

How I test all BSG:

Bench and Fatigue tests of
different Bridging Stentgraft (BSG)
in a flat FEVAR model

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Bench test of different BSG in a flat FEVAR model

Disclosures:

COOK™ ,Getinge™ , Bentley™ and Gore™
support this study.

Proctor Cook™

PD Dr. med. Martin Austermann
Director Clinic for Vascular Surgery
St. Franziskus Hospital Münster

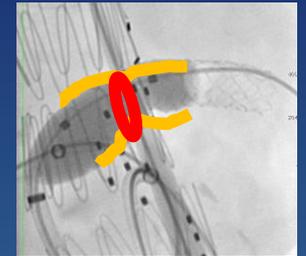
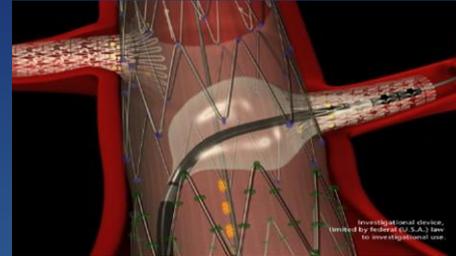
Bench test of different BSG in a flat FEVAR model

Background:

FEVAR since 1999



Bridging stentgrafts (BSG) are required for the incorporated target-vessels.



Flaring: Alining and Keeping the fenestration in front of the target-vessel.
Stable connection Fenestration and BSG.

Over many years we had no dedicated/
approved BSG on the market.

Bench test of different BSG in a flat FEVAR model

Background:

344 J ENDOVASC THER 2008;15:344-348

◆ FELLOWS COMPETITION, THIRD PLACE ◆

Fenestrated Stent-Graft Repair: Which Stent Should Be Used to Secure Target Vessel Fenestrations?

James R. H. Scurr, MRCS^{1,2}; Thien V. How, PhD²; Richard G. McWilliams, FRCS, FRCR³; Steven Lane, PhD²; and Geoffrey L. Gilling-Smith, MS, FRCS¹

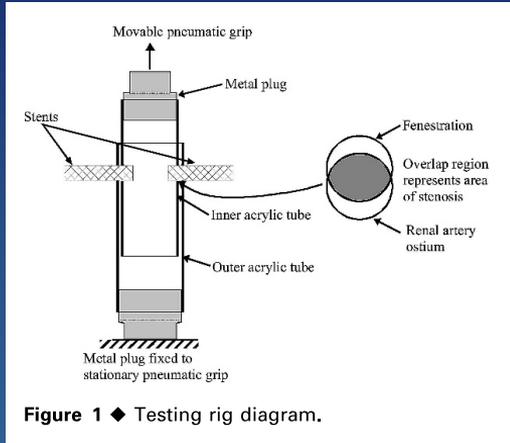
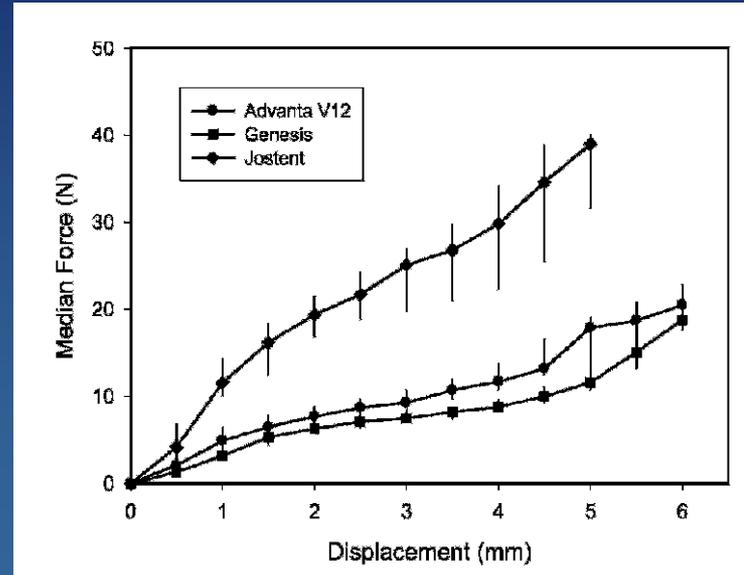


Table
Force Required to Cause Stenosis of Identical Bilateral "Renal Artery" Stents in the Model of a Fenestrated Endograft

| | 25% Stenosis, N | 50% Stenosis, N | 75% Stenosis, N |
|----------------|-----------------|-----------------|-----------------|
| Jostent | 16.2 (3.1) | 25.1 (8.1) | 34.6 (4.4) |
| Advanta V12 | 6.5 (1.9) | 9.3 (0.9) | 13.2 (1.6) |
| Palmaz Genesis | 5.3 (1.3) | 7.5 (0.7) | 10.0 (1.0) |

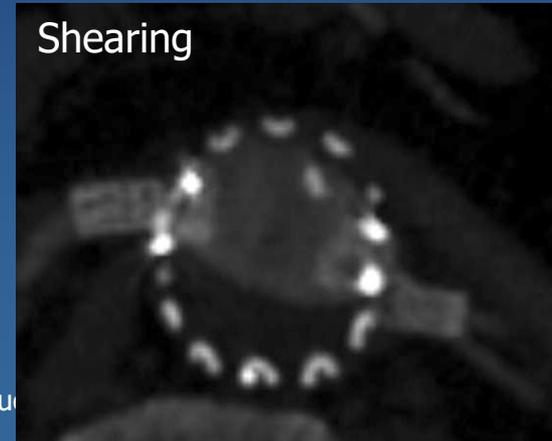
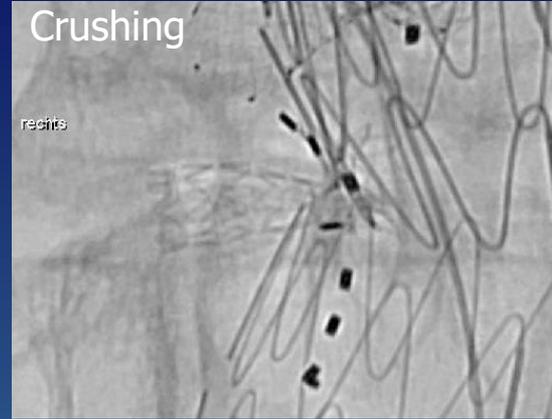
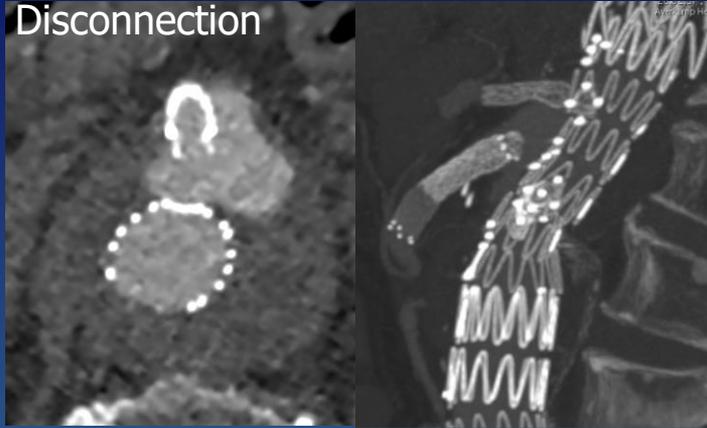
Data are given as the median (interquartile range).
P, 0.01 between stents for each category of percent area stenosis.



Bench test of different BSG in a flat FEVAR model

Background:

Critical issues of BSG after FEVAR:



Bench test of different BSG in a flat FEVAR model

Advanta V12™
Getinge



Durability

ePTFE
outside

stainless steel
(encapsulated)

ePTFE
Inside

BeGraft™
Bentley



Flexibility

ePTFE
outside

Kobaldchrom
inside

BeGraft+™
Bentley



Radial force
Kink-resistance

ePTFE
outside

Kobaldchrom
in between

VBX™
Gore



Flexibility
Additional length

Thin layer ePTFE
outside

Stainless steel
(independent struts)

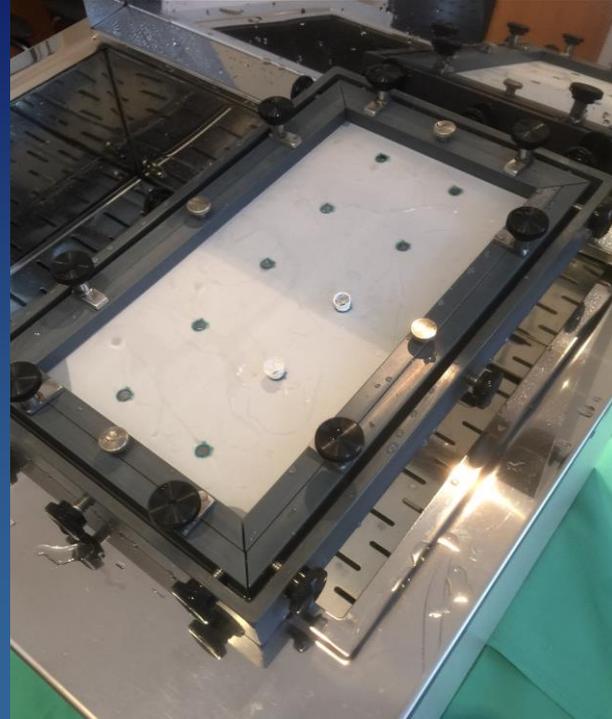
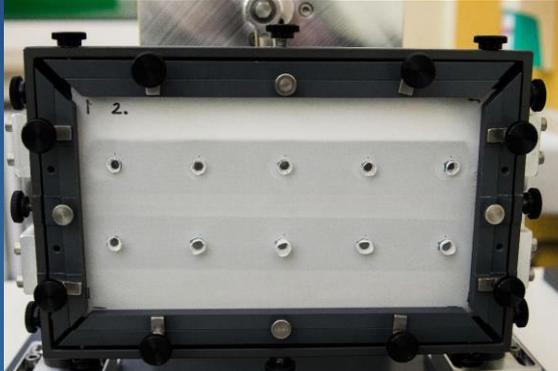
Could all these Stentgrafts be used as
Bridging stentgraft in FEVAR?
ePTFE
heparin surface

Bench test of different BSG in a flat FEVAR model

Our FEVAR-model:

Flat fenestated graft model
(polyester) with 10 reinforced
fenestrations. (COOK™)

5 x with 6mm-fenestrations.
5 x with 8mm-fenestrations.



Bench test of different BSG in a flat FEVAR model

Studydesign:

4 FEVAR-models
with **6 mm Fens**:

10 6x38 Advanta
10 6x38 BeGraft
10 6x38 BeGraft+
10 6x39 VBX

4 FEVAR-models
with **8 mm Fens**:

10 8x38 Advanta
10 8x37 BeGraft
10 8x37 BeGraft+
10 8x39 VBX

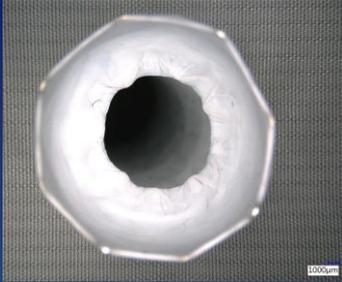
All **flared** with a 10x20 ballon.

Study:

1. Fabric (1.1 Permeability VBX) all
2. Stentstructure all
3. Pull out force (5 of each BSG)
4. Shear stability (5 of each BSG)

Bench test of different BSG in a flat FEVAR model

Advanta V12 6x38



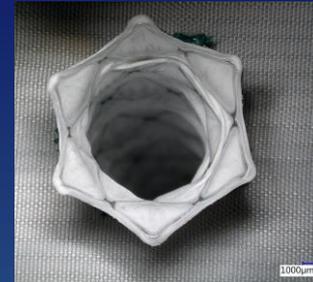
BeGraft 6x38



BeGraft+ 6x38



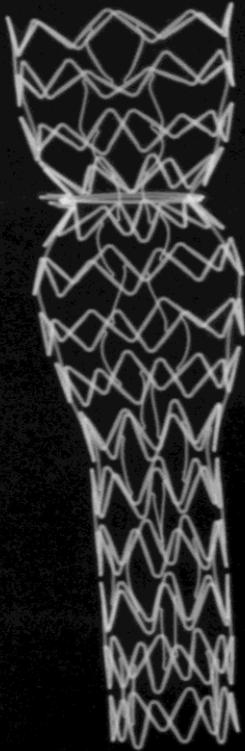
VBX 6x39



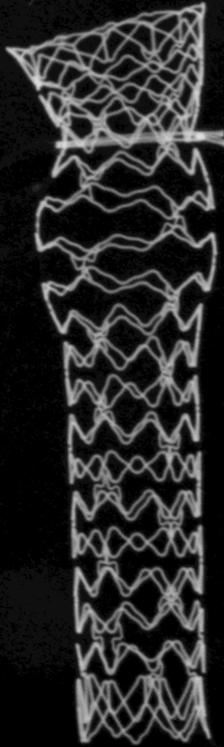
Result: No damage of the fabric

Bench test of different BSG in a flat FEVAR model

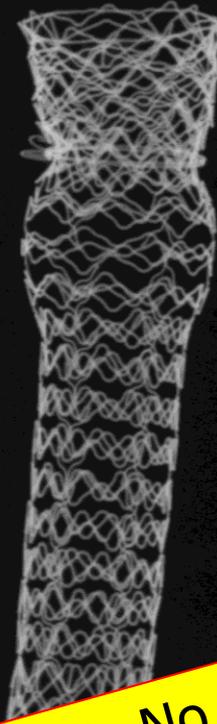
Advanta V12 6x38



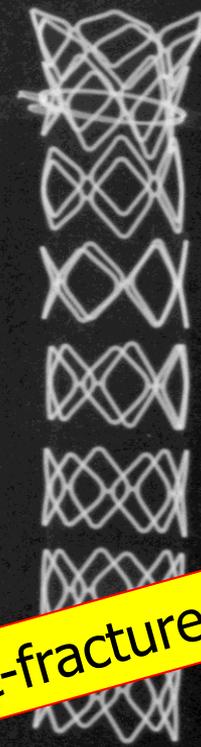
BeGraft 6x38



BeGraft+ 6x38



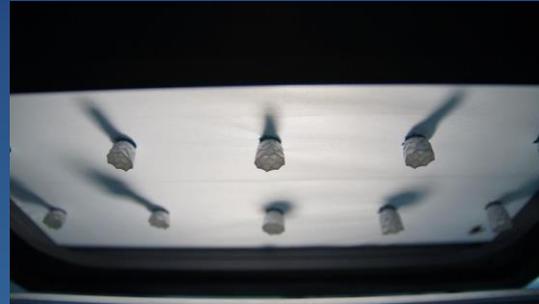
VBX 6x39



Result: No stent-fractures.

Bench test of different BSG in a flat FEVAR model

Pull out force



Bench test of different BSG in a flat FEVAR model

Pull out force

Advanta V12 6x38



BeGraft 6x38



BeGraft+ 6x38

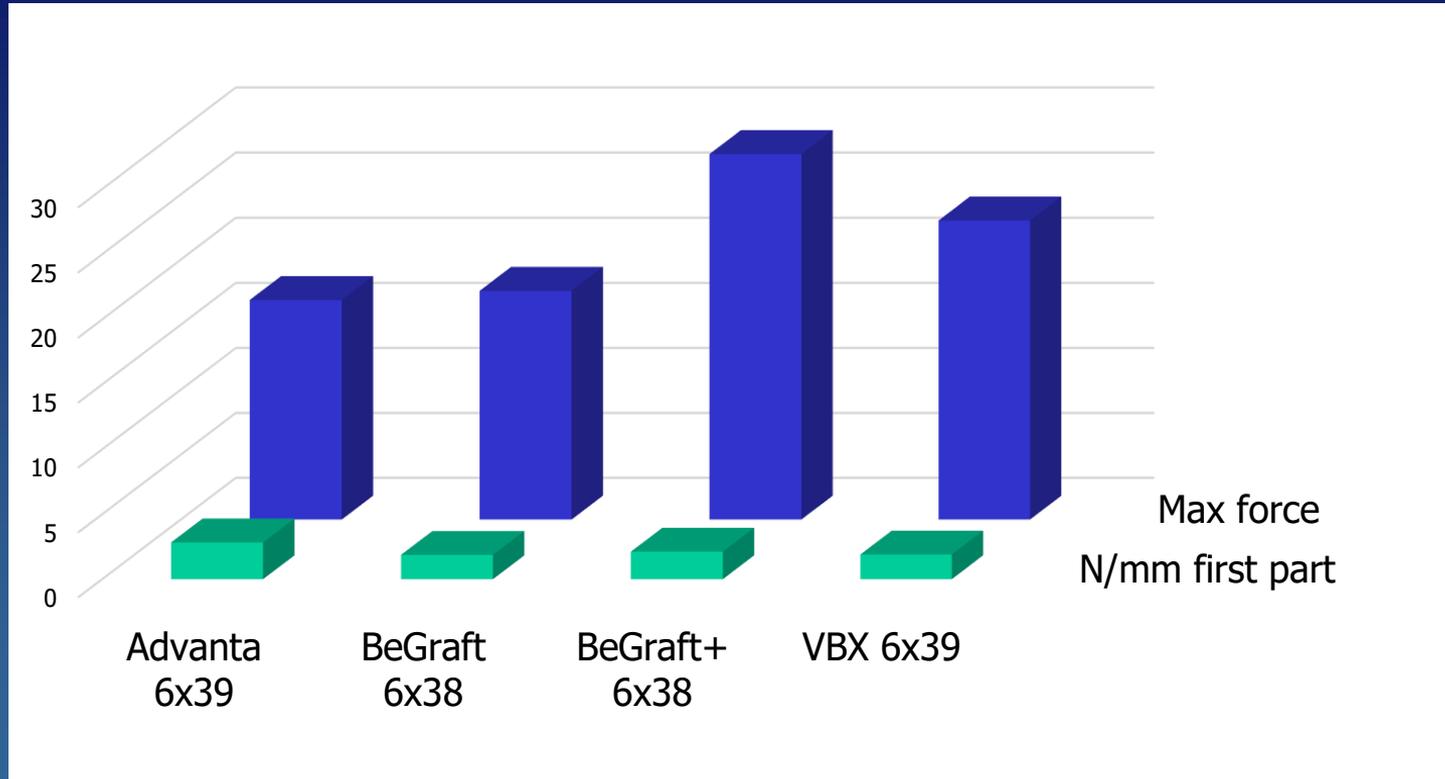


VBX 6x39



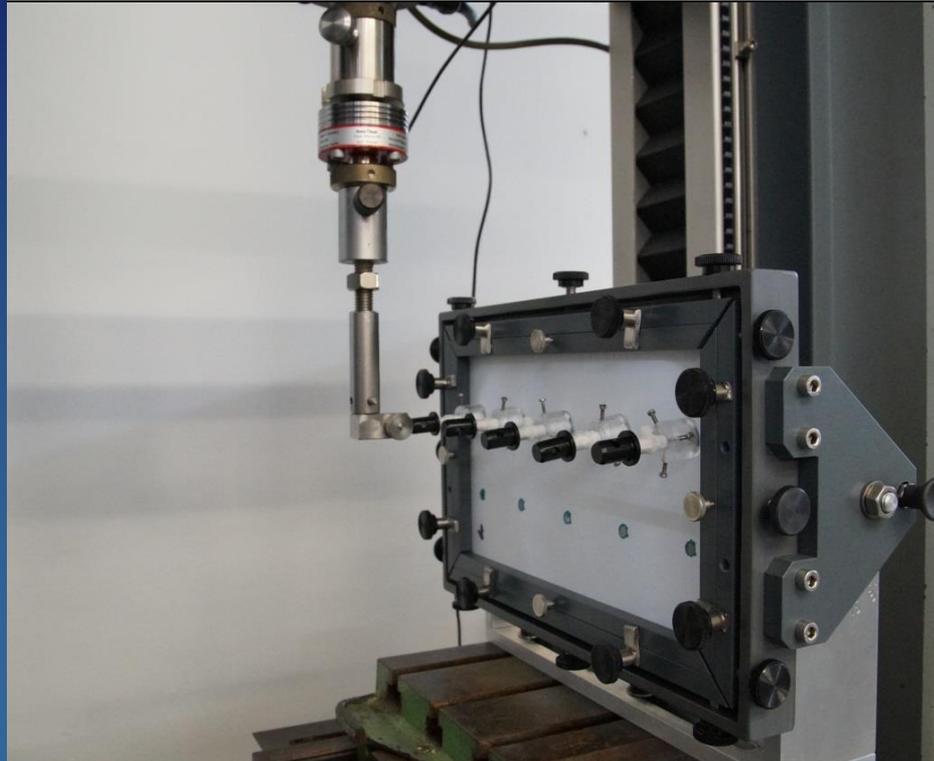
Bench test of different BSG in a flat FEVAR model

Pull out force 6 mm BSG:



Shear strength

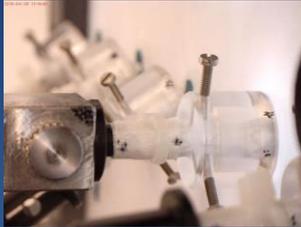
Sheet mounted at 90° (left/peripheric side)



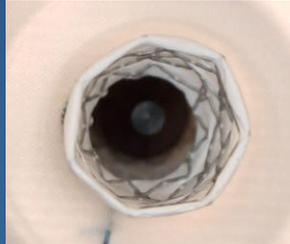
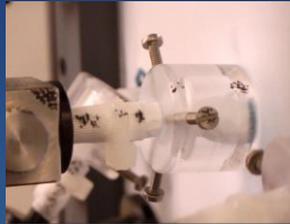
Bench test of different BSG in a flat FEVAR model

Shear strength

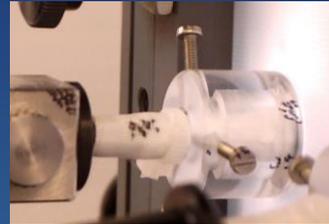
Advanta
V12 6x38



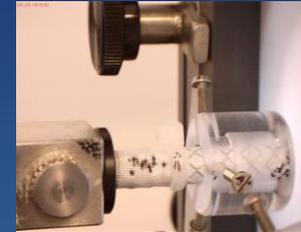
BeGraft
6x38



BeGraft
+ 6x38

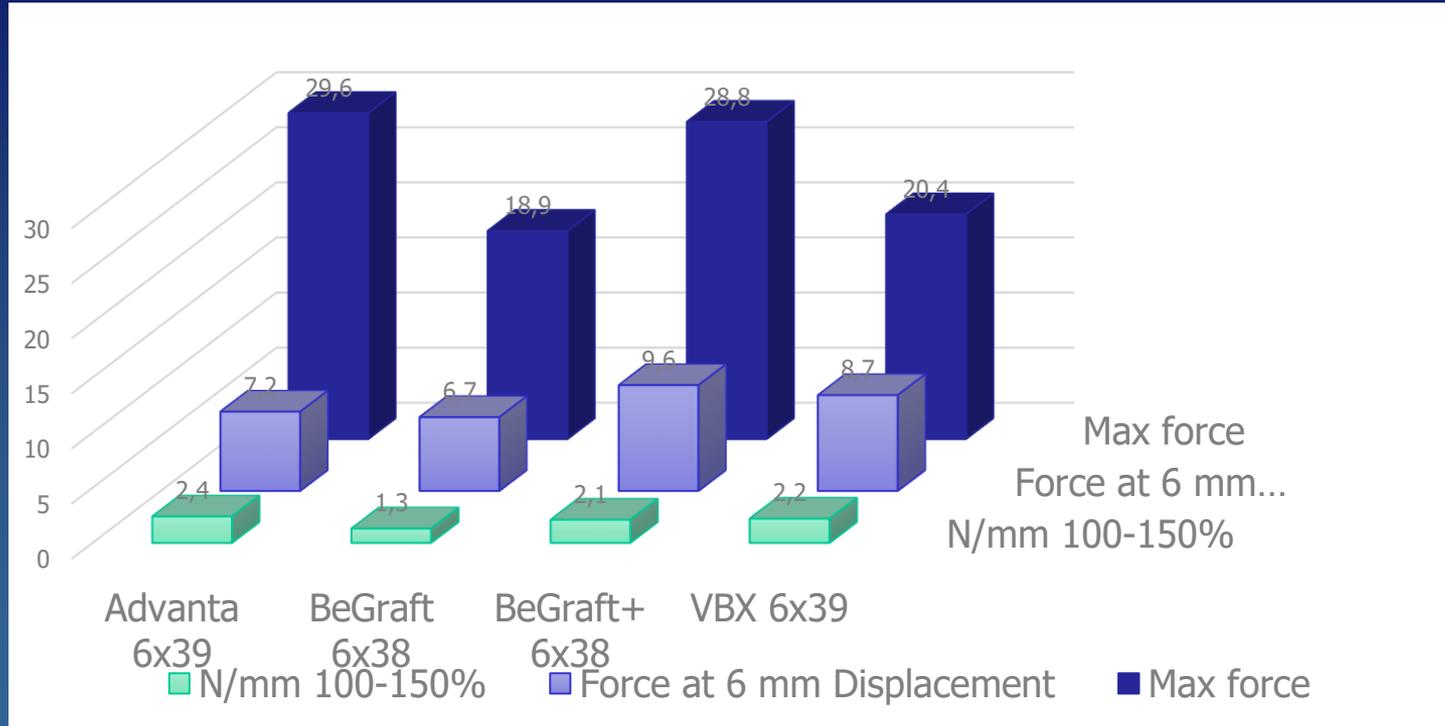


VBX
6x39



Bench test of different BSG in a flat FEVAR model

Shear strength 6 mm BSG:



Bench test of different BSG in a flat FEVAR model

Conclusion:

None of the tested covered stents shows a damage of the fabric or the stentstruts after flaring.

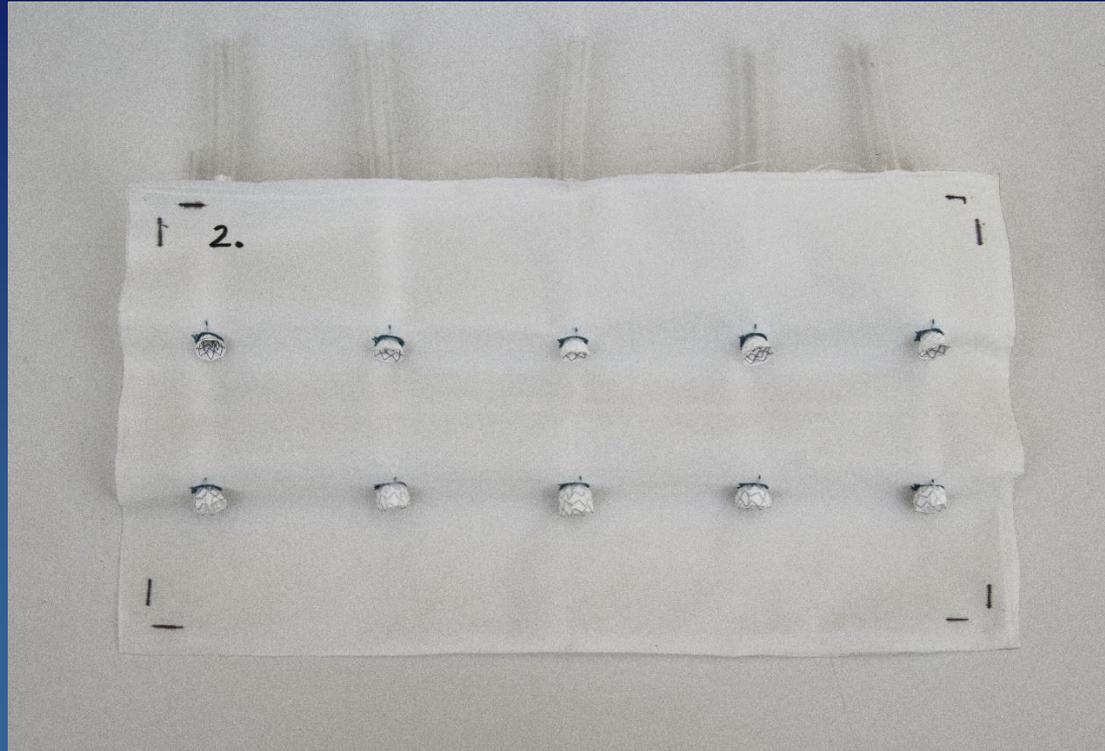
Pull out forces and shear stability were different and can help to choose the ideal BSG for different targetvessels together with the other features.

Fatigue-testings of these BSG-Fenestration-connections are necessary in order to understand better, what happens to these materials over time and in vivo.

Fatigue study

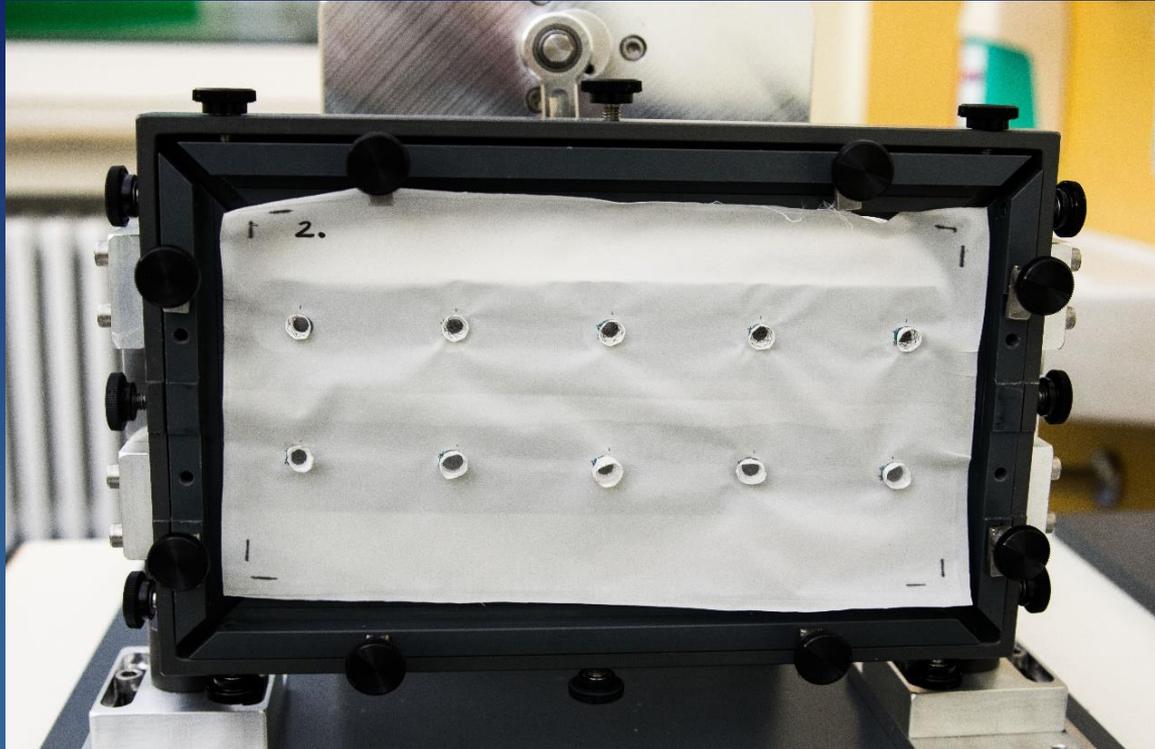
Bench test of different BSG in a flat FEVAR model

Sheet 2 following stent implantation and flaring



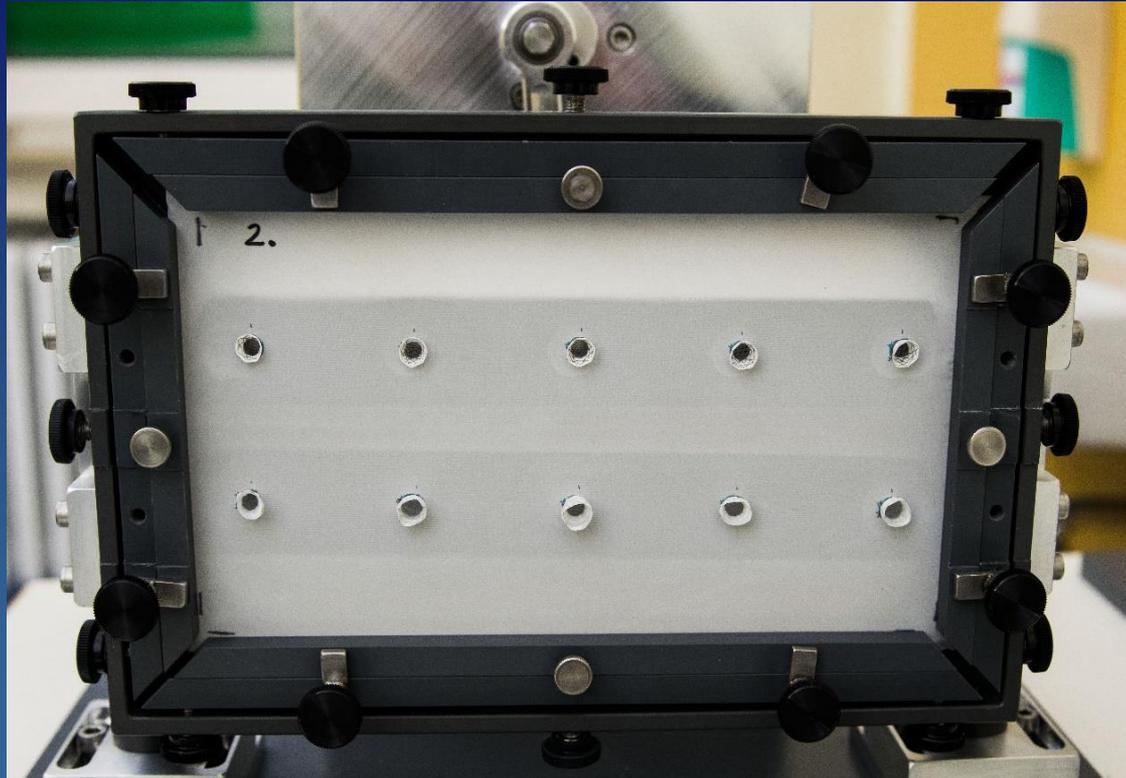
Bench test of different BSG in a flat FEVAR model

Step 1: Mount sheet in frame and connect silicon tubes to peripheric base plate



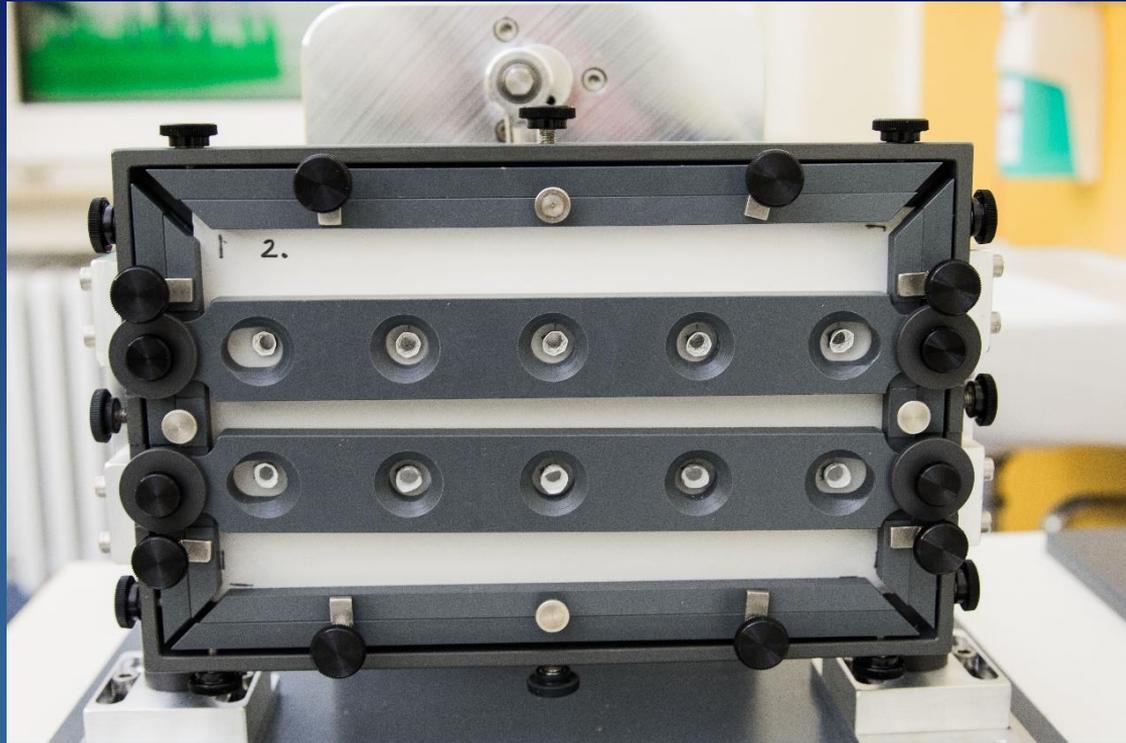
Bench test of different BSG in a flat FEVAR model

Step 2: Clamp sheet and adjust and increase sheet tension



Bench test of different BSG in a flat FEVAR model

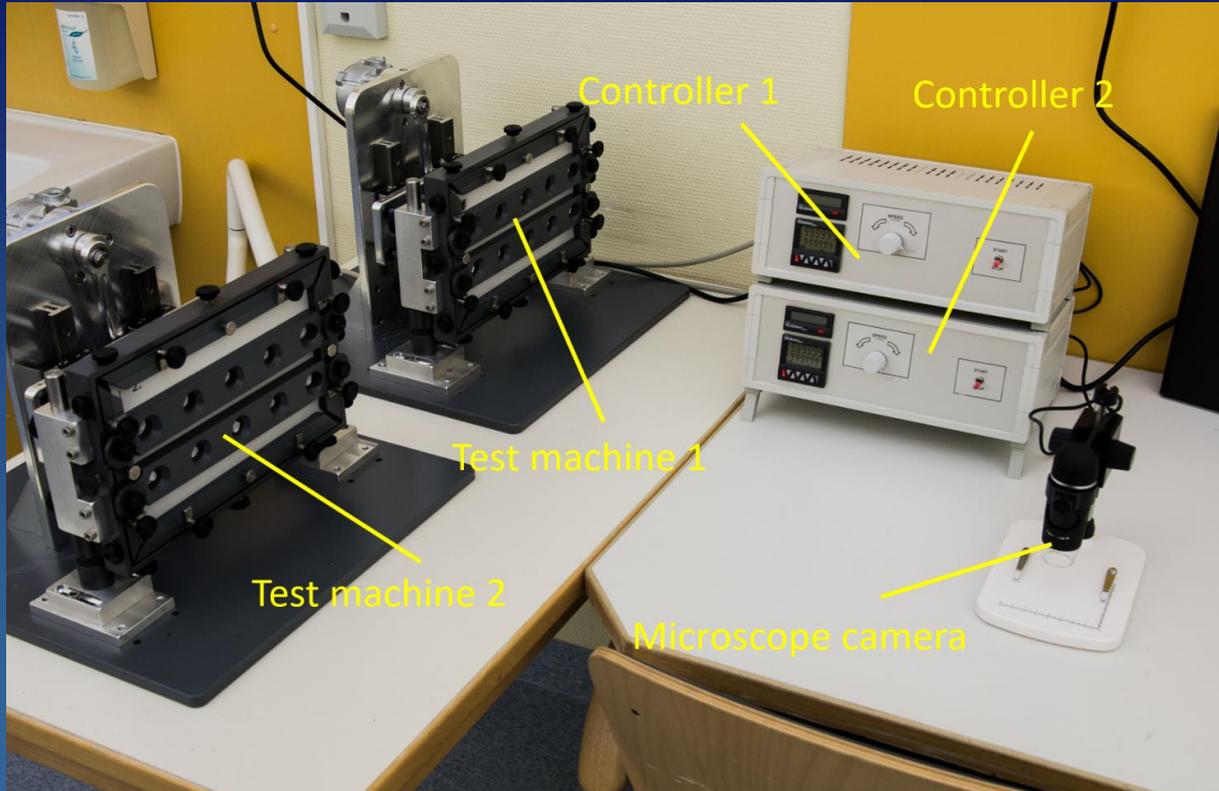
Step 3: Add fenestration restrictions to reduce wobbling movement of sheets (mimic in-vivo situation)



Bench test of different BSG in a flat FEVAR model

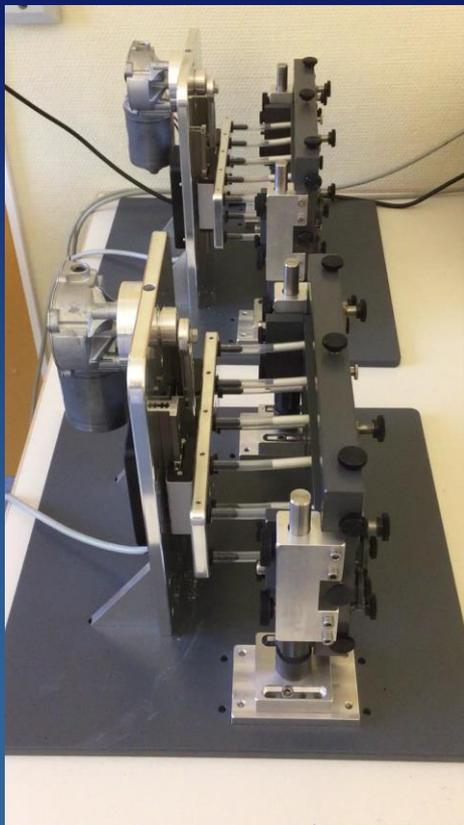
Fatigue study

Experimental Setup



Bench test of different BSG in a flat FEVAR model

Fatigue-Test:



Pre

After 100 Mio

Advanta V12
6x38



BeGraft 6x38



BeGraft+ 6x38



VBX 6x39



Bench test of different BSG in a flat FEVAR model

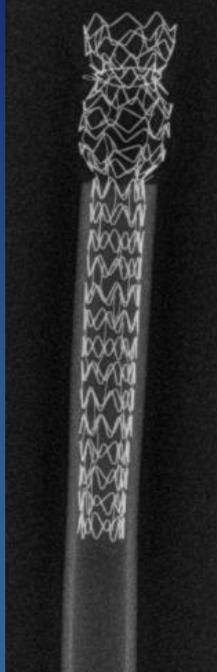
Fatigue-Test:



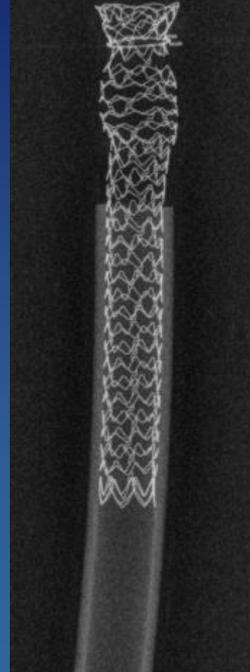
Bench test of different BSG in a flat FEVAR model

No stent fractures after 75 Mio cycles:

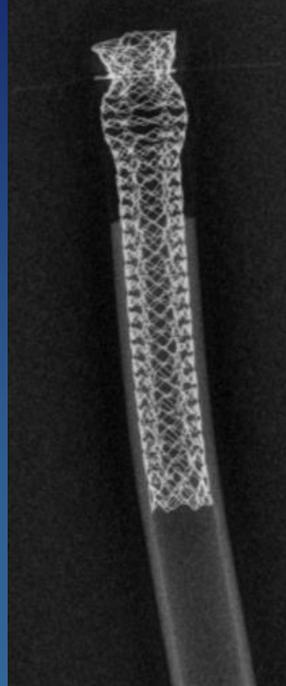
Advanta V12
6x38



BeGraft 6x38



BeGraft+ 6x38



VBX
6x39



Bench test of different BSG in a flat FEVAR model

Results:

Initial changes (IC)



Bench test of different BSG in a flat FEVAR model

Results:

Rust (Initial rust IR)



Bench test of different BSG in a flat FEVAR model

Results: PTFE-Perforation (point of break PB)



Bench test of different BSG in a flat FEVAR model

Results:

Advanta after 100 Mio Cycles



Bench test of different BSG in a flat FEVAR model

Results:

BeGraft after 100 Mio Cycles



Bench test of different BSG in a flat FEVAR model

Results:

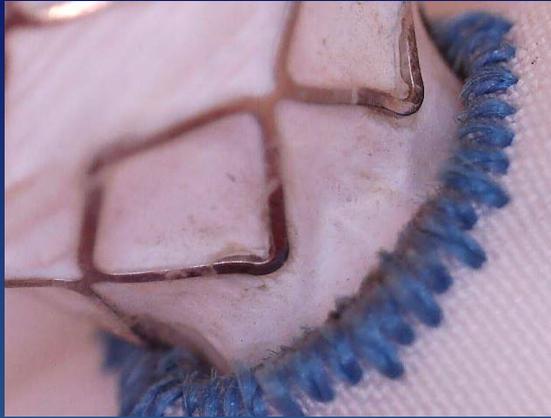
BeGraft plus after 100 Mio Cycles



Bench test of different BSG in a flat FEVAR model

Results:

VBX after 100 Mio Cycles



Bench test of different BSG in a flat FEVAR model

Results:

| Adavanta | 2-6 | 2-7 | 2-8 | 2-9 | 2-10 | MW | STABW |
|---------------------------|-------------|------------------|-------------|------------------|-------------|------------|------------|
| Freedom from | | PTFE penetration | | PTFE penetration | | | |
| IC (initial PTFE changes) | 2.000.000 | 1.000.000 | 1.000.000 | 8.000.000 | 2.000.000 | 2.000.000 | 1.000.000 |
| IR (initial rust) | 50.000.000 | 5.000.000 | 100.000.000 | 25.000.000 | 15.000.000 | 20.000.000 | 30.000.000 |
| PB (point of break) | 100.000.000 | 6.000.000 | 100.000.000 | 5.000.000 | 100.000.000 | 62.200.000 | 51.10.989 |

| BeGraft | 2-1 | 2-2 | 2-3 | 2-4 | 2-5 | MW | STABW |
|---------------------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------|
| Freedom from | | | | | | | |
| IC (initial PTFE changes) | 3.000.000 | 3.000.000 | 2.000.000 | 6.000.000 | 4.000.000 | 3.500.000 | 1.516.575 |
| IR (initial rust) | 100.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 0 |
| PB (point of break) | 6.000.000 | 8.000.000 | 7.000.000 | 8.000.000 | 8.000.000 | 7.250.000 | 94.427 |

| BeGraft plus | 1-1 | 1-2 | 1-3 | 1-4 | 1-5 | MW | STABW |
|---------------------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------|
| Freedom from | | | | | | | |
| IC (initial PTFE changes) | 3.000.000 | 6.000.000 | 5.000.000 | 8.000.000 | 7.000.000 | 5.500.000 | 1.923.538 |
| IR (initial rust) | 100.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 0 |
| PB (point of break) | 100.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 0 |

| VBX | 1-6 | 1-7 | 1-8 | 1-9 | 1-10 | MW | STABW |
|---------------------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------|
| Freedom from | | | | | | | |
| IC (initial PTFE changes) | 1.000.000 | 2.000.000 | 5.000.000 | 4.000.000 | 5.000.000 | 3.000.000 | 1.816.590 |
| IR (initial rust) | 30.000.000 | 40.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 777.088 |
| PB (point of break) | 100.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 100.000.000 | 0 |

Bench test of different BSG in a flat FEVAR model

Conclusion:

Stentfractures rarely seen after 100 Mio cycles.

PTFE on the outside of the stentstruts **wears out** inside a fenestration.

PTFE insight the stentstruts seems to be durable.

Secondary EL`s after FEVAR should be repaired by relining.

We have to **follow** our FEVAR patients **for life**.

Thank you !

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St. Franziskus Hospital Münster