Endospan Nexus for Zone 1 Disease of the Aortic Arch

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Disclosures: Dr. Andrew Holden

- Dr. Holden is a Medical Advisory Board Member for Medtronic, Boston Scientific, and Gore
- Dr. Holden is a Clinical Investigator for Medtronic, Boston Scientific, Gore, Abbott, Cagent, Endologix, Intact Vascular, Shockwave, Bard, Cook, Endospan, Intervene, Spectranetics, TriReme, Merit, Reflow, Terumo, Surmodics
- No other relevant disclosures
### Background – Current Approaches to Zone 0/1 Aortic Arch Disease

#### Open Repair
- Sternotomy required, bypass, body cooling
- 30-day mortality 8%
- Peri-procedural stroke 8%

#### Hybrid Repair: TEVAR with Debranching +/- Elephant Trunk
- Limited experience
- 30-day mortality 8 – 12%
- Peri-procedural stroke 6 – 8%

#### Fenestrated/Branch Endovascular Solution

#### TEVAR with Parallel Grafts
The Nexus™ Concept

Modular, Tubular Stentgraft System

- Aortic Arch Stent Graft
  - Integrated Branch
  - High resistant intra-modular connection of mean 20N (SD±3) (ref 10N)

- Ascending Stent Graft
  - Curved oriented ascending module
  - Inwardly bent cranial struts apesies
Nexus™ Key Deployment Steps

BCT & Main Module Deployment

- Main Module on through & through guidewire

Intra-modular Connection positioning

- Oriented to Ascending Aorta

Ascending Module

- Ascending Module release

Completed Deployment

- Ascending Module locked and deployed

CAUTION: NEXUS™ is approved for use in the European Union only and may be restricted for use in other territories
Nexus™ CE Submission Cohort

- Prospective, open-label, non-randomized single-arm and investigational clinical study
- Clinical and CTA follow-up for five-year post implantation
- Independent core lab Imaging review and CEC safety events adjudication
- 25 Patients with single branch Nexus with mean follow-up of 25 months on October 2019
- CE-mark: February 2019
Nexus™ Baseline Information CE Cohort

N=25

- Average Age (years): 73
  - Male Gender: 84%
    - Previous type A surgery (7)
    - Previous thoracic aortic surgery (13, 52%)
    - Previous TEVAR (6, 24%)

Indication for Nexus treatment:
- Aneurysm (15, 60%)
- Dissections (10, 40%)

Patient Co-morbidities

<table>
<thead>
<tr>
<th>Disease</th>
<th># of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>21 (80.8%)</td>
</tr>
<tr>
<td>Coronary disease</td>
<td>5 (19.2%)</td>
</tr>
<tr>
<td>COPD</td>
<td>8 (30.8%)</td>
</tr>
<tr>
<td>PVD</td>
<td>4 (15.4%)</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>2 (7.7%)</td>
</tr>
<tr>
<td>Previous CVA/TIA</td>
<td>2 (7.7%)</td>
</tr>
<tr>
<td>previous CABG</td>
<td>2 (7.7%)</td>
</tr>
<tr>
<td>Renal failure</td>
<td>2 (7.7%)</td>
</tr>
</tbody>
</table>
## Nexus™ Procedural Data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>25</td>
</tr>
<tr>
<td>Access successful</td>
<td>25 (100%)</td>
</tr>
<tr>
<td>Deployment successful</td>
<td>25 (100%)</td>
</tr>
<tr>
<td>Procedural survival</td>
<td>25 (100%)</td>
</tr>
<tr>
<td>Device implantation time (Nexus procedure) – Mean</td>
<td>68 min</td>
</tr>
<tr>
<td>Procedure time (skin to skin) – Mean</td>
<td>186 min</td>
</tr>
</tbody>
</table>
Procedural Steps: Clinical Case from Auckland

• 78 year old female patient
• Incidental finding of a 9cm saccular aneurysm of the aortic arch on routine CXR
• Not considered fit for open thoracic surgery
• Preliminary RCCA-LCCA-LScA bypass
• At that time, covered stenting of BCA plaque – BeGraft 16mm
Introduction of Main Component
Deployment of Main Component
Deployment of Main Component

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Deployment of Ascending Component
Deployment of Ascending Component
Deployment of Ascending Component
Left Subclavian Artery Embolization
Uneventful Recovery – CT 2 Weeks
## All Major Adverse Events < 30 days

<table>
<thead>
<tr>
<th>Event</th>
<th>&lt; 30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>2^a (8%)</td>
</tr>
<tr>
<td>Non-disabling Stroke</td>
<td>2^* (8%)</td>
</tr>
<tr>
<td>Disabling Stroke</td>
<td>0</td>
</tr>
<tr>
<td>Spinal Cord Ischemia</td>
<td>0</td>
</tr>
<tr>
<td>MI</td>
<td>0</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Conversion</td>
<td>0</td>
</tr>
</tbody>
</table>

^a Cause of Death:
- Cardiac arrest – day 7 post procedure
- Ventricular fibrillation – day 21 post procedure

* Both completely resolved by 30 days
## Major Adverse Events >30d (mean FU 25 months)

In which device relationship could not be ruled out*

<table>
<thead>
<tr>
<th>Event</th>
<th>&gt;30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>1 (4%)**</td>
</tr>
<tr>
<td>Non-disabling Stroke</td>
<td>0</td>
</tr>
<tr>
<td>Disabling Stroke</td>
<td>1 (4%)**</td>
</tr>
<tr>
<td>Spinal Cord Ischemia</td>
<td>0</td>
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<td>Renal Failure</td>
<td>0</td>
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<td>1 (4%)***</td>
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</tbody>
</table>

*Adjudication scale:*

- Not related
- Possible*
- Probable**
- Causal***

**2.5m post procedure CVA, and died 4 months post op
***3m post procedure partial conversion - retrograde type A dissection
Follow-up: mean 25.1mo (median: 24; r: 0-51; SD: 15)

No aneurysm rupture
No loss of device integrity
No device migration
96% stable size or decreasing

>30 days all cause mortality
- 3 non aortic cause
- 1 possible aortic cause
## Endoleaks

<table>
<thead>
<tr>
<th>Endoleaks</th>
<th>6 M</th>
<th>1 Yr</th>
<th>2 Yr</th>
<th>3yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Type III</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEXUS modules</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Overlap Nexus with additional distal extension</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Gutter EL* (Parallel Grafts)</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Unknown type</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* All GEL in patients implanted with parallel grafts (11 cases in the CE cohort had parallel grafts)
Conclusions

• Effective minimally invasive option for aortic pathology involving the aortic arch
• Approved Off-the-Shelf Solution
• Promising mid term results
• Low procedural time results in procedural predictability
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