

Identifying physiologically significant pumping state transitions in implantable rotary blood pumps used as left ventricular assist devices: an *in-vivo* study

P.J. Ayre^{1,2}, N.H. Lovell¹, R. W. Morris³, M. L. Wilson² and J.C. Woodard²

¹ Graduate School of Biomedical Engineering, University of New South Wales, Sydney NSW 2052, Australia.

² Ventrassist, Sydney NSW 2067, Australia

³ Sydney Medical Simulation Centre, Royal North Shore Hospital, Sydney NSW, Australia

Abstract - The VentrAssist implantable rotary blood pump (IRBP) is a centrifugal pump that uses a hydrodynamic bearing to support its impeller. The pump is to be used as a left ventricular assist device (LVAD). Varying pump speed can control the degree of left ventricular assistance. By increasing impeller speed, it is possible to transition from the normal physiological state of ventricular ejection (VE) to a state where the aortic valve remains closed (AC) throughout the cardiac cycle.

Using the non-invasive parameter of instantaneous impeller speed in an *ovine* experimental model (N=3), we investigated state transitions. The cardiovascular system of the animal was perturbed by pharmacological intervention or by exsanguination. A total of six pump speed set point changes that caused physiological state transitions (VE to AC) were examined.

A state transition index (STI) derived originally from data obtained in an *in-vitro* mock loop setup was found to be directly applicable in the *in-vivo* studies and showed statistically significant ($p < 0.0005$) reliability in differentiating between no change in state and change in state. These data indicate that the STI may be a valuable mechanism to in optimal LVAD control.

Keywords - Implantable rotary blood pump, pumping states, control strategy, left ventricular assist device.

I. INTRODUCTION

The VentrAssist (Micromedical Industries, Sydney) implantable rotary blood pump (IRBP) has a novel hydrodynamic bearing that produces a characteristically flat pump-head versus pump-flow curve [1,2,3,4]. The pump is to be used as a left ventricular assist device (LVAD) with both bridge-to-transplant and long-term implantation anticipated.

Current commercially used rotary pumps make no attempt to automatically control pump speed to optimize ventricular assistance, with fixed speed pumps being in common usage. This level of control may not be satisfactory for long-term implantation of these devices as optimal pump speed will be influenced by a myriad of factors, including variation in venous compliance, arterial resistance, heart rate, ventricular contractility and metabolic demand.

There is obviously a need to detect pumping states that cause such deleterious affects as ventricular collapse due to over-pumping or pump back flow (regurgitation) as a result of under-pumping [5]. Other physiological heart states exist within these extremes. The normal state would be where left ventricular ejection is occurring and there is a net positive aortic and pump flow (state VE). A state that would be of long-term concern to an implant recipient would occur at a higher pump speed where there is insufficient blood in the ventricle to sustain normal left ventricular ejection and the aortic valve remains closed throughout the entire cardiac cycle (state AC). In this instance there is no net positive aortic flow. Stasis of blood distal to the aortic valve could lead to significant patient complications due to clotting.

While it is a routine matter to determine aortic valve closure (and aortic flow) from invasive implantation of flow and pressure transducers, such transducers cause significant patient complications in long-term implant [5] and thus should be avoided if possible.

In-vivo experimentation in the transition of states has previously been investigated [6,7,8,9,10]. These studies concentrated primarily on the detection of ventricular collapse using motor current analysis in the time and frequency domains. Amin *et al.* [6] used an axial blood pump to examine the condition of complete aortic valve closure with increasing pump speed. Pump current was mentioned as a method of analysis but the authors made no attempt at devising an algorithm to detect this transition.

The hypothesis that we propose is that by using only the non-invasive measure of instantaneous pump impeller speed, it is possible to detect the afore-mentioned state transition from VE to AC.

II. MATERIALS AND METHODS

In-vivo Experiments

Three acute *ovine* experiments were conducted with the heart instrumented as shown in Fig. 1 to record left ventricular pressure (LVP), aortic pressure (AoP) pump differential pressure (Pump dP), aortic flow, pump flow. The transition between states was induced by changes in pump speed set point for hypertensive, normovolemic and hypovolemic

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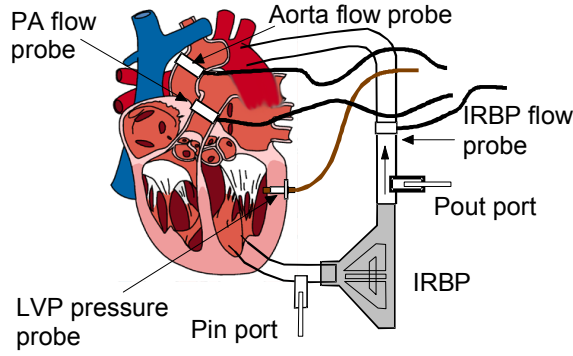


Fig. 1. Experimental arrangement showing LVAD positioning and instrumentation for measuring aortic, pulmonary and IRBP flow, and LVP, aortic and pump differential pressure.

physiological interventions. It was not possible in all animals to transition from the VE to the AC state. The hypertensive and hypovolemic conditions were induced by infusion of 0.94 $\mu\text{g}/\text{kg}/\text{min}$ noradrenaline and exsanguination of 700 ml of blood respectively. Pump speed was adjusted in increments of 100 rpm within an approximate range of 1800 rpm to 2500 rpm.

State Identification

In order to assess whether non-invasive pump speed is a potential indicator of state transition, it is necessary to independently verify the physiological state of the ventricle. This was achieved by using the physiological parameters indicated in Table 1. In a separate test the IRBP was inserted into a mock loop of the circulatory system [2,4] and used to verify these assumptions.

Table 1. A summary of physiological parameters identifying the AC and VE states.

State	Physiological Parameters		
	AoP	Maximum LVP	Qa
AC	~0	<AoP	~0
VE	+ve	>AoP	+ve

Calculation of State Transition Index

Previous studies in mock loops [2,4] have shown that as pump speed set point is increased the aortic valve will remain closed and maximum LVP will decrease. A corollary is that the minimum pump differential pressure will increase relative to the RMS of the pump differential pressure over the cardiac cycle. This transition is reflected in a rise in minimum pump speed with respect to the RMS speed.

A state transition index (STI) was derived by considering the maximum instantaneous speed $N_{\max}(n)$ and the RMS of

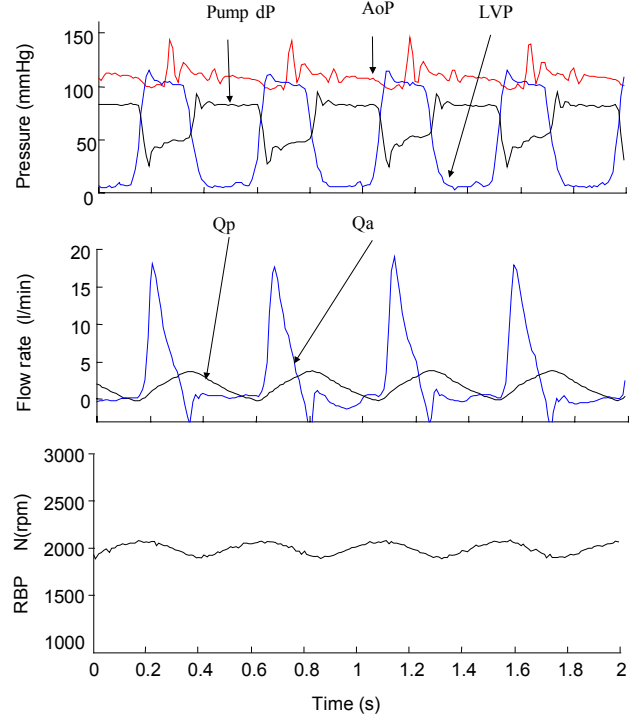


Fig. 2. Typical data from the state where the ventricle is ejecting (VE) with a pump speed set point of 2000 rpm. Pump differential pressure (Pump dP), arterial pressure (AoP), left ventricular pressure (LVP), pump flow (Qp), proximal aortic flow (Qa) and pump speed are shown.

instantaneous speed $N_{rms}(n)$ for the $(n-1)^{\text{th}}$ and n^{th} cardiac cycle relative to the change in speed set point. A true RMS was used due to the non-symmetrical nature of the cardiac cycle. Hence

$$STI = 100 \cdot \left[\frac{d((N_{\max}(n-1) - N_{rms}(n-1)) - [(N_{\max}(n) - N_{rms}(n)])])}{dN_{sp}} \right]$$

The pump controller collected impeller speed samples every 60° of rotation. For the purpose of recording speed as an analogue signal, a frequency-to-voltage converter was used. RMS speed was calculated from a moving window of n samples (S_n). The RMS of speed ($N_{rms}(t)$) was calculated at every maximum value of n throughout the cardiac cycle.

$$N_{rms}(t) = \sqrt{\frac{\sum_0^n [N(s_n)]^2}{n}}$$

III. RESULTS

Fig. 2 and 3 show typical *in-vivo* data from the states VE and AC respectively. In state VE the ventricle is ejecting blood and mean blood flow through the ventricle and pump is positive. The maximum LVP is greater than AoP. The proximal aortic flow (Qa) is positive. Minimum pump

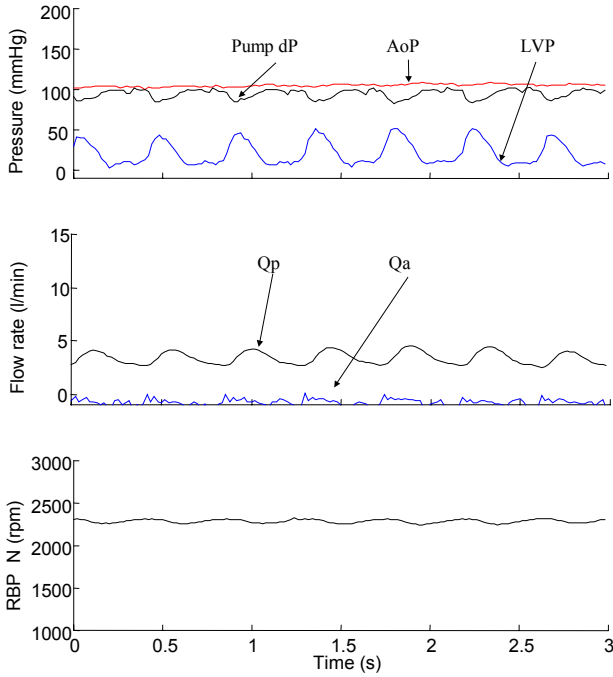


Fig. 3. Typical *in-vivo* data from the state where the aortic valve remains closed during the entire cardiac cycle (AC). Annotations are the same as in Fig. 2.

differential pressure coincides with maximum LVP, maximum pump flow, (Q_p) and minimum impeller speed. Maximum pump differential pressure aligns with minimum pump flow.

During state AC the aortic valve remains closed throughout the cardiac cycle and maximum LVP is always less than AoP. Q_a is near zero. As with state VE, the minimum pump differential pressure coincides with the maximum LVP and maximum Q_p .

Fig. 4 shows the dynamic state transition when increasing pump speed set point from 2000 rpm to 2400 rpm in

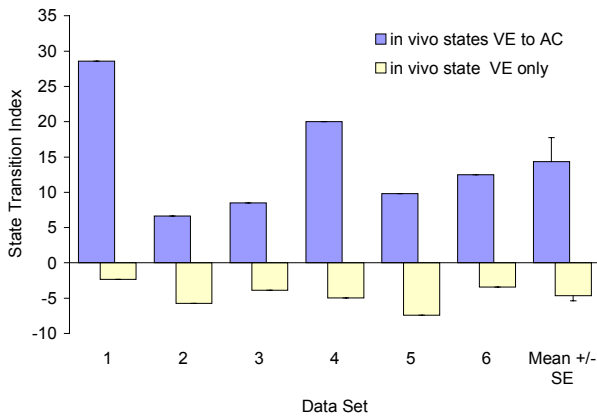


Fig. 5. State transition index shown for VE only state and for the state transition from VE to AC. Six data sets are shown along with the Mean \pm SE.

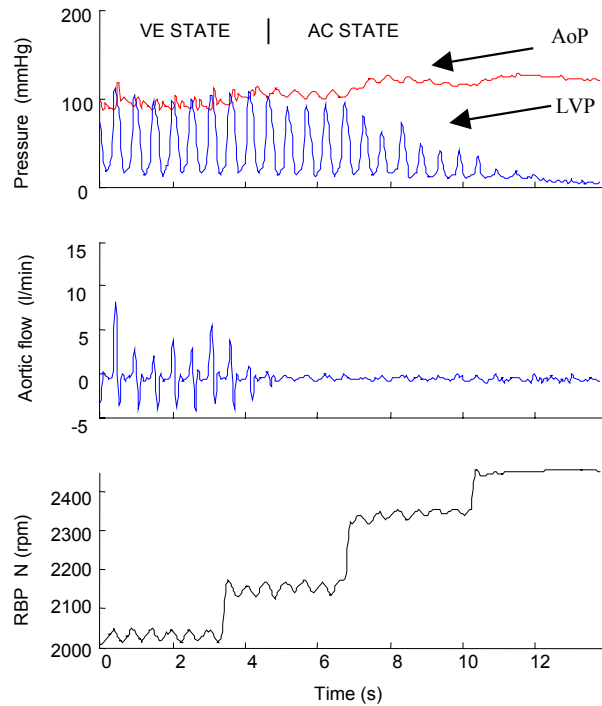


Fig. 4. Transition from state VE to AC as pump speed set point was changed from 2000 rpm to 2400 rpm in increments of 100 rpm.

increments or 100 rpm. The observable pulsatility in the instantaneous impeller speed reduces considerably. The proximal aortic flow reduces as maximum LVP reduces with increasing pump speed.

Fig. 5 shows a summary of the STI for the transitions of states VE to AC and for no state change (remaining in state VE) for changes in pump speed set point for the six data sets. In the VE state, only the STI for the pump speed change just prior to state transition is plotted although there is no statistical difference in slower speed transitions within the VE state. In the VE state, with no state transition, the STI remained slightly negative but near zero. With a speed change that induced a state change, the STI was significantly positive and large. There is a statistically significant difference between the mean STIs at the $p < 0.0005$ level with the STI being -4.6 ± 0.7 in the VE state and 14.3 ± 3.4 in the VE to AC state transition.

IV. DISCUSSION

In state VE, the cardiac cycle begins with pressurization of the right and left ventricles. As LVP rises forcing the tricuspid valve open, blood flows through the ascending aorta. The moment the aortic valve opens pressure across the pump decreases causing an increase in pump flow that continues throughout systole. End of pressurization of the left ventricle causes flow through the aorta to abruptly decrease (falling away much earlier than the flow through the

pulmonary artery). There appears to be a time delay between the aorta and pulmonary valve closing (data not shown), the difference between the ventricles being the pump, which is acting as a shunt while the aortic valve is open. The opening and closing of the aortic valve can be seen on the arterial trace. Closure of the aortic valve causes the pump differential pressure to rise, causing pump flow to decrease during diastole.

During both systole and diastole, the contracting left ventricle modulates measured instantaneous pump speed. This is caused by the ventricular pressurization during ejection, which influences the pump differential pressure. During pressurization, before the aortic valve opens, the ventricle is supporting blood through the pump, thus increasing pump flow. This can typically be seen as a small inflection of the descending flow rate just before the flow begins to rise again. When the aortic valve opens in the VE state, pressure across the pump begins to decrease rapidly causing pump flow to increase, causing a concomitant increase in pump loading and slowing the impeller.

State AC occurs when the aortic valve remains closed during the entire cardiac cycle and the aortic flow is zero or indeed slightly negative (due to flow through the coronary arteries). This state was indicated by a maximum LVP being less than the arterial pressure. The maximum LVP is not enough to open the aortic valve. Decreases in maximum LVP can occur as a result of decreased myocardial contractility, increased pump power or a decrease in blood returning from the left atrium into the left ventricle. The differential pressure across the pump decreases as LVP rises. The pump supports the majority of flow through the pulmonary artery. As in the VE state, pump flow rate increases with minimum pump differential pressure.

V. CONCLUSIONS

To our knowledge, no other reports exist in the literature that have examined sensorless detection of physiological states as a control strategy. IRBPs presented in the literature, even those in clinical trials in humans, have not solved the problem of the IRBP being automatically controlled by pre-load. Systems such as the JARVIK 2000 axial IRBP have proposed a manual speed control for the patient to cope with changing demands on cardiac output. Other groups have explored implantable sensors such as the NASA/DeBakey axial IRBP.

It is likely that the characteristically flat pump differential pressure versus pump flow curve, produced by the hydrodynamic bearing of the VentrAssist LVAD [1] will contribute to this task. These characteristics mean that impeller speed is very sensitive to changes in pump head and insensitive to pump flow unlike axial pumps or centrifugal pumps with 'controlled' impeller positioning either through contact or magnetic bearings.

The first stages in sensorless control of IRBP LVADs are the development of sensitive indexes of physiological states. The STI index proposed herein appears to be a statistically significant indicator of VE to AC state transition in the *in-vivo* data examined. Future work will further characterize this index in extended data sets as well as characterizing similar indexes incorporating both pump speed and motor current to investigate other physiologically important states

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