Wearable Soft Robotic Device Supports the Failing Heart *in vivo*

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INTRODUCTION

Soft robots fabricated from low modulus, compliant materials hold significant potential for medical device applications that warrant safe, synergistic interaction with humans. We have recently applied this technology to develop ventricular assistive devices (VADs) that can externally massage the failing heart [1][2]. In heart failure (HF), the heart cannot provide sufficient pumping support to meet the metabolic needs of the body. For patients in end-stage HF, impeller-based VADs can be implanted to supplement heart function. However, these devices are associated with complications including bleeding and thromboembolism as a result of blood clots that form on the non-biologic surfaces of the device. Direct cardiac compression devices are an alternative form of VAD which use an inflatable cuff positioned around the ventricles to apply compressive forces during systole. This allows augmentation of cardiac pumping function without the need to contact the blood directly [3]. Based on this principle, we developed a soft robotic sleeve that fits around the heart and emulates the native cardiac muscle motion in order to restore function to the failing heart [1]. Subsequently, we developed a wearable soft robotic device which could be mechanically coupled to the ventricles [2]. This work demonstrated that actuator synchronization and mechanical coupling to the heart are significant factors for augmenting cardiac output. Here, we report the use of this wearable soft robotic device [2] with additional *in vivo* data to demonstrate repeatable performance.

MATERIALS AND METHODS

Two pairs of soft actuators are wrapped around ventricles and contract when pressurized with air so as to apply compressive forces to the heart during systole (Fig. 1). The actuators can then be depressurized to relax in synchrony with the diastolic phase of the cardiac cycle. Our system makes use of the McKibben actuator design in which an inflatable bladder is placed within a braid to create an artificial muscle which contracts when pressurized. We designed the soft actuators to store elastic energy when contracting in systole. The actuators can then recoil back to an elongated state when depressurized during diastole. This function is achieved by placing an elastic rubber sleeve around the actuator braid. We mechanically couple the soft actuators to the heart using elasticated bands that are directly sutured around both ventricles. Since the actuators are coupled to the ventricles, they can apply traction forces during diastole which we hypothesize augments blood inflow.

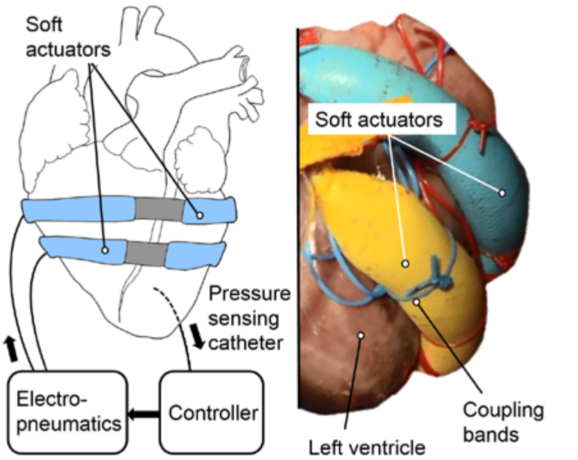

Fig. 1. The proposed soft robotic device: control schematic (left) and *in vivo* deployment showing the contracted actuator state during systole (right).

Triggering of the device is achieved through a pressure-sensing catheter (Scisense, Transonics. Inc) placed in the left ventricle (LV) which detects the end of diastole. By placing the native heart hemodynamics in to the control loop, the soft robotic device can effectively react to fluctuations in heart rate (Fig. 1). This approach also forgoes the need for a pacemaker which can further diminish cardiac output. A real-time control system (cRIO, NI) and electro-pneumatic assembly is used to supply air and vacuum to the actuators in sync with the native cardiac cycle. Further details of our system are reported in [2]. We performed *in vivo* studies (n=2) to demonstrate repeatable performance of the soft robotic device with respect to aortic flow output and LV pressure. Studies were conducted with ethical approval from the Institutional Animal Care and Use Committee at Boston Children's Hospital. Swine (75kg) were instrumented with an aortic flow probe and pressure catheter within the left ventricle (LV). We measured LV

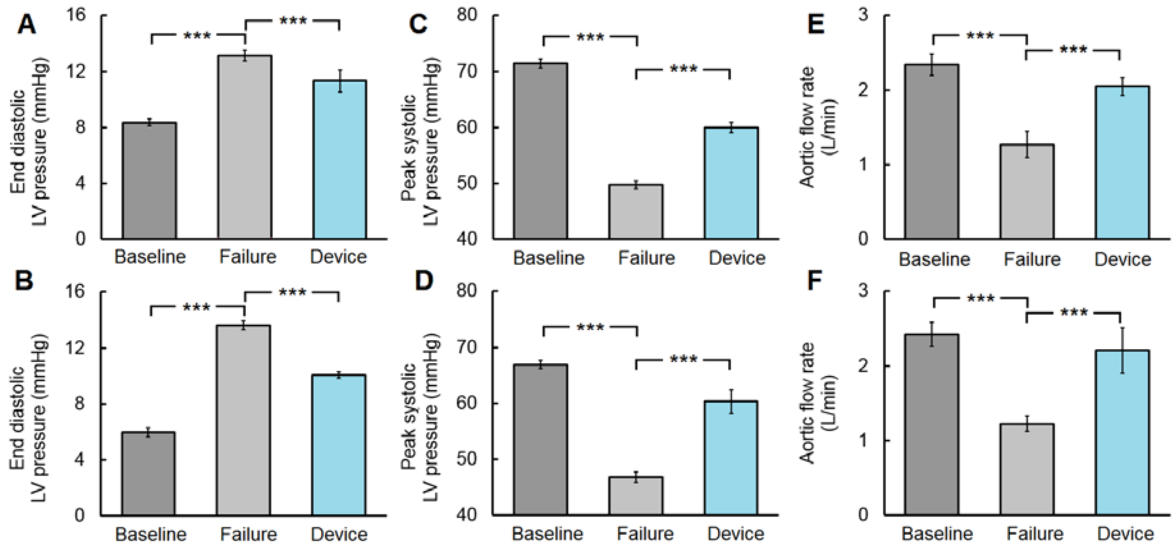

Fig. 2. (A, B) end diastolic LV pressures for animals 1 and 2, respectively. (C, D) peak systolic LV pressures for animals 1 and 2, respectively. (E, F) aortic flow outputs for animals 1 and 2, respectively. *** denotes p<0.001 (ANOVA). Error bars are +/- standard deviation.

pressure and aortic flow at a baseline state before inducing acute HF. Esmolol, a cardio-selective beta blocker was then administered to reduce heart contractility and simulate HF conditions. We actuate the soft robotic device at 10PSI and for a systolic duration of 45% of the cardiac cycle since our previous work [2] demonstrated greater cardi ac output at longer actuation periods during systole. We measured 10 consecutive cycles of end diastolic LV pressure, peak systolic LV pressure and aortic flow rate in each condition (baseline, HF, device actuating). A one-way ANOVA was used to assess significance between the conditions for each measured variable, with $p<0.05$ being considered statistically significant.

RESULTS

In acute HF, aortic flow rate and LV peak pressure were significantly reduced whilst end diastolic LV pressure increased, relative to the baseline readings. During device actuation, aortic flow rate and LV peak pressure significantly increased whereas end diastolic pressure reduced relative to HF conditions (all results are summarized in Table 1. and Fig. 2). Fig. 3. shows LV pressure profiles of animal 2 in each condition.

	Baseline	HF	Device
Animal 1 (Means)			
Aortic flow (L/min)	2.3	1.3	2.1
LVP peak (mmHg)	71.4	49.8	60.0
LVP end diastole (mmHg)	8.4	13.1	11.3
Animal 2 (Means)			
Aortic flow (L/min)	2.4	1.2	2.2
LVP peak (mmHg)	66.9	46.8	60.3
LVP end diastole (mmHg)	6.0	13.6	10.1

Table 1. The measured cardiac output variables for animals 1 and 2 at baseline, HF and with device support.

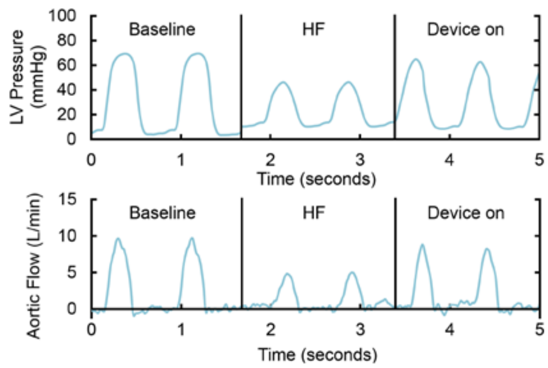

Fig. 3. LV pressure and aortic flow profiles at baseline, HF and with the device assisting the heart, for animal 2.

DISCUSSION

The results indicate that the wearable soft robotic device consistently improved cardiac function of the heart for both animals. In particular, the reduction in end diastolic LV pressure implies improved refilling of the ventricles which is important for sustaining long term cardiac output. The results are consistent with the augmentation in systolic and diastolic function from our previously reported *in vivo* data [2]. Future work will optimize the soft actuator design and coupling of the device to the ventricle walls to enable higher pressures to be generated during systole and further augmentation to ventricle refilling during diastole.

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