The “SPIDERgraft”: A Novel Graft for Thoracoabdominal Repair

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Disclosures

- I have the following potential conflicts of interest to report:
  - X 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
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%

cardiac Complications 30.4%

Pulmonary Complications 41.1%

- Despite high Expertise OR continues to be associated with complications...
## TAAA Endo Repair: Results

<table>
<thead>
<tr>
<th>Autor</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>Ferreira</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>Verhoeven</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>
</tbody>
</table>

**Total** 4-18%
TAAA: All Techniques are…

- Associated with serious complications
- Not suitable in all patients
- Main Burden: Risk of spinal cord ischemia not solved…
### Spinal Cord Ischemia: Intra-operative Factors

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I/II vs type III/IV TAA</td>
<td>2.6</td>
<td>1.1-6.4</td>
<td>0.039</td>
</tr>
<tr>
<td>Aneurysm rupture</td>
<td>3.5</td>
<td>1.1-11.2</td>
<td>0.034</td>
</tr>
<tr>
<td>Total cross clamp time (h)</td>
<td>5.2</td>
<td>1.8-14.7</td>
<td>0.002</td>
</tr>
<tr>
<td>Patent T9-L1 intercostal sacrifice</td>
<td>2.6</td>
<td>1.1-6.0</td>
<td>0.031</td>
</tr>
<tr>
<td>Intraoperative hypotension</td>
<td>2.1</td>
<td>1.1-4.0</td>
<td>0.028</td>
</tr>
</tbody>
</table>

Modified reversed Frozen Elefant 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
Study protocol

6 domestic pigs (75-85kg)
✓ 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
Surgical Procedure
Results

- Successful graft deployment in all 18 animals
Successful fixation of graft in proximal landing zone
Modification of Delivery System for easier retraction necessary
Thoracic graft implantation $4.2 \pm 1\text{min}$

<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>
Nose Cone with Guide Wire
Perspective

- Nose Cone
- Reinforcement
- Double Ring Stents
- Nose Cone
- Hooks
- Reinforcement Stents
- 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!

Anna Dupree
Harleen Sandhu
Sabine Wipper
Anna Dupree
Sebastian Debus
Tilo Kölbel
Nikos Tsilimparis
Daniel Manzoni
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
Thank you!

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29 y, female

Marfan’s Disease
Symptomatic dissected TAAA

- 2014: TEVAR in symptomatic TBAD
- Adipositas per magna (BMI 34 kg/m²)
- Symptomatic Mitral Valve Prolapse
- Hypertension
1. Crawford Incision, Thoracotomy
2. Extracorporeal Circulation via right femoral access
3. Graft insertion via Celiac Trunc (34x150 mm Thoraflex Hybrid Graft, VASCUTEC Terumo)
4. Relining to stabilize (Zenith TX2, COOK Medical)
5. Subsequent Visceral Revascularization via Clamp Repair
6. Distal Anastomosis: Bifurcated bi-iliac graft

First In Man: reversed Frozen Elephant Trunk
First In Man:
reversed Frozen Elephant Trunk

Reattachment Collar

Final Situs

Post OP CT Scan