Toward the development of a fully elastic mitral ring: Preliminary, acute, in vivo evaluation of physiomechanical behavior

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Objectives: The optimal repair of functional mitral regurgitation is still debated. No device is able to simultaneously abolish mitral regurgitation and replicate natural mitral annular dynamics. We have tested a fully elastic mitral ring in an acute animal study with the purpose of evaluating (1) ring design and implantation technique, (2) elastic performance, and (3) acute effects on the native mitral annulus.

Methods: Ten healthy sheep underwent surgical implantation of mitral devices, the elastic component of which is represented by a helicoid metallic spring. Preimplantation and postimplantation echocardiographic parameter measurements to evaluate annular dynamics and ventricular function comprise mitral annular motion, systolic tissue Doppler imaging peak wave, transmitral pressure gradient, peak transmitral flow velocity, and ejection fraction. Postimplantation angiographic analysis allowed measurement of the mitral annular area and perimeter variations by means of segmentation of the radiopaque mitral device contour.

Results: No significant difference in terms of ejection fraction ($P = .13$) and systolic tissue Doppler imaging peak wave ($P = .87$) was found before and after implantation. Mitral annular motion (1.16 cm) was preserved. The percentage of systolic annular reduction derived from angiographic analysis was 14.1% (range, 7.7%–19.7%) in terms of area and 7.2% (range, 4.9%–10.0%) in terms of perimeter.

Conclusions: A mitral elastic ring, implantable by using a standard technique, acutely preserves mitral annular dynamics, allowing area and perimeter changes. Further chronic study is needed to verify the biocompatibility and durability of the device.

The mitral annulus (MA) is a discontinuous fibromuscular ring with a rough anatomic structure and complex physiology. It is a dynamic structure that undergoes changes in size and shape throughout the cardiac cycle.[1]

The change in the size of the annular area has been demonstrated in animal and human models, and a cyclic reduction of annular area has been revealed, with minimal area in systole.[2-5] It has also been pointed out that the shape of the MA is a hyperbolic paraboloid and is therefore reminiscent of a saddle, with a higher curvature in systole.[6] Furthermore, the annulus is seen to move during the cardiac cycle; it undergoes anterior displacement toward the apex during ventricular systole and posterior displacement toward the base during ventricular diastole, as well as during atrial contraction.[7,8]

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The MA dynamics are regulated by the elastic properties of the myocardial tissue.[7] Theoretically, the ideal annuloplasty ring design for functional mitral regurgitation (FMR) should, in addition to permanently abolishing mitral insufficiency, promote an MA dynamic motion, facilitate its sphincteric contraction, and provide an active force to help in the orifice's systolic mitral area reduction. A fully elastic mitral ring prototype was developed and implanted on the MAs of 10 healthy sheep to test this hypothesis. The purpose of this study was to acutely assess the maintenance of the physiologic annular motion behavior.

MATERIALS AND METHODS

The animal study was designed to evaluate immediate (day 0) and long-term (3–6 months) results after implantation of the elastic device in healthy sheep. Long-term evaluation will mostly aim at the device's physical performance and biocompatibility assessment. The present study reports the early results, with the aim of demonstrating the feasibility of the procedure and the device's mechanical performance in its interaction with the native MA.

Mitral Device

The device used for this study is a fully elastic and flexible ring that is able to expand and bend according to MA dynamics. By definition, this device follows the law of elasticity, which states that an elastic body deforms under external forces but then returns to its original shape and dimensions when the external forces are removed.

The device is made up of 2 basic components: (1) a flexible and expandable textile suturable component that enables the implantation of the ring

Abbreviations and Acronyms

CPB = cardiopulmonary bypass
EF = ejection fraction
FMR = functional mitral regurgitation
ICC = intraclass correlation coefficient
LV = left ventricle
MA = mitral annulus
MAM = mitral annular motion
S-TDI = systolic tissue Doppler imaging

according to the usual annuloplasty surgical technique and (2) an elastic component represented by a helicoid spring made of a metallic alloy.

The spring has an elastic constant of 20 N/m, corresponding to an exerted force of 160*g* for an elongation of 20%. The elastic constant of the device has been chosen empirically after animal tests and according to Literature values of annular dynamics in healthy sheep.[3] The spring is circular at rest. For the implantation, the device is mounted on a holder that has the typical kidney-bean shape of the MA, with a linear anterior border (relative to the intertrigonal segment) and a circular posterior border (relative to the shape of the annulus between the commissures). When mounted on the holder, the device is loaded and is subjected to an elongation of 20%. The predetermined dimension of the device, relative to the intercommissural diameter at implantation, has been derived from anatomic data from previous reports.[2] Because the ring is stretched when implanted, it tends to contract the MA after implantation. Figure 1 shows the dimensions of the spring at rest and in implant configuration.

The viscoelastic properties of the annular tissue together with the left ventricular forces and pressure during the cardiac cycle determine the dynamics of the elastic device (Figure 2).

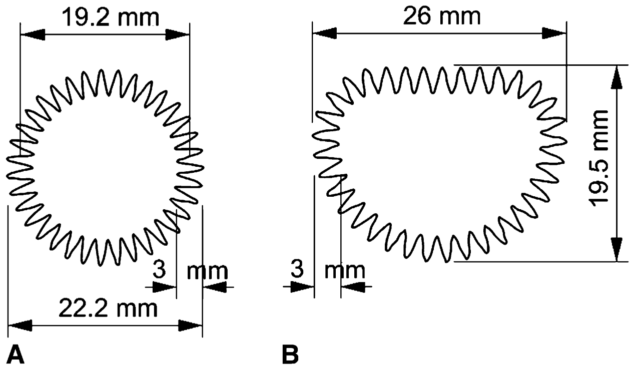

FIGURE 1. The elastic component of the device is represented by a helicoid spring: A, rest configuration with dimensions; B, implant configuration with dimensions.

Surgical Procedure

The study was approved by the institutional ethics committee for animal research, and all animals received humane care in compliance with the ''Guide for the care and use of laboratory animals'' prepared by the Institute of Laboratory Animal Resources, National Research Council, and published by the National Academy Press, revised 1996. This study follows the Italian guidelines for the protection of animals used for scientific and other experimental purposes (D.L.G.S. 27/01/1992, no. 116).

Ten female Ile de France sheep, weighing 63.5 ± 4.5 kg (range, 55–70 kg) and with a mean age of 18.17 ± 6.78 months, were anesthetized with an intravenous injection of 10 mg/kg thiopental followed by isoflurane in 100% oxygen. Mechanical ventilation was maintained with an air/oxygen mixture and a tidal volume of 20 mL/kg.

In right lateral recumbency a left fourth intercostal thoracotomy was performed, and the heart was suspended in a pericardial cradle.

After full heparinization, normothermic cardiopulmonary bypass (CPB) was instituted, cannulating the right carotid artery with a 20F cannula and the right ventricle through the pulmonary artery with a 28F cannula. The pump flow was kept at a rate of 50 mL · kg^{-1} · min^{-1} by using a roller heart-lung machine primed with 1000 mL of lactated Ringer solution and bicarbonate. Blood gases were maintained in the physiologic range with a membrane oxygenator. With the heart beating, an incision on the left atrial appendage was performed, and the device was sutured to the MA by means of 10 to 12 single U stitches. The left atrium was closed and vented, and after a period of hemodynamic stabilization, the animals were weaned from CPB. After the completion of angiographic and echocardiographic evaluation, the chest was closed, and the animals were weaned from mechanical ventilation and awakened.

Echocardiography

All epicardial Doppler echocardiographic studies were performed with a multifrequency transducer attached to a Vingmed System 5 (General Electric, Fairfield, Conn). All images were obtained in real time by an experienced echocardiographer in sleeping animals before and after CPB. Two-dimensional echocardiographic analysis was performed epicardially through the intercostal thoracotomy and through the transdiaphragmatic approach. Long-axis, short-axis, 4-chamber, and 5-chamber views were obtained.

Three sets of measurements were made in each echocardiographic view at predetermined steps. The mean value of 3 measurements was used to describe the quantitative data for each animal at each step. End-diastolic and end-systolic measurements were obtained at the time of the peak R-wave and the end of the T-wave, respectively.

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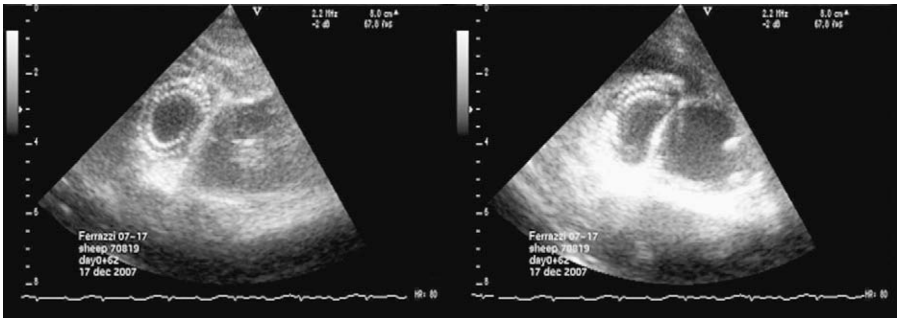

FIGURE 2. Echocardiographic imaging: change in shape and dimensions according to the cardiac cycle phases: diastole (on the left) and systole (on the right).