United States Patent

Carpentier

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[54] CARDIAC VALVULAR SUPPORT PROSTHESIS

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[30] **Foreign Application Priority Data**

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[52] **U.S. Cl.** ..... **3/1;** 128/334 R
[51] **Int. Cl.** **A61f 1/24**
[58] **Field of Search** ..... 3/1, DIG. 3; 128/334 R, 1

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[57] **ABSTRACT**

A cardiac valvular prosthesis, e.g., for the mitral valve, consisting solely of an annular or part-annular member adapted to fit against the base of the cusps of a human heart valve, and suture means for securing the member in place. The prosthesis cooperates with the natural valve cusps of the patient to form the valve.

6 Claims, 6 Drawing Figures

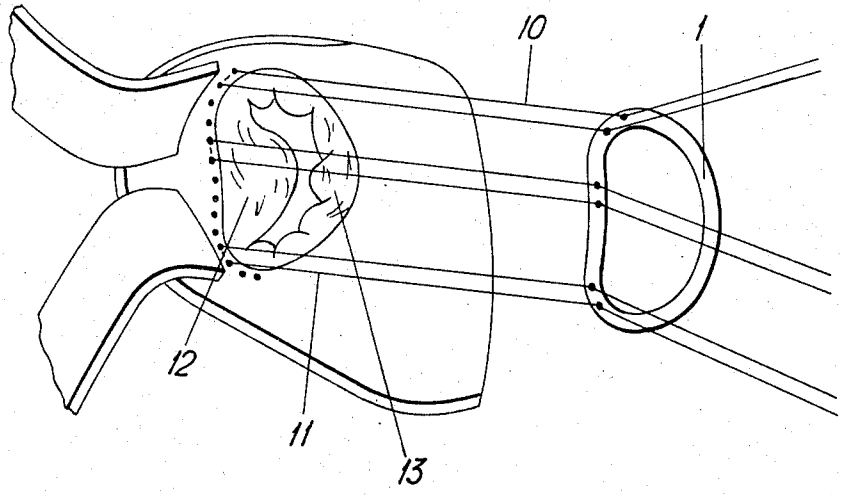

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Fig. 1.

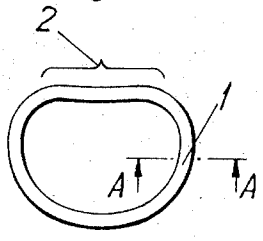

Fig. 2.

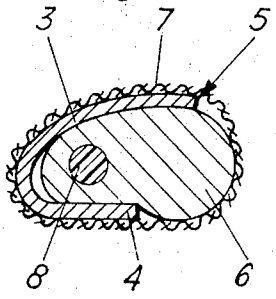

Fig. 3.

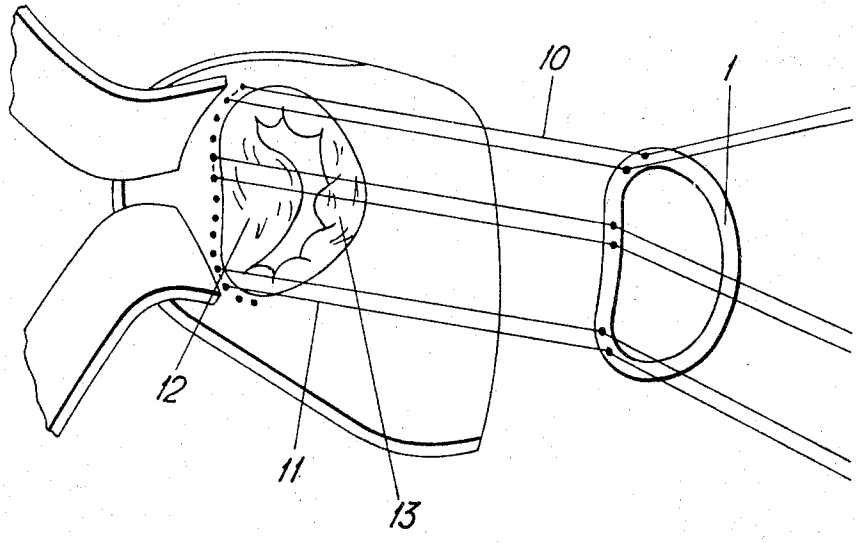

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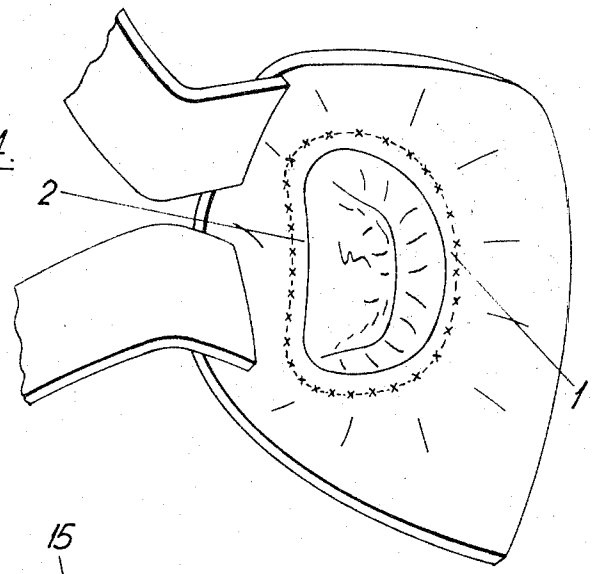
Fig. 4.



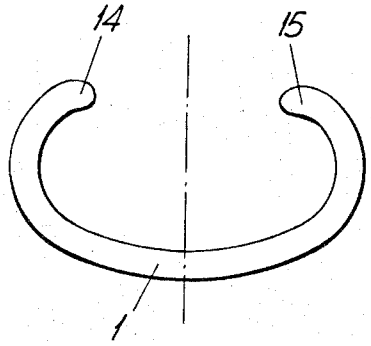
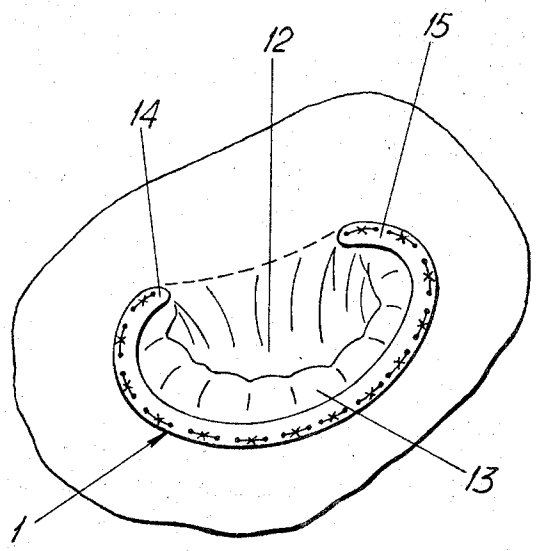


Fig. 5.

Fig. 6.



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CARDIAC VALVULAR SUPPORT PROSTHESIS

The present invention relates to a prosthesis intended for the surgical correction of valvular diseases and notably diseases affecting the mitral valve.

In the case of mitral disease, it is known to preserve the natural cusps of a valve and to correct the defects therein. However, Kay's annuloplasty, Wooler's asymmetrical annuloplasty and Reed's annuloplasty give uncertain results, because leakage may persist. In addition, the mitral ring may continue to distend and the stitches made in the commissuroplasty may yield under the action of the tensile forces to which they are subjected. This results in a reduction in the efficiency of the valve with a frequency which is given as 10 to 40 percent by the authors.

It is also known, in order to obviate valvular deformation, especially mitral valve deformation, to proceed with ablation of the defective cusps and to replace them by a prosthesis.

Such a prosthesis is described in U.S. Pat. No. 3,374,489 and includes an annular member which is inserted into the mitral ring and a valve disc provided with hooks, the disc oscillating between two extreme positions and alternately opening and closing the mitral orifice. The annular member performs the double function of retaining the valve disc and constituting the valve seat.

Such a prosthesis has various disadvantages, in that it interferes with the normal physiology of the mitral apparatus, it necessitates the prolonged use of anticoagulants and it may cause a thrombosis or a sudden mechanical defect.

According to the present invention, there is provided a cardiac valvular prosthesis consisting solely of an annular or part-annular member adapted to fit against the base of the cusps of a human heart valve, and suture means for securing the member in place. With such a prosthesis the natural valve cusps are retained, and the prosthesis is inserted at the base thereof.

The annular or part-annular member may consist of a rigid frame, suture means and a textile sheath enclosing the frame and suture means.

The invention will be more readily understood from the following description, given merely by way of example reference being made to the accompanying drawings, in which:

FIG. 1 is an elevation of one embodiment of prosthesis according to the invention;

FIG. 2 is a section taken along the line A—A, of FIG. 1, and drawn to a large scale;

FIG. 3 is a view of the mitral valve in the course of the positioning of the prosthesis of FIG. 1;

FIG. 4 is a view of the mitral valve after the positioning of the prosthesis of FIG. 1;

FIG. 5 is an elevation of a second embodiment of prosthesis according to the invention; and

FIG. 6 is a view of the mitral valve after the positioning of the prosthesis according to FIG. 5.

The prosthesis shown in FIG. 1 closely follows the form of the base of the valve cusps and it has substantially the form of a closed ring 1, which is plane, circular, oval or, as shown, slightly flattened at 2 over a length between one-quarter and one-half of its periphery. Substantially straight portion 2 corresponds to the curvature of the large cusp and the complementary zone corresponds to the curvature of the small cusp. The ring has in its plane an axis of symmetry, its largest dimensions, along this axis and along a perpendicular axis, being generally between 15 and 30 mm. and 20 and 40 mm. respectively.

As seen in FIG. 2, the ring comprises a rigid frame 3, for example of stainless steel. This frame is light since it has an asymmetric, outwardly hollow channel section defining an external groove. The flanges of the channel section are of unequal widths, the lower edge 4, which is flat being narrower and intended to rest on the mitral ring, while the upper flange 5 has a rounded profile. The width of the lower flange is generally between 0.5 and 2 mm. and that of the upper flange between 1 and 3 mm. This arrangement makes it possible for the suture stitches to be automatically embedded.

Within the groove is disposed a stitchable cord 6, which is maintained within the groove by a filament 8 of large caliber, formed for example of polytetrafluorethylene. The ring also comprises a woven textile sheath 7, for example also of polytetrafluorethylene, which simultaneously encloses or covers the frame 3 and the cord 6.

A prosthesis according to the invention may be made from any inert materials which are well tolerated by the organism and have appropriate strength, and stainless steel and polytetrafluorethylene have only been referred to by way of example. For example ethyleneglycol polyterephthalate may be used instead of polytetrafluoroethylene.

As seen in FIG. 5 and 6, the prosthesis may be in the form of an open ring, i.e., it may be part of an annulus 1, which is slightly flattened to fit closely against the base of the cusps. This part-annulus is open over a length generally between one-quarter and one-half of its periphery, so that the space between the free ends is between one-third and one times the peripheral length of the part annular member itself. This length corresponds substantially to the length of the base of the cusp which it is desired to allow to have free movement. In FIGS. 5 and 6, the ring is open over a length equal to one-third of its periphery, this length corresponding substantially to the base of the large cusp 12. The ring thus closely fits against the base of the small cusp 13 and allows the large cusp to have free movement.

The ends 14 and 15 of the ring are rounded in order not to damage the tissues in which they are disposed.

The profile of the ring is similar to that of the construction of FIGS. 1 to 4, i.e., its cross section is as shown in FIG. 2. Thus, it has an external groove, the lower flange intended to rest on the mitral ring again being plane, while the upper edge has a rounded profile. Situated inside the groove is a large-caliber filament of polytetrafluoroethylene or of ethyleneglycol polyterephthalate, which maintains a stitchable cord within the frame, after having been stretched between the two ends of the frame. For this purpose, the ends of the frame are each formed with a hole, the filament is pulled between these holes and is fused on either side of the holes so as to produce beads, and then released.

The annular mitral prosthesis of FIGS. 1 to 4 is positioned between the left auricle and the left ventricle by the surgical technique described below with reference to FIGS. 3 and 4.

First of all, the dilatation of the mitral ring is checked, and it is verified that the cusps are sufficiently supple, that the large cusp has sufficient freedom of movement and that there is no lesion of the ligaments by which the large cusp is fixed.

Two appropriate suture filaments 10 and 11 are disposed in U-form and stitched with the aid of a needle into the thickness of the mitral ring, parallel to the latter, at the ends of the large cusp 12. The distance between these two filaments corresponds to the width of the flattened zone 2 of the annular prosthesis and permits of defining the dimension of the prosthesis appropriate for the orifice under consideration.

About 20 filaments constituting as many absolutely equidistant stitches are positioned in the same way between the filaments 10 and 11 and around the whole periphery of the mitral ring, at the base of the cusps and immediately above. These filaments are then passed through the cord of the prosthesis, with an identical spacing for the filaments corresponding to the large cusp and with a reduced spacing for the filaments corresponding to the small cusp 13.

The prosthesis is then slid along the filaments against the mitral ring and thereafter fixed by knotting the filaments. The knots are substantially invisible and the projection of the prosthesis is insignificant, so that it can be rapidly overlapped and incorporated by the neighboring organic tissues.

The surgical technique of positioning the open ring is similar to that described above.

The described prosthesis permit of treating mitral inadequacies due, for example, to contraction of the large cusp, to opening of the commissural curvatures, to distension of the mitral ring in the zone of attachment of the small cusp, and so on. They also permit, after commissurotomy, of treating an orificial stricture due to a fibrous fusion of the commissures.

A prosthesis according to the invention has many advantages other than its simplicity and its safety of use. Owing to its particular form, it permits the preservation and repositioning of the valvular elements, as also the correction of various anomalies. For example, it permits repositioning and development of the large cusp, commissural remodelling, and reduction of the small cusp. Thus, it renders possible recontacting of the cusps in a mitral orifice of normal surface. The open ring prosthesis permits free movement of one of the cusps of a valve, notably the free movement of the large cusp in the mitral valve. In addition, owing to the rigid frame it is possible to distribute the tractive forces over a large number of points and to counteract secondary distension of the mitral ring. Finally, owing to the woven sheath to which the fibrin can adhere, it is rapidly incorporated in the tissues and therefore requires no prolonged anticoagulant treatment and involves no danger of thrombosis.

Although only two particular embodiments of mitral prosthesis have been described by way of example, a prosthesis according to the invention may undergo various modifications of construction and may readily be adapted to other valves, notably to the tricuspid valve, by using a ring of the same type, of circular form, or to the aortic valve by using a ring adapted to the trifoliate form of the aortic valvular orifice.

I claim:

1. A cardiac valve support for supporting the cusps of a natural human heart valve without excising said valve and cusps, consisting solely of: an elongated member curved along its length to define a generally ring-shaped rigid member of a size and shape to fit against the base of the cusps of a natural human heart valve, the central axis of said curved elongated member lying substantially in a single plane, and suture means for suturing the member in place, said suture means being substantially coextensive with said elongated member.

2. A cardiac valve support as claimed in claim 1, wherein the elongated member comprises a rigid frame, and wherein said frame and suture means are enclosed in a textile sheath.

3. A cardiac valve support as claimed in claim 2, wherein said frame comprises an asymmetric, outwardly hollow, channel section having unequal length flanges defining an external groove, and said suture means comprises a suturable cord disposed within said external groove.

4. A cardiac valve support as claimed in claim 3, wherein a reinforcing filament extends along said elongated member within said cord.

5. A cardiac valve support as claimed in claim 1, wherein said elongated member is curved in an annular shape, including a circular sector portion and a substantially straight portion together defining the annular periphery of said elongated member, said straight portion comprising between one-quarter and one-half of said periphery.

6. A cardiac valve support as claimed in claim 1, wherein said member is a part-annular member curved in an annular shape but omitting between one-quarter and one-half of the total peripheral length of said total annular shape, said part-annular member having spaced apart ends, the annular arcuate spacing between said ends being not less than about one third of the actual peripheral length of said part-annular member.

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