MiTi Developments

Mohawk Innovative Technology, Inc.

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Pre-Clinical Evaluation of the MiTi*Heart*® LVAD

Mohawk Innovative Technology, Inc. (MiTi) has successfully completed two long-term chronic animal implant studies of the MiTiHeart® Left Ventricular Assist Device (LVAD), which is an implantable blood pump (Figure 1) developed for patients suffering from end-stage heart failure. The MiTiHeart® LVAD, a rotary centrifugal blood pump with a hybrid passive/active magnetic bearing support system, has been developed with 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, a non-contact pump rotor (i.e., no rubbing surfaces), and relatively large clearances between the pump rotor and housing.

Figure 1. MiTi*Heart*® LVAD

Background

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.

Current use of mechanical circulatory cardiac devices is dominated by the indications of postcardiotomy shock and bridging to transplantation. About 6,000 patients a year receive support devices after cardiac surgery in the U.S. alone. Fully implantable and wearable devices can benefit at least 100,000 patients annually in the U.S. Based on recent clinical results, the Centers for Medicare and Medicaid Services (CMS) has 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.

The MiTi*Heart*® LVAD

The MiTiHeart® LVAD is designed specifically for destination therapy. The device is compact and fully implantable with an overall mass of 0.64 kg and volume of 160 cm^3. The device features a low power magnetic levitation system that suspends the rotating impeller. A unique and novel back-up hydrodynamic thrust bearing is also used in the unlikely event of magnetic bearing failure or extreme external shock. Experimental testing under non-pulsatile and pulsatile flow has demonstrated some of the lowest hemolysis results reported to date for the latest generation of LVADs (NIH = 0.002 ± 0.002 mg/dL).

A new control system has been developed (Figure 2) that is capable of reliable, long term operation. The new controller is compact, lightweight and consumes less power than those used in other implantable LVADs. The controller is responsible for active control of the axial magnetic bearings and pump operating speed. A new, optional user interface and battery back-up has been implemented, improving user-friendliness and making the entire system portable.

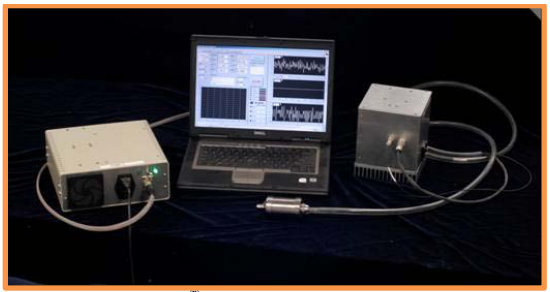

Figure 2. MiTi*Heart*® control system with battery pack and optional user-interface via PC

In Vivo Testing

Ten *in vivo* calf studies, for a total of 2,000 hours, had been performed with the MiTiHeart® LVAD prototypes prior to the recent chronic tests. Significant progress has been made toward the development of the current prototype based on the results and challenges encountered during previous studies. The primary challenges encountered include: surgical complications (cannula placement, internal bleeding) and device complications (seals, thrombus formation, sub-component failures). The issues related to complications have been addressed. Recently, two successful chronic animal studies were completed.

In the first experiment, the animal recovered quickly from surgery with no signs of discomfort, stood shortly after extubation and ate several hours later (Figure 3). The pump performance was stable and there were no issues related to device operation. Hematologic parameters returned to preoperative levels shortly after surgery. The first experiment was terminated after 18 days due to driveline infection; however, pump function was normal for the duration of the study and there were no signs of thrombus in the primary or secondary flow paths. Necropsy revealed all major organs to be grossly normal.

Figure 3. Calf shown healthy and eating shortly after implant

A second chronic implant experiment was also performed. No surgical complications were encountered; however, the ultrasonic flow sensor, used for experimental purposes only and not associated with LVAD function, became disabled after postoperative day two (POD-2). The animal showed no signs of pain or discomfort and the pump functioned normally for the duration of the study. Hematologic parameters returned to preoperative levels within 5 days after implant and remained stable for the duration of the study (Figure 4).

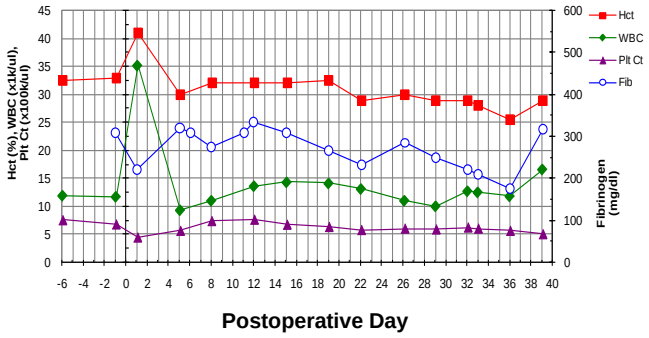

Figure 4. Typical hematological data recorded during long term chronic implant testing

During the course of the experiment, a decreasing trend observed in motor power was attributed to a decrease in pump flow. Motor power was observed to decrease quickly on POD-38, possibly due to cannula obstruction in the rapidly growing animal. Due to the concerns regarding cannula obstruction, the test was terminated at POD-39. Gross necropsy revealed small thrombi in the right kidney and all other organs grossly normal. There were no signs of thrombus on blood contacting surfaces within the pump and no fluid ingress found in the back-cap region of the pump.

Long-Term Durability Testing

In order to demonstrate the long-term reliability and durability of the MiTiHeart® LVAD, a continuous 63-day test was performed under pulsatile conditions while submerged in saline at 38°C. Testing was conducted at a speed of 4,100 rpm and flow conditions for the test were 5 L/min against 100 mmHg. A total of 6 W input power was consumed at the design point. Stable pump performance was demonstrated (Figure 5).

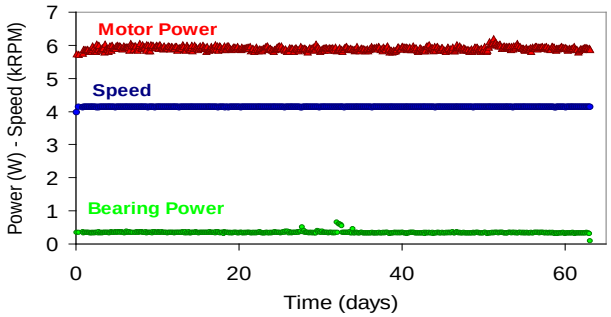

Figure 5. Data from the long-term durability testing of the MiTiHeart® LVAD

Summary

The latest MiTiHeart® LVAD system is compact, efficient and capable of long-term stable operation *in vitro* and *in vivo*. A total input power of 6 W was required at a design point of 4,100 rpm while pumping 5 L/min against 100 mmHg. This is among the lowest power reported by magnetically levitated LVADs found in literature. *In Vitro* testing showed low hemolysis under non-pulsatile and pulsatile conditions. NIH values are among the lowest reported in literature. Long-term durability testing has been demonstrated for 63 days of continuous operation while submerged in saline. Two successful chronic implant studies were performed. In both studies, the MiTiHeart® LVAD operated as expected with no device related complications. Recent test results will allow the MiTiHeart® LVAD to move forward with FDA IDE application, following additional testing that is currently underway.

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