Simplified f-EVAR by a new endovascular device

Clinical safety and functionality study of The Guidewire Fixator

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Disclosure

- I have the following potential conflicts of interest to report:
  - Receipt of grants/research support
  - Receipt of honoraria and travel support
  - Participation in a company sponsored speakers’ bureau
  - Employment in industry
  - Shareholder in a healthcare company, www.endovab.com
  - Owner of a healthcare company
- I do not have any potential conflict of interest
Problem: f/b-EVAR is far from EVAR

Retrospective single centre cohort study
Uppsala University Hospital

- 63 EVAR and 63 f/b-EVAR (2012-2015)
- Grouped by # of catheterised branches/fenestrations/scallops

<table>
<thead>
<tr>
<th>Variable</th>
<th>EVAR</th>
<th>2f/b-EVAR</th>
<th>3f/b-EVAR</th>
<th>4f/b-EVAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoroscopy (min)</td>
<td>30.3 / 10.1-102.8</td>
<td>82.0 / 37.2-237.8</td>
<td>102.5 / 52.2-174.9</td>
<td>151.5 / 91.2-289.9</td>
</tr>
<tr>
<td>DAP (mGym²)</td>
<td>22.5 / 1.8-132.0</td>
<td>26.1 / 9.6-79.3</td>
<td>39.9 / 11.3-89.3</td>
<td>52.0 / 20.4-93.9</td>
</tr>
<tr>
<td>Contrast Iodine (g)</td>
<td>30.9 / 8-72</td>
<td>42.8 / 14-115</td>
<td>51.6 / 23-132</td>
<td>78.4 / 28-148</td>
</tr>
<tr>
<td>Anaesthesia (min)</td>
<td>181 / 60-405</td>
<td>340 / 180-645</td>
<td>458 / 255-750</td>
<td>628 / 510-885</td>
</tr>
<tr>
<td>Proc. Duration (min)</td>
<td>141 / 70-349</td>
<td>392 / 250-724</td>
<td>476 / 213-900</td>
<td>559 / 383-752</td>
</tr>
<tr>
<td>Days at ICU</td>
<td>0.3 / 0-8</td>
<td>0.5 / 0-6</td>
<td>1.6 / 0-18</td>
<td>5.9 / 0-43</td>
</tr>
<tr>
<td>Days at hospital</td>
<td>5.1 / 1-27</td>
<td>6.7 / 2-26</td>
<td>11.4 / 2-40</td>
<td>17.4 / 4-46</td>
</tr>
</tbody>
</table>
Problem: f/b-EVAR is far from EVAR

- **Conclusion**
  - Linear relationship between # of catheterisations and procedure variables
  - Challenge: Finding the branch and gaining sheath access
Improvement trends

• "Off-the-shelf" **Pre-loaded** fenestrated or branched
• **Through-and-through** wires, LSA and IBD

Some Examples:

- Jotec IBD
- GORE arch-branch
- Medtronic LSA
- Cook t-branch
- Cook arch fen
- Cook p-branch
- GORE TAMBE
What if we could pre-line also the visceral arteries....
NEW APPROACH

New approach to simplify catheterisation and sheath access:
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• “Guidewire anchor” is deployed in the branches before stentgraft insertion
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• Retrograde lining of branch wires – on table
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New approach to simplify catheterisation and sheath access:

• “Guidewire anchor” is deployed in the branches before stentgraft insertion
• Retrograde lining of branch wires – on table
• Railroad graft in place over multiple wires
NEW APPROACH

• Target vessel catheterisation post stentgraft deployment – **Eliminated**
• Less need for perfect alignment to achieve wire connection
NEW APPROACH

- Target vessel catheterisation post stentgraft deployment – **Eliminated**
- Less need for perfect alignment to achieve wire connection
- Sheath access improved by *traction through tension*
New tool – Guidewire fixator

- Guidewire 0.035” + stopper
- Freely movable over the guidewire
- Moderate radial force at rest, increases with tension
- Provide distal fixation while maintaining blood flow
Is it safe?

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Clinical Study

Objectives and endpoints

- Thrombosis / occlusion
- Rupture / trauma
- Dissection
- Fixation

Test Scheme

- Femoral cross over to the **internal iliac artery**
- Fixator **Deployment**
- **Tension Test** (3N)
- Fixator **Retrieval**
- Visual and **Angiographic evaluation**
- CT imaging 30 days
Results

Male/Female 8/2, n=10
Age 68-84, mean 75.4

- Thrombotic occlusions, 0 (0%)
- Arterial trauma, 0 (0%)
- Arterial dissection, 0 (0%)
- Fixation failures, 0 (0%)

Adverse Events

- 1 SAE - Not device related
- 1 AE- Challenging retrieval
Study Conclusion

The device was considered safe and functional in the tested conditions.
Use and potential Benefits

- secure guidewire position,
- parallel work,
- tension on GW adds to stiffness,

**Distal fixation allows completely new guidewire techniques**
Use and potential Benefits
- f/b EVAR

• Stepwise, predictable
  – Shorter procedure, reduced radiation, less contrast
• Opportunity for standardized grafts
  – Less need for perfect alignment for catheterisation

• Tension adds to stiffness
  – Facilitates sheath access and bridging graft insertion

Conceptual demonstration in pig model
Summary

A guidewire fixator enables new techniques & methods

Preclinical safety study in a pig model

Clinical safety and functionality study completed

CE-approved

Clinical application study in f/b EVAR, ch-EVAR

First in man LSA successfully completed
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