Atherectomy for vessel prep (rational – evidence and clinical case)

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DISCLOSURE OF INTEREST

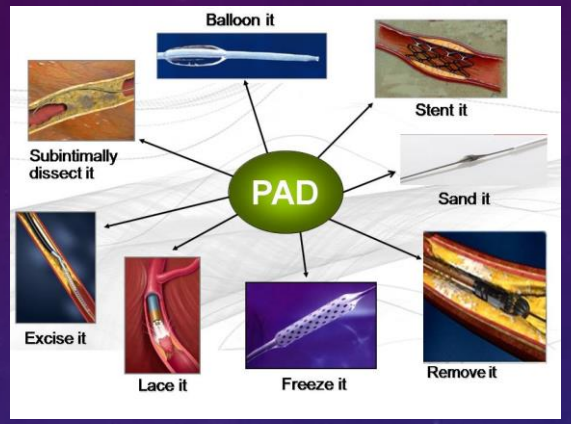
Disclosure

Speaker name: Tibor Balazs MD

- ☐ I have the following potential conflicts of interest to report:
- ■ Consulting (Boston Scientific Corporation)
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☐ I do not have any potential conflict of interest

Treatment of PAD and CLI

„leave nothing behind“ concept

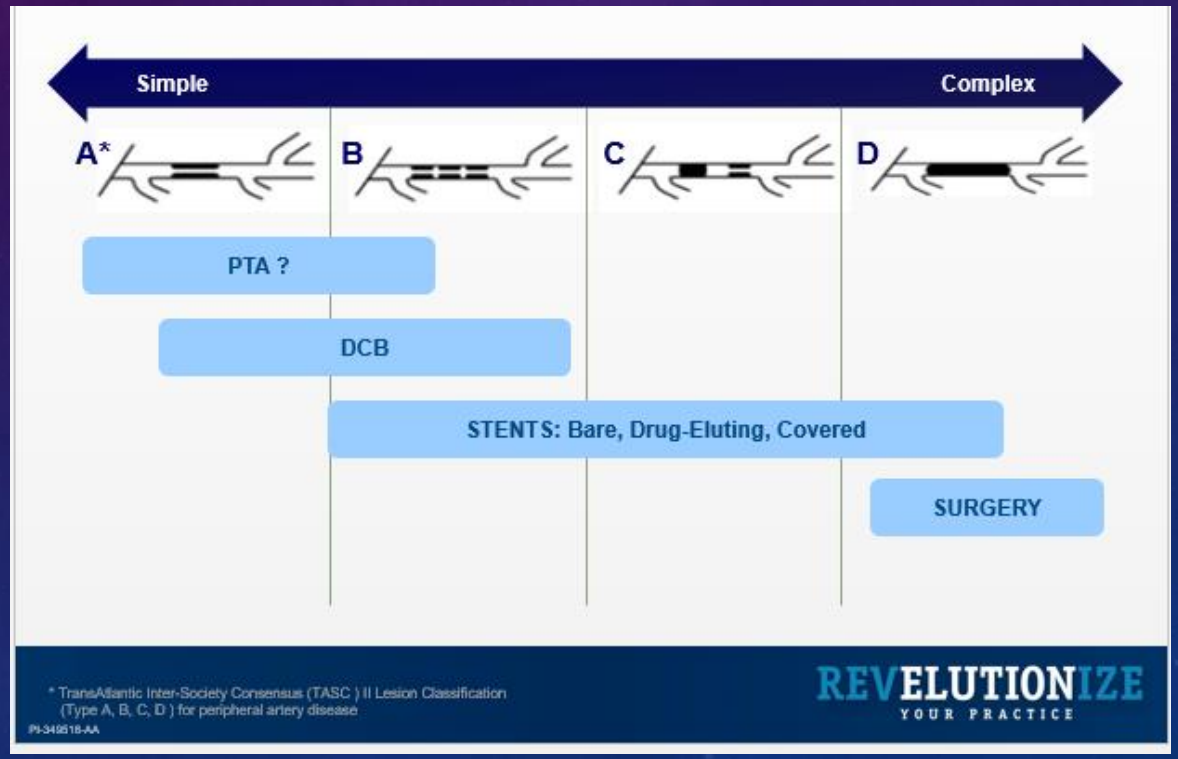


- Primary goal is the re-establishment of pulsatile, straight line flow to the foot.
- Over the past decades major advancements have been made in the treatment of PAD
- The “tool box” has expanded with several instruments : cutting/scoring balloons, wires, stents, atherectomy devices, now accompanied by the drug-eluting therapies
- The „leave nothing behind“ strategy has gained in popularity, with the aim of leave the treated vessel without stents and intact for potential future treatments and avoid potential stent-related problems. [1]

1. Optimizing Strategy in Peripheral Vascular Interventions: The Role of JETSTREAM® Atherectomy Nicolas W. Shammas, MD, EJD, MS, FACC, FSCAI, FICA

SFA Lesion Complexity Drives Therapy Selection

- There is little debate that TASC II A and B lesions are best suited for endovascular therapies.
- Although the TASC II committee recommends surgical therapy for TASC C and D lesions, these are now increasingly being handled using an endovascular approach.[1,2]

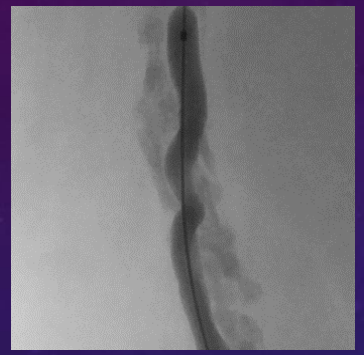


1. Addressing Challenges in the Treatment of Infrainguinal Arterial Disease: an Endovascular Specialist's Perspective Nicolas W. Shammas, MD, EJD, MS, FACC, FSCAI, FICA, The Journal of Invasive Cardiology, September 2013 Volume 25/ Supplement B
2. TransAtlantic Inter-Society Consensus (TASC) II Lesion Classification (Type A, B, C, D) for peripheral artery disease

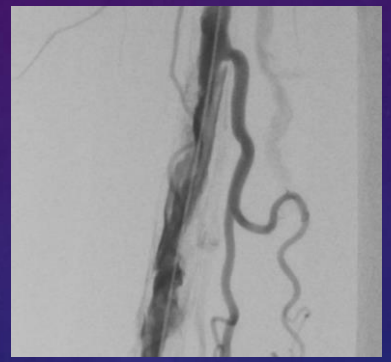
Challenges with complex calcified lesions

- In lot of cases there is an inability to dilate the lesion with higher dissection and perforation rates, leading to bail out stenting, higher stent fracture rates and subsequent lower patency rates

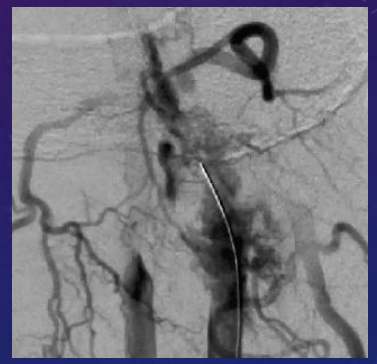
Suboptimal Outcomes



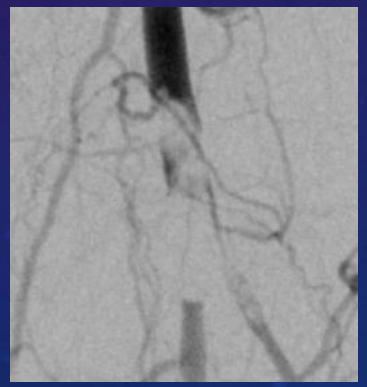
Dissections



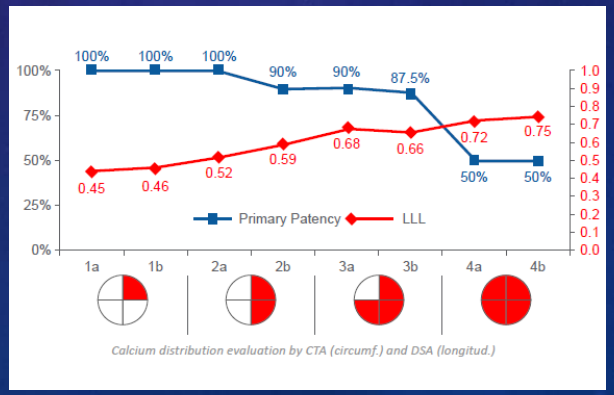
Perforation



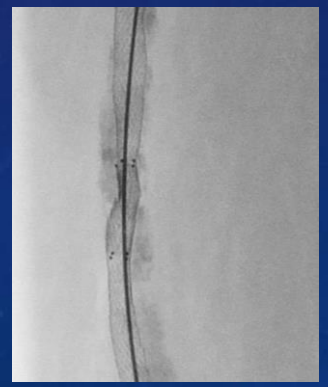
Embolisation



Limited Drug Uptake



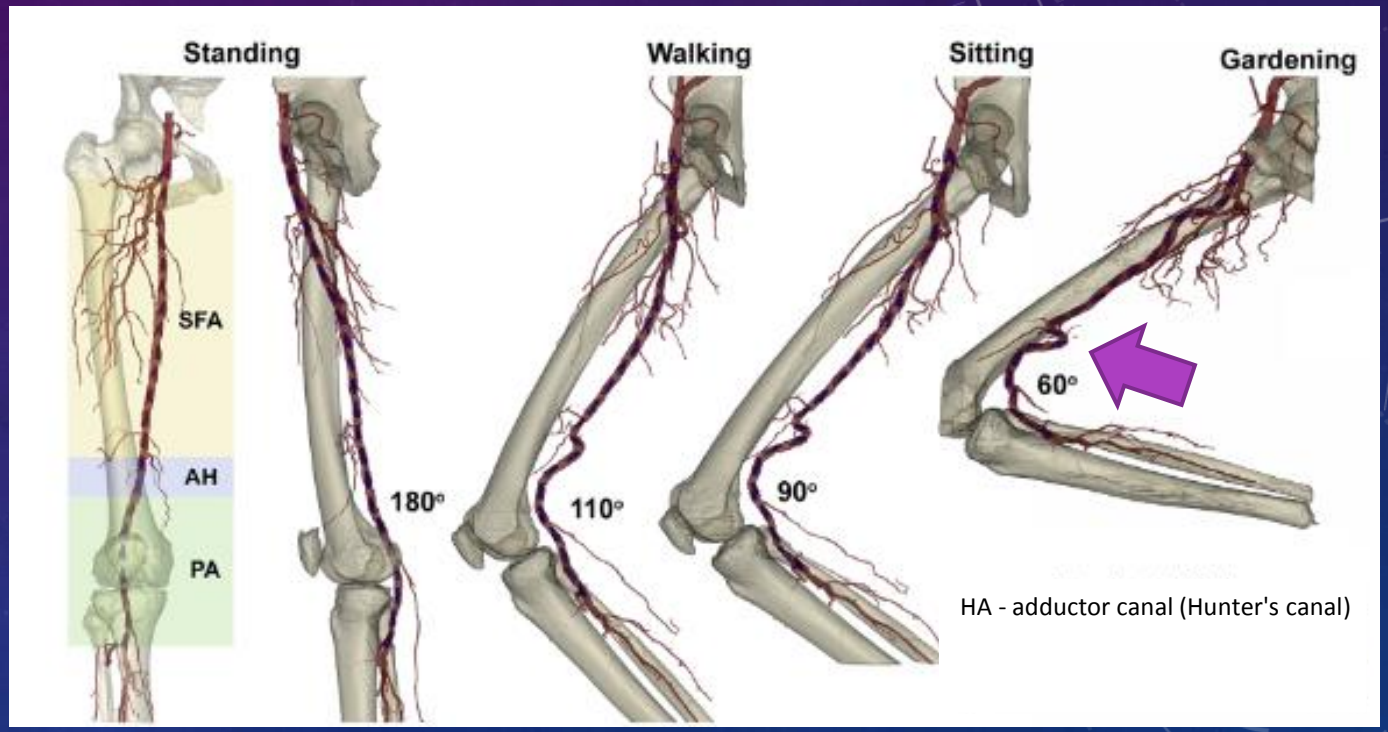
Suboptimal Stent Expansion



F. Fanelli – Cardiovasc Interv Radiol 2014

Mechanical deformation of FP segment

- Stent placement is not advisable in certain anatomical locations
- Severe mechanical impact at flexion points such as the hip and knee joints could provoke stent deformation or fracture leading to arterial occlusion
- Axial compression and bending of the FPA likely play significant roles in FPA disease development and reconstruction failure[1]

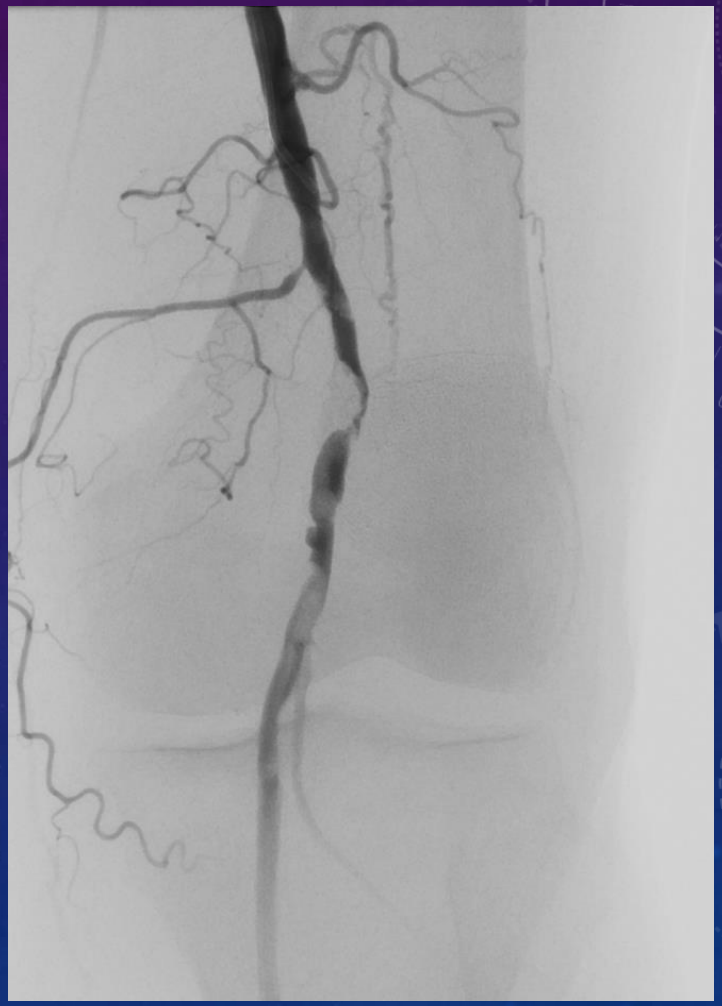


1.Limb flexion-induced axial compression and bending in human femoropopliteal artery segments William Poulson, MD,a Alexey Kamenskiy, PhD

Case 1 – Heavily calcified prox. PA

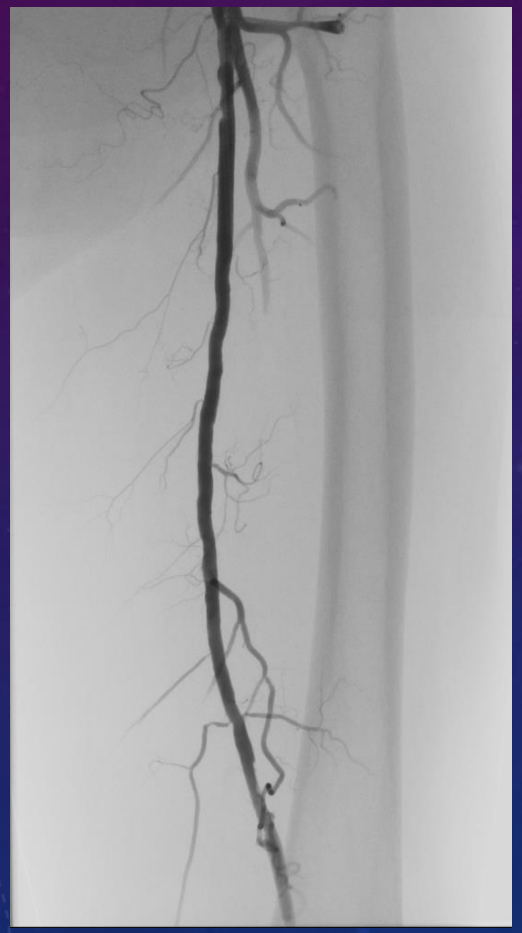
Clinical History:

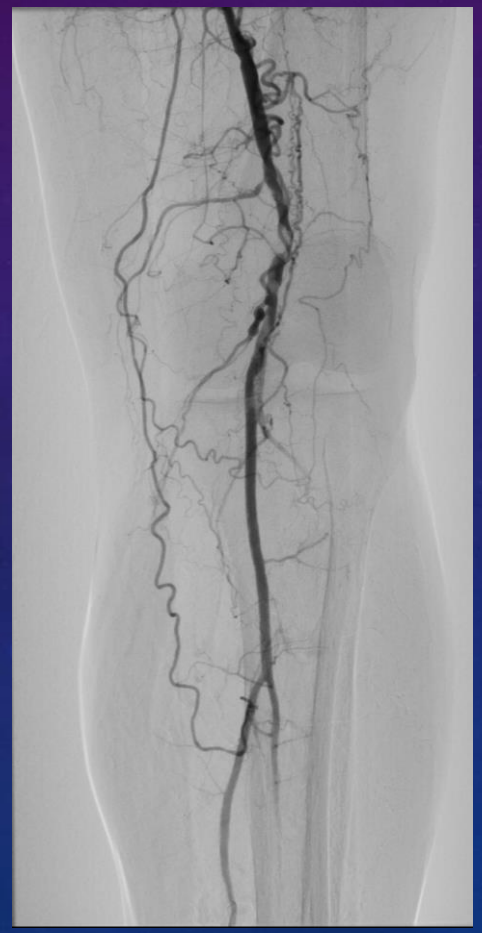
- 79-year-old high risk patient presented with clinical signs of severe, limiting claudication, and rest pain during night in the left calf.
  - Insulin dependent DM (1980) with end organ damage
  - post MI (1984), 3VD,
- Previous ultrasound examination had demonstrated severe calcified stenosis of the P2 segment of the popliteal artery
- Resting ankle-brachial index in the left leg of 1,27 (mediocalcinosis)

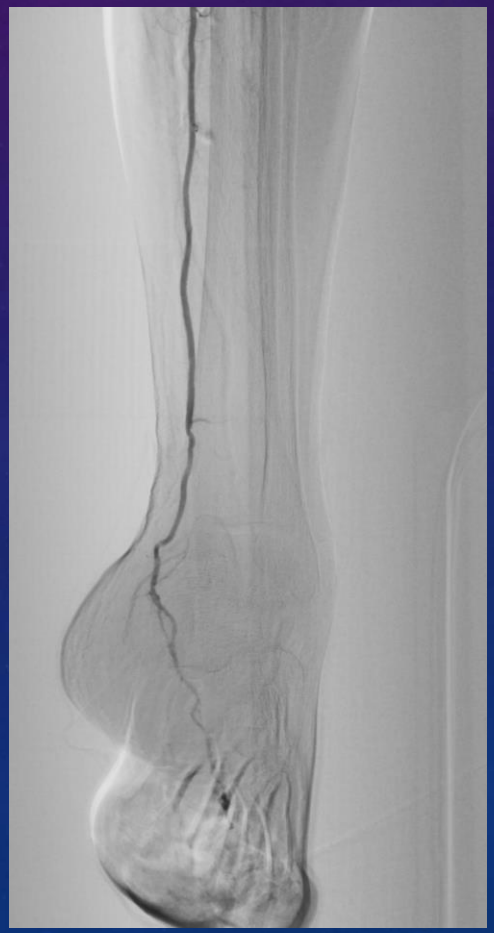


Case 1 – Heavily calcified prox. PA

- Ipsilateral antegrade approach from the CFA, selective right FP angiography demonstrated severe stenosis of the PA.



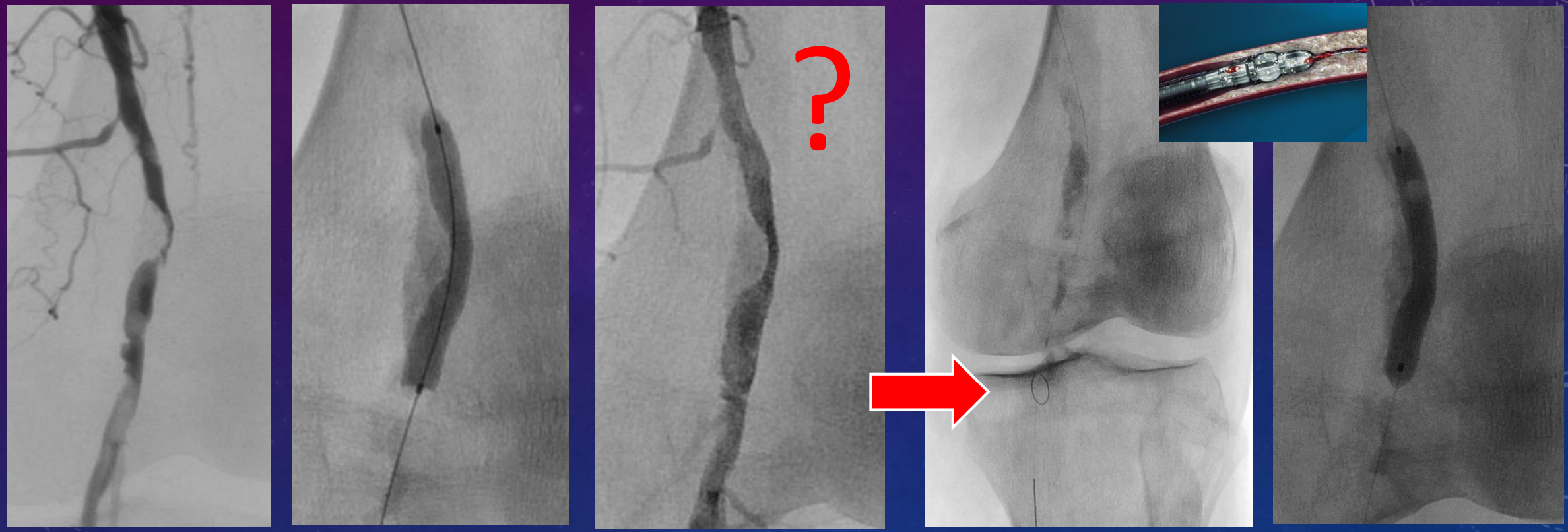




Case 1 – Heavily calcified prox. PA

- Balloon angioplasty - Early recoil

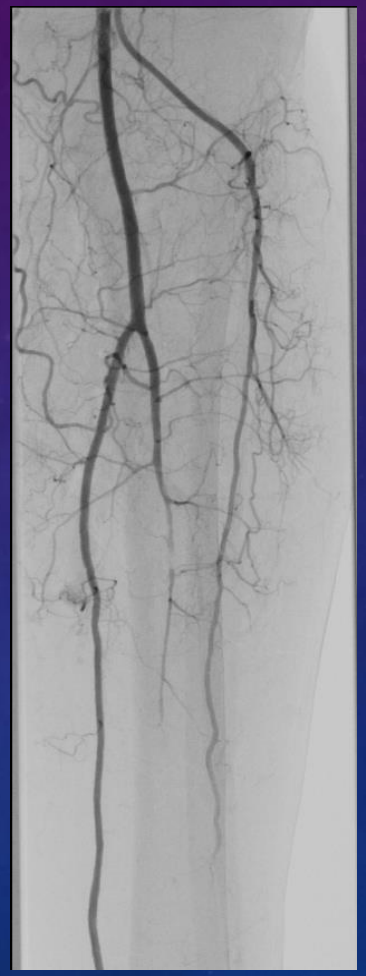
Plaque modification - rotational atherectomy

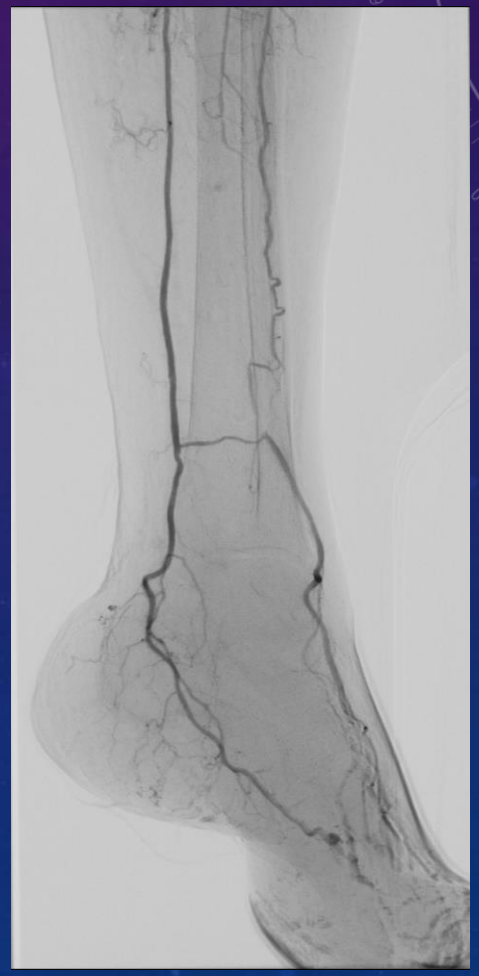


Heavily calcified eccentric lesion of the proximal PA (A). High pressure balloon angioplasty (B). Early severe recoil (C). Distal EPD (D) 6-mm X 40-mm Ranger drug coating balloon (Boston Scientific Corporation) angioplasty after plaque modification by JETSTREAM Atherectomy system 2.1 mm, the treated vessel is more compliant (E).

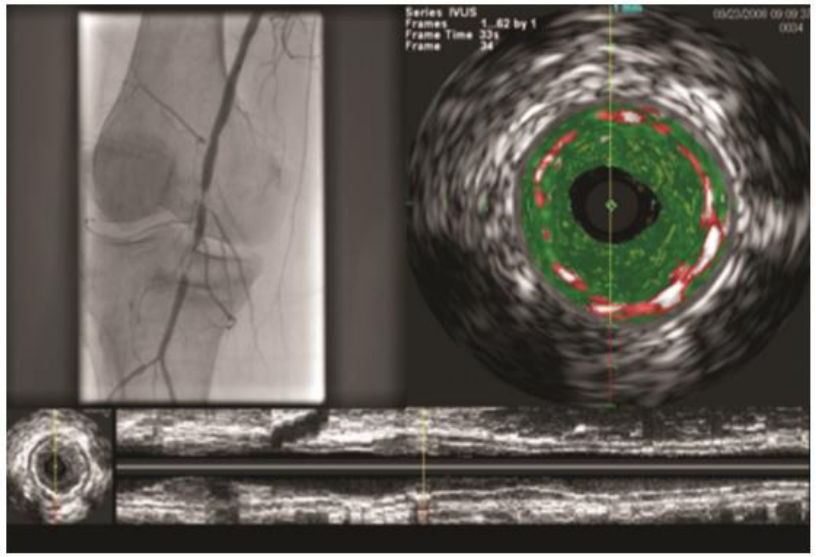
Final angiography

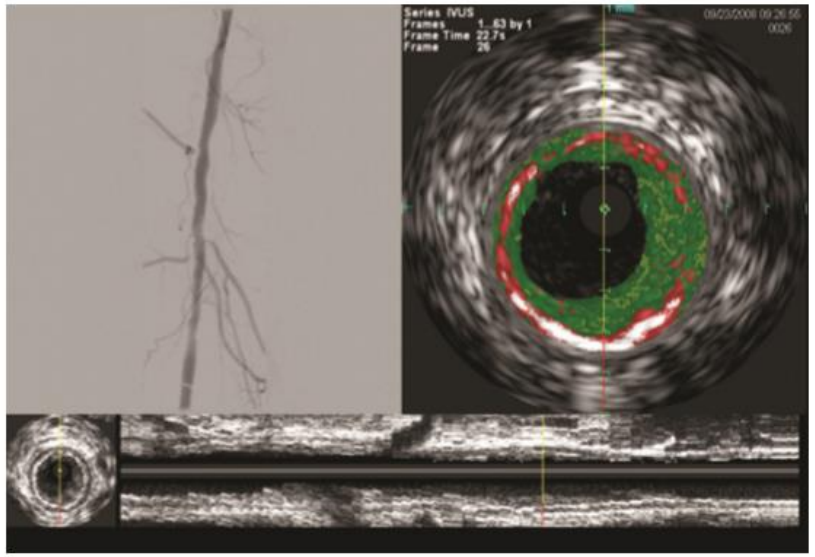
Final angiography showing significant luminal gain. The patient was discharged the following day symptom free.

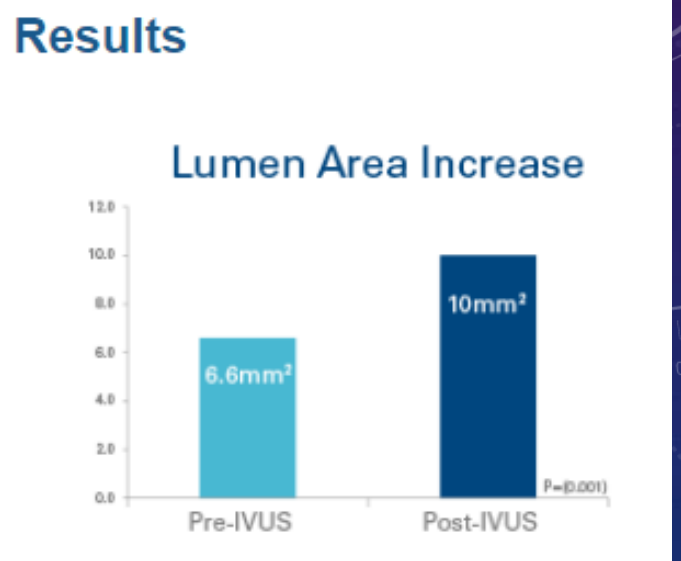




JETSTREAM CALCIUM STUDY







- Use of this device in moderate and severely femoral/popliteal calcified lesions was examined by intravascular ultrasound (IVUS) in a small (n=26) single-center study.
- Calcium removal and luminal gain, measured by comparing pre-intervention to post-atherectomy IVUS images
- 86% of lumen gain was attributed to calcium reduction
- **Conclusion:**

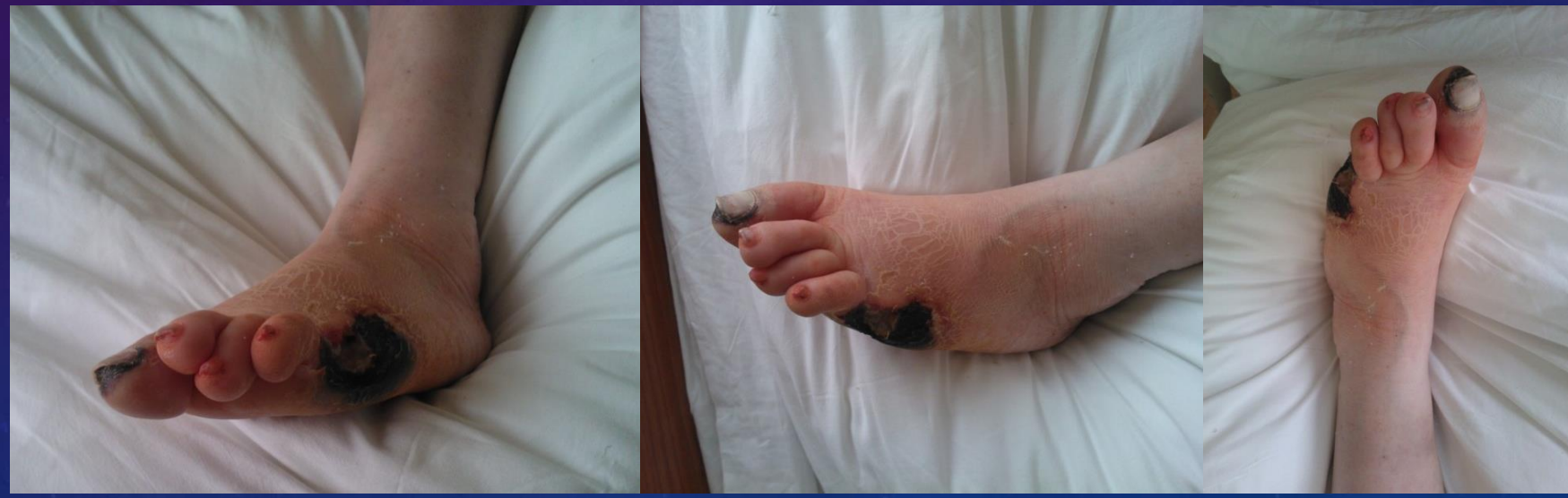
  Jetstream atherectomy system removed and modified superficial calcium to achieve significant lumen gain

Maehara A, Mintz G, Shimshak T, Ricotta J, Ramaiah V, Foster M, Davis T, Gray W. Intravascular ultrasound evaluation of JETSTREAM atherectomy removal of superficial calcium in peripheral arteries. EuroIntervention 2015;11:96-103

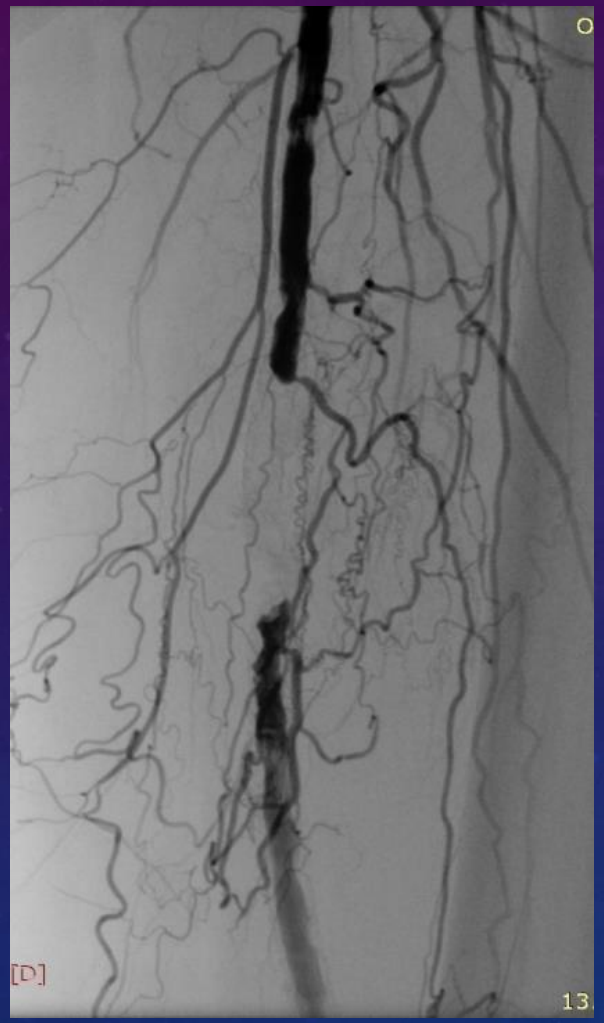
Case 2 - Extreme calcified occlusion of the left SFA/PA

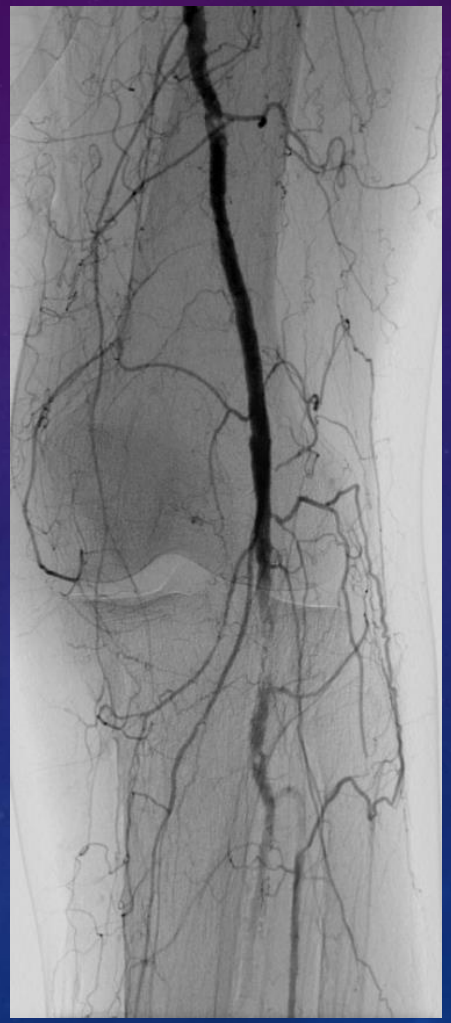
Clinical History:

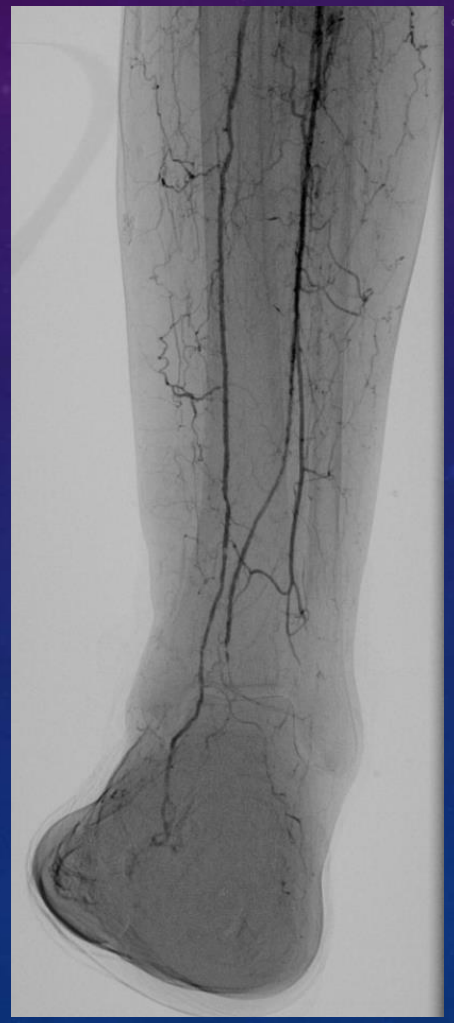
- 62 year old high-risk patient with insulin dependent diabetes suffering from micro /macroangiopathy, was admitted to our clinic with CLI of the LE (Rutherford 6), recently after amputation of the little finger of the left leg.
- Non healing ulcer after amputation of the little finger and non healing ulcer of the toe.



Baseline arteriography



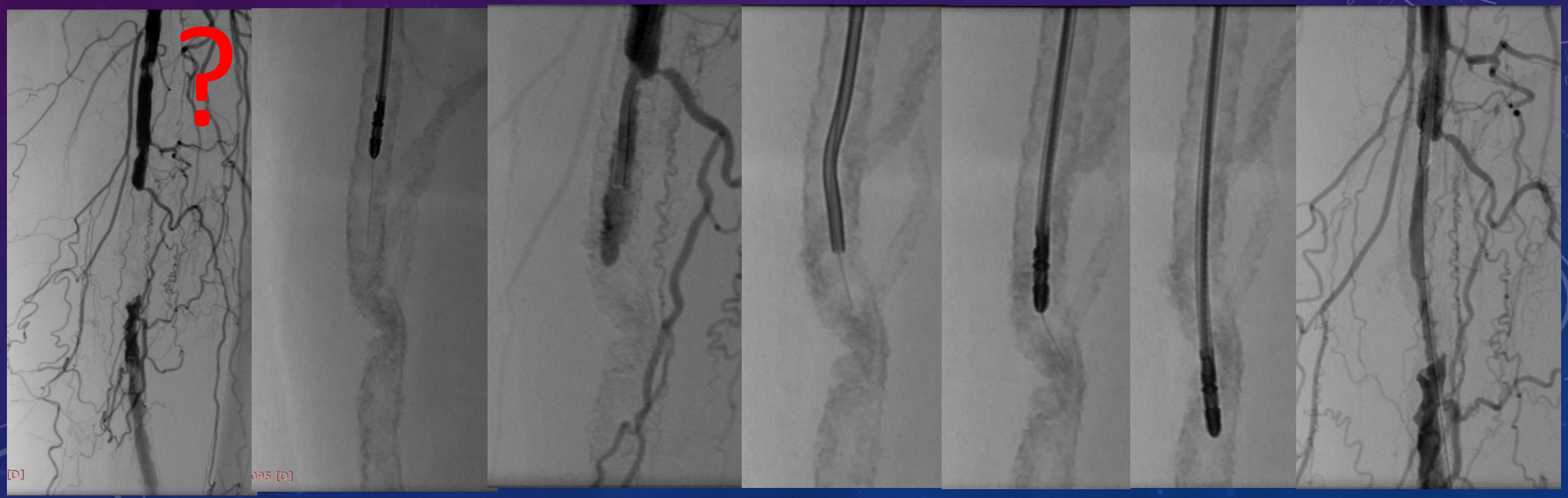




Baseline arteriography and Jetstream procedure

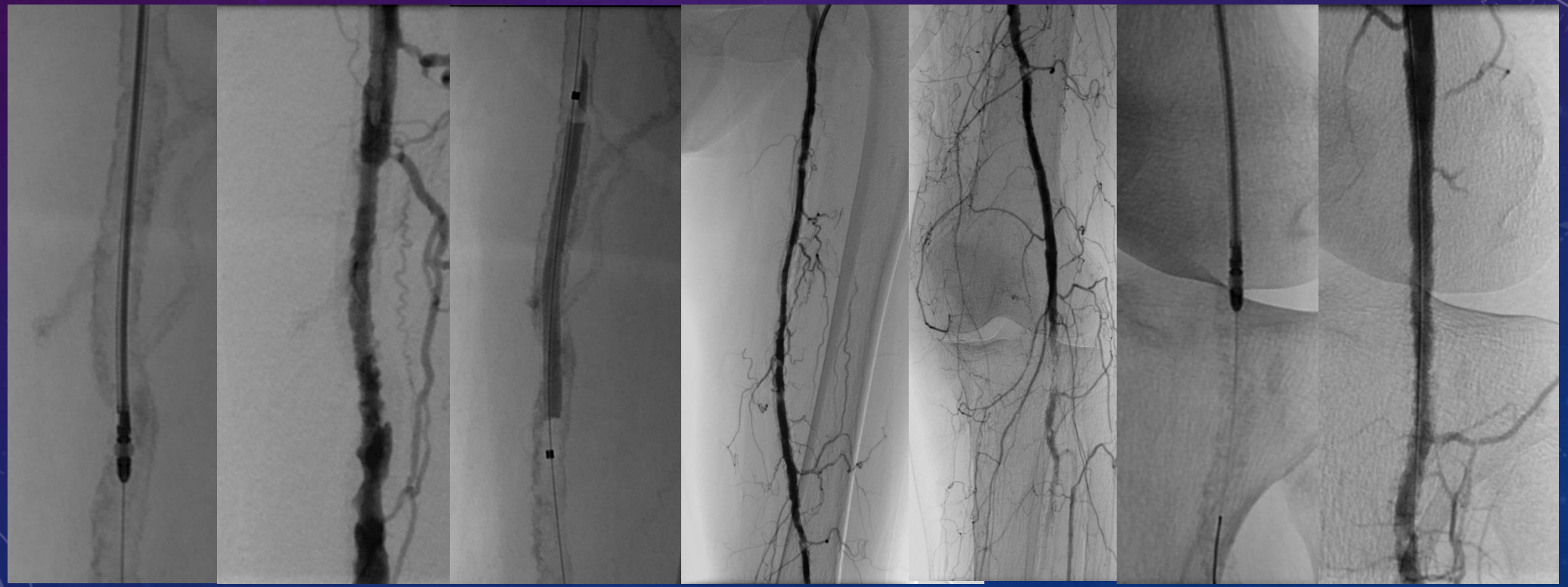
Antegrade left CFA approach, arteriography showed the heavily calcified occlusion of the SFA. Multiple wires failed to cross the lesion.

The sharp end of the 0,014" guide wire was used to navigate the Jetstream ® XC 2.1 atherectomy system into the plaque. The wire was pulled back and one passage was performed with blades down.



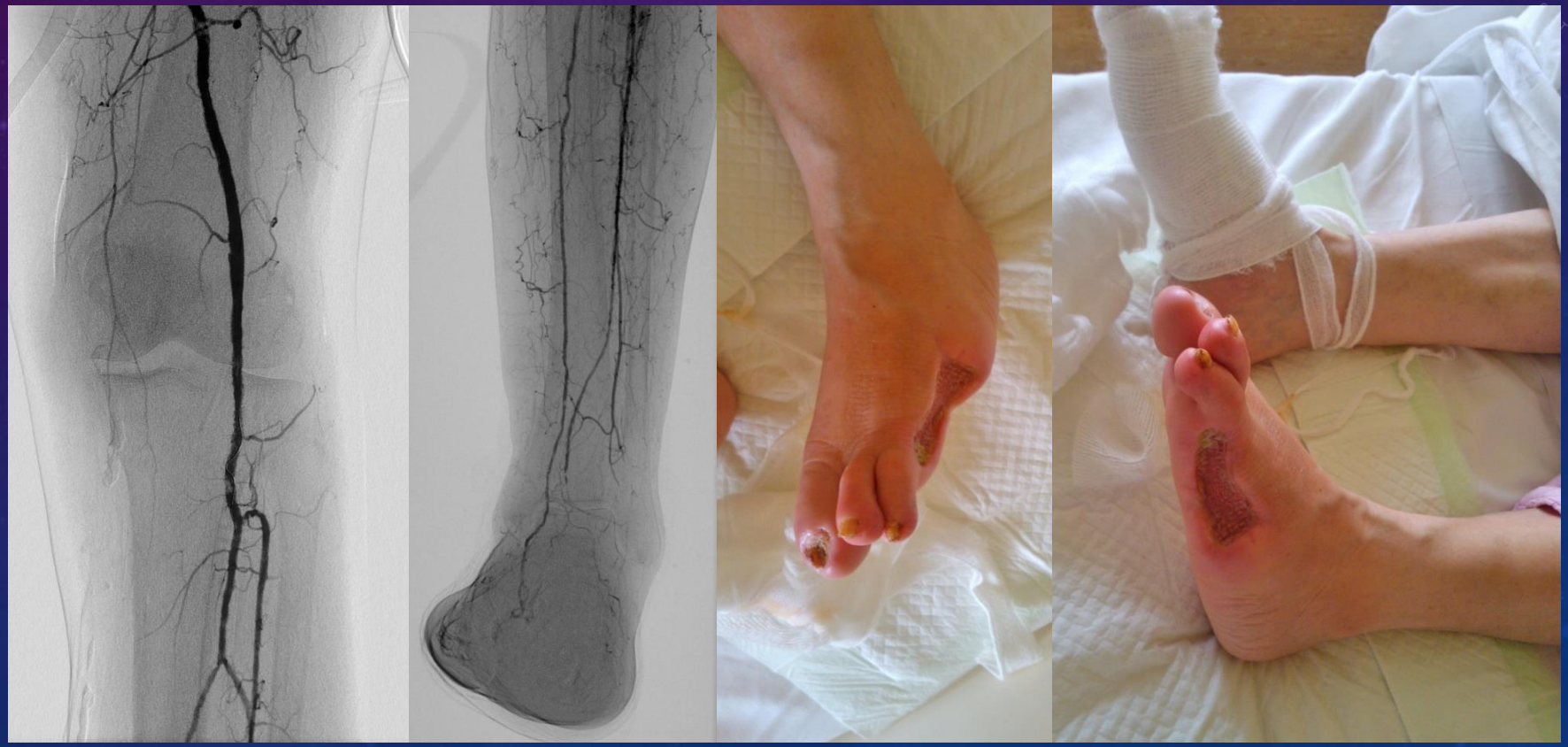
Baseline arteriography and Jetstream procedure

- After successful crossing, the wire was advanced and the created channel was gradually widened by the side blades of the Jetstream ® system. Drug-eluting balloon angioplasty followed with good angiographic result. The same Jetstream® XC system was used to open another short occlusion of the PA.

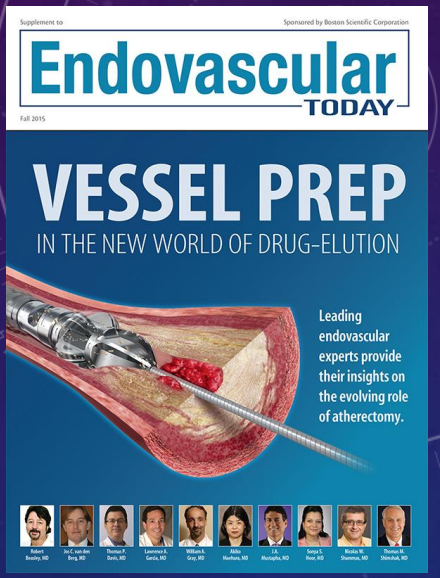


Final arteriography and 6m follow up

- Final arteriography showed the patent SFA and PA. The dorsalis pedis was missing (also at the beginning of the procedure) and only the proximal part of the plantar artery was filling.
- Despite the very poor prognosis the ulcers started to heal.



VESSEL PREPARATION STRATEGY



- Endovascular atherectomy has emerged as a novel, endovascular technology for atheroma removal

- Changing vessel compliance by plaque debulking may allow for:

  - a more uniform angioplasty result with minimal consequent vessel barotrauma and improved luminal gain,

  - decreasing the risk of plaque recoil and dissection, and preventing negative remodeling and neointimal hyperplasia [1]

1. Mittleider D, Russell E. Peripheral atherectomy: applications and techniques. Tech Vasc Interv Radiol. 2016;19(2):123–135. doi: 10.1053/j.tvir.2016.04.005.

Endovascular atherectomy devices

- Endovascular atherectomy devices can be divided into four categories according to the mechanism used for atheroma removal:

- <u>Directional atherectomy</u>

  - plaque is removed by guiding the cutting device (cutter) of the catheter directly to the plaque

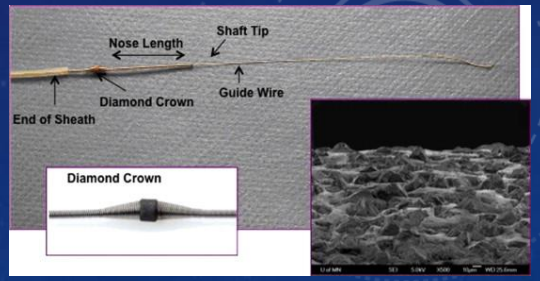
  - SilverHawk™, TurboHawk™ and the newest HawkOne™

  - Pantheris OCT-guided lumivascular atherectomy device

- <u>Orbital atherectomy</u>

  - mechanism based on the high-speed rotation of the diamond-coated crown. Plaque debulking area increases with the increase of the rotational speed of the crown.

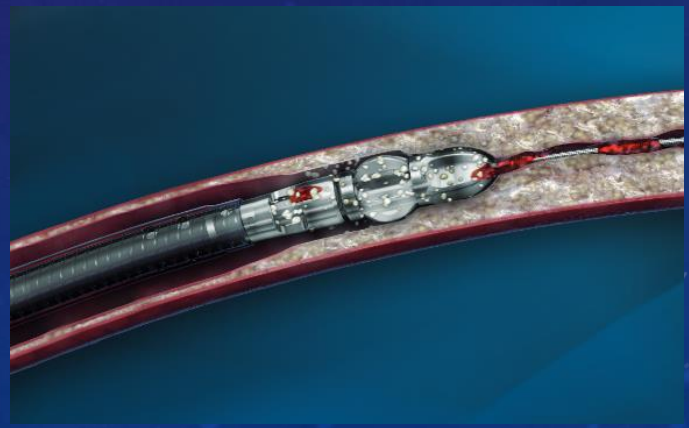
  - Diamondback 360° Peripheral Orbital Atherectomy System



Endovascular atherectomy devices

- Laser atherectomy
  - uses excimer laser (UV) technology to ablate atheroma
  - Turbo-Elite, Turbo-Power and Turbo-Tandem
  - de novo and in-stent restenosis, 10 µm with each pulse of energy (1)

- Rotational atherectomy
  - Rotablator™, Phoenix and JETSTREAM rotational atherectomy systems
  - plaque is excised by a concentrically rotating, specially designed tip (burr)
  - indicated for both acute thrombus removal and atherectomy of chronic lesions [1]



1 Akkus NI, Abdulbaki A, Jimenez E, Tandon N. Atherectomy devices: technology update. Med Devices (Auckl) 2015;8:1–10

JETSTREAM CATHETER DESIGN

- *Differential cutting*
- *XC Expandable blade technology*

- *Active Aspiration*
- *Circumferential rotational clearance*
- *Front end cutting*

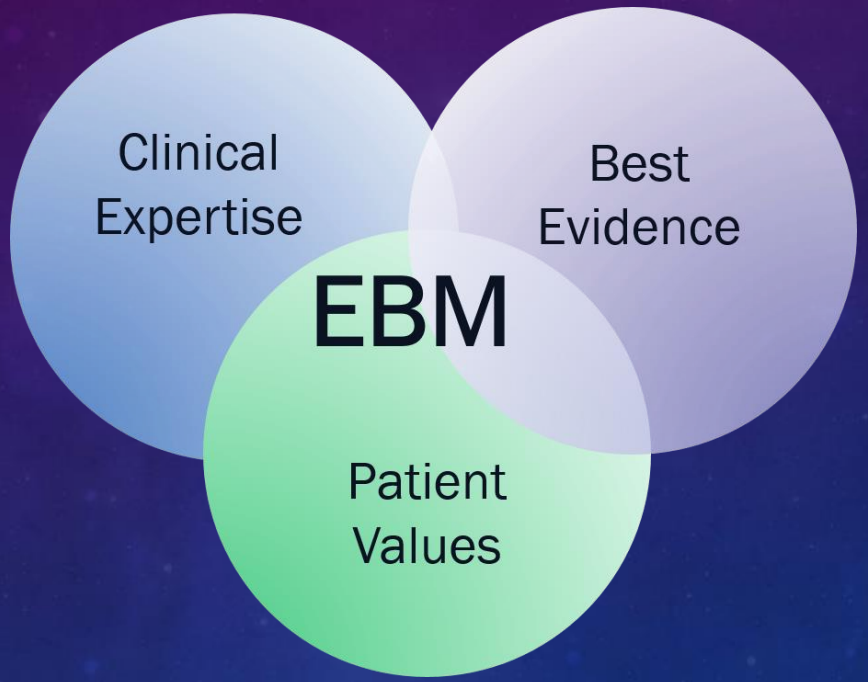
Infusion

Aspiration

Front End Cutting

Expandable Blades

Vessel Treatment- Options



MULTICENTER PATHWAY PVD TRIAL

- Zeller et al reported on a series of 210 lesions between 2006 and 2007 with the earlier version of the device.

- 31% percent were total occlusions;
- 51% had moderate to high calcium scores;
- and 15% had post-angioplasty restenosis.

- The average lesion length was 2.7 cm.

- Komplex patients:

  - diabetes (47%), hypertension (93.6%), renal disease (15.75%), prior lower extremity revascularization (51.2%), documented coronary disease (16.9%)

Zeller T, Krankenberg H, Steinkamp H, et al. One-year outcome of percutaneous rotational atherectomy with aspiration in infrainguinal peripheral arterial occlusive disease: the multicenter Pathway PVD trial. *J Endovasc Ther.* 2009;16(6):653-662.

MULTICENTER PATHWAY PVD TRIAL

Periprocedural results:

- Lesion crossing and debulking success rate was 99% with a mean device activation time of 3.5 minutes
- only 7% of lesions were stented
- minor embolic events were noted in 10% of cases and 4 perforations (2%) occurred

Follow up results :

- At 6 months major adverse events had occurred in 19% of patients. these events were target lesion revascularizations (TLR), which occurred in 15% at 6 months and 26% at 12 months
- The restenosis rate was 38.2% at 1 year based on duplex ultrasound, as per core lab analysis.

Zeller T, Krankenberg H, Steinkamp H, et al. One-year outcome of percutaneous rotational atherectomy with aspiration in infrainguinal peripheral arterial occlusive disease: the multicenter Pathway PVD trial. *J Endovasc Ther.* 2009;16(6):653-662.

Randomized Controlled Trials (RCT)

Study	Design	Treatment	Patients and lesions	Bailout stent	Immediate outcomes	Clinical outcomes
Shammas et al. [2011].	RCT	SilverHawk versus angioplasty	46 IC and 12 CLI femoropopliteal	27.6 versus 62.1% ($p = 0.017$)	Embolization: 64.7 versus 0.0% ($p < 0.001$)	1-year TLR: 11.1 versus 16.7%
CALCIUM 360 [2012]	RCT	Orbital versus angioplasty	50 CLI Infrapopliteal vessels	6.9 versus 14.3% ($p = 0.44$)	Success: 93.1 versus 82.4% ($p = 0.27$)	1-year TVR freedom: 93.3 versus 80.0% ($p = 0.14$)
COMPLIANCE 360 [2014]	RCT	Orbital versus angioplasty	50 patients, 65 lesions Calcified Femoropopliteal	5.3 versus 77.8% ($p < 0.0001$)	N/A	1-year TLR: 18.8 versus 21.7% ($p = 0.99$)
EXCITE-ISR [2015]	RCT	Excimer laser versus angioplasty	250 IC + CLI In-stent restenosis	4.1%	30-day MAE: 5.8 versus 20.5% ($p < 0.0001$)	6-month TLR: 26.5 versus 48.2% ($p < 0.005$)
DEFINITIVE AR [2015]	RCT	Hawk + DCB versus DCB alone	102 femoropopliteal	Dissection: 2 versus 19%	N/A	1-year patency: 82.4 versus 71.8%

- Shammas (2011) - during follow-up, TLR and TVR were all similar in the AT and angioplasty, but with a small numerical benefit in favor of directional atherectomy. AT plus angioplasty resulted in significantly less bailout stenting, higher macro-embolisation rate.
- CALCIUM 360 (2012) - atherectomy could increase the probability of achieving an optimal angioplasty outcome and lead to fewer dissections, decreased bailout stenting rate
- COMPLIANCE 360 (2014) – less bail out stenting noted, AT did not yield superior outcomes
- EXCITE-ISR (2015) - ELA + PTA was associated with a 52% reduction in TLR
- DEFINITIVE AR (2015) - trend in potentially better outcomes in challenging lesion subsets such as severely calcified ones, ≥10 cm lesions and CTOs.

Indications for atherectomy

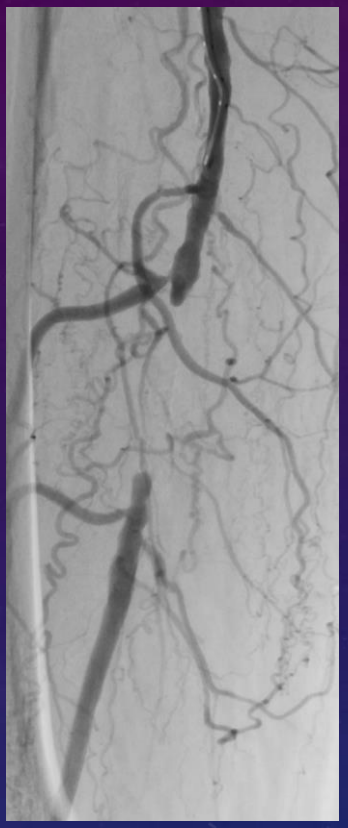
- Long calcified lesions, complex CTO with/without thrombus
- Bifurcation and “no stent” zones
- High risk patients for open repair
- In-stent restenotic lesions
- Contraindication for stent implantation or for dual antiplatelet therapy

*based on authors experience.

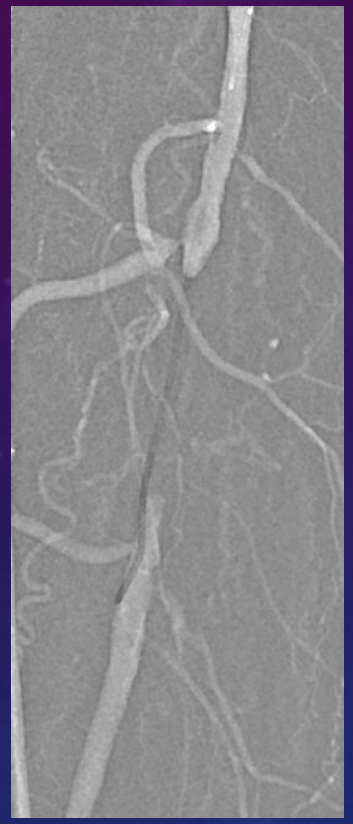
Proper technique – essential for optimal result

64 y. old patient, CLI - limiting intermittent claudication

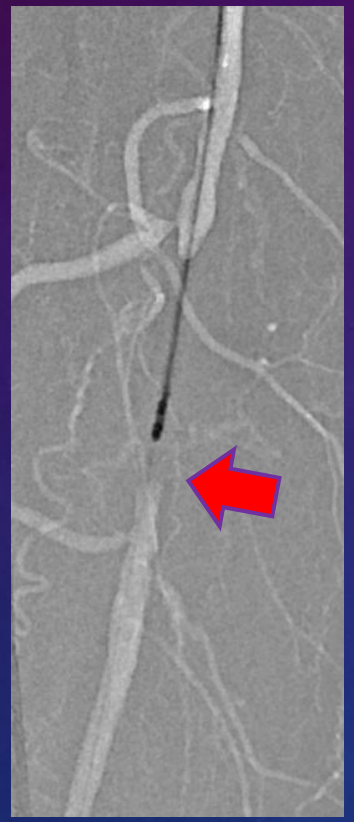
Pre-image



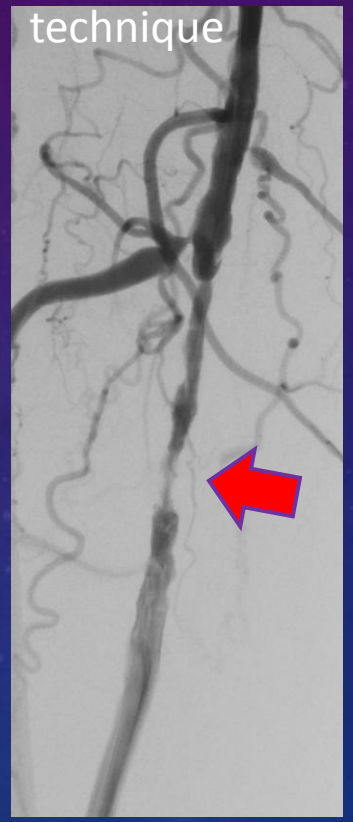
Crossing



JETSTREAM XC 2.1



Distal cap technique



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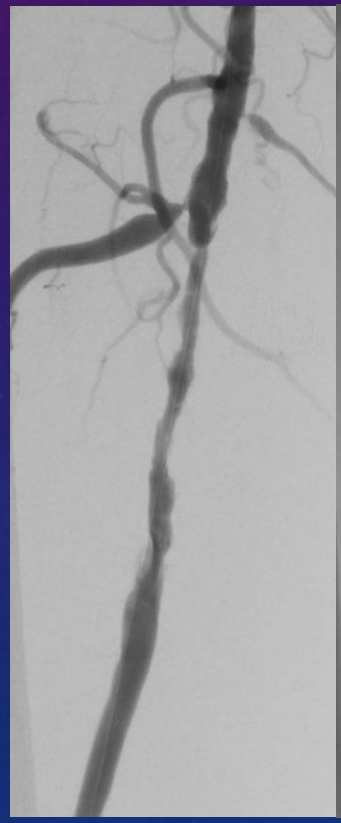
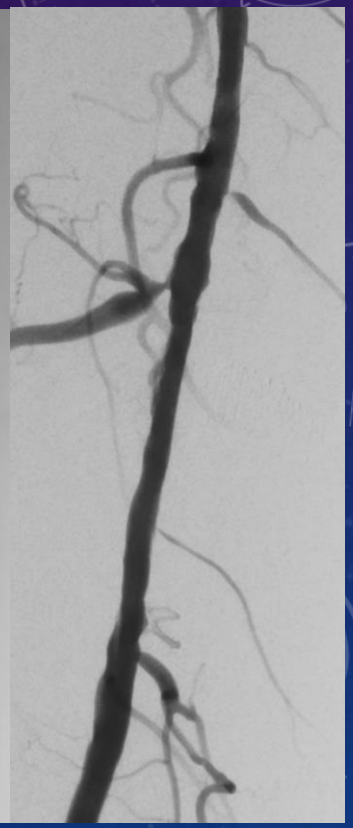


Ranger 6x100

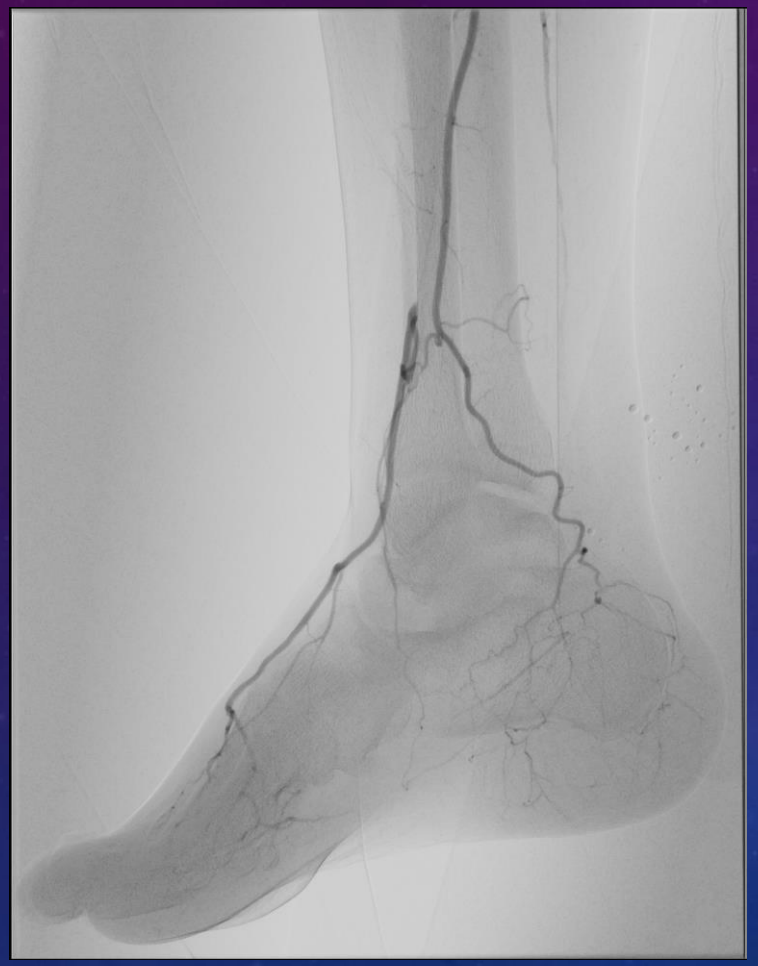
Final



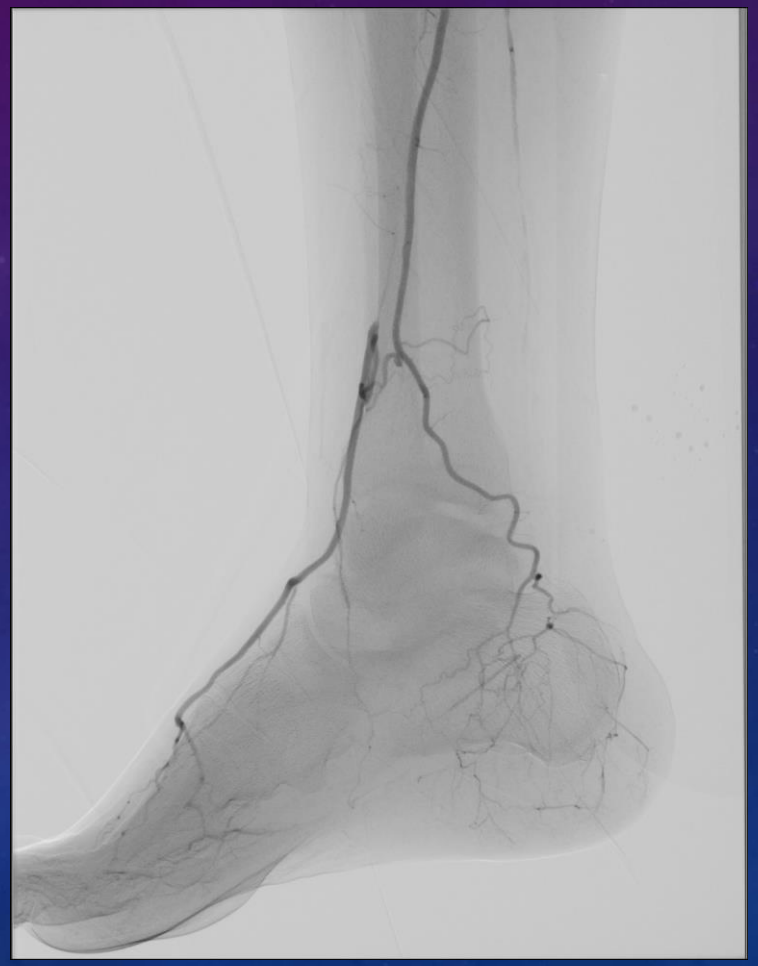
CTO of the distal right SFA (A). JETSTREAM Atherectomy system 2.1 mm keeping the distal part of the lesion intact to act as a “filter” – red arrow (B,C). After treatment of the distal part (D). 6-mm X 80-mm Ranger drug coating balloon catheter (Boston Scientific Corporation) (E). Reconstituted SFA (F).

Without distal embolisation

Pre-procedure



Final



CONCLUSION

- Recently published or presented randomized trials have shown that atherectomy can accomplish the task of vessel preparation, reducing dissections and bail out stenting.

- Proper technique is essential for excellent results

  - Slow advancement of the cutter, avoid stalling of the device and allow room for aspiration

  - Embolic protection devices have added a level of protection to the outflow vessels

  (irregular/heavily calcified lesions, ISR, TASC D lesions)

- Respect the limitations no single device is right for every case

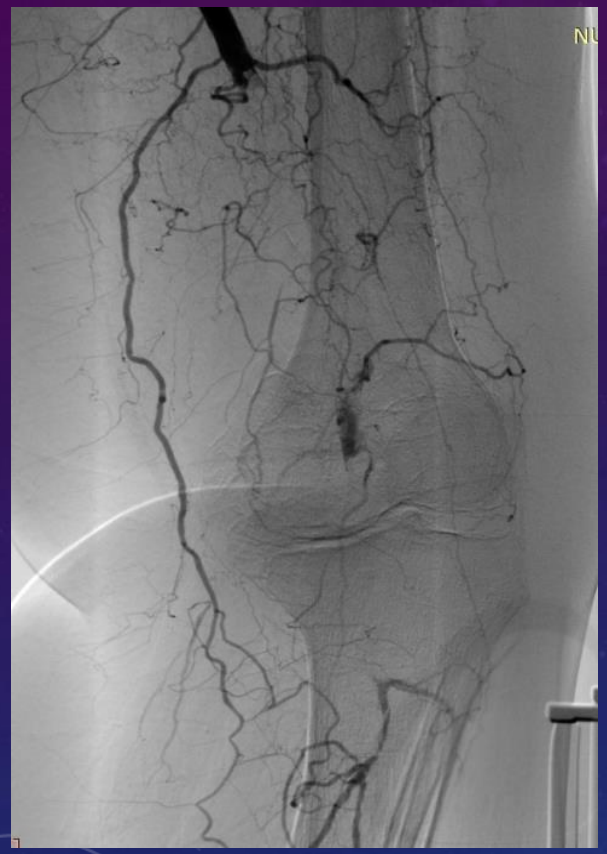
- The combination of debulking atherectomy and drug-coated balloons has shown promise in early studies, especially in the treatment of more complex lesions.

Thank you for your attention

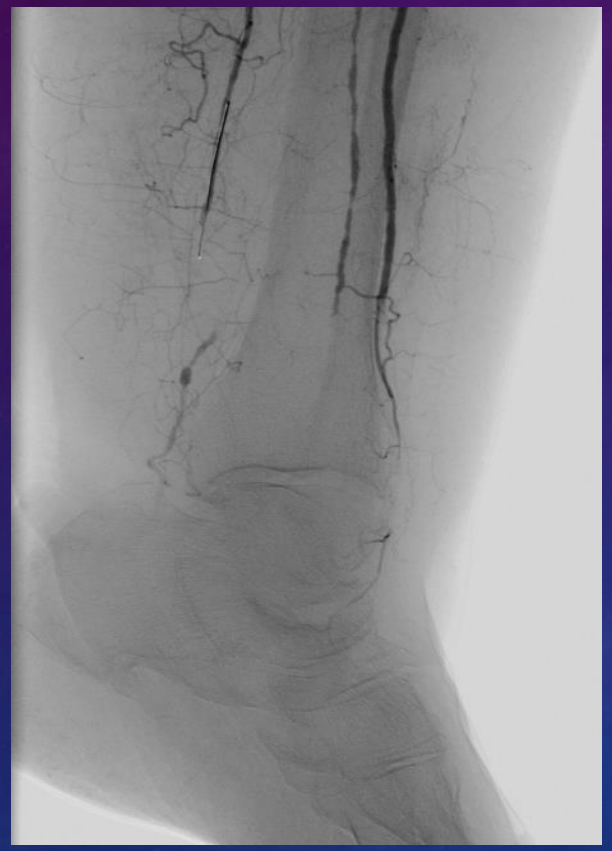
Thank you for your attention

Case 6: Atherectomy of Acute Embolic Occlusion of Distal Superficial and Popliteal Artery, Jet XC 2.4

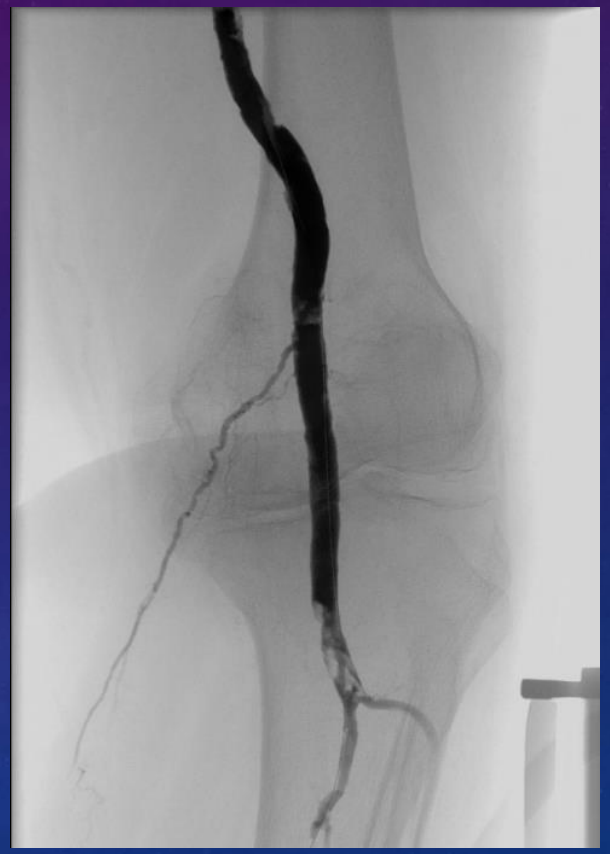
81 y. old patient, ALI lasting **11 days**



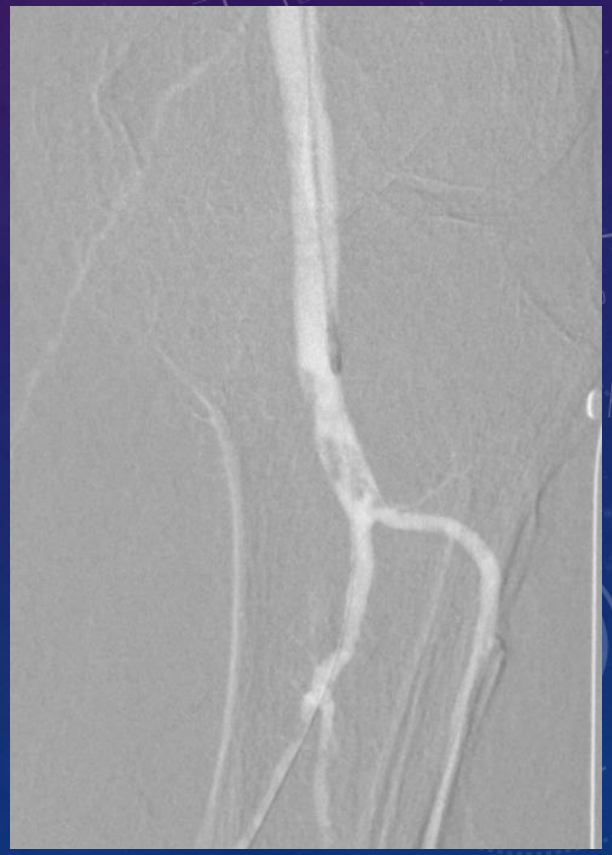
Acute, long (**22cm**) embolic occlusion of distal SFA
and Popliteal artery



Acute embolic occlusion of the peripheral vessels.

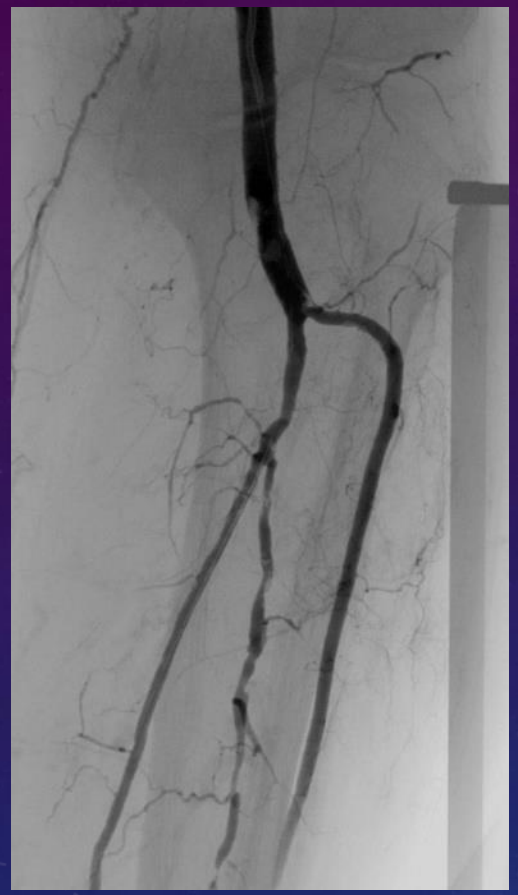


2 passes Blades Down and
1 pass Blades UP with **XC 2.4 catheter**, resulting in
exceptional debulking effect .

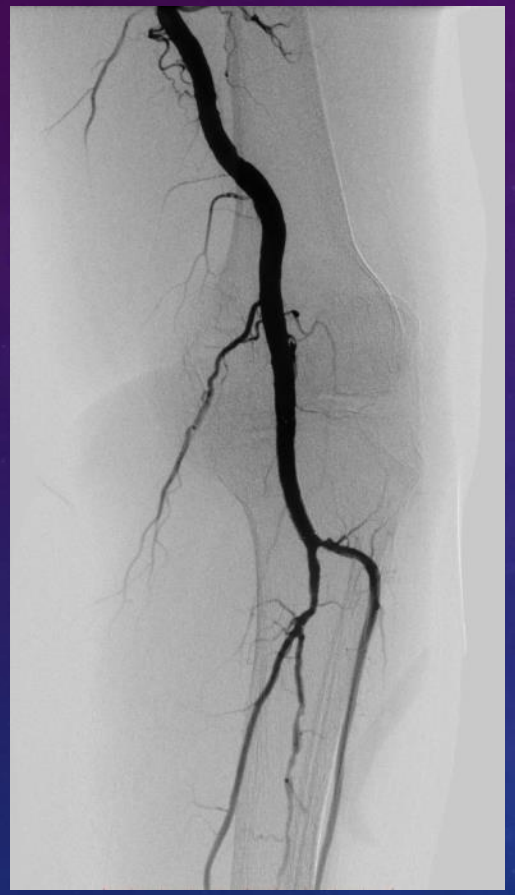


JETSTREAM® XC™
2 additional passes
Blades Down.

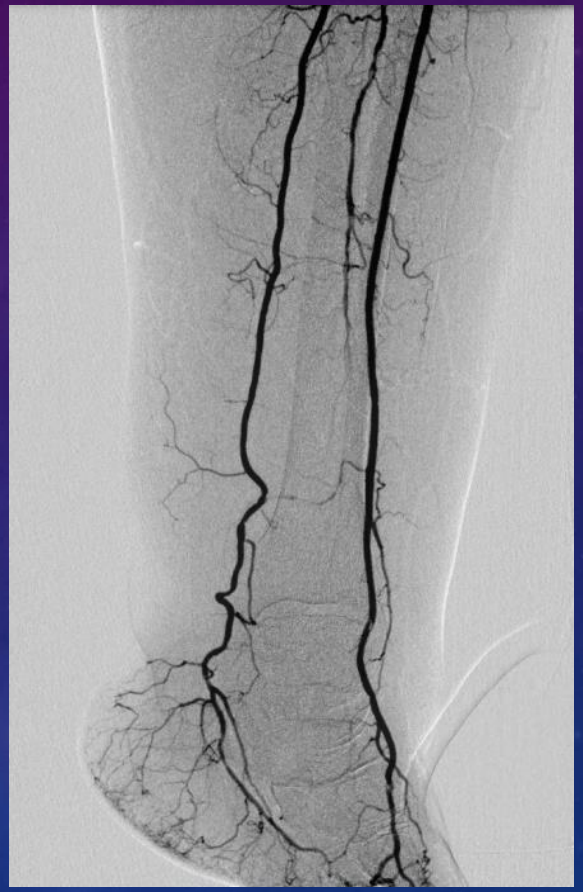
Atherectomy of Acute Embolic Occlusion of Distal Superficial and Popliteal Artery, Jet XC 2.4



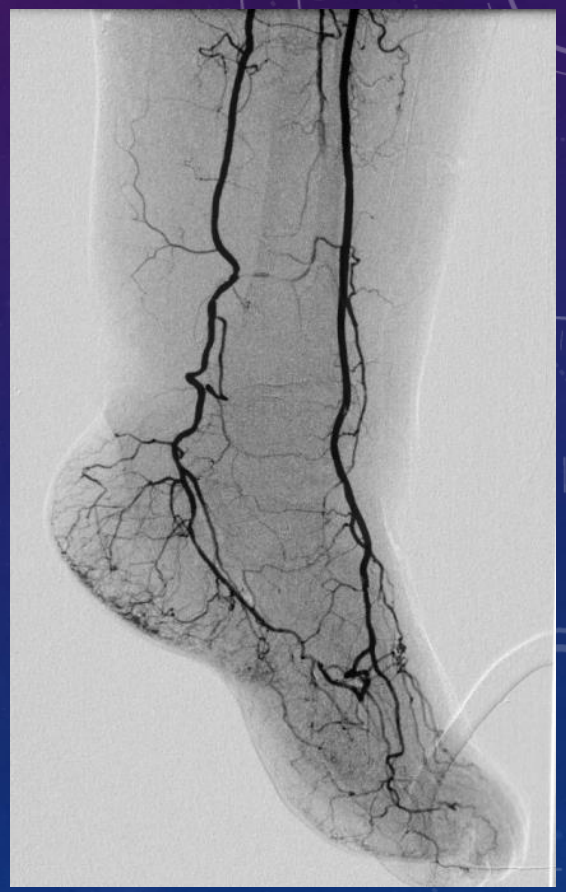
JETSTREAM® XC™
Total activation time 27 min.



Patent SFA/PA arteries post overnight thrombolysis using rt-PA 1mg/hour in total dose 15mg.



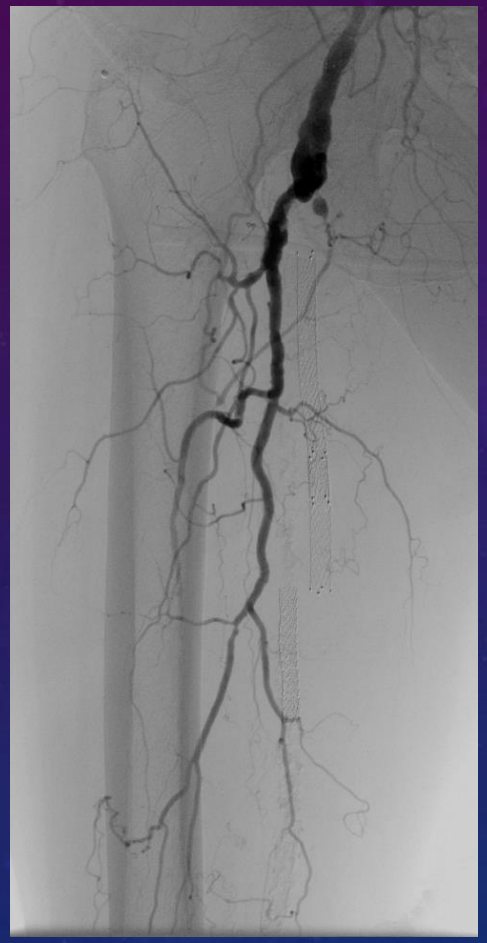
Patent posterior and anterior tibial artery

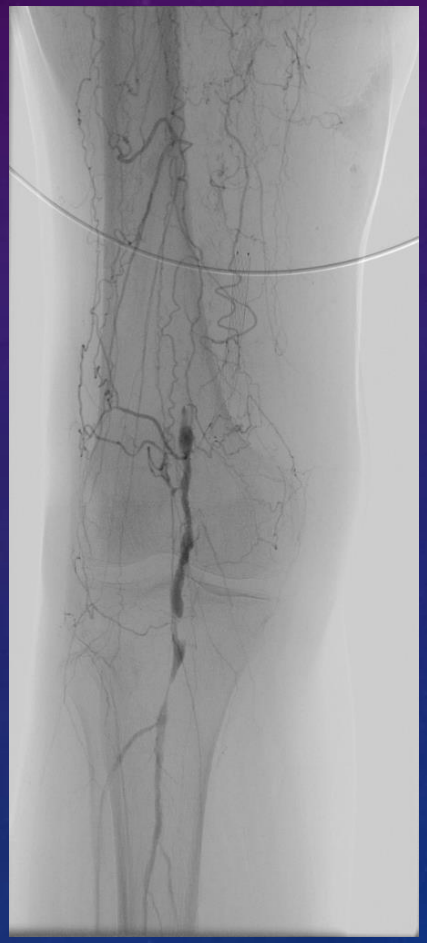


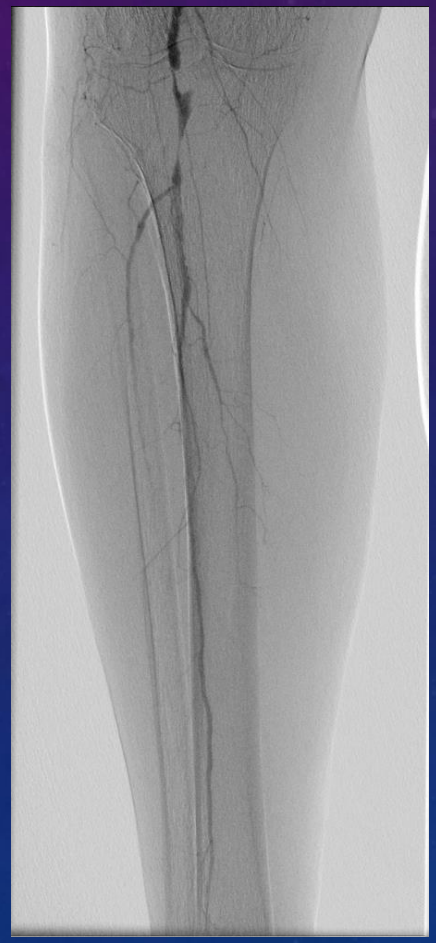
Patent plantar artery and dorsalis pedis

Case 7: Thromb/Atherectomy of Chronic FP bypass occlusion, Jet XC 2.4

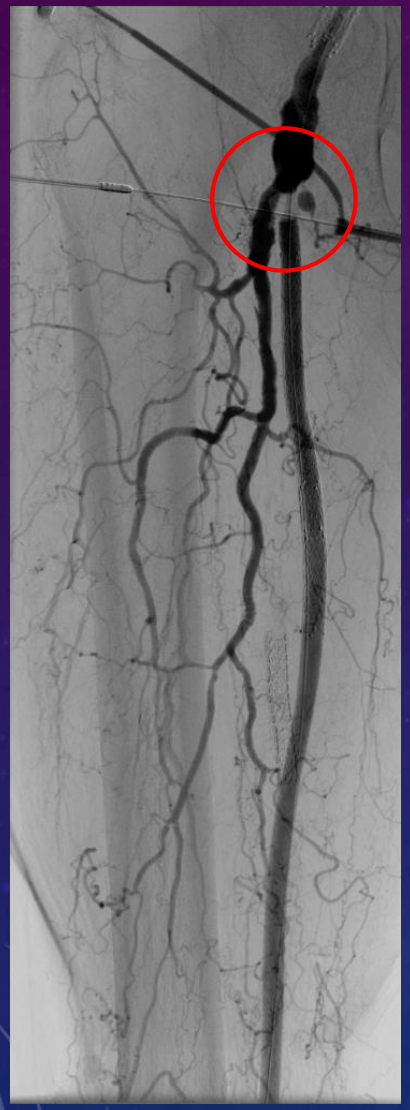
87 y. old patient, Repeated stent PTA and TL (12.2015,03.2016), **3 months old occlusion** of the FP bypass

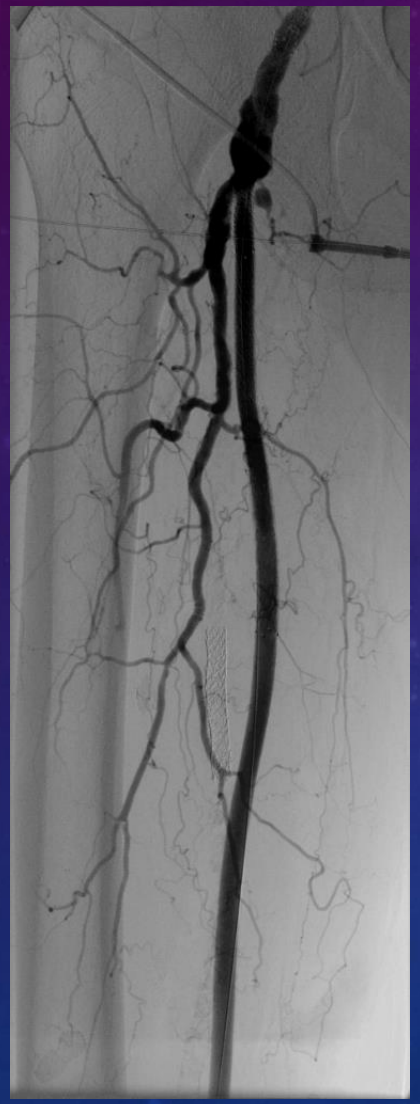


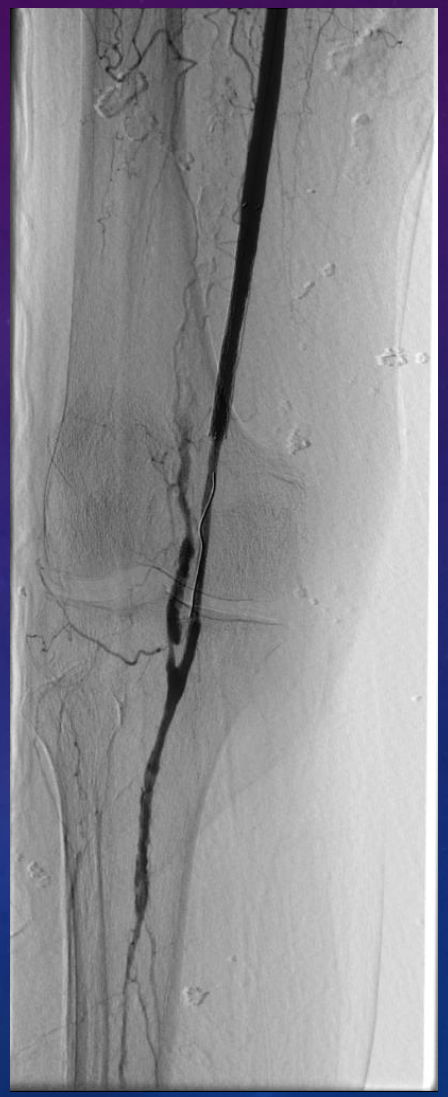




Case 7: Thromb/Atherectomy of Chronic FP bypass occlusion, Jet XC 2.4

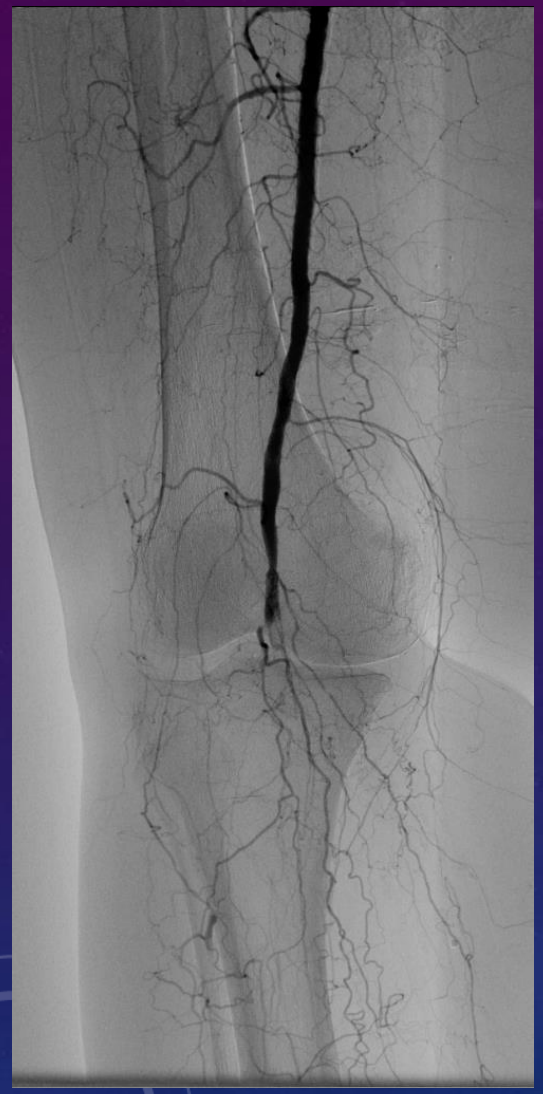
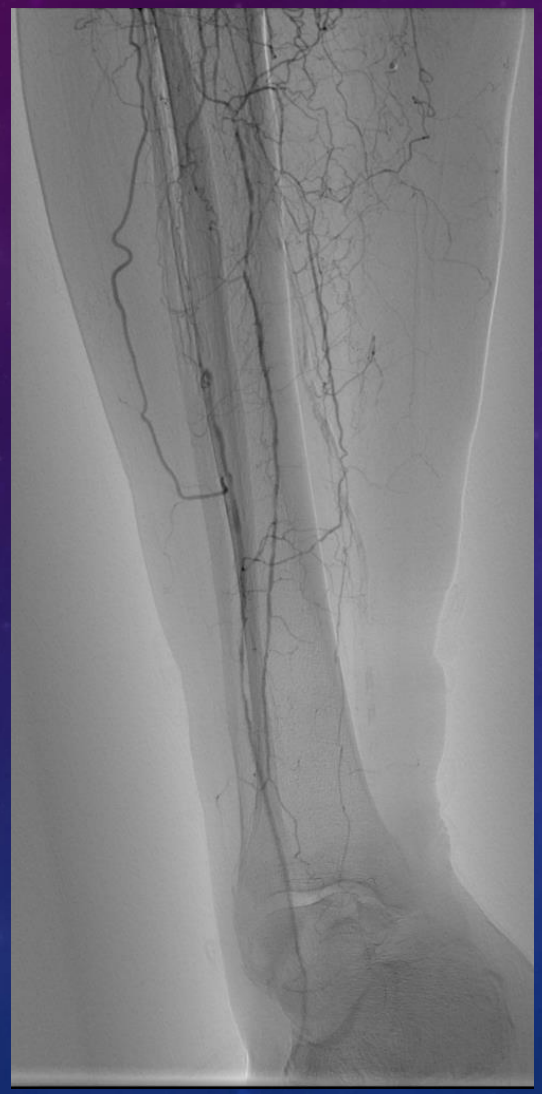
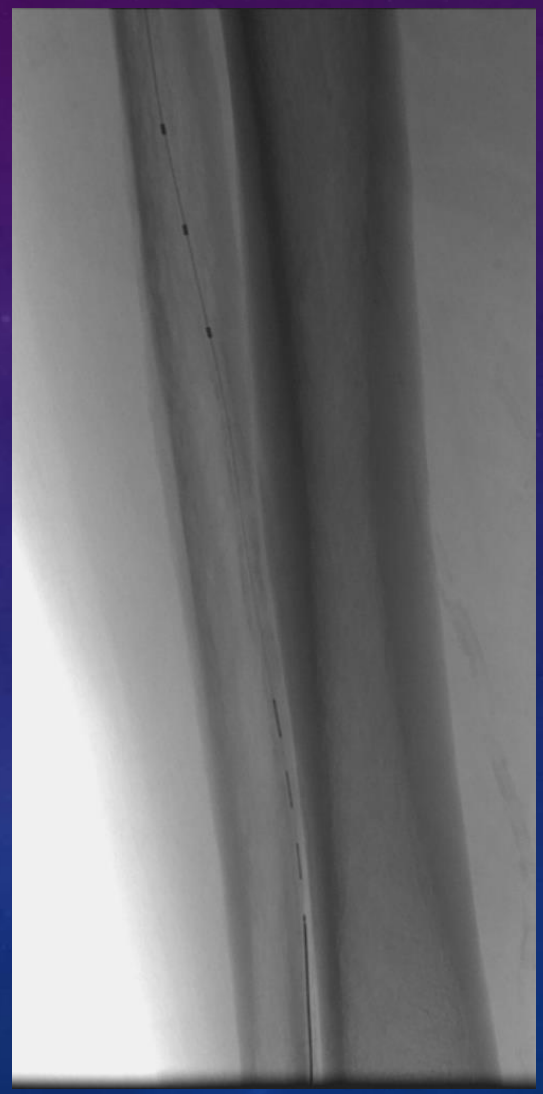
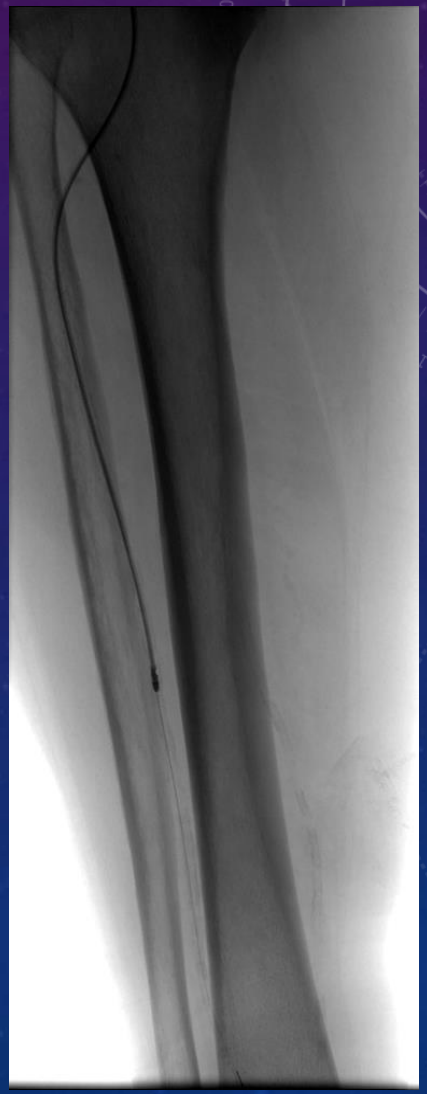




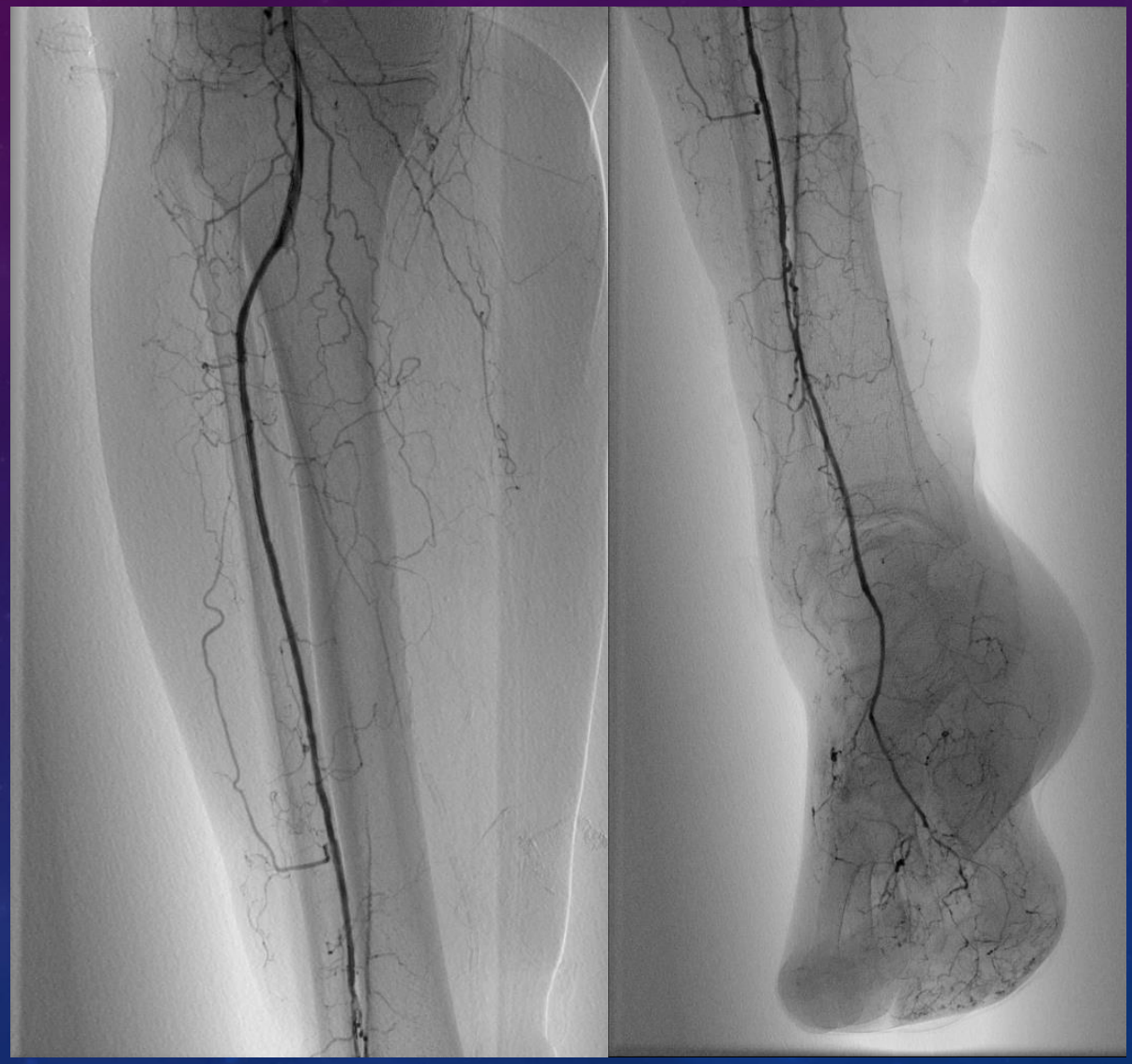


Case 8: Long segment of Occluded PA and ATA

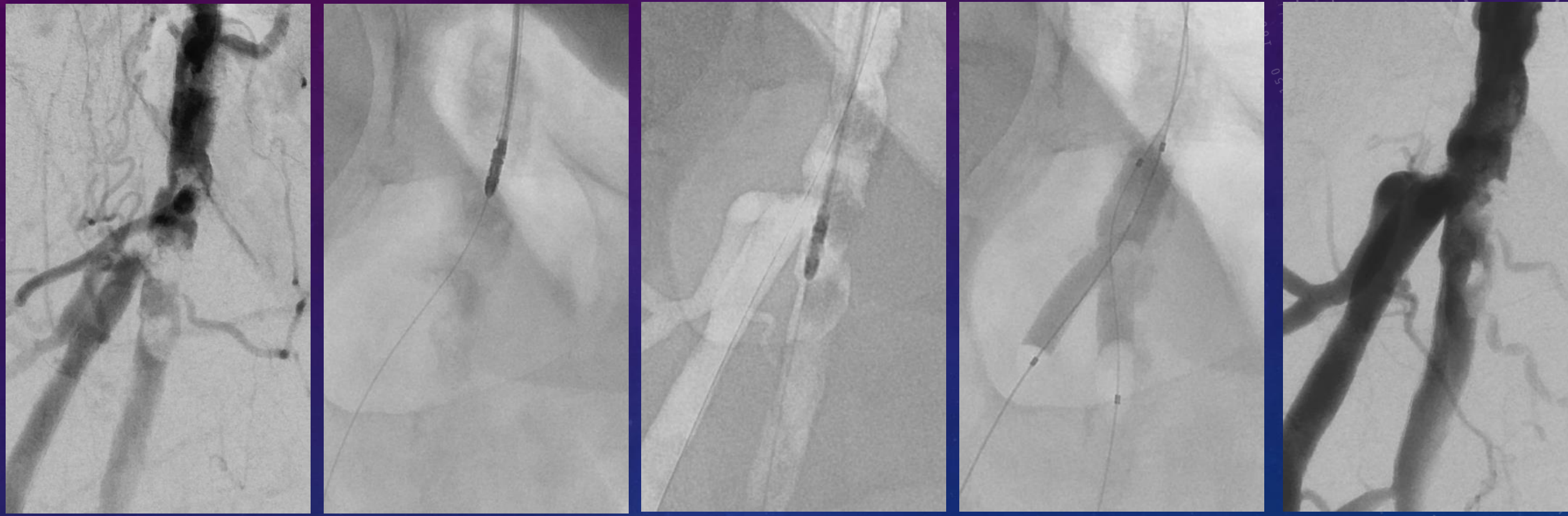
75 y. old patient, DM type II, CLI - Rutherford Stage 5 (ischemic ulceration), downgrading the lesion by JET SC 1.85

Final angiography – no DE



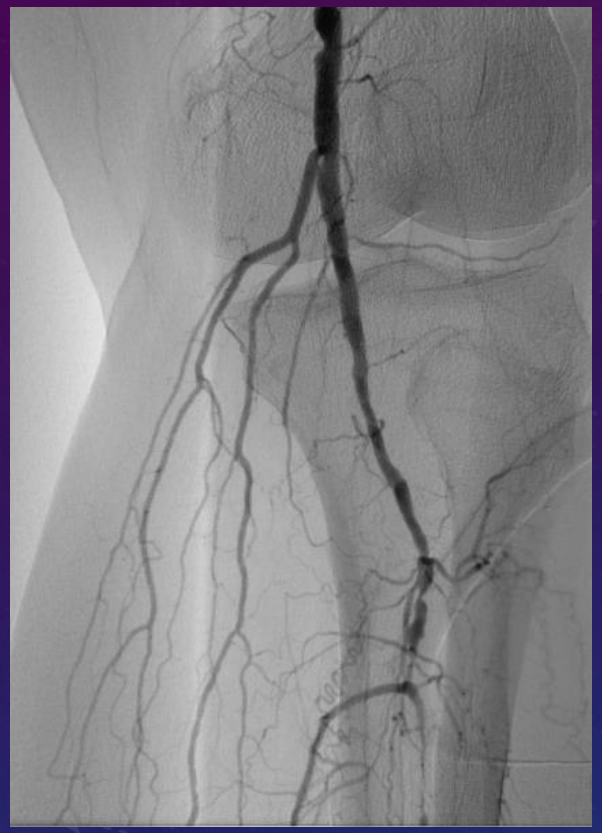
Bifurcation lesions



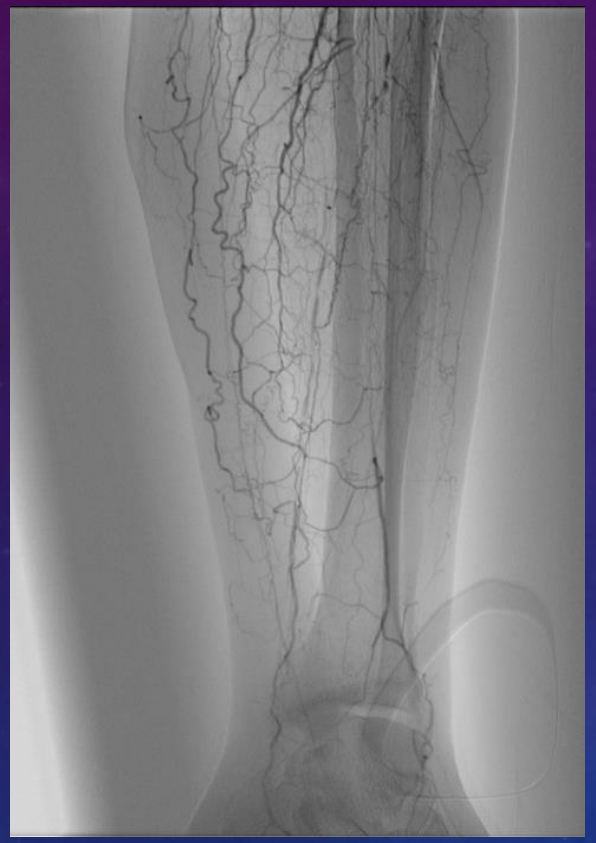
Heavily calcified lesions of the CFA and proximal SFA,PFA (A). Plaque modification by JETSTREAM Atherectomy system 2.4 mm (B,C). Two 6-mm X 40-mm Ranger drug coating balloons (Boston Scientific Corporation) angioplasty (D). Final angiography showing significant luminal gain (E).

Case 5: Atherectomy of the Peroneal artery

67 y. old patient, CLI - Rutherford stage 6 (gangrene of the digits)

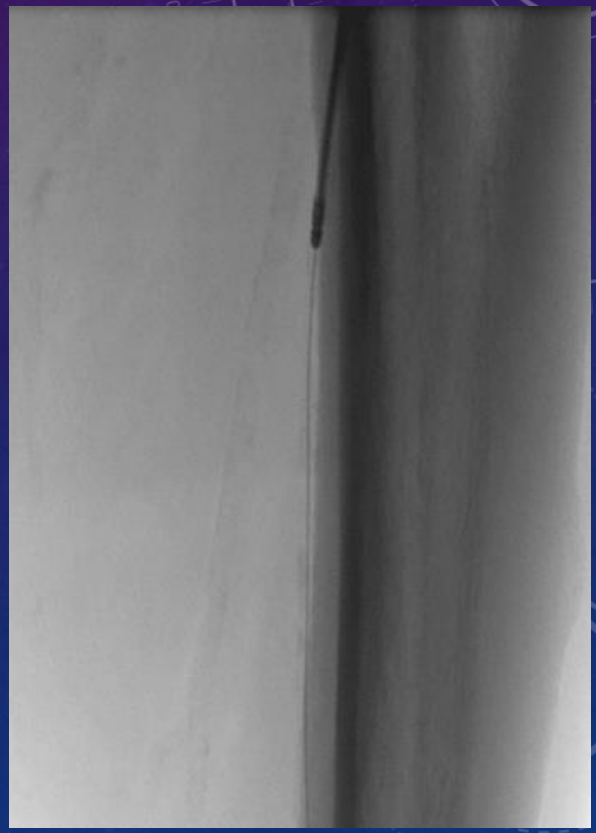


Critical lesions of the tibioperoneal trunk



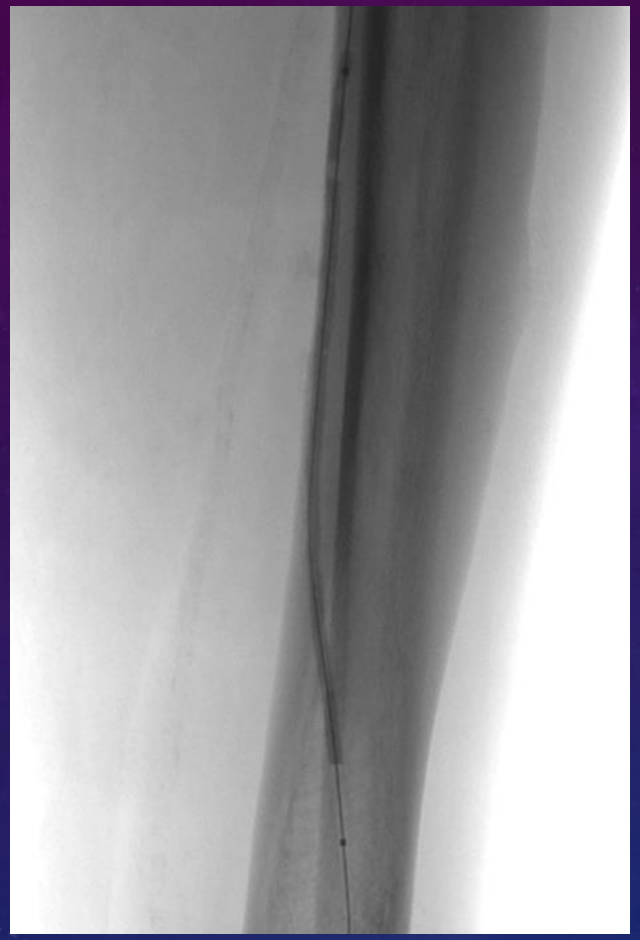
Occlusion of all major crural vessels

Due to the heavy calcifications **only the wire was able to cross** the occlusions of the peroneal artery

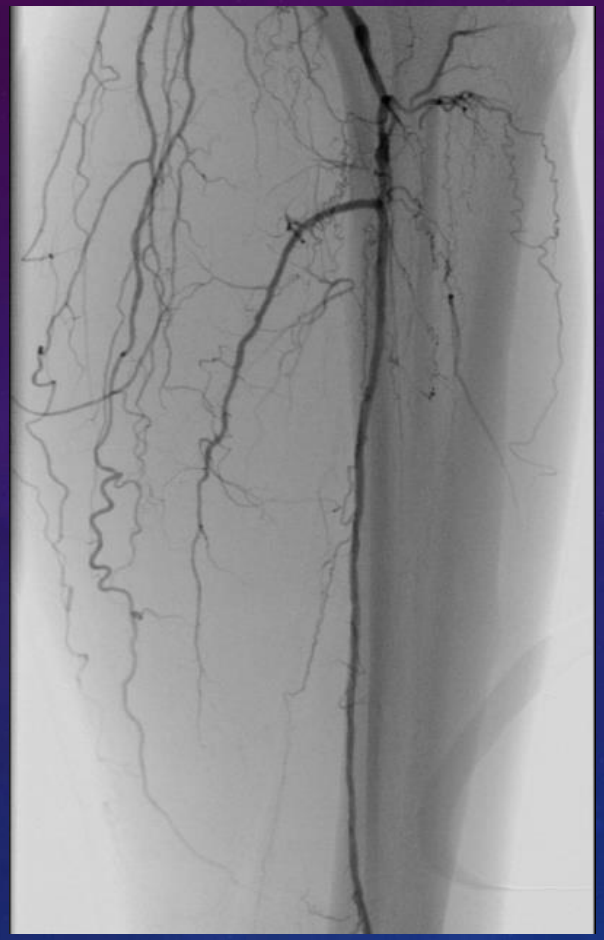


1 pass using the SC **1.6 catheter**, total activation time 15 min.

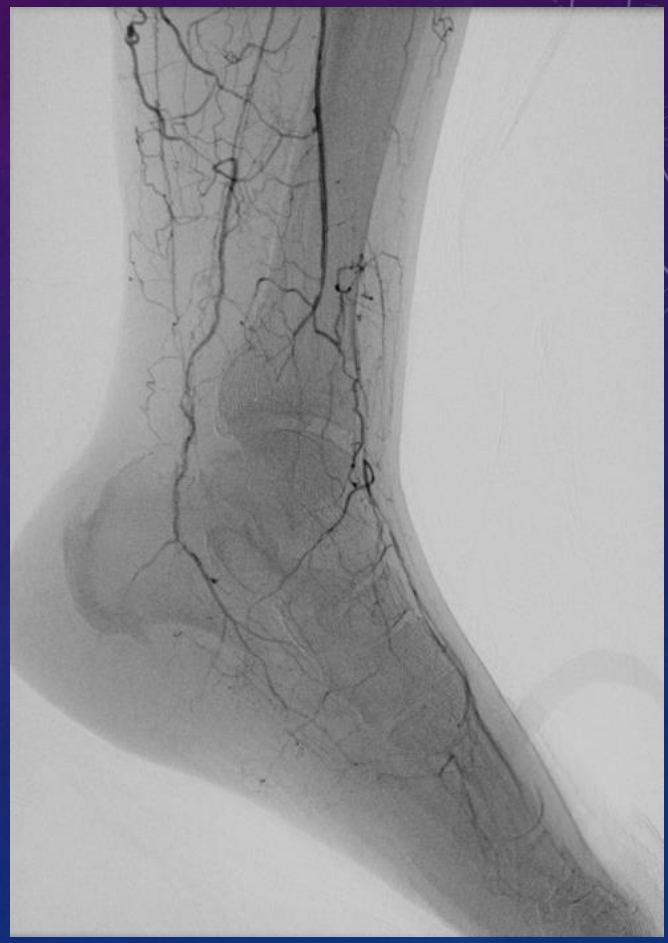
Atherectomy of the Peroneal artery



PTA using 2.5x120mm balloon



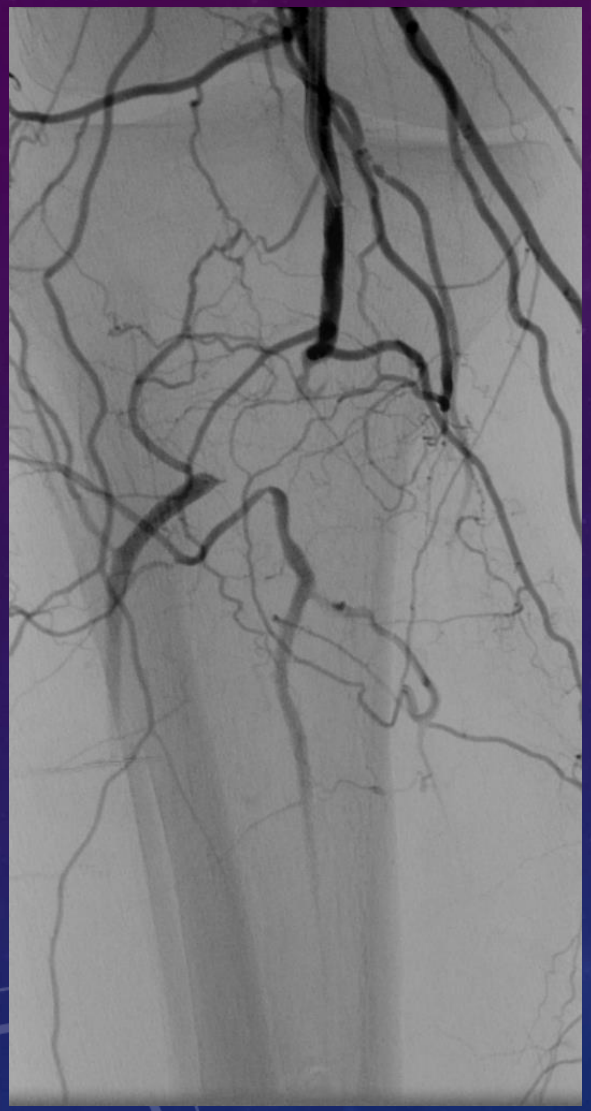
Patent peroneal artery

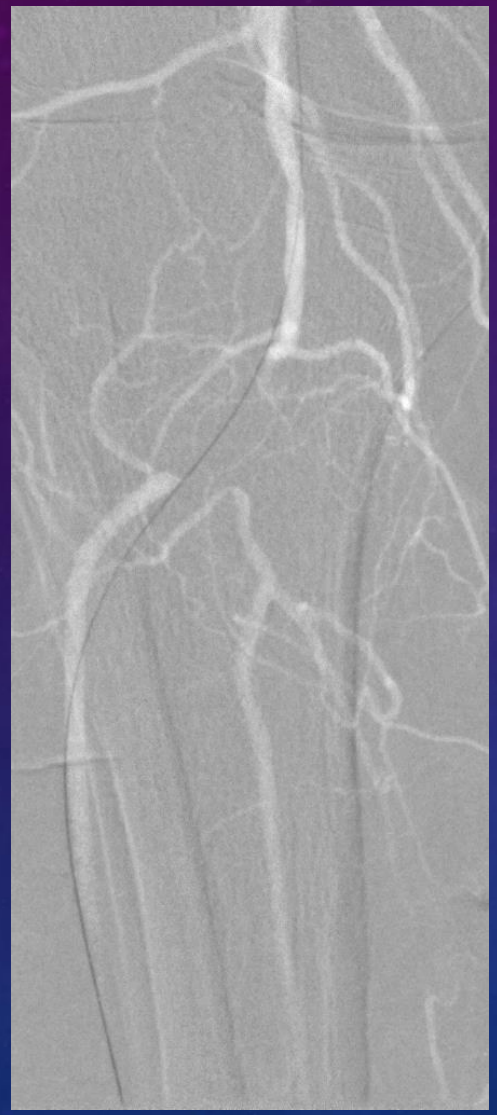


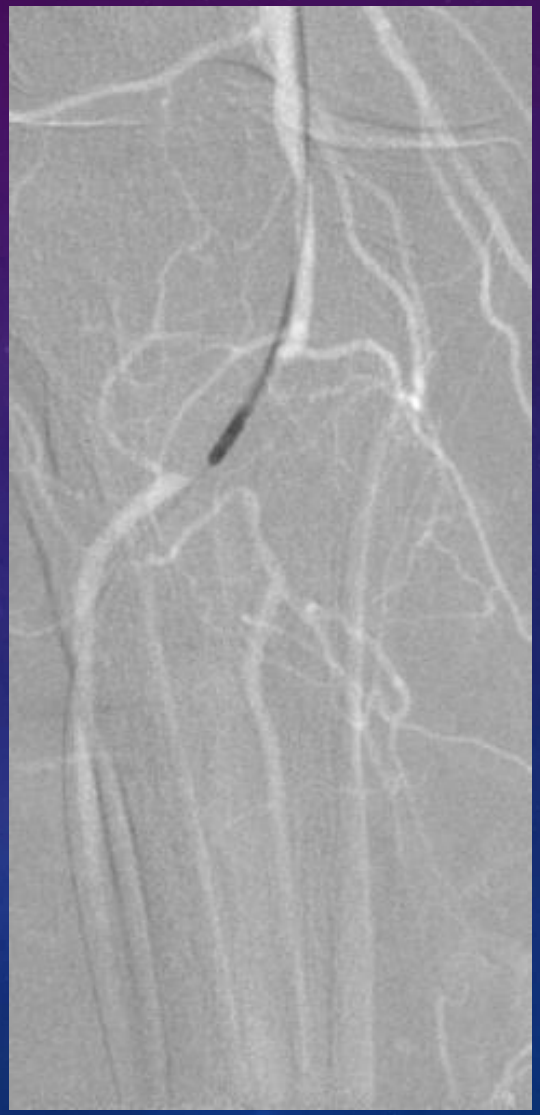
Collateral filling of the dorsalis pedis and the plantar artery

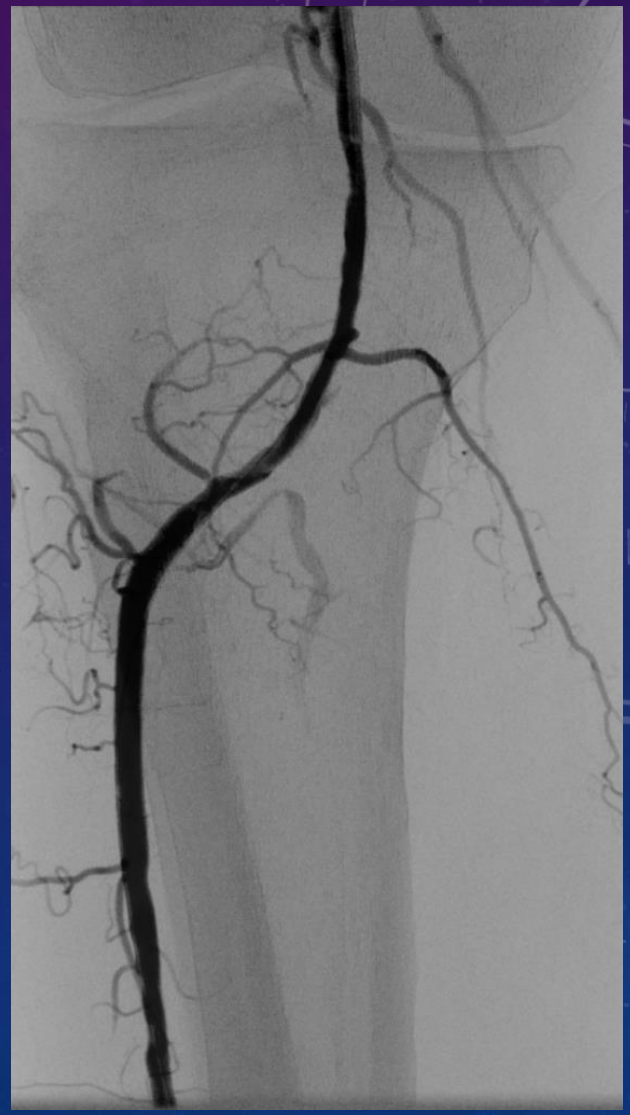
Case 4: Atherectomy of the Popliteal Bifurcation – Jet XC 2.1

68 y. old patient, CLI - rest pain in the right foot









Case 4: Atherectomy of the Popliteal Bifurcation – Jet XC 2.1