MIDTERM RESULTS OF PROXIMAL SEALING WITH OVATION STENTGRAFT ACCORDING TO THE INSTRUCTION FOR USE vs OFF-LABEL CONDITION

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Background

Traditional self-exp stent graft require an infrarenal non-aneurysmal segment (aortic neck) to adequately seal the aneurysm sac from chronic circulatory pressures.
Sealing is obtained by oversizing the stent (from 10 to 30%) prospecting that the chronic radial force exerted longitudinally against the aortic wall will circumferentially prevent any leakage.
Background

The Ovation stent graft (TriVascular, Santa Rosa – CA)

- New concept of sealing by non-expansive circumferential apposition of polymer-filled ring to the aortic wall (at 13 mm)

- Collar designed to transmit longitudinal force between graft and suprarenal stent, not radial force
# Proximal neck_IFU

<table>
<thead>
<tr>
<th>Company</th>
<th>Device</th>
<th>Neck Angulation</th>
<th>Neck Length</th>
<th>Neck Diameter</th>
<th>Iliac Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endologix</td>
<td>AFX</td>
<td>&lt; 60°</td>
<td>15mm</td>
<td>32mm</td>
<td>23mm</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Endurant</td>
<td>&lt; 60°</td>
<td>10mm</td>
<td>32mm</td>
<td>25mm</td>
</tr>
<tr>
<td>Cook</td>
<td>Zenith LP</td>
<td>&lt; 60°</td>
<td>15mm</td>
<td>32mm</td>
<td>20mm</td>
</tr>
<tr>
<td>Gore</td>
<td>C3</td>
<td>&lt; 60°</td>
<td>15mm</td>
<td>29mm</td>
<td>18.5mm</td>
</tr>
<tr>
<td>Trivascular</td>
<td>Ovation</td>
<td>&lt; 60°</td>
<td>7mm</td>
<td>30mm</td>
<td>20mm</td>
</tr>
<tr>
<td>Endologix</td>
<td>Nellix*</td>
<td>&lt; 60°</td>
<td>10mm</td>
<td>34mm</td>
<td>35mm</td>
</tr>
<tr>
<td>JNJ</td>
<td>Incraft</td>
<td>&lt; 60°</td>
<td>15mm</td>
<td>31mm</td>
<td>22mm</td>
</tr>
<tr>
<td>Terumo</td>
<td>Anaconda</td>
<td>&lt; 60°</td>
<td>15mm</td>
<td>31mm</td>
<td>21mm</td>
</tr>
</tbody>
</table>

Update April 2014
TriVascular Ovation Italian Registry (TOIS)

The Ovation stent graft (TriVascular, Santa Rosa – CA)

**Purpose**
1. Neck evolution
2. Outcomes in Off-label setting
METHODS

- Retrospective, multicenter registry (Nov 2014)
- 13 Italian Centers of Vascular Surgery
- Only patients who had undergone implantation of a Trivascular Ovation at least 24 months previously (before Nov 2012)
- CT scans available at a minimum 2-year follow-up were collected and sent for blind reading to a centralized core laboratory.
Central database for the core lab review of morphological changes

- OsiriX MD (v.6.5.1 64-bit)

- All vessel measurements after center line lumen (CLL) reconstructions
  (manual segmentation)
RESULTS

161 patients
  mean age 74 ± 5
  92% male

Median 32 months (range 24-50)

CT @ ≥ 24 months ➔ 89 pts
FOLLOW-UP

- 17 pts died (no AAA-related death)
- 15 pts lost at follow-up
Trivascular Ovation Italian Registry (TOIS)

Freedom from type 1 endoleak

<table>
<thead>
<tr>
<th>Survival</th>
<th>Number of events</th>
<th>Number at risk</th>
<th>Standard Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1y</td>
<td>98.6%</td>
<td>3</td>
<td>141</td>
</tr>
<tr>
<td>2y</td>
<td>98%</td>
<td>0</td>
<td>129</td>
</tr>
<tr>
<td>3y</td>
<td>98%</td>
<td>0</td>
<td>50</td>
</tr>
<tr>
<td>4y</td>
<td>98%</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

Neck enlargement = 0%
Migration = 0%

JVS 2016; 2016;63:8-15
Reinterventions (total n=8)
- 3 type IA endoleak
  1 aortic cuff,
  1 balloon-expandable stent
  1 coil and glue embolization
- 4 iliac limb occlusion
  1 bypass,
  3 surgical thrombectomy
- 1 type II endoleak
  coil embolization
Trivascular Ovation Italian Registry (TOIS)

CT @ ≥ 24 moths ➔ 89 pts

Proximal aortic neck

- ≤ 7 mm: off-label group 32 pts
- > 7 mm: IFU group 57 pts
IFU vs Off-L @ 4 years

- Survival
  85.9% IFU vs. 87.7% Off-L, p=0.3

- Freedom from any device-related reintervention
  94.7% IFU vs. 93.3% Off-L, p=0.6

- Freedom from neck enlargement
  100% IFU vs. 100% Off-L, p=1

- Freedom from type I endoleak
  99.2% IFU vs. 98.5% Off-L, p=.8

- Freedom from migration
  100% IFU vs. 100% Off-L, p=1.

IFU vs Off-label ➔ Similar good results
Conical neck (no neck)
O-Ring Sealing Technology Creates Continuous Wall Apposition

**Self Expanding Stent Graft**

Suitable aortic neck is required (10-15 mm)

**Ovation Prime Stent Graft**

IFU up to April 2014: Neck length 7 mm

Since April 29, 2014 IFU: No Neck length required (Aorta at IR+13 mm must be within 16-30 mm)
O-Ring Sealing Technology Creates Continuous Wall Apposition

No neck, no problem
Conclusions

- Use of Ovation stent-graft in the absence of a suitable neck length of 7 mm was not associated with poor outcomes in the mid term period.

- This data shows that the use of Ovation system is not restricted by the conventional measurement of aortic neck length.
Collaborators

- Daniele Gasparini, Gianluca Piccoli (Udine);
- Patrizio Castelli, Gianpaolo Carrafiello, Nicola Rivolta (Varese);
- Roberto Chiesa, Andrea Kahlberg (Milano);
- Giovanni Nano, Silvia Stegher (Milano);
- Claudio Novali, Carlo Rivellini (Cuneo);
- Massimo Lenti, Giacomo Isernia (Perugia);
- Nicola Mangialardi, Sonia Ronkey (Roma);
- Rocco Giudice (Roma);
- Francesco Speziale, Pasqualino Sirignano, Luciano Bresadola (Roma);
- Giustino Marcucci, Federico Accrocca (Civitavecchia);
- Pietro Volpe (Reggio Calabria);
- Francesco Talarico, Gaetano La Barbera (Palermo).
Proximal neck
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