New branched and fenestrated devices for the aortic arch

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Chapel Hill, NC
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Disclosures

- **Cook Medical:**
  - Consulting, Clinical Trials Research Support

- **WL Gore:**
  - Clinical Trials, Consulting

- **Medtronic**
  - Clinical Trials, Consulting

- **Endologix:**
  - Clinical Trials, Consulting
Why Is Endo Repair of the Arch a Challenge

- Branch Involvement
  - Distance between branches and location of take off variable
  - Varies longitudinally and axially

- Arch angulation

- Ascending – descending aortic size discrepancy
  - Arch and descending aortic aneurysms
Other Problems Unique to the Arch

- Increased pressure and migration forces
- Coronary Arteries
- Imaging difficulty
- Dealing with the aortic valve and working in LV
- Monitor LV function
- Need for overdrive pacing for deployment
- Delivery system problems
How do we achieve arch branch preservation?

- Fenestrations
  - Standard
  - Custom
  - In situ creation

- Branches
  - Standard
  - Custom
Single Fenestration/Branch: Zone 1 or 2
Left Subclavian or left Carotid

Cook Zenith
Prox Fenestration

Medtronic
Valiant
Mona LSA

Inoue Graft
Single fen
Early Outcomes – but data is old

- 15 Patients
  - 14 single branched cases
  - 1 triple branched case
- 60% Primary Success (exclusion of aneurysm at first procedure)
  - 2 had access issues
  - 4 endoleaks
    - 2 major – one treated with graft extension
    - 2 minor – one spontaneously occluded.
- Mean follow-up 12.6 months
- 73% achieved complete thrombosis of aneurysm

Current Devices

- Gore TBE
- Cook A-branch
- Cook CMD Fenestrated
- In-Situ Fenestration
- Medtronic Mona-LSA
- Bolton Medical
- Inoue
- Najuta
- Nexus

Currently no approved FDA devices
Gore TBE
Device Overview

TBE Device

• Aortic Component
• Side Branch (SB) Component
• Aortic Extender (Optional)

Additional TBE accessory

• GORE® DrySeal Side Branch Introducer Sheath (SBIS)
**Procedural Steps**

**Step 1:**
- Insert guidewires in aorta and branch vessel

**Step 2:**
- Introduce aortic component over both guidewires into position within the arch

**Step 3:**
- Deploy aortic component and withdraw catheter

**Step 4:**
- Advance introducer sheath and dilator

**Step 5:**
- Advance and deploy branch component
Gore Side Branch Device

- Completed feasibility study
- PI: Michael Dake
- Enrollment:
  - Zone 2: 50 of 85 pts
  - Zone 0/1: ~20 pts
  - Phase I: Cervical debranching
  - Phase II: TSSB
- No strokes, death or SCI
- Pivotal Trial Enrolling Sept 2016: 175 pts
Preliminary Results from Multicenter Feasibility Trial

- N=22, Mean Age - 74.1
- Fusiform (10)
- Saccular (12)
- Zone 2
- L SCA Patency: 100%
- Type I endoleaks
  - Intra-Op: 18%
  - 1 month: 0%
- Survival: 94.7% @ 6 months

Preliminary Results from Multicenter Feasibility Trial

Branched Arch Endograft – Cook Medical

Custom graft
Pre-curved

Two Internal Branches
- Carotid Artery
  + Fluency
  + Vaibahn
- Innominate
  + Custom limb
  + 14 Fr sheath

Allows for preserved peri-graft flow

Haulon S et al., JTCVS 2014; epub
Anatomic Criteria (Generalized)

- Arch aneurysms and chronic dissections
- No prior aortic valve replacement
- Ascending aortic length $\geq 50$mm (STJ to IA)
- Sealing zone in Asc. Aorta $\leq 38$ mm in diameter
- IA: $\geq 20$ mm sealing length, $\leq 20$ mm diameter
- Iliac able to accommodate 22-24 Fr sheath

Haulon S et al., JTCVS 2014; epub
Global experience with an inner branched arch endograft

Stéphan Haulon, MD, PhD, a Roy K. Greenberg, MD, b Rafaëlle Spear, MD, a Matt Eagleton, MD, b Cherrie Abraham, MD, c Christos Lioupis, MD, c Eric Verhoeven, MD, PhD, d Krassi Ivancev, MD, e Tilo Kölbl, MD, PhD, f Brendan Stanley, MD, g Timothy Resch, MD, h Pascal Desgranges, MD, PhD, i Blandine Maurel, MD, a Blayne Roeder, PhD, j Timothy Chuter, MD, k and Tara Mastracci, MD b

- Pts: 38 with a mean age of 71
- Technical Success: 84.1%
- Mortality: 13.2%
- Cerebrovascular Complications: 15.8%

## Subsequent Results with Inner Branch

<table>
<thead>
<tr>
<th></th>
<th>Group 1 ((n = 38))</th>
<th>Group 2 ((n = 27))</th>
<th>(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Procedure</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length (min)</td>
<td>250 (210–330)</td>
<td>295 (232–360)</td>
<td>.35</td>
</tr>
<tr>
<td>X-ray time (min)</td>
<td>46 (32–84)</td>
<td>39.3 (34–61)</td>
<td>.07</td>
</tr>
<tr>
<td>Volume of contrast (mL)</td>
<td>150 (95–207)</td>
<td>183 (120–290)</td>
<td>.03</td>
</tr>
<tr>
<td><strong>Early post-operative</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endoleaks</td>
<td>11 (28.9%)</td>
<td>3 (11.1%)</td>
<td>.08</td>
</tr>
<tr>
<td>Secondary procedures</td>
<td>4 (10.5%)</td>
<td>4 (14.8%)</td>
<td>.61</td>
</tr>
<tr>
<td>Cerebrovascular events</td>
<td>6 (15.8%)</td>
<td>3 (11.1%)</td>
<td>.60</td>
</tr>
<tr>
<td>Systemic complications</td>
<td>17 (44.7%)</td>
<td>13 (43.3%)</td>
<td>.79</td>
</tr>
<tr>
<td>Mortality</td>
<td>5 (13.2%)</td>
<td>0 (0%)</td>
<td>.05</td>
</tr>
<tr>
<td>Follow up ((n = 33))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endoleaks</td>
<td>3 (9.1%)</td>
<td>2 (7.4%)</td>
<td>.82</td>
</tr>
<tr>
<td>Secondary procedures</td>
<td>3 (9.1%)</td>
<td>2 (7.4%)</td>
<td>.82</td>
</tr>
<tr>
<td>Mortality</td>
<td>4 (12.1%)</td>
<td>1 (3.7%)</td>
<td>.24</td>
</tr>
<tr>
<td>Overall mortality</td>
<td>9 (23.6%)</td>
<td>1 (3.7%)</td>
<td>.02</td>
</tr>
</tbody>
</table>


Learning Curve

- Compared first 10 patients to last 28 patients
  - Similar demographics
  - Improved outcomes
    - Intraoperative complications: 40% v. 10.7%
    - All secondary procedures: 40% v. 10.7%
    - Early secondary procedures for endoleak: 20% v. 0%
    - All secondary procedures for endoleak: 30% v. 0%
    - Operative time (min): 320 v. 248
    - Radiograph duration (min): 120 v. 39

Haulon S et al., JTCVS 2014; epub
Cook Zenith
Fenestrated CMD
Bilateral Ca-SCA Bypass
Cook Arch Branch and VBX
Total Endovascular Arch Repair
Cook Arch Device

- Third retrograde portal
- Pre-catheterized
- Post-dissection Aneurysms
- N=3
- Patency 6 months: 100%
Device Design

NON STANDARD DEVICE REQUEST - PROPRIETARY COOK MEDICAL

BRANCH-ASCENDING-ARCH-DEVICE
THORACIC-ASCENDING-BRANCH

INTERNAL LOW PROFILE SIDEBRANCH #1
DIAMETER: 12 mm
LENGTH: 21 mm
DIST FROM PROX EDGE: 39 mm
CLOCK: 12:30

INTERNAL LOW PROFILE SIDEBRANCH #2
DIAMETER: 8 mm
LENGTH: 21 mm
DIST FROM PROX EDGE: 59 mm
CLOCK: 11:30

INTERNAL LOW PROFILE SIDEBRANCH #3
*Upwards Facing*
*Preloaded Catheter & Guidewire*
DIAMETER: 10 mm
LENGTH: 21 mm
DIST FROM PROX EDGE: 16 mm
CLOCK: 12:30

- 2 x sets of DIAMETER REDUCING TIES
- SPIRAL STABILISING WIRE
- STAGED RELEASE
- CURVED NITINOL CANNULA & FLEXOR SHEATH
- LOW PROFILE FABRIC

Pls:
ZTA-PT-36-32-161-W

SIDE BRANCH 1, 2, 3
INTERNAL LOW PROFILE SIDEBRANCH with STRAIGHT NITINOL WIRE

Please note the following: 1. By signing this graft plan you are confirming that the patient has consented to the provision of their personal information to Cook Medical. The patient understands that in order to plan and manufacture the requested device, Cook Medical may share his/her personal information with other Cook Group companies in the United States, Australia, Denmark, United Kingdom and Ireland and has consented to his/her personal information being so shared. 2. You are confirming that all important features i.e. penetration site/orientation, gold marker placement, sealing stents are included in this graft plan prior to your device.
In-Situ Laser Fenestration

- **N=41** (39 LSCA, 2 LCCA)
- Operative Mortality: 7.3%
- Neurologic Complications:
  - Stroke: 2 (4.9%)
  - SCI: 3 (7.3%, 2 permanent, 1 transient)
- No Type III endoleaks
- Type Ic: 3 7.3%
- All stents patent
  - 2 asymptomatic stenosis

Medtronic Mona-LSA

- 9 subjects enrolled
- Four (50%) endoleaks in 8 pts
  - Type II - 2
  - Undetermined - 2
- Major strokes: 0
- Minor strokes: 4 (3 pts - 33%)
- No L arm ischemia or deaths @ 30 days
Branched Arch Endograft
Bolton Medical

Piffarreti G et al., J Vasc Surg 2013; 57: 1664
Thoracic Branch Technology with Relay® Branch

- Based on Relay NBS (Non-Bare Stent) Plus platform

- “Off-the-shelf” (various proximal diameters, standard branch position and endograft length)

- Large single window for ease of cannulation of 2 internal tunnel(s)

- Innominate and LCCA

- Intended for Zone 0 deployment combined with extra-anatomic arch branch bypass as required
Relay NBS Plus Platform Technology has Allowed for Development and Clinical Use of Thoracic Branch Technology

- Patented proximal capture technology
- Improved arch conformation and prevention of retroflex deployment
- Self-orienting pre-curved NiTi guidewire lumen
- Dual sheath design facilitates advancement into Zone 0
Worldwide Clinical Experience

Single Branch (n=5):

- Patients treated via Custom Made Program
- 5 patients from initial feasibility experience (5 centers)
- Limited experience since the initiation of the Double Branch phase

Double Branch (n=101*):

- Patients treated via Custom Made Program (20 centers)

* Experience as of 10/1/2017
Inoue Arch Graft

- N=89
- Single-64
- Double-18
- Triple-7
- Mortality (30d): 4.5%
- Stroke: 16%
- Branch Occlusion: LSCA-1
- ACM @ 1 and 5 yrs: 85%/59%

Najuta Next-gen Fenestrated TEVAR
(Kawasumi Lab, Inc. Tokyo, Japan)

Yokoi Y et al., JTCVS 2013; 145: S103
Najuta Results

- N=54 (Jan 2008 - May 2016)
- Operative Mortality: 3.7% (embolic, resp failure)
- Stroke: 5.5%
- Survival 75% @ 41.4 months
- Endoleak: 7.4% (I, II, III, V)
- Secondary Interventions: 5.5%

Nexus Endospan Aortic Branched Graft Graft

- Comprised of a curved aortic component
- Ascending Component

Anatomic Criteria

• Exclusion
  • Prox and Dist landing zone > 42 mm
  • All supra-aortic branches involved in aneurysm wall
  • Prohibitive occlusive disease
• Required
  • Adequate proximal seal zone between supra-aortic branches and lesion on aortic wall
  • Minimal length depends on arch pathology
  • Proximal landing zone ≥ 10 mm
• 19 types of curved stent skeletons
• 8 types of graft fenestrations

Azuma T et al., Eur J Cardiothor Surg 2013; 44: e156
## Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Najuta Graft</th>
<th>Cook Graft</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time of Study</strong></td>
<td>2010-2011</td>
<td>2009-2013</td>
</tr>
<tr>
<td><strong>No. Patients</strong></td>
<td>393</td>
<td>38</td>
</tr>
<tr>
<td><strong>No. Centers</strong></td>
<td>35</td>
<td>10</td>
</tr>
<tr>
<td><strong>Patient Demographics</strong></td>
<td>NR</td>
<td>As expected</td>
</tr>
<tr>
<td><strong>ASA Class of 3 or 4</strong></td>
<td>NR</td>
<td>89.5%</td>
</tr>
<tr>
<td><strong>Proximal Aortic Diameter (mm)</strong></td>
<td>33.7±3.7</td>
<td>34 (32-38)</td>
</tr>
<tr>
<td><strong>Proximal Graft Diameter (mm)</strong></td>
<td>NR</td>
<td>40 (38-46)</td>
</tr>
<tr>
<td><strong>Mean Prox. Seal Length (mm)</strong></td>
<td>14.2±5.1</td>
<td>NR</td>
</tr>
<tr>
<td><strong>Location Proximal Landing Zone</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Zone 0</td>
<td>376 (95.5%)</td>
<td>38 (100%)</td>
</tr>
<tr>
<td>- Zone 1</td>
<td>15 (3.8%)</td>
<td></td>
</tr>
<tr>
<td>- Zone 2</td>
<td>2 (0.5%)</td>
<td>38 (100%)</td>
</tr>
<tr>
<td><strong>Card Output Modulation</strong></td>
<td>0</td>
<td>38 (100%)</td>
</tr>
</tbody>
</table>

Azuma T et al., Eur J Cardiothor Surg 2013; 44: e156
Haulon S et al., J Thorac Cardiovasc Surg 2014; epub
## Outcomes

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<tr>
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<tbody>
<tr>
<td><strong>Left Subclavian Artery</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Covered and occluded</td>
<td>281 (71.5%)</td>
<td>0</td>
</tr>
<tr>
<td>- Bypassed</td>
<td>17 (4.3%)</td>
<td>30 (79%)</td>
</tr>
<tr>
<td>- Separated</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Conduit</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Iliac</td>
<td></td>
<td>13 (34%)</td>
</tr>
<tr>
<td>- Right Axillary</td>
<td></td>
<td>8 (21%)</td>
</tr>
<tr>
<td>- NR</td>
<td></td>
<td>5 (13%)</td>
</tr>
<tr>
<td><strong>Duration of Procedure (min)</strong></td>
<td>NR</td>
<td>250 (210-330)</td>
</tr>
<tr>
<td><strong>Technical Success</strong></td>
<td>99.2%*</td>
<td>84.2%</td>
</tr>
<tr>
<td><strong>Initial Success</strong></td>
<td>95.4%**</td>
<td>84.2%</td>
</tr>
<tr>
<td><strong>ICU LOS (days)</strong></td>
<td>NR</td>
<td>2 (1.5-4)</td>
</tr>
<tr>
<td><strong>Hospital LOS (days)</strong></td>
<td>NR</td>
<td>10 (7.5-15.5)</td>
</tr>
</tbody>
</table>

*Able to deliver and deploy the graft; **No initial type 1 or 3 endoleaks

3 deaths within 24 hours
1 type 1 endoleak
1 failure to catheterize IA branch
1 conversion to chimney technique

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Haulon S et al., J Thorac Cardiovasc Surg 2014; epub
### Outcomes

<table>
<thead>
<tr>
<th>Najuta Graft</th>
<th>Cook Graft</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 1.5% 30-day mortality</td>
<td>• 13.5% 30-day mortality</td>
</tr>
<tr>
<td>Multiple embolisms</td>
<td>Cardiac arrest at induction</td>
</tr>
<tr>
<td>Stroke</td>
<td>Hemorrhagic shock</td>
</tr>
<tr>
<td>Ascending dissection</td>
<td>MI</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>Pulmonary infection</td>
</tr>
<tr>
<td>Aneurysm rupture (type 1 EL)</td>
<td>Unknown etiology</td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
</tr>
<tr>
<td>• 1.7% Neurologic Event</td>
<td>• 13.5% Neurologic Event</td>
</tr>
<tr>
<td>• 0.76% Paraplegia</td>
<td>4 TIA</td>
</tr>
<tr>
<td></td>
<td>1 Stroke</td>
</tr>
<tr>
<td></td>
<td>1 Meningeal hemorrhage</td>
</tr>
<tr>
<td></td>
<td>• 0 Paraplegia</td>
</tr>
</tbody>
</table>

Azuma T et al., Eur J Cardiothor Surg 2013; 44: e156
Haulon S et al., J Thorac Cardiovasc Surg 2014; epub
Early Endoleaks

**Najuta Graft**
- 4.6% type 1 or 3 endoleak
  - Larger proximal aortic diameter
  - Longer length of aneurysm treated
- No other information provided

**Cook Graft**
- 11 (29%) on pre-discharge CT
  - 5 proximal type 1
  - 3 type 2
  - 1 type 3
  - 2 unknown etiology
- 2 Early interventions for EL
  - PTA of type 3 leak
  - Plug in origin of IA
- At 6 months
  - 1 type 1 spontaneously resolved
  - None with type 2 had sac growth
  - Indeterminants resolved

Azuma T et al., Eur J Cardiothor Surg 2013; 44: e156
Haulon S et al., J Thorac Cardiovasc Surg 2014; epub
Follow Up

• No follow up is provided for the Najuta Graft

• **Cook Graft**
  
  • Median FU = 12 mos. (6-12)
  
  • 9.1% secondary procedures
    
    • 1 conversion to open surgery – kink in ascending aortic graft causing coarctation
    
    • 1 PTA/stent of LCC branch partially obstructed
    
    • 1 coil embolization and gluing of type 1 endoleak
  
  • 12.1% Late Mortality
    
    • Pneumonia
    
    • Sepsis
    
    • Ruptured AAA
    
    • Hemorrhagic stroke
    
    • No aortic arch-related mortality

Azuma T et al., Eur J Cardiothor Surg 2013; 44: e156
Haulon S et al., J Thorac Cardiovasc Surg 2014; epub
Conclusions

- Promising early results
- Designs are consolidating, and likely amenable to a broadly applicable standard design
- Techniques require proficiency with cardiac based interventions, as well as endovascular aortic interventions
- High volume aortic centers with open cardiac surgical programs are optimal for assessing and further development of these technologies
- Procedural stroke remains a significant issue
- Require longer-term outcomes to assess durability