Saddle-shaped mitral valve annuloplasty rings improve leaflet coaptation geometry

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Objectives: The mitral valve annulus naturally conforms to a saddle shape in systole. This configuration is believed to put the leaflets into a lower-energy equilibrium with the annulus and subvalvular apparatus. Conventional flat annuloplasty rings restrict posterior leaflet motion, which may result in a ''monocusp'' valve, affecting valvular stress distribution. It is hypothesized that saddle-shaped annuloplasty rings cause less distortion of the physiologic leaflet geometry than do flat rings.

Methods: Twelve pigs were studied in an acute setting with 3-dimensional echocardiography and sonomicrometry before and after implantation of rigid flat (n = 5) and saddle-shaped (n = 7) annuloplasty rings. The rings were true sized to the annulus with equal anterior–posterior and commissure–commissure circumferential dimensions. The saddle-shaped rings had an annular height to commissural width ratio of 15%.

Results: Saddle-shaped rings maintained both leaflets operational ($P < .01$). Flat rings made the posterior leaflet immobile and the anterior leaflet aligned flat along the annulus in systole, effectively resulting in monoleaflet function. The average distance from the papillary muscle tips to the posterior annulus decreased by 2.4 ± 0.4 mm after flat ring implantation ($P < .01$).

Conclusions: Saddle-shaped annuloplasty rings provide better leaflet coaptation geometry than do flat rings by not hoisting the papillary muscles toward the posterior annulus through the commissural chordae, allowing greater leaflet mobility. This entails a potentially beneficial impact on valvular stress distribution that could affect durability of the repaired valve. (J Thorac Cardiovasc Surg 2011;142:697-703)

During the past 20 years, mitral valve (MV) repair has been increasingly preferred over replacement.[1] As an adjunct procedure, annuloplasty ring implantation is believed to support the repair and increase durability of the operation.[2]

Improved 3-dimensional (3D) visualization techniques such as echocardiography and magnetic resonance imaging have provided new insight into the dynamic behavior of the MV apparatus and improved repair techniques.[3] The natural shape of the MV annulus changes dynamically throughout the cardiac cycle. It conforms to a saddle shape (hyperbolic paraboloid) in systole and dilates back to a flatter configuration during diastole.[4-8] This configuration is believed to increase leaflet curvature and put the leaflets into a lower-energy equilibrium with the annulus and subvalvular apparatus, hereby minimizing stresses in the leaflets and surrounding tissues.[6,7,9-12] This has prompted a re-evaluation of MV annuloplasty ring designs.[5,7,9,13-16] In conjunction with annular dynamics, leaflet and chordal geometry plays an important role in the valvular force equilibrium. It has been proposed that the triangular chordal connection between the leaflets, the annulus, and the subvalvular apparatus plays a significant role in MV functionality.[17,18] Hence, the saddle shape of the mitral annulus is part of a sophisticated geometric construct that is designed to work in concert while minimizing stress on the individual components.

The mechanical properties of conventional annuloplasty rings available today are typically uniformly distributed around the annular circumference, with no or little attention drawn to the natural 3D dynamics of the MV annulus. New

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Abbreviations and Acronyms

3D = 3-dimensional
ECG = electrocardiography
PM = papillary muscle
MV = mitral valve
RFAR = rigid flat annuloplasty ring (group)
RSAR = rigid saddle-shaped annuloplasty ring (group)

generations, however, of either nonplanar or flexible rings have become available. However, these rings either fix the annulus in a certain 3D configuration or provide insufficient support for the repair.

Annuloplasty ring implantation affects MV leaflet behavior. For example, postannuloplasty monocusp behavior of the anterior leaflet and immobilization of the posterior leaflet of the MV have been described,[19,20] and recently the influence of ring design on leaflet curvature and functionality has been investigated in vivo.[13,20,21] However, the underlying mechanism behind improving leaflet curvature is not well understood and the overall positive effect on the MV force balance remains to be answered. Hence, the impact of different mitral annular remodeling by flat and saddle-shaped annuloplastry rings on mitral leaflet coaptation geometry in vivo needs to be investigated further.

We hypothesize in this short-term, nonischemic study that true-sized saddle-shaped annuloplasty rings cause less distortion of the physiologic leaflet geometry and coaptation pattern than do true-sized flat rings. The aim was to compare 3D dynamics of leaflets, annulus, and papillary muscles (PMs) between flat and saddle-shaped annuloplasty rings.

MATERIALS AND METHODS

Surgical Preparation and Sonomicrometry

Sixteen mixed Yorkshire and Danish Landrace pigs with a body weight of 80 kg were included in a short-term setup. Three animals were excluded from the rigid flat annuloplasty ring (RFAR) group and 1 was excluded from the rigid saddle-shaped annuloplasty ring (RSAR) group owing to poor ultrasound signal quality. These issues were not caused by factors that are linked to the results in this project (risking a biasing error in the selection process), but simply owing to generic ultrasound quality assessment. All pigs were bred under standard laboratory animal conditions, and the experiment complied with the guidelines from the Danish Inspectorate of Animal Experimentation. The study was approved by this institution. The details of the surgical preparation of porcine animal experimental protocols at our institution have previously been described.[22] The pigs were humanely killed by injection of 50 mL pentobarbital directly into the left ventricle.

After establishment of cardiopulmonary bypass and cardioplegic arrest, the MV was exposed through a left atriotomy. Eight sonomicrometry crystals were placed equally spaced in the annulus plane, one on each PM tip, and one in the apex.[9] The sonomicrometry equipment consisted of 2-mm round crystals with suture loops and a data acquisition system with an external ultrasound transceiver unit and a personal computer with an installed digital circuit board to record the intercrystal distance (Sonometrics Corp, London, Ontario, Canada). The annuloplasty ring sutures were premounted in the circumference of the mitral annulus to facilitate subsequent ring implantation on the beating heart. Sutures and crystal wires were exteriorized through the left atriotomy. The wires from the PM and apex crystals were exteriorized through the apex. The atriotomy was closed, and after 1 hour of reperfusion the animals were weaned from bypass. After hemodynamic stabilization, baseline electrocardiography (ECG), 3D sonomicrometry crystal array coordinates, hemodynamics (pulmonary artery flow, left ventricular pressure, and left atrial pressure), and echocardiographic data were recorded while the animals were intubated and with the chest open.

Annuloplasty Rings

The mitral annuloplasty rings were designed on the basis of the profile of the D-shaped Carpentier–Edwards Classic annuloplasty ring (Edwards Lifesciences, Irvine, Calif). The flat (RFAR group) and saddle-shaped configuration (RSAR group) were based on the same profile and the RSARs were designed with an annular height to commissural width ratio of 15%. The dimensions of the MV annulus in an 80-kg pig are very similar to the adult human MV annulus,[23] correlating the Carpentier–Edwards ring size between 30 and 32. Hence, the rings were true sized to the annulus with equal anterior–posterior and commissure–commissure circumferential dimensions to minimize confounding adverse mechanical effects from undersizing annuloplasty.[24,25] The rings were built with the use of Rapid Prototyping Technology (DAVINCI Development, Billund, Denmark, and Danish Technological Institute, Aarhus, Denmark). Plastic was chosen as material to minimize artifacts on echocardiographic imaging.

Experimental Protocol

After baseline recordings (see above), cardiopulmonary bypass was reestablished, and the left atrium was reopened on the beating heart. Each pig was used as its own control. Five pigs received RFARs and 7 received RSARs. The rings were implanted to the annulus using the 8 premounted sutures. The heart was again weaned from cardiopulmonary bypass, and after hemodynamic stabilization, ECG, 3D sonomicrometry crystal array coordinates, and echocardiographic and hemodynamic data were recorded.

Data Acquisition

Hemodynamics. Left ventricular and left atrial pressures were acquired with Mikro-Tip pressure catheters (SPC-350MR; Millar Instruments, Inc, Houston, Tex). Cardiac output was acquired on the main pulmonary artery location with transit time ultrasound perivascular flow probes (Transonic Systems Inc, Ithaca, NY) and the CardioMed data acquisition system (model 4008; CardioMed A/S, Oslo, Norway). Analog signals from the pressure and flow acquisition systems were acquired with data acquisition hardware (NI-9215; National Instruments, Austin, Tex). ECG and hemodynamic data were recorded with custom-designed virtual instrumentation software (LabVIEW version 8.2; National Instruments).

Echocardiography. The 2D biplane echocardiographic recordings in a parasternal long-axis view was acquired by epicardial echocardiography using an ultrasound scanner (Vivid 7; GE Vingmed Ultrasound, Horten, Norway) equipped with a 3D matrix-probe 3 V with a frequency range of 2 to 5 MHz. Measurements were performed before and after implantation of the rings to assess the angles, coaptation tenting height (Figure 1), area between the annular plane and the leaflets (coaptation tenting area), and leaflet curvature (Figure 2). The sonomicrometry system was inactivated during echocardiographic imaging. Utilizing the biplane ultrasound probe and software ensured that leaflet measurements were obtained throughout the MV septal–lateral axis of symmetry (center of the fibrous trigones), ensuring that the septal–lateral axis did not shift during acquisition of the cardiac cycle. This consistency was verified by comparing the