HORIZON™ – New Single-Sided Access EVAR
Short and mid-term results

M. Hofmann, M. Lachat

The Leipzig Interventional Course, January 24 – 27, 2017
Disclosure

Michael Hofmann has no potential conflict of interest

Mario Lachat is investigator and clinical proctor of Endospan
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Agenda

- Introduction
- Device Description
- FIM / PIVOTAL Studies
- Results
- Conclusion
Introduction

Characterization of Human Aortic Anatomy Project - CHAP

- Need to introduce smaller delivery system.

T. Morrisson – Health of Women Public Workshop 2013

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Introduction

Overview of Anatomical Challenges

Exclusion Criteria

Introduction

Overview of Anatomical Challenges

Exclusion Criteria

Introduction

Overview of Anatomical Challenges

Exclusion Criteria

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Device Description

- 3 modular design
- ultra-low profile - 14 Fr outer diameter
- single-sided access
- is built of nitinol (an elastic mixture of metals) stent, attached to a polyester fabric graft
- increased stability due to fixation at proximal & distal necks
Module 1 - Base limb (iliac-to-iliac limb)
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Device Description

- single side access
- crossing from one iliac artery to another
Module 2 - Primary aortic module

Module 1 and 2 are directly connected
1st aortic module

→ no need to cannulate “short limb”

(simplifies and shortens procedure, reduces radiation and contrast media)
Module 3 - Aortic extension limb with a partially exposed supra-renal crown

Supra-Renal Bare Crown & Barbs

Proximal aortic neck, with partially exposed supra-renal crown
Module 3 –
Aortic extension limb with a partially exposed supra-renal crown transrenal fixation
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#### FIM / PIVOTAL Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>No. of patients</th>
<th>FU years</th>
<th>Primary objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>First-in-Man (FIM)</td>
<td>prospective open-label non-randomized single-arm first-in-man (FIM) clinical study</td>
<td>10</td>
<td>2</td>
<td>- safety - performance</td>
</tr>
<tr>
<td></td>
<td>10/2012 – 07/2013</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PIVOTAL</td>
<td>prospective, open-label, non-randomized single-arm and interventional clinical study</td>
<td>30</td>
<td>5</td>
<td>- safety - performance</td>
</tr>
<tr>
<td></td>
<td>04/2014 – 04/2015</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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## Results

### Table: HORIZON ™ – New Single-Sided Access EVAR

<table>
<thead>
<tr>
<th></th>
<th>FIM</th>
<th>PIVOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No of patients</strong></td>
<td>10 *</td>
<td>30</td>
</tr>
<tr>
<td><strong>Age (mean±SD / min – max)</strong></td>
<td>72.5 ±7.7 / 62 - 88</td>
<td>69 ±7.7 / 55 - 82</td>
</tr>
<tr>
<td><strong>Follow up</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>1 month</strong></td>
<td>9 (100%)</td>
<td>30 (100%)</td>
</tr>
<tr>
<td><strong>6 months</strong></td>
<td>9 (100%)</td>
<td>29 (100%)**</td>
</tr>
<tr>
<td><strong>12 months</strong></td>
<td>9 (100%)</td>
<td>28 (100%)***</td>
</tr>
</tbody>
</table>

* 1 pt - conversion to open surgery before device implantation - left the study
** 1 pt. died after completing the 1st month FU from myocardial infarction
*** 1 pt. died before completing the 1 year FU from unrelated reason to device or procedure
Results

<table>
<thead>
<tr>
<th>FREEDOM FROM:</th>
<th>FIM</th>
<th>PIVOTAL</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td>0 (9)</td>
<td>0 (30)</td>
<td>0</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0 (9)</td>
<td>0 (30)</td>
<td>0</td>
</tr>
<tr>
<td>Renal failure</td>
<td>0 (9)</td>
<td>0 (30)</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>0 (9)</td>
<td>0 (30)</td>
<td>0</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>0 (9)</td>
<td>0 (30)</td>
<td>0</td>
</tr>
<tr>
<td>Stroke</td>
<td>0 (9)</td>
<td>0 (30)</td>
<td>0</td>
</tr>
<tr>
<td>Bowel ischemia</td>
<td>0 (9)</td>
<td>0 (30)</td>
<td>0</td>
</tr>
<tr>
<td>Procedural blood loss ≥ 1000 ml</td>
<td>1* (10)</td>
<td>0 (30)</td>
<td>1 (40)</td>
</tr>
</tbody>
</table>

* One patient converted to open surgery

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#### Results

<table>
<thead>
<tr>
<th>Performance Endpoints</th>
<th>FU 1 months</th>
<th>FU 6 months</th>
<th>FU 12 months</th>
<th>FU 24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FIM – PIVOTAL</td>
<td>FIM – PIVOTAL</td>
<td>FIM – PIVOTAL</td>
<td>FIM – PIVOTAL</td>
</tr>
<tr>
<td><strong>No. of patients</strong></td>
<td>10 – 30 *</td>
<td>9 – 29 *</td>
<td>9 – 28 *</td>
<td>8 – n.c.</td>
</tr>
<tr>
<td><strong>Successful delivery and deployment</strong></td>
<td>9 – 30</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Conversion to open surgery</strong></td>
<td>1 (10%) – 0</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Stent – graft migration</strong></td>
<td>0 – 0</td>
<td>0 – 0</td>
<td>0 – 0</td>
<td>0 – n.c.</td>
</tr>
<tr>
<td><strong>Explantation</strong></td>
<td>0 – 0</td>
<td>0 – 0</td>
<td>0 – 0</td>
<td>0 – n.c.</td>
</tr>
<tr>
<td><strong>Occlusion of visceral vessels</strong></td>
<td>0 – 0</td>
<td>0 – 0</td>
<td>0 – 0</td>
<td>0 – n.c.</td>
</tr>
<tr>
<td><strong>Aneurysm rupture</strong></td>
<td>0 – 0</td>
<td>0 – 0</td>
<td>0 – 0</td>
<td>0 – n.c.</td>
</tr>
<tr>
<td><strong>Endoleak type I/ III</strong></td>
<td>0 – 0</td>
<td>0 – 0</td>
<td>0 – 0</td>
<td>0 – n.c.</td>
</tr>
<tr>
<td><strong>Growing Aneurysm &gt; 5mm (compared to baseline)</strong></td>
<td>0 – 0</td>
<td>0 – 0</td>
<td>0 – 1 (3.3%)</td>
<td>1 (8mm) – n.c.</td>
</tr>
<tr>
<td><strong>FU completion</strong></td>
<td>100%</td>
<td>100% *</td>
<td>100% *</td>
<td></td>
</tr>
</tbody>
</table>

n.c. – not completed, * 1pt. converted to open surgery (FIM), 2 deaths unrelated to the device (PIVOTAL)

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All procedures (100%) were reported to be successful.

No cases of:
- Type I or type III Endoleak
- Stent graft occlusion
- Stent graft migration
- Explantations of the Horizon stent graft
- Aneurysm rupture

1 year FU: 1 case of aneurysm grow (+0.7mm) due to endoleak type II (PIVOTAL)

→ Allows treatment of patients with severe vascular lesions on one of the iliac/femoral arteries
→ Expands the range of eligible patients and facilitates percutaneous use

Further studies including more patients and a longer follow up period are necessary to confirm durability and improved stability.
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Thank you for your attention!
Backup
Inclusion Criteria of FIM & PIVOTAL Study (amongst others...)

- Presence of AAA ≥ 5.0 cm in diameter
  AAA 4.5-5.5 cm (+ 0.5 cm/6 months or 1 cm/1 year)
  AAA > 50% larger than the normal aortic diameter

- Femoral artery diameter of ≥ 6 mm (CTA or MRA)
- Access vessels morphology suitable for endovascular repair

eligible to receive the Horizon Prothesis:

- Infrarenal aortic diameter of 18-28 mm
- Aortic length of 115-150 mm
- Iliac artery diameter of 10-19 mm
- Proximal aortic neck length ≥ 15 mm
- Proximal aortic neck angulation ≤ 60°
- Aortic bifurcation angulation of ≥ 70°
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