ABSTRACT

Described is a device for evaluating a heart valve annulus in order to choose a particular annuloplasty device to be attached to the annulus, wherein the annuloplasty device has an inter-trigonal or inter-commisural distance and an anterior-posterior ratio, the device comprising: a valve sizing element having one of a plurality of inter-trigonal or inter-commisural distances and comprising a plurality of indicia on the valve sizing element corresponding to a plurality of anterior-posterior ratios and used to compare to the annulus in order to indicate an anterior-posterior ratio of the annulus. Adjustable devices for evaluating a plurality of anterior-posterior ratios are also described. Also, methods of sizing a patient's heart valve annulus are described.
SIZER DEVICE HAVING A PLURALITY OF ANTERIOR-POSTERIOR RATIOS

PRIORITY

The present non-provisional patent application claims benefit from U.S. Provisional Patent Application having Ser. No. 61/062,412, filed on Jan. 25, 2008, by Ryan et al., and titled SYSTEM OF ANNULOPLASTY DEVICES WITH VARYING ANTERIOR-POSTERIOR RATIOS AND RELATED DEVICES AND METHODS, wherein the entirety of said provisional patent application is incorporated herein by reference.

TECHNICAL FIELD

The present invention relates generally to devices and methods for repair of heart valves, and more particularly to a sizer device used to size the inter-trigonal (or intercommisural) distance and anterior-posterior (A-P) ratio of a mitral valve annulus in order to choose an appropriate annuloplasty device for repair of the mitral valve.

BACKGROUND OF THE INVENTION

Heart valve disease is a widespread condition in which one or more of the valves of the heart fails to function properly. Various surgical techniques may be used to replace or repair a diseased or damaged valve. In just one way, in a valve replacement surgery, damaged leaflets of the valve are excised and the annulus is sculpted to receive a replacement valve. Another less drastic method for treating defective valves is repair or reconstruction by annuloplasty, in which the valve annulus is re-shaped and held in place by attaching a prosthetic annuloplasty repair segment or ring to an interior wall of the heart around the valve annulus. The annuloplasty ring is designed to support the functional changes that occur during the cardiac cycle; maintaining coaptation and valve integrity. Annuloplasty prostheses, which can generally be categorized as either annuloplasty rings or annuloplasty bands, are employed in conjunction with valvular reconstructive surgery to assist in the correction of heart valve defects such as stenosis and valvular insufficiency.

One type of valvular insufficiency is ischemic mitral regurgitation (IMR). In IMR, the coordination of the mitral leaflets, the mitral annulus, the subvalvar apparatus and the left ventricular wall is upset in some way. There are many causes, such as congenital defects, rheumatic fever, endocarditis, etc. There is a classification system for IMR, which was developed by Carpentier. IMR is classified as either Type I, II, IIa or IIb, based mainly on leaflet motion.

The effects of valvular dysfunction vary, with IMR typically having more severe physiological consequences to the patient than tricuspid valve regurgitation. In either area of the heart, however, many of the defects are associated with dilation of the valve annulus. This dilation not only prevents competence of the valve but also results in distortion of the normal shape of the valve orifice. Remodeling of the annulus is therefore central to most reconstructive procedures on the valves. Clinical experience has shown that repair of the valves, when technically possible, produces better long-term results than valve replacement.

With regard to the mitral valve, many procedures have been described to correct the pathology of the valve leaflets and their associated chordae tendineae and papillary muscles. The mitral valve, in particular, is a bicuspid valve having a posterior leaflet that has an annulus insertion length that is larger than that of an anterior leaflet, which coaps or meets with the posterior leaflet. The part of the mitral valve annulus that is attached to the anterior leaflet is called the anterior aspect, while the part attached to the posterior leaflet is called the posterior aspect. The two leaflets are fused at two commissures that are inserted in the annulus just below the level of two cardiac trigones, called the anterolateral trigone and the posterolateral trigone.

In mitral valve repair, coaptation of the posterior and anterior leaflets is important. Also, it is considered important to preserve the normal distance between the two trigones. A significant surgical diminution of the inter-trigonal distance may cause left ventricular outflow obstruction and/or distortion of the base of the aortic valve. Thus, it is desirable to maintain the natural inter-trigonal distance and shape following mitral valve repair surgery.

Mitral valve annulus dilation tends to be confined to the posterior aspect, resulting in a posterior aspect that is larger than normal. Consequently, the repair of mitral valve annulus dilation generally involves reducing the size of the posterior aspect.

In the repair of mitral valve annulus dilation, the associated procedure begins with identification of the trigones. The distance between the trigones (i.e., inter-trigonal distance) remains practically constant during the cardiac cycle in any one particular patient, but may vary from 24 to 40 mm in length in patients. Annuloplasty devices used to treat mitral valve dilation are available in different sizes based upon the distance between the trigones along the anterior aspect (i.e., the aortic curtain), which is generally in even 2 mm increments from about 24 mm to about 40 mm. It is critical to the successful outcome of the annuloplasty procedure to accurately determine the size, i.e., inter-trigonal distance, of the annulus.

There are existing sizer devices used to determine the size (i.e., inter-trigonal distance) of the annulus. Valve sizers, which resemble the shape of the valve annulus, are generally provided in various sizes. A surgeon estimates the native valve annulus size and selects a sizer accordingly. The sizer is attached to the end of the handle and guided into proximity of the annulus. If the sizer is not the appropriate size, it is withdrawn, detached from the handle, and replaced by a different sizer. Once the size of the annulus has been determined, a properly sized valve or annuloplasty ring or band may be selected and implanted.

Annuloplasty devices for mitral valve repair have generally been configured to restore the original, healthy shape of the mitral annulus at the end of systole. The device is typically semi-rigid, planar and restores the primary anterior-posterior (A-P) dimension or ratio of the mitral valve annulus. The device typically allows for sufficient coaptation of the leaflets at the end of systole to correct and/or prevent valvular insufficiency.

For a given size of valve annulus, there may be a plurality of possible types of annuloplasty devices that may be implanted. The choice of device will depend upon the disease state or physiological problem associated with the valve. For example, with Barlow's disease, excess mitral valve leaflet tissue in the anterior portion exists, which causes the mitral valve to leak back into the left atrium. Thus, with Barlow's disease, for example, an annuloplasty device having a design that accommodates excess leaflet tissue is desired.
For example, a device having a longer anterior dimension (i.e., a larger A-P ratio) than standard devices may be used.  

There is a continued desire to be able to improve annuloplasty devices to accommodate different physical structures of the heart due to different disease states of the heart. In addition, there is also a need for sizers to determine which size and type of device to use in a particular valve annulus.

SUMMARY OF THE INVENTION

The present invention generally involves sizer devices used to size the inter-trigonal (or inter-commissural) distance and the anterior-posterior (A-P) ratio of a mitral valve annulus in order to choose an appropriate annuloplasty device for repair of the mitral valve. In particular, the present invention is a sizer device that fits one of a plurality of sizes of annulus, i.e., one inter-trigonal (or inter-commissural) distance. The sizer device is also able to measure the anterior-posterior (A-P) ratio of the annulus. Preferably, each sizer device, having a specific inter-trigonal distance or size, can size an annulus for a plurality of different A-P ratios. Most preferably, the sizer device can evaluate the annulus with regard to three specific A-P ratios (e.g., about 0.6, about 0.75 and about 0.85). The three specific A-P ratios may preferably correspond to three categories of devices that are available to a surgeon in a set of annuloplasty devices, for example. It is contemplated, however, that the sizer device of the present invention may size or evaluate other valves, other A-P ratios, and may be used to size the annulus for various types of annuloplasty devices.

Embodiments of the present invention offer advantages. The sizer device of the present invention allows for sizing the A-P ratio of a valve annulus without having to use multiple sizer devices. A single sizer would replace multiple sizers that would normally be needed. The sizer device includes means for measuring, or evaluating the annulus with regard to, at least two different A-P ratios, but preferably at least three different A-P ratios. The sizer device therefore allows for easier and more efficient sizing of the annulus. There will be less procedural time necessary because changing out the sizers will not be necessary. Also, a lower cost may be associated with the invention since there will be smaller packaging necessary to house the sizer device rather than multiple devices.

A first aspect of the present invention is a device for evaluating a heart valve annulus in order to choose a particular annuloplasty device to be attached to the annulus. Each annuloplasty device has an inter-trigonal (or inter-commisural) distance and an anterior-posterior ratio. One embodiment of the device comprises: a valve sizing element having one of a plurality of inter-trigonal (or inter-commissural) distances and comprising a plurality of indicia on the valve sizing element corresponding to a plurality of anterior-posterior ratios, wherein the indicia are compared to the annulus in order to indicate an anterior-posterior ratio of the annulus. The device may further comprise an elongate element having a proximal end and a distal end, wherein the valve sizing element is coupled to the distal end of the elongate element. The valve sizing element may comprise an optically transparent material. The indicia may comprise markings on at least one surface of the valve sizing element. The markings may comprise visible markings imprinted on the at least one surface of the valve sizing element. The indicia may comprise a plurality of generally semi-circular-shaped ribs that are arranged concentrically along a surface of the valve sizing element. The indicia may comprise steps in a surface of the valve sizing element that are arranged generally concentrically and are generally semi-circular in shape.

A second aspect of the present invention is an adjustable device for evaluating a heart valve annulus in order to choose a particular annuloplasty device to be attached to the annulus. One embodiment of the device may comprise: a valve sizing element comprising first and second portions and means for moving the portions with respect to each other in order to provide the valve sizing element with one of a plurality of anterior-posterior ratios. The device may further comprise an elongate element having a proximal end and a distal end, wherein the valve sizing element is coupled to the distal end of the elongate element, and the elongate element may comprise means for controlling the movement of the first and second portions. A second embodiment of the adjustable device may comprise: a valve sizing element comprising: a plate having a first portion and a second portion; two arms comprising a center and two ends, the two arms connected to each other by an element near the center of each arm and connected to the first and second portions near the ends of the arms, wherein angular movement of the arms with respect to one another causes distance between the first and second portions of the plate to be varied resulting in a device having a plurality of anterior-posterior ratios. The valve sizing element may comprise indicia corresponding to the plurality of anterior-posterior ratios. The indicia may comprise visible markings imprinted on a surface of the valve sizing element, and ends of the arms are located near the markings in order to indicate an anterior-posterior ratio of the device corresponding to a particular configuration of the arms and plate portions. The device may further comprise an elongate element having a proximal end and a distal end, wherein the valve sizing element is coupled to the distal end of the elongate element, and angular movement of the two arms is caused by rotation of the elongate element with respect to the valve sizing element. A third embodiment of the adjustable device comprises: an elongate element having a proximal end and a distal end; a valve sizing element attached to the distal end of the elongate element, the valve sizing element comprising: a plate; and a flange extending from the plate and slidably disposed within the plate; and means for extending the flange from the plate of the valve sizing element that are remotely controlled from the proximal end of the elongate element. The means for extending and retracting the flange may comprise a first wire and a second wire in tension, and the first wire may act to extend the flange from the sizing plate and the second wire may act to retract the flange into the sizing plate. The first and second wires may extend to the proximal end of the elongate element where they are attached to a tab that is moved distally or proximally in the proximal end in order to move the wires.

A third aspect of the present invention is a method of sizing a patient's heart valve annulus. One embodiment comprises the steps of: receiving a device comprising a valve sizing element having one of a plurality of inter-trigonal distances and comprising a plurality of indicia on the valve sizing element corresponding to a plurality of anterior-posterior ratios; inserting the adjustable device into the patient such that the valve sizing element is positioned in the valve annulus; adjusting the valve sizing element so that the valve sizing element contacts the valve annulus; comparing the indicia on the valve sizing element to the valve annulus; determining the
anterior-posterior ratio of the annulus; and removing the valve sizing element from the patient. A second embodiment comprises the steps of: receiving an adjustable device for evaluating a heart valve annulus in order to choose a particular annuloplasty device to be attached to the annulus, the device comprising: a valve sizing element comprising first and second portions and means for moving the portions with respect to one another in order to adjust the valve sizing element to have one of a plurality of different anterior-posterior ratios; inserting the adjustable device into the patient such that the valve sizing element is positioned in the valve annulus; adjusting the valve sizing element so that the valve sizing element contacts the valve annulus; determining the anterior-posterior ratio of the annulus; and removing the valve sizing element from the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The present invention will be further explained with reference to the appended Figures, wherein:

[0020] FIG. 1 is a perspective view of one embodiment of a sizer device in accordance with the present invention;

[0021] FIG. 2 is a front view of a sizing plate of another embodiment of a sizer device in accordance with the present invention;

[0022] FIG. 3 is a side view of the sizing plate of FIG. 2;

[0023] FIGS. 4-6 are front views of a sizing plate of another embodiment of a sizer device in accordance with the present invention, which is shown in three different configurations (one in each FIG.) corresponding to three different A-P ratios;

[0024] FIGS. 7-9 are perspective views of another embodiment of a sizer device in accordance with the present invention, which is shown in three different configurations (one in each FIG.) corresponding to three different A-P ratios;

[0025] FIG. 10 includes a cut-away view of a handle portion of the sizer device of FIGS. 7-9; and

[0026] FIG. 11 is a see-through view of a sizer plate portion of the sizer device of FIGS. 7-9.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0027] With reference to the accompanying figures, wherein like components are labeled with like numerals throughout the several figures, a sizer device that is able to size a valve annulus for an inter-trigonal distance (or inter-commissural distance) and varying A-P ratios is disclosed, taught and suggested. The inter-trigonal (or inter-commissural) distance and A-P ratio of a mitral valve annulus is preferred to be measured in order to be able to choose an appropriate annuloplasty device for repair of a mitral valve.

[0028] In particular, the sizer device of the present invention will correspond to one of a plurality of possible sizes of annulus, i.e. inter-trigonal or inter-commissural distances. The sizer device will also be capable of sizing the annulus for (i.e., comparing the annulus to) at least two different A-P ratios. A purpose of the sizer device including varying A-P ratios is to allow a surgeon to size a particular valve annulus for a plurality of different A-P ratios using only one device. Different A-P ratios in annuli having the same inter-trigonal (or inter-commissural) distance may be due to different disease states of the valves, for example. Thus, a surgeon may measure both inter-trigonal (or inter-commissural) distance and A-P ratio in one device, allowing for an efficient and effective evaluation of the annulus. Preferably, the surgeon has a set of devices with different A-P ratios, and possibly different designs, available for each inter-trigonal (or inter-commissural) distance, or size, of annulus. The surgeon may then choose the appropriate device from the set in order to address the particular concerns with the annulus. Advantageously, the present invention provides the surgeon the ability to more specifically address a problem with a particular valve annulus.

[0029] For each size, or inter-trigonal (or inter-commissural) distance, of sizer device there are a plurality of A-P ratios that may be tested, sized, or evaluated. Preferably, the number of A-P ratios that may be tested by the device is three. The plurality of A-P ratios preferably correspond to different types or categories of annuloplasty devices. For instance, the A-P ratios may correspond to three different categories of devices that are designed to address different problems, pathologies, disease states, etc., relating to the heart. One category is preferably a remodeling (restorative) category that has a traditional annuloplasty device design, which reshapes the annulus that generally has a dilated posterior annulus. The remodeling (restorative) category of devices is preferably designed to address degenerative heart disease, myxomatous degeneration, fibroelastic deficiency, types I and II IMR, and degenerative diseases which result in a dilated posterior annulus, for examples. Another category is a restrictive category of devices, which is preferably designed to address cardiac ischemia, dilated cardiomyopathy, tethered leaflets in secondary mitral valve insufficiency, and Type IIb IMR, for examples. And, a third category is an enlarging category of devices that is preferably designed to address Barlow’s syndrome, systolic anterior motion (SAM) in Myxoid Heart Disease, septal hypertrophy, and Type II IMR, for examples. It is contemplated, however, that the set of devices may include additional types of devices that address additional or alternative heart conditions.

[0030] The present invention is described herein with regard to the treating the mitral valve of the heart. However, it is contemplated that the present invention may also apply to other valves of the heart (e.g., the tricuspid valve). Therefore, the categories and types of annuloplasty devices that the present invention may be used to size for may also be different than those specifically described herein.

[0031] One exemplary embodiment of the present invention is shown in FIG. 1. FIG. 1 shows a perspective view of a sizer device 100 comprising an elongate segment 110 with first 112 and second 114 ends. A valve sizer 120 is attached to the first end 112 of the elongate segment 110. The purpose of the valve sizer 120 as shown is to size a mitral valve annulus in particular. Although, it is contemplated that the present invention may include sizers that size other valves besides the mitral valve.

[0032] The purpose of the elongate segment 110 is to deliver the valve sizer 120 adjacent or near the valve annulus being sized. The surgeon performing the sizing may hold the device 100 from outside of a patient’s body. The elongate segment 110 may comprise a metal wire. However, the present invention is not limited to the use of metal wire for the elongate segment 110, and other materials are also contemplated.

[0033] The elongate segment 110 also preferably includes a handle 116 on the second end 114 of the elongate segment 110. The handle 116 is optional, but is preferred in order for the sizer device 100 to be handled more easily. The handle 116 is shown with optional bevels 118 on the outer surface, in
order to allow for better gripping of the device 100 by a user. The handle 116 is preferably comprised of a polymeric material. However, other materials are also contemplated. The valve sizer 120 comprises a sizing plate 122 and an attachment hub 124. The attachment hub 124 includes a socket 126 into which the elongate segment 110 of the device 100 extends and is secured. In the embodiment shown in FIG. 1, the elongate segment 110 is permanently adhered or secured to the valve sizer 120. However, it is also contemplated that the valve sizer 120 may be configured to be releasably attached to the elongate segment 110. For example, the valve sizer 120 may be snap-fit onto the elongate segment 110 or threaded onto the elongate segment 110, or attached by any other such attachment means.

The sizing plate 122 of the valve sizer 120 may have one of a plurality of possible two-dimensional (2D) and three-dimensional (3D) shapes. The shape of the sizing plate 122 depends upon, e.g., the type of valve being sized, the disease state of the valve, the shape of a corresponding annuloplasty device, etc. For example, the sizing plate 122 may be planar or saddle-shaped.

The sizing plate 122 is preferably made from biocompatible material that is also preferably optically transparent and rigid to the degree that it maintains a shape. The material could, however, have a degree of deformability to minimize tissue trauma while introducing the sizing through the surgical incision site. An exemplary material for the sizing plate 122 is polysulfone or another similar thermoplastic. However, other materials are also contemplated.

As shown in FIG. 1, the valve sizer 120 includes markings 128 on the sizing plate 122. In particular, the markings 128 shown indicate different A-P ratios. The markings 128 are used by a surgeon sizing a valve annulus in order to determine which A-P ratio best accommodates the annulus. The surgeon can preferably see through the sizing plate 122 in order to determine which A-P ratio best corresponds to the valve annulus. The markings 128 shown are letters, e.g., A, B, C, and lines, however, other similar markings are also contemplated, such as words, symbols, etc.

The thickness of the sizing plate 122 of the valve 120 is preferably minimized while still retaining substantial strength to prevent substantial flexing or bending or to prevent breakage. The thickness is minimized in order to prevent optical distortion through the sizing plate 122 and in order to allow the sizing plate 122 to fit through relatively small openings, such as an annulus.

The sizing plate 122 is shown having a continuous surface. However, the plate 122 may alternatively be discontinuous and may include voids.

Another embodiment of sizer device of the present invention is shown in FIGS. 2 and 3. Similar to sizer device 100 described above, sizer device 200 comprises an elongate segment 210 with first 212 and second 214 ends, a handle 216 on second end 214 of elongate segment 210, and a valve sizer 220 (FIG. 2) that includes a sizing plate 222 and an attachment hub 224.

The description of the components as provided with regard to sizer device 100 preferably generally also applies to similar components of sizer device 200. The sizing plate 222 is preferably used to size and determine the A-P ratio of a mitral valve annulus, although the invention contemplates other valves as well. The elongate segment 210 and handle 216, as well as the means for attaching the elongate segment 210 to the valve sizer 220 are similar to those components of sizer device 100. The sizing plate 222 is preferably rigid and preferably made of an optically transparent material.

FIG. 2 shows a front view of the valve sizer 220 with markings 228 denoting three different A-P ratios (indicated as A, B, C), just as in sizer device 100. Other markings are also contemplated, as with sizer device 100.

The side view in FIG. 3 shows that the sizing plate 222 is different from sizing plate 122 in FIG. 1. Sizing plate 222 is preferably stepped (with steps marked as 230) relating to multiple, different A-P ratios. The steps 230 are located on the side of the sizing plate 222 with the attachment hub 224 in FIG. 3. However, the steps 230 could alternatively be located on the opposite side of the sizing plate 222. The purpose of the steps 230 is for the surgeon to be able to position the sizing plate 222 directly in the valve annulus and in contact with the circumference of the valve annulus. The benefit of fitting the annulus around one of the steps 230 of the device is to get a more accurate measurement of the annulus. Also, depending upon which of the steps 230 that the annulus most closely surrounds, the approximate A-P ratio of the annulus is determined.

In sizer device 200, sizing plate 222 includes optional cut-out segments or notches 232 that may be used as left and right trigone position identifiers. When using the sizer device 200 to size a valve annulus, the surgeon inserts the sizer device 200 adjacent a valve annulus and, first, checks the inter-trigonal distance. The user may check the distance by determining if the cut-out segments 232 line up with the left and right trigones of the annulus. The inter-trigonal distance determines the size of the valve sizer 220. Alternatively, the commissures on the annulus are used to determine the size, which is called the inter-commisural distance.

Different sizes of valve sizers 220 may be released and attached to the elongate segment 210. Once the correct size of valve sizer 220 is chosen, the surgeon may then see whether the posterior aspect of the valve annulus coordinates or lines up with one of the markings (A, B or C) 228 or steps 230 corresponding to a particular A-P ratio. An annuloplasty device with a size and A-P ratio substantially identical to that of the sizer device 200 is then preferably chosen and implanted.

Although the trigones may be used to determine the size of the annulus, as described above, there are other methods for determining the size. For example, the two valve commissures (posterior and anterior), which define a distinct region where the anterior and posterior leaflets come together at their insertion into the annulus, may alternatively be used to determine the size of the annulus.

Only three potential A-P ratios are represented in sizer device 200. However, it is contemplated that a different number of and different A-P ratios may be used in the device 200. Also, the sizer device 200 shown is merely representative of many different contemplated sizes and shapes of sizer devices that are in accordance with the present invention.

Another embodiment of the present invention is shown in FIGS. 4-6 in varying 20 configurations. A sizer device, of which only the valve sizer 420 is shown, is used for sizing annuli of various A-P ratios. FIGS. 4-6 show the valve sizer 420 in three different configurations corresponding to three different A-P ratios (A, B, and C). Most of the description of the components, as provided with regard to sizer device 100, preferably generally also applies to corresponding components of valve sizer 420.
The valve sizer 420, however, comprises a sizing plate 422 that comprises two segments (anterior 421 and posterior 423). The two sizing plate segments 421, 423 are extendably connected using components allowing the segments 421, 423 to be separated or brought together to allow the sizing plate 422 to correspond to a mitral valve annulus having one of various A-P ratios. In particular, FIGS. 4-6 show three possible A-P ratios, but other A-P ratios are also contemplated by the present invention.

As shown in FIGS. 4-6, the components of valve sizer 420 shown allow the two segments 421, 423 to move relative to one another and to obtain positioning for the sizing plate 422 to obtain different A-P ratios. Such components comprise first and second arms 470, 472 rotatably connected near the middle of both arms 470, 472 by a pin 474. The arms 470, 472 preferably are controlled by direct manipulation. However, it is also contemplated that the pin 474 could possibly be remotely controlled by an attached handle, for example.

Other configurations allowing for remotely controlling the movement of arms 470, 472 are also possible.

When the pin 474 is rotated, the two arms 470, 472 rotate with respect to each other around the pin 474. Also, the rotation causes ends of the arms 470, 472 located in the posterior segment 423 of the sizing plate 422 to slide in channels 478 and either pull the two sizing plate segments 470, 472 towards each other or push them apart. Preferably, there is an alignment plate 480 on the back side of plates 421, 423, as in FIGS. 4-6, that keeps the plates 421, 423 in alignment during rotation of arms 470, 472. Preferably, the alignment plate 480 is attached to plate 421 and slidable behind plate 423. Other configurations are also contemplated, however. For example, alignment plate 423 could be guided within ribs on the back side of plate 423.

Markings (e.g., A, B, C) may be provided or printed on the sizing plate 422 to indicate the A-P ratios. The arms 470, 472 may preferably line up with the markings 428 depending on the rotation and separation of the anterior and posterior segments 421, 423 as it corresponds to the sizing plate 422 as a whole having a particular A-P ratio.

When using the valve sizer 420 to size a valve annulus, the user inserts the valve sizer 420 adjacent a valve annulus and, first, checks the inter-trigonal distance. The user may check the distance by determining if cut-out segments or notches 432 corresponding to the left and right trigones line up with the left and right trigones of the annulus. The inter-trigonal distance determines the size of the valve sizer 420 to use. Once the inter-trigonal distance of the valve sizer 420 is correct, the surgeon may then rotate the pin 474 by rotating a handle portion (not shown) attached to the pin 474. The segments 421, 423 may then move with respect to one another in order to allow until the perimeter of the sizing plate 422 to be fit to match with the annulus being measured. The arms 470, 472 may line up with a marking 428 (e.g., A, B or C) in order to indicate the A-P ratio of the annulus. An annuloplasty device with a size and an A-P ratio substantially matching that of the valve sizer 420 is then preferably chosen and implanted.

Only three potential A-P ratios are represented on valve sizer 420. However, it is contemplated that a different number of and different A-P ratios may be included on the valve sizer 420. The valve sizer 420 shown is also merely representative of many different contemplated sizes and shapes of valve sizers that are possible.

Yet another embodiment of the present invention is shown in FIGS. 7-11. Sizer device 700 shown comprises an elongate segment 710 with first 712 and second 714 ends, a handle 716 attached to the second end of elongate segment 710, and a valve sizer 720 attached to the first end 712. The valve sizer 720 comprises a sizing plate 722, and an attachment hub 724. The sizing plate 722 includes a flange 782 that is slidably disposed in the remainder of the sizing plate 722 and may be extended out of or retracted into the remainder of the sizing plate 722. The flange 782 in order to provide the sizing plate 722 with one of various A-P ratios (e.g., three in the embodiment shown in the figures). The flange 782 includes two struts 784 that are slidably disposed in channels 786 (FIGS. 8, 9) in sizing plate 722 in order to allow the flange 782 to move relative to the remainder of the valve sizer 720. The sizing plate 722 may include windows or cut-out portions 788 that allow for markings (e.g., A, B, C, as shown) on the struts 784 to show through to indicate a particular A-P ratio that corresponds to the sizing plate 722 in that configuration.

The handle 716 shown includes one exemplary means for remotely controlling the movement of the flange 782. The handle 716 preferably comprises a cylindrically-shaped housing 790, including an elongated slot 792 in the housing 790. A push tab 794 extends out through the elongated slot 792 to provide a means for remotely extending the flange 782 from, and retracting the flange 782 into, the remainder of the sizing plate 722. Push tab 794 may be moved proximally and distally along the slot 792 in order to control the movement of the flange 782. Push tab also includes a portion inside the housing 790, which is a lower element 795 of push tab 794. The lower element 795 is where wires 796, 797 are preferably attached to the push tab 794 in order to remotely control the flange 782.

Preferably, the push tab 794 pulls on at least one wire, but preferably (and as shown) there are two wires 796, 797 being acted upon by the push tab 794. Depending upon which wire 796, 797 is pulled by the push tab 794, the attached flange 782 is either extended or retracted in order to move the flange 782, and provide the sizing plate 722 with a specific A-P ratio.

The wires 796, 797 preferably comprise a material that is strong enough to move the flange 782, and in particular strong enough to pull on portions of the flange 782. Exemplary materials include, but are not limited to, braided stainless steel, nickel alloys, Nitinol®, suture, or suitable polymers. Preferably, the flange 782 is in constant tension with the wires 796, 797. Therefore, the wire material needs to be strong enough to withstand such tension.

FIGS. 10 and 11 illustrate one exemplary configuration of the components inside of the handle 716 and the sizing plate 722, which are used to control the movement of the flange 782, in particular. However, other configurations and methods for moving the flange 782 are also contemplated. With regard to FIG. 10, preferably, two wires 796 and 797 are attached to the lower element 795 of push tab 794. Thus, for example movement of the tab 794 distally pulls on wire 796, and movement of tab 794 proximally pulls on wire 797, or vice versa. Preferably, the wires 796, 797 are in constant tension in order to extend and retract the flange 782.

FIG. 11 illustrates that the two wires 796, 797 are attached to different portions of the flange 782 in order to extend and retract the flange 782. As shown, wire 796 is attached to the bottom portion of flange 782 at lower attachment point 783, and wire 797 is attached to one struts 784 of
the flange 782 at upper attachment point 785. Therefore, as shown, moving push tab 794 proximally could possibly pull wire 797 and extend flange 782. As shown in FIG. 11, wire 797 is preferably attached to flange 782 at upper attachment point 785 and is routed through the sizing plate 722 as shown. By pulling the wire 797 proximally, the wire 797 located at upper attachment point 785 would pull downward (in figure) on strut 784 of flange 782 and would extend the flange 782. Also, as shown, pushing the tab 794 distally may pull wire 796 such that the flange 782 is pulled upward or inward at lower attachment point 783 from an extended position to a retracted position. Other configurations and resulting control of the flange 782 by the wires 796, 797 is also contemplated, however. Also, it is contemplated that a different number of wires or means other than wires may be used to extend and retract the flange 782.

[0062] Other configurations of the sizer device 700 are contemplated by the present invention. The device 700 may alternatively include other means for extending and retracting the flange 782. Alternatively, the device 700 may include a rigid rod for extending and retracting the flange 782, rather than flexible wires 796, 797. For example, such a rigid rod, or actuator shaft, could be moved proximally or distally by twisting of a threaded handle component at the proximal end of the device, which in turn could move the flange 782. Other contemplated means for moving the flange include, but are not limited to, an actuator knob, an actuator trigger, or an actuating handle that can be squeezed. Also, locking features may be implemented in all such contemplated means for moving the flange 782, in order to retain the flange 782 in either a desired extended or retracted position.

[0063] Also, the device 700 may include a tactile feedback feature, as well as visual identification, shown in FIGS. 8-10, to notify the user of the A-P ratio. Another possible feedback mechanism may be audible.

[0064] When using the sizer device 700 to size a valve annulus, the user inserts the sizing plate 722 adjacent a valve annulus and, first, checks the inter-trigonal (or inter-commisural) distance. The inter-trigonal (or inter-commisural) distance determines the size of the sizer device 700. Once the inter-trigonal distance of the sizer device 700 is correct, the user may then move the push tab button 794 on the handle 716 until the perimeter of the sizing plate 722 (with flange portion 782) generally fits the annulus being measured. An indicator of some type may indicate the A-P ratio of the annulus (e.g., A, B, C showing through orifices 788). A device with a size and A-P ratio substantially identical to that of the sizer device 700 is then chosen and implanted.

[0065] Only three potential A-P ratios are represented in sizer device 700. However, it is contemplated that a different number of and different A-P ratios may be included on the device 700. The sizer device 700 shown is merely representative of many different contemplated sizes and shapes of sizer devices.

[0066] It is to be understood that while particular embodiments of the invention have been illustrated for use in typical valve repair procedures, various modifications to shape, and arrangement of parts can be made as may be desirable for varying applications as may relate to valve sizes or later developed techniques. The invention should not be considered limited to the specific methods and devices precisely described herein. On the contrary, various modifications will be apparent to those of ordinary skill upon reading the disclosure. Although certain embodiments are described with reference to the mitral valve, use with other valves or anatomical structures is also contemplated. The foregoing detailed description has been given for clarity of understanding only. No unnecessary limitations are to be understood there from. The entire disclosure of any article, patent or patent application identified herein is hereby incorporated by reference.

1. A device for evaluating a heart valve annulus in order to choose a particular annuloplasty device to be attached to the annulus, wherein the annuloplasty device has an inter-trigonal or inter-commisural distance and an anterior-posterior ratio, the device comprising:
   a valve sizing element having one of a plurality of inter-trigonal or inter-commisural distances and comprising a plurality of indicia on the valve sizing element corresponding to a plurality of anterior-posterior ratios, wherein the indicia are compared to the annulus in order to indicate an anterior-posterior ratio of the annulus.

2. The device of claim 1, further comprising an elongate element having a proximal end and a distal end, wherein the valve sizing element is coupled to the distal end of the elongate element.

3. The device of claim 1, wherein the valve sizing element comprises an optically transparent material.

4. The device of claim 1, wherein the indicia comprising markings on at least one surface of the valve sizing element.

5. The device of claim 4, wherein the markings comprise visible markings imprinted on the at least one surface of the valve sizing element.

6. The device of claim 1, wherein the indicia comprise a plurality of generally semi-circular-shaped ribs that are arranged concentrically along a surface of the valve sizing element.

7. The device of claim 1, wherein the indicia comprise steps in a surface of the valve sizing element that are arranged generally concentrically and are generally semi-circular in shape.

8. An adjustable device for evaluating a heart valve annulus in order to choose a particular annuloplasty device to be attached to the annulus, the device comprising:
   a valve sizing element comprising first and second portions and means for moving the portions with respect to one another in order to provide the valve sizing element with one of a plurality of anterior-posterior ratios.

9. The adjustable device of claim 8, further comprising an elongate element having a proximal end and a distal end, wherein the valve sizing element is coupled to the distal end of the elongate element, and the elongate element comprises means for controlling the movement of the first and second portions.

10. An adjustable device for evaluating a heart valve annulus in order to choose a particular annuloplasty device to be attached to the annulus, the adjustable device comprising:
    a valve sizing element comprising:
    a plate having a first portion and a second portion;
    two arms comprising a center and two ends, the two arms connected to each other by an element near the center of each arm and connected to the first and second portions near the ends of the arms, wherein angular movement of the arms with respect to one another causes distance between the first and second portions of the plate to be varied resulting in a device having a plurality of anterior-posterior ratios.
11. The adjustable device of claim 10, wherein the valve sizing element comprises indicia corresponding to the plurality of anterior-posterior ratios.

12. The adjustable device of claim 11, wherein the indicia comprise visible markings imprinted on a surface of the valve sizing element, and ends of the arms are located near the markings in order to indicate an anterior-posterior ratio of the device corresponding to a particular configuration of the arms and plate portions.

13. The device of claim 10, further comprising an elongate element having a proximal end and a distal end, wherein the valve sizing element is coupled to the distal end of the elongate element, and angular movement of the two arms is caused by rotation of the elongate element with respect to the valve sizing element.

14. An adjustable device for evaluating a heart valve annulus in order to choose a particular annuloplasty device to be attached to the annulus, the adjustable device comprising: an elongate element having a proximal end and a distal end; a valve sizing element attached to the distal end of the elongate element, the valve sizing element comprising: a plate; and a flange extending from the plate and slidably disposed within the plate; and means for extending the flange from and retracting the flange into the plate of the valve sizing element that are remotely controlled from the proximal end of the elongate element.

15. The adjustable device of claim 14, wherein the means for extending and retracting the flange comprises a first wire and a second wire in tension, and the first wire acts to extend the flange from the sizing plate and the second wire acts to retract the flange into the sizing plate.

16. The adjustable device of claim 15, wherein the first and second wires extend to the proximal end of the elongate element where they are attached to a tab that is moved distally or proximally in the proximal end in order to move the wires.

17. A method of sizing a patient’s heart valve annulus, comprising the steps of: receiving a device comprising a valve sizing element having one of a plurality of inter-trigonal or inter-commisural distances and comprising a plurality of indicia on the valve sizing element corresponding to a plurality of anterior-posterior ratios; inserting the adjustable device into the patient so that the valve sizing element is positioned in the valve annulus; adjusting the valve sizing element such that the valve sizing element contacts the valve annulus; comparing the indicia on the valve sizing element to the valve annulus; determining the anterior-posterior ratio of the annulus; and removing the valve sizing element from the patient.

18. A method of sizing a patient’s heart valve annulus, comprising the steps of: receiving an adjustable device for evaluating a heart valve annulus in order to choose a particular annuloplasty device to be attached to the annulus, the device comprising: a valve sizing element comprising first and second portions and means for moving the portions with respect to one another in order to adjust the valve sizing element to have one of a plurality of different anterior-posterior ratios; inserting the adjustable device into the patient so that the valve sizing element is positioned in the valve annulus; adjusting the valve sizing element such that the valve sizing element contacts the valve annulus; determining the anterior-posterior ratio of the annulus; and removing the valve sizing element from the patient.

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