How to achieve good results with the GORE® VIABAHN® Endoprosthesis for treating complex femoropopliteal occlusive disease: Results from the Japanese IDE trial

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Disclosure

Speaker name: Takao Ohki

I 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
GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface

- Ultra-thin wall ePTFE tube
- Unique, durable bonding film
- Polished nitinol support
- Contoured proximal edge
- CBAS Heparin Surface*

Lengths: 2.5, 5, 7.5, 10, 15, 25 cm
Diameters: 5–13 mm

* PROPATEN Bioactive Surface is synonymous with the CBAS Heparin Surface.
Achilles' heel of FP bypass (PTFE): Thrombosis CBAS technology

Control PTFE

Propaten

3 years post implant
Compliant with the Mechanical Forces of the SFA

- More than 700,000 GORE® VIABAHN® Endoprosthesis sold worldwide
- Very low incidence of reported fractures (< 0.015%)
- Capable of longitudinal compression with little residual force
- Superb flexibility
Mechanical Forces in the SFA
Flexion

“The curvature of the femoral vessels was studied and quantified in stretched and flexed positions...Three or more small curves were seen proximal to the knee joint in all volunteers”¹

Mechanical Forces in the SFA
Longitudinal Compression

The GORE® VIABAHN® Endoprosthesis is capable of longitudinal compression with little residual force.

Longitudinal Compression
“From the supine position to the fetal position, the SFA shortened 13% ± 11% (P < .001)”¹

#1 Achilles' heel of SFA stenting: ISR
Blocking Neointimal Hyperplasia

• Achilles' heel of SFA stenting

- Original stimulus for stenosis removed from the equation
- Pore size provides a barrier to tissue ingrowth
Difference between BMS ISR (diffuse, usually symptomatic) and covered stent edge stenosis (focal and often asymptomatic)

If stenosis does recur, have changed an initial TASC II C or D lesion to TASC A

Tough restenosis
Ideal SFA stent

- Mechanical barrier against intimal hyperplasia
- Fracture resistant
- Thrombosis resistant
Typical Viabahn restenosis
Only at the edge

Viabahn: 5.0mm - 250mm

Edge stenosis
PSVR: 2.4

Re-intervention easily performed with Viabahn 5.0mm x 2.5cm

Viabahn: 5.0-250mm
The evolution of a device

1996
Original GORE® HEMOBahn® Endoprosthesis introduced in Europe

2002
Original device introduced in US as GORE® VIABahn® Endoprosthesis

2003
TIP to HUB deployment introduced on 6-8 mm devices

2007
5-8 mm devices decreased in profile by one French size
GORE® VIABahn® Endoprosthesis with Heparin Bioactive Surface introduced in US

2009
Laser technology enables the contoured edge at proximal end
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2013
25 cm Length, longest stent-graft introduced in US

2014
5-8 mm devices introduced with radiopaque markers at ends of device

2016
GORE® VIABahn® Endoprosthesis with Heparin Bioactive Surface approved in Japan

Heparin-coated, contoured edge, low profile (0.018” compatible) device used in the Japan IDE Trial.
Japan VIABAHN® IDE Trial: Basic strategy of the trial

- No interventional treatment was approved for lesions greater than 15cm in length in Japan
- Significant number of FP bypass was done for TASC II C/D lesions at the start of the trial
- A device that was proven in long, complex lesions was needed
- Invasiveness measures devised to prove lower invasiveness of VIABAHN compared to FP bypass: if equal performance percutaneous wins
- Repeat percutaneous procedures under local anesthesia for ISR not considered as a defeat
- Avoidance of bypass surgery and maintenance of flow important
  - Led to Primary Assisted Patency ≈ avoidance of surgery as primary endpoint
For the purpose of IDE approval the downside or FP bypass was exaggerated.
# Gore Japan IDE Clinical Study:
Performance in Patients that may Otherwise Require Bypass

<table>
<thead>
<tr>
<th>Objective</th>
<th>To test the efficacy and invasiveness of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface for the treatment of long / complex superficial femoral artery (SFA) lesions (≥ 10 cm) that currently may require bypass.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>Single-arm, prospective, 15 sites, 103 patients for analysis. Invasiveness compared to retrospective review of bypass patients. Core laboratory adjudicated.</td>
</tr>
</tbody>
</table>
| Primary endpoint                                                         | **Primary assisted patency at 12 months**  
Hemodynamic evidence of flow through a device that had not required a target lesion revascularization (TLR) to restore blood flow after total occlusion.  
**Post-procedure hospital stay** (compared to historical bypass control).  
**Freedom from general anesthesia** (compared to historical bypass control). |
| Secondary Endpoints                                                      | **Safety:** Adverse events. Freedom from death, TVR, and major amputation of the treated limb through 30 days post-procedure.  
**Efficacy:** Technical success, primary patency, secondary patency, fTLR, fTVR, limb salvage, clinical success, stent fracture, ABI (or TBI), QOL.  
**Invasiveness:** Freedom from blood transfusion.                                                                     |
| Patency Definitions                                                      | **Primary Patency:** Hemodynamic blood flow through a device that had not required a TLR to maintain or restore blood flow.  
**Secondary Patency:** No performance of bypass surgery and no occlusion at the target site.                             |
| Additional Analysis                                                      | **Primary Patency:** PSVR of < 2.5 without TLR. |
Gore Japan IDE Clinical Study: Performance in patients who may otherwise require bypass

Follow-up:
- 1, 3, 6, 12 and 24 month CDUS
- Annual visits through 5 years to assess fracture, AE’s
- Primary patency data available through 24 months
- fTLR data will be collected through 60 months
Outcome depends on what you treat:
Where Viabahn Japan data fits

* Prospective Randomized or Prospective Multicenter (> 2 sites) SFA studies included. Studies that did not report primary patency at 12-months are not included. Patency definitions may vary: where Kaplan-Meier estimates with a PSVR of ≥ 2.5 are available, these were used for comparison. For the GORE® VIABAHN® Endoprosthesis, only studies that utilized the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface were included. Drug-coated balloon studies were only included for those studies that report data for devices currently approved in the US. Atherectomy: non-SFA lesions were included in the reported patency rates in the CELLO (N = 5 out of 65 total) and Pathway PVD trials (N = 76 out of 210 total). Non-SFA lesions were included in the reported patency rates in the Micari, et al. study (N = 12 out of 114 lesions total), LEVANT I Trial (N = 4 out of 49 total), LEVANT II Trial (N = 31 out of 316 total), and IN.PACT SFA I and II Trial (15 out of 221 total).1-29

** Gore RELINE clinical study was for treatment of in-stent restenosis in the SFA.27
Proper Sizing Correlates with Optimal Outcomes

Size was not measured but eyeballed in the Viper Trial

IVUS seldom used

* Gore VIPER Clinical Study: A prospective, multi-center study of 119 limbs in the U.S. (19 cm average lesion length). Overall results 73% Primary Patency. Retrospective analysis was done on device sizing by Core Lab on 95 limbs. For devices oversized < 20% at the proximal edge Primary Patency was 88%.1

** GORE® VIABAHN® Endoprosthesis Japan IDE Clinical Study demonstrated 12-month primary patency of 92% as defined by evidence of flow with no target lesion revascularization (TLR). The same study demonstrated 88% 12-month primary patency when defined by PSVR of < 2.5 without TLR.
Inclusion / Exclusion Criteria Designed to Target Complex SFA Disease

• Inclusion Criteria
  — Rutherford 2–5
  — ABI ≤ 0.9 or TBI ≤ 0.5
  — Surgical bypass candidate
  — Angiographic:
    • Lesion length ≥ 10 cm (No upper limit)
    • SFA lesion
      – 1 cm below the SFA origin and ending 1 cm above the intercondylar notch
    • Patent distal popliteal artery
    • At least one patent tibial artery
    • Lesion can be pre-dilated
    • Reference vessel diameters between 4.0 and 7.5 mm. Must be measured and not estimated
    • IVUS encouraged

• Exclusion Criteria
  — Untreated flow-limiting aortoiliac disease (could be treated during index procedure)
  — Any previous stenting or surgery in target vessel
  — Femoropopliteal aneurysm
  — Rutherford 5 with active infection
  — Known coagulation disorder
  — Current dialysis
  — Contraindication to anticoagulation or antiplatelet
Anatomical inclusion criteria

- Lesion length >10cm
- No upper limit
- Rutherford category 2-5
- Reference vessel diameter 4 to 7.5 mm
Majority of Patients Were Older Men with a History of Smoking and Diabetes

<table>
<thead>
<tr>
<th>Number of Subjects Enrolled</th>
<th>N = 103</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>n</td>
</tr>
<tr>
<td>Mean (Std Dev)</td>
<td>74.2 (7.0)</td>
</tr>
<tr>
<td>Median</td>
<td>75</td>
</tr>
<tr>
<td>Min–Max</td>
<td>55–91</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>85 (82.5%)</td>
</tr>
<tr>
<td>Female</td>
<td>18 (17.5%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Smoking History</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Smoker</td>
<td>29 (28.2%)</td>
</tr>
<tr>
<td>Former Smoker</td>
<td>52 (50.5%)</td>
</tr>
<tr>
<td>Never Smoked</td>
<td>22 (29.7%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diabetes Mellitus</th>
<th>n (%)</th>
</tr>
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<tbody>
<tr>
<td>Non-diabetic</td>
<td>41 (39.8%)</td>
</tr>
<tr>
<td>Diabetic</td>
<td>62 (60.2%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ABI</th>
<th>(N = 102)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (Std Dev)</td>
<td>0.64 ± 0.12</td>
</tr>
<tr>
<td>Median</td>
<td>0.62</td>
</tr>
<tr>
<td>Min–Max</td>
<td>0.38–0.89</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline Rutherford Category</th>
<th>(N = 103)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 2 – Moderate Claudication</td>
<td>45 (43.7%)</td>
</tr>
<tr>
<td>Category 3 – Severe Claudication</td>
<td>55 (53.4%)</td>
</tr>
<tr>
<td>Category 4 – Ischemic Rest Pain</td>
<td>1 (1.0%)</td>
</tr>
<tr>
<td>Category 5 – Minor Tissue Loss</td>
<td>2 (1.9%)</td>
</tr>
</tbody>
</table>
Evaluated in Long, Complex Lesions  Generally indicated for Bypass

Population enrolled generally suitable for bypass:
Mean lesion length 22cm and 84.5% TASC II C or D

<table>
<thead>
<tr>
<th>TASC Classification</th>
<th>Count (Percentage)</th>
</tr>
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<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>Count (Percentage)</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>
Device Evaluated in a Challenging Biomechanical Environment

With over half the patients reporting sitting seiza-style or cross-legged at least 25% of the time, this population presents a challenging biomechanical environment for long lesions that were allowed to extend through Hunter’s canal to 1 cm above the intercondylar notch.

<table>
<thead>
<tr>
<th>% of Time Study Subjects Sat on Legs or Cross-Legged</th>
<th>N = 103</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>49 (47.6%)</td>
</tr>
<tr>
<td>25</td>
<td>20 (19.4%)</td>
</tr>
<tr>
<td>50</td>
<td>16 (15.5%)</td>
</tr>
<tr>
<td>75</td>
<td>10 (9.7%)</td>
</tr>
<tr>
<td>100</td>
<td>8 (7.8%)</td>
</tr>
</tbody>
</table>


Seiza style
Stent-Grafts Were Less Invasive than Bypass

Treatment with stent-grafts shown to be less invasive than bypass by all measures

<table>
<thead>
<tr>
<th></th>
<th>GORE® VIABAHN® ENDOPROSTHESIS (N = 103)</th>
<th>BYPASS* (N = 68)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from General Anesthesia, N (%)</td>
<td>103 (100.0)</td>
<td>17 (25.0)</td>
</tr>
<tr>
<td>Procedure Time, min (mean ± SD)</td>
<td>117±60</td>
<td>175±67</td>
</tr>
<tr>
<td>Estimated Blood Loss, mL (mean ± SD)</td>
<td>16±6.8</td>
<td>115±144.8</td>
</tr>
<tr>
<td>Freedom from Blood Transfusion, N (%)</td>
<td>103 (100.0)</td>
<td>64 (94.1)</td>
</tr>
<tr>
<td>Hospitalization Duration, days (mean ± SD)</td>
<td>3.5±2.9</td>
<td>16.2±17.9</td>
</tr>
<tr>
<td>Freedom from ICU Admission, N (%)</td>
<td>103 (100.0)</td>
<td>64 (94.1)</td>
</tr>
</tbody>
</table>

* Retrospective series of 68 bypass patients collected from study sites (6 / 15 sites). Patient selection was done according to a similar set of inclusion / exclusion criteria as those treated by the study device.
Primary effectiveness endpoint met

91 / 100 patients at the end of one year follow-up were occlusion free

94.1% Primary Assisted Patency K-M at day 365

Statistically non-inferior to 80% PP of surgical bypass from literature
88% Primary Patency in 21.8 cm Average Length Lesions

• In the Gore Japan IDE Clinical Study, the GORE® VIABAHN® Endoprosthesis demonstrated 88% 12-month primary patency*

• Average Lesion Length 21.8 cm

* GORE® VIABAHN® Endoprosthesis Japan IDE Clinical Study demonstrated 12-month primary patency of 92% as defined by evidence of flow with no target lesion revascularization (TLR). The same study demonstrated 88% 12-month primary patency when defined by PSVR of < 2.5 without TLR.
Subgroup analyses
93% Primary Patency in Lesions Between 10–20 cm

- In the Gore Japan IDE Clinical Study, the GORE® VIABAHN® Endoprosthesis demonstrated 92.7% 12-month primary patency in lesions between 10 and 20 cm*.
- Average Lesion Length 16.2 cm.

* GORE® VIABAHN® Endoprosthesis Japan IDE Clinical Study demonstrated 100% 12-month primary patency as defined by evidence of flow with no target lesion revascularization (TLR) in lesions ≤ 20 cm and ≥ 10 cm (shortest length allowed for enrollment). Average lesion length 16.2 cm. N = 43 of 103. The same study demonstrated primary patency of 92.7% when calculated using PSVR of < 2.5 with no TLR in lesions ≤ 20 cm and ≥ 10 cm (shortest length allowed for enrollment).
Subgroup analyses
85% Primary Patency in Lesions > 20 cm

- In the Gore Japan IDE Clinical Study, the GORE® VIABAHN® Endoprosthesis demonstrated 84.8% 12-month primary patency in lesions greater than 20 cm*
- Average lesion length: 25.7 cm

* GORE® VIABAHN® Endoprosthesis Japan IDE Clinical Study demonstrated 86.5% 12-month primary patency as defined by evidence of flow with no target lesion revascularization (TLR) in lesions > 20 cm. Average lesion length 25.7 cm. N = 60 of 103. The same study demonstrated primary patency of 84.8% when calculated using PSVR of < 2.5 with no TLR in lesions > 20 cm.
Several Key Patient Factors Showed No Impact to Primary Patency

No significant differences in patency

- Diabetes
- Lesion calcification
- Subject age
- Number of runoff vessels
- Smoking status
- Hypertension
Merit and demerit of Covering Collaterals

PTA dilation

VIABAHN®

6 x 15cm
Covering Collaterals

Competing interests

Complete lesion coverage / Increased flow through device

Preserve Collaterals

Minimize failure

- Complete coverage prevents progression
- Prevents competing flow

Less risk of limb threat?

Collaterals provide a flow path in case of device failure
Safety endpoint
No Acute Limb Ischemia, No Fractures, No Bypass

• No cases of Acute Limb Ischemia (ALI) were observed through end of 12 month follow-up
  *Occlusions : 6

• No fractures were identified by core laboratory

• No patient required bypass

• Limb salvage 100%

• No patient death, target vessel revascularization, or major amputation within 30 days
Proper Sizing Correlates with Optimal Outcomes

Size was not measured but eyeballed in the Viper Trial

IVUS seldom used

* Gore VIPER Clinical Study: A prospective, multi-center study of 119 limbs in the U.S. (19 cm average lesion length). Overall results 73% Primary Patency. Retrospective analysis was done on device sizing by Core Lab on 95 limbs. For devices oversized < 20% at the proximal edge Primary Patency was 88%.1

** Gore® VIABAHN®: Japan IDE Clinical Study demonstrated 12-month primary patency of 92% as defined by evidence of flow with no target lesion revascularization (TLR). The same study demonstrated 88% 12-month primary patency when defined by PSVR of < 2.5 without TLR.
Unlike the Viper trial size was measured in the Japan Trial

Proper sizing is critical to achieving successful outcomes.¹,⁵

* Gore VIPER Clinical Study: A prospective, multi-center study of 119 limbs in the U.S. (19 cm average lesion length). Overall results 73% Primary Patency. Retrospective analysis was done on device sizing by Core Lab on 95 limbs. For devices oversized ≤ 20% at the proximal edge Primary Patency was 88%.¹

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How to achieve good results with the GORE® VIABAHN® Endoprosthesis: Lessons from the Japan trial

Best practices followed throughout the study

• Vessel size at landing zones was required to be measured, not estimated
  — Quantitative angiography was used in all cases
  — IVUS was used in 70%
  — Device sizes were chosen per IFU (5 – 20% oversizing)
• Landing zones were carefully selected so that all disease was covered
• Pre and post-dilation performed in all cases (high pressure balloons in most)
• Dual antiplatelets were required for six months and recommended for 12 months
  — Aspirin and clopidogrel (or other theopyridine class)
  — Cilastozol additionally prescribed in some cases
• Consistent follow-up was performed
  — 1, 3, 6, and 12 month duplex ultrasound
Figure 1

VIABAHN Japan IDE Example
3 yrs post stent

ABI unchanged at 0.9
Japan Viabahn Case with internal control

Rt SFA treated with Viabahn

Lt SFA with BMS

Courtesy of Dr Yamaoka

Viabahn

BMS
Japan Viabahn Trial: Summary

- Despite including mostly TASC II C/D lesions (84.5%), the GORE® VIABAHN® Endoprosthesis showed 88% Primary Patency and 94% Primary Assisted Patency.
- These are lesions normally recommended for treatment by above knee bypass.
- The GORE® VIABAHN® Endoprosthesis has the potential to replace bypass for treatment of long/complex lesions.
- In medium length lesions ≤ 20cm, Primary Patency was 93%.
- Other interventional devices have mainly been studied in shorter lesions.
- Stent-grafts may be preferred to other interventional treatments in medium length lesions.
- With no cases of ALI, and no patients requiring bypass or amputation, safety has been shown.
- The Japanese IDE Trial results are a result of careful technique.
  - Quantitative sizing
  - Complete disease coverage
  - Diligent post PTA
  - Dual antiplatelet administration
  - Good follow-up
Evolution of a device, evolution of techniques, accumulation of data

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Original GORE® HEMOBahn® Endoprosthesis introduced in Europe

2002
Original device introduced in US as GORE® VIABahn® Endoprosthesis

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2016
Japan IDE approval

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2 Year Results

Will be presented in Main Arena Room 1 at 17:14 in the session titled “New concepts for complex femoropopliteal disease”.

Eluvia stent (Majestic trial)
R 2-4 n=57
Mean Lesion length 7.1 cm
Primary patency 1 yr 96% 2 yr 78.2%

Hulsbeck SM LINC 2017

1yr success does not guarantee 2yr so stay tuned
Japan Viabahn conducted with Ideal SFA stent, Ideal practice

- Mechanical barrier against intimal hyperplasia
- Fracture resistant
- Thrombosis resistant
- Contour edge
- Viabahn implant tricks
  - <20% oversizing
  - Full lesion coverage
  - DAPT, Diligent FU
Proven Patency for Complex SFA Lesions

- 88% 12-month primary patency
- Good technique drives great outcomes
  — Proper sizing is critical
- 93% Primary Patency in lesions between 10–20 cm (average 16.2 cm)
- Zero cases of ALI, bypass, or amputation
References


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