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Novel Sensor Integration Approach for Blood Pressure Sensing in Ventricular Assist Devices

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Abstract

An application-specific approach for sensor integration for continuous blood pressure sensing in ventricular assist devices (VAD) is introduced. The piezoresistive absolute pressure sensor is to be located within the VAD's inflow cannula's sidewall. This diaphragm is fabricated by suspending a Parylene-C coating, covering the entirety of the cannula's interior, over a preformed recess. The recess is later sealed from the outside of the cannula, enclosing a silicone oil as pressure transmission liquid and a digital pressure sensor. First characterization measurements show that the resulting sensor assembly behaves linearly and has an absolute measurement error below 104.2 Pa (0.21 % FS) at a measurement range of 80 kPa-130 kPa.

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Keywords: Pressure Sensor; Sensor Integration; Media Separation; Packaging; Ventricular Assist Device; Hemocompatible; Parylene-C

1. Introduction

While the number of implantation of left ventricular assist devices (LVAD) for heart failure patients has increased immensely over the past decade, these devices are still affected by some fundamental shortcomings.[1] Aside from problems such as thrombus formation and driveline infections, the current lack of sensors for hemodynamic parameters denies the closed-loop operation of the device and thereby the optimal perfusion of the patient. The data obtained by such sensors could furthermore help the attending physicians to adapt and improve the patients therapy [2]. Current generation LVADs lack these hemodynamic monitors due to the potential decrease on the device's overall reliability and hemocompatibility as well as due to a lack of confidence in sensor robustness. Despite several promising approaches for the integration of pressure sensors [3–5], these concerns have so far not been resolved.

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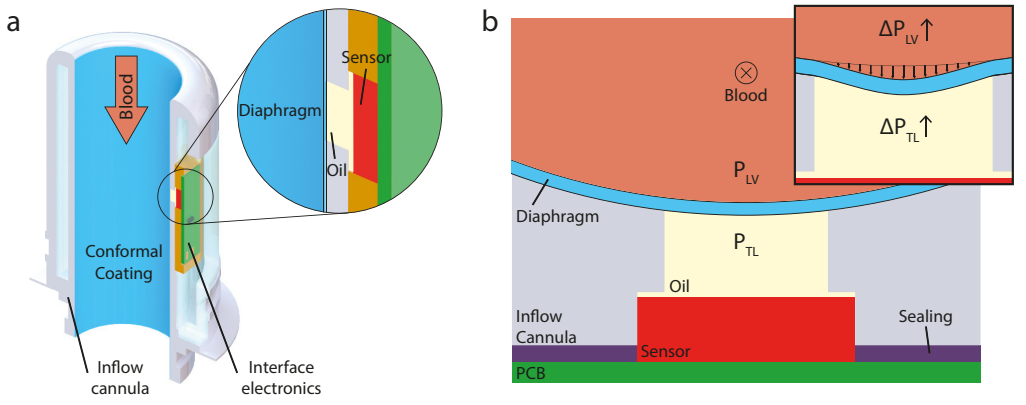

Fig. 1. Integration concept of the pressure sensor in the VAD. (a) Concept design for the integration in a real world VAD cannula. (b) Illustration of the functional principle of the integration.

2. Materials and methods

2.1. Sensor integration

Figure 1a shows the proposed, novel integration approach for pressure sensors. With this concept, we aim to maintain the hemocompatibility of the VAD while also providing long-term stable measurements results. Similar as conventional pressure sensors for hazardous environments, our design utilizes a flexible media-separating diaphragm as sensing interface. In order to minimize the sensor's intrusiveness, the diaphragm is formed as an integral part of a conformal coating, covering the entirety of the VAD's inflow cannula. Parylene-C was chosen as coating material due to its unique, room temperature chemical vapour deposition process and excellent biocompatibility [6,7]. The smooth sensing interface integration aims to eliminate the risk for increased thrombogenity and hemolysis, introduced by obstructions in the blood flow. Furthermore, this design minimizes sensor drift by preventing the accumulation and deposition of biological material on the interface. The diaphragm is suspended over a recess in the cannula's sidewall where the actual pressure sensor is later located. The recess is also filled with a pressure transmission liquid (silicone oil). As illustrated in figure 1b, Blood pressure changes are therefore transmitted to the pressure sensor by deflection of the diaphragm and via the resulting increase of the transmission liquid's pressure. The utilized absolute pressure sensor LPS25HB (STMicroelectronics N.V.) is a commercially available, fully packaged device with integrated digital interface (I^2C). It was chosen due to its small size (2.5x2.5x0.76 mm) and measurement range (26 kPa to 126 kPa).

Ignoring thermal effects, the introduced decrease in pressure change experienced by the pressure sensor can be approximated by the following equation [8]:

$$\frac{\Delta P_{TL}}{\Delta P_{LV}} = 1 - \frac{\beta_l V_0}{\beta_l V_0 + D} \tag{1}$$

where ΔP_{TL} and ΔP_{LV} are the pressure changes in the transmission liquid and left ventricle respectively, β_l is the compressibility of the transmission liquid, V_0 is the volume of the transmission liquid at the time of sealing and D is the mechanical, volumetric compliance of the suspended diaphragm. The compliance of the diaphragm design presented in this work is estimated using FEM simulations and a lies at $\approx 2.4 \times 10^{-16}\,\mathrm{m^3\,Pa^{-1}}$. With these values a transmission coefficient of 98.7 % is expected for the system (i.e. the pressure sensor experiences a signal attenuated by 1.3 %).

2.2. Diaphragm fabrication

Here the essential fabrication steps of the sensing interface diaphragm (illustrated in figure 2a) are outlined. The process is based on a sacrificial material technique and adapted for the special geometry. First, the sensor recess is formed in the inflow cannula e.g. by drilling and broaching or electrochemical machining (ECM). A core element

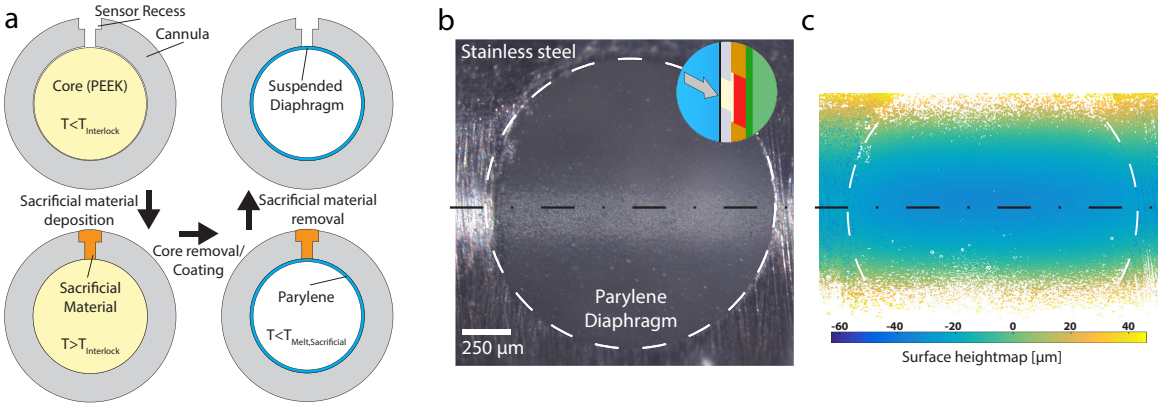

Fig. 2. (a) Fabrication process of the conformal Parylene-C diaphragm (b) Micrograph of the Parylene-C diaphragm, the insert shows the viewing angle. Due to the high transparency of Parylene the stainless steel substrate is visible. (c) A white light interferometer (WLI) height map showing the diaphragms replication of the cannulas surface. The dash dotted line indicates the center axis of the cannula.

(i.e. a rod with a tight clearance fit) serves as molding surface for the sacrificial material. The material of the core is chosen in such a way that it has a larger coefficient of thermal expansion α than the material of the cannula. For this work the material of the cannula was stainless steel ($\alpha \approx 15\,\mu m\,m^{-1}\,K^{-1}$) and the material of the core was polyether ether ketone (PEEK, $\alpha \approx 55\,\mu m\,m^{-1}\,K^{-1}$). The cannula with the inserted core is evenly heated to the interlocking temperature, such that the core is interlocked in the cavity and forms a tight seal with the sensor recess. For the sacrificial material a thermoplastic, organic material such as micro-crystalline wax or temporary bonding adhesives (e.g. Crystalbond 555-HMP, Aremco Products Inc.) can be used. By means of this method the interior surface of the sacrificial material is flush with the interior surface of the cannula. After cooling down the entire core and cannula, the core is removed and a conformal film of 10 µm thickness Parylene-C is deposited. Finally, the suspended Parylene-C diaphragm is obtained by dissolving the sacrificial wax in a warm water bath.

3. Results & Discussion

Figure 3a shows the pressure actuation setup utilized to test the sensor integration concept. The setup uses a water/glycerol mixture as pressure medium and a linear voice coil actuator controlled by a PC running Labview to generate pressure. Reference signals from an absolute and a relative pressure sensor (Keller PAA/PA-33X respectively) as

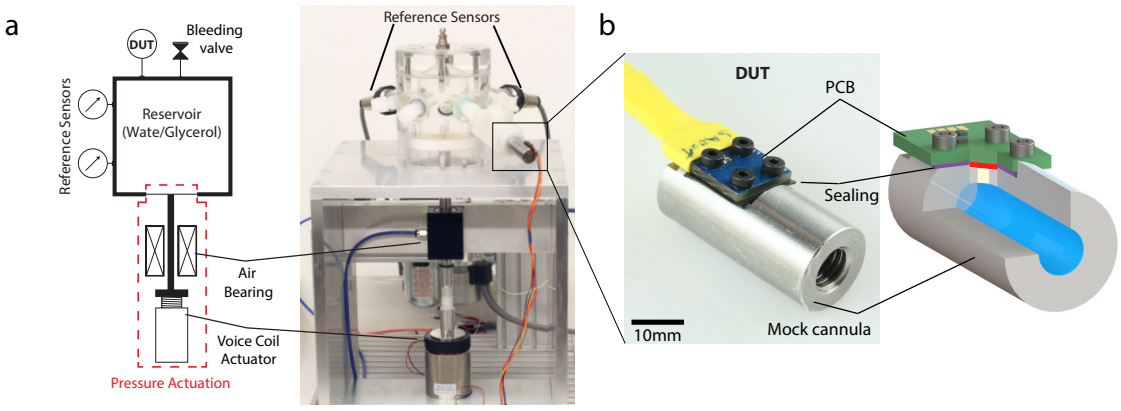

Fig. 3. (a) Schematic and photograph of the pressure actuation setup. (c) Photograph and CAD cross-section of the proof of concept device.

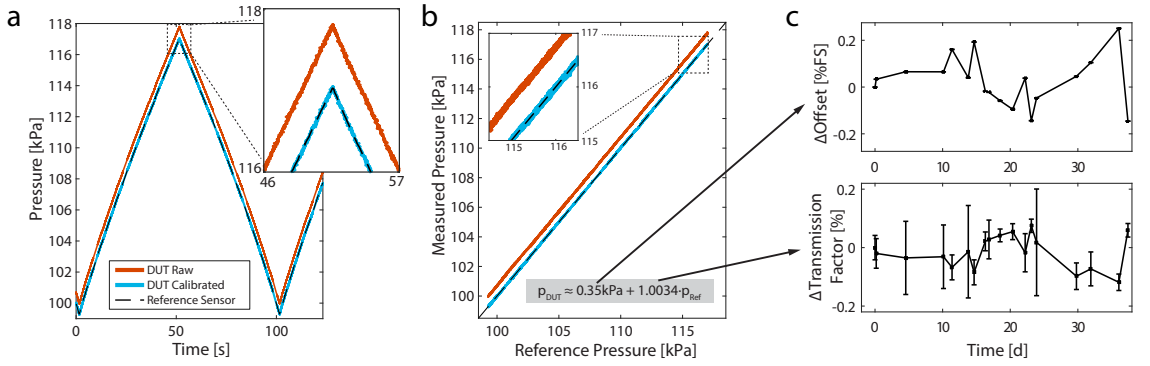

Fig. 4. (a) Pressure ramp test data from a reference sensor (Keller PAA-33X), and the raw and calibrated device under test (DUT). (b) Linearity plot of DUT. (c) Offset and transmission factor value changes relative to initial calibration over a 38 Days period.

well as the signal of the device under test (DUT) are also acquired by the Labview program. Figure 3c shows a mock cannula with the pressure sensor integrated as described in section 2.1, which served as proof of concept device.

As figures 4a&b show, the raw signal of the DUT agrees well with the high precision reference sensor. The DUT exhibits a small, positive pressure offset and its recorded pressure signal increases slightly faster than that of the reference sensor. This apparent transmission factor larger than unity is inconsistent with the value obtained from equation 1. A possible explanation for this behaviour is that the sensitivity of the LPS25HB sensor stated in its data sheet is slightly too small and/or that it gets influenced by the presence of the transmission liquid. To confirm this hypothesis, calibration measurements in air and transmission liquid should be conducted for the LPS25HB sensor.

Despite this, due to the good linearity of the DUT, these raw signal errors can easily be calibrated according to the reference sensor by linear scaling. Figure 4c shows the course of the offset and transmission factor value changes over a measurement period of 30+ days. Each data point is obtained by performing a linear regression between the signals of the reference sensor and DUT and comparing those values to the respective values of the first measurement. The observed fluctuations are small and show no significant trend, indicating a stable, drift-free behavior of the DUT. By combining the offset and transmission factor values, the measurement error of the recalibrated DUT can be determined. The calculated mean absolute error of measurement is −2.3 Pa (0.005 % FS) while the maximum absolute error recorded for a single measurement is −104.2 Pa (0.21 % FS) at a measurement range of 80 kPa-130 kPa.

4. Conclusion

A proof of concept device for a pressure sensor integration approach with excellent measurement reliability has been fabricated and evaluated. The presented fabrication process for substrate conformal, suspended diaphragms allows for an integration with foreseeably good hemocompatibility. Parylene-C diaphragms with a thickness of 10 µm were fabricated and show excellent conformity with the underlying substrate. Measurements with the proof of concept device show good sensing characteristics and no statistically significant drift over a measurement period of 30+ days. For further investigation of the integration concept's stability and hemocompatibility we aim to perform long-term *in-vivo* experiments.

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