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In Vitro Hydrodynamic Evaluation of Prosthetic Polymer Heart Valves in Steady Flow

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Hydrodynamic comparison of two polymer valves with two mechanical valves is presented. The valves were perfused in a steady flow system, and comparisons between the valves were made on the transvalvular pressure distribution and drop, opening area, and leakage volume. Particular emphasis was placed on a slit-type bileaflet polymer valve which was newly designed and fabricated in our research group. The results showed that the functional characteristics of a slit-type bileaflet polymer valve compared favorably with that of mechanical valves. This valve may be a viable and inexpensive alternative, especially for short-term use in TAH or VAD systems.

Key Words: Hydrodynamic Evaluation, Prosthetic Polymer Heart Valve, Pressure Drop, Opening Area and Leakage Volume

1. Introduction

Prosthetic heart valves intended for replacement of diseased natural valve and use in total artificaial heart(TAH) and ventricular assist device(VAD) have been improved significantly in design and material since it was used clinically (Starr and Edwards, 1961). Due to advances in technology since then, the 50 or more different prosthetic heart valves have been introduced over the past 30 years. However, only a handful of the valves are still being used clinically.

Heart valve prostheses may be classified into major types, mechanical valves and tissue valves, which are extensively summarized by Shim and Lenker(1988) recently. The mechanical valves are made of nonbiological materials such as metals, ceramics, and polymers. In contrast, the tissue valves consist wholly or partially of materials of biological origin. Those valves reveal different hydrodynamic advantages and disadvantages, however, none of these different types is superior (Heiliger, 1986). Furthermore, there there still exist major problems such as thromboembolic complications with mechanical valves and tissue calcification and leaflet tearing with tissue valves. As a result, the valve prostheses made with synthetic material have been also suggested as a viable alternative. With the recent development of TAH and VAD, additional efforts has been provided toward the development of various synthetic heart valve prostheses (Williams et al., 1978; Reul, Muller and Tillman, 1979; Russel et al., 1980; Chetta and Lloyd, 1980; Imachi et al., 1988; Jansen et al., 1991; Kim et al., 1991). Synthetic polymer valves, which can be manufactured relatively inexpensively when compared to mechanical and tissue valves, provide an economic advantage especially in the short-term procedures.

The present investigation is aimed to examine the hydrodynamic effectiveness of two types of synthetic polymer valve for permanent use in a TAH or a VAD, and temporary use in the blood pumps. Particular emphasis is placed on a slit-

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type bileaflet polymer valve which was newly designed and fabricated in our research group. Experimental comparisons which were performed with two mechanical valves in a steady flow system include the transvalvular pressure distribution and drop, the relative opening area, and the leakage volume.

2. Materials and Methods

2.1 Investigated valve types

In the current experiment, there were used two types of polymer valves fabricated in our labortary and two mechanical valves available commercially. Their denominations and dimensions are given in Fig. 1 and Table 1, respectively. Note that the detailed fabrication procedure and material of the polymer valves used in the current tests can be found elsewhere (Kim et al., 1991).

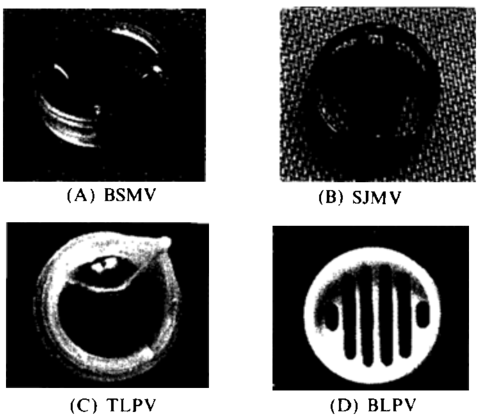

Fig. 1 The various valves used in the tests: (A) Bjork-Shiley mechanical valve, (B) Saint-Jude medical valve, (C) Trileaflet polymer valve, (D) Bileaflet polymer valve

2.2 Set-up for steady flow and mehods

The experimental set-up for steady flow measurements is schematically shown in Fig. 2. The system consisted of a 2.5 m^3 overhead reservoir tank made of a stainless steel cylinder (60 cm in diameter and 90 cm in height), a calming chamber,, a test section, two rotameters, a flow control valve, and a recirculating low loop. A plexiglas tube of 2.38 cm inner diameter was used for entry and main test sections, into which the investigated valves have been inserted with a valve mounter.

A total of ten pressure taps—three (M1 to M3) on the upstream and seven (M4 to M10) on the downstream of the valves, respectively—were fabricated along the test section. The pressure tap sites are located every one diameter distance from the valve position except the last one (M10). This arrangement facilitates the measurement of pressure variation downstream of the valve. The pressure drop measurements were conducted with a data acquisition system installed in a IBM compatible PC, which was connected to a Validyne differential pressure transducer. The negative port of a pressure transducer was coupled to a pressure tap of M1 fixedly and the positive port of it to each tap of M2 to M10 via a fluid switch wafer with vinyl tubings of 1.59 mm in diameter. The pressure drop data collected during 10 seconds with a speed of 500 points/sec were stored into a IBM compatible PC for each pressure tap (M2 to M10) by rotating a fluid switch wafer. Note that the pressure transducer

Table 1 Description of the valves tested in the current experiment

Valves (abbreviation)	Int. Orifice Dia. D (mm)	External Dia. D (mm)	Remark
Bjork-Shiley (**BSMV**)	20.0	29.0	
St. Jude Medical (**SJMV**)	20.4	25.0	
Trileaflet Polymer (**TLPV**)	22.5	29.0	$t=0.3$ mm
Bileaflet Polymer (BLMV 1)	25.2	29.5	$t=0.1$ mm
Bileaflet Polymer (BLMV 2)	24.9	29.5	$t=0.2$ mm

Here t is the thickness of a leaflet.

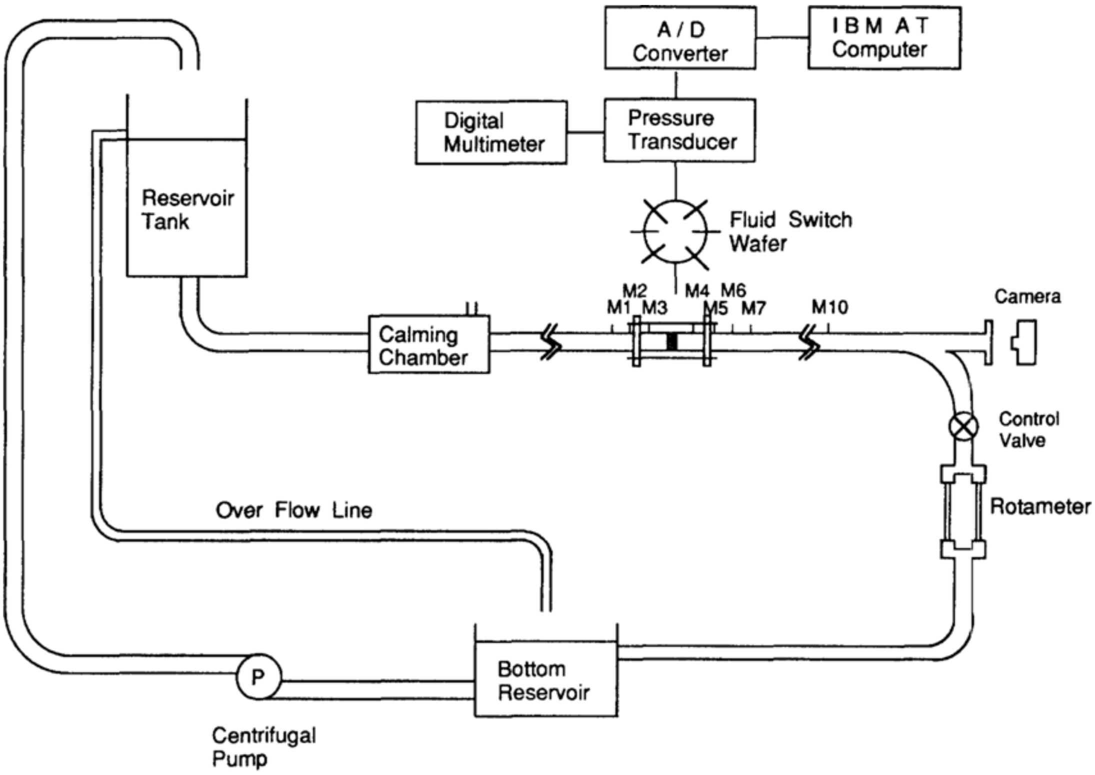

Fig. 2 Schematic diagram of set-up for the steady flow experiments

was carefully calibrated with an inclined water-column manometer before the test runs start. The aqueous solution of Carbopol-934 of 500 ppm was used as model fluid, of which the viscosity curve is relatively similar to that of blood. The flow rate was adjusted over a range from 0 to approximately 20 *l*/min and measured two rotameters in parallel, one for low flow rates and one for higher flow rates.

Especially, a bifucation with optical observation window was constructed near the end of a test section in order to measure the opening areas of the polymer valves as shown in Fig. 2. The opening areas were determined from the photographs by means of a planimeter.

2.3 Set-up for leakage volume experiments

Another experimental set-up was separately designed and constructed for the measurements of leakage volumes of each valve as shown in Fig. 3. The experiment was focused to determine the leakage volumes vs. the pressures acting on the valves at the closed phase. The valve was tightly inserted into the test section fabricated with plexiglas, and positioned in the direction of a closed phase to the adjusted pressure. To begin with, air was filled into an empty cylinder with a regulator until the desired pressure of air was reached by monitoring the digital multimeter connected to a pressure transducer. Once the air pressure filled into an empty cylinder was reached in equilibrium state, the leackage volume was collected into a beaker by opening a valve slowly over a given period of time and measured with a triple beam balance measureable to 0.01 g. The test run was repeated by increasing the air pressure up to approximately 100 mmHg. The actual pressure acting on the valves were calculated as the sum of an air pressure and the static pressure, ρgh, from the free surface of test fluid to the valve position.

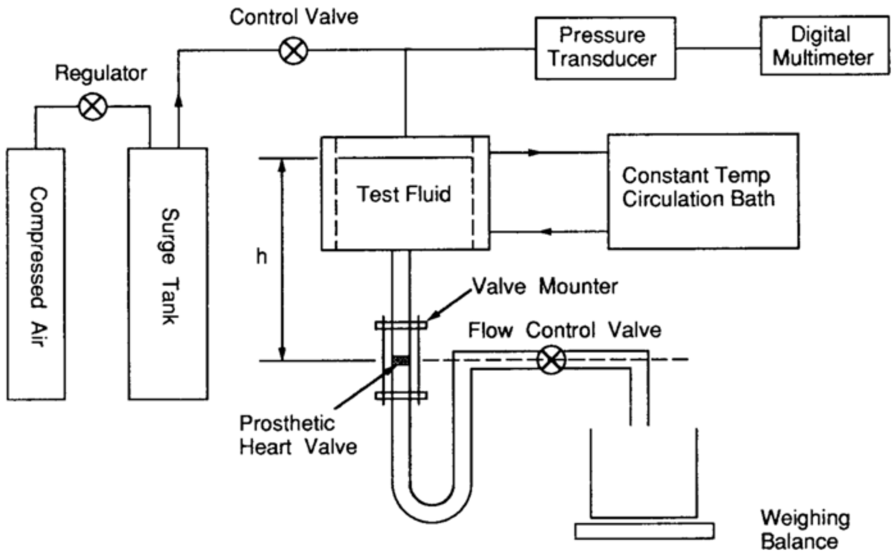

Fig. 3 Set-up for leakage volume experiments

3. Results and Discussion

3.1 Blood analog fluid

In the experiments for the hydrodynamic evaluation of prosthetic heart valves, the aqueous glycerol mixture, i.e., a Newtonian fluid, with a constant viscosity of 3.45 cP is commonly used as test fluid. However, it is a well-known fact that the rheological behavior of blood can be characterized by a shear-rate-dependent non-Newtonian viscosity and its viscoelasticity. Figure 4 shows the non-Newtonian viscosity data of normal whole blood as a function of shear rate obtained by various investigators. So far, several investigators have studied the effect of non-Newtonian rheology on comparatively complex flow in large arterial vessels numerically and experimentally. A recent numerical study by Cho and Kensey(1991) reports that the effect of the non-Newtonian viscosity of blood on flow across large arterial vessels with various degrees of atherosclerosis was found to be so significant. It implies that the effect of the non-Newtonian viscosity may be an important factor in blood flow. Therefore, a 500 ppm aqueous solution of Carbopol was used as blood analog fluid in order to include the non-Newtonian effect of blood, of

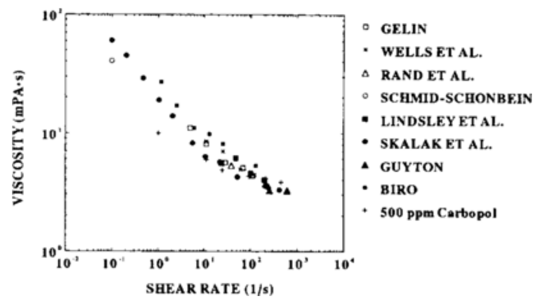

Fig. 4 The viscosities of blood and test fluid vs. shear rate. The percentage of hematocrit in blood is in the range of 33~45%

which viscosity data were also shown in Fig. 4 to facilitate the comparison.

3.2 Pressure measurements and opening areas

When fluid flows through a constriction in pipes and ducts, additional pressure drop is encountered as a result of flow separation (Fox and McDonalds, 1985). Energy eventually is dissipated by violent mixing in separated zone. Transvalvular pressure drop is primary interest in evaluation of prosthetic heart valves since it is related to clinically acceptable limit. Pressure distributions in the vicinity of the mounted-valve position are representatively shown in Fig. 5(a) and (b) for the flow rates of about 4 and 15 l/min, respectively. The main purpose of pressure distri-

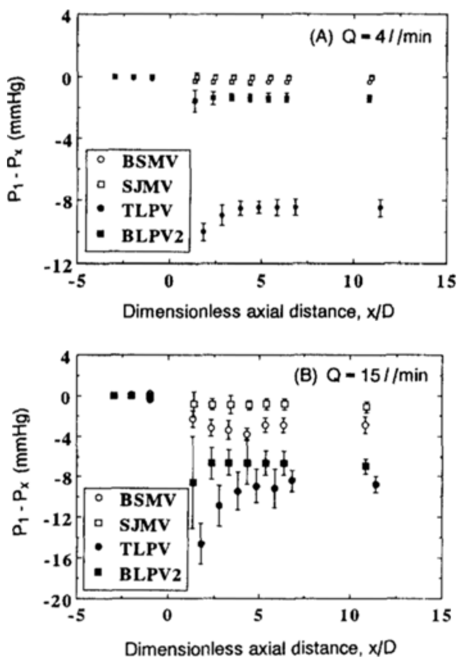

Fig. 5 Pressure distributions and fluctuations in the vicinity of the valves

bution tests was to observe the pressure fluctuation and recovery downward from the valve site ($x=0$). Figures were plotted in the form of the pressure differences between the first pressure tap (M1) and the others (M2 to M10) vs. dimensionless axial distance from the valve position (x/D). In these figures, the error bar indicates the level of pressure fluctuation. As shown in the figures, the pressure fluctuations downstream from the valve position increased significantly for all the valves, especially at higher flow rate (see Fig. 5(b)). Also, the degree of the pressure fluctuation for polymer valves were larger than those for mechanical valves. It implies that the pressure drop of polymer valves are expected higher than those of mechanical valves. According to our measurements pressure recoveries of mechanical valves were rapidly completed at about 3 to 4 diameters from the valve ring. However, the pressure recovery of a trileaflet polymer valve was continued up to 5 to 6 diameters, which indicates the existence of a recirculating zone behind the leaflets. In hydrodynamic evaluation of prosthetic heart valves, the pressure drop is conventionally determined with the interval between on diameter upstream and three to four diameter distances downstream from the valve site. The current result indicates that it should be very careful in pressure drop measurements of polymer heart valves especially. Therefore, the pressure drop across each valve in the present study was defined as the pressure difference obtained from the interval between the measuring points M3 and M9, which are located one-diameter upstream and six-diameter distances downstream from the valve position, respectively.

Figure 6 shows the results of the pressure drop for two mechanical valves which have been widely used for replacement of natural valve. The pressure drop data for a Starr-Edwards ball valve (SEMV) obtained by Yoon(1989) previously was inserted in the figure as a reference. As Gabbay et al.(1978) pointed out the dependence of pressure drop (ΔP) on the Q^2 outlined in the appendix, the experimental data were fit in a parabolic form. Here the correlation coefficient, r, indicates how well this fit reflects the trend of the data. It should be mentioned that the current data for BSMV are in good aggreement with the curve fit obtained by Gabbay et al.(1978) earlier, which confirms the validity of the current experimental system. The pressure drops of prosthetic polymer heart valves are presented in Fig. 7. To facilitate the comparion, the curve fits for two mechanical valves were inserted into the figure. The pressure drops of polymer valves are relatively greater than those of mechanical valves. In the case of a trileaflet polymer valve, the trend of pressure drops reveals

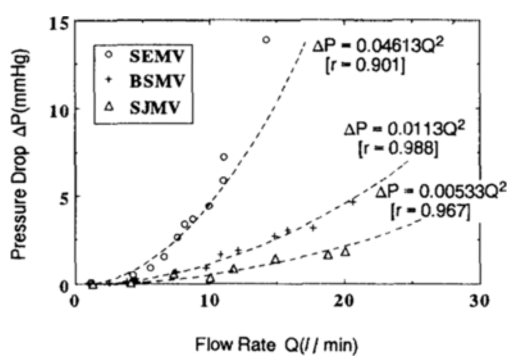

Fig. 6 Pressure drop for the mechanical valves

to be unexpectedly. At the flow rates of about 5 and 12 l/min, the pressure drop decreased significantly. This trend is thought due to flipping of the leaflets which will be discussed later with photograghs taken for the measurements of opening areas of polymer valves. The pressure drop of a bileaflet polymer valve with leaflet thickness of 0.1 mm (BLPV 1) increases with increasing flow rates. In contrast, there was observed slight flipping phenomenon in a bileaflet polymer valve with leaflet thickness of 0.2 mm (BLPV2), resulting in the sudden change of the pressure drop.

A series of photographs were taken at various flow rates in order to determine the opening areas of leaflets for each polymer valve. The figures at three different flow rates are representatively shown in Figs. 8 and 9 for a trileaflet valve and a bileaflet valve (BLPV1), respectively. From a series of figures for a trileaflet polymer valve especially, it was found that the leaflets were opened one by one and suddenly at the certain flow rates. It is thought this phenomenon, so called flipping, contributes to the sharp decrease of pressure drop at the certain flow rates as shown in the Fig. 7.

The perpendicular projected opening areas (A_V) at various flow rates were planimetered and normalized to the internal area (A_i) of a valve. The resulting plot of the relative opening area (A_O) as a function of flow rate was plotted in Fig. 10. As can be observed from the figure, bileaflet polymer valves open much more than a trileaflet polymer valve at the same flow rate, which may be attributed to different leaflet thickness of valves.

Moreover, the opening areas of the former increase monotonously with increasing flow rate, which ranges up to 53-55% at the maximum flow rate of 20 l/min, while those of the latter increase differently at certain flow ranges. With this opening behavior, so called flipping, the pressure drop data of a trileaflet polymer valve (see Fig. 6) can be explained. Note that the relative opening area for the BLPV2 is shown as a

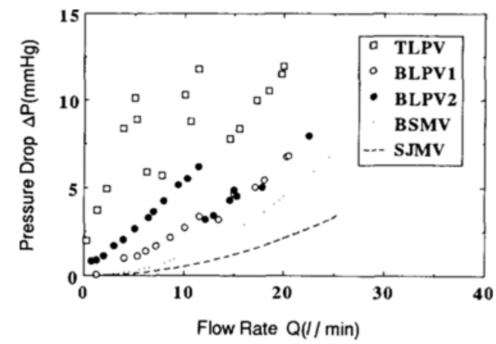

Fig. 7 Pressure drop for the polymer valves

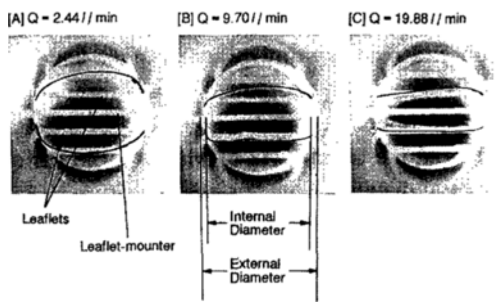

Fig. 9 Representative opening areas of a BLPV at different flow rates

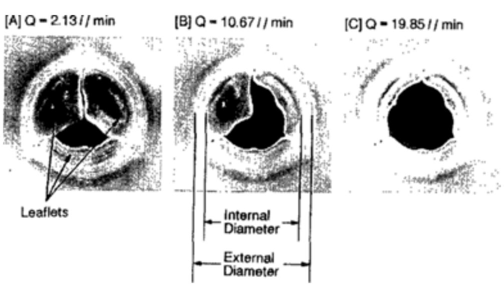

Fig. 8 Representative opening areas of a TLPV at different flow rates

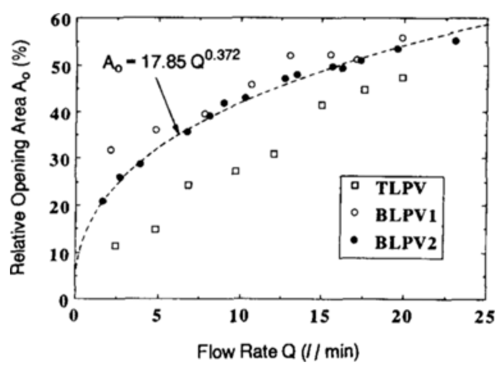

Fig. 10 The relative opening areas of polymer valves.

dashed line in Fig. 10 and can be correlated by the following relationship : $A_o = 17.85Q_o^{0.372}$

3.3 Leakage volumes of the valves

In pulsatile flow under physiological conditions, the actual output volume through a prosthetic heart valve is the effective volume defined as the ejected volume minus the reflux volume. The reflux volume can be classified into closing volume V_C and leakage volume V_l The closing volume V_C and the leakage volume V_l are the volumes flowing back during the closing process and flowing back through the crevice at the closed phase of a valve, respectively. Generally, the leakage volumes are different from each other, while the closing volumes are inevitable to a certain extent, but not much different from each other. Therefore, it is considered the leakage volume to be more importnat than the closing volume from hemodynamic point of view in that the increase of leakage volume leads to the decrease of cardiac output. Also, recent papers (Reif, 1991 ; Baldwin, 1991) report the possibility of hemolysis due to high shear stress from flow through the crevice of mechanicl valve during a closed period.

Figure 11 shows the leakage volume as a function of pressure acting on the valve at the closed phase. Generally speaking, the leakage volumes for all valves increased with increasing pressure as expected. For the mechanical valves, the leakage volumes increased almost linearly with increasing pressure except the pretty low pressure range and reached 0.4 and 1.1 l/min for the BSMV and the SJMV, respectively. However, for the trileaflet polymer valve, little amount of leakage volume was detected up to the maximum pressure of 110 mmHg. On the other hand, the leakage volumes of bileaflet polymer valves were found to be strongly dependent on the thickness of leaflets. As shown in the figure, the leakage volumes of the BLPV1 are unacceptably large compared to those of the other valves, while the leakage volumes of the BLPV2 are extremely small, suggesting that the increases of cardiac output are expected as the leaflet thickness increases slightly.

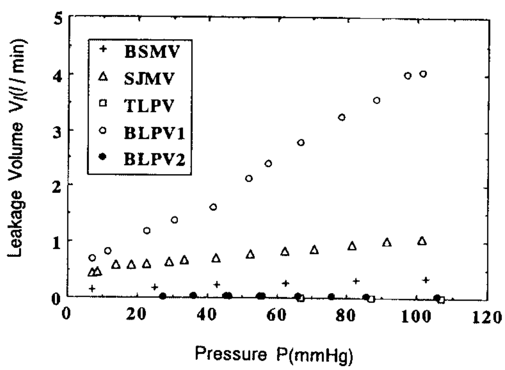

Fig. 11 Leakage volumes of the valves vs. pressure

4. Summary and Conclusions

Hydrodynamic comparison of two polymer valves with two mechanical valves of comparable size was conducted in a steady flow system. Particular emphasis is placed on a slit-type bileaflet polymer valve which was newly designed and fabricated in our research group. Although the pressure drops of a bileaflet polymer valve are, more or less, larger than those of mechanical valves, it can be considered to be within clinically acceptable limits if it is lower than 10 mmHg approximately. Especially, the excellent hydrodynamic function of a newly designed bileaflet polymer valve is the increase of cardiac output due to little amount of leakage volume. Similar encouraging results under pulsatile flow conditions will be reported later. Hence, this type of polymer valve can be a viable and inexpensive alternative in the future, especially for short-term use in total artificial heart system as well as ventricular assist devices. Moreover, with further improvements in design and material property, polymeric valves may be expected as a prosthetic valve in the near future.

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References

Baldwin, J.T., Tarbell, J.M., Deutch S. and

Geselowitz D.B., 1991, "Mean Velocities and Reynolds Stresses within Regurgitant Jets Produced by Tilting Disc Valves," ASAIO Trans., Vol. 37, pp. 348~349.

Chetta, G.E. and Lloyd, J.R., 1980, "The Design, Fabrication and Evaluation of a Trileaflet Prosthetic Heart Valve," Trans. of the ASME, Vol. 102, pp. 34~41.

Cho, Y. I. and Kensey, K.R., 1991, "Effects of the Non-Newtonian Viscosity of Blood on Flows in a Diseased Arterial Vessel. Part 1 : Steady Flows," Biorheology, Vol. 28, pp. 241~262.

Fox, R.W. and McDonalds, A.T., 1985, *Introduction to Fluid Mechanics,* Third Edition, John Wiley & Sons, pp. 365~371.

Gabbay, S., McQueen, D.M., Yellin, E.L. and Fraster, R.W.M., 1978, "*In Vitro* Hydrodynamic Comparison of Mitral Valve Prosthesis at High Flow Rates," J. of Thoracic and Cardiovascular Surgery, Vol. 76, No. 6, pp. 771~787.

Heiliger, R., Richter, H.A. and Mittermayer, C., 1986, "Hydrodynamic Comparison of Bioprostheses and Mechanical Valves in the Mitral Position," In : Bodnar R, Yacob M, eds., *Biologic and Bioprosthetic Valves,* New York : York Medical Books, pp. 835~848.

Imachi, K., Fujimasa, I. et al., 1988, "A Newly Designed Jellifish Valve for an Artificial Heart Blood Pump," ASAIO Trans., Vol. 34, pp. 726~728.

Jansen, J., Willeke, S., Reiners, B., Harbott, P., Reul, H., Lo, H.B. Dabritz, S., Rosenbaum, C., Bitter, A., Ziehe, K., Rau, G. and Messmer, B.J., 1991, "Advances in Design Principle and Fluid Dynamics of a Flexible Polymeric Heart Valve," ASAIO Trans., Vol. 57, No. 3, pp. 451~453.

Kim, I. Y., Kim, J. W. et al., 1991, "Development of Polymer Prosthetic Heart Valve-Fabrication and *In Vitro* Test," The Seoul J. of Medicine, Vol. 32, No. 1, pp. 35~42.

Reif, T.H., 1991, "A Numerical Analysis of the Back Flow between the Leaflets of a St. Jude Medical Cardiac Value Prosthesis," J. Biomechanics, Vol. 28, No. 4, pp. 733~741.

Reul, H., Muller H. and Tillman, W., 1979, "Design and *In Vitro* Evaluation of a New Shell-Type Artificial Heart Valve," Trans. Int. Soc. Art. Organs, Vol. 2, pp. 434~438.

Russel, F.B., Lenderman, D.M., Singh P.I. and et al., 1980, "Development of Seamless Trileaflet Valves," Am. Soc. Artif. Intern. Organs, Vol. 26, pp. 66~70.

Shim, Hong S. and Lenker, Jay A., 1988, "Heart Valve Porstheses," In Webster JG., ed., *Encyclopedia of Medical Devices and Instrumentation,* Vol. 3, pp. 1457~1474.

Starr, A. and Edwards, M.L., 1961, "Mitral Replacement Clinical Experience with a Ball-Valve Prosthesis," Ann. Surg., Vol. 151, pp. 726~740.

Williams, W.G., Belhouse, B.J. et al., 1978, "A Single-Leaflet Mitral Valve : Its Design, Development and Evaluation in Long-Term Animal Trials," Trans. Int. Soc. Art. Organs, Vol. 24, pp. 542~548.

Yoon, Kyoung Ho, 1989, "An Experimental Study on the Developement of Polymer Heart Valves," Master Thesis, Dept. of Chemical Engineering, Seoul National University.