Expanding to every demand:
The GORE® VIABAHN® VBX Stent Graft

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Tennessee, United States
Program Agenda

- **Strategy for treating aortoiliac disease**  
  Andrew Holden, MD

- **Results from the VBX FLEX study and case experience**  
  Chris Metzger, MD

- **European VBX experience in aortic disease**  
  Martin Austermann, MD

- Panel discussion, Q&A
Strategy for treating aortoiliac disease
Andrew Holden, MD
Speaker name: **Andrew Holden**.

I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [x] Other – **Clinical Investigator for Gore Medical**
- [ ] I do not have any potential conflict of interest
Aortoiliac Occlusive Disease (AIOD)

- Among the most common site of the occlusive atherosclerotic disease
- Often coexists with disease below the inguinal ligament
- Initial correction of inflow disease affords satisfactory clinical relief of symptoms in 75% to 80% of pts, despite uncorrected infrainguinal disease
Treatment guidelines are based on lesion complexity (TASC II 2007)

Current TASC II guidelines recommend **endovascular** for type A & B lesions

Current TASC II guidelines recommend **surgery** for type C & D lesions

Treatment guidelines are based on lesion complexity (TASC II 2007)

Current TASC II guidelines recommend **endovascular** for type A & B lesions

Current TASC II guidelines recommend **surgery** for type C & D lesions

In 2018 with current stent technology, an endovascular first approach is taken for all most all TASC lesions!
Current Treatment Algorithm for AOID

- Steno-occlusive disease involving the aortic bifurcation, CIA and EIA is usually refractory to plain balloon angioplasty, due to recoil and dissection
- Primary stenting is usually required
- Should we use balloon expandable or self-expanding stents?
Current Treatment Algorithm for AOID

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- Should we use balloon expandable or self-expanding stents?

**Self Expanding Stent**
- Shape memory alloys (e.g., nitinol)
- Deployed via release of constraining mechanism

**Balloon Expanding Stent**
- Ductile metal alloys (e.g., stainless steel)
- Deployed via angioplasty (PTA) balloon inflation

### Generalized comparison of technology attributes

<table>
<thead>
<tr>
<th>Attribute</th>
<th>SX</th>
<th>BX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radial strength / recoil resistance</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Trackability / implanted conformability</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Diameter adjustment (taper/flare)</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Deployment accuracy</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Compression recovery</td>
<td>+</td>
<td>-</td>
</tr>
</tbody>
</table>
Current Treatment Algorithm for AOID

- Little direct evidence comparing BE vs SE stents in AIOD
- The **Bravissimo Trial** was an industry sponsored trial (Abbott) comparing outcomes in TASC C and D lesions with BE and SE stent platforms
- No significant difference was seen in 12 month primary patency between the platforms
- Conclusion was that **mixed** used of BE and SE stent platforms was associated with best outcomes in AIOD

12 month primary patency

Courtesy M Bosiers LINC 2012
Current Treatment Algorithm for AOID

- Similar results were seen in the Medtronic sponsored DURABILITY Iliac and VISIBILITY Iliac Trials
- 150 patients treated, 75 with a SE stent platform (EverFlex or Protégé GPS) and 75 with a BE stent platform (Visi-Pro)
- No significant difference was seen in 9 month primary patency between the platforms – **95.8% for both studies!**
Current Treatment Algorithm for AOID

- Balloon expandable stents are widely used to manage arterial occlusive disease at the aortic bifurcation and CIAs
- The high radial resistive force, accurate deployment and ability to post-dilate are important as disease is often resistant and calcified
Current Treatment Algorithm for AOID

- Balloon expandable stents are widely used to manage arterial occlusive disease at the aortic bifurcation and CIAs.
- The high radial resistive force, accurate deployment and ability to post-dilate are important as disease is often resistant and calcified.
- The conformability advantages of self-expanding stents mean these are often used in the EIA.
- Trackability and deliverability also allow these devices to be delivered across the aortic bifurcation.
Current Treatment Algorithm for AOID

- Covered balloon expandable endoprostheses offer advantages for complex AOID:
  - Prevent plaque protrusion through stent
  - Prevent in-stent neointimal hyperplasia
  - Decrease risk of complications stemming from distal embolization, perforation, rupture, or dissection
Current Treatment Algorithm for AOID

- Covered balloon expandable endoprostheses offer advantages for complex AIOD:
  - Prevent plaque protrusion through stent
  - Prevent in-stent neointimal hyperplasia
  - Decrease risk of complications stemming from distal embolization, perforation, rupture, or dissection
- Studies such as the Cobest Trial have shown a clinical benefit with balloon-expandable stent-grafts in complex TASC II C & D lesions
The ideal device for complex AIOD would combine the conformability and deliverability advantages of a SE stent with the radial resistive force of a BE stent and include the advantages of a covered endoprosthesis!
VBX Stent Graft Technology
**Indications (EU):** The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is indicated for endovascular grafting of peripheral vessels.

**Contraindications (EU):** Do not use the GORE® VIABAHN® Balloon Expandable Endoprosthesis in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II.
VBX Advanced Technology and Performance

Highly flexible stent and catheter
• Enables contralateral deployment
• Enables implanted conformability

Ultrathin balloon cover
• Improves stent retention and deliverability

Semi-compliant covered balloon
• Enables diameter customization

CBAS Heparin Surface
• Ensures lasting thromboresistance

Proven stent graft platform
• Employs technology of the GORE VIABAHN Endoprosthesis
## VBX Configurations

<table>
<thead>
<tr>
<th>Stent Labeled/Nominal Diameter (mm)</th>
<th>Crimped Stent Length (mm)</th>
<th>Introducer Sheath Size (Fr)</th>
<th>Guidewire Diameter</th>
<th>Max. Post-Dilated Stent Diameter(^1) (mm)</th>
<th>Catheter Length (cm)</th>
<th>RBP(^2) (atm/kPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>15, 19, 29, 39, 59, 79</td>
<td>7</td>
<td>0.035&quot; (0.89 mm)</td>
<td>8</td>
<td>80, 135</td>
<td>15/1520</td>
</tr>
<tr>
<td>6</td>
<td>15, 19, 29, 39, 59, 79</td>
<td>7</td>
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<td>7</td>
<td>0.035&quot; (0.89 mm)</td>
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<td>80, 135</td>
<td>13/1317</td>
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<tr>
<td>8L</td>
<td>29, 39</td>
<td>7</td>
<td>0.035&quot; (0.89 mm)</td>
<td>16</td>
<td>80, 135</td>
<td>13/1317</td>
</tr>
<tr>
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<td>80, 135</td>
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<td>16</td>
<td>80, 135</td>
<td>12/1216</td>
</tr>
</tbody>
</table>

\(^1\) Secondary balloon required to post-dilate the stent beyond its nominal deployed diameter (secondary balloon not included).

\(^2\) RBP is Rated Burst Pressure.
8L configuration provides a Tapered solution for branch graft applications
Customized vessel stenting with VBX

- Post-dilatation capability to meet unique vessel demands
- Each stent configuration designed to provide optimal radial strength

<table>
<thead>
<tr>
<th>Stent Labeled / Nominal Diameter (mm)</th>
<th>Max. Post-Dilated Stent Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>8</td>
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<tr>
<td>6</td>
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<td>11</td>
<td>16</td>
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<tr>
<td>8L</td>
<td>16</td>
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</table>

**VIABAHN® VBX**

Unique configurations: 76

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**Bard LifeStream™**

<table>
<thead>
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<th>Max. Post-Dilated Stent Diameter (mm)</th>
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Unique configurations: 38

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**Bentley BeGraft™**

<table>
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<th>Max. Post-Dilated Stent Diameter (mm)</th>
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Unique configurations: 48

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**Maquet ADVANTA™ V12**

<table>
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<th>Max. Post-Dilated Stent Diameter (mm)</th>
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<tr>
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<tr>
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<tr>
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<td>10.2</td>
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<td>9</td>
<td>10.4</td>
</tr>
<tr>
<td>10</td>
<td>10.6</td>
</tr>
</tbody>
</table>

Unique configurations: 34

*Information obtained from product Instructions for Use*
Aortoiliac Procedural Application
Complex Bifurcation Case Study (Holden\(^1\))

- 68 year old male
- Bilateral thigh and calf claudication
- Severely atheromatous aorto-iliac arteries
- RCIA CTO, LCIA stenosis

Complex Bifurcation Case Study
Complex Bifurcation Case Study
Complex Bifurcation Case Study
## Complex Bifurcation Case Study

<table>
<thead>
<tr>
<th>Labeled device diameter (mm)</th>
<th>Max Endoprosthesis expanded diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>8</td>
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<tr>
<td>6</td>
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<td>10</td>
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</tbody>
</table>
Complex Bifurcation Case Study
Complex Bifurcation Case Study
Complex Applications
Complex Applications
Conclusions

- Complex AIOID disease is a common and challenging problem
- An endovascular approach should be considered in almost all cases
- Complex disease may require a combination of balloon expandable and self-expanding stent attributes
- Covered endoprostheses provide additional advantages
- The Gore Viabahn VBX provides all the necessary features to treat complex AIOD
Expanding to every demand:
The GORE® VIABAHN® VBX Stent Graft