An artificial heart valve for implantation in close proximity to a malfunctioning or damaged natural aortic or mitral heart valve by remote means without performing an open chest or other major surgical operation. The artificial heart valve comprises a flexible membrane in the form of an umbrella in that the apex of the umbrella resides in the direction that blood flow is to be periodically prevented while the distal end opens sufficiently to contact the inner walls of the vessel to prevent the reverse flow of blood and the membrane collapses about the axis of the umbrella to allow the forward flow of blood.

2 Claims, 3 Drawing Figures
CATHETER MOUNTED ARTIFICIAL HEART VALVE FOR IMPLANTING IN CLOSE PROXIMITY TO A DEFECTIVE NATURAL HEART VALVE

Historically, there has long existed a need for an artificial heart valve for use in persons in whom a natural heart valve has failed due to disease in such a manner that the patient no longer prevents the reverse flow, or regurgitation, of blood back through the valve with the subsequent loss of blood pressure. The prevention of two way flow through the heart valve is very important for the maintenance of proper flow, pressure, and perfusion of blood throughout the body. Generally, the defect in the natural valve is an acquired versus congenital defect caused, to a very minor degree, by syphilis but predominantly by rheumatic fever contracted by the patient at a fairly early age. This defect in the heart valve does not hamper the activities of the patient at this early age since the young heart is able to compensate for the blood pressure loss resulting from the defective valve. However, it is when the patient reaches middle age that the heart begins to tire and is less able to compensate for the losses caused by the defective valve. It is at this time that an artificial heart valve proves to be of great benefit to the patient.

Aortic or mitral regurgitation is presently corrected by opening the chest and replacing the diseased valve with an artificial valve. This is a serious operation with a resulting rather high mortality rate. There are other instances wherein the operation cannot be performed for such reasons as the critical condition of the patient, co-existing infection, or advanced age, to mention a few.

Therefore, it is an advancement in the art to develop a heart valve which is placed in close proximity to and effectively duplicates the normal functions of a natural heart valve without having to perform any major surgery upon the patient. Such an invention is disclosed herein.

The artificial heart valve disclosed in this invention is in the form of a flexible perforate membrane which is periodically distended to occlude a major blood vessel to prevent the reverse flow or regurgitation of blood through a defective or malfunctioning natural heart valve. The membrane is in the form of an umbrella wherein the apex of the umbrella resides in the vessel in the direction in which the flow of blood is to be prevented. In this embodiment the valve is affixed at or near the closed perforate distal end of a flexible catheter and is emplaced in a major vessel in close proximity to the natural valve by inserting the catheter into the body. The catheter is in the form of a cylinder with a conical section extending from the circular base of the cone, the membrane is attached at or near the apex of the conical section to a catheter of relatively small cross-sectional diameter which passes parallel to the axis of the surface thus formed by the membrane. The catheter serves as retention, insertion, and withdrawal device for the valve and also serves as a blood pressure detecting device in subderm for determining the blood pressure in the blood vessel by using a catheter which has a hole in the catheter wall at the position desired for detecting the blood pressure.

In the above-described form, the valve resides within the blood vessel with the apex of the cone extending in the direction in which the flow of blood is to be prevented and the axis of the valve is substantially parallel to the axis of the blood vessel.

In operation, the membrane of the valve collapses and enfolds the catheter to permit the almost unrestricted flow of blood in the proper direction, but when flow in that direction ceases and starts to flow in the reverse direction, the force of the blood flow causes the membrane to open in such a manner that the cylindrical section of the valve membrane contacts the inner wall of the vessel and the entire membrane occludes the vessel to further reverse flow of blood. Blood flow in the proper direction again collapses the membrane about the catheter for the free passage of blood past the valve.

To assist in the close fit of the membrane about the catheter when the membrane of the valve is in the collapsed state, inwardly extending folds along the length of the valve parallel to the axis of the valve are provided in the membrane to provide predetermined fold lines along which the membrane folds during its collapsed period of operation.

In view of the foregoing, it is an object of this invention to provide an artificial heart valve for placement in close proximity to a defective natural heart valve.

Another object of this invention is to provide an artificial heart valve which is placed in close proximity to the natural heart valve by means of a catheter inserted into a blood vessel at some distance from the heart.

These and other objects will become apparent when viewed in conjunction with the following drawings and description.

FIG. 1 is a projection of one embodiment of an artificial heart valve shown in a partially opened condition in a cutaway section of a blood vessel;

FIG. 2A and 2B show the artificial heart valve of FIG. 1 in cross section in the open-to-flow and closed-to-back-flow positions respectively, as the valve operates in close proximity to a defective natural heart valve;

Referring to FIG. 1, an artificial heart valve in a partially opened state is shown generally at 10, as it resides within a blood vessel 11. The insertion, withdrawal, and retention means for the valve 10 is the catheter 12 which is suitably attached to the membrane 13 of the valve at the apex of the membrane at position 14. A plurality of folds or creases 15 in the membrane 13 extend substantially the entire length and parallel to the axis of the membrane, which folds expedite the collapse of the membrane about the catheter 12 when the blood flows in the proper direction. When the valve is fully opened to where the outer cylindrical surface of the membrane 13 contacts the inner surface of the blood vessel 11 to prevent the back flow of blood, the profile of the cylindrical section is generally circular in cross section and the folds 15 merge with the rest of the membrane 13 to form a smooth cylindrical surface which contacts the inner wall of the blood vessel.

A hole 16 is drilled or otherwise excavated in the wall of the catheter 12 to provide a pressure sensing opening for communicating the blood pressure in the region of the hole 16 to an external pressure sensing device 16A.

Referring to FIGS. 2A and 2B, a natural heart valve is shown at 17 through which holes 18 form the defect in the heart valve which defect allows the reverse flow or regurgitation of blood through the natural valve. The arrows indicate the direction of blood flow in the vessel. As can easily be seen from FIG. 2A, a forward flow of blood in the blood vessel 11 causes the membrane 13 of the valve to collapse about the
3,671,979

catheter 12 to permit the relatively unrestricted flow of blood past the valve; however, when the valve 17 closes to prevent the reverse flow of blood, the defects 18 in the valve 17 allow the reverse flow of blood in the vessel. This reverse flow is sufficient to distend the membrane 13 of the valve as shown in FIG. 2B such that the membrane contacts the inner wall of the blood vessel 11 and it thus substantially occludes the blood vessel against the reverse flow of blood.

I claim

1. An artificial heart valve operable in the presence of a malfunctioning natural heart valve and implantable by remote means, said remote means comprising an elongated flexible catheter having a proximal end and a closed imperforate distal end insertable through a blood vessel from a point near an external body surface to a point adjacent a malfunctioning natural heart valve, said artificial heart valve comprising a flexible imperforate membrane affixed at its epicenter to said distal end of said catheter, said membrane being formed generally as a surface of a right circular cone with a cylindrical section extending from the circular base of said conical surface longitudinally in a direction towards said proximal end, the apex of said cone residing in a direction in which said membrane is operable to substantially prevent return flow of blood back through said malfunctioning natural heart valve, said membrane being operable to collapse about said catheter to allow blood flow opposite the direction of said apex, said artificial heart valve being operable solely by blood flow and in the absence of external power means.

2. An artificial heart valve as defined in claim 1, wherein said catheter is hollow and a pressure sensing hole is provided in a wall of said catheter, said hole being located downstream from said reverse flow preventing valve membrane between said apex and the proximal end of said catheter.