



CardioVascular
Learning Network

CME

BREAKING THROUGH THE CALCIUM BARRIER

A Multidisciplinary Approach
to Treating Calcified Lesions
BTK in Patients with CLTI



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Faculty Disclosures

- **Liz Genovese, MD, MS, FACS:** Consultant—Abbott, Boston Scientific, Cook, Gore, Inari, Penumbra, Reflow, Shockwave, Philips; Advisory Board—Boston Scientific, Cook, Philips, R3
- **Venita Chandra, MD:** Consultant—Shockwave, Medtronic, Boston Scientific, Cook Medical, Gore; Advisory Board—Medtronic, Boston Scientific, Cook Medical, Gore, Evident, Fastwave Medical
- **Kumar Madassery, MD, FSIR:** Consultant—Shockwave, Penumbra, Asahi, Cook Medical, Abbott, Cordis X
- **Brett Chatman, DPM, FACFAS:** Consultant—Smith & Nephew, Stryker

This CME activity includes brand names for participant clarity purposes only.

No product promotion or recommendation should be inferred.

Program Information

- This program is provided by HMP Education, an HMP Global company
- Supported by an educational grant from Shockwave IVL

Learning Objectives

- Identify the clinical challenges associated with chronic limb-threatening ischemia (CLTI) and calcified below-the-knee (BTK) arterial disease
- Evaluate current evidence and practical techniques for the use of intravascular lithotripsy (IVL) in BTK interventions, including imaging considerations, vessel access, device selection, and procedural optimization in complex calcium
- Integrate multidisciplinary approaches into the management of CLTI patients, with emphasis on post-revascularization wound care and coordinated longitudinal care pathways



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Understanding the Challenge: CLTI and Calcified BTK Disease

Liz Genovese, MD, MS, FACS

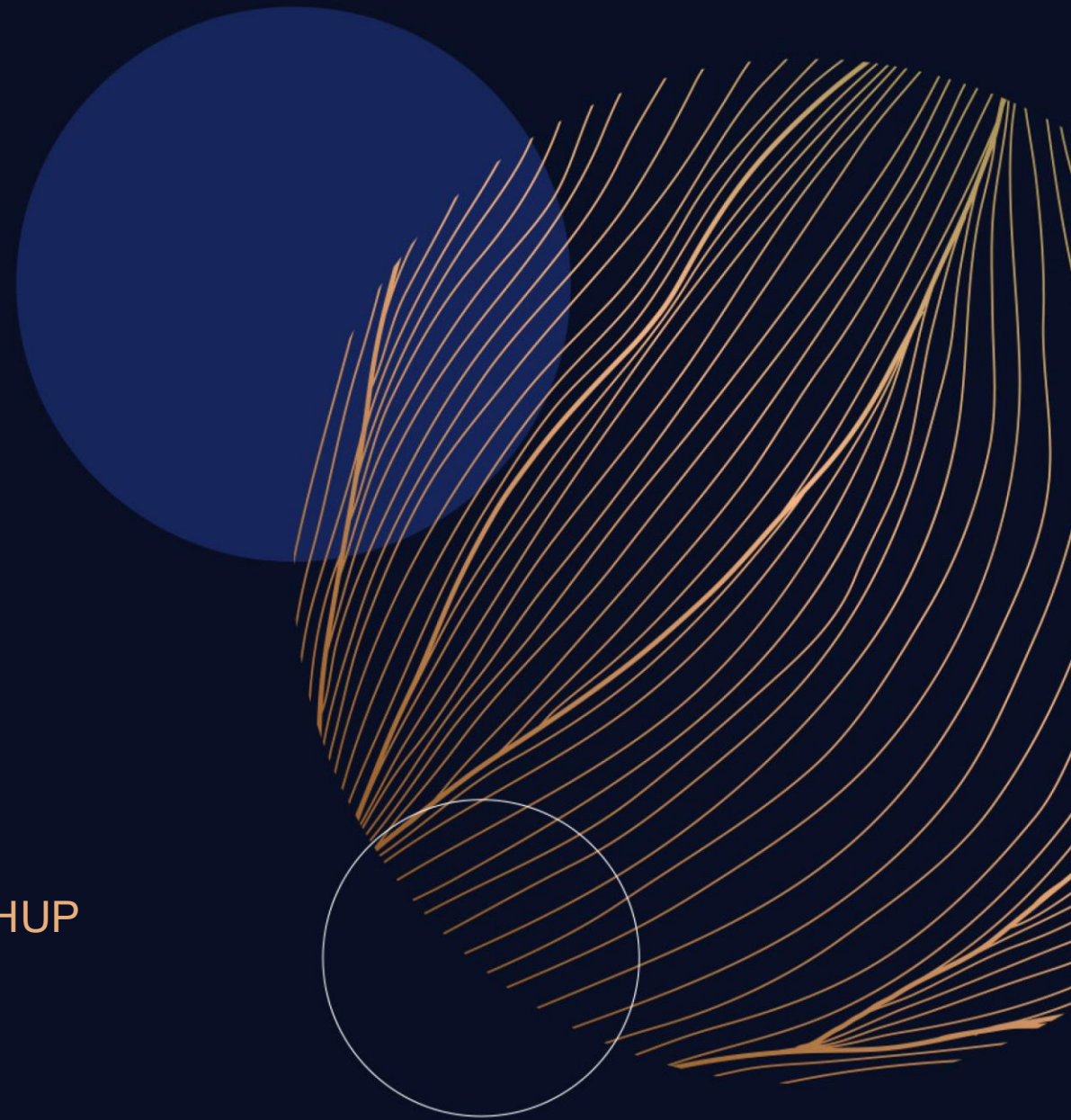
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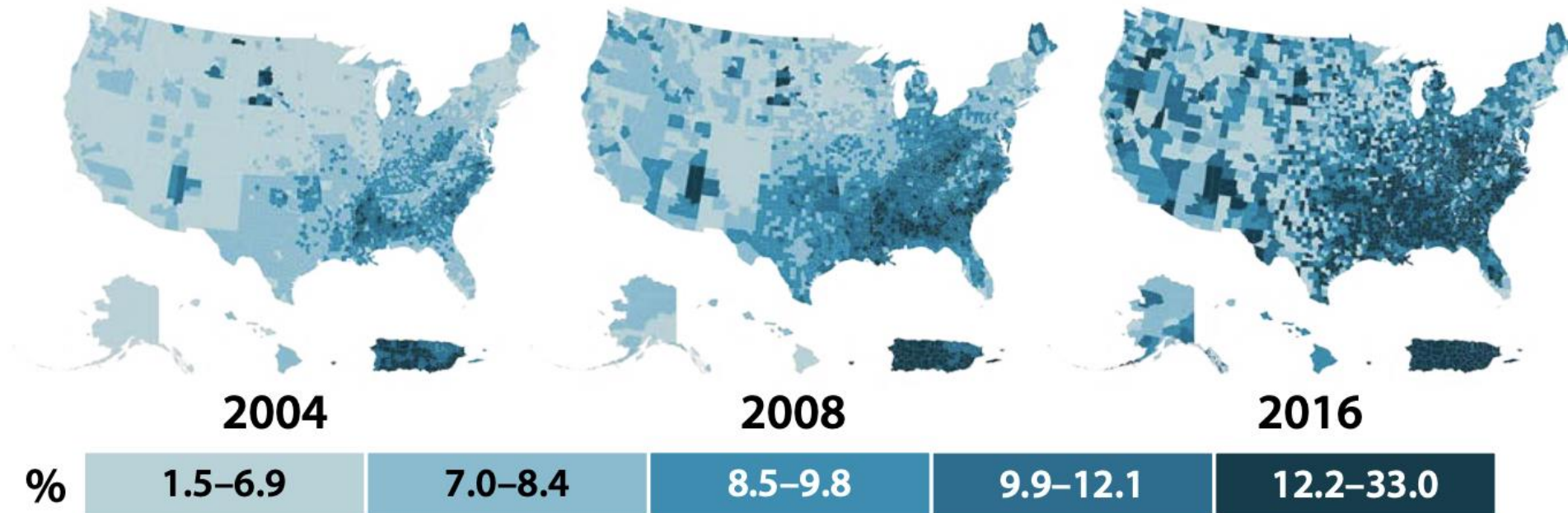
University of Pennsylvania

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Epidemic of Diabetes in the United States

- 13.0% of all U.S. adults (34 million) have diabetes
- The percentage of adults with diabetes increases with age, reaching 26.8% among those aged 65 years or older



Impact of Diabetes on Peripheral Arterial Disease

- Increase rates of PAD
 - High associated rates of concomitant neuropathy, decreased wound healing capability, infection
- Increased medial calcinosis
- Increase the risk of chronic kidney disease



Increasing prevalence of highly calcific infrainguinal occlusive disease, infra-popliteal disease and outflow disease

Highly Calcified Below-the-Knee Disease



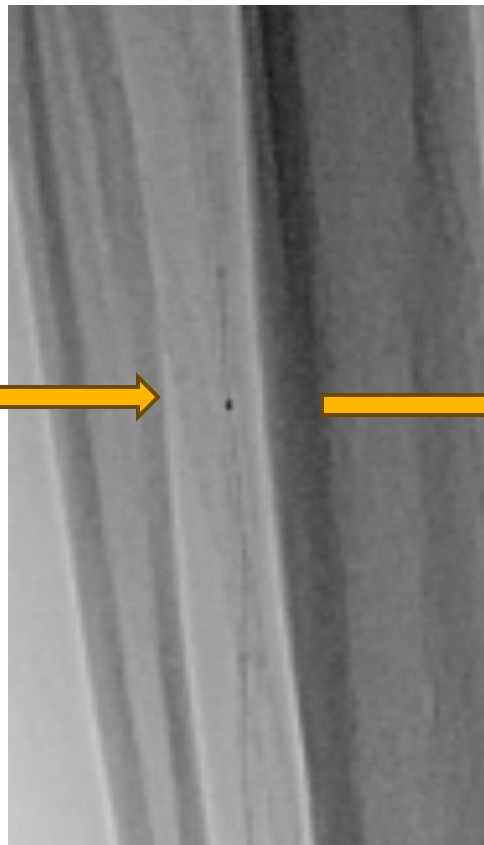
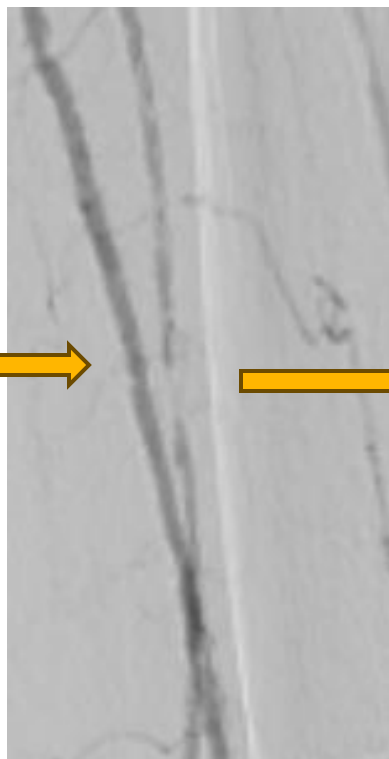
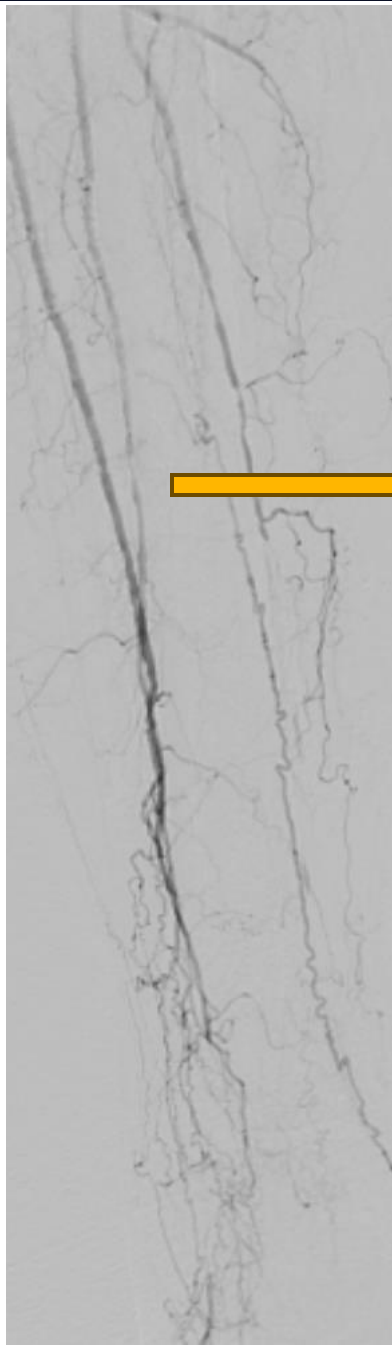
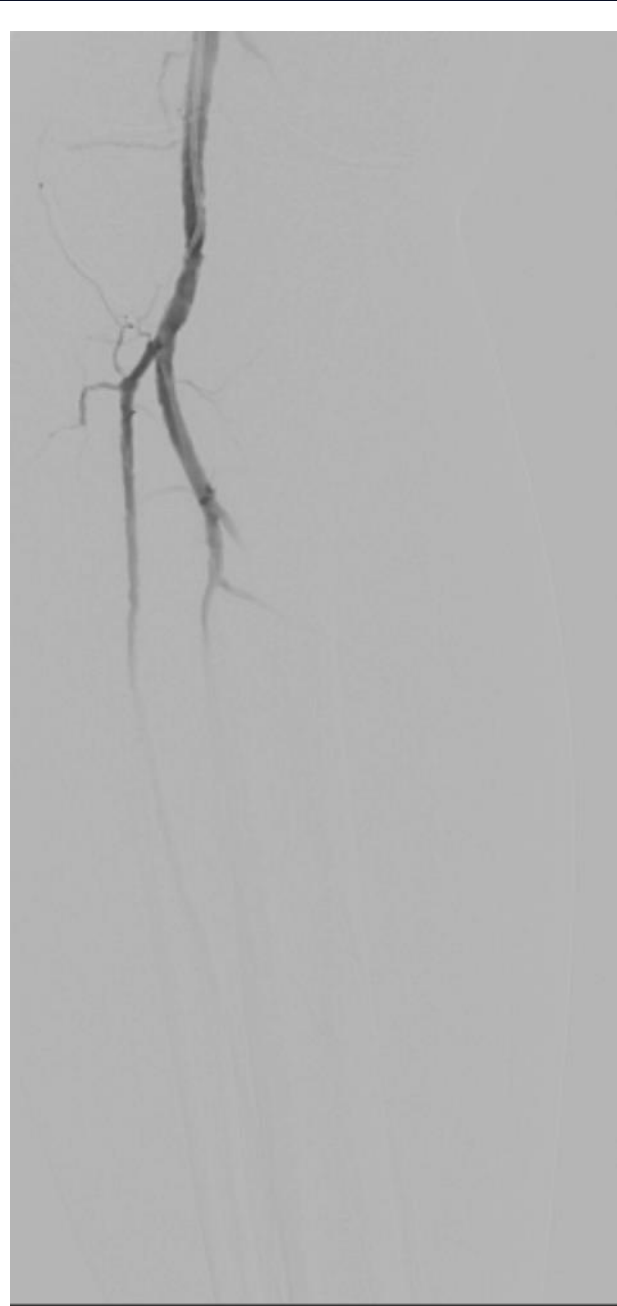
Difficulty with lesion crossing

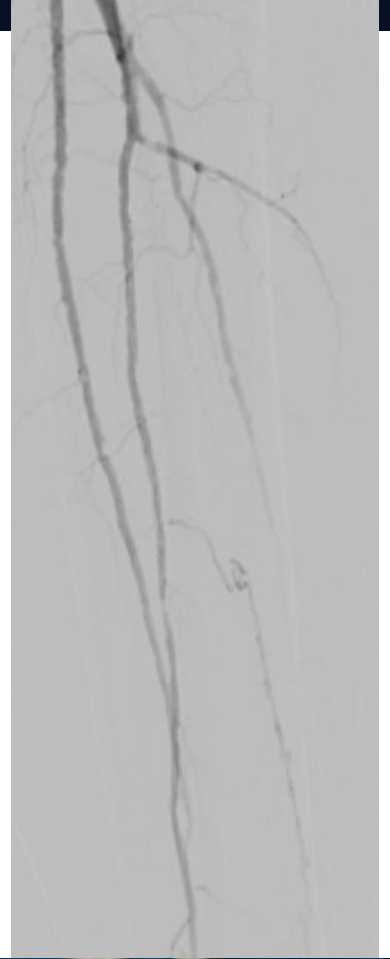
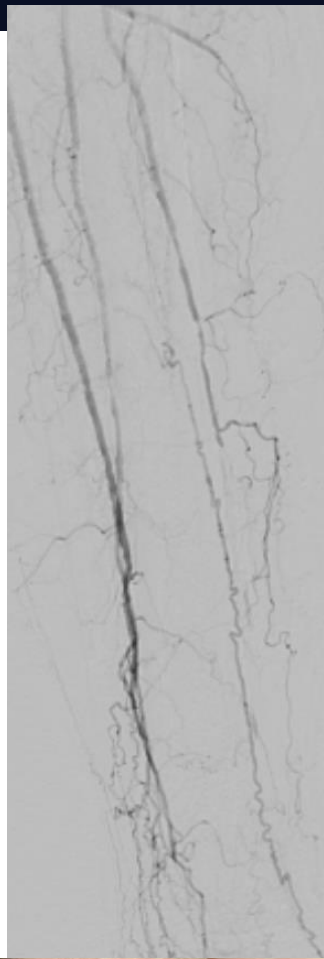
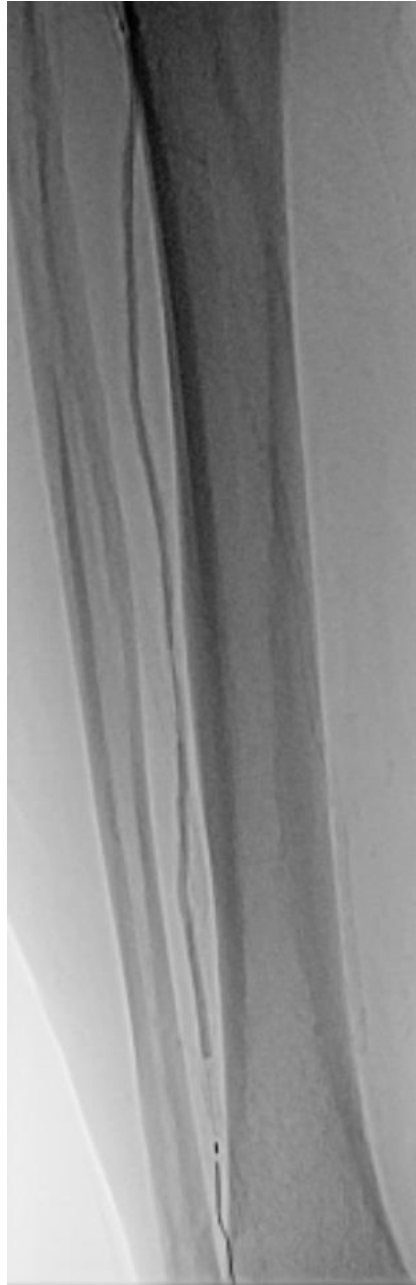
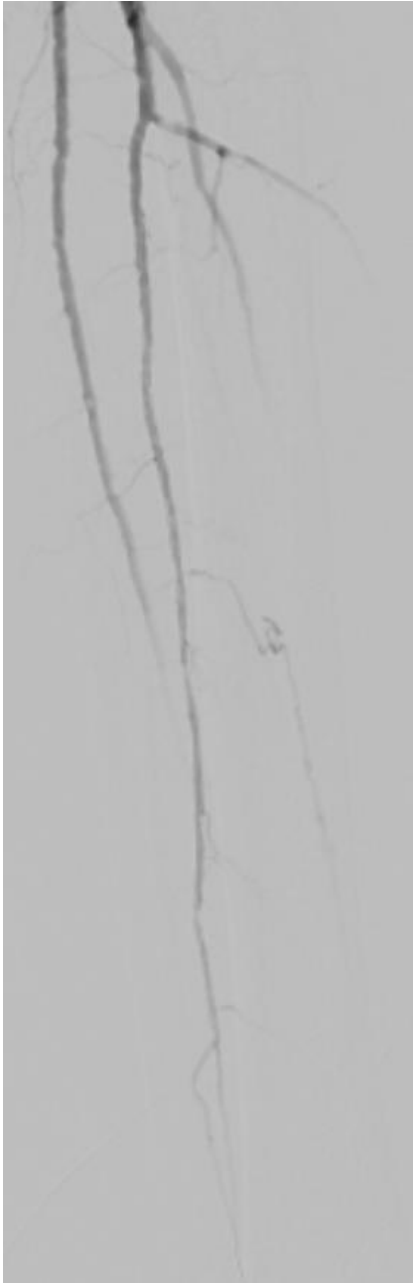
Poor luminal gain

Dissection

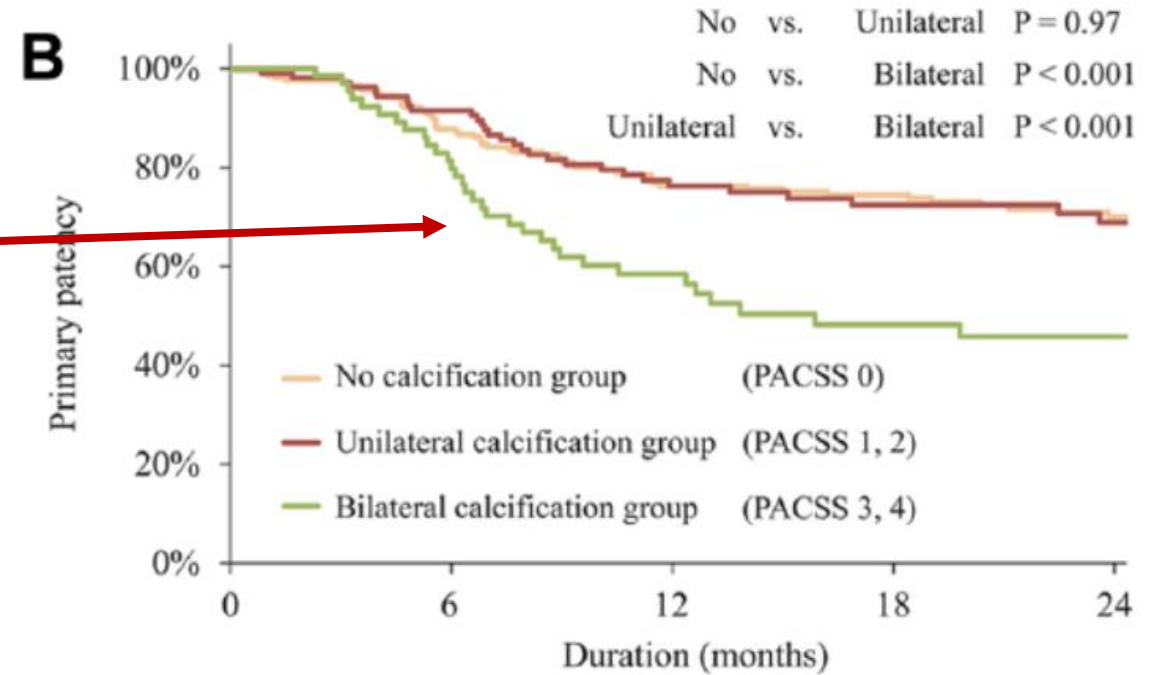
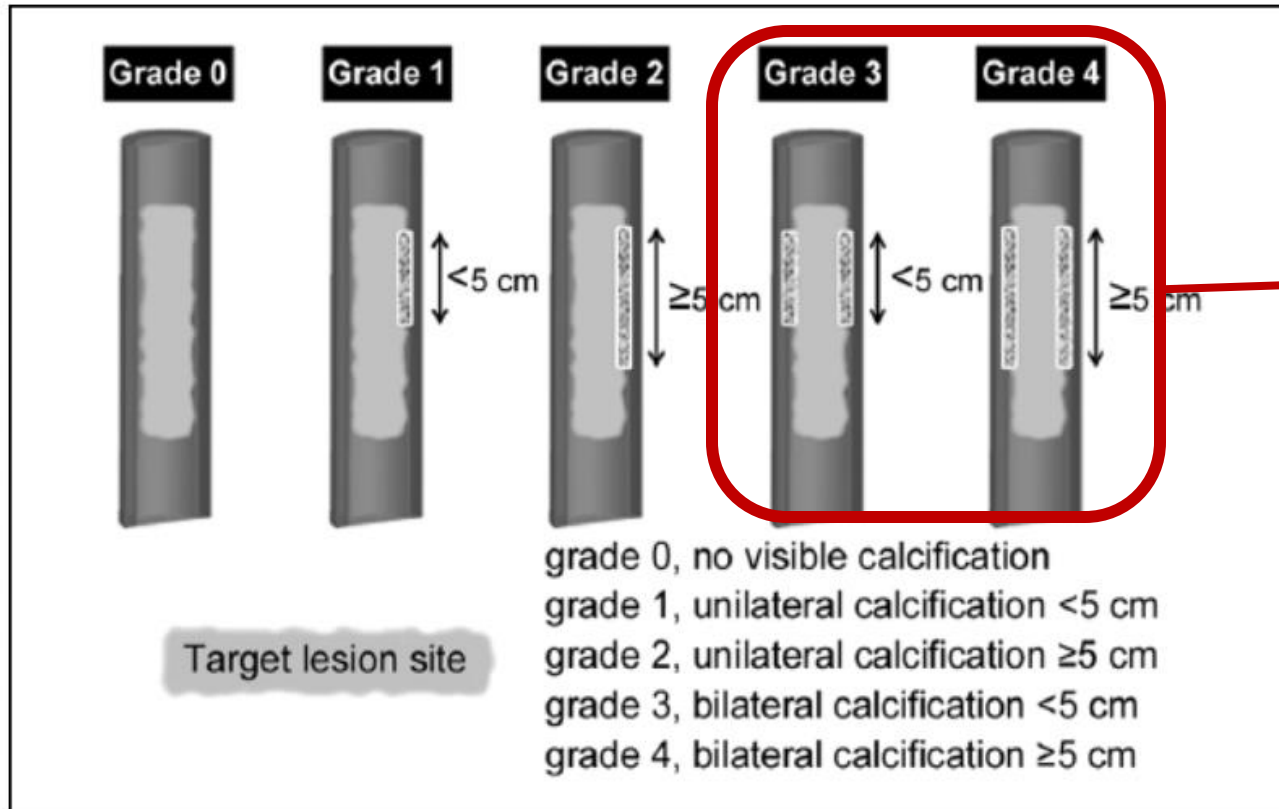
Recoil

Poor stent wall apposition



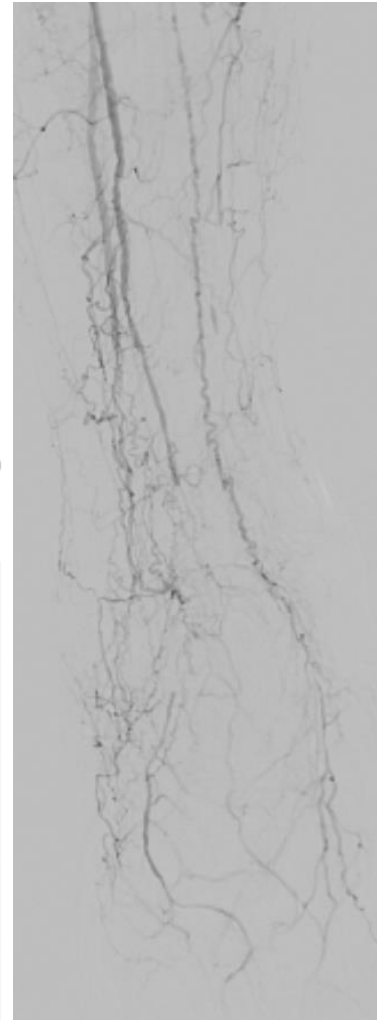
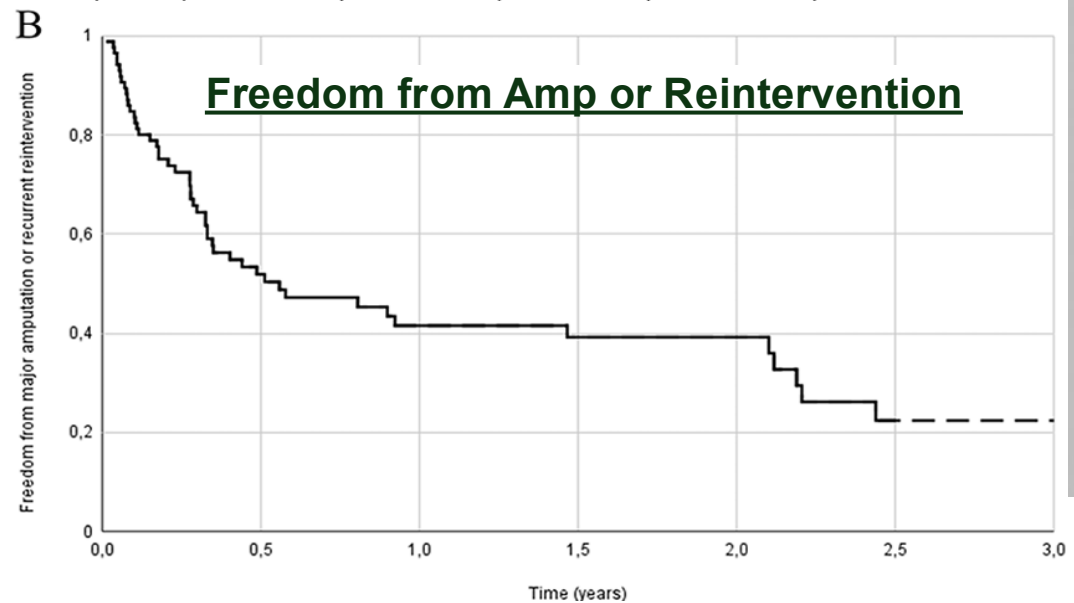
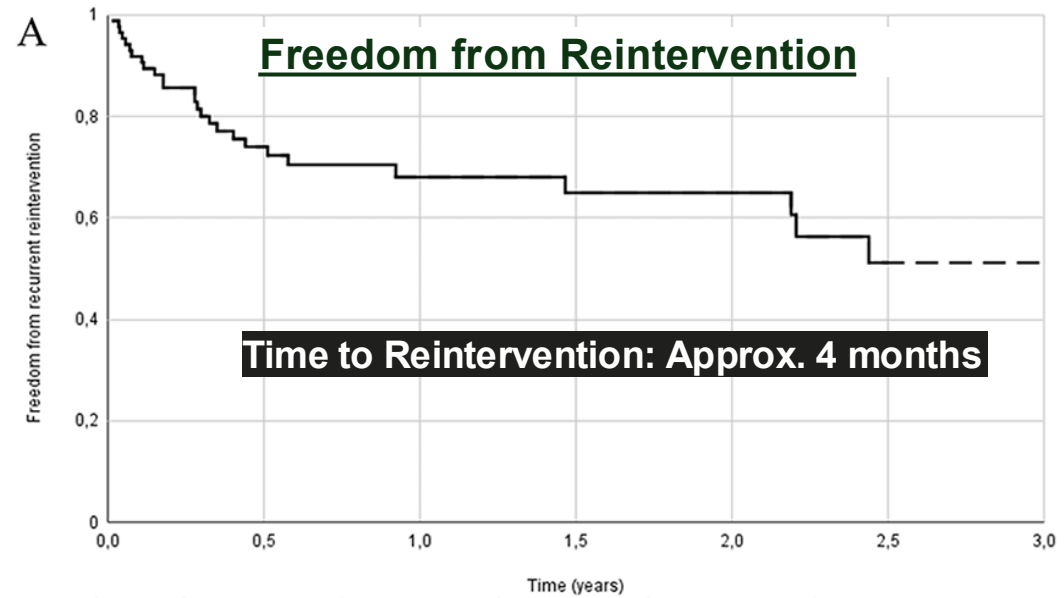


Impact of Peripheral Arterial Calcification Scoring System (PACSS) on Outcomes



Outcomes and Patency of Endovascular Infrapopliteal Reinterventions in Patients With Chronic Limb-Threatening Ischemia

| | n=81 |
|--|--------------------|
| Male sex | 53 (65%) |
| Age (years) | 78.0 [68.0, 83.0] |
| BMI (kg/m ²) | 26.8 [23.7, 29.5] |
| ASA | |
| • 2 | 7 (9%) |
| • 3 | 65 (80%) |
| • 4 | 4 (5%) |
| • Missing | 5 (6%) |
| Smoking | |
| • Yes | 18 (22%) |
| • Quit | 24 (30%) |
| • No | 39 (48%) |
| Diabetes mellitus | |
| • Type I | 10 (12%) |
| • Type II | 48 (60%) |
| Hypertension | 76 (94%) |
| Hypercholesterolemia | 43 (53%) |
| COPD | 17 (21%) |
| Coronary artery disease | 54 (67%) |
| Congestive heart failure | 15 (19%) |
| Chronic kidney disease | 38 (47%) |
| • eGFR (mL/min per 1.73 m ²) | 60.0 [41.5, 78.5] |
| • Creatinine | 97.0 [76.0, 133.0] |
| Hemodialysis | 6 (7%) |
| Stroke | 20 (25%) |



BMI = body-mass index; ASA = American Society of Anesthesiologists; COPD = chronic obstructive pulmonary disease; eGFR = estimated glomerular filtration rate.

Kleiss SF, et al. *J Endovasc Ther.* 2024;31(5):831-839.

Extensive Tibial Artery Calcification

D Survival free of any amputations



How do we overcome the barriers of tibial calcification to get controlled luminal gain without significant recoil or dissection?

| | | | | | |
|----|----|----|----|----|----|
| MC | 43 | 40 | 37 | 30 | 21 |
| IC | 36 | 27 | 24 | 19 | 14 |
| EC | 45 | 28 | 25 | 19 | 13 |

Extensive Calcification Remained an Independent Risk Factor for Technical Failure and Amputation at 2 years (HR=2, P=.004)

MC = minimal calcification; IC = intermediate calcification; EC = extensive calcification; HR = hazard ratio.

Kang IS, et al. *J Vasc Surg*. 2016;64(5):1335-1343.



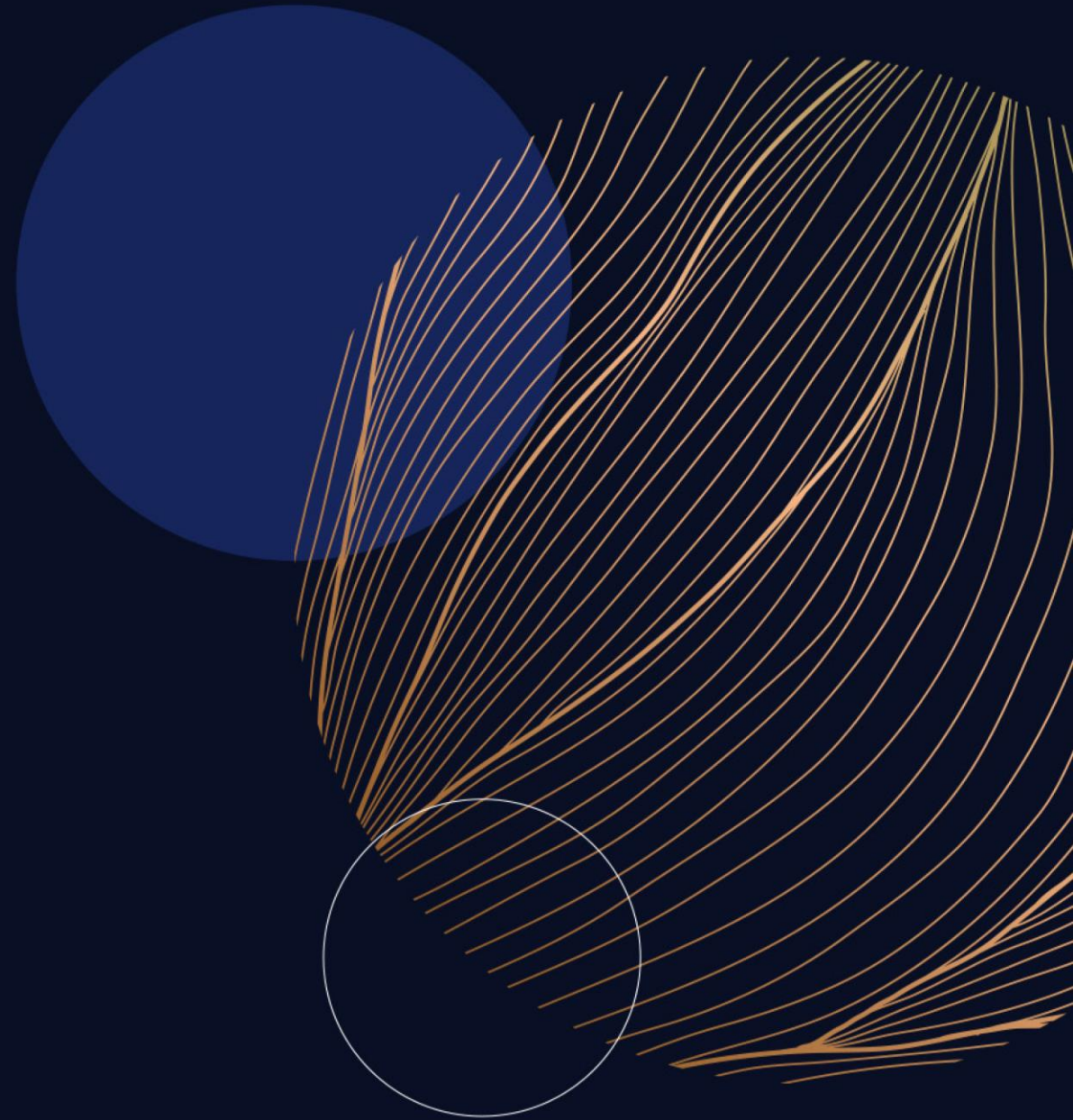
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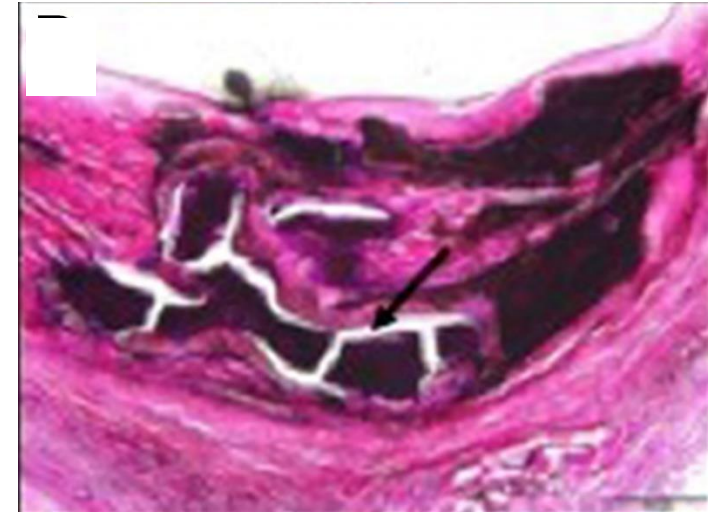
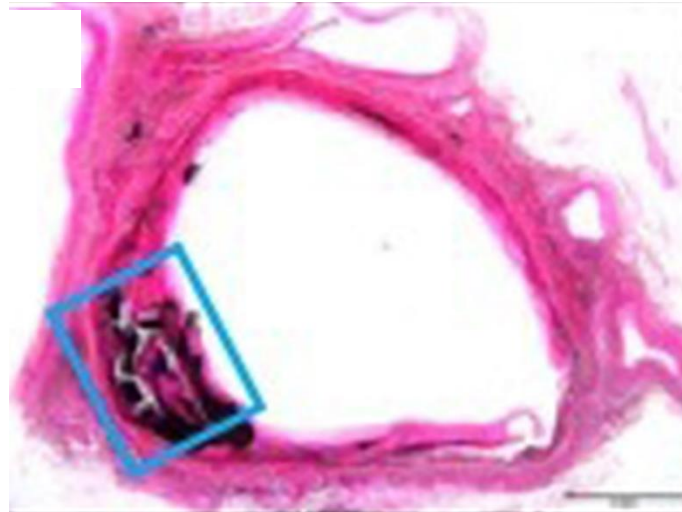
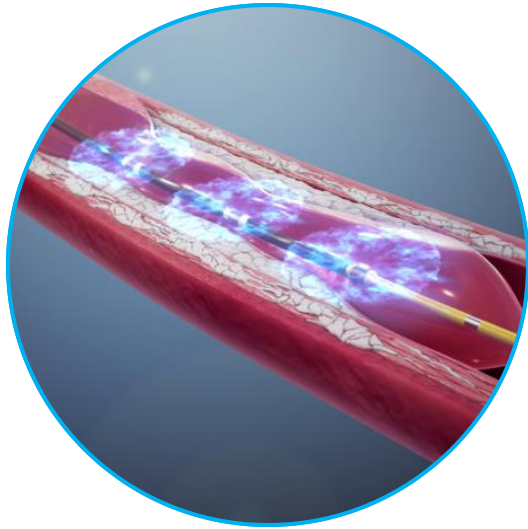
Intravascular Lithotripsy for BTK Disease: Latest Clinical Evidence

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Intravascular Lithotripsy in BTK Lesions



- Low-pressure balloon-based IVL
- Sonic pressure wave modifies medial and deep calcium

BTK IVL Platforms: Shockwave Tools

E8

- 8 emitters
- 80 mm balloon length
- 2.5-6 mm diameter
- 400 pulses








Javelin

- Single forward emitter
- Cross challenging disease
- 120 pulses

Technical Considerations

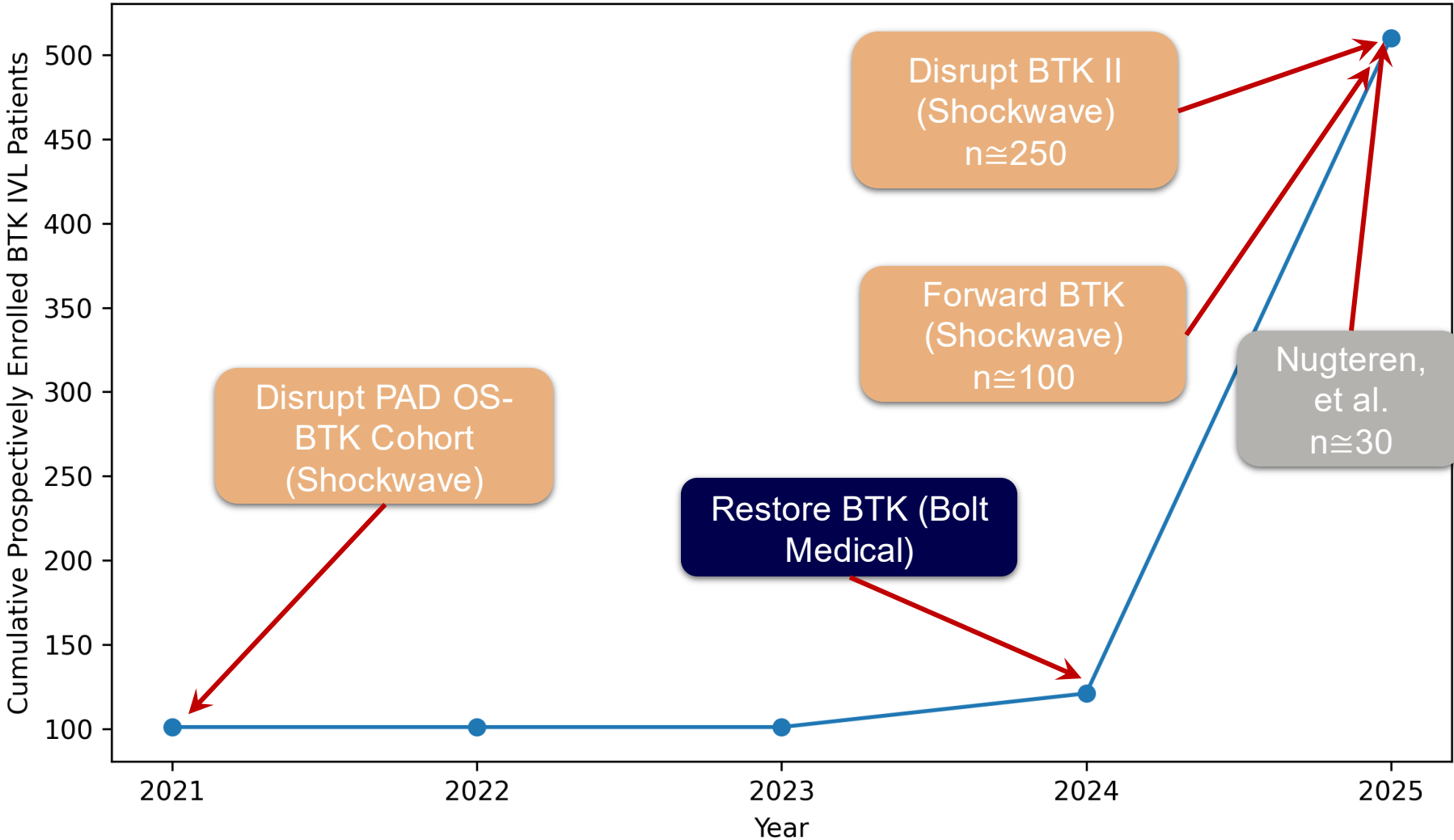
- Ability to cross disease with wire/catheter
- Lesion characteristics on imaging (IVUS, angiography, CTA)
 - Vessel location
 - Preference on IVL modality

Other IVL Platforms

| | Company | Platform | Mechanism | Beds | Status (2025) | BTK Readiness |
|--|-------------------------|--------------|---------------------|-------------------------|--|---------------------------------|
|  | Bolt Medical | Siesmiq | Acoustic IVL | Peripheral | Limited market release | Prospective BTK data available |
|  | FastWave Medical | Artero | Next-gen IVL | Coronary/ Peripheral | Investigational | BTK Program but no data as yet |
|  | Abbott | TECTONIC | Acoustic IVL | Coronary | Investigational device exemption trial | No BTK program (coronary only) |
|  | Elixir Medical | LithiX Hertz | Mechanical fracture | Coronary | Early/limited | No BTK data (coronary only) |
|  | MicroPort | Tomohawk | Acoustic IVL | Coronary/ Peripheral | Regional (Asia) | Limited BTK regional experience |

Cumulative Prospective Clinical Evidence for BTK IVL

Cumulative Prospective Clinical Evidence for BTK IVL (2021-2025)



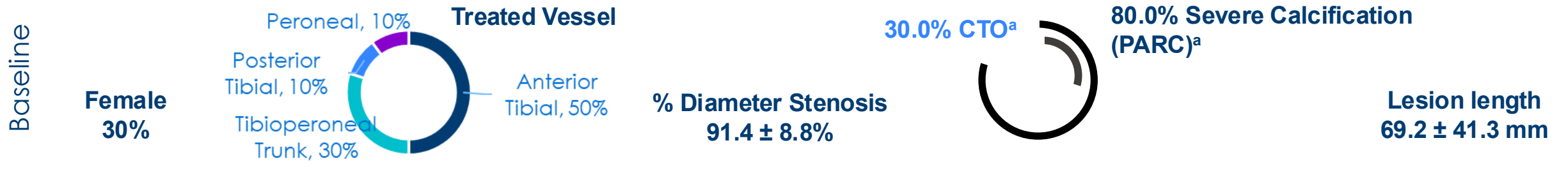
RESTORE BTK Summary

Effectiveness and Safety of SEISMIQ™ IVL BTK

| | |
|---------------------|--|
| Objective | Evaluate safety and effectiveness of the SEISMIQ™ IVL system for the treatment of calcified lesions in the peripheral BTK vasculature |
| Study Design | Prospective, single-arm, multi-center |
| Patients | <p>N=20</p> <ul style="list-style-type: none"> Target lesion de novo tibial arteries ≥70% stenosed Moderate to severe calcification |

| <u>Final Lesion Characteristics^a (N=18)^b</u> | |
|--|---------------------------------|
| Acute Reduction in % Diameter Stenosis | 47.5 ± 29.7%^c |
| Diameter stenosis | 22.8 ± 11.5% |
| Dissections | 0% |

- 100% (18/18)^b freedom from MAE at 30 days^c**
- No cases of perforation, distal embolization, abrupt closure, no reflow, or dissections meeting SAE criteria (N=18)^b**



^aAngiographic core lab; ^bAs-treated; Two subjects did not receive IVL: inability to cross lesion (1) and no therapy attempted (1); ^cPrimary endpoint met.

MAE = major adverse event; SAE = serious adverse event.

Zeller T. Presented at: Vascular InterVentional Advances (VIVA); November 3-6, 2024; Las Vegas, Nevada.

FORWARD PAD IDE and Feasibility Studies

WHY

Pre-market study to evaluate the Shockwave Javelin Peripheral Device.

WHAT

Evaluated the safety and effectiveness in the treatment of heavily, calcified, stenotic lesions in ATK and BTK arteries.

HOW

Shockwave IVL (Javelin Peripheral) in at least moderate calcification. Patients enrolled in above-the-knee (ATK) w/ stenosis $\geq 90\%$ or below-the-knee (BTK) w/ stenosis $\geq 70\%$. Lesion length of ≤ 150 mm. Results were pooled between Mini-S and Forward IDE.

DESIGN

Single
Arm

110

Patients

19

Sites

1

Year Follow-Up

PRIMARY SAFETY ENDPOINT

Major Adverse Events (MAE) defined as composite of cardiovascular death, CD-TLR, or unplanned target limb above the ankle amputation at 30 days.

PRIMARY SAFETY ENDPOINT

Technical success defined as final residual stenosis of $\leq 50\%$ without flow-limiting dissection.

Independent Clinical Events Committee (CEC) and Angiographic Core Laboratory

Enrolled 110 patients (with 124 core lab assessed lesions) with at least moderate calcium; included vessels above-the-knee and below-the-knee.

FORWARD PAD IDE 30-Day Outcomes

FULL COHORT BASELINE DEMOGRAPHICS



| Rutherford Category (RC) | Medical History | Lesions |
|--|-------------------------------------|--|
| 42.7% RC 5 – Minor Tissue Loss | 74.4% Male | 95% Mod-Severe Ca* |
| 12.2% RC 4 – Ischemic Rest Pain | 18.9% Renal Insufficiency | 76.9 ± 59.4 mm Mean Calcified Length |
| 43.3% RC 3 – Severe Claudication | 56.7% Diabetes Mellitus | 38% CTOs |



Procedural/30-Day Endpoints

- No balloon-based IVL needed after Javelin **74.3%**
- ≤50% final residual stenosis without flow-limiting dissection **99.0%**
- Device success **93.0%**
- Post-Shockwave Javelin serious angiographic complication rate **1.2%**
- Primary safety MAE @ 30-days **1.1%**
- Pre-procedure diameter stenosis **83%**
- Post-Shockwave Javelin diameter stenosis **59%**
- Final diameter stenosis **23%**

The FORWARD PAD IDE and Feasibility studies enrolled 110 patients; Primary Endpoint analysis conducted on first 90 participants enrolled

*As defined by the Peripheral Academic Research Consortium (PARC).
CTO = chronic total occlusion.
Corl JD, et al. *JACC Cardiovasc Interv.* 2025;18(3):398-399.

FORWARD PAD 12-Month Overview



12-Month Endpoints

ATK: Freedom from CD-TLR and from $\geq 50\%$ stenosis by DUS at 12 months
 BTK: Freedom from CD-TLR and from total occlusion by DUS at 12 months

| | | |
|-----|---------------------------------------|---------------|
| ATK | Primary Patency | 72.7% (40/55) |
| | Primary Assisted Patency ¹ | 74.5% (41/55) |
| | Secondary Patency ² | 76.4% (42/55) |
| BTK | Primary Patency | 61.5% (24/39) |
| | Primary Assisted Patency ¹ | 78.4% (29/37) |
| | Secondary Patency ² | 88.6% (31/35) |

Major Adverse Events (MAE)

18.6%

MAE (composite of CV death, unplanned amputation and CD-TLR)

3.9%

Cardiovascular Death

1.0%

Unplanned Target Limb Major Amputation

14.7%

CD-TLR

¹Primary assisted patency defined as freedom from diameter stenosis (≥ 50 ATK, total occlusion in BTK) determined by DUS and freedom from CD-TLR performed for 100% stenosis; ²Secondary patency defined as freedom from diameter stenosis (≥ 50 ATK, total occlusion in BTK) determined by DUS regardless of additional intervention. Both definitions based on Stoner, et al. *J Vasc Surg.* 2016;64(1):e1-e21.

CV = cardiovascular; DUS = duplex ultrasound.

Holden, et al. Presented at: VIVA; November 1-3, 2025; Las Vegas, Nevada.

DISRUPT BTK II

OBJECTIVE

Assess the continued safety and effectiveness of the Shockwave Medical Peripheral IVL System for the treatment of calcified, stenotic lesions in BTK arteries.

DESIGN

- Prospective
- Multicenter
- Single-Arm

KEY INCLUSION

- RC 3-5, RC 3 capped at 20% of enrolled patients
- Moderate to severe calcification*
- Up to two BTK lesions ≤ 200 mm in length

DESIGN

250
Patients

305
Lesions

38
Sites

2
Year Follow-Up

Products included: Shockwave M5+ and Shockwave S4

ENDPOINTS

PRIMARY SAFETY ENDPOINT

Major adverse limb events (MALE) or post-operative death (POD) at 30-days.

PRIMARY EFFECTIVENESS ENDPOINT

Procedural success, defined as $\leq 50\%$ residual stenosis for all treated target lesions without serious angiographic complications .

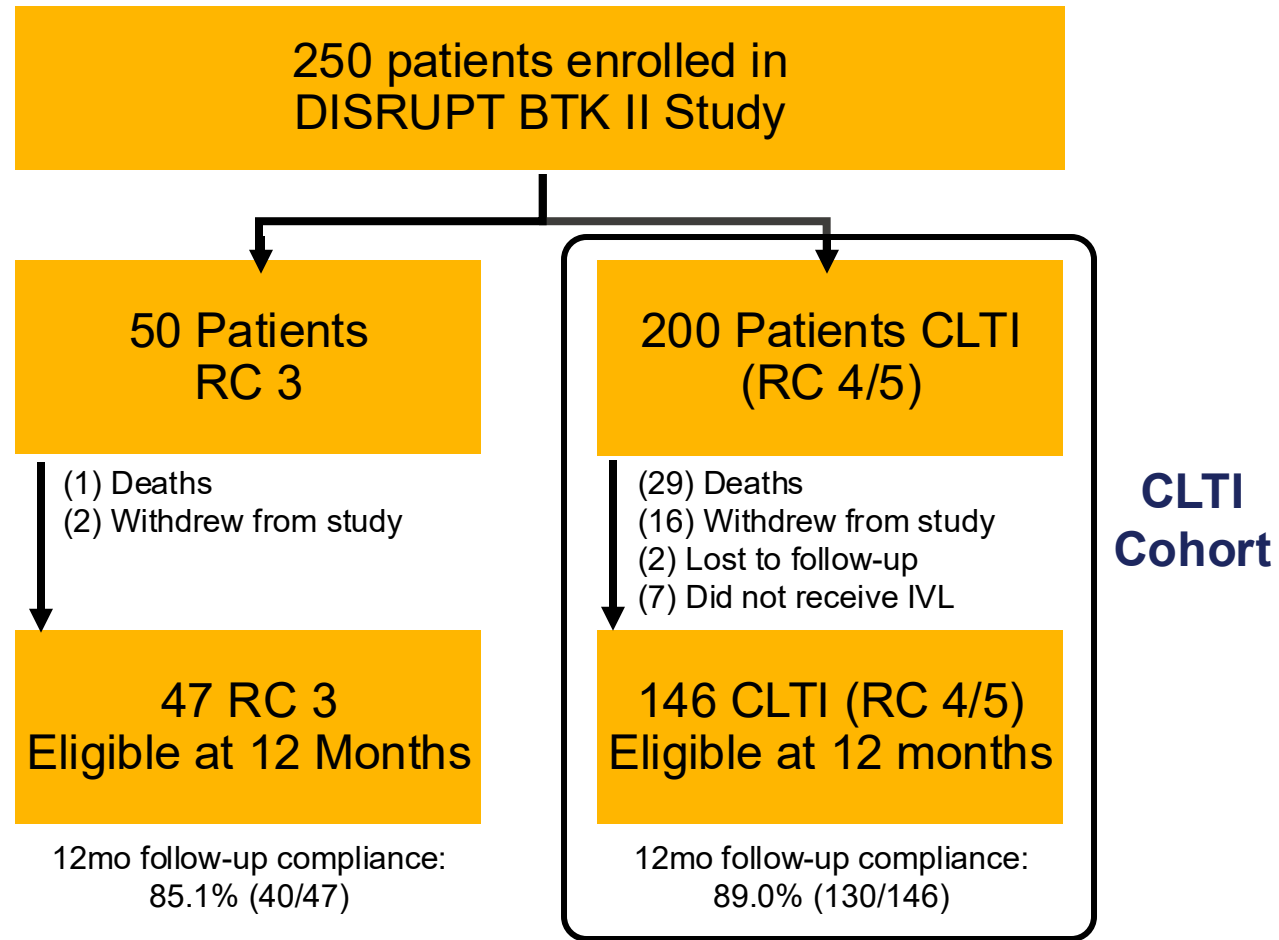
Additional analysis to include lesions with residual stenosis $\leq 30\%$ without serious angiographic complications.

Independent Clinical Events Committee (CEC), Angiographic Core Laboratory, and Duplex Ultrasound Core Laboratory

*Presence of fluoroscopic evidence of calcification by PARC definition: 1) on parallel sides of the vessel and 2) extending $>50\%$ the length of the lesion if lesion is ≥ 50 mm in length or extending for minimum of 20 mm if lesion is <50 mm in length.

Chandra V, et al. *J Vasc Surg.* 2025;81(3):710-719.e2.

DISRUPT BTK II Study CLTI Cohort Analysis

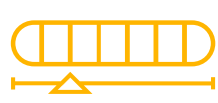


*The majority of patients enrolled had CLTI, thus a majority of the comorbidities are attributed to this population.

CLTI = chronic limb-threatening ischemia.

Armstrong, E. Presented at: VIVA; November 1-3, 2025; Las Vegas, Nevada.

CLTI Cohort Baseline Demographics



Rutherford Category

71%

RC 5 – Minor Tissue Loss*

29%

RC 4 – Ischemic Rest Pain**



Medical History

73%

Patients had wounds at baseline

18%

Hemodialysis-Dependent

77%

Diabetes Mellitus



Lesions

85.8%

Mod-Severe Ca++†

80.2mm

Mean Lesion Length

30.6%

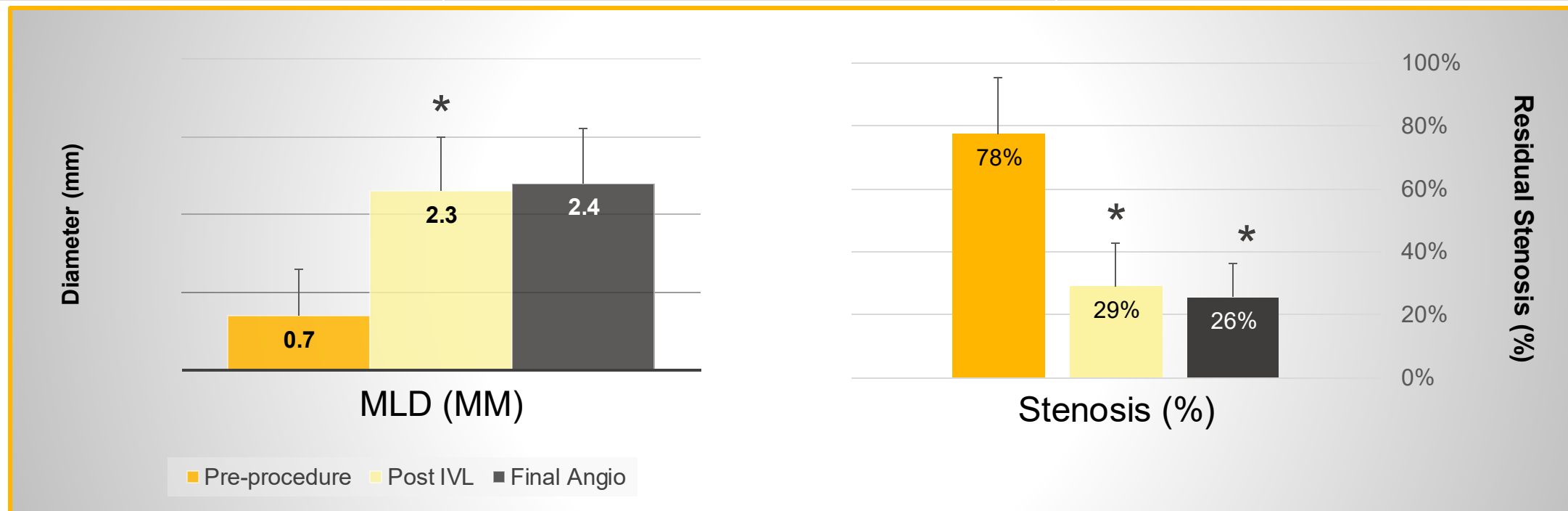
CTOs

*Per limb 143/201; **Per limb 59/201; †PARC definition.

Armstrong, E. Presented at: VIVA; November 1-3, 2025; Las Vegas, Nevada.

Acute Outcomes

| | | |
|--------------------------------|--|---|
| Primary Effectiveness Endpoint | Final RS of $\leq 50\%$ without serious angiographic complications | 97.9% (232/237, 95% CI 95.1%-99.3%) |
| Exploratory Endpoint | Final RS of $\leq 30\%$ without serious angiographic complications | 74.1% (215/290, 95% CI 68.7%-79.1%) |



*p<0.001 compared to pre-procedure.

CI = confidence interval; MLD = minimal lumen diameter.

Armstrong, E. Presented at: VIVA; November 1-3, 2025; Las Vegas, Nevada.

Clinical Procedural Insights in CLTI Cohort

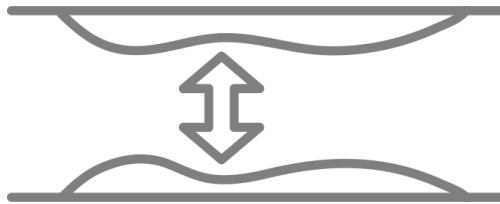
Safety



2.3% | **1.3%**
Post-IVL | Final

Total Serious Angiographic
Complications

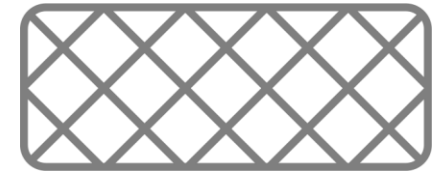
Effectiveness



30.0% | **25.7%**
Post-IVL | Final

Average Residual
Stenosis

Provisional Stenting

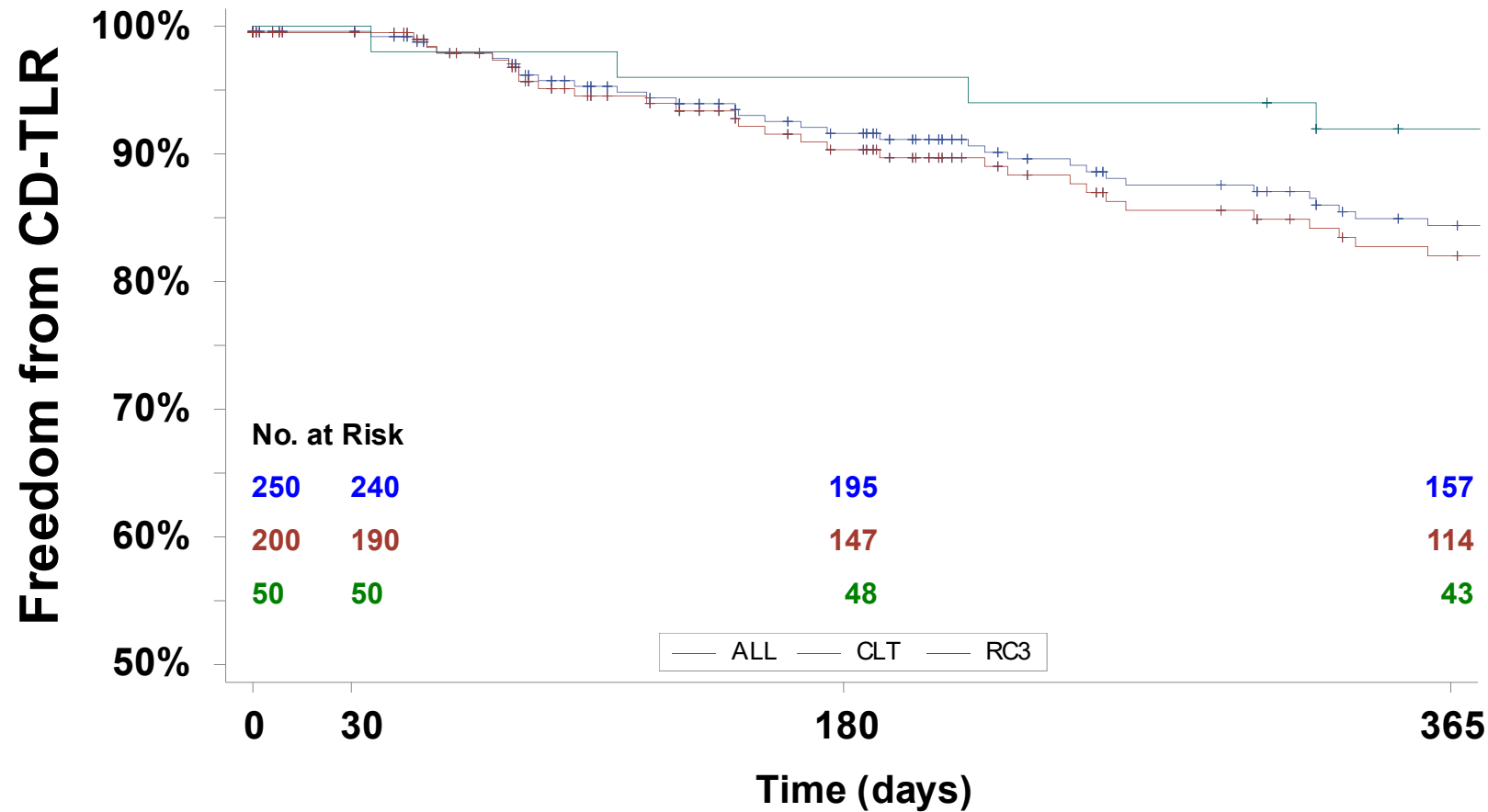


5.7% | **2.8%***
Total | Provisional

Stent/Tack
Implant

*Remaining Stent/Tack implants were part of physicians' standard algorithm.
Armstrong, E. Presented at: VIVA; November 1-3, 2025; Las Vegas, Nevada.

Full Cohort: Freedom from CD-TLR and Patency at 12 Months*



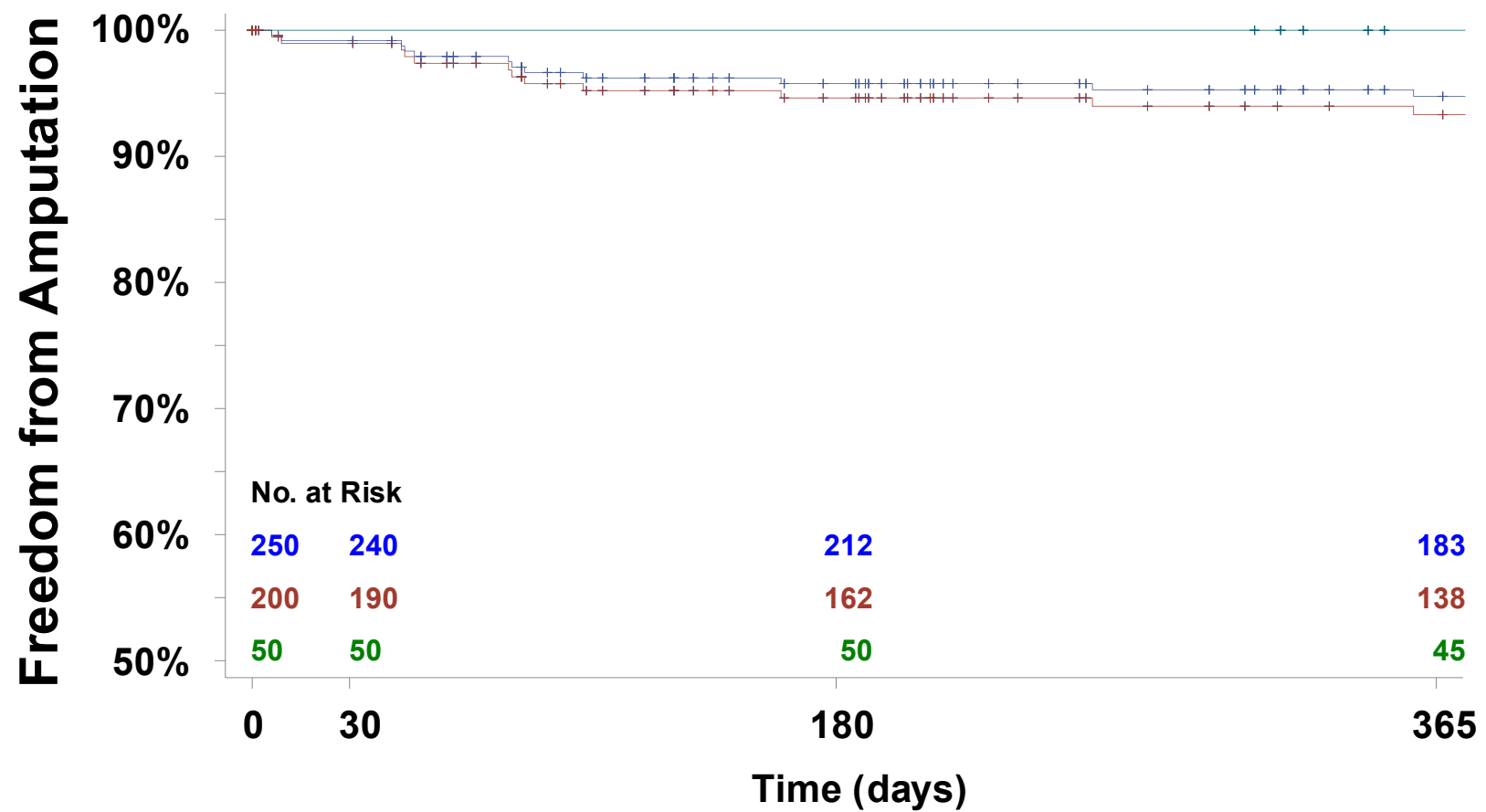
| Rutherford Category | FF CD-TLR at 12 Months** |
|------------------------------------|--------------------------|
| Full Cohort | 84.5% |
| RC 3 | 92.0% |
| CLTI | 82.7% |
| RC 4 (n=57) | 88.0% |
| RC 5 (n=143) | 80.3% |
| Patency at 12 Months (CLTI) | |
| | 64.0% |

*Kaplan-Meier (KM) is an analysis that uses probability to account for patients lost to follow-up; **Freedom from CD-TLR analysis excluded patients with above-the-ankle amputation of the target limb.

FF = freedom from.

Armstrong, E. Presented at: VIVA; November 1-3, 2025; Las Vegas, Nevada.

Full Cohort: Freedom From Major Amputation at 12 Months*



| Rutherford Category | FF Amputation at 12-Months |
|---------------------|----------------------------|
| Full Cohort | 94.8% |
| RC 3 | 100% |
| CLTI | 93.3% |
| RC 4 (n=57) | 98.1% |
| RC 5 (n=143) | 91.2% |

*Kaplan-Meier (KM) is an analysis that uses probability to account for patients lost to follow-up.

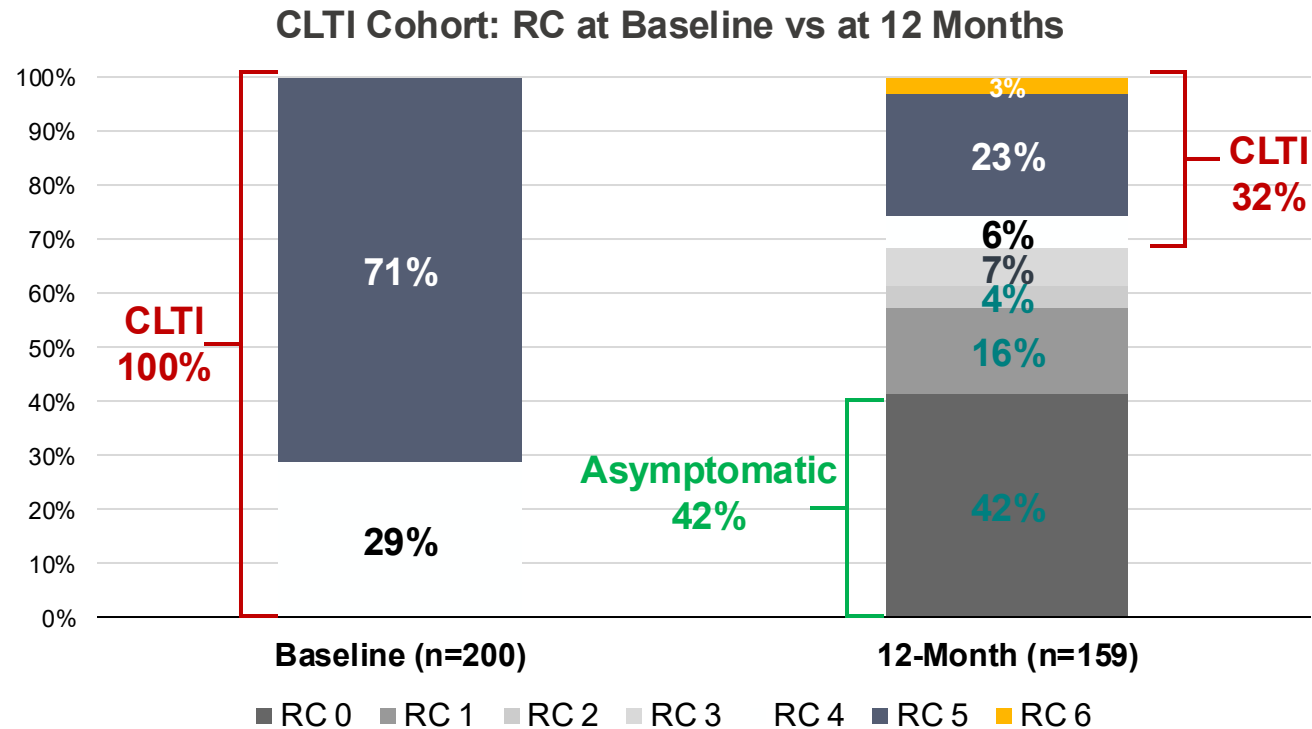
Armstrong, E. Presented at: VIVA; November 1-3, 2025; Las Vegas, Nevada.

Rutherford Classification (RC) Change at 12 Months

Available data is 159/200 limbs of patients with CLTI.



Of the patients remaining at 12 months, 68% were no longer CLTI





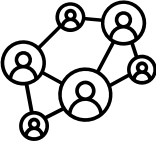



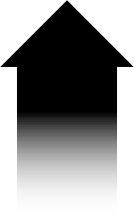
61% of wounds were healed or improving*

- Rutherford Category**
- 0 – Asymptomatic
 - 1 – Mild Claudication
 - 2 – Moderate Claudication
 - 3 – Severe Claudication
 - 4 – Ischemic Rest Pain
 - 5 – Minor Tissue Loss
 - 6 – Ulceration or Gangrene

*Mean wound follow-up time: 157 days.

Quality of Life at 12 Months*

| VascuQoL-6 Attribute | |  Activity |  Tired |  Walk |  Concern |  Social |  Pain |
|------------------------|-------------------------|--|---|--|---|--|--|
| Breakdown by Attribute | Average Score 12-Months | 2.8 | 2.6 | 3.0 | 2.9 | 3.1 | 2.8 |
| | Average Score | 1.9 | 2.0 | 2.3 | 1.7 | 2.3 | 1.8 |


 All categories improved

Total VascuQoL-6 Score (CLTI) at 12 months significantly improved from baseline ($P < .001$).

Total at 12 months was 17.2 ± 5.0 , and total at baseline was 11.9 ± 4.0 .

*The Vascular Quality of Life Questionnaire is a survey used to determine health-related quality of life (HRQoL) in patients with peripheral arterial disease (PAD). Each attribute is scored 1-4, a higher value indicates better health status. The sum of each individual attribute score is used to generate a total quality of life score.

Conclusions

- Clinical evidence for IVL BTK has grown substantially in the past year
- Forward PAD
 - Javelin safe and effective
- Disrupt BTK II trial
 - Shockwave IVL remains safe
 - Effective in terms of luminal gain and patency, wound healing, and Rutherford improvement
- Despite the allowance for long lesions, the majority were <10 cm, and the device is older generation
- Continued real-world and prospective data will be beneficial



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Optimizing IVL Procedures Below the Knee: Imaging, Access, and Technique

Kumar Madassery, MD, FSIR

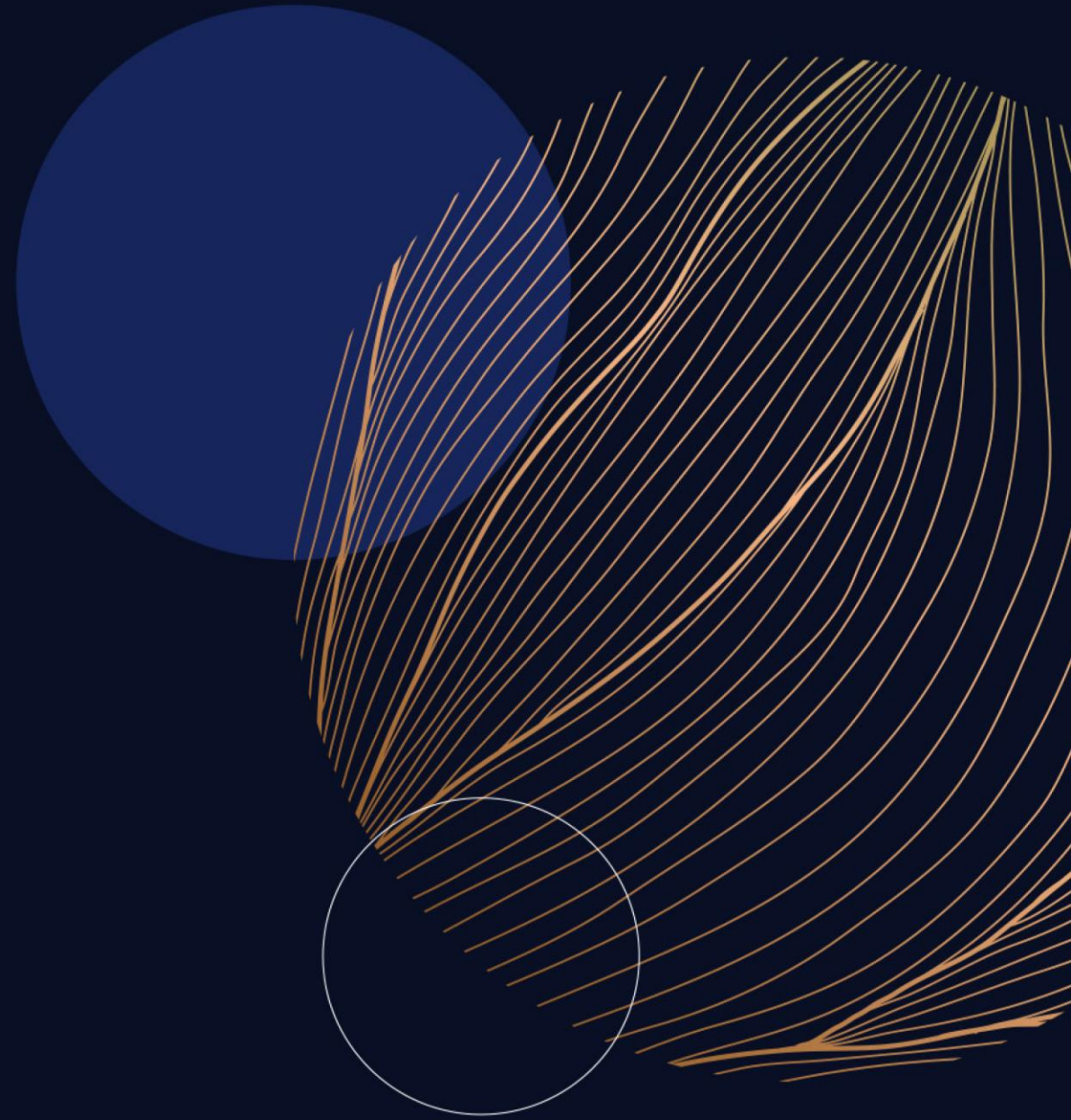
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Rush University Medical Center
Chicago, Illinois



CardioVascular
Learning Network

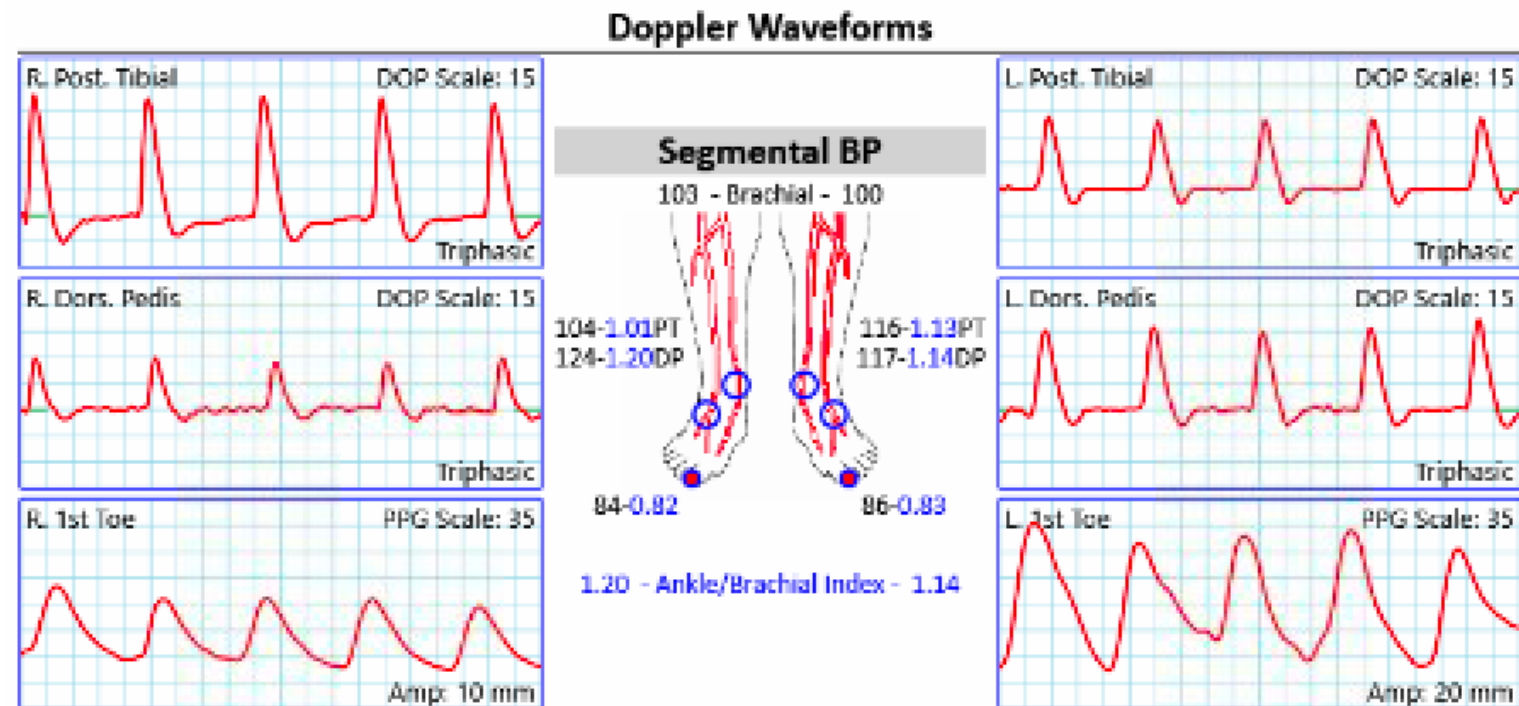
CME

1: Imaging



Basics

- Pulse Exam
- ABI w/ TBI and Toe Pressures



Toe Pressure (<30 mm Hg)

vs

TcPO2 (<25 mm Hg)




TcPO2 = transcutaneous partial pressure of oxygen.

Perimed. Accessed January 13, 2026. <https://www.perimed-instruments.com/content/toe-pressure-tbi>.

Thoughts on TcPO2

TcPO2 has been shown in studies to have higher PPV than toe pressures

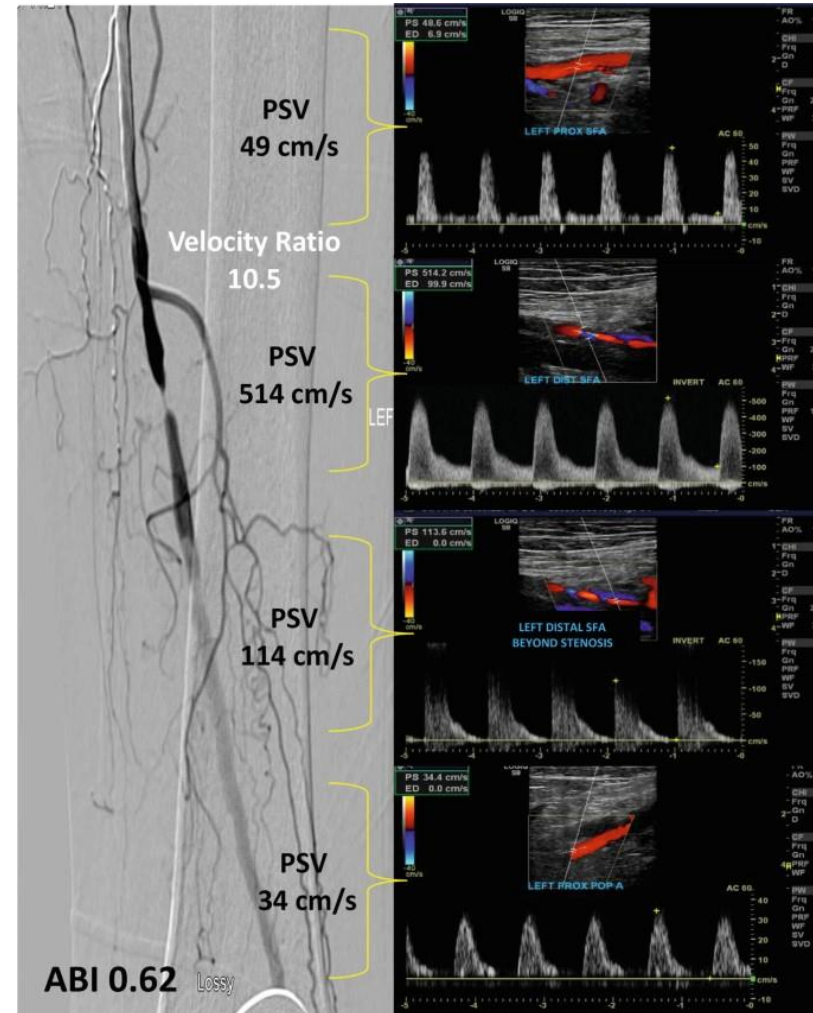
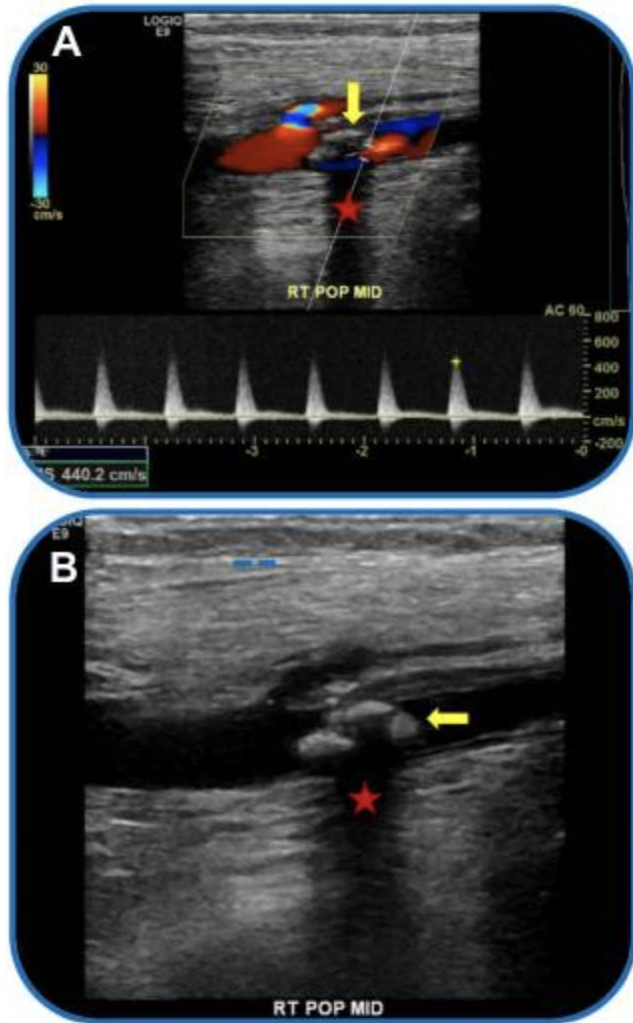


TcPO2 not readily available everywhere



There is operator variability

Duplex Can Be Very Helpful for Anatomical Planning



PSV = peak systolic velocity; ABI = ankle-brachial index.

Csore J, et al. *J Vasc Surg Cases Innov Tech*. 2023;9(4):101263. Armstrong PA and Dargan CG. *Noninvasive Vascular Diagnosis*. Springer, Cham; 2022.

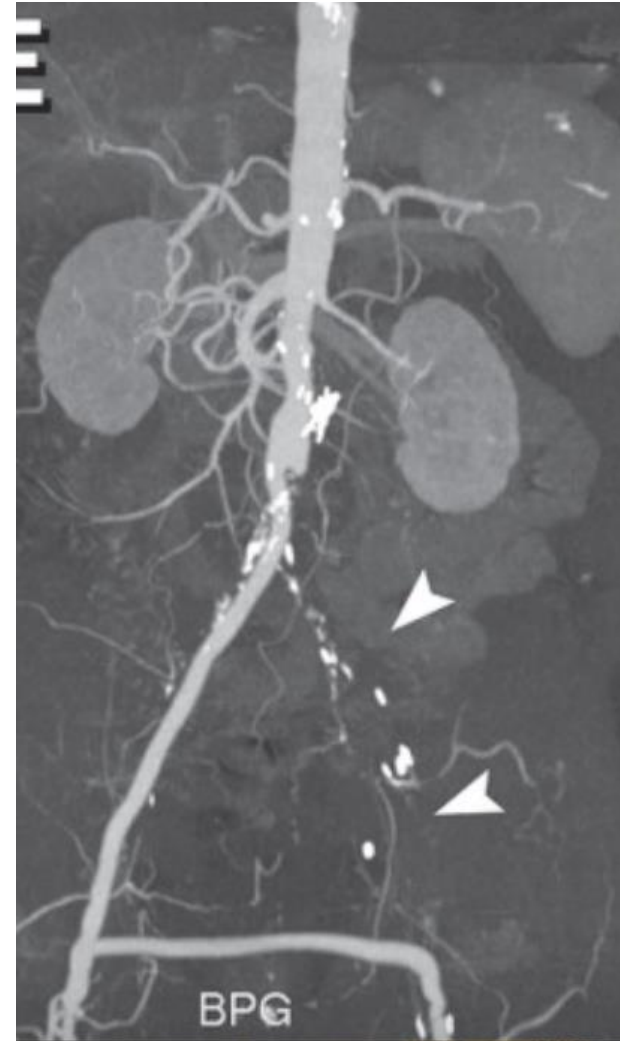
When Is CT Helpful?

- Inflow evaluation
 - Aorta and iliacs
- Outflow
 - SFA and popliteal
- Runoff
 - TibioPedal

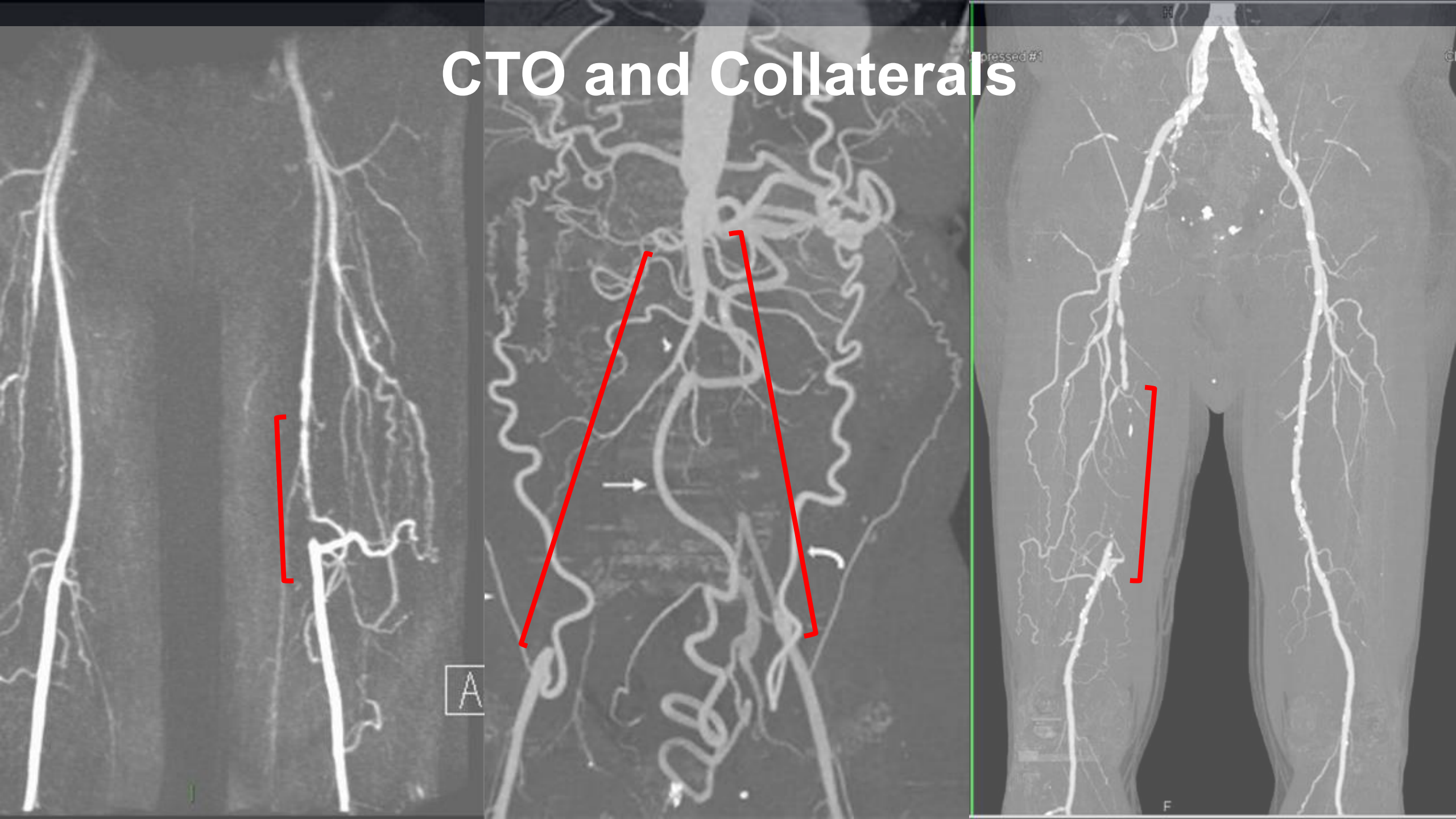
CT Is Clearly Helpful for Inflow Disease



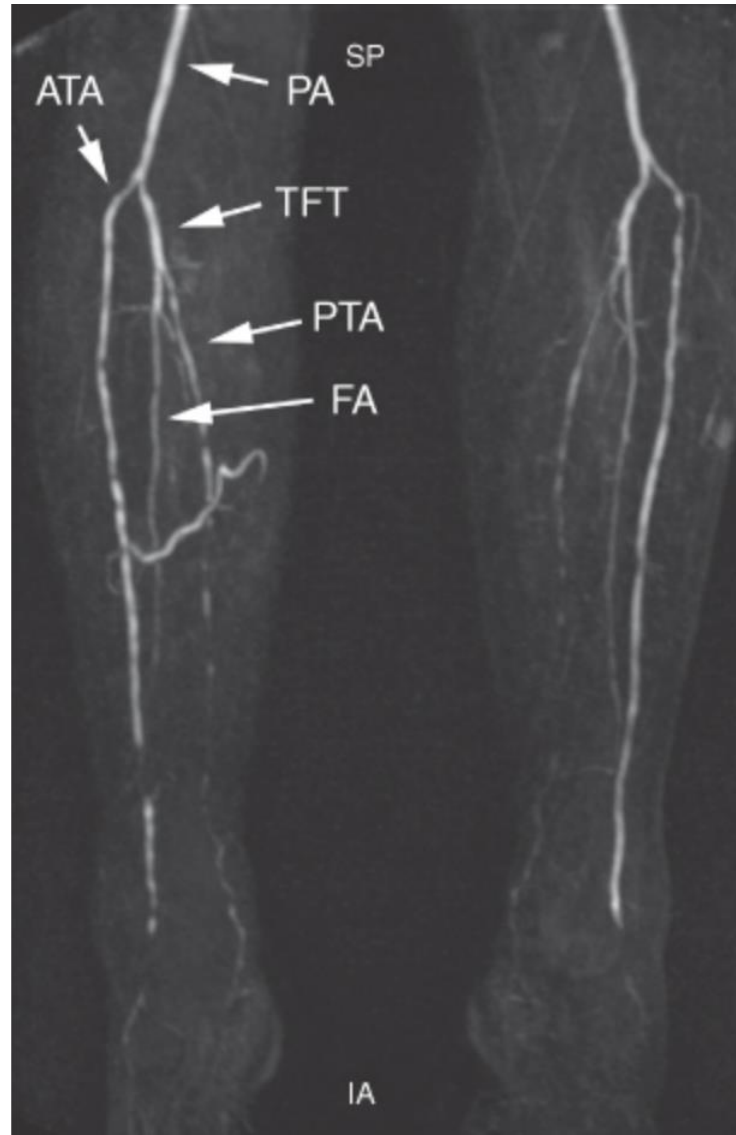
When the Pulses Don't Seem Right



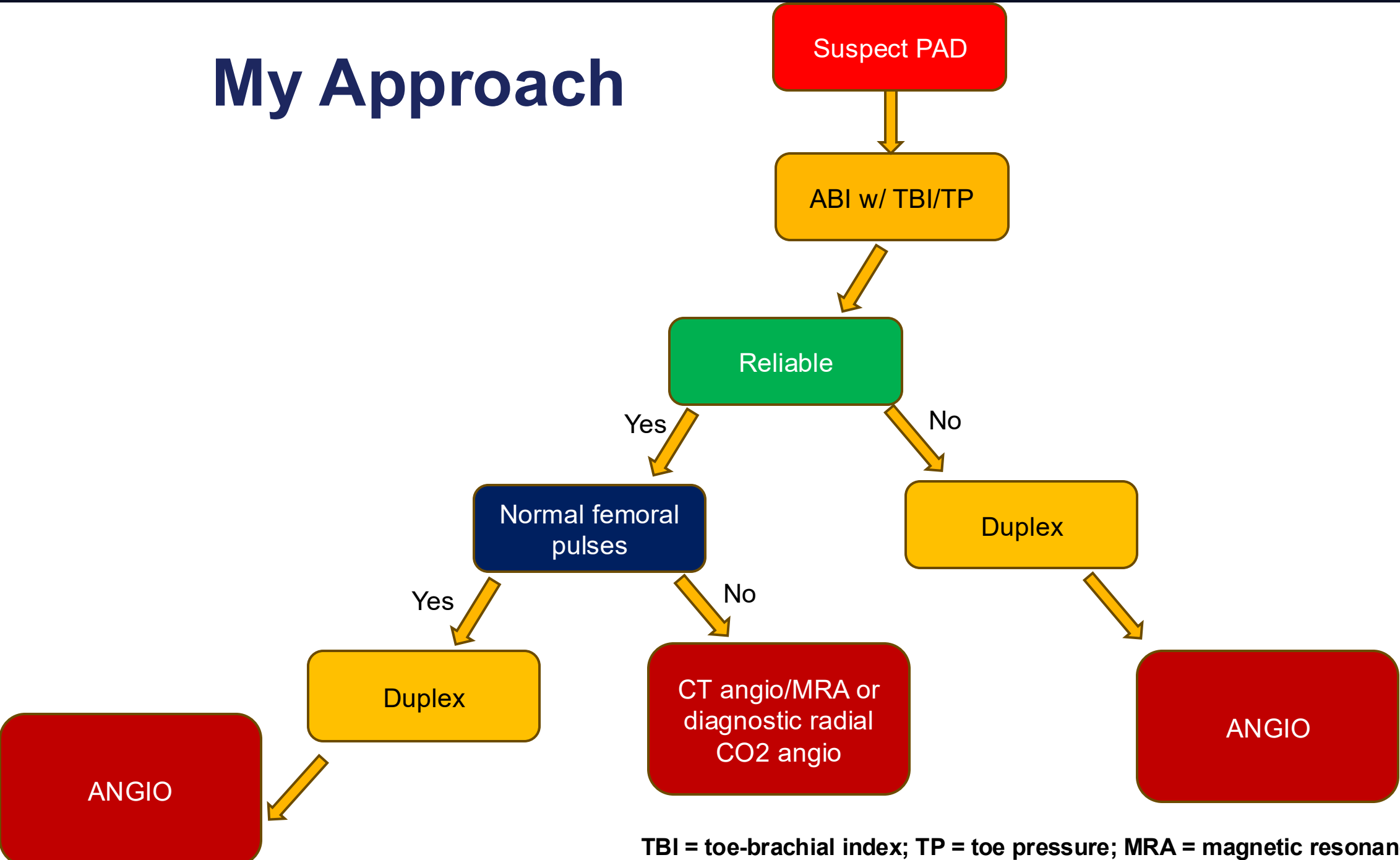
CTO and Collaterals



But for Tibiopedal... Not Great



My Approach



TBI = toe-brachial index; TP = toe pressure; MRA = magnetic resonance angiography.

SAD and MAC Classification

- Small Arterial Disease (SAD) Score

- Medial Arterial Calcification Score (MAC)

- Both attempt to predict below-the-ankle (BTA) disease and failure mode/loss of limb
- Intuitive that dismal outflow limits effect of perfusion/revascularization

A Novel Scoring System for Small Artery Disease and Medial Arterial Calcification Is Strongly Associated With Major Adverse Limb Events in Patients With Chronic Limb-Threatening Ischemia

Roberto Ferraresi Alessandro Ucci Alessandra Pizzuto Fabrizio Losurdo
 Maurizio Caminiti Daniela Minnella Andrea Casini Giacomo Clerici
 Miguel Montero-Baker Joseph Mills

- Retrospective review of 223 patients
- Validated MAC score with SAD
- Interobserver reproducibility of the MAC score was high (correlation coefficient 0.96)
- Both MAC and SAD predicted endpoints

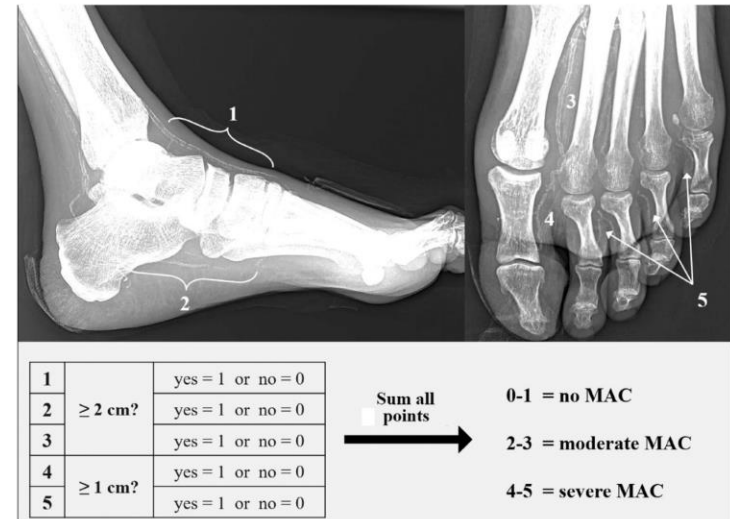
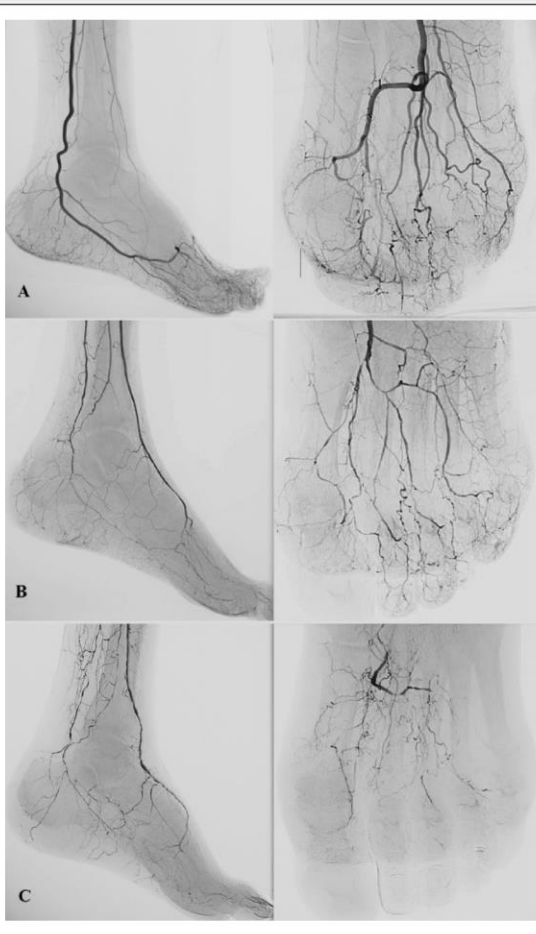


Figure 1. Laterolateral (left) and anteroposterior forefoot (right) radiographic projections. (A) An example of small artery disease (SAD) score 0: all the small arteries originating from a dominant lateral plantar artery are well visualized. Calcaneal, tarsal, metatarsal, and digital arteries are patent without any signs of obstruction. (B) An example of SAD score 1 (moderate disease): the plantar arteries and all the small calcaneal, tarsal, metatarsal, and digital arteries are patent but diffusely diseased and narrowed; only the first toe is really desert. (C) An example of SAD score 2 (severe disease): the plantar system is occluded, the plantar arch is isolated and diseased, the heel and forefoot present residual and isolated segments of small arteries, and the toes are completely desert.

Putting It Together

A high MAC score → likely SAD pattern

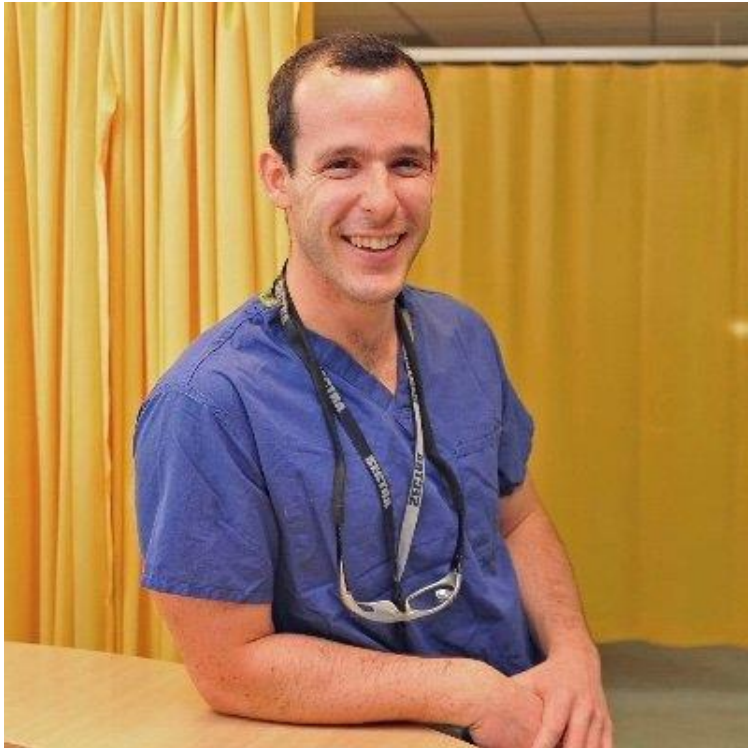
This means can expect non-reconstructable arteries

May need to change expectations in consultation

Putting It Together



How Do I Determine What's Enough on Angio?



Editorial > J Endovasc Ther. 2024 Mar 25:15266028241231745.

doi: 10.1177/15266028241231745. Online ahead of print.

The "Woundosome" Concept and Its Impact on Procedural Outcomes in Patients With Chronic Limb-Threatening Ischemia

Lorenzo Patrone ¹, Edoardo Pasqui ², Michael S Conte ³, Alik Farber ⁴, Roberto Ferraresi ⁵, Matthew Menard ⁶, Joseph L Mills ⁷, John Rundback ⁸, Peter Schneider ⁹, August Ysa ¹⁰, Kumar Abhishek ¹¹, George L Adams ¹², Naseer Ahmad ¹³, Irfan Ahmed ¹⁴, Vlad A Alexandrescu ¹⁵, Max Amor ¹⁶, David Alper ¹⁷, Martin Andrassy ¹⁸, Christopher Attinger ¹⁹, Andy Baadh ²⁰, Hashem Barakat ²¹, Lukla Biasi ²², Theodosios Bisdas ²³, Zagum Bhatti ²⁴, Erwin Blessing ²⁵, Marc P Bonaca ²⁶, Stefano Bonvini ²⁷, Michel Bosiers ²⁸, Andrew W Bradbury ²⁹, Robert Beasley ³⁰, Christian-Alexander Behrendt ³¹, Marianne Brodmann ³², Gonzalo Cabral ³³, Roberto Cancellieri ³⁴, Andrea Casini ⁵, Venita Chandra ³⁵, Emiliano Chisci ³⁶, Omar Chohan ³⁷, Edward T C Choke ³⁸, Patrick F S Chong ³⁹, Giacomo Clerici ⁴⁰, Raphael Coscas ⁴¹, Mary Costantino ⁴², Luca Dalla Paola ⁴³, Sabeen Dand ⁴⁴, Robert S M Davies ⁴⁵, Mario D'Oria ⁴⁶, Athanasios Diamantopoulos ¹⁴, Sebastian Debus ⁴⁷, Koen Deloose ⁴⁸, Costantino Del Giudice ⁴⁹, Gianmarco de Donato ², Brian De Rubertis ⁵⁰, Jean Paul De Vries ⁵¹, Nuno V Dias ⁵², Larry Diaz-Sandoval ⁵³, Florian Dick ⁵⁴, Konstantinos Donas ⁵⁵, Anahita Dua ⁵⁶, Fabrizio Fanelli ⁵⁷, Stefano Fazzini ⁵⁸, Mazin Foteh ⁵⁹, Roberto Gandini ⁶⁰, Mauro Gargiulo ⁶¹, Luca Garriboli ⁶², Elizabeth A Genovese ⁶³, Edward Gifford ⁶⁴, Yann Goueffic ⁶⁵, Peter Goverde ⁶⁶, Prem Chand Gupta ⁶⁷, Robert Hincliffe ⁶⁸, Andrew Holden ⁶⁹, Kim C Houllind ⁷⁰, Dominic Pj Howard ⁷¹, Bella Huasen ⁷², Giacomo Isernia ⁷³,



PAT

Can be helpful with noncompressible vessels and open wounds

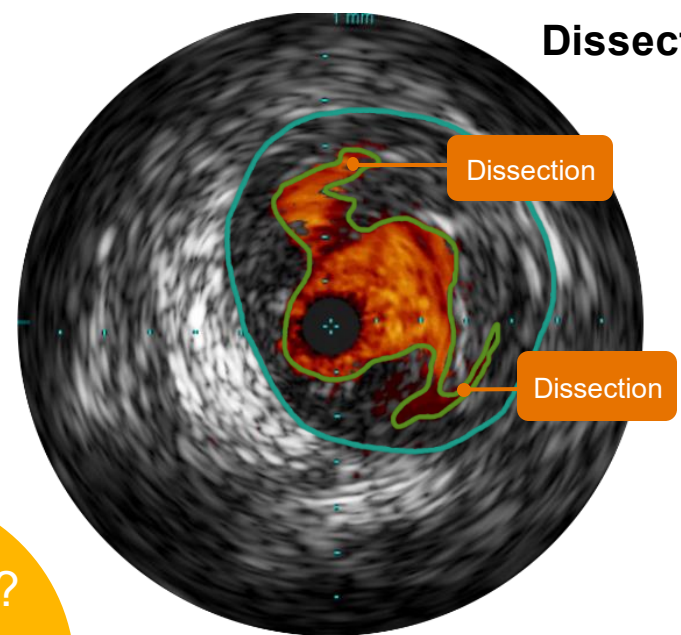
| | No ischemia Class 1 | Mild ischemia Class 2 | Moderate ischemia Class 3 | Severe ischemia Class 4 |
|--------------------------|------------------------|-----------------------------------|--------------------------------|-----------------------------|
| Clinical symptoms | Asymptomatic | Greater than 2 block claudication | Less than 2 block claudication | CLTI Tissue Loss; Rest Pain |
| PAT | 20 – 120 msec | 121 – 180 msec | 181 – 224 msec | Greater than 225 msec |
| ABI | 1.3 – 0.90 | 0.89 – 0.69 | 0.68 – 0.50 | 0.49 – 0.00 |

PAT = pedal acceleration time.
 Teso D, et al. *Ann Vasc Surg.* 2021;75:189-193.

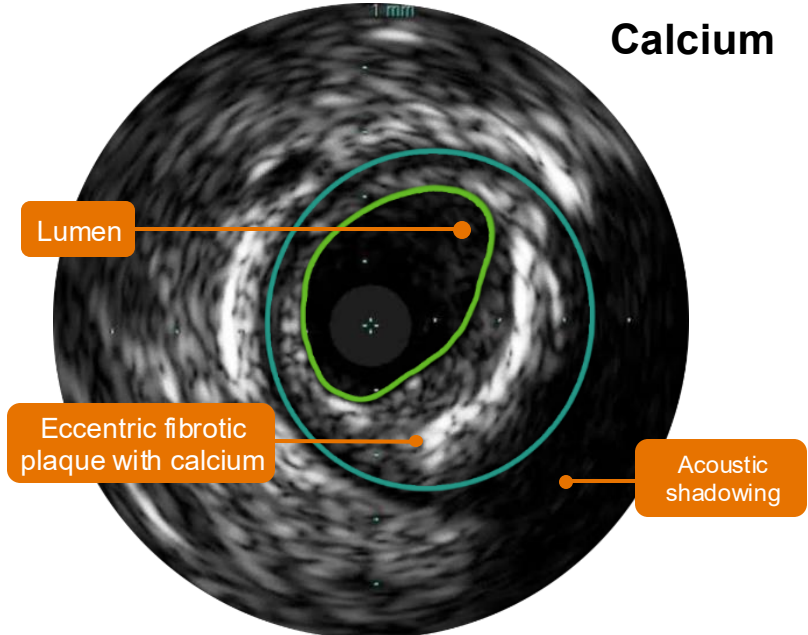


Dissection?
Calcium?
Thrombus?
Stenosis?

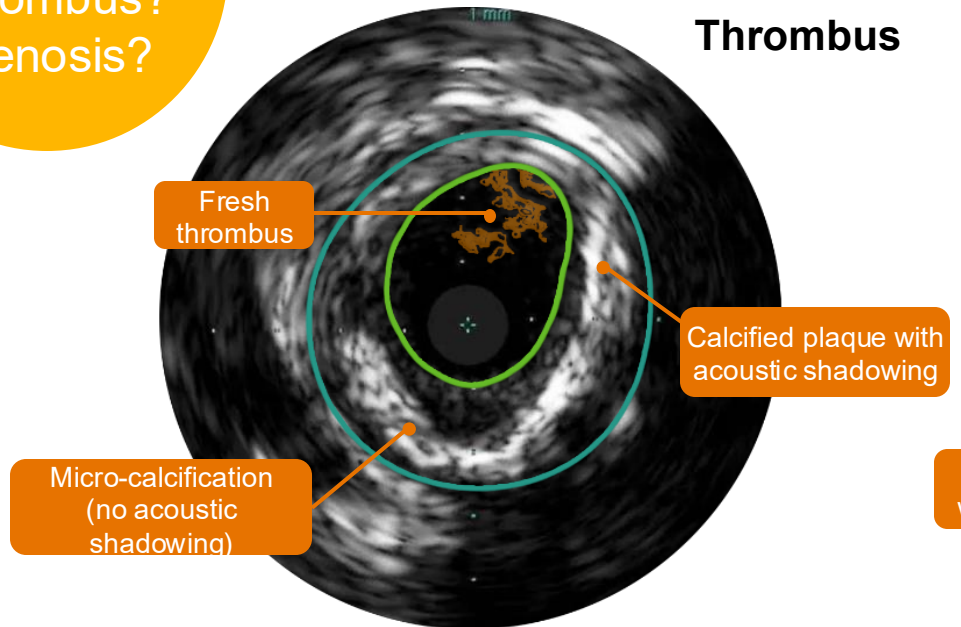
Dissection



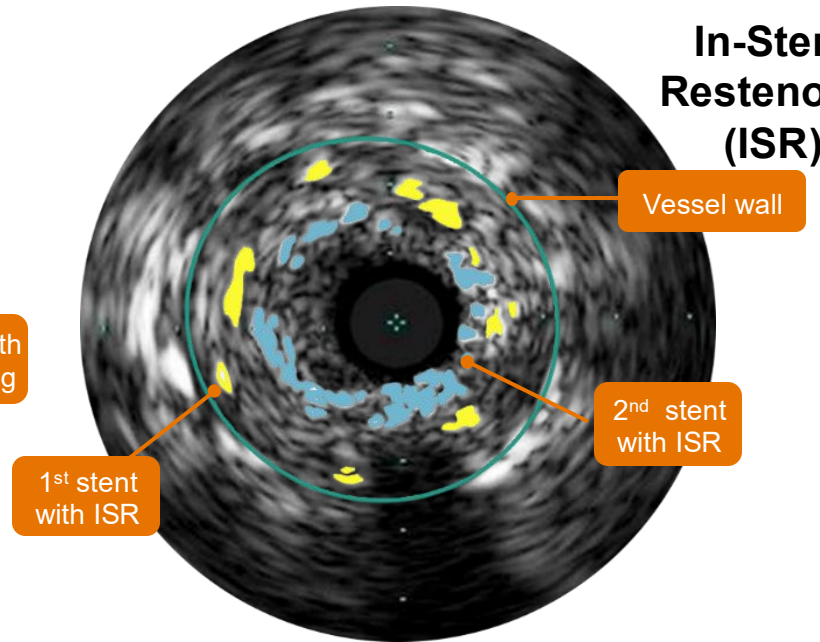
Calcium



Thrombus



In-Stent Restenosis (ISR)

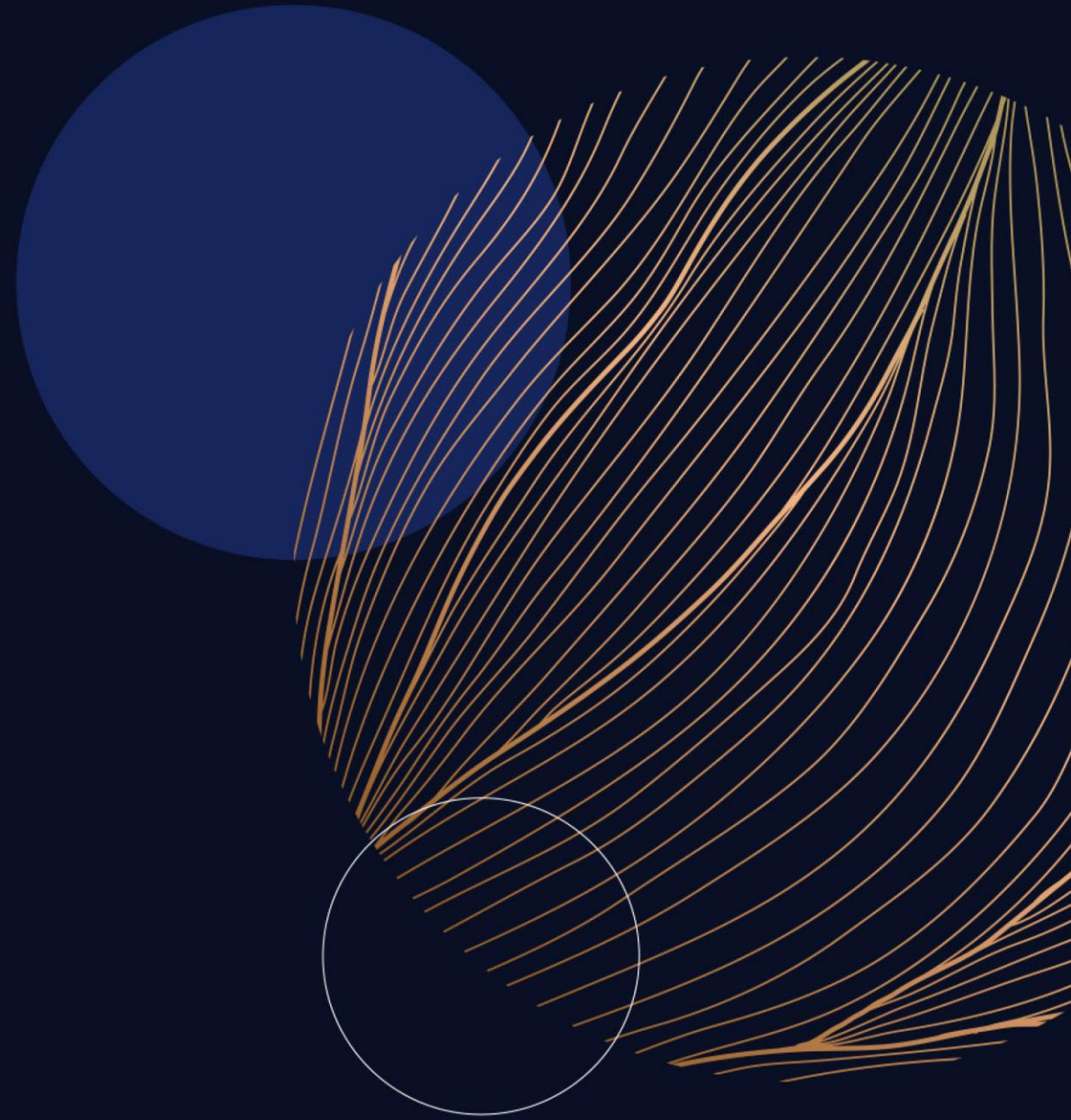




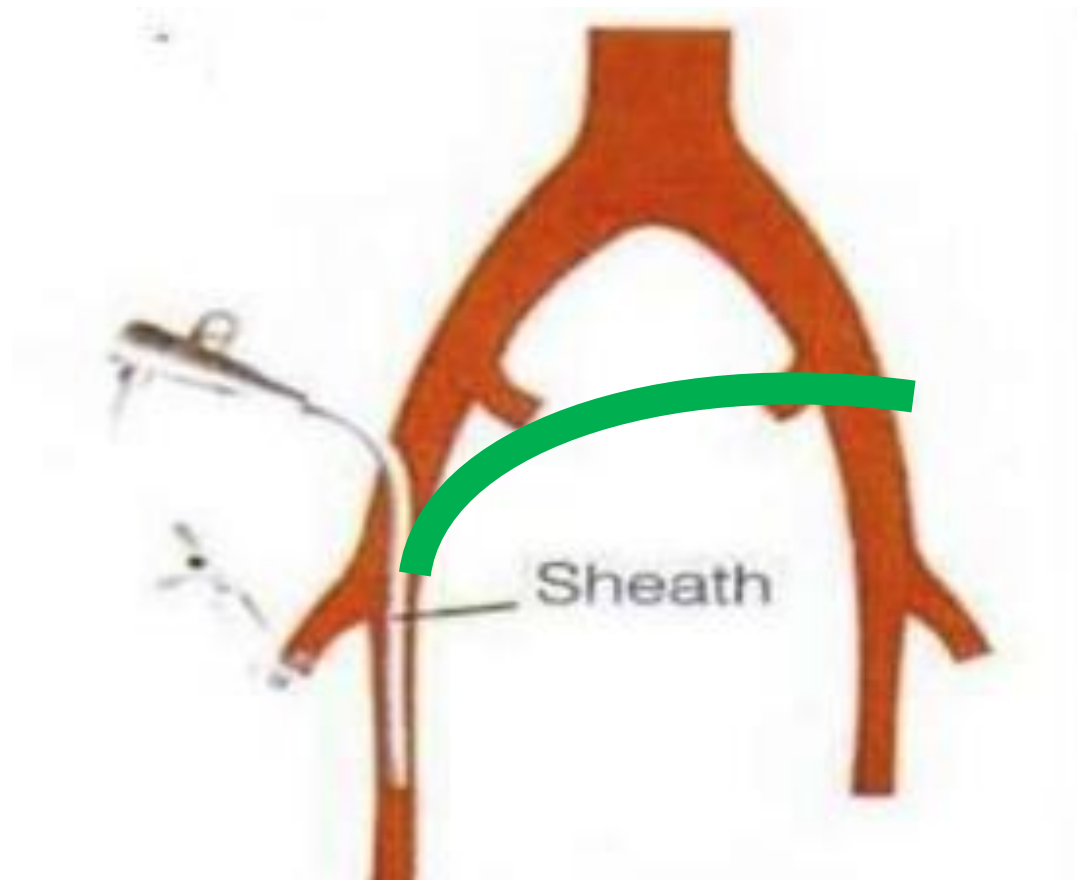
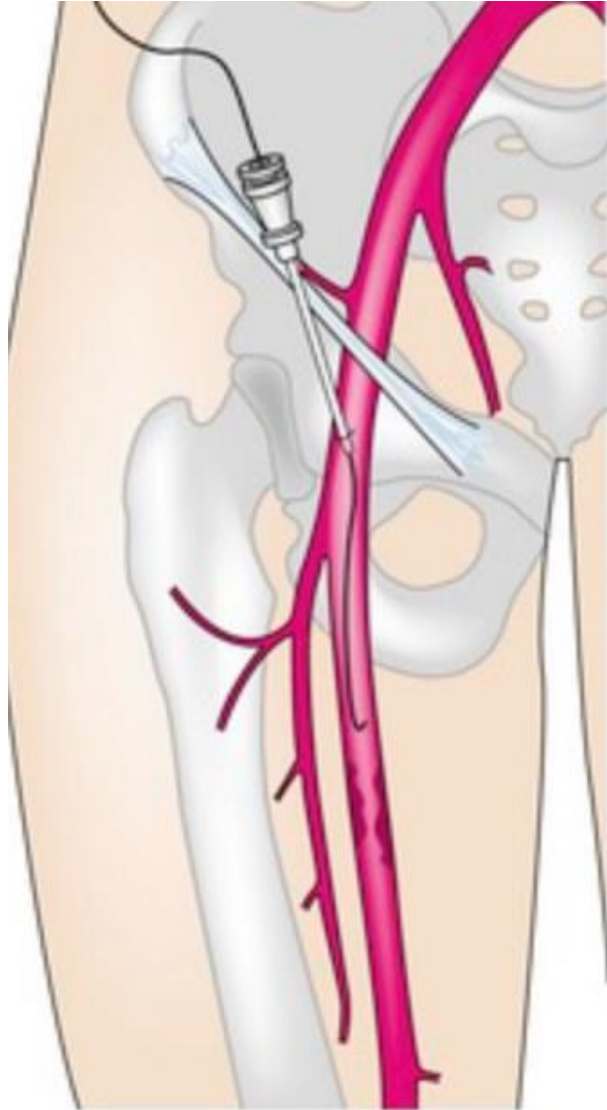
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2: Approach



Antegrade Access



Antegrade Access Problems: **Pannus**

Big issue in
the U.S.

Pannus
affects safe
access and
closure

Increasing
globally



Antegrade Access Solution: **Pannus** **Retention System**



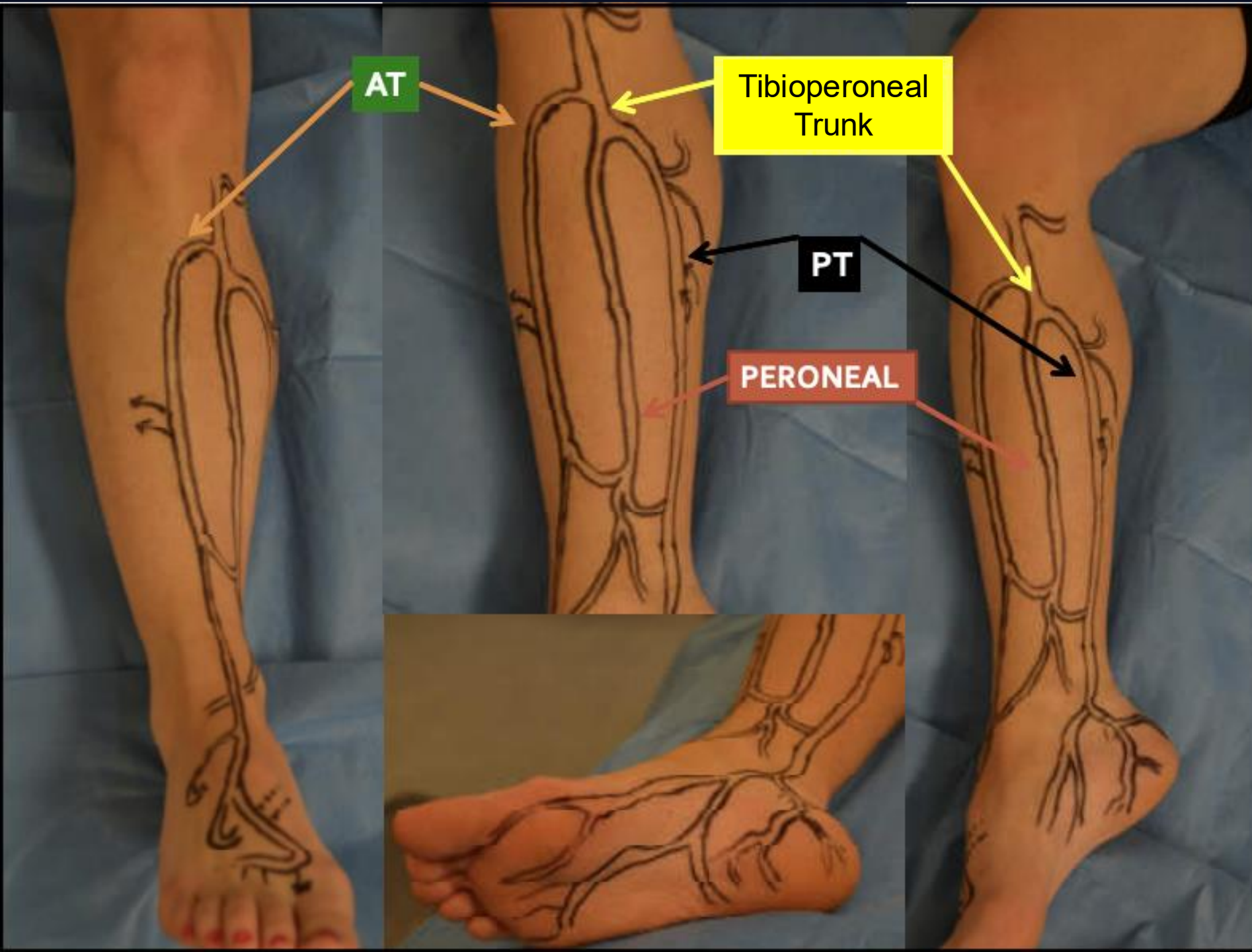


Prep the whole leg



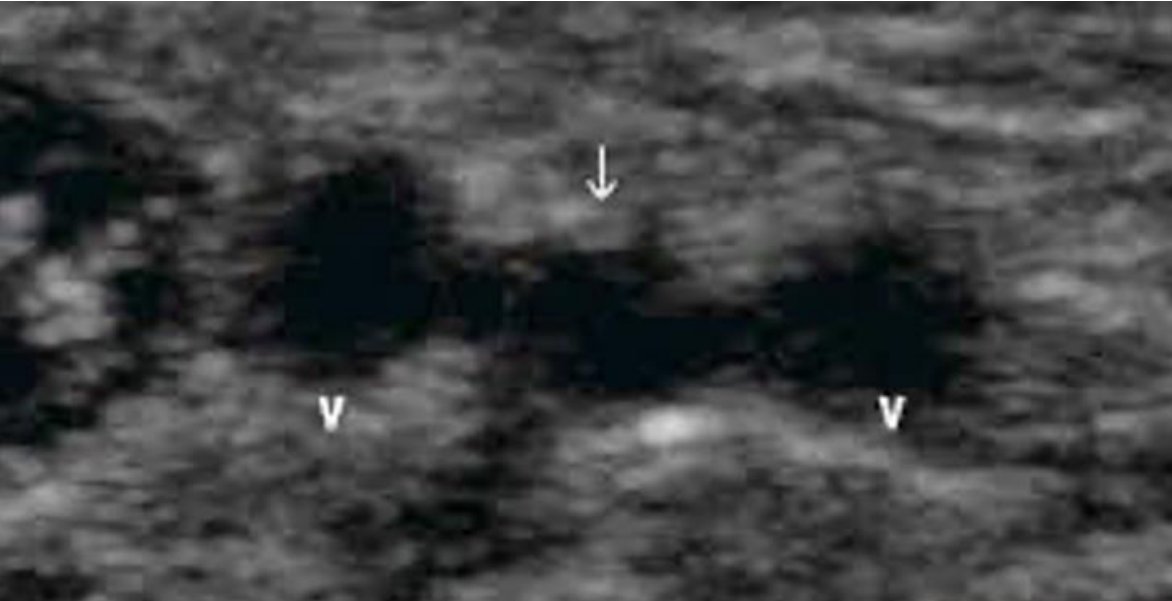
Retrograde SFA



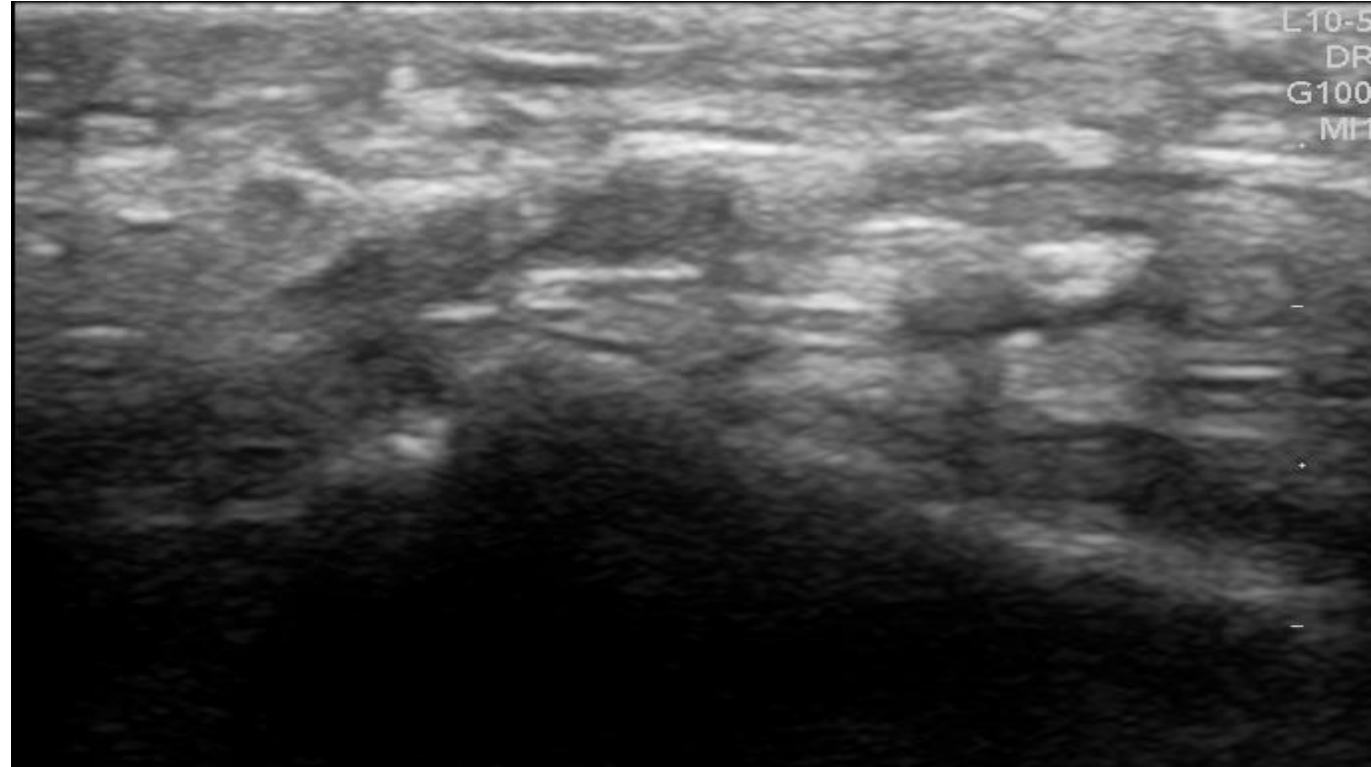


Ideally, you want to be below the calf to keep the ability to handle any bleeding issues directly.

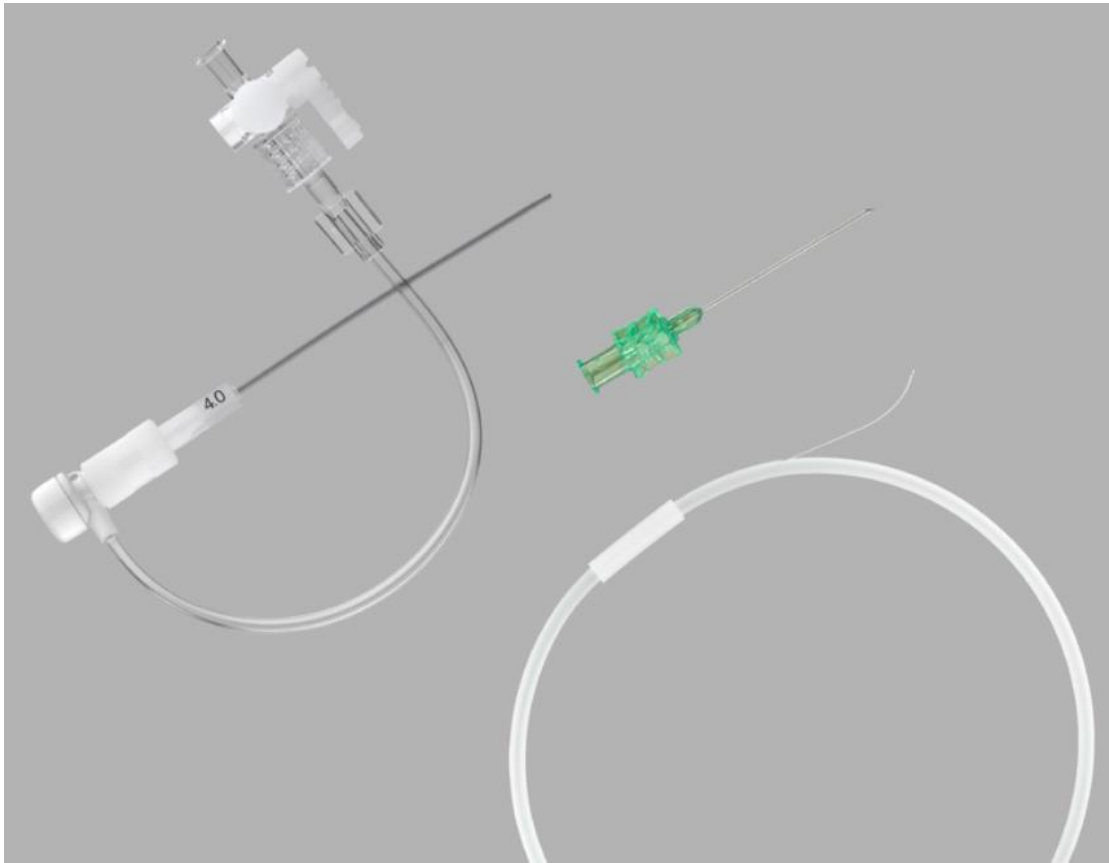
Pedal Access

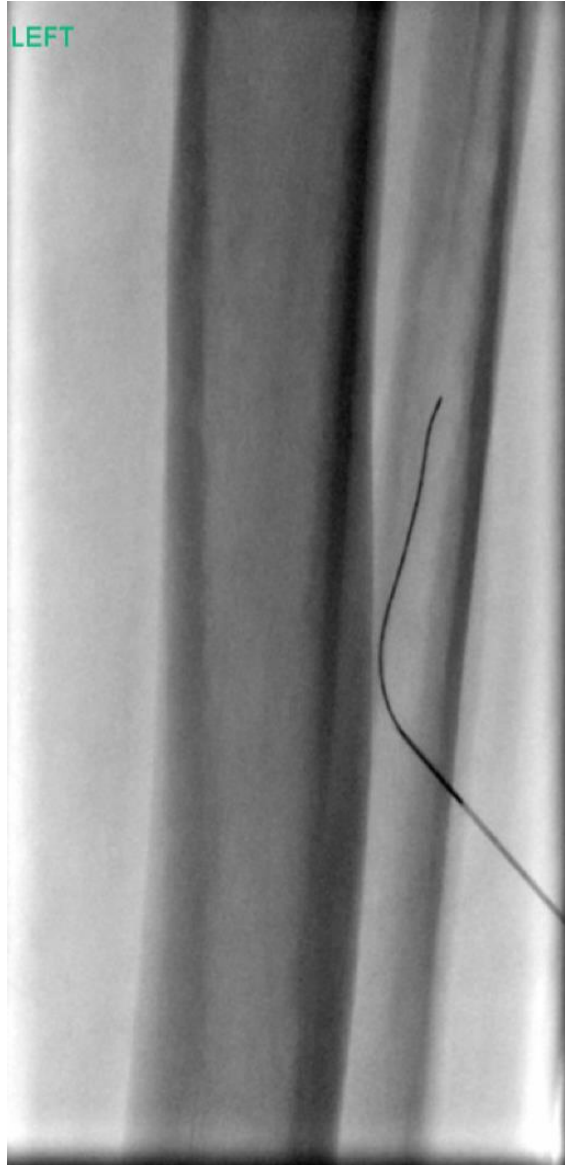


Evaluation:
Distal vessel target
Target vessel size
Outflow vessels

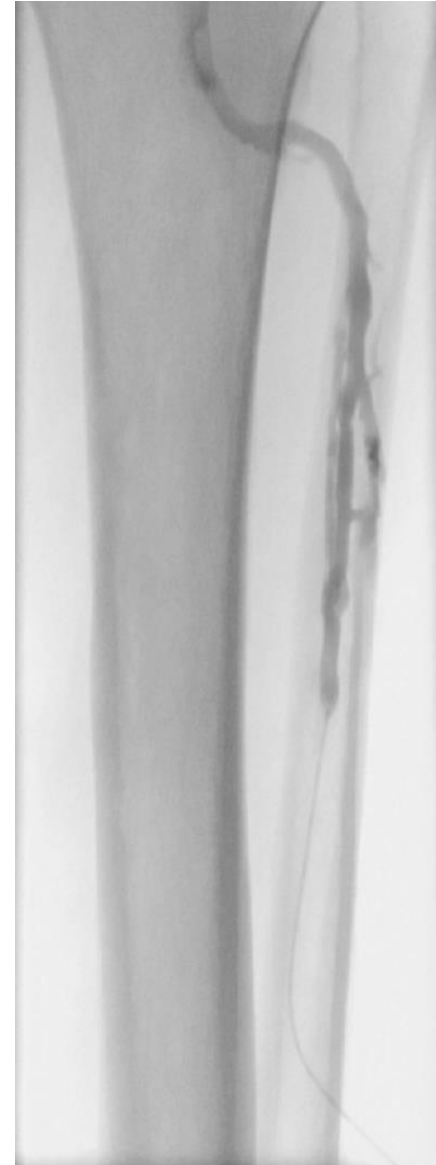


Popliteal artery
Anterior tibial artery
Posterior tibial artery
Peroneal artery
Plantar artery



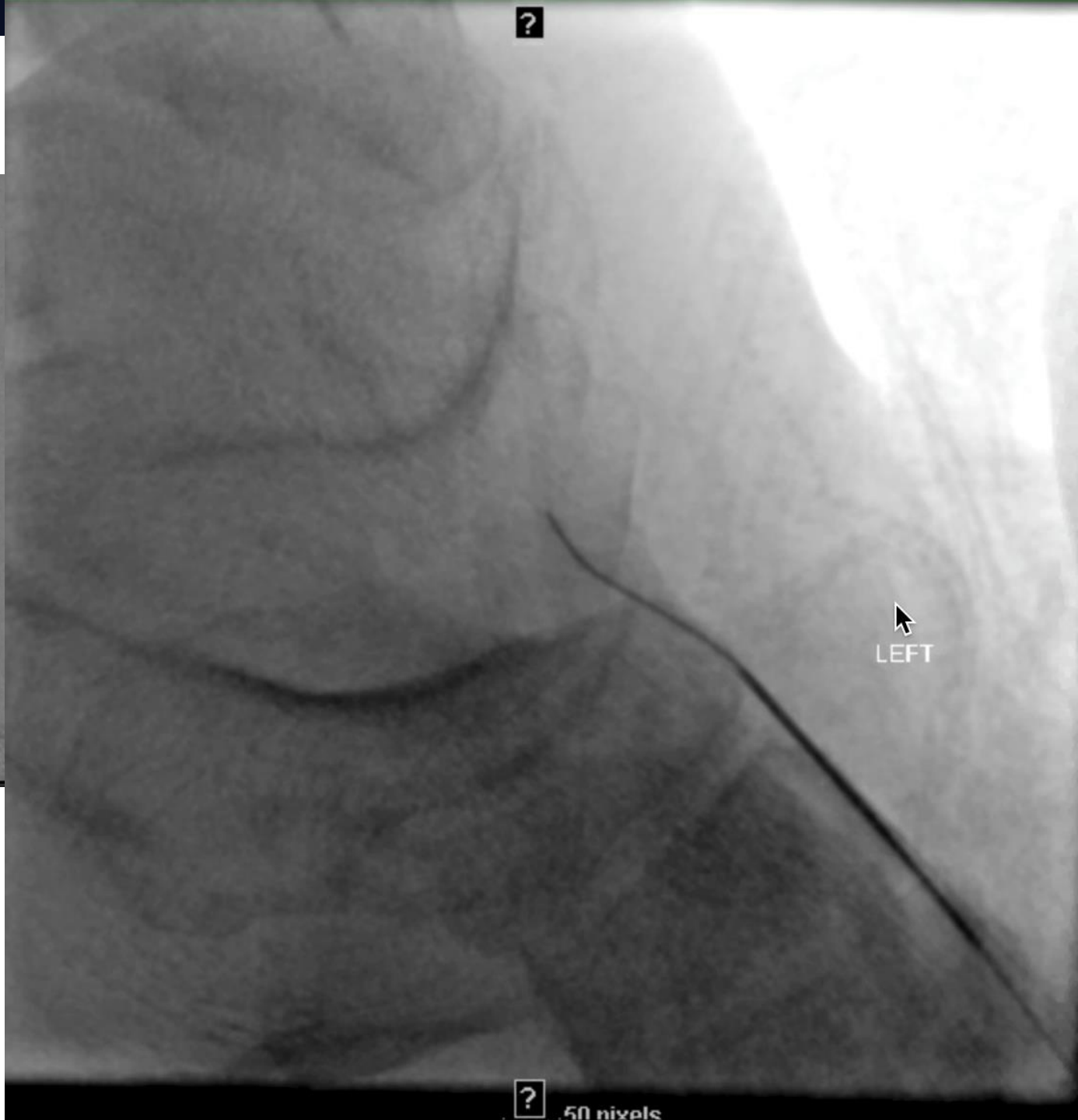
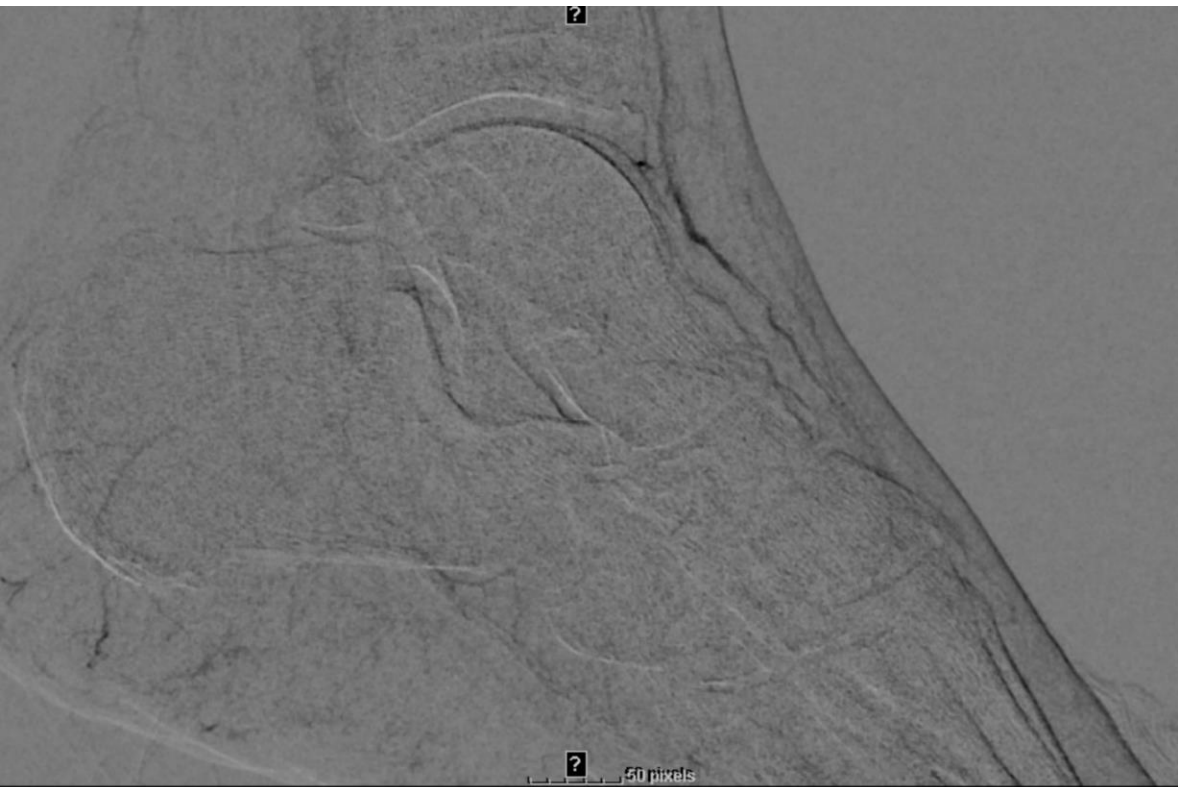


Always
check
access
first



Bareback Technique

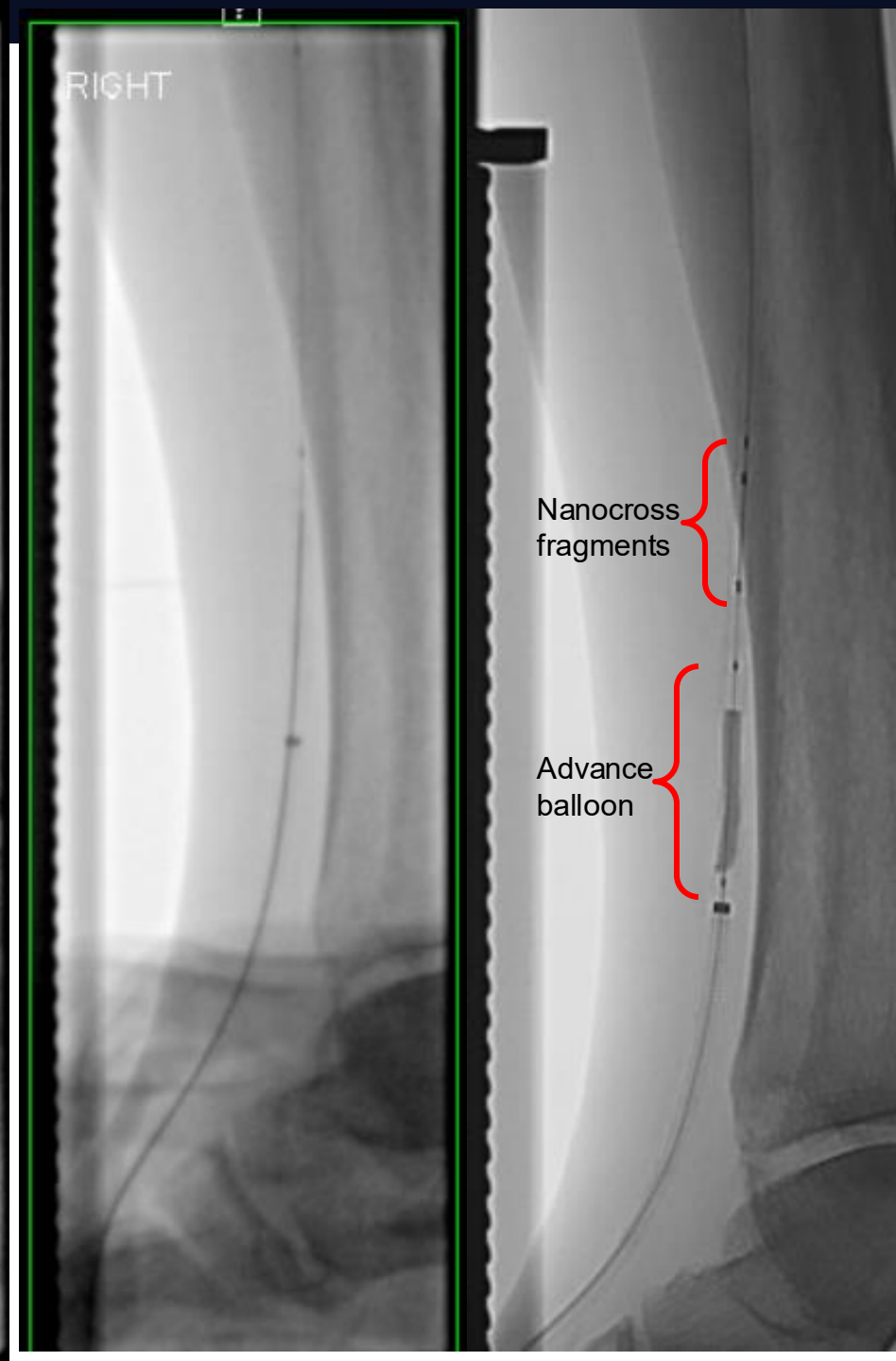




Prefer a hydrophilic **018** or
sometimes **014** wire with good
support

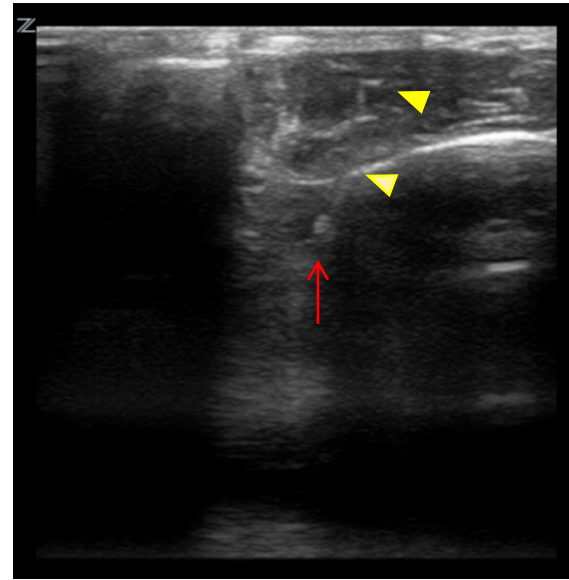
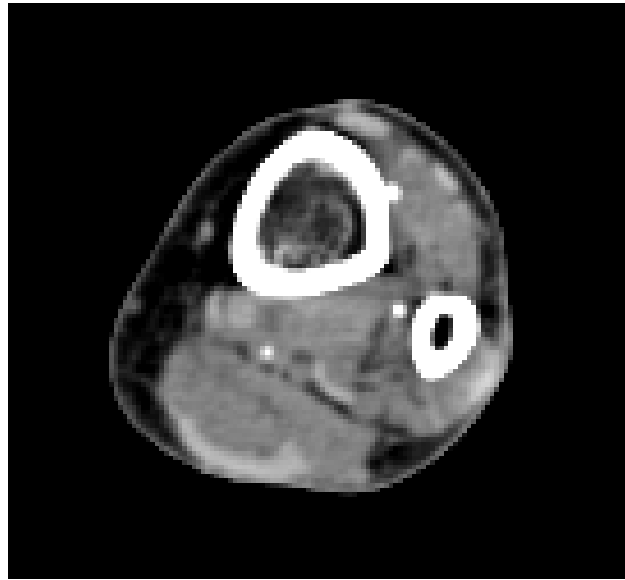
More Aggressive Retrograde

- Pedal access upsized, multiple attempts were made to advance the fragments superiorly
 - 5 Fr introducer sheath
 - 5 Fr braided sheath
 - Inner dilators
 - 2.5 mm advance low-pressure balloon
 - Accustick set – inner 3 Fr stiffeners

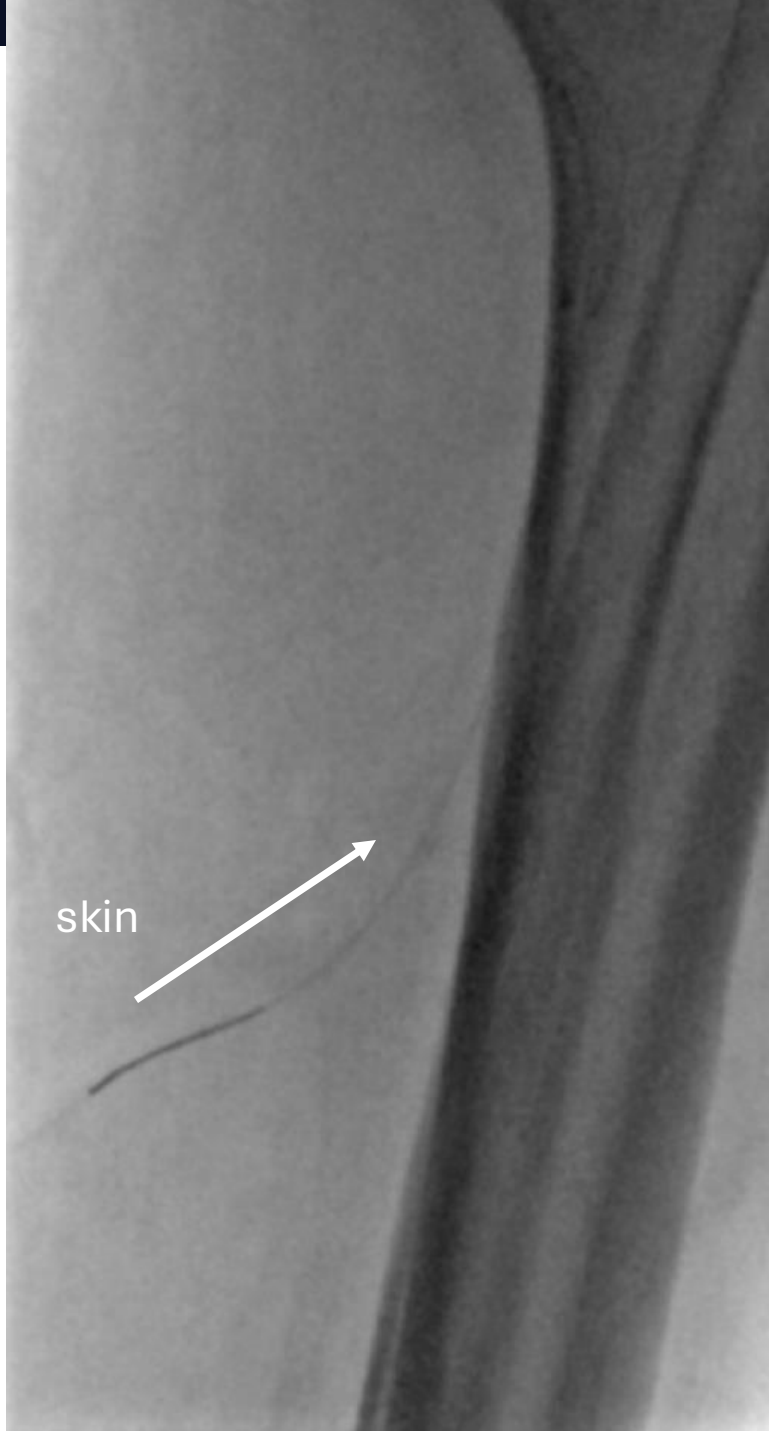




Peroneal Technique: US-Guided



US-guided anterior transmembrane access of peroneal artery.

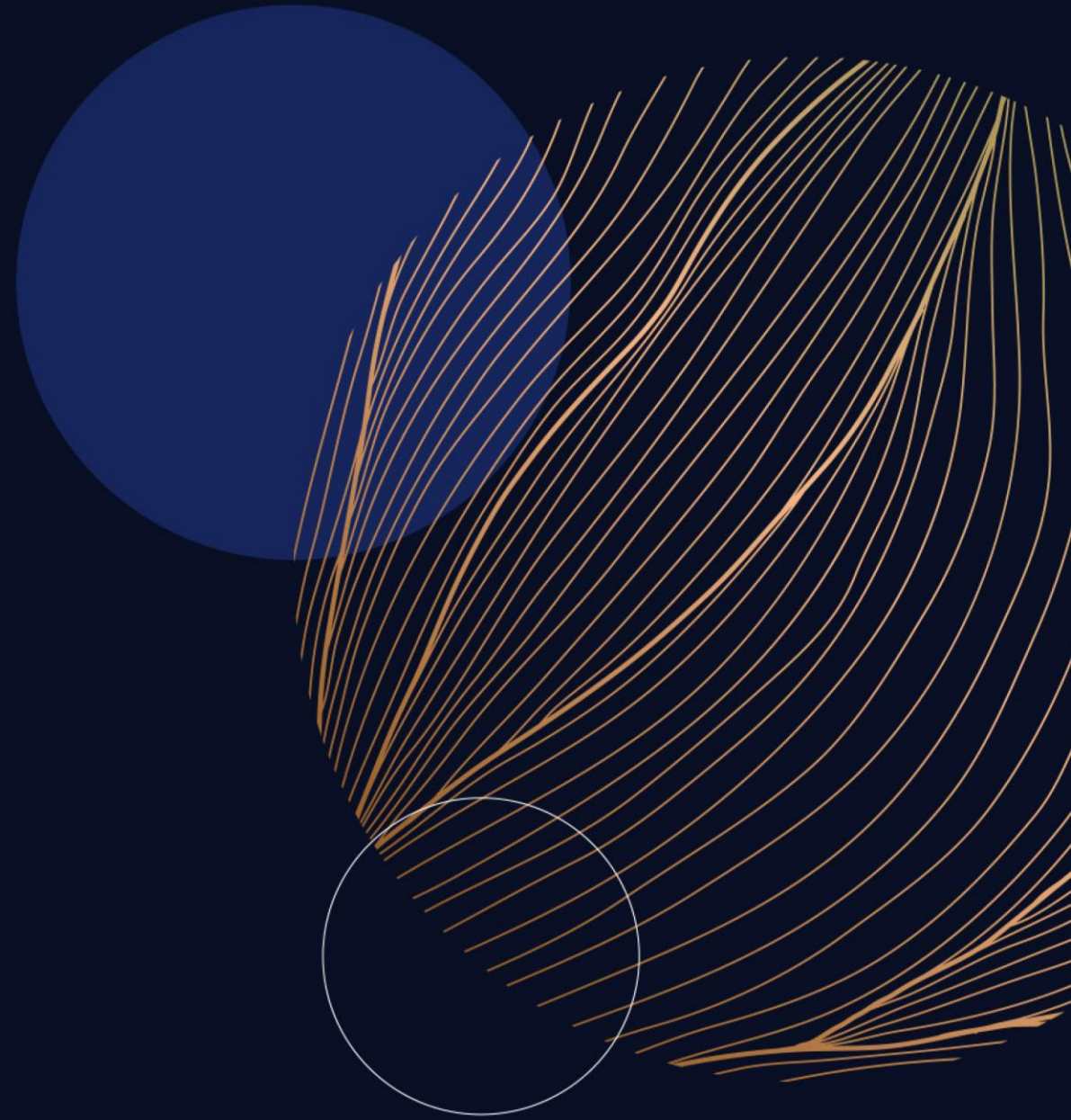




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3: Techniques



Case

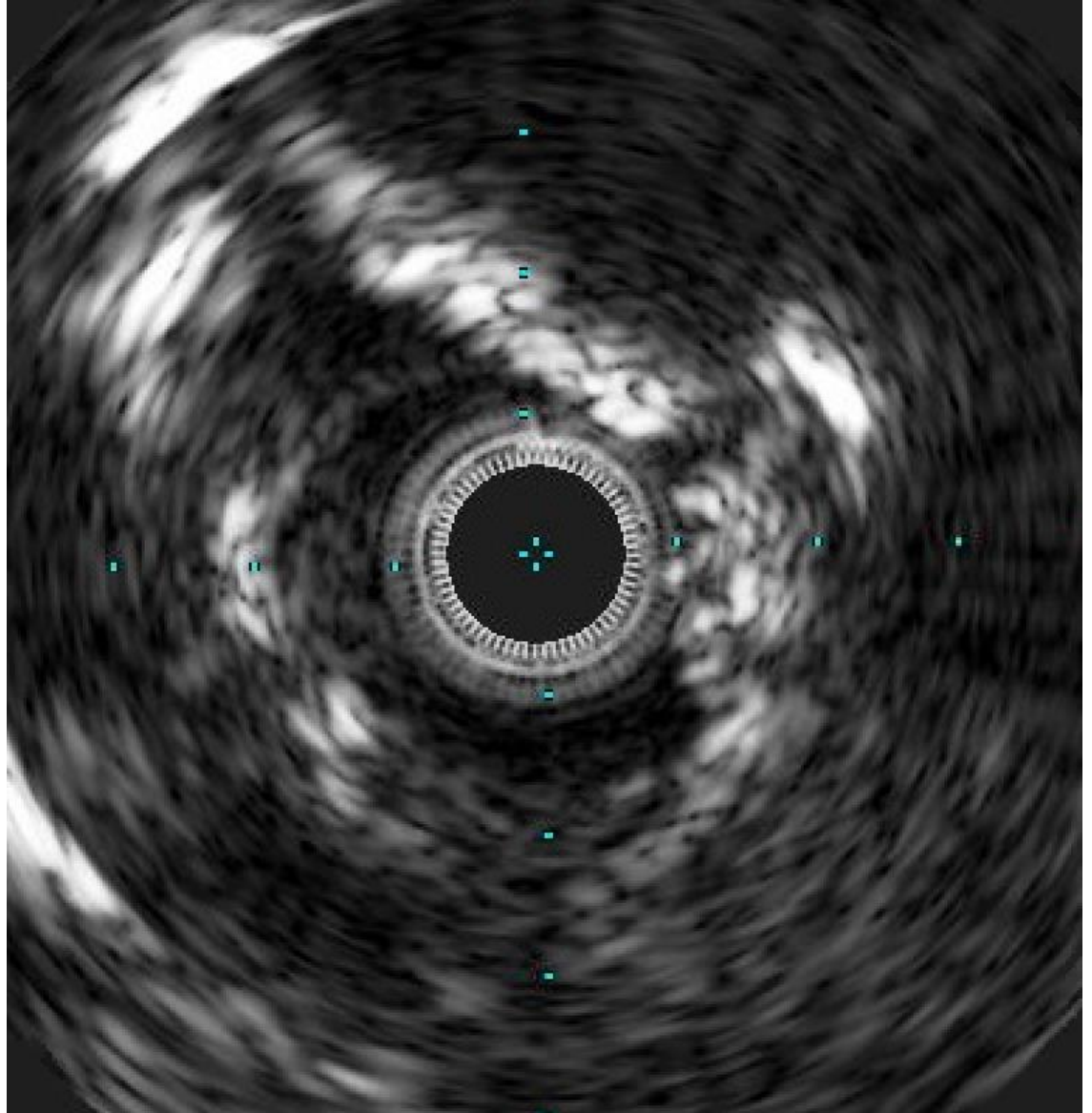
75 years old

Dorsal forefoot gangrene

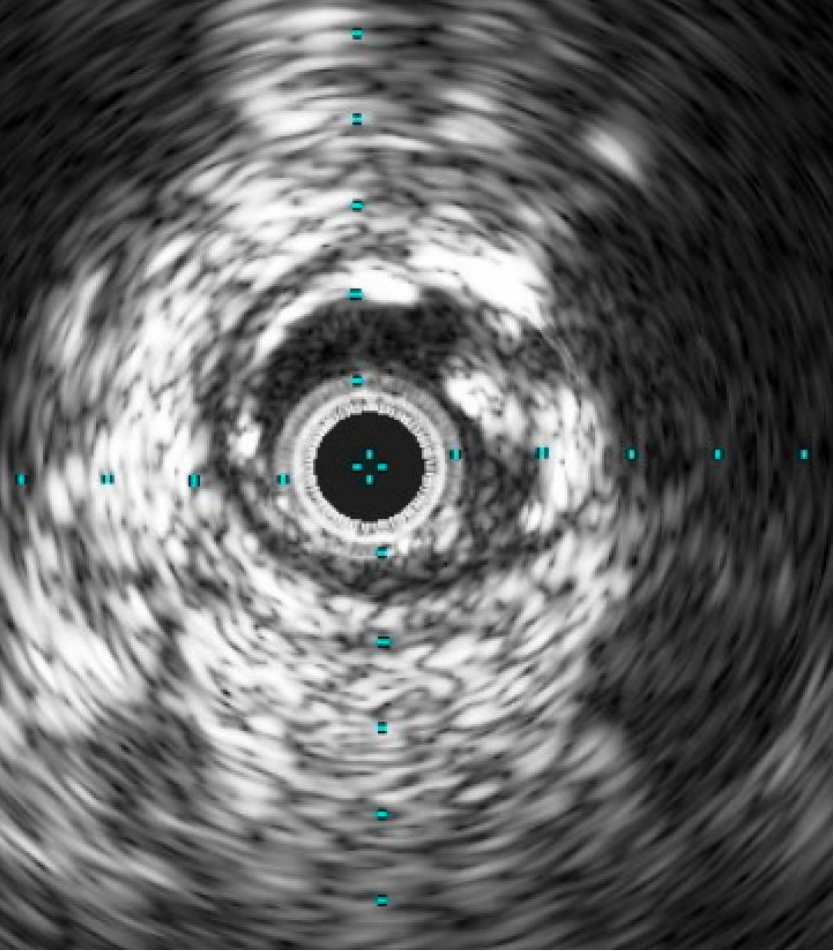
CABG

DM

CKD





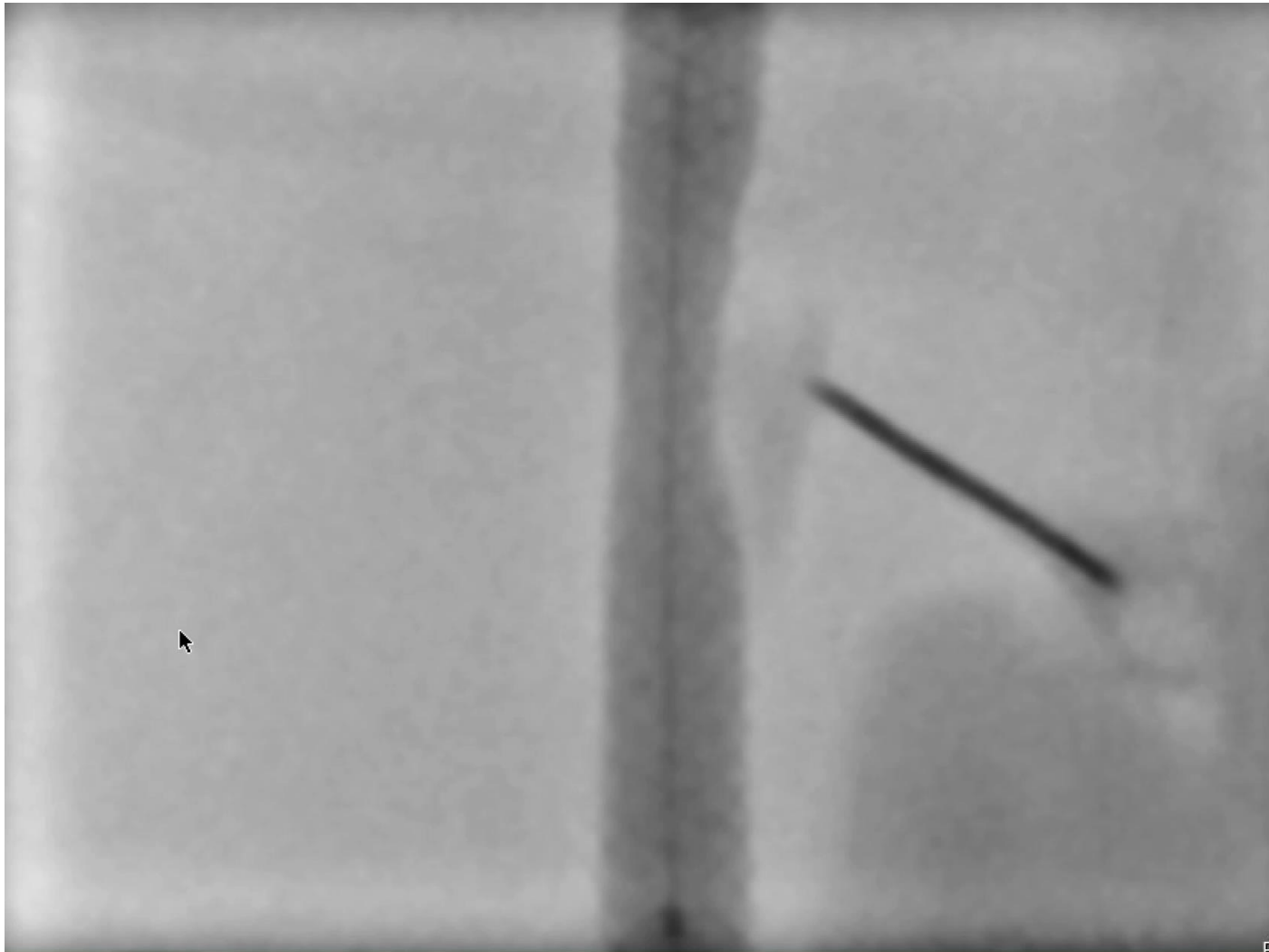


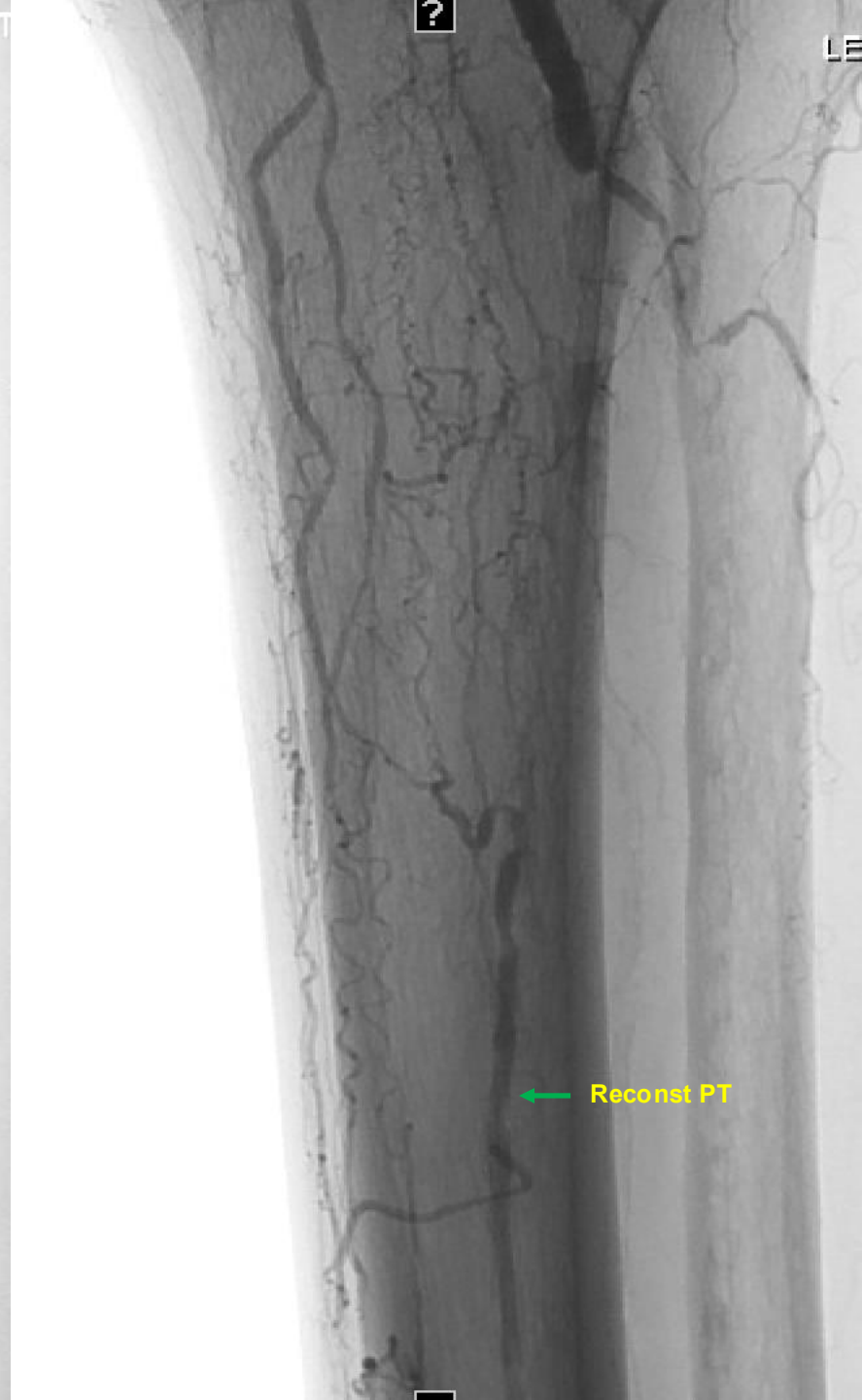


Glow 'N Tell Tape



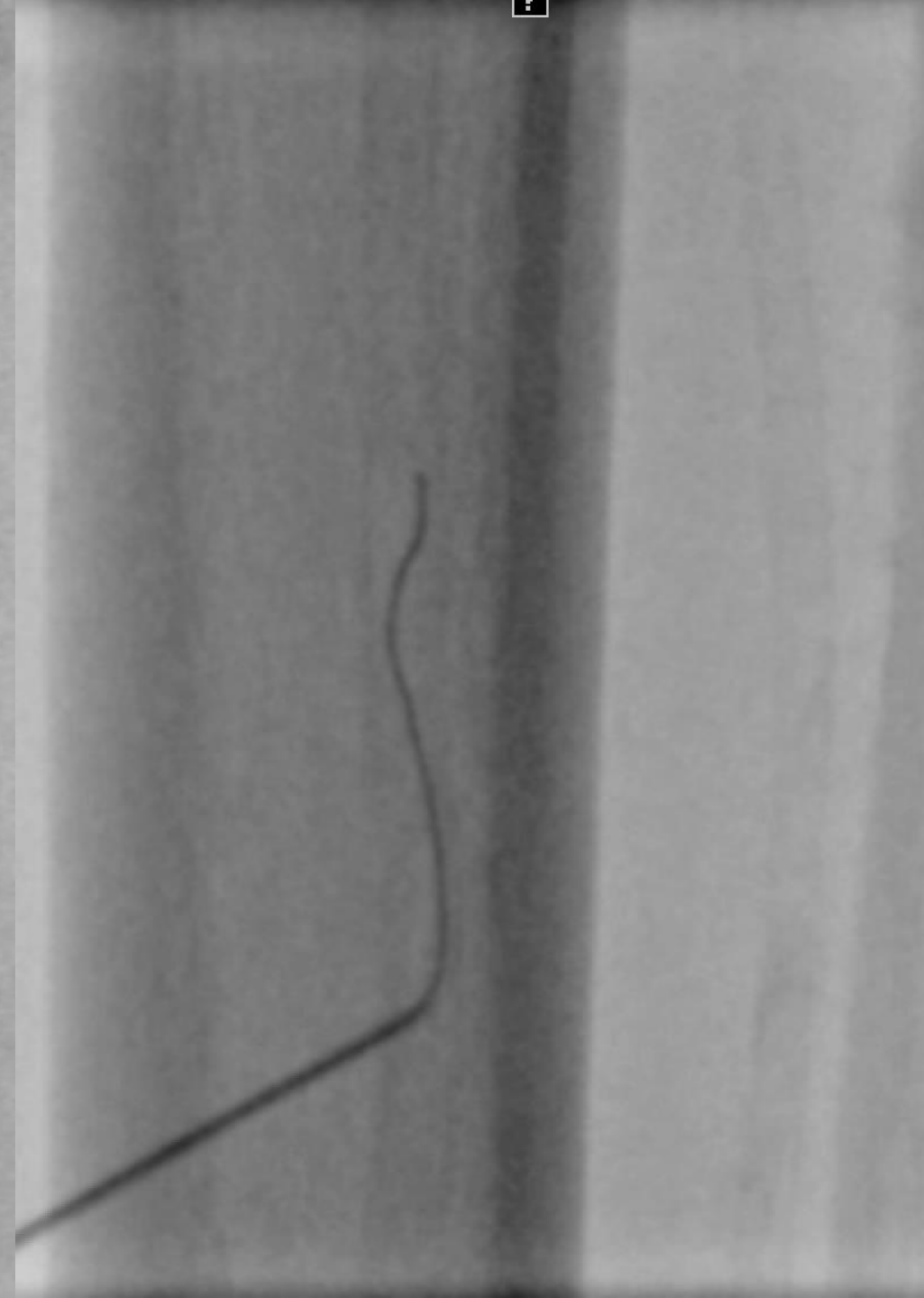
In the End, Nothing May Still Be Enough

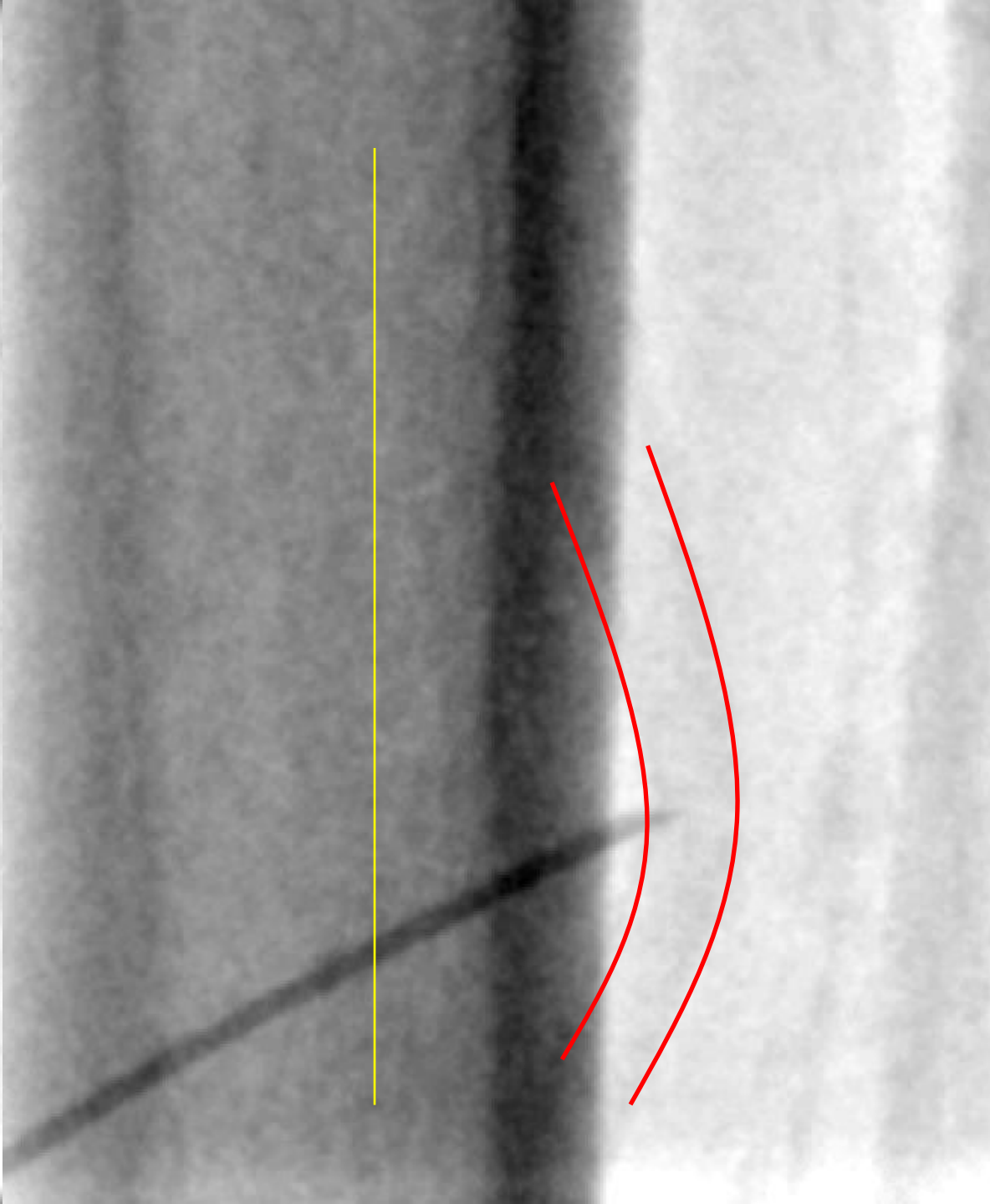
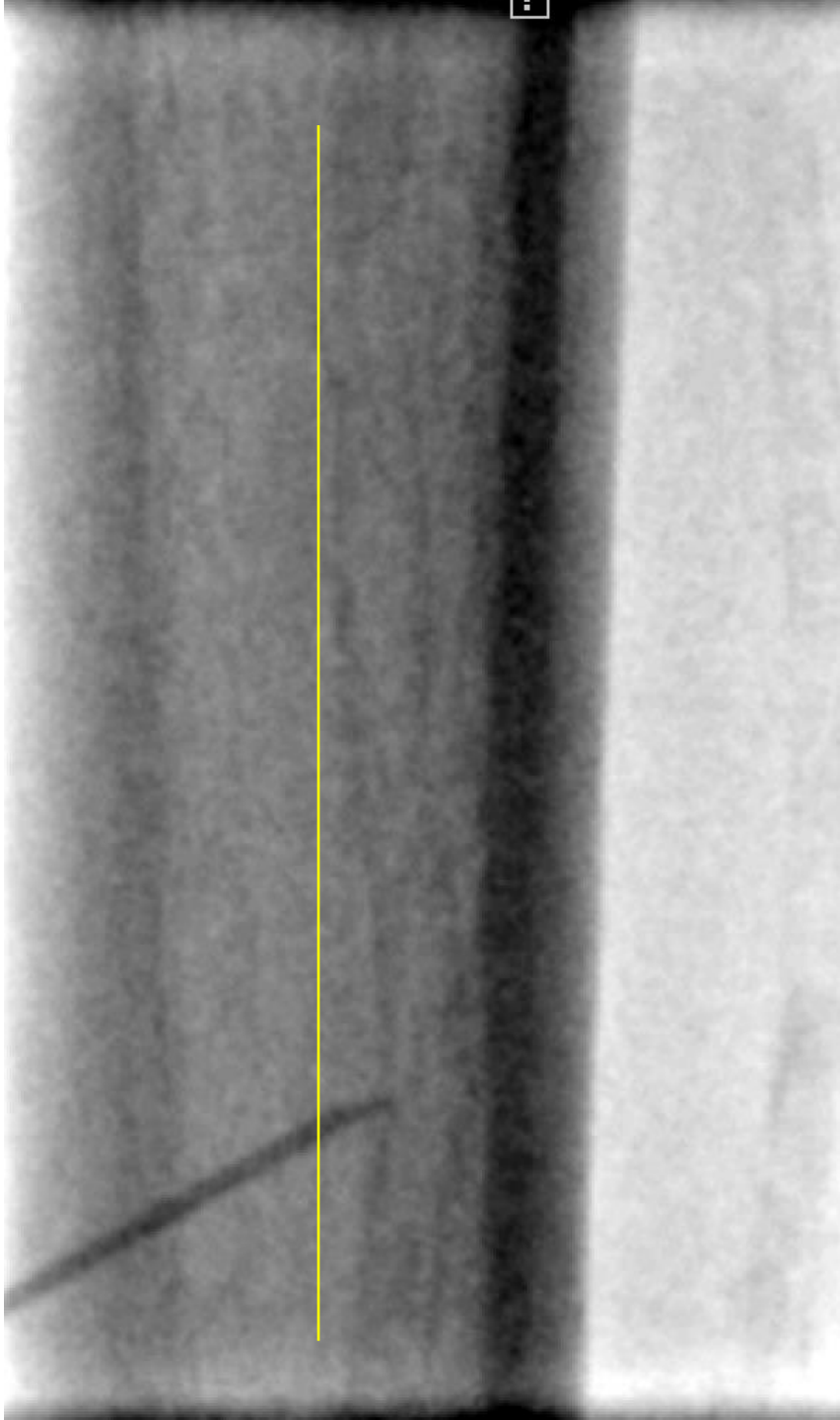


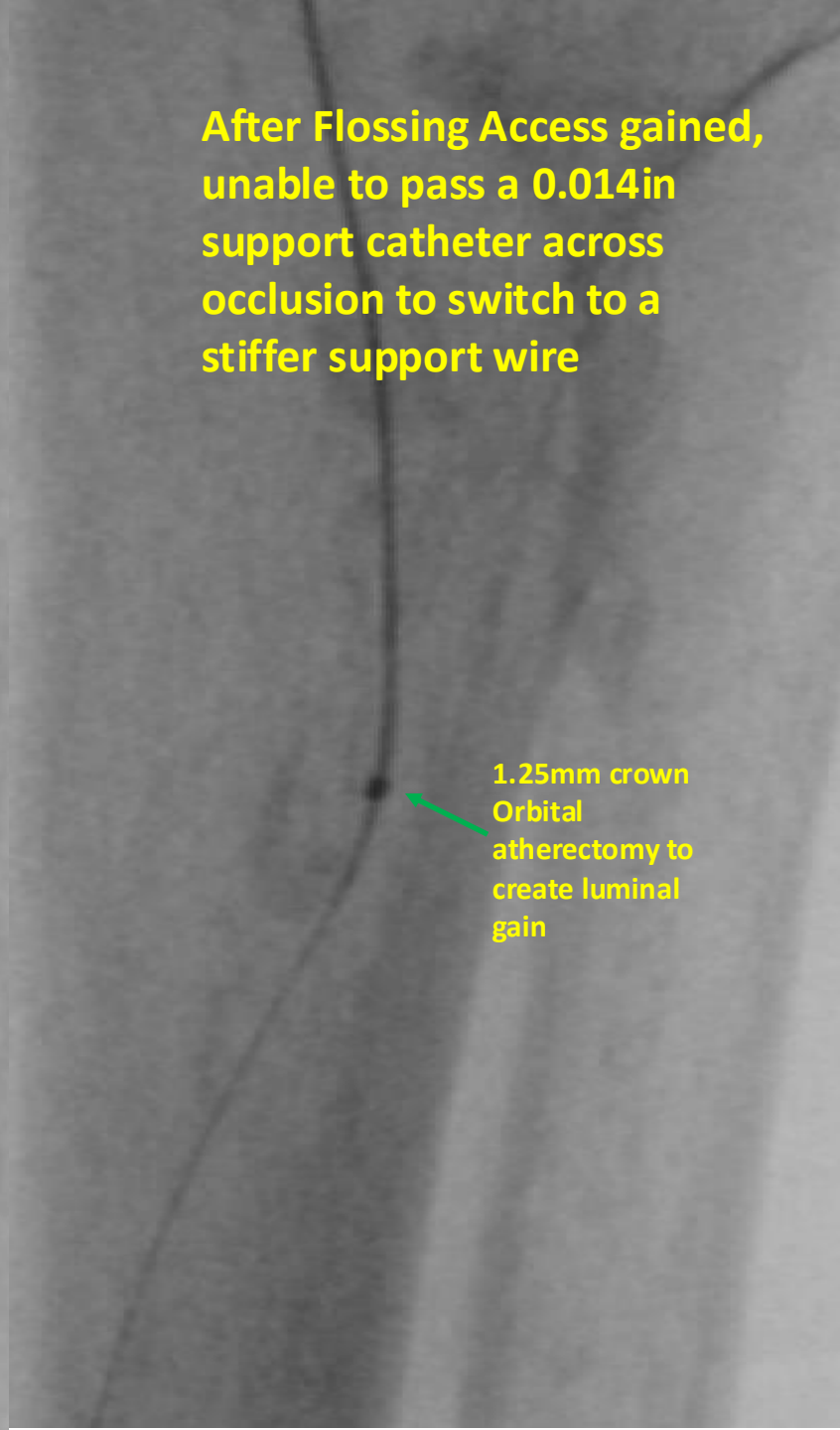
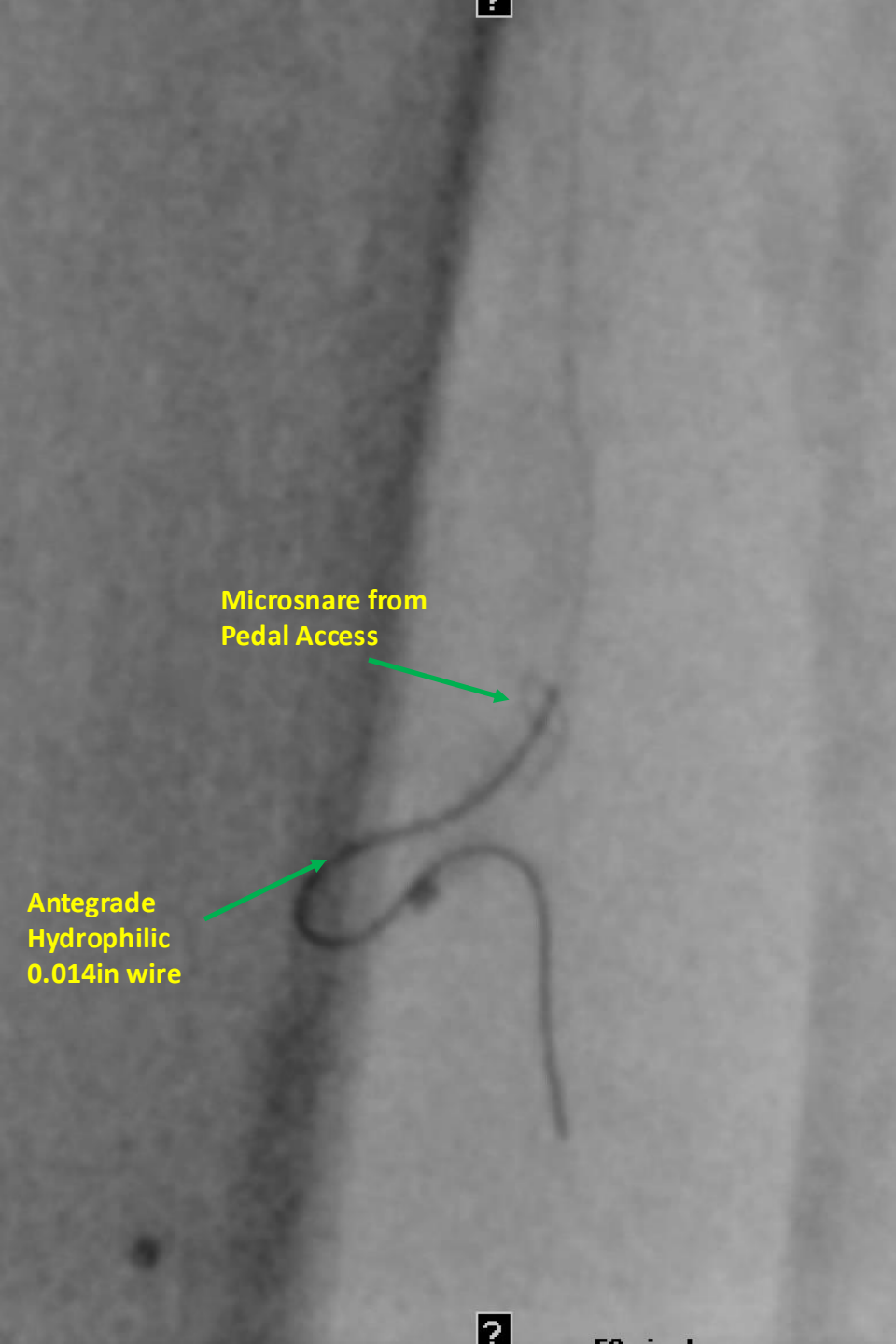




Inability to stay intraluminal

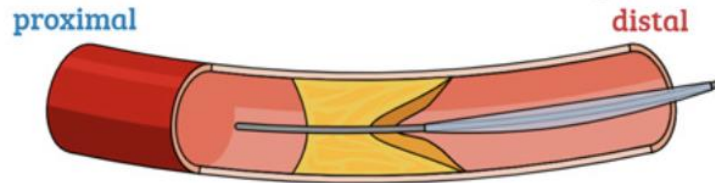






Retrograde CTO Crossing Techniques

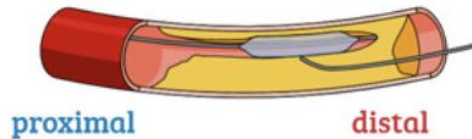
1-Retrograde wire escalation



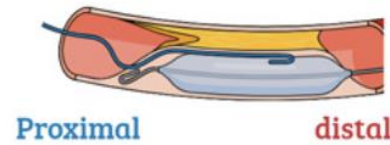
Short occlusion (<20 mm)
tapered distal cap

2-Retrograde dissection reentry

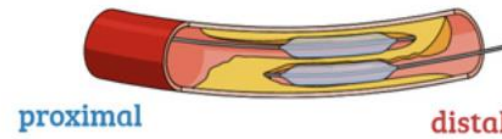
Reverse CART



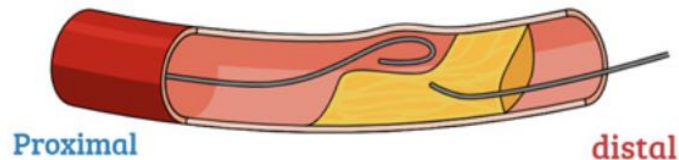
CART



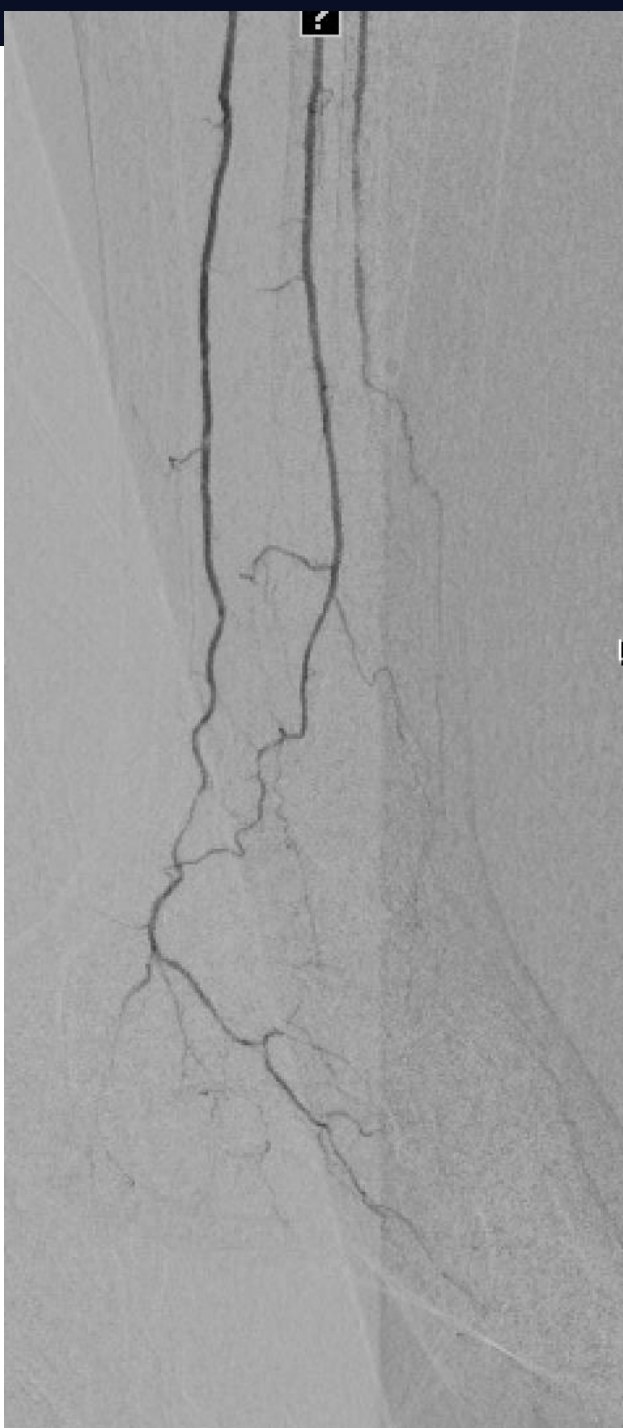
Confluent balloons



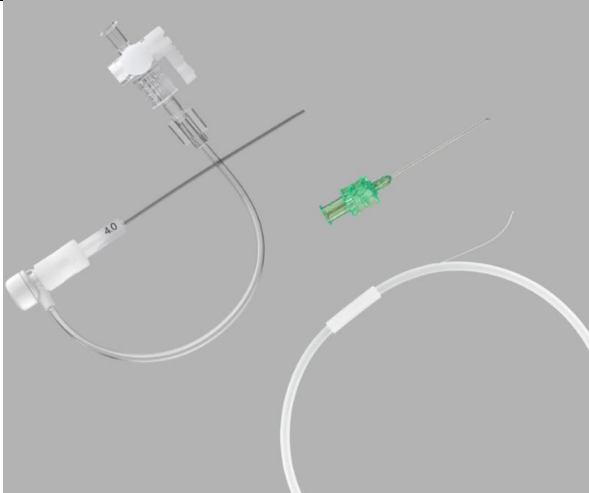
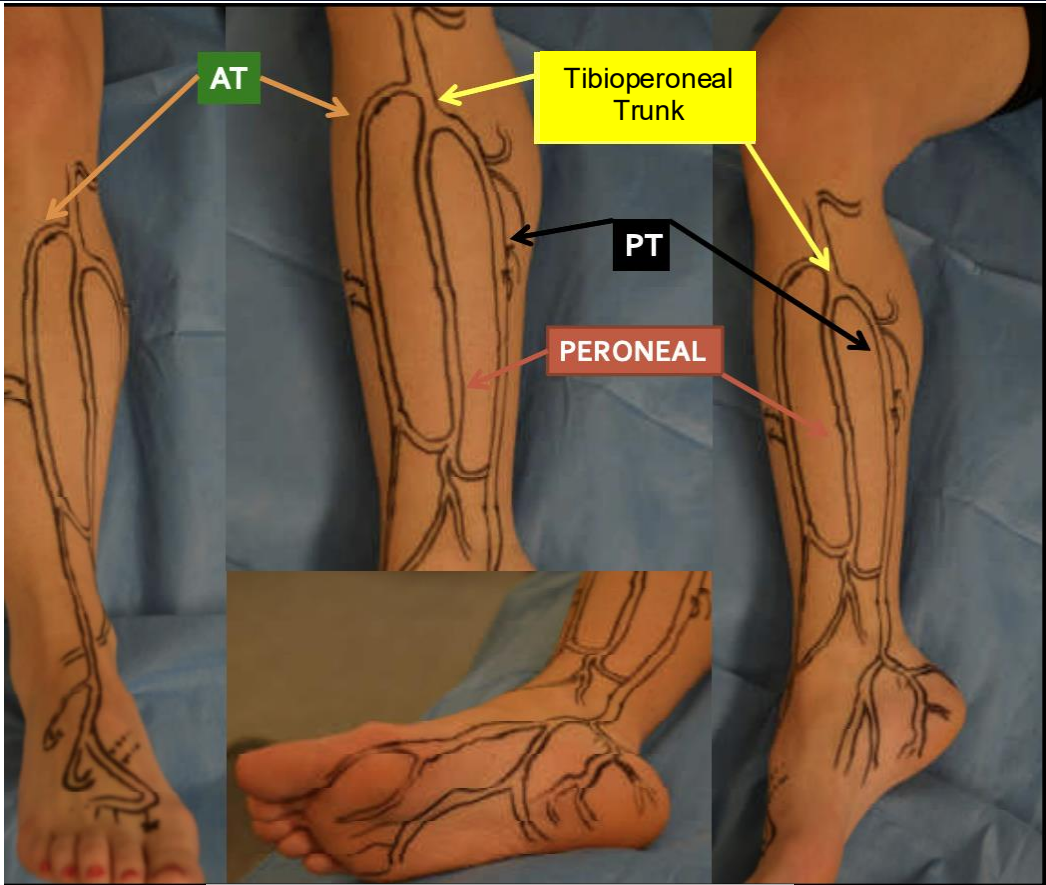
3- Marker for antegrade wiring



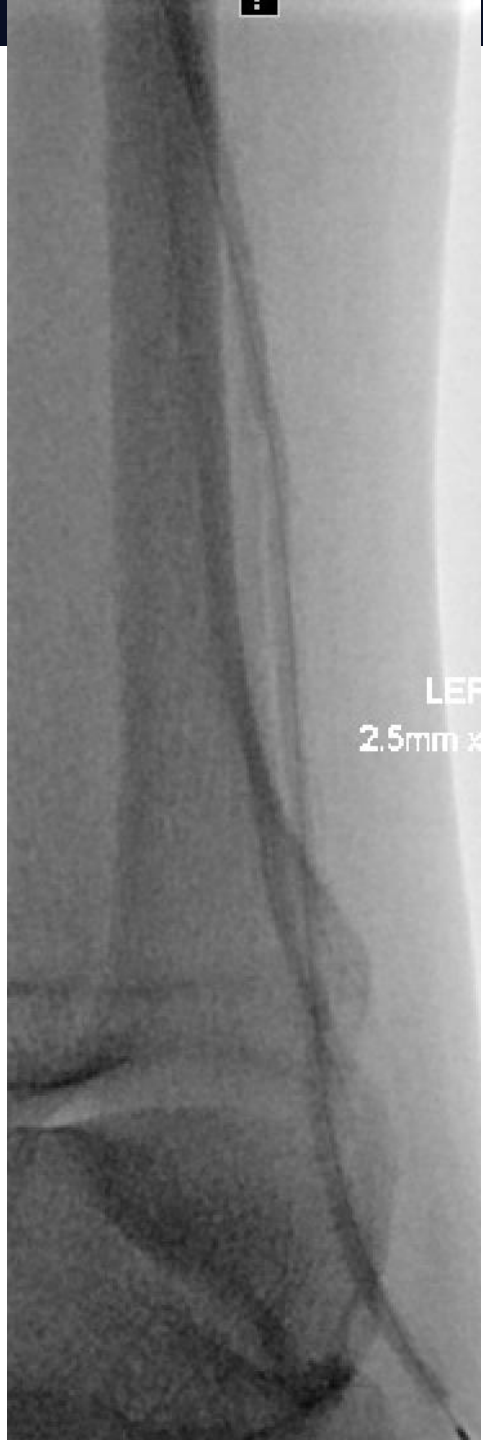
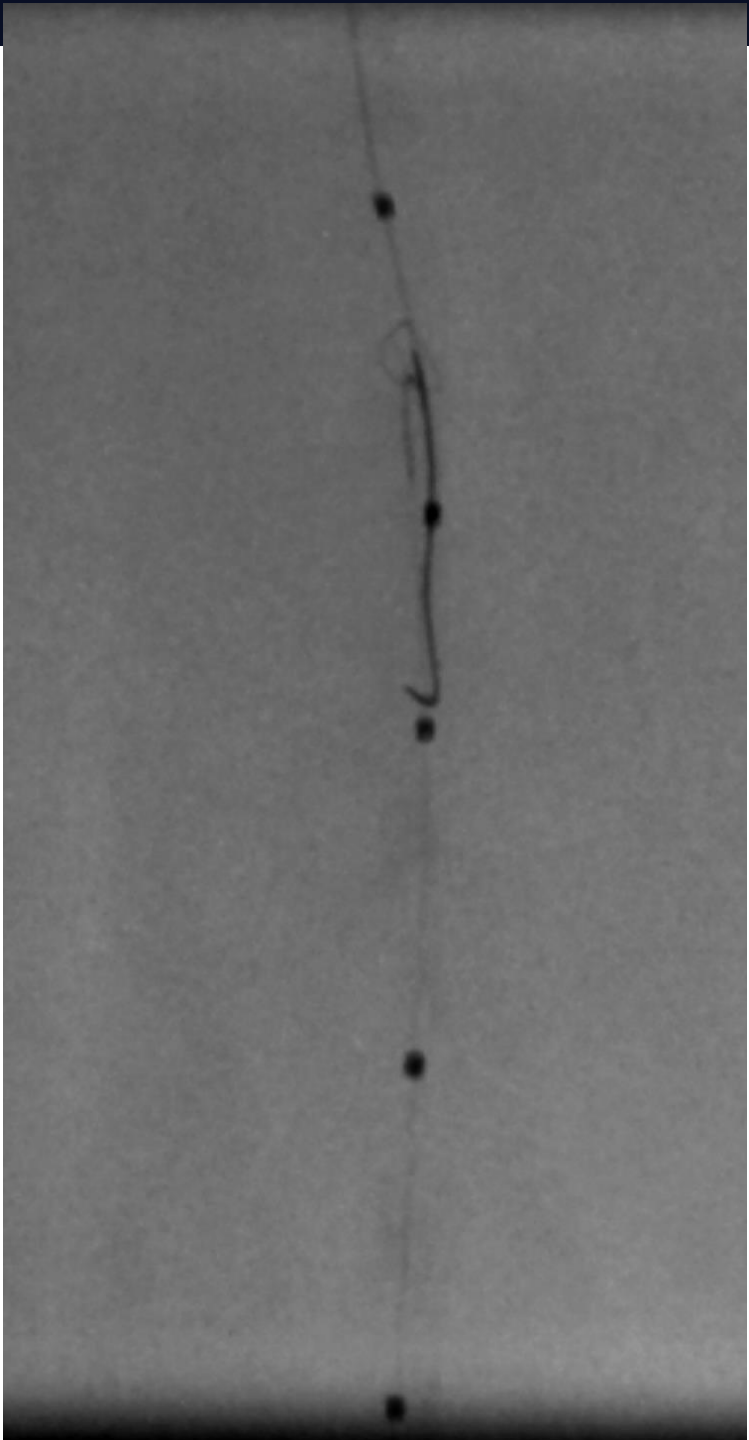
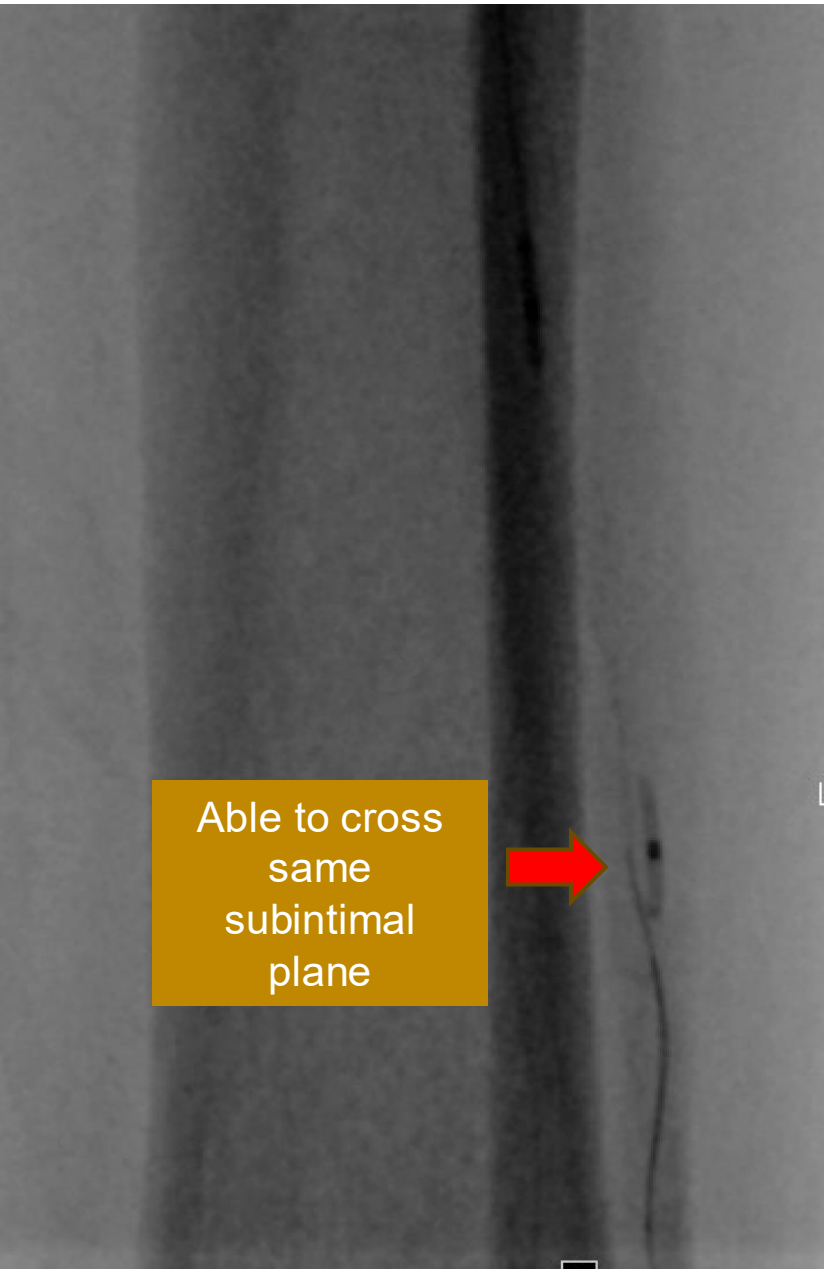
When other measures fail



Unable to cross



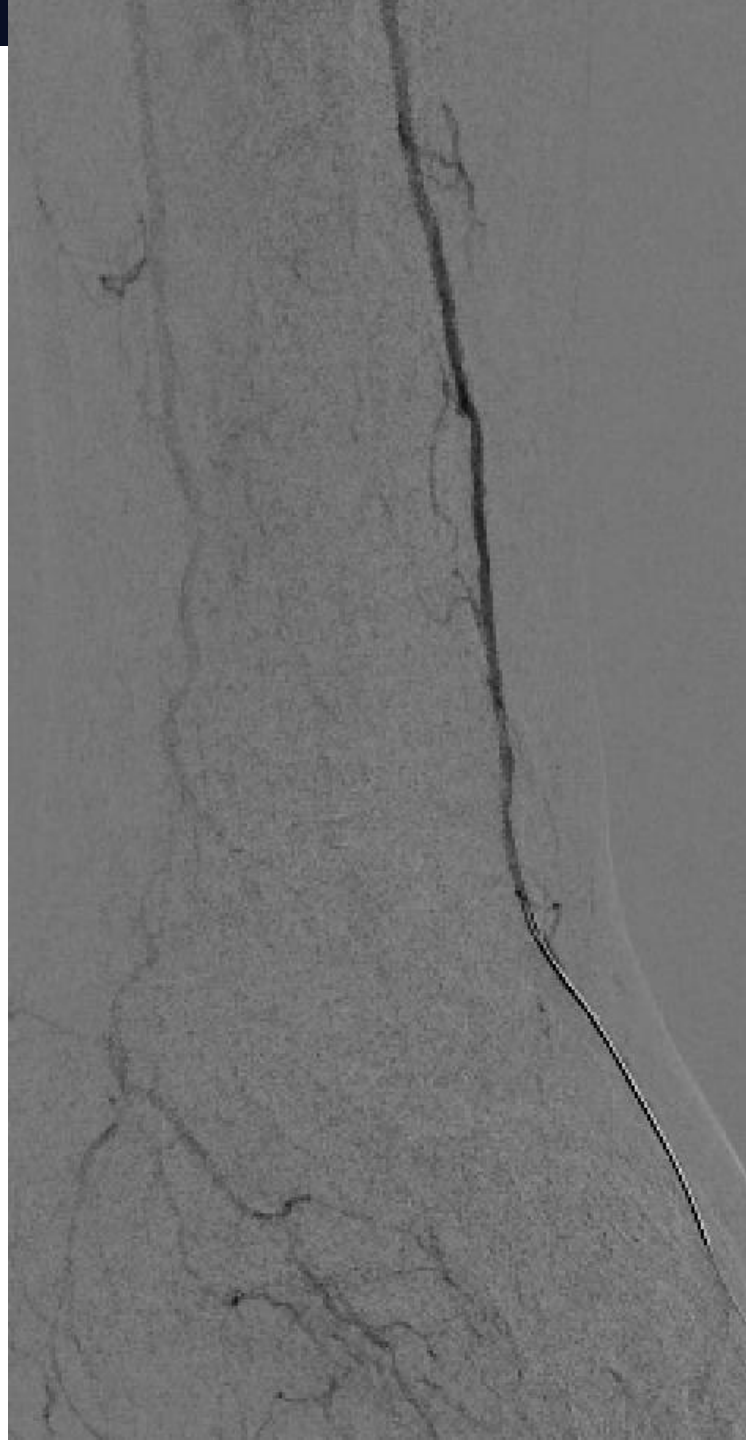




Retrograde
subintimal
wire/catheter may
create channel to
pass **Antegrade**



Completion





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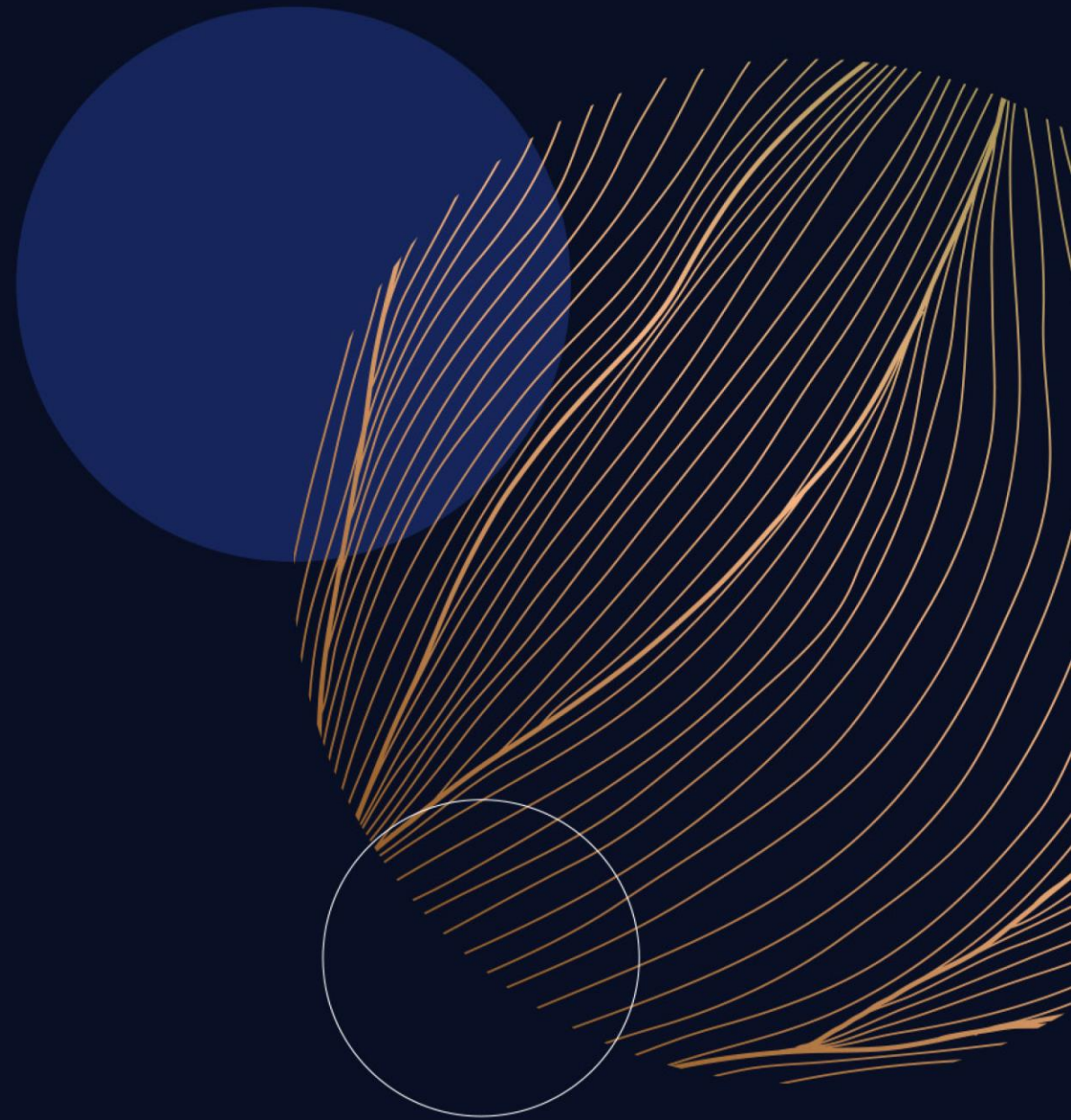
Beyond Revascularization: Wound Care and the CLTI Patient Pathway

Brett Chatman, DPM, FACFAS

Associate Professor of Clinical Surgery
Division of Plastic and Reconstructive Surgery
Hospital of the University of Pennsylvania
Philadelphia, Pennsylvania

Liz Genovese, MD, MS, FACS

Assistant Professor of Surgery
Penn Advanced Limb Preservation Program, Director at HUP
Division of Vascular Surgery and Endovascular Therapy
University of Pennsylvania
Philadelphia, Pennsylvania



Wound Care Requires a Multidisciplinary Team!



Meet the Team

Plastic Surgery

Podiatric Surgery

Vascular Surgery

Orthopedic Surgery

Infectious Disease

Endocrinology

Medicine

Nutritionist

Social Work

Hyperbarics and Wound Care

Orthotist/Prosthetist

Wound Care

- **2 Phases**
 - Initial presentation → revascularization
 - Revascularization → definitive amputation/wound healing
- **Timing is everything!**
 - TLC and hand-holding
- **Wound assessment**
- **Dry gangrene**
 - Betadine
- **Open wounds**
 - Moist wound environment
 - Gels
 - Wet to dry
- **Amputations**
 - Dermal substitutes
 - STSG
 - Non-adherent gauze
 - NPWT
- **More hand-holding**



STSG = split-thickness skin graft; NPWT = negative pressure wound therapy.

Goals of Limb Salvage

- Preserve as much of the foot as possible
- Maintain a functional extremity
- Preserve/improve patient's quality of life
- Reduce morbidity and early mortality



Tissue Necrosis: Dry and Stable?

- Post- revascularization: ~48 hours, >7 days
- Post-DVA: Wait 6-8 weeks
- Delay minor surgery/amputation
 - Until clinical evidence of tissue oxygenation and perfusion
 - Ultrasound
 - Wound assessment
- Local debridement
 - Infected tissue only
- Wound Care
 - Betadine for the first 6 weeks



Tissue Necrosis: Wet?

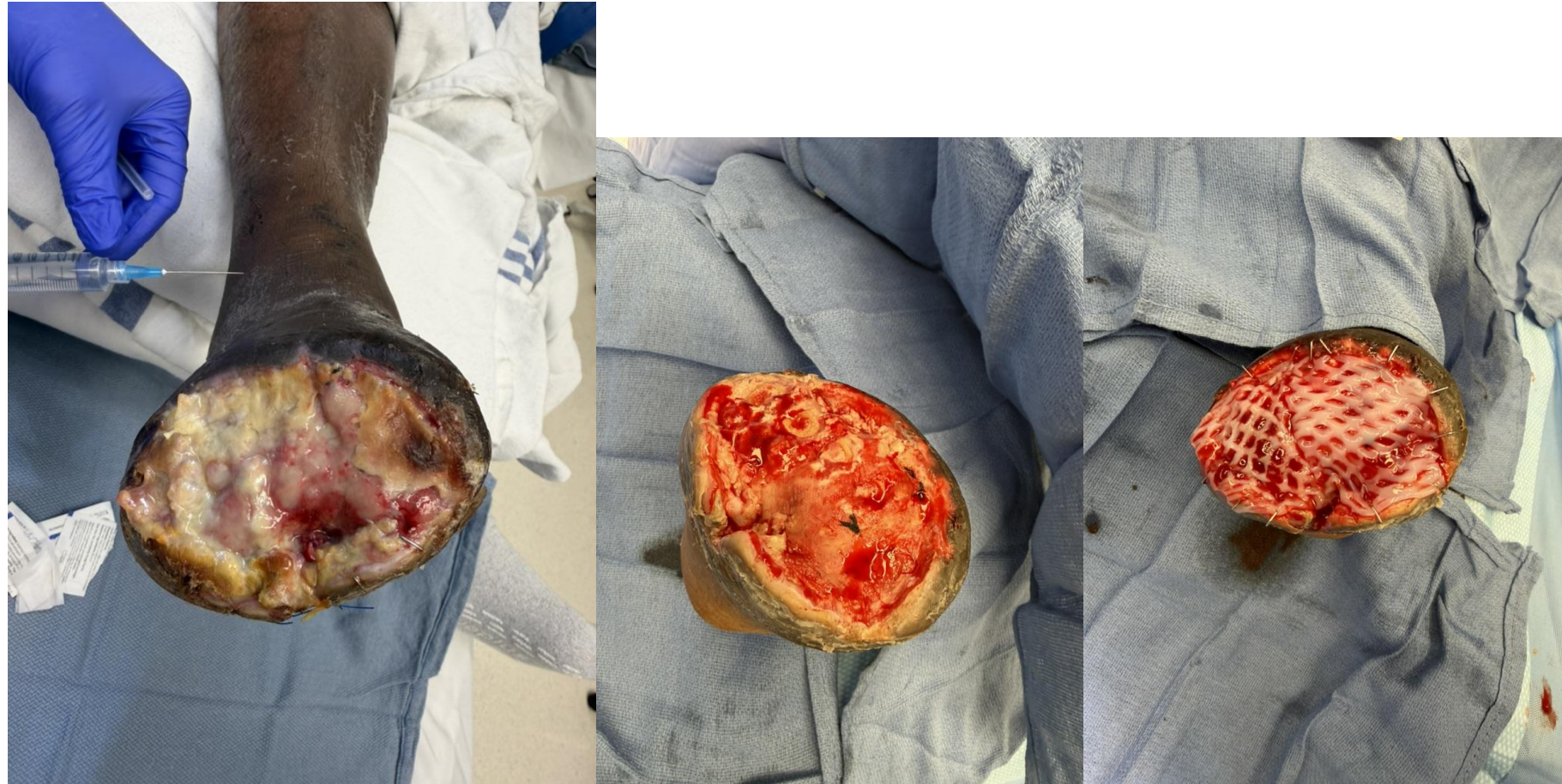
- Infection > Ischemia
- Open amputation
- Staged guillotine amputation
 - Pan-digital > TMA
 - Leave cartilage intact
- Post-DVA
 - Wait 6-8 weeks
- Wound Care
 - Wet to Dry BID
 - Saline WTD
 - Vashe



Post-Revascularization

Patient and diagnosis

- 69-year-old Male
- **PMH:** DM, PAD, HFrEF
- **Etiology:** diabetic foot infection
- **Length of time wound present:** 2 months
- **Past treatments**
 - Saline WTD



Post-Revascularization

Patient and diagnosis

- 68-year-old Female
- **PMH:** DM with PN, PAD, HTN
- **Etiology:** Sewing needle
- **Length of time wound present:** 2 months
- **Past treatments:** Patient was applying saline moistened 4x4s to her wound, followed by a dry 4x4 and woven cotton gauze



Post-Revascularization

Wound treatment/procedure

- Surgical debridement
- Endovascular revascularization
- Repeat debridement with human umbilical tissue graft applied
- NPWT 120 mm Hg continuous
- Human placental membrane re-applied weekly



Post-Revascularization

Outcome

- Time to Closure
 - Fragile closure at 20 weeks
 - Final closure picture not available due to hospital closure from COVID shutdown
 - Wound remains closed at 3 years post-op



Post-Deep Venous Arterialization

74-year-old Male with bilateral foot wounds

- PMH: PAD, chronic diastolic heart failure, angina, CAD s/p CABG x3, DM II, GERD, HLD, HLN, stroke, TIA, bilateral foot gangrene
- Journey
 - Left
 - DVA: 7/1/24
 - Open TMA: 9-11-24
 - TMA with human placental membrane: 9-13-24
 - Right
 - Right toe amputation: 12-17-2024
 - R DVA with IVL of PT and venoplasty of LPV and MMV 2/13/25



CAD = coronary artery disease; s/p = status-post; GERD = gastroesophageal reflux disease; HLD = hyperlipidemia; HLN = hyperlipidemia; TIA = transient ischemic attack; PT = posterior tibial; LPV = left portal vein; MMV = medial male vein.

Post-Deep Venous Arterialization



First Operative Trip



Second Operative Trip



Post-Deep Venous Arterialization



Post-Deep Venous Arterialization



Post-Deep Venous Arterialization





Patient: EE 053560348
April 9, 2025
20 weeks



Patient: EE 053560348
May 8, 2025
Right side

Patient: EE 053560348
February 13, 2025
Right DVA

- **Journey**

- **Left lower extremity**

- DVA: 7/1/24
 - Open TMA: 9-11-24
 - TMA with human placental membrane: 9-13-24
 - Date Healed: 1/30/2025
 - Total Time: 20 weeks

- **Right lower extremity**

- Right toe amputation: 12-17-2024
 - Right DVA with IVL of PT and venoplasty of LPV and MMV 2/13/25





Patient: EE 053560348



Patient: EE 053560348

Post-Deep Venous Arterialization



Post-Deep Venous Arterialization

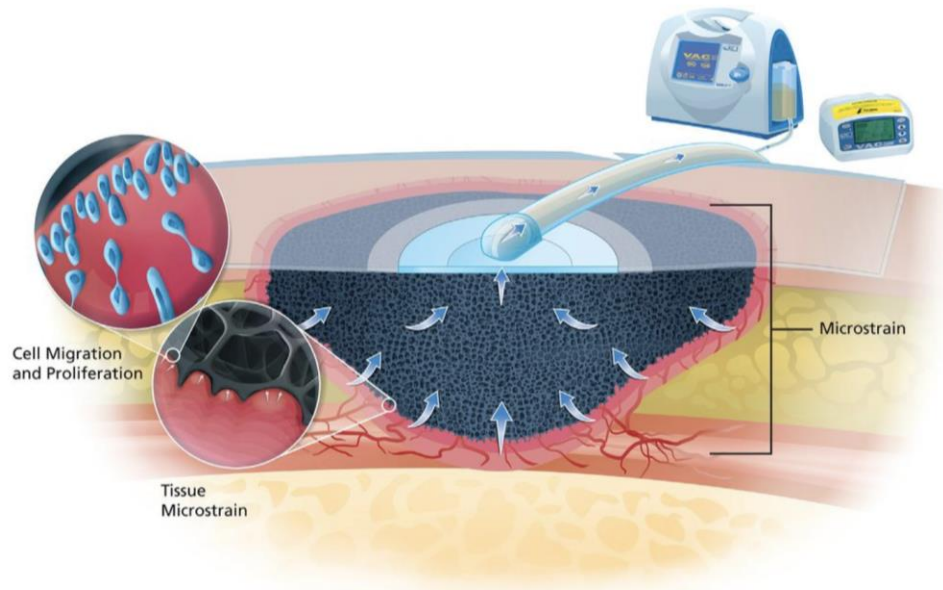


Post-Deep Venous Arterialization





Negative Pressure Wound Vac



- **American Diabetes Association**
 - Recommended in wounds that failed standard wound care
- **International Working Group on the Diabetic Foot (IWGDF)**
 - Consider use in complicated post-surgical wounds
- **Journal of Medicine: 2022**
 - Meta Analysis
 - 943 patients with DFU
 - NPWT associated with improved wound healing

DFU = diabetic foot ulcer.

Mihalache O, et al. *J Clin Med.* 2025;14(20):7193. IWGDF Guidelines. Accessed January 12, 2026. <https://iwgdfguidelines.org/wp-content/uploads/2023/07/IWGDF-Guidelines-2023.pdf>. Armstrong DG, et al. *JAMA.* 2023;330(1):62-75. Kundu A, et al. *Int J Res Orthopaedic.* 2018;4(5):803-807.

Weightbearing



- Get them up!
 - Increased NWB = increased time to reconditioning
- No vascular contraindications
- Desensitize quicker
- Decreased swelling

Team Approach!



Beyond Revascularization

Patient Optimization

Diabetes Management

Nutrition Consult

Infectious Disease

Smoking Cessation

Psychology

HBOT

O&P



CardioVascular
Learning Network

CME

Q&A

