

HeartMate II Left Ventricular Assist System: From Concept to First Clinical Use

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The HeartMate II left ventricular assist device (LVAD) (ThermoCardiosystems, Inc, Woburn, MA) has evolved from 1991 when a partnership was struck between the McGowan Center of the University of Pittsburgh and Nimbus Company. Early iterations were conceptually based on axial-flow mini-pumps (Hemopump) and began with purge bearings. As the project developed, so did the understanding of new bearings, computational fluid design and flow visualization, and speed control algorithms. The acquisition of Nimbus by ThermoCardiosys-

tems, Inc (TCI) sped developments of cannulas, controller, and power/monitor units. The system has been successfully tested in more than 40 calves since 1997 and the first human implant occurred in July 2000. Multicenter safety and feasibility trials are planned for Europe and soon thereafter a trial will be started in the United States to test 6-month survival in end-stage heart failure.

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The HeartMate II left ventricular assist device project began in 1991 with a research partnership between the Nimbus Company and the University of Pittsburgh's McGowan Center for Organ Engineering. At that time the Nimbus Company had proved the feasibility of small axial-flow rotary pumps with the successful introduction of Richard Wampler's hemopump [1]. Together we saw the wisdom of combining efforts to explore the possibilities for similar technology to improve upon the pneumatic and electrical pulsatile pumps in clinical trials. We saw size, implantability (no compliance chamber), and power efficiency as the primary advantages to a rotary blood pump [2, 3]. By 1992 we had demonstrated in vivo that our axial-flow pump could generate flows of 10 L/min at physiologic pressures, operate for 90 days, and caused minimal (3-6 g hemoglobin/day) RBC trauma. Two calves and 5 sheep received implants for up to 14 days.

Albeit bristling with plans and capability, the team was underfunded and survived through a series of four National Institutes of Health-Small Business Innovative Research grants [4]. Our bearing design evolved from the purge system inherited from the original hemopump to journal bearings to the current ball-and-socket hydrodynamic composite design. In 1997 we were awarded a share (4.8 million dollars) of the National Heart Lung and Blood Institute innovative ventricular assist program [5] inspired by John Watson [6-16]. That funding and focus permitted rapid advances in development of a clinically

qualifying pump. Since 1997 the pump has functioned well in calves at the McGowan Center. Since then, we have implanted the pump in 51 animals for an average study duration of 47 ± 49 days. The longest duration was 226 days, with 75% completing a 120-day⁺ protocol; 74% of 23 completed the 30-59-day protocol. In 1998, the Nimbus Company was acquired by ThermoCardiosystems, Inc (TCI), and the project was accelerated because of the latter's broad-based engineering capabilities and hard-earned experience with the development and commercialization of the HeartMate ventricular assist device. Much of the effort in the last 18 months has been expanded on the peripherals, including system driver and monitor, power base unit, batteries, and electrical connectors. Although the origins of a sensorless speed control began with work sponsored earlier, iterations were tested [17]. An automatic speed control based on pulsatility is now integrated into the system driver microprocessor. More than 2 years later now we can speak of the axial-flow pump that has morphed into the HeartMate II, and of its readiness for clinical trial.

On July 27, 2000, the McGowan team assisted Jacob Lavee, a previous trainee at the University of Pittsburgh, in its first human implantation at the Sheba Medical Center in Israel. Currently TCI is planning a four-center European plus Sheba/Israel performance and safety trial, and the company expects to begin a multicenter study in the United States by early 2001 to test the 6-month survival benefit for end-stage heart failure.

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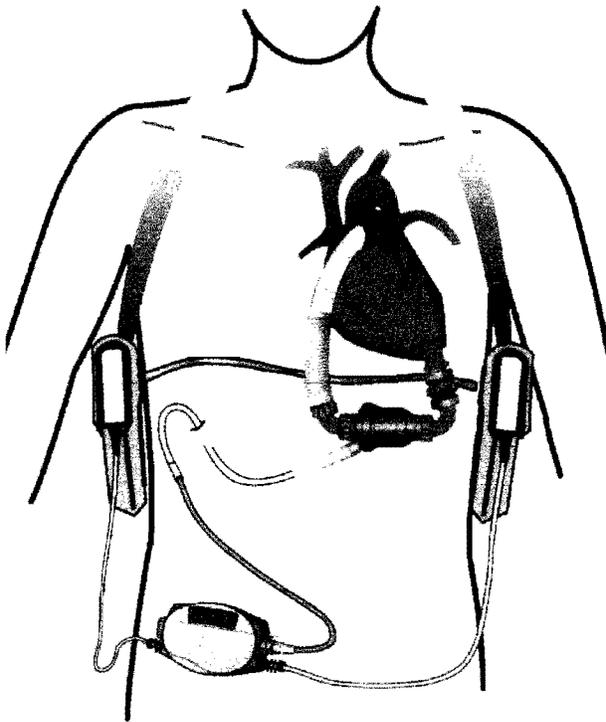


Fig 1. Battery-powered HeartMate II LVAD System.

Description of HeartMate II Left Ventricular Assist Device

The HeartMate II left ventricular assist device (LVAD) is an axial-flow rotary ventricular assist device composed of a blood pump, percutaneous lead, external power source, and system driver. It is attached between the apex of the left ventricle and the ascending aorta. It is designed for long-term use and is not targeted as a bridge to transplant. The system can be configured for battery power or tethered to an AC-supplied power base and monitor unit (Fig 1).

The pump, which is cradled between the inlet and outlet elbow connectors, lies parallel to the diaphragm and may be placed within the muscles of the abdominal wall or preperitoneally (Fig 2). The small, 124-mL LVAD greatly reduces the amount of dissection required to create a nesting pocket. The pump has only one moving part, the rotor that spins on inlet and outlet ball-and-cup bearings. The motor is contained in the pump housing and creates a spinning magnetic field that spins the rotor and imports torque to its internal cylindrical magnet. Blood flows from the inlet cannula into the 12-mm titanium pump blood path, past three neutral airfoil-shaped guide vanes. In addition to providing support for the inlet stator, the vanes straighten the flow as the blood is picked up by the rotor. Three curving blades on the spinning rotor supply kinetic energy by imparting a radial velocity to the flow field that is passed on to the outlet stator vanes. These, unlike their inlet counterparts, are of a twisted shape designed to convert the radial velocity to the axial direction. As the flow is being turned,

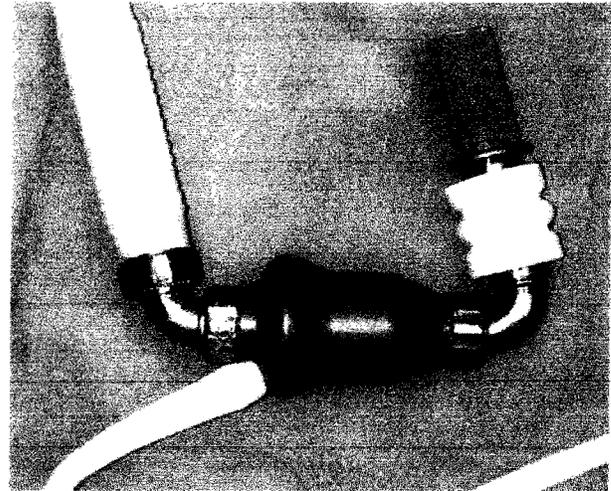


Fig 2. HeartMate II axial flow pump with inlet (right) and outlet (left) conduits.

the exit hub narrows, diffusing the flow and converting kinetic energy to static pressure. The end result is the production of a flow field that increases pressure across the pump. We used computational fluid dynamics to mathematically predict fluid flow through the pump [18] and visualized macroscopic patterns by laser flow visualization (Fig 3). The latter did not show the computational fluid dynamics-predicted micro-vortices about the stator blades that we believe relate to the excellent washing of this area observed *in vivo*.

The inlet and outlet cannulas are made of woven Dacron (C.R. Bard, Haverhill, PA) and require preclotting. Special attention has been paid to the inlet cannula

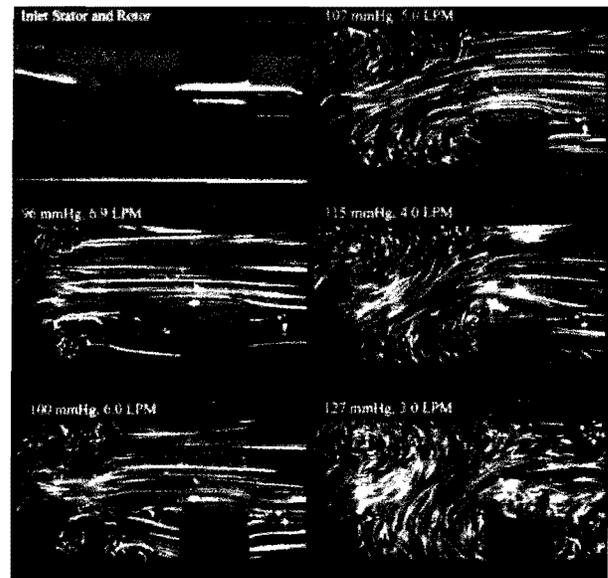


Fig 3. Flow visualization study of HeartMate II; area of inlet stator and rotor are seen with various pressure-flow conditions. Note variation in flow pattern. The micro-vortices predicted by CFD were not apparent. (LPM = liters per minute).

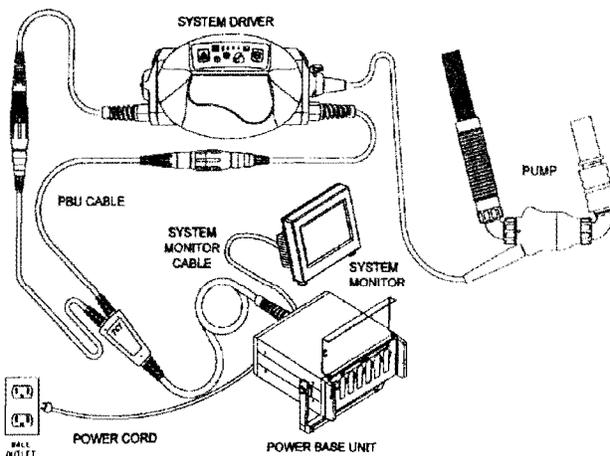


Fig 4. HeartMate II LVAD System in tethered configuration includes an AC power source and power base unit that recharges the batteries, powers the system driver, and supports the monitor screen. (PBU = power base unit.)

so that it is very flexible just before its union by screwing to a titanium 90-degree elbow joining the pump. The flexible portion is made of woven Dacron compressed accordion-like in ridges. The intraventricular portion has evolved to be longer than earlier prototypes and has tended to stent open the mid left ventricular cavity. Such stenting has improved reliability of continuous flow throughout cardiac systole and diastole and at varied levels of preload. The flexible portion of the inlet cannula was added to reduce the risk of malalignment of the long intraventricular portion, which had caused septal erosions when tested in earlier rigid models. The current inlet cannula permits the intraventricular portion to "float" untorqued by the pump within the chamber. The outflow graft is made entirely of woven Dacron and is sheathed by a polypropylene "bend relief." The end of the outflow graft is sutured to the side of the ascending aorta and, similar to the inflow graft, is screw-connected to the pump by a rigid elbow.

The pump rotor and associated pump blood tube are smooth titanium surfaces; but, attempting to duplicate the excellent biocompatibility of the original pulsatile HeartMate, the stators, inlet and outlet elbows, and intraventricular cannula are textured with titanium microsphere coatings. The Dacron portions of the inlet and outlet cannulas are rough flocked surfaces. This combination of rough and smooth surfaces is unique and is believed to be an advantage. Areas where flow visualization studies have shown low velocity and where connective crevices exist are rough, whereas the high-speed rotor and its blood tube are smooth. Currently the planned anticoagulant regimen includes aspirin, dipyridamole, and low-dose warfarin (International Reference Unit 1.5 to 2.5).

The system driver sends power and operating signals to the pump and receives information from the pump. The driver is wearable and is powered either by the power base unit (Fig 4) or by one or two 12-volt recharge-

able batteries (Fig 5) that will provide power for 2 to 4 hours under normal operating conditions. The system monitor communicates to the system driver and pump through the power base unit and is made up of clinical and system check screens.

Pressure Flow Characteristics

The hydrodynamic performance of continuous flow pumps is determined primarily by speed of the rotor and by the pressure difference that exists across the pump. Basically flow varies inversely with pressure. A family of flow-pressure relationships at varied rates of rotor speed defines H-Q pressure-flow curves. These identifying fingerprints of the pump are generated in a mock loop by measuring the pressure difference between inlet and outlet, and the rate of flow as the outflow resistance is gradually increased to a point of pump shut-off (Q equals zero) (Fig 6). Unlike rates of flow in pulsatile devices that are easily evaluated in pusher-plate pumps, these pressure flow characteristics of continuous flow pumps require a rethinking in terms of clinical management and interpretation of pump performance. At any time during the cardiac cycle the pump differential pressure will equal aortic pressure minus left ventricular pressure plus a combined pressure loss across the inlet and outlet cannulas. Because of a nonocclusive system, the HeartMate II must continue a sufficiently high pump speed to avoid pressure differentials that fall below normal expected aortic pressures and result in reverse flow. Another most important feature of the HeartMate II pump and continuous flow pumps in general is that, unlike pulsatile pusher-plate type pumps, the rotary pump can generate large negative pressures within the inlet conduit. This can occur when there is some obstruction to inflow or when the filling conditions of the left ventricular chamber are below the threshold need for the pump at any given speed. The most common cause of obstruction that we have encountered in the studies on calves has been for malalignment of the intraventricular portion of the inlet conduit. The left ventricular septal wall in

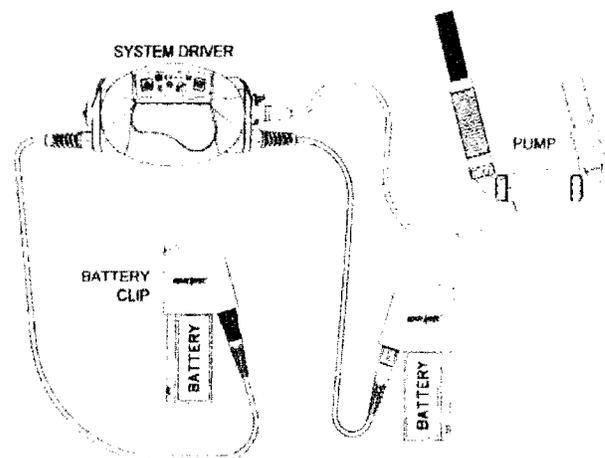


Fig 5. HeartMate II is shown in the untethered configuration, powered by portable batteries.

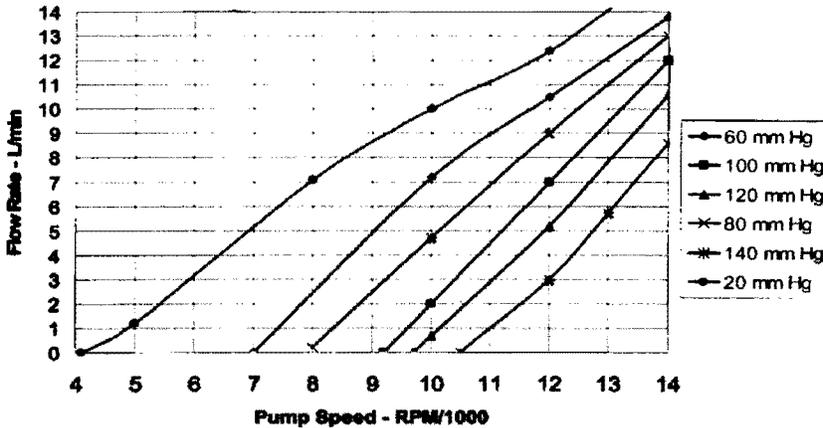


Fig 6. Pressure-flow relationship for HeartMate II axial flow pump ΔP is measured from inlet and outlet cannulas. (RPM = revolutions per minute.)

essence folds over the apical tube and the pump continues to turn and to create negative inlet pressure; much of the iterative change in the length of that tube has been a result of attempting to minimize this potential effect.

Pump Motor Characteristics

The HeartMate II motor is commutated using electromagnetic field sensing that maintains pump speed independent of rotor torque. This results in a linear current-pump flow relationship. Using this combined with the pressure-flow relationship, the pump flow and pressure inlet-to-outlet differences can be inferred. This relationship between pump speed and motor current has been used in the HeartMate II LVAD to formulate an algorithm for prediction of flow. The predicted flow values are also used to define relative levels of "flow pulse" delivered during the systolic-diastolic phases of the cardiac cycle. This forms the basis of the unique HeartMate III automatic speed control.

Speed Control—Manual Mode

The HeartMate II has a manual speed control that can be accessed only by a technical operator and that is for use intraoperatively and perioperatively. During this period of fluid shifts and physiologic adjustments, we have learned that slow rates corresponding to lower flow more reliably maintain left heart preload and prevent sudden and dramatic negative left atrial and ventricular pressures. We recommend operating in the safe margins of the H-Q curves and have been most successful at rates of 8,000 to 9,000 revolutions per minute with pressure differentials of 80 to 100 mm Hg and flows of 3 to 4 L/min.

Speed Control—Auto Mode

The system driver is usually set in the auto mode. This unique control algorithm is drawn from the previously described H-Q-I interrelationship. The pump's rotational speed is managed to maintain a prescribed pulsatility during the cardiac cycle. Maximum flow will occur during ventricular systole when the inlet-to-outlet pressure

differential is the least, and minimum flow will occur during left ventricular diastolic filling when the inlet pressures are lower and the ΔP greater. A pulsatility index (PI) has been defined as $Q_{\max} - Q_{\min} / Q_{\text{avg}}$, where Q average is the average flow during the cardiac cycle. In essence, PI is a measure of the size of flow pulse generated by the pump during the cardiac cycle. Those patients with very poor left ventricles would have minimal pulsatility and $Q_{\max} - Q_{\min} = 0$. The same low PI would be possible for a more functional left ventricle if the pump speed were excessive and the ventricle driven to collapse (speed excessive for preload). The PI index generally is set between 0.3 and 1.0 to ensure safe but responsive auto control.

Comment

The Heart-Mate II LVAD is a sophisticated system that we believe provides the potential for long-term therapy. The challenge of producing a high-speed rotary pump without creating shear injury to the formed elements of the blood has been overcome. The composite ceramic-aluminum oxide (ruby) ball-and-socket bearings have performed well without evidence of sudden obstruction or wear from axial and radial forces. The size of the pump permits its use in a broad patient population, and its electrical efficiency is advantageous relative to prolonged battery-powered use. The unique system of auto control tested well in the laboratory and in healthy calves is promising but will require human trials to evaluate its impact. The value of a sensorless auto speed control is considerable and perhaps the most distinguishing feature of the HeartMate II. We are anxious to increase our clinical experience with relatively pulseless perfusion, but we are confident that this next generation is a step toward reliable mechanical treatment of end-stage heart failure. The unusual collaborative relationship that the surgeons and scientists of the McGowan Center have shared with our corporate partners has clearly paid enormous dividends to the project and to everyone's education in this complex area.

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