Endoanchors in practice-clinical applications and techniques for success

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Disclosures

Consultant/Advisor

- Bolton Medical
- Cordis
- Bard
- Medtronic
- Aptus
- Lombard Medical
- iVascular
- MSD
- Bayer
- Astra Zeneca

Proctor

- Bolton Medical
- Cook
- Medtronic
- W.L. Gore
- Aptus
- Cordis
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- Clinical insights and results
- Case Examples & technical tips
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EVAR evidence: Reinterventions

EVAR reintervention rates worsen over time...

- **EVAR 1**
  - **Open repair** vs. **Endovascular repair**

- **DREAM**
  - **Probability of Freedom from Reintervention**

- **OVER**
  - **Cumulative Probability of Death or Secondary Procedure**


Which Proximal Necks are Hostile?

Predictor neck anatomic factors for EVAR failure

- Evaluated N=221 patients from ANCHOR post-market registry
- Failure defined as:
  - Type Ia endoleak upon endograft implantation
  - Type Ia endoleak identified in post-op follow-up*

*In endografts without EndoAnchors

Identified proximal neck variables that independently predict type Ia endoleak:

<table>
<thead>
<tr>
<th>Variable</th>
<th>Requirement</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck diameter</td>
<td>≥ 26 mm</td>
<td>.002</td>
</tr>
<tr>
<td>Neck length</td>
<td>≤ 17 mm</td>
<td>.017</td>
</tr>
</tbody>
</table>

Certain ‘on-label’ necks can be at-risk

# Neck Dilation: A Cause for 2nd Intervention

Neck dilation in EVAR remains REAL

<table>
<thead>
<tr>
<th>Author</th>
<th>Follow-Up</th>
<th>Grafts studied</th>
<th>Proximal Neck Dilatation Rate</th>
<th>Outcomes in dilated necks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oberhuber et al.¹</td>
<td>39 mos average</td>
<td>Zenith (N=29), Talent (N=35), Excluder (N=39)</td>
<td>22% (defined as &gt;2mm diam increase)</td>
<td>31% re-interventions</td>
</tr>
<tr>
<td>Pintoux et al.²</td>
<td>57 mos average</td>
<td>Talent (N=33), AneuRx (N=25)</td>
<td>24% (defined as &gt;3mm diam increase)</td>
<td>5% late type Ia endoleak 16% migration</td>
</tr>
<tr>
<td>Bastos Gonçalves et al.³</td>
<td>5 yrs median</td>
<td>Excluder (N=144)</td>
<td>37% overall, 66% in pts &gt;7 yrs f/u (defined as &gt;2mm diam increase)</td>
<td>Increased odds of migration (≥5mm) 5.5x</td>
</tr>
</tbody>
</table>

## Solutions for HOSTILE necks

### CURRENT OPTIONS:
- Open Surgical Repair (OSR)
- FEVAR
- Off-the-shelf branch
- ChEVAR (parallel graft)
- Aneurysm filling

### LIMITATIONS:

<table>
<thead>
<tr>
<th>OSR</th>
<th>FEVAR</th>
<th>BRANCH</th>
<th>ChEVAR</th>
<th>Aneurysm Filling</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patients not eligible due to significant co-morbidities&lt;br&gt;• Long recovery&lt;br&gt;• ICU</td>
<td>• Expensive&lt;br&gt;• Complex&lt;br&gt;• Custom-made - not available for rAAA&lt;br&gt;• Limited in angled anatomies&lt;br&gt;• Steep learning curve&lt;br&gt;• Long term reinterventions</td>
<td>• Experimental&lt;br&gt;• Steep learning curve&lt;br&gt;• Patient applicability not as high as originally perceived&lt;br&gt;• Lack of robust clinical evidence</td>
<td>• Lack of robust clinical evidence to prove safety and efficacy&lt;br&gt;• Technique not standardized</td>
<td>• Current technology lacks robust clinical evidence to prove safety and efficacy&lt;br&gt;• Changes to blood-flow dynamics</td>
</tr>
</tbody>
</table>
Solutions for HOSTILE necks

Complementary Technologies with existing stent graft technology

APTUS Endo Anchoring System (Heli-FX)
An off-the-shelf Solution
Tailored Seal and Fixation of EndoAnchors

CREATE THE STABILITY OF A SURGICAL ANASTOMOSIS IN EVAR AND TEVAR

Surgical Anastomosis

EndoAnchoring

Displacement force in Newtons


Case images courtesy of John Aruny MD, Bart Edward Muhs, MD, PhD.
Fixation tested to 500mm/Hg without failure
Heli-FX System: Applier + Guide + 10 EndoAnchors

Cross Bar

3 mm

1.0 mm

3.5 mm
Clinical Indications

### Prophylaxis

**Hostile Anatomy**
- Overcoming concerns for implant stability
  - Challenging neck anatomies (e.g. wide, short, conical, angulated)
  - Difficult landing (e.g. birdbeaking, close to branched vessels)

**Normal Anatomy**
- Mitigating risk of reinterventions
  - Severe comorbidities that preclude safe reintervention
  - Patients potentially lost during F/U
  - Long remaining life expectancy (young pts)

### Treatment

**Resolve proximal seal failures**
- Targeted sealing of acute type I endoleaks
- Targeted sealing of late type I endoleaks
- Augmented stability in migrated grafts

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Aptus Heli-FX Product Offerings

- **Aptus™ Heli-FX™ Thoracic EndoAnchor™ System**
  - 18Fr OD, 90cm working length

- **Aptus™ Heli-FX™ Abdominal EndoAnchor™ System**
  - 16Fr OD, 62cm working length
The Aptus EndoAnchor and Heli-FX have been evaluated and determined to be compatible with the following endografts:
Note: C-arm positions above show just one possible combination
C-Arm Positioning for 6 EndoAnchors

Note: C-arm positions above show just one possible combination
Move C-Arm in 15-20 degree increments

- Identify leak channel and then create a “suture line” along wall.
- Circumferential anchoring before/after T1 EL treatment is recommended: address concerns of long-term neck morphology changes
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## ANCHOR registry capturing real-world usage

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<tr>
<th>Registry Principal Investigators</th>
<th>Europe: Dr Jean-Paul de Vries - Chief of Vascular Surgery, St. Antonius Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>US: Dr William Jordan - Chief of Vascular Surgery/Endovascular Therapy, Emory University School of Medicine</td>
</tr>
<tr>
<td>Registry Design</td>
<td>Prospective, observational, international, multi-center, dual-arm Registry</td>
</tr>
<tr>
<td>Treatment Arms</td>
<td>“Primary” - Up to 1000 pts, Prophylactic</td>
</tr>
<tr>
<td></td>
<td>“Revision” - Up to 1000 pts, Therapeutic</td>
</tr>
<tr>
<td>Enrollment &amp; Duration</td>
<td>Enrollment began 2012 and patients will be followed for 5 years</td>
</tr>
<tr>
<td>Follow-up</td>
<td>Per Standard of Care at each center &amp; discretion of Investigator</td>
</tr>
</tbody>
</table>

**Over 600 Patients enrolled as of November 2015**
### PROXIMAL ENDOLEAKS AND MIGRATION

**MEAN FOLLOW-UP 8.2 MONTHS**

<table>
<thead>
<tr>
<th>Type Ia Endoleaks</th>
<th>All Primary Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a ELs</td>
<td>CTs</td>
</tr>
<tr>
<td>3</td>
<td>177</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Endograft Migration (&gt;10mm)</th>
<th>All Primary Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migration</td>
<td>CTs</td>
</tr>
<tr>
<td>0</td>
<td>112</td>
</tr>
</tbody>
</table>

*Migration was assessed in comparison to the 1-month CT scan*
### Persistent/Recurrent type Ia endoleaks

**CORE LAB**

**MEAN CT FOLLOW-UP 10.4 MONTHS**

<table>
<thead>
<tr>
<th>Cohort</th>
<th>1a ELs</th>
<th>CTs</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>24</td>
<td>142</td>
<td>16.9%</td>
</tr>
<tr>
<td>Primary</td>
<td>3</td>
<td>76</td>
<td>3.9%</td>
</tr>
<tr>
<td>Revision</td>
<td>21</td>
<td>66</td>
<td>31.8%</td>
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Primary EVAR - Wide Neck

Post balloon
Type 1
Primary EVAR - Short, Conical Neck
Primary EVAR - Intra-Op Type Ia endoleak
Revision EVAR - Late Type Ia endoleak

Late type I endoleak
Cuff and EndoAnchors implanted
Endoleak resolved
Primary FEVAR
Revision EVAR - endograft migration

Late endograft migration with Type Ia endoleak

Cuff and EndoAnchors implanted

Endoleak resolved
59 yo GI Surgeon
61 yo Endocrinologist
63 yo man
Primary TAA with Short/Angled Proximal Neck

- 63y/o Female
- Short proximal neck/seal zone
- LSA transposition performed prior to primary TEVAR

Case images courtesy of Thomas Naslund, MD - Vanderbilt University Medical Center
Primary TAA with Short/Angled Proximal Neck

Final angio:
• No endoleak
• Enhanced fixation in short seal zone

Case images courtesy of Thomas Naslund, MD - Vanderbilt University Medical Center
Reinforcing distal fixation:
Cranial migration and Type Ib endoleak

Distal neck =3cm, 63 yo lady
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- Hostile necks compromise early and long term outcomes for EVAR
- EndoAnchors are designed to bring long-term stability of surgical anastomosis to EVAR/TEVAR
- ANCHOR registry demonstrates
  - >90% success rate, no migration and <2% type 1a EL when Endoanchors are prophylactically applied in hostile necks (especially in young patients)
  - Endoanchors as a therapeutical tool, shows a >80% of success rate, but about 17% of type I ELs remain permanent
  - NO endoanchors-related adverse events have been reported in my knowledge.
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