

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

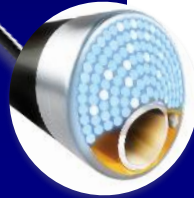
- **Laser ablates without mechanical action or moving parts, making it ideally suited for debulking ISR lesions**

- 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

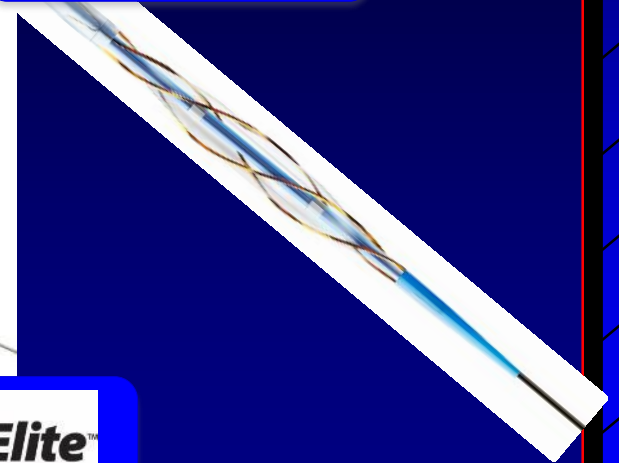
**Peripheral Atherectomy and Specialty
Scoring Balloons**

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 stents¹
- Potential for better stent apposition, leading to reduction in restenosis and stent thrombosis^{2,3}
- 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

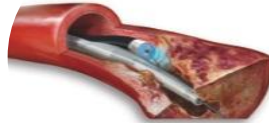
Solving Complex Challenges

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

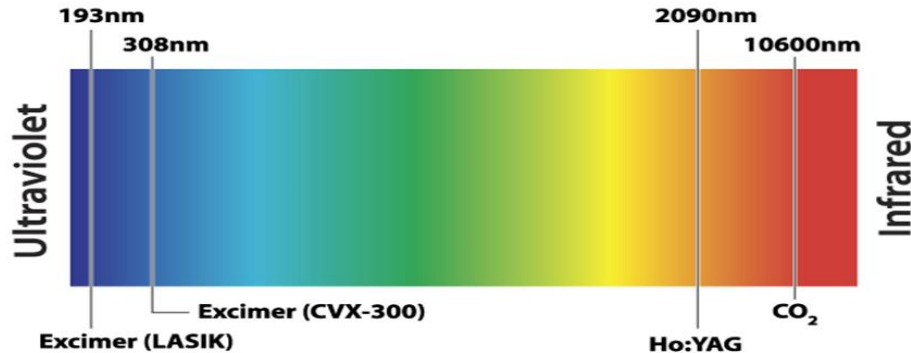
Infrared

Cool

Hot



Spectrum of Light

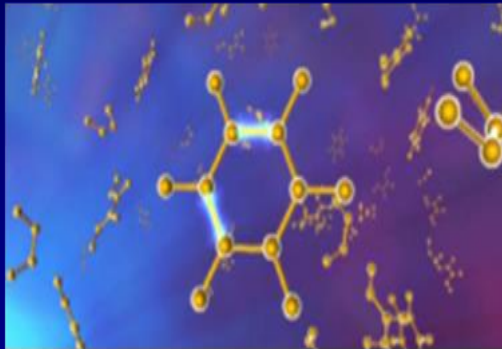


LASER: THREE MECHANISMS OF ACTION

Treat All Morphologies

Photochemical

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



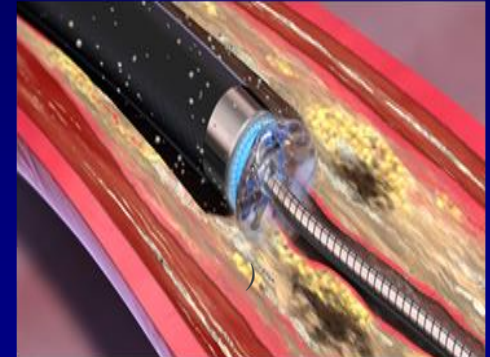
Photothermal

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

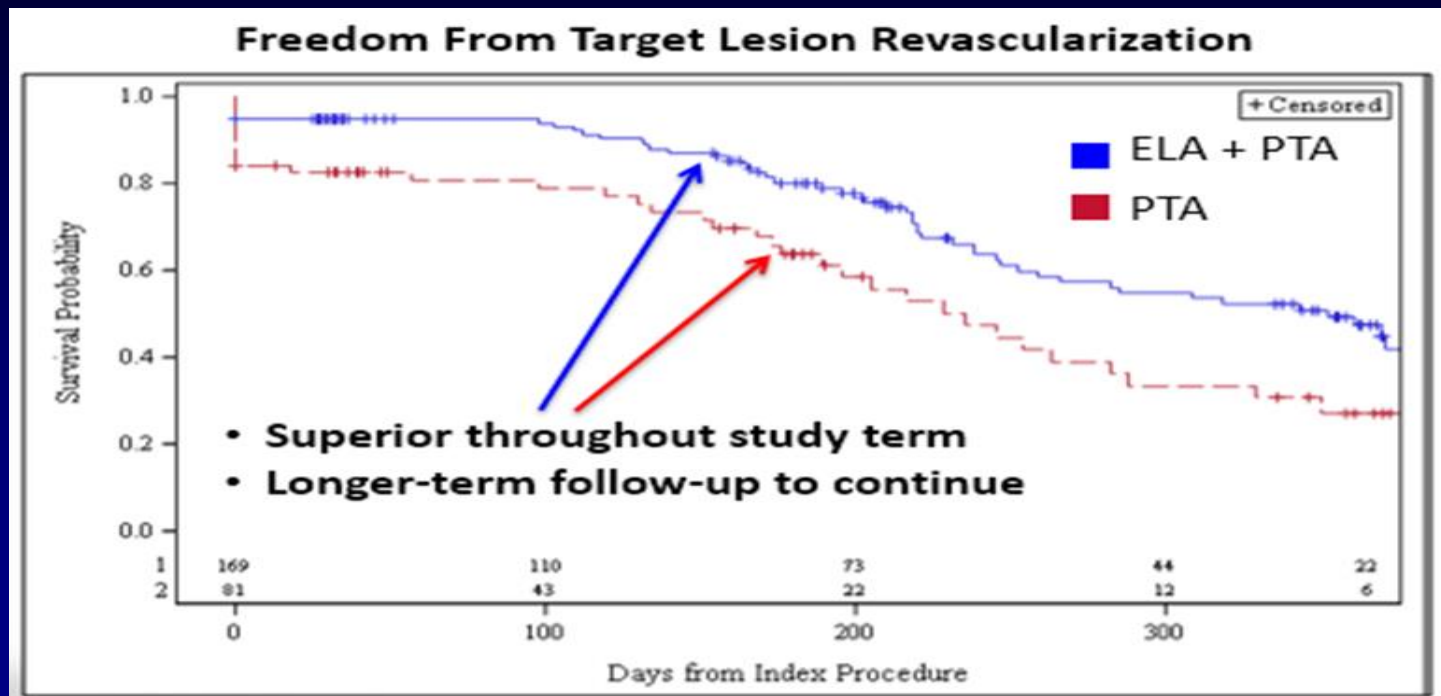
PROVEN: Superior Efficacy and Safety

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
SAFER		
Major adverse events at 30 days	5.8%	20.5%
Major dissection ^{1,2}	0.6%	7.4%
Risk of stent interaction	Minimal	Minimal
MORE EFFECTIVE		
Procedural success	93.5%	83.5%
Freedom from TLR at 6 months	73.5%	51.8%
Additional stenting after treatment	5.3%	11.3% ^{1,2}

SUPERIORITY IN FREEDOM FROM TLR

Consistent Throughout Follow-up Period



Case #1

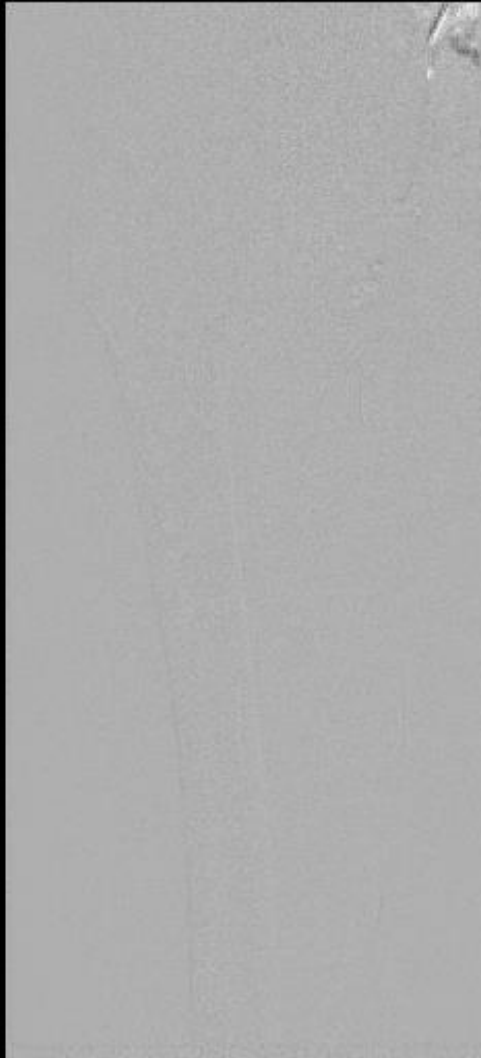
- ▶ 71M, h/o PAD, OSA, gout presents with life-limiting right leg claudication (Rutherford 3), progressively worsening.
- ▶ History of prior RLE intervention ~10y ago at OSH.
- ▶ On ASA81. Former smoker (quit ~6mo ago)
- ▶ Vitals, labs normal
- ▶ Physical exam notable for 2+ palp femoral pulses bilaterally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

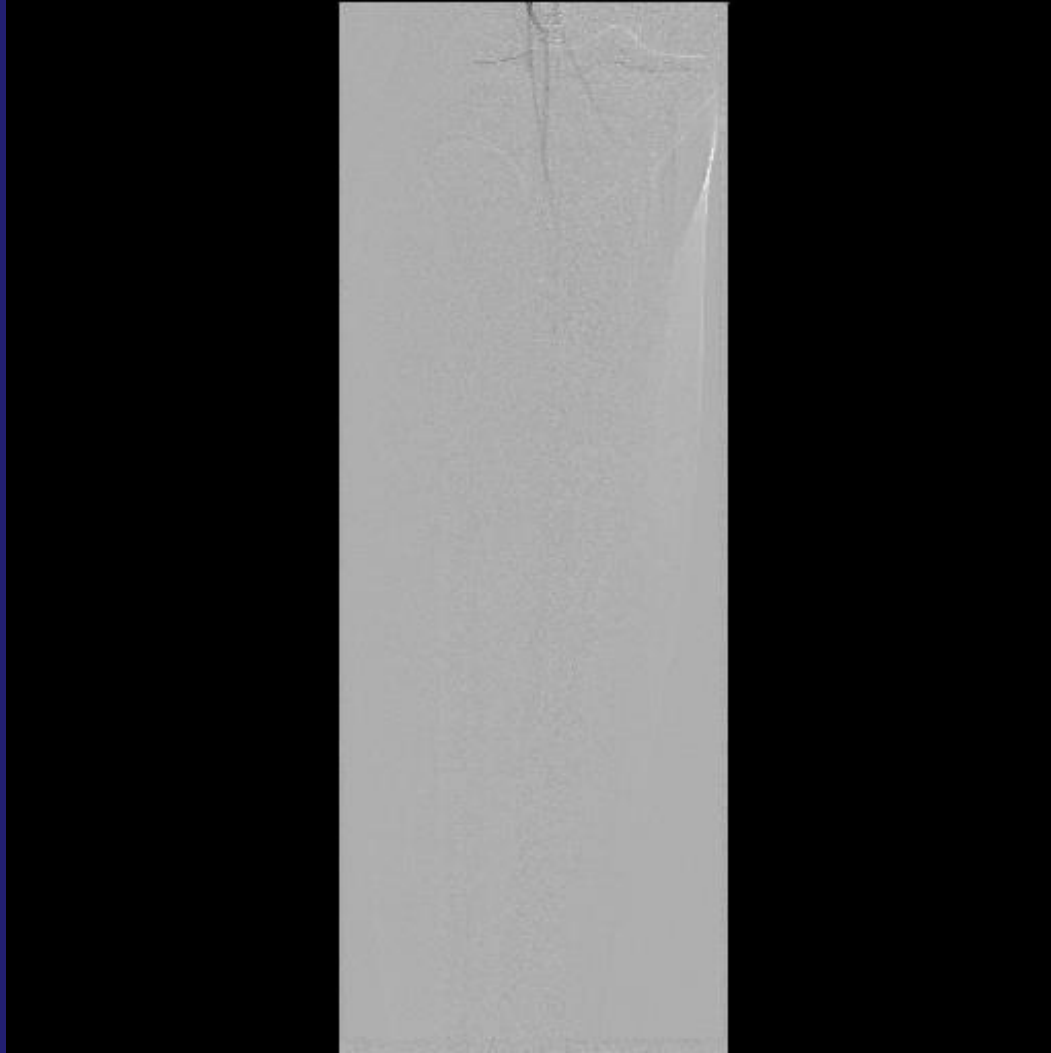
Findings: Densely calcified plaque cluster seen in the popliteal artery with occlusion in proximal to mid portion and reconstitution of flow distally. DPA PSV 15 cm/s.

Case #1

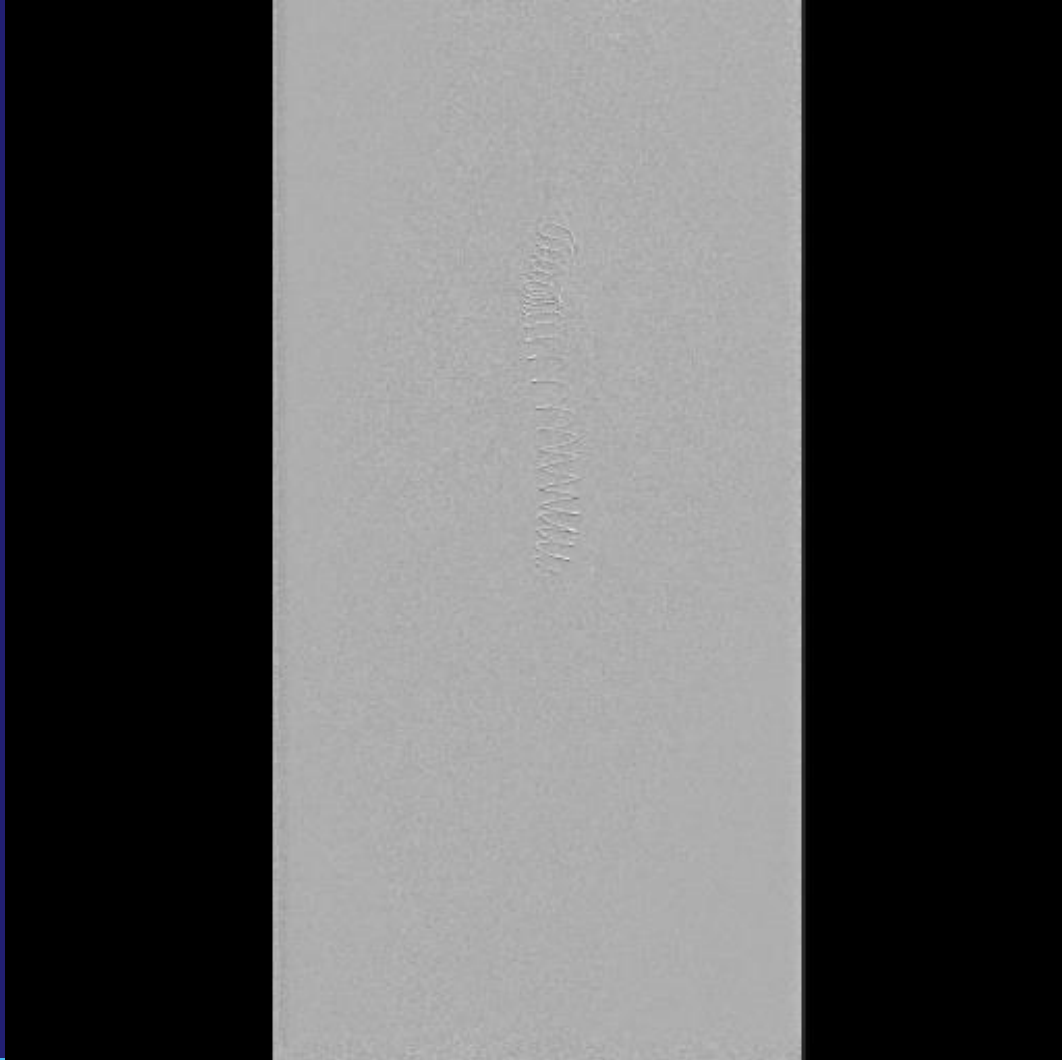


Case #1

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

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

Case #1



Case #1

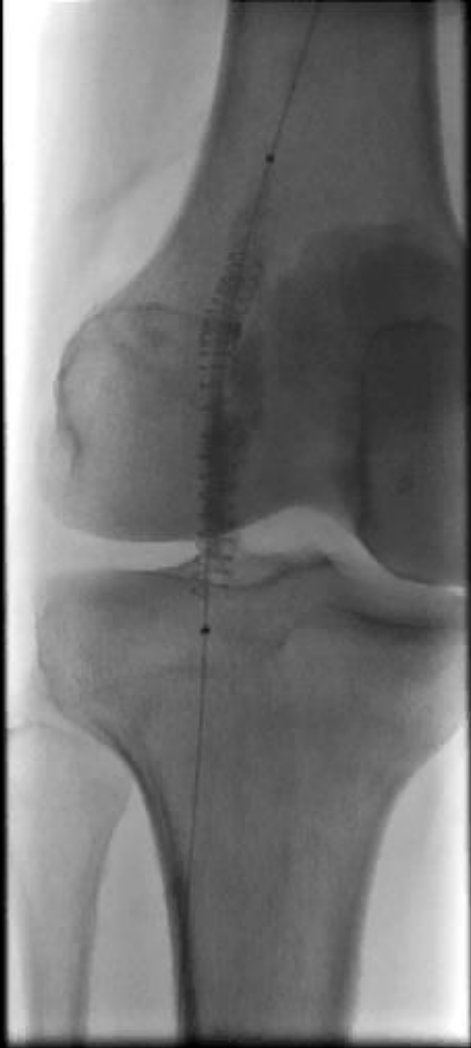
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- ▶ Cross lesion
- ▶ Switch for 0.014 Grand Slam wire
- ▶ Laser atherectomy w Spectranetics 2.0mm OTW

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- ▶ Switch for 0.014 Grand Slam wire
- ▶ Laser atherectomy w Spectranetics 2.0mm OTW – nice luminal gain

Case #1



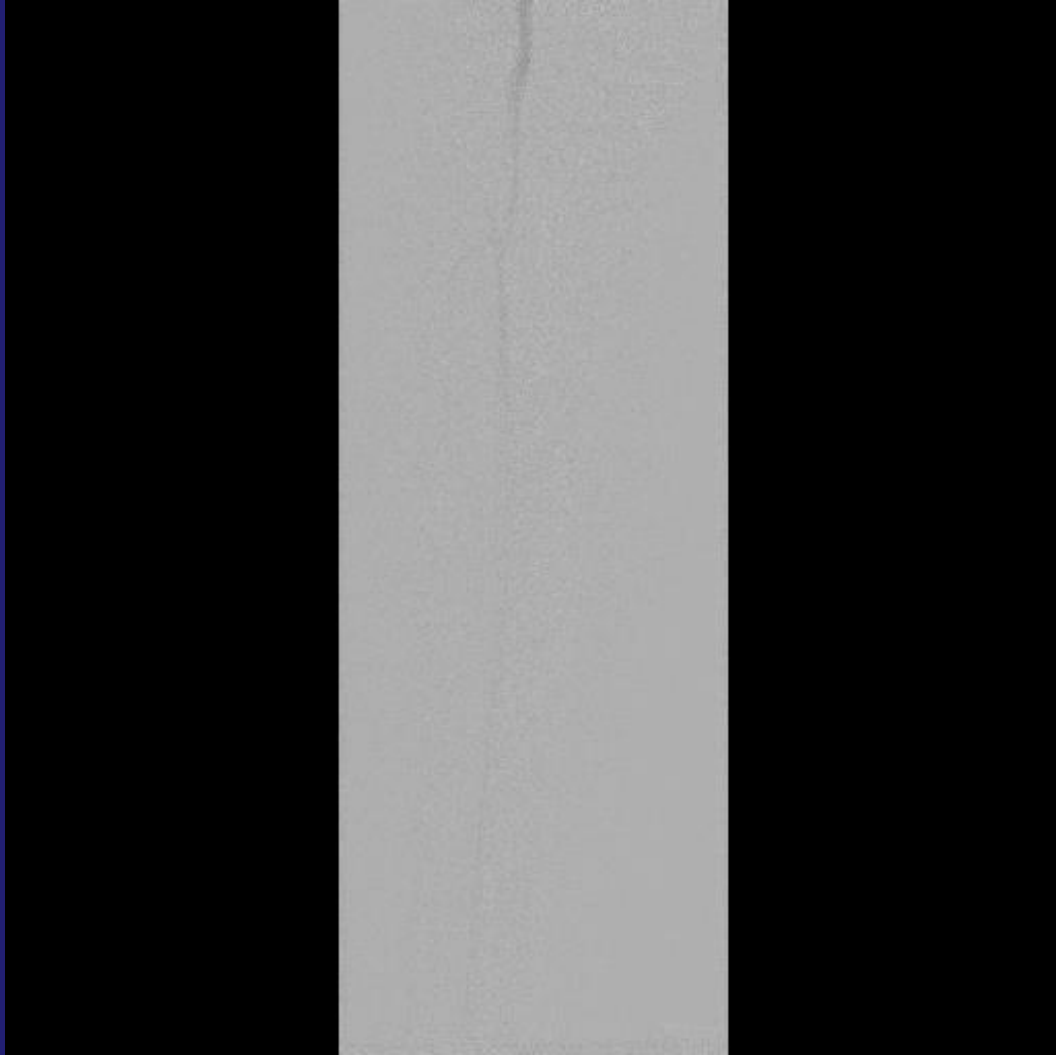
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- ▶ Cross lesion
- ▶ Switch for 0.014 Grand Slam wire
- ▶ Laser atherectomy w Spectranetics 2.0mm OTW
- ▶ Pre-dilate w/ 5mm POBA
- ▶ Finish w/ 6mm DCB

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 2nd 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 2nd 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

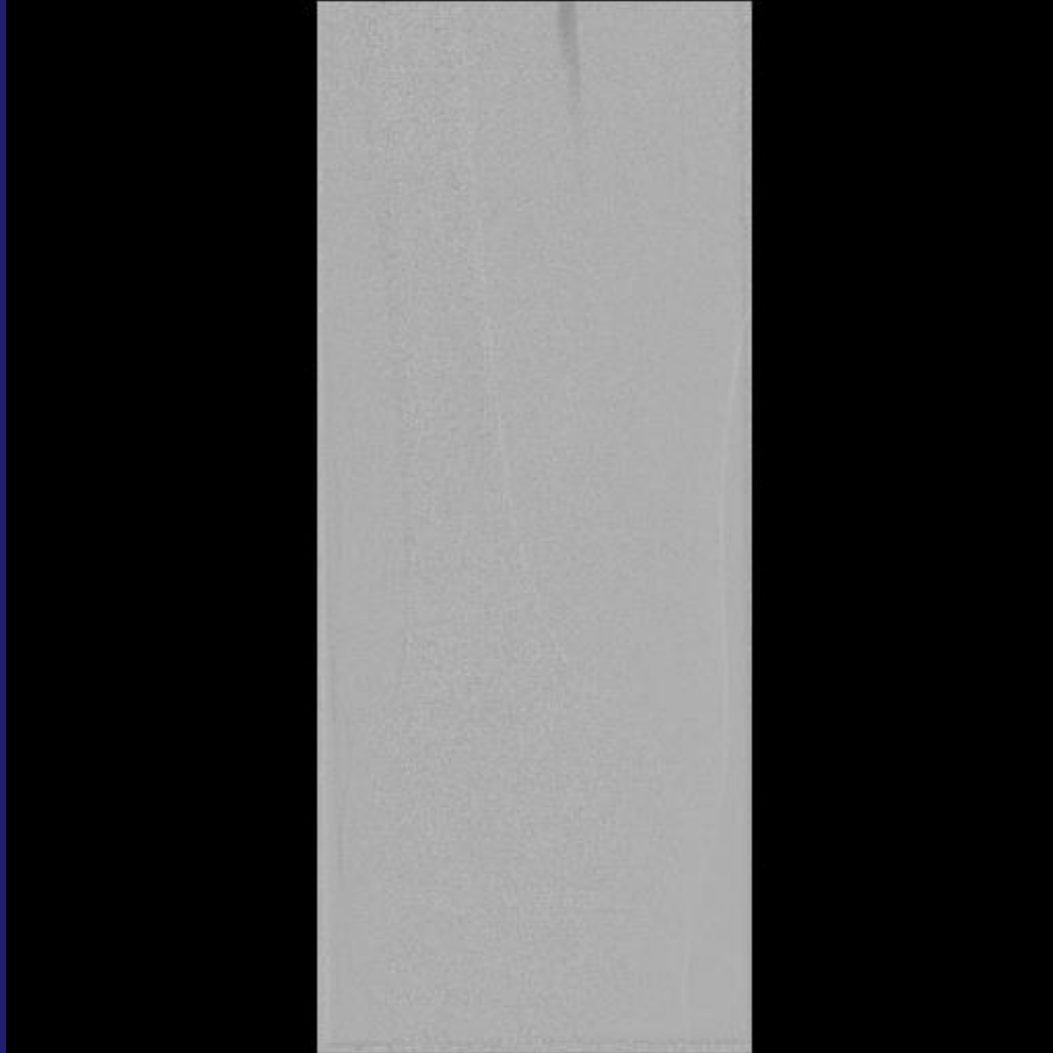
Findings: Unable to detect flow at the right posterior tibial artery. Flow reconstitutes at the posterior tibial artery at the ankle. Significant velocity increases noted at the proximal and mid peroneal artery with a PSV = 318 cm/sec at proximal and 224 cm/sec at mid. Significant velocity increase at 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



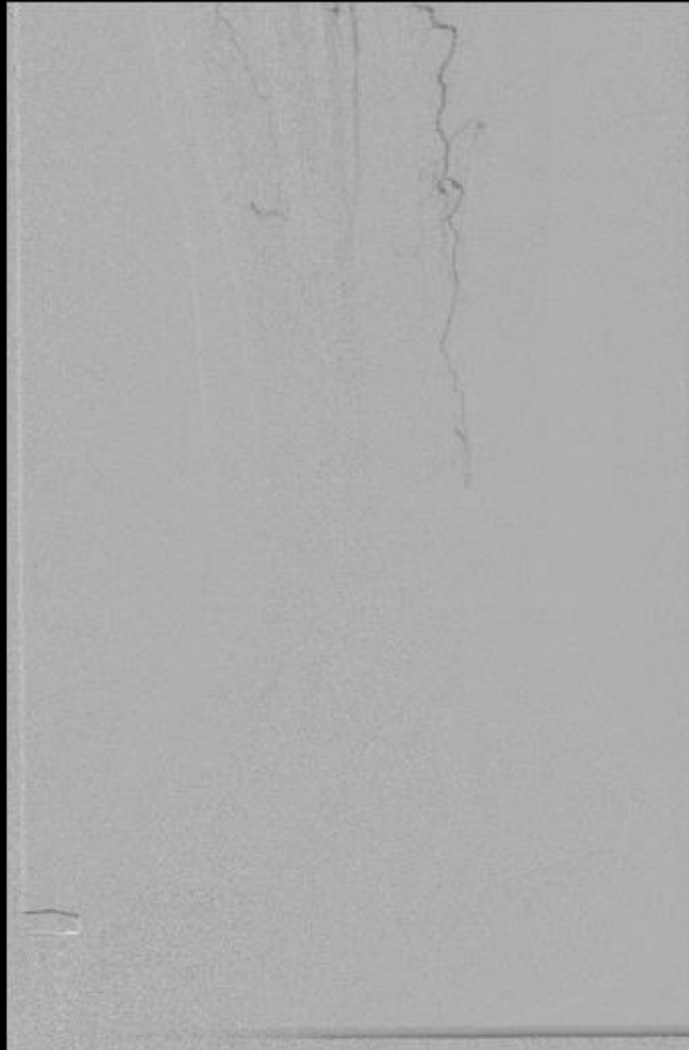
Case #2



Case #2



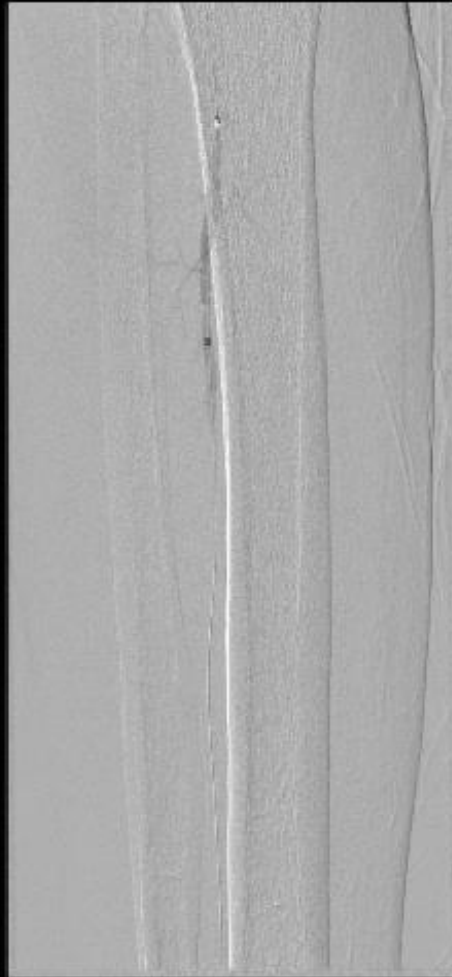
Case #2



Case #2

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

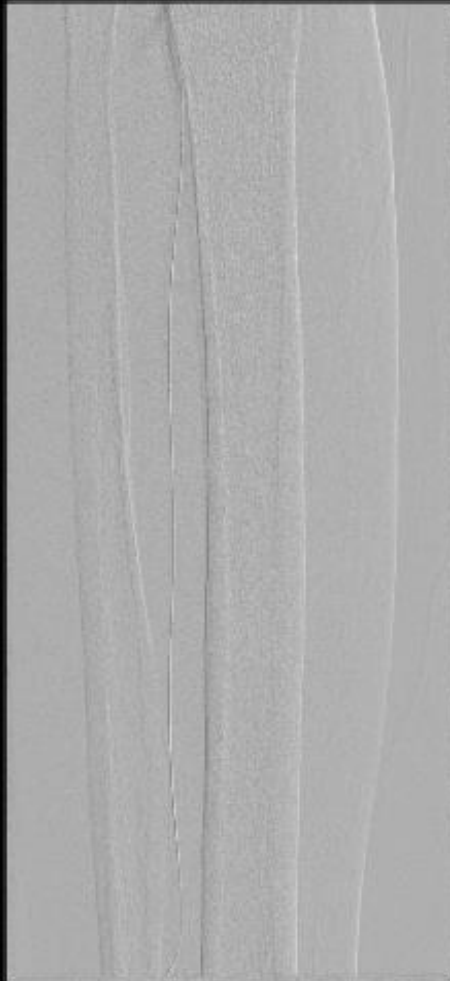
Case #2



Case #2

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

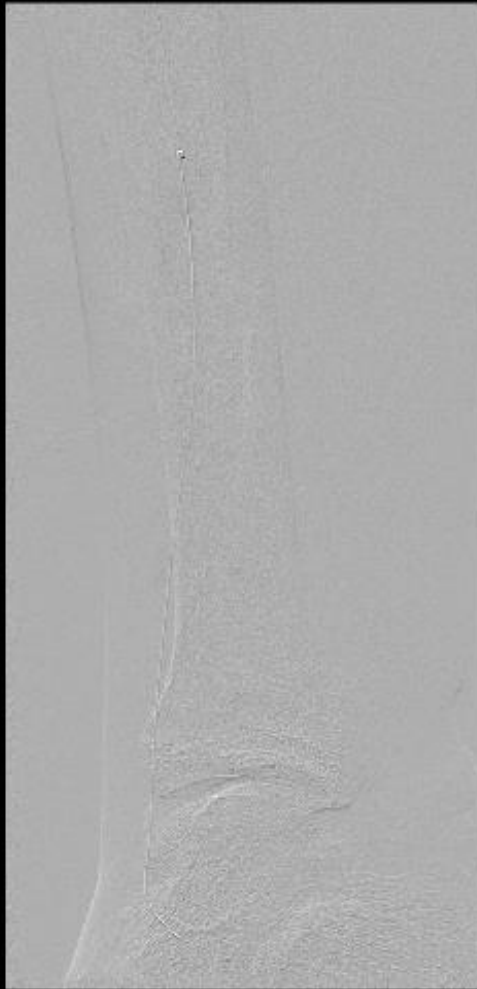
Case #2



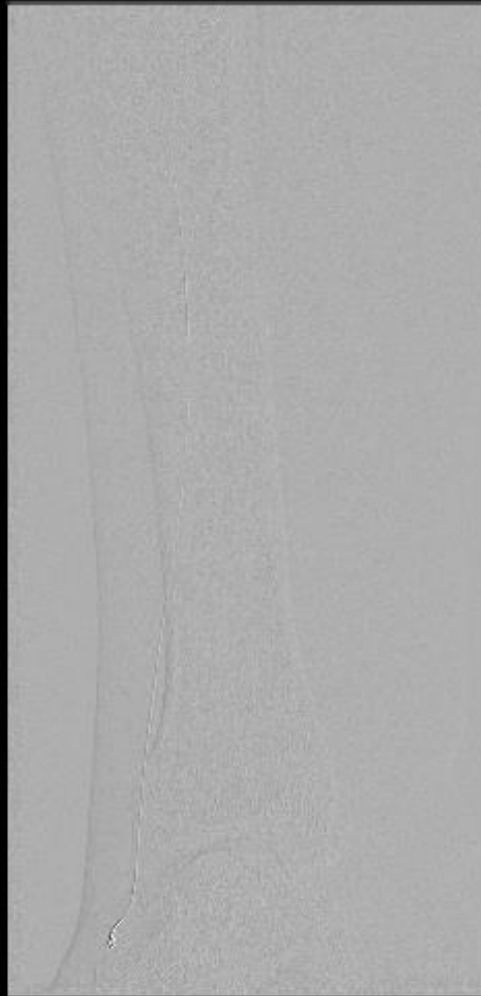
Case #2

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

Case #2



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
- ▶ 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.