APPROATUS FOR MOLDING HEART VALVES

Inventors: Donald Nixon Ross; Derek Barrie Ray, both of National Heart Hospital West Moreland Street, London W.1, England

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Primary Examiner—Robert L. Spicer, Jr.

Attorney—Woodhams, Blanchard and Flynn

ABSTRACT

The invention relates to an apparatus and method for manufacturing replacement aortic heart valves using tissue taken from a patient's own thigh. The tissue is moulded between first and second complementary surfaces of two complementary forming members, the complementary surfaces corresponding to the configuration of the heart valve. The tissue when moulded is secured to a support.

14 Claims, 4 Drawing Figures
APPARATUS FOR MOLDING HEART VALVES

The present invention relates to surgical apparatus and method.

A technique has been developed for manufacturing a replacement heart valve using tissue taken from the thigh region of a patient undergoing treatment. Because the patient's own tissue is used, this so-called autograft technique avoids the serious problems of degeneration and calcification associated with the so-called homograft technique in which a faulty heart valve is replaced by a similar valve taken from a cadaver.

However, the manufacture of the replacement valve requires the tissue to be cut and shaped into the form of the cusps of the valve by the surgeon performing the operation. This is a time-consuming process and demands a high standard of competence on the part of the surgeon.

It is an object of the invention to provide a surgical apparatus by means of which the manufacture of autogenous tissue heart valves is facilitated.

It is a further object of the invention to provide apparatus which includes formers which mould tissue to the shape required.

It is also among the objects of the invention to provide for relative movement of the formers towards and away from each other during manufacture of a valve.

Further objects of the invention will be evident when reading the following description in conjunction with the accompanying diagrammatic drawings, which illustrate by way of example embodiments of the invention, in which:

FIG. 1 is a representation of one embodiment of the invention mounted in a frame;
FIG. 2 shows a perspective view of the co-operating surfaces of formers according to one embodiment;
FIG. 3 shows in perspective a second embodiment of one former;
and
FIG. 4 shows a support for use with the embodiments shown in FIGS. 2 and 3.

Referring to the drawings, a male former 11 and a female former 12 (FIG. 2) have complementary surfaces 13 and 14 respectively, which are so shaped as to conform to the configurations of the three cusps of an aortic valve.

The formers 11 and 12 are cylindrical and have respective recesses 15 and 16 in their bases into which fit locating pegs 17 and 18 that form part of a frame 19. The peg 17 is in a form of a spring-loaded plunger to facilitate the insertion of the former 11 and 12 into the frame 19. The peg 17 is also arranged to be adjustable, so that the spring pressure can be varied and thus provides varying pressure on the tissue. The frame 19 is mounted upon a stand 20 by means of a universal joint 21.

The shapes of the co-operating surfaces 13 and 14 are determined by taking a cast of an aortic valve and transferring the configuration of the cast to the female former 12. The former 12 is then used to cast a male reproduction 22 in silicone rubber, which is mounted on a poly methyl methacrylate cylinder 23 to form the male former 11. The male former 11 is made in this fashion so that the silicone rubber would act as a cushion and reduce the possibility of damage to tissue placed between the male and female formers.

A support 24 is used to maintain the tissue in the shape formed by the formers 11 and 12 when the tissue is placed therebetween. The support 24, which conforms accurately to the shape of the cusps of the aortic valve, is made of the plastics material known as polypropylene and is covered by biologically compatible woven or knitted plastics material such as Dacron or Teflon.

Referring now to the second embodiment shown in FIG. 3, the male former 11 includes a base 37 from which depend three finger-like members, 38, 39 and 40. The free ends of the members each include a pad 31, 32 and 33 respectively. The pads 31 and 32 are made from silicone rubber.

The member 38 is integral with the base 37. The members 39 and 40 are removable from the base 37, a spring clip 34 and 35 pivoted to the base 37 securing the respective member in seatings (not shown) in the base. The base 37 also includes a recess 15.

As described above with reference to FIG. 2, the former 12 is used to cast and mould to the required shape the pads 31, 32 and 33. The members 38, 39 and 40 and base 37 of the former 11 may suitably be of stainless steel.

In use of the embodiment shown in FIG. 2 to make an autogenous heart valve, the support 24 which is to form part of a valve to be made, is placed in position on the female former 12 with projections 24' coincident with the ridges 14'. Suitable pieces of tissue (not shown) taken for example from the thigh of a patient being operated upon, is then placed between the formers 11 and 12. There are three pieces of tissue, one being placed between each pair of co-operating surfaces 13 and 14. The formers 11 and 12 are then held together and mounted in the frame 19 by means of the pegs 17 and 18. The exposed edges of the tissue are then attached to the support 24 using standard surgical sutures or careful gluing or stapling and trimmed with scissors. The tissue is attached along the curves of the support, confirming to the curvature of the valve. This operation is facilitated by the universal joint 21. The formers 11 and 12 are then removed from the frame 19 and separated and the tissue is cut along the lines where the valve cusps meet, again with the aid of scissors.

In use of the embodiment shown in FIG. 3 the support 24 is placed in position on the former 12 with fingers 24' coincident with ridges 14' as previously described. The curved surfaces in the support 24 then correspond with the curved edges on the former 12.

The former is then mounted on the frame 19, the peg 18 on the frame entering the recess 16. The former 11 with members 39 and 40 removed, is then mounted on the frame, the peg 17 which is spring mounted, entering the recess 15. A single piece of autogenous tissue having one straight edge is then wrapped around the former 12 and then held in position between the pad 31 on the fixed member 38 and one cusp 14 of the former 12. The tissue is then folded into a second cusp and the demountable member 39 is secured in position in the base 37, the spring clip 24' being pivoted downwardly to engage the member 39 and hold it securely in position. The tissue is then securely held between the second cusp 4 and the pad 32 as well as between the first cusp 31 and the pad 31. The same procedure is used with respect to the other member 40.

The tissue is then moulded into the form of a tri-cuspid aortic valve. The edges of the tissue are then attached as before to the support 17 using standard surgical sutures or careful stapling or gluing and trimmed with scissors.

This operation is facilitated by a universal joint 21 on the stand 18.

When the mould is dismantled and the support is removed, a tri-cuspid heart valve is obtained using autogenous fresh tissue, and can be placed in a defective heart.

Thus both embodiments of the invention provide a process which can be carried out quickly and simply by unskilled personnel. Furthermore, the aortic valve produced in the process and apparatus of the invention can be manufactured in the operating theatre while the surgeon is engaged in the early stages of an operation. This enables the surgeon and his assistant to concentrate on the operation and removes the onus of manufacturing the replacement from them, shortens the operation and reduces the risk of infection.

We claim:

1. An apparatus for manufacturing a replacement heart valve comprising tissue taken from a patient, and further comprising forming means including first and second forming members having first and second complementary surfaces, respectively, the first surface being defined by a plurality of projections which conform to the configuration of the cusps of a heart valve, and the second surface being defined by a plurality of recesses which also conform to the configuration of the cusps of a heart valve.
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2. An apparatus according to claim 1, including mounting means mounting said first and second forming members for relative linear movement toward and away from each other.

3. An apparatus according to claim 2, wherein the mounting means includes spring means for resiliently urging the first and second forming members in a direction toward each other.

4. An apparatus according to claim 1, including stationary support means, frame means rotatably mounted on said support means, means coacting with said frame means and said support means for selectively fixedly securing said frame means in a selected position relative to said support means, and means mounting said first and second forming members on said frame means for permitting relative linear movement of said forming members toward and away from each other.

5. An apparatus according to claim 4, wherein said frame means includes a substantially U-shaped member rotatably mounted on said support means for rotation about a substantially horizontal axis, and said first and second forming members being mounted on said U-shaped member substantially adjacent the free ends of the legs thereof for relative linear movement in a direction substantially transverse to said horizontal axis.

6. An apparatus according to claim 5, further including spring means coacting between said U-shaped member and one of said forming members for resiliently urging said one forming member into engagement with said other forming member.

7. An apparatus according to claim 1, wherein said first and second forming members are cylindrical, and wherein the projections formed on said first forming member are constructed of an elastomeric material so as to act as a cushion when the forming members are positioned in engagement with one another so as to not damage the tissue placed therebetween.

8. An apparatus according to claim 7, further including a sleeve-like support member positioned in surrounding relationship to said forming members, said support member having projections adjacent one end thereof having a configuration conforming to the shape of the cusps of the heart valve and being made of a plastics material for permitting the edges of the tissue, when positioned between the forming members, to be sewn thereto.

9. An apparatus according to claim 1, wherein the plurality of projections comprise three finger-like members spaced equidistantly around the periphery of one of said forming members for co-operating with said other forming member.

10. An apparatus according to claim 9, wherein two of said finger-like members include means whereby the two finger-like members are demountable from said one forming member.

11. An apparatus according to claim 9, wherein the finger-like members each include a pad at one extremity, which pads conform to the configuration of said recesses.

12. An apparatus according to claim 1, wherein the plurality of projections comprise three finger-like members spaced equidistantly around the periphery of one of said forming members, two of said two demountable dismantled from said one forming member.

13. An apparatus according to claim 12, wherein said one forming member includes securing means mounted on said forming member coacting with said two demountable members for securing said finger-like members in said one forming member when inserted in said one forming member.

14. An apparatus according to claim 13, wherein said securing means comprise spring means rotatably mounted on said one former member for coacting with respective stem means of said two finger-like members.

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