

QUT Digital Repository:
<http://eprints.qut.edu.au/>



Timms, Daniel L. and Fraser, John F. and Hayne, Mark S. and Dunning, John and McNeil, Keith and Percy, Mark J. (2008) *The BIVACOR rotary biventricular assist device : concept and in vitro investigation*. *Artificial Organs*, 32(10). pp. 816-819.

© Copyright 2008 Blackwell Publishing Ltd

(i)Title

The BiVACOR Rotary Bi-ventricular Assist Device: Concept and In-vitro Investigation

(ii)Authors

Daniel Timms, PhD¹, timmsd@gmail.com

John Fraser MD¹, John_Fraser@health.qld.gov.au

Mark Hayne², m.hayne@qut.edu.au

John Dunning, MD¹, John_Dunning@health.qld.gov.au

Keith McNeil, MD¹, Keith_McNeil@health.qld.gov.au

Mark Percy, PhD². m.percy@qut.edu.au

(iii)Affiliations

¹Critical Care Research Group, The Prince Charles Hospital, Brisbane, QLD, Australia, 4032
and

²Engineering Systems, Queensland University of Technology, Brisbane, QLD, Australia,
4001.

(iv) Contact Details

Dr Daniel Timms

The Prince Charles Hospital, Rode Rd, Chermside, Brisbane, Australia, 4032

Email : timmsd@gmail.com

m.ph +61438567330

w.ph +61 7 3139 5488

w.fx +61 7 3139 4651

(v) Running Title

BIVACOR: Concept and In-vitro Investigation

Abstract : The BiVACOR is a novel rotary Bi-Ventricular Assist Device (BiVAD) undergoing development to treat global end stage heart failure. The design includes left and right vanes positioned on a shared rotating hub to form a double-sided magnetically and hydro-dynamically suspended centrifugal impeller.

The performance of the device was assessed in a pulsatile mock circulation loop replicating end stage bi-ventricular heart failure, and was shown to restore flow from pathological (2L/min) to normal levels (5L/min). A novel technique to balance the left/right outflow of the BiVAD was also investigated, for which a maximum relative left to right outflow differential of 1.8L/min was achieved at normal physiologic afterloads.

The in-vitro results encouraged device progression to in-vivo animal studies. Successful development of this BiVAD will provide a suitably miniature device for patients who require bi-ventricular assistance.

Keywords : Rotary blood pump, Bi-Ventricular assist device, Heart failure

(i) Introduction

The use of mechanical device therapy to treat heart failure is increasing as the general population ages and the number of donor organs for heart transplantation remains limited (1).

Left ventricular heart failure (LHF) is the most common affliction, for which a left ventricular assist device (LVAD) can provide sufficient circulatory support. However, a significant number of patients suffer from bi-ventricular heart failure (BHF), hence implantation of an additional right ventricular assist device (RVAD) is beneficial. The degree of bi-ventricular dysfunction is frequently underestimated in these patients, and right ventricular heart failure (RHF) may develop in up to 40% of patients receiving LVAD

assistance (2, 3). This condition is associated with mortality of greater than 90 % when untreated (4, 5). Early introduction of an RVAD to complement the LVAD increases cardiac output and reduces central venous pressure (CVP), improving organ perfusion and potentially reversing the incipient multi-organ failure (MOF).

Currently, two individually and extra-corporeally connected pulsatile type Thoratec™ devices (6) are used clinically to optimally treat bi-ventricular failure. These systems increase size, complexity, and therapy cost. Therefore, research at the Prince Charles Hospital (TPCH) is focused on developing a single rotary Bi-VAD that incorporates a method for balancing the left/right outflow and is suitably sized for implantation.

The purpose of this paper is to detail the progressive design of the BiVACOR rotary Bi-VAD and present in-vitro results obtained from device operation within a mock circulation system.

BiVAD Design

The design of the BiVACOR device includes left and right vanes positioned on a shared rotating hub to form a magnetically and hydro-dynamically suspended centrifugal impeller. These respective vanes have a different outer diameter to produce the pressure required of the systemic and pulmonary systems at a common rotational speed. The instantaneous differential in flow required to balance outflow from the left and right hearts is achieved by alteration of axial clearance above each semi-open VAD impeller. The suspension system under development incorporates an electromagnetic motor and bearing system for axial suspension and drive, while radial support is achieved using a hydrodynamic journal bearing. This journal bearing is well washed by the inherent shunt flow from left to right cavities.

The relatively small size of the BiVACOR device enables intra-thoracic placement, utilizing inflow cannulation from the right atrium and left ventricle, and outflow cannulation to the

pulmonary artery and aorta. This strategy allows the intact native ventricles to provide an inflow reservoir and assist in balancing cardiac output.

Error! Reference source not found. shows an exploded view detailing the anticipated placement of hydraulic and electromagnetic components, as well as the principle of flow differential production.

(ii) Material and Methods

To test the VAD hydraulic performance, a prototype was constructed which could centrally locate the impeller using a motor, shaft and sealed bearings to substitute initially for the magnetic/hydrodynamic bearing system. A micrometer mechanism attached to the motor and shaft assembly allowed precise, reproducible, and measureable axial displacement of the impeller within the pump cavity. This allowed simultaneous alteration of axial clearances above the left and right impeller vanes. The relative hydraulic performance with an axial movement of $\pm 0.3\text{mm}$ about the centralised position was then tested in a mock circulation loop filled with water at 20°C loop replicating a bi-ventricular heart failure (7).

(iii) Results

The desired haemodynamic condition of 5 L/min flow at 100mmHg and 20mmHg were attained at a set 2300rpm and 0.5mm axial clearance above each impeller (middle position). Alteration in performance of the LVAD and RVAD impellers for $\pm 0.3\text{mm}$ axial movement in a non-pulsatile system is detailed in **Error! Reference source not found.** While maintaining arterial pressures, a 0.3mm movement toward the LVAD cavity flow increased left outflow to 6.4L/min while right outflow reduced to 4.6L/min, representing an instantaneous flow differential of 1.8L/min (36%).

Establishing the VAD into the circulation loop replicating BHF restored hemodynamics and resulted in the immediate alleviation of pulmonary and systemic congestion. Hemodynamic values for changes in arterial and atrial pressures as the impeller was moved from the right cavity toward the left cavity are displayed in Table 1. Paradoxically, RVAD outflow increased with motion to the LVAD cavity, due to an increase in hub washout leakage from left to right cavities.

(iv) Discussion

The current technique to treat BHF involves the implantation and operation of two separate pumps, which results in increased size and control complexity. The development of a safe, reliable, durable and suitably small, implantable single device BiVAD potentially removes many of the existing complications encountered whilst treating patients with global heart failure. The single device creates the inability to remove RV support after implantation, however the device can operate successfully alongside a functioning right ventricle, and thus the device may remain in place should transient RV failure return.

The double-sided impeller configuration of the BiVACOR reduces the potential for thrombus formation by eliminating areas of low flow or stagnation often found beneath single-sided centrifugal blood pump impellers. An electro- magnetic motor bearing is under development to suspend and drive the impeller, thus overcoming limitations of friction and wear at the drive shaft, seal and bearing interface. This would greatly increase the durability of the pump and reduce both heat generation and blood damage.

Although similar to a ventricular septal defect, the shunt from the high pressure left to low pressure right cavity helps to wash the impeller. Leakage in this region is minimized to less than 20% by the incorporation of a radial hydrodynamic journal bearing.

The ability of a BiVAD to alter the left and right outflow is clinically ideal, in order to match bronchial flow (8, 9) which may increase with pulmonary disease (10), accommodate relative changes in systemic and pulmonary vascular resistance, account for relative levels of ventricular contractility, alleviate chronic pulmonary or systemic congestion, and to prevent ventricular collapse by acutely maintaining adequate atrial filling pressures.

A previous attempt to create a single device BiVAD/TAH could not actively provide variation in output flow from each cavity, since the impeller has a common rotational speed (11). The BiVACOR device addresses this limitation by using the magnetic suspension system to axially re-position the impeller within the pump cavity, which inversely alters the efficiency of each chamber. This technique effectively achieved left and right relative outflow alteration by up to 1.8L/min despite maintaining rotational speed at 2300rpm. The pump characteristic curves for the respective clearance gaps can be likened to those expected for a change in rotational speed of approximately 2200rpm-2500rpm.

Analyzing the movement of impeller axial position in the simulated BHF environment (without baroreceptor reflex) not only showed an alteration of afterload pressure, but also preload atrial pressure. This represents a shift of fluid volume between the pulmonary and systemic circulations and can minimise the potential for the heart chambers to collapse.

Due to the coupled nature of the LVAD and RVAD impellers, an inherent complication may arise when attempting to accommodate relative changes in SVR and PVR. One such clinical circumstance would arise if a heart failure patient presents with pulmonary hypertension. This hypertension is commonly secondary to elevated pulmonary arterial wedge pressures, which is reduced with left heart support. However, if it is a primary condition an elevated PVR compared to SVR may be present. This latter situation would limit the venous return to the LVAD side of the device, which may lead to left ventricular collapse. Agents such as

inhaled nitric oxide or prostacyclin may be used to reduce PHT whilst inducing no change in SVR –a technique commonly used in the critically ill patients with PHT who do not require mechanical support

Since the impellers are coupled and there is a limit to the axial movement range in the device, a defined range of relative SVR and PVR can be accommodated. Potential difficulties may therefore arise in overcoming severe one sided hyper/hypotension in the current design, whereby fluid loading would be required to maintain sufficient left atrial pressure. Medical management of isolated pulmonary hypertension may be considered in these conditions. However, patients are routinely screened for pulmonary hypertension prior to heart transplant, which if severe, would preclude their eligibility for support.

(v) Conclusion

The Bi-Ventricular assist device successfully restored hemodynamic perfusion from pathological to normal levels in a mock circulation loop replicating bi-ventricular heart failure. The LVAD and RVAD impellers produced the desired hemodynamics of 5 L/min at 100mmHg and 20mmHg respectively at a common rotational speed of 2300rpm and axial clearance of 0.5mm. The instantaneous imbalance of flow from the left and right hearts was achieved by simultaneously altering the axial clearance above each impeller, for which a maximum flow differential of 1.8L/min was observed.

The in-vitro results encouraged device progression to in-vivo animal studies. Successful development of this device will provide a suitably miniature and relatively inexpensive device for patients who require bi-ventricular assistance.

(vi) Acknowledgements

The authors would like to acknowledge the financial assistance provided by the Prince Charles Hospital Foundation and the support from the TPOCH Critical Care Research Group and QUT medical engineering program.

(vii) References

1. Rose, E., et al., *The REMATCH Trial : Rationale, Design and End Points*. Ann Thorac Surg, 1999. **67**: p. 723-730.
2. Fukamachi, K., et al., *Development of a small implantable right ventricular assist device*. ASAIO J, 2005. **51**(6): p. 730-735.
3. Reesink, K., et al., *Physiologic-insensitive Left Ventricular Assist Predisposes Right-sided Circulatory Failure: A Pilot Simulation and Validation Study*. Artif Organs, 2004. **28**(10): p. 933-939.
4. Radovancevic, B., et al., *Biventricular support with the Jarvik 2000 axial flow pump: A feasibility study*. ASAIO J, 2003. **49**(5): p. 604-607.
5. Kindo, M., et al., *Biventricular support with the Jarvik 2000 ventricular assist device in a calf model of pulmonary hypertension*. ASAIO J, 2004. **50**: p. 444-450.
6. Magliato, K.E., et al., *Biventricular support in patients with profound cardiogenic shock: A single center experience*. ASAIO J, 2003. **49**(4): p. 475-479.
7. Timms, D.L., et al., *A complete mock circulation loop for the evaluation of left- right- and bi-ventricular assist devices*. Artif Organs, 2005. **29**(7): p. 564–571.
8. Frazier, O.H., et al., *Total heart replacement using dual intracorporeal continuous-flow pumps in a chronic bovine model: a feasibility study*. ASAIO J, 2006. **52**(2): p. 145-149.
9. Wada, H., et al., *Flow balance between the left and right cardiac output of an eccentric roller type total artificial heart*. Artif Organs, 1999. **23**(8): p. 741-746.
10. Bhunia, S.K. and R.T.V. Kung, *Indirect Bronchial Shunt Flow Measurements in AbioCor Implantable Replacement Heart Recipients*. ASAIO J, 2004. **50**(3): p. 211-214.
11. Qian, K.X., et al., *A novel impeller TAH using magnetic bearings for load reduction*. J Med Eng & Tech, 2002. **26**(5): p. 214-216.

Tables

Table 1 – BHF support performance for axial clearance values at 2000rpm

Axial Position	Systemic			Pulmonary		
	SQ (L/min)	LAP (mmHg)	MAP (mmHg)	PQ (L/min)	RAP (mmHg)	MPAP (mmHg)
+0.3mm	5.3	7.3	100	6.3	9.3	17.2
0mm	5.1	9	93	5.7	8.2	17.8
-0.3mm	4.9	11.8	86	5.5	6.3	19.3

Illustrations

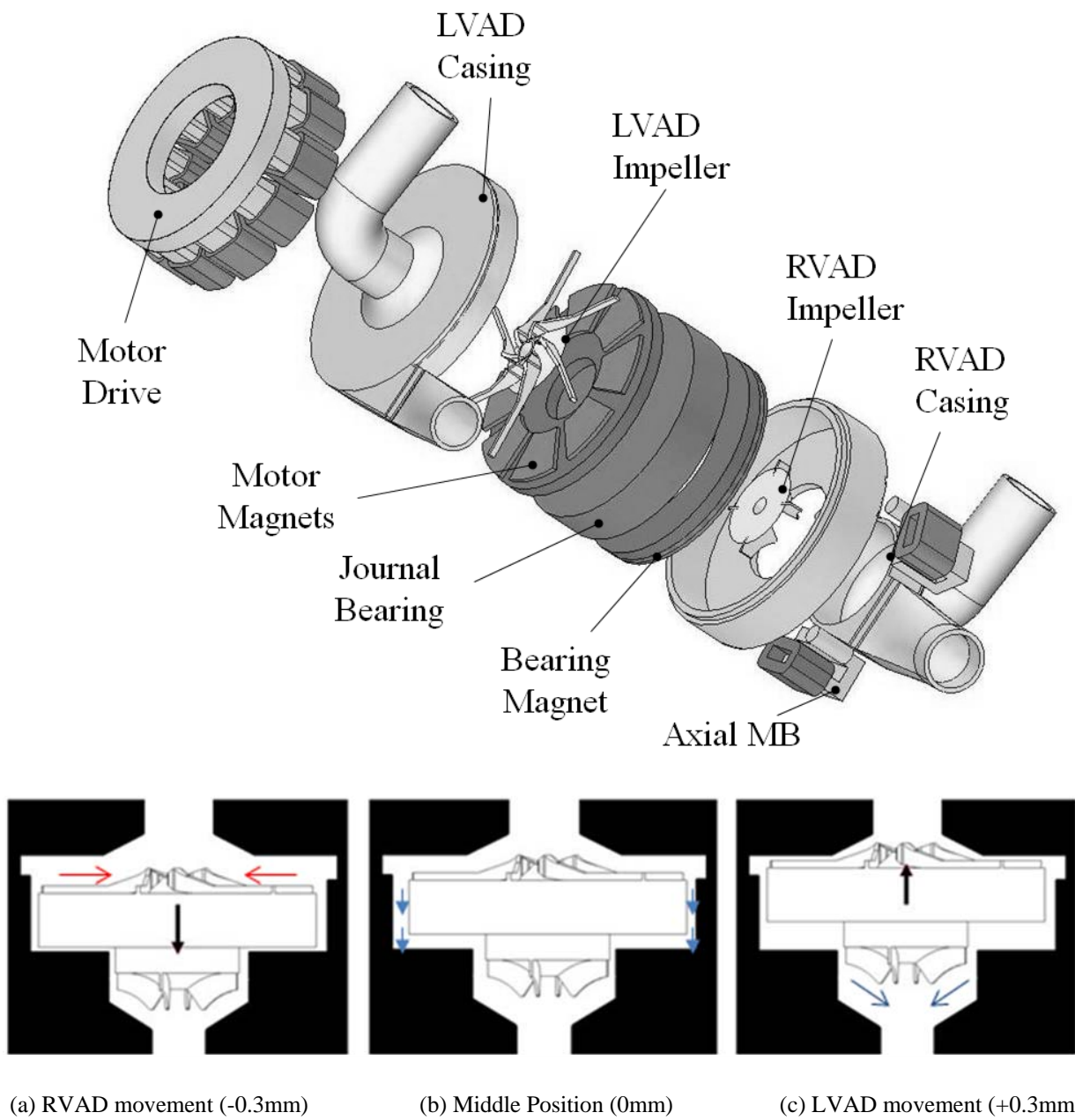


Figure 1 – Exploded View of the BiVACOR showing the placement of magnetic and hydraulic components and conceptual illustration of impeller axial motion showing (a) LVAD leakage (b) LVAD to RVAD hub washout leakage and (c) RVAD leakage

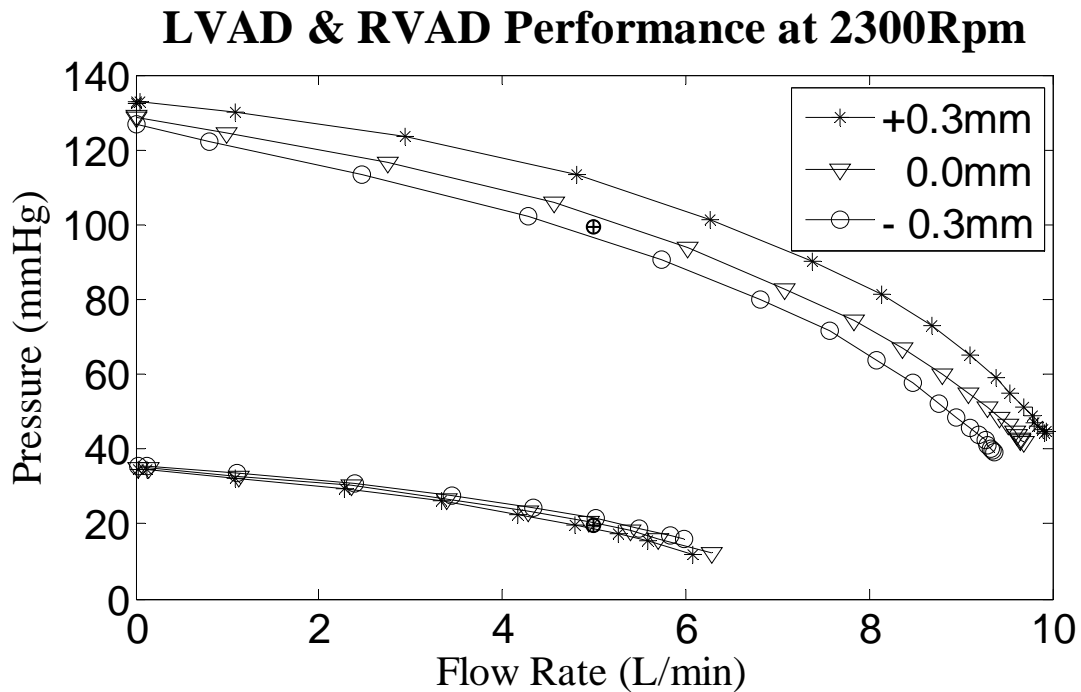


Figure 2 – Individual LVAD (Upper) and RVAD (Lower) impeller performance curves for different axial positions at 2300rpm. Positive direction denotes movement toward the LVAD cavity from the centre.

LEGEND

- LAP – Left Atrial Pressure,
- LVP – Left Ventricle Pressure,
- AoP – Aortic Pressure,
- MAP – Mean Arterial Pressure,
- RAP – Right Atrial Pressure,
- RVP – Right Ventricular Pressure,
- PAP – Pulmonary Arterial Pressure,
- MPAP – Mean Pulmonary Arterial Pressure,
- SQ – Systemic Flow Rate,
- MSQ – Mean Systemic Flow Rate,
- PQ – Pulmonary Flow Rate,
- MPQ – Mean Pulmonary Flow Rate

