Benchside Testing for Patient Safety: Assessment of Pull-out Forces before Complex Endovascular Aortic Aneurysm Repair

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Conflicts of Interest

I have the following potential conflicts of interest to report:

- X Consulting
- O Employment in industry
- O Stockholder of a healthcare company
- O Owner of a healthcare company
- O Other(s)

- O I do not have any potential conflict of interest
Type I & IV TAAA

Branched Endograft

→ Cook: min. 30mm
→ Jotec: min. 26mm
Fenestrated Endograft

→ Cook Medical

→ Jotec

→ Vascutek
Fenestrated Anaconda®

- Unsupported Fabric Region:
  - Flexible fenestration size
  - Flexible fenestration position
- Repositionability
  Retained during cannulation!
  Enhanced flexibility & security
- Cannulation from brachial & inguinal access
  Before complete deployment!!
Background

- N. Melas et al, EJVEVS 2010
- K. Liffman et al, J Endovasc Ther 2001
- WC Sternbergh et al, JVS 2004
- L. Morris et al, J Biomech 2004

An endograft needs to withstand pulsatile drag forces of 3.8 - 6 N in an aneurysmal aorta with a friendly anatomy and drag forces up to 14 N in 'hostile anatomies'.

Vascutek threshold: **14.546 N**
Aim

→ Assessment of pull-out resistance

→ Assessment of damage to thoracic device
Methods

→ 30mm, 32mm and 34mm Anaconda devices
→ five different 28mm thoracic tube grafts: Cook Zenith, Medtronic Valiant, Jotec E-vita, Bolton Relay and Gore CTAG
→ four 30mm thoracic tube grafts: Medtronic Valiant, Jotec E-vita, Bolton Relay and Gore CTAG
→ oversizing of at least 2mm for any combination.

→ Only results of 34mm in 28mm shown! (20% OS)
Test Set Up
Test Set Up
Test Set Up

→ Instron® Tensile Tester

→ Environmental Chamber, 37 ± 2°C Celsius

→ Continuously increasing pull force 0 – 100 N
Results

OLB34 With Hooks in Bolton 28mm Graft
Results

<table>
<thead>
<tr>
<th></th>
<th>Bolton</th>
<th>Cook</th>
<th>Gore</th>
<th>Jotec</th>
<th>Medtronic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Break Force</td>
<td>46,77</td>
<td>32,00</td>
<td>19,57</td>
<td>49,77</td>
<td>49,08</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>8,5</td>
<td>2,0</td>
<td>4,1</td>
<td>30,4</td>
<td>13,2</td>
</tr>
</tbody>
</table>
Fabric Damage

Bolton Captivia

Cook TX2
Results

Medtronic Valiant  Jotec E-Vita  Gore TAG
## Results

<table>
<thead>
<tr>
<th>Fabric Damage</th>
<th>Bolton</th>
<th>Cook</th>
<th>Gore</th>
<th>Jotec</th>
<th>Medtronic</th>
</tr>
</thead>
<tbody>
<tr>
<td>puncture holes</td>
<td>puncture holes, minor tear</td>
<td>puncture holes, large tear</td>
<td>large tears</td>
<td>large tears</td>
<td></td>
</tr>
</tbody>
</table>

Falkensammer
Clinical Results

<table>
<thead>
<tr>
<th>N</th>
<th>F/U</th>
<th>Type I EL</th>
<th>Type III EL</th>
<th>Migration</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 / 135</td>
<td>9 months (range 1 – 25)</td>
<td>0</td>
<td>2 (visc. connecting stents)</td>
<td>0</td>
</tr>
</tbody>
</table>
Conclusions

→ The combination of a thoracic tube graft and a fenestrated Anaconda device is a viable option for the treatment of patients with Type IV TAAA with no adequate landing zone above the CT

→ While pull-out testing has shown sufficient stability with the majority of assessed grafts, the risk of major fabric damage appears to be less in Bolton and Cook thoracic devices