METHOD AND DEVICE FOR MANUFACTURE OF HEART VALVE

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ABSTRACT

A method and device for the manufacture of a replacement heart valve made of a heart valve ring or frame having a metal ring base and struts and being covered with suture-accepting fabric and tissue. A rotatable valve ring holder has a means to hold the ring firmly and is movable axially. Opposed to the holder on a common axis is a rotatable arbor adapted to hold, successively, a primary mandrel and a secondary cusp-forming mandrel. The primary mandrel is provided with recesses in its side wall so as to nest with the ring and its struts and to enable wrapping and securing in place, e.g., by stapling, a precisely sized strip of animal, advantageously autologous, tissue to cover surfaces of the valve ring. The secondary mandrel is inserted in the arbor after removal of the first mandrel, and it is provided with pivotally attached arms. Each arm has a block at its end with a protruding, interior surface to hold the tissue cusps in coaptation, there being a corresponding number of such arms and blocks and such cusps. The tissue is sutured to the ring while the cusps are so held by the secondary mandrel, and thereafter the finished heart valve is removed from the device or assembly.

15 Claims, 6 Drawing Figures
METHOD AND DEVICE FOR MANUFACTURE OF HEART VALVE

BACKGROUND OF THE INVENTION

A number of types of artificial heart valves have been developed in the art. Those valves which are constructed from tissues commonly located elsewhere in the patient's body have many advantages over non-autologous tissues or fabrics. For instance, with autologous tissues to form blood-exposed surfaces, there is freedom from coagulation, and, in addition, with such tissues there is tissue compatibility, availability at the desired time of surgery, and good flexural strength.

In using such tissues, it is common practice to mount a membranous tissue, usually fascia lata, on a valve frame so that the tissue is made to assume the shape of a cusped heart valve. However, the nature of this tissue material is such that it is extremely difficult to work with, being slippery and very tough. Also, since this heart valve is usually fabricated at the time of cardiac surgery it is imperative that the fabrication procedure be both rapid and precise.

Current practice in this field is to excise the required amount of tissue, then to drape the piece over the valve ring or frame and hold the cusps together with one's fingers while sewing the tissue to the ring; or to mechanically hold the cusps together while sewing or suturing. It is a disadvantage of current and prior art procedures that they do not provide precision sizing of tissue, and another disadvantage is the lack of reproducible shaping of valve cusps. A further important disadvantage is that a relatively long time is required during surgery to prepare the prior art valves.

The above and other disadvantages are overcome by the present invention and further advantages are obtained thereby as will be seen from the description below and the annexed drawings. It is an advantage of the device of this invention that it provides centerline fixation of both the ring and tissue. A further advantage is that there is provided precision sizing of the tissue, so that when the valve is completed there will be sufficient coaptation. Another important advantage of the device of this invention is that the complete assembly can be rotated about its long axis for rapid and easy suturing of the tissue to the ring. Still another advantage is that preparation of the valve is accelerated compared to prior art methods, which is very desirable because such preparation must be done at the time of surgery.

SUMMARY OF THE INVENTION

The assembly of this invention is a lathe-like device which includes a rotatable valve holder means and a rotatable arbor mounted opposite and spaced from each other advantageously on a common axis, on a suitable base. The rotatable valve holder means is movable back and forth along its central axis and includes an expandible means, at the end facing the arbor, to receive the valve ring and to hold it firmly in operative position to enable suturing of tissue thereto. Means are also provided to hold the valve holder in axial position, if desired. A pair of cusp-forming mandrels are provided, to be detachably affixed to such arbor.

A primary mandrel which is detachably affixed to the arbor, is adapted to receive the struts of the valve frame or ring, which comprises a metal ring base and two or more metal struts extending therefrom, at the same surface of the ring, generally parallel to the central axis thereof, the metal surfaces being covered with a suitable fabric such as Dacron or Teflon, and especially knitted Teflon (polymerized tetrafluoroethylene), to enable suturing. Suitable such primary mandrel is of generally frusto-conical shape tapering inwardly toward the top or end facing the valve holder means, and has recesses in its sides and generally parallel to its axis to receive the struts in a nesting arrangement or fit.

At the base of this mandrel is an annular shoulder to locate the edge of the tissue to be employed. The configuration of this mandrel is such that it locates and it determines the size and shape of the tissue required for each cusp.

A secondary mandrel, which is detachably affixed to the arbor, e.g., by screwing, is inserted into the assembly after removal of the first or primary mandrel in the procedure described more in detail below. The secondary mandrel comprises a base adapted to be affixed, e.g., by screwing, to the arbor and a plurality of arms extending from the outer surface of such base, i.e., the surface facing the valve holder means, and pivotally affixed to such base whereby the arms can be swung outwardly from the central axis of this element and inwardly, as desired. Disposed at the outermost end of each arm is a block having a centrally facing protruding portion adapted to maintain the valve cusps in coaptation position for final suturing of the tissue to the valve ring. In preparation of a tricuspid valve, which will be described below as illustrative of this invention, the protruding portion is suitably of triangular cross-section; and in preparation of a bicuspid valve, such portion is approximately rectangular in cross-section taken perpendicular to the longitudinal axis of the valve. In this secondary mandrel, means are also provided to hold the block faces or protruding portions in position adjacent each other so as to maintain the valve cusps in coaptation position during suturing. Such means can be a threaded ring, operable by hand, whereby as such threaded ring is advanced toward the valve, it provides clamping force on the block faces.

In performing the method of this invention, the valve holder is fitted with the valve frame or ring and the expandible means is expanded to press against the interior of such ring and hold it firmly in place. The primary mandrel is affixed to the arbor, and the valve holder is moved inwardly axially until the mandrel abuts the ring and the struts of the ring nest in the recesses of the mandrel, the number of recesses corresponding to the number of struts. Since both the arbor and the valve holder are rotatable, positioning is readily effected.

A strip of autologous tissue, suitably cleaned and of appropriate size, is draped around the mandrel into which the ring struts are nested, then is attached, preferably by means of metal staples, to each of the struts in turn, thereby locating and determining the tissue for each cusp. After fixation of the last pair of staples, the primary mandrel is withdrawn by retracting the valve holder along its axis and the primary mandrel is detached. A single stitch is taken through the tissue at the exact center of each cusp and the secondary mandrel is inserted in the arbor. The arms of the latter are extended outwardly to pass over the exterior surface of the tissue-covered ring and the valve holder is
moved inwardly until the blocks of the secondary mandrel are in position over the corresponding valve cusp portions of the tissue and clear the ring so that the arms and blocks can now be pivoted inwardly to fold the tissue partially around each strut and to hold the valve cusps in coaptation position. The free ends of the single stitch are drawn towards the secondary mandrel to position the free edges of the tissue. With the block faces adjacent to the tissue, the clamping ring is tightened. The tissue is now sutured to the valve ring around each strut and along the ring base. The valve holder is now retracted, the valve removed, and the center stitch is removed — and, if desired, the staples may be removed — from the finished valve, which is now ready for insertion.

**BRIEF DESCRIPTION OF THE DRAWINGS**

One embodiment of the present invention is shown in the following description and in the annexed drawings, wherein:

FIG. 1 is a perspective view of the lathe-like assembly of this invention.

FIG. 2 is a cross-sectional view of the assembly of FIG. 1, taken on line 2—2.

FIG. 3 is a front elevational view of the valve holder, valve ring, and primary mandrel in position abutting each other, the valve tissue being shown in phantom.

FIG. 4 is a perspective view of the secondary mandrel in an approach position to the tissue-wrapped valve ring and holder.

FIG. 5 is a perspective view of the secondary mandrel and showing the blocks thereof in engagement with the valve cusps on the valve ring.

FIG. 6 is a perspective view of a tricuspid valve made by the assembly of this invention.

**DETAILED DESCRIPTION OF THE INVENTION**

The invention will be described with reference to one embodiment, i.e., the production of a tricuspid valve having an autologous fascia lata coating, as illustrative of this invention.

Referring to the drawings, a lathe-like assembly or device 10 on a base 19 includes a valve-ring holder means 11, having a central shaft 12 terminating in a spherical head 13 at its forward end 14 and having a hand-operable wheel 15, suitably knurled, at its opposite end 16. The shaft 12 passes through a hollow second shaft 30 which is threaded at its inmost end 18 to engage similar threading on the shaft 12 whereby the latter can be moved axially as desired. The shaft 30 also has at least two positioning annular indentations 20 in its exterior side wall. The indentations 20 are adapted to receive a ball detent 21 to retain the shaft in desired position relative to either of the mandrels to assure proper placement and suturing of the tissue to the ring in operation of the device, and also access to insert or remove the valve or mandrels. The ball detent 21 is spring-loaded in conventional manner (not shown) in its threaded housing 21a and tension is adjusted as desired by adjusting the detent 21.

Affixed to the forward end of the valve holder means 11 is an expansion element or chuck 23 comprising an annular collar 24 on the shaft or arbor 30 having an outer surface or periphery to which is threadedly attached an annular holding element 25. The element 25 is spaced from the forward surface of the collar 24 and centered with the aid of a shoulder 22 to provide space to receive in fixed position, shoulder portion 26 of the chuck 23 having four forwardly extending segments 27 so that the chuck 23 can be suitably expanded and contracted by the outward and inward movement of the shaft 12 and the spherical head 13. An interior wall 31 of element 27 tapers outwardly from where it reaches the forward surface 28 to its rear end to accommodate the spherical head 13 which accomplishes the expansion and contraction. As can be seen especially from FIG. 2, as the head 13 is moved back by rotating the threaded shaft 12, the elements 27 can move inwardly to collapse the chuck 23 toward the axis of the shaft 12, for release of the valve ring during operation of the device. A second hand-operable wheel 17 is affixed to the shaft or arbor 30 and acts to rotate the shaft or arbor 30 and attached parts to bring the workpiece surface within easy reach of the operator.

Disposed opposite the chuck 23 and suitably supported on the base 19 is an arbor 33 having affixed thereto a handwheel 34 to enable rotation of the arbor 33 and attached pieces, as desired.

A first or supporting mandrel 35 is shown in FIGS. 1 and 2 as threadedly affixed to the arbor 33 and is a generally cylindrical device with a frusto-conical wall 36 tapering inwardly at the upper portion toward the front of a head 37 and having at its rear end an annular collar 38. A plurality of recesses 39 (FIG. 1) are provided in the frusto-conical wall 36 to receive struts 40 of a later-inserted valve frame or ring 42, as shown in FIG. 3, when the shaft 30 and its attached elements are set inwardly in operating position as in FIGS. 2 and 3. In this embodiment, the mandrel 35 and supported parts screw into the arbor 33, and there are provided in the illustrated embodiment three recesses 39, in order to make a tricuspid valve. For a bicuspid valve, there would be only two recesses 39. This mandrel 35 is used in an initial phase to place a tissue 41 on the valve ring or frame 42.

For positioning the cusps for suturing, the mandrel 35 is replaced by a secondary or second mandrel 45, shown in FIG. 4, and comprising a cylindrical base 46, which is then threadedly attached to the arbor 33, (arrangement not shown) when in operation. Spring arms 48 are attached to a threaded cylindrical extension 49 on hub 46, so that these arms 48 and attached blocks 50 tend to spring outwardly. In the embodiment for a tricuspid valve there are three such arms 48, each having a block 50 at its outer end. Each block 50 has a protruding inner surface 51 adapted to hold valve tissue cusps 60 in coaptation positions during suturing, as shown in FIG. 5. In this embodiment, the surface 51 is of substantially triangular cross-section taken perpendicularly to the finger or arm 48, whereby the later-formed cusps 60 meet in coaptation at a central apex 61 as in FIG. 6. The mandrel 45 is also provided with an actuating ring 53 threadedly connected to an extension 49 suitably made of stainless steel, surrounding the arms 48 and adapted to be moved by hand up and down along these arms 48 to move them inwardly against the spring pressure and to hold the blocks 50 in place during suturing of tissue to the fabric 54 on the ring and then to allow them to be moved out when suturing is finished. As shown in FIG. 5, after the tissue 41, such as
autologous fascia lata, has been wrapped around the valve ring 42, (as in FIG. 4), the blocks 50 engage the cusp portion 60 of the tissue 41 and hold them in coaptation position, and the ring 53 is disposed along the length of the arms 48 to hold the blocks 50 firmly in position.

In operating the device of this invention and carrying out the method, the primary mandrel 35 and supported parts are screwed into the arbor 33, and the fabric-coated valve frame or ring 42 is placed on the expandable element or chuck 23. The shaft 12 is moved inwardly, forcing the spherical head 13 against the walls 31 and causing the elements 27 to move outwardly and engage the interior of the valve ring 42. Then the shaft 30 and its affixed elements including the shaft 12 are moved inwardly until the struts 40 nest in the recesses 39 of the mandrel 35. A strip 41 of fascia lata or similar tissue is excised and is suitably cleaned and then is wrapped around the mandrel 35, abutting the shoulder 38, and the valve ring 42, as shown in phantom in FIG. 3, and is stapled at the face of each strut 40. The staples 55, set into the valve ring at the time of manufacture are closed in sequence to attach tissue 41 to each strut 40. The mandrel 35 and its supported parts are then removed, and a single stitch is taken through the tissue at the exact center and near the free edge of each cusp 60. The mandrel 45 is screwed into the arbor 33, and its arms 48 set in outward position. The valve holder 51 with tissue and the ring 42 are moved inwardly toward the mandrel 45 until the blocks 50 are above the cusp portions 60 between the struts 40. Then the blocks 50 are lowered into position forcing the cusps 60 to coapt, by moving the clamping ring 53 forwardly along the arms 48. With the block faces 51 adjacent to the tissue 41 in almost closed position, the free ends of the single stitch are drawn towards the mandrel 45 to position the free edges of the tissue and the clamp or ring 53 is tightened. Suturing is then effected along the struts 40, and the upper surfaces of the ring base 62 of the valve ring 42, rotating the device as needed to bring the entire periphery into easy reach of the operator. The ring 53 is then moved back, the blocks 50 are raised out of contact with the tissue, the valve holder 11 retracted to open position, and the finished valve removed by withdrawing the shaft 12, thus moving the spherical head 13 axially to permit the elements 27 on the chuck 23 to move in toward the axis, disengaging the valve ring 42. The stitch holding the centers of the cusps 60 together is then removed, and, at the option of the surgeon, the staples 55 may also be removed.

The above specific description and the drawings have been given for purposes of illustration only and it will be understood that variations and modifications can be made therein without departing from the spirit and scope of the appended claims.

Having now described the invention, what is claimed is:

1. A device for the production of a heart valve which comprises in combination:
   means of aligning two independent rotatable arbors,
   each said arbor having at least one detachable holding member, along a common axis,
   means of detachably securing a valve frame to a first said holding member of one said arbor,
   means to bring a second said holding member of the other said arbor into abutting relationship with said first holding member holding said valve frame,
   said second holding member tapering outwardly from the area of abutment to provide a frusto-conical shape to tissue that may be applied thereto, and
   means to hold said tissue to form a plurality of cusps in coaptation position on said valve frame.
2. A device for making a heart valve which comprises in combination:
   a first and a second rotatable arbor, said arbors being aligned along a common axis in lathe-like fashion, each said arbor having a detachable holding member likewise aligned therewith,
   means to detachably affix a heart valve frame to one said holding member on said second arbor,
   means to bring said other holding member on said first arbor into abutting relationship with a heart valve frame on said one holding member when in operation, whereby a strip of later-applied tissue is accommodated to form a frusto-conical shape, and
   a third holding member successively affixable to said first arbor to coat with said valve frame to hold said later-applied tissue in coapting cusp position for suturing.
3. In a lathe-like device or assembly for production of a heart valve and having a longitudinal axis, the improved combination including:
   a. a rotatable arbor,
   b. a rotatable heart valve ring holder disposed opposite said arbor on a common longitudinal axis and spaced therefrom, and movable along said axis,
   c. said heart valve ring holder having at its forward end a radially expandible valve ring holding element,
   d. a primary mandrel of generally frusto-conical shape tapering toward the top and having a plurality of recesses in the side wall thereof parallel to said longitudinal axis,
   e. a secondary mandrel having a top surface and a plurality of arms pivotally attached to said surface and extending therefrom toward said valve ring holder,
   f. said primary and secondary mandrels being successively affixed detachably to said arbor,
   g. a block attached at the outer end of each said arm and having a protruding surface at the inner portion of each said block adapted to maintain a cusp shape to applied tissue in coaptation position therewith,
   h. means to hold said arms in position, and
   i. means to maintain said valve ring holder in desired position.
4. The device or assembly of claim 3 having means to hold said valve ring holder in desired position along said axis.
5. The device or assembly of claim 4 wherein said valve ring holder has at least two annular recesses and said means to hold said holder is a ball detent to engage said recesses.
6. The device or assembly of claim 3 having means to hold said blocks in contact with said cusps.
7. The device or assembly of claim 6 wherein said means to hold is a metal ring surrounding said arms and movable thereover.

8. The device or assembly of claim 3 wherein said secondary mandrel has three of said arms and said device or assembly is adapted to form a tricuspid valve.

9. The device or assembly of claim 3 wherein said primary mandrel has three said recesses adapted to receive three struts of a later-inserted valve ring in nest ing fit and said mandrel is adapted to form a tricuspid valve.

10. The device or assembly of claim 3 wherein said secondary mandrel has three of said blocks and said protruding surface is of substantially triangular cross-section taken perpendicularly to said arm, and said device is adapted to form a tricuspid valve.

11. A method for making a heart valve from a fabric covered frame having a ring base and a plurality of struts extending generally axially from said ring base, and from animal tissue, comprising

   fixedly supporting said ring base,
   abutting said struts with a frusto-conical mandrel,
   draping tissue on said frame and mandrel,
   securing said tissue to said struts,
   withdrawing said mandrel,
   taking a single stitch through said tissue through the center of each cusp,
   extending the free ends of said single stitch to position the free edges of said tissue while simultaneously and uniformly forcing in said tissue toward the axis of said frame at all locations midway between struts, to form a plurality of cusps having a common vertex distant from the ring,
   forcing in said tissue further toward said axis, simultaneously and uniformly, to take up slack in the tissue,
   suturing said tissue to the fabric covering of each said strut and to the fabric covering of said ring base,
   releasing the tissue from the pressure forcing it in, and
   withdrawing said single stitch.

12. The method of claim 11 wherein the fixedly supported ring base is rotated during the suturing step.

13. The method of claim 11 wherein said securing step is done by stapling the tissue to the fabric covering of the struts.

14. The method of claim 13 wherein the staples are removed after the suturing step.

15. The method of claim 11 wherein the ring base is withdrawn from its fixed support at a time following said releasing step.

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