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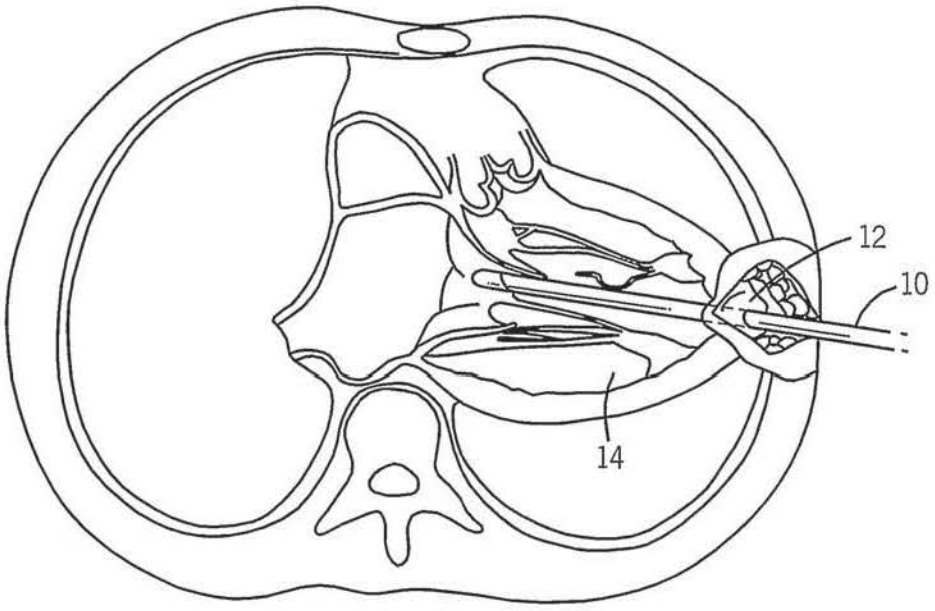
(54) **Title:** THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS



(57) **Abstract:** An instrument for performing thorascopic repair of heart valves includes a shaft for extending through the chest cavity and into a heart chamber providing access to a valve needing repair. A movable tip on the shaft is operable to capture a valve leaflet and a needle is operable to penetrate a capture valve leaflet and draw the suture therethrough. The suture is thus fastened to the valve leaflet and the instrument is withdrawn from the heart chamber transporting the suture outside the heart chamber. The suture is anchored to the heart wall with proper tension as determined by observing valve operation with an ultrasonic imaging system.

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THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is based on U.S. Provisional Patent Application Serial No. 60/645,677 filed on January 21, 2005 and entitled "THORASCOPIC HEART VALVE REPAIR METHOD AND APPARATUS."

BACKGROUND OF THE INVENTION

[0002] Various types of surgical procedures are currently performed to investigate, diagnose, and treat diseases of the heart and the great vessels of the thorax. Such procedures include repair and replacement of mitral, aortic, and other heart valves, repair of atrial and ventricular septal defects, pulmonary thrombectomy, treatment of aneurysms, electrophysiological mapping and ablation of the myocardium, and other procedures in which interventional devices are introduced into the interior of the heart or a great vessel.

[0003] Using current techniques, many of these procedures require a gross thoracotomy, usually in the form of a median sternotomy, to gain access into the patient's thoracic cavity. A saw or other cutting instrument is used to cut the sternum longitudinally, allowing two opposing halves of the anterior or ventral portion of the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the surgical team may directly visualize and operate upon the heart and other thoracic contents.

[0004] Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system, and arrest of cardiac function. Usually, the heart is isolated from the arterial system by introducing an external aortic cross-clamp through a sternotomy and applying it to the aorta between the brachiocephalic artery and the coronary ostia. Cardioplegic fluid is then injected into the coronary arteries, either directly into the coronary ostia or through a puncture in the aortic root, so as to arrest cardiac function. In some cases, cardioplegic fluid is injected into the coronary sinus for retrograde perfusion of the myocardium. The patient is placed on cardiopulmonary bypass to maintain peripheral circulation of oxygenated blood.

[0005] Of particular interest to the present invention are intracardiac procedures for surgical treatment of heart valves, especially the mitral and aortic valves. According to recent estimates, more than 79,000 patients are diagnosed with aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral valve or aortic valve replacement procedures are performed annually in the U.S., along with a significant number of heart valve repair procedures.

[0006] Various surgical techniques may be used to repair a diseased or damaged valve, including annuloplasty (contracting the valve annulus), quadrangular resection (narrowing the valve leaflets), commissurotomy (cutting the valve commissures to separate the valve leaflets), shortening mitral or tricuspid valve chordae tendonae, reattachment of severed mitral or tricuspid valve chordae tendonae or papillary muscle tissue, and decalcification of valve and annulus tissue. Alternatively, the valve may be replaced, by excising the valve leaflets of the natural valve, and securing a replacement valve in the valve position, usually by suturing the replacement valve to the natural valve annulus. Various types of replacement valves are in current use, including mechanical and biological prostheses, homografts, and allografts, as described in Bodnar and Frater, Replacement Cardiac Valves 1-357 (1991), which is incorporated herein by reference. A comprehensive discussion of heart valve diseases and the surgical treatment thereof is found in Kirklin and Barratt-Boyes, Cardiac Surgery 323-459 (1986), the complete disclosure of which is incorporated herein by reference.

[0007] The mitral valve, located between the left atrium and left ventricle of the heart, is most easily reached through the wall of the left atrium, which normally resides on the posterior side of the heart, opposite the side of the heart that is exposed by a median sternotomy. Therefore, to access the mitral valve via a sternotomy, the heart is rotated to bring the left atrium into a position accessible through the sternotomy. An opening, or atriotomy, is then made in the left atrium, anterior to the right pulmonary veins. The atriotomy is retracted by means of sutures or a retraction device, exposing the mitral valve directly posterior to the atriotomy. One of the fore mentioned techniques may then be used to repair or replace the valve.

[0008] An alternative technique for mitral valve access may be used when a median sternotomy and/or rotational manipulation of the heart are undesirable. In this technique, a large incision is made in the right lateral side of the chest, usually in the region of the fifth intercostal space. One or more ribs may be removed from the patient, and other ribs near the incision are retracted outward to create a large opening into the thoracic cavity. The left atrium is then exposed on the posterior side of the heart, and an atriotomy is formed in the wall of the left atrium, through which the mitral valve may be accessed for repair or replacement.

[0009] Using such open-chest techniques, the large opening provided by a median sternotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for manipulation of surgical instruments, removal of excised tissue, and/or introduction of a replacement valve through the atriotomy for attachment within the heart. However, these invasive, open-chest procedures produce a high degree of trauma, a significant risk of complications, an extended hospital stay, and a painful recovery period for the patient. Moreover, while heart valve surgery produces beneficial results for many patients, numerous others who might benefit from such surgery are unable or unwilling to undergo the trauma and risks of current techniques.

[0010] The mitral and tricuspid valves inside the human heart include an orifice (annulus), two (for the mitral) or three (for the tricuspid) leaflets and a subvalvular apparatus. The subvalvular apparatus includes multiple chordae tendinae, which connect the mobile valve leaflets to muscular structures (papillary muscles) inside the ventricles. Rupture or elongation of the chordae tendinae result in partial or generalized leaflet prolapse, which causes mitral (or tricuspid) valve regurgitation. A commonly used technique to surgically correct mitral valve regurgitation is the implantation of artificial chordae (usually 4-0 or 5-0 Gore-Tex sutures) between the prolapsing segment of the valve and the papillary muscle. This operation is generally carried out through a median sternotomy and requires cardiopulmonary bypass with aortic cross-clamp and cardioplegic arrest of the heart.

SUMMARY OF THE INVENTION

[0011] The present invention is a method and apparatus for performing a minimally invasive thoracoscopic repair of heart valves while the heart is beating. More specifically the method includes inserting an instrument through the subject's chest wall and through the heart wall. The instrument carries on its distal end a movable element which is manipulated to grasp a valve leaflet and hold it while a needle mechanism punctures the valve leaflet and loops a suture around a portion of the valve leaflet. The instrument is withdrawn from the heart along with the suture and the suture is tied off at the apex of the heart after adjusting its tension for optimal valve operation as observed with an ultrasonic imaging system.

[0012] In addition to grasping and needle mechanisms, the instrument includes fiber optics which provide direct visual indication that the valve leaflet is properly grasped. A set of illuminating fibers terminate at the distal end of the instrument around the needle mechanism in close proximity to a set of sensor fibers. The sensor fibers convey light from the distal end of the instrument to produce an image for the operator. When a valve leaflet is properly grasped, light from the illuminating fibers is reflected off the leaflet surface back through the sensor fibers. On the other hand, if the valve leaflet is not properly grasped the sensor fibers see blood.

[0013] A general object of the invention is to provide an instrument and procedure which enables heart valves to be repaired without the need for open heart surgery. The instrument is inserted through an opening in the chest wall and into a heart chamber while the heart is beating. The instrument enables repair of a heart valve, after which it is withdrawn from the heart and the chest.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0014] Under general anesthesia and double-lumen ventilation, the patient is prepped and draped so as to allow ample surgical access to the right lateral, anterior and left lateral chest wall (from the posterior axillary line on one side to the posterior axillary line on the other side). As shown in Fig. 1, one or more thoracoscopic ports are inserted in the left chest through the intercostal spaces and an instrument 10 is inserted through one of these ports into the chest cavity. Alternatively, a small (3-5 cm) left thoracotomy is performed in the fifth or sixth intercostals space on the anterior axillary line. The patient is fully heparinized. After collapsing the left lung,

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