

Supera in popliteal aneurysms: proof of concept and clinical outcomes

Jörg Tessarek MD

Vascular Center Emsland

Bonifatius Hospital Lingen

Germany

Disclosure

Speaker name:

.....Jörg Tessarek MD.....

I have the following potential conflicts of interest to report:

- Consulting: Abbott, AB medica, Phillips Volcano, Taryag medical
- honoraria : Abbott, AB medica, Phillips Volcano, Medtronic, Terumo aortic
- research grants : Abbott

Intention of treatment

Exclusion of the aneurysms / fixation of thrombus to

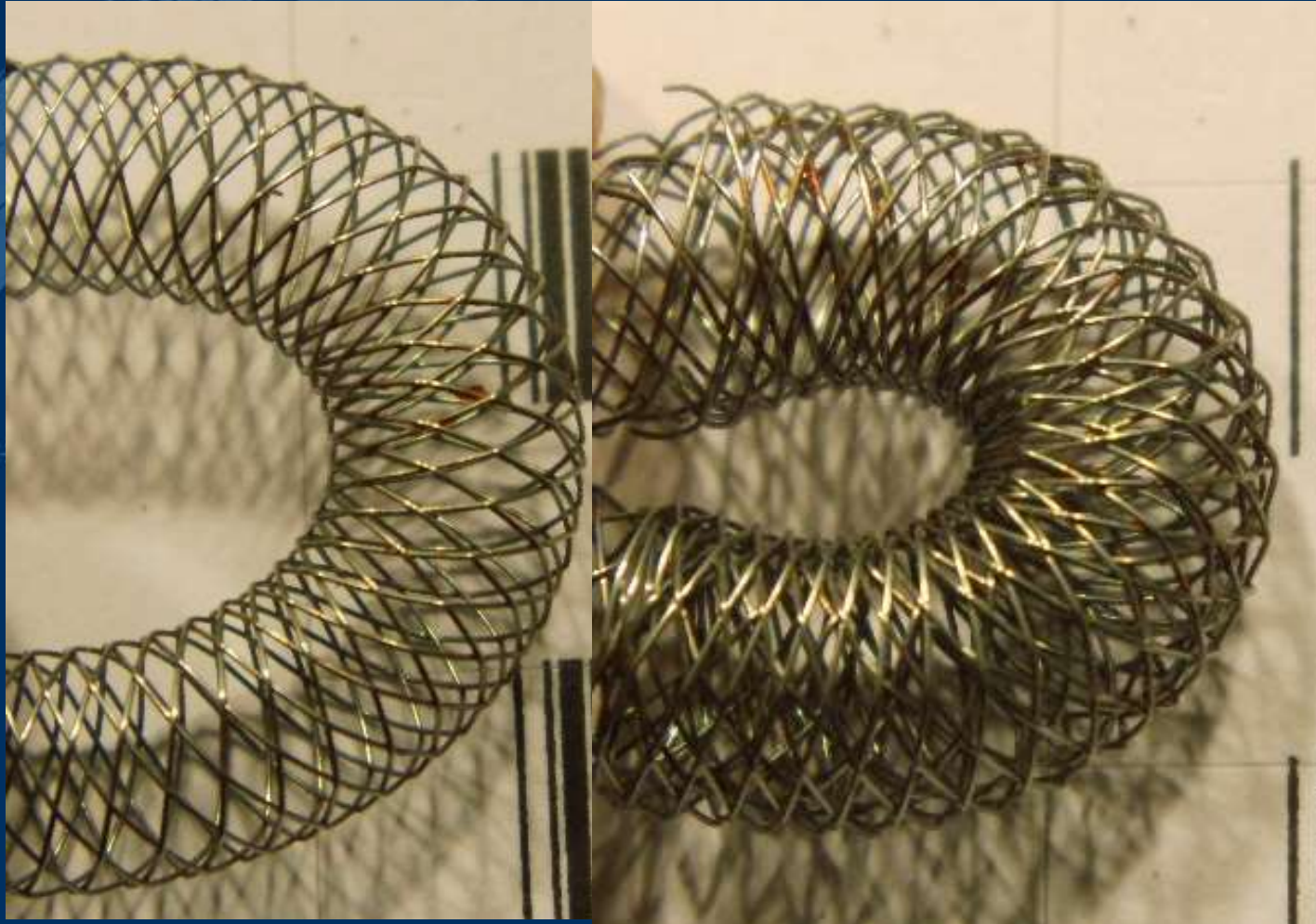
- prevent thromboembolic events with subsequent PAD/ tissue loss
- preserve outflow
- prevent rupture (anecdotal) and compression of vicinity structures

Implant related benchmark: PP, PAP, SP, option for bail out

The historic background and underlying principle

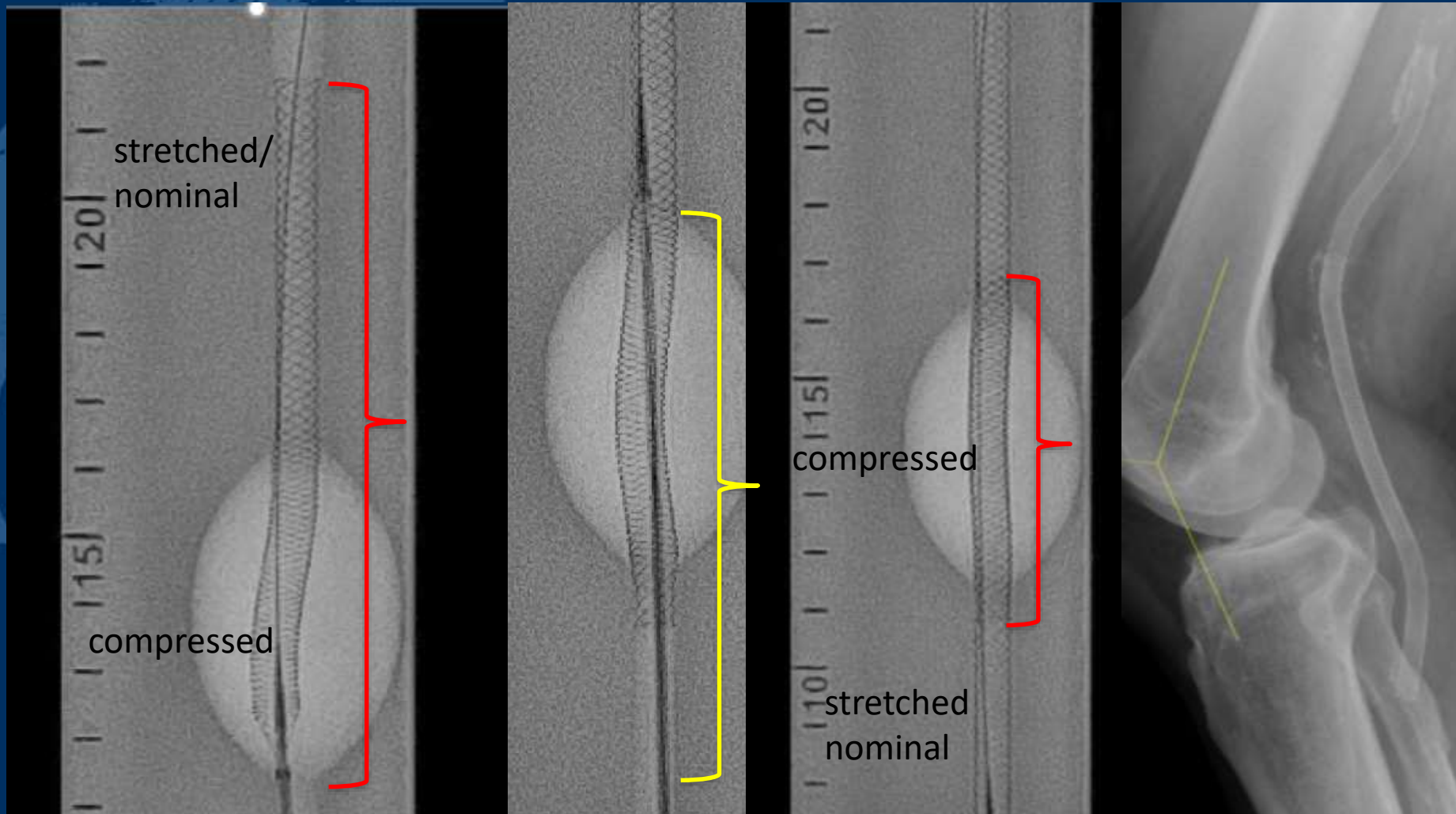
- First used 2010 for temporary sealing of bleeding bypass pseudoaneurysm in a drug abusing patient
- 2011 PAA as implant extension
- Two dedicated devices as a dual layer flow diverter to induce thrombosis
 - dense mesh (extra closed design) to fix thrombotic material and prevent embolization
 - Device characteristics dedicated to fem-pop segment

Dual layer modification: higher density of mesh without loss of flexibility

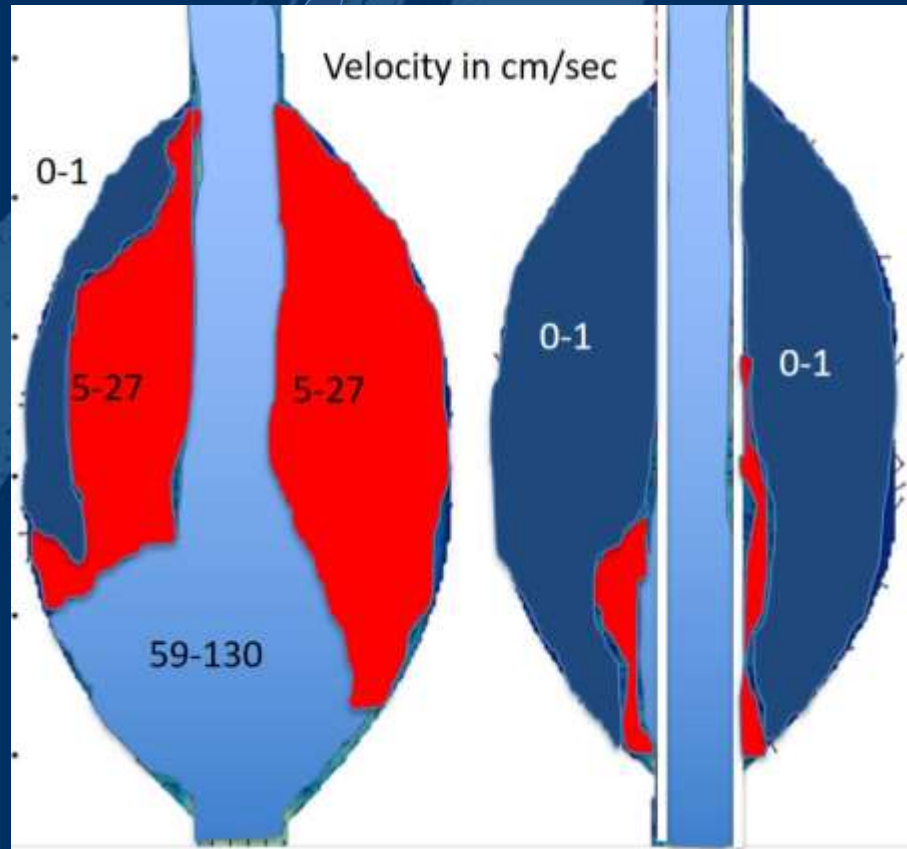


[New Aspects of Endovascular Treatment for Popliteal Aneurysms: First Results of a Pilot Trial]. **Tessarek J** et al.; Zentralbl Chir. 2015 Oct;140(5):535-41

Proof of concept (flow model/ lab test Bonifatius Hospital/ University of Twente)



Proof of concept in PAA flow models



Straight and curved flow modes
(University of Twente)

Stent free PAA (left)

Stented PAA (right)

Expansion of low to zero flow areas
Centralisation of high laminar flow in
stent tube

Explains excentric thrombus formation in untreated PAA

Explains the ordered thrombus formation after stent placement

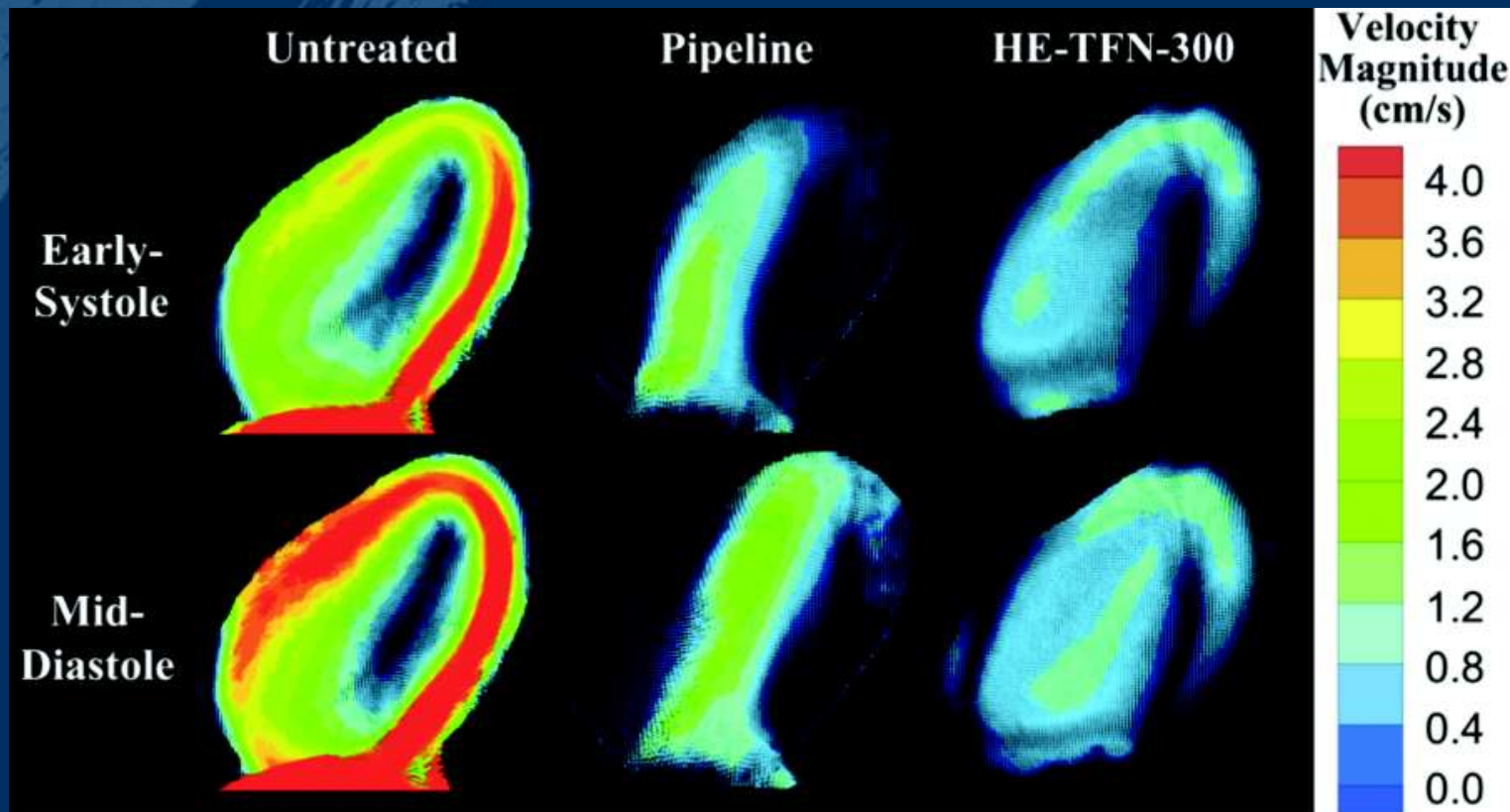
Low flow and high residence time → thrombogenicity

Explains thrombus stability without wash out even with stent sideways migration

In Vitro Investigation of a New Thin Film Nitinol-Based ...Journal of Medical Devices - American Society of Mechanical Engineers 2017

Flow velocity vector fields after treatment with the PED and HE-TFN-300 flow diverter

- Flow patterns in a intracranial arterial aneurysm before and after flow diverter



Supera for elective PAA treatment

Jan 2011 - 2019 (FU 26 d – 72mo)

- 38 (144) PAA : 1.8-5.1cm
- 59,8 (48-7) yrs , 37 m, 1f
- Single/ 2 stents/3/4 : 1/ 34/2/1
- Lost to FU > 22/ 38 mo : 2 (5,26%)

- Complete thrombosis at discharge : 35 (92,10%)
- Complete thrombosis during FU : 36 (94,37%)
- 1 type II EL/ 1 thrombosed stent but patent side branches
- Periprocedural/ 30 d mortality : 0%
- 1 adjunctive procedure (thrombolysis): 2,6%

Long term results for elective PAA repair with Supera double layer: close to CS

2011 - 2019

FU 38.4mo (26 days to 72 mo)

	: Supera	: CS (literature)
12 mo PP	: 84,22%	: 50-91.2%
12 mo SP	: 97,37%	
> 12 mo PP	: 75,87% (22/29)	: 73.6-85.5%
Limb salvage	: 100%	: 100%
TLR	: 5 with 3 recurrent events (13,15%)	
Conversion	: 4 (10,52%)	
Growth/shrinkage	: 0 (0%)/ 11 (28,94%)	

In conclusion

- Supera in PAA is a safe and effective therapeutic approach (7mm landing zone diameter maximum)
- Lab tests coherent with clinical results: early thrombosis
- Principle of flow diverting devices is reliable (residence time, depressurisation of the aneurysm) in mobile vessel segments
- 100% limb salvage, no rupture and 28% of PAA shrinking
- PP/ SP in the range of covered stents
- no device related complications (fractures, migration, separation)
- Focal occlusion, with patent collaterals and no loss of outflow vessels → bail out options are present or even not necessary
- Careful recommendation: DAPT / mono/ anticoagulation was more effective than anticoagulation alone and prolonged DAPT (6 mo) more effective than 30 d dual therapy



Thank you for your attention

joerg.tessarek@hospital-lingen.de

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