Update On The Cook p-Branch OTS Device for Treatment Juxta and Pararenal AAAs

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Disclosure
• The Zenith p-Branch feasibility and pivotal studies are sponsored by Cook Medical
• Feasibility study: NCT01740700
• Pivotal study: NCT02396199

Zenith p-Branch Endovascular Graft

Off-The-Shelf Design with Two Configurations

Cook Zenith p-Branch Studies

Zenith p-Branch Feasibility Study (NCT01740700)
• Prospective, non-randomized, multicenter
• 30 patients at up to 10 sites in the US
• 5-year follow-up
• Objective
  • To assess procedural outcomes, clinical outcomes, and device performance
  • To refine patient selection and develop physician experience

Zenith p-Branch Pivotal Study (NCT02396199)
• Prospective, non-randomized, multicenter
• 82 patients at up to 30 sites in the US
• 5-year follow-up
• Objective
  • To evaluate the safety and effectiveness of the Zenith p-Branch
  • Primary safety and effectiveness endpoint: treatment success at 12 months

Zenith p-Branch Feasibility Study
• 30 patients enrolled at 10 US sites between January 2013 and June 2015

Demographics
- Mean ± SD (N = 30)
  - Age (years)
  - Male, % (n/N)
  - Maximum aneurysm diameter
  - Diameter at celiac artery
  - Diameter at SMA
  - Diameter at aortic bifurcation
  - Length
  - Proximal neck length

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Feasibility Study – Procedural Outcomes

- Technical difficulties in the first 2 cases at a same site
  - p-Branch was deployed below the renal arteries due to cannulation difficulties; no renal or SMA stents were placed; protocol defined technical failure, N = 1
  - Right renal stent could not be placed, N = 1
- An updated physician training/proctoring program was then implemented
- Technical success was achieved in all 28 subsequent patients

### Variable Mean ± SD (N = 30)

- Procedure time (min): 229 ± 70.5
- Total fluoroscopy time (min): 64 ± 26°
- Amount of contrast used (cc): 106.8 ± 68°
- Days to discharge: 3.6 ± 2.1

### 30-day mortality
- 0%

### Freedom from all-cause mortality
- 92.9 ± 4.9% at 1 year and 89.3 ± 5.8% 2 years

### No rupture of the study aneurysm or surgical conversion

### Mean study follow-up of 28.7 ± 12.5 months (as of October 2017)

Feasibility Study – Clinical Outcomes

- 3 deaths after 30 days, none related to p-Branch repair

### Days to Death Cause

- 234 Cerebral aneurysm
- 276 Dissection of a pre-existing proximal thoracic aortic aneurysm
- 640 Nonischemic dilated cardiomyopathy

Feasibility Study – Renal Artery Patency

- Primary patency of stented renal arteries: 89% ± 4% at 1 year and beyond

### ZFEN Multicenter Study (N = 67)

- Primary patency (elective group): 95% ± 2% at 1 year
- 91% ± 3% at 2 years
- 81% ± 5% at 5 years

### Farber et al. JVS 2017;66:982-90

- Primary patency (elective group): 94% ± 2% at 1 year
- 92% ± 3% at 2 years
- 90% ± 3% at 3 years

### Secondary Interventions (SI)

- SI overall: 32% (52/163) for p-Branch Feasibility Study (N = 28) excluding the first 2 cases, 32% (21/66) for p-Branch 4 Single-Center Study (N = 65), and 22% (15/67) for ZFEN Multicenter Study (N = 67)

- SI within 30 days: 11% (3/28) for p-Branch Feasibility Study (N = 28) excluding the first 2 cases, 8% (5/65) for p-Branch 4 Single-Center Study (N = 65), and 1% (1/67) for ZFEN Multicenter Study (N = 67)

- Mean study follow-up: 28.7 ± 12.5 months for SI overall

- Mean study follow-up: 25 ± 13 months for SI within 30 days

- Mean study follow-up: 37 ± 17 months for SI overall

### Zenith p-Branch Pivotal Study

- Study status
  - Enrollment began in November 2015
  - 62/82 (76%) enrolled as of October 2018
  - 28 active sites in the US
  - Preliminary information on 61 patients (enrolled as of May 1, 2018) is included in this presentation

### Top enrolling sites

- Mayo (S. Oderich) 9
- Stanford (J. Lee) 6
- Houston VA (P. Kougias) 6
- UAB (C. Abraham) 6
- UTMC (S. Timonen) 5
- Kaiser (S. Yano) 4
- UKBB (A. Schanzer) 4

### Site (P) Number of patients

- ZFEN Multicenter Study (N = 67)

- 25 ± 13 months

- 37 ± 17 months

### Cumulative rate, including all events during available follow-up

- Occlusion: 11% (3/28) for p-Branch Feasibility Study (N = 28), 12% (8/65) for p-Branch 4 Single-Center Study (N = 65), and 6% (4/67) for ZFEN Multicenter Study (N = 67)

- Stenosis requiring reintervention: 14% (4/28) for p-Branch Feasibility Study (N = 28), 8% (5/65) for p-Branch 4 Single-Center Study (N = 65), and 13% (9/67) for ZFEN Multicenter Study (N = 67)
### Pivotal Study – Preliminary Patient Characteristics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Mean ± SD (N = 51)</th>
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</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>70.9 ± 8.2</td>
</tr>
<tr>
<td>Male, % (n/N)</td>
<td>96.1% (49/51)</td>
</tr>
<tr>
<td>Diameter (mm)</td>
<td></td>
</tr>
<tr>
<td>Maximum aneurysm diameter</td>
<td>63.0 ± 11.4</td>
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<tr>
<td>Diameter at celiac artery</td>
<td>25.4 ± 1.9</td>
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<tr>
<td>Diameter at SMA</td>
<td>24.1 ± 2.2</td>
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<tr>
<td>Diameter at aortic bifurcation (inner-wall to inner-wall)</td>
<td>17.8 ± 4.1</td>
</tr>
<tr>
<td>Length (mm)</td>
<td></td>
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<td>Proximal neck length</td>
<td>22.1 ± 12.1</td>
</tr>
</tbody>
</table>

### Pivotal Study – Preliminary Procedural Results

<table>
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<tr>
<th>Variable</th>
<th>Mean ± SD (N = 51)</th>
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<tbody>
<tr>
<td>Procedure time (min)</td>
<td>258.4 ± 84.0</td>
</tr>
<tr>
<td>Total fluoroscopy time (min)</td>
<td>104.5 ± 120.4</td>
</tr>
<tr>
<td>Amount of contrast used (cc)</td>
<td>126.2 ± 68.9</td>
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<tr>
<td>Days in ICU</td>
<td>0.9 ± 1.3</td>
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<tr>
<td>Days to discharge</td>
<td>4.1 ± 5.2</td>
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</tbody>
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*Data from 50 patients

### Pivotal Study – Preliminary Clinical Outcomes

- **Within 30 days**
  - No deaths
  - No renal failure or bowel ischemia
  - No stroke, paraplegia, or paraparesis
  - No rupture of the study aneurysm or surgical conversion
  - Occlusion of fenestrated vessel: N = 3
    - Left renal artery occlusion reported on POD 23, POD 23, POD 30, respectively
    - Two patients underwent reintervention subsequently
    - None developed renal insufficiency or renal failure at the time of analysis

### Conclusions

- Patient selection, physician technical abilities, and proper device training will continue to be important for p-Branch implantation.
- From the feasibility study, early and intermediate results support the safety and feasibility of the off-the-shelf Zenith p-Branch device. Follow-up through 5 years is ongoing to assess long-term results.
- Enrollment is still ongoing in the pivotal study (< 20 cases to complete).