Zenith Alpha AAA Endograft (Cook) 
Low Profile EVAR Device

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On behalf of the Zenith Alpha Abdominal Canadian investigators

Disclosure
- This study is sponsored by Cook Research Incorporated (ClinicalTrial.gov: NCT03061825)
- TLF – no personal financial conflicts, our Division receives financial support from Cook Medical in the form of unrestricted education grants

Background
- Around 50% of patients are unsuitable for endovascular repair based on iliac anatomy
- Women require an iliac conduit to facilitate device delivery much more often than men (28.6% of women versus 1.2% of men), possibly due to smaller iliac arteries
- The Zenith Alpha Abdominal Endovascular Graft provides an alternative treatment option using traditional endovascular graft deployment techniques through a lower profile (16 French or 17 French) introduction system
- It is expected that many patients with access vessels that are too small for introduction of the current stent-graft delivery systems, which are typically 18 to 24 French in diameter, will be treated with this device

Objective of This Presentation
- To report on preliminary results from 100 patients enrolled in a post-market study on the commercial use of the Zenith Alpha Abdominal Endovascular Graft

Device Description
- 3-piece modular design
- Zenith Alpha Abdominal Main Body (ZIMB)
  - Low profile woven polyester fabric
  - Self-expanding nitinol stents with braided polyester and monofilament polypropylene sutures
  - Gold markers on proximal edge of graft material, iliac limbs and at bifurcation to facilitate fluoroscopic visualization
- Zenith Alpha Spiral-Z Iliac Leg (ZISL)
  - Spiral external stent design (Spiral-Z)
  - Same materials as ZIMB
  - Discrete internal sealing stents

Device Deployment System
- Deployment
  - Low profile (16 French or 17 French) introduction system
  - The proximal bare stent and ipsilateral limb of the main body are tethered to the delivery system by wires, which are integrated into the handle and connected to dual locking mechanisms
- Features
  - Wire Guide Compatibility: 0.035 in
  - Flexor introducer sheath
  - Captor Hemostatic Valve

Study Design

- Prospective, multicentre, non-randomized, post-market study conducted in Canada
- Primary objective:
  - To evaluate the performance of the Zenith Alpha abdominal endovascular graft in a post-market setting
- 100 patients at up to 6 sites in Canada (maximum of 30 patients per site)
- Follow-up: Data will be collected for 2 years post-procedure according to each centre’s standard of care

Inclusion Criteria

- Eligibility:
  - Infrarenal abdominal or aorto-iliac aneurysm intended to be treated with the Zenith Alpha Abdominal Endovascular Graft (ZIMB and ZISL) in accordance with the IFU

Exclusion Criteria

- Patients are excluded from the study if they meet any of the following criteria:
  - Less than 18 years of age
  - Life expectancy less than 2 years
  - Inability or refusal to give informed consent by the patient or legally authorized representative
  - Unable or unwilling to comply with follow-up schedule
  - Marfan’s or connective tissue disorder
  - Leaking, pending rupture, or symptomatic aneurysm
  - Mycotic or inflammatory aneurysm
  - Uncorrectable coagulopathy
  - Previous open or endovascular repair of infrarenal aortic aneurysms
  - Post traumatic or anastomotic aneurysms

Primary Study Endpoint

- Device success, defined as:
  - Technical success
  - Freedom from:
    - Abdominal aneurysm rupture
    - Conversion
    - Type I/III endoleak
    - Graft limb occlusion
    - Abdominal aneurysm size increase >5 mm

Secondary Study Endpoints

- Procedural variables, clinical utility measures
- Abdominal aneurysm size change
- Type I/III endoleaks
- Device integrity
  - Fracture or covering tear of any portion of the stent or attachment system, including metallic fracture or barb separation
- Device patency
- Major adverse events
  - Re-intubation, bowel ischemia, renal failure requiring dialysis, Q-wave myocardial infarction, paralysis, stroke, all-cause death
- Secondary interventions

Enrollment

<table>
<thead>
<tr>
<th>Clinical Site</th>
<th>PI Name</th>
<th>Patients Enrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamilton General Hospital</td>
<td>John Harlock, MD</td>
<td>30</td>
</tr>
<tr>
<td>Nova Scotia Health Authority</td>
<td>Christine Herman, MD</td>
<td>25</td>
</tr>
<tr>
<td>Vancouver General Hospital</td>
<td>Jerry Chen, MD</td>
<td>18</td>
</tr>
<tr>
<td>Toronto General Hospital</td>
<td>Thomas Lindsay, MD</td>
<td>14</td>
</tr>
<tr>
<td>London Health Sciences CH/Victoria Campus</td>
<td>Adam Power, MD</td>
<td>13</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100</strong></td>
<td></td>
</tr>
</tbody>
</table>
Patient Characteristics

Data current as of 23 October 2018:

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Total (N = 100)</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>75.2 ± 7.4</td>
</tr>
<tr>
<td>Male (%)</td>
<td>88%</td>
</tr>
<tr>
<td>Female (%)</td>
<td>12%</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>5%</td>
</tr>
<tr>
<td>Black</td>
<td>2%</td>
</tr>
<tr>
<td>First Nations</td>
<td>1%</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>1%</td>
</tr>
<tr>
<td>White</td>
<td>91%</td>
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</tbody>
</table>

Comorbidities N = 100

- Coronary artery disease: 36%
- Chronic obstructive pulmonary disease: 21%
- Diabetes: 24%
- Renal failure requiring dialysis: 2%
- Smoking
  - Current: 24%
  - Prior: 59%
  - Never: 17%

Location of Treated Aneurysm N = 100

- Aorta (only): 80%
- Aortobiliac: 20%

Devices Deployed

<table>
<thead>
<tr>
<th>Device</th>
<th>N = 100</th>
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<tbody>
<tr>
<td>Main body graft + two leg grafts</td>
<td>100%</td>
</tr>
<tr>
<td>Right iliac leg graft extension</td>
<td>7%</td>
</tr>
<tr>
<td>Left iliac leg graft extension</td>
<td>7%</td>
</tr>
</tbody>
</table>

Procedural Measures

<table>
<thead>
<tr>
<th>Access method</th>
<th>N = 100</th>
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<tbody>
<tr>
<td>Percutaneous</td>
<td>77%</td>
</tr>
<tr>
<td>Cutdown</td>
<td>23%</td>
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</table>

<table>
<thead>
<tr>
<th>Anesthesia</th>
<th>N = 100</th>
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<tbody>
<tr>
<td>General</td>
<td>80%</td>
</tr>
<tr>
<td>Local</td>
<td>19%</td>
</tr>
<tr>
<td>Regional</td>
<td>1%</td>
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Procedural outcomes Mean ± SD

- Procedure time (min): 93.4 ± 41.7
- Fluoroscopy time (min): 15.3 ± 12.5
- Amount of contrast used (cc): 92.7 ± 32.6
- Duration of ICU stay (days): 0.2 ± 0.5
- Duration of hospital stay (days): 1.7 ± 1.6

Completion Angiography

- Proximal Type I endoleak in 2 patients
  - One patient resolved at first imaging follow-up visit
  - One patient awaiting first imaging follow-up to determine if unresolved
- No Type III endoleaks
- Unknown endoleak in 2 patients
  - One patient resolved at first follow-up visit
  - One patient had reported Proximal Type I endoleak at first imaging follow-up visit (POD 33), which had resolved at second follow-up visit (POD 133) with no need for reintervention.

Preliminary Clinical Outcomes

- 30-day outcomes (90 patients with available clinical follow-up)
  - All-cause mortality: 0
  - Re-intubation: 0
  - Bowel ischemia: 0
  - Renal failure requiring dialysis: 0
  - Q-wave MI: 0
  - Paralysis: 0
  - Stroke: 0

- No ruptures or conversion to open surgery
  - One secondary intervention
    - POD 1: prophylactic SMA angioplasty and stenting due to post-operative pain. Patient was clinically stable; reintervention was successful.
Initial Imaging Findings

• At Follow-up #1 (~1 month, 86 patients with available imaging)
  • Proximal type I endoleak: 1 patient
    • POD 33 – unknown endoleak noted at completion angiography as described earlier; no aneurysm growth; endoleak resolved spontaneously at next imaging follow-up.
  • No distal type I or type III endoleaks
  • No device integrity issues, component separation, or device migration
  • Limb occlusion: 1 patient
    • POD 43 – loss of patency in the right iliac leg graft; surgical bypass (left to right femoral-femoral crossover) performed on POD 70.

Conclusions

• Enrollment was completed for this post-market study of 100 patients.
• Percutaneous access was achieved in most patients. The average hospital stay was short.
• No 30-day mortality or other MAEs; no aneurysm rupture or conversion.
• Initial results of early clinical and imaging outcomes appeared favorable. Follow-up is ongoing.