Role of Off-The-Shelf Fenestrated and Branched Grafts for Treating Aneurysms Involving the Visceral Segment of the Aorta (Cook p-Branch and t-Branch) Devices: What Percent of Patients are Suitable

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Disclosures

- Consultant:
  - WL Gore
  - Cook Medical
  - Bolton Medical
  - Endologix
- Research Support
  - Cook Medical
- Clinical Trial Support
  - Cook Medical
  - WL Gore

Goals for OTS Devices

- Reduce delivery time for device in elective cases
  - ZFEN: 3-4 week delivery time
- Manage acute aortic problems
  - Emergent TAAA presentation < 10% of all cases

Avoid significant treatment delays
Must be applicable to a significant proportion of the patients

Localization on SMA


Zenith p-Branch Device

Current Status of p-Branch

- Completed US Feasibility Trial
- Pivotal Trial Currently Enrolling in the US
- Comprise 82 patients at 30 sites
Off-the-Shelf Devices: Applicability for Juxta And Pararenal Aneurysms

- Determine the applicability of non-FDA approved OTS device to current patient population
- Study Dates: July 2012 and October 2013
- University of North Carolina Hospitals
- Prospectively Managed Database
- Aortic procedures
- Aneurysms were classified according to Crawford’s original description


Type IV TAAA (including paravisceral and juxtarenal)

- Eligible for implantation of Non-FDA approved "Off-the-Shelf" Device
- 23 (48%)

Pararenal Aneurysms

- 16 (35%)

Not Eligible for "Off-the-Shelf" Device

- 25 (52%)

p-Branch Applicability

<table>
<thead>
<tr>
<th>Study</th>
<th>Patient Cohort</th>
<th>Applicability Overall</th>
<th>Renal loc. *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original</td>
<td>353 Fen/CMD-Fen (CCF + EU)</td>
<td>N/A</td>
<td>76%</td>
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<tr>
<td>Sobocinski et al.</td>
<td>100 consec. Fen/CMD-Fen</td>
<td>N/A</td>
<td>72%</td>
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<tr>
<td>Mendes et al.</td>
<td>520 consec. OpenPM-Fen/Fen/CMD-Fen</td>
<td>33-49%</td>
<td>61%</td>
</tr>
<tr>
<td>Cheng</td>
<td>51 consec. Chinese Open/Fen/CMD-Fen</td>
<td>N/A</td>
<td>61%</td>
</tr>
<tr>
<td>Farber et al.</td>
<td>85 Type IV/Pararenal</td>
<td>45%</td>
<td>56%</td>
</tr>
<tr>
<td>Multicenter Study</td>
<td>Feasibility Study</td>
<td></td>
<td>35% ~75%</td>
</tr>
</tbody>
</table>

* Applicability of p-branch only evaluating renal position

p-Branch Applicability

- 66 patients presenting with TAAA
- Measurement made wrt SMA orientation
- 88% met restriction criteria based on angle, location, size and distance for target vessel

Standard Multi-Branch

- 85 Type IV TAAA (including paravisceral and juxtarenal)
- Eligible for implantation of Non-FDA approved "Off-the-Shelf" Device
- 23 (48%)

Pararenal Aneurysms

- 16 (35%)

Not Eligible for "Off-the-Shelf" Device

- 25 (52%)

Suitability for Endovascular TAAA Repair

- Analyzed 14 anatomic components to difficulty
- Results: 60% of TAAA would be suitable for B/FEVAR
- Exclusions:
  - arch angulation: 27%
  - DTA angulation: 26%
  - Visceral stenosis: 7-31%

**UNC Fenestrated/Branched Device Implants**

ZFEN + Physician Sponsored-IDE
All Complex Aneurysm Patients

<table>
<thead>
<tr>
<th>FY 13</th>
<th>FY 14</th>
<th>FY 15</th>
</tr>
</thead>
<tbody>
<tr>
<td>65</td>
<td>18</td>
<td>10</td>
</tr>
<tr>
<td>54</td>
<td>6</td>
<td>0</td>
</tr>
</tbody>
</table>

- **Mortality:** 1.6%
- **Procedural BV patency:** 99%
- All Complex Aneurysm Patients
- 2 patients presented with rupture while waiting for device (2 weeks)

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**Zenith Fenestrated Device**

**US Approval - April 2012 - First Year**

- FDA Approves Cook's Zenith Fenestrated AAA Endovascular Graft
- US Version
- US Approval - April 2012
- First Year

**Over 7,500 implants worldwide**
- Number of US Physicians Trained: 400
- Percentage of physicians ≤ 3 implants: 80%
- Percentage with > 10 implants: ~7.5%

- **Mortality:** 1.6%
- **Procedural BV patency:** 99%
- Dissections/Short Neck infrarenal AAA
- Occluded vessels
- Additional aortic coverage -> risk of SCI
- Staged Repair

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**OTS Devices**

OTS devices must not impart any significant increase in procedural risks to patient outcomes (mortality/target vessel patency)

- **Typical device delivery time is 3-4 weeks**
- Most elective cases are posted 7-14 days after clinic visit.
- Therefore treatment delay is 2 weeks
- Thue, for a 6 cm aneurysm (yearly rupture risk of 6-12%) 2 week delay —> 0.25 - 0.5% increased mortality risk

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**Custom Manufactured versus OTS**

- 46 pts (23 CMD, 22 OTS)
- Technical Success: 100%
- **Mortality:** C 8%/ O: 0% p=NS
- **Freedom from Re-intervention**
  - C:100% vs O: 90% p=0.07
  - all renal arteries

Not powered enough to detect a 0.5% difference in mortality

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**Emergency Procedures**

- **What about intact emergent cases?**
  - Encompasses less than 7% of cases
  - NSOP - Between 2005-2010
  - Elective: 418 Emergent: 32
  - Open Mortality 22%
  - Assume EV-OTS repair:
    - applicable to 50%
    - reduce mortality by 50%
  - Overall reduction in mortality by 5.5%

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**Issues**

- As of Spring 2012 Fenestrated options approved in the US
  - Device delivery time 3-4 weeks
  - **Patient Selection** is Critical
  - Must ensure near 100% target vessel success
  - Complications can lead to death
  - Limitations in the configuration design
  - Fenestration locations
  - Number of fenestrations
  - Maximal three fenestrations/scallops
  - US Version
Risk of CMD Delivery Delay

- If CMD production and delivery requires 4 weeks for typical delivery
- Assuming that most practices perform elective procedures (>95%)
  - 7-10 days after patient encounter
  - Results in a delay of 2-3 weeks for repair at most
- Risk of rupture for a 6 cm aneurysm (< 30 days)
  - ~ 0.5% - 1.0%
- Therefore, OTS devices must not increase the mortality risk associated with major complications > 1%

Conclusions

- Approximately 30-50% of patients will be eligible for some type of OTS device
- Minimal risks in waiting if CMD manufacturing times < 4 weeks
- Risk assessment of procedural risk vs. delay in tx risk
- OTS devices will have its greatest impact on emergent cases (minority of EV-TAAA cases)
- Goals: Optimize procedural outcomes by fitting the device to the patient