Is ChEVAS the answer to complex AAA treatment?
The future of Nellix in 2020

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Disclosures

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- Bentley InnoMed GmbH
- Terumo Aortic
- Endologix Inc.
- W.L. Gore and associates
- Medtronic
Endovascular treatment of juxtarenal AAA

- Custom-made FEVAR is the endovascular ‘gold standard’, but is not always available, costly and has a high turn-down rate

- CHEVAR seems to be a valid alternative, but limited by stent compression and gutter formation
Chimney-EVAS

Why chimney’s in combination with EVAS?

1. The polymer-filled endobags are likely to reduce gutter formation
2. The cured polymer will no longer exert external pressure on the chimney grafts, which may reduce stent compression
ASCEND
ANEURYSM SEALING FOR COMPLEX AAA: EVALUATION OF NELLIX DURABILITY

- Physician sponsored
- Open-label, single-arm, no prospective screening
- Early in global and institutional experience
- Endpoints typical of EVAR therapy in complex AAA

Post-market registry of the Nellix system with chimney stents

187 patients
154 primary
9 rAAA
25 EVAR
5 EVAS

Chimney configurations

DE NOVO PROCEDURES (154)

<table>
<thead>
<tr>
<th>Chimney Configuration</th>
<th>N</th>
<th>Single</th>
<th>Double</th>
<th>Triple</th>
<th>Quadruple</th>
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<tr>
<td></td>
<td></td>
<td>40.3%</td>
<td>35.1%</td>
<td>17.5%</td>
<td>7.1%</td>
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<tr>
<td>Single</td>
<td>62</td>
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</tr>
<tr>
<td>LRA = 33, RRA = 27</td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>SMA = 1</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Not Specified = 1</td>
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<td></td>
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</tr>
<tr>
<td>Double</td>
<td>54</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both RA = 49</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>RA and SMA = 4</td>
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</tr>
<tr>
<td>Triple</td>
<td>27</td>
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<tr>
<td>Both RA, SMA = 24</td>
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<tr>
<td>RA, SMA, CA = 2</td>
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<td>Quadruple</td>
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<tr>
<td>Both RA, SMA, CA</td>
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</table>

Procedural characteristics

- **Procedure (min):**
  - Single: 161.4
  - Double: 209.8
  - Triple-Quadruple: 287

- **Fluoroscopy (min):**
  - Single: 26.3
  - Double: 35.5
  - Triple-Quadruple: 62.5

- **Contrast (mL):**
  - Single: 217
  - Double: 203
  - Triple-Quadruple: 245.7

- **Blood loss (mL):**
  - Single: 280.5
  - Double: 261.2
  - Triple-Quadruple: 489.6

78% balloon expandable stents / 22% self expanding stents

Achieved neck lengths

Many patients treated with a short seal length

Endoleaks

At one-year follow-up;
- Freedom from all endoleaks 94%
- Freedom from type Ia endoleak 96%
Re-interventions

Freedom from secondary interventions

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<th>30d</th>
<th>1 yr</th>
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<td>94%</td>
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<td>89%</td>
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Reinterventions

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<tr>
<td>Type Ia</td>
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<td>Chimney stents</td>
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<td>PTA and stenting</td>
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<td></td>
<td>Thrombolysis</td>
<td>N=2</td>
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<tr>
<td>Nellix stents</td>
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<tr>
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<td>PTA and stenting</td>
<td>N=3</td>
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<tr>
<td></td>
<td>Thrombolysis</td>
<td>N=1</td>
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</table>

Target vessel patency

CELIAC 98.1%
SMA 100%
RRA 99%
LRA 98%

Freedom from Mortality

30d  1 yr
ARM  97.2%  94.3%
ACM  97.2%  89.8%

Early Experience With Endovascular Aneurysm Sealing in Combination With Parallel Grafts for the Treatment of Complex Abdominal Aneurysms: The ASCEND Registry

Matt Thompson, MD, FRCS1, Marwan Youssef, MD2, Rudolf Jacob, MD3, Sebastian Zerwes, MD3, Michel Reijnen, MD, PhD4, Piotr Szopinski, MD5, Patrick Berg, MD6, Grzegorz Oszkinis, MD, PhD7, and Andrew Holden, MBChB, FRANZCR, EBIR8

Conclusion: The ASCEND Registry supports a proof of concept for the use of polymer technology and EVAS with parallel grafts in managing patients with complex aortic disease. The future role of chEVAS will be defined by studies that assess mid- to long-term durability.
Cardiac stability of CHEVAS

- 11 CHEVAS cases
  - 9 primary cases
  - 2 CHEVAS for revision EVAS
- The maximum change in distance
  - EVAS-to-EVAS stent 0.2 ± 0.1 mm
  - EVAS-to-chimney stent 0.2 ± 0.1 mm
- Mean change in chimney deflection angle
  1.2 ± 0.7°
- The EVAS stent-to-chimney angles
  - LRA 0.7 ± 0.3°
  - RRA 1.0 ± 0.3°
  - SMA 0.8 ± 0.4°

The CHEVAS configuration is stable during the cardiac cycle; Only minimal cyclical changes in angulation and distance between components
Long-term stability after CHEVAS

- Retrospective, observational cohort study
- 31 patients with primary CHEVAS
  - single  n=13
  - double  n=13
  - triple  n=5
- Median CTA follow-up 17 months
- Freedom from clinically relevant migration
  - 1 year  100%
  - 2 years  100%
- Freedom from caudal movement of 5-9 mm
  - 1 year  81.3%
  - 2 years  73.9%

The incidence of clinically relevant migration after CHEVAS is 6.7% at 3-year follow-up

Zoethout S, et al. Submitted for publication
Revision after CHEVAS

Before CHEVAS

Primary single CHEVAS

Secondary triple CHEVAS
Summary

- Promising use of new technology – could fill a therapeutic gap

- Theoretical advantages in using polymer-based sealing

- Early results are acceptable

- Prospective long-term results and proof of endograft durability are required

<table>
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<tr>
<th>Recommendation 98</th>
<th>Class</th>
<th>Level</th>
<th>References</th>
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<td>In patients with juxtarenal abdominal aortic aneurysm, new techniques/concepts, including endovascular aneurysm seal, endostaples, and in situ laser fenestration, are not recommended as first line treatment, but should be limited to studies approved by research ethics committees, until adequately evaluated.</td>
<td>III</td>
<td>C</td>
<td>[142,224,313, 460,687]</td>
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</table>
CHEVAS in 2020

**CHEVAS IDE Clinical Trial**

*Description*

- ChEVAS System is comprised of:
  - Nellix System
  - Ovation distal extenders
  - Covered self-expanding branch stent
- Indication to include up to 3 branch vessels
- Minimum seal length 15 mm

*Clinical Study Strategy*

- 120 subjects
- 50 global sites
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