Flow Modelling of POLVAD-MEV Ventricular Assist Device in the Apex of the Heart-Artery Configuration

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***Abstract*—The paper presents flow modelling method for pulsatile heart support devices working in the apex of the heart-artery configuration. It describes the measurement stand, which consists of ventricular assist device working in connection with hybrid simulator of cardiovascular system. The method of model development is presented and explained. The results obtained for different cases of pump operation and simulated patient conditions are included. Resulting description of the artificial ventricle seems to be independent of hemodynamic conditions or control parameters of the pump.**

***Index Terms*—artificial organs, flow modelling, parallel apex of the heart-aortic assistance, Ventricular Assist Device (VAD)**

I. Introduction

Cardiovascular diseases have been the major cause of death in high developed countries in recent years. One of the common heart ailments is ventricular failure which results in reduction of the cardiac output and may lead to ischemia of major organs. In some cases, there is a need for invasive treatment. One of them is application of Ventricle Assist Devices (VAD). These blood pumps, connected in parallel with cardiac system, are implanted as a shunt of the natural flow path through the patient's ventricle. This means that in the apex of the heart-artery configuration of the implantation, some part of the blood is taken directly from the inefficient ventricle and pumped into the arterial system. We can distinguish continuous-flow devices such as Thoratec's HeartMate III, Berlin Heart's Incor or HeartWare's HVAD, which are impeller or axial-flow pumps and pulsating flow devices (positive displacement pumps e.g. World Heart's Novacor, Thoratec's HeartMate XVE and PVAD). One of the pulse flow pump used clinically is the POLCAS system consisting of a POLVAD-MEV pulse pump with an assigned controller [1]. It consists of two chambers separated by a flexible membrane. One of the chambers (air) is provided alternately with high and low (vacuum) pressure. The changes of pressure are achieved by connecting alternately the air chamber with the reservoir of high or low pressure. This causes the membrane movement and thus the change of pressure in the blood chamber. Under the influence of changing pressure, the blood is sucked in and then ejected from the device through mechanical valves. Due to the variable pump load conditions (pressure in the arterial system) estimating the amount of blood being pumped by this device is a difficult task with no answer so far. There were earlier attempts to develop a dedicated measuring system but the problem is yet to be solved [2], [3]. In practice this means, that the control parameters for devices are selected intuitively, on the basis of medical experience and information on general physical condition of the patient being assisted. That is why, the model of actual flow value in the device is desired.

In the last years, attempts had been made to designate models of pulsating flow devices. Most of the models use CFD methodology [4], [5]. It gives satisfying results in cases of modelling of stagnation regions whether volume of blood cells activation [6], [7] or study of the effect of device valve type on the flow conditions [8], [9]. However, boundary conditions have to be defined and the time of the simulation is far too long to allow real time modeling in clinical conditions. The use of other modeling methods is also problematic due to the wide range of possible control and working conditions. Models based on neural networks proved not to be useful [10]. Determining purely parametric models also did not bring satisfactory results. Quite good results can be achieved with the use of fuzzy logic [11], but in these models, the value of the pressure difference between input and output cannula has to be known. A lot of models is based on the lumped parameter or electric analogy description [12], [13]. They are useful in the case of device modeling in connection with models of cardiovascular system. Then, they allow for determination of the impact of the pump action on hemodynamic conditions prevailing in the circulatory system. However, they also need information on the pressures or flow values at the inlet and outlet of the device. In clinical cases, such measurements are not performed. That is why, our studies were conducted with the aim to elaborate the mathematical model in which simulated value of the flow generated by the device is determined only on the basis of signals measured in the controller or in the pneumatic side of the chamber.

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II. Materials and Methods

A. Research Stand

In order to develop an adequate mathematical description of the assist device working in the apex of the heart-artery configuration, it was necessary to conduct identification tests of the pump. For the sake of security and ethical issues, it is impossible to carry out such measurements on patients. Instead, the hybrid simulator of the cardiovascular system was used. It is based on a numerical model of the cardiovascular system implemented in real-time computer. That allows for easy changing of the model parameters allowing simulation of normal, as well as pathological conditions (including cardiac insufficiency). The physical part is limited to impedance transformers, which are mechanical devices allowing reconstruction of hydraulic conditions in chosen points of the system. The simulator initially allows for the simulation of conditions in the passive points of the cardiovascular system, such as the atrium or aorta [14]-[16]. The device was not adapted for simulation of conditions in the ventricle, which was represented numerically as a pressure source. Recent medical studies indicate, however, that implantation of blood pumps in the apex of the heart-aorta configuration is clinically more advantageous because the ventricle is better rinsed, what reduces the risk of blood clot formation. For this reason we have implemented a method for simulation of physical conditions prevailing in the apex of the heart, which allow for attaching and testing of pulsatile assist device working in the apex-aorta configuration [17]. We have also provided the possibility to set the pump control parameters through the application of a hybrid simulator and to enable the synchronization between MEV pump operation and hybrid simulator, i.e. to ensure the repeatable ejection from the device in the right phase of work of a natural ventricle. The measurement stand is presented in Fig. 1.

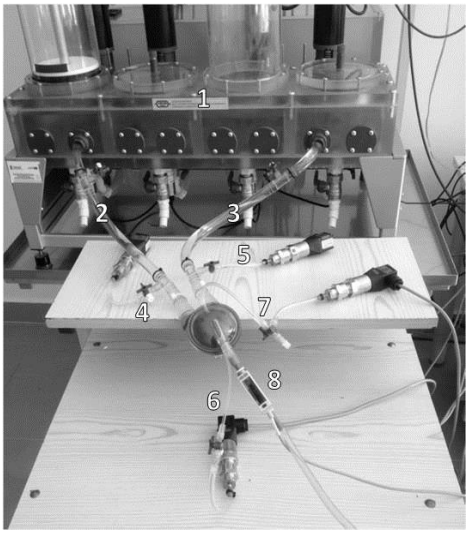

Figure 1. The measurement stand. 1 – physical part of hybrid simulator of cardiovascular system, 2,3 – connection points of hydraulic flow measurements probes (not connected in the photo, Transonic TS410 with ME-11PXL probes), 4,5 – measurements of input and output pressure (Wika S-20), 6,7 – measurements of blood and air chamber pressure (Wika S-20), 8 – air flow meter (CKD FSM2).

B. Measurements

The measurements were conducted with connected assist device for different simulated patient conditions and pump control parameters (14 series of measurements). Depending on the case, the driving maximum pressure was set on 250-150 mmHg, the minimum pressure was set between -25 and -75 mmHg, beat per minute was set on 60-100, and the percentage duration of the ejection time to the time of one cycle was 30-50%. The time of the device ejection delay, in relation to the work time of a natural ventricle was set between 0 and 45% of time cycle. The simulated patient conditions in most of series were set with the aim to reproduce the hemodynamic conditions of advanced left ventricle failure. However, a series of measurements for healthy heart and partial cardiac insufficiency were also performed.

Measurement signals were determined from: the numerical part of the hybrid simulator, its physical part, the assist device and its controller. From the hybrid simulator we have registered modeled hemodynamic values such as pressures, flows and volumes in selected points of cardiac system as well as a set of simulator parameters (approximately 30 signals). From the physical part of the hybrid simulator the values of pressures in connection tanks were measured as well as the value of the flow supplying the impedance transformers. On the assist device the following values were measured: pressures in the inlet and outlet cannulas (P_{in}, P_{out}), pressures in the blood and air chamber (P_{bl}, P_{pn}), flows in the inlet and outlet cannulas (Q_{in}, Q_{out}) and the air flow in the supply drain (Q_{pn}). From the device controller we collected information about values of pressures in the supply reservoirs: high and low (P_{hi}, P_{lo}), driving pressure in the outlet of the controller (P_{dv}) and the control signal of a linear valve connecting supply reservoirs with the outlet drain (*Ster*) as well as a set of control parameters. Control parameters are: driving systole and diastole pressure (*DSP*, *DDP*), percentage duration of the ejection time (*%SYS*) and ejection delay (*DEL*).

C. Modelling Method

This work was aimed at determination of the flow in the pulsatile support pump in the apex of the heart-artery configuration. The model was supposed to be based on the measured values, available in the assist device controller and the pneumatic part of the device. It is a complicated task due to the complexity of the processes occurring in the support pump. The artificial ventricle consists of two chambers, pneumatic and hydraulic (blood), separated by flexible diaphragm. The diaphragm is characterized by a certain flexibility and elasticity, hard for quantification and reproduction in the mathematical model. At the same time, the chamber has a limited volume. This means that the complete filling or ejection can occur. In those situations, despite the duration of the filling or ejection phase, there is no corresponding input or output flow due to limited range of the chamber volume. This implies situations in which, with the same control parameters, the work of the chamber is different, depending on whether there is or not a full filling or ejection.

Another complication is the modeling of mechanical disk valves located at the inlet and outlet of the blood chamber. These are the nonlinear elements with movement limitations, the work of which is dependent on the pressure drop across the valve. Of course the pump flow itself is also dependent on preload and afterload values, which in clinical conditions are unknown.

Therefore, in our work we searched for a universal description, which takes into account all aspects of the work of the artificial ventricle for all operating conditions. For this reason we decided to base on the analysis of the signals that could be realized in clinical conditions. We found, (Fig. 2), that the course of measuring volumetric flow in the air drain (Q_{pn}) is similar to the differential value of the outlet and inlet flow of the blood chamber (Q_{bl}). The coefficient of determination (R^2) for those signals amounts about 0.8, which refer to satisfactory level of fitting.

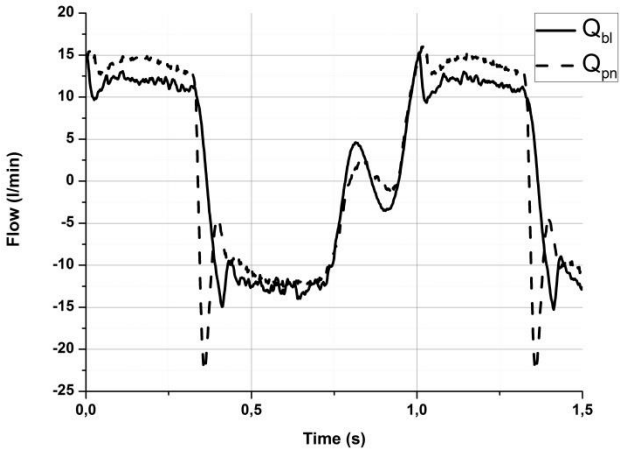

Figure 2. The measured values of blood flow through the device (Q_{bl}) and air flow in pneumatic supply drain (Q_{pn}).

Further research was aimed at determining whether it was possible to determine the inlet and outlet flow of the blood chamber (Q_{in}, Q_{out}) basing on the air flow measurement. For this purpose we adopted the valve model described in [13], where the resistance of the valve is described as a function of time and resistance limit values. That model assumes constant valve resistance R_c in its open position, constant resistance R_0>0 in closed position (representing the reverse leakage through the valve) and a linear function of transition between those resistances in periods of opening and closing of the valve. In our case, the resistances of the valves were replaced with a coefficient of valves permeability K. This means that the character of the function course remained similar, however, a high function value, close to unity, occurs in open position and low, approach zero, when the valve is closed (Fig. 3).

In order to obtain universal description for all operation cases, the valves permeability function was set, on the basis of a control signal of supply unit (*Ster*). The time of opening and closing of the valves and the delay in relation to the control signal were determined experimentally basing on the measurement data. Function parameters are given in Table I.

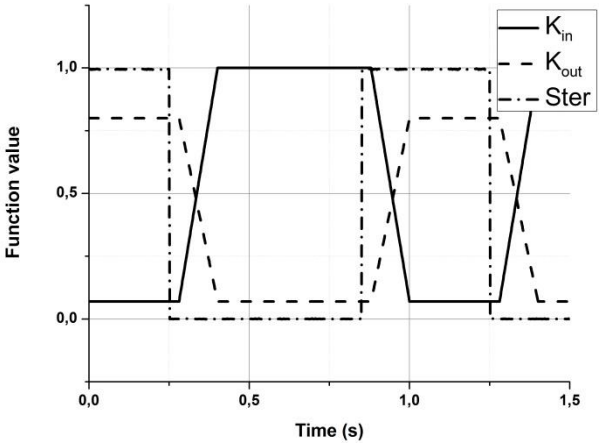

Figure 3. The time course of permeability function for the inlet (K_{in}) and outlet (K_{out}) valve and a control signal (*Ster*) normalized to one. High value of control signal indicates ejection phase.

TABLE I. PARAMETERS OF THE VALVES PERMEABILITY FUNCTION

Parameter	Symbol	Value
time delay in relation to *Ster*	τ (s)	0.03
valve opening time	t_0 (s)	0.12
valve closing time	t_c (s)	0.12
min/max input permeability	$K_{in\ min}$	0.07
	$K_{in\ max}$	1
min/max output permeability	$K_{out\ min}$	0.07
	$K_{out\ max}$	0.8

The input and output blood flow is given by equations:

$$Q_{in_m}(t) = Q_{pn}(t) \cdot K_{in}(t) \quad (1)$$

$$Q_{out\_m}(t) = Q_{pn}(t) \cdot K_{out}(t) \quad (2)$$

and the modelled differential value of these flows is:

$$Q_{bl\_m}(t) = Q_{out}(t) - Q_{in}(t) \quad (3)$$

where: Q_{in}, Q_{out} – input and output flow from the blood chamber of the device, Q_{pn} – air flow in pneumatic supply drain, K_{in}, K_{out} – input and output permeability function and Q_{bl} – blood flow through the device.

It can be noticed that the inertia of the liquid depends on its acceleration:

$$M \frac{dQ_{bl}(t)}{dt} \quad (4)$$

The flow of the blood is a modelled value, so in the extended model of the flow we included the air flow derivative signal instead:

$$Q_{bl\_me}(t) = Q_{out}(t) - Q_{in}(t) - M \frac{dQ_{pn}(t)}{dt} \quad (5)$$

where coefficient of inertia (M) was determined experimentally at the level of 0.013.

III. RESULTS

As a result of the simulations, the modelled values of blood flow through the device were obtained. Fig. 4 shows the measured flow and the flow modelled

according to (3). Fig. 5 shows the measured flow and the flow modelled according to (5).

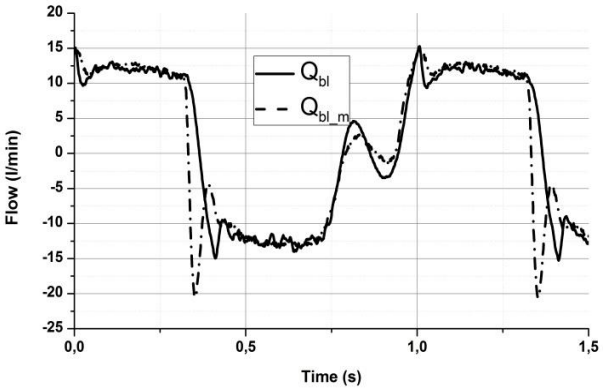

Figure 4. The measured values of blood flow through the device (Qbl) and modeled flow (Qbl_m).

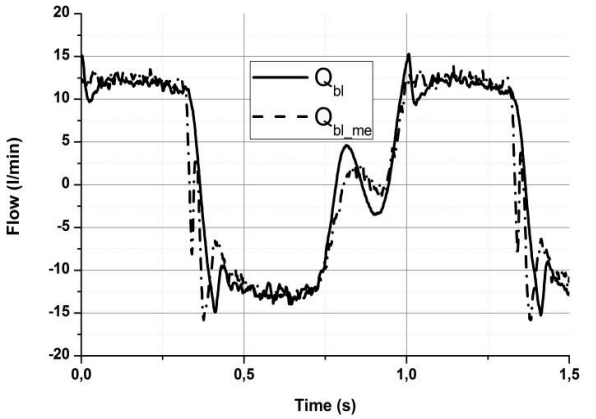

Figure 5. The measured values of blood flow through the device (Qbl) and modeled flow (Qbl_me).

The models with the same coefficients of permeability function (K_{in}, K_{out}) were tested for all 14 different cases of assist device operation (different control parameters and simulated cardiovascular states). We have calculated determination coefficients of measured blood flow signal (Q_{bl}) according to: measured signal of the air flow (Q_{pn}), model of blood flow (Q_{bl_m}) and the model taking into account the inertia of the flow (Q_{bl_me}). Values of R^2 for each case and its average value ($\overline{R^2}$) are shown in Table II.

IV. Discussion

As it can be seen in Table II, the average coefficient of determination for the measured signal of air and blood flow is about 0.8 which gives only the satisfactory level of fitting. An nddition of valves permeability function improves the result only in a small extent, but gives a good level of fitting. However the consideration of flow inertia improves results significantly. Average coefficient of determination is then about 0.91 which is a very good level of fitting in almost every case. What is most important, the proposed model gives similar fitting results for different cases of device operation parameters. A disadvantage of the proposed model is the need for air flow measurement which is not provided in the existing control units. Luckily, the sensor is not large, heavy or expensive, so there is an opportunity to complete driving units with this measurement.

V. Conclusions

The obtained model allows for good reconstruction of the support device flow for different work conditions without any measurements performed in the blood-side of the device. Further work will focus on attempts of model improvements, on better estimation of the inertia coefficient and on development of the method of chamber volume estimation based on the flow model. Furthermore, we will investigate the possibility of automatic selection of the control unit parameters that ensure performance of the set value of output volume.

TABLE II. Coefficient of Determination R^2 for Different Models and Various Operating Cases

Data	Model	R^2 value for each case														$\overline{R^2}$
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Q_{bl}	Q_{pn}	0.81	0.85	0.82	0.78	0.84	0.69	0.79	0.80	0.80	0.80	0.78	0.81	0.80	0.77	**0.80**
Q_{bl}	Q_{bl_m}	0.82	0.89	0.82	0.79	0.84	0.77	0.80	0.81	0.80	0.81	0.79	0.82	0.81	0.78	**0.81**
Q_{bl}	Q_{bl_me}	0.92	0.93	0.91	0.91	0.94	0.82	0.89	0.99	0.87	0.92	0.91	0.90	0.89	0.90	**0.91**

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