VIASTAR Trial

Randomized, multi-center data supporting the use of GORE® VIABAHN® Endoprosthesis in complex SFA lesions.

VIASTAR Trial Design

**Objective:** Evaluate the performance of GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface (5–8 mm diameters) and bare metal stents (BMS) in treating long SFA disease.

**Primary Endpoints:**
- Primary Patency at 12 months
- Proportion of subjects experiencing composite adverse events within 30 days of procedure

VIASTAR Trial Randomization

<table>
<thead>
<tr>
<th>141 PATIENTS RANDOMLY ALLOCATED TO TREATMENT</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>72 patients allocated to GORE® VIABAHN® Endoprosthesis (Intent-to-Treat)</td>
<td>69 patients allocated to Bare Metal Stent (Intent-to-Treat)</td>
</tr>
<tr>
<td>66 patients analyzed (Per-Protocol)</td>
<td>63 patients analyzed (Per-Protocol)</td>
</tr>
</tbody>
</table>

Lesion Characteristics

<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>GORE® VIABAHN® Endoprosthesis (n = 72)</th>
<th>Bare Metal Stent (n = 69)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Chronic Occlusions</td>
<td>79%</td>
<td>70%</td>
<td>0.21</td>
</tr>
<tr>
<td>Mean Lesion Length (mm)</td>
<td>190</td>
<td>173</td>
<td>0.13</td>
</tr>
</tbody>
</table>

Patency advantage with GORE® VIABAHN® Endoprosthesis amplified in lesions ≥ 20 cm.

When treating lesions at the same TASC II level, BMS were 2.71 times more likely to lose patency.

Statistically fewer restenosis in GORE® VIABAHN® Endoprosthesis group.

No statistical difference in occlusions or incidence of Acute Limb Ischemia (ALi) between GORE® VIABAHN® Endoprosthesis and Bare Metal Stent arms of the study.
VIATOR Clinical Study Conclusions

- “When treating PAD in patients with long diffuse femoropopliteal artery disease, [the use of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface yields] clinical and patency benefits compared with BMS.”

- Primary patency significantly higher for the GORE® VIABAHN® Endoprosthesis in all lesions, particularly in lesions ≥ 20 cm.

- When treating lesions at the same TASC II level, BMS were 2.71 times more likely to lose patency.

- Significantly higher ABI in patients treated with GORE® VIABAHN® Endoprosthesis than with BMS at one-year.

- No statistical difference in occlusions or incidence of ALI.