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Saddle-Shaped Mitral Valve Annuloplasty Rings Experience Lower Forces Compared With Flat Rings

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- **Background**—New insight into the 3D dynamic behavior of the mitral valve has prompted a reevaluation of annuloplasty ring designs. Force balance analysis indicates correlation between annulus forces and stresses in leaflets and chords. Improving this stress distribution can intuitively enhance the durability of mitral valve repair. We tested the hypothesis that saddle-shaped annuloplasty rings have superior uniform systolic force distribution compared with a nonuniform force distribution in flat annuloplasty rings.
- *Methods and Results*—Sixteen 80-kg pigs had a flat (n=8) or saddle-shaped (n=8) mitral annuloplasty ring implanted. Mitral annulus 3D dynamic geometry was obtained with sonomicrometry before ring insertion. Strain gauges mounted on dedicated D-shaped rigid flat and saddle-shaped annuloplasty rings provided the intraoperative force distribution perpendicular to the annular plane. Average systolic annular height to commissural width ratio before ring implantation was $14.0\% \pm 1.6\%$. After flat and saddle shaped ring implantation, the annulus was fixed in the diastolic ($9.0\% \pm 1.0\%$) and systolic ($14.3\% \pm 1.3\%$) configuration, respectively (P < 0.01). Force accumulation was seen from the anterior ($0.72N \pm 0.14N$) and commissural annular segments (average $1.38N \pm 0.27N$) of the flat rings. In these segments, the difference between the 2 types of rings was statistically significant (P < 0.05). The saddle-shaped annuloplasty rings did not experience forces statistically significantly larger than zero in any annular segments.
- *Conclusions*—Saddle-shaped annuloplasty rings provide superior uniform annular force distribution compared to flat rings and appear to represent a configuration that minimizes out-of-plane forces that could potentially be transmitted to leaflets and chords. This may have important implications for annuloplasty ring selections. (*Circulation*. 2008; 118[suppl 1]:S250–S255.)

Key Words: mitral valve ■ mitral annuloplasty rings ■ heart valve diseases

S urgical repair of the mitral valve (MV) is generally favored over complete MV replacement because of maintenance of the subvalvular mechanical support of the left ventricle (LV).^{1,2} For degenerative MV disease, a mitral annuloplasty ring is routinely implanted as an adjunct procedure to repair. The annuloplasty ring relieves tensile stresses on the repaired valve tissue and decreases tension on suture lines, intuitively enhancing durability.³

Conventional MV annuloplasty rings are either stiff or flexible with a flat or curved outline along the annular perimeter. However, natural 3D dynamics and force distribution of the MV annulus is not taken into account in these designs.

New insight into the 3D dynamic behavior of the mitral valve has prompted a reevaluation of annuloplasty ring designs. Several studies in combination prove that the natural annulus conforms to a saddle-shape (hyperbolic paraboloid) in systole and dilates back to a flatter configuration during diastole.⁴⁻⁹ To describe the height of the saddle, the average Annular Height to Commissural Width Ratio (AHCWR) reported in literature is typically between 10% and 20%.⁴⁻⁹ Correlation between annulus and leaflet dynamics, and between stresses in leaflets, papillary muscles (PMs), and chords have been demonstrated.⁸⁻¹³ Therefore, remodeling annuloplasty rings that respect cyclic 3D dynamic changes of the annulus may optimize annular, valvular, and suture stresses and hereby increase repair durability by diminishing out-of-plane forces that are transmitted to the repaired leaflets and chords.

We assessed the hypothesis that saddle-shaped annuloplasty rings have superior systolic force distribution compared with a nonuniform force distribution in flat annuloplasty rings. The aim of this study was to compare the 3D

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Figure 1. Sonomicrometry crystals placed around the mitral valve annulus and the subvalvular apparatus, defining the location of the following annular, subvalvular, and left ventricular regions: 1: Center of trigones (Saddle Horn), 2: Right trigone, 3: Posterior commissure, 4: P3 scallop, 5: Center of posterior annulus (P2 Scallop), 6: P1 scallop, 7: Anterior commissure, 8: Left trigone, 9: Anterior papillary muscle (APM), 10: Posterior papillary muscle (PPM), 11: Left ventricular apex. AML indicates anterior mitral leaflet; PML, posterior mitral leaflet.

force distribution in saddle-shaped mitral annuloplasty rings with their flat counterpart.

Materials and Methods

Surgical Preparation and Sonomicrometry

Sixteen mixed Yorkshire and Danish Landrace pigs (University of Aarhus Experimental Animal Farm, Aarhus, Denmark) with a body weight of 80 kg were used in an acute setup. All pigs were bred under standard laboratory animal conditions, and the experiment complied with the guidelines from the Danish Inspectorate of Animal Experimentation. The present study was approved by this institution. The details of the porcine model have previously been described.^{14,15} The pigs were euthanized with injection of 50 mL pentobarbital directly into the LV.

After establishment of cardiopulmonary bypass and cardioplegic arrest, the mitral valve was exposed through a left atriotomy. Eight sonomicrometry crystals were placed equally spaced at the annulus plane, one on each PM tip, and one in the apex (Figure 1). Sutures used to fix the annular crystals were exteriorized through the left atriotomy for subsequent annuloplasty ring implantation. Noncompliant suture material (Etibond Excel Polyester 2-0) was used to ensure proper force transmission. The annular crystal wires were exteriorized through the left atriotomy with the sutures. Attachment of crystals to PMs and apex was performed with Surgipro II 5-0 Monofilament Polypropylene suture. The PM and apex crystal wires were exteriorized through the LV apex. The animals were weaned from cardiopulmonary bypass and studied with the chest open.

Annuloplasty Ring Force Transducers

The mitral annuloplasty rings were designed based on the profile of the D-shaped Carpentier-Edwards Classic annuloplasty ring (Figure 2). The dimensions of the MV annulus in an 80-kg pig are very similar to the adult human MV annulus,¹⁶ correlating the Carpentier-Edwards ring size between 30 and 32. The saddle-shaped ring had an



Figure 2. Design of (a) flat and (b) saddle-shaped annuloplasty rings to measure forces in the mitral valve annulus. c, Strain gauges mounted at the anterior (ANT), posterior (POST), anterior commissural (ACOM), and posterior commissural (PCOM) segments of a saddle-shaped measurement ring.

AHCWR of 15%.⁵ Using Rapid Prototyping Technology (DAVINCI Development, Billund, Denmark and Danish Technological Institute, Aarhus, Denmark), the 2 designs were dedicated to measure bending strain (in the apical/basal direction) at 4 specific locations within the mitral annulus. Plastics were chosen as material to increase the strain gauge signal-to-noise ratio. The strain gauges were mounted on the rings positioned above each commissure, between the trigones, and at the center of the posterior annulus (Vishay Measurements Group UK Ltd; Figure 2c). The strain gauges were connected in quarter bridge circuits and operated by dedicated data acquisition hardware and software (see Data Acquisition below). The rings were tested for strains from circumferential forces,¹⁵ and this component was found to be less than 10% of the strain obtained from 'bending' forces perpendicular to the annular plane.

A calibration setup was designed and used to convert the regionally measured unit (strain) to restraining force in the annuloplasty



Figure 3. Calibration set-up of restraining force measurement annuloplasty rings. One of 4 calibration setups is shown for the saddle-shaped ring; the calibration of anterior and posterior strain gauges in the positive strain direction, with positive direction forces pointing down toward the apex. The U-shaped device is holding the ring in place during calibration.

rings (Figure 3). All data on restraining force were adjusted according to this calibration. Restraining forces acting in the apical direction were defined positive. With this definition, forces creating (positive) strain in the anterior segment are positive. The MV annulus structural integrity along the annular perimeter is complex, and the fixation arrangement of annuloplasty rings in the MV annulus could not be precisely replicated in this calibration setup.

A frequency response test of the rings was performed to determine the upper limiting frequencies of the system. The response curves were flat within ± 3 dB up to approximately 150 Hz, sufficient for intracardiac measurements.¹⁷

Experimental Protocol

After baseline recordings cardiopulmonary bypass was reestablished, and the left atrium was reopened on beating heart. Eight pigs received flat annuloplasty rings and eight received saddle-shaped annuloplasty rings. The rings were mounted on the mitral annulus using the premounted sutures. The heart was again weaned from cardiopulmonary bypass, and ECG, 3D sonomicrometry crystal array coordinates, four channels strain gauge measurements of the annuloplasty ring, and hemodynamic data were recorded.

To investigate the effect of LV filling on the restraining force balance in the MV annulus, data were acquired before and 10 seconds after onset of inferior vena cava occlusion.

Data Acquisition

Annuloplasty ring strain measurements were acquired with data acquisition hardware (compact DAQ model 9172 and NI-9237, National Instruments). Left ventricular and left atrial pressures were acquired with Microtip pressure catheters (SPC-350MR, Millar). Pulmonary artery flow was acquired with transit time ultrasound perivascular flowprobes (Transonic Systems Inc) and the CardioMed data acquisition system (Model 4008, CardioMed A/S). Analog signals from the pressure and flow acquisition systems were acquired with data acquisition hardware (NI-9215, National Instruments). ECG and hemodynamic data were recorded with virtual instrumentation software LabVIEW version 8.2 (National Instruments). The sonomicrometry equipment consisted of 2-mm round crystals with suture loops and a system consisting of an external ultrasound



Figure 4. Representative curves of left ventricular pressure (LVP) and average commissural restraining force as a function of time (seconds [s]) during vena cava occlusion after a flat ring annuloplasty. Vena cava occlusion significantly reduced the systolic restraining force, but did not impact annular restraining forces in diastole. Trend curves for the systolic and diastolic relationship illustrate the difference.

transceiver unit and a PC with an installed digital circuit board to record the intercrystal distance (Sonometrics Corp).

Data Analysis

For offline analysis, all signals were initially preprocessed with a 10 heart cycle ensemble average. Mid-systole and -diastole were defined as center points between LV dp/dt max and min. Cardiac output was calculated by integrating the flow measurement through one cardiac cycle, which was defined as the time from QRS peak-to-peak. ECG and hemodynamic parameters were used for synchronization between the sonomicrometry and the LabVIEW data acquisition systems.

Based on the sonomicrometry data, Multi Dimensional Scaling techniques (MDS, CardioSOFT and SonoXYZ; Sonometrics Corp)18 were used to assess the relative difference in mitral annulus geometry and AHCWR between mid-systole and -diastole before and after ring implantation. A least-square fit plane was constructed with data from the annulus crystals to define the saddle height.⁴⁻⁸ The plane was obtained from all 8 annulus crystals, and the height was defined as the sum of distances from the center of the trigones (saddle horn⁶) and the average distance from the commissural crystals to this plane. Zero adjustment of the annulus force signals was accomplished during sustained vena cava occlusion, as the annulus was assumed to be relaxed in mid-diastole before atrial systole (as confirmed by echo) in the unloaded heart (see Figure 4). In addition, the change in restraining force for each cardiac cycle as a function of pressure change during caval occlusion was utilized in regression analysis of the dependency between LV filling and restraining force magnitude.

Statistical Analysis

All data were analyzed with STATA (StataCorp LP) and reported as mean plus and minus the standard error of the mean (\pm SEM) unless otherwise stated. Differences in AHCWR between mid-systole and -diastole and hemodynamic parameters before and after ring insertion were tested by paired *t* tests. *P*<0.05 was considered statistically significant. The Wilcoxon matched pairs signed-rank nonparametric test was used to verify the statistical conclusions on AHCWR data and hemodynamic parameters.

The force measurements on individual annuloplasty ring areas were not independent. Therefore, repeated measurements analysis of variance was performed to test the hypothesis that the difference in force between individual annulus segments within and between rings

Ring Type	HR (bpm)	LVP (mm Hg)	CO (L/min)
No ring (before flat)	102±7	103±14	6.0±0.9
Flat ring	113±6	85±8	$5.4 {\pm} 0.7$
No ring (before saddle)	114±7	$108{\pm}10$	5.9±1.1
Saddle ring	119±9	96±14	4.9±0.9

Table 1. Hemodynamic Parameters

Data stated as mean ± standard error of mean.

HR indicates heart rate in beats per minute; LVP, peak-systolic left ventricular pressure in mm Hg; CO, cardiac output in liters per minute.

No statistically significant difference in hemodynamic parameters was observed before and after ring implantation.

is zero can be rejected. Differences between individual annulus segments were investigated with the Wilcoxon rank-sum equality test.

Box and whisker plots were used to summarize the force measurements, showing outliers, upper and lower range, upper and lower 75th percentiles, and median. An outlier as defined by STATA is a value that is more than 3/2 times the interquartile range away from the median.

The nonparametric Kruskal–Wallis equality-of-populations rank test was used to reject the possibility of a false-positive result when comparing the absolute diastolic and systolic force values within and in-between rings.

The percentage change in restraining force as a function of LV pressure percentage change was performed by regression analysis of midsystolic data from each heart cycle during caval occlusion.

The authors had full access to the data and take responsibility for its integrity. All authors have read and agree to the manuscript as written.

Results

Hemodynamic data are summarized in Table 1. The AHCWR measurements before and after ring implantation are summarized in Table 2. The annulus was fixed in the diastolic and systolic configuration with the flat and saddle-shaped ring implanted, respectively (P < 0.01).

Representative curves of annular restraining forces in relation to hemodynamic recordings are illustrated in Figures 5 and 6. Comparison of the magnitude of annular restraining force (from mid-diastole to mid-systole) for the flat and saddle-shaped rings are shown in Figure 7. Force accumulation was seen from the anterior $(0.72N\pm0.14N)$ and commissural annular segments (average $1.38N\pm0.27N$) of the flat rings. The saddle shaped ring did not experience forces statistically significantly different from zero in any annular segments (P > 0.05).

Absolute diastolic and systolic restraining force values are summarized in Table 3. For the flat annuloplasty ring in systole, positive restraining forces were experienced from the anterior segments and negative restraining forces were expe-

Table 2. Annular Height to Commissural Width Ratio

	No Ring (%)	Flat Ring (%)	Saddle-Shaped (%)
Systole	14.0±1.6	8.9±1.3†	14.4±1.9
Diastole	10.0±1.9*	9.1±1.7†	14.2±1.8

*Statistically significant difference between systole and diastole (P<0.05). †Placement of crystals on native annular structures before ring implantation caused maintenance of diastolic nonplanarity after flat ring annuloplasty. See text.

Data stated as mean \pm standard error of mean.



Figure 5. Representative curves of restraining forces in relation to left ventricular pressure (LVP), left atrial pressure (LAP), and ECG throughout a cardiac cycle (aligned at end-diatole) following a flat ring annuloplasty. ANT indicates anterior segment; POST, posterior segment; PCOM, posterior commissural segment; ACOM, anterior commissural segment.

rienced from the commissural segments. The difference in magnitude in-between annulus segments of the restraining forces generated in the flat ring in systole was significantly higher than forces of the saddle-shaped ring (P < 0.05). The



Figure 6. Representative curves of restraining forces in relation to left ventricular pressure (LVP), left atrial pressure (LAP), and ECG throughout a cardiac cycle (aligned at end-diatole) following a saddle-shaped ring annuloplasty. ANT indicates anterior segment; POST, posterior segment; PCOM, posterior commissural segment; ACOM, anterior commissural segment.



Figure 7. Magnitude of the relative restraining forces (Newton) of the anterior (ANT), posterior (POST), posterior commissural (PCOM), and anterior commissural (ACOM) segment after flat and saddle-shaped ring annuloplasty. Box and whisker plots show upper and lower range, upper and lower 75th percentiles, and median. Positive forces were directed toward the left ventricular apex. *Statistically significant difference between flat and saddle-shaped ring annuloplasty (P<0.05).

diastolic forces of the 2 ring types were not statistically significantly different in any annular segments.

Decreasing diastolic LV filling (preload) and systolic LV pressure by vena cava occlusion reduced the systolic restraining forces (Figure 4). This procedure was performed successfully in 7 of 8 animals (flat ring annuloplasty group). The correlation between absolute average commissural and anterior restraining forces versus systolic LV pressure by linear regression analysis for the flat ring was positive in all seven animals, and r^2 >0.6 in 5 animals. Vena cava occlusion did not impact annular restraining forces in diastole either of the 2 rings (Figure 4).

Discussion

Even though the mitral annuloplasty remodeling concept introduced by Carpentier¹⁹ is widely accepted, the optimal shape and flexibility of mitral annuloplasty rings are still controversial.²⁰

In this study, different regional force patterns of the flat and saddle-shaped mitral annuloplasty rings suggest that the mitral valve annulus and its attached valvular and subvalvular structures are applying torque onto the flat annuloplasty ring attempting to conform it into the saddle-shaped configuration in systole. The saddle-shape of the mitral annulus apparently

Table 3. Absolute Annular Restraining Forces

	Flat Ring (Newton)		Saddle-Shaped Ring (Newton)	
	Diastole	Systole	Diastole	Systole
ANT	0.01 ± 0.06	0.64±0.08*	$-0.10 {\pm} 0.07$	-0.22±0.16*
POST	$-0.05 {\pm} 0.09$	$0.15 {\pm} 0.21$	$-0.05 {\pm} 0.04$	$-0.34{\pm}0.15$
PCOM	$-0.20 {\pm} 0.12$	$-1.30 \pm 0.38^{*}$	$0.05{\pm}0.07$	0.18±0.20*
ACOM	$0.06 {\pm} 0.13$	$-1.59 \pm 0.38^{*}$	$-0.33 {\pm} 0.22$	$-0.29 \pm 0.39^{*}$

Force data stated as mean±standard error of mean.

ANT indicates anterior segment; POST, posterior segment; PCOM, posterior commissural segment; ACOM, anterior commissural segment.

*Indicates a statistically significant difference between flat and saddle-shaped rings (P < 0.05).

constitutes a low-force configuration in systole, and accordingly, the saddle-shaped annuloplasty ring provided a lowforce condition of the mitral annulus in systole. These observations may have important implications for annuloplasty rings selections. Furthermore, special caution to avoid ring dehiscence at the high-stress areas should be taken during annuloplasty ring implantation.

The exact mechanism of systolic saddle-shape in the native mitral annulus is yet unknown. In vitro we have previously demonstrated a relative reduction of forces in the commissural chords with a saddle-shaped annulus compared with a flat annulus.¹² Even though clinical extrapolation from this stiff left ventricular in vitro model may be limited, the data indicate that if the normal saddle shape of the annulus is forcibly restrained by a flat ring, the commissural chordae are placed under tension.

Decreasing diastolic LV filling and systolic LV pressure by caval occlusion resulted in a reduction in the restraining forces of the anterior and commissural segments in the flat annuloplasty rings. This indicates that the restraining forces are load-dependent and coupled to myocardial contraction according to the Frank-Starling mechanism. Previous experimental studies have shown that annular shrinkage and shape change is initiated in end-diastole.²¹ This is in accordance with our observations showing a 'hump' on the restraining force curves in end-diastole (Figure 5). Maximum restraining forces were experienced when the saddle-shape was most pronounced (peak AHCWR) at the end of LV ejection (Figure 5).

The increased stress in the commissural segment induced by the flat ring may affect natural alignment of the papillary muscles and chords to the mitral leaflets and hereby have negative impact on leaflet coaptation geometry and leaflet stress distribution. This concept is supported by data from our own laboratory illustrating that ring shape influences leaflet copatation geometry (Ref. Abstract # 14824 presented at AHA Scientific Sessions 2007: Jensen et al: 'Saddle-shaped Mitral Valve Annuloplasty Rings Improve Leaflet Coaptation Geometry').

Limitations

This study was performed on healthy nonischemic pig hearts. Hence, the findings of the present study may particularly address ring annuloplasty performed as an adjunct procedure in degenerative valve repair. In accordance with our observations, annular flattening as observed in ischemic mitral regurgitation may potentially augment the leaflet and chordal stresses, and it is plausible that saddle-shaped annuloplasty rings in these cases may relieve the stresses of the functionally impaired MV apparatus.

The restraining forces were derived from a well defined external calibration set-up, which is not replicating the fixation of the annuloplasty ring in vivo. The zero-adjustment of the restraining force signals was based on the assumption that the annulus and hereby the ring is unloaded at the end of a caval occlusion.

Conclusion

In this experimental evaluation of two rigid annuloplasty ring designs, the saddle-shaped annuloplasty ring provided a more

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favorable and uniform annular force distribution compared to flat annuloplasty rings. The study provided basic insights into the mechanisms of mitral annular dynamic shape-change, which is essential to improve surgical techniques that protect valvular structures after mitral valve repair. The results from this study may form a rational basis for innovative annuloplasty ring designs that allow sufficient mobility and flexibility to improve stress distribution at the attachment and of the leaflet tissue while offering sufficient stability to ensure proper leaflet coaptation and to reduce valvular incompetence.

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Disclosures

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