Viabahn demonstrates powerful patency in 20+ cm SFA lesions

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

☒ Consulting: unpaid consultant W.L. Gore; global PI RELINE MAX trial
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company

Other(s)

☐ I do not have any potential conflict of interest
Studies of VB for 20+ cm lesions using current heparin bonded device with proximal contoured edge

- Ultra-thin wall ePTFE tube
- Durable bonding film
- Polished nitinol support
- Contoured proximal edge
- CBAS Heparin® surface

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

- 4 gold radiopaque markers bonded to the ends (5-8 mm diameters)
VIPER Clinical Study

- Prospective, multicenter, 12 US sites
- 119 limbs
- Independent core lab vessel sizing
- Primary patency (PSVR <2.5)
- Average lesion length 19 cm
- 56% CTOs

Core lab: significant stent oversizing in 30%

Saxon et al, J Vasc Inter Radiol 2013;24(2):165-73
VIPER: Lessons Learned

- Patency improved when device not oversized by >20% proximally.
- Patency independent of device diameter (5, 6, 7 cm devices utilized, p=0.22).
- Primary patency independent of lesion length (lesion length >20 cm vs. ≤ 20 cm, p=0.51).

Saxon et al, J Vasc Inter Radiol 2013;24(2):165-73
Gore Japan IDE Clinical Study

• RC 2-5
• Surgical bypass candidate
• Lesion length ≥ 10 starting at least 1 cm below SFA origin, ending 1 cm above intercondylar notch
• Patent distal popliteal
• At least one patent tibial artery
• Ref diameter 4.0-7.5mm
• QA or IVUS (70%) mandated for proper sizing

Mean lesion length 21.8±5.8 cm

<table>
<thead>
<tr>
<th>Mean target lesions length (cm) ± SD</th>
<th>21.8 ± 5.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total occlusions</td>
<td>67 (65.7%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TASC classification</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TASC II A</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>TASC II B</td>
<td>16 (15.5%)</td>
</tr>
<tr>
<td>TASC II C</td>
<td>75 (72.8%)</td>
</tr>
<tr>
<td>TASC II D</td>
<td>12 (11.7%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SFA lesion location (lesion may cross over)</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal</td>
<td>72 (69.9%)</td>
</tr>
<tr>
<td>Mid</td>
<td>99 (96.1%)</td>
</tr>
<tr>
<td>Distal</td>
<td>77 (74.8%)</td>
</tr>
</tbody>
</table>

65.7% CTOs

Ohki, J Vasc Surg 2017;66/130-42
Japan IDE Study: 12M Results

Ohki, J Vasc Surg 2017;66/130-42
Stent-Graft Patency Independent of Lesion Length and Optimized with IVUS guidance

Ohki, J Vasc Surg 2017;66/130-42
VIASTAR: RCT of VB vs. BMS in long complex SFA disease

• Objective: Evaluate the performance of the heparin coated VB vs. BMS in long SFA disease
• Mean lesion length 19 cm
• Primary endpoints: PP at 12M (PSVR>2.5)
• Secondary endpoints: PAP & SP at 1, 2 years, TVR and TLR at 1, 2 years
• BMS used: Lifestent, Everflex, SMART

VIASTAR Lesion Characteristics

<table>
<thead>
<tr>
<th>Lesion Characteristic</th>
<th>GORE® VIABAHN® Endoprosthesis</th>
<th>Bare-Metal Stents</th>
<th>Lesions ≥20 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Chronic Occlusion</td>
<td>54%</td>
<td>33%</td>
<td></td>
</tr>
<tr>
<td>Mean Lesion Length</td>
<td>78%</td>
<td>73%</td>
<td></td>
</tr>
<tr>
<td>TASC Classification</td>
<td>TASC II A</td>
<td>TASC II D</td>
<td></td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>

*p-values: 0.21, 0.13, 0.09

“real-world” data
VIASTAR: 2-Year Outcomes

1° Patency-Overall

- BMS: 40%
- Viabahn: 70%

1° Patency-Stent Length ≥20cm

- BMS: 27%
- Viabahn: 65%

BMS 2.71 times more likely to lose patency than VB


but TLR p=NS
VB 25 cm Study

Number limbs: 71
Mean lesion length: 26.5 cm
CTOs (%): 93%
TASC C/D: 100%
Freedom from fracture: 100%

Zeller, JET 2014;21/765-774
REAL PTX: RCT of DES vs. DCB

Mean lesion length 152.6 ±88.2mm

* > 40% had >30% residual stenosis

Scheinert, LINC 2018
Primary Patency in SFA Stenting:
Relation of Primary Patency to Lesion Length
Different Patterns of Restenosis

• **FOCAL** vs. diffuse ISR w/VB
• Majority of pts. with stent-graft restenosis are asymptomatic, with nl resting ABI
• Therefore **MUST** follow with close DUS surveillance

Which one would you rather fix?

VB vs BMS
SuperB: RCT of VB vs. Bypass

- Dutch MC, RCT of VB vs. bypass (66.7% vein, 31.7% prosthetic)
- Primary endpoint: Primary patency at 1 year, 30-day QOL
- Mean lesion length of 23 cm
- 12M DAPT

<table>
<thead>
<tr>
<th>RC (%)</th>
<th>Surgical (n=62)</th>
<th>Endo (n=63)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>68.3</td>
<td>61.9</td>
</tr>
<tr>
<td>4</td>
<td>15.9</td>
<td>23.8</td>
</tr>
<tr>
<td>5</td>
<td>14.3</td>
<td>14.3</td>
</tr>
<tr>
<td>6</td>
<td>1.6</td>
<td>0</td>
</tr>
</tbody>
</table>

Reijnen, J Am Coll Cardiol Intv 2017;10:2320-31
SuperB: Patency & TVR

- NO difference in outcomes of:
  - Mortality
  - RC
  - ABI
  - Walking impairment
- Less morbidity, shorter LOS
- 100% limb salvage

<table>
<thead>
<tr>
<th>ITT analyses</th>
<th>Surgical (n=61)</th>
<th>Endoluminal (n=62)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>12 MONTHS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total primary patency</td>
<td>84.6%</td>
<td>82.5%</td>
<td>0.978</td>
</tr>
<tr>
<td>Secondary patency</td>
<td>91.1%</td>
<td>90.2%</td>
<td>0.785</td>
</tr>
<tr>
<td>Freedom from TVR</td>
<td>67.7%</td>
<td>75.7%</td>
<td>0.455</td>
</tr>
<tr>
<td>Freedom from amputation</td>
<td>100%</td>
<td>100%</td>
<td>1.000</td>
</tr>
<tr>
<td><strong>24 MONTHS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total primary patency</td>
<td>75.4%</td>
<td>68.3%</td>
<td>0.671</td>
</tr>
<tr>
<td>Secondary patency</td>
<td>79.4%</td>
<td>82.2%</td>
<td>0.757</td>
</tr>
<tr>
<td>Freedom from TVR</td>
<td>65.9%</td>
<td>56.1%</td>
<td>0.613</td>
</tr>
<tr>
<td>Freedom from amputation</td>
<td>100%</td>
<td>100%</td>
<td>1.000</td>
</tr>
</tbody>
</table>

*Time to first TVR 3.0 (1-10) months in surgical vs. 7.0 (2.5-14.5 months in endo group (p=0.035)*

Reijnen, J Am Coll Cardiol Intv 2017;30:2320-30
RELINE: RCT of VB vs. PTA for BMS ISR

Mean lesion length 19 cm

RELINE RCT: 12M Primary Patency & TLR
RELINE: 2-Yr. Freedom from TLR

![Graph showing Freedom for TLR (%) over time in days.](image)

- 365 days: 79.9%
- 720 days: 66.3%
- 365 days: 42.2%
- 720 days: 27.9%
RELINE MAX Post-Approval Study

- Prospective, MC, single-arm study to evaluate the safety & efficacy of VB for treatment of symptomatic SFA ISR in RC 2-5 patients with lesion lengths up to 270 cm

- 1° endpoint- PP @ 12M; 3-yr. F/U

- Completed 108 subject enrollment
VB for 20+ cm SFA lesions: Summary

• There is level 1 evidence (Viestar, Reline) that covered stents are *SUPERIOR* to BMS and PTA in the treatment of long complex SFA disease and ISR, respectively

• The SuperB RCT showed no difference in patency between covered stents and the traditional gold standard of fem-pop bypass surgery, with less morbidity and shorter length of stay

• Optimal technique, vessel diameter ≥5 mm, and surveillance are critical for best outcomes
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