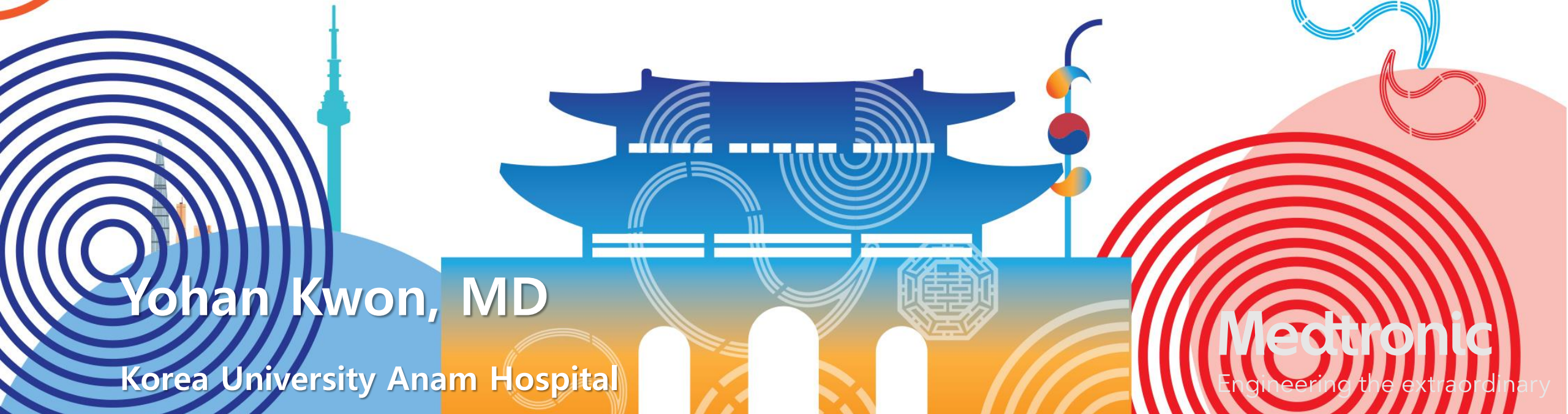
A Registry-based Study of Paclitaxel Drug-coated Balloon Angioplasty for the Treatment of In-stent Restenosis of the Femoral-popliteal Artery



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Medtronic

Engineering the extraordinary

Disclosures

I have the following potential conflicts of interest to report:

	Consulting
	Employment in industry
	Stockholder of a healthcare company
	Owner of a healthcare company
✓	Other(s) – IN.PACT Admiral DCB In-stent Restenosis (ISR) Post-market Registry Project supported by Medtronic, MDT16049
	I do not have any potential conflict of interest

Introduction

- Present interim, 24-month results of the prospective, non-randomized,
  VQI-registry based, post-market surveillance study of IN.PACT™ Admiral™ drug-coated balloon for in-stent restenosis (ISR) of the femoral-popliteal artery

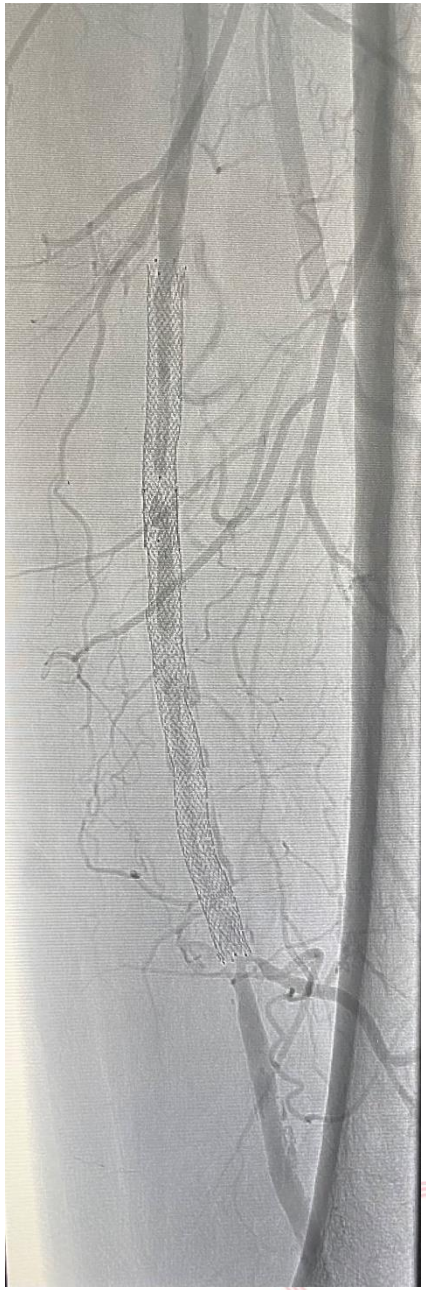
- Compare to other registry studies

Methods

Primary Objective

Assess long-term safety and performance of the IN.PACT Admiral Paclitaxel DCB for the treatment of ISR lesions of the SFA-popliteal arteries in a US population

- Multicenter study at 43 US sites within the SVS Vascular Quality Initiative
- 300 patients
- Follow-up 12, 24, 36 months
- Data collection using modification of existing VQI PVI case report form



DCB: drug-coated balloon; ISR: in-stent restenosis; PVI: peripheral vascular intervention; SFA: superficial femoral artery; SVS: Society for Vascular Surgery; VQI: Vascular Quality Initiative

Methods

Primary Endpoint

Target lesion revascularization (TLR)

within 12 months post-index procedure

Secondary Endpoint

12, 24, and 36 months

- All-cause mortality
- Target lesion revascularization (TLR)
- Target vessel revascularization (TVR)
- Major target limb amputation
- Technical success
  - defined as successful deployment of the balloon without resulting in occlusion and having residual stenosis ≤30% and resting systolic pressure gradient <10 mmHg (if measured)

TLR: target lesion revascularization; TVR: target vessel revascularization

Methods

Inclusion

1. Patient ≥ 18 years of age
2. Single-limb and single-lesion treatment during index procedure
3. ***de novo* or recurrent ISR** in the superficial femoral and/or popliteal artery
4. Documented ischemia with **Rutherford classification 2, 3, or 4**
5. Primary treatment of the ISR lesion with IN.PACT Admiral DCB

Exclusion

1. Patients with bilateral femoropopliteal artery treatment
2. Patients who have a history of tissue loss in the target limb
3. Failure to successfully cross the target lesion with a guide wire

Patient Characteristics

Patient Characteristic	IN.PACT DCB (N=300 ISR Subjects)
Age (years)	67.7 ± 10.0
Male	58.0% (174)
Race	
White	73.0% (219)
Black or African American	21.0% (63)
Asian	1.0% (3)
Other	5.0% (15)
Hispanic/Latino Ethnicity	3.3% (10)
BMI (kg/m²)	28.7 ± 5.7
Obesity (BMI ≥ 30 kg/m²)	36.8% (110)
Hypertension	93.3% (278)
Diabetes	56.0% (168)
Insulin Dependent Diabetes	30.7% (92)
Coronary Artery Disease	40.0% (120)
Current Smoker	30.7% (92)
Renal Insufficiency (CR≥ 1.5 mg/dL)	10.3% (30)
On Dialysis	2.7% (8)
Rutherford Classification	
0-1	--
2	27.3% (82)
3	52.7% (158)
4	20.0% (60)
5	--
Prior Limb Amputation†	8.3% (25)
Digit	5.0% (15)
Below-the-knee or above-the-knee	3.0% (9)

80% claudication
20% CLTI with rest pain

† One patient had both a prior toe amputation and a below-the-knee amputation. Among the sub-categories, an additional 3 patients had transmetatarsal amputations (these patients are included in the overall 8.3% rate).

Lesion and Procedural Characteristics

- Majority within SFA
- Over 50% TASC C/D
- Mean lesion length: 18 cm
- 43% total occlusions

	IN.PACT DCB (N=300 ISR Subjects)
TASC Lesion Type	
A	17.0% (51)
B	29.3% (88)
C	38.3% (115)
D	15.3% (46)
Lesion Length (cm), mean ± SD	17.8 ± 11.8
Total Occlusion	42.7% (128)
Occluded Lesion Length (cm), mean ± SD	16.3 ± 10.1
Calcification†	**N=248**
None	33.0% (99)
Focal	4.7% (14)
Mild	12.3% (37)
Moderate	17.7% (53)
Severe	15.0% (45)
Not Evaluated	17.3% (52)
Lesion Location	
SFA	67.7% (203)
POP	6.7% (20)
SFA-POP	25.7% (77)

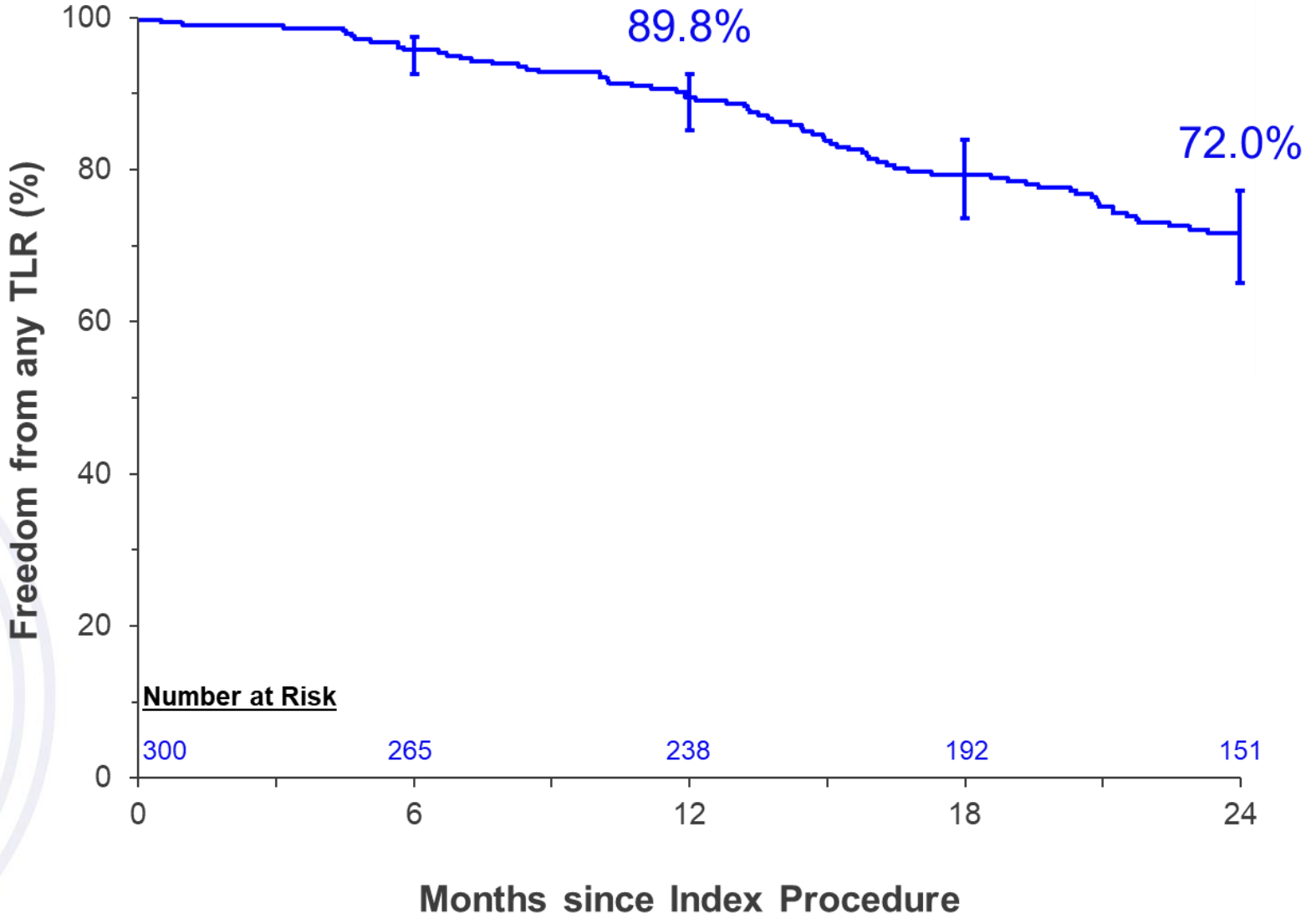
† Proportions are shown out of a denominator of 300 patients

Primary and Secondary Endpoints

	IN.PACT Admiral DCB ISR Post-Market IN.PACT DCB (N=300 ISR Subjects)
Primary Effectiveness Endpoint	
Target Lesion Revascularization (TLR) through 12 months	10.1% (28/276)
Secondary Endpoints within 12 months	
All-Cause Mortality	4.7% (14/299)
Target Vessel Revascularization (TVR)	12.0% (33/276)
Major Target Limb Amputation	0.4% (1/275)
Technical success†	98.7% (296/300)
Primary and Secondary Endpoints within 24 months	
Target Lesion Revascularization (TLR)	29.5% (71/241)
All-Cause Mortality	10.8% (32/297)
Target Vessel Revascularization (TVR)	33.6% (82/244)
Major Target Limb Amputation	1.3% (3/235)

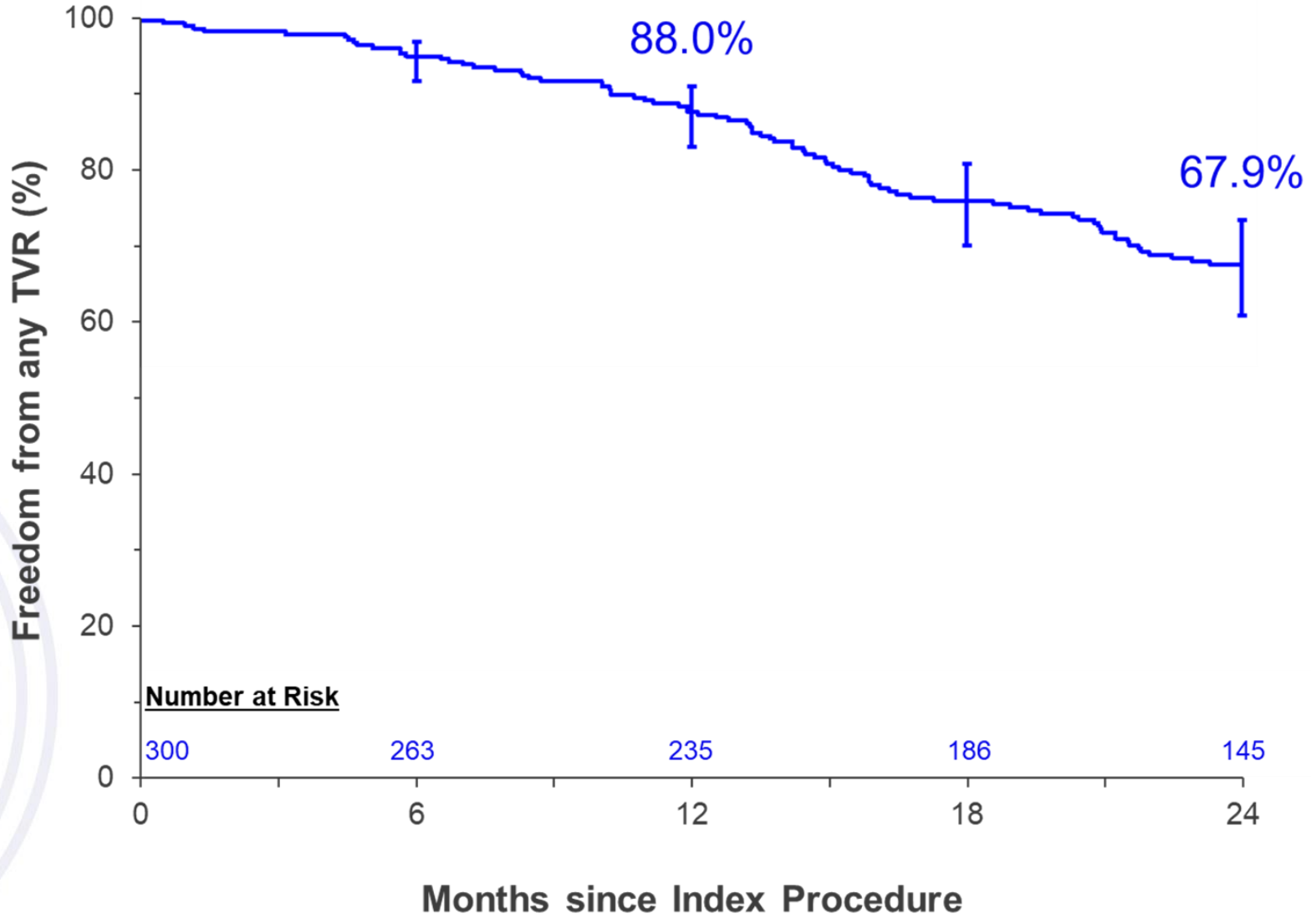
†Technical success defined as successful deployment of the balloon without resulting in occlusion and having residual stenosis ≤30% and resting systolic pressure gradient < 10 mmHg (if measured)

Freedom From Any TLR



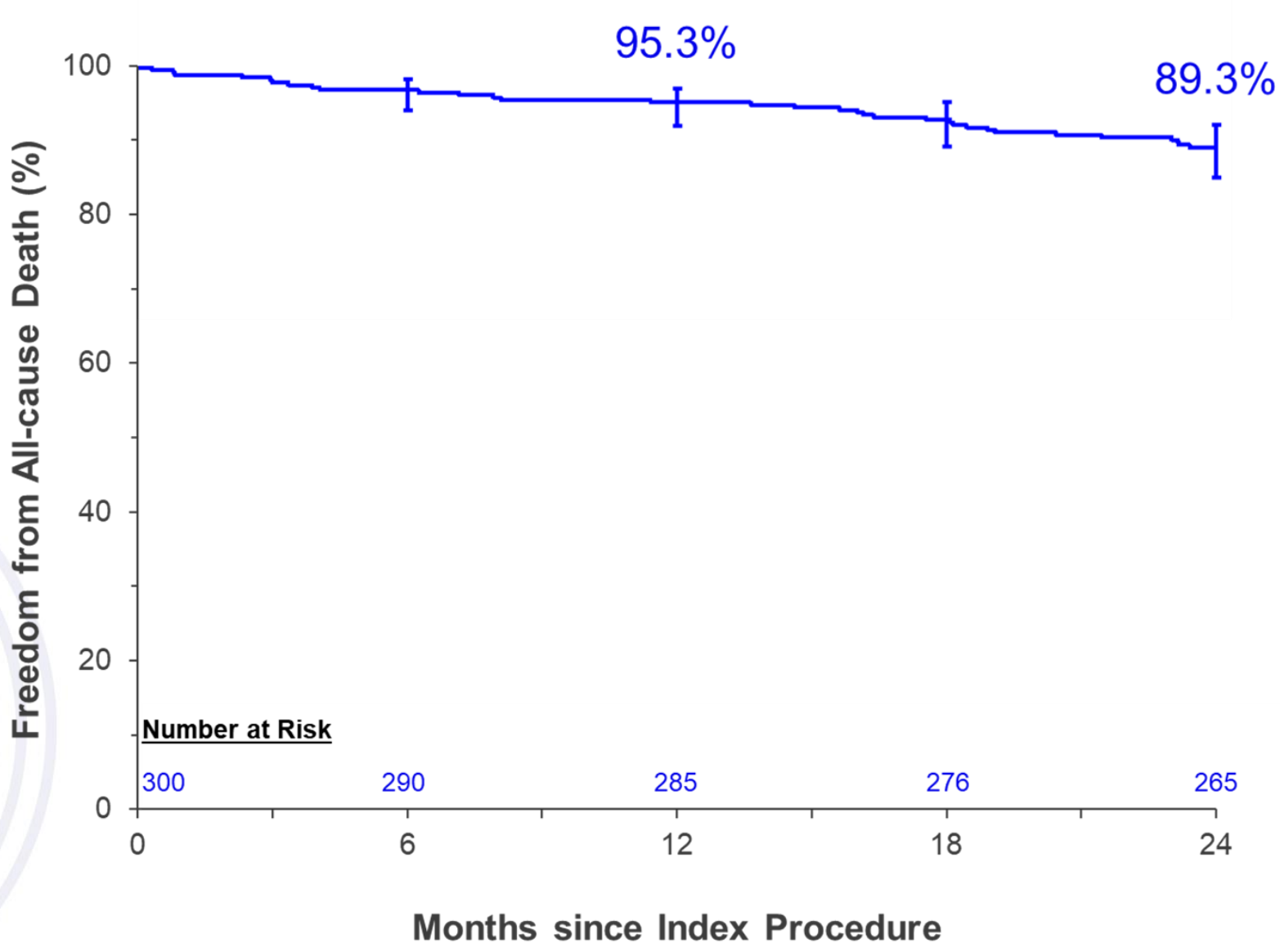
TLR: target lesion revascularization

Freedom From TVR



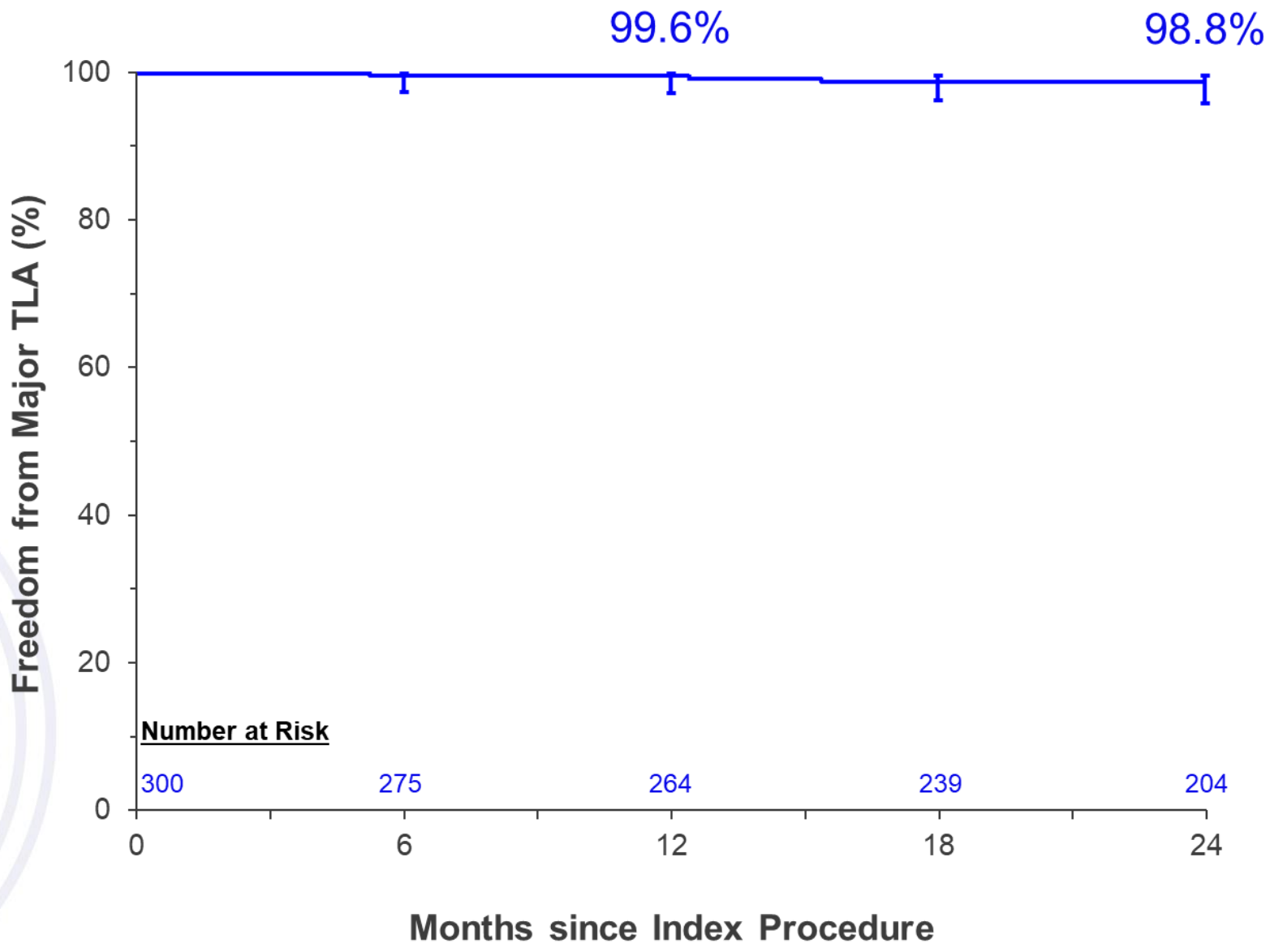
TVR: target vessel revascularization

Survival



TLR: target lesion revascularization

Freedom From Target Limb Major Amputation



TLA: target limb amputation

	Lutonix Global SFA Registry ISR Cohort (n=89)[1]	IN.PACT Global ISR Cohort (n=131)[2]	IN.PACT SVS ISR Registry (n=300)	Zilver PTX Japan Post-Market ISR (n=177)[3]	BIOLUX P-III Global Registry ISR Cohort (n=88)[4]	XLPAD Registry ISR Cohort (n=347)[5]
Key Inclusion Criteria	Femoropopliteal stenosis or occlusion, RCC ≤4, at least one patent outflow	RCC 2-4, de novo or restenotic if severely stenosed or occluded ≥2 cm.	RCC 2-4, de novo or recurrent ISR, single-limb, single-lesion.	Femoropopliteal, all comers (consecutive)	Infrainguinal artery lesions suitable for DCB (all comers)	Infrainguinal artery lesions undergoing endovascular revascularization
CLI (%)	9.1 (8/88)	9.2 (12/130)	20.0 (60/300)	22.3 (43/193)	31.9 (23/72)	36.6 (127)
Diabetes (%)	28.1 (25/89)	35.1 (46/131)	56.0 (168/300)	61.0 (108/177)	42.0 (37/88)	51.9 (177)
Lesion Length (cm)	15.4 ± 9.7	17.2 ± 10.5	17.8 ± 11.8	17.8 ± 10.4	8.4 ± 7.4	14.5 ± 9.9
Calcified (%)	37.7 (26/69)	59.1 (78/132)	60.1 (149/248)	--	53.5 (53/99)	--
Total Occlusion (%)	28.1 (25/89)	34.0 (48/141)	42.7 (128/300)	35.3 (72/204)	0.0	47.3 (175)
TASC A-B (%)	76.2 (48/63)	58.0 (76/131)	46.3 (139/300)	--	82.7 (81/98)	--
TASC C-D (%)	23.8 (15/63)	42.0 (55/131)	53.7 (161/300)	--	17.3 (17/98)	--
FF-TLR 12 months	90.7%	91.9%	89.8%	85.8%	89.4% ‡	--
FF-TLR 24 months	84.6%		72.0%	79.5%	--	--
FF-TVR 12 months	--	90.3%	88.0%	--	88.5%‡	88.5%†

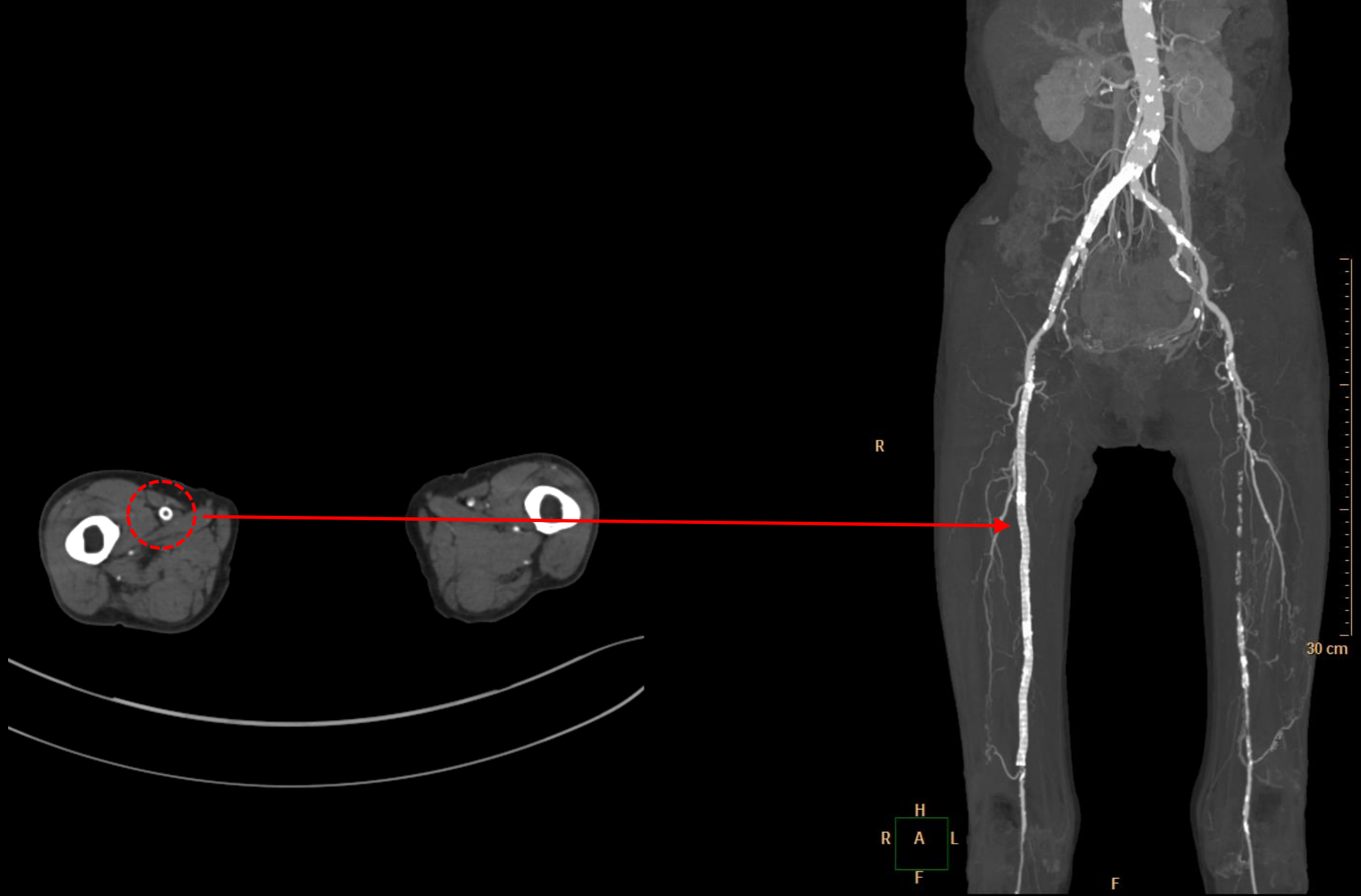
1. Thieme et al. JACC Cardiovasc Interv. 2017;10:1682-90.
2. Brodmann et al. JACC Cardiovasc Interv. 2017;10:2113-23.
3. Sugimoto et al. J Endovasc Ther. 2021;28(2):229-235
4. Tepe et al. J Endovasc Ther. 2020;27(2):304-315
5. Vu et al. J Interv Cardiol. 2022;2022:5935039

†Target Limb Revascularization, Femoropopliteal ISR lesions
‡Clinically driven

Data come from different individual studies and may differ in a head-to-head comparison, and therefore may not be predictive of clinical results.

Case 1

- F/91
- Claudication
  - RCC 4
- PMHx
  - DM
  - HTN
  - SFA stent placement, 8MA


R
30 cm
H
R
A
L
F
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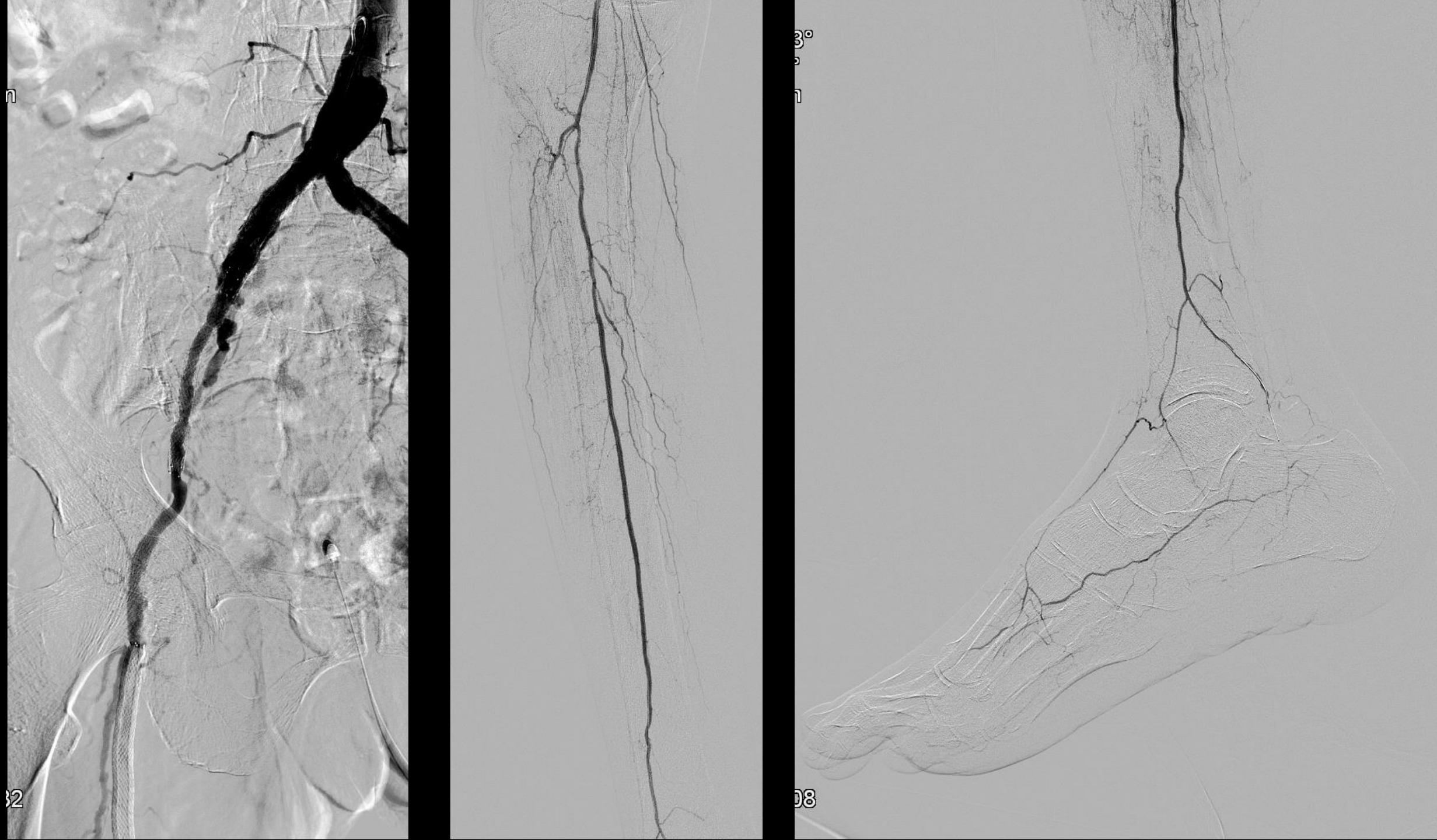
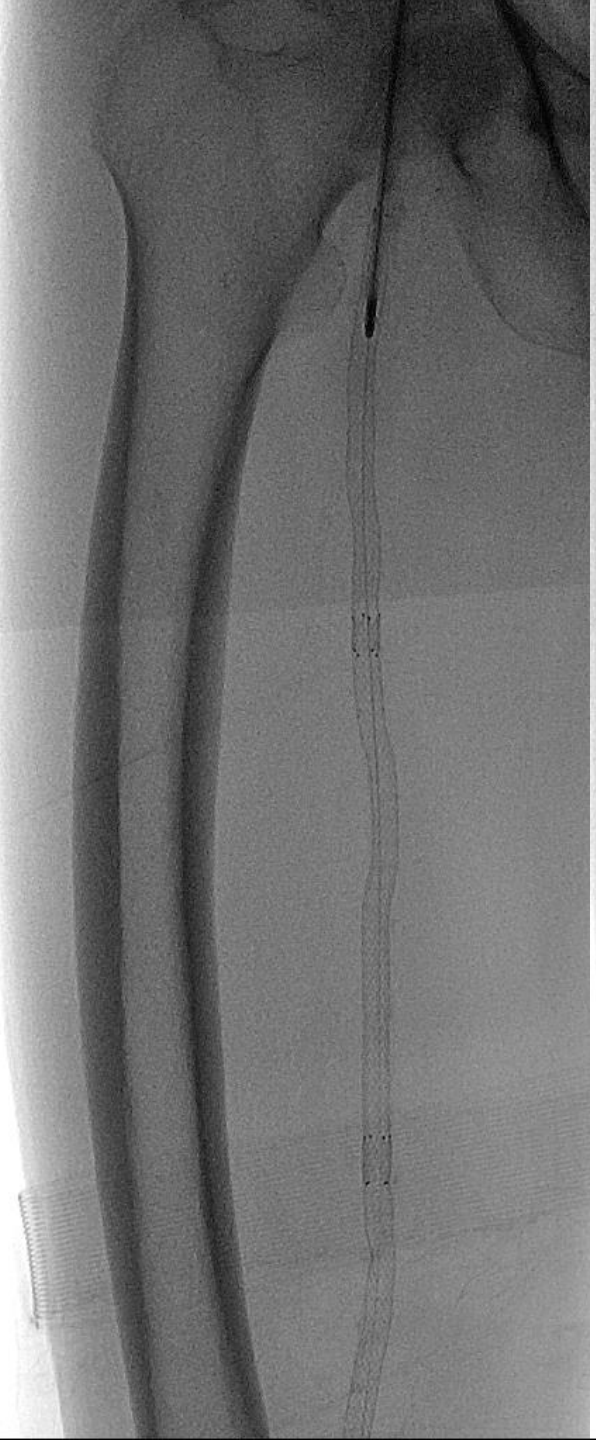
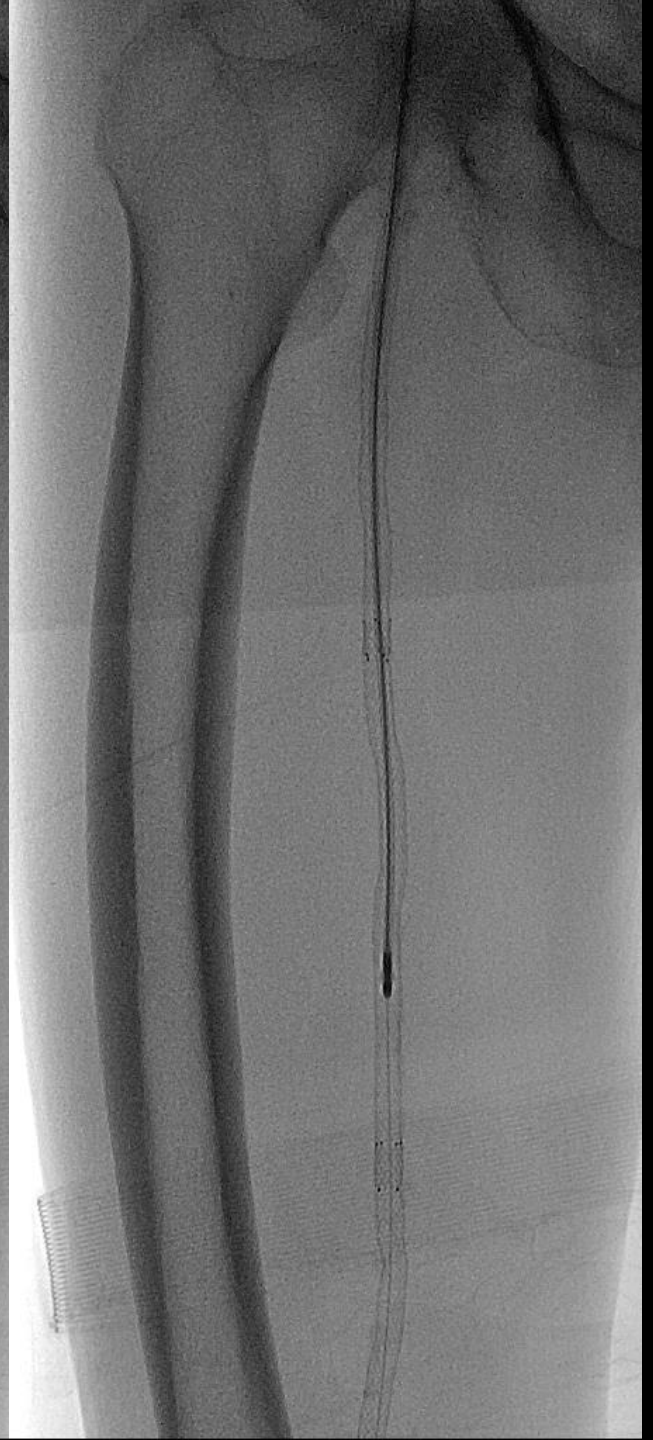
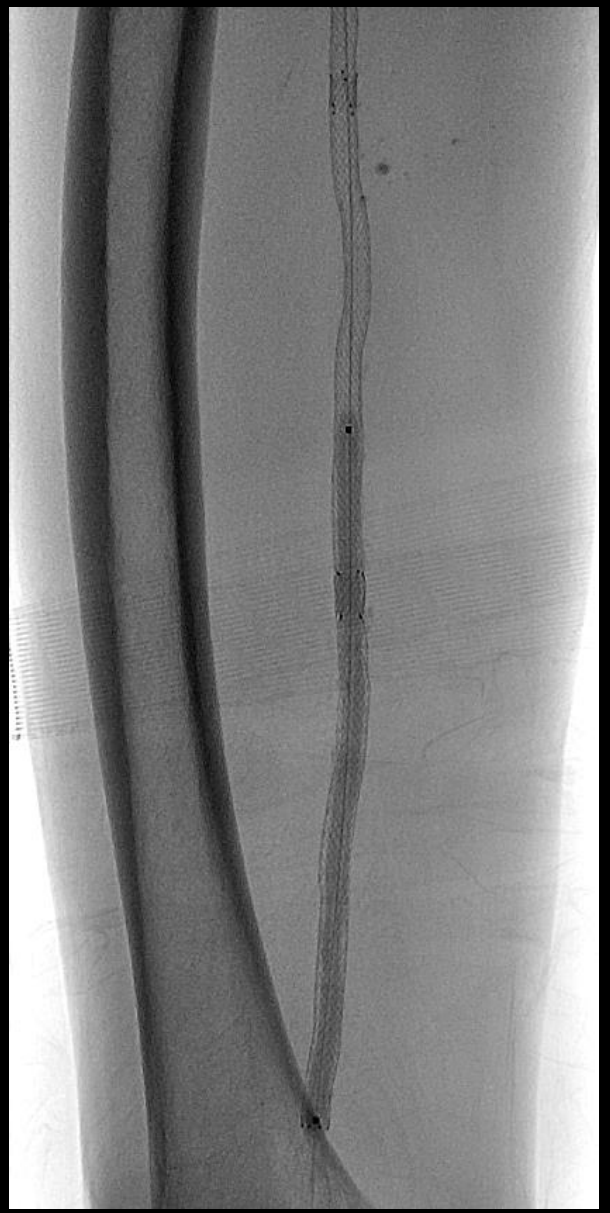
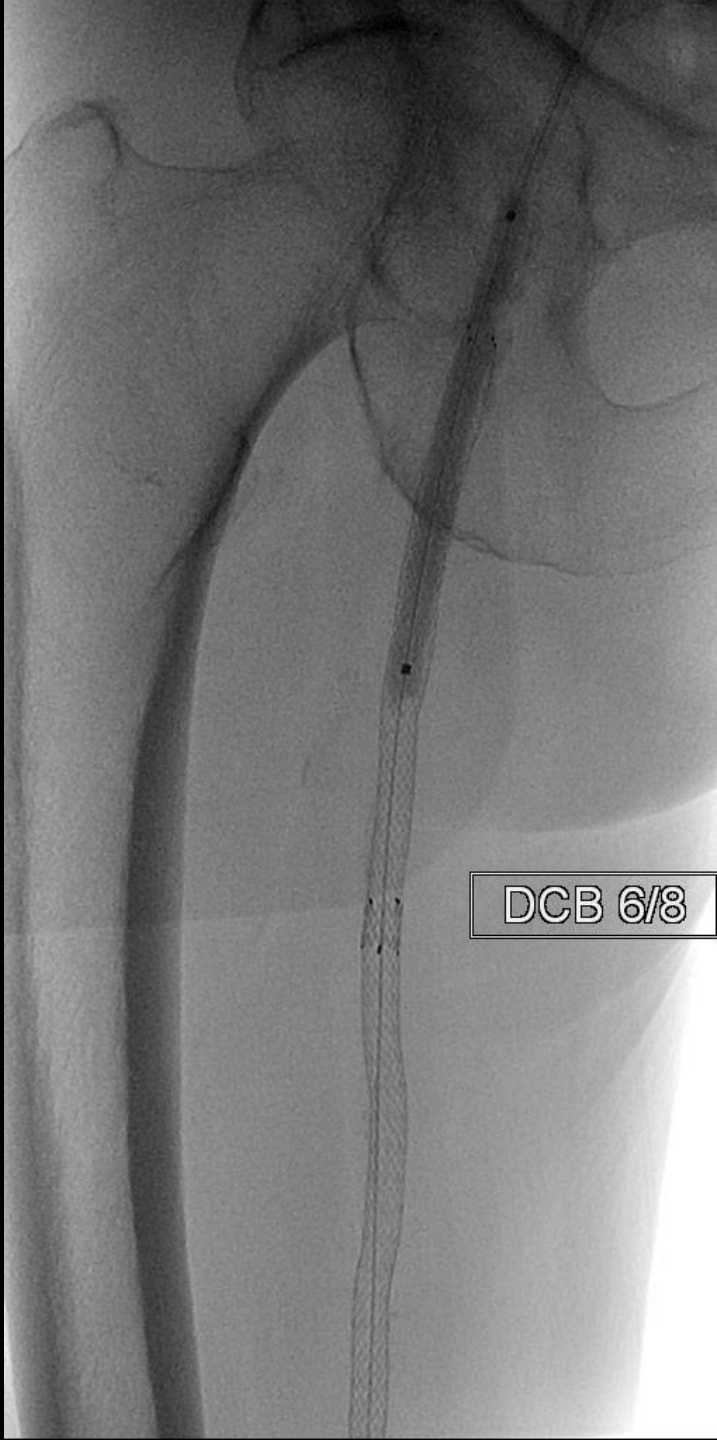
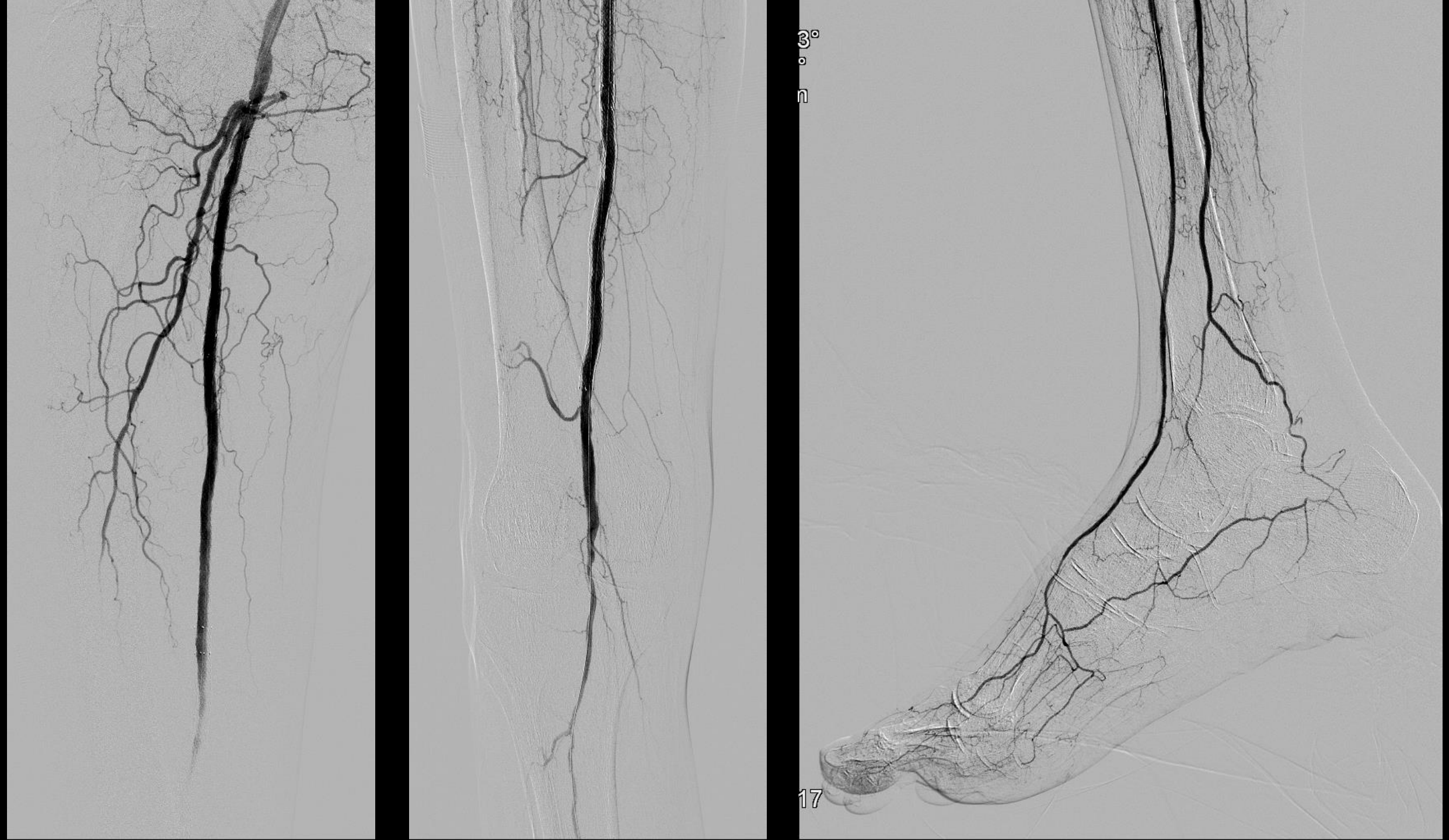
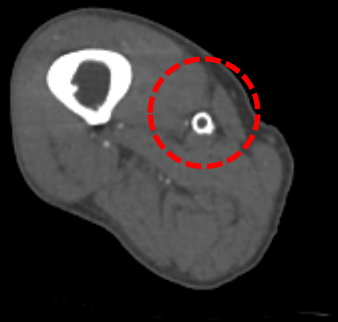
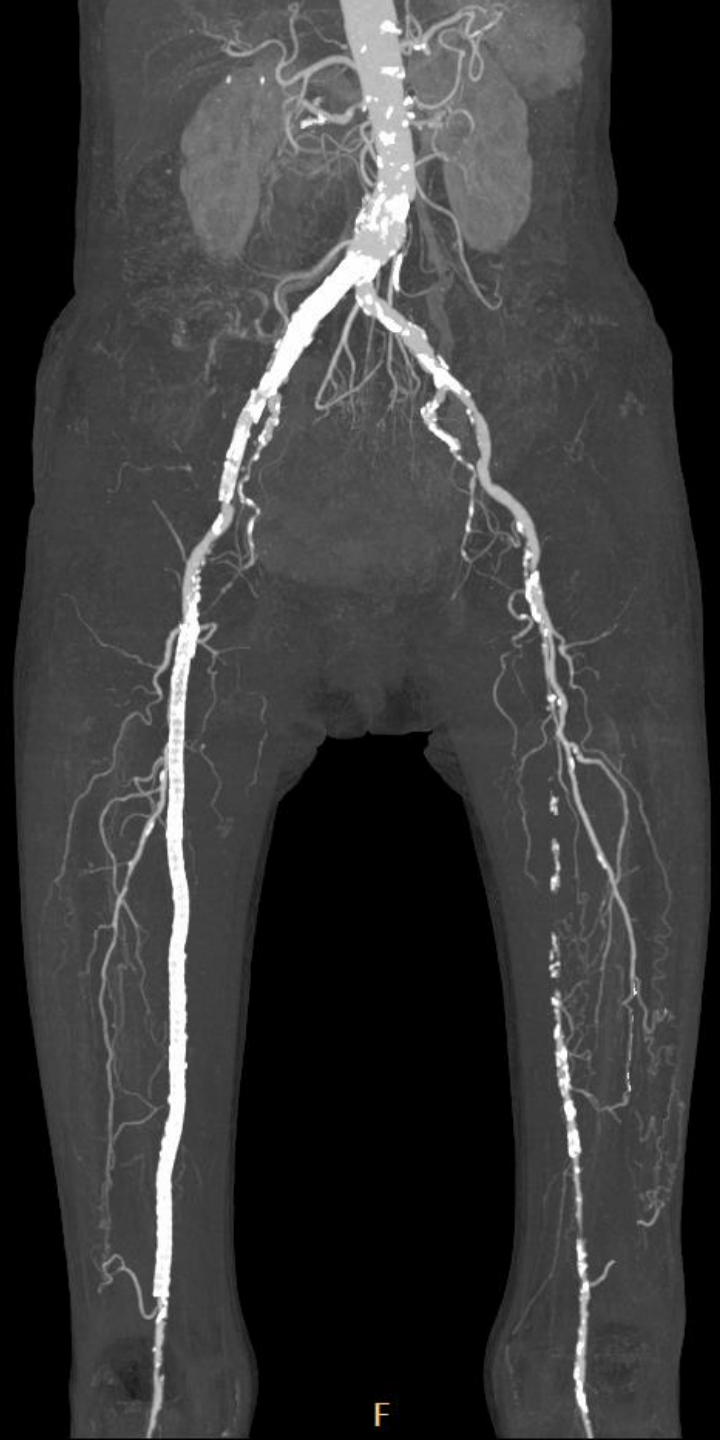






DCB 6/8



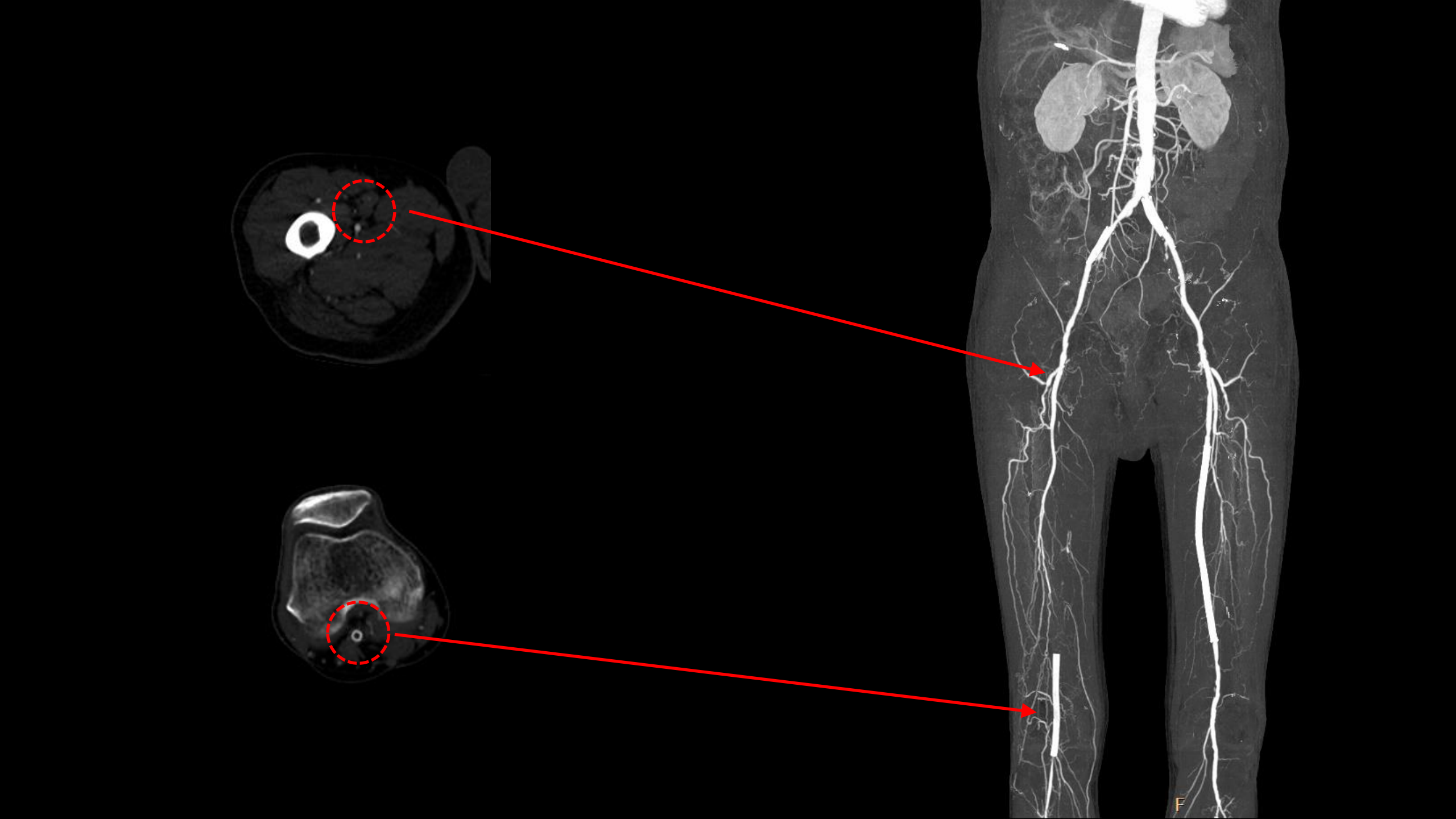
- CT angiography
  taken 15 month later

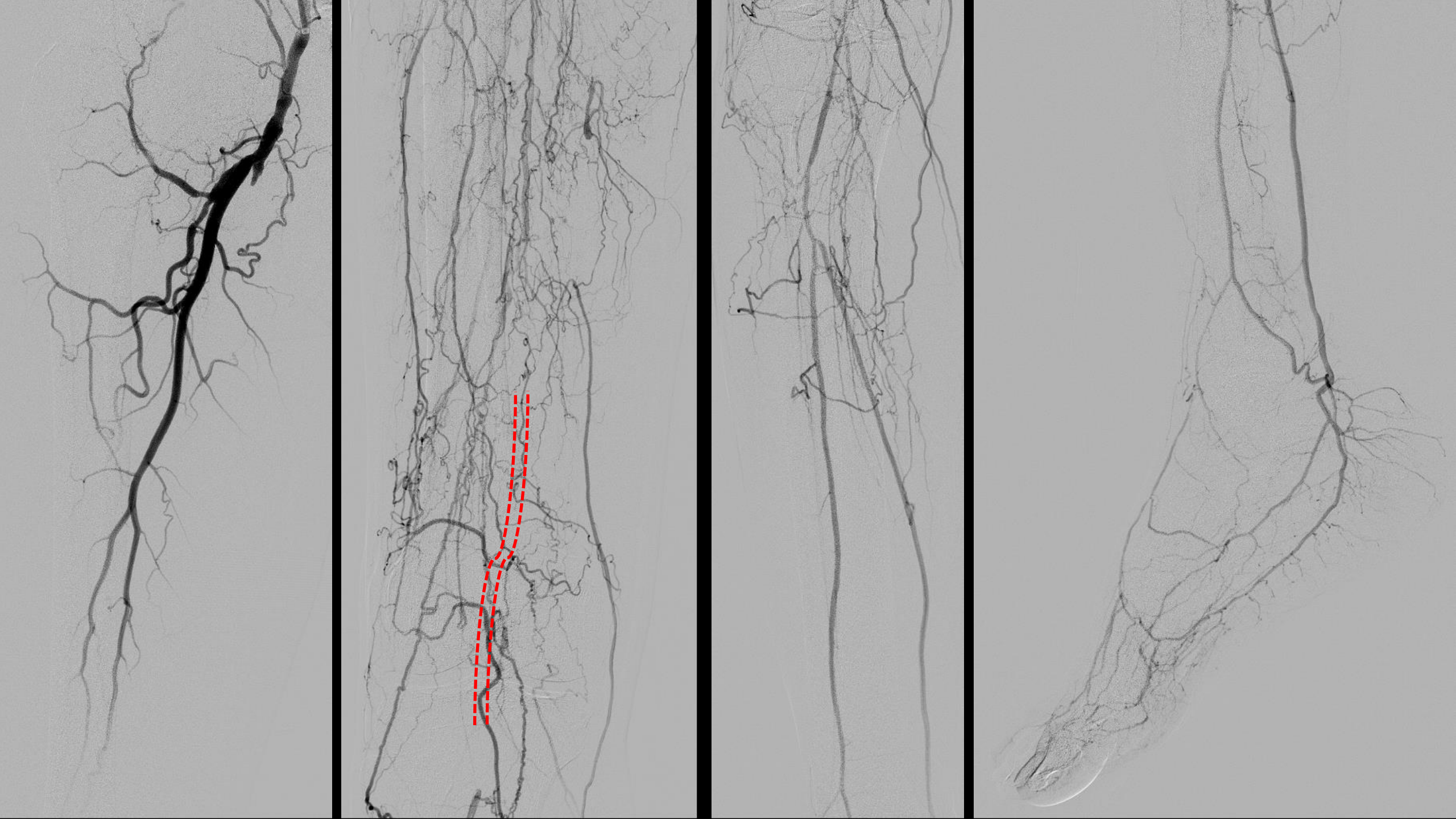


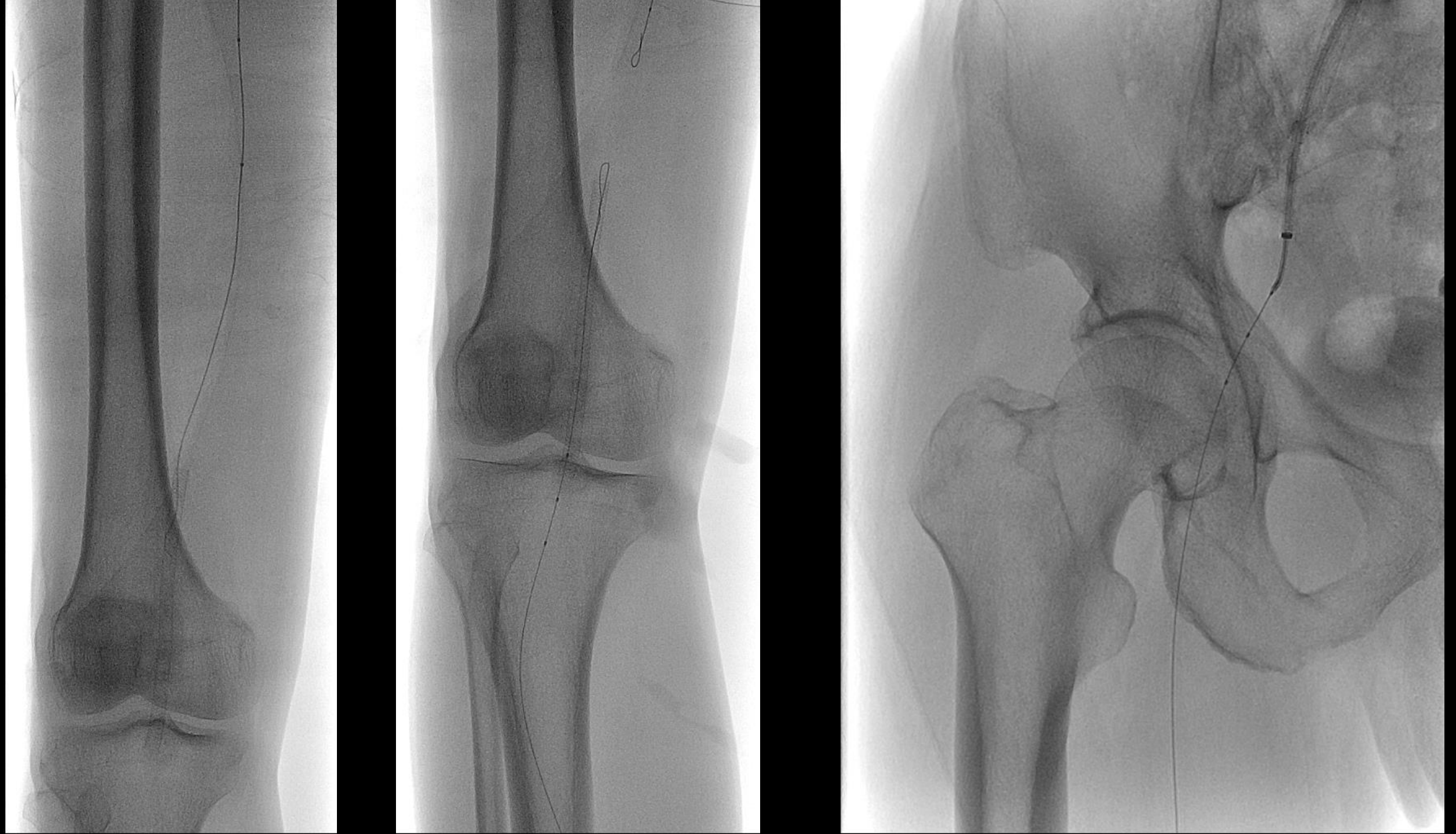


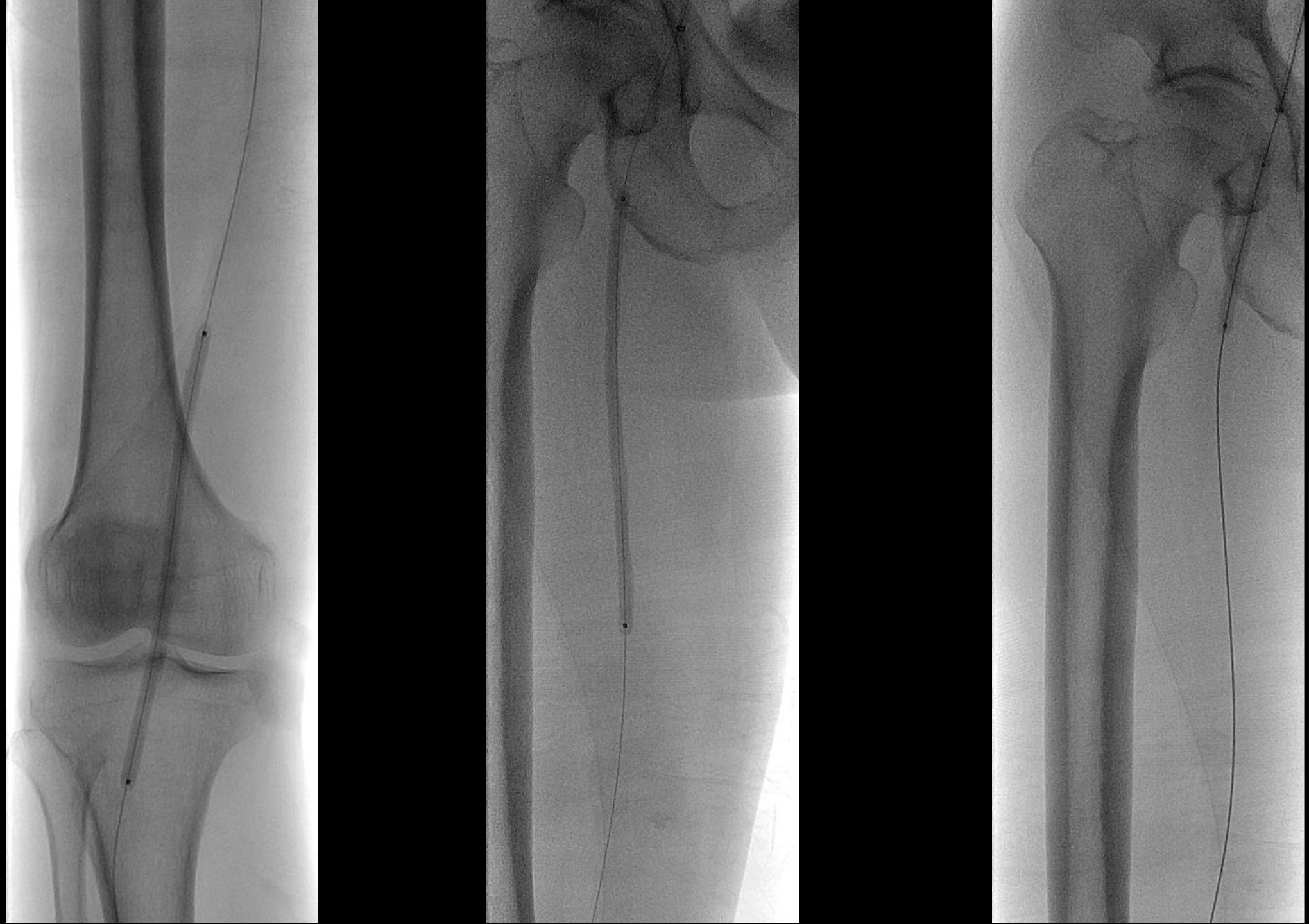
Case 2

- M/83
- Claudication
  - RCC 4
- PMHx
  - DM
  - HTN
  - PoA stent placement, 15MA









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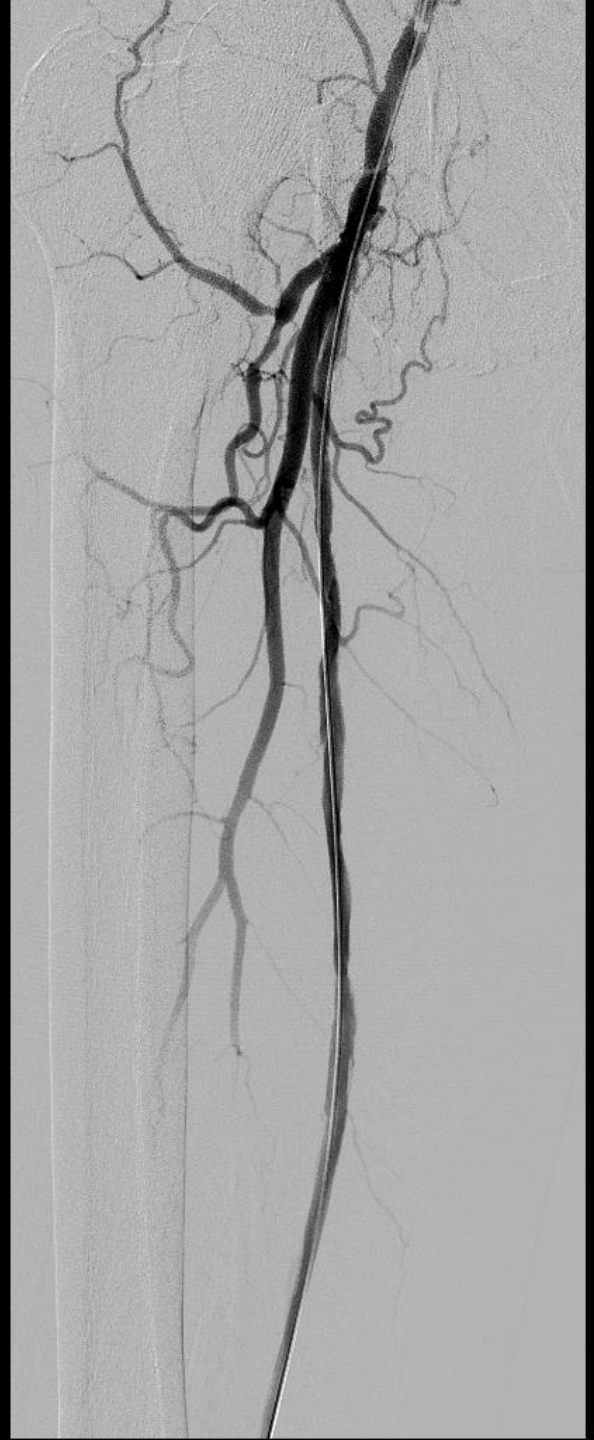
FD 48 cm



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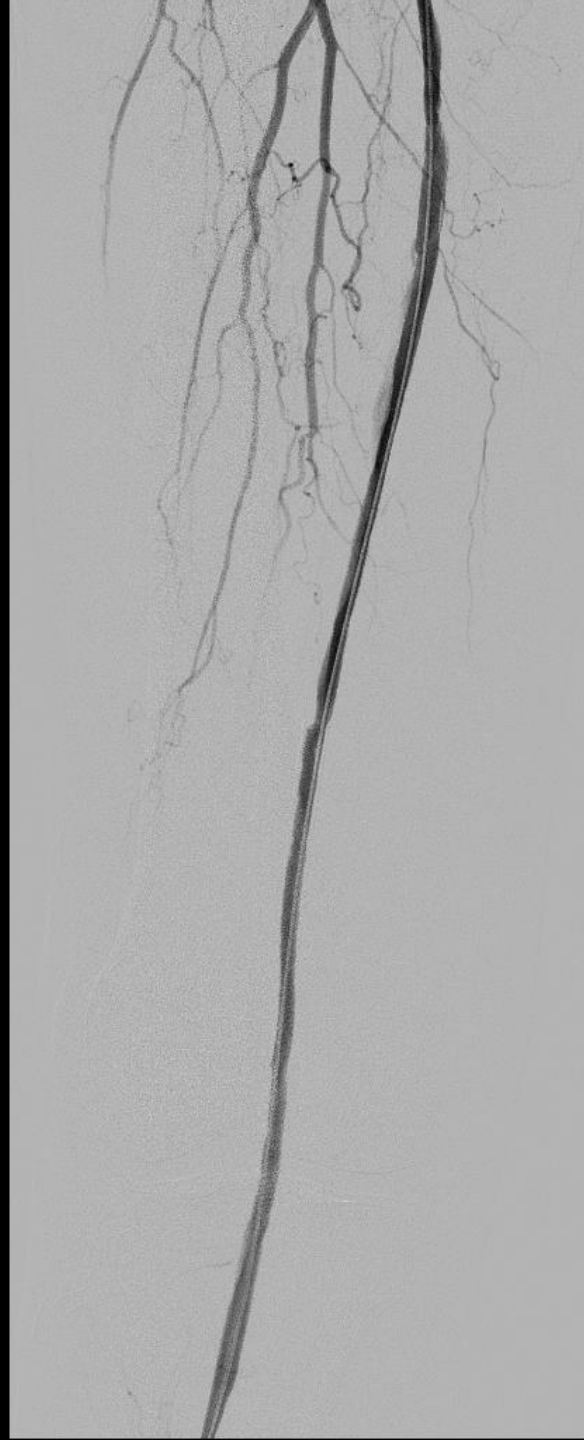
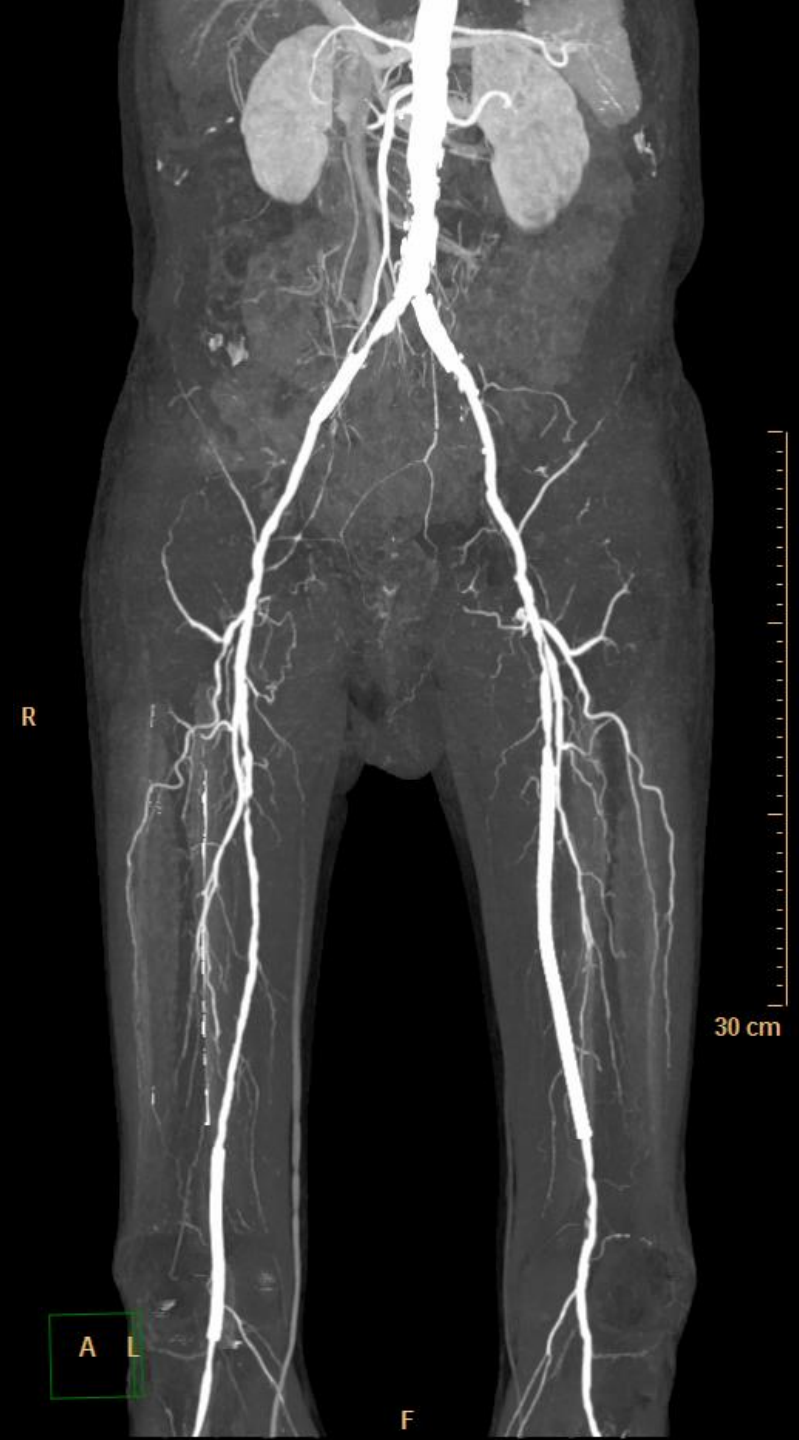


0:17
3:83
10:43:29

41
1-12

- CT angiography
  taken 26 month later



Conclusions

- This post-market registry-based study of a paclitaxel DCB shows promising results in treating femoral-popliteal ISR with freedom from TLR of 90% at one year and 72% at two years

- Results demonstrate the ability of the VQI to conduct post-market evaluation of peripheral devices in partnership with industry and federal regulators

- Limitation
  - Does not describe or analyze preparatory treatment