Value of Gore Viabahn Endografts to treat ISR
Tips and Tricks for successful durable use in this setting

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Conflict of interest
☐ 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

Results with DCB, SES & DES in the SFA

Classification if ISR: TOSAKA I, II and III

The RELINE trial

RELINE study

Physician initiated, randomized, controlled, multi-center trial comparing the new generation Viabahn endoprosthesis (Gore & Associates, Flagstaff, AZ) and POBA in the treatment of femoral in-stent restenosis

1:1 randomization
83 patients*
Rutherford 2-5

39 Viabahn
Endoprosthesis

44 PTA alone

* After Protocol Deviations were excluded
RELINE study: Endpoints

- **Primary patency at 12 months**
  - No evidence of restenosis/occlusion within the treated lesion based on CFDU (peak systolic velocity ratio ≤2.5) & without TLR within 12 months

- **Primary Patency at 24 months**
  - No evidence of restenosis/occlusion within the treated lesion based on CFDU (peak systolic velocity ratio ≤2.5) & without TLR within 24 months

RELINE study: Inclusion Criteria

- **Rutherford classification 2-5**
- Ankle-brachial index ≤0.8
- Restenosis/reocclusion in a stent (implanted >30 days) in the superficial femoral artery
- Total target lesion length between 4 - 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 (74.4%)</td>
<td>52 (72.7%)</td>
<td>0.853</td>
</tr>
<tr>
<td>Female (%)</td>
<td>10 (25.6%)</td>
<td>12 (27.3%)</td>
<td></td>
</tr>
<tr>
<td>Age (min – max; ±SD)</td>
<td>67 (94; 9.7)</td>
<td>68 (84; 7.1)</td>
<td>0.791</td>
</tr>
<tr>
<td>Rutherford categorization</td>
<td>54 (75.8%)</td>
<td>56 (85.7%)</td>
<td>0.508</td>
</tr>
<tr>
<td>Classification (R-2-3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Critical Limb ischemia (R-4-5)</td>
<td>5 (10.4%)</td>
<td>8 (16.4%)</td>
<td></td>
</tr>
<tr>
<td>Rutherford 2 (%)</td>
<td>12 (26.6%)</td>
<td>5 (13.6%)</td>
<td></td>
</tr>
<tr>
<td>Rutherford 3 (%)</td>
<td>22 (44.2%)</td>
<td>30 (69.4%)</td>
<td>0.005</td>
</tr>
<tr>
<td>Rutherford 4 (%)</td>
<td>4 (8.2%)</td>
<td>3 (6.8%)</td>
<td></td>
</tr>
<tr>
<td>Rutherford 5 (%)</td>
<td>1 (2.1%)</td>
<td>5 (11.4%)</td>
<td></td>
</tr>
</tbody>
</table>

RELINE study: 12-month Primary Patency

- **VIABAHN** vs. **PTA**
  - **72.50 %** vs. **26.40 %**
  - **p<0.001**
RELINE study: 12-month freedom from TLR

**VIABAHN vs. PTA**

<table>
<thead>
<tr>
<th>Number at risk</th>
<th>Baseline</th>
<th>1MFU</th>
<th>6MFU</th>
<th>12MFU</th>
<th>24MFU</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA</td>
<td>53</td>
<td>39</td>
<td>33</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Viabahn</td>
<td>47</td>
<td>46</td>
<td>43</td>
<td>33</td>
<td></td>
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81.20 %

40.60 %
P<0.001

RELINE study: 24-month Primary Patency

**VIABAHN vs. PTA**

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<td>26</td>
<td>11</td>
<td>4</td>
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<tr>
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<td>39</td>
<td>37</td>
<td>35</td>
<td>26</td>
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58.4 %

11.6 %
P<0.001

RELINE study: 24-month freedom from TLR

**VIABAHN vs. PTA**

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<td>38</td>
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66.3 %

23.0 %
P<0.001

First conclusion RELINE study

- ISR is the Achilles heel of the current SFA treatment
- The RELINE results prove that a mechanical barrier (like the Viabahn stentgraft) against tissue ingrowth is also a promising tool for treatment of in-stent restenosis

Alternatives to treat ISR?

**Chemical block**
- Inhibiting smooth muscle cell migration and proliferation
  - DEB
  - DES

**Mechanical block**
- Creating physical barrier & Remove the stimulus for ISR from the equation
  - Covered stents
Drug Coated Balloon Angioplasty? IN.Pact Global in-stent restenosis cohort

**Overview DCB results**

<table>
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<th>DCB</th>
<th>Laser</th>
<th>POBA</th>
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<td>72.50%</td>
<td>50.50%</td>
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**Final Conclusion**

- ISR remains a difficult to treat clinical problem
- Viabahn stenting obtains good results in these challenging lesions. Significant better when compared to PTA.
- There is absolute need for a new RCT comparing Viabahn stenting with DCB in femop ISR lesions.