Effect of Transcatheter Mitral Annuloplasty With the Cardioband Device on 3-Dimensional Geometry of the Mitral Annulus

Mani Arsalan, MD[a], Eustachio Agricola, MD[b], Ottavio Alfieri, MD[b], Stephan Baldus, MD[c], Antonio Colombo, MD[d], Giovanni Filardo, PhD[a], Christophe Hammerstingl, MD[e], Michael Huntgeburth, MD[c], Felix Kreidel, MD[f], Karl-Heinz Kuck, MD[f], Giovanni LaCanna, MD[b], David Messika-Zeitoun, MD[g], Francesco Maisano, MD[h], Georg Nickenig, MD[e], Benjamin D. Pollock, MSPH, CPH[a], Bradley J. Roberts, RDCS, ACS[a], Alec Vahanian, MD[g], and Paul A. Grayburn, MD[a,*]

This study was performed to assess the acute intraprocedural effects of transcatheter direct mitral annuloplasty using the Cardioband device on 3-dimensional (3D) anatomy of the mitral annulus. Of 45 patients with functional mitral regurgitation (MR) enrolled in a single arm, multicenter, prospective trial, 22 had complete pre- and post-implant 3D transesophageal echocardiography (TEE) images stored in native data format that allowed off-line 3D reconstruction. Images with the highest volume rate and best image quality were selected for analysis. Multiple measurements of annular geometry were compared from baseline to post-implant using paired *t* tests with Bonferroni correction to account for multiple comparisons. The device was successfully implanted in all patients, and MR was reduced to moderate in 2 patients, mild in 17 patients, and trace in 3 patients after final device cinching. Compared with preprocedural TEE, postprocedural TEE showed statistically significantly reductions in annular circumference (137 ± 15 vs 128 ± 17 mm; p = 0.042), intercommissural distance (42.4 ± 4.3 vs 38.6 ± 4.4 mm; p = 0.029), anteroposterior distance (40.0 ± 5.4 vs 37.0 ± 5.7 mm; p = 0.025), and aortic-mitral angle (117 ± 8° vs 112 ± 8°; p = 0.032). This study demonstrates that transcatheter direct mitral annuloplasty with the Cardioband device results in acute remodeling of the mitral annulus with successful reduction of functional MR. **© 2016 Elsevier Inc. All rights reserved.** **(Am J Cardiol 2016;118:744–749)**

Mitral valve repair remains the standard of care for patients with severe mitral regurgitation (MR).[1,2] However, because of co-morbidities, poor left ventricular function, and/or age, ~50% of patients with symptomatic severe MR are not referred for surgery.[3] Thus, percutaneous, catheter-based techniques are being developed to treat high-risk patients with severe MR. MitraClip (Abbott Vascular, Santa Clara, California) is Food and Drug Administration approved for patients with primary MR at high risk for surgery but not for secondary MR.[4] The MitraClip resembles Alfieri's surgical edge-to-edge technique but does not include mitral annuloplasty, which has been shown to improve the results of surgical edge-to-edge repair.[5] Percutaneous annuloplasty has been reported,[6–9] typically through the coronary sinus approach. Cardioband (Valtech, Inc., Or Yehuda, Israel) is a transcatheter mitral annuloplasty system that directly anchors to the mitral annulus from the left atrium.[10,11] After implantation into the beating heart (Figure 1), a Dacron posterior annuloplasty band is cinched under transesophageal echocardiography (TEE) guidance to optimize reduction of MR severity (Figure 2). Here we report the acute intraprocedural effects of the Cardioband device on 3-dimensional (3D) anatomy of the mitral annulus.

Methods

We enrolled 45 patients into a single arm, multicenter, prospective trial to assess the performance and safety of the Cardioband system in patients with functional MR who were deemed by the local heart team to be at excessively high risk for mitral surgery. Details of the study protocol and clinical results at 6 months have been recently reported.[11] Of the 45 patients, 22 patients had complete pre- and post-implant 3D TEE images stored in native data format that allowed off-line 3D reconstruction of mitral annular geometry. Real-time 3D TEE imaging was performed during implantation using either Philips iE33

[a]Baylor University Medical Center, Dallas, Texas; [b]San Raffaele University Hospital, Milan, Italy; [c]Hart Center, University of Cologne, Cologne, Germany; [d]Interventional Cardiology Unit, San Raffaele Scientific Institute, Milan, Italy; [e]Department of Cardiology, Heart Center Bonn, University Hospital Bonn, Germany; [f]Department of Cardiology, Asklepios Klinik St. Georg Hospital, Hamburg, Germany; [g]Bichat Claude Bernard Hospital-Paris VII University, Paris, France; and [h]Valve Clinic, University Heart Center, University Hospital Zürich, Zürich, Switzerland. Manuscript received April 15, 2016; revised manuscript received and accepted June 3, 2016.

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See page 748 for disclosure information.

*Corresponding author: Tel: (214) 820-7500; fax: (214) 820-7533.
E-mail address: paulgr@baylorhealth.edu (P.A. Grayburn).

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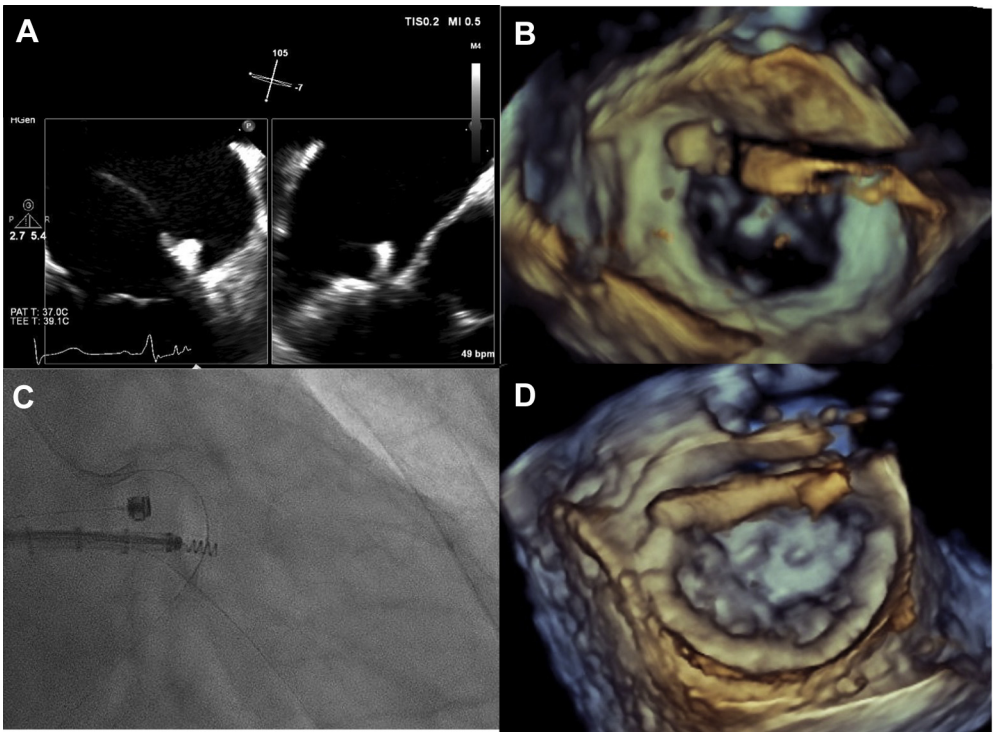


Figure 1. Deployment of Cardioband device under transesophageal echocardiography (TEE) guidance. *(A)* X-plane TEE image demonstrating insertion site for anchor 1 of the device and *(B)* corresponding 3D TEE image. *(C)* Fluoroscopic image with anchor 1 embedded in mitral valve annular tissue. *(D)* 3D TEE image demonstrating full deployment of device along mitral valve annulus and before cinching.

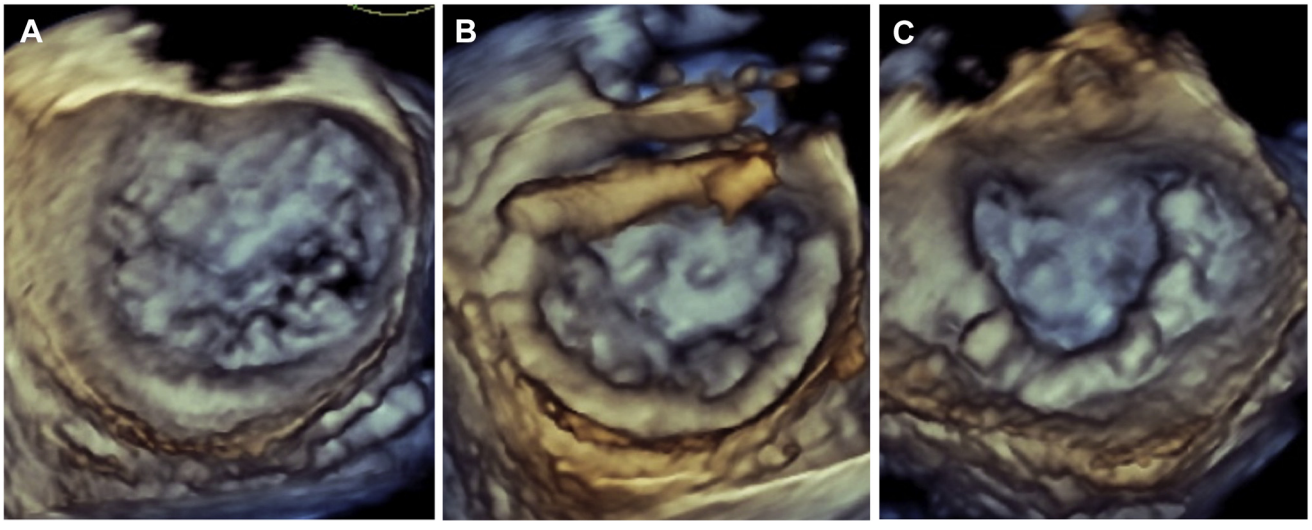


Figure 2. 3D transesophageal echocardiography images demonstrating the mitral valve annulus at baseline *(A)*, after full implantation of Cardioband device *(B)*, and after final cinching *(C)*.

(Philips Ultrasound, Bothell, Washington) or GE Vivid (GE Healthcare, Horten, Norway). Imaging data sets were analyzed using either Philips QLab Mitral Valve Navigation software or TomTec 4D-mitral valve (MV) Assessment software (TomTec, Munich, Germany). Images acquired on GE Vivid ultrasound platforms were analyzed with the TomTec program; and data sets from Philips iE33 ultrasound systems were analyzed with QLab Mitral Valve Navigation. Images with the highest volume rate and best image quality were selected for baseline and post-implant analysis. Average volume rate across all measured data sets was 15 volumes per second. Data points were manually placed by a single experienced observer (BJR) along anatomic landmarks at end-systole, generating a 3D model of the mitral valve apparatus. The following measurements in 3D space were measured and reported by the software programs: (1) annular circumference in 3D, (2) length of the coaptation line (from anterolateral to posteromedial

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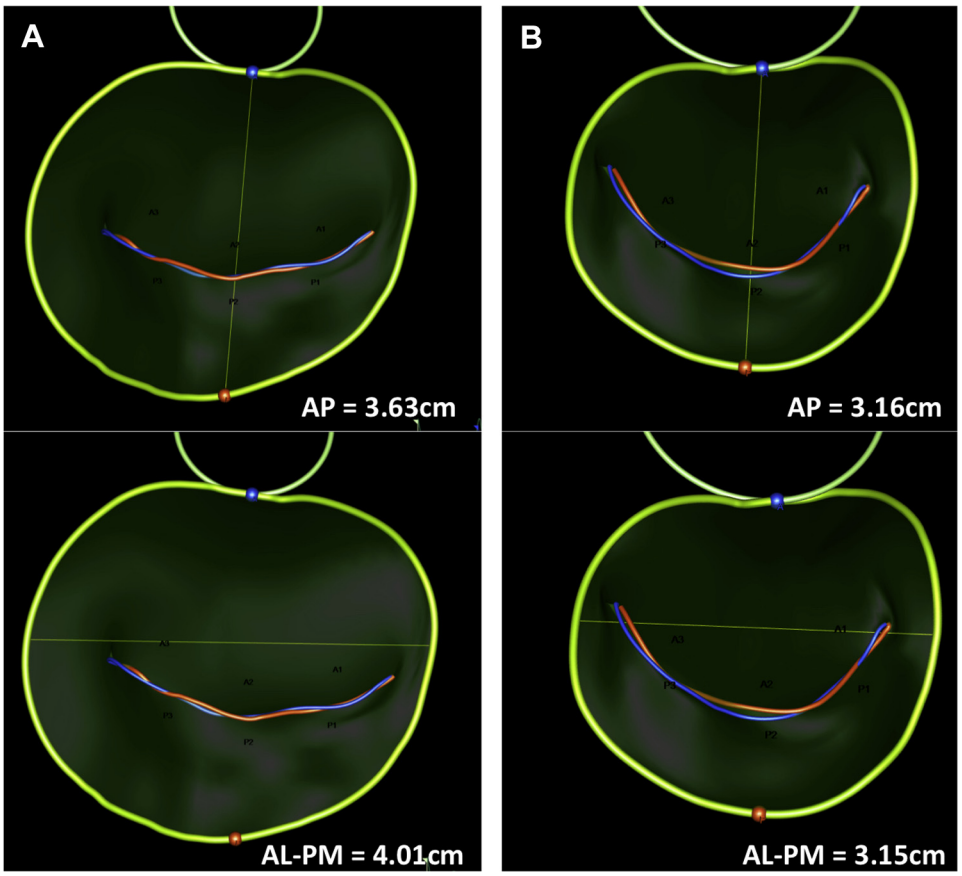


Figure 3. Baseline *(A)* and post-implantation *(B)* 4D models of mitral valve annulus with corresponding anteroposterior (AP) and anterolateral-posteromedial (AL-PM) dimension measurements.

commissure), (3) intercommissural diameter, (4) anterior posterior diameter, (5) saddle height (distance on the same surface from the highest point of the annulus between the fibrous trigones to the lowest point at the commissures), (6) tenting height (minimal distance between the leaflet coaptation and the mitral annular plane), (7) tenting volume (volume enclosed between the annular plane and mitral leaflets) of the mitral valve at the time of maximal mitral valve closure in systole, (8) anterior leaflet area by 3D echo, (9) length at A2 segment by 3D echo, (10) posterior leaflet area, (11) length at P2, (12) posterior leaflet angle, (13) anterior leaflet angle, and (14) aortic valve-mitral valve angle. Figures 3 and 4 show examples of the reconstructed 3D images.

MR severity was assessed by the core laboratory echocardiographer (PAG) using the integrated approach recommended by the guidelines.[12,13] Effective regurgitant orifice area, vena contracta width and/or area, color flow jet eccentricity, mitral inflow velocities, and pulmonary venous flow patterns were used to determine MR severity as none/trace, mild, moderate, or severe at baseline and immediately after final device cinching.

Means and SDs of clinical and physiological variables were prospectively collected and tabulated for the 22 patients who had complete baseline and intraoperative 3D TEE measurement profiles (Table 2). Differences between baseline and intraoperative measurements were tested using unadjusted paired *t* tests to determine significance at the alpha = 0.05 level. Additionally, Bonferroni correction was performed to correct for multiple comparisons. Analyses were performed using SAS 9.3 (Cary, North Carolina).

Results

Baseline characteristics are presented in Table 1. Increased age, high Euroscore II, and reduced ejection fraction variables all demonstrated the high-risk profile of the treated patients. All patients were felt to have significant functional MR (effective regurgitant orifice area $\geq$0.2 cm^2) by the site heart team. During intraoperative TEE, MR was severe in 14 and moderate in 8 patients by the Core Laboratories. The device was successfully implanted in all patients, and MR was reduced to moderate in 2 patients, mild in 17 patients, and trace in 3 patients after final device cinching. Compared with preprocedural TEE, postprocedural TEE showed statistically significantly reductions in annular circumference (137 $\pm$ 15 vs 128 $\pm$ 17 mm; p = 0.042), intercommissural distance (42.4 $\pm$ 4.3 vs 38.6 $\pm$ 4.4 mm; p = 0.029), anteroposterior distance (40.0 $\pm$ 5.4 vs 37.0 $\pm$ 5.7 mm; p = 0.025), and aortic-mitral angle (117 $\pm$ 8° vs 112 $\pm$ 8°; p = 0.032). The impact of the procedure on the MV geometry measured by echocardiography is summarized in Table 2.

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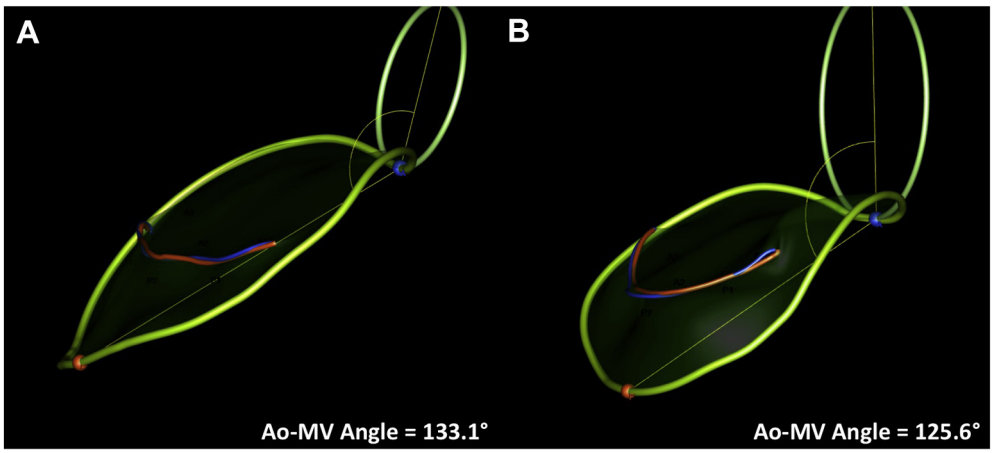


Figure 4. Four-dimensional mitral valve (MV) reconstruction models demonstrating the change in angle formed between the MV annulus and aorta at baseline *(A)* and after device manipulation *(B)*.

Table 1
Baseline characteristics (n = 22)

Characteristic	
Age (years)	70 ± 7*
Women	2 (11%)
EuroScore II	6.7 ± 5.7*
LVEF (%)	30.9 ± 10.7
NYHA Class III or IV	16 (89%)
MR (on intraoperative TEE by Core Lab)	
Severe	14
Moderate	8
Ischemic functional MR	12 (67%)
Previous CABG	5 (28%)
COPD	2 (11%)
Renal Failure (moderate/severe)	17 (94%)
Atrial fibrillation	15 (83%)

* Mean ± SD.

Table 2
Baseline and intra-operative measurements

Measurement	Time of measurement		p values	
	Baseline	Intra-op	p-value*	Corrected p†
Intercommissural diameter (mm)	42.3 ± 4.2	38.3 ± 4.4	**0.001**	**0.017**
Anterior posterior diameter (mm)	39.4 ± 5.0	36.6 ± 5.5	**0.002**	**0.025**
Saddle height (mm)	9.0 ± 2.3	9.3 ± 2.2	0.481	>0.99
Annular circumference (mm^2)	136 ± 14	126 ± 17	**0.002**	**0.032**
Anterior leaflet area (mm^2)	908 ± 142	831 ± 194	0.023	0.391
Posterior leaflet area (mm^2)	661 ± 195	569 ± 229	0.050	0.853
Tenting volume (cm^3)	3.2 ± 2.1	2.9 ± 1.6	0.263	>0.99
Anterior leaflet length (mm)	31.9 ± 2.7	30.9 ± 4.6	0.236	>0.99
Posterior leaflet length (mm)	14.1 ± 3.9	12.1 ± 3.5	0.014	0.243
Anterior leaflet angle (°)	19.8 ± 5.8	18.5 ± 4.4	0.413	>0.99
Posterior leaflet angle (°)	46.9 ± 12.1	50.9 ± 11.8	0.078	>0.99
Tenting height (mm)	7.2 ± 3.5	7.1 ± 2.6	0.851	>0.99
Length of coaptation line (mm)	43.8 ± 8.2	40.9 ± 9.0	0.043	0.724
Aortic valve-mitral valve angle (°)	118 ± 8	113 ± 8	**0.002**	**0.032**

The variables that were still significant after Bonferroni correction are indicated in bold.

* Paired t-test, unadjusted.

† Bonferroni p-value corrected for multiplicity.

Discussion

During surgical MV repair, annuloplasty is performed in most cases, either alone or in conjunction with artificial chords, leaflet resection or augmentation, closure of perforations or clefts, and edge-to-edge repair. The long-term benefit of annuloplasty with surgical procedures suggests that transcatheter approaches to annuloplasty are needed if transcatheter MV repair is to reach its full potential. The Cardioband device uses transseptal puncture to gain access to the left atrium from the venous system. A steerable catheter is used for sutureless fixation of an annuloplasty Dacron band to the mitral annulus. Fixation is established by helical metallic anchors 6 mm in length. After implantation of all anchors, the band is contracted under TEE guidance until the MR jet is sufficiently reduced or has disappeared altogether. This study demonstrates that favorable 3D remodeling of the human mitral annulus occurs immediately after implantation and cinching, demonstrating direct effect of the implanted device on mitral annular geometry. As all measurements were obtained intraprocedurally under similar hemodynamic conditions, it can be inferred that the reduction of MR severity is attributable to these effects, which include reduced annular circumference, anteroposterior dimension, intercommissural dimension, and mitral-aortic angle.

The mechanism of secondary MR has been well studied and includes a combination of annular dilation, leaflet tethering by outward expansion of the left ventricular walls, and reduced closing force because of left ventricular systolic dysfunction.[14–19] In a substudy of the Surgical Treatment of

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Ischemic Heart Failure trial, 3D TEE was used to assess the mechanism and severity of MR.[20] MR grade was significant related to annulus area, tenting area, left ventricular end-systolic volume index, and ejection fraction.[20] In the present study, the Cardioband significantly reduced annulus dimensions but did not change tenting height or tenting volume. This may be because the latter are related to left ventricular volume, which would not be expected to change acutely during Cardioband implantation. It remains possible that reverse remodeling of the left ventricle would occur as a consequence of MR reduction and lead to reduction in these parameters over time.[21]

In addition to the Cardioband device, several other percutaneous devices are currently under development. The Cardioband device, however, is the only device that reproduces direct surgical annuloplasty by a transfemoral transseptal approach. The Carillon Mitral Contour System (Cardiac Dimensions, Inc., Kirkland, WA), for example, is implanted into the coronary sinus. Two trials investigating this device showed low successful implantation rates (62.5% and 67%, respectively) because of interference with the left circumflex artery or reduction by <1 MR grade.[6,7] The Mitralign system (Mitralign, Inc., Tewksbury, Massachusetts) facilitates a suture-based plication of the posterior annulus retrograde through the aortic valve on the ventricular side of the mitral annulus. It has been successfully implanted with improvement in MR, symptoms, and quality of life at 30-day follow-up.[22] However, the retrograde approach might not be well tolerated in patients with depressed left ventricular function. Thus, direct annuloplasty through the left atrium mimics the surgical implantation of an annuloplasty ring and might be the best approach to treat high-risk patients with functional MR.

In functional MR, mitral annuloplasty is often performed alone and may restore mitral valve competence completely.[23] A recent randomized study failed to show that mitral annuloplasty was superior to replacement in secondary MR.[24] Further analysis showed that MR recurrence after annuloplasty occurred predominantly in patients with posterior aneurysm and severe tethering.[25] Such patients might benefit from valve replacement, but most patients with secondary MR can be treated successfully with annuloplasty.

Disclosures

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