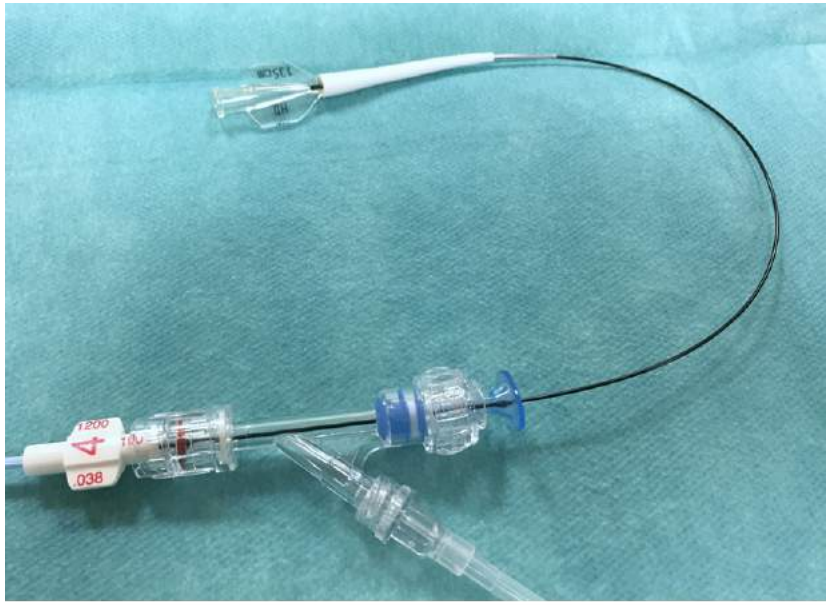
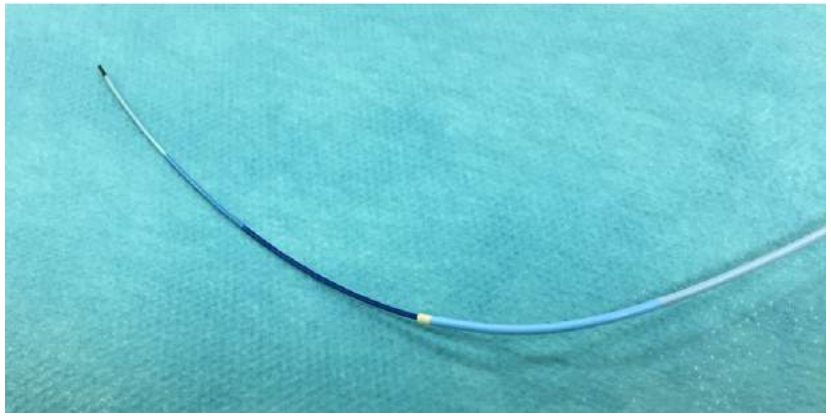
The Challenges of Calcified Femoropopliteal Disease:
From Access and Crossing to Treatment

Jos C van den Berg MD PhD
Ospedale Regionale di Lugano
University of Bern
Switzerland

Challenges of calcification

- Access
  - Puncture
  - Placement of sheath
- Crossing
  - Antegrade
  - Retrograde
  - Use of co-axial catheter systems
- Vessel preparation
- Definitive treatment

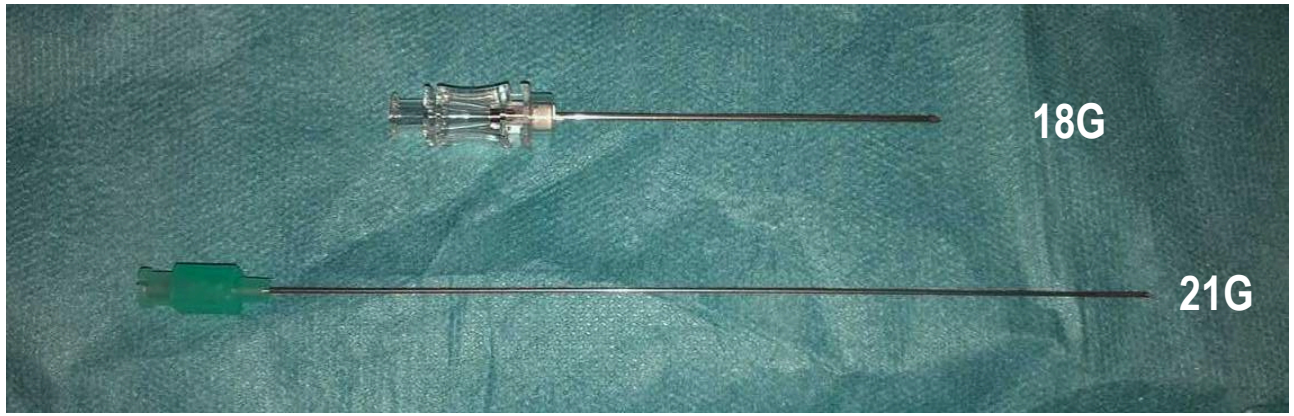


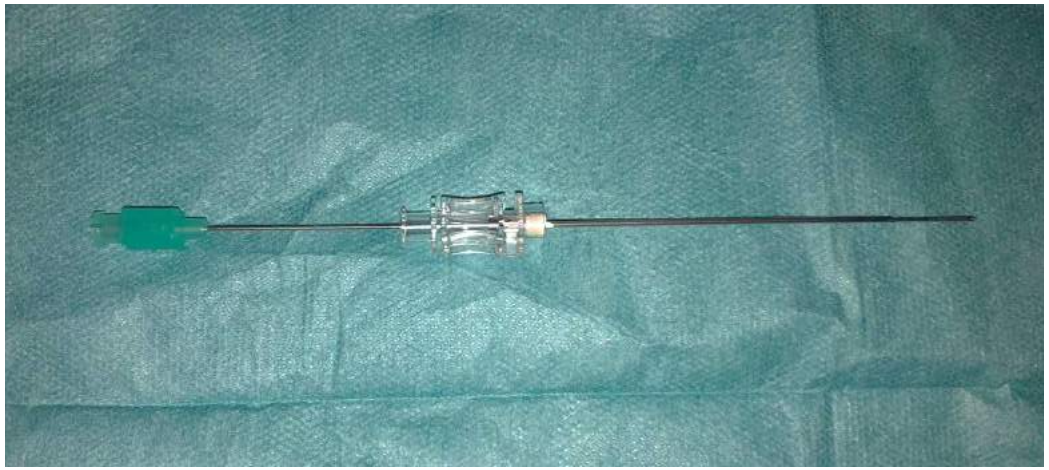


Access

- Puncture
  - Difficult needle entry
    - ‘chase’ the calcium under fluoroscopy
    - Use co-axial needle (combination of standard 18G puncture needle and 21G needle of 15 cm)

Puncture (co-axial needle)

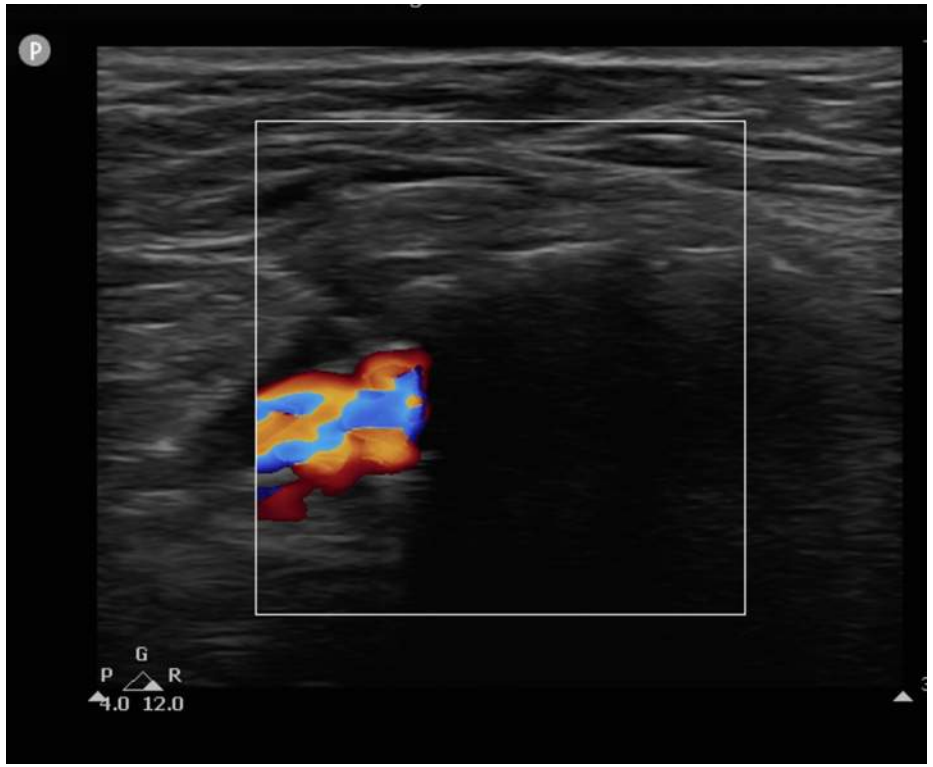




Access

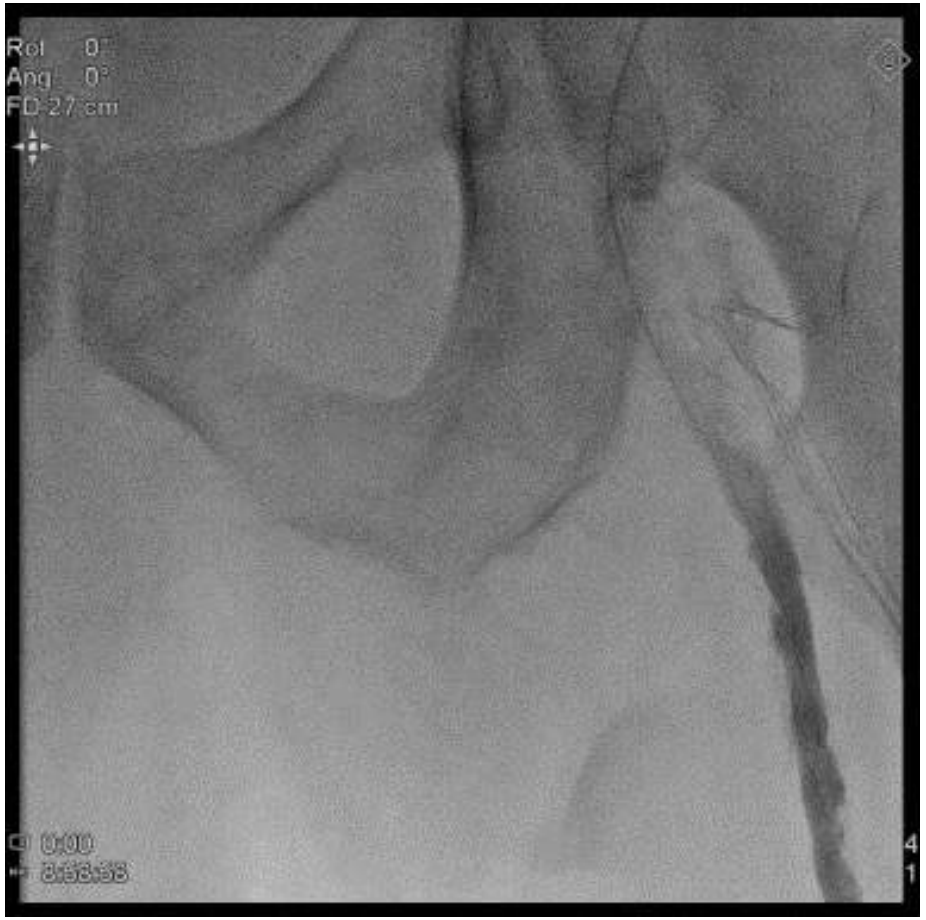
- Placement sheath
  - Use of micro-puncture set (4F)
  - Use of ‘stiff guidewire’ (Lunderquist 75 cm) to provide additional support

Access (micro-puncture set)



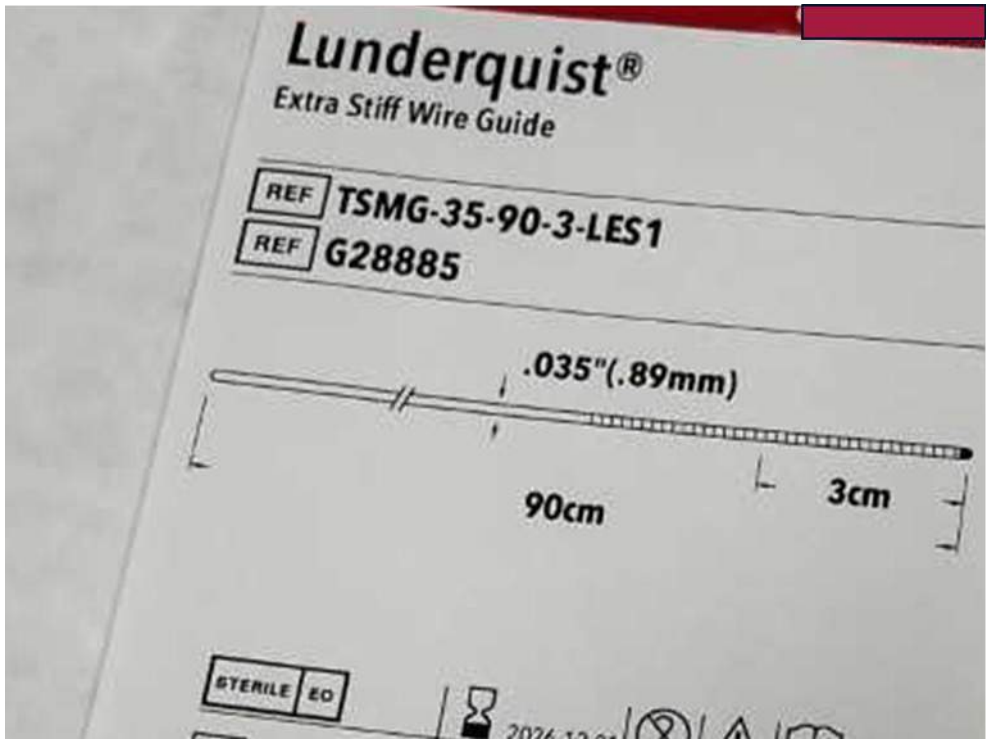
Access (micropuncture set)

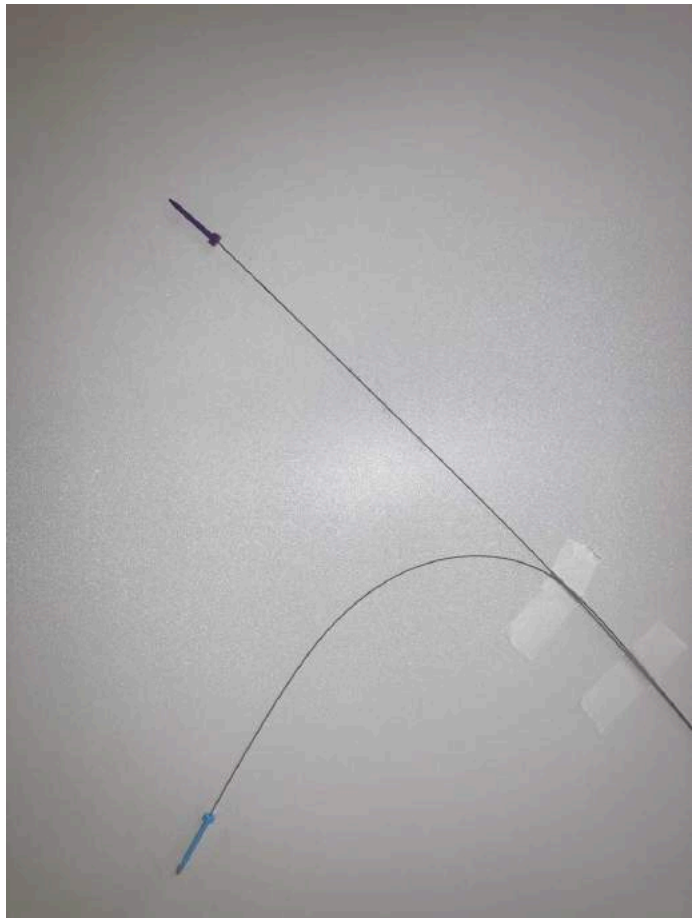
18G needle and 0.018”/0.021” guidewire



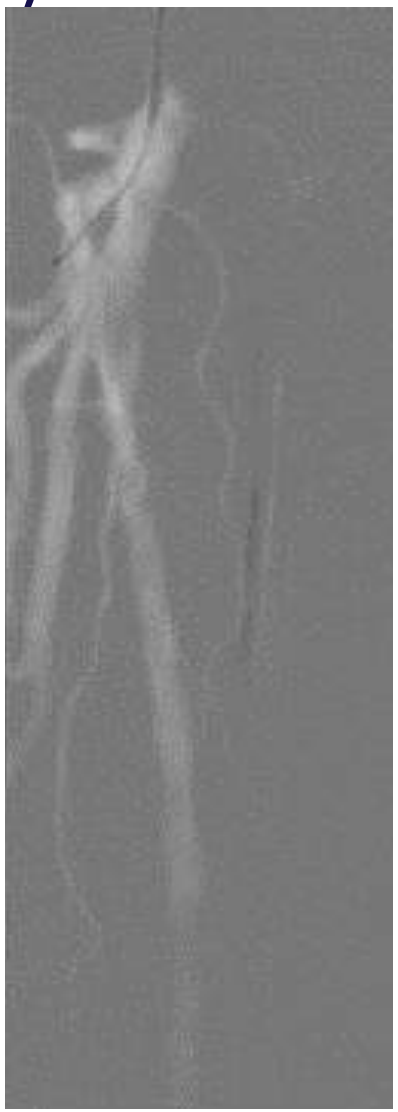
Dilator only

Access (Lunderquist wire)

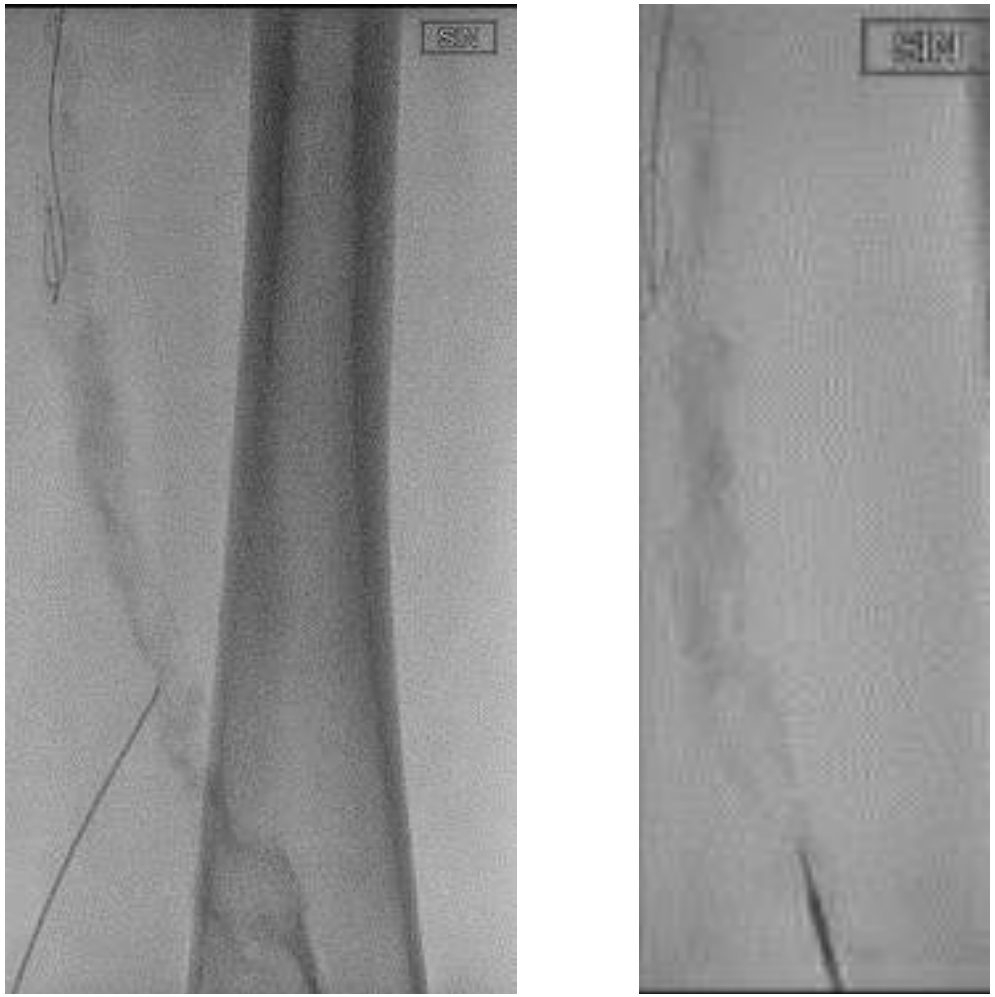




Access (Lunderquist wire)



Retrograde access (‘proximal’)



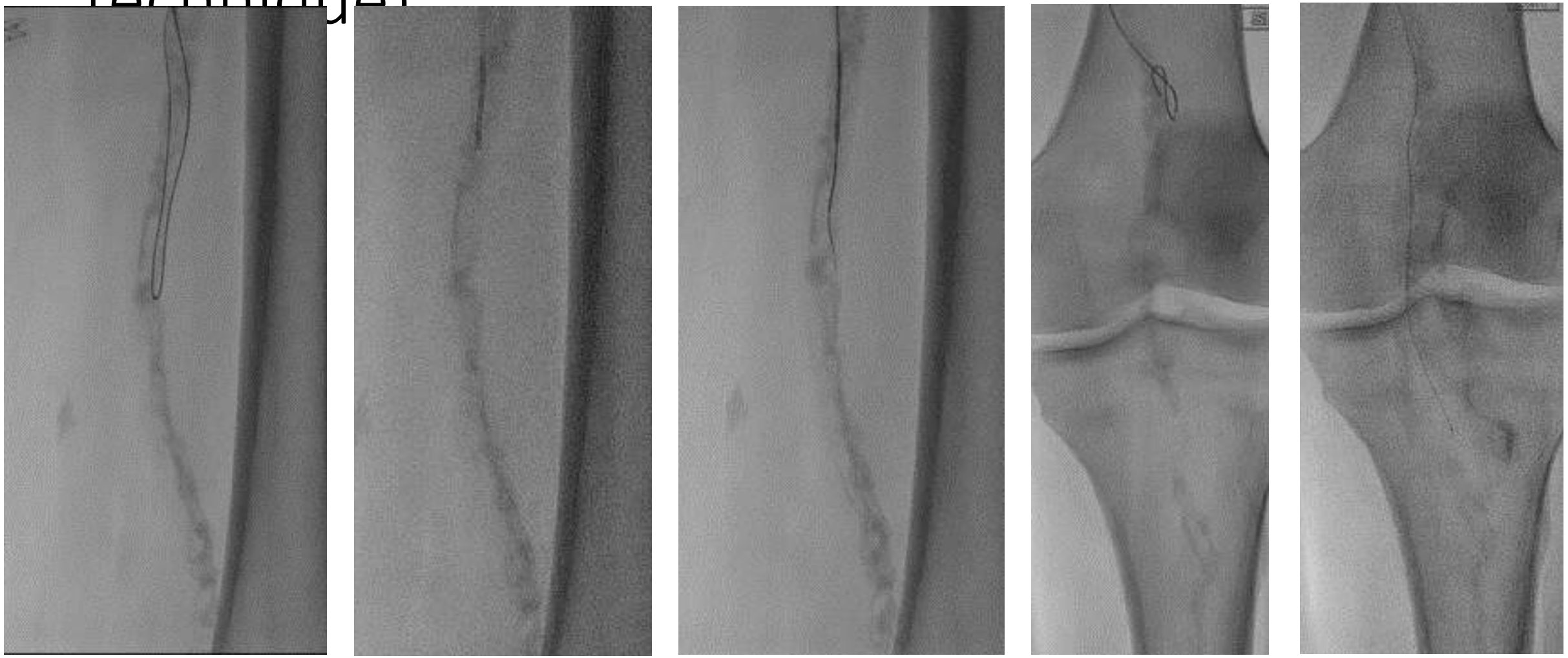
21 G needle does not enter; co-axial needle system (18G and 21 G)

Retrograde access (‘distal’)

SFA occlusion and occlusion stent popliteal artery

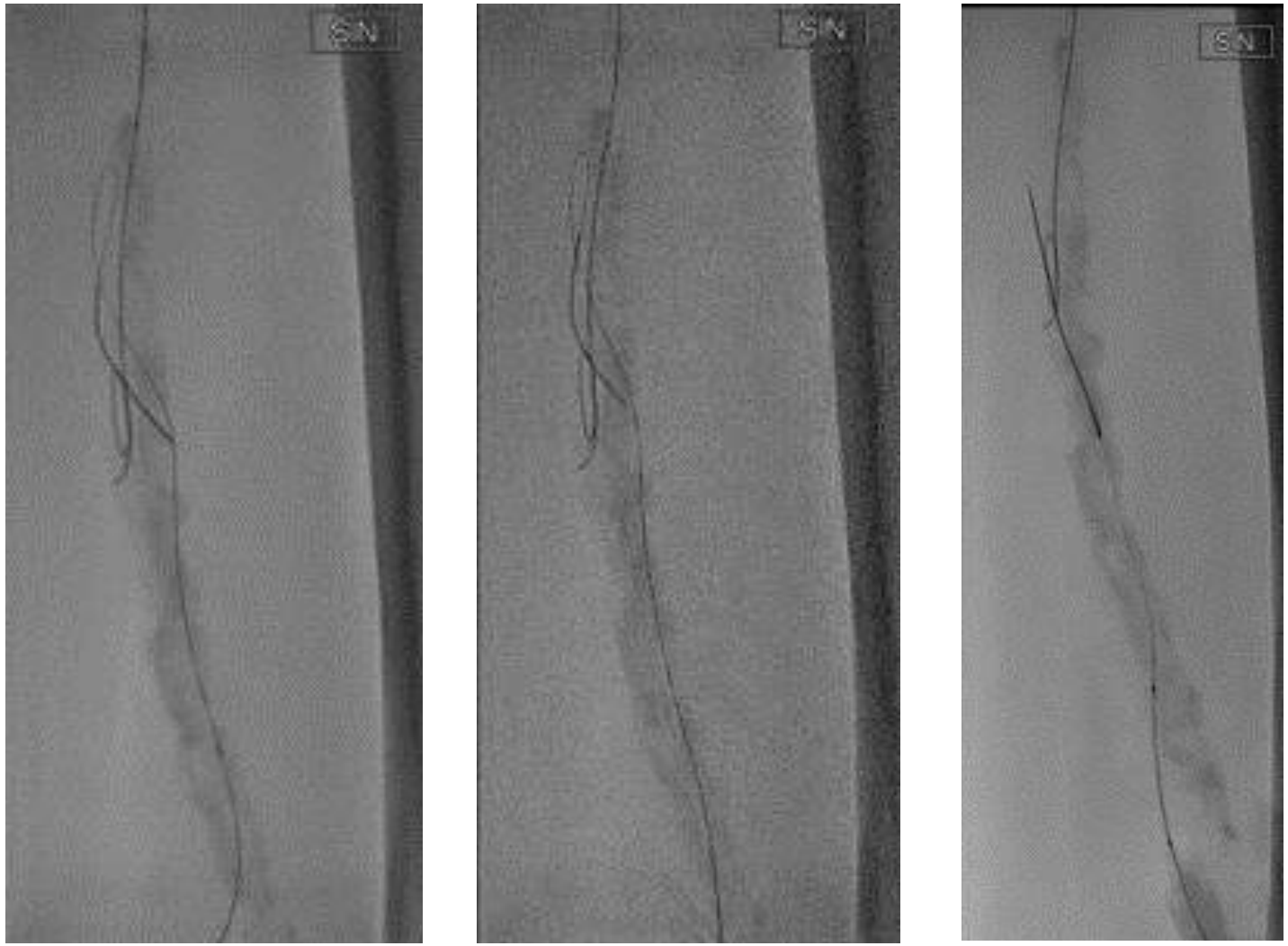
Antegrade crossing (0.018” guide wire)

Antegrade crossing (co-axial catheter technique)

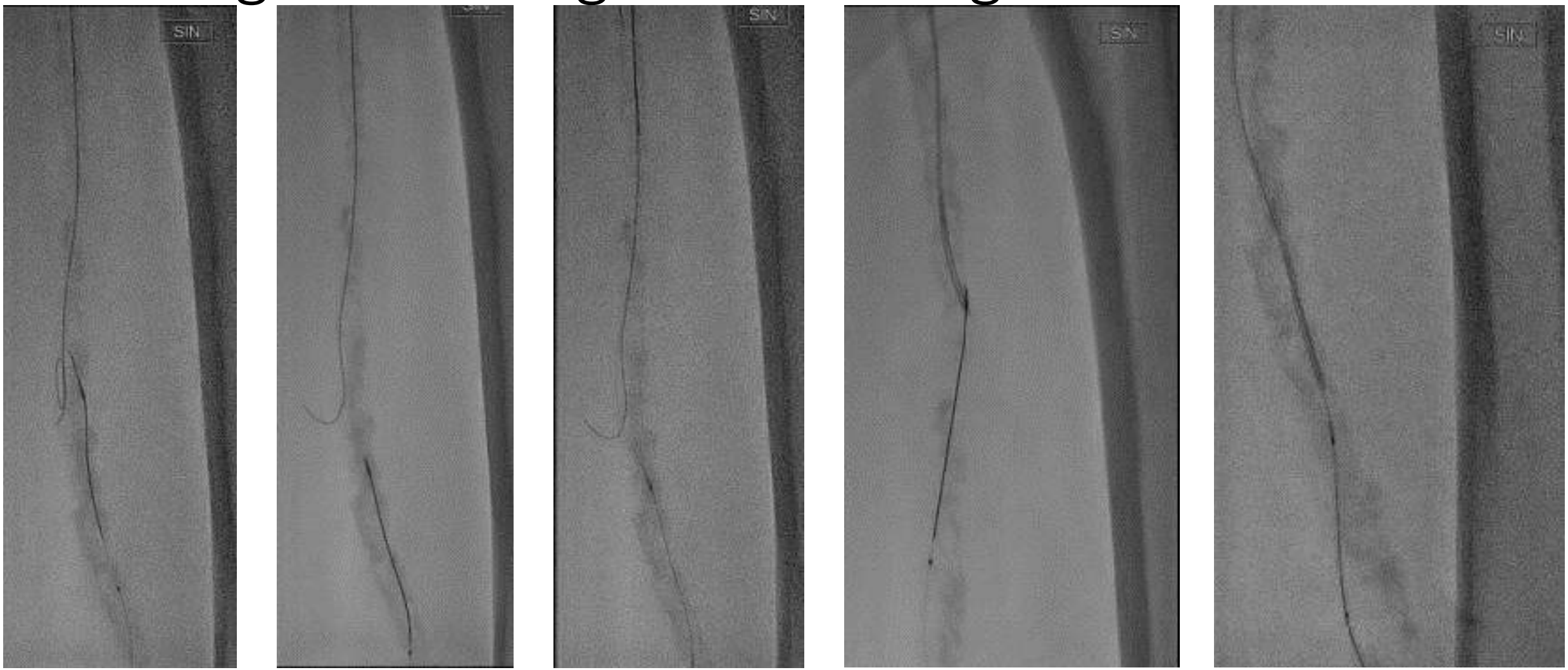


Subintimal recanalization 4F MP catheter and 0.035” Terumo glidewire followed by co-axial crossing

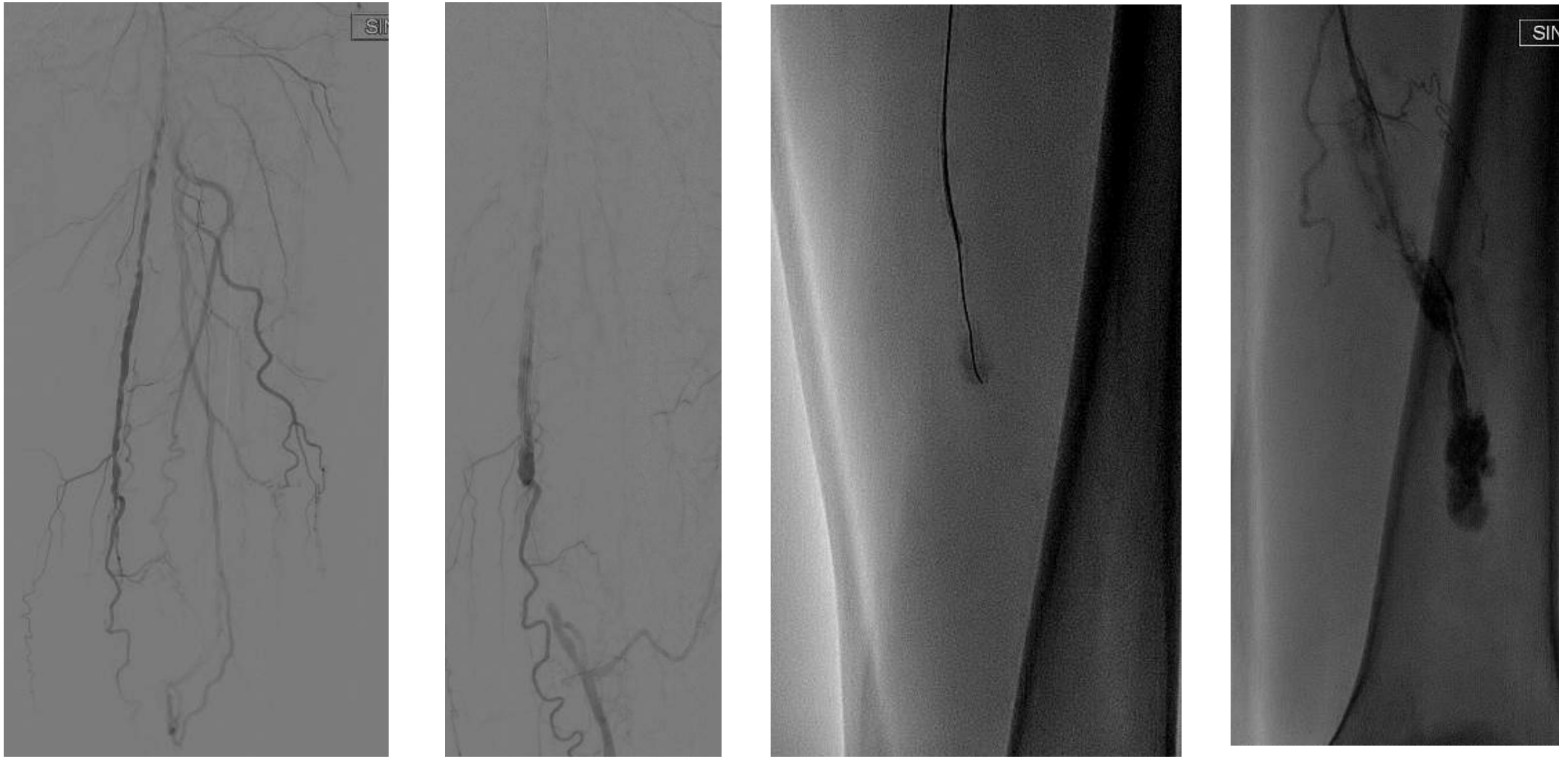
Antegrade-retrograde crossing



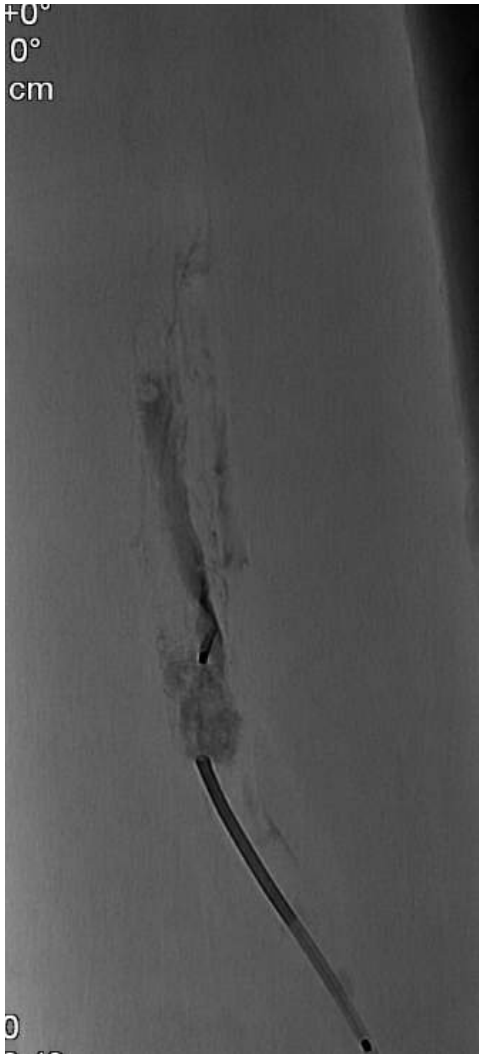
Antegrade-retrograde crossing

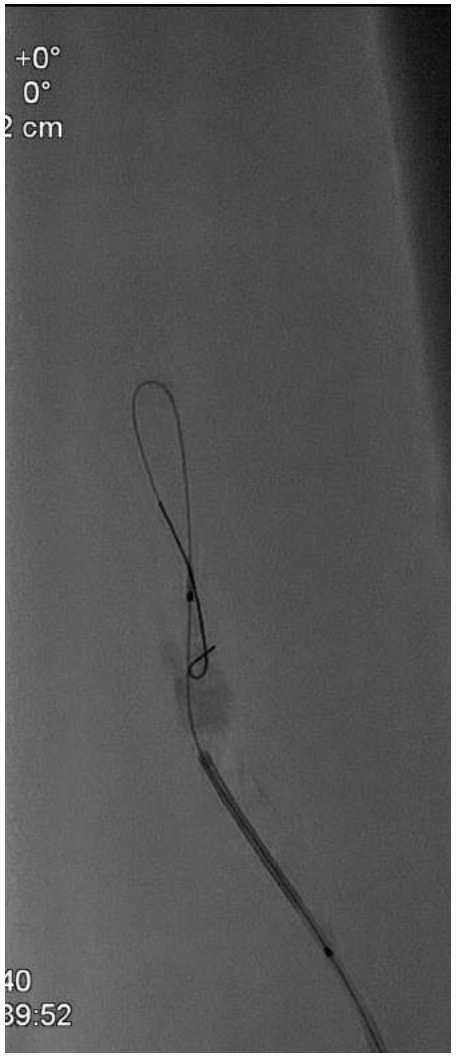


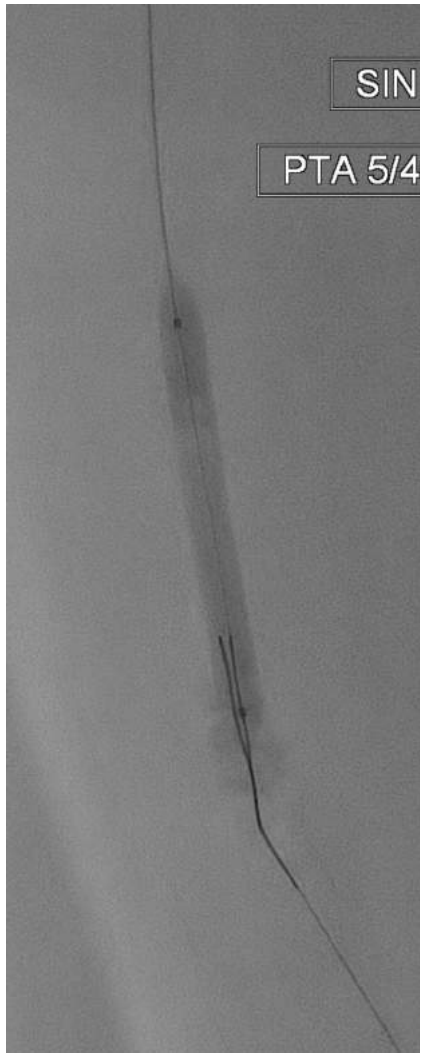
Antegrade-retrograde crossing (CART)

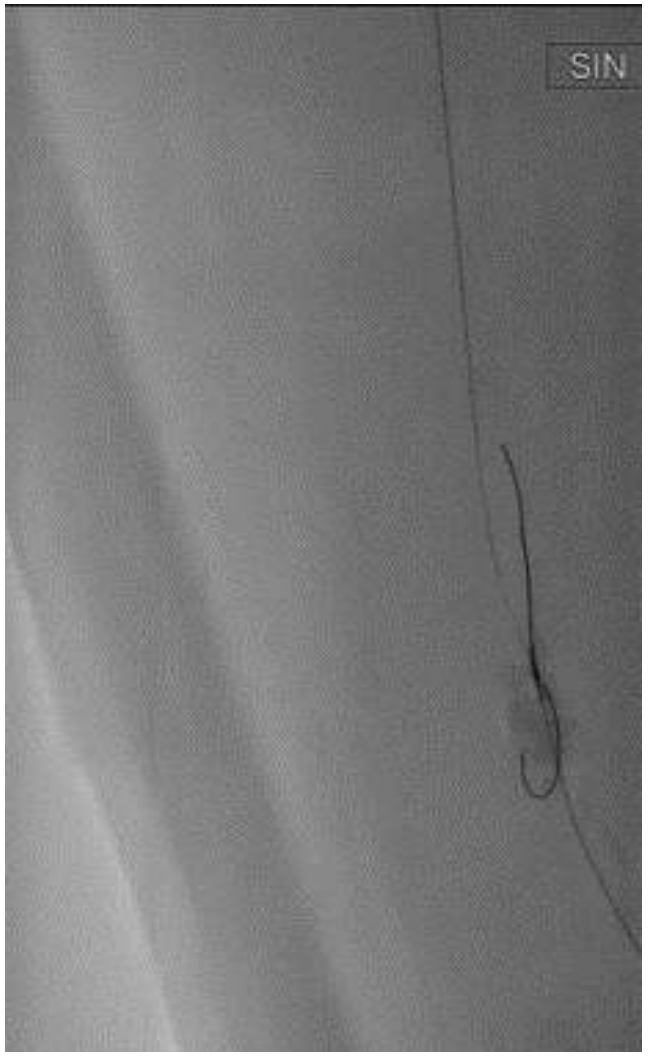


Antegrade-retrograde crossing (CART)

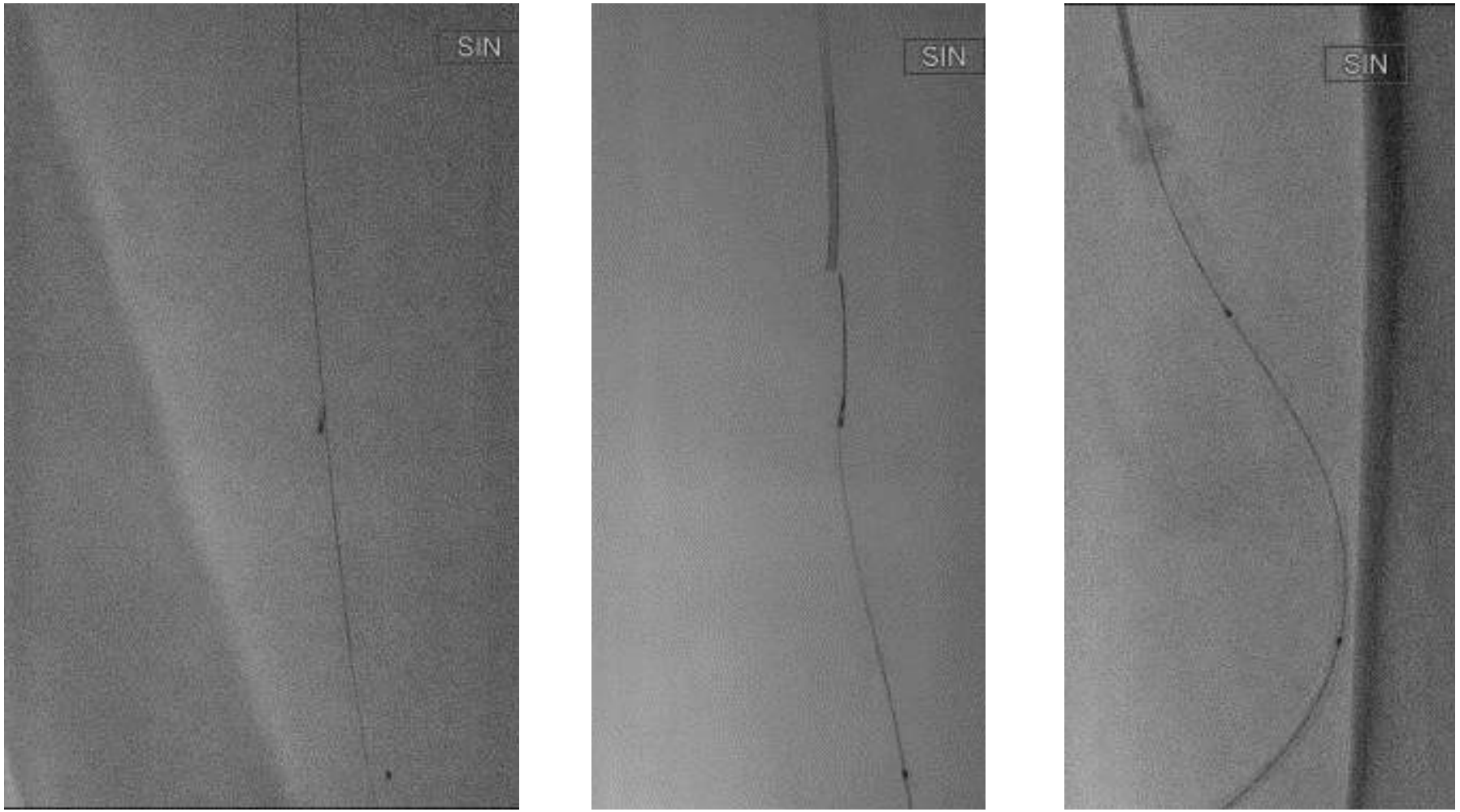




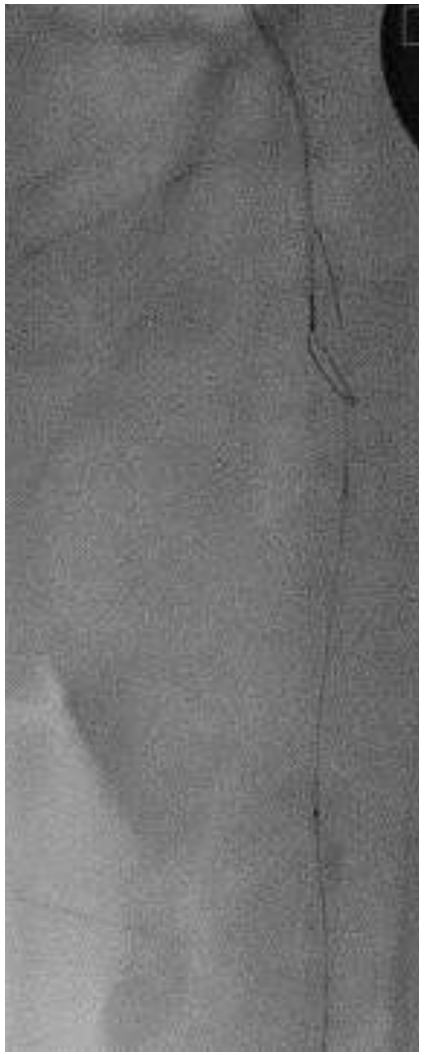


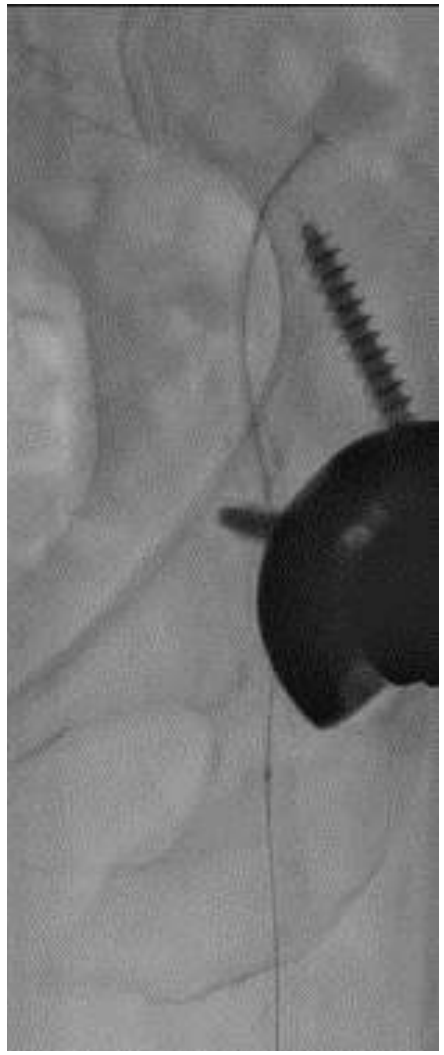


Antegrade-retrograde crossing (CART)



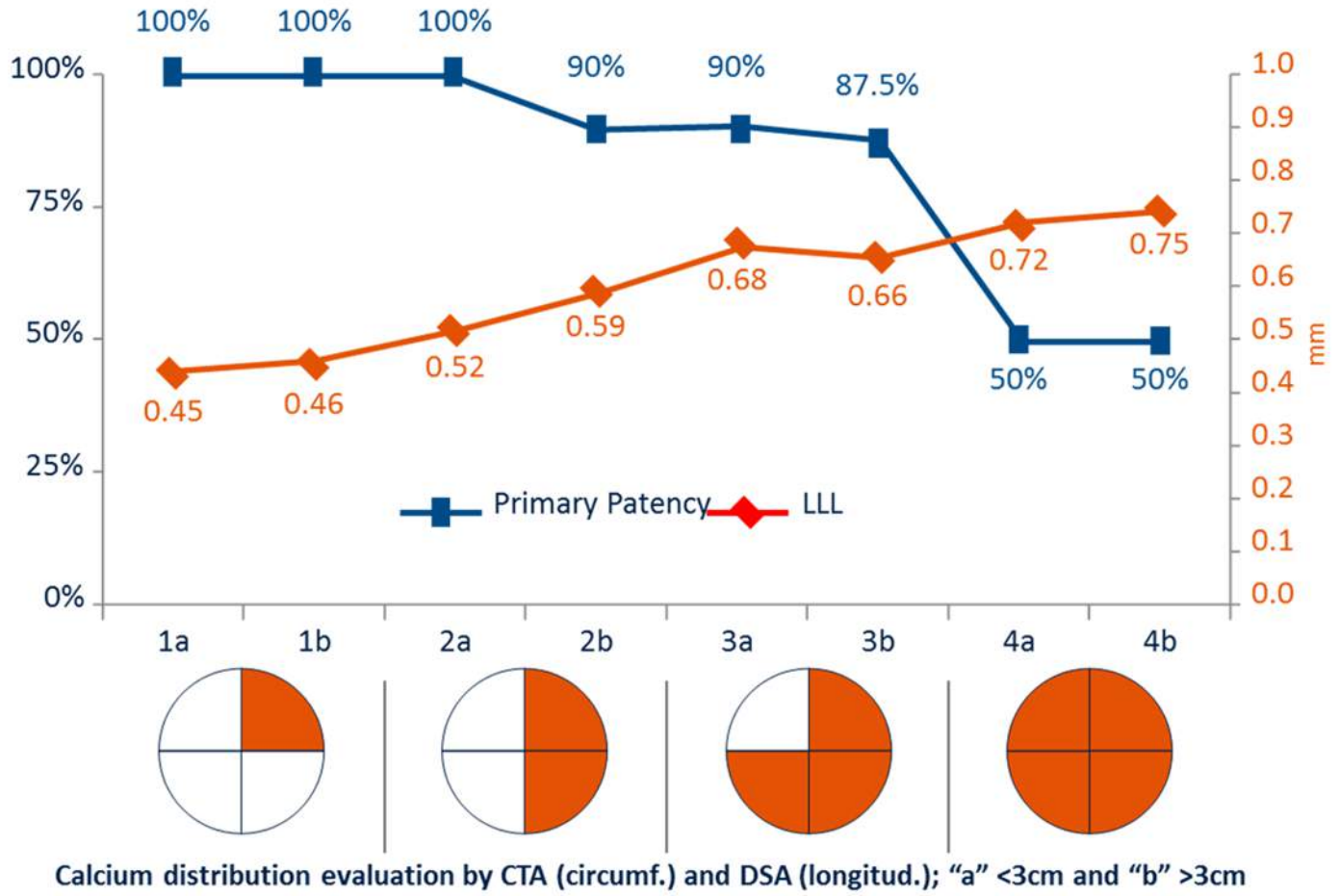
Antegrade-retrograde (‘classical snare’)





Calcium May Present a Challenge for DCBs

Calcium is a Barrier to Optimal Drug Absorption



Calcium distribution evaluation by CTA (circumf.) and DSA (longitud.); "a" <3cm and "b" >3cm

- **Calcium is a potential barrier to optimal drug absorption**
- **Calcium distribution and severity may affect late lumen loss (LLL) and primary patency**

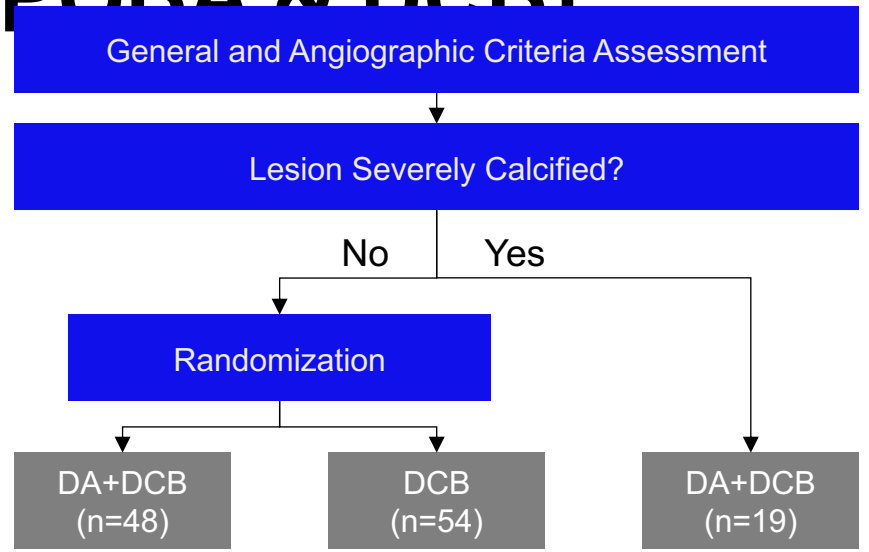
Primary patency defined as freedom from restenosis by duplex based on PSVR<2.4 and TLR

Fanelli F, et al. Cardiovasc Interv Radiol 2014; 37:898-907

DEFINITIVE AR (DA & DCB versus POBA & DCB)

- *Pilot study* designed to assess the effect of treating a lesion with directional atherectomy followed by a paclitaxel-coated balloon (DA+DCB) vs. a paclitaxel-coated balloon alone (DCB)
  - Small study to detect trends in treatment differences between groups
  - Observational investigation of outcomes; non-powered primary outcome

- Prospective, multicenter, randomized (DA+DCB vs. DCB alone); plus non-randomized DA+DCB registry arm for severely calcified lesions
- 121 subjects enrolled at 10 investigational sites
- Primary Outcome
  - Target Lesion Percent Stenosis at 1 Year: Defined as the narrowest point of the target lesion divided by the estimated native vessel diameter at that location, as determined by the angiographic core laboratory
- Clinical follow-up at pre-discharge, 30 days, 6 months, and 1 year post-procedure
- Independent CEC, angiographic and DUS core laboratory analyses

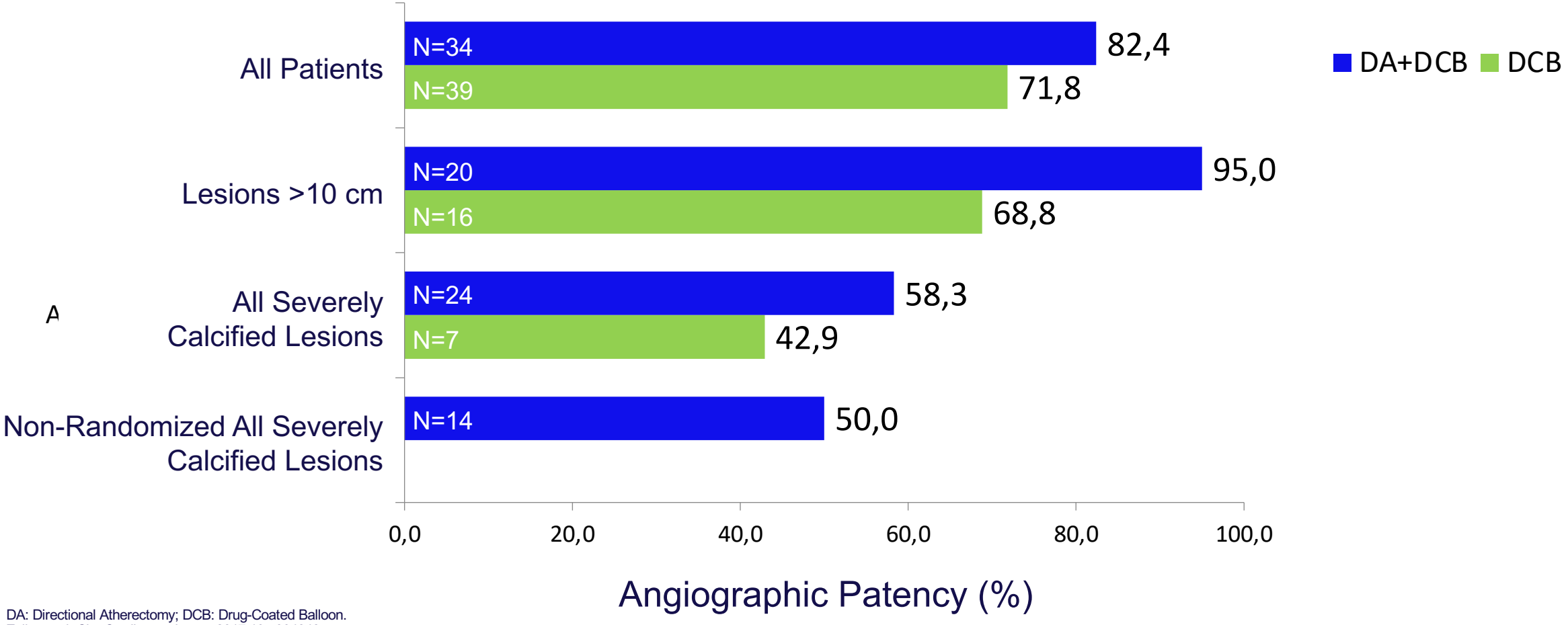


SilverHawk™ or TurboHawk™ Peripheral Plaque Excision Systems

Peripheral Paclitaxel-coated Angioplasty Catheter with Paccocath™* Coating

- DA: Directional Atherectomy; DCB: Drug-Coated Balloon; DUS: Duplex Ultrasonography; POBA: Plain Old Balloon Angioplasty.
  Zeller et al. Circ Cardiovasc Interv. 2017;10:e004848.

DEFINITIVE AR (DA & DCB versus POBA & DCB)

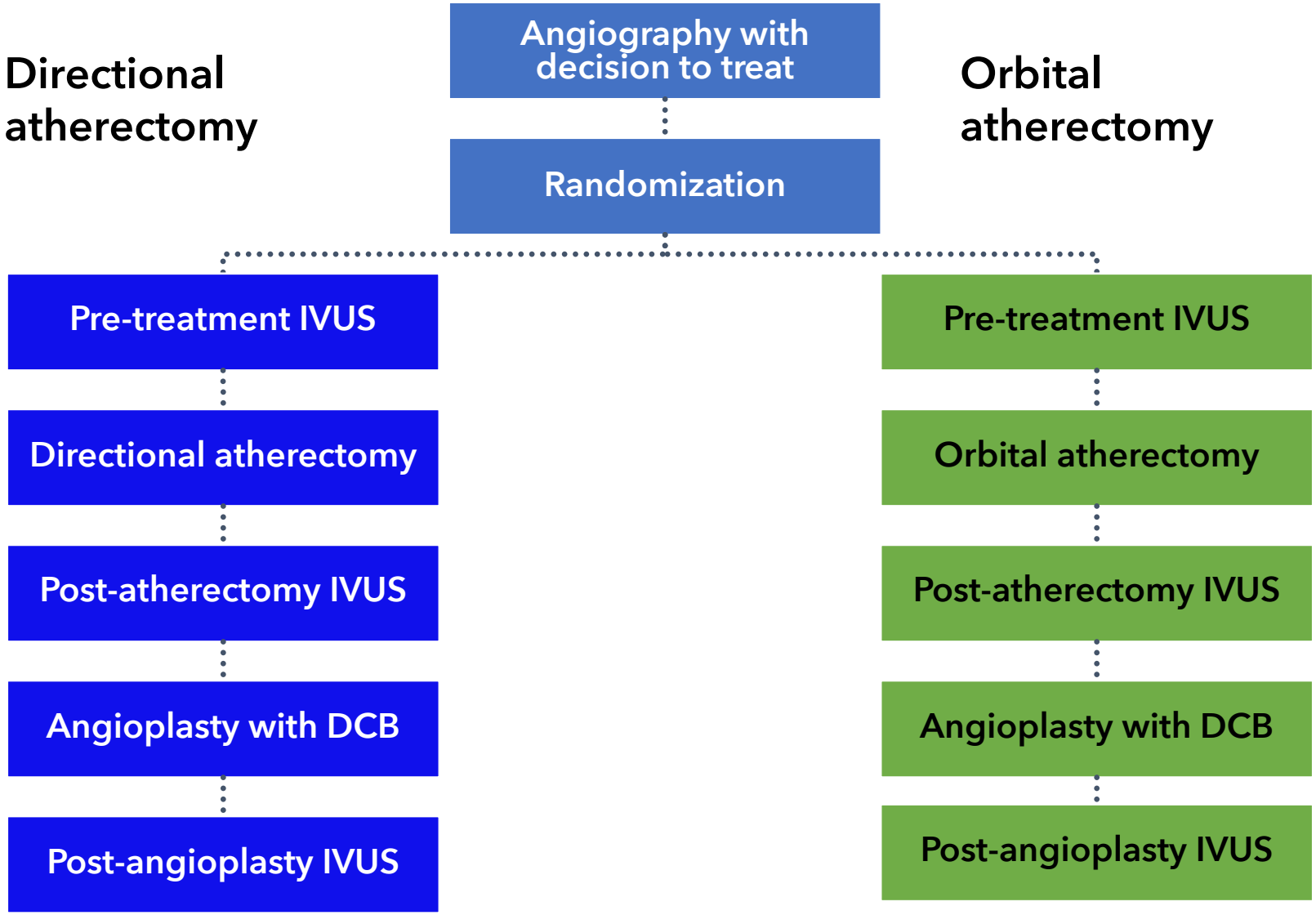


DA: Directional Atherectomy; DCB: Drug-Coated Balloon.
Zeller et al. Circ Cardiovasc Interv. 2017;10:e004848.

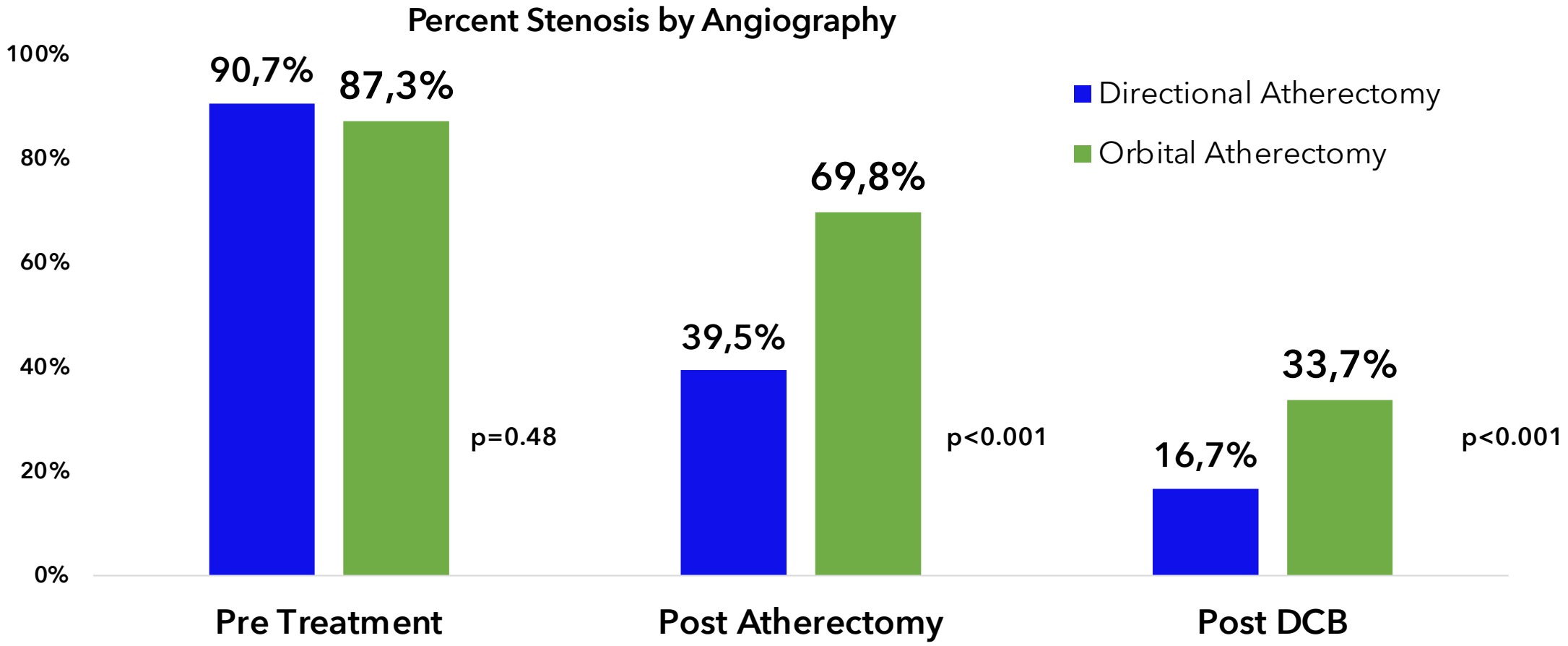
DIRECT Trial

- Medtronic HawkOne™ directional atherectomy system ("DA")
  - 360° cutting
  - Minimum 6 passes
- CSI Diamondback 360™* peripheral orbital atherectomy system ("OA")
  - 2.0mm solid crown used
  - Minimum 2 passes on each speed (60/90/120 rpm)
- Medtronic IN.PACT™ Admiral™ drug-coated balloon (DCB)
- Boston Scientific Opticross™* 18 intravascular ultrasound catheter

- Presented by Dr Babaev. TCT 2021



DIRECT Trial



There was a greater reduction in stenosis following directional atherectomy compared to orbital atherectomy. This difference persisted after DCB.

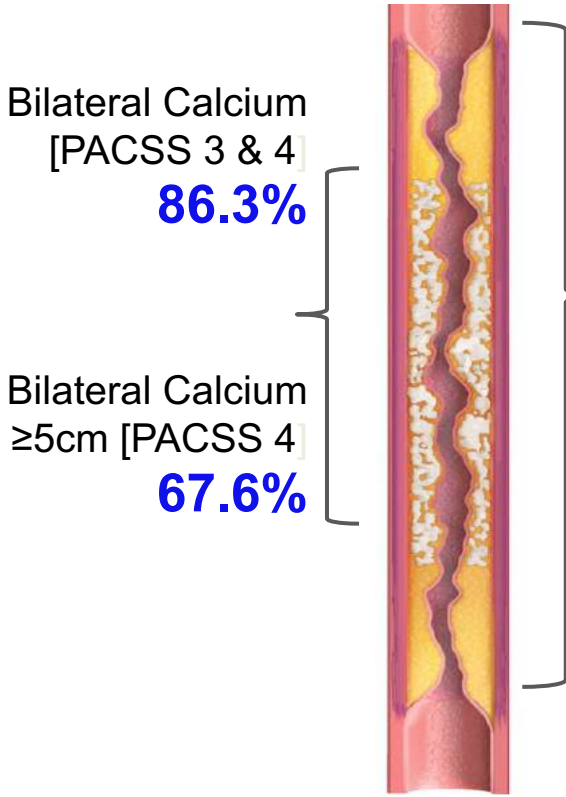
Presented by Dr Babaev. TCT 2021

REALITY Study

- Multicentre, prospective, non-randomized, single-arm study to evaluate the safety and effectiveness of the HawkOne™ directional atherectomy system to debulk moderate and severely calcified femoropopliteal artery atherosclerotic lesions followed by treatment with the IN.PACT™ Admiral™ drug-coated balloon (DCB)
- 102 subjects enrolled at 13 sites in the US and Germany

Key Lesion & Procedural Characteristics	DA+DCB (n=102)
Lesion Length (mm)	179.4 ± 81.4
Lesion Length ≥ 150mm	55.6%
CTO Length (mm)	226.0 ± 86.0
Provisional Stenting	8.8% (9/102)
Stenting for Perforations (cases)	3
Stenting for Dissection (cases)	5
Stenting for Embolization (cases)	1

Key calcium metrics

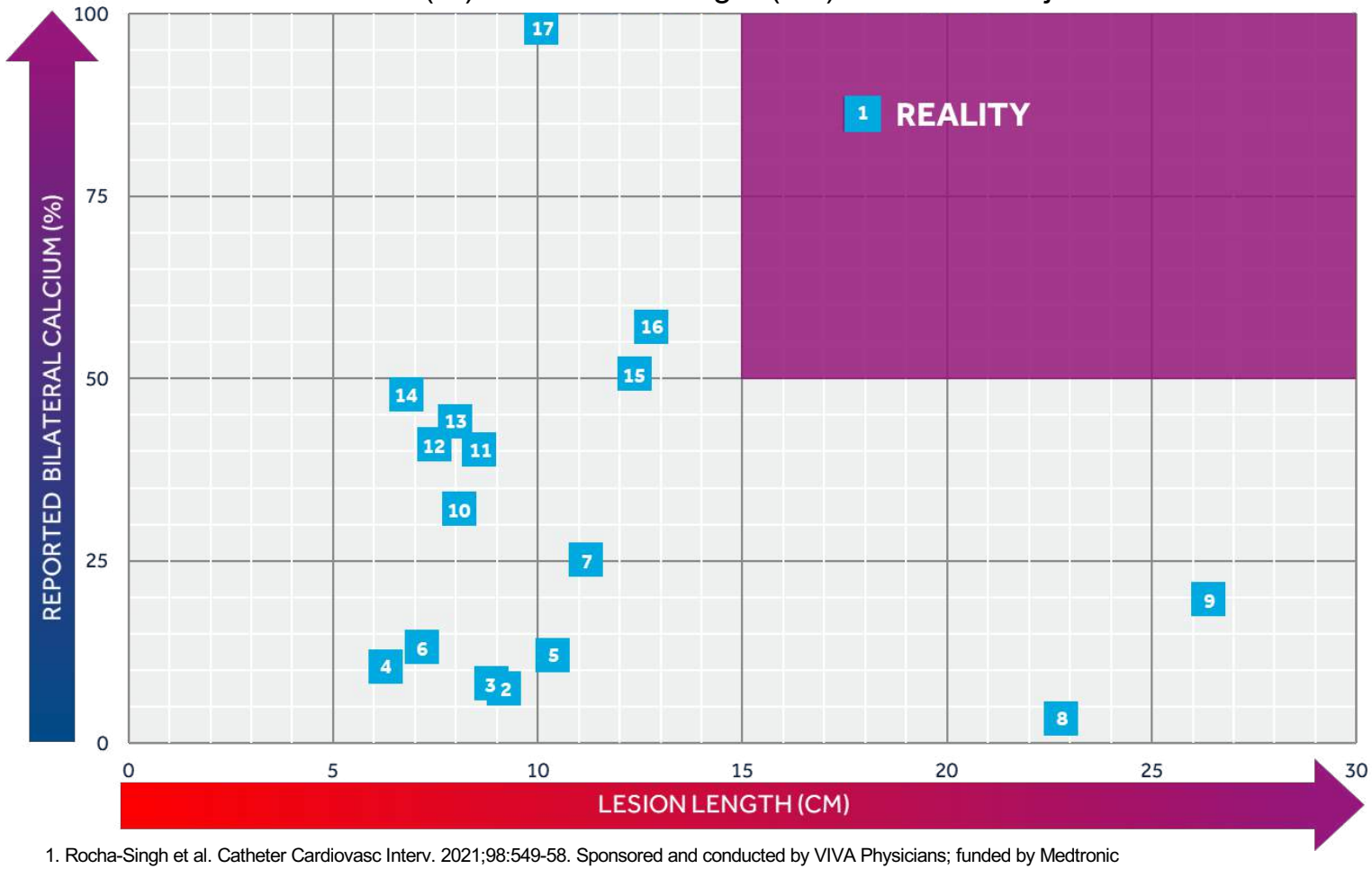


PACSS Index: $\frac{Total\ bilateral\ calcification}{lesion\ length} x100 = 55.7 \pm 26.2$

Rocha-Singh et al. Catheter Cardiovasc Interv. 2021;98:549-58. Sponsored and conducted by VIVA Physicians; funded by Medtronic.

REALITY Study

Bilateral Calcium (%) and Lesion Length (cm) of core lab adjudicated studies [2]



Lesion Characteristics

86.3% Bilateral Calcium

179 mm Average Lesion Length

39.0% Chronic Total Occlusion

Outcomes

92.6% FF-CD TLR

76.7% Patency

12-month data include patients beyond the follow-up window

Preserved Treatment Options

8.8% Bailout stent rate

Rocha-Singh et al. Catheter Cardiovasc Interv. 2021;98:549-58

1. Rocha-Singh et al. Catheter Cardiovasc Interv. 2021;98:549-58. Sponsored and conducted by VIVA Physicians; funded by Medtronic
2. Calcium definitions differ across studies. These are angiographic, core lab adjudicated reported calcium results. This graph is for illustration purposes only. References are at the end of this presentation.

Conclusion

- Challenges with calcium are many, from access to treatment
- Knowledge of various techniques to overcome technical challenges is mandatory
- Final treatment outcomes depend on optimal vessel preparation

The Challenges of Calcified Femoropopliteal Disease:
From Access and Crossing to Treatment

Jos C van den Berg MD PhD
Ospedale Regionale di Lugano
University of Bern
Switzerland