Comparison of Aortic Annulus Dimension After Aortic Valve Neocuspidization With Valve Replacement and Normal Valve

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Aortic valve replacement (AVR) remains the standard surgical intervention for aortic valve disease and is preferred by many surgeons, despite its associated clinical issues. The clinical efficacy of aortic valve neocuspidization (AVNeo) with glutaraldehyde-treated autologous pericardium, the Ozaki procedure, has recently been reported. Although it is presumed to preserve the normal aortic annulus motion, changes to the aortic annulus during the cardiac cycle after AVNeo remain unclear. From March to December 2014, aortic annular dimensions were measured for 23 patients; the sample included 8 patients who had undergone AVNeo, 10 patients with normal aortic valves, and 5 patients who had undergone AVR. Measurements were recorded using electrocardiography-gated multidetector computed tomography. Data were analyzed using automated aortic root analysis software. Postoperative peak pressure gradients for the AVNeo and AVR groups were compared. No statistically significant differences in annulus variation were observed between patients who had undergone AVNeo and those with normal aortic valves. Annular area was larger during systole than during diastole in both groups. Postoperative peak pressure gradients were significantly lower in the AVNeo group than in the AVR group. The results of the present study demonstrated that aortic annular dimensions after AVNeo are similar to the dimensions of normal aortic valves. This was evidenced using electrocardiography-gated multidetector computed tomography, previously reported as the most reliable method, to evaluate annulus motion during the cardiac cycle. Lower postoperative peak pressure gradients might underlie the observed changes. These advantages will help in rectifying AVR defects.

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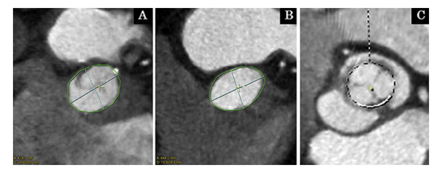
Keywords: aortic valve neocuspidization, aortic valve replacement, multidetector computed tomography, aortic annulus motion



Measurement of annular dimensions: (A) AVNeo, (B) normal aortic valve, and (C) AVR.

Central Message

Natural aortic annulus expansion is preserved following AVNeo and it will increase the likelihood of good hemodynamics.

Perspective statement

Aortic valve neocuspidization (AVNeo) has substantial utility for the treatment of aortic valve disease as it provides lower postoperative peak pressure gradients than AVR and does not require anticoagulation management. Multidetector computed tomography was used to demonstrate normal aortic annulus motion after AVNeo. This result will likely provide greater insight into flow dynamics after AVNeo.

INTRODUCTION

Valvular heart disease treatment accounts for 10%-20% of all cardiac surgical procedures performed in the United States, with aortic valve replacement (AVR) accounting for approximately two-thirds of all heart valve operations.[1] AVR remains the standard surgical intervention for aortic valve disease. However, anticoagulation (due to the use of mechanical valves) and the durability of prosthetic valves remain substantial clinical issues. To overcome these issues, aortic valve repair may be considered; however, its use is currently limited to patients with aortic valve regurgitation (AR). Accordingly, there is a substantial clinical need for a method that does not require anticoagulation management and is suitable for a wide spectrum of aortic valve diseases, including aortic valve stenosis (AS).

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Good short- and mid-term results without anticoagulation were reported for aortic valve reconstruction (aortic valve neocuspidization [AVNeo]) with glutaraldehyde-treated autologous pericardium.[2] The reported method entailed the replacement of 3 cusps with glutaraldehyde-treated autologous pericardium based on the distance between the commissures of each cusp.[3] It is suitable for patients with AS and has the advantages of increasing the maximum valve orifice area and preserving the natural motion of the aortic annulus, as pericardial grafts are sewn directly to the aortic annulus. This method thus confers lower postoperative peak pressure gradients than those conferred by AVR.[2] However, the actual change to the annulus during the cardiac cycle after AVNeo is yet to be reported. We consider evaluating this change to be of clinical importance.

Transcatheter AVR (TAVR) has recently become the standard procedure for patients considered ineligible for conventional surgical valve replacement. However, paravalvular AR is associated with increased mortality, predominantly as a result of valve undersizing.[4-6] Accordingly, accurate annulus measurements are crucial for ensuring appropriate valve size. Multidetector computed tomography (MDCT) is more reliable than transesophageal echocardiography (TEE). Further, reproducible annulus measurements play an increasingly important role in pre-TAVR evaluations.[7-9]

The aim of the present study was to use MDCT to evaluate changes to the aortic annulus during the cardiac cycle after AVNeo.

PATIENTS AND METHODS

Study Population and Design

All patients underwent AVNeo between December 2012 and April 2014. The AVNeo group comprised 4 women and 4 men aged between 63 and 77 years who did not have renal dysfunction (estimated glomerular filtration rate [eGFR], <45 mL/min per 1.73 m^2). Several previous studies have identified a baseline eGFR <45 mL/min per 1.73 m^2 to be associated with an increased risk of contrast-induced nephropathy.[10,11] We therefore excluded patients with an eGFR below baseline. No significant AR was observed with postoperative ultrasound cardiography (UCG) in the AVNeo group. Patients underwent AVR using porcine aortic-stented valves between April 2014 and December 2014. The AVR group comprised 3 women and 2 men aged between 69 and 83 years who did not have renal dysfunction. All AVR procedures were performed by the same surgeon using horizontal mattress suturing.

Patients underwent MDCT for coronary artery evaluation preoperatively and postoperatively, and UCG showed neither AS nor AR. All the patients who underwent MDCT postoperatively also underwent coronary artery bypass grafting. The normal aortic valve group comprised 2 women and 8 men, aged 54-84 years. Computed tomography imaging was performed 3-12 months postoperatively for the AVNeo group, 3-5 weeks postoperatively for the AVR group, and either preoperatively or approximately 2 weeks postoperatively for the normal aortic valve group.

The statistical power was set as power = $1-\beta$ = 80%, and sensitivity as α = 5% to enable detection of difference of average annular diameter based on area (Darea) in the groups between AVNeo and normal, and between AVNeo and AVR. Power analysis consequently set the required number of patients at 8 patients per group in the comparison of Darea between AVNeo and Normal, and at 5 patients in the comparison of Darea between AVNeo and AVR.

All patients provided written informed consent, and the present study was approved by the institutional review board for human research at Kanazawa University.

MDCT Image Acquisition

MDCT was performed using a 64-slice scanner (Definition Flash, Siemens Healthcare, Erlangen, Germany). All evaluations were performed with 128×0.625 mm^2 collimation, a gantry rotation time of 280 ms, and a scan pitch of 0.17. The tube current was 1100 mA with 120-kV tube voltage. Contrast enhancement was achieved using $1.25 \times$ (body weight $\times$ 0.5) + 20 mL of iopamidol (Iopamiron: 370-80; Bayer Schering Pharma, Osaka, Japan). Additional beta-blockers were not administered to any patient. Images were reconstructed (slice thickness = 0.75 mm; increment = 0.7 mm; B36f kernel) at every 10% of the cardiac cycle.

MDCT Image Analysis

Commercially available automated aortic root analysis software was used (syngo, CT Cardiac Function—Valve Pilot, Siemens Healthcare, Erlangen, Germany) with a retrospective electrocardiography (ECG)-gating technique (Fig. 1). The software detects the annulus plane by connecting the 3 lowest insertion points of the valve leaflets and performing automated luminal planimetry at this level (Fig. 1A-D). Although the utility of semiautomated analysis software has been reported,[12,13] automated analysis software remains to be fully validated. For semiautomated analysis, datasets were automatically evaluated to identify anatomic landmarks and automatically delineate and manually adjust aortic annulus contours. We used semiautomated analysis for the AVNeo and normal aortic valve groups. One patient in the AVNeo group required major correction (equivalent to manual reconstruction) because of an incorrect plane level.

Annulus measurements included cross-sectional annulus areas (Fig. 2) and minimum/maximum diameter (D_{max}/D_{min}). Mean diameter (D_{mean}) was calculated

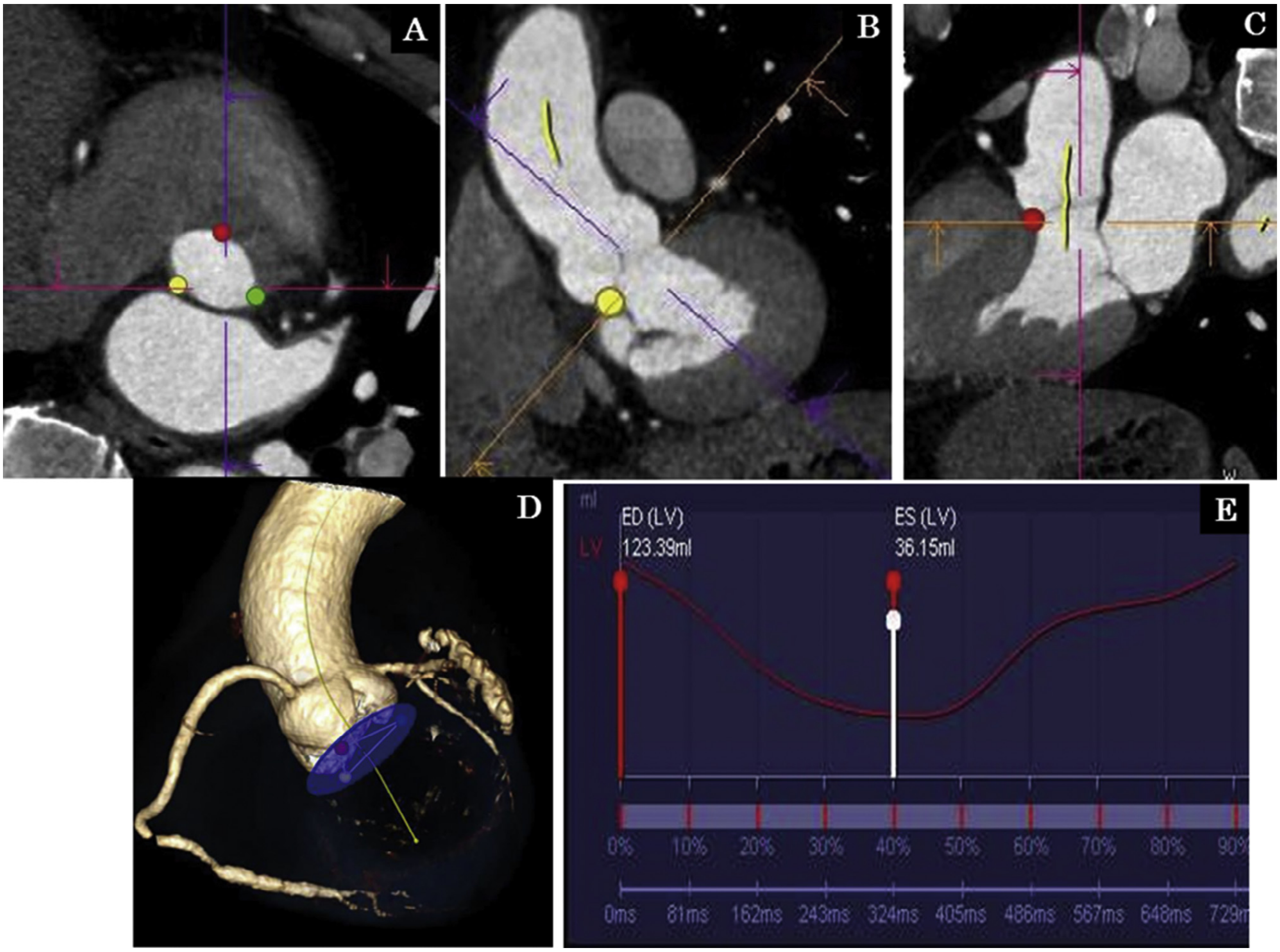

Figure 1. Aortic root analysis with automated software: (A) the aortic annulus is shown as seen from the left ventricle, (B) the plane of the right coronary artery ostium, (C) the plane of the noncoronary artery cusp, (D) image of 3-D volume rendering, and (E) time-volume curve demonstrating the dynamic behavior of the left ventricular volume during the entire cardiac cycle. 3-D, 3-dimensional; ED, end diastole; ES, end systole.

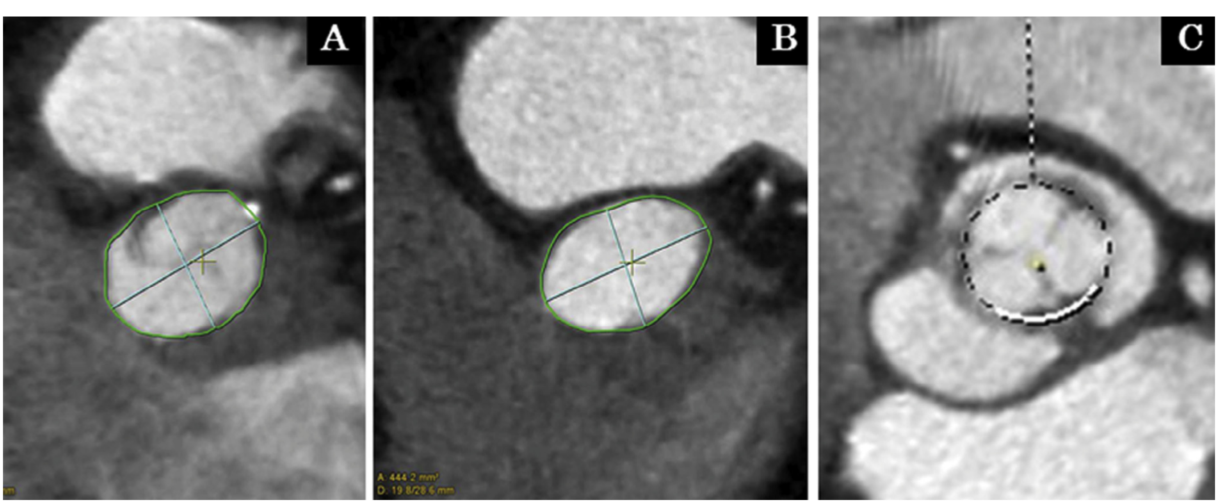

Figure 2. Measurement of annular dimensions. Images of annulus measurements are shown. The encircled area (green contour) represents the annulus area and the orthogonal line (blue line) represents the maximum and minimum diameter. (A) AVNeo group. (B) Normal aortic valve group. (C) AVR group, which does not use the same measurement as that used in (A) and (B). AVNeo, aortic valve neocuspidization; AVR, aortic valve replacement. (Color version of figure is available online.)

Table 1. Patient Characteristics

s	AVNeo* ($n = 8$)	AVR† ($n = 5$)	Normal ($n = 10$)	P value
Age, y	72.1 ± 5.5	77.6 ± 5.4	68.0 ± 13.0	0.193
Sex, male (%)	4 (50)	2 (40)	8 (80)	0.241
Diabetes	1 (12.5)	1 (20)	6 (60)	0.081
BSA‡, m^2	1.57 ± 0.11	1.41 ± 0.17	1.61 ± 0.19	0.112
Hypertension	8 (100)	4 (80)	3 (30)	0.006
Chronic kidney disease	1 (12.5)	0 (0)	4 (40)	0.258
Hyperlipidemia	4 (50)	1 (20)	8 (80)	0.078
Carotid artery stenosis	1 (12.5)	1 (20)	3 (30)	0.667
Cerebral infarction	1 (12.5)	1 (20)	0 (0)	0.386
Smokers	4 (50)	3 (60)	7 (70)	0.688
LVEF§, %	63.6 ± 10.8	69 ± 7.2	56 ± 14.4	0.170
Annular diameter, mm	20.8 ± 1.9	20.8 ± 2.9	20.2 ± 1.6	0.596

Values are presented as means ± SD or n (%). SD, standard deviation.
*Aortic valve neocuspidization.
†Aortic valve replacement.
‡Body surface area.
§Left ventricular ejection fraction.

as the average of D_{max} and D_{min}. The average diameter was calculated using the cross-sectional area of the aortic annulus ($D_{area} = 2 \times \sqrt{[area/\pi]}$) and the annulus perimeter ($D_{perimeter} = perimeter/\pi$). We compared annulus size during systole and diastole. ECG-gated reconstructions were performed (Fig. 1E) and analyzed at every 10% of the cardiac cycle.

In the AVR group, a prosthetic valve stent was used to manually measure annular areas, as the aortic annulus could not be correctly detected automatically (Fig. 2C).

Statistical Analysis

Normally distributed data are presented as means ± standard deviation. Categorical variables are expressed as numbers and percentages. Between-group differences were evaluated using the independent Student's t-test for normally distributed data and the Mann-Whitney U test for nonnormally distributed data. The chi-squared test was used to compare categorical variables. Data among the 3 groups were compared using a 1-way repeated-measures analysis of variance. All analyses were performed using SPSS statistics software (version 22.0, SPSS Inc., Chicago, IL).

RESULTS

Baseline Characteristics

Patient characteristics are summarized in Table 1. The AVNeo, AVR, and normal aortic valve groups comprised of 8, 5, and 10 patients, respectively. Barring hypertension, patient characteristics were similar between groups. In the AVR group, Mosaic bioprostheses (Medtronic Inc, Minneapolis, MN) were used in 4 patients and a Carpentier-Edwards Magna pericardial prosthesis was used (Edwards Lifesciences, Irvine, CA) in 1 patient. The size of implanted valves was 19 mm in 3 patients and 23 mm in 2 patients. Appropriate sized valves were used for all patients, and indexed effective orifice areas were greater than 0.85 cm^2/m^2 for all patients. In the normal aortic valve group, preoperative and postoperative examinations were conducted for 3 and 7 patients, respectively. All patients examined postoperatively had undergone coronary artery bypass grafting.

Comparison of Aortic Annulus MDCT Measurements Between AVNeo and Normal Aortic Valve Groups

Detailed aortic annulus variations between systole and diastole are shown in Table 2. MDCT annular area

Table 2. Aortic Annulus Changes in the AVNeo and Normal Aortic Valve Groups

	AVNeo ($n = 8$)	Normal ($n = 10$)	P value
ΔD_{max},* mm	1.875 ± 2.0	1.480 ± 3.2	0.767
ΔD_{min},† mm	2.575 ± 2.5	2.840 ± 2.3	0.819
ΔD_{mean},‡ mm	2.225 ± 1.0	2.160 ± 0.9	0.882
$\Delta D_{perimeter}$,§ mm	1.838 ± 1.0	2.010 ± 0.8	0.690
ΔD_{area},‖ mm	2.063 ± 0.8	2.400 ± 0.8	0.394
Δ Area, mm^2	82.612 ± 32.0	97.130 ± 36.5	0.390

Values are presented as means ± SD. SD, standard deviation.
*Maximum annular diameter.
†Minimum annular diameter.
‡$(D_{max} + D_{min})/2$.
§Average annular diameter based on perimeter.
‖Average annular diameter based on area.

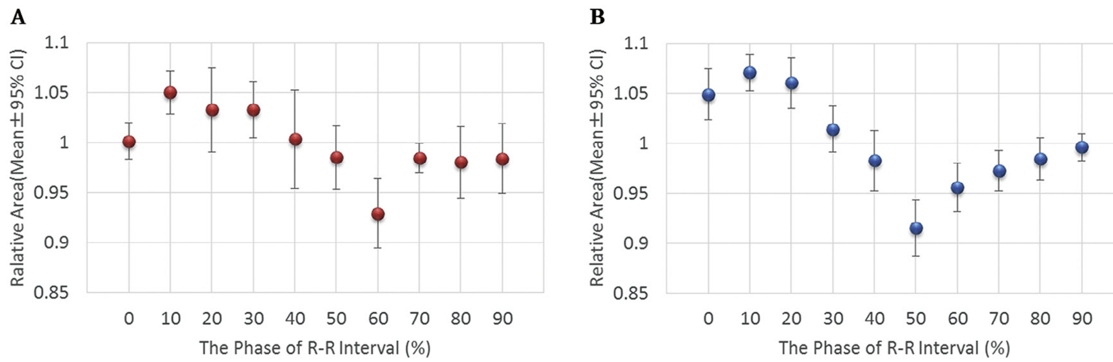

Figure. 3. Mean relative area of the aortic valve annulus during the cardiac cycle. Mean overall relative areas (absolute area divided by mean area of the patient) are shown with 95% CIs during each of the 10 reconstructed phases of the cardiac cycle. (A) AVNeo group. (B) Normal aortic valve group. AVNeo, aortic valve neocuspidization. (Color version of figure is available online.)

measurements were compared between systole when areas were largest and between diastole when areas were smallest. Previous studies have demonstrated that the annular diameter and area are significantly larger during systole than during diastole.[9,14] No statistically significant difference in annulus size variation was observed between the AVNeo and normal aortic valve groups. The mean aortic annulus area changes were 82.6 ± 32.0 mm^2 in the AVNeo group and 97.1 ± 36.5 mm^2 in the normal aortic valve group. Relative area changes in both groups during the cardiac cycle are shown in Figure 3. A variable course was observed in both groups.

Comparison of MDCT and UCG Assessments of the Aortic Annulus for the AVNeo and AVR Groups

Detailed aortic annulus variations between systole and diastole and ECG data are shown in Table 3. Aortic annulus areas in the AVR group were practically unchanged. The postoperative peak pressure gradient was significantly lower in the AVNeo group than in the AVR group (14.4 mm Hg vs. 28.9 mm Hg, $P = 0.008$). Left ventricular ejection fractions were similar between groups (68.0% vs 68.2%, $P = 0.96$).

Table 3. Aortic Annulus Measurements and Ultrasound Cardiographic Data. For the AVNeo and AVR Groups

	AVNeo ($n = 8$)	AVR ($n = 5$)	P value
Δ Area, mm^2	82.612 ± 32.0	2.600 ± 0.5	<0.001
Δ D_{area},* mm	2.063 ± 0.8	0.052 ± 0.02	<0.001
LVEF,*,† %	68.0 ± 6.5	68.2 ± 10.3	0.96
PPG,†,‡ mm Hg	14.4 ± 5.4	28.8 ± 9.9	0.008

Values are presented as means ± SD. SD, standard deviation.
*Average annular diameter based on area.
†Left ventricular ejection fraction.
‡Peak pressure gradient.

DISCUSSION

AVNeo with glutaraldehyde-treated autologous pericardium grafting has been postulated to provide good hemodynamics[2] because the direct suturing of the pericardium to the annulus preserves natural aortic root expansion with maximal effective orifice area. However, changes to the annulus during the cardiac cycle after AVNeo are yet to be reported. Therefore, using ECG-gated MDCT, we examined changes to the aortic annulus during the cardiac cycle following AVNeo. MDCT is widely used for the evaluation of the annulus before TAVR and is deemed the most reliable and reproducible method of annular evaluation.[7-9] The results of the present study demonstrated that the aortic annulus after AVNeo is similar to that of a normal aortic valve. The AVNeo group had lower peak pressure gradients than the AVR group, as demonstrated by postoperative UCG. These results strongly suggested that AVNeo preserves the natural motion of the aortic annulus, thereby leading to good hemodynamics.

Aortic root dynamics have been extensively studied using experimental animals [15-19] and MDCT in humans.[20-24] Dimension changes have been reported by animal studies;[17-19] however, results from human studies have been inconsistent. Although a few studies have not observed significant changes in systolic and diastolic dimensions,[20,21] a recent study reported significant changes to the aortic annulus during the cardiac cycle.[23,24] In the present study, changes in annular dimensions during the cardiac cycle were observed between AVNeo, AVR, and normal aortic valve groups using MDCT. No statistically significant difference in annulus size variation was observed between the AVNeo and normal aortic valve groups. Aortic annulus dimensions were larger during systole than diastole in both groups, as reported by previous studies.[9,14,23,24] Although the phase of minimal aortic annulus area differed slightly between the AVNeo and normal aortic valve groups and its reason is unclear, the pattern of change (Fig. 3) was similar to that reported by a previous study,[24] which demonstrated that annulus diameter was maximal during the 10%-30% phase of R-R intervals and minimal during the 50%-70% phase of R-R intervals.

A significant difference in changes to aortic annular size was observed between the AVNeo and AVR groups. This result was anticipated as the rigid stent of the prosthetic valve was sutured to the aortic annulus. Postoperative peak pressure gradients were significantly lower in the AVNeo group than in the AVR group, as reported by previous study.[2]

Recently, AVNeo with glutaraldehyde-treated autologous pericardium has provided good short- and mid-term results and good hemodynamics.[2] The efficacy of this technique has been demonstrated in bicuspid aortic valve and dialysis patients.[25,26] The advantages of preserving the natural aortic annulus expansion are thought to underlie the lower postoperative lower peak gradients observed with AVNeo. In a sheep model, stenting of biological valves was shown to influence cuspal calcification.[27] AVNeo may prevent cuspal calcification as the stent is not sutured directly to the annulus.

The present study demonstrated that natural aortic annulus expansion was preserved following AVNeo. We believe the results of the present study are particularly relevant as they demonstrate changes to the aortic annulus following AVNeo for the first time.

Study Limitations

The present study had a number of limitations. First, a relatively small number of patients were included in the present study. Due to the relatively rare nature of conditions requiring AVNeo, only a limited number of subjects who fit the baseline criteria were identified. Second, it was difficult to automatically detect accurate annular area in the AVR group; these were therefore manually measured using a prosthetic valve stent.

Although this method was less accurate than automatic measurement, we do not think it affected the changes observed in annular dimensions after AVR because the annulus is fixed with a rigid stent, and it is thought to be unchanged in general.

CONCLUSIONS

A meaningful outcome was observed in the present study as no significant change to the aortic annulus was observed following AVNeo. Aortic annulus measurements following AVNeo were similar to those of normal aortic valves. AVNeo postoperative peak pressure gradients were lower than those observed with AVR. Maintaining normal annular motion increases the likelihood of good hemodynamics. However, despite increases in effective orifice areas made possible by improvements in prosthetic valves, maintaining an entirely natural annular motion is not possible. In this regard, AVNeo is substantially more advantageous than AVR.

Acknowledgments

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SUPPLEMENTARY MATERIALS

Supplementary data associated with this article can be found in the online version at http://dx.doi.org/10.1053/j.semtcvs.2016.11.002

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