

OVERVIEW OF NEW MECHANICAL CIRCULATORY SUPPORT DEVICES

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Summary

Continuous-flow left-ventricular assist devices (LVADs) have emerged as the standard of care for advanced heart failure patients, who require long-term mechanical circulatory support. In this review, we describe in brief the basics of the development of various devices, both the old (pulsatile-flow) and the new (continuous-flow) devices. A clinical review of modern devices and their today's relevance are given in a brief outline.

Keywords: assist device; heart transplantation

THE HISTORY OF THE MECHANICAL SUPPORT DEVICE DEVELOPMENT

Akutsu and Kolff are credited with the first reports on a successful experimental implantation of a total artificial heart (TAH) in 1958. Cooley used the TAH as a temporary support device until transplantation in 1969. The heart performed 64 hours of support. In 1982, Jarvik-7 TAH was used by Dr. Jarvik as a first permanent heart support device. Copeland and colleagues performed the first planned TAH implant as a bridge-to-transplantation (BTT). After having undertaken several trials and multiple studies, the FDA gave an approval for HeartMate I as destination therapy (DT) in 2002; for TAH (CardioWest) in 2004; for HeartMate II as BTT in 2009; and for HeartMate II as DT in 2010 (Table 1) [1].

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THE REQUIREMENTS FOR A SUCCESSFUL MECHANICAL SUPPORT DEVICE

Circulatory support systems are being developed to take over the pumping functions of the natural heart. Blood components must operate continuously, without maintenance, for years. Mechanical components are necessarily small and must operate without failing under highly stressed conditions. The development of these highly sophisticated devices is very demanding, and only the most qualified engineers are included in the process. Technologic barriers for successful Mechanical Circulatory Support that must be overcome are listed in Table 2.

Table 2. Technologic barriers for successful Mechanical Circulatory Support

-
- Development of specific materials
 - Development of specific surfaces for blood-biomaterial interactions
 - Blood pump designs
 - Methods of storage of energy
-

Minimally six basic engineering disciplines are necessary for mechanical circulatory support system development (Table 3).

Table 3. Engineering disciplines necessary for mechanical circulatory support system development

-
- | | |
|--------------|-----------------------|
| • Mechanical | • Biomedical |
| • Electrical | • Manufacturing |
| • Software | • Quality engineering |
-

The criteria for the selection of materials for mechanical support device must be chosen based on specific requirements for circulatory support (Table 4). [2]

Table 4. Criteria for selection of materials for mechanical support device:

-
- Structural strength
 - Corrosion resistance
 - Surface properties
 - Toxicity levels
-

A major challenge for biomedical engineers is designing cost-effective long-term support, which should be small, efficient, quiet and capable of continuous use for ye-

ars of service without maintenance, while pumping blood in a hostile environment. The system should operate at least 5 to 10 years maintenance-free (Table 5).

The main objectives in mechanical circulatory support design are biocompatibility; reliability; functionality; cost. The components of biocompatibility are the avoidance of the mechanical compression of vital organ or tissues; the minimization of the need for surgical dissection; the avoidance of the migration of implanted elements; the avoidance of the damage to formed elements in blood; the avoidance of the pathologic stimulation of the coagulation system; the avoidance of heat and electrical damage to tissue; the anatomic compatibility; the avoidance of leaching toxic elements to the surrounding tissue [3,4].

Table 5. Special requirements for designing cost-effective long-term support:

- Small
 - Efficient
 - Quiet
 - Capable of continuous use for years of service without maintenance
 - Capable of pumping blood in a hostile environment
 - The system should operate at least 5 to 10 years maintenance-free
-

A SURVEY OF PULSATILE AND CONTINUOUS-FLOW PUMPS

The blood pressure and flow can be generated by either positive displacement (pulsatile) or rotary (turbodynamic continuous-flow) pumps (Figure 1). Positive displacement (pulsatile) pumps propel fluid (blood) by cyclically changing the internal volume of the pumping chamber, similar to the native heart, and by moving a particular volume of blood with each ejection. The output requirement for a pulsatile configuration is a flow rate 5 to 10 L/min at a mean pressure of 100 to 150mmHg, and a rate less than 120 beats per minute.

Rotary pumps (also designated as turbodynamic) are characterized by a rotating component that has one or more impellers, which are supported within the pump by a bearing; they are powered either through a spinning shaft or magnetic forces that act on magnets within the impeller. The assembly comprised of all the rotating elements is called the rotor of the pump.

The hydrodynamic performance of rotary pumps with axial-flow design is determined by the speed of the rotor and the pressure difference across the inlet and the outlet orifices of the pump. As the difference decreases, blood flow through the pump increases with the increased speed of the pump. The relationship between the flow, the pump speed and the pressure is shown in Figure 2.

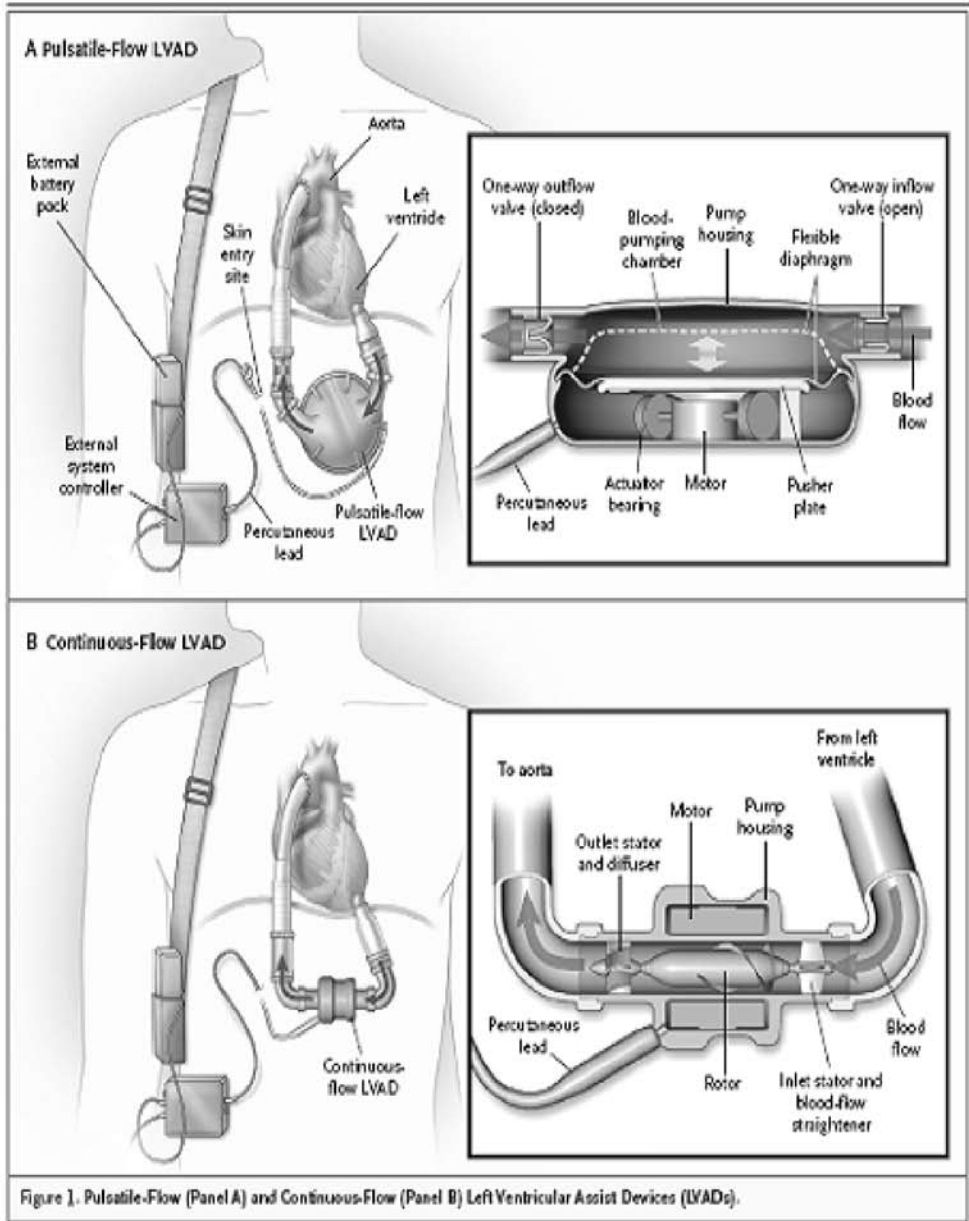


Fig. 1. Pulsatile and continuous-flow Left Ventricular Assist Devices (LVADs)

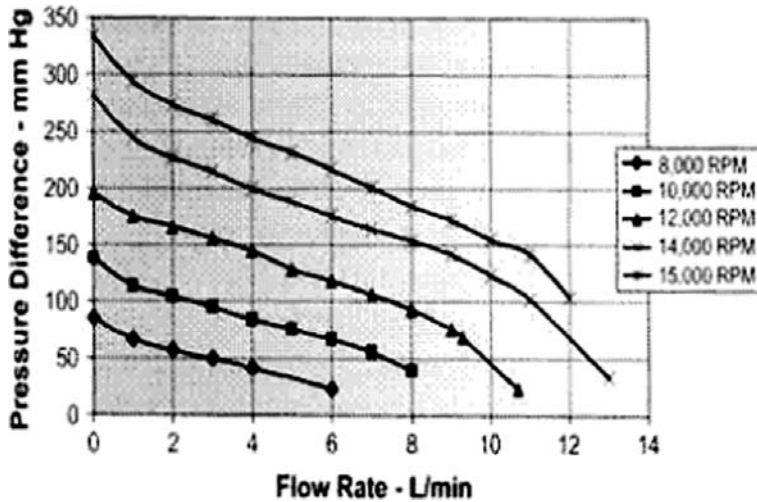


Fig. 2. The H-Q curve demonstrates the relationship between the pump speed (RPM) and the pressure difference across the inlet and outlet orifices of an axial-flow pump

Paracorporeal positive displacement ventricular assist device (PVAD) (Figure 3) has been implanted in over 3,000 patients. It produces a beat rate range of 40–110 beats per minute, and a flow rate of 1.3 to 7.2 L/min. It is suitable for use in smaller patients ($BSA > 0.73m^2$) due to its external position. Chronic warfarin anticoagulation (International normalized ratio INR 2.5–3.5 units) is required with the Thoratec pump. The PVAD is actuated pneumatically by the dual drive console for in-hospital use and portable TLC-II pneumatic driver for ambulatory use, either inside or outside the hospital. In 2003, the TLC-II was approved by the FDA for home discharge.

Out of 1,941 patients who had received PVAD, BVADs were used in 54 %, isolated LVADs in 34 %, and RVADs in 3 % of patients. For all patients who were receiving PVAD assistance, the mean

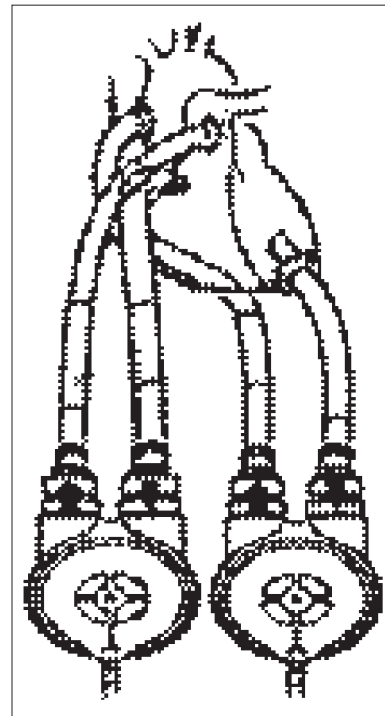


Fig. 3. Paracorporeal positive displacement ventricular assist device (PVAD)



Fig. 4. HeartMate XVE

period of support was 51.8 days, and the longest time that BVAD had been implanted was 3.3 years. Worldwide, survival from implant to transplantation or recovery was 64.8 % for patients who had BVAD, 56.6 % for patients with LVAD, and 31.2 % for patients with RVADs (Table 9). Five hundred patients had undergone cardiectomy and were supported with PVADs (BVAD 31.2 %; LVAD 42.8 %; RVAD 13.4 %; in combination with other pumps 12.6 %). Mean PVAD support duration was 21.9 days (the longest duration 340 days). The survival was 44.7 %.

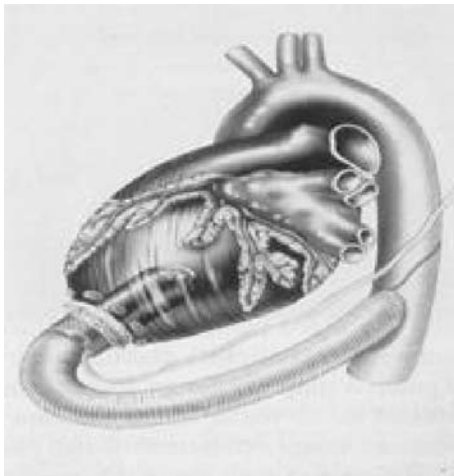


Fig. 5. Jarvik 2000 Left Ventricular Assist Device



Fig. 6. Micromed – DeBakey Left Ventricular Assist Device assembly

In the period between its first application in 1986 and 2001, nearly 5,000 patients had been supported with **HeartMate XVE** (Figure 4); the survival of patients until transplantation or recovery was 65 %. The HeartMate LVAD is a positive displacement pulsatile pump, which – unlike all the other such LVADs available – is unique, as its textured inner surface allows for circulatory assistance without anticoagulation other than antiplatelet agents [5,6].

The Jarvik 2000 Left Ventricular Assist Device is a miniature electrically powered axial-flow pump that provides continuous flow from the left ventricle to the descending thoracic aorta (Figure 5). It is placed within the left ventricle. The pump's operating range is between 8,000 and 12,000 rpm, and it can generate a flow of up to 8 L/min. It can be implanted through a left thoracotomy, median sternotomy, or extrathoracically. It requires the application of anticoagulation dicumarol therapy. In the period 2000–2005, the device has been implanted in 110 patients. The median period support with Jarvik 2000 was 148 ± 204 until BTT, and 477 ± 544 until DT. The technology is associated with minimal infections and other complications, and it offers an optimistic option for terminal and heart failure patients [7].

The Micromed – DeBakey Left Ventricular Assist Device (Figure 6) is a rotary pump of axial-flow design, which has



Fig. 7. Incor (Berlin Heart)

been developed in a collaborative effort of engineers from National Aeronautics and Space Administration (NASA), Dr. DeBakey and Dr. George Noon, MicroMed Technology in 1996. The support was first implanted clinically in Europe in 1998, and it received CE Mark approval.

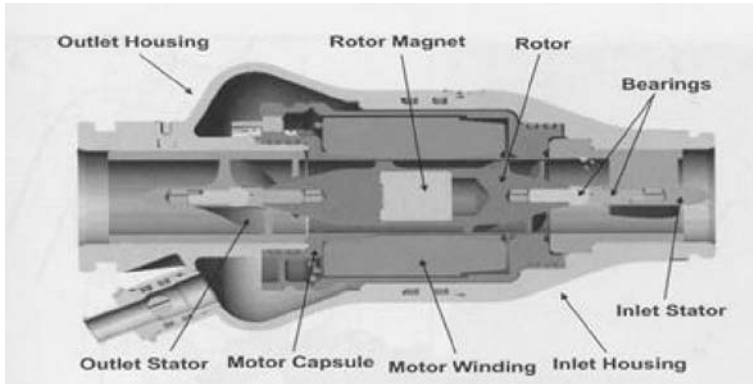


Fig. 8. Diagram of an internal view of the Heart Mate II pump

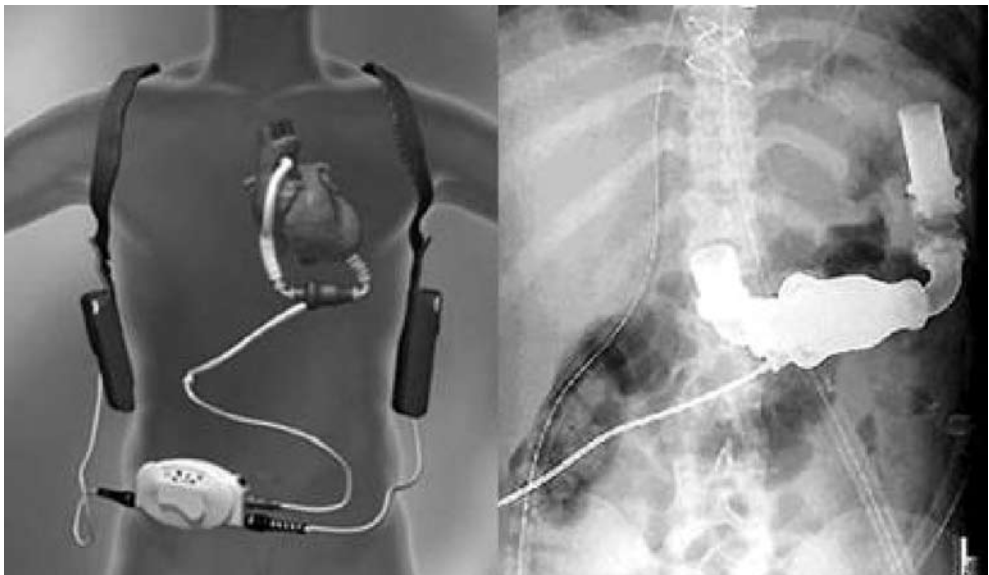


Fig. 9. (A) HeartMate II Schematic representation of the anatomic position and placement of Heart Mate II LVAS; (B) Chest radiograph demonstrating anatomic positioning of the Heart Mate II LVAS

The implantation of the device requires classical surgical techniques, and anti-coagulation therapy with dicumarol and aspirin/dicumarol is required. Monitoring with thromboelastography is recommended. Not many postoperative complications, like bleeding and thromboemboly, have been noted. Until 2005, the device had been implanted in 326 patients. The Micromed – DeBakey LVAD is specially recommended with pediatric patients [8].

The Incor (Berlin Heart) LVAD is a small axial-flow pump (Figure 7). The pump weighs 200g and generates flows up to 7L/min. It can be used with children (Excor Pediatric), and clinical BTT and DT trials have reported good initial results.

The HeartMate II left ventricular assist system (LVAS) is a rotary blood pump with axial-flow design, and it represents the second generation of implantable assist devices designed to be small, more reliable devices, suitable for long-term circulatory support. The major advantage of this device is its axial flow, which reduces its size by excluding the existence of a reservoir necessary for pulsatile flow.

HeartMate II blood pump has inlet and outlet cannula and percutaneous driveline, the HeartMate II system driver (computer controller) and power source (batteries). The power base unit has an alternative power source and battery charging system.

The internal parts of the Heartmate II pump are the titanium tube; the pump rotor; the rotor magnet; inlet and outlet stators with bearings and motor windings (Figure 8). The pump is designed for surgical implantation at the left costal margin below the heart and in the left pleural space (Figure 9). The inflow cannula exits in the left ventricle and is attached to the pump. The pump lays parallel to the diaphragm. The outflow cannula is tunneled back under the sternum to the ascending aorta. The percutaneous driveline is connected to an external system driver and a power source.

The anticoagulation regime is based on antiplatelet therapy (aspirin) and warfarin therapy (INR 2.0–3.0) at expected therapeutical range.

HeartMate II provides excellent support in the outpatient setting as well, with significant improvement in functional activity, ease of use and comfort due to the small size of the driveline. Excellent device reliability has also been noted.

It is at the moment used as both a device for patients awaiting heart transplantation and a device for patients meeting criteria for destination therapy.

Conclusion

Axial-flow implantable devices for mechanical circulatory support had shown a certain advantage as a bridge-to-transplantation and, for some patients, as destina-

tion therapy. Specialized centers with heart transplantation programs should develop a ventricular assist device program. Multidisciplinary teams participate in the evaluation and treatment of patients with the "end-stage" heart disease. Collecting all the relevant medical data, and monitoring the patients' health and – particularly – quality of life should represent the major part of the program.

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Sažetak

Pregled novijih uređaja za asistiranje srce i asistirano cirkulaciju

Uređaji za asistiranje srce i asistirano cirkulaciju postali su standard u liječenju pacijenata s kroničnim zatajenjem srca, kojima je neophodna dugoročna mehanička potpora srcu i cirkulaciji. U ovom članku ukratko su opisane povijest razvoja različitih starijih (pulsatilnih) i novijih (kontinuirani tok) uređaja te važnost kliničke primjene ovih modernih uređaja.

Ključne riječi: asistiranje srce; transplantacija srca

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