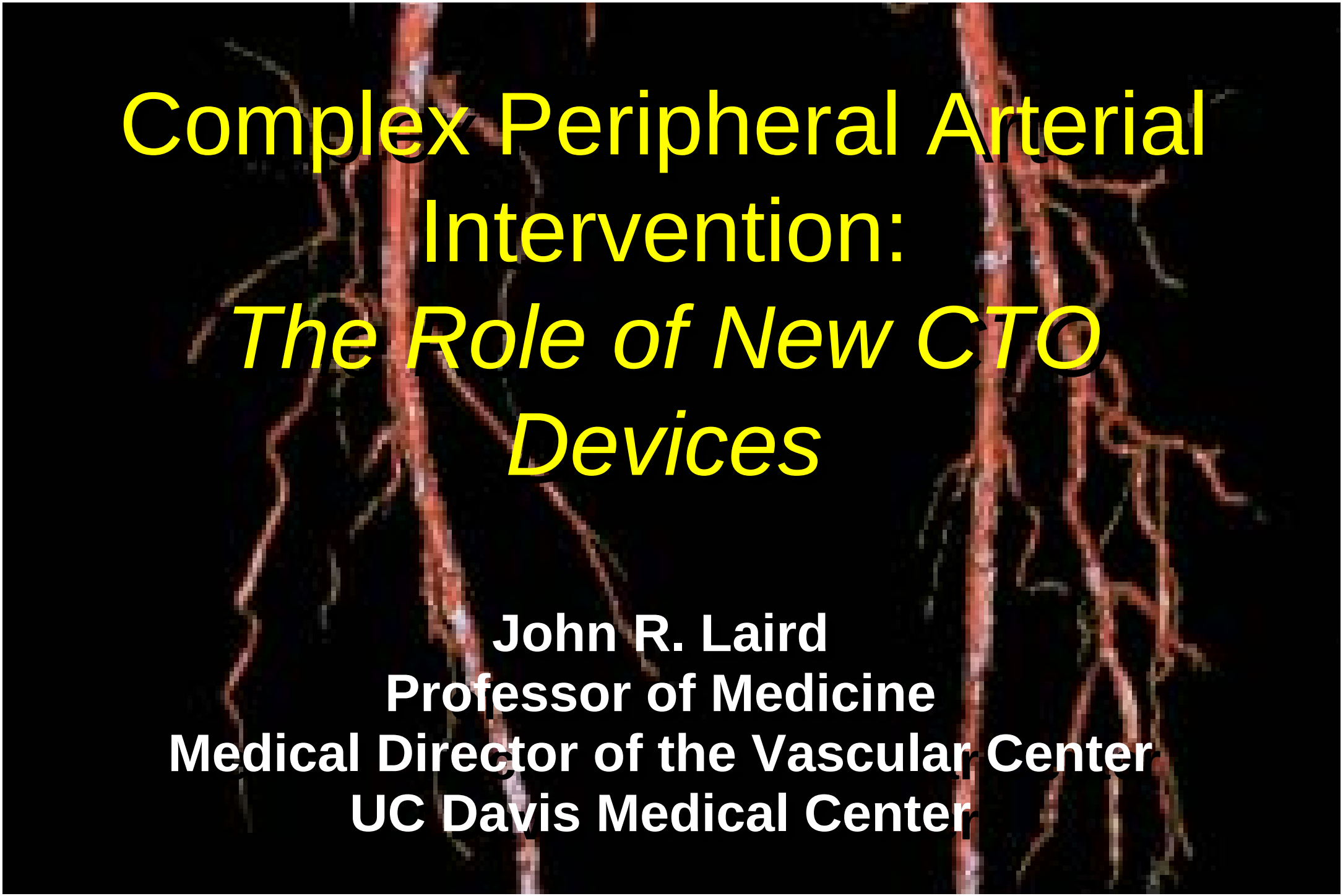


Complex Peripheral Arterial Intervention: *The Role of New CTO Devices*

John R. Laird
Professor of Medicine
Medical Director of the Vascular Center
UC Davis Medical Center

CTOs in the Periphery

- Presence of Total Occlusion – 20-40%
- Often very old - Difficult to Treat
  - Time intensive without incremental reimbursement
  - Significant contrast and radiation exposure
  - Complications
    - Dissection, Perforation, Embolization.
  - Historical Success rate - <80%
- Late events - Restenosis, Reocclusion
- Risk – Benefit
- Most common reason to send to surgery

Long SFA Occlusions

CLINICAL CHALLENGES:

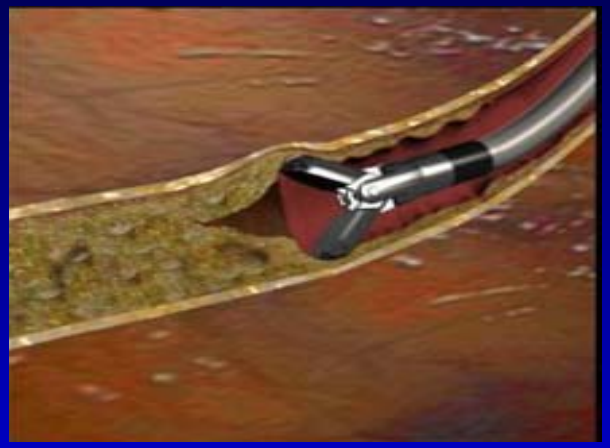
- Penetration of CTO fibrous cap
- Presence of collaterals
- Lack of Guidewire tip maneuverability
- Tough, calcified lesions
- Subintimal trapping of the guidewire
- Difficulty regaining access to the true lumen

Total Occlusion Wires

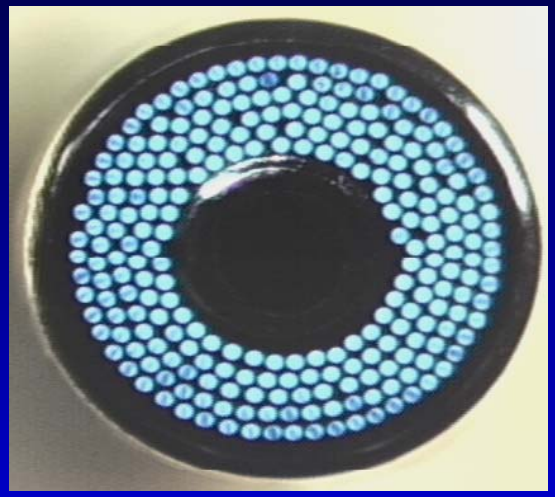
- The very stiff and hydrophilic wires are strong enough (with patience) to get through even tough occlusions
- They are steerable enough to control direction, even in mid occlusion
- Unfortunately, they are not smart or selective enough to follow the latent vessel lumen rather than a cleavage plane (dissection) or vasa vasorum (perforation)

Hydrophilic Glidewire (Terumo)

New Ways to Cross Total Occlusions



Lumend Frontrunner



Laser

Crosser

Pioneer

Outback

Pioneer Catheter

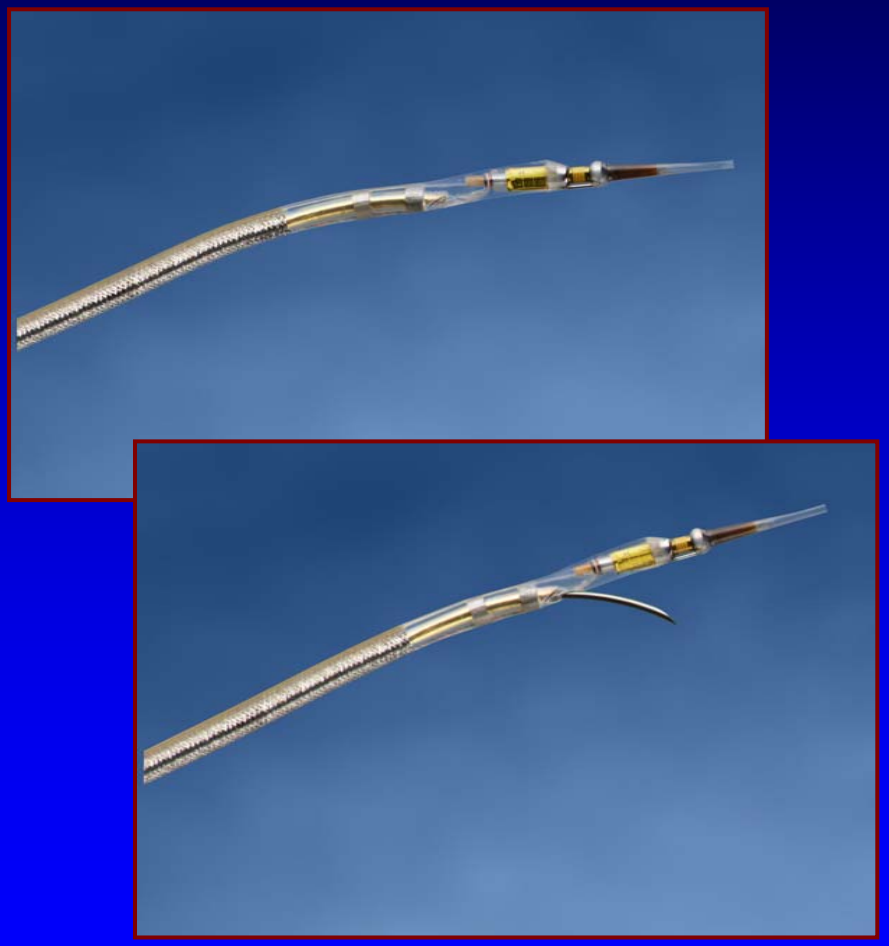
Why Pioneer Catheter?

- Subintimal wire trapping is the largest cause of failure during revascularization of chronic total occlusions*.
- 18 - 22% failure rate in patients with chronically occluded peripheral arteries due to failure to cross with a guidewire.

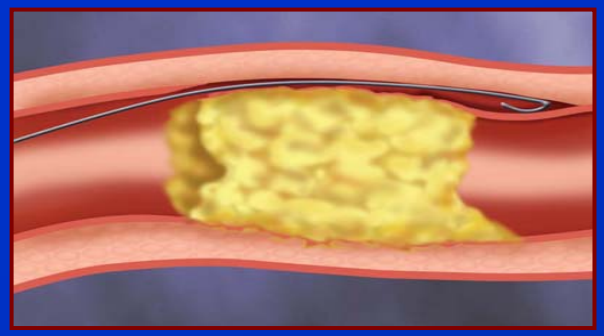
Pioneer Catheter

Key Features:

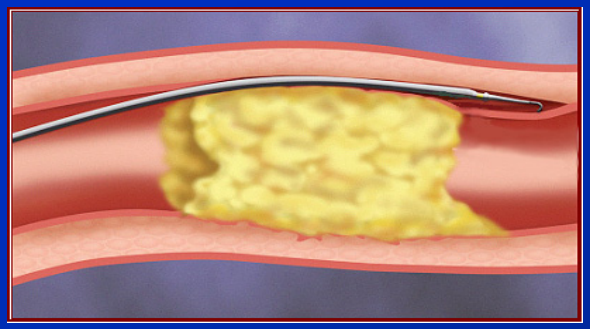
- 24G needle allows for delivery of a 0.014” guidewire
- Flexible shaft allows for contralateral approach
- 7F Introducer sheath compatibility (0.087” I.D.)



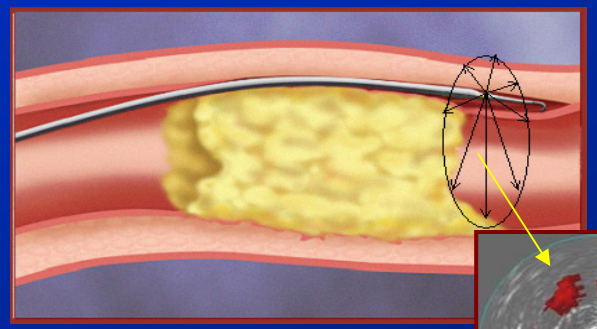
Pioneer Catheter

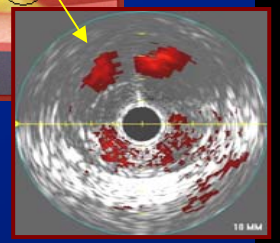


Step 1: Guidewire entrapment

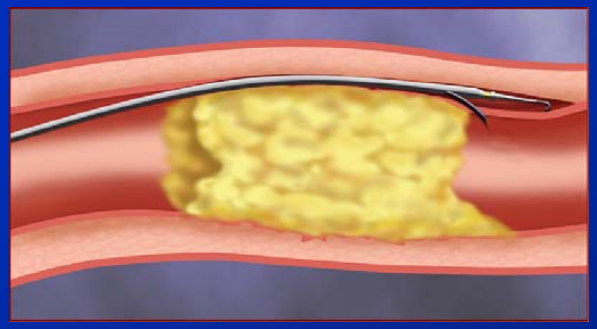


Step 2: Catheter insertion

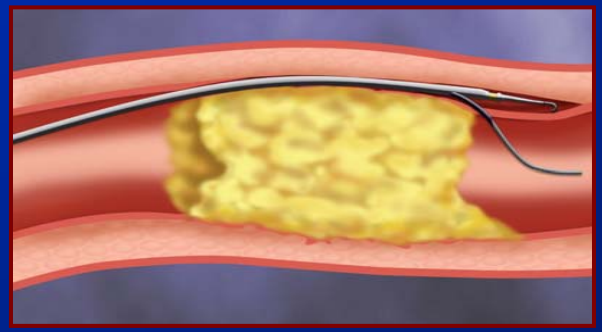




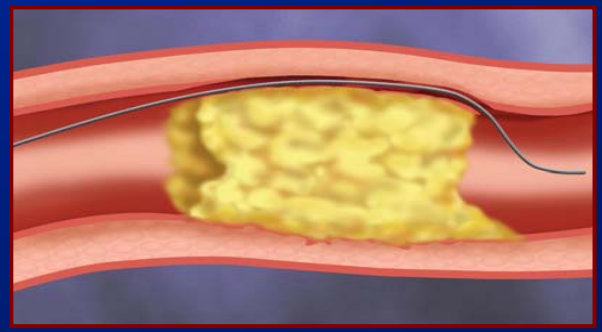
Step 3: Catheter rotation



Step 4: Deploy needle

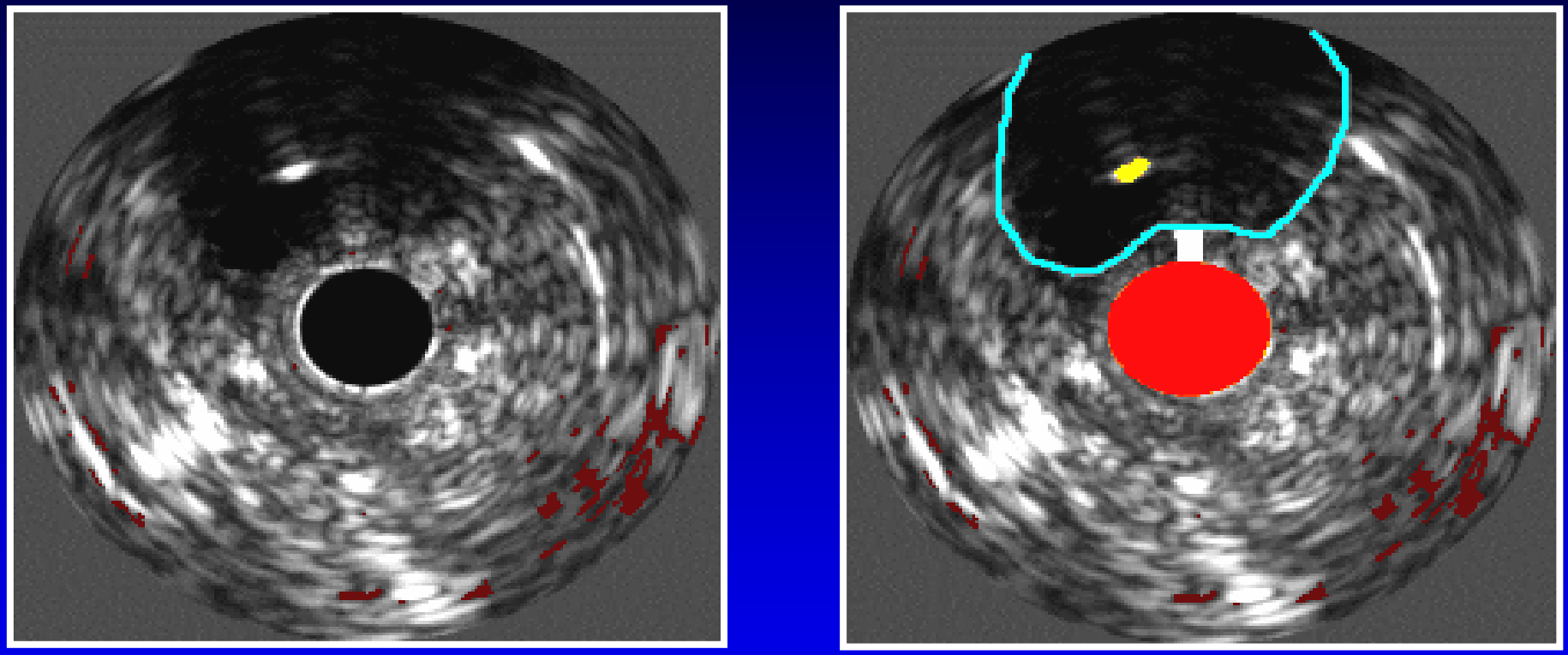


Step 5: Pass guidewire to true lumen



Step 6: Remove catheter

Subintimal TransAccess® IVUS Image

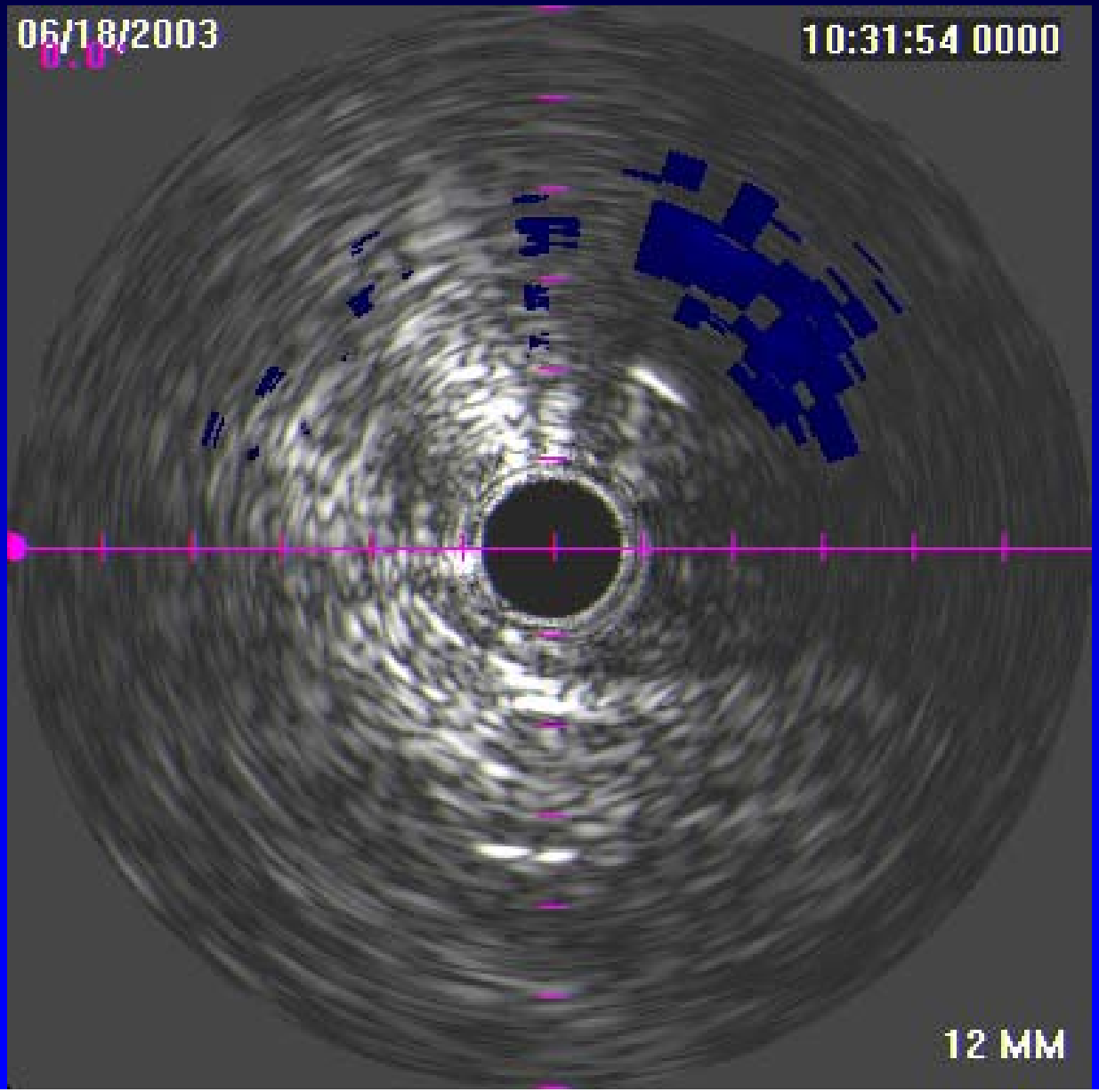


- IVUS allows for direct imaging of true lumen from subintimal position
- Lumen is aligned at top of screen
- Nitinol needle is advanced across intima and back into true lumen
- Guidewire is advanced into true lumen via needle

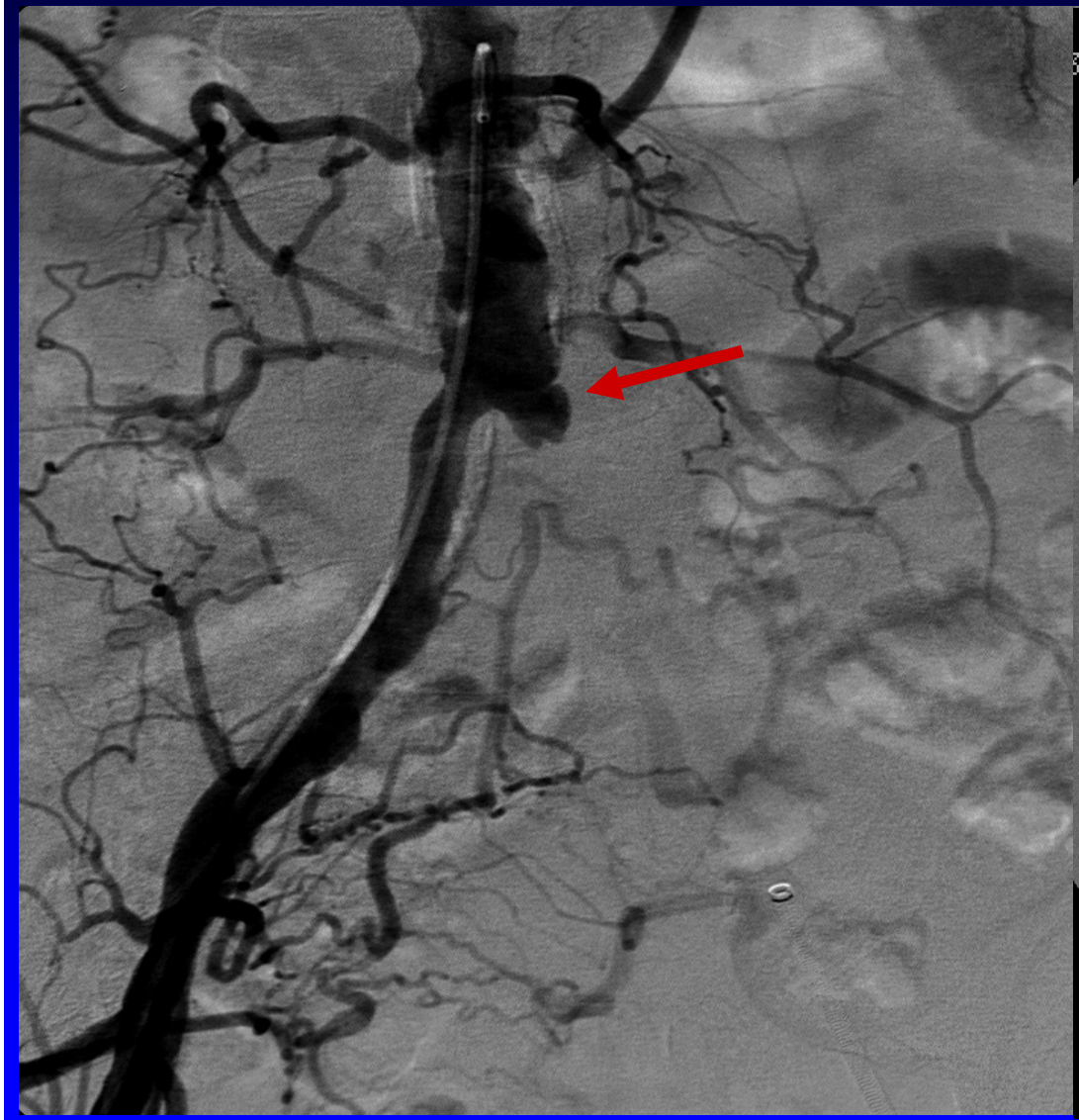
Chronic Iliac Occlusion

- 57 year old male
- Chronic left hip claudication
- Failed previous attempt at percutaneous recanalization
- Referred for 2nd attempt

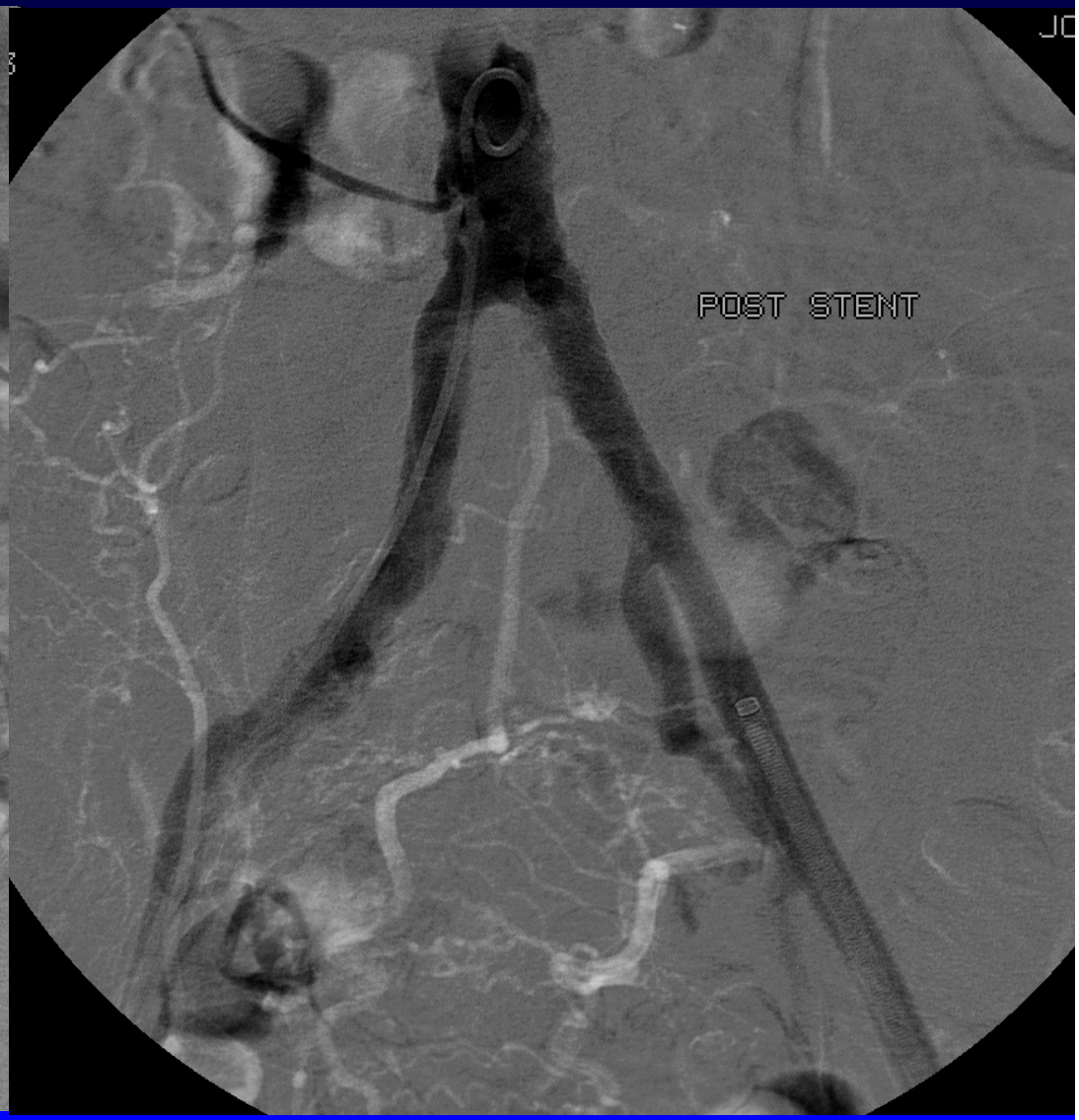
Pioneer IVUS Images



Chronic Iliac Occlusion

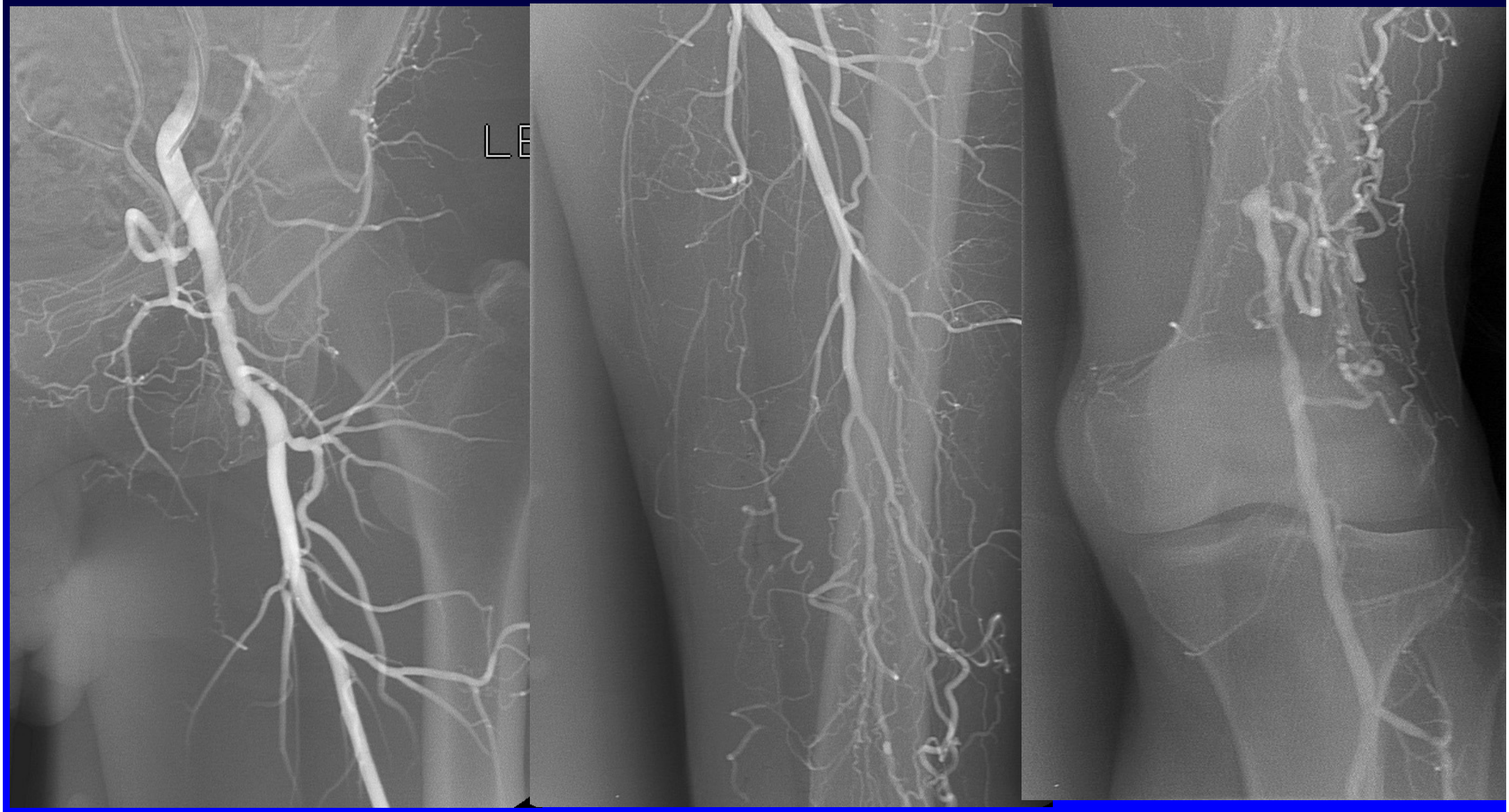


Baseline



Final

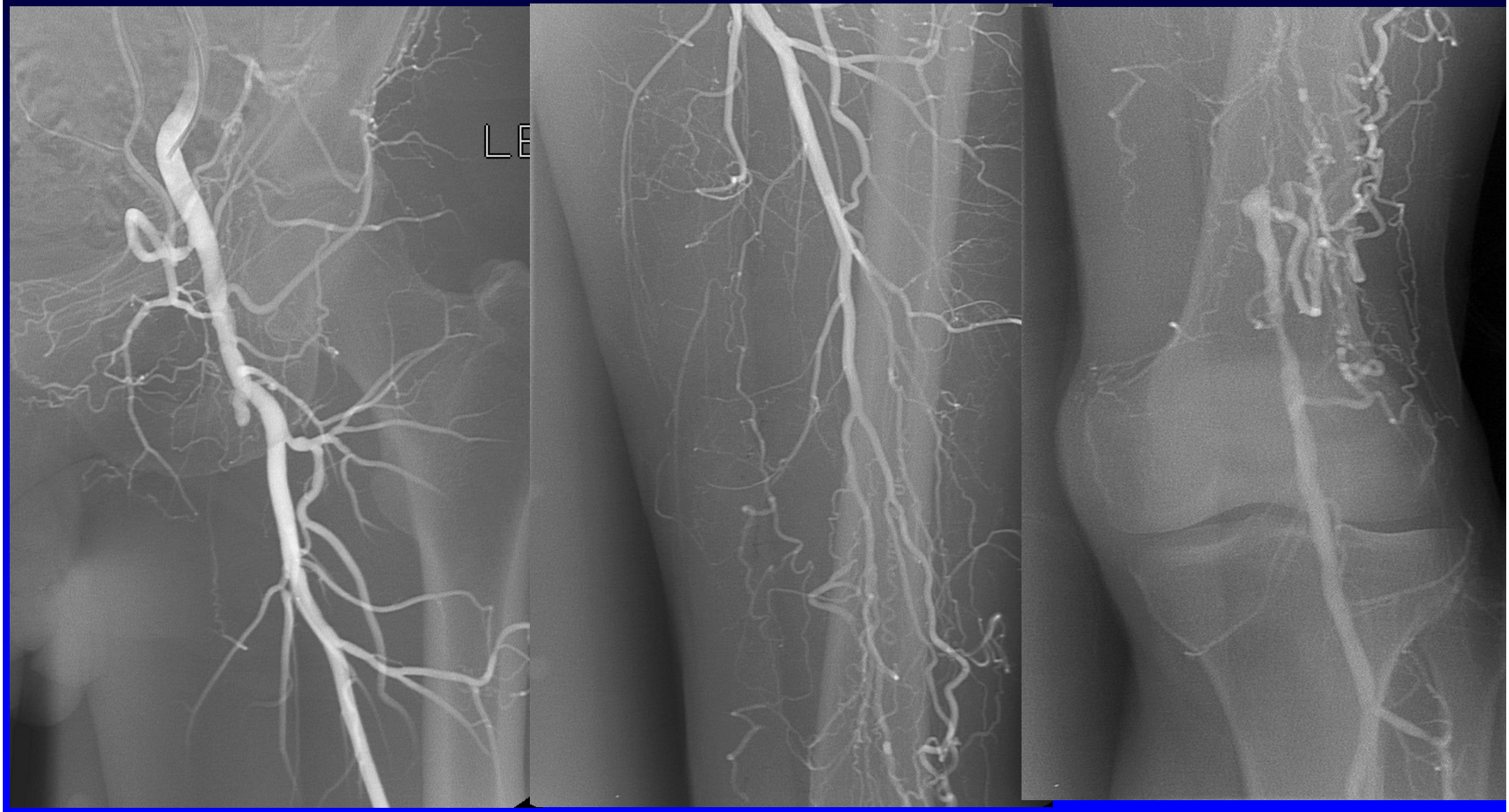
SFA Occlusions



Recanalization Approaches

- Intraluminal Approaches
  - Laser
  - Safe-Cross
  - Frontrunner
  - FlowCardia Crosser
- Subintimal Approaches
  - Bolia (PIERS) tecnique
  - Pioneer reentry
  - Outback reentry

SFA Occlusions

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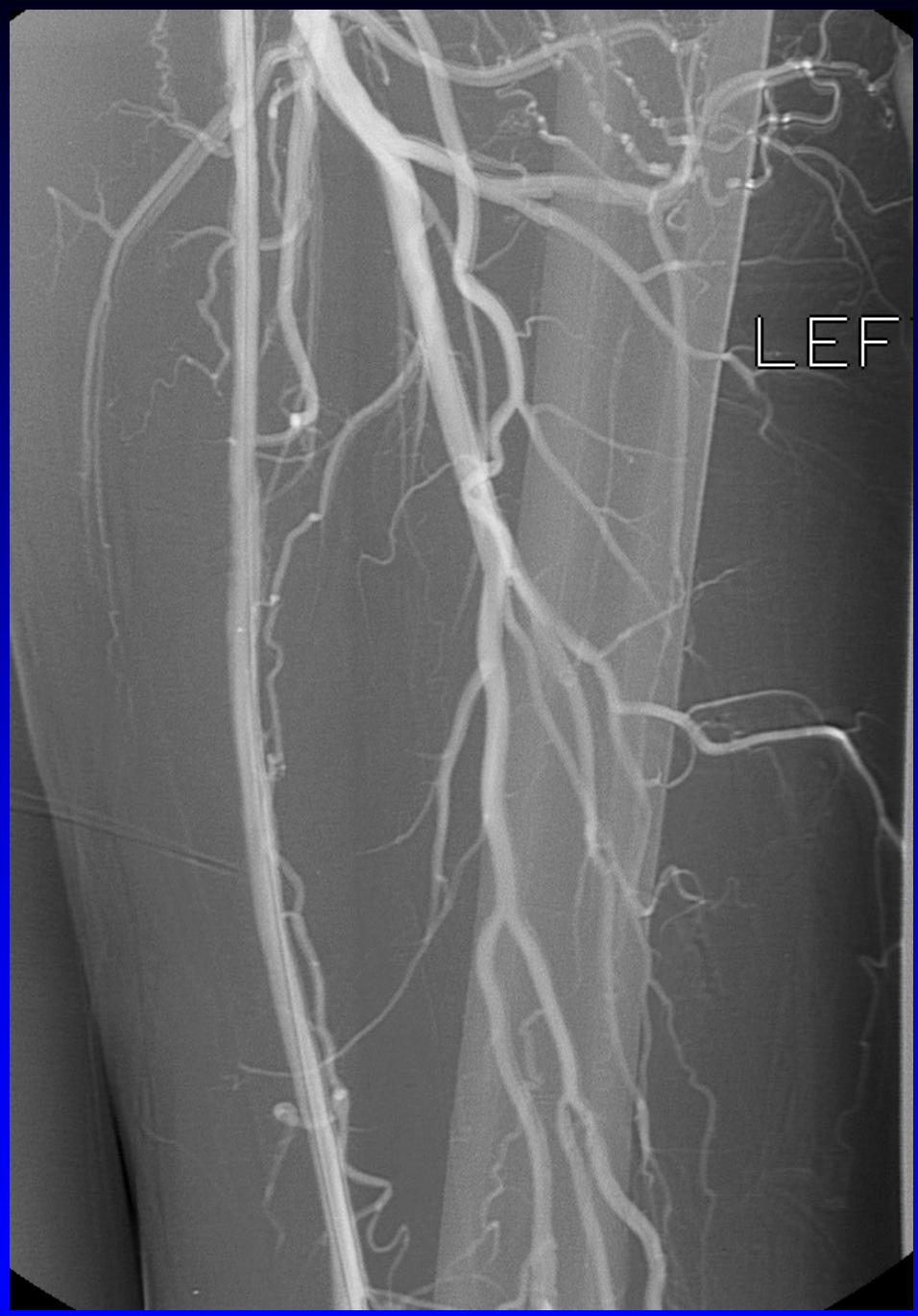
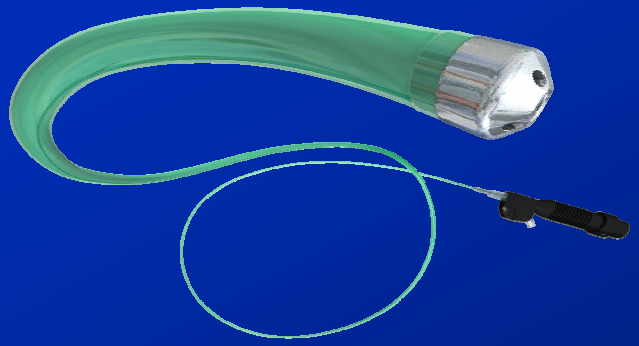

LEF

The CROSSER™ System

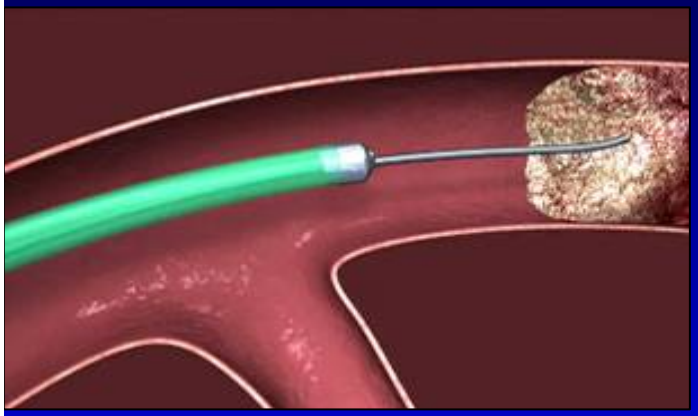
Generator

- Converts AC power into high frequency current
- Piezoelectric crystals within the Transducer convert high frequency current into vibrational energy

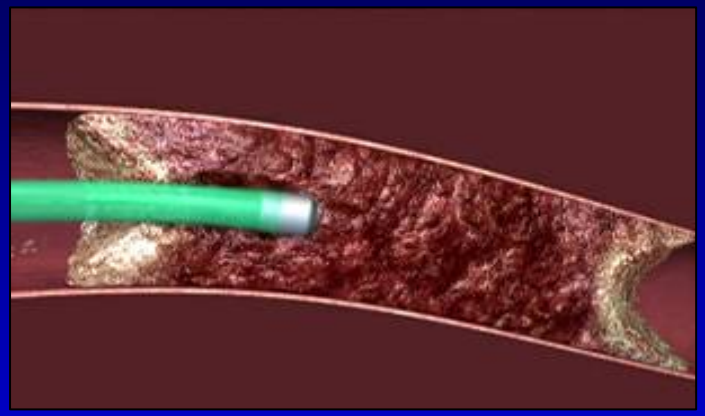


- ## CROSSER Catheter
- Nitinol core wire transmits mechanical vibration to the stainless steel tip of the Catheter at 20,000 cycles/second
  - 20 micron amplitude (stroke depth)

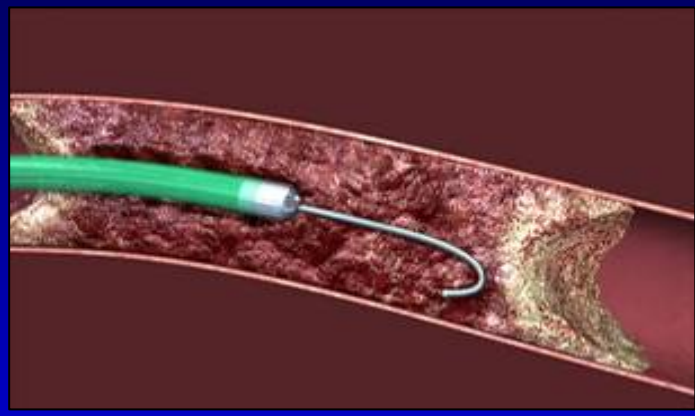
Procedural Steps



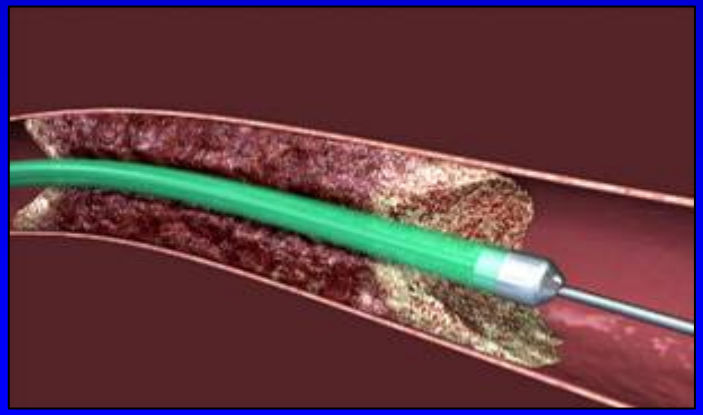
Guidewire Probing then CROSSER



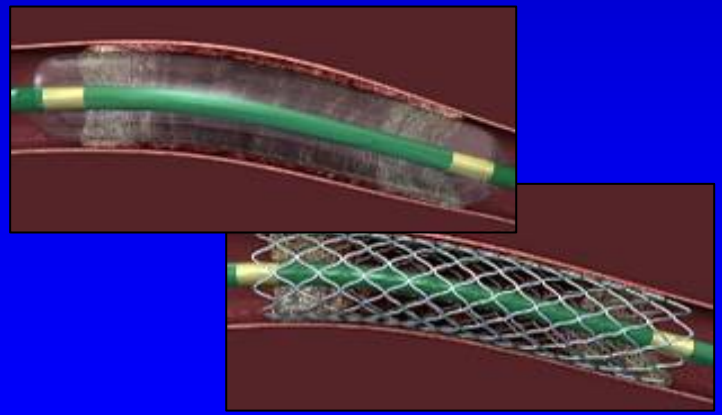
CROSSER Activation



Optional: Wire Probe Mid-lesion



CROSSER through, Wire Advanced

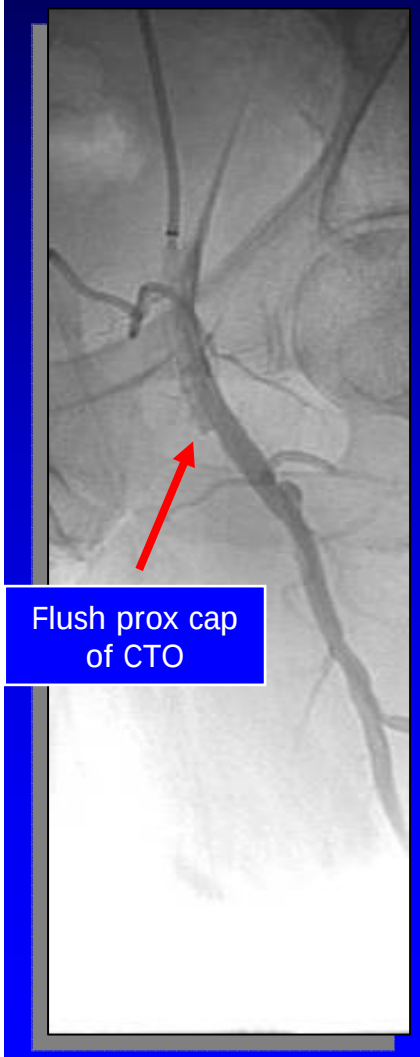


Debulk / Balloon / Stent over Existing Wire

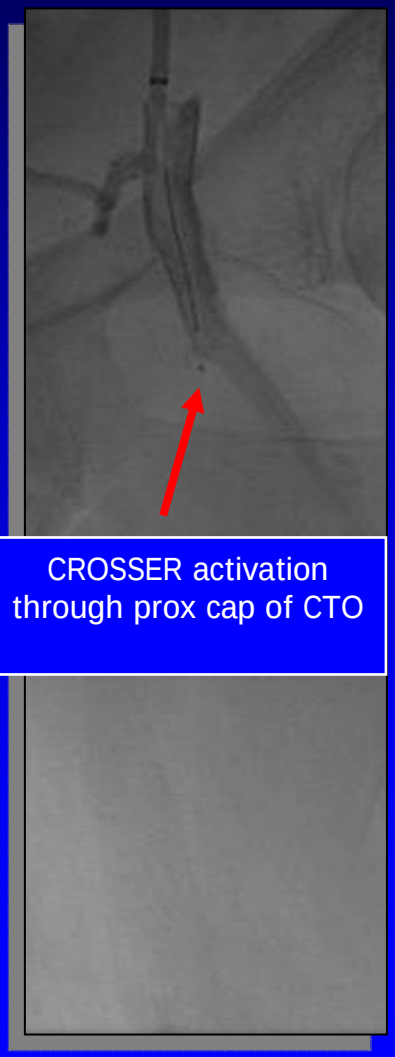
PATRIOT Study

27cm Left SFA CTO

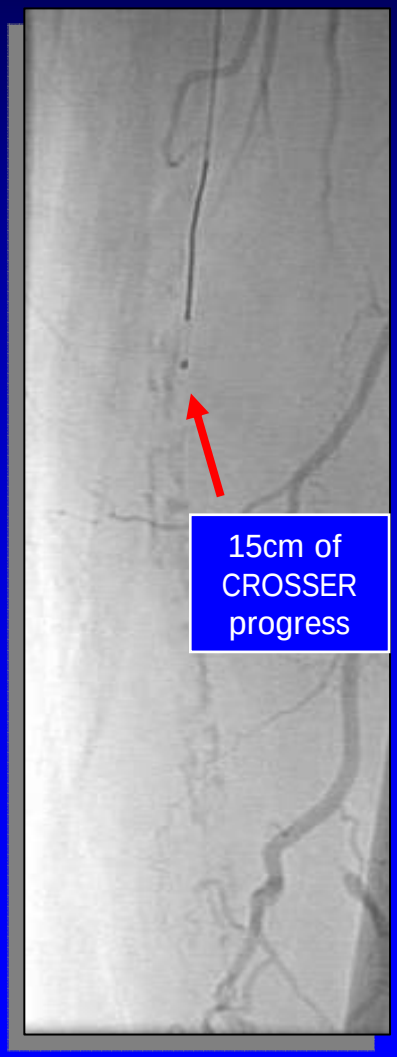
103-006



Flush prox cap of CTO

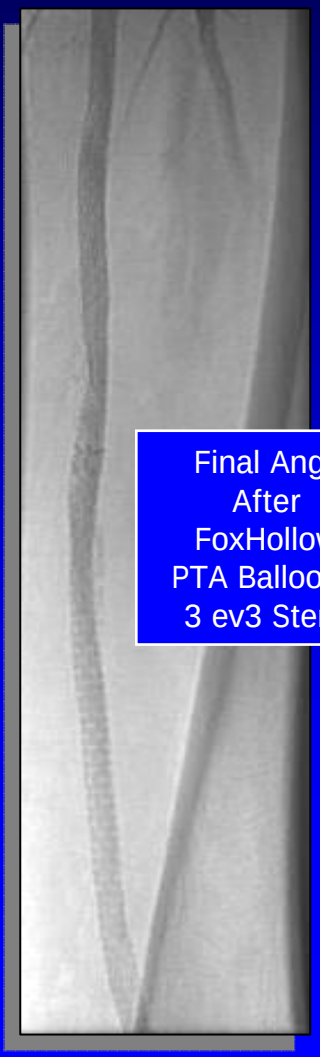


CROSSER activation through prox cap of CTO



15cm of CROSSER progress

Wire in True Distal Lumen



Final Angio After FoxHollow, PTA Balloon & 3 ev3 Stents

PATRIOT Feasibility Study

Patient & Procedural Detail

Patient

CTO Locations:
- 50% SFA
- 23% Tibial
- 22% Popliteal
- 5% Peroneal

Target Lesion Length:
- 106mm (5, 300)
- Occlusions >10cm = 45%

Reference Diameter:
- 4.6mm (2.5, 6)

Age of Occlusion:
- 6.6 months (1,24)

Calcification:
- Severe 35%
- Moderate 38%
- None/Mild 27%
- CTO previously bypassed = 5%

Procedure

Total Procedure Time:
- 120 min (27, 324)

Total Fluoro Time:
- 39 min (12, 113)

Contrast Used:
- 192cc (75, 350)

Length of Stay Following Procedure:
- 1.3 days (0.2, 8.9)

PATRIOT Feasibility Study
Procedural Results

CROSSER

CROSSER Delivered to CTO
92.5% (37/40)

CROSSER Activation Time
150 sec (22 sec, 506 sec)

CROSSER Procedure Time
18min (2, 117)

CROSSER Facilitated CTO Recanalization
78% (29/37)

Perforation Caused by CROSSER
0.0% (0/40)

Post-CROSSER

Therapy Following CROSSER

PTA only: 13.3% (4/30)

Stenting: 46.7% (14/30)
Ave No. of Stents: 3.1 (1, 8)

Laser: 20.0% (6/30)

Cryoplasty: 30.0% (9/30)

Atherectomy: 23.3% (7/30)

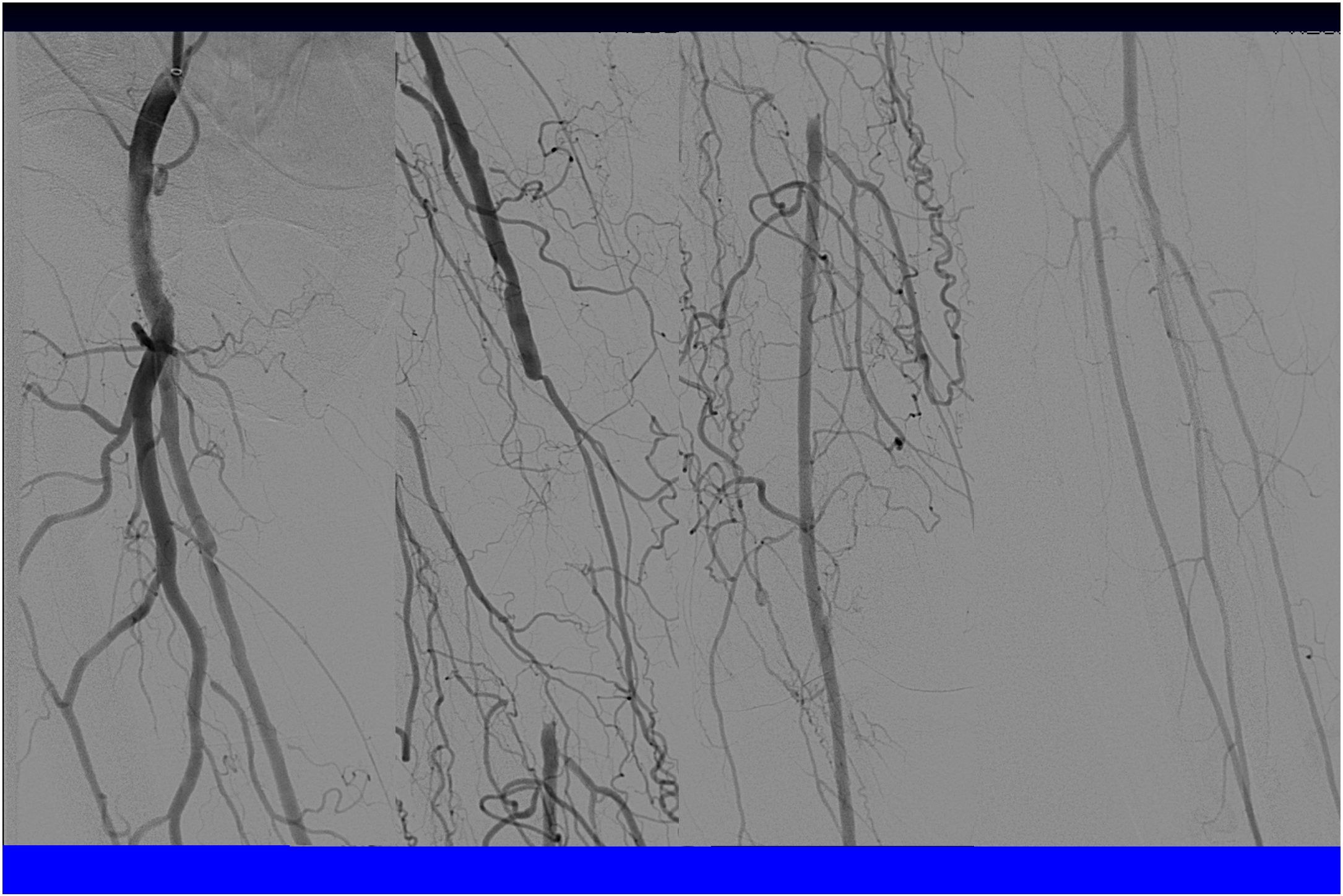
No Treatment: 6.7% (2/30)

Case Presentation

- 68 year old male
- Lifestyle limiting right calf claudication
- Right ABI = 0.7
- Right distal SFA occlusion

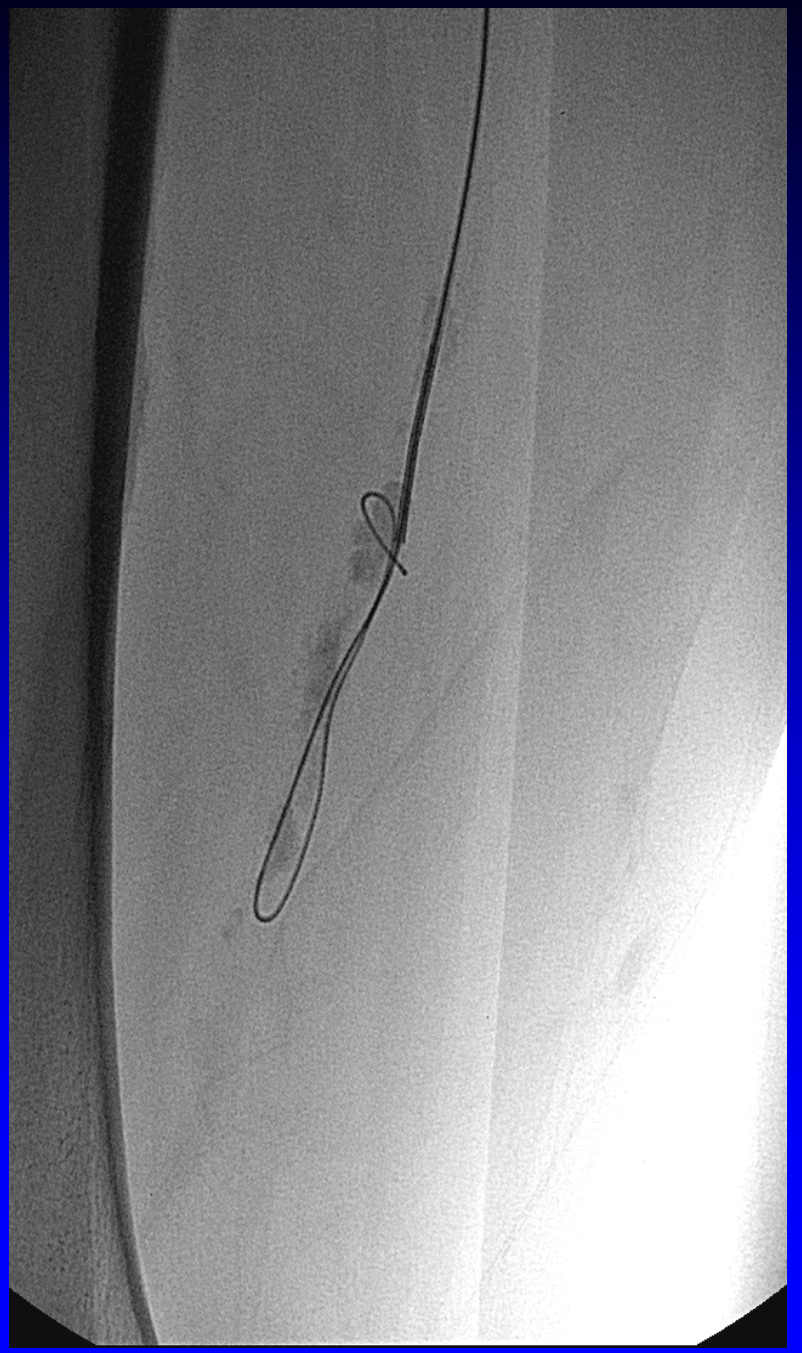
Interventional Approaches

- Hydrophilic guidewire with support catheter
- Subintimal recanalization
- Alternative technologies: Frontrunner catheter, SafeCross wire, Flowcardia device, Excimer Laser
- Reentry device (Pioneer, Outback)

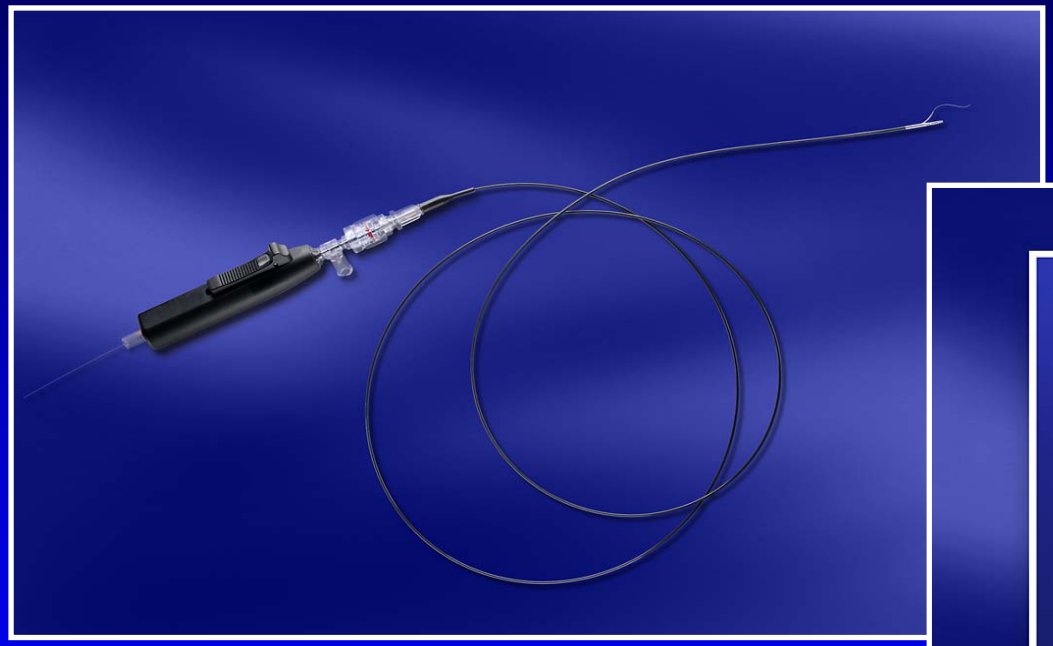


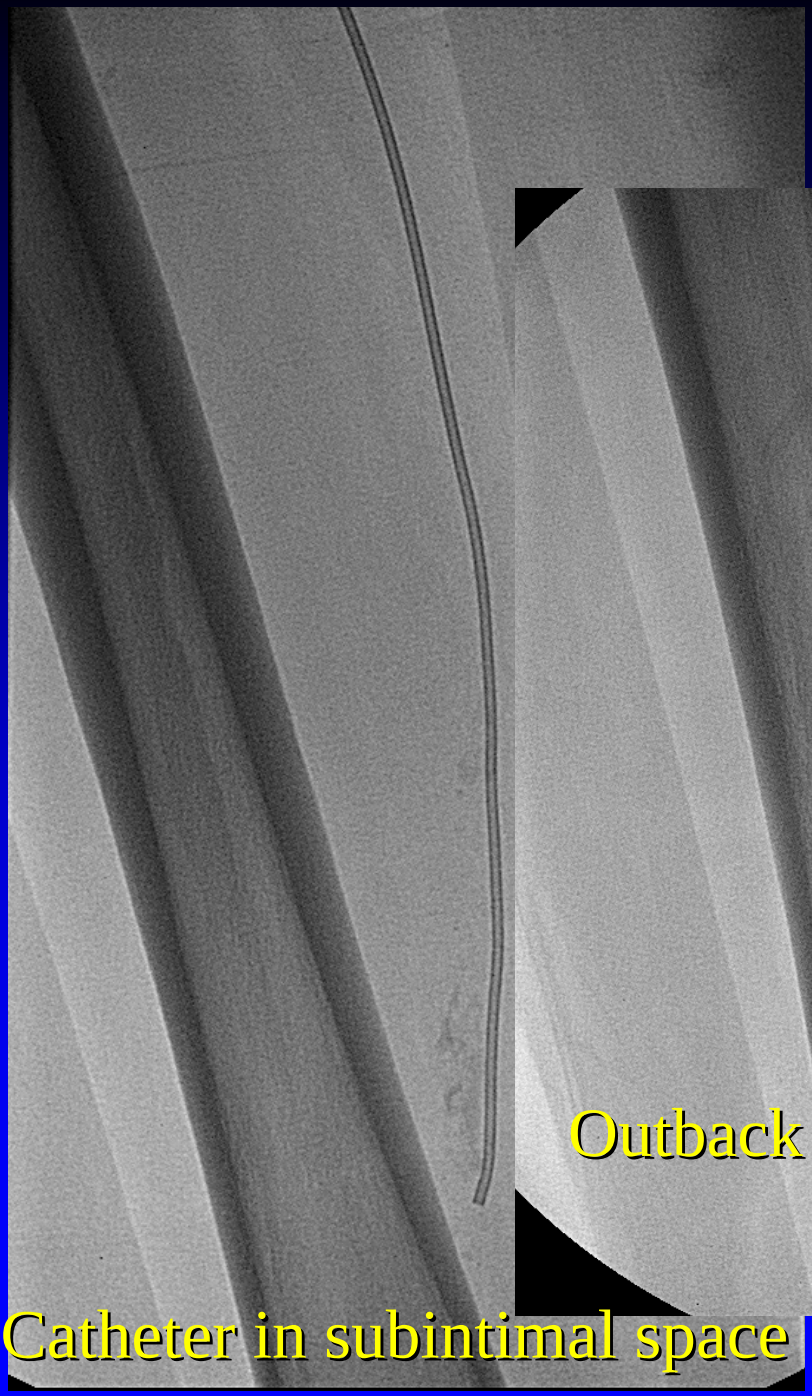
Simple Case, Right?

- Lesion is actually quite calcified
- Guidewire goes subintimal and will not reenter true lumen
- What next?

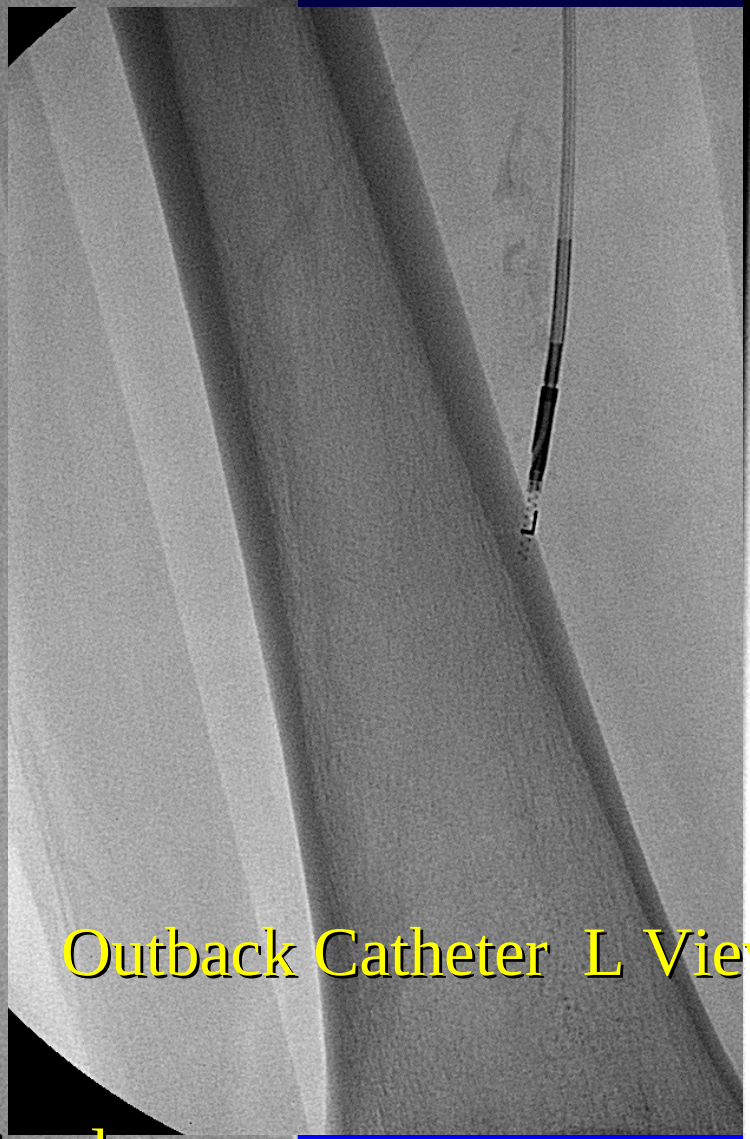


Controlled Re-entry
Outback® LTD Re-Entry Catheter

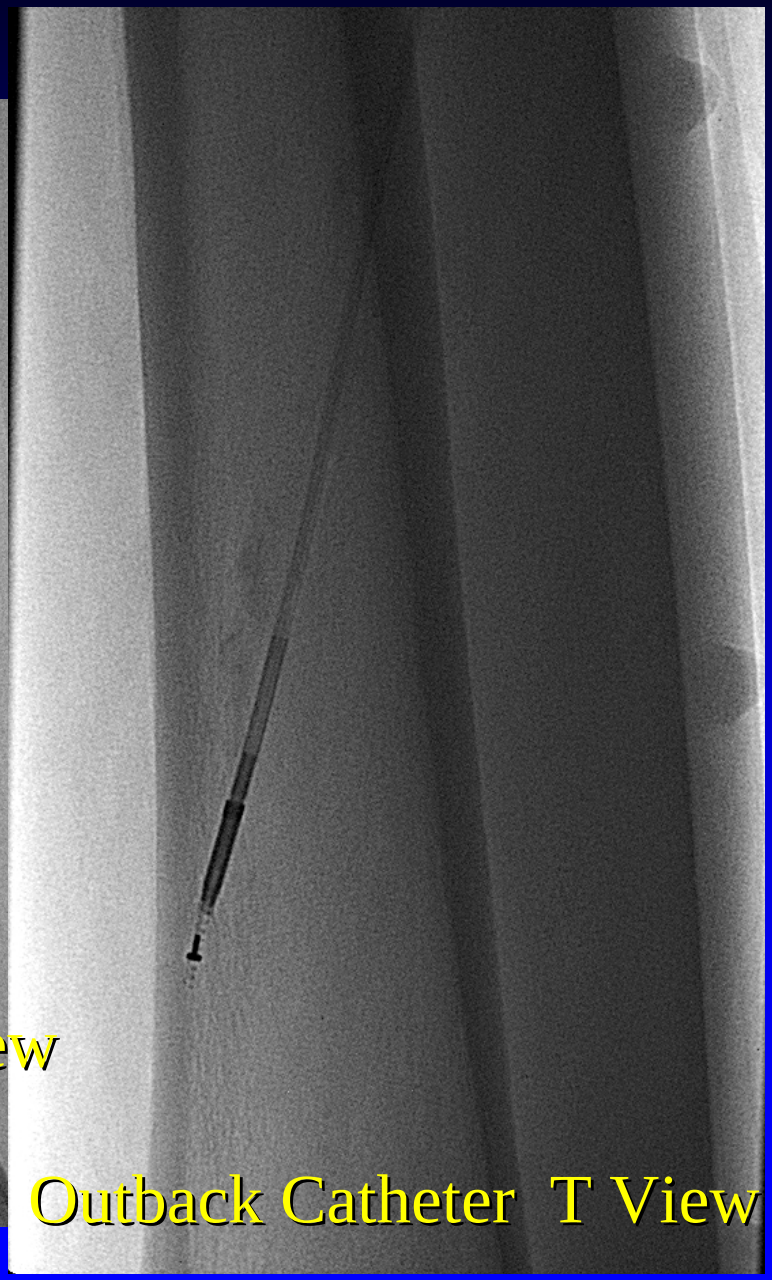




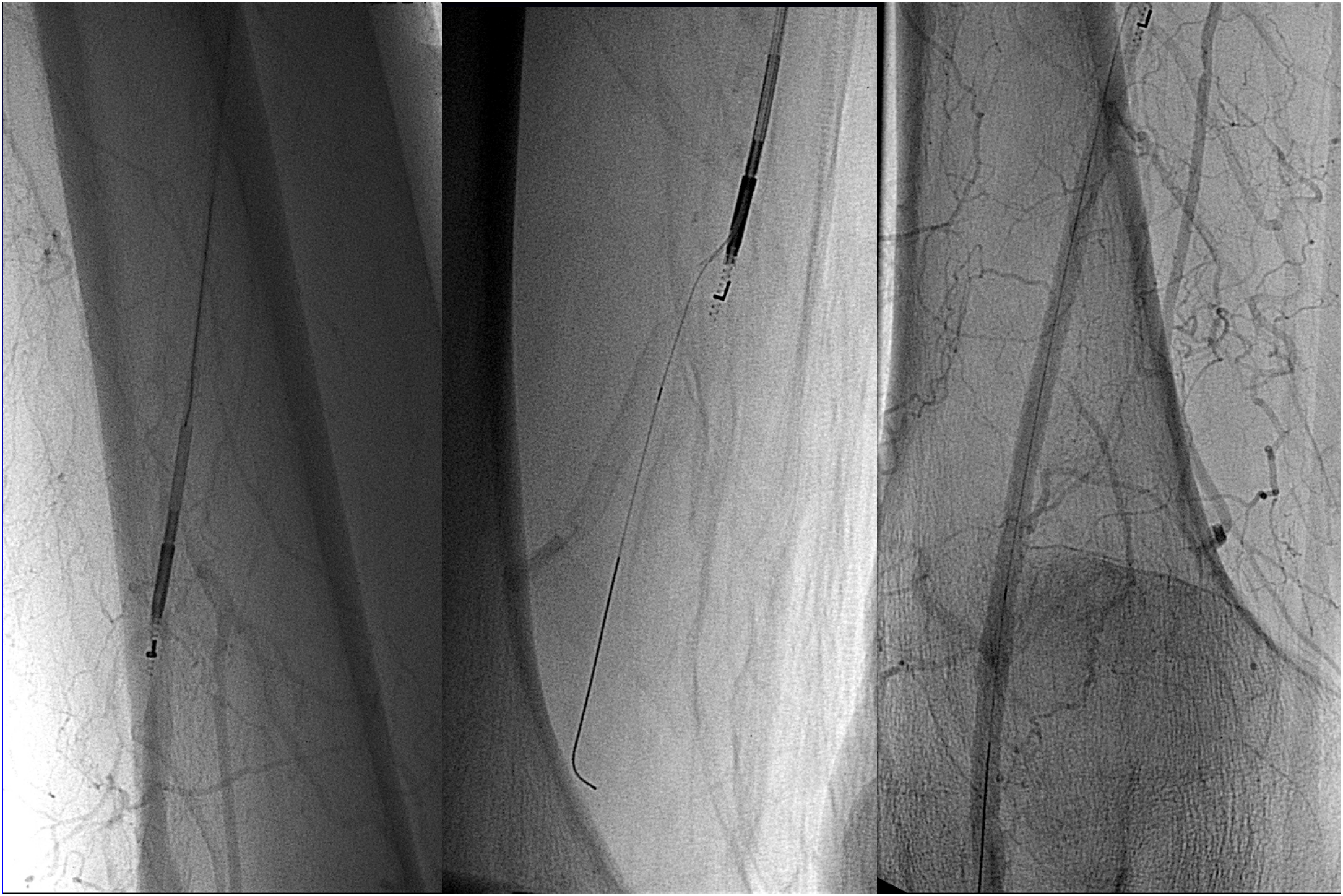
Catheter in subintimal space

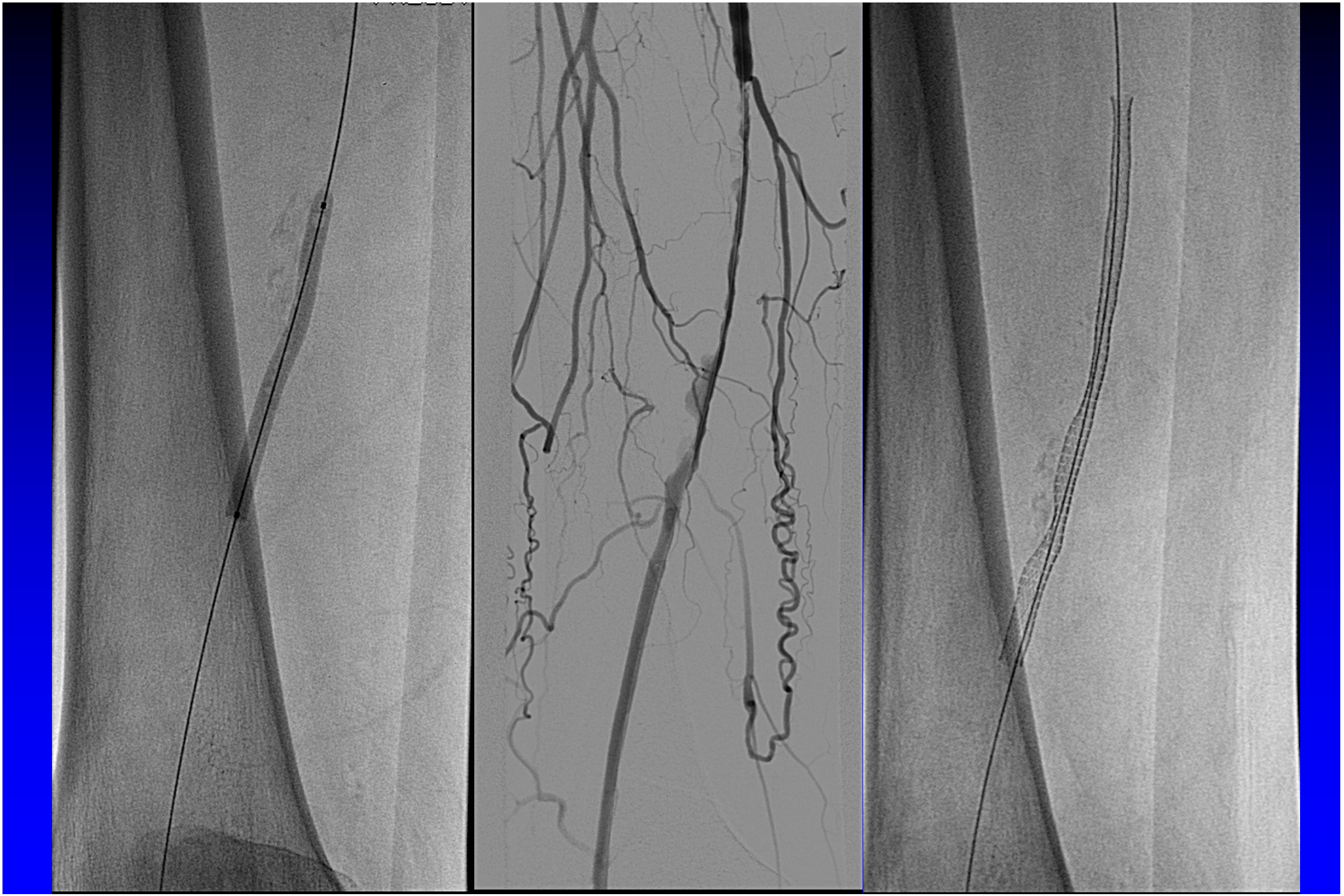


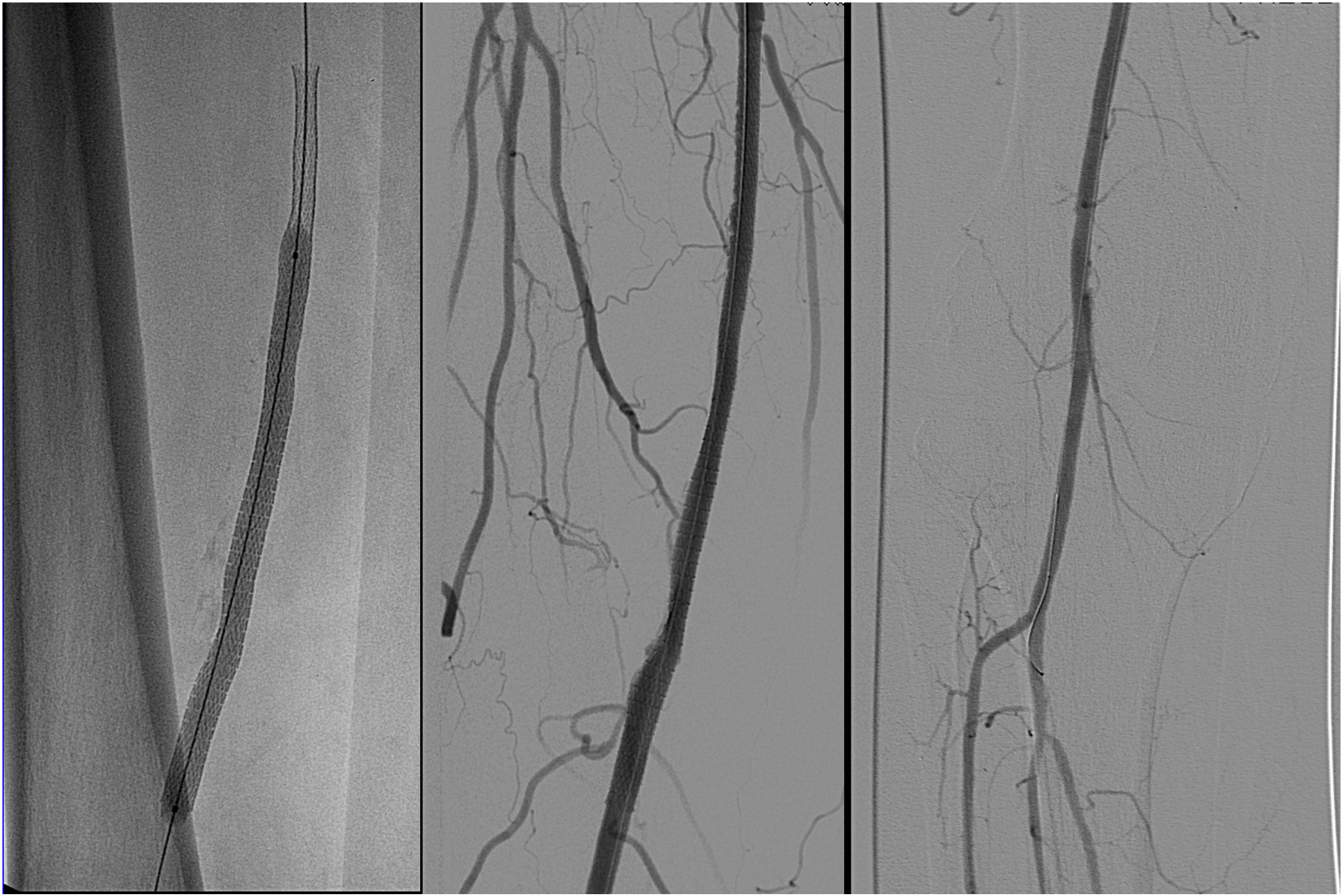
Outback Catheter L View



Outback Catheter T View







Conclusions

- Complex peripheral arterial occlusive disease can be approached with a high likelihood of procedural success
- Variety of devices available to increase the likelihood of success when hydrophilic guidewires fail
- Re-entry devices address the most common reason for failure – subintimal wire trapping
- Should increase success rates for CTO crossing to close to 100%