Mechanical blood pumps for cardiac assistance

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Abstract: Cardiac assist devices are classified into the traditional engineering categories of displacement and rotary pumps. Clinical use and indications of the various pump categories are outlined and a detailed description of currently available systems is given. The first part deals with extracorporeal as well as implantable ventricular assist devices (VAD) of the displacement type and is followed by a section on current developments in the field of total artificial hearts (TAH). The second part covers the rotary pump category from cardiopulmonary bypass applications to implantable systems, including specific design aspects of radial, diagonal, and axial pumps.

Key words: Congestive heart failure, ventricular assist device, total artificial heart, blood pumps.

INTRODUCTION

During the last decade, mechanical cardiac assist devices have gained widespread acceptance as therapeutic instruments for the treatment of cardiac insufficiency. Their primary task is to maintain blood circulation and, thus, to provide sufficient oxygen supply to organs and body tissue, if the natural heart is failing.

Modern development in mechanical circulatory assist devices has resulted in a large number of different pumping principles reaching from intraaortic balloon pumps (IABP) to the total artificial heart (TAH) according to specific clinical indications. Application times may vary between a few hours over days and weeks to chronic. Indication, timing of introduction and the selection of appropriate device are, therefore, as important as the specific pump design itself. Other issues taken for consideration are quality of life, reliability, and cost-effectiveness.

GENERAL BLOOD PUMP CLASSIFICATION

Generally, pumps can be classified into two main categories: displacement pumps and rotary pumps. The energy transfer in displacement pumps is characterized by periodic changes of a working space. In rotary pumps the energy transfer to the fluid is established by velocity changes within the impeller vanes.

Depending on impeller geometry, rotary blood pumps can be classified into three main categories: *axial, radial* (centrifugal), and *diagonal* (mixed flow) pumps.

Generally, rotary pumps are best suited for high flows up to 20 l/min at differential pressure lower than 500 mmHg. The radial design is most capable of producing high pressures and low flows, whereas axial pumps generate high flows at low pressure difference. Diagonal pumps, often referred to as mixed flow systems, tend to have the capability of high-generated pressures and high flows. This simple classification of potential pump designs must be put into perspective with pump size, taking into consideration that a 60-mm diameter centrifugal pump can naturally pump more fluid at significantly higher pressure than a 6 mm diameter axial pump.

Rotary blood pumps have a number of potential, physiological and technological advantages, yet they have their own hazards. They are characterized by low blood trauma, lower anticoagulation levels and, thus, less hemorrhage. Depending on pump design, priming volume may be low and surface modifications like heparin coating are possible. Due to their small size rotary pumps also allow implantability, transportability and integration into more complex devices. Potential hazards include bearing design related risks of thrombosis and hemolysis risks due to high shear rates in small gaps.

CLINICAL USE AND INDICATIONS

In the medical arena displacement type pumps (e.g. roller pumps) have been established over decades for cardiopulmonary bypass in heart–lung machines or in dialysis machines. Roller pumps are still predominant and are

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commonly used for several hours. Their main advantages are simplicity of operation, low cost of disposable tubing, and reliability, whereas disadvantages can be seen in blood damage and spallation.

Rotary blood pumps have several theoretical and practical advantages in ECC in terms of lower blood damage, smaller size, lower filling volume, better transportability, absence of spallation, less bleeding, less neurological complications and shorter stay in intensive care, among others. Also, the application times may be extended up to several days, if necessary. Therefore, for ECC applications, centrifugal pumps are gaining market share, especially in the USA.

Main cause of death after open heart surgery is an insufficiently low cardiac output, known as "low output syndrome (LOS)". Due to its relatively high blood damage (hemolysis) and the high doses of anticoagulation drugs, the use of roller pumps is usually limited to several hours. Therefore, LOS is subsequently treated with positive inotropic and vasoactive drugs as well as with IABP in extreme cases. Cardiogenic shock or cardiac fibrillation require more efficient means of cardiac support. For this purpose, continuous flow centrifugal, micro-axial, or pulsatile pneumatic displacement blood pumps are used.

The micro-axial pumps have the advantages of quick applicability and minimal invasiveness. They are introduced via the femoral artery and the inflow cannula is placed through the aortic valve into the left ventricle. The first axial-type blood pump, the so-called HEMOPUMP^{TM}, was an intra-arterial miniature circulatory support system. It is no longer available, but the newly developed IMPELLA^{TM} pumps are an excellent alternative.

End-stage heart failure is today the leading cause of death in the western hemisphere. In Europe an estimated number of 3.5 million people (US: 5 million) suffer from terminal cardiac failure. The natural history of these patients is comparable to patients with intestinal or breast cancer: 5 years after diagnosis only 50% of the patients are still alive. Every year 250,000 patients (EU) die with this primary diagnosis, and in 350,000 patients (EU) this disease is diagnosed *de novo*. Conservative treatment includes ACE-inhibitors, Angiotensin II-receptor blockers, ß-receptor blockers and diuretics. However, even under this modern neurohumoral therapy mortality rates are still high: 34% mortality after 4 years. Until recently, cardiac transplantation represented the only treatment with acceptable long-term survival in end-stage heart failure. However, donor shortage limits this therapeutic modality to less than thousand recipients per year all over Europe (US: 2500), compared to an estimate of at least 25,000 (EU, i.e. 10% of patients) candidates requiring hemodynamic assist.

Recently, mechanical cardiac support systems have reached the threshold of long-term applicability. European centers were among the first to apply these devices in clinical studies, and achieved excellent results. Nevertheless, the success varied widely between different centers with regards to selected patients and devices used, indicating the still non-standardized and complex interactions between the interdisciplinary contributors to this new therapeutic approach.

Today these pumps can provide a very acceptable quality of life for several months to a couple of years. However, the inherent risks of thromboembolism, infection and pump-related complications still require a lot of concomitant medical and technical support. Until now, most of these pumps are produced in the United States, but currently some European companies follow these developments and have achieved important advantages such as miniaturization down to catheter implantability and magnetic levitation. Furthermore, necessary monitoring and therapeutic interventions remain to be clarified and standardized.

Particularly rotary pumps, which are smaller in size, yield fewer infections, complement activation and potentially fewer thromboembolic complications than previous systems, may be eligible for extended use.

For medium-term bridging periods of a few days to a few months, pneumatic displacement blood pumps are successfully used for left-, right-, or bi-ventricular support. The pneumatically activated displacement pumps require thoracotomy and are connected between left atrium or left ventricular apex and aorta, or right atrium and pulmonary artery, respectively. Disadvantageous are the percutaneous blood cannulae that lead from the heart to the extracorporeal pumps. They present an inherent risk of infection at their skin penetration sites. Additionally, the patients have restricted mobility due to the bulky driving consoles.

If recovery of the heart cannot be established by means of the above systems, the emphasis of mechanical circulatory support shifts from recovery to bridging until a donor heart is available. For bridging periods ranging from several months up to 2 years, which may either be caused by the lack of a suitable donor heart or by a longer than anticipated recovery period, fully implantable electromechanical left ventricular assist devices (LVAD) are in clinical use since 1984 in the USA and since 1993 in Europe. Several systems are currently available: the Novacor^{TM} from World Heart Inc. (Portner 1984, Portner 1993), USA, the HeartMate I^{TM} from Thoratec Corporation, USA (Myers et al 1994) and the LionHeart^{TM} from Arrow International, USA (El-Banayosy et al 2003).

A second category of blood pumps, namely rotary pumps, has entered the clinical arena with growing numbers and success rates. The most prominent examples are currently the Micromed DeBakey^{TM} (DeBakey 1997), the Jarvik 2000^{TM} (Westaby et al 2002), the HeartMate II^{TM} (Griffith et al 2001), and the Berlin Heart Incor^{TM} (Thierry 2004). Other systems like the Terumo DuraHeart^{TM} (Nojiir et al 2000), the Australian VentrAssist^{TM} (Watterson et al 2000), the CorAide^{TM} (Gerhart et al 2002) and the HeartQuest^{TM} (Allaire et al 1999) are currently being tested in clinical studies.

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About 20–30% of the patients requiring long-term left ventricular support, also have right ventricular complications which may lead to complete cardiac failure (Kolff 1993). Also, in the presence of additional complications such as septum or valvular defects, singular left ventricular support is not sufficient (Cabrol et al 1990, Pierce 1992). In these cases, either transplantation or the use of a TAH is indicated.

An orthotopic TAH is defined as a blood pump that replaces the explanted natural heart in terms of anatomical placement and function. Until recently, only pneumatic TAHs with extracorporeal driving systems have been clinically used, the most prominent examples being the JARVIK 7™ and its successor, the CARDIOWEST™. They have been used as a bridge to transplant or, in a few cases, as permanent replacement systems (Copeland et al 1989). A novel electrohydraulic TAH, the Abiomed ABIOCOR™ is currently being tested in clinical studies. In May 2004, Abiomed announced its 14th implantation of the Abiocor system since the start of its clinical trial in July 2001.

ASSORTED INVENTORY OF EXISTING PUMP SYSTEMS AND CURRENT DEVELOPMENTS

Due to the large number of different pumps, which are already in clinical use or under development, the following section includes only an assortment of pumps selected under the criteria of clinical importance, technology, novelty and partly of personal bias. The collection of technical data for each of the listed pump systems was extremely difficult. Therefore, the data presented are neither complete nor consistent.

Displacement pumps

Novacor

The Novacor® left ventricular assist system (LVAS) (Figure 1) is an electromechanically driven pump (Portner 1984, Portner 1993), which is implanted within the abdominal space. The system is monitored by an electronic controller and powered by primary and reserve battery packs, worn on a belt around the waist or carried in a shoulder bag, or by a small bedside monitor. The controller is connected to the implanted pump by a percutaneous lead. The system is self-regulating, responding instantaneously to the recipient's circulatory demands. The Novacor® LVAS was designed primarily for long-term use.

In Europe, the device has unrestricted approval for use as bridge to recovery, bridge to transplant, and as alternative to transplant. It is commercially approved as a bridge to transplantation in the United States and Canada. There have been over 1500 Novacor® LVAS recipients worldwide.

HeartMate I

The HeartMate I LVAD (Myers et al 1994) (Figure 2) is indicated for use in adult patients both awaiting heart transplantation and for permanent application for those not eligible for transplantation. It is manufactured by Thoratec Corporation, and is utilized in over 100 medical centers in the United States. The pump dimensions are: 2 inches in thickness, 4 inches in diameter and weighs about 2.5 pounds. It contains an internal motor and a driveline, enabling electrical wires to exit through the patient's upper abdominal wall.

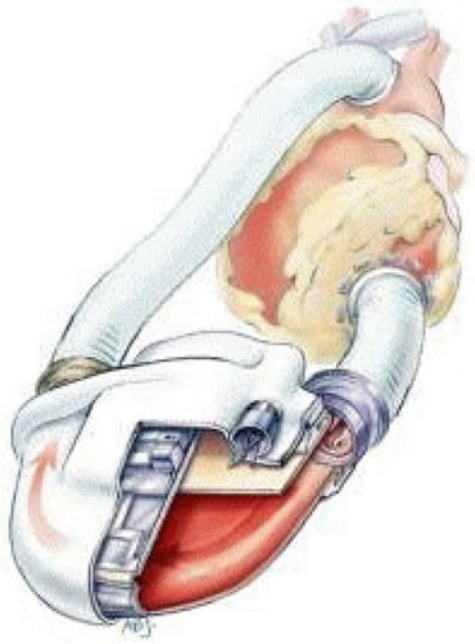

Figure 1 Novacor.

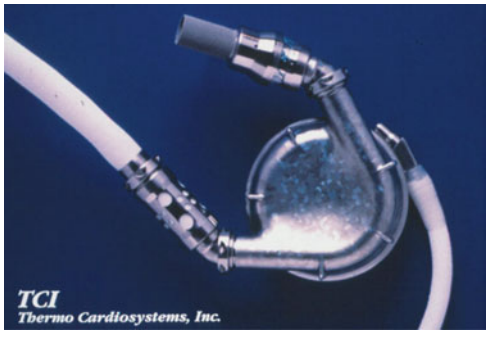

Figure 2 HeartMate I.

The HeartMate® system is FDA approved as a long-term permanent implant (destination therapy) for end-stage heart failure patients who are not eligible for heart transplantation. Although the HeartMate LVAS has been approved as a bridge to transplant since 1994 and used in more than 2300 patients worldwide, FDA approval of the HeartMate SNAP-VE marks the first time in history that a LVAD has been approved for permanent implantation.

Lionheart

The Arrow LionHeart™ (El-Banayosy et al 2003) (Figure 3) LVAS, manufactured by Arrow International, Inc., is designed to be used as a "destination therapy" for patients with progressive, irreversible, end-stage (Class IV)

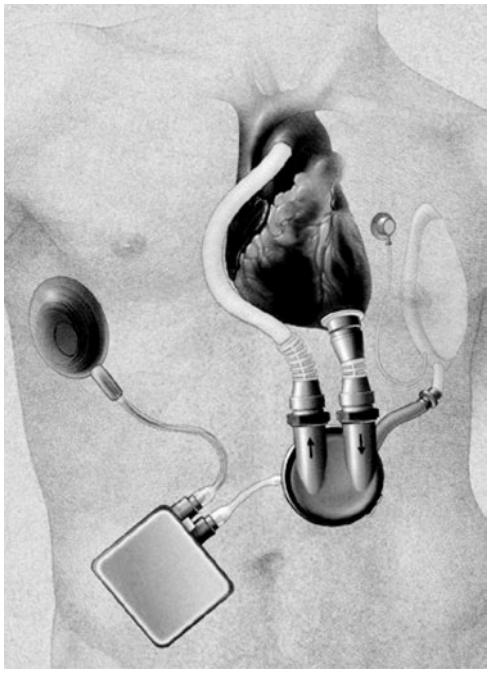

Figure 3 Lionheart.

congestive heart failure, for which heart transplantation is not an option. It is not intended as a bridge to transplant or as a bridge to recovery of ventricular function. Its fully implantable transcutaneous energy transmission system eliminates the currently required lines (drive and venting) through the skin of other commercially available VADs. This is expected to result in significant reduction in the risk of infection, improved mobility and enhanced quality of life, which represents a significant advance in mechanical circulatory assist technology. The combined weight of the implanted components is 3.2 pounds or 1.3 kg. The blood pump is electrically powered and is implanted in the pre-peritoneal space, beneath the left costal margin.

The LionHeart has been approved both in Europe and in the United States, and by mid-2004 26 patients have been implanted in Europe and 10 in the United States.

Abiocor™ TAH

The AbioCor™ implantable replacement heart (Dowling et al 2004) (Figure 4) is a fully implantable prosthetic system intended as a substitute for severely diseased human hearts in patients suffering from coronary heart disease or some form of end-stage congestive heart failure. After implantation, the device does not require any tubes or wires to pass through the skin. Power to drive the prosthetic heart is transmitted across the intact skin, avoiding skin penetration that may provide opportunities for infection. Each of the two pumps is capable of delivering more than 8 liters of blood per minute. An internal controller regulates power delivered to the prosthetic heart. A rechargeable internal battery allows the patient to be completely free from the external power transmission unit for some period of time monitored by the internal system. The AbioCor system is

Figure 4 Abiocor™ TAH.

designed to increase or decrease its pump rate in response to the body's needs. It also includes an active monitoring system that provides detailed performance feedback and alarms in the event of irregularities.

Through an initial clinical trial that began in July 2001, the AbioCor has so far been implanted in 14 patients (status May 2004) as a replacement heart. Candidates for the clinical trial are those who suffer from biventricular heart failure, not eligible for heart transplantation, nor can be helped by any other available therapy, and have a high probability of death in less than 30 days. ABIOMED has announced its intention to seek initial FDA market approval this year for the AbioCor to treat a defined subset of irreversible end-stage heart failure patients under a humanitarian device exemption.

Rotary pumps

(a) Axial pumps

Jarvik 2000. The Jarvik 2000 (Westaby et al 2002) (Figure 5) is an axial flow rotary blood pump. It is connected between the left ventricular apex and the descending or ascending aorta. The impeller is a neodymium-iron-boron magnet, which is housed inside a welded titanium shell. The impeller is supported by ceramic bearings. A small cable, which exits the body through the abdominal wall or is connected to the scull, delivers power to the pump. The normal operating range for the pump is 8000–12,000 rpm, which generates an average pump flow rate of 5 l/min.

The speed of the pump is controlled by an analog system controller. It can be manually adjusted in increments of 1000 rpm. The control unit monitors the pump function and the remaining power in the batteries. Audible and visual alerts notify the user of any problem.

Technical data: Diameter 25 mm, length 55 mm, weight 85 g, flow rate 5–6 l/min, rotational speed 8000–12,000 rpm, power requirement 7–10 W, blood immersed ceramic bearings.

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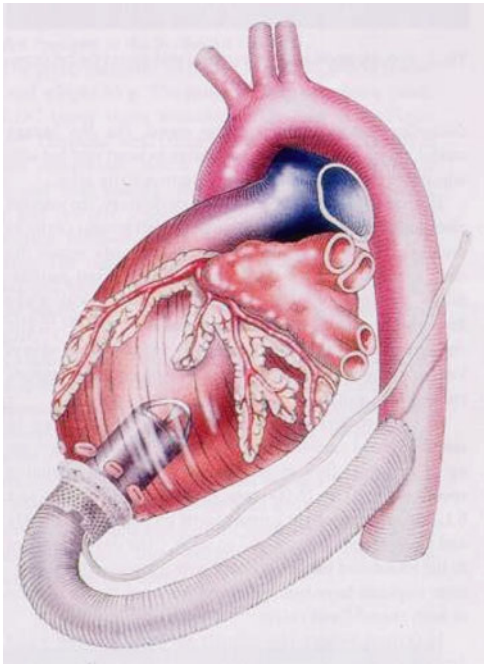

Figure 5 Jarvik 2000.

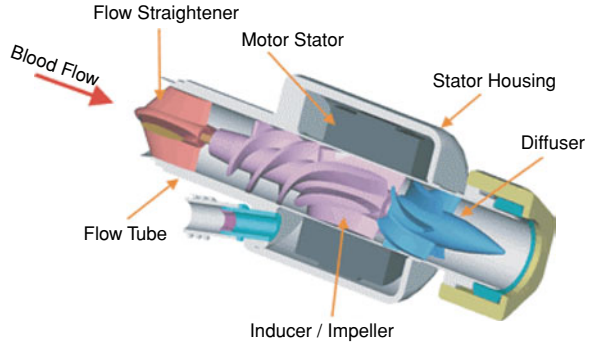

Figure 6 DeBakey VAD.

DeBakey VAD. The DeBakey VAD® (DeBakey 1997) (Figure 6) was developed by MicroMed Technology, Inc. in conjunction with Drs. Michael DeBakey, George Noon and NASA engineers. The DeBakey VAD® is a miniaturized axial continuous flow LVAD capable of fully supporting the left ventricle with over 10 liters of flow per minute. Its mechanical blood immersed bearings showed no significant wear or failures after 2 years of continuous operation. The pump is usually implanted by a median sternotomy. The titanium inflow cannula is inserted through a core in the left ventricular apex and the outflow graft is anastamosed to the ascending aorta.

The pump is attached to the controller, which monitors its functions, e.g., speed, current, power, battery status, and flow. The DeBakey VAD® is the only VAD with an integral flow meter. The entire blood contacting surface is coated with Carmeda®.

In August 2003, the DeBakey system has been implanted in its 200th patient. The DeBakey VAD® is CE marked and has received FDA approval (January 2004) for destination therapy clinical trial in the United States.

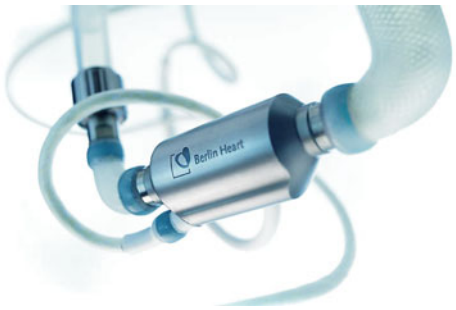

Figure 7 Incor®.

Technical data: Weight 95 g, flow rate 5–10 l/min, rotational speed 7500–12,000 rpm, power requirement 6 W, blood immersed ceramic bearings.

Incor®. The implantable LVAD Berlin Heart INCOR (Thierry 2004) (Figure 7) is an electrically powered axial pump with a percutaneous pump cable. The pump is placed in the thoracic cavity. The inflow cannula is anastomosed to the left ventricle and the outflow cannula to the ascending or descending aorta. The blood contact surfaces are coated by Carmeda® BioActive treatment. The pump impeller is suspended by wear-free magnetic bearings. Flow information is obtained from internal control signals, no additional flowmeter is requested.

As of June 2004, the system has been implanted in more than 120 patients in 20 different centers. The longest implantation period is more than 720 days and the average implantation period is 130 days. The cumulative experience with the device is more than 16,000 days. Clinical results are very encouraging.

Technical data: External diameter 30 mm, length 114 mm, mass 200 g, volume 60 cm^3, design point: 5 l/min at 8500 rpm against 100 mmHg, power requirements 1 W magnetic bearings, 2–4 W motor, 5 W electronics, magnetic bearings

Radial pumps

DuraHeart™. The DuraHeart™ (Nojiir et al 2000) (Figure 8) left ventricular assist system incorporates a three-dimensional magnetically levitated centrifugal pump. The primary system is composed of the implantable magnetically levitated centrifugal pump and drive unit, a wearable controller, wearable Li-ion battery packs, AC/DC converter, battery charger and hospital console. In the past years, several key clinical milestones have been successfully met: the final cadaver fit studies (conducted at the Cleveland Clinic Foundation) verified a body surface area (BSA) $\geq 1.1\ m^2$ relative to device placement; and multiple animal tests verifying component integrity. At the Utah Artificial Heart Institute, final calf studies have been successfully completed as preparation for human clinical studies. In June 2004, the DuraHeart™ system had its

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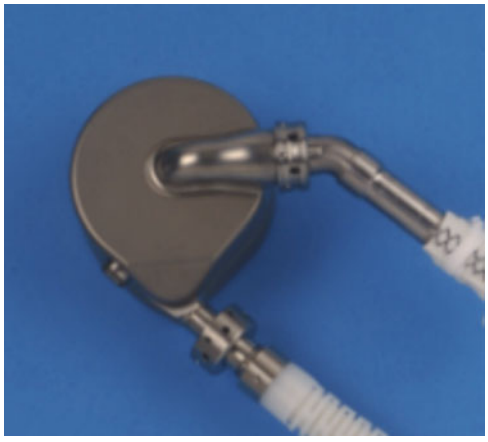

Figure 8 DuraHeart™.

Figure 9 Coraide™.

seventh human implantation in Germany since its first clinical trial on January 19, 2004. Throughout the clinical trial phase the system will be tested in up to 25 patients at up to five clinical centers in Europe.

Technical data: Weight 400 g, volume 96 cm^3, design point 5 l/min at 2000 rpm, power requirements: 15 W (9 W for magnetic suspension), magnetic bearing.

Coraide™. The Arrow Coraide™ (Gerhart et al 2002) (Figure 9) ventricular assist device (VAD) is an electrically powered centrifugal rotary pump. It is composed of an implanted blood pump with inlet and outlet cannulae, a percutaneous cable, an external portable electronic module with electrical cables, and Ni-metal hybrid battery packs. The pump is fabricated from titanium with a biocompatible surface coating.

The rotating assembly does not require mechanical bearings, but utilizes a combination of magnetic and hydrodynamic forces for its suspension and function. An automatic control algorithm has been designed to calculate and control the flow through the pump. One R&D pump is operated for 2 years of continuous operation. Eighteen

Figure 10 VentrAssist™.

chronic *in vivo* experiments were previously completed in the calf model through a test period between 30 and 90 days.

The first human implant of the CorAide was performed in a 65-year-old German male patient on May 8, 2003. The operation was performed without incident. However, after 3 days, the patient's plasma-free hemoglobin was sufficiently above normal to warrant replacement of the CorAide™. Currently, the clinical trial has been stopped and the CorAide is undergoing R&D investigation to elucidate the hemolysis problem.

Technical data: Weight 210 g, volume 62 cm^3, design point 5 l/min at 3000 rpm, power requirement 6–7 W, combination of magnetic and hydrodynamic bearing.

VentrAssist™. VentrAssist™ (Watterson et al 2000) (Figure 10) device consists of a small diameter diagonal flow impeller with an integrated rare-earth-magnet motor. The rotor is suspended by contact-free hydrodynamic forces. The pump is encased in a biocompatible titanium alloy shell. An externally worn battery and controller provides power and regulates operation according to physiological demands. Based on current battery technology, operation for periods of over 8 hours is possible without battery changes. The pump is implanted below the diaphragm and is connected to the left ventricular apex and the ascending aorta using standard grafts. Animal testing have been successfully completed. On March 10, 2004 the fifth VentrAssist human implantation has been successfully performed in a pilot trial at The Alfred Hospital in Melbourne, Australia.

Technical data: Weight 400 g, diameter 60 mm, hydrodynamic bearing, passively suspended rotor, 7–8 W, rotational speed 1800–3000 rpm, sensorless motor control.

Diagonal pumps

DeltaStream™. The DeltaStream™ (Goebel et al 2001) (Figure 11) blood pump, manufactured by Medos AG, Stolberg, Germany is a rotary pump with a diagonal flow impeller. It has been developed for extracorporeal circulation with the main focus on simplified bypass systems. Small size and an embedded electric motor are basic pump properties. The option of a pulsatile flow mode for VAD

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Figure 11 DeltaStream™.

Figure 12 Microdiagonal pump.

applications has also been demonstrated *in vitro*. Seal life times of up to 28 days have been achieved, using different blood substitutes. In animal tests, biocompatibility, low hemolysis and non-thrombogenicity have been demonstrated. In addition to the heart–lung machine and simplified bypass system applications, ventricular assist and extracorporeal membrane oxygenation up to several days appear also as promising potential applications. The pump can be placed extremely flexible and very near to the patient due to the compact construction with integrated electric motor. The pump is in successful clinical use since end of 2001.

Technical data: Diameter 41 mm, length 150 mm, flow 0–10 l/min, rotational speed 1000-10,000 rpm, pressure head 0–600 mmHg, priming volume 30 cm^3, polymeric shaft seal.

Microdiagonal pump. As a follow-up version of the DeltaStream the microdiagonal pump (MDP) (Figure 12) is a mixed flow type rotary blood pump, which is currently being developed at the Helmholtz Institute Aachen as a long-term VAD for clinical use (Akdis et al 2002). The compact rotary pump consists of a brushless DC motor, which drives the mixed flow impeller by means of a magnetic coupling system. Inside the pump, the blood stream simultaneously serves to cool the integrated electric motor. Two pump designs have been worked out for mid-term and long-term use, respectively. The mid-term MDP comprises a hybrid bearing structure based on a combination of a mechanical pivot bearing and a fluid film bearing. This pump will be used as a paracorporeal VAD system. The long-term MDP has a completely contact-less impeller suspension without friction and wear. The unique feature of this rotor bearing lies in its sole use of passive elements based on a permanent magnetic bearing and a fluid film bearing, without the need for any additional sensors and actuators. Both pump configurations are currently in the animal testing phase.

Technical data: Diameter 30 mm, length 80 mm, flow 0–10 l/min, rotational speed 1000–10,000 rpm, pressure head 0–300 mmHg, priming volume 15 cm^3, hybrid bearing system.

CONCLUSIONS

The various pump configurations presented and their clinical applications, from short-term use in cardiopulmonary bypass to long-term implantation, demonstrate that the field of blood pumps is extremely broad and challenging. Also, basic physiological questions such as the need for pulsatile flow in long-term applications have not yet been fully answered. Therefore, both pump categories, i.e., displacement and rotary pumps, have their specific value in terms of cardiac and circulatory support. It is hoped that combined research efforts will lead to new technical solutions that will improve patient care together with quality of life in a wide variety of applications.

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