FLEX Study: three-year follow-up of patients with iliac occlusive disease treated with the Viabahn balloon-expandable endoprosthesis

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Disclosure

Speaker name: Jean Panneton, MD

I have the following potential conflicts of interest to report:

- Consulting: Getinge, WL Gore
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest.
73 year old female patient
Bilateral buttock & thigh claudication
Less than ½ block distance
No femoral pulses on exam
PMHx: Hypertension
Hyperlipidemia
Former smoker
ABI = 0.49 bilaterally

Pre procedural aortogram

Calcified distal aortic stenosis and bilateral ostial CIA stenoses
VBX Case Study

High visibility
Kissing VBX deployed
Accurately

@ 4 year follow up
Asymptomatic
Improved from
RC 3 to RC 0
Normal ABI bilaterally

Completion aortogram
VBX FLEX Study: 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 restenotic lesions in the common and/or external iliac arteries

Methodology / Design
• Prospective, multicenter, single-arm clinical study
• 134 patients meeting all eligibility criteria enrolled across 27 sites*
• Primary endpoint composite of major adverse events at nine 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 Study baseline clinical and procedural characteristics

<table>
<thead>
<tr>
<th>Rutherford category</th>
<th>N = 134 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 2 – Moderate claudication</td>
<td>26 (19.4%)</td>
</tr>
<tr>
<td>Category 3 – Severe claudication</td>
<td>101 (75.4%)</td>
</tr>
<tr>
<td>Category 4 – Ischemic rest pain</td>
<td>7 (5.2%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TASC II classification</th>
<th>N = 134 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type A</td>
<td>50 (37.3%)</td>
</tr>
<tr>
<td>Type B</td>
<td>41 (30.6%)</td>
</tr>
<tr>
<td>Type C</td>
<td>32 (23.9%)</td>
</tr>
<tr>
<td>Type D</td>
<td>11 (8.2%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Access approach</th>
<th>N = 134 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ipsilateral</td>
<td>27 (20.1%)</td>
</tr>
<tr>
<td>Contralateral</td>
<td>24 (17.9%)</td>
</tr>
<tr>
<td>Bilateral</td>
<td>83 (61.9%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treated limbs</th>
<th>N = 134 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right</td>
<td>29 (21.6%)</td>
</tr>
<tr>
<td>Left</td>
<td>38 (28.4%)</td>
</tr>
<tr>
<td>Bilateral</td>
<td>67 (50.0%)</td>
</tr>
<tr>
<td>Kissing stents</td>
<td>57 (42.5%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treated vessels</th>
<th>201 limbs</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIA</td>
<td>154 (76.6%)</td>
</tr>
<tr>
<td>EIA</td>
<td>31 (15.4%)</td>
</tr>
<tr>
<td>CIA and EIA</td>
<td>16 (8.0%)</td>
</tr>
</tbody>
</table>


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Freedom from TLR

Freedom from Clinical driven TLR

Change in Rutherford Category

ABI and TBI

Walking Impairment Questionnaire

Panneton JM et al, Journal of Endovascular Therapy 2020, Vol. 27(5) 1-9
VBX FLEX Study 3-year: Freedom from TLR by lesion

VBX FLEX Study 36-month fTLR results by lesion

Kaplan-Meier graph of freedom from target lesion revascularization (TLR) per lesion with number of lesions at risk

Panneton JM et al, Journal of Endovascular Therapy 2020, Vol. 27(5) 1-9
VBX FLEX Study 3-year: Freedom from TLR by TASC

VBX FLEX Study 3-year fTLR results by TASC II classification*

Kaplan-Meier graph of freedom from target lesion revascularization (TLR) per lesion with number of lesions at risk

Panneton JM et al, Journal of Endovascular Therapy 2020, Vol. 27(5) 1-9
VBX FLEX Study 3-year: Rutherford Category

Distribution of Rutherford categories (RCs) from baseline to 3-year follow-up.

Change in Rutherford category

<table>
<thead>
<tr>
<th>Months from</th>
<th>9 month\textsuperscript{t,1}</th>
<th>24 month\textsuperscript{t,1}</th>
<th>36 month\textsuperscript{t,2}</th>
</tr>
</thead>
<tbody>
<tr>
<td>pre-procedure</td>
<td>(N = 112 patients)</td>
<td>(N = 102 patients)</td>
<td>(N = 89 patients)</td>
</tr>
<tr>
<td>Improved</td>
<td>94.6%</td>
<td>94.1%</td>
<td>92.1%</td>
</tr>
<tr>
<td>Maintained</td>
<td>5.4%</td>
<td>4.9%</td>
<td>7.9%</td>
</tr>
<tr>
<td>Worsened</td>
<td>0.0%</td>
<td>1.0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Of evaluable patients who achieved a Rutherford 0...

- Improved from a baseline Rutherford of 3 or 4
- Improved at least 1 Rutherford category versus baseline

Panneton JM et al, Journal of Endovascular Therapy 2020, Vol. 27(5) 1-9
The mean ABI was 0.93+0.19 at 3 years, which was 0.17+0.26 higher than the mean baseline ABI (p<0.001)

Panneton JM et al, Journal of Endovascular Therapy 2020, Vol. 27(5) 1-9
VBX FLEX Study 3-year: Walking Impairment Questionnaire (WIQ)

Walking impairment questionnaire (WIQ) changes from baseline to 36-month follow-up.

Panneton JM et al, Journal of Endovascular Therapy 2020, Vol. 27(5) 1-9
VBX FLEX Study: Conclusions

VBX FLEX Clinical Study design included patients with complex disease\(^1\)
- “Real world” eligibility criteria
- TASC II C and D (32.1 percent)
- Kissing stent (42.5 percent)

Excellent outcome durability through 36 months in all patients, including kissing stent and TASC II C and D subgroups\(^2\):
- > 91 percent fTLR
- 92 percent improved at least 1 Rutherford category
  - Of evaluable patients who improved to Rutherford 0, 80 percent progressed from Rutherford 3 or 4\(^*\)
- Mean ABI = .93, .17 improvement\(^\dagger\)
- Median WIQ scores improved 2–3 fold\(^*\)

VBX Stent Graft performed well in disadvantaged and complex lesions which support
- Trackability / Stent retention
- Radial strength
- Conformability