

The HeartMate III: Design and In Vivo Studies of a Maglev Centrifugal Left Ventricular Assist Device

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Abstract: A compact implantable centrifugal left ventricular assist device (LVAD) (HeartMate III) featuring a magnetically levitated impeller is under development. The goal of our ongoing work is to demonstrate feasibility, low hemolysis, and low thrombogenicity of the titanium pump in chronic bovine in vivo studies. The LVAD is based on so-called bearingless motor technology and combines pump rotor, drive, and magnetic bearing functions in a single unit. The impeller is rotated (θ_z) and levitated with both active (X, Y) and passive (Z, θ_x , θ_y) suspension. Six prototype systems have been built featuring an implantable titanium pump (69 mm diameter, 30 mm height) with textured blood contacting surfaces and extracorporeal electronics. The pumps were implanted in 9 calves (≤ 100 kg at implant) that were anticoagulated with Coumadin

($2.5 \leq \text{INR} \leq 4.0$) throughout the studies. Six studies were electively terminated (at 27–61 days), 1 study was terminated after the development of severe pneumonia and lung atelectasis (at 27 days) another study was terminated after cardiac arrest (at 2 days) while a final study is ongoing (at 100 days). Mean pump flows ranged from 2 to 7 L/min, except for brief periods of exercise at 6 to 9 L/min. Plasma free hemoglobin ranged from 4 to 10 mg/dl. All measured biochemical indicators of end organ function remained within normal range. The pumps have met performance requirements in all 9 implants with acceptable hemolysis and no mechanical failures. **Key Words:** Left ventricular assist device—Rotary blood pump—Magnetic suspension—Centrifugal pump—In vivo studies.

Thermo Cardiosystems Inc. (TCI), in a research partnership with the Swiss firm Sulzer AG, is developing a compact implantable centrifugal left ventricular assist device (LVAD) (HeartMate III) featuring a bearingless motor incorporating a magnetically levitated impeller. This device combines the functions of impeller rotation and levitation in a single magnetic structure. The result is a pump that fits in an acceptably small package and can operate completely sheathed in titanium. Total power consumption (including rotation, levitation,

and control) below 10 W should be achievable under nominal operating conditions, in league with both HeartMates I and II.

The HeartMate III represents a new, third-generation LVAD, after the reciprocating (pusher-plate) HeartMate I, now in full production and clinical use and the continuous axial flow HeartMate II, now in clinical trials (Fig. 1). The distinctions among the 3 generations have to do with 2 important parameters: size and longevity (Table 1).

The HeartMate I, although a relatively large device, is ideally matched in function to the natural heart and is therefore comparatively easy to adapt to the circulatory needs of the body, using the simplest of control systems (1,2). Because it includes several moving parts and conventional ball bearings, however, its estimated life in vivo is 2 to 3 years.

The HeartMate II, the smallest of all TCI blood

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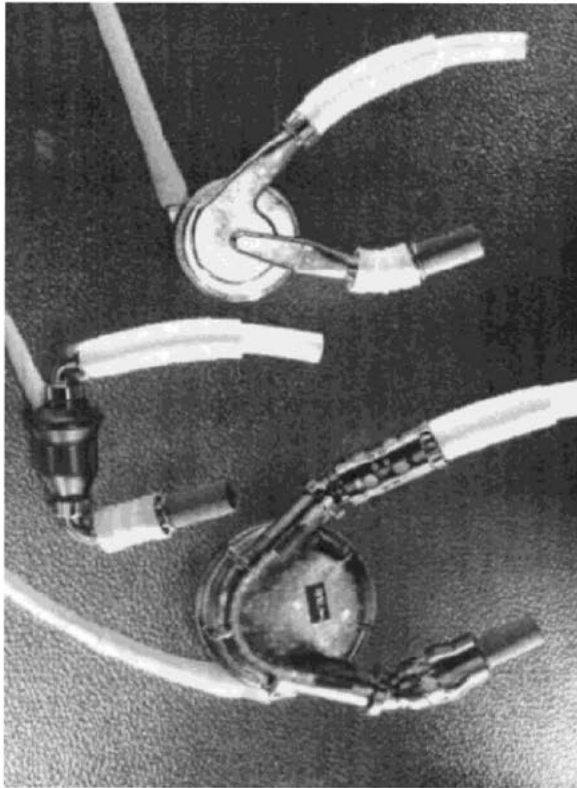


FIG. 1. A comparison of the HeartMate I, II, and III LVAD geometry (bottom to top) is shown.

pumps, incorporates a set of precision jeweled bearings and a high-speed impeller that maintain the same blood pumping capacity as the HeartMate I, but in a package approximately one-eighth its volume (3,4). It could prove invaluable in providing cardiac assistance to an entire spectrum of patients, from very young children to large adults. Animal tests suggest that our operational goal of 5 years can be met (3). Control of the pump flow is by an auto-responsive algorithm based on various motor parameters.

The ultimate service life goal for LVADs intended for alternative-to-transplant use is 10 to 15 years. This may not be feasible with mechanical, blood immersed bearings. Rotating mechanical seals are not feasible for long-term applications either. Therefore, we (5) and several other groups (6–14) are developing rotary blood pumps with magnetically levitated rotors.

The HeartMate III is the result of an intense search for a miniature low-cost blood pump design that could be used, in similar fashion to the HeartMate II, to provide cardiac assistance from childhood through old age. The HeartMate III implantable pump occupies approximately one-third the volume of the HeartMate I and just less than 3 times

the volume of the HeartMate II. Being a centrifugal pump, it is disk-shaped rather than cylindrical (as in the case of the HeartMate II) and has the appearance of a miniature HeartMate I.

MATERIALS AND METHODS

The HeartMate III LVAD is based on magnetic technology that combines drive, magnetic bearing, and pump rotor functions in a single unit (15). Three spatial degrees of freedom are stabilized passively and the remaining 3 by active control. Active control of the rotational (θ_z) and the radial (X and Y) position of the rotor is provided by feedback electronics, implemented by appropriately placed sensors. Axial position (Z) and tilting (θ_x and θ_y) are stabilized by passive magnetic forces.

Six prototype systems were built featuring an implantable titanium pump (69 mm diameter, 30 mm height) with textured blood contacting surfaces and extracorporeal electronics. An exploded view of the pump is provided in Fig. 2. The simple centrifugal pump housing is made of an upper housing containing inflow and outflow channels and a lower housing containing the motor, which are held together by a screw ring. The rotor includes a permanent magnet structure and a shrouded titanium impeller with blades of a number, size, and shape found to be most hydrodynamically efficient near the design point. A flexible cannula is fitted upstream of the pump inflow to improve anatomical fit, to decouple the pump from cardiac motion, and to provide a point for clamping and ligation for pump explant. An out-



FIG. 2. The exploded view is of the HeartMate III LVAD.

flow cannula includes a woven polyester graft for aortic anastomosis, protected from collapse by a bend-relief. Self-locking screw rings and polytetrafluorethylene washers are used at the joints between the cannulas and the pump. An electronic cable (not shown) is exteriorized percutaneously to connect to the shelf-mounted power and control electronics.

Hydrodynamic characterization of 1 pump was performed in vitro using a steady flow mock circulatory loop with water as the working fluid. The head-flow characteristic was determined from measurements using an ultrasonic flowmeter (H9XL probe, T110 meter, Transonic Systems, Ithaca, NY, U.S.A.) and 2 catheter-type pressure transducers (CDX-III, Cobe Cardiovascular, Arvada, CO, U.S.A.). The hydraulic efficiency also was determined from these measurements using additional motor torque and speed measurements performed by proprietary motor controller software. Analog outputs of the previously mentioned values were collected and analyzed using a computer data acquisition system (LabVIEW 5, National Instruments, Austin, TX, U.S.A.).

Separate in vitro studies characterized the power consumption of the bearingless motor as well as the magnetic stiffness along both active and passive axes of levitation. Instrumentation included a single phase spectral power converter (PC10, Infratek AG, Uetikon am See, Switzerland) and custom-made test fixtures.

The 6 pumps were implanted sequentially in 9 calves (≤ 100 kg at implant). The pumps were attached to the circulation in a left ventricle to descending thoracic aorta bypass, with placement in the sulcus between the diaphragm and the rib cage. The implants were done without cardiopulmonary bypass. Anticoagulation was by heparin perioperatively (activated clotting time 250 s) and then by oral Coumadin ($2.5 \leq \text{INR} \leq 4.0$) for the duration of the study. Blood chemistry, coagulation properties, and cell count were measured once or twice each week. All in vivo studies were performed in accordance with the *Guide for the Care and Use of Laboratory Animals* (NIH publication No. 86-23, Revised 1985) and the guidelines determined by the Institutional Animal Care and Use Committee of the University of Pittsburgh.

Instrumentation included a flocked, fluid-filled pressure monitoring line in the carotid artery and ultrasonic flow probes around the pump outflow graft and pulmonary artery (Models 16SB and 24A probes with Model T206 meter, Transonic Systems). In 2 animals, solid-state pressure probes were placed in the left ventricle and the pump outflow graft

(Model SPR524, Millar Instruments, Houston, TX, U.S.A.). In 5 other animals, a thermistor temperature probe (Model 08442-15 probe with Model P-08502-14 meter, Cole-Parmer Instrument Co., Vernon Hills, IL, U.S.A.) was glued to the outer surface of the pump. In 3 of these 5 animals, an identical temperature probe also was implanted in the mediastinum.

The pump was preset to run at 3,500 rpm until a flow signal was received and then gradually increased to provide a pump flow of 5 ± 1 or 6 ± 1 L/min thereafter. At approximately 30 day intervals and at the end of the study, most animals had 10 to 15 min treadmill workouts, inducing pump flows greater than 6 L/min and allowing study of the hemodynamic interactions between the pump and the native heart.

RESULTS

In vitro testing has demonstrated the desired steady-state flow and pressure characteristics (the design point 7 L/min at 135 mm Hg achieved at 4,800 rpm) and hydraulic efficiency (30% at the design

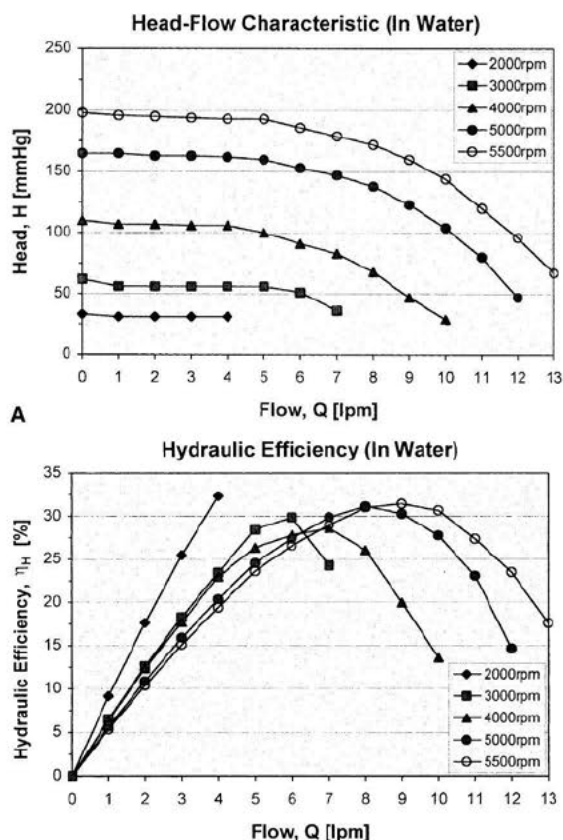


FIG. 3. The graphs show head versus flow characteristics (A) and hydraulic efficiency versus flow curves (B) for the HeartMate III LVAD.

point in water) as illustrated in Figs. 3A and 3B. The nominal maximum flow (10 L/min at 135 mm Hg) is delivered at just over 5,000 rpm when hydraulic efficiency remains in the 27% to 30% range.

The power consumption of the motor and the bearing at the design point (not including control electronics) was on average 8.1 W. In addition, the magnetic bearings can handle forces of up to 10.8 N radially and 7.9 N axially. With a rotor weight of only 34.9 g, a very robust system results.

The pumps were implanted in 9 calves as illustrated in Fig. 4 and described in Table 2. Six studies were electively terminated (at 27–61 days), 1 study was terminated after the development of untreatable pneumonia secondary to lung atelectasis (at 27 days), another study was terminated after cardiac arrest (at 2 days), and a final study is ongoing (at 100 days). Mean pump flows ranged from 2 to 7 L/min except for brief periods of exercise at 6 to 9 L/min. Plasma free hemoglobin ranged from 4 to 10 mg/dl. In appropriately instrumented animals, the pump housing exterior temperature ranged from 39.5 to 41.5°C, about 1 to 1.5°C higher than the surrounding mediastinal tissue. All measured biochemical indicators of end organ function remained within normal range. The pumps have met performance requirements in all 9 implants with no mechanical failures.

The pump linings upon explant appeared similar to HeartMate I bovine implants. Figure 5 shows the lower pump housing from a pump explanted from Study 3 after 59 days. The structured titanium surface is completely covered with a thin well-adherent biological lining. Several pumps showed small well-adherent islands of fibrous tissue within the volute and outflow port. In Study 4, in which retrograde

TABLE 1. Comparison of the HeartMate I, II, and III left ventricular assist device volumes and masses

Pump	Priming volume (ml) ^a	Displaced volume (ml) ^a	Mass (g) ^a
HeartMate I (VE)	153	511	1,050
HeartMate II	7	63	281
HeartMate III	25	168	474

^a Excluding inflow and outflow subassemblies.

flow had been deliberately induced in a brief study just prior to sacrifice, very fresh red thrombus was found under the rotor and in the volute. In the first 6 studies, rings of white thrombus partially occluded the joint between the pump and the outflow graft. After design and procedural changes, the 2 subsequent pump explants have shown no such occlusion at this joint.

DISCUSSION

A fundamental goal of the HeartMate III mechanical design was to achieve optimal pumping performance and extended life in the simplest possible way. For example, it was important to maintain an ample and straightforward flow path to minimize hemolysis and thrombus formation. Based on earlier work designing clinical LVADs, it was considered advantageous to provide textured blood contacting surfaces within the pump, a flexible inflow section, and a bend relief for the outflow graft.

Pump flows were maintained in the target range for all studies except Study 7. This animal experienced a kink in the outflow graft due to malposition of the pump flow probe. The outflow stenosis seen in the first 6 studies has been addressed with minor modifications to the outflow joint and the implant procedure, which are being tested in ongoing studies.

The performance of the textured surfaces appears favorable, and evaluation is ongoing. Fresh thrombus found in 1 pump (Study 4) under the rotor and in the volute was probably caused by stagnant flow induced in a brief study just prior to sacrifice. Plasma free hemoglobin values that did not depart from baseline in all 9 in vivo studies demonstrated that the HeartMate III hemolysis is of no clinical importance.

Thermal dissipation appears well managed. Temperature of the pump exterior was maintained less than 42°C, the accepted maximum for the device-to-tissue interface (16). This represents a temperature rise of less than 2°C.

The pumps used in the first set of animal studies had percutaneous leads that exited the pump directly beneath the outflow (visible in Fig. 4). Although this is an ideal orientation for the human configuration, it was not effective for the bovine model. In order to



FIG. 4. The photograph shows the HeartMate III LVAD ready for implant.

TABLE 2. Summary of cumulative HeartMate III left ventricular assist device in vivo study data

Implant number	Study duration (days)	Pump flow (L/min) ^a	Plasma free hemoglobin (mg/dl) ^a	Pump temperature (°C) ^a	Pump temperature rise (°C) ^a	Notes
1	40	5.3 ± 0.6	7.8 ± 1.6	—	—	Electively terminated
2	27	4.3 ± 1.1	5.8 ± 1.3	40.9 ± 0.5	—	Electively terminated
3	59	4.0 ± 0.5	5.6 ± 2.4	40.3 ± 0.5	—	Electively terminated
4	42	4.0 ± 0.6	5.3 ± 2.4	40.1 ± 0.3	1.4 ± 0.2	Electively terminated
5	27	5.7 ± 1.1	5.3 ± 4.7	40.5 ± 0.4	1.2 ± 0.3	Terminated due to pneumonia
6	49	5.4 ± 0.5	5.1 ± 1.9	40.3 ± 0.8	1.2 ± 0.4	Electively terminated
7	61	3.2 ± 1.1	6.7 ± 2.4	—	—	Electively terminated, kinked outflow graft
8	100	5.5 ± 1.5	6.6 ± 2.5	—	—	Ongoing
9	2	—	—	—	—	Terminated due to cardiac arrest

^a Mean ± SD.

exteriorize at the dorsum, the lead was forced into a half-loop in the thorax that occupied a volume normally occupied by the left lung. As a result, there was some degree of atelectasis in the first 6 animals, and 1 animal had to be sacrificed due to untreatable pneumonia secondary to atelectasis (Study 5). The orientation of the percutaneous lead was rotated by 75 degrees (visible in Fig. 1), and the problem has been averted in all subsequent animal implants.

CONCLUSIONS

The HeartMate III development effort has established the feasibility of the Sulzer bearingless motor for use in an LVAD. Ongoing in vitro studies suggest that the desired hydrodynamic design point (a mean flow of 7 L/min at a mean head of 135 mm Hg) should be achievable with a power consumption (including rotation, levitation, and control) below 10 W. In vivo studies are well under way, with 7 bovine implants of 27 to 61 days completed and another ongoing at 100 days. The pumps have met performance requirements with acceptable hemolysis and

no mechanical failures. Current design efforts are focused on a fully sealed, single-fault-tolerant implantable subsystem. In this version, the microelectronic control module is entirely contained within the titanium LVAD housing.

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FIG. 5. The interior of the HeartMate III LVAD in Study 3 at 59 days is shown.

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