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Rotary blood pump control using integrated inlet pressure sensor

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Abstract— **Due to improved reliability and reduced risk of thromboembolic events, continuous flow left ventricular assist devices are being used more commonly as a long term treatment for end-stage heart failure. As more and more patients with these devices are leaving the hospital, a reliable control system is needed that can adjust pump support in response to changes in physiologic demand. An inlet pressure sensor has been developed that can be integrated with existing assist devices. A control system has been designed to adjust pump speed based on peak-to-peak changes in inlet pressure. The inlet pressure sensor and control system have been tested with the HeartMate II axial flow blood pump using a mock circulatory loop and an active left ventricle model. The closed loop control system increased total systemic flow and reduced ventricular load following a change in preload as compared to fixed speed control. The increase in systemic flow occurred under all operating conditions, and maximum unloading occurred in the case of reduced ventricular contractility.**

I. INTRODUCTION

Long-term mechanical circulatory support is being used more frequently as bridge-to-transplantation and destination therapy for heart failure patients because of improved safety and reliability of left ventricular assist devices (LVADs) [1]–[4]. Recently, the use of continuous flow assist devices has become more common due to their small size and valve-less design. However, optimal management of these devices has not been defined. In previous generation pulsatile LVADs, pump filling and ejection were determined in part by the patients physiology and inlet cannula suction pressure was limited by atmospheric pressure. Current generation continuous flow LVADs produce a flow-dependent differential pressure as a function of pump speed as described by the characteristic pressure versus flow (H-Q) curve. If the speed is too slow, the patient may not receive enough blood flow and their activities may still be limited by their heart failure. If the pump speed is too fast, the pump can empty the ventricle, pulling the ventricular wall towards the pump inlet and subsequently limiting flow, a phenomenon referred to as a suction event, which can cause myocardial damage and dangerous ventricular arrhythmias [5], [6]. As more and more LVAD patients leave the hospital and return home, the unloading point with a fixed pump speed is subject to changes in heart rate, arterial pressure, and blood volume that occur due to normal daily activities (e.g. sleep, exercise, positional changes, etc.). An automatic control algorithm that will adjust pump speed in response to hemodynamic changes in order to provide sufficient support but reduce the risk of suction-induced arrhythmogenesis is desirable [7]–[11].

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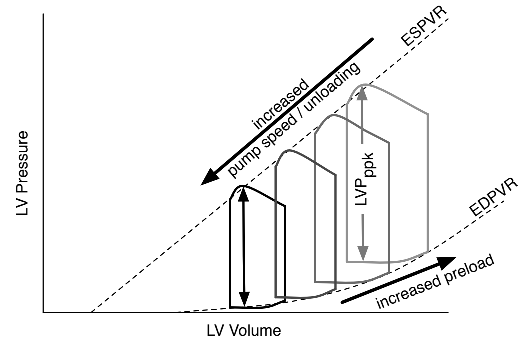

Fig. 1. Schematic of control algorithm. Peak-to-peak LVP (LVP_{ppk}) decreases with increased unloading / pump support. P_{ppk} measured from the inlet pressure sensor will be used as a surrogate for LVP_{ppk} for the pump control system.

The proposed control system uses inlet pressure to assess ventricular loading. A pressure sensor that can be integrated to the the inlet of a continuous flow LVAD has been developed by our group and tested in vitro and in vivo [12]. Semiconductor strain gages were bonded to a thinned diaphragm region on a titanium shell creating a seamless blood interface to the pump inlet for maximum biocompatibility. The purpose of the control system is to (1) adjust pump speed to match physiologic demand and (2) reduce pump speed to resolve ventricular suction events. Previous testing has demonstrated the functionality of the inlet pressure sensor to detect suction during an in vivo animal study [12]. The goal of this study was to test the feasibility of using inlet pressure to assess ventricular loading and adjust pump speed due to changes in circulatory demand. A mock circulatory loop with an pneumatically driven left ventricle was used to evaluate the performance of the control system.

II. METHODS

A. Preload control algorithm

In the native heart, an increase in circulatory demand increases ventricular preload (i.e. end-diastolic pressure and volume increases). The increased myocardial stretch causes an increase in contractile force and cardiac output through the Frank-Starling mechanism. In failing hearts this mechanism is compromised, and continuous flow LVADs operating at fixed pump speed cannot adequately respond to changes in preload. The proposed control algorithm uses the peak-to-peak change in LV pressure to measure changes in preload,

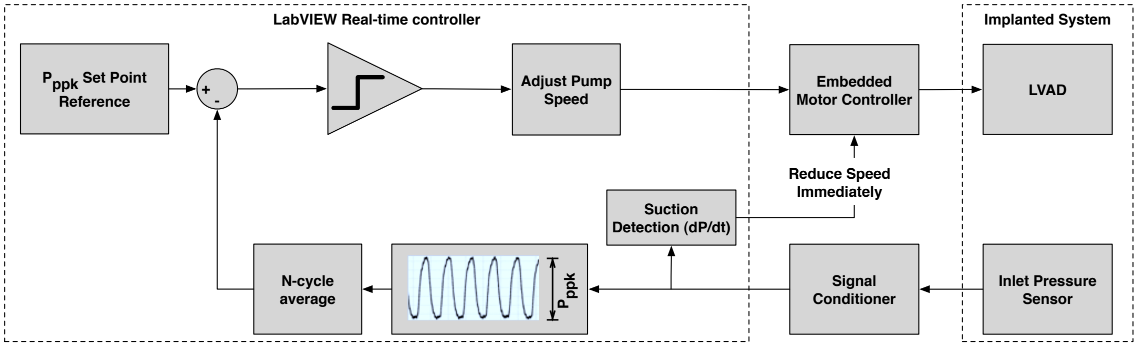

Fig. 2. Diagram of pump control system. An embedded microcontroller controls the LVAD pump speed. A LabVIEW Real-time control system adjusts pump speed based on peak-to-peak changes in inlet pressure (P_{ppk}) measured over N cardiac cycles. Suction is detected using the time derivative of the inlet pressure, and if detected pump speed is reduced immediately to resolve the suction event

as depicted in Figure 1. As preload increases, LVP_{ppk} increases, and the control algorithm will increase pump speed to reduce ventricle load (i.e. shift the pressure-volume loop to the left) and increase circulatory support. The inlet pressure sensor will be used as a surrogate measure of LV pressure.

B. Control system design

A block diagram of the proposed control system is shown in Figure 2. An embedded motor control has been developed using the ARM Cortex-M3 microprocessor (ST Microelectronics). Field Oriented Control with sinusoidal commutation is used to provide precise control of rotor position and speed with balanced rotor forces and minimal torque ripple. The microcontroller has been tested to function with the standard-of-care HeartMate II axial flow pump (Thoratec Co., Pleasanton, CA) [13]. This in-house motor controller allows for direct modulation of pump speed for developing the real-time control system.

The pressure sensor bridge amplifier output is filtered at 50 Hz and used as the input to the control system. The dynamic pump speed control system is implemented in a LabVIEW-based real-time control system (National Instruments, Inc.) and adjusts pump speed via a serial interface with the motor controller. Suction is detected via negative dP_{in}/dt values that exceed a predetermined threshold [12]. Unloading is controlled using the peak-to-peak inlet pressure signal (P_{ppk}) averaged over N-cycles (N=10 in the mock-loop study, but is expected to be larger in clinical use). A bang-bang controller is used to adjust pump speed based on comparison of average P_{ppk} to the P_{ppk} set point.

C. Mock circulatory loop

A modified version of the mock circulatory system developed by the Penn State University was utilized to perform the study [14]. The mock circulatory loop consists of two spring-loaded, rolling diaphragm-type piston cylinders that simulate the venous compliance and systemic arterial compliance and an adjustable systemic resistance. A compressible, transparent silicone mock left ventricle (ViVitro Labs Inc., Victoria, Canada) that mimics the shape and motion of ventricular contraction is driven using a pneumatic driver (Sarns/3M Inc., Ann Arbor, MI). By controlling the pneumatic driveline pressure the contractility of the mock left ventricle can be adjusted. The HeartMate II inlet cannula with integrated inlet pressure sensor is connected to the apex of the mock ventricle.

The volume of the LV was assessed using six sonomicrometry crystals (2 mm, 34 AWG, Cu) (Sonometrics Inc., Ontario, Canada) anchored to the inner surface of the silicone ventricle along the basal-apical, free wall-septal, and anterior-posterior axes dimensions. Volume was calculated from these dimensions using an ellipsoid shape approximation. The LV pressure was monitored using a Millar Mikro-Tip Catheter Pressure Transducer (Millar Instrument. Inc, Houston, TX) placed in the LV cavity. Pressure and volume of the LV were recorded continuously by the Sonometrics Data Acquisition System (Sonometrics Inc., Ontario, Canada). Data analysis was performed using a custom program developed in Matlab (Mathworks, Natick, MA).

D. Preload step test

The response of the P_{ppk} control system to a step change in preload was evaluated. A manually controlled valve was placed at the inlet to the mock ventricle to control preload. At baseline, the valve was set at a prescribed position that partially obstructed inlet flow. The valve was then opened to provide a step increase in return flow that increased preload to the mock ventricle. The increase in LV end-diastolic pressure was between 2 and 7 mmHg, and was dependent on the mock ventricle contractility and baseline operating conditions. The test was repeated with fixed speed control at the same baseline valve setting and pump speed.

III. RESULTS

As shown in Figure 3A, LVP_{ppk} increased with increasing ventricular contractility and decreased with increasing pump speed. At low speeds the aortic valve opened on every beat and the relationship between LVP_{ppk} and pump speed was flat. At the point of aortic valve closure, LVP_{ppk} decreased sharply with increasing pump speed. Inlet P_{ppk} decreased with increasing pump speed and did not exhibit a transition in slope at aortic valve closure (data not shown).

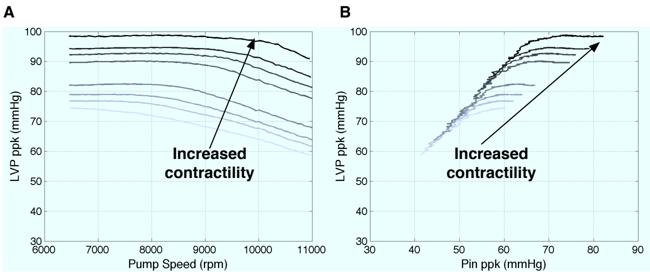

Fig. 3. LVP_{ppk} and P_{ppk} measured with increasing pump speed and LV contractility. *A* LVP_{ppk} remained constant with the aortic valve opening, and decreased with increasing pump speed after the aortic valve closed. *B* LVP_{ppk} was linearly related to P_{ppk} with the aortic valve closed and was independent of P_{ppk} with the aortic valve opening.

As shown in Figure 3B, LVP_{ppk} was linearly related to P_{ppk} for all contractility operating conditions when the aortic valve closed. With the aortic valve opening the relationship between LVP_{ppk} and P_{ppk} was flat with an offset that increased with contractility.

Figure 4 shows the response of the control system to a step change in preload. Immediately following the step change, the pressure-volume loop shifted to the right due to the increase in preload. The control system responded by increasing pump speed from 9000 rpm to 10200 rpm. At steady state the control system shifted the pressure-volume loop to the left indicating a reduction in ventricular load. However, the control system did not reduce the ventricular load to the baseline condition. Total systemic flow increased from 3.8 lpm to 4.7 lpm with P_{ppk} control, as compared to a flow increase to 4 lpm with constant speed control.

The performance of the control system as a function of ventricular contractility is shown in Figure 5. In each test case results are shown after a preload step increase at fixed speed (gray bars) and P_{ppk} steady state control (black bars). The x-axis categories indicate the active ventricle driveline pressure (i.e. contractility), increasing from left to right in the graphs, and the opening status of the aortic valve at baseline. For each case, the pump speed at baseline with P_{ppk} control was equal by design to the fixed speed value. With the control system, pump speed and total systemic flow increased in all test conditions. At the strongest contractility levels with the aortic valve open, the increase in flow during fixed speed control was largest due to the effect of the native ventricle. However, even in those conditions the P_{ppk} control system greatly improved flow. Maximum LVP, end diastolic LVV, and ventricular stroke work were measured before and after the step change to quantify ventricular loading (Figure 5 C-E). In all cases, ventricular loading increased following the step change. However, P_{ppk} control reduced ventricular loading following the step change as compared to fixed speed control.

IV. Conclusions

A. Conclusions

This study demonstrated the feasibility of using peak-to-peak variation in inlet pressure to control a continuous flow blood pump. The inlet pressure sensor can be integrated to existing blood pumps to create a seamless blood interface [12]. A major limitation to continuous flow blood pumps is the inability to respond to changes in patients' circulatory needs [11]. Native ventricles respond to variations in preload through the Frank-Starling mechanism and adjust cardiac output appropriately. Traditional pulsatile LVADs can adjust filling and ejection times based on inlet filling which is determined in part by preload variations. Using the inlet P_{ppk} control system the continuous flow blood pump was responsive to preload. Following a step change in preload, the pump speed and subsequent systemic flow increased. In addition, there was a reduction in ventricular loading with the control system as compared to fixed speed operation.

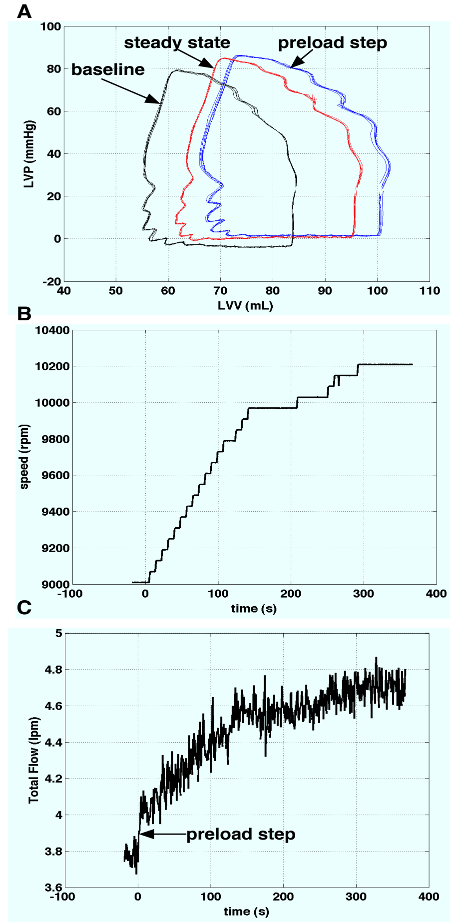

Fig. 4. Results from mock-loop testing of control system following step change in preload. *A* Pressure-volume loops at baseline, immediately following preload step change, and at steady state. *B* Increase in pump speed during P_{ppk} control. *C* Increase in system flow due to control loop. Active ventricle driveline pressure was fixed at 160 mmHg, 70 bpm.

Previous reports have demonstrated the effectiveness of using the pulsatility in pump flow [8] or the pressure drop across the pump [9], [15] to detect suction and adjust pump speed appropriately. The idea being that the optimal pump speed would be the maximum speed just short of causing suction to occur. The proposed system is the first to measure ventricular loading directly for pump speed control.

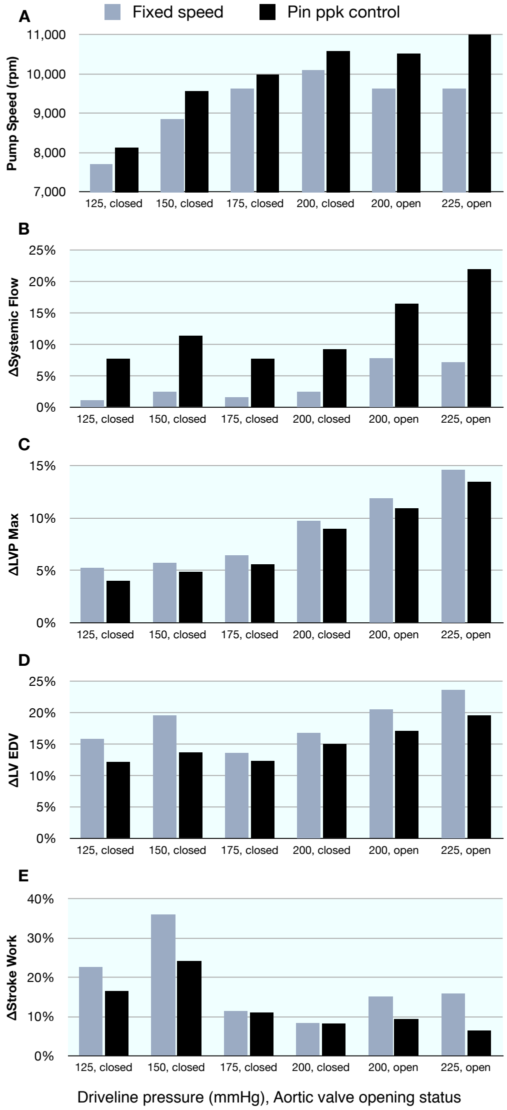

Fig. 5. Mock-loop testing of control algorithm as a function of active ventricle contractility. Results are shown at steady state following a step change in preload with fixed pump speed (gray bars) and P_{ppk} control (black bars). *A* pump speed, *B* increase in systemic flow, *C* increase in maximum LV pressure, *D* increase in LV end diastolic volume, and *E* increase in stroke work. *B-E* are normalized to baseline data prior to preload step change.

Detecting suction and optimizing ventricular unloading are separated in the control scheme and may provide a greater factor of safety in pump control. In addition, the control system lends itself to weaning applications where loading is transferred to the native ventricle and maximum pump support is not desirable.

B. Limitations

From Figure 4A, although pump support was increased, the steady state control PV loop was more loaded than the baseline condition. This was due to the shift in the LVP_{ppk} vs inlet P_{ppk} that occurred with changes in preload due to the increased flow causing a pressure drop along the inlet cannula. The mock circulatory loop has significant inlet cannula length (to accommodate additional sensors and test points) that contributes to the error. The newest generation blood pumps have minimal inlet cannula length and therefore, the control system response is expected to improve in vivo. If the cannula length remains an issue for performance a flow estimation algorithm can be incorporated to compensate for the pressure drop.

C. Future Works

The next step in the validation is to test the control system in vivo using an animal model with direct manipulation of preload and contractility. After validation, the control system will be ported from the LabVIEW control system to a complete embedded platform.

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