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Theory and Design

Miniature Rotary Blood Pumps for Use in Pediatric Cardiac Surgery

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This review addresses the challenge of miniaturizing rotary blood pumps for use in pediatric heart surgery in patients with severe heart failure. This problem is relevant because of the high mortality of patients on pediatric heart transplant waiting lists as compared with other age groups and the lack of alternative mechanical support. This has driven studies on the miniaturization of adult pumps.

Introduction

Heart failure is one of the most important pathophysiological syndromes in economically developed countries in relation to the morbidity, overall mortality, and cost of treating patients [1, 2]. Survival after hospitalization has gradually approached 70% in recent years. American assessments indicate that the population in 2030 will grow to eight billion, which will increase the cost of supporting patients to $70 billion [3].

There are now many different types of circulatory support devices, though because of the dimensions, the complexity of implantation, and the concomitant complications, not all are optimal for use in children. Thus, solutions based on miniaturization and modification of devices are needed not only to decrease device weight, but also to reduce the risk of thrombus formation and blood hemolysis.

Most circulatory support devices in children are used to support the cardiac muscle prior to transplantation. This also applies to patients with end-stage cardiac failure who are unable to undergo transplantation [4]. Children currently receive the same courses of medication for cardiac failure as adults, though it is clear that this is insufficient for patient survival [1].

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A study was performed in 2009 using the US Scientific Registry of Transplant Recipients. All children aged up to 18 years who had undergone transplantation in the period between 1999 and 2006 were studied. Of 3416 pediatric patients, 3098 required heart transplants (308 were excluded because of heart retransplantation and 10 because of combined transplantation). Among these 3098 patients, mean age was two years (0.3-12 years) and mean weight was 12.3 kg (5-38 kg). The main diagnoses leading to heart transplantation were congenital heart defects in 1494 children (48%), cardiomyopathy in 1186 (38%), and myocarditis in 178 (6%) [4].

The study reported [4] that 533 children (17%) died, 1943 (63%) underwent transplantation, 252 (8%) were taken off the list because of recovery, and 370 (12%) remained on the list. Independent mortality factors were identified such as extracorporeal membrane oxygenation, mechanical ventilation of the lungs, and others.

The study found that children in the under-18 heart transplant waiting list group had higher mortality than other age groups, as there were no alternatives for mechanical circulatory support [4].

Thus, in 2004 a program headed by Baldwin to support the development of pediatric circulatory support devices (CSD) was initiated. From this time, the National Heart, Lung, and Blood Institute (NHLBI) awarded five grants to institutes and companies to develop a ventricular assist device for children. Despite the fact that some developmental progress was made, none of the devices

TABLE 1. Summary of Implantable Devices in the PumpKIN Program

Device	Size/age	Cardiac output, liter/min	Volume, mL	Duration of support, months	O_2 delivery	Implantable	Pulsatile flow
PediaFlow, Pittsburgh	Neonatal to 2 years	0.3-1.5	0.5	6	–	+	–
Jarvik Pediatric 2000	Infants – 25 kg	0.25-4.0	1	120	–	+	–
Program standard	Neonatal – 25 kg	0.25-4.0	Total 0.5	Not greater than 120	+	+	+

was approved for clinical use by the end of the five-year project. A new program, PumpKIN (Pumps for Kids, Infants, and Neonates) was initiated in October 2010. This program clearly demonstrated the desire of the NHLBI to help develop effective, long-lasting, and reliable ventricular assist devices (VAD) for children and infants with heart failure [5, 6].

The program funded four study devices, two of which are extracorporeal membrane oxygenators (ECMO): pCAS and PediPL. The other two CSD in the program are the PediaFlow and the Jarvik Pediatric 2000 (Table 1) [7].

Types of Pump

Jarvik 2000. Development of the Jarvik 2000 VAD started in 1987 and improvements have been made over the following 25 years. The system consists of implantable components – an intraventricular blood pump, a cuff, and an aortic transplant, a supply cable, and a behind-the-ear connector – and external components – a controller, accumulators, external cables, and chargers.

The arguments for using an axial pump were given in [8]. First, there is a need to avoid backflow of hydraulic fluid. Second, an axial pump has the greatest specific speed, i.e., it operates most efficiency at high speeds and small sizes for a given output and pressure.

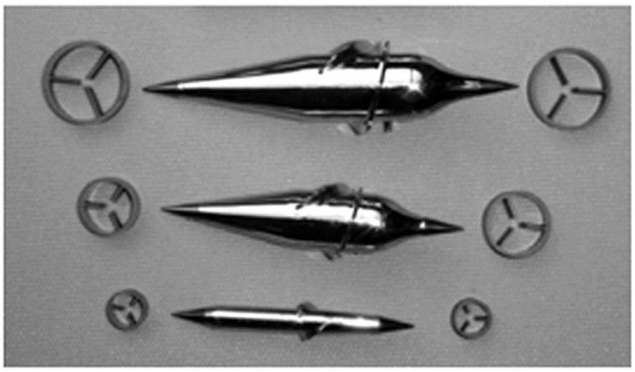

Fig. 1. Jarvik 2000 adult, child, and infant rotors with conical bearings.

Use of a low-inertia motor with a bearing produced the required output with a high hydraulic maximum and an efficiency of 76%. This significantly decreased the pump switching time (to 20 ms) from a rate of 12,000 rpm clockwise to 12,000 rpm anticlockwise [8].

A conical rotor with a large diameter at the center allows the use of small-diameter bearings; this limits wear, energy consumption at the bearing, and heat production [7].

In the bearing system of the device, the rotor of the hydrodynamic blood pump is rotationally supported on the mating portions of the tips of support impellers which contact its hub close to the center of rotation. In the preferred embodiment, two opposing bearings at each end of the rotor limit axial and radial motion to as little as 50 millionths of an inch, while providing completely unconstrained rotational freedom [9].

The most important aspect of the Jarvik 2000 CSD involves the pattern of washing of the bearings, by blood flow across them, to prevent thrombus. All mechanical bearing designs, except those that support the rotor on the impeller blade tips, present a complete circumferential ring of bearing material to the bloodstream. This is an area of local flow stasis. If high enough flow is provided across this area of the pump, a ring of thrombus may remain in the form of a thin torus, not becoming sufficiently large to interfere with the normal function of the pump. But if the material becomes infected, or if the flow is reduced to too low a level, the amount of thrombus may increase. The present design eliminates the risk of forming a ring of thrombus because the bearing diameter is much less than the pump impeller tip diameter [9].

Figure 1 shows the adult, child, and infant rotors and bearings of the Jarvik 2000. Miniaturization of axial blood pumps has physical limits. The smallest model of the Jarvik 2000 uses a 7-mm motor, very small conical bearings, and a hermetically sealed part-welded body 10 mm in diameter. This pump achieves a blood flow of only 2 liters/min at 50,000 rpm, consuming 12 W. This is bare-

ly sufficient flow to augment cardiac index in adults. The pump requires four times the power for the same flow. This illustrates the limits of miniaturization. On the other hand, miniaturization increases the size and weight of the battery, which in turn has significant effects on the patient's quality of life.

Jarvik [8] presented study results (experiments in adult sheep) obtained using conical bearings. The results were satisfactory (the pump was clean, with no signs of thrombus formation).

PediaFlow. The PediaFlow CSD (PF) is used for maintenance of blood flow in infants and young children weighing 2-25 kg with cardiac failure and circulatory collapse due to congenital or acquired cardiovascular diseases [10, 11].

The device consists of an implantable pump, two cannulas, and an external control unit connected to the implant via a transcutaneous cable (Fig. 2). Of particular interest is the pump design, which moves blood as a result of the rotation of a magnetically levitated impeller. Magnetic suspension supports the rotor with five degrees of freedom. The radial pitch angle and the yaw angle are achieved by two sets of rings of permanent magnets in the front and rear parts of the pump. These magnets create instability along the rotor axis, which is compensated for by a feedback-controlled electromagnetic coil. This active system uses eddy current sensors in the front and rear parts of the body to identify the axial position of the rotor, along with an amplifier and an external control unit. The rotor is driven by a quadrupole brushless direct current motor consisting of an electromagnetic field coil in the body, which is coupled with the permanent magnet in the rotor. A thin titanium sheath on the outer and inner parts of the body protects the magnetic components from contact with the blood and vice versa [10].

The advantages of a turbodynamic pump are clear: a minimum of moving parts, no valves or flexible diaphragms, noiseless operation, and hospital follow-up of patients. For the same reasons, a group of researchers at Pittsburgh University preferred to use magnetic rather than hydrodynamic bearings [10].

More than 100 configurations were tested, and from these a single-gap mixed-flow pump was selected for its biocompatibility, the fluid motion mechanism, and the absence of flow recirculation [10].

The most recent development of the PF, the third generation, has ports at both ends to connect to the input and output cannulas of the transplant. The magnetic components are encased in a two-part housing: a cover and an end body. These components are shaped asymmetrically to conserve volume. The single streamlined annular flow path includes a mixed-flow (diagonal)

Fig. 2. PediaFlow CSD: size of implantable part of pump compared with AA battery.

impeller integrated with a principally cylindrical rotor (8 mm diameter) within a cylindrical bore (11 mm diameter) having a conical diffuser and collector at the fore and aft ends respectively. Flow straighteners are machined on the interior bore of the aft housing that cooperate with the conical tail of the rotor to recover pressure from the dynamic head induced by the velocity of the blood exiting the impeller [10].

An additional benefit of super-critical design is the relatively large gap in the annular region (approximately 1.5 mm) of the flow path, which maintains shear stress below an acceptable level (<50 Pa at nominal pressure and flow). This is an important distinguishing feature of the pump design that obviates any secondary or tertiary flow paths, which were present in previous turbodynamic blood pumps.

Experiments with a prototype pump were performed with a blood-analog solution of water and glycerol and confirmed acceptable hemodynamic performance. At an operating speed of 18,000 rpm, the pump was able to produce a nominal flow rate of 1.2 liter/min/m^2 against a pressure head of 75 mm Hg, which corresponds to the hemodynamics of a healthy 8-kg infant. Subsequent experiments with ovine blood also demonstrated an acceptably low level of hemolysis. The normalized index of hemolysis was 0.0467. The corresponding hydrodynamic efficiency was slightly greater than 10%, which, combined with a motor efficiency of 85%, translates to an electrical power requirement of 1.8 W [10].

The pump underwent successful clinical trials; encapsulation did not occur and the inflow and outflow tubes were not damaged. In general, serum chemistry and hematology were unaltered from pre-operative baseline, indicating normal organ function. Hemolysis, evidenced by plasma free hemoglobin (9.2 ± 2.2 mg/dl) was close to initial throughout the study [10].

No adverse reactions were found to the cannula position in the ventricle or evidence of thrombotic embolism in the lungs, liver, or spleen. Further examination of the disassembled pump and its components revealed clean housing and impeller surfaces with no evidence of thrombus or scratches that could cause complications. Overall, the first clinical experience was positive [10].

Miniature "Adult" Pumps

MVAD HeartWare. The MVAD pump is a miniature copy of an axial continuous flow VAD. The MVAD uses platinum alloy impellers suspended in a ceramic tube. The pump motor, which surrounds the ceramic tube, is sequentially activated by the stator winding (Fig. 3). The rotor is suspended using a hybrid system based on magnetic and hydrodynamic forces. The magnetic interaction between the stator and the impeller ensures axial rigidity, while dual hydrodynamic support bearings with the impeller surface produce the radial forces needed for suspending the impeller inside the ceramic tube [12]. The construction of the motor pump in the MVAD operates using ferromagnetic plates and six slots with copper coils as a three-phase, four-pole, brushless motor with a direct current stator. During operation, the ferromagnetic core in the motor is magnetized by alternating and rotating magnetic fields, creating energy losses in the core material. These losses are fundamental to the operation of the pump. As eddy currents are undesirable, as they reduce magnetic flux and create direct power losses; the main approach to decreasing these is to build the motor core from thin metal plates or leaves rather than a solid block. In addition to eddy currents, alternating currents generate power losses due to hysteresis. In rotating systems, losses to hysteresis are due to changes in the magnetization vector on each rotation [13].

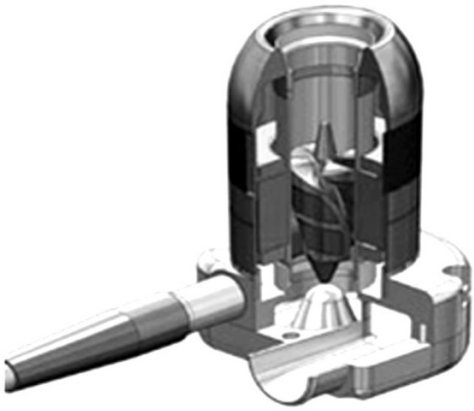

Fig. 3. Section of MVAD pump motor.

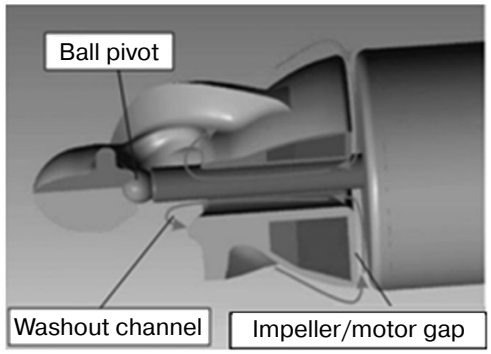

Fig. 4. Stimulation of washout flow.

In pediatric VAD, the stator is located further from the rotor than in a traditional DC motor. The narrow gap – a critical parameter in the design of normal motors – is replaced by a large gap, filled with circulating blood. Because of this design, the requirements of the stator are related to hematological limitations such as hemolytic potential and trans-pump erythrocyte passage time. Large gaps are introduced to avoid areas of high fluid stasis, trauma, or recirculation [9].

The complexity of the magnetic interactions occurring in the stator during VAD operation also applies to power losses. In essence, there are several sources of loss in the core: the basic material, the thickness tolerance, the number of rotations, the geometry, and the installation process. The main losses can affect the pump, increasing the power consumption of the pump; they can also affect control of the motor parameters such as flow evaluation, as well as the mechanical parameters such as the axial suspension of the impeller. Thus, changes to the stator may ensure stable pump performance. Such changes cover losses to eddy currents and hysteresis created by external oscillations of the magnetic field [13].

CircuLite. The system of this pump includes a two-bladed impeller, with blades of diameter 6.6 mm. Blood is sucked though an inflow cannula by the impeller. The flow is redirected into an annular channel between the electric motor and the casing and is delivered tangentially into the output of the graft. In physiological conditions, the system reaches a flow rate of 3.5 liter/min and can be operated at a maximum rotational speed of 28,000 rpm. Power consumption is 6-9 W. The impeller is driven by a magnet so hermetic sealing is not needed. It is mounted on top of a fixed cylindrical axle, thereby forming a constant radial gap as shown in Fig. 4. The combi-

nation of the rotor and motor gap and two holes in the impeller hub creates a washout channel. During operation of the pump, flow through this bypass washout channel is induced such that thrombus formation at the critical ball pivot is prevented [15].

The results were structured as follows: the simulated operating points were compared against measured performance curves; the washout flow was then determined and analyzed in more detail for different impeller/motor gap widths; the computed general flow field was described and compared with the experimental data; finally, the minimum static pressure and liftoff force were derived [15].

The results obtained by experimental simulations and calculation were in good qualitative and quantitative agreement. The washout flow was maximal with an axial impeller/motor gap at 500 μm. An increase of the free cross-section of the gap led to a decrease in pressure loss and, thus, an increase in washout flow. Thus, any increase in the bypass flow counteracts the pressure load and net flow rate at the working point. Furthermore, the liftoff force measured experimentally was well below the magnetic attraction and the minimum static pressure [14, 15].

Conclusions

Analytical assessment of the construction of four CSD systems led to the following conclusions: total pump weight (excluding connectors) should not be greater than 60 g; total pumped liquid volume should be in the range 12-25 mL for each age group; pump rotation for different age groups should not exceed 10,000 rpm; output should reach 10 liter/min [16, 17].

Assessment of all existing VAD showed that patient survival rates were around 75%. Expected survival with VAD was individual for each patient and could be good or not. Unfortunately, it is impossible to exclude many specific patient factors [18-20].

Currently only preliminary cost assessments for pediatric VAD are available. The total cost of pediatric VAD implantation is US $174,753. Other studies have shown the approximate cost of VAD as US $119,937. Increases in survival were linked with decreases in the incidence of complications, increases in the potential for discharging patients after short post-operative in-patient periods, and decreases in the costs associated with increases in quality of life and decreases in delays, with increases in acceptable social levels [20].

The field of pediatric heart surgery is developing quite quickly with the use of previously unavailable methods and instruments. Pediatric VAD have shown significant improvements compared with ECMO. Treatment using VAD continues to be developed, and specialists have started to regard VAD as an approach to treatment for various diseases.

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