Aortic root restoration using an implantable geometric ring

G T Stavridis MD FETCS
DISCLOSURES

Conflicts of interest: none
History of Aortic Valve Repair

External ring annuloplasty

A
B
C

History of Aortic Valve Repair

Early Results After Implantation of a New Geometric Annuloplasty Ring for Aortic Valve Repair

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New Model Of Aortic Valve & Root Anatomy

Clarifies relationship between leaflet and annular anatomy required for coaptation

High-Resolution CT Angiography

The Normal Aortic Root is not Expansile
Suggesting the Utility of a Rigid Titanium Ring
Human cadaver observations
Dia. Sinus ≈ Dia. valve (D)
Free edge length (L) ≈ ½ sinus circumference

Predicted diameter algorithm
L=πD/2, therefore

D≈L/1.5
Sievers Type 0 and Type 1 valves

Creates 180° commissure orientation
- Centralizes blood flow pattern
- Simplifies leaflet reconstruction

Sized to non-fused leaflet
- Dia ≈ L/1.8
- Verified against inter-commissure distance

9 sutures
- 2 post sutures
- 7 looping sutures (4 under the fused cusp)
HAART 300 Aortic Annuloplasty Device

Replicates complex 3-D annulus
  2:3 elliptical base geometry
  3 equally space subcommissural posts
  10 degree outward post flare

4 proportional sizes
  Size designation is set to the diameter of a circle with equivalent circumference

<table>
<thead>
<tr>
<th>Size (mm)</th>
<th>Minor Axis (mm)</th>
<th>Major Axis (mm)</th>
<th>Circumference (mm)</th>
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<tbody>
<tr>
<td>19</td>
<td>16.0</td>
<td>23.5</td>
<td>60</td>
</tr>
<tr>
<td>21</td>
<td>17.5</td>
<td>26.0</td>
<td>66</td>
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<tr>
<td>23</td>
<td>19.0</td>
<td>28.0</td>
<td>72</td>
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<tr>
<td>25</td>
<td>20.5</td>
<td>30.5</td>
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</table>


BioStable Science & Engineering - Confidential
Aortic Valve Repair

8/30/16 | 1
Prof. Alain Carpentier – AATS Meeting 1983

Aortic Aneurysm with AI
“Aortic Valve and Root Restoration”

1. Aortic Geometric Ring Annuloplasty, Either Tri-Leaflet and Bicuspid
2. Appropriate Valve Leaflet Reconstruction
3. Aneurysm Resected with Coronary Buttons
4. Remodeling Root Replacement with Valsalva Graft
5. Coronary Implantation and Distal Anastomosis
Applicable Conditions

| Isolated Aortic Insufficiency | Aortic Aneurysm | Aortic Root Aneurysm | Ascending Aorta Aneurysm |

**Indications for Use:**
The HAART 300 Aortic Annuloplasty Device is intended to be used to correct annular dilatation and/or maintain annular geometry of the aortic valve in patients undergoing valve repair for aortic valve disease. It is designed to return aortic annular geometry toward normal for a given leaflet size and to assist in producing adequate leaflet competence by recovering normal coaptation geometry and area. The Device is intended for use in patients with tri-leaflet valve morphology.
## Improved Valve Sparing Root Repair Option

### Ascending Aortic Aneurysm (AAA) w/ AI
- **AAA Graft**
  - Normal coronary sinuses
  - Supracoronary anastomosis

### Aortic Root Aneurysm w/ AI
- **Yacoub Remodeling**
  - Coronary sinus resection
  - Creation of coronary buttons
  - Coronary reimplantation

### Aortic Root Restoration

#### Advantages vs. David:
- Eliminates deep root resection
- Shorter operative times
- Fewer hemostasis concerns
- Provides anatomic annuloplasty
Advantages of Ascending Aortic Aortic Valve Repair

1. Deep Root Dissection

- Wall of the aorta
- Anatomic ventriculo-arterial junction
- Basal attachment of aortic valvar leaflet to ventricular myocardium (valvar hinge)
Annuloplasty Techniques

<table>
<thead>
<tr>
<th></th>
<th>Subcommissural annuloplasty</th>
<th>VSR reimplantation</th>
<th>External Ring</th>
<th>Suture Annuloplasty</th>
<th>Internal Ring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circumferential</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
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<tr>
<td>Root dissection</td>
<td>-</td>
<td>++</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Rigid</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Root Expansibility</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Durability &gt;10y</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</tbody>
</table>

- SCA
- Reimplantation
- External ring
- Suture Annuloplasty
- Internal ring
3. Survival is Better with Aortic Valve Repair

Aortic valve repair benefits vs. replacement

- Lower operative mortality\(^1\)
- Better long-term survival\(^2\)
- Improved quality of life\(^3,4,5\)
- No life-long anticoagulation therapy

Worries

- RCA ostium adjacent to R-N comissure
- R. sinus with high A-V junction
- Not available HAART 200 in Europe..yet!!

- Asymmetric sinuses
Patient-tailored aortic root repair in adult marfanoid patients: Surgical considerations and outcomes

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ABSTRACT

Objective: The aim of the study was to evaluate the operative and functional results after individual, patient-tailored aortic root repair in marfanoid patients.

Methods: Among 518 patients who underwent operation between 2002 and January 2016, using patient-tailored aortic root repair with isolated sinus replacement, 42 patients fulfilled the original Ghent criteria. None/trivial, mild, moderate, and severe insufficiency grades were present in 5, 16, 10, and 11 patients, respectively.

Results: The repair was adjusted to the existing aortic annulus diameter. Replacement of 1, 2, or 3 sinuses of Valsalva was performed in 1, 14, and 27 patients, respectively. Concomitant cusp repair was performed in 17 patients (40.5%), and 10 patients (23.8%) underwent arch repair (total in 3). All patients survived surgery, and the follow-up (mean, 6.1 ± 3.1; range, 0.8-14.2 years) was 100% complete. No patient had a change in the form or size of the aortic neo-root, especially the size of aortic annulus and sinotubular junction during the follow-up time. No and trivial/mild insufficiency were present in 22 and 18 patients, respectively, and 2 patients with recurrent aortic insufficiency caused by cusp pathology underwent aortic valve replacement 43 and 66 months after the primary surgery, respectively. Thus, the estimated survival free from aortic valve/root reoperation for any reason at 5 and 8 years was 96.8% ± 3.2% and 91.4% ± 6.0%, respectively.

Conclusions: Patient-tailored root repair using isolated sinus replacement is an effective and durable method of valve-sparing repair in select marfanoid patients with a satisfactory quality of aortic cusps, which seems to be decisive for long-term valve function. (J Thorac Cardiovasc Surg 2017; ■:1-9)

Selective Coronary Sinus Replacement
## OCC initial experience Valve Repair

**24 patients (17-68)**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Marfan’s (one with Barlow’s)</td>
<td>(HAART + sSR +AscAR)</td>
</tr>
<tr>
<td>3 A root aneurysm – symmetric</td>
<td>(HAART + sSR +AscAR)</td>
</tr>
<tr>
<td>4 A. Root + Asc.Ao Aneurysm</td>
<td>(HAART + AscAR)</td>
</tr>
<tr>
<td>1 Asc. Ao An. &amp; cusp prolapse &amp; fenestration</td>
<td>(HAART)</td>
</tr>
<tr>
<td>1 Marfan’s asymmetric cusp size</td>
<td>(HAART)</td>
</tr>
<tr>
<td>1 Triple valve Ring repair</td>
<td>(HAART + MVrep + TVPl)</td>
</tr>
</tbody>
</table>

### 4 BAV

<table>
<thead>
<tr>
<th>Condition</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 A root aneurysm – asymmetric</td>
<td>(2 leaflet repair, 1 sub/com, leaflet reconstruction)</td>
</tr>
<tr>
<td>1 An.AscAo and single sinus dilatation</td>
<td>(asym. Root Remodelling)</td>
</tr>
<tr>
<td>3 A Root aneurysm</td>
<td>(sSR +AscAR)</td>
</tr>
<tr>
<td>1 Leaflet prolapse</td>
<td>A. Root Remodelling</td>
</tr>
<tr>
<td></td>
<td>no ring available...AVR</td>
</tr>
</tbody>
</table>
Aortic Valve Repair with Tri-Leaflet and Bicuspid Ring Annuloplasty during Ascending Aortic/Root Aneurysm Resection

Reoperation and Complication-Free Survival = 94%
Aortic Valve Repair with Tri-Leaflet and Bicuspid Ring Annuloplasty during Ascending Aortic/Root Aneurysm Resection

Clinically and Statistically Reduced AI Grade
Aortic Valve Repair with Tri-Leaflet and Bicuspid Ring Annuloplasty during Ascending Aortic/Root Aneurysm Resection

Low Transvalvular Mean Systolic Pressure Gradients
Aortic Valve Repair with Tri-Leaflet and Bicuspid Ring Annuloplasty during Ascending Aortic/Root Aneurysm Resection

NYHA Class Over Time after Aneurysm Resection and Aortic Valve Repair with Tri-Leaflet and Bicuspid Annuloplasty Rings

p<0.0001
n=47

Clinically and Statistically Improved Symptoms
Reoperation in First 2-Years
- First 81 Patients = 9
- Last 285 Patients = 3 (1.7%)
  Two untied plications, one loose post suture
Aortic Valve Disorders Managed with Ring Annuloplasty

1. Isolated Leaflet Prolapse
2. Ruptured Leaflet Fenestrations
3. Ascending Aneurysms with AI
4. Aortic Root Aneurysms with AI
5. Multiple Valve Disease
6. Coronary Artery Bypass + AI
7. Bicuspid Aortic Valve Disease
8. Unicuspid Aortic Valve Disease
9. Rheumatic Aortic Insufficiency
10. Aortic Root Dissections
11. Moderate Calcific Stenosis
12. Aortic Stenosis + Insufficiency
13. Traumatic Commissural Rupture
14. Dilated Ross Root Procedures
15. VSD with AI
16. LVOT Membrane with AI
17. TGA s/p Arterial Switch with AI
18. Congenital Aortic Root Aneurysms / Truncus Valves
19. Endocarditis
20. VAD’s with AI
Leading Global Centers

- **United States**
  - 33 trained surgeons / 23 centers
  - 145 procedures
  - Leading centers:
    - Duke (Hughes, Turek, Schroder)
    - WVU (Badhwar, Wei, Cook, Roberts)
    - Cincinnati (Smith, Park)
    - Indianapolis (Gerdisch)
    - WakeMed (Williams)
    - Northwestern (Malaisrie, Phan)
    - Penn State (Conte)

- **Europe**
  - 23 trained surgeons / 19 centers 7 countries
  - 220 procedures
  - Leading centers
    - Zurich (Weber)
    - Milan (Glauber, Miceli)
    - Athens (Stavridis)
    - Katowice (Deja)
    - Wroclaw (Jasinski)
    - Nuremburg (Fischlein)
    - Cologne (Choi)
Aortic valve sparing operations are complex operative procedures because the surgeon has to have a sound knowledge of functional anatomy of the aortic valve; ability to recognize anatomically abnormal components of the aortic root; judgment to select appropriate surgical techniques; and technical skill to execute the operation.


“To be most useful, an operation needs to be standardized and reproducible, so that any good surgeon can achieve excellent results.”

John W. Kirklin, Ward Rounds, 1970
Conclusions

1. Geometric ring annuloplasty is a simple and effective technique for aortic valve repair during aortic aneurysm surgery.

2. Important technical points include:
   - Downsizing ring size whenever a question exists.
   - Positioning ring posts low in the subcommissural triangles.
   - Applying “lateral suture fixation” to every annular suture.
Conclusions (cont.)

3. Selective replacement of only the abnormal sinuses using a remodeling graft further simplifies the procedure.

4. Aortic ring annuloplasty and selective sinus remodeling could simplify and standardize surgery for aortic root aneurysm.
5. Even in the original clinical trials, outcomes were excellent - despite being early in the technical learning curve.

6. Problems identified in the trials, such as annular suture untying and leaflet lacerations from long annular suture tails, have been completely eliminated in the subsequent 250 cases by lateral suture fixation, and future clinical outcomes are likely to be even better.