Design of a Mechanical Heart Valve’s Occluder to Start Closing by Gravity*

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Conventional mechanical mitral valves close rapidly, which is one of the reasons for the attendant hemolysis and the closing click. Safer mechanical valves which close more slowly will be realized if the occluder (opening and closing movement element) starts closing without any backflow. A new self-closing occluder was designed by adjusting the center of gravity of the occluder. Blood flow becomes nearly zero for around 250 msec from the middle of left ventricular relaxation. The valve is expected to start closing by gravity during the nearly zero flow periods. Thus, the time from the maximally open state to complete closure should be designed to be no more than 250 msec. In this paper, a new design process for a self-closing occluder was proposed. A new prototype occluder made of aluminum alloy was produced by optimizing the center of gravity, torque by gravity and moment of inertia. The prototype occluder with a piano wire as the rotational axis was mounted on an acrylic resin base. The closing motion of the valve was measured by a high-speed video camera (125 pictures per second). The calculation and measurement of the closing motion were carried out, and qualitative agreement was observed with the motion in air. The time from the maximally open state to complete closure by gravity in glycerin solution as a blood substitute was 208 msec, which is thought to be satisfactory available for the cases requiring mitral valve replacement. The results showed the validity of the proposed design process.

Key Words: Design, Valve, Medical Engineering, Bio-Fluid Mechanics, Mechanical Heart Valve, Occluder, Closing Motion, Torque by Gravity, Momentum of Inertia

1. Introduction

Natural valves are replaced with mechanical valves when they do not close completely or provide high resistance to blood flow. A mechanical valve consists of an occluder moved by fluid (blood) force, housing with a hinge mechanism and a sewing ring which is sutured to heart muscle. Since the 1960s, prosthetic heart valve configurations and the materials employed have been improved keeping in mind the objective of a lower flow resistance, higher durability and higher blood compatibility. Most surgeons now choose a bi-leaflet (two occluders) type mechanical valve made of pylonite carbon. Problems such as thromboembolism, hemolysis (red blood cell destruction) and mental stress owing to the occurrence of the closing click sound still remain.

Closing motion is different between natural and mechanical valves. In mechanical valves, the occluders start closing after the left ventricular contraction (systole), while natural mitral valves start closing before systole (Fig. 1). This delay in closing after systole results in rapid closure (high final closing speed). High final closing speed is said to be one of the reasons for hemolysis and the closing click sound.

Two types of valves designed for closing before systole have already been studied. Both types used magnetic force and have not yet been applied for clinical use due to their complexity.

The author has proposed a new type of occluder that starts closing by gravity (self-closing occluder). A self-closing occluder can be fabricated by simply adjusting the center of gravity of the valve (Fig. 2). A preliminary study using a clinical bi-leaflet valve (sewing ring diameter: 29 mm) with a
shifted center of gravity showed the ability to start closing and provided direction for the design strategy(7). The self-closing occluder fabricated for this former study was, however, not meant for clinical study as the center of gravity of the pylonite carbon occluder (weight: 0.3 g, density: 2.48 g/cm³) was adjusted by attaching a block of lead (weight: 2 g and 4 g, density: 10.4 g/cm³) to it. It was determined from this experiment that the momentum of inertia of the occluder $J$ should be less than $15 \times 10^{-6}$ kg·m² and the torque by gravity $T_g$ should be more than $4.2 \times 10^{-6}$ N·m for a sewing ring diameter of 29 mm.

The objectives of this study are 1) to propose a new design process for a self-closing occluder, 2) to fabricate a prototype occluder, and 3) to check its closing motion by simulations and experiments.

A flow-chart of this study is shown in Fig. 3. The physiological data regarding the hemodynamics around the mitral valve are summarized in section 2. In section 3, the design process of a self-closing occluder (above the broken line in Fig. 3) is described. Optimization of $J$ and $T_g$ is a new approach in the design of an occluder. In section 4, closing motion considering the inclination of the valve housing is compared between simulations and experiments.

**Nomenclature**

$A_1, A_2$: occluder model divided into two parts for easy calculation
$g$: acceleration of gravity
$H$: thickness of the valve housing
$J$: momentum of inertia of the occluder
$J_{a_1}, J_{a_2}, J_{a_3}$: momentum of inertia about the axis through the center for gravity of the whole shape ($J_{a_1}$, $J_{a_2}$), $A_1$ ($J_{a_1}$) and $A_2$ ($J_{a_2}$)
$k$: dimensionless parameter for designing the shape of the occluder
$L$: length of the occluder
$LA$: left atrium
$LV$: left ventricle
$LVP$: inner pressure of left ventricle
$m$: mass of the occluder
$m_1, m_2$: mass of $A_1$ ($m_1$), $A_2$ ($m_2$)
$R_c$: center of gravity of the occluder
$R$: inner radius of housing
$r$: radius of a piano wire as a substitute of the hinge mechanism
$T_g$: torque by gravity
$t$: thickness of the occluder
\( V \) : volume of the occluder  
\( \alpha \) : vertical angle of the cross section of A1  
\( \beta \) : angle used for calculating the momentum of inertia  
\( \rho \) : density of material  
\( \theta_{oc} \) : complete closure angle  
\( \theta_{max} \) : maximum open angle  
\( \theta \) : angle between occluder and housing

2. Hemodynamics around the Mitral Valve

Before describing the designing of a self-closing occluder, the hemodynamics around the mitral valve will be stated. The occluders of mechanical valve are forced to move by the fluid force of blood flow. Consideration of a typical blood flow and pressure pattern is necessary for efficient designing.

2.1 Blood flow

The mitral valve is located between the left atrium (LA) and left ventricle (LV). It opens during LV relaxation (LV filled with oxygenated blood) and closes during LV contraction (systole; ejection into the peripheral vascular system). As shown in Fig.1, the natural mitral valve starts closing twice during LV relaxation, the first time as a result of a decrease of blood flow into the LV and the second due to LA contraction. Most patients requiring valve replacement have lost their LA contracting ability due to disease. The LV relaxes for less than 700 msec. Blood flow becomes nearly zero for around 250 msec from the middle of LV relaxation. The start of valve closure by gravity is expected during the nearly zero flow periods. Thus, the time from the maximally open state to complete closure should be designed to be no more than 250 msec.

2.2 Pressure

The pressures in the LV (LVP) exhibit a pulse-like pattern. The LVP increases from 0.39 kPa (3 mmHg) to 15.6 kPa (120 mmHg) after systole. Torque caused by the LVP after systole is more than \( 1 \times 10^{-2} \text{ N\cdotm} \), enough to keep the occluder shut against the torque by gravity. This means a self-closing valve will remain shut during LV systole even if patients change their posture.

3. Design of the Self-Closing Occluder

3.1 Shape of the occluder

The occluder shape was modeled as shown in Fig. 4. A hinge mechanism was not modeled in this study. Coordinates were defined from the bottom as shown in Fig. 4. A piano wire (radius: \( r \)) was used to connect the occluder and the element used for rotation (for example, a ball bearing). The centerline of the piano wire was attached at \( (kR-r) \) from the bottom. In order to obtain a center of gravity inside A2, the cross section of A1 was set to be triangular, while that of A2 was set to be rectangular. As this model was not intended for clinical use, its strength against impact between the occluder edge and the inner housing was not considered. The center of gravity \( R_c \), expressed by Eq. (1), was calculated and was expected to be located inside A2 as derived from Eq. (1). The fluid force acting on the occluder is proportional to the projection area. The projection area of A2 should be smaller than that of A1 in order to let the occluder rotate expressing by Eq. (2).

\[
R_c = \frac{2k^3 + 1.57(k + 0.35)}{4k + 1.57} R < kR - r \tag{1}
\]

\[
\frac{\pi}{2} R^2 > 2kR^2 \tag{2}
\]

The range of \( k \) was determined by the above 2 equations, that is,

\[
0.55 < k < 0.84 \tag{3}
\]

The momentum of inertia \( J \) about the rotational axis can be calculated by the following equations.

\[
J = J_{11} + (R_c - kR + r)^2 (m_1 + m_2) \tag{4}
\]

where

\[
J_{11} = J_{11} + J_{22} \left( 0.35 + \frac{k}{2} \right) R^2 \frac{m_1 m_2}{m_1 + m_2} \]

\[
J_{11} = J_{11} + m_1 (0.35 R^2) \]

\[
I_1 = 2 \rho R^4 \tan a \int_0^\frac{\pi}{2} \sin^2 \beta \cos^2 \beta (1 - \sin \beta) d\beta \]

\[
m_1 = 0.785 R^4 \tan a \rho \]

\[
J_{22} = \frac{1}{12} m_2 (kR)^2 \]

\[
m_2 = 2kR^4 \tan a \rho \]

Torque by gravity was calculated by considering the buoyancy.

\[
T_s = (\rho - 1060) V g (kR - r - R_c) \tag{6}
\]

\[
V = (2k + 0.785) R^3 \tan a \tag{7}
\]

\[
t = R \tan a \tag{8}
\]

The shape of the self-closing occluder was designed using Eq. (1), Eq. (2), Eq. (4) and Eq. (6). The dimensions of the self-closing occluder were
determined for a sewing ring diameter of 29 mm. The width $2R=20.45$ mm used was the same as that in a clinical bi-leaflet valve. A prototype occluder was fabricated using an aluminum alloy (density: $2.800 \text{ kg/m}^3$) for this first stage of the planned series of studies. Figure 5 shows the relationship of with $(T_g - 4.2 \times 10^{-9})$ and $(J - 15 \times 10^{-9})$ under the condition of $t=0.5$, 1.0 and 1.5 mm. The arrow in the figure denotes the adequate range of $k$ following Eq. (3). $k$ value satisfying $(T_g - 4.2 \times 10^{-9}) > 0$ and $(J - 15 \times 10^{-9}) < 0$ should be chosen according to the preliminary study. Optimal $k$ exists from 0.76 to 0.84 only in the case of $t=1.0$ mm. $k=0.8$ was chosen as one example from the middle of the range. The $T_g$ was $5.4 \times 10^{-6}$ N·m and the $J$ was $12 \times 10^{-9}$ kg·m$^2$ in this case. Some other $k$ values will be examined taking into consideration the added mass effect in the future.

3.2 Complete closure angle

The relationships among the length of the occluder $(L)$, thickness of the valve housing $(H)$, complete closure angle $(\theta_c)$, and the inner radius of the valve housing $(R)$ are expressed in Eqs. (9) and (10) (Fig. 6). Equation (11) was established from Eq. (9).

$$L = (1 + k)R = \frac{R}{\cos \theta_c}$$  \hspace{1cm} (9)

$$H = L \sin \theta_c$$  \hspace{1cm} (10)

$$1 + k = \frac{1}{\cos \theta_c}$$  \hspace{1cm} (11)

Figure 7 shows the relation between $\theta_c$, $H$ and $k$ under $R=10.225$ mm. In this figure, the range of $k$ required according to Eq. (3) is shown by the arrow.

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**Fig. 5** Relationship of dimensionless shape parameter $k$ with torque by gravity $(T_g - 4.2 \times 10^{-9})$ and momentum of inertia $(J - 15 \times 10^{-9})$ under the condition of $t=0.5$, 1.0 and 1.5 mm. The arrows in the graphs indicate the adequate range of $k$ determined according to Eq. (3).

**Fig. 6** Definition of length of the occluder $(L)$, thickness of the valve housing $(H)$, complete closure angle $(\theta_c)$, and inner radius of the valve housing $(R)$.

**Fig. 7** Relationship between thickness of the valve housing $H$, complete closure angle $\theta_c$, and dimensionless shape parameter $k$ under $R=10.225$. The arrow in the graph indicates the adequate range of $k$ determined according to Eq. (3).
As described in section 2.1, \( k \) was determined to be 0.8. In this case, the complete closure angle was 55 degrees and the thickness of the valve housing was 15 mm. These values were 25 degrees and 3 mm bigger than those in the St. Jude Medical valve of the same size. Decrease of the backflow volume can be expected, because the traveling angle (maximum open angle minus complete closure angle) is smaller than in a conventional mechanical valve. If the backflow volume decreases, the ejection efficiency of the left ventricle improves and the resistance to flow is decreased. It is desirable to design a smaller value of \( H \) in order to prevent thrombogenesis due to stagnation of blood when the valve housing protrudes into the left ventricle. The optimal \( H \) has not yet been determined, thus it cannot be concluded that the higher \( H \) is a fatal shortcoming of the self-closing valve.

4. Closing Motion of the Designed Occluder

4.1 Methods

1) Inclination of the valve housing

People change their posture throughout the day. The inclination of the implanted valve housing against gravity (\( \phi \), Fig. 8) should therefore be considered for motion analysis. The patients move around even in their houses and are not always lying in bed. The inclination of the mitral valve ring with respect to the gravitational direction was measured from the MRI (MRHS500; Hitachi, Tokyo, Japan) images obtained in a healthy volunteer (age 22, male; Fig. 9). The \( \phi \) was chosen to be the 45, 60 or 75 degrees for the simulation and experiment below, taking into consideration variability of the anatomy among people.

2) Simulation

The rotation of the occluder acting only on gravity was expressed in Eq. (12). Equation (12) was solved by the 4-th order Runge-Kutta method. The maximum open angle \( \theta_{\text{m.o}} \) was 85 degrees and the complete closure angle \( \theta_c \) was 55 degrees. The time interval for calculation was 0.2 msec. This study was planned as a first step for the continuing simulation studies taking into consideration the viscous fluid-structure interactions.

\[
J\dot{\theta} = -mg(kR - r - R_c)\cos(\theta - \phi)
\]  \hspace{1cm} (12)

3) Experiment

The occluder motion was measured by a high-speed video camera (Fastcam-ultra; Photron, Tokyo, Japan). The recording rate was 125 pictures per second. The designed occluder with a piano wire was mounted on an acrylic resin base (Fig. 10). A protractor was attached to the base and used for the measurement of the occluder angle. The occluder was rotated both in air and in a 40% glycerin solution (viscosity 3.6 mPa·s, density 1.06 g/cm³) as a blood substitute.

![Fig. 8 Self-closing occluder model for calculation and definition of the inclination of the valve housing against gravity (\( \phi \))](image)

![Fig. 9 MRI image of the inclination of the mitral valve ring against gravitation obtained from a healthy volunteer (22, male)](image)

![Fig. 10 Photograph of the experimental set up for the measurements of closure of the occluder](image)
4.2 Results and discussion

The simulation and experimental results in air are shown in Fig. 11. The time from $\theta_{n,o}$ to $\theta_c$ increased from 48 to 56 msec, when $\phi$ decreased from 75 to 45 degrees. The effect of $\phi$ is not expected to cause a functional failure as satisfying the requirement described in section 2.1. The calculations and measurements are in qualitative agreement.

The experimental result of time from $\theta_{n,o}$ to $\theta_c$ in the glycerin solution was 208 msec, which is more than three times as much as the result in air, although the effects of $\phi$ were not observed. The value also met the desired value (no more than 250 msec).

Thus, the results show the validity of the design strategy in regard to $T_g$ and $J$.

5. Conclusion

A new design for a self-closing occluder is proposed. The occluder shape was determined by optimizing the center of gravity, torque by gravity and momentum of inertia. A prototype occluder could be fabricated using an aluminum alloy. The results of calculation and measurement of the valve closure qualitatively agreed with those of valve closure in air. The time from the maximally open state to complete closure by gravity in glycerin solution as a blood substitute was 208 msec, which is thought to be satisfactory for cases requiring mitral valve replacement. The results thus show the validity of the proposed design. Future studies are planned to design and fabricate valves using material for clinical use, such as pyrolyte carbon.

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