Innovations In EVAR Technologies: What Does the Future Hold

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Disclosures

- On the speaker’s bureau for: Endologix, Lombard Medical, TriVascular, Edwards and Medtronic
- Training courses for: W.L. Gore, Endologix, TriVascular, Medtronic and Lombard Medical
First Gen. devices had suboptimal performance!

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<tbody>
<tr>
<td>Ancure Guidant</td>
<td>AneuRx Medtronic</td>
<td>Excluder Gore</td>
<td>Zenith Cook</td>
<td>Powerlink Endologix</td>
<td>Talent Medtronic</td>
<td>Endurant Medtronic</td>
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- **New Devices**
Newer generation devices offer active fixation: less risk of migration!

Suprarenal Fixation

Infrarenal Fixation
Newer devices are more conformable!
Expanding indications for short and angulated necks

- Designed to treat highly angulated aortic necks (0-90°)
- Highly flexible, conformable
- Kink resistant
Smaller profile devices lead to improved PEVAR results

Ovation Prime Pivotal Trial

<table>
<thead>
<tr>
<th>Access Type</th>
<th>Cut-Down (S-EVAR) N=92</th>
<th>Percutaneous (P-EVAR) N=69</th>
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<tbody>
<tr>
<td></td>
<td>Major Adverse Event @ 30 Days</td>
<td>3.3%</td>
</tr>
<tr>
<td></td>
<td>Treatment Success @ 1-year</td>
<td>98.9%</td>
</tr>
<tr>
<td></td>
<td>Anesthesia Time (mean)</td>
<td>191 minutes</td>
</tr>
<tr>
<td></td>
<td>Procedure Time (mean)</td>
<td>118 minutes</td>
</tr>
<tr>
<td></td>
<td>Hospitalization (median)</td>
<td>2 days</td>
</tr>
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</table>
Integrated cross-over lumen port facilitates contralateral gate access in challenging anatomies

Ovation iX
FEVAR (Fenestrated AAA grafts for juxtarenal AAA) offer alternatives to surgery for patients with co-morbid conditions.

Donas et al. J Endovasc Ther 2013:20;1-6
Cook IBD Results

- No peri-op deaths
- 95% technical success
- 5 intra-op IBD occlusions
- 2 later IBD occlusions
  - 2 EIA occlusions at 30d

Gore IBE

EndoAnchors are beneficial for treatment of type I and gutter endoleak and prevention/treatment of migration.
EVAS is beneficial for prevention of type II endoleak and treatment of challenging infrarenal neck and iliac aneurysms.

Investigational device, not approved for clinical use in the US.
Altura Endograft System: Key Features and Benefits

- Fully supported, flexible nitinol braided stent
- Ultra low porosity, woven polyester (Dacron) grafts
- 14 Fr introducer sheath
- Integrated contrast injection for precise targeting
- 6 piece inventory

Investigational device, not Approved for Clinical use in US
**Altura Key Features and Benefits**

- **Aortic endografts**
  - D-shaped
  - Independent positioning ≤ 10 mm
  - **Suprarenal anchoring**
  - Repositionable/Recapturable
  - **Diameter 24, 27&30**

- **Iliac endografts**
  - **No contralateral limb cannulation**
  - Precise deployment
  - **Diameter 13, 17&21**

- **No redocking necessary for atraumatic removal**

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*Investigational device, not approved for clinical use in the US. Altura Endograft System is approved in EU*
Altura: Accuracy of Deployment

Pre

Post

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Altura Endograft System is approved in EU
Altura FIH/ Feasibility

**Standard (N=47)**
- Neck length ≥ 15 mm
- Angle ≤ 60°
- Chile & Latvia
- May 2011-2014

**Complex (N=10)**
- Chile and Latvia
- May 2014-2015

*Altura is not available in the US. Altura is approved in the EU*
### Altura FIH Results

<table>
<thead>
<tr>
<th>Clinical Success</th>
<th>30 Days (N=55)</th>
<th>1 Year (N=41)</th>
</tr>
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<tbody>
<tr>
<td>Delivery Success</td>
<td>98% (54/55)</td>
<td>_</td>
</tr>
<tr>
<td>Freedom from Type I/III endoleak</td>
<td>98% (54/55)</td>
<td>95% (39/41)</td>
</tr>
<tr>
<td>Freedom from rupture</td>
<td>100 (55/55)</td>
<td>100% (41/41)</td>
</tr>
<tr>
<td>Freedom from migration (5 mm)</td>
<td>_</td>
<td>98% (40/41)</td>
</tr>
<tr>
<td>Freedom from conversion</td>
<td>100% (55/55)</td>
<td>100% (41/41)</td>
</tr>
<tr>
<td>Freedom from sac growth</td>
<td>_</td>
<td>100% (41/41)</td>
</tr>
<tr>
<td>Freedom from graft occlusion</td>
<td>98% (54/55)</td>
<td>98% (40/41)*</td>
</tr>
</tbody>
</table>

1 patient not treated with a device due to delivery system failure (Gen1)
2 patient-Type IA endoleak due to Ca++ neck; 1 patient Type IB due to iliac under-sizing
3 Circumferential thrombus in the neck
Standard & Complex (N=50)

- 8 sites in Chile and EU
- Clinical results resemble FIH
- **New delivery system**
- Procedure time reduced from 135 min (FIM) to 101 min (Elevate) ($p<0.001$)
- CE mark granted in July 2015

**Altura Global Experience**

**ELEVATE Registry**

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Future Studies

Altitude Registry

- International prospective study
- Anticipating 2016 Enrollment
- N=up to 1000 patients
- Capture real world experience

US IDE Study

- 2017 Enrollment
- US and International sites
- N=150
- Standard anatomy

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Altura Endograft System is approved in EU
Newer generation devices are easier to use, lower in profile, repositionable, more suitable for challenging anatomy and more durable.

FEVAR & CHIMPS offers advantages for patients at increased risk from open repair.

SEVAR is a promising new technology to treat short necks and prevent type II endoleak.
What does the future hold?

- Reduction in delivery system profile
- Integrated sheath delivery systems
- Simplified deployment
- *No contra lateral gate cannulation*
- New dedicated closure devices
- Broader application of PEVAR
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