

# Total Atherectomy Solution for Laser Vessel Preparation and Treatment

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# Advantages to Having Laser in My Practice...

- **Laser ablates plaque and thrombus with a low embolic potential (4%)**
  - Well suited for BTK CLI cases where the lesions are long/diffuse and where maintenance of small vessel collaterals and the microcirculation is crucial for tissue viability and wound healing
  - Also ideally suited for subacute thrombosis ATK where the volume of plaque and thrombus is often quite large and the chronic thrombus is more resistant to thrombolysis
- **Laser ablates without mechanical action or moving parts, making it ideally suited for debulking ISR lesions**
  - PTA alone yields poor results in ISR lesions (TLR rate 53.3% at 6 mos)
  - Debulking essential in ISR lesions to maintain patency of Viabahn endografts and may also be synergistic with DEB

# PERIPHERAL VESSEL PREP AND TREAT PORTFOLIO

Peripheral Atherectomy and Specialty Scoring Balloons

**Turbo-Power™**  
Laser Atherectomy Catheter

**Turbo-Elite™**  
Laser Atherectomy Catheter

**AngioSculpt® PTA**  
Scoring Balloon Catheter

**Spectranetics**  
Always Reaching Farther

# VESSEL PREP IS IMPORTANT

## For all Disease Types

*If you can CROSS,  
you can PREP and  
TREAT.*

### Examples of Outcomes with Vessel Preparation

- Easier delivery of balloons and stents<sup>1</sup>
- Potential for better stent apposition, leading to reduction in restenosis and stent thrombosis<sup>2,3</sup>
- Balloon at lower pressures
- May facilitate definitive therapy

1. Pratsos, A. (2009). Atherectomy and the role of excimer laser in treating CAD. *Cardiac Interventions Today*, January/February, 27-34.
2. Mehran, R., Mintz, G., et. al. (1997). Treatment of in-stent restenosis with excimer laser coronary angioplasty. *Circulation*, 96(7), 2183-2189.
3. Dahm, J., Kuon, E. (2000). High energy eccentric excimer laser angioplasty for debulking diffuse in-stent restenosis leads to better acute and 6-month follow-up results. *Journal of Invasive Cardiology*, 12, 335-342

# Cross, Prep & Treat Portfolio

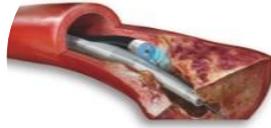
## Solving Complex Challenges

### Cross



- Quick-Cross
- Quick-Cross Select
- Quick-Cross Extreme
- Quick-Cross Capture
- Turbo-Elite

### Prep



- Turbo-Elite
- Turbo-Power
- AngioSculpt PTA
- AngioSculpt PTCA
- Quick-Cat
- ELCA

### Treat (general)



- Stellarex DCB
- Not approved for ISR

### Treat (specialty)



- AngioSculpt PTA
- AngioSculpt PTCA

**#1** Crossing Solutions

**#2** Atherectomy

Featuring *EnduraCoat Technology*

**#1** Specialty Balloons

# LASER ATHERECTOMY OVERVIEW



# SPECTRANETICS LASER BENEFITS



- **Only FDA indicated** atherectomy technology for ISR
- Treat multiple lesion morphologies
- **Debulk lesion from the tip** with no moving parts
- **Gain 27% larger lumen** with Turbo-Power vs. Turbo-Elite
- **Directional debulking** with Turbo-Power

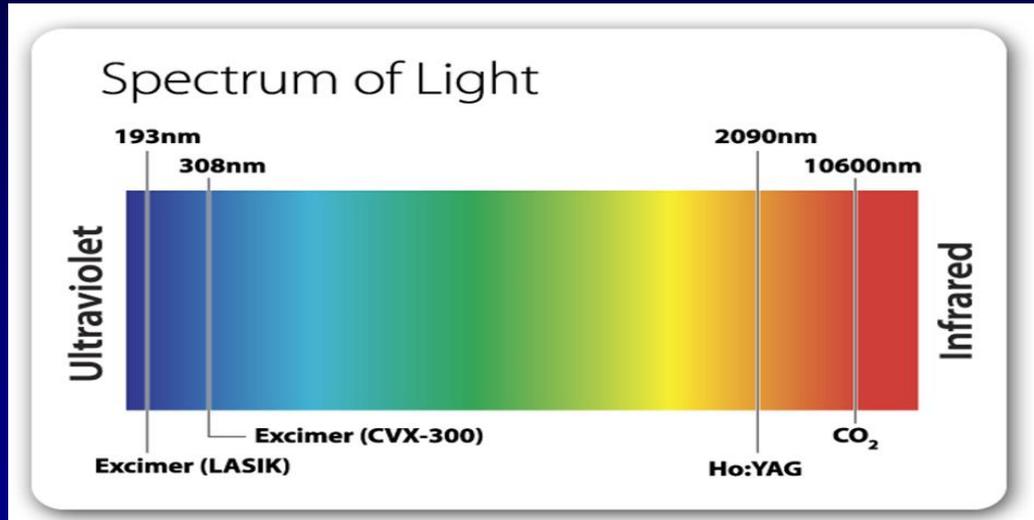
# EXCIMER LASER ATHERECTOMY

Ultraviolet

Infrared

Cool

Hot

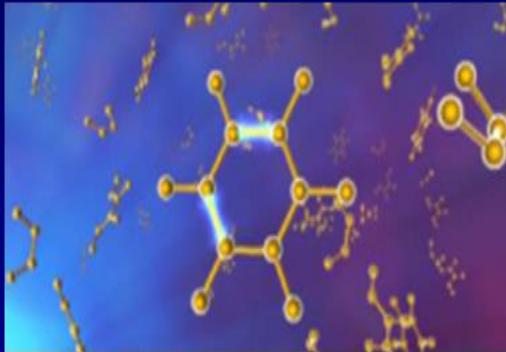


# LASER: THREE MECHANISMS OF ACTION

## Treat All Morphologies

### Photochemical

Breaks **molecular bonds**: UV light **vaporizes** plaque directly in front of the catheter tip.



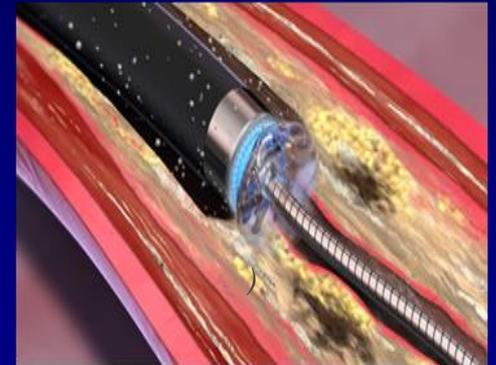
### Photothermal

Produces **thermal energy**: thermal energy **softens** collagen and protein fibers, and creates vapor bubble.



### Photomechanical

Creates **kinetic energy**: repeated expansion and contraction of vapor bubble **hammers** through hard plaque.



# PHOTOMECHANICAL EFFECT



# THE STANDARD FOR ISR:

- ✓ Level 1 **CLINICAL DATA** proves superiority
- ✓ Greater **LUMINAL GAIN\***
- ✓ Exclusive **FDA INDICATION**



**Turbo-Power™**  
Laser Atherectomy Catheter



Treats **at the tip**  
Remote automatic rotation offers **precise directional control**  
Creates a pilot channel and debulks the lesion **in one step**

\*When compared to Turbo-Elite™

# EXCITE STUDY OVERVIEW

## Purpose

Evaluated the safety and effectiveness of Excimer Laser Atherectomy (ELA) with adjunctive PTA vs. PTA alone in the treatment of FemPop ISR



## Method

Prospective, randomized (2:1), multi-center study

Primary Safety = 37 day MAE

Primary Efficacy = freedom from 6 month clinically driven TLR

Third-party assessment for all clinical events & angiographic/ultrasound readings

## Patients

Real-world population

Enrollment: 169 ELA + PTA vs. 81 PTA alone

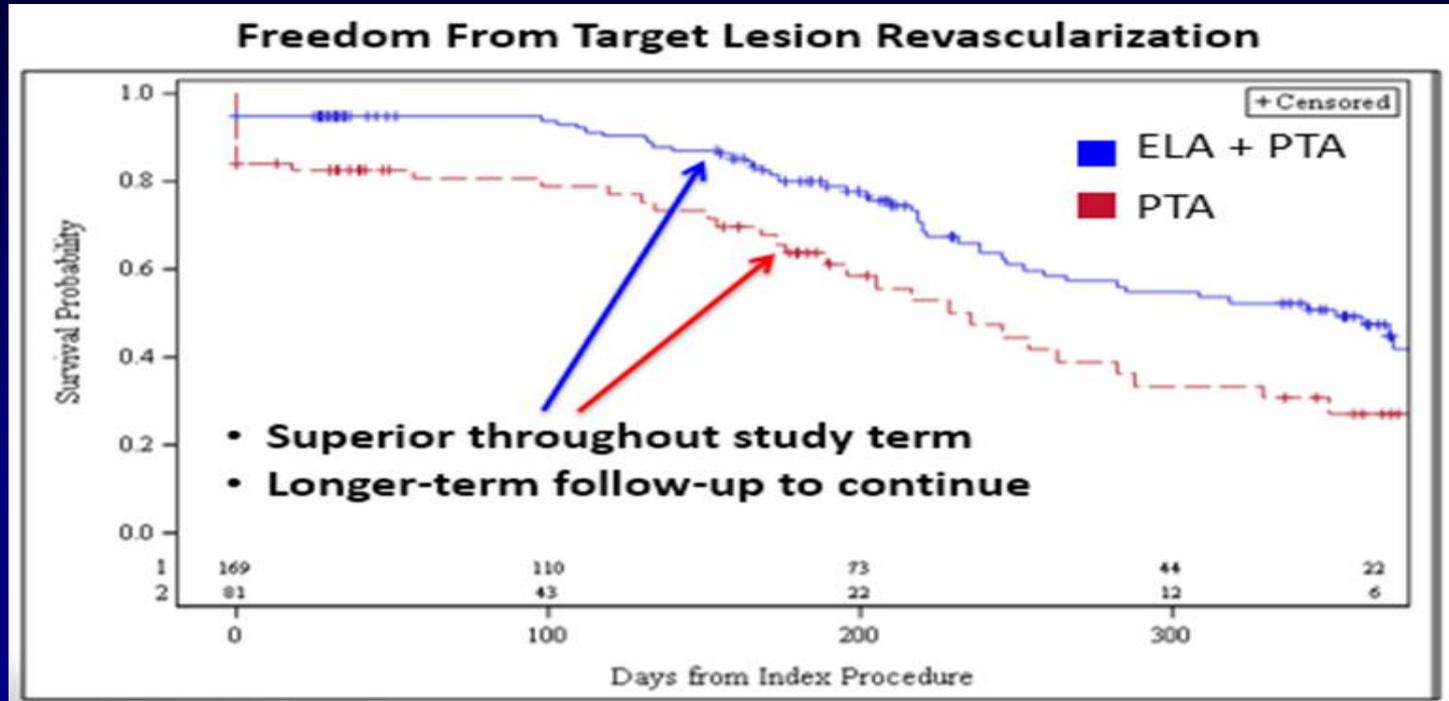
# PROVEN: Superior Efficacy and Safety

Level 1 clinical data proves **Turbo-Power™ + PTA** is proven **safer and more effective** than PTA alone in treating FemPop ISR.\*

	Turbo-Power™ + PTA	PTA Alone
<b>SAFER</b>		
Major adverse events at 30 days	5.8%	20.5%
Major dissection <sup>1,2</sup>	0.6%	7.4%
Risk of stent interaction	Minimal	Minimal
<b>MORE EFFECTIVE</b>		
Procedural success	93.5%	83.5%
Freedom from TLR at 6 months	73.5%	51.8%
Additional stenting after treatment	5.3%	11.3% <sup>1,2</sup>

# SUPERIORITY IN FREEDOM FROM TLR

Consistent Throughout Follow-up Period



## Case #1

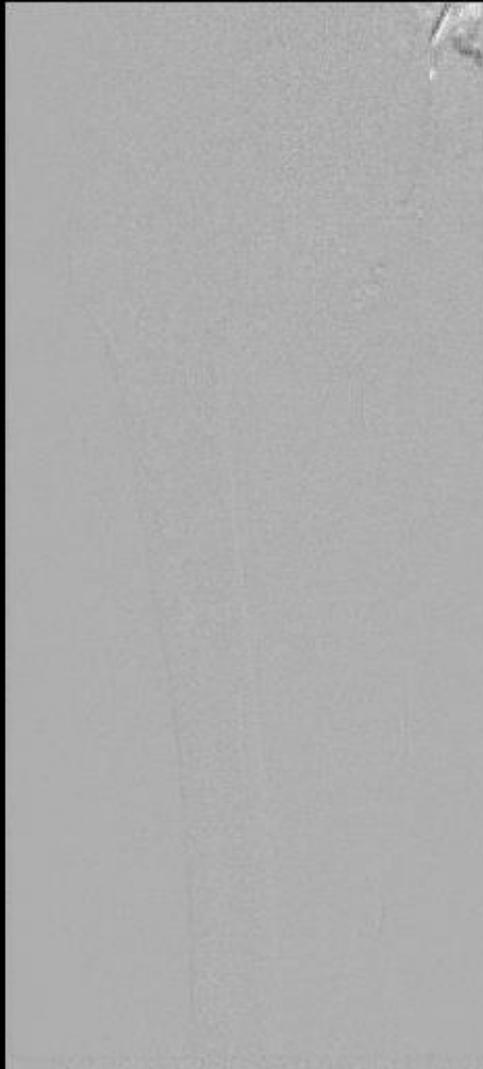
- ▶ **71M, h/o PAD, OSA, gout presents with life-limiting right leg claudication (Rutherford 3), progressively worsening.**
- ▶ **History of prior RLE intervention ~10y ago at OSH.**
- ▶ **On ASA81. Former smoker (quit ~6mo ago)**
- ▶ **Vitals, labs normal**
- ▶ **Physical exam notable for 2+ palp femoral pulses bilaterally**
- ▶ **LLE: 2+ palpable DP, PT**
- ▶ **RLE biphasic signal DP, PT**

## Case #1: Non-invasives

Right LE	PSV cm/sec	Waveform
CFA	118	Biphasic
PFA	140	"
SFA P	58	Biphasic
SFA M	61	"
SFA D	22	"
POPA P	460	
POPA M	32	
POPA D	31	
PTA	71	"
Peroneal A	0	Absent
ATA	45	Biphasic

**Findings:** Densely calcified plaque cluster seen in the popliteal artery with occlusion in proximal to mid portion and reconstitution of flow distally. DPA PSV 15 cm/s.

## Case #1



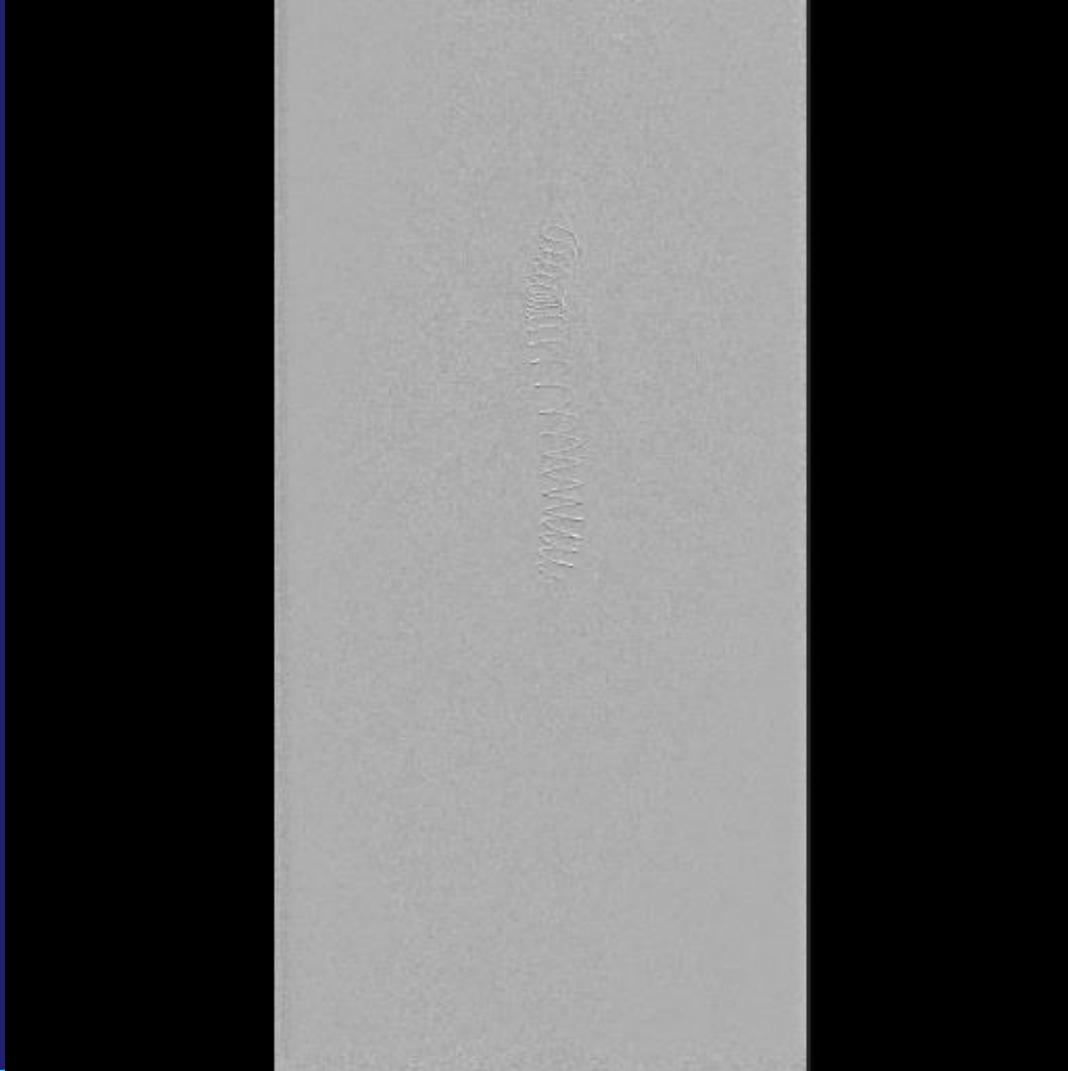
## Case #1



## Case #1



## Case #1



## Case #1

- ▶ L CFA access: right leg diagnostic angiogram
  - In-stent restenosis, occlusion of popliteal artery
- ▶ 6Fr sheath to RLE mid-SFA

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- ▶ L CFA access: right leg diagnostic angiogram
  - In-stent restenosis, occlusion of popliteal artery
- ▶ 6Fr sheath to RLE mid-SFA
- ▶ Cross lesion
- ▶ Switch for 0.014 Grand Slam wire

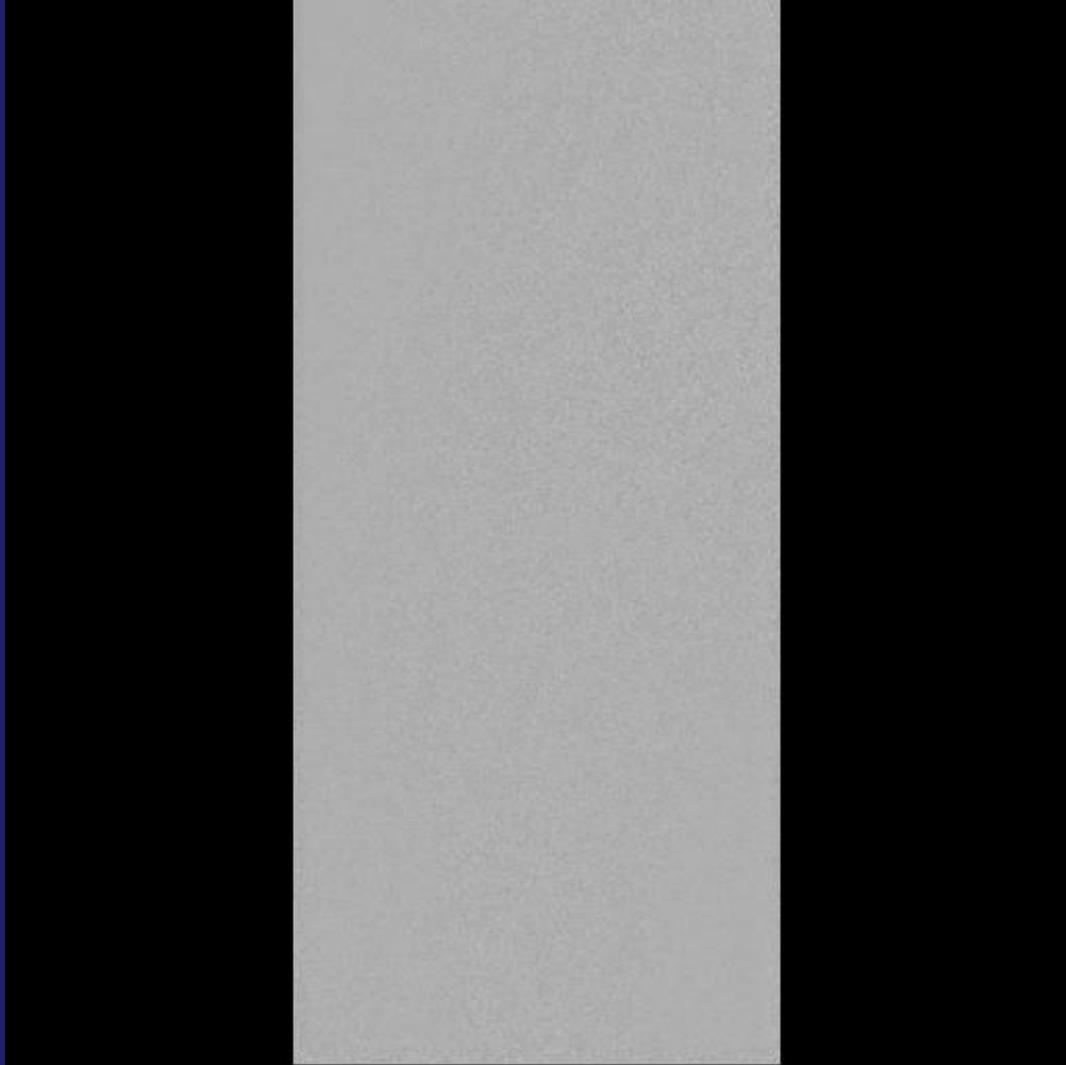
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- ▶ Cross lesion
- ▶ Switch for 0.014 Grand Slam wire
- ▶ Laser atherectomy w Spectranetics 2.0mm OTW

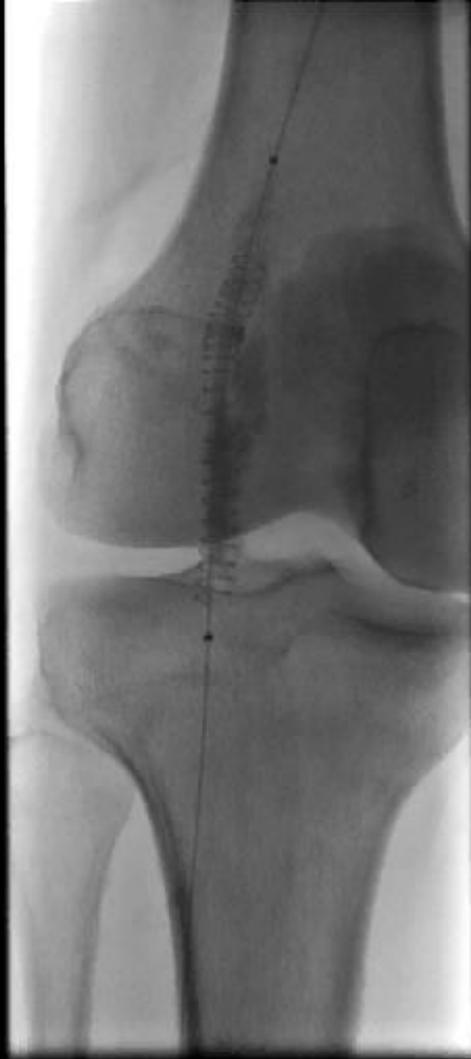
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  - In-stent restenosis, occlusion of popliteal artery
- ▶ 6Fr sheath to RLE mid-SFA
- ▶ Cross lesion
- ▶ Switch for 0.014 Grand Slam wire
- ▶ Laser atherectomy w Spectranetics 2.0mm OTW – nice luminal gain

## Case #1



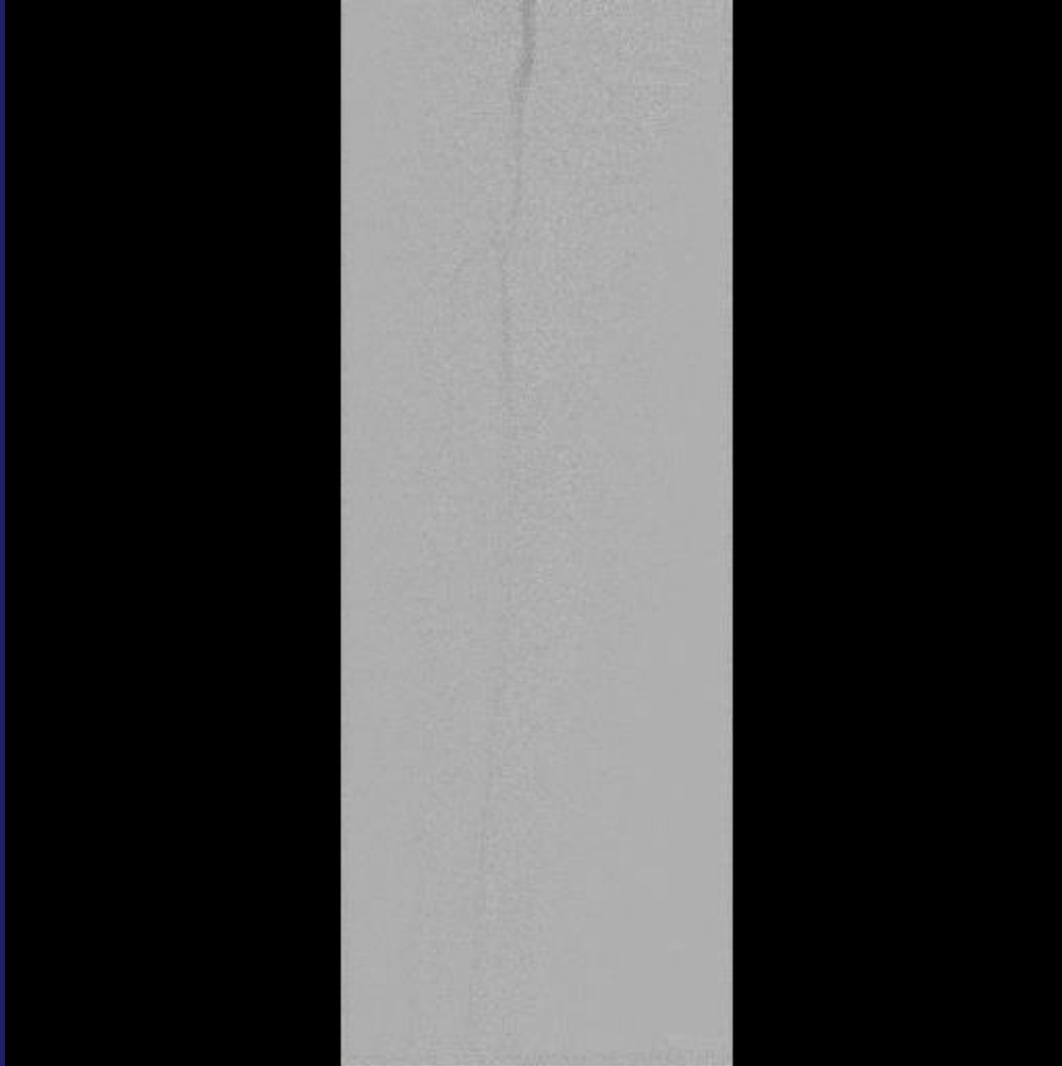
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- ▶ L CFA access: right leg diagnostic angiogram
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- ▶ 6Fr sheath to RLE mid-SFA
- ▶ Cross lesion
- ▶ Switch for 0.014 Grand Slam wire
- ▶ Laser atherectomy w Spectranetics 2.0mm OTW
- ▶ Pre-dilate w/ 5mm POBA
- ▶ Finish w/ 6mm DCB

## Case #1



## Case #1



## Case #1

- ▶ L CFA access: right leg diagnostic angiogram
  - In-stent restenosis, occlusion of popliteal artery
- ▶ 6Fr sheath to RLE mid-SFA
- ▶ Cross lesion
- ▶ Switch for 0.014 Grand Slam wire
- ▶ Laser atherectomy w Spectranetics 2.0mm OTW
- ▶ Pre-dilate w/ 5mm POBA
- ▶ Finish w/ 6mm DCB
- ▶ Completion angiogram
  - In-line flow to foot via AT, PT
- ▶ Pt off table w palpable DP, PT pulses, home later that day

# Case #2

## Case #2

- ▶ 64M, h/o CAD, PAD, CKD (Cr ~2.2), presents w non-healing R 2<sup>nd</sup> toe amputation site/gangrene (Rutherford 5) following blunt trauma 2mo. prior. Since amputation, progressively worsening gangrene.
- ▶ No prior interventions, on ASA81
- ▶ Vitals, labs normal
- ▶ Physical exam notable for 2+ palp femoral, popliteal pulses bilaterally
- ▶ LLE: Triphasic DP, PT
- ▶ RLE monophasic signal PT
- ▶ Right 2<sup>nd</sup> toe amputation site, open, w surrounding necrosis

## Case #2: Non-invasives

Right	PSV cm/sec	Waveform
CFA	98	Triphasic
PFA	108	Biphasic
SFA P	132	Triphasic
SFA M	92	Triphasic
SFA D	260	Stenotic
POPA P	69	Triphasic
POPA M		
POPA D	121	Triphasic
TPT	87	Triphasic
PTA	0	Absent
Peroneal A	318	Stenotic
ATA	63	Biphasic

▶ ABI 0.49

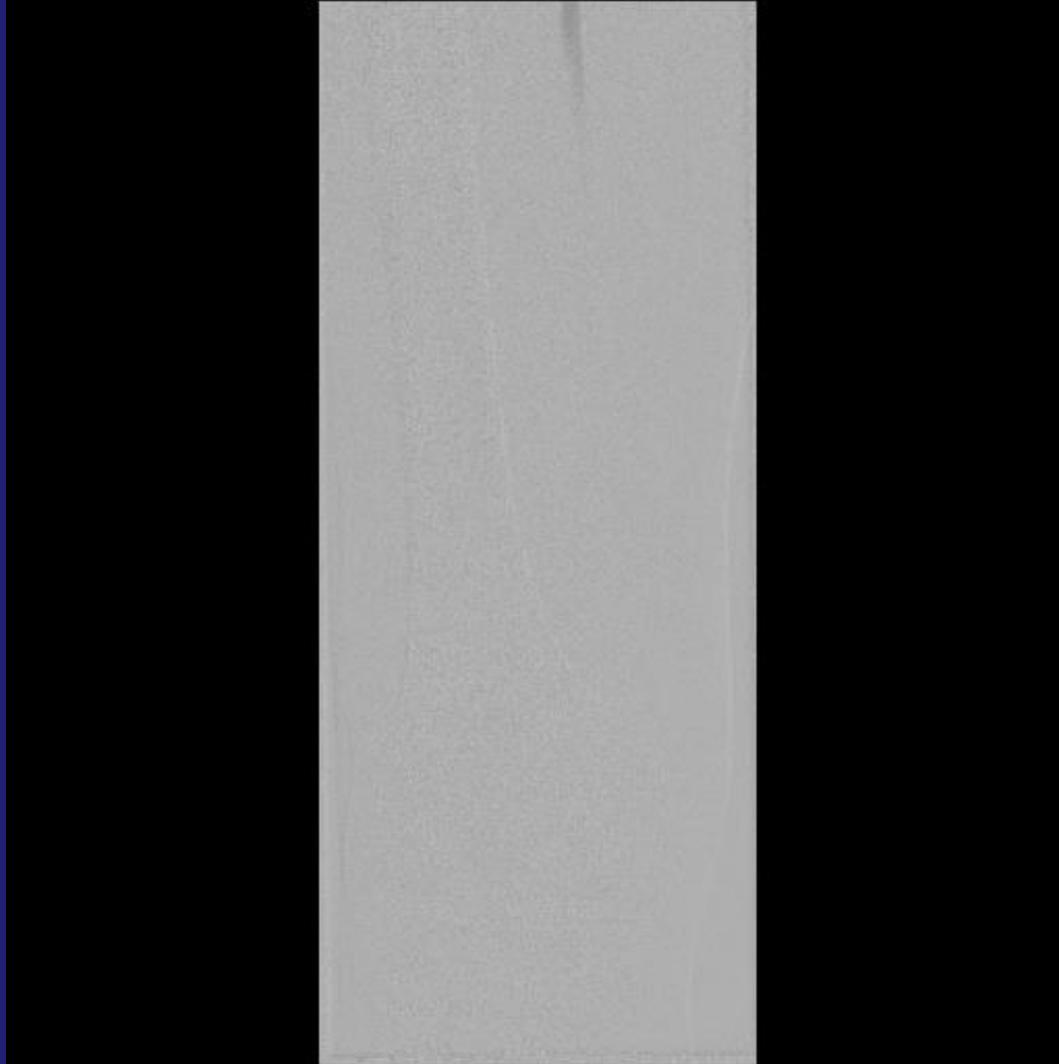
**Findings:** Unable to detect flow at the right posterior tibial artery. Flow reconstitutes at the posterior tibial artery at the ankle. Significant velocity increases noted at the proximal and mid peroneal artery with a PSV = 318 cm/sec at proximal and 224 cm/sec at mid. Significant velocity increase at the distal anterior tibial artery with a PSV = 155 cm/sec (pre-velocity = 32 cm/sec). Patent DPA with a PSV = 49 cm/sec. Mild to moderate velocity increase noted at the right distal superficial femoral artery.

**Impression:** Occlusion of the right PTA. Moderate to severe stenosis of the proximal and mid Peroneal A and distal ATA. Mild stenosis of the distal SFA. Patent right CFA, PFA, POPA, TPT.

## Case #2



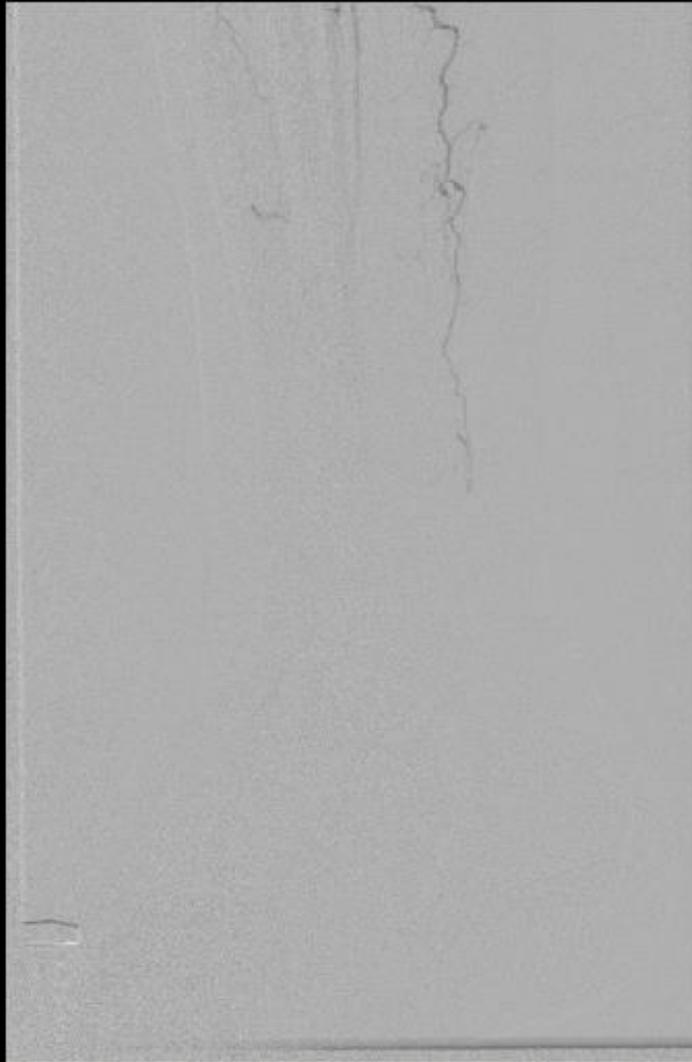
## Case #2



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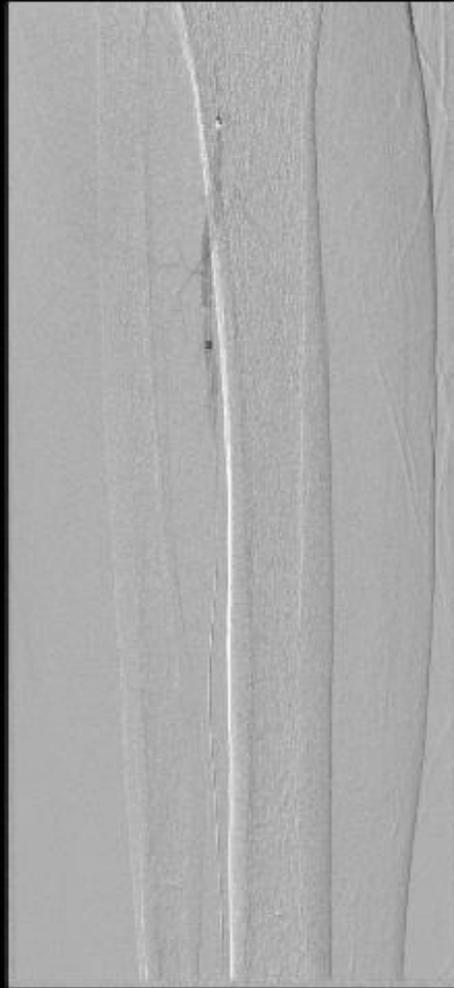
## Case #2



## Case #2

- ▶ L CFA access: right leg diagnostic angiogram
  - P2 popliteal stenosis, CTO of AT, PT, mid-peroneal
- ▶ 6Fr sheath to RLE mid-SFA

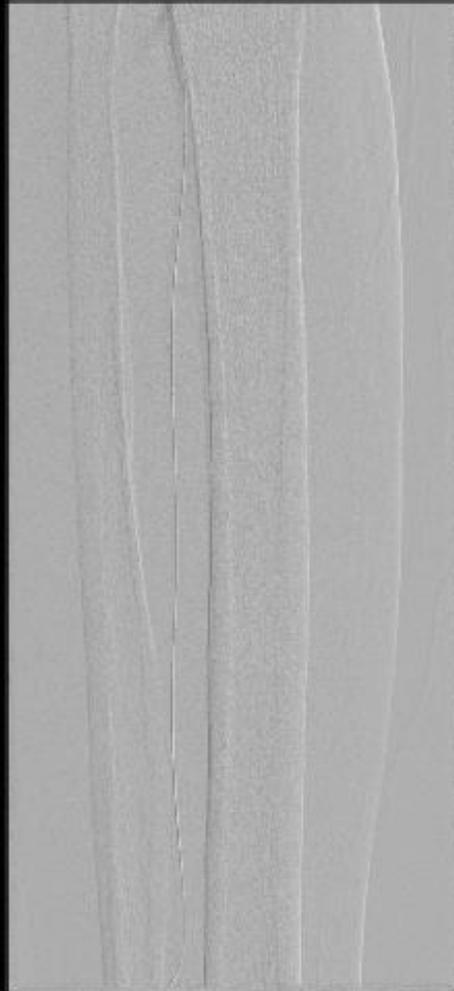
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- ▶ L CFA access: right leg diagnostic angiogram
  - P2 popliteal stenosis, CTO of AT, PT, mid-peroneal
- ▶ 6Fr sheath to RLE mid-SFA
- ▶ Crossed peroneal lesion
- ▶ Switch for 0.014 Grand Slam wire
- ▶ Laser atherectomy w Spectranetics 1.4mm OTW

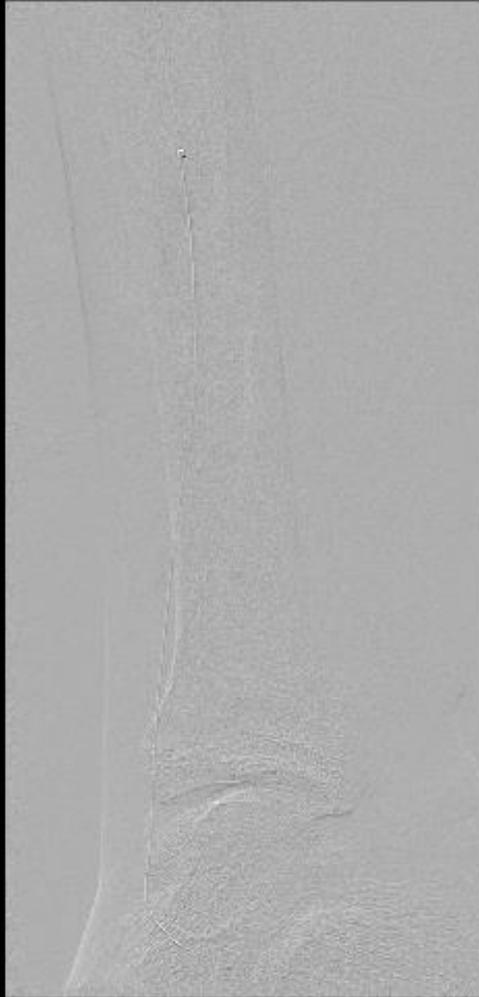
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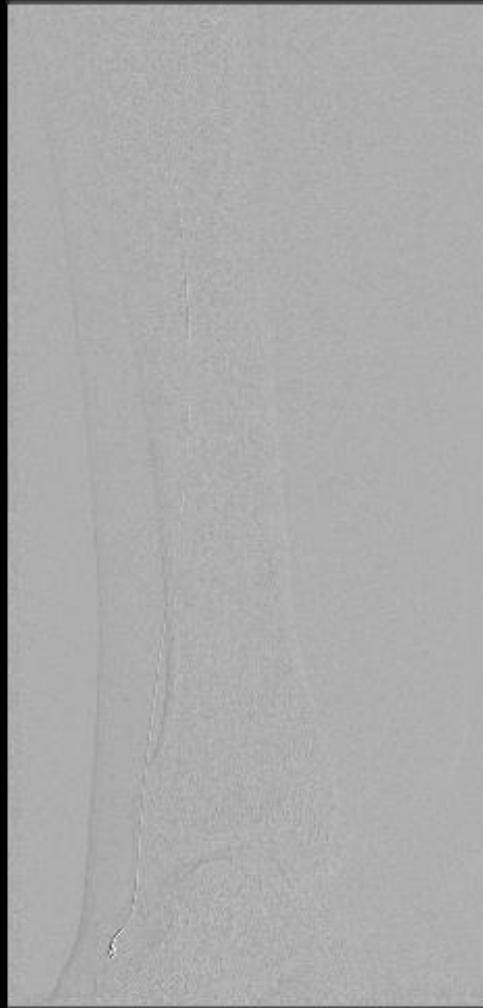
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  - P2 popliteal stenosis, CTO of AT, PT, mid-peroneal
- ▶ 6Fr sheath to RLE mid-SFA
- ▶ Crossed peroneal lesion
- ▶ Switch for 0.014 Grand Slam wire
- ▶ Laser atherectomy w Spectranetics 1.4mm OTW
- ▶ Repeat for AT lesion

## Case #2



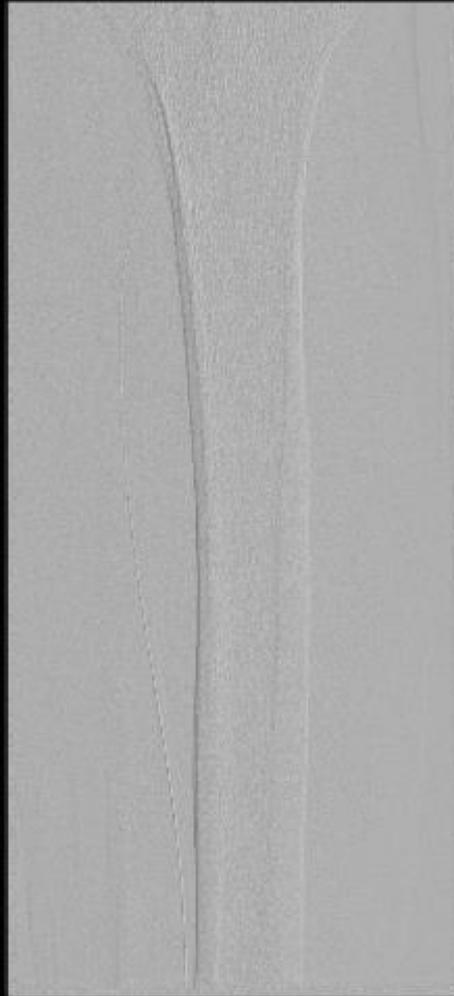
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- ▶ L CFA access: right leg diagnostic angiogram
  - P2 popliteal stenosis, CTO of AT, PT, mid-peroneal
- ▶ 6Fr sheath to RLE mid-SFA
- ▶ Crossed peroneal lesion
- ▶ Switch for 0.014 Grand Slam wire
- ▶ Laser atherectomy w Spectranetics 1.4mm OTW
- ▶ Repeat for AT lesion
- ▶ Treated popliteal lesion w/ 6mm DCB
- ▶ Completion angiogram
  - Flow to foot via dominant peroneal

## Case #2



## Case #2

- ▶ Most recent follow-up, amputation site healing well
- ▶ AT and peroneal open without significant stenosis via arterial duplex

Right	PSV cm/sec	Waveform
CFA	130	Triphasic
PFA	135	Triphasic
SFA P	103	Triphasic
SFA M	96	Triphasic
SFA D	101	Triphasic
POPA P	125	Triphasic
POPA M	105	Triphasic
POPA D	154	Triphasic
TPT	152	Triphasic
PTA	0	Absent
Peroneal A P	172	Biphasic
ATA	243	

**Impression:** Occlusion of the right PTA. Patent right CFA, PFA, SFA, POPA, TPT. Patent ATA and Peroneal A with mildly diffused velocities throughout.