

Directional Atherectomy For Complex Femoropopliteal Artery Disease Where Are We, And How To Do

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Disclosure

Ravish Sachar, MD

I have the following potential conflicts of interest to report:

- Consulting – Medtronic, Boston Scientific
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company – Contego Medical
- Other(s)
- I do not have any potential conflict of interest

What is Complex Fem-pop Disease?

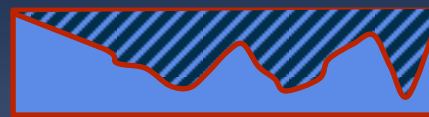
- Severe calcium
- Chronic total occlusions (CTOs)
- Complex lesions (TASC C and D)
- Long lesions
- In-stent restenosis
- Thrombus



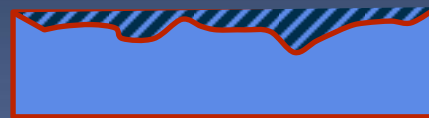
- Reduced chance of procedural success
- Increased chance of bailout stenting
- Increased rate of complications
- Negatively impact stent expansion
- Likely reduce the effectiveness of anti-proliferative drugs
- Adversely affect long term outcomes

Unique Benefits of Directional Atherectomy for Complex Disease

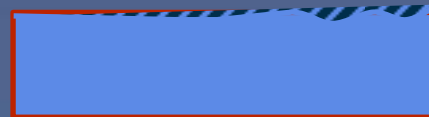
- Remove Plaque and Calcium
 - Improves vessel compliance
 - Lower risk of re-occlusion due to recoil
 - Lower risk of dissection/bailout stenting
- Directionality allows treatment of lesions and sparing of healthy tissue
- Maximize lumen gain
 - Flow increases exponentially as radius of the vessel increases



➔ Pre-Treatment



➔ Post Atherectomy

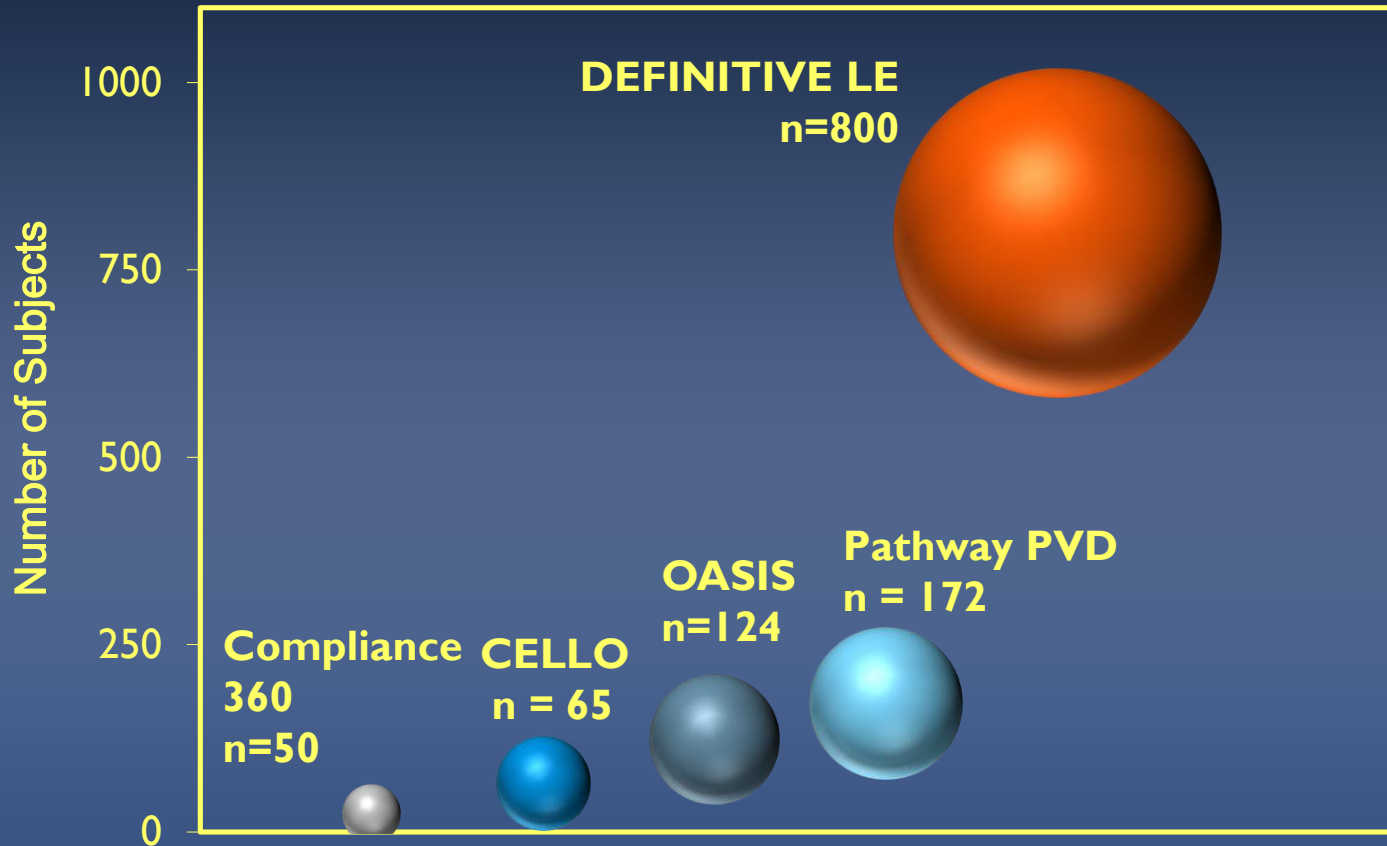


➔ Post PTA

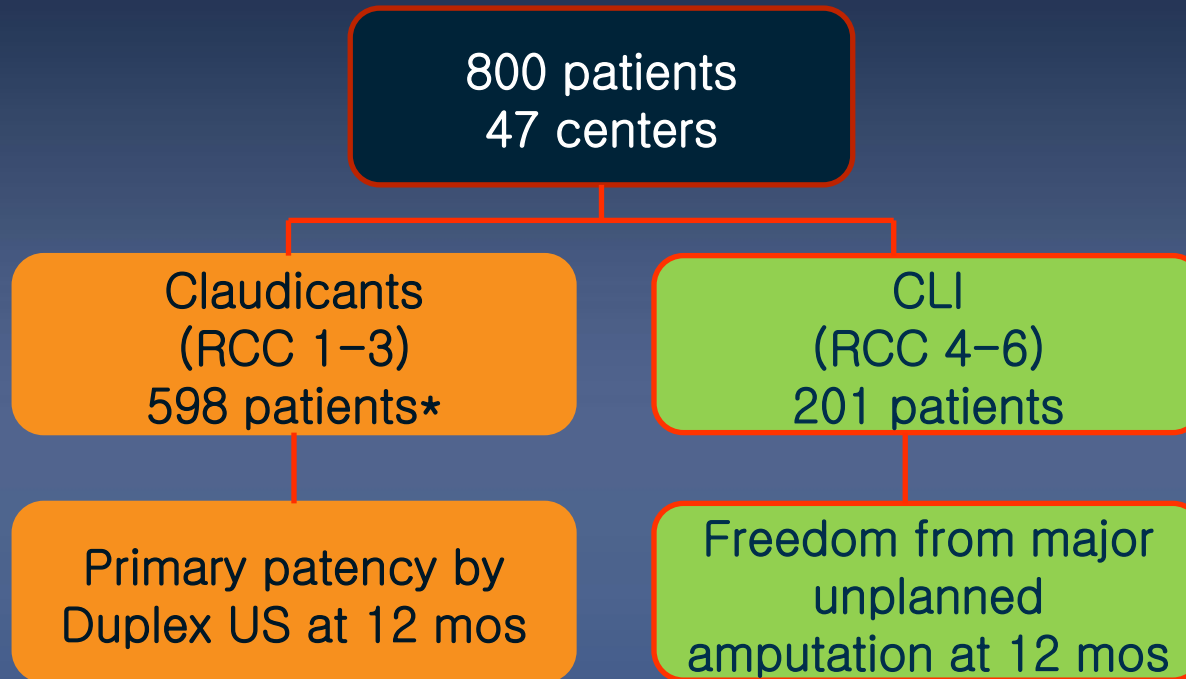
$$Q = \frac{\pi Pr^4}{8\eta l}$$

Poiseuille's Law

DEFINITIVE LE



Directional Atherectomy: Definitive LE Study



*1 censored due to informed consent violation

Primary Patency Claudicant Cohort

743

Lesions

7.5 cm

Mean lesion length

72.7%

Mean baseline stenosis

PSVR \leq 2.4



78%

Primary Patency: Stenosis vs. Occlusion

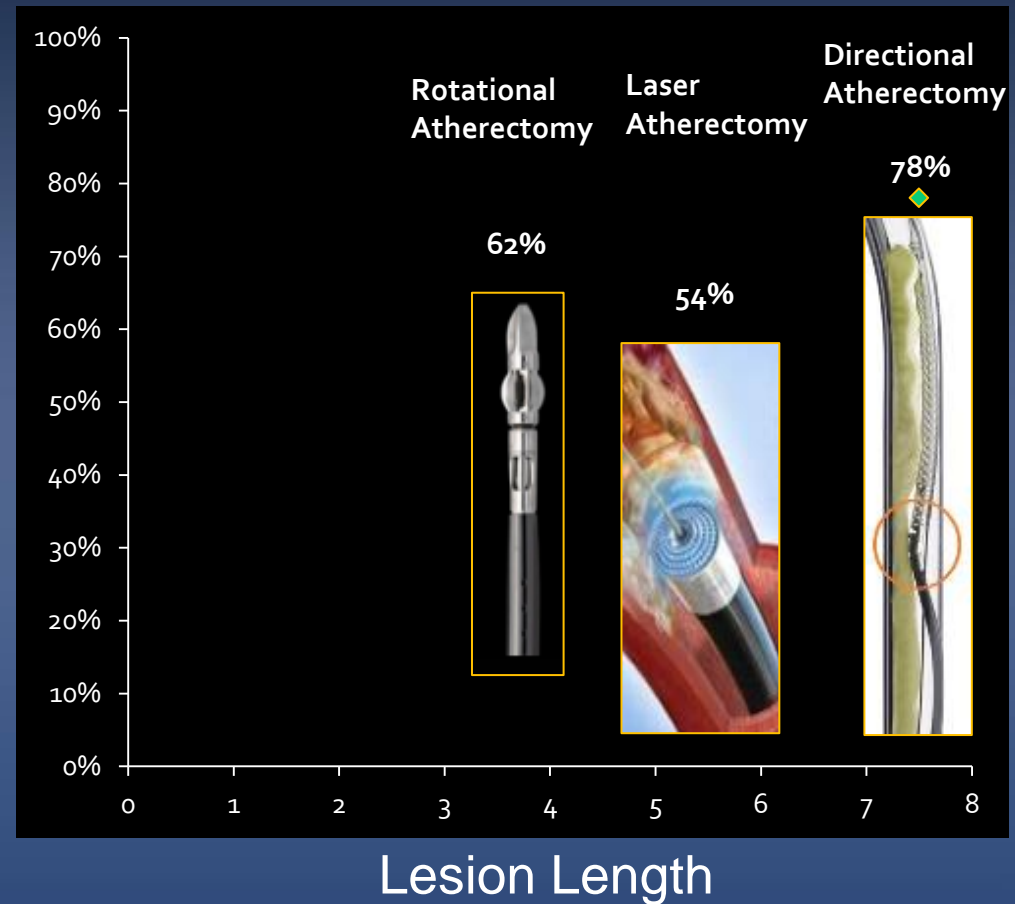
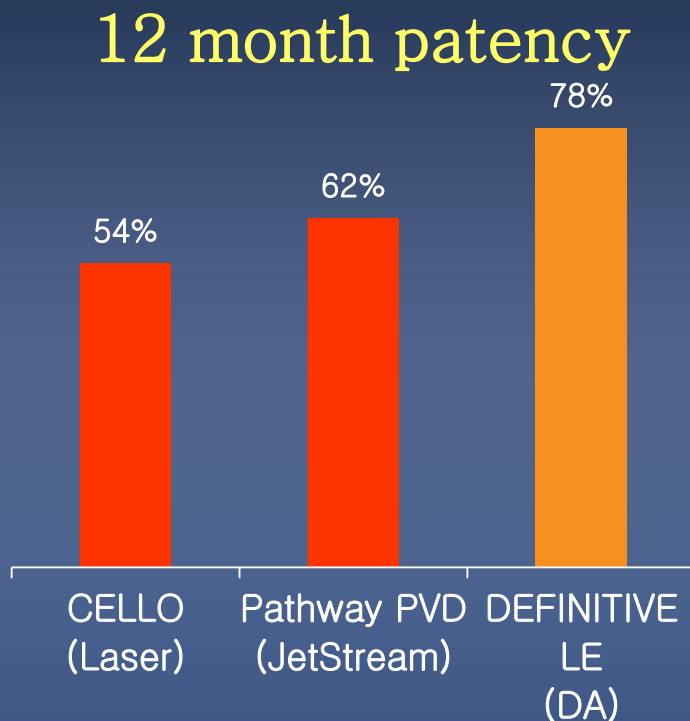
	Patency (PSVR \leq 2.4)	Lesion Length (cm)
All Claudicants (n= 743)	78%	7.5
Lesion type		
Stenoses (n=611 lesions)	81%	6.7
Occlusions (n=128 lesions)	64%	11.1

Primary Patency by TASC Classification

Claudicant Cohort (PSVR \leq 2.4)

	Patency (PSVR \leq 2.4)	Lesion Length (cm)
All (n=743)	78%	7.5
TASC Classification		
TASC A (n=440)	81%	4.6
TASC B (n=212)	71%	9.9
TASC C (n=85)	72%	16.5

12 Month Patency for Atherectomy Only in the Fem-Pop Segment

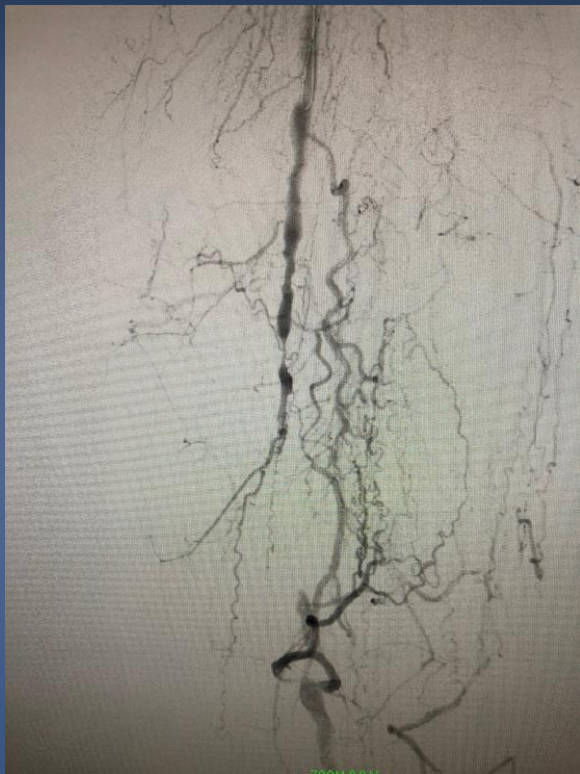


1. Dave J. *Endovasc. Ther.* 2009;13:665-675
 2. Zeller et al. *J Endovasc. Ther.* 2009;16:653-662
- ***Patency data for CSI is not available***

Case #1 Patient History

- 78 y/o male
- RCC 3 symptoms
- Hx of tobacco use, s/p cessation 3 years ago
- CAD, s/p CABG
- HTN
- Dyslipidemia

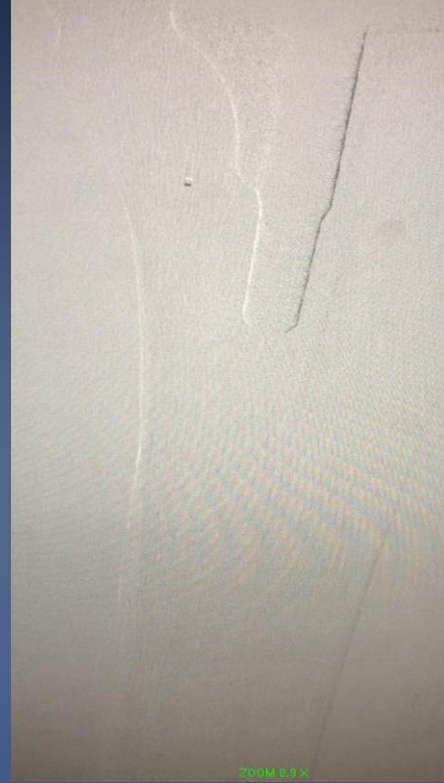
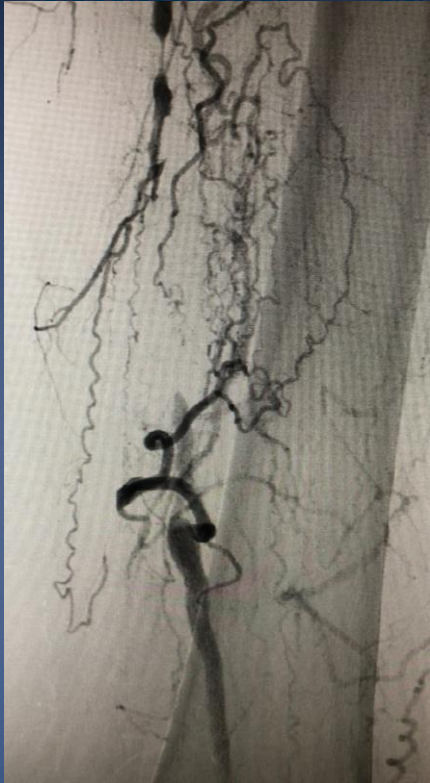
Left SFA Heavily Calcified CTO With Infrapop Disease



Procedural Angiograms

Miracle™ Wire

True Lumen

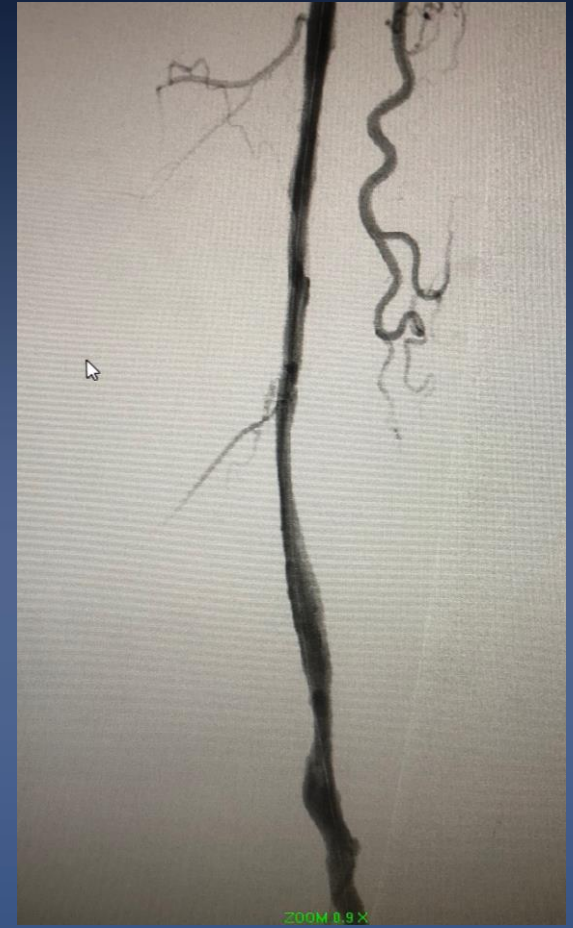


6 mm SpiderFX™ embolic protection device delivered via 4F Navicross™* catheter

6 mm SpiderFX™ embolic protection device

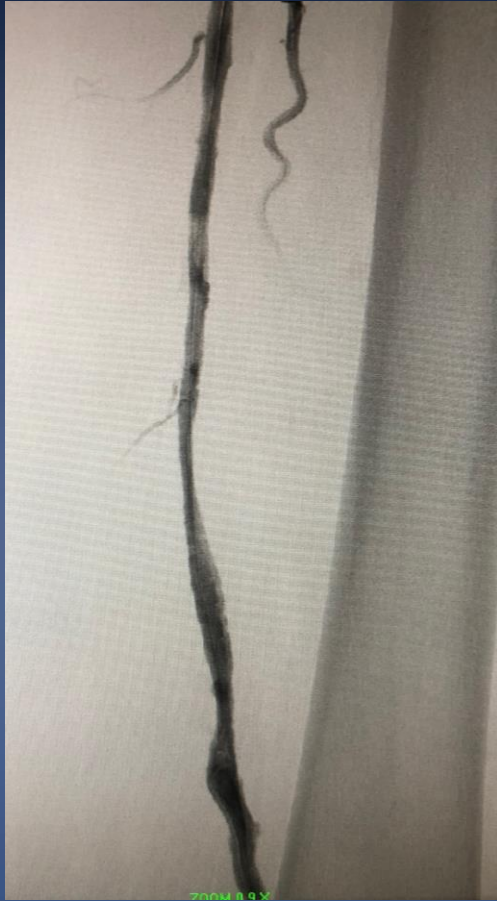


Directional Atherectomy: HawkOne™ LX directional atherectomy system



10868452DOC

Good enough result after DA, or are more passes needed?



Sectra
10004200

Angiogram after Additional Atherectomy + DCB



CASE #2: LEFT LLE CLI

- 55 year old man
- DM, HTN, hyperlipidemia, CAD, PAD s/p right SFA stenting 10 years ago
- Left anterior shin wound after trauma – nonhealing x 6 months despite wound care
- ABI on left 0.6 with monophasic waveforms at the ankle



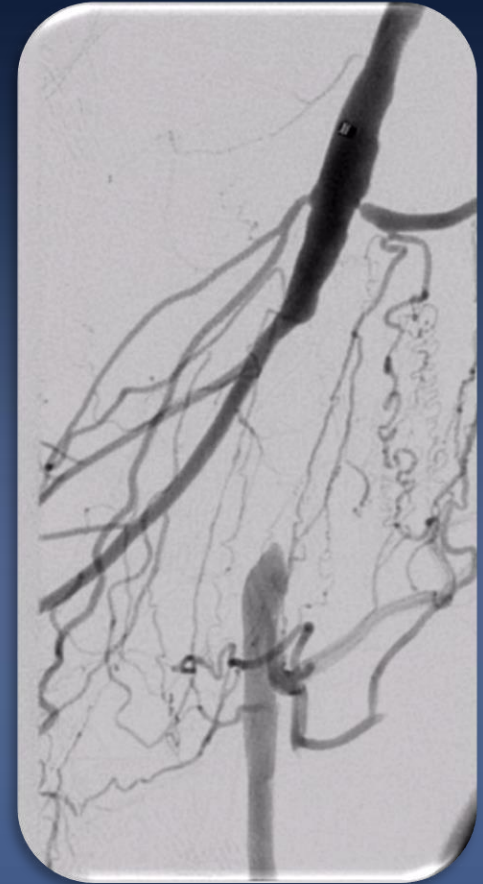
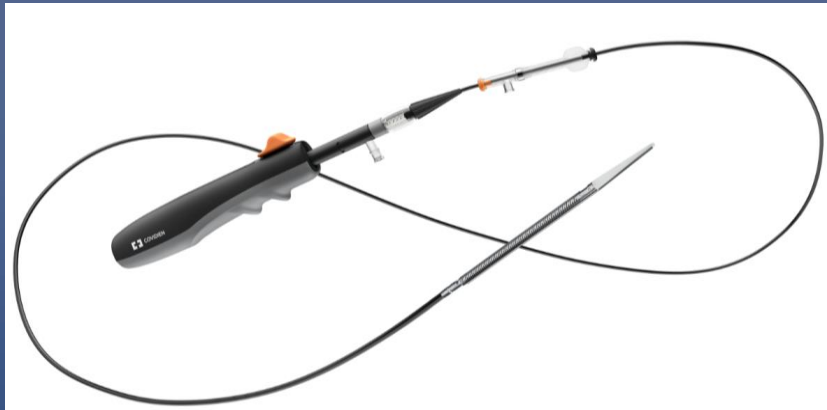
Initial angiography – short SFA occlusion – 3 vessel runoff



Left superficial femoral artery

Plan for Intervention:

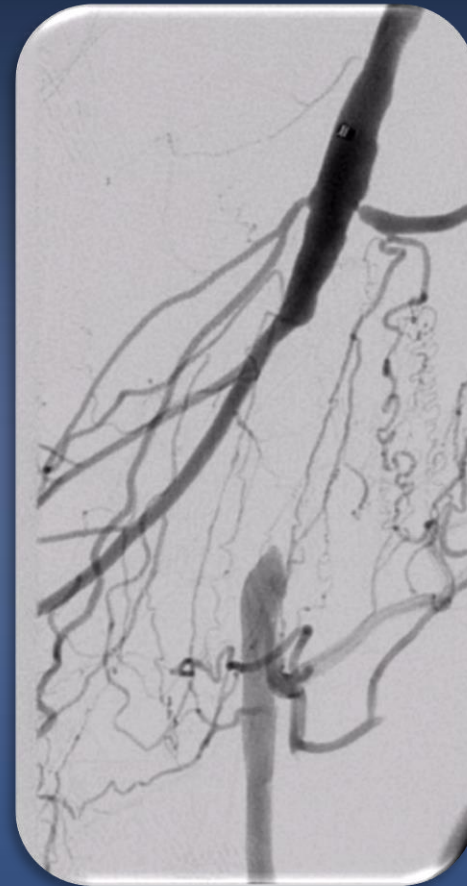
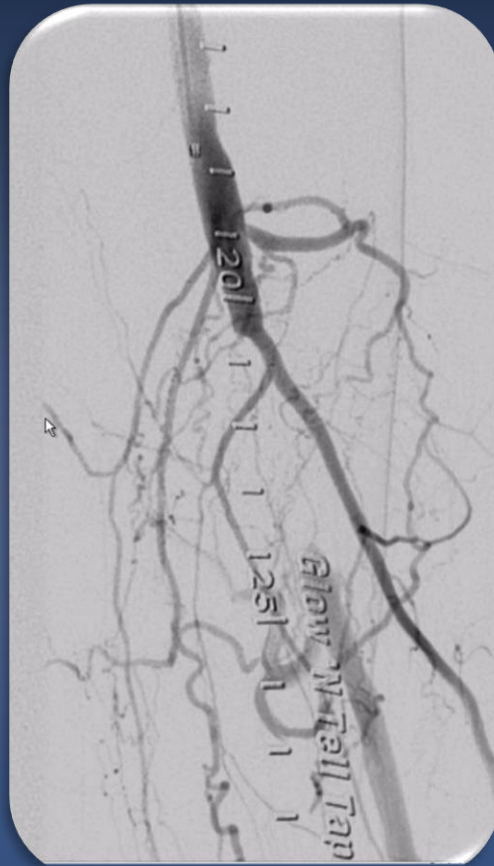
- 7F 45cm crossover sheath
- Cross occlusion with wire/catheter techniques
- 7mm SpiderFX™ Filter deployed in distal popliteal vessel above the trifurcation
- HawkOne™ LX device



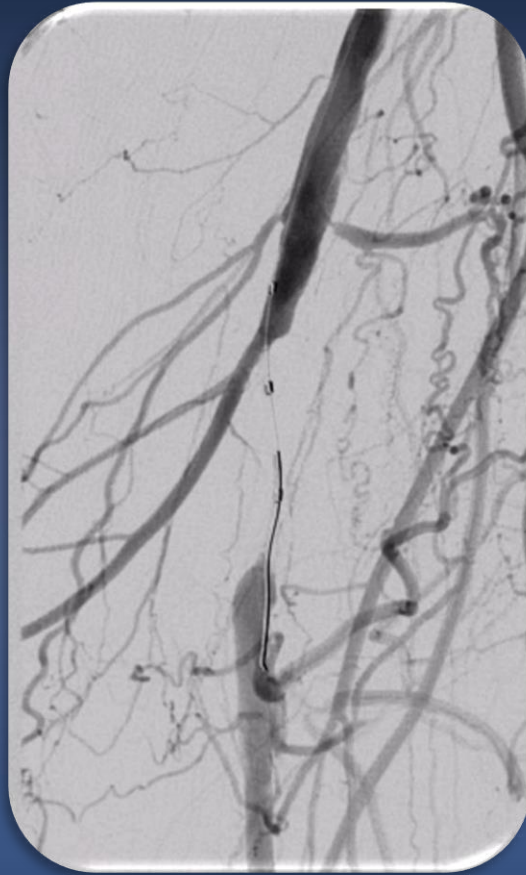
LEFT SFA OCCLUSION

Lao 45

Rao 30



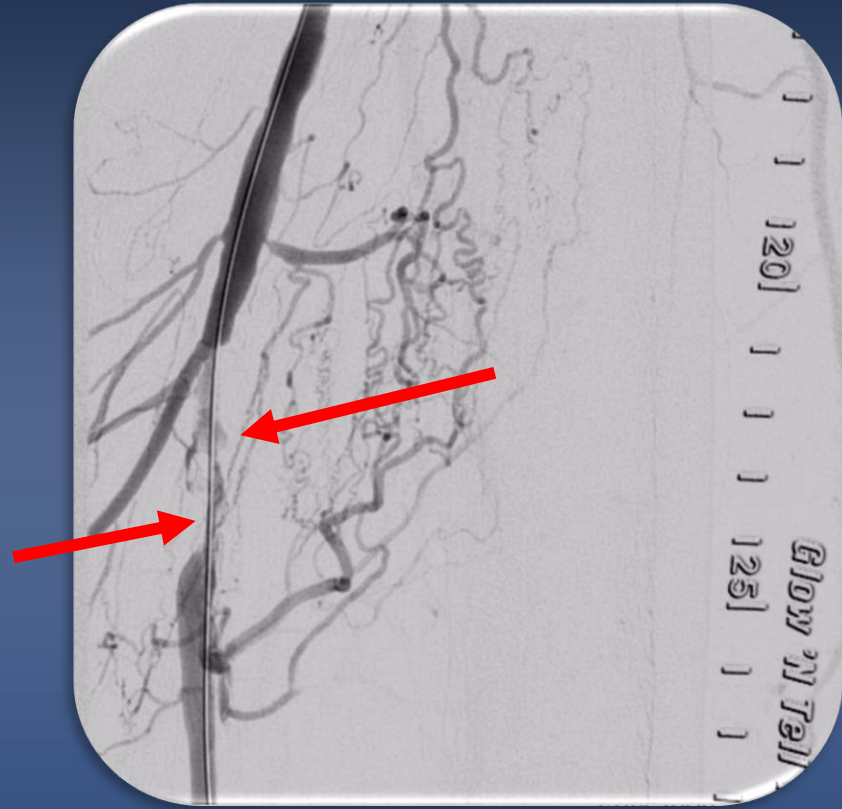
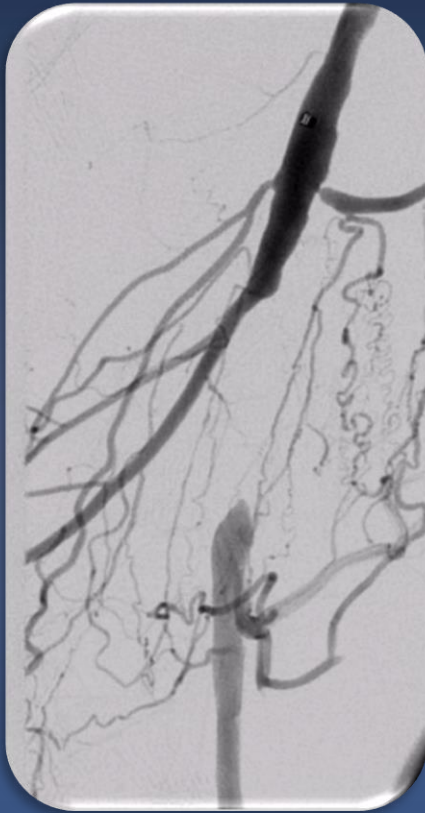
Intraluminal crossing with wire/catheter



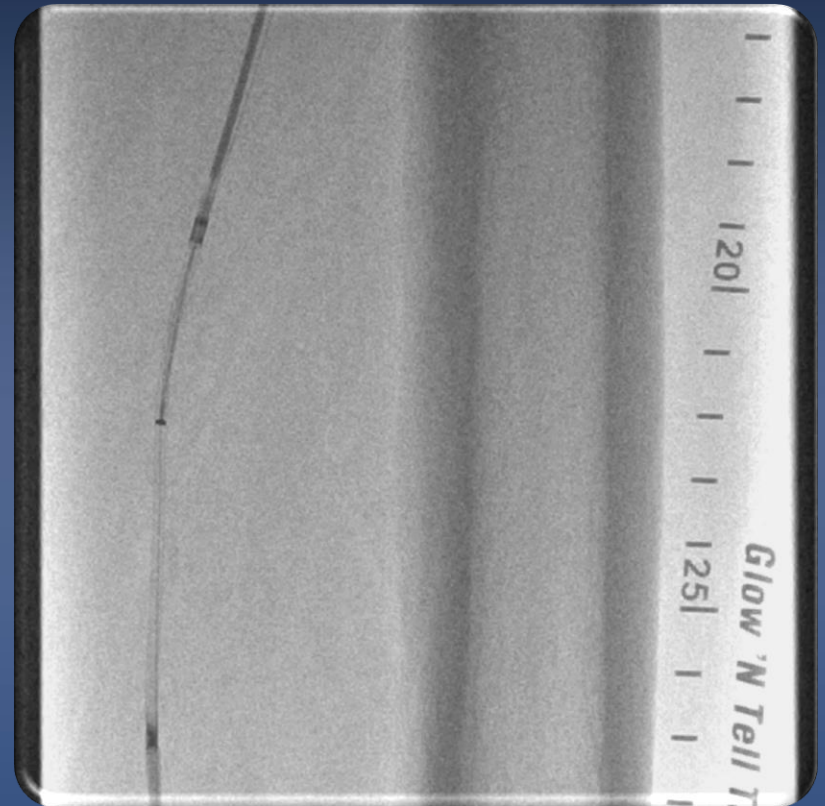
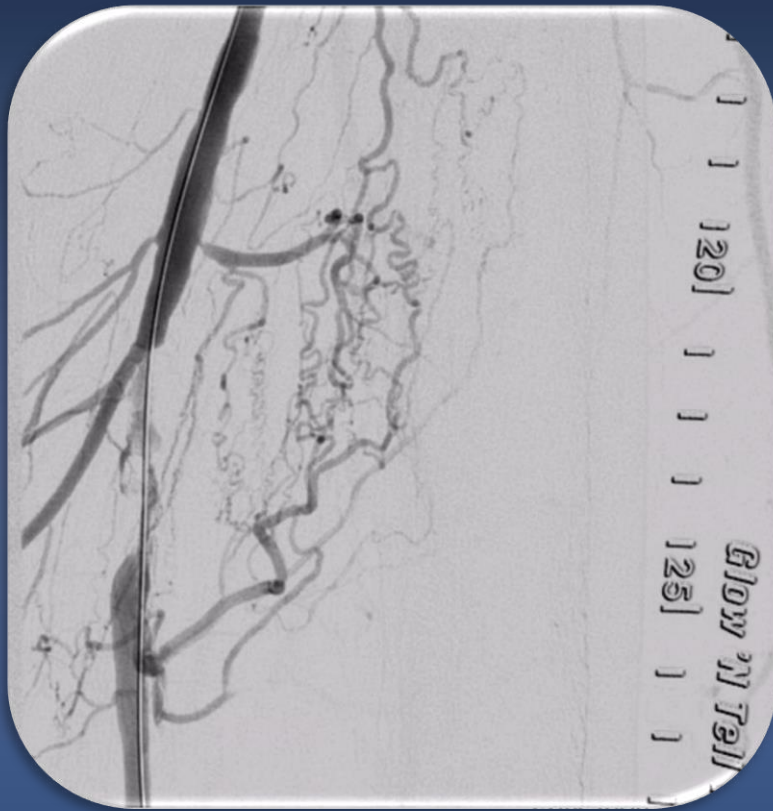
7MM SpiderFX™ FILTER DELIVERED THROUGH A TRAILBLAZER™ CATHETER



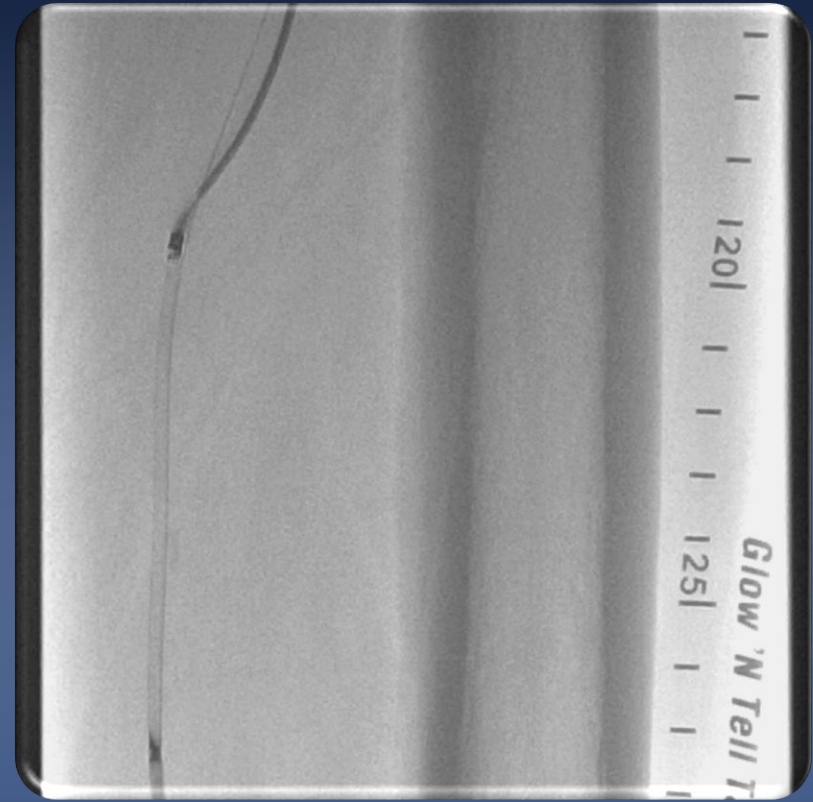
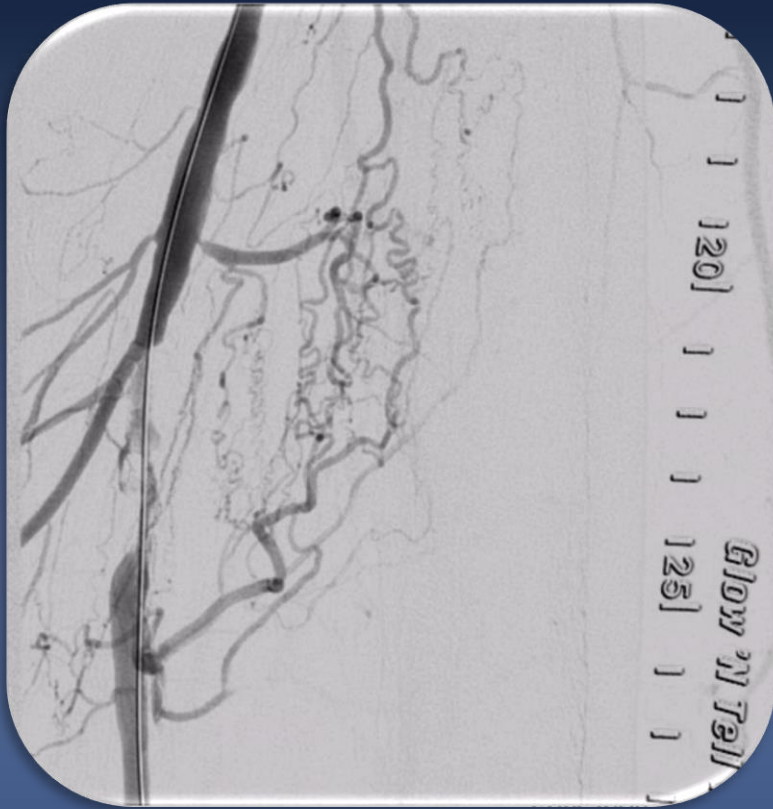
ANGIO Before And After Dotter WITH DEVICE – Rao 20 DEGREES



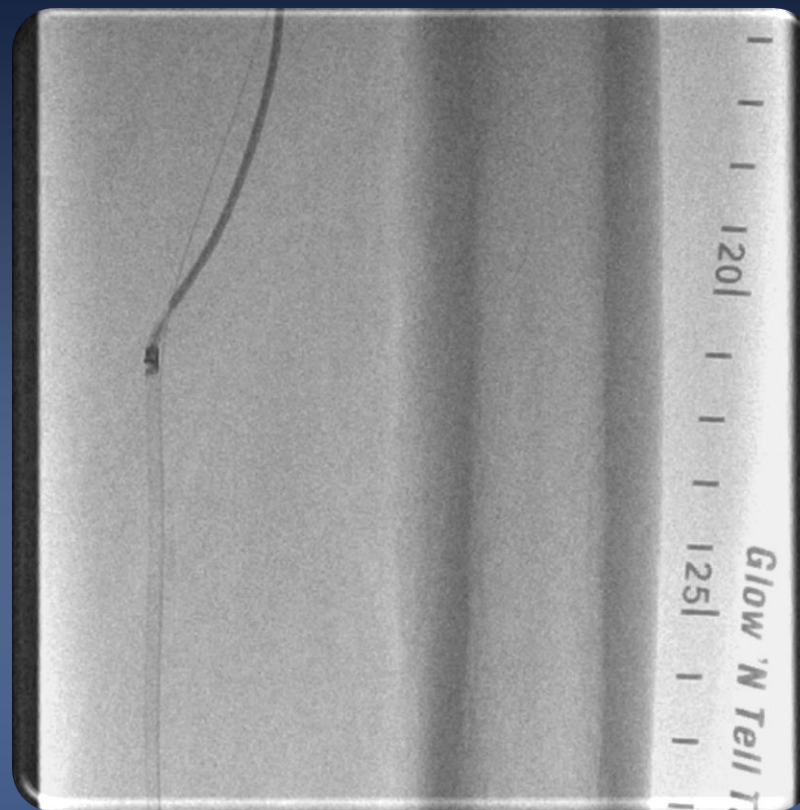
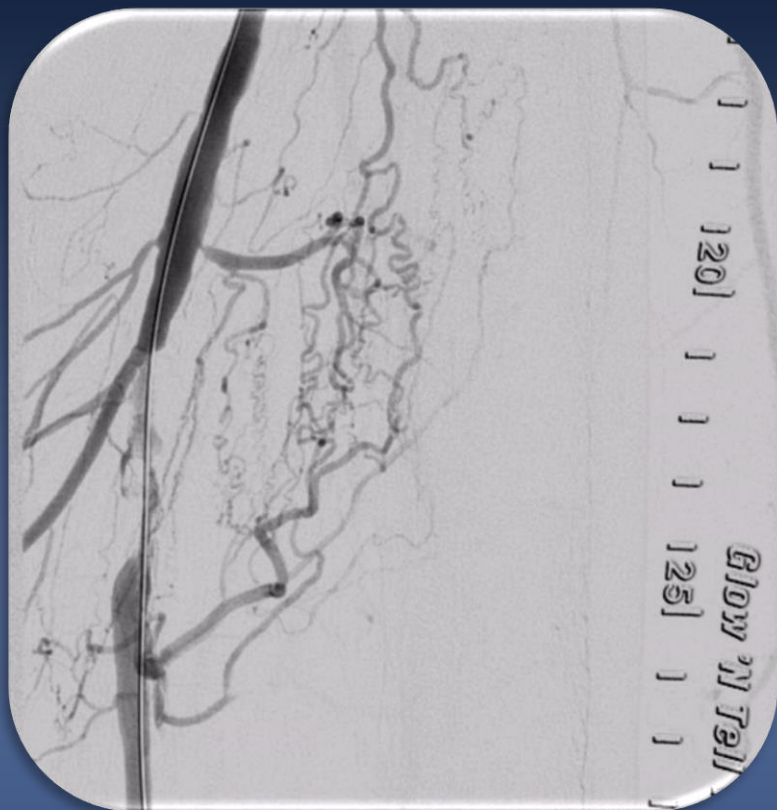
Torque THE DEVICE MEDIAL (SCREEN LEFT) – RAO 20 DEGREES



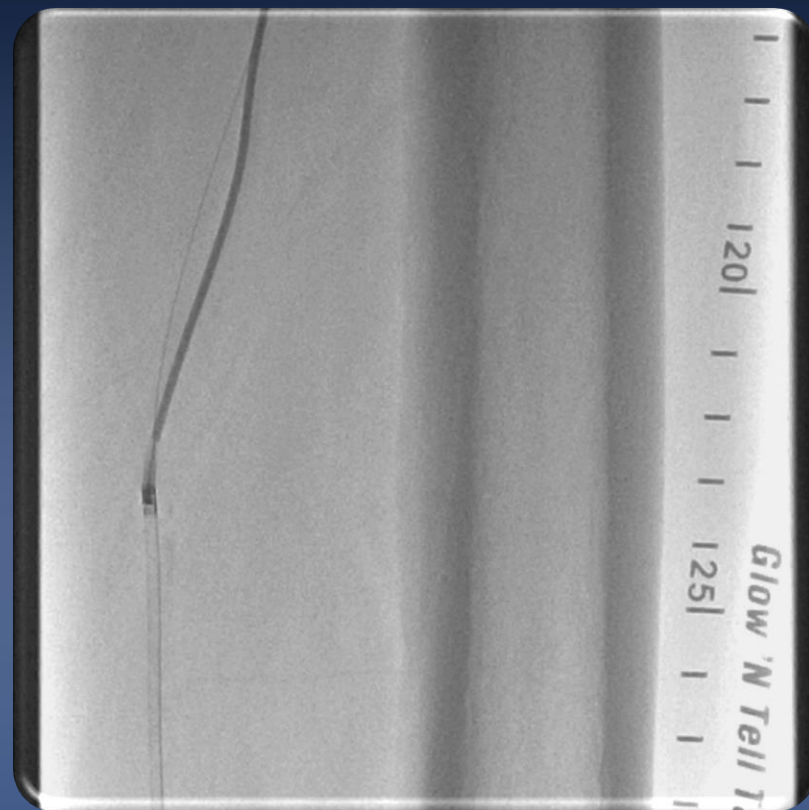
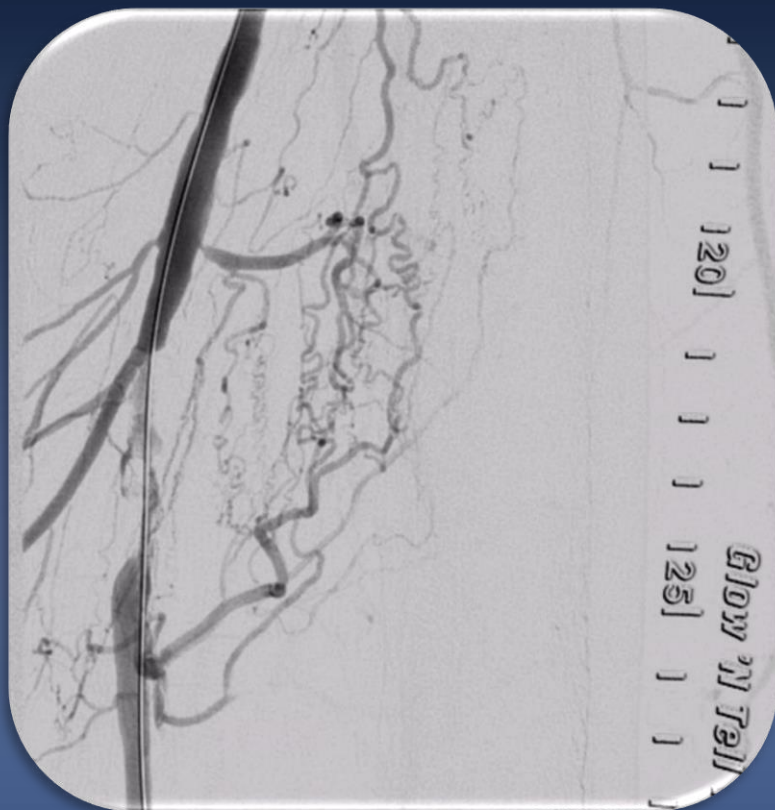
SHAVE MEDIAL – RAO



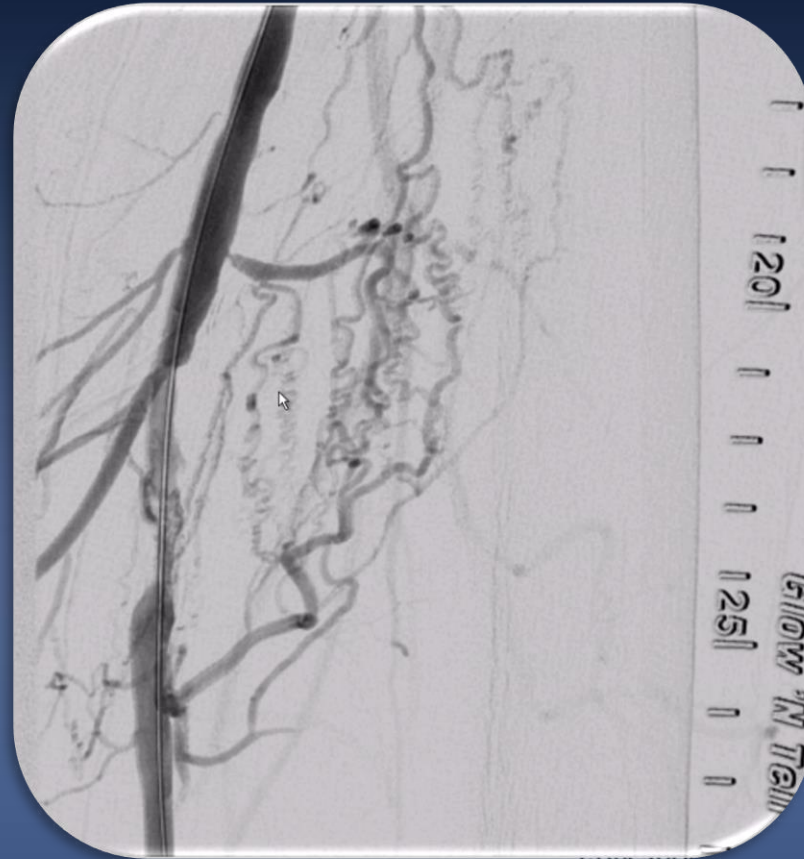
SHAVE MEDIAL – RAO



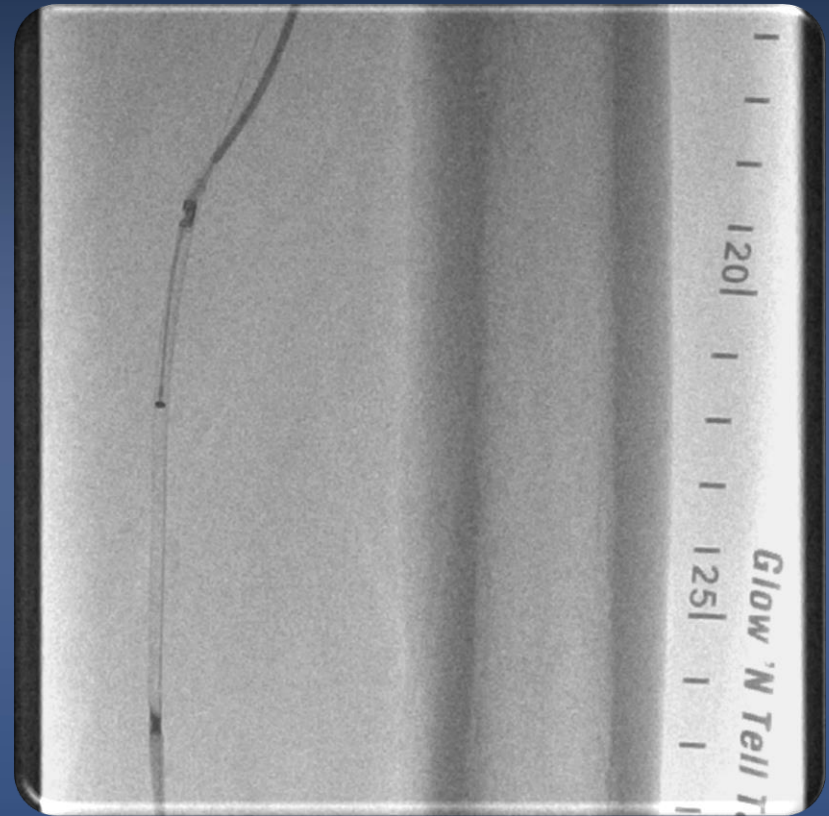
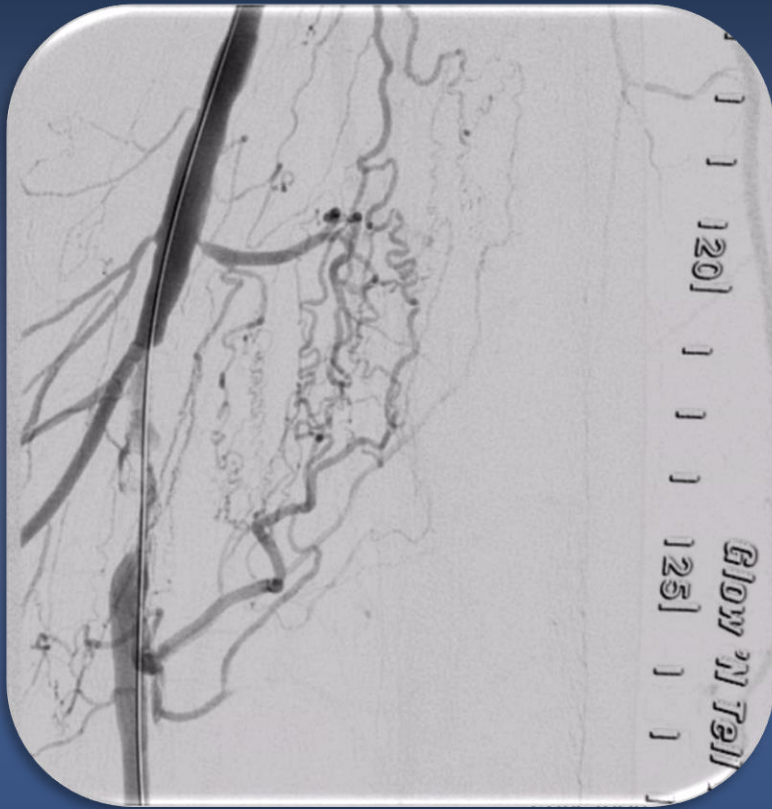
SHAVE MEDIAL – RAO



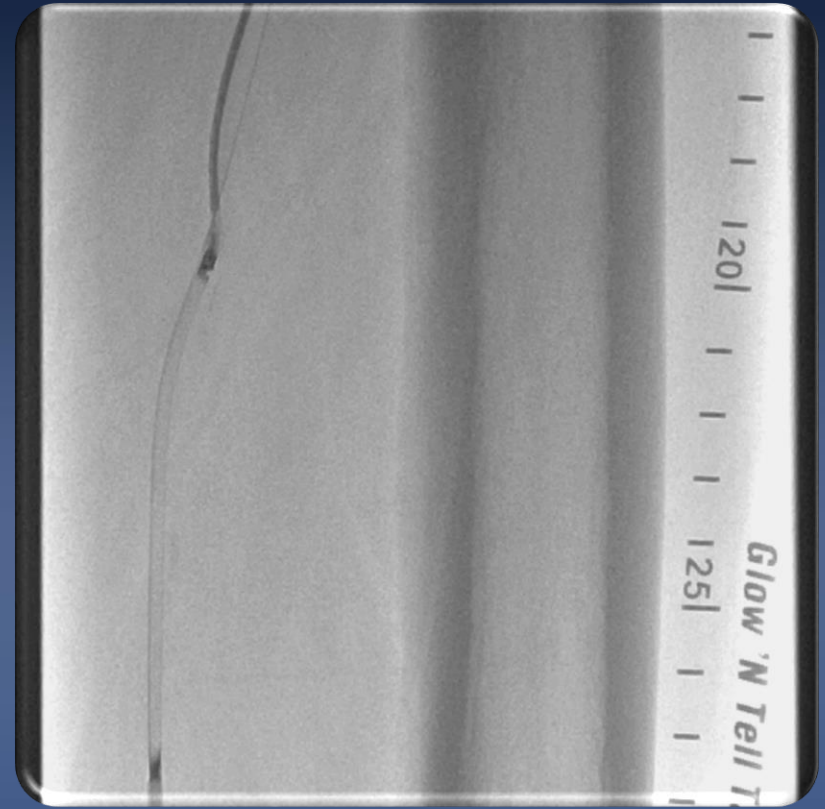
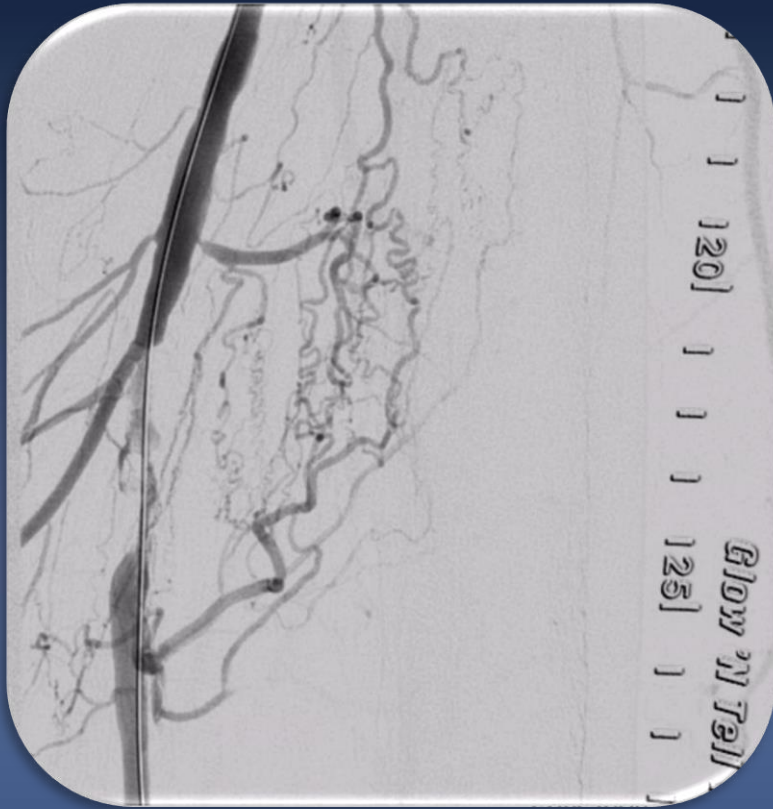
ANGIO After medial cut – RAO



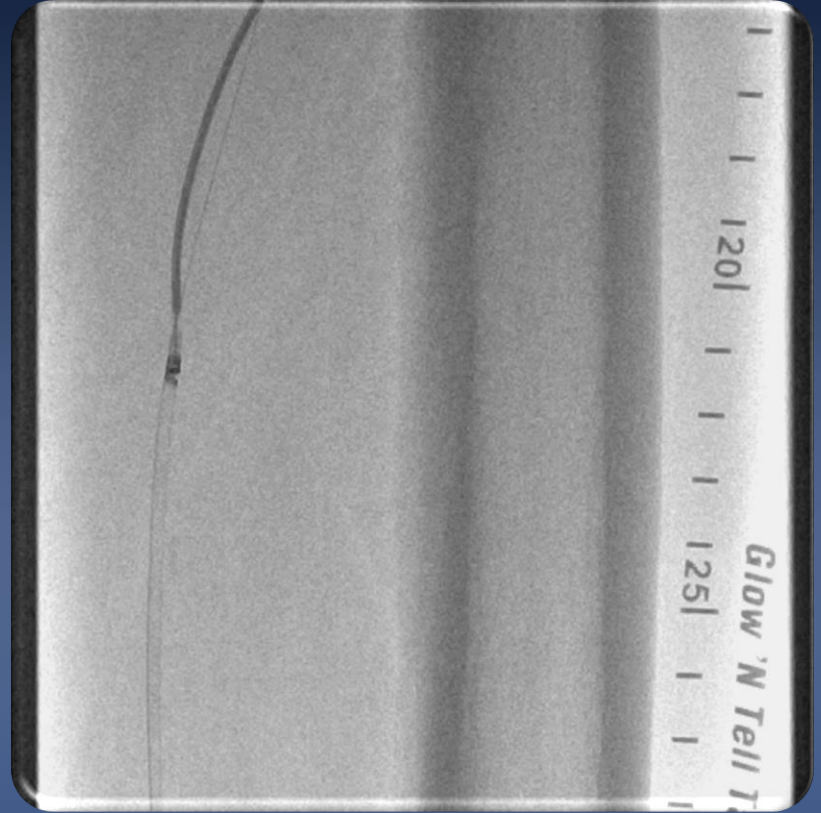
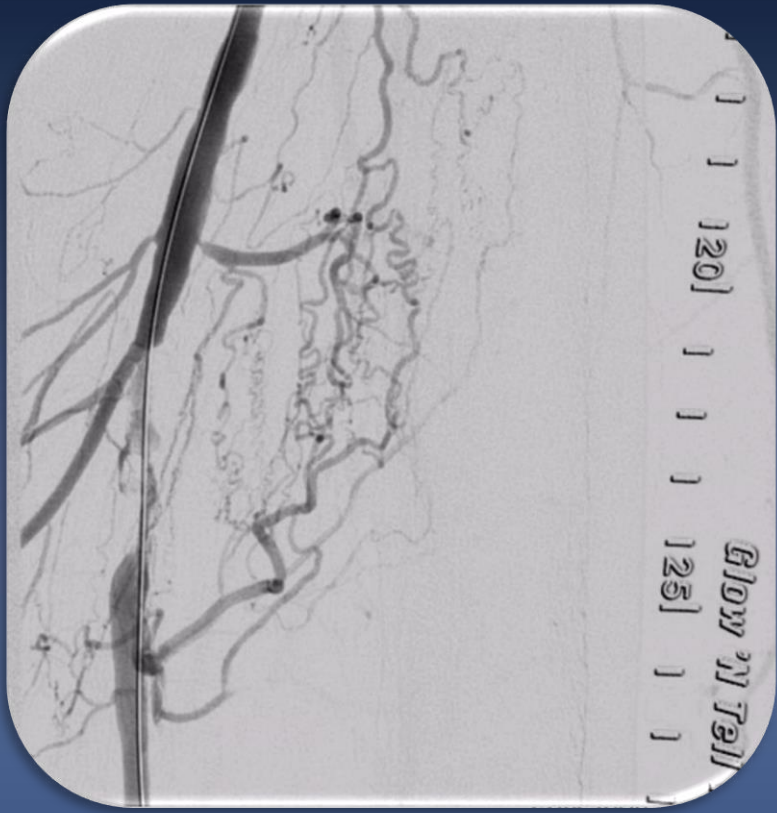
Torque THE DEVICE LATERAL (SCREEN RIGHT)– RAO



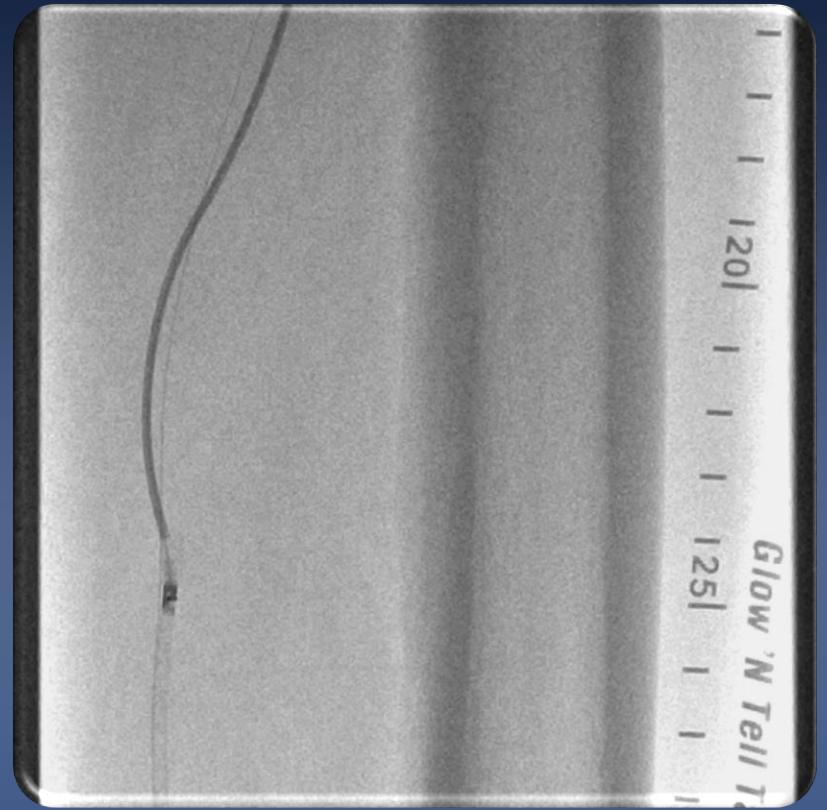
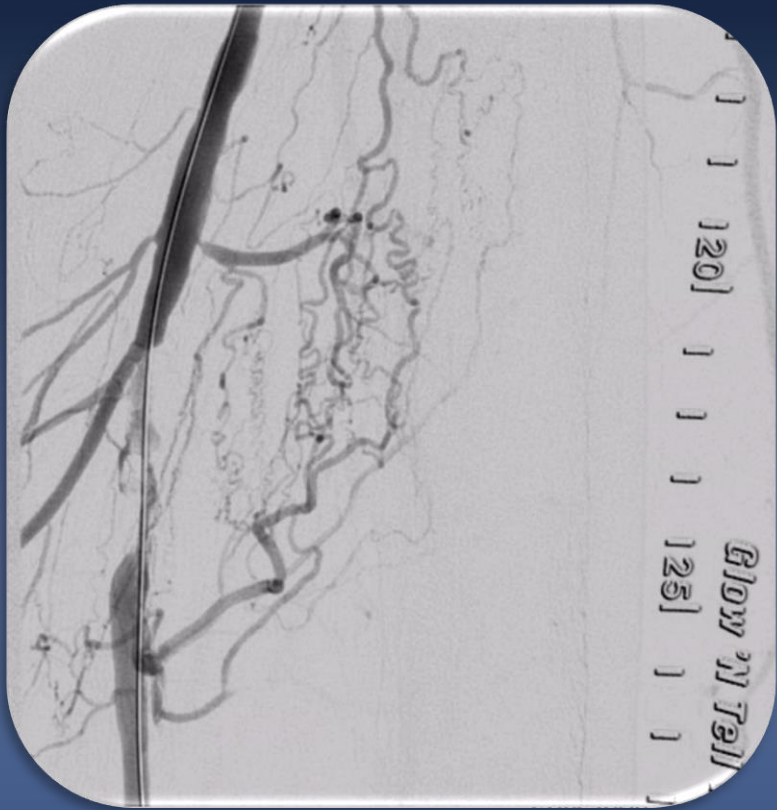
SHAVE LATERAL RAO



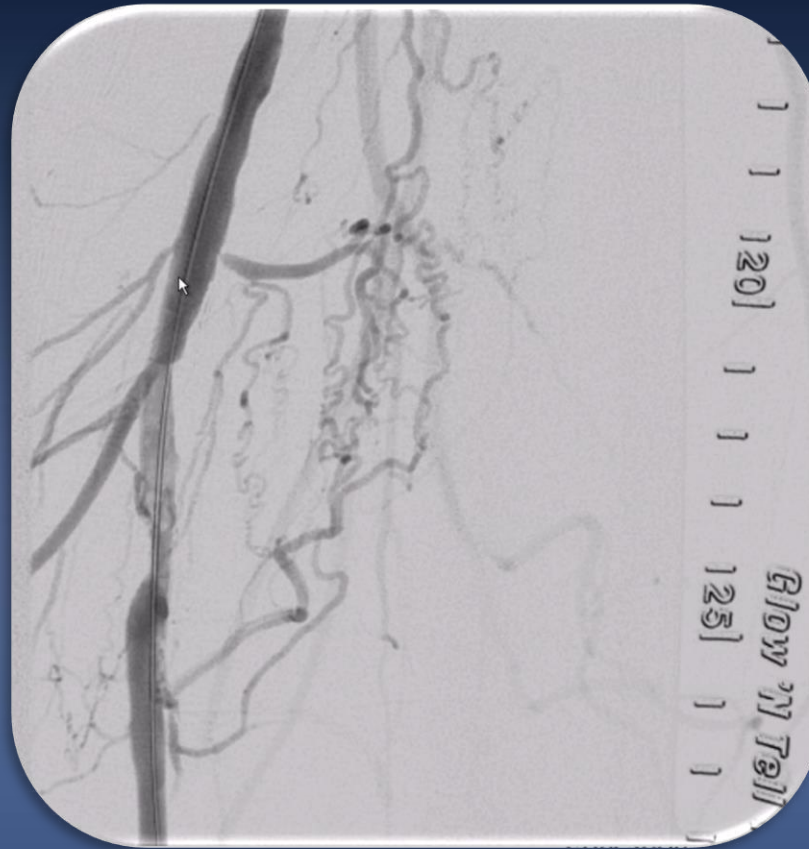
SHAVE LATERAL RAO



SHAVE LATERAL RAO



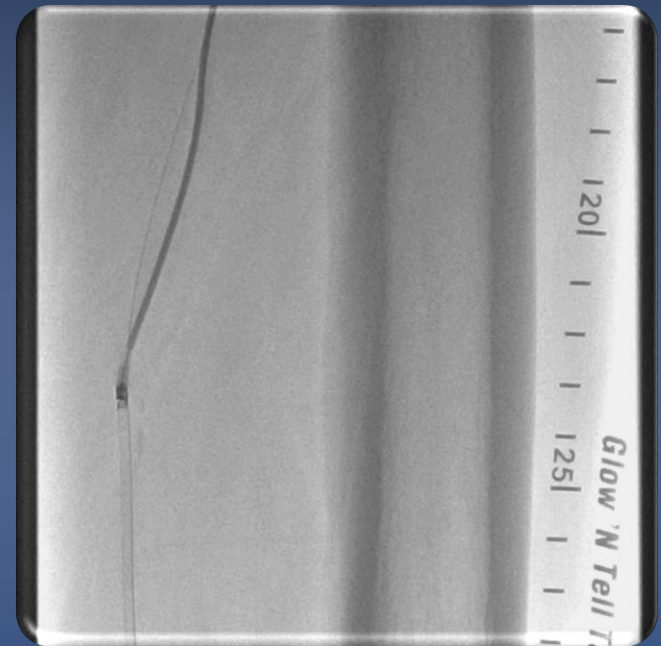
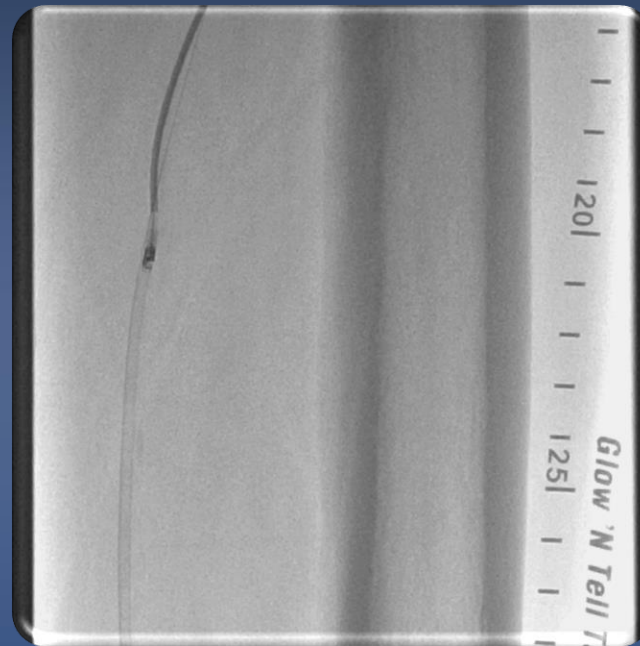
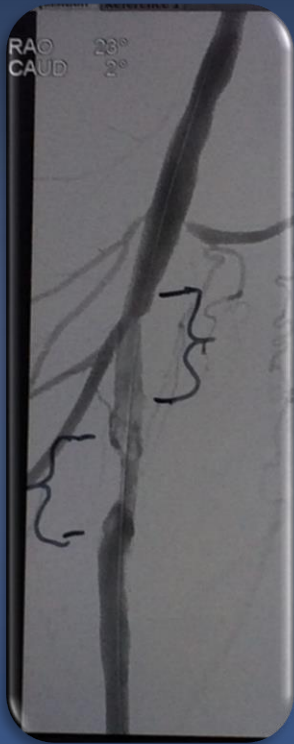
ANGIO After lateral cut RAO



MARK THE SCREEN FOR PRECISE DIRECTIONALITY – RAO



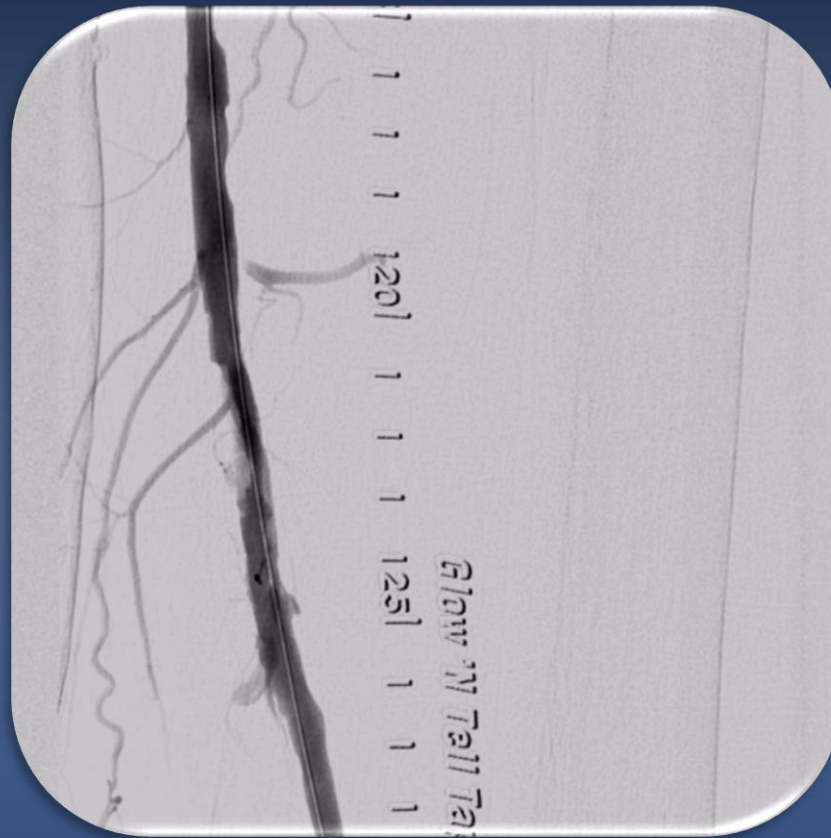
ADDITIONAL CUTS LATERAL (PROXIMALLY) AND MEDIAL (DISTALLY) RAO



After THOSE 2 CUTS – RAO



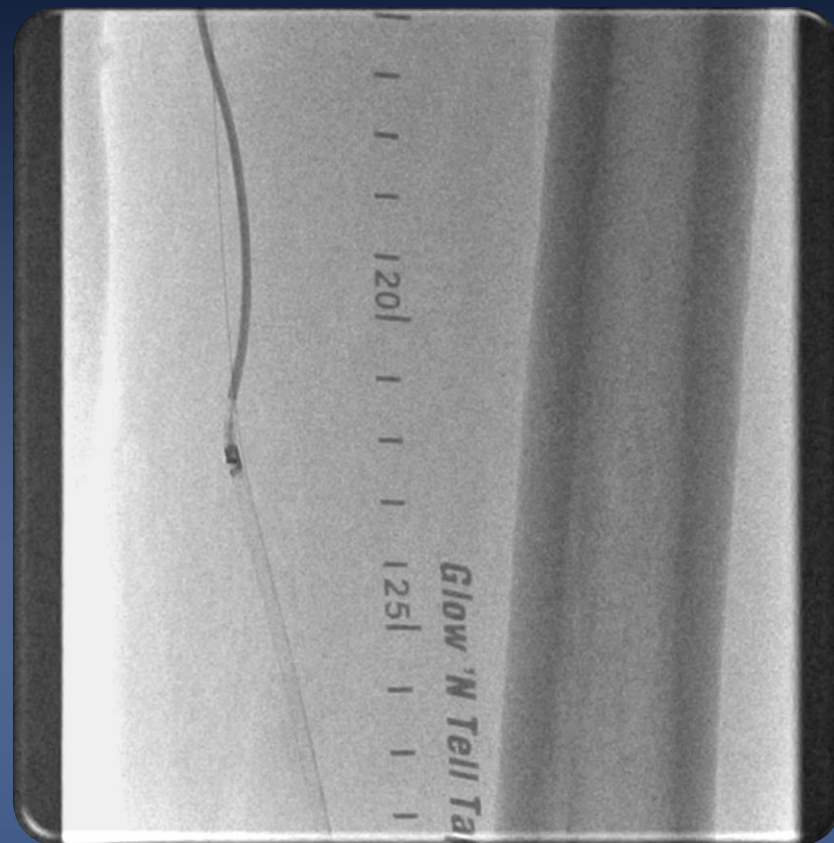
Rotate Camera Lao 30 For Orthogonal View



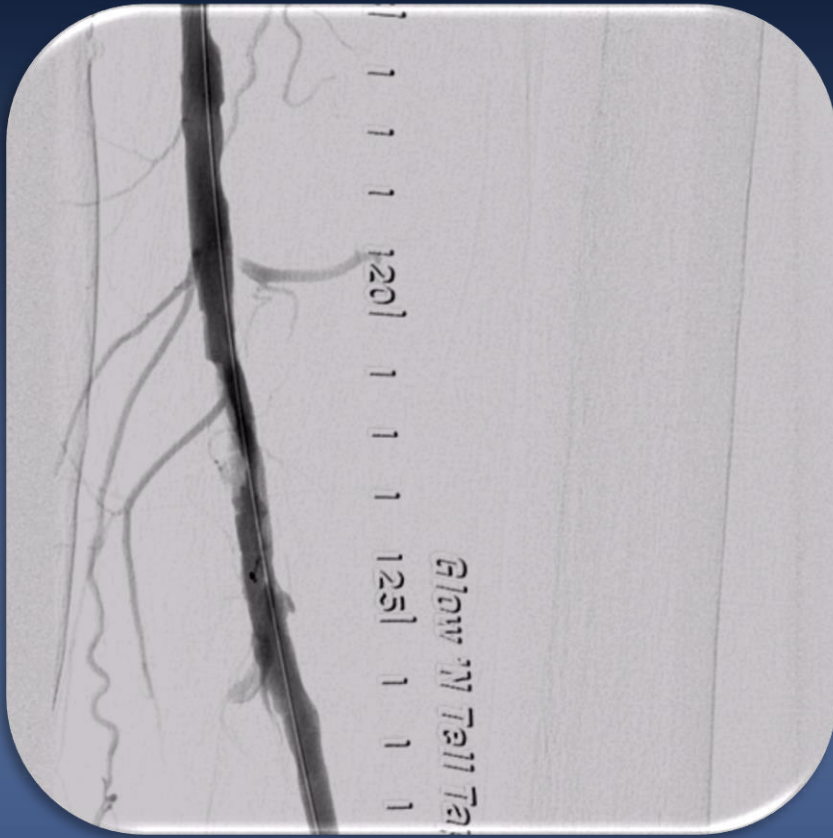
CUT SCREEN LEFT - LAO



CUT SCREEN LEFT – LAO



CUT SCREEN LEFT – LAO

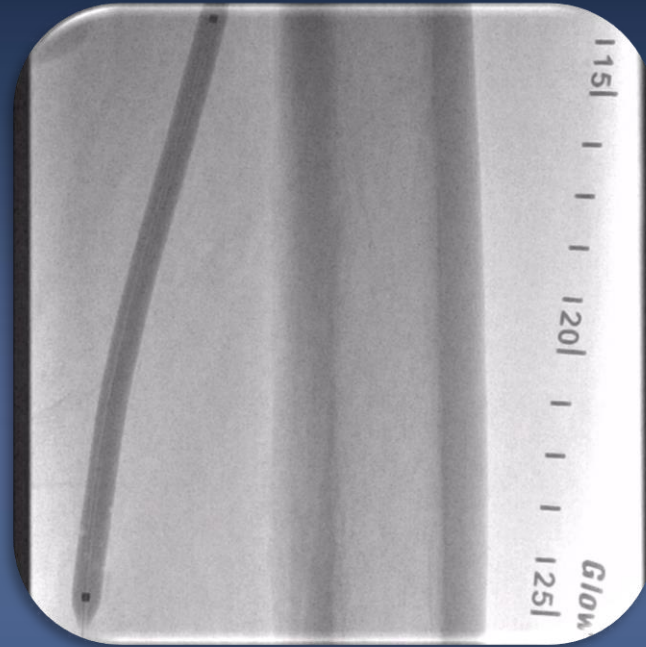


6.0 X 120MM In.PACT™ Admiral™ DCB AT 4 ATM

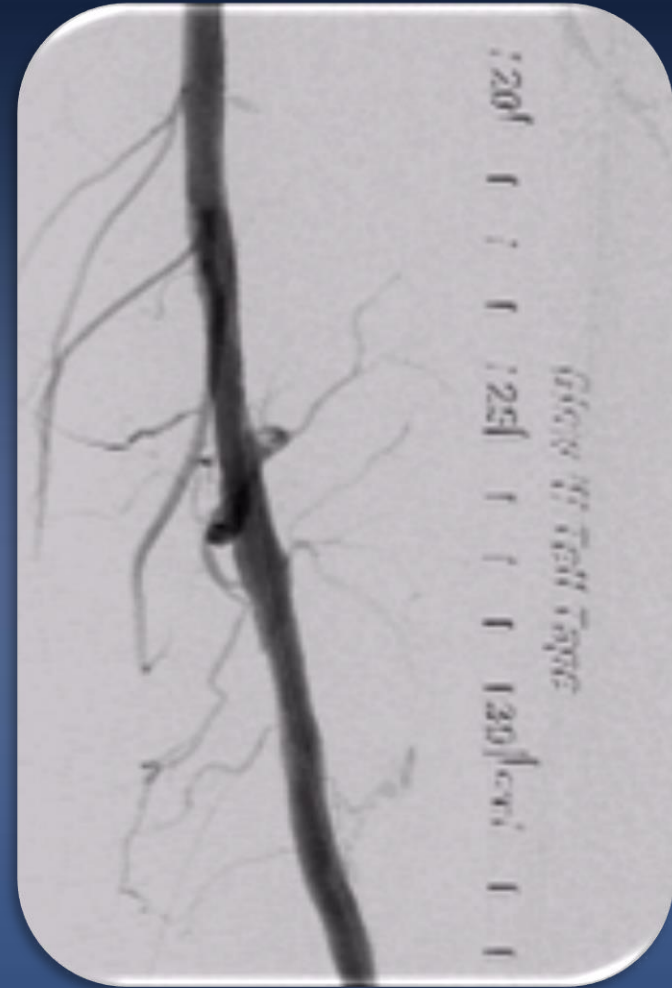
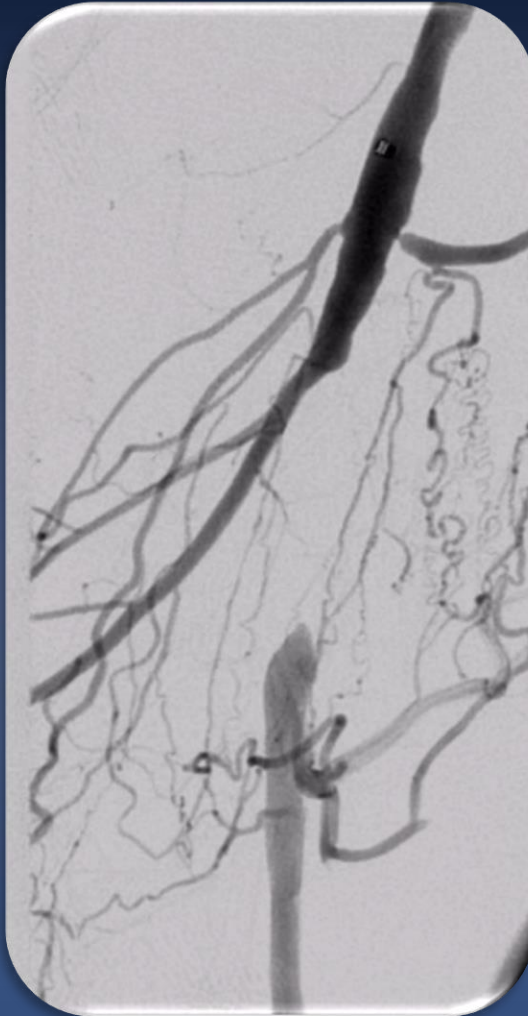
LAO



RAO



Final angio

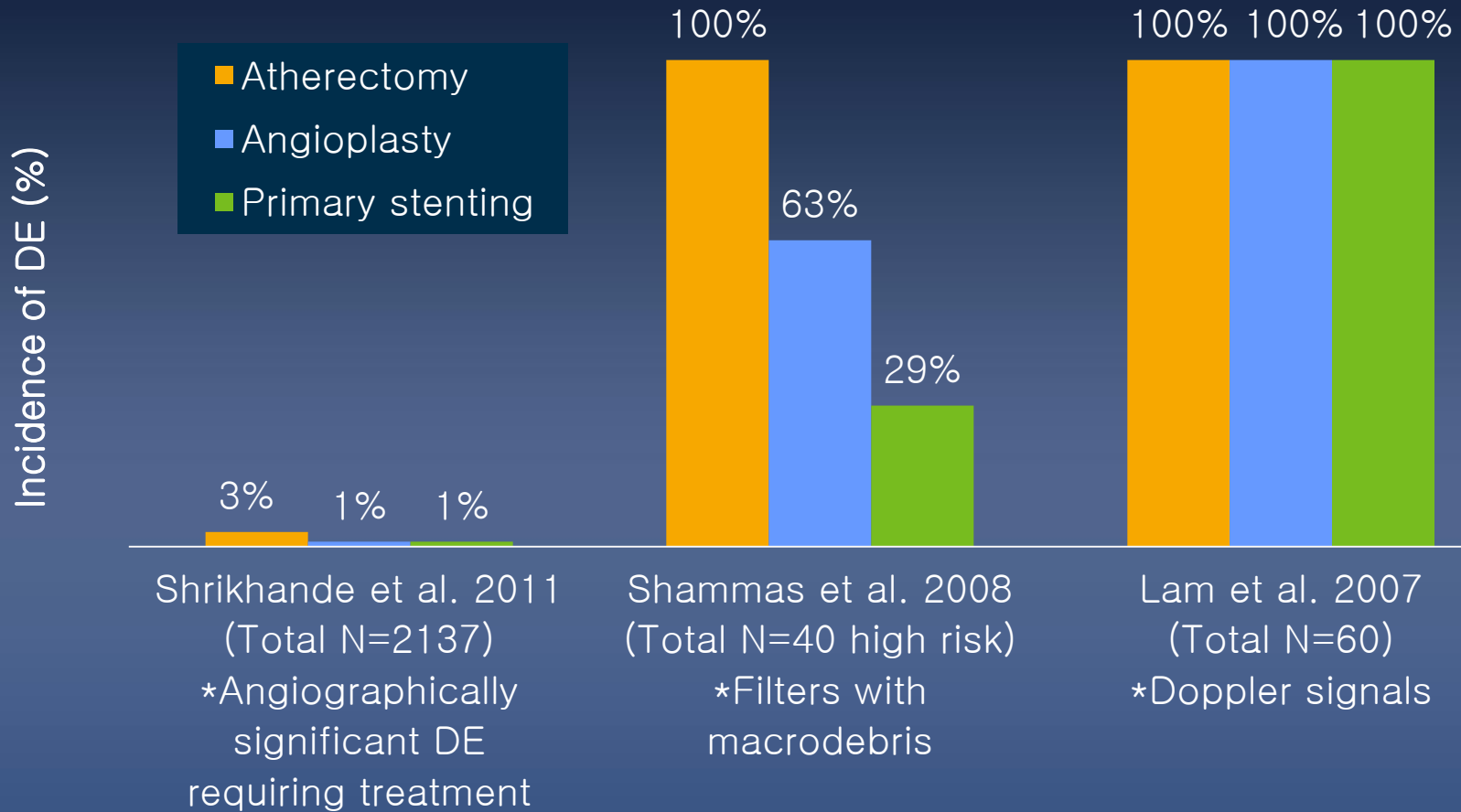


Directional Atherectomy

- Versatile for complex femoro–popliteal disease
- Directionality allows treatment of diseased segments without disturbing other areas
- Large luminal gains are possible

Distal Embolization

Variation in DE Rates by Procedure & Methods



PATIENT AND LESION FACTORS IN CO-RELATION TO DISTAL EMBOLIZATION

Patient Factors	Lesion Factors
Critical limb ischemia ^{1,10}	Occlusion ^{1,2,8,9,10,11}
No / Fewer runoff vessels ^{1,10}	TASC-D ^{1,9,10,11}
Tissue loss ¹	Thrombus ^{2,8,9,10}
Prior amputation ¹⁰	Calcium ^{1,10}
Acute onset of symptoms ¹⁰	Longer length ^{2,8,10}
Current smoker ¹	Larger diameter ^{2,8}
Metabolic syndrome ¹	Reduced TIMI flow ¹⁰
Female ¹	Below-the-knee ⁹

Note: **Bold** indicates characteristics supported by data from more than one study.

1. Davies MG. *Ann Vasc Surg*. 2010;24(1):14-22.

2. Kambalidis D. *J Endovasc Ther*. 2006;13(3):289-290.

8. Shamas NW. *J Endovasc Ther*. 2008;15(3):270-276.

9. Shamas NW. *Vasc Dis Mgt*. 2009; 6(3):58-61.

10. Shamas NW. *J Invasive Cardiol*. 2009;21(12):628-631.

11. Shrikhande GV. *J Vasc Surg*. 2011;53(2):347-352.

Summary

- Directional atherectomy requires a learning curve and appropriate patient selection
- Directional atherectomy is versatile and can treat the majority of complex fem-pop disease
- Use embolic protection in all but the most simple lesions
- Long term outcomes in the fem-pop segment with stand alone directional atherectomy are satisfactory
- Still need better data on atherectomy + DCB

Thank You!