The development, evolution, and clinical utilization of artificial heart technology

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Abstract

The ventricular assist device has evolved into an effective clinical tool to treat patients with severe heart failure. Left ventricular assist systems, such as the HeartMate, have demonstrated their utility as short- and long-term bridges to heart transplantation and their ability to effect a degree of ventricular recovery in some patients. These devices will soon be used more commonly as an alternative to transplantation. © 1997 Elsevier Science B.V.

1. Introduction

In 1964, an artificial heart program was begun at the National Heart Institute. The program included multifaceted research on circulatory support and replacement devices for the heart, including left ventricular assist devices (LVADs). In 1969, a task force on cardiac replacement sponsored by the National Heart Institute concluded that the LVAD was a promising area of research. After extensive testing for both safety and reliability of such a device in vitro and in animals, in 1975 the National Heart and Lung Institute approved clinical trials at the Texas Heart Institute in Houston and at the Children's Hospital Medical Center in Boston for a pneumatically driven, LVAD for post-cardiotomy heart failure. Although survival was uncommon with the use of this device, the ventricle recovered its function in some patients who survived the immediate post-operative period. In 1977 the National Heart, Lung, and Blood Institute (NHLBI) requested proposals for the development of: (1) electrical energy converters to power left ventricular assist devices; and (2) left ventricular assist blood pumps. This research and development was undertaken by a variety of organizations in clinical-commercial partnerships.

By 1980, development of energy converters and pumps had progressed to the point that the NHLBI could request proposals for the development of an implantable, integrated, electrically powered, left ventricular assist system (LVAS) that would enable total mobility for patients. The major goals in the development of this LVAS were durability and reliability (2 years or longer) and tether-free operation. Development and testing began, but shortly thereafter, cyclosporin was introduced and heart transplantation became an acceptable therapy for patients with end-stage heart failure. Consequently, the LVAS, which was originally intended to be long-term therapy, was brought into short-term clinical use as a bridge to transplantation, and LVAS research focused on its utility as a bridge to transplantation, rather than as a permanent system.

At the Texas Heart Institute, we used the LVAS as a bridge to transplantation but simultaneously continued to develop it for long-term use, now as an alternative to heart transplantation. Our clinical experience with LVASs leads us to believe that their potential for such a use is considerable. Furthermore, an expanded use for the LVAS seems justified by two other important facts: the disparity between supply and demand for donor hearts and the cost savings afforded by LVAS therapy over conventional medical therapy for long-term congestive heart failure. Intensive care units may cost $3000/day, whereas home care for an LVAS patient can cost less than $100/day [1,2].
2. The HeartMate left ventricular assist system

We use the HeartMate® LVAS (Thermo Cardiosystems, Inc., Woburn, MA), which is a direct descendant of the LVAD first used at the Texas Heart Institute in 1975. The HeartMate has two versions that are structurally and functionally similar. Both versions enable tether-free existence for the patient. However, the older implantable pneumatic (IP) system is powered by an external pneumatic drive console, whereas the vented electric (VE) system contains an electric motor that is powered via a wearable battery pack. The IP-LVAS portable driver weighs 8.5 kg and can be carried on a shoulder strap or pulled on wheels. The patients or their family members operate and maintain the LVAS equipment, which connects to a personal computer or a display monitoring unit that controls the system. Other than their method of actuation, the versions of the HeartMate pump are similar. Each has a flexible polyurethane diaphragm inside a rigid titanium alloy housing unit. The inlet and outlet tracts have 25-mm porcine valves (Medtronic Blood Systems, Irvine, CA) to provide blood flow in one direction to the ascending aorta. Each pump has a maximum effective stroke volume of 83 ml and flow rates ranging from 5 to 10 l/min.

A major concern in the choice of materials for the HeartMate LVAS was the desire to decrease the risk of thromboembolism. Instead of using smooth linings to prevent cell adhesion, an approach that has failed to prevent thrombus formation, textured surfaces were used to promote natural cell adhesion and the formation of an intimal lining over the coated surfaces [3]. The diaphragm is textured with polyurethane fibrils, and the titanium surface is textured with sintered titanium microspheres. A pseudoneointimal lining begins to form on the two surfaces within 5 days after implantation, and thrombogenesis has been insignificant in this device. A HeartMate that was explanted from a patient after 505 days showed no continuous buildup of cellular material. In pumps explanted from other long-term LVAS patients, the two blood-contacting surfaces display a lining of smooth, adherent neointimal tissue of fibrin and collagen containing white blood cells, red blood cells, and platelets. After long periods of implantation, macrophages and smooth muscle cells predominate in the neointimal lining. Assays have also identified endothelial cells on the pump surfaces, which may explain the decreased incidence of thromboembolism in long-term patients. We have experienced only one thromboembolic episode with the HeartMate, and we believe that this episode was a complication of device implantation rather than a result of problems with the device [4].

2.1. Mechanism of the HeartMate

The left ventricular apex is cored, and the inflow conduit is secured such that blood drains passively from the left ventricle into the pump. The pump then propels the blood through the outflow conduit that has been anastomosed to the ascending aorta.

2.2. Placement of the HeartMate

The pump in the IP-LVAS is placed intraabdominally to prevent coagulopathy associated with implantation in the extraperitoneal space [5]. However, we have implanted the VE-LVAS extraperitoneally without complications. In these cases, a capsule, which may guard against infection, has formed around the pump [6].

2.3. Post-implantation care

After the implant operation, patients receive standard hospital care until they are able to care for themselves. Aspirin and dipyridamole (and sometimes warfarin) are given to prevent coagulation. If appropriate criteria are met, the patient is released from the hospital to resume normal activities while awaiting a donor heart. The LVAS can easily be maintained by the patient or family members.

2.4. Outcomes with the HeartMate

The HeartMate LVAS has been implanted in more than 500 patients worldwide. In 1991, an important goal in the development of artificial heart devices was achieved when a patient with a VE-LVAS left the hospital and resumed his normal activities. We have performed long-term patient survival rates of patients with LVASs have been good, probably because support with the LVAS helps improve patients’ physiologic conditions. We studied 16 patients who had prolonged LVAS support (a mean of 106 days), and at transplantation, their organ function was normal. The survival rate 2 years after transplantation in this group was 100%, which exceeded survival rates of both a control group and the overall transplant population [7]. In a multicenter, FDA-approved evaluation of 75 IP-LVAS patients and 33 control patients, most of the LVAS patients were in New York Heart Association class IV at implantation. After physical rehabilitation and by the time of their heart transplantation, the patients’ functional status had improved to class I. Further, the post-transplant survival rate was 91% for the LVAS patients, whereas it was only 67% for control patients [6]. Again, the better survival rate for the LVAS patients is likely the result of the physical rehabilitation that accompanies implantation of the LVAS.
3. The future

Because multicenter clinical trials have shown the HeartMate’s safety and effectiveness, in 1994 the FDA approved commercial use of the IP-LVAS as a bridge to heart transplantation. Clinical trials are still underway with the VE-LVAS, but it shows even greater promise in treating patients, because its battery-powered operation enables a patient to undertake activities without any impediment from the LVAS. Some patients with vented electric HeartMates have been discharged from the hospital and returned to work while awaiting appropriate donor hearts. Because of our continuing positive outcomes with these patients, I believe that the vented electric version of the HeartMate will one day be used as an alternative to cardiac transplantation. In fact, the FDA has recently approved clinical trials for this use of the HeartMate. Also in the future, it may be possible to remove the HeartMate from some patients after their native heart has recovered sufficiently, thereby eliminating the need for cardiac transplantation in those patients.

References