



L I N C

BEnefit of arterial preparation by
LONGitudinal incisions before
paclitaxel eluting balloon angioplasty of the
superficial femoral and
popliteal artery:
concept and inclusion status of the Swiss
multicentric **BE****LONG** Study

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Disclosure

Speaker name:

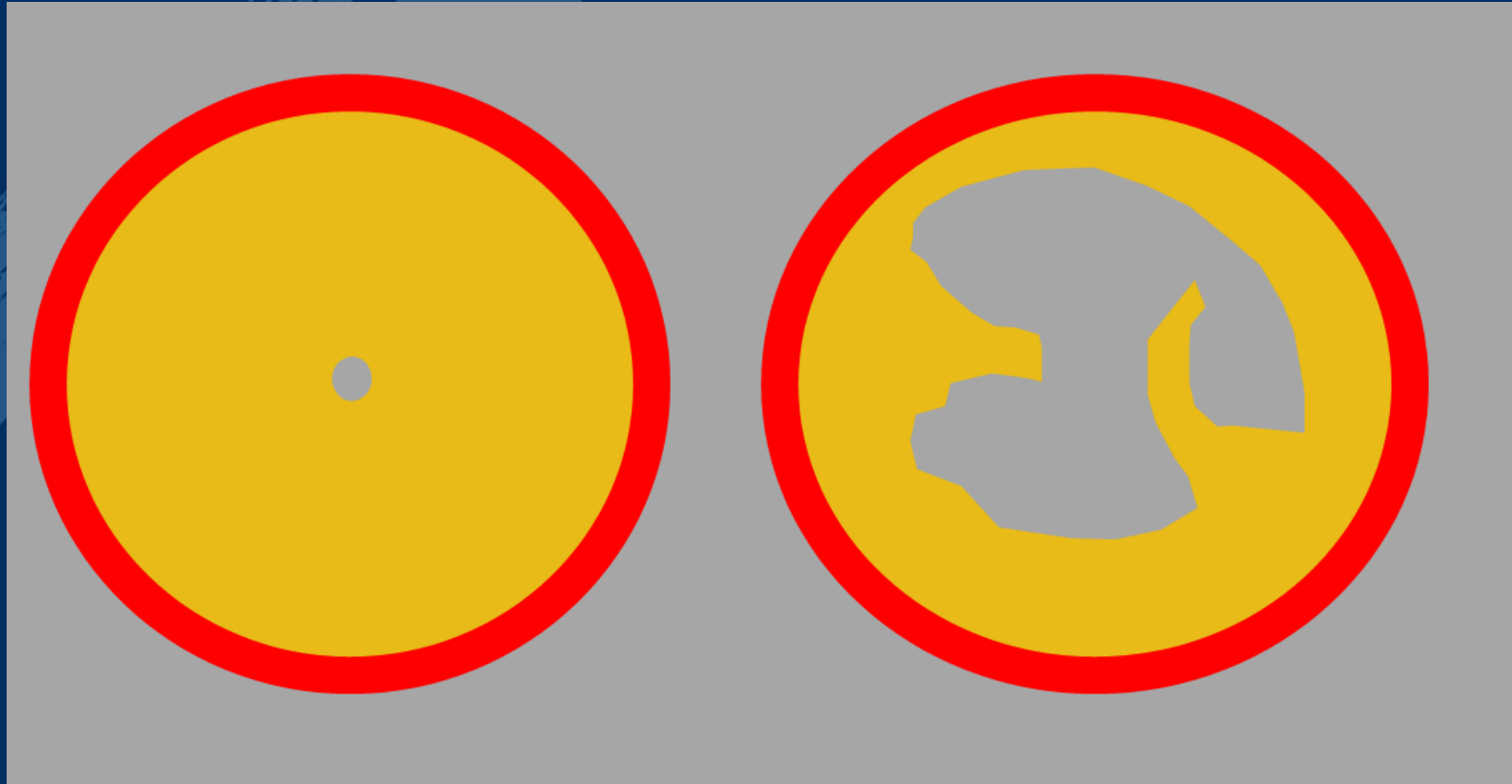
Daniel Périard

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)

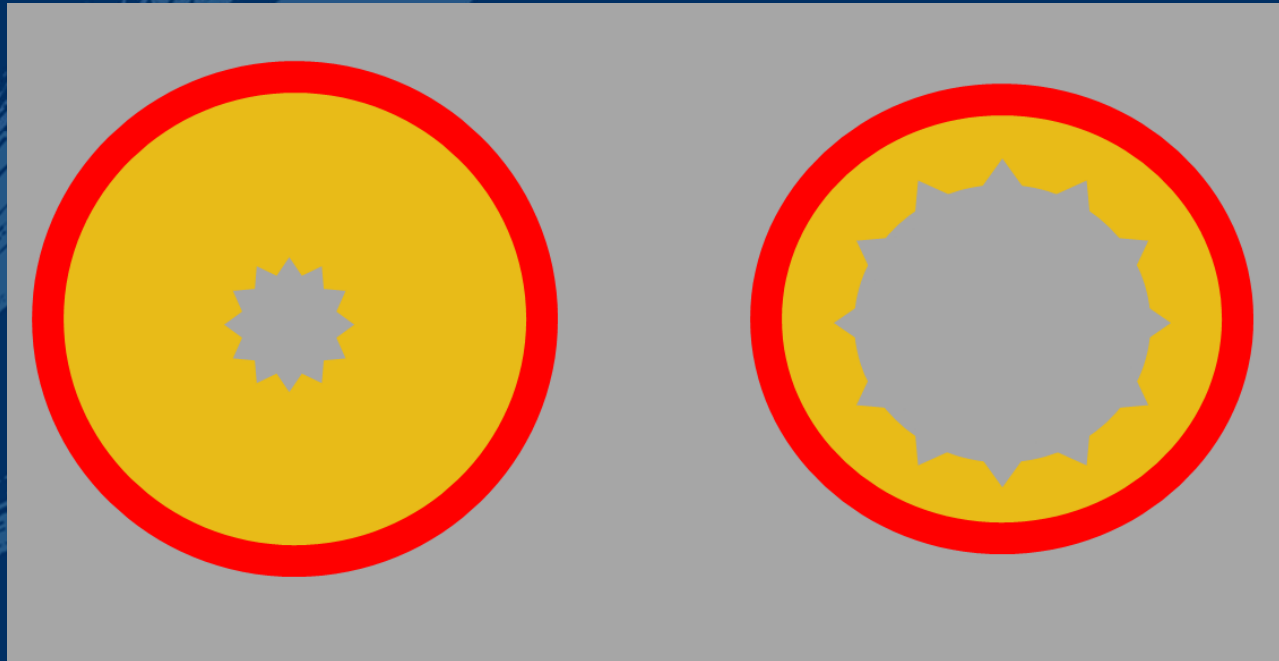
- ☒ I do not have any potential conflict of interest

Angioplasty without preparation



Large uncontrolled plaque dissection

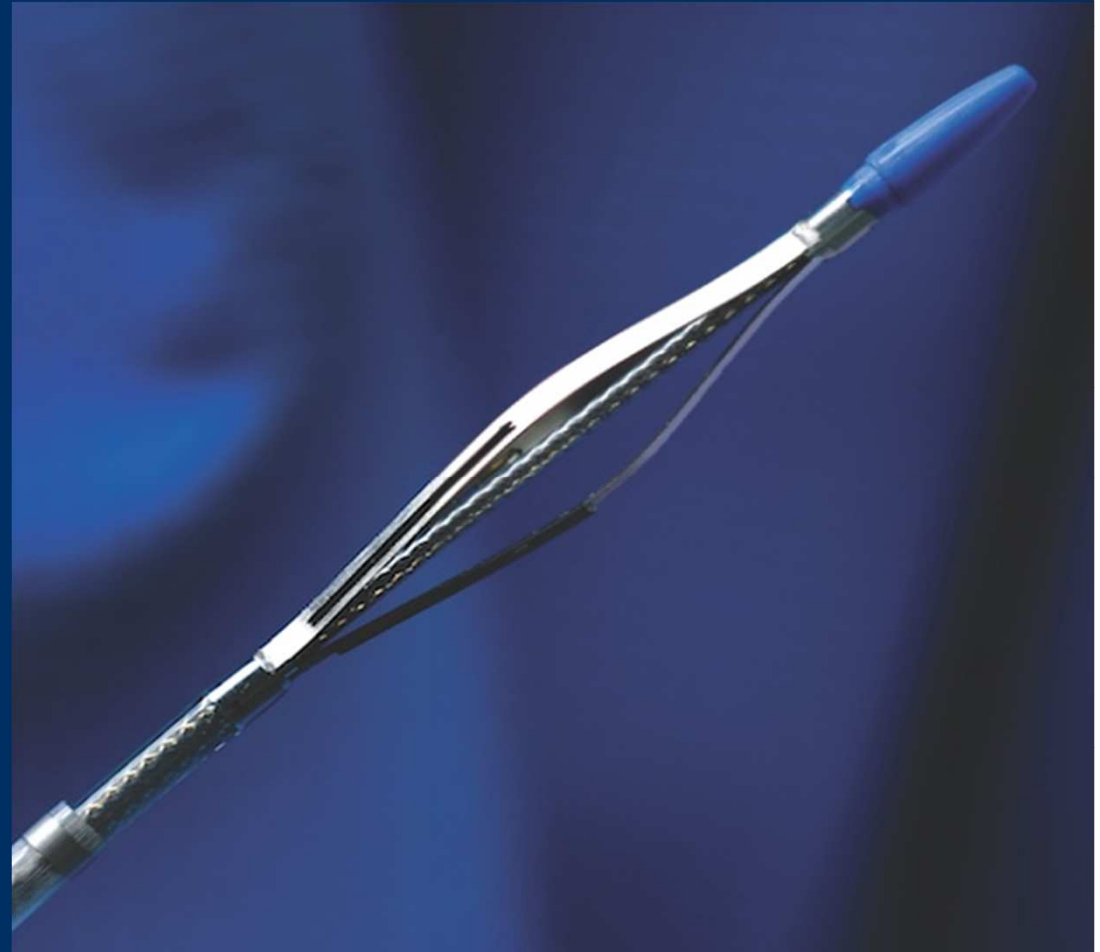
Artery preparation by longitudinal incisions



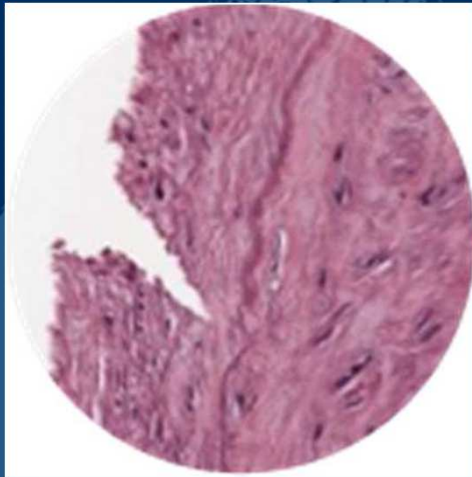
- Regular expansion of the atheroma
- Reduces the risk of flow-limiting dissection and the need of stenting
- Favor regular impaction/diffusion of paclitaxel to its target

The FLEX Vessel Preparation System

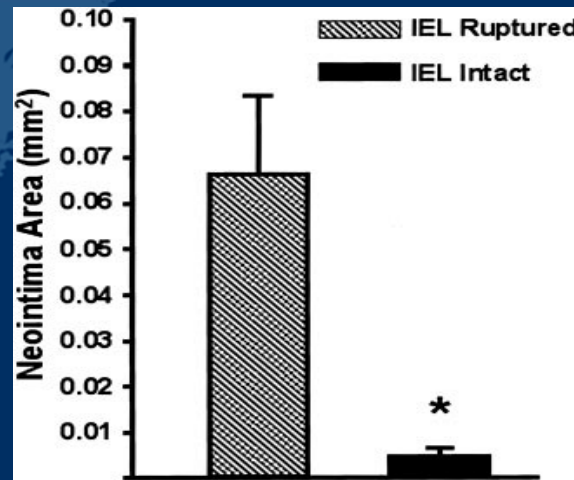
- 6Fr introducer, 0.018 GW, OTW
- Dynamic **longitudinal incisions** by pull-back
- 2-4 passages with 30° rotation
- Incisions depth 250 microns
- Manufactured by VentureMed Group
- One size fits all



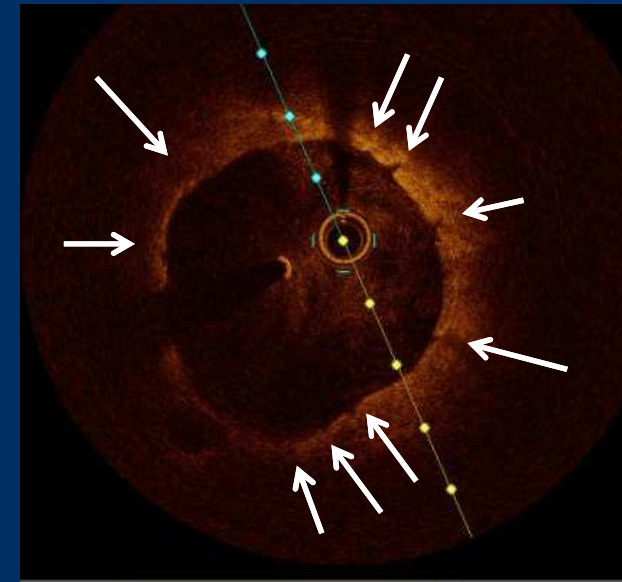
Incisions do not disrupt the internal lamina elastica



Histology of Micro-Incision
(Cadaveric Human SFA)



Indolfi C et al. Am J Physiol Heart Circ Physiol
283: H760–H767, 2002



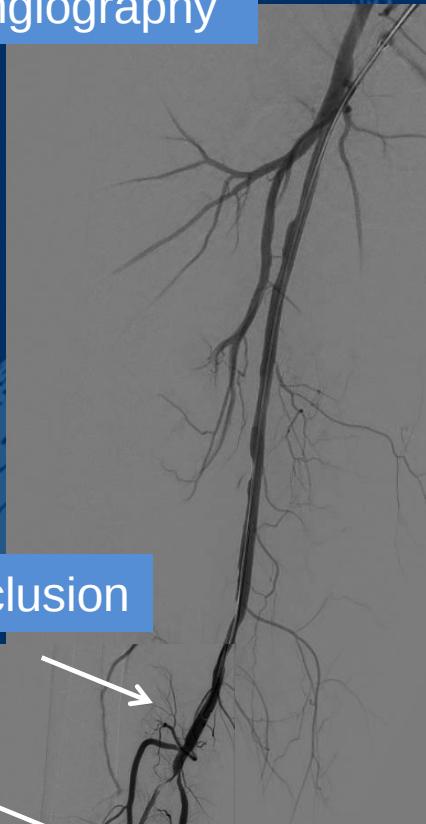
Optical Coherence Tomography (OCT) Angiography (courtesy Dr. PD R. Engelberger, Fribourg)



44y man

- PAD Rutherford class 4, (rest pain in right foot)
- Diabetic, smoker, hypercholesterolemia
- Duplex: short occlusion of right distal SFA

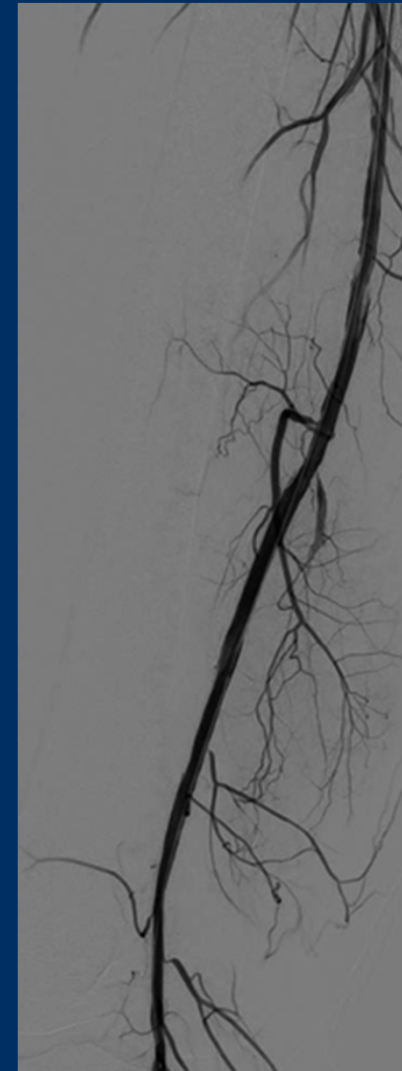
Initial angiography



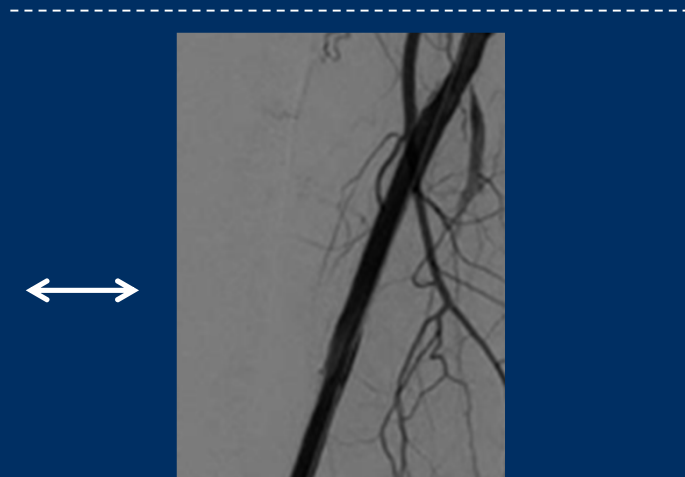
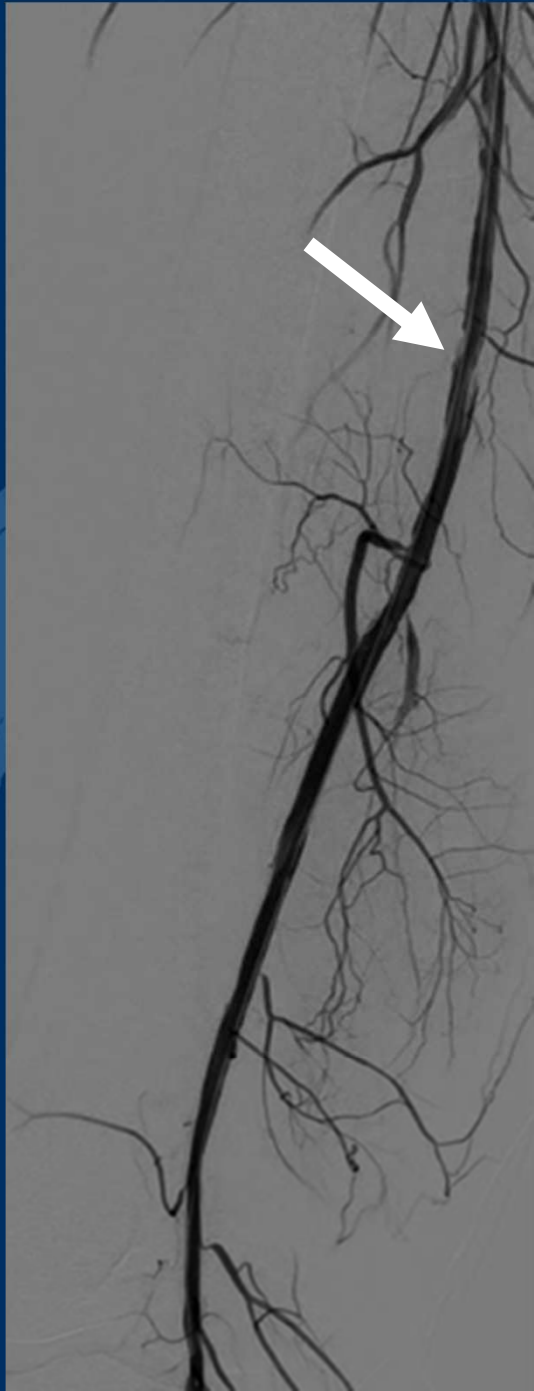
SFA occlusion



After 4 passes of
FLEX Vessel
Preparation System



Result after drug-
eluting
angioplasty



Occluded segment
prepared by Flex

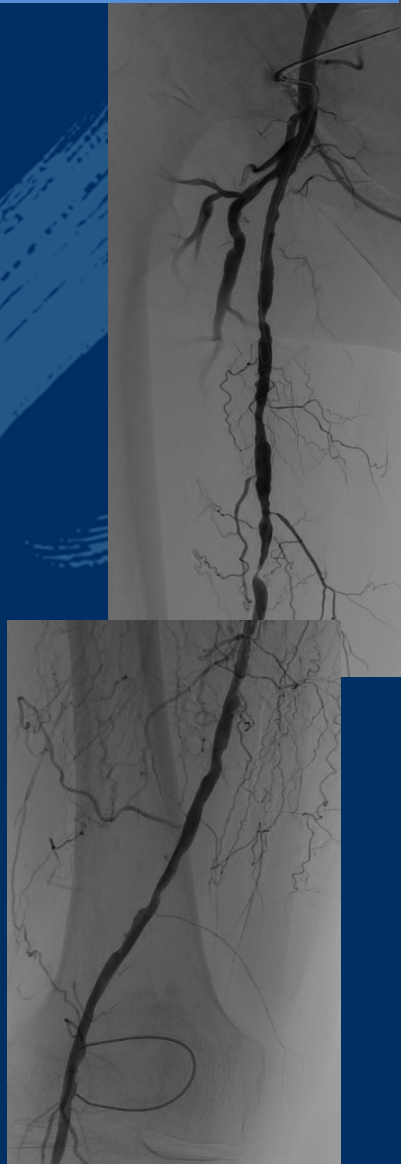


Result of
angioplasty of a
moderate stenosis
that was not
prepared

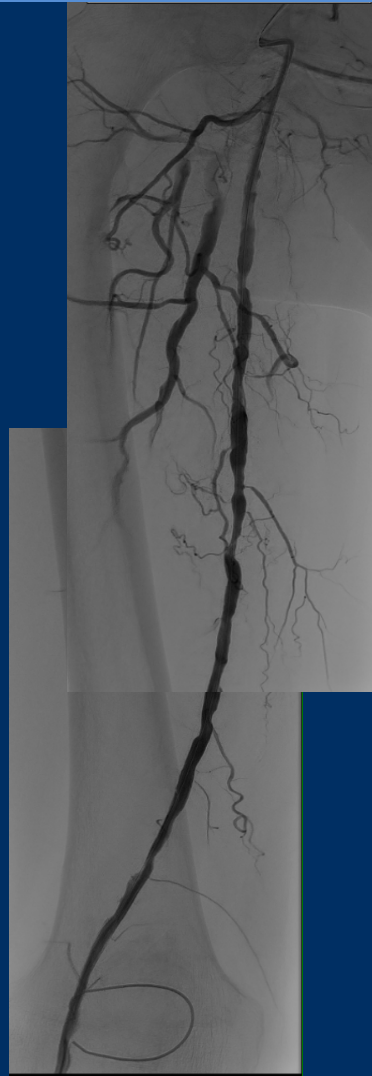
79y man

- PAD Rutherford class 3
- Hypertensive, former smoker, hypercholesterolemia
- Right carotid endarterectomy
- Duplex: multiple short sub-occlusions of the SFA, occlusion of the tibial arteries

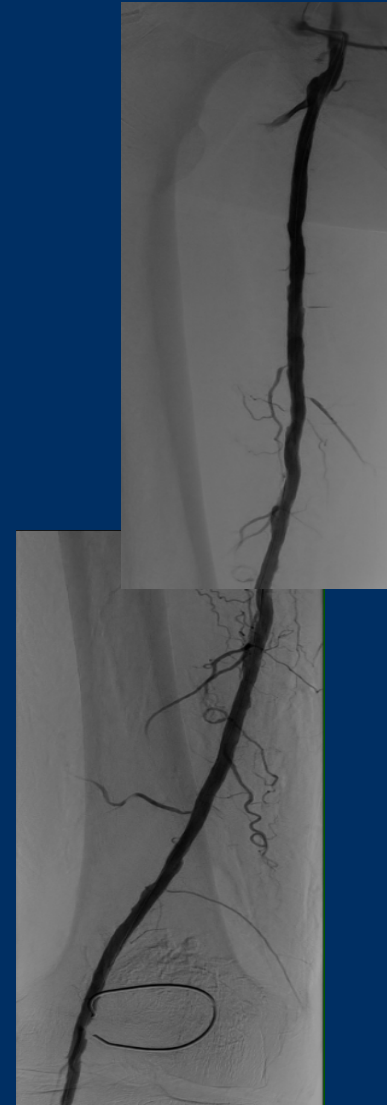
Initial Angiography



After FLEX Vessel Preparation System

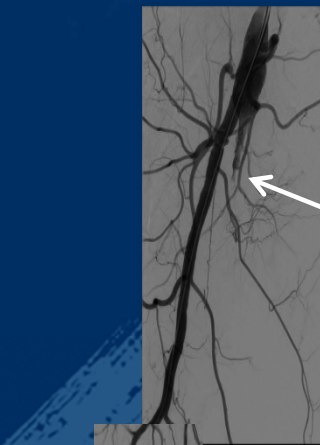


After Flex and DCB

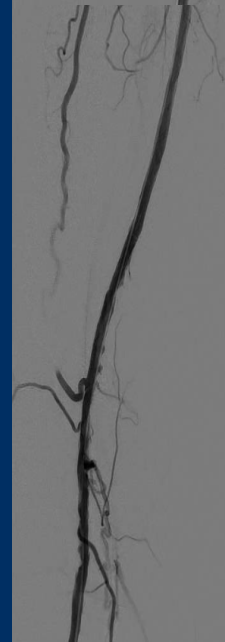
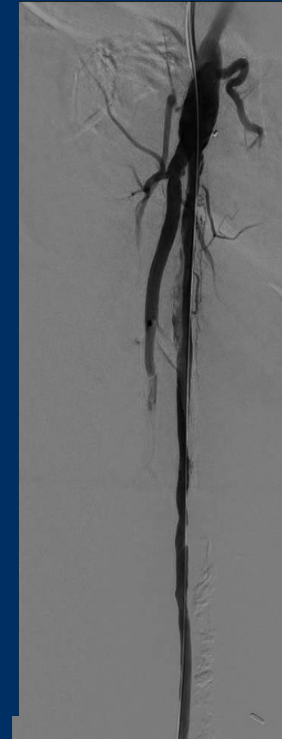


66y man

- Rutherford class 3 (R calf claudication)
- Right Ilio- femoral and femoro-popliteal bypass (saphenous) in 2009, followed by rapid occlusion
- Duplex : occlusion of the native SFA and the Fem-Pop bypass.



Bypass
occluded since
8 years



Result after 4
Flex
passages and
DCB
angioplasty (3x
Freeway
5x150)

around 120 interventions performed in
21 months

Most in the SFA/popliteal

de novo lesions

Restenosis/occlusion

In-stent lesions

Bypass stenosis/occlusion

Dialysis vascular access

Iliac lesions

Tibio-fibularis trunc

Characteristics of the *de novo* stenosis treated by longitudinal incisions and DEB

50 interventions on SFA/popliteal			
age (y)			71±13
class of symptoms			
	claudication		67.4 %
	CLI		32.6 %
lesion lenght (mm)			202±118
mean degree of stenosis			88%
occlusion			42%
occlusion lenght (mm)			190±111
lenght of longitudinal incisions/DEB (mm)			202±118
stenting			9 (18.0%)
stent lenght (mm)			80±70
technical success of Flex device			100%
follow-up (months)			9 (1 to 22)
TLR			4 (8%)
major amputation			0

Questions

- Is there a risk of premature loss of patency, by elastic recoil, due to the low rate of stent implantation?
- Does this apparent immediate good results persist after 1 year?

Design of the **Belong Study**

- Multicentric Swiss prospective study (4 centers)
- A non-comparative, single arm, interventional study evaluating the 12 months efficacy of an endovascular recanalization of the SFA and PA by longitudinal incisions followed by conventional DCB angioplasty $\pm$ provisional stenting
- Core lab adjudication for angio/duplex images
- External monitoring (Uni Bern), independent data safety monitoring
- www.clinicaltrial.com

Inclusion criteria

- Patients ≥ 18 -year-old, with symptomatic lower extremity occlusive arterial disease
- Rutherford class **2 to 5**
- Atheromatous ≥ 70 % stenosis or occlusion of SFA and/or PA
- Absence of $> 50\%$ residual stenosis of the run-in vessels at the end of procedure
- Presence of at least one patent (no ≥ 50 % stenosis) run-off tibial or fibular vessel to the foot at the end of procedure
- **De novo or restenotic lesions, including in-stent restenosis**

Primary efficacy outcome

- Absence of clinically driven target lesion revascularization (CDTLR) at 12 months

Secondary efficacy outcomes:

- 3 and 12 months primary patency of the treated lesion (defined by PSVR ≤ 2.5 at duplex scan) (core lab for the 12 months duplex scan)
- Absence of CDTLR at 3 months
- 3 and 12 months absence of major amputation
- 3 and 12 months change in ankle brachial index (ABI)
- 3 and 12 months change in Rutherford class of symptom
- Technical success of the scoring procedure

Primary safety outcome

- Composite of (1) death from cardiovascular origin or (2) major amputation of target limb

Secondary safety outcomes:

- Proportion of adverse event associated to the scoring step

BELONG Study: inclusion status

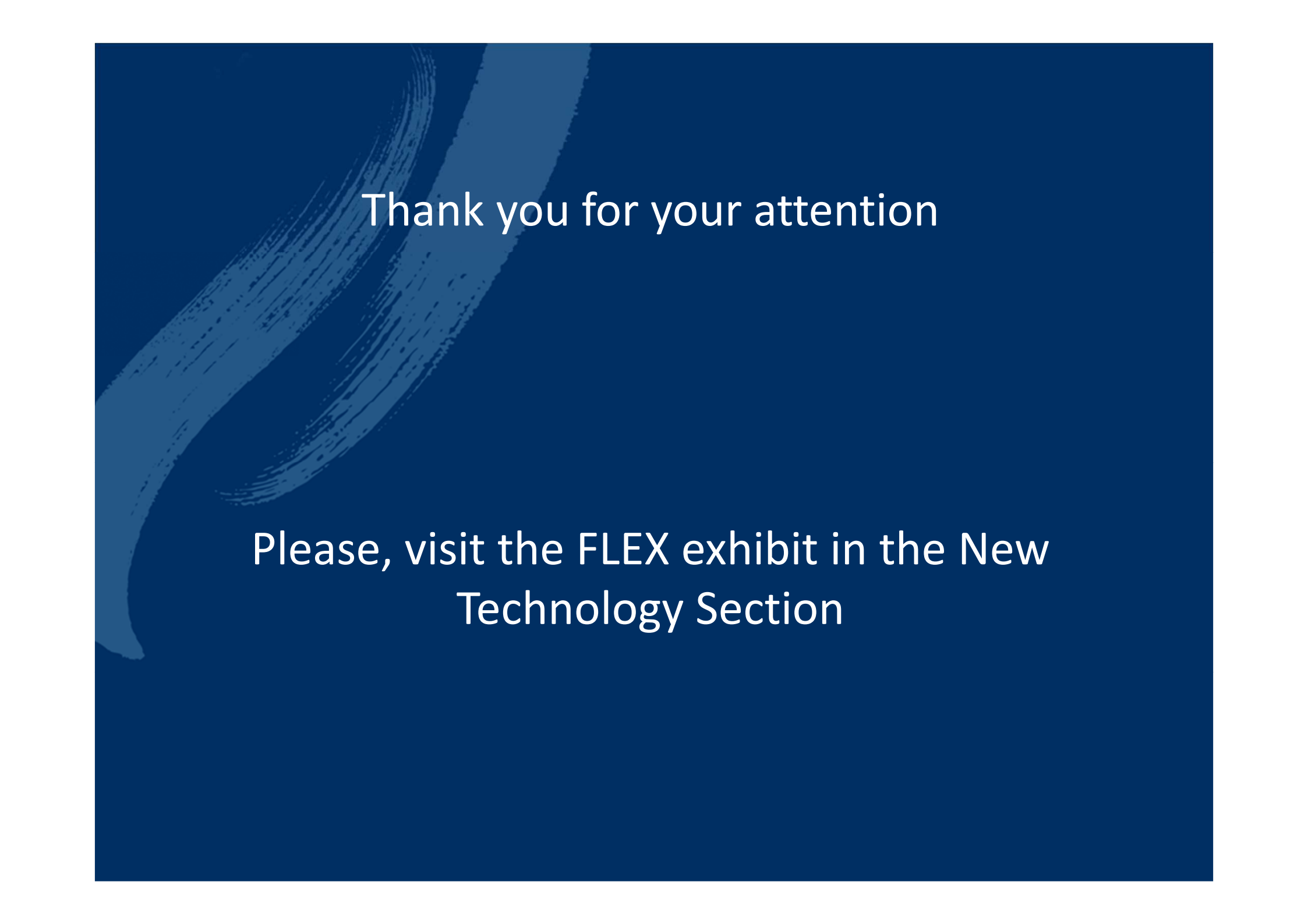
study start date:			22.oct 2018	
open center			1 (Fribourg)	
intended number of centers			4	
patients included			21	
patients treated			13	
planned inclusion period			up to 12.2019	

Characteristics of the patients treated in the Belong Study

13 interventions on SFA/popliteal		
age (y)		70±12
hypertension		69.2%
hyperlipidemia		61.5%
smoking (ever)		61.5%
diabetes		15.4%
coronary disease		38.5%
cerebrovascular disease		15.4%
Rutherford class of symptom		
	2	6 (46%)
	3	5 (38%)
	4	2 (15.4)
	5	0
lesion lenght (mm)		193±88
mean degree of stenosis		88%
occlusion lenght (mm)		180±41
lesion calcification		
	mild	38.4%
	severe (circum.)	38.4%
	massive	7.7%
technical success of Flex device		100%
DEB		100%
stenting		6 (46%)
stent lenght (mm)		73±48

conclusions

- The arterial preparation by longitudinal incisions is a new technology that opens many perspectives.
- The recanalization of long femoro-popliteal occlusions seems possible, with implantation of little or no stent, and thus without modifying the mechanics of the artery.
- The Belong Study will provide 1year results of this approach.



Thank you for your attention

Please, visit the FLEX exhibit in the New
Technology Section