Aortic challenges, quantitative analysis in fenestrated procedures

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Disclosure

Speaker name: ..........................................................G.Torsello............................................................

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): Research grant by Gore

☐
Fracture of the bare stent due to graft migration
Complete fracture and separation of the fragments
Dislocation of the SMA bridging stent from the graft
The ideal bridging stent should:

- Cover the distance between the main body and the target vessel (many length options)
- Good visibility during implantation
- Respect the angulation of the target vessel
- Durable and flexible after flaring, during the cardiac cycles, the diaphragm movements and after aortic remodelling
- High radial forces and resistance to compression (calcified ostium, CHEVAR)
- Stent retention during navigation
- High trackability of the delivery system
- Wide range of sizing and oversizing
Advanced technology and performance of VBX

Independent stainless steel rings
- Independent rings for flexibility and conformability
- Minimizes foreshortening
- Provides high radial strength

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

Products listed may not be available in all markets.

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Aim of the in vitro study

To evaluate a new balloon expandable covered stent with increased flexibility as a potential bridging device in fenestrated EVAR (VBX)
Framed polyester test sheet with fenestrations on the water bath

Two stentgrafts are already flared
Keyence VHX 6000 Digital Microscope
Topology of the flared zone
Radiological analysis in two planes for detecting stent fractures
Endpoint 1

Evaluation of ideal configuration of VBX in 6mm and 8 mm fenestrations

- flaring with 10mm, 12mm and Reliant balloon
- having 1 ring/2 rings/3 rings in the fenestrations
VBX 6x29 flared with 10x20 PTA
1, 2 or 3 stent rows?

1 stent row  
2 stent rows  
3 stent rows
VBX8x29 mm; two rows
How to flare?

10 x 20 mm PTA

12 x 20 mm PTA

12x20 PTA + Reliant
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)
Protocol for pull out test

1. Preloading: 2N
2. Settling cycle: 2N ramp to 3N and back to 2N (at 20mm/min)
3. Ramp to failure - Pull-Out test (at 50mm/min)
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
Max. load for first and second stent row

VBX 8x29 mm flared with 12 mm balloon + Reliant
Max. load for one stent row

VBX 8x29 mm flared with 12 mm balloon
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
Cardiovascular implants and extracorporeal systems — Vascular prostheses — Tubular vascular grafts and vascular patches (ISO 7198:2016)

EUROPEAN STANDARD
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EUROPÄISCHE NORM

EN ISO 7198
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ICS 11.040.40

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 (version 3.1)](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
Conclusions

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

Thank you!
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