Hemodynamic outcomes of geometric ring annuloplasty for aortic valve repair: A 4-center pilot trial

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Objectives: A geometric annuloplasty ring could improve efficacy and stability of aortic valve repair. Toward this goal, a 1-piece 3-dimensional titanium annuloplasty ring with Dacron covering was developed and tested successfully in animals. The purpose of this study was to define hemodynamic outcomes with this device used as the annuloplasty component of human aortic valve repair.

Methods: In a 4-center pilot trial with informed consent, 16 patients underwent aortic valve repair for aortic insufficiency, with the annuloplasty device sutured into the annulus beneath the leaflets. Preoperative annular diameter averaged 26.5 ± 2.0 (mean ± standard deviation) mm, and average ring size was 22.3 ± 1.2 mm. After annuloplasty, leaflet defects were easy to identify, and 14 of 16 patients (88%) required leaflet plication and/or autologous pericardial reconstruction for leaflet defects. Three patients had ascending aortic replacement, and 2 had remodeling root replacement. One had ultrasonic leaflet decalcification and another tricuspid valve annuloplasty. Follow-up data were from site-specific studies at the 6-month postoperative time point.

Results: There were no in-hospital mortalities or major complications. Preoperative aortic insufficiency grade (0-4 scale) was 3.6 ± 1.0 and fell to 1.0 ± 0.8 at 6 months ($P < .0001$). New York Heart Association class fell from 2.5 ± 0.5 to 1.1 ± 0.3 ($P < .0001$). Postrepair valve area was 2.7 ± 0.2 cm^2, and 6-month mean systolic gradient was 11.3 ± 3.3 mm Hg. Left ventricular end-diastolic diameter and ejection fraction both normalized (both $P < .0001$).

Conclusions: Geometric ring annuloplasty facilitated aortic valve repair, allowing more precise reconstruction of leaflet defects. Aortic insufficiency reduction and systolic gradients were excellent, and expansion of valve reconstruction into broader categories of aortic valve disease seems indicated. (J Thorac Cardiovasc Surg 2014;148:168-75)

ACD

Prosthetic replacement of the aortic valve is associated with significant long-term valve-related complication rates, whether considering tissue or mechanical valves.[1,2] By contrast, several large series of aortic valve reconstruction with autologous tissues have observed late complication rates of approximately 1% per year or less,[3,4] even considering reoperations for repair failure. Moreover, results with aortic valve repair for aortic insufficiency (AI) continue to improve[3,5] as knowledge and techniques of leaflet reconstruction advance. Consequently, aortic valve repair is being performed with increasing frequency for a variety of aortic valve disorders.[6]

One current problem with aortic valve repair is the lack of a proper annuloplasty method. Subcommissural annuloplasty, as described by Cabrol in 1966,[7] is somewhat effective but has the disadvantage of suturing the annulus only at 1 point–the tops of the commissures. It is now clear that suture annuloplasty does not control the size and shape of the entire annulus and, as such, is prone to fail over the long-term.[8-10] As with the mitral and tricuspid valves, a full ring annuloplasty device for the aortic valve could improve efficacy and stability of repair.[11] Accordingly, a geometric aortic annuloplasty device was developed,[12] tested in animals,[13] and applied to patients undergoing aortic valve repair.[14] This article analyzes the early

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Drs Mazzitelli, Stamm, Pirk, and Meuris are the principal investigators in the clinical trial. The HAART 300 aortic annuloplasty ring is an investigational device, undergoing regulatory-monitored clinical trials in Europe.

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Abbreviations and Acronyms
AI = aortic insufficiency
TEE = transesophageal echocardiography
TTE = transthoracic echocardiography

hemodynamic results of aortic ring annuloplasty in a trial of human aortic valve repair.

METHODS

The HAART 300 aortic annuloplasty ring (Hemispherical Aortic Annuloplasty Reconstructive Technology; BioStable Science and Engineering, Inc, Austin, Tex; US Patent No. 8,163,011 B2) was developed from computed tomography angiographic analyses of normal human aortic valves.[15] The ring is designed to restore normal annular circumference and elliptical geometry (defining the ''annulus'' as the annulus fibrosis[16] or leaflet-aortic junction), and the device could facilitate quality of valve repair in trileaflet AI.[14] The rings are computer-milled from 1-piece titanium blocks and are covered with Dacron cloth to promote endothelialization. Ring geometry is elliptical with a 2:3 base diameter ratio (Figure 1), and with 3 subcommissural posts that are spaced equidistant around the circumference. The left/noncoronary post is located on the posterior minor diameter, and all 3 posts flare outward by 10° (Figure 1), as shown in computed tomography angiographic studies of normal human valves.[15] The device was formally evaluated in chronic animal trials with positive results,[13] and 5 initial human cases were reported.[14]

In this study, the device was tested in a multicenter Pilot trial in Europe (ClinicalTrials.gov identifier: NCT01400841), with the trial protocol approved by the German Federal Competent Authority and the ethics committees of the 4 centers. Selection criteria were mandated by the regulatory body, including elective status, patient age over 50 years, and no concomitant valve or coronary disease. Each patient was explained the risks and potential benefits of the device in detail, and provided written informed consent. The 16 patients in this report were operated for aortic valve repair between February and October of 2012 at the German Heart Center Munich, the German Heart Center Berlin, the Institute for Clinical and Experimental Medicine (Prague, Czech Republic), and University Hospital Leuven (Belgium).

Baseline transthoracic (TTE) and/or transesophageal echocardiograms (TEE) were obtained prior to valve repair and constituted the reference for future measurements. Median sternotomy and standard cardiopulmonary bypass/myocardial protection techniques were used. Prebypass TEE guided the preoperative understanding of valve and root pathology. Aortic valves were approached through transverse near-complete aortotomies, 1.5 cm above the right coronary artery. Traction sutures were placed above each commissure to facilitate exposure. After performing an accurate valve

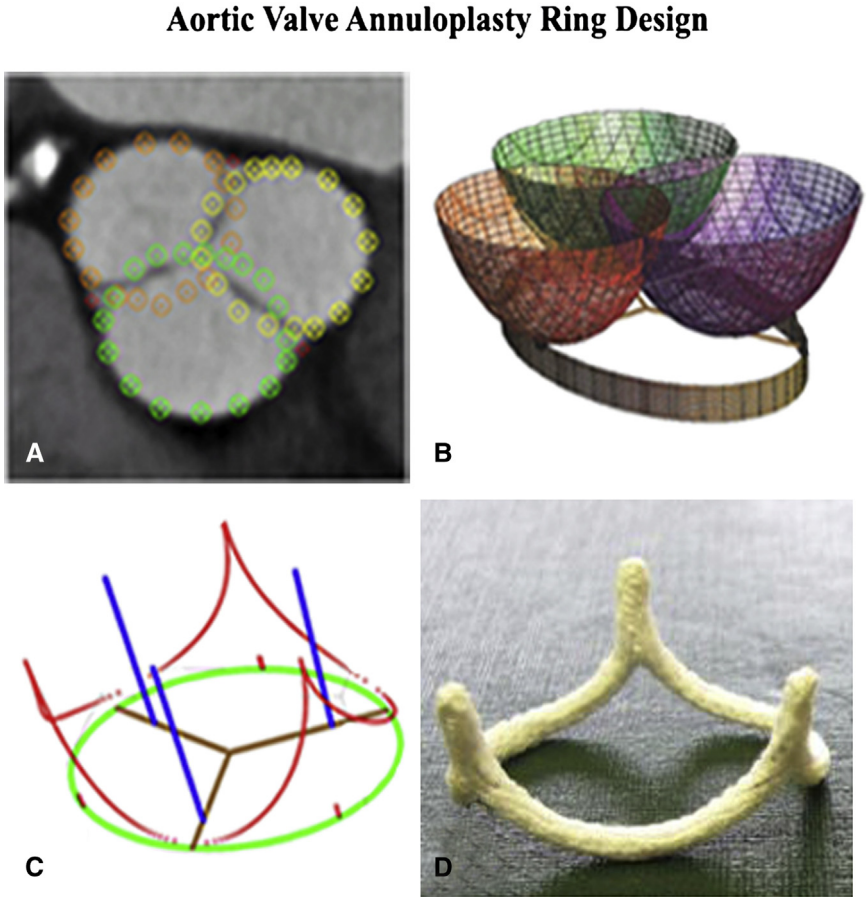

FIGURE 1. Geometric basis of the ring design. A, Three-dimensional coordinates of the valve were digitized from computed tomographic angiograms of 10 normal patients. B, Average valve geometry was determined by ellipsoidal 3-dimensional least squares regression analysis. C, *Green ellipse* illustrates normal 2:3 elliptical base geometry, and the *red coronet-shaped structure* is the leaflet-aortic junction, or aortic annulus. D, Analyzed 3-dimensional coordinates were used to mill a 1-piece titanium annuloplasty ring covered with Dacron.