4 and 5 Year US And European Results With the CTAG for TEVAR: Concept, Advantages and Limitations

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- Major Stakeholder – None

First commercial implant on 19.10.2009 in Heidelberg, Germany

100.000 implants worldwide

Concept of CTAG
FDA-approved treat various thoracic aortic pathologies

Concept: Device Modifications

Design – Size - Configurations

CTAG - engineered for 6-33% oversizing conditions
IMH with 31 mm > CTAG 34 mm = 10% Oversizing
TAA with 31 mm PLZ > CTAG 37 mm = 20% Oversizing
4-5 Years – Results with CTAG (mean 2 yrs.)

- Prospective Multicentre Regulatory US- Study
- Prospective Multicentre Europen Registry
- GREAT Registry
- Single Center Experience
- Heidelberg Experience (407 devices/163 pat.)

Device Conformability and Morphological Assessment After TEVAR for Aortic Type B Dissection: A Single-Centre Experience with a Conformable Thoracic Stent-Graft Design

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HUMAN STUDY

Aneurysm Related Survival: 97% (n=2)

1 rupture of ascending aneurysm
1 arterial access rupture for secondary intervention
both separate from procedure

Technical Results

- Device deployment 100%
- Accuracy deployment 99%
- Conformability 95%

Predicting Risk Factors for Death and SAE

<table>
<thead>
<tr>
<th>Variables (30 day outcome)</th>
<th>p</th>
<th>HR</th>
<th>CI (95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aneurysm</td>
<td>.29</td>
<td>0.499</td>
<td>0.135–1.887</td>
</tr>
<tr>
<td>Traumatic transaction</td>
<td>.91</td>
<td>0.887</td>
<td>0.045–6.035</td>
</tr>
<tr>
<td>Other pathologies</td>
<td>.48</td>
<td>0.627</td>
<td>0.163–2.341</td>
</tr>
<tr>
<td>Urgency</td>
<td>.13</td>
<td>0.509</td>
<td>0.206–1.325</td>
</tr>
<tr>
<td>Gender</td>
<td>.79</td>
<td>0.892</td>
<td>0.361–2.027</td>
</tr>
<tr>
<td>Age</td>
<td>.007</td>
<td>1.071</td>
<td>1.002–1.131</td>
</tr>
</tbody>
</table>

SAE

- Aneurysm .46 | 0.622 | 0.177–2.260 |
- Traumatic transaction .84 | 0.796 | 0.046–5.394 |
- Dissections, IMH and PAU .59 | 0.705 | 0.181–3.584 |
- Urgency .14 | 1.503 | 0.206–11.325 |
- Male gender .58 | 0.991 | 0.419–2.189 |
- Age .01 | 1.058 | 1.003–1.113 |

SAE = serious adverse event; HR = hazard ratio.
GREAT - Real World Registry
(n=133 through 2 years follow up)

• 2 Type Ia endoleaks
• 4 Type Ib endoleaks
• 2 type II endoleaks
• 1 migration
• 3% device related re-intervention through 2 yr. FU
• 8% death rate through 2 year follow up

Device – Conformability

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Indications for TEVAR with CTAG

<table>
<thead>
<tr>
<th>Indication</th>
<th>N</th>
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</thead>
<tbody>
<tr>
<td>Acute type B-Dissection</td>
<td>35</td>
</tr>
<tr>
<td>PAU</td>
<td>27</td>
</tr>
<tr>
<td>TAA</td>
<td>19</td>
</tr>
<tr>
<td>TAAA</td>
<td>18</td>
</tr>
<tr>
<td>IBH</td>
<td>17</td>
</tr>
<tr>
<td>Traumatic rupture</td>
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</tr>
<tr>
<td>CEAD**</td>
<td>10</td>
</tr>
<tr>
<td>rTAA</td>
<td>7</td>
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<tr>
<td>ABF</td>
<td>5</td>
</tr>
<tr>
<td>Anastomotic Aneurysm</td>
<td>5</td>
</tr>
<tr>
<td>Aneurysm</td>
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<tr>
<td>Acute Type A-Dissection</td>
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<tr>
<td>Posttraumatic TAA</td>
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<tr>
<td>Patchaneurysm</td>
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<tr>
<td>Patchrupture</td>
<td>1</td>
</tr>
<tr>
<td>Corpus alienum</td>
<td>1</td>
</tr>
<tr>
<td>(Palacos®)</td>
<td></td>
</tr>
<tr>
<td>Symptomatic Aortic Thrombus</td>
<td>1</td>
</tr>
</tbody>
</table>

Advantages - Personal Opinion

• Oversizing windows for each pathology
• Unsheated device
  • very flexible for arch and tortuous anatomy
  • easy access for multiple devices
• Highly conformable in the arch
• Fast or slow deployment
Example of Complex Arch Morphology

Limitations – Personal Opinion
- Deployment sequence in distal arch aneurysms

Future Refinements of the CTAG
- Branched technology
- Steering delivery system to enhance control and vessel wall Partial deployment
- Partial deployment

Conclusions
- Concept is proven
- Modifications of CTAG increased conformability
- CTAG shows very favorable results at mean 2 years
- No device failures, low major device events
- CTAG is our preferred device for aortic arch pathologies
- Continued FU over the next 5 yrs. will be important