Endo-Bentall: Fact or Fiction?

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Disclosures

Bolton  Consultant, Investigator
Cook   Speaker, Investigator
Cryolife  Consultant
Edwards  Consultant, Investigator
Gore   Consultant, Investigator
LivaNova  Speaker, Investigator
Medtronic  Consultant, Investigator
St Jude  Speaker, Investigator
Vascutek  Speaker, Investigator
Endovascular repair of descending aortic dissections using an endograft

Matthew J. Metcalfe, MD, MRCS, Aberystwyth, UK
Ian M. Loftus, MD, FRCS, Robert D. Mears, MD, London, United Kingdom

Endovascular repair of descending aortic dissections using an endograft

Prashanth Vallabhajosyula, MD, MSc, Nimesh D. Desai, MD, PhD, and William D. Harshbarger, MD

Objective: Although endovascular repair is the current treatment for descending thoracic aortic dissection, there are some patients with high risk of open repair who may benefit from endovascular therapy.

Endovascular Stent Grafting for Open Repair

S. Ronchey *, E. Serrao *, V. Alberti *, M. Reiter, MD, S. Wipper, MD, Kupferberg Hospital, New York, NY, USA

Aortic Dissections

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**Thoracic Aortic Research Center, Policlinico, University of Rome, Rome, Italy
Endovascular Proximal Aortic Repair

Two Critical Questions:
1) Should we?
2) Can we?
Thoracic Aortic Surgery: Japanese Database

- 2000 thru 2005; JADSD 180 Hospitals
- N = 4,707 from 97 hospitals
- Root 10%, Asc 47%, Arch 44%: Desc 27%, TAA 8%
- OpMortality 8.6%; 7% Root, 8% Asc, 9% Arch; MajorMorb 30%
- Risks: OR
  - Emergency (25%) 3.7
  - Cr >3.0 3.0
  - Unexpected CABG 2.64

Root Replacement in North America: Valve Preserving vs Composite

• 2000 thru 2011, STS Database

• N = 31,747; 11% AVSp, 89% CVG
  – High Risk (~20K)
    >75, endocarditis, AStenosis, Dialysis, Multi-valve, Reop, or Emergency
  – Low Risk (~11K)

– Overall Mortality 8.4%
  – AVSp 4.5%; 1.4% LR, 10.5% HR
  – CVG 8.9%; 3.1% LR, 11.7% HR

– AS with CVG 5.1%
– Emergency with CVG 22.5%

Volume to Outcome Relationship in North America

• 2004 – 2007, STS Database, 741 Centers
• N = 13,358; all elective, total roots AND AVR+Ascending
• 25% of operations performed at 3% centers
  —Quartiles: <6, 6-13, 13-30, >30 cases
  —Endocarditis and reops common at high volume center
• Mortality 4.5%
  —Quartiles: 6%, 5%, 4%, 3%

Elective Aortic Replacement is Safe and Effective

Outcomes After Elective Proximal Aortic Replacement: A Matched Comparison of Isolated Versus Multicomponent Operations

Jay J. Idrees, MD, Eric E. Roselli, MD, Ashley M. Lowry, MS, Joshua M. Reside, BS, Hoda Javadikasgari, MD, Daniel J. Johnson, BS, Edward G. Soltesz, MD, Douglas R. Johnston, MD, Costa R. Pettersson, MD PhD, Eugene H. Blackstone, MD

Annals of thoracic surgery, 2016

<table>
<thead>
<tr>
<th></th>
<th>Operative Mortality</th>
<th>Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isolated</td>
<td>0.5%</td>
<td>4%</td>
</tr>
<tr>
<td>Multi-component</td>
<td>2%</td>
<td>2%</td>
</tr>
</tbody>
</table>
Four Root Procedures

- Mechanical CVG
- Biologic CVG
- Homograft
- Valve-Preserving Root

Long-term survival, valve durability, and reoperation for 4 aortic root procedures combined with ascending aorta replacement

Lars G. Svensson, MD, PhD, a,b Saila T. Pillai, MD, MPH, a Jeevanantham Rajeswaran, PhD, c Milind Y. Desai, MD, b,d Brian Griffin, MD, b,d Richard Grimm, DO, b,d Donald F. Hammer, MD, b,d Maran Thamilarasan, MD, b,d Eric E. Roselli, MD, a,b Gösta B. Pettersson, MD, PhD, a,b A. Marc Gillinov, MD, a,b Jose L. Gonzalez-Ulla, MD, a,b,c,d, Joseph F. Sabik III, MD, a,b Bruce W. Lytle, MD, a,b and Eug

1995 - 2011
N = 957

- Mechanical CVG
  N = 156
- Biologic CVG
  N = 297
- Homograft
  N = 243
- Valve-Preserving Root
  N = 261

- Mortality
  0.73%
- Stroke
  1.4%
Reoperations Post Root Replacement

- Allograft
- Composite biologic
- Composite mechanical

Valve preservation

Years after Surgery

Reoperation (%)
Saving the Living Valve

![Bar chart showing the number of living valves saved from 2012 to 2016. The number of living valves increased from 40 in 2012 to 87 in 2016.]

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Risks and Benefits Must be Tailored to the Patient

- Aortic Details
- Non-aortic Comorbidities
- Surgical Results
Outcomes of a Less-Invasive Approach for Proximal Aortic Operations

Melissa M. Levack, MD, Muhammad Aftab, MD, Eric E. Roselli, MD, Douglas R. Johnston, MD, Edward G. Soltesz, MD, MPH, A. Marc Gillinov, MD, Gösta B. Pettersson, MD, PhD, Brian Griffin, MD, Richard Grimm, DO, Donald F. Hammer, MD, Adil H. Al Kindi, MD, MS, Turki B. Albacker, MD, MS, Y Thuita, MS, Eugene H. Blackstone, MD, Lars G. Svensson, MD, PhD

Levack M, et al. JTCVS, ’16.
Unmet Need in Aortic Dissection

4% Type A Op; 4.5% Type B

Inoperable Patients (2005-2015)

- 53 of 686 (7.7%)
- Mean 78y/o; 62% > 80y/o
- 53% female
- 81% from other hospitals
- 63% DeBakey Type I
Reasons for Inoperability

Prohibitive: 34%

Very High-Risk: 66%

Imaging Analysis
N=24

Diameters (mm)
- Innominate: 39
- Mid-Ascending: 42
- STJ: 35
- Sinus: 38
- Annulus: 28

STJ-Innominate Distance (mm)
- Lesser Curve: 62
- Greater Curve: 96
Can We Stentgraft Them?

- STJ to entry tear distance: 21mm
- Entry tear coverable in 19 (79%)
  - 18 between STJ and innominate
  - 1 distal to left subclavian
- Other 5
  - 1 each in aortic root and arch
  - 3 not identifiable

High Risk Ascending TEVAR

2006-2014
N = 22
Thru 2017
N = 42

- Acute Type A Dissection  
  9  14

- IMH with PAU  
  2  3

- Pseudoaneurysm  
  9  23
  4 with contained rupture

- Complicated Chronic Dissx  
  2  2

Roselli EE, et al. JTCVS, ‘15.

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Challenges to Proximal TEVAR

• Aorta/Patient Related
  — Anatomy, Morphology, Physiology, Pathology

• Procedure Related
  — Stentgraft Device
  — Delivery System
Pt Related: Anatomy / Morphology

- Diameter
  - Usually dilated:
    - mean 3.5 cm
    - commonly 4.5 cm
    - esp. dissx

- Length of a curve

- Entry tears difficult to characterize

<table>
<thead>
<tr>
<th>Greater</th>
<th>Center</th>
<th>Lesser</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.6</td>
<td>7.8</td>
<td>6.4</td>
</tr>
</tbody>
</table>
Ascending Aorta is \textit{Curved}
## Outcomes Based on Modified Zone Zero

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Disease</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operative Mortality</strong></td>
<td>Root 0A 2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Proximal Asc 0B 3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Distal Asc 0C 0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Late Death</strong></td>
<td>Root 0A 2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Proximal Asc 0B 8</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Distal Asc 0C 1</td>
<td>1</td>
</tr>
</tbody>
</table>
Modified Landing Zone Classification System

Zone 0

C: RtPA to Innom
B: cors to RtPA
A: annulus to cors
Mechanisms of Aortic Dissection

• Altered cell-matrix mechanosensing

• Protease imbalance
  – Structural vulnerability

• Proteoglycan accumulation understudied
Important Device Characteristics
Procedure Related: Device

• Stentgraft
  — Highly conformable, Elastic
  — Strong fixation in hostile environment
    — Radial force
    — Active fixation
      — Internal or external?
  — Flush edge vs root component
  — Curved shape
  — ? Branch / branches for distal and proximal seal
• Proximal Seal Zone Length
Branch Challenge: Endoleaks, Patency?

In-Situ Fenestration and Durability?

Procedure Related: Delivery & Deploy

• Delivery Technique
  – Transfemoral vs alternate access
  – Disease dependent
  – Pre-curved – self orienting
  – Crossing the valve
  – Branch Access

• Deployment System
  – Exceedingly precise, controlled
  – Staged deployment
  – Repositionable
  – Flexible / steerable for coaxiality
Embolic Risk
Transfemoral Deployment
Coronary Occlusion
Balloon Repositioning
ON THE ENDOVASCULAR CLIMB TO THE TYPE A DISSECTION SUMMIT, REACHING A NEW BASE CAMP

Michael D. Dake, MD

With type A dissection, Li et al. (13) have succeeded in moving the discussion beyond the novelty level of “look, it can be done” to the next developmental stage, poised on the threshold of a prospective clinical trial. This is a valuable contribution. I wonder, however, if the current TEVAR technology is ready to withstand the rigors it will face when we enter the

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Endo CVG Issues

1) Proximal Fixation AND SEAL
2) Coronary Patency
52 y/o s/p esophagectomy and colon interposition, new Type A
84 y/o, s/p TF TAVR 6 mos prior, recovered well, new Type A with asc and desc tears
Endo Composite Valve Graft
Patent Issued

- US Issued patent 2007 (US 7,771,467 B2) Apparatus for repairing the function of a native aortic valve
- Prosthetic valve with ascending
- Coronary artery openings
- Method of deployment coverage
Invention: Greenberg Valve + COOL Stent

✓ US, PCT and Non-PCT (Australia, Canada) patents issued (7,799,072 and 8,979,924)

✓ US Issued patent (US 8,968,386) Stent and method for maintaining the area of a body lumen
Mild PVL is routine

Moderate or worse PVL is common

- Balloon expandable 6-14%
- Self expanding 9-21%
PVL Associated with Mortality

New Valves to Reduce PVL

Paravalvular Leak at 1 Year
Core Lab Assessment – Intent-to-Treat

Improving, but ≥ Mild ~12%

Superiority achieved for secondary endpoint

Presented at Euro PCR 2017
Fixation May Be Disease Dependent
Coronaries Can be Treated with Covered Stents
Coronaries Can be Treated with Covered Stents
# Covered Coronary Stents For Perfs

## TABLE I. Graftmaster Rx Coronary Stent Graft System
(Abbott Vascular)

<table>
<thead>
<tr>
<th>Stent graft diameter (mm)</th>
<th>Stent graft length (mm)</th>
<th>Minimum deployment (nominal) and rated burst pressure</th>
<th>Guide catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.8</td>
<td>16, 19, 26</td>
<td>15/16 ATM</td>
<td>6 Fr</td>
</tr>
<tr>
<td>3.5</td>
<td>16, 19, 26</td>
<td>15/16 ATM</td>
<td>6 Fr</td>
</tr>
<tr>
<td>4.0</td>
<td>16, 19, 26</td>
<td>15/16 ATM</td>
<td>6 Fr</td>
</tr>
<tr>
<td>4.5</td>
<td>16, 19, 26</td>
<td>15/16 ATM</td>
<td>7 Fr</td>
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**Indication:** for use in the treatment of free perforations, defined as free contrast extravasation into the pericardium, in native coronary vessels or saphenous vein bypass grafts ≥2.75 mm in diameter. Requires IRB approval for use.

**Stent material:** Stainless steel 316 L.

**Graft material:** expandable polytetrafluoroethylene (ePFTE) sandwiched between two identical stents.
What about Cost?

- Endografts: $10-45K
- TAVR: $25K +
- Surgical Grafts: $200 - $2000

(Plus other direct hospital costs...)