ZILVER PTX IN MY PRACTICE

Awais Siddique M.D.
Endovascular Radiology
Wisconsin, USA

Disclosure

Speaker name: Awais Siddique M.D.

.....

I have the following potential conflicts of interest to report:

- ☐ Consulting, Cook Medical
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any current potential conflict of interest

How Does Paclitaxel Work

Special Properties of Paclitaxel

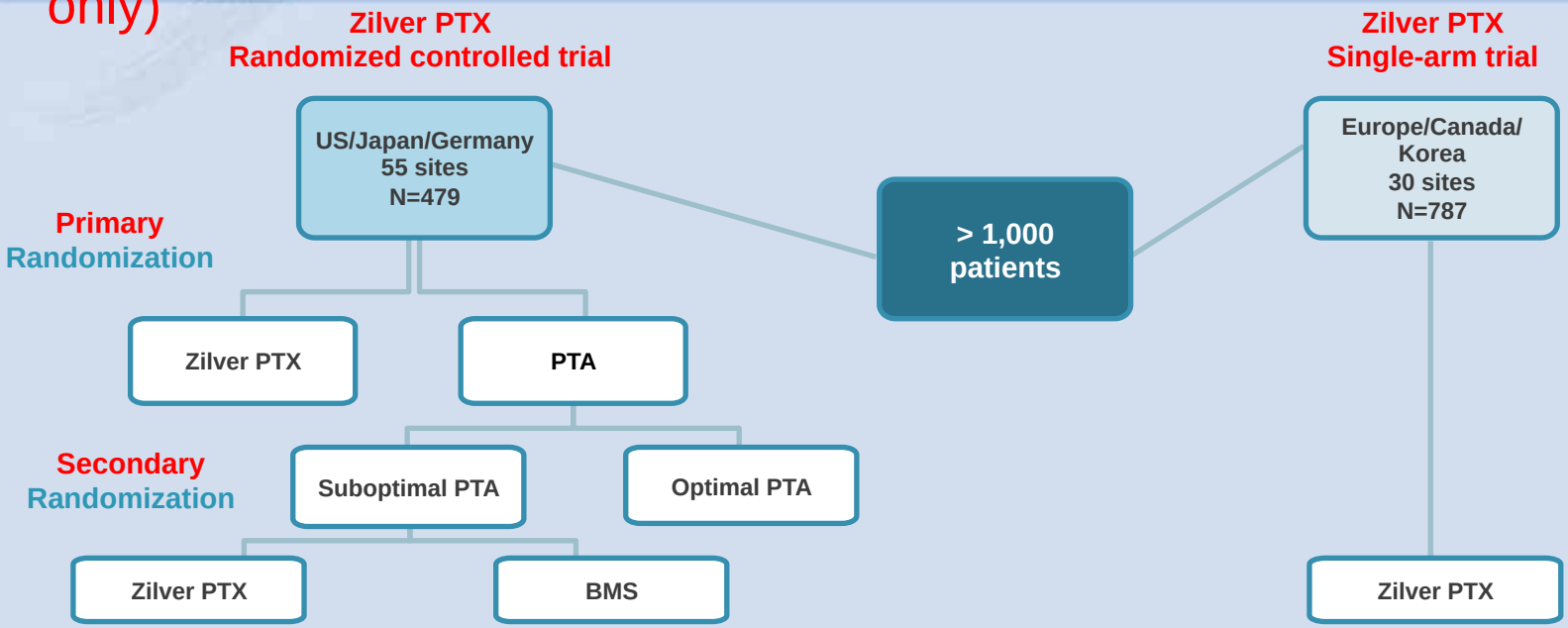
- Hydrophobic, Lipophilic. Antiproliferative Agent.
- 98% of the drug is released with in 72 hours after deployment.
- 100% of the drug in the artery 30 minutes after deployment.
- 0.2% left in the artery at 56 days. (IFU)

The proven drug effect of Zilver PTX

PTX advantage was demonstrated in the Randomized Controlled Trial (RCT) and Single-Arm Study (SAS)

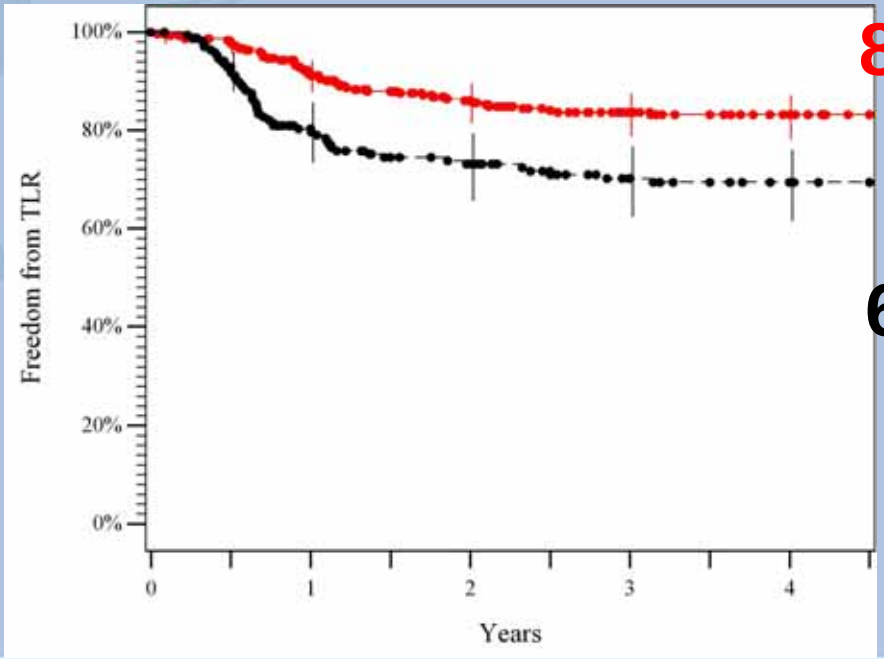
Largest SFA study ever conducted.

- More than 1,000 patients enrolled in the two trials
- Planned for 5-year follow-up (Randomized Control Trial only)



SUMMARY OF THE RCT TRIAL

- Reduction of Re-intervention by 45%.
- Similar results in diabetic and non-diabetics.
- Similar results in lesions ≤ 7 cm and lesions > 7 cm.
- Similar results in lesions ≤ 10 cm and lesions > 10 cm.
- Superior to the standard care in lesions > 10 cm.
- 41% reduction in re-stenosis due to the drug.
- **4-year results** (There was no evidence of late "catch-up"). (Dake et al.)



83.2% Zilver PTX

69.4% Optimal PTA + BMS

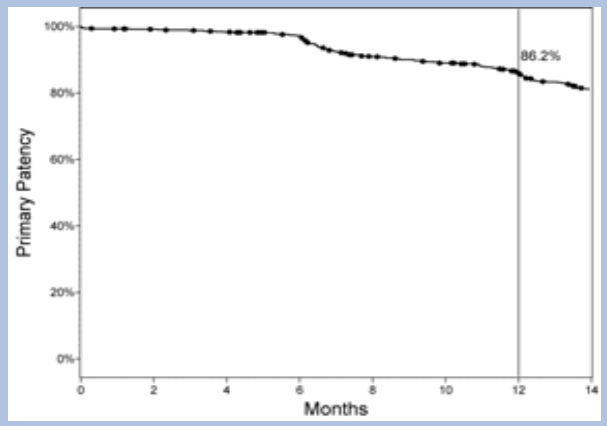
$p < 0.01$ log-rank

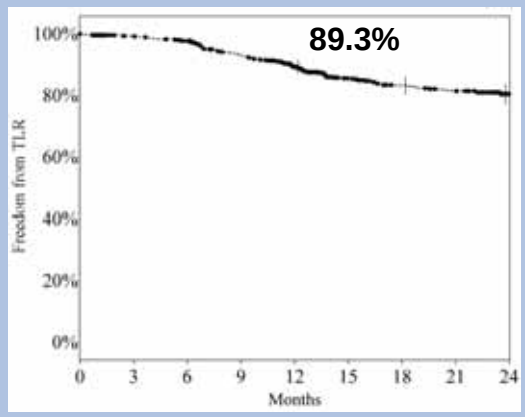
5-year data for Zilver PTX versus standard care

- 5 year freedom from 48% reduction in re-intervention compared to standard of care.
- 5 year Primary patency rate equates to 41% reduction in re-stenosis.
- Results with Zilver PTX continue to diverge from standard care over 5 years with no late catch-up.
- 5-year results confirm long-term superiority of Zilver PTX versus bare metal stents
- .

Overview

- Zilver PTX Single-Arm Study
  - Basically all comers, no length exclusion.
    - 86.2% primary patency rate at 1 year
    - 80.5% freedom from TLR through 2 years
    - Sustained clinical benefit through 2 years





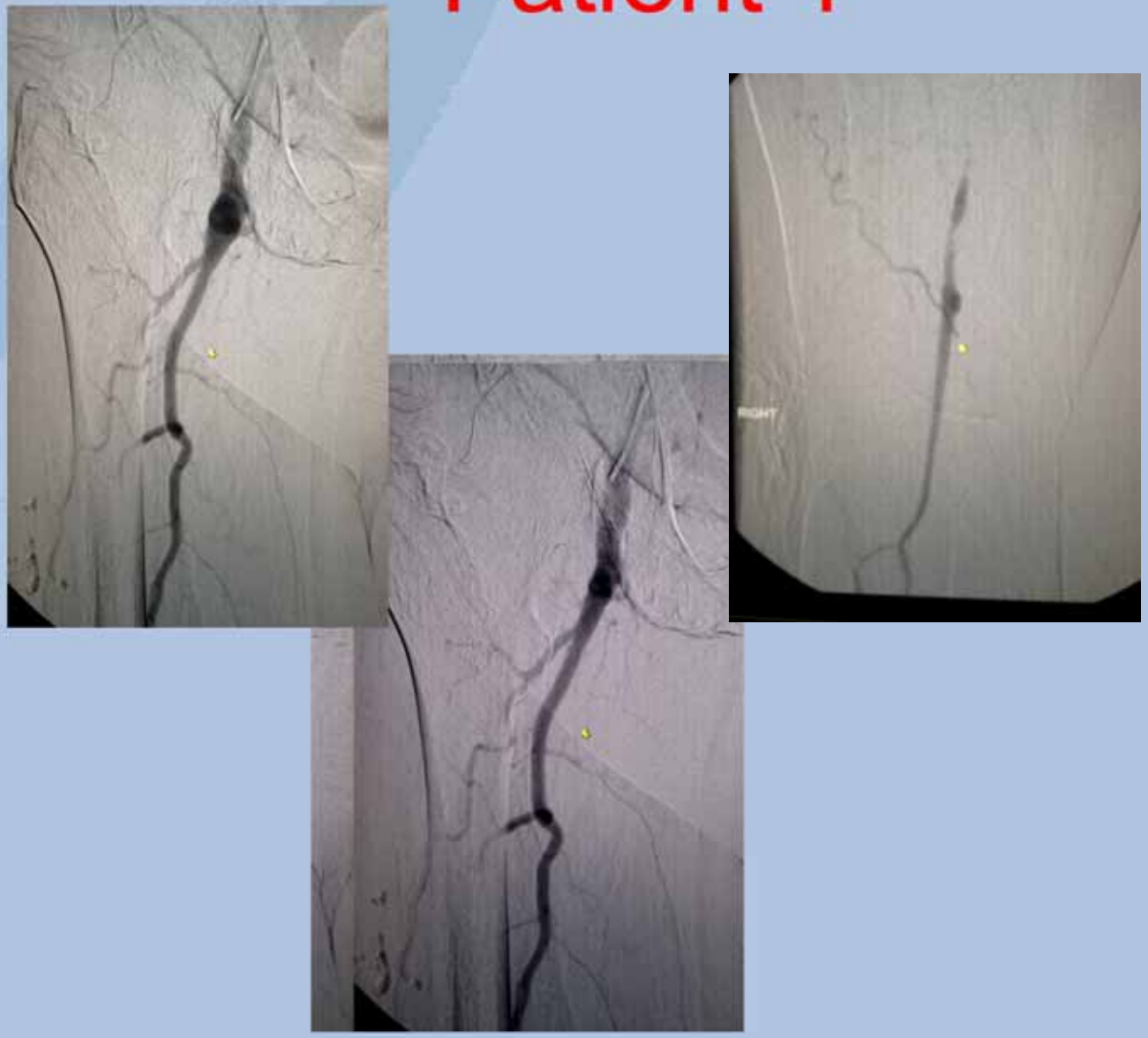
80.5%

FINANCIAL IMPACT
Significance of Re-intervention.

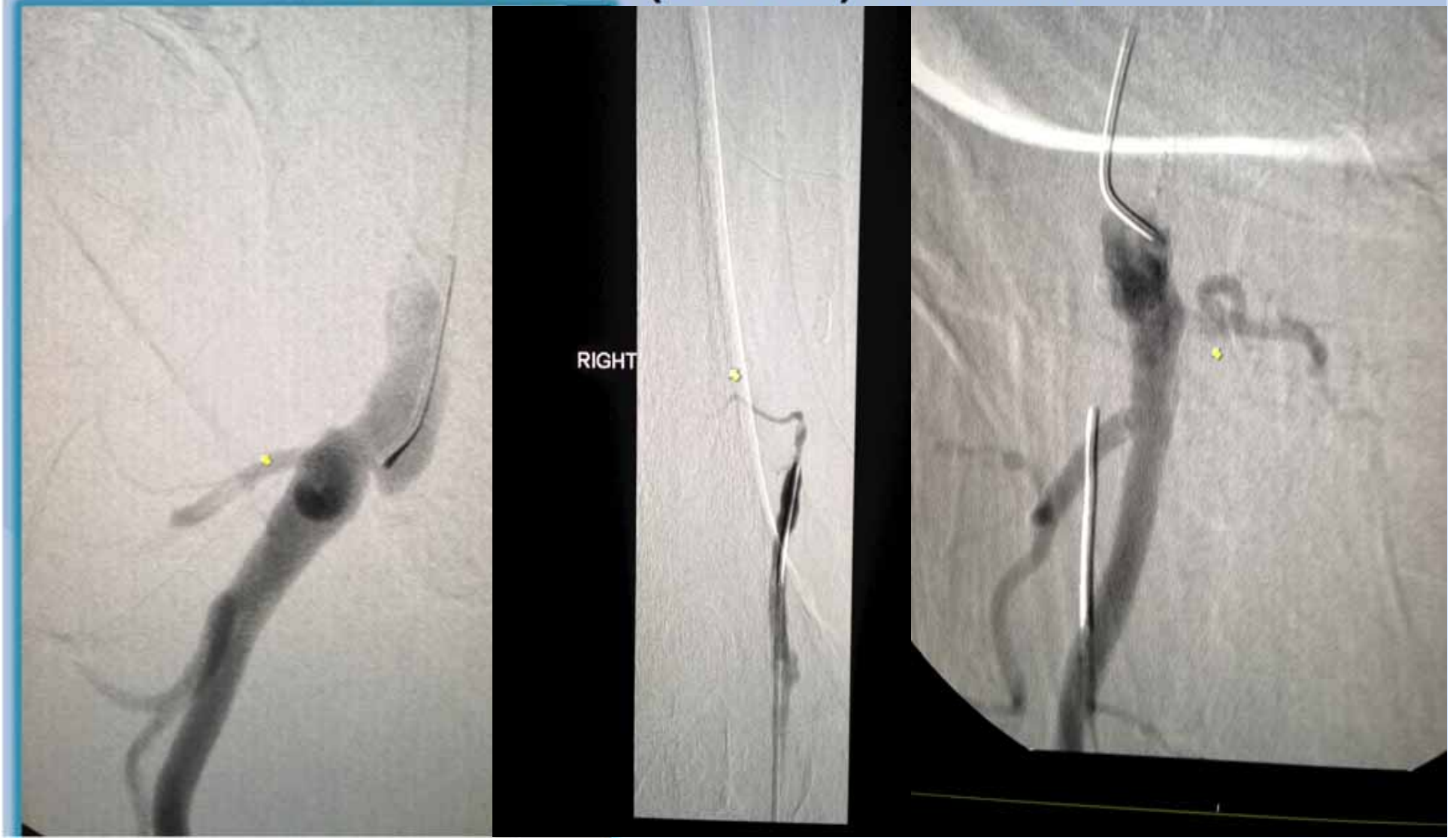
Patient 1

- 71 year male patient.
- History of CAD. Multiple Co-morbidities (Stage 4 renal disease, COPD, Hx of BPH).
- Smoker, 1.5ppd x 53 years.
- History of 2 months of toe ulcerations.
- Fontaine 4, Rutherford 5.
- CT angiogram could not be performed given the Stage 4 renal disease. CO2 and diluted isosmolar contrast angiograms are performed.

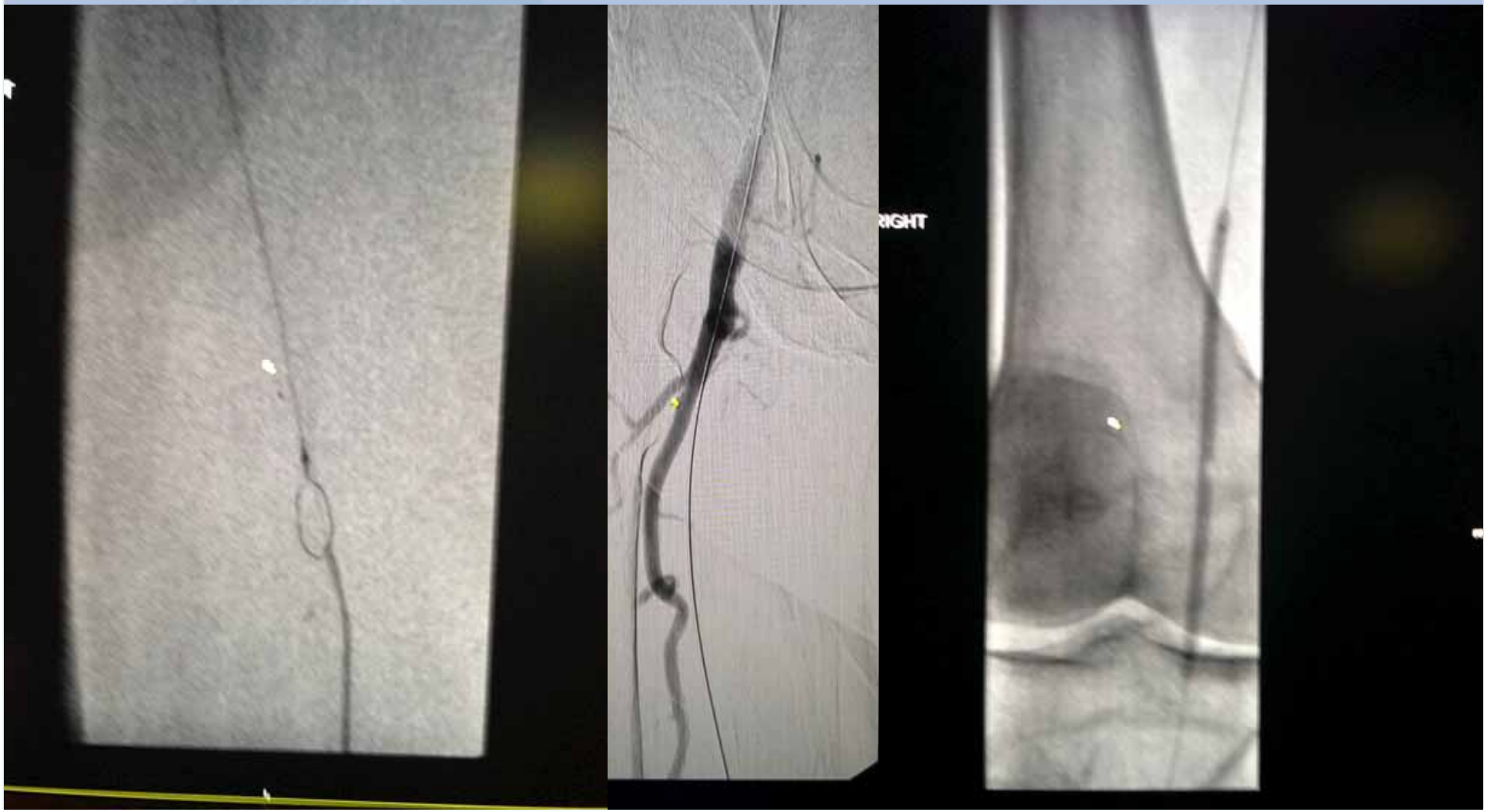
Patient 1



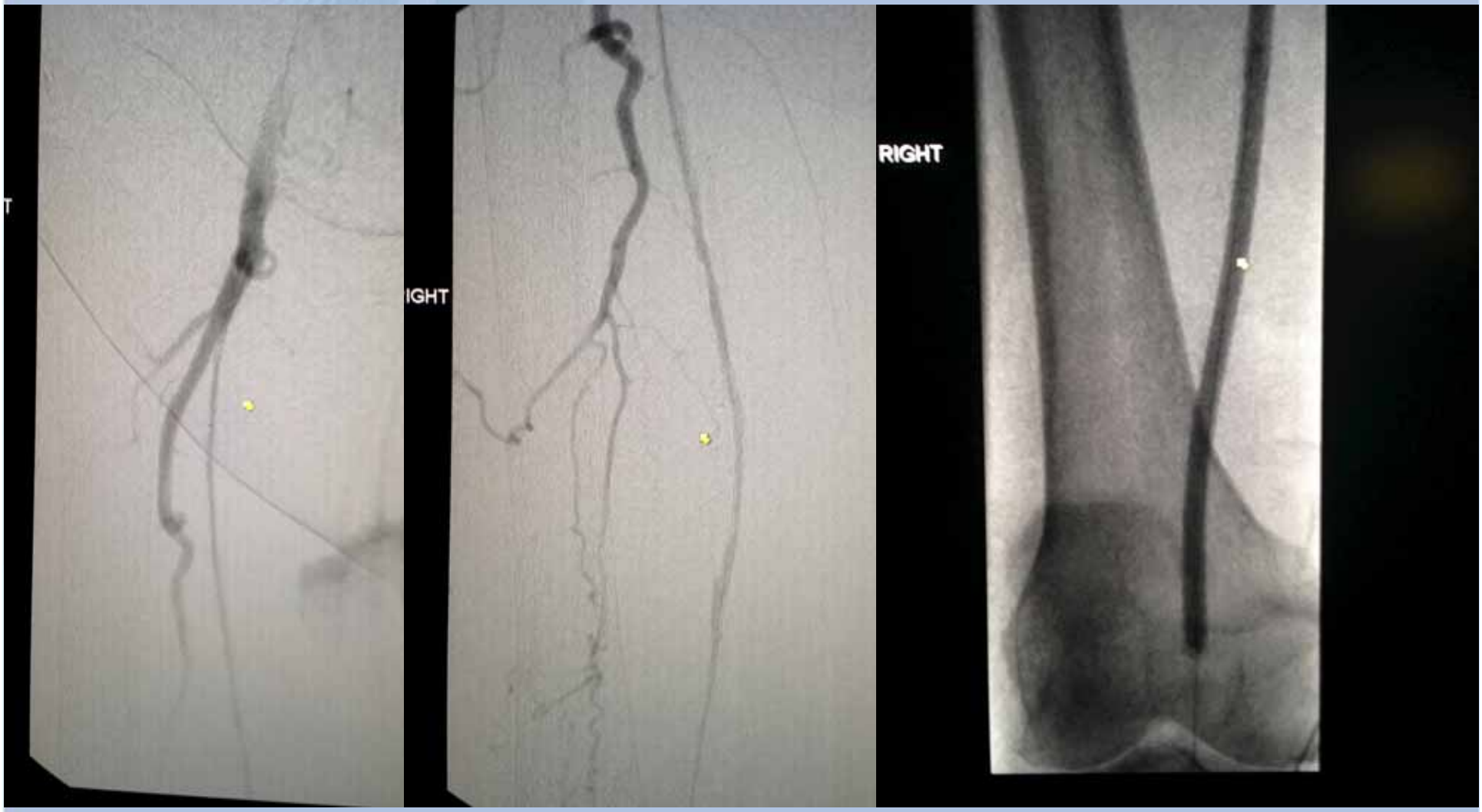
Patient 1
SAFARI
Subintimal Arterial Flossing with Antegrade-Retrograde Intervention (SAFARI) via the AT



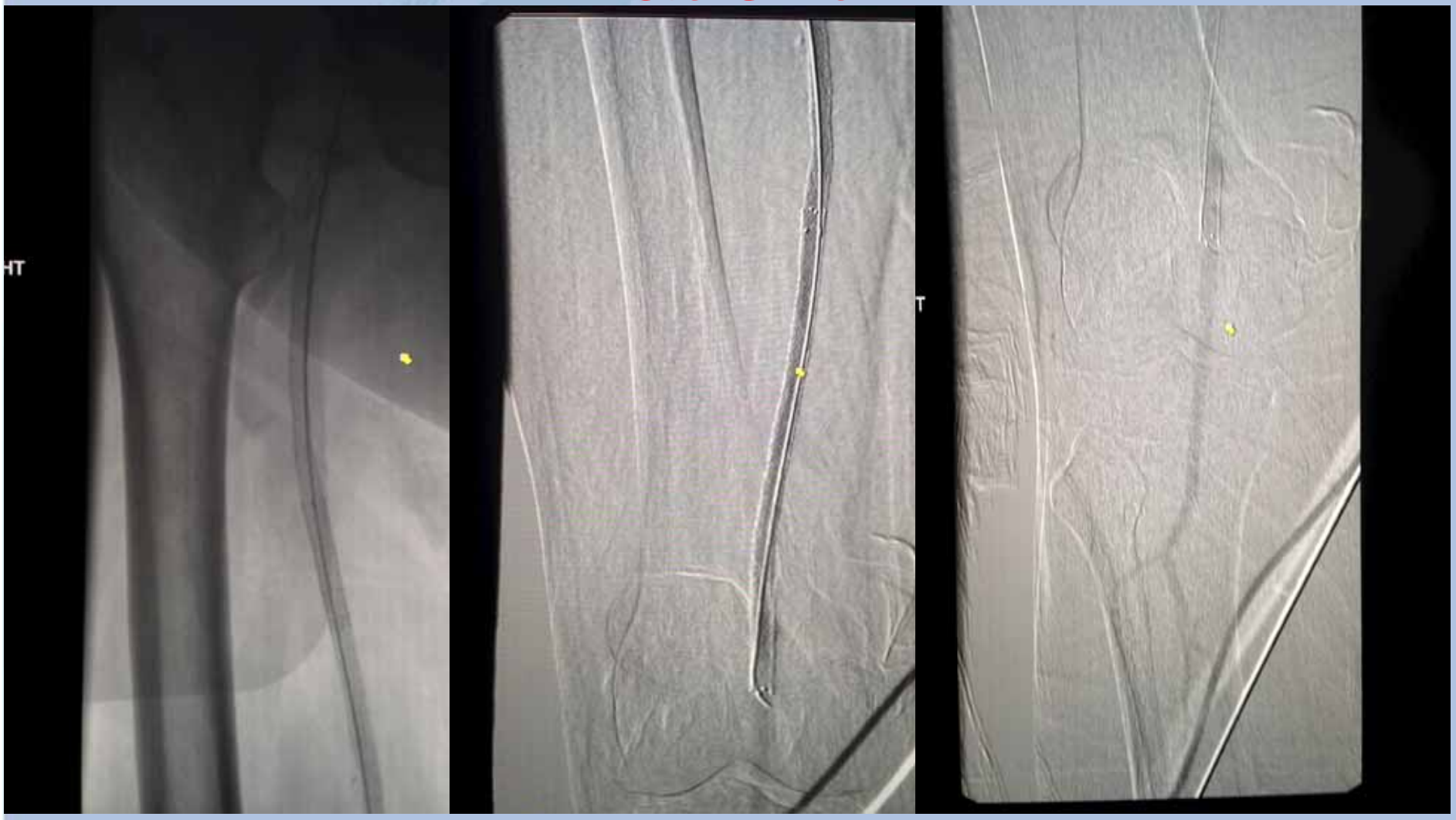
Patient 1



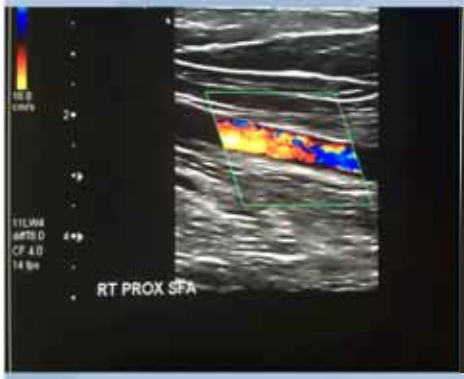
Patient 1

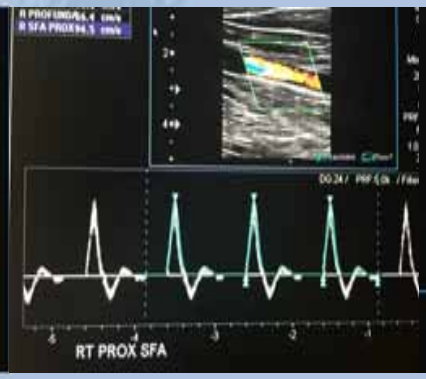


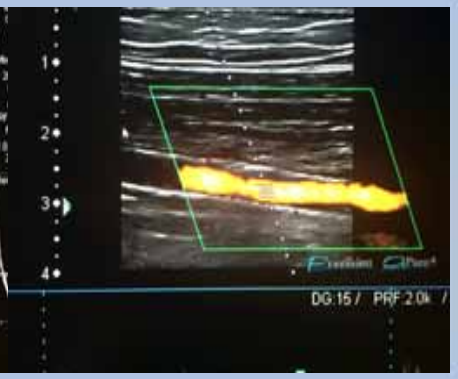
Patient 1

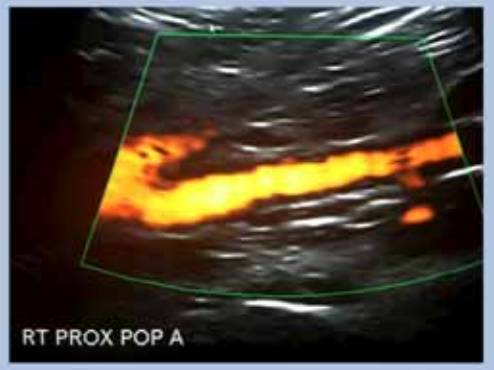


Sonographic images at 12 months





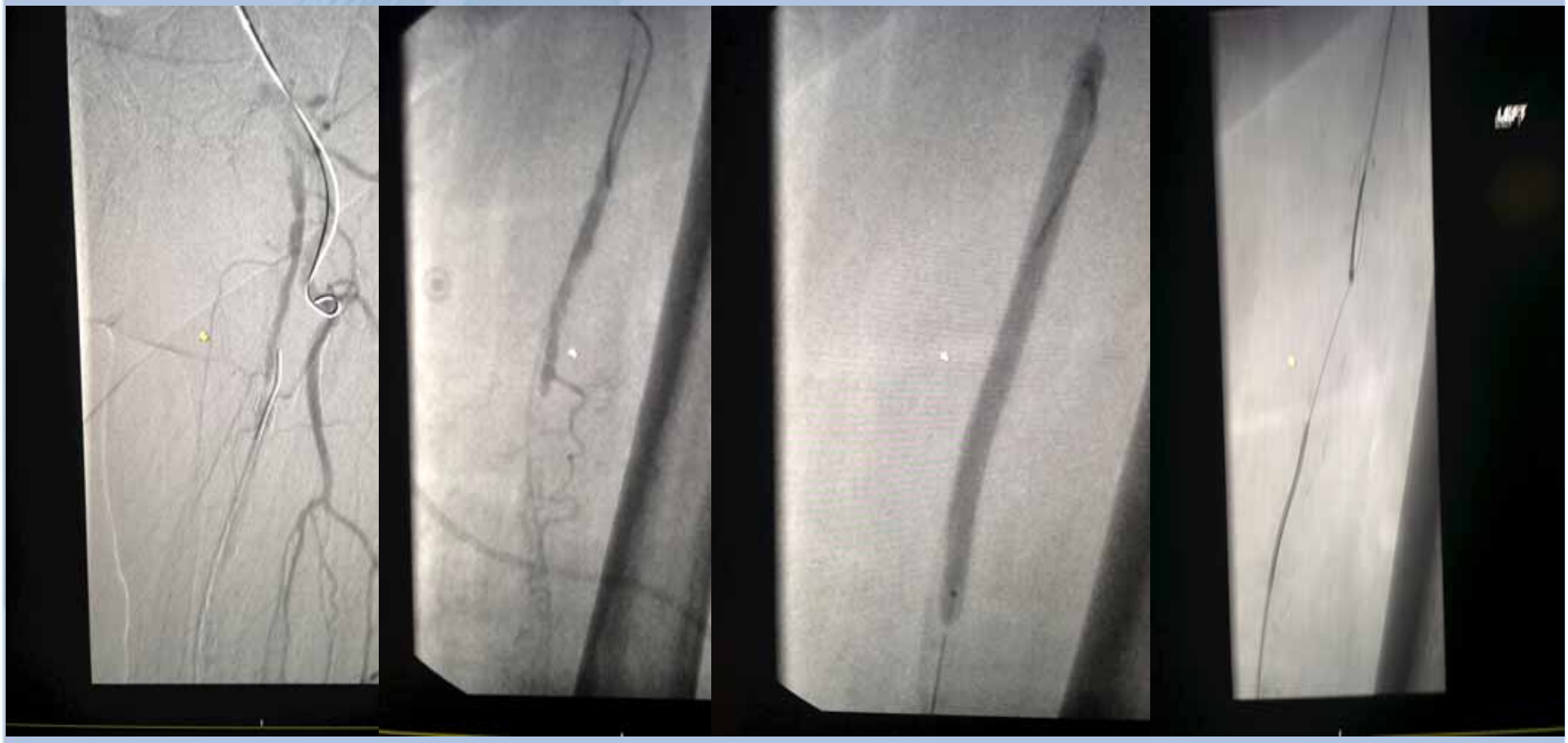




Patient 2

- 74 yo male.
- Multiple Co-Morbidities (DM, Smoker, COPD, CAD, PAD, Hx of ETOH use, admitted for back pain).
- Consulted by Orthopedics, for leg evaluation.
- Critical Limb Ischemia.
- Rutherford 6, Fontaine 4.
- CT angiogram demonstrated CTO of the left out flow.

Patient 2
SAFARI via AT



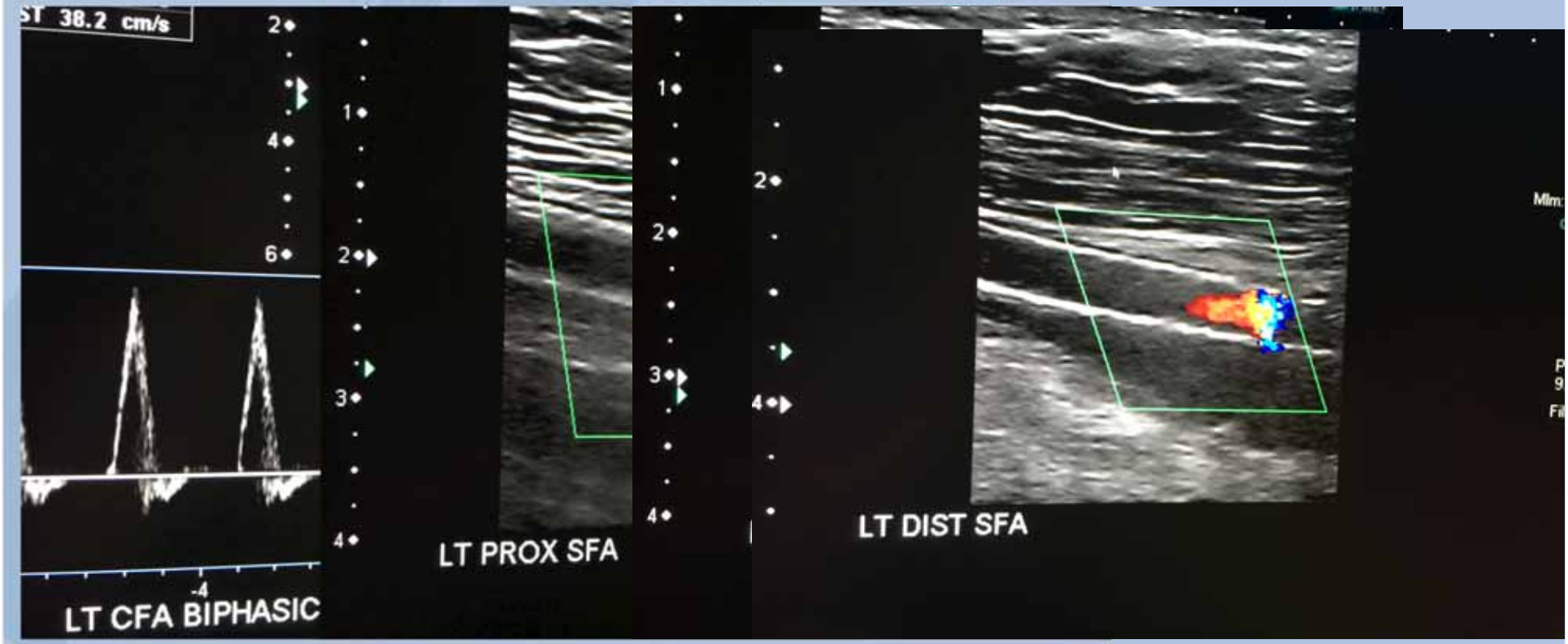
Patient 2

Patient 2

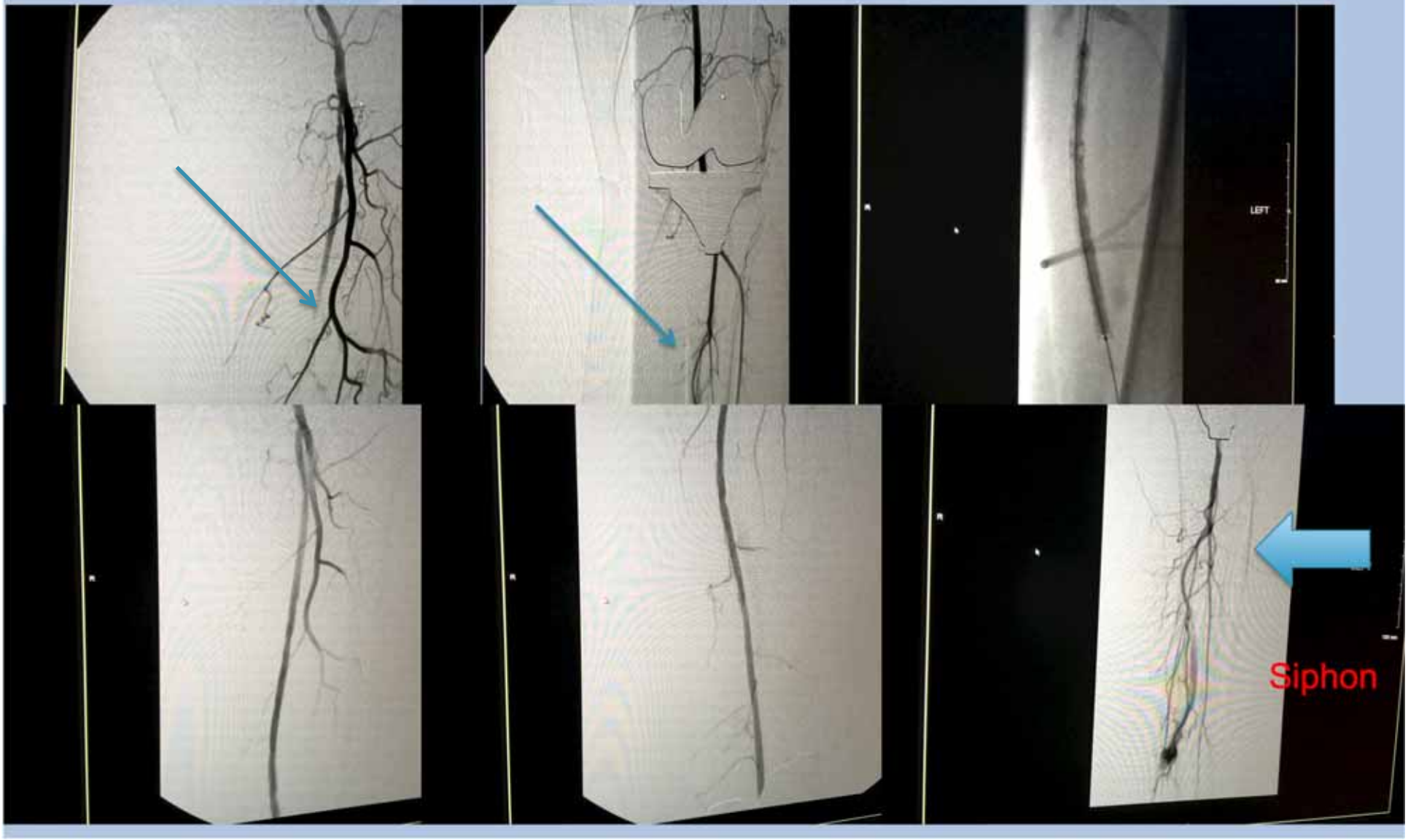
CASE 3

- 73 y old Male.
- Multiple co-morbidities (DM, Smoker 2ppd, CAD,TIA, CHF).
- Non healing ulcerations of the left great toe, digit 4 and 5.
- Rutherford 5 Fontaine 4.
- Patient has had previous BMS placed 3 months prior at an outside facility.
- Ultrasound confirmed occlusion.

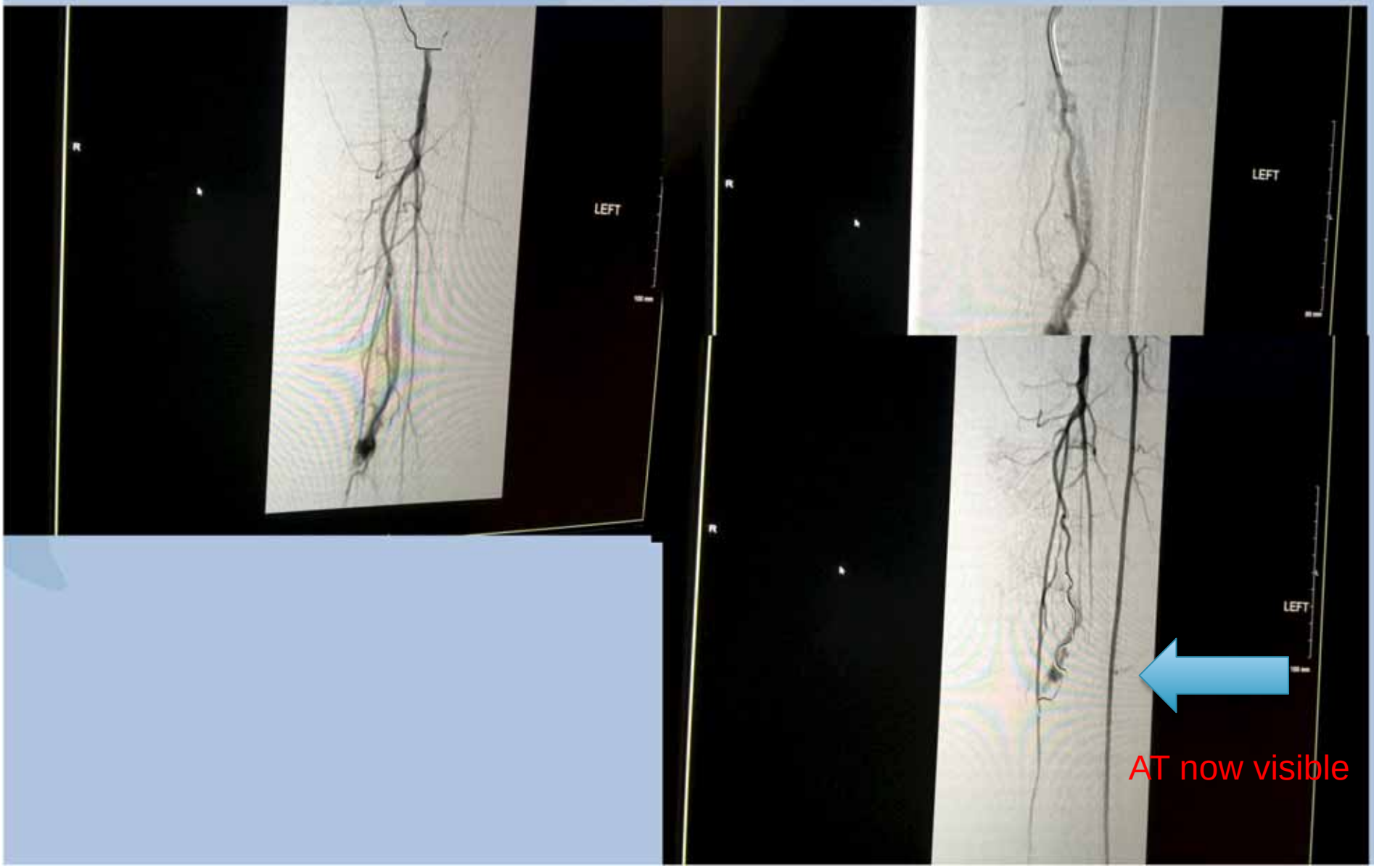
US
Shows occlusion of the BMS



Angiography



Embolization



Experience with the PTX

- 323stents utilized in approximately 126 limbs in 12 months.
- Approximately 2.56 stents per limb.
- Majority lesions greater than 10cm.
- 58% male, 42% female.
- Approximately 40% DM,
- 77% smokers or previous smokers.
- Approximately 20% diffusely calcified.
- 13% single vessel runoff.
- 94% placed on aspirin and plavix.
- 2 acute limb occlusions in heavily calcified diffuse out flow disease.
- 14 additional late limb occlusions and or symptomatic re-stenosis requiring re-intervention.
- Primary patency rate of 87.3% after 1 year, pSVR< 2.
- If Ultrasound positive then stratified into symptomatic or asymptomatic.
- If symptomatic then intervene.
- If asymptomatic then more frequent ultrasounds.
- High risk patients follow-up ultrasound q 1day-1week, then Strict q3 month follow-up duplex for first year.
- If sonographic stability is demonstrated then recommend evaluation q 6 months. (Possibly q 1 year after 2 year stability)
- Thank you for your attention.

Experience with the PTX

- 323stents utilized in approximately 126 limbs in 12 months.
- Approximately 2.56 stents per limb.
- Majority lesions greater than 10cm.
- 58% male, 42% female.
- Approximately 40% DM,
- 77% smokers or previous smokers.
- Approximately 20% diffusely calcified.
- 13% single vessel runoff.
- 94% placed on aspirin and plavix.
- 2 acute limb occlusions in heavily calcified diffuse out flow disease.
- 14 additional late limb occlusions and or symptomatic re-stenosis requiring re-intervention.
- Primary patency rate of 87.3% after 1 year, pSVR< 2.
- If Ultrasound positive then stratified into symptomatic or asymptomatic.
- If symptomatic then intervene.
- If asymptomatic then more frequent ultrasounds.
- High risk patients follow-up ultrasound q 1day-1week, then Strict q3 month follow-up duplex for first year.
- If sonographic stability is demonstrated then recommend evaluation q 6 months. (Possibly q 1 year after 2 year stability)
- Thank you for your attention.