

Development of Polymer Prosthetic Heart Valve — Fabrication and *In Vitro* Test —

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Abstract—Prosthetic heart valves (PHV) with various types and materials have been developed and used until now, but PHVs have various problems that need improving. A new type of polymer PHV have been developed to ameliorate these problems. A hydrodynamic tester has also been developed for the precise evaluation of hydrodynamic performance of the developed PHV.

PHV are composed of polyurethane, a material commonly used in biomedical materials because of its good biocompatibility and mechanical properties. To investigate its hydrodynamic properties, a trileaflet and bileaflet type polymer valve was fabricated. The results of comparative tests with the 2 polymer valves and a mechanical valve showed that the trileaflet polymer valve had a better hydrodynamic performance than the others. Though the bileaflet polymer valve showed a higher pressure drop and regurgitation than the trileaflet valve due to thicker leaflet flexion of the bileaflet valve, if its fabrication method and design were corrected, a better result could be expected.

For a study of the long-term stability of the PHV, accelerated endurance tests and stress analysis of PHVs are needed.

Key Words: *Prosthetic heart valve, Hydrodynamic tester, Trileaflet polymer valve, Bileaflet polymer valve*

INTRODUCTION

Prosthetic heart valves have been used successfully to some degree since 1960. As advances in technology have led to new and improved designs and materials, the 50 or more different PHVs have been introduced over the past 30 years. However, only a handful of the valves are still being used clinically. But these currently-used PHVs have various problems that need improving such as

thromboembolism, hemolysis, fatigue failure and calcification (Schoen 1982; Wisman 1982; Webster 1988). We developed a new type polymer synthetic PHV to alleviate these problems.

Although the final assessment of the PHV's performance must come from the results of long-term clinical implantations, the initial evaluation of any new design can be obtained from appropriate and well-designed *in vitro* tests. The interpretation of such test results must be approached with caution by recognizing their limitations when extrapolated to *in vivo* and clinical situations. Systematic *in vitro* testing can provide valuable information for both the valve designer and cardiac surgeon and also indicate weaknesses in the basic design, performance, and materials. Thus the development of

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a well-designed *in vitro* hydrodynamic tester (HDT) is essential to PHV evaluation (Reul 1988; Yosr 1989). The first objective of our study was the development of a hydrodynamic tester satisfying the following conditions:

1. All pertinent valve test conditions (such as the heart rate, systole-diastole ratio, pressures of the atrium, ventricle, and aorta, and the waveform of ventricular pressure) had to be well-specified for each particular test.
2. The HDT had to provide the parameters, such as transvalvular pressure drop, transvalvular flow rate, systolic energy loss, and regurgitation which represent hydrodynamic performance.
3. The HDT had to provide image data of the flow pattern from which the perivalvular velocity profile and the magnitude of shear stress on blood cells could be obtained by image processing.

The next objective of our study was to develop a new PHV design. With the selection of the polymeric material used in our new PHV, the hemocompatibility and mechanical properties of the material were considered. The material had to be non-irritating to tissue and compatible with blood and tissue. It also had to be sufficiently strong to avoid rupture or prolapse of the valve and yet flexible enough to move readily from the closed to open position. Excellent fatigue resistance was also required to enable the valve to withstand repeated stress. With the selection of the material, an optimal design of the new PHV was obtained. First, its design parameters were determined. Next, the optimal design parameters were obtained to effect smooth washout, minimize occluder stress, facilitate opening of the valve at a reasonable value of the transvalvular pressure, and ensure adequate longevity from given leaflet materials fatigue data. After the selection of the material and optimal design, the fabrication and *in vitro* hydrodynamic performance tests of the newly designed valves were carried out.

MATERIALS AND METHODS

A. Hydrodynamic tester

The HDT is a pressure-controlled fluid flow gene-

rator composed of three parts: (1)the mock circulation system, (2) the pneumatic pump driving system, and (3)the data acquisition and processing system.

A schematic diagram of the HDT is shown in Fig. 1. The mock circulation system consisted of an oil chamber, an artificial ventricle, and 2 reservoirs. The artificial ventricle and its orientation were patterned on the shape of a natural heart with polyurethane, and its total volume was 200 ml. The artificial ventricle was submerged into an acrylic chamber filled with highly viscous silicone oil to create a homogeneous pressure transmission through the polyurethane diaphragm at the bottom of the oil chamber from the pneumatic pump driven system. Three parts of inflow, outflow, and an artificial ventricle from the mock circulation system were prepared to measure pressure changes. The outflow rate was monitored with an electromagnetic flowmeter (CME Clima flowmeter). Three pressure signals were monitored with HP CATH LAB, and the 4 signals (3 pressures + 1 flow rate) were transmitted to an IBM-PC through an A/D converter (12 bit/1kHz A/D converter). Compressed air was guided to the oil chamber diaphragm through a solenoid valve. A pressure regulator and control unit board regulated the solenoid valve to change the heart rate and the systole-diastole ratio. The cardiac output was also controlled by pressure regulator. Four signals of 3 pressures and the flow rate were analyzed within the an IBM-PC by Pascal software developed to calculate the hydrodynamic performance of heart valves.

Under the pulsatile flow condition, the following hydrodynamic parameters were calculated from the 3 pressures and the flow rate to evaluate the prosthetic heart valves *in vitro*:

1. Pressure drops across the prosthetic valves
2. Regurgitation volumes against the aortic position of the PHV
3. Energy loss across the prosthetic valve

$$\Delta E = \int p(t) dQ$$

ΔE : Energy loss

$p(t)$: Pressure drop

Q : Flow rate

\int : Integration for one stroke

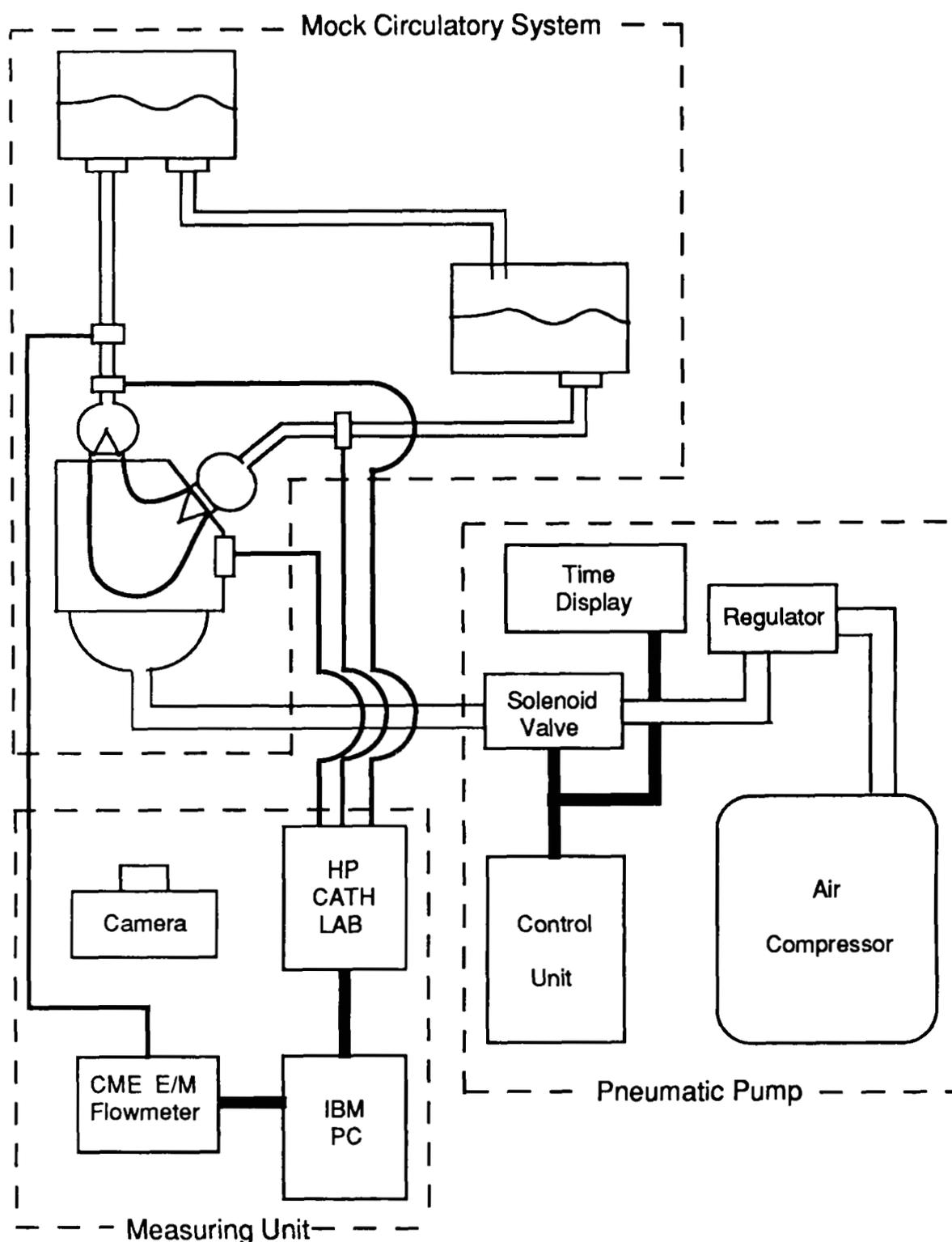


Fig. 1. Block diagram of hydrodynamic tester

4. Effective valve orifice area (EVOA) (Gorlin & Gorlin 1951)

$$\text{EVOA (Cm}^2\text{)} = Q / (44.5\sqrt{\Delta P})$$

Q: Mean flow rate in systole

ΔP : Mean pressure drop in systole

5. Maximum change of pressure gradient
6. Valve performance index (VPI)

$$\text{VPI} = (\text{Energy loss} \times \text{Regurgitation})^{\frac{1}{2}}$$

B. Trileaflet polymer valve (TPV)

The shape of the TPV is analogous to that of a natural aortic valve. Chong, *et al.* (1973) made careful measurements of the geometry of an excised human aortic valve. This valve leaflet geometry is characterized in terms of the parameters R_1, R_2, ϕ_1, ϕ_2 illustrated in Fig. 2; R_1, R_2 are the principal radii of the curvature of the leaflet surface, and ϕ_1, ϕ_2 the subtended angles. Ghista *et al.* (1976)

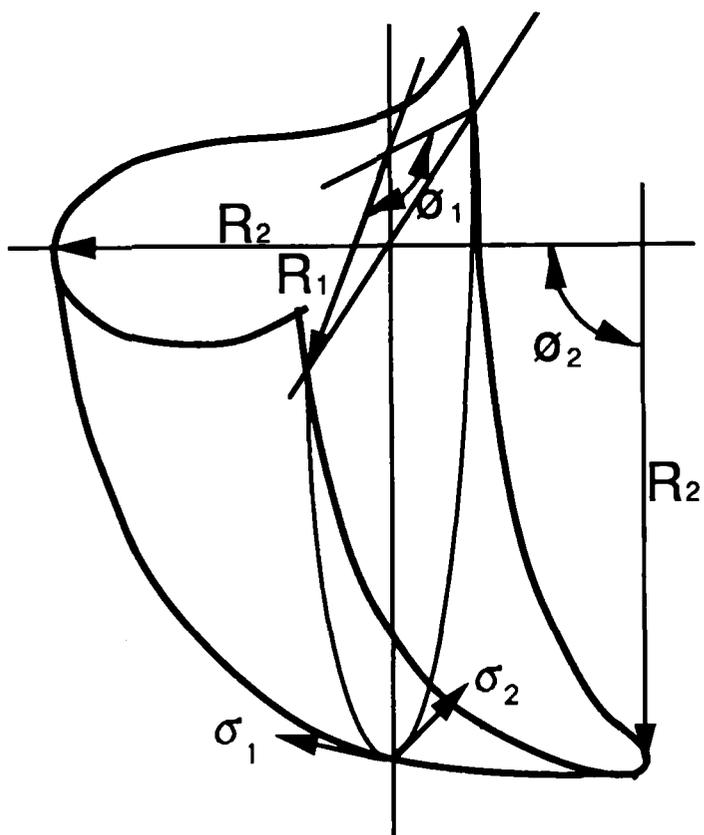


Fig. 2. Human aortic valve leaflet model by Chong et al. (1973)

proposed the following design criteria of PHV:

1. The shape of the valve leaflets should promote smooth washout, while at the same time when the valve closes, the leaflets must come together over minimal contact surface so that RBC damage between the contacting surfaces is minimized.
2. The shape of the valve leaflet must keep the leaflet stress to a minimum.
3. The pressure differential loading which causes the valve leaflet to open must be minimal.

According to the above design criteria, the following values of the parameters for the optimal design can be obtained, where R is the radius of the valve frame:

$$0.87 < R_1 / R < 0.95, 0.87 < R_2 / R < 0.95$$

$$150 < \phi_1 < 170, 85 < \phi_2 < 100$$

In the range of parameters for the optimal design obtained by the Chong model and the Ghista design criteria, we choose one value of each parameter as follows:

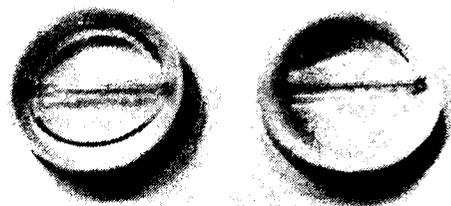
$$R = 10 \text{ mm}, R_1 = R_2 = 0.9 R, \phi_1 = 160,$$

$$\phi_2 = 90$$

We used Pellethane[®] as the material for the valve leaflet and Isoplast[®] as the material for the valve frame. Pellethane[®] 2363-series thermoplastic resin from Dow Chemical, which is a polyether-based polyurethane for biomedical application because of its good antithrombogenic and mechanical properties. The valve leaflets were made by dipping a metallic valve mold in dimethylacrylamide diluted Pellethane[®] solution (Fig. 3a).



a)



b)

Fig. 3. Polymer prosthetic valve

a) trileaflet polymer valve

b) bileaflet polymer valve

C. Bileaflet polymer valve (BPV)

The problem of thrombus formation around the hinge portion of the St. Jude valve gave us an idea of BPV, which is hingeless. The BPV consisted of an Isoplast[®] valve frame and a titanium alloy wire-inserted Pellethane[®] valve leaflet. To lower the pressure drop through the valve during the opening phase and to open readily, the flexion

portion of the BPV was biconcave, and to prevent prolapse of the valve leaflet, 0.5 mm diameter titanium alloy (Ti-Ni) wires were inserted in the center and edge of the leaflet. Pellethane® (20%) was poured into a metal mold for this valve leaflet and dried for 72 hrs at 40°C (Fig. 3b).

D. Comparative test

For the control value of the comparative test for the newly designed valves, we used a Björk-Shiley mechanical valve (BSMV), which is a com-

monly used mechanical valve. We examined the change of hydrodynamic performance parameters of each valve with the change of heart rate and ventricular systolic pressure, which controls the systolic flow rate and cardiac output. The tested valves had the following inner diameter size: BSMV 24 mm, TPV 20mm, BPV 20mm.

RESULTS

Three pressure signals and a flow rate signal

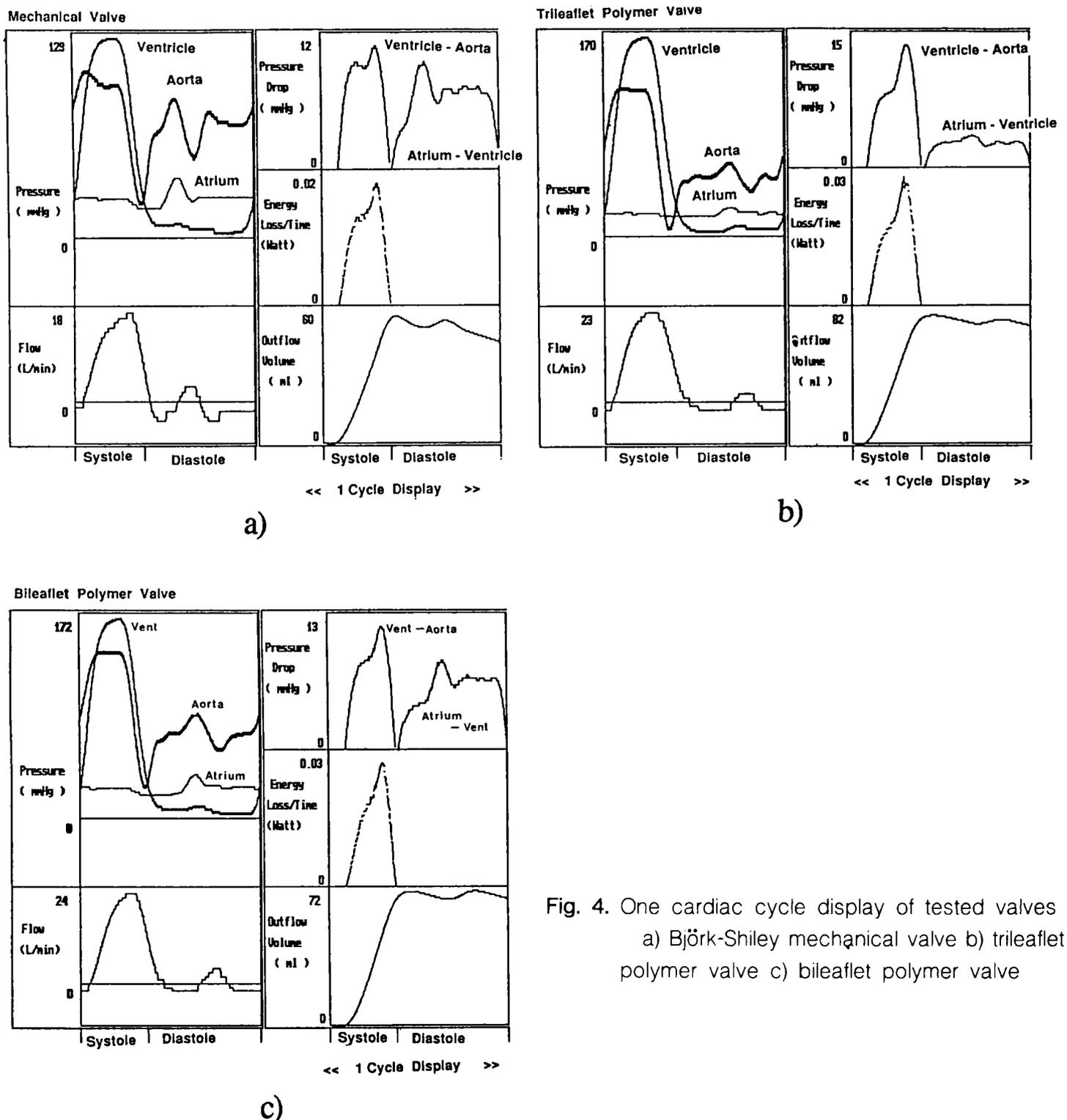


Fig. 4. One cardiac cycle display of tested valves
 a) Björk-Shiley mechanical valve b) trileaflet polymer valve c) bileaflet polymer valve

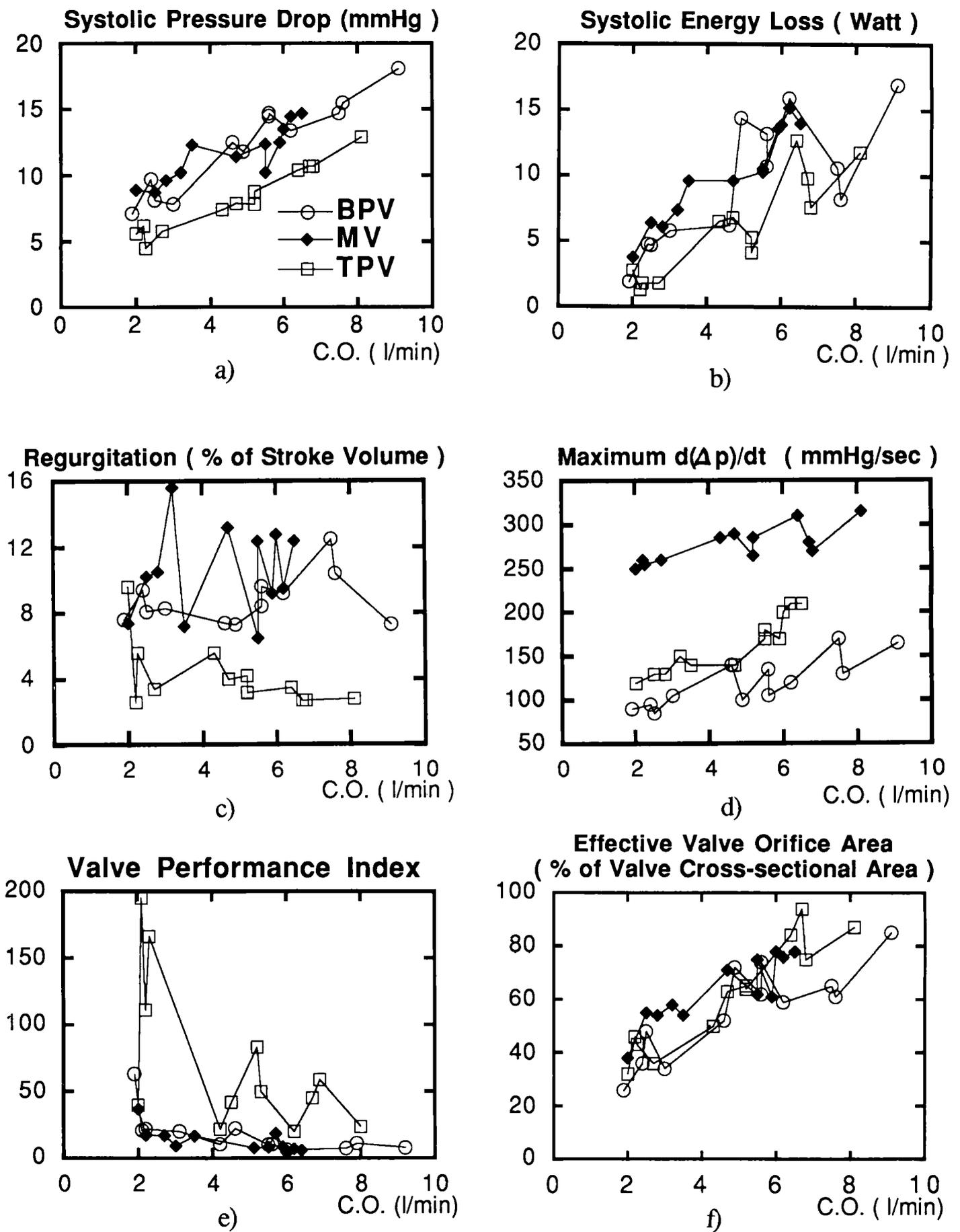


Fig. 5. Hydrodynamic data of tested valves

a) systolic pressure drop b) systolic energy loss c) regurgitation volume d) effective valve orifice area e) maximum $d(\Delta p)/dt$ f) valve performance index

were acquired for the 3 types of valves and pre-processed for filtering and calibration. Fig. 4 shows pressure waveforms, pressure difference, energy loss, and outflow volume for each valve at the conditions of heart rate 80 bpm and the maximum aortic flow rate 25 l/min. There was no major difference among the pressure waveforms of each valve, but in the case of the flow rate, BSMV had a larger regurgitation flow than the others at the aortic position during the closing phase. It corresponds to the fact that the outflow volume of BSMV is reduced during the initial diastolic phase. The temporal gradient of systolic pressure drop of the BSMV was much larger than the others, meaning the time to reach a steady pressure state was minimum.

Fig. 5 shows the variation of hydrodynamic performance parameters of each valve obtained. Systolic pressure drop increased in the order of TPV, BPV, and BSMV. Similar ordering was shown in the case of systolic energy loss and regurgitation. BSMV had the largest EVOA at low CO, but TPV had the largest above 5 l/min of CO. Temporal gradient of pressure drop increased in the order of BPV, TPV, and BSMV. BSMV had the lowest VPI, followed in order by BPV and TPV.

DISCUSSION

In the case of BSMV, the hydrodynamic performance parameters estimated from the developed hydrodynamic tester such as systolic pressure drop, regurgitation, and EVOA were in similar level to the values in previous paper (Lawrence *et al.* 1981).

Monitored pressure waveforms at the outflow side were shown as large fluctuations (Fig. 4). These fluctuations may have been due to less compliance of our mock circulation system. The low viscosity of water used as the test fluid in our mock circulation system may also have affected the instant pressure variations. It is necessary to test with more blood-like test fluid such as glycerin mixed water by 30 ~ 40 volume% in order to make equal viscosity with blood (3-4 centipose).

Lower systolic pressure drop and energy loss of TPV comes from the flexibility of the well designed

leaflet of the valve. In the case of BPV, the valvular leaflet was more rigid than that of the original design, since the thickness of the leaflet was not well-controlled through fabrication of the valve.

Since calculated regurgitation is the percentage of regurgitant flow volume to the stroke volume, it is reduced with increments of CO. In the case of BSMV, since a large part of regurgitation occurs during the valve closing phase, it increases with increments of HR. In the case of TPV, as regurgitation occurs mainly through leakage during diastole, its level is independent of HR.

EVOA of TPV increased more rapidly with CO augmentation than the others because of its leaflet shape and flexible material.

The VPI was newly designed in this study and provided the simple criterion of the PHV in relation to hydrodynamic performance such as energy loss and regurgitation. High VPI levels may be required for the ideal hydrodynamic property of PHV.

The feasibility of applying the developed hydrodynamic tester for evaluating PHVs was examined through comparative tests with 3 valves. Hydrodynamic performance parameters such as energy loss, regurgitation, and VPI, obtained by our hydrodynamic tester, represented the hydrodynamic performance of each valve precisely.

The TPV had lower systolic pressure drop and diastolic regurgitation than the others, and its VPI changes were smaller with varying CO.

The test results for BPV showed lower hydrodynamic performance than TPV, but if its fabrication method is more stable and its design corrected, good hydrodynamic performance is anticipated.

To evaluate the fatigue properties of PHVs, an accelerating test for durability and stress analysis of the PHV are needed to estimate the lifespan of polymer valves. The fatigue test results of the polymer valve were insufficient for a permanent valve implantation. But good hydrodynamic performance of the polymer valve provided a sufficient condition for temporary uses combined with a total artificial heart or a ventricular assist device.

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= 국 문 초 록 =

고분자 인공 심장판막의 개발 - 제작과 성능실험 -

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김인영 · 김종원 · 정대영 · 김철생 · 민병구

지금까지 여러가지 형태와 재료의 인공 심장판막이 개발, 사용되어 왔지만, 여러가지 개선되어야 할 문제점들을 가지고 있었다. 이런 문제점들을 해결할 수 있는 새로운 인공 심장판막의 개발을 시도하였다. 그리고 개발한 인공 심장판막의 성능을 비교실험할 수 있는 실험장치를 개발하였다. 이 비교실험장치는 각 판막의 수력학적 성능을 잘 나타내고 있음을 알 수 있었다.

새로 개발한 판막은 혈액적합성과 기계적 특성이 우수하다고 알려진 의학용 폴리우레탄을 사용하였다. 판막의 형태는 유체특성과 내구성이 우수하도록 설계된 삼엽식과 이엽식의 두 가지 형태로 설계하였다. 이 두 고분자 판막과 기계식 판막을 비교시험한 결과 삼엽식 고분자 판막의 수력학적 성능이 우수하였다. 이엽식 고분자 판막이 삼엽식이나 기계식 판막보다 좋은 결과를 볼 수 없었지만, 이의 제작과정과 형태의 개선을 한다면 더 좋은 성능을 보이리라 예상한다.

제작한 판막의 내구성을 측정하기 위한 가속 실험장치의 개발과 판막에 걸리는 응력을 분석하는 일이 앞으로 필요할 것이다.