Reexamining remodeling

Hans-Joachim Schäfers, MD,^{a,c} Alexander Raddatz, MD,^b Wolfgang Schmied, Dipl Psych,^a Hiroaki Takahashi, MD,^a Yujiro Miura, MD,^a Takashi Kuniyara, MD,^a and Diana Aicher, MD^a

Objective: Root remodeling was proposed as valve-preserving root replacement to treat patients with aortic regurgitation and root aneurysm. The objective of this retrospective study was to review 18 years of experience with root remodeling and to identify predictors of valve durability.

Methods: Between October 1995 and December 2013, root remodeling was performed in 747 patients. The aortic valve anatomy was tricuspid in 431 patients, bicuspid in 290 patients, and unicuspid in 26 patients. Aortic aneurysm was present in 688 patients, and 59 procedures were performed for acute aortic dissection type A. The severity of aortic regurgitation ranged from grade 0 to IV (grade 0, 1%; grade 1, 8%; grade 2, 26%; grade 3, 62%; grade 4, 3%; median, 3). All patients underwent root remodeling, concomitant operations were performed in 352 patients, and cusp repair was used in 690 procedures.

Results: Hospital mortality was 2%. Overall freedom from reoperation was 92% at 10 years and 91% at 15 years. Overall freedom from reoperation was 95% for tricuspid valves at 10 and 15 years, 89% for bicuspid aortic valves at 10 years ($P = .006$), and 83% for bicuspid aortic valves at 15 years. By multivariate analysis, the strongest risk factors for failure were an aortoventricular junction 28 mm or greater (hazard ratio, 1.43) and the use of a pericardial patch as part of cusp repair (hazard ratio, 6.24).

Conclusions: Root remodeling continues to be a viable option in valve-preserving root replacement. If combined with careful assessment and, if necessary, correction of aortic valve geometry, reproducible restoration of aortic valve function can be achieved with good long term durability. (J Thorac Cardiovasc Surg 2015;149:S30-6)

Root remodeling was proposed by Sarsam and Yacoub¹ as valve-preserving root replacement to treat patients with aortic regurgitation (AR) and root aneurysm. The hypothesis was that AR was solely due to aortic dilatation, and the goal was to normalize valve function by replacing all dilated aortic root tissue.

The early results were positive, but the technique did not always yield sufficient valve competence.^{2,3} Also, the late results of the original series were suboptimal, in that a relevant proportion of patients required reoperation for recurrent AR.⁴ The inferior stability was related to the lack of annular stabilization in root remodeling.⁵

On the basis of initially positive results and the physiologically superior cusp motion, we started to use root remodeling for root aneurysm, initially mainly for patients without marked annular dilatation.⁶ We observed that root aneurysm not infrequently coexisted with cusp prolapse,⁷

and later we found that the probability of prolapse seemed to increase with increasing degree of AR.⁸ In addition, we realized that cusp prolapse could be induced or aggravated through reduction of aortic diameter in root replacement.⁹ We showed that the combination of root remodeling and cusp repair was safe and led to improved aortic valve function postoperatively.¹⁰

The finding of postoperative prolapse stimulated research on the normal configuration of aortic valve function; the introduction of the effective height concept with the possibility of intraoperative measurements helped in achieving normalized postoperative valve function irrespective of the preoperative degree of AR.^{11,12} On the basis of the decreased durability of isolated aortic valve repair, we introduced the concept of suture annuloplasty as an addition to root remodeling.¹³ Its use resulted in higher proportion of competent aortic valves.¹⁴

After initial careful exploration of root remodeling,¹⁵ we were positively impressed by the reproducibility of achieving good aortic valve function. We extended its application to bicuspid aortic valves¹⁶ and, more recently, unicuspid aortic valves. We hypothesized that normalized aortic valve configuration should lead to a low early failure rate, and the near-physiologic cusp motion should lead to good valve durability. More recently, we added a suture annuloplasty as quick and simple annular stabilization for individuals with large basal ring.¹³ The objective of this retrospective study was to review 18 years of experience with root remodeling and to identify predictors of valve durability.

From the Departments of Thoracic and Cardiovascular Surgery^a and Anesthesia,^b Saarland University Medical Center, Homburg Saar, Germany; and Xanit Hospital Internacional,^c Malaga, Spain.

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Address for reprints: Hans-Joachim Schäfers, MD, Department of Thoracic and Cardiovascular Surgery, Saarland University Medical Center, Homburg/Saar, Germany (E-mail: h-j.schafers@uks.eu).

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Abbreviations and Acronyms

AR = aortic regurgitation
HR = hazard ratio

METHODS AND PATIENTS

Between October 1995 and December 2013, root remodeling was performed successfully in 747 patients at Saarland University Medical Center. One patient was excluded in whom root remodeling plus closure of several fenestrations led to unacceptable regurgitation requiring intraoperative conversion to replacement. The retrospective analysis of the data and publication in an anonymized fashion was approved by the local ethics committee.

Patients' age ranged from 3 to 86 years (mean, 54 ± 15 years), and 610 were male. The aortic valve anatomy was tricuspid in 431 patients, bicuspid in 290 patients, and unicuspid in 26 patients. Aortic aneurysm was present in 688 patients, and 59 procedures were performed for acute aortic dissection type A. A total of 29 individuals had Marfan syndrome according to Ghent criteria, and 1 patient had Loeys-Dietz syndrome.

Partial aortic arch involvement was present in 136 patients with aneurysmatic disease, and in 33 patients, the aneurysm involved the total arch. The primary indication for surgery was severe AR ($n = 405$), acute dissection ($n = 59$), or aortic aneurysm ($n = 283$). The severity of AR ranged from grade 0 to IV (grade 0, 1%; grade 1, 8%; grade 2, 26%; grade 3, 62%; grade 4, 3%; median, 3). Preoperative and postoperative severity of AR were quantified according to current guidelines.¹⁷ Cardiac comorbidity included coronary artery disease ($n = 112$), mitral regurgitation ($n = 42$), tricuspid regurgitation ($n = 35$), and persistent atrial fibrillation ($n = 42$). Previous aortic or cardiac surgery had been performed in 40 patients.

The operative technique has been described in detail and has undergone only minor changes.¹⁸ In all patients, the chest was opened by a median sternotomy, and aortic and right atrial cannulation were used; an 8-mm Dacron graft sutured to the right axillary artery was used for arterial inflow only in the presence of acute dissection. After root mobilization and excision of the sinus wall, a tubular graft was tailored to accommodate the configuration of the aortic root and sutured to the cusp insertion lines. The cusps were inspected for prolapse, and prolapse was corrected by central plication sutures on the cusp margin,¹⁹ if necessary extending it into the belly of the cusp.

Remodeling originally was primarily used for patients with a basal diameter of less than 30 mm, and a graft size was chosen 1 to 2 mm smaller than the basal diameter. With increasing experience, all patients were included, and graft size was chosen according to the body surface area of the patient (24 mm for <1.8 m², 26 mm for 1.9–2.2 m², and 28 mm for ≥ 2.3 m²). Since 2004, visual inspection for prolapse was replaced by measurement of effective height¹¹; any effective height of less than 9 mm was considered as prolapse and corrected. Since 2009, a suture annuloplasty was added in the last 295 patients; braided polyester was used in 61 patients, and polytetrafluoroethylene was used in 234 patients.¹³ Postoperative anticoagulation consisted of aspirin (100 mg/d) given for 2 months unless persistent atrial fibrillation had been present preoperatively, in which case phenprocoumon (Marcumar; 3M Healthcare, Loughborough, UK) was used.

All patients were followed, and follow-up was complete in 723 patients (96.8%). Cumulative follow-up was 4582 patient-years (mean, 6.2 ± 4.4 years).

Statistical Methods

Data are expressed as means $\pm$ standard deviation, and categorical data are expressed as frequencies or ratios of patients. Demographic and baseline variables were analyzed by using the Mann-Whitney *U* test for

continuous variables and the Fisher exact test for qualitative variables. Univariate associations with reoperation among clinical variables were obtained with 2×2 tables and the chi-square, Fisher exact, and Mann-Whitney *U* tests. End points included death and reoperations for aortic valve dysfunction. Variables that reached a *P* value less than .05 in the univariate analysis or that were considered clinically important were included in a multivariable Cox regression analysis to determine the predictors of reoperation after aortic root remodeling. The following variables were included in the Cox regression analysis: age, gender, severity of AR, nontricuspid morphology, effective height at follow-up (millimeters), use of a pericardial patch, cusp plication, large diameter of aortoventricular junction, and use of annuloplasty. Survival was analyzed using the Kaplan-Meier method. Statistical differences in Kaplan-Meier survival estimates were determined using the log-rank test. Data were analyzed using StatView 5.0 for Windows (SAS Institute Inc, Cary, NC).

RESULTS

All patients underwent root remodeling with replacement of the ascending aorta. Concomitant procedures were performed in 352 patients; these included partial ($n = 195$) or total ($n = 33$) arch replacement, coronary artery bypass grafting ($n = 112$), mitral repair ($n = 42$), tricuspid repair ($n = 35$), or left atrial ablation ($n = 42$).

Cusp repair was performed in 690 patients, with plication for prolapse correction being the most frequent maneuver ($n = 664$; 89%). In 69 patients, partial cusp replacement or augmentation with pericardium was performed in the setting of unicuspid ($n = 26$), bicuspid ($n = 43$), or tricuspid ($n = 26$) anatomy. In tricuspid aortic valves, 1 cusp was plicated in 141 patients, 2 cusps were plicated in 154 patients, and 3 cusps were plicated in 100 patients. In those with bicuspid valves, 1 cusp was plicated in 60 patients and both cusps were replicated in 209 patients. The time of extracorporeal circulation varied from 66 to 464 minutes (mean, 108 ± 34 minutes), and myocardial ischemic time ranged from 51 to 222 minutes (mean, 78 ± 19 minutes).

Fifteen patients died in the hospital, for a mortality of 2%. The causes of death were cardiac ($n = 5$), multiorgan failure ($n = 5$), sepsis ($n = 2$), cerebral embolism ($n = 2$), and pulmonary embolism ($n = 1$). Eighteen patients (2.4%) required reexploration for bleeding; no pacemaker implantation was required for atrioventricular conduction disturbance. In 1 patient, a pacemaker was implanted for sinus node dysfunction after atrial ablation. Actuarial survival was 93% at 5 years, 86% at 10 years, and 85% at 15 years.

A total of 42 patients underwent valve-related reoperation between 1 month and 11 years postoperatively. The aortic valve morphology was tricuspid in 15 patients, bicuspid in 25 patients, and unicuspid in 4 patients. Reasons for reoperation were secondary AR ($n = 32$), aortic stenosis ($n = 6$), and endocarditis ($n = 4$).

Overall freedom from reoperation was 92% at 10 years and 91% at 15 years. Overall freedom from reoperation was 95% for tricuspid valves at 10 and 15 years, 89% for bicuspid aortic valves at 10 years ($P = .006$), and 83% for bicuspid aortic valves at 15 years. At this time,

FIGURE 1. Kaplan–Meier analysis of freedom from reoperation after root remodeling for different aortic valve morphologies. Stability is significantly superior for tricuspid aortic valve anatomy compared with bicuspid or unicuspid anatomy.

10-year follow-up is not available for unicuspid aortic valves. Freedom from reoperation was significantly better in tricuspid versus bicuspid or unicuspid anatomy ($P < .001$) (Figure 1).

Freedom from AR II or greater showed significant differences between different periods of surgery for both bicuspid and tricuspid anatomy (Figures 2 and 3). In conjunction with the application of the effective height concept, a lower proportion of patients developed AR grade II over time. Five-year freedom from AR II or greater seemed to improve with annuloplasty from 65% to 90% in unicuspid

aortic valves ($P = .3$), 81% to 92% in bicuspid aortic valves ($P = .8$), and 93% to 98% in tricuspid aortic valves ($P = .6$), although the differences were not significant. Five-year freedom from reoperation was identical with or without annuloplasty in bicuspid (92% vs 94%, $P = .9$) and tricuspid (98% vs 97%, $P = .9$) aortic valves.

By univariate analysis, different parameters were associated with increased risk of reoperation, such as young patient age, larger aortoventricular diameter, nontricuspid aortic valve anatomy, low effective height at echocardiography, use of a pericardial patch, and less use of cusp

FIGURE 2. Kaplan–Meier analysis of freedom from AR II or greater after root remodeling in bicuspid aortic valves analyzed by time periods related to operative modifications. The use of the effective height concept was started in late 2004, and a suture annuloplasty was added in 2009. There was a significant and stepwise increase in the proportion of valves with good function. AR, Aortic regurgitation.

FIGURE 3. Kaplan–Meier analysis of freedom from AR II or greater after root remodeling in tricuspid aortic valves analyzed by time periods related to operative modifications. The use of the effective height concept was started in late 2004, and a suture annuloplasty was added in 2009. There was a significant and stepwise increase in the proportion of valves with good function. AR, Aortic regurgitation.

plication (Table 1). Of note, the use of annuloplasty positively correlated with an increased risk of failure. This may be related to preferential use of annuloplasty in the presence of a large aortoventricular diameter and the use of a pericardial patch.

By multivariate analysis (Table 2), the strongest predictors of failure were a larger diameter of aortoventricular junction (hazard ratio [HR], 1.43) and the use of a pericardial patch (HR, 3.27) for partial cusp replacement. Higher effective height (HR, 0.58) was significantly protective from failure.

DISCUSSION

Root remodeling was designed as 1 of the 2 principal techniques of valve-sparing aortic replacement,¹ intended to normalize aortic valve function through establishing normal root dimensions. Later, suboptimal functional results were reported, in both root aneurysm and acute dissection.²⁰ In patients with Marfan syndrome, a comparison between root remodeling and valve reimplantation showed superior valve stability with reimplantation, although 10-year freedom from reoperation was identical.²¹ The authors related the findings to the lack of annular stabilization in root remodeling.²¹ No exact analysis of the valve failures was provided in these studies.

Nonetheless, we started to use root remodeling, initially in patients with a lesser degree of annular dilatation.¹⁸ We found remodeling a shorter procedure compared with valve reimplantation, saving an average of 30 minutes of myocardial ischemic time. In addition, remodeling is not limited in its applicability by discrepancy between aortoventricular

junction and basal ring.²² The more physiologic cusp motion²³ led us to hypothesize that remodeling should be associated with good long-term aortic valve function. We later learned that reduction of root dimensions through root replacement could lead to induction of prolapse through reduction of intercommissural distance,⁹ in both root remodeling and valve reimplantation. Because prolapse could be corrected safely by cusp plication,⁷ we combined these techniques to generate near-normal aortic valve form and function. This was aided by the use of the effective height concept,¹¹ which had not been used by us in the early experience or reported by other groups.^{24,25} With the use of this concept, we have continued to use root remodeling for an increasing proportion of patients with root aneurysm. In fact, it has become our preferred approach to all individuals with root enlargement and a noncalcified aortic valve irrespective of preoperative AR. More recently, we have also treated patients with connective tissue disease by this approach. Our midterm results with this patient group have been satisfactory so far.²⁶

The current results confirm the hypothesis that good early and stable late valve function can be achieved with this approach. Our current results have to be seen in the light that the majority of patients in our series had relevant AR preoperatively, whereas this was a minority in other series.^{5,12,20,21,27,28} In retrospect, the suboptimal results with root remodeling in other series^{2,3,28} possibly can be explained by the limited use and aggressiveness in correcting cusp prolapse. Cusp configuration in those series was assessed by judgment only; although many operations were performed by experienced surgeons, symmetric cusp

TABLE 1. Analysis of risk factors for aortic valve reoperation after aortic root remodeling (n = 747)

Variable	No reoperation (n = 703)	Reoperation (n = 44)	HR	P value
Preoperative clinical profile				
Age, y	53 ± 15	48 ± 17	0.96	<.01*
Gender				
Female	132 (19%)	5 (11%)	0.32	.02*
Male	571 (81%)	39 (89%)	3.11	.02*
Body weight (kg)	83.8 ± 16.6	81.9 ± 18.1	1.01	.29
Body surface area (m ²)	2.0 ± 0.3	2.0 ± 0.4	1.03	.96
AR				
Grade 0	7 (1%)	1 (3%)	0.69	.71
Grade 1	56 (8%)	2 (6%)	0.60	.49
Grade 2	183 (26%)	6 (13%)	0.36	.06
Grade 3	436 (62%)	32 (72%)	2.65	.01*
Grade 4	21 (3%)	3 (6%)	0.72	.66
Diameter AV junction (mm)	29.1 ± 3.6	30.3 ± 3.7	1.56	<.01*
Operative variables				
Nontricuspid aortic valve	287 (41%)	29 (66%)	4.28	<.01*
Concomitant CABG	106 (15%)	5 (11%)	0.46	.10
Concomitant MVR	27 (4%)	2 (5%)	0.90	.89
Use of annuloplasty	280 (40%)	15 (34%)	1.36	<.01*
CPB time (min)	108 ± 35	106 ± 26	0.99	.02*
Myocardial ischemia (min)	78 ± 19	80 ± 18	0.99	.16
Effective height (mm)†	9.5 ± 1.2	8.7 ± 2.0	0.80	.02*
Use of pericardial patch	83 (12%)	12 (27%)	8.64	<.01*
Cusp plication	560 (80%)	29 (66%)	2.23	.03*
No. of cusps with plication	1.9 ± 0.7	1.8 ± 0.6	1.32	.26
Triangular resection	86 (12%)	9 (20%)	1.96	.08

Data shown are numbers of cases (%) and mean ± standard deviation. AR, Aortic regurgitation; AV, aortoventricular; CABG, coronary artery bypass grafting; CPB, cardiopulmonary bypass; HR, hazard ratio; MVR, mitral valve repair. *Significant with $P < .05$. †Determined postoperatively by echocardiography.

prolapse may have evaded intraoperative inspection. In fact, persistent or recurrent prolapse (defined by suboptimal effective height) was a predictor of failure in a previous report²⁹ and our current analysis; most of the procedures with prolapse diagnosed postoperatively were performed before the introduction of intraoperative measurement of effective height. In general, most failures were related to cusp pathology, because of persistence of prolapse or inadequate durability of the pericardium used for cusp repair in some bicuspid or all unicuspid valves.

Prolapse also can explain the observed discrepancies between root remodeling and valve reimplantation.^{2,21,28} In general, smaller grafts are used for root remodeling than for valve reimplantation, and the smaller graft increases the probability and frequency of cusp prolapse in root

remodeling compared with valve reimplantation. Reproducible detection or avoidance of generalized prolapse requires a special approach, such as the measurement of effective height.¹¹ This consideration can explain our previous observation that larger root size and annular size were associated with lesser valve durability after both valve reimplantation and remodeling.²⁹ Most likely, this occurred because of an unrecognized induction of prolapse before the use of the effective height concept.⁹ The current data partially confirm this hypothesis, and with more cusp plication the risk of reoperation was less. In fact, with aggressive use of cusp plication for prolapse correction, the durability in our tricuspid aortic valves was comparable to results obtained with valve reimplantation.³⁰

We have previously thought that remodeling would also accommodate the specifics of root anatomy seen in conjunction with bicuspid¹⁶ and unicuspid anatomy. We were positively impressed by the early results,¹⁶ and initially, the results in the setting of bicuspid anatomy were even superior to those with tricuspid valves.⁶ With increasing experience, however, nontricuspid aortic valve anatomy has been associated with inferior durability. In the earlier postoperative years, this is most likely related to the use of pericardial patches for cusp augmentation in some bicuspid and all unicuspid valves, a finding that we

TABLE 2. Risk factors by multivariate Cox regression analysis (−2 log-likelihood function = 161.87, chi-square = 72.79, $P < .001$)

Variable	P value	HR	95% CI
Diameter of AV junction (mm)	<.001	1.43	1.21-1.69
Use of annuloplasty	.01	1.28	1.89-66.26
Myocardial ischemia (min)	.04	0.96	0.93-1.00
Effective height	<.001	0.58	0.43-0.79
Use of pericardial patch	<.001	6.24	2.30-16.90

AV, Aortoventricular; CI, confidence interval; HR, hazard ratio.

also observed in isolated aortic valve repair.³¹ Consequently, we have become more restrictive in using this otherwise simple adjunct. In the later period, this is also related to the fact that calcific stenosis was seen in 5 of 54 bicuspid valves and zero of 113 tricuspid valves. Although the durability was significantly inferior to that of root remodeling for tricuspid valves, a 15-year freedom from reoperation of 83% in the bicuspid valves translates into a mean durability far exceeding 15 years. At a mean patient age of 54 years, the durability is thus superior to what is published for biologic prosthesis used in this age group.

Despite the good valve stability, we decided to explore whether valve function and durability could be improved further by adding an annuloplasty.¹⁴ To have a concept that was easy to use and independent of the anatomic characteristics of the aortic root, we developed a suture annuloplasty.¹⁴ So far, we have not yet seen a reduction in the early and mid-term need for reoperation. Nonetheless, as we reported previously for repair of bicuspid valves, the use of annuloplasty has increased the proportion of completely competent valves. At this time, the differences are not significant. It remains to be seen whether annuloplasty will have an additional positive effect on long-term durability.

So far, we have only limited experience with the application of root remodeling in connective tissue disease. The long-term stability of root remodeling will have to be analyzed carefully, particularly with respect to the efficacy and durability of annuloplasty. Clinical limitations to the application of remodeling primarily relate to the extent of cusp pathology. Partial cusp replacement for calcification in the presence of bicuspid morphology is associated with an increased risk of failure.³¹ Most important, the presence of cusp retraction³² renders the aortic valve a suboptimal substrate for preservation or repair.

Study Limitations

The limitations of the current study are primarily related to its retrospective nature, the stepwise adaptations to the learning process, and the lack of a control group. On the other hand, it was not the purpose of the study to compare root remodeling with valve reimplantation, but rather to define the long-term results of remodeling and predictors of valve failure or stability. In addition, our results currently reach a follow-up of only 18 years; longer follow-up will be needed to determine the long-term results of this procedure.

CONCLUSIONS

Root remodeling continues to be a viable option in valve-preserving root replacement. If combined with careful assessment and, if necessary, correction of aortic valve form, reproducible restoration of aortic valve function can be achieved. The concept of root remodeling also can be applied to bicuspid or unicuspid aortic valves, although

long-term durability is inferior with nontricuspid anatomy of the aortic valve.

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