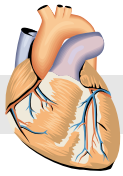

Mechanical Alternatives to the Human Heart: Intracorporeal Assist Systems and Total Artificial Heart

Jacob Lavee MD and Yoav Paz MD

Heart Transplantation Unit, Department of Cardiac Surgery, Sheba Medical Center, Tel Hashomer, Israel

Key words: ventricular assist device, artificial heart, heart transplantation, congestive heart failure

IMAJ 2002;4:209–212

In the previous part of this review [1] we outlined the currently available paracorporeal assist systems used in patients terminally ill with congestive heart failure. Since all these systems require continuous hospitalization of the patient due to the cumbersome bedside hardware, intracorporeal assist systems have been developed that enable the patient's discharge while on the device. This part of the review will outline the currently available intracorporeal assist systems and the total artificial heart.

There are currently two intracorporeal assist systems approved for use: the HeartMate LVAD (Thoratec Corporation, formerly Thermo Cardiosystems Inc., Wobourn, MA, USA) and the Novacor LVAD (WorldHeart, Ottawa, Ontario, Canada)

The HeartMate LVAD

The HeartMate LVAD is an implantable pulsatile blood pump that is available in pneumatically driven (implantable pneumatic) or electrically powered (vented electric) models. More than 2,300 devices have been implanted since 1986, establishing it as one of the major cornerstones in long-term, often out-of-hospital, left ventricular assistance.

Both models of the HeartMate are fabricated from sintered titanium and house a flexible, textured, polyurethane diaphragm bounded to a rigid pusher-plate. In the IP model the pusher-plate is actuated pneumatically from a portable external console, while in the VE model the pusher-plate is actuated by a low-speed torque motor that drives a pair of nested helical cams. A single, two channeled, velour-covered drive-line leads from the implanted LVAD, through the skin, to the external environment [Figure 1]. In the IP model one of the channels contains an electric cable conveying performance data to the bedside console, while the other provides for the air transfer. In the VE model one of the drive-line channels contains the electric cable leading from the portable battery pack to the motor, while the other acts as an air vent allowing air transfer in and out of the motor chamber in order to maintain it near atmospheric conditions. A unique feature of the HeartMate is the design of the blood-contacting parts, whereby the titanium housing incorporates titanium microspheres and the flexible diaphragm is covered with textured polyurethane, both promoting the adherence of cellular blood elements and the formation of a pseudo-intimal layer. This configuration assures an exceptionally low thromboembolic risk with this device [2]. Both models of the HeartMate are equipped with inflow and outflow porcine xenograft valves. Both models can generate a maximum stroke volume of 85 ml and a maximum pump output of 11 L/min, and they are usually operated in an automatic mode whereby the eject cycle begins only after the pump is at least 90% filled. The VE model with its wearable two battery pack provides patients with 6–8 hours of untethered activity.

Most HeartMate LVADs were implanted in a preperitoneal pocket behind the left rectus abdominis posterior sheath. Some centers prefer the intraabdominal placement; however internal organ erosions, bowel obstruction, and intraabdominal adhesions have rendered this approach less favorable. Following preparation of the preperitoneal pocket, the patient is placed on cardiopulmonary bypass, and an apical silicone cuff is sewn to the left ventricular apex that has been cored out by a circular coring knife. The LVAD is inserted into its pocket, tunneling its drive-line subcutaneously to exit in the right mid to upper quadrant

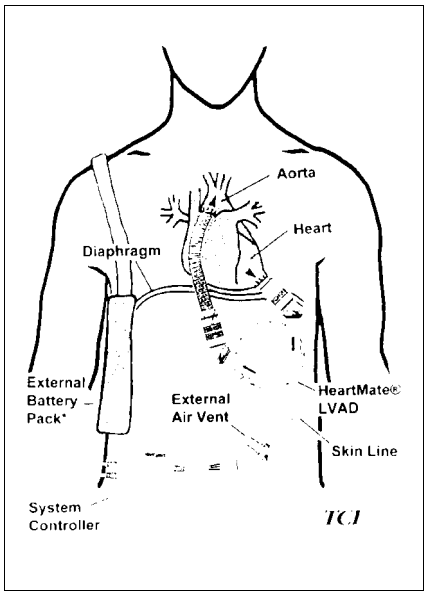

Figure 1. Schematic illustration of the implanted HeartMate VE LVAD. (With permission from Thermo Cardiosystems, Inc., Wobourn, MA, USA).

IP = implantable pneumatic
VE = vented electric

area. The pump inflow cannula is then brought through the diaphragm and inserted through the apical cuff. The outflow Dacron graft is anastomosed to the right lateral surface of the ascending aorta, and following meticulous de-airing maneuvers the outflow graft is screwed to the pump outflow port [Figure 1]. As cardiopulmonary bypass is weaned, the device is activated first in a slow fixed mode, to be replaced by automatic mode when the hemodynamic status stabilizes.

Patients assisted by the HeartMate LVAD are maintained on aspirin alone, with no need for anticoagulation. Patients implanted with the HeartMate VE experience a significant improvement in quality of life during LVAD support, as many of them are frequently discharged from the hospital while on the device and can return to their families and their work or school activities [Figure 2].

The HeartMate LVAD is usually used as a bridge-to-transplantation device. As such, the presence of any contraindication to transplantation negates candidacy for long-term support. The incidence of right heart failure and the need for temporary RVAD assistance following HeartMate LVAD implantation have been greatly reduced since the routine introduction of inhaled nitric oxide [3]. Preoperative low pulmonary artery pressure and low right ventricular stroke work index have been shown to be significant risk factors for RVAD use [4]. The following predictive factors have been shown [5] to be associated with perioperative mortality: oliguria (urine output < 30 ml), elevated central venous pressure (>16 mmHg), the need for mechanical ventilation, elevated prothrombin time (>16 sec), and prior mediastinal operation.

According to the last reported data from the Thermo Cardiosystems Worldwide Registry in September 2000, 65% of the 2,265 patients implanted with the HeartMate IP or VE have survived implantation; 63% were transplanted and in 2% the native heart recovered and the device was explanted. Infections, the achilles heel of all devices, have always been a major cause for failure with this device [6,7]. More than 250 patients were supported with the device for more than 6 months, and more than 60 patients were supported for more than one year. Some patients were supported for more than 2 years, which sparked interest in the use of the device as an alternative to transplantation, leading to the REMATCH trial [8]. The multicenter REMATCH trial (**R**andomized **E**valuation of **M**echanical **A**ssist **T**reatment for **C**ongestive **H**eart failure) compared the outcomes of 68 non-transplant candidates in New York Heart Association class IV heart failure supported with the HeartMate VE LVAD to 61 similar patients on current maximal medical therapy. The one year survival rates were 52% in the device group and 25% in the medical therapy group ($P = 0.002$).

The Novacor LVAD

The Novacor LVAD was the first electrically powered implantable assist device, and since its first human use at the Stanford University Medical Center in 1984 more than 1,000 patients were supported by it worldwide.

The Novacor LVAD blood pump is made of a smooth polyurethane sac actuated by a pulsed solenoid energy converter motor, which activates two identical pivoted pusher-plates. Inflow and outflow porcine valves maintain unidirectional blood flow through knitted, gelatin-sealed Vascutek inflow and outflow grafts. A percutaneous vent tube, containing power and control leads, connects the internalized blood pump to an extracorporeal electronic control and wearable batteries.

Figure 2. Our first HeartMate VE LVAD recipient at the Sheba Medical Center, bridged to heart transplantation for 350 days, spent more than 300 days at home conducting his normal daily activities.

The implantation technique of the Novacor LVAD is very similar to that of the HeartMate [Figure 3], with the pump implanted usually in a preperitoneal pocket behind the left rectus muscle. The device's vent tube is tunneled subcutaneously to be exteriorized midway between the right costal margin and the anterosuperior iliac crest. Similar to the experience with the HeartMate LVAD, the need for temporary RVAD assistance following implantation of the Novacor LVAD has been greatly decreased to less than 6% since the introduction of inhaled nitric oxide [3]. Patients assisted by the Novacor LVAD are usually maintained on warfarin and aspirin. Novacor-assisted patients can be discharged from the hospital and return home to normal daily activities, allowing for a better quality of life while waiting for transplantation.

Figure 3. Schematic illustration of the implanted Novacor LVAD. (With permission from WorldHeart Corporation, Ottawa, Ontario, Canada).

The recent results of the global experience with the Novacor LVAD, comprising 1,040 implants, show that in 93.4% of the patients the device was used as a bridge to transplant, in 4.3% as a bridge to recovery and in 2.3% as an alternative to transplant. Half of the patients were supported

for more than 6 months, with mean support duration of 254 days. The longest support duration was more than 4 years – the lengthiest time that any recipient has lived with continuous support from a heart assist device. A high incidence of embolic stroke – ranging from 21% with the previously used, woven unsupported Cooley grafts, to 12% with the more recently used, knitted, gelatin-sealed, supported Vascutek grafts – has been one of the major hallmarks of the Novacor LVAD [9,10]. In contrast, an excellent reliability record with a pump replacement incidence of only 0.8% has been one of its virtues. In a U.S. multicenter bridge-to-transplant study that included 156 Novacor LVAD recipients, 73% were successfully bridged to transplant [9]. In a single center (Deutches Herzzentrum in Berlin) that used the Novacor LVAD as a bridge to recovery in 23 patients, stable cardiac recovery occurred in 13 patients for 3–49 months; 7 patients had recurrent cardiac failure after 4–24 months, transplantation was performed in 6 of them and one died while on the waiting list; and 3 patients died of non-cardiac causes within 4 months and 3 days after removal of the assist device [11]. To date, the data are insufficient to determine the viability of this form of therapy.

The CardioWest Total Artificial Heart

The total artificial heart was first used at the University of Utah in 1982 and was known as the Jarvik-7 TAH [12]; it continued for several years as the Symbion TAH until its use was halted in 1991 following loss of its investigational device exemption due to a high incidence of morbidity and mortality. Since 1993 a new investigational device exemption study was begun at the University Medical Center in Tucson, Arizona with the now-called CardioWest TAH (CardioWest Technologies, Inc.) and a multicenter trial was undertaken.

The CardioWest TAH is a pneumatic biventricular pump that is implanted in the orthotopic position. It consists of two ventricles connected to the respective native atria and great vessels. A velour-covered air drive-line passes from each of the ventricles transcutaneously to a large console that pulses pressurized air and monitors pump function [Figure 4]. Each of the two ventricles consists of a spherical polyurethane chamber, half of it immobile and anchored to the chamber rigid wall, and the other half a mobile four-layered diaphragm. Pulses of air pressure from the console push the diaphragm and thus blood is ejected from the chamber. Vacuum added to the device in diastole improves ventricular filling at low venous pressures. Medtronic-Hall mechanical valves located at the inflow and outflow of each of the chambers provide for unidirectional blood flow. Specialized cuffs anastomosed to the native atria allow for quick connection of the ventricles, while Dacron outflow grafts provide connection to the great vessels. The maximal blood volume of each of the chambers is 70 ml, and the cardiac output is generally between 6 and 8 L/min.

Due to the considerable size of the implanted two chambers of the CardioWest TAH, adherence to stringent fitting criteria guidelines must be followed carefully to prevent a poor outcome. Patients with a body surface area less than 1.7 m^2, thin chest, or cardiothoracic ratio less than 0.5 are at increased risk of inferior vena cava or left pulmonary vein compression. The implan-tation technique, as recently described [13], starts with total cardiectomy, leaving behind a maximal length of the great vessels and the two atria, which are cut at the atriventricular groove. The atrial quick connector cuffs are anastomosed to each of the two native atria, followed by end-to-end anastomosis of the two outflow grafts to the aorta and pulmonary artery. Next, the atrial connector of the left ventricle is snapped on to the left atrial quick connector, the ventricle is filled with saline and the aortic connection is made. A similar approach is followed with the right ventricle. After de-airing maneuvers, console pumping is started and the patient is rapidly weaned off cardiopulmonary bypass. The device's two air drive-lines are tunneled to the left epigastrium.

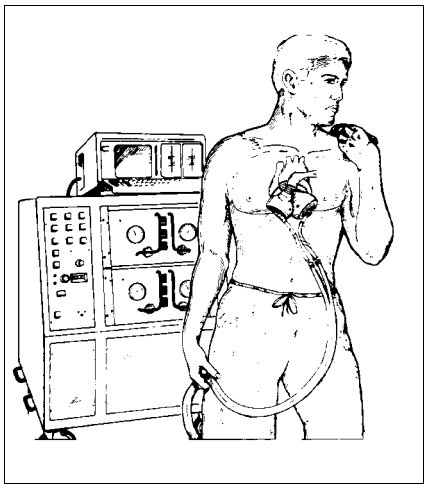

Figure 4. Schematic illustration of a CardioWest total artificial heart recipient. (Reproduced with permission from reference 13).

Patients on the CardioWest TAH are maintained on warfarin, aspirin, dipyridamole and pentoxyphyllin). The need for these patients to be permanently tethered to a large console makes out-of-hospital existence with this device impractical, however walking within the confines of the hospital is possible for short periods with battery power and air tank backup of the console.

The current indication for using the CardioWest TAH is as a bridge to transplant in patients with rapid decompensation involving biventricular failure that is unresponsive to maximal medical therapy [14].

The results of a U.S. national trial of the CardioWest TAH [14] have shown that of 27 patients supported for an average of 52 days (range 12–186 days), 93% underwent heart transplantation and 89% were discharged home. The most common source of morbidity was infection, occurring in 90% of the patients but only in 10% was it considered severe. No serious neurologic events causing death occurred, however non-serious events included nine transient ischemic attacks, three seizures, two episodes of impaired state of consciousness, one retinal hemorrhage, one retinal embolus and one cerebrovascular accident. Internationally, there were 175 implants with a 65% transplantation rate and 88% discharge rate for transplanted patients [15].

Summary

The currently available intracorporeal assist systems and total artificial heart provide long-term support for patients terminally ill with congestive heart failure, often in an out-of-hospital environ-

TAH = total artificial heart

ment. While they are currently widely used mainly as a long-term bridge to heart transplantation, their inherent risks of infection or stroke are prompting interest in future devices that will be smaller, fully implantable and hopefully stroke-free. These devices will be described in the last part of this review.

References

1. Lavee J, Paz Y. Mechanical alternatives to the human heart: paracorporeal assist systems. *IMAJ* 2001;4:125–30.
2. Rose EA, Levin HR, Oz MC, et al. Artificial circulatory support with textured interior surfaces: a counterintuitive approach to minimizing thromboembolism. *Circulation* 1994;90(Suppl II):II87–91.
3. Argenziano M, Choudhri AF, Moazami N, et al. Randomized, double-blind trial of inhaled nitric oxide in LVAD recipients with pulmonary hypertension. *Ann Thorac Surg* 1998;65:340–5.
4. Fukamachi K, McCarthy PM, Smedira NG, Vargo RL, Starling RC, Young JBÛ Preoperative risk factors for right ventricular failure after implantable left ventricular assist device insertion. *Ann Thorac Surg* 1999;68:2181–4.
5. Oz MC, Goldstein DJ, Pepino P, et al. Screening scale predicts patients successfully receiving long term implantable left ventricular assist devices. *Circulation* 1995;92(Suppl II):II169–73.
6. Holman WL, Skinner JL, Waites KB, Benza RL, McGiffin DC, Kirklin JK. Infection during circulatory support with ventricular assist devices. *Ann Thorac Surg* 1999;68:711–16.
7. El-Banayosy A, Arusoglu L, Kizner L, et al. Novacor left ventricular assist system versus Heartmate vented electric left ventricular assist system as a long-term mechanical circulatory support device in bridging patients: a prospective study. *J Thorac Cardiovasc Surg* 2000;119:581–7.
8. Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term use of a left ventricular assist device for end-stage heart failure. *N. Engl J Med* 2001; 345:1435–43.
9. Kormos RL, Ramasamy N, Sit S. Bridge to transplant experience with the Novacor left ventricular assist system: results of a multicenter US study [Abstract]. *J Heart Lung Transplant* 1999;18:163.
10. Portner PM, Jansen PG, Oyer PE, Wheeldon DR, Ramasamy N. Improved outcomes with an implantable left ventricular assist system: a multicenter study. *Ann Thorac Surg* 2001:71:205–9.
11. Hetzer R, Muller JH, Weng YG, Loebe M, Wallukat G Midterm follow-up of patients who underwent removal of a left ventricular assist device after cardiac recovery from end-stage dilated cardiomyopathy. *J Thorac Cardiovasc Surg* 2000;120:843–55.
12. DeVries WC, Anderson JL, Joyce LD, et al. Clinical use of the total artificial heart. *N Engl J Med* 1984;310:273–8.
13. Arabia FA, Copeland JG, Pavie A, Smith RG. Implantation technique for the CardioWest total artificial heart. *Ann Thorac Surg* 1999;68:698–704.
14. Copeland JG, Arabia FA, Banchy ME, et al. The CardioWest total artificial heart bridge to transplantation: 1993 to 1996 national trial. *Ann Thorac Surg* 1998;66:1662–9.
15. Arabia FA, Copeland JG, Smith RG, et al. International experience transplantation with the CardioWest total artificial heart as a bridge to heart transplantation. *Eur J Cardiothorac Surg* 1997;11(Suppl):S5–10.

Correspondence: Dr. J. Lavee, Director, Heart Transplantation Unit, Department of Cardiac Surgery, Sheba Medical Center, Tel Hashomer 52621, Israel.
Phone: (972-3) 530-2225, Cell 058-546271
Fax: (972-3) 535-2777
email jaylavee@netvision.net.il