How to deal with complex popliteal lesions

SAINT-LEBES Bertrand, MD
Toulouse – FRANCE
Disclosure

Speaker name:
SAINT-LEBES

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

☐ I do not have any potential conflict of interest
ANATOMY - BIOMECHANIC
« Stressed » SFA+PA

Machan L
Drug eluting stents in the infrainguinal circulation Tech Vasc Interv Radiol 2004
Biomechanical specifics: Axial Shortening

**Length Change, %**

- 6.4 +/- 4.9%
- 7.7 +/- 1.9%
- 7.4 +/- 4.3%

Biomechanical specifics: **twisting deformation**

**Twist/cm**

- Top: $1.4 \pm 1.2^\circ /cm$
- Middle: $2.1 \pm 2.9^\circ /cm$
- Bottom: $2.8 \pm 4.4^\circ /cm$

Biomechanical specifics: wall shear stress

- WSS in the SFA+PA varies based on body position, location along the artery and activity level

Wood NB, J Appl Physiol 2006
Vascular stent design matters

- Stent design should accommodate natural anatomic forces
- Goal: allow arteries to maintain as much natural behavior and function
- Dynamic forces of the SFA/PA require a compliant stent to minimize chronic vessel injury and stresses on stent that can lead to fracture
Stent fractures significantly influenced the patency of the stented segment

TIGRIS
Unique Dual-Component Stent Design

Designed to:

- Maximize flexibility while minimizing risk of stent fracture
- Allow axial compression while resisting stent elongation
- Naturally conforms and allows vessel movement

GORE® and designs are trademarks of W. L. Gore & Associates. © 2014 W. L. Gore & Associates, Inc.
Dual-Component Stent Design (Nitinol+ePTFE)✪

Carmedia bioactive surface (Heparin Bonding)
Ideal stent?
Unlocking the delivery system

- When unlocking the catheter will advance 0.5cm
- Reposition before deployment

<table>
<thead>
<tr>
<th>Device Sizing</th>
<th>Labeled Device Diameter (mm)</th>
<th>Recommended Vessel Diameter (mm)</th>
<th>Introducer Sheath Size (Fr)</th>
<th>Guidewire Diameter</th>
<th>Recommended Balloon Diameter for Device Touch-up (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5</td>
<td>4.0 – 4.7</td>
<td>6</td>
<td>0.035&quot; (0.889 mm)</td>
<td>5.0</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>4.8 – 5.5</td>
<td>6</td>
<td>0.035&quot; (0.889 mm)</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>5.6 – 6.5</td>
<td>6</td>
<td>0.035&quot; (0.889 mm)</td>
<td>7.0</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>6.6 – 7.5</td>
<td>7</td>
<td>0.035&quot; (0.889 mm)</td>
<td>8.0</td>
</tr>
</tbody>
</table>

1. Recommended stent compression within the vessel is approximately 5 – 20%.

Lengths: 30, 40, 60, 80, 100mm
Catheter Lengths: 80, 120cm
CLINICAL CASES
Mr B
Male
76 y old
Risk factors:
  o Tobacco use
  o Dyslipidemia
  o Diabetes

CLI, Rutherford IV, ABP 0.7
Long stenosis of Popliteal artery and BTK lesions
After PTA
Tigris 5x100
DATAS
Twelve-month experience with the GORE TIGRIS Vascular Stent in the superficial femoral and popliteal arteries

M. Piorkowski et al: J CARDIOVASC SURG

- Prospective, single center evaluation

- Treated legs 32
- Number of lesions 40
- Popliteal location: 34%
- Critical Limb Ischemia: 25.0%
- Diseased artery segment
  - Proximal SFA 8 (17.0%)
  - Medial SFA 17 (36.2%)
  - Distal SFA 6 (12.8%)
  - P1 5 (10.6%)
  - P2 8 (17.0%)
  - P3 3 (6.4%)

- Lesions length (mm), 43.1 ± 27.8 (10-90)
- Total occlusions 2 (5%)
- Calcification *
  - None/minor 18 (45%)
  - Moderate 16 (40%)
  - Severe 6 (15%)

- Vessel runoff
  - 1 7 (21.9%)
  - 2 13 (40.6%)
  - 3 12 (37.5%)
Twelve-month experience with the GORE TIGRIS Vascular Stent in the superficial femoral and popliteal arteries
M. Piorkowski et al: J CARDIOVASC SURG

• **Outcomes at 1 year:**
  - Primary patency 85.5 ± 6.0%
  - Primary assisted patency 94.3 ± 3.9%
  - Secondary patency 97.1 ± 2.9%
  - Freedom from TLR 90%

*Note:*
Most patients only received 4W of dual antiplatelet instead of 6M due to reimbursement constraints

M. Piorkowski et al: J CARDIOVASC SURG 2015;56:89-95
Use of a New Hybrid Heparin-Bonded Nitinol Ring Stent in the Popliteal Artery: Procedural and Mid-term Clinical and Anatomical Outcomes
Parthipun A et al: Cardiovascular & Interventional Radiology 2015

- Prospective, single center evaluation
- 48 patients
- Occlusions: 74%
- Lesion Length: 11.4cm
- Popliteal location: 100%
- Calcification (moderate/severe) 46%
- Critical Limb Ischemia: 70.0%
- 1Y primary patency 69.5%

### Use of a New Hybrid Heparin-Bonded Nitinol Ring Stent in the Popliteal Artery: Procedural and Mid-term Clinical and Anatomical Outcomes

Parthipun A et al: Cardiovascular & Interventional Radiology 2015

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient (n)</td>
<td>48</td>
<td>32</td>
<td>101</td>
<td>119 (RCT)</td>
</tr>
<tr>
<td>Occlusions</td>
<td>74.0%</td>
<td>5.0%</td>
<td>47.5%</td>
<td>32.8%</td>
</tr>
<tr>
<td>Les length (cm)</td>
<td>11.4 ± 3.7</td>
<td>4.3 ± 2.8</td>
<td>5.8 ± 3.4</td>
<td>4.1 ± 3.1</td>
</tr>
<tr>
<td>Calcification (mod/severe)</td>
<td>46%</td>
<td>55%</td>
<td>51.5%</td>
<td>n/a</td>
</tr>
<tr>
<td>Critical leg ischemia</td>
<td>70.0%</td>
<td>25.0%</td>
<td>22.8%</td>
<td>20.7%</td>
</tr>
<tr>
<td>Vessel run off 0-1 vessel</td>
<td>44.0%</td>
<td>21.9%</td>
<td>40.6%</td>
<td>58.5%</td>
</tr>
<tr>
<td>Popliteal artery</td>
<td>100.0%</td>
<td>34.0%</td>
<td>Fem-pop</td>
<td>100.0%</td>
</tr>
<tr>
<td>Primary patency</td>
<td>69.5%</td>
<td>85.5%</td>
<td>87.7%</td>
<td>67.4%</td>
</tr>
<tr>
<td>TLR events</td>
<td>13.5%</td>
<td>n/a</td>
<td>10.0%</td>
<td>14.9%</td>
</tr>
</tbody>
</table>

**NOTES**

- Mostly CLI long popliteal
- TIGRIS single arm
- SUPERA 500 – 83.3%
- Randomized trial

Our clinical experience

French multicenter experience with GORE® TIGRIS® Vascular Stent in superficial femoral and popliteal arteries (JVS, 2017, accepted)

Maxime Sibe, M.D., Adrien Kaladji, MD, PhD, Claire Boirat, MD, Alain Cardon, MD, Xavier Chaufour, MD, PhD Jean-pierre Bossavy, MD, PhD, Bertrand Saint-Lèbes, MD

• 1st EU Series presentation > 200 patients (SFA/POP – early and FU results)
• Multicenter serie (EU/ France) in patients with symptomatic peripheral artery disease (PAD)
• Efficacy endpoint: primary patency
• Primary, secondary, primary assisted patency rates at 3, 6, 12, 18 and 24 months
• 239 lesions (215 patients) were successfully treated with the GORE® TIGRIS® Vascular Stent
• 141 lesions were located in the superficial femoral artery (SFA)
• 98 in the popliteal artery

• This experience with the GORE® TIGRIS® Vascular Stent validates the preliminary experience described by Piorkowski et al. and Parthipun et al.
## Baseline characteristics

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>N=215</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (yrs)</td>
<td>74.1 ± 11.7 (range 49 – 102)</td>
</tr>
<tr>
<td>Men</td>
<td>145 (67.8%)</td>
</tr>
<tr>
<td>Rutherford</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>114 (48.9%)</td>
</tr>
<tr>
<td>IV</td>
<td>48 (20.6%)</td>
</tr>
<tr>
<td>V</td>
<td>67 (28.8%)</td>
</tr>
<tr>
<td>VI</td>
<td>4 (1.7%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lesion characteristics</th>
<th>N=239</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion location</td>
<td></td>
</tr>
<tr>
<td>SFA</td>
<td>141 (59%)</td>
</tr>
<tr>
<td>Popliteal</td>
<td>98 (41%)</td>
</tr>
<tr>
<td>Lesion type</td>
<td></td>
</tr>
<tr>
<td>Stenotic</td>
<td>196 (88.8%)</td>
</tr>
<tr>
<td>Thrombotic</td>
<td>25 (12.7%)</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td></td>
</tr>
<tr>
<td>SFA</td>
<td>82.4 ± 35.0 (range 30 – 200)</td>
</tr>
<tr>
<td>Popliteal</td>
<td>93.0 ± 55.3 (range 30 – 360)</td>
</tr>
</tbody>
</table>
Outcomes – Patency all lesion

1Y primary patency: 82%

2Y primary patency: 67%
Outcomes – Patency SFA VS Pop

- SFA 12M primary patency: 84%
- Popliteal 12M primary patency: 79%

Similar outcomes for SFA and Popliteal lesions supporting the need for conformable stents in this region
Conclusion

- PA is unique!
  - Anatomical
    - Common site for aneurysm formation
    - Wall properties affected by age and gender
    - Exposed to natural anatomic forces
  - Biomechanical
    - Stressed vessel
    - Axial shortening
    - Twist deformation
    - Low WSS
- Accurate placement, conformability and fracture resistance are key features
- Our experience demonstrates a good performance in both the SFA and the popliteal arteries.
Thanks for your attention
bsl@saintlebes.com
How to deal with complex popliteal lesions

SAINT-LEBES Bertrand, MD
Toulouse – FRANCE