

HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor

KEVIN BOURQUE,* DAVID B. GERNES,* HOWARD M. LOREE II,* J. SCOTT RICHARDSON,* VICTOR L. POIRIER,* NATALE BARLETTA,† ANDREAS FLEISCHLI,† GIAMPIERO FOIERA,† THOMAS M. GEMPP,† RETO SCHOEB, † KENNETH N. LITWAK, † TAKEHIDE AKIMOTO,‡ MARY J. WATACH,‡ AND PHILIP LITWAK‡

A long-term, compact left ventricular assist device (LVAD), the HeartMate III, has been designed and fabricated, featuring a centrifugal pump with a magnetically levitated rotor. The pump has been optimized by *in vitro* testing to achieve a design point of 7 L/min against 135 mm Hg at high hydrodynamic efficiency (30%) and to be capable of up to 10 L/min under such a load. Furthermore, the pump has demonstrated no mechanical failures, low hemolysis (4–10 mg/dl plasma free Hb), and low thrombogenicity during six (40, 27, 59, 42, 27, and 49-day) *in vivo* bovine studies. ASAIO Journal 2001; 47:401–405.

Each year in the United States, 400,000 people are diagnosed with congestive heart failure (CHF),¹ some of whom are eligible for a heart transplant (1% or so),² but many of whom are not. The prognosis of CHF patients is poor; the 5 year survival rate is approximately 50%.¹ The advent of the left ventricular-assist device (LVAD) has provided significant benefit to certain CHF patients since becoming clinically available. These devices seek to ameliorate increases in mortality due to the divergence of the increasing population of those awaiting cardiac transplant and the somewhat dwindling availability of organs.³ For example, in the United States as of June 2000, the waiting list exceeded 4,000, but only 2,185 transplants were performed in 1999.² Presently, the indications for these devices are limited to bridging those eligible for transplant and emergently sustaining perioperative patients either in cardiogenic shock or those having difficulty weaning from cardiopulmonary bypass. Such limitations are expected to change, and the number of patients that can benefit from mechanical circulatory assistance is expected to increase 10-fold or more.⁴ Clinical studies such as REMATCH (Randomized Evaluation of Mechanical Assistance for Treatment of Congestive Heart failure)⁵ and PRIDE (Patients at Risk of Imminent Death Evaluation) aim to expand the use of LVADs to a larger group of healthier patients, thereby imposing requirements for longer device lives without failure.

Since those LVADs presently clinically available (e.g., HeartMate, Thoratec Corp. (Woburn, MA) are positive displacement-type pumps, they contain mechanical parts that

wear, such as ball bearings, flexible diaphragms or sacs, and valves. Many researchers have focused their efforts on continuous flow-type pumps (e.g., HeartMate II, Thoratec Corp.) for the second generation of LVADs to exploit inherently fewer mechanical parts and many additional benefits such as smaller size and lower cost.

The HeartMate III is intended to feature the advantageous qualities of such second generation pumps, while carrying expected device life one step further: the pump has no mechanical bearings. The rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely. It is anticipated that this design will profoundly increase reliability.

Materials and Methods

The HeartMate III pump (Figures 1 and 2) comprises an *upper housing* that includes the inflow and outflow channels and the upper half of the volute; a *lower housing* that includes the lower half of the volute and a cavity for the rotor, in which the motor is enclosed; a *rotor* that includes an impeller and passively magnetic elements; an *inflow subassembly* that includes a left ventricular (LV) cannula and a section that partially decouples the position and motion of the heart from the pump and facilitates pump recovery at explant; an *outflow subassembly* that includes a graft for aortic anastomosis, protected from collapse by a bend-relief; an *electronic cable* to be exteriorized percutaneously; a *screw ring* to clamp together the upper and lower housings; and various *connecting hardware*, including self-locking screw rings that permit the inflow and outflow subassemblies to swivel with set resistance.

The mass of the HeartMate III is 475 g, including the motor (535 g, including the inflow cannula, recovery section, outflow graft, bend relief, and all connecting hardware). The diameter and height of the puck shaped portion of the pump are 69 mm and 30 mm, respectively; the inflow and outflow protrude several millimeters outside of that. The pump displaces 175 ml. All of the wetted surfaces of the pump are titanium, except for the woven polyester grafts and the PTFE washers at joints. Most of the titanium surfaces were textured in the same way as the HeartMate and HeartMate II, described in detail elsewhere.^{6,7} The textured surface is intended to promote the development of a stable, adherent pseudoneointima immediately upon contact with blood, thereby insulating subsequent blood flow from contact with nonbiologic materials and reducing the risk of thromboembolism. The one component excluded from this process was the rotor, which was fabricated with smooth, polished surfaces.

From the *Thoratec Corp., Woburn, Massachusetts; †Levitronix GmbH, Zurich, Switzerland; and ‡University of Pittsburgh, Pittsburgh, Pennsylvania.

Submitted for consideration June 2000; accepted for publication in revised form November 2000.

Reprint requests: Kevin Bourque, Thoratec Corporation, Inc., 470 Wildwood Street, Woburn, MA 01888-2697.

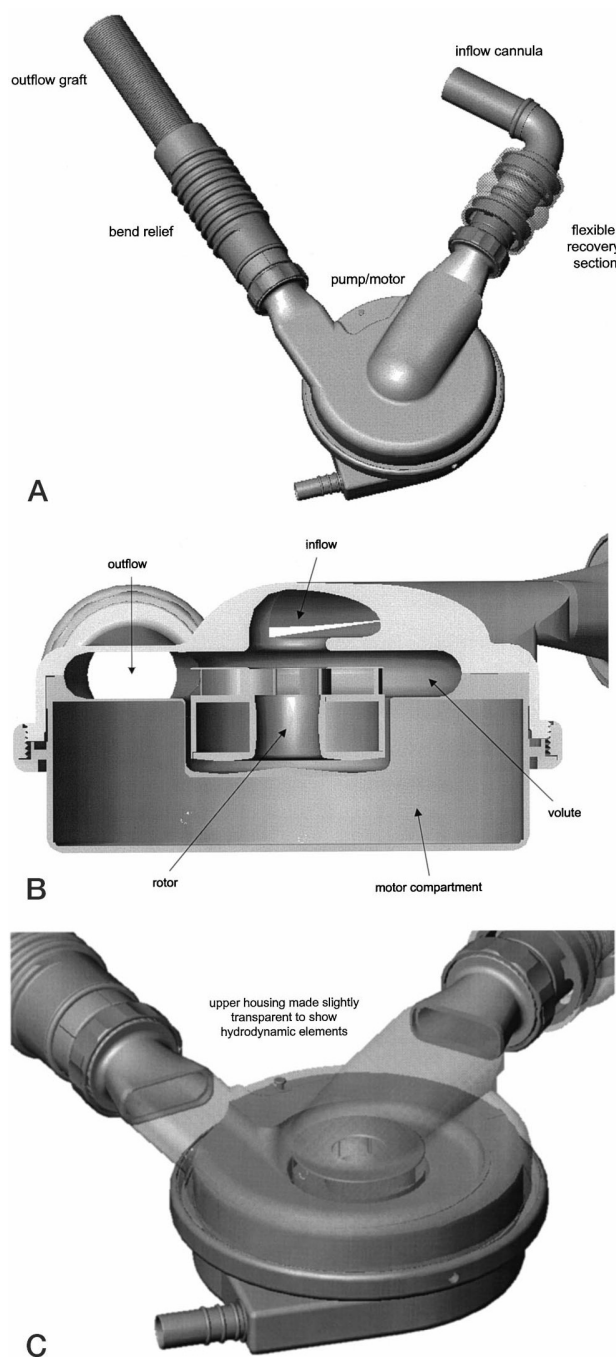


Figure 1. Solid model of the HeartMate III pump (present version). a, Overall view. b, Cross-sectional view. c, View of flow paths.

The flow path is of circular cross-section through the inflow and outflow sections. This shape was gradually flattened near the pump at both the inflow and outflow to reduce the effective pump height. To orient the pump in the least obtrusive position (*i.e.*, in the human configuration, as in **Figure 3**), it was decided that the rotational axis of the pump's rotor should be perpendicular to the body's long axis. That resulted in a sharp bend in the flow before it enters the impeller. To minimize the losses in this transition, the flow is slightly accelerated through

this elbow. The flow exits the backswept blades of the impeller into a volute of uniformly increasing width, which terminates at a cutwater, peeling off most of the flow and directing it toward the outflow.

An opening in the shroud (*i.e.*, the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades. By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the rotor. However, both of these backflows consume hydraulic power without contributing to physiologic perfusion. Thus, the clearances above and below the rotor were chosen to balance reduced hydraulic efficiency with sufficient washing of blood contacting surfaces. Backflow clearances were further constrained by the stiffness of the magnetic suspension (passive in the axial direction, actively controlled in the radial direction), which describes the levitation system's capacity to counteract imposed deviations of rotor position; the gaps permit up to $7\times$ gravitational loads in any direction without contact between the rotor and housing.

The pump components were designed to achieve the desired flow paths, accommodate the motor, and provide convenient, reliable connections in the simplest, most cost effective way. All of the components were designed using solid-modeling software (SolidWorks Corporation, Concord, MA), which was in some cases directly transferred to numerically controlled equipment for fabrication. For initial *in vitro* testing, rapid prototyping (Santin Engineering, Peabody, MA) was utilized to create inexpensive parts for testing of multiple configurations to optimize the hydrodynamic design. Implantable titanium and PTFE parts were fabricated in the United States; motors were fabricated in Switzerland. After installing the motors in the pump lower housings at Levitronix GbmH (Zurich), the pumps were assembled at Thoratec (Woburn, MA).

The HeartMate III motor includes drive and levitation in a single magnetic structure as shown in **Figure 4**. The rotor is



Figure 2. Photograph of the HeartMate III pump (version used in the first six implants).

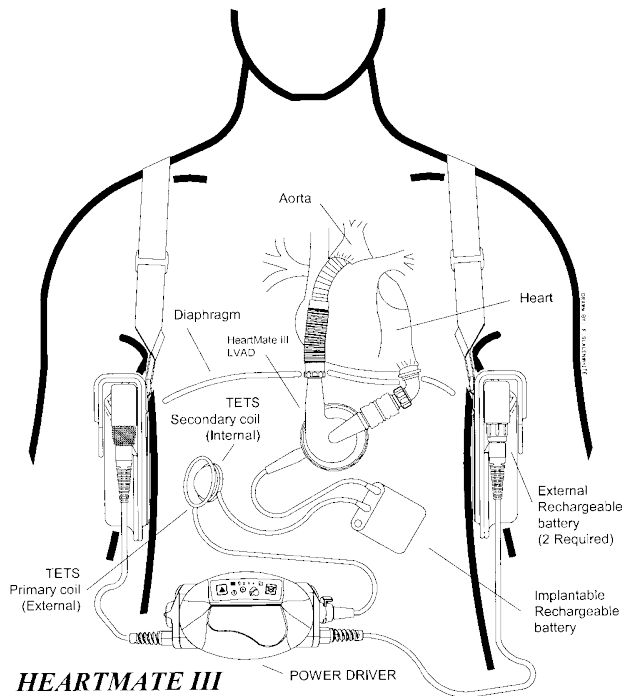


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom (**Figure 5**) and actively magnetically levitated in the remaining degrees of freedom.⁸

For *in vitro* characterization, the pump was attached to a mock physiologic laboratory flow loop. Although this loop is generally equipped to simulate vascular compliance, and can even be configured with a pulsatile pump to represent a beating ventricle, the steady-state results reported here reflect time invariant measurements recorded after changed flow conditions had settled. Tests were repeated with several working fluids, including water, a blood analog aqueous solution (40% glycerin), and whole bovine blood. Flow measurements were made with an ultrasonic flow probe (Transonic Systems, Ithaca, NY), and pressure measurements were made with solid-state, catheter-type pressure transducers (Cobe Cardiovascular, Arvada, CO). Speed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III. All measurements were automatically processed and recorded using Labview (National Instruments, Austin, TX).

For *in vivo* testing, a young bovine model (<100 kg) was used (**Figure 6**). Surgeries were performed at the University of Pittsburgh McGowan Center for Artificial Organ Development in accordance with *Guide for the Care and Use of Laboratory Animals*.⁹ The pump was implanted with routine surgical techniques via left ventricular apical cannulation and anastomosis to the descending aorta.

The electronics for power and control of the LVAD and for data acquisition resided on a shelf and alongside the cages containing the calves. The animals were continuously monitored for general welfare, and certain parameters such as

arterial pressure, pump and pulmonary artery volume flow rates, pump speed, and blood chemistry (including plasma free hemoglobin) were periodically recorded. In two animals, measurement of pressure head throughout the duration of the studies were made with flocked carotid lines and fluid filled LV catheters.

The pump was prescribed to run at 3,500 rpm perioperatively, then gradually adjusted to maintain volume flow rates at 5 ± 1 L/min throughout the study.

Necropsies were performed immediately after sacrifice. The positions of the heart, pump, and instrumentation were photographed at various stages of resection. The heart, lungs, kidneys, pancreas, liver, and adrenal glands were harvested, sectioned, photographed, and sampled for histologic examination. The pump was immediately disassembled and photographed; remarkable findings were recorded on a pump map.

Results

Three sets of parts were fabricated, from which three fully functional, implantable LVADs were assembled. All three have been implanted in calves, reused, and remain available for future implants, although a second set of three LVADs, bearing a modified exit angle for the percutaneous lead (explained below), are now being prepared for continued animal studies.

The steady-state pump pressure head *versus* volume flow rate (H-Q) characteristic is shown in **Figure 7**. Note that the design point (7 L/min at 135 mm Hg) occurs between 4,500 rpm and 5,000 rpm, which happens to be near the optimal speed for maximum motor efficiency. Furthermore, the desired maximum flow (10 L/min at 135 mm Hg) is achieved below 5,500 rpm, also at high efficiency and well below the motor's maximum capability.

The hydraulic efficiency of the pump is shown in **Figure 8**. Note that these efficiencies are ideally maximum near the design point and higher. (It is less important to be efficient at low speeds, where power consumption is lower.)

Five of six bovine calves implanted with the HeartMate III survived to their elective termination dates. No mechanical or electronic failures occurred in the six implanted pumps. The implant durations for the electively terminated animals were 40, 27, 59, 42, and 49 days. (Note that the actual lengths of studies that were nominally "30-day" or "60-day" were governed by coordinating surgical schedules.) Pump volume flow

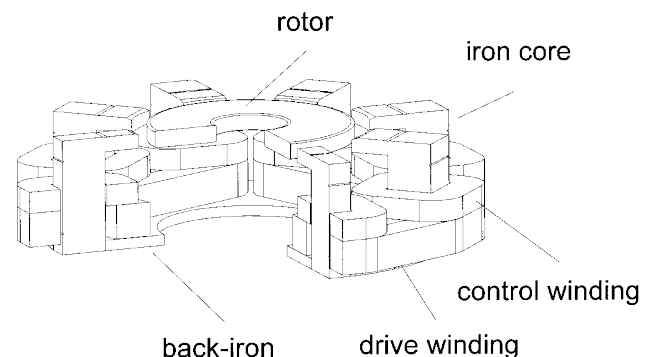


Figure 4. HeartMate III motor, drive, and levitation (control) in a single magnetic structure.

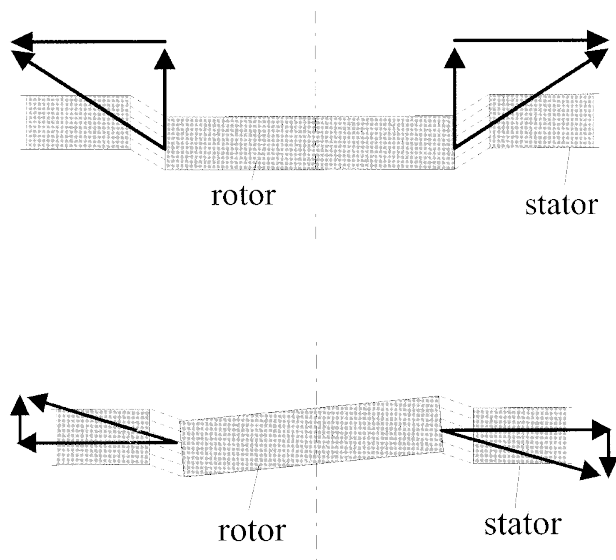


Figure 5. Passive magnetic levitation. Above, Restoration force when axially displaced. Below, Restoration force when tilted.

rates were consistently maintained between 3 L/min and 6 L/min during sedentary periods and elevated to a range of 6 L/min to 11 L/min during treadmill exercise. The implanted pumps were tolerated very well by the calves with few complications (excepting several instances of immediately postoperative, moderate bleeding, several instances of chronic pulmonary atelectasis, and one drive line infection).

One calf was sacrificed on the 27th postimplant day (earlier than the planned day 1 week later) due to severe, untreatable pneumonia secondary to left lung atelectasis. This condition was caused by the LVAD's percutaneous lead, which interfered with the expansion of the left lung.

Except for small, apparently stable and adherent islands of fibrous tissue in several of the explanted *in vivo* pumps, there was only one incidence of significant tissue deposition within the pump. This was a 4 mm thick disc of thrombus under the rotor, and a nearby, similarly sized mural thrombus in the

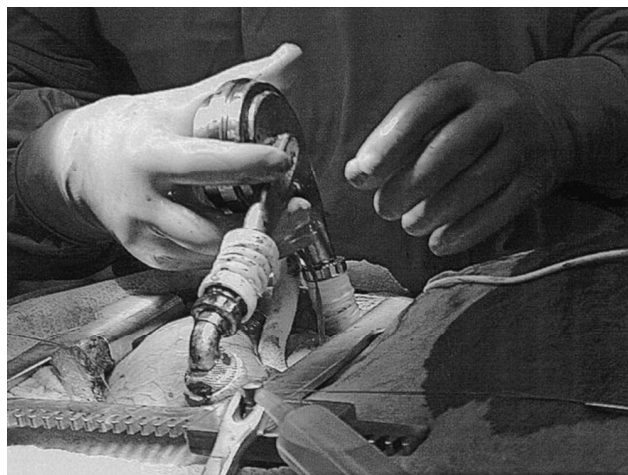


Figure 6. HeartMate III ready for placement in the thorax.

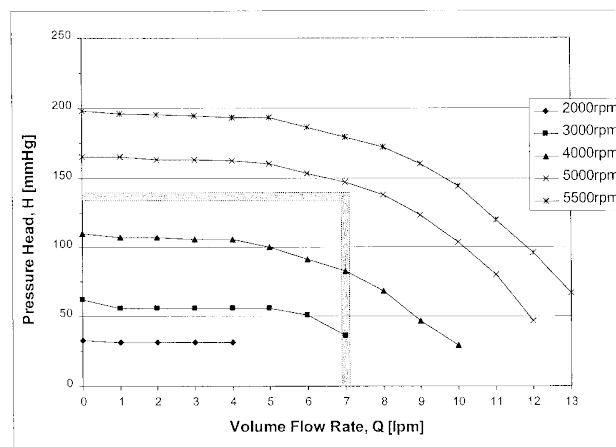


Figure 7. HeartMate III H-Q characteristic (the heavy, gray line indicates the design point).

volute, both of which appeared to be very fresh and were surmised to be a consequence of a study performed just prior to sacrifice in which flows were alternately very low and retrograde. (This was a planned exercise.) In addition, rings of white thrombus, starting at the outflow edge of the pump and extending a few millimeters toward the graft, and consequent partial outflow occlusion were observed.

In vivo plasma free hemoglobin values remained statistically indistinguishable from baseline values (4–10 mg/dl) in all six animal studies, demonstrating that whatever hemolysis was caused by the pump was of no clinical importance (Table 1).

Discussion

It was a fundamental goal of the HeartMate III mechanical design to achieve optimal pumping performance and to enclose a sophisticated motor in the simplest possible way, this being the best means of achieving immediate success (*i.e.*, early implant experience characterized by no mechanical failures). Furthermore, optimal peripheral hardware was incorporated in even the earliest versions of implantable pumps, again seeking immediate success.

The very simple main flow path is a consequence of the motor's "J" core configuration (*i.e.*, the stator laminations are J shaped), which places an imaginary plane near the mid-height of the pump, below which are confined the motor and levitation elements, and above which the hydrodynamic elements are permitted free reign. The burden was thus placed on the motor design to fit around the optimal hydrodynamic arrangement to minimize the risk of thrombogenesis, a choice that paid off with very low deposition of thrombus in the first six implants. It has already been mentioned that the fresh thrombus found in one pump under the rotor and in the volute was likely caused by stagnant flow induced in a brief study just prior to sacrifice. Outflow stenosis seen in explants has been addressed with a modification to the outflow joint, which will be tested in the next series of implants. Plasma free hemoglobin values that do not depart from baseline in all six *in vivo* studies have demonstrated that HeartMate III hemolysis is of no clinical importance.

Designing with access to the resources and infrastructure of established, FDA approved LVADs (*i.e.*, HeartMate) has afforded the wherewithal to develop the HeartMate III pump (*i.e.*, hydrodynamic elements) and peripheral hardware (*i.e.*, inflow and outflow components) concurrently, borrowing from the enormous clinical experience gained with presently available HeartMate systems. Although generally regarded as secondary in importance when setting out on a new pump design (compared to the primary purpose of “pumping”), items such as cannula, grafts, articulating mechanical joints, valves (if any), connectors, and cables can account for most of the propensity for clinical troubles when implanted. This is expected to be increasingly true as the indications for LVAD use are expanded, imposing requirements for longer implant durations.

For example, clinical experience has suggested that some freedom of movement between the native heart and pump ameliorates stresses imposed on the heart by an imperfectly placed pump, subdues unnecessary pump motion and potential tissue trauma caused by cardiac motion, and accommodates a certain amount of reverse remodeling in a convalescing cardiomyopathic patient, should such occur. Furthermore, a convenient way to retrieve an implanted pump when salvaging the native heart (*i.e.*, in a recovered patient, when a transplant is not to occur) is to have a section of flexible graft suitable for ligation available near the inflow cannula. In the HeartMate III, both of these requirements are met with a flexible “recovery section” between the pump and apical cannula (*i.e.*, in order that the pump can be removed, leaving behind the cannula).

For another example, although the high pressure in an outflow graft tends to assist patency, in certain circumstances (*e.g.*, a severe bend in the graft), there is a risk of graft collapse or kinking. To preclude that, a reinforced e-PTFE tube has been attached to surround the graft, providing bend relief and maintaining patency.

The pumps used in the first set of animal studies had percutaneous leads that exited the pump directly beneath the outflow (visible in **Figure 2**), an ideal orientation for the human configuration. However, in the calf model, to exteriorize at the dorsum, the lead was forced into a half-loop in the thorax that subsumed a volume normally occupied by the left lung. This method resulted in some degree of atelectasis in all six animals, and ultimately to the demise of one of them. The orien-

Table 1. HeartMate III *In Vivo* Study Durations and Level of Hemolysis

Implant Number	Implant Duration (days)	Plasma Free Hemoglobin (mean $\pm$ SD) [mg/dl]
1	40	7.8 $\pm$ 1.6
2	27	5.8 $\pm$ 1.3
3	59	5.6 $\pm$ 2.4
4	42	5.3 $\pm$ 2.4
5	27	5.3 $\pm$ 4.7
6	49	5.1 $\pm$ 1.9

tation of the percutaneous lead has been rotated by 75° (visible in **Figure 1**) to avert this problem in the next series of animal implants.

Other than that change to be implemented for future bovine studies, the only difference between the pump used for *in vivo* studies and the eventual human configuration is the presence of the elbow in the inflow segment, included to accommodate the bovine anatomy and presently regarded as unnecessary in humans.

Conclusion

The progress of HeartMate III from concept, through design, and into animal studies has been rapid, and the successful performance has been very encouraging. Several enhancements to HeartMate III are presently being implemented, including incorporation of motor drive and control electronics within the pump, and integration of a TETS (transcutaneous energy transmission system) to eliminate the percutaneous drive line. These enhancements will continue the progression of this LVAD's development as a compact, reliable device to treat CHF, and a viable commercial endeavor.

References

1. Data Fact Sheet. National Heart, Lung, and Blood Institute, National Institutes of Health (NHLBI-NIH), September, 1996.
2. Critical Data: U.S. Facts about Transplantation. United Network for Organ Sharing (UNOS), June 6, 2000.
3. Hosenpud JD, Bennett LE, Keck BM, Fiore B, Boucek MM, Novick RJ: The Registry of the International Society for Heart and Lung Transplantation: Fifteenth official report, 1998. *J Heart Lung Transplant* 17: 656–668, 1998.
4. Funk D: Epidemiology of end-stage heart disease. (Committee to Evaluate the Artificial Heart Program of the National Heart, Lung, and Blood Institute, The Artificial Heart: Prototypes, Policies, and Patients). National Academy Press, 1991, p. 251.
5. Rose EA, Moskowitz AJ, Packer M, *et al*: The REMATCH trial: Rationale, design, and end points. *Ann Thorac Surg* 67: 723–730, 1999.
6. Dasse KA, Chipman SD, Sherman CN, Levine AH, Frazier OH: Clinical experience with textured blood contacting surfaces in ventricular assist devices. *ASAIO J* 10: 418–425, 1987.
7. Menconi MJ, Pockwinse S, Owen TA, Dasse KA, Stein GS, Lian JB: Properties of blood-contacting surfaces of clinically implanted cardiac assist devices: Gene expression matrix composition, and ultrastructural characterization of cellular linings. *J Cell Biochem* 57: 557–573, 1995.
8. Schoeb R, Barletta N: Principle and application of a bearingless slice motor. *Int Symposium on Magnetic Bearings*. 40: 593–598, 1997.
9. *Guide for the Care and Use of Laboratory Animals*. National Academy Press (ISBN 0309053773), August, 1997.

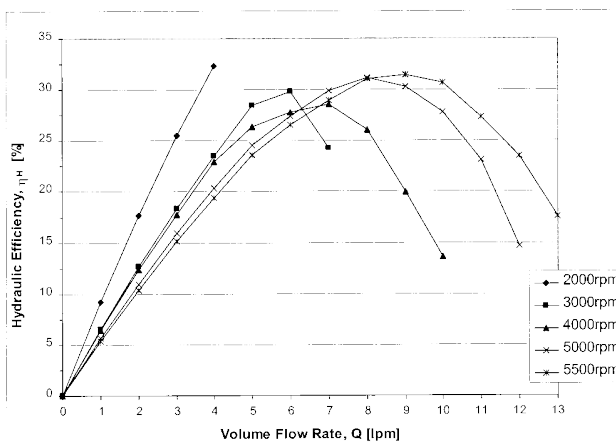


Figure 8. HeartMate III hydraulic efficiency.