THE EVOLUTION OF FET-TECHNIQUE

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Disclosure

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☒ I have the following potential conflicts of interest to report:

☒ Receipt of grants/research support
☐ Receipt of honoraria and travel support
☐ 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
FET Devices

• 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
• 22-40 mm diameters
• Individual choice of LZ for sufficient sealing (tube configuration)

Jakob et al., EJCTS 2012

E-vita Open Plus

Jotec GmbH

Thoraflex

Vascutec Ltd

• Blood tight polyester vascular graft
• Collar for distal anastomosis
• Ring stent configuration
• Branched configuration

Shrestha et al., EJCTS 2013
FET Classic Indications

Acute Type I  Chronic Type I  Chronic Type III  Distal Arch Aneurysm
FET Extended Indications

Megaaorta

Complicated Acute Type III

- No proximal landing zone
- No proximal sealing zone
- “Gothic” arch

FET as docking graft for 2nd stage repair
FET Concept

• E-vita open Plus
Angioscopy Pathology and Landing Zone Visualization

Angioscopy Demonstration

Location of re-entry sites
Distance (cm) LSA to lesion
Zone 2 Surgery – current Status
FET – Essen Results / 2005 – 3/2017

<table>
<thead>
<tr>
<th>(%)</th>
<th>Overall N = 245</th>
<th>Acute AD N = 131</th>
<th>Chronic AD N = 62</th>
<th>Aneurysm N = 52</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality 30 days</td>
<td>11</td>
<td>11</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Stroke</td>
<td>6</td>
<td>5</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

10 Years Results

Survival

Freedom from re-intervention downstream

Periprosthetic healing almost 100% overtime
Acute Type I AD
Survival and Freedom of secondary Aortic Intervention

Cumulative survival + freedom from ao. re-intervention
Acute Type I AD – With FET vs. Without - FET (FU mean 1.9 ± 1.7 yrs.)

<table>
<thead>
<tr>
<th></th>
<th>3 years</th>
<th></th>
<th>5 years</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>With FET</td>
<td>Without FET</td>
<td>p</td>
<td>With FET</td>
</tr>
<tr>
<td>Cumulative survival + Freedom from ao. reintervention</td>
<td>74%</td>
<td>44%</td>
<td>0.017</td>
<td>74%</td>
</tr>
</tbody>
</table>

Tsagakis et al, AHA 2015
Multisegmental Thoracic Aortic Aneurysm
Survival and Freedom from Reintervention

Survival

Freedom from Reintervention
Aortic Remodeling after FET in Acute Type I AD

Aortic Levels
Remodeling based on volume changes

Fig. 2: Evaluation of the aortic diameter in the descending aorta after or before repair in type II aortic dissection (A), after isolated proximal repair in type I aortic dissection (B), and after proximal repair combined with transaortie fenestration in type I aortic dissection (C).

Tsagakis et al Eur J Cardiothorac Surg 2012
Frozen Elephant Trunk
The Surgical Option to Deal with Multisegmental Thoracic Aortic Disease

12 yrs after E-vita open for acute type I AD
New Concepts

• E-novia

• E-vita open NEO
### Preoperative variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall</th>
<th>AAD</th>
<th>CAD</th>
<th>TAA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.021</td>
<td>0.065</td>
<td>0.199</td>
<td>0.502</td>
</tr>
<tr>
<td>Emergency</td>
<td>0.050</td>
<td>0.139</td>
<td>0.064</td>
<td>1.000</td>
</tr>
<tr>
<td>Male</td>
<td>0.022</td>
<td>0.660</td>
<td>0.156</td>
<td>0.033</td>
</tr>
<tr>
<td>Previous proximal aortic surgery</td>
<td>0.003</td>
<td>0.004</td>
<td>1.000</td>
<td>0.154</td>
</tr>
<tr>
<td>Compromised hemodynamics</td>
<td>0.003</td>
<td>0.004</td>
<td>1.000</td>
<td>0.154</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>0.660</td>
<td>0.156</td>
<td>0.033</td>
<td>0.154</td>
</tr>
<tr>
<td>Peripheral artery disease</td>
<td>0.003</td>
<td>0.004</td>
<td>1.000</td>
<td>0.154</td>
</tr>
<tr>
<td>Compromised hemodynamics</td>
<td>0.003</td>
<td>0.004</td>
<td>1.000</td>
<td>0.154</td>
</tr>
<tr>
<td>Compromised hemodynamics</td>
<td>0.003</td>
<td>0.004</td>
<td>1.000</td>
<td>0.154</td>
</tr>
</tbody>
</table>

### Intraoperative variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall</th>
<th>AAD</th>
<th>CAD</th>
<th>TAA</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPB duration</td>
<td>0.012</td>
<td>0.036</td>
<td>0.316</td>
<td>0.186</td>
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</tbody>
</table>

### Multivariate analysis

| Compromised hemodynamics      | 0.001   |

| CPB duration                  | 0.016   |

Jakob et al, EJCTS 2017
E-novia Concept

One hemostatic suture line for Arch + Descending Ao.
E-novia in Acute Type I AD

68y, male, Visceral ischemia since 8 hours with hematemesis, free rupture Asc.
Design E- novia 2nd Generation

Lessons learned

Technical modifications:

- Uncovered stent remains crimped within the longer covered stent during release
- Uncovered Stent mobile within the covered stent
- Additional 5 – 10mm tissue bridge at the concavity
- Modified nitinol mesh angle and better memory characteristics for better expansion and significant reduction of thrombogenicity

Successful mechanical durability testing
E-novia 2\textsuperscript{nd} Generation
CT – Case 2 (Zone 2-Concept)

2D-MPR

Branciocephalic trunk

Left Carotid Artery
Unknown Perspectives / Suspected Shortcomings

Radial + longitudinal aortic movement
Prevention of Type I Endoleak
New Concepts

- E-novia
- E-vita open NEO
The E-Vita Open NEO Concept

Ascending + Arch Aortic Repair with 2 anastomoses
Combining debranching with E-vita open principle

- Suture line in Zone 0, no touch arch principle
- Stentgraft length 16 – 19 cm
- Trifurcation graft (Spielvogel type)
- Separate Perfusion port lower body
- Short introducer
- Maximum flexibility, easyness of surgery
- Short ischemic times
STENT GRAFT DESIGN

ø26, 28, 30

ø22 bis 40

Ø12

30mm

ø14

95

47

60

130 - 140

Ø8

ø10

Ø8

0

47

60

95
E-vita open NEO
90° Rotation of the Trifurcation
FET - Gold Standard in Complex Aortic Arch Surgery?

- durable repair
- at low risk in experienced centers
- shortened period of hypothermic arrest
- shortened CPB time
- applicable in elective and emergency cases
- perfect docking for open and endo reintervention
Conclusion

The E-Vita Open Plus, E-Novia and E-Vita Open NEO will represent a family of graft variations to enable us to deal with all kinds of pathologies of the arch, but remains open surgery...
Total aortic endovascular repair versus open surgery

• Currently in early phase of application in selected centers with great interventional experience for a highly selected patient population

Today: Open Gold Standard

But …
The Future: Open Surgery embraces Endovascular
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Chronic Type A Aortic Dissection (AD)

St. p. prox. ao. repair for acute Type I AD

Patent false lumen distally ~ 70 - 89%

- Aortic growth
- Aortic rupture
- Malperfusion

Redo Surgery at 5 - 12 yrs: 16 – 39%

Glauber, Murzi 2010
Park 2009, Ishihara 2009
Zierer 2007
Geirsson, Bavaria 2007
Kirsch 2002
Whole body selective perfusion during arch replacement

Tsagakis, Jakob et al, MITAT, 2015

SACP 22°C (blood), 50-60 mmHg [steroids]

Left axillary artery

Right axillary artery

Cooling 28°C (bladder)

Selective whole body perfusion 28°C

Separate circuit for selective perfusion of
- Left subclavian/axillary artery
- Downstream aorta
Angioscopy to Secure Guide Wire Position and SG Deployment

Guide wire repositioning

Guide wire retrieval
Real World Experience

Retro-Type A after TEVAR for Complicated Type B
1st EACTS/ESVS
Endovascular Skills Course
Educational and Training Program
for Endovascular Skills
E-vita open NEO

• Facilitation of Surgery - Zone 0 Anastomosis

  Shortening of ischemic times

• Spielvogel type trifurcated head branches

  Maximum Flexibility, easiness
Zone 2 Arch Repair + Selective Distal Perfusion

Times Reduction

Current perfusion management - Results

<table>
<thead>
<tr>
<th>Metric</th>
<th>Median, min</th>
<th>SACP + LSA + SDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPB</td>
<td>225</td>
<td>N = 78</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>120</td>
<td></td>
</tr>
<tr>
<td>SACP</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>Visceral ischemia</td>
<td>31</td>
<td></td>
</tr>
</tbody>
</table>

SDP = Selective Distal Perfusion
E-vita open Neo® (Prototype)
E-novia 2nd Generation
CT Examinations

Case 1

Case 2
New hybrid graft (3-Zone Graft = E-novia) for fast asc. / arch and desc. aortic repair

Aim

Transfer of E-vita open zone 2 hemostatic sutureline to zone zero

Reduction of distal ischemic/SACP

Time < 20 min

Downstream splinting of TL

LZ for add. TEVAR/SURGERY

Components

<table>
<thead>
<tr>
<th>Ascending Ao</th>
<th>Arch</th>
<th>Descending Ao</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular graft</td>
<td>Uncovered Stent</td>
<td>Stentgraft (5cm)</td>
</tr>
</tbody>
</table>
01: Ausgangszustand
Draht und Gewebe, die das Implantat begrenzen

02: Start Freisetzung
Draht zurückgezogen (durch EFS)
Implantat teilweise geöffnet

03: Vollständige Freisetzung
Draht vollständig zurückgezogen (durch EFS)
Implantat geöffnet

EFS entriegelt und teilweise zurückgeführt

EFS vollständig zurückgeführt
E-vita Open
Sufficient Sealing for One Stage Repair

CAD, Marfan, 44y male, 204cm/115KG
St.p. prox. ao. replacement for AAD
New Entry in the arch (A)
Dissection in desc. ao. (B)

One stage treatment
E-vita open (28x130mm)

Anastomosis
No stented part
SG part

Distance to distal LZ
20cm