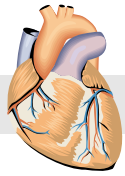

Mechanical Alternatives to the Human Heart: Future Devices

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In the previous two parts of this review [1,2] we outlined the currently available paracorporeal and intracorporeal assist systems, as well as the CardioWest total artificial heart. This review of the currently existing mechanical alternatives to the human heart would not be complete without a short glimpse at a few alternatives that are "in the pipeline," some of them already undergoing preliminary clinical investigation. One or more of the following devices will probably dominate the future of mechanical heart assistance or even permanent replacement: axial flow pumps, the LionHeart left ventricular assist system (Arrow International Inc., Reading, PA, USA), the Penn State University total artificial heart (Abiomed, Danvers, MA, USA), the AbioCor total artificial heart (Abiomed, Danvers, MA), and the HeartSaver ventricular assist device (WorldHeart Corp., Ottawa, Ontario, Canada)

Axial flow pumps

The cumulative experience with the various pulsatile systems has highlighted their drawbacks regarding long-term durability due to the need for moving flexible diaphragms and unidirectional valves. Hence, research has simultaneously focused on the probability to produce axial non-pulsatile flow devices, which would contain a single moving part and be valveless, and thus potentially more durable and suitable for chronic ventricular assistance. Long-term support with axial flow pumps in various animal models has failed to demonstrate significant clinical, biochemical, or microscopic end-organ damage for up to 6 months of non-pulsatile support [3,4].

Three axial blood flow pumps are currently undergoing preliminary clinical investigation: the Jarvik 2000 Ventricular Assist System (Jarvik Heart, Inc. and the Texas Heart Institute), the HeartMate II Left Ventricular Assist System (Thoratec Corporation, formerly Thermo Cardiosystems Inc., Woburn, MA), and the MicroMed-DeBakey Ventricular Assist Device (MicroMed Technology, Inc., Houston, TX)

The Jarvik 2000 VAD

This axial flow pump measures 2.5 cm in diameter and 5.5 cm in length and weighs 90 g. The pump's only moving part is the impeller, which is housed in a titanium casing and is supported by ceramic bearings that are immersed in the bloodstream. The impeller is actuated at a fixed rate of 8,000–12,000 rpm by an electromagnetic field across the motor air gap through which the blood flows, delivering a blood flow of 3–8 L/min depending on the systemic vascular resistance. Implantation of the device is performed through a left thoracotomy incision, the device is implanted inside the left ventricle, via its apex, with the outflow Dacron graft anastomosed to the descending aorta [Figure 1]. Power is supplied through a small cable that passes from the device to the apex of the chest, then through the neck to a titanium pedestal screwed into the skull behind the mastoid process. This percutaneous pedestal transmits the cable to an external portable controller and battery, both of which are worn unobtrusively on the patient's belt or waistcoat.

Fourteen human implantations of the Jarvik 2000 VAD have been performed so far: in 10 patients at the Texas Heart Institute as a bridge to transplantation and in 4 patients in Europe as a

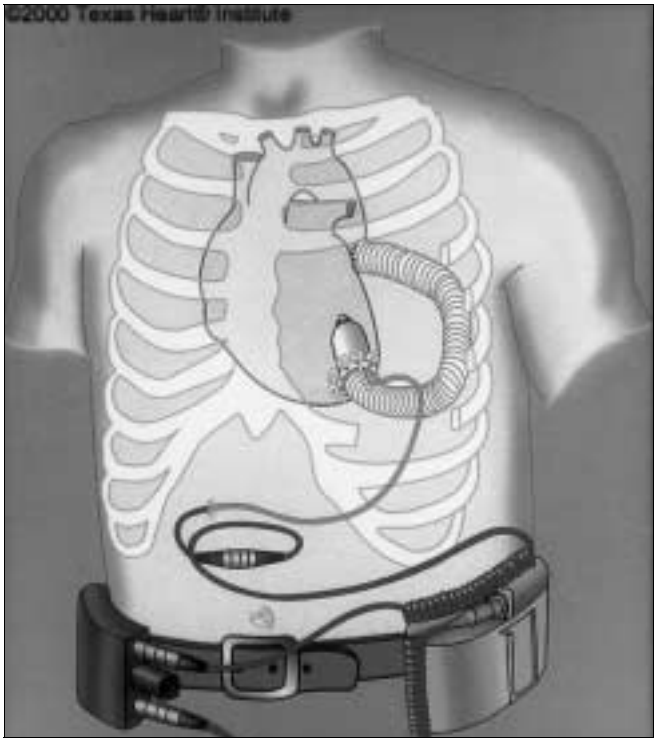

Figure 1. Schematic illustration of the implanted Jarvik 2000 VAD.

permanent device. The first implantation took place in April 2000 and involved a 52 year old woman in whom the device was successfully implanted for 79 days as a bridge to transplantation [5]. Seven of the 10 bridged patients were transplanted and 6 of them were discharged home. The longest duration on the device so far has been 214 days. In June 2000, at the Oxford Heart Center, a 61 year old male with end-stage congestive heart failure due to idiopathic dilated cardiomyopathy received the device as an alternative to heart transplantation, and was discharged home [6]. One additional patient who received the Jarvik 2000 VAD as an alternative to transplantation was also discharged home, one patient died and one is waiting to be discharged.

The HeartMate II LVAS

This device, developed jointly by Nimbus Inc. and the University of Pittsburgh [7], is an electromagnetically driven axial flow rotary blood pump. Measuring 2.5 cm in diameter and 4 cm in length, and weighing 370 g, this titanium device incorporates a high speed rotor whose integral vanes create a blood vortex that accelerates the blood using axial and centrifugal force. Operating at up to 12,000 rpm, the device is capable of producing over 10 L/min flow. One feature of the pump is that a decrease in pressure difference between the pump inlet and outlet results in a significant increase in flow. Thus, at any set speed of the pump, small pulsations from the left ventricle will be magnified, resulting in pulsatile blood flow amplifications. The textured surface – of the sintered titanium technology used in the HeartMate I devices to reduce thromboembolic risk was also used in all blood-contacting surfaces of the HeartMate II. The device is implanted in a small preperitoneal pocket, draining blood from the left ventricular apex via a rigid inlet cannula and ejecting into the aortic root via an outflow graft [Figure 2]. Power and control of the pump from wearable batteries and system driver are delivered through a thin electrical cable that exits the skin on the right abdomen [Figure 2]. An already animal-tested transcutaneous energy transmission system will eliminate the need for perforating the skin and will minimize the risk of infection in the future.

We performed the first human implant of the HeartMate II LVAS at the Sheba Medical Center in Israel in July 2000 [7]. This implant marked the start of a multinational study aimed at evaluating the efficacy and safety of the device in patients at risk of imminent death from refractory end-stage heart failure. A 64 year old man suffering from end-stage heart failure resulting from ischemic cardiomyopathy was implanted with the device because a prostate malignancy precluded heart transplantation. The device functioned flawlessly for 4 days before the patient succumbed to irreversible pulmonary hypertension that caused severe right-heart failure. An additional five patients were since implanted in Europe. Two implantations of the device at the Heart and Diabetes Center in Bad Oeynhausen, Germany, were also unsuccessful and terminated with the patients' death due to multiorgan failure or sudden cardiac arrest. One patient was transplanted after 33 days, and one patient who was implanted by Prof. Magdi Yacoub at the Harefield Hospital in England recovered the use of his natural heart after 156 days of support on the device; the sixth patient is still ongoing.

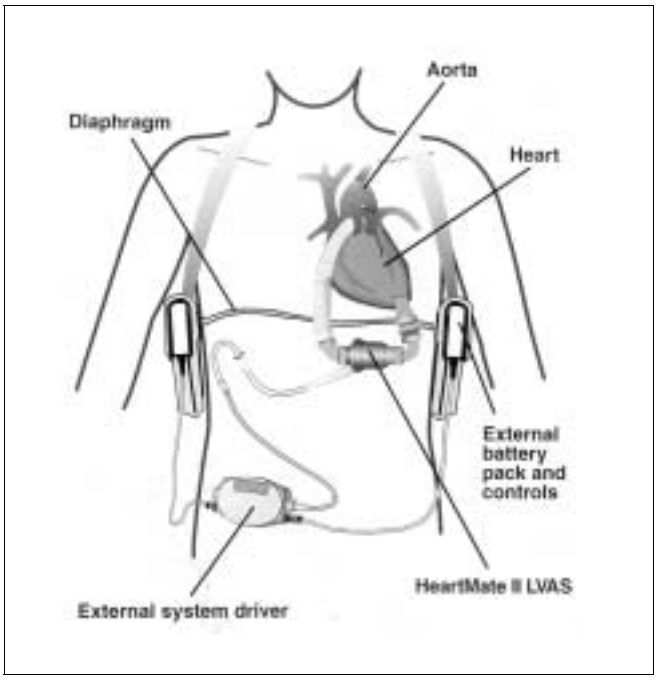

Figure 2. Schematic illustration of the implanted HeartMate II LVAS. (With permission from Thermo Cardiosystems, Inc., Wobourn, MA)

The MicroMed-DeBakey VAD

This axial flow pump measures 3.5 cm in diameter and 7.6 cm in length, and weighs 93 g. An electromagnetic motor stator drives the six-bladed impeller, which is housed within a titanium tube, at speeds of 7,500–12,500 rpm. An inflow cannula connects the device to the left ventricular apex and a flow probe-fitted Dacron outflow graft connects the pump to the ascending aorta [Figure 3]. The electric cable, which traverses the skin at the right lower abdomen, connects the pump to an external wearable controller that provides energy to the device from the clinical data acquisition system or

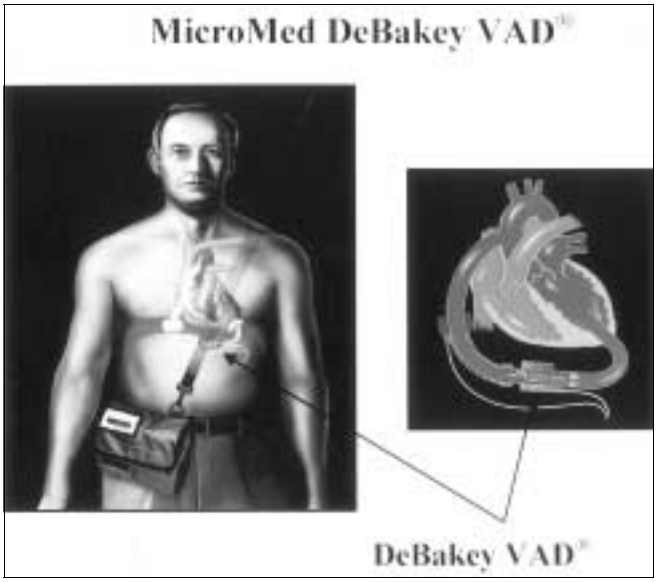

Figure 3. Schematic illustration of the implanted Micromed-DeBakey VAD. (With permission from MicroMed Technology, Inc., Houston, TX)

batteries [Figure 3]. The CDAS receives measurements of pump speed, flow, power and current signals from the controller and is also used to adjust pump speed while the patient is in the hospital. The MicroMed-DeBakey VAD is implanted via a mid-sternotomy incision, in a preperitoneal abdominal pocket.

As reported by Noon [8], one of the device's co-inventors, as of September 2000 a total of 51 patients have been implanted with the MicroMed-DeBakey VAD in 12 European centers and at the Methodist Hospital in Houston, Texas. All implants were done as a bridge to transplantation. Fourteen patients have undergone successful transplantations. The principal complication has been late bleeding, with most events occurring more than 5 days after the implantation. Some incidences of hemolysis have also been observed, but there have been no device-related infections. In a small number of patients, a pump thrombus or embolus has affected pump function, requiring pump exchange or outflow graft ligation to prevent regurgitant flow.

The LionHeart LVAS

The LionHeart completely implanted LVAS, developed at the Penn State College of Medicine, is designed for use as long-term destination therapy for patients with progressive, irreversible, end-stage congestive heart failure for which heart transplantation is not an option [9]. It is not intended as a bridge to transplant or as a bridge to recovery of ventricular function. The electrically powered blood pump is implanted in the pre-peritoneal space, beneath the left costal margin. The blood pump features a motor, a pusher-plate mechanism, a smooth blood sac, and two tilting disk valves for unidirectional flow. The blood pump is connected to the native circulation via a left ventricular apical inlet and an aortic outlet cannula. The current percutaneous drive lines and external tethers are eliminated through the use of a transcutaneous energy transmission system, implanted subcutaneously under the anterior chest wall, which delivers power by induction from wearable batteries. Rechargeable implanted batteries allow patients to be untethered for approximately 20 minutes. An implantable motor controller is placed under the anterior abdominal wall in the preperitoneal space, beneath the right costal margin. Finally, a compliance chamber, approachable by an access port, serves as a gas-volume accumulator, providing gas to evacuated chambers of the blood pump during its operation, eliminating the need for a vent tube. The compliance chamber, which is placed in the left pleural space, is periodically charged with room air via the access port, which is passed through the intercostal space and located in the subcutaneous tissue over the left anterior chest wall.

The first human implant of the LionHeart LVAS was performed in October 1999 at the Heart and Diabetes Center in Bad Oeynhausen, Germany. This patient had a stroke early on, but has recovered and is living at home with the device continuing to function as expected. As of January 2001, 10 patients have been implanted with the device as part of an ongoing European clinical investigation to demonstrate the safety and performance of the device. Six patients have expired of multiorgan failure and four are at home. There has not been any significant pump or controller dysfunction (Private communication, courtesy of Benjamin C. Sun, MD, Penn State University).

The Penn State University total artificial heart (BeneCor)

This total artifical heart is an electrically driven pump with no percutaneous connections. The pump's titanium casing encloses two polyurethane blood sacs separated by a central energy converter, including a motor that actuates a roller screw with pusher plates at either end. The pusher plate-induced mechanical compression of the blood sacs against the rigid housing results in alternate emptying of the blood sacs. Unidirectional blood flow is maintained by Delrin monostrut valves, located at the inlet and outlet connectors of each pumping chamber. Implantable controller, rechargeable batteries, and telemetry hardware, all encased in a single electronics canister, as well as an implantable compliance chamber complete the device components. Power is supplied by a transcutaneous energy transmission system from externally wearable batteries. The implanted batteries can provide up to 45 minutes of totally untethered activity. The Penn State University device is implanted in an orthotopic position following total cardiectomy, which leaves behind the native atria and the great vessels [10]. Animal implants and durability studies are ongoing, with clinical implants planned to commence in 2002.

The AbioCor total artificial heart

The AbioCor total artificial heart is a fully implantable device, consisting of two blood sacs encased within a titanium housing, separated by an electric motor driving the centrifugal pumping system [Figure 4] [11]. The blood sacs, as well as the four unidirectional valves incorporated in the device, are made of Angioflex, a proprietary Abiomed material. An internal controller regulates power delivered to the prosthetic heart. Without penetrating the skin, an external unit transmits power to the internal unit using a transcutaneous energy transmission system. A

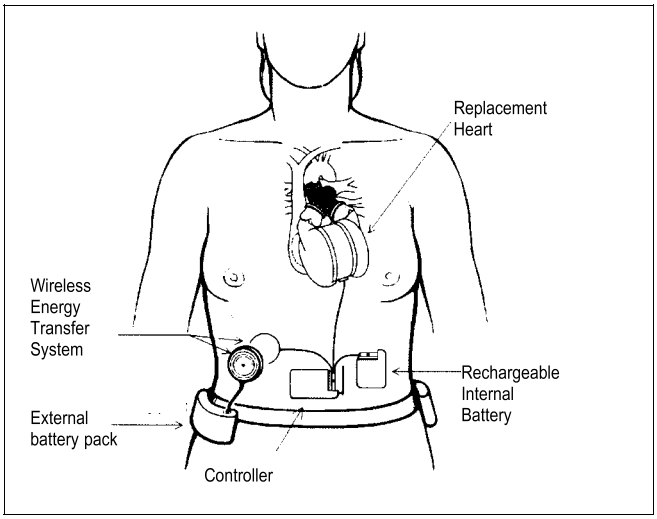

Figure 4. The AbioCor fully implantable total artificial heart. (With permission from Abiomed, Danvers, MA)

CDAS = clinical data acquisition system

rechargeable internal battery will allow the patient to be completely free of the external power transmission unit for some time. The system is designed to increase or decrease its pump rate in response to the body's needs.

The first human implant of the AbioCor total artificial heart was performed on 2 July 2001 at the Jewish Hospital in Louisville, Kentucky. The patient, a 59 year old male, who was deteriorating rapidly from severe end-stage ischemic heart disease, was implanted with the device after being considered unsuitable for heart transplantation. The highly publicized patient who was living with the AbioCor device, making good progress overall, enjoying a relatively high quality of life, making frequent trips outside the hospital and beginning to improve his ability to eat, suffered a major stroke 135 days after the implantation. Five months after the implantation the patient died of complications due to gastrointestinal bleeding. To date, another five patients, all of them non-transplant candidates, were implanted with the AbioCor total artificial heart. Two of them are alive 154 and 100 days after implantation. One of these two patients was discharged 70 days after the implantation and was recently readmitted due to breathing difficulties and was put back on a ventilator, and the other is still hospitalized although reported to be making good progress in his recovery with frequent daily trips outside the hospital. One patient died intraoperatively secondary to uncontrolled bleeding due to coagulopathy, One patient survived 5 months in hospital and died following a major stroke, and one patient died 56 days after implantation due to multiorgan failure.

The HeartSaver VAD

The HeartSaver VAD, developed at the University of Ottawa Heart Institute, is a unique heart assist device that will be fully implantable in the left hemithorax for long-term use. The device's unique key features include the incorporation of the controller and the hydraulic fluid volume displacement chamber into the implanted unit, which also includes the blood chamber and the electrohydraulic axial flow pump. The device will be remotely powered, monitored and controlled using the transcutaneous energy transfer and biotelemetry technologies. The device has a unique shape that follows the contour of the chest wall and connects via short conduits, equipped with porcine valves, to the apex of the left ventricle and to the ascending aorta. Following the successful long-term *in vitro* and *in vivo* studies in calves [12], the initial clinical use of the HeartSaver VAD is planned to commence in 2002.

Summary

Since 1963 when the first intrathoracic LVAD was implanted in a patient [13], major technological advances in the field of mechanical alternatives to the failing heart have been made by combined efforts of the medical and industrial communities. Although heart transplantation is currently still the preferred choice for patients with end-stage cardiomyopathy, the supply of human donor hearts will continue to fall far short of the demand. Moreover, with xenotransplantation still waiting to be proved as a safe and suitable solution for human use, there is a definite need for long-term mechanical circulatory support. As smaller and more durable cardiac assist devices and total artificial hearts become available, with a decreased potential for thromboembolism and lack of need for percutaneous drive lines, the number of patients who will benefit from permanent circulatory support should increase considerably.

L.Frank Baum predicted this future in *The Wizard of Oz* when he wrote:

Wizard of Oz:
As for you, my galvanized friend – you want a heart;
You don't know how lucky you are not to have one.
Hearts will never be practical until they can be made unbreakable.

Tin Man:
But I – I still want one.

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