

MEET 2008 – Session 4

Update in femoral angioplasty & stenting

MELOPEE-study:
-- 12 month data --
Clinical duplex and
X-ray outcome of
the Lifestent in
popliteal lesions

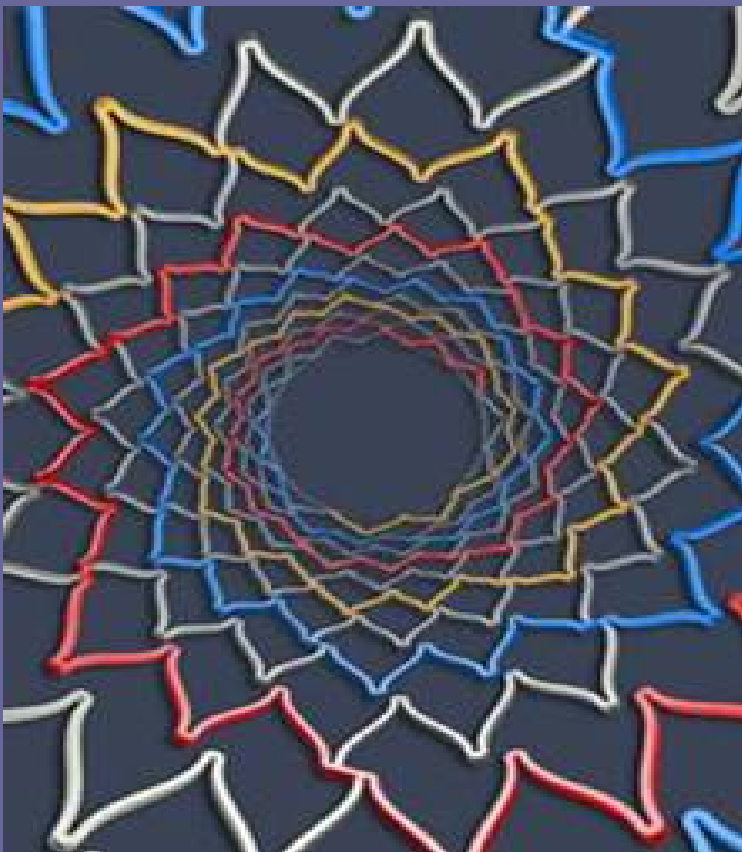
M. Bosiers

K. Deloose

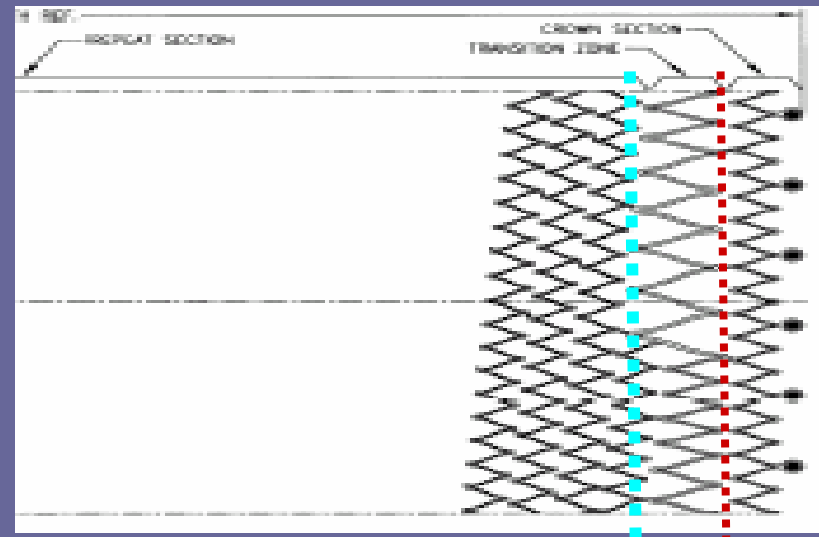
P. Peeters

LifeStent NT

- Triple helical structure with 3 different zones

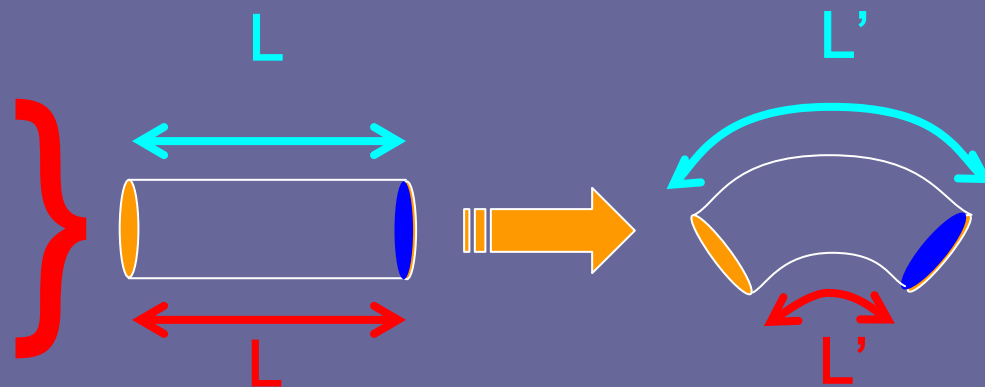


- Flared ends with markers
- Transition zones
- Triple helical structure



LifeStent NT

- Less structural tensions
 - Helical structures behave differently during axial deformations
 - Excellent ability to extend and compress



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Study design

- Multicenter Edwards LifeStent NT Outcomes: Popliteal European Evaluation
 - Daily clinical performance of the Edwards LifeStent in patients with popliteal vascular disease in 5 European clinics on an intention to treat basis

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P. Peeters	Imelda Hospital, Bonheiden, Belgium	
P. Pattynama	Erasmus Hospital, Rotterdam, Netherlands	
T. Zeller	Heart Center, Bad Krozingen, Germany	
C. Rabbia	Azienda Sanitaria Ospedaliera S. Giovanni Battista-Molinette, Torino, Italy	

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Study follow-up

- Clinical evaluations & Rutherford categorization
 - 30 days, 6 & 12 months
- Duplex evaluation
 - 30 days, 6 & 12 months
- X-rays @ 6 months
 - AZ Sint-Blasius, Dendermonde
 - Imelda hospital, Bonheiden

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Main inclusion criteria

- Stenotic (> 50%) or occlusive atherosclerotic disease of the **popliteal artery**
 - Lesion located in between 3 cm proximal of Hunters' canal to infrapopliteal trifurcation
- Length of lesion **<15cm**
- Life altering claudication or critical limb ischemia (Rutherford 3-5, Fontaine IIb-IV)
- At least single vessel run-off until the ankle
- Age at least 50 years

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Study primary endpoints

- Performance
 - **12-month patency** defined as the absence of
 - a) any reintervention to restore blood flow
 - b) amputation due to restenosis or occlusion
 - c) conversion to bypass surgery to restore blood flow
 - d) untreated significant restenosis/occlusion on duplex
- Safety
 - **Death or unexpected major amputations** defined as amputations at or above the ankle at 30 days

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Study secondary endpoints

- Procedure Success
 - maximal 30% residual stenosis
- Rutherford
- Limb-salvage
 - lack of major amputation

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Baseline data

Demographics

N=64

Age (yrs)	72.3	± 9.6
Male	31	48.4 %
Female	33	51.6 %
Arterial hypertension	47	73.4 %
Hypercholesterolemia	32	50.0 %
Nicotine Abuse	25	39.1 %
Coronary artery disease	7	10.9 %
Diabetes	22	34.4 %

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Baseline data

Symptomatology

N=64

Rutherford 2	13	20.3
3	25	39.1
4	9	14.1
5	17	26.6

40.7% CLI

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Baseline data

Lesion characteristics

N=67

Reference vessel Ø (mm)	5.4	± 0.5
Pre-proc. stenosis (%)	92.4	± 10.6
Lesion length (mm)	63.3	± 30.3
Stenosis	35	52.2 %
Occlusion	32	47.8 %

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Procedural data

Acute results

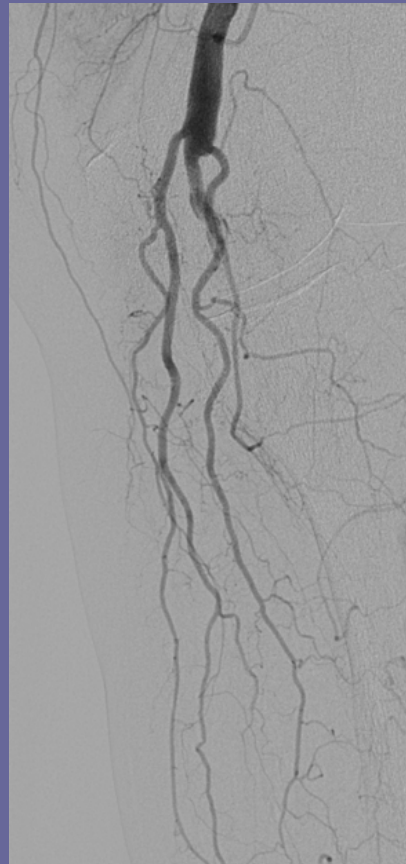
N=64

Procedural success	64.0	100.0 %
Post-proc. stenosis (%)	2.3	± 5.6
Death	0	0.0 %
Stroke	0	0.0 %
Myocardial infarction	0	0.0 %
Emergent surgical revasc.	0	0.0 %
Distal embolization	1	1.6%
Thrombosis	1	1.6%

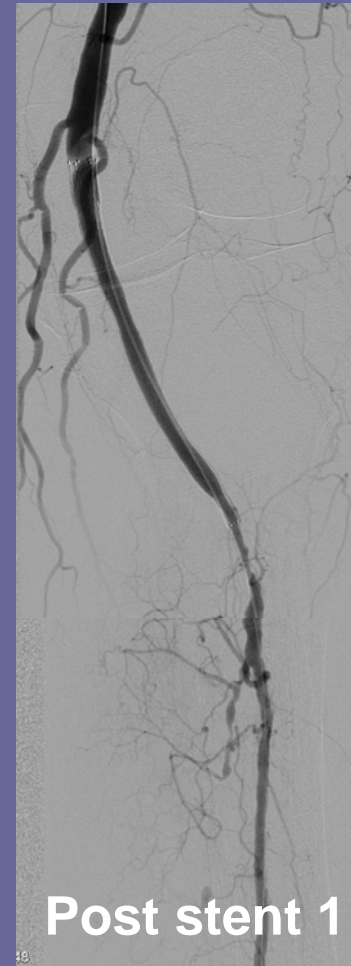
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Procedural example

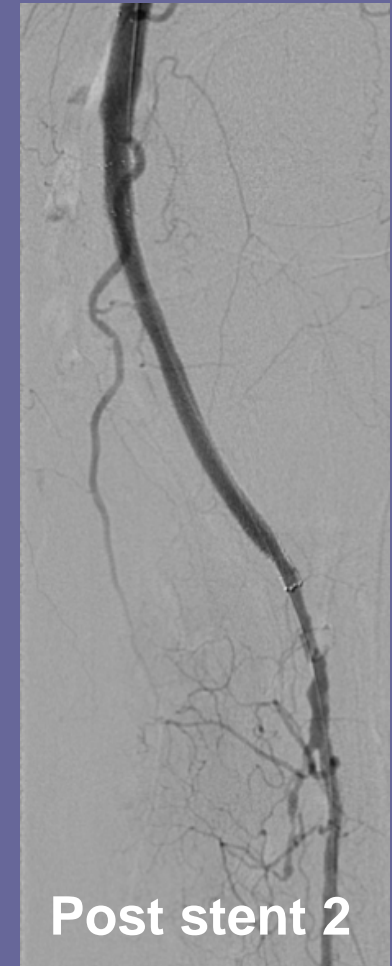
- Female
 - 79 yrs
- DOP
 - 03/01/2006
- 2 LifeStent NT
 - Proximal
 - 6.0/90
 - Distal
 - 6.0/40



Pre



Post stent 1

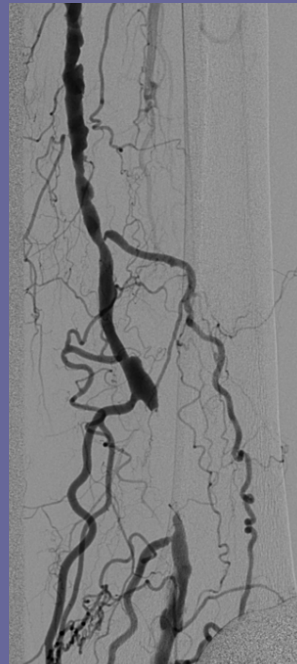


Post stent 2

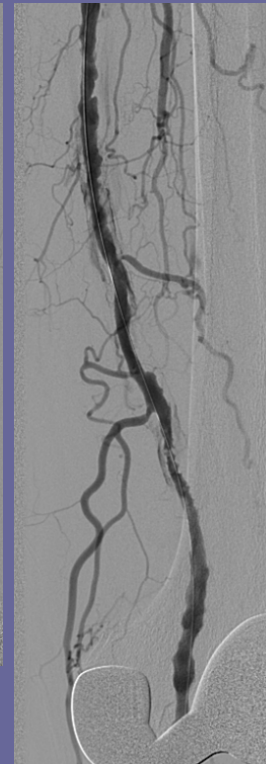
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Procedural example

- Male
 - 80 yrs
- DOP
 - 25/07/2005
- 1 LifeStent NT
 - 6.0/60

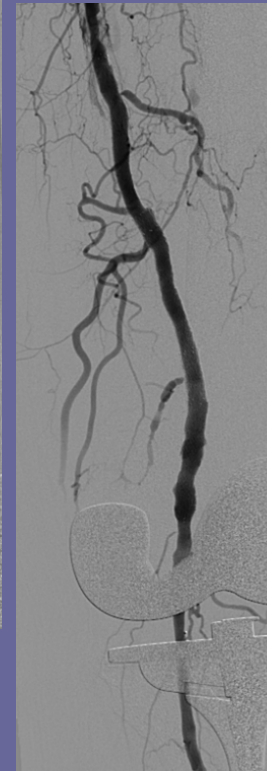


Pre

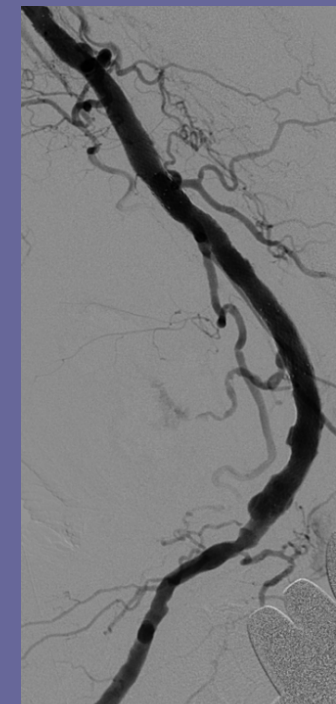


After PTA

Post straight



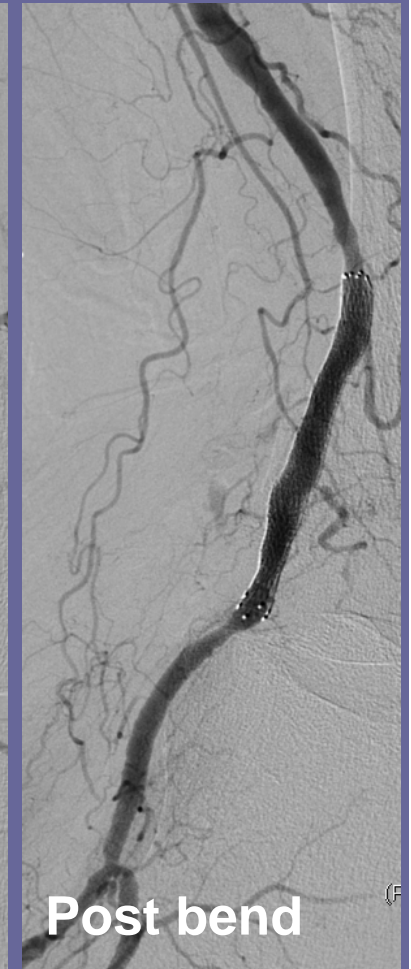
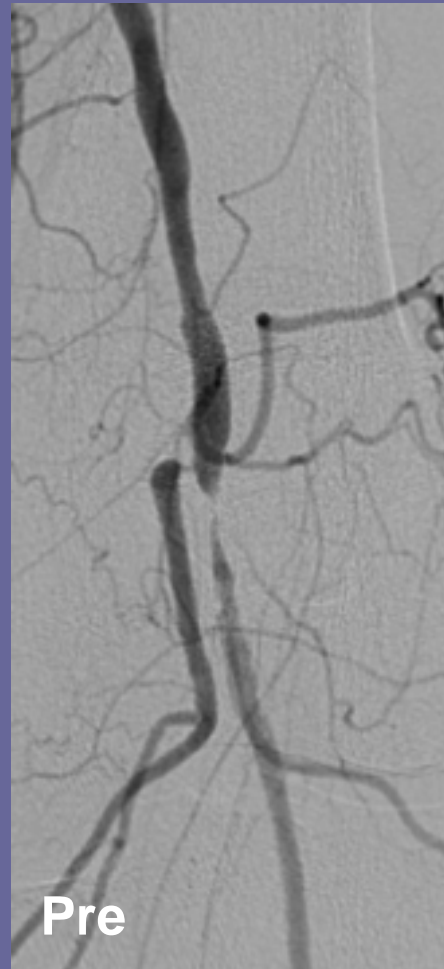
Post bend



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Procedural example

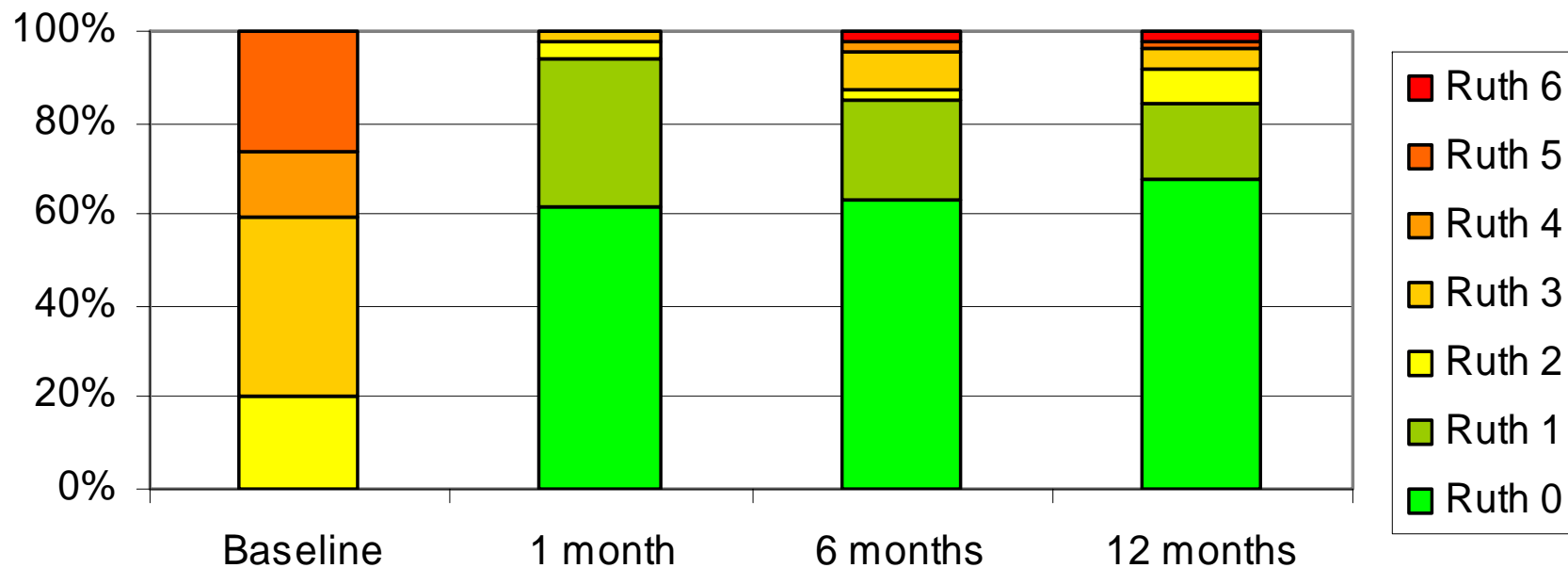
- Female
 - 73 yrs
- DOP
 - 30/03/2006
- 1 LifeStent NT
 - 6.0/60



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Follow-up outcome

Rutherford evolution (distribution)



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Follow-up outcome

12-month outcome

N=64

Primary patency rate

70.2 %

Limb salvage rate

96.9 %

Survival

87.4 %

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Follow-up outcome

X-ray substudy (6 months RX)

N=19

No fracture observed	16	84.2 %
Mild fracture	1	5.3 %
<i>Single strut fracture</i>		
Moderate fracture	2	10.5 %
<i>Fracture of more than one strut but without complete separation</i>		
Severe fracture	0	0.0 %
<i>Complete separation</i>		

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Follow-up outcome (6 months)

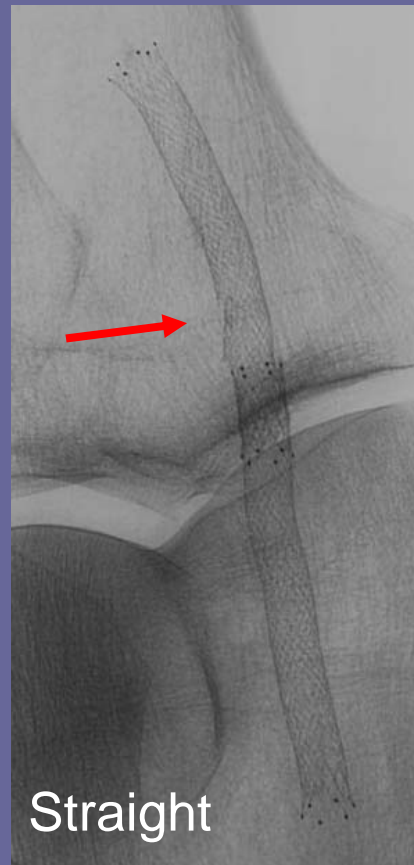
X-ray substudy

- 2x Lifestent NT
 - 6.0/60



- 6-month RX
 - Single strut fracture
 - Moderate #

N=19



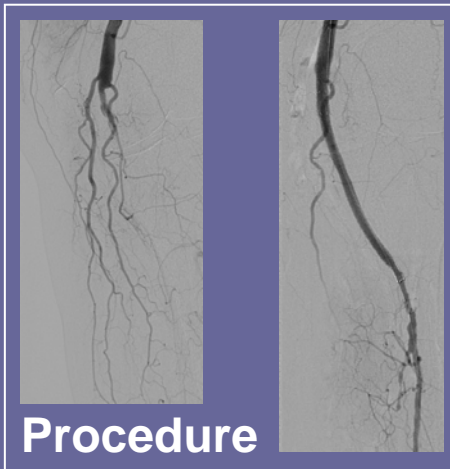
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Follow-up outcome (6 months)

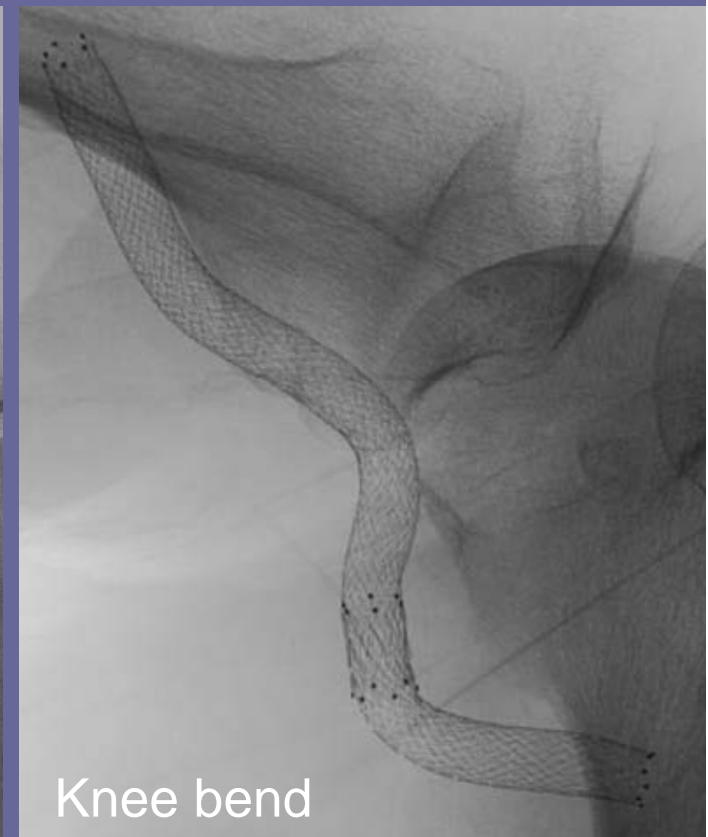
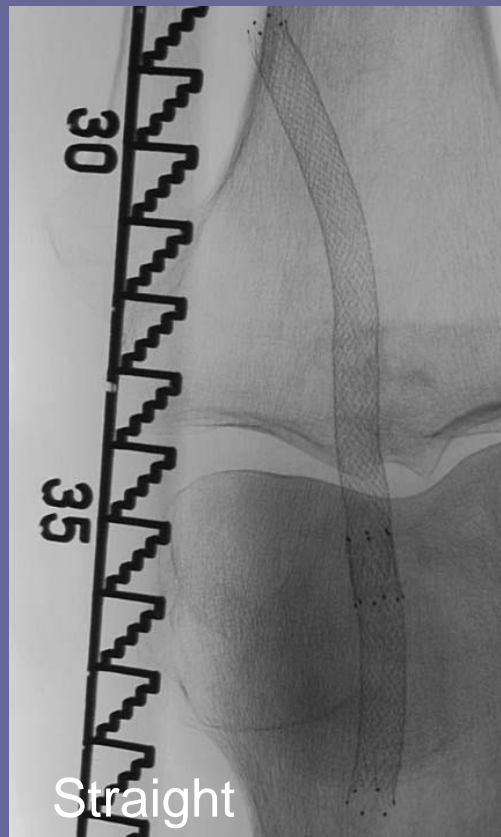
X-ray substudy

N=19

- 2x Lifestent NT
 - 6.0/90 + 6.0/40



- 6-month RX
 - No fracture



Conclusion



- 12-month patency of **70%** in popliteal segment
→ Very promising
- Triple helical structure proves to be **fracture resistant** in a challenging anatomy