Protect the Neck

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Disclosure

Speaker name: MAENE LIEVEN

I have the following potential conflicts of interest to report:

- Consulting – Trivascular Medical Educator
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest
Protect the neck...
Protect the neck...
Protect the neck...
Protect the neck...

Pre & intra-operative

Post-operative

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... Pre and Intra-operative

- Identification of the correct juxta-renal sealing zone
- Appropriate graft-size selection
- Correct deployment of the graft.
Sealing mechanisms

A. SE Stent graft:
   - Expanding diameter
   - Spot apposition
   - Long segment

B. BE Stent graft
   - Fixed diameter
   - Spot contact ~ Balloon
Sealing mechanisms

C. Polymer filled O-ring and PTFE body

- Full wall apposition
- Moulding
1. Juxtarenal **Sealing zone** identification

a. In relation to the sealing mechanism

b. Risk-factor evaluation: thrombus, calcium,...

c. Preoperative image processing

→ to predict how the graft will take position in the aorta
1. Juxtarenal Sealing zone identification

A. Traditional case planning
1. Juxtarenal Sealing zone identification

B. Graft orientation planning

Axial

Centerline

Sealing Ring @ IR+13

Sealing Ring @ IR+13

Sealing Ring @ IR+13

32.7mm avg = Eval.
26.9mm min = AB 34

25.7 mm avg
AB 29

22.2 mm avg.
AB 26

38.5 mm
22.4 mm
20.7 mm
26.9 mm
22.4 mm
23.7 mm

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1. Juxtarenal Sealing zone identification

B. Graft orientation planning

Short sealing => Selective lower placement
1. Juxtarenal Sealing zone identification

C. Risk factor calculation

- Thrombus
- Calcifications
- Hourglass neck
- Conical neck
- Renal stents
- ...

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1. Juxtarenal Sealing zone identification

D. Intraoperative marking of Sealing zone
1. Juxtarenal Sealing zone identification

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... Postoperative protection

Sealing without

- Endoleak
- Future aortic neck dilatation
2. Juxtarenal sealing zone stability

A seal can be achieved in a very short sealing zone.

A change in the neck can compromise the sealing, resulting in late type 1a endoleak and/or migration.

Neck dilatation:
- Stent Graft induced?
- Natural evolution?
- …
Forces at work in the aorta: SE Stentgraft

Stent graft is implanted with 10-15% over sizing. Stent graft exerts outward radial force which is resisted by the blood vessel.

Stent graft dilates diseased vessel wall over time. As stent graft reaches its original size the outward radial force declines.

Note: radial force = 0 at stent graft free size
Long-term follow-up of neck expansion after endovascular aortic aneurysm repair

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

Fig 2. Rate (mm/month) of proximal neck dilation after endovascular aneurysm repair (mean ± standard deviation) is shown.

Conclusions: After EVAR with the Zenith stent graft, the neck dilates until its diameter approximates the diameter of the stent graft. Neck dilation was not associated with type I endoleak or migration of the stent graft. (J Vasc Surg 2010;52:303-7.)
Evolution of the upper and lower landing site after endovascular aortic aneurysm repair

Adrien Kaladjii, MD, a,b,c Alain Cardon, MD, a Bruno Laviolle, PhD, d,e,f Jean-François Heautot, MD, g Guillaume Pinel, MD, a and Antoine Lucas, MD, a,b,c Rennes, France

Fig 3. Evolution of diameters of the proximal aortic neck.

Fig 6. Evolution of distal landing site diameters.
What we observe ...BE stent grafts

**Conclusion:** The study showed that the diameter reached at initial deployment did not increase further in the long term, which supports the safety and reliability of this modular balloon-expandable stent-graft and illustrates that this device does not produce dilatation of the proximal neck after deployment. Future dilatation of the aortic neck is unlikely, and consequently, migration or delayed type I endoleak are also unlikely.

*J Endovasc Ther. 2009;16:696–707*
What we observe ... BE stentgrafts & SE stentgrafts

Figure 1. Dilatation in aortic neck diameter at the level of renal arteries (A) and 10 mm distal (B) at follow-up with a self-expanding stent graft, which was treated with a giant balloon-expandable stent to achieve sealing. The inner balloon-expandable stent stays at the same diameter while the self-expanding stent graft has enlarged the aortic neck seal zone.
Sealing by non-expansive polymer-filled rings

- No graft induced chronic outward force at the infrarenal aorta
- Change in outward blood pressure to the aortic wall?
- Stabilising the infrarenal wall stress?
Aortic neck evolution after endovascular repair with TriVascular Ovation stent graft

Gianmarco de Donato, MD, Francesco Setacci, MD, Luciano Bresadola, MD, Patrizio Castelli, MD, Roberto Chiesa, MD, Nicola Mangialardi, MD, Giovanni Nano, MD, and Carlo Setacci, MD, Siena, Rome, Varese, and Milan, Italy

Conclusions: No aortic neck dilation occurred in this series at CT scan after a minimum 24-month follow-up. This may suggest that aortic neck evolution is not associated with EVAR at midterm follow-up when an endograft with no chronic outward radial force is implanted. (J Vasc Surg 2015; 1-10.)
Volumetric Case analysis

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Case

Neck: straight – 8 mm

- Trivascular Ovation Stent graft (23)
- Bilateral extensions
Case 5 years follow-up

- Fixed diameter of the proximal sealing zone
- Complete exclusion of the aneurysm with dramatic decrease of AAA diameter
Can we protect the neck ...

Aortic Neck Dilatation Over Time*

*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 Trial\(^3,4\).

1 Monahan JVS 2010: 52: 303-7 N=46. Devices: Cook Zenith
3 Core Lab Data. Ovation Global Pivotal Trial
4 Neck dilation in proximal neck defined as growth > 3mm at 10mm below renals, 13mm below renals, and 15mm below renals

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Ovation Global Pivotal Trial  
3 Year Results

A pivotal clinical study to evaluate the safety and effectiveness of the TriVascular Ovation Abdominal Stent Graft System. 138 patients were available for evaluation at 3 years.

### Technical Success

<table>
<thead>
<tr>
<th></th>
<th>All (N=161)</th>
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<tbody>
<tr>
<td>Defined as successful, delivery and deployment of one aortic body and two iliac limbs</td>
<td>100%</td>
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</table>

### Safety

<table>
<thead>
<tr>
<th></th>
<th>Treatment to 30 Days</th>
<th>31 to 365 Days</th>
<th>366 to 730 Days</th>
<th>731 to 1095 Days</th>
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</thead>
<tbody>
<tr>
<td>Freedom From Major Adverse Events</td>
<td>97.5%</td>
<td>96.2%</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Freedom From Device Related Major Adverse Events</td>
<td>100%</td>
<td>100%</td>
<td>--</td>
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</tr>
<tr>
<td>Freedom from Rupture</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
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### Effectiveness

<table>
<thead>
<tr>
<th></th>
<th>30 Day</th>
<th>1 Year</th>
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<tr>
<td>Freedom from Type I and III Endoleaks</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Freedom from Migration</td>
<td>Baseline</td>
<td>100%</td>
</tr>
</tbody>
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Data as of July 25, 2014

1. Technical Success based on investigator reports
2. Major Adverse Events and Device Related Major Adverse Events based on Clinical Events Committee (CEC) adjudicated data based on investigator reports
3. Endoleaks and Migration rates based on Core Lab Data (M2S)
4. Type II endoleaks reported in all cases of AAA Enlargement. Analysis windows are: 1 year (305 to 547 days) and 2 years (548 to 911 days).

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Can we protect the neck ... 

✓ YES

✓ Preoperative image processing, graft-selection and intraoperative accurate visualisation are mandatory
INDICATIONS FOR USE: The TriVascular Ovation platform (including Ovation, Ovation Prime and/or Ovation iX Abdominal Stent Graft Systems) is indicated for treatment of patients with abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair, including: adequate iliac/femoral access compatible with vascular access techniques (femoral cutdown or percutaneous), devices, and/or accessories; proximal aortic landing zone: with an inner wall diameter of no less than 16 mm and no greater than 30 mm at 13 mm below the inferior renal artery, and with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm; distal iliac landing zone: with a length of at least 10 mm, and with an inner wall diameter of no less than 8 mm and no greater than 25 mm (no greater than 20 mm for Ovation/Ovation Prime).

CONTRAINDICATIONS: The systems are contraindicated for use in patients who have a condition that threatens to infect the graft and in patients with known sensitivities or allergies to the device materials (including polytetrafluoroethylene [PTFE], polyethylene glycol [PEG]-based polymers, fluorinated ethylene propylene [FEP] or nitinol). Also consider the information in Section 4 Warnings and Precautions of the systems’ Instructions for Use.

Refer to Instructions for Use at TriVascular.com for more information concerning Indications, Contraindications, Warnings and Precautions, and Adverse Events.

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NOTE: Not all product components are available in every country. Please consult with your TriVascular representative to confirm product availability.

CE marked. Please refer to current product Instructions for Use.