NEW HORIZON IN ENDOVASCULAR CARE: EARLY EXPERIENCE WITH AN INNOVATIVE BRANCHED DEVICE

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FACULTY DISCLOSURES

• Consulting*
  Cook Medical Inc., WL Gore, Bolton Medical, GE, Syncthax

• Research grants*
  Cook Medical Inc., WL Gore, GE Healthcare

• Investigational, off-label use of devices
  Cook Fenestrated and Branched Grafts, Gore Branched Technology

* All consulting fees and research educations grants paid to Mayo Clinic
AREAS OF CLINICAL NEED

- Arch
- Ascending
- TAAA
- Iliac
AREAS OF CLINICAL NEED

- Ascending
- Arch
- TAAA
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AREAS OF CLINICAL NEED

- Arch
- Ascending
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- Iliac
CLINICAL APPLICATION OF ZFEN

Maximum of 3 fenestrations

- 4-14mm neck
- 2/3 patients were excluded from US ZFEN trial due to insufficient neck length

FROM BENCH TO BEDSIDE…
TAMBE® DESIGN

26-31-37mm

20mm

31-37mm

20mm

170mm

215mm

MAYO CLINIC
Bifurcated device & Iliac limbs

23 mm

Trilumen catheter
## VBX® BALLOON EXPANDABLE STENT

<table>
<thead>
<tr>
<th></th>
<th>Viabahn</th>
<th>VBX</th>
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</thead>
<tbody>
<tr>
<td>Length</td>
<td>5, 7.5, 10-cm</td>
<td>39, 59, 79 mm</td>
</tr>
<tr>
<td>Diameter</td>
<td>6-9 mm</td>
<td>5-9 mm</td>
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<tr>
<td>Sheath profile</td>
<td>7-9 Fr</td>
<td>7-8 Fr</td>
</tr>
</tbody>
</table>

Pre-loaded wires & controlled proximal deployment
Sequential vessel catheterization using pre-loaded wires
TAMBE ANTEGRADE
First In-Man Implant Team
March 8th, 2016
0.035” Rosen Wire
7Fr Ansel Sheaths
6 mm x 59 mm VBX
RENAL 6X59 mm Balloon Expandable VBX
SMA & CELIAC VBX® STENTS
TAMBE EARLY FEASIBILITY TRIAL

National PI: Michel Makaroun MD
University of Pittsburg Medical Center

- 13 patients enrolled

<table>
<thead>
<tr>
<th>Site</th>
<th>Principal Investigator</th>
<th>Patients enrolled</th>
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<tbody>
<tr>
<td>Mayo Clinic</td>
<td>Gustavo Oderich MD</td>
<td>5</td>
</tr>
<tr>
<td>UNC</td>
<td>Mark Farber MD</td>
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<td>U Florianopolis</td>
<td>Pierre Silveira MD</td>
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<td>U Pittsburgh</td>
<td>Michel Makaroun MD</td>
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<td>Mount Sinai</td>
<td>Michael Marin</td>
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<tr>
<td>Dartmouth</td>
<td>Mark Fillinger MD</td>
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# 30-DAY & IN-HOSPITAL RESULTS

<table>
<thead>
<tr>
<th>Event</th>
<th>No. of Events</th>
<th>Overall</th>
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<tbody>
<tr>
<td>30-day Mortality</td>
<td>0</td>
<td>0%</td>
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<tr>
<td>Any MAE</td>
<td>4</td>
<td>31%</td>
</tr>
<tr>
<td>EBL &gt;1L</td>
<td>4</td>
<td>31%</td>
</tr>
<tr>
<td>eGFR &gt;50%</td>
<td>0</td>
<td>0%</td>
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<tr>
<td>New-onset dialysis</td>
<td>0</td>
<td>0%</td>
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<tr>
<td>Myocardial infarction</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Bowel ischemia</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>
EARLY RESULTS

- No 30-day or in-hospital mortality
- 51/52 target vessels stented (98%)
- 1 early Type Ic endoleak (Renal stent seal)
- No stroke, spinal cord injury or dialysis

- 3-month follow up completed in all patients
- No Type I or III endoleaks
- No target vessel occlusions
- 2 of 25 renal arteries required redo stenting for restenosis
CONCLUSIONS

- Side branch incorporation has expanded the indications of EVAR to patients with arch, thoracoabdominal and aortoiliac aneurysms.
- Preliminary data on the use of the TAMBE device demonstrates that the technique is safe with low morbidity.
- Important considerations are learning curve, need for optimal imaging and familiarity with advanced endovascular techniques.
- Larger clinical experience and longer follow up data are needed.
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150 Years SERVING HUMANITY