ABSTRACT

MiTiHeart® LVAD is a rotary centrifugal blood pump with a hybrid passive/active magnetic bearing support system. It 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 washing blood flows, non-contact pump rotor, i.e., no rubbing surfaces, and relatively large clearances between the pump rotor and housing. The first prototype was constructed from medical grade polycarbonate. To reduce the possibility of thrombosis, the internally exposed surfaces were coated with a biocompatible polymer. Hemolysis test results showed a low normalized index of hemolysis of 0.01 mg/dL. An acute animal test was successfully completed at the 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 and incorporating a redundant hydrodynamic thrust bearing. This prototype was successfully evaluated in two chronic implant studies in a calf animal model for a total of 130 hours.

Keywords: blood pump, magnetic bearing, thrust bearing, biotribology, heart failure.

INTRODUCTION

According to the American Heart Association, 1, 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 (see, for example, reference), 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, a third generation blood pump, 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 flow path for both main and auxiliary flows, non-contact pump rotor, i.e., no rubbing surfaces, and relatively large clearances between the pump rotor and housing.

Another unique feature of the design is the use of a redundant hydrodynamic thrust bearing. Under normal pump operation this bearing is not active. However, this bearing is activated to prevent potential contacts under most severe transient loading conditions, for example, when the patient falls accidentally and in case of failure of the magnetic bearing. With the hydrodynamic thrust bearing in place, failure of the axial magnetic suspension will not be catastrophic, thus providing a fail-safe operation. Several configurations for the hydrodynamic thrust bearing were considered based on the taper-land design. These designs were optimized based on maximizing the bearing performance and minimizing the potential for hemolysis. The published hemolysis models were reviewed and modified to include a threshold value, below which no hemolysis would occur. The performance of the selected bearing designs with blood analog were evaluated using a unique thrust bearing tribometer developed in-house. The hemolysis potential of these designs were determined with the proposed model. The most optimal bearing design was selected for implementation into the MiTiHeart™ LVAD. Prior to implementation of the redundant hydrodynamic bearing, the pump was redesigned to allow fabrication with a titanium alloy.

**IN VITRO AND IN VIVO RESULTS**

Performance of the new titanium alloy prototype, Figure 1, was evaluated in a series of in vitro and in vivo animal tests. In vitro performance tests were performed with water and blood analog to map out the performance envelop of the new pump. A rotational speed ranging from 2,000 rpm to 3,000 was used in these tests, which generated a flow rate of 3-6 L/min with the pressure rise ranging from 30 mmHg to 80 mmHg. Tests of longer duration were also performed to ensure pump operational stability. These tests confirmed the efficacy of the new MiTiHeart™ LVAD prototype.

The in vivo performance of the new 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. While the pump performed as expected, the first test was interrupted due to surgical complications after 30 hours. The pump operation was also successful in the second test, but failure of the motor electrical connection caused premature termination of the test after 100 hours. Autopsy indicated several infarcts in the kidneys. Post explant, the pump showed thrombus in narrow crevices. These areas and the electrical connections will be redesigned in the next version of the prototype.

Under a recent Grant from NIH, the MiTiHeart™ LVAD is being redesigned to reduce the overall dimensions by at least 40% and incorporate a novel bio-and hemo-compatible coating to further reduce the potential for thrombosis and hemolysis. The new pump will be evaluated in a series of in vitro and in vivo animal tests.

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