Advantages Of and Indications For the VIABAHN VBX Balloon Expandable Stent (Gore):
Technical Tips, Limitations, and Value in Treating Aortoiliac Disease

Jean Bismuth, MD FACS
Associate Professor of Surgery
Houston Methodist Hospital
Houston, Texas

GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Stent Graft)

- The VBX Stent Graft was FDA approved on January 27, 2017
- FDA approval was supported by 9-month follow-up in the VBX FLEX Clinical Study
- 12-month follow-up data from the study are now available

Post FDA approval implants

February 3, 2017

Treatment guidelines for IOD based on lesion complexity – 2007

Current treatment algorithm for iliac occlusive disease

Primary stentgraft publications for complex IOD treatment

- Prospective, multi-center study with SXSG. 51 iliac patients
  - 5 yr primary patency and patient outcomes favorable

- Prospective, dual-center study with BXSG. 65 patients
  - 5 yr primary patency and patient outcomes favorable

- Retrospective, single center study comparing BMS vs BXSG. 54 patients.
  - 2 yr primary patency greater with BXSG (p = 0.02)

- Retrospective, single center study comparing BMS vs SXSG. 162 patients (37 BXSG)
  - 3 yr primary patency trended higher with SXSG, significant with long-segment TASC D (p = 0.03)

- Prospective, multicenter, randomized trial comparing 46 iliac patients (23 SXSG, 23 BXSG)
  - 5 yr primary patency trended higher with SXG, significant with TASC C-D (p = 0.08)
Publication Highlights

• Complex long segment lesions can be easily treated with iliac stenting
• TASC classification does not alter outcome significantly
• In TASC II D lesions CS showed improved outcomes
• COBEST Trial showed enduring benefits of CS over BMS at 5 years


The role of stent grafts in complex IOD treatment

Studies have reported excellent outcomes with stent grafts for complex IOD
• TASC II C & D lesions
• Aortic bifurcation lesions (kissing stent treatment)
• Highly calcified / non-compliant lesions
• Chronic total occlusions (CTO)

Stent grafts offer proven and theoretical advantages for complex lesions
• Exclude plaque and prevent in-stent neo-intimal hyperplasia
• Decrease risk of complications stemming from distal embolization, perforation, rupture, or dissection
• Promote hemodynamic flow via a new flow lumen

The role of stent grafts in complex IOD treatment

Resultant shift from surgery to stent-graft usage for treating complex IOD
• Multiple consensus and practice guidelines now generally endorse an endovascular-first strategy for TASC II C & D IOD lesions in experienced endovascular centers¹, ², ³
• Society for Vascular Surgery guidelines recommend stent grafts in instances of severe calcification at risk of vessel rupture⁴


Where is the unmet need in IOD treatment?

VBX FLEX objective and methodology

Objective
• Evaluate the safety and efficacy of the VBX Stent Graft for the treatment of arterial occlusive disease in patients with de novo or re-stenotic lesions in the common and/or external iliac arteries

Methodology / Design
• Prospective, multi-center, single-arm clinical study
• 134 patients meeting all eligibility criteria enrolled across 27 sites
• Primary endpoint composite of MAEs at 9 months; patient follow-up through three years

Eligible patients included
• Rutherford category 2–4
• Unilateral or bilateral disease
• Total occlusions
• Severe calcification
• Tortuous iliacs
• Kissing stent placement
• Direct stenting without predilation
VBX FLEX baseline clinical and procedural characteristics

<table>
<thead>
<tr>
<th>Measure (per lesion)</th>
<th>Baseline</th>
<th>Baseline Intention-to-Treat</th>
<th>Technical Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up (%)</td>
<td>94.6</td>
<td>94.7</td>
<td>100%</td>
</tr>
<tr>
<td>Lesion improvement</td>
<td>94.6</td>
<td>94.7</td>
<td>100%</td>
</tr>
<tr>
<td>Abbott futility</td>
<td>0.20</td>
<td>0.19</td>
<td>0.20</td>
</tr>
<tr>
<td>Device-related SAEs</td>
<td>0</td>
<td>1*</td>
<td>1*</td>
</tr>
<tr>
<td>Unplanned adverse event</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
| * Abbott futility defined as follow-up ≥ 62 and ≤ 30% residual stenosis

VBX FLEX procedural results and primary endpoint

Procedural results:
- 100% technical success (device successfully delivered and ≤ 30% residual stenosis)
- 234 devices implanted in 213 lesions
- 97% acute procedural success (four subjects with procedural-related SAEs that successfully resolved)

VBX FLEX 9-month and 12-month results

Conclusions

- Flexible strength of the device design
  - Ensures trackability in tortuous anatomies
- Proven to achieve clinical success in complex lesions
  - Real world study
  - Included total occlusions, kissing stents, tortuous iliacs, severe calcification
- The only balloon expandable (BX) stent graft
  - Indicated to treat de novo and restenotic lesions in the iliac arteries
  - With an indication statement including the aortic bifurcation