New Concepts And Data Regarding Frozen Elephant Trunk Procedures And The Thoraflex Graft (Vascutek/Terumo) In The Treatment Of Thoracic Aortic Disease

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Contemporary Traditional Open Repair
STAGE I                    STAGE II

Traditional Elephant Trunk + TEVAR Repair
STAGE I                    STAGE II
Retrograde delivery
of the stent graft

Frozen Elephant Trunk : New Concept and data
Hemiarch with antegrade stent delivery DOES NOT INVOLVE IMPLANTATION OF THE HEAD VESSELS. We don't consider it FET

Mortality of Elephant Trunk
Cumulative Mortality Table Summary

<table>
<thead>
<tr>
<th></th>
<th>1st Stage Mortality</th>
<th>Interval or Nonreturning Mortality</th>
<th>2nd Stage Mortality</th>
<th>All Cause Total Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.3 – 13.9%</td>
<td>0 – 24.6%</td>
<td>0 – 10.0%</td>
<td>8.3 – 35.8%</td>
</tr>
</tbody>
</table>

Etz et al, 2008
Laurent et al, 2009
Svensson et al, 2004
Heinemann et al, 1995
Safi et al, 2005
Sundt et al, 2004

Disclosures
Preventza: Consultant Medtronic, Gore, travel expenses paid by Cook
Frozen Elephant Trunk (FET) is created with antegrade delivery of a c-TAGs Gore endograft inside the marking graft (8 cm) of the ET during the circulatory arrest.

New Concepts And Data Regarding Frozen Elephant Trunk Procedures

- **1 STAGE REPAIR**
  - Total arch replacement with frozen elephant trunk technique
  - Preventza, Coselli et al: Ann Cardiothorac Surg 2013 2(5);649-652

- **2 STAGE REPAIR**
  - Preventza, Coselli et al: Ann Cardiothorac Surg 2013 2(5);649-652

### Short-term Outcomes

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Total Cohort</th>
<th>t-ET</th>
<th>FET</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permanent total neurological</td>
<td>18 (7.8)</td>
<td>7 (7.4)</td>
<td>3 (0.1)</td>
<td>1.00</td>
</tr>
<tr>
<td>spinal cord ischemia transient</td>
<td>5 (3.9)</td>
<td>3 (3.3)</td>
<td>2 (0.4)</td>
<td>0.62</td>
</tr>
<tr>
<td>permanent</td>
<td>1 (0.8)</td>
<td>1 (1.1)</td>
<td>0 (0.0)</td>
<td>1.00</td>
</tr>
<tr>
<td>transient stroke</td>
<td>7 (5.4)</td>
<td>3 (3.8)</td>
<td>2 (5.4)</td>
<td>1.00</td>
</tr>
<tr>
<td>permanent stroke</td>
<td>3 (2.1)</td>
<td>1 (1.1)</td>
<td>1 (0.0)</td>
<td>0.20</td>
</tr>
</tbody>
</table>

Methods

- 2010-2015
- IRB approval by BCM
- 129 patients:
  - 92 underwent traditional Stage I repair (t-ET)
  - 37 had the simplified FET procedure
- Pathology treated:
  - atherosclerotic aneurysm (mFET)
  - chronic dissecting aneurysm (mFET)

Outcomes:

- 37.0% vs. 48.1%
- Transient stroke
- Permanent total neurological
- Spinal cord ischemia transient
- 1.00
- 1.00
- 1.00
- 1.00
- 0.62
- 1.00
- 1.00


*All patients were treated with the Gore aortic stent graft (GORE® Endovascular, Santa Cruz, CA).*
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Changes over time/ “Fine Tuning” of the operative technique

- We avoid single-stage repair (fear of spinal cord injury)
- Procedure performed in the regular and not the hybrid operating room
- No need for fluoroscopy or dye

Preventza, Coselli et al:

100 cases FET

Preoperative

- Acute dissection: 37
- Chronic dissection: 31
- Aneurysm: 32

Postoperative

- Early death: 7%
- Stroke: 9%
- Paraparesis: 7%
- Dialysis: 14%

Shrestha et al. The Journal of Thoracic and Cardiovascular Surgery - July 2014

Advantages

- Allows single-stage repair
- Facilitates TAAA reintervention
- Reduces need for additional distal repair
- Branched FET simplifies reconstruction of arch vessels

Disadvantages

- Increased risk of SCI
- Technically demanding
- Cost of device
- Only 1 branched FET currently available

Evolution of FET: Technical Improvements

Branched FETs simplifies reconstruction of arch vessels

Shrestha et al. The Journal of Thoracic and Cardiovascular Surgery - July 2014

Frozen Elephant Trunk: Devices

One piece

Evita

Evita plus

Thoraflex

Evolution of FET: Technical Improvements

Sponsor Terumo CVS in collaboration with Vascutek Ltd.

NCT02724072

Trial Start Date August 22, 2016

Estimated End Date July 2019 (Final data collection date for primary outcome measure); July 2021 (Estimated completion date)

Enrollment 40 subjects as of October 2017 (Estimated total enrollment: 83)

Principal Investigator Joseph S. Coselli, MD (Baylor College of Medicine, Houston, TX)

Clinical Sites (12) Baylor College of Medicine, Northwestern, Mount Sinai, Cleveland Clinic, University of Michigan, UPMC, Emory, UT Houston, UPenn, Columbia, Stanford

Indication Treatment of aortic disease affecting the aortic arch and the descending thoracic aorta, with or without involvement of ascending aorta. Conditions include:

- Aortic Aneurysm
- Aortic Dissection
- Aortic Rupture
Conclusions

- FET approaches with hybrid devices hold promise
  - Simplify ET repair with a single device
  - Permits flexible, contemporary open arch repair
  - Readily extends aorta repair distally
  - Long-term evaluation is necessary
  - Judicious use is needed
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