Superficial Femoral Artery Occlusion: Recanalization Techniques

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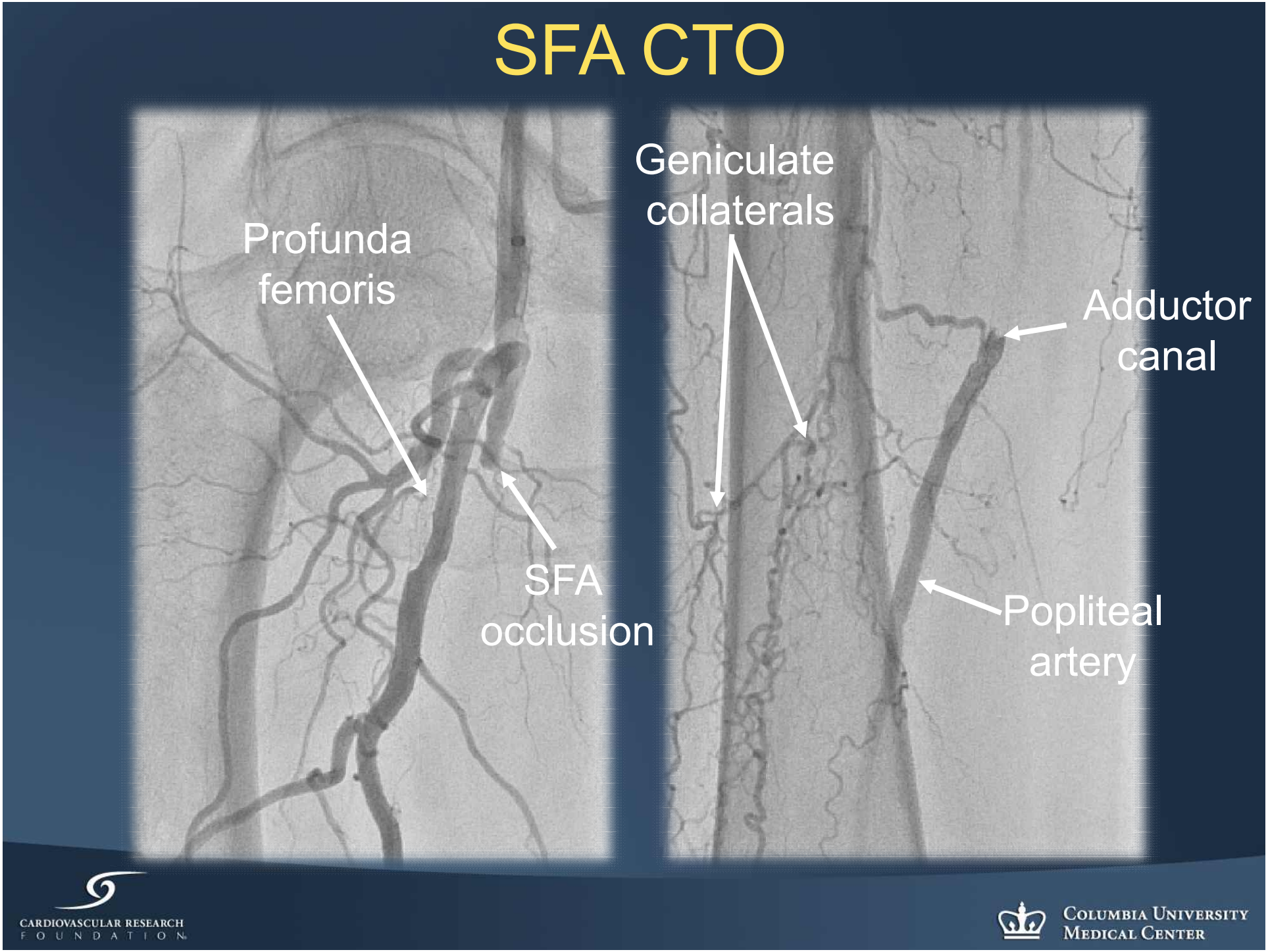
SFA: Prime target (and model) for CTO

- The Superficial Femoral Artery (SFA) is the most common site of peripheral arterial involvement
  - Leading cause of claudication (read: significant experience)
  - Disease tends to be “mirrored” in the contralateral limb
- Occlusions:
  - 3 times more common than stenoses in the SFA and they are frequently 20-30 cm long
  - ~50% of SFA disease is occlusive
  - Reliable collaterals via profunda femoris to the geniculate vessels to popliteal artery
- Plaque in the distal SFA (Adductor canal) becomes occluded, and the occlusion propagates retrograde to the next largest branch point, the profunda femoris
  - Plaque is bulky, calcified, and typically has a admixture of atheroma and organized thrombus
  - Adventitia represents 70%-80% of vessel strength

SFA CTO



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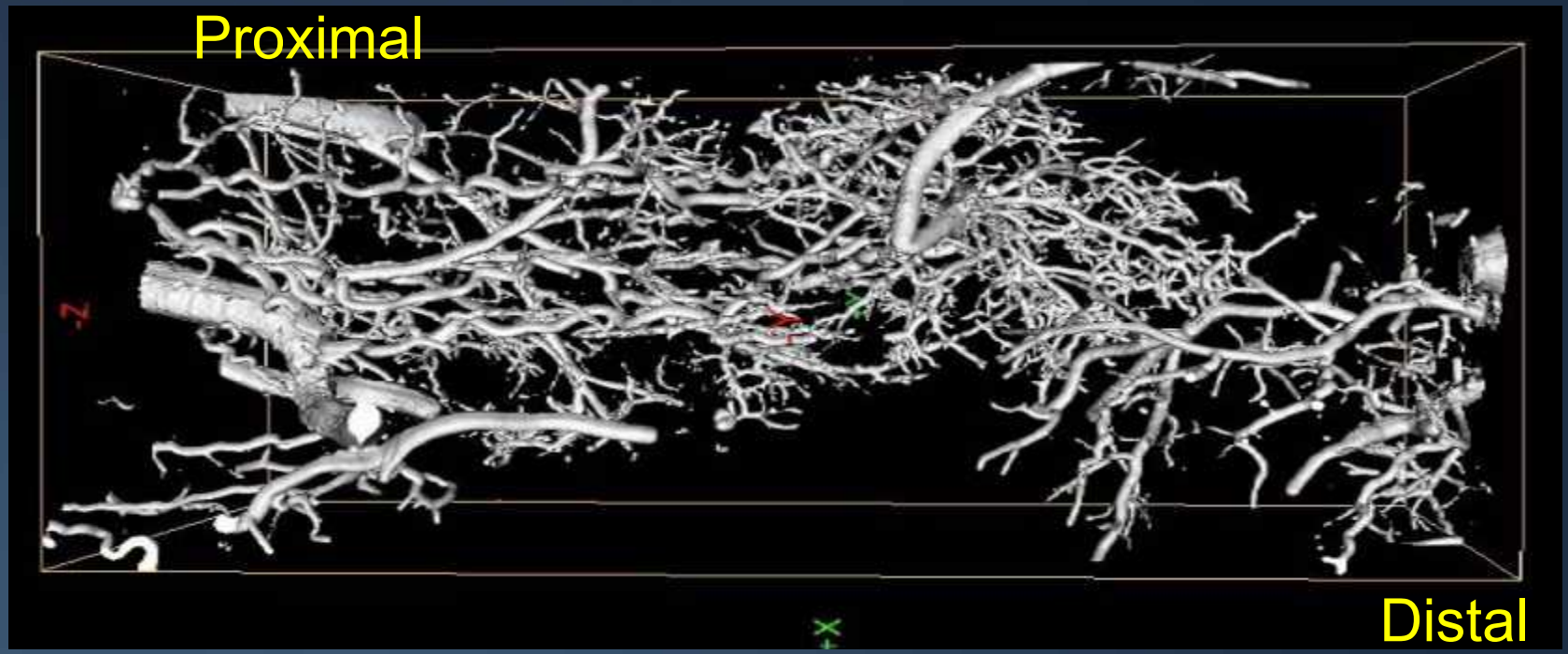
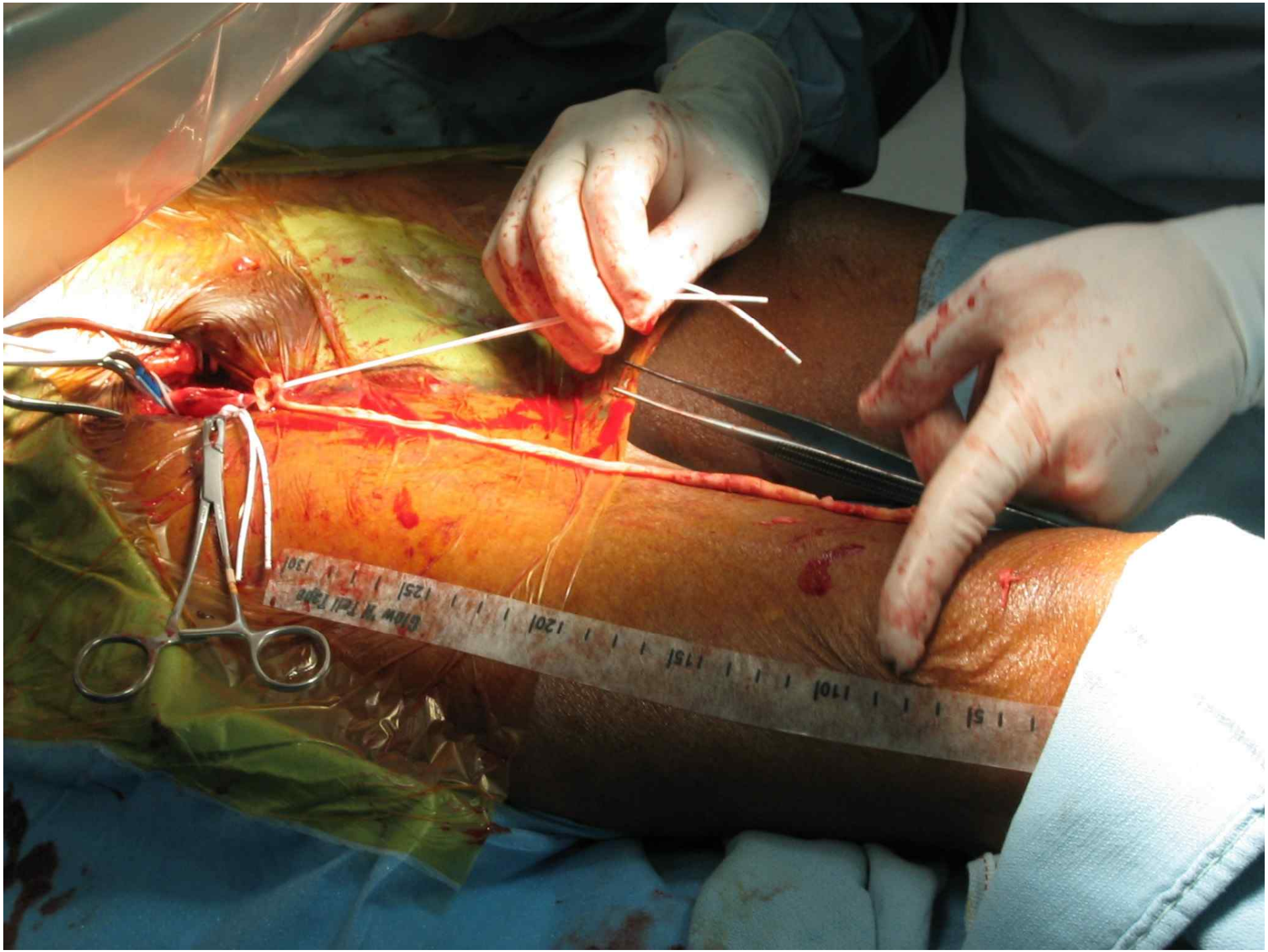
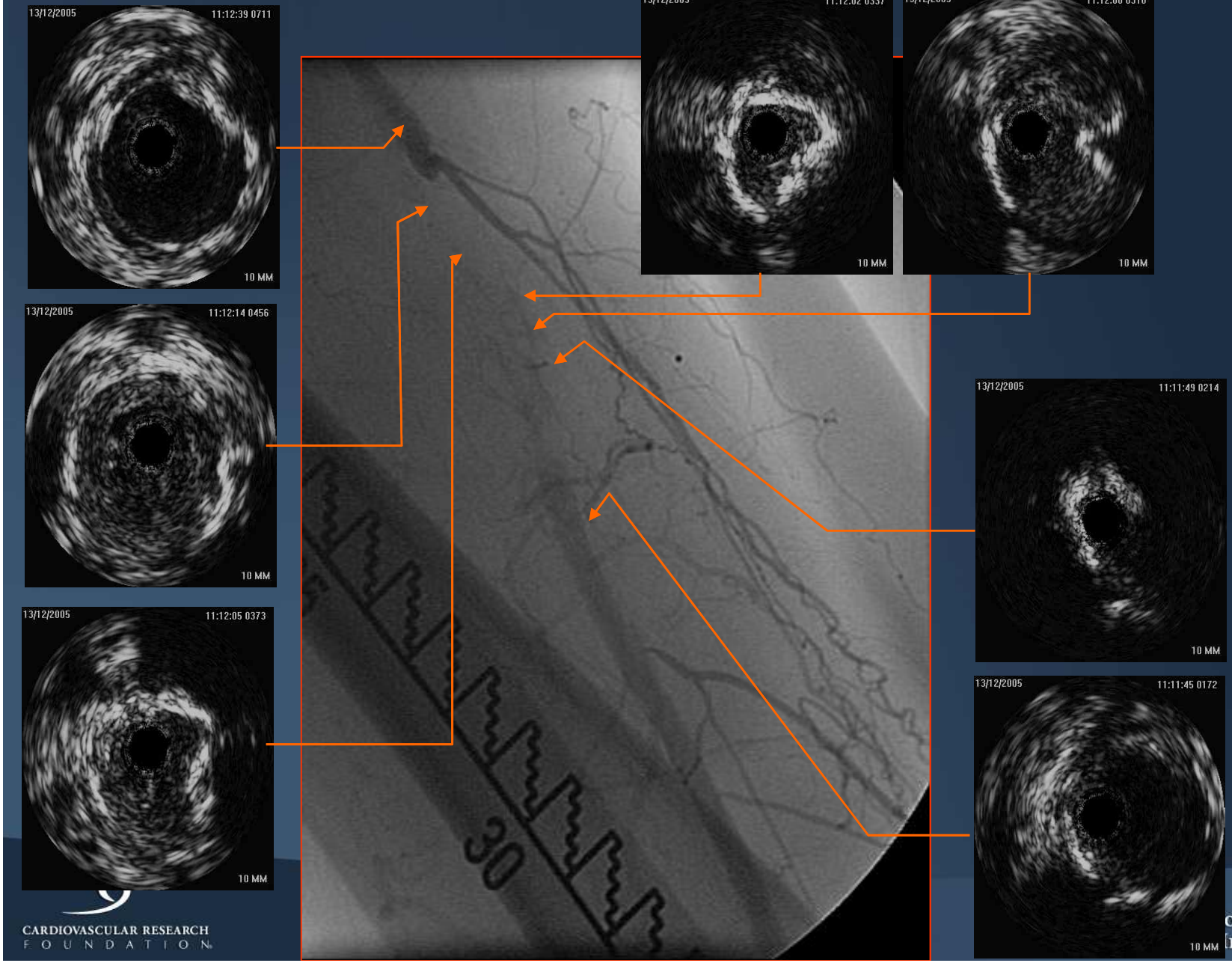
Micro CT scan of a CTO



The challenge of the CTO



Intravascular Ultrasound of SFA CTO



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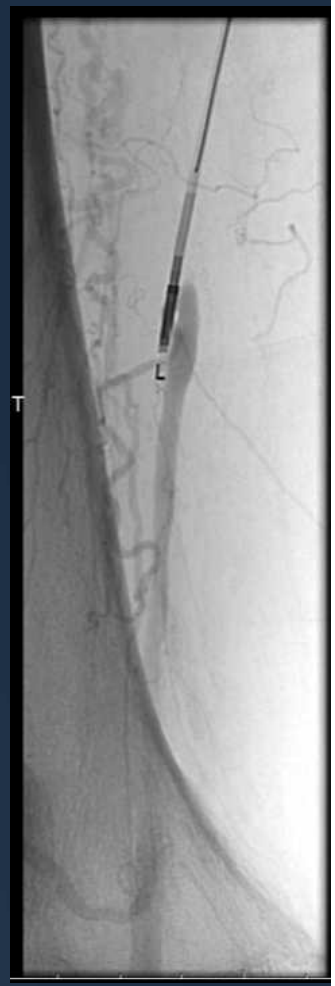
CTO Crossing
Definition of Success: a Proposal

- Overall Crossing Success
  - Overall crossing success measured by gaining wire access to the distal true lumen.
- Secondary Success
  - Bail-out technique, often using a re-entry tool to access the distal true lumen from a subintimal channel
  - Introduce: “Re-Entry Ratio”
    - Utilization rate of Re-Entry devices in CTO crossing cases
    - Ex. 1:5 – 1 Re-entry device used for every 5 CTO cases

Re-Entry Ratio Significance

- Re-entry catheters are important adjuncts to crossing devices
  - Secondary, bail-out devices should your initial CTO crossing effort take a “wrong turn”.
- A low Re-Entry ratio (1:30) means:
  - Low re-entry device utilization and high central lumen success
    - Re-entry devices are being used only 1 in 30 cases
- Central lumen navigation:
  - Maximizes subsequent therapeutic options
    - Atherectomy, balloon and stent utilization



Literature on endovascular CTO

- Success rates with wire and catheter vary widely (26%-100%), averaging 70%-80%
  - However much of this literature is 10-20 years old and unlikely to represent the complexity of lesions being approached today (lack of nitinol stents, covered stents, re-entry devices, etc)
- Subintimal passage rates are not well described

SFA plaque volume=distal embolization?

Incidence and clinical significance of distal embolization during percutaneous interventions involving the superficial femoral artery

Russell C. Lam, MD, Syed Shah, MD, Peter L. Faries, MD, James F. McKinsey, MD, K. Craig Kent, MD, and Nicholas J. Morrissey, MD, *New York, NY*

Conclusion: While ES were recorded at each step of SFA intervention, the frequency was greatest during stent deployment. Despite the frequency of these events, only one patient developed angiographically and clinically significant embolization. Thus, our findings do not support the routine use of protection devices during percutaneous SFA intervention. (J Vasc Surg 2007;46:1155-9.)

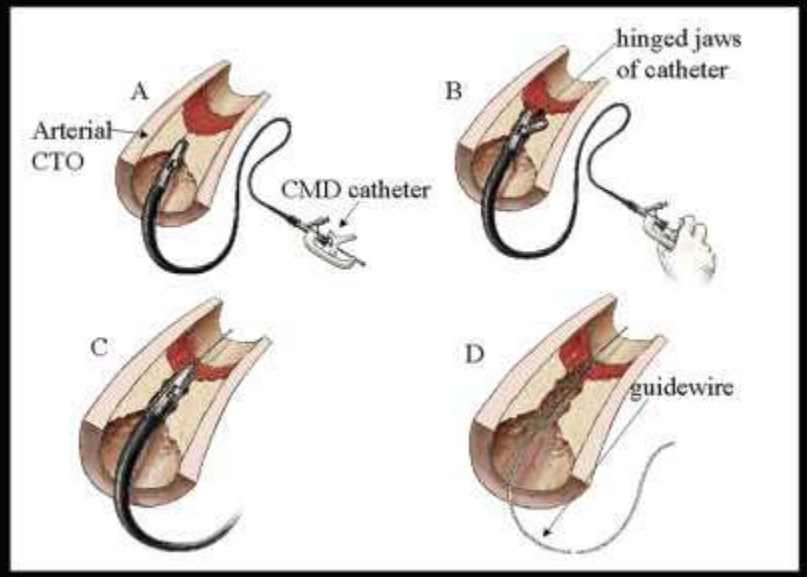
Assessment of true lumen re-entry devices

- 87 CTO: 58 iliac and 29 SFA
- Previous attempts failed
- 26% true lumen could not be re-entered
  - Iliac (34%) >SFA (13%)
- Re-entry ratio (devices successful in all cases)
  - Overall: 4:1
    - Iliac 3:1
    - SFA 8:1

Jacobs et al. JVS 2006 June;43(6):1291-6

Frontrunner use in endovascular CTO

- Prospective evaluation of the Frontrunner in 36 patients in aiding in recanalizing CTO's
- Previous attempts at CTO had failed
- No determined effort or ability to maintain a central lumen passage



Mossop PJ et al. CCI 68:304-310 (2006)

Achievement of primary endpoint: 91%

TABLE III. Results of Percutaneous Recanalization Using Controlled Blunt Microdissection

Characteristics of CTO	Procedural outcome		
	Successful recanalization	Failed recanalization	Total
Location of CTO			
Iliac	21	3	24
CFA	1	0	1
SFA	14	1	15
Popliteal	2	0	2
Terminal aorta	2	0	2
Total	40	4	44
Length (cm)	9 ± 7	14 ± 6	9.5 ± 7
Calcification grade	1.8 ± 0.1	2.3 ± 0.5	1.9 ± 0.9

Adjunctive therapy and adverse events

- Adjunctive Rx:
  - Re-entry catheter use: 35% (RER 3:1)
  - Stent implantation: 85%
- Adverse events
  - No deaths
  - No perforations
  - One stent thrombosis

Peripheral CTO Options

- Glidewire manipulation
  - Subintimal angioplasty and re-entry
- FrontRunner Catheter
- FlowCardia Crosser
- Subintimal Re-entry Devices
  - Lumend Outback and Medtronic Pioneer
- Step-By-Step Laser Technique

The CROSSER System

FlowCardia Generator

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

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CROSSER Catheter Attributes

- Front Line Therapy
  - Use before guidewire attempt to avoid subintimal path
- Enables Central Lumen Crossing of CTO's
  - Blunt, atraumatic CROSSER tip is 3x guidewire diameter
  - Short, 4 RBC (20μ) stroke depth with CROSSER
  - CROSSER takes path of **most** resistance
    - CROSSER most effective against in-elastic material
- Central Lumen Navigation Maximizes Therapeutic Options
  - Optimizes Atherectomy, PTA & stenting

PATRIOT: US Pivotal Study

85 Guidewire refractory, peripheral CTO Patients

- **84% CROSSER success rate** in guidewire resistant CTOs
- 0% CROSSER Clinical Perforations
- 94.1% Freedom from limb loss, clinical perforation & repeat revascularization through 30 days (80/85)

CTO Specs

63.5% SFA & Above
20.0% Popliteal
16.5% Tibial/Peroneal
117.5mm Long
16.0 Months Old
75.0% Mod/Severe Calcium

Procedure Detail

2min 6sec Avg CROSSER Activation
36 min Fluoro Time Avg
102 min Procedure Time Avg

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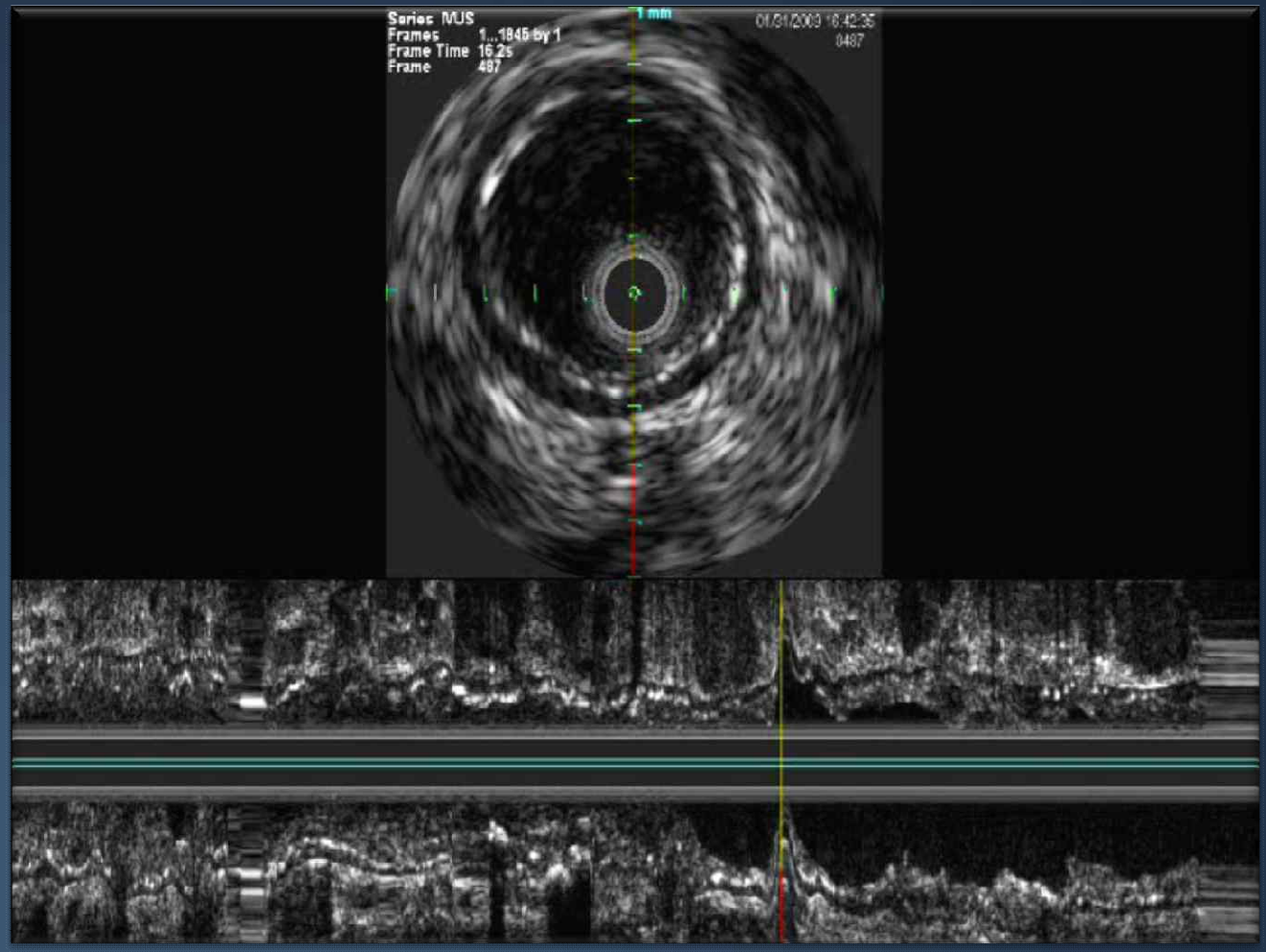
Central Lumen IVUS Run
Post CROSSER Catheter CTO Recanalization



CROSSER/IVUS case courtesy of Tom Davis, MD, St. John's Hospital, Detroit, MI

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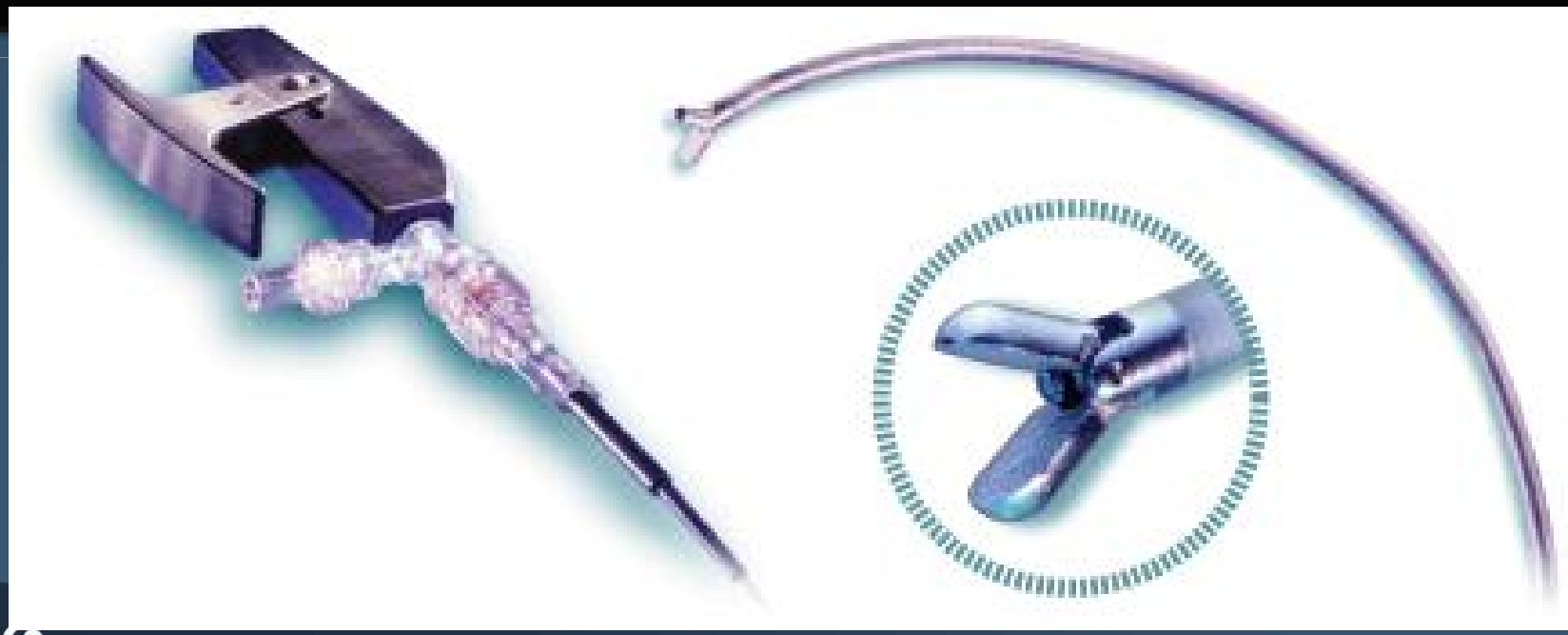
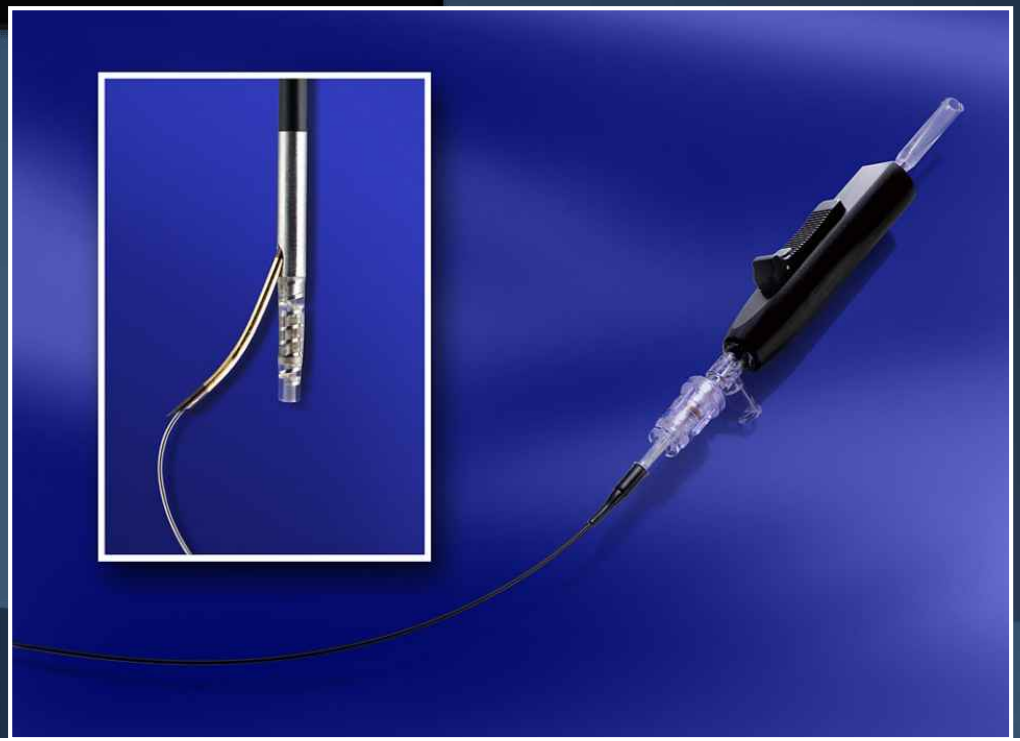
Frontrunner XP blunt dissection catheter

- FRONTRUNNER® XP CTO Catheter
  - .039” distal tip & crossing profile when jaws closed
  - 2.3 mm maximum diameter when jaws open
  - 90cm & 140cm lengths
  - Braided, hydrophilic shaft with shapeable distal tip



Outback re-entry catheter
Device Specifications

- Second generation device
- 5.9 F profile
- 6F sheath compatible
- .014” guidewire compatible
- 120 cm length
- 22 gauge re-entry cannula



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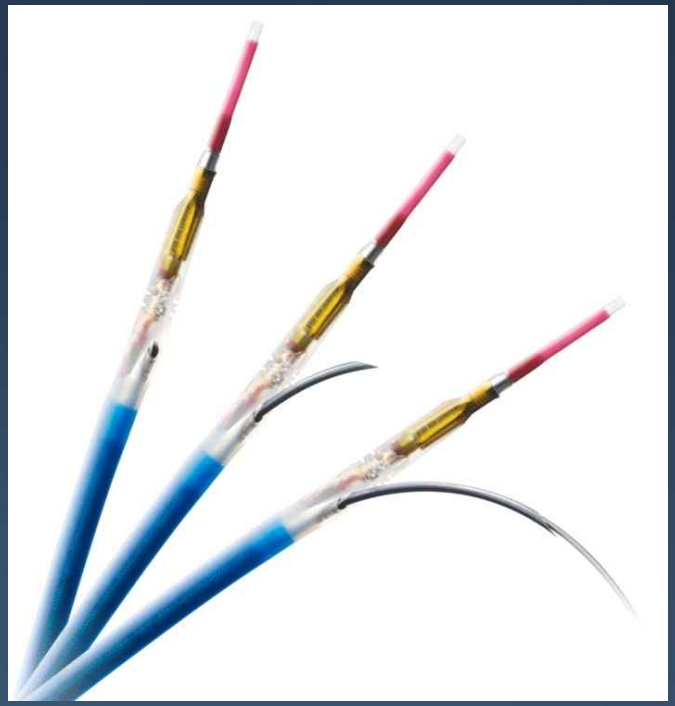
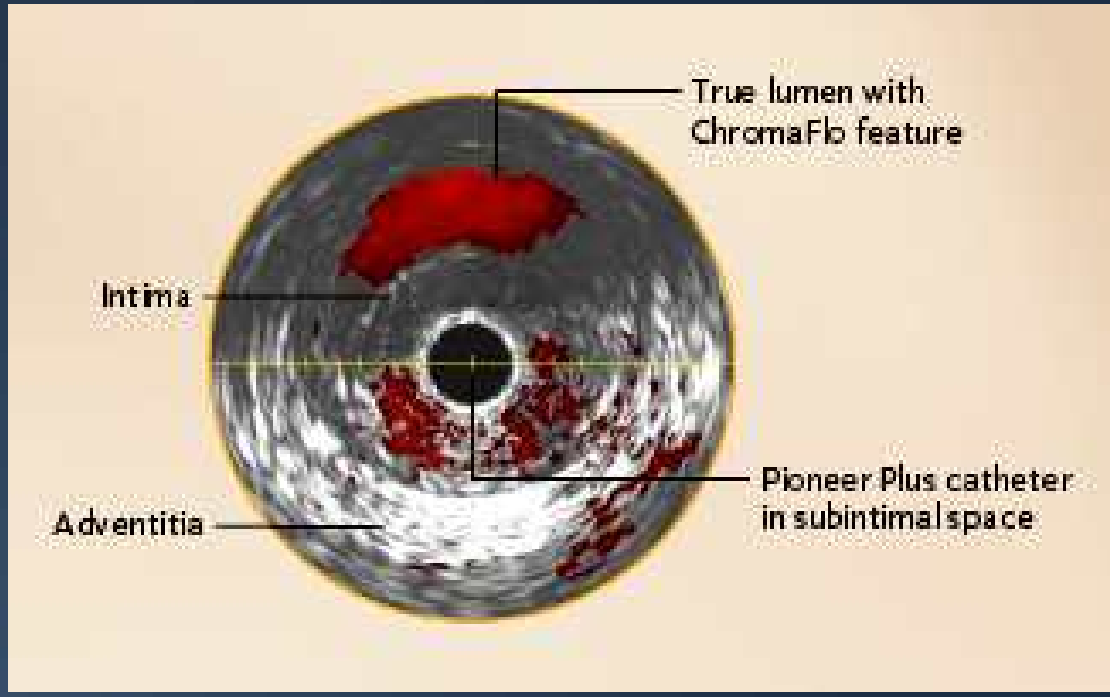
Pioneer catheter for US guided re-entry





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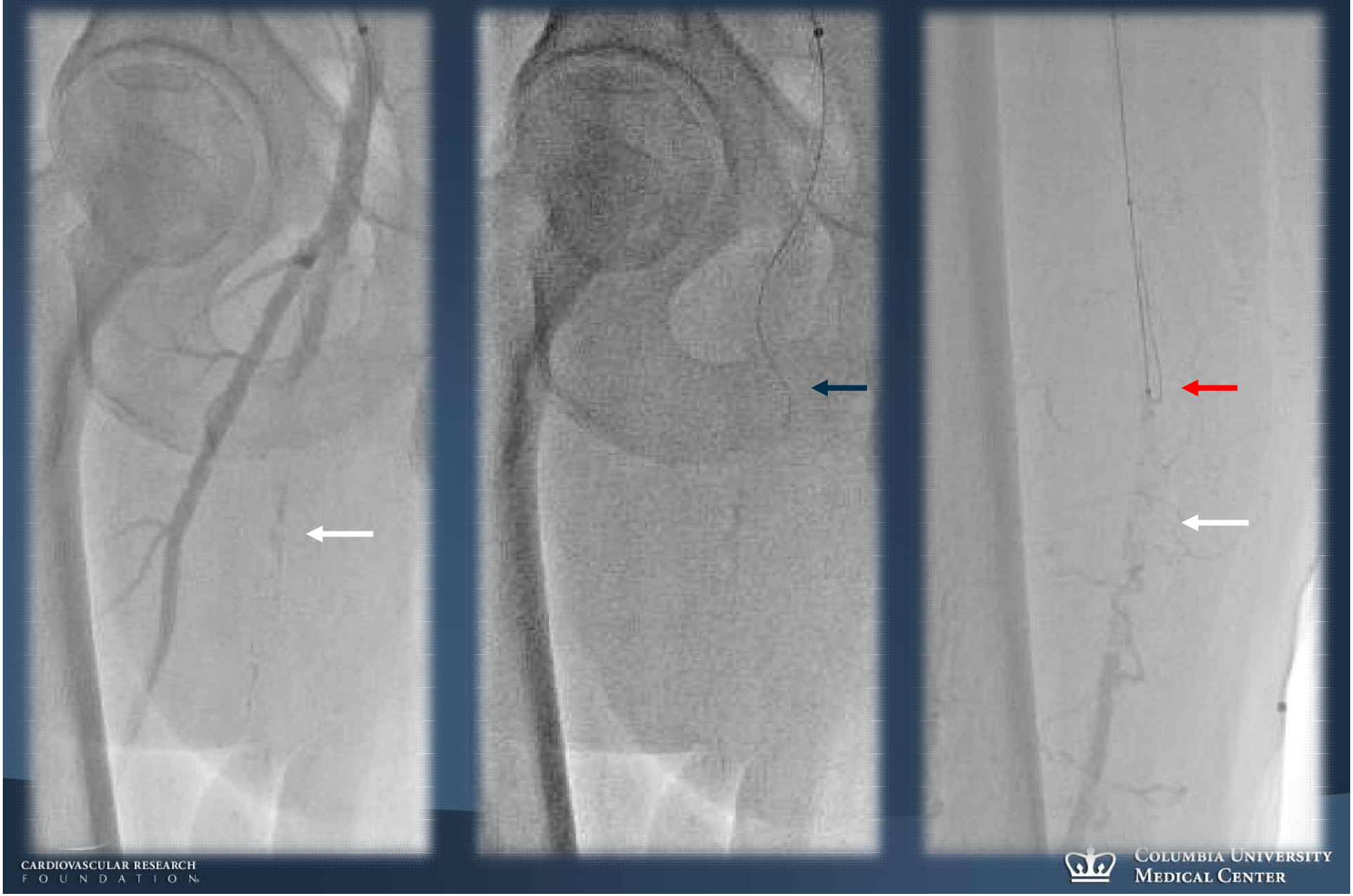
Dominant method

- Sub-intimal tracking and re-entry (STAR)
  - Glidewire (0.035” straight) as far as can be delivered
  - Glidewire (0.035” angled) is looped---tightly---and used to bluntly dissect the subintimal space
  - Re-entry distally is accomplished by “feathering” into the true lumen
  - Where re-entry is not possible (calcification), re-entry devices are useful (~5% of cases)
  - With this algorithm, ~95% of CTO’s are successful, usually in a matter of a few minutes

SFA CTO: Glidewire Method



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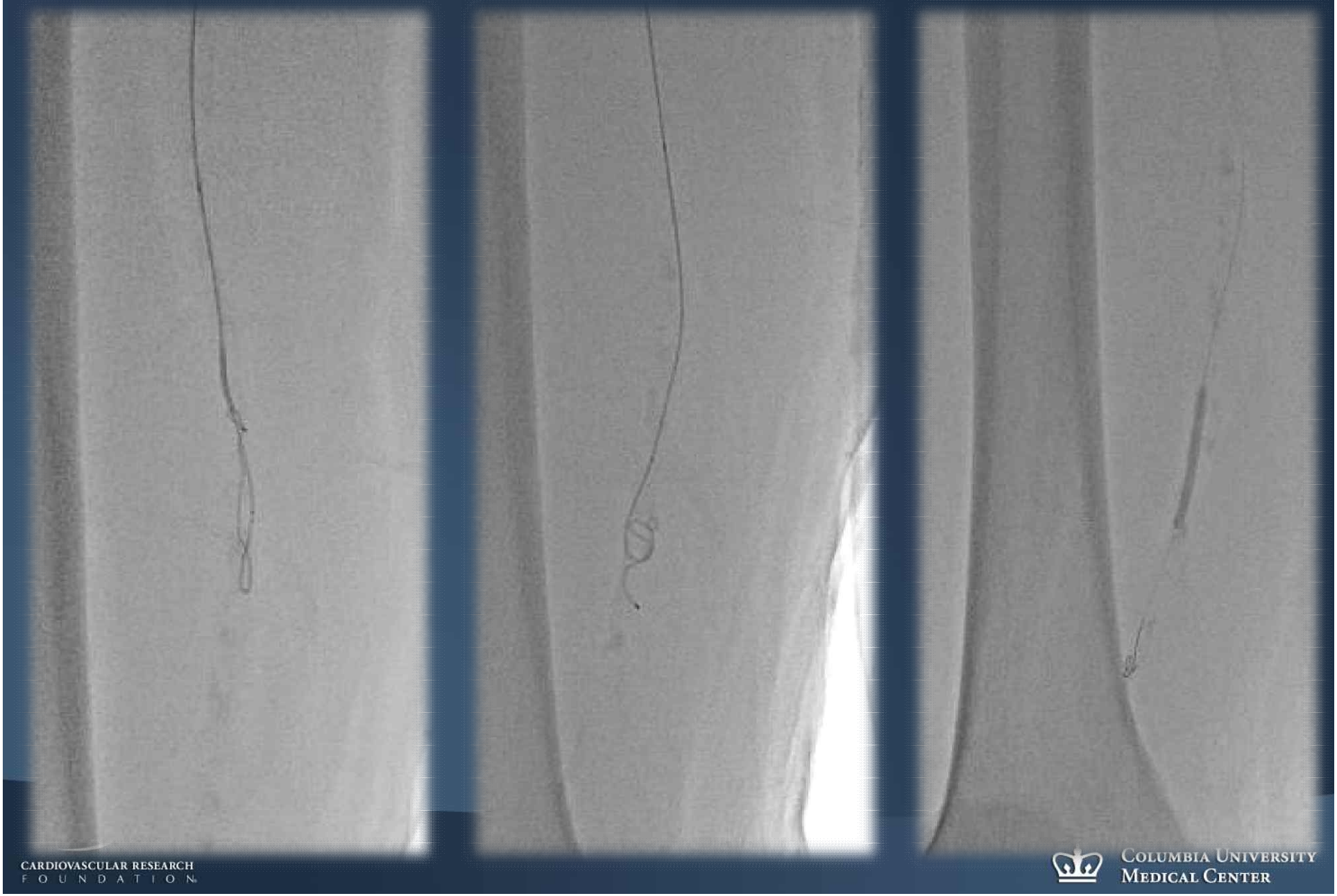
SFA CTO: “Dead-end”



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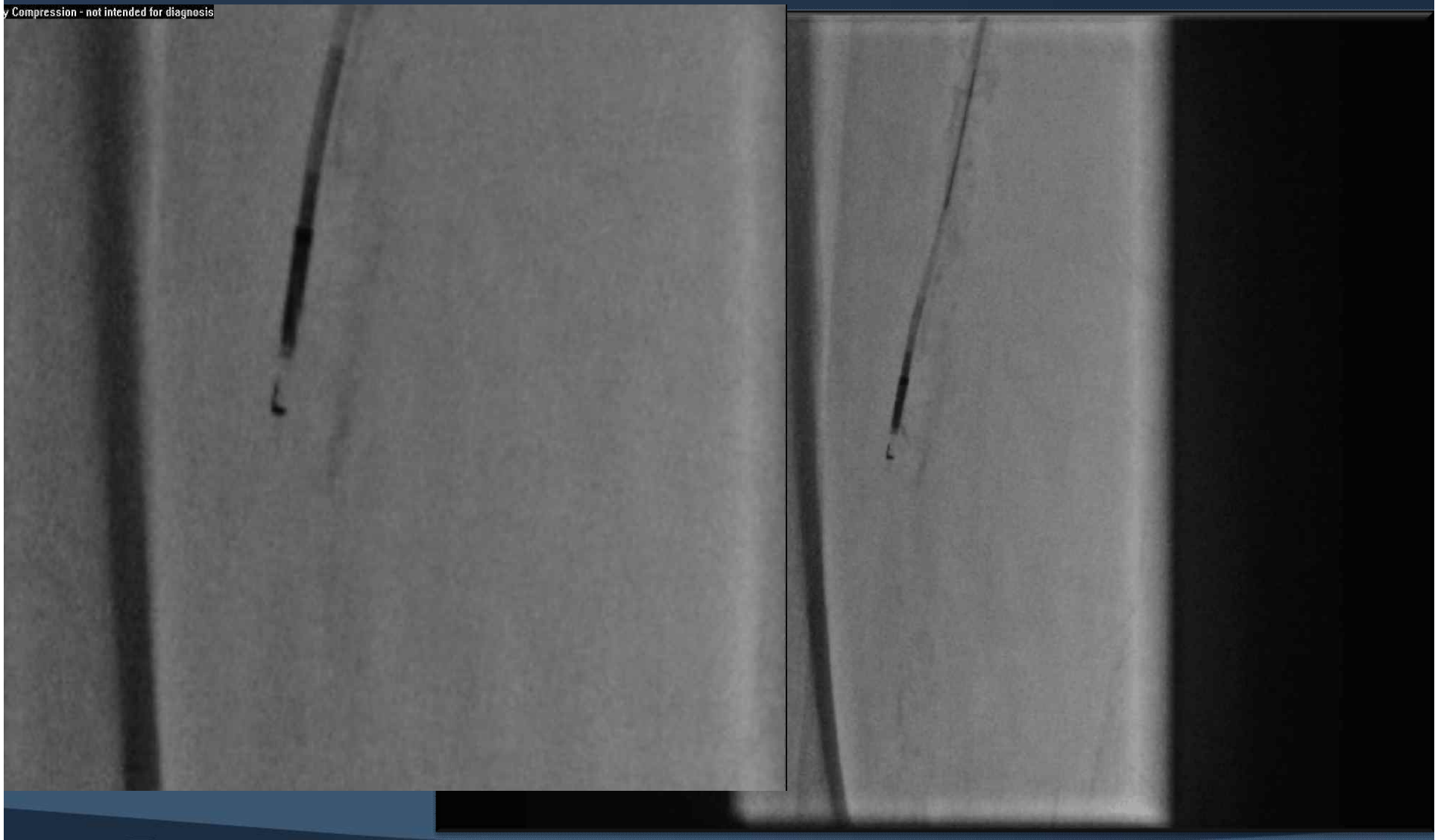
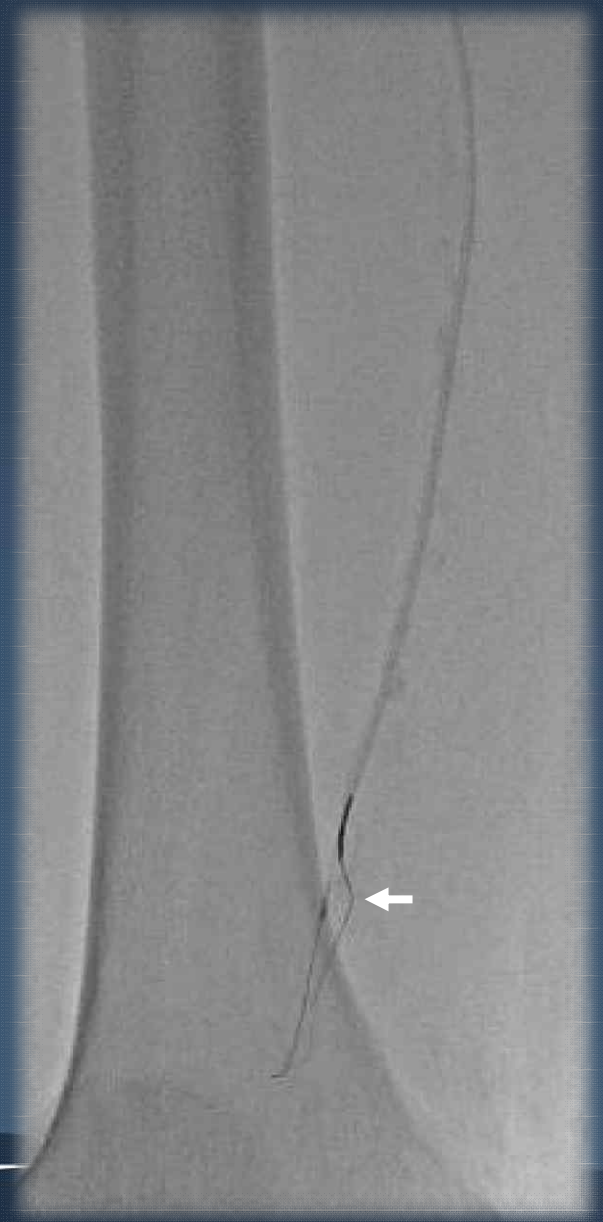
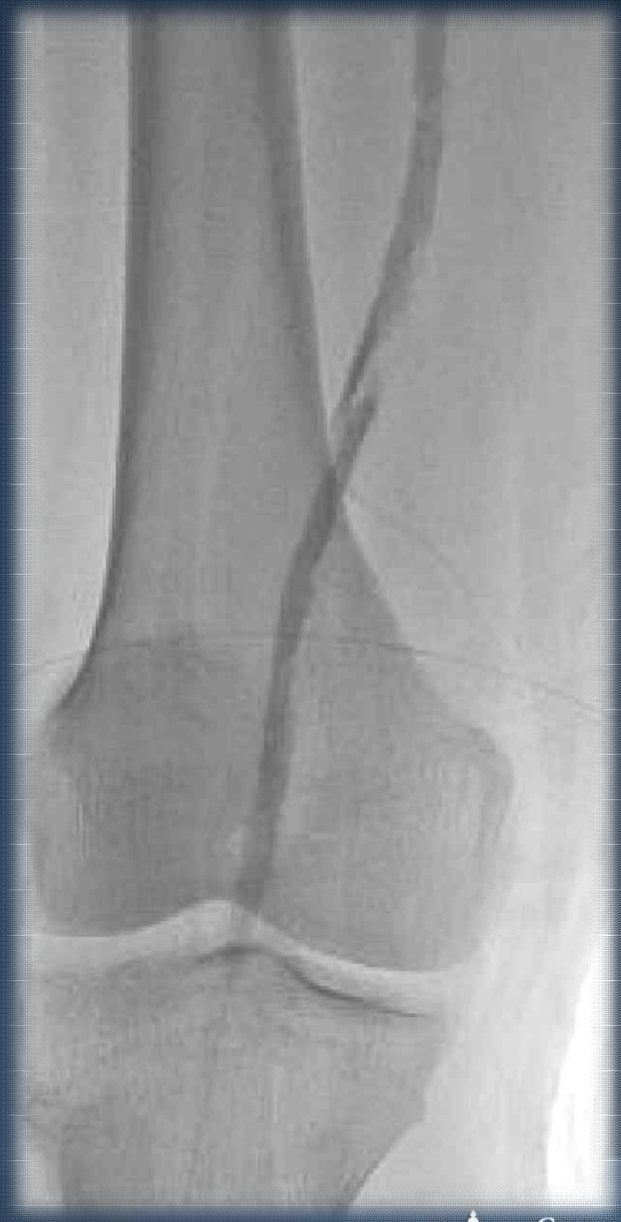
Re-entry Devices: Outback



SFA CTO: Outback Re-entry





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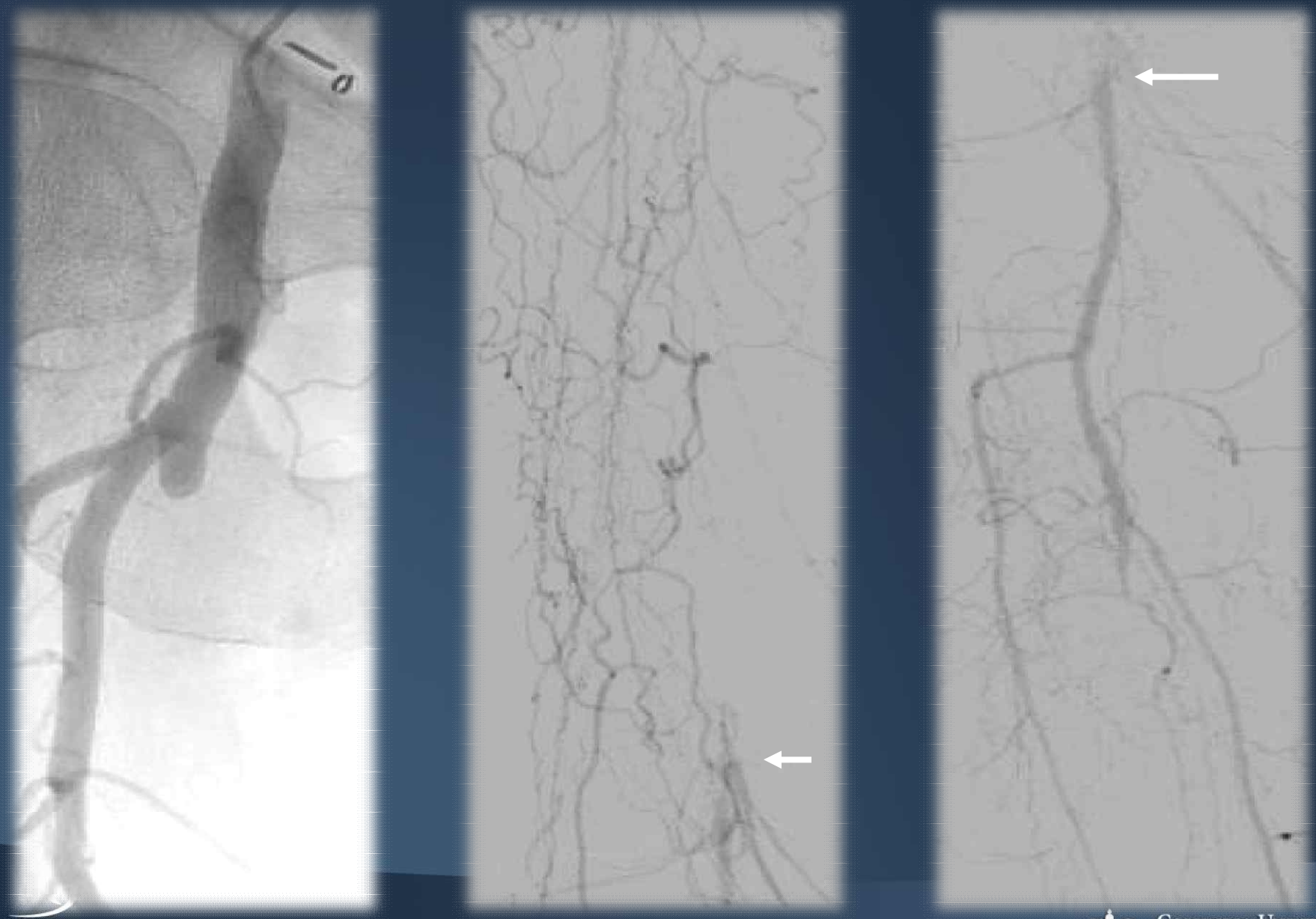
SFA CTO: Frontrunner method



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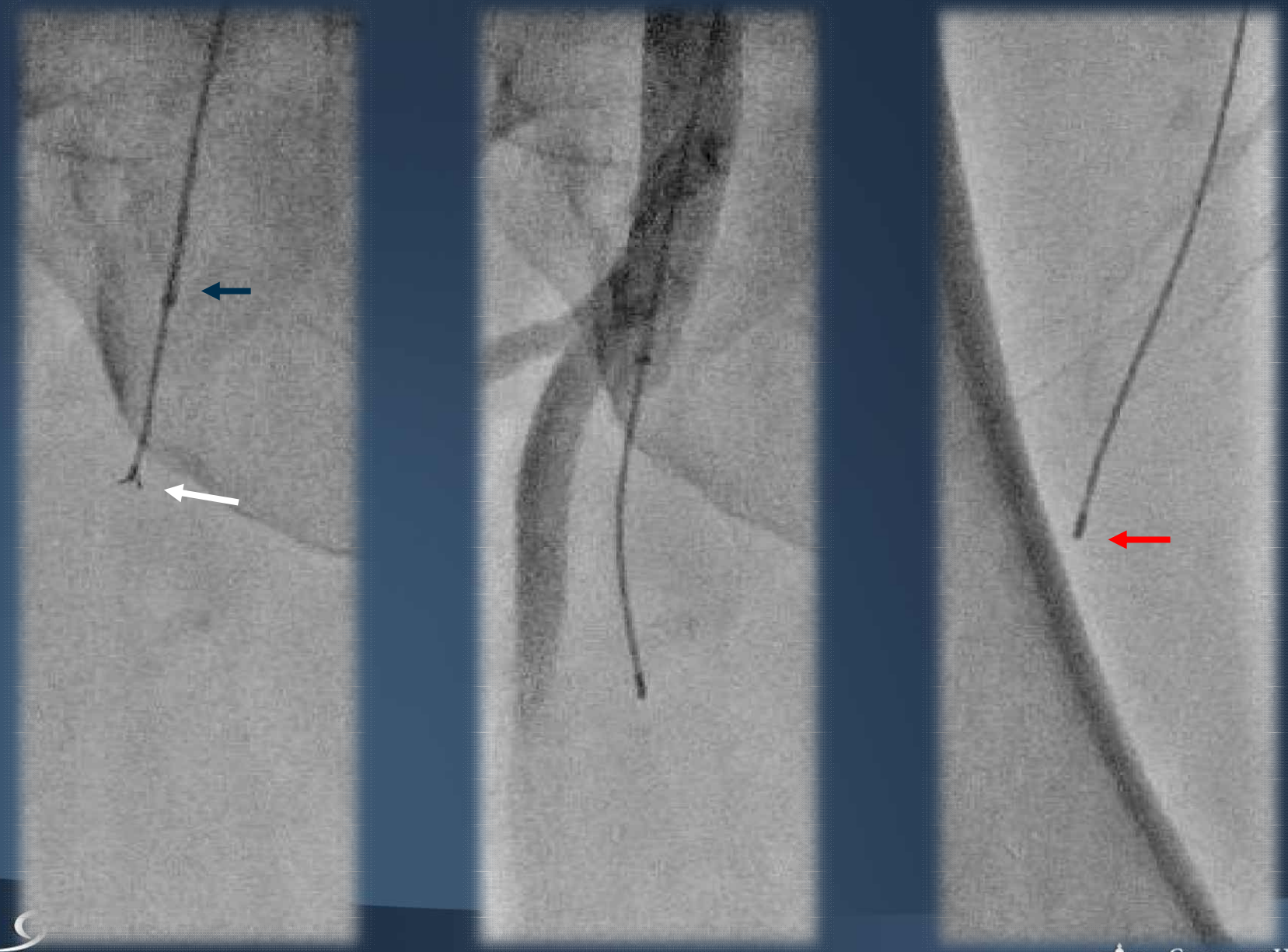
SFA CTO: Frontrunner method



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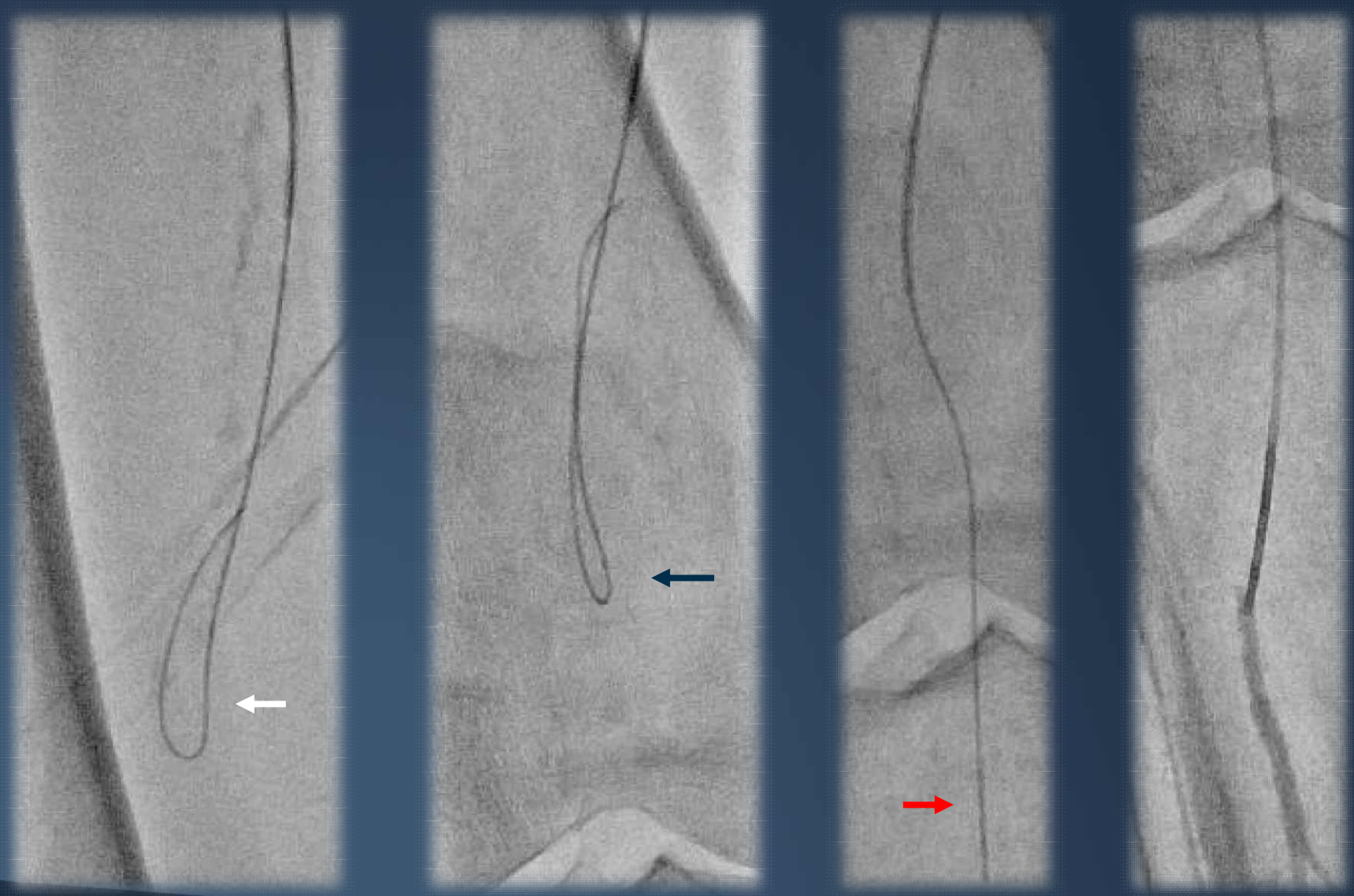
SFA CTO: Combined method



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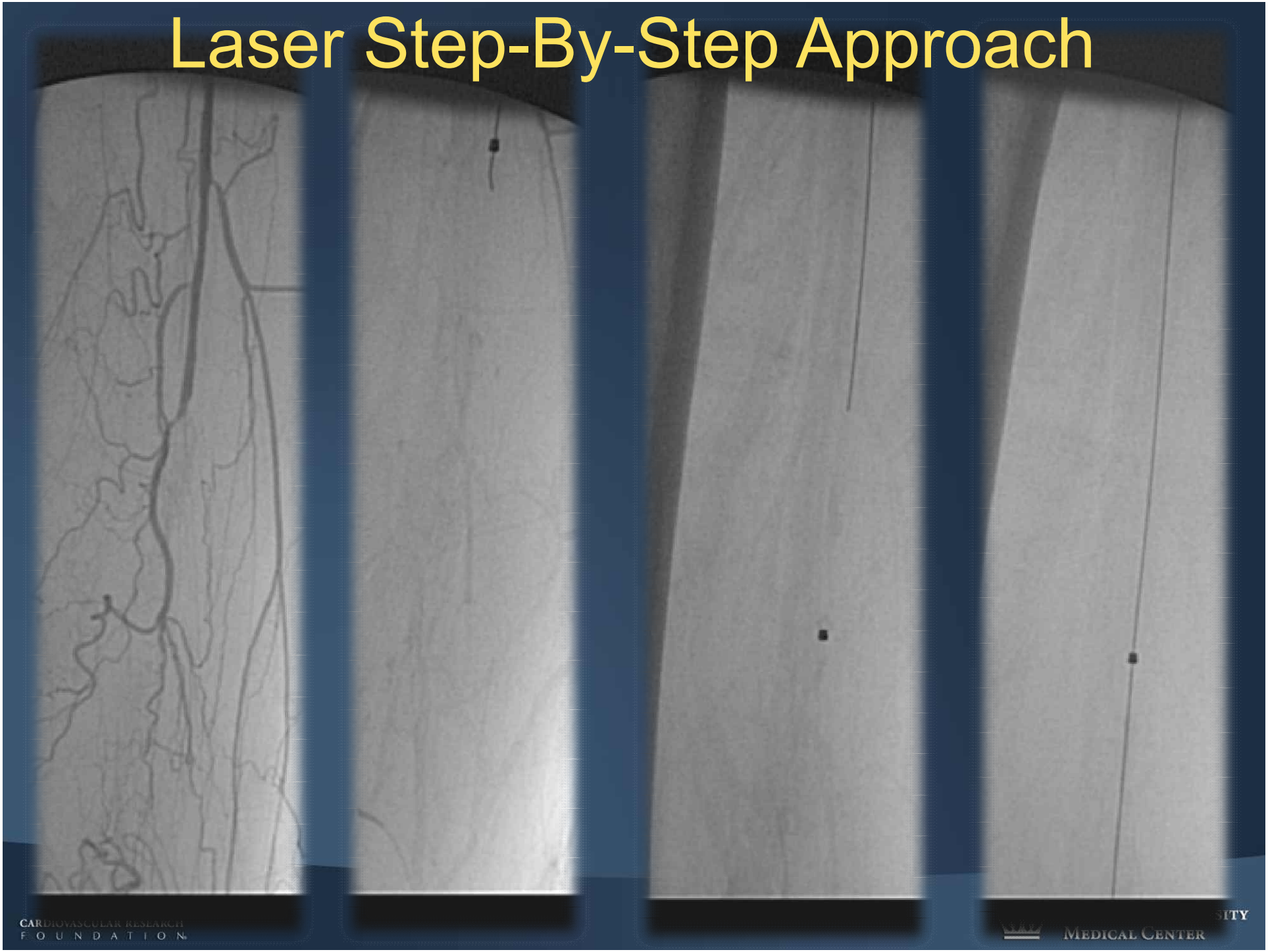
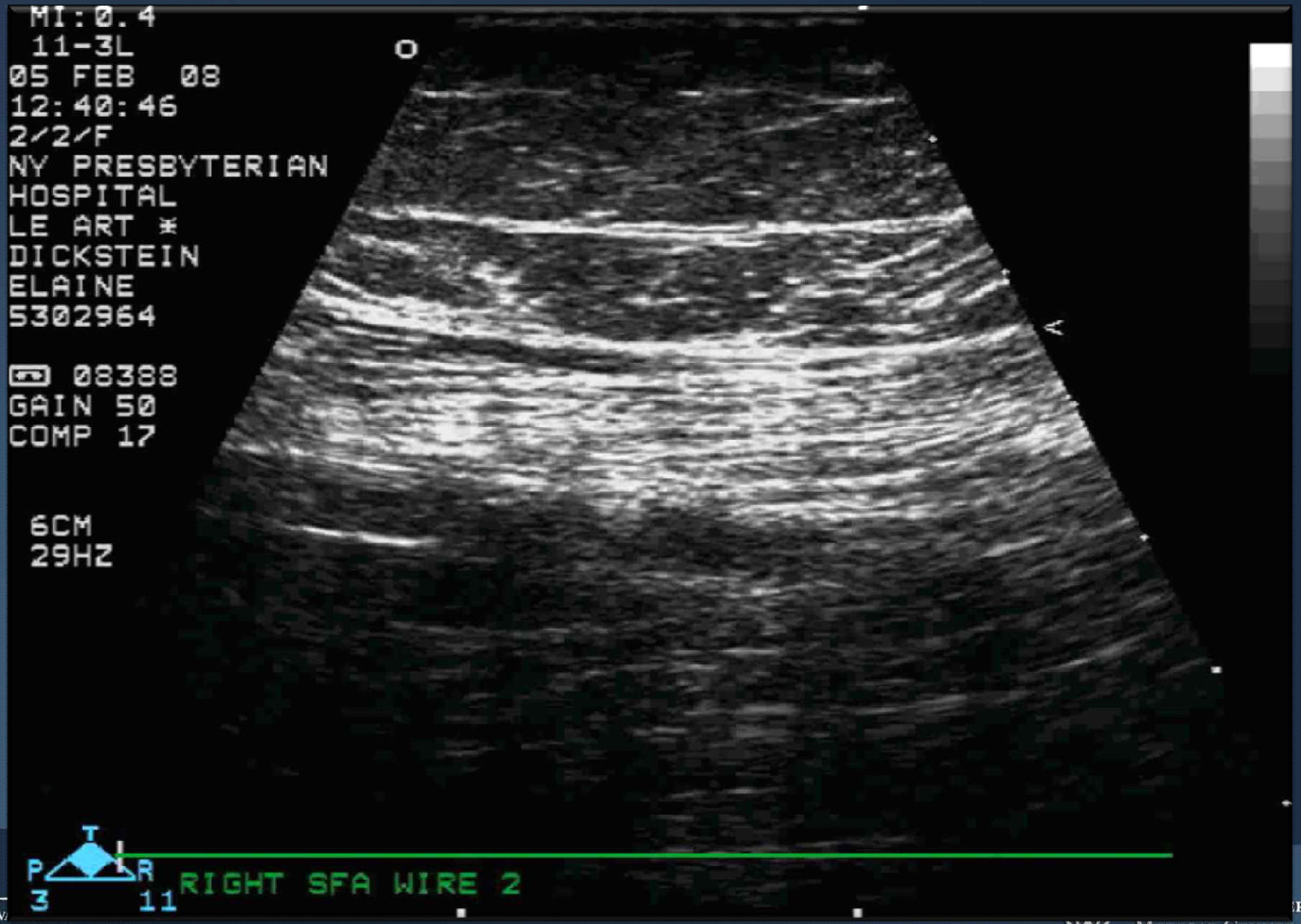
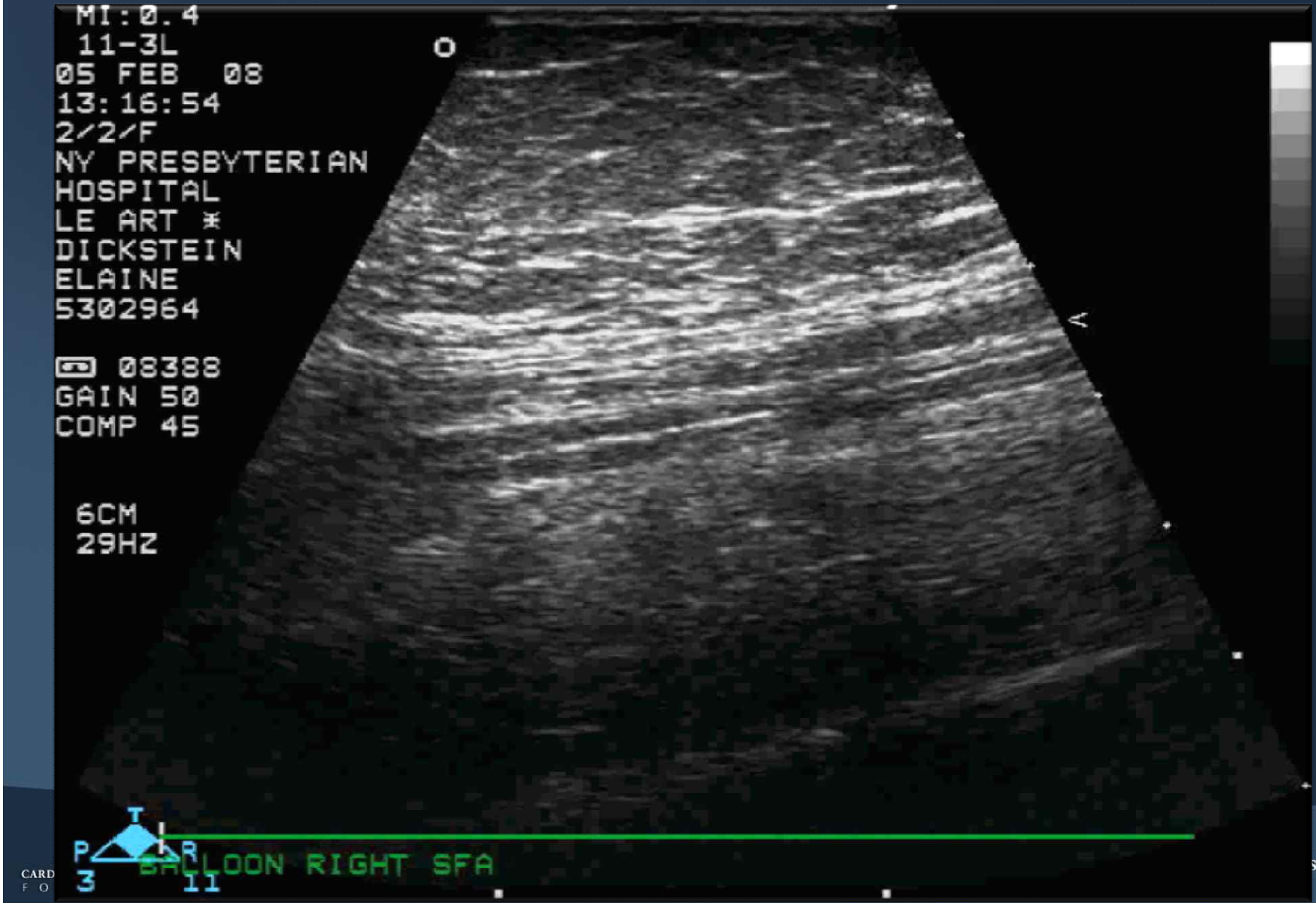
Laser Step-By-Step Approach



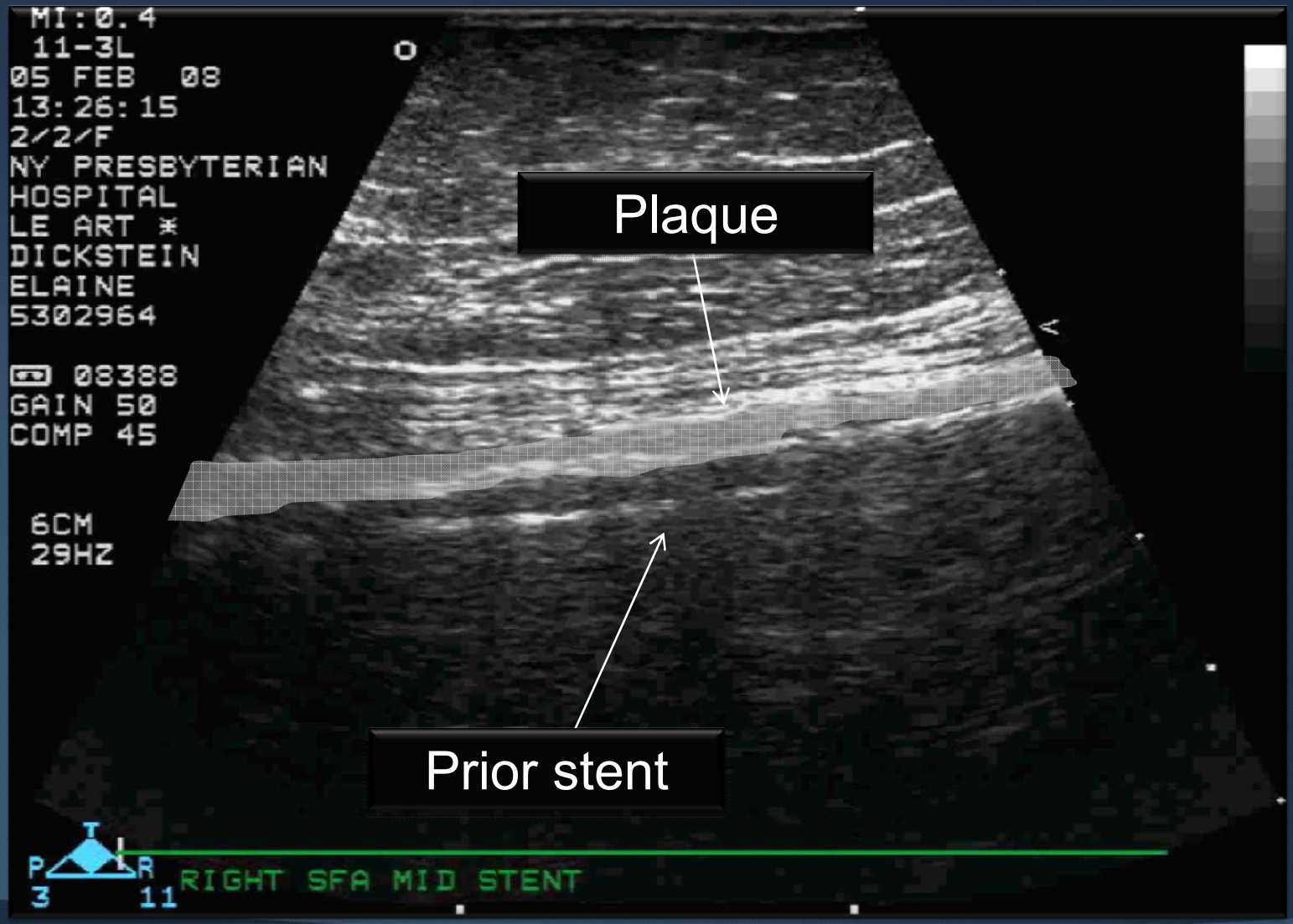
Sub-intimal tracking: US guidance



Sub-intimal tracking: US guidance



Sub-intimal stent deployment



Relevance of central lumen passage

- Opens other therapeutic options:
  - Atherectomy
- Reduced stent usage
- Setting the stage for DEB availability?

Conclusions

- As compared to coronary CTO, peripheral CTO:
  - Has considerably greater:
    - Plaque volume
    - Length
    - Calcification
    - Thrombus
  - Has less:
    - Tortuousity
    - Concern regarding dissection perforation

Conclusions

- The mechanistic causes of occlusion appears to be distal occlusion and proximal cap
- Greater tool selection reflects both the greater challenge, greater tolerance, and better “visibility” of procedure
  - STAR the “rule”, re-entry tools enable success
- Accordingly, success rates in experienced hands are >95% with very limited complication
- The concept of central lumen passage appears to be a potentially important one if drug coated balloons prove effective vs. PTA
  - ?DCB efficacy in stented segments

Thank you

Two strategies for CROSSING CTOs

- Subintimal Navigation
  - Well characterized, historical technique
  - Often as bail-out with re-entry devices necessary
  - Limits choices for adjunctive devices
- Central Lumen Navigation
  - Clinically preferred strategy
  - Maximizes therapeutic options
    - All adjunctive devices designed to operate in the arterial lumen