Computer aided interactive design/analysis of mechanical bi-leaflet heart valves
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Abstract

The work presents results from a newly developed interactive design tool for mechanical heart valves using ‘application builder’ visualisation tools. The software provides an environment where a large range of valve designs can be created/analysed and either passed or rejected within a single session. The geometry of the valve is defined using the relatively new technique of P.D.E. (partial differential equation) solution methods. By this the pde generated geometry, fluid flow analysis and dynamic modelling are tightly integrated and the designer may investigate the design variants. A concept design process is illustrated by considering important criteria which include the separation zone size behind the stiffening ring and the leaflets, the shear stress distribution over the leaflets, the location of the leaflet with respect to the stiffening ring and the corresponding dynamic behavior. The results show that the closing behavior of the leaflets and the required regurgitant volumes to complete closure depend on the orientation of the gravity force and the location of the leaflet with respect to the stiffening ring.

1 Introduction

In recent years computational fluid dynamics (CFD) and the visualisation of numerically generated data have become increasingly important in the heart valve design cycle. However due to the variation of geometry for this design and the urge to solve the full equations modelling the flow phenomenon, each analysis of a specific geometry still takes a considerable amount of computer time. This makes the initial evolution of the design somewhat slow and expensive. There is therefore a strong need to provide an initial
‘quick’ design tool which can create a large range of valve designs whilst at the same time provide vital robust information from the analysis on the initial design with reference to the design criteria.

In order to achieve this ‘quick design’ philosophy, the authors\(^3\) have developed a computer aided interactive design/analysis environment using Iris Explorer\(^\text{TM}\) (software originally available with Silicon Graphics hardware platforms) for the integrated design work. By this the interactive design environment, the geometry model, fluid flow analysis and dynamic model are tightly integrated and designer may create/analyse the design variants interactively.

The attempt here is to use the design environment to aid the design of mechanical heart valve in the very early stage of the design cycle. The results shown below give an outline of how an optimal design can be achieved using the design environment. The results presented here should not be taken as representative of final designs, further use of detailed and more complex mathematical models would be required further downstream of the design cycle.

## 2 Design Environment

An example of the integrated design environment for heart valve designs is demonstrated in Fig.1. The main components of the design environment consist of:

1. an input module, where geometry boundary conditions are input, e.g., \texttt{hsu} module.
2. a surface generator, this creates the valve surfaces and others such as the stiffening ring, e.g., \texttt{aorta} module and \texttt{leaflet} module.
3. a fluid flow algorithm, here the conservation equations are discretised and solved, e.g., \texttt{wax3d} module.
4. a render window, the results such as pressure contours, flow vectors etc. are visualised along with the geometry.

We refer the reader to David and Hsu\(^3\) for a full description of the design environment.

## 3 Theory and Modelling

The generation of the surfaces modelling the full valve geometry (e.g. leaflets and stiffening ring) can be accomplished using the solution to a particular set of \(m^{th}\) order elliptic partial differential equations, initially developed by
Bloor and Wilson\cite{1}, in the independent variables $u$ and $v$ given in the form as

\begin{equation}
\left( \frac{\partial^2}{\partial u^2} + a^2 \frac{\partial^2}{\partial v^2} \right) X = 0
\end{equation}

$a$ is a parameter which essentially scales the $v$ coordinate.

Fig. 2 shows the coordinate system and boundary conditions of eqn. (1) for the leaflet geometry model\cite{2}. The leaflet is designed as an elliptic leading edge span with height $r$, in order to parametrically study the blood mass flux through each of the three orifices, and a simple cubic curve geometry from leading to trailing edge.

Fig. 3 shows the coordinate system and boundary conditions of eqn. (1) for a basic model of the stiffening ring\cite{3}. The $x$ direction is that of the main blood flow, the $y$ direction essentially models the valve pivoting axis with the $z$ direction orthogonal to both $x$ and $y$. The origin is located at the centre of the stiffening ring. This is modelled as an axisymmetric ring about the $x$ axis of width $w$ and with radius $R_1$ on the inlet cross section and radius $R_2$ on the outlet cross section. The $u = 0$ boundary maps to the inlet cross section at $x = \frac{-w}{2}$ and the $u = 1$ boundary maps to the outlet cross section at $x = \frac{w}{2}$.

The boundary conditions are listed in Table I.

<table>
<thead>
<tr>
<th>$u = 0$</th>
<th>$u = 1$</th>
</tr>
</thead>
<tbody>
<tr>
<td>$x$</td>
<td>$y$</td>
</tr>
<tr>
<td>$-w$</td>
<td>$R_1 \cos v$</td>
</tr>
<tr>
<td>$-w$</td>
<td>$R_2 \cos v$</td>
</tr>
</tbody>
</table>

Table I. Boundary conditions of stiffening ring geometry

Here the constants $S_1, S_2, S_3, S_4$ are used to provide simple interactive geometry changes without having to alter the full boundary conditions at every step.

As the blood flows through the ascending aorta it is constrained by the aortic wall and will additionally be accelerated/decelerated due to the variation of the aortic diameter. To simulate this flow situation it is essential to establish an internal flow model which can simulate the boundaries both of the heart valve and the aortic root. The internal flow model is achieved by utilising an irrotational, inviscid algorithm comprising vortex-ring elements simulating the leaflets and the downstream wake and source/sink elements simulating the aortic root and the stiffening ring. A coupled boundary layer model simulates the viscous component of the valve designs\cite{4,5}.

The opening and closing characteristics of the leaflet are simulated by considering the leaflet to be a 2nd order rotating system. The equation of motion of the angular derivation of the leaflet is derived from the condition of moment equilibrium. We refer the reader to Hsu and David\cite{6} for a full
description of the stiffening ring geometry, the fluid flow model and the dynamic model.

4 Results

Since the heart valve geometry can influence the bulk blood flow, it is important that this aspect is modelled and analyzed. As has been suggested in David and Hsu\(^3\), the leaflet geometry must be produced such that it provides a ‘smooth’ transition between the small valve diameter and larger aortic root diameter to reduce shear stress in the fluid and a leaflet shape with sharp trailing edge that allows blood to flow downstream in a smooth fashion. On the stiffening ring design, an internal flow analysis carried out by Hsu and David\(^5\) has shown that the stiffening ring geometry affects the size of the recirculation zone behind the stiffening ring, the effective orifice area of the leaflet and the associated leaflet dynamic behavior.

As an illustrated and actual application for the design environment in determining valve geometry, we restrict ourselves to evolving an ‘optimal’ heart valve design by considering important criteria which include the separation zone size behind the stiffening ring and the leaflets, the shear stress distribution over the leaflets, the location of the leaflets with respect to the stiffening ring and the corresponding leaflet dynamic behavior. We illustrate below a procedure in determining these parameters associated with the valve design.

4.1 Determination of \( r \)

In the 3D CFD experiments carried out by King\(^6\) it has been shown that as the blood flows through the reduced diameter formed by the stiffening ring, three jets are generated in the orifices between the stiffening ring and the leaflets. The strength of the jets is dominated by the size of the orifice area which is determined by the design parameter \( r \) (the height of the leaflet leading edge). As the orifice area between the leaflets in the fully open position decreases, the strength of the central jet increases thus inducing an increased shear stress in the central flow downstream the leaflet. On the other hand, as the central orifice area increases the flow velocity through the central orifice decreases thus producing an increased pressure acting on the suction side of the leaflet surface. This increased pressure tends to resist opening of the leaflet during the systolic phase. Hence in searching for a balance between these two effects the height of the leaflet leading edge, \( r \), is chosen by ensuring equivalent blood flow through all three orifices of valve (i.e. equal orifice area). This is given by \( A_c = A_o \). Here \( A_c \) is the central orifice area which is equal to \( rR\pi \) and \( A_o \) is the outer orifice area which is equal to \( (R^2\pi - rR\pi)/2 \). Thus \( r \) is evaluated to be \( R/3 \).
4.2 Determination of $\lambda$

Fig. 4 shows the calculated separation points evaluated along the centre streamline and parallel lines across the leaflet span. The shear-stress, $\tau_w$, evaluated as a function of the non-dimensionalised streamwise coordinate at the leaflet surface is also shown, along the centre streamline for $\lambda = 0.1$, $0.2$ and $0.3$ implanted in the initial prototype stiffening ring (King et al.\textsuperscript{6}) which has a uniform square cross sectional area and a ‘sharp’ angular geometry in the inlet and outlet cross sections.

Here the effect of an increase in $\lambda$ is to produce the onset of separation closer to the leading edge of the leaflet. This will produce a larger recirculation zone behind the valve and increase the probability of clotting in the blood due to slow moving fluid. On the other hand, changing the value of $\lambda$ seems to have little effect on the shear stress. Hence on the consideration of minimizing the size of the separation zone, the leaflet chosen for further analysis is the one of $\lambda = 0.1$.

4.3 Determination of stiffening ring geometry

Fig. 5 shows the location of the separation point $S_{sep}$, nondimensionalised by the total arclength of the ring $S_{ring}$, as a function of $S_1$ and $S_2$ when $S_3 = S_4 = 1.5$. The associated ring geometries are listed graphically vertically on the right of the figure with region A when $S_1 = 0$, B when $S_1 = 0.5$, C when $S_1 = 1.0$ and D when $S_1 = 0.5$. Since the separation point is approximately located at the position of maximum surface curvature, the effect of increasing $S_1$ is to produce a stiffening ring geometry for which the separation point appears closer to the ventricle thus inducing a larger recirculation zone behind the stiffening ring. An opposite effect occurs when $S_2$ is increased. It therefore seems reasonable to find a stiffening ring design with a high value of $S_2$ and a low value of $S_1$. The real physical criterion here is that the size of the ring vortex generated by the flow separation from the ring should be of a minimum size/strength.

Hence the stiffening ring geometry with $S_1 = 0$ and $S_2 = 1.5$ is utilised to combine with the leaflet geometry with $\lambda = 0.1$ for further analysis.

4.4 Determination of the location of the leaflets

To validate the dynamic model, a comparative study has been investigated with the experimental results of Canning\textsuperscript{2} for a 29mm CarboMedics valve. The leaflet opens to the maximum angle after about 39 msec from the initiation of the opening and the time required to fully close the leaflet is shown to be 41 msec. A numerical simulation using the presented model for this case shows that the time required to fully open the leaflet is 37 msec and 43 msec to fully close the leaflet when the orientation of gravity is
perpendicular to the main flow direction. These results are in accord with the experimental result of Canning.

A further comparative study is investigated with the experimental result of van Steenhoven et al. For the case of a 21mm St. Jude valve at the haemodynamic condition of peak aortic flow (200 ml/s) and heart rate (60 beats/min) i.e. the cardiac output is approximately 3 l/min. The time required to open the leaflet is 65 msec and 60 msec to fully close the leaflet. The leaflet closes only for 5% of its cross-section area during systolic ejection. It therefore needs regurgitant flow to complete the closure. The ratio of the closing valve regurgitant flow to the main flow is approximately 2.5%. A numerical simulation using the presented model for this case shows that the time required to open the leaflet is 68 msec and 60 msec to fully close the leaflet when the orientation of gravity is perpendicular to the main flow. The ratio of the closing valve regurgitation flow to the main flow is approximately 2.6%. These results are in excellent accordance with the experimental results of van Steenhoven et al.

To investigate the effect of the location of the leaflet with respect to the stiffening ring in determining the corresponding dynamic characteristics, three cases of 29 mm new heart valve designs are studied. Case A corresponds to the leading edge of the leaflet located at the centre of the stiffening ring, case C the leading edge is located at the inlet cross section of the stiffening ring and case B is with the leading edge located at the midpoint between that of case A and C. The pivot axis is located at the centre of the stiffening ring for all three cases. Fig.6 shows the dynamic characteristics for the case of the gravity vector parallel to the main flow ($\phi = 0^\circ$). The leaflet begins to close in the early phase of diastole. This is not an unexpected result due to the larger inertia of the mechanical prosthesis, additionally this has been observed experimentally (van Steenhoven et al). However the required amount of the regurgitant flow to fully close the leaflet depends on the orientation of gravity and the location of the leaflet.

Fig.6 shows a slightly different closing behavior for the cases A, B and C. The ratio of the closing valve regurgitation to the main flow is lowest for case A (9.12%) followed by case B (10.48%) and highest for case C (12.83%). There are two effects influencing the regurgitation, firstly due to the effective increase in the orifice area at the position of the leaflet leading edge for case C, therefore the lift is lower owing to the decreased strength of singularity elements maintaining the zero normal flow condition along the leaflet surface. Secondly, the magnitude of the radius vector from the pivot axis to the centre of lift is smallest for case C. These two effects induce a lower lifting moment for case C to close the leaflet during the diastole thus increasing the closing valve regurgitation.

Fig.7 shows the dynamic behavior for case A, B and C when gravity is opposite to the main flow. This is similar to the aortic valve opening when a person is in the standing position. The ratio of the closing valve
regurgitation to the main flow is significantly lower than that of $\phi = 0$ (Fig.6). It is 0.103% for case A, 0.134% for case B and 0.17% for case C. This is not an unexpected result because the moment due to the gravity force tends to close the leaflet in this orientation thus making the valve close very gradually during the flow deceleration phase of systole mainly. After that only a minor regurgitant flow is necessary to complete the closure. The physiological criterion here is that a gradual valve closure with only a minor regurgitant flow decreases the occurrence of haemolysis and total energy loss, which takes into account the energy loss during forward and reverse flow, across the heart valve.

5 Discussion

Since even with the small number of parameters describing the leaflet and the stiffening ring a large number of designs may be derived, we restrict our discussion to a small subset thought to be of importance. Meanwhile the design criteria are confined at present to be the separation zone size behind the stiffening ring and the leaflets, the shear stress distribution over the leaflets, the location of the leaflets with respect to the stiffening ring and the corresponding dynamic behavior. The purpose here is to provide a concept design process for evolving optimal prosthetic heart valves by utilising an interactive design environment. It must be noted however that different criteria could lead to very different conclusions in determining the design parameters. The choice of best overall valve depends on how much weight should be placed on each criterion.

In the in vitro closing behavior analysis for Bjork-Shiley, St Jude and Hancock heart valve prostheses carried out by van Steenhoven et al., it has been shown that the mechanical prostheses mainly close due to the regurgitant flow in the early phase of diastole whilst the natural valve closure is very gradual and has already started during the deceleration phase of systolic ejection consequently only a minor regurgitant flow in the valve is required to complete valve closure. Due to the higher regurgitant volumes of the mechanical prostheses, the shear stress and the occurrence of haemolysis are correspondingly higher. However, it must be noted that the regurgitant volumes depends very much on the orientation of the gravity force. The analysis of the presented new heart valve designs leads to a conclusion that the difference of the ratio of the valve closing regurgitation to the main flow between the case of $\phi = 0$ and $\phi = \pi$ can be as high as 12%. This is because the moment due to gravity force tends to close the leaflet in the orientation of $\phi = \pi$ in contrast to the case of $\phi = 0$ thus making the valve close very gradually during the flow deceleration phase of systole therefore only a minor regurgitant flow is required to complete the closure.

From the analysis of Fig.6 and Fig.7, it is noted that the location of
the leaflet leading edge with respect to the stiffening ring can be another factor influencing the regurgitant volumes especially for the case of the gravitational force parallel to the main flow. It is believed that this model is the first numerical simulation of the full opening and closing characteristics using potential flow theory modelled in an internal domain.

References


Figure 1: An example of one of the design environments with the network editor space
Figure 2: Co-ordinate system and pde boundary conditions for the leaflet

Figure 3: Co-ordinate system and pde boundary conditions for the stiffening ring
Figure 4: Separation points along the centre streamline and shear stress, $\tau_w$, as a function of the non-dimensionalised streamwise coordinate for the leaflets of $\lambda = 0.1$, 0.2 and 0.3

Figure 5: Separation points along the stiffening ring as a function of $S_2$ for $A : S_1 = 0$; $B : S_1 = 0.5$; $C : S_1 = 1.0$ and $D : S_1 = 1.5$
Figure 6: Opening angle as a function of time for the new valve designs ($\phi = 0^\circ$)

Figure 7: Opening angle as a function of time for the new valve designs ($\phi = 180^\circ$)