Infrarenal Seal is \textit{NOT} Best Achieved by 10% Oversizing of the Reverse Tapered Neck with a Device that Delivers Chronic Outward Radial Force

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Disclosures

- Endologix Corp: Consultant
- Nellix IDE study, site-investigator

Debating Dr. Chuter...

Varying Thoughts on What Constitutes a Reverse Taper
**Hostile Neck Anatomy**

Known to affect the ability to seal between the device and the aorta

- Neck diameter >28 mm
- Neck angulation >60°
- Neck length <15mm or <10mm
- Circumferential neck thrombus ≥2mm thickness
- Calcific proximal neck ≥50%
- Reverse Taper

Reverse taper neck is the most common hostile-neck feature (Dillavou, 2003)

**Reverse Taper are Common**

Reverse Taper necks are common with the following frequencies:

- AbuRahma (2011): 22%
- Schanzer (2011): 32%
- Welborn (2014): 28%
- Montagnabhalli (2014): 27%
- Dillavou (2003): 28%
- Mwypatayi (2013): 29%

**M2S Analysis**

Within 10mm from lowest renal

N=16,357 patients

38% ≈ 1/3 of patient have reverse taper

MM change in Proximal Neck Diameter from Lowest Renal

**Does it make sense to oversize a graft with high radial force?**

Oversizing AFX and Zenith in a tube
Which EVAR Challenges have You Witnessed in Reverse Taper Anatomies?

- Commonly reported complications associated with reverse taper:
  - Device Infolding
  - Early Type 1a endoleak (P<.0001) 1
  - Need for adjunctive proximal components 1 (P = .0146)
  - Malposition from inadequate fixation
  - Increased risk for AAA sac enlargement 2

2 A. Schanzer et al, Circulation 2011; 123: 2848-2855

High radial force devices cause neck expansion

Long-term follow-up of neck expansion after endovascular aortic aneurysm repair

Thomas S. Monahan, MD, Timothy A. M. Clouter, MD, Linda M. Reilly, MD, Joseph H. Rupp, MD, and Jade S. Hiramoto, MD, San Francisco, Calif

Objectives: This study determined the rate, extent, and clinical significance of neck dilatation after endovascular aneurysm repair (EVAR).

Methods: The study included 46 patients who underwent elective EVAR using biotissue endografts (Cook, Bloomington, Ind) and had at least 48 months of clinical and radiographic follow-up. Computed tomography images were analyzed on a 6-dimensional workstation (Vitrea, Oakville, Ont, Canada). Neck diameter was measured 10 mm below the most inferior renal artery in planes orthogonal to the aorta. Nominal endograft size was determined from implantation records.

Results: Median follow-up was 59 months (range, 48-126 months), Neck dilatation occurred in all 46 patients. The rate of neck dilatation was greatest at early follow-up (months). At 60 months, median neck dilatation was 6.0 mm (range, 2.9-9.8 mm). The extent of neck dilatation at 60 months correlated with percentages of nearest graft overgrowth (ipsilateral < P = .001). There were no evidences of endoleaks or evidence of type II endoleak.

Reintervention Rates Increase Over Time; Greater Prevalence in Hostile Anatomy

Favorable Neck
353 pts mean F/U: 49 m
Hostile Neck
199 pts mean F/U: 49m

Long-Term Effectiveness of EVAR
Remains a Challenge

- Long-term prevalence of sac growth:
  - 3% @ 1 year
  - 17% @ 3 years
  - 41% @ 5 years

- Effect of off-IFU implants:
  - Close to 40% of patients

<table>
<thead>
<tr>
<th>Covariates</th>
<th>Prevalence, %</th>
<th>HR</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt;80 y.o.</td>
<td>20.0 - 26.3</td>
<td>1.32</td>
<td>0.05</td>
</tr>
<tr>
<td>Neck diameter 28-32mm</td>
<td>4.7 - 7.3</td>
<td>1.80</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Neck diameter &gt;32mm</td>
<td>1.4 - 2.3</td>
<td>2.07</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Neck angle &gt;60 deg</td>
<td>6.2 - 9.5</td>
<td>1.96</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>One aneurysmal CIA</td>
<td>7.8 - 9.5</td>
<td>1.46</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Any endoleak</td>
<td>32</td>
<td>2.70</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

A Schenzer et al, Circulation 2011; 23: 2848

Are we dealing with old technology?

Does Low Radial-Force make a difference?

Anatomical fixation distributes migration forces onto the bifurcation, significantly reducing the need for hooks, barbs or anchors

AFX with ActiveSeal: Stent-Graft Design For Proximal and Distal Seal

Coil elements allows for oversizing without excessive radial force
High density ePTFE material external to stent
Material apposes aortic wall beyond stent, driven by pressure gradient between aorta and excluded sac
AFX® – Largest on-IFU Oversizing Range
(Proximal Neck Treatment)

Large US Cohort: 1-y Follow-up (n=108)

Endoleak (Core Lab Analysis)

Why AFX in Reverse Taper?
ActiveSeal™ Principles

- Radial force – initial sac exclusion
- Aorta-sac pressure difference promotes fabric-to-wall apposition (dynamic seal)
- Fabric-to-wall apposition beyond stent frame
Summary of Findings:

- Aortic apposition within the neck averaged 19 ± 13 cm² in surface area
- Material was circumferentially apposed beyond the anatomic neck in 54%
- In those with extension beyond neck, the length below the neck averaged 14 mm

Extended Seal Zone as a Predictor of Early Sac Regression

<table>
<thead>
<tr>
<th>Variable</th>
<th>Median</th>
<th>Effect on Sac Regression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>76 years</td>
<td>Younger: No Effect</td>
</tr>
<tr>
<td>Gender</td>
<td>70%</td>
<td>Male: No Effect</td>
</tr>
<tr>
<td>AAA Diameter</td>
<td>47 mm</td>
<td>Smaller: No Effect</td>
</tr>
<tr>
<td>Suprarenal Neck Angulation</td>
<td>9 degrees</td>
<td>Less: No Effect</td>
</tr>
<tr>
<td>Infrarenal Neck Angulation</td>
<td>16 degrees</td>
<td>Less: No Effect</td>
</tr>
<tr>
<td>Proximal Neck Diameter</td>
<td>22 mm</td>
<td>Smaller: No Effect</td>
</tr>
<tr>
<td>Anatomic Aortic Neck Length</td>
<td>18 mm</td>
<td>Longer Length → Increased Regression (P=0.019)</td>
</tr>
<tr>
<td>Conical Neck</td>
<td>27%</td>
<td>Conical: No Effect</td>
</tr>
<tr>
<td>Apposition Length</td>
<td>24 mm</td>
<td>Longer: No Effect</td>
</tr>
<tr>
<td>Apposition Surface Area</td>
<td>18 cm²</td>
<td>Greater ASA → Increased Regression (P=0.039)</td>
</tr>
</tbody>
</table>

Ovation System Protects the Aortic Neck

Self expanding stent graft systems exert continual radial force which can lead to neck dilation, device migration, endoleaks and aneurysm rupture

- Ovation iX O-ring is designed to seal by blocking flow of blood between aortic wall and graft
- Biocompatible polymer delivered to inflate O-ring
- O-ring creates a water-tight seal that provides uniform non-expansive continuous wall apposition
- O-ring designed to conform to irregular luminal surface in aortic neck
- O-ring insulates aortic neck from blood pressure

Does Polymer technology provide a solution?
Ovation System Protects the Aortic Neck

Ovation Global Pivotal study demonstrates encouraging results with stable neck diameter and durable seal through 4 years due to the unique sealing ring technology which creates no chronic outward force and insulates the neck from blood pressure.

*Based on all known peer-reviewed published clinical data with clearly outlined methodology to measure neck dilation in patients with self-expanding AAA stent grafts; measurement methodology in cited studies is comparable to measurement methodology in Ovation Pivotal Trial1,4.

Polymer Sealing may be advantageous in challenging neck anatomy

Conventional wire and fabric grafts may not be able to fully conform to an irregular luminal surface.

Polymer is injected in a low viscosity liquid state, allowing sealing rings to mold and conform to irregular luminal surfaces, creating a customized seal.

EVAS: the ultimate solution?

Nellix® EndoVascular Aneurysm Sealing System

- Next generation technology
- Designed to seal the entire aneurysm using a contained biostable polymer
**Case Study: Conical Neck**

69 y.o. male w/ 5.5 cm AAA

Complete seal of AAA sac and absence of lumbar arteries upon completion angiogram

Above case is presented for educational purposes only, and the results may not be typical.

**EVAS FORWARD Global Registry: Design and Status**

- **Principal Investigators**
  - Matt Thompson, MD, London, UK
  - Andrew Holden, MBChB, Auckland, NZ

- **Total Patients** (n=300*)
  - Cohort 1 (n=192)
  - Cohort 2 (n=39)
  - Cohort 3 (n=37)
  - Cohort 4 (n=25)

- **Enrollment completed** September, 2014 (enrollment period 10 months)
- **Mean follow-up** 308 days; range 0 to 17 months

**Total Patients** (n=300*)

- 6 (2%) CTs still in review
- 1 patient enrolled but not implanted

**Principal Investigators**

- Andrew Holden, MBChB, Auckland, NZ
- Matt Thompson, MD, London, UK

300 patients, 30 centers with five year follow-up

- Real-world experience: no prospective screening of patients
- CT scan core lab analysis (Cleveland Clinic Core Lab)
- Independent adverse events adjudication
- Primary outcomes typical of EVAR therapy

**EVAS Forward Global Registry Includes more Complex AAAs**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>ENGAGE Registry (n=1262)</th>
<th>GREAT Registry (n=400)</th>
<th>EVAS Global Registry (n=300)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chimney</td>
<td>9%</td>
<td>6%</td>
<td>0%</td>
</tr>
<tr>
<td>Iliac diameters &gt;25mm</td>
<td>14%</td>
<td>14%</td>
<td>17%</td>
</tr>
</tbody>
</table>

**Persisting Endoleaks at 12 Months**

<table>
<thead>
<tr>
<th>Type</th>
<th>EVAS Registry</th>
<th>Zenith IDE</th>
<th>Endurant IDE</th>
<th>Aorfix IDE</th>
<th>Excluder IDE</th>
<th>Incraft CE Study</th>
<th>Ovation IDE</th>
</tr>
</thead>
<tbody>
<tr>
<td>IA</td>
<td>0.7%</td>
<td>6.9%</td>
<td>9.7%</td>
<td>16.5%</td>
<td>17.0%</td>
<td>38.0%</td>
<td>38.2%</td>
</tr>
<tr>
<td>IB</td>
<td>17.0%</td>
<td>17.0%</td>
<td>17.0%</td>
<td>17.0%</td>
<td>17.0%</td>
<td>38.0%</td>
<td>38.2%</td>
</tr>
<tr>
<td>II</td>
<td>25%</td>
<td>25%</td>
<td>25%</td>
<td>25%</td>
<td>25%</td>
<td>38%</td>
<td>38%</td>
</tr>
<tr>
<td>III/IV</td>
<td>0.1%</td>
<td>0.6%</td>
<td>1.5%</td>
<td>0%</td>
<td>0.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indeterminate</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* (2%) CTs still in review
1 patient enrolled but not implanted
Major Adverse Events

<table>
<thead>
<tr>
<th>MAEs</th>
<th>&lt;30 days</th>
<th>&gt;30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Cause Death</td>
<td>3 (1.1%)</td>
<td>7 (2.7%)</td>
</tr>
<tr>
<td>Peri-operative mortality</td>
<td>3 (1.1%)</td>
<td>-</td>
</tr>
<tr>
<td>Aneurysm related mortality</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>0</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>2 (0.7%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Bowel Ischemia</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>3 (1.1%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>1 (0.4%)</td>
<td>0</td>
</tr>
<tr>
<td>Blood loss &gt;1000 mL</td>
<td>2 (0.7%)</td>
<td>-</td>
</tr>
<tr>
<td>Patients with one or more MAE</td>
<td>9 (3.4%)</td>
<td>9 (3.4%)</td>
</tr>
</tbody>
</table>

Peri-operative mortality: 30 days
- Hospital-acquired pneumonia
- Aspiration pneumonia
- Gastrointestinal hemorrhage

Freedom from Secondary Intervention

Summary

- Reverse taper neck anatomy is the most cause of hostile neck anatomy
- High radial force devices must be sized to seal in the largest diameter of the anatomic neck to allow seal and prevent endoleak
- Chronic outward force is known to cause aortic neck dilatation
- The use of high radial forces devices in reverse neck anatomy are associate with endoleak, need for secondary intervention and sac enlargement

Conclusions

- Infrarenal Seal is NOT Best Achieved by 10% Oversizing of the Reverse Tapered Neck with a Device that Delivers Chronic Outward Radial Force
- Alternatives include:
  - Anatomic fixation with use of low radial force cuffs
  - Polymer based O-ring sealing with zero radial force
  - EVAS with all polymer-based fixation and seal
So Professor Chuter...