# Endovascular Revascularization is the Best Option in CLI: When and How?

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# Critical Limb Ischemia

Definition:

- Critical reduction of the arterial perfusion
- Arterial pressure

  < 50 mmHg (ankle)

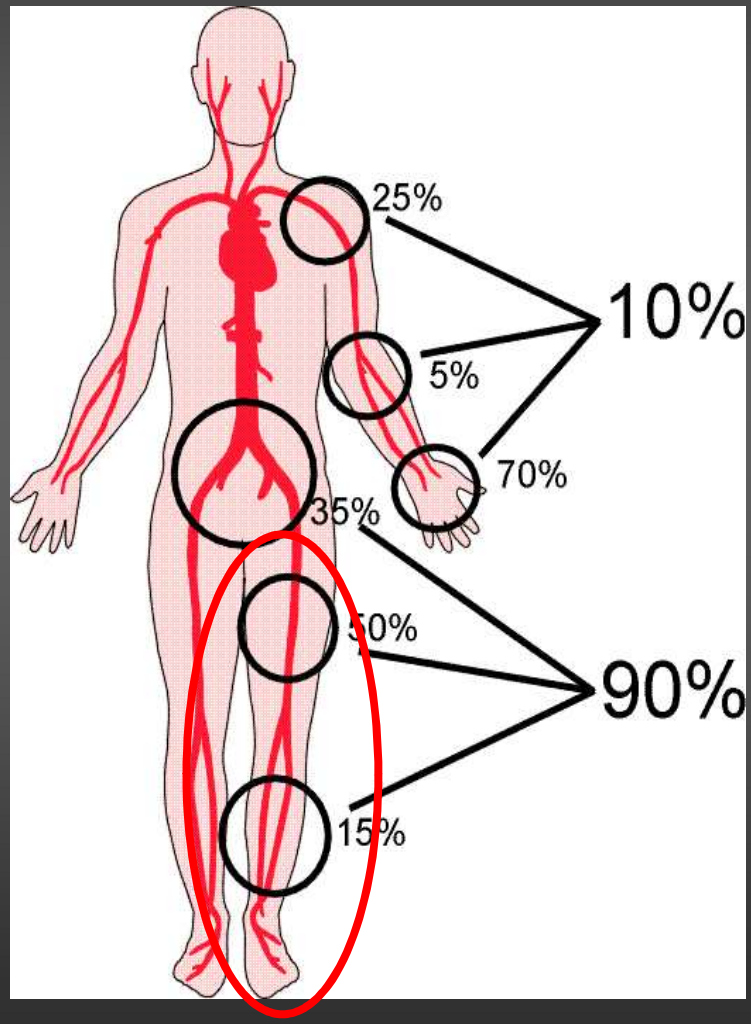
  < 30 mmHg (toe)

Rutherford Category

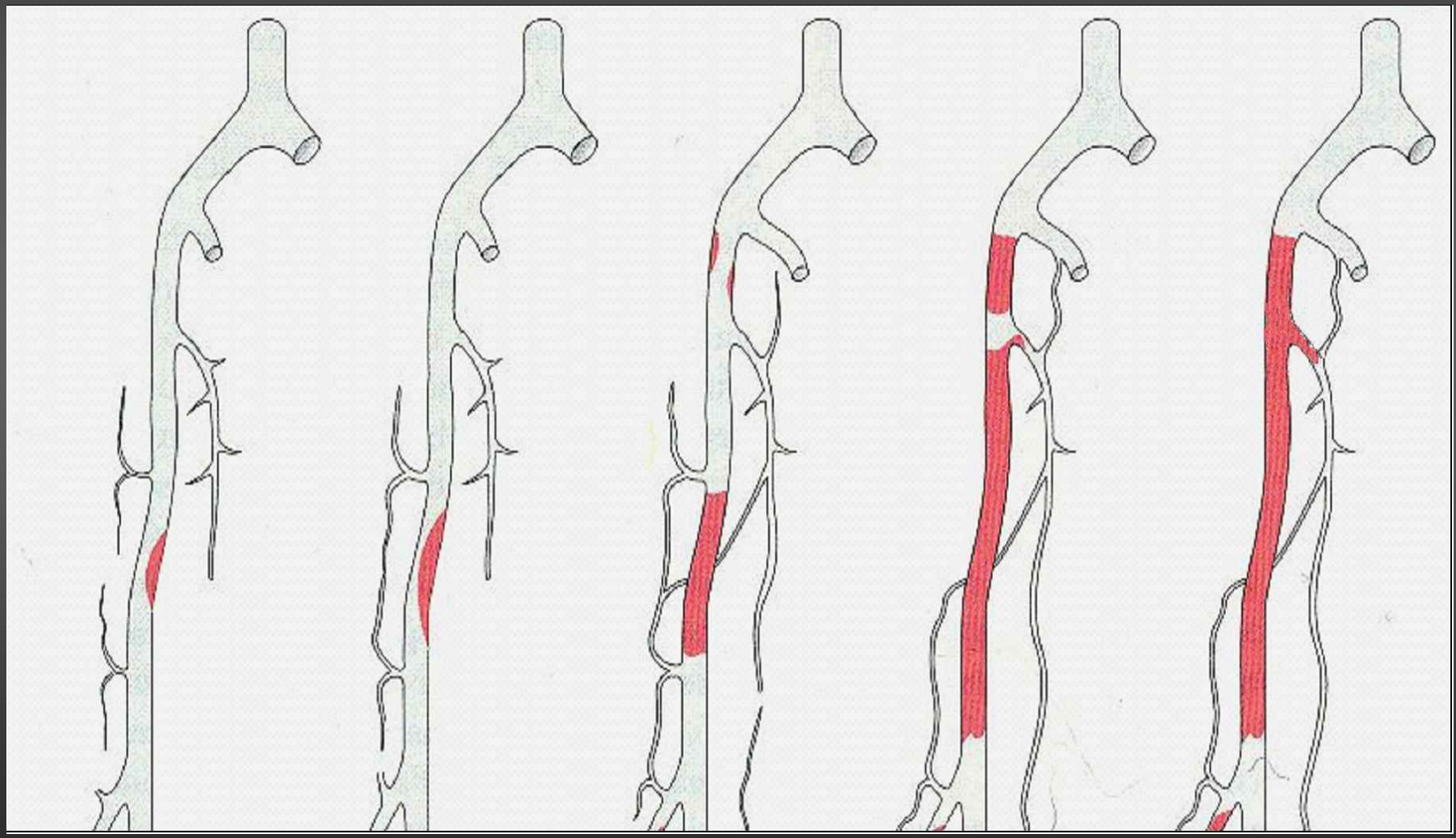
4 Ischaemic rest pain

5 Ulcera and gangrene

# Distribution of Lesions in CLI



# The SFA-CTO

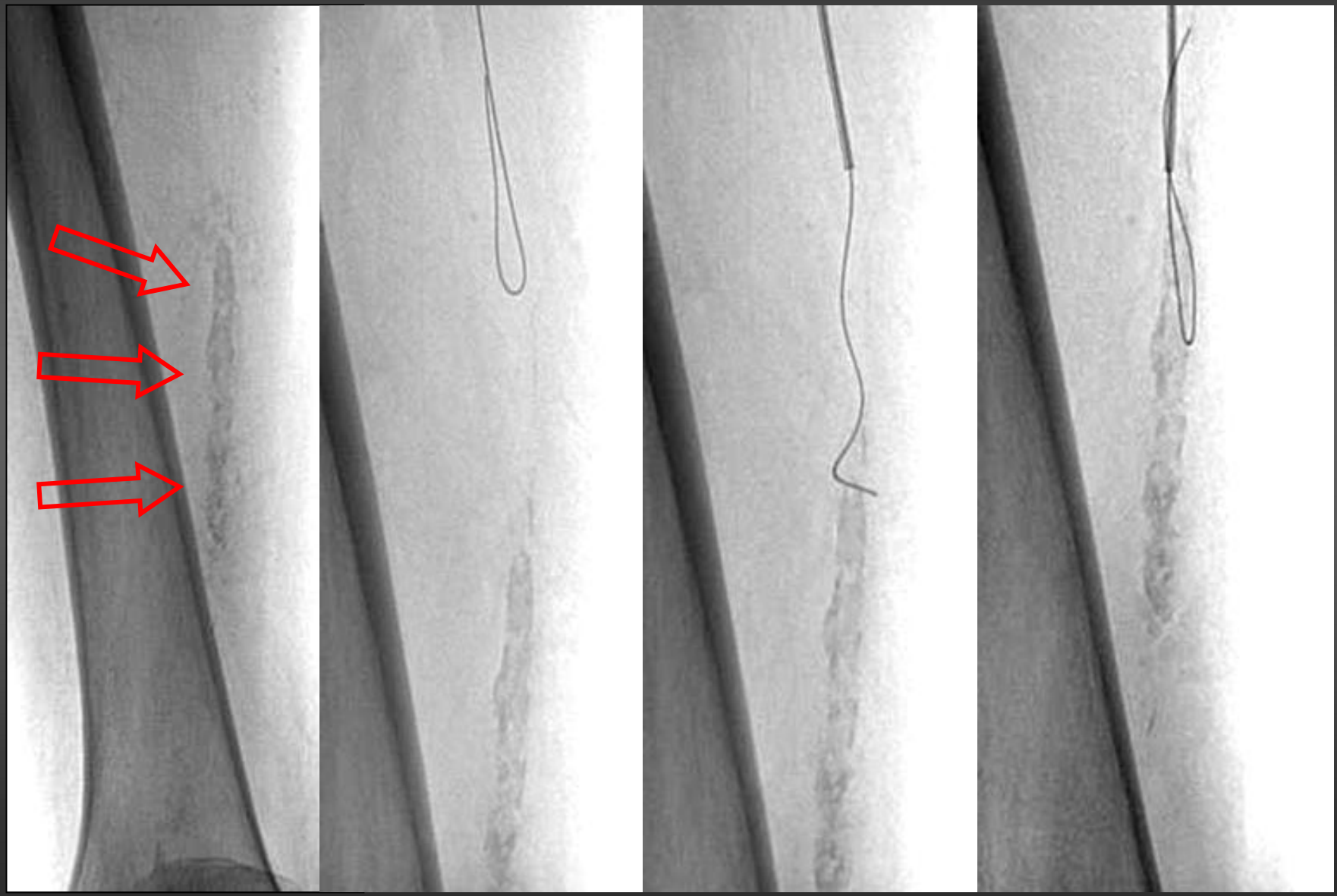


# Highly calcified occlusion right SFA

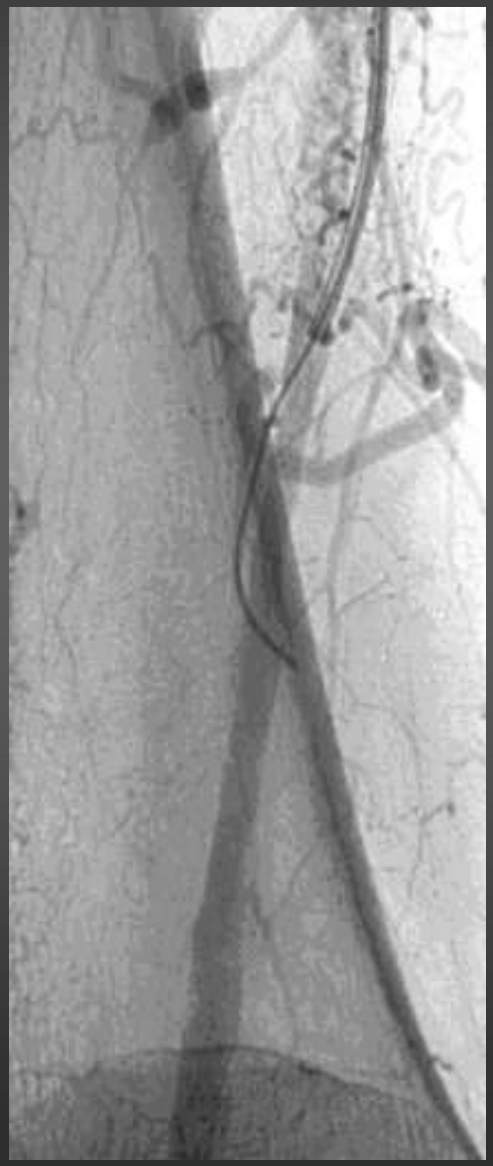
Unsuccessful wire-passage

2.5mm Turbo-Laser

# Subintimal Recanalization



# Subintimal Angioplasty

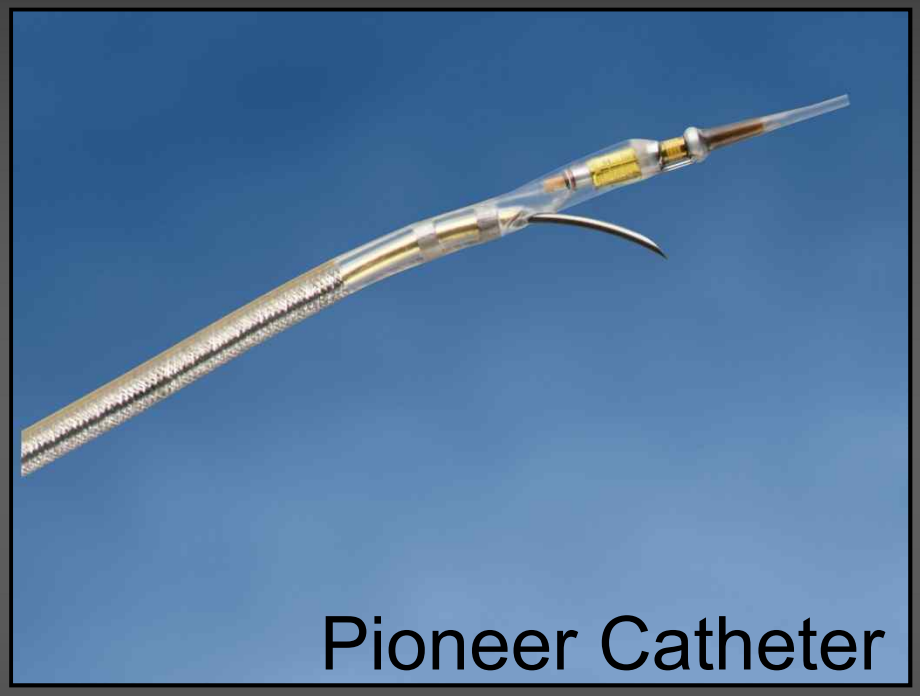


**10-15% failures due to inability to re-enter the true lumen .**

**Major potential problem :**

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

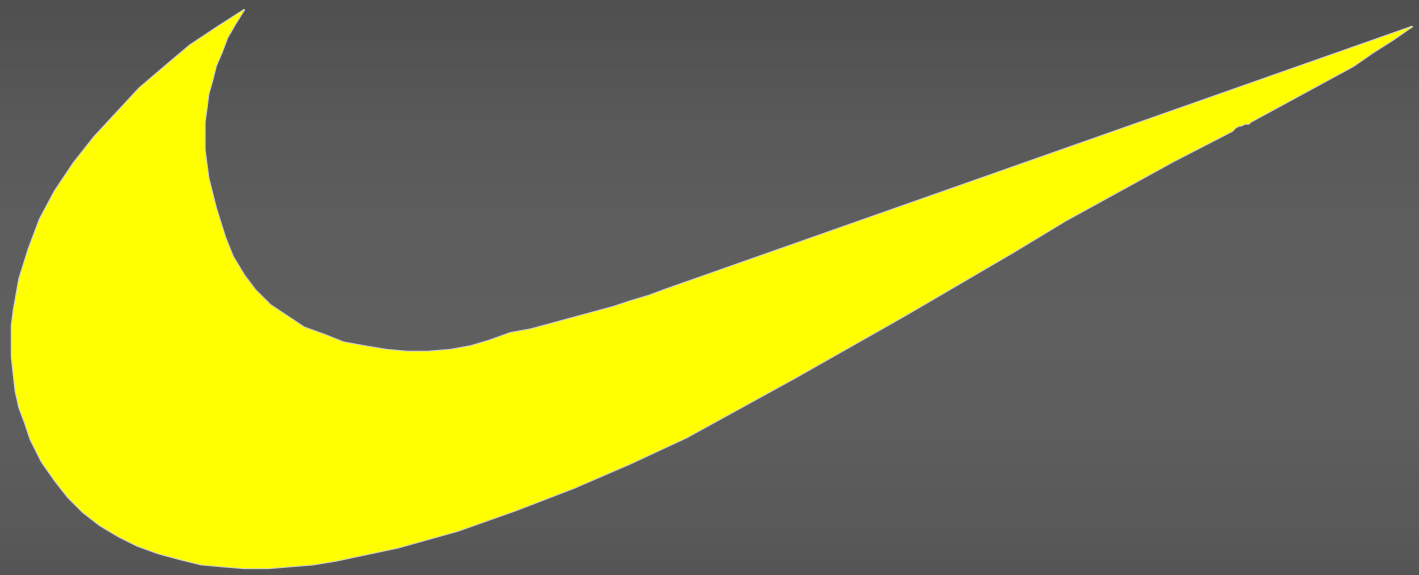
# Re-Entry-Devices





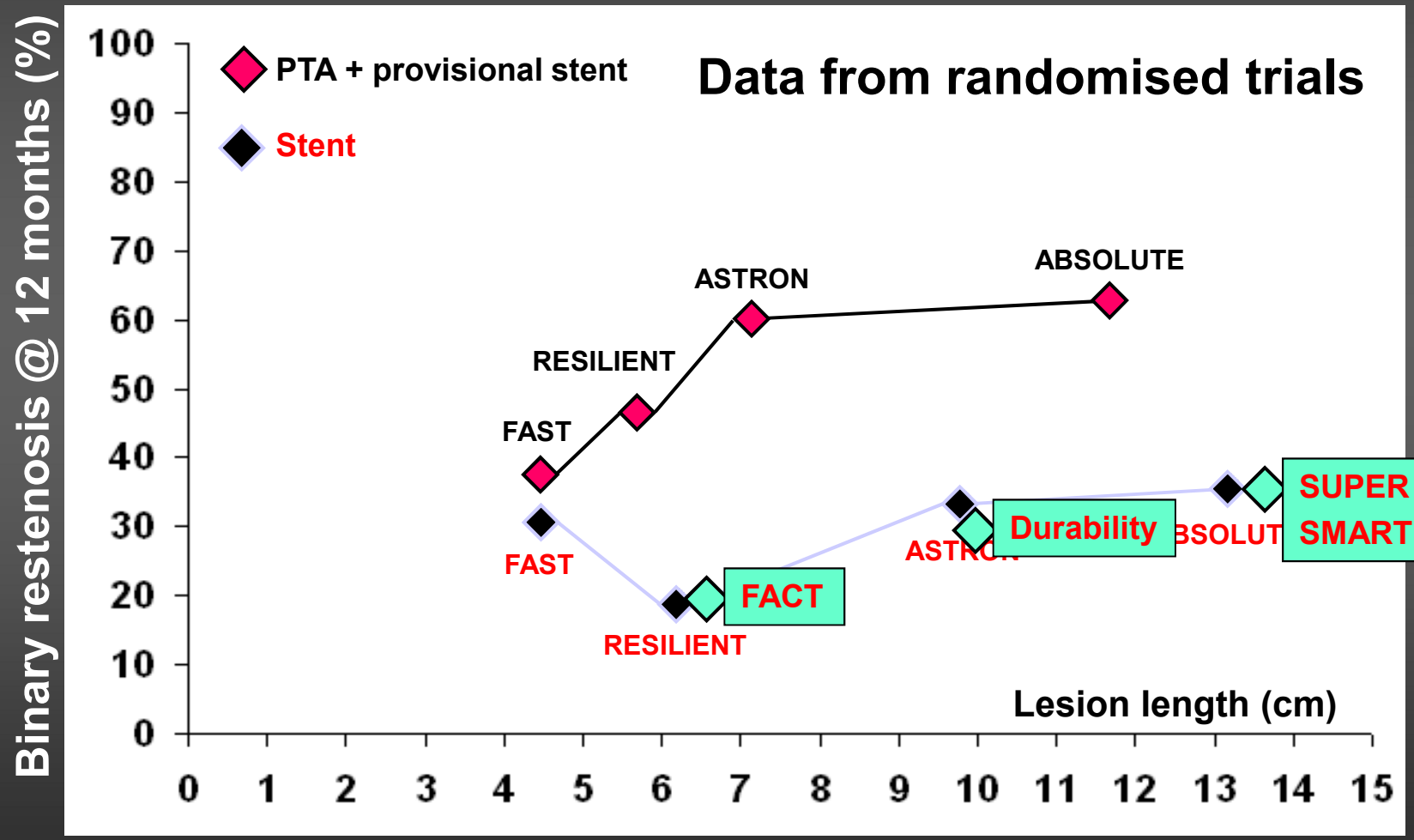
Crossing Success
> 95%

## After Crossing ... What`s next?



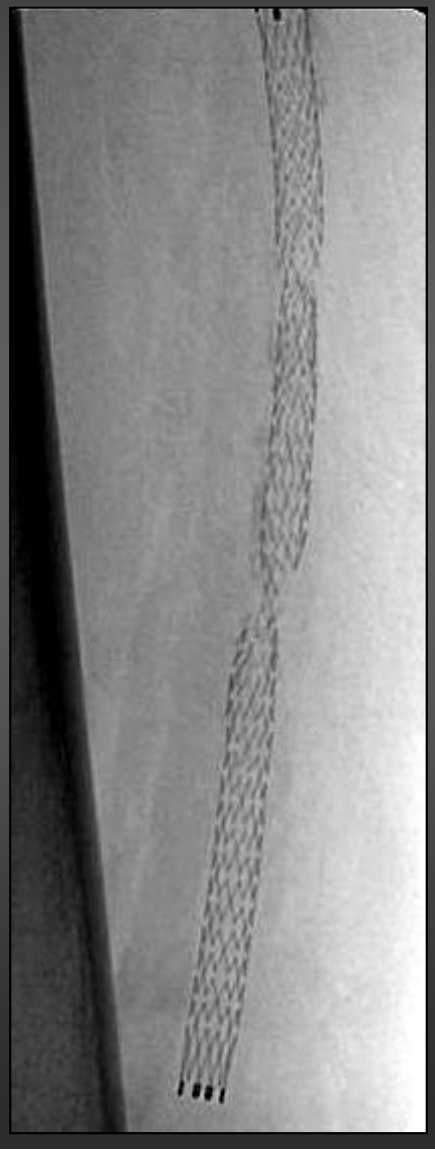
# Just stent it.

# Summary
## 12 months restenosis vs. lesion length




Modified from Schillinger et al, EURO-PCR 2008

# Risk Factors for Stent-Fractures



- Multivariante Analysis

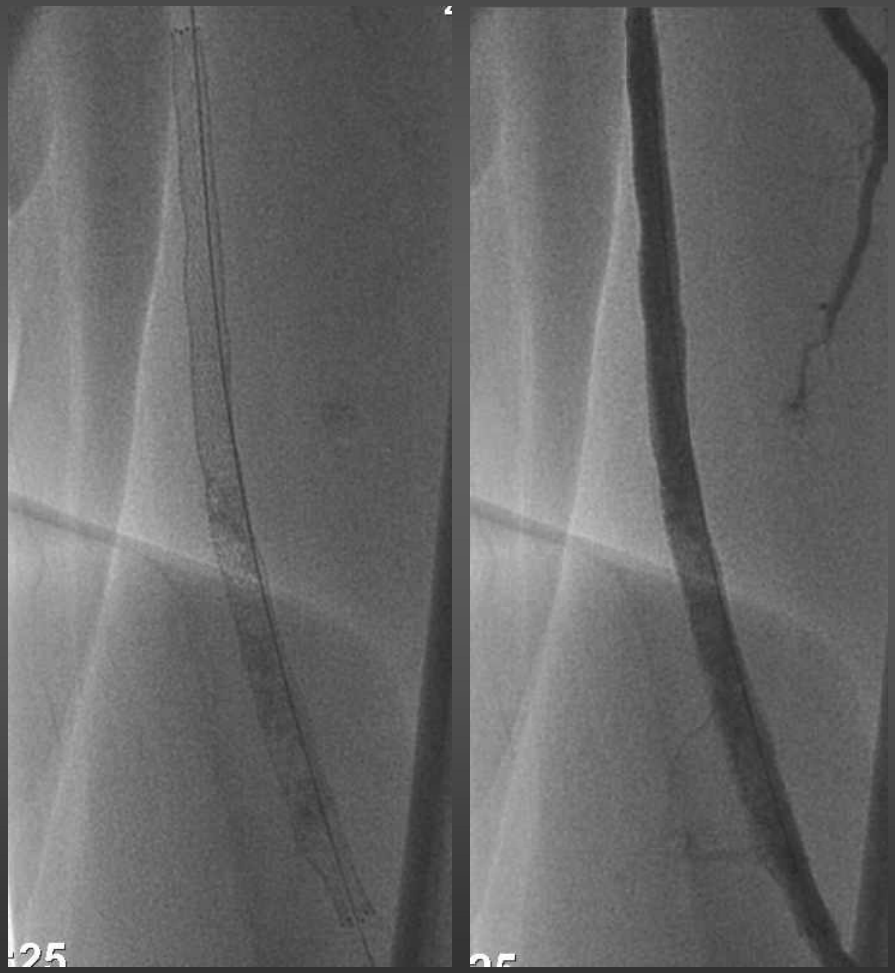
| | | RR | p | 95% KI |
|---|---|---|---|---|
| **Stent length >160mm** | **5.559** | **<0.001** | **3.166** | **9.763** |
| **Severe Calcification** | **3.941** | **<0.001** | **2.261** | **6.868** |

**Location of the stent was no predictor !**

Scheinert D, Sax J et al. TCT 2007

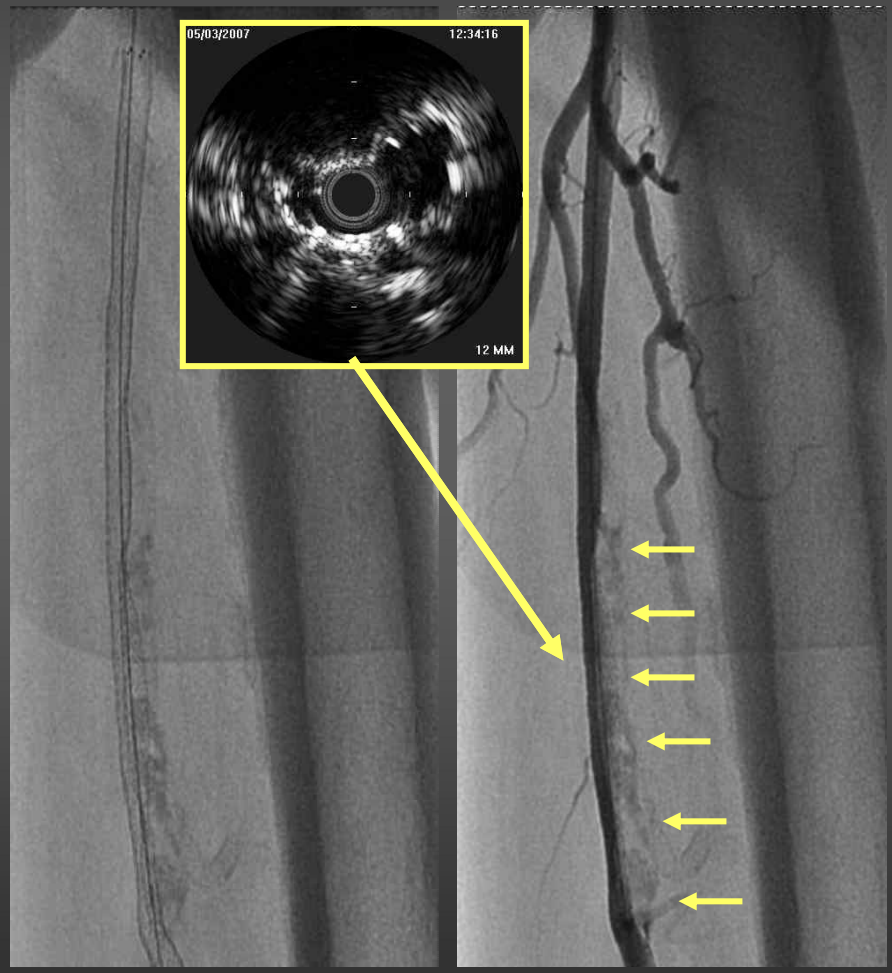
# Insufficient Radial Resistive Force Results in Suboptimal Deployments

Angio AP projection



% MLD 15%

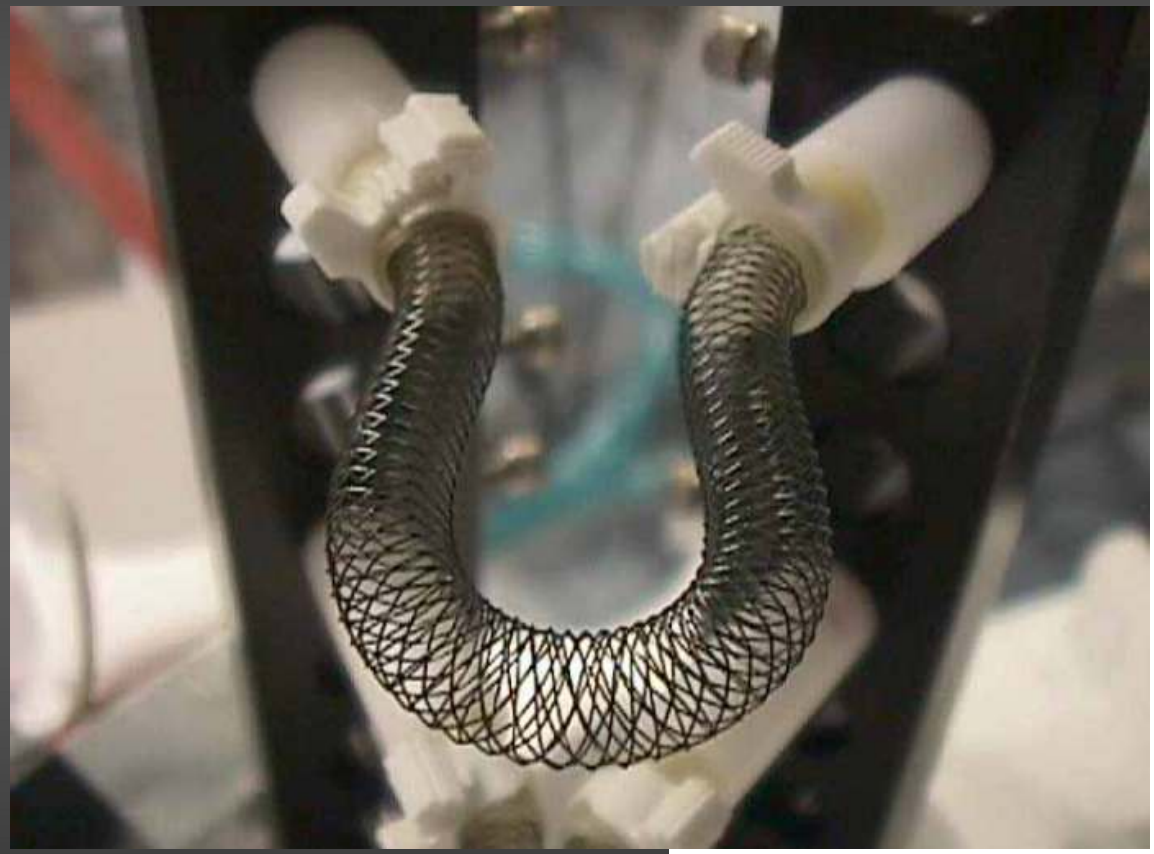
Angio LAO projection




% MLD 42%

# SUPERA Stent
## Interwoven Nitinol Design

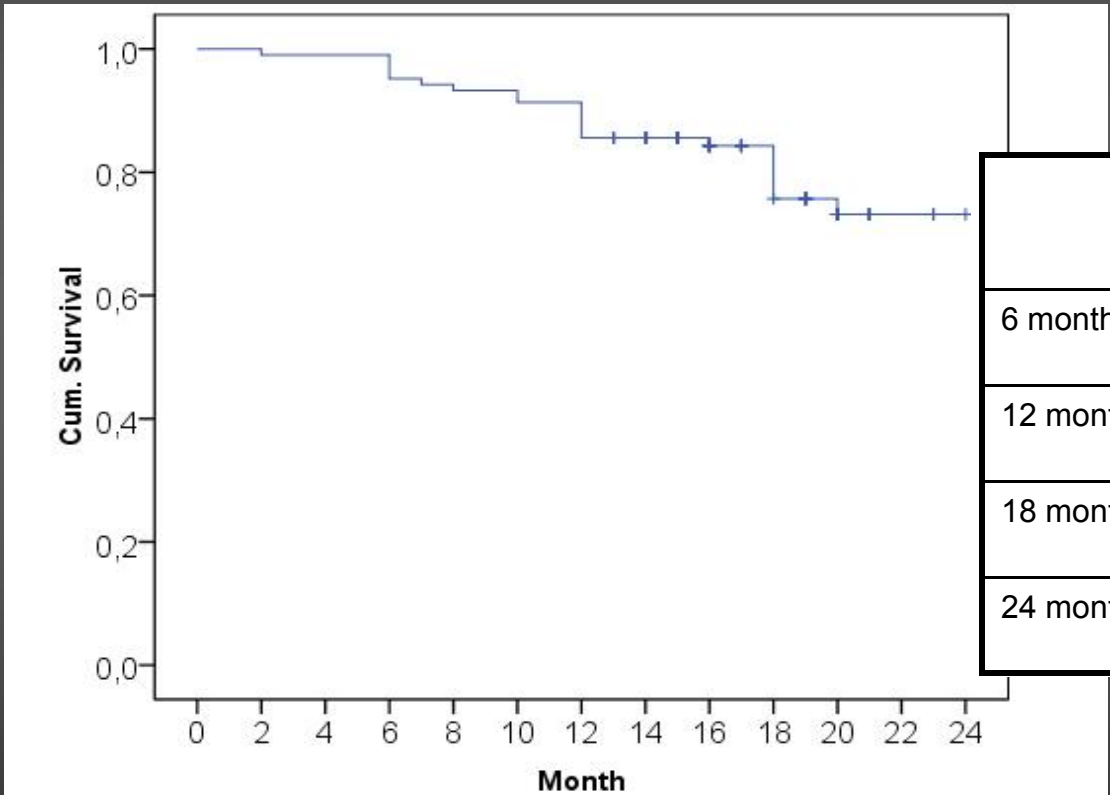
- Diameter:
  - 4.0 – 10.0 mm
- Length:
  - 40 – 150 mm
- Introducer:
  - 7F
- Working length:
  - 90 cm
  - 120 cm



IDEV®

# Leipzig SUPERA-Registry

## SFA-Registry (n=107)




| | Primary Patency | Assisted primary Patency | Secondary Patency |
|---|---|---|---|
| 6 month | 95.2% (SE 0.21) | 97.1% (SE 0.16) | 97.1% (SE 0.16) |
| 12 month | 85.6% (SE 0.24) | 92.3% (SE 0.26) | 93.3% (SE 0.25) |
| 18 month | 75.7% (SE 0.49) | 90.6% (SE 0.31) | 93.3% (SE 0.25) |
| 24 month | 73.2% (SE 0.53) | 88.3% (SE 0.37) | 93.3% (SE 0.25) |

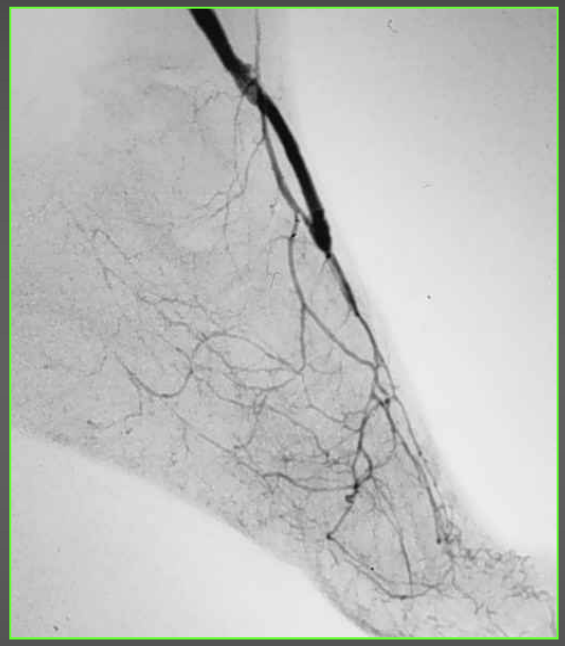
88 patients had an x-ray screening after 14.1 +/- 4 months:
No stent fractures detected!

# Characteristics of Patients with Infrapopliteal Obstructions

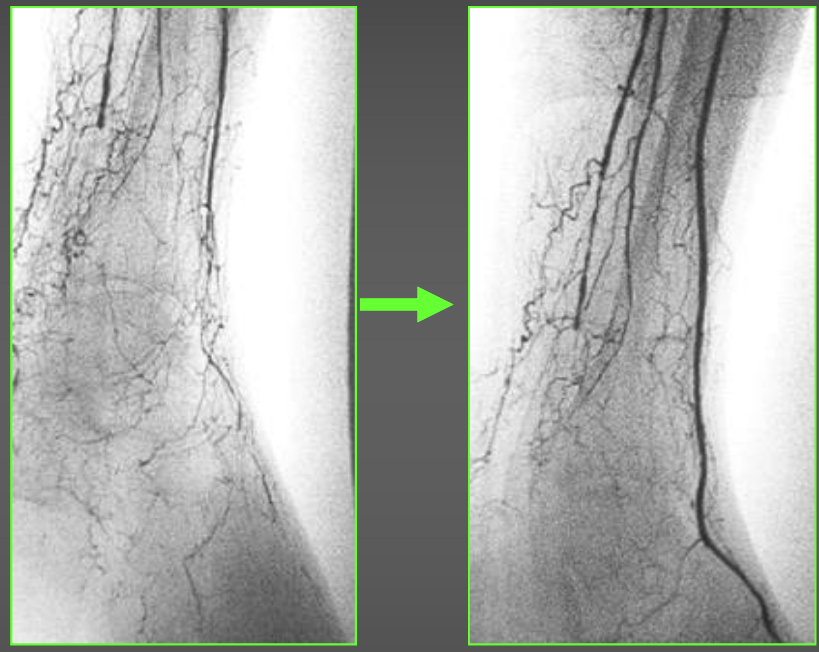
- Severe symptoms
  - Often critical ischemia
- Diabetes mellitus in up to 80%
- Older patients
- Significantly more concomitant diseases
  (Cardiac, cerebrovascular, renal, pulmonar)

# OP vs. Interventional Therapy

- **Surgery**



- **Interventional therapy**

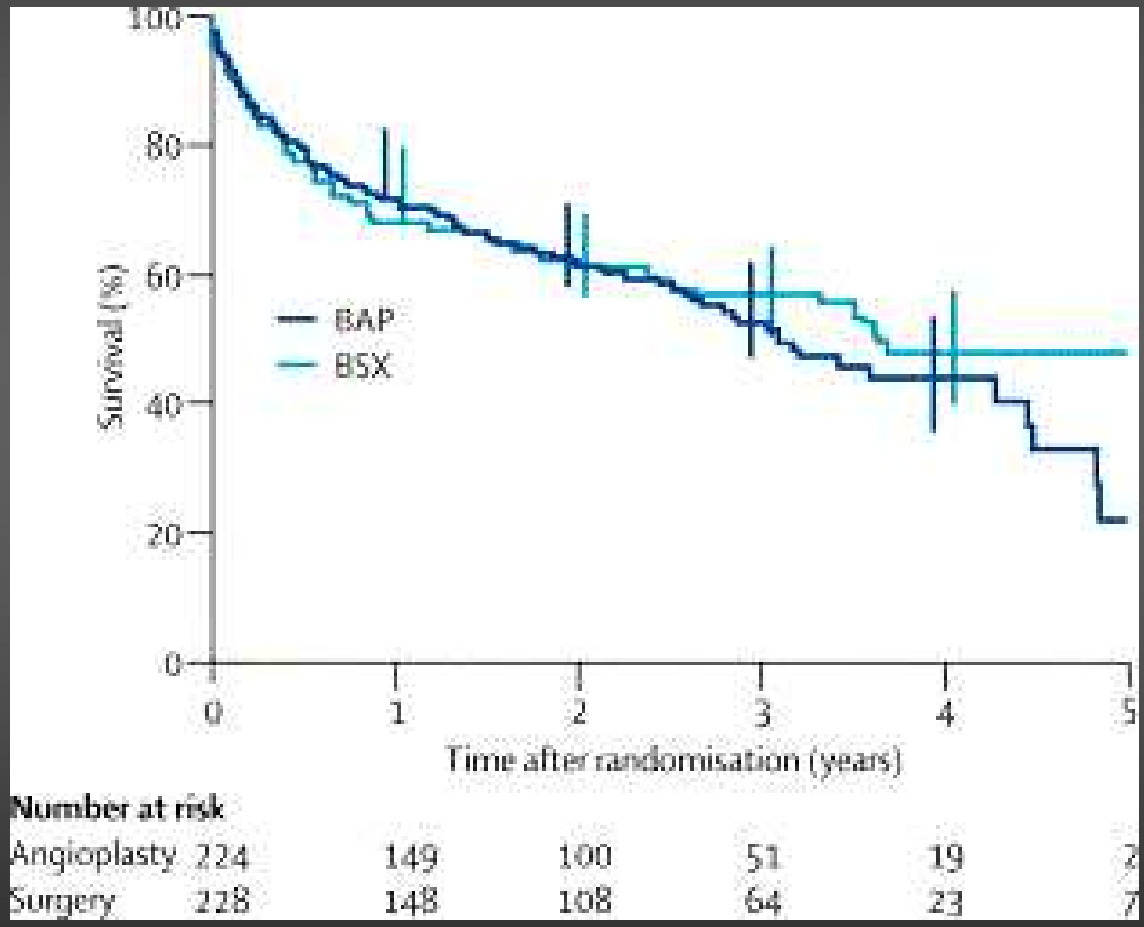


Decision depending on

- Comorbidity
- Availability of veins
- Morphology of the obstruction

# Bypass vs. Angioplasty in Severe Ischemia of the Leg (BASIL)

Amputation-free Survival




Surgery

PTA

*Lancet* 2005:366: 1925

# Recommendations for Treatment of Critical Limb Ischemia

## **T**rans**A**tlantic Inter-**S**ociety **C**onsensus 2007

**Recommendation 35**: Choosing between techniques with equivalent short- and long-term clinical outcomes

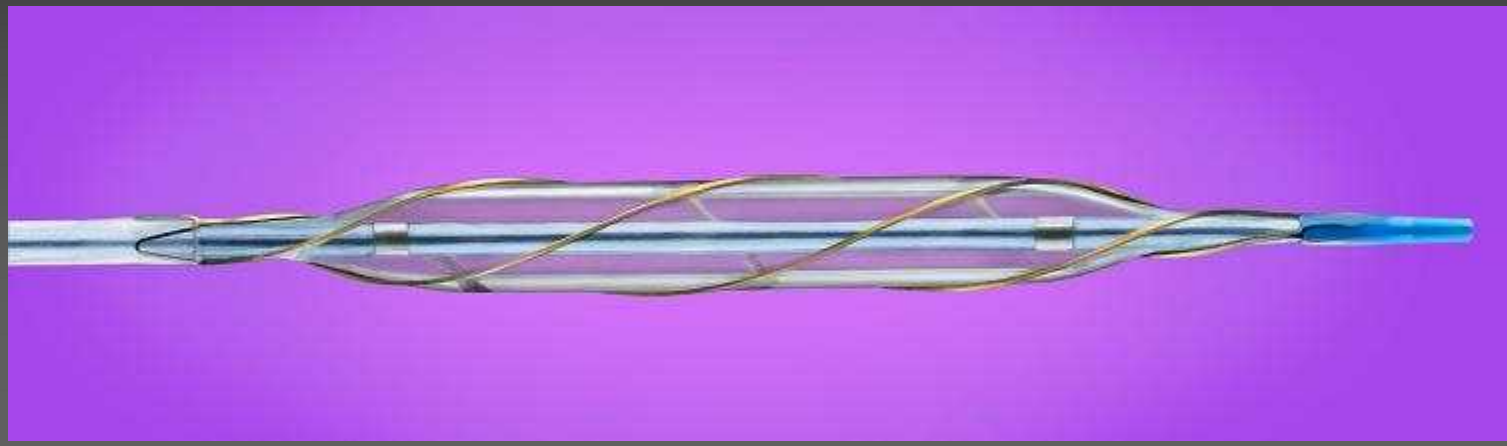
- In a situation where endovascular revascularization and open repair/bypass of a specific lesion causing symptoms of peripheral arterial disease give equivalent short-term and long-term symptomatic improvement, endovascular techniques should be used first [B]

The less invasive Technique should be preferred

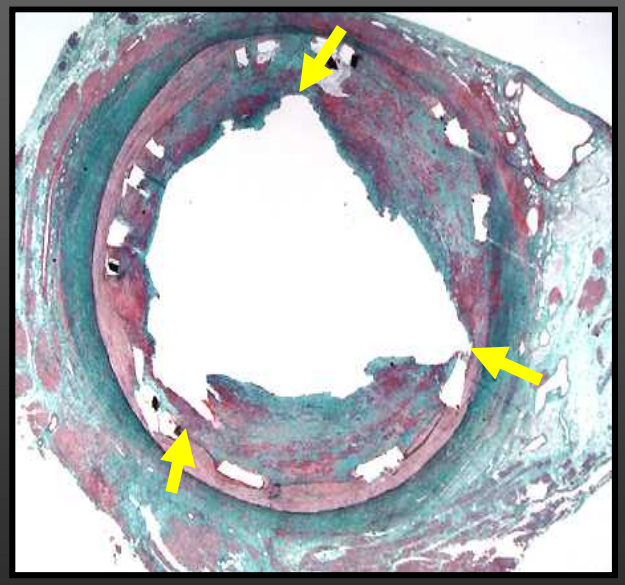
# Techniques for Recanalization of Infrapopliteal Lesions

- Cutting/ Scoring balloon
- Atherectomy
- Laser-recanalization
- Stent-implantation
- DES / DEB

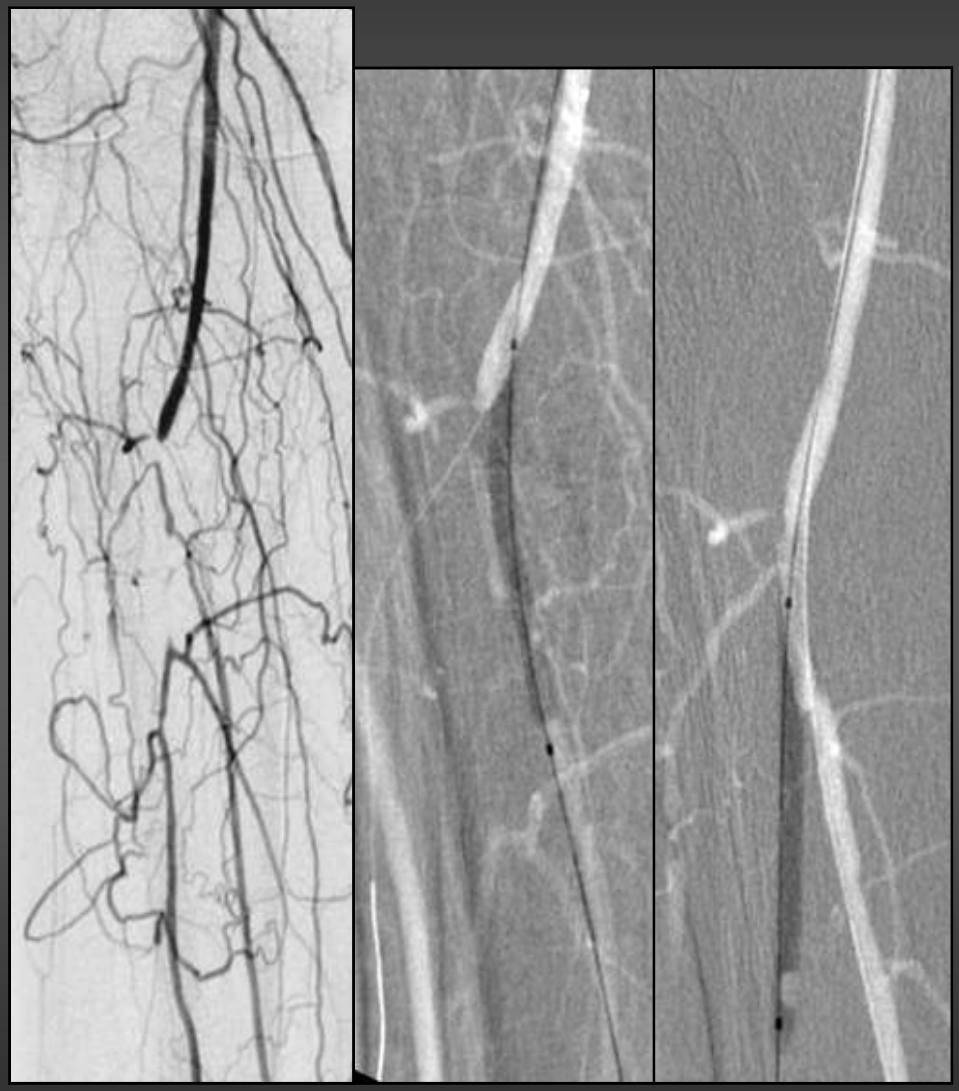
# Angioscuplt Scoring Balloon



Semi-compliant balloon with an external nitinol shape memory helical scoring edge

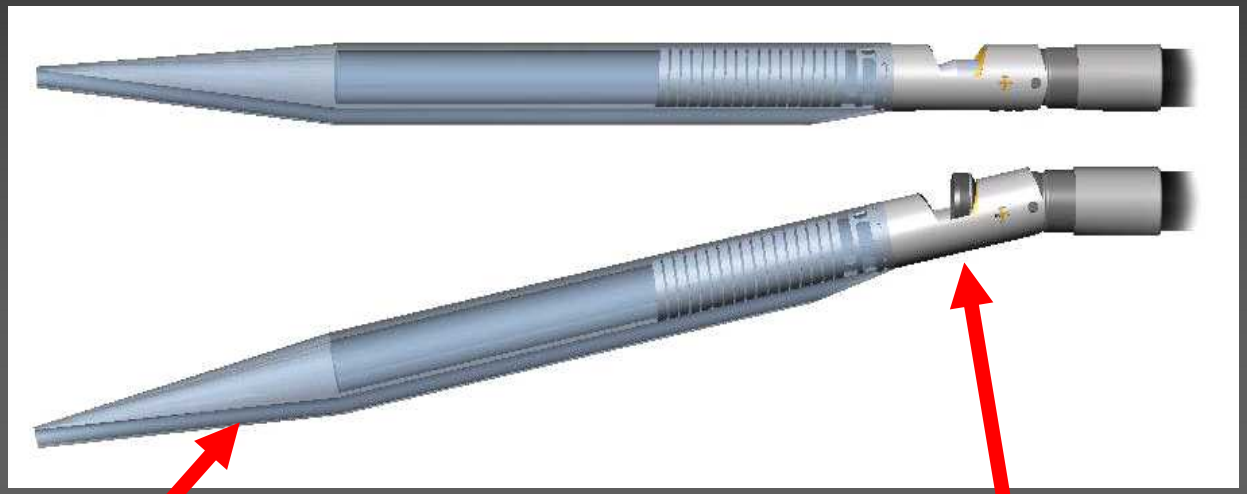


# Short Infrapopliteal Lesions



TPT-occlusion

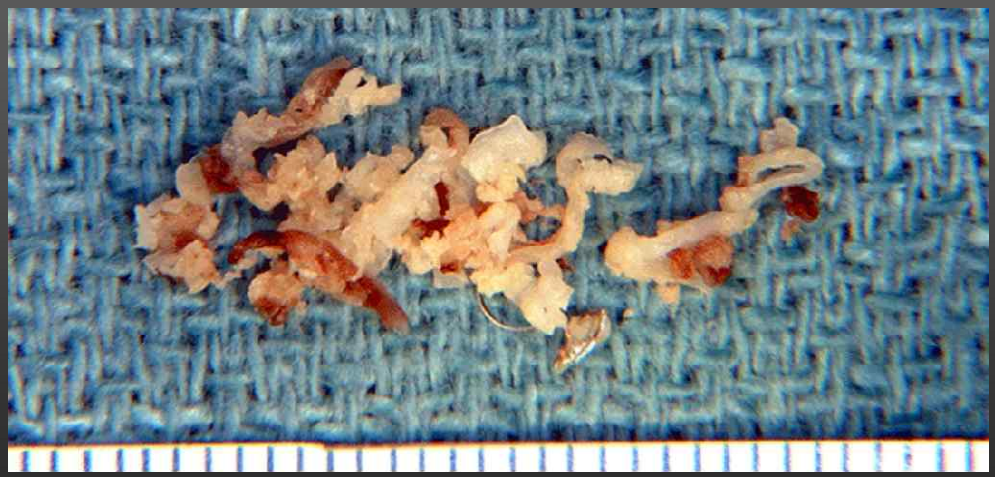
# Silverhawk Atherectomy Device



Tissue Storage Tip

Cutter

Tissue excised from the lesion



# ZilverHawk Experience BTK

- 36 patients, 53% CLI
- 49 infrapopliteal lesions

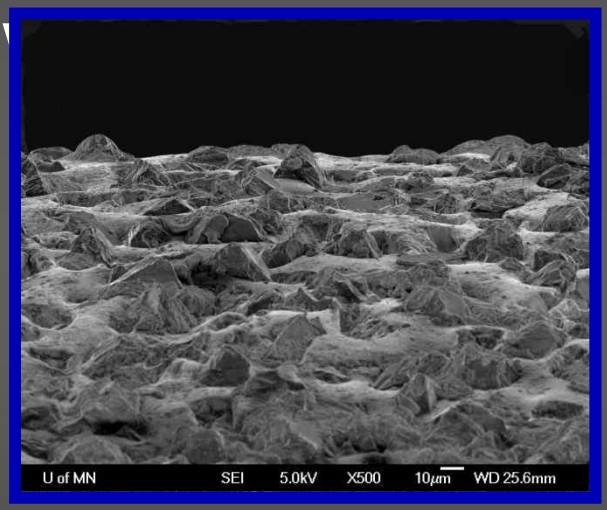
- 98% technical success using the SilverHawk

- 2-years follow-up
  - No major amputation, no bypass-surgery
  - Primary patency (duplex) 60 %

Zeller et al., *J Endovasc Ther* 2007

# CSI Orbital Atherectomy System (OAS)

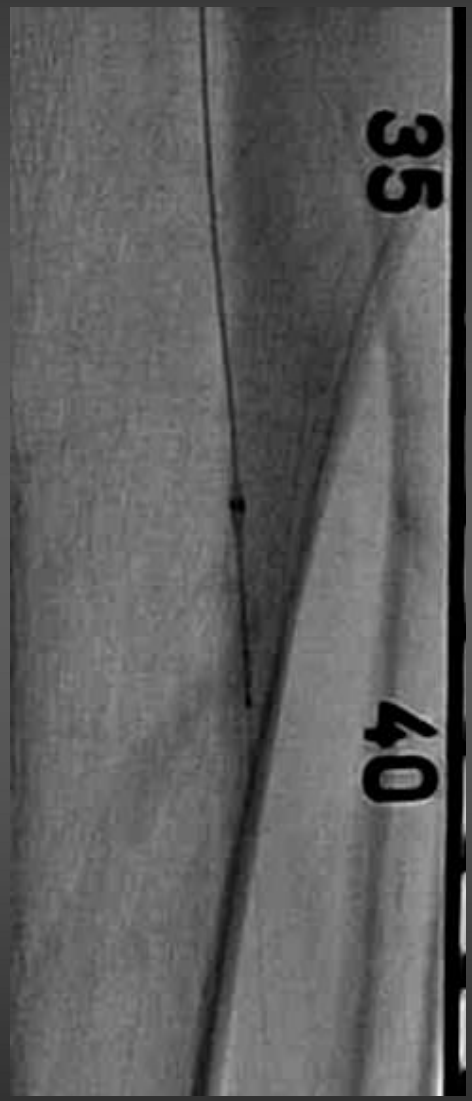
- Rotational atherectomy system using an excentric diamond cro
- Crown sizes
  - 1.2 mm
  - 1.7 mm
  - 1.9 mm
- Three different speeds:
  - 80.000 rpm
  - 140.000 rpm
  - 200.000 rpm





# OAS Atherectomy System

TPT-occlusion

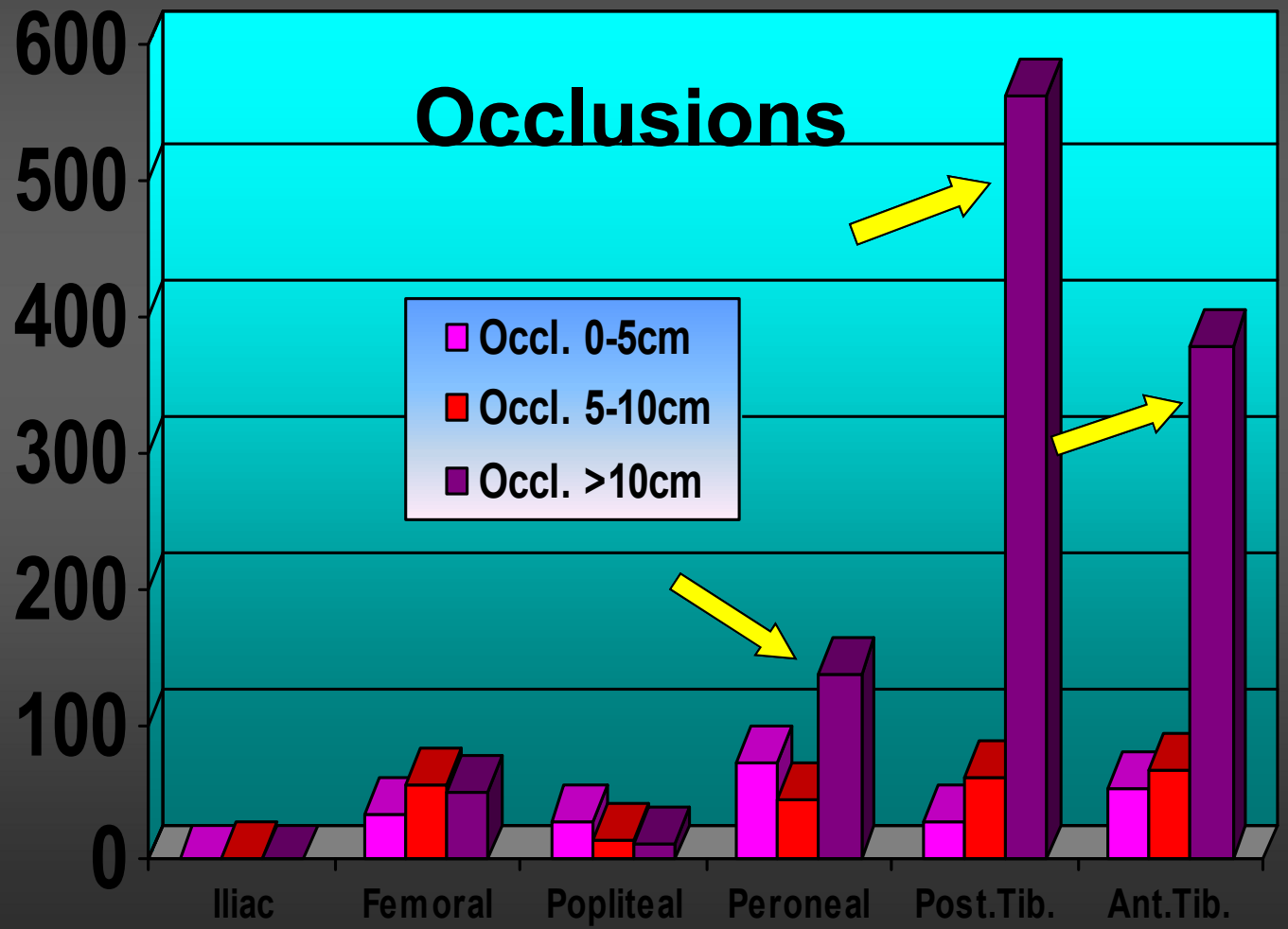



OAS 1.7 mm


Stand-alone result

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

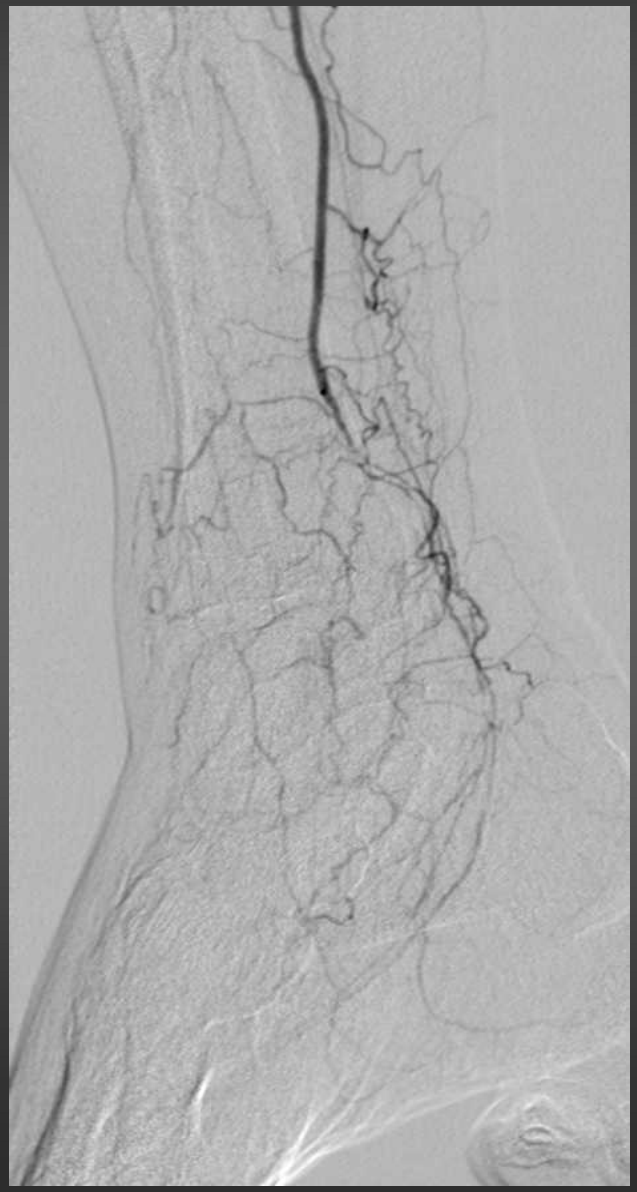
(Graziani et al. unpublished data)

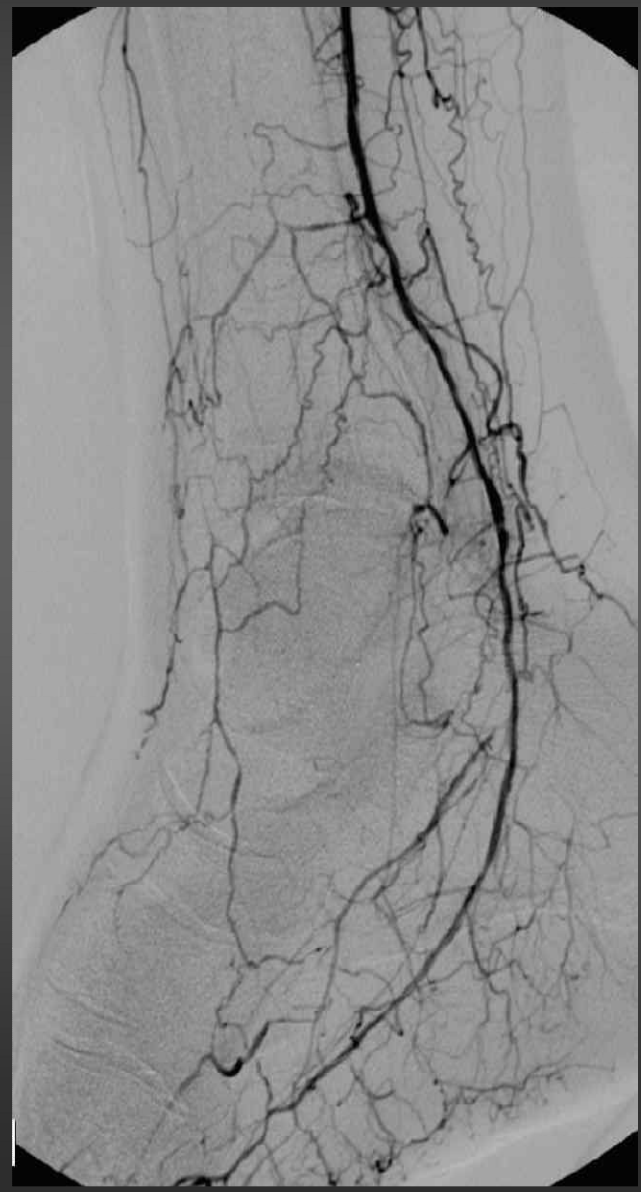


# Equipment for PTA of Extensive Infrapopliteal Lesions

- 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. Pacific Extreme (Invatec)
    - OTW 0.014“ eg. Amphirion (Invatec)

# 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 %)**

Schmidt et al. LINC 2006

# 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 |

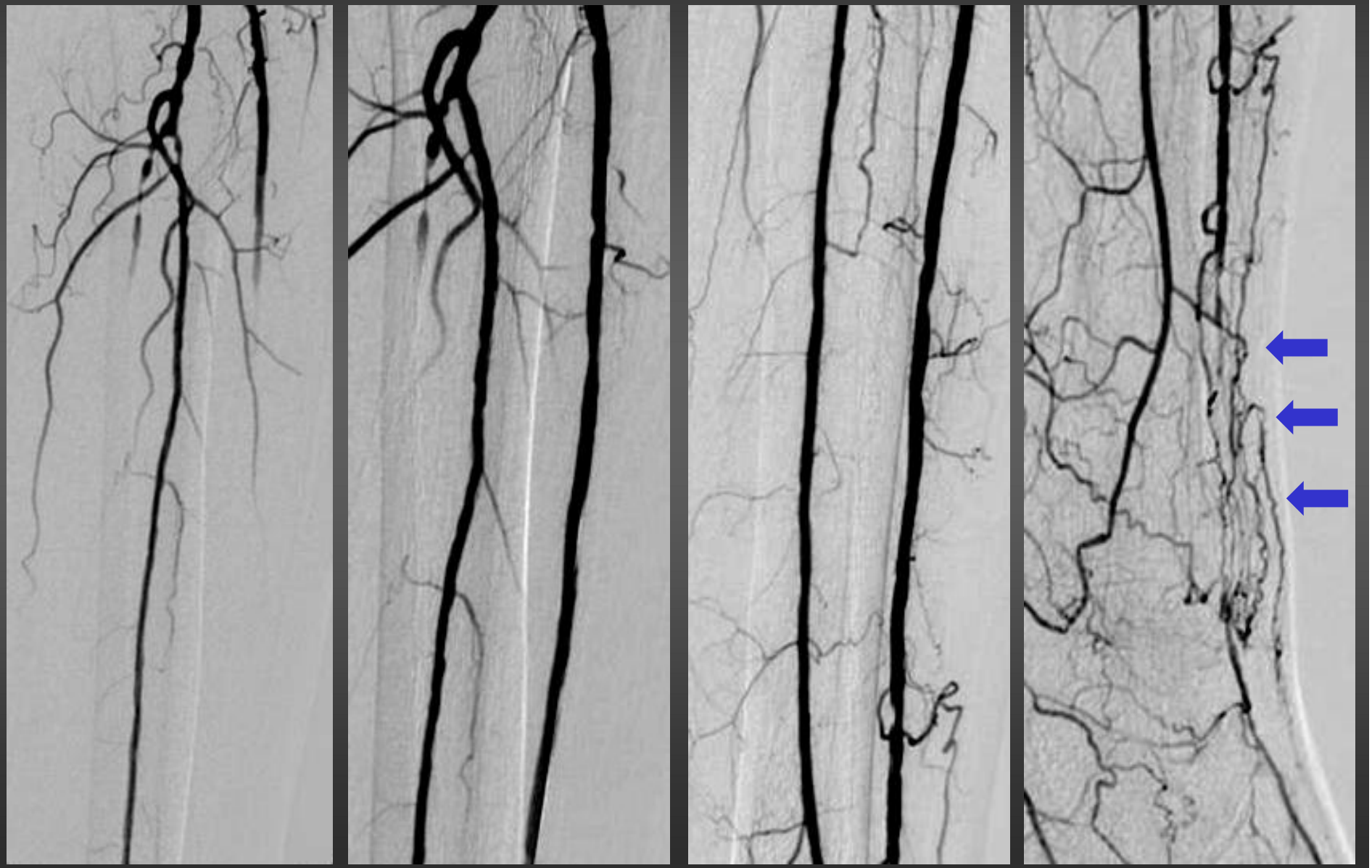
Schmidt et al. LINC 2006

# How can we improve the results of BTK angioplasty?

- Revascularization of multiple vessels ?

# Angioplasty in Diabetes-Patients

# Angioplasty in Diabetes-Patients



# Angioplasty in Diabetes-Patients

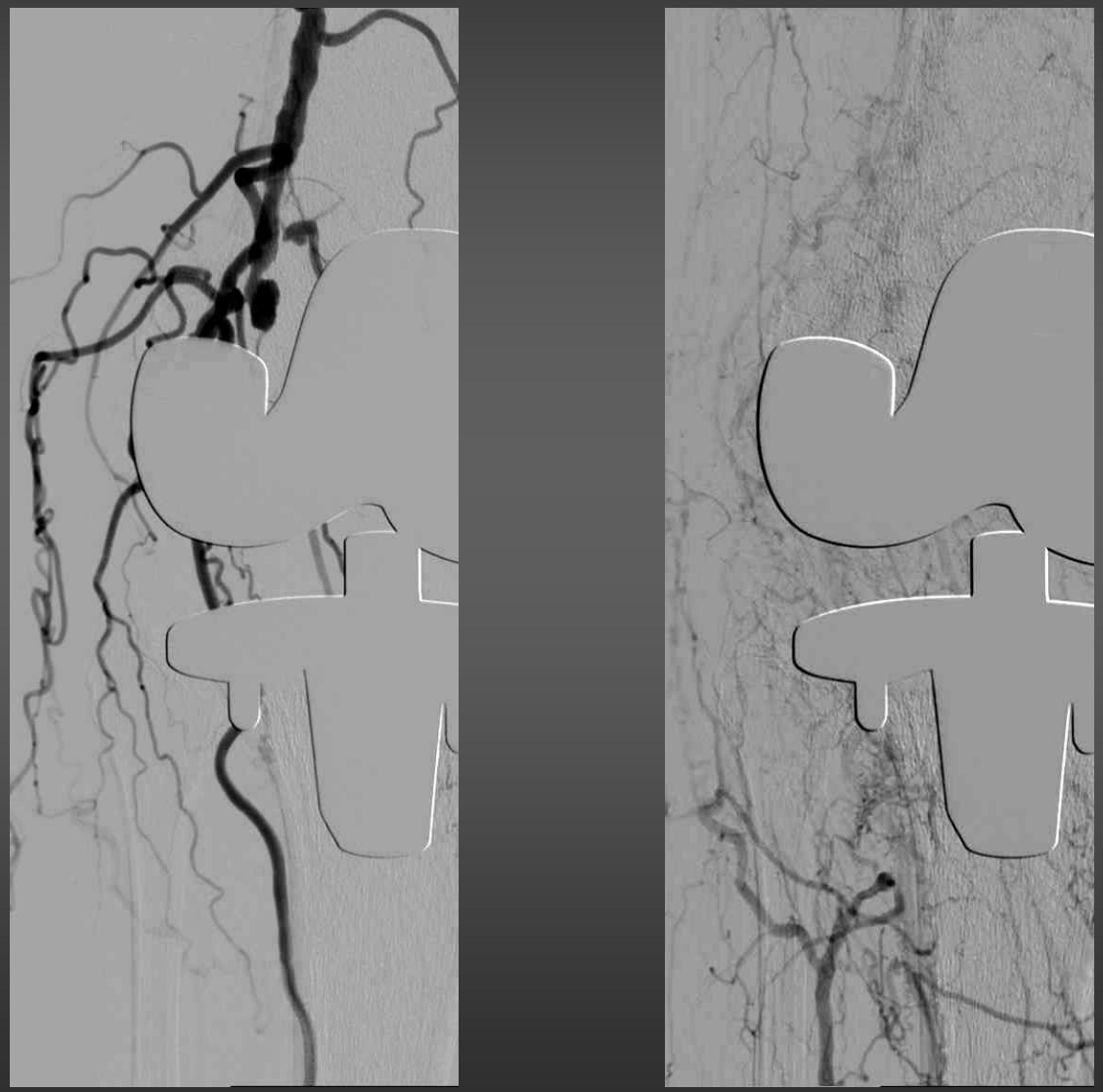
# Angioplasty in Diabetes-Patients

# How can we improve the results of BTK angioplasty?

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

# Transpedal Recanalization
# - Sheathless lechnique -

# Transpedal Recanalization



# Transpedal Recanalization

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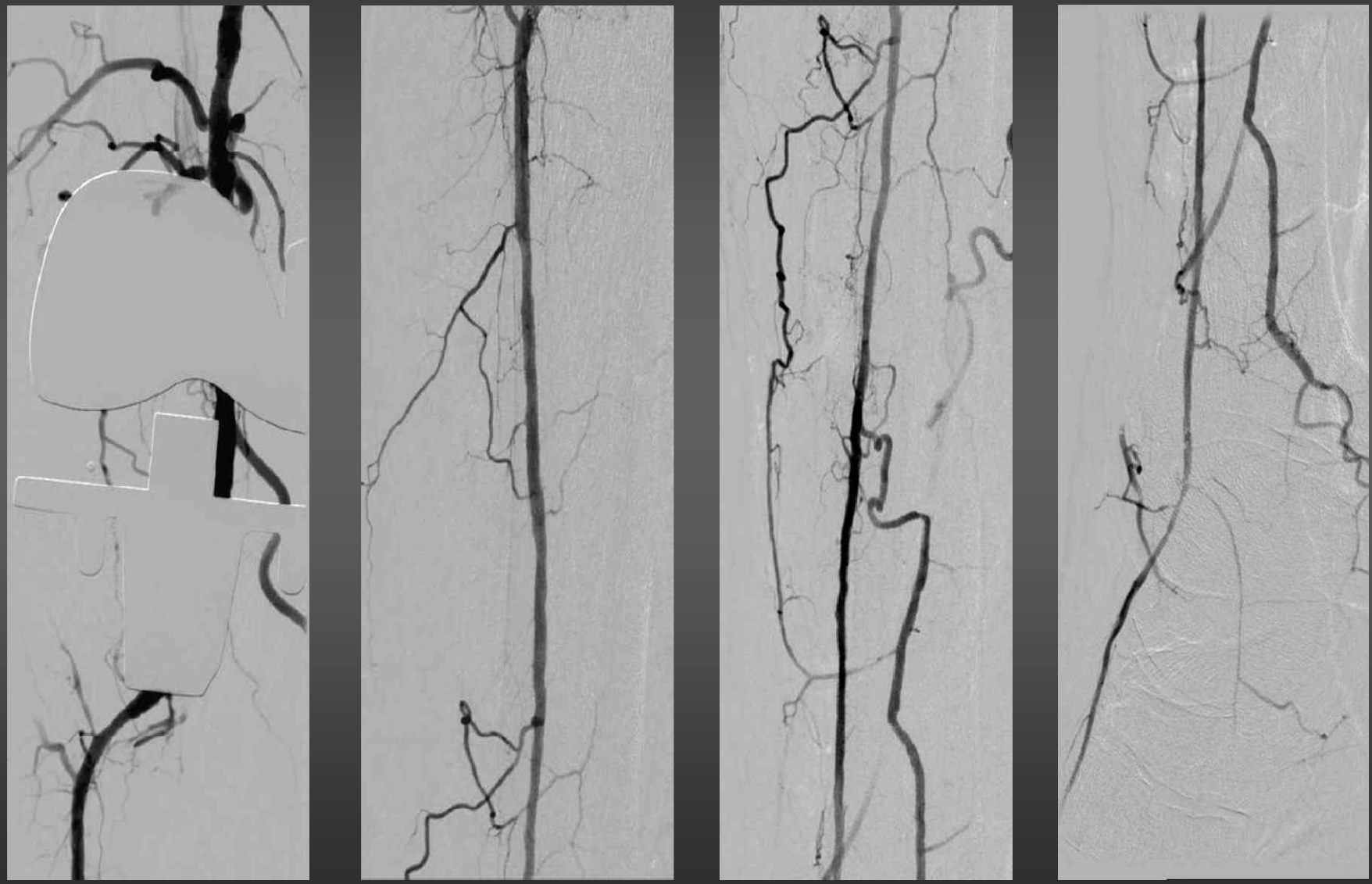


# Transpedal Approach for infrapopliteal Angioplasty

- 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

# 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

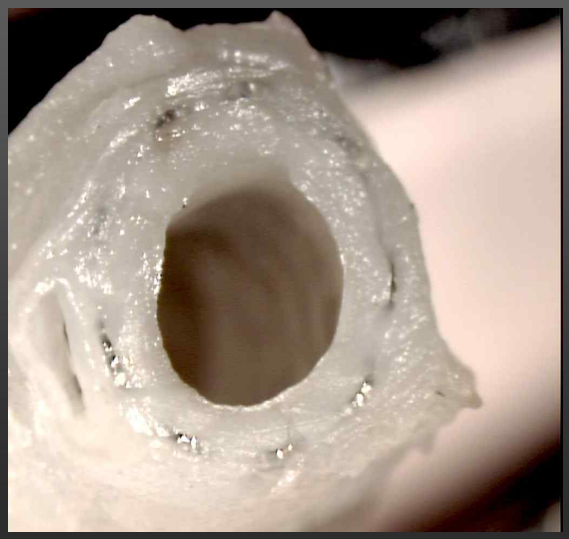
# Stents dedicated for Infrapopliteal Arteries

- **Selfexpanding stents**
  - Astron Pulsar (Biotronik)
  - Xpert-Stent (Abbott)
  - Maris Deep (Invatec)
- **Balloon-expandable stents**
  - Chromis Deep (Invatec)

| Ø | Max. length |
|---|---|
| 3, 4 mm | 80 mm |
| 2-4 mm | 80 mm |

# 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%

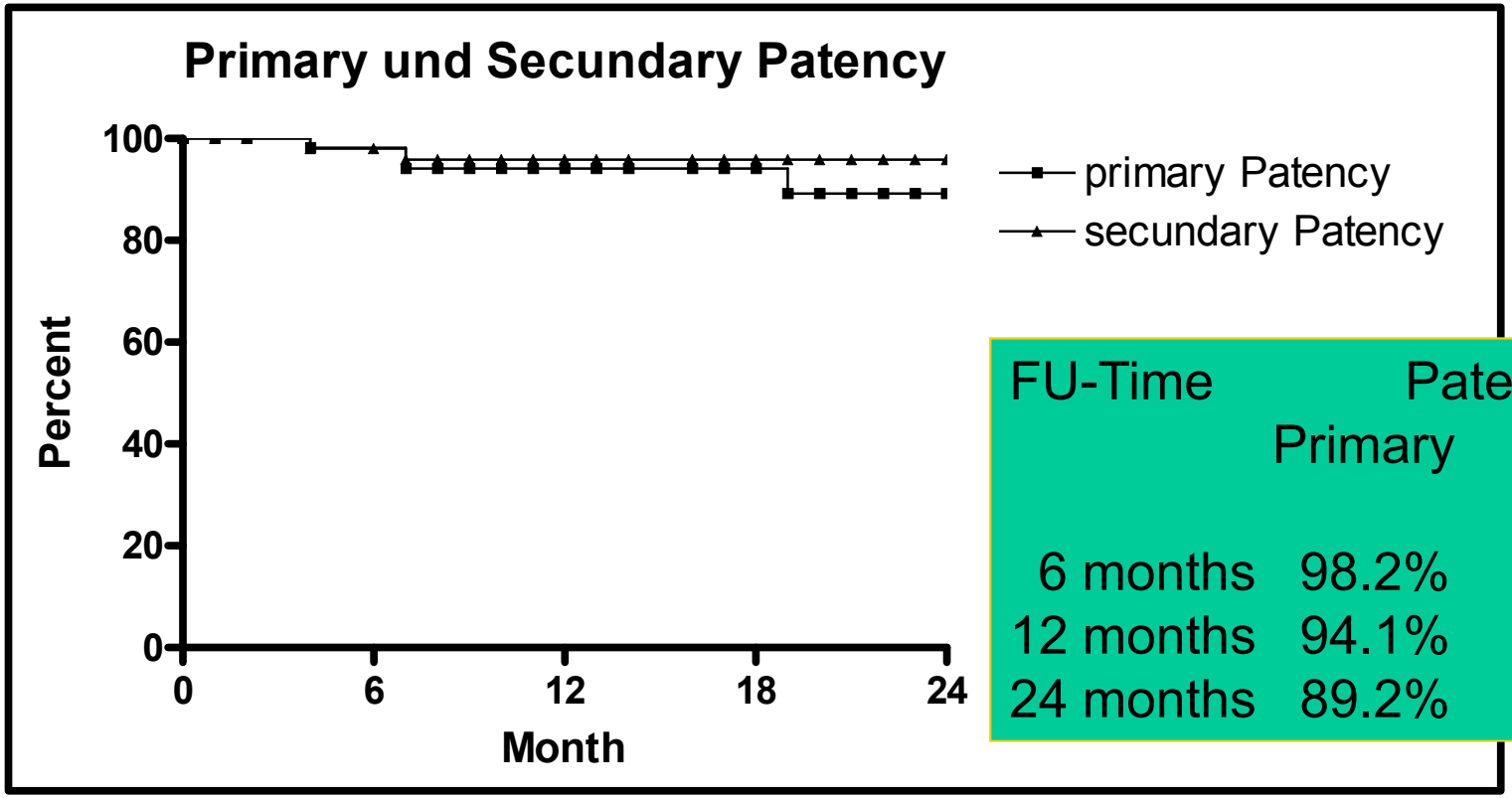
Scheinert D et al. EuroPCR 2003

# DES vs. Bare-metal Stent in Infrapopliteal Arteries

- Non-randomized comparison BMS vs. Cypher
- **6-months angiographic binary restenosis**

| | BMS | DES |
|---|---|---|
| Scheinert 2006 | 56 % | 0 % |
| Siablis 2006 | 55 % | 4 % |
| Bosiers 2006 | - | 0 % |

# Cypher – BTK Registry
# Angiographic Stent Patency



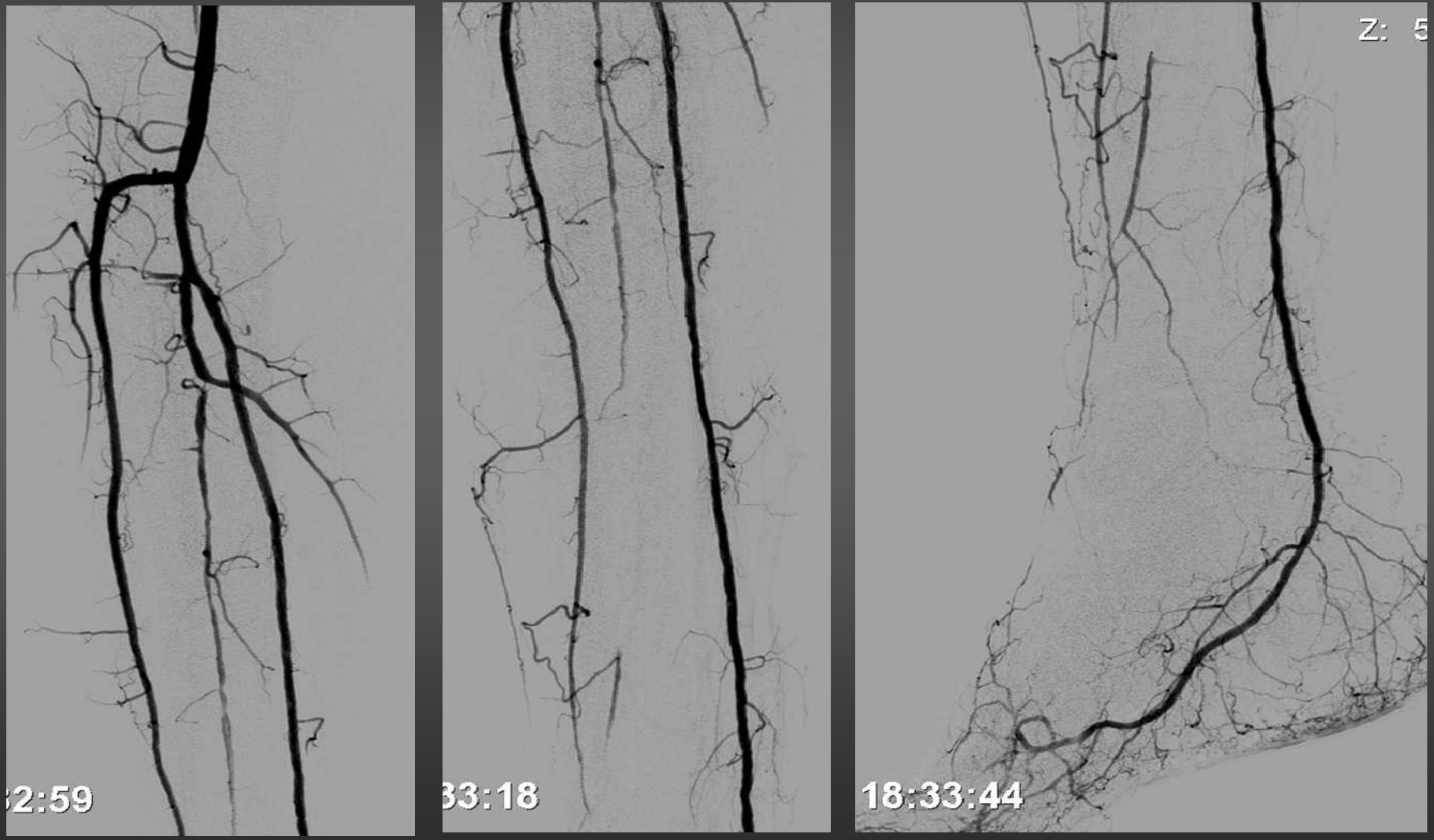

| FU-Time | Patency | |
|---|---|---|
| | Primary | Secondary |
| 6 months | 98.2% | 98.2% |
| 12 months | 94.1% | 95.9% |
| 24 months | 89.2% | 95.9% |

Log Rank = 0,4551

Scheinert D et al. TCT 2006

# Cypher for BTK

# Cypher for BTK 6-months FU

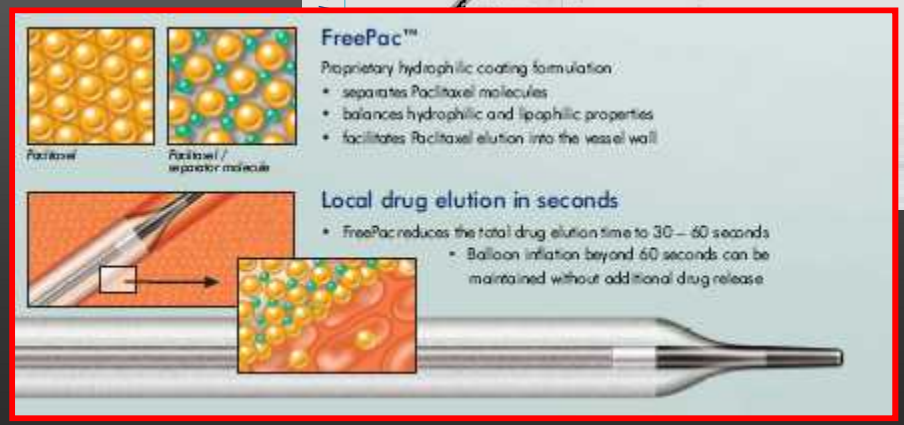


# Novel Treatment Concept

IN.PACT AMPHIRION

**Paclitaxel-eluting PTA Balloon Catheter**

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

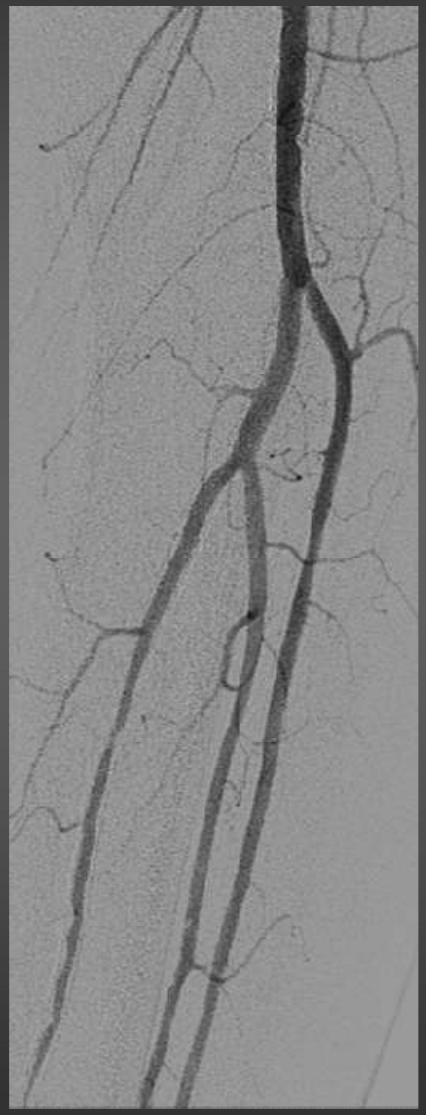




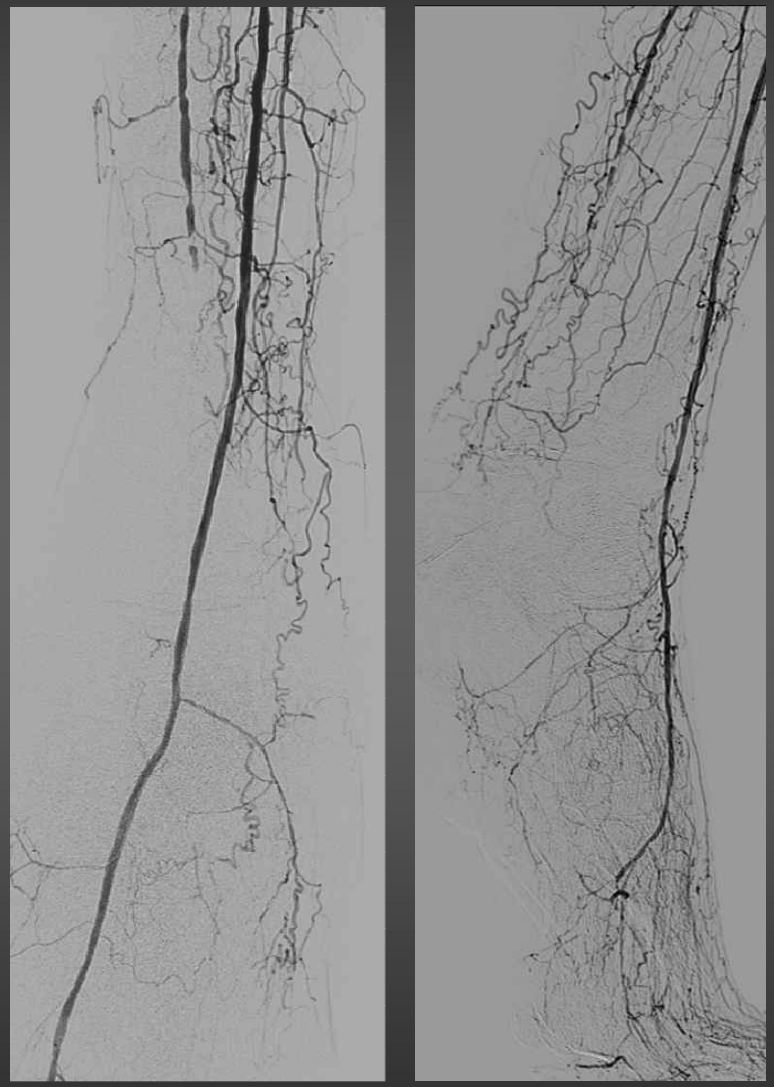

INVAtec Innovative Technologies

**Worldwide first case performed LIVE @ LINC 2009**

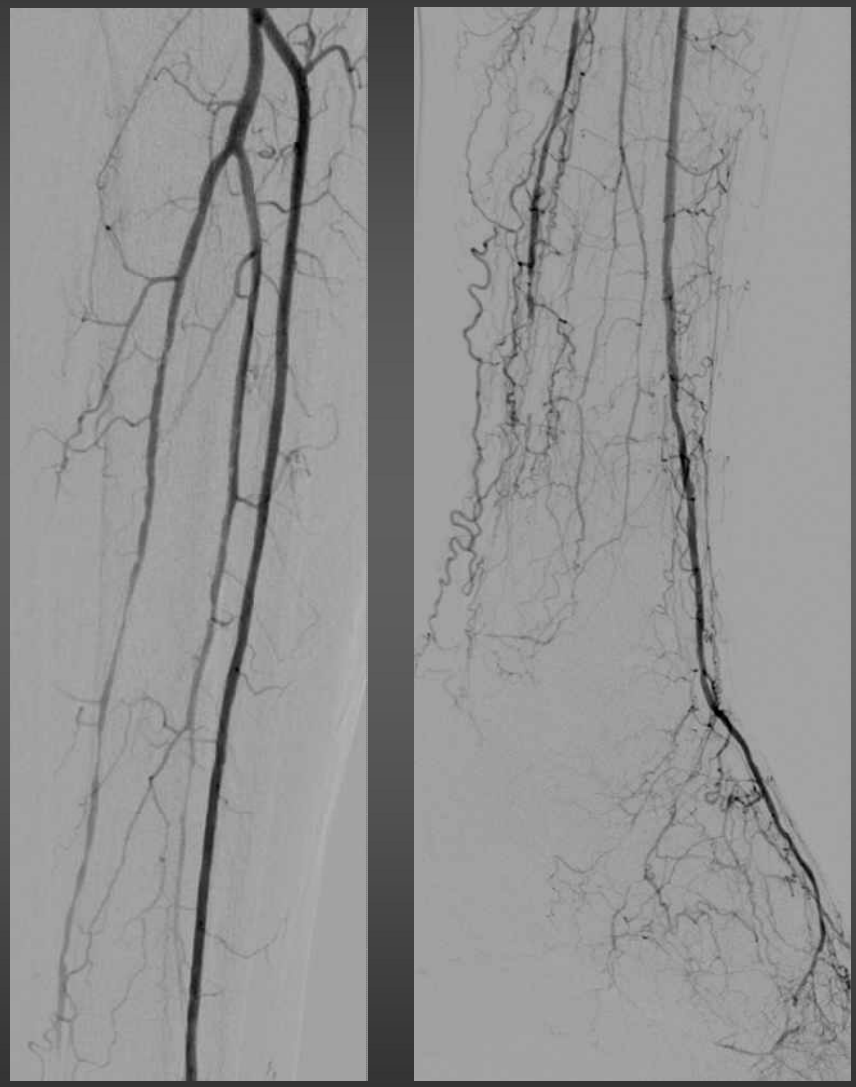
# Leipzig Experience with DEB BTK



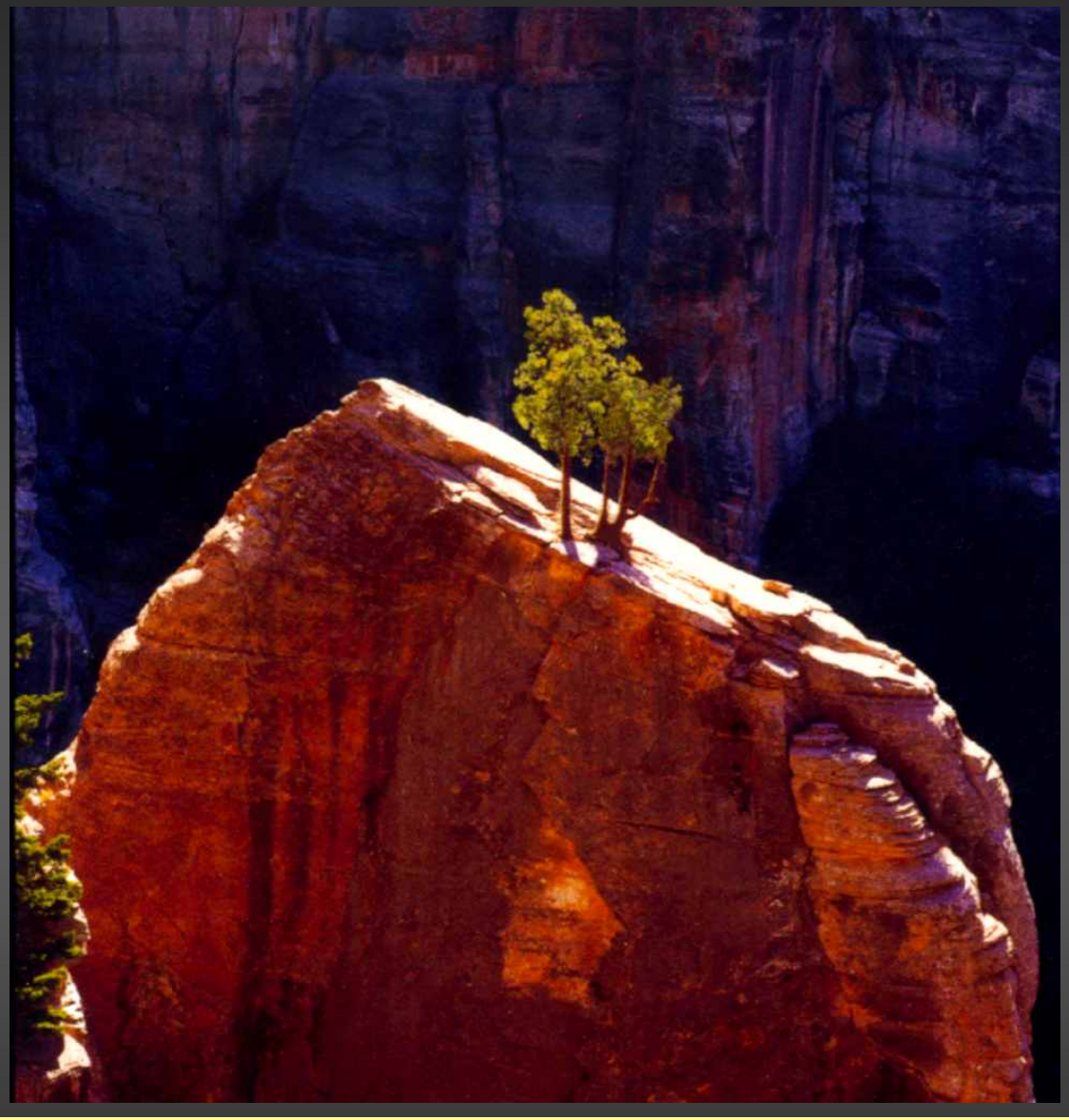
# Leipzig Experience with DEB BTK



After 2.5/120mm In.PACT Deep



3 months – follow-up



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