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Mitral annuloplasty ring with selective flexibility for septal–lateral contraction and remodelling properties†

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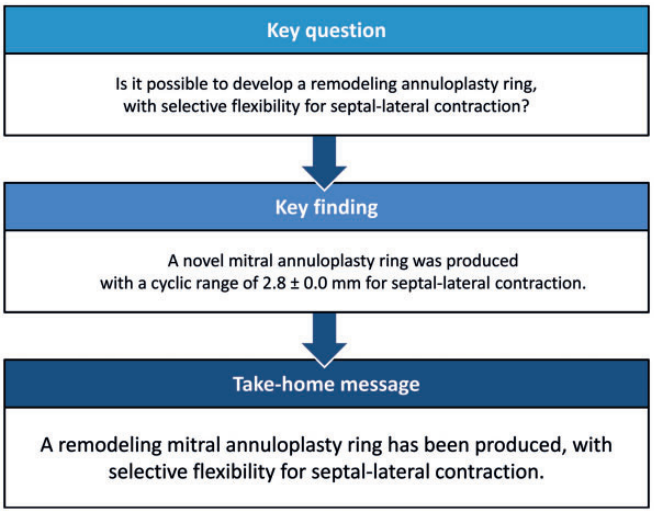

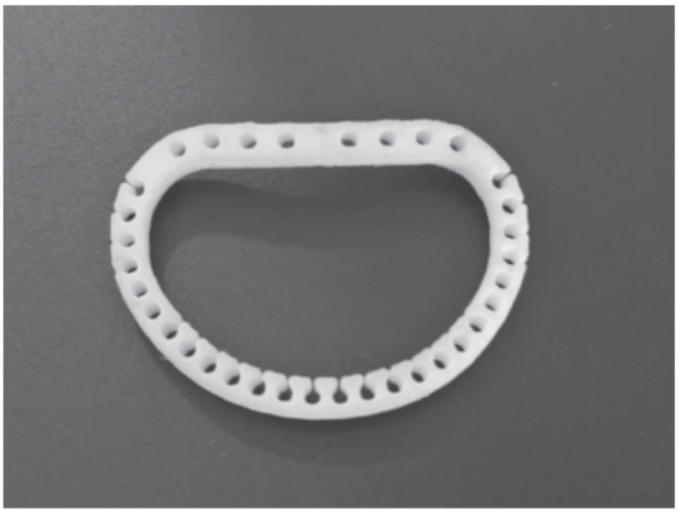

Abstract

OBJECTIVES: To develop and evaluate a novel mitral annuloplasty ring with selective flexibility for septal–lateral contraction and rigidity for septal–lateral dilatation in an acute porcine model.

METHODS: The novel mitral annuloplasty ring was designed with slits in the luminal posterior segment and annular lateral segments. The slits were designed to allow inward motion during contraction and to block outward motion during dilation. The novel mitral annuloplasty ring was tested *in vitro* with a dedicated mechanical test bench, followed by *in vivo* characterization, using sonomicrometry and echocardiography for annular and leaflet geometry, in an acute porcine model.

RESULTS: From the *in vitro* characterization, we verified that the ring could easily contract (0.7 mm/N) in the septal–lateral dimension, while dilatation was restrained (0.4 mm/N). *In vivo* characterization showed a cyclic range of 2.8 ± 0.0 mm for septal–lateral contraction.

CONCLUSIONS: A novel saddle-shaped remodelling mitral annuloplasty ring was developed with selective flexibility for septal–lateral contraction and rigidity for septal–lateral dilatation. The advantages of this specific ring is that it re-establishes the coaptation plane, ensures leaflet mobility and septal–lateral flexibility and at the same time improves tissue adaptation and thereby decreases the risk of ring

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dehiscence and redilatation of the mitral annulus. This concept may prove beneficial for patients with ischaemic mitral valve regurgitation or degenerative valve disease.

Keywords: Mitral valve • Mitral valve annuloplasty • Ischaemic mitral valve regurgitation • Degenerative valve disease • Undersized mitral annuloplasty ring

INTRODUCTION

More than a decade ago, Bolling *et al.* [1] published an article on the use of an undersized mitral annuloplasty ring for patients with severe mitral valve regurgitation. Since then, undersized mitral annuloplasty rings have been considered the gold standard for patients with ischaemic mitral valve regurgitation without basal aneurisms, severe leaflet tethering or severe ventricular enlargement [2–4]. An undersized mitral annuloplasty ring brings the annulus together, which consequently re-establishes the coaptation plane and reduces the central regurgitant jet, created by leaflet tethering and the annulus dilatation itself [5]. For these patients, it is advantageous to use a complete ring rather than a partial ring, and a remodelling ring rather than a flexible ring, to prevent redilatation of the annulus [6, 7]. For patients with primary mitral regurgitation, a repair is favourable and often involves the use of a semi-rigid ring (Physio I or Physio II Ring™, Edwards Lifesciences, Irvine, CA, USA) [3, 4, 8]. The Physio I and Physio II rings were designed for degenerative valve disease with a larger antero-posterior/septal–lateral diameter, compared to other rings, and with a saddle shape [8]. For both ischaemic mitral valve regurgitation and degenerative valve disease, the optimal ring must ensure the optimal coaptation, as well as a ring size as close to the native annulus as possible.

The use of undersized remodelling mitral annuloplasty rings, with a smaller septal–lateral annular diameter, might lead to several complications. As the posterior part of the mitral annulus is dynamic during a systolic contraction, the forces acting on the undersized remodelling mitral annuloplasty ring and the ring sutures will be increased compared to a no-ring situation [9–11]. In contrast to the anterior mitral annulus, the posterior part of the annulus has a reduced collagen content. Along with the augmented forces acting on the ring, these factors increase the risk of ring dehiscence [12, 13]. This is true for patients not only with ischaemic mitral valve regurgitation but also with degenerative valve disease [14, 15]. Some semi-rigid annuloplasty rings have even been designed to accommodate septal–lateral annular contraction. However, a recent study indicated that the septal–lateral diameter of a semi-rigid ring behaved comparably to a rigid ring following implantation [10].

We therefore hypothesize that a saddle-shaped remodelling mitral annuloplasty ring, with selective flexibility for septal–lateral contraction and rigidity for septal–lateral dilatation, would be beneficial for patients with ischaemic mitral valve regurgitation or degenerative valve disease. The aim of the study was to develop a saddle-shaped remodelling mitral annuloplasty ring, with selective flexibility for septal–lateral contraction, and to evaluate it both *in vitro* and *in vivo*, in a single porcine animal model in an acute setting as a proof of concept.

MATERIALS AND METHODS

Development of a novel mitral annuloplasty ring

The concept of a mitral annuloplasty ring with selective septal–lateral flexibility was proposed by co-author Jean-Paul Couetil. The novel prototype mitral annuloplasty ring was three-dimensional printed with DuraForm® PA—a durable, bio-compatible thermoplastic (DAVINCI Development, Billund, Denmark). As the ring is a prototype, it is non-sleeved as opposed to a ring used in the clinical setting. The holes in the ring are used for the implantation (Fig. 1). A D-shaped novel mitral annuloplasty ring was designed with slits in the luminal posterior segment and annular lateral segments (Fig. 1A). The slits were designed to widen during contraction and narrow or even block further motion with dilatation. The flexibility of the slits was optimized to previously described septal–lateral force measurements [16]. During a contraction in the septal–lateral dimension, the slits widen in the luminal posterior segment and in the annular lateral segments (Fig. 1B). The widening of the slits allows for a shorter septal–lateral distance together with a wider anterior segment during contraction. When the ring is dilated, the edges of the slits are designed to collide and block dilatation exceeding the *in vitro* size. Hence, a selective septal–lateral flexibility for mitral annular contraction is the result, with widening of the anterior segment together with prevention of mitral annular dilatation. The novel mitral annuloplasty ring was also designed with a saddle shape of 10% in the anterior segment and 5% in the posterior segment [17]. These dimensions were comparable to a Carpentier-Edwards Physio I Ring M32 (Edwards Lifesciences).

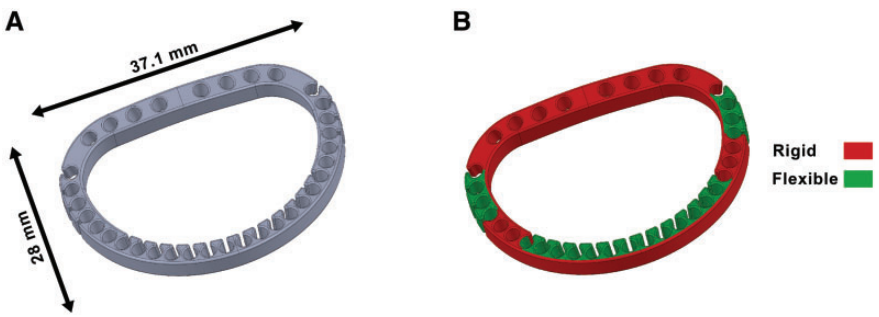

Figure 1: (**A**) Concept illustration of the novel ring design. (**B**) Flexible and rigid parts of the novel ring. The red colour represents the rigid parts, and the green colour represents the flexible parts.

In vitro ring characterization

The novel mitral annuloplasty ring was tested using a dedicated mechanical test bench. The forces ranged from -5 to 5 N in both the septal–lateral and commissure–commissure directions with contralateral point-to-point fixation during measurement. Compression was defined as a decrease in distance with a force range of 0–5 N. Tension was defined as an increase in distance with a force range of 0 to -5 N.

Sonomicrometry and echocardiography

To measure the mitral annular geometry, 8 miniature piezoelectric crystals (2 mm) were used. The technique is based on ultrasound sonomicrometry (Sonometrics Corp., London, ON, Canada) [18, 19]. The leaflet geometry was measured with two-dimensional (2D) epicardial echocardiography (Vivid I and EchoPAC 113.0.4, GE Vingmed Ultrasound AS, Horten, Norway).

Animal experimental characterization

An acute 80-kg porcine model was used (Mixed Yorkshire and Danish Landrace pig provided by University of Aarhus Experimental Animal Farm, Aarhus, Denmark). The porcine anatomical properties are similar to that of their human counterpart [20]. The study population comprised one animal because this study was a proof of concept. The study complied with national guidelines for experimental animal research, and the study was approved by the Danish Inspectorate of Animal Experimentation.

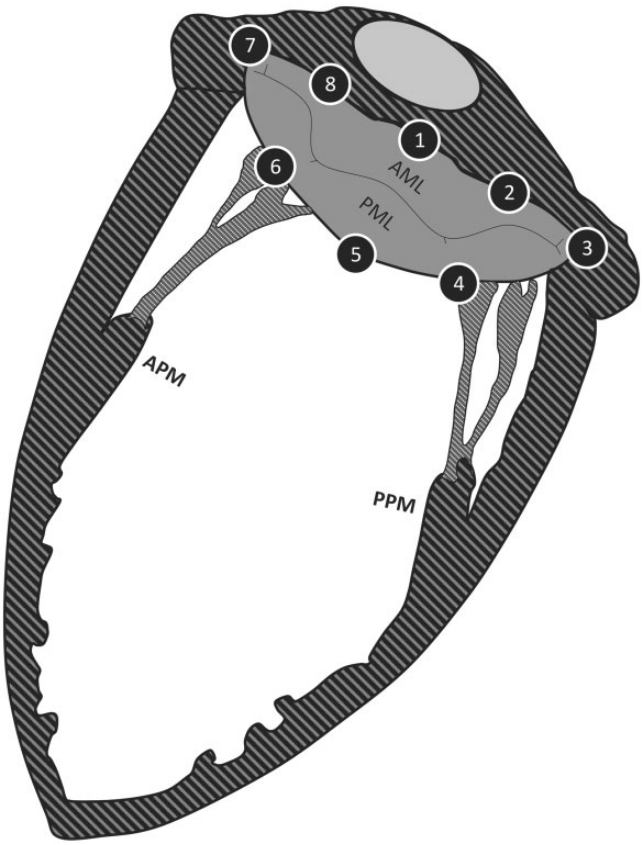

Figure 2: Implanted sonomicrometry crystals distributed at the native mitral annular circumference: (1) centre of trigones, (2) right trigone, (3) posterior commissure, (4) P3 scallop, (5) P2 scallop, (6) P1 scallop, (7) anterior commissure and (8) left trigone. AML: anterior mitral valve leaflet; APM: anterior papillary muscle; PML: posterior mitral valve leaflet; PPM: posterior papillary muscle.

Study design

The study design used was an acute porcine experimental model, where the pig was investigated before and after the implantation of the novel mitral valve annuloplasty ring, and thus it served as its own control.

Experimental animal preparation

Premedication, transportation, anaesthesia and handling of the animal have previously been described in detail [19, 21, 22]. After the institution of cardiopulmonary bypass and cardioplegic arrest, 8 sonomicrometry crystals were implanted together with the novel ring (Fig. 2). The wires of the sonomicrometry crystal were exteriorized through the left atrium [19]. Microtip pressure catheters were placed in the left ventricle and the left atrium. After surgery, weaning off cardiopulmonary bypass and following haemodynamic stabilization, geometric and haemodynamic measurements were acquired [19]. Echocardiographic measurements were performed at baseline and after ring implantation in 2D modality. The pig was euthanized thereafter under continued anaesthesia, with an intravenous overdose of pentobarbital, and the heart was explanted to verify the positions of the sonomicrometry crystals.

Data acquisition

The 8 sonomicrometry crystals were connected directly to an external ultrasound transceiver unit and analysed off-line [19]. The signals from the pressure microtip catheters (SPR-350S, Millar Instruments, Houston, TX, USA) were amplified with a pressure control unit (PCU-2000, Millar Instruments). For the

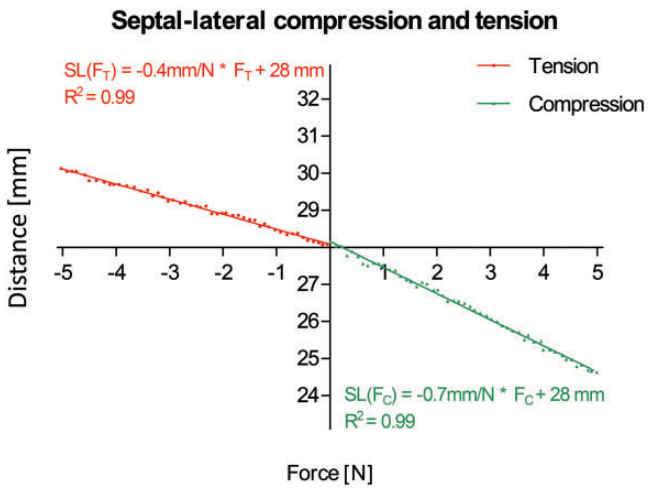

Figure 3: *In vitro* measurements for compression and tension in the septal–lateral dimension. Trend lines are shown for tension (top) and for compression (bottom). F_C: force compression; F_T: force tension; SL: septal-lateral.

electrocardiography (ECG), a CardioMed system was used (Model 4008, CardioMed A/S, Oslo, Norway). All the analogue data signals were recorded with dedicated virtual instrumentation software (LabVIEW 11.0, National Instruments, Austin, TX, USA).

Data analysis

Time derivate of the left ventricular pressure was used for synchronization between the analogue and sonomicrometry signals. End systole was defined as the time derivate of the left ventricular pressure minimum, and end diastole was defined by the R-peak on the ECG.

The off-line analyses of inter-crystal distances were post-processed using a multidimensional scaling technique to depict each crystal in a Cartesian coordinate system (SonoSOFT and SonoXYZ, Sonometrics Corp.) [19]. The mitral annular circumference was calculated as the summarized distance between the 8 annular crystals [19]. The mitral annular area was calculated as the summarized area of the 8 adjacent triangular areas [19]. The inter-crystal distance of 2 adjacent crystals was used to find local variations. The direct septal–lateral distance was calculated between crystal 1 to crystal 5, and the direct commissure–commissure distance was calculated between crystal 3 to crystal 7 (Fig. 2). The geometry parameters were reported as the maximum and minimum values, and the cyclic difference was calculated as the difference between the maximum and minimum values.

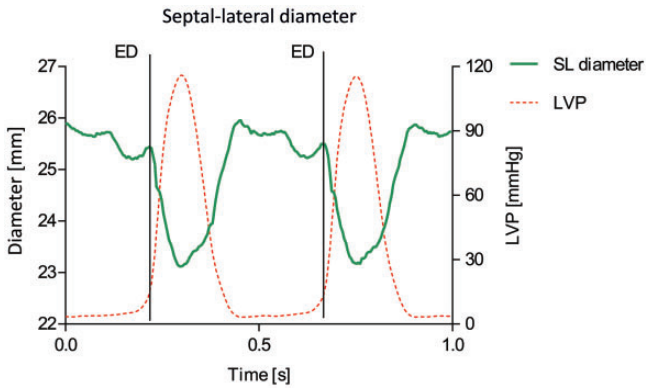

Figure 4: Septal–lateral dynamics with the correlation to the left ventricular pressure as a function of time. ED: end-diastole; LVP: left ventricular pressure; SL: septal-lateral.

Figure 5: Segmental mitral annular circumferential changes from end-diastole to end-systole illustrated for the novel ring. The annular circumferential changes are illustrated with a scaled colour legend, where red represents a systolic annular compression, and blue represents a systolic annular circumferential expansion. ES: end-systole; ED: end-diastole.

Statistics

This study is a proof-of-concept 1-animal study, so comparative statistics were not used. *In vitro* data are presented graphically with trend lines. *In vivo* sonometric data are presented as mean ± standard deviation (SD) for a 10 heart-cycle ensemble average. The echocardiographic data are presented as mean ± SD for a 3 heart-cycle ensemble average.

RESULTS

In vitro characterization

In vitro measurements in the septal–lateral dimension are presented in Fig. 3. For the septal–lateral compression, the distance decreased with 3.5 mm (28.1 to 24.6 mm) with a force correlation of 0.7 mm/N. A more flattened D-shape of the ring was seen with increased compression. Tension increased the septal–lateral distance with 2 mm (28.1 to 30.1 mm) with a force correlation of 0.4 mm/N. With tension, the ring changed from D-shape to a triangular shape. The commissure–commissure force correlation was 0.2 and 0.1 mm/N for compression and tension, respectively.

In vivo characterization

The heart rate was 134 ± 1 min^{-1} at measurements with a peak left ventricular pressure of 115 ± 0.4 mmHg, peak left atrial pressure of 12 ± 0.1 mmHg and peak time derivate of the left ventricular pressure of 2309 ± 23 mmHg/s.

The valve was assessed with echocardiographic colour Doppler and was found competent without regurgitation.

The maximum and minimum values and the cyclic range for the mitral annular area and mitral annular circumference are presented in Table 1, representing a minor cyclic range of 34.4 ± 3 mm^2 and 2.3 ± 0.3 mm, respectively. The septal–lateral and commissure–commissure distances, which are also presented in Table 1, represent a cyclic range of 2.8 ± 0.0 and 0.9 ± 0.2 mm, respectively. The septal–lateral diameter during the cardiac cycle and correlation to the left ventricular pressure are presented in Fig. 4. The segmental mitral annular circumferential changes from end-diastole to end-systole are illustrated in Fig. 5 as a scaled colour legend.

At baseline, the annulus diameter measured in an apical 5 chamber view was 34.3 ± 0.6 mm in diastole and 29.6 ± 0.6 mm in systole. The coaptation length of the leaflets was 8.7 ± 0.6 mm with the coaptation point being two-thirds posterior to the mitral annulus. With the novel ring implanted, the annulus diameter decreased to 27.3 ± 0.6 mm in diastole and 23.6 ± 0.6 mm in systole. The coaptation length of the leaflets increased to 15 ± 1.0 mm with both leaflets being mobile and the coaptation point being two-thirds posterior to the mitral annulus.

DISCUSSION

We have successfully produced a novel saddle-shaped remodelling mitral annuloplasty ring with selective flexibility for septal–

Table 1: *In vivo* dynamic range measurements for the novel ring

Parameter	Maximum	Minimum	Cyclic range
Mitral annular area (mm^2), mean ± SD	649 ± 3	614 ± 2	34.4 ± 3
Mitral annular circumference (mm^2), mean ± SD	98.2 ± 0.2	95.8 ± 0.2	2.3 ± 0.3
Septal–lateral diameter (mm), mean ± SD	25.9 ± 0.0	23.1 ± 0.0	2.8 ± 0.0
Commissure–commissure diameter (mm), mean ± SD	32.1 ± 0.2	31.2 ± 0.1	0.9 ± 0.2

The maximum and minimum values together with the maximum range.
SD: standard deviation.

lateral contraction. These built-in functions result in a mitral annuloplasty ring that functions as a normo-sized ring during diastole and as an undersized ring during systole. The systolic downsizing of the septal–lateral diameter increases the coaptation plane, while the diastolic normo-sizing seem to decrease the risk of functional mitral stenosis. The remodelling properties restrict the mitral annulus to potentially prevent further dilatation.

From the *in vitro* characterization, we found a septal–lateral compression rate of 0.7 mm/N with a total decrease of 3.5 mm equivalent to a force of 5 N. This is well within the septal–lateral force and septal–lateral dynamic range of the native heart [16]. For septal–lateral distension, we found a rate of 0.4 mm/N with development of a triangular ring shape. *In vivo*, a triangular shape will not develop due to the annular fixation of the ring. Therefore, we expect an even lower septal–lateral distension rate than what the *in vitro* data suggest. The novel ring was rigid for both commissure–commissure compression as well as for distension.

The flexibility of the septal–lateral diameter found *in vitro* was confirmed in the *in vivo* characterization. We found that the cyclic range of the septal–lateral diameter was 2.8 ± 0.0 mm, which is in the same range as that of the native heart [16]. The septal–lateral compression was found to be primarily in systole and to a smaller extent in the diastolic atrial contraction (Fig. 4). The shortest septal–lateral diameter was measured at peak left ventricular pressure, and the widest septal–lateral diameter correlated with minimum left ventricular pressure (Fig. 4). This septal–lateral flexibility leads us to postulate a minimized risk of ring dehiscence in patients with ischaemic mitral valve regurgitation or degenerative valve disease.

The cyclic range of the mitral annular area, presented in Table 1 (34.4 ± 3 mm^2), mitral annular circumference (2.3 ± 0.3 mm) and commissure–commissure (0.9 ± 0.2 mm) are comparable to a rigid Classic Annuloplasty Ring™ (Edwards Lifesciences) [11, 16]. The novel ring can thereby be characterized as an overall rigid ring, and thus it is advantageous for patients with ischaemic mitral valve regurgitation [6, 7]. Furthermore, the novel ring had native septal–lateral flexibility. Hence, the novel ring is a rigid ring with selective flexibility for septal–lateral contraction.

The novel ring did not exceed the predefined septal–lateral diameter of 28 mm. Hence, we have an indication that no further annular dilatation is to be expected.

The leaflets were mobile with a coaptation point being two-thirds posterior to the mitral annulus without causing systolic anterior motion of the anterior leaflet or interfering with the posterior leaflet mobility as reported for restrictive mitral annuloplasty rings [23]. With the novel ring, the coaptation length of the leaflet increased to 15 ± 1.0 mm, well within recommendations for satisfactory coaptation.

The segmental contraction of the annulus was comparable to a rigid ring but with additional widening of the anterior segment (Fig. 5). This widening was possible due to the slits in the annular lateral segments. For patients with degenerative valve disease, this might be beneficial due to a commissure–commissure unfolding of the anterior leaflet which intuitively will decrease the risk of systolic anterior motion. However, for patients with ischaemic mitral valve regurgitation, this widening may be problematic if the anterior leaflet becomes tethered. This issue is a subject of further investigations.

Limitations

Being an experimental study, several inherent limitations are present, and the results should be evaluated with this in mind. The animal used was healthy without any cardiac defect or disease, and one should therefore be careful to translate the results directly to a clinical setting. However, we anticipate that the remodelling and flexible properties of the novel ring would be similar in patients, despite no pathologies in the present study. It was only possible to describe the short-term behaviour and properties of the ring design in this acute model. As only 1 animal was included in this proof-of-concept study, the study is of a descriptive nature. Furthermore, the measurements were performed on an anaesthetized animal during open-chest conditions after several hours of complicated surgery, which might affect the haemodynamics and our measurements. From the *in vitro* and the acute *in vivo* experimental conditions, we cannot draw any conclusions on the durability of this new device concept.

CONCLUSION

We have developed and evaluated a novel saddle-shaped remodelling mitral annuloplasty ring with selective flexibility for septal–lateral contraction and rigidity for septal–lateral dilatation. We found that the cyclic range in the septal–lateral dimension was comparable to the native heart. The novel ring resulted in a very satisfactory coaptation geometry and preserved the mobility of both leaflets, which may be attractive features for future mitral annuloplasty rings to treat patients with mitral valve regurgitation of either degenerative or ischaemic origin.

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Conflict of interest: none declared.

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