# SFA In-Stent Restenosis: What is the Optimal Treatment Strategy

**RICHARD R. HEUSER, MD, FACC, FACP, FESC, FSCAI**
**Chief of Cardiology, St. Luke's Medical Center, Phoenix, Arizona**
**Professor of Medicine, Univ. of Arizona College of Medicine, Phoenix, Arizona**

# *Presenter Disclosure Information*

*Name: RICHARD R. HEUSER M.D.*

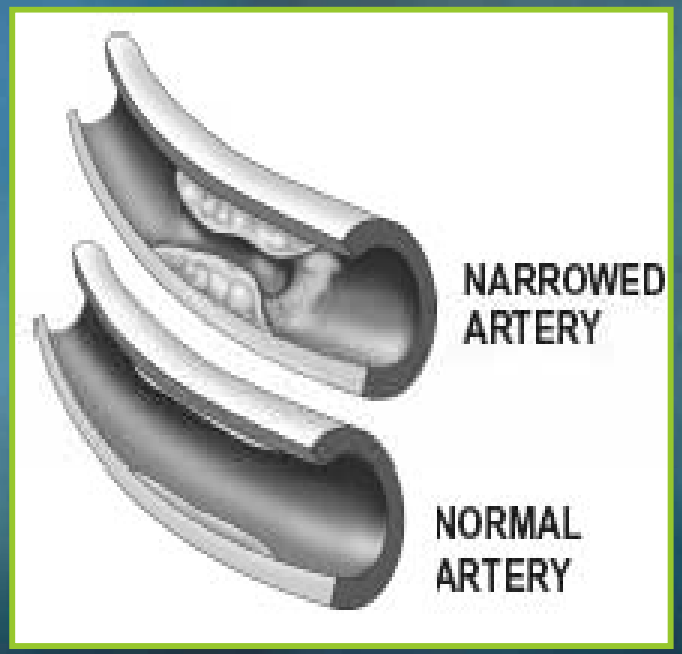
*Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.*

- *QuantumCor, Major Stock Holder/Medical Director;*
- *Radius Medical, Avinger and Claret Medical, Major Stock Holder;*
- *PQ ByPass, Founder and Major Stock Holder;*
- *CSI, Stockholder;*
- *Spectranetics, Abbott, Medtronic, Bard, Abiomed, Honorarium;*
- *Medtronic, Abbott, AngioScore, Speaker;*
- *Acist Medical Systems Grant; and*
- *Verve Medical, Inc., Major Stockholder*

*<u>Patents</u> -- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure*

# Peripheral Arterial Disease (PAD)

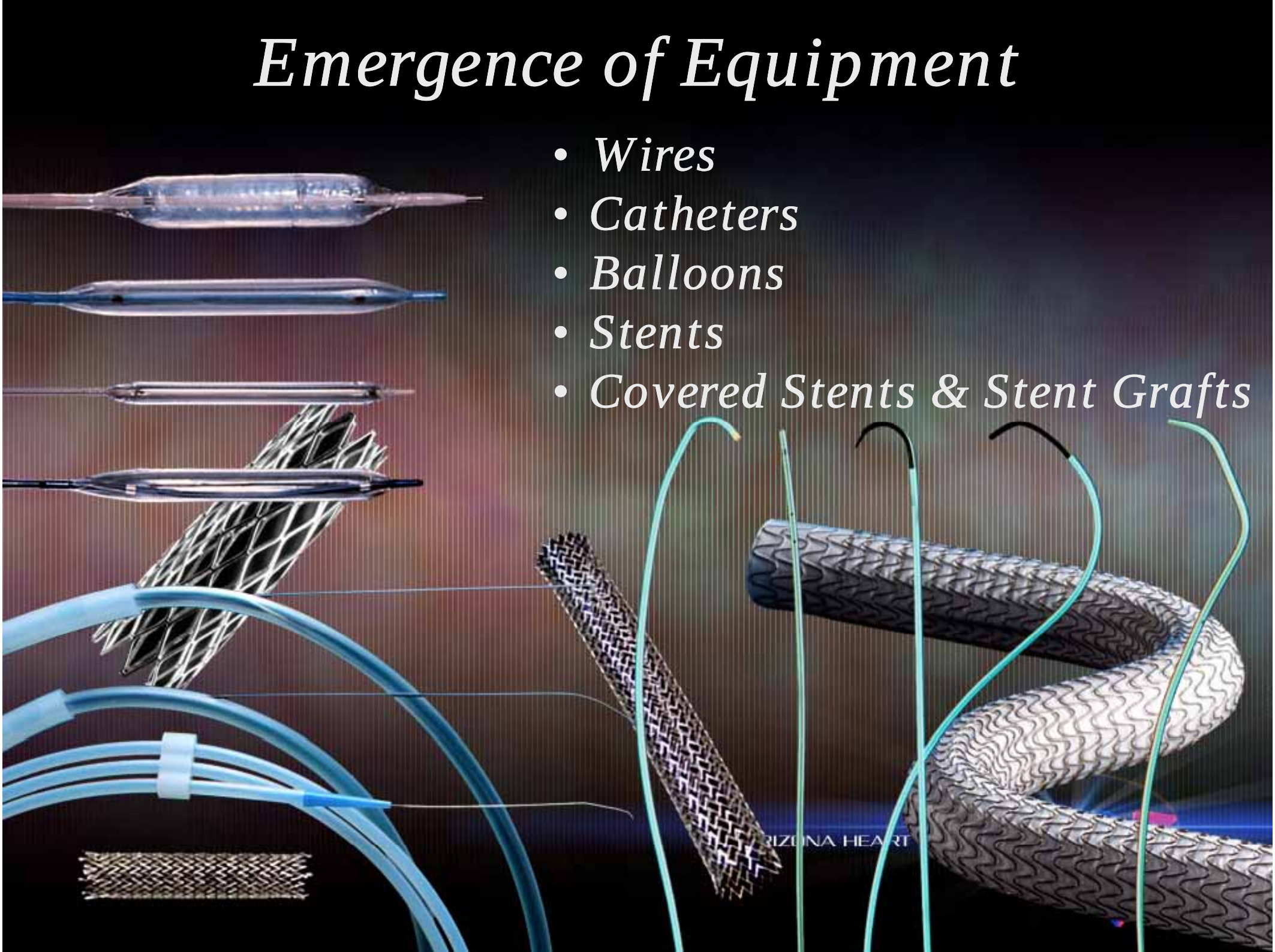
Circulatory problem affecting
8 –12 million people in the U.S.

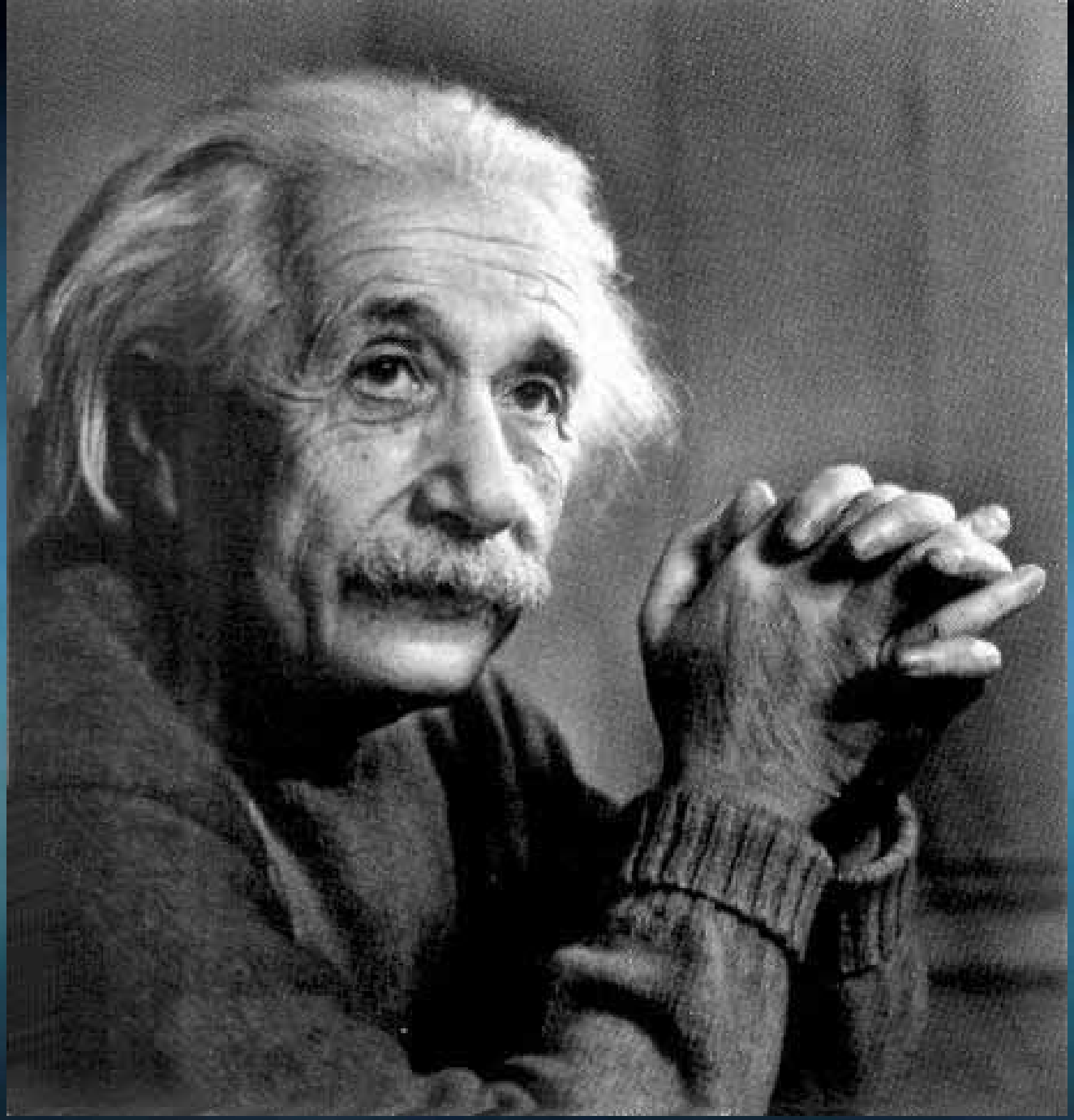



Source: Journal of American Medical Association.

# *Emergence of Equipment*

- *Wires*
- *Catheters*
- *Balloons*
- *Stents*
- *Covered Stents & Stent Grafts*







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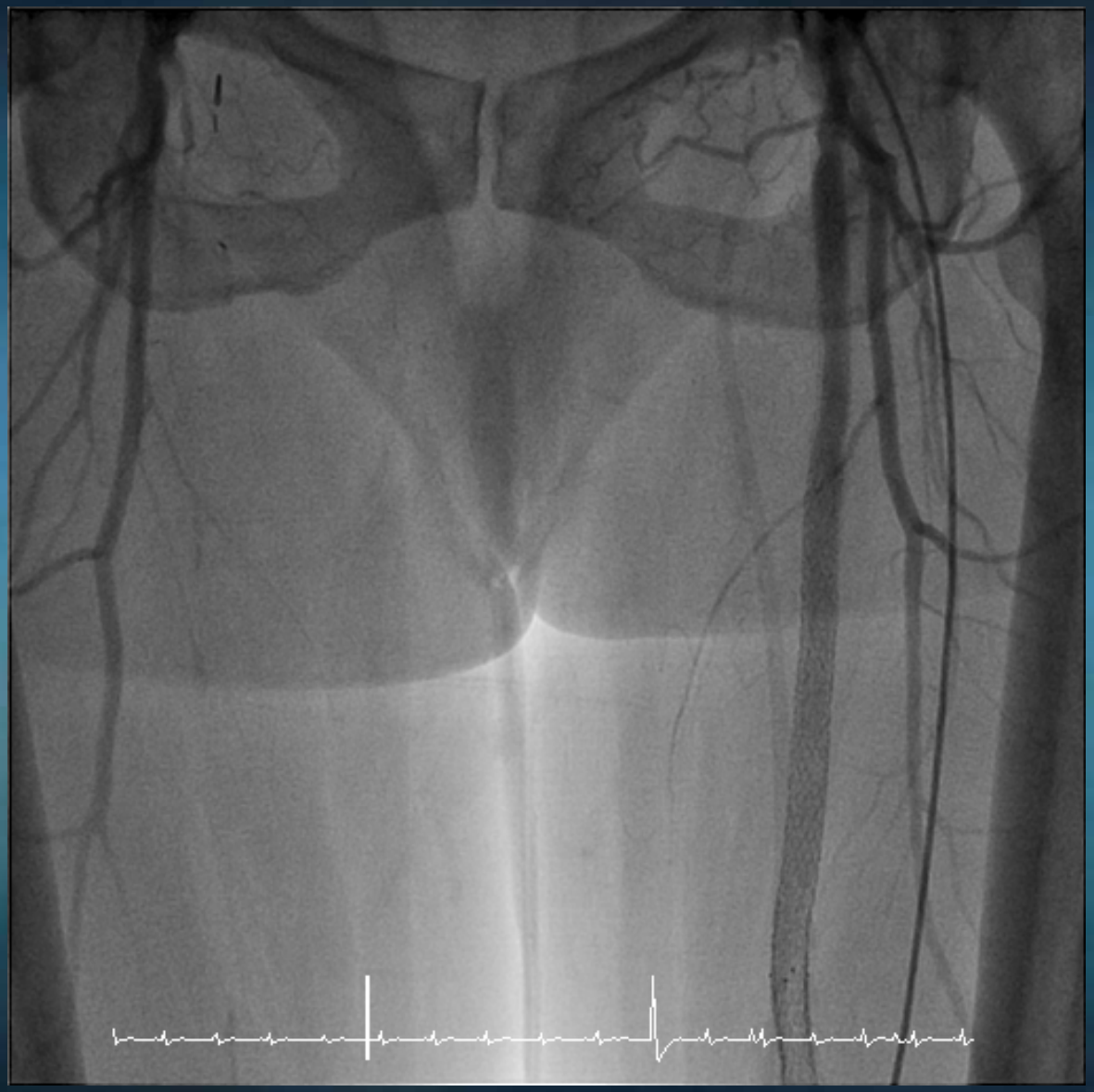
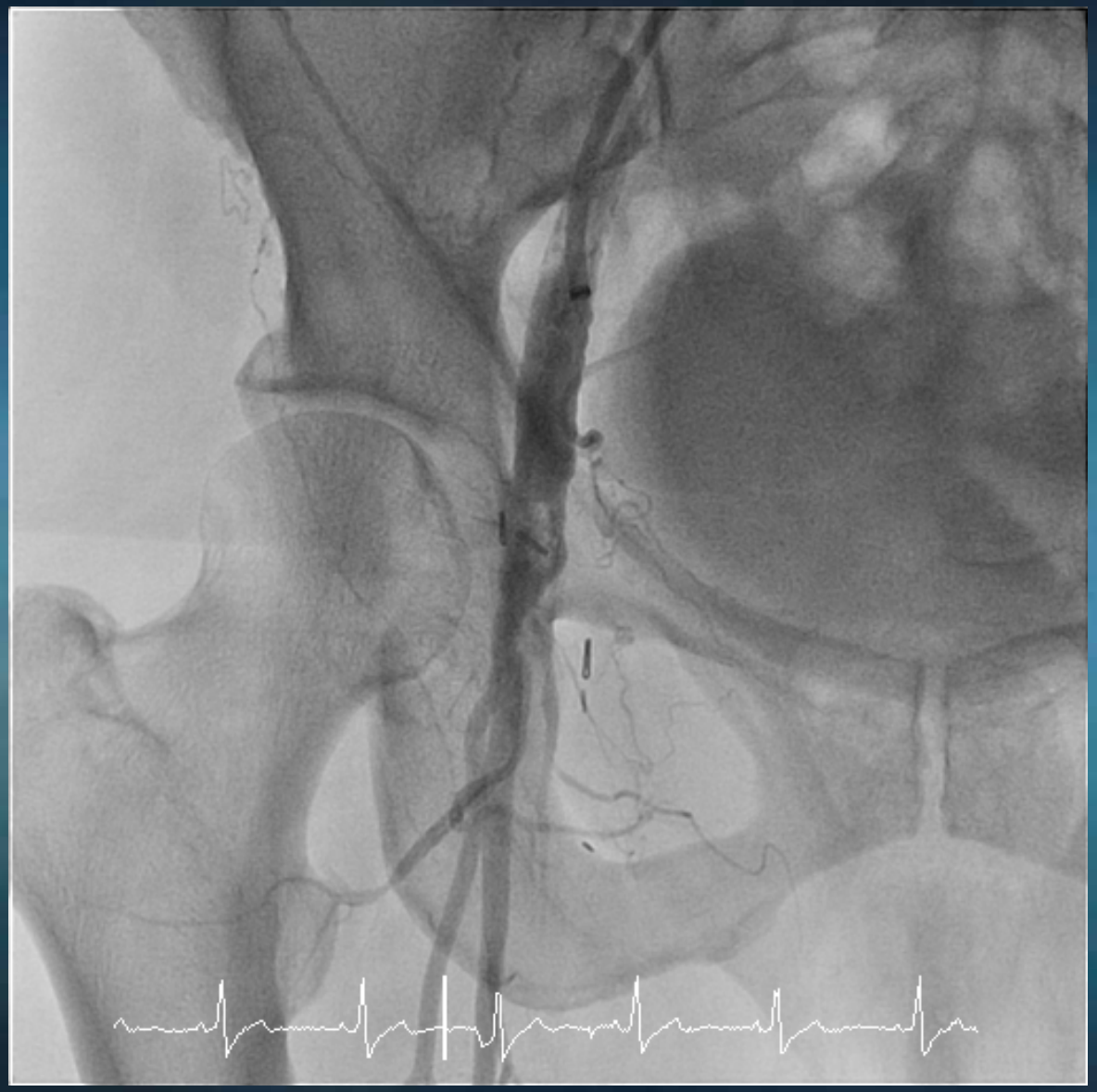
**70 year old African American female with recurrent claudication of her right leg, previous atherectomy, ABI .2**



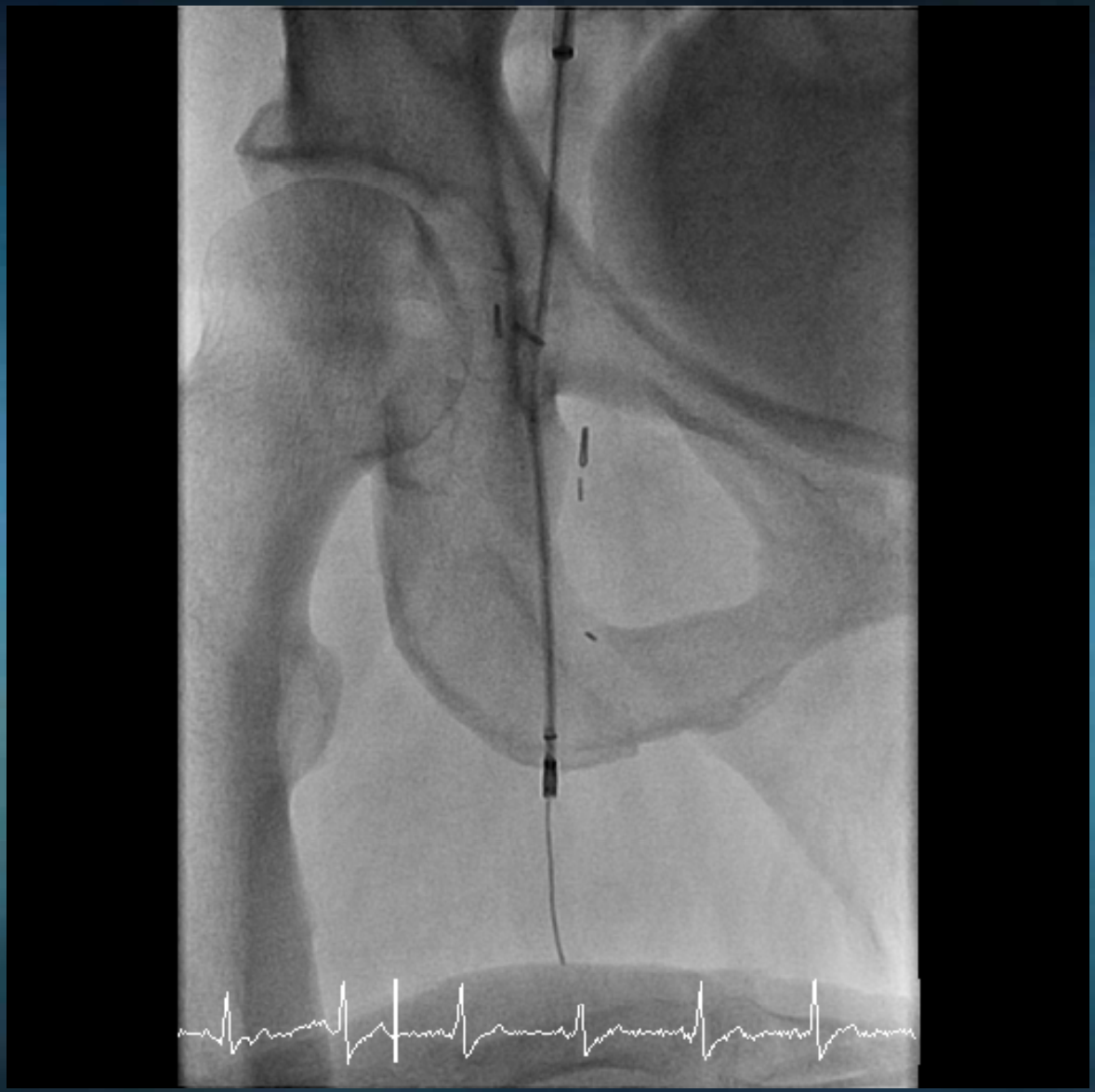
# VW – SFA CTO



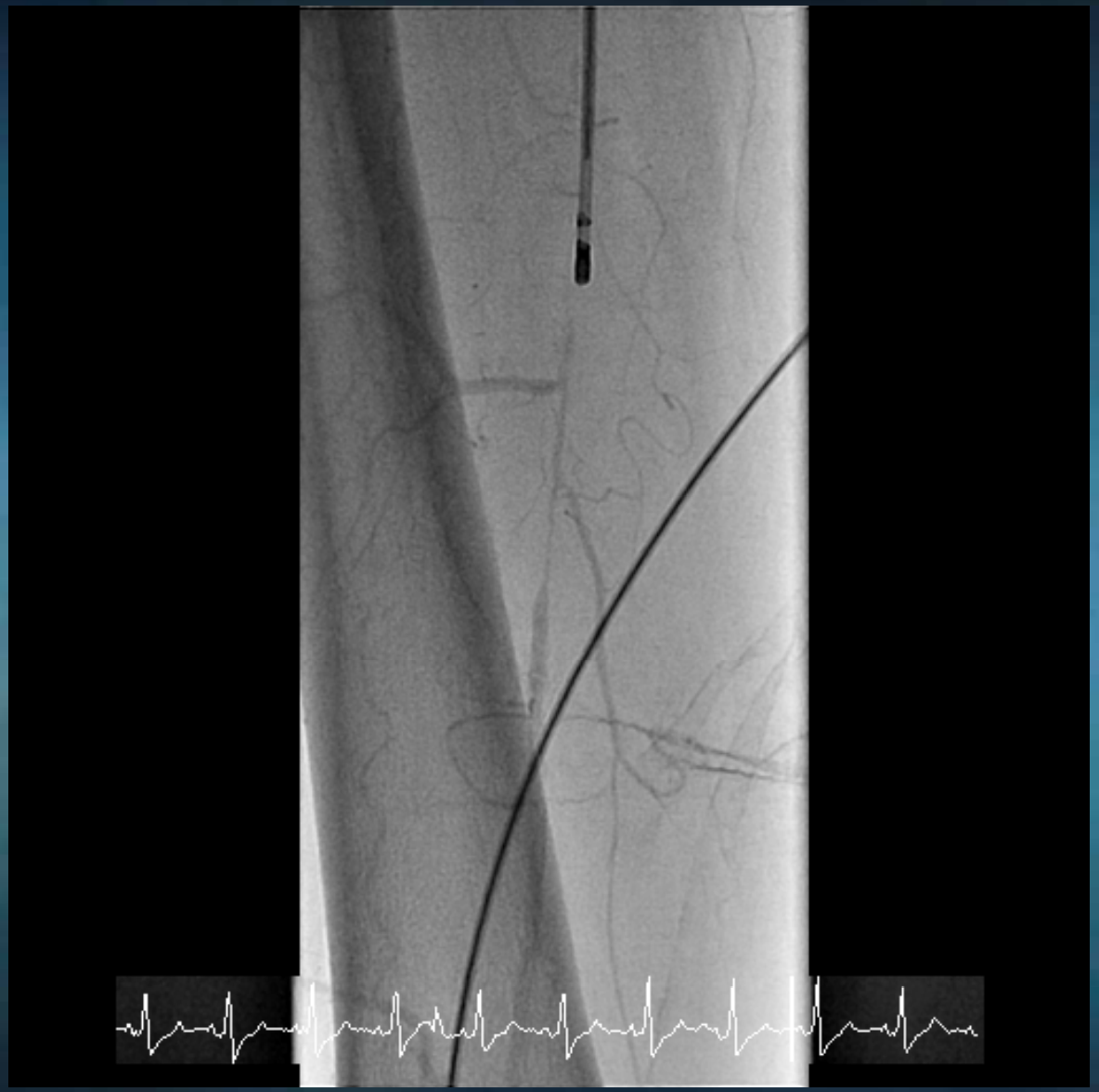
# VW – SFA origin CTO



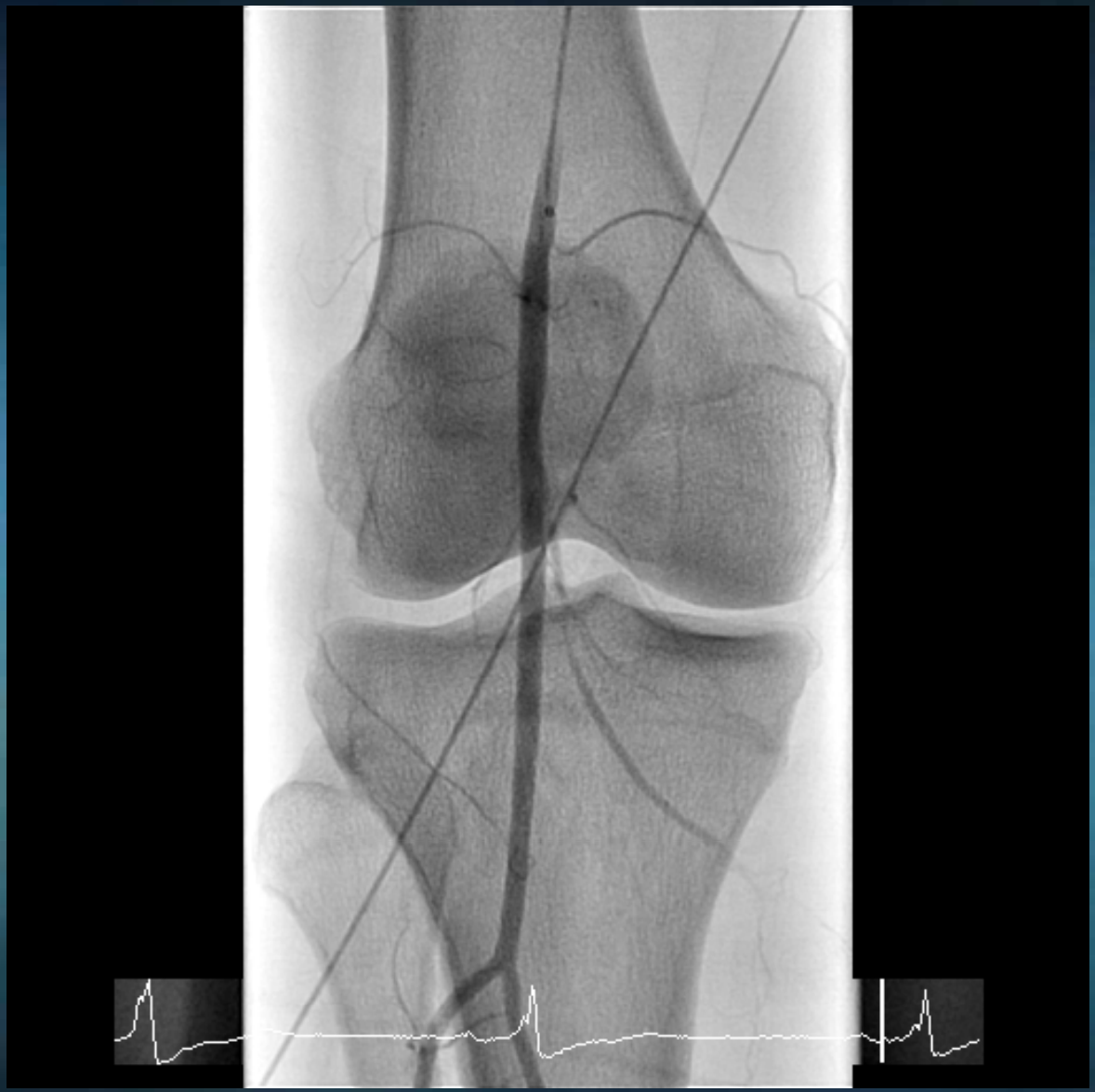
# VW – Wildcat crossing



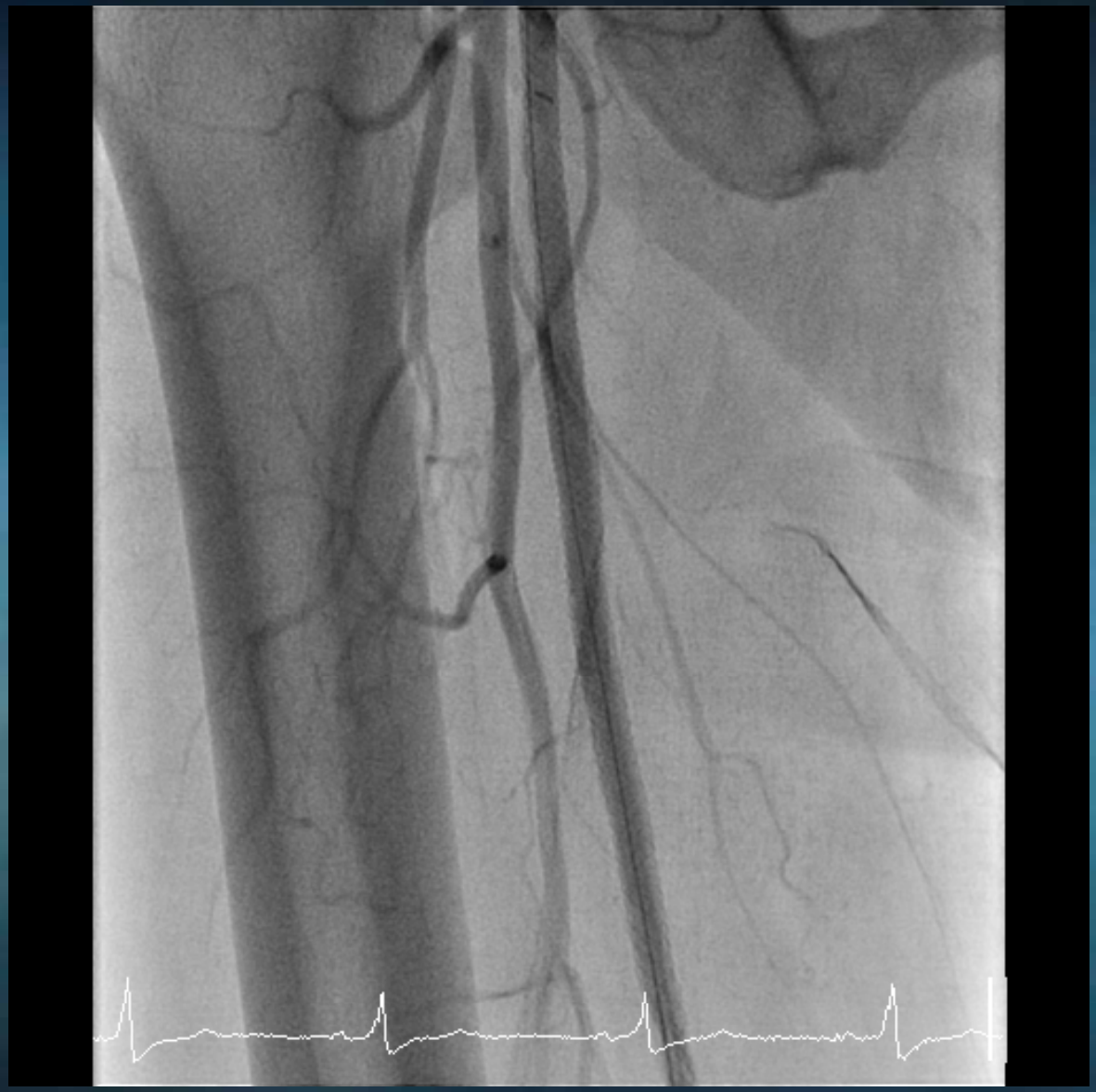
# VW – Injection through Wildcat



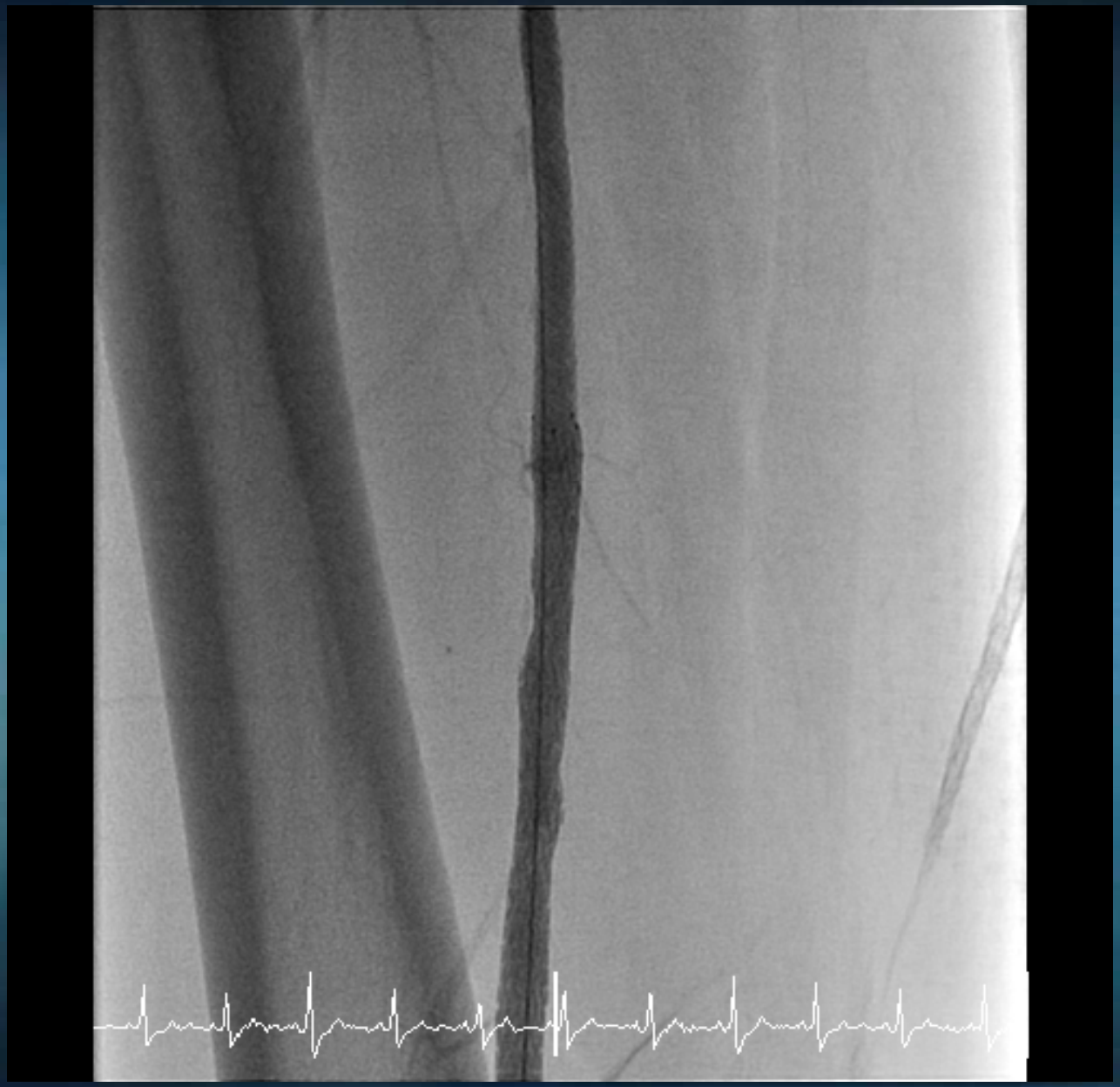
# VW – Successful recanalization



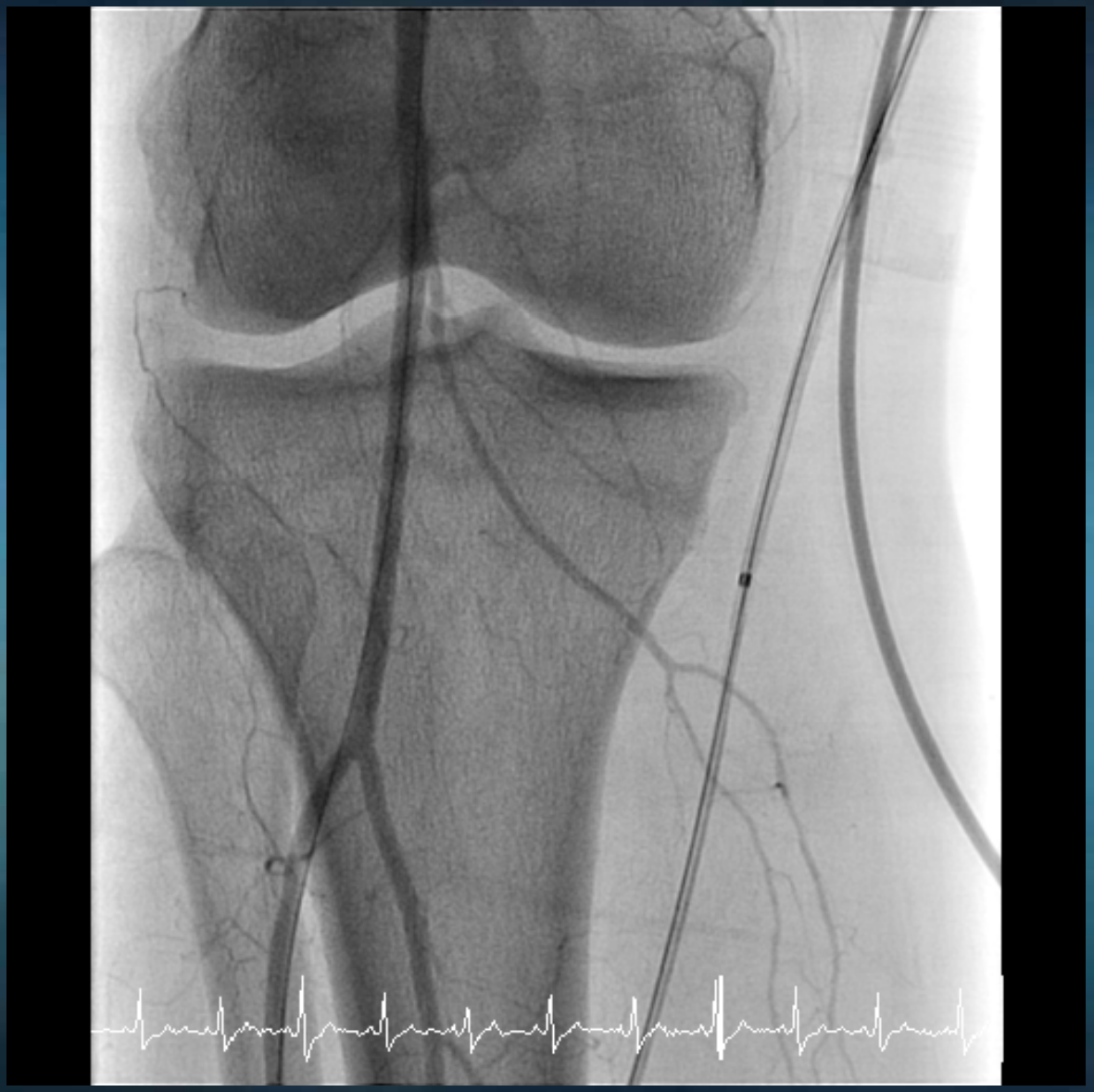
# VW – Post recanalization



# VW – Mid SFA



# VW – Popliteal post



This 50 year old diabetic female presented 2 years ago with a non-healing ulcer.

We recanalized her infrapopliteal vessels and placed an SFA stent. She presents with resting claudication and her ABI has gone from .95 to .2.

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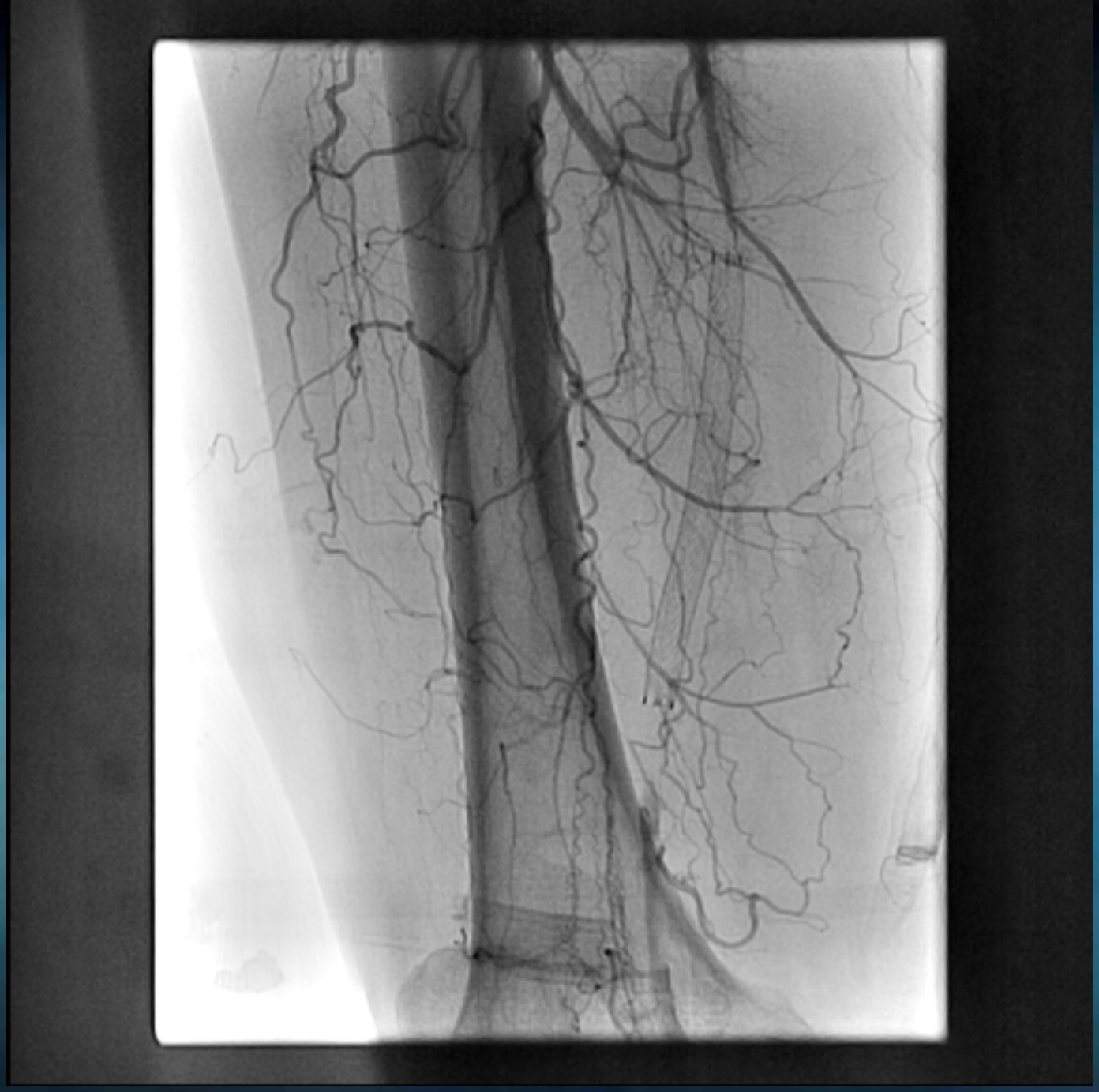
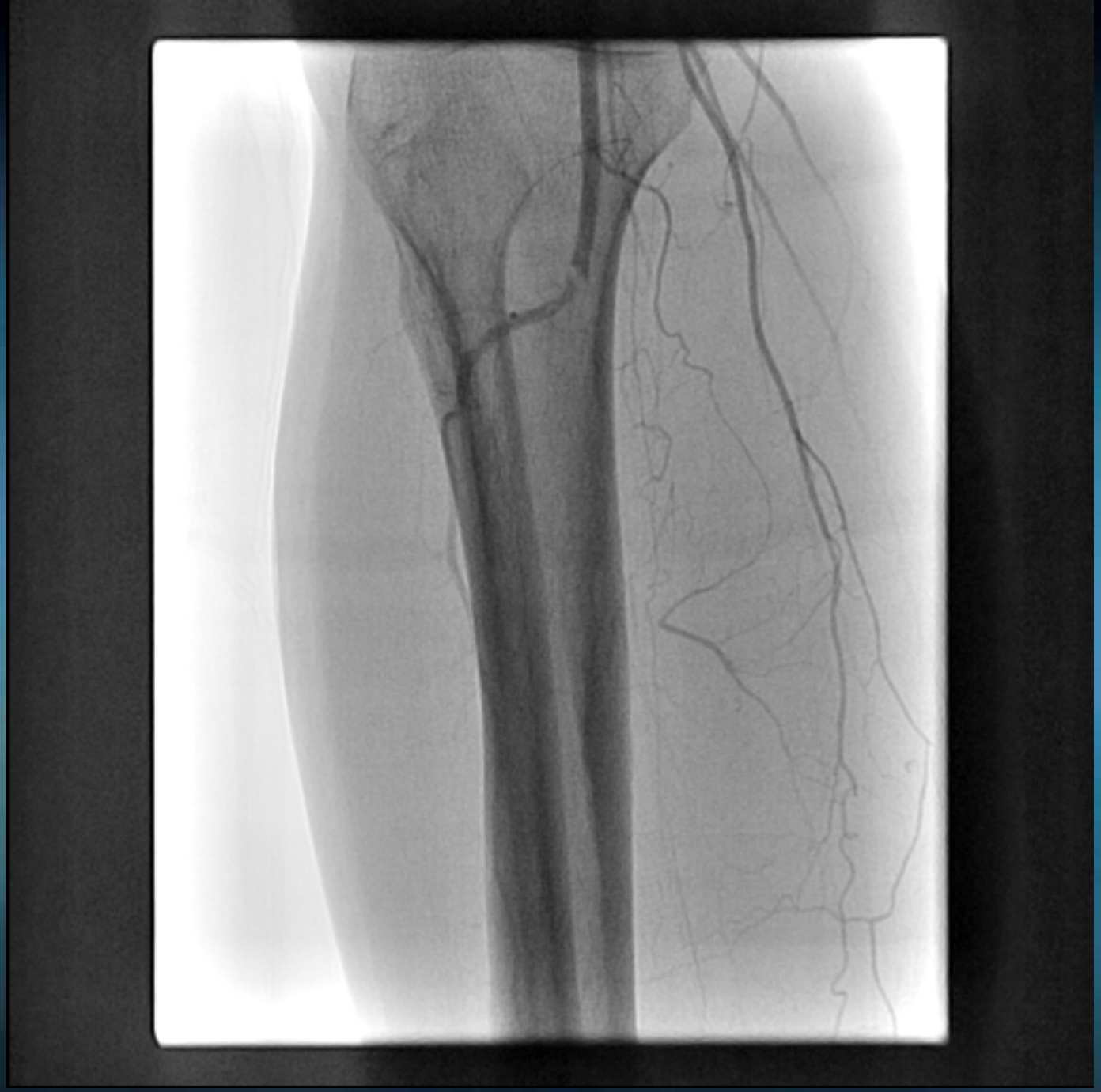
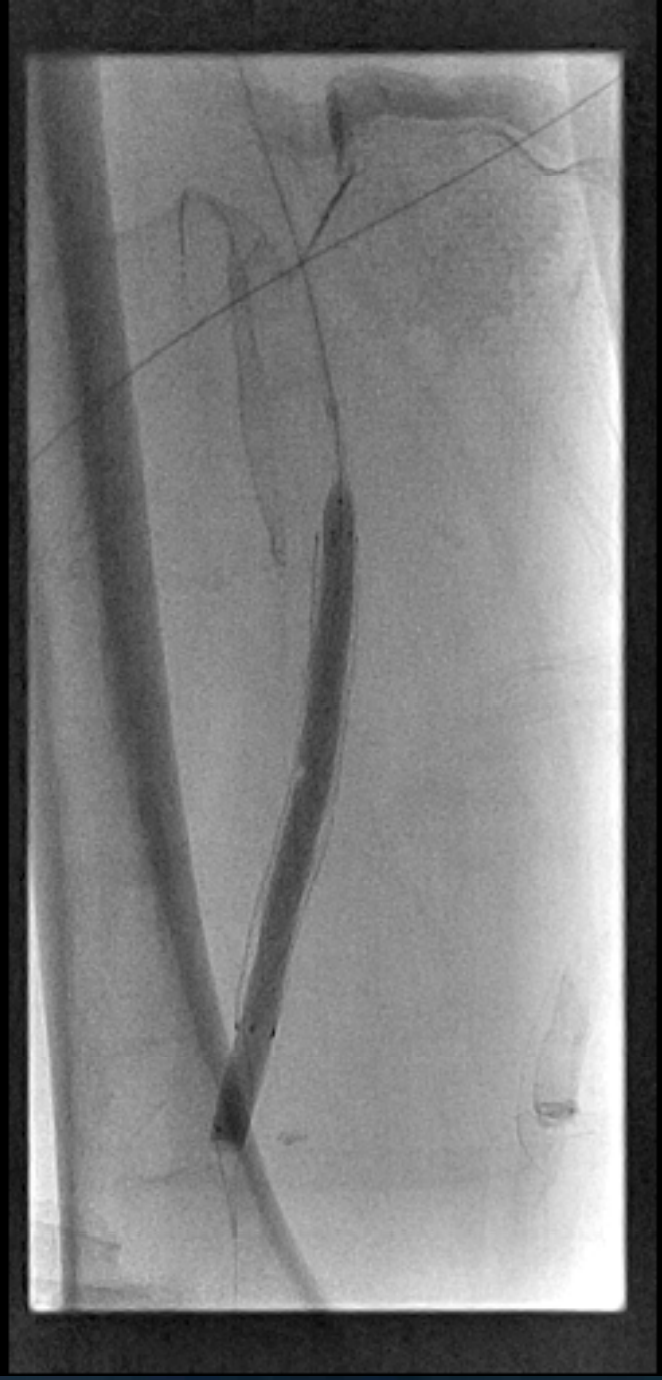
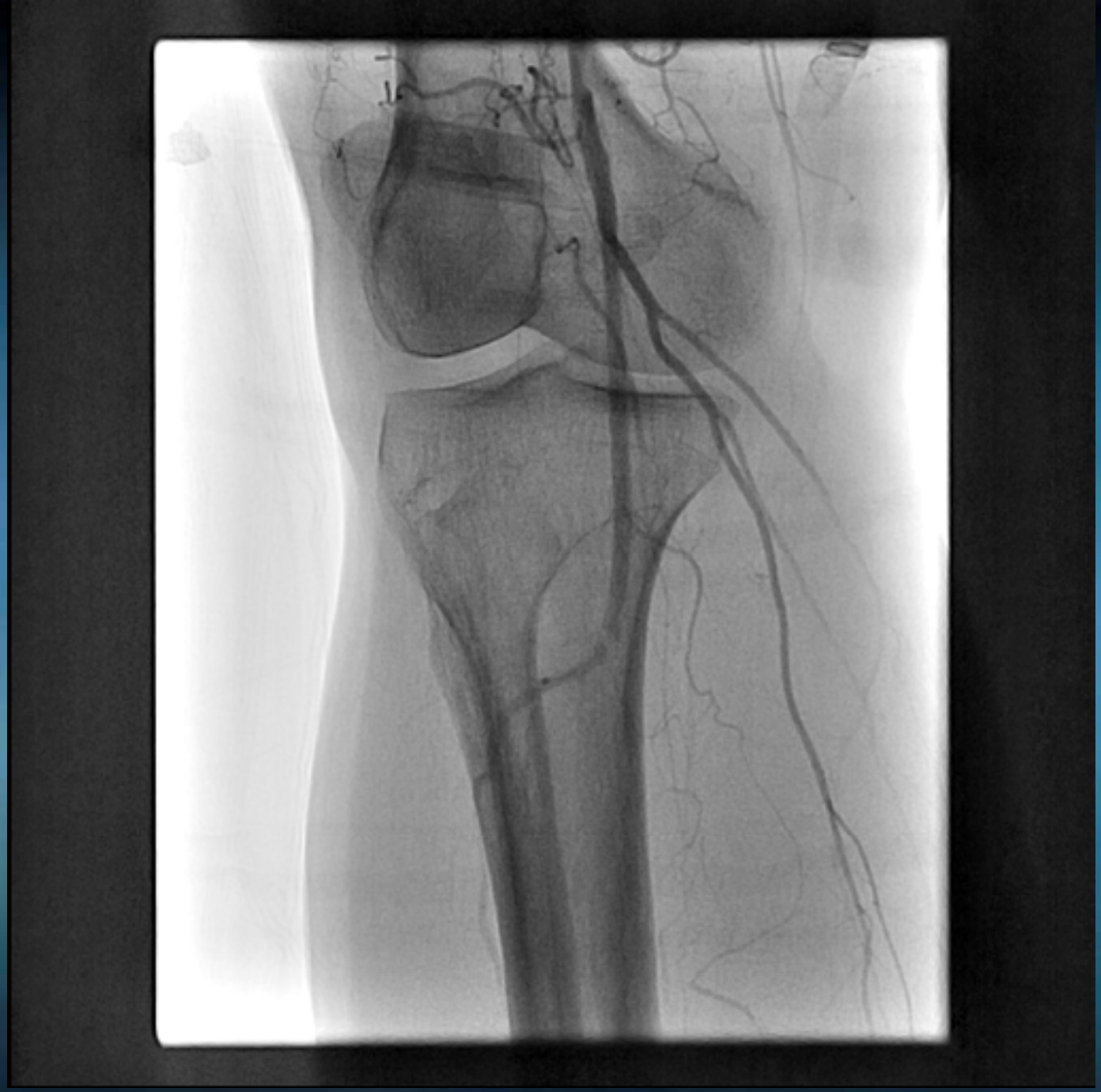
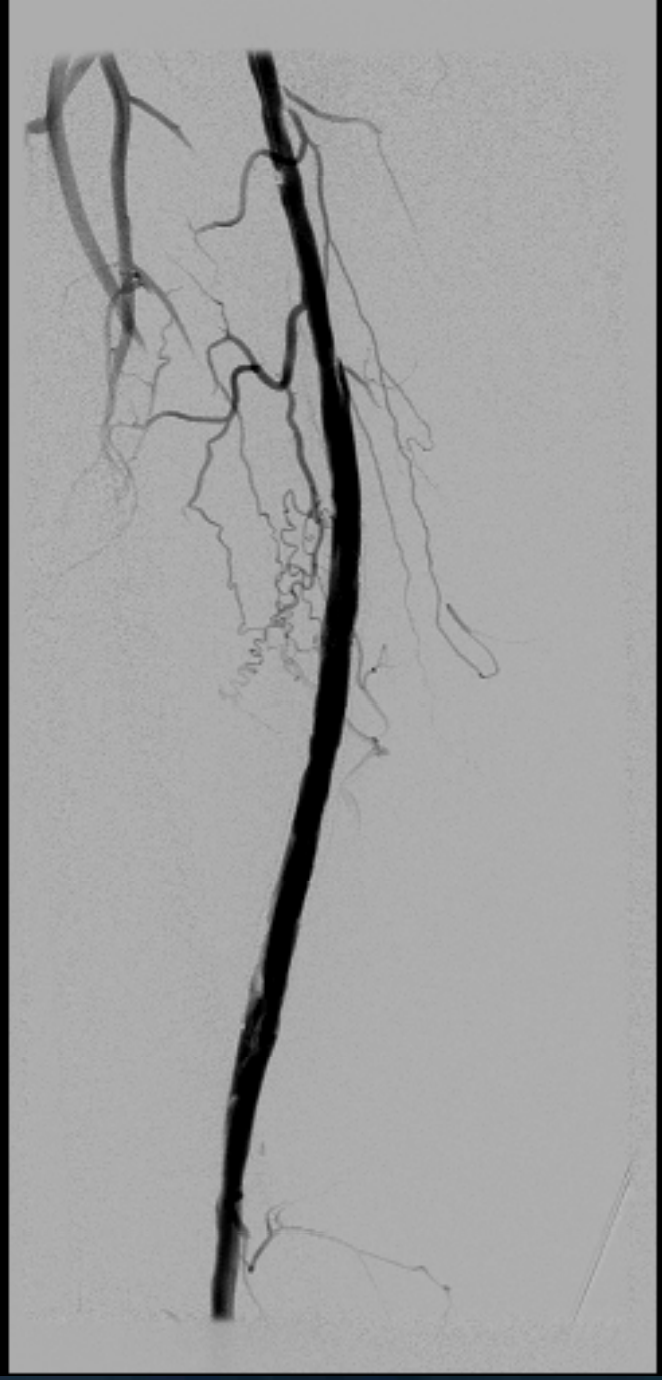
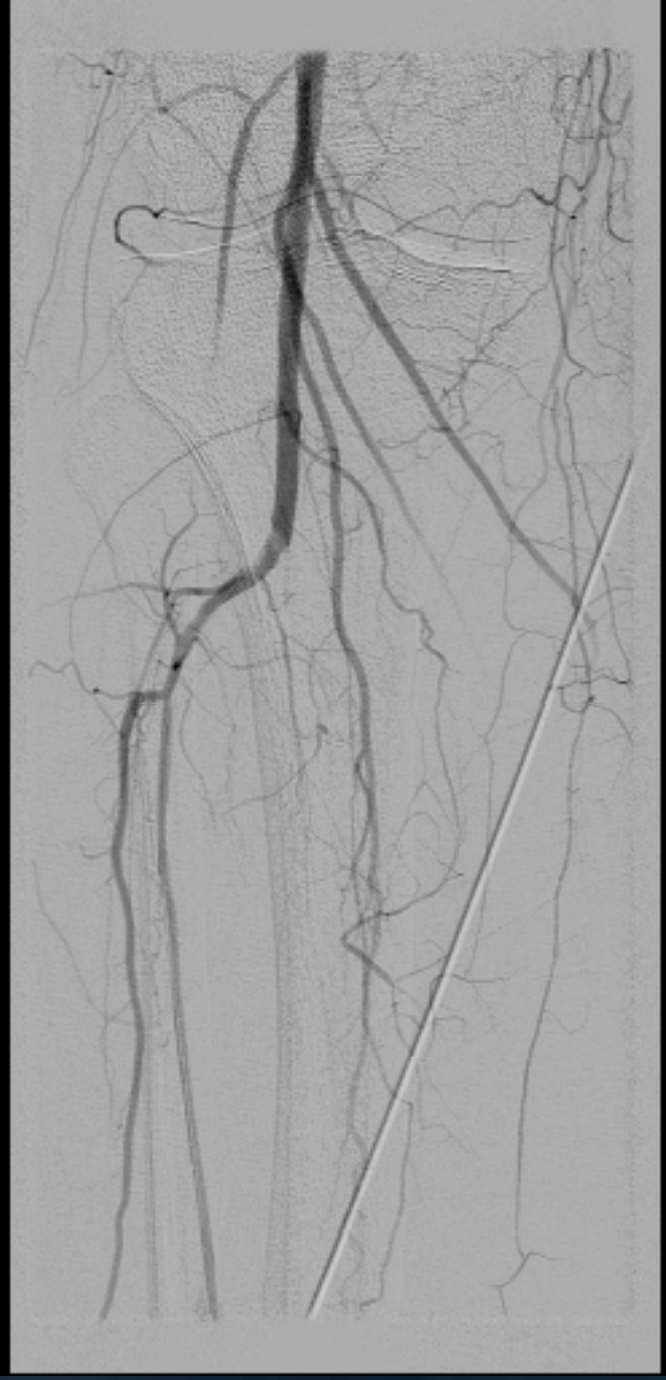








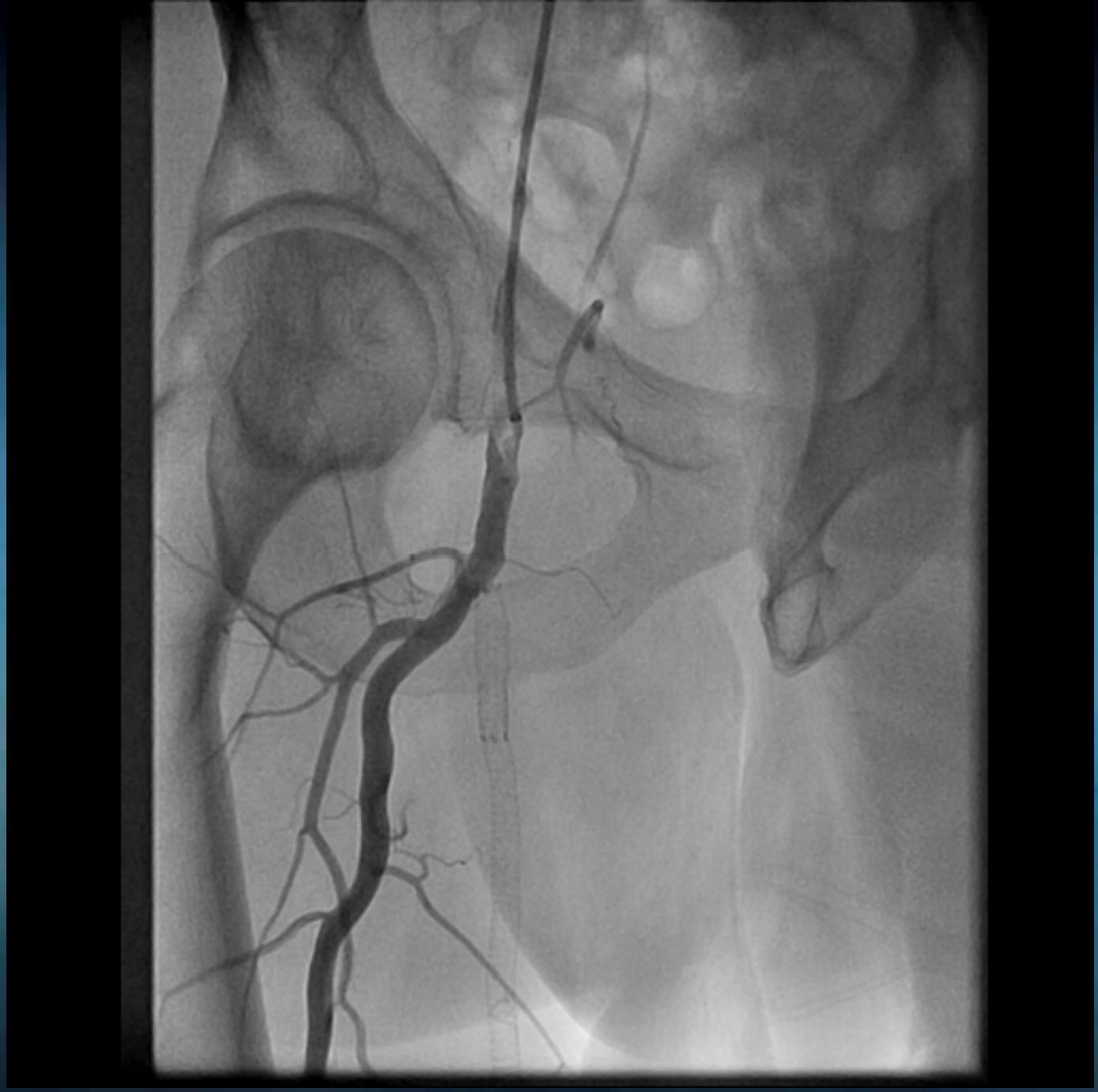


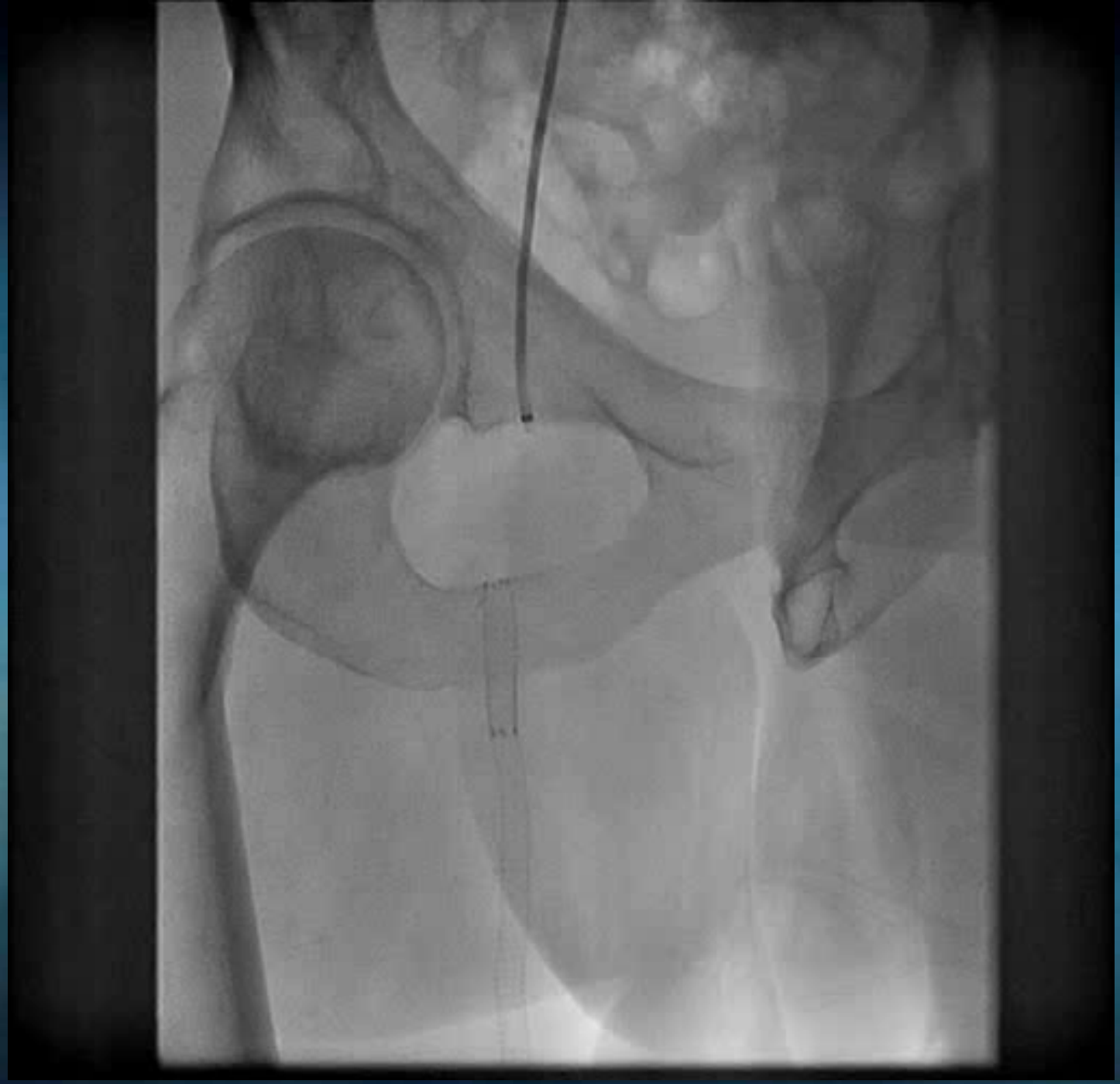


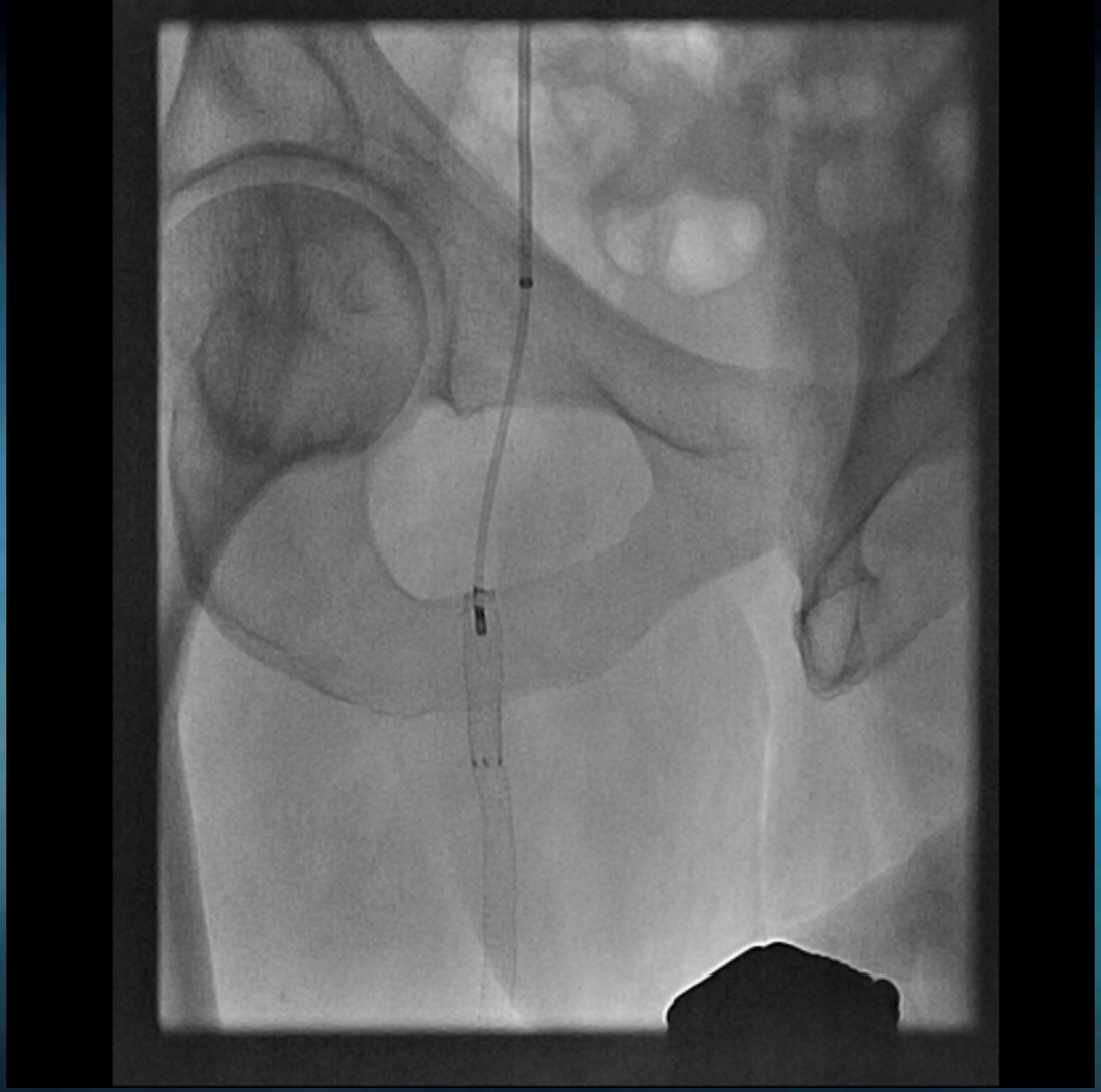
58 year old African American gentleman with Huntington's Chorea has critical limb ischemia of his right heel.

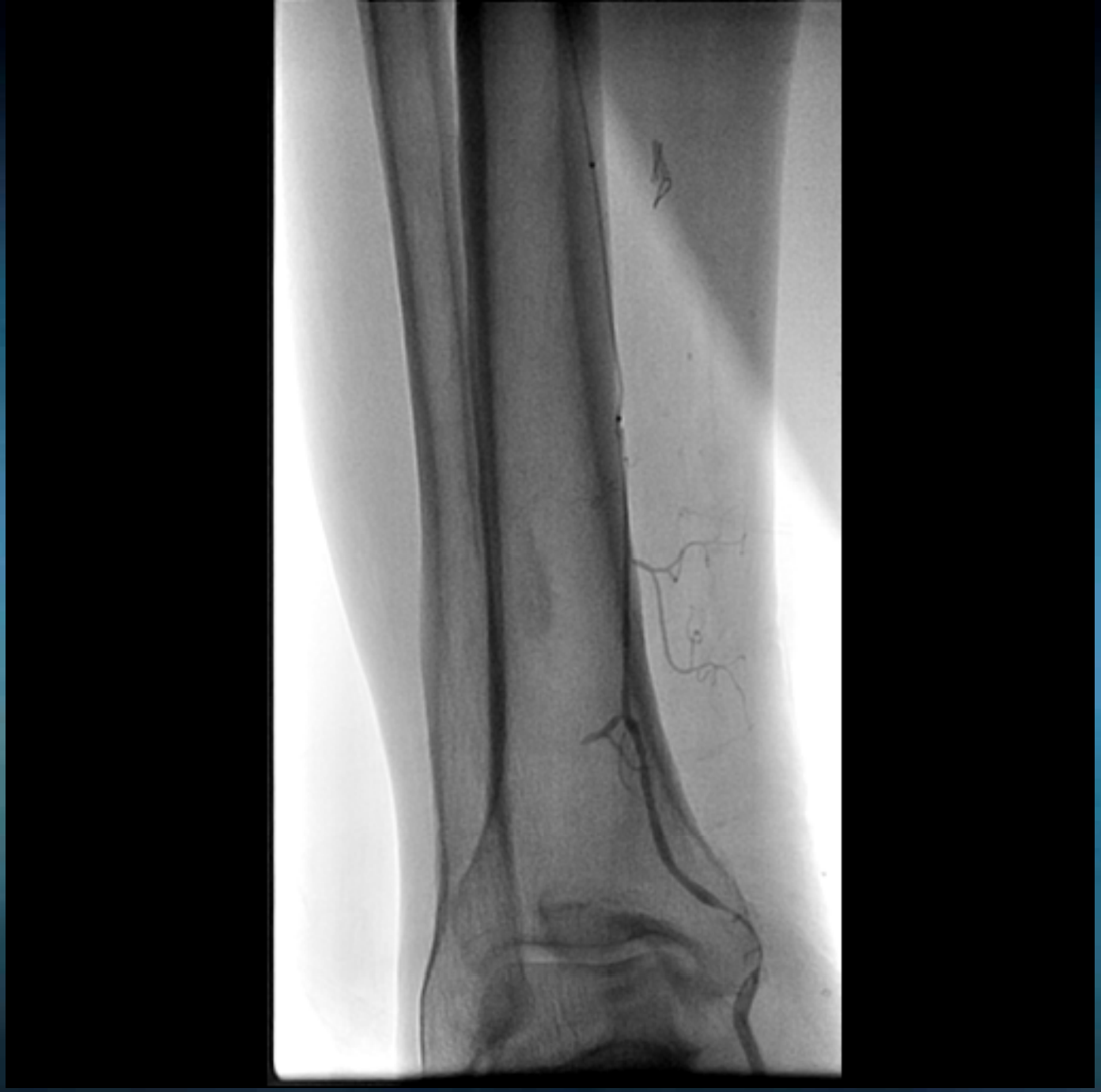
In 2010, I recanalized a totally occluded series of self expanding stents of his SFA.

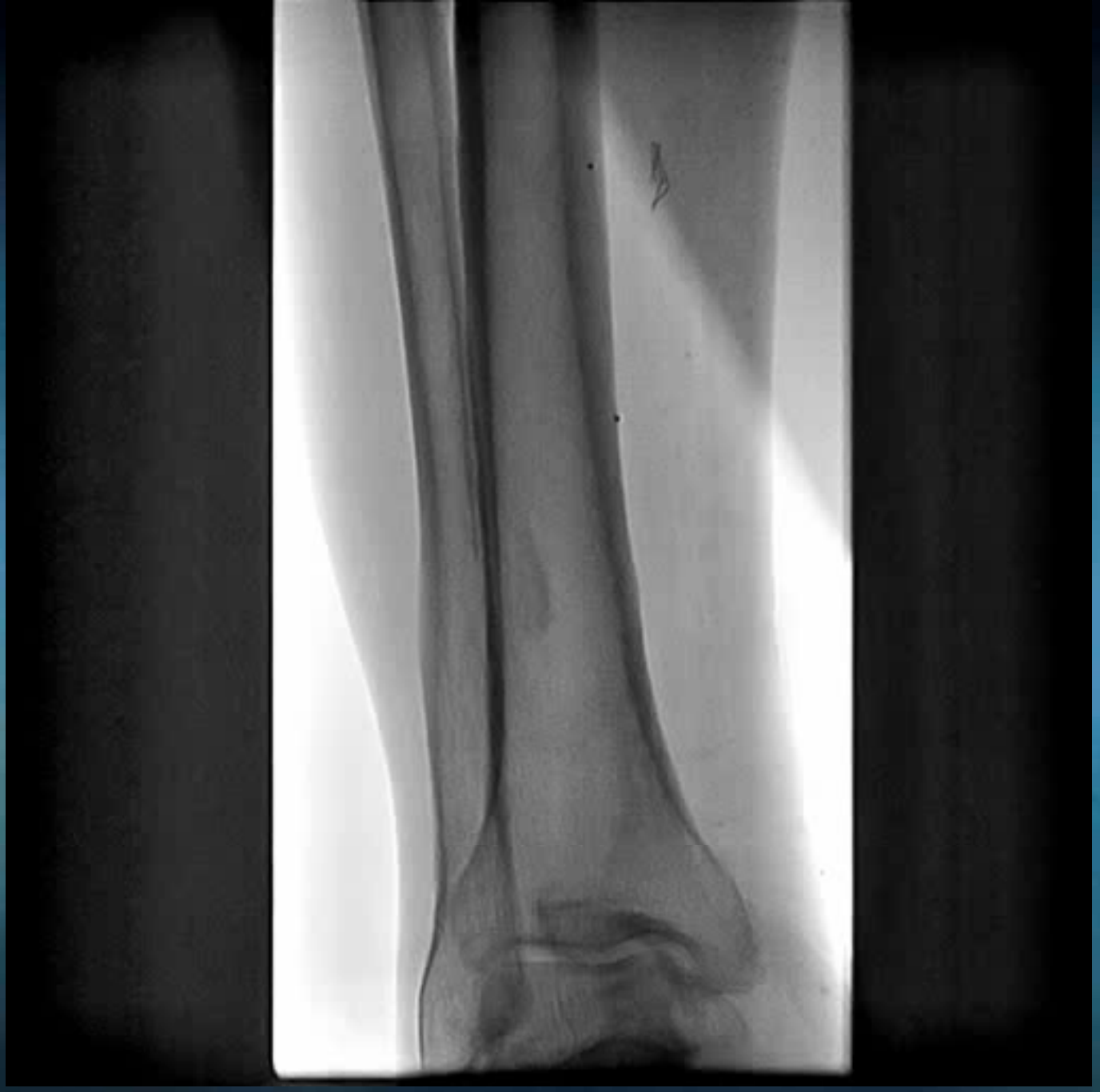
He presents with recurrence of symptoms in his heel.

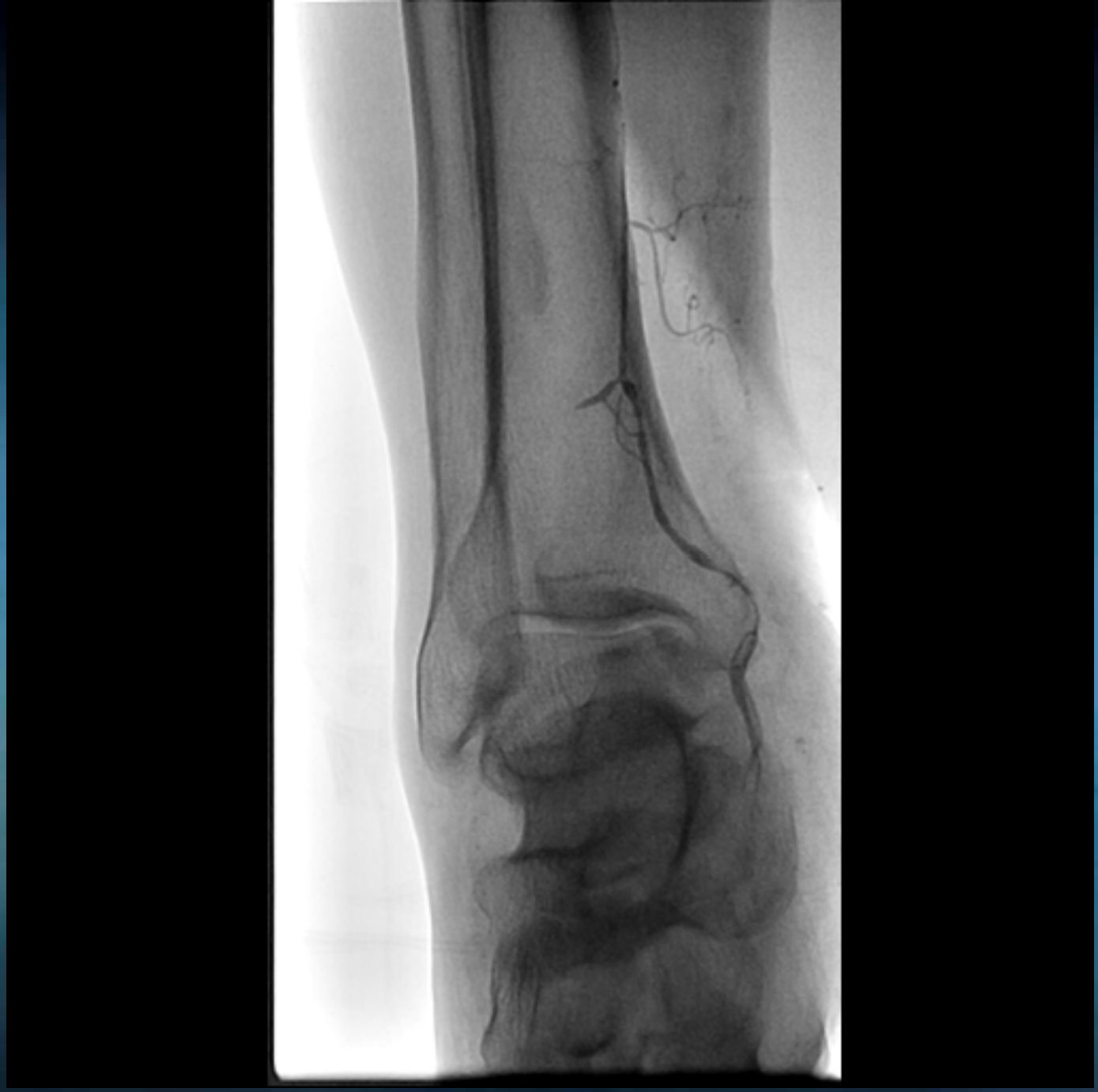


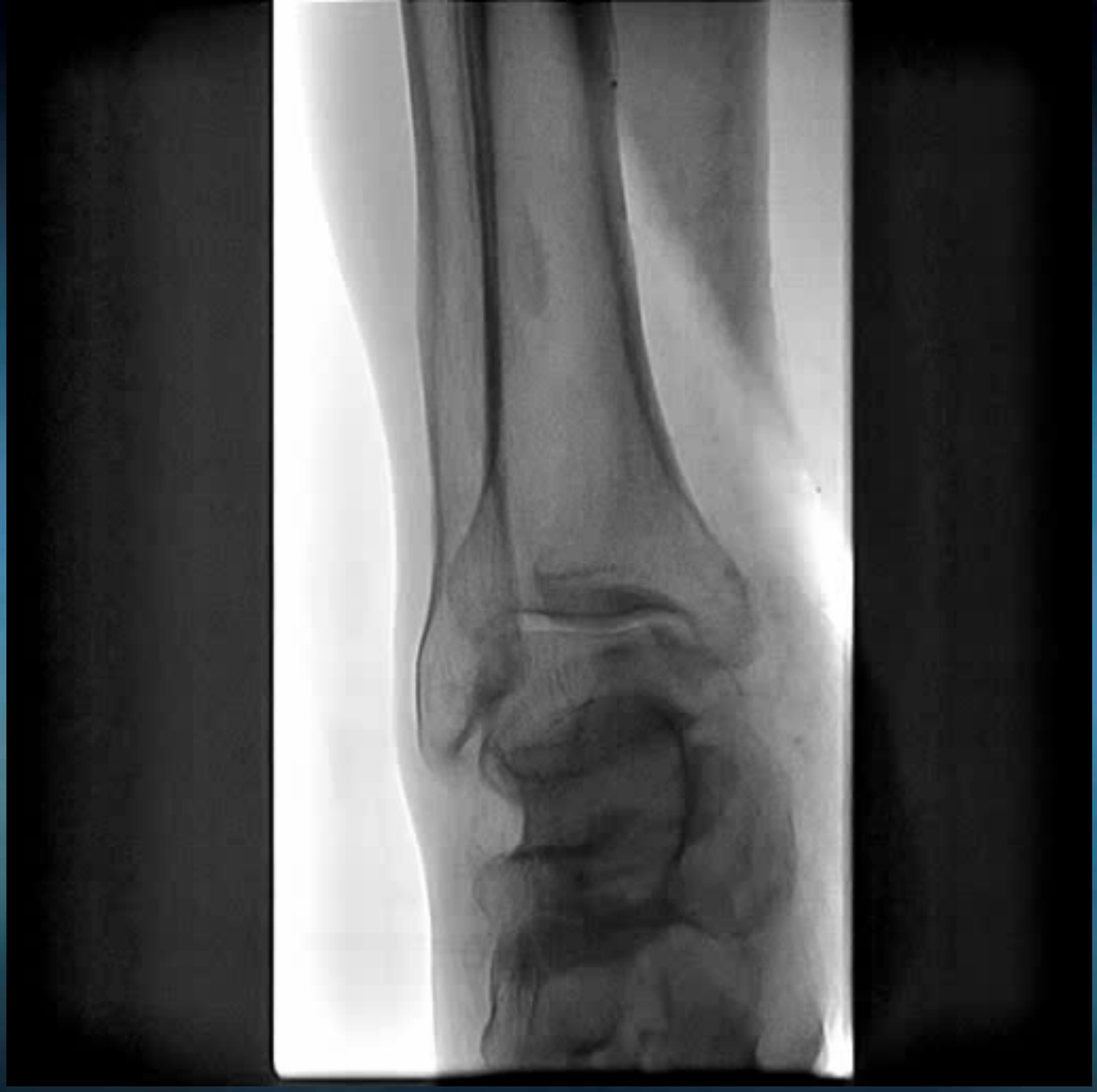


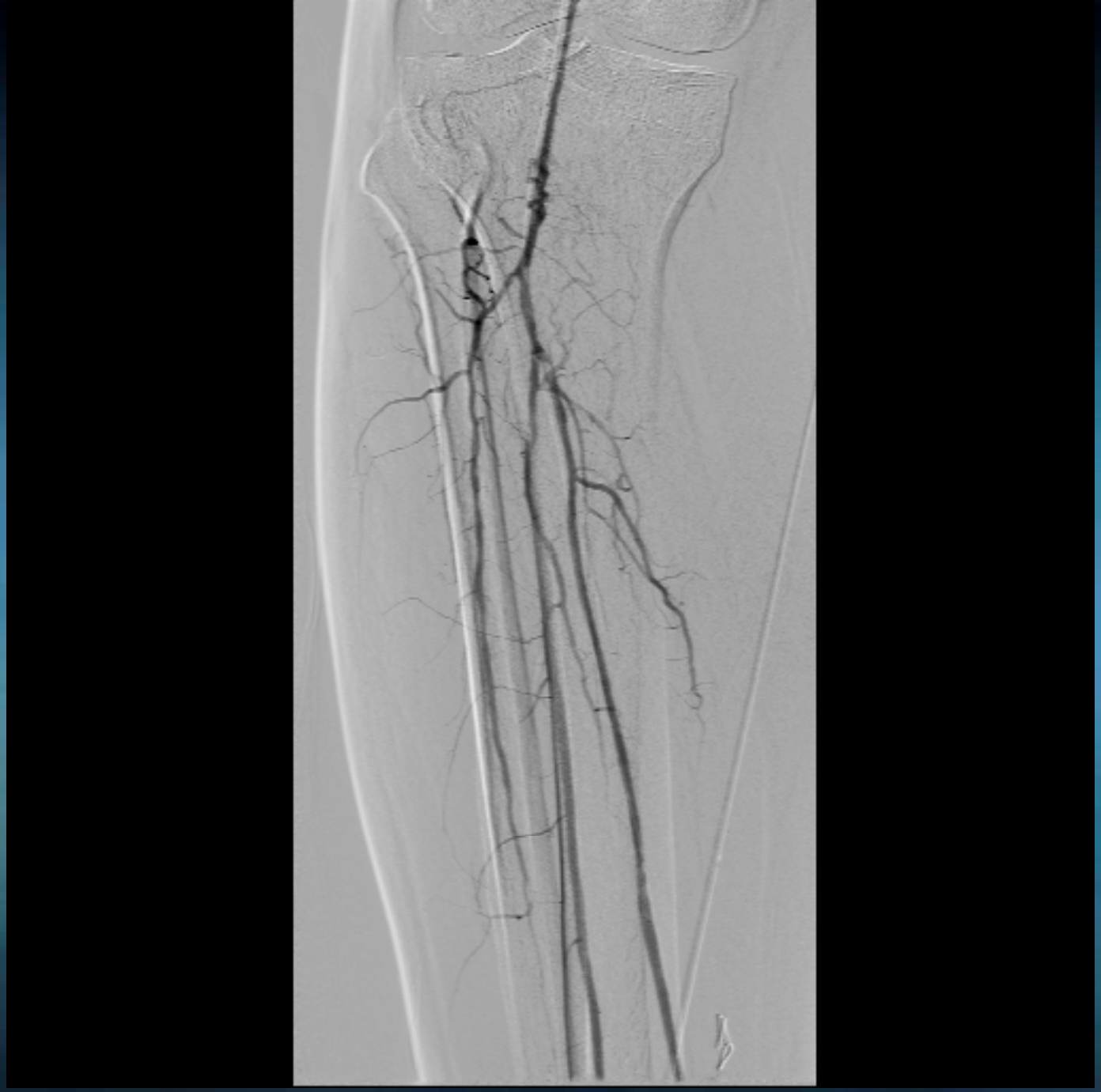


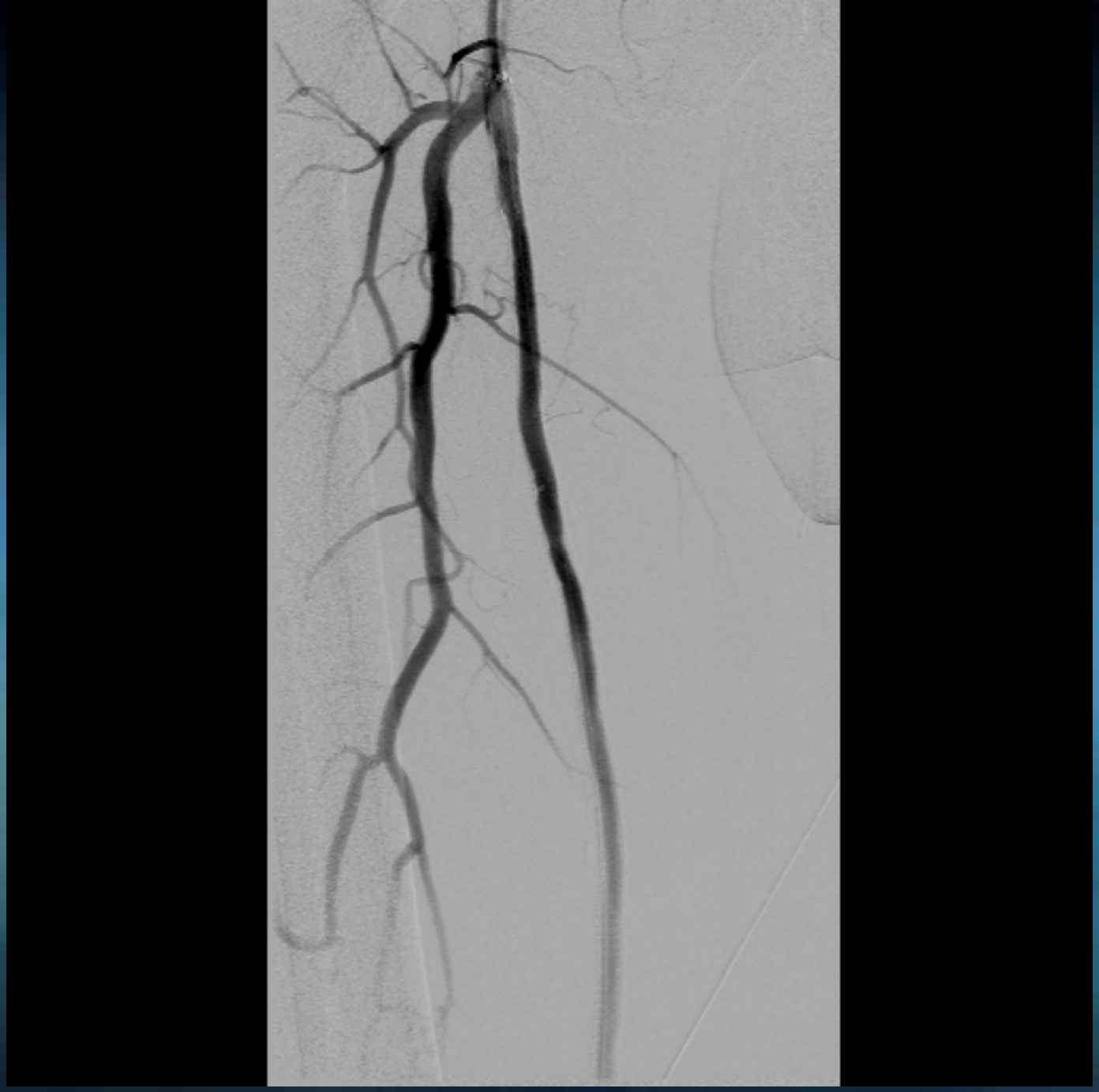


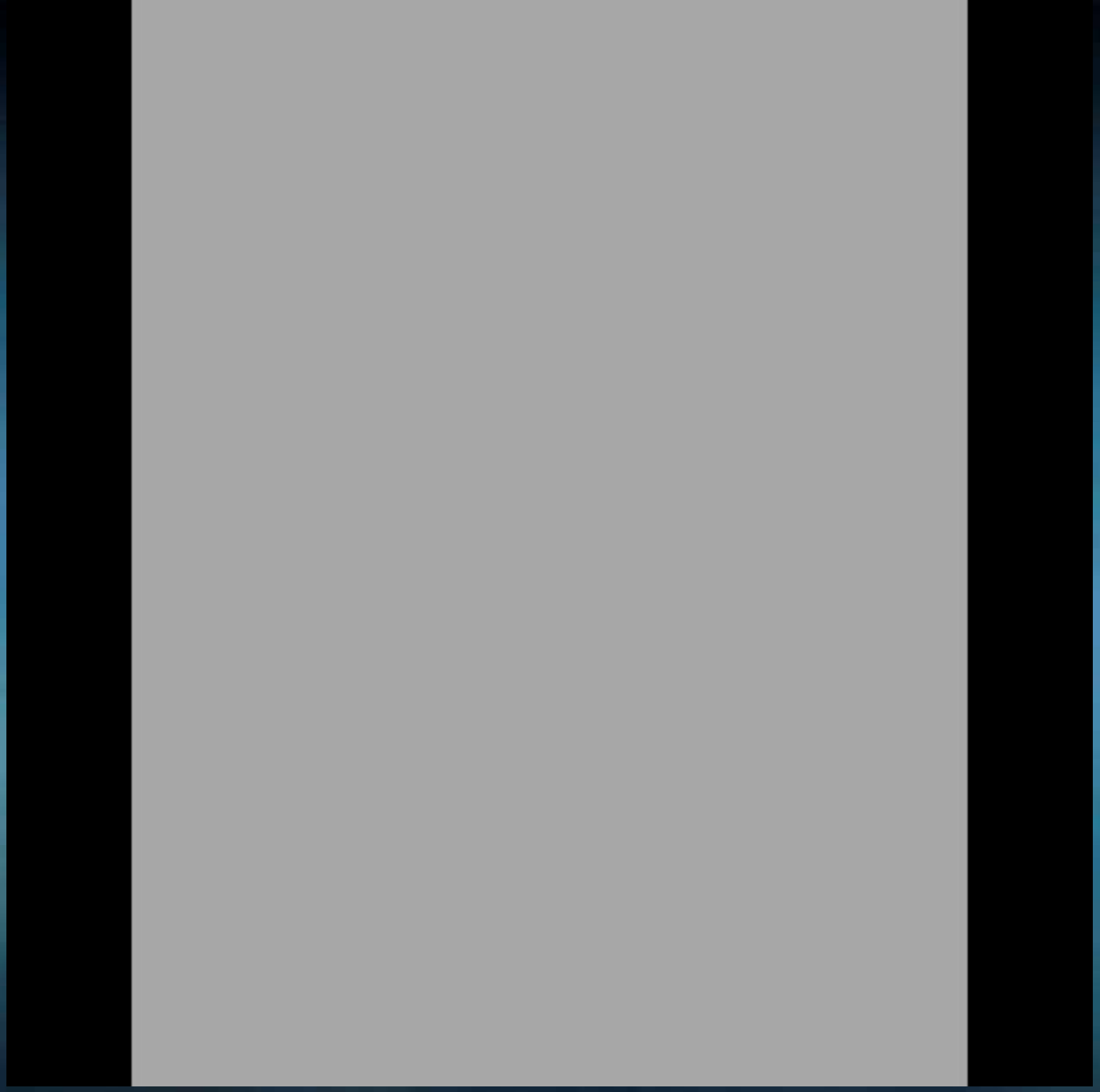


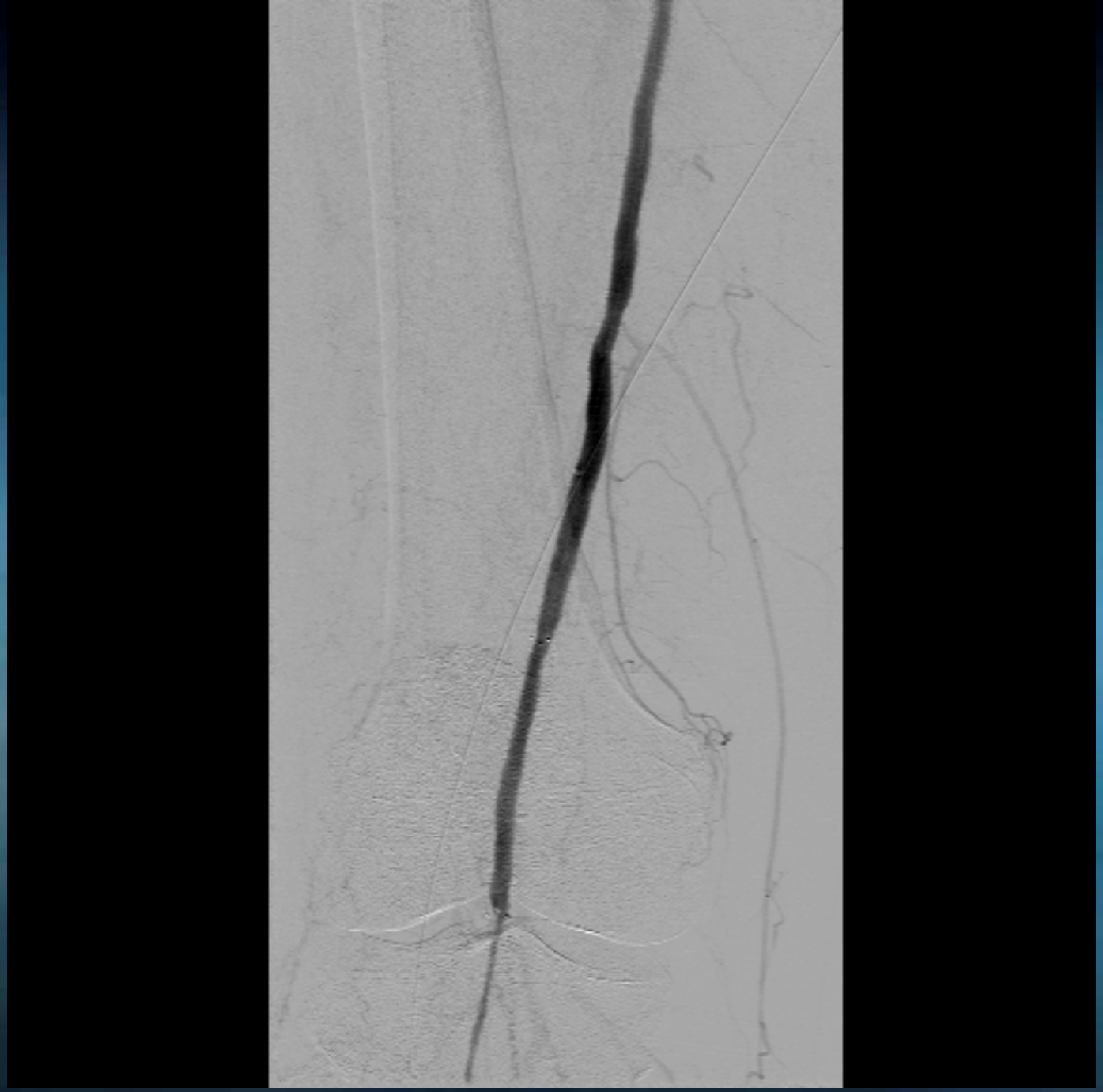


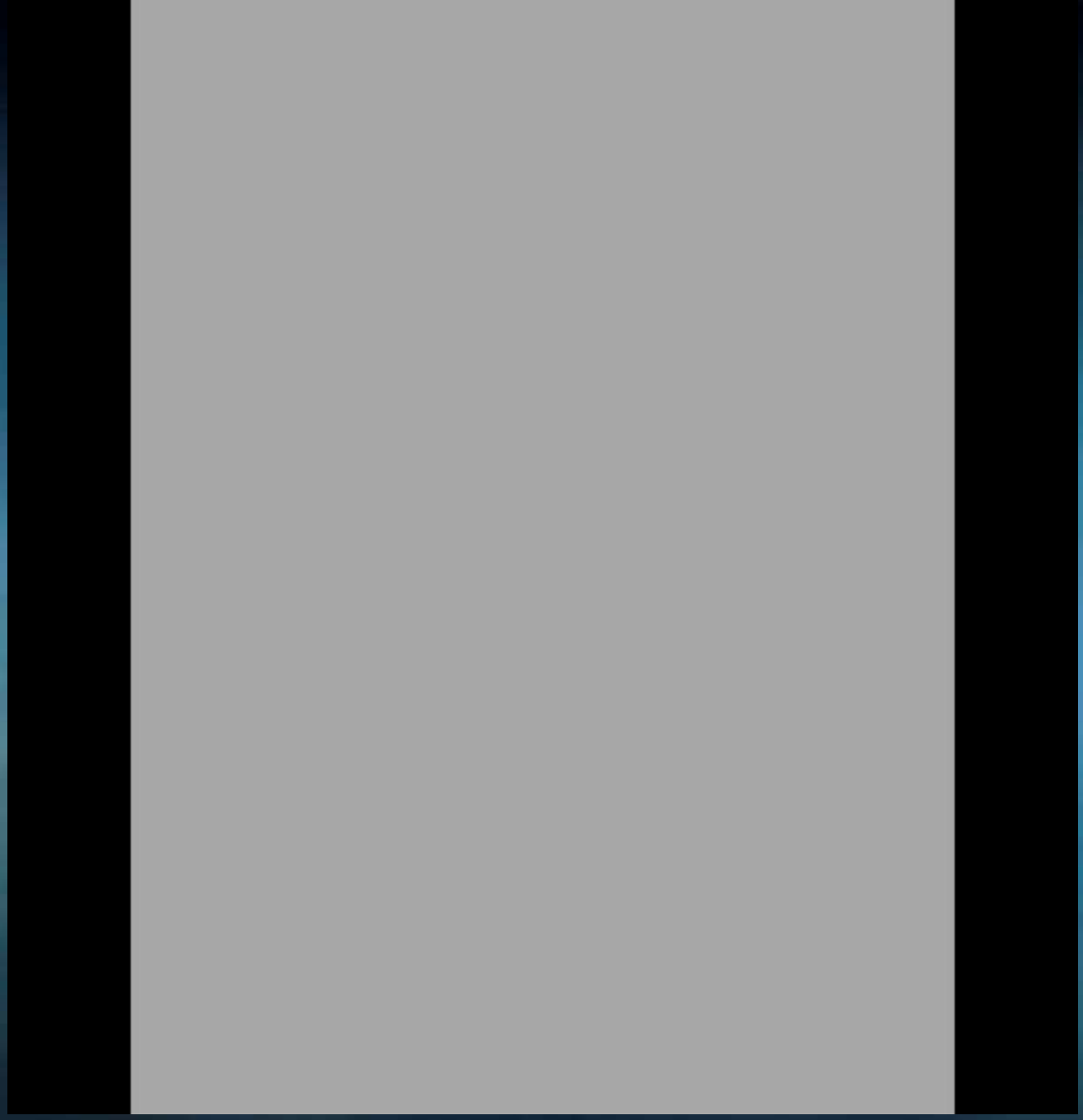


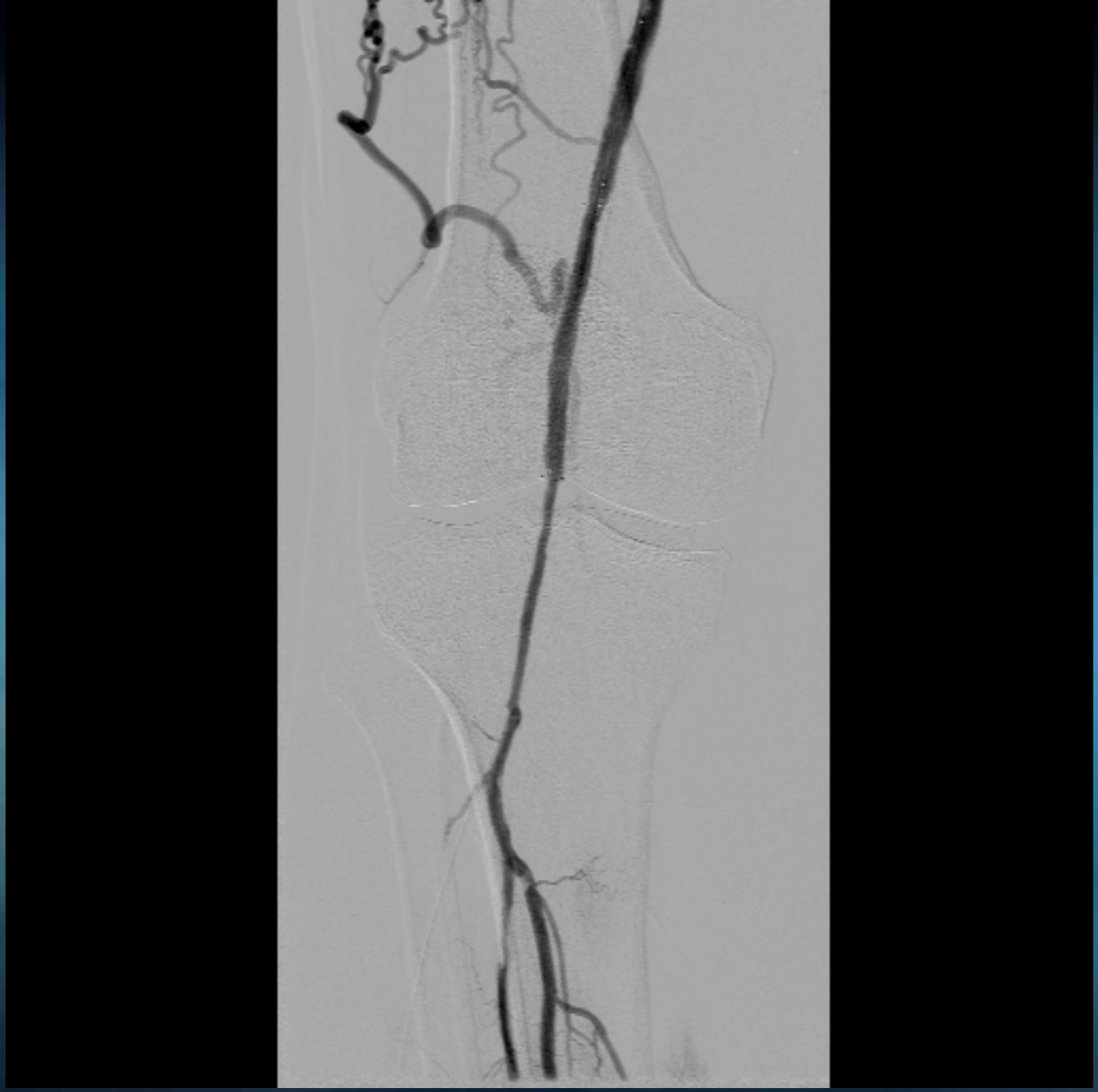


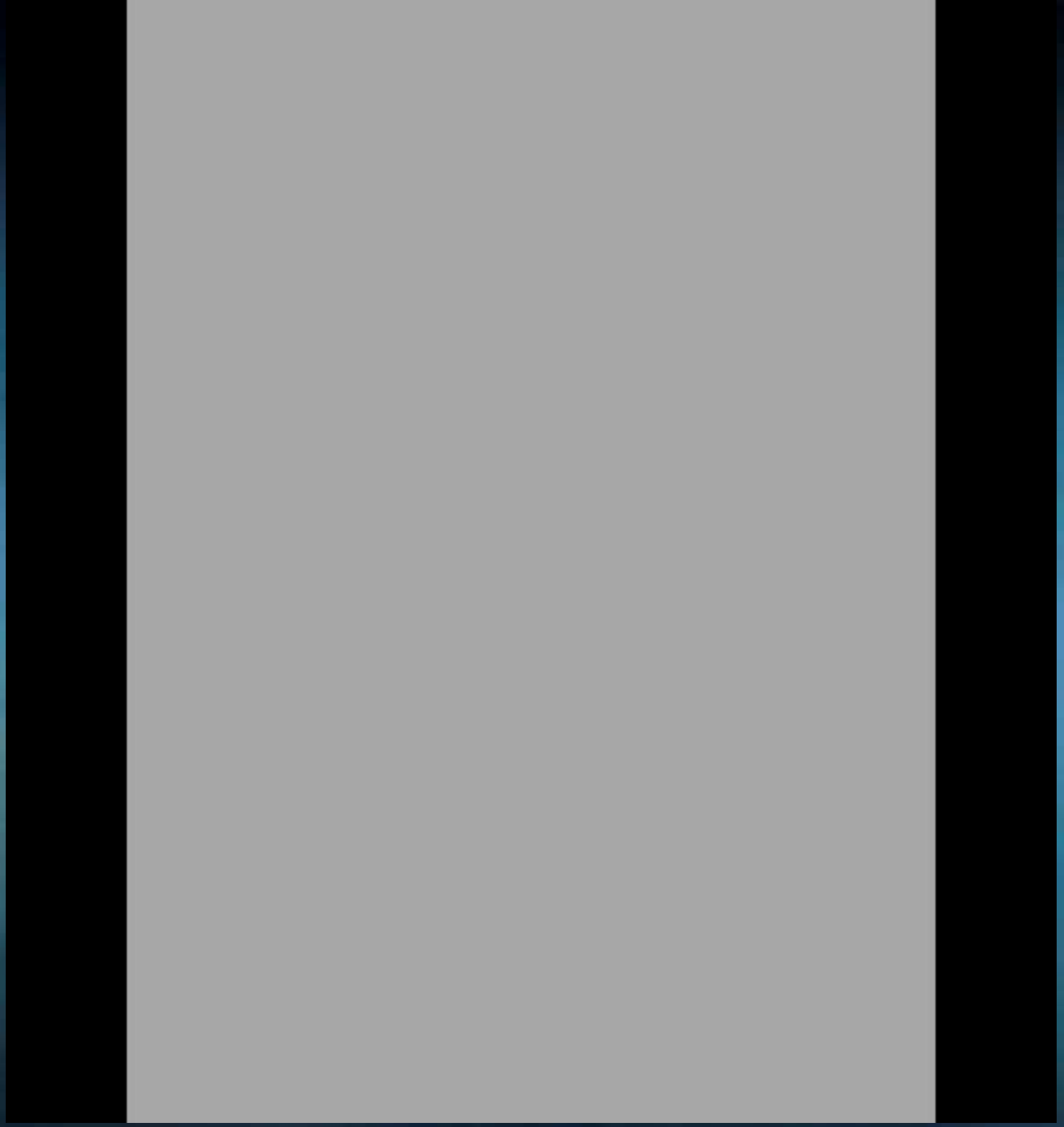












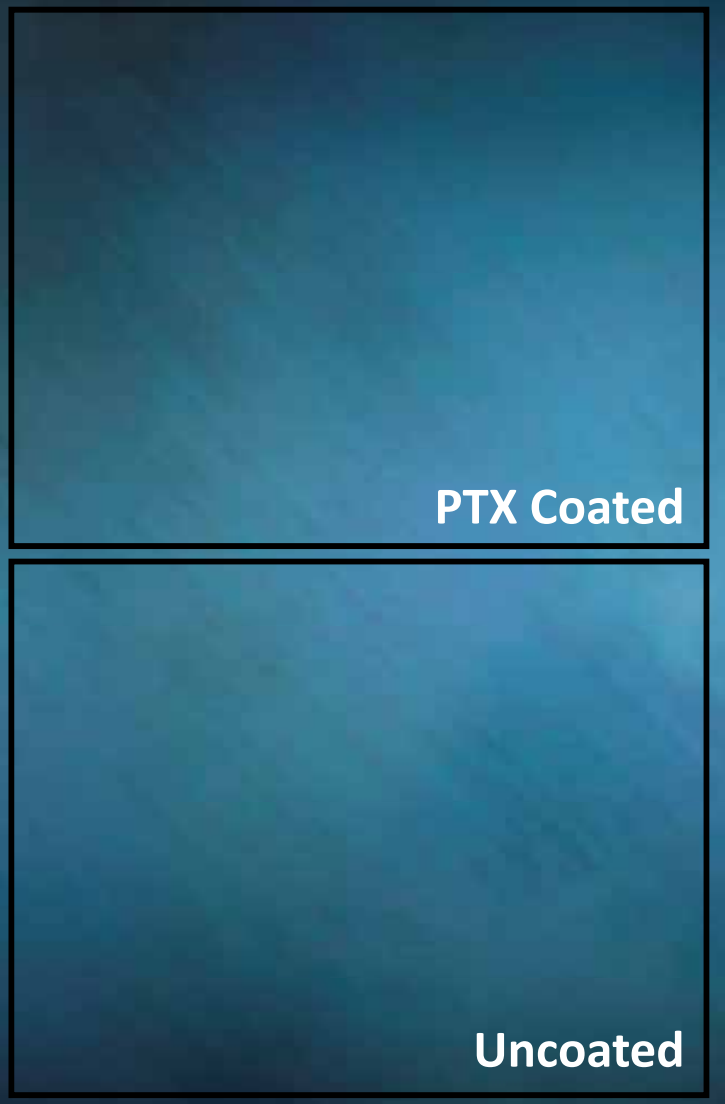
# In-Stent Restenosis with Nitinol Stents is Common

- 19%-37% at 1 year follow-up

Schilliger M, et al. *N Eng J Med 2006; 354:1879-88.*
Laird J et al. *Circ Cardio Interv 2010; 267-71.*

# Zilver PTX® Drug-Eluting Stent

- Designed for the SFA
- CE Marked
- FDA Approved
- Paclitaxel only
  - No polymer or binder
  - 3 µg/mm$^2$ dose density
- Zilver Flex® Stent Platform
- Sponsor: Cook Medical



# Zilver PTX® effectiveness in treating in-stent restenosis

R. Heuser

CLINICAL RESEARCH

# Treatment of Femoropopliteal In-Stent Restenosis With Paclitaxel-Eluting Stents

Thomas Zeller, MD,* Michael D. Dake, MD,† Gunnar Tepe, MD,‡ Klaus Brechtel, MD,‡ Elias Noory, MD,* Ulrich Beschorner, MD,* Patricia L. Kultgen, PHD,§ Aljoscha Rastan, MD*

*Bad Krozingen and Rosenheim, Germany; Stanford, California; and West Lafayette, Indiana*

**Objectives** This study sought to evaluate the outcomes of drug-eluting stent treatment for femoropopliteal in-stent restenosis (ISR).

**Background** ISR after femoropopliteal interventions is an increasing problem. Although the role of drug-eluting stents in the treatment of coronary ISR is well defined, no published studies have examined drug-eluting stents in the treatment of femoropopliteal ISR.

**Methods** This study examines 108 patients with 119 ISR lesions who were enrolled in the ZILVER-PTX single-arm study, a prospective, multicenter clinical trial of 787 patients. All patients were treated with paclitaxel-eluting nitinol stents.

**Results** Mean patient age was 68.3 ± 9.4 years; 61.1% of patients were men. Mean lesion length was 133.0 ± 91.7 mm; 33.6% of lesions were >150 mm long and 31.1% of lesions were totally occluded. Procedural success was achieved in 98.2% of lesions with 2.1 ± 1.2 stents placed per lesion. Primary patency was 95.7% at 6 months and 78.8% at 1 year. Freedom from target lesion revascularization was 96.2% at 6 months, 81.0% at 1 year, and 60.8% at 2 years. Forty patients experienced major adverse events, exclusively target lesion revascularization. Before treatment, 81.1% of patients had Rutherford scores ≥3; at 2 years, 60.9% of patients had Rutherford scores ≤1. Both ankle brachial index and walking impairment questionnaire scores significantly improved following treatment. The 1-year fracture rate of stents used in ISR lesions was 1.2%. No significant risk factors associated with loss of patency were identified.

**Conclusions** Treatment of femoropopliteal ISR with paclitaxel-eluting stents results in favorable acute, midterm, and long-term outcomes. (Zilver PTX Global Registry [ZILVER-PTX]; NCT01094678) (J Am Coll Cardiol Intv 2013;6:274–81) 



# SFA In-Stent Restenosis: What is the Optimal Treatment Strategy

108 patients (119 ISR Lesions)

- Mean lesion length 133.0±91.7mm
- 33.6% > 150mm
- 31.1% CTO

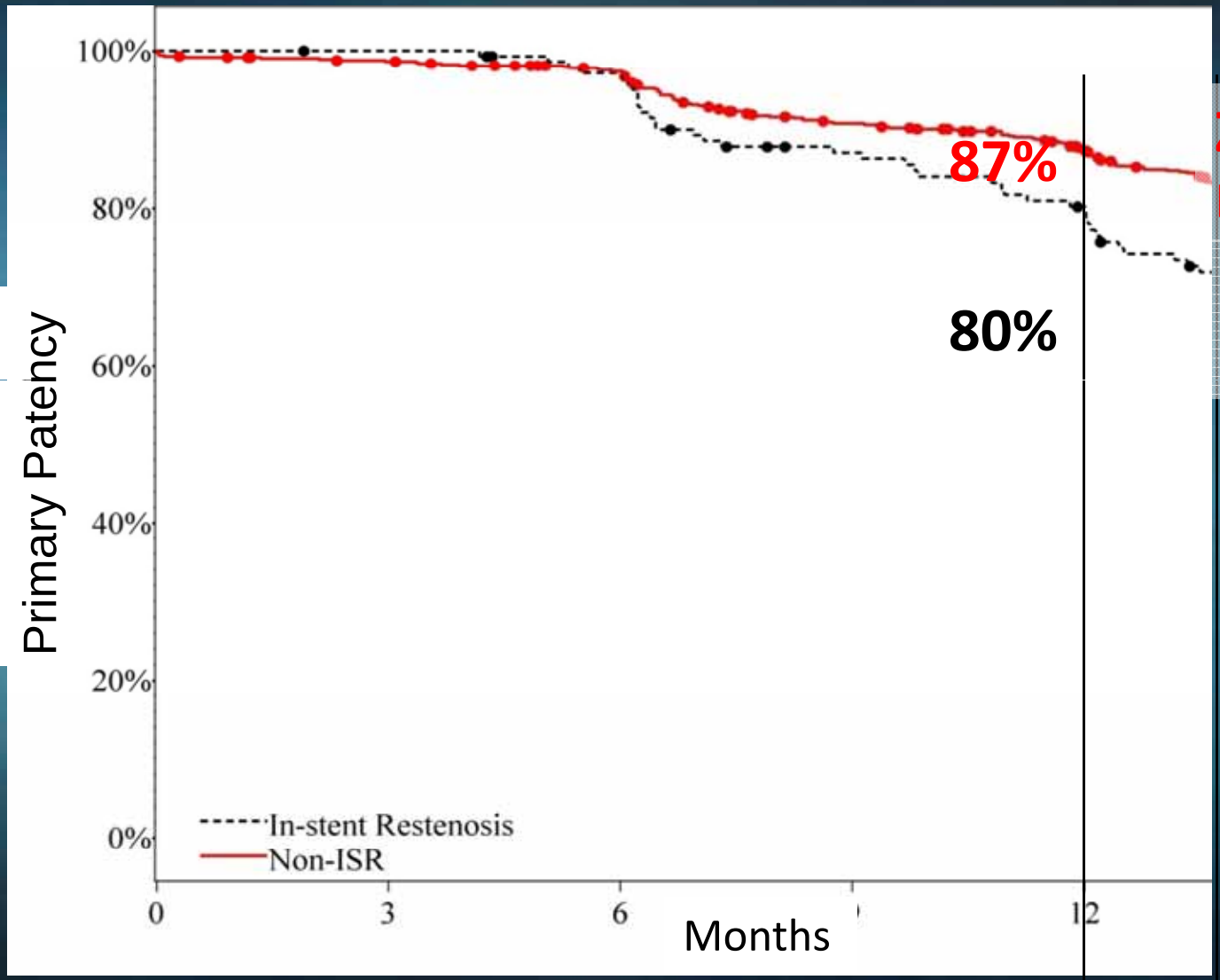
Zeller T, Dake M, Tepe G, et al. Treatment of Femoropopliteal In-stent Restenosis with Paclitaxel-Eluting Stents. *J AM Coll Cardiol 2013; Vol 6, No. 3, 2013.*



# Paclitaxel-Eluting Stents for Femoropopliteal ISR

- 98.2% success
- 95.7% primary patency 95.7%
- 78.8% at 1 year
- 1 year fracture rate 1.2%

# Zilver PTX® effectiveness in treating ISR
# Primary Patency (PSVR < 2.5)




**Zilver PTX®**
No in-stent restenosis

**Zilver PTX®**
In-stent restenosis

R. Heuser

**Table 5. Comparison of Published Primary Patency and TLR Rates Following Treatment of Femoropopliteal ISR**

| Study/First Author (Ref. #) | Treatment | Patients, n | Lesions, n | Lesion Length, mm | Primary Patency | | | Freedom From TLR | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 6 Months | 12 Months | 24 Months | 6 Months | 12 Months | 24 Months |
| ZILVER-PTX single-arm study | Zilver PTX stent | 108 | 119 | 133 ± 92 | 96% | 79% | — | 96% | 81% | 61% |
| Tosaka et al. (14) | PTA | 133 | 133 | 91 ± 67 for stenoses | — | 69% | 48% | — | — | — |
| | | | | 198 ± 62 for occlusions | — | 23% | 15% | — | — | — |
| Dick et al. (13) | PTA | 22 | 22 | 74 ± 65 | 27% | — | — | 64% | — | — |
| | Cutting balloon angioplasty | 17 | 17 | 84 ± 74 | 35% | — | — | 59% | — | — |
| Shammas et al. (30) | Directional atherectomy; adjunctive PTA and stenting in some cases | 41 | 41 | 126 ± 79 | — | — | — | — | 66% | — |
| Trentmann et al. (24) | Directional atherectomy; adjunctive PTA and stenting for some cases | 33 | 35 | 141 ± 81 | 68%* | 25%* | — | — | — | — |
| Zeller et al. (26) | Directional atherectomy | — | 43 | 131 ± 111 | — | 54% | 49% at 18 months | — | 53% | 51% at 18 months |
| Shammas et al. (31) | Laser atherectomy + PTA; adjunctive stent | 40 | — | 210 ± 104 | — | — | — | — | 49% | — |
| Laird et al. (22) | Laser atherectomy, PTA, and heparin-coated stent graft | 27 | — | 207 ± 103 | — | 48% | — | — | 83% | — |
| Yeo et al. (25) | Laser atherectomy, angioplasty, excisional atherectomy, and/or cryoplasty | 20 | 22 limbs | 132 ± 113 | 55% | 48% | — | — | 77% | — |
| Silingardi et al. (23) | Rotational thrombectomy and PTA | 32 | 32 limbs† | 160 | 75% | 58% | — | — | 47%‡ | — |
| Zeller et al. (27) | Rotational thrombectomy and PTA | 40 | 40 | — | 46% | 19% | — | — | — | — |
| Werner et al. (32) | PTA and brachytherapy | 90 | — | 246 ± 122 | 95% | 80% | — | — | — | — |
| Stabile et al. (33) | Paclitaxel-eluting balloon; adjunctive stent and laser atherectomy | 39 | — | 83 ± 79 | — | 92% | — | — | 92% | — |

For this analysis of the ZILVER-PTX single-arm study, PSVR <2.5 was used as the patency threshold. Patency was defined as duplex ultrasound PSVR <2.5 by Trentmann et al. (24); <2.4 by Dick et al. (13), Zeller et al. (26), Werner et al. (32), and Stabile et al. (33); and <2.0 by Yeo et al. (25) and Laird et al. (22). Tosaka et al. (14) defined patency as <2.4 PSVR by duplex ultrasound or <50% stenosis by angiography. Silingardi et al. (23) and Zeller et al. (27) did not provide a PSVR patency threshold in their reports. Dashes indicate data were unavailable. *Data only available for 25 lesions at 6 months and 17 lesions at 12 months. †Six iliac and 26 femoropopliteal arteries. ‡Mean follow-up of 13.1 months (range 3 to 45 months).

ISR = in-stent restenosis; PSVR = peak systolic velocity ratio; PTA = percutaneous transluminal angioplasty; TLR = target lesion revascularization.

# Drug Eluting Balloon (paclitaxel/urea): Clinical Trial Data

R. Heuser

# 2-Year Results of Paclitaxel-Eluting Balloons for Femoropopliteal Artery Disease

## Evidence From a Multicenter Registry

Fausto Castriota, MD,‡ Armando Liso, MD,§ Alfredo Marchese, MD,‖ Chiara Grattoni, MD,‡ Paolo Pantaleo, MD,¶ Alberto Cremonesi, MD,‡ Paolo Rubino, MD,† Giancarlo Biamino, MD, PHD†

**Primary Patency at 27 Months was 72.4%**

**Secondary Patency was 84.7%**

**Objectives** This study aimed to appraise 2-year outcomes after percutaneous treatment of femoropopliteal artery disease with paclitaxel-eluting balloons.

**Background** Percutaneous transluminal angioplasty with paclitaxel-eluting balloons for femoropopliteal artery disease has provided favorable 1-year results.

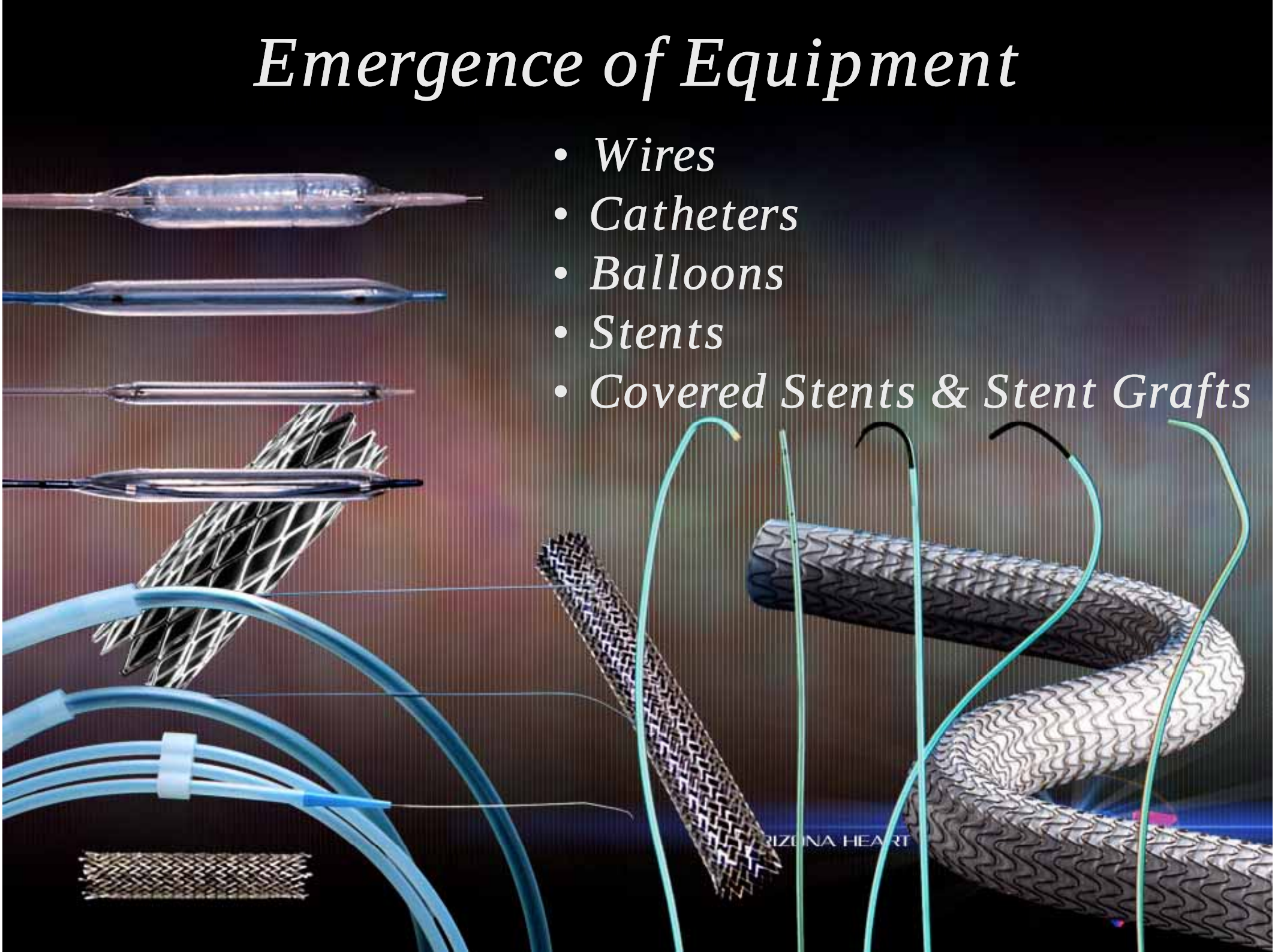
**Methods** Consecutive patients with Rutherford class 2 to 4 disease due to femoropopliteal lesions [illegible] long and with [illegible]-mm reference vessel diameter were prospectively enrolled in a multicenter registry and primary patency, major adverse events (the composite of death, amputation, or target lesion revascularization), changes in Rutherford class, ankle-brachial index, absolute claudication distance, and quality of life after ≥24 months.

**Results** A total of 105 patients (114 lesions) treated with paclitaxel-eluting balloons and provisional stenting were enrolled and final procedural success was obtained in all. Follow-up after 27 ± 3 months was obtained in 98 (93.3%) patients, showing that primary patency was maintained in 71 (72.4%), and major adverse events had occurred in 17 (17.5%), with persistently significant benefits in Rutherford class, ankle-brachial index, absolute claudication distance, and quality of life (all $p < 0.001$). Secondary patency rate was achieved in 89 cases (84.7%).

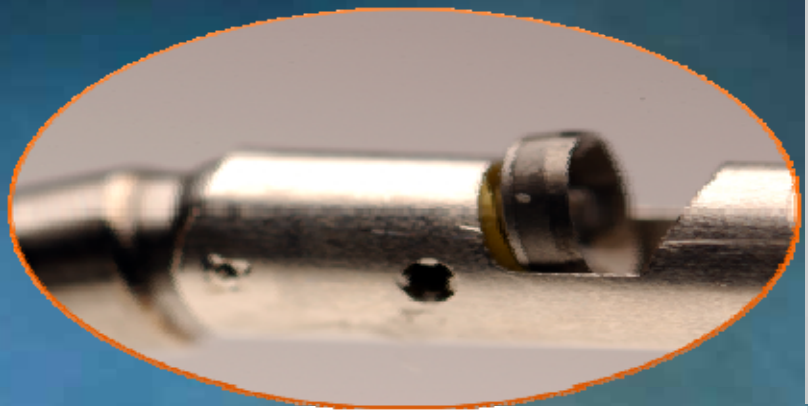
**Conclusions** PEBs are associated with favorable functional and clinical outcomes at 2 years in patients with femoropopliteal artery disease requiring percutaneous revascularization. (J Am Coll Cardiol Intv 2013;6:282–9) 

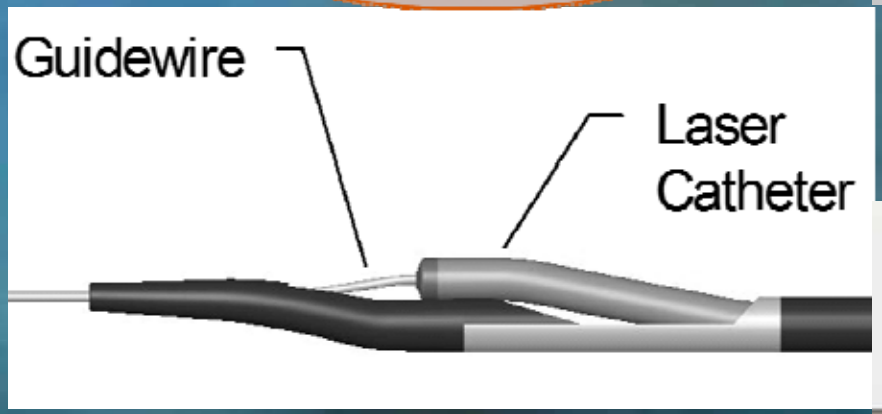
# *Emergence of Equipment*

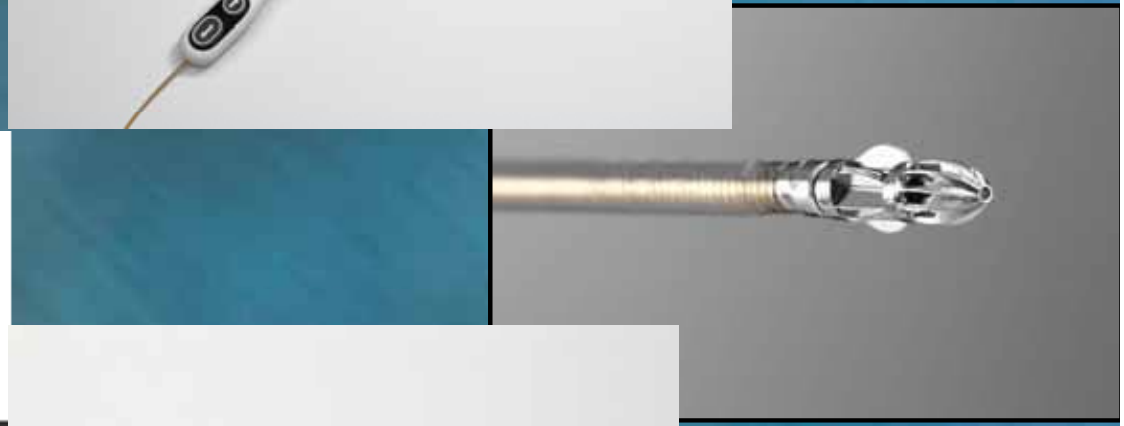
- *Wires*
- *Catheters*
- *Balloons*
- *Stents*
- *Covered Stents & Stent Grafts*

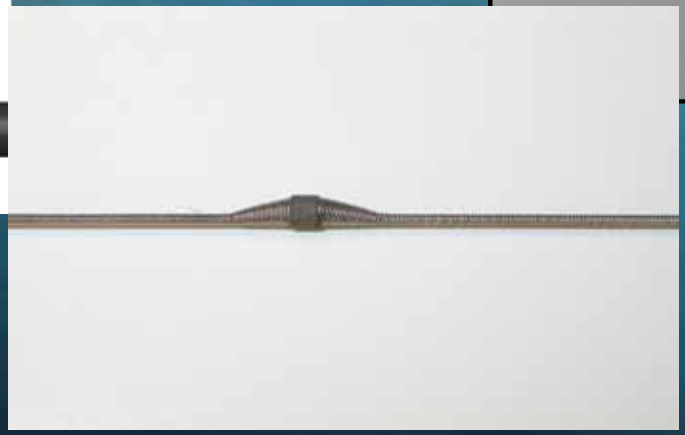


# Currently Available Atherectomy Devices







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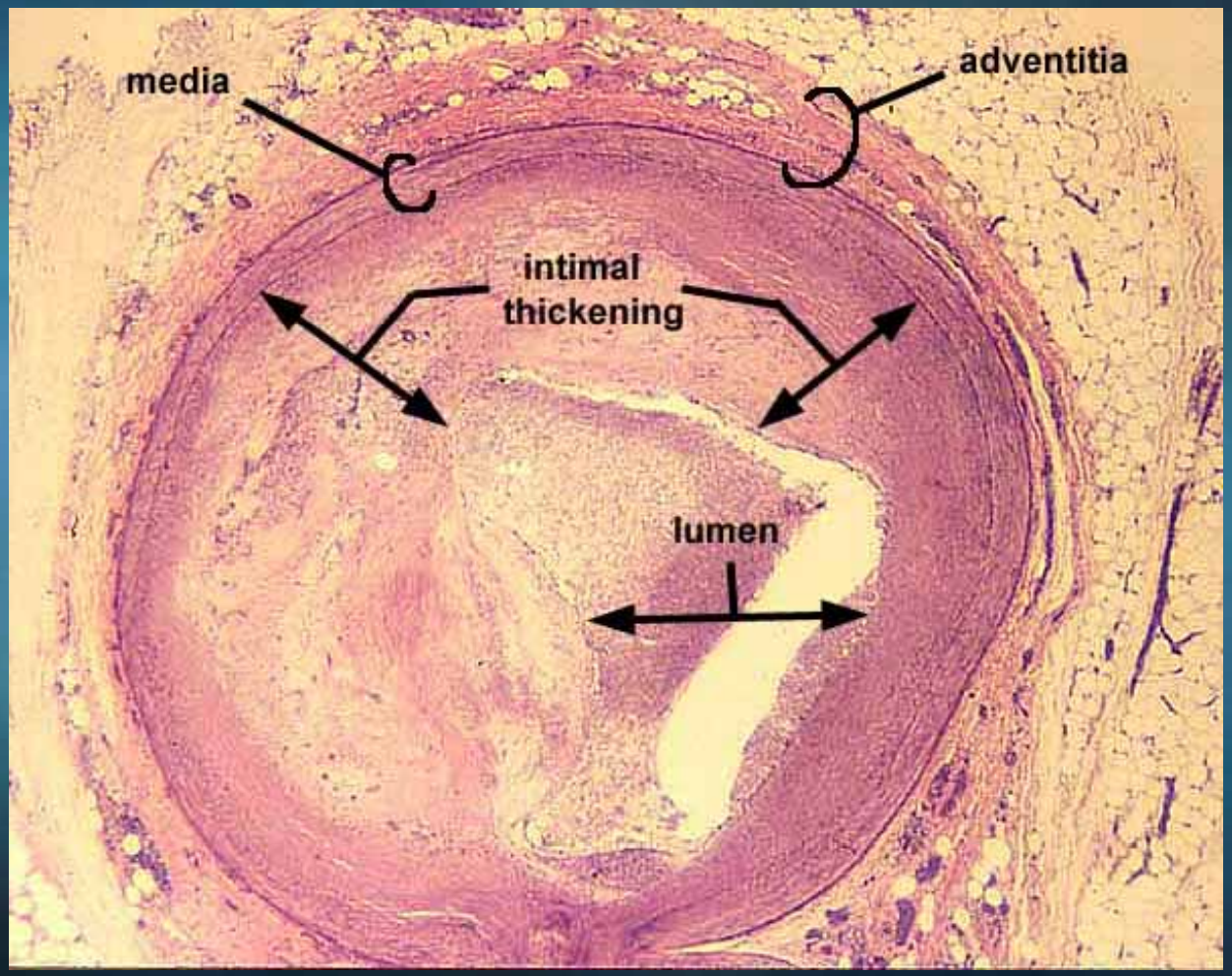
# Rationale for plaque excision and drug-delivery as an essential combination




1. Mechanically re-canalize the vessel without overstretch
2. Remove the perfusion barrier – better and more homogenous drug uptake?
3. Reduce the likelihood of bail-out stenting and preserve the native vessel

Is there anything definitive that can be done with these patients?

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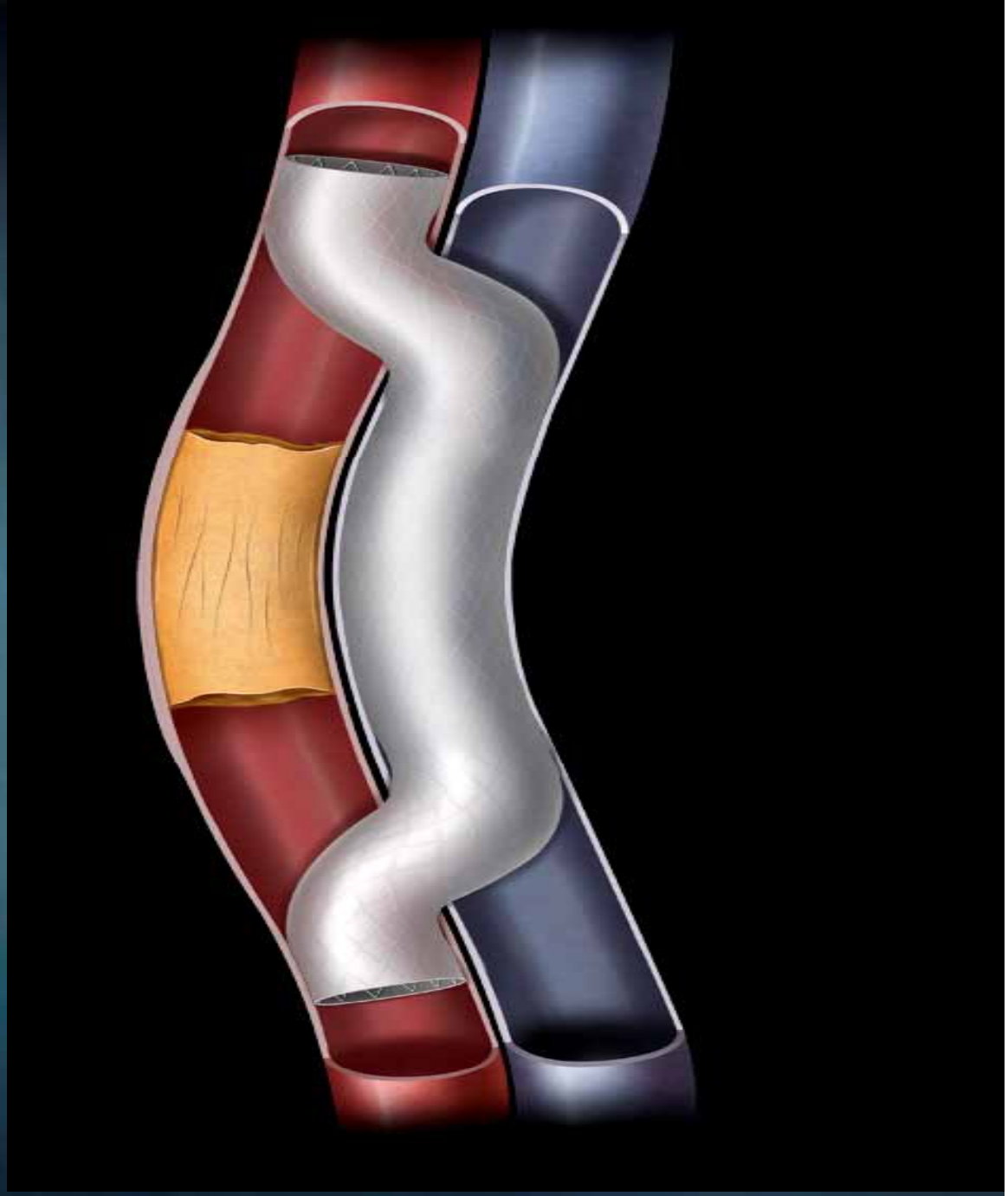
# Introducing Percutaneous Bypass



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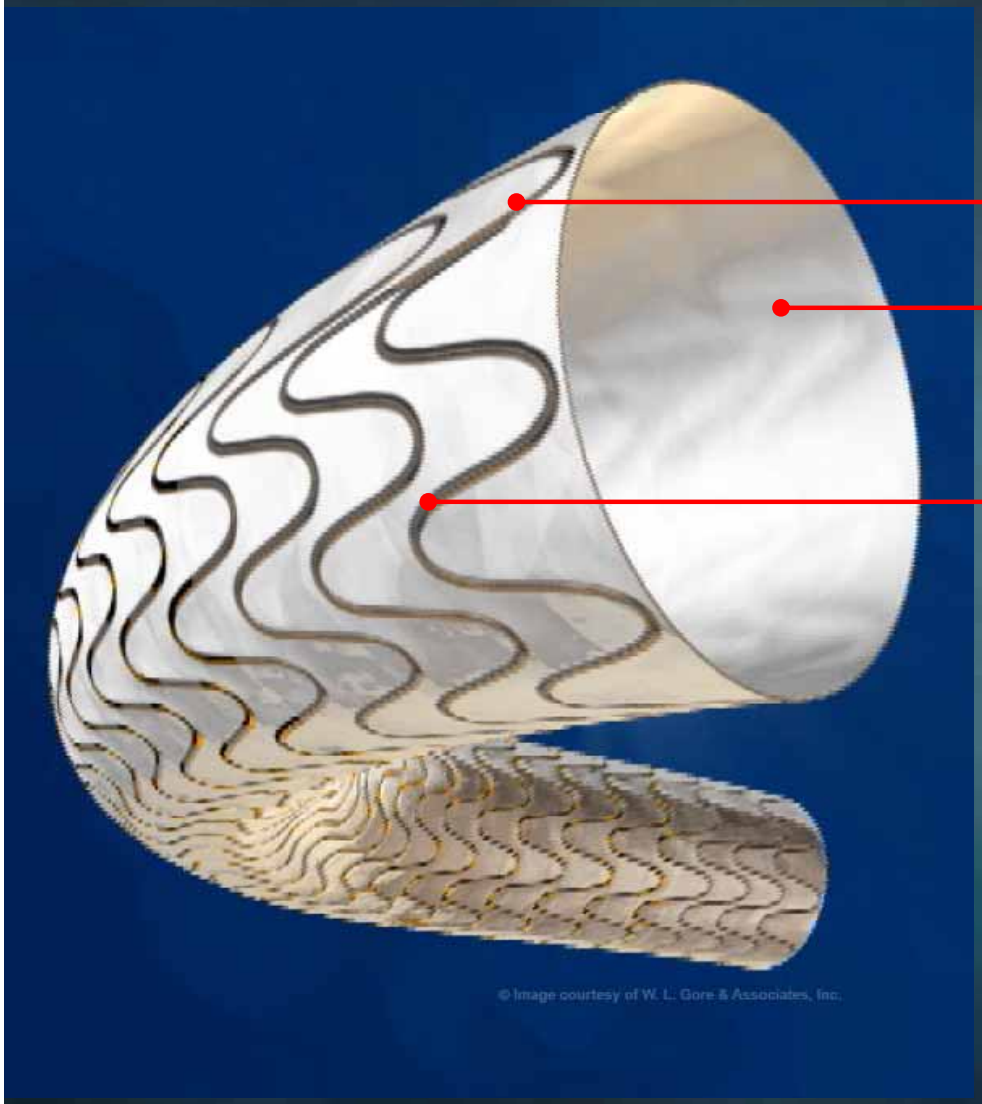
# *Description*

New
HEPARIN-BONDED
Surface




- Polished nitinol support
- Ultra-thin wall ePTFE tube
- Unique, durable bonding film
- Heparin Bioactive Surface
- Lengths: 2.5, 5, 10, and 15 cm
- Diameters: 5 – 8 mm

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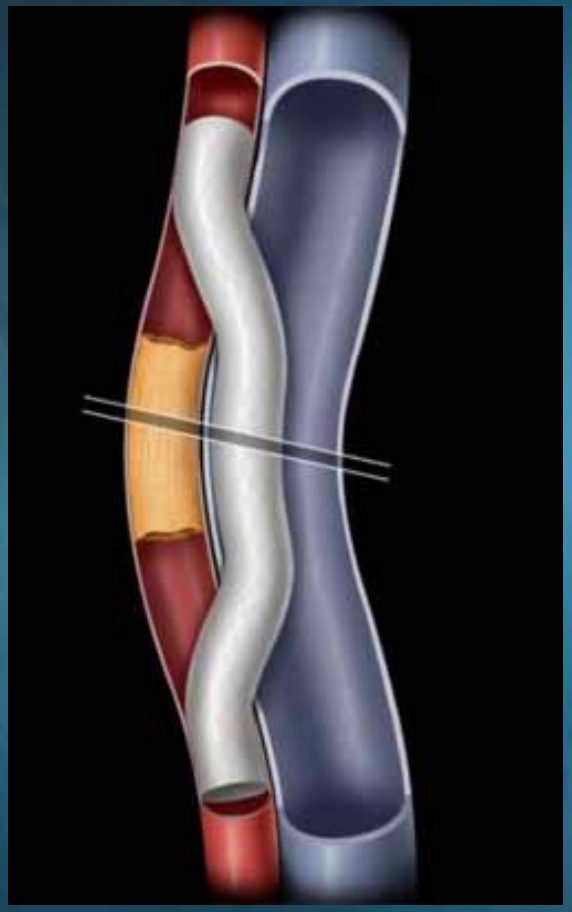
# THE CONCEPT: PERCUTANEOUS BYPASS

- Percutaneous access only
- Conscious sedation / local
- Creation of proximal and distal anastomosis
- Utilization of adjacent femoral vein as conduit
- Endograft deployment
- Outpatient bypass!



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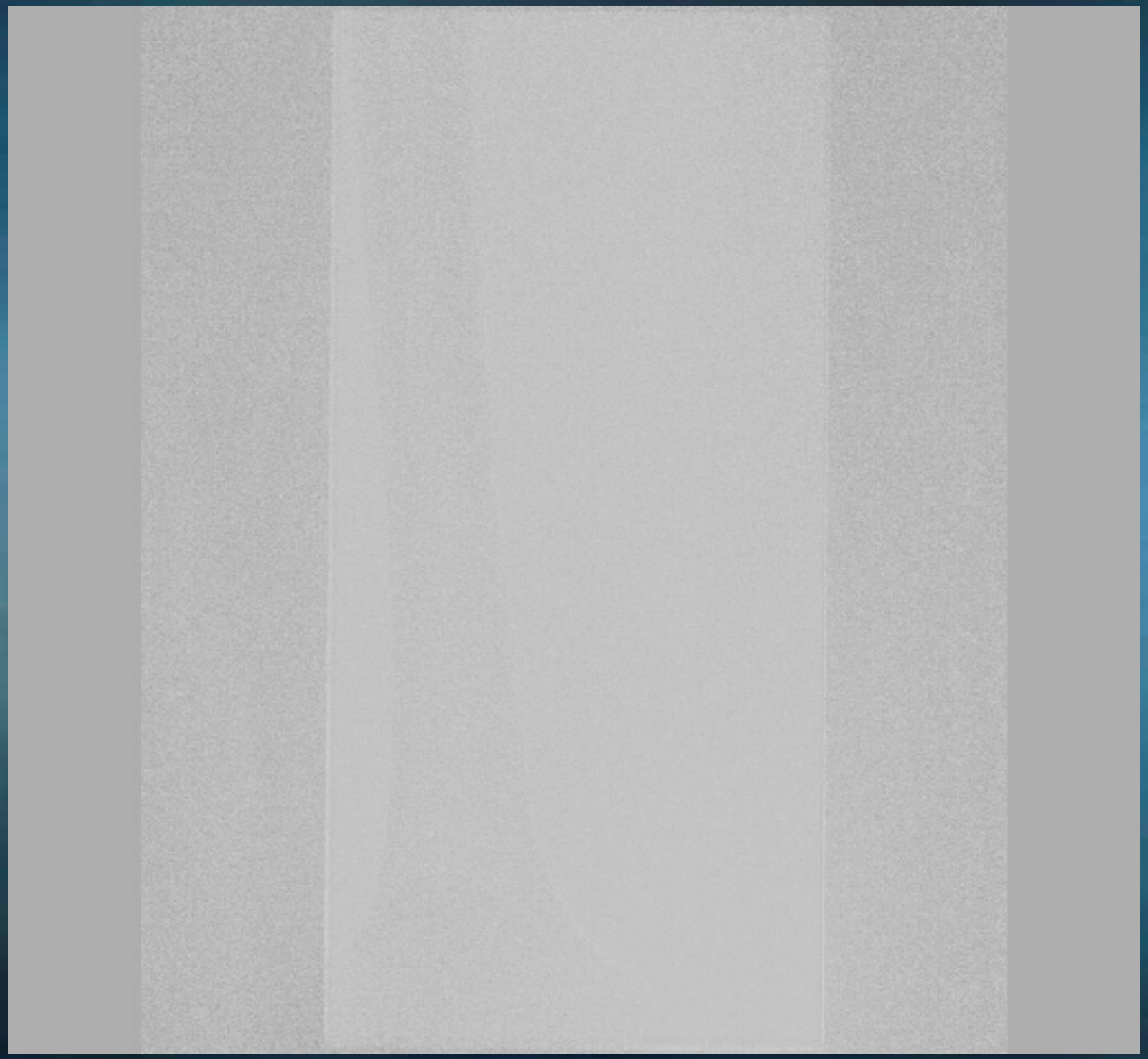
# *Occluded Popliteal Aneurysm*

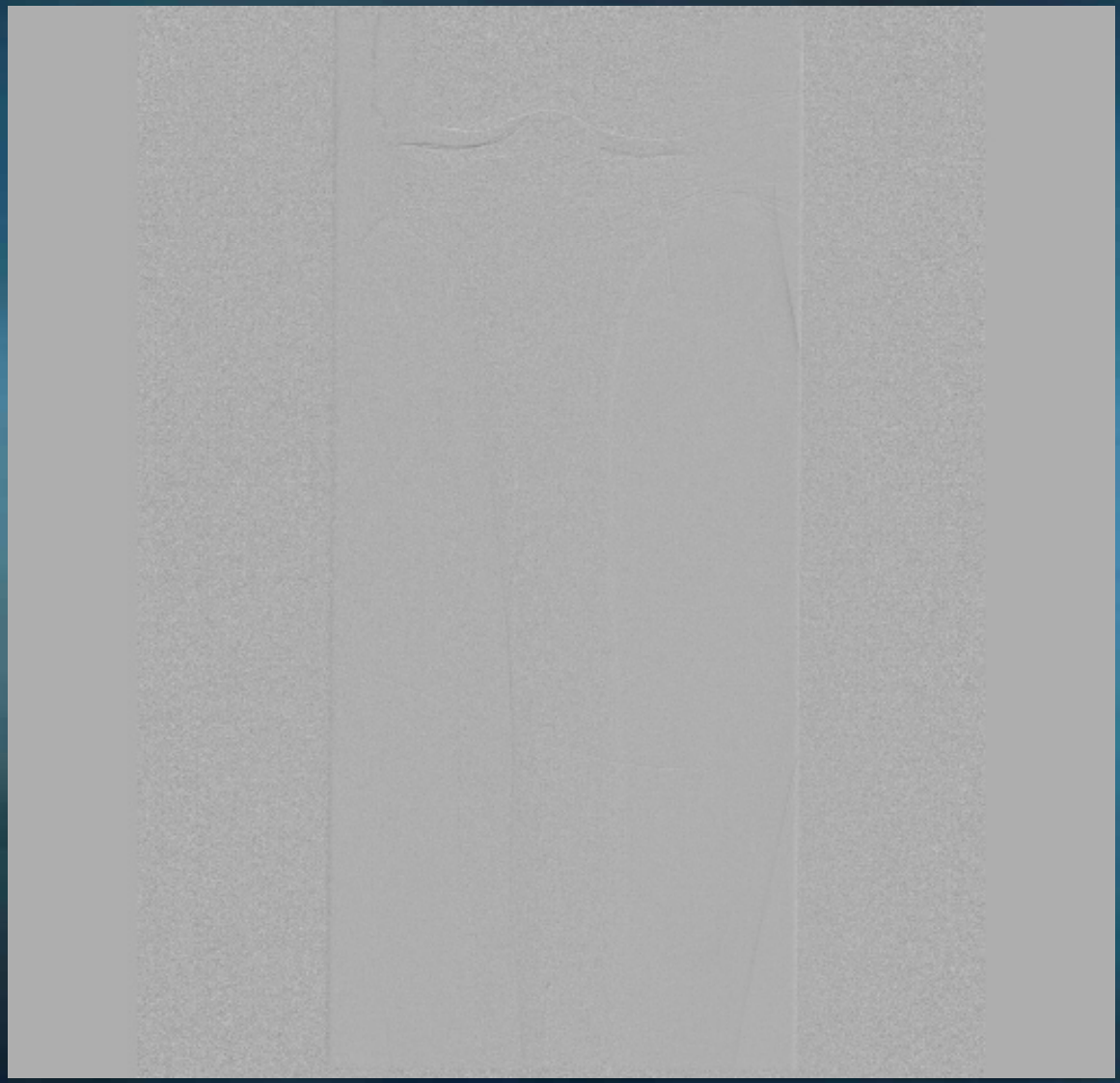
- *64 year-old male presents 2 months after a complicated recovery from CABG with right lower extremity rest pain.*
- *Ischemic cardiomyopathy (LVEF 35%)*
- *Remote heavy smoker with COPD*
- *Newly diagnosed diabetic*
- *Bilateral popliteal aneurysms*



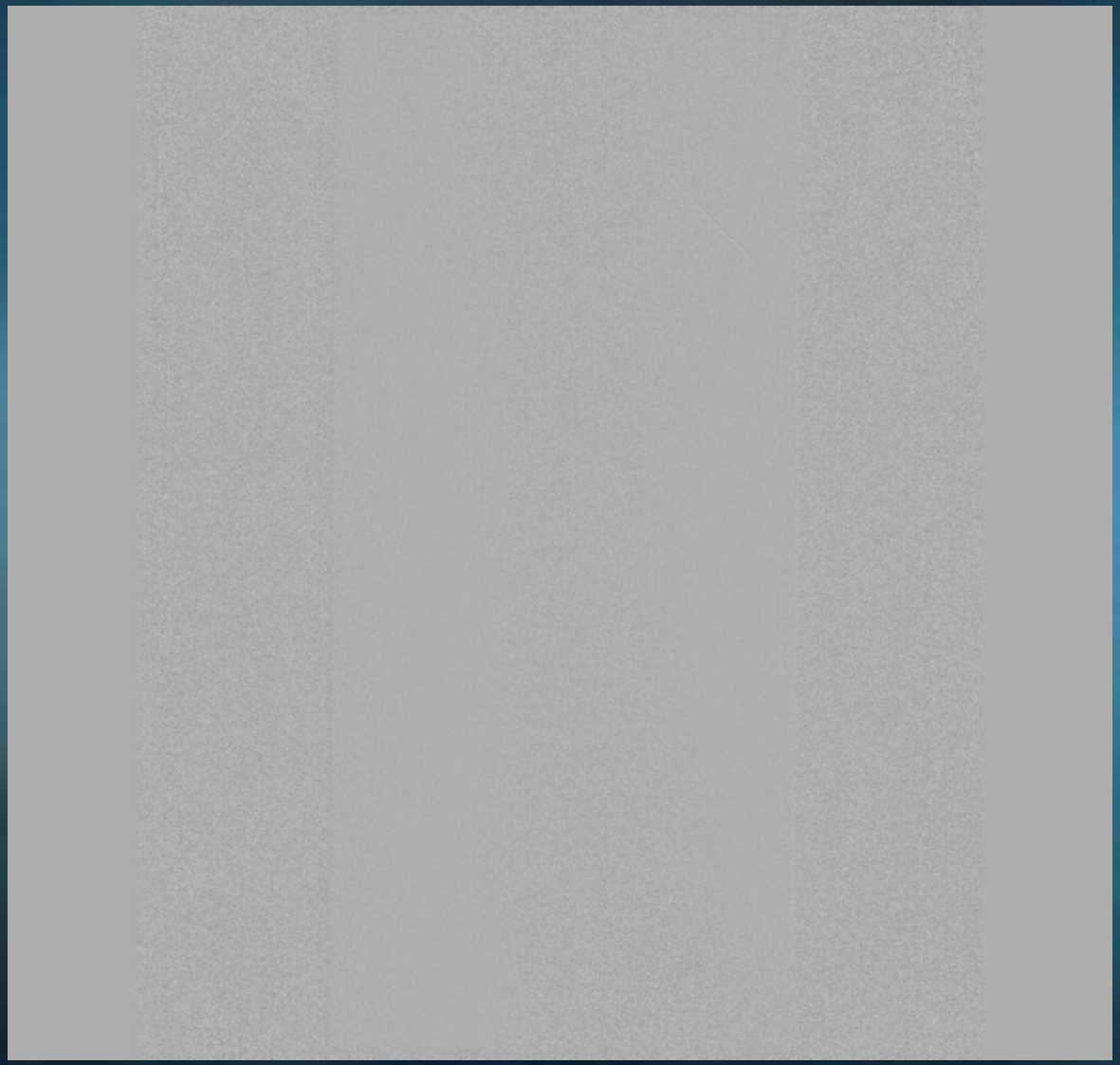
# *Baseline Images*



# *Baseline Images*



# *Baseline Images*





# *Treatment Options*

- *Femoropopliteal Bypass*
  - *Below the knee*
  - *Availability of quality veins*
  - *Prosthetic outcomes*
- *Endovascular Options*
  - *Limited at best*
  - *Percutaneous bypass?*



# *Retrograde Popliteal Access*

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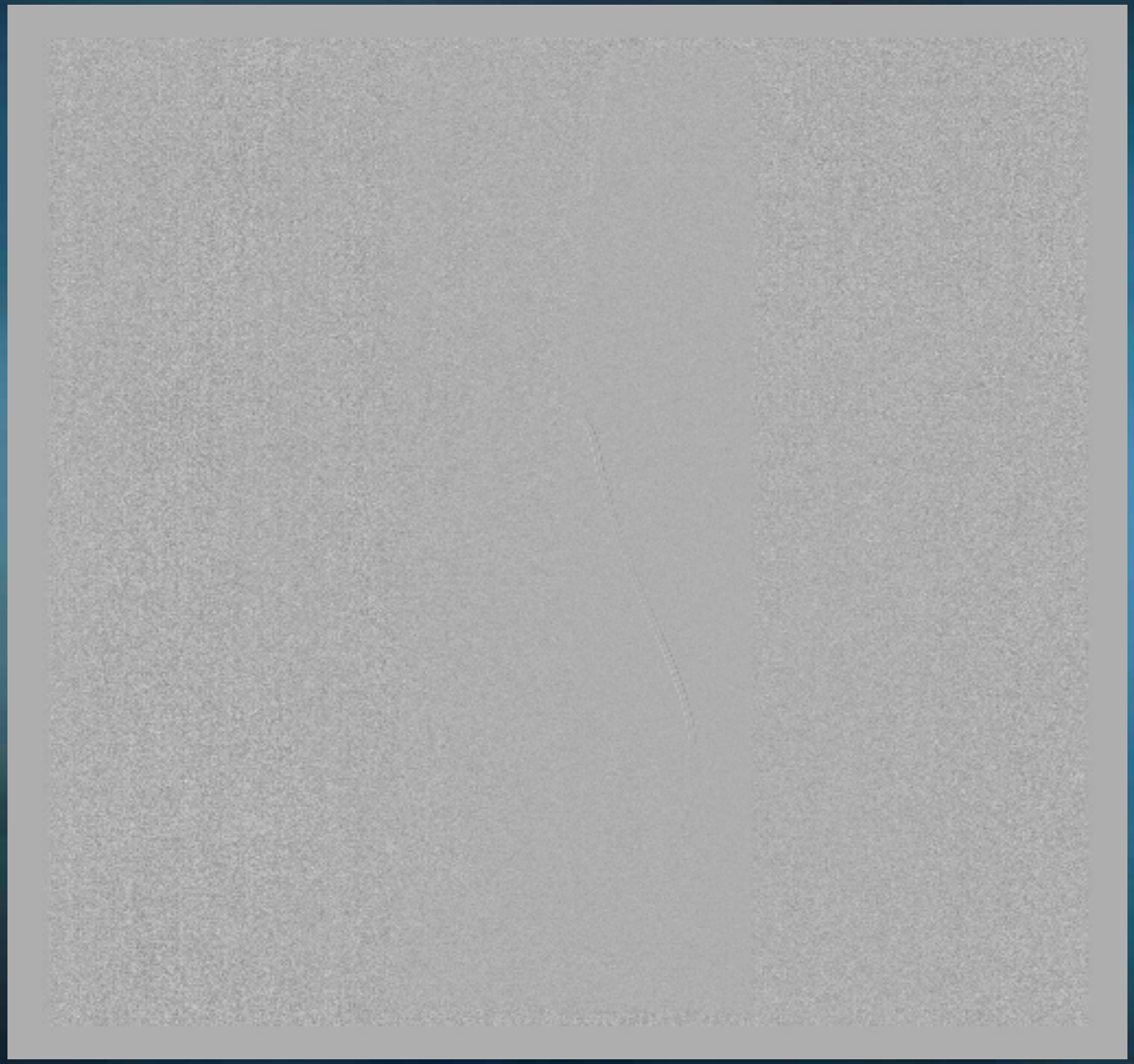
# *Outback into the Adjacent Vein*



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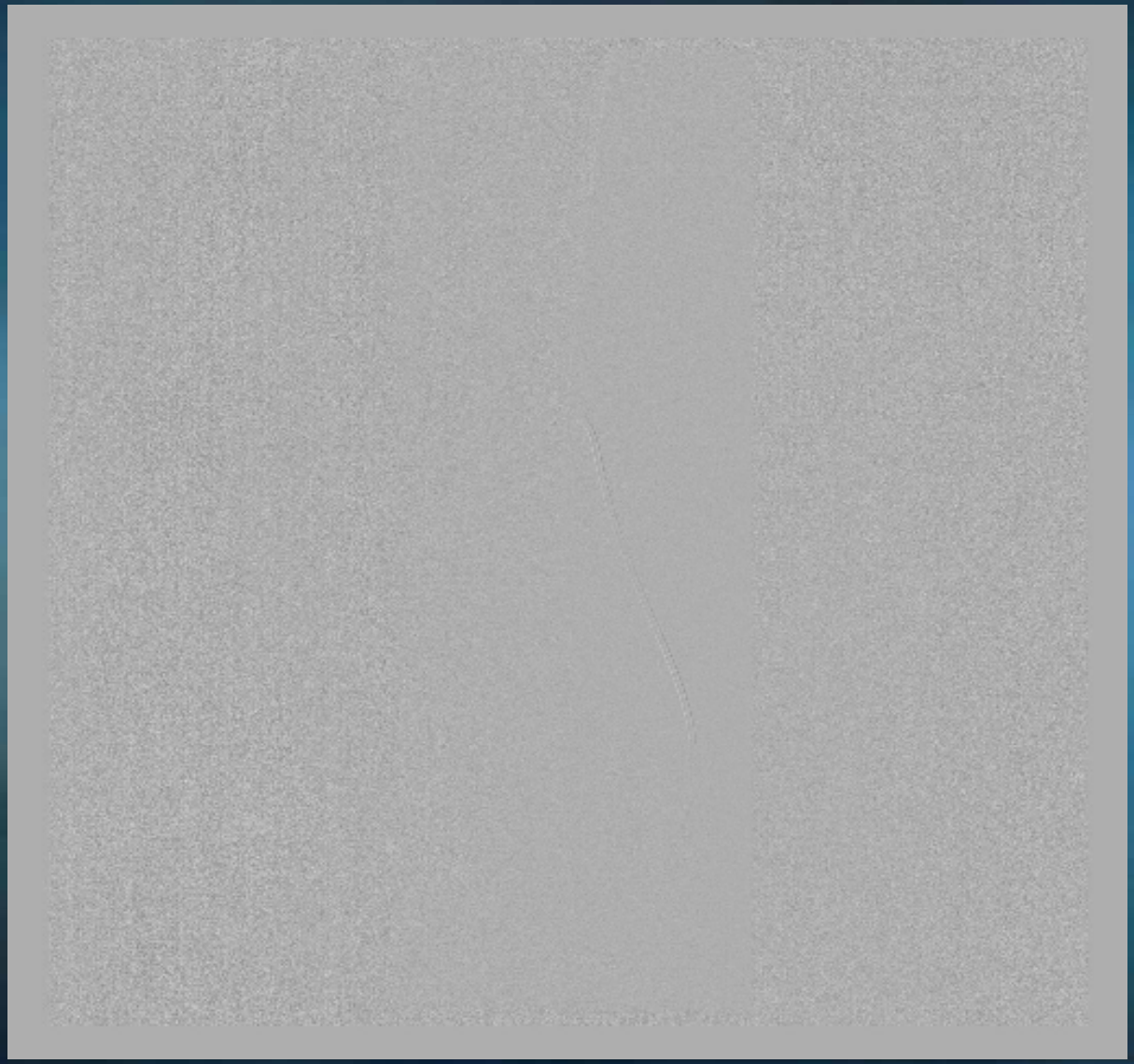
# *Outback into the Adjacent Vein*



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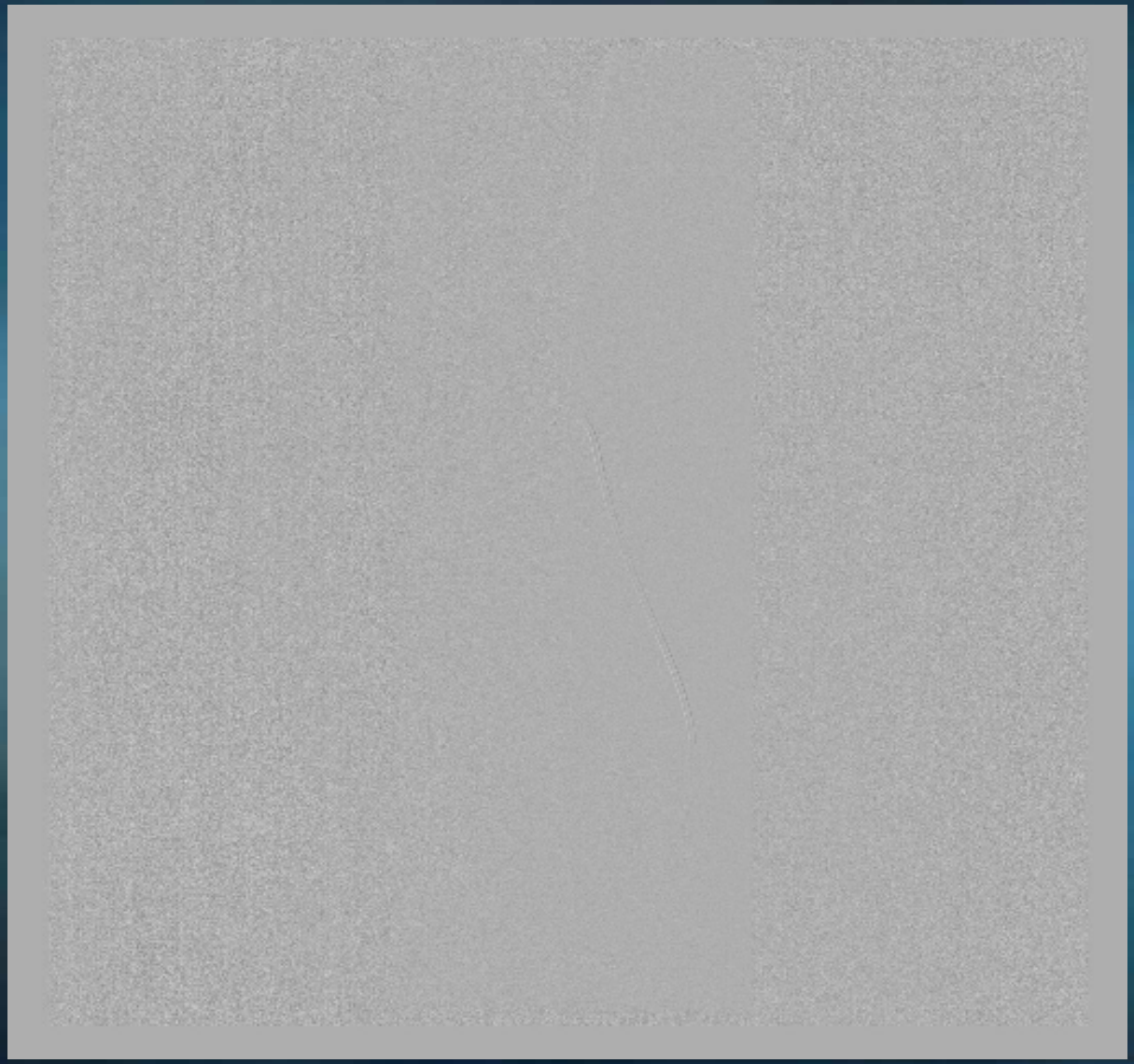
# *Outback into the Adjacent Vein*



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# *Outback into Vein from Above*

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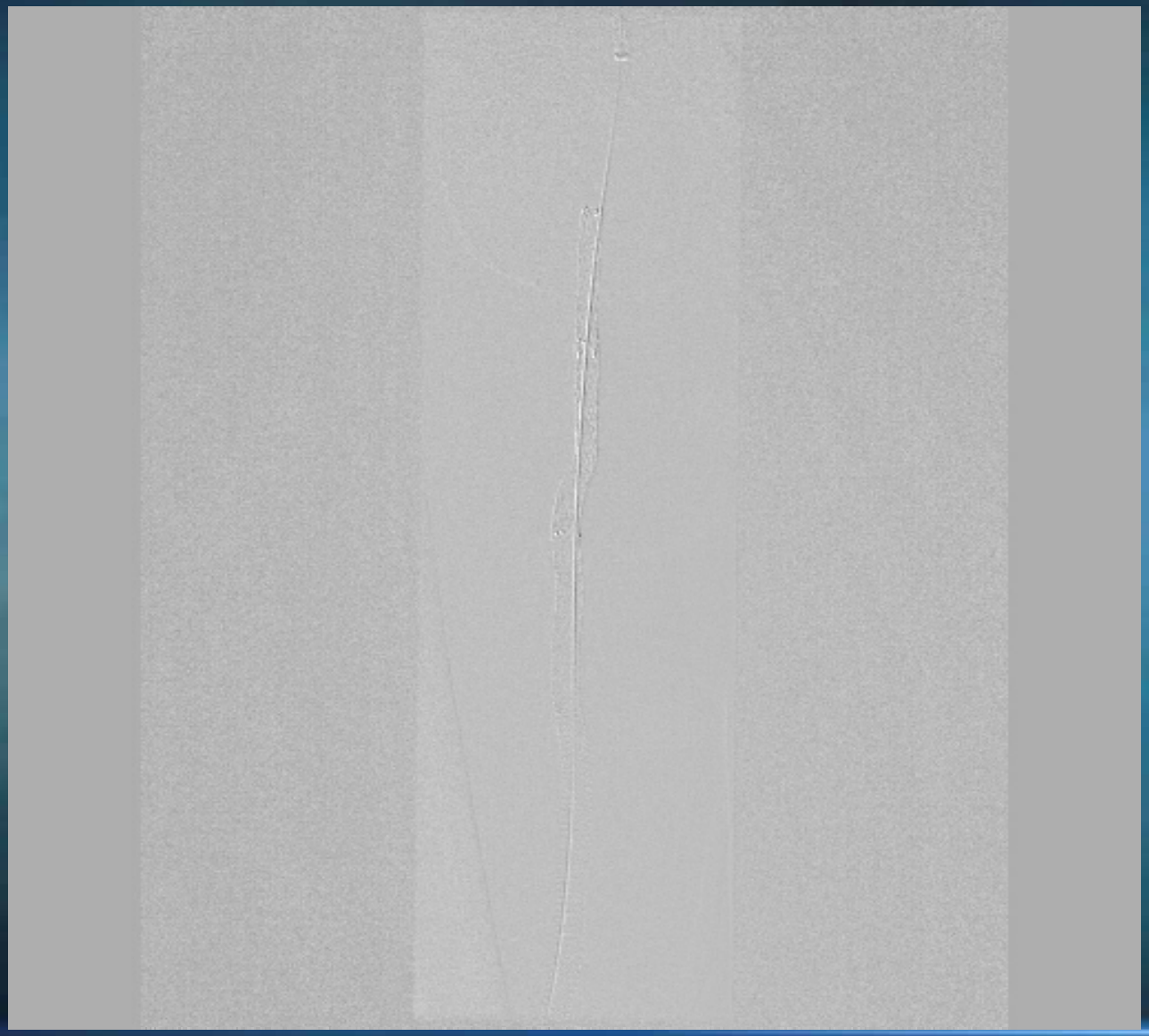
# *After Endografting*



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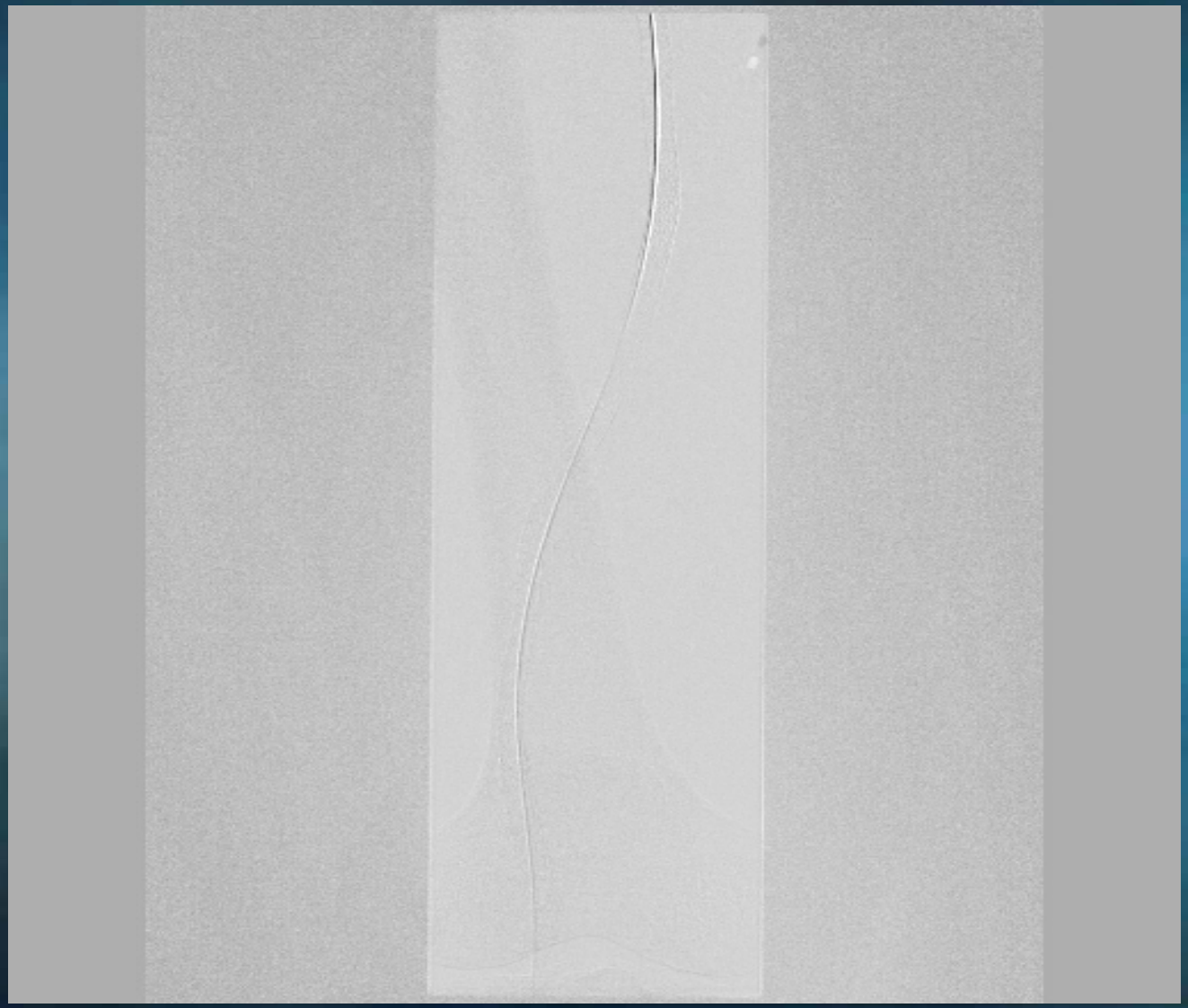
# *After Endografting*



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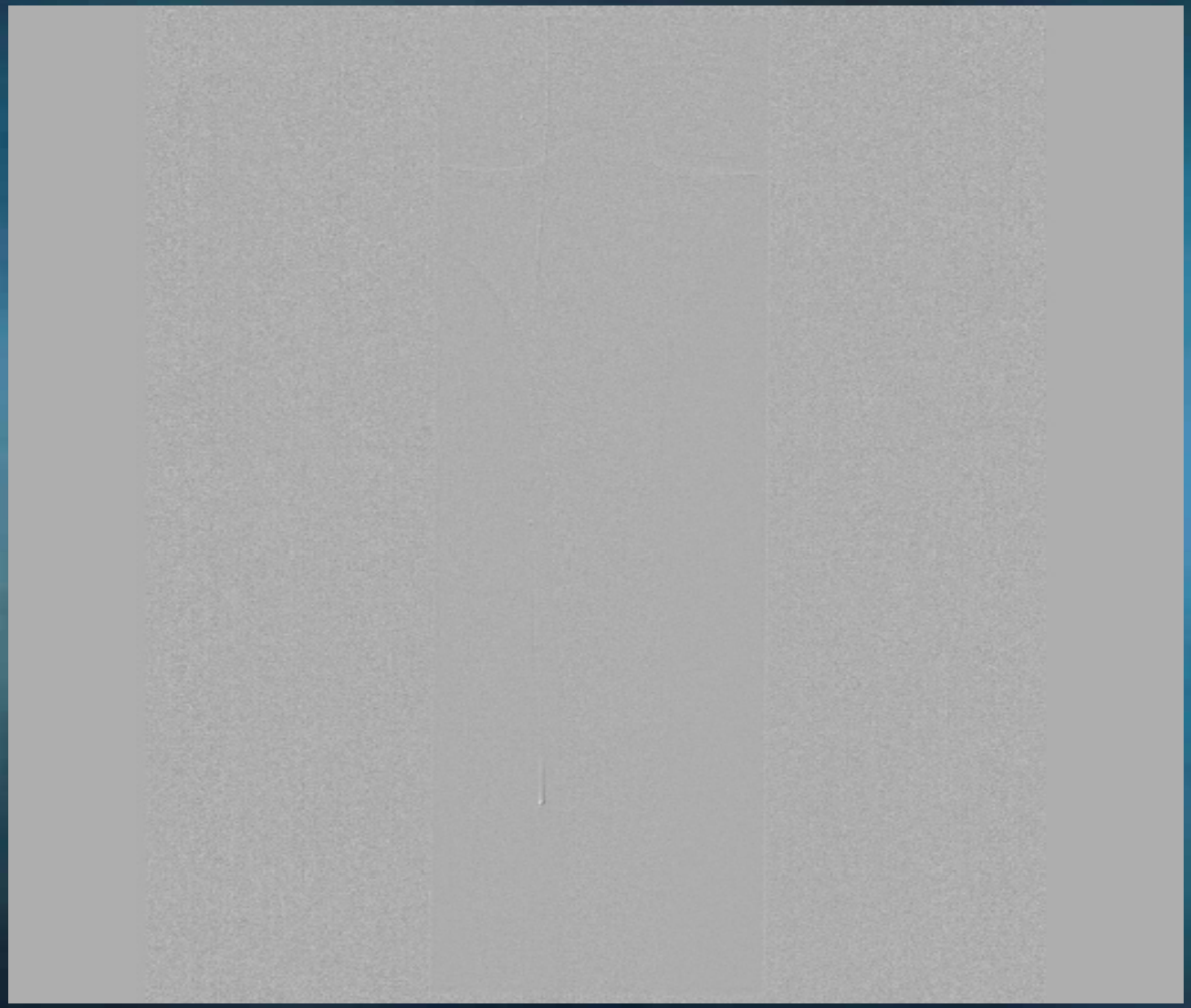
# *After Endografting*



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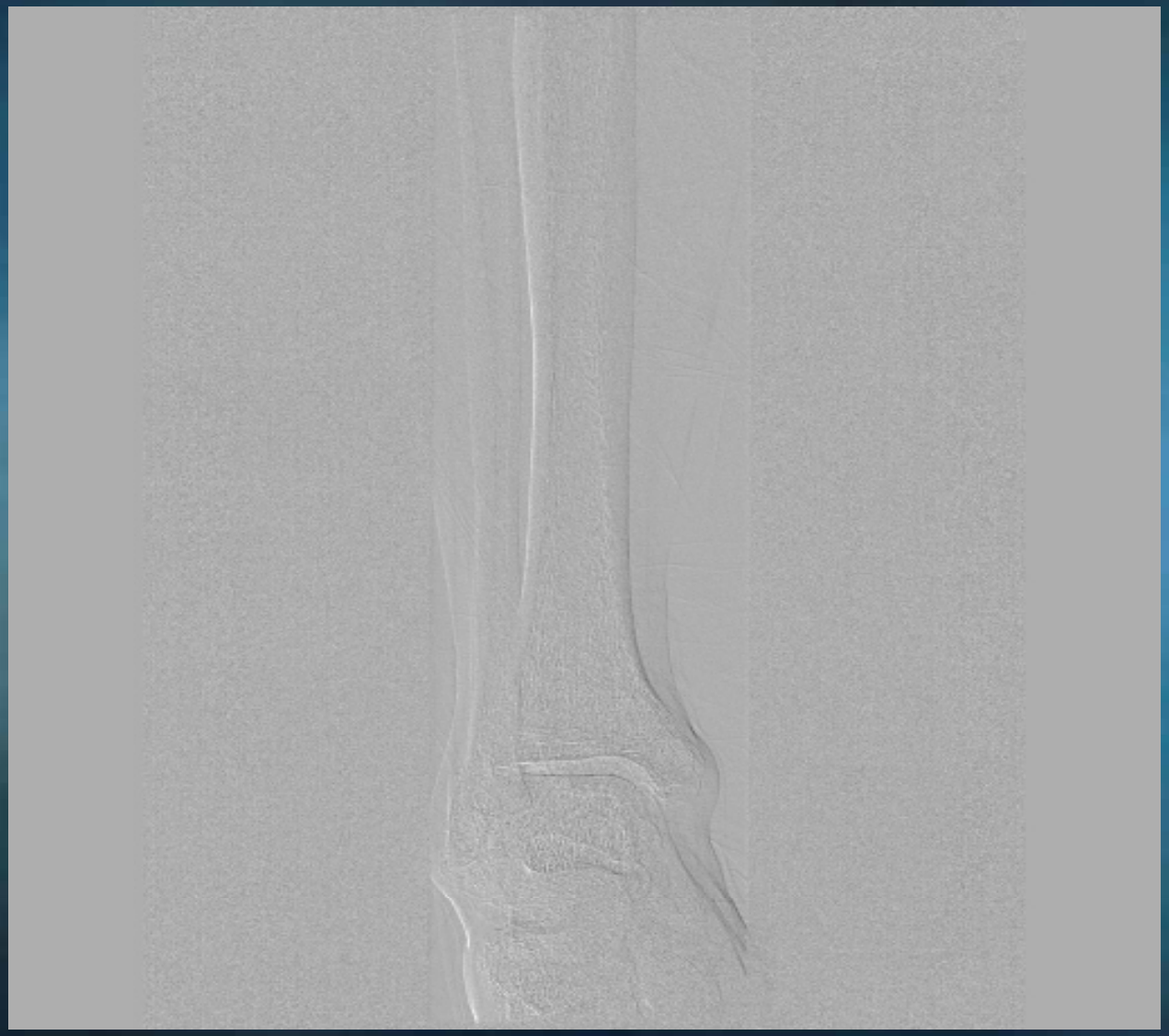
# *Distal Run-Off*



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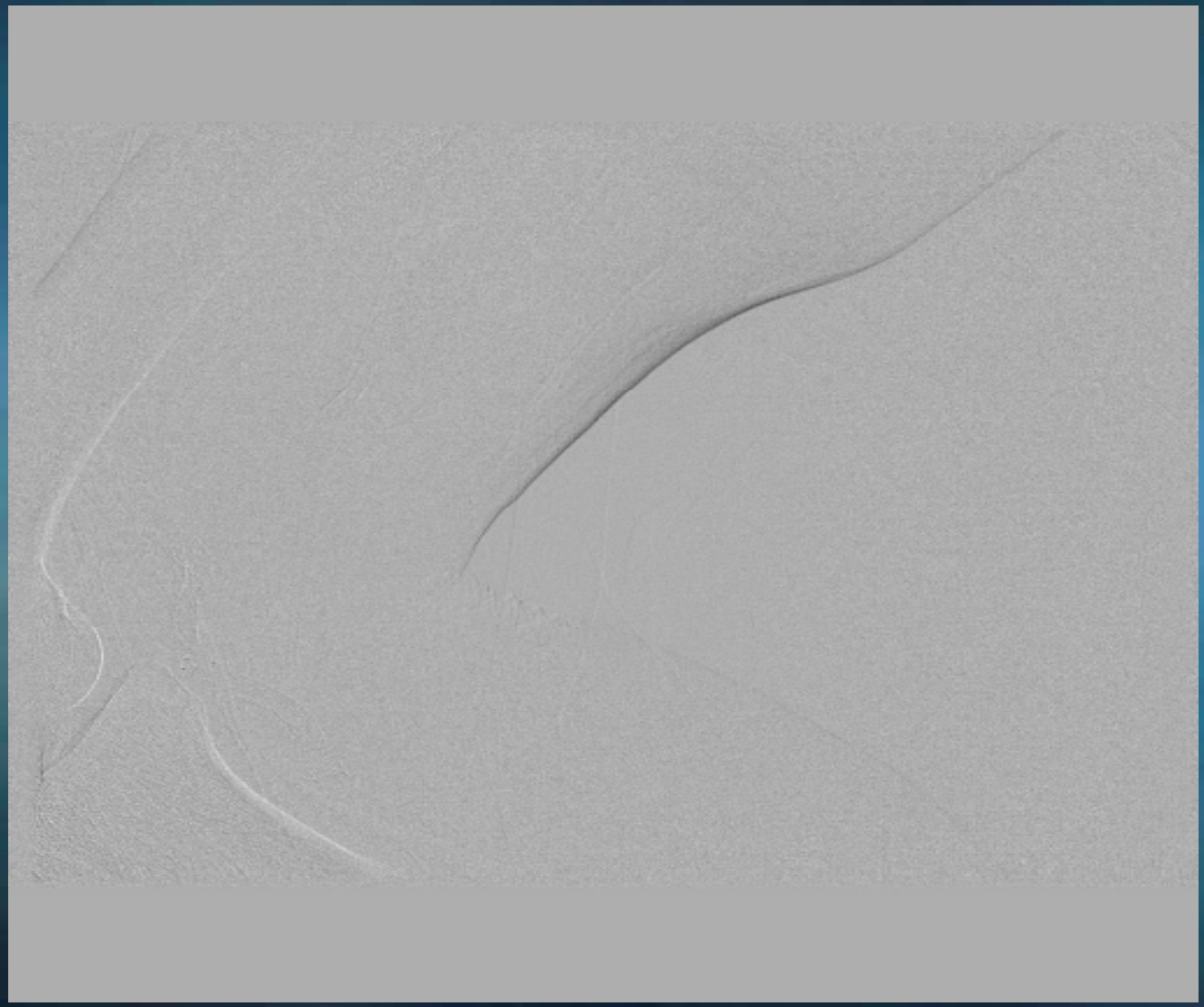
# *Flexion Angiogram*



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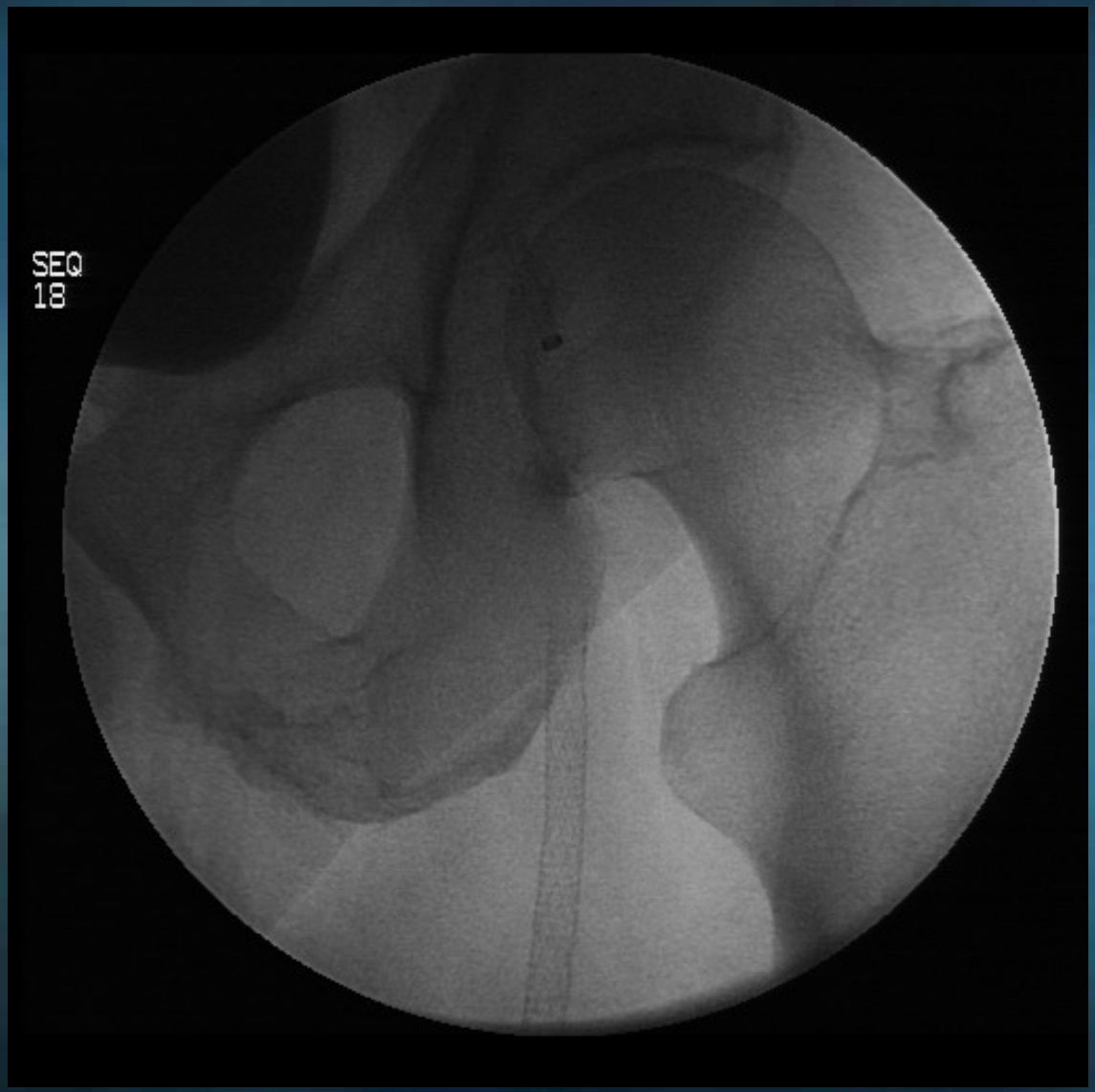
# Results of PQB at 5yrs



# Intellectual Property

(12) **United States Patent**
**Heuser**

(10) **Patent No.: US 6,464,665 B1**
(45) **Date of Patent: Oct. 15, 2002**

(54) **CATHETER APPARATUS AND METHOD FOR ARTERIALIZING A VEIN**

(75) Inventor: **Richard R. Heuser**, 2626 E. Arizona Biltmore Cir., No. 9, Phoenix, AZ (US) 85016

( * ) Notice: Subject to any disclaimer, the term of this

(12) **United States Patent**
**Heuser et al.**

(10) **Patent No.: US 8,062,321 B2**
(45) **Date of Patent: Nov. 22, 2011**

(54) **CATHETER SYSTEM FOR CONNECTING ADJACENT BLOOD VESSELS**

(75) Inventors: **Richard R. Heuser**, Phoenix, AZ (US); **James D. Joye**, Saratoga, CA (US)

(73) Assignees: **PQ Bypass, Inc.**; **Saratoga, Inc.**

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 624 days.

(21) Appl. No.: **11/735,382**

(22) Filed: **Apr. 13, 2007**

(65) **Prior Publication Data**

US 2008/0065019 A1 Mar. 13, 2008

**Related U.S. Application Data**

(63) Continuation-in-part of application No. 11/340,324, filed on Jan. 25, 2006, now Pat. No. 7,374,567.

(60) Provisional application No. 60/887,277, filed on Jan. 30, 2007.

(51) **Int. Cl.**
***A61B 17/34*** (2006.01)

(52) **U.S. Cl.** ..... **606/185**

(58) **Field of Classification Search** ..... 606/153, 605/170, 183, 167, 181, 185, 180, 194, 198, 606/219, 200, 213–215; 604/95.01, 104, 604/164.01; 623/1.1, 1.11–1.15, 1.2, 1.23, 623/1.35, 1.36

See application file for complete search history.

(56) **References Cited**

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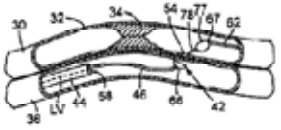
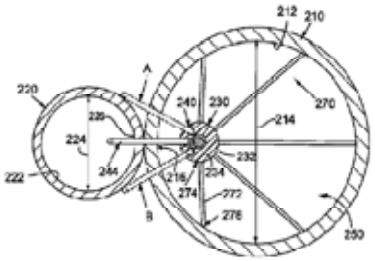
3,751,305 A 8/1973 Huebscher
3,788,318 A 1/1974 Kim et al.


(12) **United States Patent**
**Heuser**

(54) **STENT WITH COVERING AND DIFFERENTIAL DILATION**


3,828,770 A 8/1974 Kuris et al.
3,828,782 A 8/1974 Polin
4,000,739 A 1/1977 Stevens
4,241,289 A 12/1980 Bowling
4,430,081 A 2/1984 Timmermans
(Continued)

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EP 0696447 2/1996
(Continued)

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Hauser, M.D., Richard R., et al. "The Use of a New Wire in a 6-Year-Old Coronary Artery Occlusion: The Jagwire Recanalization Guidewire." Catheterization and Cardiovascular Diagnosis. 1995. pp. 173-176. vol. 29.
(Continued)


*Primary Examiner* — S. Thomas Hughes
*Assistant Examiner* — Katherine M Shi
(74) *Attorney, Agent, or Firm* — Wilson Sonsini Goodrich & Rosati

(57) **ABSTRACT**

The catheter apparatus may be used to assist in creating a fistula between two adjacent blood vessels. The apparatus includes a catheter for inserting into a first blood vessel which lies adjacent to a second blood vessel, the catheter having a plurality of openings through which a physician may navigate a piercing tool. The physician maneuvers the tip of the catheter to a position within the first blood vessel adjacent to a portion of the first blood vessel wall in which the physician intends to create an opening. The physician may then rotate the piercing tool within the catheter and extend the piercing tool through one opening at a time, without rotating the catheter, until the physician chooses an opening that is properly aimed at the second blood vessel. Such a configuration allows for a wide arc of potential firing spots.

**24 Claims, 7 Drawing Sheets**

(10) Patent No.: US 7,300,459 B2
(45) Date of Patent: Nov. 27, 2007

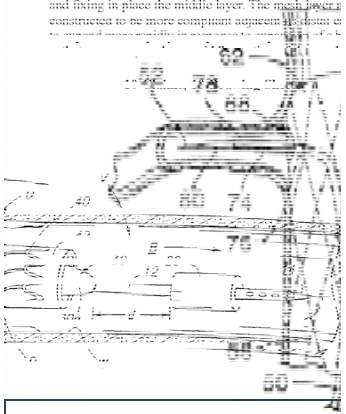

4,637,814 A 1/1987 Leiboff
4,650,466 A 3/1987 Luther
4,650,472 A 3/1987 Bates
4,665,906 A 5/1987 Jervis
4,700,705 A 10/1987 Kensey
(Continued)

OTHER PUBLICATIONS

(Continued)


*Primary Examiner*—Suzette Gherbi
(74) *Attorney, Agent, or Firm*—Kolisch Hartwell, P.C.

(57) ABSTRACT




(12) **United States Patent**
**Heuser**

(10) **Patent No.: US 6,858,038 B2**
(45) **Date of Patent: Feb. 22, 2005**

(12) **United States Patent**
**Heuser**

(10) **Patent No.: US 7,402,141 B2**
(45) **Date of Patent: Jul. 22, 2008**

(54) **CATHETER GUIDEWIRE SYSTEM USING CONCENTRIC WIRES**

(76) Inventor: **Richard R. Heuser**, 500 W. Thomas Rd., Suite 900, Phoenix, AZ (US) 85013

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/927,340**

(22) Filed: **Aug. 25, 2004**

(65) **Prior Publication Data**

US 2006/0047222 A1 Mar. 2, 2006

**Related U.S. Application Data**

(60) Provisional application No. 60/498,427, filed on Aug. 27, 2003.

(51) **Int. Cl.**
***A61B 5/00*** (2006.01)
***A61M 25/00*** (2006.01)

(52) **U.S. Cl.** ..... **600/585**

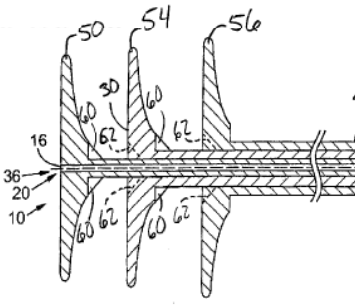
(58) **Field of Classification Search** ..... 600/433, 600/434, 435, 585; 604/164.13

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS


2,729,211 A 1/1956 Peter
3,751,305 A 8/1973 Huebscher
3,788,318 A 1/1974 Kim et al.
3,828,770 A 8/1974 Kuris et al.
3,828,782 A 8/1974 Polin
4,000,739 A 1/1977 Stevens


(12) **United States Patent**
**Heuser**

(10) **Patent No.: US 7,374,567 B2**
(45) **Date of Patent: May 20, 2008**

(54) **CATHETER SYSTEM FOR CONNECTING ADJACENT BLOOD VESSELS**

(76) Inventor: **Richard R. Heuser**, 500 W. Thomas Rd., Suite 900, Phoenix, AZ (US) 85013

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **11/340,324**

(22) Filed: **Jan. 25, 2006**

(65) **Prior Publication Data**

US 2007/0173878 A1 Jul. 26, 2007

(51) **Int. Cl.**
***A61B 17/34*** (2006.01)
***A61B 17/08*** (2006.01)

(52) **U.S. Cl.** ..... **606/185**; 606/153

(58) **Field of Classification Search** ..... 606/153, 606/157, 170, 181, 184, 185, 219–220, 213–215; 623/1.11; 227/175.1, 182.1

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS


2,729,211 A 1/1956 Peter
3,751,305 A 8/1973 Huebscher
3,788,318 A 1/1974 Kim et al.
3,828,770 A 8/1974 Kuris et al.
3,828,782 A 8/1974 Polin
4,241,289 A 12/1980 Bowling
4,430,081 A 2/1984 Timmermans
4,445,892 A 5/1984 Hussein et al.
4,590,669 A 5/1986 Imamura
4,637,814 A 1/1987 Leiboff
4,650,466 A 3/1987 Luther
4,682,981 A 7/1987 Strekl et al.
(Continued)

FOREIGN PATENT DOCUMENTS

EP 0696447 2/1996
(Continued)

OTHER PUBLICATIONS

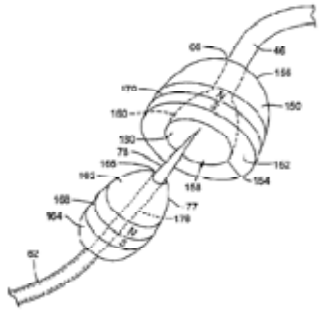
*JAMA. Effects of an Arteriovenous Fistula on the Devascularized Limb.* Feb. 22, 1965.
(Continued)


*Primary Examiner*—Michael J. Hayes
*Assistant Examiner*—Christina Gettman
(74) *Attorney, Agent, or Firm*—Kolisch Hartwell, P.C.

(57) **ABSTRACT**

A catheter system is provided for creating a fistula between blood vessels, using a first catheter with a piercing tool adjacent its distal end, and a second catheter with a receptor adjacent its distal end. The receptor includes an opening and a channel providing a guide surface for receiving the piercing tool. The receptor and piercing tool include one or more magnets to draw the piercing tool into the channel of the receptor. The piercing tool and the receptor are provided with a complementary configuration, such as a mating conical shapes. A third catheter may be provided with a double balloon for use in sealing off the fistula site. The piercing tool may be provided on a metal guidewire that includes a lumen with a distal opening. The piercing tool may include a base and a needle coupled to the base at a nominal angle of at least about 20-degrees. The piercing tool may be selectively moved between an extended position wherein the needle is positioned outside the guidewire at the nominal angle and a retracted position wherein the needle is positioned substantially within the guidewire.

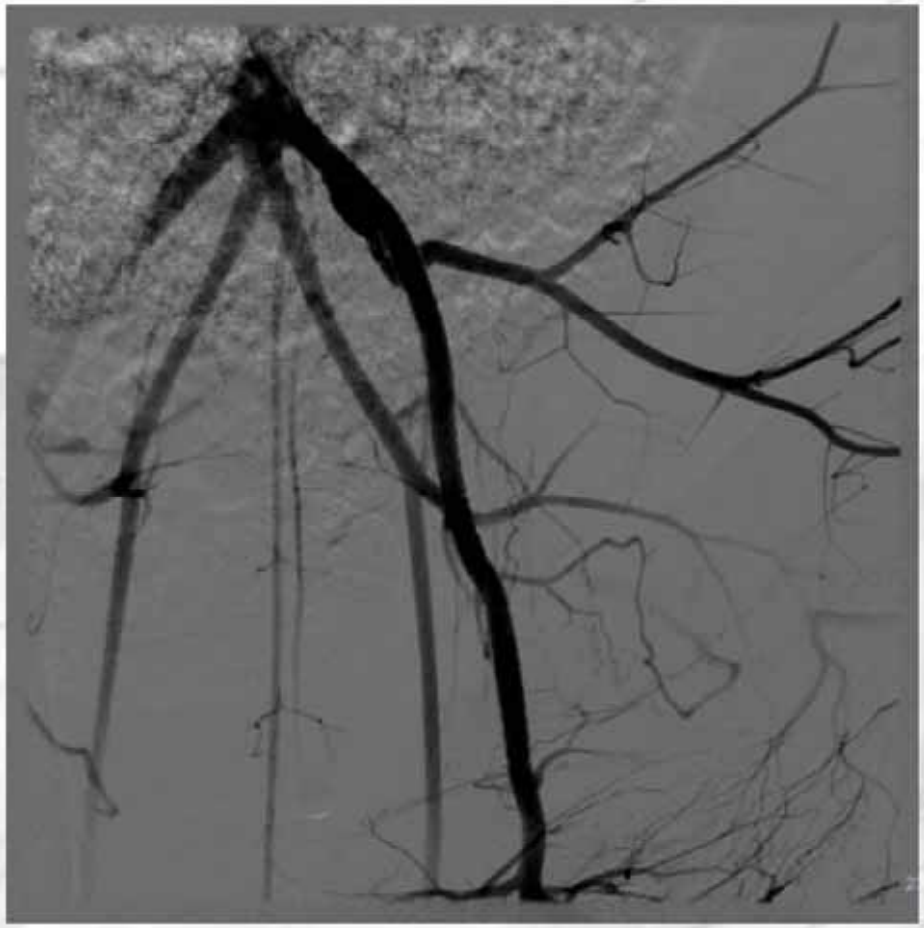
**21 Claims, 4 Drawing Sheets**




R. Heuser

# Pre-Clinical @ 30 days

**PQB Gen2**

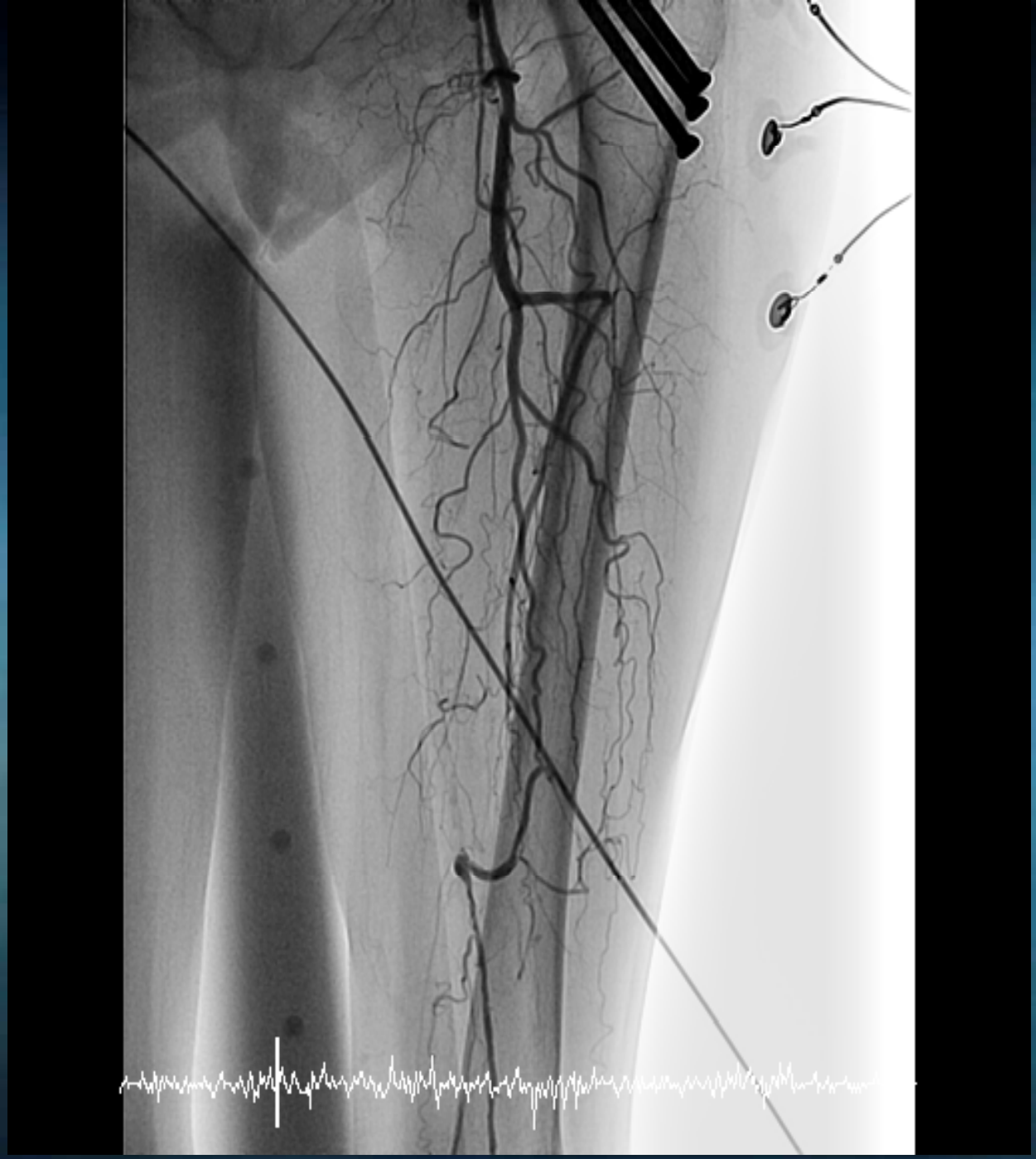


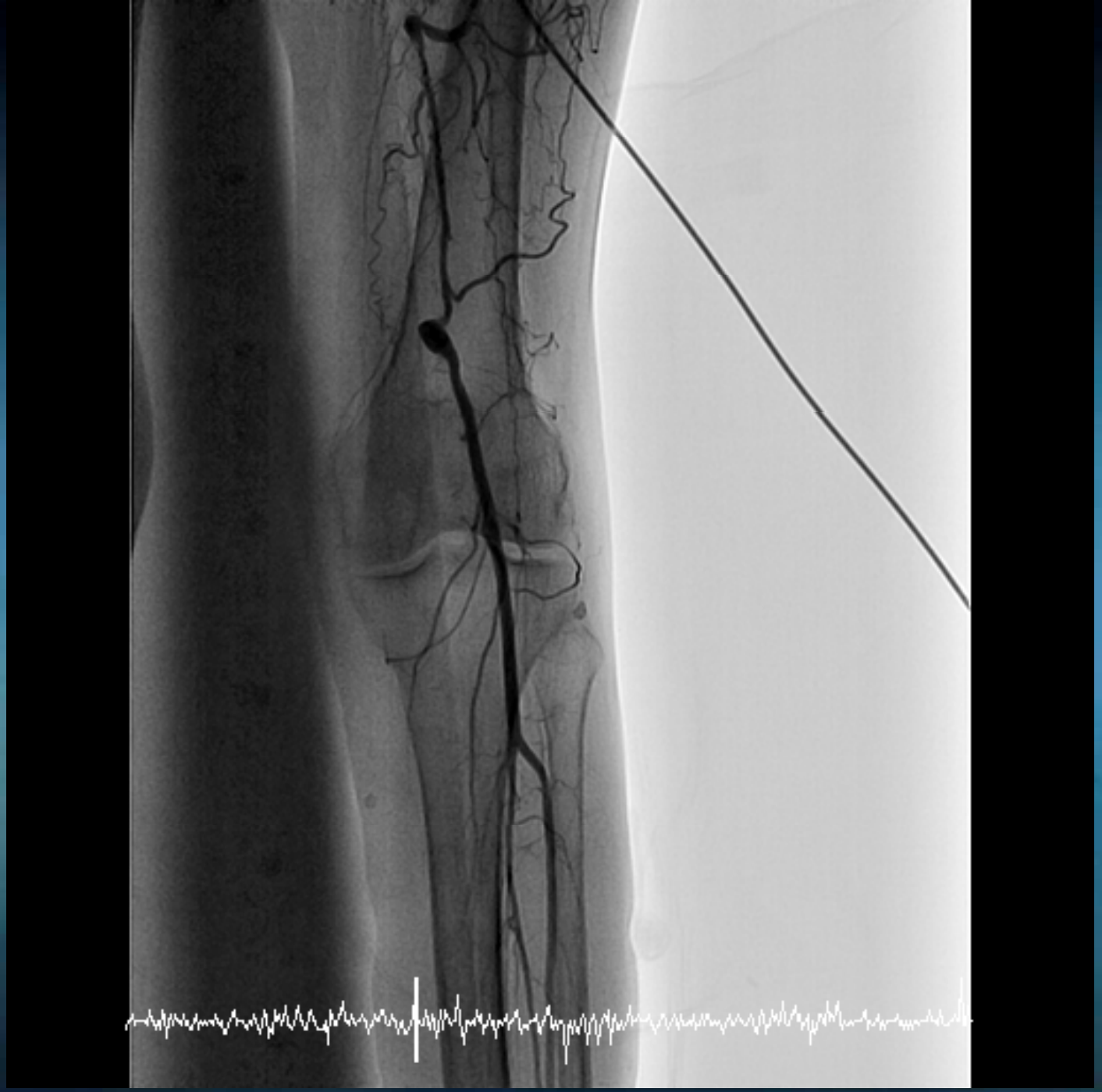
# TARGET LESIONS: PERCUTANEOUS BYPASS

- Stenoses and occlusions that are traditionally and appropriately suited for open bypass.
  - SFA occlusions ≥15cm
  - Aggressive or recurrent ISR
  - Densely calcified adductor canal lesions
  - Claudication and CLI
  - Patients at increased risk for conventional bypass



48 y/o mother who has had recurrent non-healing ulcers of her left foot. She is 4 years status post femoral/popliteal bypass on her left leg





# CONCLUSION

## SFA In-Stent Restenosis: What is the Optimal Treatment Strategy

**In select patients, drug eluting stents or drug eluting balloons appear to be a reasonable option. Perhaps in the future the PQ Bypass option may be possible in select patients. The role of debulking devices is still a fertile area for investigation.**