Contemporary Management of Aortic Pathology

Mark W. Fugate MD, FACS
No relevant disclosures
Objectives

• Identify the benefits of Endovascular vs Open aortic aneurysm repair
• Define the standard anatomic criteria for Endovascular Aortic Aneurysm repair
• Discuss challenges beyond standard anatomy
• Identify examples of novel devices and strategies for dealing with aortic pathology beyond standard anatomic criteria
Pathophysiology of AA

AA is a permanent localized dilatation with a diameter at least twice the normal diameter of the given segment.
Pathophysiology of AAA

- There are two main types of AAA:

  - Fusiform
  - Saccular
• 1.2 million people in the U.S.
• Responsible for 15,000 deaths annually
• 3rd leading cause of sudden death in men >60
• One of the most preventable causes of death because they are highly treatable and curable in 95% when detected before rupture
Aortic Aneurysms (AA)

- Exact cause unknown, most theories involve abnormalities in collagen production/metabolism
- Risk Factors
  - Smoking
  - HTN
  - Hypercholesterolemia
  - Male gender
  - 1st degree relative with AAA
  - Emphysema
  - Obesity
  - Diabetes
  - Genetic factors (Marfans, Ehlers-Danlos, Loewys-Dietz)
Abdominal Aortic Aneurysms (AAA)

• Rupture Rates (per year)
  • <4.0 cm – essentially zero
  • 4.0 – 4.9 cm – 0.5 – 5%
  • 5.0 – 5.9 cm – 5 – 13%
  • 6.0 – 6.9 cm – 10 – 20%
  • 7.0 – 7.9 cm – 20 – 40%
  • 8.0 cm or > - 30 – 50%

• Risk of Rupture
  • Increased with uncontrolled HTN, ongoing smoking, rapid growth (>0.5 cm over 6 – 12 months)
Thoracic Aortic Aneurysms (TAA)

- Descending TAA >6cm
  - Rupture risk 4%/year, odds ratio for rupture increased 27-fold
  - Dissection risk 7%/year
  - Risk of Death 12%/year
  - Risk of rupture, dissection or death 15.6%/year

Yearly rupture or dissection rates for thoracic aortic aneurysms: simple prediction based on size.
Davies RR¹, Goldstein LJ, Coady MA, Tittle SL, Rizzo JA, Kopf GS, Elefteriades JA.
Endovascular vs Open repair of AAA
<table>
<thead>
<tr>
<th></th>
<th>EVAR</th>
<th>OPEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 - Day Mortality</td>
<td>1.7 %</td>
<td>4.7 %</td>
</tr>
<tr>
<td>Secondary Interventions</td>
<td>9.8 %</td>
<td>5.8 %</td>
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</tbody>
</table>

*The Lancet, August 2004*
<table>
<thead>
<tr>
<th></th>
<th>EVAR</th>
<th>OPEN</th>
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</thead>
<tbody>
<tr>
<td>30 - Day Mortality</td>
<td>1.2%</td>
<td>4.6%</td>
</tr>
<tr>
<td>Combined Op Mortality &amp; Complications</td>
<td>4.7%</td>
<td>9.8%</td>
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</table>

**NEJM**
October 14, 2004
Endovascular vs Open Repair of TAA
# Gore TAG Pivotal Trial

<table>
<thead>
<tr>
<th>Condition</th>
<th>Endo</th>
<th>Open</th>
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<tbody>
<tr>
<td>Mortality</td>
<td>2.1%</td>
<td>11.7%</td>
</tr>
<tr>
<td>Resp. Insufficiency</td>
<td>4%</td>
<td>20%</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>1%</td>
<td>13%</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>3%</td>
<td>14%</td>
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### Trials and comparisons ENDOVASCULAR STENT GRAFT TRIALS vs OPEN

<table>
<thead>
<tr>
<th>TRIAL NAME</th>
<th>STARZ-TX2</th>
<th>TAG</th>
<th>VALOR (Talent)</th>
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<tbody>
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<td></td>
<td>Endo</td>
<td>Open</td>
<td>Endo</td>
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<tr>
<td>Arm</td>
<td>114 min</td>
<td>244 min</td>
<td>150 min</td>
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<tr>
<td>Procedure time</td>
<td>216 ml</td>
<td>2,538 ml</td>
<td>471 ml</td>
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<td>Blood loss</td>
<td>2.2 days</td>
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<td>ICU stay</td>
<td>5.0 days</td>
<td>16.1 days</td>
<td>7.4 days</td>
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<td>Hospital discharge</td>
<td>2.5%</td>
<td>8.6%</td>
<td>4%</td>
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<td>Stroke</td>
<td>1.3%</td>
<td>5.7%</td>
<td>3%</td>
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<tr>
<td>Paraplegia</td>
<td>5.8%</td>
<td>11.8%</td>
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<td>One-year mortality</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Author</td>
<td>Year</td>
<td>Device</td>
<td>N</td>
</tr>
<tr>
<td>-----------------------</td>
<td>------</td>
<td>-------------</td>
<td>----</td>
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<tr>
<td>Bastos Congalves et al</td>
<td>2012</td>
<td>Excluder</td>
<td>144</td>
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<td>Mairou et al</td>
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<td>Hiramoto et al</td>
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<td>Cho et al</td>
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<tr>
<td>Alric et al</td>
<td>2002</td>
<td>Zenith</td>
<td>88</td>
</tr>
</tbody>
</table>

Abbreviations: NS, not stated.
Anatomic Criteria for Endovascular AAA Repair (EVAR)

Endovascular Candidacy

Anatomic criteria: Ideal

- Neck angulation <45°
- 8-22 mm diam 20 mm length
- Patent IIA
- 15-20 mm
- 18-32 mm
- >7-8 mm

Minimum Ca+ and tortuosity
Anatomic Criteria for Endovascular AAA Repair (EVAR)

Endovascular Candidacy

Anatomic Criteria: deviations from ideal = ↑ chances for failure

 despair length
>32 mm diam
Neck angulation
>45°
CIA <2 cm length
>22 mm diam
< 7 mm

Moderate/severe Ca++ and tortuosity
### Table 1 | Anatomical criteria from the instructions for use for AAA endovascular devices approved by the FDA

<table>
<thead>
<tr>
<th>Endovascular device</th>
<th>Year of FDA approval</th>
<th>Neck diameter (mm)</th>
<th>Neck length (mm)</th>
<th>Neck angulation (°)</th>
<th>Iliac neck length (mm)</th>
<th>Iliac neck diameter (mm)</th>
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</thead>
<tbody>
<tr>
<td>Ancure™ (EndoVascular Technologies, Inc., USA)*</td>
<td>1999</td>
<td>18–26</td>
<td>≥15</td>
<td>NS</td>
<td>≥20</td>
<td>&lt;13.5</td>
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<tr>
<td>AneuRx® (Medtronic Vascular, Inc., USA)</td>
<td>1999</td>
<td>18–25</td>
<td>≥10*</td>
<td>≤45</td>
<td>NS</td>
<td>NS</td>
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<tr>
<td>Excluder® (W. L. Gore &amp; Associates, Inc., USA)</td>
<td>2002</td>
<td>19–26</td>
<td>≥15</td>
<td>≤60</td>
<td>≥10</td>
<td>10–18.5</td>
</tr>
<tr>
<td>Zenith® (Cook Medical Technologies, USA)</td>
<td>2003</td>
<td>18–28</td>
<td>≥15</td>
<td>≤60</td>
<td>≥15</td>
<td>10–20</td>
</tr>
<tr>
<td>Low-permeability Excluder® (W. L. Gore &amp; Associates, Inc., USA)</td>
<td>2004</td>
<td>19–26</td>
<td>≥15</td>
<td>≤60</td>
<td>≥10</td>
<td>10–18.5</td>
</tr>
<tr>
<td>Powerlink® (Endologix, Inc., USA)</td>
<td>2004</td>
<td>18–26</td>
<td>≥15</td>
<td>≤60</td>
<td>≥15</td>
<td>8–18</td>
</tr>
<tr>
<td>Enlarged-neck Zenith® (Cook Medical Technologies, USA)</td>
<td>2006</td>
<td>18–32</td>
<td>≥15</td>
<td>≤60</td>
<td>≥15</td>
<td>10–20</td>
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<tr>
<td>Talent® (Medtronic Vascular, Inc., USA)</td>
<td>2008</td>
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<td>≥10</td>
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<td>≥15</td>
<td>8–22</td>
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<td>Enlarged-neck Powerlink® (Endologix Inc., USA)</td>
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<td>≥15</td>
<td>≤60</td>
<td>≥15</td>
<td>10–23</td>
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<tr>
<td>Enlarged-neck Excluder® (W. L. Gore &amp; Associates, Inc., USA)</td>
<td>2009</td>
<td>19–29</td>
<td>≥15</td>
<td>≤60</td>
<td>≥10</td>
<td>10–18.5</td>
</tr>
<tr>
<td>Endurant® (Medtronic Vascular, Inc., USA)</td>
<td>2010</td>
<td>19–32</td>
<td>≥10</td>
<td>≤60</td>
<td>≥15</td>
<td>8–25</td>
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<tr>
<td>Ovation® (Trivascular, Inc, USA)</td>
<td>2011</td>
<td>15.5–30</td>
<td>≥7</td>
<td>45–60</td>
<td>≥10</td>
<td>8–20</td>
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<td>Fenestrated Zenith® (Cook Medical Technologies, USA)</td>
<td>2012</td>
<td>19–31</td>
<td>≥4</td>
<td>&lt;45</td>
<td>≥30</td>
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<tr>
<td>Aorfix® (Lombard Medical, UK)</td>
<td>2013</td>
<td>19–29</td>
<td>≥15</td>
<td>≤90</td>
<td>≥15</td>
<td>9–19</td>
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</tbody>
</table>

* Device discontinued in 2003. † Changed to ≥15 mm in 2003. Abbreviations: AAA, abdominal aortic aneurysm; NS, not specified.
Anatomic Criteria for Thoracic Endovascular Aortic Aneurysm Repair (TEVAR)
Complete Indications for Use

The Valiant thoracic stent graft with the Captivia delivery system is indicated for the endovascular repair of all lesions of the descending thoracic aorta in patients having the appropriate anatomy including:

- Iliac or femoral artery access vessel morphology that is compatible with vascular access techniques, devices, or accessories;
- Nonaneurysmal aortic diameter in the range of:
  - 18 mm to 42 mm (fusiform and saccular aneurysms/penetrating ulcers), or
  - 18 mm to 44 mm (blunt traumatic aortic injuries), or
  - 20 mm to 44 mm (dissections); and
- Nonaneurysmal aortic proximal and distal neck lengths ≥20 mm (fusiform and saccular aneurysms/penetrating ulcers),
- Landing zone ≥20 mm proximal to the primary entry tear (blunt traumatic aortic injuries, dissections). The proximal extent of the landing zone must not be dissected.
The Valiant Thoracic Stent Graft with the Captivia Delivery System is indicated for endovascular repair of all lesions of the descending thoracic aorta. Some examples include:

- Aneurysm
- Penetrating Ulcer
- Dissection
- Transection
The proximal end of the covered Valiant thoracic stent graft should not be placed beyond the origin of the left common carotid artery (ie, Zone 0 or Zone 1).

Avoid occluding arterial branches that do not have collateral or protected perfusion to end organs or body structures. If the left subclavian artery (LSA) is to be covered, check the blood flow of the vertebral or cerebral arteries and the retrograde flow of the LSA.

If occlusion of the left subclavian artery ostium is required to obtain adequate neck length/landing zone for fixation and sealing, transposition or bypass of the LSA should be considered.

Caution: Patients with a patent LIMA (left internal mammary artery)-LAD (left anterior descending artery) bypass should not be considered for coverage of the LSA unless additional bypasses are performed prior to the stent graft procedure.
Can We Advance Beyond These Criteria?

“Pushing the envelope. How about you?”
EVAR Distal Landing Zone Issues

- Involvement of Common and/or Internal Iliac arteries
- Short distal landing zones requiring internal iliac exclusion or revascularization
EVAR Proximal Landing Zone Issues

• Short neck - <10mm

• “Reverse taper” or conical neck

• Thrombus

• Involvement of renal or visceral segment of aorta
EVAR Proximal Landing Zone Solutions

- Aptus™ Endoanchor System
- Snorkel/Chimney grafts
- Fenestrated/branched endografts
- Debranching procedures
**EVAR Proximal Landing Zone Issues**

- **Aptus™ Endoanchor System**
  - EndoAnchor Implant for Stable Fixation and Durable Seal
  - 3.0mm diameter x 4.5mm length helix
  - 0.5mm MP35N-LT wire
  - Atraumatic conical tip (similar to SH1 needle)
  - Crossbar feature prevents over-penetration
EVAR Proximal Landing Zone Issues
EVAR Proximal Landing Zone Issues

- Short proximal landing zone – 5mm
- Conical (reverse taper) proximal neck
EVAR Proximal Landing Zone Issues

Well – positioned ASG with no obvious leak
EVAR Proximal Landing Zone Issues

Four endoanchors placed due to concerns about long term durability
“Zero Neck” AAA with successful Endoanchor placement and no endoleak
2014 Aptus US and EU Registry

Analysis of EndoAnchors for endovascular aneurysm repair by indications for use.


- During a 2-year period, 319 patients were enrolled at 43 sites in the Aneurysm Treatment Using the Heli-FX Aortic Securement System Global Registry (ANCHOR) study.
  - Primary Arm = 242
    - 178 hostile neck anatomy
    - 60 patients with type 1a endoleak evident during initial endograft deployment
    - 4 patients In conjunction with extender cuffs after unsatisfactory endograft deployment with extender cuffs
  - Revision Arm = 77
    - 45 patients presenting with type 1a endoleak alone
    - 11 patients presenting with migration
    - 21 with migration and endoleak
- Technical (successful deployment of endoanchors) and Procedural (no endoleak at final angio) success reported in 172 out of 178 patients 96.6% success
- Primary prophylactic patients were free from type Ia endoleak in 110 of 114 cases (96.5%).
Results of the ANCHOR prospective, multicenter registry of EndoAnchors for type Ia endoleaks and endograft migration in patients with challenging anatomy

Objective

• To evaluate the potential benefit of EndoAnchors for Proximal Neck attachment site complications.
  • Specifically Endograft Migration and type 1a Endoleak

Methods

• 23 Months, ending in Dec 2013
• 319 patients at 43 sites in US and EU
• EndoAnchors were implanted in 242 patients (75.9%) at the time of an initial EVAR procedure (primary arm) and in 77 (31.8%) with an existing endograft and proximal aortic neck complications (revision arm).
• Technical success was defined as:
  • Deployment of the desired number of EndoAnchors
  • Adequate penetration of the vessel wall
  • Absence of EndoAnchor fracture
• Procedural success was defined as:
  • Technical success without a type Ia endoleak at completion angiography.
  • Values are expressed as mean ± standard deviation and interquartile range.
Results

- The 238 male (74.6%) and 81 female (25.4%) subjects
- Mean age of 74.1 ± 8.2 years.
- Aneurysms averaged 58 ± 13 (51mm-63mm) in diameter at the time of EndoAnchor implantation (core laboratory measurements).
- The proximal aortic neck averaged (7mm-23mm) in length
  - 42.7% <10 mm and Conical
- 27 ± 4 mm (25-30 mm) in diameter;
- Technical success was achieved in 303 patients (95.0%)
- Procedural success in 279 patients (87.5%), 217 of 240 (89.7%) and 62 of 77 (80.5%) in the primary and revision arms, respectively.
- There were 29 residual type Ia endoleaks (9.1%) at the end of the procedure.
- 301 patients (94.4%) were free from secondary procedures.
- Among the 18 secondary procedures, eight were performed for residual type Ia endoleaks and the others were unrelated to EndoAnchors.
- No open surgical conversions, no aneurysm-related deaths, no aneurysm ruptured during follow-up.

Conclusions

- Use of EndoAnchors to treat existing and acute type Ia endoleaks and endograft migration was successful in most cases. Prophylactic use of EndoAnchors in patients with hostile aortic neck anatomy shows an increased benefit.
EVAR Proximal Landing Zone Issues

Snorkel or Chimey graft technique
EVAR Proximal Landing Zone Issues
EVAR Proximal Landing Zone Issues
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EVAR Proximal Landing Zone Issues
Early experience with the snorkel technique for juxtarenal aneurysms
Lee JT, Greenberg J, Dalman RL
Published Online: January 16, 2012


- 56 snorkel grafts in 28 patients were successfully placed between 2009 and 2011
- Not Open Candidates
- Mean Aneurysm size of 6.5cm
- Mean Neck diameter of 24.5mm, Mean Length of 18mm
- 5 unilateral snorkels, 17 bilateral snorkels, and 6 celiac/SMA/Renal combo
- Technical success of snorkels 98.2% (loss of wire leading to renal stent deployment failure)
- 30 Day mortality was 7.1%
- Mean follow-up was 10.7 months (3-25 months)
- Secondary Intervention was 3.6% (bridging cuff placement)
- No Aneurysm Enlargement
- Endografts used:
  - Zenith (Cook) 19 patients (68%), 2 Renu 2 Endurant, 1 Talent, 1 Excluder, 1 TAG, 2 TX2,
# Grafts Used in US Snorkel Early Experience

Table II. Operative strategy, snorkel components, and complications

<table>
<thead>
<tr>
<th>Pr</th>
<th>Main body</th>
<th>Snorkel configuration</th>
<th>Stent type*</th>
<th>Endoleak</th>
<th>F/U time (months)</th>
<th>Complications, F/U</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>32 Renu</td>
<td>Left renal</td>
<td>iCAST</td>
<td>I</td>
<td>25</td>
<td>Endoleak resolved at 6 months</td>
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<tr>
<td>2</td>
<td>28 Zenith</td>
<td>Bilateral renal</td>
<td>iCAST</td>
<td>None</td>
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<td>32 Talent</td>
<td>Left renal</td>
<td>iCAST</td>
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<td>II</td>
<td>19</td>
<td>Brachial plexus injury</td>
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<td>22 Zenith</td>
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<td>None</td>
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<td>III</td>
<td>18</td>
<td>Renal branch injury</td>
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<td>III</td>
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<td>Died of MI, 3 months post-op</td>
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<td>None</td>
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<td>Endoleak resolved at 6 months</td>
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<td>28 Zenith</td>
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<td>Viabahn</td>
<td>None</td>
<td>9</td>
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<td>14</td>
<td>32 Zenith</td>
<td>Bilateral renal</td>
<td>Viabahn</td>
<td>I</td>
<td>8</td>
<td>Lost right renal access, post-op renal insufficiency resolved by 6 months</td>
</tr>
<tr>
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<td>Bilateral renal</td>
<td>Viabahn</td>
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<td>7</td>
<td>Died of pneumonia, post-op day 8</td>
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<td>Viabahn</td>
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<tr>
<td>17</td>
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<td>SMA/celiac</td>
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<td>Right renal/SMA</td>
<td>iCAST</td>
<td>None</td>
<td>3</td>
<td>Renal failure at 3 mon, on dialysis</td>
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<td>21</td>
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<td>Bilateral renal</td>
<td>iCAST</td>
<td>None</td>
<td>3</td>
<td>Died of stroke post-op day 7</td>
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<td>22</td>
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<td>Bilateral renal/SMA</td>
<td>Mixed</td>
<td>None</td>
<td>3</td>
<td></td>
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<tr>
<td>23</td>
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<td>Bilateral renal/SMA</td>
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<td>None</td>
<td>3</td>
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</tr>
<tr>
<td>24</td>
<td>26 Zenith</td>
<td>Bilateral renal</td>
<td>Mixed</td>
<td>None</td>
<td>3</td>
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</tr>
<tr>
<td>25</td>
<td>30 Zenith</td>
<td>Bilateral renal</td>
<td>iCAST</td>
<td>None</td>
<td>3</td>
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<tr>
<td>26</td>
<td>36 Zenith</td>
<td>Bilateral renal</td>
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</tr>
<tr>
<td>27</td>
<td>28 Endurant</td>
<td>Bilateral renal</td>
<td>iCAST</td>
<td>None</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>36 TX2</td>
<td>Bilateral renal/SMA/celiac</td>
<td>Mixed</td>
<td>3</td>
<td>Endoleak resolved at 3 months</td>
<td></td>
</tr>
</tbody>
</table>

*SMA, Superior mesenteric artery.
*Balloon-expandable or self-expandable.