Long SFA Disease: When a Covered Fracture Resistant Stent is Best

Barry Weinstock, MD, FACC
Florida Heart & Vascular Center
Leesburg Regional Medical Center
Leesburg, Florida
Disclosures

Speaker’s Bureau:
• W.L. Gore & Associates

Consultant:
• W.L. Gore & Associates
Limitations of SFA Trials

• Balloon angioplasty results extremely poor except for short, focal stenoses

• Bar is set low -- Easy for new devices to show superiority to “POBA” for moderate length lesions either in randomized trials or in comparison to OPC

• Follow-up is short – typically one year, occasionally two-three years
Viabahn Endoprosthesis

6F/7F Sheath Compatible / 0.018 Wire Compatible

- Ultra-thin wall ePTFE tube
- Unique, durable bonding film
- Polished nitinol support
- Contoured proximal edge
- CARMEDA® Bioactive Surface (CBAS® Surface)

Lengths: 2.5, 5, 10, 15, 25 cm
Diameters: 5 mm – 13 mm

Viabahn Clinical Indications

- Long lesion lengths, often >15 – 40 cm (or more)
- Chronic Total Occlusions, often ostial SFA

- Calcified vessels, especially in older patients, diabetics, and patients with renal insufficiency / failure

- Recent FDA approval for treatment of stent restenosis
- Other: Aneurysms and Perforations
Viabahn for long SFA CTO
PTA, Viabahn Stent x 3
Primary Patency in SFA Stenting

- ZILVER PTX
- Supera
- Dual-center, single arm, EU
- Multi-center registry
- Trend of randomized BMS studies

Lesion Length (cm)

One-Year Primary Patency

- Multi-center, randomized
- Multi-center, single arm
- Dual-center, single arm, EU
- Absolute
- VIBRANT BMS
- Durability
- Resilient
- FACT
- ASTRON
- ZILVER

Durability 200
The GORE® VIABAHN® Endoprosthesis exhibits proven performance in long, challenging SFA lesions.

Prospective Randomized or Prospective Multi-Center (> 2 sites) SFA studies included. 5, 14, 15, 19-30, 32-37 Registry studies not included. Patency definitions may vary: where Kaplan-Meier estimates with a PSVR of ≥ 2.5 are available, these were used for comparison. P-values indicate results of t-test on slope of weighted linear regression compared to zero. Note that McQuade et al, 2010 reported stented length, not lesion-length.
Randomized trial: VIABAHN vs. PTFE fem-popliteal bypass

<table>
<thead>
<tr>
<th></th>
<th>GORE® VIABAHN® Endoprosthesis (n = 50)</th>
<th>ePTFE or Dacron® Bypass (n = 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter</td>
<td>5.7 mm</td>
<td>7.4 mm</td>
</tr>
<tr>
<td>Mean Stented Length</td>
<td>25.6 cm</td>
<td>--</td>
</tr>
<tr>
<td>TASC II A and B</td>
<td>n = 39</td>
<td>n = 35</td>
</tr>
<tr>
<td>TASC II C and D</td>
<td>n = 11 (22%)</td>
<td>n = 15 (30%)</td>
</tr>
<tr>
<td>1 Year Patency</td>
<td>Primary: 72% Secondary: 83%</td>
<td>Primary: 76% Secondary: 86%</td>
</tr>
<tr>
<td>2 Year Patency</td>
<td>Primary: 63% Secondary: 74%</td>
<td>Primary: 63% Secondary: 76%</td>
</tr>
<tr>
<td>3 Year Patency</td>
<td>Primary: 63% Secondary: 74%</td>
<td>Primary: 63% Secondary: 76%</td>
</tr>
<tr>
<td>4 Year Patency</td>
<td>Primary: 59% Secondary: 74%</td>
<td>Primary: 58% Secondary: 71%</td>
</tr>
</tbody>
</table>

Recent Clinical Studies: VIPER Study

VIPER Clinical Study Data:
73% primary patency and 92% secondary patency at 1-year

- Prospective, multi-center
- 119 limbs at 12 sites
- Primary patency by duplex (peak systolic velocity ratio (PSVR) < 2.5)

- Average lesion length 19 cm
- 56% Chronic Total Occlusions

12-Month Patency: Gore VIPER Clinical Study Data

© 2013 W. L. Gore & Associates, Inc.

Lessons from VIPER

**Device Sizing**
Patency improved when device not oversized > 20% proximally

**Device Diameter**
Patency independent of device diameter (5, 6, 7 mm devices utilized, p = 0.22)

**Lesion Length**
Patency independent of lesion length (lesions > 20 cm versus ≤ 20 cm, (P = 0.51)
VIABAHN® Endoprosthesis outperformed bare-metal stents in complex lesions—especially those ≥ 20 cm

Randomized Trial vs. BMS

N=129

CTO’s: 79% VB 70% BMS

### 12-month Data from Multiple studies of VIABAHN Endoprosthesis with Heparin Bioactive Surface*

<table>
<thead>
<tr>
<th>Author</th>
<th>Journal</th>
<th>Year</th>
<th>No. of Limbs</th>
<th>Lesion Length (cm)</th>
<th>CTOs (%)</th>
<th>Primary Patency</th>
<th>Secondary Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>LENSVELT</td>
<td>Journal of Vascular Surgery, Vol 56, Iss 1, July 2012, P 118-125</td>
<td>2012</td>
<td>56</td>
<td>18.5</td>
<td>NR</td>
<td>76%</td>
<td>89%</td>
</tr>
<tr>
<td>VIPER</td>
<td>Journal of Vascular Interventional Radiology; 24: 165-173</td>
<td>2013</td>
<td>119</td>
<td>19</td>
<td>56%</td>
<td>73%</td>
<td>92%</td>
</tr>
<tr>
<td>VIASTAR</td>
<td>Journal of the American College of Cardiology</td>
<td>2013</td>
<td>66</td>
<td>19.0</td>
<td>79%</td>
<td>78%</td>
<td>90%</td>
</tr>
<tr>
<td>25 cm Study</td>
<td>Journal of Endovascular Therapy 2014;21:765-774</td>
<td>2014</td>
<td>71</td>
<td>26.5</td>
<td>93%</td>
<td>67%</td>
<td>97%</td>
</tr>
<tr>
<td>TOTAL weighted results</td>
<td></td>
<td></td>
<td>312</td>
<td>20.6</td>
<td>72%</td>
<td>73%</td>
<td>92%</td>
</tr>
</tbody>
</table>
Recent Randomized or Prospective Multicenter Trials for Drug-Coated Balloons and the VIABAHN Endoprosthesis*

Compared to drug-coated balloons, the GORE® VIABAHN® Endoprosthesis is studied in more complex SFA lesions.
Recent Randomized or Prospective Multicenter Trials for Drug-Eluting Stents and the VIABAHN Endoprosthesis*

Compared to drug-eluting stents, the GORE® VIABAHN® Endoprosthesis is studied in more complex SFA lesions.
Recent Randomized or Prospective Multicenter Trials for Bare-Metal Stents and the VIABAHN Endoprosthesis*

Compared to bare-metal stents, the GORE® VIABAHN® Endoprosthesis is studied in more complex SFA lesions.
Recent Randomized or Prospective Multicenter Trials for Atherectomy and the VIABAHN Endoprosthesis

Compared to atherectomy, the GORE® VIABAHN® Endoprosthesis is studied in more complex SFA lesions.

Mean % Chronic Total Occlusion Studied

Mean Lesion Length Studied (cm)
Conclusions

- Viabahn is currently best treatment option for long, complex femoro-popliteal lesions, including chronic total occlusions
- Superior results to bare-metal stents and equivalent results to PTFE fem-pop bypass surgery in randomized trials
- Only device with length-independent restenosis rate
- New technologies such as drug coated balloons offer promise and potential advantages but have yet to be studied in lesions as complex as those treated in multiple Viabahn trials
• Related issues will be addressed in separate lectures

• Management of Viabahn thrombosis

• Use of Viabahn for treatment of bare metal stent restenosis / occlusion
Thank You for your attention

Barry Weinstock, MD
Long SFA Disease: When a Covered Fracture Resistant Stent is Best

Barry Weinstock, MD, FACC

Florida Heart & Vascular Center

Leesburg Regional Medical Center

Leesburg, Florida