# United States Patent [19]

**McQueen et al.**

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[45] **Date of Patent: Jun. 25, 1991**


[54] **CURVED BUTTERFLY BILEAFLET PROSTHETIC CARDIAC VALVE**


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[21] Appl. No.: **434,621**

[22] Filed: **Nov. 14, 1989**

**Related U.S. Application Data**

[63] Continuation of Ser. No. 758,611, Jul. 24, 1985, abandoned.

[51] **Int. Cl.**[5] ..... **A61F 2/24**

[52] **U.S. Cl.** ..... **623/2**; 137/512.1; 137/527

[58] **Field of Search** ..... 623/2



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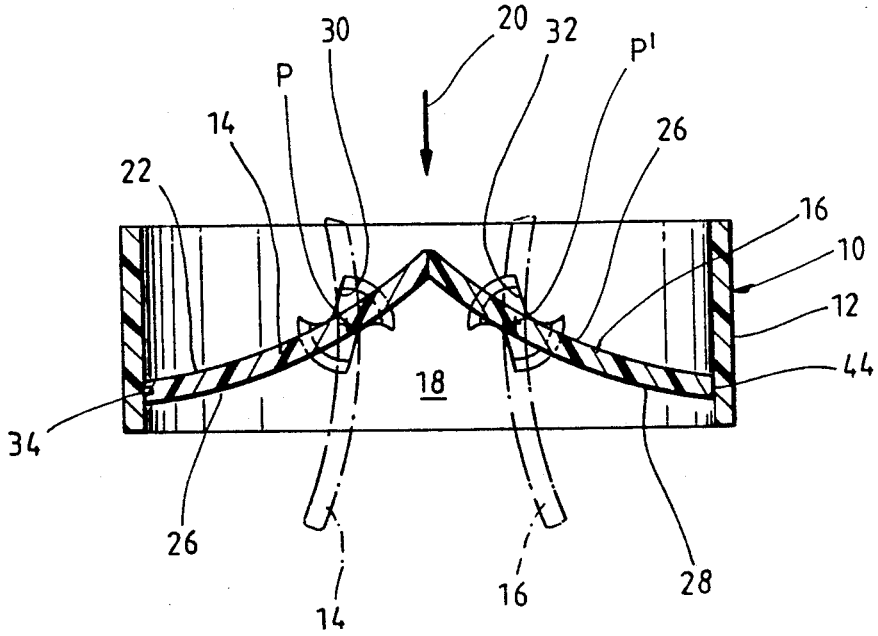
*Assistant Examiner*—Stephanie L. Iantorno
*Attorney, Agent, or Firm*—Fulbright & Jaworski



[57] **ABSTRACT**

An annular valve body having a central passageway for the flow of blood therethrough with two curved leaflets each of which is pivotally supported on an accentric positioned axis in the central passageway for moving between a closed position and an open position. The leaflets are curved in a plane normal to the eccentric axis and positioned with the convex side of the leaflets facing each other when the leaflets are in the open position. Various parameters such as the curvature of the leaflets, the location of the eccentric axis, and the maximum opening angle of the leaflets are optimized according to the following performance criteria: maximize the minimum peak velocity through the valve, maximize the net stroke volume, and minimize the mean forward pressure difference, thereby reducing thrombosis and improving the hemodynamic performance.


**5 Claims, 9 Drawing Sheets**



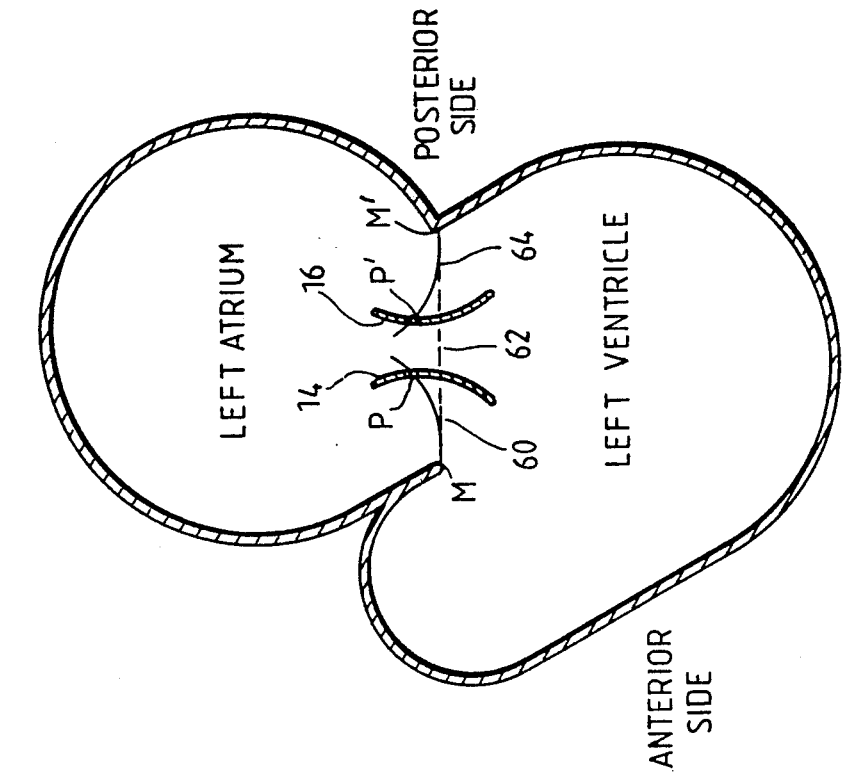



Fig. 1B

PRIOR ART

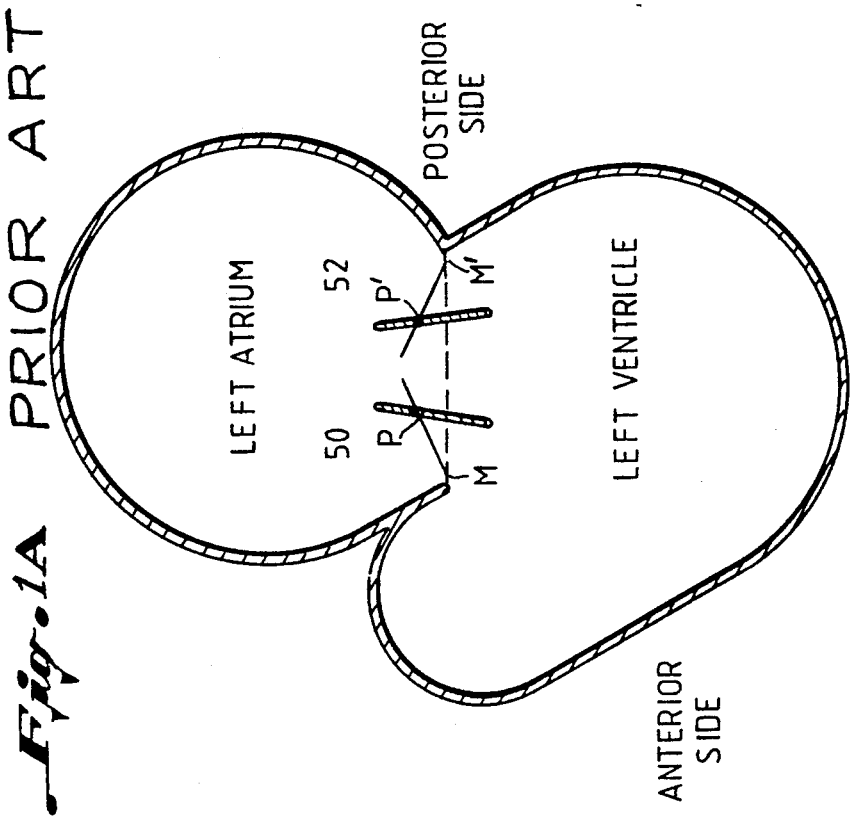



Fig. 1A

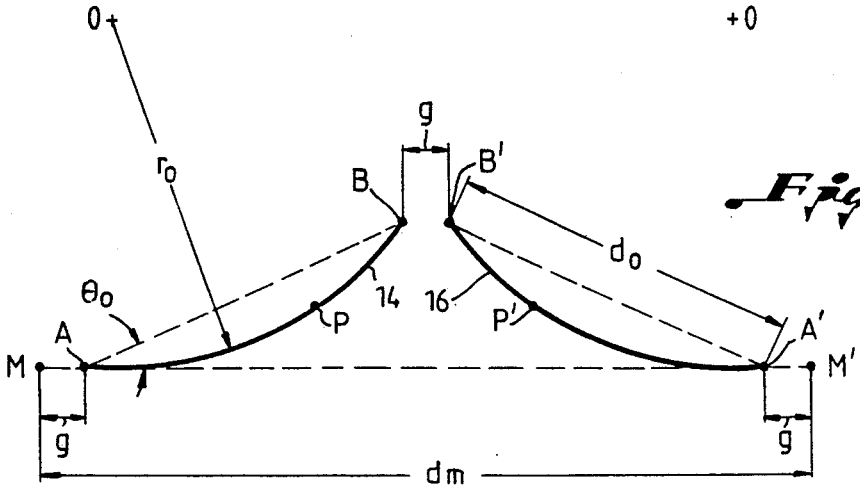



Fig. 2A

Fig. 2B

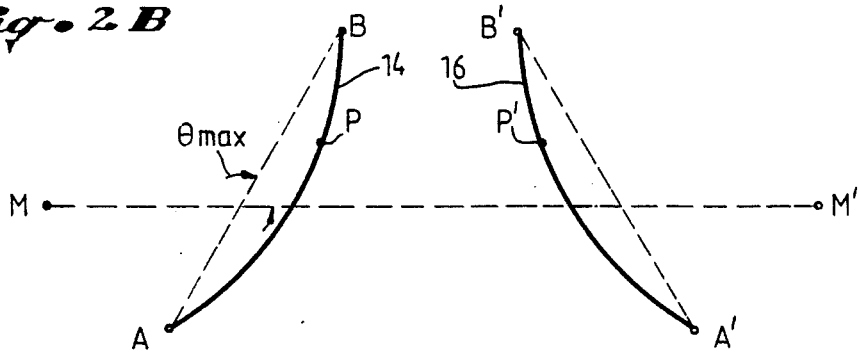
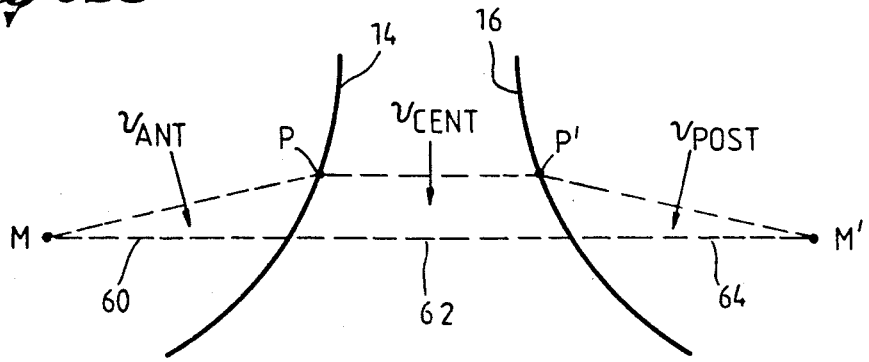



Fig. 2C



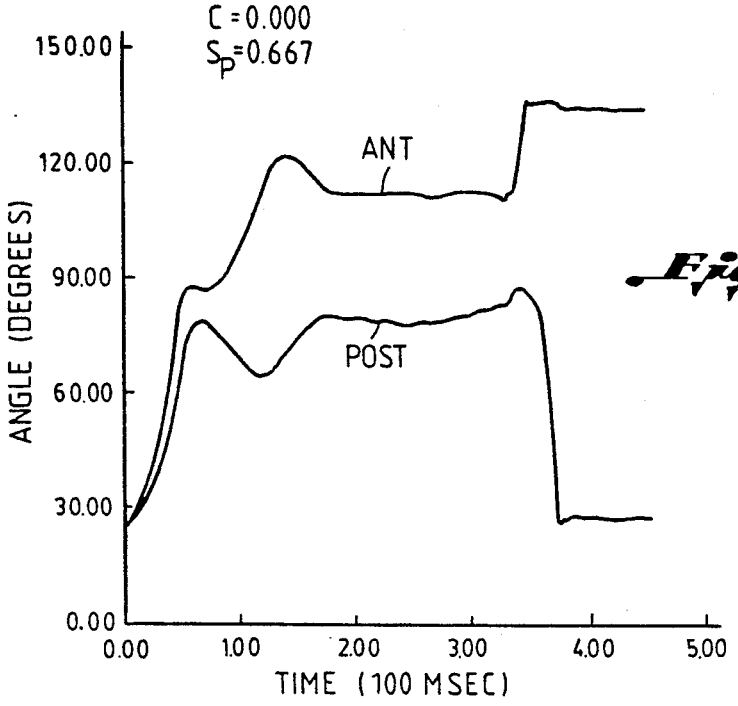



Fig. 3

Fig. 4A

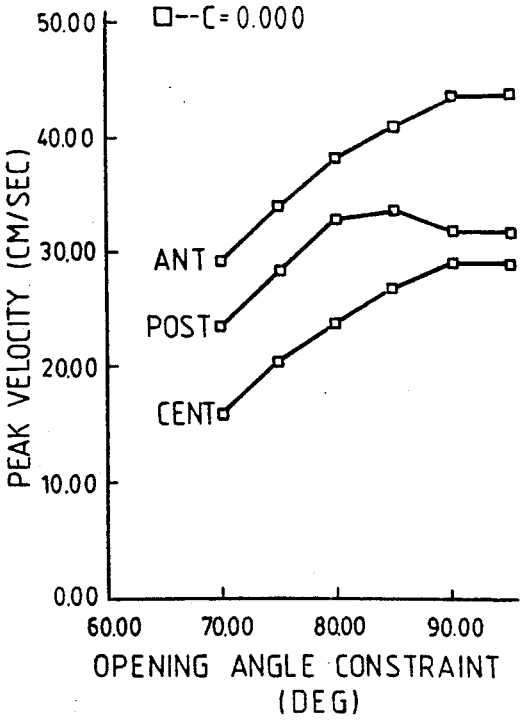



Fig. 4B

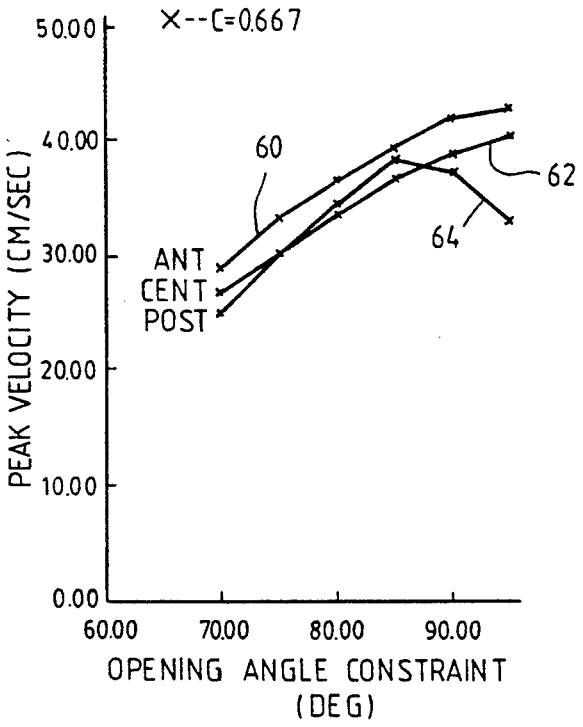
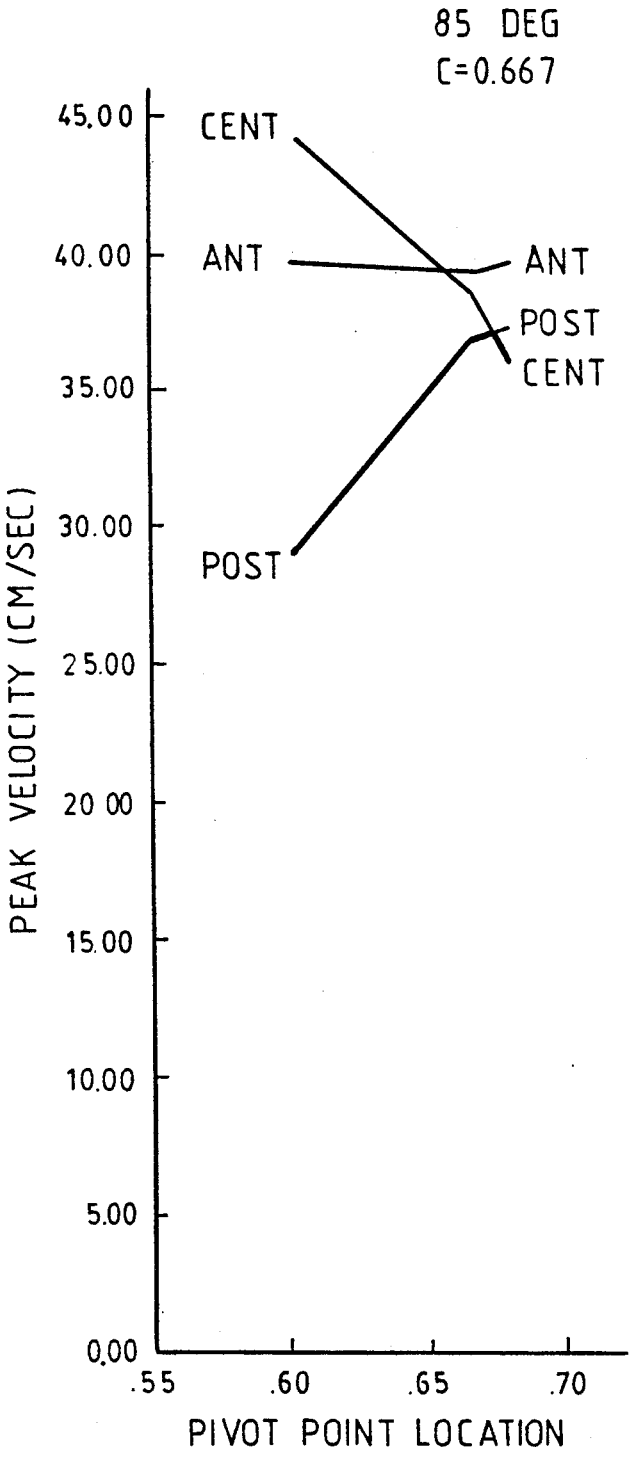


Fig. 5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PIVOT POINT LOCATION

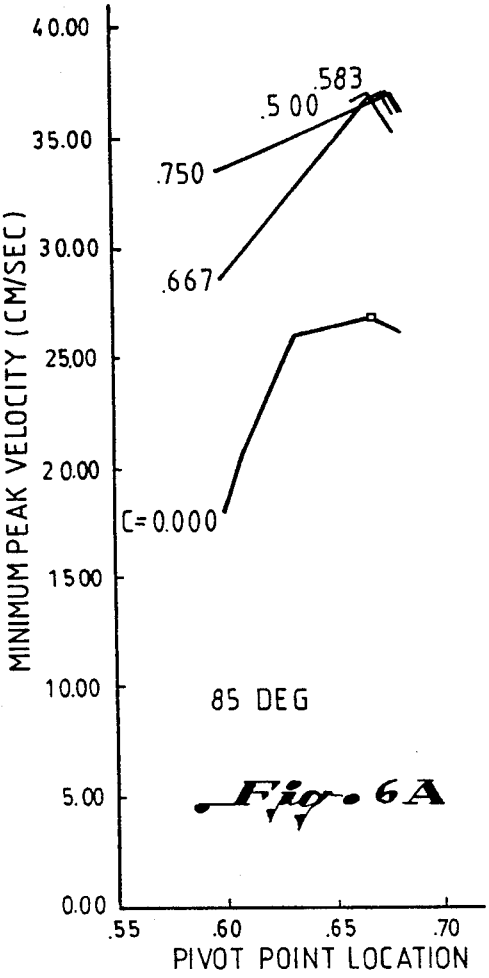



Fig. 6A

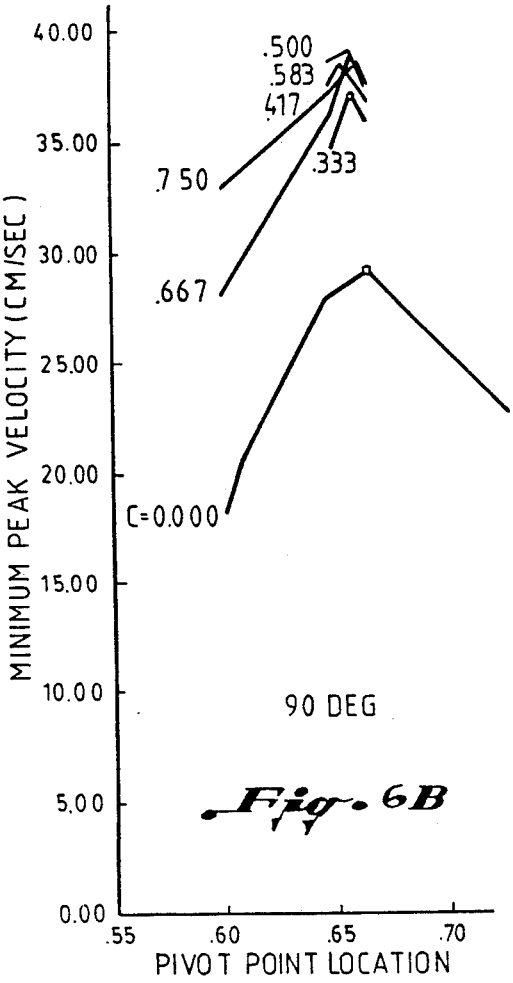



Fig. 6B

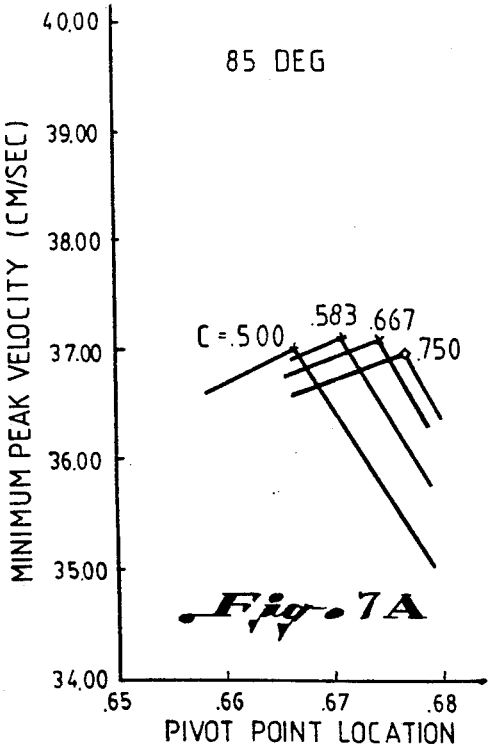



Fig. 7A

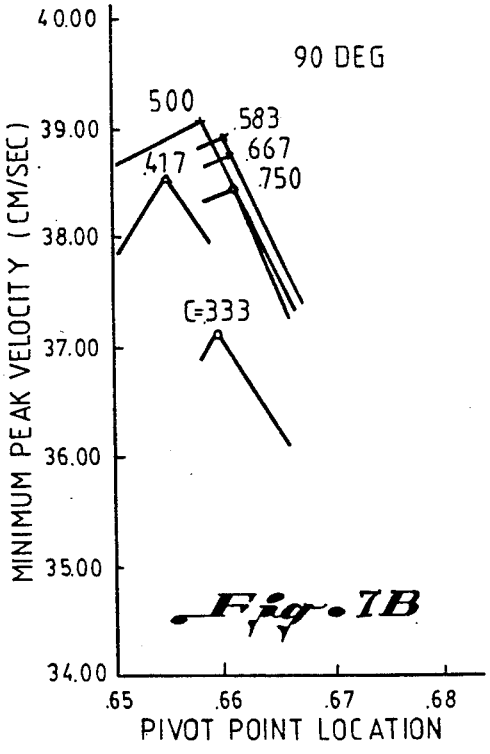



Fig. 7B

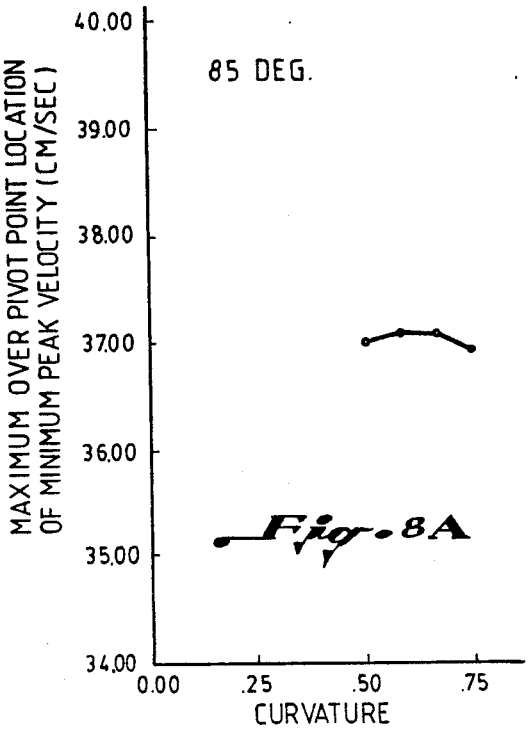



Fig. 8A

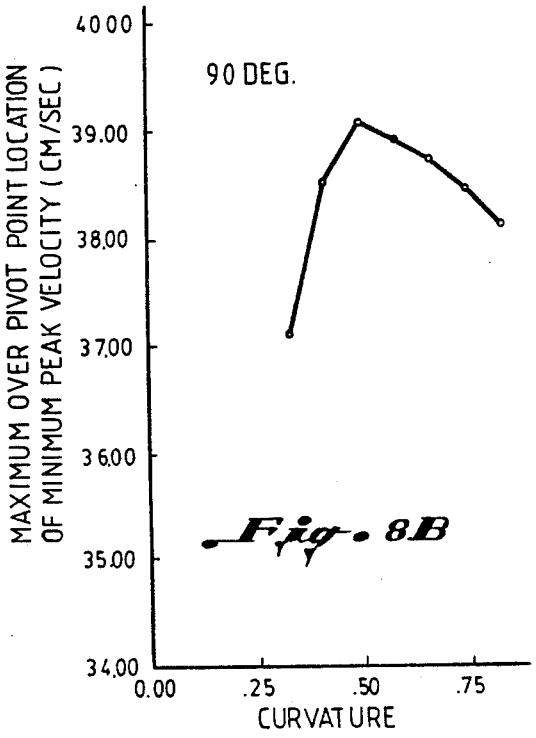



Fig. 8B

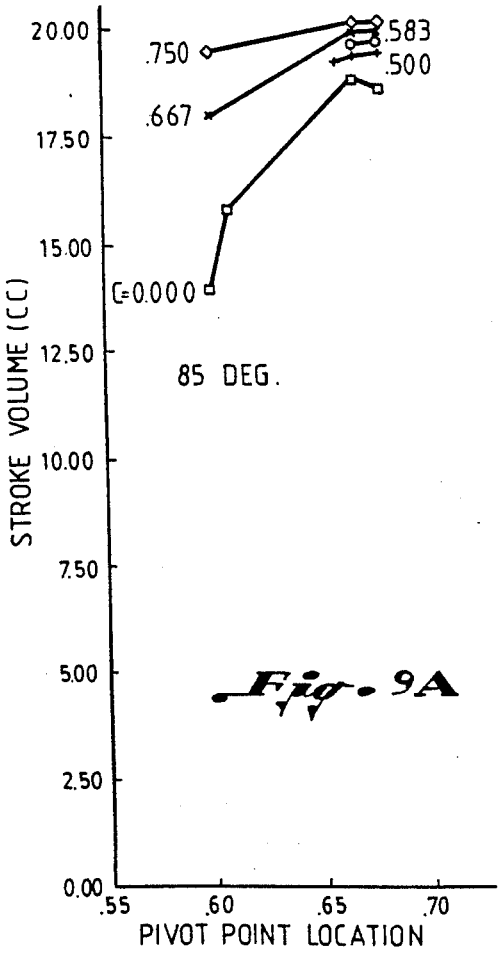



Fig. 9A

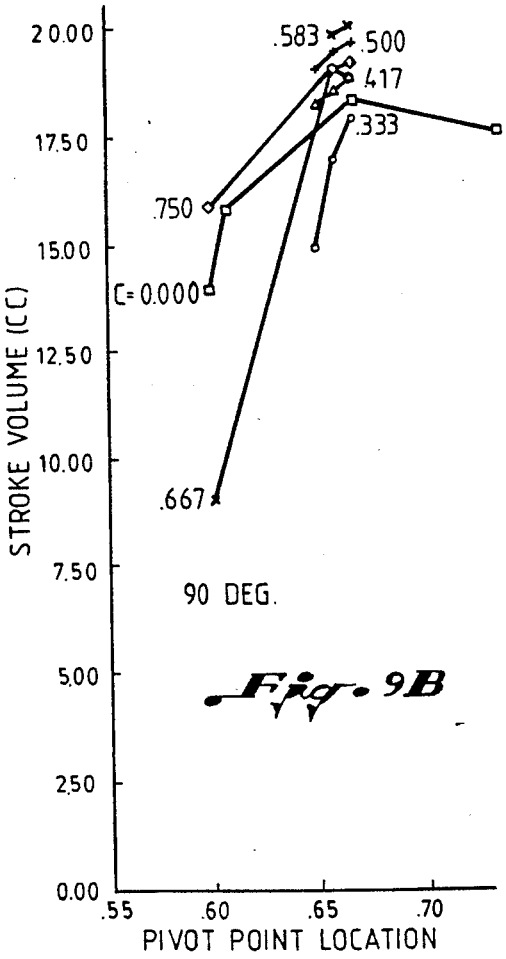



Fig. 9B

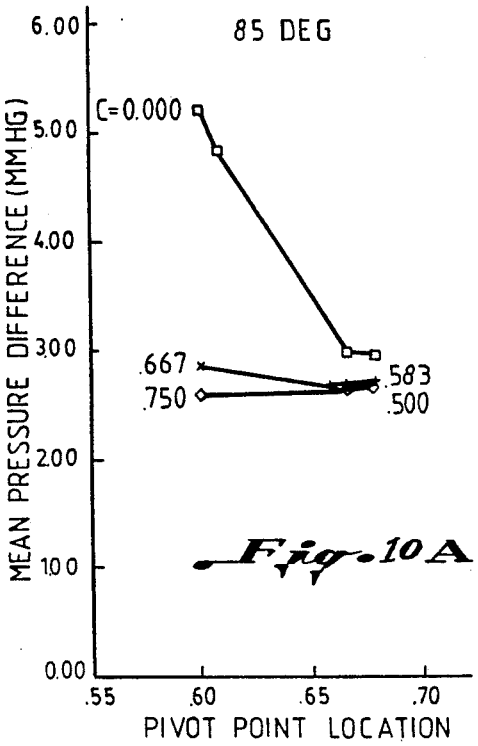



Fig. 10A

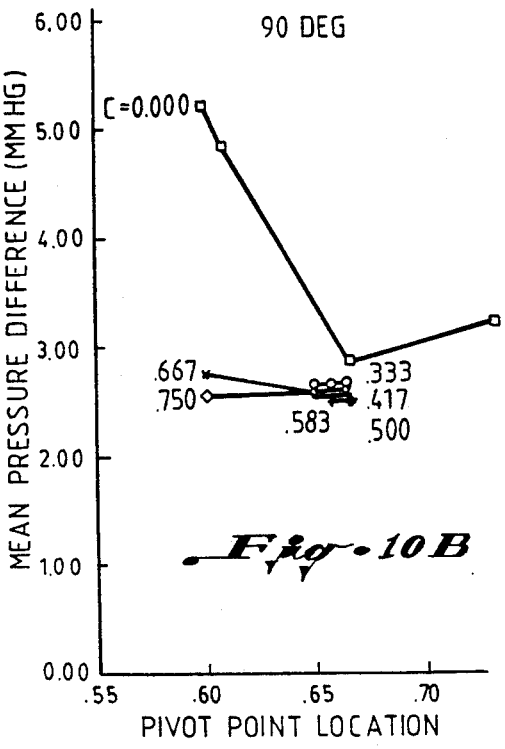



Fig. 10B

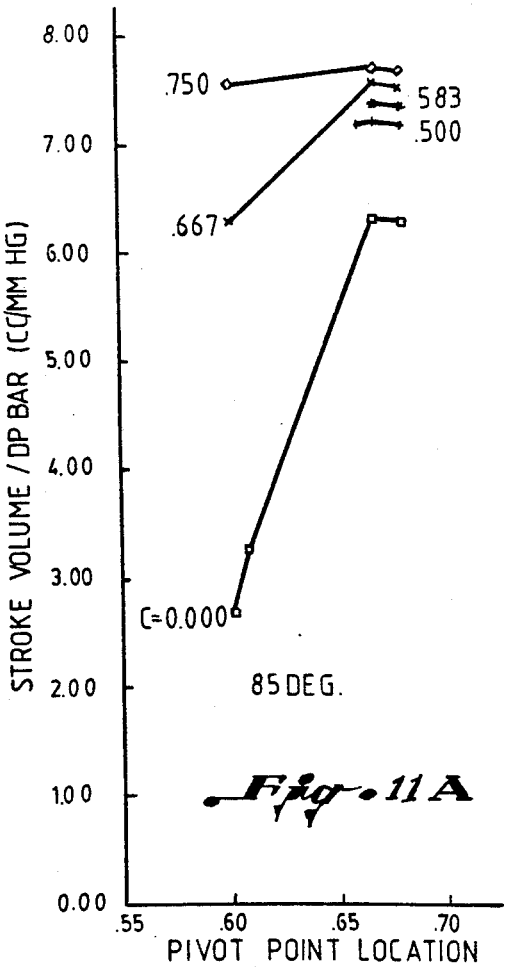



Fig. 11A

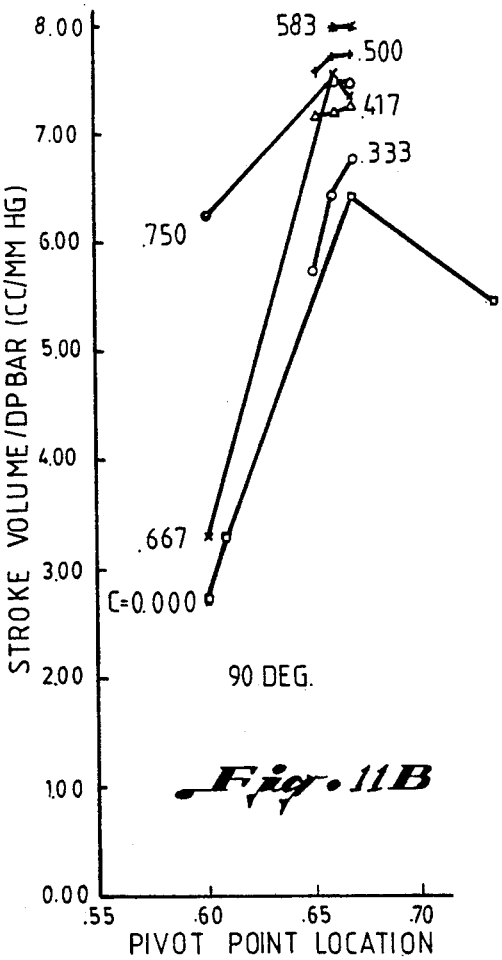



Fig. 11B

TABLE I

PIVOT POINT THAT MAXIMIZES $V^{*}_{MIN.}$ AT EACH CURVATURE

| MAX. OPENING ANGLE $\theta_{MAX.}$ | CURVATURE C | PIVOT POINT $S_P^{**}(C)$ | MINIMUM PEAK VELOCITY $V^{**}_{MIN.}(C)$ |
|---|---|---|---|
| 85° | 0. | 0.667 | 26.89 |
| | 0.500 | 0.667 | 37.00 |
| | 0.583 | 0.671 | 37.10 |
| | 0.667 | 0.674 | 37.08 |
| | 0.750 | 0.677 | 36.95 |
| 90° | 0. | 0.667 | 29.16 |
| | 0.333 | 0.660 | 37.11 |
| | 0.417 | 0.655 | 38.52 |
| | 0.500 | 0.658 | 39.05 |
| | 0.583 | 0.660 | 38.90 |
| | 0.667 | 0.661 | 38.72 |
| | 0.750 | 0.661 | 38.45 |

Fig. 12A

Fig. 12B

TABLE II

PARAMETERS THAT MAXIMIZE $V^{*}_{MIN}$

| MAX. OPENING ANGLE $\theta_{MAX.}$ | CURVATURE $C_{OPT.}$ | PIVOT POINT $S_P^{**}(C_{OPT.})$ | MINIMUM PEAK VELOCITY $V^{**}_{MIN.}(C_{OPT.})$ |
|---|---|---|---|
| 85° | 0.583 | 0.671 | 37.10 |
| 90° | 0.500 | 0.658 | 39.05 |

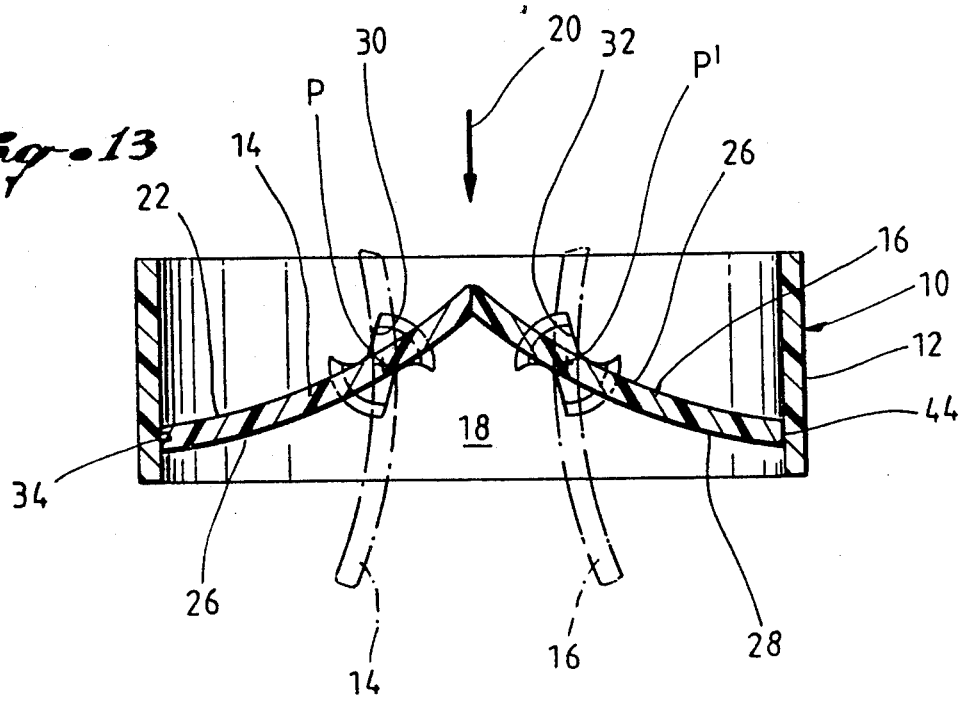
Fig. 12C

TABLE III

PARAMETERS THAT MAXIMIZE $SV/\overline{\Delta P}$

| MAX. OPENING ANGLE $\theta_{MAX.}$ | CURVATURE | PIVOT POINT | BENEFIT/COST $SV/\overline{\Delta P}$ |
|---|---|---|---|
| 85° | 0.750 | 0.667 | 7.73 |
| 90° | 0.583 | 0.667 | 7.97 |

Fig-13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20
32
P
P'
14
26
22
16
10
12
18
44
34
26
14
16
28

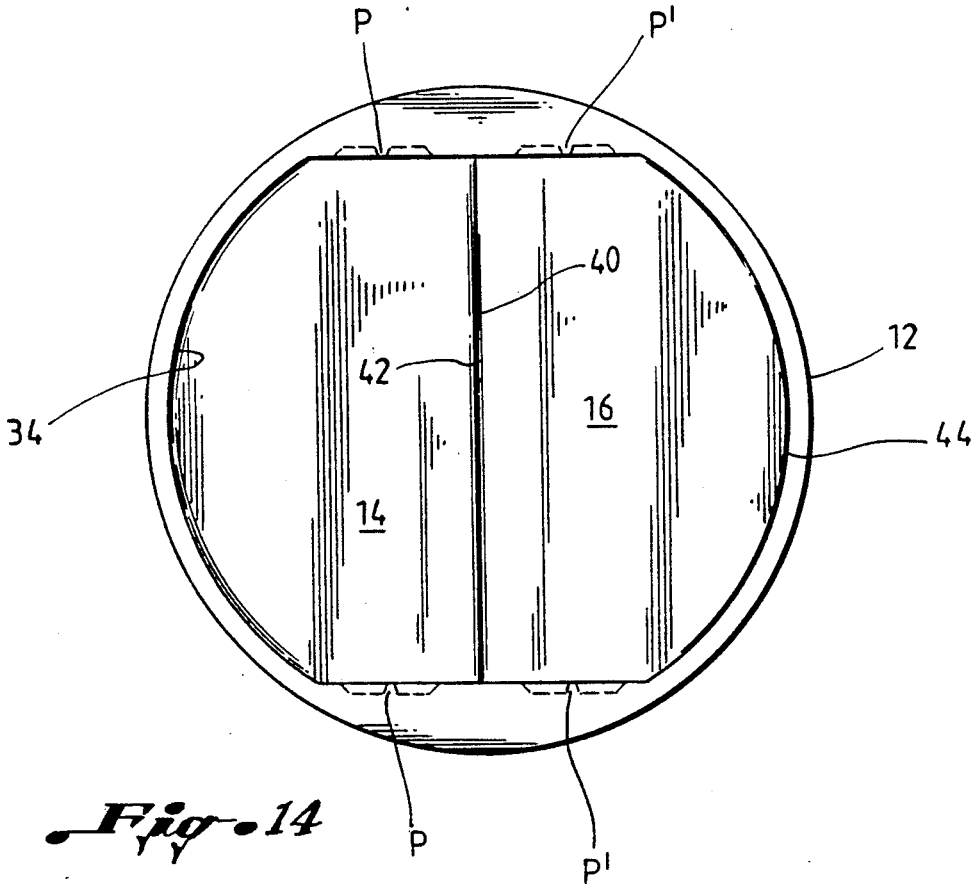
P
P'
40
12
42
34
16
44
14
P
P'

Fig-14

# CURVED BUTTERFLY BILEAFLET PROSTHETIC CARDIAC VALVE

## BACKGROUND OF THE INVENTION

This invention was made under a research grant HL17859 of the National Institutes of Health and supported in part by the Department of Energy under Contract DE-AC02-76ER0377.

This application is a continuation of application Ser. No. 06/758,611, filed July 24, 1985, now abandoned.

Various types of heart valve prostheses have been developed which operate hemodynamically as a result of the pumping action of the heart in which they generally function as check valves. Such valves have taken the form of a ball and cage arrangement, or use one or more plates or discs. One type of valve commercially available is the St. Jude valve using two flat leaflets, and another type is the Hemex valve which is a bileaflet valve in which the leaflets are curved in a plane parallel to the pivot axis of the leaflets.

The number of heart valves being used is increasing and as human life depends upon the functioning of these valves, it is important that these prosthetic cardiac valves be improved and optimized as much as possible.

The present invention is directed to a curved butterfly bileaflet valve in which the shape and design criteria are selected to maximize the minimum peak velocity through the various compartments of the valve for reducing stagnant blood flow which may lead to valve thrombosis, and to improve the hemodynamic performance by increasing the net stroke volume and decreasing the mean forward pressure difference.

## SUMMARY OF THE INVENTION

The present invention is directed to a heart valve prosthesis having an annular valve body with a central passageway for the flow of blood therethrough from upstream to downstream. First and second curved leaflets are pivotally supported in the central passageway of the body for moving between a closed position blocking blood flow through the passageway and an open position allowing blood flow therethrough. Each curved leaflet has a concave and a convex side. Eccentric position axis means are provided for pivotally supporting each of the leaflets. The leaflets are curved in a plane normal to the eccentric axis and positioned with the convex sides of the leaflets facing each other when the leaflets are in the open position.

Another object of the present invention is wherein the concave sides of the leaflets face upstream when in the closed position.

Still a further object is wherein the leaflets are circularly curved.

A still further object of the present invention is the provision of means in the body for limiting the maximum angle of opening of the leaflets to no more than approximately 90 degrees from a transverse plane to the central passageway.

Yet a further object of the present invention is wherein the first and second leaflets are pivotally supported along an axis located approximately two-thirds of the greatest distance form an arcuate body-contacting edge to a leaflet-mating edge of each leaflet.

Yet a still further object of the present invention is wherein the curvature of the curved leaflets is circular and is of a value to maximize the minimum peak velocity flowing between the leaflets and on the outside of each leaflet.

Other and further objects, features and advantages will be apparent from the following description of a presently preferred embodiment of the invention, given for the purpose of disclosure and taken in conjunction with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1A** is a schematic of a prior art butterfly valve with flat leaflets in the mitral position shown in both the open and closed positions,

FIG. **1B** is a view similar to FIG. **1A** but showing the curved leaflets of the present invention,

FIGS. **2A**, **2B** and **2C** are schematic views of the butterfly bileaflet valve of the present invention for illustrating the design of various parameters,

FIG. **3** is a graph illustrating the opening angles of the anterior and posterior leaflets of a conventional bileaflet butterfly flat valve as a function of time,

FIG. **4A** is a graph illustrating the peak velocity in each of the three openings of a valve as a function of opening angle constraint on a conventional valve with flat leaflets,

FIG. **4B** is a graph similar to that of **4A** but with the valve of the present invention with curved leaflets,

FIG. **5** is a graph illustrating the peak velocity in each of the three openings of the valve of the present invention as a function of the axis pivot point location,

FIG. **6A** is a graph of the minimum peak velocity as a function of the pivot point location for various leaflet curvatures with a maximum valve opening of 85 degrees,

FIG. **6B** is a graph similar to FIG. **6A** for a valve opening of 90 degrees,

FIGS. **7A** and **7B** are enlarged views of FIG. **6A** and **6B**, respectively,

FIG. **8A** is a graph of maximum over pivot point location of minimum peak velocity as a function of leaflet curvature with a maximum valve opening of 85 degrees,

FIG. **8B** is a graph similar to FIG. **8A** but with a valve maximum opening of 90 degrees,

FIG. **9A** is a graph of stroke volume as a function of pivot point location for various leaflet curvatures with a maximum valve opening of 85 degrees,

FIG. **9B** is a graph similar to that of FIG. **9A** for a maximum valve opening of 90 degrees,

FIG. **10A** is a graph of mean transvalvular pressure difference as a function of pivot point location for various leaflet curvatures with a maximum valve opening of 85 degrees,

FIG. **10B** is a graph similar to that of FIG. **10A** but with a maximum valve opening of 90 degrees,

FIG. **11A** is a graph of the net stroke volume/mean forward pressure difference or hemodynamic benefit/-cost ratio as a function of pivot point location for various leaflet curvatures with a maximum valve opening of 85 degrees,

FIG. **11B** is a graph similar to that of FIG. **11A** but with a maximum valve opening of 90 degrees,

FIG. **12A**, **12B** and **12C** are respectively tables I, II and III of various data,

FIG. **13** is an elevational view, in cross section, of a preferred embodiment of the curved butterfly bileaflet valve of the present invention, and

FIG. **14** is a cross-sectional view taken along the line **14—14** of FIG. **13**.

## DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, and particularly to FIGS. **13** and **14**, the curved butterfly bileaflet prosthetic cardiac valve of the present invention is generally indicated by the reference numeral **10** and includes an annular body or housing **12** which supports first and second pivoting leaflets or occluders **14** and **16** that open and close to control the flow of blood through a central passageway **18**. The normal flow of blood through the valve **10** is in the direction of the arrow **20**. Any suitable means may be connected to the body **12** for attaching a suturing ring to the annular body **12** to facilitate sewing the valve **10** to the heart tissue as is conventional.

The valve housing **12** and leaflets **14** and **16** may be made of any suitable material that is biocompatible and non-thrombogenic. For example, the body **12** and leaflets **14** and **16** may be made of isotropic graphite which is suitably coated with pryolitic carbon.

The leaflets **14** and **16** are each pivotally supported on an eccentric positioned axis at pivot points P and P', respectively. The leaflets **14** and **16** are curved in a plane normal to the eccentric axis. The leaflets **14** and **16** have a concave side **22** and **24**, respectively, and a convex side **26** and **28**, respectively. The convex sides **26** and **28** face each other when the leaflets **14** and **16** are in the open position and the concave sides **22** and **24** face upstream when the valve is in the closed position. Preferably, the curve of the leaflets **14** and **16** is circular and preferably the leaflets **14** and **16** are flat in a plane parallel to the eccentric axis although the leaflets **14** and **16** could also be curved in a plane parallel to the pivot axis.

The body **12** may include stop shoulders **30** and **32** positioned in the path of movement of the leaflets **14** and **16**, respectively, for limiting the maximum opening angle of the leaflets **14** and **16** as will be more fully discussed hereinafter. The leaflets **14** and **16** are generally semi-circular in cross section and are adapted to engage and seat on a valve seat **34** in the body **12** when in the closed position by the outside edges **36** and **44** of the leaflets **14** and **16**, respectively. The inside edges **40** and **42** are positioned to engage each other when the valve is in the closed position. Blood flowing in the direction of the arrow **20** from upstream to downstream will open the leaflets **14** and **16** until they reach their shoulder stops **30** and **32**, respectively. When the downstream flow of blood is discontinued, the back pressure which is present will cause the leaflets **14** and **16** to swing or pivot around the pivot points P and P', respectively, towards the closed position.

As in the prior art valves using two flat leaflets, the present valve **10** when opened has three separate channels for forward blood flow, that is, two lateral channels and one central channel. However, both physical studies measurements and computer studies show that the blood flow in the central channel of the prior art flat leaflets tends to be stagnant relative to the flow in the lateral channels of the valve. Stagnant flow is dangerous because it may lead to valve thrombosis. One of the features of the present invention is the reduction of this problem by curving the valve leaflets **14** and **16** as described above to form a central venturi channel which helps open the leaflets **14** and **16** and also funnels flow into the previously stagnant central channel of the valve.

In addition, various parameters have been considered to improve the performance of the valve **10** to select an optimal valve that not only maximizes the minimum peak velocity in any of the flow channels, but also maximizes the net stroke volume of blood crossing the valve per heart beat and minimizes the mean pressure difference during forward flow, thereby improving the hemodynamic performance. In order to provide an optimal valve, the parameters considered are the position of the pivot points P and P', the radius of curvature of the leaflets **14** and **16**, and the opening angle of the leaflets **14** and **16**. A computer was used to define the parameters of a model valve and the performance criteria that are used to select an optimal valve.

Referring now to FIG. **1A** and **1B**, a prior art flat butterfly bileaflet valve is shown in FIG. **1A** having flat leaflets **50** and **52** which are positioned in the mitral annulus between the left ventricle and the left atrium while the valve of the present invention using curved leaflets **14** and **16** is shown in FIG. **1B**. The open position of the leaflets **50**, **52** and **14** and **16** are shown in heavy dotted lines. The initial (closed) position is indicated by the light solid lines. Points M and M' are the extreme anterior and posterior points of the mitral annulus. Points P and P' are the pivot points. As previously indicated, the prior art valve of FIG. **1A** in tests showed that the blood flow in the central channel between the leaflets **50** and **52** tends to be stagnant relative to the flow in the outside channels which may lead to valve thrombosis. On the other hand, the present design of FIG. **1B** provides a venturi channel between the leaflets **14** and **16** which not only helps to open the leaflets **14** and **16** but to funnel additional flow into the channel between the leaflets **14** and **16**.

Referring now to FIGS. **2A**, **2B** and **2C**, the geometrical construction of a model valve of the present invention is shown in which the valve is shown in its closed configuration in FIG. **2A** and in its open configuration in FIG. **2B** and FIG. **2C**. The valve is treated as symmetrical despite the asymmetry that is inherent in the mitral position. The valve is constructed starting from the points M and M' that define the mitral ring and the diameter of that ring is $d_m$.

The gap distance g separates the ends of the leaflets or occluders **14** and **16** from the mitral ring and from each other. Because all boundaries have an effective thickness (of about 2 mesh widths of the computational mesh used in the computer model), these gaps are effectively closed when the valve is in the closed position. The chords AB and A'B' of the leaflets **14** and **16** are constructed in the closed position at an angle $\theta_0$ to the line MM' that defines the level of the mitral ring. Throughout, we take $\theta_0 = 25°$. This 25 degrees initial angle of the leaflets **14** and **16** relative to the mitral ring was chosen to approximately minimize the volume swept out by the leaflets during their opening or closure movement. This result is independent of the position of the pivot points P and P' and the curvature of the leaflets **14** and **16** and roughly minimizes the volume swept for leaflets having a maximum opening angle in the range between 85 degrees and 90 degrees, which opening angle will be further discussed herein.

The occluders **14** and **16** themselves are the circular arcs APB and A'P'B' with centers of curvature at **0** and **0'**, respectively, on the upstream (atrial) side of the valve. Let

$r_o$ = radius of curvature of the occluders

$d_o$ = length of AB = chord of the occluders

$R = r_o/d_o$
$C = 1/R$

Then R is the dimensionless radius of curvature, and C, the reciprocal of R, is the dimensionless curvature. The special case of a flat valve is characterized by $r_o = \infty$, $R = \infty$ and $C = 0$. In the flat case the occluder coincides with the chord AB. We shall use the parameter C to characterize the curvature of the valve. This is one of the principal design parameters.

Another important parameter is the position of the pivot points such as P (which remains fixed relative to the points M and M' as the occluder rotates). Its location is defined by measuring arc length from the outer border of the occluder. Let

$s_p$ = length of the arc AP
$s_o$ = length of arc APB
$S_P = s_p/s_o$

Then $S_P$ gives the position of the pivot point in dimensionless form. By definition, $0 < S_P < 1$, with the larger values of $S_P$ corresponding to pivot points which are closer to the center of the valve apparatus. In practice, $S_P$ must be chosen, as will be discussed hereafter, in the neighborhood of $\frac{2}{3}$ to achieve reasonable performance. If $S_P < 0.5$, the valve does not open at all.

The final design parameter is the maximum angle of opening of the valve. This angle, $\theta_{max}$, is the angle of the chords AB and A'B' to the plane of the mitral ring, as shown in FIG. 2B. Most of the computations in the current study were conducted with $\theta_{max} = 85°$ or 90°, as will be more fully discussed hereinafter.

Two other of the performance criteria are the net stroke volume (SV) and the mean forward pressure difference ($\overline{\Delta p}$). The net stroke volume is defined as the net volume of blood crossing the plane of the mitral annulus during the time interval when the valve is open. It is the difference between the forward volume and the regurgitant volume associated with the closure movement of the occluders **14** and **16**.

The mean forward pressure difference is defined by the formula

$$\overline{\Delta p} = \frac{1}{T}\int_0^T (p_{LA}(t) - p_{LV}(t))dt$$

where $p_{LA}(t)$ and $p_{LV}(t)$ are the left atrial and left ventricular pressures at time t. The time t=0 is defined as the onset of mitral flow, and t=T is defined as the time of the first zero-crossing of the mitral flow, which occurs during early ventricular systole. The rationale for this choice of times is that it eliminates an inertial component of the pressure difference. These two performance criteria are combined into a single benefit/cost ratio: $SV/\overline{\Delta p}$. This seems appropriate because SV and $\overline{\Delta p}$ are not really independent measures of performance.

The following performance criterion is concerned with valve thrombosis. Let $Q_{ant}(t)$ be the volume rate of flow crossing the line MP in FIG. 2C, let $Q_{cent}(t)$ be the volume rate of flow crossing the line PP' and let $Q_{post}(t)$ be the volume rate of flow crossing P'M'. Thus $Q_{ant}$, $Q_{cent}$, $Q_{post}$ are the anterior **60**, central **62** and posterior **64** flows, respectively. Let $A_{ant}$, $A_{cent}$, and $A_{post}$ be the cross-sectional areas of the three openings of the valve. That is, let

$A_{ant}$ = (length of MP)·$L_0$
$A_{cent}$ = (length of PP')·$L_0$
$A_{post}$ = (length of P'M')·$L_0$

where $L_0 = 1.84$ cm is a reference length ($L_0$ is the diameter of the mitral ring) that is used to convert length in the two-dimensional model to cross-sectional area.

Next define

$v_{ant}(t) = Q_{ant}(t)/A_{ant}$
$v_{cent}(t) = Q_{cent}(t)/A_{cent}$
$v_{post}(t) = Q_{post}(t)/A_{post}$

The quantities $v_{ant}(t)$, $v_{cent}(t)$, $v_{post}(t)$ have units of velocity; they are the spatially averaged velocity at time t in each of the three openings of the valve. (These velocities are independent of $L_0$ because both Q and A contain factors of $L_0$ in their definition.)

The maximum over time of the velocities $v_{ant}$, $v_{cent}$, and $v_{post}$ will be designated by the symbol *. Thus

$$V_{ant}^* = \operatorname{Max}_t\{v_{ant}(t)\}$$

$$V_{cent}^* = \operatorname{Max}_t\{v_{cent}(t)\}$$

$$V_{post}^* = \operatorname{Max}_t\{v_{post}(t)\}$$

These peak velocities are important because a low peak velocity implies stagnation and hence a tendency to thrombosis. To avoid thrombosis altogether, we adopt a worst-case criterion. Let

$$v_{min}^* = \operatorname{Min}\{v_{ant}^*, v_{cent}^*, v_{post}^*\}$$

If $v^*_{min} = 30$ cm/sec, for example, then a velocity of at least 30 cm/sec is achieved at some time during filling in each opening of the valve. We seek design parameters that make $v^*_{min}$ as large as possible.

In the case of single-disc valves, good performance can be achieved without any built-in constraint on the opening angle. For the curved butterfly bileaflet mitral valve, however, we were unable to find any combination of pivot point and curvature for which the valve would exhibit good performance without a constraint. The difficulty is related to asymmetrical movement of the leaflets **14** and **16** which, in turn, must be caused by the asymmetry of the mitral position, since the valve is symmetrical. FIG. **3** shows the opening angle as a function of time for a prior art flat, bileaflet valve effectively unconstrained ($\theta_{max} = 135°$) pivoted at $S_P = 0.67$. Note that the anterior leaflet opens much faster than the posterior leaflet and that it becomes caught in the open position. This makes the valve incompetent. Competent performance can be achieved by reducing $S_P$, but then the posterior leaflet fails to open sufficiently and the valve is very stenotic. One way out of this dilemma would be to construct an asymmetrical valve in which the asymmetry of the valve compensates for the asymmetry of the mitral position. In the present study, which is restricted to symmetrical valves, the only solution is to impose a constraint on the maximum opening angle. With such a constraint, and with the pivot point and curvature in an appropriate range both leaflets **14** and **16** hit the constraint (albeit at slightly different times) and the open configuration of the valve is symmetrical.

Valve performance has not been systematically optimized with respect to maximum opening angle $\theta_{max}$. Instead we have chosen two reasonable values of $\theta_{max}$

and conducted the rest of the study with these values fixed. The motivation for this choice is shown in FIG. **4**, in which peak velocity is plotted in each of the three openings **60**, **62**, **64** of the valve as a function of the opening angle constraint. The results are shown both for the flat valve of FIG. **1A** (FIG. **4A**) and for a curved valve of the present invention of FIG. **1B** (FIG. **4B**). The pivot point in both cases is $S_P=0.67$.

The goal is to make the minimum of the three peak velocities as large as possible. For the flat valve (FIG. **4A**) at this pivot point, the minimum peak velocity always occurs in the central opening of the valve. (This has also been observed in vitro.) This minimum peak velocity builds up to its largest value at about a 90 degree opening angle constraint and then levels off. (Competent performance cannot be maintained much beyond 90 degrees, since the anterior leaflet tends to get stuck in the open position and fail to close.) For the curved valve of the present invention, FIG. **4B**, the situation is somewhat more complicated, since the smallest peak velocity occurs first in the posterior opening **64**, then in the central opening **62**, and finally again in the posterior opening **64** as the maximum opening angle increases from 70 degrees to 90 degrees. Here the minimum of the three peak velocities is largest where the center and posterior velocities cross near a maximum opening angle of 85 degrees. These results suggest that opening angle constraints in the range 85 degrees to 90 degrees are most likely to produce good performance.

For the rest of this study, we fix the maximum opening angle at $\theta_{max}=85°$ or $\theta_{max}=90°$. The figures which follow will show results for these two values of $\theta_{max}$ side by side.

Minimum peak velocity ($v^*_{min}$) varies as a function of pivot point ($S_P$) and (C). FIG. **5** shows a typical plot of peak velocity in the three openings, **60**, **62**, and **64**, of the valve as a function of pivot point with curvature held fixed (in this case C=0.667). Note that the different peak-velocity curves intersect and that the minimum peak velocity (heavy line) is largest at the pivot point where the posterior and central peak velocities are equal. In subsequent figures, we plot only the minimum peak velocity without specifying the opening of the valve in which it occurs.

FIGS. **6A** and **6B** plot the minimum peak velocity ($v^*_{min}$) as a function of pivot point ($S_P$) at various curvatures (C=0, 0.333, 0.417, 0.500, 0.583, 0.667, 0.750). There are two remarkable points. First, at every curvature there is a pivot point that maximizes the minimum peak velocity. These pivot points are clustered around $S_P=0.67$. Second, the curved valves have substantially higher values of $v^*_{min}$ (minimum peak velocity) than the flat valves of FIG. **1A**. In fact, by curving the occluders **14** and **16**, as shown in FIG. **1B**, one can increase $v^*_{min}$ by about 10 cm/sec (more than 30%) in comparison with the best flat valve.

The optimal combination of pivot point and curvature can be found by expanding FIGS. **6A** and **6B** in the neighborhood of the best valves. The result is shown in FIGS. **7A** and **7B**. For each curvature there is an optimal pivot point, denoted by $S^{**}_P(C)$ which maximizes $v^*_{min}$. The value of $v^*_{min}$ at This optimal pivot point is denoted by $v^{**}_{min}$ (C). FIGS. **8A** and **8B** are plots of $v^{**}_{min}$ as a function of C.

The values of $v^{**}_{min}$ and $S^{**}_P$ are listed in Table I (FIGS. **12A**). For each value of $\theta_{max}$ there is one curvature, denoted by $C_{opt}$, which results in the largest value of $v^{**}_{min}$. The values of $C_{opt}$, $S^{**}_P$ ($C_{opt}$), and $v^{**}_{min}$ ($C_{opt}$) for $\theta_{max}=85°$ and 90° are listed in Table II (FIG. **12B**). These values define the two best valves in the study.

Hemodynamic performance is another important criteria. The foregoing choice of an optimal valve was based on considerations relating to stagnation and thrombosis. Considering the design problem from a hemodynamic pressure-flow) viewpoint, FIGS. **9A** and **9B** plot the stroke volume (i.e., the net volume of blood crossing the mitral valve during one heartbeat) as a function of pivot point at several curvatures FIGS. **10A** and **10B** plot the mean pressure difference across the valve in the same way. FIGS. **11A** and **11B** combine these two performance criteria into a single benefit/cost ratio: the quotient of the net stroke volume and the mean pressure difference across the valve.

At each curvature in FIGS. **11A** and **11B** there is an optimal pivot point. As before these optimal pivot points are clustered in the neighborhood of $S_P=0.667$. Starting from the flat valve, C=0.000, and increasing the curvature, we find that performance (the quotient of stroke volume and mean pressure difference) first improves dramatically and then falls off. Of the valves that we have tested, those with the best hemodynamic performance are listed in Table III (FIG. **12C**).

In choosing the best overall valve, how much weight should be given to the minimum peak velocity (a criterion related to thrombosis) in comparison with the hemodynamic benefit/cost ratio of the net stroke volume divided by the mean pressure difference? Fortunately, there is no real need to answer this question because the two criteria lead to very similar conclusions (compare Table II and Table III). Moreover, we can adopt either criterion without much reduction in performance as measured by the other criterion. Suppose, for example, that we select the best valve by the criterion of maximizing $v^*_{min}$ (the minimum peak velocity). While this valve is suboptimal with respect to hemodynamic performance, the reduction in $SV/\overline{\Delta p}$ (the ratio of stroke volume to mean pressure difference) is only 3.8% for the valve with $\theta_{max}=85°$ and only 3.5% for the valve with $\theta_{max}=90°$. We are therefore in the fortunate situation of being able to select the valve which will minimize thrombosis while sacrificing very little in terms of hemodynamic performance.

In conclusion, a built-in constraint on the maximum angle of opening ($\theta_{max}$) is a necessary design feature of symmetrical butterfly bileaflet valves for the mitral position. The parameter $\theta_{max}$ should be set in the approximate range of 85 degrees 90 degrees.

With $\theta_{max}=85°$, the valve with least stagnation (technically, the valve with the largest value of $v^*_{min}$, the minimum peak velocity) has pivot point $S_P=0.671$ and curvature C=0.583. With $\theta_{max}=90°$, the valve with least stagnation has $S_P=0.658$ and C=0.500.

These valves are also nearly optimal from a hemodynamic viewpoint. That is, they come close (within 4%) to achieving the optimal value of net stroke volume divided by mean forward pressure difference.

The most important conclusion is that modest curvature of the leaflets **14** and **16** can make a substantial improvement in the performance of butterfly bileaflet valves. The type of curvature used is in a plane perpendicular to the pivot axes P and P′ of the valve **10** and in a direction such that the open valve has a slight waist, like reversed parentheses: )(. When the optimal curvature is selected, the best valve of this type is superior to the best flat valve both with regard to the minimum

peak velocity (which should be larger to prevent stagnation and thrombosis) and also with regard to the ratio of net stroke volume to mean forward pressure difference. For the two constraint angles that are considered (85° and 90°) the improvements in minimum peak velocity are 38% and 34%, while the improvements in the hemodynamic benefit/cost ratio are 16% and 20%. These conclusions are predictions made with the help of a computer model to produce the charts and tables of FIGS. 3–12.

The present invention, therefore, is well adapted to carry out the objects and attain the ends and advantages mentioned as well as others inherent therein. While presently preferred embodiments of the invention have been given for the purpose of disclosure, numerous changes in the details of construction and arrangement of parts may be made without departing from the spirit of the invention and the scope of the appended claims.

What is claimed is:

1. A heart valve prosthesis comprising,

an annular valve body having a central passageway for the flow of blood therethrough from upstream to downstream,

first and second curved symmetrical leaflets pivotally supported for movement between closed and open positions in the central passageway of the body, said leaflets when closed preventing flow through said passageway and when open defining a posterior opening, a central opening, and an anterior opening through the passageway, each curved leaflet having a concave and a convex side,

eccentric position axis means pivotally supporting said curved leaflets,

said leaflets being curved in a plane normal to the eccentric axis and positioned with the convex sides of the leaflets facing each other when the leaflets are in the open position, and said concave sides of the leaflets facing upstream when in the closed position,

means in the body for limiting the maximum angle of opening of the leaflets to approximately 90° from a transverse plane to the central passageway, and

said first and second leaflets are pivotally supported at a position and have a curvature for maximizing the minimum peak velocity flowing through said openings and for maximizing the ratio of the net stroke volume to the mean pressure difference across the valve during forward flow thereby avoiding stagnation in all of said openings of the valve and reducing the pressure drop that is required to move fluid through the valve.

2. The apparatus of claim 1 wherein the leaflets are circularly curved.

3. The apparatus of claim 1 wherein the first and second leaflets are pivotally supported along an axis located approximately two-thirds of the greatest distance from an arcuate body-contacting edge to a leaflet-mating edge of each leaflet.

4. The apparatus of claim 3 wherein the curvature C of the leaflets is in the range of approximately 0.4 to 0.7 wherein $C=d_o/r_o$, and $r_o$=the radius of curvature of the leaflets, and $d_o$=the length of the chord of the leaflets.

5. The apparatus of claim 1 wherein the curvature C of the leaflets is in the range of approximately 0.4 to 0.7 wherein $C=d_o/r_o$, and $r_o$=the radius of curvature of the leaflets, and $d_o$=the length of the chord of the leaflets.

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