Disclosures

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I have the following potential conflicts of interest to report:

- Clinical Research – Endologix Corporation
- Consultant and Teaching Programs – Endologix Corporation
Endovascular Treatment of Type C/D Aorto Iliac Occlusive Disease

Challenging Subsets

• Flush or very proximal common iliac occlusions
• Involvement of both distal aorta and common iliac arteries
• Excessive calcium
• Narrow, diseased distal aorta
• Diffuse degenerative disease with thrombus, calcium
Traditional Endovascular Strategies for AIOD

- Distal aortic and proximal iliac lesions can be challenging to treat with endovascular techniques
  - Kissing balloons
  - Kissing stents (BE, SE, Covered)
  - Aortic stent and kissing stents
Limitations of Traditional Stenting of AIOD

Patency affected by

- incomplete coverage of disease
- radial mismatch associated with failure
- crossing stent configuration associated with patency loss

Raised or crossing iliac stents limits future contralateral access

AFX Endologix Bifurcated Stent Graft

• Designed and approved for aneurysmal disease
• Nitinol endoskeleton, ePTFE graft
• 17 Fr main body and 9 Fr sheath compatible contralateral limb
• Unibody stent – graft design
• Distal Ao and iliac arteries stented with single bifurcated main body piece
• Positioned on anatomic Ao-Iliac bifurcation
• Percutaneous access possible with pre-closure
Advantages of a Bifurcated Stent Graft for Aorto-Iliac Occlusive Disease

• Preserves aortic bifurcation
• Avoids ‘missing’ common iliac a. ostial lesion(s)
• Allows for significant oversizing without in-folding of fabric
• “Covered” stent is protective in cases of potential rupture (heavily calcified lesions) or distal emboli
• Does not limit future contra-lateral interventions
Bifurcated Stent Graft for AIOD

Patient Characteristics

- Retrospective, IRB-approved review of a consecutive series of patients
- 9 centers (1 OUS)
- 80 patients
- Mean age (yrs) $68 \pm 10$
- Male gender 64%
- Concomittant AAA ≤ 3.5 cms 1.7%
- Smoking 90%
- Hypertension 85%
- Hyperlipidemia 89%
- CAD 51%
- COPD 31%
Deployment of single bifurcated covered stent at distal aorta into each iliac limb within previous iliac stents.
Procedure Results

- Technical success: 96%
- Median length of stay: 3 days
- Planned surgical access°: 63%
  °CFA disease, concerns regarding embolic risk

- Adverse Events
  - Stroke: 1%
  - MI: 0%
  - Death: 0%
  - Distal emboli/dissection/fem a. thrombosis: 3/4/1%

- Adjunctive procedures
  - Endovascular: 41/80 (51%)
    - Non ostial Iliac stenting: 39/41 (95%)
  - Surgical: 26/80 (32%)
    - Endarterectomy: 24/26 (92%)
Procedure Results

Procedure time (mins)

- < 90: 19%
- ≥90, < 150: 30%
- ≥ 150, < 210: 20%
- > 210: 31%

Fluoro Time (mins)

- < 10: 35%
- ≥ 10, < 20: 23%
- ≥20, < 30: 15%
- > 30: 27%
Results

Improvement in ABI

- 0-40%: 24%
- 41-80%: 35%
- 81-100%: 42%
# Graft Patency at Follow up

<table>
<thead>
<tr>
<th>Patency</th>
<th>30d</th>
<th>6 mo</th>
<th>1 yr</th>
<th>2 yr</th>
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</thead>
<tbody>
<tr>
<td><strong>Primary</strong></td>
<td>98.1% (n=51/52)</td>
<td>93.1% (n=27/29)</td>
<td>94% (n=31)</td>
<td>100% (n=16)</td>
</tr>
<tr>
<td><strong>Assisted</strong></td>
<td>98.1% (n=51/52)</td>
<td>100% (n=29/29)</td>
<td>96.7% (n=29/30)</td>
<td>100% (n=16)</td>
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</tbody>
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Limitations of the Device and Procedure

- Larger profile sheath (17 Fr)
- Device designed for aneurysmal disease – radial force low
- 4cm long main body
- Potential for coverage of collaterals
- Procedural complexity increased
  - Length of procedure
  - Requires higher level of endovascular skill
- Cost (depends on procedure being compared)
Conclusions

Initial experience with a bifurcated aorto-iliac stent graft for aorto-iliac obstructive disease was associated with:

- High technical success for TASC C and D anatomy (96%)
- Low 30-day mortality and low procedural complication rates
- Favorable primary patency rate throughout follow-up (95-100%)
- Rate of freedom from Secondary intervention of 92%
Summary

• Though only an initial experience, the procedural and late results using the bifurcated stent graft for this complex disease subset are favorable.

• Improved results may occur through device modification including:
  • greater radial force
  • lower profile
  • integrated distal embolic protection system (which could allow safer percutaneous access)
  • reduced device cost
Initial Experience with a Bifurcated Aorto-Iliac Stent Graft for Aorto-Iliac Occlusive Disease

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