The “SPIDERgraft”: A New Hybrid Graft for Treatment of TAAAs: How Does it Work – Advantages and Results

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Disclosures

- I have the following potential conflicts of interest to report:
  - Receipt of institutional grants/research support (Vascutek)
  - Participation in a company sponsored speakers' bureau
  - Employment in industry
  - Shareholder in a healthcare company
  - Owner of a healthcare company
  - I do not have any potential conflict of interest

TAA Endo Repair: Results

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>n/Vessels</th>
<th>30-Day Mortality</th>
<th>Dialysis</th>
<th>P-Plegia/P-Paresis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferrera</td>
<td>2008</td>
<td>11/33</td>
<td>18%</td>
<td>0%</td>
<td>9%/18%</td>
</tr>
<tr>
<td>Greenberg</td>
<td>2010</td>
<td>406/1200</td>
<td>4%</td>
<td>1.5%</td>
<td>4.3%</td>
</tr>
<tr>
<td>Verhoefen</td>
<td>2011</td>
<td>50/173</td>
<td>8%</td>
<td>2%</td>
<td>6%</td>
</tr>
<tr>
<td>Haulon</td>
<td>2012</td>
<td>89/192</td>
<td>9%</td>
<td>6.7%</td>
<td>7.8%</td>
</tr>
<tr>
<td>Chuter</td>
<td>2012</td>
<td>81/306</td>
<td>6%</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td><strong>4-18%</strong></td>
<td></td>
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</tr>
</tbody>
</table>

Open TAAA Repair: State of the Art


Texas Heart Institute 819 Pt for TAAA

- 25.4% Type I, 32.1% Type II, 19.1% Type III, 23.5% Type IV
- In-hospital mortality 8.4%
- Permanent Paraplegia 5.1%
- Stroke 3.3%
- Permanent Dialysis 5.5%
- Cardiovascular Complications 30.4%
- Pulmonary Complications 41.1%
- Despite high Expertise OR continues to be associated with complications...

The SPIDER Hybrid Graft Device

Modified reversed Frozen Elephant Trunc (FET) for novel hybrid repair of thoracoabdominal aortic disease

- Avoid aortic crossclamping by preliminary distal aortic bypass
- Avoid thoracotomy by endovascular treatment of the thoracic part
- Avoid extracorporeal circulation by perfusion of the visceral branches via transient distal aortic perfusion
- Avoid SCI by reattachment of lumbar arteries

Surgical Procedure
Successful graft deployment in all 18 animals

Results

- Study protocol
  - 18 domestic pigs (75-85 kg)
  - Technical feasibility
  - Hemodynamic parameters (HD)
  - Blood flow (Transit-Time flow measurement)
  - Ischemic time of related organs
  - Angiography
  - Post mortem CT angiography

- Swan-Ganz Catheter:
  - CVP, PAP, LAP, PVR, BGA

- PiCCO:
  - MAP, HR, CO, SVR, GEDV, BGA

- Transit-Time flow measurement (TTFM):
  - Coeliac trunc, superior mesenteric artery, left renal artery, iliac arteries

- Successful fixation of graft in proximal landing zone
- Modification of Delivery System for easier retraction necessary
- Thoracic graft implantation 4.2 ± 1 min

Results

<table>
<thead>
<tr>
<th></th>
<th>Ischemic Time (min)</th>
<th>TTFM Base (ml/min)</th>
<th>TTFM Post (ml/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC</td>
<td>11.5 ± 2.3</td>
<td>585 ± 65</td>
<td>534 ± 110</td>
</tr>
<tr>
<td>SMA</td>
<td>9.0 ± 2.1</td>
<td>492 ± 113</td>
<td>722 ± 115</td>
</tr>
<tr>
<td>RRA</td>
<td>13.4 ± 3.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LRA</td>
<td>21.2 ± 4.0</td>
<td>246 ± 97</td>
<td>163 ± 97</td>
</tr>
<tr>
<td>RIA</td>
<td>9.0 ± 3.3</td>
<td>565 ± 192</td>
<td>326 ± 67</td>
</tr>
<tr>
<td>LRA</td>
<td>15.6 ± 6.5</td>
<td>592 ± 156</td>
<td>400 ± 127</td>
</tr>
</tbody>
</table>

Papers accepted at EJVES, Nov 14 2017

Perspective

- Nose Cone with Guide Wire
- Double Stents
- Reinforcement
- Side Branch
- Apposition and Biiliac/-femoral bifurcation
Perspective

- Nose Cone
- Hooks
- Reinforcement
- Stents
- Side Branch
- Apposition
- SAFI Loop
- Distal Bifurcation

Thank you to the Team!

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Conclusions

- Hybrid graft implantation is technically feasible
- Crossclamping, visceral, renal and spinal ischemia can be kept in a short limit
- Thoracotomy can be avoided
- Modifications are Mandatory: SPIDERgraft
- First in Man Clinical Study planned

First In Man:
reversed Frozen Elephant Trunk

- 29 y, female
- Marfan’s Disease
- Symptomatic dissected TAAAn
  - 2014: TEVAR in symptomatic TBAD
  - Adipositas per magna (BMI 34 kg/m²)
  - Symptomatic Mitral Valve Prolapse
  - Hypertension

First In Man:
reversed Frozen Elephant Trunk

1. Crawford Incision, Thoracotomy
2. Extracorporal Circulation via right femoral access
3. Graftinsertion via Celiac Trunc (34x150 mm Thoraflex Hybrid
   Graft, VASCUTEC Terumo)
4. Retaining to stabilize (Zenith TX2, COOK Medical)
5. Subsequent Visceral Revascularization via Clamp Repair
6. Distal Anastomosis: Bilurculated bi-iliac graft
First In Man: reversed Frozen Elephant Trunk

Reattachment Collar

Final Sites

Post OP CT Scan