Design of a Hydrodynamic Mock Circulation System For Prosthetic Heart Valve Testing

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Abstract

A new hydrodynamic mock circulation system was developed, which can test prosthetic heart valves of various sizes in order to obtain valve parameters, such as pressure drop, regurgitation and valve performance index with a high reproducibility. High reproducibility can be obtained only under equal testing conditions, i.e., the compliance, resistance and inertance of the mock circulation system must be constant. Parameter estimation using actual pressure and flow data was applied to calculate these systemic variables in order to adjust them to create the necessary equal testing conditions.

Introduction

The human cardiovascular system consists of complex network of blood vessels and arteries, with various dimensions. Important parameters in addition to vessel and artery dimensions are the elasticity of vessel walls and blood, the density of the blood and the viscosity, resulting in compliance, resistive and inertia effects. Earlier research has showed that the cardiovascular loop in good approximation can be modeled by a controllable pump (modeling the heart), two prosthetic heart valves and a lumped three element windkessel model, consisting of a closed windkessel, a throttle and an open cylinder, representing the compliance, resistive and inertia effects respectively. See figure 1.

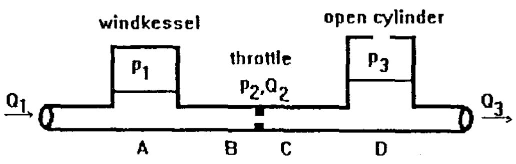

Figure 1: Schematic diagram of a lumped 3 element windkessel model.

Unfortunately, in practice, it will be impossible to realize a model with perfectly lumped parameters, since the connecting tubes will also influence the compliance, inertance and resistance values of the system. For reproducible valve testing, however, it is necessary to know these values in order create equal and physiological testing conditions. Therefore, the method of parameter estimation was applied. Parameter estimation uses actual flow and pressure data to calculate the parameters of a known model (i.e., only the presence of the elements is known, not the value), based on the principle that the output *Y(n)* of is determined by input *U(n)* and earlier in- and output values.

In this paper, hydrodynamic valve parameter experiments are discussed, using the above described three element windkessel model in combination with parameter estimation.

Theory

For pulsate flow conditions and constant cross-sectional area **A**, it can be shown that the pressure drop across a heart valve can be described [24] by formula (1).

$$\Delta p = \frac{\rho}{2A}\cdot Q_{rms}^{\;2} + \rho\cdot\frac{dQ_{rms}}{dt}\cdot\frac{l}{A} = R\cdot Q_{rms}^{\;2} + I\cdot\frac{dQ_{rms}}{dt} \qquad (1)$$

Δp = pressure drop *Qrms = root mean square of flow*
ρ = blood density *l=distance related to pressure drop*
A = cross-sectional area *R = resistance* *I = inertance*

Formula (1) shows that the pressure drop across a valve can be described as the sum of 2 terms, a resistive term and an inertia term. Formula (1) forms the basis for valve parameter calculations. The first parameter is the energy loss per beat, which can be calculated by time-integrating the pressure drop - flow product [5]:

$$\text{Energy loss} = \int_T \Delta p(t)\cdot Q_{rms}(t)\cdot dt \qquad (2)$$

The second parameter that will be calculated is the effective valve orifice area, defined as [4,6,21]:

$$EVOA = \frac{Q_{rms}}{51.6 \cdot \sqrt{\overline{\Delta p}}} \quad (3)$$

with $$\overline{\Delta p} = \frac{1}{T} \cdot \int_0^t \Delta p \cdot dt \quad (4)$$

Another important valve parameter is the back flow or regurgitation, which can simply be calculated by time-integrating the flow $\boldsymbol{Q_{rms}(t)}$ when negative:

$$Reg. = \int_0^t Q_{rms,t} \cdot dt \qquad (Q_{rms,t} < 0) \qquad (5)$$

Finally, a valve performance index ***VPI*** [21] can be calculated (6), where SRA represents the valve sewing ring area:

$$VPI = \frac{EVOA}{SRA} \qquad (6)$$

As described above, the compliance, resistance and inertance of the mock system will be calculated using parameter estimation

A dynamic system with input *u(t)*, output *y(t)* and noise *n(t)*, sampled in discrete time $k = 1,2,3,...$ can be related through a linear difference equation (7).

$$\begin{aligned} &a_0 y(k) + a_1 y(k-1) + .. + a_n y(k-n) \\ &= b_0 u(k) + b_1 u(k-1) + .. + b_n u(k-m) \end{aligned} \qquad (7)$$

Equation (7) can be rewritten into equation (8) through (10),

$$y(k) = \theta^T \varphi(k) + n(k) \qquad (8)$$

$$\varphi^T = (-y(k-1),...,-y(k-n),u(k),u(k-1),...,u(k-m)) \qquad (9)$$

$$\theta^T = \frac{1}{a_0}[a_1,...,a_n,b_0,...,b_n] \qquad (10)$$

where φ^T(k) is called the observed vector, θ^T(k) the parameter vector and *n(k)* the noise. The parameter vector θ is to be estimated from measurements of *y(k)* and $\varphi(k)$, minimizing the noise *n(k)*. The following so called *least square* criterion function can be written down (23), which expresses the equation error caused by noise after N measurements:

$$n_N(\theta) = \frac{1}{N}\sum_{k=1}^{N} \alpha_k [y(k) - \theta^T \varphi(k)]^2 \qquad (11)$$

In this equation α_k represent a sequence of positive numbers to give different weight to different observations. In [23] it explained that an optimal choice should be related to the variance of the noise term *n(k)*. Minimizing equation (11) with respect to θ will result in the so called *least square estimate* (12),

$$\hat{\theta}^T(N) = [\sum_{k=1}^{N} \alpha_k \varphi(k)\varphi^T(k)]^{-1} \sum_{k=1}^{N} \alpha_k \varphi(k) y(k) \qquad (12)$$

provided the inverse exists. Using equation (12) it is now possible, using observed data, to calculate the estimate vector. For computer calculations, however, expression (12) is not very suitable. In [24] it is shown that equation (12) can be rewritten into recursive equations (13) through (16):

$$\varepsilon(k) = y(k) - \hat{\theta}^T(k-1)\varphi(k) \qquad (13)$$

$$L(k) = \frac{P(k-1)\varphi(k)}{\lambda(k) + \varphi^T(k)P(k-1)\varphi(k)} \qquad (14)$$

$$\hat{\theta}(k) = \hat{\theta}(k-1) + L(k)\varepsilon(k) \qquad (15)$$

$$P(k) = P(k-1) - L(k)\varphi^T(k)P(k-1) \qquad (16)$$

Vector $\hat{\theta}^T(k)$ is the *estimated parameter vector* with dimension Nx1, $\lambda(k)$ is a data dependent *forgetting factor*, $\varepsilon(k)$ is the *predicted estimation error*, *P(k)* is called the *covariance matrix* with dimension NxN and *L(k)* is the so called *gain vector* with dimension Nx1. The initial conditions can be chosen as follows [23], where c represents a large constant, typically of the magnitude 100 to 1000:

$$P(0) = cI \qquad (17a)$$

$$\hat{\theta}(0) = \overline{0} \qquad (17b)$$

Figure 2 shows a schematic of an electrical analog of the mock-circulation system in terms of resistances, capacitors and an inductor. The aortic flow is considered an input current, the aortic pressure as an output voltage.

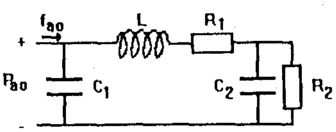

Figure 2: Electrical analog of the mock circulation system.

The z-transform of the transfer function *G(z)* of the system is defined as in equation (18). Since there exist 3 energy storing elements, the transfer function will be of the third order.

$$G(z)=\frac{p_{ao}(z)}{q_{ao}(Z)}=\frac{u(z)}{i(z)}=\frac{a_0'+a_1'z^{-1}+a_2'z^{-2}+a_3'z^{-3}}{b_0'+b_1'z^{-1}+b_2'z^{-2}+b_3'z^{-3}} \qquad (18)$$

Unfortunately, a direct z-transformation of the electrical analog, which will express the coefficients of the transfer function in terms of R1, R2, C1, C2 and L is difficult. Therefore the Laplace transform (19) is calculated first and then, using the bilinear transformation, de coefficients $a_0',\ldots,b_3'$ can be obtained, expressed in R1, R2, C1, C2 and L.

$$\frac{u(s)}{i(s)}=\frac{s^2LR_2C_2+s(L+R_1R_2C_2)+R_1+R_2}{s^3LR_2C_1C_2+s^2(LC_1+R_1R_2C_1C_2)+s(R_1C_1+R_2C_1+R_2C_2)+1} \qquad (19)$$

Finally, the following discrete auto regressive least square parameter estimation model can be derived:

$$y(k)=\varphi(k)^T\theta(k) \qquad (20)$$

$$\varphi(k)^T=[-y(k-1),-y(k-2),-y(k-3),\ u(k),u(k-1),u(k-2),u(k-3)] \qquad (21)$$

$$\theta(k)^T=\frac{1}{b_0'}[b_1',b_2',b_3',a_0',a_1',a_2',a_3'] \qquad (22)$$

$$y(k)=p_{ao}(k);\quad u(k)=q_{ao}(k) \qquad (23)$$

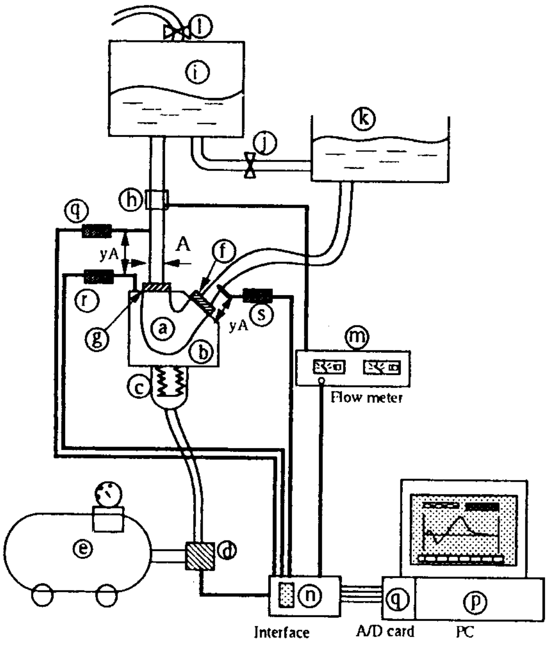

Figure 3: Hydrodynamic valve testing system setup

Materials and Methods

Figure 3 shows a schematic diagram of the used mock circulation system. In figure 3, (a) is a polyurethane sac. Its shape is similar to the human heart ventricle and has a total volume of 250 ml. The sac has 1 inlet (f) and 1 outlet (g), both containing a prosthetic heart valve.

This sac is placed into a 100% closed chamber (b), which is completely filled with water. At the bottom of this chamber, there is a membrane, which is connected to a rubber, expandable sac (c). This sac is connected through an electronically controlled throttle (d) to either an air compressor (e) ('closed state' of the throttle) or the open air ('open state' of the throttle), i.e., the pressure within the rubber sac will be equal to the pressure generated by the air compressor (throttle is in closed state) or equal to the open air pressure (throttle is in open state). In closed state, the rubber sac (c) will expand, causing the membrane of the chamber (b) to expand. Since the chamber is closed and the water inside the chamber can be presumed to be incompressible, an expansion of the rubber sac (c) by a volume x will cause the polyurethane sac (a) to compress by the same volume x and also volume x of the fluid inside the polyurethane sac (a) to be pumped upwards through the prosthetic heart valve (g) into the 'aorta' (the heart valve at position (f) will close). Using this setup, it is now possible to model the systolic and diastolic period of one heart stroke by controlling the throttle (d). The heart rate is equal to the switching frequency of the throttle, the systolic/diastolic ratio is dependent on the duty cycle of the throttle switching. The stroke volume is dependent on the amount of expansion of the rubber sac (c), which is related to the pressure generated by the air compressor. The maximum volume expansion of the rubber sac is about 70 ml. Therefore, using switching frequencies up to 140 bpm, a cardiac output in the range of about 2-10 lpm can be achieved, which is sufficient to model the normal human cardiac output (ca. 7.5 lpm).

The fluid pumped through the heart valve (g) will float through an ultrasonic blood flow sensor (h) to the compliance, a closed cylinder (i). The value of the compliance can be changed by pumping air into the closed chamber through throttle (l). After this, the fluid floats through a tube containing a throttle (j) (the systemic resistance) to an open cylinder (k). Finally, the open cylinder (k) is connected through another throttle to the inlet of the polyurethane sac (a) and the cardiovascular loop is completed.

During the tests the pressure as a function of time was monitored and resistance and compliance were adjusted so that the pressures in the system correspond with physiological values (i.e. in the aorta between 120/80 mmHg and in the pulmonary artery between 40/20 mmHg).

The fluid that was used is a 33% glycerin/water blood analog, having a viscosity similar to that of normal human blood. As mentioned in [15] and [16] this will not affect the performance of any kind of heart valve, especially in short testing periods.

The flow signal is measured by an ultrasonic flow sensor (h) and transferred to a blood flow meter (m). The blood flow meter (m) outputs an analog signal through interface (n) to an A/D-card (o), which is installed in a PC (p).

Pressure sensors (q), (r) and (s) measure the pressure in respectively aorta, chamber (b) and pulmonary, and also output an analog signal through interface (n) to the A/D-card (o) installed in PC (p). The used pressure sensors convert an absolute fluid pressure into an analog, electrical signal, using a built-in temperature compensated electrical circuit. Pressure sensor (q) measures the aortic pressure. The ventricular pressure is measured by pressure sensor (r), which is connected to chamber (b) at the same vertical height as the heart valve.

The A/D-card consists of an 11-bit A/D-converter and can acquire analog data in the range of 0-5V of eight channels simultaneously at a sample frequency of maximally 1 kHz per channel, which is sufficient since the maximum frequency in pressure and flow signals will not exceed 100 Hz. The experiments in this paper were performed at f_{sample} = 200 Hz.

A software system was developed, which can monitor, acquire and process the pressure and flow signals so that all discussed valve parameters can be calculated. It also controls the heart rate and systolic/diastolic duration by controlling switch (d) in figure (3). The software calculates the valve parameters using n cycles (n varies between 2 and all acquired cycles, as desired), since, when averaged, the error of all parameters will decrease by $\sqrt{n}$ as the number of cycles used for calculation increases by n.

Table 2: Parameter Update Algorithm
Step 1: Initialization, assign: k=0; P(k)=1000*I; θ(k)=0
Step 2: Calculate prediction error $\varepsilon(k) = y(k) - \hat{\theta}^{T}(k-1)\varphi(k)$
Step 3: Calculate gain vector $L(k) = \dfrac{P(k-1)\varphi(k)}{\lambda(k) + \varphi^{T}(k)P(k-1)\varphi(k)}$
Step 4: Update the parameter estimate $\hat{\theta}(k) = \hat{\theta}(k-1) + L(k)\varepsilon(k)$
Step 5: Update the covariance matrix $P(k) = P(k-1) - L(k)\varphi^{T}(k)P(k-1)$
Step 6: Calculate R1, R2, C1, C2 and L
Step 7: Increase k by 1 and proceed to step 2 until k=500.

Although all electrical connections are made using shielded wires, some noise occurs. This noise is eliminated by software, using a three point moving averaging algorithm, which has a low-pass filtering effect. Since the pressure and flow signals consist of frequencies less than 100 Hz, this software filtering will not effect the reliability of the acquired pressure and flow signals.

To monitor the mock system parameters the software can also calculate R_1, R_2, C_1, C_2 and L using the previous mentioned parameter estimation model with actual pressure and flow data. The selected pressure and flow data samples are converted into 500 samples, using interpolation. The used algorithm is summarized in table (1).

Results

Three types of prosthetic heart valves with a diameter of 2.2 cm were tested: a Bjork-Shiley mechanical valve, a Bileaflet polymer valve and a newly developed polymer parachute valve. All tests were performed, following the method described above. In figure (4) the captured pressure and flow wave forms are displayed. In figure (5) through (7), the most important testing results are presented, i.e., the average systolic pressure drop as a function of Q_{rms}, the VPI and regurgitation as a function of the cardiac output.

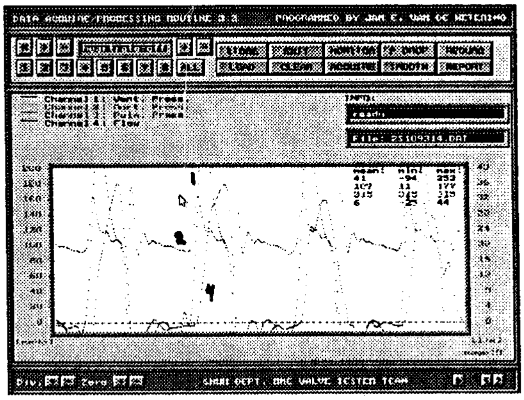

Figure 4: The pressure and flow wave forms of a Bjork-Shiley prosthetic valve tested in the mock circulation system.

Discussion

The main objective when designing a mock circulation system for valve testing is that it must represent the human physiological cardiovascular system as close as possible. Figure (4) shows that the pressure and flow wave forms created with our mock circulation system matches very well with

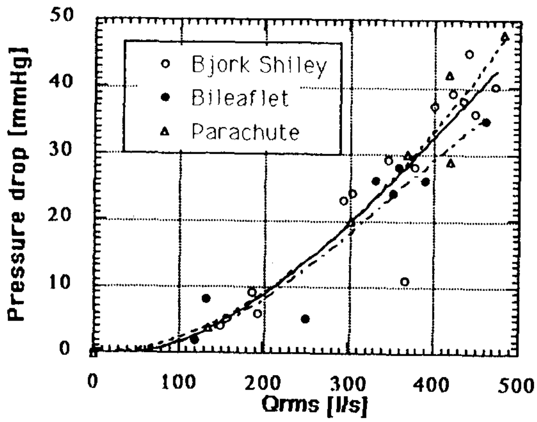

Figure 5: Average systolic pressure drop vs. Q_{rms} of three different valve types.

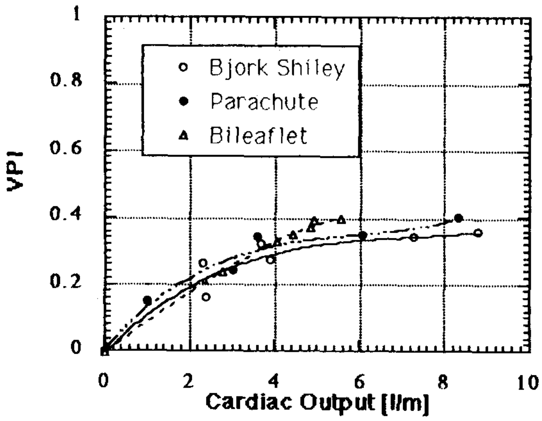

Figure 6: *VPI* vs. cardiac output of three different valve types.

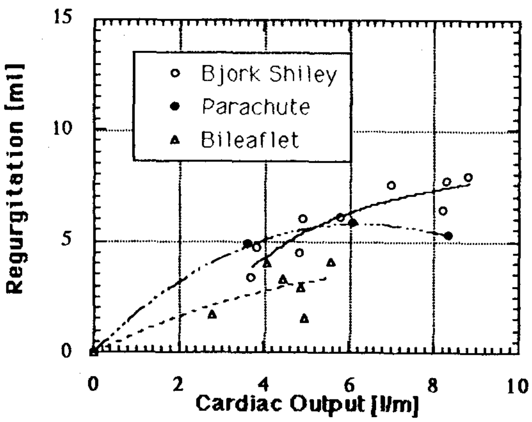

Figure 7: Regurgitation vs. cardiac output of three different valve types.

physiological data, i.e., both, shape and value are very close to reality. Also, the shape of the calculated pressure drop as a function of Q_{rms}, displayed in figure (5), is in agreement with the theory (formula (1)) and earlier testing results in other laboratories [4,5]. Therefore it can be concluded that our mock circulation system is able to simulate the human physiological system in very good approximation.

Besides this, the mock circulation system has some advantages above other existing systems, i.e., all systemic variables can be adjusted easily and are on-line monitored using parameter estimation, which guarantees high reproducibility; Heart rate, duty cycle and cardiac output can simply be regulated by the software; All kinds of valves with different diameters can be tested; The software is mouse-controllable and easy to operate. The system is also designed to integrate flow visualization experiments as well, without any necessary modifications.

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