Gore Viabahn for ISR in the SFA at 3-years

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Disclosure
Speaker name: Peter A. Soukas, MD

I have the following potential conflicts of interest to report:
☒ Consulting: Endologix, Shockwave Medical, W.L. Gore
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☒ Other(s): Global PI for the Gore RELINE MAX trial

☐ I do not have any potential conflict of interest
ISR & Fractures: the Achilles Heel of Stenting!
# RELINE RCT of Viabahn vs. PTA in SFA ISR

<table>
<thead>
<tr>
<th>Design</th>
<th>Prospective, randomized, multicenter study (7 European sites), 100 patients.</th>
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<tbody>
<tr>
<td>Objective</td>
<td>To evaluate the performance of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface and percutaneous transluminal angiography (PTA) in treating in-stent restenosis of the SFA.</td>
</tr>
</tbody>
</table>
| Primary endpoints | - Primary patency at 12 months.  
- Primary safety endpoint was serious device-related adverse events within 30 days post-procedure. |
| Secondary endpoints | - Technical success.  
- Primary patency at 1, 6 and 24 months.  
- Clinical success at 1 day and 1, 6, 12 and 24 months.  
- Target lesion revascularization (TLR) at 1, 6, 12 and 24 months.  
- Stent fracture at 12 months. |
RELINE: RCT of Viabahn vs PTA for SFA ISR

- MC, RCT of VB vs. PTA in ISR, n = 83
- Mean lesion length: 17.3 cm vs 19.0 cm
- CTO: 23% vs 25%

RELINE: 1 & 2 Year Freedom From TLR

Core lab: 0 stent fractures at 12 months

Viabahn

PTA

1 Year

2 Year

0%

20%

40%

60%

80%

P<0.001


80%

42%

66%

23%
• 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 mm

• 1° endpoint- PP @ 12M; 3-yr. F/U

• 2° endpoints
  • Acute procedural success
  • PP, PAP, SP, fTLR at 30 d, 12m, 24m, 36 m
  • Freedom from major amp at 30 d, 12m, 24m, 36m
  • Change in ABI & RC pre, 30d, 12m, 24m, 36m
  • Sent fracture assessment at 12m, 24m, 36m
Three-Year Results of the GORE VIABAHN Endoprosthesis in the Superficial Femoral Artery for In-Stent Restenosis

Peter Soukas, MD a,*, Matthew Becker, MD b, Karl Stark, MD c, Gunnar Tepe, MD d, on behalf of the RELINE MAX Investigators

a Lifespan Cardiovascular Institute, The Miriam Hospital, Alpert School of Medicine of Brown University, Providence, Rhode Island; b Lake Erie College of Medicine Heart and Vascular Institute, Cardiovascular Medicine, Interventional Cardiology and Cardiac Catheterization Laboratory, Ambulatory Surgical Vascular Institute, Erie, Pennsylvania; c Midwest Arterial and Vascular Institute, University of Missouri at Kansas City School of Medicine, University of Health Sciences, Kansas City, Missouri; d Department of Diagnostic and Interventional Radiology, RoMed Clinic Rosenheim, Germany

ABSTRACT

Background: The study objective was to assess the postmarket safety and effectiveness of the GORE VIABAHN endoprosthesis with heparin bioactive surface for the treatment of in-stent restenosis (ISR) of the superficial femoral artery (SFA).

Methods: A prospective, single-arm, international study enrolled patients at 23 sites from October 2015 to April 2018. Patients with ≥50% ISR or occlusions in the SFA, Rutherford categories 2–5, and at least 1 patent runoff vessel were eligible. The primary effectiveness endpoint was primary patency at 12 months. The primary safety endpoint was the rate of device- or procedure-related serious adverse events at 30 days.

Results: One hundred and eight patients were enrolled, and 86 were included for analysis through 3 years (mean age, 70.0 ± 10.4 years; 48.8% female). The mean core lab-reported lesion length was 12.4 ± 6.92 cm (29.1% occlusions); 10.5% presented with chronic limb-threatening ischemia, and 81.9% of lesions were TASC IIa and II. Acute procedural success was 98.8%. Freedom from device- or procedure-related SAE was 96.5% through 30 days. At 1-year, primary, primary-assisted, and secondary patency rates were 74.7%, 80.4%, and 96.4%, respectively. Freedom from target lesion revascularization was 84.8%, 74.6%, and 65.0% at 1, 2, and 3 years, respectively. Per core laboratory assessment, no major amputations or device failures occurred through 3 years. At 3 years, 80.4% of patients had ≥1 Rutherford category improvement.

Conclusions: The VIABAHN endoprosthesis is a safe and effective treatment for long and complex lesions in the SFA through 3 years.
Key Inclusion Criteria

- Patient had Rutherford score 2-5
- Patient demonstrated an ABI ≤ 0.9.
- ≥ 50% in-stent restenosis and/or an occlusion in a previously implanted (>30 days) non-covered stent(s) located in the superficial femoral artery
- Maximum total lesion length of 270 mm, consisting of in-stent and adjacent occlusive disease
- Reference vessel diameter between 4.0 and 6.5 mm
- At least 1 patent infra-popliteal runoff vessel (<50% stenosis) not requiring intervention
- Angioplasty balloon can be fully expanded in the target lesion during pre-treatment step
## RELINE MAX: Patient Demographics & Clinical Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>(N = 86)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>44 (51.2%)</td>
</tr>
<tr>
<td>Age</td>
<td>70.9±10.4</td>
</tr>
<tr>
<td>Co-morbidities</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>46 (53.5%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>73 (84.9%)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>68 (79.1%)</td>
</tr>
<tr>
<td>CAD</td>
<td>45 (52.3%)</td>
</tr>
<tr>
<td>Smoking history</td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>24 (27.9%)</td>
</tr>
<tr>
<td>Former</td>
<td>44 (51.2%)</td>
</tr>
<tr>
<td>Never</td>
<td>18 (20.9%)</td>
</tr>
</tbody>
</table>

### Rutherford category

<table>
<thead>
<tr>
<th>Category</th>
<th>(N = 86)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>8 (9.3%)</td>
</tr>
<tr>
<td>3</td>
<td>69 (80.2%)</td>
</tr>
<tr>
<td>4</td>
<td>1 (1.2%)</td>
</tr>
<tr>
<td>5</td>
<td>8 (9.3%)</td>
</tr>
</tbody>
</table>

### Resting ABI

- 0.68±0.178

### Resting TBI

- 0.425±0.163

### Lesion length, cm

- 12.4±6.0

### Percent stenosis

- 69.2±13.5

### Total occlusion

- 25 (29.1%)

### Moderate/severe calcification

- 28 (32.6%)

### Tosaka Class II (N=83)

- 43 (51.8%)

### Tosaka Class III (N=83)

- 25 (30.1%)
## RELINE MAX: Treatment Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>(N = 86)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure time, minutes</td>
<td>66±31.8</td>
</tr>
<tr>
<td>Femoral access</td>
<td></td>
</tr>
<tr>
<td>Ipsilateral antegrade</td>
<td>21 (24.4%)</td>
</tr>
<tr>
<td>Contralateral retrograde</td>
<td>65 (75.6%)</td>
</tr>
<tr>
<td>Number of devices implanted</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>57 (66.3%)</td>
</tr>
<tr>
<td>2</td>
<td>27 (31.4%)</td>
</tr>
<tr>
<td>3</td>
<td>2 (2.3%)</td>
</tr>
<tr>
<td><strong>Stented length, cm</strong></td>
<td><strong>19.5±7.66</strong></td>
</tr>
<tr>
<td>Additional procedure required</td>
<td>11 (12.8%)</td>
</tr>
<tr>
<td>Resting ABI at discharge</td>
<td>0.948±0.129</td>
</tr>
<tr>
<td>Resting TBI at discharge</td>
<td>0.600±0.329</td>
</tr>
<tr>
<td>Acute procedural success</td>
<td>85/86 (98.8%)</td>
</tr>
</tbody>
</table>
RELINE MAX: 3-Year Patency Rates

### Kaplan-Meier Estimation

**At risk, % (95% CI)**

<table>
<thead>
<tr>
<th></th>
<th>Days (30)</th>
<th>Days (365)</th>
<th>Days (760)</th>
<th>Days (1095)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Secondary Patency</strong></td>
<td>83, 100% (100-100%)</td>
<td>79, 98.4% (89.4-99.8%)</td>
<td>61, 89.4% (77.8-95.1%)</td>
<td>41, 82.3% (68.5-90.5%)</td>
</tr>
<tr>
<td><strong>Primary Assisted Patency</strong></td>
<td>83, 100% (100-100%)</td>
<td>80, 80.4% (69.2-87.9%)</td>
<td>55, 64.6% (51.8-74.8%)</td>
<td>34, 56.4% (42.9-67.9%)</td>
</tr>
<tr>
<td><strong>Primary Patency</strong></td>
<td>83, 100% (100-100%)</td>
<td>80, 74.7% (62.9-83.3%)</td>
<td>51, 55.9% (43.2-66.9%)</td>
<td>31, 44.7% (32.0-56.6%)</td>
</tr>
</tbody>
</table>
RELINE MAX: Patency

Tosaka Class

Lesion Length

Stenosis vs Occlusion
There were no statistically significant differences in fTLR with respect to degree of calcification, gender, and diabetes status.
RELINE MAX: fTLR

Lesion length

Tosaka class

Stenosis vs. Occlusion
RELINE MAX: Reasons for Reintervention

- 82% due to occlusion
- 14% due to restenosis (PSVR > 2.5)
- 4% due to claudication
- 97% freedom from acute limb ischemia (ALI) at 3 years
80.4% of patients had ≥ 1 Rutherford category improvement at 3-years

No major Amputation at 3 years

No Viabahn stent fractures at 3 years
Case Presentation: BMS ISR & Fractures

• Morbidly obese male smoker with HBP, HLD, IDDM, alcohol abuse, metabolic syndrome, Hep C, p/w severe right leg claudication
• Underwent traversal of R SFA CTO with PTA and DCB
• Returned to OSH with re-occlusion, underwent placement of a Bard Lifestent c/b distal embolization
• Returned to us with recurrent IC with **nocturnal rest pain** and found to have stent thrombosis by duplex
Lifestent fractures

Distal 3-vessel runoff

EKOS lysis
Final: post relining with Viabahns
Case Presentation- Tosaka III Occlusive ISR

• 73 yo male former smoker with PMH of HBP, HLD, DM2, prior stroke, PAD
• S/P prior L SFA CTO traversal with adjunctive BMS 2016
• Now referred for RC III left calf claudication with DUS confirming occlusive ISR
Long Tosaka III occlusive ISR

X’d w/Glide
PTA of ISR  
Post-dilation  
Placed 6 x 25, 6 x 150, 6 x 50 VB’s
## VIABAHN Endoprostheses Best Practices

### Device sizing
- Treat all of the disease-stent ‘healthy to healthy’
- Overlap devices by at least 1-2 cm
- Avoid oversizing by >20% (use IVUS!)

### Procedural considerations
- Ensure adequate inflow and outflow
- Don’t dilate outside stent margins
- Place device flush with SFA ostium if any proximal disease

### Follow-up considerations
- Prescribe adequate anti-platelet therapy (DAPT ≥12 months, (Plavix + 2.5 mg bid rivaroxaban for stent thrombosis)
- Regular DUS F/U forever
- Treat progressive disease, even if asymptomatic (PSVR ≥2.5)
RELINE MAX: Summary

- RELINE MAX is the first report of long-term 36-month outcomes of the Gore Viabahn endoprosthesis for the treatment of ISR in the SFA
  - Freedom from device or procedure-related SAE was 96.5% at 30 days
  - 1-year PP, PAP, SP, rates of 74.7%, 80.4%, 98.4%
  - 3-year PP, PAP, SR, rates of 44.7%, 56.4%, 82.3%
  - Freedom from TLR was 84.8%, 74.6%, 65% at 1-, 2-, 3-years
- No major amputations or device fractures out to 3-years
- 80.4% of patients had ≥1 Rutherford category improvement
- 97% freedom from ALI at 3 years
- Device was found to be a safe and effective treatment for long, complex ISR lesions
- Comparative long-term studies on the safety and efficacy of stent-grafts with DES, DCB w/wo atherectomy are needed to determine the optimal strategy for the difficult treatment of F-P ISR