Leaflet Reconstructive Techniques for Aortic Valve Repair

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Background. Refining leaflet reconstruction has become a primary issue in aortic valve repair. This descriptive analysis reviews leaflet pathology, repair techniques, and early results in a prospective regulatory trial of aortic valve repair.

Methods. Sixty-five patients underwent valve repair for predominant moderate to severe aortic insufficiency (AI). The mean age was 63 ± 13 years, and 69% of the patients were male. Ascending aortic/root replacement (AI). The mean age was 63 ± 13 years, and 69% of the patients were male. Ascending aortic/root replacement was performed, and then leaflet repair included leaflet plication for prolapse, nodular unfolding, double pericardial patching of commissural defects or holes, complete pericardial leaflet replacement, leaflet extension, and Gore-Tex reinforcement. Leaflet techniques and causes of adverse outcomes were evaluated.

Results. The follow-up time was 2-years maximal and 0.9 years mean, with a survival of 97%. Eighty percent of patients required repair of leaflet defects: leaflet prolapse (52/65–80%), ruptured commissures (6/65–9%), leaflet holes (4/65–6%), and nodular retraction (6/65–9%). The average preoperative AI grade of 2.9 ± 0.8 fell to 0.7 ± 0.7 (p < 0.0001). Three patients (4.6%) required interval valve replacement because of (1) suture untying, (2) iatrogenic leaflet tear, or (3) diphtheroid endocarditis. Five other patients experienced grade 2 or grade 3 AI: probable suture untying in 1 patient, ineffective leaflet extensions in 2 patients, and unsuccessful Gore-Tex reinforcements in 2 patients. Two patients with single pericardial leaflet replacements and all those with double pericardial reconstructions did well.

Conclusions. Leaflet defects are common in patients with moderate to severe AI. Leaflet plication, nodular unfolding, and double pericardial patching performed well. Gore-Tex and leaflet extension seemed less satisfactory. Standardization and experience with leaflet reconstruction will be important for optimizing the outcomes of aortic valve repair.

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Aortic valve repair is being applied more frequently [1], and although direct outcome comparisons between repair and replacement have not been performed, repair may be associated with lower valve-related adverse events [2–6]. Recently, a clinical trial of aortic valve repair supported by geometric ring annuloplasty was instituted, and an interesting initial finding was a high proportion of leaflet defects when selection was based on moderate to severe aortic insufficiency (AI) [7]. Previously, with the exception of pericardial patches having higher failure rates [8, 9], little information has been available on the success profiles of various leaflet reconstructive techniques. Thus, the purpose of this descriptive analysis was to document leaflet pathology, repair techniques, and early results of various approaches to leaflet reconstruction during aortic valve repair.

Material and Methods

The design characteristics and clinical application of the hemispherical aortic annuloplasty reconstructive technology (HAART) 300 aortic annuloplasty ring have been described elsewhere [10]. Briefly, the ring restores annular circumference and elliptical geometry toward normal to facilitate valve repair in trileaflet AI [11]. The elliptical rings are computer machined from one-piece titanium blocks and covered with Dacron cloth to promote endothelialization. The device was tested successfully in chronic animal models [12] and also in AI patients,
with good demonstrated efficacy [13]. In this study, the ring was used as the annuloplasty component of aortic valve repair for a regulatory safety and efficacy trial in nine centers in Europe (ClinicalTrials.gov Identifier: NCT01400841). The trial protocol was negotiated with and approved by the Federal Competent Authorities and the Ethics Committees of the centers. Data were collected according to standard regulatory practices for CE Mark applications and clinical device approvals.

Selection criteria were mandated by the regulatory bodies and resulted in the recruitment of 65 symptomatic male and female individuals, 18 years of age or older, with moderate to severe AI of trileaflet aortic valves, accompanied by aortic annular dilation, and a ventricular ejection fraction of 35% or higher. Emergency cases, endocarditis, and multiple valve surgical procedures were excluded, as were patients with active infections, recent strokes, or myocardial infarctions. Patients with minor stable coronary disease or aortic aneurysms were included. Each patient provided written informed consent, and the 65 patients were operated on for aortic valve repair between February 2, 2012, and November 13, 2013. Follow-up was obtained at the 2-year time point after the first implantation, or February 2, 2014.

Baseline transthoracic echocardiograms (TTE) were recorded preoperatively and then serially after the surgical procedures. Median sternotomy and standard cardiopulmonary bypass and myocardial protection techniques were used. Prebypass transesophageal echocardiography guided the procedures, and general operative techniques are given elsewhere [13]. The rings were sized with specially designed ball sizers placed behind the leaflets and resulted in the recruitment of 65 symptomatic male and female individuals, 18 years of age or older, with moderate to severe AI of trileaflet aortic valves, accompanied by aortic annular dilation, and a ventricular ejection fraction of 35% or higher. Emergency cases, endocarditis, and multiple valve surgical procedures were excluded, as were patients with active infections, recent strokes, or myocardial infarctions. Patients with minor stable coronary disease or aortic aneurysms were included. Each patient provided written informed consent, and the 65 patients were operated on for aortic valve repair between February 2, 2012, and November 13, 2013. Follow-up was obtained at the 2-year time point after the first implantation, or February 2, 2014. Baseline transthoracic echocardiograms (TTE) were recorded preoperatively and then serially after the surgical procedures. Median sternotomy and standard cardiopulmonary bypass and myocardial protection techniques were used. Prebypass transesophageal echocardiography guided the procedures, and general operative techniques are given elsewhere [13]. The rings were sized with specially designed ball sizers placed behind the leaflets in the coronary sinus (http://www.jsrmd.com/ftp/99_STS_FIM_Compressed.mp4). The algorithm assumed that twice the leaflet free-edge length equaled the required ring circumference, as previously validated [14]. Elliptical ring size was described as the diameter of a circle with an equivalent circumference, so that desired ring size basically equaled leaflet free-edge length / 1.5. During implantation, it was important to prevent abrasive contact between ring Dacron and the fragile leaflets. To this end, the three ring posts were sutured to the subcommissural spaces by use of Cabrol-like sutures of 4-0 Prolene. Then the ring was lowered below the valve, and two “looping” sutures were placed around each ring body and up through the annulus [13, 14]. All nine sutures were tied over small Dacron supraannular pledgets, and at the end, the ring was not visible. Careful ring placement with this technique avoided abrasive leaflet contact or other complications related to the device. All sutures were cut short to prevent leaflet contact, and all surgeons had been trained on animal hearts and received proctoring on at least the first three clinical cases.

After ring placement, leaflet prolapse became better defined and was corrected using central plication sutures of 7-0 Gore-Tex or Prolene to equalize free-edge length and effective height of all three leaflets to greater than 8 mm: (http://www.jsrmd.com/ftp/99_STS_FIM_Compressed.mp4). The Schäfers effective height caliper and the Frater stitch were useful in this assessment [15–18]. Plication sutures were placed symmetrically into the thickened leaflet free-edge cord, adjacent to the central nodulus Arantius, to keep the nodulus in the midline (Fig 1). Scarred retracted noduli also were released by “unfolding” [19], by use of either sharp surgical dissection or the CUSA device (Fig 2). The goal of these maneuvers was to maintain normal function of the noduli Arantii in closing the midline coaptation gap and in achieving maximal reduction in residual leak. Disrupted commissures or leaflet holes were repaired with glutaraldehyde-fixed autologous pericardium (10-minute immersion in 0.6% buffered/glutaraldehyde and three washes in normal saline). In most cases, double patches were sutured to both sides of the leaflet tissue with fine vertical mattress sutures of 6-0 Prolene, leaving the knots on the aortic aspect (Fig 3). If a commissure was bridged, the pericardial strips were sutured from the aorta (at the commissural insertion)
to the nodulus Arantius to prevent late suture line disruption in the high-stress commissural region (Fig 4) [20, 21]. Dilated sinotubular junctions or aortic root/ascending aortic aneurysms were managed as described elsewhere [22]. In general, the goal was to achieve a sinotubular junction 5 to 7 mm greater than the ring diameter [11]. An alternative prolapse corrective method of Gore-Tex free-margin reinforcement [23] was used in 2 patients with extensive fenestrations. Pericardial leaflet extension was used in 2 patients with scarred retracted leaflets, a pericardial strip being sutured to the existing leaflet to augment the leaflet free-margin [24]. Finally, severely defective leaflets were completely replaced in 2 patients with autologous pericardial leaflets, by use of shape and dimensional algorithms described elsewhere [25, 26]. The new leaflets were sutured to the annulus and then plicated to fit the native leaflets (Figs 5 and 6). Repairs were not concluded until leaflet effective height was 8 mm or greater. Minimizing the handling of fragile leaflet tissue was important at all times—and instead, the leaflets were pushed around with closed forceps tips whenever possible.

All patients were followed clinically and with periodic TTE after operation. Echocardiograms were sent to a central core laboratory for analysis (MedStar Research Institute, Washington, DC). Echocardiographic time points included preoperative screening, discharge, and 3-month and 6-month examinations. Echocardiographic aortic valve function was evaluated according to

![CUSA Device](image1.png)

**Fig 2.** Release of a retracted nodulus Arantius by use of CUSA unfolding.

![Scared Retracted Nodulus](image2.png)

![Fig 3. Sequential steps in double patching of a leaflet hole with autologous pericardium.](image3.png)

(A) Hole in noncoronary cusp. (B) Double autologous pericardial patch is sutured over the hole with fine mattress sutures. (C) Hole closed after sutures are tied. (D) No residual leak by transoesophageal echocardiography.
American Association of Echocardiography criteria, with AI described as grade 0 to grade 4 [27]. Mean systolic aortic valve gradients were assessed by standard echo-Doppler methods, and changes in clinical and echocardiographic variables were evaluated by two-tailed paired t tests, assuming a p value of <0.05 as significant. If core lab echo data were unavailable, site-specific readings were substituted. Of the 260 (65 × 4) echo data points, 11 (4.2%) were missing because of valve replacement, death, or lost studies. These 11 missing data points were interpolated for the analysis with the last available values. Only aspirin antiplatelet therapy was used in sinus rhythm.

Results

In the 65-patient trial, baseline patient characteristics included an average age of 63 ± 13 years (mean ± SD) (range, 28 to 84 years), male gender of 69%, and all operations were elective. On the screening TTE, grade 3 or 4 AI was present in 46 of 65 patients (70%), grade 2 AI (moderate) was evident in 16 of 65 patients (25%), and grade 1 AI (mild) was observed in 3 patients (5%). All 3 patients with grade 1 AI had aortic root aneurysms as their primary surgical indication. Prerrepair annular diameter was 27 ± 2 mm, and average required ring size was 22 ± 2 mm. Of the 65 patients, 12 (18%) received No. 19 rings, 25 (38%) had No. 21 rings, 26 (40%) had No. 23 rings, and 2 (3%) had No. 25 rings. Eighty percent of patients (52/65) had leaflet prolapse, and 22% (14/65) had structural leaflet defects (commissural ruptures or holes).
Aortic root, ascending aortic aneurysms, or both were replaced in 40 of 65 patients (62%). Three patients had concomitant coronary bypass procedures, and 1 patient had tricuspid ring annuloplasty. The average aortic cross-clamp time was 115.8 ± 37.5 minutes. After aortic ring annuloplasty and leaflet reconstruction, mean systolic gradients across the repairs averaged 8.9 ± 4.8 mm Hg, and valve area was 2.6 ± 0.5 cm².

In the 65 patients, there were no in-hospital operative mortalities. One patient experienced a sternal infection and transient renal failure requiring short-term dialysis, and 1 patient underwent reoperation for bleeding. No other serious adverse events occurred; specifically, no strokes, heart block/pacemakers, myocardial infarctions, pneumonia, or cases of prolonged ventilation were encountered. No direct complications of the rings were observed. The maximal follow-up time was 2 years, and the mean follow-up time was 0.9 years. To the follow-up date of February 2, 2014, there were no cases of late stroke, thromboembolism, major bleeding, or any other types of valve-related complications. Two patients died during the 2 postoperative years, both with echocardiographically documented normal aortic valve function. Thus, survival at an average follow-up time of 0.9 years after aortic valve repair was 97%, comparing favorably with prosthetic valve replacement [28].

With a predesignated follow-up time for echocardiography of 6 months, AI grade fell from 2.9 ± 0.8 at preoperative screening to 0.7 ± 0.7 at discharge to 1.1 ± 0.9 at 3 months and to 1.2 ± 0.9 at 6 months (all p < 0.0001 compared with preoperative screening). New York Heart Association Class also was improved significantly, from a preoperative value of 2.1 ± 0.7 to 1.2 ± 0.4 at 1 year (p = 0.001). Thus, more than 75% of patients became completely asymptomatic by 1 year after valve repair, and most of the others were only mildly limited.

Of the surviving 63 patients, 3 (4.6%) required reoperative aortic valve replacement at the average follow-up time of 0.9 years (Table 1). One patient had valve replacement for Corynebacterium endocarditis 8 weeks postoperatively. The second had valve replacement because of untying of a post suture and partial ring dehiscence (Fig 7A). The third experienced a leaflet tear 5 days postoperatively, probably from a long annular suture tail (Fig 7B). Another patient experienced an early suture-induced leaflet tear at 7 days and underwent repeated repair with an autologous pericardial leaflet. In response to these suture adverse events, a technique was developed wherein the 4-0 Prolene annular sutures were tied with eight tight knots, and then one needle was passed downward through the lateral aspect of the pledget and tied again (Fig 8). After the suture tails were cut very short, the cut ends were completely away from any leaflet contact, preventing subsequent cusp injury.

In the ongoing 60 patients with intact repairs, 55 (92%) have stable none-to-mild AI (grade 0 to grade 1). Three are clinically stable with grade 3 AI and 2 with grade 2 AI; all 5 are being followed up medically at present (Table 1).

Table 1. Patients With Suboptimal Outcomes

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Patients were numbered sequentially in time from 1 to 65, so seven of nine suboptimal outcomes were in the first half of the series.

AI = aortic insufficiency; AVR = aortic valve replacement; CP = commissural patch; CR = commissural rupture; Endocard. = endocarditis; F = female; GT = Gore-Tex reinforcement; H = hole in leaflet; L = left coronary; LE = leaflet extension; Leaf. = leaflet; M = male; N = noncoronary; P = prolapse; PH = patch hole; Pl = plication; PLR = pericardial leaflet replacement; R = right coronary leaflet; Reop. = reoperation; Ret. = retracted; RR = aortic root replacement; Untie sut. = untying of annular sutures.
One of these patients experienced central migration of a ring post as seen on the discharge echocardiogram, probably from another suture untying. Two others had pericardial leaflet extensions (early in the series before pericardial leaflet replacement was available), and 2 had Gore-Tex free-margin sutures. These were the only cases of leaflet extension and Gore-Tex in the series, but they all obtained less than desirable outcomes. Thus, of the 9 patients with suboptimal results, 4 had potentially preventable technical causes, and 4 had leaflet repair techniques that were ineffective, at least in our hands. All plication stitches, double pericardial patches, and pericardial leaflet replacements in this series maintained good integrity and seemed satisfactory. Finally, it is significant that most technical and procedural problems occurred in the first half of the series (Table 1) during the early part of the learning curve. Once leaflet repair and suture techniques were refined, functional stability became quite satisfactory.

Comment
An unexpected finding of this study was the high incidence of structural leaflet defects, and two explanations exist for this difference with other reports. First, many aortic valve “sparing” series include patients operated...
primarily for aortic root aneurysms but with minimal AI [29, 30]. Anatomic leaflet defects probably are less common in patients with less severe AI, and they also may be less frequent in patients with aortic root aneurysms [31]. Second, valve sparing has been used predominantly in patients with relatively normal valve leaflets: a described selection criterion for the reimplantation procedure [32]. Therefore, previous patients with severe AI and leaflet defects may have been selected for Bentall valve replacements [6] rather than repair. On the basis of our data, it seems probable that leaflet reconstruction will need to be refined and better understood if the objective is to repair most AI valves, as it was in this study.

This analysis was not powered to make statistical conclusions about efficacy of the various techniques, but perhaps several preliminary descriptive and hypothesis-generating observations can be made. First, as defined previously [18], leaflet plication is an effective and stable method for correcting leaflet prolapse, and no complications of plication were observed in this study. The technical variation used in this series was termed symmetrical perinodular plication, which maintained the noduli in the midline and seemed to minimize residual central leaks. Additionally, it might be emphasized that plication sutures should be placed in the thickened leaflet free-edge cord rather than in the thin leaflet tissue, where knots can slice through. Nodular unfolding had the same effect of recovering nodulus function and was simple and straightforward with use of the CUSA device. We suggest that aortic valve reconstruction will more frequently achieve grade 0 AI if nodulus function is respected during valve repair [19].

The use of pericardium for leaflet reconstruction has been associated with an increased rate of repair failure in most publications [9, 10]. In fact, suturing thin leaflets with running suture lines has always been problematic [33]. To avoid pericardial patch disruption, we used double pericardial patches, joined across the leaflet by fine 6-0 Prolene mattress sutures. If the tissues seemed stronger, full pericardium was placed only on the coaptation surface, and small pericardial pledgets were used on the aortic aspect. But if there was any question, double patches were used. This approach seemed quite stable, with good results achieved in 10 of 10 cases. Double pericardial strips or patches, placed with fine interrupted sutures, could potentially neutralize the previously observed negative prognostic effects of using pericardium. For commissural reconstructions, the suture lines spanned the leaflet from the nodulus to the aorta, anchoring the patches to stronger tissues. If multiple defects exist in a given leaflet, it may be better to replace the entire leaflet with glutaraldehyde-fixed autologous pericardium [25, 26], although more data will be required for full validation. However, leaflet mobility with complete leaflet replacement is excellent, and suturing to the aortic annulus has been very stable [34]. Reconstructing leaflets with pericardial extensions sutured to the existing leaflets was not effective in this series, and full leaflet replacement may be better for severely defective valve cusps [25, 26]. Finally, Gore-Tex leaflet reinforcement did not seem adequate in either of our 2 patients and was abandoned as the series progressed, in favor of pericardial techniques. It is possible that full conversion to better leaflet reconstructive approaches could eliminate half of the suboptimal results in this series.

A learning curve was evident in this study. Many of the surgeons were performing their first aortic valve repairs, and certainly, everyone was unsure of the best leaflet techniques. This type of learning curve has been described repeatedly for aortic valve repair [2, T. Malas, unpublished data, 2014], and as this series progressed and surgeons became more experienced, the incidence of recurrent AI seemed to decrease. Especially important was the prevention of iatrogenic defects, especially leaflet tearing from long suture tails and suture untying. Because similar problems have occurred with commissural annuloplasty in the past, we were aware of these possibilities, and we taught preventive maneuvers in the training protocol. Despite the training, however, we still had several preventable iatrogenic suture complications. Future teaching will incorporate lateral attachment of the sutures to the pledgets (Fig 8), which, it is hoped, will completely prevent annular suture problems. If long-suture tails and untied knots were prevented, most of the remaining suboptimal outcomes could be neutralized, and the results with this approach might become nearly pristine. The potential for very low valve-related complications with repair also are evident in this experience, and better late annular stabilization with ring annuloplasty may further improve the results. Certainly, even when the technical uncertainties are considered, AI reduction and postoperative valve gradients in this study were quite acceptable, especially for a first application. Finally, previous analyses of ventricular volumes and ejection fractions in a subset of these patients demonstrated good recovery of ventricular function after aortic valve repair with ring annuloplasty [7].

In conclusion, this study evaluated leaflet reconstructive techniques used in a prospective series of aortic valve repairs. Although the findings were descriptive, certain preliminary observations were made that seemed to improve results as the series progressed. Leaflet reconstruction appeared more stable with the use of combinations of plication for prolapse, nodular unfolding, and double autologous pericardial patches for ruptured commissures or holes. The limited early results of complete pericardial leaflet replacement for severely abnormal leaflets were satisfactory. Future studies and more experience with reconstruction of defective aortic valve leaflets may clarify these issues.

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References


