SOFT SHELL MUSHROOM SHAPED HEART

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ABSTRACT

The output volume of the artificial heart of this invention is highly responsive and directly proportional, within limits, to the atrial filling pressure of the blood flowing into the pumping chamber of the artificial heart. Flexible wall construction is responsible for the output volume being a function of the inlet pressure and also serves to reduce tissue damage to the surrounding body organs when the artificial heart is placed in the same general locality as that usually occupied by the natural heart. An integral valve means operable in conjunction with an inflatable blood displacement member occludes the inlet to the heart during the pumping phase of the heart.

4 Claims, 6 Drawing Figures
SOFT SHELL MUSHROOM SHAPED HEART

In developing of an artificial heart pumping device to replace or assist a natural heart, it is desirable for the output volume of the artificial heart to be responsive to and substantially directly proportional to the blood input pressure. It is estimated that the atrial filling pressure to the natural heart is responsible for approximately 80 percent of the control of the output volume of the heart in response to body needs. This concept has been amply demonstrated by natural heart transplantations wherein all the nerves to the transplanted heart have been severed and yet the transplant heart continues to function adequately. Regulation of the pumping output capacity of the artificial heart as a function of body needs is one of the problems to be overcome in producing an artificial heart for placement in the chest cavity of a human being. Numerous attempts have been made to make the artificial heart responsive to the needs of the body through means of pressure sensors or other sensing elements which cause either speed up or slow down of the pumping action of the artificial heart. The relationship between output volume and inlet pressure is known as Starling's Law and is one of the important considerations in the design of an artificial heart since this relationship will prevent the collapse of inlet blood vessels from an oversuction by the pumping chamber or blood pooling from insufficient output volume. To be responsive to Starling's Law, it is necessary for the output volume of the pumping chamber to change in direct proportion to the inlet or filling pressure of blood entering the pumping chamber. Prior attempts to design an artificial heart have generally been unsuccessful since the inlet pressure responsive areas of the pumping chamber which change the capacity of the pumping chamber with corresponding changes in inlet pressure are usually too small and intricate to be effective. Some of these inlet pressure responsive devices are in the form of bellows which, in turn, create other problems such as crowding in an already congested area and reduction of usable pumping volume.

Further restrictions to the usefulness of prior modifications of an artificial heart are in the external design and materials of construction. The external configuration is usually grossly dissimilar to that of a natural heart. They are also generally constructed of a rigid material which causes considerable damage to surrounding tissue when the artificial heart is placed in the same general vicinity as that usually occupied by a natural heart.

In the present embodiment of the natural heart, the blood pumping chamber is defined as the area between a flexible external wall of the artificial heart and an inflatable pumping member inside the heart. Blood is forced from the pumping chamber by the inflation of the pumping member. The direction of flow of the blood is appropriately controlled by valves in inlet and outlet conduits. The inlet valve to the pumping chamber is formed as an integral part of the pumping member thus giving rise to the name "Mushroom Heart" since the valve comprises the head or button of the mushroom and the pumping member is the stem. The inlet blocking member or valve head acts in a manner similar to a ball valve since the valve head is formed as an extension of the pumping member and is comprised of an inflatable membrane having a surface which contacts the periphery of the inlet opening to the pumping chamber to occlude the inlet when the valve is inflated. Inflation of the valve is accomplished either simultaneously with the inflation of the pumping member or separately as desired to achieve optimal pumping efficiency.

The flexible external wall is restrained from flexing beyond certain limits by a nonelastic but flexible restraining surface such as a flexible wall located either in the external wall or located exteriorly thereto. In circumstances where the remaining surface hinders the necessary flexibility of the external wall, it is suggested that the two surfaces not be joined but operate independently of each other.

Therefore, it is an object of this invention to provide an artificial heart which is similar in size and external shape to a natural heart.

It is a further object of this invention to provide an artificial heart of flexible external construction.

It is a further object of this invention to provide an artificial heart with an integral valve means closely connected with the pumping member to provide a means for occluding the inlet to the heart pumping chamber during the pumping phase for the prevention of the reverse flow of blood.

These and other objects of this invention will become obvious when viewed in conjunction with the following description and drawings in which:

FIG. 1 is a cross-sectional schematic of the soft shell mushroom heart during the inlet phase of blood into the pumping chamber of the artificial heart.

FIG. 2 is a cross-sectional schematic of the soft shell mushroom heart during the pumping phase; and

FIGS. 3A, 3B, 3C, and 3D are cross-sectional schematic views of one modification of the soft shell mushroom heart during different stages of the pumping cycle.

Referring to FIG. 1, the artificial heart as shown in schematic comprises a blood pumping chamber 10 enclosed within a flexible, and (to a limited extent) elastic, external wall 11 which is restrained from distending beyond certain limits by a nonelastic, flexible net 12. Pumping member 13 is periodically inflated by a working fluid, which in the presently preferred embodiment is air. A valve head 14 is formed as an integral part of pumping member 13. As indicated by the dashed arrows in the drawings, blood enters the pumping chamber 10 through an opening between a valve seat 15 and valve head 14. As indicated by the collapsed state of the external wall 11, the volume of pumping chamber 10 is responsive to the atrial filling pressure in response to Starling's Law. Flexibility of external wall 11 of pumping chamber 10 allows blood to flow into the pumping chamber 10 of the heart from the atrial filling chamber without undue negative pressure being exerted upon the blood when the working fluid or air is withdrawn from pumping member 13.

A valve 16 prevents the reverse flow of blood from the atrial system during the filling phase of the artificial heart.

Referring to FIG. 2, the artificial heart is shown in schematic during the pumping stage in which all air is forced into pumping member 13 and simultaneously forces valve head 14 against valve seat 15. The inlet to the pumping chamber is thus closed and the back flow of blood through the inlet is prevented. Blood is pumped out of pumping chamber 10 through valve 16 as shown by the solid arrows and the flexible net 12 lies closely adjacent the external wall 11 and prevents the further distention of the latter beyond certain limits when the pumping member 13 is inflated. Even when the atrial filling pressure is insufficient to completely fill the pumping chamber 10, the pumping member 13 is still inflated to its full extent and forces external wall 11 against net 12. The only change resulting from a partial filling of the pumping chamber 10 is a reduction in the output volume of the artificial heart.

As illustrated in the drawing, valve head 14 and pumping member 13 are inflated simultaneously. However, this could result in a reverse flow of some of the blood from the pumping chamber 10 at the onset of inflation of pumping member 13. Therefore it is suggested that that material comprising the elastic portions of valve head 14 be constructed of a material which stretches under less pressure than the material comprising the pumping member 13. In this manner, the more elastic material of valve 14 would preferentially distend to cause valve head 14 to occlude the blood inlet before pumping member 13 starts to distend.

Referring to FIGS. 3A-3D, another embodiment of an artificial heart is shown in four stages of pumping. The stages of filled pumping chamber, closed inlet valve, inflated pumping member, and deflated pumping member and valve are shown in FIGS. 3A, 3B, 3C, and 3D, respectively.

Referring to FIG. 3A, the elastic material of valve head 14 is shown in a relaxed state and enveloping a support member 17.

Blood is free to flow under normal atrial filling pressure
between valve head 14 and valve seat 15 into pumping chamber 10. The support member 17 is in turn supported by an inflation conduit 18 that passes interiorly through the pumping member 13. The inflation medium for valve head 14 passes through inflation conduit 18 and into the confines of valve 14 through passageways or holes 19 in the support member 17. In this particular embodiment there is no communication of the valve inflation medium with the interior of pumping member 13.

The inflation control system for the valve head 14 operates separately from the inflation control system for pumping member 13. However, it is envisioned that the same inflation medium for valve head 14 could also be used to inflate pumping member 13 after a suitable delay in passage from valve head 14 into pumping member 13. The delay in passage of the inflation medium would create the necessary sequencing between inlet valve closure and pumping member 13 inflation for optimal pumping efficiency. In either manner, it is possible to achieve the sequential inflation of the valve and pumping member for the optimal pumping efficiency of the artificial heart.

Referring to FIG. 3B, the valve head 14 is shown in its fully inflated state wherein it contacts the valve seat 15 to occlude the blood inlet into the pumping chamber.

Base 21 serves as an attachment point between inflation member 13 and external wall 11 and as a means for segregating the inflation medium of valve head 14 and pumping member 13 from the area immediately surrounding the artificial heart. Inflation medium for pumping member 13 passes through conduit 20 which serves both as an inflation port and as a deflation port through base 21. Upon deflation, the inflation medium is either returned to a control device (not shown) located either interiorly or exteriorly of the body, or in the case of air, allowed to escape to the atmosphere.

Referring to FIG. 3C, pumping member 13 is shown in its fully inflated state wherein it almost completely fills pumping chamber 10 and thus expels almost all the blood from pumping chamber 10 through valve 16.

Referring to FIG. 3D, both valve head 14 and pumping member 13 are depicted in their deflated states to allow for the filling of pumping chamber 10. External wall 11 is drawn inwardly by the negative pressure created by the deflation of pumping member 13. Blood enters pumping chamber 10 under the force of the atrial filling pressure through the opening between valve head 14 and valve seat 15. The quantity of blood in pumping chamber 10 will thus depend upon the atrial filling pressure of the blood and in this manner make the artificial heart of this invention highly responsive to Starling's Law.

Valve 16 in all drawings may be any one of a number of appropriate valves used in blood flow systems.

Although only one pumping chamber has been depicted in the drawings and accompanying description, a complete artificial heart would comprise two such chambers which would serve to completely replace and duplicate the functions of the natural heart.

A single pumping chamber may be used in heart bypass operations to replace or assist the pumping function of a ventricular of the natural heart for any period of time required for healing of the diseased natural heart.

All materials of construction in contact with blood and living tissue are compatible with and noninjurious to the blood and living tissue.

I claim:

1. A blood pumping device to replace or temporarily assist the natural heart, said device comprising:
   a. a blood pumping chamber of flexible wall construction, and having separate blood inlet and outlet means; and
   b. an inflatable blood displacement member of elastic wall construction located within said pumping chamber and operable upon periodic inflation to forcibly eject blood from said pumping chamber through said outlet means, an inflatable valve head for periodically blocking said inlet means, said valve head being affixed to said displacement member and operable as a valve means, said valve head including means for operating said valve head separately from said inflation of said inflatable blood displacement member to thereby achieve optimum pumping efficiency of said blood pumping device.

2. A blood pumping device as defined in claim 1 wherein the external configuration of the pumping device conforms substantially to that of a natural human heart.

3. A blood pumping device as defined in claim 1 wherein said flexible wall construction of the pumping chamber is restrained from expansion beyond predetermined limits by a nonelastic but flexible restraining surface.

4. A blood pumping device as defined in claim 3 wherein the elastic wall construction of the pumping member is operable to completely distend the elastic walls of the pumping chamber to the restraining limits of the restraining surface even in the presence of a differential amounts of blood in the blood pumping chamber at any given time.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Inventor(s)  Willem J. Kolff

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 1, after the title "SOFT SHELL MUSHROOM SHAPED HEART" should read -- This invention was made in the course of research supported by a grant from the Department of Health, Education and Welfare; and the assignee of this patent hereby grants and conveys to the United States Government a royalty-free, non-exclusive and irrevocable license for governmental purposes for the term of the patent. --

Signed and sealed this 7th day of November 1972.

(SEAL)
Attest:

EDWARD M. FLETCHER, JR.  ROBERT GOTTSCHALK
Attesting Officer  Commissioner of Patents