2 year results of the VIABAHN Japan IDE trial for complex SFA lesions

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Jikei University, Tokyo, Japan
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
Confession

Missed last flight from Frankfurt to Leipzig
Came by taxi
4 hr drive
750 Euro

Door to door from Tokyo to Leipzig 27 hours

750 Euro
**GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface**

- Originally launched in Europe as the HEMOBAHN® Endoprosthesis, the device has been continually approved with the addition of the CBAS Heparin Surface, a contoured proximal edge, radiopaque markers, and lower profiles.
- It was approved in Japan in February 2016 for the treatment of complex SFA disease based on the 1 year results of this trial.

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

**Specifications:**
- Lengths: 2.5, 5, 10, 15, 25 cm
- Diameters: 5–13 mm

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*Heparin Bioactive Surface is synonymous with the CBAS Heparin Surface.*
Heparin-coated, contoured edge, low profile (0.018” compatible) device used in the Japan IDE Trial.
Opportunity to test the Latest version of an Ideal SFA stent in an IDE setting

Ideal stent
- Mechanical barrier against intimal hyperplasia
- Fracture resistant
- Thrombosis resistant
**Gore Japan IDE Clinical Study:**
**Performance in Patients that may Otherwise Require Bypass**

<table>
<thead>
<tr>
<th><strong>Objective</strong></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><strong>Design</strong></td>
<td>Single-arm, prospective, 15 sites, 103 patients for analysis. Invasiveness compared to retrospective review of bypass patients. Core laboratory adjudicated.</td>
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</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

**Diligent 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
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 recommended

**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
Proper Sizing Correlates with Optimal Outcomes: Results of the VIPER Trial

Proper sizing is critical to achieving successful outcomes.¹

* 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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  — Current dialysis
  — Contraindication to anticoagulation or antiplatelet
Anatomical inclusion criteria

Inclusion criteria
- Lesion length >10 cm
- 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>Age (Years)</th>
<th>n</th>
<th>Mean (Std Dev)</th>
<th>Median</th>
<th>Min–Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (Std Dev)</td>
<td>74.2 (7.0)</td>
<td>0.64 ± 0.12</td>
<td>0.62</td>
<td>0.38–0.89</td>
</tr>
<tr>
<td>Median</td>
<td>75</td>
<td>0.62</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min–Max</td>
<td>55–91</td>
<td>0.62</td>
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<table>
<thead>
<tr>
<th>Gender</th>
<th>n (%)</th>
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<tbody>
<tr>
<td>Male</td>
<td>85 (82.5%)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>18 (17.5%)</td>
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<table>
<thead>
<tr>
<th>Smoking History</th>
<th>n (%)</th>
<th></th>
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<tbody>
<tr>
<td>Current Smoker</td>
<td>29 (28.2%)</td>
<td></td>
</tr>
<tr>
<td>Former Smoker</td>
<td>52 (50.5%)</td>
<td></td>
</tr>
<tr>
<td>Never Smoked</td>
<td>22 (29.7%)</td>
<td></td>
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</tbody>
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<tr>
<th>Diabetes Mellitus</th>
<th>n (%)</th>
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<tbody>
<tr>
<td>Non-diabetic</td>
<td>41 (39.8%)</td>
<td></td>
</tr>
<tr>
<td>Diabetic</td>
<td>62 (60.2%)</td>
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</table>

Evaluated in Long, Complex Lesions  Generally indicated for Bypass

Mean lesion length 22cm, 66% CTO and 84.5% TASC II C or D

<table>
<thead>
<tr>
<th>TASC Classification</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>TASC II A</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>TASC II B</td>
<td>16</td>
<td>15.5%</td>
</tr>
<tr>
<td>TASC II C</td>
<td>75</td>
<td>72.8%</td>
</tr>
<tr>
<td>TASC II D</td>
<td>12</td>
<td>11.7%</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>SFA Lesion Location (Lesion may cross over)</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal</td>
<td>72</td>
<td>69.9%</td>
</tr>
<tr>
<td>Mid</td>
<td>99</td>
<td>96.1%</td>
</tr>
<tr>
<td>Distal</td>
<td>77</td>
<td>74.8%</td>
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</table>
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>
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* 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.
12-Month Data Review
Ohki T, et al JVS 2017 in press

- Primary Patency:
  - 92.1% patency protocol definition (flow through the device with no TLR)
  - 88.1% Primary patency (PSVR < 2.5 with no TLR)
- Primary Assisted Patency: 94.1%
- Secondary Patency: 98.0%
- fTLR: 93.1%

These results obtained in a patient population with average 21.8 cm long lesions, 65.7% total occlusions
1yr success does not guarantee 2yr patency

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
Japan IDE 24-Month Patency

2 year Primary Patency 78.7% in Avg lesion length 22cm

* Primary Patency-Interventional defined by PSVR of < 2.5 without TLR.
24-Month Results: fTLR

- Freedom from TLR (%) over time post treatment (months).
- The graph shows a steady decline in the percentage of freedom from TLR, with a notable plateau at around 87.2% at 24 months.

Graph details:
- Y-axis: Freedom from TLR (%)
- X-axis: Time post treatment (months)
- Significant percentage drop observed at 12 months.
Sub analyses
24 Month Results: Primary Patency* by Lesion Length

- Average lesion length for the ≤ 20 cm group: **16.2 cm**
- Average lesion length for the > 20 cm group: **25.7 cm**

*Primary Patency defined by PSVR of < 2.5 without TLR.*
As long as sized correctly, bigger is better

24 Month Results: Primary Patency* by Device size

- A function of device performance or simply small patient vessels?
- VIPER results showed no difference here at 12 months
  - May have been a function of oversizing more with 6 mm devices
  - 12 month patency value numerically higher in the current study with 5mm devices than overall results in VIPER

* Primary Patency-Interventional defined by PSVR of < 2.5 without TLR.
24 Month Results: fTLR by Device Diameter

- fTLR not statistically different by device diameter
- Even though primary patency is statistically different, PSVR failures often did not result in TLR in 5 mm patients
24 month results:
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
24 month safety data

• Despite “complete lesion coverage policy”, no cases of Acute Limb Ischemia (ALI) were observed through end of 24 month follow-up  *Occlusions : 13

• No fractures identified by core laboratory

• No bypasses performed by 2 years

• Limb salvage 100%

• No patient death, target vessel revascularization, or major amputation within 30 days
Clinical Trial Case: Male, 88y/o SFA (Type D) Rutherford 5
Lesion Length: >30cm (CTO: 20m)

Courtesy of Dr Yamaoka
Clinical Trial Case: post VIABAHN placement

Courtesy of Dr Yamaoka

VIABAHN®: 5.0-250mm, 5.0-150mm
Clinical Trial Case: 3.5 year follow-up post VIABAHN placement

Looks identical with angio at 1 year!

VIABAHN®: 5.0-250mm, 5.0-150mm

Courtesy of Dr. Yamaoka
Japan Viabahn Case with internal control

Rt SFA treated with Viabahn

Lt SFA with BMS

 Courtesy of Dr Yamaoka

Pre  post  2Yrs

Viabahn  BMS

Pre  post  6Month
Conclusions
Excellent result obtained with Best Practices and Best device

Best practices
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)

• Complete lesion coverage policy
• Pre and post-dilation performed in all cases (high pressure within stent)
• Dual antiplatelets were required for six months and recommended for indefinite
  — Aspirin and clopidogrel (or other theopyridine class)
• Diligent follow-up
  — 1, 3, 6, and 12 month duplex ultrasound

Excellent result
• 88% 12-month and 78% 24-month primary patency in 21.8 cm avg length lesions
• 87% fTLR at 24 months
• Zero ALI, amputations
Conclusions

- 88% 12-month and 78% 24-month primary patency* in 21.8 cm average length lesions
- 87% fTLR at 24 months
- Lower hospitalization time and no usage of general anesthesia show VIABAHN Device usage is less invasive than bypass
  - Preliminary data for SuperB Trial show equivalent patency to first available bypass conduit
  - SuperB also shows greater 30-day QOL measures for VIABAHN Device vs. bypass
- Good technique drives great outcomes
  - Proper sizing is critical
    - Can be achieved utilizing angiography alone, or with IVUS
- Zero cases of ALI or amputation

* Primary Patency-Interventional defined by PSVR of < 2.5 without TLR.
Conclusions

- **88% 12-month and 78% 24-month primary patency** in 21.8 cm average length lesions
- **87% fTLR at 24 months**
- **Lower hospitalization time and no usage of general anesthesia show VIABAHN Device usage is less invasive than bypass**
  - Preliminary data for SuperB Trial show equivalent patency to first available bypass conduit
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