# IVUS Applications
## in the Veins and Arteries

A Case-Based Symposium

Supported by an educational grant from Philips

# Faculty

- **Mary Costantino, MD, FSIR** — Medical Director, Advanced Vascular Centers; Portland, OR, Eugene, OR
- **Kush Desai, MD, FSIR** — Professor of Radiology, Surgery, and Medicine, Northwestern University Feinberg School of Medicine; Chicago, IL
- **Kumar Madassery, MD** — Associate Professor of Vascular and Interventional Radiology, Director of Advanced Vascular & Interventional Radiology Fellowship, Director of Peripheral Vascular Interventions, CLTI & Limb Preservation Program and the IVC Filter Clinic, Rush University Medical Center, Rush Oak Park Hospital; Chicago, IL
- **Erin H. Murphy, MD, FACS** — Director, Venous and Lymphatic Institute, Sanger, Atrium Health; Charlotte, NC

# Faculty Disclosures

- **Mary Costantino, MD, FSIR** — *Consultant, Speakers Bureau:* Abbott; Asahi Intecc; Merit; Philips; Siemens; *Patent holder, Investor, Developer:* Moonrise
- **Kush Desai, MD, FSIR** — *Consultant:* Asahi Intecc Medical EnVVeno Medical; Terumo; Varian; W.L. Gore; *Consultant, Speakers Bureau:* Becton Dickinson; Boston Scientific; Cook Medical; Medtronic; Penumbra; Philips; Tactile Medical
- **Kumar Madassery, MD** — *Consultant:* Abbott Vascular; Argon; Cook; Philips; Penumbra Shockwave
- **Erin H. Murphy, MD, FACS** — *Consultant:* BD; Boston Scientific; Gore; Medtronic; Philips; *Research Support:* BD; Gore; Medtronic; Mercator; *Stock Ownership:* Vector Vascular; Synervention

# Disclosures

The faculty have been informed of their responsibility to disclose to the audience if they will be discussing off-label or investigational use(s) of drugs, products, and/or devices (any use not approved by the US Food and Drug Administration)

- Applicable CME staff have no relationships to disclose relating to the subject matter of this activity
- This activity has been independently reviewed for balance

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# Learning Objectives

- Understand the applications for intravascular imaging in both arteries and veins
- Apply intravascular ultrasound (IVUS) imaging techniques to practice
- Comprehend and apply global guidelines for venous and arterial diseases

IVUS = intravascular ultrasound.

Where We Are:

# Venous IVUS Updates and NIVL Guidelines

**Erin H. Murphy, MD, FACS**
Director, Venous and Lymphatic Institute
Sanger, Atrium Health
Charlotte, NC

# Venous Stent Placement

- Access and Crossing
- Imaging: Venography, IVUS, and Decision Making
- Vessel Prep: Pre-Dilation
- Stent Placement
- Post-Imaging: Venogram / IVUS

# Procedural Steps

Procedure:

- Access and Recanalization
- Imaging: Venography and IVUS
- Vessel Prep: Pre-dilation
- Proper Stenting Technique
- Post-imaging: Venogram / IVUS

- Confirm Wire Crossing

# Procedural Steps

Procedure:

- Access and Recanalization
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- Confirm Wire Crossing
- Assess Disease Severity, Extent
- Define Anatomical Landmarks
- Determine Landing Zones
- Stent Sizing

# Procedural Steps

Procedure:

- Access and Recanalization
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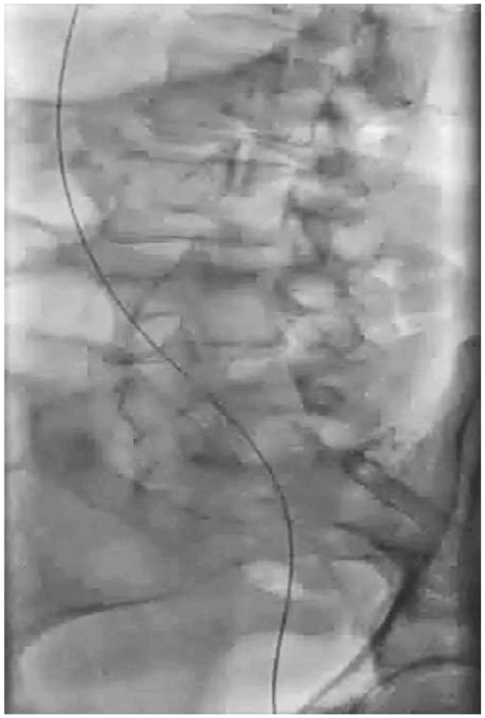
- Confirm Wire Crossing
- Assess Disease Severity, Extent
- Define Anatomical Landmarks
- Determine Landing Zones
- Stent Sizing
- Confirm Stent Apposition/ Lesion Coverage

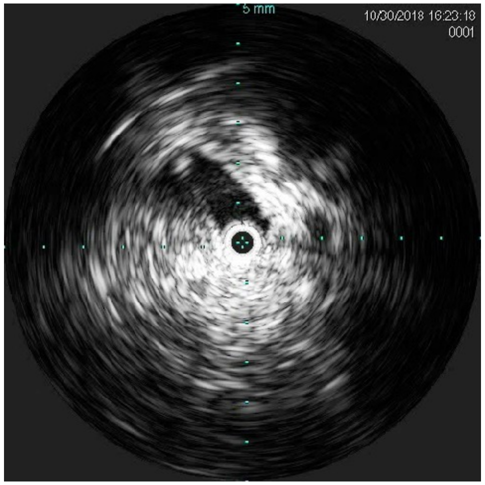
# What Does This Look Like ...

# Confirm Wire Path

YES!

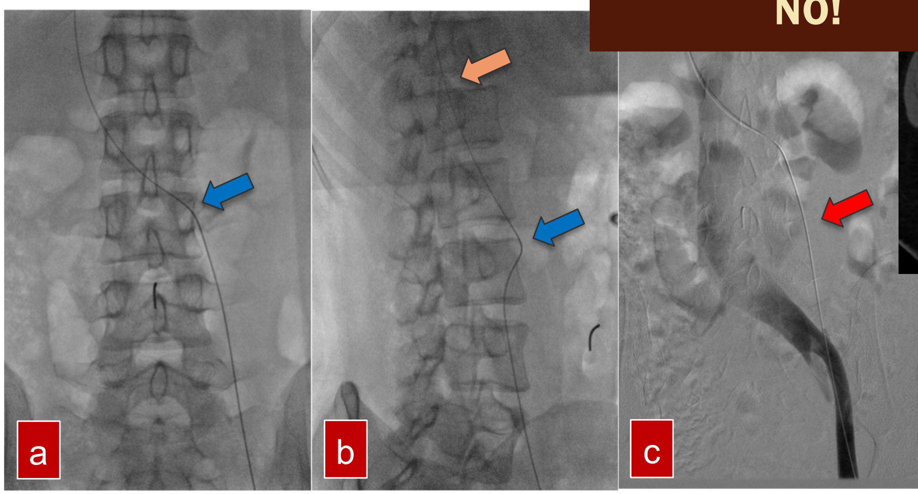


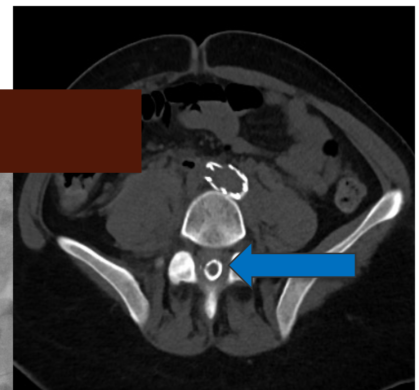
YES!



# Confirm Wire Path

NO!



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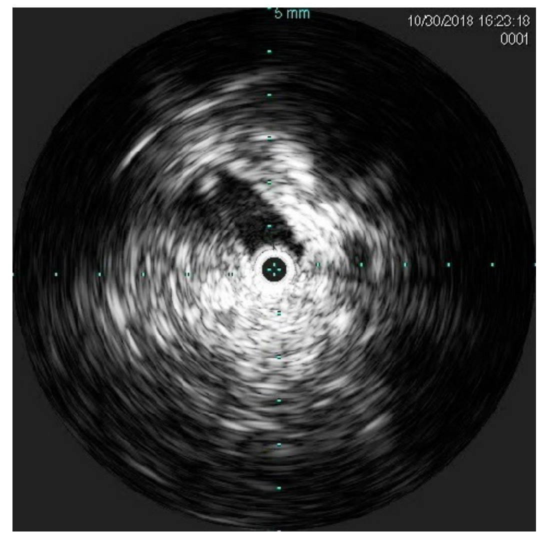
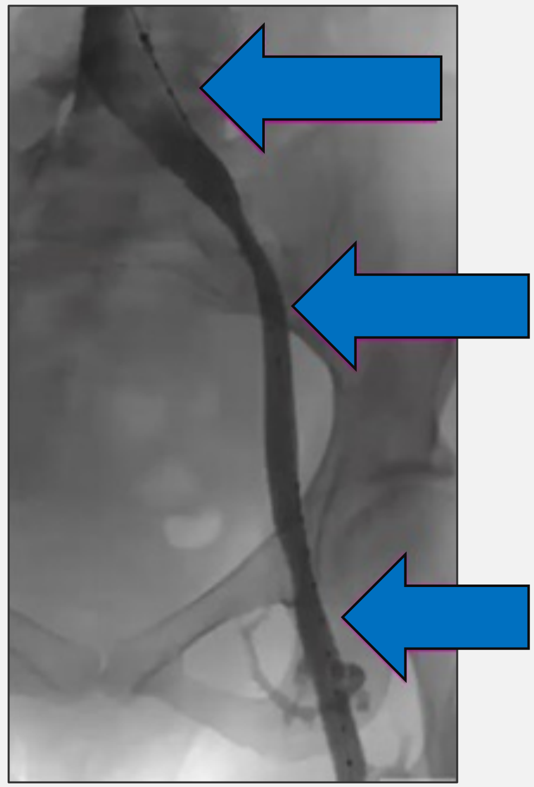
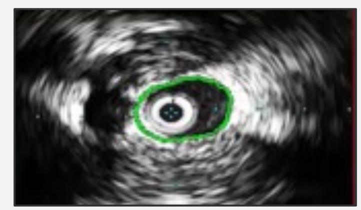


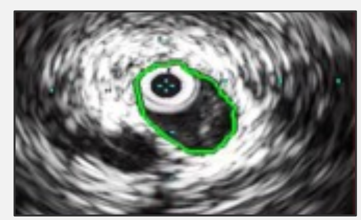
# Determine Degree of Stenosis



CIV: $30mm^2$, 88% stenosed



EIV: $68mm^2$, 55% stenosed



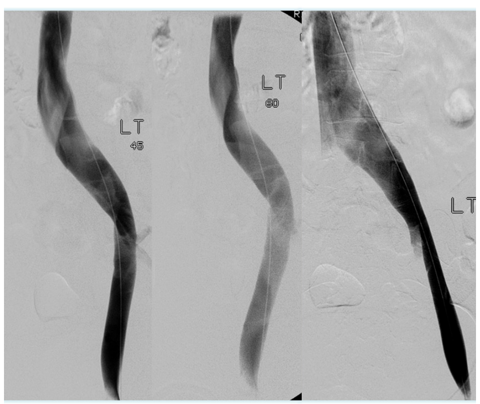
CFV: $58mm^2$, 54% stenosed

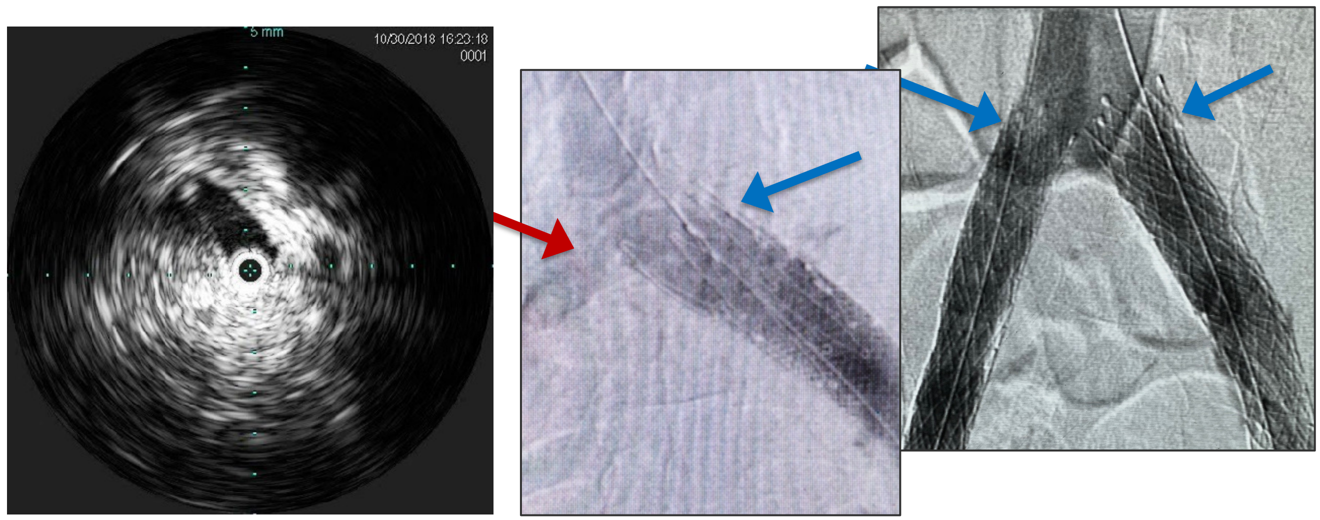
# Determine Anatomic Landmarks: Iliac Confluence

**** MUST LAND HEALTHY TO HEALTHY ****

**Preserving the Iliac Confluence and Femoral/Profunda Confluence**

Venogram can differ from IVUS by a full vertebral body.

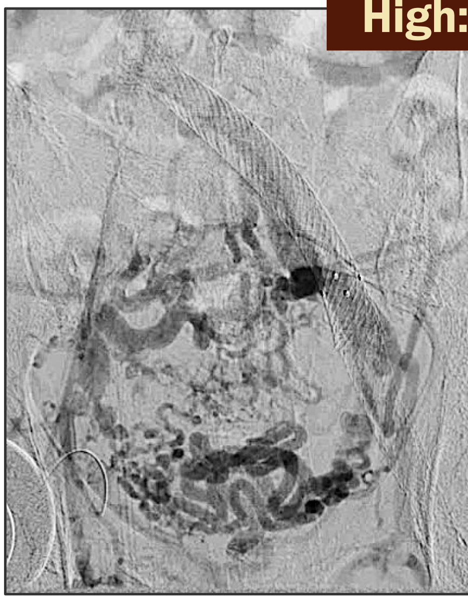



- Move IVUS UP& DOWN to see contralateral iliac leave and join
- Mark location of confluence on the fluoro screen for reference

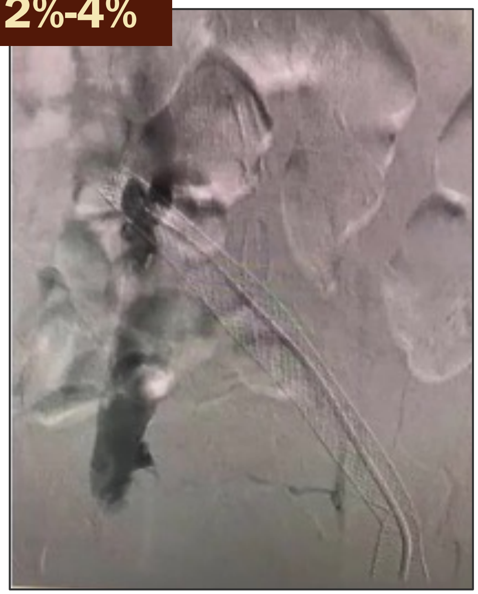
# Cranial Landing Zone Challenges

**High: 2%-4%**



**Contralateral DVT**

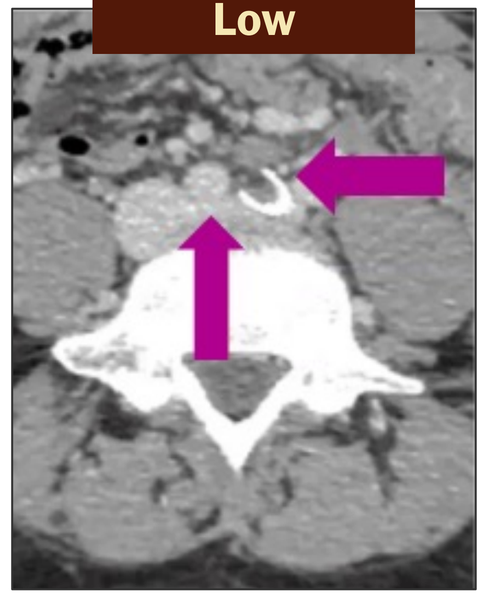
If stent is placed too high into IVC, it can jail contralateral iliac flow as the stent develops a neointimal lining.



**Stent Erosion**

If stent is placed too high into IVC and against the contralateral IVC wall, it has the potential to cause erosion through the vessel.

**Low**



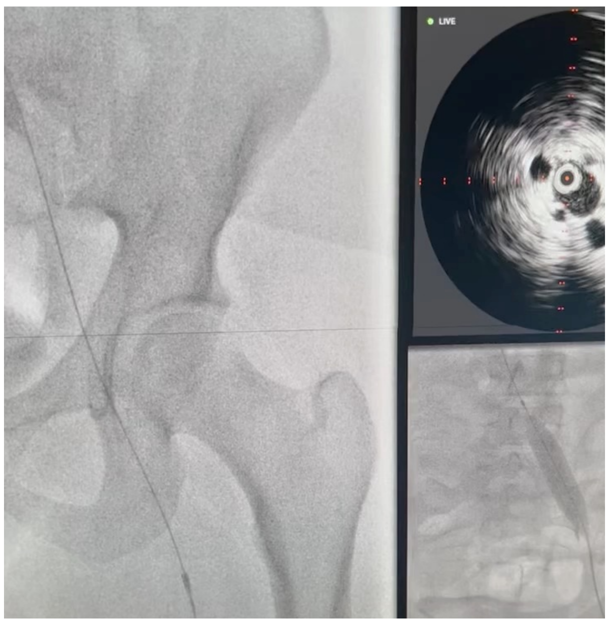
**Missed Lesion "Watermelon Seed"**

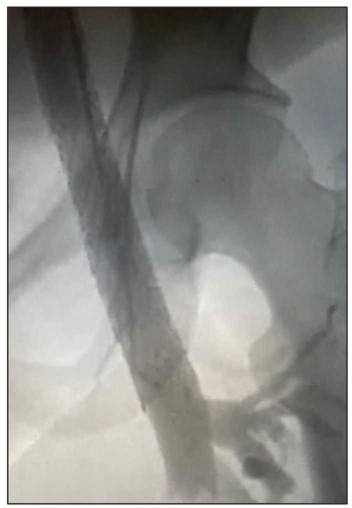
If stent is placed too low, it has the potential to caudally displace, in this instance it eroded through the vessel after displacement because of the poor stent positioning.

# Determine Anatomic Landmarks: Profunda

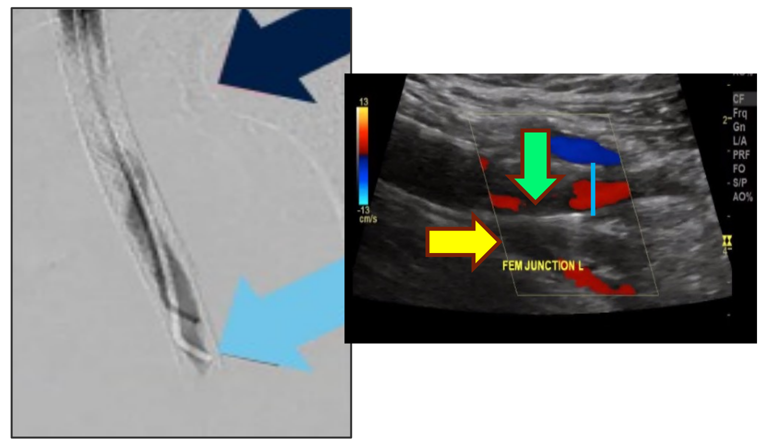
- Generally at the top of the lesser Trochanter
- Use IVUS to identify and mark on flouro

**Tip:** Do not confuse with bifid femoral



**Stents across profunda**

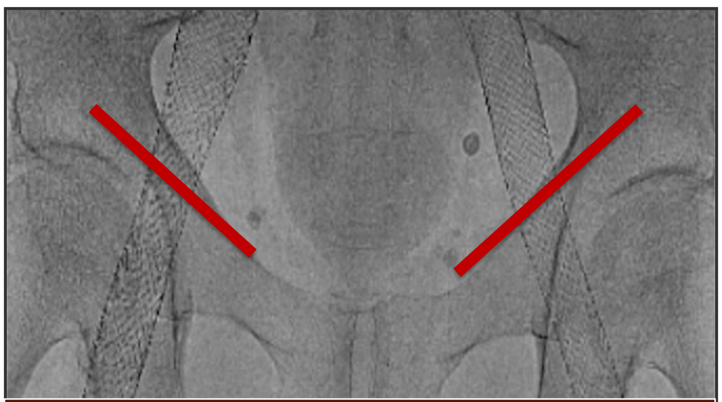


# Determine Stent Landing Zone

**** MUST LAND HEALTHY TO HEALTHY ****

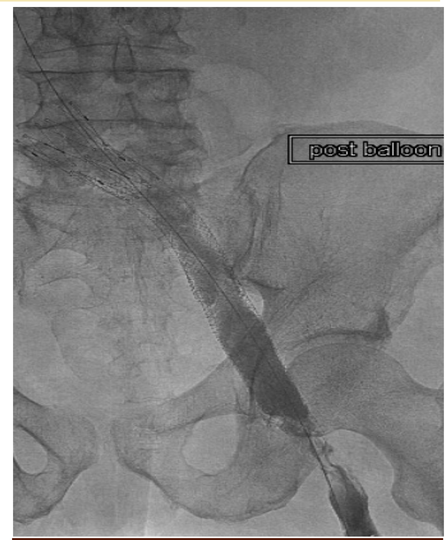
**Preserving the Iliac Confluence and Femoral/Profunda Confluence**

**Tip:** Do not leave disease between stent edge and profunda



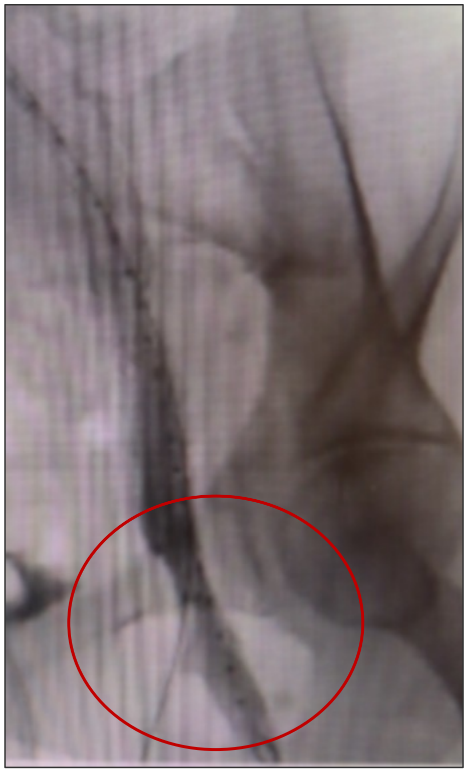
Tip: Required in almost all PTS patients

Stent Occlusion

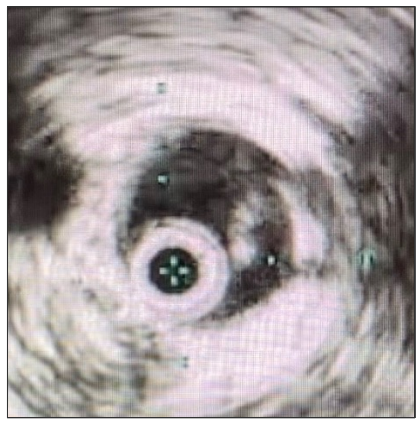



Post: PMT / Lysis

# Errors in Landing Zones

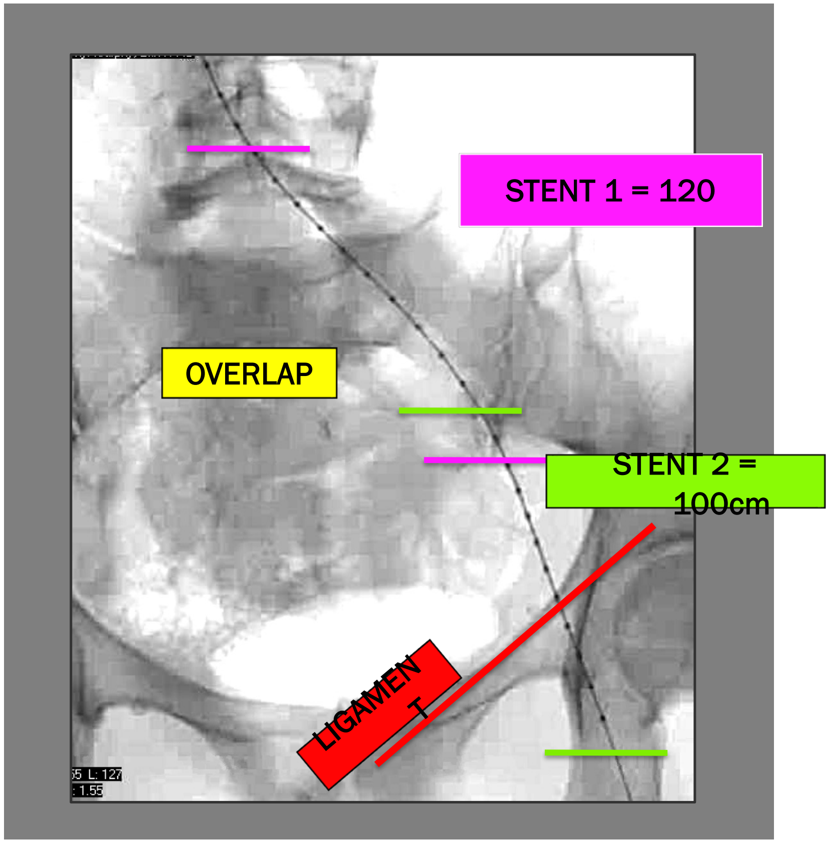


Below Stent

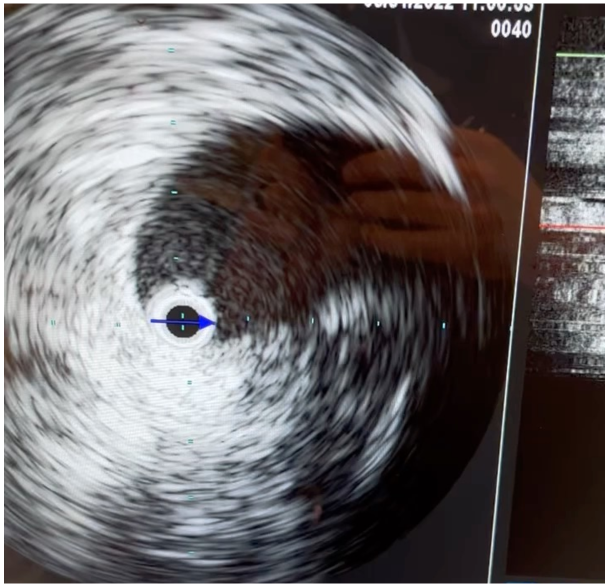


# Determine Stent Lengths and Diameters

- INFLOW to OUTFLOW
- Keep overlap in straight portion of the EIV
- Avoid overlap under ligament
- 2mm OVERLAP
- NO ISOLATED SHORT STENTS! No stents <100
- IVUS for Reference Vessel Size: 2 mm oversize



# Completion Imaging

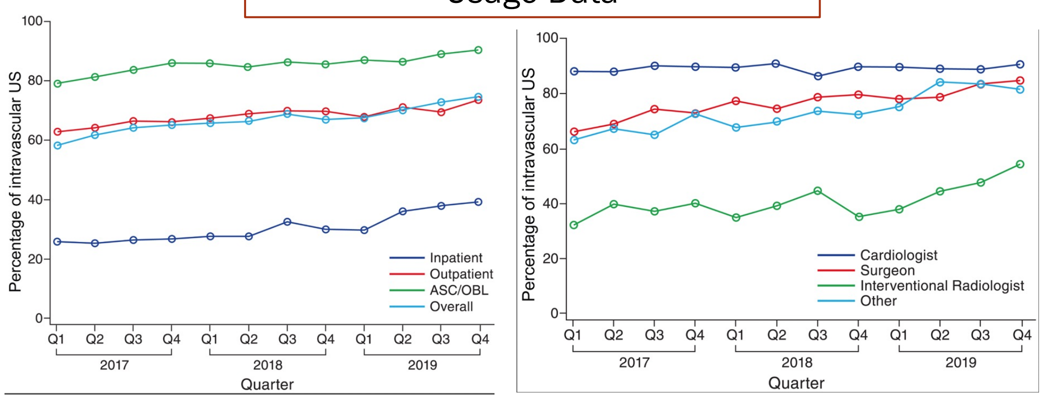


# Utilization of and Outcomes Associated with Intravascular Ultrasound during Deep Venous Stent Placement among Medicare Beneficiaries

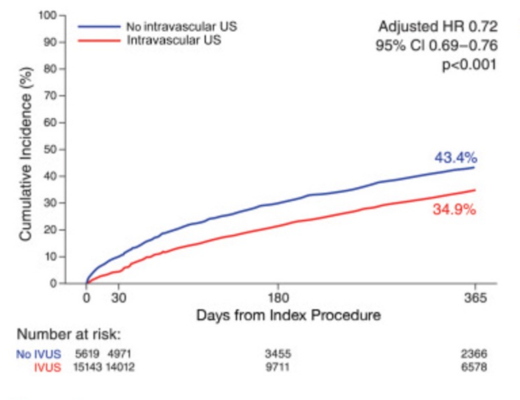
Sanjay Divakaran [1], Mark H Meissner [2], Maureen P Kohi [3], Siyan Chen [4], Yang Song [4], Beau M Hawkins [5], Kenneth Rosenfield [6], Sahil A Parikh [7], Eric A Secemsky [8]

- Temporal trends in Medicare beneficiaries undergoing IVUS guided venous stent placement

Usage Data




Cumulative Incidence
of primary composite outcome




*J Vasc Interv Radiol.* 2022;33(12):1476-1484.e2.

# Experts Agree…

# Appropriate Use of Intravascular Ultrasound During Arterial and Venous Lower Extremity Interventions

**Consensus; NOT GUIDELINES**

Eric A. Secemsky, MD,[a,b,c] Ramya C. Mosarla, MD,[d] Kenneth Rosenfield, MD,[e] Maureen Kohi, MD,[f] Michael Lichtenberg, MD,[g] Mark Meissner, MD,[h] Ramon Varcoe, MBBS,[i,j,k] Andrew Holden, MBChB,[l] Michael R. Jaff, DO,[b,m] David Chalyan, MD,[n,o] Daniel Clair, MD,[p] Beau M. Hawkins, MD,[q] Sahil A. Parikh, MD[r]

| | Pre-intervention | | | | | Intra-procedure | | Procedure optimization |
|---|---|---|---|---|---|---|---|---|
| | Lesion characteristics | Lesion severity | Filling defects | Vessel sizing | Minimizing contrast | Determination of next therapeutic step | Vessel sizing for device | Stent optimization/post-dilation |
| **Venous** | Green | Green | Green | Green | Green | Green | Green | Green |

| Score | Appropriateness |
|---|---|
| 7-9 | Appropriate for specific indication |
| 4-6 | May be appropriate for specific indication |
| 1-3 | Rarely appropriate for specific indication |

Presented by Dr. Eric Secemsky at VIVA 2021

Secemsky E, et al, *J Am Coll Cardiol Intv*. 2022;5(15):1558-1568.

JSCAI
The official journal of the Society for Cardiovascular Angiography & Interventions

Journal of the Society for Cardiovascular Angiography & Interventions 3 (2024) 101205

Standards and Guidelines

# Intravascular Ultrasound Use in Peripheral Arterial and Deep Venous Interventions: Multidisciplinary Expert Opinion From SCAI/AVF/AVLS/SIR/SVM/SVS

Eric A. Secemsky, MD, MSc[a,b,*], Herbert D. Aronow, MD, MPH[c,d], Christopher J. Kwolek, MD, MBA[b,e], Mark Meissner, MD[f], Patrick E. Muck, MD[g], Sahil A. Parikh, MD[h], Ronald S. Winokur, MD[i], Jon C. George, MD[j], Gloria Salazar, MD[k], Erin H. Murphy, MD[l], Mary M. Costantino, MD[m], Wei Zhou, MD[n], Jun Li, MD[o], Robert Lookstein, MD[p], Kush R. Desai, MD[q]

| | Iliofemoral Vein |
|---|---|
| **Preintervention scenarios** | |
| Lesion characteristics | A (8) |
| Occlusion | N/A |
| Plaque morphology | N/A |
| Ambiguous lesion/severity | A(9) |
| Filling defects | A (9) |
| Vessel sizing | A (9) |
| Minimizing contrast | A (9) |
| **Intraprocedure scenarios** | |
| Location of crossing track | N/A |
| Determination of next therapeutic step | A (9) |
| Vessel sizing for device | A (9) |
| **Postintervention optimization scenarios** | |
| Residual stenosis/plaque after debulking | N/A |
| Stent optimization/post-dilation | A (9) |
| Dissection detection | N/A |

# Editor's Choice – Management of Lower Extremity Venous Outflow Obstruction: Results of an International Delphi Consensus

> Eur J Vasc Endovasc Surg. 2024 Feb;67(2):341-350.

Stephen A Black [1], Manjit Gohel [2], Rick de Graaf [3], Paul Gagne [4], Mitchell Silver [5], Bruce Fleck [6], Lawrence V Hofmann [7]; International Venous Delphi Consensus Study Group

Consensus reached on IVUS for:

- Degree of stenosis: Area measurements for intervention threshold determination
- Residual thrombus burden
- IVUS is needed for accurate determination of lesion length and stent landing zones
- Luminal gain
- Lesion coverage
- Stent expansion / apposition

Black S, et al, *Eur J Vasc Endovasc Surg*. 2024;67(2):341-350.

## Society of Interventional Radiology Position Statement on the Management of Chronic Iliofemoral Venous Obstruction with Endovascular Placement of Metallic Stents

Suresh Vedantham [1], Ido Weinberg [2], Kush R Desai [3], Ronald Winokur [4], Kanti Pallav Kolli [5], Sheena Patel [6], Kari Nelson [7], William Marston [8], Ezana Azene [9]

- Recommends use of IVUS as an adjunct to catheter venography to increase accuracy of identifying and characterizing iliac vein lesions compared to venography alone
- **Caution:** Advised when using to diagnose NT lesions as technical and patient factors can influence venous caliber lumen estimation

Although IVUS clearly adds complementary information and enhances overall insight, care should be exercised in relying on supine IVUS assessments as a sole method of evaluating iliac vein lesions.

9. In most patients undergoing ETR for acute iliofemoral DVT, the use of IVUS along with venography is suggested to improve assessment of the veins after thrombus removal (**Level of Evidence C, Strength of Recommendation Weak**).

Vedantham S, et al, *J Vasc Interv Radiol.* 2023;34(10):1643-1657.e6.

2024

# Circulation: Cardiovascular Interventions

## Consensus Statement on the Management of Nonthrombotic Iliac Vein Lesions From the VIVA Foundation, the American Venous Forum, and the American Vein and Lymphatic Society

Kush R. Desai, MD; Saher S. Sabri, MD; Steve Elias, MD; Paul J. Gagne, MD; Mark J. Garcia, MD; Kathleen Gibson, MD; Misaki M. Kiguchi, MD; Santhosh J. Mathews, MD; Erin H. Murphy, MD; Eric A. Secemsky, MD; Windsor Ting, MD; Raghu Kolluri, MD

# IMAGING CONSIDERATIONS FOR NIVL DIAGNOSIS

Consensus recommendations:

1. In a patient considered for NIVL treatment, an invasive diagnosis with the complementary use of venography and IVUS is recommended.
2. Dynamic IVUS evaluation of NIVL is recommended; this includes breath hold and maneuvers that increase intra-abdominal pressure. Fixed lesions are more likely to be pathological, whereas dynamic compressions vary with such maneuvers and are less likely to be pathological.
3. Using thresholds of >50% area reduction or >61% diameter stenosis on IVUS at the NIVL is correlated with symptom improvement following venous stent placement. Intervention below the stated thresholds is not recommended.
4. The use of venography thresholds alone for the diagnosis and treatment of NIVL is less well established.
5. Axial imaging with CT or magnetic resonance imaging can help confirm the presence of anatomy that may be associated with a clinically significant NIVL. The final diagnosis and intention to treat, however, are based on clinical evaluation and venography/IVUS.

# TECHNICAL CONSIDERATIONS FOR NIVL STENT PLACEMENT

Consensus recommendations:

1. The choice of stent size and length in NIVL should depend on IVUS for diameter/length measurements with complementary fluoroscopy for length measurements.
2. Stent migration in NIVL can have devastating consequences. Measures to mitigate the possibility of stent migration and complications, including appropriate device diameter and length, are mandatory.
3. Although the approach to selecting stent diameter in NIVL is variable, sizing based on the normal reference vessel (eg, the external iliac vein) is generally recommended. In the presence of a significant compression, prestenotic dilation may be present and should not be used for sizing.
4. Stents for NIVL should be extended into the straight portion of the external iliac vein to limit stent migration and other complications.

Stent sizing differs based on design. Nitinol stents are more likely to reach their rated diameter compared with elgiloy stents. The final diameter of elgiloy stents is a function of the deployed length and adequate fixation at the ends of the stent. Length determinations can be aided with the use of marker catheters or markings on IVUS catheters during fluoroscopy. Measurement of vessel diameters is most accurate utilizing IVUS, as previously noted.

# Summary

- IVUS is an essential tool for deep venous stenting and is associated with improved outcomes
- There is consensus on the importance of IVUS at all steps of the procedure
- Guidelines are a bit behind consensus but support the use of IVUS
- More progress to make: Technology, Reimbursement, Guidelines

# Thank You!

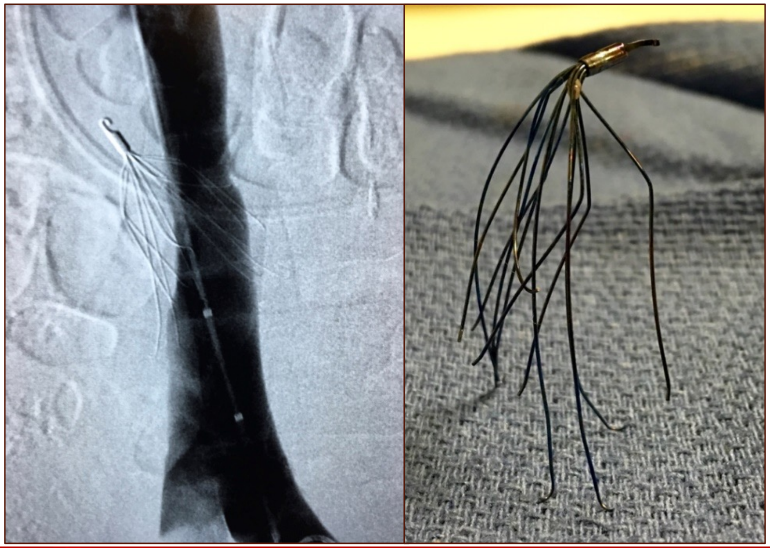
**Erin H. Murphy, MD FACS**
Director, Venous and Lymphatic Program
Sanger Heart and Vascular, Atrium Health, Charlotte, NC
erinmurphy79@gmail.com
214-384-4087 (cell)

# IVC Filter Retrieval with Laser

Kush Desai, MD, FSIR
Professor of Radiology, Surgery, and Medicine
Northwestern University Feinberg School of Medicine
Chicago, IL

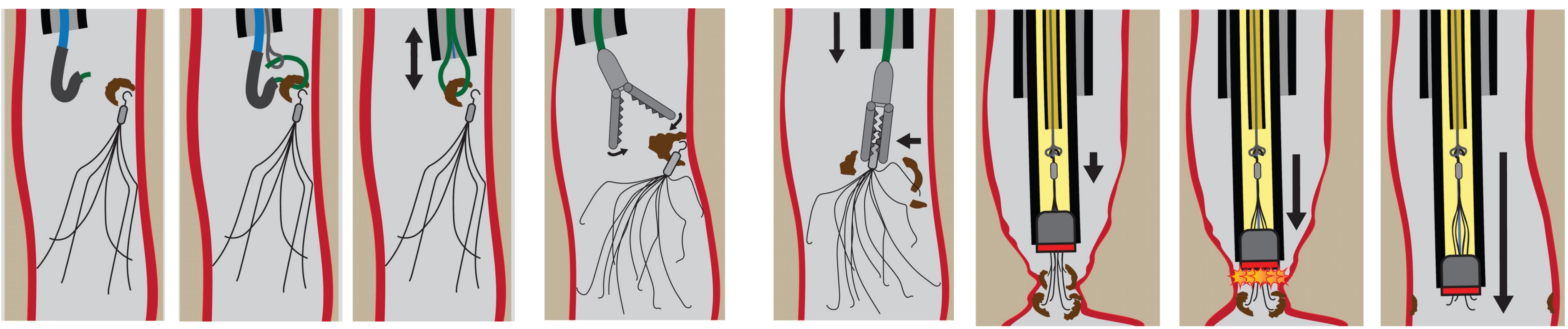
# FDA Safety Communication 2014

Implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed.



# Advanced Techniques

- Advanced techniques have had a significant impact on retrieval success
- Techniques include loop wire snare, rigid endobronchial forceps, and excimer laser sheath-assisted ablation

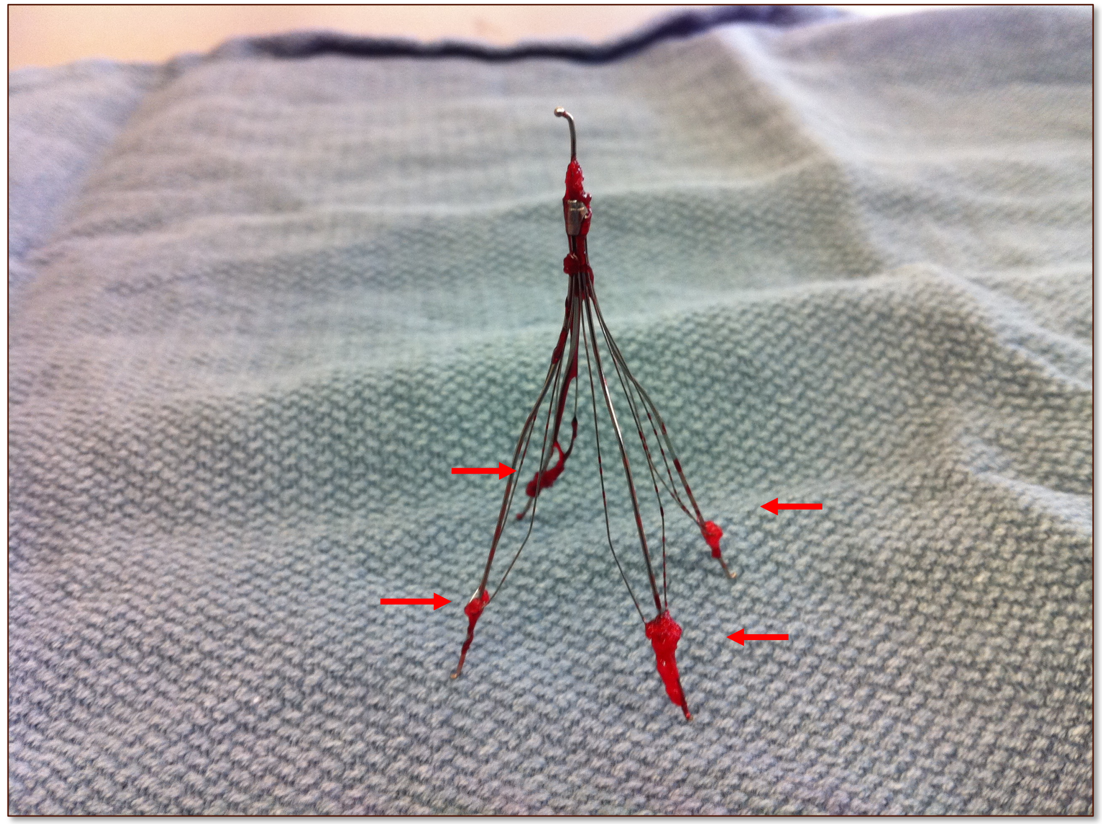


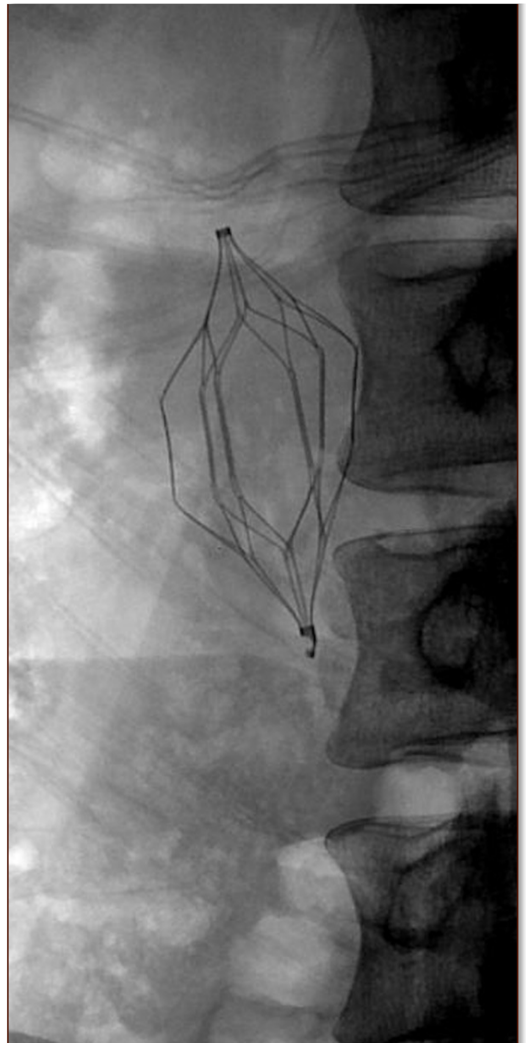
- IVC filter struts incorporated into caval wall from extended implantation
- Would require large forces to detach with standard sheath/snare technique

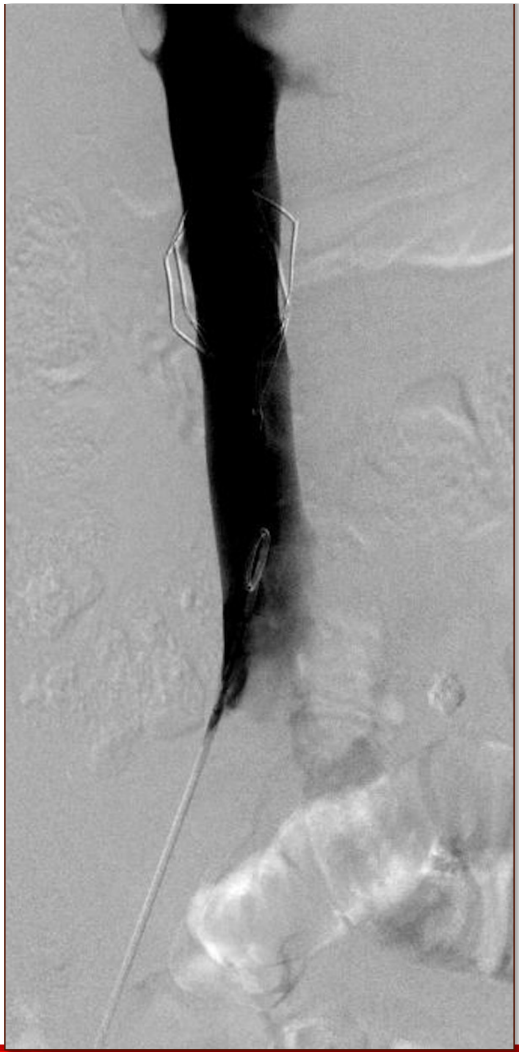
# Excimer Laser Technology

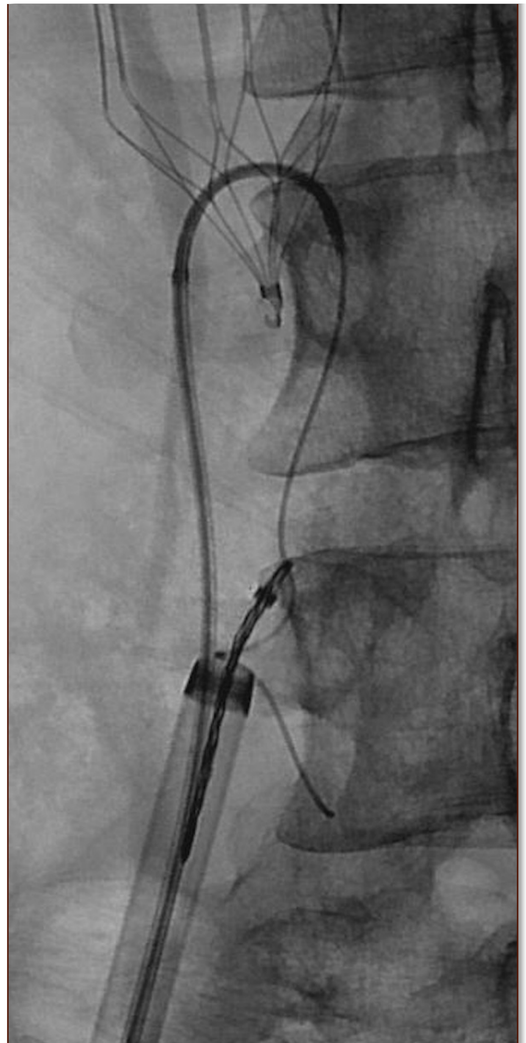
- Ultraviolet cool laser
- Laser technology uses photothermal issue ablation
- Laser mechanism of action does not damage the IVC filter
- Laser has penetration depth of 50 microns (less than the width of a human hair)
- Most effective when equal traction / counter traction is applied
- Application of laser allows reduction of forces needed to retrieve the foreign body

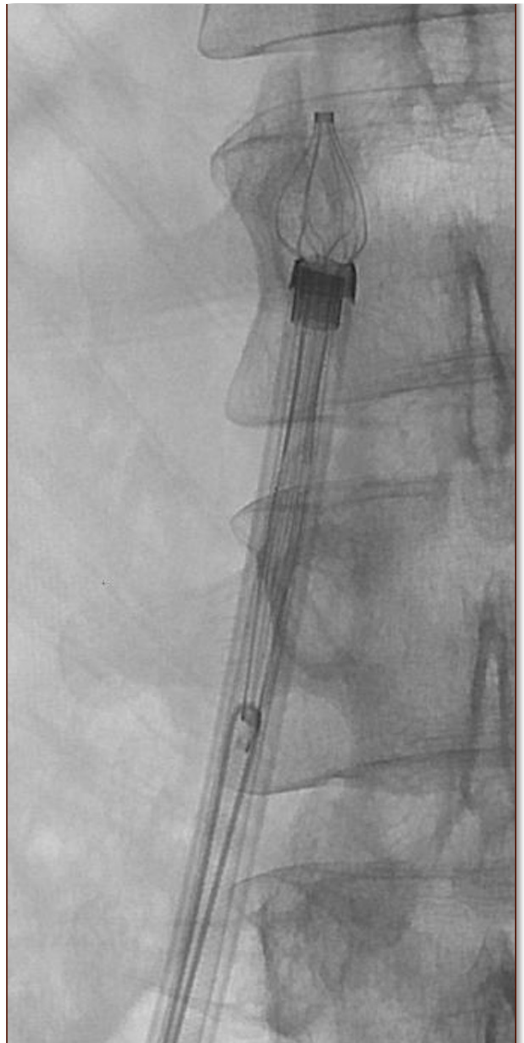
- Note fibrin at filter implantation site; laser used to ablate this tissue and permit release of the filter

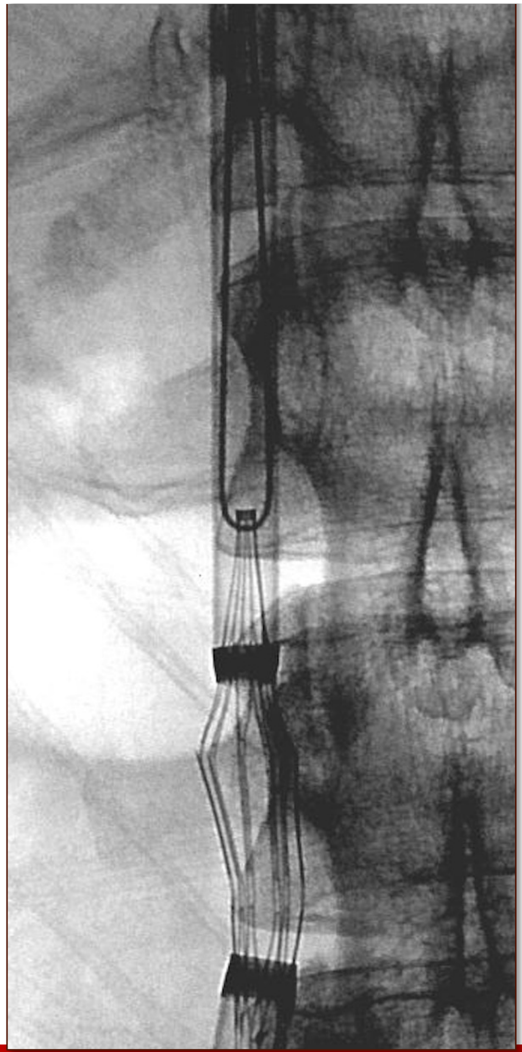


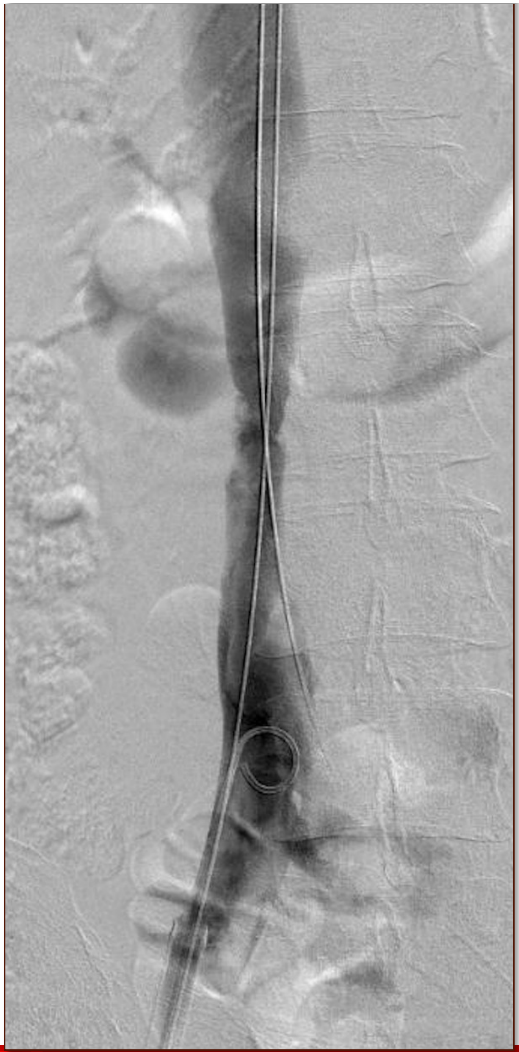


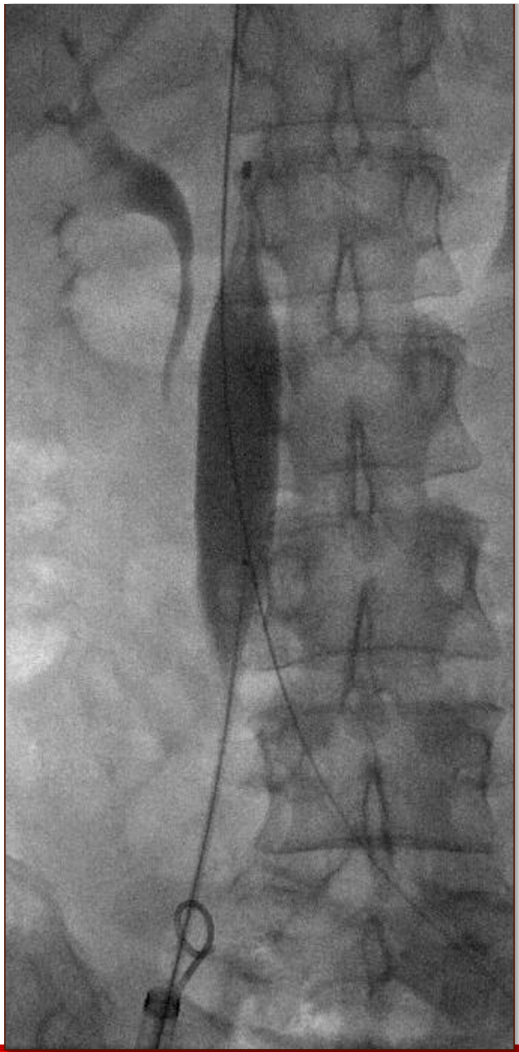


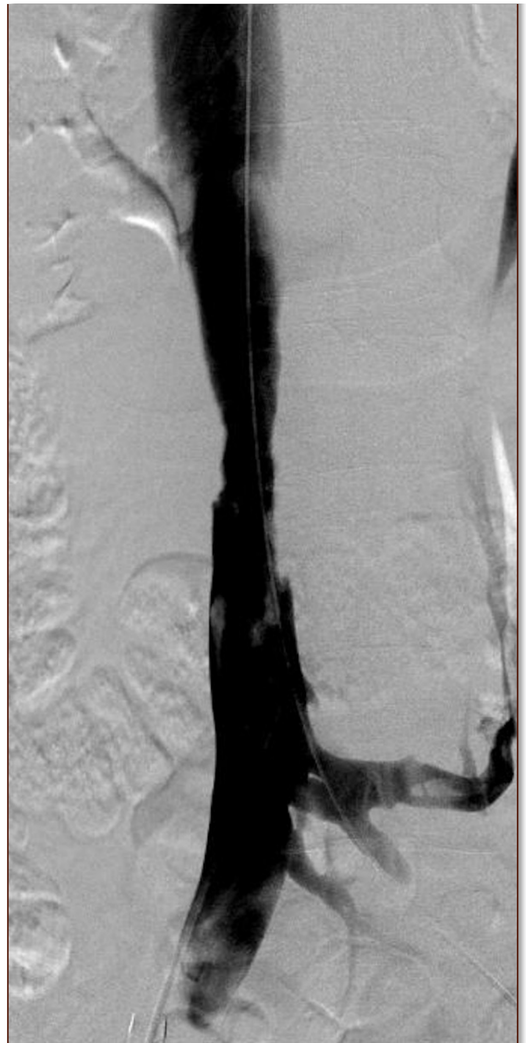












# Single-Center Studies Demonstrate Safety and Efficacy IVC Filter Removal with Excimer Laser Sheath

A 500-patient single-center study showed laser-assisted retrievals have low major complication rate (2.0%) and high success rate (98.7%) [1]

441-patient single-center study[2] showed low major adverse event rate (0.6%) and high technical success (96%) [2]


Journal of the American Heart Association

ORIGINAL RESEARCH

Laser-Assisted Removal of Em… Cava Filters: A First-In-Human Trial in 500 Patients Refractory … Force Retrieval

William T. Kuo, MD; Ankur A. Doshi, MD; John M. Ponting, MD; Jarrett K. R…; Lawrence V. Hofmann, MD

10.1161/JAHA.119.017916

Journal of the American Heart Association

ORIGINAL RESEARCH

Excimer Laser Sheath–Assisted Retrieval of “Closed-Cell” Design Inferior Vena Cava Filters

Kush R. Desai, MD; Nicholas Xiao, MD; Riad Salem, MD, MBA; Jennifer K. Karp, RN; Robert K. Ryu, MD; Robert J. Lewandowski, MD

J Am Heart Assoc. 2020;9:e017240. DOI: 10.1161/JAHA.120.017240

**No multi-center studies to date have evaluated the broader safety and success, limiting the generalizability of the technique**

1. Kuo WT, et al. *J Am Heart Assoc.* 2020;9(24). 2. Desai KR, et al. *J Am Heart Assoc.* 2020;9(17).

# Purpose and Design

## Objective

- To evaluate the safety and performance utilizing excimer laser sheath assisted retrieval of embedded IVC filters
- To understand operator experience and learning curve when using laser sheath for IVC filter retrieval

## Study Design

- Multi-center, real-world, observational retrospective data collection; October 2012 – February 2021 from 7 clinical sites
- Sub-stratification between high-volume single-center (N=139) and the multi-center dataset with variable case volume and experience (N=126)
- A blinded physician committee was utilized to adjudicate all reported major and minor complications

# Endpoints

- **Primary safety endpoint:** Device-related major complication rate based on Society of Interventional Radiology (SIR) classification criteria C-E
  - **Safety endpoint of ≤10%** (Upper confidence limit of device-related major complication rate)

- **Primary efficacy endpoint:** Technical success of IVC filter retrieval defined as retrieval of filter body and any fragments deemed retrievable of the lumen based on the clinical judgement of the interventionalist
  - **Efficacy endpoint of ≥ 89.4%** (Lower confidence limit of technical success rate)

- Target performance goals were based on a weighted average rate of safety and technical success among 8 studies

# Results: Demographics, Medical History, Filter Characteristics

| | Single-Center N=139 | Multi-Center N=126 |
|---|---|---|
| Mean Age (yrs) | 52±16 | 52±16 |
| Female | 56.1% | 59.5% |
| Deep Vein Thrombosis | 85.2% | 89.7% |
| Pulmonary Embolism | 62.6% | 62.1% |
| Prophylactic filter placement | 26.6% | 57.1% |

| Filter model | Single-Center | Multi-Center |
|---|---|---|
| Retrievable | 89.2% | 83.3% |
| Gunther Tulip (Cook Medical) | 65 | 56 |
| OptEase (Cordis) | 32 | 35 |
| Option (Rex Medical) | 15 | 9 |
| Celect (Cook Medical) | 11 | 2 |
| ALN (ALN) | 1 | 1 |
| Meridian (Bard) | None | 1 |
| Recovery (Bard) | None | 1 |
| Permanent | 10.8% | 16.7% |
| Simon Nitinol (Bard) | 6 | 3 |
| TrapEase (Cordis) | 7 | 15 |
| Greenfield (Steel/Titanium, BSC) | 2 | 3 |

| | Single-Center | Multi-Center |
|---|---|---|
| Mean Filter Dwell Time (months) | 57.1±51.8 | 69.7±62.0 |
| Median Filter Dwell Time (min, max) | 40 (1.0, 186.0) | 64 (1.0, 261.0) |
| Prior Failed Retrieval Attempts | 100.0% | 42.1% |
| Pre-procedural imaging evaluation of filter | 84.1% | 88.9% |
| Filter Malfunction | 8.8% | 40.5% |
| Filter Tilt >15 degrees | 31.4% | 39.7% |
| Penetration of the IVC | 14.0% | 54.8% |
| Whole device Embolization/Migration | 3.7% | 1.6% |
| IVC Occlusion | 0.7% | 13.6% |

# Results: Primary Endpoints

**Efficacy target performance: ≥89.4%**

| Primary Efficacy Endpoints | Single-Center N=139 | Multi-Center N=126 |
|---|---|---|
| **Technical success rate** | 95.7% | 95.2% |
| **Reasons for procedural failure** | *p*=0.007 | *p*=0.016 |
| Failure to capture filter apex | None | 1 |
| Failure to ablate tissue/free filter from caval wall | None | 4 |
| Other | 6 | 1 |

*p*-value is 1-sided for comparison against the efficacy performance goal of 89.4%

**Safety target performance: ≤10%**

| Safety Endpoints | Single-Center N=139 | Multi-Center N=126 |
|---|---|---|
| Device Related Major Complication | | |
| | *p*=0.001 | *p*=0.011 |

One subject reported multiple complications/SIR grades – Multi-Center
*p*-value is 1-sided for comparison against the safety performance goal of 10%.
Major Complications include C. Require therapy, minor hospitalization (<48 hrs);
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hrs); E. Permanent adverse sequelae; F. Death.

# Safety Endpoints

| Safety Endpoints | Single-Center N=139 | Multi-Center N=126 |
|---|---|---|
| **Device-Related Major Complication** | 2.9% (4/139) *p*=0.001 | 4.0% (5/126) *p*=0.011 |
| **Procedure-Related Major Complication** | 3.6% | 4.0% |
| Filter fracture with embolization | 2 | 0 |
| Filter penetration | 1 | 0 |
| IVC perforation | 1 | 0 |
| Access site hematoma | 1 | 0 |
| IVC injury with extravasation | 0 | 2 |
| Hematoma, major | 0 | 2 |
| Hemorrhage | 0 | 1 |
| **Device related Minor Complication** | 15.8% (22/139) | 11.1% (14/126) |
| **Procedure related Minor Complication** | 26.6% | 15.1% |

One subject reported multiple complications/SIR grades – Multi-Center
*p*-value is 1-sided for comparison against the safety performance goal of 10%.
Major Complications include C. Require therapy, minor hospitalization (<48 hrs); D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hrs); E. Permanent adverse sequelae; F. Death.
Minor Complications include A. No therapy, no consequence; B. Nominal therapy, no consequence; includes overnight admission for observation only.

Original Investigation | Surgery

# Safety and Success Rates of Excimer Laser Sheath–Assisted Retrieval of Embedded Inferior Vena Cava Filters

Kush R. Desai, MD; John Kaufman, MD; Parker Truong, DO; Jonathan D. Lindquist, MD; Osman Ahmed, MD; Siobhan M. Flanagan, MD; Mark J. Garcia, MD; Rashmi Ram, PhD; Yu-Rong Gao, PhD, MBA; Robert J. Lewandowski, MD; Robert K. Ryu, MD

- First multicenter "real-world" of safety and effectiveness of excimer laser sheath for IVC filter retrieval
- The technical success rate for laser sheath assisted IVC filter retrieval was >95% for both cohorts in the setting of prolonged dwell times (average of >4.5 yrs)

*JAMA Network Open* 2022

Original Investigation | Surgery

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- Major complication rates were low for both single and multi-center data at 2.9% and 4.0%, respectively → **no major complications scored as "definitely related"** to the use of the laser
- Broader generalizability of laser sheath assisted retrieval with appropriate training in centers with variable case volume and experience

*JAMA Network Open* 2022

# Discussion: Venous Disease, IVUS Applications in the Veins

# Global Update on Arterial IVUS

Kumar Madassery, MD
Associate Professor of Vascular and Interventional Radiology
Director, Advanced Vascular & Interventional Radiology Fellowship
Director of Peripheral Vascular Interventions, CLTI & Limb Preservation Program and the IVC Filter Clinic
Rush University Medical Center, Rush Oak Park Hospital
Chicago, IL

# Outline

- Discuss global IVUS findings and thoughts
- Australian data
- Korean data

# Australian Data

# The impact of IVUS on femoropopliteal artery endovascular interventions:

## A randomised controlled trial; 36 months follow up

**Dr. Phil Puckridge**
Department of Vascular and Endovascular Surgery
Southern Adelaide Local Health Network,
Flinders Medical Centre, Adelaide, Australia
Flinders University, Adelaide, Australia

# Published 12-month Outcomes in 2022

*JACC: Cardiovascular Interventions.* 2022;15(5):536-546

PERIPHERAL

## The Impact of Intravascular Ultrasound on Femoropopliteal Artery Endovascular Interventions

### A Randomized Controlled Trial

Richard B. Allan, BHlthSc (Hons), PhD,[a,b] Phillip J. Puckridge, MBBS,[a,b] J. Ian Spark, MBChB, MD,[c] Christopher L. Delaney, BMBS, PhD[a,b]

# Study Design

Detailed description of design previously reported

150 patients

Undergoing femoropopliteal interventions

Parallel-group design with balanced randomization

Control group (angiography information only available)

# Outcome Measures at 36 Months

## Primary Outcome

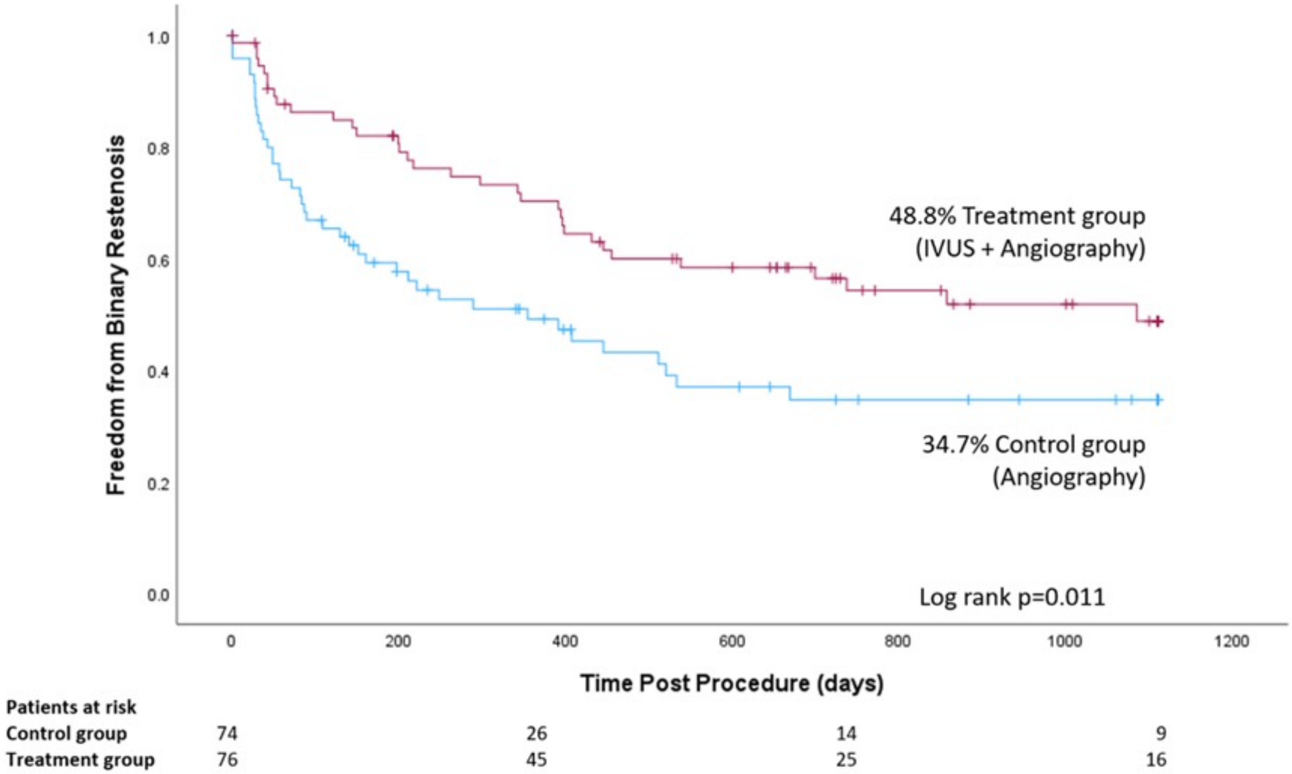
- Binary restenosis within 36 months of index procedure
  - >50% stenosis on duplex ultrasound
  - PSV ≥2.4

## Secondary Outcomes

- Clinically driven target lesion revascularization (TLR)
- Major adverse events (MAE)

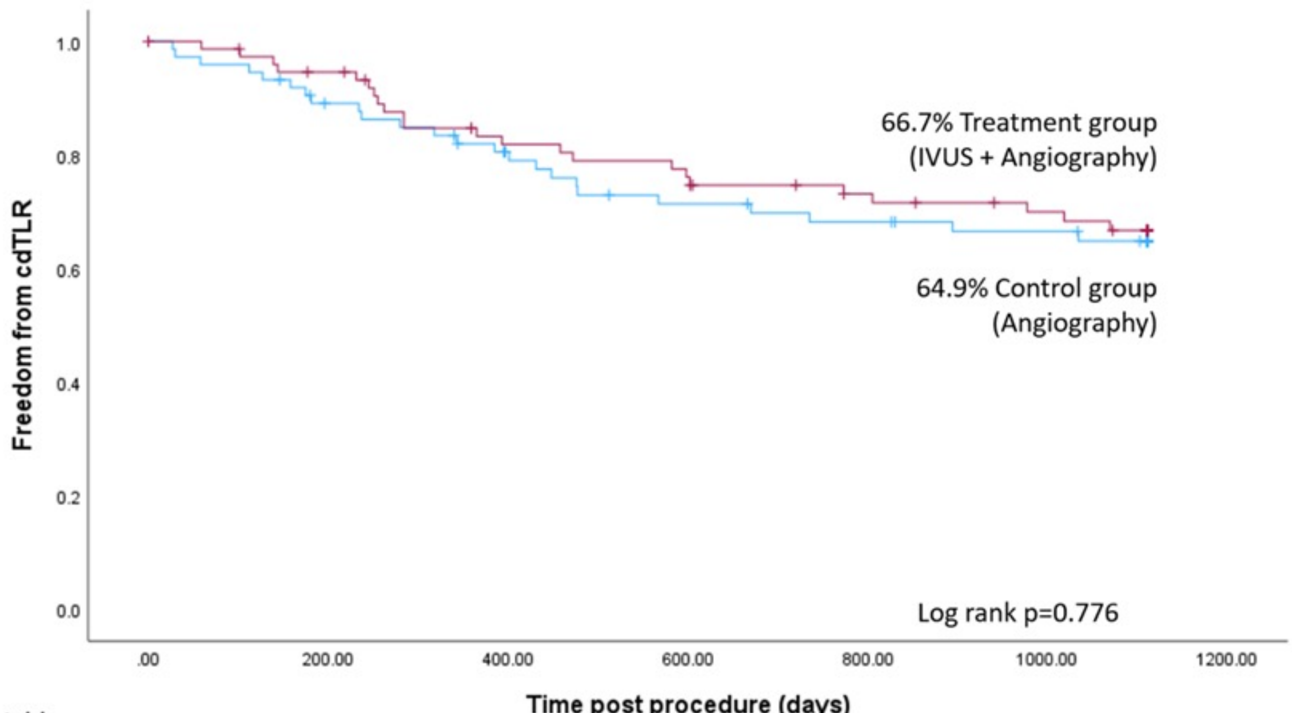
# Primary Outcome 36 Months

- Significant benefit at 12 months
- Persistent **reduction in binary re-stenosis at 36 months**
- Freedom from binary restenosis 48.8% with IVUS vs 34.7% using angiography alone (*P*=0.011)



# Secondary Outcomes 36 Months

- No difference in cdTLR rates at 12 or 36 months




| Patients at risk | | | | |
|---|---|---|---|---|
| Control group | 74 | 59 | 43 | 37 |
| Treatment group | 76 | 63 | 49 | 40 |

# Use of IVUS Was Safe

- **No significant difference in MAE** within 36 months between treatment and control groups
  - 32.9% vs 40.5%, *p*=0.397

| | **Control group** (angiography) (n=74) | **Treatment Group** (IVUS and angiography) (n=76) | *p* value |
|---|---|---|---|
| Death | 18 (24.3%) | 10 (13.2%) | 0.077* |
| Myocardial infarction | 21 (28.4%) | 17 (22.4%) | 0.405† |
| Stroke/TIA | 4 (5.4%) | 1 (1.3%) | 0.206† |
| Major amputation | 2 (2.7%) | 3 (5.3%) | 1.000† |
| Acute kidney failure | 0 (0.0%) | 1 (3.9%) | 1.000† |
| Thrombolysis | 0 (0.0%) | 1 (1.3%) | 1.000† |
| Re-admission | 2 (2.7%) | 1 (1.3%) | 0.617† |
| Individuals with at least 1 MAE | 30 (40.5%) | 25 (32.9%) | 0.397† |

# Subgroup Analysis Benefit in DCB Use

- Original publication IVUS availability significantly increased mean DCB size chosen
- At **36 months, higher freedom from binary restenosis** in treatment group vs control group
  - Treated with DCB
  - 68.2% in IVUS treatment vs 31.8% without IVUS
  - *P*=0.005
- No differences seen in patients with POBA or stents
- No difference observed in cdTLR between different treatment types

DCB = drug-coated balloon; POBA = plain old balloon angioplasty; cdTLR = clinically directed target lesion revascularization

# Conclusions

- Published first prospective RCT evidence demonstrating benefit from IVUS in femoropopliteal interventions at 12 months
- IVUS changes treatment
- Improves outcomes by reducing binary restenosis
- IVUS guided accurate vessel sizing in DCB use

# Conclusions: 36 Month Outcomes

Combined IVUS and angiography results in significant benefit in freedom from binary restenosis

IVUS provides greater understanding of the target vessel in femoropopliteal segment

Primary benefit seen with use of DCB technology

# Korean Data

# Intravascular ultrasound-guided drug-coated balloon angioplasty for femoropopliteal artery disease: a clinical trial

**Young-Guk Ko [1]*†, Seung-Jun Lee[1†], Chul-Min Ahn[1], Sang-Hyup Lee [1], Yong-Joon Lee [1], Byeong-Keuk Kim[1], Myeong-Ki Hong [1], Yangsoo Jang[1], Tae-Hoon Kim[2,3], Ha-Wook Park[3], Ji Yong Jang[4], Jae-Hwan Lee[5,6], Jae-Hyeong Park[6], Su Hong Kim[7], Eui Im[8], Sang-ho Park[9], and Donghoon Choi[1]*; on behalf of the IVUS-DCB investigators**

[1]Severance Cardiovascular Hospital, Yonsei University College of Medicine, Seodaemungu, Seoul 03722, Korea; [2]Division of Cardiology, Hanil General Hospital, Seoul, Korea; [3]Division of Cardiology Cardiovascular Center, Bucheon Sejong Hospital, Bucheon, Korea; [4]Division of Cardiology, National Health Insurance Service Ilsan Hospital, Goyang, Korea; [5]Division of Cardiology, Chungnam National University Sejong Hospital, Sejong, Korea; [6]Division of Cardiology, Chungnam National University Hospital, Daejeon, Korea; [7]Division of Cardiology, Busan Veterans Hospital, Busan, Korea; [8]Division of Cardiology, Yongin Severance Hospital, Seoul, Korea; and [9]Cardiology Department, Soonchunhyang University Cheonan Hospital, Cheonan, Korea

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Ko YG, et al. *Eur Heart J*. 2024;45(31):2839-2847.

**Abstract**

**Background and Aims** Drug-coated balloons (DCBs) have demonstrated favourable outcomes following endovascular therapy for femoropopliteal artery (FPA) disease. However, uncertainty remains whether the use of intravascular ultrasound (IVUS) can improve the outcomes of DCBs.

**Methods** This prospective, multicentre, randomized trial, conducted at seven centres in South Korea, compared the outcomes of IVUS-guided vs. angiography-guided angioplasty for treating FPA disease with DCBs. Patients were assigned to receive IVUS-guided ($n = 119$) or angiography-guided ($n = 118$) angioplasty using DCBs. The primary endpoint was 12-month primary patency.

**Results** Between May 2016 and August 2022, 237 patients were enrolled and 204 (86.0%) completed the trial (median follow-up; 363 days). The IVUS guidance group showed significantly higher primary patency [83.8% vs. 70.1%; cumulative difference 19.6% (95% confidence interval 6.8 to 32.3); $P = .01$] and increased freedom from clinically driven target lesion revascularization [92.4% vs. 83.0%; difference 11.6% (95% confidence interval 3.1 to 20.1); $P = .02$], sustained clinical improvement (89.1% vs. 76.3%, $P = .01$), and haemodynamic improvement (82.4% vs. 66.9%, $P = .01$) at 12 months compared with the angiography guidance group. The IVUS group utilized larger balloon diameters and pressures for pre-dilation, more frequent post-dilation, and higher pressures for post-dilation, resulting in a greater post-procedural minimum lumen diameter ($3.90 \pm 0.59$ vs. $3.71 \pm 0.73$ mm, $P = .03$).

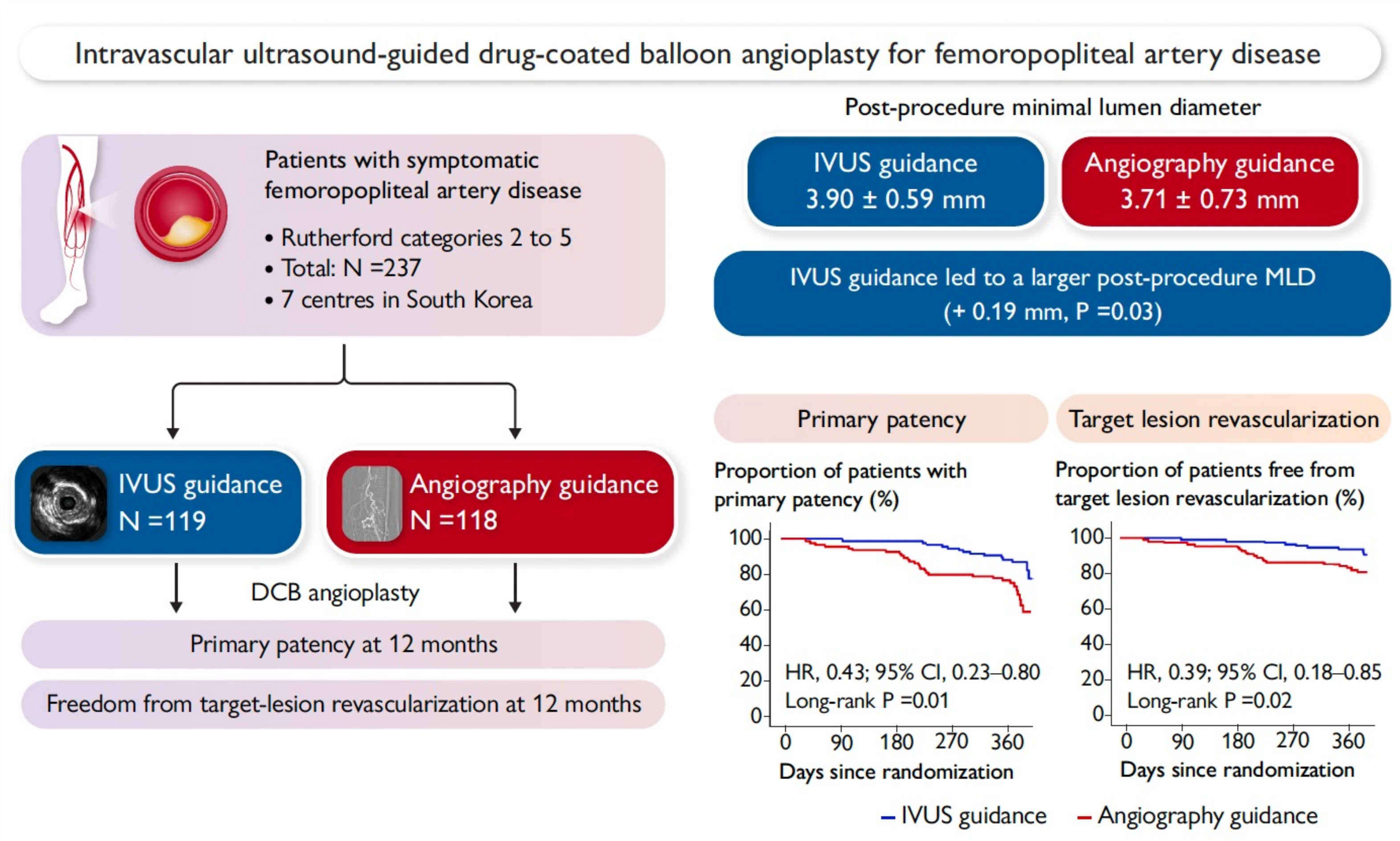
**Conclusions** Intravascular ultrasound guidance significantly improved the outcomes of DCBs for FPA disease in terms of primary patency, freedom from clinically driven target lesion revascularization, and sustained clinical and haemodynamic improvement at 12 months. These benefits may be attributed to IVUS-guided optimization of the lesion before and after DCB treatment.

Ko YG, et al. *Eur Heart J*. 2024;45(31):2839-2847.

# Does IVUS Improve PP and Clinical Outcomes for Femoropopliteal Interventions with DCB Compared to Angio Alone?

# Design

- Multicenter
- Randomized SINGLE-blinded superiority trial
- Independent Clinical Event Adjudication Committee (CEAC)
  - Masked to the assignments
- Funded by Medtronic and Korea United Pharm
  - No involvement in design, data collection, analysis, etc.
- Rutherford 2-5
- Lesion length <150mm
- POBA 1mm less than planned DCB size
- Atherectomy for calcium was allowed


Intravascular ultrasound-guided drug-coated balloon angioplasty for femoropopliteal artery disease
Patients with symptomatic femoropopliteal artery disease
• Rutherford categories 2 to 5
• Total: N =237
• 7 centres in South Korea
IVUS guidance N =119
Angiography guidance N =118
DCB angioplasty
Primary patency at 12 months
Freedom from target-lesion revascularization at 12 months
Post-procedure minimal lumen diameter
IVUS guidance 3.90 ± 0.59 mm
Angiography guidance 3.71 ± 0.73 mm
IVUS guidance led to a larger post-procedure MLD (+ 0.19 mm, P =0.03)
Primary patency
Proportion of patients with primary patency (%)
HR, 0.43; 95% CI, 0.23–0.80
Long-rank P =0.01
Days since randomization
Target lesion revascularization
Proportion of patients free from target lesion revascularization (%)
HR, 0.39; 95% CI, 0.18–0.85
Long-rank P =0.02
Days since randomization
IVUS guidance
Angiography guidance

# Summary

- IVUS has demonstrated consistent benefit for optimal interventions and outcomes in consensus and randomized control studies in both the U.S. and globally

# Arterial Case Examples

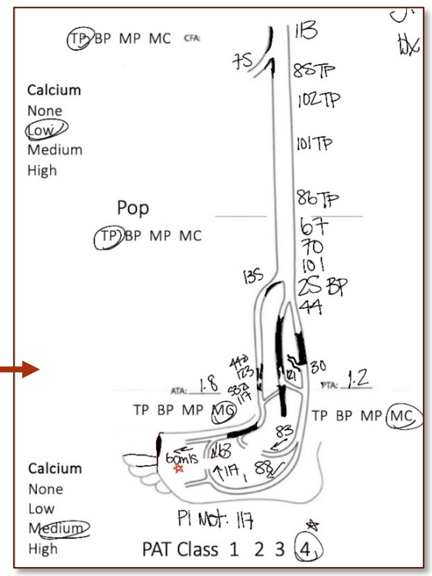
**Mary Costantino, MD, FSIR**
Medical Director
Advanced Vascular Centers
Portland, OR
Eugene, OR

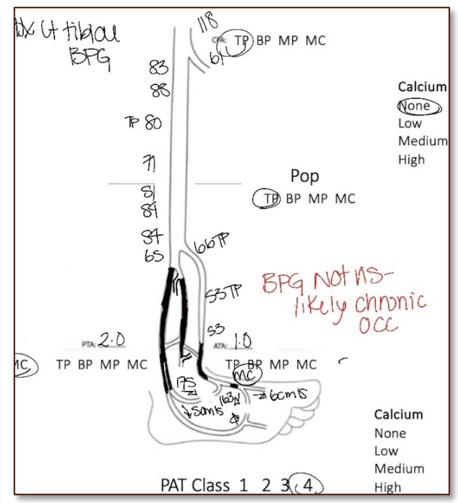
# Arterial: Why IVUS?

1. Reduce contrast, increase efficiency
2. Confirm intraluminal location
3. Stent landing/vessel sizing (veins>arteries)
4. **Learn more about atherosclerosis**

# Case 1: Reduce Contrast, Increase Efficiency

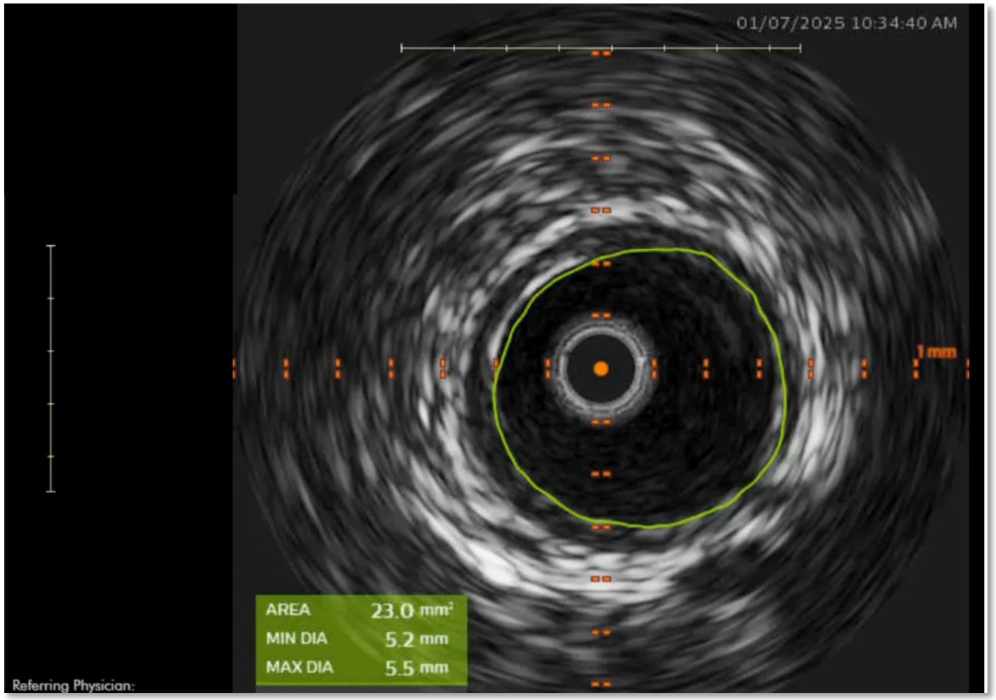
- Negative ultrasound/CT — the most important place to use IVUS?
- If you exclude disease, you never need to look at that leg again (or likely the other one…)
  - CASE 1: 43y PPD (now ½ PPD)
  - Admitted 12/10/24 with infected wound; left AMA
  - Right ABI: 0.6
  - CT: Single vessel AT, inflow normal
  - Presents 1/3/25 with gangrene, right great toe
  - Approach: Efficient US:
    - 5Fr access
    - 0.014 to distal pop, IVUS, 0.035 cath to pop
    - Shoot tibials, intervene

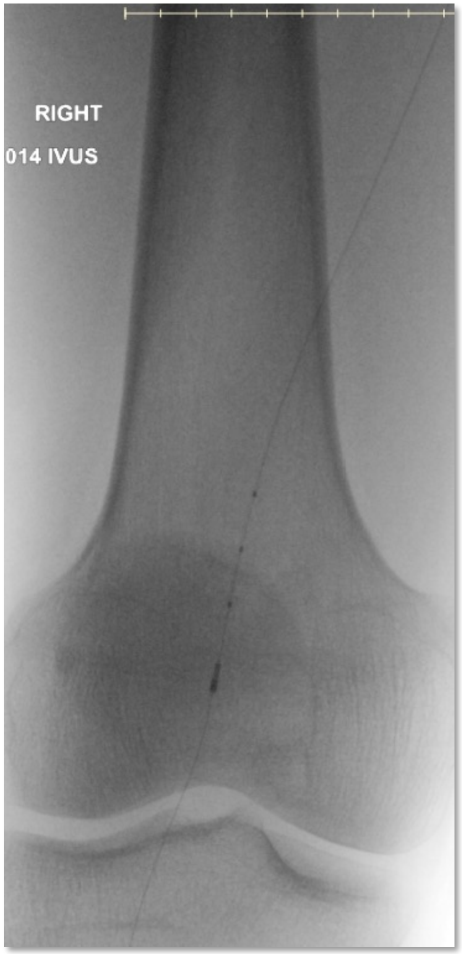


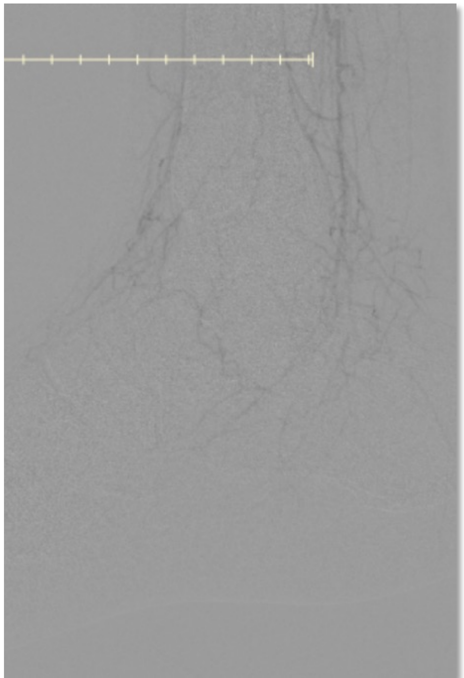
# Normal Inflow:
## IVUS to confirm, efficient, contrast reduction

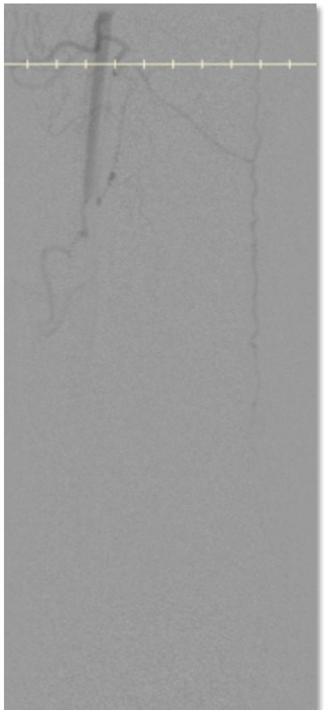
**Step 1 – IVUS the inflow**

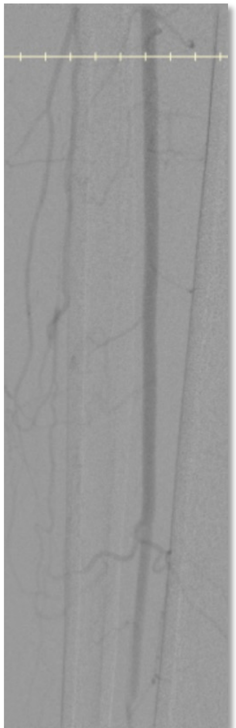


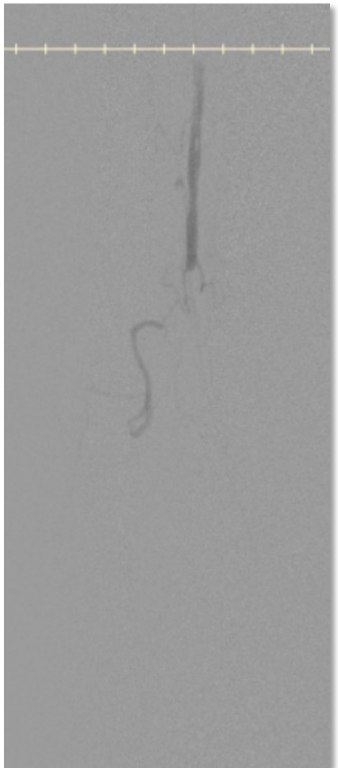
**Step 2 Anterior tibial**







**Step 3**

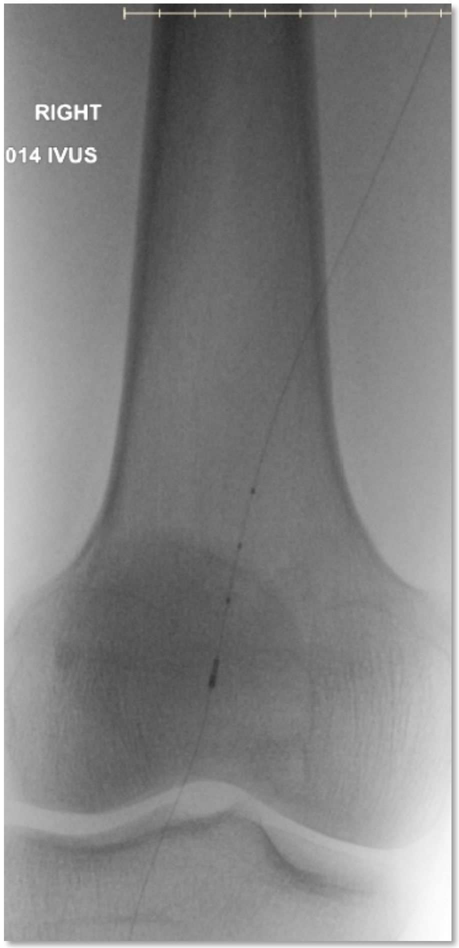


**Step 4**

# IVUS with Predicted Normal Flow

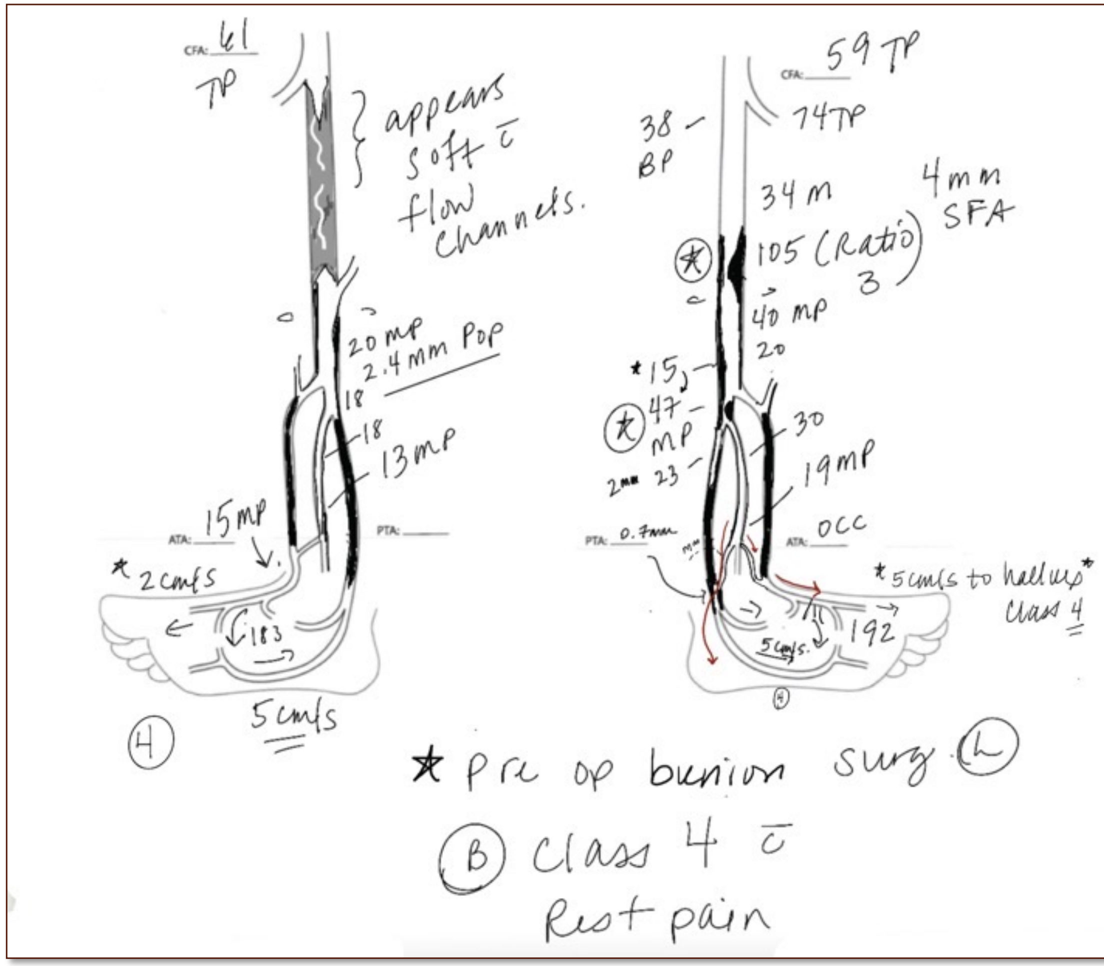
- By going right to IVUS, disease to popliteal is excluded
- Quick; more diagnostic than angio
- Allows for evaluation of “character” of artery
- Already know what the contralateral leg will look like

- Utility debatable?



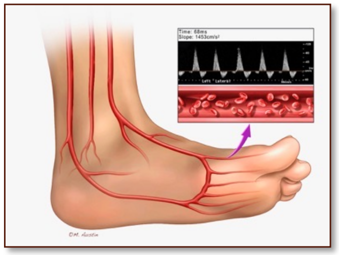
# Case 2: Confirm Intraluminal Location

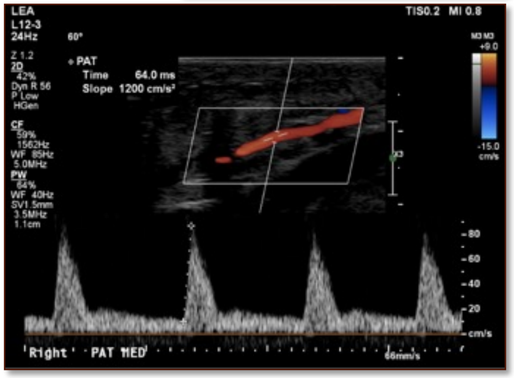
- 76y Female; no wounds, reports bilateral foot pain at night
- Told pain is due to bunion
- Patient is referred for "pre-op" **LEFT** bunion surgery
- No palpable pulses
- No vascular surgical history

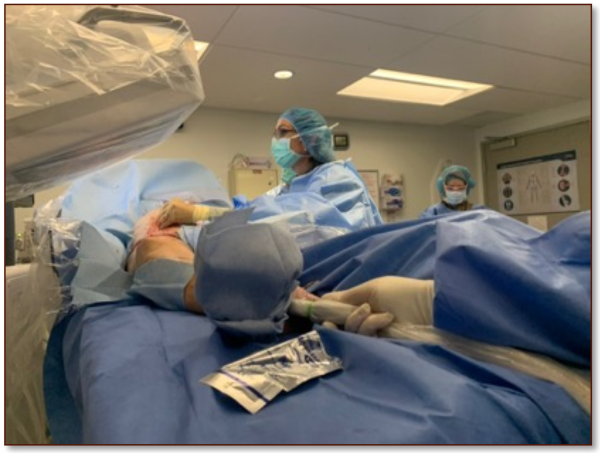

CFA: 61 TP
appears soft c̄ flow channels.
20 mp
2.4 mm Pop
18
18
13 mp
15 mp
ATA:
PTA:
* 2 cm/s
183
5 cm/s
(R)
CFA: 59 TP
38 BP
74 TP
34 m
4 mm SFA
105 (Ratio 3)
40 mp
20
*15
47 MP
2mm 23
30
19 mp
PTA: 0.7mm
ATA: OCC
*5 cm/s to hallux*
class 4
192
5 cm/s.
* pre op bunion surg (L)
(B) class 4 c̄
Rest pain

# Pedal Acceleration Time (PAT)

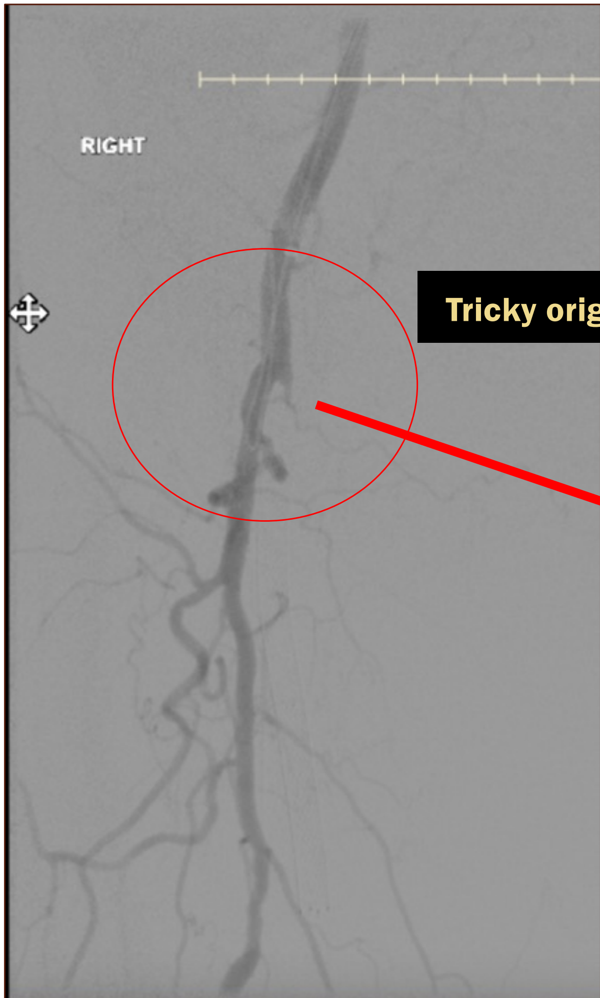
| | No Ischemia Class 1 | Mild Ischemia Class 2 | Moderate Ischemia Class 3 | Severe Ischemia Class 4 |
|---|---|---|---|---|
| Clinical Symptoms | Asymptomatic | Less than 2 block claudication | Greater than 2 block claudication | CLTI (Tissue Loss, rest pain) |
| PAT | 20 – 120 ms | 121 – 180 ms | 181 – 224 ms | Greater than 225ms |
| ABI | 1.3 – 0.90 | 0.89 – 0.69 | 0.68 – 0.50 | 0.49 – 0.00 |

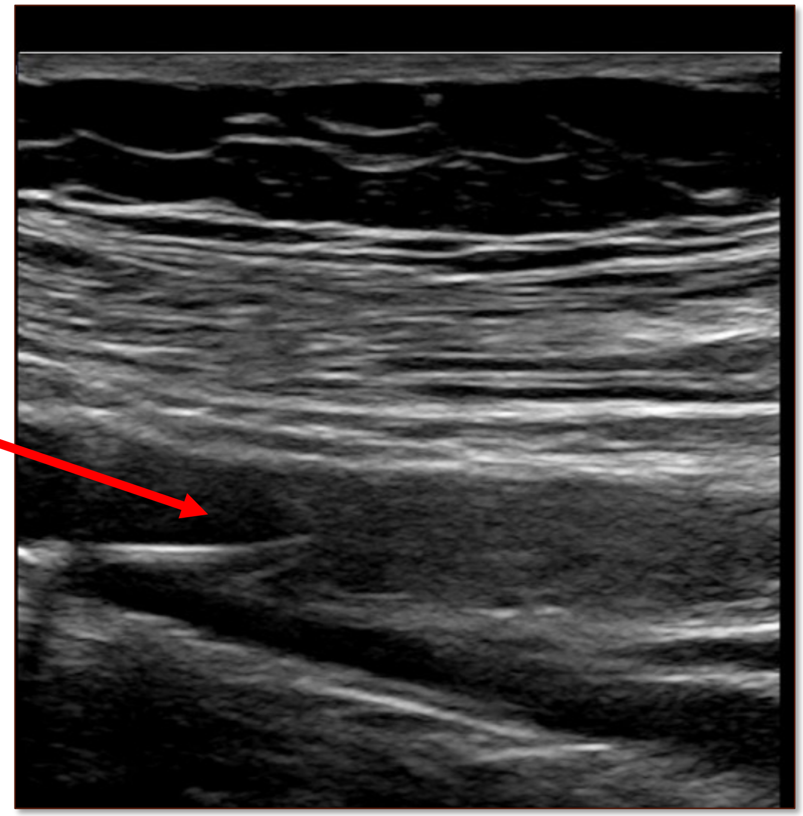




# RIGHT

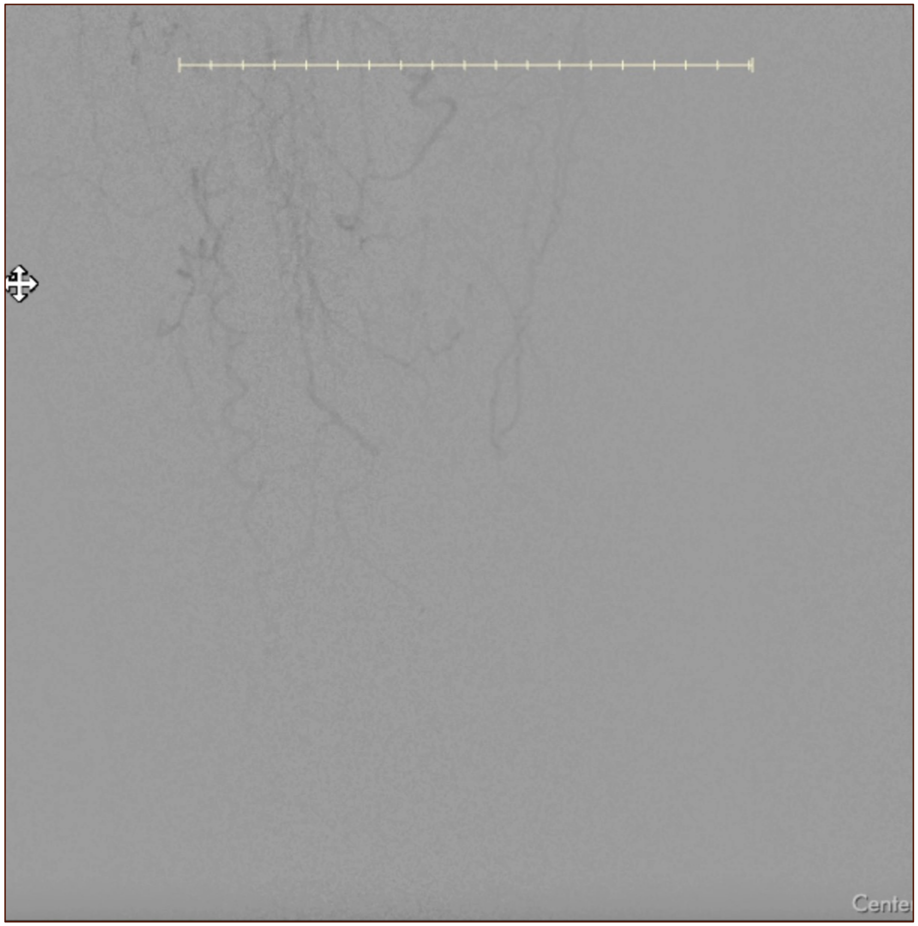


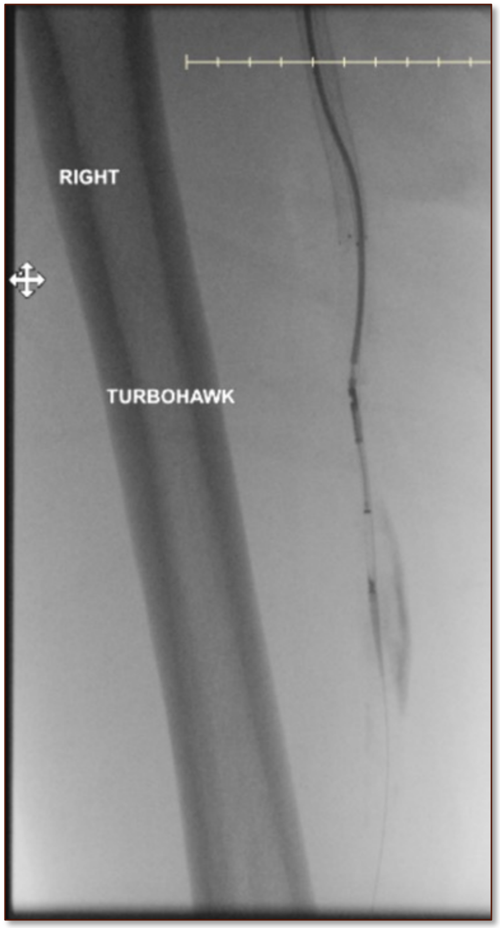
# Crossing the CTO

- Bern + Benson/Glide
- Then Trailblazer, Navicross, any x-cath
- 0.035>0.014

- Elevated disease
- Asahi CTO wire
- Maybe a 0.014 system
- Tibial access
- Chiba needle
- BeBack

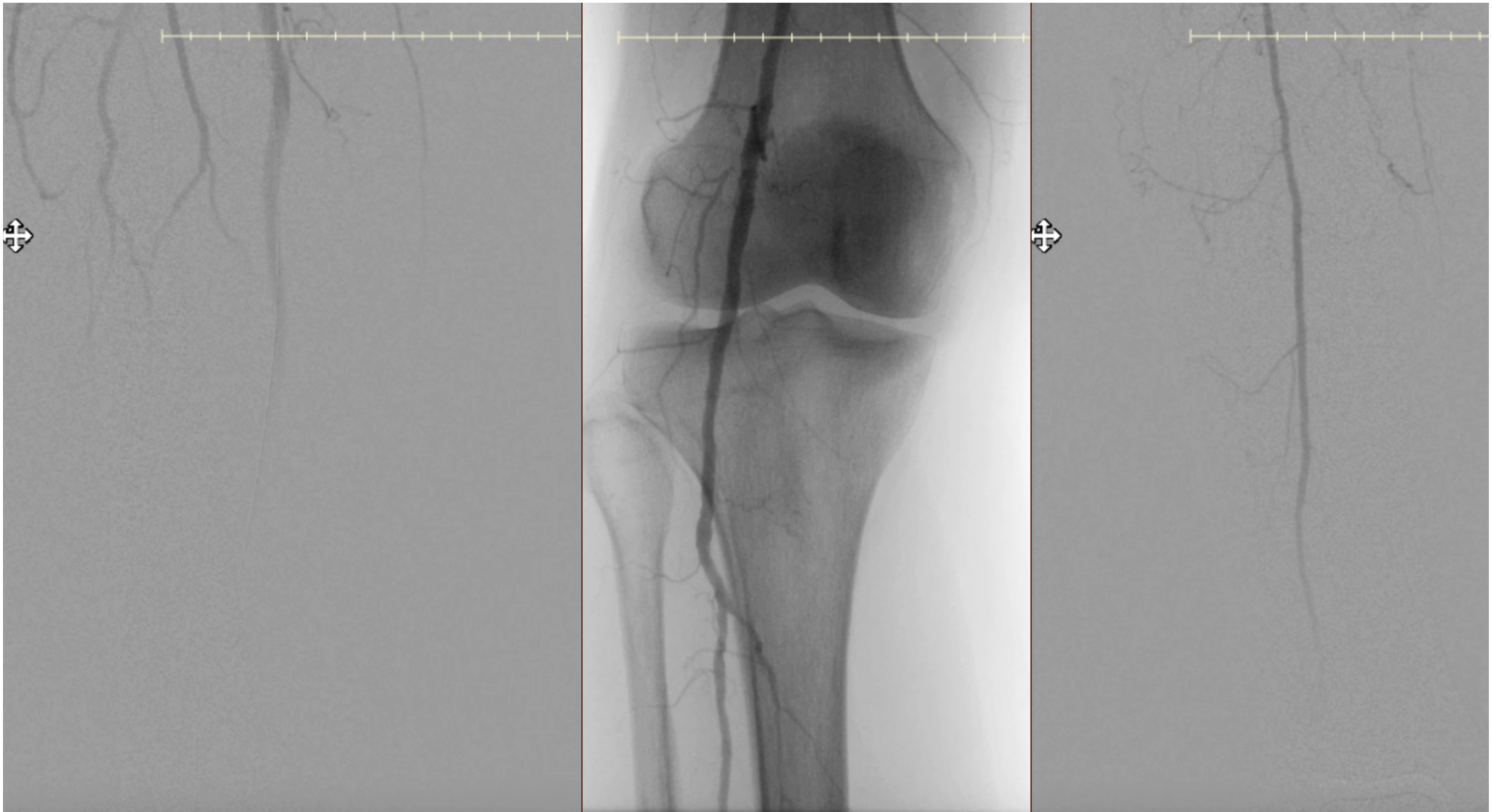



RIGHT
014 IVUS
04:51:09PM
30

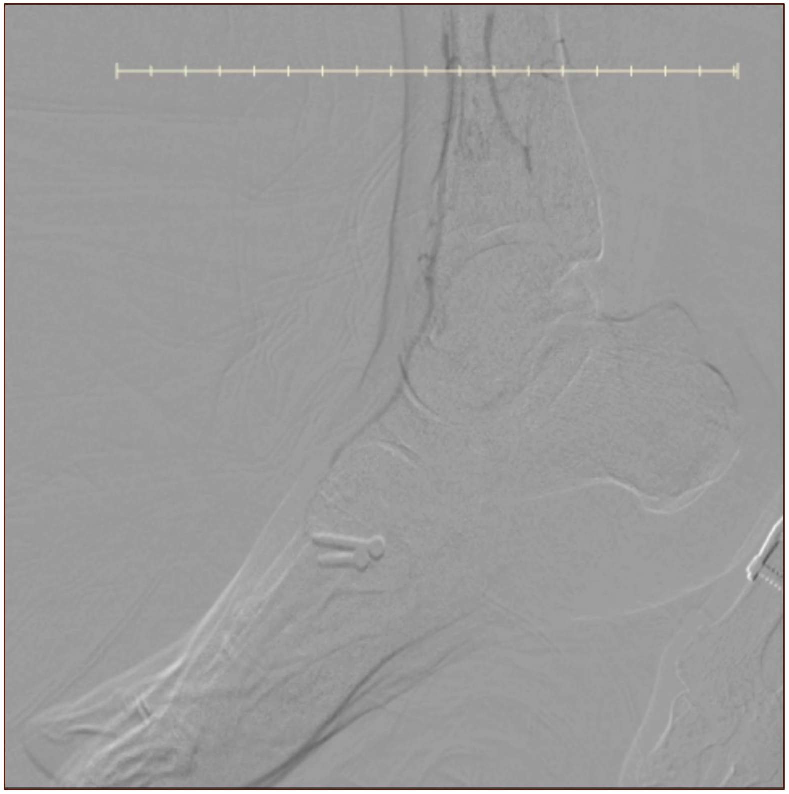


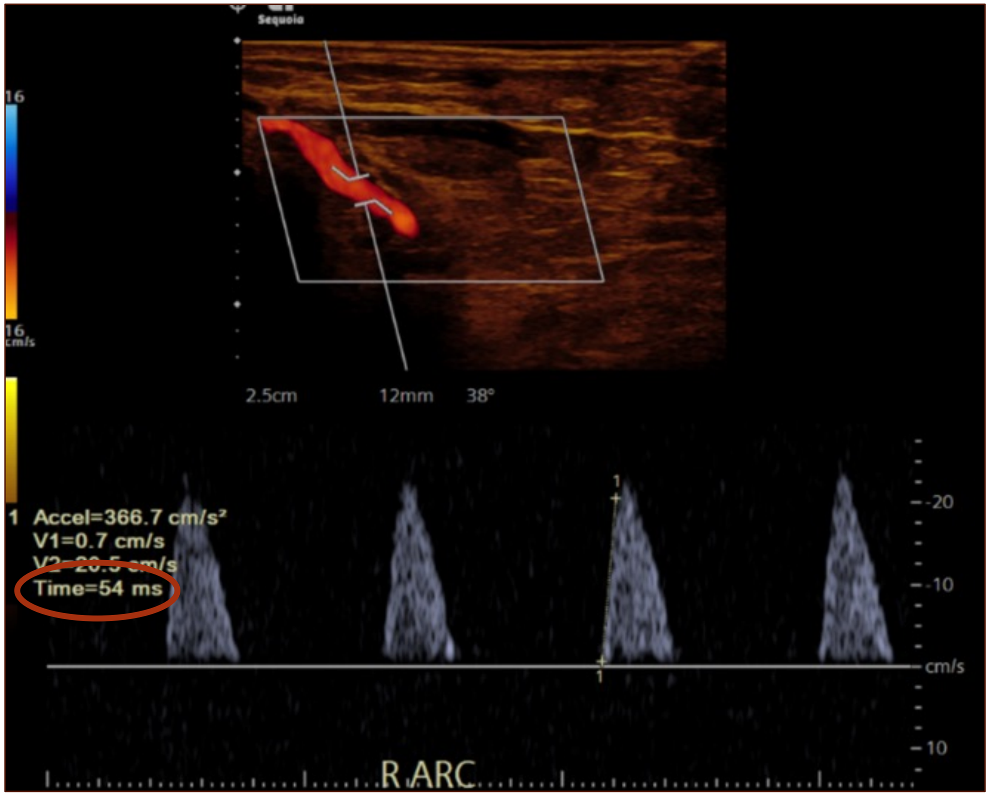


- This means the wire was subintimal at one point; even more reason to use IVUS
- I've never intervened without IVUS confirmation in a case like this
- If sub-I
  - Short-segment, soft wall: Stent
  - Long-segment, ca wall: Pull back and re-attempt

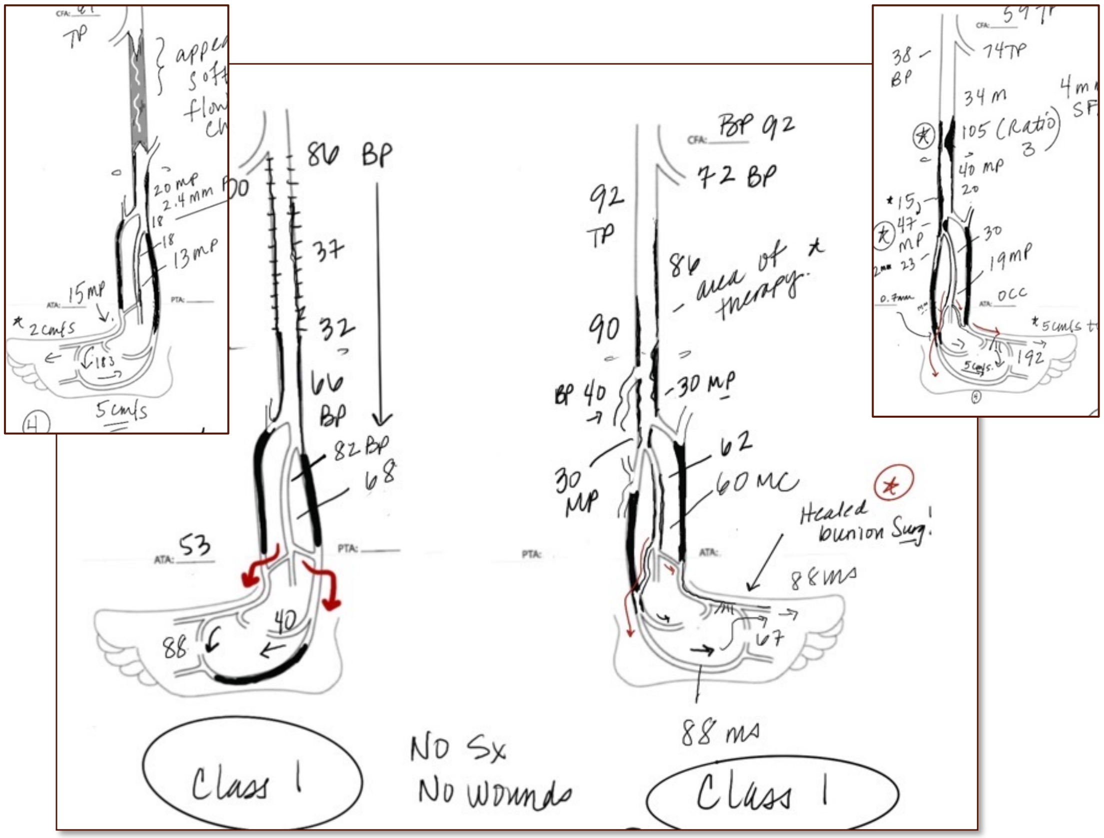


# On Table Class 1 PAT





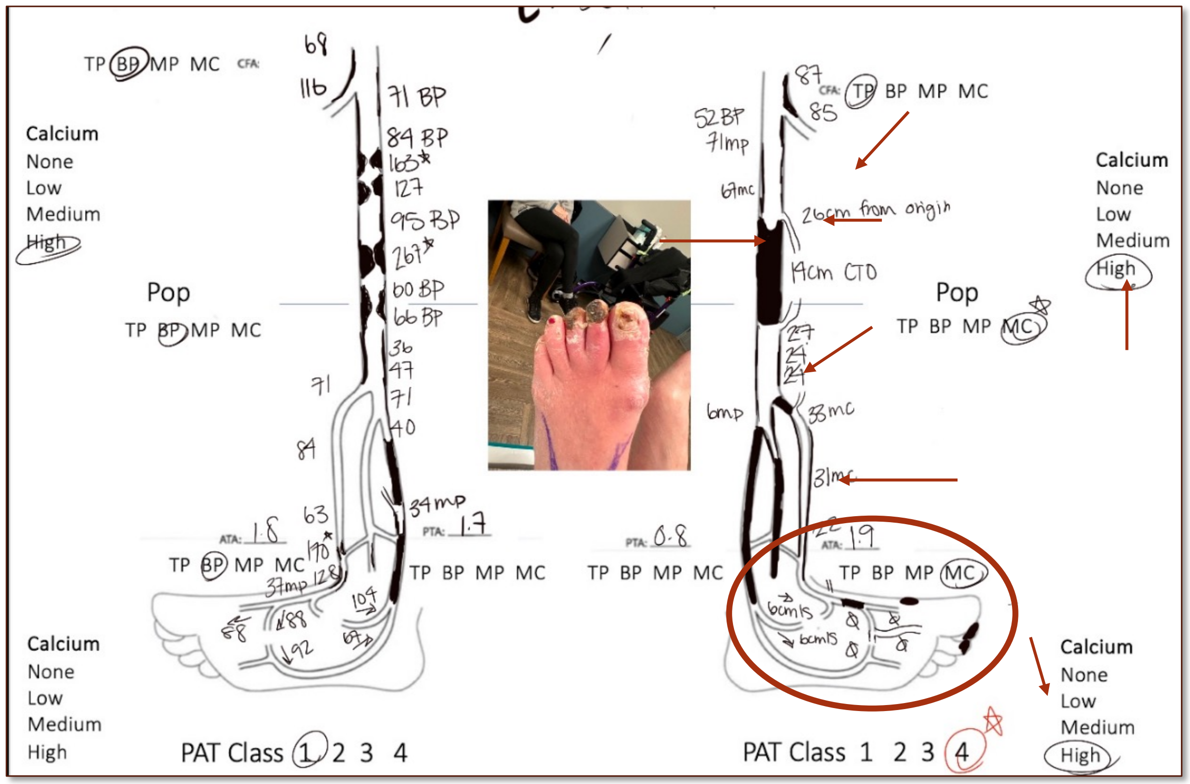
# Post-op bunionectomy; pain resolved

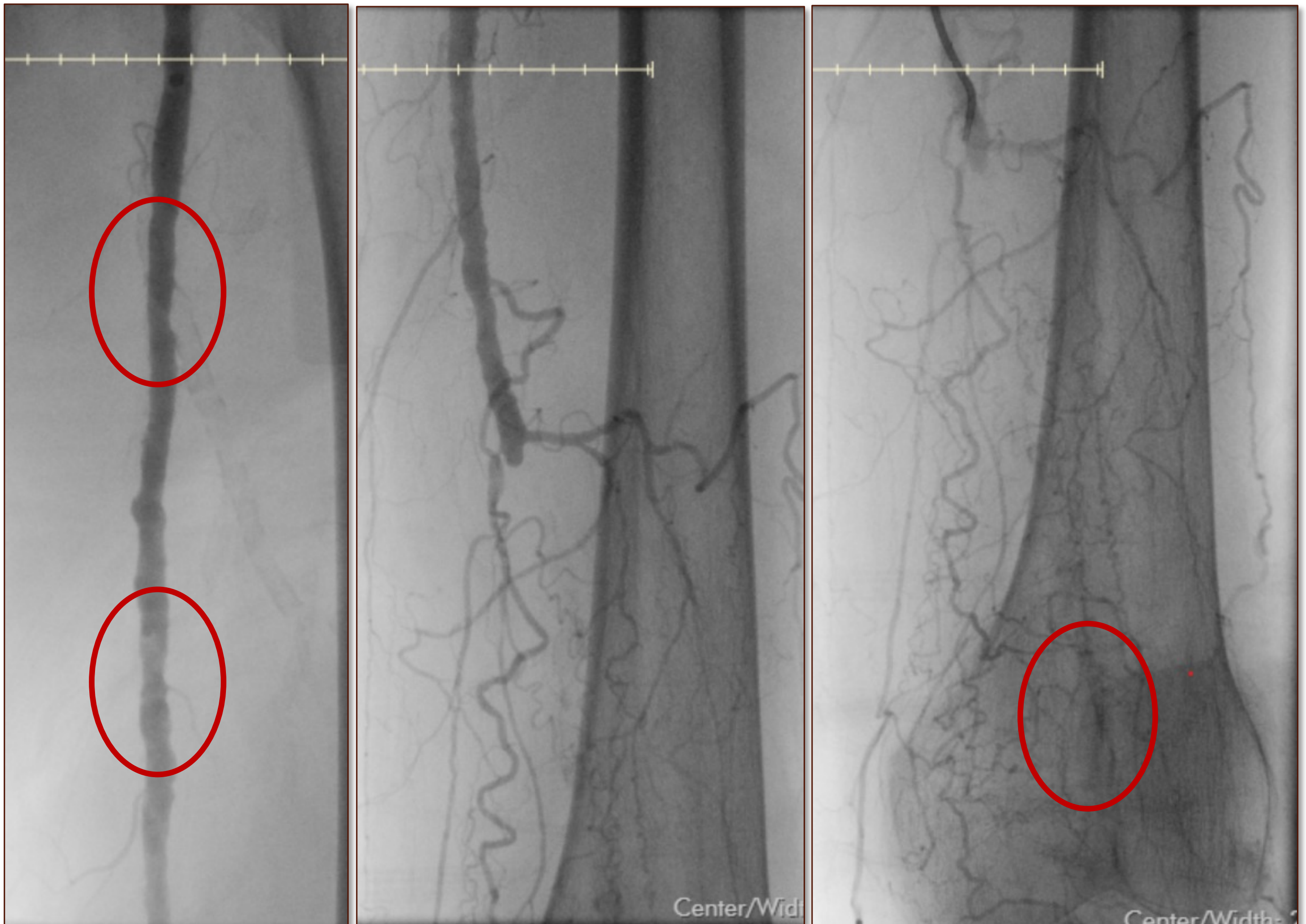



# Case 3: IVUS Is Awesome

## Contrast, confirmation, time on table, efficiency

- 90y, severe rest pain, wounds, gangrene
- Options: Palliative vs endo
- GFR >50, mild/moderate dementia



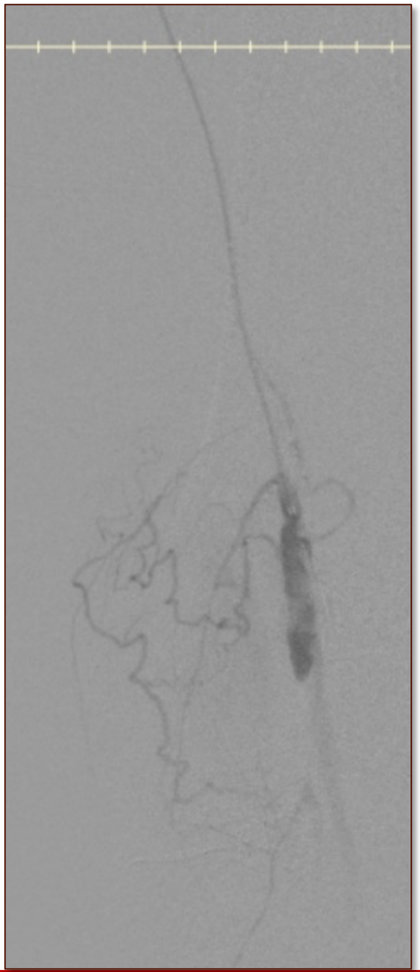


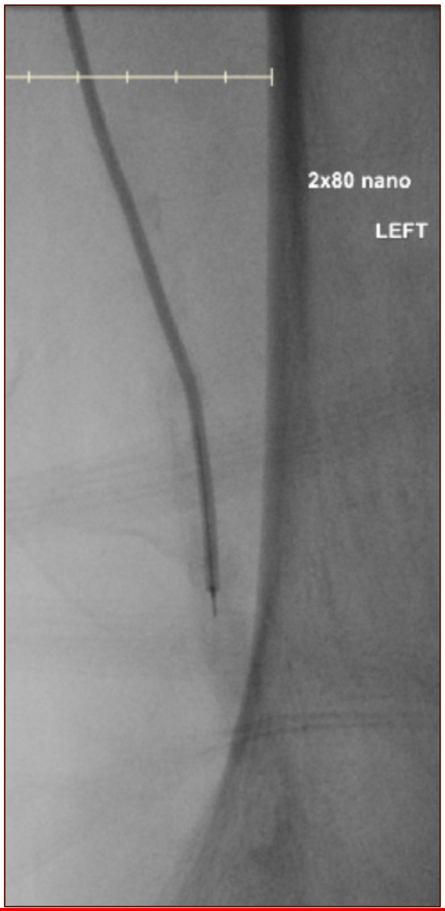
## Considerations

- Wire selection
- Tibial
- How can I make her worse?

- Back-end glide with straight crossing pushed against nubbin
- Didn't change to Bentson = subintimal

- Hubbed TrailBlazer™, back end of glide
- Is the track subintimal already? If long segment, that's hard to recover from in heavily ca arteries

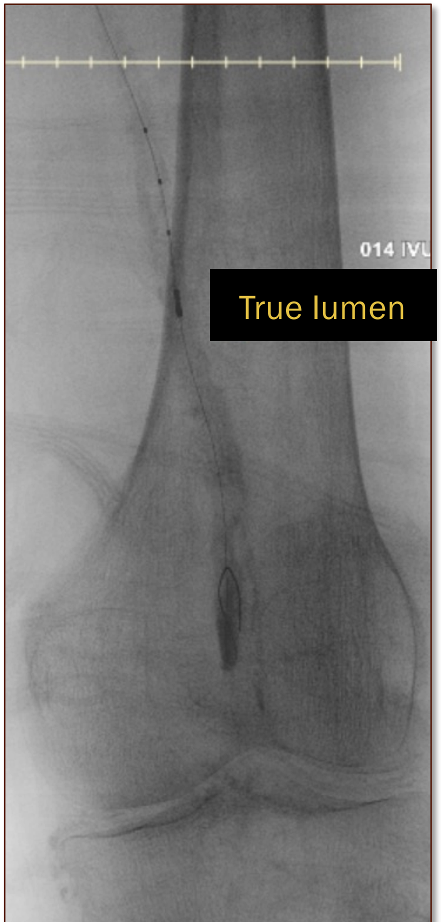


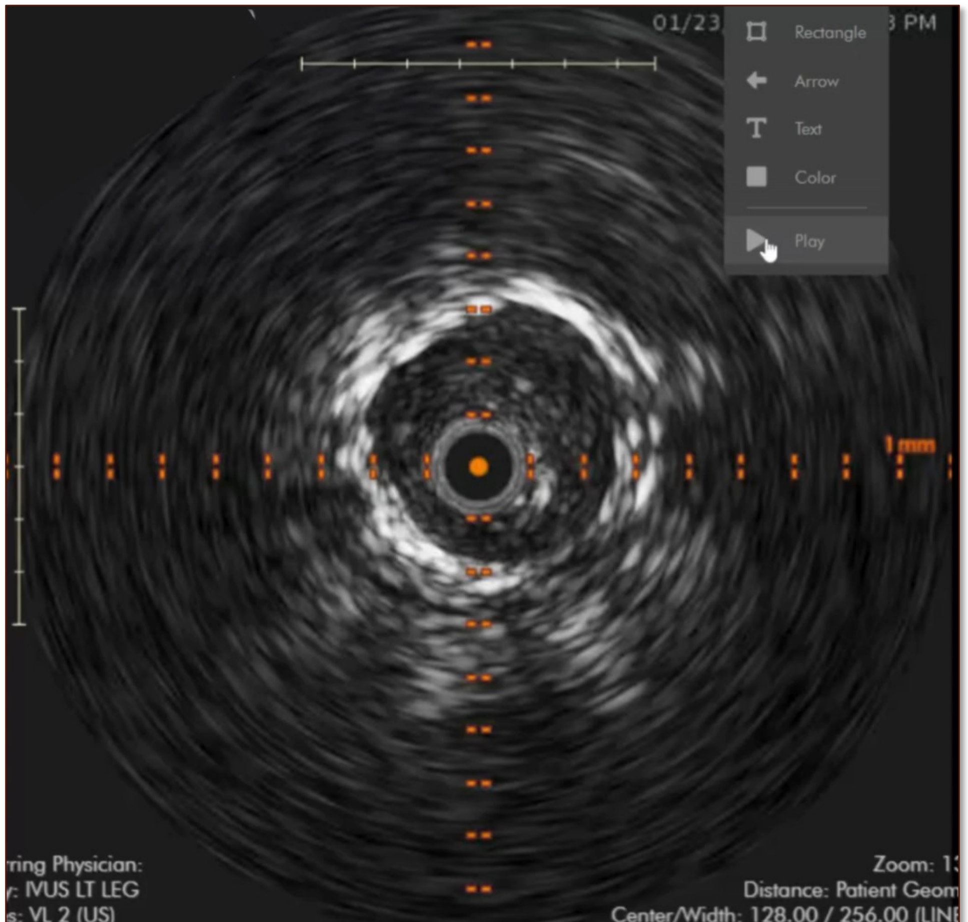


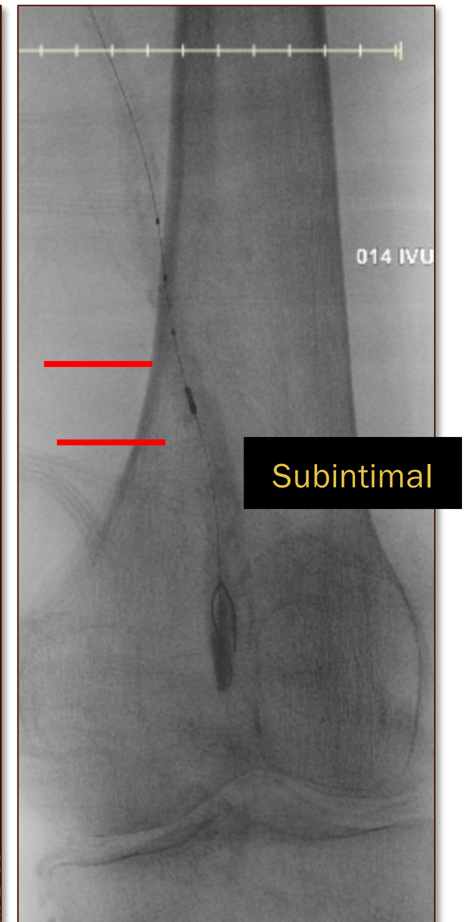


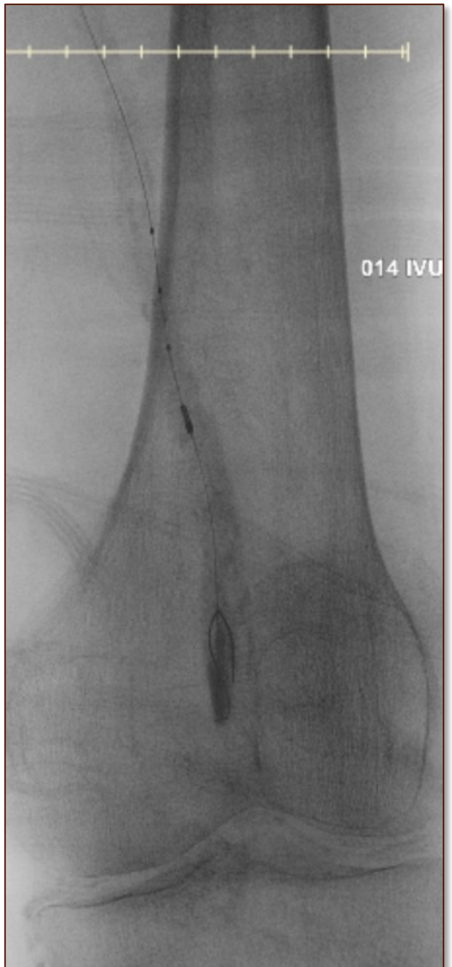
- IVUS is key, in this case, to allow me to be sure I'm luminal as I balloon down
- Balloon can center wire
- Mark true lumen with screenshot, save on adjacent screen

# IVUS Marks the Subintimal Location



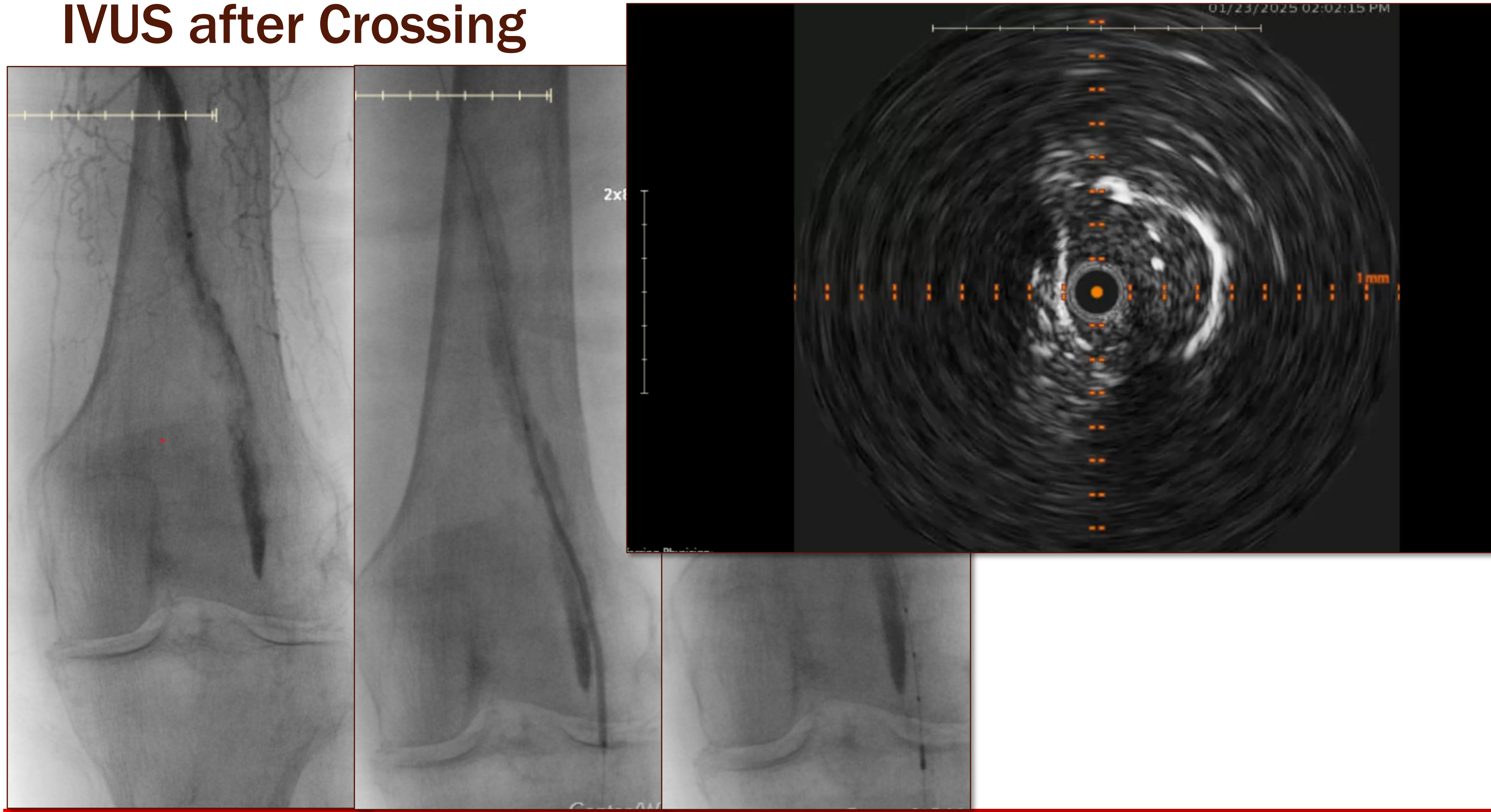



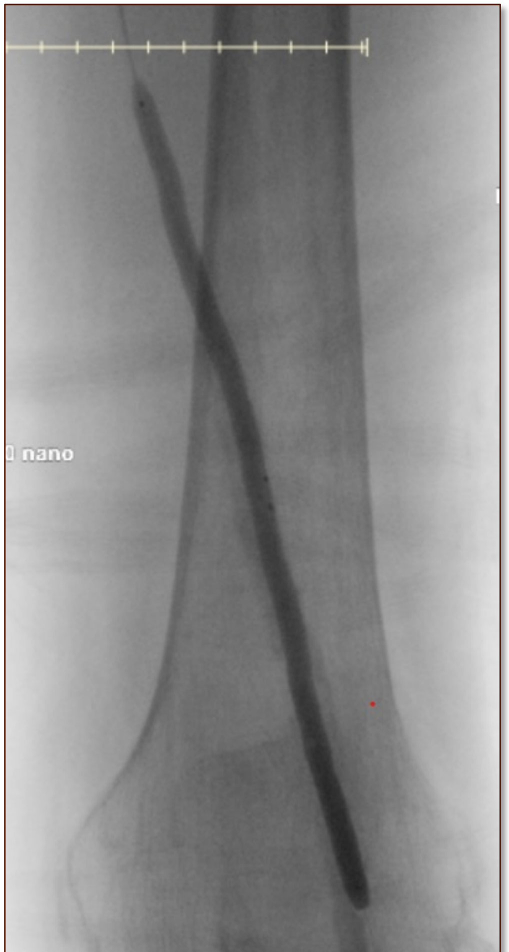



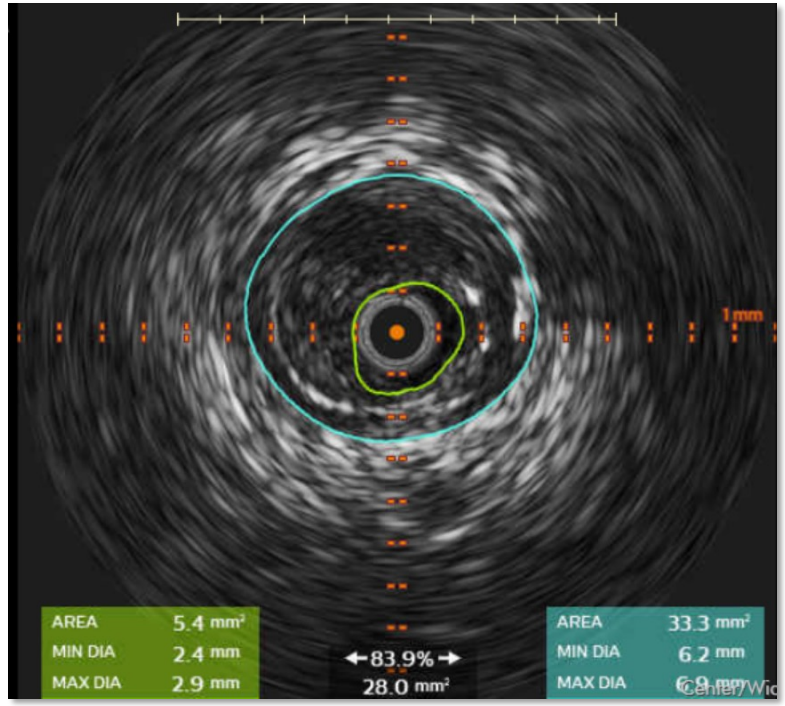



- Fun benefit: IVUS moves with the patient

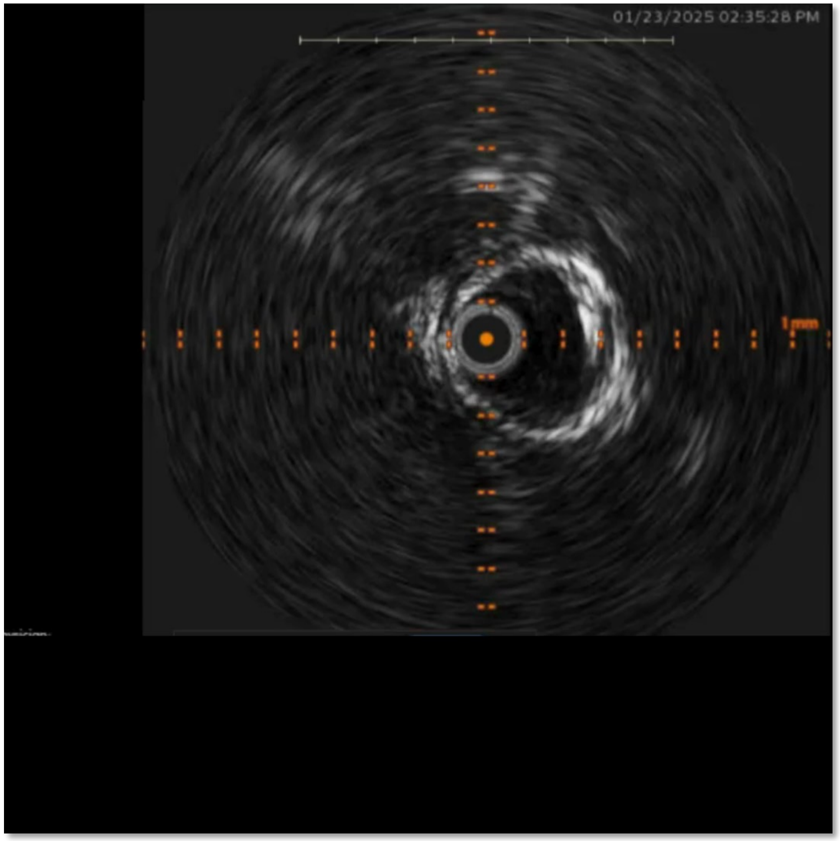
# IVUS after Crossing




nano


1 mm
AREA 5.4 mm²
MIN DIA 2.4 mm
MAX DIA 2.9 mm
83.9%
28.0 mm²
AREA 33.3 mm²
MIN DIA 6.2 mm
MAX DIA

# Information from IVUS



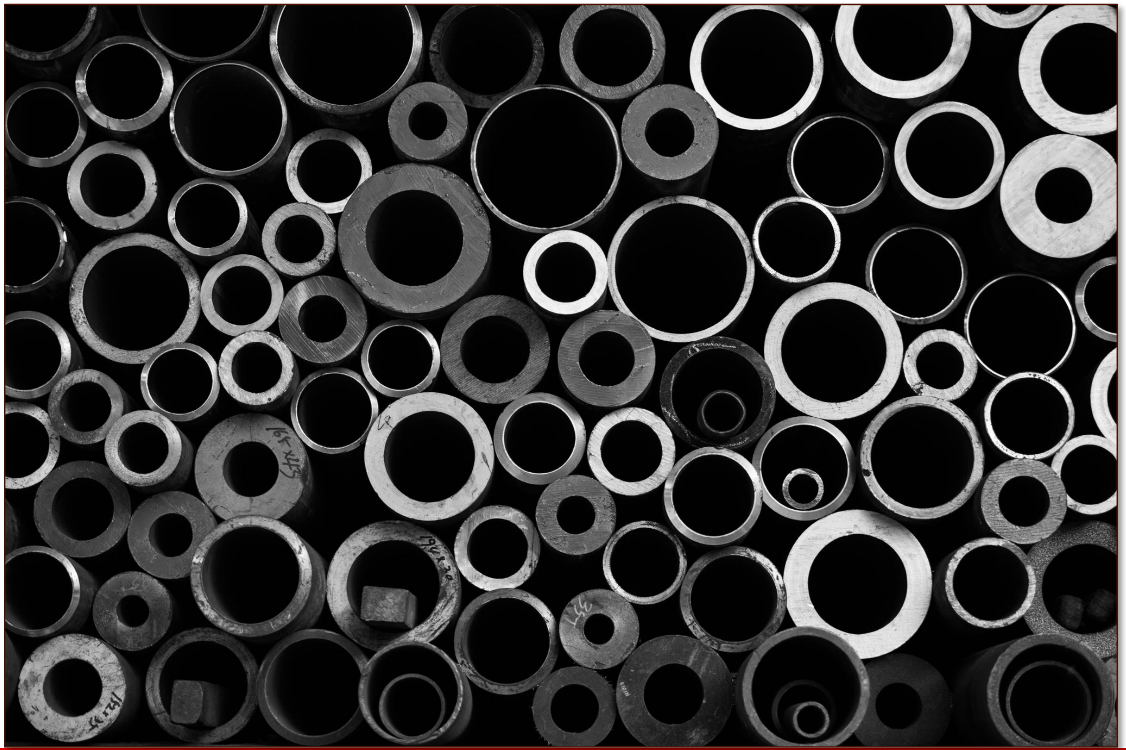

- True lumen
- Calcified thrombus
- Soft vs hard atherosclerosis
- Beating thrombus at tail end – "emboli ready"
- Vessel size
- Assumption that calcium is "stronger" than non-calcified plaque, but we don't know that

## Summary

- IVUS for
  - Contrast reduction
  - Speed
    - Important with older patients
- Confirmation of intraluminal position
- Location of flap
- After confirmed CTO crossing, the work is basically done

- Need IVUS to be
  - Fast
  - Cost-effective
  - Easy to turn on and manipulate
  - Reliable

# Thank You



# Discussion: Arterial Disease, IVUS Applications in the Arteries

# Panel Discussion

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# Audience Q&A

# THANK YOU

# IVUS Applications
## in the Veins and Arteries

A Case-Based Symposium

Supported by an educational grant from Philips