Saint Louis University experience with Biomimetic stent technology in complex lesions

Donald L. Jacobs, MD
C. Rollins Hanlon Professor and Chair
Department of Surgery
Saint Louis University
Saint Louis, Missouri, USA
Disclosure

I have the following potential conflicts of interest for this presentation to report:

Consultant and Proctor for Abbott
Saint Louis University experience with biomimetic stent technology in complex lesions

- Retrospective review
- April 2010 and December 2011
- 54 limbs in 48 consecutive patients
- Mean follow up of 27.5 ± 12.3 months
- Median follow up of 30 months
Clinical Follow Up and Definitions

• Exam and/or interview
  – ABIs routinely and duplex US in majority

• Clinical primary patency
  – clinical resolution of symptoms and freedom from secondary interventions (TLR)

• Primary assisted patency
  – requiring a secondary intervention due to in-stent restenosis

• Secondary patency
  – requiring a secondary intervention to restore patency after occlusion of the stent
Lesion characteristics and patency

- Excellent overall patency rates
- Notably high in TASC II C/D lesions

<table>
<thead>
<tr>
<th></th>
<th>Overall (n=54)</th>
<th>TASC A/B (n=12)</th>
<th>TASC C/D (n=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in years)</td>
<td>24.0 ± 11.6</td>
<td>9.5 ± 4.8</td>
<td>27.9 ± 13.2</td>
</tr>
<tr>
<td></td>
<td>24.8 ± 10.9</td>
<td>13.2 ± 5.8</td>
<td>27.8 ± 10.2</td>
</tr>
<tr>
<td>Percentage</td>
<td>43 (79.6%)</td>
<td>9 (75%)</td>
<td>34 (80.1%)</td>
</tr>
<tr>
<td></td>
<td>48 (88.9%)</td>
<td>10 (83.3%)</td>
<td>38 (90.5%)</td>
</tr>
<tr>
<td></td>
<td>50 (92.3%)</td>
<td>11 (91.7%)</td>
<td>39 (92.9%)</td>
</tr>
<tr>
<td>Time (in months)</td>
<td>27.5 ± 12.3</td>
<td>34.2 ± 5.7</td>
<td>25.8 ± 13.0</td>
</tr>
</tbody>
</table>
## Overall patency by lesion length

Mean follow up of 27.5 months

<table>
<thead>
<tr>
<th></th>
<th>&lt; 15 cm (n=18)</th>
<th>15 - 30 cm (n=18)</th>
<th>&gt; 30 cm (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary patency</strong></td>
<td>72.3% (13)</td>
<td>83.3% (15)</td>
<td>83.3% (15)</td>
</tr>
<tr>
<td><strong>Primary assisted patency</strong></td>
<td>88.9% (16)</td>
<td>88.9% (16)</td>
<td>88.9% (16)</td>
</tr>
<tr>
<td><strong>Secondary patency</strong></td>
<td>94.4% (17)</td>
<td>88.9% (16)</td>
<td>94.4% (17)</td>
</tr>
</tbody>
</table>

*Patency rates did not drop with increased lesions lengths*
Kaplan Meier analysis of all patients

Primary Patency

<table>
<thead>
<tr>
<th>Follow-up Time (months)</th>
<th>Primary Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 months</td>
<td>85.6%</td>
</tr>
<tr>
<td>24 months</td>
<td>83.1%</td>
</tr>
<tr>
<td>36 months</td>
<td>76.7%</td>
</tr>
</tbody>
</table>

Secondary Patency

<table>
<thead>
<tr>
<th>Follow-up Time (months)</th>
<th>Secondary Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 months</td>
<td>93.8%</td>
</tr>
<tr>
<td>24 months</td>
<td>93.8%</td>
</tr>
<tr>
<td>36 months</td>
<td>89.3%</td>
</tr>
</tbody>
</table>
Discussion

• Differentiation of the Supera

• What explains these clinical results?
  • Flexible, kink resistant, fracture free
  • No chronic outward force
  • When deployed to nominal diameter it has high crush resistance

• Clear relationship to length and patency seen in the SUPERB Trial
Primary Patency (K-M) by Percent Compression/Elongation at 12 months

SUPERB Freedom From TLR at 1, 2, and 3 Years

Discussion

Relationship of the diameter to the length of the stent

- Compress it and it elongates
- The farther the stent is from its nominal diameter, the greater the amount of elongation for any given amount of further compression/deformation
- With compression and elongation, there is force transmission for axial motion of stent in the vessel
- Such motion/stress may cause inflammation and neointimal response in the vessel wall
Good Technique - Good Results

- Prepare the vessel well
  - pre-dilation to diameter at or greater than the nominal stent diameter
- Do not oversize the stent
- Deploy slowly with forward pressure
  - Anticipate elongation in areas of calcification/recoil

*Not difficult, just different*
Saint Louis University experience with Biomimetic stent technology in complex lesions

Donald L. Jacobs, MD
C. Rollins Hanlon Professor and Chair
Department of Surgery
Saint Louis University
Saint Louis, Missouri, USA