Approaches to Real-Time Ventricular Wall Strain Measurement for the Control of Soft Robotic Ventricular Assist Devices

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INTRODUCTION

Soft robotic ventricular assist devices (SR VADs) have recently been developed for the assistance of the failing heart [1, 2]. SR VADs are actuated on the surface of the heart or inside the cardiac chamber in synchrony with the native motion of the heart. SR VADs primary function is to cause additional ejection of blood by inducing wall deformation. Current prototypes of SR VADs have relied upon blood pressure and flow measurements to assess device function, which are the secondary results of the VAD, as opposed to measuring wall deformation. Further, control inputs determining the level of deformation to apply to the heart have relied on preset parameters after optimization. Therefore, there exists a need for a continuous real time assessment of the level of strain being caused by the SR VAD both as a way to assess the local effects of the device on the heart muscle wall but also as a feedback input for the real-time optimization of device control.

While strain sensors have been extensively developed and characterized in the biological disciplines, only a handful have been optimized for function in the large strain environment of soft biological tissue [3]. Moreover, sensing strain of the heart wall has added challenges of obtaining a robust measurement in a dynamic and highly curved surface, reducing attachment area on the heart wall, measuring strains ranging 15%-35% [4], and maintaining native tissue motion. We identified two sensors corresponding with the design criteria and thus examined the accuracy and characteristics of these sensors in measuring ventricular wall strain continuously and in real time using explanted pig hearts placed on a pulsatile flow pump.

MATERIALS AND METHODS

Sensors: The first sensor is a 30mm long soft elastomer, Ecoflex 00-30 (Smooth-On Inc., PA, USA), with embedded microchannels containing liquid metal (eutectic Gallium Indium, "EGain") that change geometry when stretched resulting in a resistance change. By measuring the change in resistance it is possible to calculate strain, as previously described [5]. The liquid is encapsulated in silicone and does not contact tissue. The advantage of this sensor is its flexibility, compatible with the deformation of the heart wall, and its elastic modulus is within the range of values for passive myocardial tissue [1]. However, piesoresistive sensors are prone to drift.

The second sensor is a Hall Effect (HE) sensor composed of, a detector plate (TK2723-ND, Melexis Inc., MI, USA) and a neodymium magnet (8g). The detector plate senses magnetic field strength. These sensors do not drift but have not been commonly characterized in biological applications. The magnet's experimental size/weight would not be used clinically but was appropriate for the purpose of investigating the concept.

Voltage to strain calibration: Both sensors were calibrated to generate displacement of voltage curves upon linear deformation. The EGain sensor was calibrated using a tensile testing machine (Instron, Instron Inc., MA) that applied a controlled displacement starting from a neutral length of 20 mm in 1 mm increments to a length of 45 mm. The HE sensor was calibrated by separating the neodymium magnet and the detector plate, each attached to separate micrometer stages, in 1 mm increments from a distance of 0 mm apart to a total distance of 25 mm apart. The HE records reliably when the magnet and the detector plate are placed within a range between 6mm and 20mm and when they two components are axially aligned. The associated voltage output was recorded using an Arduino Nano (Arduino AG, Italy).

Ex-vivo comparison of the sensors on a pulsatile pig heart: Three pig hearts were placed in a pulsatile flow loop and inflated/deflated to simulate beating heart conditions. Sensors were sutured along the right ventricular (RV) wall. (Figs.1, 2).
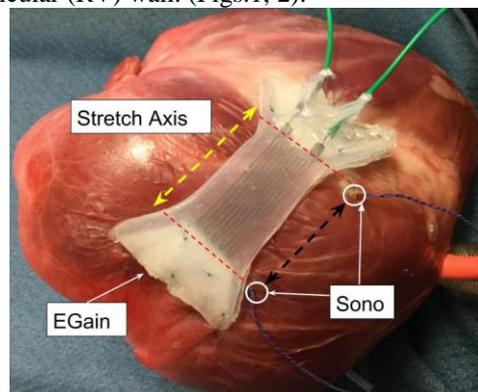
Fig. 1 - EGain sensor and sono crystals are sutured to the heart. Arrows demonsrate the axes of stretch.
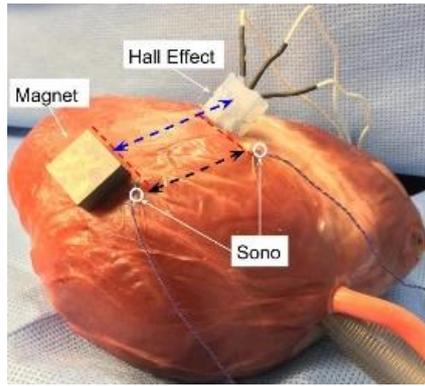
Fig. 2 - Hall Effect sensor and sono crystals are sutured to the heart. Arrows demonsrate the axes of stretch.

To validate the sensors, we implanted two 2 mm sonomicrometry (Sono) crystals (Sonometrics Corp., London ON, Canada). Sono is the accepted method of choice for detecting heart wall linear displacement in animal research studies, but is limited as an implantable device due to high operating voltages. In addition, this method is prone to noise when used in conjunction with certain perioperative monitoring equipment. The crystals were implanted such that they measured in real time the RV free wall displacement across the same wall distance as each of the sensors. Readings from the sensors and from the Sono crystals were collected. Displacement values of each sensor between inflation and deflation were converted to strain as:

$$\varepsilon = \frac{L_1 - L}{L_1} \qquad \text{(I)}$$

Where L_1 and L are segment length at peak inflation and deflation respectively [4]. A one-way ANOVA was used to assess significance between the conditions for each measured variable.

RESULTS.

EGain, HE, and Sono sensors all measured the displacement between sensor endpoints on the heart.
The strain values calculated, see eqn. (I), were an average of 10 beating inflation/deflation cycles. The hearts used for each sensor had different levels of RV wall deformation between the cycles.
The EGain produced strain results with ~52% difference compared to Sono. These results were found to be statistically significant (Fig.3).
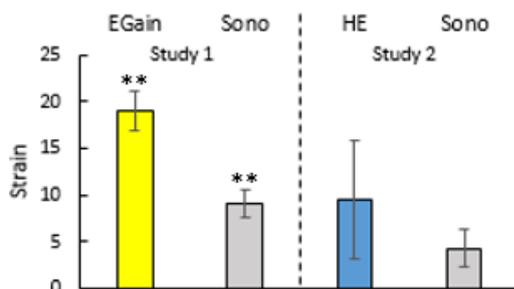
Fig. 3 - Average strain over the course of 10 beating cycles for EGain and HE compared to Sono. Error bars show +/- 1 SD; ** denotes p<0.005, (ANOVA). N = 3.

The HE sensor produced strain results with a ~55% difference compared to Sono. These results were not found to be statistically significant.

DISCUSSION

The purpose of this study was to examine the accuracy and characteristics of two implantable sensors in measuring RV wall strain by testing the sensors ex-vivo and comparing their strains to Sono - strain being a potential determinant of SR VAD function and control.
The EGain sensor conformed to the curved surface of the heart, measuring a curved axis of strain, compared to Sono, which measures a linear strain axis (Fig. 4).
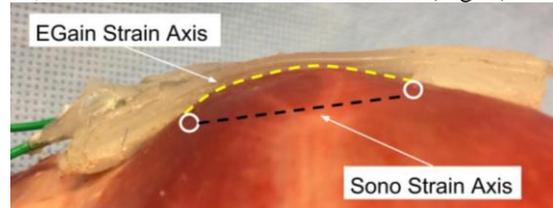
Fig. 4 - EGain and Sono axes of measurement

A discrepancy in strain between the sensors was expected - due to changing heart curvature increasing the curved axis distance versus straight axis distance – however, this may not alone explain the dissimilarity between the results. The EGain's behaviour on heart surfaces must be further characterized in order to determine its suitability as a control sensor for SR VADs.
The HE sensor showed an average accuracy of 18% compared to Sono, but recorded large variations in strain measurement across the three experiments. The limitation of HE is that its measurement is dependent on alignment of components.
In conclusion, following further experimentation the EGain concept may become a promising solution for detecting the stain of the curved heart wall. For the HE sensor, altering the method of adherence to accommodate for the sensor's reliance on component alignment must be implemented to in order to integrate it as an SR VAD strain sensor.

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