

New Aspects Treating Critical Limb Ischemia



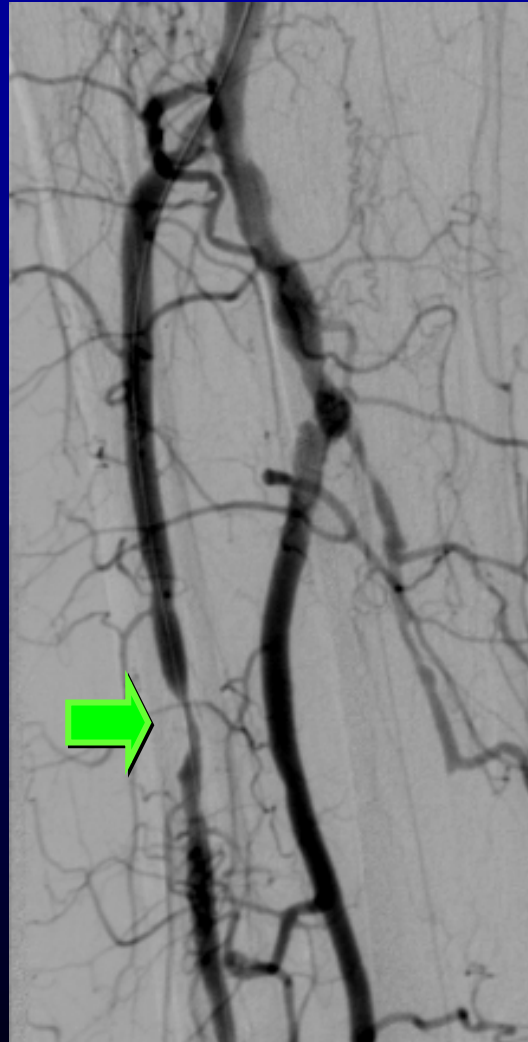
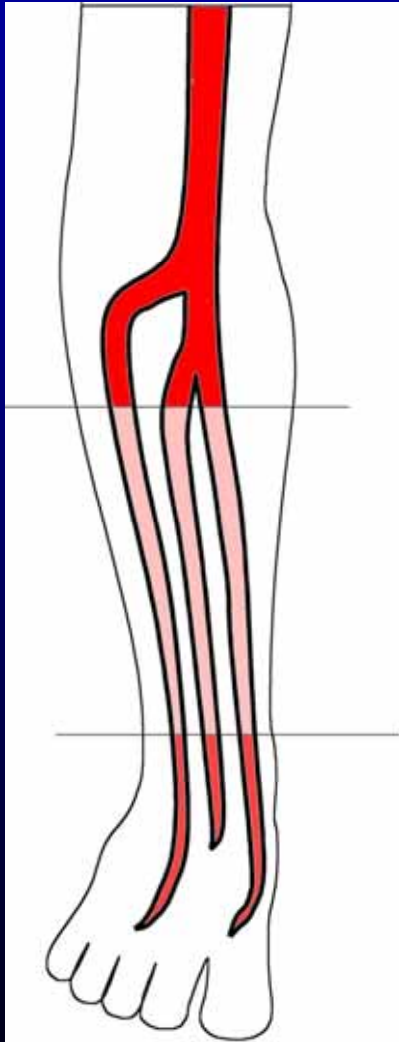
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Characteristics of Patients with Infrapopliteal Obstructions

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



Infrapopliteal Obstructive Lesions in Critical Ischemia (CI)

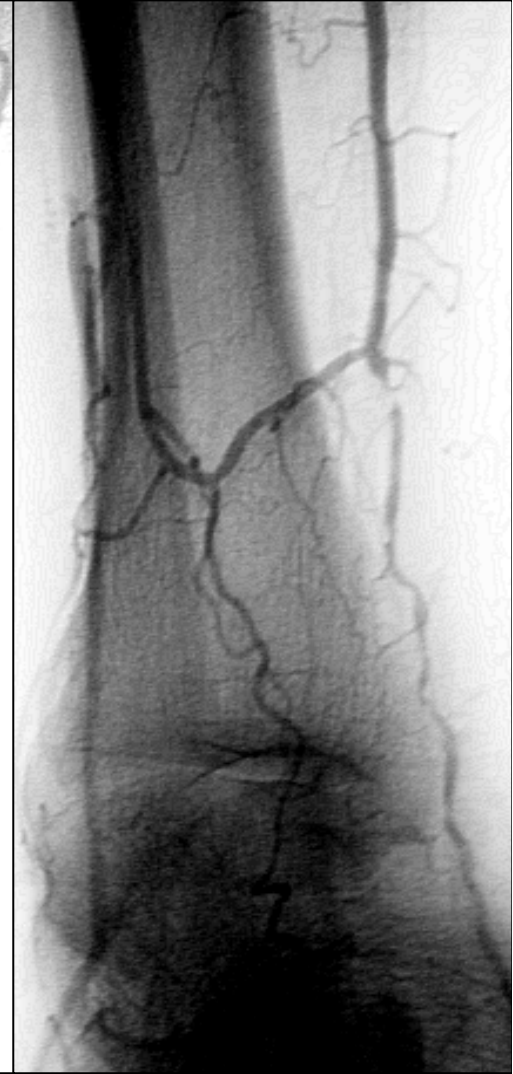
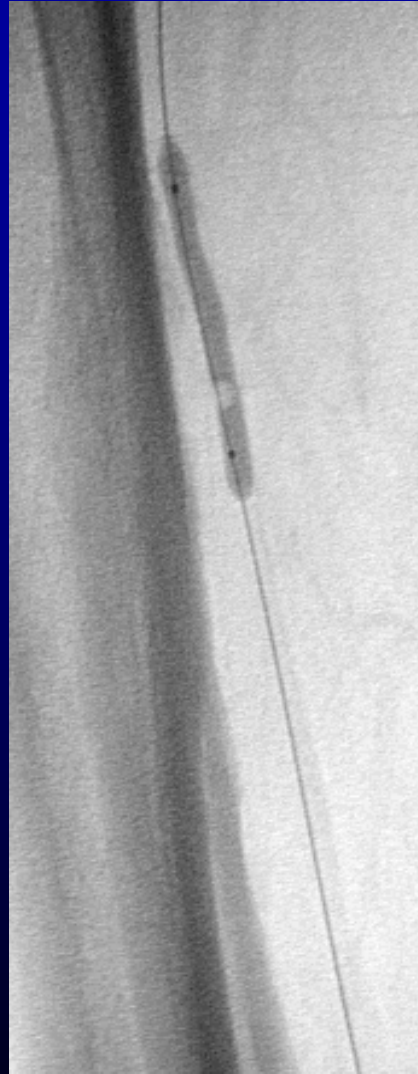


No CI



CI

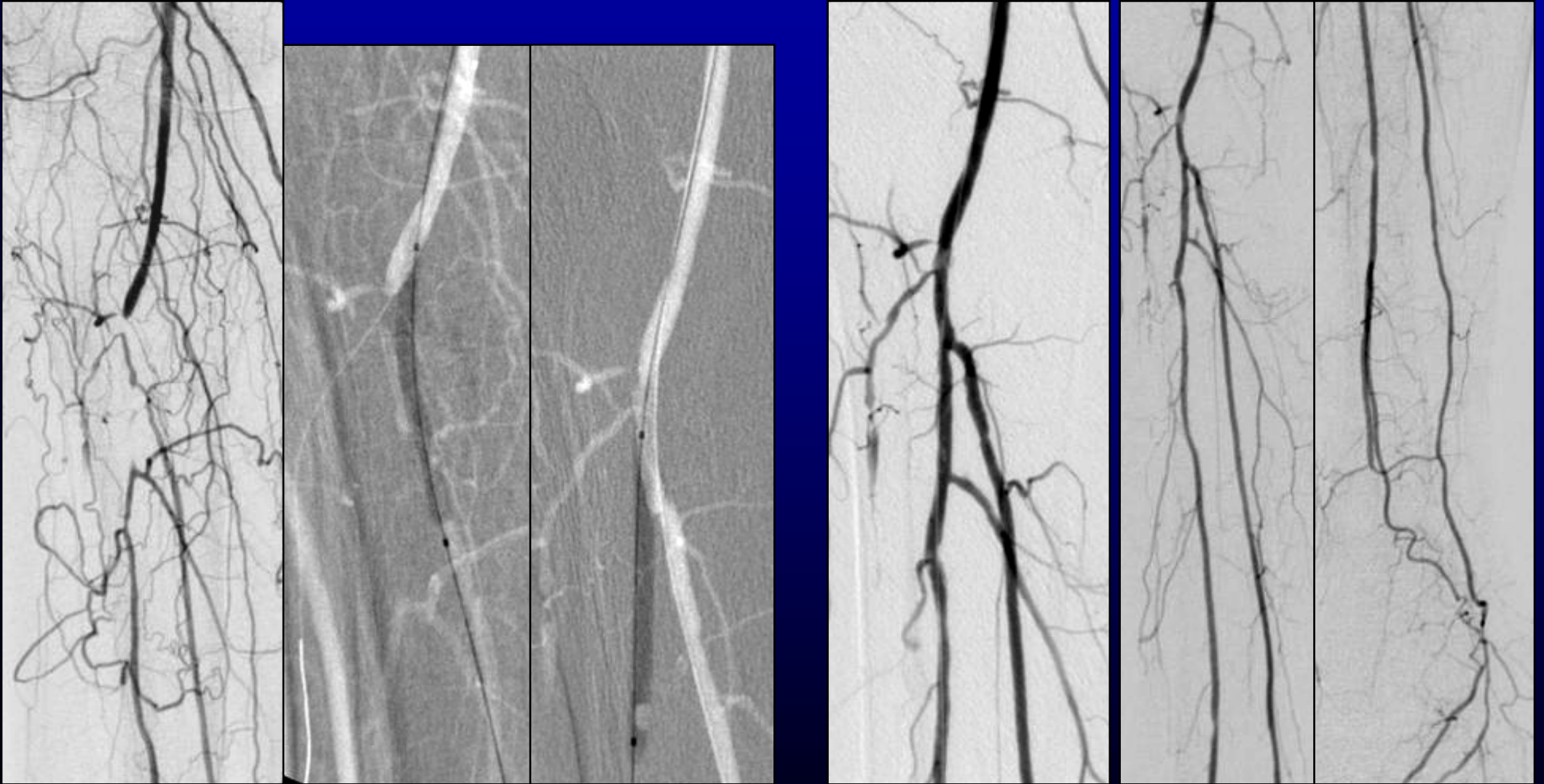
Infrapopliteal Lesions in CI



Trunc-stenosis

Result

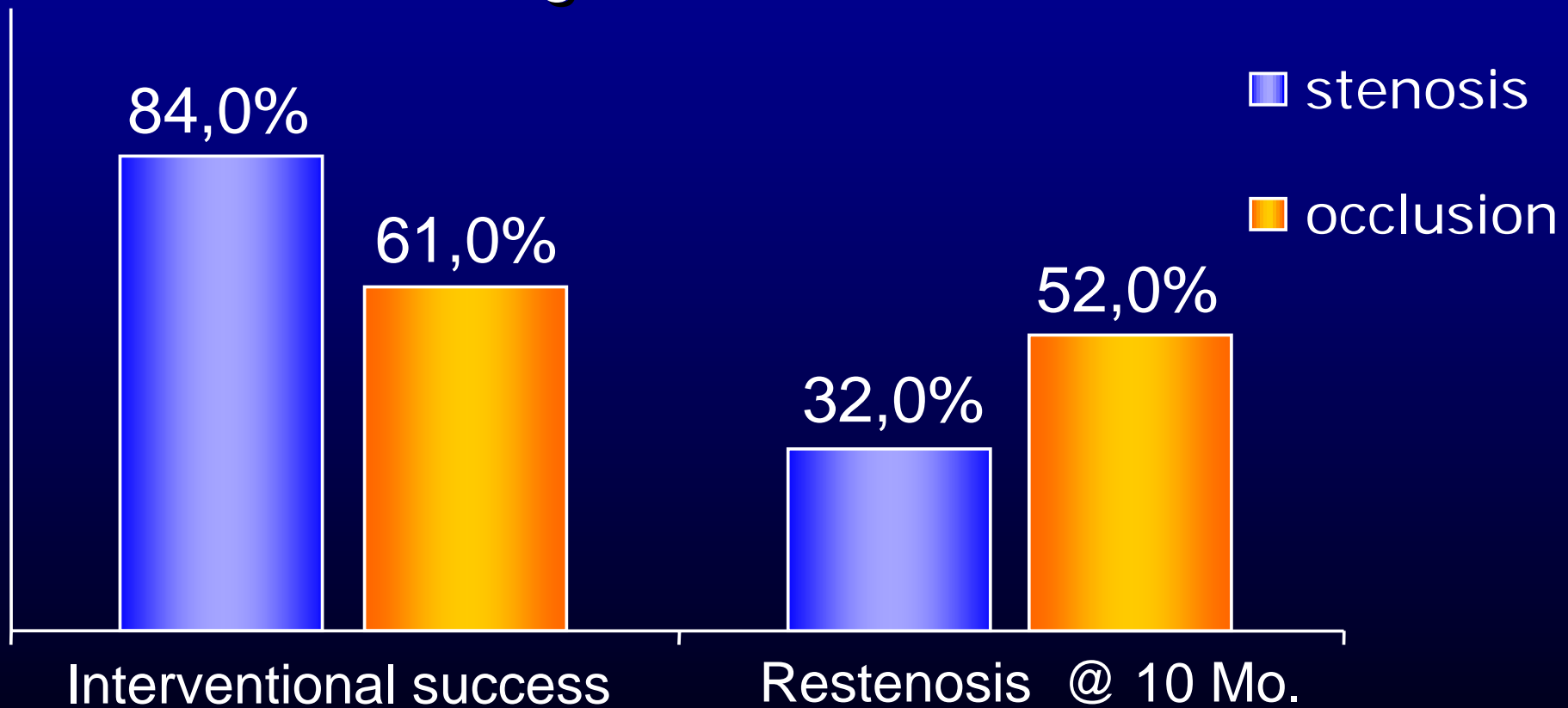
Short Infrapopliteal Lesions



TPT-occlusion

Balloon-Angioplasty of Infrapopliteal Arteries in Critical Limb Ischemia

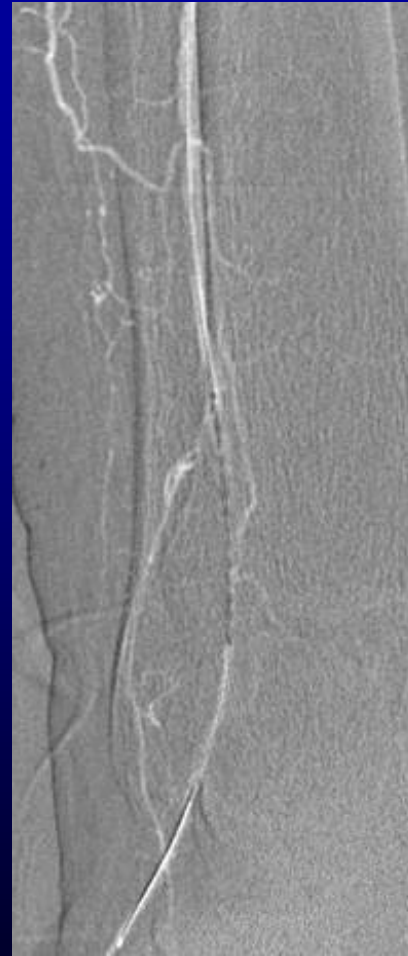
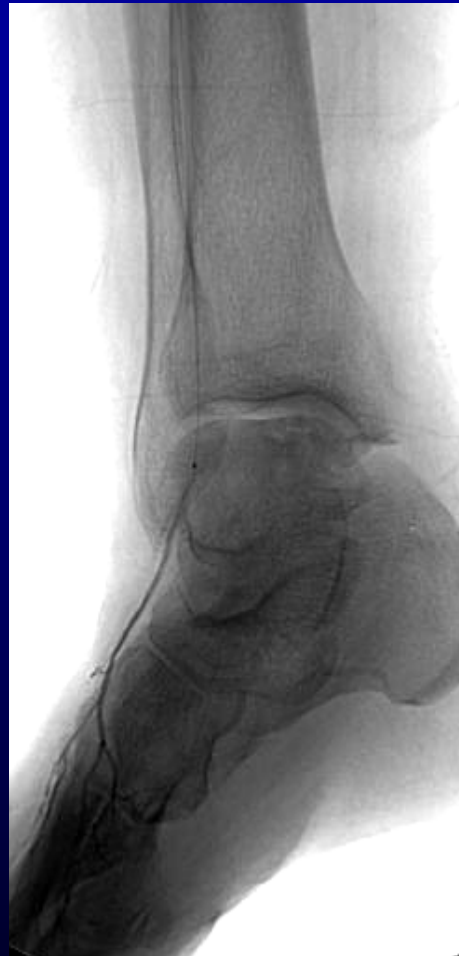
- 60 pat., 72 limbs, 12-24 Mo F/U
- Lesion-length 3.8 ± 3.0 cm



Stents for Revascularisation of Infrapopliteal Arteries



Re-occlusion PTA
2 weeks after PTA



Sonic 2.5/33mm



PTA vs. Stenting of Infrapopl. Lesions

Prospective registry, 112 pat. / 132 limbs

	Angioplasty	Stenting
Limbs, n	74	58
Rutherford		
3	60%	57%
4	37%	41%
5	3%	2%
Occlusion	43%	57%
Lesion-length	6.2 cm	6.8 cm

PTA vs. Stenting of Infrapop. Lesions

	Angioplasty	Stenting	p
Interventional Success	79%	95%	<0.01
Marked clinical Improvement	74%	90%	<0.05
Clinical patency At 12 months	53%	84%	<0.01



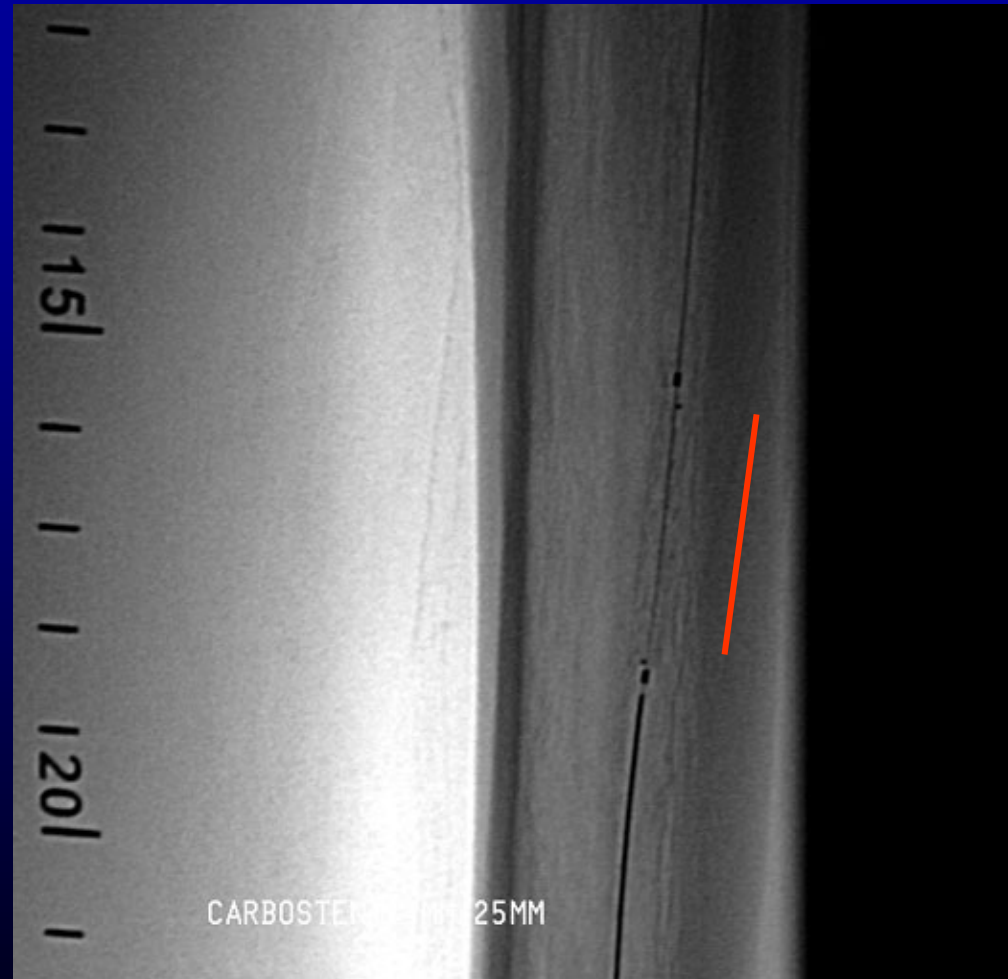
Angiographic restenosis-rate 53%

Space for improvement

Randomized Trials PTA vs Stent

- PTA vs carboflim-coated stents of infrapopliteal arteries
- Carbostents (Sorin, Biomedica, Italy)
Ø 2.0 – 4.0 mm; length 15-25mm

PTA vs Carbofilm-Coated Stents In Infrapopliteal Arteries: Pilot Study



Rand et al. *Cardiovasc Intervent Radiol* 2005

PTA vs Carbofilm-Coated Stents In Infrapopliteal Arteries: Pilot Study



Case 2

Post stent F/U
MS-CTA



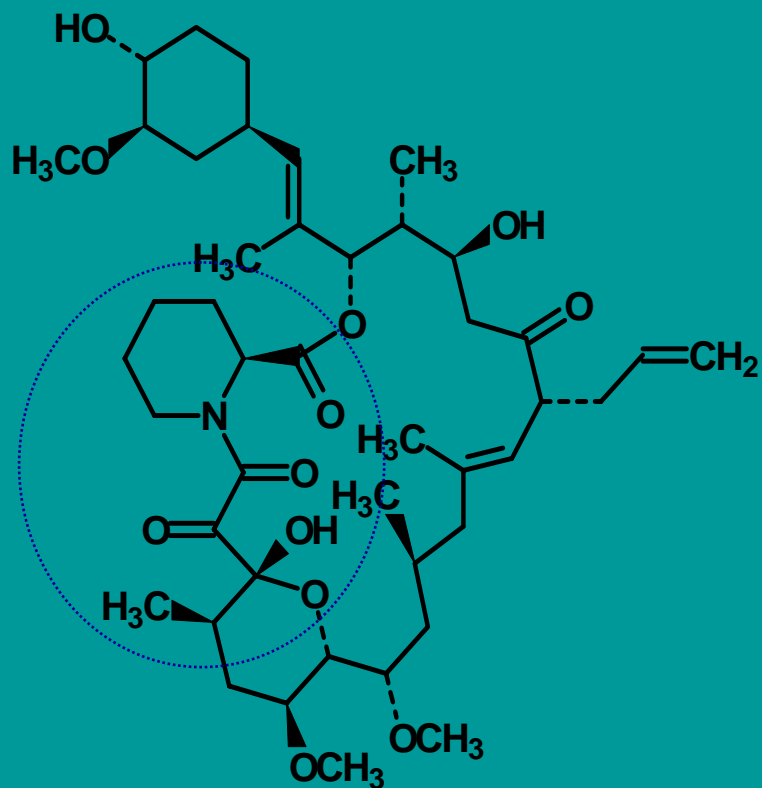
PTA vs Carbofilm-Coated Stents In Infrapopliteal Arteries: Pilot Study

6 months follow-up

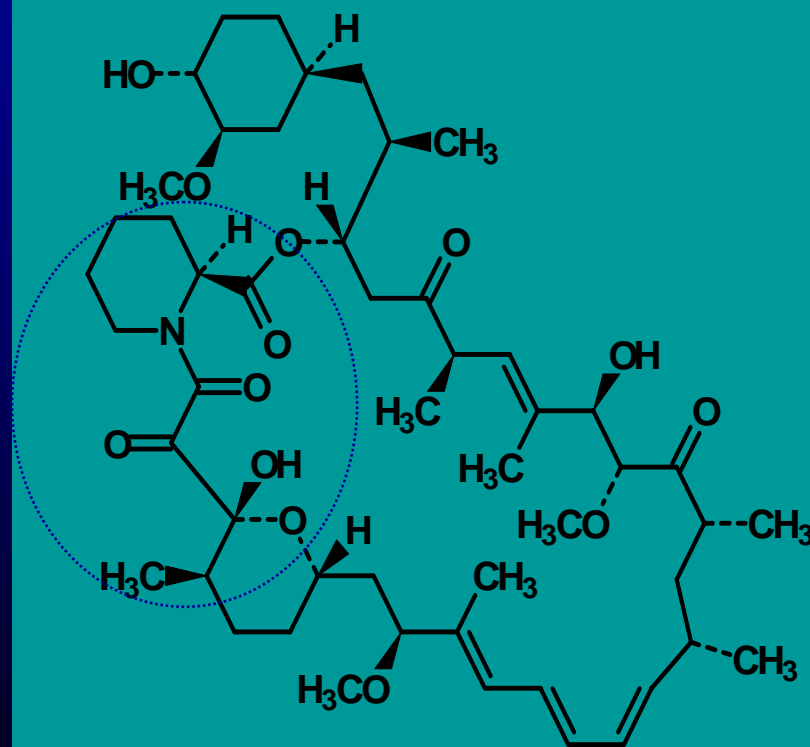
	Stents (n=25)	PTA (n=32)	P
Restenosis > 70%	16.3 %	38.9 %	0.02
Restenosis > 50%	20.3 %	44.4 %	0.02

Drug-Eluting-Stents

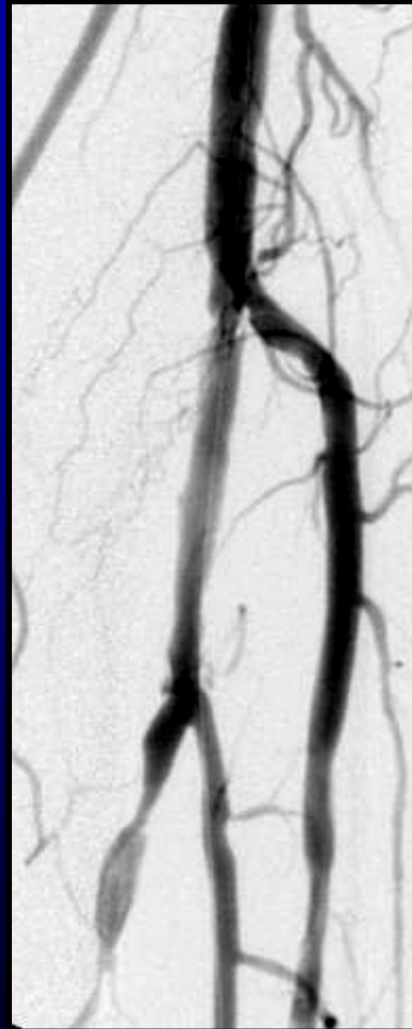
Tacrolimus (FK506)



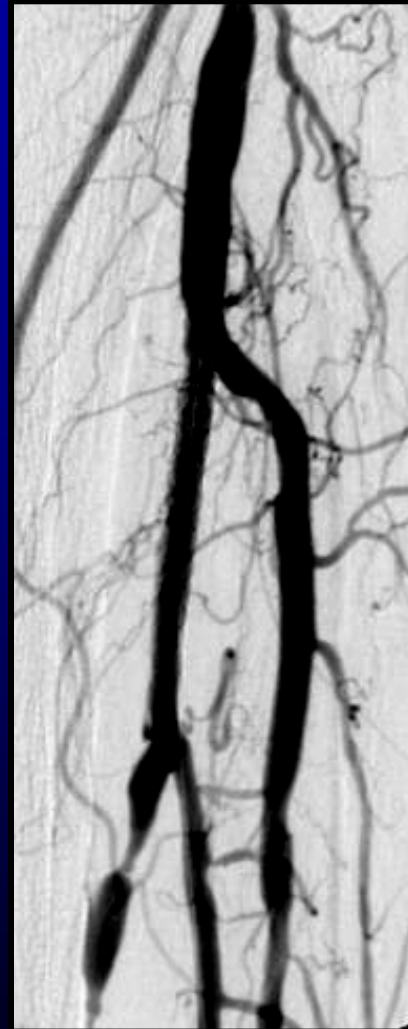
Sirolimus (Rapamycin)



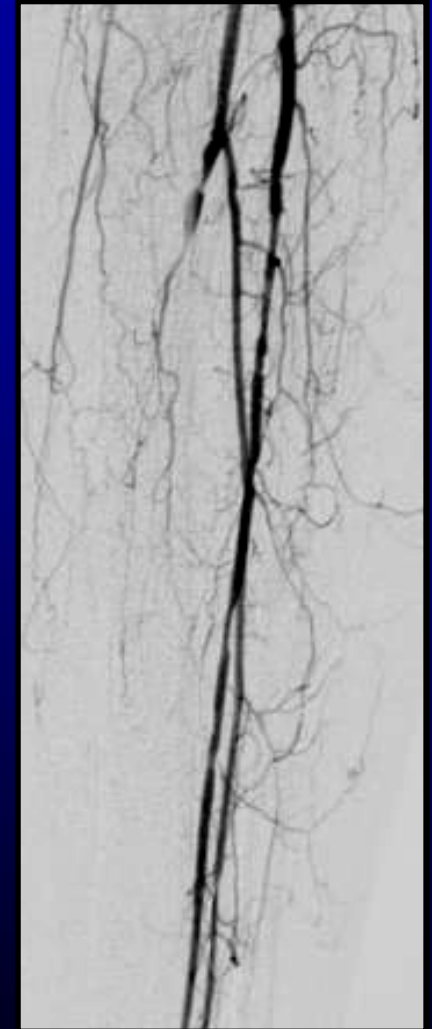
Occlusion right TPT



Predilatation



Cypher 3.5/33



Baseline - Data

	Cypher	Control	p
n	30	30	
Age	71,4	73,0	NS
Male	16 (57%)	19 (65%)	NS
Diabetes mellitus	25 (83,3%)	23 (76,6%)	NS
Rutherford class. 3	11	10	NS
Rutherford class. 4	8	11	NS
Rutherford class. 5	11	9	NS

Angiographic Follow-up (6-12 Months)

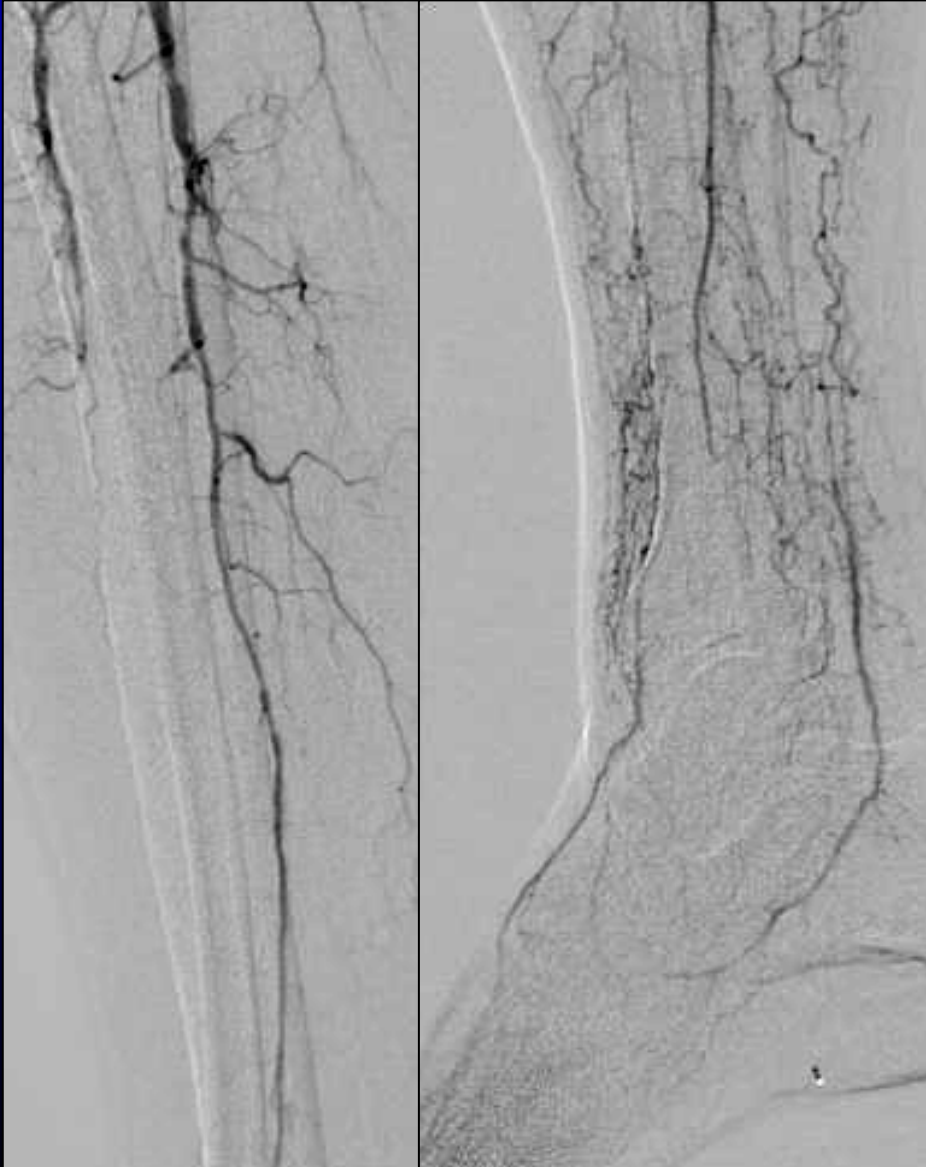
	Cypher n=24	Control n=23	p
Stent occlusion	0	4 (17,4%)	0,032
Restenosis > 50%	0	9 (39,1%)	0,0007
Grade of restenosis (mean)	1,8 ± 4,8 %	53 ± 40,9 %	< 0,0001

Clinical Results

n	Cypher n=30	Control n=30	p
Death	3 (10,0%)	4 (13,3%)	NS
Major amputation	0	3 (10,0%)	NS
Bypass Surgery	0	0	NS
Repeat revascularization	0	7 (23,3%)	0,0049
MAE in total	3 (10,0%)	14 (46,6%)	0,0016

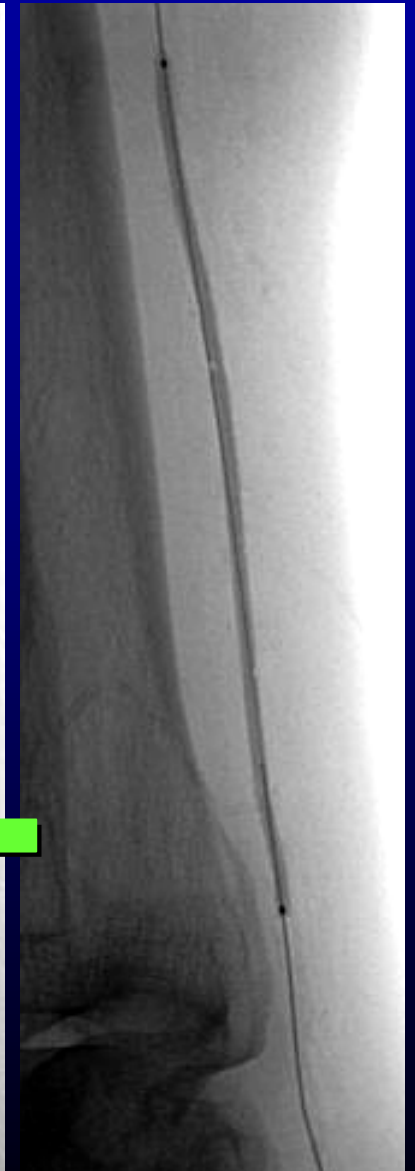
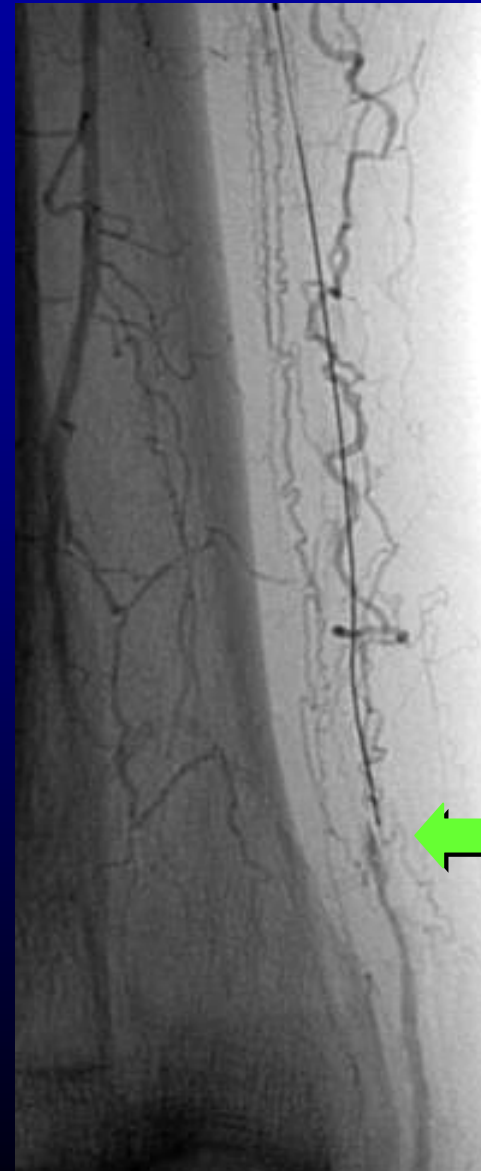
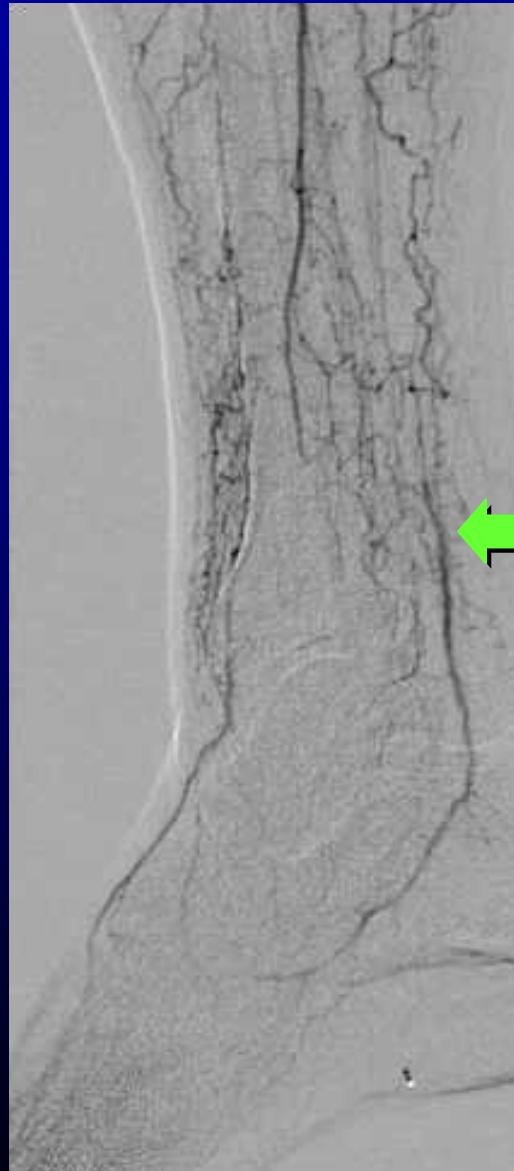
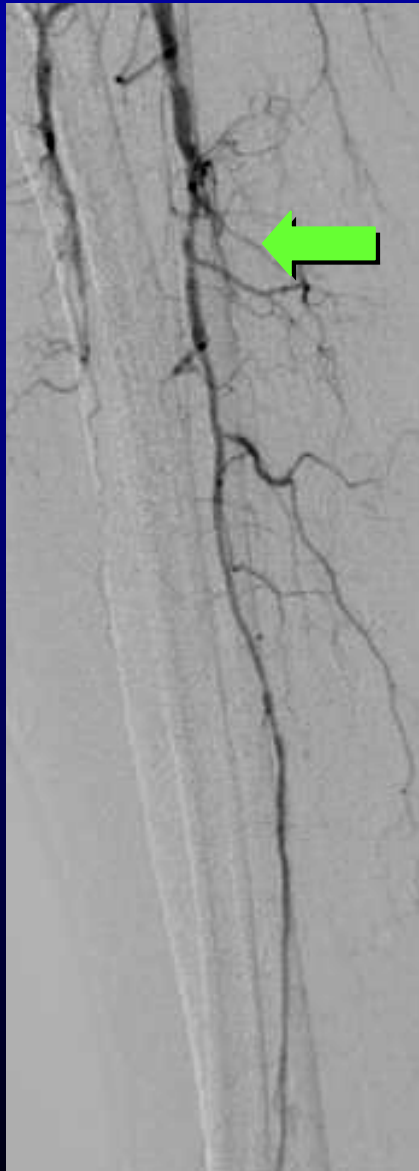
Scheinert D et al. J Am Coll Cardiol submitted

Critical Ischemia in Diabetes-Patients

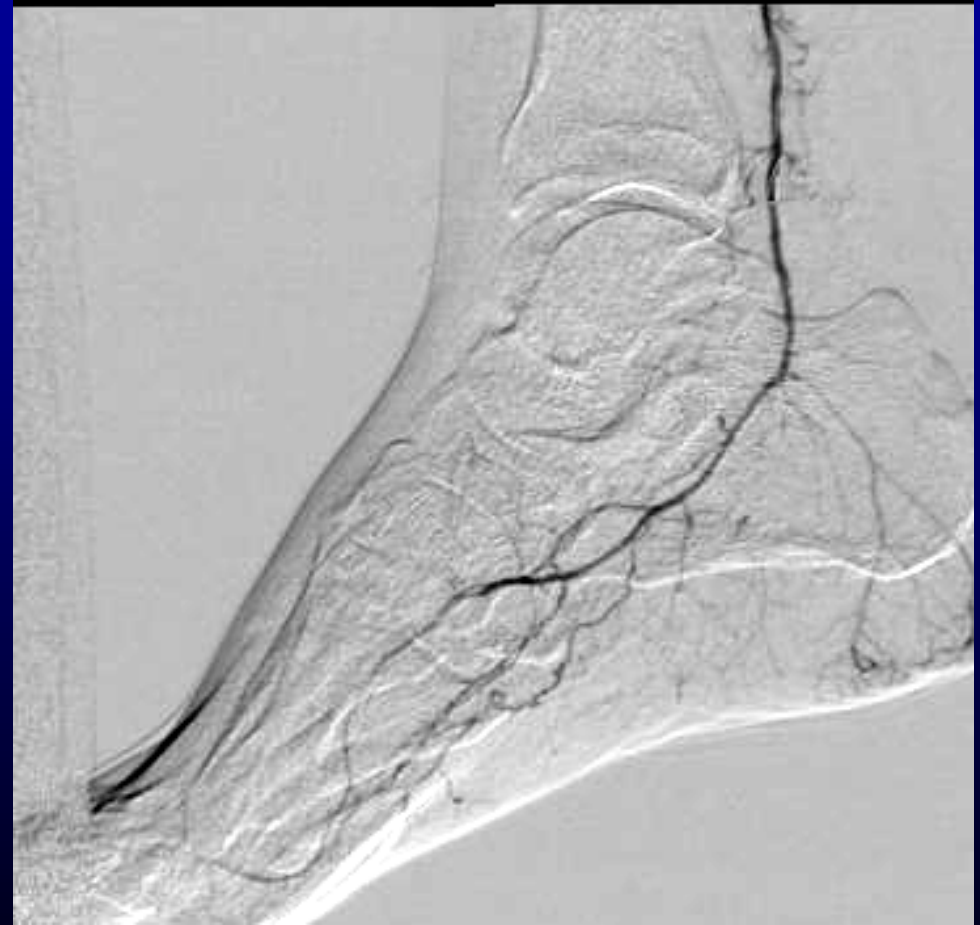


- Extensive intrapopliteal lesions
- Poor collateralization
 - ✘ Stenoses / occlusions of plantar arch and metatarsale arteries

Diffuse Lesions in Diabetes-Patients



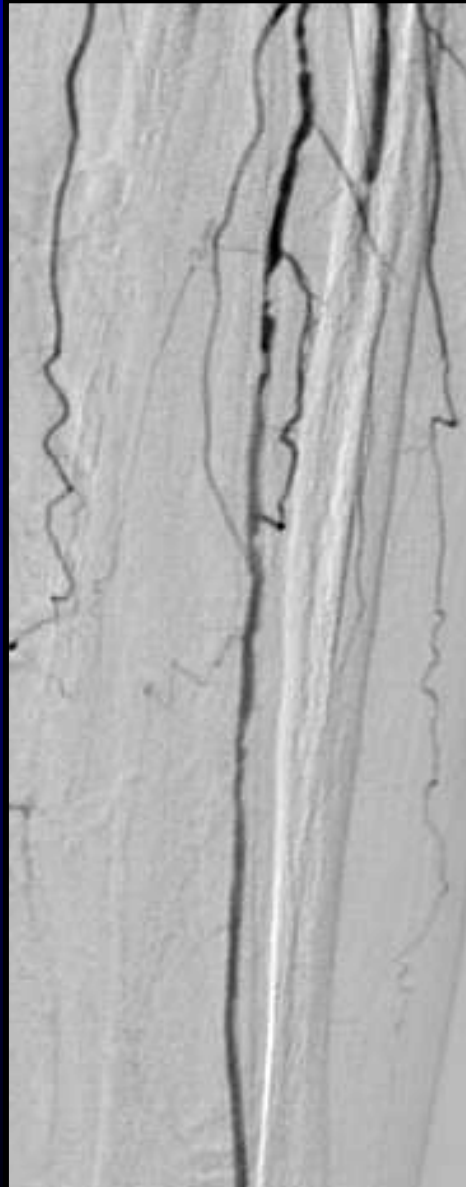
2,5 / 120mm Balloon



Equipment for PTA of Extensive Infrapopliteal Lesions

- Hydrophilic 0.018" guidewire
 - ✗ V18 Control-wire (Boston Scientific)
- Low-profile balloons
 - ✗ Diameter 2.0 – 3.5 mm
 - ✗ Length 80 – 120 mm
 - ✓ OTW 0.018" (Submarine Plus, Invatec, Italy)
 - ✓ OTW 0.014" (Amphirion Deep, Invatec, Italy)

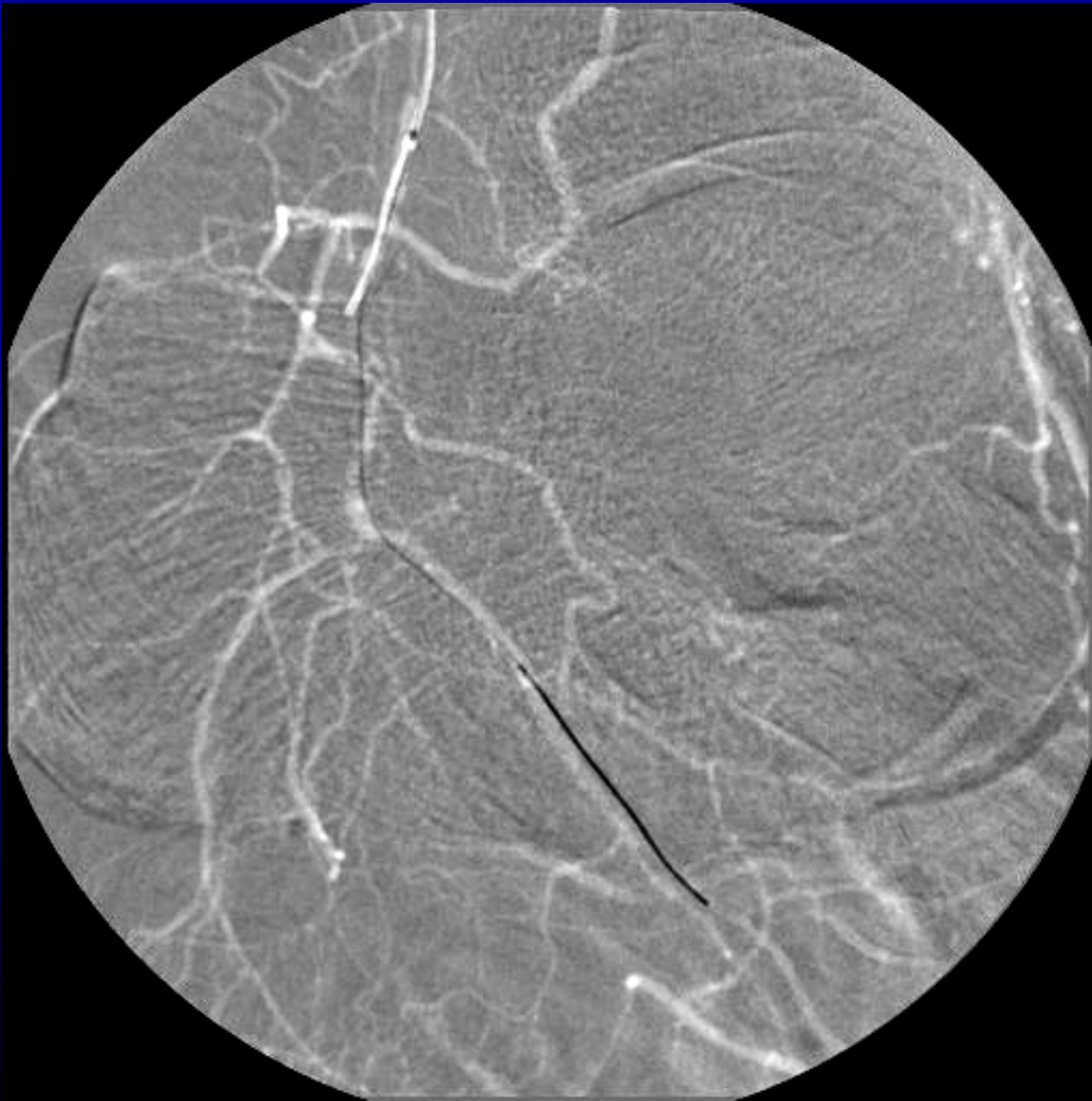
Angioplasty in Diabetes-Patients



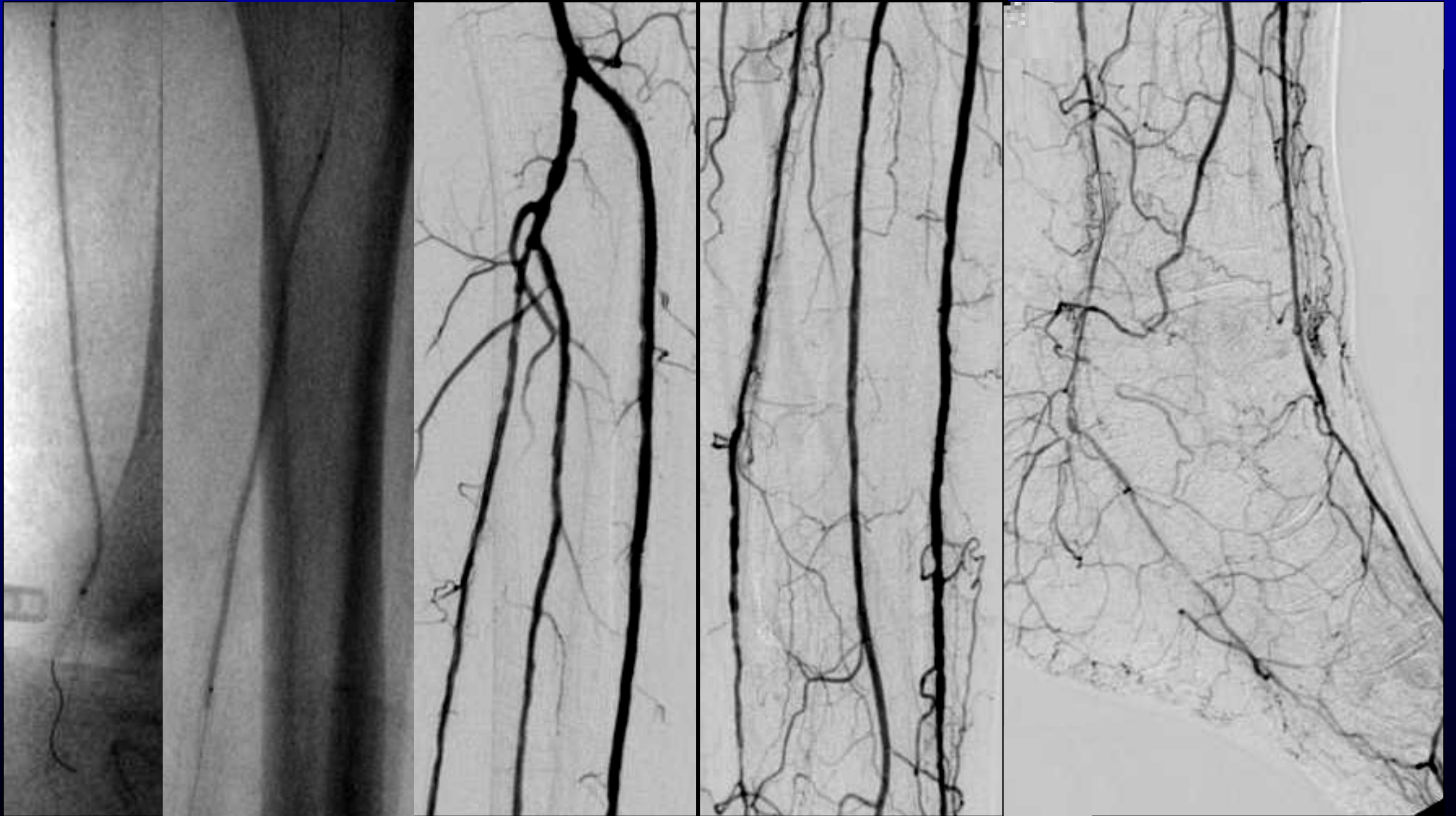
Angioplasty in Diabetes-Patients



Angioplasty in Diabetes-Patients



Angioplasty in Diabetes-Patients



PTA of diffuse infrapopliteal lesions

- Average lesion length **18.5 cm** (5 – 30 cm)
- Occlusion 45 (80 %)

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

Conclusion

- Balloon-angioplasty of long infrapopliteal lesions is
 - feasible
 - safe
 - shows promising clinical results.
- Improvement of the patency-rate
e.g. by stent-implantation ?