Advantages of the VBX balloon expandable endoprosthesis: technical and clinical value in treating aortic disease

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting: Gore, Medtronic, Cook, Cordis
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s): Research grant by Gore


Fracture of bridging stents in FEVAR and BEVAR
Dislocation of the SMA bridging stent from the graft
Why such stent-related complications?

The bridging stents undergo continual stress, secondary to:

- inspiration and expiration
- the cardiac cycle
- the possible migration of the stent grafts inside the aorta
- the modification of the aortic volume
- Compression by diaphragm muscle
Reduce long-term complications

It is crucial to understand in vivo arterial geometry

How diaphragmatic excursion affects vessel mobility?
Three-dimensional analysis of renal artery bending motion during respiration

The renal artery centerlines were displaced approximately 2.5 mm at a distance of 1 cm from the ostia, with little displacement change in the second centimeter.

Three-Dimensional Analysis of Visceral Arteries and Kidneys during Respiration

From inspiration to expiration
the celiac artery exhibited axial shortening of 4.8% greater than other visceral arteries

With expiration
SMA, LRA and RRA angled upward by -9.8°, -6.4°, and -5.2°, respectively.
All vessels translated superiorly and posteriorly, and the SMA translated rightward additionally.

Anatomic alterations are generated early as a consequence of the procedure itself.

- Postoperatively: branches angle upward or downward depending on the technique.
- Ch-RENALS exhibited increased end-stent angulation immediately after stenting.

Ullery et al Ann Vasc Surg 2017;43:85-95
After ChEVAR renal branches angle downward and exhibit increased end-stent angulation.
After FEVAR renal branches angle upward, visceral branches angle downward
After BEVAR renal and visceral branches angled downward first and then often upward.
To improve repair techniques

Target vessel patency and durability of bridging stents are related to the effect of stent-graft configuration on the anatomy and how the stents accommodate to the anatomy of the target vessels.
VBX balloon expandable endoprosthesis

Advanced technology and unique design

- Stainless steel independent rings enhance flexibility
  - Minimizes foreshortening
  - Provides high radial strength

- Semi-compliant covered balloon
  - Enables diameter customization
  - Improves device retention and trackability in tortuous anatomies

- CBAS Heparin Surface for lasting thromboresistance

- Expanded range of diameters and lengths
Aim of the in vitro study

To evaluate the new balloon expandable covered stent with increased flexibility as a potential bridging device in fenestrated EVAR
Framed polyester test sheet with fenestrations on the water bath
Two stentgrafts are already flared
Keyence VHX 6000 Digital Microscope
Microscopy (20-fold magnification) after implantation and flaring
No damage of the fabric or separation of the graft
Integral water permeability (IWP) testing according to ISO 7198

-Purpose-

To measure the rate of water leakage through the entire prosthesis under a pressure of 16 kPa
Fluid simulation system designed to simulate blood flow using a **pulsatile pump unit** in non-organic (water-resistant and water-tight) model.

![User interface for pump control](image)

**Figure 5:** User interface for pump control (version 3.1)

The parameters can be changed individually using the arrow keys:

- **Frequency:** Setting range 40 - 120 beats / minute, adjustment in 5-step distance
- **V in ml:** Volume per pulse, setting range 0 - 75 ml, adjustment in 5ml- distance
- **P in %:** Pump capacity in%, setting range 0 - 100%, adjustment in 5% - distance
- **Temp.:** Fluid temperature, setting range 30 - 42 °C, adjustment in 1-degree distance
Pressure-measuring device for monitoring the intraluminal graft pressure
No stent fracture on digital radiography or multiplanar CT
Failure mode:
Dislocation of the bridging stent from the graft
Biomechanical testing of pull-out forces

Was performed with several tensile force testers (i.e. Zwick/Roell Z005; TA Instruments Electroforce LM-1; Instron®, Norwood)
Components of pull-out testing

The stent-graft (A) is implanted in the fenestration (B) and connected via a conduit (C) with the axial testing machine (D)

Courtesy of GF Torsello
Max. load for first and second stent row

VBX 6x29 mm flared with 10 mm balloon for 30 sec
Max. load for first and second stent row

VBX 8x29 mm flared with 10 mm balloon for 30 sec
### Pull-out forces – Advanta vs VBX 6 mm

<table>
<thead>
<tr>
<th></th>
<th>Peak 1</th>
<th>Peak 2</th>
<th>Max. Abs.</th>
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<tbody>
<tr>
<td><strong>Advanta</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Ave.</td>
<td>14,8</td>
<td>16,5</td>
<td>16,9</td>
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<tr>
<td>Std.Dev.</td>
<td>0,6</td>
<td>2,3</td>
<td>1,9</td>
</tr>
<tr>
<td><strong>VBX</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ave</td>
<td>12,7</td>
<td>23,0</td>
<td>23,0</td>
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<tr>
<td>StdDev</td>
<td>3,5</td>
<td>4,3</td>
<td>4,3</td>
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</tbody>
</table>
Failure mode: Fracture of the bare stent due to graft migration
Test setup for shear-stress force testing

The renal side of the bridging stent-graft is fixated with a cuff (B) to emulate 90° shear stress at the level of the fenestration. The stent-grafts are connected to the axial testing machine (D) via conduits (C).
### Stability to shear stress

**Advanta vs. VBX 6 mm (N/mm)**

<table>
<thead>
<tr>
<th></th>
<th>50-100%</th>
<th>100-150%</th>
<th>50-150%</th>
<th>ave. From 50-100 and 100-150</th>
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<tr>
<td><strong>Ave</strong></td>
<td>1.6</td>
<td>2.4</td>
<td>1.9</td>
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<tr>
<td><strong>StdDev</strong></td>
<td>0.3</td>
<td>0.1</td>
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<tr>
<th></th>
<th>50-100%</th>
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<th>ave. From 50-100 and 100-150</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ave</strong></td>
<td>2.0</td>
<td>2.2</td>
<td>1.8</td>
<td>2.2</td>
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<tr>
<td><strong>StdDev</strong></td>
<td>0.2</td>
<td>0.6</td>
<td>0.3</td>
<td>0.4</td>
</tr>
</tbody>
</table>
Conclusions

• Several failures of fenestration device combinations have been reported
• Device failures may result in endoleaks or occlusions
• Preliminary results of in vitro studies show that the new VBX has excellent features as bridging device for FEVAR
home page: www.gefaesschirurgie-muenster.de

Thank you!
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