



Magnetically Suspended Rotary Blood Pump

Mohawk Innovative Technology, Inc. (MiTi[®]) has developed a next generation, implantable blood pump for patients suffering from end stage heart failure. The MiTiHeart[™] left ventricular assist device (LVAD), a rotary centrifugal blood pump with a hybrid passive/active magnetic bearing support system, has been developed with substantial support from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) and internal company funds. The blood pump exhibits low power loss, low vibration and high reliability under transient operating conditions. Unique features of the design include a simple and direct flow path for both main and wash blood flows, non-contact pump rotor, i.e., no rubbing surfaces and relatively large clearances between the pump rotor and housing. An acute animal test was successfully completed at the Pennsylvania State University (PSU) Hershey Medical Center. During the test, the pump was implanted in a calf and operated in parallel with the heart. Following the acute test, a chronic 200-hour implant study was completed. A second prototype was constructed using a titanium alloy for all blood contacting surfaces. This new unit incorporated a hydrodynamic thrust bearing and was successfully evaluated in two chronic implant studies in a calf animal model for a total of 130 hours.

According to the American Heart Association, 62 million Americans suffer from heart disease and approximately one million die each year. Heart failure, the number one cause of death in the United States, accounts for one death every 30 seconds. Approximately 4.7 million Americans have congestive heart failure (CHF) and more than half a million new cases are reported every year. CHF is a chronic condition in which at least one chamber of the heart is not pumping well enough to meet the body's need. Heart failure presents an increasing public burden of morbidity and mortality, even as the mortality from coronary artery disease and hypertension is decreasing. It is estimated that at least 40,000 of these patients are candidates for heart transplantation; however, only 2,200 donor hearts are made available each year. While effective pharmacologic therapies have improved outcomes for mild to moderate CHF, the need for mechanical circulatory support is well defined and growing. In light of this need, the NIH has funded the development of both pulsatile and nonpulsatile mechanical circulatory assist devices for these patients. While much of the early funding supported the development of diaphragm pulsatile type pumps, continuous flow pumps also received funding from NIH

and have been used in short duration circulatory assistance for many years.

Current use of mechanical circulatory cardiac devices is dominated by the indications of post-cardiotomy shock and bridging to transplantation. About 6,000 patients a year receive support devices after cardiac surgery in the U.S. alone. If fully implantable and wearable devices were available, at least 100,000 patients annually in the U.S. could benefit from this technology. Based on recent clinical results, the Centers for Medicare and Medicaid Services (CMS) have approved reimbursements for implantation of LVADs. This decision, which has also been followed by several major private insurance groups, has established a clear market for treatment of heart failure with LVADs.

MiTiHeart[™] LVAD Design Concept

The MiTiHeart[™] LVAD, as shown in Figure 1, is a third generation blood pump that has been under development at MiTi[®] since 1994 as destination therapy for adult heart failure patients of small to medium frame that are not being served by present pulsatile devices. The pump design is based on a novel, patented, hybrid passive/active magnetic bearing system. The MiTiHeart[™] LVAD is a high-efficiency, non-pulsatile centrifugal pump and exhibits extremely low power loss, low vibration, low hemolysis and high reliability under transient conditions and varying pump orientations. Unique features of the design include a simple and direct path for main and wash flows, non-contacting operation of the pump rotor and large clearances between the pump rotor and housing.



Figure 1. MiTiHeart[™] LVAD Prototype.

Another unique feature of the design is the use of a redundant hydrodynamic thrust bearing. This bearing is not active under normal pump operation. Rather, the bearing is designed to prevent rotor contact under most severe transient loading conditions by sharing load carrying responsibilities of the magnetic bearing. For example, transient loads that may be encountered if the patient falls accidentally. Additionally, the hydrodynamic thrust bearing provides emergency back-up support and, hence, fail-safe operation in the event of a failure of the magnetic thrust bearing. As seen in Figure 2, it is predicted that the rotor peak response will be approximately 0.002 inch for a 12.9-g shock pulse when the hydrodynamic bearing is not included in the system. When the hydrodynamic thrust bearing is included, axial motions are predicted to be less than half, even for a larger 20-g impulse. Experimental testing with a baseline pump without the thrust bearing confirmed the analytical models, giving a high degree confidence for the inclusion of the hydrodynamic thrust bearing. Using the test and analysis results, the thrust design was optimized both for load carrying ability and to minimize the potential for hemolysis.

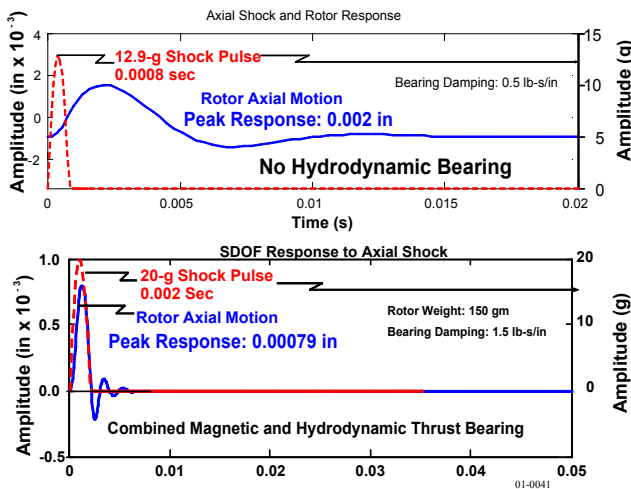


Figure 2. Rotor axial motion under shock event with and without hydrodynamic effects.

The performance of the selected bearing were evaluated designs with blood analog in a unique MiTi[®] developed thrust bearing tribometer. The optimal bearing design was then selected for implementation into a new titanium alloy MiTiHeart[™] LVAD.

In Vitro Performance Results

Performance of the new titanium alloy prototype was evaluated in a series of *in vitro* and *in vivo* animal tests. *In vitro* tests were conducted with water and blood analog to map the performance envelop of the new pump. A rotational speed ranging from 2,000 rpm to 3,500 was used in these tests, which generated a flow rate of 3-7 L/min with the pressure rise ranging from 30 mmHg to 145 mmHg. A series of pump curves generated from these data is shown

in Figure 3. Tests of longer duration were also performed to ensure pump operational stability. These tests confirmed the efficacy of the new MiTiHeart[™] LVAD prototype.

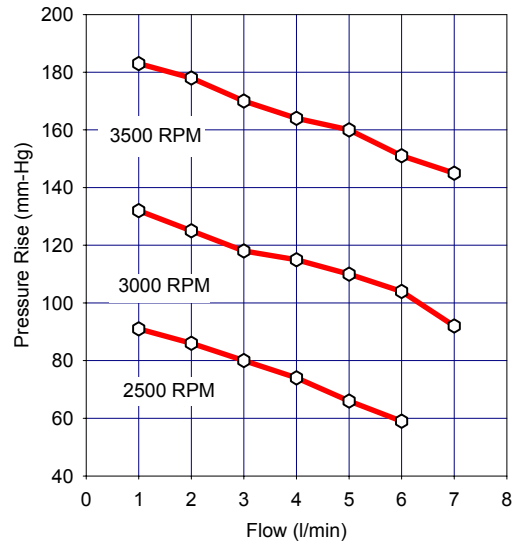


Figure 3. Pump flow rate as a function of speed and pressure head with distilled water.

Hemolysis test results showed a low normalized index of hemolysis of 0.01 mg/dL for the titanium alloy MiTiHeart[™] (Figure 4).

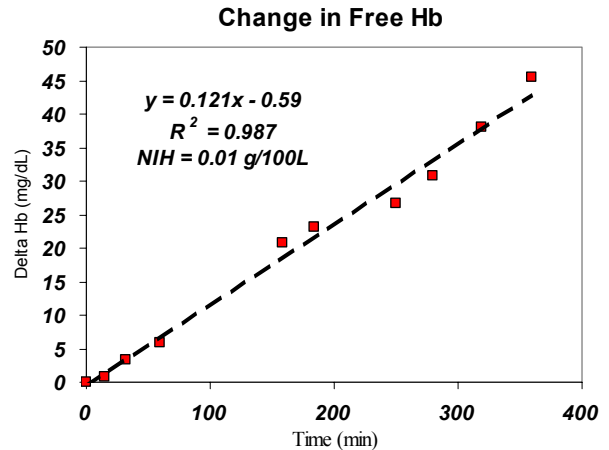


Figure 4. Hemolysis data with bovine blood.

Stable operation of the titanium MiTiHeart[™] was exhibited during *in vitro* testing in water for a time period of greater than 24 hours. A plot of motor current versus speed at different afterloads is shown in Figure 5. A clear correlation between the two parameters suggests that motor current could be used for controlling the motor speed and flow rate. This relationship, among others, will be investigated further in order to develop sensorless physiologic control algorithms in the future. Once all *in vitro* test results were carefully analyzed and the pump was

tested in numerous start/stop tests, arrangements were made for animal testing at Hershey Medical Center.

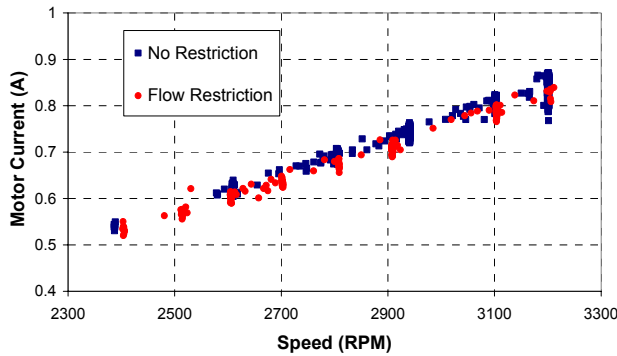


Figure 5. LVAD pump motor current versus speed.

In Vivo Performance Verification

The *in vivo* performance of the new titanium pump was evaluated in two chronic implant studies in a calf animal model at the Hershey Medical Center. The pump speed was set at 2,500 rpm to achieve a mean flow rate of 5-6 L/min against arterial pressure of 80-110 mmHg. The pump operated successfully during the 30 hour implant test. In the second calf implant test, the pump was operated successfully for approximately 100 hours, with a total power consumption of less than 8.0 watts. Typical data obtained during the study are shown in Figure 6.

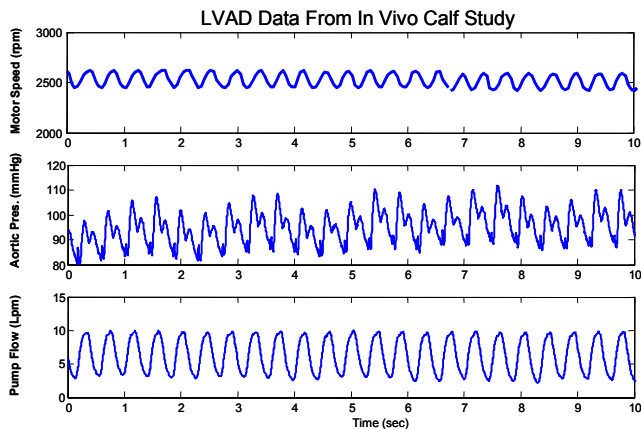


Figure 6. Pump speed, aortic pressure and flow during the implant study.

While the pump speed and flow rate were constant during the *in vitro* tests, the implant data clearly show that the MiTiHeart™ LVAD is capable of stable operation in the presence of strong pulsatility imparted by the calf’s native heart.

Recent Developments

Under a recent Grant from the NIH, the MiTiHeart™ LVAD is being redesigned to dramatically reduce the overall dimensions and incorporate a novel bio- and hemo-compatible coating to further reduce the potential for

thrombosis and hemolysis. The new pump, shown in Figure 7, will be evaluated in a series of *in vitro* and *in vivo* animal tests.

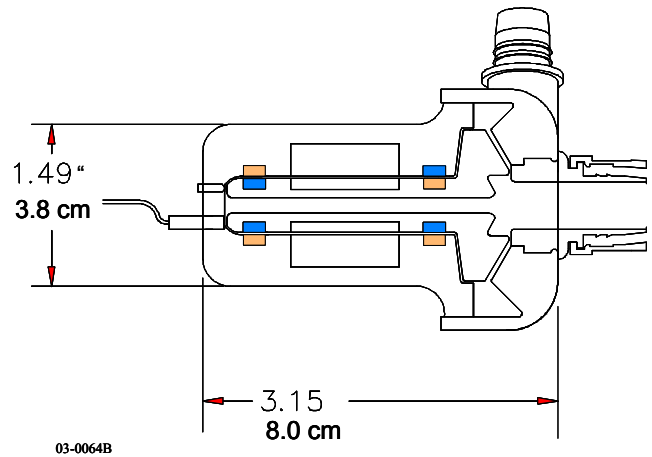


Figure 7. The new MiTiHeart™ design.

MiTiHeart™ also plans to conduct R&D jointly with other companies to develop the needed power supply and electronic controller used to monitor and adjust the pump speed as demanded by the patient’s hemodynamic needs.

Acknowledgments

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