1990 年度 大韓醫用生體工學 秋季 學術大會 論文集 90/11

A Study on the Development of Polymer Prosthetic Heart Valve

In Young Kim°, Jong Won Kim, Jun Keun Chang, Byoung Goo Min

Dept. of Biomedical Engineering
Inst. of Biomedical Engineering
College of Medicine
Seoul National University

Introduction

Prosthetic heart valves (PHV) with various types and materials have been developed and used till now, but the PHV have various problems to be improved (i.e. thromboembolism, hemolysis, fatigue failure and calcification). New typed PHV are developed to eliminate these problems.

Although the final assessment of PHV 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 the in vivo and clinical situations. In vitro testing can provides valuable information for both the valve designer and the cardiac surgeon, and can also indicate weakness in basic design, performances and materials. Thus the development of well-designed hydrodynamic tester (in vitro tester) is essential to PHV development. the first objective of our study is the development of hydrodynamic tester (HDT) satisfying the following conditions ;

i) All partinent valve test condition (surch as heart rate, systole/diastole ratio, pressures of atrium, ventricle, and aorta, and wave form of ventricular pressure.) should be well specified for each particular test.

ii) HDT should provide parameters, which represent hydrodynamic performance, such as transvalvular pressure drop, transvalvular flow rate, systolic energy loss and regurgitation.

iii) HDT should provide image data of flow pattern from which perivalvular velocity profile and the magnitude of shear stress to blood cell can be obtained by image processing.

The Next objective of our study is the development of new designed PHV. With the selection of material used in our new PHV, the hemocompatibility and mechanical property of material are considered. These material should be non-irritating to tissue and be compatible with blood and tissue. These must be sufficiently robust to avoid rupture or prolapse of the valve and yet flexible enough to move readily from the closed to open position. Excellent fatigue resistance is also required to enable the valve to withstand adequate lifetime. With the selection of material, the optimal design of new PHV should be obtained. First, its design parameters are determined. Next, optimal design parameters are obtained to effect smooth washout, minimize occluder stress, facilitate opening of the valve at a reasonable value of the transvalvular pressure and ensure an adequate lifetime (for a given leaflet materials fatigue data). After the selection of material and optimal design, the fabrication and in vitro hydrodynamic perpormance test of new designed valves are carried out.

Materials and Methods

1) Hydrodynamic Tester (HDT)

HDT is composed of three parts as follows ;

i) Mock circulation system
ii) Pneumatic pump driving system
iii) Data aquisition and processing system

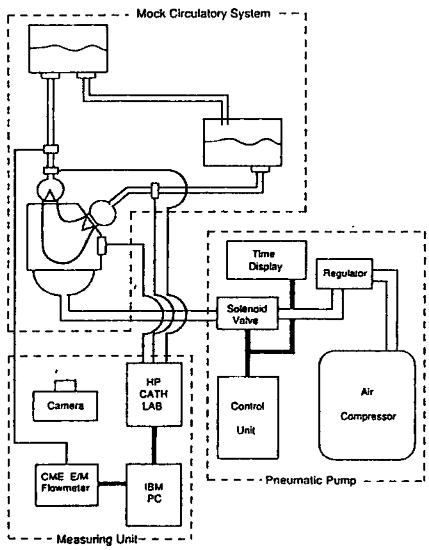


Fig. 1. Block diagram of hydrodynamic tester

Schematic diagram of the HDT is shown in Fig. 1. Mock circulation system consists of an oil chamber, an artificial ventricle, two reservoirs. Artificial ventricle and the orientation is patterned on the shape of natural heart with polyurethane and its total volume is 200 ml. The artificial ventricle is submerged into the acryl chamber filled with the highly viscous silicone oil to make homogeneous pressure transmission through the polyurethane diaphragm at the bottom of the oil chamber from the pneumatic pump driving system. Three parts of inflow, outflow and artificial ventricle from the mock circulation system are prepared to measure pressure change. Outflow rate are monitored with a electromagnetic flowmeter (CME Clima flowmeter). Three pressure signal are monitored with HP CATH LAB and four signals (3 pressure + 1 flow rate) are transmittered to IBM-PC through A/D converter (12 bit/ 1kHz A/D converter). Compressed air is guided the oil chamber diaphragm through solenoid valve. Pressure regulator and control unit board regulates the solenoid valve to change the heart rate and the systole-diastole ratio. Cardiac output is also regulated by pressure regulator. Four signals of three pressures and flow rate are analyzed within the IBM-PC by Pascal software developed for the calculation of the hydrodynamic preformance of the heart valves.

Under the pulsatile flow condition, following hydrodynamic parameters are calculated from the three pressures and the flow rate to evaluate the prosthetic heart valves in vitro ;

i) pressure drops across the prothetic valves
ii) regurgitation volumes against the aortic position of the PHV
iii) energy loss across the prosthetic valve

$$\Delta E = \oint p(t)\, dQ$$

ΔE : Energy loss
$p(t)$: Pressure drop Q : Flow rate
$\oint$: Integraion for one stroke

iv) effective valve orifice area (EVOA)

$$EVOA = \frac{Q}{44.5\sqrt{\Delta P}}$$

Q : Mean flow rate in systole
ΔP : Mean pressure drop in systole

v) maximum change of pressure gradient
vi) valve performance index (VPI)

$$VPI = \text{Energy loss} \times \text{Reguritation}$$

2) Trileaflet polymer valve (TPV)

The shape of TPV is analogous to that of a natural aortic valve. In 1973, Chong, et al. had careful measurement of geometry of excised human aortic valve. This valve leaflet geopmetry 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 principle radii of curvature of the leaflet surface and ϕ_1, ϕ_2 the substended angles. In 1976, Chista proposed the following design criteria of PHV;

i) The shape of the valve leaflets 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 surface is minimized.

ii) The shape of teh valve leaflet must make the leaflet stresses minimum.

iii) The pressure differential loading which causes the valve leaflet to open must be minimal.

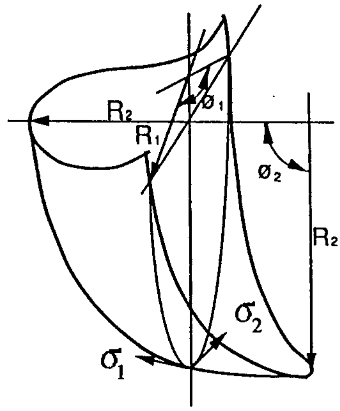


Fig. 2. Human aortic valve leaflet model by Chong(1973)

According to above design criteria, the following values of the parameters for the optimal desing can be obtained

$$0.87 < R_1/R < 0.95 \;,\; 0.87 < R_2/R < 0.95$$
$$150^\circ < \phi_1 < 170^\circ \;,\; 85^\circ < \phi_2 < 100^\circ$$

R : Radius of valve frame

In the range of parameters for the optimal design obrained by Chong model and Chista design criteria, we choose one value of each parameters as follows.

$$R = 10\text{ mm},\; R_1 = R_2 = 0.9R,\; \phi_1 = 160^\circ,\; \phi_2 = 90^\circ$$

We use pellethane as materials of valve leaflet and isoplast as material of valve frame. Pellethane 2363-series thermoplastic resin from Dow Chemicl, which is a polyether-based polyurethane for biomedical application because of its good antithrombogenic and mechanical properties. Valve leaflets were made by dipping valve mold in dimethylacrylamide diluted pellethane solution.

a) b)

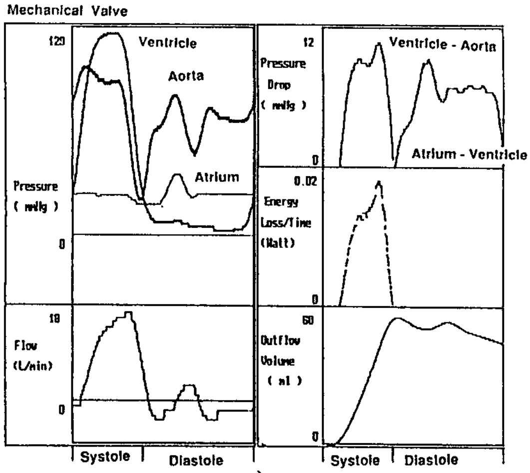
Fig. 3. Polymer prosthetic valve
a) trileaflet polymer valve , b) bileaflet polymer valve

3) Bileaflet polymer valve (BPV)

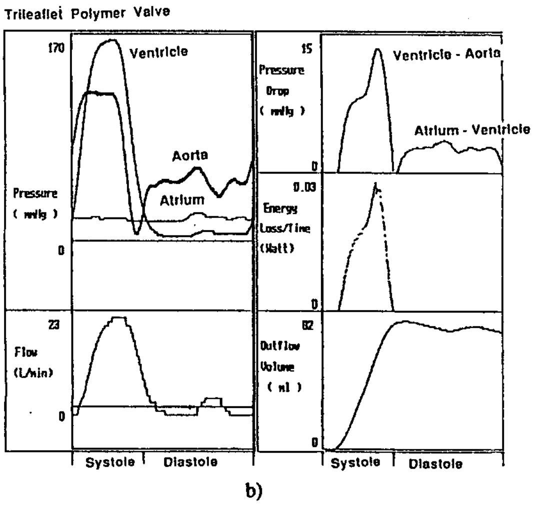
The problem of thrombus formation around hinge protion of the St. Jude valve give the idea of BPV, which is hingeless. BPV consists of a Isoplast valve frame and a titanium alloy wire-inserted pellethane valve leaflet. To lower pressure drop and to open readily, the flexion portion of BPV is biconcave. And to be highly resistant to wear, 0.5 mm diameter titanium alloy wires are inserted in valve leaflet. For this valve leaflet, acryl mold is needed. 20% pellethane is poured into acryl mold and dried for 72 hrs at 40°C.

4) Comparative Test

For the control value of comparative test for new desinged valves, we use Bjork-Shiley valve, most commonly used mechanical valve We examine the change of hydrodymanic performance parameters of each valves with change of heart rate and change of vertricular systolic pressure, which cause change of systolic flow rate and cardiac output. And we analyze flow pattern around each valve by photography.



a)



b)

Result

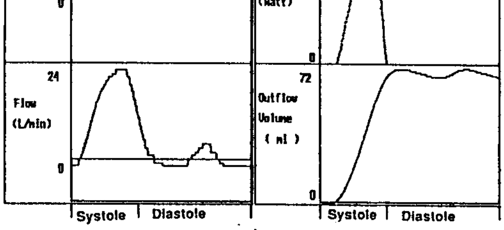
Three pressure signals and a flow rate signal are acquired for the three types of valves and preprocessed for filtering and calibration. Fig. 4 showes pressure waveforms, pressure difference, energy loss, and outflow volume for each valves at the conditions of heart rate 80 bpm and the maximum aortic flow rate 25 l/min. There is little difference between pressure waveforms of each valves, but for the case of the flow rate, Bjork-Shiley mechanical valve (BSMV) has larger regurgitation flow than others at the aortic position during closing phase. There is corespondent to the fact that outflow volume of BSMV is reduced during initial diastolic phase . The temporal gradient of systolic pressure drop of the BSMV is much larger than others and it means the time to arrive steady pressure state is minimum.

Fig. 5 show hydrodynamic performance parameters comparatively as varing cardiac output (CO). Systolic pressure drop decreases in the order TPV, BPV and BSMV. Similar ordering is shown for the case of systolic energy loss and regurgitation. BSMV has the largest EVOA at low CO, but TPV has the largest above 5 l/min of CO. Temporal gradient of pressure drop increases in the order of BPV, TPV and BSMV. BSMV has the lowest VPI, followed in order by BPV and TPV.

Discussion

For the case of BSMV, hydrodynamic performance parameters estimated from the developed hydrodynamic tester such as systolic pressure drop, regurgitation and EVOA are similar level to the values in previous paper. (L.H.Scotten ,1981)

Measured pressure waveforms at outflow side are shown as large fluctuation. This fluctuation are caused from less compliance of our mock circulation system. Since



c)

Fig. 4. 1 cardiac cycle display of tested valves
a) Bjork-Shiley mechanical valve , b) trileaflet polymer valve , c) bileaflet polymer valve

water was used as test fluid in our mock circulation system, 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 moving occluder of PHV. For the case of BPV, valvular leaflet is more rigid than that of original design since thickness of leaflet is not controlled through fabrication of the valve.

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

EVOA of TPV increases more rapidly than others because of its flexible leaflet shape and material

VPI is newly designed in this paper and gives the simple criterion of the PHV about hydrodynamic performance such as energy loss and regurgitation. Low VPI level may be required for the ideal hydrodynamic property of PHV.

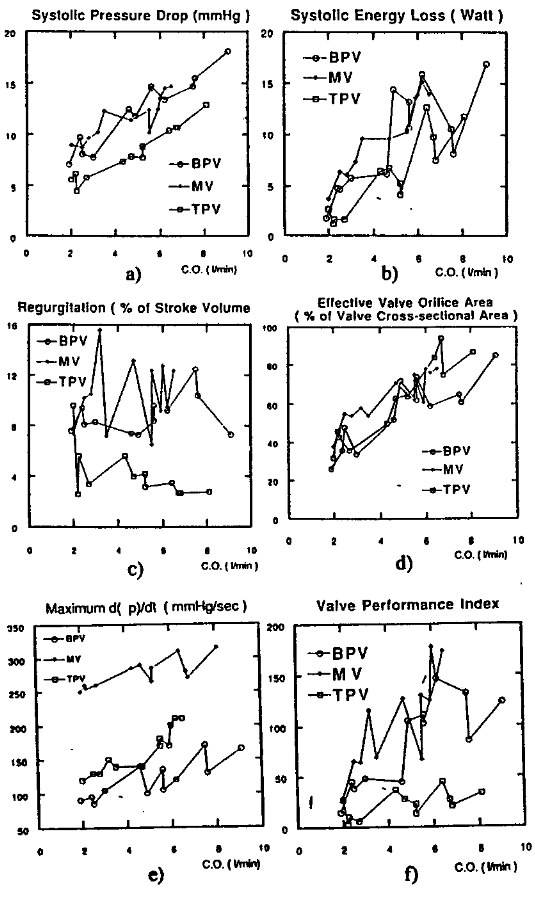


Fig. 5. Hydrodynamic data of tested valves
a) systolic pressure drop , b) systolic energy loss , c) regurgitation volume , d) effective valve orifice area , e) maximum d(Δp)/dt , f) valve performance index

Conclusion

The feasibility of application of the developed hydrodynmic tester for the evaluation the PHV is tested through comparative test with three valves. Hydrodynamic performance parameters such as energy loss, regurgitation and VPI, obtained by our hydrodynamic tester, represent hydrodynamic performance of each valves precisely.

TPV has lower systolic pressure drop and diastolic regurgitation than others and its VPI changes smaller with varying CO.

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

For the evaluation of fatigue property of the PHV, accelerating tester for durability is needed. and stress analysis of the PHV is also needed to estimate the lifespan of polymer valves.

Reference

J.G.Webster, Encyclopedia of medical devices and instrumentation , Wiley,1988, 3:1457

C.B. Wisman, " A polyurethane trileaflet cardiac valve prothesis : in vivo and in vitro studies " ASAIO Abstracts, 1982, 11:88

F.J. Schoen, et al., " Bioengineering aspects of heart valve replacement : Ann Biomed. Engineer. , 1982, 10:97

S.H. Hilbert, et al., " Evaluation of explanted polyurethane trileaflet cardiac valve prostheses." J. Thorac. Cardiovasc. Surg., 1987, 94:419

Yosr. A.M. Haggag, " In vitro engineering testing of prosthetic cardiac valves. " 1989,14:469

Chong, et al., " Stress analysis of normal human aortic valve leaflets during diastole." Biomat. Med. Der. Art. Organs, 1973, 1:307

D.N.Ghista, H.Reul, " Optimal prosthetic aortic leaflet valve : design parameteric and longivity analysis." J. Biomechanics, 1977, 10:313

L.N. Scotten, et al., " New tilting disc cardiac valve prosthesis : in vitro comparision of their hydrodynamic performance. " J. Thorac. Cardiovasc. Surg., 1981, 82:136

H. Reul, et al., " In vitro testing of bioprostheses ",TASAIO, 1988, 34:1033

J.M. Gross, et al., " Vortex shedding in bileaflet heart valve prosthesis." TASAIO, 1988, 34:845

K.B. Chandran, et al., " Effect of prosthetic mitral valve geometry and orientation on flow dynamics in a model human left ventricle. " J. Biomechanics, 1989, 22:51