Endologix Ovation ALTO Procedure

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Early Experience with Ovation ALTO at Auckland Hospital

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Auckland, New Zealand

Disclosure

Speaker name:

Andrew Holden

I have the following potential conflicts of interest to report:

☑ Consulting – Clinical Investigator for Endologix
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Trivascular Ovation

- Polymer sealing technology used in the proximal neck seal and composite junction seal
- Shortest IFU neck length for any EVR device (7.5mm)
- 161 patient Core Laboratory adjudicated IDE trial showed 0% incidence of type 1A endoleak @ 30 days and 1 year
Trivascular Ovation Global Pivotal Clinical Study

5 year results

<table>
<thead>
<tr>
<th></th>
<th>0 to 30 days N=161</th>
<th>31 to 365 days N=159</th>
<th>366 to 730 days N=154</th>
<th>731 to 1095 days N=140</th>
<th>1096 to 1460 days N=124</th>
<th>1461 to 1825 days N=105</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAEs</td>
<td>2.5%</td>
<td>3.8%</td>
<td>--</td>
<td>--</td>
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</tr>
<tr>
<td>Device Related MAE</td>
<td>0%</td>
<td>0%</td>
<td>--</td>
<td>--</td>
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</tr>
<tr>
<td>Rupture</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>Conversion</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>30 Day</th>
<th>1 Year</th>
<th>2 Years</th>
<th>3 Years</th>
<th>4 Years</th>
<th>5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I/III Endoleak</td>
<td>0% (0/153)</td>
<td>0% (0/143)</td>
<td>0% (0/120)</td>
<td>0% (0/109)</td>
<td>0% (0/87)</td>
<td>0% (0/66)</td>
</tr>
<tr>
<td>Migration</td>
<td>Baseline</td>
<td>0% (0/150)</td>
<td>0% (0/133)</td>
<td>0% (0/117)</td>
<td>0% (0/96)</td>
<td>0% (0/78)</td>
</tr>
<tr>
<td>Occlusion/Stenosis</td>
<td>0% (0/159)</td>
<td>0% (0/151)</td>
<td>0.7% (1/135)</td>
<td>0% (0/120)</td>
<td>2% (2/98)</td>
<td>2.5% (2/79)</td>
</tr>
</tbody>
</table>
Why the Limited Impact of Trivascular Ovation?

• How can the device treat a neck length of 7.5mm when the middle of the sealing ring is 13mm below the top of the graft?
• Are ancillary procedures such as Palmaz stents frequently required?
• Is cannulating the contralateral gate difficult?
• What is the impact of the high T2EL rate?

Based on 2017 estimated number of EVAR procedures performed in top 20 countries. Market data on file at Endologix.
Fixation and Seal with Ovation iX

- Fixation and seal are completed separately with Ovation iX.
- Conventional EVAR devices require a length of parallel vessel ≥ 10-15mm for seal.
- Circumferential seal with Ovation occurs at the midpoint of the sealing ring, 13mm below the proximal edge of the graft.
- Assuming the device is deployed with the proximal edge at the level of the inferior renal (IR) artery, the seal is at IR + 13mm.
Next Generation Ovation platform will help physicians to broaden patient applicability

More intuitive design for increased confidence in Ovation

- Ovation ALTO FIM cases performed in Auckland August 2016

First Patients Treated With Endologix's Investigational Ovation Alto EVAR System for Complex AAAs

August 17, 2016—Endologix, Inc. announced that the first two patients have been treated with the investigational Ovation Alto abdominal stent graft system, which is designed for the endovascular aneurysm repair (EVAR) of abdominal aortic aneurysms (AAAs). The patients were treated by Andrew Holden, MD, and Andrew Hill, MD, of Auckland City Hospital in Auckland, New Zealand.

The Ovation Alto is not approved in any market; Ovation Alto is an investigational device in the United States, limited by federal (or United States) law to investigational use only.
Ovation ALTO

More intuitive design for increased confidence in Ovation

Elevated Sealing Ring
\~ 7 mm IR

Ultra-low profile for small access and tortuous anatomy

1

Webbing at bifurcation to facilitate cannulation

2

Offset aortic body legs for improved visualization

3

Contralateral leg extends \~ 5mm below ipsilateral leg (contralateral length maintained \@ 80mm)

4
Ovation ALTO

- Delivery system simplified with integrated crossover port for contralateral limb cannulation
Ovation ALTO – Delivery System

- 8 RO markers at graft edge, no RO marker on delivery system at graft flap
- 2 RO markers define balloon working length
- Highest balloon marker is positioned under proximal sealing ring

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Ovation ALTO Case Example

- 57mm AAA
- Approximately 10mm long neck below renal arteries

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Ovation ALTO Case Example

• Device introduced, orientated and positioned relative to the renal arteries
Ovation ALTO Case Example

- Mid crown of proximal stent deployed
Ovation ALTO Case Example

- Compliant balloon inflated
Ovation ALTO Case Example

• Final re-positioning if necessary
Ovation ALTO Case Example

- Angiographic catheter withdrawn and proximal crown of stent then deployed
Ovation ALTO Case Example

• Polymer rings then filled
Ovation ALTO Case Example

- Contralateral limb cannulated
Ovation ALTO Case Example

- Limb lengths planned, deployed and post-dilated

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Ovation ALTO Case #2

Guidewire Withdrawn

Polymer Fill

Re-ballooning
Ovation ALTO Case #2

- Contralateral limb unable to be cannulated
- The crossover port, 0.018” guidewire and snare used
Pre-recorded Live Case

- 60mm AAA in an 80 year old male
- Previous left nephrectomy

Device Planning Recommendation

Aortic Body

<table>
<thead>
<tr>
<th>Device Recommendation</th>
<th>29mm</th>
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</thead>
<tbody>
<tr>
<td>Lowest Renal Artery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Min</td>
</tr>
<tr>
<td>IR - Erlan</td>
<td>23.2</td>
</tr>
<tr>
<td>IR (for int. position)</td>
<td>24.8</td>
</tr>
<tr>
<td>IR + Tine</td>
<td>25.4</td>
</tr>
<tr>
<td>IR + Tine</td>
<td>23.5</td>
</tr>
<tr>
<td>IR - 80 mm (PLA Lumi)</td>
<td>21.4</td>
</tr>
<tr>
<td>IR - 80 mm (PLA Lumi)</td>
<td>25.4</td>
</tr>
</tbody>
</table>

Notes:
- Date of CT unknown
- Confirm all measurements intra-operatively
- No left renal artery found
- IR is below lowest right renal artery
- Anterior angle of 31.2° noted at IR-5
- Retract guidewire during polymer fill
- Do not place tension on the aortic body
- Confirm seal balloon if necessary
- Calcium in seal zone
- Patent lumbar artery noted in proximal seal zone at IR+10
- Patent IMA noted at IR+55
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Post-Procedural Update

- Uneventful recovery, discharge post-operative day 2
- CT @ 1 month
Next Generation Ovation platform will help physicians to broaden patient applicability

<table>
<thead>
<tr>
<th></th>
<th>Nellix®</th>
<th>Nellix® CHEVAS</th>
<th>AFX®2</th>
<th>Ovation ix™</th>
<th>Ovation Alto™</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TRADITIONAL AAA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>40%</td>
<td>55%</td>
<td>69%</td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td><strong>COMPLEX AAA</strong></td>
<td>50%</td>
<td>26%</td>
<td></td>
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</tbody>
</table>

“Traditional AAA” – Infra-renal AAA with a neck length ≥ 10mm
“Complex AAA” – Short/no neck/juxta-renal AAA

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EXPANDING PATIENT APPLICABILITY WITH POLYMER SEALING Ovation Alto STENT GRAFT

**ELEVATE IDE**
US FDA Pivotal Trial
75 patients / Up to 12 Centers
Enrollment to begin Q1 2017

**ELEVATE2**
EU Post Market Registry
300 patients / Up to 30 Centers
Enrollment to begin Q3 2017

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Conclusions

- Ovation ALTO represents a significant improvement on Ovation iX
- The shift of sealing ring to 7mm below the material edge provides confidence in treating short necked patients on IFU
- Procedural steps simplified and intuitive
- Provides broad patient applicability

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