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In vitro evaluation of artificial valve regurgitation

KRYSPIN MIROTA

Department of Mechanical Engineering Fundamentals, University of Bielsko-Biala

An arbitrary test procedure for the evaluation of artificial heart valve was used to assess two basic kinds of flow characteristics related to forward flow and regurgitant flow. The forward-flow characteristics describe valvular throttling effect. Methodology is well documented in literature and based on long-term engineer's experience in throttling device exploration. Contrary to this, the measurements of back-flow are always difficult and very problematic. In this paper, a new method of regurgitant flow evaluation is presented. It was formulated based on a flow equation analysis for this particular class of fluid motion. As an example some results from in vitro tests were presented.

1. Introduction

Artificial heart valves like natural ones – in mechanical sense – are one-way directional valves. The flow of fluid in the direction required opens the valve, while backflow closes the valve. Therefore, one of the most important characteristics of the valve as a flow-control device is the volume of fluid that flows in an opposite direction during one cycle. The volume of fluid in regurgitant flow *RV* is the sum of:

- closing volume *CV*, the component of the regurgitant volume associated with the dynamics of valve closure;
- leakage volume *LV*, the component of regurgitant volume associated with leakage through a closed valve.

In a single heart cycle:

$$RV = CV + LV \,, \tag{1}$$

$$1 = \frac{CV}{RV} + \frac{LV}{RV} \,. \tag{2}$$

In physiological sense, it is much-desirable to attain closing fraction as large as possible and simultaneously leakage fraction

$$\frac{LV}{RV} \to 0\,. \tag{3}$$

Only under these conditions we can reach sufficiently strong washing-out effect of Valsalva sinuses to minimize intravascular clotting threat, and simultaneously myocardial ballast.

2. Standard in vitro testing procedure

The standard and commonly used procedure of in vitro testing of the valve back-flow has been formulated by Technical Committee ISO TC 150/SC 2 – Implants for Surgery. These recommendations are generally based on U.S. Food and Drug Administration guidance [2], [3].

It prefers pulsatile flow testing in a pulse duplicator, which produces flow waveforms that approximate physiological conditions. Based on instantaneous paravalvular flow rates recorded we shall calculate regurgitant volume, regurgitant fraction, closing volume, leakage volume and the corresponding mean pressure difference.

Figure 1 presents the results for tilting disk valve prosthesis. Measurements were conducted at simulated cycle rate on the level of 70 cycles/min [4], [5].

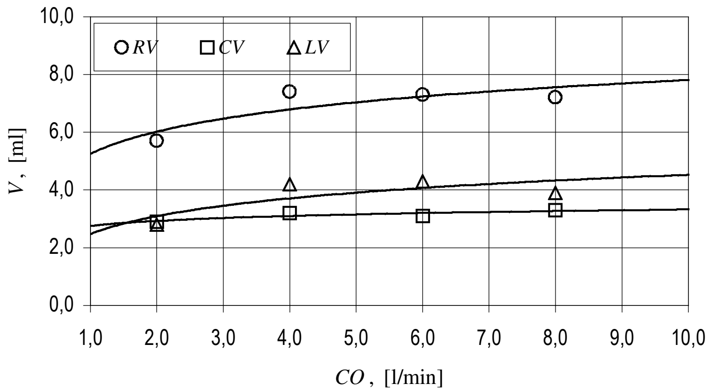

Fig. 1. Regurgitant volume (RV), closing volume (CV) and leakage volume (LV) at HR = 70 cycles/min

Entire regurgitant volume ranges form 5.7 to 7.4 cm^3, with a mean value of 6.9 cm^3. Therefore, its acceptable level is between 16.6 and 6.0% of stroke volume (SV). As we can expect regurgitant volume increases with an increase in a cardiac output (CO). Graduation between closing and leakage fractions is uniform, on average

CV/*RV* = 45.8% and *LV*/*RV* = 54.2%. Figure 2 illustrates prosthesis back-flow when heart rate reaches 100 cycles/min.

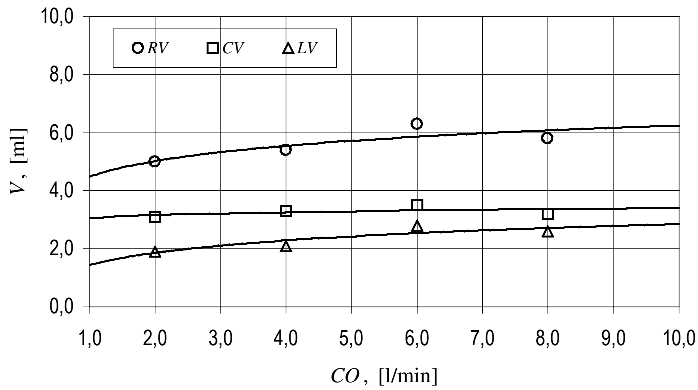

Fig. 2. Regurgitant volume (*RV*), closing volume (*CV*) and leakage volume (*LV*) at *HR* = 100 cycles/min

Despite a drastic change in the cycle rate (more than 40%) we do not observe any significant changes, a mean value of back-flow volume is 5.6 cm^3. But – what is more interesting – despite regurgitant flow changes, closing volume stays almost the same. Figure 3 presents this interesting phenomenon.

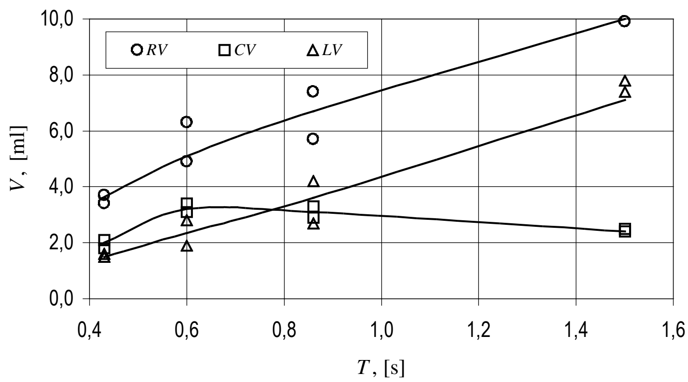

Fig. 3. Regurgitant volume (*RV*), closing volume (*CV*) and leakage volume (*LV*) versus total cycle time

A regurgitant volume successfully increases with a decrease in both simulated heart rate and a total cycle time. A closing volume varies slightly, reaching 3.0 cm^3 for tilting disk valve, somewhat less for bileaflet valve (form 1.0 to 2.0 cm^3), and a little more for ball valve. However, in all cases it is relatively small and fully acceptable in physiological sense, therefore

$$RV = LV + C \quad \text{and} \quad C = CV = \text{idem}. \tag{4}$$

Therefore, we can, in author's opinion, we even should treat a closing volume as common factor of valve design. There are not significant differences in tilting disk valves, ball valves and bileaflet valves. Contrary to this, leakage volume seems to be the parameter, which determines regurgitant volume and is of primary importance for hemodynamical quality of artificial valve.

3. New insight into regurgitation testing

Based on the measurement results presented we can expect that leakage is of crucial importance. A remaining volume of regurgitant blood reaches the level of few cubic centimeters and it is not pathogenic factor (or it can be easy reduced due to modification of a valve design).

Based on this assumption a paravalvular back-flow insufficiency (assessed as paravalvular leakage) can be evaluated using very simple and inexpensive measuring techniques. We can perform all measurements under steady or quasi-steady flow conditions and we must not use pulse duplicator and expensive measuring equipment.

In fact, it becomes noticeable that the ISO 5840 and FDA guidance provides us with this method of tests. ISO standard suggests the measurements of steady state back-flow through the test valve at five equidistant back-pressures ranging from 40 to 200 mm Hg and collects volumes of flow [2], [3]. Figure 4 presents the results of the measurements of leakage flow rate, calculated from volumes of flow registered at various back-pressure levels. The results presented are limited to the pressure lower than 100 mm Hg, because it is hard to imagine greater systolic/diastolic pressure difference.

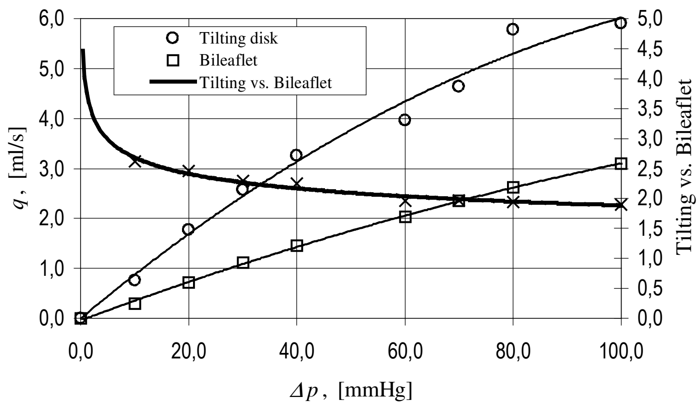

Fig. 4. Quasi-state leakage flow rate at various values of back-pressure
(two arbitrarily selected prostheses of similar sizes)

Of course, the leakage flow rate increases with an increase in pressure difference and we observe significant differences between various valve designs (despite the size similarity). But if we would like to perform comparative evaluation of numerous valves it was not so simple – we should look for a more practical and robust method.

It is hard to describe analytically a paravalvular leakage flow, but we can expect its qualitative similarity to ring interstice flow. Therefore, according to the Navier–Stokes equation we have [1]

$$\frac{d}{d}(r\tau_{rz}) = r\frac{\Delta p}{\Delta l}, \tag{5}$$

where for shear stress we may assume Newtonian approximation

$$\tau_{rz} = \eta \frac{d\,u_r}{d\,z}. \tag{6}$$

Now, if an internal diameter of the valve ring is R_0 and the size of the ring interstice will be

$$\frac{\delta}{R_0} = \frac{R_0 - r_0}{R_0} = 1 - \frac{r_0}{R_0} = 1 - k \tag{7}$$

and simultaneously

$$u_z(R_0) = u_z(r_0 = k\,R_0) = 0\,, \tag{8}$$

where r_0 is an external diameter of valve leaflet or disk, after elementary transformation we arrive at the equation of velocity distribution in a ring interstice:

$$u_z = \frac{1}{\eta}\frac{R_0^2}{4}\frac{\Delta p}{\Delta l}\left(1-\left(\frac{r_0}{R_0}\right)^2+\left(\frac{1-k^2}{\ln\left(\frac{1}{k}\right)}\right)\ln\left(\frac{r_0}{R_0}\right)\right). \tag{9}$$

Thus, the mean velocity in the interstice cross-section is given by:

$$u = \frac{\int_0^{2\pi}\int_{kR_0}^{R_0} u_z\, r\,dr\,d\vartheta}{\int_0^{2\pi}\int_{kR_0}^{R_0} r\,dr\,d\vartheta} = \frac{1}{\eta}\frac{R_0^2}{8}\frac{\Delta p}{\Delta l}\left(1+k^2+\frac{1-k^2}{\ln(k)}\right). \tag{10}$$

Now, let us transform this equation into dimensionless form. We have

$$\frac{\frac{\eta}{\rho}}{u\,2R_0} = \frac{\Delta p}{\rho u^2}\frac{R_0}{16\Delta l}\left(1+k^2+\frac{1-k^2}{\ln(k)}\right) \tag{11}$$

and after introduction of the Reynolds and Euler numbers into equation (11) we obtain

$$\frac{1}{Re} = Eu\frac{R_0}{16\Delta l}\left(1+k^2+\left(\frac{1-k^2}{\ln(k)}\right)\right). \tag{12}$$

Considering arbitrarily selected prosthesis multiplier

$$\frac{R_0}{16\Delta l}\left(1+k^2+\left(\frac{1-k^2}{\ln(k)}\right)\right) = \text{const}\,, \tag{13}$$

we arrive at

$$Re\cdot Eu = La = \text{const}\,, \tag{14}$$

where *La* is the Lagrange number. As a result, the most general and unique characteristics of valvular back-flow seems to be [5]

$$\Phi(La) = 0\,. \tag{15}$$

Now, let us compare the values of the Lagrange number obtained earlier and given in figure 4.

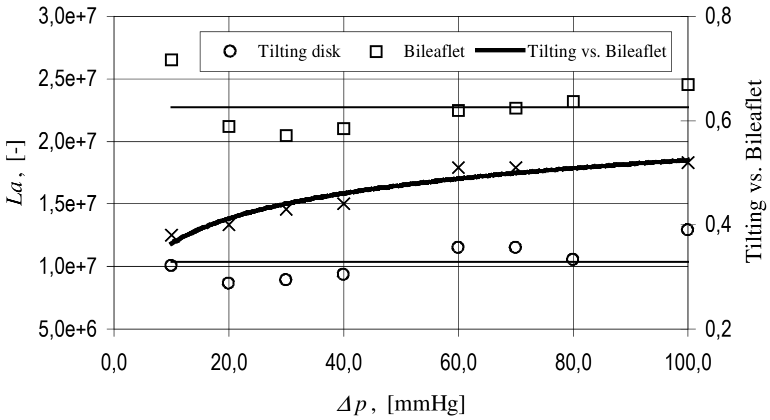

Fig. 5. Comparison of the values of the Lagrange number for two selected prostheses (of similar sizes)

In general, the values of the Lagrange number reach very high level ranging form 10 to 25 million. This result is obvious – prosthesis causes very strong throttling effect because it is a non-return valve. However, the differences between these two valves are most interesting. It is well known fact that bileaflet valve has clearly smaller regurgitation than tilting valve, and we have here corroborative evidence of this fact.

All measurements are to some extent uncertain. According to ISO standard the accuracy of the regurgitant volume *RV* measurements should be ±2 cm^3. In practice, it is very hard to reach such an accuracy, but in the case of the stroke volume (usually $SV \approx$ 10 cm^3) this accuracy should be 5–10 times greater. The Lagrange number, owing to the sensitivity of multiplier (eq. (13)) to the parameter *k*, responds rapidly to the throttling changes. The values obtained for a bileaflet valve were 1.9–2.6 times greater than these for a tilting one.

4. Conclusions

In this paper, two extremely different methods of testing an artificial valve regurgitation have been presented. The first one based on ISO standard and U.S. FDA

guidance is considered to be very complex and expensive procedure, which requires estimation of a large set of flow parameters. Moreover, these parameters are very difficult to measure with a required accuracy, and even if they are measured, their comprehensive evaluation and comparison do not seem to be a simple task.
Contrary to this, the invariant-based method proposed utilizes quasi-steady leakage flow rate measurements. It is very fast and practical method, which gives a unique measure of artificial valve performance. This measure allows very efficient parameter of regurgitant throttling effect to be established in the form of the flow Lagrange number. We neither must use expensive equipment, advanced measurement techniques, nor repeat measurements. Moreover, this method is more resistant to measuring errors.

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