VEITH 2015, New York

Does stent design influence the results of SFA stenting?

Marc Bosiers, MD

Stent design related factors

- Flexibility
- Axial Compression Resistance
- Torsion Resistance
- Radial Resistant Force (RRF)
- Chronic Outward Force (COF)
- Crush Resistance (CR)
- Fractures
- Physical irritation
- Endothelial trauma/neo-intimal hyperplasia
- RESTENOSIS

Newest BMS generations: the designs, the data

<table>
<thead>
<tr>
<th>STENT</th>
<th>COMPANY</th>
<th>STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supera VMII</td>
<td>Abbott Vascular</td>
<td>Leipzig exp, Auroraa, CWS, Tucson</td>
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<tr>
<td>Tigris</td>
<td>Gore &amp; Associates</td>
<td>Retrospective study, Tigris IDE Study</td>
</tr>
<tr>
<td>Biomimics 3D</td>
<td>Veryan Medical</td>
<td>MIMICS study</td>
</tr>
</tbody>
</table>

- 6 stable closed-ends interwoven nitinol wires
- Extreme flexibility & kink resistance
- Low chronic outward force
- High crush resistance & radial resistive force
- Dedicated preparation & delivery technique

Disclosure slide

☐ 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
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- Helical single nitinol wire spiral frame
- Heparin coated ePTFE bridges
- High flexibility
- Elongation-axial compression resistance ++

**STENT COMPANY STUDY**

**TIGRIS Gore & Associates**

Retrospective analysis of 40 SFA lesions, mean lesion length 62.3mm

<table>
<thead>
<tr>
<th>Measure</th>
<th>Tigris</th>
<th>Lifestent</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedural success (%)</td>
<td>100</td>
<td>95</td>
<td></td>
</tr>
<tr>
<td>ABI shift @ 12 m</td>
<td>0.65±0.18</td>
<td>0.91±0.18</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Rutherford shift @ 12 m</td>
<td>3.0</td>
<td>1.0</td>
<td>&lt;0.0005</td>
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<tr>
<td>Primary patency @ 12 m (%)</td>
<td>85.5</td>
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<td></td>
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</table>

**STENT COMPANY STUDY**

**TIGRIS Gore & Associates**

Tigris US IDE Trial

Prospective, multicenter, 3:1 randomized SFA trial, Tigris (Gore°) vs Lifestent (Bard°)
36 clinical sites (US – EU); 274 inclusions (197 Tigris – 77 Lifestent)
Mean lesion length: 10.7 cm (Tigris) – 11.79 cm (Lifestent)
Results summer 2015

**STENT COMPANY STUDY**

**BioMimics 3D Veryan Medical**

Mimics study

Unique 3 dimensional helical centerline geometry
short & long spiral oriented connectors

- Promotes Swirling flow → shear stress
- Enables coil-spring shortening
- Reduces risk of stent compression

**STENT COMPANY STUDY**

**BioMimics 3D Veryan Medical**

Mimics study

Prospective, randomized multicenter controlled trial
8 German centers, PI T. Zeller
2:1 randomization
Mean lesion length (mm):

<table>
<thead>
<tr>
<th>Study</th>
<th>BioMimics 3D</th>
<th>BMS</th>
<th>p</th>
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<tbody>
<tr>
<td>1yr primary patency (%)</td>
<td>80.4</td>
<td>71.0</td>
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<tr>
<td>2yr primary patency (%)</td>
<td>72.0</td>
<td>55.0</td>
<td>0.0467</td>
</tr>
<tr>
<td>1yr freedom CD TLR (%)</td>
<td>91.0</td>
<td>90.0</td>
<td></td>
</tr>
<tr>
<td>2yr freedom CD TLR (%)</td>
<td>91.0</td>
<td>76.0</td>
<td>0.125</td>
</tr>
<tr>
<td>Died</td>
<td>0</td>
<td>1</td>
<td></td>
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</table>
Does stent design influence the results?

**Conclusion**

- Stent design related factors as flexibility, axial compression and torsion resistance, COF, RRF and CR are important to avoid fractures, collapse and restenosis.

- Supera, Tigris and Biomimics 3D are perfect examples of the latest generation nitinol stents.

- Especially in long challenging lesions, adapted designs might play a role in improving outcome results.