**RESULTS FROM A MULTI-CENTER, RETROSPECTIVE REVIEW OF THE AFX ENDOGRAFT FOR USE IN AORTOILIAC OCCLUSIVE DISEASE**

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**Treatment of Aortoiliac Occlusive Disease**

**Aortobifemoral bypass**

- **Operative mortality 3 – 7%**
  - Higher for elderly and comorbidities
- **Hospital length of stay 6-13 days**
- **10-year patency 75 – 95%**
  - Lower for younger and female patients
- **SVS-reported patency lower in patients with critical limb ischemia**

1. Chiu KW et al. EJVES 2010  
3. Indes JE et al. JVS 2010  
4. Hertzer NR et al. JVS 2007  
5. SVS Guidelines Writing Group, JVS 2015

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**“Kissing” Balloons and Stents**

- Distal aortic and proximal iliac lesions difficult to treat endovascularly
- **Kissing balloons described in 1985**
- **Kissing stents described in 1991**
- **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  

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**Kissing Stents**

- Patency affected by
  - Radial mismatch associated with failure
  - Crossing stent configuration associated with patency loss
- **Raises the bifurcation**


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**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>Shafafuddin 2008</td>
<td>81%, 94%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abello 2012</td>
<td>65%, 82%</td>
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</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
CERAB Technique

- 3 Covered Stents to Reduce Radial Mismatch
- Requires large, covered stents to cover distal aorta -- not available in U.S.

Endologix AFX 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?

Division of Vascular and Endovascular Surgery

AFX : Advantages for AIOD

- 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 etc)
- "Covered" stent - protective in cases of potential rupture (heavily calcified lesions)

Why AFX? Pro’s and Con’s

PROS

- Avoid the possibility of ‘missing’ CIA lesion as with CIA stents (kissing technique)
- No limb competition in a narrow distal aorta
- No gate cannulation in narrow distal aorta
- Low profile, at least on one side
- Has percutaneous approval
- Recreates/preserves aortic bifurcation (no competing kissing stents)
- Useful in recannalization
- Does not preclude future aortic interventions (TEVAR etc)
- Just one piece
- Low morbidity and mortality

CONS

- Larger profile sheath
- Poor radial force
- Adjunct stenting is required
- Procedure is time consuming for occlusive disease
- Requires higher level of endovascular skill
- Procedure Code not available (yet)
- Risk of thromboembolism (?)

Multicenter Retrospective Review: AFX for AIOD

- 91 patients (10 centers)
- IRB approved retrospective review
- Aorto-Iliac Occlusive disease (non-aneurysmal)
- Demographics
- Procedural detail
- Technical Success
- Clinical Success (Rutherford classification, ABI’s)
- Follow-up: Mean 363d ± 275
Multicenter Retrospective Review
10 Centers, 91 patients

Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>68 ± 10</td>
</tr>
<tr>
<td>Male Gender (n)</td>
<td>62%</td>
</tr>
<tr>
<td>ASA Class</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>19%</td>
</tr>
<tr>
<td>III</td>
<td>61%</td>
</tr>
<tr>
<td>IV</td>
<td>20%</td>
</tr>
<tr>
<td>Ambulatory Status</td>
<td></td>
</tr>
<tr>
<td>Ambulatory</td>
<td>93%</td>
</tr>
<tr>
<td>Amb w/ assistance</td>
<td>5%</td>
</tr>
<tr>
<td>Wheelchair</td>
<td>2%</td>
</tr>
</tbody>
</table>

Baseline Risk Factors / Medical History

- Smoker
- Hypercholesterolemia
- Hypertension
- Coronary Artery Disease
- Cerebral Disease
- PCI
- PAD Endovascular
- CTA
- CTA
- COPD
- CABG
- CVI
- CVA/CAS
- Major Amputation
- AAA Repair

Rutherford Classification

<table>
<thead>
<tr>
<th>Rutherford Classification</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>16</td>
</tr>
<tr>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>

TASC Classifications

- A: n=1 (1%)
- B: n=12 (13%)
- C: n=4 (4%)
- D: n=74 (82%)

Candidates for Open Surgery

- Unfit for open repair: 39%
- Candidates for open repair: 61%
Oversizing in 12mm tube…

TASC D Lesions

Courtesy of Zachary Arthurs, MD
**Procedural Characteristics**

- General Anesthesia 98.9%
- Technical success 100%
- Non-percutaneous access 59%
- Mean Blood Loss 200cc
- Median hospital stay 3 days

**Procedural Complications**

<table>
<thead>
<tr>
<th></th>
<th>N=70</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Groin Infection</td>
<td>6</td>
<td>7%</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>4</td>
<td>4%</td>
</tr>
<tr>
<td>Groin Hematoma</td>
<td>3</td>
<td>3%</td>
</tr>
<tr>
<td>Rupture</td>
<td>4</td>
<td>4%</td>
</tr>
<tr>
<td>Hemodynamic Instability</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Dissection</td>
<td>4</td>
<td>4%</td>
</tr>
<tr>
<td>Thromboembolic Event</td>
<td>4</td>
<td>3%</td>
</tr>
<tr>
<td>Iliac Injury</td>
<td>2</td>
<td>3%</td>
</tr>
<tr>
<td>Femoral Thrombosis</td>
<td>2</td>
<td>2%</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
<td>1%</td>
</tr>
</tbody>
</table>

30 Day Mortality: 1 (1%)

**Improvement in Rutherford Classification**

Over 80% improvement between 3 to 5

Follow-up = Change from baseline to last available visit

**Improvement in ABI**

Follow-up = Change from baseline to last available visit
Division of Vascular and Endovascular Surgery

**Type** | **Number of Patients (n=80)** | **Planned vs Unplanned**
--- | --- | ---
Total patients | 56 (64%) | 
Endovascular Procedures | 51 (63%) | 25 planned
  - Aortic Stent | 10 (11%) | Palmaz (unplanned)
  - Iliac Stent | 41 (51%) | 
Surgical Procedures | 34 (39%) | 23 planned
  - CFA Endarterectomy | 30 (37%) | 25 planned
  - Bypass | 6 (7%) | 5 planned

**Adjunctive Procedures:**
56 patients (64%)

**Secondary Interventions:**
8 patients (9%): angioplasty/stenting

<table>
<thead>
<tr>
<th>Intervention Site</th>
<th>Total (n patients)</th>
<th>1 Month</th>
<th>6 Months</th>
<th>1 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aorta</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Common Iliac Artery - Left</td>
<td>3</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Common Iliac Artery - Right</td>
<td>3</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>External Iliac Artery - Left</td>
<td>3</td>
<td>-</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>External Iliac Artery - Right</td>
<td>3</td>
<td>-</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Common Femoral Artery - Left</td>
<td>3</td>
<td>-</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Common Femoral Artery - Right</td>
<td>3</td>
<td>-</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

**Freedom from Secondary Interventions:**
90% @ 1 Year

**Graft 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>98.4% (n=62/63)</td>
<td>97.2% (n=69/71)</td>
<td>94% (n=44/47)</td>
<td>100% (n=24/24)</td>
</tr>
<tr>
<td>Assisted</td>
<td>100% (n=63/63)</td>
<td>100% (n=71/71)</td>
<td>97.8% (n=46/47)</td>
<td>100% (n=24/24)</td>
</tr>
<tr>
<td>Secondary</td>
<td>100% (n=47/47)</td>
<td>100% (n=24/24)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Limitations of the Technique**
- Larger profile sheath
- 4cm main body
- Potential for coverage of collaterals
- Requires higher level of endovascular skill
- Cost? (depends on procedure being compared)

**Conclusions:**
AFX for treatment of AIOD
- High technical success, even in TASC C and D
- Low 30-day mortality and low procedural complication rate
- Primary patency 95-100% throughout follow-up
- Freedom from Secondary interventions: 90%
- Procedure can be safely combined with adjunctive lower extremity interventions (usually planned)
Conclusions: What's next?

- Improvement in design: increased radial strength of limbs to avoid need for adjunctive iliac stenting
- Prospective trial
- Cost analysis/Coding