Viabahn relining is usually the best treatment for ISR

Based On Updated 2Year Results of the RELINE Trial

Patrick Peeters, MD
Chief. Dept. of Surgery
Chief. Dept Cardio-Vascular & Thoracic Surgery
Imelda Hospital Bonheiden (Belgium)

Disclosure
Speaker name: Patrick Peeters, MD
I have the following potential conflicts of interest to report:

- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest

The big challenge: the SFA

The golden standard
Fempop bypass

The Challenger
Minimal invasive endovascular therapy

But stenting in the SFA can give complications

- In stent restenosis
- Stent fractures with/without ISR
- Occlusion

Solution...the endoluminal bypass...

Stent-Grafts to Prevent Neointimal Hyperplasia...

Original stimulus for stenosis removed from the target lesion

Pore size provides a barrier to tissue ingrowth
But does the theory work in practice...???

**Next generation: Gore VIABAHN Endoprosthesis**

- Contoured proximal edge
- Propafen Bioactive Surface
- Ultra-thin wall ePTFE tube
- Unique, durable bonding film
- Polished nitinol support

**Lengths:** 2.5, 5, 10, 15, 25 cm

**Diameters:** 6 – 11 mm

*After Protocol Deviations were excluded*

---

**RELINE study**

*Prospective, randomized (PTA vs Viabahn), multicenter trial*

- Recruiting patients with an in-stent restenosis in the superficial femoral artery (4-27 cm)

1:1 randomization

- **83 patients***
- **Rutherford 2-5**
- **44 PTA alone**

---

**RELINE study**

**Participating centers**

- **BELGIUM**
  - M. Bosiers, K. Deloose - AZ Sint-Blasius, Dendermonde
  - P. Peeters, K. Keirse - Imelda Hospital, Bonheiden
  - J. Hendriks, P. Lauwers, O. D’archambeau - UZA, Edegem
  - W. Lantsink, G. Lauwers, H. Schrötl - ZOL, Genk

- **GERMANY**
  - D. Scheinert, A. Schmidt - Herzzentrum Leipzig
  - T. Zeller - Herz-zentrum Bad Krozingen
  - G. Torsello - St. Franziskus Hospital, Münster

---

**RELINE study**

**Primary endpoints**

- **Primary patency at 12 months**
  - No evidence of restenosis or occlusion within the originally treated lesion based on color-flow duplex ultrasound (CFDU) measuring a peak systolic velocity ratio ≤2.5 and without target lesion revascularization (TLR) within 12 months

- **Serious device-related adverse events**
  - Within 30 days post-procedure

---

**RELINE study**

**Key inclusion criteria**

- **Rutherford classification from 2 to 5**
- Ankle-brachial index ≤0.8
- Restenotic or reoccluded lesion located in a stent (implanted >30 days) in the superficial femoral artery
- Total target lesion length between 4 and 27 cm (comprising in-stent restenosis and adjacent stenotic disease)

---

**RELINE study: Patient demographics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>VIABAHN ISR N=39</th>
<th>PTA N=44</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (%)</td>
<td>29 (76.9%)</td>
<td>32 (72.7%)</td>
<td>0.853</td>
</tr>
<tr>
<td>Female (%)</td>
<td>10 (23.1%)</td>
<td>12 (27.3%)</td>
<td></td>
</tr>
<tr>
<td>Age (min – max; ± SD)</td>
<td>67.69 (49 – 86; 9.77)</td>
<td>68.98 (48 – 86; 9.71)</td>
<td>0.791</td>
</tr>
</tbody>
</table>

| Rutherford classification (R 2-3) (%) | 51 (87%) | 51 (87%) | 0.508   |
| Critical Limb Ischemia (R 4-5) (%) |         | 3 (5%)   |         |
| Rutherford 2 (%)              | 12 (22.4%) | 12 (22.4%) | 0.874   |
| Rutherford 3 (%)              | 22 (44.9%) | 20 (46.5%) | 0.553   |
| Rutherford 4 (%)              | 4 (7.7%)  | 3 (6.8%)  | 0.665   |
| Rutherford 5 (%)              | 1 (2.1%)  | 6 (12.8%) |         |
### RELINE study: Patient demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>VIABAHN ISR N=39</th>
<th>PTA N=44</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical history</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nicotine abuse</td>
<td>Never 13 (33.3%) 12 (27.3%)</td>
<td>Current 15 (38.5%) 16 (36.4%)</td>
<td>0.969</td>
</tr>
<tr>
<td>Hypertension</td>
<td>No 12 (30.8%) 16 (36.4%)</td>
<td>Yes, medically treated 36 (91.4%) 27 (61.4%)</td>
<td>0.865</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>No 26 (66.7%) 29 (65.9%)</td>
<td>Yes, insulin dependent 8 (19.5%) 7 (15.9%)</td>
<td>0.951</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>No 37 (94.9%) 30 (68.2%)</td>
<td>Yes 2 (5.1%) 1 (2.3%)</td>
<td>0.889</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>No 22 (56.4%) 21 (47.7%)</td>
<td>Yes 17 (41.4%) 29 (65.9%)</td>
<td>0.099</td>
</tr>
<tr>
<td>Obesity</td>
<td>No 28 (71.8%) 33 (75.0%)</td>
<td>Yes 11 (28.2%) 11 (25.0%)</td>
<td>0.935</td>
</tr>
</tbody>
</table>

### RELINE study: Lesion characteristics

<table>
<thead>
<tr>
<th>Lesion characteristic</th>
<th>PTA (N=44)</th>
<th>Viabahn (N=39)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg lesion length (mm)</td>
<td>190 (30-270)*</td>
<td>173 (30-330)</td>
</tr>
<tr>
<td>Stenosis (pre) %</td>
<td>75.0 %</td>
<td>76.9 %</td>
</tr>
<tr>
<td>Chronic occlusion %</td>
<td>25.0 %</td>
<td>20.5 %</td>
</tr>
<tr>
<td>Acute occlusion %</td>
<td>0.0 %</td>
<td>2.6 %</td>
</tr>
<tr>
<td>Calcified lesion %</td>
<td>25.0 %**</td>
<td>33.3 %</td>
</tr>
</tbody>
</table>

* Missing data of 3 patients
** Missing data of 1 patient

9 bail-out procedures after failed PTA

### Viabahn: pre-op

100% in-stent restenosis of 180mm

### Viabahn: post-op

First Viabahn E150
Second Viabahn E150
Second Viabahn E150

### PTA: pre-op

Oclusion in stent of 220mm

### PTA: dilation & post-op

2 inflations with 8*5100 FoxCross balloon
The RELINE Trial: 1–2 yr primary patency

<table>
<thead>
<tr>
<th>Time</th>
<th>Viabahn</th>
<th>PTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>74.8%</td>
<td>28.0%</td>
</tr>
<tr>
<td>2 year</td>
<td>58.4%</td>
<td>11.6%</td>
</tr>
</tbody>
</table>

p<0.001

The RELINE Trial: 1–2 yr freedom TLR

<table>
<thead>
<tr>
<th>Time</th>
<th>Viabahn</th>
<th>PTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>80.0%</td>
<td>42.0%</td>
</tr>
<tr>
<td>2 year</td>
<td>66.3%</td>
<td>23.0%</td>
</tr>
</tbody>
</table>

p<0.001

Conclusion

There is some evidence that chemical solutions (DEB) are valuable in the battle against ISR. The RELINE results prove, even on the longer run, that a mechanical barrier (like the Viabahn stentgraft) is also a promising tool for treatment of in-stent restenosis.

Conclusion

Next generation Viabahn endoprosthesis seems to be an efficient bridge towards bypass surgery in SFA in-stent restenosis treatment (endoluminal bypass).