Worldwide Outcomes in Bicuspid Aortic Valve Repair
Analysis of Mid-Term and Long-Term Outcomes

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Director, Thoracic Aortic Surgery Research Program
University of Pennsylvania
**BAV repair: Survey of the Literature**

- Primarily Expert/pioneer series from 5-10 groups
- No RCTs, limited controls and rapidly changing techniques
- Opportunity to summarize current concepts
Data to Examine

- Effect of Annular diameter:
  - Subcommisural Annuloplasty / Rings
  - Re-modeling / Re-implantation

- Nuances:
  - Patches
  - Dilated LV/Low EF

- Compare to TAV repair

- TAVR options

- A Word of Caution
Preoperative aortic root geometry and postoperative cusp configuration primarily determine long-term outcome after valve-preserving aortic root repair

Takashi Kunihara, MD, PhD, a Diana Aicher, MD, a Svetlana Rodionycheva, MD, a Heinrich-Volker Groesdonk, MD, a Frank Langer, MD, a Fumihiro Sata, MD, PhD, b and Hans-Joachim Schäfers, MD, PhD a

Objective: Technical controversies exist in valve-preserving aortic root replacement. We sought to determine predictors of long-term stability of the aortic valve.

Methods: A total of 430 patients (aged 57 ± 15 years, 323 male) underwent valve-preserving aortic root surgery (remodeling in 401, reimplantation in 29) between 1995 and 2009 and were followed echocardiographically. Factors influencing late recurrence of aortic valve regurgitation grade II or greater (n = 45) or need for reoperation on the aortic valve (n = 25) were analyzed.

Results: Early mortality was 2.8% (1.9% for elective cases), and actuarial survival at 10 years was 83.5% ± 2.4%. Ten-year freedom from aortic valve regurgitation grade II or greater was 85.0% ± 2.5%. Preoperative aortoventricular junction diameter greater than 28 mm and postoperative effective height of the aortic cusp less than 9 mm were identified as significant predictors for late aortic valve regurgitation grade II or greater in multivariate analysis (both P < .001). Ten-year freedom from reoperation on the aortic valve was 89.3% ± 2.5%. Preoperative aortoventricular junction diameter greater than 28 mm (P < .001), use of pericardial patch (P = .022), and effective height of the aortic cusp less than 9 mm (P = .049) were identified as significant predictors for reoperation in multivariate analysis. Operative technique (remodeling, reimplantation), Marfan syndrome, bicuspid valve anatomy, concomitant central cusp plication, size of prosthesis used, and acute dissection were not associated with an increased risk of late aortic valve regurgitation grade II or greater or reoperation. In patients with preoperative aortoventricular junction diameter greater than 28 mm (n = 94), the addition of central cusp plication significantly improved freedom from aortic valve regurgitation grade II or greater (P = .006) regardless of root procedures (remodeling, P = .011; reimplantation, P = .053).

Conclusions: Long-term stability of valve-preserving aortic root replacement was influenced not by the technique of root repair but by the preoperative aortic root geometry and postoperative cusp configuration. (J Thorac Cardiovasc Surg 2012;143:1389-95)
Summary/ Interesting or Distinctive Points

- Primarily remodeling; Large expert series
  - Avg age = 57
  - 10 year freedom from reop = 89%
- Most patients did NOT have any significant Annular Ring or Fixed Stabilization
- All were ROOT procedures
Predictors of late failure

**Predictors of BOTH late recurrent AI>2+ and Reoperation:**
- AVJ diameter >28 mm
- Effective height <9 mm
- Use of pericardial patch

**10 year freedom from recurrent AI>2+: 88.9% ± 2.5% (≤28 mm) vs 69 ± 8% ≥28 mm**

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**Table 1. Predictors of late aortic valve stability**

<table>
<thead>
<tr>
<th></th>
<th>Univariate</th>
<th>Multivariate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>P value</td>
<td>P value</td>
</tr>
<tr>
<td>AR grade ≥ II</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AVJ diameter &gt; 28 mm</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>eH &lt; 9 mm</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>STJ diameter</td>
<td>.025</td>
<td>.563</td>
</tr>
<tr>
<td>Use of pericardial patch</td>
<td>.068</td>
<td>.071</td>
</tr>
<tr>
<td>Concomitant CABG</td>
<td>.142</td>
<td>.177</td>
</tr>
<tr>
<td>Reoperation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AVJ diameter &gt; 28 mm</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Use of pericardial patch</td>
<td>.005</td>
<td>.022</td>
</tr>
<tr>
<td>eH &lt; 9 mm</td>
<td>.042</td>
<td>.049</td>
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<tr>
<td>Body height</td>
<td>.115</td>
<td>.505</td>
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<tr>
<td>Operative procedure</td>
<td>.177</td>
<td>.986</td>
</tr>
<tr>
<td>Use of cusp plication</td>
<td>.188</td>
<td>.303</td>
</tr>
</tbody>
</table>

Kunihara T… Schafers HJ et al. JTCVS 2012.
Predictor of late Reoperation: >28 mm AVJ diameter

Kunihara T… Schafers HJ et al. JTCVS 2012.
Predictor of late failure
Recurrent AI>2: Effective Height <9

EH: height difference between the central coaptation of cusp margin and the nadir of the sinuses or aortic insertion

Kunihara T… Schafers HJ et al. JTCVS 2012.
Valve sparing-root replacement with the reimplantation technique to increase the durability of bicuspid aortic valve repair

Laurent de Kerchove, MD, a Munir Boodhwani, MD, MMSC, d David Glineur, MD, a Michel Vandyck, MD, b Jean-Louis Vanoverschelde, MD, PhD, c Philippe Noirhomme, MD, a and Gebrine El Khoury, MD a

N=151; 89 SCA vs 72 reimplantation
•53 patients matched in each group

- 24 patients (49%) in SCA group had peak gradient >20 mmHg, compared to 10 patients (19%) in Reimplantation group

- At follow-up, freedom from reoperation was better in Reimplantation group (100% vs 90%), and freedom from AI> 2+ was also better in Reimplantation group (100% vs 77%)

- Conclusions: Compared to BAV repair only (SCA), valve repair + root reimplantation stabilizes the ventriculoaortic junction (ie Annulus), provides improved valve gradients, and is associated with much improved outcomes

PENN: Root reimplantation versus Sub-Commissural Annuloplasty in BAV repair

- VSRR: 92 ± 6%
- SCA: 64 ± 12%

5 years
Log-Rank P: 0.04

<table>
<thead>
<tr>
<th>Years since surgery</th>
<th>Number at risk</th>
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<tr>
<td></td>
<td>VSRR:</td>
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<tr>
<td>0</td>
<td>36</td>
</tr>
<tr>
<td>1</td>
<td>28</td>
</tr>
<tr>
<td>2</td>
<td>17</td>
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<td>3</td>
<td>12</td>
</tr>
<tr>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

Bavaria et al; Presented at STS 2013
Some more Data to Ponder ......

SCA in Dilated Aortic Annulus .... Which many, if not most, BAV patients have!
Simple BAV repair (SCA) with dilated annulus (>27mm): fails in short term
Actuarial freedom from reoperation after aortic valve repair in patients with a BAV and a preoperative AVD of >28 mm depending on the use of root replacement.

This data shows that there is a **SUBSTANTIAL** failure at 6 years requiring **REOPERATION** in patients with a > 28 mm Annulus (This is a lot of BAV patients!!) whether they have a SCA or “Remodeling” (Yacoub) style Root. Simple BAV repair here, Without Annular Reduction and stabilization is a **DISASTER**!

Aicher D et al. Circulation 2011;123:178-185 (Germany)
Annuloplasty Suture

Figure 5. Freedom from reoperation after isolated aortic valve repair (- annular suture: without annuloplasty, + annular suture: with annuloplasty). IA, isolated aortic valve repair

TABLE 4. Echocardiographic data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preoperative echocardiography</th>
<th>Postoperative TEE control</th>
<th>TTE at discharge</th>
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<tr>
<td></td>
<td>Repair</td>
<td>CVG</td>
<td>P value</td>
</tr>
<tr>
<td>AI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>20 (15.4%)</td>
<td>9 (6.9%)</td>
<td>.0022*</td>
</tr>
<tr>
<td>I</td>
<td>37 (28.5%)</td>
<td>18 (13.7%)</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>30 (23.1%)</td>
<td>37 (28.2%)</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>26 (20.0%)</td>
<td>41 (31.3%)</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>17 (13.1%)</td>
<td>26 (19.8%)</td>
<td></td>
</tr>
<tr>
<td>Cusp coaptation height (mm)</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

Lansac et al. CAVIAAR Study JTCVS 2015
Tirone David valve-sparing aortic root replacement and cusp repair for bicuspid aortic valve disease

Fabian A. Kari, MD, David H. Liang, MD, PhD, John-Peder Escobar Kvitting, MD, PhD, Elizabeth H. Stephens, MD, PhD, R. Scott Mitchell, MD, Michael P. Fischbein, MD, PhD, and D. Craig Miller, MD

Objectives: The durability of valve-sparing aortic root replacement with or without cusp repair in patients with bicuspid aortic valve (BAV) disease is questioned. We analyzed the results of 75 patients with a BAV undergoing Tirone David reimplantation valve-sparing aortic root replacement.

Methods: Average age was 45 ± 10 years; 80% were male; 31% had 2+ or greater aortic regurgitation (AR); annular diameter averaged 28 ± 3 mm; 32% had a Sievers’ type 0 BAV, and 66% underwent concomitant cusp repair (usually cusp free margin shortening) to correct prolapse. Early (6 ± 3 days) and late (2.9 ± 1.7, 1-10 years) postoperative echocardiographic results were compared (cumulative echocardiographic follow-up, 190 patient-years; median late interval, 2 years [interquartile range, 0.68, 4.2]). Seven patients remained at risk beyond 6 years. Clinical outcome and valve function were analyzed using log-rank calculations.

Results: Actuarial survival was 99% ± 2%; freedom from reoperation was 90% ± 5%, infection 98% ± 2%, and stroke 100% at 6 years. After initial improvement in degree of AR \( (P < .001) \), minor subclinical progression of AR was observed \( (P > .5) \); however, freedom from AR of more than 2+ was 100%. Cusp free margin shortening was not associated with valve deterioration, but commissural suspensory polytetrafluoroethylene neo-chord creation \( (n = 4) \) portended a higher probability of recurrent AR \( (P = .025) \).

Conclusions: After David procedure and cusp repair in patients with a BAV, midterm clinical and valve function outcomes were favorable out to 6 years. More follow-up is required to determine long-term valve durability and the hazard of other clinically important late adverse events, including eventual reoperation, to beyond 10 years. (J Thorac Cardiovasc Surg 2013;145:S35-40)
Summary/Interesting or Distinctive Points

- 100% reimplantation; Large expert series; very conservative
  - Avg age = 45
  - 6 year freedom from reop = 90%
- All patients had significant Annular Stabilization
- 31% had +2 or greater PRE-OP AI
- All were ROOT procedures
Tirone David valve-sparing aortic root replacement and cusp repair for bicuspid aortic valve disease

Fabian A. Kari, MD,* David H. Liang, MD, PhD,* John-Peder Escobar Kvitting, MD, PhD,* Elizabeth H. Stephens, MD, PhD,* R. Scott Mitchell, MD,* Michael P. Fischbein, MD, PhD,* and D. Craig Miller, MD*

METHODS

- Free margin shortening was major technique used for cusp repair
- Perforated cusps were replaced – NO PATCH repair
- BAV presenting with dilated aortic annulus underwent valve-sparing root reimplantation regardless of root aneurysm size (NOT Subcommissural Annuloplasty)
- Avoid triangular raphe resection and cusp plication to reduce risk of impaired cusp mobility

“If the 2 fused cusps are thin, not excessively prolapsing, and the raphe is not densely fibrotic or calcified, free margin shortening is usually adequate.”
Use of Pericardial Patch for Reconstruction

Substantial Thickening and Calcification BUT an AI presentation: Not Really repairable WITHOUT resection and Pericardial patch augmentation …..
Actuarial freedom from reoperation after aortic valve repair in patients with a BAV depending on the use of a pericardial patch.

Use of Pericardial Patch

In patients requiring raphe repair, use of a patch was associated with greater recurrence of AI (**p=.02).

Should we do a BAV Repair in a patient with lower EF (Dilated LV) and Symptoms???
Overall Survival:
symptomatic vs asymptomatic patients

5 yrs: 96% vs 93%
10 yrs: 96% vs 77%
15 yrs: 96% vs 71%

Multivariate regression analysis identified increasing age as the sole predictor of overall survival hazard in the whole cohort

Freedom from aortic valve reoperation

- 5 yr: 90% vs 93%
- 10 yr: 82% vs 89%
- 15 yr: 82% vs 89%

No Real difference

Freedom from aortic valve reintervention: This may point to a need for earlier intervention ..... as maybe the Dilated low EF LV does not tolerate any residual AI

10 yr freedom from AV reintervention:

90.8 ± 7.6% vs 76 ± 6%

log-rank $P = 0.003$
BAV repair vs TAV Repair
5 yrs: 95 ± 1.3%
10 yrs: 90 ± 3%

Preoperative AI was not a risk factor

Risk of Valve-Related Events After Aortic Valve Repair

Joel Price, MD, MPH, Laurent De Kerchove, MD, David Glineur, MD, PhD, Jean-Louis Vanoverschelde, MD, PhD, Philippe Noirhomme, MD, and Gebrine El Khoury, MD

Department of Cardiovascular and Thoracic Surgery, Cliniques Universitaires Saint-Luc, Université Catholique de Louvain, Brussels, Belgium

Outcomes with BAV Repair + Root Reimplantation:

How do they compare to tricuspid aortic valve root reimplantation?
PENN: Root Reimplantation Outcomes: Bicuspid Aortic Valve vs. Tricuspid Aortic Valve

Outcomes are similar.
**A quarter of a century of experience with aortic valve-sparing operations**

Tirone E. David, MD, Christopher M. Feindel, MD, Carolyn M. David, BN, and Cedric Manlihot, BSc

**Objective:** To examine the late outcomes of aortic valve-sparing operations to treat patients with aortic root aneurysm with and without aortic insufficiency (AI) in a cohort of patients followed up prospectively since 1988.

**Methods:** A total of 371 consecutive patients had undergone aortic valve-sparing surgery (mean age, 47 ± 15 years; 78% men) from 1988 through 2010. In addition to the aortic root aneurysm, 90% had moderate or severe AI, 35.5% had Marfan syndrome, 12.1% had type A aortic dissection, 9.2% had bicuspid aortic valve, 8.4% had mitral insufficiency, 16.1% had aortic arch aneurysm, and 18.2% had bicuspid mitral valve. Reimplantation of the aortic valve was used in 296 patients and remodeling of the aortic root in 75. Cusp repair by plication of the free margin along the nodule of Arantius was used in 36.6% of patients, and reinforcement of the free margin with a double layer of fine Gore-Tex suture in 24.2%. The patients were followed up prospectively with images of the aortic root for a median follow-up of 8.9 ± 5.2 years.
Cleveland Clinic Experience
728 pts – 15 year follow-up

(A) Repair sutures for most repairs
(B) Mobilization of commissures for a large root
(C) Closure of gaps in aortic root
(D) Reattachment of commissures resuspended at a higher level in ascending aorta tube graft

### Cleveland Clinic Experience

<table>
<thead>
<tr>
<th>Variable</th>
<th>n or Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demography</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>728 (87)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>728 42 ± 12</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>661 27 ± 4.6</td>
</tr>
<tr>
<td><strong>Symptoms</strong></td>
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<tr>
<td>NYHA class</td>
<td></td>
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<tr>
<td>I</td>
<td>321 (44)</td>
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<tr>
<td>II</td>
<td>345 (48)</td>
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<tr>
<td>III</td>
<td>47 (6.5)</td>
</tr>
<tr>
<td>IV</td>
<td>15 (1.8)</td>
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<tr>
<td><strong>Valve pathology</strong></td>
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<tr>
<td>Aortic valve regurgitation</td>
<td>618 (85)</td>
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<tr>
<td>Aortic valve regurgitation grade</td>
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<tr>
<td>0</td>
<td>76 (11)</td>
</tr>
<tr>
<td>1+</td>
<td>52 (7.8)</td>
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<tr>
<td>2+</td>
<td>69 (10)</td>
</tr>
<tr>
<td>3+</td>
<td>149 (22)</td>
</tr>
<tr>
<td>4+</td>
<td>318 (48)</td>
</tr>
<tr>
<td>Aortic valve stenosis</td>
<td>63 (8.7)</td>
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<tr>
<td>Mean gradient (mm Hg)</td>
<td>236 12 ± 8.6</td>
</tr>
<tr>
<td>Peak gradient (mm Hg)</td>
<td>252 23 ± 16</td>
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<tr>
<td>Mitral valve regurgitation</td>
<td>173 (24)</td>
</tr>
<tr>
<td><strong>Cardiac comorbidity</strong></td>
<td></td>
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<tr>
<td>Previous cardiac operation</td>
<td>33 (4.5)</td>
</tr>
<tr>
<td>Previous myocardial infarction</td>
<td>50 (6.9)</td>
</tr>
</tbody>
</table>

**Noncardiac comorbidity**

- Hypertension: 694 (280 (40))
- Stroke: 728 (18 (2.5))
- Pharmacologically treated diabetes: 711 (16 (2.3))
- Chronic obstructive pulmonary disease: 694 (25 (3.6))
- Smoking: 717 (262 (37))
- Bilirubin (mg/dL): 660 (0.71 ± 0.47)
- Creatinine (mg/dL): 681 (1.01 ± 0.26)
- Blood urea nitrogen (mg/dL): 681 (16 ± 4.4)
- Concomitant surgical procedure: 728

**Aortic root, ascending aorta, or aortic arch procedure**

- 275 (38)
- Mitral valve repair: 48 (6.6)
- Mitral valve replacement: 4 (0.55)
- Coronary artery bypass grafting: 46 (6.3)
- Partial to full incision: 205 (38)
- Minimally invasive: 283 (45)

**Support**

- Circulatory arrest: 631 (51 (8.1))
- Myocardial ischemic time (minutes): 631 (49 ± 25)
- Cardiopulmonary bypass time (minutes): 728 (66 ± 34)
- Left ventricular morphology and function: 640 (5.9 ± 1.04)

**NYHA = New York Heart Association; SD = standard deviation.**

Gradients over time

Fig 5. Aortic valve (AV) gradient after repair of bicuspid aortic valve disease. Circles represent grouped data without regard to repeated measurements. Solid lines are model-based estimates. Preoperative (Preop) values shown as a bold dot. (A) Mean gradient. (B) Peak gradient.
LV mass over time

Fig 6. Left ventricular (LV) mass index after aortic valve repair for bicuspid disease. Circles represent grouped data without regard to repeated measurements. Solid line is model-based estimate. Late increase in LV mass index is about 0.85 g/m² per year. Preoperative (Preop) value shown as a bold dot.
Bicuspid aortic valves have a larger annulus size, sinus of Valsalva and ascending aorta dimensions.

BAV aortic annuli appear circular and most will fit currently available commercial valved stents.

### Table IV. Published Reports of Transcatheter Aortic Valve Implantation and Bicuspid Aortic Valves

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>N</th>
<th>Valve type</th>
<th>Post-deployment prosthetic shape</th>
<th>AR grade</th>
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<tr>
<td>Delgado [16]</td>
<td>2009</td>
<td>1</td>
<td>ES</td>
<td>C</td>
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<tr>
<td>Chiam [17]</td>
<td>2010</td>
<td>1</td>
<td>ES</td>
<td>C</td>
<td>Trivial</td>
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<td>Ferrari [18]</td>
<td>2010</td>
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<td>ES</td>
<td>N/A</td>
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<td>Jialaiwai [23]</td>
<td>2010</td>
<td>1</td>
<td>CV</td>
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<td>Raja [19]</td>
<td>2011</td>
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<td>C</td>
<td>&lt;1+</td>
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<td>Kochman [24]</td>
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<td>CV</td>
<td>E</td>
<td>N/A</td>
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<td>Baralis [20]</td>
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<td>1</td>
<td>BS-XT</td>
<td>C</td>
<td>&lt;1+</td>
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<td>Himbert [14]</td>
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<td>CV</td>
<td>E</td>
<td>&lt;1+ (13)</td>
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<td>Zegdi [25]</td>
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<td>BS-XT</td>
<td>E</td>
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<td>Maluenda [21]</td>
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<td>1</td>
<td>BS-XT</td>
<td>C</td>
<td>&lt;1+</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>CV</td>
<td></td>
<td>2+ (4)</td>
</tr>
</tbody>
</table>


*CT not performed in all patients.
Techniques have evolved to enable repair of the most complex pathologies

But the patient still has a BAV.....

Kari, Miller JTCVS 2012
Thickening, calcification, and reduced mobility.

0 (normal)
1 (mild alteration)
2 (moderate alteration)
3 (severe alteration)
The Alternative is not a FAILURE!!! Excellent Aortic Root outcomes in patients < 60

Original article
Durability of Porcine Bioroots in Younger Patients With Aortic Root Pathology: A Propensity-Matched Comparison With Composite Mechanical Roots


Nimesh D. Desai, MD, PhD, Fenton McCarthy, MD, William Moser, CRNP, Wilson Y. Szeto, MD, Ahmad Zeeshan, MD, Danielle Brown, MD, Y. Joseph Woo, MD, Alberto Pochettino, MD, Patrick Moseler, BS, Joseph E. Bavaria, MD

Division of Cardiovascular Surgery, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania

Fig 1. Long-term survival of the porcine bioroot (black line) and the mechanical root (gray line).
Freedom from aortic reoperation for SVD

All Patients < 60 years

Fig 3. Freedom from reoperation of aortic root for structural valve deterioration (SVD) for the porcine bioroot (black line) and the mechanical root (gray line).
A Word of Caution...

**Dr. Bavaria.** Any purely insufficient valve with enough leaflet surface area can be repaired …… We are getting close

**AORTIC VALVE REPAIR:**
A STEP BY STEP APPROACH

06-07 MAR 2014,
PARIS FRANCE

**Dr David.** He underscores what I said again. It is not a simple repair; **reimplantation of BAV is not simple.**

AATS discussion 2011
Conclusions:

- SCA in Large Annulus is NOT enough, neither is a Yacoub
  - Although in small annulus works well!!
- Large annulus needs stabilization and reduction
  - Reimplantation, Ring, ....
- Pericardial patch leaflet augmentation (for calcification or decreased cusp surface area) is probably not a long term solution
- BAV results, in most (but not all) series, are equivalent to TAV repair
- Root Replacement is an excellent bailout with very satisfactory long term results

- Still no data that BAV repair is equivalent/better than replacement strategies in the TAVR era:
  - Has the field evolved enough to look at performing RCTs?
Thank You

Hospital of the University of Pennsylvania c.1891