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Modeling, characterization and test of a pediatric ventricular assist device

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Abstract. This paper presents a 0D model for the pulsatile pediatric Ventricular Assist Device (pVAD), as well as its characterization and test results obtained by using an experimental hydraulic system that provides operational conditions close to the physiological conditions observed in pediatric patients. The measurements of the physical quantities used in characterization of the pVAD have been obtained by using the LabVIEW platform. The air chamber pressure signal is used to model the pneumatic actuation system behaviour, whereas the pressure-volume relationship inside the blood chamber is applied to model the pVAD compliance. The set of test and validation results demonstrated the correctness of the proposed model.

1. Introduction

Heart transplantation is still the best alternative for the treatment of terminal heart disease. However, the number of patients on the heart transplant waiting list is large due to the limited availability of donor heart, what results in a high rate of death among these patients. Thus, mechanical circulatory support devices that assist in the pumping of the heart, also denominated as Ventricular Assist Devices (VADs), can be applied in these patients to maintain the hemodynamic variables at physiologically acceptable levels and to prolong the life expectancy [1].

Before the implantation of VADs, lumped parameter models, usually referred as 0D model, can be used to evaluate the interaction of these devices with the human cardiovascular system. A 0D model uses the concept of analog electrical circuit, in which the electric current represents the flow in blood vessels and the electrical voltage represents the pressures in the circulatory system [2].

The modeling of these devices is, in general, realized by physical tests in hydraulic system, to avoid *in vivo* experiments. These hydraulic systems are of great importance to correct problems and to improve the performance of VADs, as well as to assist in the development of control techniques [3].

In Brazil, a widely used pneumatic type of VAD is developed by Bioengineering Division of the Heart Institute, Hospital das Clínicas, Faculty of Medicine on the University of São Paulo (InCor - HCFMUSP). This device is used as a bridge to the transplantation procedure and is implanted in adult patients with chronic heart failure, which are on the heart transplant waiting

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list. In the case of pediatric patients, a new pediatric device called pVAD is being developed at the same Institute.

To understand the influence of the pVAD in the circulatory system of pediatric patients, a 0D model of this device will be developed in this work. For that, the pVAD is coupled to a hydraulic system so that physical tests can be performed and measurements of pressure and flow of this VAD can be recorded and used in the estimation procedure. The organization of the paper is as follows. The hydraulic system and the methods used to model the pVAD are presented in Section 2. In section 3, physical measurements of the hydraulic system and the pVAD are compared with the estimated 0D model. Concluding remarks are presented in Section 4, and some directions for further work are suggested.

2. Materials and Methods

This section describes the hydraulic system and presents the methods to model the pVAD.

2.1. The hydraulic system

The hydraulic system that was used to evaluate the pulsatile pVAD is shown in figure 1. It is basically composed by: a pVAD, a pneumatic actuation driver, two acrylic reservoirs (aortic and atrial) and cannulas. A simplified schematic of this system can be seen in figure 2.

The pulsatile pVAD (15 mL ejection volume) has an air chamber, a blood chamber with two opening and a membrane between them. There are one-way biological values on both the inlet and outlet that only allow the inflow or outflow liquid of the pVAD. The liquid used in the experiments is a solution composed by $\frac{2}{3}$ of saline and $\frac{1}{3}$ glycerin to reproduce the blood viscosity. To avoid fungal proliferation, 1% of benzyl alcohol was added in the solution.

The pneumatic actuation driver consists of one solenoid valve (SV), used for the control the filling and the ejection times of the pVAD, and of two pressure regulators that are used for the adjustment of both ejection pressure (P_e) and filling pressure (P_f) . This driver generates periodically a membrane displacement which reproduces the pulsation and pumping of the liquid. The acrylic reservoirs are called aortic and atrial because they provide pressure levels close to pressure levels in a pediatric patient.





Figure 1. The hydraulic system coupled with the pVAD and pneumatic actuator driver.



The available signals in this system are: a rtic pressure (P_{ao}) at the artic reservoir, atrial pressure (P_a) at the atrial reservoir, blood chamber pressure (P_{bc}) at the blood chamber of the pVAD, air chamber pressure (P_{ac}) at the air chamber of the pVAD, inflow (Q_i) at the inlet cannula and outflow (Q_o) at the outlet cannula.

To read and save these signals from sensors, a 16 bit National Instruments (NI) myDAQ module was used, which is connected to the computer by means of USB cable. The signals can be monitored by an Human Machine Interface (HMI) implemented on LabVIEW platform. The

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flow signals, Q_i and Q_o , are acquired using one non-invasive ultrasound flow sensor [4], which gives the mean flow (L/min).

There is one pressure sensor based on a strain gauge that is used to measure the pressure signals P_{ao} , P_{bc} and P_a (mmHg), one at a time in the system [5]. Inside of the pneumatic actuation driver, there is another dedicated pressure sensor, also based on a strain gauge, used to measure the signal P_{ac} [6], which is the signal used to synchronize all measurements, i.e., all signal are recorded along with the P_{ac} . This synchronization method is valid because the entire system operates in a periodic cycle, as shown in Torres *et al.* [7].

2.2. Model of the pneumatic actuation system

For the complete modeling of the pVAD behaviour, it is necessary to model the pneumatic actuation system. This system is similar to that described by Ferrari *et al.* [8], as highlighted in a simplified schematic shown in figure 3. The SV output, with pressure levels P_e or P_f , is connected to the air chamber by an air tubing.

Based on this description and using the analogy between hydraulic and electric systems, the 0D model of the pneumatic actuation system is modeled as a RC circuit where: the resistor R_{ac} represents the air tubing resistance; the capacitor C_{ac} represents the compliance of the air chamber; and the pressure P_{ac} , equivalent to the voltage across the capacitor C_{ac} , is the air chamber pressure in according to input pressure P_e or P_f . Since there is no fluid exchange through the membrane, an interface between the pneumatic actuation system and the blood chamber is necessary to separate them. The electrical element chosen for that purpose was a voltage controlled voltage source, αP_{ac} , where α represents the pressure drop across the membrane. In this work, this pressure drop was negligible and, therefore, $\alpha = 1$. Figure 4 shows the 0D model of the pneumatic actuation system.





Figure 3. Simplified schematic of the pneumatic actuator system.

Figure 4. 0D model of the pneumatic actuation system.

The resistance R_{ac} can be calculated according to the air tubing resistance using the Poiseuille law as follow [9]:

$$R_{ac} = \frac{8\eta l_{ac}}{\pi r_{ac}^4} \tag{1}$$

where η is the air viscosity, l_{ac} is the length of the tube and r_{ac} is the radius of the tube.

The z-domain transfer function of the first order RC system, using the Euler discretization method, are the following:

$$\frac{Y(z)}{U(z)} = \frac{b_1}{1 - a_1 z^{-1}} \tag{2}$$

where $a_1 = R_{ac}C_{ac}/(R_{ac}C_{ac} + T_s)$, $b_1 = T_s/(R_{ac}C_{ac} + T_s)$ and T_s is the sampling time of the system. The least squares method (LSM) was used to determine the parameter vector $\theta = [a_1 \ b_1]^T$. In turn, the time constant $\tau_{ac} = R_{ac}C_{ac}$ can be calculated using these parameters. With the value of R_{ac} , calculated by equation 1, the value of the parameter C_{ac} is calculated directly.

2.3. Model of the pVAD

The modeling of the pVAD is based on the study done by Hunsberger [10]. Firstly, the device was decoupled from the hydraulic system, the two valves were removed and the output of the pVAD was blocked. From these preliminary steps, a static test was performed to obtain the compliance of the blood chamber (C_{bc}) based on the pressure-volume (PV) relationship inside this chamber. The procedures of this test are:

- (i) a syringe was coupled to the pVAD input to fill this device injecting 35 mL of solution;
- (ii) quantities of 1 mL were withdrawn from the inside of pVAD using the same syringe;
- (iii) the pressure (P_{bc}) and the blood chamber volume (V_{bc}) were recorded each 1 mL.

At the end of the static test, a PV curve is generated with the recorded values. The compliance C_{bc} is calculated according to the following expression:

$$C_{bc} = \frac{\Delta V_{bc}}{\Delta P_{bc}} \tag{3}$$

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where ΔV_{bc} is the change in the blood chamber volume and ΔP_{bc} is the change in the blood chamber pressure. The pVAD is designed to work in a safe operating region, defined from 24 mL to 33 mL. Inside this operating region, the compliance C_{bc} can be approximated by a linear function and its value is given by the inverse of the PV curve slope.

In this work, a 0D model was developed for the cannulas, pVAD and pneumatic actuation driver. The hydraulic system was used to produce reasonable pressure levels at the input and output of the pVAD cannulas. The model structure and a simplified schematic of the pVAD, cannulas and the pneumatic actuation driver are shown in figure 5. The biological valves were considered ideal and the opening and closing state was modeled by the diodes D_i and D_o [10]. The inductances L_i and L_o are both calculated as follows [9]:

$$L_{i,o} = \frac{\rho l_{i,o}}{\pi r_{i,o}^2} \tag{4}$$

where ρ is the density of the fluid, $l_{i,o}$ is the length of the cannulas and $r_{i,o}$ is the radius of the cannulas. The resistance of the inlet and outlet cannulas, R_i and R_o respectively, were calculated by the following pressure relationship: $P_a - P_{bc} = R_i Q_i + L_i \dot{Q}_i$. At the instant of the maximum flow, the flow derivative is null and $\hat{R}_i = (P_a - P_{bc})/Q_i$ and $\hat{R}_o = (P_{bc} - P_{ao})/Q_o$. The value of the maximum instantaneous flow was obtained by the em-tec flow sensor using a sampling rate of 10 Hz. Thus, it is possible to obtain the values of theses resistance in a more accurate way then using equation 1.



Figure 5. (a) 0D model and (b) simplified schematic of the pVAD, cannulas and pneumatic actuation driver.

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3. Results and Discussion

Figure 6 shows the input pressure signal with values $P_e = 180 \text{ mmHg}$ and $P_f = 0 \text{ mmHg}$. As can be seen in this figure, the measured pressure P_{ac} has a behavior very similar to a RC circuit response. That way, equation 1 leads to $R_{ac} = 0.25 \text{ mmHg.s/mL}$. The value of the time constant, calculated using the LSM and the estimation dataset ($N_e = 1600 \text{ samples}$), is $\tau_{ac} = 0.0343 \text{ s}$. So, the compliance of the air chamber is $C_{ac} = 0.1370 \text{ mL/mmHg}$. All measured signals were recorded with a sampling time $T_s = 0.001$ seconds.

Using the proposed 0D model depicted in figure 4, the estimated air chamber pressure \hat{P}_{ac} was very close to the measured signal. The dataset used to validate this model was different from the estimation dataset, but with the same size ($N_v = 1600$ samples). The normalized mean square error (NMSE) between the measured and estimated curve is defined as



Figure 6. Input pressure $(P_e \text{ and } P_f)$ and pressure curves in the air chamber $(P_{ac} \text{ and } \hat{P}_{ac})$.

Figure 7 shows the PV curve obtained by the static test. The value of the blood chamber compliance is $C_{bc} = 0.2521 \text{ mL/mmHg}$, with $P_{ac} = 0 \text{ mmHg}$, in according to equation 3.





Figure 8 shows the curves of the measured and estimated blood chamber pressures (P_{bc} and \hat{P}_{bc}), with $R_i = 0.5 \text{ mmHg.s/mL}$, $R_0 = 1.3 \text{ mmHg.s/mL}$ and $L_i = L_o = 0.04 \text{ mmHg.s}^2/\text{mL}$. The P_{bc} curve was obtained with the pVAD coupled to the hydraulic system and the \hat{P}_{bc} curve was obtained by numerical simulation of the 0D model proposed here. At the time interval between 0.2 and 0.4 seconds, or between 1.0 and 1.2 seconds, it can be noticed that the estimated curve does not reach the measured curve. This time interval refers to the start of filling phase, when the outlet valve is closing and the inlet valve is opening. Before closure of the outlet valve, it can occur a backflow that is not modeled in this work, once that the pVAD valves were

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modeled by ideal diodes. Moreover, the membrane displacement can influence the C_{bc} . These two phenomena must be investigated to improve the model response. Figure 9 shows the HMI implemented on LabVIEW to monitor the available signals of the hydraulic system.





Figure 8. Validation of the 0D model using the pressure signal.

Figure 9. Snapshot of the HMI showing the signals P_{ac} and P_{ao} .

4. Conclusions

A 0D model for the pVAD, as well as for the cannulas and pneumatic actuation driver, was proposed in this work. The available signals in the experimental hydraulic system were defined somehow similar to a pediatric patient's health condition and these signals were monitored by using the HMI implemented on LabVIEW platform. The values of the parameters R_{ac} and C_{ac} were estimated using the least square method and based on the measurements of the air chamber pressure. The compliance of the blood chamber, C_{bc} , was obtained by the pressurevolume relationship inside the blood chamber (static test). The validation results using these parameters demonstrate the correctness of the proposed 0D model. This model will be very useful to design and test feedback control laws used to impose proper operating conditions for the pVAD. A more accurate model for the pVAD is currently being developed taking in account the backflow through the valves and the influence of the membrane displacement.

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