인공심장 및 심실보조장치용 고분자 인조판막의 개발

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The Development of a New Polymer Valve for Artificial Blood Pumps

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ABSTRACT

Some cardio-vascular assist systems need more inexpensive artificial heart valves for short-term use. To meet with this need, we have developed a new polymer valve that is very simple to manufacture and of which its dimensions are easy to change, depending on its application. We have tested the hydrodynamic performance of the new polymer valve using a mock circulatory testing system and studied the flow through the valve using high-speed camera combined with image processing techniques. The results show that this valve is superior in its performances to the other valves (Bjork-Shiley mechanical valve and trileaflet polymer valve) and have no stagnation points. We also have tested the hemolytic potential of the valve. The valve is less hemolytic than the Bjork-shiley mechanical valve. Finally, we have applied this valve to a left ventricular assist device that we are developing.

INTRODUCTION

Artificial heart valves have been used for more than two decades. There are many kinds of mechanical and tissue valves for heart valve replacement and most of them are highly costly. On the other hand, some cardio-vascular assist systems need more inexpensive artificial heart valves for short-term use. Polymer heart valves have many advantages compared to the other artificial heart valves. They are less thrombogenetic than the mechanical valves and more inexpensive than tissue and mechanical valves. Moreover, various shapes of the valve using thermoplastic polymer - polyurethane can easily be made. Using these properties, we have designed a new easily to manufacture polymer valve that demonstrates an acceptable flow pattern without stagnation points. We tested its performance using an in-vitro heart valve function tester and flow visualization techniques and we compared its hemolytic potential with that of mechanical valves. We applied it to a ventricular assist device.

MATERIALS AND METHODS

DESIGNING CONCEPTS

The new polymer valve was designed with the following concepts

1. Stagnation of the blood flow causes thrombus formation. To minimize the stagnation region by the wash-out effect of the vortex flow, the leaflets of the valve were designed with a concave shape;
2. The attachment point of the leaflet onto the frame often causes thrombus formation and deformation of the leaflet membrane. The leaflet and the frame were designed to assemble perfectly to minimize this thrombus formation;
3. The thickness of the leaflet was minimized so that the flapping motion of the leaflet could remove small thrombus particles.

DESIGN AND MANUFACTURING OF THE VALVE

A 15% PELLETHANE 2363-80AE solution dissolved in dimethylacrylamide was used to make the leaflets and ISOPLAST was used to make the frame. The membrane of the valve was made by a dip-coating technique under clean-room conditions within an anaerobic glove box. A CAD-CAM system was used to design and manufacture the frame of the new polymer heart valve. The dimensions of the valve frame are shown in figure (1).

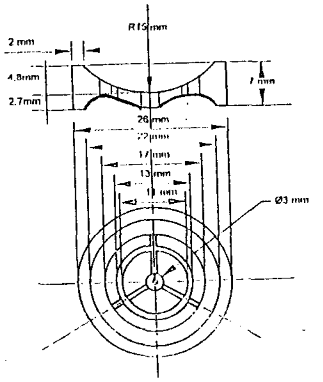

Figure 1: The parachute valve dimensions

IN-VITRO FUNCTION TESTING SYSTEM

The performance of the new polymer valve was tested using an in-vitro hydrodynamic function tester that was developed in our laboratory. The testing system is based on the lumped parameter principle, i.e., all compliance, resistive and inertia effects, which occur in the human cardiovascular system, are modeled by one (variable) hydrodynamic element and are assumed to be located at one position only. Aortic and ventricular pressure, and aortic flow as well are measured by pressure and flow sensors and are acquired by a normal PC. Within the PC, the following parameters were calculated using a newly developed software system: pressure drop, regurgitation, energy loss per beat, effective valve orifice area and overall valve performance index. The obtained pressure and flow wave forms assent with physiological data. A 33% glycerin/water solution was used as a blood analog. The viscosity of the solution was chosen'similar to that of normal human blood. For detailed description of the testing procedure, see [1].

FLOW PATTERN ANALYSIS

The flow through the valve was studied using a flow visualization method, using a CCD-camera combined with image processing techniques. A He-Ne laser was used to illuminate small amberlite particles, which were added to the testing fluid. A CCD-camera was utilized to record the movement of these illuminated particles near the prosthetic heart valve, passing through a transparent tube. After this, the recorded images were captured subsequently by an image board installed in a PC. A software system was developed to process these captured images in order to obtain the velocity profile. The finally obtained velocity profile provided the desired information of occurring vortices and stagnation points.

HEMOLYSIS TESTING

The hemolytic potential of the new polymer valve was compared with mechanical valve using an in-vitro hemolysis testing system. In this system, a fixed volume of blood circulates through a closed loop system including a pair of artificial heart valves that are to be tested.

500 ml of heparinized blood (12.5 unit of heparin/ml) was circulated also within the blood analog. About 60-70 ml of the blood was ejected at each stroke at a pumping rate of 50 bpm, resulting in a cardiac output of about 3 l/min. 5 ml of the circulating blood was sampled at each hour and centrifuged for 15 min. at 3000 rpm. The plasma Hb concentration was analyzed using the obtained plasma from the centrifuged blood.

ANIMAL EXPERIMENT

The new polymer heart valve was applied to a left ventricular assist device developed in our department. We have tested its In-vivo performance using mongrel dogs (body weight : 38-45 Kg) . up to three days. The pumping rate of the left ventricular assist device was set from about 120 to 160 beats per minute, the assist volume was about 1.8 lt. per minute.

RESULTS AND DISCUSSION

IN-VITRO TESTING

All data were acquired under pulsatile testing conditions at a heart rate of 70 bpm, 35% systolic/diastolic duration, Aop 120/80 mm Hg, mean Aop 100 mm Hg, and at sample frequency of 512 Hz. The testing fluid was a 33% glycerin/water blood analog.
Figure (2) presents an example of obtained flow and pressure data.

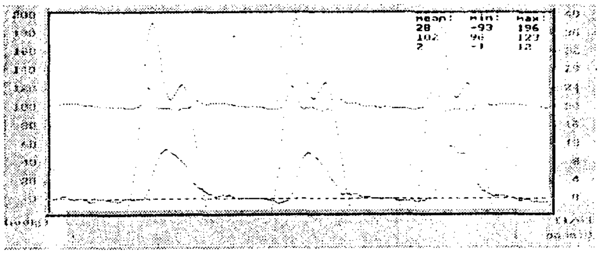

Figure 2: The obtained pressure and flow signals; (a) ventricular pressure, (b) aortic pressure, (c) flow.

FLOW VISUALIZATION

Figure (3) presents a processed image of the flow at the beginning of the diastolic period(cardiac output 2 lpm, heart rate 70 bpm) through a parachute valve taken by a still camera (shutter speed 1/15s), showing the illuminated particle within a transparent tube. These images were captured by means of a matrox - image board. and were filtered (low-pass filter), smoothened. After thinning and combining of images, several vortices can be distinguished. An occurring vortex guarantees no stagnation of blood flow and therefore few possibilities of thrombosis formation.

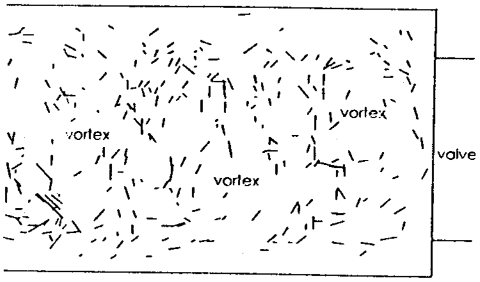

Figure 3: A processed image of the parachute valve; the lines indicate the velocity field.

ANIMAL EXPERIMENT

The new polymer valve was applied to left ventricular assist device (LVAD) attached to left ventricle of a 50 Kg mongrel dog for 3 days without heparin administration and then sacrificed.
During the experiment, the plasma hemoglobin level, plasma protein concentration, oxygen saturation and several hematological items were checked. Figure (4) presents a photograph of the new polymer valve after 3 days of application.

Figure 4: The polymer valve after animal experiment

As shown in the photograph, the valve was free from thrombosis. Figure(5) presents the plasma hemoglobin level during the experiment. The valve was less hemolytic than the mechanical valves.
The valve worked well during the experiment without any complications. According to the results, this valve would be very useful for artificial heart pumps such as left ventricular assist devices and a total artificial heart.

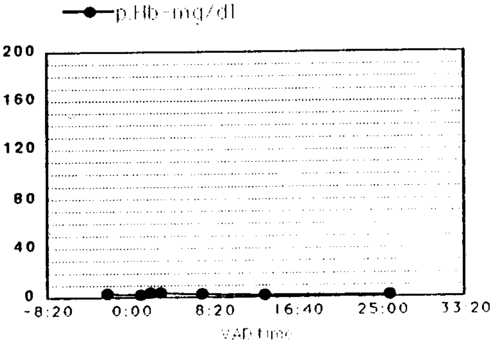

Figure 5. : plasma hemoglobin level during the animal experiment

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