LONGTERM RESULTS OF BRIDGING STENTS IN FENESTRATED & BRANCHED ENDOVASCULAR REPAIR

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Chair, Vascular and Endovascular Surgery
Professor of Surgery
Director of Aortic Center
Gustavo S. Oderich

- Consulting: Cook Medical Inc., WL Gore and GE Healthcare
- Research grants: Cook Medical Inc., WL Gore, GE Healthcare

* All consulting fees and grants paid to Mayo Clinic
STENT GRAFT DESIGNS

Off-the-Shelf
Cook t-Branch®
Cook p-Branch®
Gore TAMBE®
Medtronic

Patient Specific
Cook platform
Jotec
Terumo Aorta
Fenestrated and branched endovascular aneurysm repair outcomes for type II and III thoracoabdominal aortic aneurysms

Matthew J. Eagleton, MD, Matthew Follansbee, BS, Katherine Wolski, MPH, Tara Mastracci, MD, and Yuki Kuramochi, BScN, Cleveland, Ohio

2-year Kaplan-Meier Estimates

<table>
<thead>
<tr>
<th></th>
<th>Primary patency</th>
<th>Secondary patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celiac axis</td>
<td>98%</td>
<td>99%</td>
</tr>
<tr>
<td>SMA</td>
<td>97%</td>
<td>99%</td>
</tr>
<tr>
<td>R renal artery</td>
<td>94%</td>
<td>99%</td>
</tr>
<tr>
<td>L renal artery</td>
<td>93%</td>
<td>99%</td>
</tr>
</tbody>
</table>
Twelve-year results of fenestrated endografts for juxtarenal and group IV thoracoabdominal aneurysms

Tara M. Mastracci, MD, Matthew J. Eagleton, MD, Yuki Kuramochi, BScN, Shona Bathurst, and Katherine Wolaki, MPH, Cleveland, Ohio

<table>
<thead>
<tr>
<th>Renal stent occlusion</th>
<th>n (Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>22 (1.9%)</td>
</tr>
</tbody>
</table>
DIRECTIONAL BRANCHES IN TAAAS

Standard off-the-shelf versus custom-made multibranched thoracoabdominal aortic stent grafts

Charlene C. Fernandez, BS, Julia D. Sobel, BS, Warren J. Gasper, MD, Shant M. Vartanian, MD, Linda M. Reilly, MD, Timothy A. M. Chuter, MD, and Jade S. Hiramoto, MD, San Francisco, Calif

133 patients with 235 renal directional branches

CUMMULATIVE EVENT RATE

<table>
<thead>
<tr>
<th>(Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean follow up (days)</td>
</tr>
<tr>
<td>Occlusion or stenosis requiring intervention</td>
</tr>
</tbody>
</table>
RENAL OUTCOMES WITH FENESTRATIONS OR BRANCHES

Mid-term Outcomes of Renal Branches Versus Renal Fenestrations for Thoraco-abdominal Aneurysm Repair


- 449 patients with 856 renal arteries
  - 445 branches and 411 fenestrations
- Mean follow up, 19 months
- Renal branch stents ~60% self-expandable and 40% BES

<table>
<thead>
<tr>
<th></th>
<th>Fenestrations</th>
<th>Branches</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-year freedom from</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occlusion</td>
<td>97%</td>
<td>90%</td>
<td>0.01</td>
</tr>
<tr>
<td>Reintervention</td>
<td>99%</td>
<td>92%</td>
<td>0.03</td>
</tr>
<tr>
<td>Branch instability</td>
<td>98%</td>
<td>86%</td>
<td>0.01</td>
</tr>
<tr>
<td>&gt;20% decline eGFR</td>
<td>37%</td>
<td>43%</td>
<td>NS</td>
</tr>
<tr>
<td>Mortality</td>
<td>82%</td>
<td>73%</td>
<td>NS</td>
</tr>
</tbody>
</table>
PHYSICIAN PREFERENCE & TYPE OF INCORPORATION

FENESTRATIONS

BRANCHES
VARIATIONS IN USE OF DIRECTIONAL BRANCHES

- Lille: 255 patients, 16% treated
- Nuremberg: 71 patients, 30% treated
- St Thomas: 29 patients, 55% treated
- Malmo: 53 patients, 63% treated
- Royal Free: 41 patients, 78% treated
SELECTION OF FENESTRATIONS OR BRANCHES

Small lumen

Large lumen

Small lumen

Large lumen
PROBLEMS WITH F-BEVAR LITERATURE

- Variations on definitions of end-points
- Physician bias towards fenestrations or branches
- Significant variations on selection of bridging stent type
- Underreporting on bridging stent type
- Lack of reporting on key outcomes such as primary patency, target vessel instability, endoleaks and secondary interventions
Durability of branches in branched and fenestrated endografts

Tara M. Mastracci, MD, Roy K. Greenberg, MD, Matthew J. Eagleton, MD, and Adrian V. Hernandez, PhD, Cleveland, Ohio

- Composite of any branch-related event:
  - Death or aneurysm rupture
  - Occlusion
  - Reintervention for:
    - Type IC or IIIC endoleak
    - Stenosis or kink
    - Disconnection, fracture or integrity issues
REVISED ENDOLEAK CLASSIFICATION (SVS REPORTING STANDARD)

- Type IA
- Type IIIB (Tears...)
- Type IIIC (Branch)
- Type IIIC (Branch)
- Type IC (Branch)
- Type II
- Type IIA (Inter component)
Target Artery Outcomes After Branched and Fenestrated Endovascular Repair of Pararenal and Thoracoabdominal Aortic Aneurysms in the US IDE Experience

Darren B. Schneider, Gustavo S. Oderich, Mark A. Farber, Andres Schanzer, Adam W. Beck, Carlos H. Timaran, Matthew P. Sweet, and Emanuel R. Tenorio

On Behalf of the United States Fenestrated and Branched Research Consortium Investigators

Disclosures
DBS: consulting and research grants from Cook, WL Gore, Endologix and Medtronic; GSO: consulting and research grants from Cook and WL Gore paid to Mayo Clinic; MAF: consulting and research grants from Cook, WL Gore, Endologix and Medtronic; AS: consulting and research grants from Cook; AWB: none; CHT: consulting and research grants from Cook; MPS: none; ERT: none
US FENESTRATED-BRANCHED CONSORTIUM

- 10 US sites
- Prospective, physician-sponsored studies
- Monitored, audited
- Similar device design with selective use of fenestrations and branches
661 patients enrolled
(January 1st, 2018)

- 232 pararenal (36%)
- 221 Extent 4 TAAA (33%)
- 208 Extent 1-3 TAAA (31%)
STENT DESIGN

Off-the-Shelf

*Cook t-Branch*

\[ t\text{-}Branch = 63 (10\%) \]

Patient Specific

Fenestrations or branches

\[ n = 597 (90\%) \]
## SELECTION OF FENESTRATIONS OR BRANCHES

**2428 target visceral arteries (3.8/patient)**

<table>
<thead>
<tr>
<th></th>
<th>Overall n = 2428</th>
<th>Pararenal n = 801</th>
<th>Type IV n = 881</th>
<th>Type I-III n = 746</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (Percent) or Mean ± Standard Deviation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vessels per patient</td>
<td>3.8±0.6</td>
<td>3.8±0.6</td>
<td>3.8±0.6</td>
<td>3.8±0.7</td>
<td>0.8</td>
</tr>
<tr>
<td>Fenestrations</td>
<td>1701 (70)</td>
<td>671 (84)</td>
<td>734 (83)</td>
<td>296 (40)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Directional branches</td>
<td>631 (26)</td>
<td>34 (4)</td>
<td>147 (17)</td>
<td>450 (60)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Double-wide scallops</td>
<td>96 (4)</td>
<td>96 (12)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* All patients with <4-vessels had variant anatomy (e.g. single kidneys, pelvic transplants, celio-mesenteric trunks, etc)
STENT SELECTION FOR FENESTRATIONS

1679 target visceral arteries incorporated with fenestrations (2.5 vessels/ patient)

<table>
<thead>
<tr>
<th></th>
<th>Overall n = 1679</th>
<th>Pararenal n = 660</th>
<th>Type IV n = 729</th>
<th>Type I-III n = 290</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>iCAST stent</td>
<td>1648 (98)</td>
<td>649 (98)</td>
<td>715 (98)</td>
<td>284 (98)</td>
<td>0.89</td>
</tr>
<tr>
<td>Fluency stent</td>
<td>3 (0.2)</td>
<td>0</td>
<td>2 (0.3)</td>
<td>1 (0.3)</td>
<td>0.36</td>
</tr>
<tr>
<td>Viabahn stent</td>
<td>8 (0.5)</td>
<td>1 (0.1)</td>
<td>4 (0.5)</td>
<td>3 (1)</td>
<td>0.17</td>
</tr>
<tr>
<td>VBX stent</td>
<td>3 (0.2)</td>
<td>2 (0.3)</td>
<td>0</td>
<td>1 (0.3)</td>
<td>0.31</td>
</tr>
<tr>
<td>Others</td>
<td>17 (1)</td>
<td>8 (1.2)</td>
<td>8 (1)</td>
<td>1 (0.3)</td>
<td>0.44</td>
</tr>
<tr>
<td>Adjunctive bare metal</td>
<td>470 (28)</td>
<td>153 (23)</td>
<td>234 (32)</td>
<td>83 (29)</td>
<td>0.001</td>
</tr>
</tbody>
</table>
## STENT SELECTION FOR DIRECTIONAL BRANCHES

625 target visceral arteries incorporated with branches (1 vessel/patient)

<table>
<thead>
<tr>
<th></th>
<th>Overall n = 625</th>
<th>Pararenal n = 34</th>
<th>Type IV n = 146</th>
<th>Type I-III n = 445</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (Percent)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>iCAST stent</td>
<td>155 (25)</td>
<td>17 (50)</td>
<td>38 (26)</td>
<td>100 (22)</td>
<td>0.002</td>
</tr>
<tr>
<td>Fluency stent</td>
<td>107 (17)</td>
<td>0</td>
<td>27 (18)</td>
<td>80 (18)</td>
<td>0.02</td>
</tr>
<tr>
<td>Viabahn stent</td>
<td>282 (45)</td>
<td>16 (47)</td>
<td>76 (52)</td>
<td>190 (43)</td>
<td>0.13</td>
</tr>
<tr>
<td>VBX stent</td>
<td>63 (10)</td>
<td>0</td>
<td>0</td>
<td>63 (14)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Others</td>
<td>18 (3)</td>
<td>1 (3)</td>
<td>5 (3)</td>
<td>12 (3)</td>
<td>0.9</td>
</tr>
<tr>
<td>Adjunctive bare metal</td>
<td>258 (41)</td>
<td>6 (18)</td>
<td>68 (47)</td>
<td>184 (41)</td>
<td>0.009</td>
</tr>
</tbody>
</table>

**Note:** Percentages and p-values indicate the statistical significance of the differences in stent selection across different categories.
## EARLY OUTCOMES (<30 DAYS)

<table>
<thead>
<tr>
<th></th>
<th>Overall  n = 661</th>
<th>Pararenal  n = 232</th>
<th>Extent IV  n = 221</th>
<th>Extent I-III  n = 208</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n (Percent)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any Mortality</td>
<td>13 (2)</td>
<td>3 (1)</td>
<td>5 (2)</td>
<td>5 (2)</td>
<td>0.82</td>
</tr>
<tr>
<td>Any MAE</td>
<td>97 (15)</td>
<td>26 (11)</td>
<td>33 (15)</td>
<td>38 (18)</td>
<td>0.11</td>
</tr>
<tr>
<td>EBL &gt;1L</td>
<td>29 (5)</td>
<td>6 (3)</td>
<td>9 (4)</td>
<td>14 (7)</td>
<td>0.10</td>
</tr>
<tr>
<td>Acute Kidney injury</td>
<td>36 (5)</td>
<td>7 (3)</td>
<td>14 (6)</td>
<td>15 (7)</td>
<td>0.11</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>12 (2)</td>
<td>4 (2)</td>
<td>7 (3)</td>
<td>1 (0.4)</td>
<td>0.11</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>20 (3)</td>
<td>2 (1)</td>
<td>10 (5)</td>
<td>8 (4)</td>
<td>0.053</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>11 (2)</td>
<td>1 (0.4)</td>
<td>1 (0.4)</td>
<td>9 (4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stroke</td>
<td>12 (2)</td>
<td>3 (1)</td>
<td>4 (2)</td>
<td>5 (2)</td>
<td>0.68</td>
</tr>
<tr>
<td>Bowel ischemia</td>
<td>22 (3)</td>
<td>5 (2)</td>
<td>10 (5)</td>
<td>7 (3)</td>
<td>0.37</td>
</tr>
</tbody>
</table>
TARGET VESSEL INSTABILITY

![Graph showing target vessel instability over follow-up years with 95±0.6 at 2 years.]

- Target vessel instability (%) vs. Follow-up (years)
- At risk (no.)
  - 2428
- Follow-up (years)
  - 0
  - 1
  - 2

- Number of patients at risk: 2428, 1222, 662
PRIMARİY PATENCY FOR FENESTRATIONS vs BRANCHES

P=0.83

- Fenestration
- Directional branches

At risk (no.)
- Fenestration: 1701
- Directional branches: 631

Follow-up (years)
- 0
- 1
- 2

Primary Patency (%)
- 100
- 50
- 0

97±0.5
97±0.9
TARGET VESSEL INSTABILITY BY VESSEL

- Celiac: 97±1.0
- SMA: 95±1.2
- Renal: 93±0.9

P=0.03

At risk (no.): Celiac (578), SMA (636), Renal (1184)
Follow-up (Years): 0, 1, 2

Risk at 1 year: Celiac 290, SMA 319, Renal 597
Risk at 2 years: Celiac 163, SMA 175, Renal 319
# Predictors of Target Vessel Instability

<table>
<thead>
<tr>
<th></th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>R renal artery</td>
<td>2.001</td>
<td>1.21</td>
<td>3.317</td>
</tr>
<tr>
<td>L renal artery</td>
<td>1.862</td>
<td>1.11</td>
<td>3.112</td>
</tr>
<tr>
<td>Chronic Dissection TAAA</td>
<td>3.141</td>
<td>1.69</td>
<td>5.836</td>
</tr>
<tr>
<td>Celiac Stenosis ≥ 50%</td>
<td>2.181</td>
<td>1.32</td>
<td>3.603</td>
</tr>
<tr>
<td>Number of target vessels</td>
<td>1.722</td>
<td>1.11</td>
<td>2.682</td>
</tr>
</tbody>
</table>
RENAL VESSEL INSTABILITY FOR FENESTRATIONS vs BRANCHES

Target vessel instability (%)

P=0.19
- Fenestration
- Directional branches

At risk (no.)
- 962
- 222

Follow-up (Years)
- 514
- 83
- 282
- 37

93±1.0
90±2.7
RENAL ARTERY PRIMARY PATENCY BY ANEURYSM EXTENT

P = 0.0148

- Extent IV TAAA and Pararenal AAAs
- Extent I-III TAAA

At risk (no.)
- 824
- 360

Follow-up (Years)
- 463
- 146
- 255
- 74

97 ± 0.7
93 ± 1.9
RENAL ARTERY ENDOLEAK TYPE IC/IIIC BY ANEURYSM EXTENT

Freedom from branch-related type IC and IIIC endoleak (%)

- Extent IV TAAA and Pararenal AAAs
- Extent I-III TAAA

P = 0.0029

At risk (no.)
- 824
- 360

Follow-up (Years)
- 461
- 148
- 255
- 73

97 ± 0.7
95 ± 1.5
RENAL ARTERY REINTERVENTION BY ANEURYSM EXTENT

Freedom from branch-related secondary intervention (%)

P<0.0001

- Extent IV TAAA and Pararenal AAAs
- Extent I-III TAAA

At risk (no.)
- Extent IV TAAA and Pararenal AAAs: 824
- Extent I-III TAAA: 360

Follow-up (Years)
- Extent IV TAAA and Pararenal AAAs: 457
- Extent I-III TAAA: 142

96±0.8
90±2.3
### PREDICTORS OF RENAL VESSEL INSTABILITY

<table>
<thead>
<tr>
<th></th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of target vessels</td>
<td>2.1</td>
<td>1.3</td>
<td>3.6</td>
</tr>
<tr>
<td>Extent I-III TAAAs</td>
<td>1.9</td>
<td>1.1</td>
<td>3.3</td>
</tr>
</tbody>
</table>
Update on the first 250 patients enrolled in a F-BEVAR prospective, non-randomized study

Gustavo S. Oderich MD, Emanuel Tenorio MD PhD, Jan Hofer RN, Jean Wigham RN, Stephen Cha MS and Thanila A. Macedo MD

Division of Vascular and Endovascular Surgery
and Departments of Radiology, Epidemiology and Biostatistics
## Type of Incorporation

954 renal-mesenteric arteries (3.8/patient)
211 patients (85%) had ≥ 4-vessels

<table>
<thead>
<tr>
<th></th>
<th>Overall n = 250</th>
<th>Pararenal n = 91</th>
<th>Type IV n = 63</th>
<th>Type I-III n = 96</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n (Percent) or Mean ± Standard Deviation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total target vessels</td>
<td>954</td>
<td>353</td>
<td>246</td>
<td>355</td>
<td></td>
</tr>
<tr>
<td>Vessels per patient</td>
<td>3.9±0.5</td>
<td>3.9±0.5</td>
<td>3.9±0.5</td>
<td>3.8±0.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Fenestrations</td>
<td>631 (66)</td>
<td><strong>308 (87)</strong></td>
<td><strong>218 (89)</strong></td>
<td>105 (30)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Directional branches</td>
<td>284 (30)</td>
<td>6 (2)</td>
<td>28 (11)</td>
<td><strong>250 (70)</strong></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Double-wide scallops</td>
<td>39 (4)</td>
<td>39 (11)</td>
<td>0</td>
<td>0</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
CHOICE OF BRIDGING STENT

FENESTRATIONS

Atrium Maquet Getinge Icast
Covered Stent

2007 Dec-2015 Present

BRANCHES

Renals Viabahn®
Mesenterics Fluency®

AORTIC LIVE
<table>
<thead>
<tr>
<th></th>
<th>Viabahn</th>
<th>VBX</th>
</tr>
</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 (16)</td>
</tr>
<tr>
<td>Sheath profile</td>
<td>7-11 Fr</td>
<td>7-8 Fr</td>
</tr>
</tbody>
</table>
FLEXIBILITY
RENAL DIRECTIONAL BRANCHES: PRIMARY PATENCY

Median Follow up
SE Viabahn 24 months
VBX 6 months

P=0.76

At risk
57
51

1-year
45
6

Self-Expandable Viabahn®
Balloon-Expandable Viabahn® (VBX®)
RENAL DIRECTIONAL BRANCHES: TYPE IC AND IIIC ENDOLEAKS

Freedom from Type IC and IIIC endoleak (%)

- SELF-EXPANDABLE VIABAHN®: 98 ±2
- BALLOON-EXPANDABLE VIABAHN® (VBX®): 84 ±7

P=0.001

At risk:
- SELF-EXPANDABLE VIABAHN®: 57
- BALLOON-EXPANDABLE VIABAHN® (VBX®): 51

1-year:
- SELF-EXPANDABLE VIABAHN®: 46
- BALLOON-EXPANDABLE VIABAHN® (VBX®): 6
RENAL DIRECTIONAL BRANCHES: SECONDARY INTERVENTIONS

**Graph: Freedom from secondary intervention (%)**

- **SELF-EXPANDABLE VIABAHN®**
  - 1-year: 98±2
  - At risk: 57

- **BALLOON-EXPANDABLE VIABAHN® (VBX®)**
  - 1-year: 94±3
  - At risk: 51

- **83±2**
- **89±6**
- **P=0.01**

**At risk**

- 57
- 51

**1-year**

- 46
- 6
CONCLUSION

- There is controversy on optimal stent design and bridging stent selection
- Fenestrated-branches aligned by balloon-expandable covered stents have consistently shown high patency rates and low rates of target vessel instability
- Although fenestrated branches have shown superior patency in many series, directional branches have an important role and should be considered in patients with proper anatomy
- Early results with newer bridging stent-grafts are promising, but the jury is out on the ideal stent for branch alignment