Miniaturisation of Cardiovascular Devices

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Abstract

VAD’s can unburden the heart at an early stage even allowing for a complete recovery. However, the requirements for those devices are high. This includes, among others, long-term durability, safety and reliability, small over-all size, low power consumption, easy handling, adaptive control (patient need), and transcutaneous energy transfer. Especially for children and infants low priming volumes and exchangeability are needed (4).

Particularly rotary pumps offer a good possibility to fulfil those requirements. Yet a further miniaturisation and better control can improve the patients quality of life.

At the Helmholtz – Institute, in collaboration with Impella CardioSystems AG, we are developing axial blood pumps with a length of 25-50 mm and an outer diameter of less than 15 mm, dependent on its intended use. While the first generation pumps are already commercially available, we are working on pumps for long-term use of several months up to a few years.

The main advantage of those miniaturized systems is their easy implantability, resulting in an easier recovery of the patients after surgery. The smallest can even be implanted minimally invasive by means of a catheter. Due to its size, they also can be implanted in smaller patients, namely children and infants.

Introduction

According to the American Heart Association, in the US alone some 950,000 people die of cardiovascular diseases (CVD) each year (1). About 150,000 cardiovascular surgeries are performed annually on people of age 15 and younger. In 2001, 2,200 heart transplants have been performed in the US. Each year an estimated 16.6 million people die of CVDs worldwide (2).

Since 1928 the New York Heart Association (NYHA) publishes a classification of patients with cardiac diseases based on clinical severity and prognosis, classes I through IV. While class IV includes patients that cannot carry out any physical activity without discomfort, there is a huge number of people with classification II and III, who have a regular but already limited life style. An early therapy for this patient group can prevent a worsening of their condition.

Over the years, many different systems have been developed and adopted for clinical use depending on the therapeutic indication. The pumping principles range from displacement pumps to rotary pumps and the total artificial heart (TAH).

The REMATCH study of 2001 (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure) has shown that the survival rate for patients with advanced heart failure is double as high for those supported by a ventricular assist devices (VAD) compared to those with medical therapy (3).

Therefore, the focus has shifted to develop implantable rotary blood pumps for long-term use (5). Their advantages among others are their compactness while maintaining a comparable energy density to other devices. They require no inlet and outlet valves and usually contain only one moving part, the impeller, thus reducing the system’s complexity (6).

Rotary blood pumps

Rotary pumps are divided into three categories depending on the type of flow: axial, diagonal, and radial pumps (fig. 1).
They all have in common the energy transfer into the blood stream through velocity changes within the impeller blades. Radial flow pumps are know for their capability of producing high pressure, while axial flow pumps are better suited to generate high flows at comparable sizes. Diagonal flow pumps, also referred to as mixed flow pumps, combine both advantages of high flow and pressure. The actuation of the rotor either results through a driving shaft, sealed off from the motor, or through magnetic coupling to a hermetically sealed motor unit. In the latter case, new impeller bearings have to be developed avoiding any kind of blood damage.

For long-term applications, axial flow pumps are often preferred due to their small size. This allows for less invasive operating procedures, more placement possibilities like intravascular implantation, and the treatment of smaller patients like children and infants.

**Micro pumps at the Helmholtz-Institute**

During the last few years, a number of different implantable micro pumps are being developed at the Helmholtz-Institute in collaboration with industrial partners or under public funding. Several devices for short-term use are already commercially available like the intravascular impella® recover system (Impella Cardiosystems AG, Germany) or the extracorporeal DELTASTREAM® (Medos Medizintechnik AG, Germany). Recent developments focus on long-term implantable ventricle assist devices such as a micro-axial and a micro-diagonal flow blood pump (fig. 2).

Both designs feature a hermetically enclosed motor unit, coaxially coupled to the impeller by means of a magnetic face-coupling. Magnetic/mechanical hybrid bearings support the rotor. The MICROVAD rotates at the design speed of 32,000 rpm to obtain a hydraulic output of 5 l/min against a pressure head of 80 mmHg. The outer diameter of the housing measures 12mm at a length of 50 mm. The MDP has an outer diameter of 40 mm and a length of 100 mm. The design speed is 5,500 rpm to obtain a flow of 5 l/min against a pressure head of 100 mmHg. At this stage of development, both pumps still have a percutaneous electrical connection that can eventually be replaced through a wireless transcutaneous energy transmission system (TETS).

The MDP generates flows from 1.5 l/min up to 8 l/min at physiological pressures and therefore is able to take over the complete function of a ventricle when needed. Because of its low priming volume and small size, the MICROVAD is suited very good for smaller patients and even children and infants.
In order to have an automated control, these pumps need to record blood flow and pressure to adjust pump speed to the required levels.

**Sensors for micro blood pumps**

Pumps for short-term use are typically used in critical care settings. Patients are under permanent observation in the hospital. Trained personnel controls and adjusts pump function as needed using implanted or external sensors (7). The requirements for long-term implantable pumps are much higher. Here, the pump needs to function maintenance-free over a period of up to several years. The system should be totally implantable avoiding any percutaneous lines for energy or signal transmission. Handling and control of the pump should be easy and to a large extent automated to allow a maximum quality of life for the patient (8).

In order to establish a sophisticated pump management system, two of the three pump parameters – flow rate, pressure head, and impeller speed – have to be sensed and controlled. The third parameter, e.g. pump flow rate, can be estimated through a previously assessed flow field for each pump that is stored within the control algorithm. In the Impella miniature blood pump (Impella CardioSystems AG), a differential miniature pressure sensor is integrated into the pump head and the rotor speed is obtained from the motor controller. By means of this sensor, the flow rate can be estimated with an accuracy of ±10% for an undisturbed inflow (9,10).

Other pumps include an additional implantable flow sensor like the MicroMed DeBakey VAD (MicroMed Technology, Inc. USA) (see fig. 3). They omit pressure acquisition completely (11,12).

![Figure 1. The MicroMed DeBakey VAD with flow sensor](image)

For long-term use it is desirable to have direct measurements of all hydraulic parameters. It cannot be guaranteed that the inflow of the pump is undisturbed at any time and changing pulsatility may also alter the accuracy of the flow estimation. It is also necessary to determine the pressure head of the pump in order to determine the exact hydraulic status of the pump and adjust it to the body’s need of oxygen supply.

At the same time miniaturisation is needed to keep the overall size of the miniature pump small.

**Where to go next**

Boston et. al. (7) describe a control structure for pumps using the device inputs (voltage and current) combined with control criteria provided by heart transplant clinicians. The pump is always set up in order to achieve maximum cardiac output, i.e. the pump is operated just below the beginning of suction (complete depletion of the ventricle). It has been found, that only with direct measurement of the flow rate, a safe and stable control algorithm for the pump could be obtained.

This means for long-term implantable miniature pumps that long-term stable miniature flow sensors need to be developed to allow a safe and reliable pump operation during its life cycle. Additional pressure sensors can help to monitor the body’s need of oxygen, i.e. its need for a higher flow. With an intelligent control algorithm the pump can be adjusted to the requested condition (13).
It even can be envisioned that with intelligent controls the pump output may be reduced over time at the same level as the natural heart may recover. Hence, the pump would start autonomously to wean the heart from the support system.

References