layer is attached to a flexible circuit board and then encapsulated by polydimethylsiloxane (PDMS) for biocompatibility. Due to the FPS' outstanding flexibility in comparison to natural arteries, veins, and synthetic vascular grafts, it can be wrapped around target conduits to monitor blood pressure for short-term surgical and long-term implantation purposes. In this study, we analyze the power spectrum of the FPS data to determine the ideal bandwidth of the wireless FPS device to preserve heart rate and hemodynamic waveforms while rejecting noise. The strain response of FPS wrapped around silicone tube, vascular graft and artery was simulated using COMSOL®, showing a linear relationship between pressure and FPS strain. The optimized bandpass filter of 0.2-10 Hz was simulated and implemented on a flexible polyimide circuit board. The circuit board also included a low-power microcontroller for data conversion and transmission via simple 4-MHz on-off keying. The performance of the prototype was evaluated by recording wireless data from a vascular phantom under different pressure and flow settings. The results indicate that the peak-to-peak FPS voltage responds linearly to RMS blood pressure and systolic-diastolic pressure.**

Clinical Relevance— Early detection of a failing vascular graft could leverage sensors for near real-time monitoring. The presented wireless flexible sensor measures and transmits vessel distension data as a proxy for internal lumen pressure.

I. Introduction

Synthetic vascular grafts have wide applicability in vascular bypass and hemodialysis vascular access, and over one million grafts are implanted in the United States every year [1]. Yet, current synthetic graft options are vulnerable to failures, e.g. due to intimal hyperplasia where endothelial cell migration leads to reduced diameter in the graft lumen, blood clotting, reduced graft blood flow, and eventual graft occlusion. To detect failing grafts before occlusion, current solutions rely on regular expert surveillance and medical imaging of implanted grafts. Considering the 20-38% failure rate for synthetic vascular grafts within one year of implantation, such surveillance is still difficult to manage [2]. One approach to alleviate this challenge is to initiate daily monitoring of blood flow for early intervention, since a 25% drop in blood flow serves as a suitable indicator for a failing vascular graft [3]. This approach thus requires frequent measurement of the implanted graft function, realizable by flexible pulsation sensors (FPS). By wrapping the FPS around the graft or blood vessel during surgery, the sensor can monitor patients' blood flow using near-field electronic transceivers (Fig. 1).

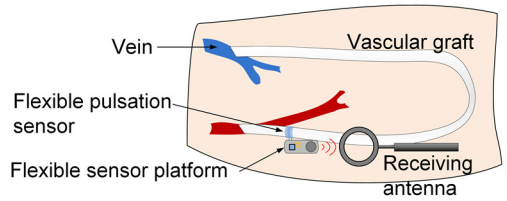

Fig. 1. The FPS was designed to be wrapped around a synthetic graft or vein to detect impending graft failure.

Implanting sensors within the lumen of the graft enables monitoring of blood pressure and blood flow [4]. Yet this measurement comes with the expense of changing the graft's mechanical structure and accelerating rate of graft failure because of platelet and protein deposition on sensor surfaces [1]. Prior developments in FPS devices focused narrowly on observing synthetic grafts using polymer films such as polyvinyl-fluoride [5] or aluminum nitride [6] or sensors constrained to rigid metal rings [7]. In other words, they relied on low elasticity and fixed geometry of synthetic grafts, thus requiring sensors adhering to grafts prior to implantation.

An alternate approach to FPS devices relies on using it operatively, e.g. on native blood vessels or during graft implantation procedures to remain implanted. This approach requires an FPS that is highly flexible and open-ended. To realize such capabilities, we adapted piezoresistive elastomer composites for the FPS transduction material. Prior work established that a composite of polydimethylsiloxane (PDMS) and conductive nanoparticles resulted in robust piezoresistive strain response [8], [9]. In this work, we optimized the sensor dimensions based on strain simulations on synthetic and natural blood vessels. We designed an analog interface amplifier based on the FPS signal bandwidth and designed a wireless prototype using flexible circuitry bonded to a conductive PDMS composite. The performance of the prototype was evaluated on a bench vascular phantom over a range of physiologic pressures and flows.

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H. Chong, J. Lou, and C. Zorman are with the Department of Electrical, Computer & Systems Engineering, Case Western Reserve University, Cleveland, OH, 44106, USA (e-mail: hxc499@case.edu).

C. Zorman and S. Majerus are with the Advanced Platform Technology Center, Louis Stokes Cleveland Veterans Affairs Medical Center, Cleveland, OH, 44106, USA (e-mail: steve.majerus@va.gov)

II. Wireless Flexible Pulsation Sensor Design

A. Computer Model of FPS Strain Response on Vessel

The FPS dimensions were optimized using finite-element model simulations in COMSOL® Multiphysics. This modeled the stress-strain and mechanical behavior of the FPS device on blood vessels and vascular grafts. Additionally, the performance when wrapped on a silicone tube was modeled to describe the expected performance on a vascular phantom, which used silicone to mimic the dimensions and elasticity of human blood vessels.

The FPS had an overall width of 10 mm, and a thickness of 0.5 mm or 1 mm in order to investigate the influence of FPS thickness on the strain response. The CB-PDMS composite sensing layer, consisting of a total of four continuous and parallel sensors along the strain-sensitive axis, each with a width of 1 mm, and a thickness of either 0.1, 0.13, or 0.18 mm. The stripe thickness determined the sensor's gauge factor, and overall resistance. The CB-PDMS stripes were positioned on top of a PDMS base layer and packaged by an upper PDMS layer, resulting in a sandwiched structure with a total thickness of 0.5 – 1.0 mm. The dimensions of the base and composite layers are in congruence with experimentally fabricated FPS devices. The FPS device was wrapped around a blood vessel, graft, or silicone tube model with thickness of 0.8 mm but different inner diameter of 3, 4, 6, 8, and 12 mm in order to investigate the relationship between vessel size and strain response of FPS under same pressure conditions. The overall assembly of the simulation combined the PDMS, CB-PDMS, along with the vessel (Fig. 2). Three materials were used to simulate the vessel: human artery, synthetic expanded polytetraethylene (ePTFE) graft, and silicone tube. MED-4210 PDMS was selected as the FPS substrate layer. Mechanical properties for simulated materials are listed in Table 1.

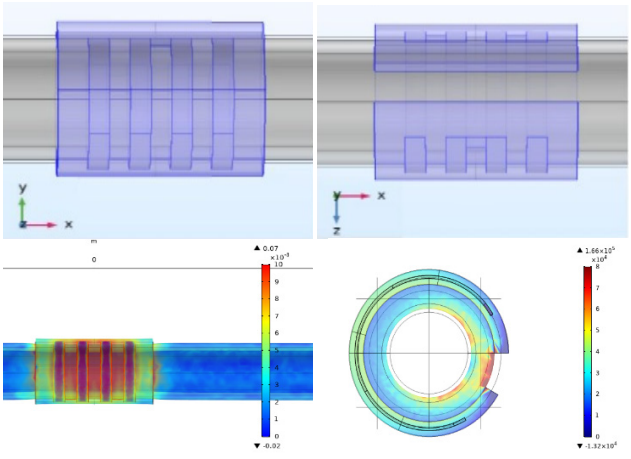

Fig. 2. COMSOL® model for simulating FPS pressure and strain under various circumstances

TABLE I. Mechanical Properities of Materials Used

Material	Young's Modulus	Density	Poisson Ratio
EcoFlex 00-10	55.0 kPa	1041 kg/m^3	0.45
MED-4210	550 kPa	1120 kg/m^3	0.45
CB-PDMS	45.0 kPa	970 kg/m^3	0.45
Human Artery	264 kPa	1160 kg/m^3	0.49
ePTFE Graft	10.7 MPa	2200 kg/m^3	0.42

Simulations were performed by applying pressures of 80 - 200 mmHg with a increment of 10 mmHg on the inner wall of the hollow cylinder structure to model the strain response of the FPS to human systolic blood pressures. The first principle strain along the strain-sensitive axis of the FPS was calculated. As seen from Fig. 3, first principle strain possessed a positive linear relationship with varying blood pressure applied for all combinations of PDMS base layer and artery/vascular graft combinations.

The simulation showed that the CB-PDMS thickness had negligible effect on strain response, while the thickness of the substrate PDMS had only a moderate effect in reducing the strain sensitivity. The Young's modulus of the vessel affected the response the most; more rigid conduits produced lower strain in the FPS. While the ePTFE graft had an order of magnitude lower strain response, it was still within the range of measurable strain based on previous reports of gauge sensitivity for CB-PDMS sensors [10]. These simulations also suggested that FPS thickness up to 1.0 mm had enough flexibility to measure the strain in human arteries during pulsatile flow at physiological pressures.

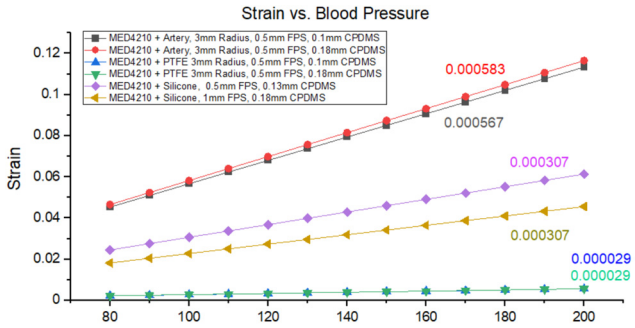

Fig. 3. Variation of first principle strain along with variation of blood pressure on PTFE vascular grafts, and variation of first principle strain along with variation of blood pressure on artery.

B. Wireless Sensor Interface Design

Because data transmission consumes significant energy, optimization of the sample rate for a wireless sensor is critical. This required characterizing the signal bandwidth of the arterial pressure waveform and designing an interface amplifier to provide an anti-aliasing filter. The power spectral density of FPS data collected from previous work [10], indicated a 95% power bandwidth below 2 Hz (Fig. 4a,b), suggesting that the hemodynamic pressure waveform bandwidth was about twice the pulse rate. Since the heart rate of adults ranges from 60-180 beats per minute, the bandwidth of the FPS amplifier interface was designed to be 0.2-10 Hz.

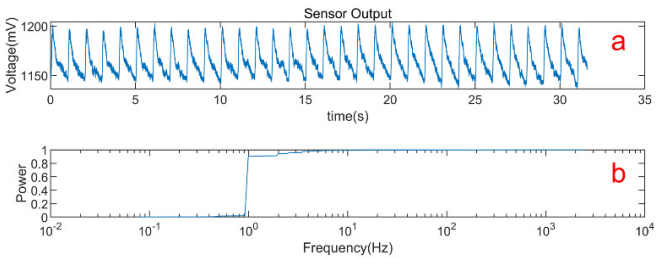

Fig. 4. (a) FPS signal from previous work [10]; (b) integrated power spectral density showed a 95% power bandwidth below 10 Hz.

The FPS interface amplifier (Fig. 5) was designed to have optimized bandwidth and gain to transform the FPS response to a full-scale range of 2 V for data conversion. Component selection to tune the front-end amplifier gain and bandwidth was performed through SPICE simulation (Table 2).

Wireless readout from the sensor used a low-power microcontroller with integrated analog-to-digital converter (ADC) and data signal modulator peripheral (DSM). The FPS was measured by a bridge circuit, amplified and filtered, and digitized by the ADC to 10-bit resolution at 100 samples/s. Data were transmitted in a burst of 10 samples every 100 ms to save power. Transmission used Manchester-encoded on-off-keying of a 4 MHz carrier using the DSM. A resonant LC circuit with a matching capacitor was used as a simple magnetic antenna. This enabled short-range inductive communication to an external antenna and data receiver. The measured transmission range of 30 cm was sufficient for most peripheral vascular depths.

The microcontroller software was designed to transmit data continuously for 15 minutes before entering a low-power sleep state. The wireless FPS was activated from sleep by applying a large RF pulse which was received by the inductive antenna to trigger a wake-from-sleep interrupt. This activation system was developed to save power in an implanted application. When active, the sensor drew 86 µA, which would enable powering via a miniature battery, or a battery-less technology (e.g. NFC or RFID). However, for demonstration in this paper wired leads were used for power.

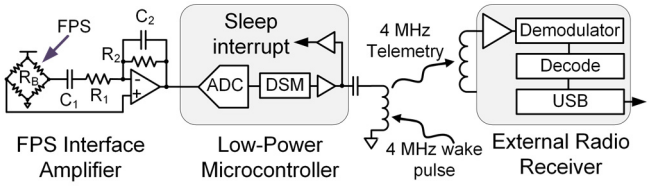

Fig. 5. The wireless FPS platform used a bridge amplifier to amplify and set the sensor signal bandwidth. A microcontroller with an integrated ADC transmitted data wirelessly to an external radio.

TABLE II. MEASURED PERFORMANCE OF SENSOR PROTOTYPE

Name	Value	Specification	Measured value
R_B	100 kΩ	Bandwidth	0.2 – 10 Hz
R_1	100 kΩ	Dynamic range	10 bits
C_1	4.7 µF	Sample rate	100 Hz
R_2	2.8 MΩ	Current draw	86 µA
C_2	5.6 nF	Transmit range	30 cm

C. Carbon Black – PDMS Nanocompsite Fabrication

We modified the fabrication process of the conductive PDMS sensing layer reported in [10] in order to connect the FPS to a flexible circuit board. First, a pure PDMS substrate (MED-4210) was cast on a flexible transparency film and degassed. Next, a rectangular hole with the same size of the flexible circuit board was cut into the substrate. The flexible circuit board was designed with circuitry on the front side and connection pads for the FPS on the back; electroless nickel followed by immersion gold plating was used to provide a gold contact layer to the conductive sensor composite. The flexible circuit board was placed in the rectangular hole with the side of FPS contact pads facing up. A stencil was then placed and aligned on the PDMS substrate and conductive PDMS paste was cast over the stencil. After removing the stencil and curing for 30 minutes at 80 °C, another layer of pure PDMS was applied and cured over the FPS and flexible circuit board. The sandwich structure was carefully peeled off, flipped and placed on a glass slide.

At this time, the conductive sensing layer was reliably connected to the flexible circuit board and the other side of the board was exposed for the soldering of electronic components. Solder paste (Indium 8.9E) was then applied under a microscope using a dispensing tool (Nordson EFD X100), followed by component placement and reflow soldering (Puhui T-962). Two stainless steel wires were soldered to the board for connections to a power supply (BK Precision 1550). Then, small drops of medical grade epoxy (Loctite EA M-121HP) were applied to the soldering joints to mechanically protect the soldering and to act as moisture barriers. Finally, a layer of pure PDMS was cast over the flexible board as the encapsulation. Pictures of the prototype device in different fabrication stages are shown in Fig. 6.

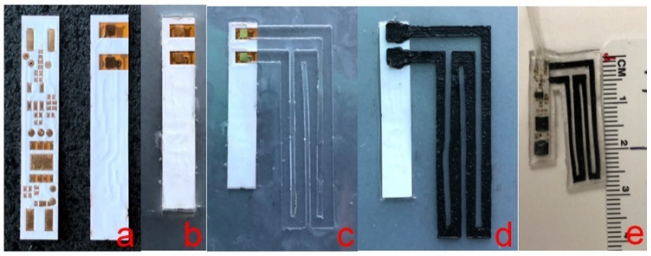

Fig. 6. (a) Flexible circuit board, (b) flexible circuit board within a rectangular hole on the PDMS substrate, (c) a stencil aligned with the flexible board for conductive PDMS printing, (d) conductive PDMS layer after curing, and (e) FPS prototype after reflow soldering and PDMS encapsulation.

III. IN VITRO WIRELESS TESTING ON PULSATILE VASCULAR PHANTOM

After fabrication, the FPS was wrapped around a 6-mm silicone tube simulating a peripheral vascular graft and affixed with Parafilm (Fig. 7). The system used a peristaltic roller pump (Cole Parmer Masterflex L/S 07522) and a variable-voltage diaphragm pump (Shurflo 4008) to produce arterial pressure waveforms. Blood-mimicking fluid simulated shear-thinning properties of blood flow. The silicone tube was connected between the high and low pressure systems of the phantom to simulate an arteriovenous vascular access graft. Low-resistance pressure sensors (Pendotech PREPS-N-50) monitored the graft inlet (arterial) and outflow (venous) pressures and an electromagnetic flow meter (Omega FMG90) measured pulsatile and average flow rate.

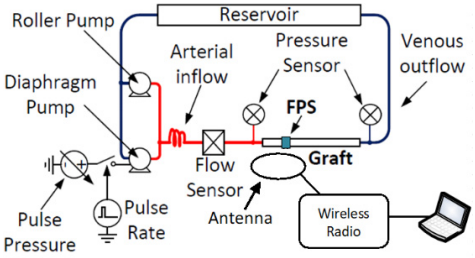

Fig. 7. Schematic of the pulsatile graft flow circuit used for FPS *in vitro* test.

A wireless radio was used for data recording with the receiving antenna held 30 cm from the wireless FPS prototype (Fig. 8). The wireless radio consisted of a custom 4-MHz on-off-keying receiver and Teensy 3.6 development board running data demodulating and recording software.

Received data were saved to a microSD card and transmitted to a PC over a USB serial port for display in a custom LABVIEW program. FPS data points sampled at 30 Hz were reconstructed in MATLAB and filtered using a 5th-order, length 9 Savitzky-Golay to filter out single-bit ADC noise.

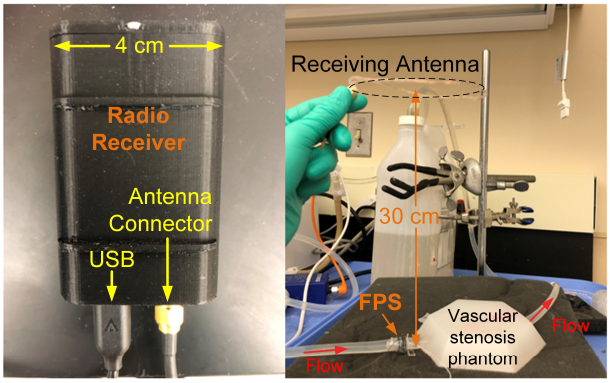

Fig. 8. The wireless radio for data reception (Left) and a wireless FPS on the silicone phantom showing the trasmission range of 30 cm (Right).

The wireless prototype was tested under different pressures by changing the drive voltage of the diaphragm pump from 4-10 V, producing flow rates of 200-700 mL/minute and systolic-diastolic pressures of 70-190 mmHg in the vascular phantom. Fig. 9 shows the phantom pressure and transmitted sensor data (V_{out}). There was good agreement between the V_{out} data and the pulsatile blood pressure waveform. The peak-to-peak voltage of V_{out} versus peak-to-peak and RMS pressure at different pump driven voltage varied linearly (Fig. 10). This relationship was expected based on COMSOL® simulations of the pressure-strain relationship of the FPS.

In this *in vitro* test the wireless FPS measured blood pressure with an accuracy of ±3.3 mmHg, or 5.2% error. However, the amplitude of the sensor signal was lower than expected from simulations. This is likely because the Parafilm used to affix the FPS to silicone phantom significantly reduced the strain of the sensor. Despite a reduction in sensitivity, this experiment demonstrated the feasibility of using a wireless FPS for real-time monitoring of blood pressure in a peripheral vessel.

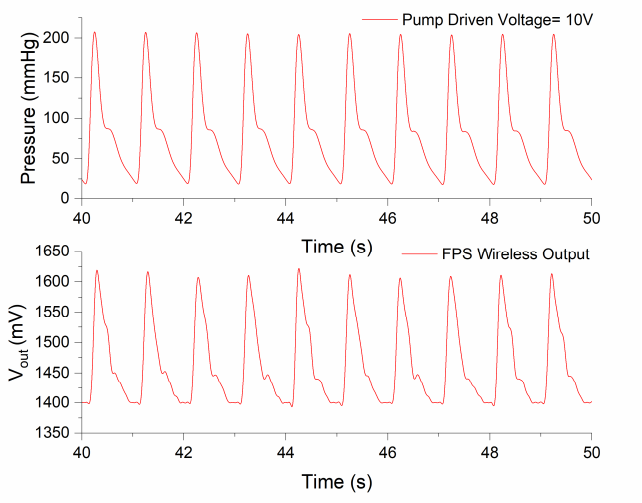

Fig. 9. Pressure data recorded by an intraoperative blood pressure sensor (Top) and FPS output signal trasmitted wirelessly (Bottom).

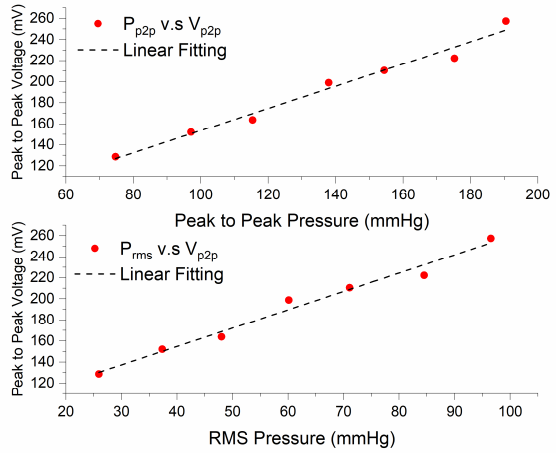

Fig. 10. FPS comparison to diastolic-systolic pressure (Top) and RMS blood pressure vs. FPS voltage (Bottom) under flows of 200-700 mL/min.

IV. Conclusion

By extending our previous work on conductive PDMS pulsation sensors, we enabled sensor integration with a flexible wireless transmitter for real-time data readout. The FPS and data transmitter circuit were fully encapsulated with PDMS to maintain flexibility and biocompatibility. The prototype was wrapped around a vessel phantom for continuous wireless monitoring of blood pressure. Test and simulation data showed a linear relationship between sensor data and blood pressure. Future work includes *in vitro* tests on a vascular graft, and *ex vivo* tests in cadaveric tissue.

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