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(54) **METHODS AND DEVICES FOR IMPROVING MITRAL VALVE FUNCTION**

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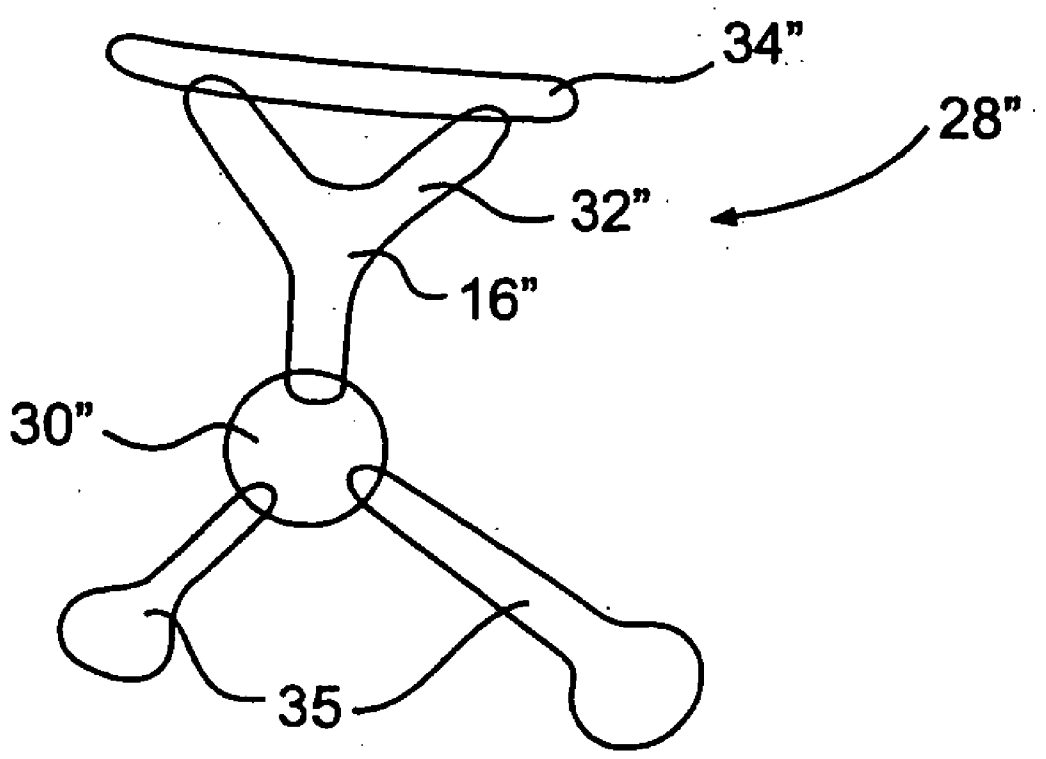
(52) **U.S. Cl.** **600/37**; 623/904

(57) **ABSTRACT**

The various aspects of the invention pertain to devices and related methods for treating heart conditions, including, for example, dilatation, valve incompetencies, including mitral valve leakage, and other similar heart failure conditions. The devices and related methods of the present invention operate to assist in the apposition of heart valve leaflets to improve valve function. According to one aspect of the invention, a method improves the function of a valve of a heart by placing an elongate member transverse a heart chamber so that each end of the elongate member extends through a wall of the heart, and placing first and second anchoring members external the chamber. The first and second anchoring members are attached to first and second ends of the elongate member to fix the elongate member in a position across the chamber so as to reposition papillary muscles within the chamber.



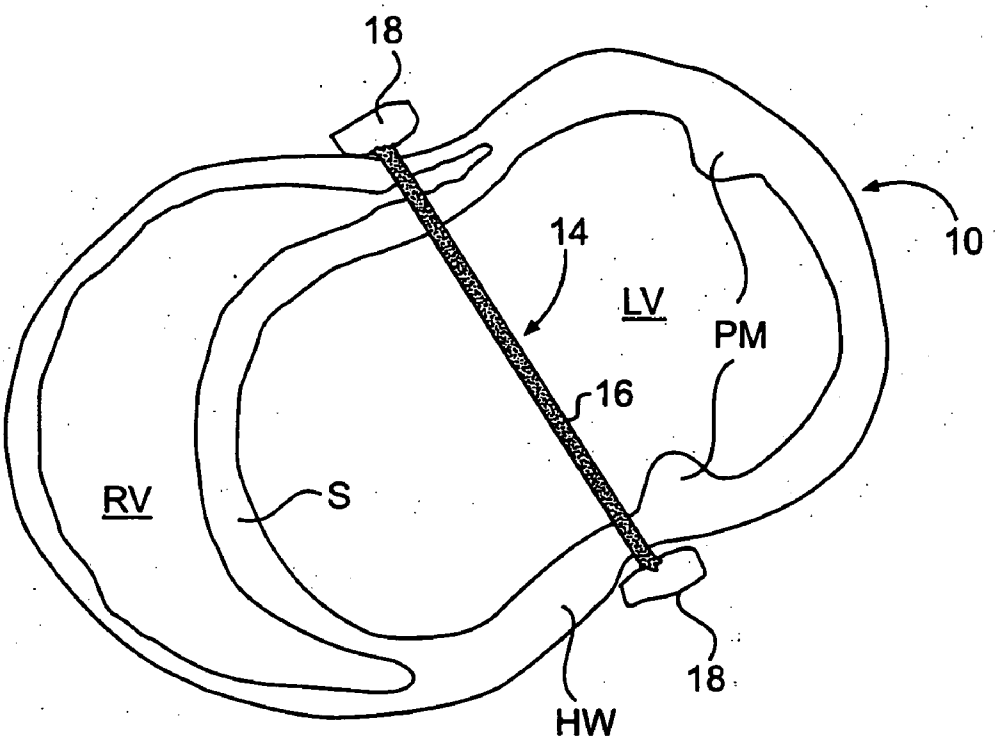


FIG. 1

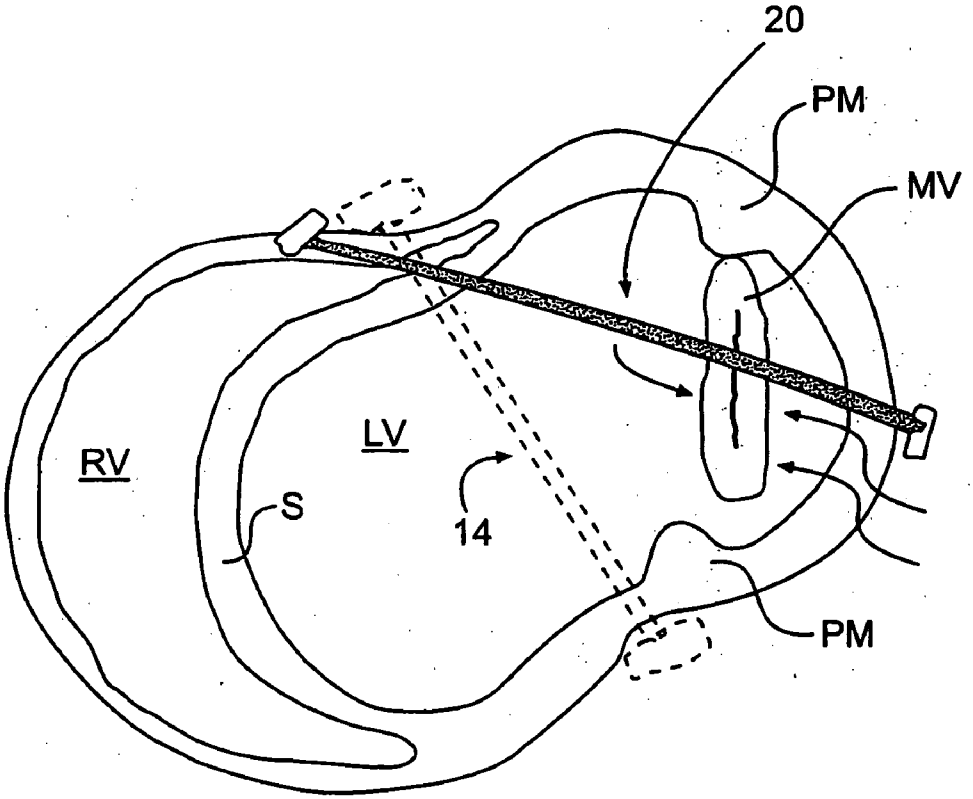


FIG. 3a

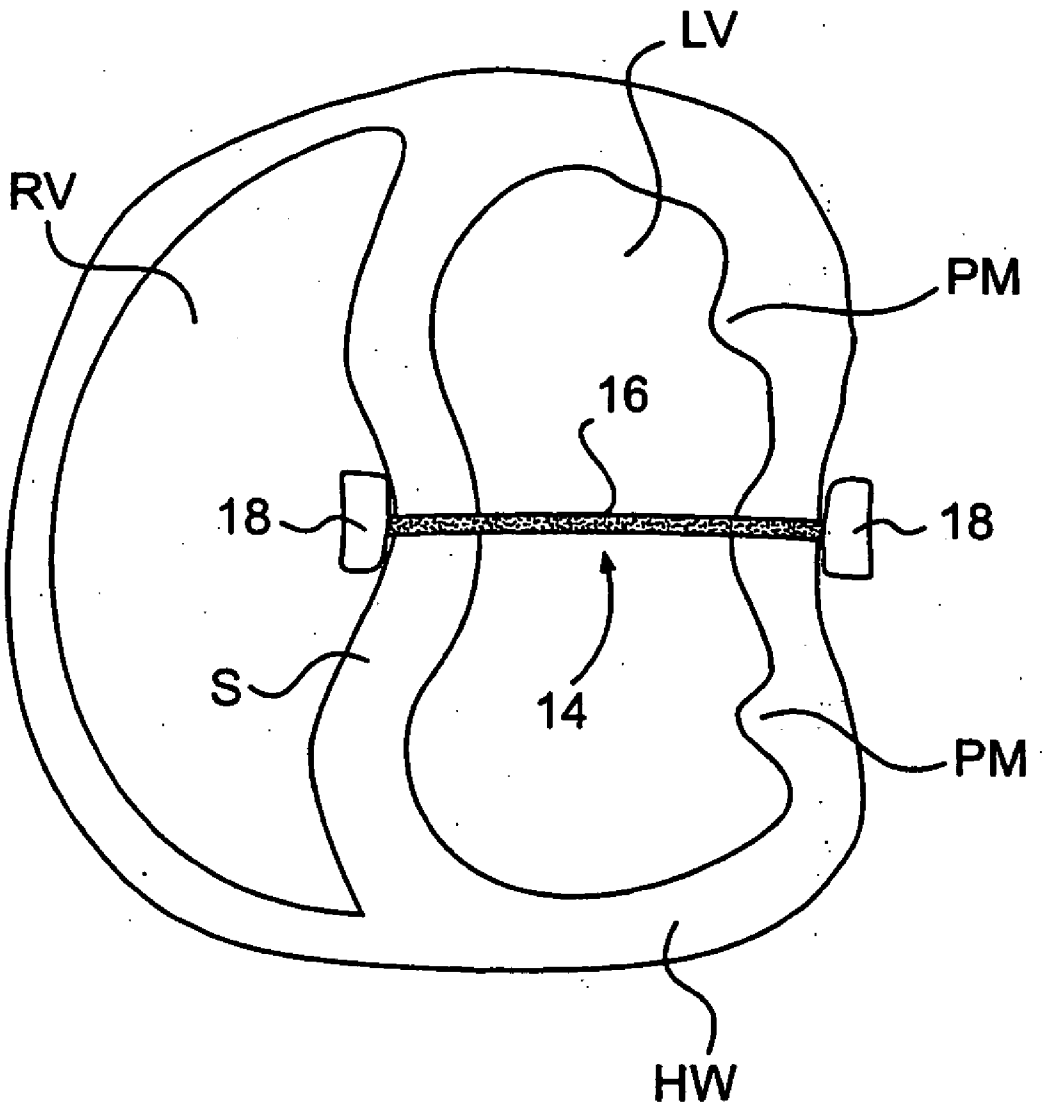


FIG. 2a

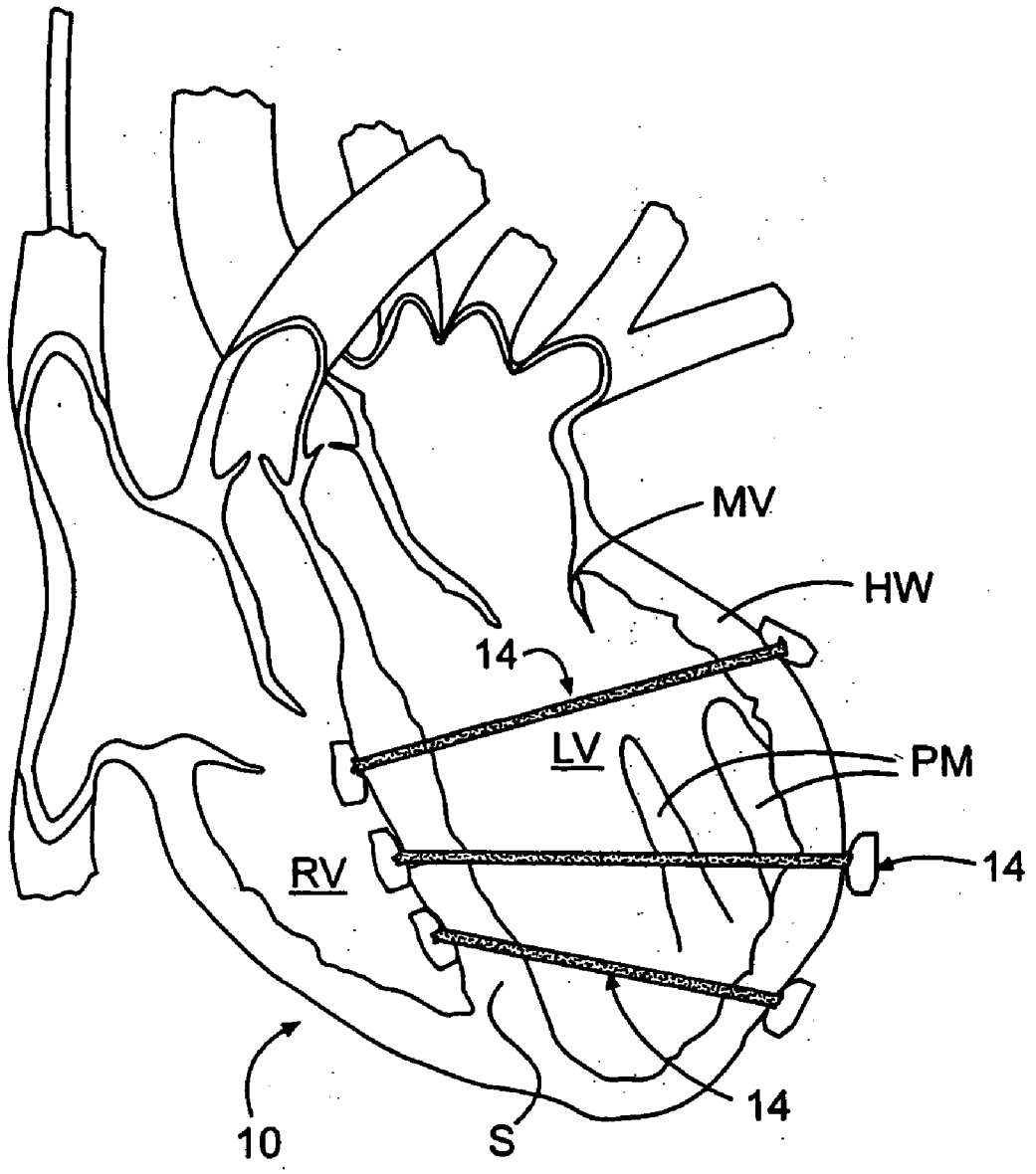


FIG. 2b

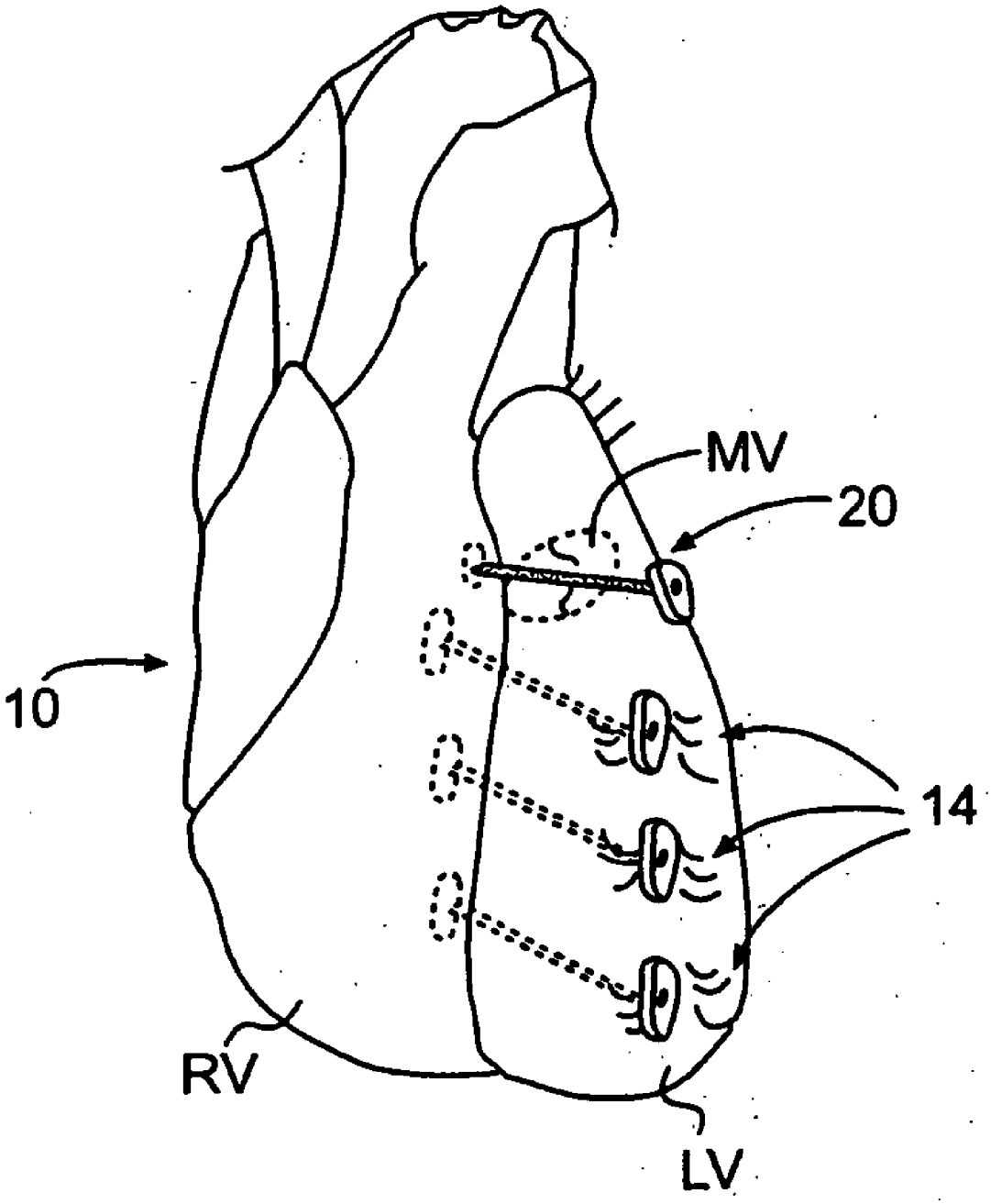


FIG. 3b

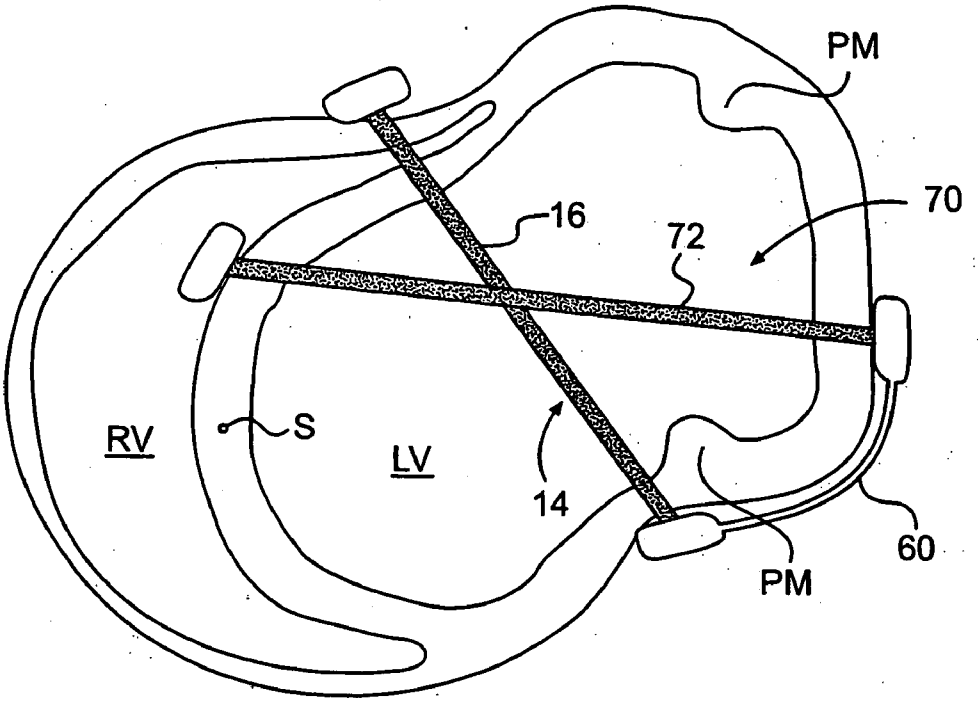


FIG. 6

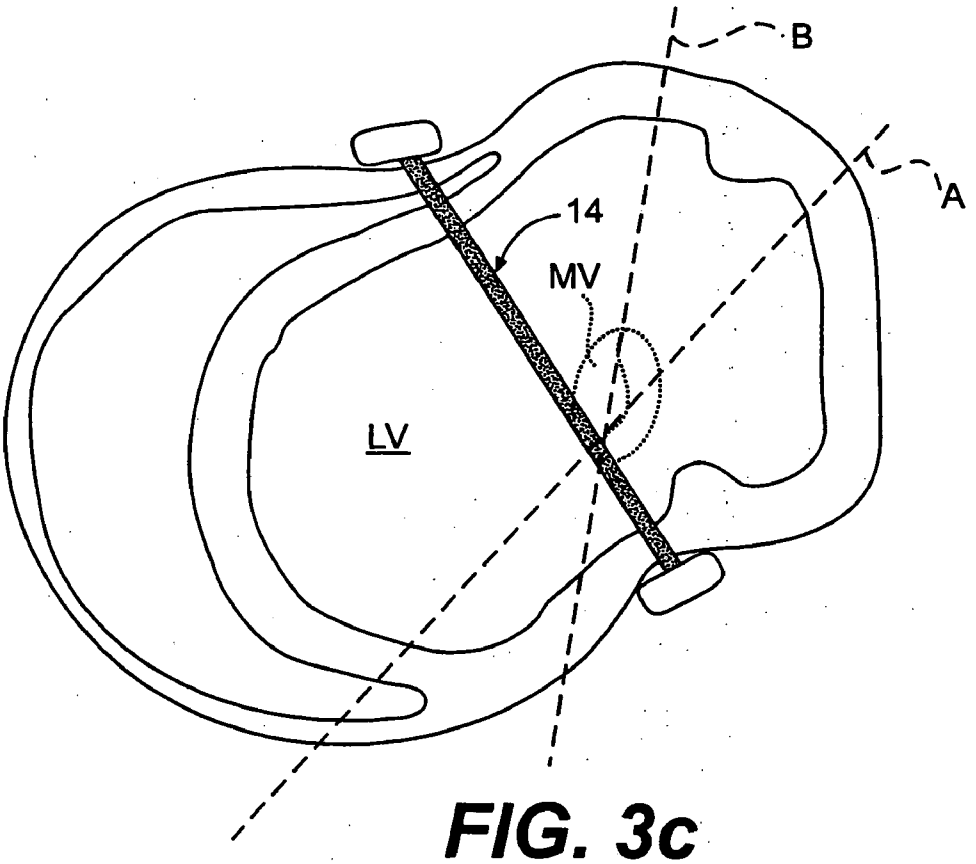


FIG. 3c

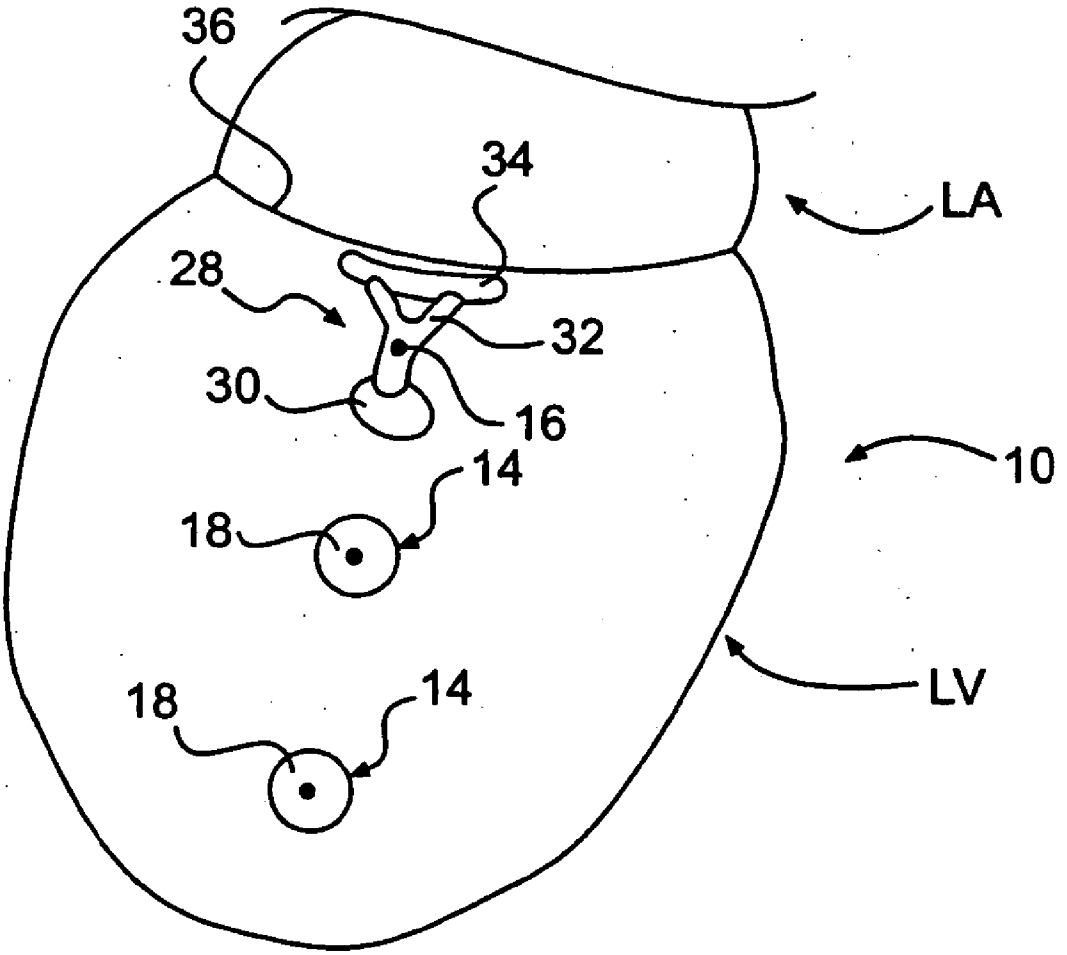


FIG. 4a

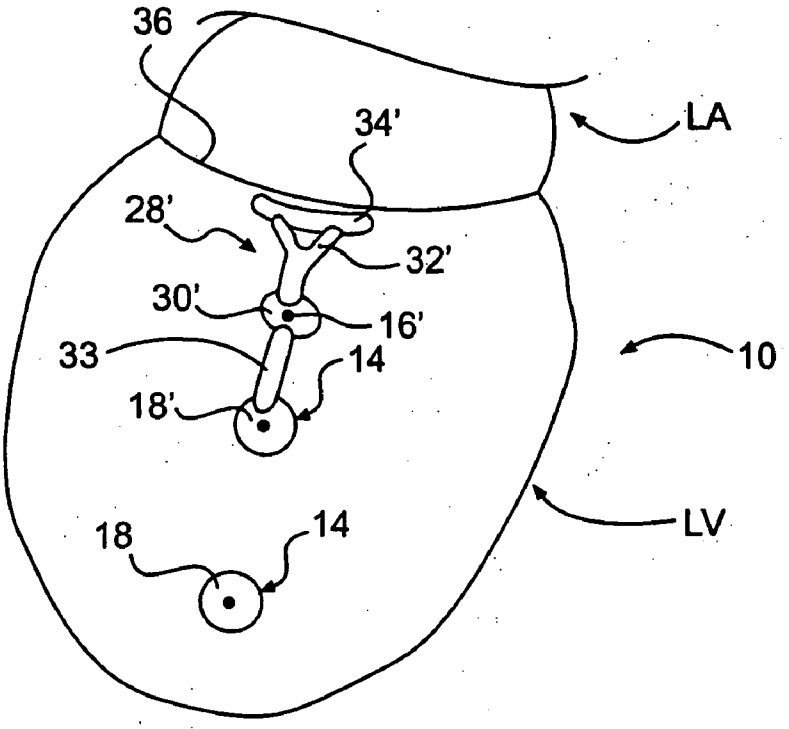


FIG. 4b

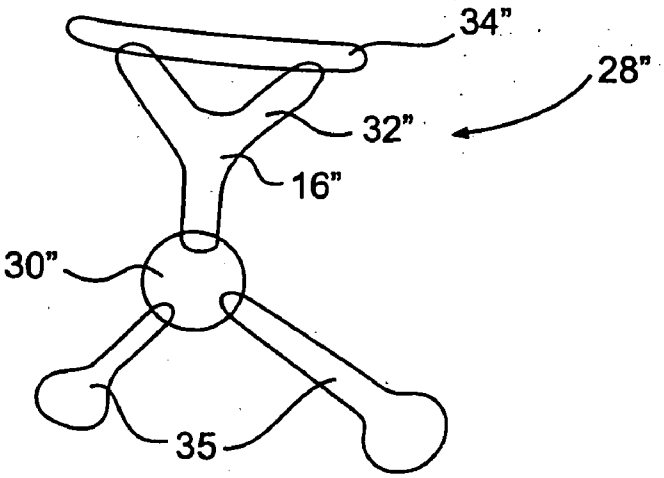


FIG. 4c

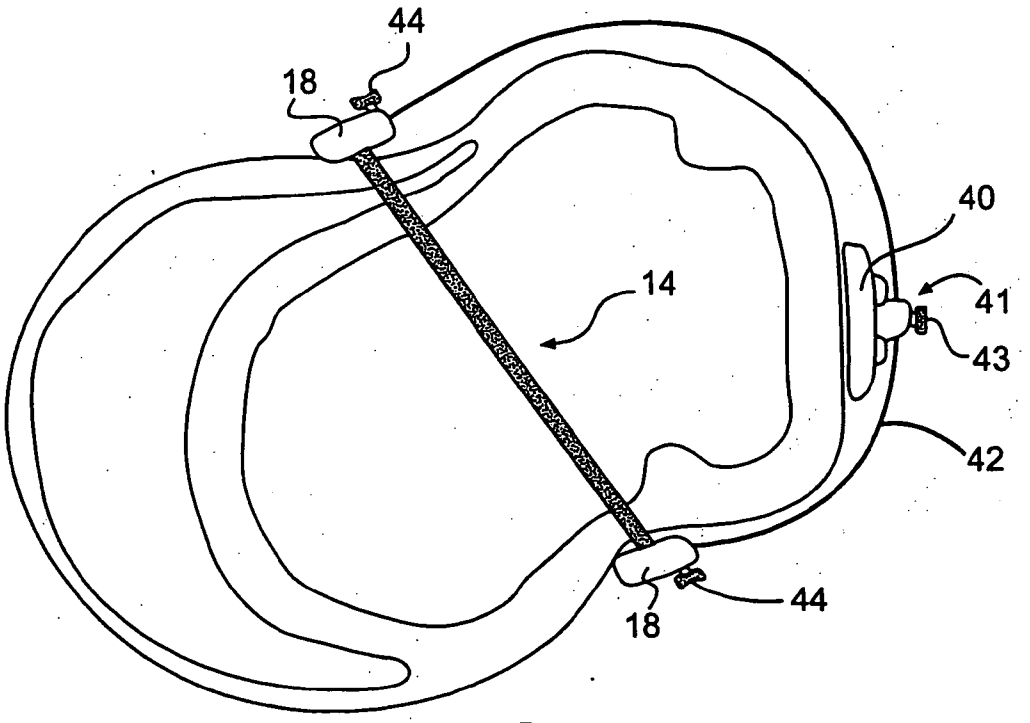


FIG. 5a

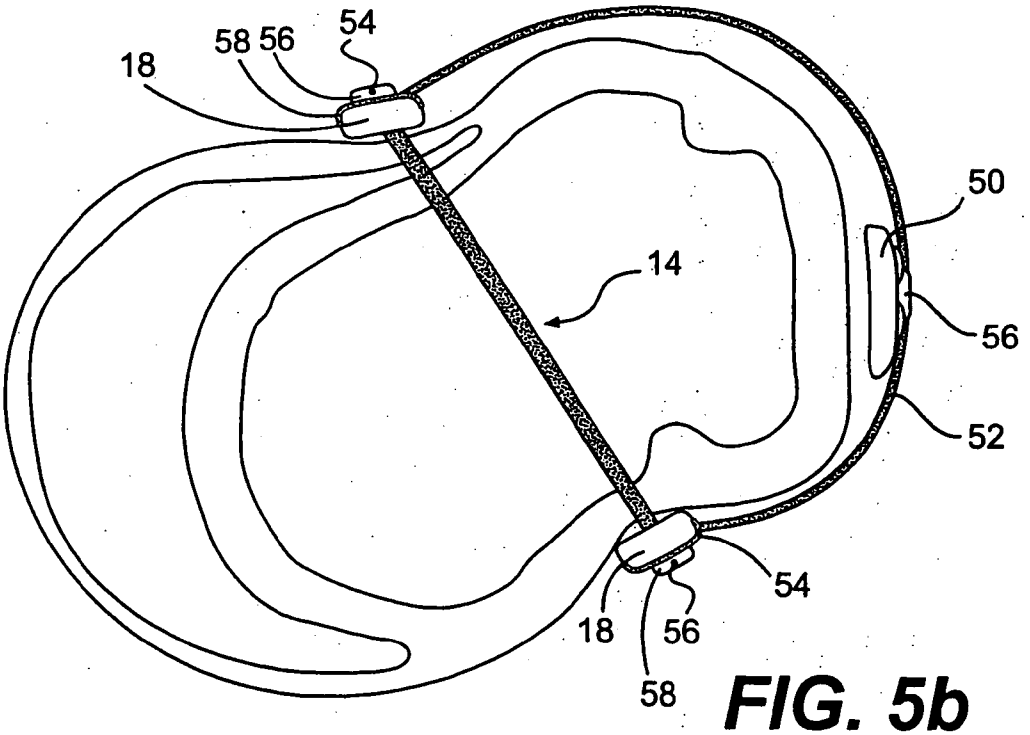


FIG. 5b

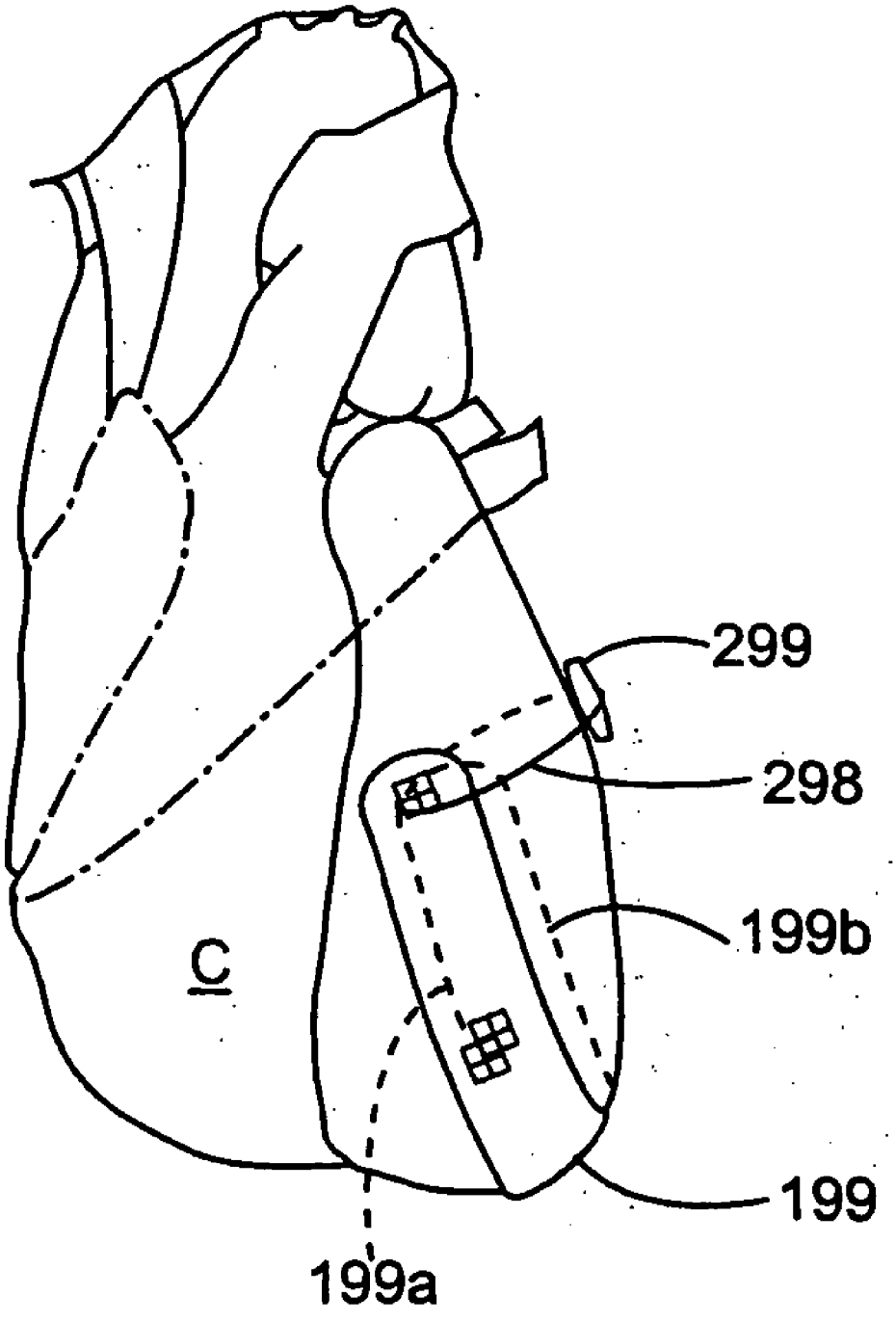


FIG. 7

METHODS AND DEVICES FOR IMPROVING MITRAL VALVE FUNCTION

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] The present invention relates to devices and related methods for improving the function of heart valves, and more particularly to devices and related methods that passively assist in the apposition of heart valve leaflets to improve valve function of poorly functioning valves.

[0003] 2. Description of the Related Art

[0004] Heart failure is a condition whereby the left ventricle becomes enlarged and dilated as a result of numerous etiologies. Initial causes of heart failure include chronic hypertension, myocardial infarction, mitral valve incompetency, and other dilated cardiomyopathies. With each of these conditions, the heart is forced to overexert itself in order to provide the cardiac output demanded from the body during its various demand states. The result is an enlarged left ventricle.

[0005] A dilated heart, and particularly a dilated left ventricle, can significantly increase the tension and/or stress in the heart wall both during diastolic filling and systolic contraction, which contributes to ongoing dilatation of the chamber. Prior treatments for heart failure include pharmacological treatments, assist devices such as pumps, and surgical treatments such as heart transplant, dynamic cardiomyoplasty, and the Batista partial left ventriculectomy. These prior treatments are described briefly in U.S. Pat. No. 5,961,440 to Schweich, Jr. et al., issued Oct. 5, 1999 and entitled "Heart Wall Tension Reduction Apparatus and Method," the complete disclosure of which is incorporated by reference herein.

[0006] A more recent concept for treating heart failure applies one or more splints onto the heart, and particulary the left ventricle, to reduce the myocardial muscular stresses encountered during pumping. Many examples of such approaches are disclosed in the incorporated U.S. Pat. No. 5,961,440. One example includes one or more transventricular splints placed across the left ventricle. Each splint may include a tension member extending across the ventricle and anchors disposed on opposite ends of the tension member and placed on the external surface of the heart.

[0007] Mitral valve incompetency or mitral valve regurgitation is a common comorbidity of, congestive heart failure. As the dilation of the ventricle proceeds, valve function may worsen. The resultant volume overload condition, in turn, increases ventricular wall stress thereby advancing the dilation process, which may further worsen valve dysfunction.

[0008] In heart failure, the size of the valve annulus (particularly the mitral valve annulus) increases while the area of the leaflets of the valve remains constant. This may lead to an area of less coaptation of the valve leaflets, and, as a result, eventually to valve leakage. Moreover, in normal hearts, the annular size contracts during systole, aiding in valve coaptation. In heart failure, there is poor ventricular function and elevated wall stress. These effects tend to reduce annular contraction and distort annular size, often exacerbating mitral valve regurgitation. In addition, as the chamber dilates, the papillary muscles (to which the leaflets are connected via the chordae tendonae) may move radially outward and downward relative to the valve, and relative to their normal positions. During this movement of the papillary muscles, however, the various chordae lengths remain substantially constant, which limits the full closure ability of the leaflets by exerting tension prematurely on the leaflets. This condition is commonly referred to as "chordal tethering." The combination of annular changes and papillary changes results in a poorly functioning valve.

[0009] It has been observed that for at least certain placements, or orientations, of the one or more transventricular splints in humans, a pre-existing mitral valve incompetency can be exacerbated by the presence and impact of the tightened splints. The splints and the local deformation they impart may further alter the positions of the papillary muscles in such a way that the chordae do not allow as complete of a closure of the mitral valve, or that rotation of portions of the ventricular wall (to which additional chordae may be attached) may "tighten" one valve leaflet and "loosen" the other. In this manner, the leaflets may not close at the same level relative to the annulus, causing increased retrograde leakage through the valve.

[0010] Even in instances where the placement of splints does not contribute to further mitral valve leakage, it may be desirable to provide a therapy which could also correct the valve incompetency. A heart with even a small amount of regurgitation may benefit from not only the stress reducing functions of the ventricular splints as described above, but also from the elimination of the regurgitation, which will further off-load the pumping requirements of the myocardium.

[0011] While currently available methods of mitral valve repair or replacement are possible to employ in conjunction with ventricular splinting, they typically require opening the heart to gain direct access to the valve and its annulus. This type of access necessitates the use of cardiopulmonary bypass, which can introduce additional complications to the surgical procedure. Since the implantation of the splints themselves do not require the patient to be on cardiopulmonary bypass, it would be advantageous to devise a technique which could improve the mitral valve without the need for cardiopulmonary bypass. The ability to improve the mitral valve function without the need for cardiopulmonary bypass would be an, advantage, both in conjunction with ventricular splinting, and also as a stand-alone therapy.

SUMMARY OF THE INVENTION

[0012] Objects and advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims. To achieve the objects and in accordance with the purpose of the invention, as embodied and broadly described herein, one aspect of the invention comprises a method for improving the function of a valve of a heart. The method includes the steps of placing an elongate member transverse a heart chamber so that each end of the elongate member extends through a wall of the heart, and placing first and second anchoring members external to the chamber. The

first and second anchoring members are attached to first and second ends of the elongate member to fix the elongate member in a position across the chamber so as to reposition papillary muscles within the chamber.

[0013] According to another aspect, the invention comprises a method for improving the function of a valve of a heart. The method includes the steps of placing an elongate member transverse a heart chamber so that a first end of the elongate member extends through a wall of the heart between two papillary muscles, and a second end of the elongate member extends through a septum of the heart; placing a first anchoring member external the heart; and placing a second anchoring member inside the heart adjacent the septum. The first and second anchoring members are attached to the first and second ends of the elongate member respectively to fix the elongate member in a position across the heart chamber.

[0014] According to a further aspect, the invention comprises a method for improving the function of a valve of a heart. The method includes the steps of placing an elongate member transverse a heart chamber so that each end of the elongate member extends through a wall of the heart; and placing first and second anchoring members external the chamber. The first and second anchoring members are attached to the ends of the elongate member to fix the elongate member in a position across the chamber. The position is superior to the papillary muscles and proximate and substantially across the valve.

[0015] According to an even further aspect, the invention comprises a splint for improving the function of a valve of a heart. The splint includes an elongate member configured to be positioned transverse a heart chamber so that each end of the elongate member extends through a wall of the heart, and first and second anchoring members configured to be positioned external the chamber and attached to the ends of the elongate member to fix the elongate member in a position across the chamber. The first anchoring member includes a first portion configured to contact a first region of the heart proximate the valve to change a shape of the valve. Preferably, the first portion will contact a first region of the heart proximate the valve annulus to change the shape of the valve annulus.

[0016] According to another aspect, the invention comprises a splint for improving the function of a valve of a heart. The splint includes an elongate member configured to be positioned transverse a heart chamber so that each end of the elongate member extends through a wall of the heart, first and second anchoring members configured to be positioned external the chamber and attached to the ends of the elongate member to fix the elongate member in a position across the chamber, a third anchoring member connected to at least one of the first and second anchoring members by a connection member. The third anchoring member is configured to contact a region of the heart proximate the valve to change a shape of the valve.

[0017] According to a further aspect, the invention comprises a device for improving the function of a valve of a heart. The device includes a first splint having a first elongate member configured to be positioned transverse a heart chamber so that each end of the elongate member extends through a wall of the heart, and a first anchoring member configured to be positioned external the chamber and attached to a first end of the first elongate member. The device further includes a second splint having a second elongate member configured to be positioned transverse a heart chamber so that each end of the second elongate member extends through a wall of the heart, and a second anchoring member configured to be positioned external the chamber and attached to a first end of the second elongate member. The device also includes a connecting mechanism configured to be connected to the second ends of each of the first and second elongate members external the chamber and press the wall of the heart chamber to change a shape of the valve.

[0018] Yet a further aspect of the invention includes a method for improving cardiac function, comprising placing a first member relative to a heart chamber to alter the cross-sectional shape of the chamber and placing a second member relative to a valve of the heart chamber to assist in apposition of leaflets of the valve.

[0019] According to an even further aspect, the invention includes a method of improving the function of a valve of a heart comprising applying a force to an exterior surface of a wall surrounding a chamber of the heart substantially at a location of the valve to alter a shape of the valve.

[0020] Yet a further aspect of the invention includes a method for improving the function of a valve of a heart comprising placing a device relative to the heart to alter a shape of the valve and adjusting the device relative to the heart based on data obtained during the adjusting from real-time monitoring of valve function.

[0021] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

[0023] **FIG. 1** is a transverse cross section of the left and right ventricles of a human heart showing the placement of splints according to an orientation for lessening myocardial muscular stresses;

[0024] **FIG. 2*a*** is a transverse cross section of the left and right ventricles of a human heart showing the orientation of splints according to an embodiment of the present invention for lessening myocardial muscular stresses and assisting in apposition of valve leaflets;

[0025] **FIG. 2*b*** is a vertical cross section of the left and right ventricles of a human heart showing another orientation of ventricular shape change splints according to an embodiment of the present invention for lessening myocardial muscular stresses and assisting in apposition of valve leaflets;

[0026] **FIG. 3*a*** is a transverse cross section of the left and right ventricles of a human heart showing an orientation of a mitral valve splint used in combination with a series of transventricular splints according to an embodiment of the present invention for lessening myocardial muscular stresses and assisting in apposition of valve leaflets;

[0027] **FIG. 3***b* is an external view of a human heart showing the orientation of the mitral valve splint and series of transventricular splints of **FIG. 3***a;*

[0028] **FIG. 3***c* is a transverse cross section of the left and right ventricle of a human heart showing a various orientations for a mitral valve splint used in combination with a series of transventricular splints according to an embodiment of the present invention;

[0029] **FIG. 4***a* is an external view of a human heart showing a series of transventricular splints, with the superior-most splint having an anchor structure according to an embodiment of the present invention that assists in apposition of valve leaflets;

[0030] **FIG. 4***b* is an external view of a human heart showing a series of transventricular splints, with the superior most splint having an anchor structure and a connection mechanism between the superior most and middle anchors according to yet another embodiment of the present invention that assists in apposition of valve leaflets;

[0031] **FIG. 4***c* is a perspective view of an anchor assembly for a transventricular splint according to yet another embodiment of the present invention that assists in apposition of valve leaflets and repositioning of papillary muscles;

[0032] **FIG. 5***a* is a transverse cross section of the left and right ventricles of a human heart showing the placement of splints according to an orientation for lessening myocardial muscular stresses with an accessory anchor assembly according to an embodiment of the present invention to assist in apposition of valve leaflets;

[0033] **FIG. 5***b* is a transverse cross section of the left and right ventricles of a human heart showing the placement of splints according to an orientation for lessening myocardial muscular stresses with an accessory anchor assembly according to another embodiment of the present invention to assist in apposition of valve leaflets;

[0034] **FIG. 6** is a transverse cross section of the left and right ventricles of a human heart showing an orientation of a mitral valve splint used in combination with a series of transventricular splints, with an interconnecting mechanism according to an embodiment of the present invention for lessening myocardial muscular stresses and assisting in apposition of valve leaflets; and

[0035] **FIG. 7** is a perspective view of a heart with an external splint device and mitral valve anchor assembly and connecting mechanism disposed relative to the left ventricle to alter the shape of the left ventricle and to assist in apposition of valve leaflets according to an embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0036] The various aspects of the invention to be discussed herein generally pertain to devices and methods for treating heart conditions, including, for example, dilatation, valve incompetencies, including mitral valve leakage, and other similar heart failure conditions. Each device of the present invention preferably operates passively in that, once placed in the heart, it does not require an active stimulus, either mechanical, electrical, or otherwise, to function. Implanting one or more of the devices of the present invention operates to assist in the apposition of heart valve leaflets to improve valve function. In addition, these devices may either be placed in conjunction with other devices that, or may themselves function to alter the shape or geometry of the heart, locally and/or globally, and thereby further increase the heart's efficiency. That is, the heart experiences an increased pumping efficiency through an alteration in its shape or geometry and concomitant reduction in stress on the heart walls, and through an improvement in valve function.

[0037] The inventive devices and related methods offer numerous advantages over the existing treatments for various heart conditions, including valve incompetencies. The devices are relatively easy to manufacture and use, and the surgical techniques and tools for implanting the devices of the present invention do not require the invasive procedures of current surgical techniques. For instance, the surgical technique does not require removing portions of the heart tissue, nor does it necessarily require opening the heart chamber or stopping the heart during operation. For these reasons, the surgical techniques for implanting the devices of the present invention also are less risky to the patient than other techniques. The less invasive nature of the surgical techniques and tools of the present invention may also allow for earlier intervention in patients with heart failure and/or valve incompetencies.

[0038] The disclosed inventive devices and related methods involve geometric reshaping of the heart and treating valve incompetencies. In certain aspects of the inventive devices and related methods, substantially the entire chamber geometry is altered to return the heart to a more normal state of stress. Models of this geometric reshaping, which includes a reduction in radius of curvature of the chamber walls, can be found in U.S. Pat. No. 5,961,440 incorporated above. Prior to reshaping the chamber geometry, the heart walls experience high stress due to a combination of both the relatively large increased diameter of the chamber and the thinning of the chamber wall. Filling pressures and systolic pressures are typically high as well, further increasing wall stress. Geometric reshaping according to the present invention reduces the stress in the walls of the heart chamber to increase the heart's pumping efficiency, as well as to stop further dilatation of the heart.

[0039] Although many of the methods and devices are discussed below in connection with their use in the left ventricle and for the mitral valve of the heart, these methods and devices may be used in other chambers and for other valves of the heart for similar purposes. One of ordinary skill in the art would understand that the use of the devices and methods described herein also could be employed in other chambers and for other valves of the heart. The left ventricle and the mitral valve have been selected for illustrative purposes because a large number of the disorders that the present invention treats occur in the left ventricle and in connection with the, mitral valve. Furthermore, the devices disclosed herein for improving valve function can be "stand-alone" devices, that is, they do not necessarily have to be used in conjunction with devices for changing the shape of a heart chamber or otherwise reducing heart wall stress. It also is contemplated that a device for improving valve function may be placed relative to the heart without altering the shape of the chamber, and only altering the shape of the valve itself.

[0040] Reference will now be made in detail to the present preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[0041] A currently preferred orientation of transventricular splints for lessening myocardial muscular stresses is shown in **FIG. 1**, which shows the short-axis left ventricular cross-section from an anterior perspective. Examples of particular transventricular splints that are especially suitable for this application include those shown and described in copending U.S. patent application Ser. No. 09/532,049 to Vidlund et al., filed Mar. 21, 2000, entitled "A Splint Assembly for Improving Cardiac Function in Hearts, and Method for Implanting the Splint Assembly," and comunonly assigned to the assignee of the present invention. The complete discosure of that application is incorporated by reference herein. That application will be referred to as "the '049 application" in the remainder of this disclosure.

[0042] In the preferred orienation shown in **FIG. 1**, three splints are placed in a coplanar fashion, along the long axis of the ventricle, bisecting the left ventricle LV of the heart **10**. **FIG. 1** is a cross-section (short axis) view looking from the superior side of the heart. The superior-most splint **14** is placed at approximately the level of the heads of the papillary muscles PM and below the level of leaflet coaptation, and the additional two splints (not shown in **FIG. 1**) are placed inferiorly toward the apex. The preferred orientation shown in **FIG. 1** both bisects the left ventricle LV and avoids key structures such as coronary vessels and the like. The splints according to this orientation also extend through the septum S near its edge and enter a small portion of the right ventricle RV.

[0043] Each splint includes a tension member **16** and an anchor assembly **18** at each end of the tension member **16**. Presently preferred embodiments of tension members **16**, anchor assemblies **18**, and their connection to one another are disclosed in the '049 application incorporated by reference above. As shown in **FIG. 1**, tension member **16** extends through the the heart wall HW, across the left ventricle LV, and through the septum S and a portion of the right ventricle RV. Anchor assemblies **18** are placed adjacent the external surface of the heart wall HW.

[0044] As mentioned above, human implantations of splints, including in an orientation shown in **FIG. 1**, may exacerbate any pre-existing mitral valve incompetency, including mitral valve regurgitation (MVR), or at the least, may not improve any pre-existing MVR. **FIG. 2***a* shows an orientation of splints **14** according to an embodiment of the present invention which may assist in both offloading myocardial wall stress and in aiding the apposition of valve leaflets. According to this orientation, each tension member **16** of splint **14** extends through the heart wall HW at a position approximately midway between the antero lateral papillary muscle PM and the posterio medial papillary muscle PM, extends transverse the left ventricle LV, and extends through the septum S at approximately its midpoint. A first anchor assembly **18** is placed external the heart **10** adjacent the heart wall HW and a second anchor assembly is placed inside the right ventricle RV adjacent septum S. **FIG. 2***a* shows the superior-most splint **14** of preferably three splints, with the other two splints placed inferiorly towards the apex. More or less than three splints may be used. The splints in this orientation are generally parallel to one another and substantially perpendicular to the long axis of the left ventricle.

[0045] The orientation of splints **14** shown in **FIG. 2***a* helps to "pull" both of the papillary muscles PM toward the center of the left ventricle LV and reposition those muscles closer to their normal physiological position relative to the mitral valve annulus during the complete cardiac cycle. During the course of heart failure dilation, the papillary muscles PM are moved laterally away from their normal position, which causes the chordae connected to both valve leaflets to become excessively taut. This in turn inhibits the leaflets from fully closing against each other. By bringing the papillary muscles PM closer to the center of the ventricle LV, the chordae are slackened enough to allow the leaflets to appose, thereby improving on mitral valve function. Additionally, although the splints **14** in this approach are preferably positioned at and below the level of the tops of the papillary muscles PM, the shape change deformation at the superior-most splint **14** would extend in a region further superior, and potentially include the annulus itself. To the extent that the annulus in the region of the posterior leaflet is deformed, this would further benefit the valve function by reducing the cross-sectional area of the annulus and positioning the posterior leaflet and its attachment zone closer to the anterior annulus. This, in turn, will cause the leaflets to more fully appose, minimizing MVR.

[0046] Various methods may be employed to implant the splints **14** in the orientaion shown in **FIG. 2***a*. One particularly advantageous method is an endovascular delivery technique shown and described in co-pending U.S. patent application Ser. No. _____, to Robert M. Vidlund et al., entitled "Endovascular Splinting Devices and Methods," filed on the same day as this application and commonly assigned to the assignee of this application, the entire i disclosure of which is incorporated by reference herein. Splints **14** also may be positioned in the orientation shown in **FIG. 2***a* by other surgical techniques, such as those described in the '049 application incorporated by reference above. For example, to gain access to the ventricular septum S, a small incision can be placed within the right ventricular wall to allow for positioning tension member **16** and the anchor assembly **18** within the right ventricle RV. The methods of implantation shown and described in the applications referred to above may be used in connection with any of the embodiments shown and described herein.

[0047] **FIG. 2***b* shows another orientation of splints **14** according to an embodiment of the present invention which may assist in the offloading of myocardial wall stress and in the apposition of valve leaflets. According to this orientation, at least one splint **14** is angled with respect to the long axis of the left ventricle LV, in contrast to orienting the at least one splint **14** perpendicular to the axis of the left ventricle LV. In the embodiment shown in **FIG. 2***b*, the lower two splints **14** are angled relative to the ventricular axis and relative to the superior-most splint **14**, which is approximately perpendicular to the ventricular axis. In this example, all three splints **14** are coplanar, as is preferred for optimizing the ventricular shape change. While **FIG. 2***b* illustrates the ventricular splints having an anchor pad disposed on the septum, it is contemplated that the benefits of angling one or more splints relative to the long axis of the

ventricle could be achieved at other cross-sectional orientations including, for example, the orientation shown in **FIG. 1**, in which an anchor pad is located on an exterior wall of the heart as opposed to the septum wall.

[**0048**] Because the lower two splints **14** are positioned at an angle, they tend to "lift" one or both papillary muscles PM as they impart shape change to the left ventricle LV. By lifting the papillary muscle(s) PM, some slack may be provided to the chordae connected to the valve leaflets to permit improved apposition of the leaflets of mitral valve MV. It is contemplated that more or less splints than the lower two splints may be angled (other than perpendicularly) relative to the ventricular axis to achieve the benefits to MVR, and that each splint may have a different angle relative to that axis. For example, all three splints could be angled, or only one splint could be angled. The number of splints to be angled, and the degree of such angles, would be chosen to optimize the improvement in MVR and would depend on factors such as the particular anatomy of a heart. The splint positioning can be iteratively changed and the impact on MVR, and mitral valve function in general, can be monitored using appropriate "real-time" imaging techniques and equipment, such as, for example, ultrasound and other suitable mechanisms. The ventricular splints **14** shown in **FIG. 2***b* may be oriented in any suitable cross sectional position, including the positions shown in **FIG. 1** or **2***a*. The benefits to MVR of angularly positioning one or more of the ventricular splints **14** relative to the ventricular axis, as shown in **FIG. 2***b*, may be achieved independent of the particular cross sectional position of the splints **14**.

[**0049**] According to an embodiment of the present invention, a method of improving mitral valve function, while maintaining the positions and orientations of the ventricular splints shown in **FIG. 1**, includes the use of an additional splint. This additional splint, referred to herein as a mitral valve splint or MV splint, preferably has the same construction as the other splints and may be implanted using the similar delivery techniques. The primary function of the MV splint is to impart a shape change to the mitral valve annulus, adjacent the left ventricular wall, as well as reposition the papillary muscles PM.

[**0050**] **FIGS. 3***a* and **3***b* show an MV splint according to an embodiment of the present invention. **FIGS. 3***a* and **3***b* show the three ventricular splints **14** in the positions and orientations shown and described in connection with **FIG. 1** (the dashed lines in **FIGS. 3***a*, **3***b*) and show an exemplary orientation of an MV splint **20**. It should be noted that in **FIGS. 3***a* and **3***b* the shape change to the left ventricle caused by the transventricular splints **14** is not illustrated. MV splint **20** is positioned superior to the papillary muscles PM and oriented primarily across the mitral valve MV and on or below the mitral valve annulus while avoiding key vascular structures. In this orientation, MV splint **20** is "out of plane" with the other ventricular splints **14**, as the overall function of MV splint **20** is to improve and optimize the mitral valve function. In the example shown in **FIGS. 3***a* and **3***b*, the MV splint extends through the heart wall between the papillary muscles of the left ventricle LV, and extends transverse the left ventricle LV, through the septum S, through the right ventricle RV, and once again through the heart wall.

[**0051**] The MV splint **20** improves mitral valve function through a combination of effects. First, the shape of the annulus is directly altered, preferably during the entire cardiac cycle, thereby reducing the annular cross sectional area and bringing the posterior leaflet in closer apposition to the anterior leaflet. Second, the position and rotational configuration of the papillary muscles PM and surrounding areas of the left ventricle LV are further altered by the tightening of the MV splint **20**. This places the chordae in a more favorable state of tension, allowing the leaflets to more fully appose each other. Third, since the annulus of the valve is muscular and actively contracts during systole, changing the shape of the annulus will also reduce the radius of curvature of at least portions of the annulus, just as the shape change induced by the ventricular splints reduces the radius of at least significant portions of the ventricle. This shape change and radius reduction of the annulus causes offloading of some of the wall stress on the annulus. This, in turn, assists the annulus's ability to contract to a smaller size, thereby facilitating full closure of the mitral valve MV during systole.

[**0052**] The position of the MV splint **20** shown in **FIGS. 3***a* and **3***b* is exemplary. The ventricular splints **14** preferably are positioned prior to positioning MV splint **20**, through the use of, for example, both angiographic and ultrasonic visualization tools. This positioning technique, described in the '049 application incorporated above, achieves optimal positioning of splints **14** to bisect the left ventricle LV and avoid key anatomic structures. After positioning the ventricular splints **14**, a device such as the probe/marking device shown and described in the '049 application may be used to repeatedly probe and deform possible areas near the mitral valve to find the optimal position for the MV splint **20**., By utilizing, for example, standard "real-time" ultrasonic imaging techniques, the direct impact of the probing on MVR can be assessed, and pre-existing MVR or MVR exacerbated by placement of the ventricular splints **14** can be corrected. Once the optimal position for an MV splint **20** is determined and marked, the MV splint **20** is implanted and positioned by any of the delivery techniques referred to above, including the endovascular delivery technique or the more direct surgical approaches. The use of the MV splint **20** allows for the optimal placement of the ventricular splints **14**, which reduce heart wall stress, independent from the optimal subsequent positioning of the MV splint **20**, which improves mitral valve function. During implantation, the splint can be adjusted (either in position or in tightness or both) to optimize improvement to valve function, as determined by observation of the valve using real-time imaging techniques.

[**0053**] It is anticipated that the optimal position of the MV splint **20** could be at virtually any orientation relative to the valve leaflets, depending on the heart failure and mitral valve regurgitation associated with the particular heart at issue. For example, in some hearts, the position shown and described in connection with **FIGS. 3***a* and **3***b* may yield the most improvement of MVR, whereas in other hearts, alternative positions such as shown in **FIG. 3***c* may yield the most improved results. Note that in **FIG. 3***c*, the transventricular splint is shown positioned between the papillary muscles, which may be another preferred orientation for certain hearts. Alternative "A" places MV splint to cause shape change between the papillary muscles Alternative "B" for MV splint positioning would be in a line more parallel to the valve leaflet edges, as shown in **FIG. 3***d*. Other placements of the MV splint, as well as the position of the transventricular splints, relative to the heart also are con-

templated and could be selected based on the condition of the heart and the mitral valve.

[0054] According to another embodiment of the present invention, an alternative anchor assembly for the ventricular splints **14** may be provided to aid in mitral valve function. In the embodiment shown in **FIG. 4***a*, the superior-most splint **14** includes an anchor assembly **28** configured for connection to the "free wall" end of that splint **14**, i.e., at the exterior wall of the left ventricle. Anchor assembly **28** includes a lower portion in the form of, for example, a lower pad portion **30** which contacts the external surface of the left ventricle wall somewhat below the level of the tension member **16**. In a preferred embodiment, the lower pad portion **30** resembles the shape, size, and construction of the anchor pads described in the '049 application incorporated above. Anchor assembly **28** further includes an upper portion in the form of, for example, an upper pad portion **34** which contacts a superior region of the left ventricle wall near the mitral valve annulus. Tension member **16** connects to a spanning structure **32** that, in one embodiment, is preferably integrally fabricated with the lower and upper pad portions **30** and **34**, and connects portions **30** and **34**. Suitable materials for anchor assembly may include, but are not limited to, those described in the '049 application. At least the lower and upper pad portions **30** and **34** preferably include a covering or a coating of a material, such as, for example, a woven polyester fabric, to encourage tissue in-growth. The spanning structure **32** also may be made of, or include a covering or coating made of, a material to encourage tissue in-growth

[0055] In the exemplary, preferred embodiment shown in **FIG. 4***a*, the lower pad portion **30** has a circular shape and the upper pad portion **34** has an oblong shape. The oblong shape of the upper pad portion **34** has the advantage of inducing relatively extensive shape change along the periphery of the valve annulus, preferably during the entire cardiac cycle. Therefore, in an embodiment, the length and shape of the upper pad portion may extend a significant distance around the valve annulus. For example, the upper pad portion **34** may extend from about 1 cm in length to about 10 cm in length, depending on the desired shape change of the valve annulus. The width of the upper pad portion **34**, however, is preferably relatively narrow, so as to concentrate its shape change impact to the region near the valve annulus.

[0056] The upper pad portion **34** may be positioned near, but below, the valve annulus. In other embodiments of the present invention, the upper pad portion may be positioned directly on the exterior surface of the annulus or somewhat above the annulus to contact the left atrium wall. The position of the upper pad portion preferably avoids direct compressive contact with important vascular structure near or on the exterior surface of the heart. Significant coronary vasculature often lies on or near the atrio-ventricular groove **36**, which corresponds with the posterior annular region of the mitral valve. For this reason, it may be desirable to position the upper pad portion onto the left atrial surface.

[0057] Anchor assembly **28** permits selection of a position that causes valve annulus shape change relatively independent from the positioning of the ventricular splints that cause ventricular shape change. The incorporation of an anchor assembly **28** is most suitable for instances where the desired shape change for the mitral valve is relatively co-planar with the main ventricular shape change splints. In addition, anchor assembly **28** provides for annulus shape change without the need for an additional MV splint, such as that shown in **FIGS. 3***a* and **3***b*.

[0058] An alternative embodiment of a splint with a mitral valve anchor assembly according to the invention is illustrated in **FIG. 4***b*. In the embodiment of anchor assembly **28**, shown in **FIG. 4***a*, the tension member **16** was connected to the spanning structure **32** approximately in the middle of the spanning structure **3**, yielding a relatively stable structure that remains substantially parallel to the exterior surface of the heart. However, the embodiment of the anchor assembly **28'** shown in **FIG. 4***b* places the ventricular shape change caused by the lower pad portion **30'** below the end of the tension member **16'**. The anchor assembly **28'** illustrated in **FIG. 4***b* is similar to the anchor assembly **28** of **FIG. 4***a*, except that the tension member **16'** is anchored within the lower pad portion **30'**. In order to provide mechanical balance to the anchor assembly, and to give leverage to the upper pad portion **34'** such that it can properly alter the region of the valve annulus, a second spanning structure **33** is provided to mechanically connect the anchor assembly **28'** to an anchor pad **14** of the splint disposed below the superior-most splint. This second spanning structure **33** also may be integrally formed with the anchor assembly **28'** and, in turn, with the anchor pad **14**. Alternatively, the second spanning structure **33** can be a separate component connecting anchor assembly **28'** and anchor pad **14'** once they are positioned with respect to the heart. This could be done, for example, by mechanical fastening, such as with screws or the like.

[0059] A further alternative anchor assembly **28"** is shown in **FIG. 4***c*. This anchor assembly **28"** is similar to the anchor assembly **28** shown in **FIG. 4***a*, except that anchor assembly **28"** also includes one or more additional papillary pad portions **35** connected to lower pad portion **30"** at a location substantially opposite to spanning structure **32"** The papillary pad portion or portions **35** serve to provide one or more additional sites of deformation of the ventricular wall, preferably to further reposition one or both papillary muscles to aid in appoistion of the valve leaflets. The papillary pad portions **35** may be formed integrally with the anchor assembly **28"** or may be separate and connected thereto via suitable connection mechanisms.

[0060] In certain cases, the optimal orientation of shape change for improving the mitral valve function may be significantly offset from the position and orientation of transventricular splints **14**. It is therefore desirable to have an approach to cause mitral valve shape change at positions away from the transventricular splints **14**, and even more desirably, without the addition of another splint structure traversing the ventricle.

[0061] **FIG. 5***a* shows such an approach according to an embodiment of the present invention. **FIG. 5***a* shows an accessory anchor pad structure **40** attached to a connection member, shown as a runner **42**. Runner **42** connects at its ends to both anchor pads **18** of preferably the superior-most splint assembly **14**. As an alternative, runner **42** may connect to one anchor pad **18** and extend between that anchor pad **18** and structure **40**. The accessory pad structure **40** is positioned at the location on the heart wall that yields the greatest improvement in MVR, as determined with repeated

probing and deforming at the exterior of the heart proximate the mitral valve annulus, as described above in connection with positioning the MV splint **20** in **FIGS. 3***a* and **3***b*.

[**0062**] Since runner **42** preferably connects to the two anchor pads **18** of the upper-most splint assembly **14**, runner **42** generally runs at approximately the same level on the heart wall as those anchor pads **18**. In one embodiment, accessory anchor pad structure **40** may be of the same shape and material as the anchor pads **18**. While this embodiment may result in significantly improved MVR in some instances, in another embodiment, accessory pad **40** may take a form, including shape and material, similar to the anchor assemblies **28**, **28'**, **28"** shown in **FIGS. 4***a*-**4***c*. This latter configuration permits positioning accessory pad **40** at a position higher than the level of the anchor pads **18** of the superior-most transventricular splint, resulting in even greater shape change to the mitral valve annulus. Also according to this latter configuration, the preferred construction of accessory pad **40** would include, in addition to characteristics of anchor assembly **28**, **28'**, **28"**, shown in **FIGS. 4***a*-**4***c*, a connecting mechanism **41** which would allow for adjustable positioning and securing of the accessory pad **41** to runner **42**. For example, a locking screw **43** may be used to secure runner **42** to pad **41**. Other mechanisms suitable for securing the pad **41** to the runner **42** and permitting adjustment of the pad position along the runner are within the scope of the present invention. Runner **42** preferably includes a wire-like, or braid-like, structure which secures to each of the splint anchor pads **18** also through any suitable means, such as, for example, a locking screw mechanism **44**, a pinning connection for a braid-like runner, or the like.

[**0063**] **FIG. 5***b* shows an alternative embodiment for connecting an accessory anchor pad assembly **50** to a runner **52** and for connecting runner **52** to anchor pads **18**. Each end of runner **52** connects to a connection mechanism in the form of a cap **54**. Each cap **54** locks in place over a pad **18**. At least one of the caps **54** includes an adjustable locking mechanism for adjusting the length of the runner **52** between the caps **54**, and also thereby adjusting the position of the accessory pad **50** on the heart wall, and locking the runner **52** to cap **54**.

[**0064**] In one embodiment, runner **52** is a braid formed of a high strength polymer, such as that used in the tension members described in the '049 application incorporated above. A suitable connection mechanism includes the use of one or more pins **56** placed through the braided runner **52** and connected to cap **54** through a flange **58**, for example, situated on the cap **54**. This pinning connection mechanism may be similar to the connection used for the braided tension members and anchor pads shown and described in the '049 application. The same connection mechanism may be used to connect accessory pad **50** to braided runner **52**. In an alternative embodiment according to the present invention, the braided runner **52** may more directly connect to anchor pads **18**, without the use of caps **54**, by, for example, a pinning securement mechanism incorporated into the superior splint pads themselves. In another contemplated embodiment, the external anchor pad assembly **50**, including the runner **52** and anchor pads **18**, can be used without the transventricular splint to improve valve function by causing a shape change to the valve annulus without an overall shape change to the left ventricle.

[**0065**] As mentioned above, a mechanism that may exacerbate MVR is the relative rotation of the papillary muscles PM and the adjacent left ventricular wall as the transventricular splints **14** are tightened into position. This relative rotation results in slack in some chordae and tightening in other chordae, which may "pull" one valve leaflet (or portion of the leaflet) while "loosening" the other valve leaflet (or portion of the leaflet).

[**0066**] **FIG. 6** shows an embodiment of a device according to the present invention that would alleviate this rotation phenomenon. **FIG. 6** shows an accessory splint **70** connected to the superior-most ventricular splint **14** by a connecting bar **60**. Accessory splint **70** and connecting bar **60** preferably are placed at approximately the same level along the ventricular wall as splint **14**. Splint **14** preferably is positioned near to, and in this case medial to, the anterior papillary muscle PM. Accessory splint **70** then is positioned through the septum S, across the left ventricle LV, and through the ventricular free wall between the, papillary muscles PM, similar to MV splint **20** described in connection with **FIGS. 3***a* and **3***b* but at about the same level as the superior splint **14**.

[**0067**] Connecting bar **60** attaches to the ends of tension members **16** and **72** at their left ventricular "free wall" ends. Both tension members **16** and **72** are tensioned, pressing connecting bar **60** into the left ventricle and effecting shape change to the ventricle and the mitral valve annulus. Connecting bar **60** prevents rotation of the left ventricle LV in the region of the anterior papillary muscle PM and causes uniform tensioning of the chordae associated with that papillary muscle PM and any associated ventricular wall. This is believed to lessen any degradation in MVR, and potentially improve the MVR, because the papillary muscles PM are brought to a more desired position, with less rotation, particularly as to the anterior papillary muscle.

[**0068**] The embodiments of the present invention described in connection with **FIGS. 2***a* to **6** have been described in connection with the use of transventricular splints used to geometrically reshape a chamber of the heart and thereby lessen heart wall stresses and reduce dilatation. While the devices and related methods described herein would further benefit the ventricular splinting procedure and its effects, the devices and related methods of the present invention may be used independent of the ventricular splinting to improve dilatation and instead be used for repairing heart valves, and particularly mitral valves, without the use of adjunctive ventricular splints. For example, a mitral valve splint such as that shown in **FIGS. 3***a*, **3***b*, and **3***c* could be utilized without additional ventricular shape change splints.

[**0069**] Moreover, while many of the embodiments of the present invention have been described in connection with modifications to transventricular splinting structures, the same or similar modifications may be made to external-type devices for causing ventricular shape change. Examples of such external devices are shown in co-pending U.S. patent application Ser. No. 09/157,486 ("the '486 application") filed Sep. 21, 1998 and entitled "External Stress Reduction Device and Method," the complete disclosure of which is incorporated by reference herein. Modifying those external devices in a similar manner as with the transventricular splints will achieve beneficial impacts to the mitral valve function. For example, the accessory anchor pad shown in

FIGS. 5*a* and **5***b* could be utilized in conjunction with an external stress reduction device, as shown, for example, in **FIG. 7**. In **FIG. 7**, an external splint **199** having a generally U-shaped configuration and including an anterior arm **199***a* and a posterior arm **199***b*, is positioned with respect to the left ventricle to create a substantially bi-lobed shape. In a preferred embodiment, the U-shaped external splint is made from a material that permits the splint to elastically deform under operational loads and also from a material that is biocompatible. Examples of preferred materials include e-PTFE, or a polyester such as Dacron, for example. Such a splint, as well as other suitable external splints, is described in more detail in the '486 application incorporated above. As shown in **FIG. 7, a** runner **298**, similar to the runner described with reference to **FIGS. 5***a* and **5***b*, attaches at its ends to the arms **199***a*, **199***b*. An accessory anchor pad **299**, also similar to the accessory anchor assembly discussed with reference to **FIGS. 5***a* and **5***b*, attaches to the connecting runner **298**. The runner **298** and accesory anchor pad **299** are positioned with respect to the heart so as to alter the shape of the mitral valve annuls to assist in coaptation of the valve leaflets. Alternatively, the runner and accessory anchor pad could be positioned so as to provide a repositioning of the papillary muscles, also to assist in coaptation of the valve leaflets.

[0070] It will be apparent to those skilled in the art that various modifications and variations can be made in the devices and related methods for improving mitral valve function of the present invention and in construction of such devices without departing from the scope or spirit of the invention. As an example, a combination of devices depicted above may be used for achieving improved mitral valve function. In one such combination, an accessory splint such as MV splint **20** shown in **FIGS. 3***a* and **3***b* may include an anchor assembly **28** as shown in **FIG. 4** and/or an accesory anchor pad structure **40** or **50** shown in **FIGS. 5***a* and **5***b*. Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. The specification and examples are exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

What is claimed is:

1. A method for improving the function of a valve of a heart, the method comprising the steps of:

placing an elongate member transverse a heart chamber so that a first end of the elongate member extends through a wall of the heart between two papillary muscles, and a second end of the elongate member extends through a septum of the heart;

placing a first anchoring member external the heart; and

placing a second anchoring member inside the heart adjacent the septum, the first and second anchoring members being attached to the first and second ends of the elongate member respectively to fix the elongate member in a position across the heart chamber.

2. The method of claim 1, wherein the heart chamber is the left ventricle and the valve is the mitral valve.

3. The method of claim 2, wherein the first end of the elongate member extends through a wall of the heart approximately midway between the antero lateral papillary muscle and the posterio medial papillary muscle.

4. The method of claim 3, wherein the elongate member is placed proximate the mitral valve.

5. The method of claim 1, wherein the elongate member is fixed in the position so as to change a shape of the heart chamber.

6. The method of claim 1, wherein the elongate member is fixed in the position so as to reposition the papillary muscles.

7. A method for improving the function of a valve of a heart, the method comprising the steps of:

placing a first elongate member transverse a heart chamber so that each end of the first elongate member extends through a wall of the heart;

placing first and second anchoring members external the chamber, the first and second anchoring members being attached to the ends of the first elongate member to fix the first elongate member in a first position across the chamber;

placing a second elongate member transverse the heart chamber so that each end of the second elongate member extends through a wall of the heart;

placing third and fourth anchoring members external the chamber, the third and fourth anchoring members being attached to the ends of the second elongate member to fix the second elongate member in a second position across the chamber, wherein the first and second positions are substantially coplanar and have differing angles relative to an axis of the chamber.

8. The method of claim 7, wherein the heart chamber is the left ventricle and the valve is the mitral valve.

9. The method of claim 7, wherein the first and second elongate members are fixed in the first and second positions so as to change a shape of the heart chamber.

10. The method of claim 7, wherein the first and second elongate members are fixed in the first and second positions so as to reposition papillary muscles within the chamber.

11. A method for improving the function of a valve of a heart, the method comprising the steps of:

placing an elongate member transverse a heart chamber so that each end of the elongate member extends through a wall of the heart; and

placing first and second anchoring members external the chamber, the first and second anchoring members being attached to the ends of the elongate member to fix the elongate member in a position across the chamber, wherein the position is superior to the papillary muscles and proximate and substantially across the valve.

12. The method of claim 11, wherein the heart chamber is the left ventricle and the valve is the mitral valve.

13. The method of claim 11, wherein the position of the elongate member alters a shape of an annulus of the valve.

14. The method of claim 11, wherein the position of the elongate member repositions the papillary muscles within the chamber.

15. A splint for improving the function of a valve of a heart, the splint comprising:

an elongate member configured to be positioned transverse a heart chamber so that each end of the elongate member extends through a wall of the heart; and

first and second anchoring members configured to be positioned external the chamber and attached to the ends of the elongate member to fix the elongate member in a position across the chamber, wherein the first anchoring member includes a first portion configured to contact a first region of the heart proximate the valve to change a shape of the valve.

16. The splint of claim 15, wherein the heart chamber is the left ventricle and the valve is the mitral valve.

17. The splint of claim 16, wherein the first region of the heart is a superior portion of the left ventricle proximate an annulus of the mitral valve.

18. The splint of claim 16, wherein the first region of the heart is a portion of the left atrium proximate an annulus of the mitral valve.

19. The splint of claim 15, wherein the first portion has an oblong shape.

20. The splint of claim 15, wherein the first anchoring member further includes a second portion configured to contact a second region of the heart below the first region.

21. The splint of claim 20, wherein the second portion includes a first structure connected to the elongate member and a second structure connected to the first portion by the first structure.

22. A splint for improving the function of a valve of a heart, the splint comprising:

an elongate member configured to be positioned transverse a heart chamber so that each end of the elongate member extends through a wall of the heart;

first and second anchoring members configured to be positioned external the chamber and attached to the ends of the elongate member to fix the elongate member in a position across the chamber; and

a third anchoring member connected to at least one of the first and second anchoring members by a connection member, the third anchoring member configured to contact a region of the heart proximate the valve to change a shape of the valve.

23. The splint of claim 22, wherein the third anchoring member connects to the first and second anchoring members by the connection member.

24. The splint of claim 22, wherein the third anchoring member includes a connection mechanism for connecting the third anchoring member to the connection member.

25. The splint of claim 24, wherein the connection mechanism includes a locking screw.

26. The splint of claim 24, wherein the connection mechanism includes a pin.

27. The splint of claim 22, further comprising a connection mechanism for connecting the connection member to the at least one of the first and second anchoring members.

28. The splint of claim 27, wherein the connection mechanism includes a locking screw.

29. The splint of claim 27, wherein the connection mechanism includes a pin.

30. The splint of claim 27, wherein the connection mechanism includes a cap configured to fit over the at least one of the first and second anchoring members.

31. The splint of claim 23, further comprising an adjustment mechanism for adjusting a length of the connection member between the first and second anchoring members.

32. A device for improving the function of a valve of a heart, the device comprising:

a first splint having a first elongate member configured to be positioned transverse a heart chamber so that each end of the elongate member extends through a wall of the heart, and a first anchoring member configured to be positioned external the chamber and attached to a first end of the first elongate member;

a second splint having a second elongate member configured to be positioned transverse a heart chamber so that each end of the second elongate member extends through a wall of the heart, and a second anchoring member configured to be positioned external the chamber and attached to a first end of the second elongate member; and

a connecting mechanism configured to be connected to the second ends of each of the first and second elongate members external the chamber and press the wall of the heart chamber to change the shape of an annulus of the valve.

33. The device of claim 32, wherein the connection mechanism is a bar.

34. The device of claim 32, wherein the heart chamber is the left ventricle and the valve is the mitral valve.

35. The device of claim 32, wherein the device is configured so that the connecting bar presses the wall of the heart chamber to change the shape of chamber.

36. A method for improving the function of a valve of a heart, the method comprising the steps of:

placing an elongate member transverse a heart chamber so that each end of the elongate member extends through a wall of the heart; and

placing first and second anchoring members external the chamber, the first and second anchoring members being attached to first and second ends of the elongate member to fix the elongate member in a position across the chamber so as to reposition papillary muscles within the chamber.

37. The method of claim 36, wherein the first end of the elongate member extends through a wall of the left ventricle between papillary muscles.

38. The method of claim 37, wherein the second end of the elongate member extends through a septum of the heart.

39. The method of claim 36, wherein the chamber is the left ventricle and the valve is the mitral valve.

40. The method of claim 36, wherein the position is superior to the papillary muscles and proximate and substantially across the valve.

41. The method of claim 36, wherein the elongate member is fixed in the position so as to alter the shape of an annulus of the valve.

42. A method for improving cardiac function, comprising:

placing a first member relative to a heart chamber to alter the cross-sectional shape of the chamber; and

placing a second member relative to a valve of the heart chamber to assist in apposition of leaflets of the valve.

43. The method of claim 42, wherein each of the first and second members includes a portion placed transverse the chamber.

44. The method of claim 42, wherein each of the first and second members includes an elongate member.

45. The method of claim 44, wherein the placing each of the first and second elongate members includes securing the

elongate members relative to the heart chamber with anchors configured to engage each end of the elongate members and configured to engage an exterior surface of a wall surrounding the hears chamber.

46. The method of claim 45, wherein the securing the second elongate member includes engaging one of the anchors with an exterior surface of the heart wall proximate the valve to alter a shape of an annulus of the valve.

47. The method of claim 42, wherein the heart chamber is a left ventricle.

48. The method of claim 42, wherein the valve is a mitral valve.

49. The method of claim 42, wherein the placing the second member includes altering the cross-sectional shape of an annulus of the valve.

50. The method of claim 42, wherein the placing the second member includes reducing a radius of an annulus of the valve.

51. The method of claim 42, wherein the placing the second member includes placing the second member so as to alter a position of at least one papillary muscle of the heart chamber.

52. The method of claim 51, wherein the placing the second member includes securing the second member with respect to the heart chamber with an anchor configured to engage an exterior surface of a wall surrounding the heart chamber substantially at a location of the at least one papillary muscle.

53. The method of claim 42, wherein the placing the first member includes placing an elongate member transverse the heart chamber and through a wall surrounding the heart chamber at substantially opposite locations on the heart wall.

54. A method of improving the function of a valve of a heart, the method comprising:

applying a force to an exterior surface of a wall surrounding a chamber of the heart substantially at a location of the valve to alter a shape of the valve.

55. The method of claim 54, wherein applying the force alters the shape of an annulus of the valve.

56. The method of claim 54, wherein altering the shape of the valve includes appositioning leaflets of the valve.

57. The method of claim 54, wherein altering the shape of the valve includes reducing a radius of an annulus of the valve.

58. The method of claim 54, wherein the force is applied by a device having an elongate member placed transverse the chamber and a first anchor assembly connected at a first end of the member external the chamber and a second anchor assembly connected at a second end of the member external the chamber.

59. A method for improving the function of a valve of a heart, comprising:

placing a device relative to the heart to alter a shape of the valve; and

adjusting the device relative to the heart based on data obtained during the adjusting from real-time monitoring of valve function.

60. The method of claim 59, wherein the device is a splint.

61. The method of claim 59, wherein the device is a splint and adjusting the splint includes changing a distance between at least two portions of the splint that contact respective portions of the heart.

62. The method of claim 59, wherein the real-time monitoring includes imaging the valve.

63. The method of claim 62, wherein the imaging of the valve includes ultrasound imaging.

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