

**DETC2015- 47567**

**SOFT PRESSURE SENSING SLEEVE FOR DIRECT CARDIAC COMPRESSION  
DEVICE**

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**ABSTRACT**

A direct cardiac compression (DCC) device is a non-blood contacting sleeve placed around the failing heart to actively assist blood pumping function. For design optimization of a DCC device, it is necessary to monitor the surface pressure exerted on the heart surface at multiple points during active assist, and to correlate this with device performance and cardiac output. In this paper, we present the design, fabrication and characterization of a soft, elastic, conformable pressure sensing sleeve that is placed at the heart/device interface to monitor device performance without affecting device function. This sleeve enables identification of optimal pre-tensioning, positioning and user-controlled parameters of the DCC device. Individual sensors (8x8x3 mm) were fabricated using a surface mount device (SMD) barometer on a custom double-sided flexible printed circuit board and casting the assembly in

urethane rubber. A typical sensor has a dynamic range of 2.5 kPa to 50 kPa with a sensitivity of 11.3 counts per kPa. An array of up to 24 sensors was integrated into a flexible, stretchable circuit embedded in a thin (500 micron) silicone sheet using a multi-step layering fabrication process. Continuous magnet wires were wrapped around an alignment fixture, soldered to individual sensors in place and the entire circuit was transfer printed on to a silicone sheet. This assembly allows stretch corresponding to the fractional shortening of the heart muscles (up to 50%). The sleeve successfully measured static and dynamic pressures with a mechanical tensile tester and did not affect DCC device performance. Preliminary results demonstrated that the sleeve is robust enough to withstand >10000 cycles, compression forces from the DCC device and can achieve sensing range and repeatability suitable for procedural pressure monitoring for a DCC device. In addition to allowing performance measurements for iterating DCC

device designs, the sensing sleeve can enable increased understanding of the response of the cardiovascular system to compressive assistance.

## INTRODUCTION

Direct cardiac compression (DCC) is a method of compressing the failing heart from the external (epicardial) surface of the heart to provide assistance to the ventricles (pumping chambers) of the heart (Fig 1a). DCC is a non-blood contacting method of ventricular assistance that can avoid the complications of blood clotting associated with blood-contacting pumps [1].

*In vivo* measurement has been hindered by the rigid, planar nature of traditional sensors, rendering them inherently incompatible with establishing intimate, large area interfaces with the curvilinear surfaces of the beating heart. In the past, designers of these devices could do global testing on a mechanical tester but could only get a rough idea of what force was being applied locally to the beating heart by painstakingly placing force sensors at the heart/device interface and moving them from one area of the epicardial surface of the heart to another.

Recent soft [2–5] and stretchable [6–14] electronics can potentially surmount these limitations, but offer simple modes of functionality, often without the levels of performance to provide clinically useful, real-time spatio-temporal mapping at the speeds of the beating heart, or the robustness to withstand compression from an external device operating with as low as 100 ms compression periods. A broad range of soft sensors have been investigated for various applications. The two principal strategies used to create stretchable sensor networks involve (1) implementation of intrinsically stretchable components and (2) shape engineering by creating flexible interconnections between rigid islands of active components. Popular sensing elements for soft pressure sensing include capacitive elements separated by elastic insulator layers [15–18], liquid embedded elastomers [3,4,19] and resistive sensing elements embedded in elastomeric structures [20,21]. Form-fitting cardiac sensing sleeves have been designed to measure electrophysiological parameters [22,23], pH, temperature and mechanical strain [23], but to our knowledge none have been designed to measure dynamic pressure between a DCC device and the heart. A sensing sleeve that was tailored to the specific application and requirements of measuring pressure on the epicardial surface from a DCC device required customized design and fabrication techniques, borrowing from established methods of soft and stretchable sensing.

Here we report the development of such a pressure sensing sleeve. The result is a mechanically flexible silicone layer containing an array of pressure sensors for measurements of pressure in an intimate, conformal integrated fashion on the dynamic, three-dimensional surfaces of the beating heart (Fig 1b).

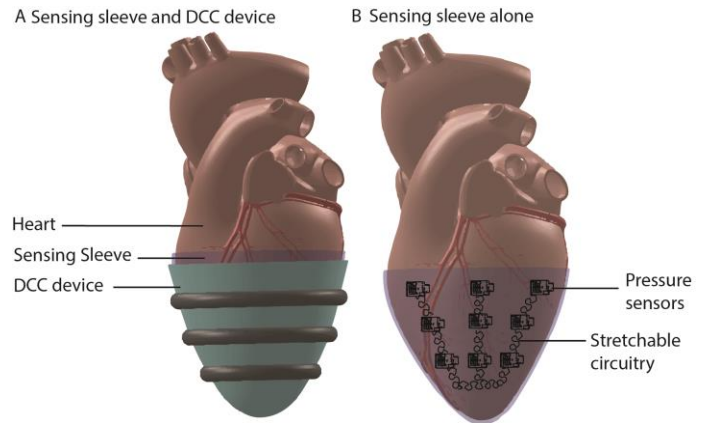


Figure 1: A) SENSING SLEEVE AND DCC DEVICE ON HEART SHOWING SENSING SLEEVE AT HEART/DEVICE INTERFACE. B) SENSING SLEEVE ALONE WITH SCHEMATIC OF PRESSURE SENSOR ARRAY.

## DESIGN REQUIREMENTS

Measurement of compression from a soft robotic device placed on the epicardial surface conferred multiple requirements on the design of the pressure sensing sleeve; the sleeve needed to be (i) flexible to conform intimately with the curvilinear surface of the heart (ii) robust to withstand repeated handling and application during *in vivo* trials (iii) capable of measurements of continuous cyclical compression of up to 160 beats per minute (iv) sensitive to measure static compression applied by the pre-tensioning of the device, and dynamic (100-300 ms period) compression due to the cyclical actuation of the device (v) have predictable viscoelastic response and predictable behavior at body temperatures (vi) operate while fully submerged in biological fluids (vii) able to sense while stretched and compressed and finally (viii) should not affect the functioning of the DCC device.

## COMPONENT SELECTION

When selecting the appropriate sensor for this application we explored capacitive, resistance and barometric sensors. We decided to use MEMS barometric sensors because of their low cost, low interference, small size and I<sup>2</sup>C digital communication. The MPL115A2 (Freescale Semiconductor Inc., USA), commercial off-the-shelf barometric sensor is compatible with standard flexible circuit board fabrication and contains a silicon diaphragm which is fitted with a Wheatstone bridge. A temperature sensor is enclosed to thermally decouple the sensor output as well as a high-quality instrumentation amplifier.

To realize a stretchable, conformable, yet robust circuit that ensures the power supply and communication with multiple sensors we chose a 40 gauge magnet wire. For the stretchable matrix we fabricated a thin (500  $\mu\text{m}$ ) silicone layer from Dragon Skin F/X Pro (Smooth-on Inc., USA).

## FABRICATION PROCESS

### Sensor fabrication

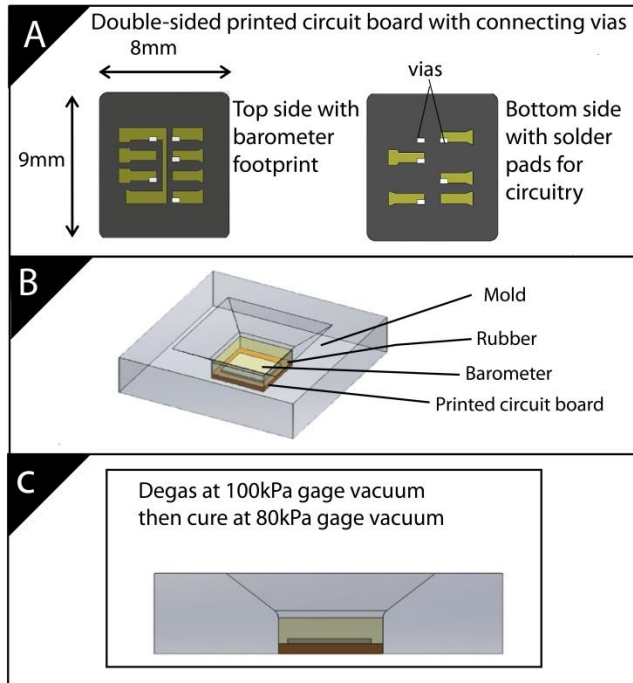


Figure 2: SENSOR FABRICATION. A) DOUBLE-SIDED PRINTED CIRCUIT BOARD DESIGNED TO PROTECT ELECTRICAL CONNECTIONS. B) MOLD WITH RESERVOIR FOR CASTING BAROMETER/PCB ASSEMBLY WITH RUBBER. C) ASSEMBLY IS DEGASSED AT 100kPa AGE VACUUM AND CURED AT 80 kPa GAGE VACUUM.

A barometric MEMS sensor has previously been used for tactile sensing by casting it in rubber and removing trapped air by degassing [24]. We adapted this fabrication process to use for our sensing sleeve by changing the printed circuit board (PCB) design, sensor dimensions and casting material.

The barometric MEMS sensor was mounted on a double sided PCB (Fig 2a) which allowed, on the top side the essential pin connections and capacitor fixations for a robust digital communication while, on the bottom side, enabled proximal fixation to the circuit of the readout electronics. This eliminated having vulnerable electrical connections on the edges of the sensor/PCB assembly and minimized bending and potential damage to electronic connections during use.

The barometer/PCB assembly was centered in a 3D printed mold with a reservoir (Fig 2b) that allows degassing while preventing loss of material. Urethane rubber (Vytaflex 40, Smooth-on Inc., USA) was poured into the mold and degassed

under 100 kPa gage vacuum for five minutes. Subsequently the assembly was cured at 80 kPa gage vacuum (Fig 2c) at 20°C for 24 hours without removing it from the vacuum chamber so that the barometer diaphragm slightly relaxed, thereby increasing the functional range of the resulting sensor.

### Sleeve fabrication and interconnection scheme

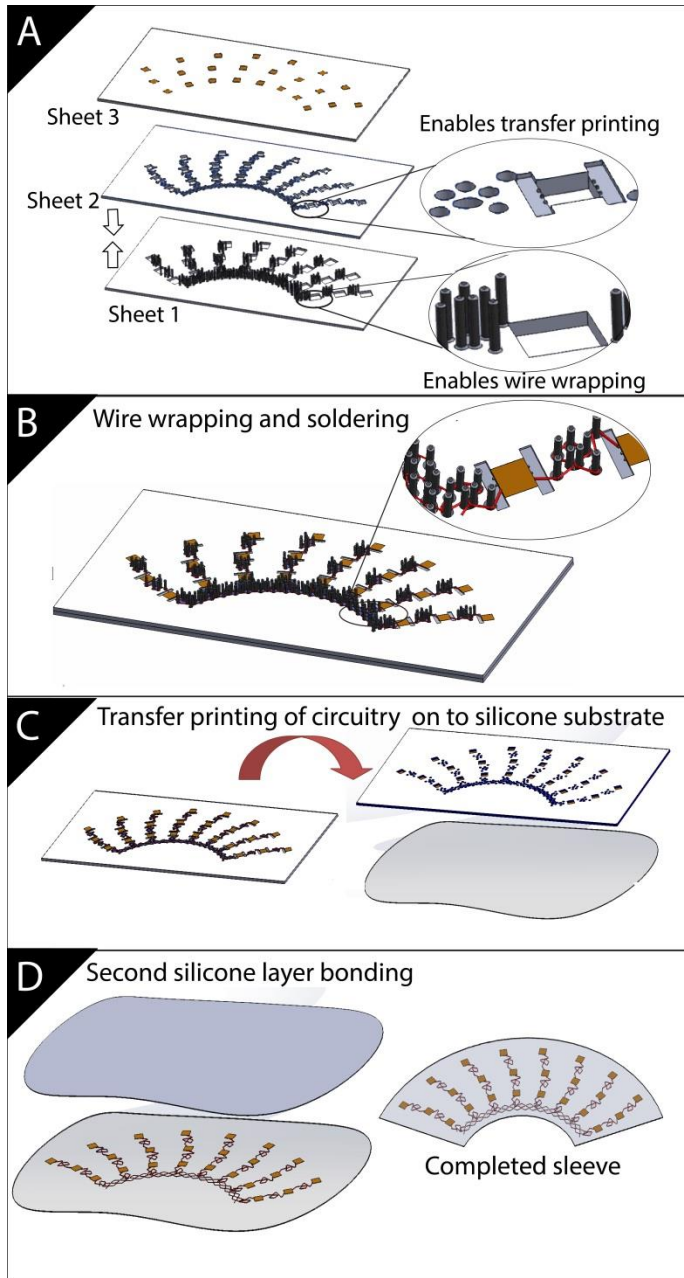


Figure 3: A) MULTI-SHEET FABRICATION TOOL ALLOWS TRANSFER PRINTING OF CIRCUITRY ON TO A FLEXIBLE SILICONE LAYER. SHEET 3 IS USED TO POSITION AN ARRAY OF SENSORS ON TO AN ASSEMBLY OF SHEET 1 AND SHEET 2. B) SHEET 1 AND 2 WERE ASSEMBLED, AND WIRES WERE WRAPPED AROUND POSTS FROM SHEET 1. SHEET 3 WAS USED TO PLACE SENSORS, AND THEN REMOVED. WIRES WERE SOLDERED TO SENSORS IN-PLACE, AND WIRE WRAPPING WAS REPEATED FOR EACH OF FIVE LINES. C) AFTER WRAPPING, SHEET 2 CAN BE LIFTED OFF SO THAT THE ASSEMBLY AND ALL CIRCUITRY (SENSORS AND INTERCONNECTING WIRES) CAN BE TRANSFERRED TO A THIN (250  $\mu\text{m}$ ) SILICONE SHEET. D) A SECOND SILICONE SHEET COATED WITH 50  $\mu\text{m}$  OF

UNCURED PREPOLYMER IS TRANSFERRED ONTO ASSEMBLY AND CURED WITH SELECTIVE PRESSURE BETWEEN SENSORS, AND THEN COMPLETED SLEEVE IS TRIMMER TO SIZE.

We designed a multi-part fabrication tool for allowing us to transfer print an array of interconnected sensors on to a flexible silicone layer (Fig 3a). The tool is comprised of three sheets; sheet 1 is the wire wrapping sheet, sheet 2 the transfer printing sheet and sheet 3 the sensor alignment sheet. Sheet 3 allows placement of sensors in the desired configuration for the DCC device, sheet 2 allows lifting and transfer of the entire circuit, and sheet 1 allows positioning of circuitry wire in a stretchable configuration considering the actuator design of the DCC device. We used flexible flat cables (FFC) for communication between the sleeve and the processing unit. The interconnection scheme was designed to mimic features of the DCC device and so that the circuit connections would experience the least amount of strain when on the beating heart.

Sheet 1 and 2 were assembled and magnet wire was continuously wrapped around the alignment fixtures in a meandering pattern (Fig 3b). Wires were wrapped so they passed over the sensor space-holders. Up to 24 sensors were manufactured and positioned, PCB side down, in sheet 3 then placed on to the subassembly of sheet 1 and 2. Wrapped wires were spot-soldered from the bottom side of the assembly. This was repeated for a total of five connections per sensor; power (VCC), ground (GND), data line (SDA), clock line (SCL) and a chip select line (CS). To ensure sensor array functionality during malfunction of a single sensor the four supply and communication lines (VCC, GND, SDA, SCL) are shared among multiple sensors and were fabricated from continuous wires. As multiple MEMS barometric sensors cannot be addressed individually by the I<sup>2</sup>C bus for read out one CS-line was connected to each sensor to avoid on/off switching during usage and thereby not impede the sampling rate.

Sheet 2 was lifted from the wire alignment sheet with the entire circuitry (sensor array with wires) (Fig 2c). This flat configuration allowed the circuit to be transferred on to a 250  $\mu\text{m}$  silicone sheet (fabricated using an automatic film application, Elcometer). The circuit was pressed onto the silicone and sheet 2 was removed. As electrically active devices can leak current inside the body the bottom side of the PCBs with the fixed circuit was protected by vapor deposition coating of 25  $\mu\text{m}$  Parylene C (Specialty Coating Systems Inc., USA).

Finally, a second layer of 200  $\mu\text{m}$  thick silicone (Dragon skin F/X Pro, Smooth-on Inc.) was coated with a 50  $\mu\text{m}$  uncured layer of prepolymer, and placed on top of the silicone/circuit assembly. (Fig 3d) Pressure was applied to the sheets in between the sensors and the silicone was allowed to cure at room temperature. Finally, the sleeve was trimmed to match the geometry of the DCC device (Fig 3d).

## RESULTING SENSOR SLEEVE

The sensor (Fig 4a) and sensing sleeve (Fig 4b) were successfully fabricated. Fig 4c shows how the sleeve can conform to the surface of a heart and Fig 4d shows the sleeve with the DCC device.

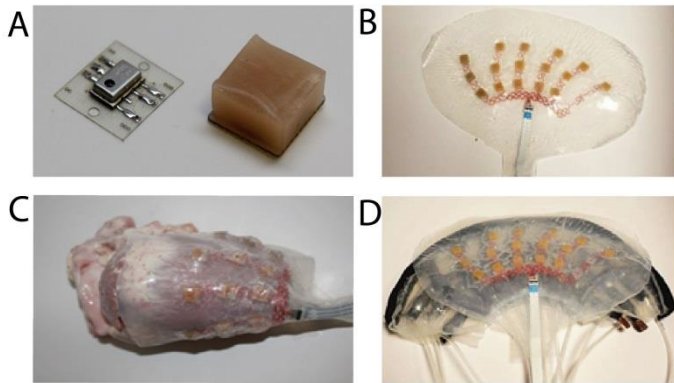


Figure 4: A) MEMS BAROMETER ON A DOUBLE-SIDED PCB ALONGSIDE SENSOR CAST IN URETHANE RUBBER. B) FINAL SENSING SLEEVE. C) SENSING SLEEVE CONFORMING TO HEART. D) SENSING SLEEVE ALIGNED WITH DCC DEVICE.

## SENSOR CHARACTERIZATION

To characterize the sensors their performance was evaluated with a mechanical tensile tester (Instron 5544, Instron, USA). Sensor values were sampled at 250 Hz with an Arduino Uno with a serial interface to LabView. The sensor read-out algorithm of the sensor was altered in order to not be calibrated for atmospheric pressure. We first tested the material properties of the sensor, then static and dynamic sensitivity (with clinically relevant loading parameters), temperature correlation measurements and we finally conducted simulated use testing. For all the tests described here, force values from the mechanical tensile tester were converted to pressure values. This was appropriate because the entire surface of the sensor was in uniform contact with the load cell during the entire test, corresponding to clinical use, where the sensor remains constantly in contact with the heart surface.

For material properties testing, the sensor was mounted on the lower compression plate of the mechanical tensile tester and a circular upper compression plate of 10 cm diameter was used to compress the sensor at a load rate of 0.1 mm/second and held for 200 seconds at various loads. Figure 5 below shows a typical stress relaxation curve of the rubber sensor material at each load and demonstrates the need for separate static and dynamic sensitivity testing.

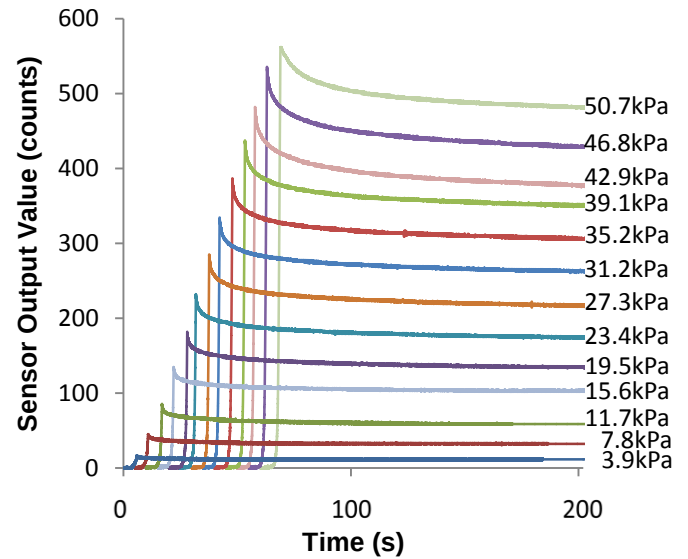


Figure 5: OFFSET CORRECTED SENSOR OUTPUT AT VARIOUS STATIC SURFACE PRESSURES (CURVES ARE OFFSET BY 5 SECONDS). STRESS RELAXATION OF THE RUBBER IS SEEN AFTER EACH INITIAL PRESSURIZING.

Values from figure 5 at 200 seconds ( $n=10$  for each data point) were used to plot static sensitivity. Fig 6 shows a linear correlation between pressure and sensor output ( $r^2 > 98$ , mean sensitivity 9.2 counts/kPa).

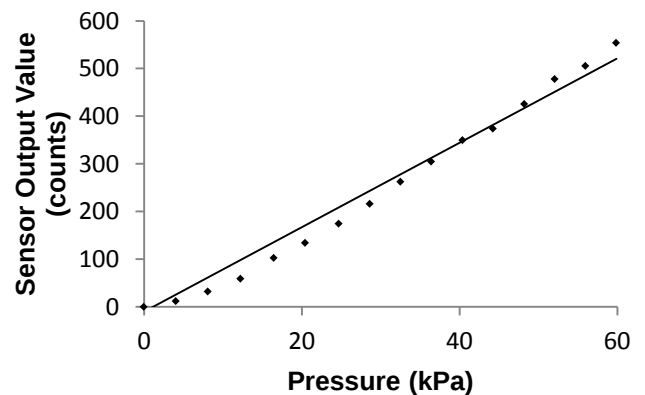


Figure 6: SENSITIVITY OF SENSOR OUTPUT TO STATIC SURFACE PRESSURE. REPRESENTATION OF THE OFFSET CORRECTED SENSOR READING WITH A LINEAR FIT ( $R^2 > 98$ ). MEASUREMENTS WERE TAKEN AFTER A DEFINED SURFACE PRESSURE WAS DEPLOYED FOR 200 SECONDS.

Due to the observed stress relaxation of the sensor material (Fig 5), further analysis of load rate dependency was carried out. The sensor was mounted on the lower compression plate of the mechanical tensile tester and an upper compression plate of 10cm diameter was used to compress the sensor. The sensor was tested at multiple compression rates from 0.1-

2.0 mm/second and loaded to 2.5 kPa of pressure. Figure 7 demonstrated that the sensor output had a linear correlation with the changing rate of compression ( $r^2 > 98$ ).

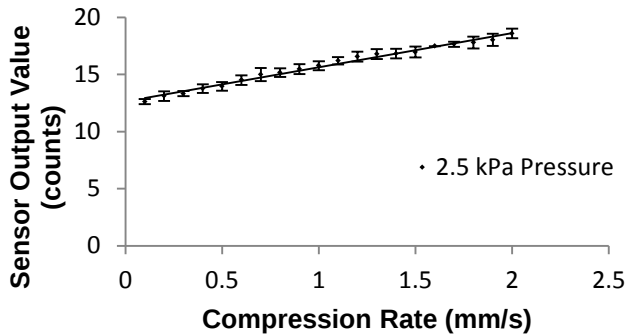


Figure 7: VARIATION OF THE SENSOR OUTPUT AS A LINEAR FUNCTION OF THE COMPRESSION RATE ( $R^2 > 98$ ). DISPLAY OF THE OFFSET CORRECTED SENSOR READINGS FOR A SURFACE PRESSURE OF 2.5 kPa. DATA POINTS ARE AVERAGED OVER THE PEAK PRESSURES OF 10 CYCLES.

As the sensor sleeve will be used in a highly dynamic environment, we calibrated it at clinically representative loading rates using the pneumatic actuators of the DCC device. An actuator was mounted on the lower compression plate of the mechanical tensile tester and the sensor was positioned on top of the actuator. The upper crosshead was lowered until it was just touching the sensor. The actuator was cyclically pressurized for 200ms periods at 1 Hz for 40 cycles for varying actuator pressures, and the last 10 cycles were used for dynamic sensitivity testing. The resulting sensor output values had a linear correlation ( $r^2 > 99$ , mean sensitivity of 11.3 counts/kPa) with the readouts from the mechanical tester (Fig 8).

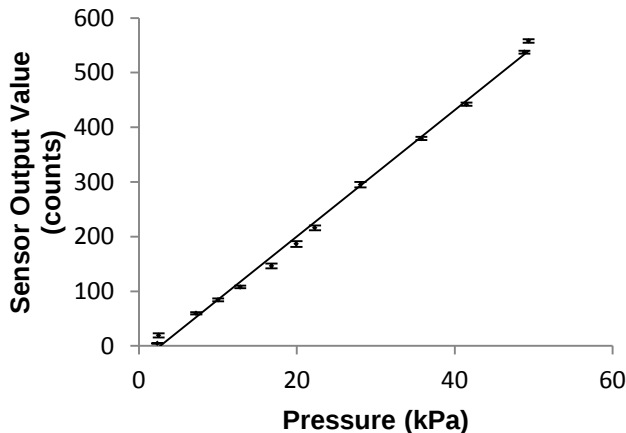


Figure 8: SENSITIVITY OF SENSOR OUTPUT TO DYNAMIC SURFACE PRESSURES. SURFACE PRESSURES WERE APPLIED CYCLICALLY AT A LOAD RATE ACCORDING TO CLINICAL APPLICATION. THE OFFSET CORRECTED SENSOR READINGS FOR THE PEAK PRESSURES WERE

AVERAGED OVER 10 CYCLES AND A LINEAR FIT WAS APPLIED ( $R^2 > 99$ ).

We correlated sensor output with temperature by placing the sensor in a heat chamber and increasing temperature in 1 degree increments from 25°C to 37°C. At each temperature the sensor output at a constant pressure was recorded for 5 minutes and the last 10 seconds of output were averaged. Sensor output is linearly correlated with temperature ( $r^2 > 98$ ) (Figure 9).

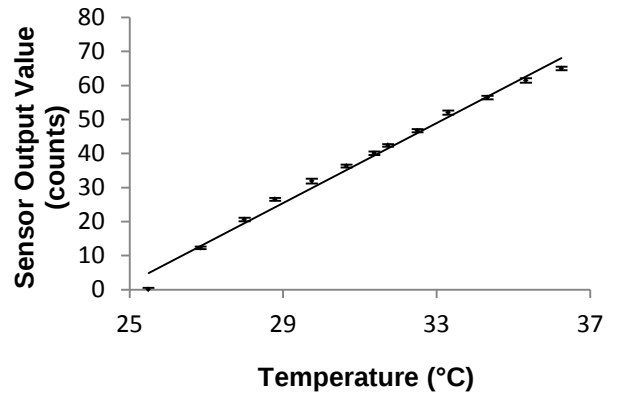


Figure 9: LINEAR DEPENDENCY OF SENSOR OUTPUT TO VARYING TEMPERATURES AT CONSTANT SURFACE PRESSURE ( $R^2 > 98$ ).

### Simulated use testing

As the sensor is required to measure pre-tensioning of the DCC device as well as cyclical actuation, a representative test was conducted to demonstrate ability of the sensor to measure both of these loading conditions. Testing was repeated as described for the dynamic sensitivity measurements with the exception that the crosshead was lowered to a pre-load of 15.6 kPa and held for 10 seconds before cyclically actuating (1 Hz, 200 ms period actuation) to 39.6 kPa for 20 cycles and then returning to the pre-load of 15.6 kPa. The sensor was capable of measuring both loading conditions (Fig 10).

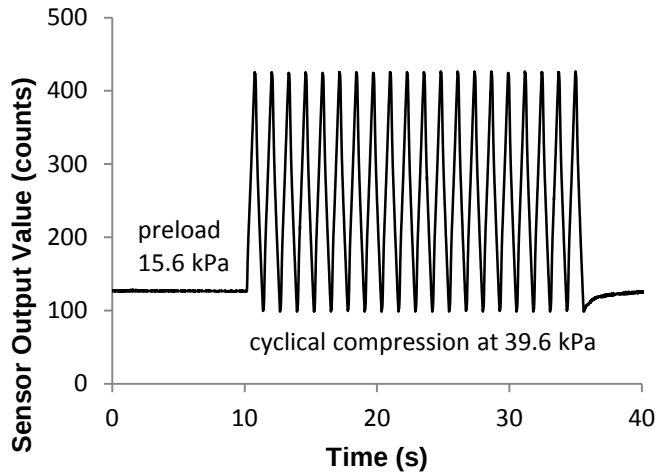


Figure 10: MEASUREMENT OF PRE-TENSION AND CYCLIC LOADING. OFFSET CORRECTED SENSOR READ OUT DEMONSTRATES FUNCTIONALITY AT SIMULATED PRE-TENSIONING OF THE dcc DEVICE AROUND THE HEART WITH SUBSEQUENT CYCLICAL PRESSURIZING.

A life cycle test was performed on the sensor and it remained functional after actuation to 24 kPa at a frequency of 1.33 Hz and a compression rate of 1.5 mm/seconds for 10,000 cycles.

Finally we demonstrated that the sensing sleeve does not impede the function of the DCC device. We measured the volume displacement of the device on a cardiac simulator (Figure 11) and showed that there was no significant difference (t-test  $p < 0.05$ ) between the output from the device with and without the sensing sleeve.

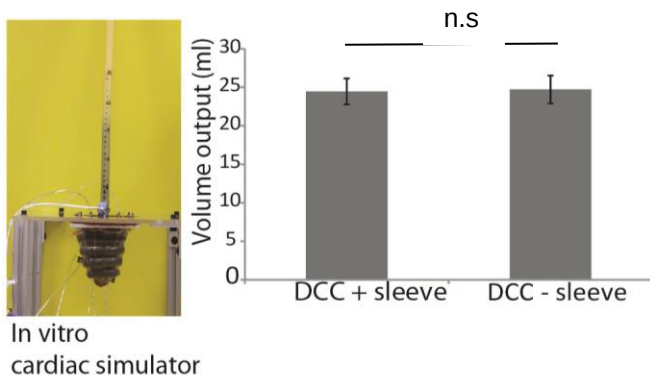


Figure 11: TESTING OF INTERFERENCE BETWEEN SENSING SLEEVE AND DCC DEVICE. THE SIMULATED CARDIAC OUTPUT DOES NOT IMPEDE SIMULATED CARDIAC OUTPUT DUE TO SLEEVE FIXATION BETWEEN THE HEART SIMULATOR AND THE CARDIAC ASSIST DEVICE.

## DISCUSSION

We present fabrication methods for a pressure sensor and a soft sensing sleeve for measuring the pressure at the interface of a DCC device and the heart. The conformal, bio-interfaced sensing sleeve discussed here represents an example of a customized design tool that can map regions of the epicardial surface pressure at high speed, eliminating the need for manual repositioning. The device combines barometric sensors in circuits on a thin silicone sheet, with the following characteristics (i) water-proof design for reliable operation when submerged for extended periods of time in biological fluids (ii) smart designs that locate the sensors in a stiffer elastomeric island so that they are not subjected to strain, thereby eliminating variation in behavior with bending and stretching (iii) low overall bending stiffness that encourages adhesion to the incessantly moving epicardial surface.

Mechanical flexibility is a valuable characteristic that can be achieved with thin devices and substrates, and/or clever engineering approaches such as local islands of higher durometer silicone or neutral mechanical plane designs. Stretchability enables integration of electronics with systems whose range of motion demands reversible deformation to large levels of strain. Many biomedical applications fall into this category. Stretchability is possible with meandering patterns when integrated on silicone substrates, even with brittle materials. The amplitudes and wavelengths of these patterns change to accommodate strains applied to the silicone [8].

Advancements in electronic circuit design and fabrication using soft sensor techniques, as reported here, enable pressure sensors to stay in close contact with biological tissue when being actuated by an externally placed device. This makes monitoring of epicardial compression on the beating heart an attainable goal. Applications for this type of sensing sleeve go beyond the specific utility described here; the mechanical properties of the sleeve may also enable packaging in a catheter for non-surgical delivery to other organs while its flexibility allows the sleeve to be deployed on and conform to irregular curvilinear surfaces in the body.

## ACKNOWLEDGMENTS

We would like to acknowledge the Wyss Institute for Biologically Inspired Engineering, the AHA Pre-doctoral fellowship and Boston Children's Hospital Translational Research Program for funding this research.

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