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COMPUTER-ASSISTED DESIGN OF MITRAL VALVE PROSTHESES

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INTRODUCTION

We have developed a computational method for modelling the in vivo fluid dynamics of the mitral valve. The valve is studied in a "computer test chamber" with contractile walls that have the mechanical properties of cardiac muscle. A digital computer is used to solve the coupled equations of motion of the blood, the muscular heart wall and the valve. The results of the computation represent a prediction of how a specified valve, natural or prosthetic, would perform under specified physiological conditions. The prediction takes the form of plots of pressures, flows, simulated echocardiograms and phonocardiograms as functions of time, plots of streamlines and pressure contours within the heart at selected times, and computer-generated motion pictures showing the positions of the heart wall, the valve and a set of fluid markers throughout the computation. The present model is two-dimensional; we are currently developing a 3-D model.

The mathematical aspects of this work have been described elsewhere [1,2], as have the physiological aspects [3]. Here we wish to describe an application of our computational method to the design of prosthetic mitral valves, and we will give only the mathematical and physiological background needed to make the method comprehensible. We will summarize some of the results from a finished optimization study of a single-pivoting-disc prosthesis and from a study-in-progress of a butterfly-bileaflet prosthesis. A detailed description of the single-disc results is available [4]; the bileaflet results are new. We will review the single-disc study in some detail. This is to provide a reference point for the bileaflet valve results which are still being obtained and are not yet conclusive.

METHODS

A digital computer is used to solve the equations of blood motion in the heart. The heart is treated as though it were immersed in fluid, and the assumption is made that the blood, valves, heart muscle, and external fluid all have the same constant density. This makes it possible to formulate the mathematical problem in such a way that the valves and heart muscle appear as special regions of space where extra forces are applied to an otherwise homogeneous fluid. These forces give the valves and the heart walls their material and physiological properties.

The fluid velocity at any given time is stored on a computational mesh with 64 points in each direction. The configuration of the immersed boundary (valve and heart muscle) is stored in terms of the coordinates of about 300 points. A typical time step of the computational method is as follows. At the beginning of each time step, the fluid velocity and the boundary configuration are known. Boundary forces are computed and applied to the fluid. The fluid velocity is changed under the influence of the boundary forces. The boundary is then moved at the new fluid velocity to complete the time step. Each computational experiment uses 640 time steps to span the part of the cardiac cycle that includes ventricular diastole, atrial systole and early ventricular systole. This is the time period of greatest interest for the fluid dynamics of the mitral valve.

SINGLE-PIVOTING-DISC VALVE MODEL

The design parameters of the single-disc valve model are given in Fig.1, which shows the valve in its closed position at the beginning of the computation (end-systole). The line AB represents the

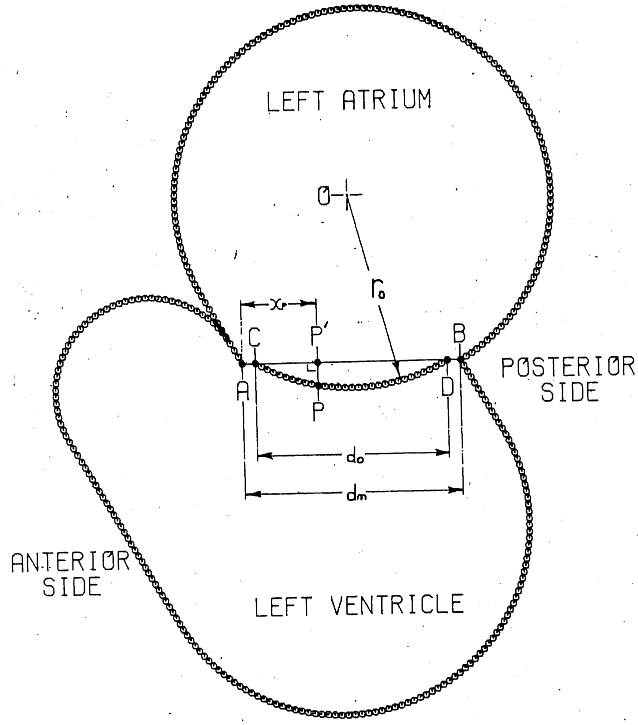

Fig.1. Design parameters of single-disc valve model

plane of the mitral annulus. The valve is constructed as a circular arc CPD whose center O lies on the atrial side of the line AB and whose endpoints C,D are symmetrically placed on this line. The valve is pivoted about the point P, and P' is the projection of the pivot point onto the plane of the mitral ring. Let:

d_m=diameter of the mitral ring(AB).
d_o=diameter of the occluder(CD).
r_o=radius of curvature of the occluder.
x_p=distance along the mitral ring from its anterior border to the projection of the pivot point(AP').

Then the geometry of the valve is completely determined (except for scale) when we specify the dimensionless parameters:

$$R = r_o/d_o$$
$$X_p = x_p/d_m$$
$$G = \tfrac{1}{2}(d_m-d_o)/d_m$$

For example: $R=\infty$ means that the occluder is flat, whereas R=0.5 means that it takes the form of a semicircle. Similarly, X_p=G means that the occluder is pivoted at the anterior end of the valve, while X_p=0.5 means that the pivot point is in the center of the occluder. In this report we are confining our attention to pivot points on the anterior half of the occluder; thus $G < X_p < 0.5$. (In passing we note that the behavior of the flat valve which is described below was qualitatively unaffected by reflecting a given pivot point location about the center of the ring.)

The parameter G determines the relative size of the gaps at the ends of the valve. Throughout this study G=0.06. These gaps each correspond to one mesh-width on the computational mesh that is used to solve the equations of fluid dynamics. Since each boundary point in the valve and heart wall has an effective radius of about one mesh-width, these gaps are effectively closed when the occluder is in the closed position.

The model valve is equipped with a stop which prevents it from rotating past the closed position during ventricular systole. However, there is no corresponding stop to limit the maximum angle of opening during ventricular diastole. As a result, some of the model valves become caught in the open position and fail to close. Such valves will be called "incompetent" since they exhibit massive regurgitation leading to a very small net stroke volume. The significance of this mode of failure for the design of pivoting disc valves will be discussed.

The parameters R and X_p are the crucial design parameters of the single-disc model study. Our goal is to determine the best choice of these parameters. To do this, we shall examine three indices of predicted valve performance as functions of R and X_p. These are the net stroke volume, the mean forward pressure difference, and the peak anterior velocity.

The net stroke volume is the net volume of fluid which crosses the plane of the mitral annulus while the mitral valve is open. This is the difference between the forward volume and the regurgitant volume associated with closure of the valve. If the valve fails to close, we stop integrating the flow at the end of the experiment, but the result is a very low net stroke volume. Such results define the incompetent valves in the study.

The mean forward pressure difference ($\overline{\Delta P}$) is defined as

$$\overline{\Delta P} = \int_0^T (p_{1a}(t) - p_{1v}(t))\, dt$$

where t=0 is the time when flow begins at the onset of ventricular diastole and t=T is the first zero-crossing of the flow, which occurs during early ventricular systole. These two times are chosen to eliminate the inertial contribution to the mean forward pressure difference [5].

The peak anterior velocity is essentially the maximum velocity that occurs on the anterior side of the occluder. The precise definition of peak anterior velocity is as follows. First, let $Q_a(t)$ be the volume rate of flow through the anterior opening of the valve and let A_a be the area of this opening. Then define

$$v_a(t) = Q_a(t)/A_a$$

Thus $v_a(t)$ is the (spatial) mean velocity on the anterior side of the valve at time t. Peak anterior velocity is the maximum over t of $v_a(t)$.

The significance of peak anterior velocity is its relation to the problem of stagnation and small-orifice valve thrombosis. In the absence of a theory that explains the interaction between fluid dynamics and blood clotting, it is impossible to say exactly how stagnation should be measured, but it seems reasonable to assume that low peak velocities are the essence of "stagnation". Thus we try to design the valve in such a way that the peak anterior velocity is as large as possible.

In summary, the computational results will be presented in terms of plots of net stroke volume, mean forward pressure difference, and peak anterior velocity as functions of the pivot point position (X_p) for selected values of the radius of curvature (R). The incompetent valves are characterized by exceptionally low net stroke volumes. Among the competent valves, we seek the values of R and X_p that maximize peak anterior velocity while minimizing mean forward pressure difference.

Fig.2 shows the computed values of net stroke volume as a function of pivot point position for various radii of curvature (R=∞,1.5,1.0 and 0.75).

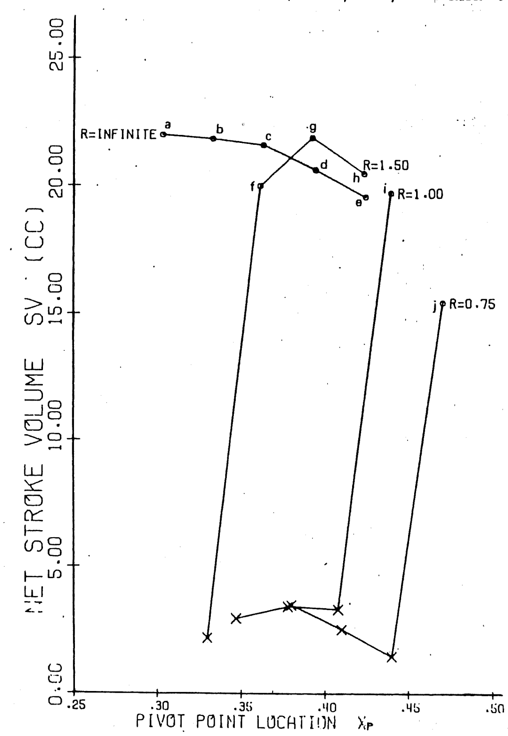

Fig.2. Net stroke volume vs pivot position.

The valves that we have tested fall into two well-separated groups. The competent valves all have a net stroke volume on the order of 20 cc, and the incompetent valves have a net stroke volume ten times smaller. All of the flat valves that we have tested are competent. The curved valves all have a critical point at which a rapid transition from competence to incompetence occurs. The sensitivity of this transition is striking: the net stroke volume changes by a factor of 10, and the change in pivot position is about 3% of the mitral ring diameter. The place where this transition occurs varies in a systematic way with the curvature of the valve. Greater curvatures (smaller R) require that the valve be pivoted closer to its center for competent performance. We have also tested semi-circular valves (R=0.5, not shown). These are incompetent at all pivot point positions. Incompetent valves are indicted by the symbol ✕ in Fig.2, since they must be rejected. The valves that remain are each given an identifying letter (a to j) for ease of identification from one figure to the next.

Fig.3 shows that the mean forward pressure difference can be reduced by placing the pivot point closer to the anterior border of the mitral ring (i.e., further from the center of the valve).

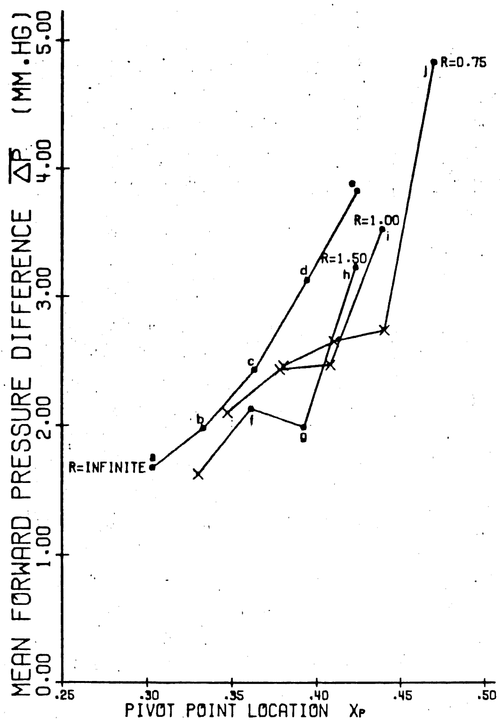

Fig.3. Mean pressure difference vs pivot position.

For the curved valves, however, this conflicts with the overriding criterion of competent closure. If the incompetent valves marked are rejected, then Fig.3 may be used to identify the competent valve with the lowest value of mean forward pressure drop at each curvature. These are valves a, f or g, i, and j. Among these valves a, f, and g all have a pressure drop $\cong$ 2 mm Hg, while valves i and j have substantially larger values (3.5 and 5 mm Hg, respectively). (These results are for physiological resting conditions; under exercise the pressure drops would be greatly increased.)

Fig.4 contains perhaps the most interesting results. It shows the relationship between pivot point position, curvature, and peak anterior velocity. At each curvature the peak anterior velocity has a clear maximum at a certain pivot point. Moreover, the optimal pivot point shifts toward the center of the valve as the curvature is increased (decreasing R), and the value of the peak anterior velocity at the optimal pivot point increases with increasing curvature. If peak anterior velocity were the only design criterion, one would conclude that the curvature should be very large and that the pivot point should be close to the center of the valve. However, the incompetent valves must again be excluded, and the highest values of peak anterior velocity for the competent valves are seen to be about 48 cm/sec. Valves f, g, i, and j all perform similarly in this respect.

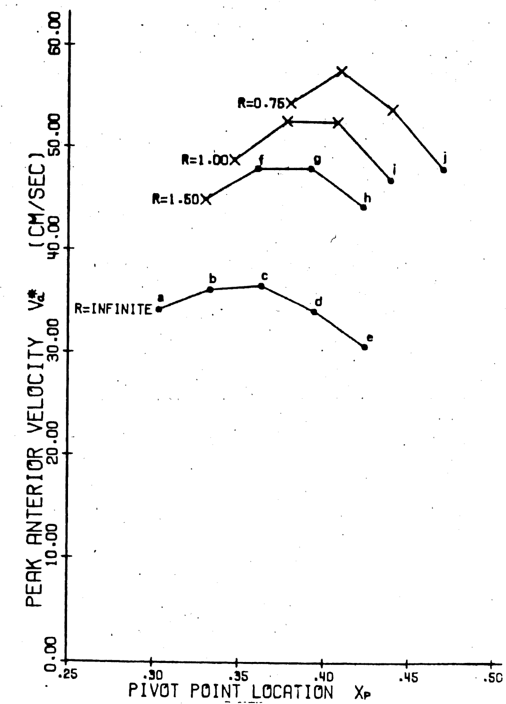

Fig.4. Peak anterior velocity vs pivot position.

We are now in a position to choose the best overall valve in this study. Valves f and g are competent, and they achieve very nearly the lowest values of mean forward pressure drop and the highest values of peak anterior velocity of any of the competent valves. We can choose between f and g by recalling that g has a stroke volume about 10% higher and a mean forward pressure difference about 10% lower than f. Thus valve g (R=1.5, X_p=0.39) is the best overall valve in this study.

The extent to which the curvature of valve g contributes to its superior performance is seen by comparing valve g with valve d, which is the flat valve pivoted at the same value of X_p. The net stroke volume is very similar for these two valves. The mean forward pressure difference, however, is 35% lower for valve g and the peak anterior velocity is 40% higher. The latter figure is similar to the 60% improvement in minor-orifice velocity reported by Yoganathan, et.al. [6], who compared flat-disc and curved-disc Bjork-Shiley valves by laser-Doppler anemometry. Yoganathan's group did not find any difference in the pressure drop of the two Bjork-Shiley valves, however. (Complete agreement with Yoganathan's results should not be expected because of significant differences in the valves themselves and in the conditions of the tests.)

In this study all of the flat discs were competent, but some of the curved discs open too far and become caught in the open position at the onset of ventricular systole. Clearly, this could be prevented by including a stop that limits the angle of opening. All of the valves in clinical use have such a stop, and we believe that such a stop is indeed necessary for safety even if the limitation it imposes is not normally reached. Such a stop introduces a third design parameter, maximum opening angle, which we have not considered here. We do not believe that its inclusion would lead to better overall performance than that of the best valves considered here. We reason that for any curved valve whose opening angle is actually limited by a stop, there must be another valve with a smaller curvature and the same pivot point which just achieves the same angle of opening (i.e., would contact the stop with zero force). Our guess is that the latter valve would give better performance by our criteria. It would also "wear" better since the impact on the stop would be smaller or even zero. This suggests the design concept of a "redundant stop" in which the opening of the valve is normally limited by fluid dynamic forces, but the mechanical design of the valve prevents further opening in unusual circumstances.

BUTTERFLY-BILEAFLET VALVE MODEL

The design-parameter study of the bileaflet valve is similar in spirit to the single-disc study described above. (We wish to emphasize that the results to be described below are preliminary; additional parameter variations are currently being studied.) Fig.5 shows the initial configuration of the bileaflet valve model in the test chamber.

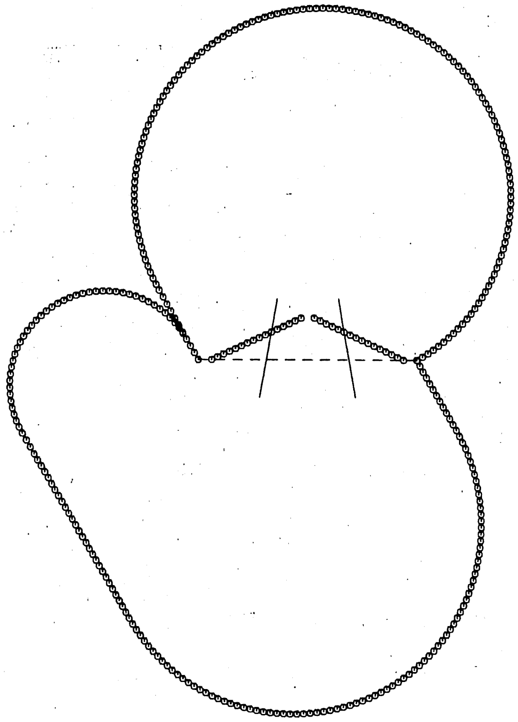

Fig.5. Design of butterfly-bileaflet valve model.

The parameters we are currently interested in are the pivot point locations, the initial angle of the leaflets relative to the ring, and the maximum permissible opening angle. The inclusion of a constraint on the maximum opening angle is dictated by our observation of a very limited range of satisfactory competent performance of this model valve in the absence of such a constraint. The valve shown in Fig.5 has a maximum permissible opening angle of 80° which is indicated by the solid lines passing through the ring and the leaflets. The two leaflets are constructed symmetrically about the center of the ring with an initial angle of 25° and pivot point locations whose projections onto the ring trisect the ring. Thus if the leaflets opened to 90°, i.e., perpendicular to the ring, they would divide the ring into three equal openings for flow.

We have completed a series of experiments in which just one parameter, the maximum permissible angle of opening, has been varied, over the range 135° to 70°. Fig.6 is a summary of some of the measures of valve performance as functions of time.

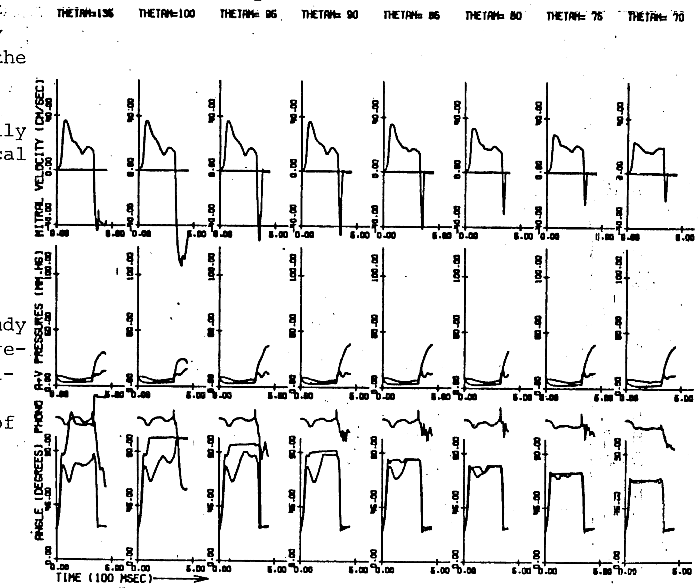

Fig.6. Physiological waveforms of bileaflet models.

Each column contains results for a different constraint angle, indicated at the top of the column (e.g., THETAM=135 means a maximum permissible angle of 135°). The columns are in order of increasing constraint (i.e., decreasing THETAM) from left to right. The first row shows the spatial average velocity across the entire ring as a function of time. Choosing THETAM=135 or 100 produces an incompetent valve, which is remedied by more severe constraints. Increasing the degree of constraint decreases the amount of regurgitation on closure, but does so at the cost of reduced forward flow. It is interesting to note that decreasing THETAM from 135 to 100 actually produces a less competent valve, contrary to the trend for the remaining valves. The reason for this is partially seen in the bottom row, which shows the opening angles for the two leaflets. In all cases the uppermost of the two curves corresponds to the anterior leaflet. Apparently because of the asymmetry of the mitral position geometry, the anterior leaflet always opens more quickly than the posterior leaflet. The flow induced by the motion of the anterior leaflet prevents the posterior leaflet from opening fully (i.e., hitting its constraint) in all but the most constrained case (last column), and, in fact, causes the posterior leaflet to stop and move briefly toward closure before reopening. In the 135° case, the anterior leaflet opens to such an extent that the posterior leaflet opens to less than 90°; subsequently, ventricular systole closes the posterior leaflet, but locks the anterior leaflet in the open position. In the 100° case the effect of the anterior leaflet on the posterior leaflet is not so pronounced, and ventricular systole locks both leaflets in the open position. In the 95° case the posterior leaflet closes slightly earlier than the anterior leaflet, and in all other cases closure of both leaflets is essentially simultaneous. It is clear that competent function with this choice of pivot position and initial angle requires the constraint on the opening angle.

Fig.7 shows the peak value (in time) of the spatial average velocity in each of the three openings as functions of the constraint angle for the competent valves in this series.

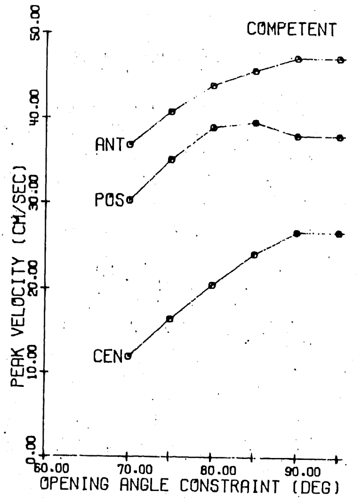

Fig.7. Peak velocities vs constraint angle.

ANT, POS, and CEN denote the anterior, posterior, and center opening results respectively. For all cases the peak velocity is greatest through the anterior opening and least through the center opening with a general trend toward higher velocity with increased constraint angle. The significantly lower velocities in the center opening might be thought to be due to fluid viscosity. (In the center, viscous shear on both leaflets acts to retard the flow, while on either side there is viscous shear from only one leaflet.) We will argue against this interpretation below. The preference for the anterior side may be due to asymmetry of the test chamber (mitral position), which may be affected only by putting some compensating asymmetry in the valve design. It is also possible that the peak velocities in the center and posterior openings occur before the posterior leaflet is sufficiently open, resulting in lower values of those velocities. (As for the single-disc valve, we believe this valve should be designed so as to avoid low values of the peak velocity. We have an intuitive feeling that the overall performance of this valve would be improved with design parameters which equalized flow through the three openings. Further experimentation is under way to test this intuition.)

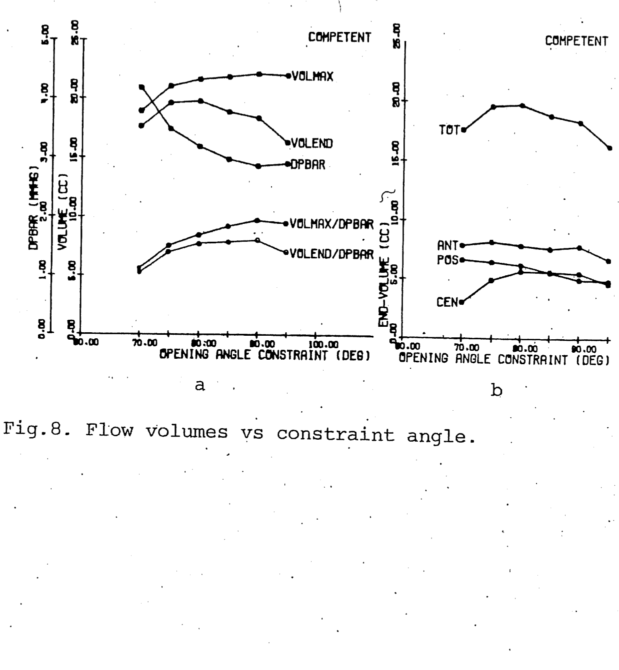

Fig.8. Flow volumes vs constraint angle.

Fig.8a shows the maximum filling volume (VOLMAX), the net stroke volume at end-experiment (VOLEND), the mean forward pressure difference (DPBAR), and the ratios VOLMAX/DPBAR and VOLEND/DPBAR as functions of the constraint angle for the competent valves in this series. Increasing the angle of constraint leads to a general decrease in the pressure drop and an increase in the maximum volume passing through the valve, but also leads to an increase in the regurgitant volume (not shown) so that the net stroke volume increases at first and then decreases. The ratio VOLEND/DPBAR, which is an ad-hoc sort of benefit/cost ratio, has its maximum at 90°.

Fig.8b shows the breakdown of the net stroke volume (TOT) into the component volumes passing through each of the three openings. (TOT in Fig.8b is the same as VOLEND in Fig.8a.) The volumes passing through the center and posterior openings are roughly equal, contrary to what one might expect based on the peak velocity results. This argues against the role of viscosity suggested earlier. The preference for flow to pass through the anterior opening is still quite clear.

Fig.9 shows the streamlines for the 90° case during early ventricular filling.

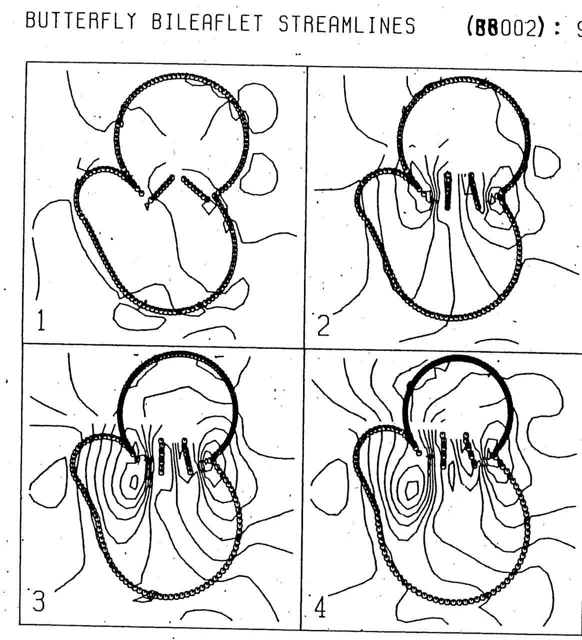

Fig.9. Streamlines for the 90° bileaflet model.

Successively numbered frames are separated in time by about 25 msec; frame 1 is about 30 msec after the onset of ventricular filling. The flow patterns in this figure make the behavior of the valve, which we have described verbally, much clearer. The relatively unobstructed space below the anterior side of the valve seems to provide a freer passage for flow, opening the anterior leaflet more quickly. Flow in the atrium is directed toward the anterior opening, resulting in a torque tending to open the anterior leaflet and a torque tending to impede opening of the posterior leaflet. A large vortex forms in the aortic outflow tract (frame 3) which tends to pull the flow passing through the ring anteriorly. In addition, motion of the posterior ventricular wall due to filling pulls some of the posterior-side flow toward the posterior wall. The net result of this is that the anterior leaflet is fully open by frame 2 while the posterior leaflet never fully opens and has actually retreated from frame 3 to frame 4. Stagnation in the center opening is noticeable in frame 4. In later frames (not shown) the vortex pattern dies away before ventricular systole, and subsequent closure of the valve is without benefit of the vortex flow which seemed to aid closure of both the natural valve and the single-disc valve in our earlier studies [3,4]. The flow pattern for the 90° case is generally what was observed for all the competent valves in this series.

In addition to this series, we have investigated the effect of moving the pivot point position. Moving the pivots closer to the center aggravates the center stagnation by reducing the central flow area. Moving the pivots away from the center, i.e., toward the centers of each leaflet, also aggravates stagnation because the leaflets tend to open less. We are currently investigating the effect of the initial angle of the leaflets. In the event that stagnation still seems to be a problem we will consider asymmetric designs and curved leaflets.

CONCLUSION

At this point it seems appropriate to restate the principal limitations of our approach. The model is two-dimensional, the model valves do not correspond in every detail to clinical valves in current use, and (so far) the valves have been tested under a fixed set of (resting) conditions. Given these limitations, we believe that experimental verification of our findings, in pulse duplicators and in animals, is essential. However, we believe that it is possible to use this computational approach to aid in optimizing the design of valves, and to use the optimal designs as the starting points for experimental studies aimed at improving cardiac prostheses.

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BIOGRAPHICAL SKETCH

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