Degeneration of the Neck
Post Implementation
- a New Era of AAA Stent -

Steve Henao MD
New Mexico Heart Institute
Albuquerque, New Mexico USA
Current FDA-Approved EVAR Devices – Sealing Mechanism

Gore  Endologix  Lombard  Medtronic  Cook  TriVascular
Current FDA-Approved EVAR Devices – Sealing Mechanism

Self-Expanding

- Gore
- Endologix
- Lombard
- Medtronic
- Cook
- TriVascular
Current FDA-Approved EVAR Devices – Sealing Mechanism

Self-Expanding
- Gore
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Polymer Ring
- TriVascular
O-Ring Sealing Technology

O-Ring Sealing in Proven Engineering Solutions

O-rings are designed to seal by blocking the flow of fluid between two closely spaced surfaces

- O-rings create a water-tight seal once two surfaces establish intimate contact
- O-rings are designed to be flexible to accommodate variation in the two surfaces

O-Ring Sealing in Aorta

Ovation Prime 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

*water has a lower viscosity than blood and does not clot

Steve Henao MD
O-Ring Sealing Technology Creates Continuous Wall Apposition

Wire and fabric grafts create *discontinuous* points of apposition in irregular and/or tapered anatomy

Ovation Prime sealing ring creates uniform *continuous* wall apposition, even in irregular and/or tapered anatomy

Note: FEA simulations illustrate the spectrum of wall apposition from low (blue) to high (red)
O-Ring Sealing Technology Creates a Custom Seal

Self Expanding Stent Graft In Diseased Aorta

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

Ovation Prime Sealing Ring In Diseased Aorta

Polymer is injected in a low viscosity liquid state, allowing sealing ring to mold and conform to irregular luminal surfaces, creating a customized seal
O-Ring Seals Without Exerting Chronic Outward Radial Force

**Self Expanding Stent Graft**

- Seal created by chronic outward force with discontinuous points of wall apposition across a minimum 10-15 mm length

**Ovation Prime Stent Graft**

- Water-tight seal created by O-ring provides uniform continuous wall apposition

- Non-expansive circumferential apposition from sealing ring creates no chronic outward radial force and no aortic neck dilatation*

*Neck dilatation in proximal neck defined as growth > 2mm at renals, 10mm below renals, and 15 mm below renals; Core Lab Data, N=131

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O-Ring Insulates Aortic Neck From Additional Outward Force of Blood Pressure

**Untreated Aneurysm**
Blood pressure results in a bulge in aortic wall where tissue is weak

**Self Expanding Stent Graft**
Oversized wire and fabric graft allows transmission of blood pressure, and exerts pressure of its own

**Ovation Prime Stent Graft**
Polymer-filled O-ring insulates aortic neck from blood pressure

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**Blood Pressure ➔ Aneurysm**

**Blood Pressure**
- + Stent Outward Radial Force ➔ Contributes to Neck Dilatation

**Minimal Blood Pressure**
- + NO Stent Outward Radial Force ➔ No Neck Dilatation
Durability of Seal in EVAR

Self Expanding Stent Graft

- Several studies show evidence of aortic neck dilatation with self-expanding EVAR stent grafts

- Aortic neck dilatation can compromise seal and may lead to Type 1 endoleak and/or migration

Ovation Prime Stent Graft

- Ovation™ Global Pivotal Study
  - No aortic neck dilatation at 1 and 2 years
  - No Type 1 endoleaks and no migration at 1 and 2 years

2- Mehta et al. J Vasc Surg 2013; 1-9 and Core Lab data on file
Aortic neck dilatation after endovascular abdominal aortic aneurysm repair: A word of caution

Nicolas Diehm, MD, Florian Dick, MD, Barry T. Katzen, MD, Juerg Schmidli, MD, Christoph Kalka, MD, and Iris Baumgartner, MD, Miami, Fla; and Bern, Switzerland

Studies Reporting Aortic Neck Dilatation in Self Expanding Stents

- Literature review summarizes current evidence on infrarenal aortic neck dilatation

- **Conclusion**: “Current evidence on AND [aortic neck dilatation] raises serious concerns about long-term durability of stent graft fixation in the proximal aortic neck”

- **Clinical Consequence**: “Continuing expansion of aortic necks poses a substantial threat to the mid-and long-term durability of EVAR because proximal fixation is jeopardized once the diameter of the neck exceeds that of the endograft.”

Table II. Summary of studies reporting neck dilatation in patients undergoing endovascular abdominal aortic aneurysm repair

<table>
<thead>
<tr>
<th>First author</th>
<th>N</th>
<th>Neck measurement specifications</th>
<th>Definition of AND</th>
<th>Follow-up</th>
<th>Graft type</th>
<th>Quantification of AND</th>
<th>Clinical impact of AND</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sampaoi &amp; associates</td>
<td>144</td>
<td>CT&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Relative diameter increase, 10%-15%</td>
<td>Median 257 days (AneuRx)&lt;sup&gt;2&lt;/sup&gt;, 629 days (AneuRx)&lt;sup&gt;2&lt;/sup&gt;</td>
<td>100% SXS</td>
<td>10% increase at 2 years in 36.1% (AneuRx) and in 23.5% (Anshuc); 15% increase at 2 years in 12.4% (AneuRx) and in 9.1% (Anshuc)</td>
<td>Patients with graft migration had higher mean percentages of AND at 1.5 years (p=0.013).</td>
</tr>
<tr>
<td>Weyer</td>
<td>33</td>
<td>CT&lt;sup&gt;15&lt;/sup&gt;</td>
<td>Absolute change, % surface area</td>
<td>Median 12 months</td>
<td>100% SXS</td>
<td>10.3% surface area increase at 6 months; 15.5% surface area increase at 1 year</td>
<td>No correlation with early or late endoleak.</td>
</tr>
<tr>
<td>Napoli &amp; associates</td>
<td>90</td>
<td>CT and DUS&lt;sup&gt;3&lt;/sup&gt;</td>
<td>2.5 mm diameter increase</td>
<td>Mean 15 months</td>
<td>1.1% BEA; 98.9% SXS</td>
<td>Cumulative incidence: 21.8%; 13% at 1 year; 58% at 2 years</td>
<td>35.3% of patients with AND had distal migration.</td>
</tr>
<tr>
<td>Badger</td>
<td>161</td>
<td>CT&lt;sup&gt;15&lt;/sup&gt;</td>
<td>Absolute change, mm</td>
<td>Up to 2 years</td>
<td>100% SXS</td>
<td>For EVAR: 0.99 ± 1.1 mm/y at 2 years for asymptomatic; 2.64 ± 3.8 mm/y at 2 years for those treated for rupture</td>
<td>Graft migrations were associated with AND in asymptomatic patients as well as in patients with ruptured AAA.</td>
</tr>
<tr>
<td>Diehm &amp; associates</td>
<td>6383</td>
<td>CT&lt;sup&gt;15&lt;/sup&gt;</td>
<td>Relative change, ≥15% diameter increase</td>
<td>Mean 21 months</td>
<td>3% BEA; 97% SXS</td>
<td>24.9% of patients at 2 years; 45.1% of patients at 4 years</td>
<td>n/a</td>
</tr>
<tr>
<td>Qin</td>
<td>230</td>
<td>CT&lt;sup&gt;11&lt;/sup&gt;</td>
<td>4 mm diameter increase</td>
<td>Median 24 months</td>
<td>100% SXS</td>
<td>26% of patients at 2 years; 50% of patients at 4 years</td>
<td>Late repeat intervention associated with AND (p&lt;0.0001).</td>
</tr>
<tr>
<td>Sonesson &amp; associates</td>
<td>34</td>
<td>CT&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Absolute change, % diameter, mm</td>
<td>Mean 25 months</td>
<td>100% SXS</td>
<td>1.66-mm increase at 25 months</td>
<td>n/a</td>
</tr>
<tr>
<td>Badran</td>
<td>78</td>
<td>CT&lt;sup&gt;5&lt;/sup&gt;</td>
<td>Relative change, % diameter, mm</td>
<td>Mean 26 months</td>
<td>4% BEA; 96% SXS</td>
<td>8.6% increase at 2 years, 10.8% increase at 4 years</td>
<td>n/a</td>
</tr>
<tr>
<td>Matsumura &amp; associates</td>
<td>59</td>
<td>CT&lt;sup&gt;15&lt;/sup&gt;</td>
<td>Absolute change, mm</td>
<td>Mean 27 months</td>
<td>100% SXS</td>
<td>0.7 ± 2.11 mm/y</td>
<td>n/a</td>
</tr>
<tr>
<td>Makaroun &amp; associates</td>
<td>314</td>
<td>CT&lt;sup&gt;15&lt;/sup&gt;</td>
<td>2.5-mm diameter increase</td>
<td>Up to 3 years</td>
<td>100% SXS</td>
<td>1.3% after 1 year, 21% after 2, 19% after 3</td>
<td>Migration in 1 patient associated with AND.</td>
</tr>
<tr>
<td>Prinsen &amp; associates</td>
<td>37</td>
<td>CT&lt;sup&gt;15&lt;/sup&gt;</td>
<td>Relative change, % surface area</td>
<td>Up to 3 years</td>
<td>100% SXS</td>
<td>20% surface area increase at 2 years; 56% surface area increase at 5 years in 20% AND of patients after 2 years</td>
<td>AND significantly influenced incidence of late type I endoleaks (p=0.001).</td>
</tr>
<tr>
<td>Dillavou</td>
<td>729</td>
<td>CT&lt;sup&gt;15&lt;/sup&gt;</td>
<td>3-mm diameter increase</td>
<td>Up to 5 years</td>
<td>4.3% BEA; 95.7% SXS</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

AAA, Abdominal aortic aneurysm; AND, aortic neck dilatation; EVAR, endovascular aneurysm repair; NS, not specified; BEA, balloon expandable stent graft; SXS, self expandable stent graft; CT, computed tomography; DEX, duplex ultrasound.
CONCLUSION: “Aortic neck dilatation following endovascular AAA repair appears to be correlated with self-expanding endografts, which may contribute to a higher incidence of graft migration compared to that occurring with balloon-expandable endografts.” N=242 patients

Type 1 Endoleak and Migration in Patients with Aortic Neck Dilatation

Predictive factors and clinical consequences of proximal aortic neck dilatation in 230 patients undergoing abdominal aorta aneurysm repair with self-expandable stent-grafts

Piergiorgio Cao, MD, Fabio Verzini, MD, Gianbattista Pariani, MD, Paola De Rango, MD, Basso Parente, MD, Giuseppe Giordano, MD, Stefano Mosca, MD, and Agostino Maselli, MD

1. Aortic neck dilatation, defined as diameter growth >3mm, occurred in 28% of patients at a median follow-up of 24 months
   - Type 1 endoleak occurred in 9% of patients with neck dilatation and 1% of patients with no neck dilatation
   - Migration >10mm occurred in 27% with neck dilatation

2. Late repeat intervention was more frequently necessary in patients with aortic neck dilatation

Aortic Neck Dilatation Risk Factor for Type 1 Endoleak and Migration

Is Neck Dilatation After Endovascular Aneurysm Repair Graft Dependent?

Results of 4 US Phase II Trials

Ellen D. Dillavou, MD, Satish Muluk, MD, FACS, and Michel S. Makaroun, MD, FACS, Pittsburgh, PA

Conclusions

The incidence of neck dilatation ≥ 3 mm approaches 20% regardless of the endograft used. For most endografts, neck dilation was a significant risk factor for endograft migration and late proximal endoleak but did not influence AAA sac behavior. Small necks at the time of EVAR appear to be at higher risk for subsequent dilation than those over 25 mm.

- 729 Patients with follow up of at least 24 months
- Type 1 endoleak occurred in 4.1% of patients with aortic neck dilatation. Rates similar among graft types
- Aortic neck dilatation associated with migration in Ancure and Gore Excluder
Patients treated with the Ovation™ system had no neck dilatation and no late Type I endoleaks at 2 years.⁴

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⁴ Neck dilatation in proximal neck defined as growth > 2mm at renals, 10mm below renals, and 15 mm below renals; N=131
Case Studies From Ovation Global Pivotal Study Demonstrate Stable Aortic Neck Diameters

**Straightforward**
No aortic neck growth at 4 years

**Reverse Tapered Neck**
No aortic neck growth at 2 years

**Heavy Calcification**
No aortic neck growth at 2 years

Steve Henao MD
Long-Term Data on O-Ring Sealing Technology

Professor John P. Fletcher
University of Sydney, Department of Surgery, Westmead Hospital, Sydney, Australia

- 12 patients followed for mean of 8 years and 2 months
- No AAA related deaths
- 3 deaths (25%) 54 to 93 months after EVAR from cancer, cardiac and respiratory failure
- No late Type I Endoleaks

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Conclusion

- Ovation O-Ring Sealing Technology
  - Provides a water tight seal in aorta
  - Creates uniform continuous wall apposition, even in irregular and/or tapered anatomy
  - Molds and conforms to aorta, offering a customized seal
  - Non-expansive circumferential wall apposition of sealing ring creates no chronic outward radial force and no aortic neck dilatation

- Ovation Global Pivotal study demonstrates encouraging results with stable neck diameter and durable seal in 2 year follow up

- With over 2,500 patients treated worldwide, Ovation and Ovation Prime Systems represent next generation EVAR technology – today
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