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Abstract

With the advent of several valve repair techniques, mitral valve repair is now preferred over mitral valve replacement as the treatment of choice for several mitral pathologic conditions. Because annular dilation is a vital component in most cases of chronic mitral regurgitation (MR), annular support is necessary to provide adequate repair and optimum long-term results. Annular reinforcement permits shrinking of the dilated annulus, allowing adequate coaptation of the valve leaflets, thereby preventing recurrent dilation.

Reference


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Mitral Annuloplasty Using A Biodegradable Annuloplasty Ring

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With the advent of several valve repair techniques, mitral valve repair is now preferred over mitral valve replacement as the treatment of choice for several mitral pathologic conditions. Because annular dilation is a vital component in most cases of chronic mitral regurgitation (MR), annular support is necessary to provide adequate repair and optimum long-term results.1 Annular reinforcement permits shrinking of the dilated annulus, allowing adequate coaptation of the valve leaflets, thereby preventing recurrent dilation.2

It is vital to bear in mind that the mitral annulus is a dynamic structure that is flexible and changes shape throughout the cardiac cycle,3 assuming a 3-dimensional “saddle-shape”4 that reduces mechanical stress on the leaflets. Although for surgical purposes, the mitral annulus is considered the area of attachment of the valve leaflets to the atrial muscle, the firmest site of support for the mitral valve is in the region of the fibrous continuity between the aortic and mitral valves, the extent of which is delineated by the right and left fibrous trigones.5

Although traditionally available rigid, semirigid, and flexible rings meet the demands in adults, they do not permit growth of the native mitral annulus in children.6 Furthermore, anticoagulation is required following annuloplasty with the conventional rings to prevent thromboembolic complications.7 Recent advances in biotechnology have enabled the development of a novel biodegradable annuloplasty ring made of 1,4-polydioxanone polymer that undergoes degradation by hydrolysis over a period of 6 months, triggering a controlled inflammatory response that induces the formation of fibrous scar tissue.8

Our group had earlier published experimental findings of this new biodegradable Kalangos annuloplasty ring (Parvulus, Lonay, Switzerland) (Fig. 1).4,9 Following approval for clinical application, these rings were implanted in patients with MR secondary to various mitral pathologic conditions.6,9 Unlike conventional annuloplasty rings that are sutured directly “onto” the mitral annulus, this biodegradable ring is inserted “into” the annulus within the subendocardial plane. In addition to providing annular support in the immediate postoperative period owing to its semirigid consistency, this ring also provides good mid-term results5 due to the fibrosis induced along the mitral annulus. It also preserves the growth potential of the annulus, while maintaining annular dynamics and geometry.10 Furthermore, the intra-annular position of the ring negates the need for postoperative anticoagulation.

In this article, we present the intra-annular implantation techniques and the rationale of the biodegradable annuloplasty ring in mitral valve repair.

Criteria for Mitral Repair

In our practice, we routinely advise surgical intervention to all symptomatic patients with severe MR, strictly following the guidelines outlined by the American College of Cardiology and American Heart Association.10 We recommend mitral valve surgery for asymptomatic patients with chronic severe MR, with mild to moderate left ventricular dysfunction, with an ejection fraction of 0.30 to 0.60, and/or end-systolic dimension greater than or equal to 40 mm.10 Mitral valve surgery is also reasonable for asymptomatic patients with preserved left ventricular function, if the patient has recent onset of atrial fibrillation or pulmonary hypertension (pulmonary artery systolic pressure greater than 50 mm Hg at rest, or greater than 60 mm Hg with exercise).10

With increasing experience with the biodegradable annuloplasty ring, we attempt to repair almost all our mitral valve patients, with valve replacement being undertaken only if repair is not feasible.

The exclusion criterion for implanting Kalangos biodegradable annuloplasty ring is in cases of severely calcified posterior segment of the mitral annulus. However, fibrosis of the mitral annulus is not a contraindication for Kalangos biodegradable annuloplasty ring.
Operative Approach

After induction of anesthesia, the heart is approached through a median sternotomy. Following standard aortic cannulation and cannulation of the superior and inferior vena cavae, the patient is placed on cardiopulmonary bypass. The heart is arrested using antegrade cold blood cardioplegia delivered through the ascending aorta, with perfusion maintained at normothermia, and the heart is vented through the left atriotomy.

Exposure and Examination of the Mitral Valve

The superficial tissue overlying the Waterston’s groove is dissected before incising the dilated left atrium to improve exposure of the mitral valve. The left atriotomy is extended superiorly along the groove under the superior vena cava, and inferiorly up to the level of the inferior vena cava. If the left atrium is small, we prefer the extended vertical transseptal approach (onto the roof of the left atrium) as proposed by Guiraudon and coworkers.11 Insertion of the mitral retractor, traction on the caval tourniquets, and rotating the operating table away from the surgeon facilitate adequate visualization of the mitral valve. Preliminary inspection of the valve is performed using 2 nerve hooks, taking care to examine thoroughly all segments of the valve, including the leaflets, subvalvular apparatus, and annulus, correlating the intraoperative findings with the preoperative transesophageal echocardiography. Once the initial repair, using various techniques as proposed by Carpentier12 and others,13-16 has been completed, mitral annuloplasty using Kalangos biodegradable ring is undertaken.

Sizing of the Biodegradable Ring

The anterior mitral leaflet is unfurled, and the corresponding sized Kalangos biodegradable ring that matches the surface area of the anterior mitral leaflet (Fig. 2) is chosen for implantation.

Ring Implantation and Positioning

One of the needles of Kalangos biodegradable annuloplasty ring is inserted along the subendocardial plane into the annulus at the level of the posterior commissure, 2 mm away from the hinge point of the posterior leaflet, at a depth of approximately 2 to 3 mm (Fig. 3). The suture bites should not be oriented deep toward the left atrioventricular groove,17 with care taken to insert Kalangos biodegradable ring into the annulus, and not into the mitral leaflet tissue.

The needle is advanced in the intra-annular plane along the posterior segment of the mitral annulus and exited approximately 3 to 4 cm from the point of entry (Fig. 4A). The point of entry of the next stitch is the same as the exit point of the previous stitch, thus moving the Kalangos biodegradable ring forward along the posterior annulus (Fig. 4B). By taking approximately 3 such stitches, the ring is gradually advanced and positioned along the posterior segment of the mitral annulus (Fig. 4C). The last stitch exits at the level of the anterior commissure, thereby placing the ring along the entire circumference of the posterior segment of the mitral annulus, in an intra-annular plane (Fig. 4D).

Kalangos Biodegradable Annuloplasty Ring Fixation

The corresponding needles are passed into the anterior and posterior trigones (Fig. 5A), with the sutures passed twice through the respective trigones to fix the ring firmly in place within the posterior mitral annulus (Fig. 5B). The sutures are finally tied on themselves at the respective trigones (Fig. 5C). Kalangos biodegradable ring annuloplasty facilitates plication of the posterior mitral annulus and both commissural areas, thereby improving coaptation of the anterior and posterior mitral leaflets (Fig. 5D).

An alternative technique involves passing the suture extensions beyond the level of the trigones and continuing the sutures along the anterior annulus up to its mid point, where the sutures are tied to each other. This technique is used when the anterior segment of the mitral annulus is dilated as occasionally seen in Barlow’s disease. In mitral insufficiency due to ischemic and idiopathic dilated cardiomyopathy, this complete circumferential version of Bioring implantation is recommended (Fig. 6).
Figure 1 Characteristics of biodegradable ring. The biodegradable mitral annuloplasty ring consists of a “C”-shaped segment of the polymer that is attached on either end with monofilament polyvinylidene fluoride suture extensions with a swaged stainless steel needle on each end. The polyvinyl suture material (2-0 for adult sizes, and 3-0 for pediatric sizes) is in continuity over the entire central portion of the polymer ring. The specific molecular weight of this annuloplasty ring provides structural memory that prevents morphological deformity. Kalangos biodegradable annuloplasty ring is available in sizes ranging from 16 to 36.
Figure 2 Sizing of Kalangos biodegradable annuloplasty ring. The size of the mitral annulus corresponds to the surface area of the anterior mitral leaflet, which equates to the intertrigonal distance. In other words, the anterior mitral leaflet is unfurled, and the corresponding annuloplasty ring sizer that matches the surface area of the anterior mitral leaflet determines the correct size of the ring for implantation. This ideal sizing technique reduces the annular size and produces a coaptation surface of at least 0.5 cm between the anterior and posterior leaflets.
Kalangos biodegradable annuloplasty ring implantation. Kalangos biodegradable ring annuloplasty commences with subendocardial insertion of its needle into the annulus at the level of the posterior commissure 2 mm away from the hinge point, at a depth of approximately 2 to 3 mm. Because the circumflex coronary artery runs adjacent to the annulus along the left atrioventricular groove, the suture bites should not be oriented deep toward the left atrioventricular groove. Care is taken to insert Kalangos biodegradable ring into the annulus and not into the mitral leaflet tissue.
Figure 4 (A) Kalangos biodegradable annuloplasty ring positioning. The needle is advanced in an intra-annular plane along the posterior segment of the mitral annulus and exited approximately 3 to 4 cm from the point of entry. (B) It is vital that the point of entry of the next stitch is the same as the exit point of the previous stitch, thus moving forward along the posterior annulus. This prevents direct contact between the annuloplasty ring and circulating blood, thereby inhibiting premature biodegradation of the annuloplasty ring. (C) By taking approximately 3 such stitches, the ring is gradually advanced and positioned along the length of the posterior segment of the mitral annulus. (D) The last stitch exits at the level of the anterior commissure, thereby placing the ring along the entire circumference of the posterior mitral annulus, in an intra-annular plane.
Figure 5  (A) Kalangos biodegradable annuloplasty ring fixation. Once the ring is in place, the corresponding needles are passed into the anterior and posterior trigones. (B) The sutures are passed twice through the respective trigones to fix the ring firmly in place within the posterior mitral annulus. (C) The sutures are finally tied on themselves at the respective trigones. (D) When the ring implantation and fixation have been completed, it can be noted that the posterior mitral annulus is well-plicated, improving the coaptation between the anterior and posterior mitral leaflets. Furthermore, the entire annuloplasty ring is embedded within the annular tissue, with only the final suture knots being visible at the anterior and posterior trigones.
Figure 6. Alternative technique. An alternative technique involves passing the suture extensions beyond the level of the trigones and continuing the sutures along the anterior annulus up to its mid point, where the sutures are tied to each other. This technique is used when the anterior segment of the mitral annulus is dilated as occasionally seen in Barlow’s disease. In mitral insufficiency due to ischemic and idiopathic dilated cardiomyopathy, this complete circumferential version of Kalangos biodegradable ring implantation is recommended.
Figure 7  Experimental morphologic analysis following Kalangos biodegradable annuloplasty ring implantation. Cut section of an experimental human cadaveric heart following the ring implantation, and color-coded latex injection into the coronary vasculature. The white bold arrow indicates cut section of the ring. Black arrow indicates the coronary sinus, and the white broken arrow indicates the circumflex coronary artery. Despite the intra-annular plane of insertion, the ring is at a safe distance from the coronary sinus and the circumflex artery, suggesting minimal risk of iatrogenic ischemic complications following Kalangos biodegradable ring annuloplasty. (Color version of figure is available online.)
Postoperative Assessment

Once the annuloplasty is complete, the ventricle is pressurized with cold saline solution using the syringe bulb, and the presence of any residual leak is assessed. During the saline injection, it is vital to open the aortic vent cannula to prevent coronary air embolism. Minimal regurgitation by visual examination is considered acceptable. The atrium is closed using 3-0 polypropylene sutures; the heart is de-aired through the aortic vent, and the patient is gradually weaned off cardiopulmonary bypass in the standard fashion. With the systolic blood pressure at over 100 mm Hg, mitral valve competence and adequacy of repair are reassessed by intra-operative transesophageal echocardiography. The presence of more than mild (grade 1) mitral regurgitation is considered unacceptable, and the inability to obtain less than grade I-II MR by re-repair techniques warrants mitral valve replacement. Patients are managed postoperatively in the intensive care unit as routine and undergo a pre-discharge transthoracic echocardiography on the 4th or 5th postoperative day.

Discussion

Kalangos biodegradable annuloplasty ring represents a new concept in the constantly evolving science of annuloplasty owing to its unique intra-annular implantation technique and biodegradable properties. This ring encircles the entire length of the posterior segment of the mitral valve, as well as both commissural areas, and supports the posterior annulus from trigone to trigone. Although the ring does not encircle the entire annulus, this can be considered acceptable, because the results of posterior annuloplasty have been suggested to be equivalent to circumferential annuloplasty.18

The semirigid structure of the ring at the time of implantation enhances good leaflet coaptation and permits mobility of the mitral valve annulus during the cardiac cycle, yet it does not interfere with the motion of the posterior annulus and the leaflets. The gradual biodegradation of the ring induces annular fibrosis and ensures optimal annular reinforcement and good results in the midterm.19 Although the concept of intra-annular implantation of an annuloplasty ring is new, and may raise concerns about the safety of its implantation technique, our experimental studies9,10 have confirmed that Kalangos biodegradable annuloplasty ring does not cause ischemic complications secondary to circumflex coronary artery occlusion (Fig. 7).

Kalangos biodegradable ring annuloplasty is easily facilitated by a single continuous suture, unlike the multiple interrupted sutures used in conventional annuloplasty. Hence, the implantation time and the aortic cross-clamp time are significantly shorter.6 This is particularly important when performing complex mitral valve repairs, or in concomitant procedures. The intra-annular position of the ring prevents contact with blood; hence, it negates the need for anticoagulation. Most of all, the ring preserves the growth potential of the native mitral and tricuspid annulus.20,21

Conventional annuloplasty rings consist of woven, non-degradable prosthetic material that may be a source for the colonisation and proliferation of bacteria, and may adversely affect the surgical outcome in patients.22,23 The sub-endocardial implantation of the biodegradable ring prevents direct contact of the ring with the blood circulation, which is an added advantage in patients with acute infective endocarditis. Pektok et al. published their results using the biodegradable ring in 17 consecutive patients with acute infective endocarditis.24 During median follow-up of the survivors (14 patients, 83 %) at 29.6 months, no mortality, recurrence, or re-operation was noted. At follow-up, transthoracic echocardiography revealed no regurgitation, or trivial regurgitation in 11 patients, and mild regurgitation in 3 patients.

Yakub et al. shared their experience using the biodegradable ring in young children.25 Between 2006 and 2011, 68 patients underwent mitral valve repair for congenital mitral valve disease. They divided their patients into two groups, which included 39 patients with biodegradable annuloplasty ring implantation, and 29 patients with non-ring annuloplasty techniques. There was a significant difference between the two groups concerning freedom from mitral valve repair failure (p =0.04) and mitral valve re-operation free survival (p=0.026). Follow-up echocardiography on 24 patients with the biodegradable ring was undertaken to assess growth of the native annulus. The mean Z-score was noted to undergo normalisation at 3 and 5 years, which suggests normal annular growth following biodegradable ring implantation. This again is an added advantage of the biodegradable ring in the paediatric population, since it permits growth of the native valve annulus.

Our experience with the Biodegradable Ring

Between 2003 and 2014, 457 patients underwent mitral valve repair using Kalangos biodegradable annuloplasty ring for MR. The etiologies for MR included rheumatic disease in 155, Barlow’s disease in 123, congenital mitral malformations in 84, mitral degeneration in 37, ischemic mitral disease in 31, endocarditis in 17, Marfan syndrome in 9, and trauma in 1. The mean age of the patients was 38.6 years (range 1-86) and comprised 251 men (55 %). Moderate to severe MR was present in all patients preoperatively, which reduced to trivial or mild regurgitation in 434 (93%) at a mean follow-up period of 6.2 years (range 1-11 years). There were a total of 4 deaths (0.8 % mortality) in this series, with a 30-day mortality of 2 (0.4 %). Mitral valve reoperation was necessary in 13 (2.8 %) rheumatic patients, at a median period of 6.7 months from the time of initial repair to redo operation.

Conclusions

Mitral annuloplasty using Kalangos biodegradable annuloplasty ring is safe and effective. Its surgical implantation technique is easily reproducible and can be performed successfully. The unique intra-annular position and biodegradable properties of the ring help overcome some of the limitations of currently available annuloplasty rings. (Fig. 6).

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References