A 15-year Experience with Zenith Endografts for Standard Infrarenal EVAR: The Grafts are Durable

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Endovascular Aortic Aneurysm Repair
• Short-term advantages of EVAR over open surgical repair
  - Improved perioperative and 30-day mortality
  - Shorter operations and hospital stays
• Trials have called into question the long-term stability and benefits of EVAR
  - OVER Trial
  - DREAM Trial
  - UK EVAR 1 Trial
  - ACE Trial

Stent-Graft Evolution
• Most early generation stent-grafts now obsolete
  - Modified or replaced to eliminate failure modes
• Continual evolution of device design: paucity of device-specific data on long-term performance

Zenith Stent-Graft
• Shares many of the same basic features of original device:
  - Supra-renal stents
  - Caudally-oriented barbs
  - Densely woven fabric
  - Tight attachment between stents and fabric
  - Long trunk

Study Purpose/Study Cohort
• Examine 15-year single center experience of EVAR using Zenith stent-graft
• 325 high-risk patients underwent elective EVAR between 10/1998-12/2005
  - Hostile abdomen
  - >75 years of age
  - Poor renal function
  - FEV1 <1 liter
  - Home oxygen therapy
  - Ejection fraction < 25%
  - Myocardial infarction within last 6 months
• Physician-sponsored IDE approved by IRB and FDA
Inclusion Criteria

1. Proximal neck
   A. > 15 mm in length
   B. < 28 mm in diameter
   C. Infrarenal neck/AAA angulation < 80 degrees
2. Iliac diameter > 7mm (after balloon angioplasty if necessary)
3. Dispensable IMA
4. Iliac artery angulation < 90 degrees or < 60 degrees if severe calcification
5. Iliac implantation site > 2 cm in length
6. Not pregnant
7. No anaphylaxis to contrast material
8. No allergy to stainless steel or polyester
9. Willingness and ability to comply with follow-up schedule
10. No serious systemic or groin infection
11. No coagulopathy

Follow-up Protocol

• CTA, multi-view abdominal x-rays, and clinical examination at 1, 6, and 12 months, and yearly thereafter

2007: If CTA at 1 month did not demonstrate type I or type III EL, non-contrast CT scans subsequently performed

Study Design

• Data collected prospectively until 2006
• Subsequent follow-up data collected retrospectively
   - Hospital records
   - Death certificates
   - National Death Registry

Study Endpoints

• Mortality (all-cause and aneurysm related)
• Late-occurring stent-graft failure (>30 days after index procedure):
   - Type I/type III endoleak
   - Enlarging aneurysm sac requiring revision
   - Link kink/occlusion
   - Stent-graft infection
   - Renal artery occlusion
   - Aneurysm rupture

Study Cohort

<table>
<thead>
<tr>
<th>Variable</th>
<th>N=325 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at operation (years)</td>
<td>Mean ± SD 75.9 ± 7.4</td>
</tr>
<tr>
<td>Sex</td>
<td>Male 300 (92%)</td>
</tr>
<tr>
<td>Follow-up (years)</td>
<td>Mean ± SD 5.9 ± 4.0</td>
</tr>
<tr>
<td>Medical comorbidities</td>
<td>Diabetes mellitus 51 (16%)</td>
</tr>
<tr>
<td></td>
<td>Current or past smoker 258 (80%)</td>
</tr>
<tr>
<td></td>
<td>Cardiac disease 273 (85%)</td>
</tr>
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<td></td>
<td>COPD 102 (31%)</td>
</tr>
<tr>
<td></td>
<td>Preoperative creatinine ≥ 2 mg/dL 21 (7%)</td>
</tr>
<tr>
<td>Aneurysm size (mm)</td>
<td>Mean ± SD 80 ± 9</td>
</tr>
<tr>
<td>Stent-graft diameter (mm)</td>
<td>Median 26</td>
</tr>
<tr>
<td></td>
<td>Range 22-52</td>
</tr>
</tbody>
</table>

Causes of Stent-Graft Failure After 30 Days

<table>
<thead>
<tr>
<th>Stent-Graft Failure</th>
<th>N=19</th>
<th>Time Since Operation (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type III endoleak</td>
<td>5</td>
<td>0.1, 1.5, 2.4, 8.6, 14.6</td>
</tr>
<tr>
<td>Type I endoleak</td>
<td>3</td>
<td>3.5, 7.9, 11.5</td>
</tr>
<tr>
<td>Enlarging aneurysm sac</td>
<td>3</td>
<td>4.1, 5.3, 7.2</td>
</tr>
<tr>
<td>Aneurysm rupture</td>
<td>3</td>
<td>0.6, 6.1, 6.6</td>
</tr>
<tr>
<td>Limb occlusion</td>
<td>2</td>
<td>0.1, 0.8</td>
</tr>
<tr>
<td>Limb kink without occlusion</td>
<td>1</td>
<td>4.0</td>
</tr>
<tr>
<td>Infected stent-graft</td>
<td>1</td>
<td>1.5</td>
</tr>
<tr>
<td>Renal artery occlusion</td>
<td>1</td>
<td>0.6</td>
</tr>
</tbody>
</table>
KM Estimates
- 5 years: 96%
- 10 years: 91%
- 15 years: 77%

KM Estimates
- 5 years: 60%
- 10 years: 29%
- 15 years: 12%

Limitations
- Single center study
- Retrospective data collection after 2006
- Change in follow-up imaging protocol after 2007
- Cause of death unknown in 46% patients

Conclusions
- Late-occurring failures and aneurysm-related death are rare after EVAR using Zenith stent-graft
  - High-risk patients with diminished life expectancy
- Steady trickle of ongoing life-threatening failure modes warrants lifelong follow-up