What does the data tell us about outcomes of EVAR in challenging anatomy?

UCSF Vascular Surgery Symposium 2018

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DISCLOSURES

- Cook Medical: Consultant, Proctor for TX2, Zenith, Alpha, Zenith Fenestrated

- Gore & Associates: Consultant
Challenging Anatomy

“I say, if it feels right, do it.”
EVAR Devices and IFU

Typical Anatomical Requirements

- Neck Length, ≤ 15 mm*
- Neck Diameter, 18 - 32 mm
- Angulation, ≤ 60°
- Landing zone, 10 - 23^
- Access, 5.5 - 7 mm

* one was ≤ 10 mm
^ one was as small as 8 mm
Anatomic Eligibility

Results from device with the largest range in anatomical parameters

- Men, at most 65%
- Women, at most 35%

Percentage eligible

Sac Diameter ranges (mm)

[40-45], [45-50], [50-55], [55-60], [60-65], [65-70], [70-75], [75+]
Reasons for Ineligibility

| Characterization of Human Aortic Anatomy Project, 2013 |

**Median Neck Length < 15mm**

Men & Women = 40%
A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy

George A. Antoniou, MD, PhD, a George S. Georgiadis, MD, b Stavros A. Antoniou, MD, c Ganesh Kuhar, MD, FRCS, a and David Murray, MD, FRCS, a Manchester, United Kingdom; Alexandroupolis, Greece; and Marburg, Germany

- **Pooled data of 1559 patients**
  - 714 hostile neck
  - 845 friendly neck
- **Hostile neck anatomy:**
  - 4 x increased type Ia endoleaks
  - 9 x increased 1 year mortality
Outcome-based anatomic criteria for defining the hostile aortic neck

William D. Jordan Jr, MD, a Kenneth Ouriel, MD, b Manish Mehta, MD, MPH, c David Varnagy, MD, d William M. Moore Jr, MD, e Frank R. Arko, MD, f James Joyce, DO, g and Jean-Paul P. M. de Vries, MD, h

Birmingham, Ala; New York and Albany, NY; Orlando, Fla; West Columbia, SC; Charlotte, NC; Mountain View, Calif; and Nieuwegein, The Netherlands

- N=221 from ANCHOR registry
- Independent Risk Factors for Type Ia Endoleaks:
  - Neck diameter > 26mm
  - Neck length < 17mm
    - 3%/1mm incremental risk of Type Ia
  - Conical neck configuration
• 10,228 patients on M2S database
• 59%, 30% outside Restrictive, Liberal IFUs
• Overall trend towards shorter, angulated necks treated with EVAR
• Higher sac enlargement with outside IFUs
Next Generation Devices with Expanded IFU

<table>
<thead>
<tr>
<th></th>
<th>Gore Excluder</th>
<th>Endologix AFX</th>
<th>Cook Flexa</th>
<th>Medtronic Endurant II</th>
<th>Cook Fenestrated</th>
<th>Trivascular Ovationb</th>
<th>Lombard Aorfix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck diameter, mm</td>
<td>19-29</td>
<td>18-32</td>
<td>19-32</td>
<td>19-31</td>
<td>16-30</td>
<td>19-29</td>
<td></td>
</tr>
<tr>
<td>Neck length, mm</td>
<td>≥ 15</td>
<td>≥ 15</td>
<td>≥ 15</td>
<td>≥ 4</td>
<td>≥ 10</td>
<td>&gt; 7</td>
<td>≥ 15</td>
</tr>
<tr>
<td>Infrarenal neck angulation, deg</td>
<td>≤ 60</td>
<td>≤ 60</td>
<td>≤ 60</td>
<td>≤ 45&lt;sup&gt;c&lt;/sup&gt;</td>
<td>≤ 60</td>
<td>≤ 45&lt;sup&gt;c&lt;/sup&gt;</td>
<td>≤ 90</td>
</tr>
<tr>
<td>Iliac diameter, mm</td>
<td>10-18.5</td>
<td>8-23</td>
<td>8-20</td>
<td>8-25</td>
<td>7-21</td>
<td>8-20</td>
<td>9-19</td>
</tr>
<tr>
<td>Smallest delivery system OD&lt;sup&gt;d&lt;/sup&gt; Profile, Fr</td>
<td>20.5</td>
<td>19</td>
<td>21</td>
<td>18</td>
<td>23</td>
<td>14</td>
<td>22</td>
</tr>
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</table>

Shorter, more angulated necks
Smaller delivery system
Early Results from the ENGAGE Registry: Real-world Performance of the Endurant Stent Graft for Endovascular AAA Repair in 1262 Patients

R.A. Stokmans a,b, J.A.W. Teijink a,b,* , T.L. Forbes c, D. Böckler d, P.J. Peeters e, V. Riambau f, P.D. Hayes g, M.R.H.M. van Sambeek a

• Multicenter registry of Endurant
• N=1263

• Type I/III Endoleak: 1.5%
• Average Neck=27mm
• 27 (2.2%) patients had neck ≤10mm
  • 7x Type Ia endoleak
One-year outcomes from an international study of the Ovation Abdominal Stent Graft System for endovascular aneurysm repair

Manish Mehta, MD, MPH, Francisco E. Valdés, MD, Thomas Nolte, MD, Gregory J. Mishkel, MD, William D. Jordan, MD, Bruce Gray, DO, Mark K. Eskandari, MD, and Charles Botti, MD, on behalf of “A Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the Ovation Abdominal Stent Graft System”

- Prospective multicenter trial of Ovation Stent Graft
  - N=161
  - Type I Endoleak: 0
  - Type II Endoleak: 34%
  - Average Neck=23mm
  - 15% Patients had Neck ≤ 10mm
Results of the ANCHOR prospective, multicenter registry of EndoAnchors for type Ia endoleaks and endograft migration in patients with challenging anatomy

William D. Jordan Jr, MD, a Manish Mehta, MD, MPH, b David Varnagy, MD, c William M. Moore Jr, MD, d Frank R. Arko, MD, e James Joyce, DO f Kenneth Ouriel, MD g and Jean-Paul de Vries, MD h Birmingham, Ala; Albany and New York, NY; Orlando, Fla; Lexington, SC; Charlotte, NC; Mountain View, Calif; and Nieuwegein, The Netherlands

- **Approved for 4mm neck IFU**
- **Prospective multicenter registry**
- **319 patients with “hostile neck”**
  - 242 primary arm + 77 revision
- **87% procedural success**
- **9.1% residual type Ia endoleak @ 9months F/U**
ANCHOR Registry

• Average neck length = 16mm
  • 16% (51 patients) had neck < 5mm

• Enrollment Criteria:
  “To exclude selection bias, investigators were asked to enroll patients before the acquisition of first postop imaging”

“Patients in the primary arm were treated for prophylaxis of endoleak migration when in the opinion of the investigator, the anatomy of the patient put the patient at risk for future proximal neck complications"
What basis does short-neck IFU have?

- Gore Excluder
- MDT Endurant
- TriVascular Ovation
- Zenith Flex

![Graph showing Trial Ave Neck Length and Indicated Min Neck Length for different IFU devices.](chart.png)
Zenith Fenestrated

IFU CLAIM

- Trivascular
- Talent
- Endurant
- Flex
- ZFEN

Neck Length = Seal Zone

Neck Length ≠ Seal Zone
Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms

Gustavo S. Oderich, MD,a Roy K. Greenberg, MD,a,b,c Mark Farber, MD,c Sean Lyden, MD,d Luis Sanchez, MD,a Ron Fairman, MD,e Feiyi Jia, PhD,f and Priya Bharadwaj, PhD,f on behalf of the Zenith Fenestrated Study Investigators, Rochester, Minn; Cleveland, Ohio; Chapel Hill, NC; St. Louis, Mo; Philadelphia, Pa; and West Lafayette, Ind

• Prospective trial
• N=67 patients with 178 visceral, renals targetted
• Mean neck length= 7.5mm (4~12mm)
• Mean F/U: 37 months
U.S. ZFEN trial

• 100% technical success
• 1.5% 30-day mortality
• Endoleaks:
  • Type I: 1.5% (1 patient at 3 years)
  • Type II: 29% at discharge
    20% at 1 year
    19% at 2 years
ZFEN branch patency

<table>
<thead>
<tr>
<th>Alignment stents</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zenith alignment stent (Cook Medical Inc, Bloomington, Ind)</td>
<td>58</td>
<td>43</td>
</tr>
<tr>
<td>Express LD stent (Boston Scientific, Bloomington, Minn)</td>
<td>29</td>
<td>21</td>
</tr>
<tr>
<td>eV3 Intratherapeutics stent (Cordis, W)</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>iCAST Covered stent (Atrium M)</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Palmaz Genesis stent (Cordis, W)</td>
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<td>1.5</td>
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<td>Bridge Assurant stent (Medtronic)</td>
<td>0.7</td>
<td>0.7</td>
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<tr>
<td>Total number of alignment stents</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

![Graph showing patency rates over years for primary and secondary procedures.](image)
Type 1a endoleak after ZFEN case example
Summary

• Challenging anatomy for EVAR, mainly driven by hostile neck

• Neck generation devices aimed at hostile neck seal are available, but pivotal trials have not provided adequate data

• Results of ZFEN for short neck AAA are favorable. Careful patient selection may be more important in ZFEN