Current Treatment in Critical Limb Ischemia

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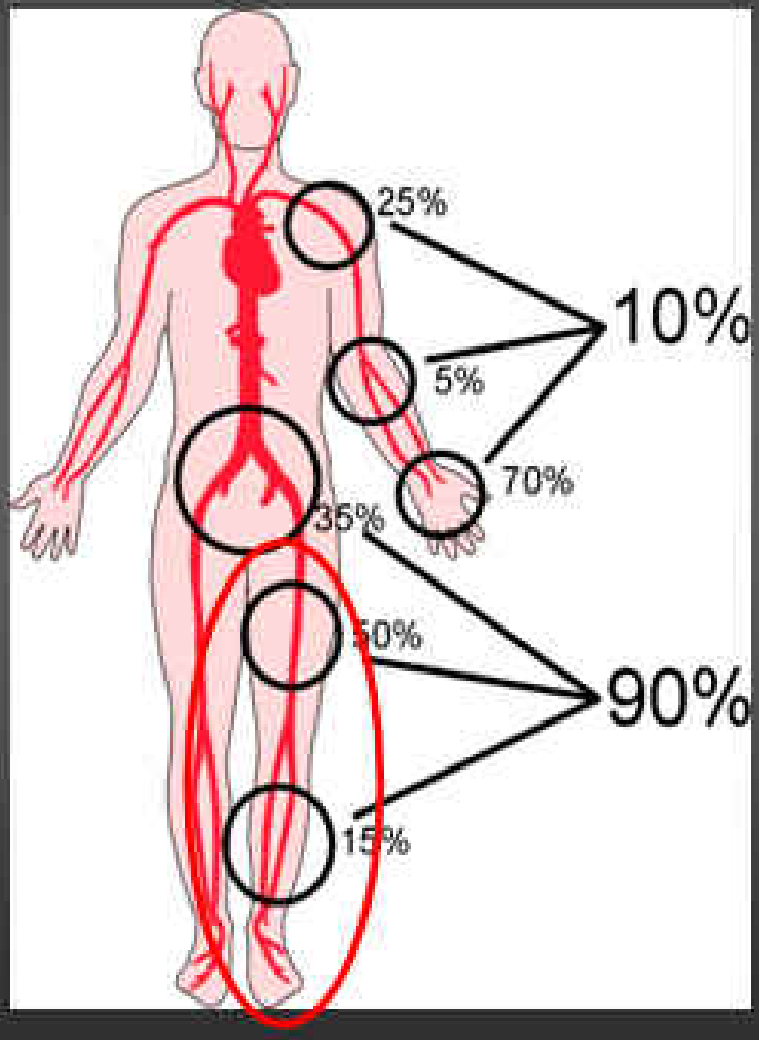
Distribution of Lesions in CLI



Critical Limb Ischemia

Definition:

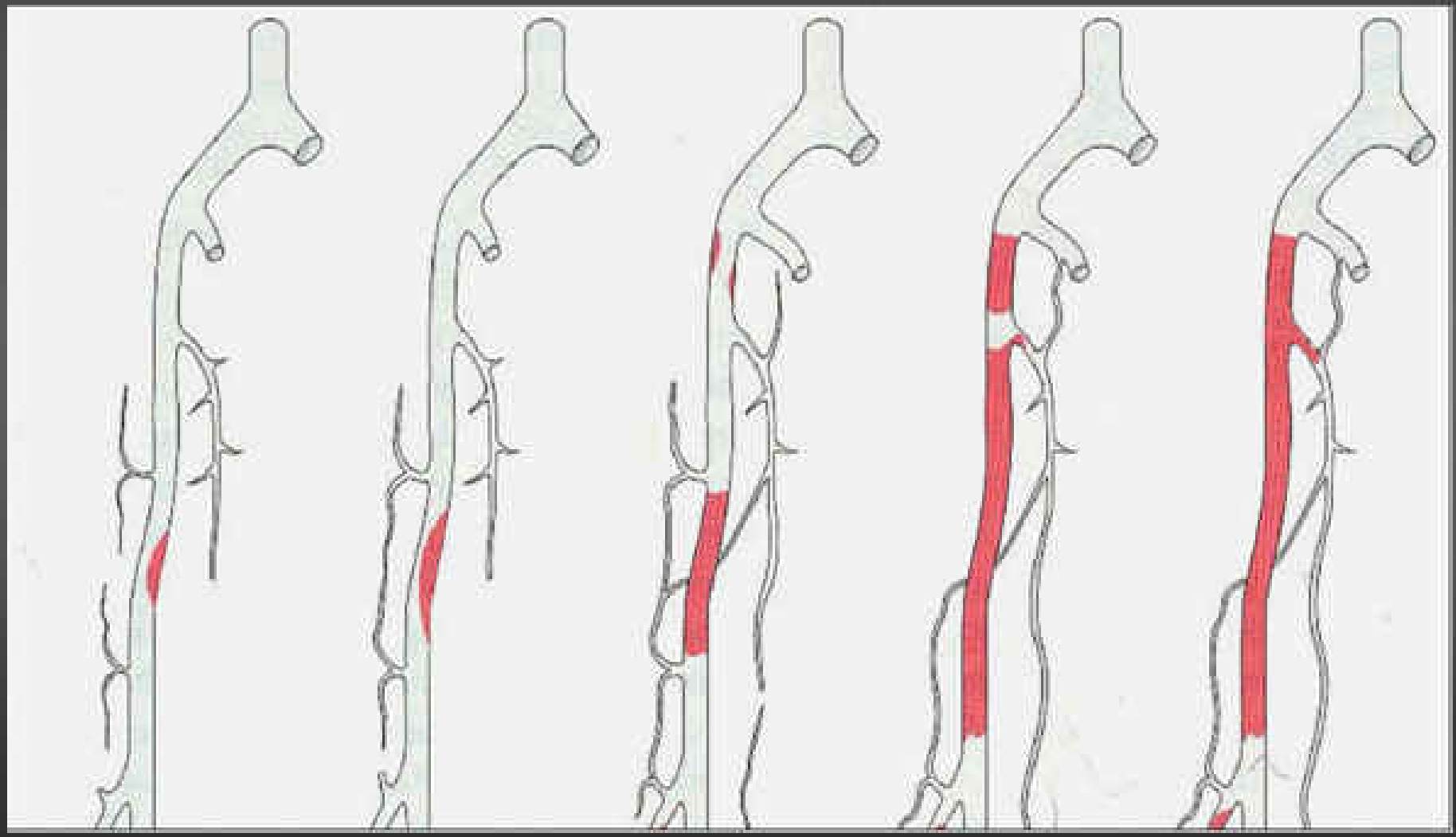
- Critical reduction of the arterial perfusion
- Arterial pressure
  < 50 mmHg (ankle)
  < 30 mmHg (toe)

Rutherford Category

4 Ischaemic rest pain

5 Ulcera and gangrene

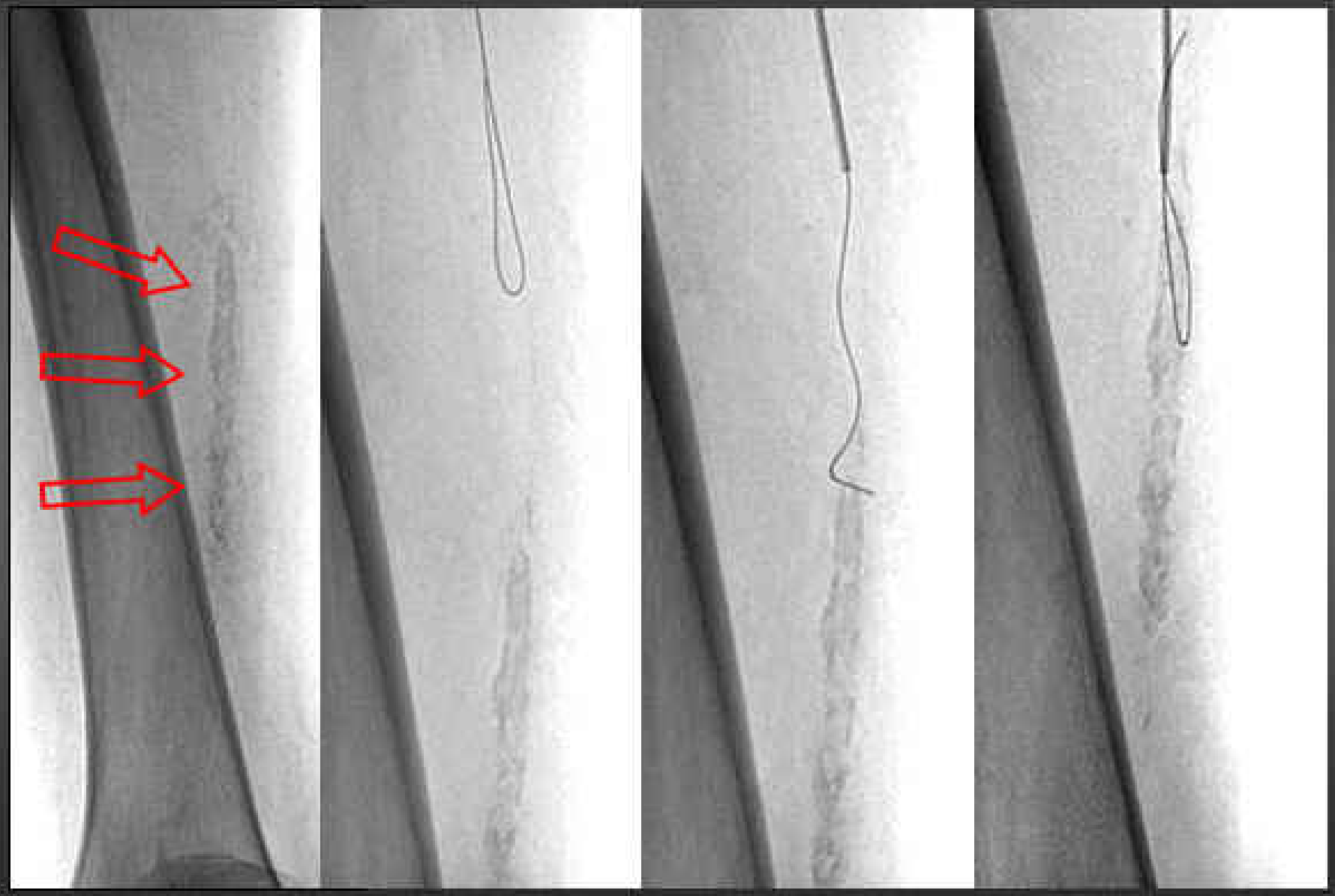
The SFA-CTO



Initial Passage of the Occlusion

Subintimal vs. Intraluminal?

Subintimal Recanalization



Subintimal Angioplasty

10-15% failures due to inability to re-enter the true lumen .

Major potential problem :

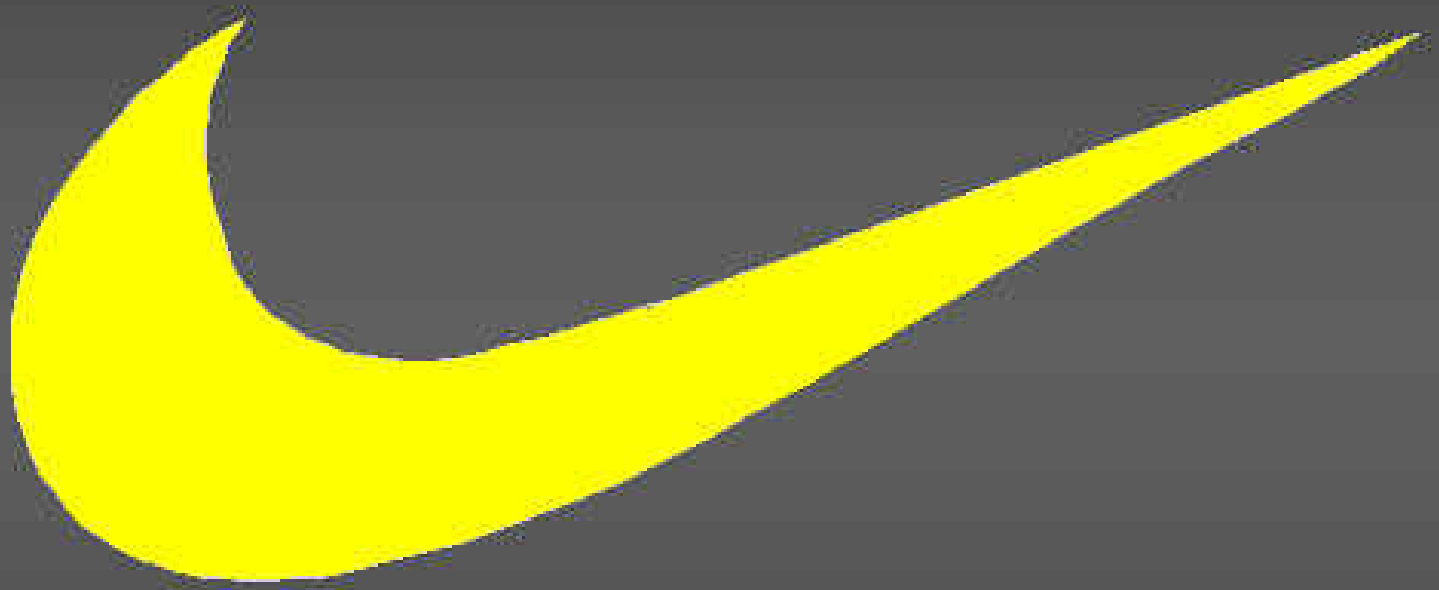
Distal extension of the dissection with involvement of the first popliteal segment or below.

Re-Entry-Devices

Crossing Success

> 95%

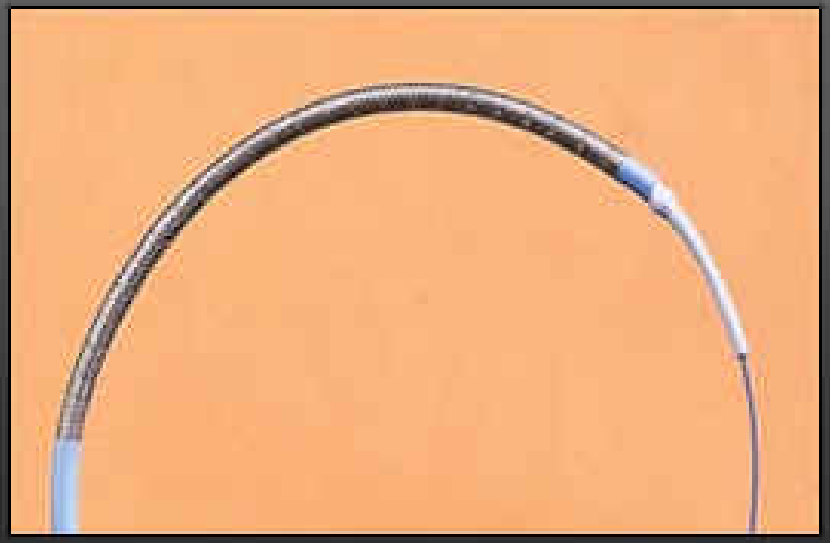
After Crossing ... What`s next?

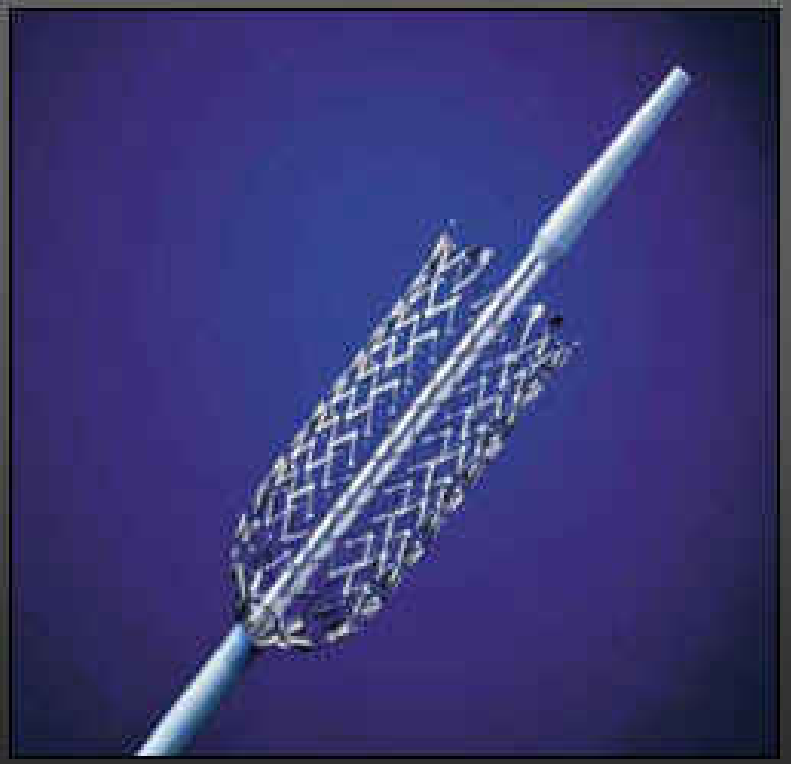


Just stent it.

Nitinol Stents

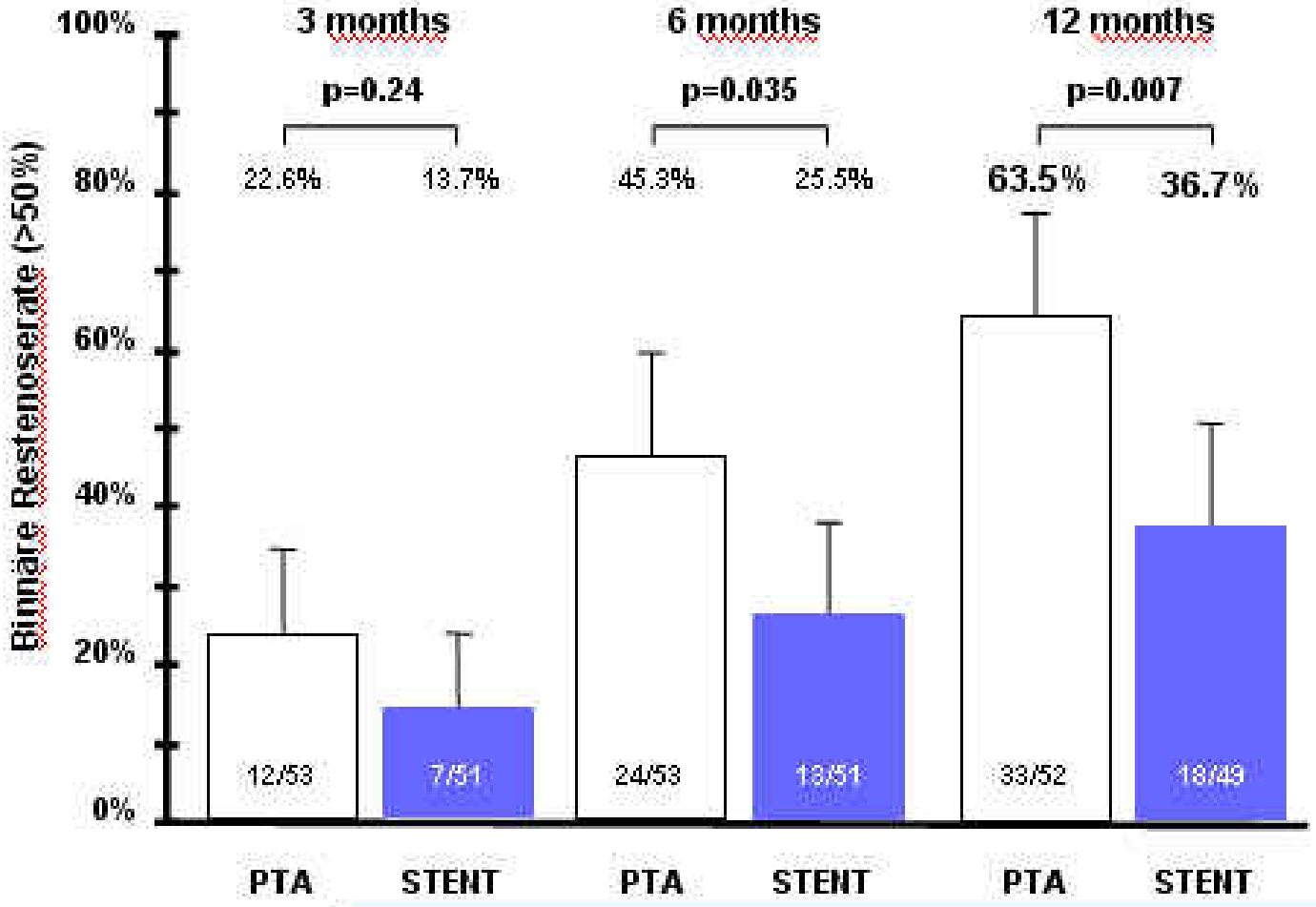
- Nickel-Titanium Alloy:
  - High flexibility
  - No deformation due to external compression
  - No foreshortening
  - Precise placement





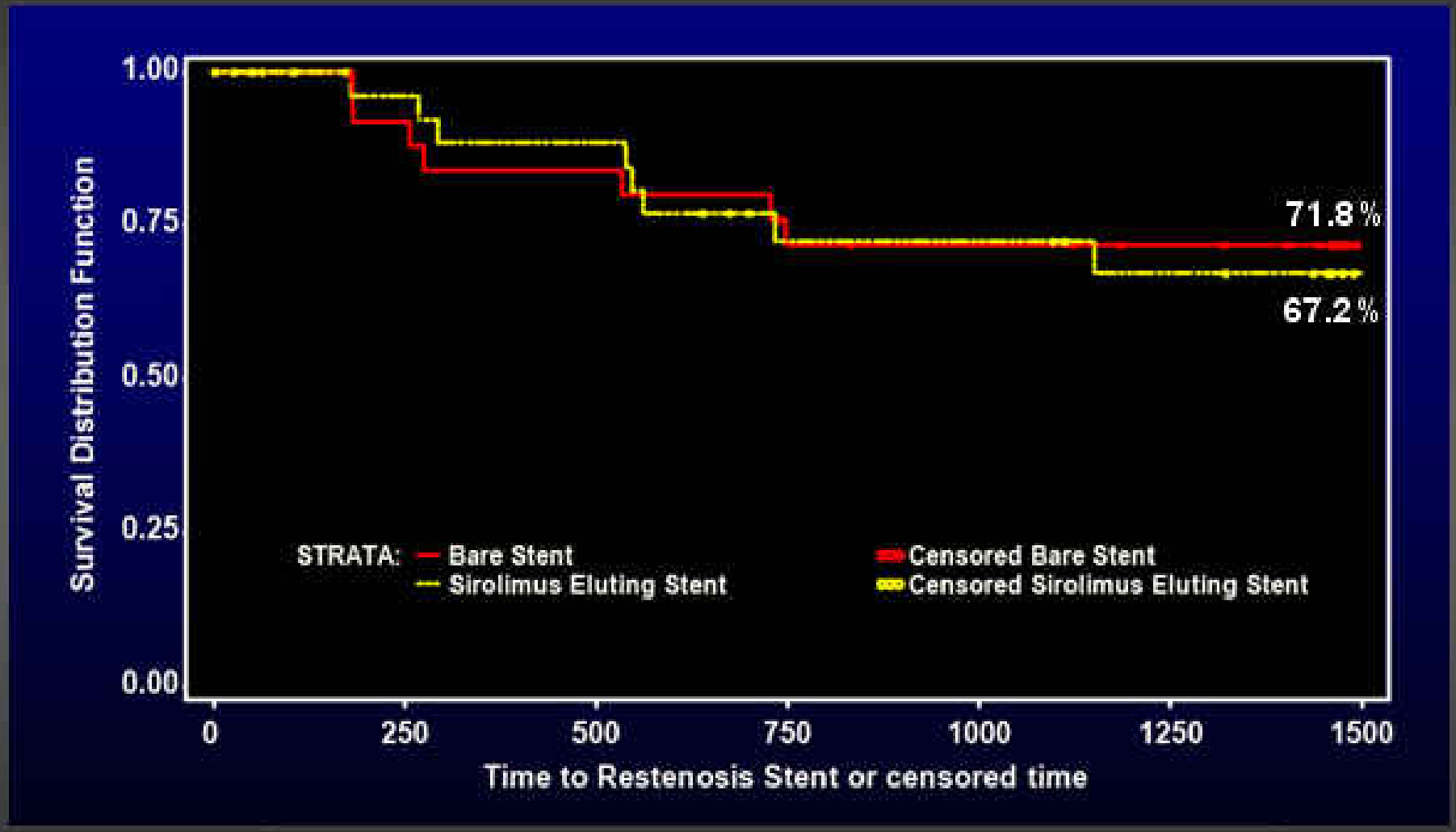
Nitinol-Stent vs. Balloon-Angioplasty

Mean lesion-length 9 – 10 cm (TASC B-D)



Schillinger M et al. N Engl J Med 2006;354:1879-88

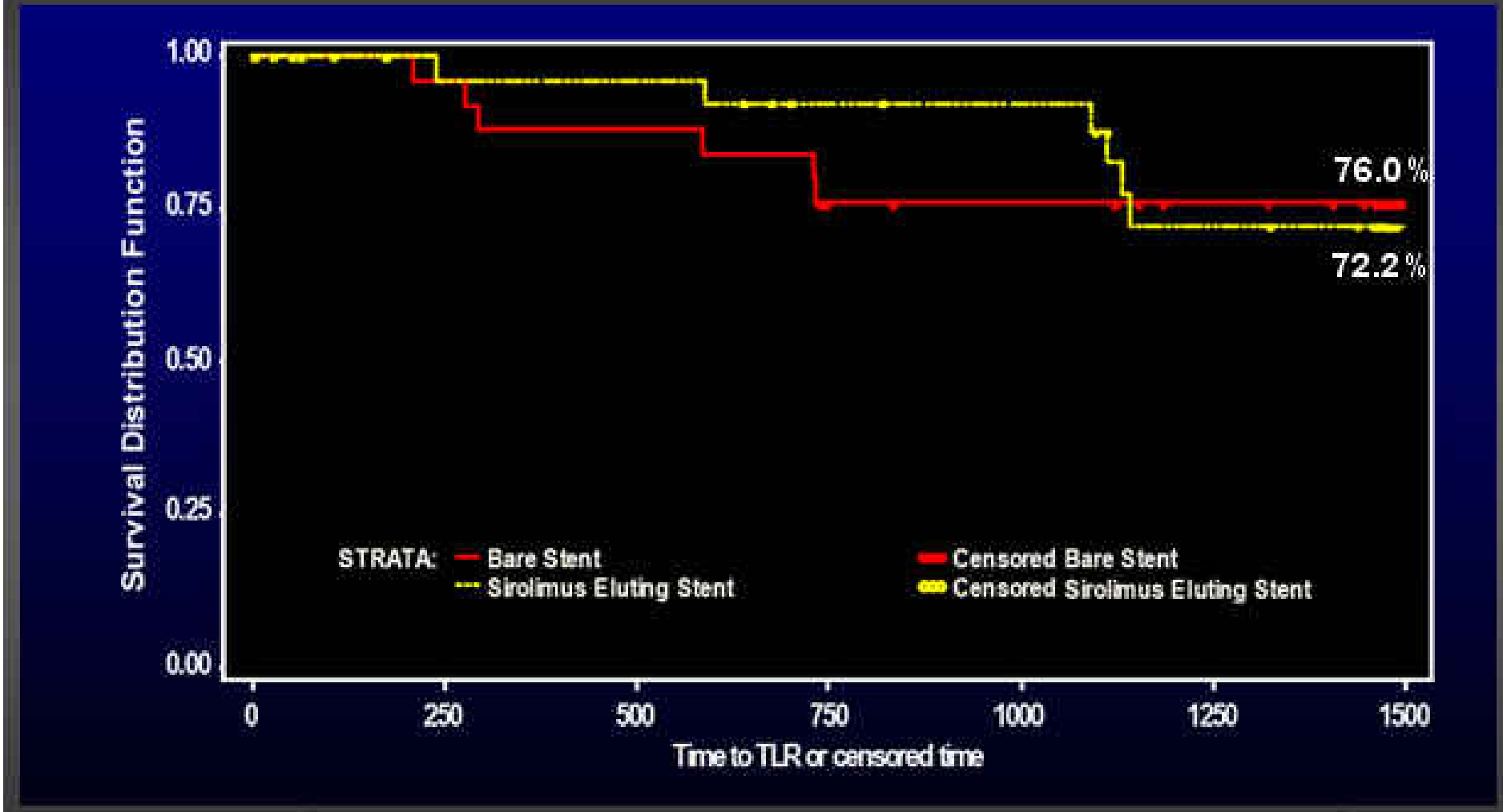
SIROCCO II:
Freedom from Restenosis to 1500 Days



	0	360	720	1080	1440	1500
Sirolimus-Eluting Stent	29	25	22	16	13	11
Bare-metal Stent	28	25	20	16	14	12

Preliminary data

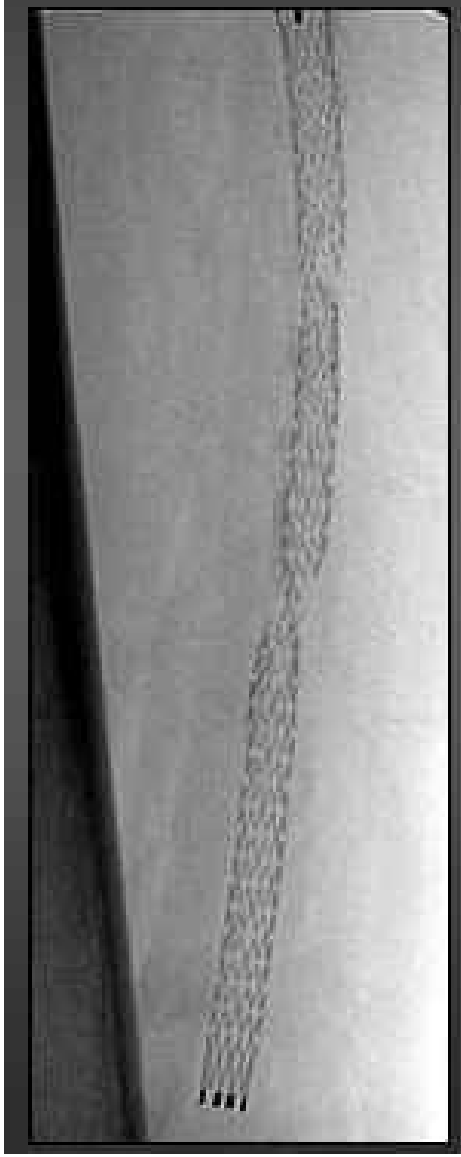
SIROCCO II: Freedom from Reintervention (TLR) to 1500 Days



	0	360	720	1080	1440	1500
Sirolimus-Eluting Stent	29	26	25	20	14	12
Bare-metal Stent	28	25	22	16	13	11

Preliminary data

Risk Factors for Stent-Fractures



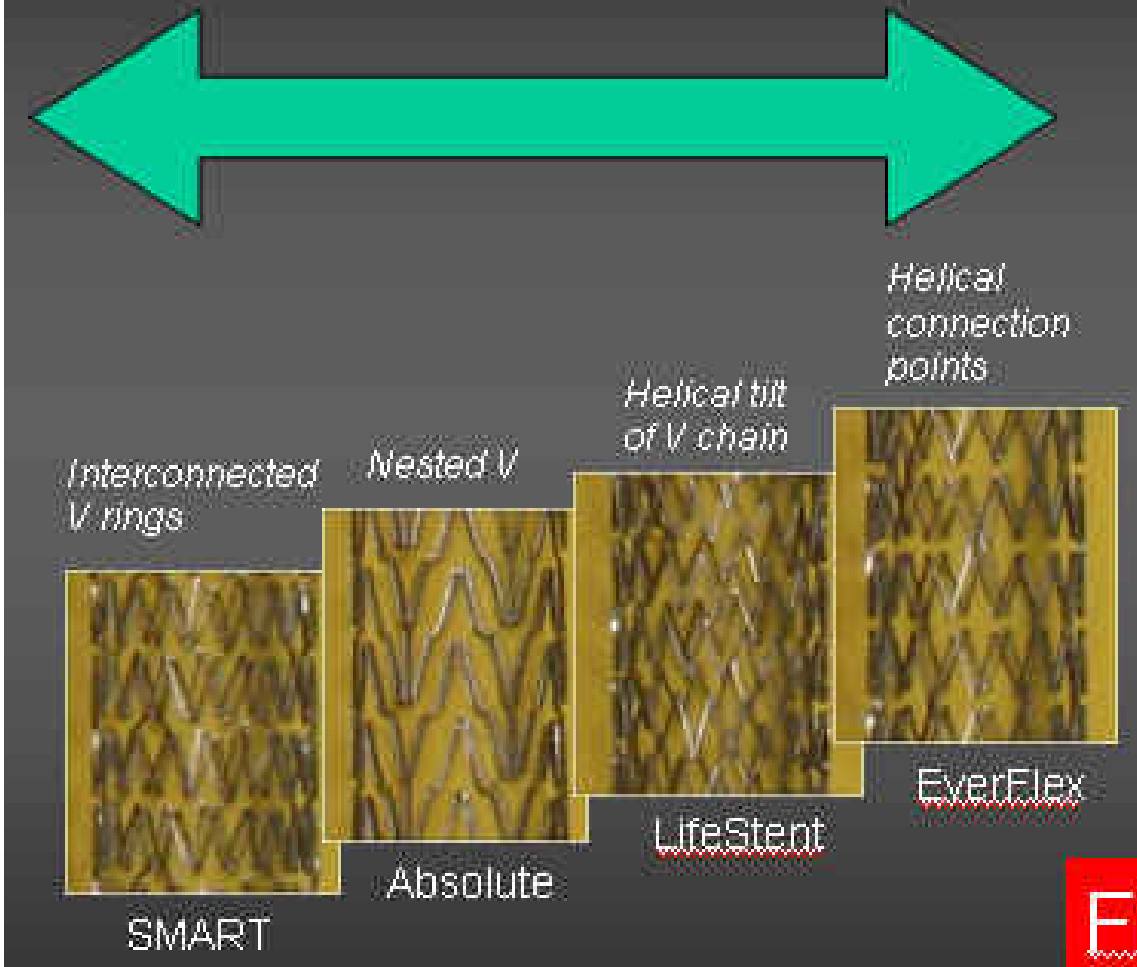
- Multivariante Analysis

	RR	p	95% KI
Stent length >160mm	5.559	<0.001	3.166 – 9.763
Severe Calcification	3.941	<0.001	2.261 – 6.868

Location of the stent was no predictor !

Scheinert D, Sax J et al. TCT 2007

The Evolution of Slotted-Tube SFA-Stent Design



Enhanced Flexibility by

- Reduction of cell interconnections
- Spiral orientation of interconnections

Fracture rate ~ 2-6%

1st Generation

2nd Generation

Nitinol Stent Results in Long SFA-Lesions

Parameter	DURABILITY I	SCHILLINGER	RESILIENT	SIROCCO
Mean Lesion Length (mm)	96.4	101	62	83
Max. Stent Length (cm)	15	10	8	8
Mean Stents/Patient	1.1	1.7	1.6	1.8
Diabetics (%)	46	38	38	35
Rutherford 3 (%)	55	87	57	43
Rutherford 4 (%)	8	3	0	
Rutherford 5 (%)	4	10	0	0
0 to 1 Runoff Vessels (%)	27	14	NA	NA
Total Occlusions (%)	40	37	17	57
1-yr Primary Patency	72%	63%	80%	91% (9 mo)
1-yr TLR-Free	79%	72% (TVR)	87%	NA

How does the next generation SFA stent look like?

Maybe even more flexible ??

Next Generation SFA-Stents:

NovoStent's Alternating Helix

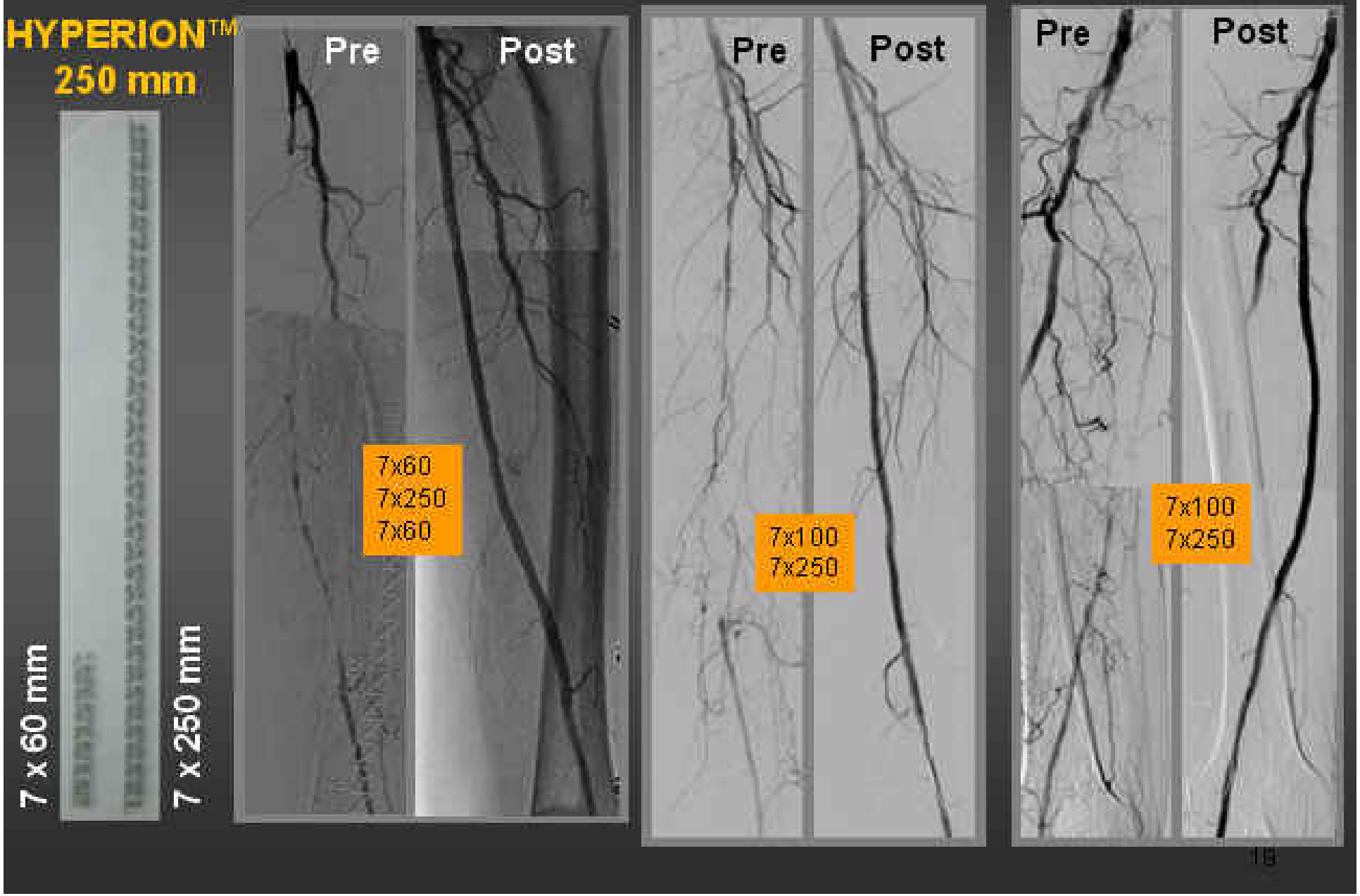
7 mm Free State

6 mm Treatment

5 mm Treatment

- Self-expanding nitinol
- Closed cell pattern
  - *strength from helix*
- Flexible, durable design
  - *no axial connectors (no clinical fractures)*
- Variable metal area
- 60 - 75 microns strut thickness
  - *thinner than coronary technology*
- Simple pullback delivery
  - *segmented unwrapping*

World's Longest Peripheral Stent

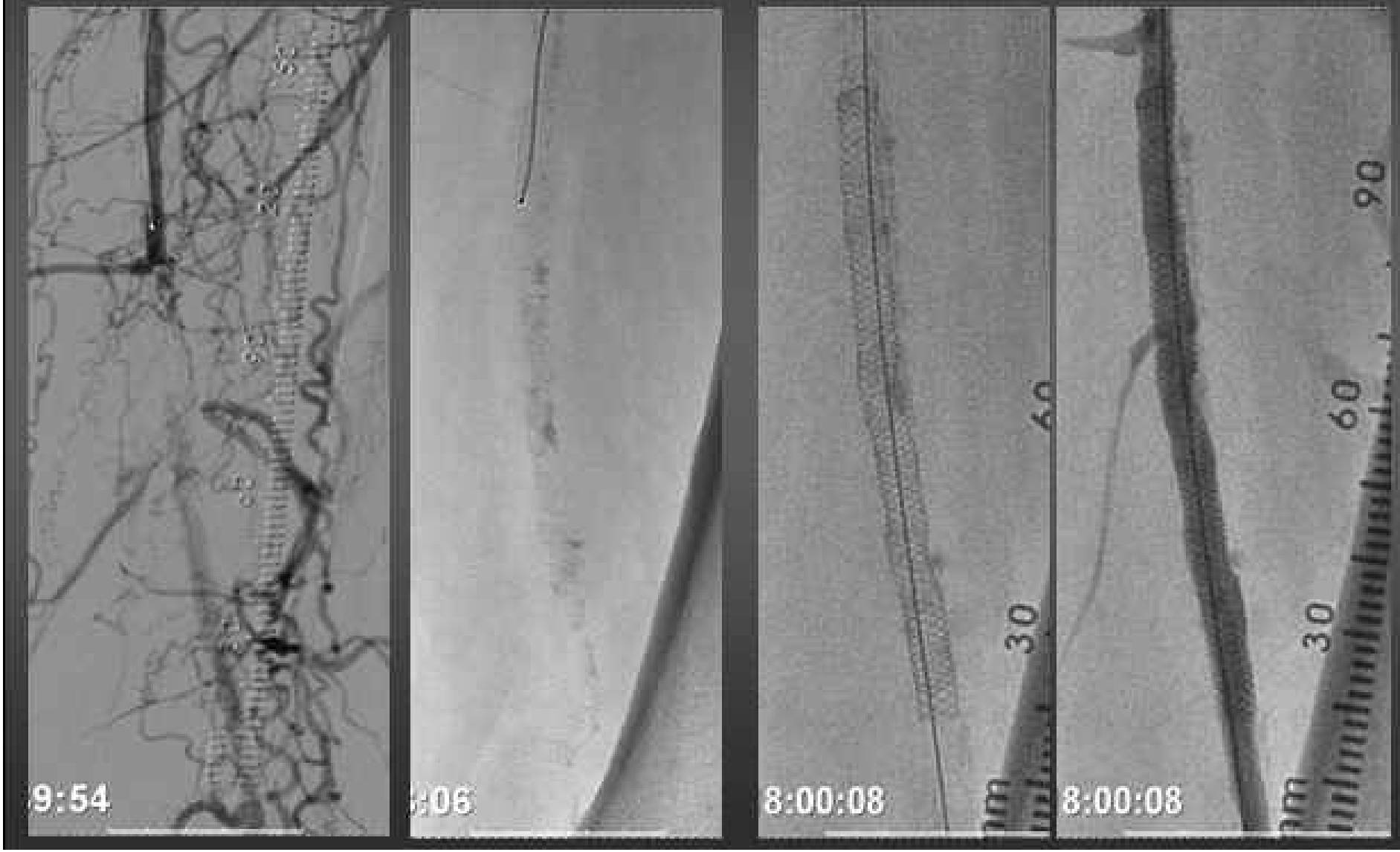


How does the next generation SFA stent look like?

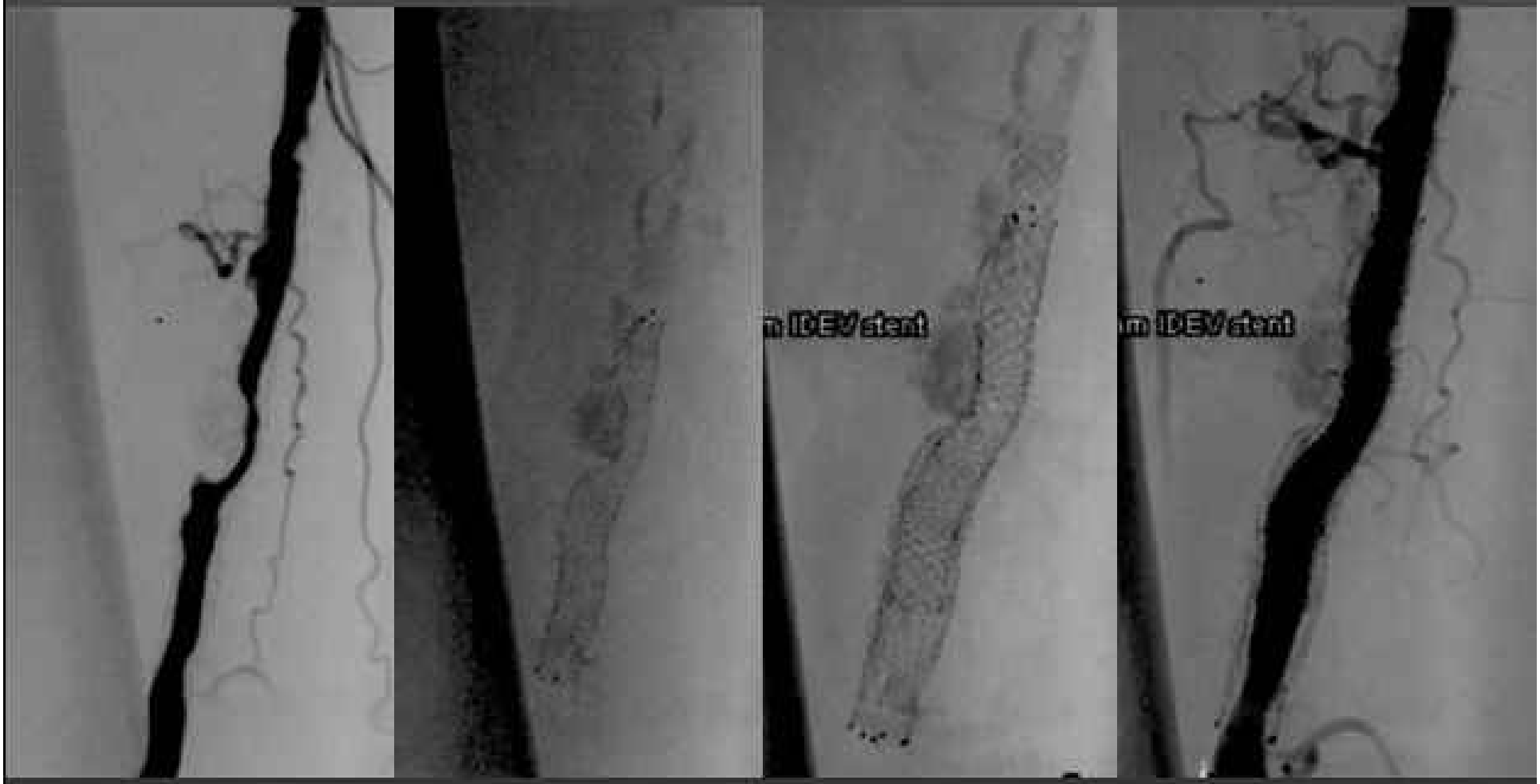
Maybe stronger and still flexible ??

SUPERA Stent (IDEV Techn.)

Interwoven self-expanding nitinol stent design



SUPERA Stent for Stent-Recoil



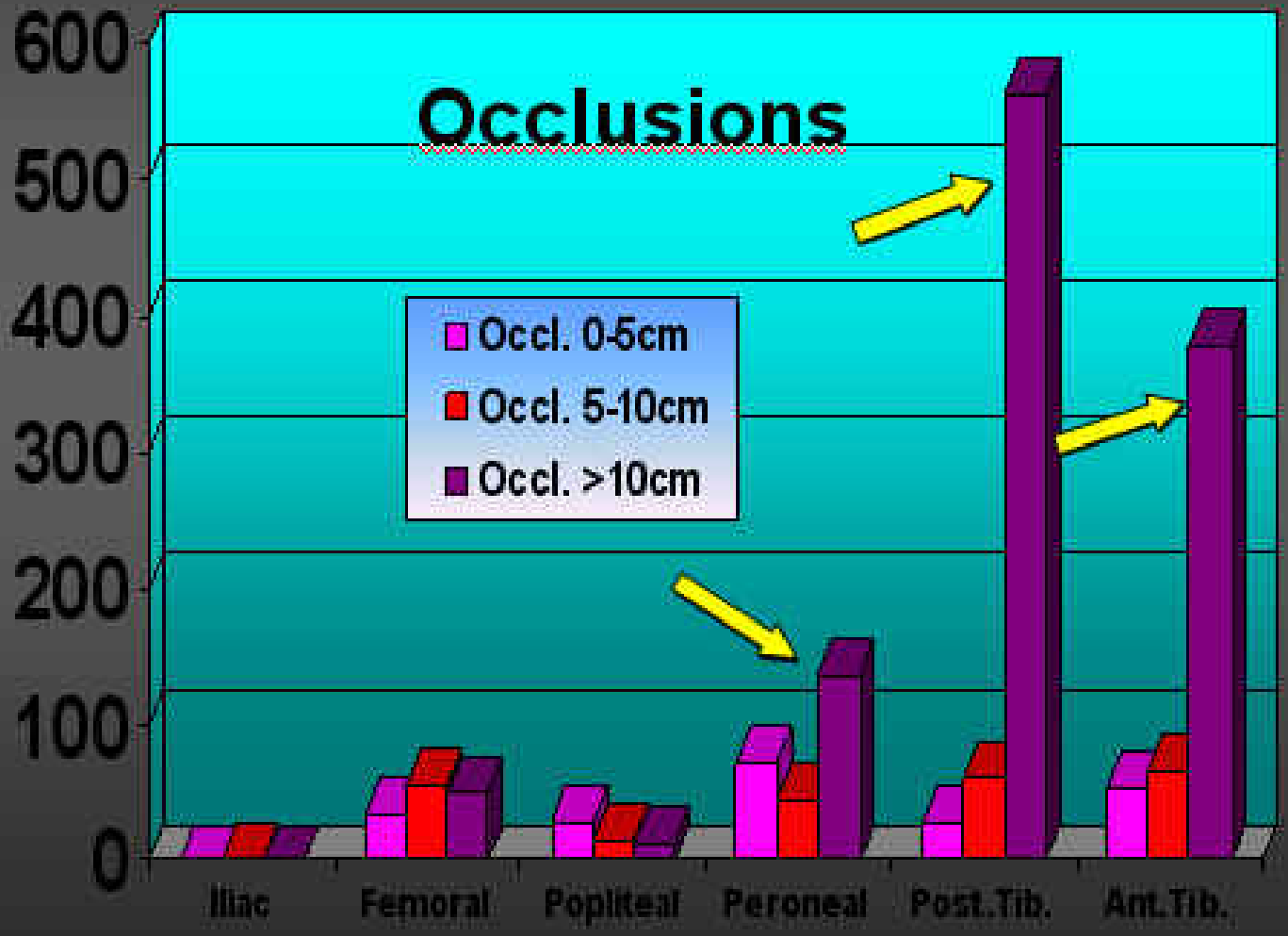
Courtesy of Dr. David Cohen, Valley Hospital

Characteristics of Patients with Infrapopliteal Obstructions

- Severe symptoms
  - Often critical ischemia
- Diabetes mellitus in up to 80%
- Older patients
- Significantly more concomitant diseases (Cardiac, cerebrovascular, renal, pulmonar)

TYPE AND DISTRIBUTION OF 2,893 LESIONS in 417 Consecutive Diabetic with Ischaemic Foot Ulcer:

(Graziani et al. unpublished data)



Equipment for PTA of Extensive Infrapopliteal Lesions

- Hydrophilic 0.018“ or 0.014“ guidewire
  - V18 Control-wire (Boston Scientific)
  - PT2, PT Choice, PT Graphix (Boston Scientific)
- Low-profile balloons
  - Diameter 2.0 – 3.5 mm
  - Length 80 – 210 mm
    - OTW 0.018“ eg. Savvy (Cordis)
    - OTW 0.014“ eg. Amphirion (Invatec)
    - RX 0.014“ eg. Sleek (Cordis)

Diabetes Patient with Foot Ulcers

PTA of diffuse infrapopliteal lesions

- Patients 56
- Diabetes mellitus 82 %
- Clinical vascular status
  - Rutherford Class IV 15 (27 %)
  - Rutherford Class V 43 (73 %)
- Average lesion length **18.5 cm** (5 – 30 mm)
- Occlusion 45 (80 %)

- Successfully recanalized limbs 50 / 56 **(89 %)**
- Successfully recanalized arteries 54 / 71 **(76 %)**

Clinical and angiographical follow-up after PTA of diffuse BTK-lesions

Follow-up in (n)	29
– Mean follow-up (months)	3.4 ± 1.6

Clinical follow-up:

Improvement	21 (72.4 %)
Unchanged	7 (24.1 %)
Worsened	1 (3.4 %)

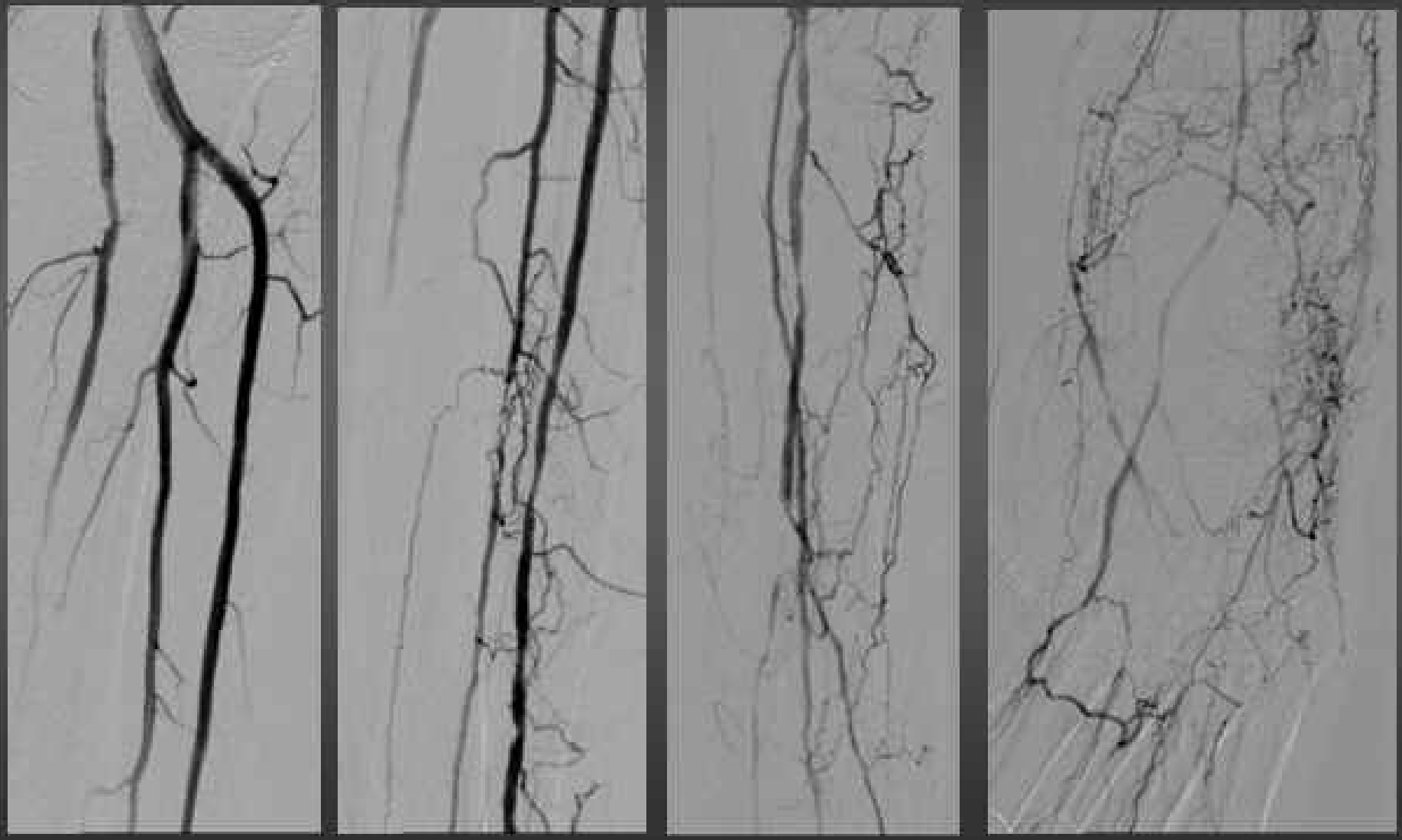
• Bypass-surgery	0
• Minor amputation	5 (17 %)
• Major amputation	0

Schmidt et al. LINC 2006

How can we improve the results of BTK angioplasty?

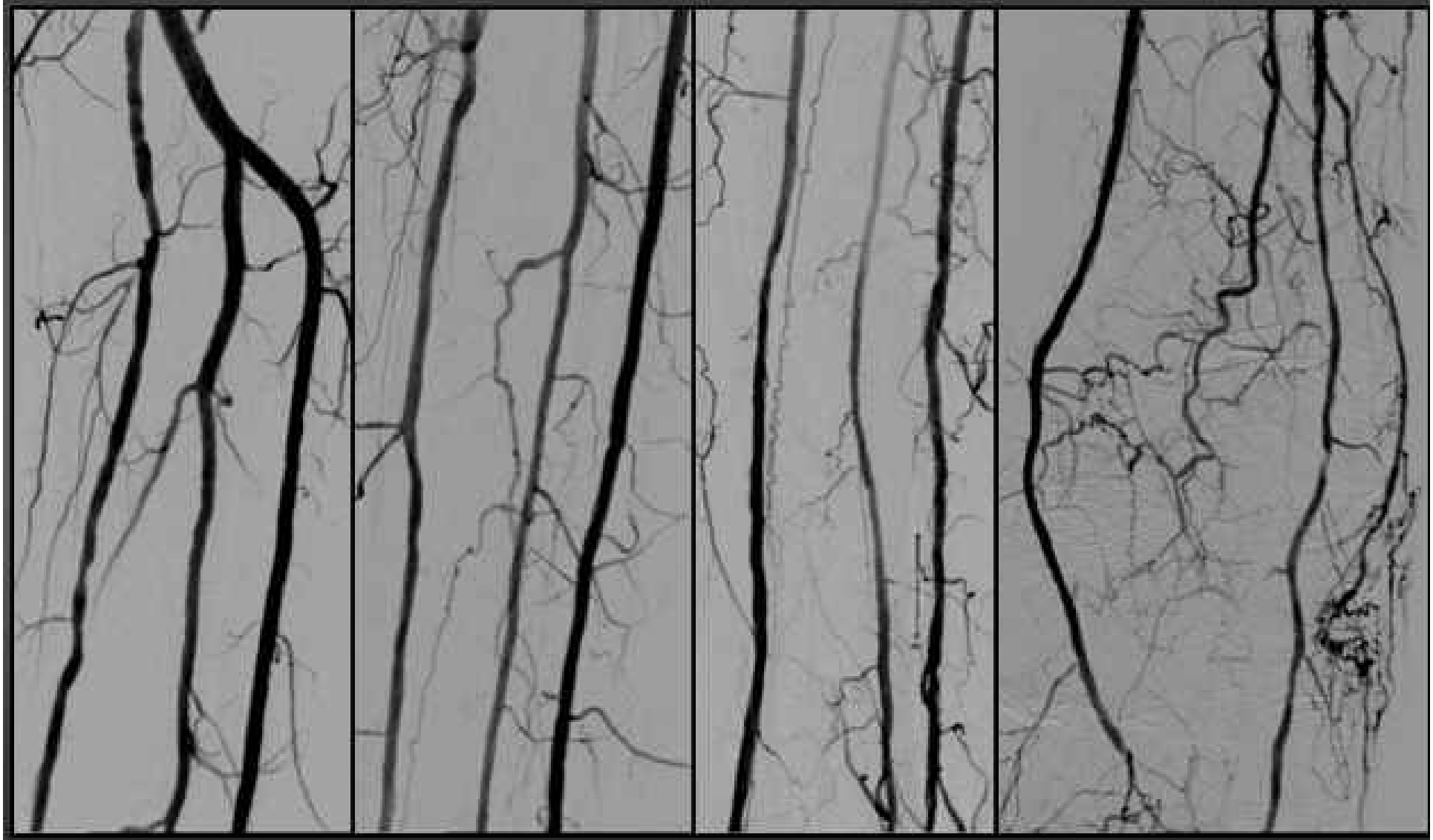
- Revascularization of multiple vessels ?

PTA of extensive BTK-Obstructions



PTA of extensive BTK-Obstructions

PTA of extensive BTK-Obstructions

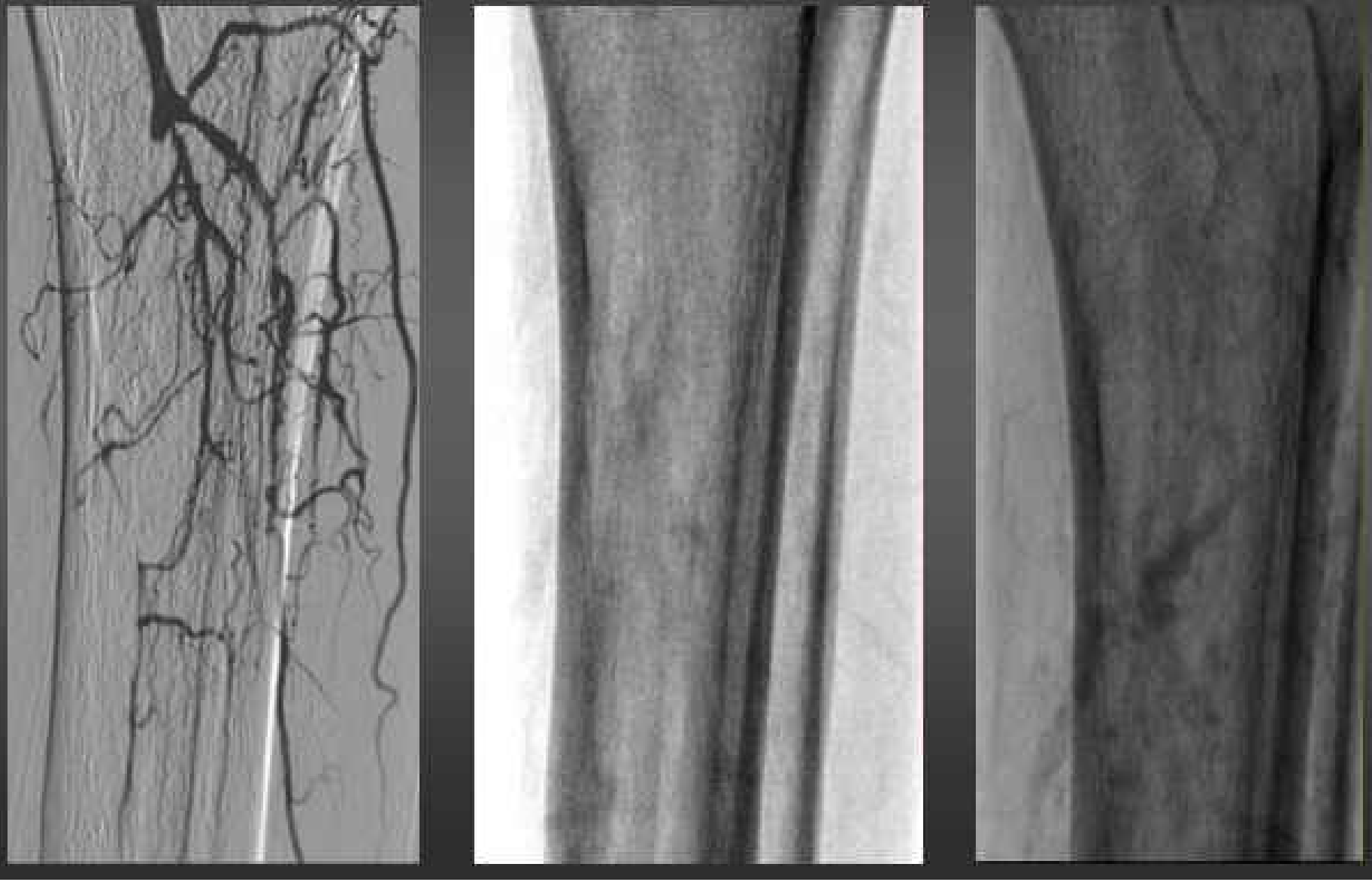


PTA of extensive BTK-Obstructions

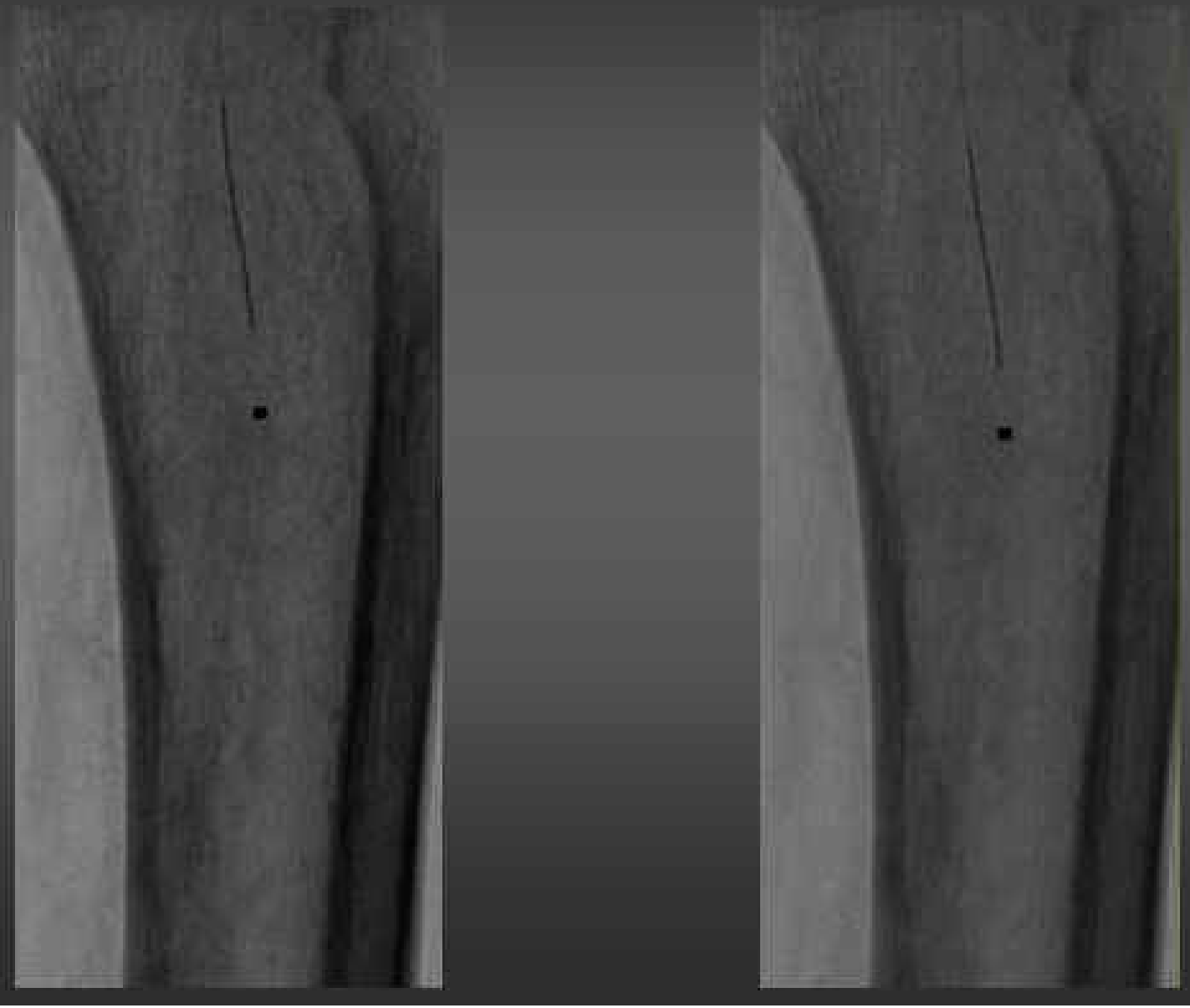
How can we improve the results of BTK angioplasty?

- Dedicated CTO-Devices
- Alternative approaches for CTO`s in case of failure to cross:
  - Transpedal
  - Transcollateral

Turbo-Laser below the Knee in CLI



Turbo-Laser below the Knee in CLI

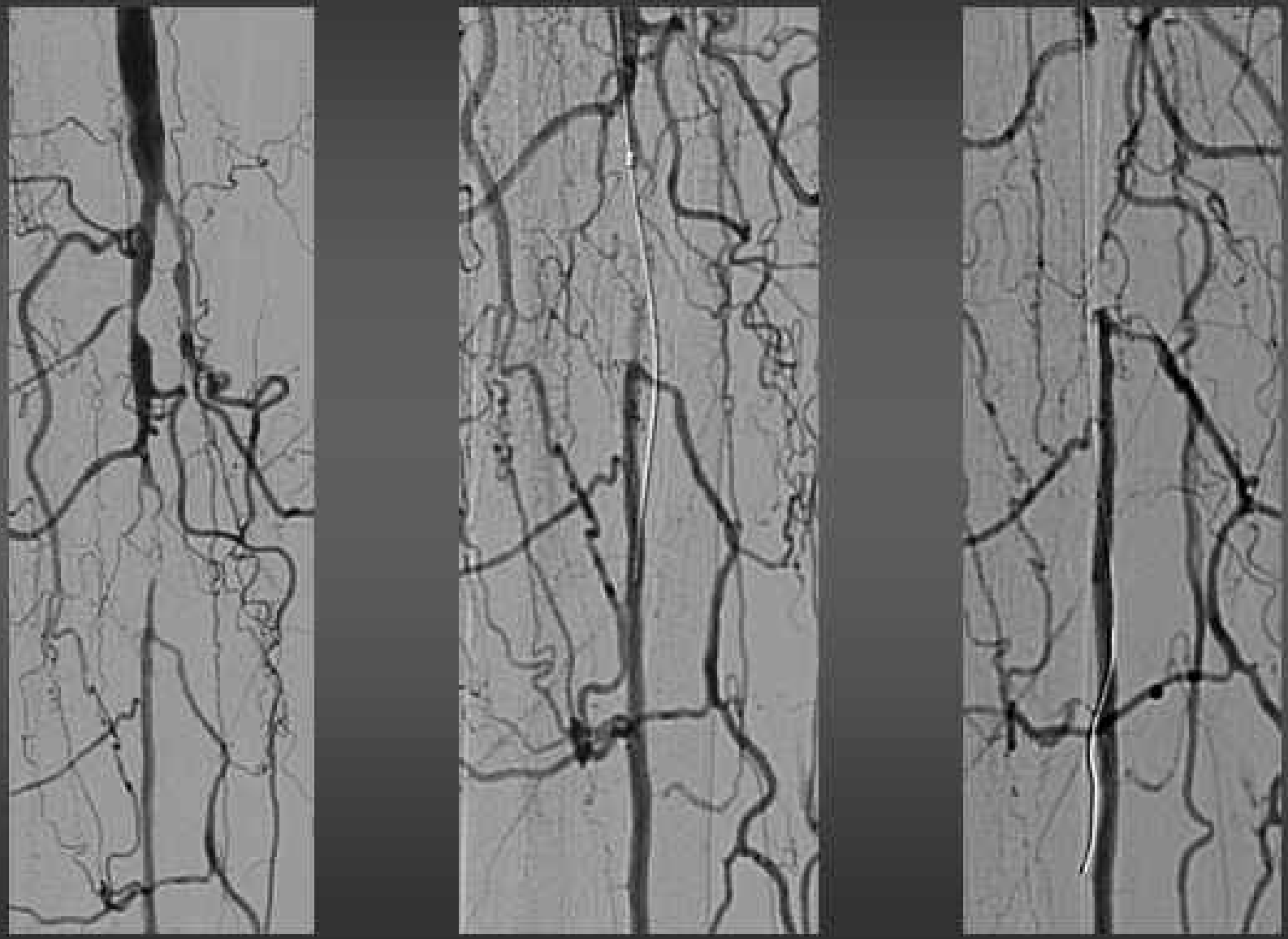


Turbo-Laser below the Knee in CLI

Result after
laser-angioplasty
and low-pressure PTA

Calcified Chronic Occlusion of Tibial Arteries

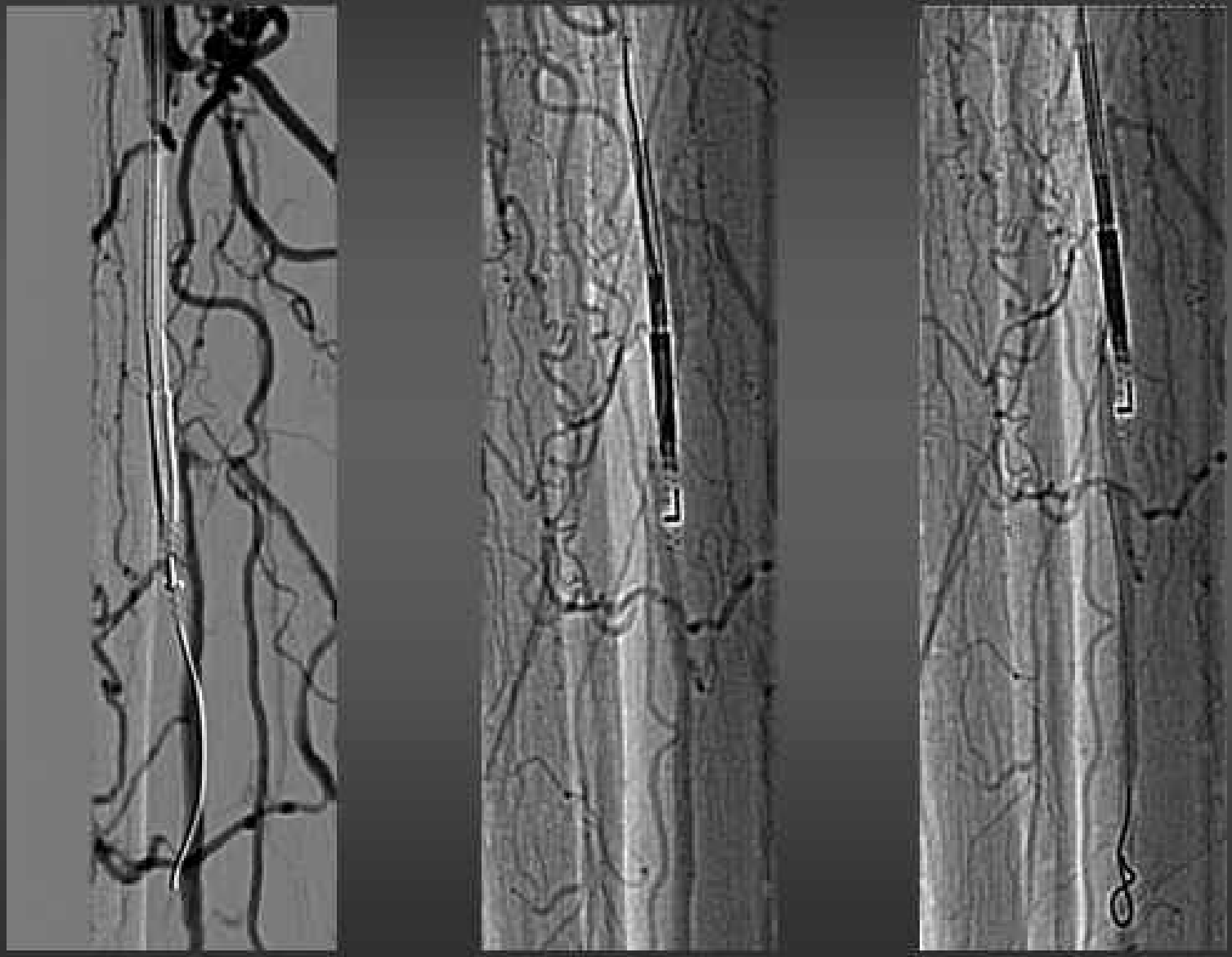
Calcified Chronic Occlusion of Tibial Arteries



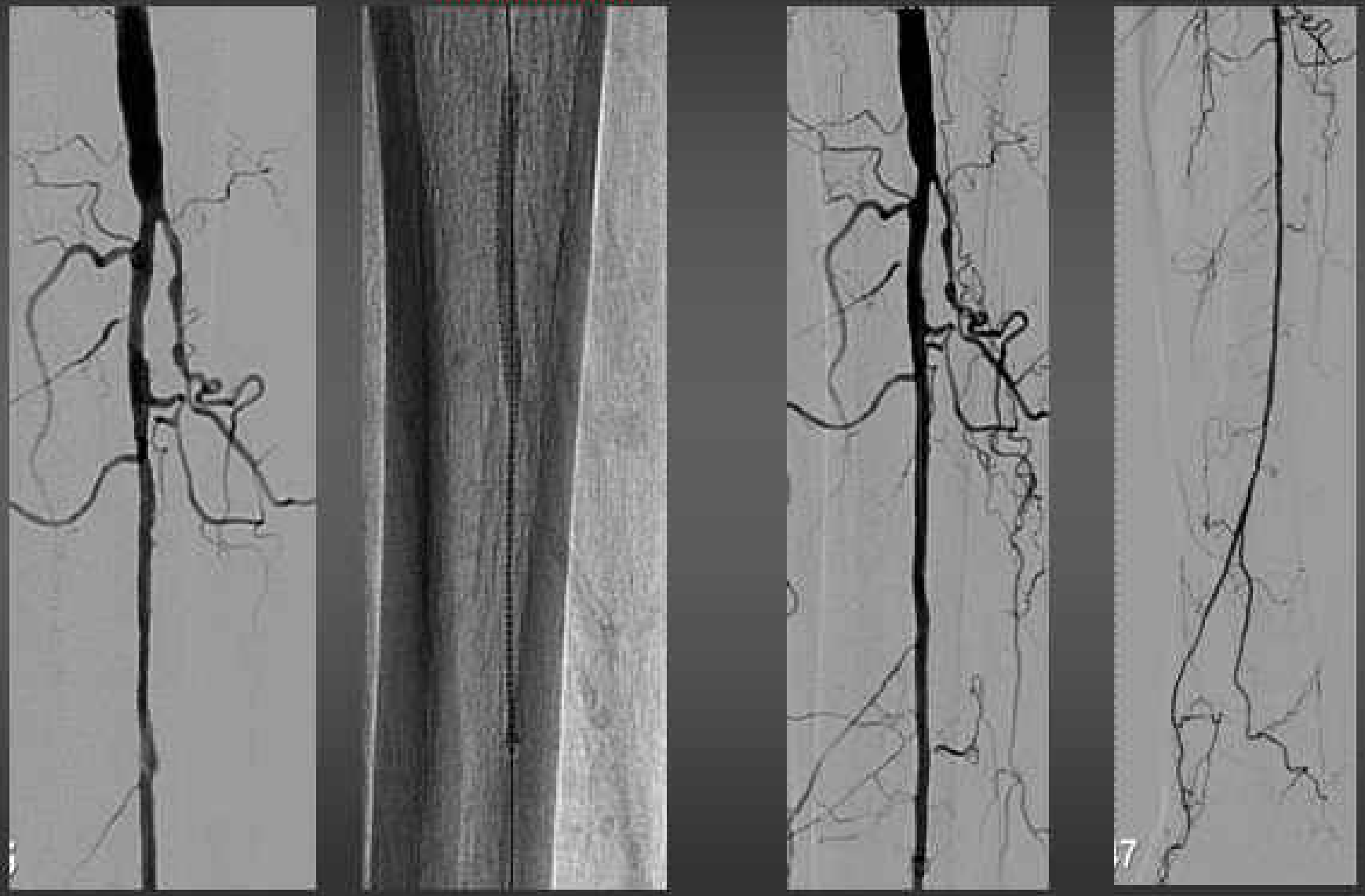
Re-Entry-Devices

Crossing Success in the SFA
>95%

Outback-Revascularization in Tibial Arteries



Outback-Revascularization in Tibial Arteries



Transpedal Recanalization
- Sheathless lechnique -

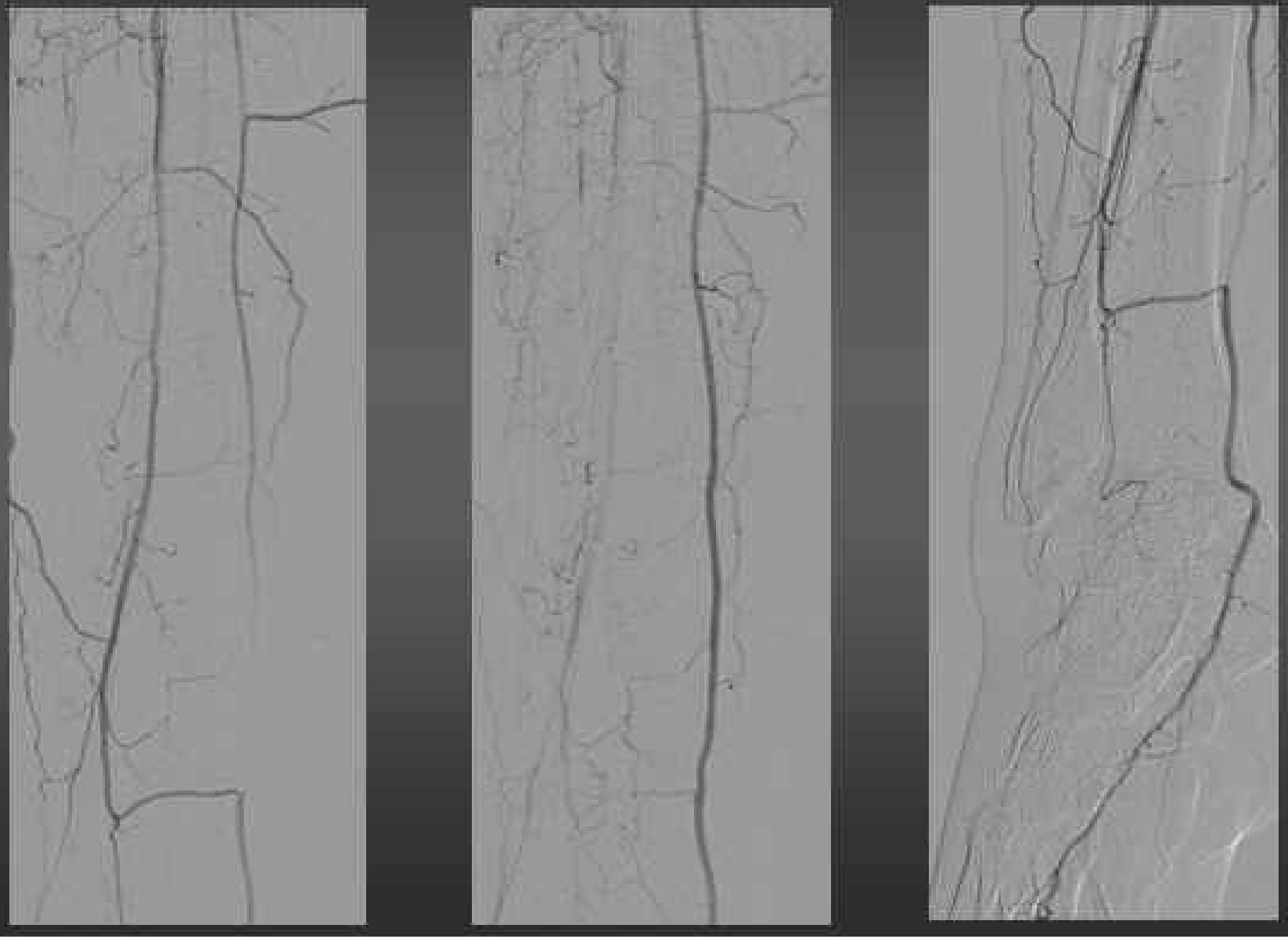
Transpedal Approach for infrapopliteal Angioplasty

- Success-rate in long BTK-oclusions ~ 80%
- 29 patients with infrapopliteal occlusions and failed antegrade intervention
- Retrograde access in all patients possible
- Interventional success in 21 / 29 (72.4 %)

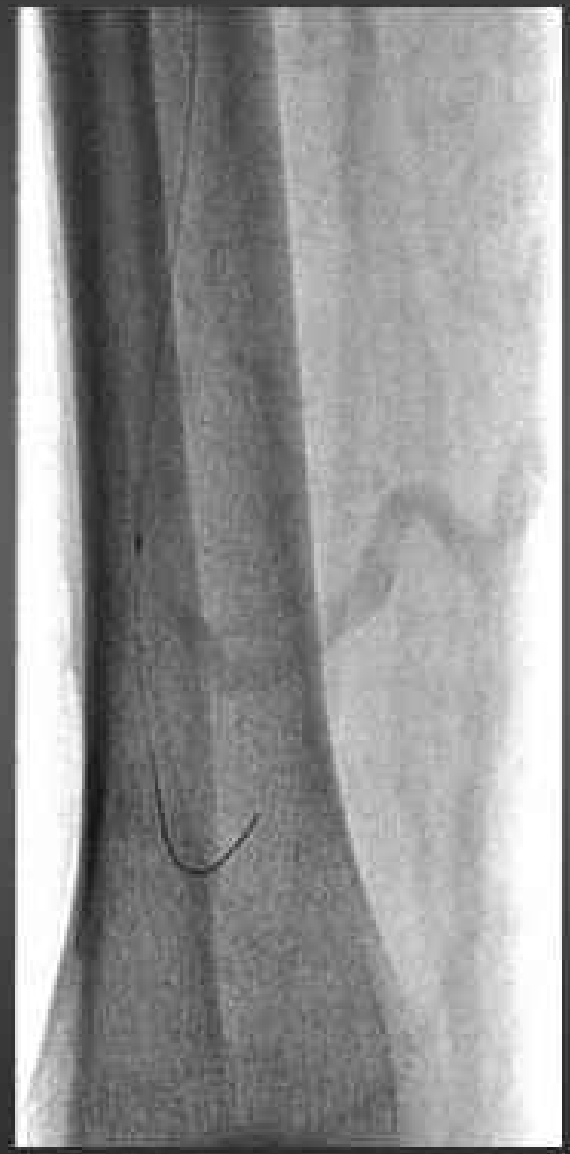
Baker et al. J Endovasc Ther 2008

Retrograde Recanalization BTK

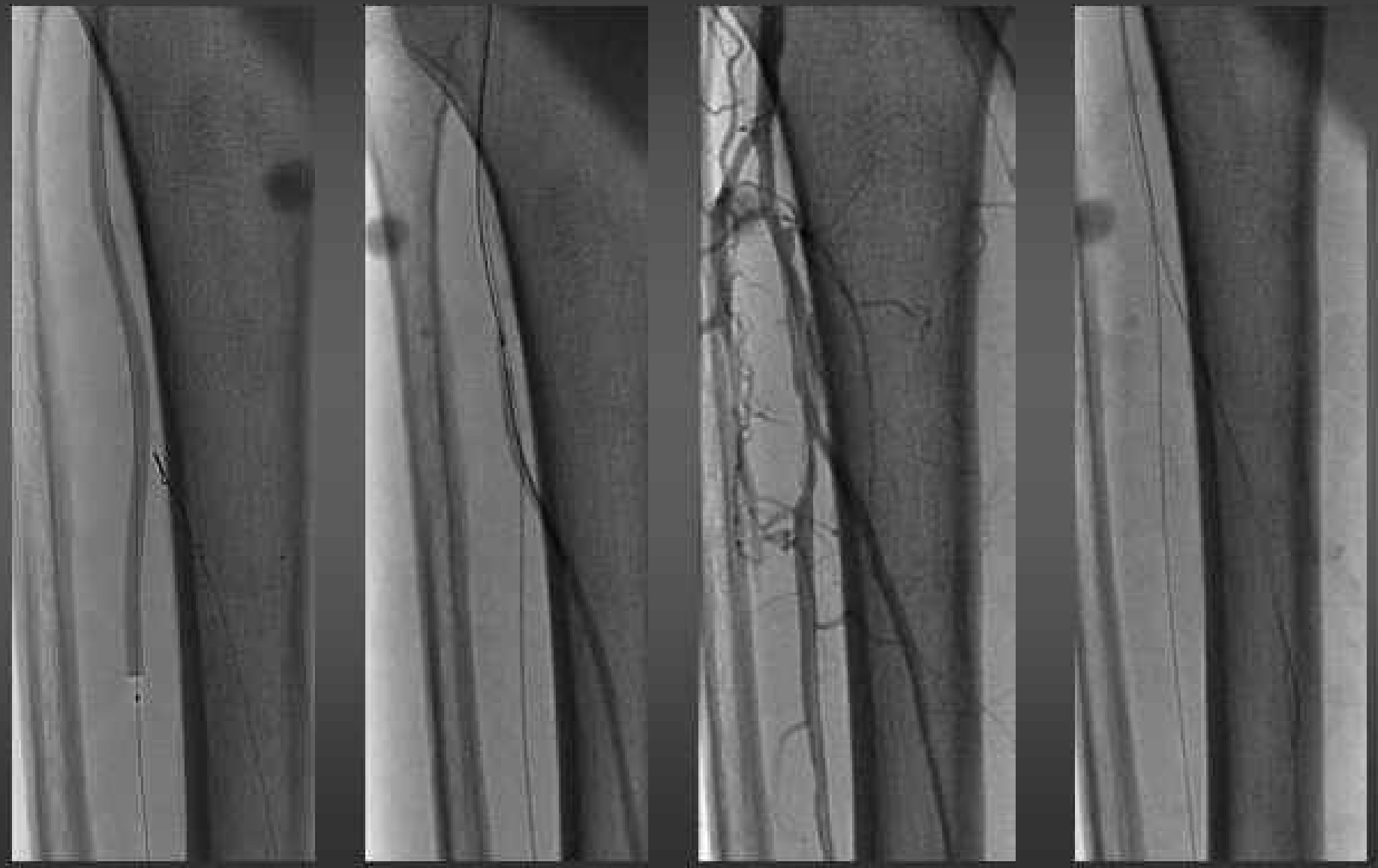
Retrograde Recanalization BTK



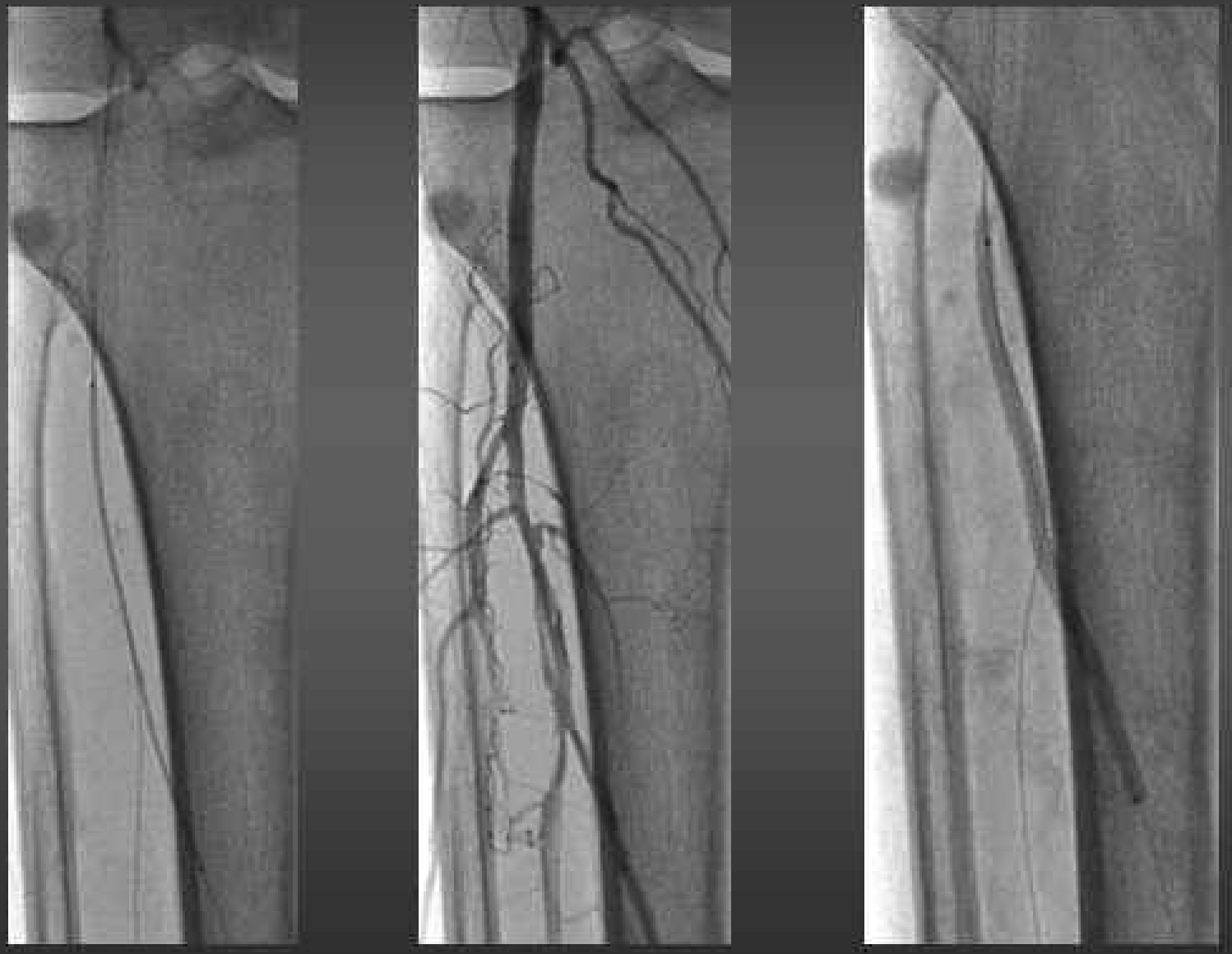
Retrograde Recanalization BTK



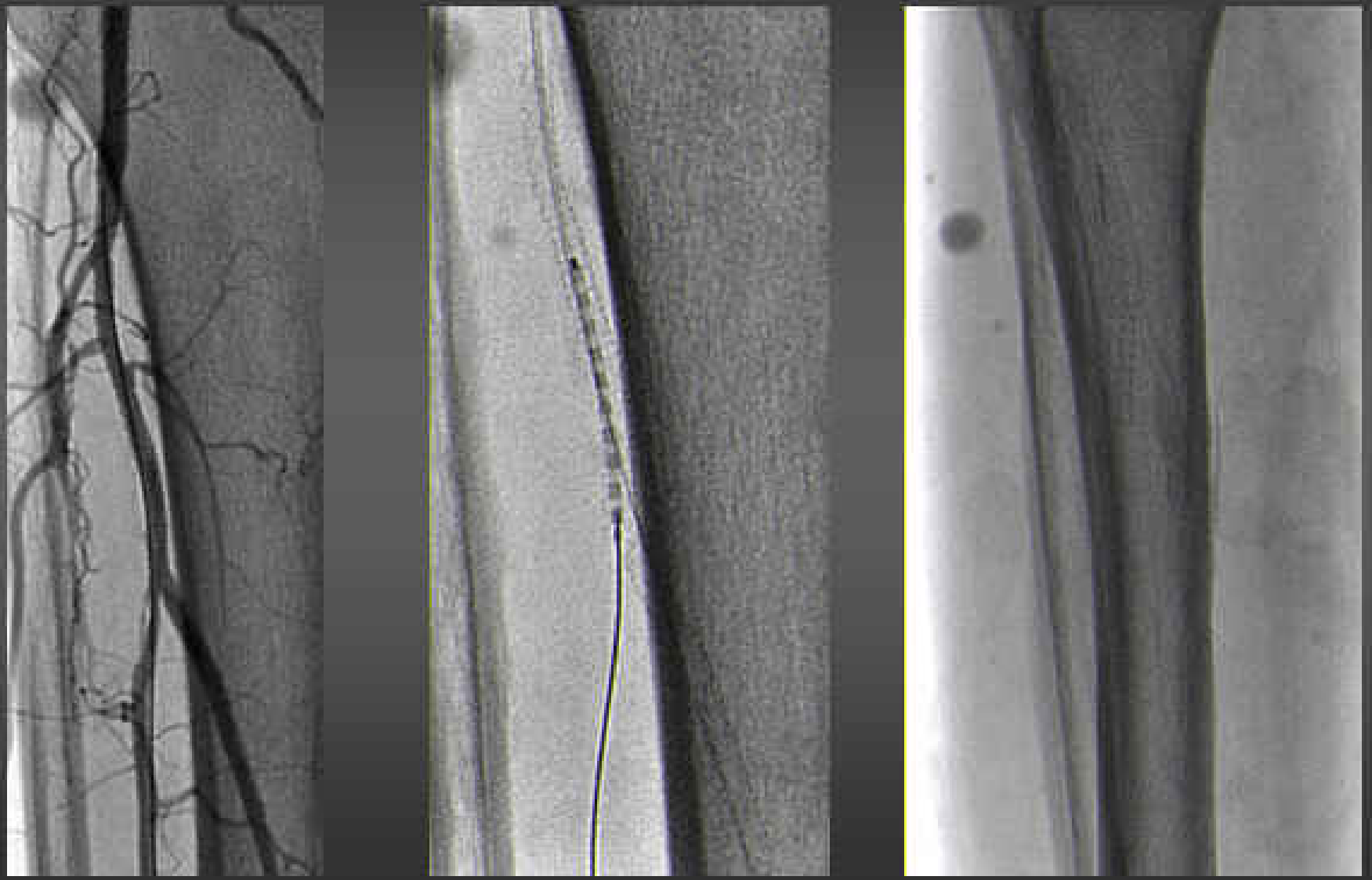
Retrograde Recanalization BTK



Retrograde Recanalization BTK



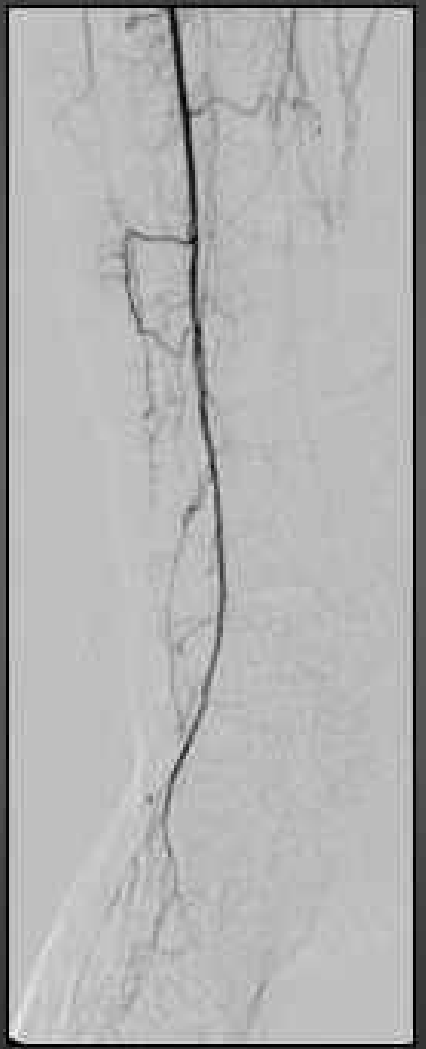
Retrograde Recanalization BTK



How can we improve the results of BTK angioplasty?

- Stents and DES ?

Stents for Revascularisation of Infrapopliteal Arteries



Re-occlusion PTA
2 weeks after PTA

BX-Stent 2.5/33mm

Stent devices for infrapopliteal arteries

There is a need for dedicated stent-devices for infrapopliteal arteries!

- Balloon-expandable stents
  eg. Chromis Deep (Invatec)
  - Stent length up to 8 cm

- Self-expanding stents
  eg. Maris Deep (Invatec),
  Expert (Abbott), Astron Pulsar (Biotronik)
  - Stent length up to 8 cm

PTA vs. Stenting for infrapopliteal Obstructions

	Angioplasty n=74	Stenting n=58	P
Procedural Success	79%	95%	<0.01
Clinical Improvement	74%	90%	<0.05
Clinical Patency 12 Months	53%	84%	<0.01

Angiographic Restenosis Rate 53%

Scheinert D et al. EuroPCR 2003

SES vs. BMS – Pilot Study

Baseline Clinical Data

	Cypher	Control	p
n	30	30	
Mean age	71,4	73,0	NS
Male gender	17 (56,7%)	19 (63,3%)	NS
Diabetes mellitus	25 (83,3%)	23 (76,6%)	NS
Arterial Hypertension	29 (96,6%)	30 (100%)	NS
HLP	19 (63,3%)	20 (66,6%)	NS
Smoker	9 (30,0%)	11 (36,6%)	NS

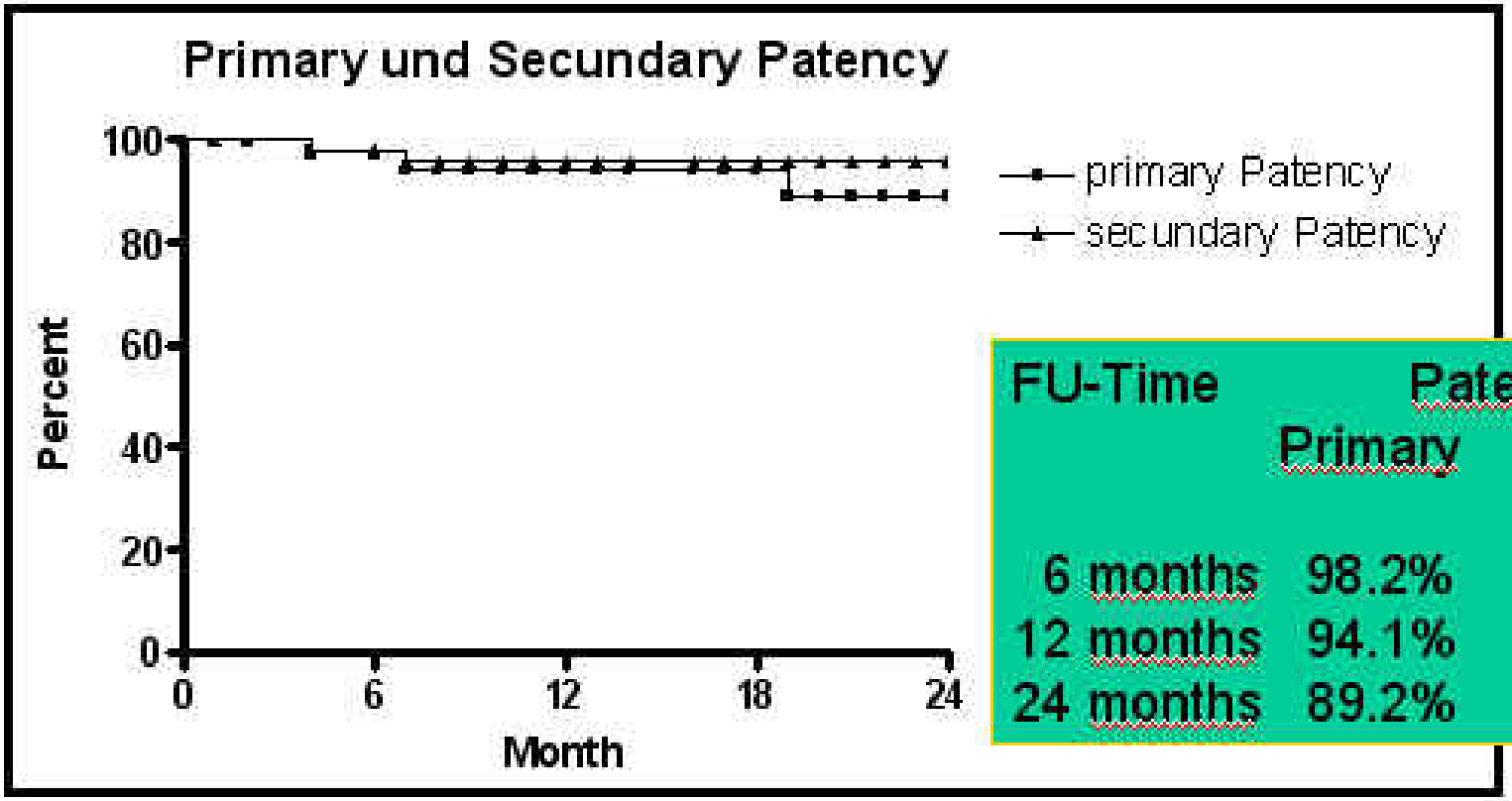
Scheinert D et al. Eurointervention 2006

SES vs. BMS – Pilot Study
Angiographic Follow-up

	Cypher n=24	Control n=23	p
Stent occlusion	0	4 (17,4%)	0,032
Restenosis >50%	0	9 (39,1%)	0,0007
Mean Degree of In-Stent-Restenosis	1,8±4,8 %	53±40,9 %	< 0,0001

Scheinert D et al. Eurointervention 2006

Cypher BTK Registry
- Angiographic Patency -

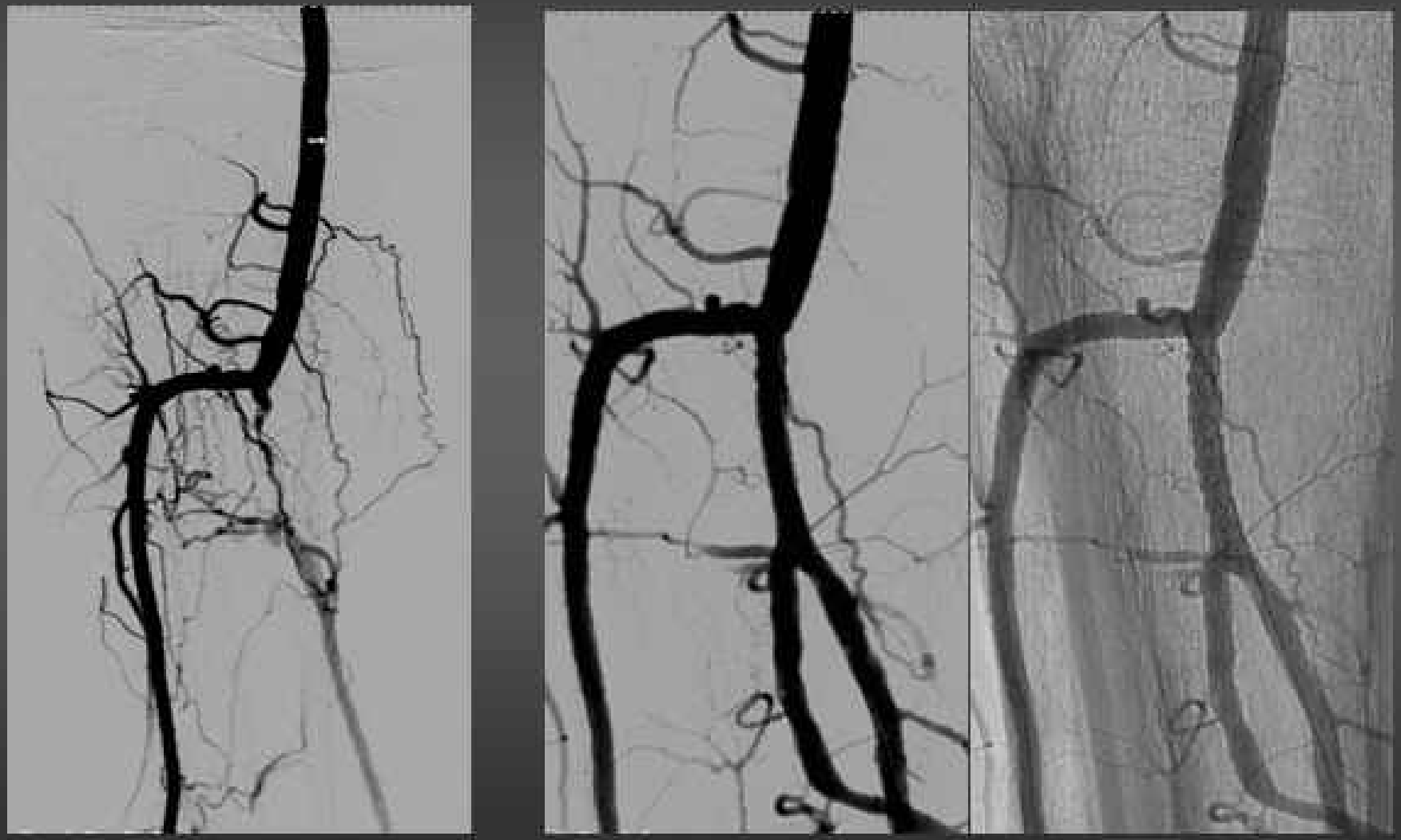


FU-Time	Patency	
	Primary	Secondary
6 months	98.2%	98.2%
12 months	94.1%	95.9%
24 months	89.2%	95.9%

Log Rank = 0,4551

Scheinert D et al. TCT 2006

Cypher for BTK



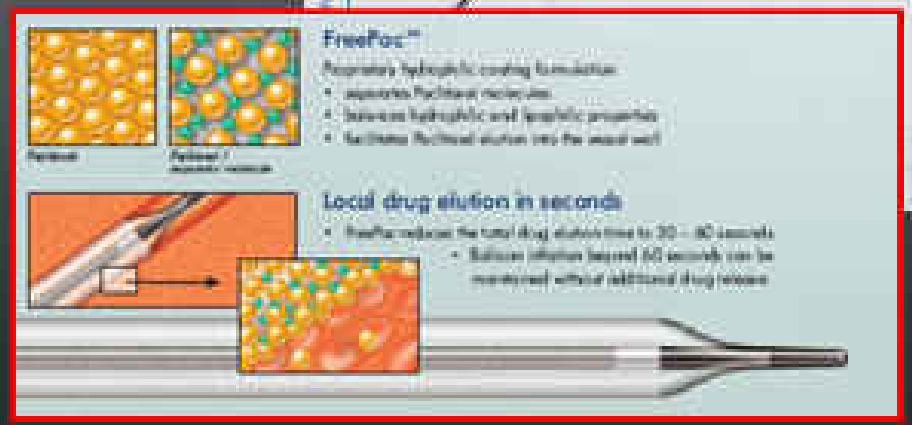
Cypher for BTK 6-months FU

Novel Treatment Concept

IN.PACT AMPHIRION

Paclitaxel-eluting PTA Balloon Catheter

built on the proven, first BTK dedicated,
Amphirion DEEP™ balloon platform



INVATEC

Worldwide first case performed
LIVE @ LINC 2009

Study Design

CLI
(RC 4-5-6)

Index lesion qualifies for Angio FU?

yes

randomization

std. PTA

DEB

co-1° Endpoint
1Y Angio % DS

no

randomization

std. PTA

DEB

co-1° Endpoint
1Y % ↓ CL driven TLR

3y, 4y, 5y
AFS

1y, 2y
AFS, WH, TLR free

Unless you try to do something beyond what you have already mastered, you will never grow