Novel Approach to Treatment of Aortoiliac Disease with Bifurcated Unibody Graft

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Disclosures

Speaker/Trainer/Advisory Board:

• Abbott Vascular
• BARD
• BSCI
• Cardinal Health/Cordis
• Cook Medical
• CSI
• Endologix

• Gore
• Lake Region Medical
• Medtronic
• Penumbra
• Phillips/Volcano
• Spectranetics
• Terumo/Bolton
Treatment of Aortoiliac Occlusive Disease

Aorto-bifemoral bypass
• Operative mortality 1 – 4%
  • Higher for elderly and comorbidities
• 10-year patency 75 – 95%
  • Lower for younger and female patients, and those with critical limb ischemia

DeVries SO et al. JVS 1997
Hertzer NR et al. JVS 2007
“Kissing” Balloons and Stents

- Distal aortic and proximal iliac lesions difficult to treat endovascularly
- Kissing balloons described in 1985\(^1\)
- Kissing stents described in 1991\(^2,3\)
- Limitations:
  - Limited data on performance in CLI
  - Decreased patency in more complex lesions, particularly involving significant portions of the infrarenal aorta

1. Tegtmeyer CJ. Radiology. 1985
Kissing Stents

• Patency affected by
  • Radial mismatch associated with failure\(^1\)
  • Crossing stent configuration associated with patency loss\(^2\)

• Raises the bifurcation

Data on Patency of Kissing Stents

<table>
<thead>
<tr>
<th>Study</th>
<th>3 year</th>
<th>4 year</th>
<th>5 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haulon 2002</td>
<td>79%, 98%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sharafuddin 2008</td>
<td></td>
<td>81%, 94%</td>
<td></td>
</tr>
<tr>
<td>Abello 2012</td>
<td></td>
<td></td>
<td>65%, 82%</td>
</tr>
</tbody>
</table>

- Above studies have significant variability of TASC classification and Rutherford category
- Primary assisted patency 65% at 2 years in more advanced TASC lesions
- Covered stents appear to have better patency than bare metal stents in TASC C and D lesions
- This effect may also apply to “kissing” stents

5. Mwipatayi BP, COBEST Co-investigators. JVS 2011
CERAB Technique

• Covered Endovascular Reconstruction of the Aortic Bifurcation
• 3 Covered Stents to Reduce Radial Mismatch
• Requires large, covered stents to cover distal aorta -- not available in U.S.
Unibody Stent Graft

- Unibody design for AAA repair (EVAR)
- Sits on the aortic bifurcation
- Sizes from 22mm to 28mm with various iliac sizes and lengths
- Low 17F profile (percutaneous)
- Percutaneous approval

Role in Aortoiliac Occlusive Disease?

CAUTION: The AFX Stent Graft is not approved in any market for the treatment of aortoiliac occlusive disease
Unibody Stent Graft

- Preserves aortic bifurcation
- Avoid the possibility of ‘missing’ CIA lesion
- No limb competition in a narrow distal aorta
- Fabric allows for significant oversizing without wrinkle / in-folding
- Does not preclude future aortic interventions (TEVAR, PTA, etc)
- “Covered” stent - protective in cases of potential rupture (heavily calcified lesions)

CAUTION: The AFX Stent Graft is not approved in any market for the treatment of aortoiliac occlusive disease
Multicenter Experience of AFX

- Multicenter review of 91 patients
- TASC C and D lesions; 63% unfit for open surgery
- Technical success 100%
- 30d mortality 1% (1/91)
- Mean follow-up 22 months
- 1- and 2-yr primary patency rates ≈90%
- Freedom from secondary interventions 92%

The AFX System has not been approved for treatment of aortoiliac occlusive disease in any geography.
## Adjunctive Procedures at Time of Treatment

<table>
<thead>
<tr>
<th>Patients, n (%)</th>
<th>Planned vs. unplanned</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n = 87</strong></td>
<td></td>
</tr>
<tr>
<td>Endovascular procedures</td>
<td>56 (64)</td>
</tr>
<tr>
<td>Aortic stent</td>
<td>51 (59)</td>
</tr>
<tr>
<td>Iliac stent</td>
<td>10 (11)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Arteries treated</th>
<th>EIA = 25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iliac stent</td>
<td>53 (61)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CIA = 56</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical procedures</td>
</tr>
<tr>
<td>CFA endarterectomy</td>
</tr>
<tr>
<td>Bypass</td>
</tr>
</tbody>
</table>

Maldonado et al., EJVES 2016
## Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>n = 20/91 (22)</th>
<th>Unfit for open surgery n = 9/34 (26)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Groin infection</td>
<td>6 (7)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>4 (4)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Groin hematoma</td>
<td>4 (4)</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Rupture</td>
<td>4 (4)</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Hemodynamic instability</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Dissection</td>
<td>4 (4)</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Thromboembolic event</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intestinal</td>
<td>1 (^a)</td>
<td></td>
</tr>
<tr>
<td>Spinal cord</td>
<td>3 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Buttock</td>
<td>2 (^a)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Lower extremity</td>
<td>2 (2)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Femoral thrombosis</td>
<td></td>
<td>1 (3)</td>
</tr>
<tr>
<td>Stroke</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Contrast nephropathy</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>30-d mortality (^a)</td>
<td>1 (1) (^a)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Note. Data are n (%).

\(^a\) Single mortality occurred as a result of a thromboembolic event resulting in diffuse pelvic ischemia and intestinal infarction.
Multicenter Experience of AFX

Patient improvement in ischemic claudication and ABI at 6 month follow-up

73% patients had 3 to 5 Rutherford Scale improvement
42% patients had increased ABI of 81%-100%

Maldonado et al. Eur J Vas Endovasc Surg 2016;52:64-74

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Patency

<table>
<thead>
<tr>
<th>Patency</th>
<th>30d</th>
<th>6 mo</th>
<th>1 yr</th>
<th>2 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>100%</td>
<td>98%</td>
<td>91%</td>
<td>89%</td>
</tr>
<tr>
<td>Assisted</td>
<td>100%</td>
<td>100%</td>
<td>97%</td>
<td>97%</td>
</tr>
<tr>
<td>Secondary</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>
Freedom from Secondary Intervention

88.9% and 87.5% at 1 and 2 years

Maldonado et al., EJVES 2016
Case 3
Case 4
Case 5
Conclusions

• High technical success, even in TASC C and D
• Low 30-day mortality and low procedural complication rate
• 89% - 100% patency throughout follow-up
• 88% freedom from secondary interventions at 2 years
• Procedure can be safely combined with adjunctive lower extremity interventions (usually planned)

Maldonado et al., EJVES 2016
THANK YOU!
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