First Use of an Untethered, Vented Electric Left Ventricular Assist Device for Long-term Support

O.H. Frazier, MD

Abstract This report describes the first long-term (505-day) application of the vented electric (VE) HeartMate left ventricular assist device (LVAD) (Thermo CardioSystems, Inc). The device consists of an abdominally placed, battery-powered, titanium blood pump that, in contrast to earlier pneumatically powered systems, allows patients untethered freedom of movement. The batteries last 5 to 8 hours and can be changed on a rotating basis indefinitely. The patient, a 33-year-old man (90 kg, blood type O) with idiopathic cardiomyopathy, experienced end-organ heart failure (New York Heart Association [NYHA] class IV) while he was awaiting heart transplantation. When his hemodynamic criteria met those outlined in the protocol, we implanted the VE-LVAD as a bridge to transplantation. The patient was supported by the device for more than 16 months. His cardiac status returned to NYHA class I, and he was eventually allowed to take day trips outside the hospital as he awaited transplantation. The VE-LVAD enabled the patient to participate in activities such as eating in restaurants, going to movies, and practicing basketball shots. Unfortunately, the patient died suddenly due to a neurological thromboembolic event that occurred on day 503 of VE-LVAD support. The VE-LVAD improved native left ventricular function by chronic unloading, and ventricular remodeling resulted in a more normal configuration anatomically, physiologically, and ultimately, histologically and pathologically. (Circulation. 1994;89:2908-2914.)

Key Words • heart-assist device • transplantation • cardiomyopathy

Since 1986, the HeartMate (Thermo CardioSystems, Inc), an implantable, pneumatically powered left ventricular assist device (LVAD), has proved to be an effective means of providing long-term circulatory support as a bridge to heart transplantation.1,2 Patients supported by the pneumatic LVAD, however, are attached to a portable console. The activities they can perform are thereby limited to where the console can be pushed. In May 1991, the Texas Heart Institute received approval from the US Food and Drug Administration to implant a new, battery-powered vented electric (VE) version of this device. On September 3, 1991, the VE-LVAD was successfully implanted in a 33-year-old man with end-stage idiopathic cardiomyopathy (New York Heart Association [NYHA] class IV status). This report details the results observed in this case after 16 months of VE-LVAD support.

Device Description

The vented electric HeartMate consists of a positive-displacement, pusher-plate pump activated by a low-speed torque motor that can produce a stroke volume of 83 mL at rates varying from 50 to 120 beats per minute (bpm). Both the inlet and outlet conduits are fitted with 25-mm porcine valvular (Medtronic Blood Systems). All blood-contacting surfaces of the pumping chamber are textured to encourage the deposition of cells to form a biological layer to interface with the blood.3,4 The flexing diaphragm is fabricated from Biomer polyurethane and has an integrally textured fibrillar surface, whereas all metal components have a sintered, porous titanium surface. The device may be implanted intraperitoneally5 or extraperitoneally.6

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The electromechanical actuator fits beneath the pumping diaphragm. The rotor carries two cam followers that contact two nested, helical cams, which are attached to the pusher-plate/diaphragm assembly. This interaction converts the rotary motion of the torque motor to the linear motion of the pump diaphragm. After the motor switches on and makes one complete revolution pushing the diaphragm, blood ejects from the pump. Then the motor turns off, and the pump passively refills.

A percutaneous electric line connects the blood-pump assembly to the portable system controller, which clips easily onto a belt or waistband (Fig 1). The system controller contains a microprocessor that controls motor function and monitors pump performance. The pump can be operated in either a fixed-rate or automatic mode. In the automatic mode, the device increases output in response to increased activity. The pump can generate an output of up to 10 L/min.

The system controller is connected to two lead-acid, gel-cell batteries, which are contained in a shoulder holster or a belt bag worn around the patient's waist. A portable power base unit is used to recharge extra batteries or to power the device when the patient sleeps or sits for prolonged periods. However, two batteries used in parallel last from 5 to 8 hours, and they can be exchanged on a rotating basis to provide untethered support indefinitely. The system controller has audible and visual alarms to inform the patient when 30 minutes of battery power remains.

The pump is vented by a percutaneous Silastic tube coated with Dacron velour. The vent may allow for pneumatic actuation of the pump in emergencies—for example, during power failures.

Case Report

In July 1990, a 33-year-old man was admitted with flulike symptoms that had persisted despite medical
therapy. His symptoms were severe enough to require hospital admission and were, in fact, attributed to congestive heart failure secondary to dilated cardiomyopathy. He was treated medically with digoxin, furosemide, and nitrates as well as full anticoagulation with warfarin sodium.

One year later, the patient sustained a cardiac arrest secondary to ventricular fibrillation, from which he was successfully resuscitated. At this time, he was evaluated for heart transplantation and placed on the transplant waiting list. The patient weighed 90 kg, had a body surface area of 2.14 m², and had blood type O. Two weeks later his condition deteriorated further, and he required maximal pharmacological support as well as intra-aortic balloon pump support. His hemodynamic status remained critical (aortic pressure, 82/56 mm Hg; pulmonary pressure, 49/31 mm Hg; mean pulmonary artery pressure, 42 mm Hg; pulmonary capillary wedge pressure, 27 mm Hg; cardiac index, 1.77 L ⋅ min⁻¹ ⋅ m⁻²; central venous pressure, 13 mm Hg; and venous oxygen saturation, 32%). In addition, his hepatic and renal functions had deteriorated (Table 1). Chest roentgenograms showed increasing pulmonary infiltrates. Hemoptysis also developed. The patient experienced increasing hypoxia, reflected by decreasing arterial oxygen pressure, decreasing oxygen saturations, and increasing oxygen requirements. Despite infusion of procarbamide, ventricular arrhythmias increased. At this point, the criteria for VE-LVAD implantation had been met, and on September 3, 1991, the VE-LVAD was successfully implanted.

Table 1. Preimplantation and Postimplantation Values of Hepatic and Renal Functions

<table>
<thead>
<tr>
<th></th>
<th>Preimplantation</th>
<th>Postimplantation</th>
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</thead>
<tbody>
<tr>
<td>Total bilirubin, mg/dL</td>
<td>6.3</td>
<td>1.2</td>
</tr>
<tr>
<td>SGOT, IU</td>
<td>1929</td>
<td>31</td>
</tr>
<tr>
<td>SGPT, IU</td>
<td>2319</td>
<td>26</td>
</tr>
<tr>
<td>BUN, mg/dL</td>
<td>67</td>
<td>7</td>
</tr>
<tr>
<td>Creatinine, mg/dL</td>
<td>4.1</td>
<td>0.6</td>
</tr>
</tbody>
</table>

SGOT indicates serum glutamic-oxaloacetic transaminase; SGPT, serum glutamic-pyruvic transaminase; and BUN, blood urea nitrogen.

one exception: the electric line and the vent tube are tunneled through separate incisions in the left anterior abdominal wall just above the iliac crest.

After the VE-LVAD was implanted, the patient’s hemodynamic status improved immediately. He was extubated 36 hours later. By day 3, he could take liquids, and by day 7, he was able to eat a regular diet for the first time in more than a month. By that time, the patient had also been weaned from all intravenous vasoactive drugs, and his end-organ function had improved. He was able to walk without assistance. By the end of the second postoperative week, all laboratory values were within normal ranges (Table 1).

The patient’s capacity for exercise improved rapidly. He began an aggressive physical rehabilitation program that included treadmill exercise (3% grade at 3 to 3.5 mph), discontinuous aerobic training (42 minutes), and walking (3 miles per day). During exercise, the patient changed his pump to the automatic mode, which allowed increased blood flow and improved exercise tolerance. During peak exercise, pump flow averaged 8.82±0.73 L/min, pump rate averaged 118±6 bpm, oxygen saturation averaged 96.7±0.63%, and heart rate averaged 112±8 bpm. Within 5 minutes of discontinuation of exercise, pump flow averaged 6.2±0.58 L/min, with an average pump rate of 91±8 bpm, heart rate of 85±12 bpm, and oxygen saturation of 98±0.67%.

Pulmonary venous congestion, shown on chest roentgenograms, continued until 6 weeks after implantation; after that, the chest roentgenogram remained clear (Fig 2). Transthoracic echocardiographic examination at 8 months after surgery showed decreasing left ventricular chamber size as well as improvement in native cardiac function (Fig 3).

After implantation of the VE-LVAD, the patient’s cardiovascular status normalized. After 3 months in the hospital, however, the patient became increasingly distressed. He felt well enough to go home and wait for his transplant with his family, but he could not leave the hospital because of the limitations included in the clinical protocol. During this time, the patient, a former computer programmer, relieved his boredom by assisting the hospital computer staff. The longer he remained in the hospital living on the transplant floor, however, the more he believed he would die whether or not he received a transplant. The medical team sympathized with his predicament and appealed for an amendment to the protocol. In August 1992, the patient received approval to take day trips, during which he dined at restaurants, went to movies, and practiced his basketball shots. The success of these trips led to approval for overnight stays outside the hospital.
Fig 2. Comparison of chest roentgenograms before implantation (top) and after 40 weeks of assist device support (bottom) shows a significant decrease in cardiothoracic ratio, with no signs of pulmonary congestion.
On January 17, 1993, the patient suffered a stroke—the first and only evidence of an embolic event—that was ultimately fatal. At the time of VE-LVAD implant, all four chambers of the patient's heart had been markedly dilated, and bilateral infarcts had been present. Therefore, warfarin sodium therapy, which was prescribed in 1990, was continued during VE-LVAD support to maintain a prothrombin time of 18 seconds or greater. The patient's stroke occurred 7 days after he stopped taking warfarin sodium. We theorize that discontinuing treatment caused the sudden hypercoagulable rebound.7,8

The patient was declared brain dead 24 hours after he had returned to the hospital, at which time VE-LVAD support was discontinued. The heart, however, had recovered sufficiently to maintain circulation without the LVAD or vasopressor support (Fig 4). Echocardiography showed improved ejection fraction and, even more importantly, decreased diastolic dimension (Fig 3). In accordance with the patient's wishes, the family agreed to donate his kidneys and liver to other transplant candidates.

At postmortem examination, there was no evidence of thrombi within the dilated left ventricular cavity or within the pumping chamber of the VE-LVAD. The pathological findings of the stroke were compatible with a thromboembolus to the cerebral arterial supply, a complication of dilated cardiomyopathy. Although the heart itself was still grossly enlarged (620 g), there was histological evidence of left ventricular recovery (Fig 5).

Discussion

The vented electric HeartMate LVAD supported the patient described in this report for more than 16 months. The pneumatic HeartMate had already proved valuable in the bridge-to-transplant population. The only difference between the VE-LVAD and the pneumatic model is the battery-driven energy converter. Because the energy converter is driven by batteries, patients are fully mobile, able not only to leave the hospital but also to perform routine activities.

The issue of allowing LVAD patients to be discharged from the hospital has gained importance as the gap between the number of heart donors and the number of transplant candidates has widened. The United Network for Organ Sharing registered 2843 heart transplant candidates as of May 31, 1993; on the average, only six donor hearts are procured each day. Therefore, despite the success of new immunosuppressive regimens, few patients dying of heart failure will actually have the opportunity to receive a heart transplant.
The HeartMate VE-LVAD is a product of 20 years of research by Thermo Cardiovascular, Inc., begun with the support of the National Heart, Lung, and Blood Institute. In the early 1970s, we had envisioned an implantable LVAD for long-term or permanent support in patients with chronic heart failure. In 1986, after extensive animal studies, we began testing this pneumatic LVAD clinically in bridge-to-transplant operations.1.10 Although we initially intended to keep support times short, in many cases, a donor heart could not be found, so we were obligated to continue support for prolonged periods (>30 days).11,12

One might expect that prolonged LVAD support and two operations—i.e., LVAD implantation and heart transplantation—would yield poor results. On the contrary, LVAD patients undergoing prolonged support fare better than routine transplant patients. In the multicenter report,2 we described the results of routine transplantation in six historical control subjects who would have met the inclusion criteria for LVAD support. Only three of the patients lived to transplantation; even more significantly, all six died within 77 days of having met the LVAD criteria. In our own experience,12 1-year survival was 100% in patients who were supported by the LVAD for 30 days or longer (up to 233 days).

Patients supported with the LVAD usually return to NYHA class I status, decreasing the risk of reoperation. In the multicenter experience,2 improved hepatic perfusion during LVAD support was reflected by a 60% decrease in the total level of bilirubin. Improved renal perfusion in these patients was reflected by similar decreases in the levels of serum creatinine and blood urea nitrogen. During LVAD support, patients were able to exercise, which further strengthened them for the transplant operation.

Even during prolonged support, the HeartMate has been associated with a low risk of complications. At our institution, the cumulative support time with the pneumatic HeartMate is 2908 days, or 7.97 years. During this time, there was only one thromboembolic complication. As of June 1993, a total of 92 patients had been treated with this LVAD at various centers, and the rate of device-related thromboembolic complications was 2.2% (personal communication, Kurt A. Dasse, PhD, October 11, 1993). This incidence is much lower than that reported for other devices.13,14 Furthermore, the HeartMate does not predispose patients to complications after transplant. In a previous report,15 we compared three groups of patients by pretransplant regimen—i.e., routine medical support, intra-aortic balloon pump support, and LVAD support—and found no significant differences among the groups regarding the incidence of

![Figure 4](http://circ.ahajournals.org/) Top, ECG showing normal sinus rhythm with no change in rate after vented electric left ventricular assist device (VE-LVAD) support was stopped (arrow). Bottom, Arterial pressure tracing from the same patient, showing opening of the native aortic valve as well as VE-LVAD ejection. After VE-LVAD support was stopped (arrow), the tracing shows a continuous, normal arterial pulse of the patient's native left ventricle. Arterial pulse pressure was maintained at approximately 120/70 mm Hg before and after VE-LVAD support.

### Table 2. Median Waiting Time for Heart Transplants by Weight and Blood Type in 1991

<table>
<thead>
<tr>
<th>Weight, lb</th>
<th>Blood Type</th>
<th>Median Wait Time, d</th>
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<tbody>
<tr>
<td>&lt;150</td>
<td>A</td>
<td>54</td>
</tr>
<tr>
<td></td>
<td>AB</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td>O</td>
<td>96</td>
</tr>
<tr>
<td>150-200</td>
<td>A</td>
<td>184</td>
</tr>
<tr>
<td></td>
<td>AB</td>
<td>92</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>155</td>
</tr>
<tr>
<td></td>
<td>O</td>
<td>405</td>
</tr>
<tr>
<td>&gt;200</td>
<td>A</td>
<td>428</td>
</tr>
<tr>
<td></td>
<td>AB</td>
<td>358</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>359</td>
</tr>
<tr>
<td></td>
<td>O</td>
<td>595</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>197</td>
</tr>
</tbody>
</table>
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Fig 5. Top, At the time of vented electric left ventricular assist device implantation, tissue specimens from the apical core of the left ventricle showed attenuated cardiac myocytes. Bottom, At autopsy, the cardiac myocytes were hypertrophic (hematoxylin and eosin, original magnification ×250).
rejection, infection, length of hospitalization, or survival.

Finally, the HeartMate has proved cost-effective for treating patients with end-stage heart failure. According to the most recent Registry report, 52% of transplant candidates were hospitalized at the time of transplantation — i.e., they were status I transplant candidates — and 42.3% of them were on life support. The cost to support a status I patient until transplant averages $200,000, assuming that the total cost for hospitalization in the intensive care unit is $4000/d. In contrast, although all HeartMate patients are considered status I candidates before LVAD implantation, they generally recover quickly and await transplant on the regular transplant floor. Supported by the VE-LVAD, patients could potentially wait at home.

The real application for the VE-LVAD, however, is as an alternative to transplantation — a remedy for the donor crisis. In 1990, 650 transplant candidates died while they were waiting for hearts, and the median wait for those lucky enough to receive a heart was 186 days, a 65% increase over the waiting time in 1988. As of June 1991, the median wait for all patients had increased to 197 days, but that time was substantially longer for particular subgroups of candidates: for example, patients with type O blood who weighed more than 200 lb waited 595 days (Table 2). Finally, even after a successful transplant operation, the potential for long-term survival is still hampered by complications such as accelerated coronary atherosclerosis and malignancies.

The case reported here shows that the VE-LVAD may be a valid option for providing long-term survival without transplantation in selected patients. In the pretransplant era, Burch proposed that complete bed rest would unload and rest the diseased heart. Given enough rest, the heart could recover. He believed that complete bed rest accomplished ventricular unloading by decreasing heart rate, arterial blood pressure, cardiac output, heart size, and velocity of myocardial contraction. Later, in an uncontrolled study, Burch and his colleagues (McDonald et al.) reported ventricular recovery in patients with ischemic cardiomyopathy who had undergone only prolonged, complete bed rest. Burch theorized that bed rest reduces myocardial workload and, thus, myocardial tension. As a result, myocardial oxygen requirements decrease.

In conclusion, the VE-LVAD can provide the potential benefits of Burch's bed-rest therapy, yet return the patient to an active, vigorous, and more cost-effective lifestyle. If the ventricle can recover, we may eventually be able to remove the device and return the patient to routine medical management and, in some cases, avoid heart transplantation altogether. Our experience leads me to believe that we now have sufficient evidence to warrant a randomized clinical trial to test the effectiveness of chronic ventricular unloading on ventricular recovery.

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