The LionHeart LVD-2000: A Completely Implanted Left Ventricular Assist Device for Chronic Circulatory Support

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Management of patients with end-stage cardiac disease remains a vexing problem. Limitations in medical management and a fixed supply of donor organs for cardiac transplant have a continued impact on this growing population of patients. Mechanical circulatory support has proved very successful as a means of bridging patients to cardiac transplant when all medical options have been exhausted. The development of a chronic system of circulatory support has been underway at the Pennsylvania State University for nearly 30 years. These efforts have been recently merged with the industrial partnership with Arrow International toward the development of the LionHeart LVD-2000 (Arrow International, Reading, PA) completely implanted left ventricular support system. We present an overview of the system, details of implantation, a review of preclinical studies, and a synopsis of the first European implants. Early results have demonstrated the system to be safe, effective, and reliable. Transcutaneous energy transmission and the compliance chamber have been validated.

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The bridge-to-transplant experience has been a valuable clinical endeavor. However, neither this continued experience nor heart transplantation can address the public health issue of end-stage congestive heart failure. Three to four million Americans are diagnosed with heart failure, with 400,000 new cases each year. These patients represent only a portion of the worldwide scope of this disease. As opposed to other cardiovascular diseases, the incidence and prevalence are increasing. As the majority of patients with heart failure are older than 65 years, and as the population in the United States is aging, based solely on aging the number of heart failure patients is expected to double by the third decade of the 21st century. Despite recent advances in the management of heart failure, the survival and quality of life remain unacceptably poor. Heart transplant may improve the survival, functional capacity, and quality of life of patients with end-stage heart failure, but the limited donor pool will not fulfill the need for acceptable candidates. Furthermore, the much larger group of patients who are not transplant candidates because of comorbidities or age are left with few therapeutic options as medical management becomes ineffective. The positive clinical bridge experience with mechanical circulatory support has led to the concept of permanent support or destination therapy, which holds promise for this large group of patients.

The Arrow LionHeart LVD 2000 left ventricular assist device (LVAD) (Arrow International, Reading, PA) is the first system to undergo clinical testing as a device exclusively designed as means of destination support. We describe the device, implant technique, in vitro and in vivo preclinical testing, and a brief summary of the first clinical implants that have been undertaken.

Device Description

Implanted Components

The LionHeart LVD 2000 LVAD is comprised of multiple implanted components including the blood pump with inlet and outlet cannula assemblies, motor controller, compliance chamber, and transcutaneous energy transmission system (TETS), as depicted in Figure 1. These components are implanted such that there is no need for percutaneous lines or connectors, which are a constant portal for infection. A titanium case encloses the blood pump components including motor, blood sac and inlet/outlet valves. The
pump is driven by a direct current, brushless motor that actuates a roller screw and attached pusher plate. Linear motion of the screw results in reciprocating compression of the blood sac against the case, via the attached pusher plate. Hall effect sensors are mounted within the assembly and allow continuous monitoring of the pusher plate position by the system controller. There is no bond between the blood sac and the pusher plate, which ensures passive filling of the pump during diastole. Unidirectional blood flow is maintained via two Delrin disk monostrut valves (27-mm inlet; 25-mm outlet). Blood enters the pump via an inlet cannula, which is attached at the left ventricular apex. The outlet cannula is comprised of a bonded Hemashield graft (Boston Scientific, Watertown, MA), attached as an end-to-side anastomosis to the ascending aorta. Maximum pump outflow is approximately 8 L/min with a dynamic stroke volume of 64mL.

The system controller is housed within a titanium case with a set of rechargeable batteries, which provide an emergency power supply and allow uncoupling of the external power supply for approximately 20 minutes at a time. The controller regulates power from the external power supply and provides motor control and telemetry. The control system is dependent on continual monitoring of end-diastolic volume, which is estimated by motor speed and voltage requirements. Thus, the patient's physiologic demands have an impact on the filling volume of the pump. Pumping characteristics are subsequently adjusted to ensure complete filling of the pump, which is achieved by altering pump speed. An ongoing history of support characteristics is recorded and may be intermittently accessed by using the telemetry module that is included as part of the control system.

Percutaneous energy delivery has been replaced by a transcutaneous energy transmission system. External DC power is converted to an alternating current, which, by induction coupling, allows transcutaneous transmission of energy to an implanted secondary coil. This energy source is subsequently rectified to a DC that, in turn, drives the motor and its associated electronic hardware. Continuous operation of this completely implanted system under different patient and environmental conditions is achieved by coupling the system with a gas-filled compliance chamber. The compliance chamber consists of a circular polymer sac and an attached subcutaneous port infusion system. Intermittent monitoring of system pressures via the infusion port allows introduction or removal of air from the system, which is accomplished through this same port. It is recognized that gas will diffuse through the polymer and therefore require “recharging” at approximately 1-month intervals.

The LionHeart LVD 2000 implanted system has been designed as a modular assembly to allow replacement of individual components, without need for complete replacement of the system, in the event of a component failure or internal battery end of life.

External Components

The external components include the power pack, power transmitter, charger with battery packs, telemetry wand and system monitor, and various power supply options (Fig 2). These components ensure safe, continuous operation of the pump with enough flexibility to allow patients to return to a normalized lifestyle after discharge from the hospital.

The power pack provides DC to the power transmitter from a variety of sources. The standard power supply would consist of a lightweight unit that allows direct

![Fig 1. Components of the LionHeart LVS-2000 including the motor controller, pump assembly, and compliance chamber.](image1)

![Fig 2. Communication and diagnostic evaluation are provided by the system monitor and attached telemetry wand.](image2)
conversion of “wall power” to an applicable DC source. Alternatively, rechargeable batteries may be coupled with the power pack to allow portability for the patient, providing a return to reasonable daily activities. Furthermore, a power supply has been developed for conversion of vehicular power (12-volt DC), thus allowing convenient transportation for the patient. Additional equipment includes a battery charger, telemetry wand with antenna for communication with the controller, and the system monitor for interpreting transmitted data. A modem exists in the system monitor allowing for “real time” transtelephonic transmission of system data. The external power coil is secured over the secondary coil with a belt, which has an additional pocket for carrying the power transmitter. The coil can also be held in place with a special atraumatic skin tape adhesive, as depicted in Figure 3. Thus patients may be completely uncoupled for short periods of time (such as when showering) by using the internal back-up batteries, and the remainder of the day may tailor the type of power supply to their needs.

Implantation Technique

The surgical technique, which has been developed for the LionHeart LVD-2000, is designed to facilitate the training of surgeons and operating room staff to ensure a structured and reproducible set of steps at each device implant.

Device preparation is quite limited and may proceed concurrently with anesthetic preparation of the patient. Each component required at implant is distributed in an individually labeled sterile pouch. The packets should be inventoried and subsequently opened in a systematic fashion to allow quick access to components as they are needed. The pump is filled with a heparinized 5% albumin solution for at least 15 minutes before implant to ensure adequate time for development of a passive protein coat over the blood contacting surfaces. The electrical conduit of the pump is capped, and the vent port to protect the inside of the pump assembly from fluids and other foreign materials at implant. The motor controller and compliance chamber are similarly prepared with protective caps over connectors, and the internal batteries are charged before the planned implant.

Patient preparation including anesthetic management mirrors that for standard open heart procedures, with the addition of transesophageal echocardiography. Aprotinin administration should be tailored to the patient’s history of prior exposure. Care must be taken to ensure that the operative preparation widely includes the chest and abdomen. An extended median sternotomy is fashioned, with the incision extended to the umbilicus and the left pleural space opened widely anterior to the pericardium. A pericardial well is developed to allow urgent cannulation for cardiopulmonary bypass if the patient’s hemodynamics deteriorate during ongoing implant preparation. All efforts should be made to complete the remaining dissection before systemic heparinization to minimize the potential for significant bleeding. A subcutaneous or submuscular pocket is developed in the right lower quadrant, as dictated by patient size, through the midline incision. An additional incision is developed over the right chest wall for the internal TETS coil. The internal coil position requires that the overlying external coil will lie flat against the chest wall, does not lie over the patient’s nipple, and that the interposing tissue between the coils does not exceed 1 cm in thickness. The internal coil is secured in place by anchoring sutures. The final position of the implanted system is depicted in Figure 4.

The pocket for the pump is developed by exposing the left posterior rectus sheath lateral to the linea alba in a paramedian fashion through the midline incision. This dissection is continued laterally to develop a pocket that will accommodate the pump between the posterior sheath and the rectus muscle. It is critical that this incision be large enough and extended to a lateral position such that the pump can be seated without significant kinks or twists of the inlet cannula. A tunneling device is provided to create tunnels between the components for passage of the intervening conduits. The inlet cannula is secured to the blue inlet port (direction of flow through the pump is marked by arrows). The cannula is secured in place by a collet and nut after ensuring appropriate orientation of the cannula. Loosening of the collet during operation of the pump is prevented by the integral locking tab.

Cardiopulmonary bypass is initiated after systemic heparin is administered, and the patient is maintained at normothermia throughout the procedure. The apical cannulation site is identified, usually just anterior to the apex; interrupted double-armed, 2-0 pledgeted, nonabsorbable sutures are placed circumferentially to create a circle approximately 3 to 4 cm in diameter around the apex. A coring punch is used after a stab incision through the apex at the center of this circle. The ventricular cavity is carefully inspected and cleared of mural thrombus or muscular debris, and the apical cuff is grasped with the included holder and secured in place with the previously placed anchoring sutures. This inlet cannula is subsequently brought through a 3-cm incision in the dia-
phragm so its distal end lies in proximity to the planned position of the inlet cannula. The pump assembly is positioned in its pocket. The apical cuff is coupled to the inlet cannula with the apical cuff clamp after ensuring that no twists or kinks are created with this connection, and the inlet cannula tip is aligned along the major axis of the left ventricle. Continuous deairing and venting may then proceed by cutting the end of the pump outlet cap and securing a cardiotomy suction to this cap (Fig 5).

The outlet cannula graft is sized and cut. It should allow end-to-side anastomosis to the ascending aorta and, if possible, protective positioning off the midline of the sternum. A partial occlusion aortic clamp is placed along the lateral wall of the ascending aorta and an anastomosis fashioned with a 4-0 polypropylene suture. This may be buttressed with felt or pericardial strips. The graft is slowly deaired by partial removal of the clamp, which is subsequently replaced by a soft vascular clamp just above the anastomosis. The graft is repositioned in proximity to the pump assembly. Careful deairing and subsequent attachment of the outflow graft ensues, once again using the collet assembly and integral locking tab. The electrical conduit of the pump assembly is tunneled to the controller and remaining connections secured among the internal coil, controller, and pump. The external coil is secured in place with a single loop suture. The internal batteries are inactivated, which may be accomplished immediately by simply uncoupling the TETS coils, to allow rapid cessation of pumping if the pump entrains air. Deairing is completed by an 18-gauge needle placed into the outflow cannula. Pumping is subsequently initiated, after placing the telemetry wand over the controller, with the start-up mode. System telemetry displays hemodynamic parameters, as illustrated in Figure 6. Ventricular decompression and retained air is monitored by transesophageal echocardiography, and the patient is slowly weaned from cardiopulmonary bypass with a concurrent steady increase in pump rate.

When stable pumping has been established, the compliance chamber assembly is placed in the left pleural space, and the compliance chamber conduit is tunneled to the pump assembly and subsequently connected. The access port is placed in a stable subcutaneous pocket along the left chest, and its tubing tunneled through the chest wall and secured to the port. Adjustments are made with a Huber tip needle to ensure that the compliance chamber walls are parallel before completion of the implant. Protamine is administered, drains placed, and the incisions closed in a standard layered fashion. The internal batteries are enabled, external coil secured with interrupted loop sutures, and the patient transferred to the intensive care unit, whereupon the compliance chamber is once again evaluated. Postoperative chest and abdominal radiographs are obtained to confirm component positioning (Fig 7).

Fig 4. Components of the LionHeart LVS-2000 are shown as they would appear in the implant position.

Fig 5. Pump deairing and venting is facilitated by securing cardiotomy suction to the pump assembly outlet cap.
Preclinical In Vitro and In Vivo Studies

An extensive process of preclinical testing was undertaken to prove the system safe and reliable before initiating clinical trials. Studies were divided into in vitro and in vivo testing to ensure a complete evaluation of the system. Early studies comprised the research and development phase of this testing, which provided information used to analyze and rectify problems identified, which subsequently could be reevaluated with further testing. Completion of this phase of study provided a working system, which subsequently was subjected to further testing directed at assessing the reliability of the system for clinical use.

In Vitro Testing

Physiologic conditions are simulated in circuits that have been designed to test these devices over extended time intervals. Conditions may be maintained as constant or varied, and rheologic data and pump parameters are monitored continually. There were eight devices during the initial period of testing, and the failures identified resulted in modifications of several components. System performance testing began in January 1998 and 12 systems have undergone continuous testing. A total of 5,200 days of support were accrued by June 2000, ranging from 105 to 892 days for the individual systems. Six of the systems continue to be tested at this time. Summary data from these devices continue to be accrued for regulatory as well as long-term reliability evaluation. Initial assessments suggest that the blood pumps and controllers will operate reliably for the first year, although continued evaluation of ongoing systems will be required before statistical reliability conclusions about longer intervals can be determined.

In Vivo Testing

Animal studies in Holstein calves were approached in a fashion similar to in vitro testing, with the initial implants comprising the research and development phase. The subsequent study animals were used to assess preclinical in vivo reliability. All animals received humane care in accordance with the “Guide for the Care and Use of Laboratory Animals” published by the National Institutes of Health (NIH publication 85-23, revised 1985).

Ten animals underwent implant of the system during the research and development phase of testing. The support period ranged from 0 to 90 days. Three studies were terminated electively at completion of the preplanned duration of support. One animal succumbed to a systemic infection within 13 days of implant, and the remaining studies were terminated early because of various device failures. Each of these problems was subsequently addressed before initiation of the second phase of animal testing.

The preclinical, system reliability phase comprised 13 animal implants that were undertaken between April 1998 and July 1999. The design of this study was for an intended support period of 30 (2 calves) and 90 (11 calves) days. Nine of the animals (2 for 30-day studies, and 7 for 90-day studies) were supported for the duration of the predetermined period and were electively terminated. The remaining animals were terminated early. Calves 10 and 12 had system failures consisting of a controller failure and cable failure, respectively, each of which resulted in system changes. Significant congenital ventricular hypertrophy resulting in impaired inflow to the pump in calf 4, and skin erosion around the energy converter in calf 6 resulted in early termination of these studies.
animals. The support periods for these animals are summarized in Figure 8. The early in vivo studies resulted in changes to the system, which have proved durable in the ensuing animal implants. Ultimately, the preclinical phase implants demonstrated that the external components were able to withstand normal daily activities, and that implanted systems were reliable for the 3 months that constituted the duration of this study. Laboratory parameters were normal except for mild, expected postoperative anemia. Growth and development were normal, and there were no clinically apparent thromboembolic events or evidence of hemolysis. Autopsy studies did reveal evidence of minor renal infarcts in 7 of the 13 animals, and these were most pronounced in the animals that were exposed to extended periods of low flow. These renal findings have been correlated with subclinical evidence of thromboembolic events in the bovine model and were also found in the preclinical trials for the Pierce-Donachy pumps.

Summary of Implants

A European study is now underway, with five centers currently identified to enroll patients. The first patient treated underwent device implant October 26, 1999, at Bad Oyenhausen in Germany. Five additional patients have undergone device implant, with 3 additional patients at Bad Oyenhausen and a single patient each at La Patie in Paris and in Vienna, respectively. The mean age of these patients is 64.2 ± 8.6 years. These patients all had significantly depressed cardiac function, the majority were on inotropes at time of implant, and each had been excluded from consideration for cardiac transplant because of age or comorbid conditions. The first patient to undergo implant of the LionHeart LVD-2000 is 1 of 2 patients currently receiving ongoing support at home. There have been no system failures among this original group of patients and no device-related deaths. One power pack sustained minor damage after being dropped, but remained fully functional. However, a single battery proved unusable after it was dropped. Obviously this limited clinical experience precludes meaningful analysis of adverse events.

Each of these centers continues to evaluate potential recipients for the European arm of this study; and the next planned implants include the fifth patient in Bad Oyenhausen and the first in Berlin. An Investigational Device Exemption for feasibility study has been submitted to the United States Food and Drug Administration. It is hoped that the initial study in the US will be started later this year.

Comment

The LionHeart LVD 2000 has evolved as the culmination of years of dedicated support toward the advancement of mechanical circulatory support at Pennsylvania State University, and the seamless collaboration between our institution and Arrow International. This system provides the first true alternative to cardiac transplant for the chronic support and rehabilitation of patients with end-stage cardiac disease. Early results with European trials have proved the device to be an effective means of supporting these critically ill patients. Evolving knowledge is certain to enhance our ability to identify the most suitable candidates and to safely support them for extended periods. The components of the LionHeart LVD 2000 have been designed to consider patient comfort and lifestyle. The ultimate aim of supporting these patients is to provide the opportunity to return to normalized daily routines including the ability to exercise, travel, and return to work at their discretion. Many of these goals have been realized in patients supported with alternative devices for bridge to transplant; thus each certainly seems obtainable.

Transcutaneous energy transmission of this magnitude, without obvious adverse local effects, and the feasibility of a compliance chamber have finally been accomplished, although to date this has been in a limited study population. These are the critical steps in realizing a pulsatile mechanical circulatory support system that is totally implantable and shows acceptable reliability.

Continued study in Europe at these skilled centers will provide the earliest data to evaluate the efficacy and safety of this device. We hope that testing within the United States will be underway in the near future. Thus the advantages and limitations of the LionHeart LVD 2000 can be identified, and a broader base of patients with end-stage heart disease may be given consideration for destination circulatory support when other treatment options have been exhausted.

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