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HEMODYNAMIC EVALUATION OF A NEW PULSATILE FLOW GENERATION METHOD IN CARDIOPULMONARY BYPASS SYSTEMS

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This paper proposes a new method of generating pulsatile flow using non-pulsating pumps (NPP) without modulating the rotation speed of the pump rotor. At the initial stage, this method was proposed for NPP-based cardiopulmonary bypass (CPB) systems. The method is based on parallel connection to the NPP shunt (input-output) on which a controlled valve is installed. This valve ensures periodically clamps and opens the shunt partially. A comparative evaluation of the operation of pumps with and without a pulsator was done on a hydrodynamic bench with simulation of heart failure (HF) conditions. The pump-shunt system was connected according to the "vein-artery" CPB scheme under copulsation mode. Rotaflow (Maquet Inc.) was used as the NPP. For a comparative assessment of the hemodynamic efficiency of the method, the following were used: aortic pulsatility index Ip, energy equivalent pressure (EEP) and surplus hemodynamic energy (SHE). The indices in the pulsating mode compared with the non-pulsating mode increased: Ip by 3 times, EEP index by 3.76% and SHE index increased by 4 times. Results show that the proposed method of generating a pulsating flow is effective.

Keywords: cardiopulmonary bypass, continuous flow, pulsatile flow, hydrodynamic stand, shunt, controlled valve.

INTRODUCTION

The current clinical practice mainly applies NPP systems that have certain advantages over pulsating flow pumps (PPs), especially in terms of size, reliability, durability, and ease of control [1–3]. However, the prolonged use of implantable NPP systems often causes such complications as GI bleeding, hemorrhagic strokes, and aortal insufficiency [4–12]. Besides, recent reports show the importance of the pulsating flow not only for the implanted systems but also for such short-term extracorporeal CPB systems as extracorporeal membrane oxygenation (ECMO) and CPB [13–16].

To evaluate the performance of pulsating systems, these reports use the EEP and SHE indicators which reflect the additional energy received by the blood circulatory system due to the pulsating flow [17]. Those and other observations recently raised interest in the development of control methods for the NPP that generate pulsating flow and pressure with the pump rotor speed (RS) modulation [18–22]. The main problem of the converting a non-pulsating flow to pulsating is the rotor response lag leading to limitation of the maximum flow amplitude and the phase shift relative to heartbeat phases. Besides, the RS modulation mode is featured with high shear stresses formed at the acceleration and braking of the rotor. This is confirmed by the lack of data on blood haemolysis in the mentioned publications, though in early works on the analysis of blood haemolysis in the RS modulation systems, the authors note an increased haemolysis [23]. We expect the new method of pulsating flow generation [24] to be less traumatic for blood due to the constant PP RS.

MATERIALS AND METHODS

The proposed method for pulsating flow generation is based on the parallel connecting a graft line with an adjustable solenoid valve to the input-output of the NPP pump and oxygenator. As applied to the CPB system, an option of this method shown in Fig. 1.

The proposed scheme for pulsating flow generation in the CPB systems is shown in Fig. 1. As an NNP pump, the Rotaflow centrifugal pump (Maquet Inc.) is used. The bypass line is a polyurethane tube of 6 mm outer diameter, 0.2 mm wall thickness. In the pumping (systole) phase, a voltage is applied to the valve for partial closure of the graft. At this, at the output of the pump-graft system, the flow pulse amplitude is formed, which depends on the preset constant RS and the graft closure

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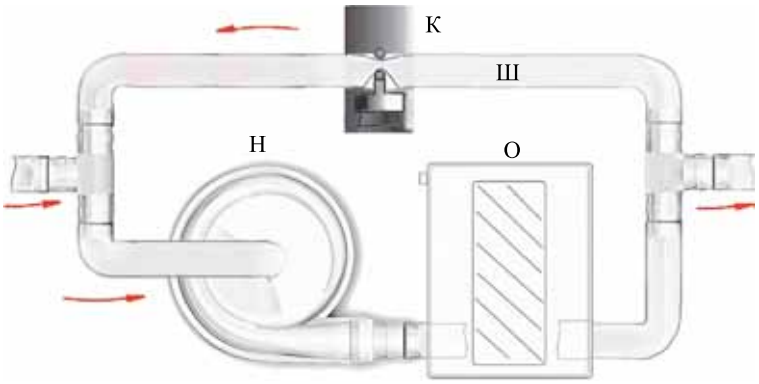

Fig. 1. Pulse generation's scheme: H – pump; K – valve; III – shunt; O – oxygenator. The flow movement show by red arrows

degree. In the next (diastole) phase, the valve opens the graft. In this case, due to bypassing the main NPP flow, the reduced flow amplitude is formed at the output of the pump-graft system, which depends more on the graft diameter. Thus, at the constant preset RS, a pulse flow is formed at the output of the pump-graft system.

The valve is a solenoid designed for controlled cross-clamping of the graft. The valve configuration (Fig. 2) includes a frame (1) with an electromagnetic coil (2) and an anchor (3) connected to the valve (4). The valve control system is based on the pulse width modulation (PWM). To trigger the anchor and switch it to the upper position, a short PWM pulse with 20 ± 10 ms duration and 15 V voltage, synchronized with the heart rate, is applied to the electromagnetic coil. At this, the anchor moves the valve to the upper stop (5), partially over-clamping the graft. Then the seal-in voltage is applied to the electromagnetic coil, determined by the pressure inside the graft. In the diastole phase, the voltage from the electromagnetic coil is removed and the graft opens due to hydrodynamic pressure. To adjust the graft cross-clamping and opening degrees, for each phase of the valve operation, the valve stops (6) and (7) are used.

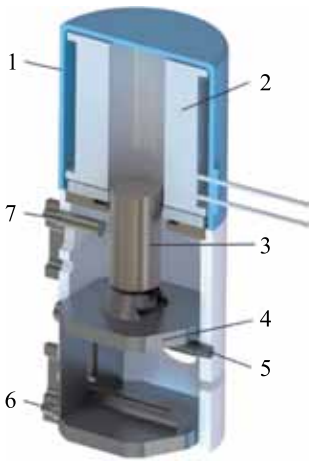

Fig. 2. AV design: 1 – shell; 2 – electromagnetic coil; 3 – anchor; 4 – valve; 5 – upper locking pin; 6 – lower stroke limiter; 7 – upper stroke limiter

Hydrodynamic bench

At the first stage of the research, the effectiveness of this pulsating flow generation method was evaluated at the hydrodynamic bench (HB) with the pump connected in the CPB mode. The overview of the bench is shown in Fig. 3. It includes the artificial heart ventricle (AHV) (1), Quadrox-i Adult (Maquet) oxygenator (2), aortal tank (3), system hydraulic resistor (4), aortal reservoir (5), venous tank (6), and pulmonary resistor (7). The NPP Rotaflow (Maquet) input (8) is connected to the AHV (1), and its output – to "aorta". The graft (9) and the valve (10) have a parallel connection with the Rotaflow. As the AHV, the Medos VFD 80 ml (Medos, Aachen) pump was used, with the SINUS-IS (MZEMA, Russia) 2-channel pneumatic drive. The flow in the aorta and at the output of the pump-graft system was recorded with the Transonic, Ithaca, NY Transonic Inc. ultrasonic flow meters (UFMs) (11, 12). The pressures in the aorta (13), the left atrium (14), and the AHV (15) were recorded by the Edwards (Edwards Life Sciences, Irvine, CA) sensors. The pressure and flow measurements were recorded with the Angioton (Biosoft-M, Moscow) multichannel pressure and flow measurement module and visualized by the Pumpax software (Biosoft-M, Moscow).

Preliminary modelling of the standard conditions was made, those set by the AHV pneumatic pressure, adjustment of the aortal tank, and peripheral resistor according to the recommendations in G.M. Pantalos et al. [25]. The cardiac insufficiency mode was set by changing the AHV pressure and peripheral resistors without changing the aortal tank capacity. The following parameters were set: average aortal flow rate – 2.5 ± 0.3 l/min, aortal pressure – 80/60 mm Hg.

The cardiac output in non-pulsating and pulsating modes was maintained the same. The flow (systole) amplitude at the output of the pump-graft system was preset by changing the pump RS and the graft cross-clamping degree. At this, the flow through the graft was 6.2 ± 0.5 l/min. To obtain the minimum flow rate at the output of the pump-graft system in the diastole phase, the graft was fully opened. The pressure in the AHV was ma-

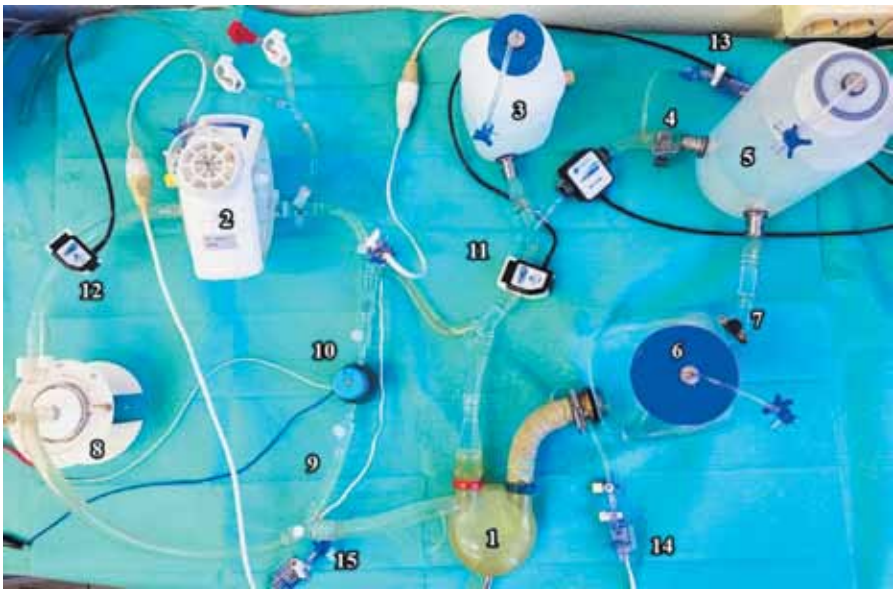

Fig. 3. Mock circulation loop: 1 – artificial left ventricle (LV); 2 – oxygenator Quadrox-i Adult (Maquet); 3 – aortic capacitance; 4 – system hydraulic resistance; 5 – aortic reservoir; 6 – venous reservoir; 7 – pulmonary resistance; 8 – Rotaflow; 9 – shunt; 10 – valve; 11 – aortic flowmeter; 12 – flowmeter pump; 13 – pressure sensor of aorta; 14 – pressure sensor of left atrium; 15 – pressure sensor of LV

nually set at 60 mm Hg with the pump operating in the non-pulsating mode, and 40 mm Hg during operation of the pump-graft system. Such pressure decrease in the left ventricle was observed in vivo, as well as on the benches, with the AHV reproducing the Frank-Starling's law. The pump-graft system was synchronized with the AHV operation by applying the pulses of the preset AHV systole duration from the "Sinus-IS" drive to the valve control unit.

The aortal pulsation obtained during the tests was determined by the pulsation index (Ip) determined by the formula [26]:

$$I_p = (P_{ao\,(max)} - P_{ao\,(min)}) / P_{ao\,(av.)}, \quad (1)$$

where $P_{ao\,(max)}$ – aortal systolic pressure, $P_{ao\,(min)}$ – aortal diastolic pressure, and $P_{ao\,(av.)}$ – average aortal pressure. Equivalent energy of pressure (EEP) was calculated by the formula [26]:

$$EEP\ (mm\ Hg) = \int_{t1}^{t2} fp\ dt\ / \int_{t1}^{t2} f\ dt, \quad (2)$$

where f(t) – aortal flow temporal curve over a fixed time, p(t) – aortal pressure temporal curve over the same time. Surplus hemodynamic energy (SHE) was calculated according to the Shepard equation [26]:

$$SHE\ (ergs/cm^3) = 1332 \cdot (EEP - P_{ao\,(av.)}). \quad (3)$$

RESULTS

Fig. 4 shows the hemodynamic parameters obtained on the assembled bench when modelling the standard cardiac insufficiency. At cardiac insufficiency, the average aortal flow rate was 2.5 ± 0.2 l/min, the aortal pressure was 80/60 mm Hg.

Fig. 5 shows the hydrodynamic parameters in non-pulsating (a) and pulsating (co-pulsation) (b) modes. The non-pulsating flow was provided by Rotaflow at RS of 2100 rpm, the pulsating flow – at RS of 2600 rpm. For both modes, the mean aortal pressure at 75 ± 2 mm Hg and average aortal flow rate at 4.8 ± 0.2 l/min were maintained. The pressure loss on the oxygenator was 40 mm Hg, which influenced the obtained RS value.

The summary of the main hydrodynamic indicators, Ip, EEP, SHE indices for the non-pulsating flow and pulsating flow modes is given in Table.

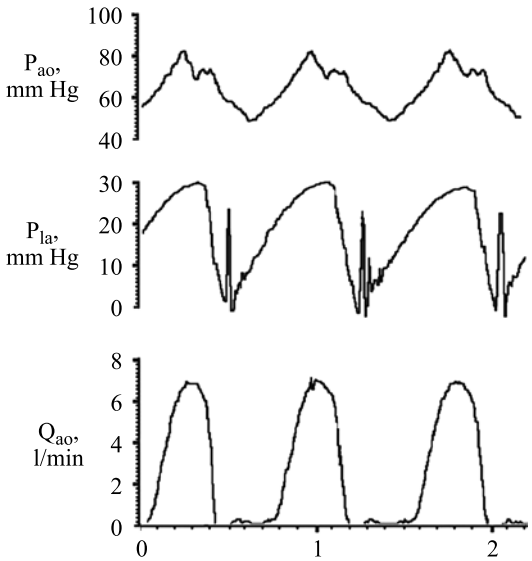

Fig. 4 The simulation results of heart failure: P_{ao} – aortic pressure; P_{la} – pressure in the left atrium; Q_{ao} – aortic flow

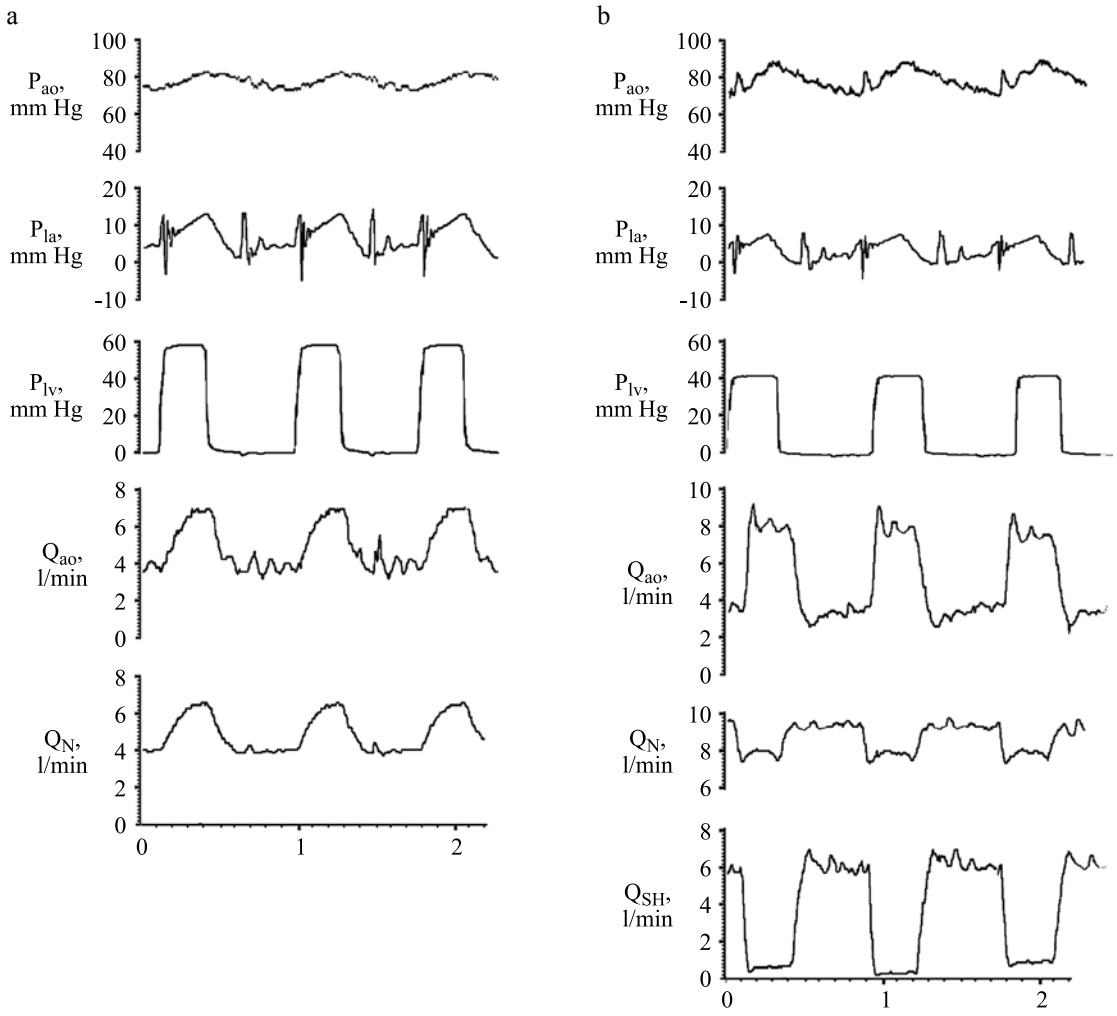

Fig. 5. Comparative results of the hydrodynamic parameters in constant speed (a) and pulsating (b) modes: P_{ao} – aortic pressure; P_{la} – pressure in the left atrium; P_{lv} – pressure in LV; Q_{ao} – aortic flow; Q_N – flow through Rotaflow; Q_{SH} – flow through shunt

Table

Hemodynamic parameters with and without graft

	P_{ao} (max / av. / min), mm Hg	Q_{ao} (max / av. / min), mm Hg	I_p	EEP, mm Hg	SHE, ergs/cm^3
Without graft	81 / 76 / 74	6.9 / 4.9 /4.1	0.092 ± 0.002	77.07 ± 1.20	1333.5 ± 1598.4
With graft	91 / 76 / 69	8.3 / 5 / 3.2	0.29 ± 0.007	79.86 ± 1.94	5141.2 ± 2584.0

According to table 1, the IP index increased by 3 times in the pulsating mode compared to the non-pulsating mode, the EEP index increased by 3.76%, and the SHE index increased by almost 4 times.

DISCUSSION

The proposed method is based on the parallel connection of graft with a controlled solenoid valve to a rotary pump. The pulsating flow is formed due to the cardiosynchronized closing and opening of the graft, which is provided by a controlled solenoid valve. The bench tests showed that in the cardiac insufficiency simulation this method shows the normalization of pulse pressure in the aorta in the co-pulsation mode. Comparison of these findings with hemodynamic parameters obtained during non-pulsating NPP operation showed that the proposed method can be more efficient in the increase of the aortal pressure and flow pulsation. Compared to the systems with RS modulation, this method is featured with smaller response lag of the system due to the rapid (15–20 ms) response of the solenoid valve which supposed to ensure more efficient operation, especially in the co-pulsation mode.

Another advantage of the proposed method for pulsating flow generation is its versatility. The method allows using any rotary pumps. The disadvantages of the method

include the difficulties of implementing the implantable version of the system. Nevertheless, this method can be used to generate a pulsating flow in the CPB systems and extracorporeal LV bypass, which has recently been of the increasing concern of many researchers [18, 20, 21].

In the present study, the first stage of research of the pulsating flow generation method for non-pulsating flow pumps without changing the pump's RS is introduced, which can be considered effective for increasing the aortal pulsation in the ECMO systems. We suggest that the pulsating flow in these systems has a positive effect on blood oxygen saturation due to blood recirculation through the oxygenator. In the future, we plan to evaluate the blood haemolysis when using this method and consider the possibilities of using the method in left ventricular, biventricular bypass, and artificial heart systems.

The authors declare no conflict of interest.

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