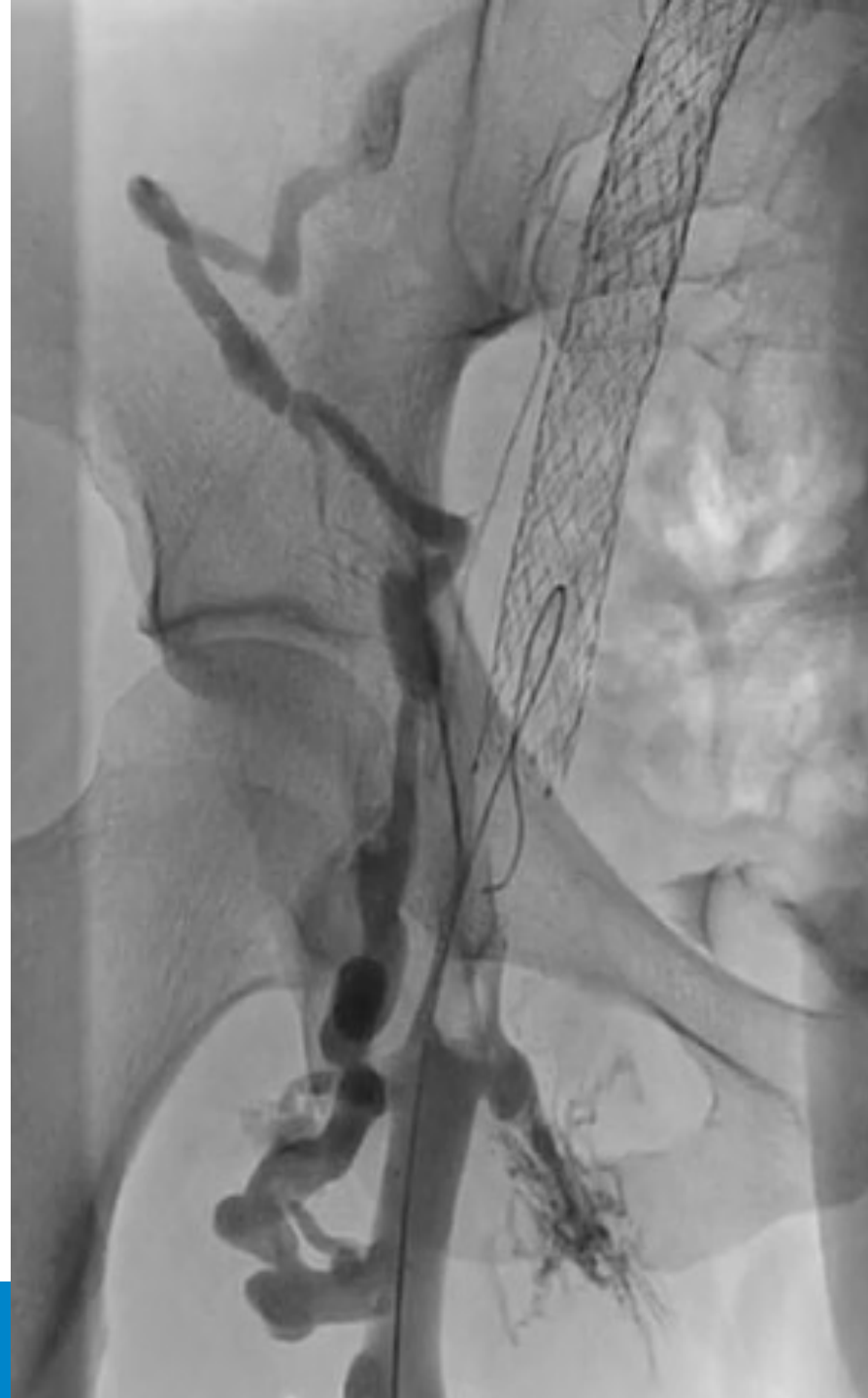
Insights from the ABRE IDE Trial

PREDICTORS OF STENT OUTCOMES



Erin H. Murphy, MD, FACS

STENT OCCLUSIONS – 12 MONTHS

Primary patency at 12 months (%, n)				
	All Subjects	**PTS**	**NIVL**	**aDVT**
Patency (%, n)	**88.0% (162/184)**	79.8% (67/84)	98.6% (68/69)	87.1% (27/31)
Occlusions (n)	**8**	**7**	**1**	**0**

Originally presented by Erin Murphy MD at Charing Cross, April 21, 2021

BASELINE DEMOGRAPHICS

Baseline Demographic	All Subjects (n=200)	Stent Thrombosis at 12 Months		
		Yes (n = 8)	No (n = 192)	P-value
Age (years)	51.5 ± 15.9	46.1 ± 18.2	51.7 ± 15.8	0.290
Female	66.5% (133/200)	62.5% (5/8)	66.7% (128/192)	1.000
White	78.5% (157/200)	62.5% (5/8)	79.2% (152/192)	0.373
BMI (kg/m²)	29.5 ± 7.1	28.6 ± 7.4	29.6 ± 7.1	0.638
Initial Clinical Presentation				
PTS	47.5% (95/200)	87.5% (7/8)	45.8% (88/192)	0.028
NIVL	36.0% (72/200)	12.5% (1/8)	37.0% (71/192)	0.263
aDVT	16.5% (33/200)	0.0% (0/8)	17.2% (33/192)	0.357
Previous history of VTE	52.0% (104/200)	87.5% (7/8)	50.5% (97/192)	0.067
Venous claudication	30.0% (60/200)	0.0% (0/8)	31.3% (60/192)	0.108
Known family history of DVT	22.0% (44/200)	12.5% (1/8)	22.4% (43/192)	0.688
Pulmonary embolism	17.0% (34/200)	37.5% (3/8)	16.1% (31/192)	0.137
Smoking (active)	12.0% (24/200)	0.0% (0/8)	12.5% (24/192)	0.599
Thrombophilia	11.5% (23/200)	25.0% (2/8)	10.9% (21/192)	0.231
Cancer (ongoing or remission)	11.0% (22/200)	12.5% (1/8)	10.9% (21/192)	1.000
IVC filter present	5.0% (10/200)	12.5% (1/8)	4.7% (9/192)	0.342

PTS, post thrombotic lesion; NIVL, non-thrombotic iliac vein lesion; aDVT, acute deep vein thrombosis, VTE, venous thromboembolism

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DISEASE/PROCEDURE CHARACTERISTICS

Representing subjects with extensive disease

Imaging Core Lab Assessment – Pre-Stenting	All Subjects (n=200)	Stent Thrombosis within 12 Months		
		Yes (n = 8)	No (n = 192)	P-value
Subjects with occluded lesions†	25.6% (50/195)	57.1% (4/7)	24.5% (46/188)	0.073
Lesion length (mm) †	112.4 ± 66.1	189.5 ± 48.2	109.4 ± 65.0	0.004

Imaging Core Lab Assessment – Post-Stenting	All Subjects (n=200)	Stent Thrombosis within 12 Months		
		Yes (n = 8)	No (n = 192)	P-value
Total stented length (mm) †	134.3 ± 58.0	194.3 ± 42.4	132.0 ± 57.3	0.006
Number of Abre stents implanted per subject	1.5 ± 0.6	2.4 ± 0.9	1.5 ± 0.6	0.002
Stented Vein Location**				
Common iliac vein	96.0% (192/200)	100.0% (8/8)	95.8% (184/192)	1.000
External iliac vein	80.5% (161/200)	100.0% (8/8)	79.7% (153/192)	0.359
Common femoral vein	44.0% (88/200	87.5% (7/8)	42.2% (81/192)	0.023

†Data from venogram (n = 22)
** Site data was used when core laboratory data was not available, stent extended across the locations

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PRIMARY ENDPOINTS RESULTS – 12 MONTHS

Primary patency at 12 months (%, n)			
All Subjects	PTS	NIVL	aDVT
88.0% (162/184)	79.8% (67/84)	98.6% (68/69)	87.1% (27/31)

Primary patency at 12 months for subjects where stent extended into CFV (%, n)			
All Subjects	PTS	NIVL	aDVT
78.0% (64/82)	71.9% (41/57)	100.0% (11/11)	85.7% (12/14)

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ABRE STUDY SUBJECTS WITH STENT THROMBOSIS AT 12 MONTHS

Duplex Ultrasound - Baseline

Case Study	Initial Clinical Presentation	Days to TLR	Duplex		
			CFV	DFV	FV
1	NIVL	108	Patent	Patent	Patent
2	PTS	159	Non-occlusive	Partial Occlusive	Non-occlusive
3	PTS	196	Non-occlusive	Patent	Occluded
4	PTS	113	Non-occlusive	Patent	Patent
5	PTS	21	Occluded	Patent	Patent
6	PTS	5	Occluded	Partial Occlusive	Occluded
7	PTS	1	Occluded	Partial Occlusive	Occluded
8	PTS	355	Non-occlusive	Partial Occlusive	Occluded

NIVL, non-thrombotic iliac vein lesion; PTS, post thrombotic lesion; CVO, chronic venous obstruction; CIV, common iliac vein; EIV, external iliac vein; CFV, common femoral vein; DFV, deep femoral vein; FV, femoral vein; TLR, target lesion revascularization

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SUMMARY OF FACTORS CONTRIBUTING TO STENT OCCLUSION

Case Study	Indication for Intervention	Days to TLR	Factors Contributing to Stent Occlusion				
			TECHNICAL ERRORS			ANTICOAGULATION DECISIONS	
			INADEQUATE STENT INFLOW				
			Under-stenting: Missed Distal Disease (CFV)	Inadequate Inflow (2 vessel inflow disease: Femoral/Profunda)	Other Technical Errors	Made by Physician	Patient Noncompliance
1	NIVL	108	--	--	--	--	YES
2	PTS	159	YES	YES	--	--	--
3	PTS	196	--	YES	YES	YES	--
4	PTS	113	YES	--	--	--	YES
5	PTS	21	YES	--	--	--	--
6	PTS	5	--	YES	--	--	--
7	PTS	1	YES	YES	YES	--	--
8	PTS	355	--	YES	--	--	--

NIVL, non-thrombotic iliac vein lesion; PTS, post thrombotic lesion; CVO, chronic venous obstruction; CIV, common iliac vein; EIV, external iliac vein; CFV, common femoral vein; DFV, deep femoral vein; FV, femoral vein; TLR, target lesion revascularization

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TECHNICAL ERRORS: MISSED DISTAL DISEASE

Distal disease remaining between stent edge and profunda

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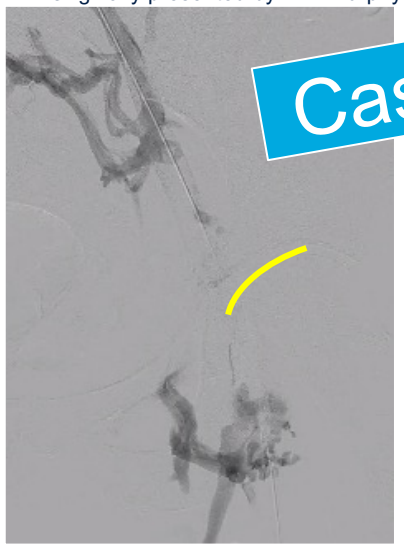
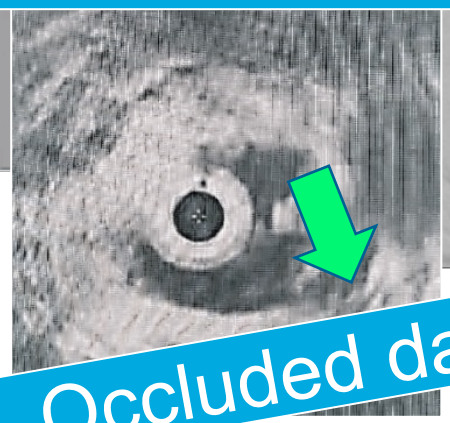
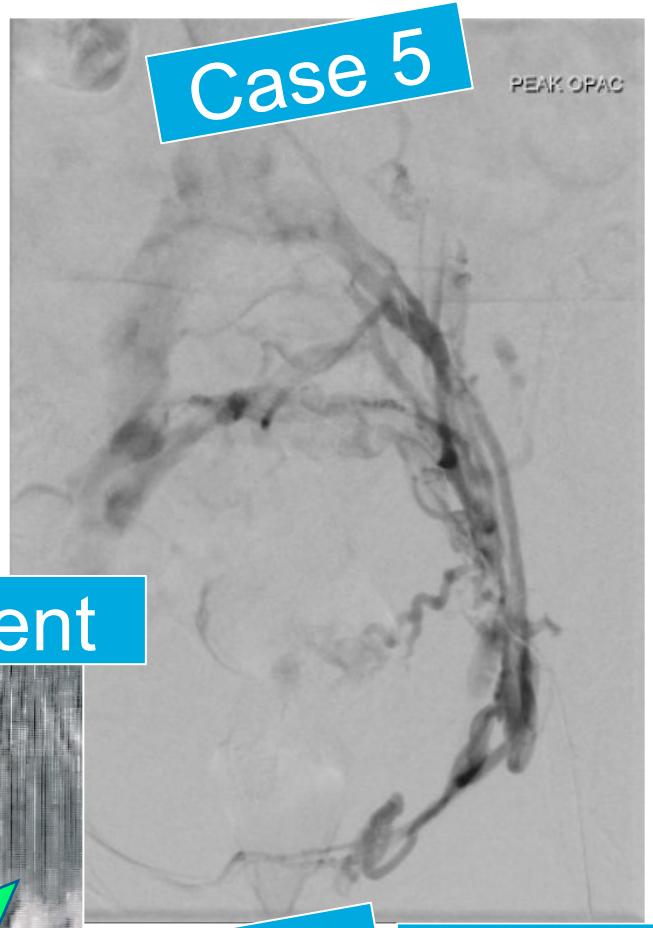


Case 2

Below Stent

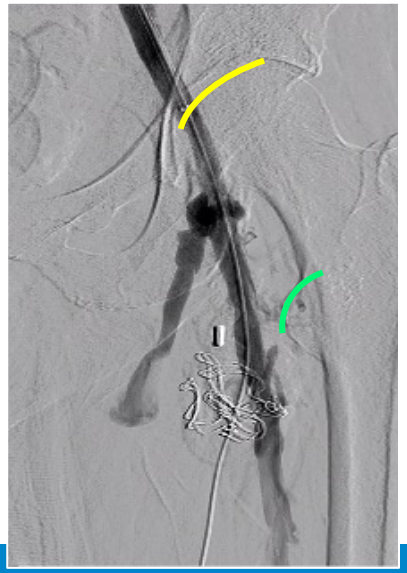


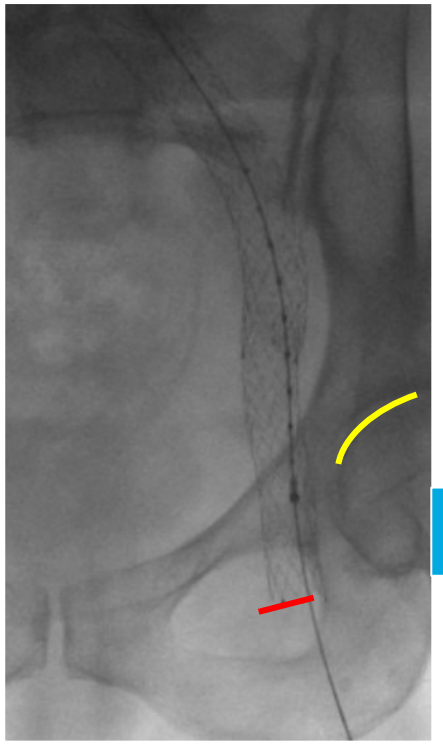
Occluded day 159

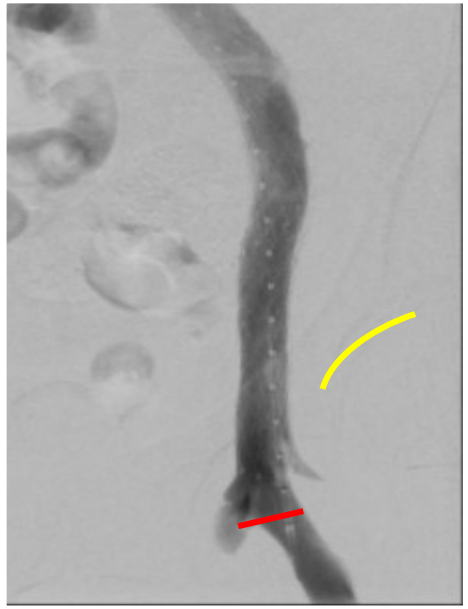


Case 5

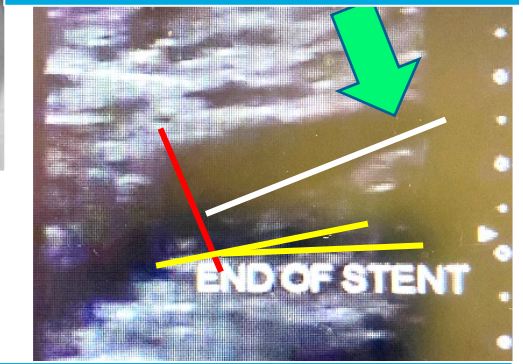
Occluded day 21







Below Stent



Post-op US

IMAGE AND TREAT TO FEMORAL/PROFUNDA CONFLUENCE

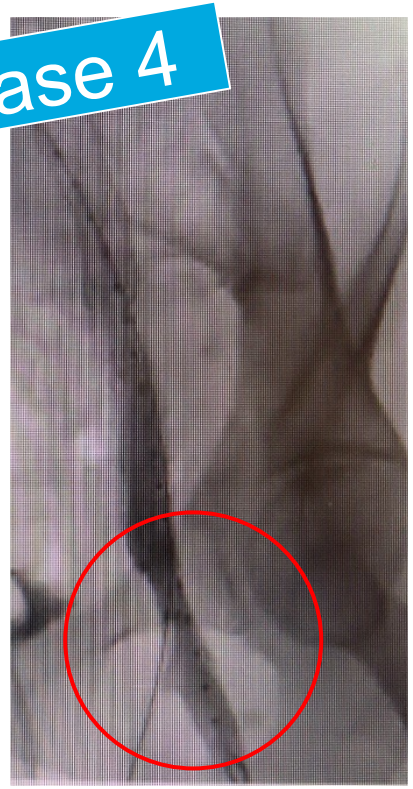
TECHNICAL ERRORS: MISSED DISTAL DISEASE

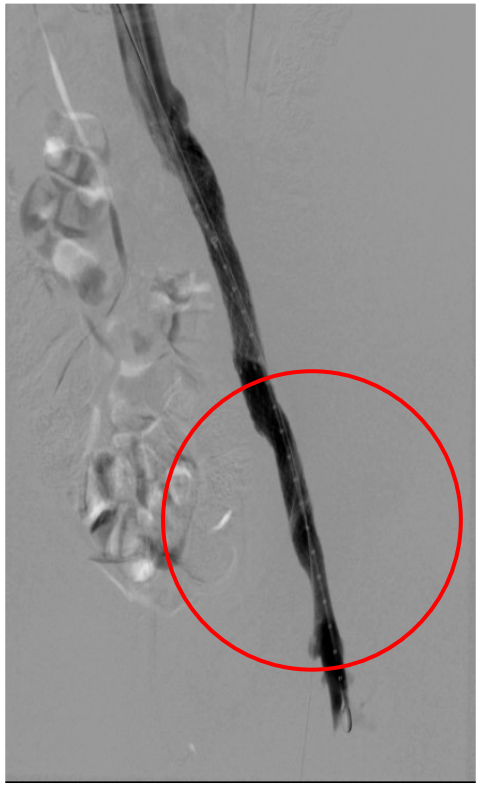
Distal disease remaining between stent edge and profunda

Originally presented by Erin Murphy MD at Charing Cross, April 21, 2021

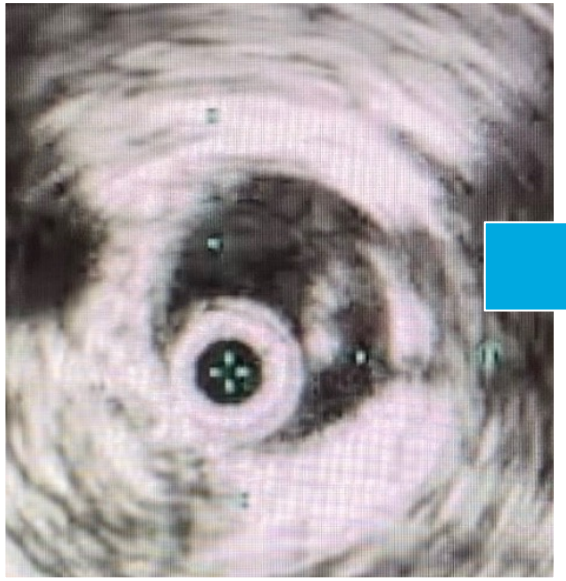
Patient was also noncompliant with AC

Case 4





Below Stent



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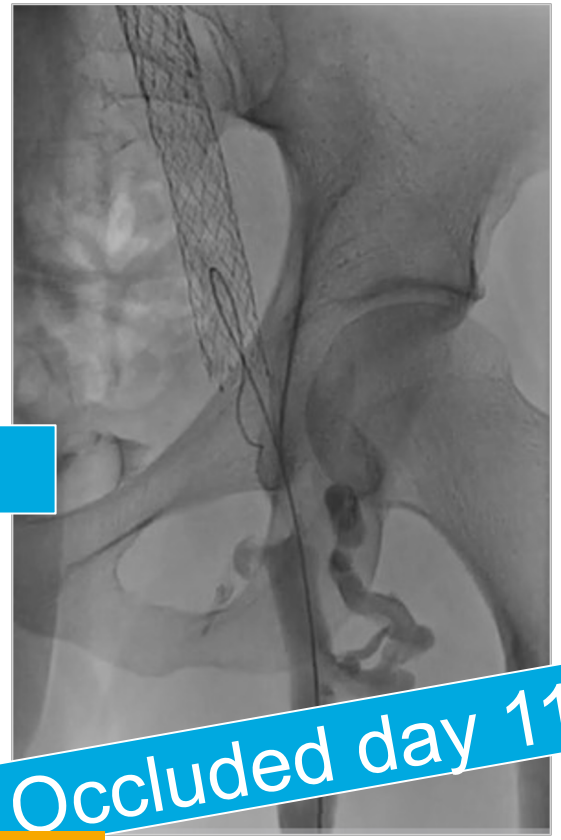

Occluded day 113

IMAGE AND TREAT TO FEMORAL/PROFUNDA CONFLUENCE

TECHNICAL ERRORS: CFV ACCESS - MISSED DISTAL DISEASE

Distal disease remaining between stent edge and profunda

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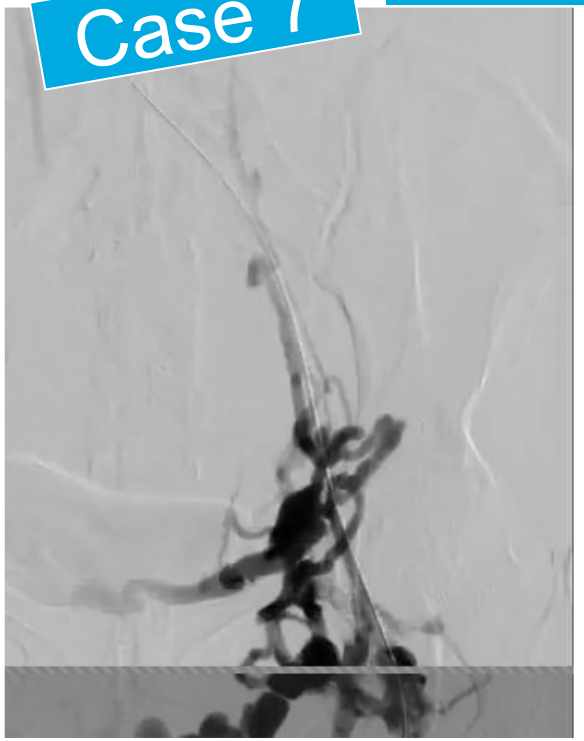
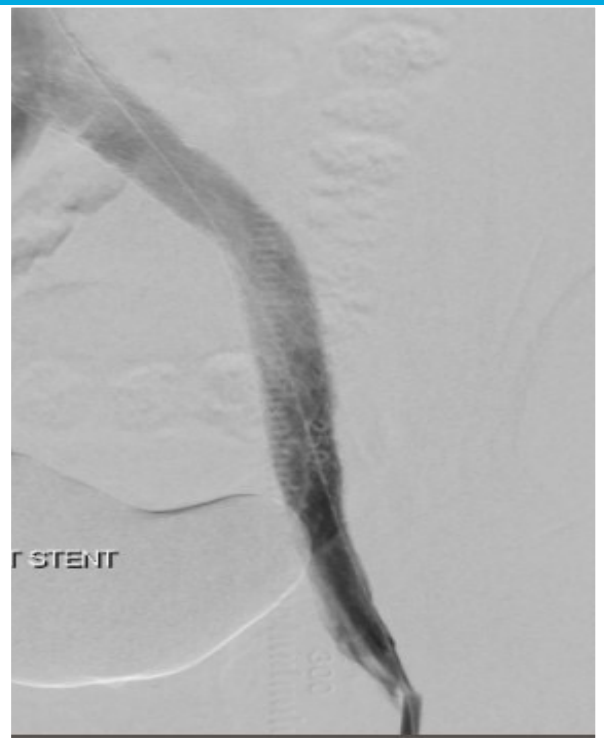
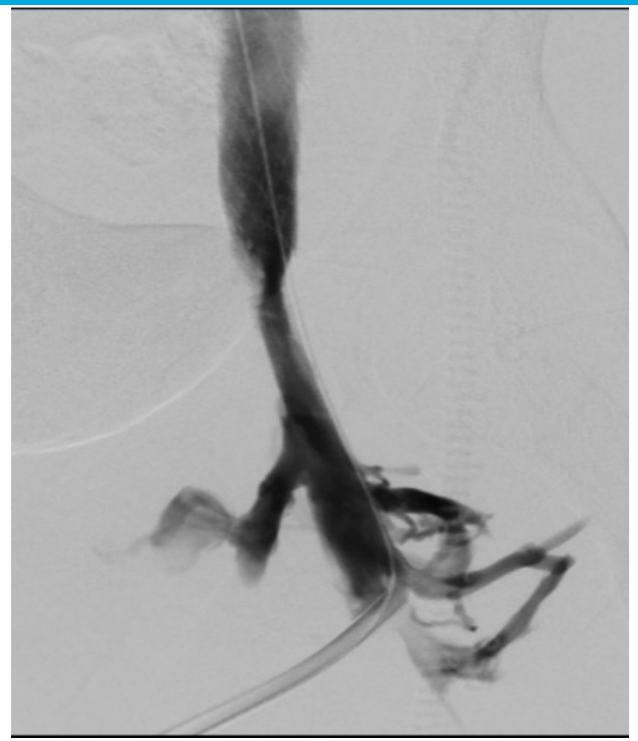
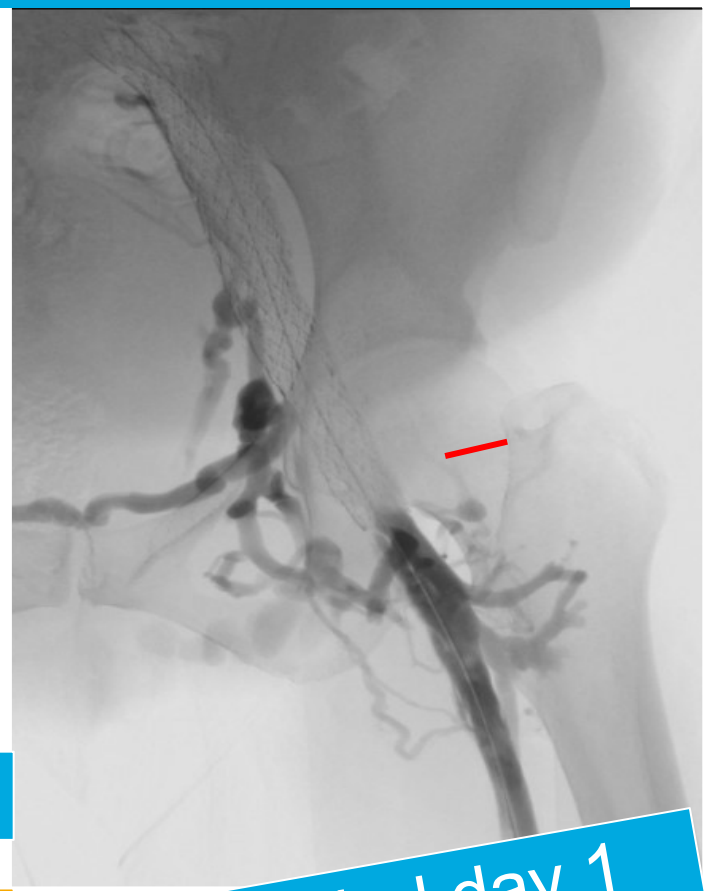
Case 7

Occluded CFV, Occluded femoral vein, Diseased profunda









Occluded day 1

No ability to image or treat CFV between GSV - Profunda

DO NOT ACCESS THE CFV IN POST-THROMBOTIC CASES

TECHNICAL ERRORS: INADEQUATE INFLOW VESSELS

Stenting into the Femoral Vein + AC Stopped at 5 months

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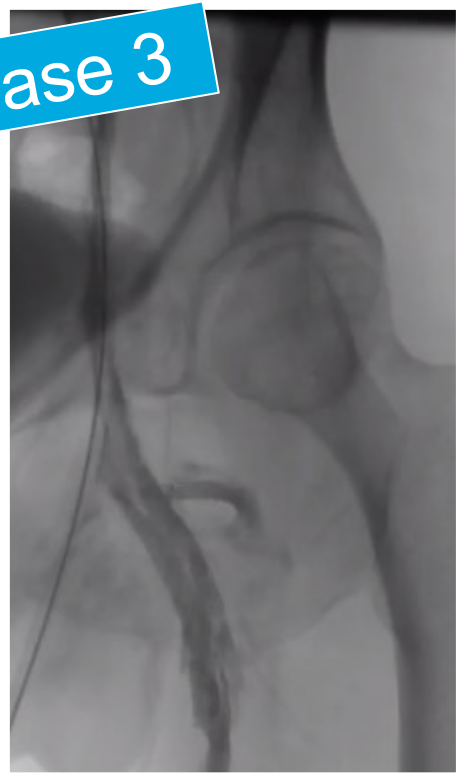
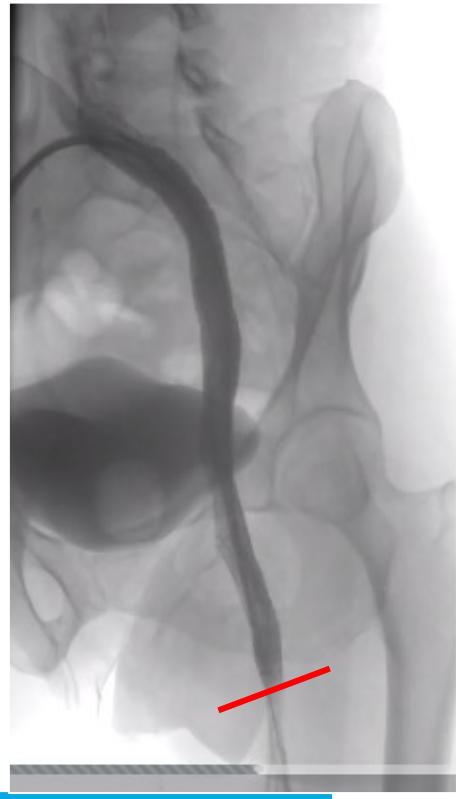
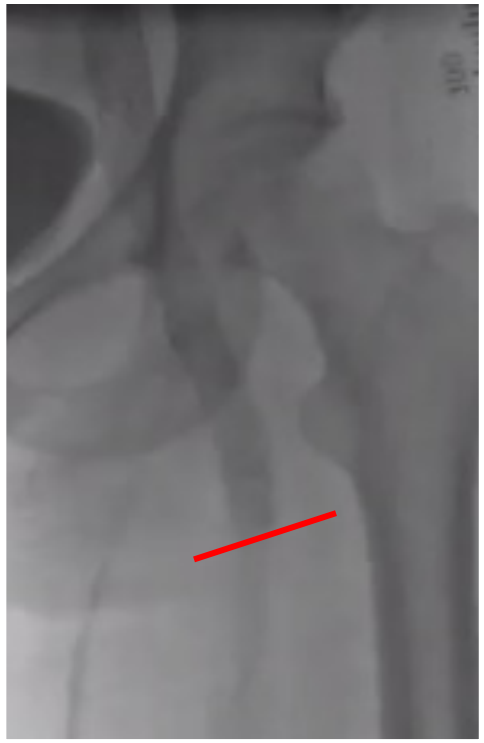
Case 3

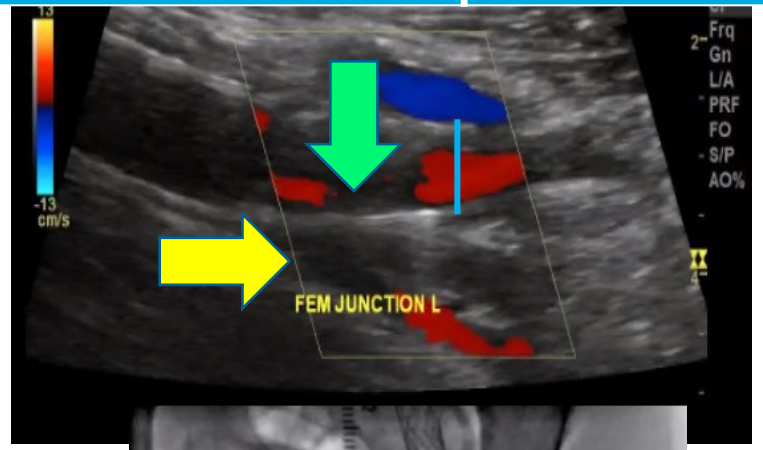


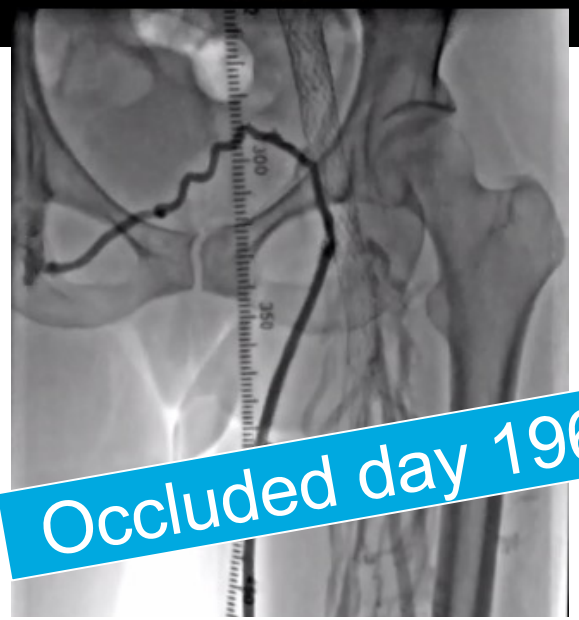




Femoral Occluded
Profunda patent per US

Stent across profunda





Occluded day 196

DO NOT STENT INTO THE FEMORAL VEIN

Medtronic

TECHNICAL ERRORS: INADEQUATE INFLOW VESSELS

Stenting above severely obstructed Profunda & Femoral – no Inflow

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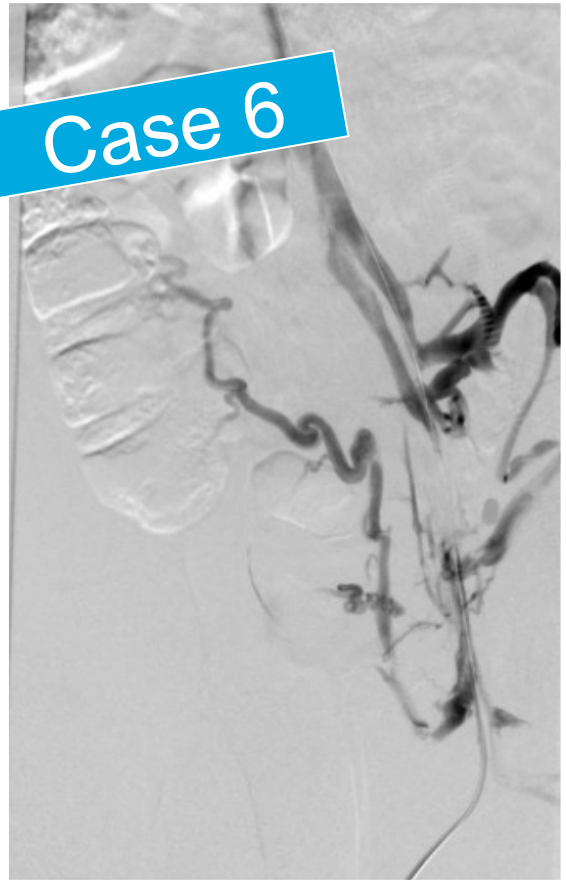
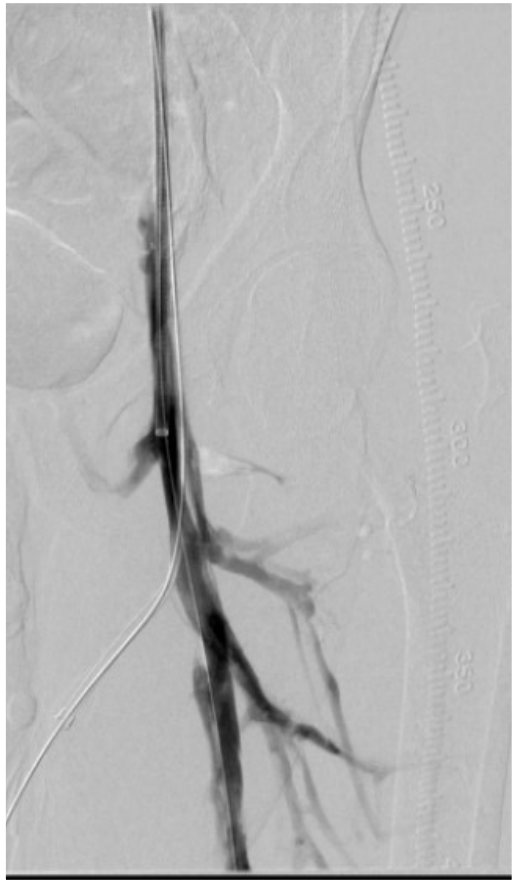
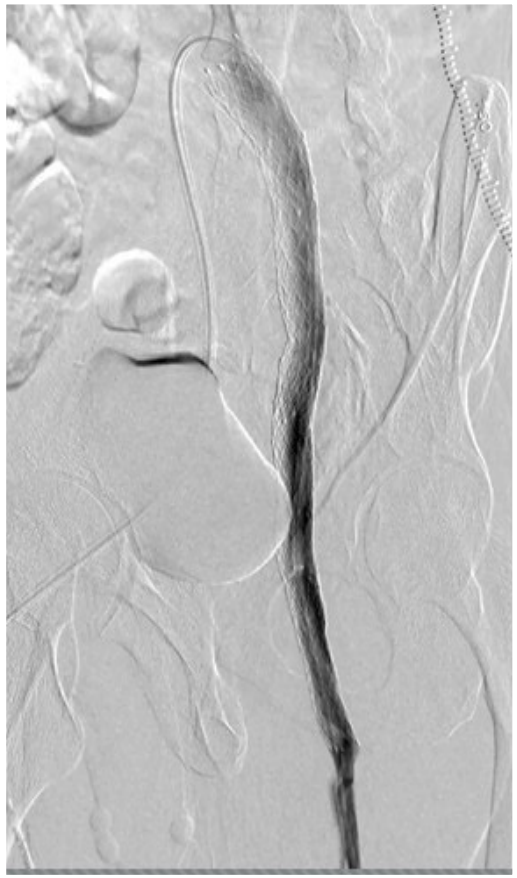
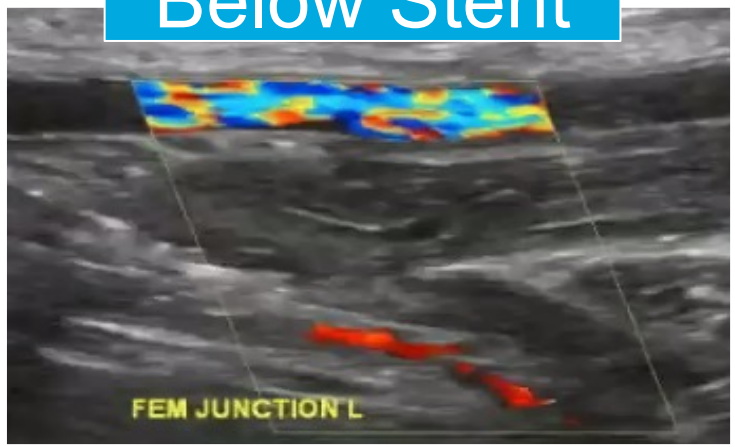
Case 6

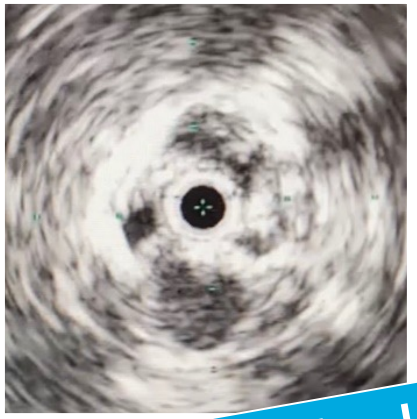


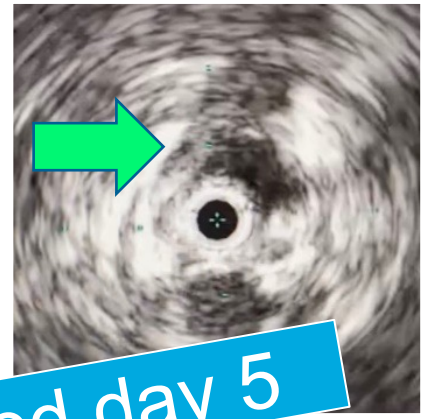




Below Stent







Occluded day 5

Femoral Occluded
Profunda Diseased per US

TECHNICAL ERRORS: INADEQUATE INFLOW VESSELS

Stenting into Occluded CFV – no Inflow

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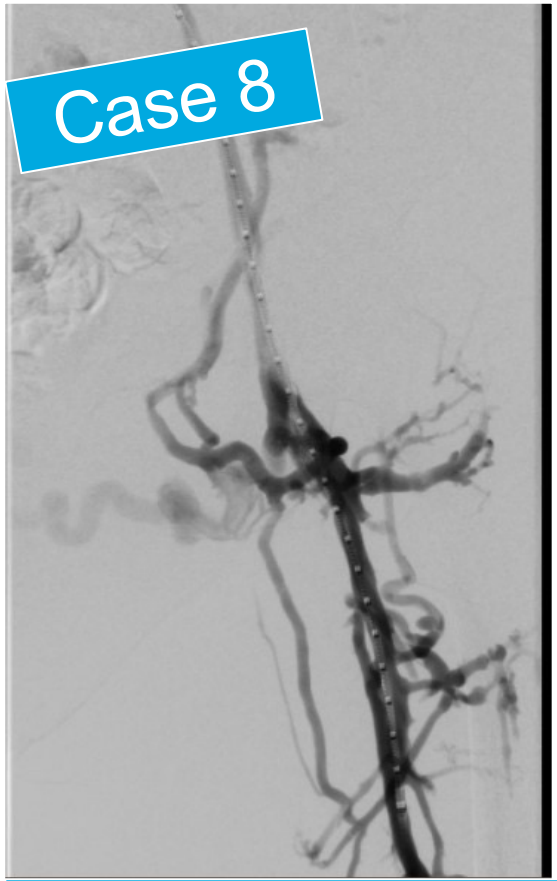
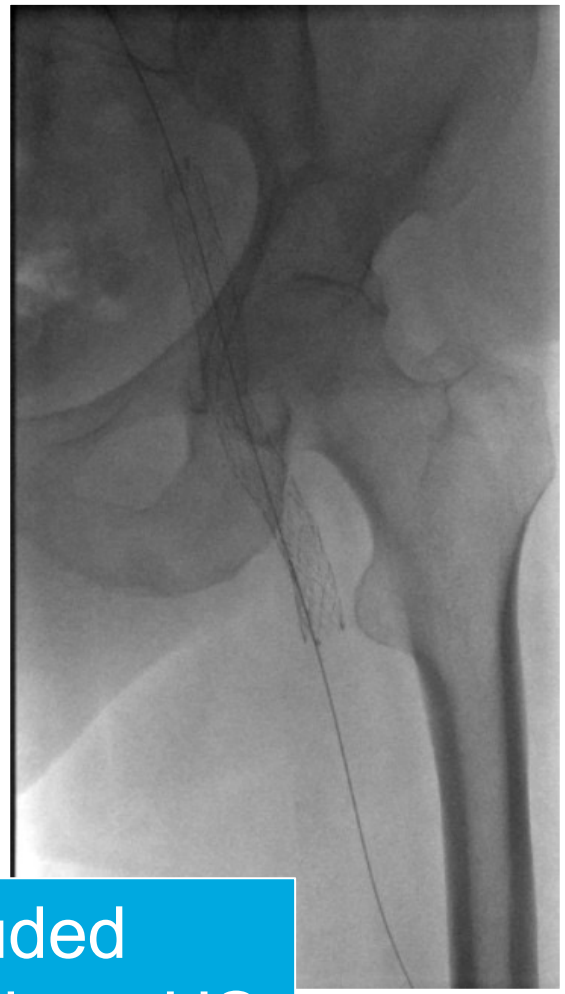
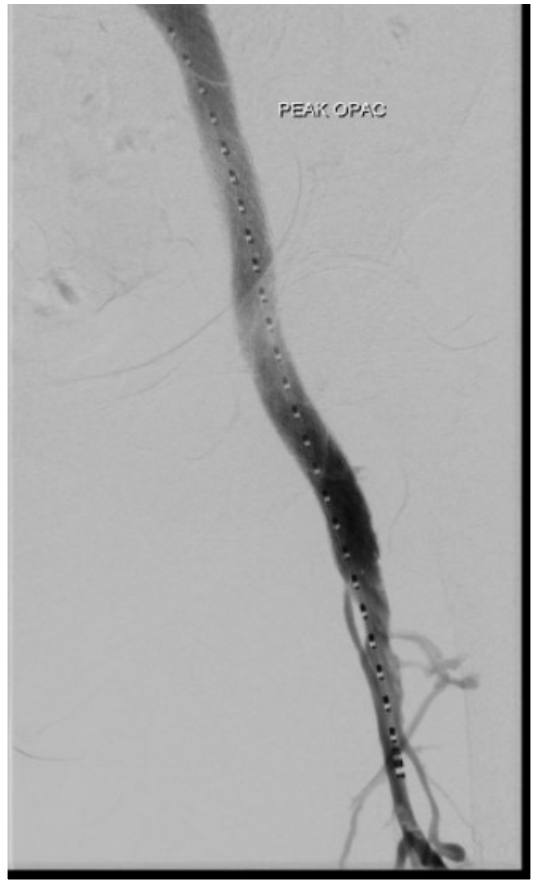
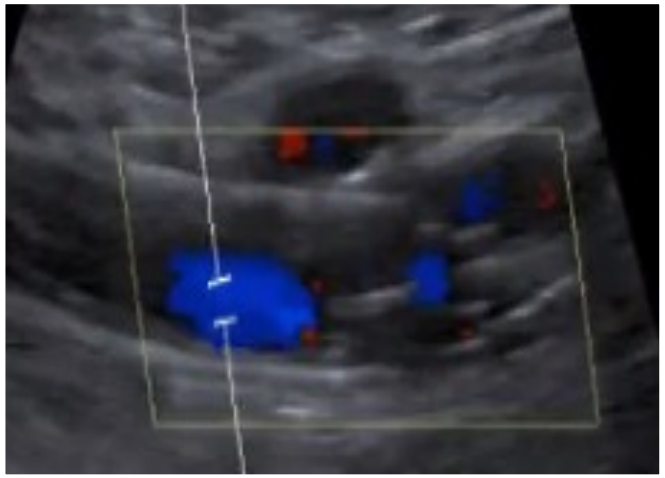


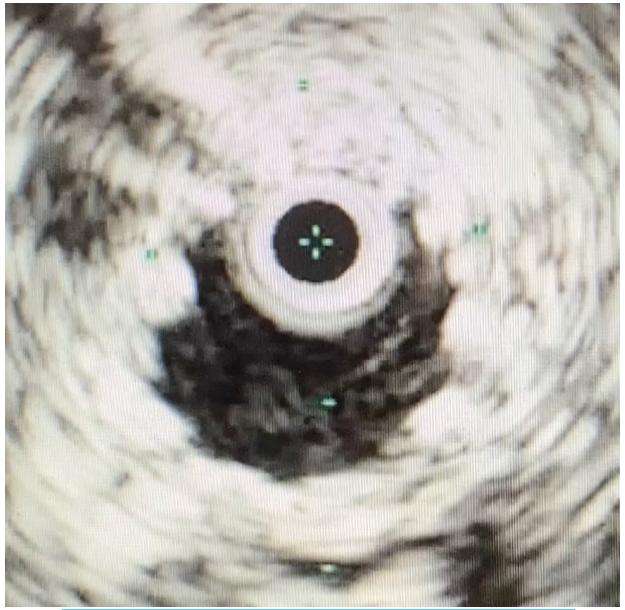


Femoral Occluded
Profunda Diseased per US



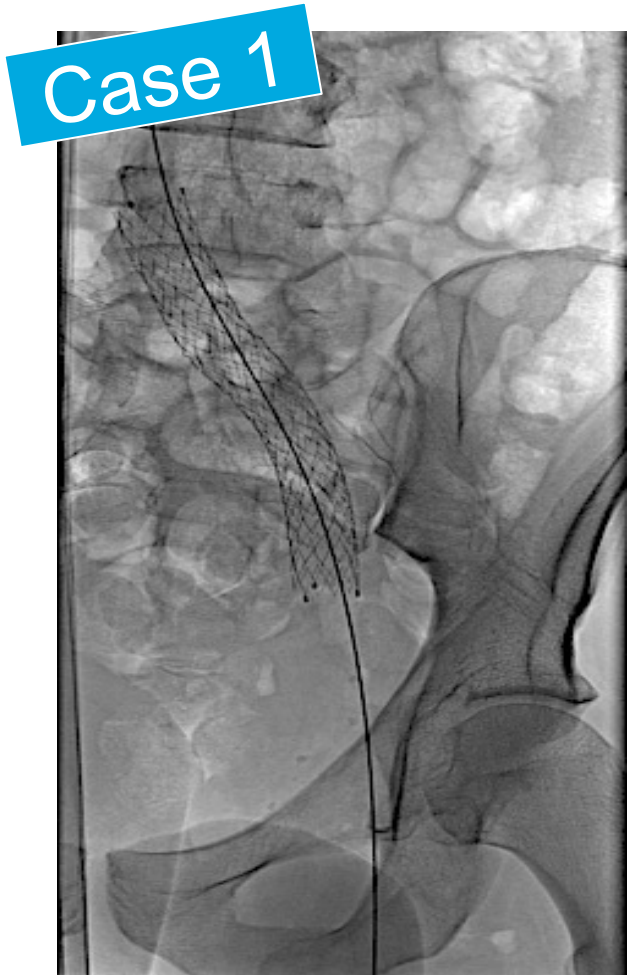
Occluded day 355





Below Stent

PATIENT COMPLIANCE - NIVL



The patient that asks himself...

Should I stop my anticoagulation, smoke pot, and fly to another country?

And then answers…

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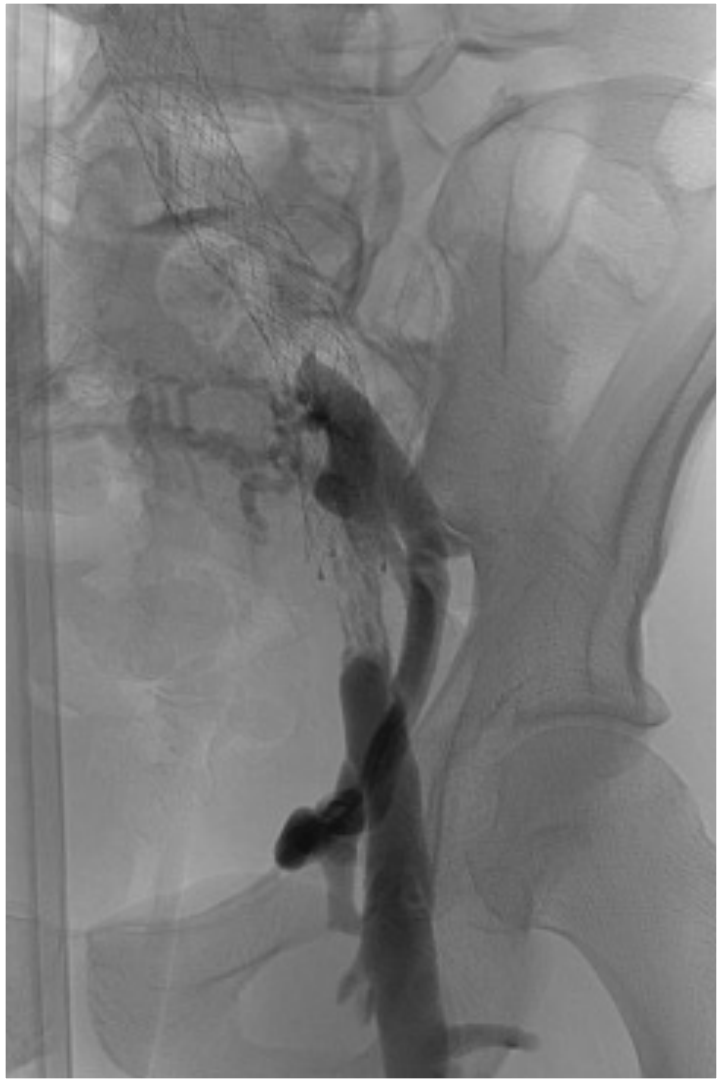
PATENT COMPLIANCE - NIVL



= The ONLY venous stent occlusion not related to poor inflow, missed disease, or technical errors

**Be aware: inhaled marijuana is highly irritating to the endothelium & very prothrombotic

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STENT OCCLUSIONS SUMMARY

- Stent occlusions in the ABRE trial were associated with:
  - Post-thrombotic disease
  - More extensive disease involving the CFV and inflow vessels
  - Disease between the stent edge and femoral/profunda confluence
  - Significant 2 vessel (profunda and femoral disease)
  - Significant technical errors (CFV access & stenting into femoral)
  - Cessation of anticoagulation in the presence of remaining inflow disease
  - Noncompliance: stopping AC, marijuana use, inactivity

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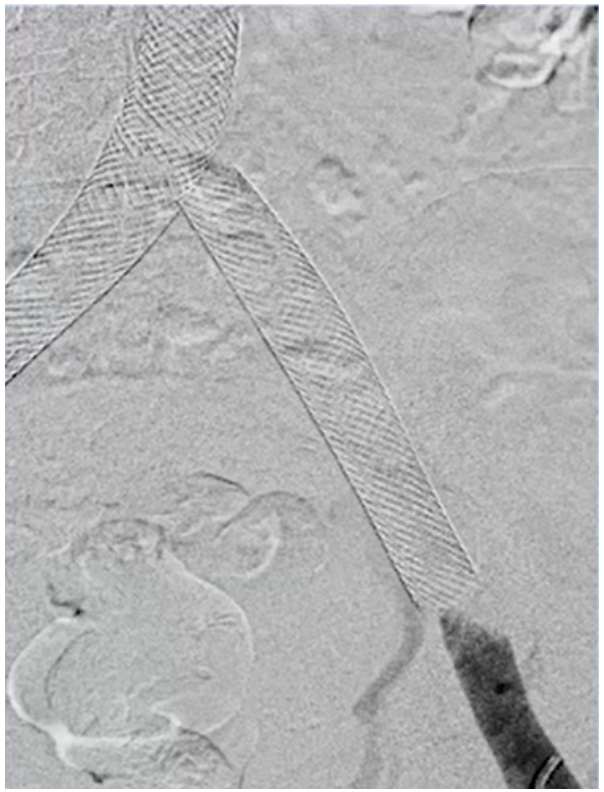
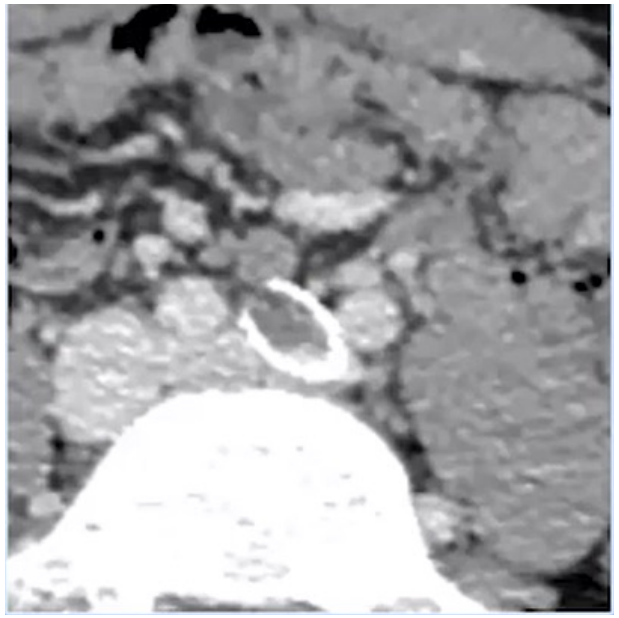
OTHER CAUSES OF STENT OCCLUSIONS

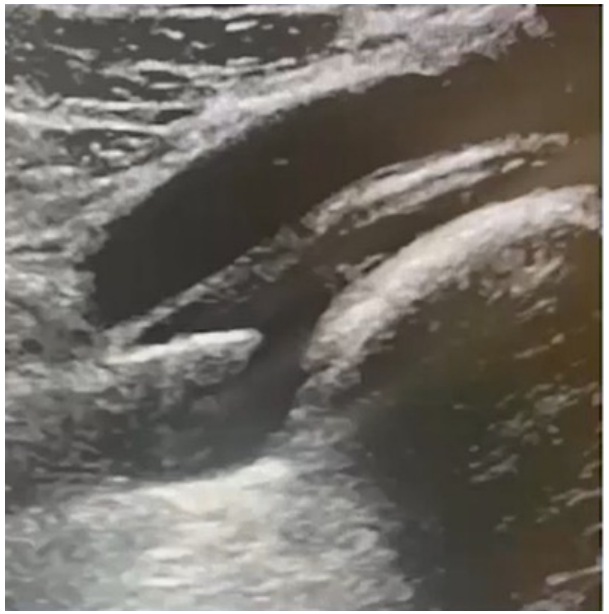
Jailing contralateral iliac

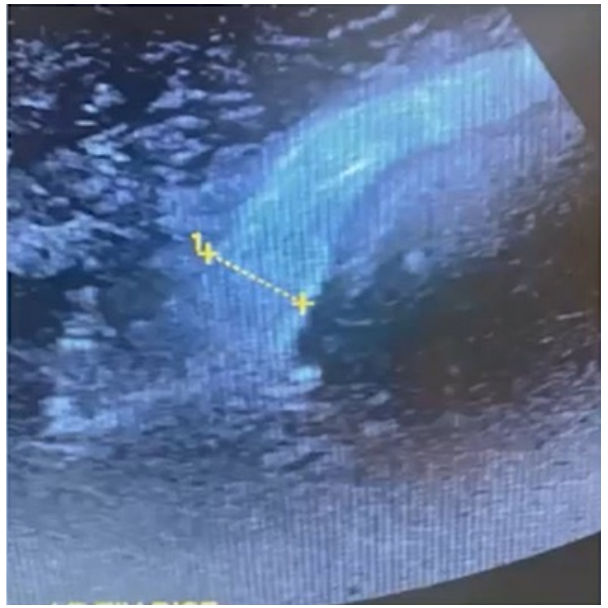


OTHER CAUSES OF STENT OCCLUSIONS

Landing in a curve:
Stent Erosion vs Jailing Distal Vein







STENT OCCLUSIONS SUMMARY

- Steps to prevent stent occlusion
  - Determine the patient has adequate inflow preoperatively with Duplex US
  - Plan access to visualize entire CFV with IVUS
  - Use IVUS for all decision making (prior to venoplasty)
  - Leave no disease between stent edge and profunda/femoral
  - Never stent into the femoral vein/do not jail confluences
  - Do not land stents on a turn of the vein
  - Proceed with high caution if femoral and profunda are diseased
  - Inflow quality should be a consideration when making AC decisions

ABRE™ VENOUS SELF-EXPANDING STENT SYSTEM
Brief Statement

- Intended Use/Indications: The Abre™ venous self-expanding stent system (Abre™ stent system) is indicated for use in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction.
- Contraindications: Do not use the Abre™ stent system with patients with known hypersensitivity to nickel titanium (nitinol), with patients who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system, and with patients in whom anticoagulant or antiplatelet therapy is contraindicated.
- Potential Adverse Effects of the Device on Health: The potential adverse effects (e.g., complications) associated with the use of the Abre™ stent system include, but are not limited to, access failure, access site infection, allergic reaction to contrast medium or procedure medications; aneurysm; AV fistula; bleeding; bruising; death; device breakage; device maldeployment; edema; embolization; fever; hematoma; hypertension; hypotension, nausea, or other vasovagal response; infection; myocardial infarction, arrhythmia, or other cardiovascular insufficiency; open surgical repair; pain; pseudoaneurysm; renal insufficiency or renal failure (new or worsening); respiratory distress or pulmonary embolism; sepsis; stent fracture; stent malapposition; stent malposition; stent migration; stroke, paradoxical embolism, transient ischemic attack, or intracerebral hemorrhage; tissue necrosis; venous occlusion, restenosis, or thrombosis, within or outside of stented segment; and vessel damage, including intimal injury, dissection, perforation, or rupture.

- Warnings, precautions, and instructions for use can be found in the product labeling at http://manuals.medtronic.com.

- CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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