New Concepts in Open Arch Repair

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Disclosure

I have the following potential conflicts of interest to report:

☑ Consulting CryoLife/JOTEC
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Overview

JOTEC/CRYOLIFE Equipment

- E-vita Open Plus
- E-vita Open Plus NEO
- E-novia
E-vita Open Plus
E-vita Open Plus – Tube Graft*

- 1st hybrid stent graft system on the CE-market in 2005
- Available worldwide, except USA and Japan
- Extensive proof of clinical success with almost 10.000 implants
- International E-vita OPEN PLUS Registry with more than 1000 patients treated and 15 centers involved worldwide
- Blood tight polyester vascular graft
- Collar for distal anastomosis
- Endovascular Z-shaped nitinol skeleton
- High SG and introducer flexibility
- Inflatable tip-balloon for atraumatic delivery

Jakob et al., Herz, 2005
<table>
<thead>
<tr>
<th>Variable</th>
<th>n= 300</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>59±12</td>
</tr>
<tr>
<td>Male</td>
<td>208 (69)</td>
</tr>
<tr>
<td>Disease</td>
<td></td>
</tr>
<tr>
<td>Acute AD</td>
<td>164 (55)</td>
</tr>
<tr>
<td>Chronic AD</td>
<td>71 (23)</td>
</tr>
<tr>
<td>Aneurysm</td>
<td>65 (22)</td>
</tr>
</tbody>
</table>
Freedom from aorta related death at 10 years = 91%
Freedom from Desc. Ao. Re-Intervention (Open, Endo)

Overall Freedom from Desc. Ao. Re-Intervention at 10 years = 69%

Disease | Freedom at 5-year
---------|------------------
AAD      | 92%              
CAD      | 72%              
TAA      | 73%              

<table>
<thead>
<tr>
<th>Years</th>
<th>0</th>
<th>2</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAD, n</td>
<td>164</td>
<td>88</td>
<td>44</td>
</tr>
<tr>
<td>CAD, n</td>
<td>71</td>
<td>41</td>
<td>19</td>
</tr>
<tr>
<td>TAA, n</td>
<td>65</td>
<td>23</td>
<td>10</td>
</tr>
</tbody>
</table>
### Exclusion of False Lumen Downstream

<table>
<thead>
<tr>
<th></th>
<th>Acute AD</th>
<th>Chronic AD</th>
</tr>
</thead>
<tbody>
<tr>
<td>96%</td>
<td>90%</td>
<td></td>
</tr>
<tr>
<td>49%</td>
<td>29%</td>
<td></td>
</tr>
<tr>
<td>26%</td>
<td>19%</td>
<td></td>
</tr>
</tbody>
</table>

CT-results after 1 year
complete thrombosis ±
obliteration of false lumen (%)

Tsagakis et al., STS, 2017
E-vita Open NEO
FET in Zone 0 → E-vita Open NEO
FET in Zone 0 → E-vita Open NEO
First Case (Aortic-Live 2017)

79 years, male
186 cm, 76 kg
Aortic arch aneurysm 55mm

S/p. Stroke 02.2017
S/p. RCCA stenting 2016
S/p. LCCA TEA 2008

X-clamp time → 62min
Visceral ischemia → 32min

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E-novia
Primary Indication

- Very acute Type I AD
- PENN class B, C, BC
- Patients > 75 years
- Severe concomitant disease

One hemostatic suture line Zone 0
E-novia → Longitudinal Stabilization of Uncovered Stent
Case #10: 69 years ♀, acute type I AD, end stage COPD (FEV1 0,5 l/min), pulmonary cachexia, fainting, hemodynamic collapse, intubated elsewhere
Case #10

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Case #10

CTA - 6th postoperative day

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## E-novia → Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>n= 11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>68 ± 11</td>
</tr>
<tr>
<td>Male</td>
<td>6 (54)</td>
</tr>
<tr>
<td>Penn Classification</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>1 (9)</td>
</tr>
<tr>
<td>B</td>
<td>8 (73)</td>
</tr>
<tr>
<td>BC</td>
<td>2 (18)</td>
</tr>
<tr>
<td>Bentall</td>
<td>3 (27)</td>
</tr>
<tr>
<td>CABG</td>
<td>1 (9)</td>
</tr>
<tr>
<td>30-day /hospital mortality</td>
<td>2 (18)</td>
</tr>
<tr>
<td>Stroke (residual)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Late mortality</td>
<td>2 (18)</td>
</tr>
</tbody>
</table>
Conclusion

E-vita Open Plus, E-vita Open NEO & E-novia

- Family of graft variations
  - all kinds of pathologies
  - all situations involving arch and adjacent aorta

- New gold standard complex thoracic aortic disease
Thank you!

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Reduction of FET Surgery by Arch Stenting

Ius et al, Ann Thoracic Surg. 2010

Djumbodis Experience

Adverse FL evolution

Residual False Lumen

N = 22

<table>
<thead>
<tr>
<th>FL patency</th>
<th>72%</th>
<th>58%</th>
<th>75%</th>
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</thead>
<tbody>
<tr>
<td>Arch</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isthmus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Descending ao.</td>
<td></td>
<td></td>
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Djumbodis vs. proximal repair
p=ns

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First in man Ascyrus uncovered Stent
E-novia clinical experience 2016 - 2018

Case #6: 42 years ♀, S/p. complicated Caesarean Section

Visceral Ischemia/SAP time: 21 min
X-Clamp time: 68 min
CPB time: 108 min
Survival 6.6 months

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**Summary**

**E-vita Open Plus**

- Zone 2 or 3 anastomosis, all indications, high standard, reliability over time (12 years), no prox. endoleakage reported, no material failures, no retraction.

**E-novia**

- Zone 0 anastomosis, AAD in the very acute situation, very fast, very easy.

**E-vita Open NEO**

- Zone 0, 1 or 2 anastomosis, AAD, CAD, TAA combines debranching with arch/descending stent-grafting, fast and easy.

**Milano variation**

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Ao. Remodeling in Arch Aneurysm post E-vita Open

preoperative, 69y ♀, 57mm  postoperative  5.5 years later

<table>
<thead>
<tr>
<th></th>
<th>TAA (N = 90)</th>
<th>TAAA (N = 23)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete aneurysm exclusion</td>
<td>76 (84)</td>
<td>13 (57)</td>
<td>0.008</td>
</tr>
<tr>
<td>Additional postoperative intervention</td>
<td>6 (7)</td>
<td>5 (22)</td>
<td>0.045</td>
</tr>
</tbody>
</table>

Mestres et al., EJCTS 2013
International E-vita Open Registry

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