

Ventricular Assist Devices – Evolution of Surgical Heart Failure Treatment

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Abstract

End-stage heart failure represents a substantial worldwide problem for the healthcare system. Despite significant improvements (medical heart failure treatment, implantable cardioverters, cardiac resynchronisation devices), long-term survival and quality of life of these patients remains poor. Heart transplantation has been an effective therapy for terminal heart failure, but it remains limited by an increasing shortage of available donor organs along with strict criteria defining acceptable recipients. For the last 50 years, mechanical alternatives to support the circulation have been investigated; however, during the early years device development has been marked in general by slow progress. However, in the past two decades, the technology has evolved dramatically. The purpose of this review is to give a short summary on the evolution of ventricular assist device (VAD) therapy and to give perspectives for future treatment of heart failure.

Keywords

Ventricular assist device, mechanical circulatory support, heart failure

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History of Mechanical Circulatory Support

The first reported clinical use of a left ventricular assist device (LVAD) was by Liotta and Crawford in 1963. Via a left thoracotomy, an intracorporeal pneumatically driven pump was implanted using left atrial inflow and descending thoracic aortic outflow. Despite the successful implantation, the patient died within a short period of time after the surgery.¹ A few years later, De-Bakey implanted a paracorporeal pneumatic LVAD to support the left ventricle of a woman with left ventricular failure after prior cardiac surgery. The patient recovered and could be weaned from the device successfully.^{2,3} The first clinical use of a total artificial heart (TAH) was reported in 1969 by Cooley. The Dacron® and Silastic® pneumatic device was placed as a bridge to transplant (BTT) in a patient who could not be weaned from cardiopulmonary bypass. The procedure was successful, heart transplantation could be performed 32 hours after the implantation, but the patient died due to pneumonia.⁴ Over the subsequent 20 years results after cardiac transplantation improved to modern standards, therefore mechanical circulatory support was not at the centre of investigation and clinical use was scarce, but shortage of donor organs became an increasing problem.^{5,6}

Concerning TAH development, the Jarvik/CardioWest™ device has to be mentioned. This device would ultimately led to the development of today's SynCardia TAH, which led to extreme publicity but limited clinical use.⁷

Ventricular assist devices (VADs) were initially primarily used as bridge to recovery (BTR) for patients unable to wean from cardiopulmonary bypass despite inotropic support and intra-aortic Balloon pump (IABP) or as BTT.^{7,8} A milestone in VAD development was the Thoratec® VAD, engineered at Penn State University. Despite the fact that this

pneumatically driven pump has undergone several modifications over the years, in its basic structure it is still in clinical use today. McBride et al., published a series of BTT and BTR patients supported on the pneumatic Thoratec device. Major adverse events were: bleeding complications (31–45 %), thromboembolic events (8 %) and device-related infection (18 %). Twelve of 44 patients recovered and 39 of 67 were successfully bridged to heart transplantation (HTx).⁹ The Thoratec paracorporeal VAD (PVAD) is the direct descendant of this device, and is currently approved as a BTT or BTR (see *Figure 1*).

The more contemporary Levitronix® CentriMag® is an extracorporeal device approved for midterm support for patients in cardiogenic shock as a bridge to decision (BTD) (see *Figure 2*).

It is also approved for use as a right ventricular assist device (RVAD) for up to 30 days of support. In contrast to the PVAD the CentriMag is a continuous flow centrifugal pump with a magnetically levitated rotor, is preload dependent and afterload sensitive and can deliver flows of nearly 10 litres per minute. The advantages of magnetic levitation technology in blood pumps are improved durability and minimisation of blood trauma.¹⁰ The CentriMag system has provided satisfying results over the past years: the Utah Artificial Heart Program reported 83 patients (2004 to 2009), 30 RVAD, eight LVAD, 25 biventricular assist device (BiVAD) and 30 patients supported with CentriMag-driven venoarterial extracorporeal membrane oxygenation (ECMO). Survival ranged from 63 % in the LVAD group to 30 % in the veno-arterial (V-A) ECMO group. There were no device failures and bleeding related to anticoagulation was the most common complication.¹⁰

Major concerns on the mentioned devices were reduced quality of life especially due to the fact that these devices were extracorporeal.

With improvements in technology the pumps became smaller and the era of fully implantable devices began.

Devices in this category have a driveline, which connects the intracorporeal device to either an external electrical power supply or a pneumatic driver. A broad variety of devices in this category were developed: The HeartMate® XVE, the HeartMate II (HMII), Micromed DeBakey, Jarvik 2000 FlowMaker®, HeartWare VAD (HVAD), DuraHeart and Berlin Heart INCOR. In the following years, long-term implantable LVADs have been studied and approved for BTT and destination therapy (DT) indications. Device development has progressed in a relatively orderly fashion in terms of both strategy for use and pump mechanism. Initially, pumps were conceived as a method of rescue and support to recovery. As experience grew and reliability improved implementation in a BTT scheme became common. Naturally, as data were acquired to support longer-term assistance and the devices themselves became more durable in general, DT implantation accelerated. As pulsatility was felt to be critical for organ recovery, initial LVAD designs featured pulsatile flow. Initial pulsatile devices were pneumatically driven and later electrically driven. Progress in the design and testing of newer continuous flow pumps was relatively rapid. Studies confirmed that pulsatile aortic flow was not required to resuscitate and maintain organ function in patients with end-stage heart failure.¹¹⁻¹⁴ In addition, continuous flow LVADs were shown to provide significant benefits in objective quality of life and functional capacity.^{15,16}

Current Clinically Important Second Generation Devices

The Thoratec HMII (see *Figure 3*) is the most successful of the second generation LVAD cohort, with over 10,000 patients supported worldwide.¹⁷⁻¹⁹ It is a rotary continuous axial flow pump with an external electrical power source. Inflow cannula is inserted apically and an outflow graft anastomosed to the ascending aorta (in most of the cases) or alternatively to the subclavian artery as bailout strategy. The pump is preload dependent and afterload sensitive, runs in a fixed speed mode and is capable of up to 10 litres per minute flow at a mean aortic pressure of 100 mm mercury (Hg). The only moving part is the axial rotor, which spins on ruby ball-and-cup bearings, which are continuously washed by the flow stream. It is smaller and lighter than the HeartMate I (HMI) offering the possibility of fully intrathoracic implantation and implantations even in small adults. Recently, even minimal invasive approaches for both pump exchange and pump implantation over a subcostal incision have been described. The HMII is typically implanted into a properly sized preperitoneal pocket in the left subcostal region and utilises a driveline, which generally exits on the upper abdomen. The HMII is Food and Drug Administration (FDA) approved for both BTT and DT and has proven to be safe and effective. However, in the US the device has received approval for DT only recently, while in Europe implantation of the HMII for DT indication has already been performed for several years. The HMII BTT pivotal trial enrolled 133 patients at 26 centres in the US between March 2005 and May 2006.²⁰ Patients were listed for transplantation as either United Network for Organ Sharing (UNOS) status IA or IB, and all had New York Heart Association (NYHA) class IV symptoms. Twenty-five percent were receiving more than one inotrope and 41 % were supported by an IABP. Seventy-five percent of patients reached the primary endpoint (number of patients who either survived to transplant, recovered and survived explant or were still alive on device) at 180 days. Fifty-six patients were transplanted, with an 80 % one-year survival. One

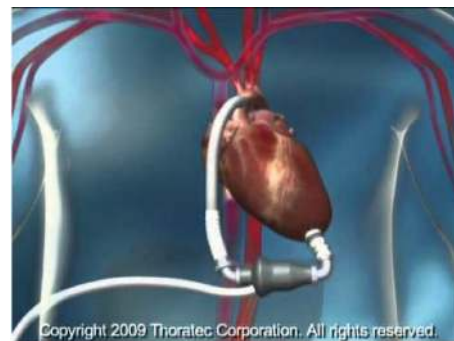
Figure 1: Thoratec Paracorporeal Ventricular Assist Device Ventricle



Figure 2: CentriMag System



Figure 3: HeartMate II



patient recovered and had the device explanted. Twenty-five patients died before 180 days (19 %). Seventy-five percent of patients were discharged after LVAD implant; the median length of stay was 25 days. Adverse events included stroke in 11 patients (8 %), five of which occurred within the first 48 hours, device-related infection

Figure 4: HeartWare Ventricular Assist Device

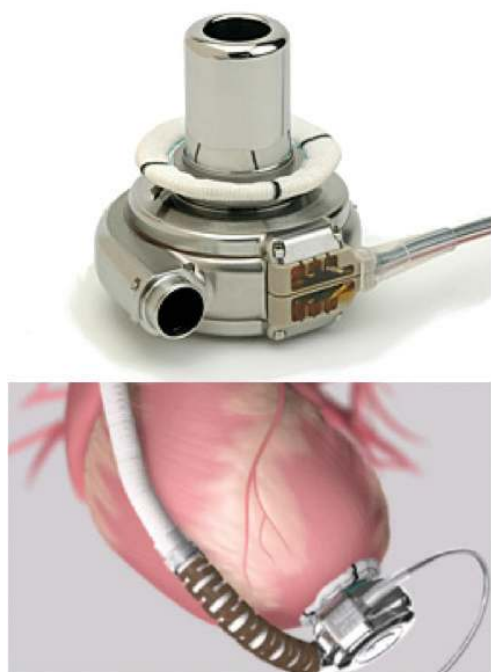


Figure 5: HeartMate III



(14 %), bleeding requiring surgery (31 %) and pump thrombosis in two patients. There were no device failures, and improvements in quality of life as well as functional capacity were significant.

Survival of patients still on VAD support was 72 % at three years. Main complications were bleeding requiring surgical re-intervention in 26 %, driveline/pump infections in 16 %, right ventricular (RV) dysfunction in 13 % and RV failure requiring a RVAD in 6 %, 5 % had ischaemic stroke and 3 % haemorrhagic stroke. Four pumps have been removed due to thrombus. Likewise to the initial study, quality of life and functional capacity were significantly improved. The HMII was approved for BTT on the basis of the results reported above. Post-approval market analysis as required by the FDA was published in 2011. Implantation of the now commercially available HMII allowed the data to be registered by the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), and the comparison group for this study was an INTERMACS cohort of 169 patients receiving another commercially available LVAD for BTT.²¹ The comparison group contained 135 patients with the Thoratec HeartMate XVE and 34 patients with the Thoratec IVAD, both pulsatile pumps. Ninety percent of the HMII group versus 80 % of the comparison group reached survival to transplant, survival on support or survival after device explant at six months. Overall, 12 months survival was 85 % in the

HMII group versus 70 % in the comparison group. In-hospital survival in the HMII group was significantly better at 94 % compared with the comparison group at 85 %. Ninety-two percent of the HMII patients were discharged versus 75 % of the comparison group.

Adverse events in the HMII included bleeding (21.0 %), device infection (20.2 %), stroke (6.5 %), RV failure (15.0 %) and device replacement (1.2 %). The important aspects of this trial were that it confirmed the good results seen in previous studies, even in an uncontrolled setting, and it suggested that the morbidity and mortality associated with HMII implantation and support are decreasing with time. The encouraging device performance in the BTT pivotal trial resulted in FDA approval for the DT indication.²² In a separate DT trial, 38 centres in the US randomised patients 2:1 to receive either the HMII or the HeartMate XVE. Thirty-three percent of the HMII versus 41 % of the HeartMate XVE patients died within two years. In the HMII group stroke occurred in 11 % and pump replacement in 10 % compared with 36 % and 12 %, respectively in the HeartMate XVE group. The HeartMate XVE replacements were required for bearing wear, valve deterioration or infection, while broken percutaneous leads were the cause of the majority of the HMII replacements. Actuarial survival rates at one and two years for the HMII patients were 68 % and 58 % compared with 55 % and 24 % in the HeartMate XVE patients. This trial showed improved survival and complication rates in advanced heart failure patients supported with the HMII continuous flow LVAD compared with those supported with the pulsatile HeartMate XVE.

Very low rates of pump thrombosis of the HMII has been advocated as a major advantage of the system also in comparison with other contemporary devices. However, recently a report came out showing an unexpected sudden increase in rates of pump thrombosis in HMII patients.²³ It remains a matter of debate what is causing this increase (changes in anticoagulation management, variability of implantation technique, pump-related factors, patient-related factors, etc.) and it is not clear if this increase in pump thrombosis is only temporary and will return to normal rates again. Nevertheless special attention has to be paid to this phenomenon.

The HeartWare® left ventricular assist system (LVAS) is an advanced continuous flow device, which is approved in Europe and recently for BTT indication in the US (see *Figure 4*).²⁴

This centrifugal pump utilises an innovative combination of passive magnetic levitation and hydrodynamic suspension to eliminate any contact between the impeller and pump housing. There are no mechanical bearings. The HeartWare is small and designed for completely intrapericardial implantation, with inflow from the left ventricular (LV) apex and outflow via a graft to the ascending aorta (HeartWare International Inc, Framingham, MA, US).⁷ Like other continuous flow pumps it is preload dependent and afterload sensitive, operates at a fixed speed mode and is capable of delivering up to 10 litres per minute. Results of HeartWare trials have been encouraging. In a BTT evaluation in 50 European patients six and 24 months survival to orthotopic heart transplantation (OHT), recovery or ongoing LVAD support was 90 % and 79 %, respectively. Nine deaths were observed: three cases of sepsis, three multiple organ failures and three strokes. RV failure was seen in six cases. There was an 18 % incidence of device-related infection. (mainly driveline related) Seven devices were replaced, two for complications related to the hydrodynamic suspension mechanism and four for pump thrombus.

Anticoagulation was adjusted for an international normalised ratio (INR) of 2.5–3.5.¹⁶ Action in Diabetes and Vascular Disease: Preterax and Diamicon MR Controlled Evaluation (ADVANCE) is a BTT trial performed at 30 American centres from 2008 to 2010 and includes 140 patients in the treatment group with end-stage heart failure listed for cardiac transplant. Results in these patients were compared with 499 patient controls from INTERMACS, who had received a LVAD as BTT during the same time period. The primary outcome was survival on the original device, survival to OHT or recovery to explant at 180 days. Success was achieved in 92.0 % of the HeartWare group versus 90.1 % of the controls. Survival at 180 days and one-year in the HeartWare group was 94.0 % and 90.6 % versus 90.2 % and 85.7 % in the controls. Adverse events included bleeding requiring surgery (15.0 %), driveline infection (10.7 %), stroke (10.0 %), RV failure (22.0 %) and pump thrombus requiring replacement (3.0 %).²⁵ Follow-up data was presented at the 2011 meeting of the International Society for Heart and Lung Transplantation (ISHLT) and included 110 additional patients approved by the FDA on a continued access protocol (CAP). The same inclusion criteria were used but the CAP patients, based on INTERMACS classification, had more advanced heart failure. Adverse events among the total 250 patient study group were as follows: bleeding requiring surgery 9.2 %, gastrointestinal bleeding 15.6 %, ischaemic stroke 7.2 %, haemorrhagic stroke 3.2 %, driveline infections 11.6 %, RV failure 19.6 % and death by 180 days 5.0 %. Sixteen pumps developed thrombus (6.4 %), 11 were exchanged and five were treated with intracavitary tissue plasminogen activator (tPA). Seventy-eight patients were transplanted with a 93 % 180 day post-transplant survival.²⁶ A HeartWare DT trial, 'Evaluation of the HeartWare Ventricular Assist System for Destination Therapy of Advanced Heart Failure (ENDURANCE)', is currently accruing patients in the US. In the US the HeartWare system is currently only approved for BTT indication, FDA approval for DT is ongoing. In Europe the HVAD is already in use for BTT as well as for DT indication.

There is some evidence that the rate of pump thrombosis in HVAD patients could be slightly higher in comparison with other contemporary devices. Therefore, some centres including our own, started to change the anticoagulation regimen. At our department we give HeartWare patients two doses of 100 mg aspirin daily in addition to the standard treatment with phenprocoumon with a target INR of 2.5.

One of the major advantages of the HeartWare device is its easy implantability and its small size. This facilitates even minimally invasive implantation of the HVAD over sternotomy sparing approaches.²⁷

Future Outlook – Third Generation Device HeartMate III, HeartWare MVAD® Driveline Free Devices

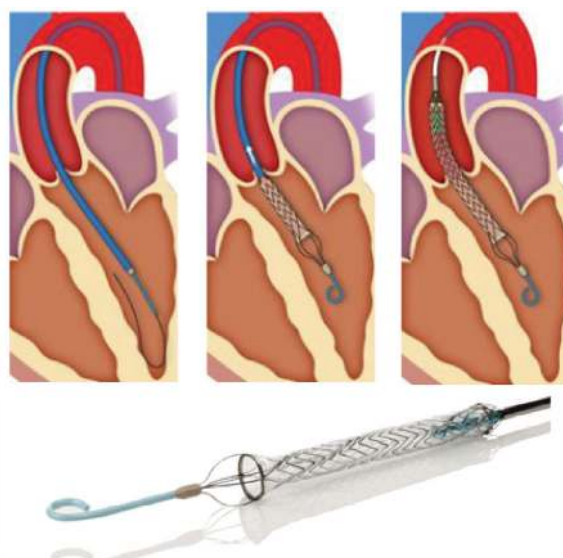
Currently the field of LVADs is undergoing an evolution towards smaller pumps with less blood trauma. Even catheter-based systems are on the horizon. The closer developments are the HeartMate III (HMIII) from Thoratec and the MVAD® from HeartWare.

The HMIII (see *Figure 5*), a compact LVAD, has been designed and fabricated, featuring a centrifugal pump with a magnetically levitated rotor. The pump has been optimised by *in vitro* testing to achieve a design point of 7 litres per minute (L/min) against 135 mm Hg at high hydrodynamic efficiency (30 %) and to be capable of up to 10 L/min under such a load. Furthermore, the pump has demonstrated no mechanical failures, low haemolysis (4–10 mg/dl plasma free haemoglobin [Hb]) and low thrombogenicity during six (40, 27, 59,

Figure 6: HeartWare MVAD®



Figure 7: Thoratec® Percutaneous Heart Pump



42, 27 and 49 day) *in vivo* bovine studies.^{28,29} Key features include the device's 'bearingless' (magnetic levitation) design, textured surfaces similar to the HeartMate XVE LVAD to reduce anticoagulation requirements and thromboembolism, a sensorless flow estimator and an induced pulse mode for achieving an increased level of pulsatility with continuous flow assistance. *In vitro* design verification testing is underway. Preclinical testing has been performed in calves demonstrating good *in vivo* performance at an average flow rate of 6 L/min (maximum: >11 L/min) and normal end-organ function and host response. Induced pulse mode demonstrated the ability to produce a physiological pulse pressure *in vivo*. Thirteen LVADs have achieved between 16 and 40 months of long-term *in vitro* reliability testing and will be continued until failure. Both percutaneous and fully implanted systems are in development, with a modular connection for upgrading without replacing the LVAD.³⁰

HeartWare's MVAD pump (see *Figure 6*) is a continuous axial flow pump, approximately one-third the size of the HVAD pump. The

MVAD pump is based on the same proprietary 'contactless' impeller suspension technology used in the HVAD pump, with its single moving part held in place through a combination of passive magnetic and hydrodynamic forces. *In vitro* and *in vivo* studies showed promising results. Within one *in vivo* study the MVAD pump was implanted in an ovine model (n=9) for 90 days. Results demonstrated the safety, reliability, haemocompatibility and biocompatibility of the MVAD pump. Nine animals were implanted for 90 ± 5 days. No complications occurred during surgical implantation. Seven of the nine animals survived until elective sacrifice. Each sheep that survived to the scheduled explant appeared physically normal, with no signs of cardiovascular or other organ compromise.³¹ Even a transapical implantation approach was tested.³² A new cannula configuration has been developed for transapical implantation, where the outflow cannula is positioned across the aortic valve. The two primary objectives for this feasibility study were to evaluate anatomic fit and surgical approach, and efficacy of the transapical MVAD configuration. Anatomic fit and surgical approach were demonstrated using human cadavers (n=4). Efficacy was demonstrated in acute (n=2) and chronic (n=1) bovine model experiments and assessed by improvements in haemodynamics, biocompatibility, flow dynamics and histopathology. Potential advantages of the MVAD pump include flow support in the same direction as the native ventricle, elimination of cardiopulmonary bypass and minimally invasive implantation.

One of the major obstacles of current LVAD therapy is driveline infections. While wireless technologies have become daily routine

in all our lives it is still not safe enough to run an LVAD. Eliminating of the driveline as a source of infection with VADs powered transcutaneously without wires running through an open wound will make the devices far safer. Currently all major LVAD companies and several researchers are working on this problem and experimental testing is being performed – however, it is not a clinical reality as yet.

Another approach to minimise implantation trauma is the percutaneous heart pump (PHP) by Thoratec (see *Figure 7*). This novel device is a fully catheter-based axial flow pump with a low profile consisting of a collapsible elastomeric impeller and nitinol cannula expandable to about 24 F. It is designed to deliver over 4 litres of flow. This device is currently under investigation. First-in-human use has already been reported.

Conclusion

Taken together it can be stated that VAD therapy has developed from a pioneer era towards a solid clinical option for an increasing number of patients. In times of decreasing numbers of available donor organs, mechanical circulatory support might not only be the future of surgical heart failure treatment but also its present. Nevertheless careful patient selection, meticulous surgical handling and post-operative treatment have to be performed at a very high level in order to improve clinical outcome. The future will tell us which devices will be the best for patients. Apart from that the increasing number of LVAD patients represents an increasing challenge for the social systems all over the world. ■

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