

Supera Stent in popliteal aneurysms

Jörg Tessarek

Vascular Center Emsland

Bonifatius Hospital Lingen

Germany

Disclosure

Speaker name:

.....Jörg Tessarek MD.....

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)

- I do not have any potential conflict of interest

Clinical pathology of popliteal aneurysms determined

- Low risk of rupture or bleeding (0.9-4.6%)
- Main risk: chronic embolisation (symptomatic chronic debris shower in >40%) progressive rarefaction of outflow vessels
- PAD of various degree Therapy resistant occlusive disease with high risk of limb loss
- Acute on chronic PAA thrombosis
- Worst case scenario: angiographical “blind popliteal” or “empty calf” with up to 70% risk of limb loss and 36% mortality

Lowell RC et al.; Annals of Vascular Surgery (1994) 8, 1, pp 14–23 ; **Popliteal artery aneurysms: The risk of nonoperative management**

Kassem MM et al Aneurysm, Popliteal Artery Stat Pearls Last Update: October 9, (2017)

Clinical endpoints for PAA

1. Limb salvage
2. Prevention of embolisation related PAD
3. rupture
4. PP, assisted PP, SP...

Therapeutic options for PAA treatment

surgery

- Invasive
- vein/graft dependent outcome
- Results run off dependent
- No adjunctive thrombolysis

covered stent

- Minimal invasive
- Adjunctive thrombolysis
- Implant costs
- Device dependent complications (dislocation, fracture, diameter mismatch...)

multilayer (MFM)

- Minimal invasive
- Adjunctive thrombolysis ?
- Implant costs
- Device dependent complications (dislocation, end stent stenosis due to device stiffness, diameter mismatch...)

Surgery comparable to Endo

>50% thrombosis during 12 mo FU

Challenges for any femoropopliteal endo-implant as often reported

- Dislocation and migration → landing zone/ fixation
- Diameter mismatch with crimping → thrombogenicity
- Resistance to component separation → thrombosis/ no endo repair
- Crushing and stent fractures → thrombosis/ no endo repair
- Reliable thrombus fixation → run off preservation
- dedicated device → morphological challenges

J Vasc Surg. 2012 Jun;55(6):1647-53. Outcome of endovascular repair of popliteal artery aneurysm using the Viabahn endoprosthesis. Garg K et al.

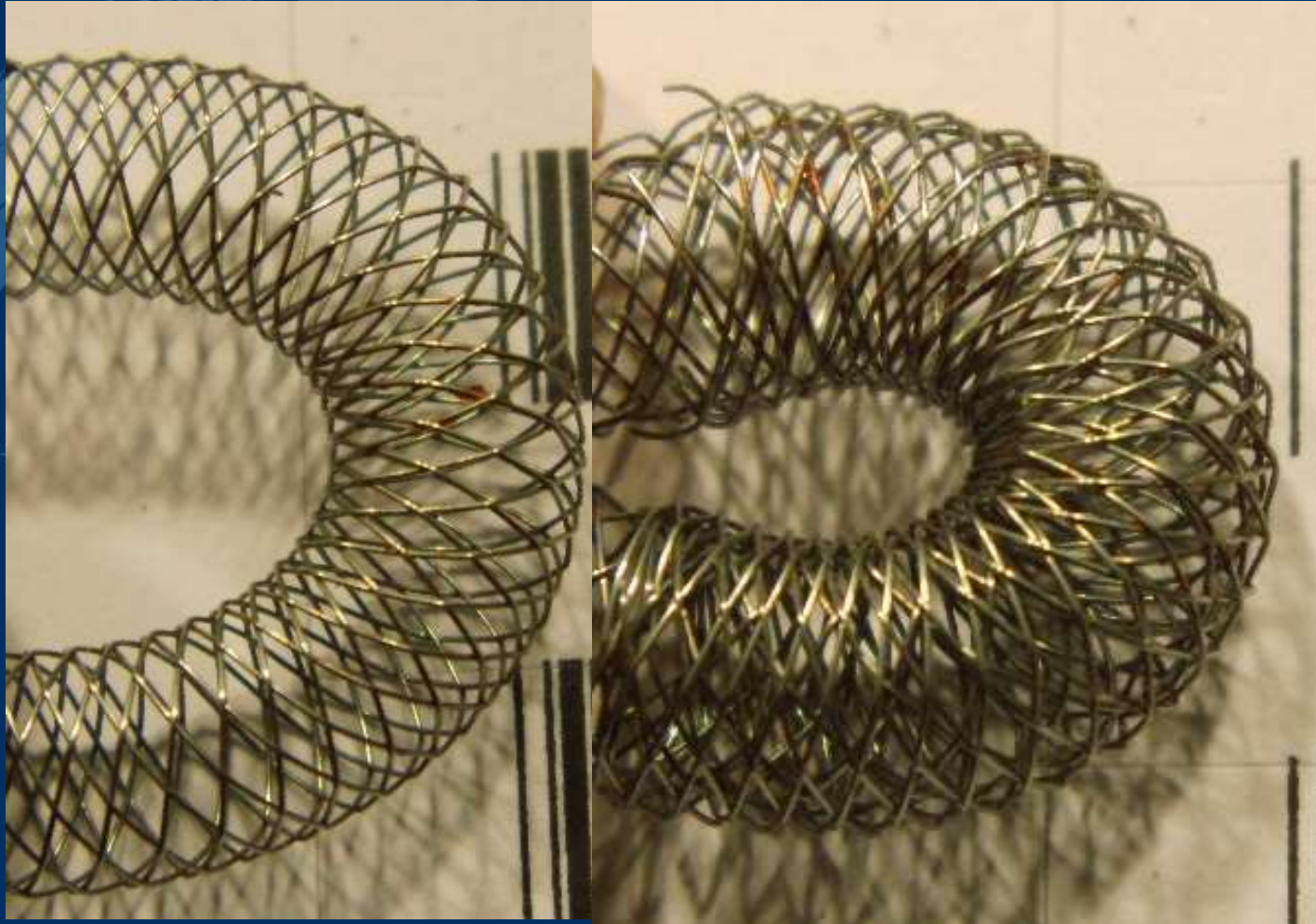
Ann Vasc Surg. 2015 Jul;29(5):941-9. Ten years' experience in endovascular repair of popliteal artery aneurysm using the Viabahn endoprosthesis: a report from two Italian vascular centers. Speziale F et al.

Therapeutic options for PAA exclusion: dedicated nitinol intervoven stent

Double layer Nitinol Intervoven Stent with adaptable mesh design dedicated for the femoropopliteal segment

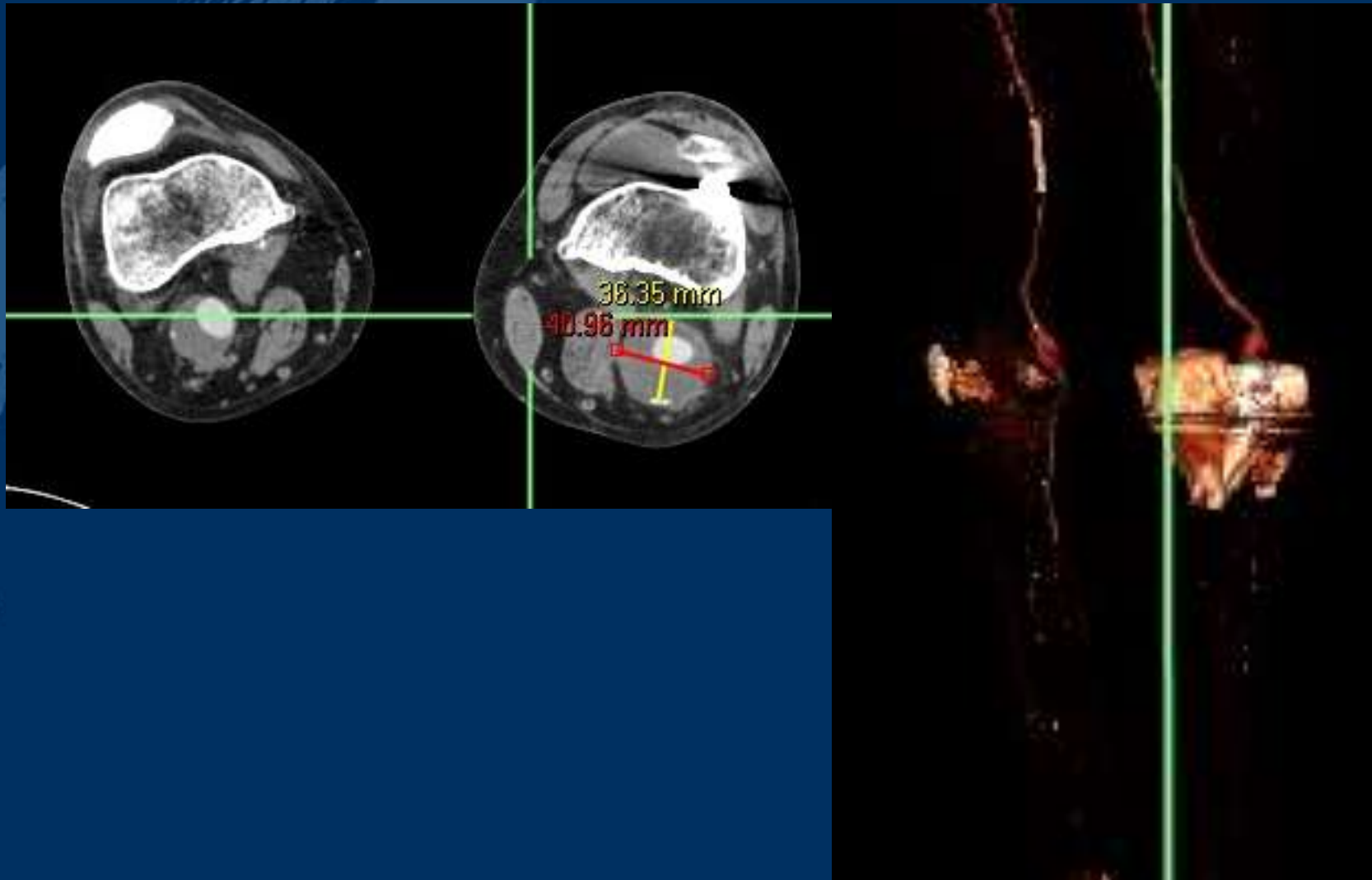
(CE marked for use in arterial segments)

dual layer modification of Supera stent: 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

Technical aspects of the procedure: Bilateral PAA with left limb claudication



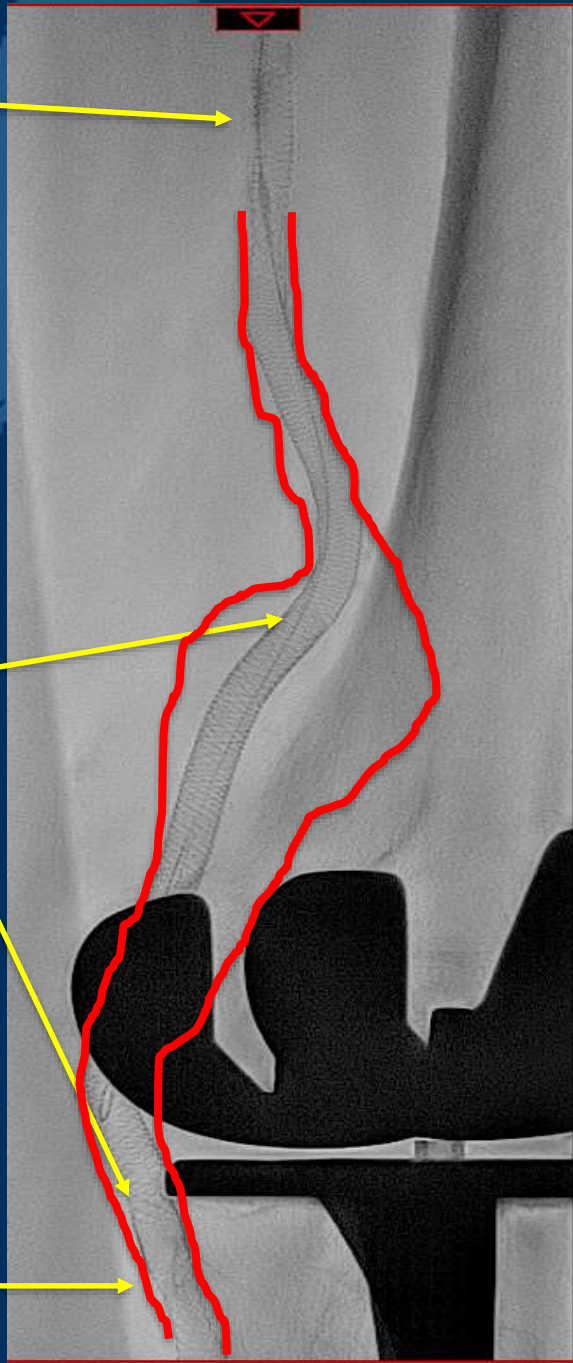
Technical aspects of the procedure: telescope technique for mesh density



- Monolayer

- Double layer

- Monolayer



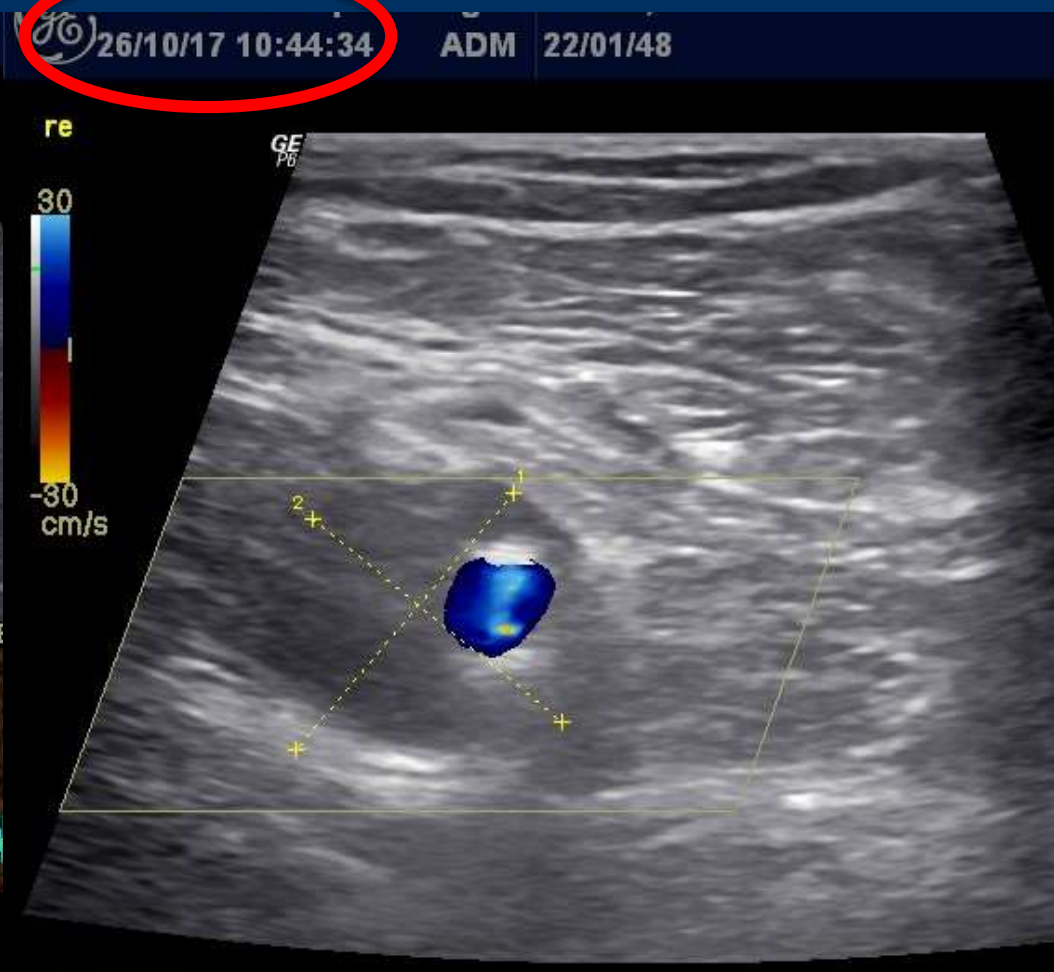
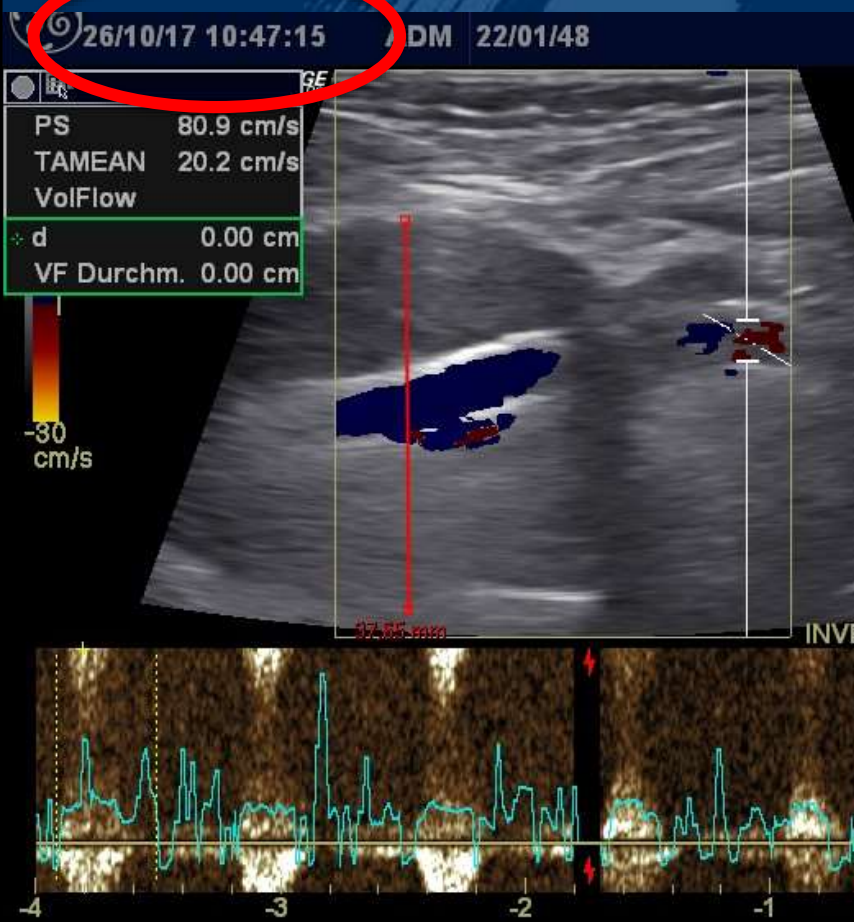
Technical aspects of the procedure: time



Technical aspects of the procedure: preservation of collateral run off



Baseline FU examination : DUS / ABI/ 0-3-9-15...



Lingen experience with Supera for elective PAA

January 2011 - January 2018 (FU 3-55 Mon)

- 28 (132) elective PAA (19 pat.) : 1,9-5,1cm
- Single/ two stent : 1/ 20
- Fusiform PAA → more stents : 7
- Re-Interventions : 8 (4 PAA)
- conversions : 4
- Minor/ major amputation : 0
- PAA growth /shrinkage : 0 / 11 (0/ 39.2%)
- detected embolisation/ trash : 0

Lingen experience with Supera for elective PAA

January 2011 - January 2018 (FU 31.7mo (3-55))

	: Supera	: CS
30 d mortality	: 0%	: 0%
Lost to FU	: 3.6 %	
12 Mo PP	: 85.7%	: 50-91.2%
> 12 mo PP	: 82.1%	: 73.6-85.5%
TLR	: 15.7%	
Conversion	: 15.7%	
Limb salvage	: 100%	: 100%
Device failure	: 0% (#, migration)	: -4%

Sacciforme PAA (1/ 2 stents) did better then fusiform PAA

Costs benefits for Supera

Meaning of run off and initial clinical appearance: acute TASC IIB or Rutherford 4-6

	1	2	3	4	5	6	7	8
TASC II	IIA	IIB	IIA		IIA	IIB	IIB	
Rutherford				VI				IV
Procedure time: puncture to closure 44-71 min. followed by local thrombolysis								
Patency BTK	0,5	0	0,5	0,5	0,5	0,5	1	0
Patency po	1,5	1	2	1,5	1,5	1	2	1,5
Secondary procdures	0	Reocclusion after 8 Mon. Successful Lysis	0	US Amp. 6 Mo.	0	Aspiration of emboli BTK and Stenting during index procedure	0	0
Complications		Fasciotomie	Local hematoma		Local hematoma			

Aspiration thrombectomy with stenting and thrombolysis : Bolus 5-10mg
+1,5mg/h = Bolus +10,5-36mg rTPA

In conclusion: Supera in PAA is a safe and effective therapeutic approach

- Primary endpoint : limb salvage
 - 100% limb salvage up to 55 mo
- Secondary endpoint: rupture, embolisation, run off preservation
 - 100% freedom from rupture, growth and embolisation
- Technically: stable solution without device related complications
- Economically: cheaper and „affordable“ bridging device for thrombus fixation under thrombolysis (index procedure) in acute settings
- Limitations: maximum vessel diameter at landing zones: 7mm
- Starting flow lab in vitro testings for further proof of concept and standardisation in the „femoro-popliteal“ setting



Thank you for your attention

joerg.tessarek@hospital-lingen.de

Bonifatius Hospital Lingen

Supera Stent in popliteal aneurysms

Jörg Tessarek

Vascular Center Emsland

Bonifatius Hospital Lingen

Germany