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BENCH STUDIES OF A SMALL AXIAL PUMP FOR IMPLANTATION IN PATIENTS WITH LOW ANTHROPOMETRY

A.S. Buchnev[1], A.P. Kuleshov[1], A.A. Drobyshev[1], V.A. Elenkin[1], G.A. Shevchenko[2], N.V. Grudinin[1]

[1] Shumakov National Medical Research Center of Transplantology and Artificial Organs, Moscow, Russian Federation

[2] Peoples' Friendship University of Russia named after Patrice Lumumba, Moscow, Russian Federation

Objective: to conduct bench tests and determine the working range of the pump speed for an implanted left ventricular bypass system aimed at diagnosing and treating patients with low anthropometric status. **Materials and methods.** The axial pump was investigated using a custom-developed hydrodynamic test bench simulating the cardiovascular system. The bench included systems for pressure and flow measurement and registration, along with software for processing both technical and biomedical parameters. **Results.** The operating range of the rotor speed for the STREAM CARDIO pump required to achieve a flow rate of 2.5 ± 0.5 L/min at a pressure drop of 80 ± 5 mm Hg is 8000 ± 1000 rpm, with a power consumption of 6.5 ± 1 W.

Keywords: heart failure, left ventricular bypass, hydrodynamic bench, pump flow rate, pump head, axial pump.

INTRODUCTION

Heart transplantation remains the gold standard treatment for patients with end-stage heart failure (HF) [1]. However, a critical shortage of organs continues to pose a major challenge. Despite efforts to expand donor eligibility, many patients die while waiting for a suitable heart [2].

Over the past decade, significant progress has been made in the use of mechanical circulatory support (MCS) systems for managing HF [3]. MCS, including first-, second-, and third-generation left ventricular assist devices (LVADs), is increasingly being adopted as a viable treatment option for end-stage HF [4–7].

First-generation devices include pneumatically driven systems such as the Thoratec (Thoratec Laboratories Corporation, USA) and EXCOR (Berlin Heart, Germany) ventricular assist devices, which are used in both adult and pediatric patients. However, these systems are associated with some limitations, including the extracorporeal placement of artificial ventricles and the bulky size of external actuators. Additionally, these devices had a limited lifespan and relatively low reliability [8].

Second-generation devices include low-pulsatile flow rotary pumps, such as the HeartAssist (MicroMed Cardiovascular, Houston), Jarvik 2000 FlowMaker (Jarvik Heart, Inc., New York), HeartMate II (Thoratec Corporation, Pleasanton, CA), AVK-N (Russia), and Stream Cardio (Dona-M, Russia). These systems are small in size and weight, silent, relatively inexpensive, have enhanced reliability and service life [9–11].

Third-generation devices consist of pumps equipped with electromagnetic drives. Notable systems in this category include the Incor axial pump (Berlin Heart AEG), HeartWare HVAD centrifugal pump (HeartWare, Inc., Miami Lakes, FL), HeartMate III (Thoratec Inc., Pleasanton, CA), EvaHeart LVAS (Sun Medical Technology Research Corporation, Nagano, Japan), and Terumo DuraHeart (Terumo Heart Inc., Ann Arbor, MI) [12–14].

In many cardiology centers, implanted MCS has become one of the primary treatment modalities for adult patients with end-stage chronic heart failure (CHF). However, in children and patients with small anthropometric measurements, the implantation of circulatory support systems is often constrained by limited body surface area, low body weight, and an insufficiently sized thoracic cavity to accommodate the device.

As Russian-made pediatric pump systems remain under development, and the HeartMate III is primarily used for patients with a low body mass index, we propose considering the use of the compact axial-flow pump Stream Cardio (LLC "DONA-M", Russia). Although originally designed for patients with a high body mass index, this device can also function effectively at reduced blood flow rates (2 ± 0.5 L/min).

The operational control of implanted MCS systems is typically based on maintaining a preset pump rotor speed (PS), which ensures the required blood flow to sustain vital organ function [15]. This RS is established intraoperatively and subsequently adjusted throughout the phases of postoperative care and patient rehabilitation [16].

Corresponding author: Alexander Buchnev. Address: 1, Shchukinskaya str., Moscow, 123182, Russian Federation.
Phone: (926) 470-09-88. E-mail: labbts@mail.ru

Alternatively, rotor speed, pressure differential across the pump, blood flow, and power consumption can be estimated indirectly by analyzing the pump's flow-pressure curve (FPC) [17–20]. These FPC data can be obtained both during isolated pump operation and in conjunction with a ventricular assist device.

The present study presents bench testing of the Stream Cardio axial rotary pump, focusing on its flow-pressure, energy, and hemodynamic characteristics. These data help determine the optimal operating speed ranges of the pump for use in clinical settings, particularly for patients with low body mass index (BMI) requiring left ventricular bypass (LVB).

MATERIALS AND METHODS

Stream Cardio is a compact axial-flow blood pump with an outer diameter of 28 mm, a length of 60 mm, a weight of 120 grams, and operates at speeds between 5000 and 10000 rpm. It can deliver up to 10 liters of blood per minute and is powered by a control unit with a single rechargeable battery and AC adapter. Since 2020, it has been implanted in Russian patients either as a long-term support or for bridge-to-transplant use, effectively replacing left ventricular function in patients with HF. The device is implanted via the apex of the left ventricle, with its outlet connected to either the ascending or descending aorta.

The core component of the axial flow pump is the impeller with vanes, which generates rotational energy and imparts it to the blood, initiating and directing flow (Fig. 1). The impeller is mounted on bearings at both ends, ensuring stable rotation. Downstream of the impeller is a flow straightener – a stationary blade assembly oriented opposite to the direction of impeller rotation. This component induces a "reverse spinning" effect, which transforms the kinetic energy of the rotating blood into pressure-based potential energy [21].

The pump's DC motor stator is integrated directly into the pump casing, while permanent magnets are embedded within the impeller.

In the initial stage of the study, FPCs were obtained using a hydrodynamic bench setup to determine the operating range of pump speeds at low blood flow rates and axial pump power (Fig. 2).

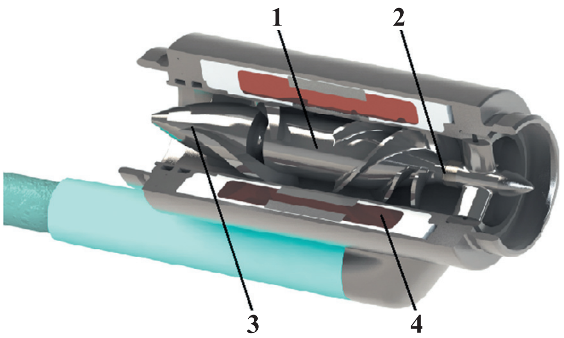

Fig. 1. 3D model of axial pump: 1, pump impeller; 2, bearing; 3, flow straightener; 4, electric motor stator

The hydrodynamic bench (HB) comprises a 400 mL CAPIOX reservoir (Terumo), 10 mm diameter Tygon tubing (Saint-Gobain, France), a variable hydraulic resistance, and integrated pressure and flow sensors. Pump inlet and outlet pressures of the HB were measured using Edwards pressure transducers (Life Sciences), while flow rates were recorded with a Transonic TS402 ultrasonic flow sensor (Transonic Systems Inc., USA) positioned on the bench outlet line.

Pressure and flow measurements were monitored via a multichannel Angioton module (Biosoft-M, Russia) and visualized in real-time using Pumpax software (Biosoft-M, Russia). The pump's rotor speed was adjusted systematically, and at each set speed, the corresponding pressure drop vs. flow rate curve was plotted by varying the inlet and outlet pressures.

Fig. 2. Mock circulation loop. 1, axial pump; 2, tank; 3, fluid flow sensor; 4–5, pressure sensors at the pump inlet and outlet; 6, hydraulic resistance

In the second stage of the study, hemodynamic parameters of the axial flow pump at low blood flow conditions were evaluated within a LVB configuration, using a hydrodynamic bench designed to simulate the cardiovascular system (CVS) [22].

The CVS model incorporated key physiological characteristics, including arterial compliance (pliability/elasticity), inertia, total hydraulic resistance, a programmable heart ventricle simulator, replicating left ventricular contractility, including parameters such as heart rate, systole/diastole ratio, and corresponding pressure and flow profiles.

HF conditions were simulated by adjusting pressure in the artificial heart ventricle using the Sinus IS control system (Russia) and modifying peripheral resistances, while aortic capacitance remained unchanged. The system was initially set to reflect HF hemodynamics with the following baseline parameters: mean aortic flow 1 ± 0.3 L/min, mean arterial pressure (MAP) 65 ± 5 mmHg, mean left atrial pressure 20 ± 1 mmHg.

Following this, the pump was activated in LVB mode, leading to the restoration of hemodynamics flow rate 2.5 ± 1 L/min, MAP 80 ± 5 mm Hg, and mean atrial pressure 5 ± 1 mm Hg.

The obtained data were processed and summarized in Table.

RESULTS

The performance of the circulatory assist pump is inherently linked to cardiac hemodynamics. During each cardiac cycle, the contractility of the heart fluctuates in response to varying physiological conditions, particularly changes in preload and afterload, which lead to changes in pump parameters, namely pump power and fluid flow through the pump.

Fig. 4 presents the hydrodynamic parameters recorded on the HB across a range of pump speeds from 5000 to 10000 rpm.

Analysis of the obtained differential pressure and flow curves indicates that, to achieve a target flow rate of 2.5 ± 0.5 L/min, the rotational speed of the Stream Cardio axial flow pump must be maintained within the range of 8000 ± 1000 rpm. The Stream Cardio pump exhibits a relatively steep FPC, indicating that its output is less sensitive to variations in pressure differential.

The pressure difference across the pump can be approximated by the gradient between left ventricular pressure and aortic pressure. Consequently, the pump flow is inversely proportional to this pressure difference, as illustrated in Fig. 5.

This flow behavior is observed throughout each cardiac cycle: during diastole, as the pressure difference across the pump increases, flow rate decreases; conversely, during systole, when the pressure gradient narrows, flow rate increases.

Pump power – a function of the voltage and current supplied to the pump motor – serves as a direct indicator of mechanical load and system performance. Power output fluctuates in response to hemodynamic variations or pathophysiological changes. For instance, pump power

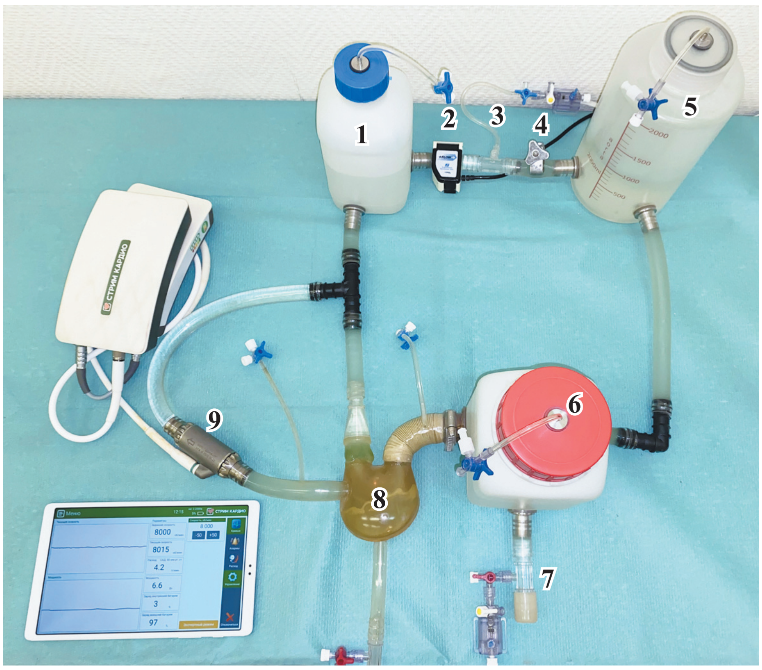

Fig. 3. Mock circulation loop. 1, arterial reservoir; 2, aortic flow sensor; 3, arterial pressure measurement sensor; 4, systemic hydraulic resistance; 5, venous reservoir; 6, reservoir simulating the "pulmonary veins, left atrium" system; 7, atrial pressure measurement sensor; 8, cardiac ventricle simulator simulating the left ventricle of the heart during a left ventricular bypass; 9, test pump

may rise in the presence of reduced blood viscosity or onset of rotor thrombosis, with such changes occurring either gradually or abruptly. Power also varies with preload and afterload conditions, and the sensitivity of this relationship is modulated by the pump's set rotational speed (see Fig. 6).

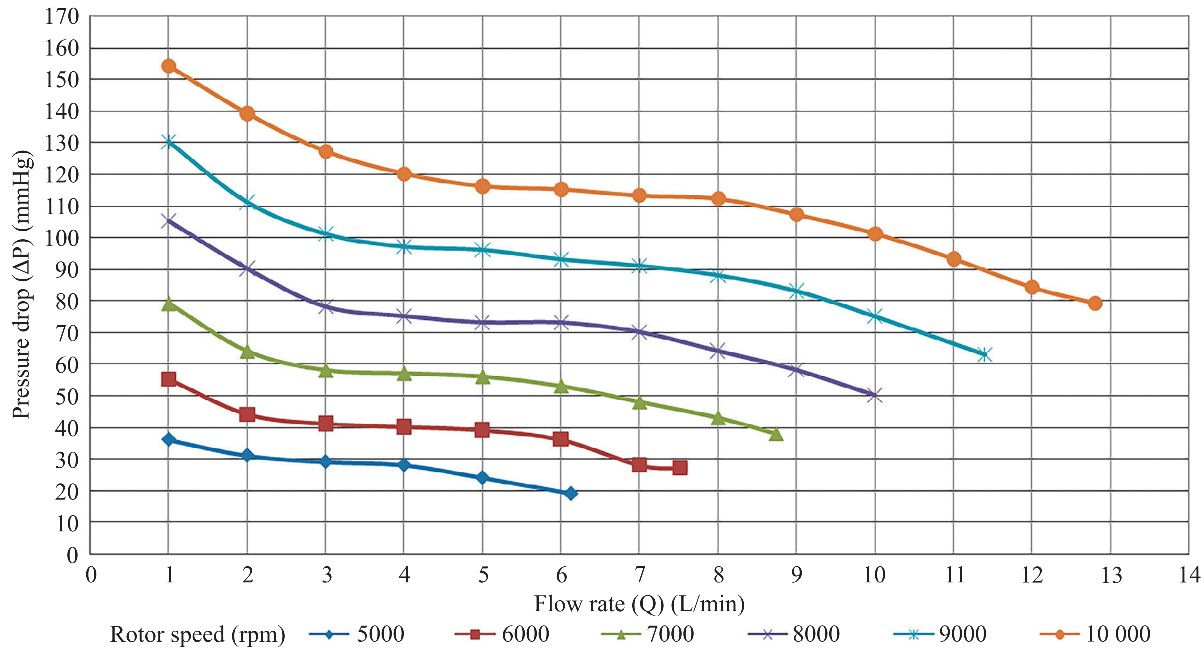

Fig. 4. Flow-pressure curve of the Stream Cardio left ventricular assist device

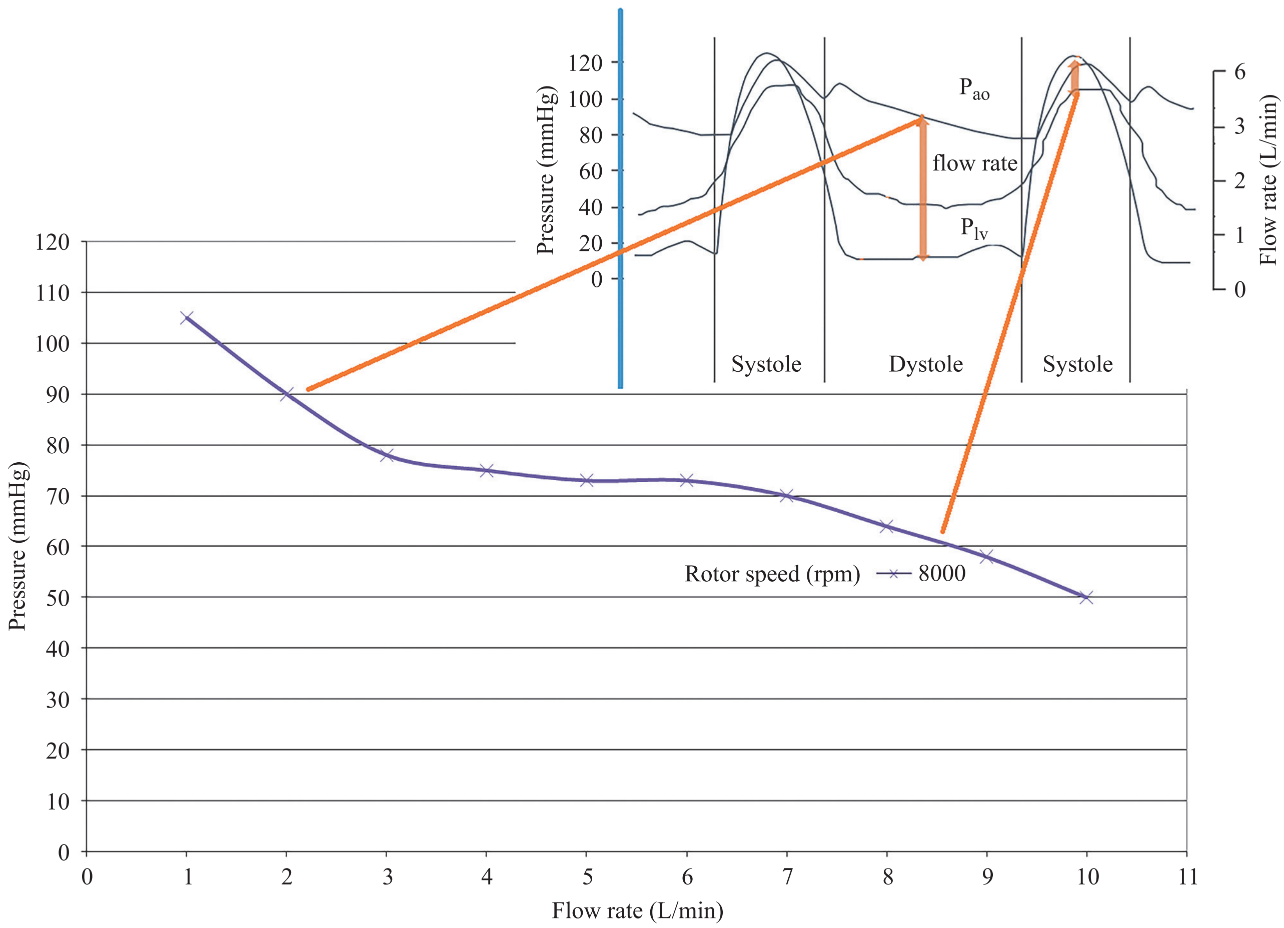

Fig. 5. Flow variation in the pump during cardiac cycle. P_{AO}, aortic pressure; P_{LV}, left ventricular pressure

The design constraints of the axial flow pump inherently limit its speed and flow rate. To achieve a target flow of 2.5 ± 0.5 L/min, the Stream Cardio pump requires a rotational speed of about 8000 ± 1000 rpm, with an associated power consumption of 6.5 ± 1 W.

This low power requirement is a key advantage, as it contributes to reduction in size and weight of critical system components – namely, the control unit and battery pack. Consequently, this enhances autonomous operation time, extending the period between battery replacements.

Fig. 7 presents the hemodynamic parameters of CVS under HF conditions and during Stream Cardio operation in LVB mode. Flow during LVB was provided by pump

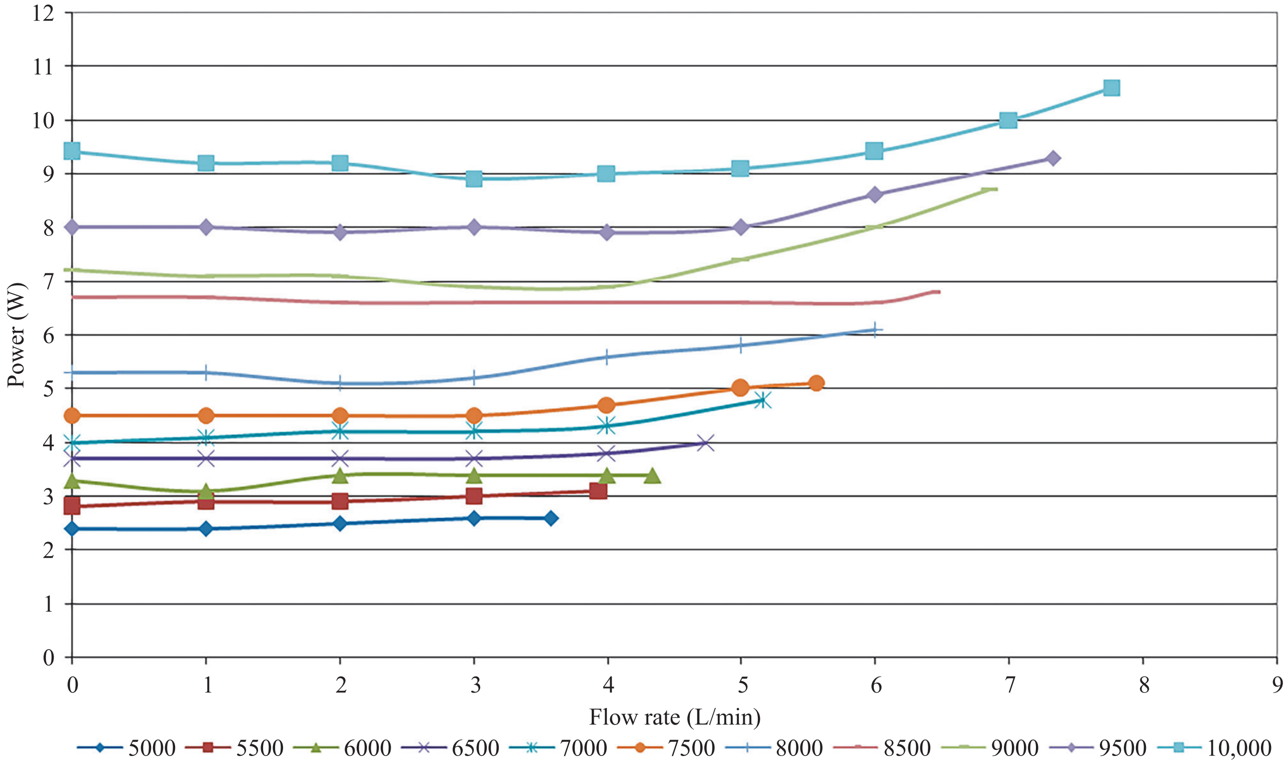

Fig. 6. Flow-power curve of the Stream Cardio ventricular assist device

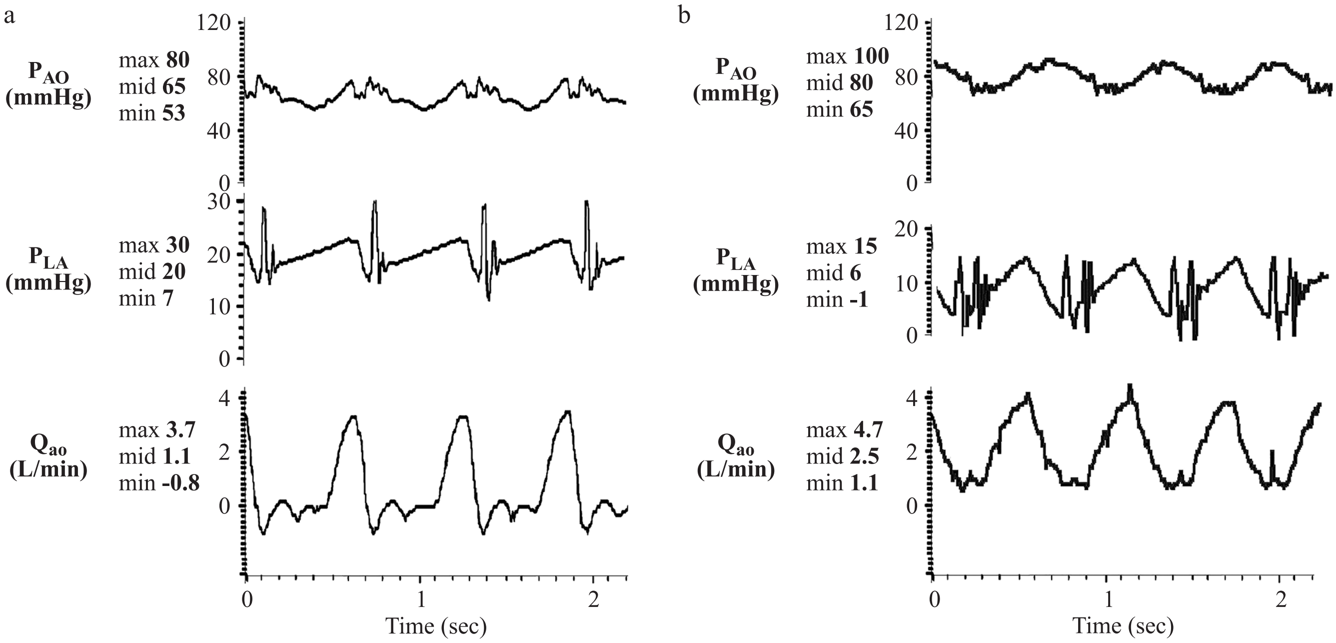

Fig. 7. Hemodynamic parameters of Stream Cardio under conditions of heart failure (a) and left ventricular bypass (b). P_{AO}, aortic pressure; P_{LA}, left atrial pressure; Q_{AO}, aortic flow

Table

Hemodynamic parameters of the Stream Cardio pump at different rotor speeds under conditions of left ventricular bypass

Rotor speed (rpm)	P_{AO} (mmHg)	P_{LA} (mmHg)	Q_{AO} (L/min)
6900	90/75/65	5	1.5
7300	91/75/61	4	2.0
7800	95/75/59	3	2.5
8100	95/75/60	5	3.0
7000	95/80/69	4	1.5
7500	95/80/70	4	2.0
8100	100/80/65	6	2.5
8400	100/80/64	4	3.0
7400	103/85/73	4	1.5
7900	102/85/71	5	2.0
8400	104/85/69	3	2.5
8700	105/85/71	4	3.0
7700	110/90/76	3	1.5
8100	107/90/75	4	2.0
8600	109/90/73	4	2.5
8900	110/90/73	3	3.0

Note. P_{AO}, aortic pressure; P_{LA}, mean left atrial pressure; Q_{ao}, aortic flow.

speed 8100 ± 50 rpm, MAP at 80 ± 2 mm Hg, and mean aortic flow of 2.5 ± 0.1 L/min.

Table presents the summarized results of key hemodynamic parameters, including various combinations of aortic flow and MAP, measured at specific pump speeds in the LVB configuration.

According to the data in Table, achieving a target flow rate of 2.5 ± 0.5 L/min at a pressure gradient of 80 ± 5 mmHg requires a pump speed of approximately 8000 ± 1000 rpm for the Stream Cardio device.

These experimentally derived values of pump speed under both hydrodynamic and hemodynamic testing conditions at defined MAP levels provide an indirect estimation of the blood flow needed to sustain vital organ function.

The *in vitro* data obtained on pump speed and power consumption of the Stream Cardio pump at low flow conditions offer valuable guidance for defining optimal operating modes during left ventricular bypass procedures, particularly in patients with low BMI. This enables precise adjustment of pump speed during both intraoperative support and the rehabilitation phase.

DISCUSSION

The Stream Cardio pump operates on a relatively steep FPC curve, which makes it less sensitive to changes in the pressure differential that are typical for axial flow pumps. Despite its compact size, the pump is capable of providing sufficient power to achieve a pressure drop of 80 ± 5 mm Hg at a flow rate of 2.5 ± 0.5 L/min.

In LVB mode, at a flow rate of 2.5 ± 0.5 L/min, the rotor speed of the Stream Cardio pump is set at 8000 ± 1000 rpm, which is similar to the rotor speed of the HeartMate II pump. The HeartMate II has been FDA approved since April 2008 and has been implanted over 27,000 times [23], including in four adolescent patients aged 12 to 15 years, with body surface areas ranging from 1.5 m^2 to 1.7 m^2 [24]. The primary goal of these pumps is to enhance systemic cardiac output and reduce ventricular loading throughout the cardiac cycle, while minimizing the risk of significant biological or hematologic complications. The hydrodynamic and hemodynamic characteristics of the Stream Cardio pump at low blood flow rates, combined with the encouraging clinical outcomes observed with the HeartMate II pump in adolescent patients, suggest that the Stream Cardio pump holds significant potential for clinical application in patients with small anthropometric indices, for accurate assessment, diagnosis and treatment of such patients during left ventricular bypass procedures.

CONCLUSION

In today's rapidly evolving medical landscape, it is crucial for the medical community to evaluate and integrate emerging technologies effectively. Programs aimed at supporting patients with drug-naive heart failure must consider a range of devices that can meet the diverse clinical needs and body sizes of patients. A more thorough understanding of the pressure-drop and flow relationship in LVADs will be instrumental in optimizing hemocompatibility and hydraulic efficiency during pump design.

Looking ahead, future research will focus on testing the Stream Cardio pump at low blood flow rates to evaluate potential blood element injury. Besides, a series of animal experiments will be conducted to assess and rule out thrombosis in the pump.

The authors declare no conflict of interest.

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