

Crossing the Uncrossable: Advanced Strategies for Resistant Lesions in PAD & CLTI

Ashwani Sastry, MD
Sunrise Vascular
North Carolina

Disclosures

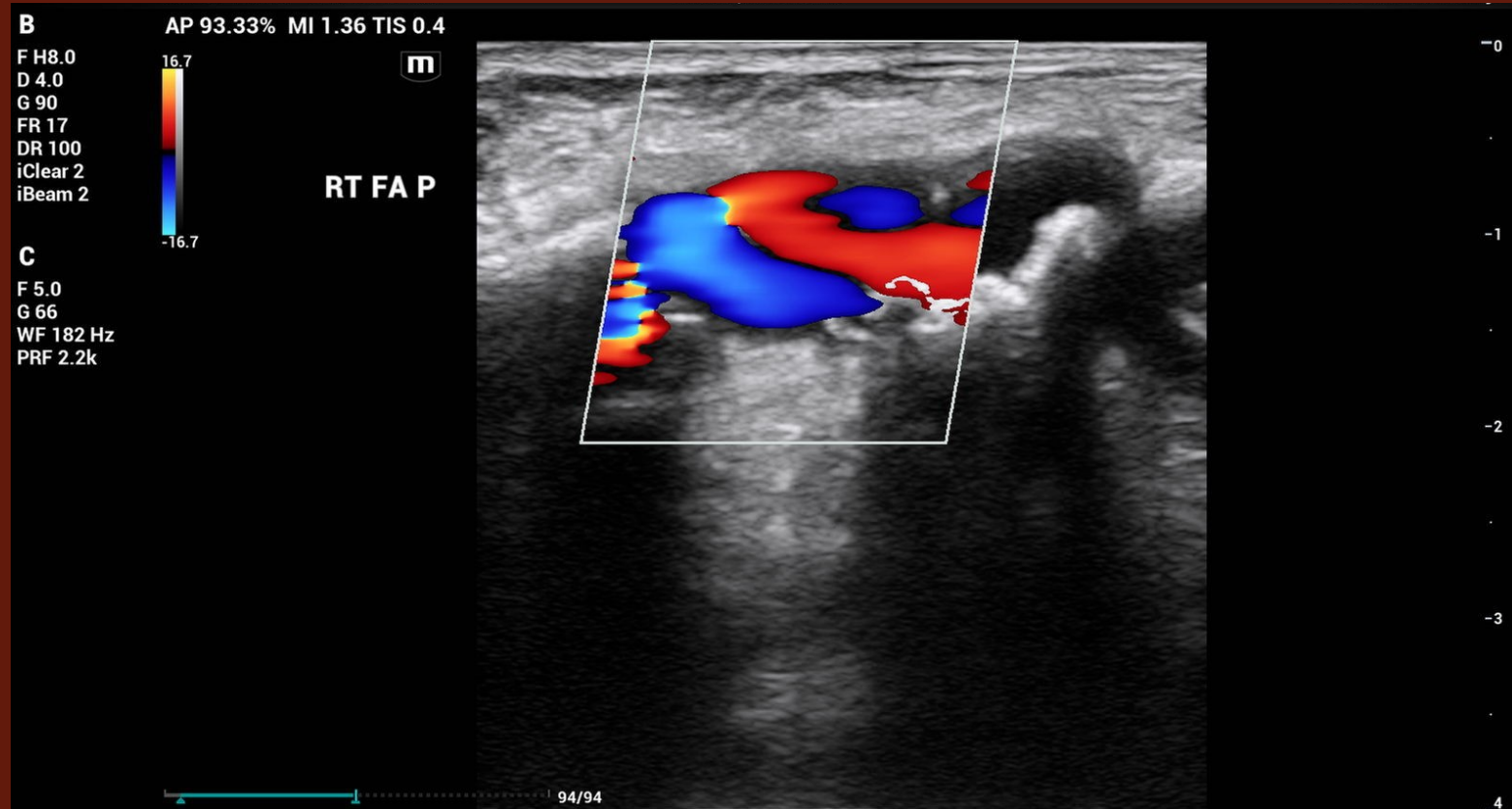
**Asahi Intecc, Reflow Medical, AngioSafe Inc, Chiore Medical,
Hippocratic AI, Provisio Medical, PorTal Inc, DisTal Inc, Vasorum
Inc, Argone Medical**

Case Example

Patient History

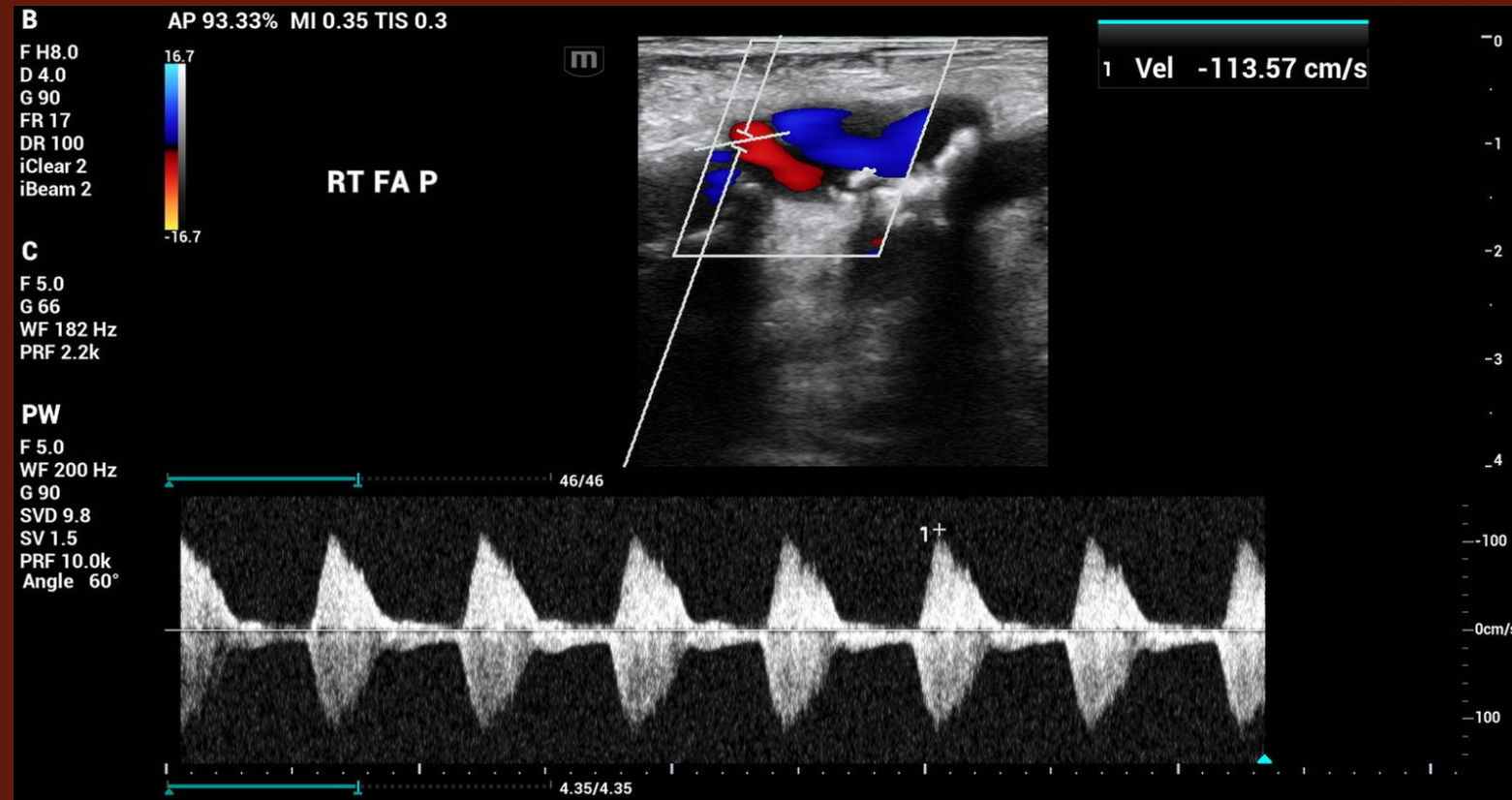
- 91 year old with Rutherford 6 CLI
- Failed fem-distal bypass graft (~ 1 year ago)
- Ultrasound with extreme calcification, SFA occlusion, multi-vessel tibial occlusion
- Hostile femoral vessels with extreme calcification
- Marked rest pain restless leg

Pre Procedure Ultrasound



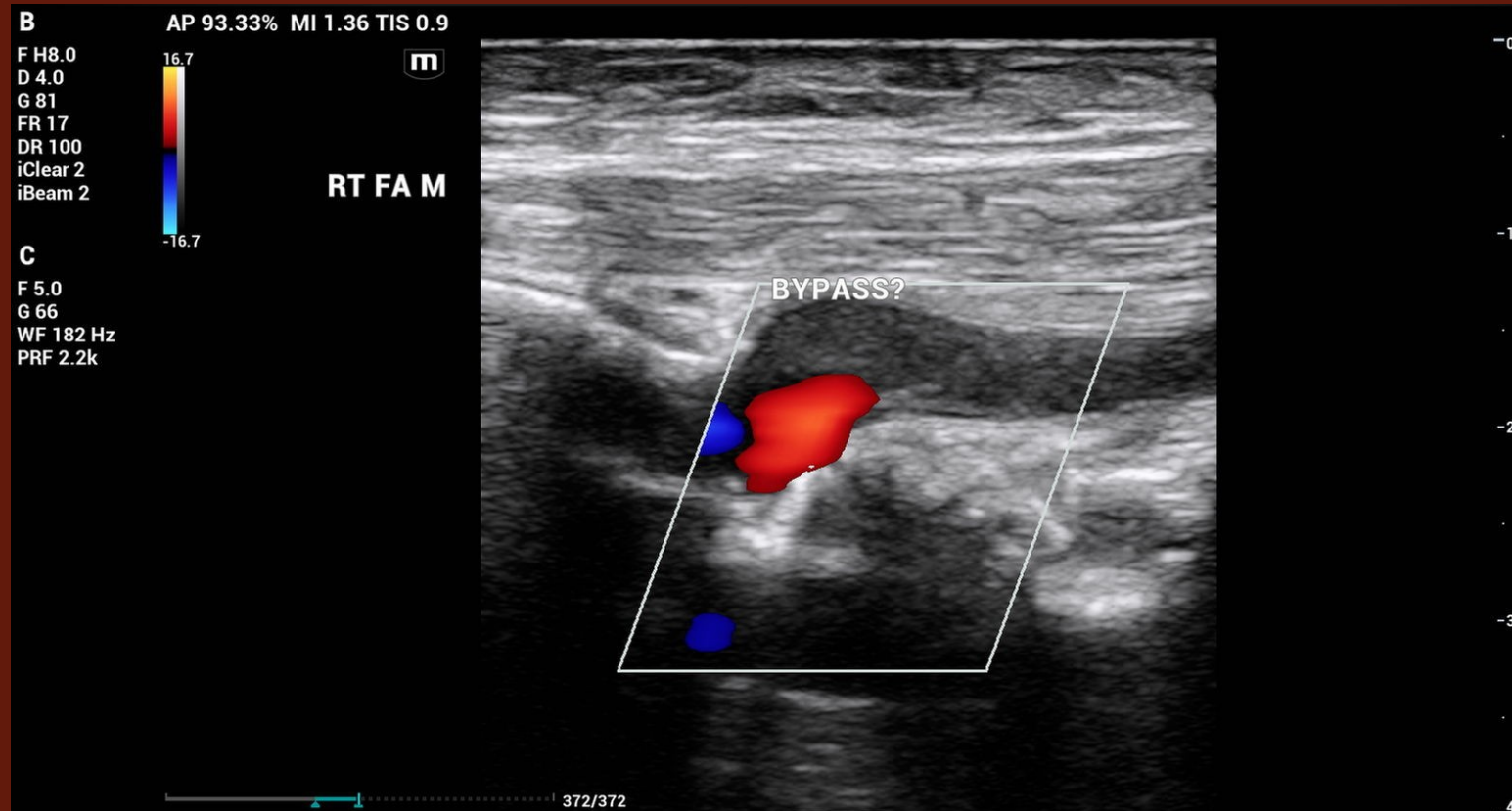
- CFA and prox SFA patent

Pre Procedure Ultrasound



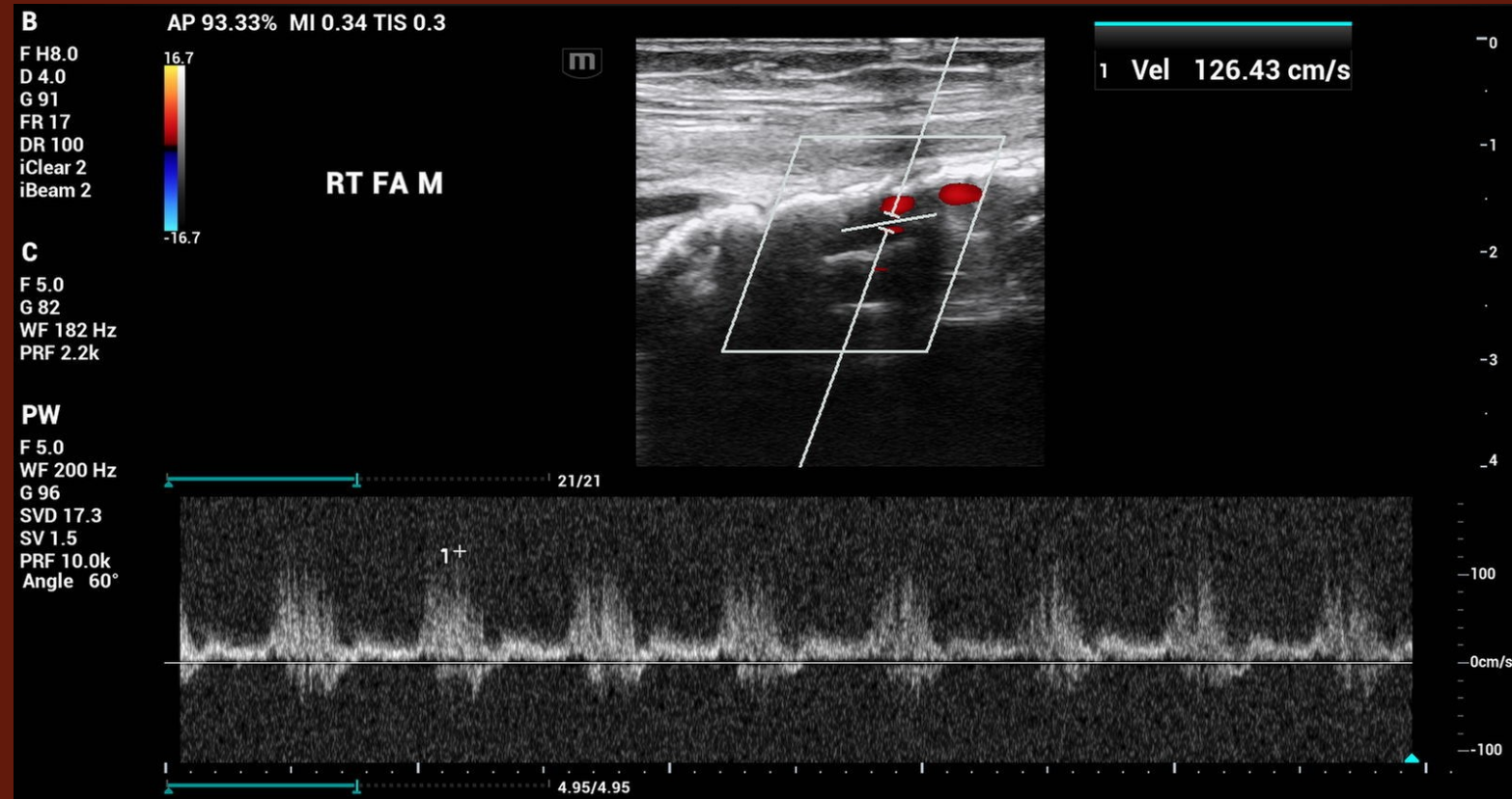
- CFA and prox SFA patent

Pre Procedure Ultrasound



- Bypass graft occlusion (Graft < 1 year old, but not acute graft occlusion)

Pre Procedure Ultrasound



- Significant disease mid SFA, but there is flow

Pre Procedure Ultrasound



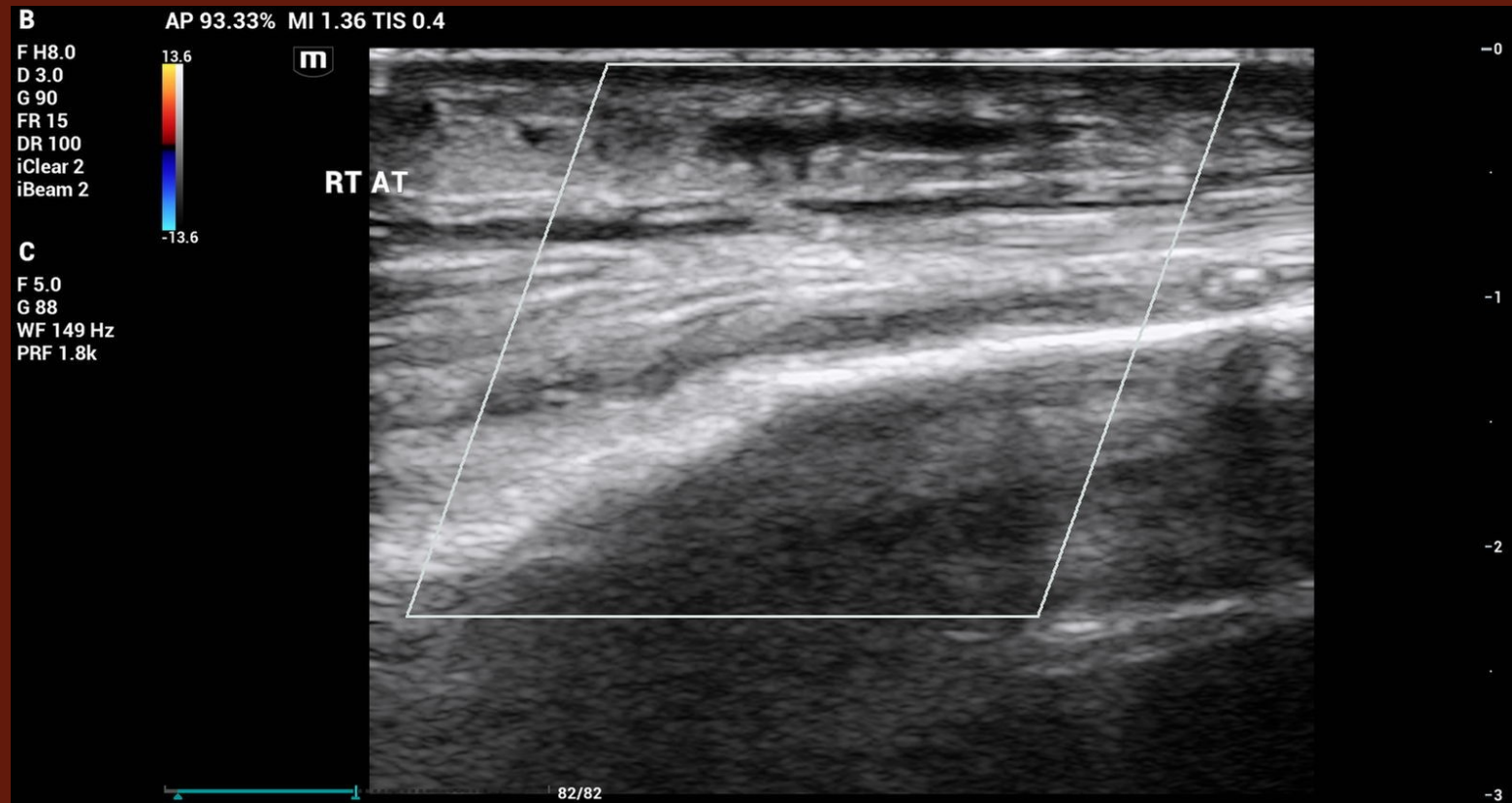
- Extremely calcified, occluded distal SFA

Pre Procedure Ultrasound



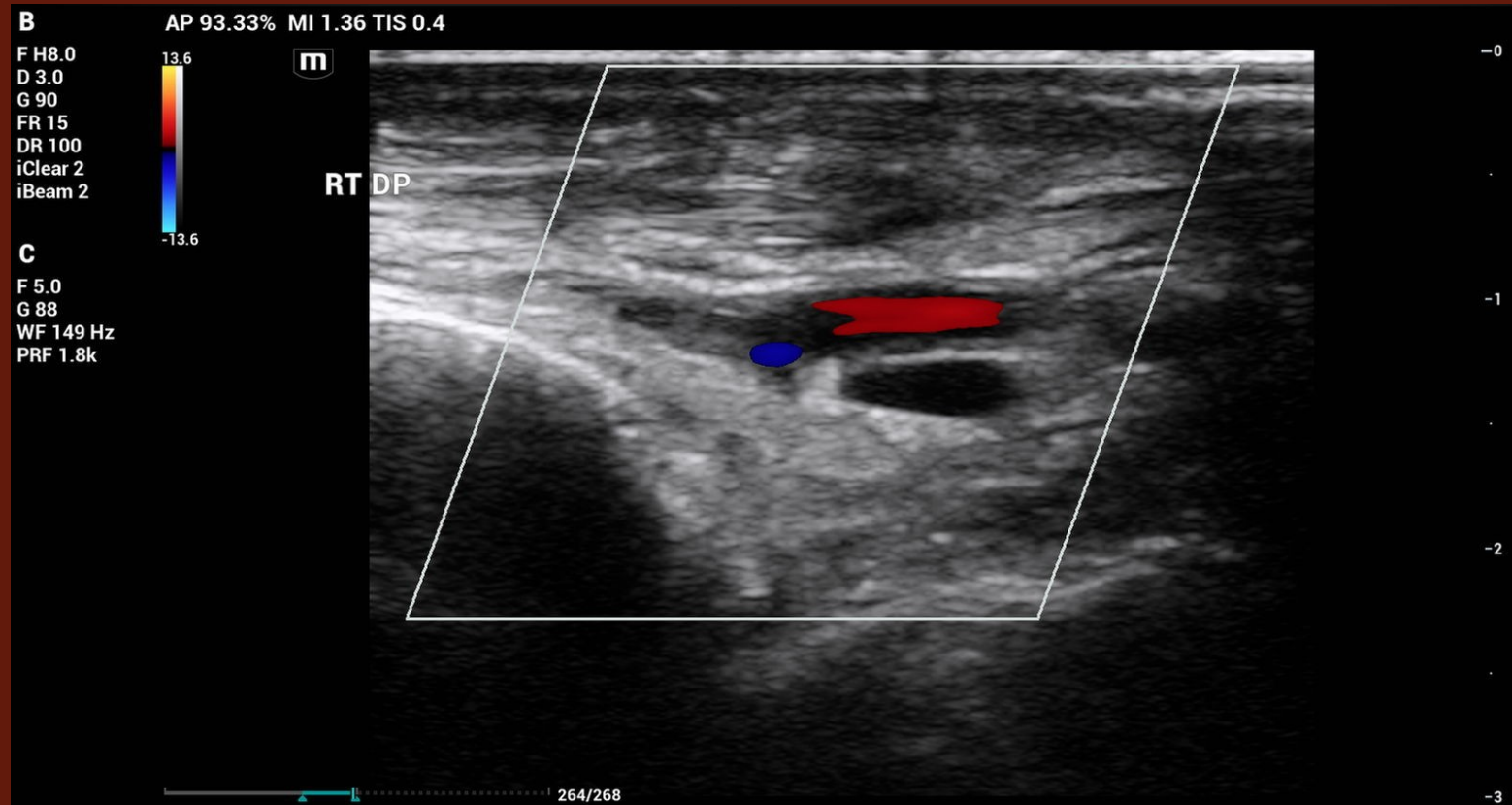
- Distal reconstitution of popliteal with poor collateralization

Pre Procedure Ultrasound



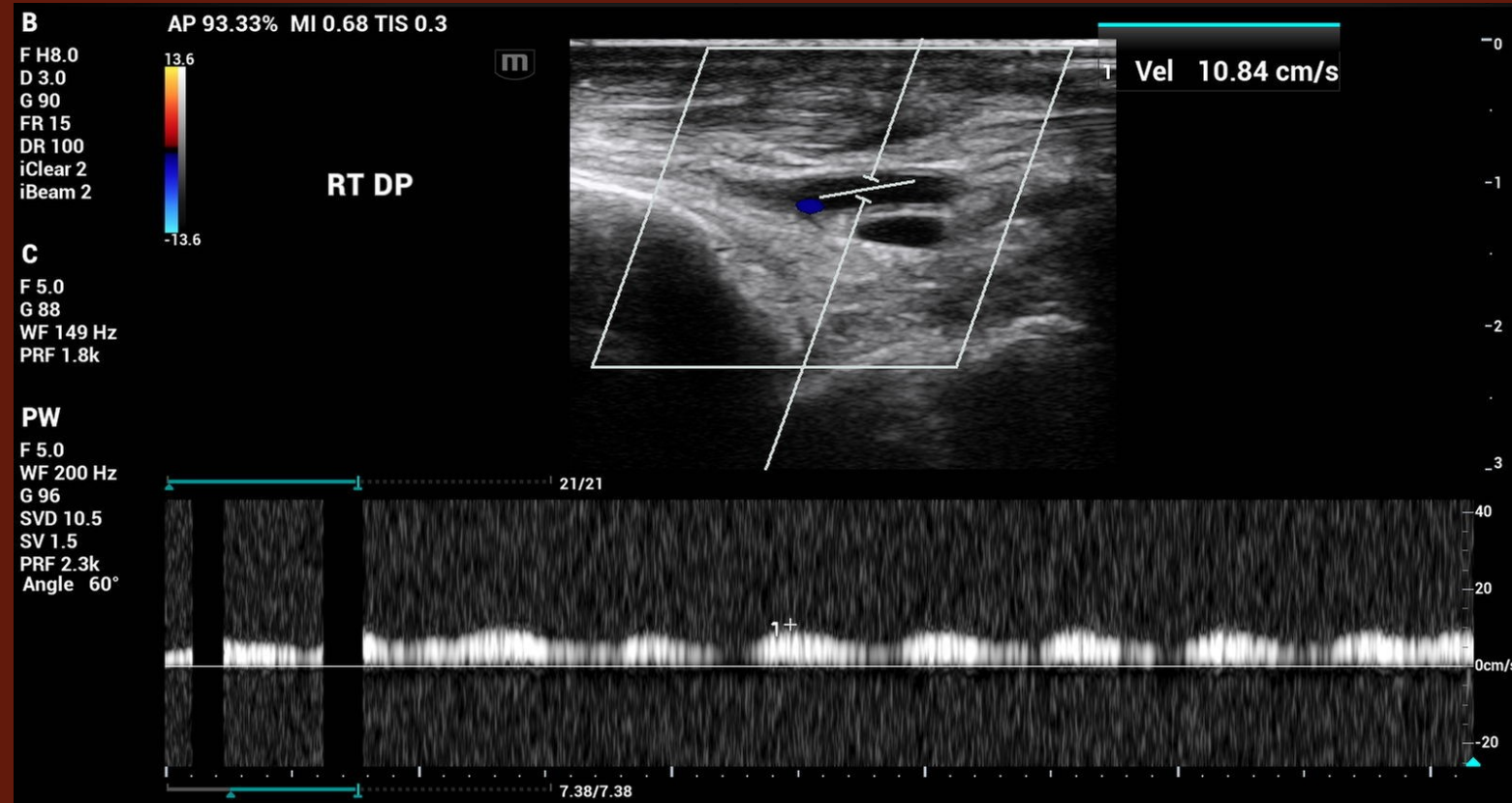
- Long segment occlusion of the anterior tibial artery

Pre Procedure Ultrasound



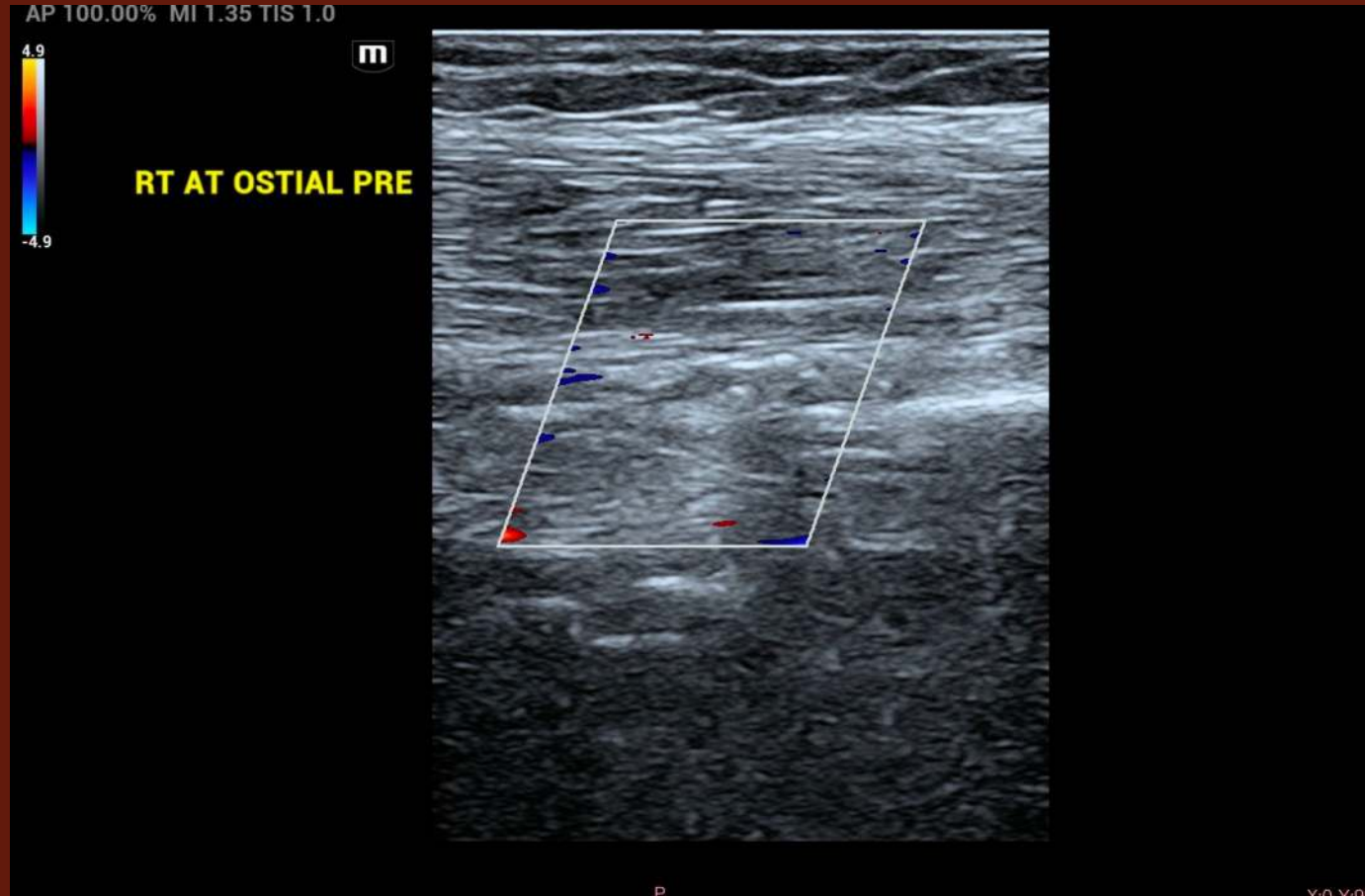
- Foot is alive via DP reconstituted from collaterals; PT occluded distally, Plantar vessels occluded

Pre Procedure Ultrasound



- Extremely diminished flow in DP

Pre Procedure Ultrasound



- Extremely calcified ostial / proximal ATA
- No flow in the ostial ATA
- There is no patent segment in the ostial ATA to reenter – this will be very difficult

Procedural Planning - Considerations

- For a long segment occlusion retrograde crossing is (almost) always easier
- Small female with advanced age, rest pain and inability to keep legs, severely calcified femoral and iliac vessels - increased bleeding risk with femoral approach.
- Reduced ability to achieve linear push with up and over approach, which is critical in such calcified occlusions. Antegrade approach is a consideration but increased risk with severe calcification at the femoral access points.
- Elected to perform occluded vessel access of ATA. Near-zero access site risk (no bleeding risk, no occlusion risk), and maximum linear push. Also no major issues with patient movement or post procedure bedrest
- Based on the ultrasound, crossing will be difficult due to ostial ATA occlusion. Try and plan re-entry point on EVUS even prior to starting. Trying to do this antegrade is unlikely to work.

Occluded Vessel Access - Distal ATA



- Occluded vessel access of distal ATA (zero bleeding risk, zero occlusion risk, highest likelihood of success)
- My preferred wires – 014 / 018 Crosslead Pro, 014/018 Mongo ES



CROSSLEAD® Pro 018

Product Specifications



Catalog No.	Tip Shape	Length	Coil Length	Coating
CPR01820S	Straight	200 cm	3cm	PJ + Hydrophilic Coating (SLIP-COAT®) 12cm
CPR01820P	Pre-shape	200 cm	3cm	PJ + Hydrophilic Coating (SLIP-COAT®) 12cm
CPR01830S	Straight	300 cm	3cm	PJ + Hydrophilic Coating (SLIP-COAT®) 12cm
CPR01830P	Pre-shape	300 cm	3cm	PJ + Hydrophilic Coating (SLIP-COAT®) 12cm



CROSSLEAD® Pro 018

Tip Durability



	Before	After
CROSSLEAD® Pro 018		
Asahi Gladius® Mongo® 18 PV ES		
V-18™		

Test method



TEST METHOD: After pushing it in until the tip formed a small loop, the guidewire was removed and the extent of change in the tip shape was recorded.



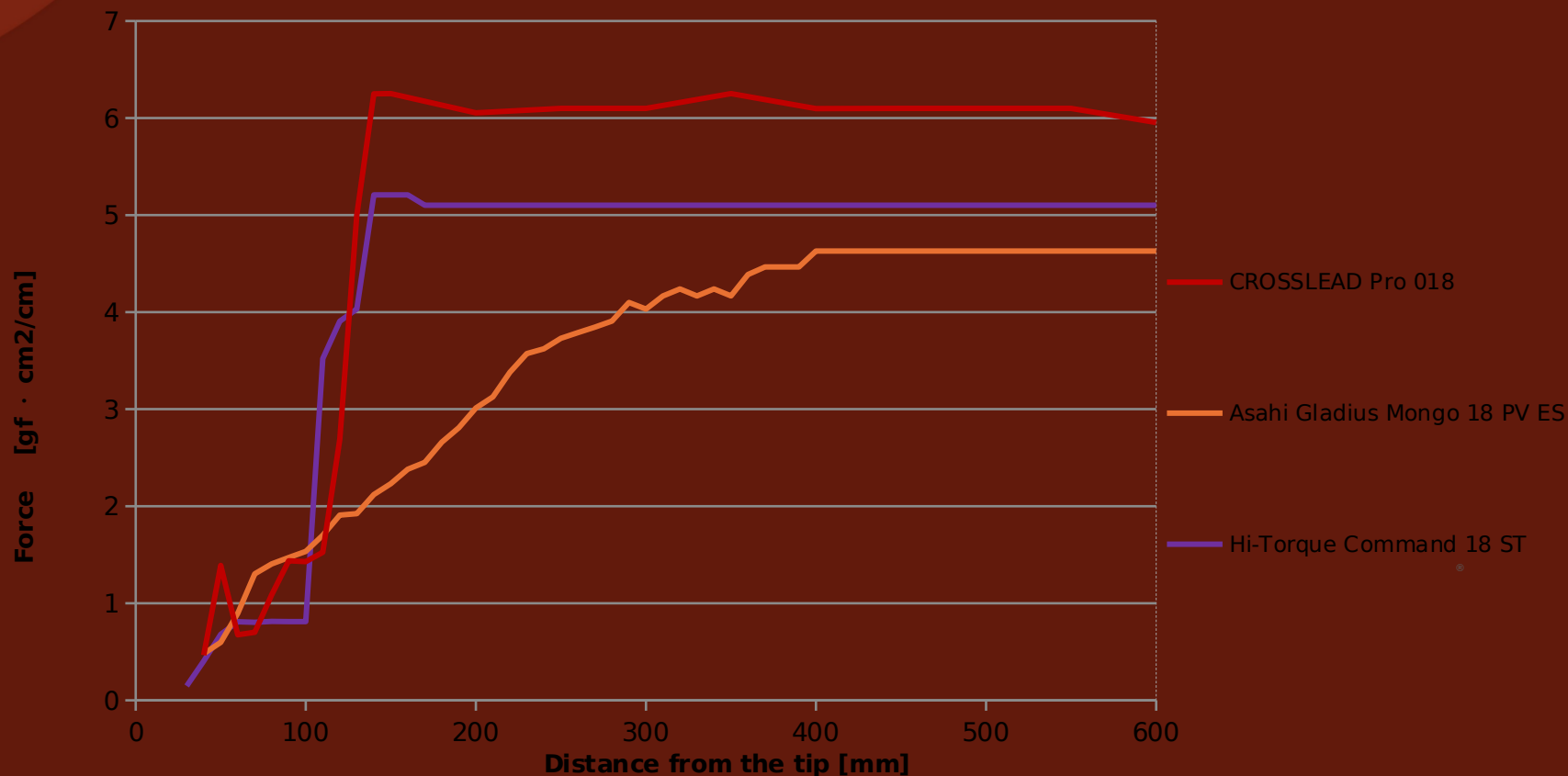
CROSSLEAD Pro 018 has more durability than SUS core wires

The above data was (All the data were) obtained by company standardized test, which may differ from industry standardized tests.
The above data (All the data) does not prove that all devices have exactly the same performance with the samples used for these tests.

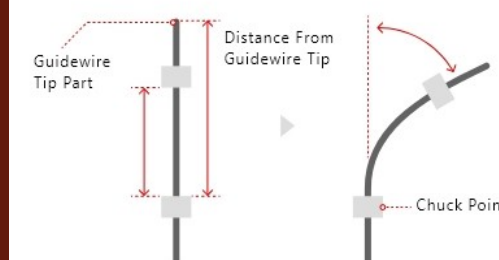


CROSSLEAD® Pro 018

Shaft Support



TEST METHOD: The shaft is fixed, and the reaction force against bending is measured.



CROSSLEAD® Pro 018 delivers good shaft support, leading to good pushability and stable device delivery

The above data was (All the data were) obtained by company standardized test, which may differ from industry standardized tests.
The above data (All the data) does not prove that all devices have exactly the same performance with the samples used for these tests.



CROSSLEAD® Pro 018

Takeaways

- Nitinol core creates unique shapeability while maintaining durability
- Can loop for subintimal crossing and still salvage wire afterwards and continue to use
- Maximal shaft support of any 014 / 018 wire on the market – allows tracking equipment “bareback” over the wire, even 014 wire / balloon combination.
- Can often achieve a one wire case even in very complex anatomy

ATA Occlusion Wiring



- Looped wire advanced proximally progressing well until proximal segment. Follow wire on EVUS to make sure not diverting extraluminal.
- Stop at point of significant resistance, don't just shove the looped wire out of vessel
- Advance microcatheter and get imaging. My microcatheter of choice for "bareback" advancement - Angled Crosswalk 018

ATA Ostial Occlusion



- Imaging via crosswalk 018 at ostium reveals luminal status with small branches visible
- Ostial ATA occlusion with extreme calcification

Ostial AT Occlusion Into Popliteal



- This is the most anatomically challenging location due to acute angle of AT and Popliteal
- Once subintimal in the popliteal likelihood of success drops significantly
- Wire escalation – Astato 40 initially, given extreme calcification. More acute bend then the usual CTO bend given angle of popliteal to AT
- Angled crosswalk 018 to help direct

Ostial AT Occlusion Into Popliteal



- To some extent this looks correct, but checking in multiple angulations, the wire does not respect the calcium outline
- What other options are there?
 - Can switch to looped wire technique, will likely windup subintimal in the popliteal and need to reenter, which is not optimal. Stiffer wire to penetrate lumenally ?

0.014"

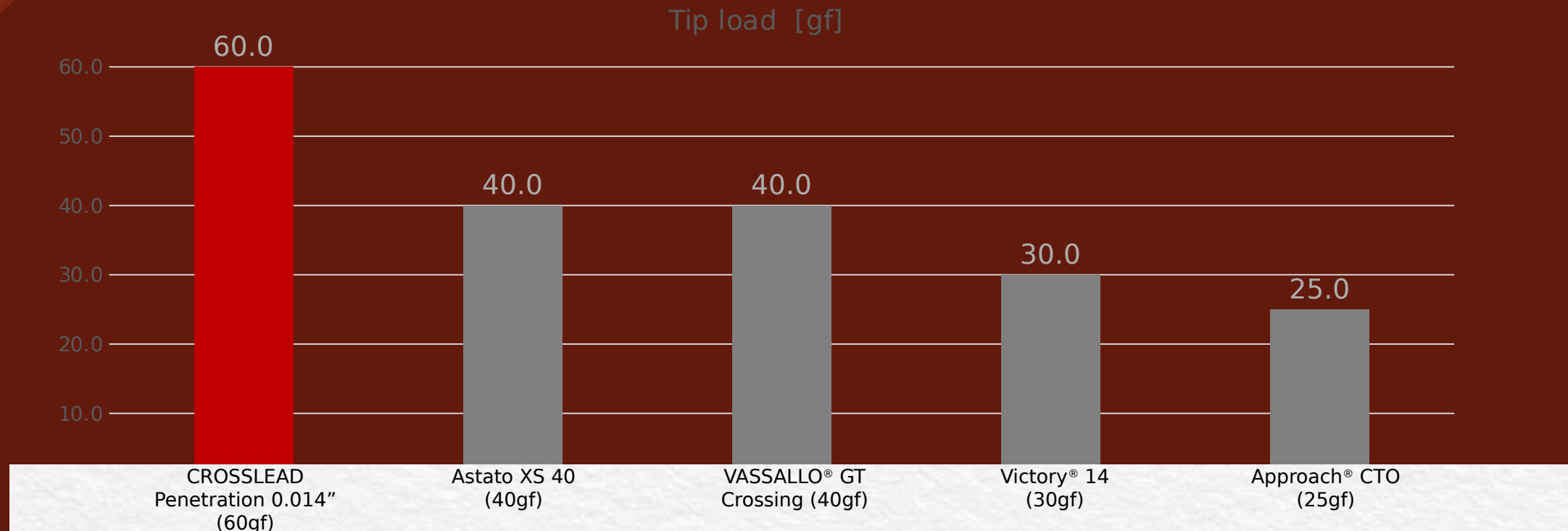
Tip Load Test

(0.014" wires)

✓ High tip load

Unique tip construction

High effective penetration force



CROSSLEAD Penetration offers the highest tip load available on the market*¹.

*¹ As of September 2024

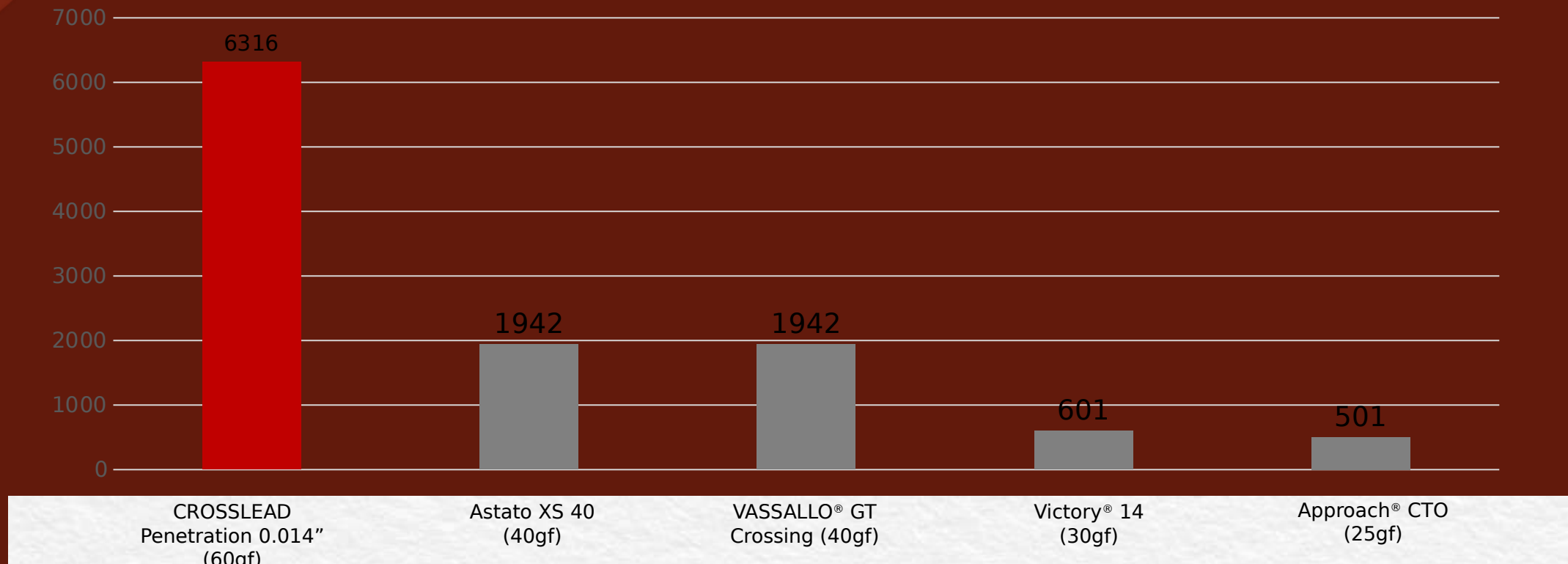
0.014"

Effective Penetration Force

(0.014" wires)

- High tip load
- Unique tip construction
- ✓ High effective penetration force

Effective Penetration Force (gf/mm2)



Enhanced penetration ability & penetration force

Ostial AT Occlusion into Popliteal



- Escalate to 60 gm penetration wire (I prefer 014 as easier to track equipment after crossing)
- Calcium landmarks for wire manipulation, in multiple angulated views

Liberal Use of EVUS with Penetration Wire



Penetration wire is across the occlusion / intraluminal

... But then diverts out

The wire is so stiff that it will penetrate virtually any calcium, but tends to go straight line

exercise caution at the ostial AT

Success!



- Wire progression stalls at this point

Popliteal Occlusion



- Calcified popliteal occlusion and distal runoff - nonexistent
- Crosswalk 018 advances after balloon dilation with 1.25 parafleet balloon

SFA / Popliteal occlusion wiring



- Probing with 60 gm penetration wire (014, preshaped)
- Calcium landmarks
- Wire is uncoated distally, designed to grip CTO rather than slide and go subintimal

Cap Engagement - Tip Construction

High tip load

✓ Unique tip construction

High effective penetration force

What's new?

Unique distal tip construction designed for successful cap engagement and penetration

FEATURE 1

Uncoated Distal Tip
Improve Cap Engagement



FEATURE 2

**Micro-cone Tip
& Tapered Coil**
Enhanced Penetration Force



0.014"

Cap Engagement Test

(0.014" wires)

High tip load

✓ Unique tip construction

High effective penetration force



**CROSSLEAD
Penetration**
0.014"
(60 gf)



Astat XS 40
(40 gf)



Victory® 14
(30 gf)



Approach® CTO
(25 gf)



**VASSALLO® GT
Crossing**
(40 gf)

CROSSLEAD Penetration is designed to enhance lesion cap engagement and minimize slipping on the lesion surface.

0.014"

Pre-shaped Tip

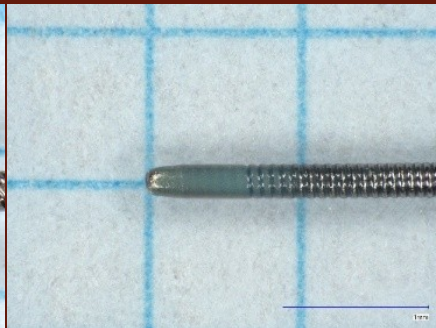
(0.014" wires)

CROSSLEAD
Penetration 0.014"
(60 gf)



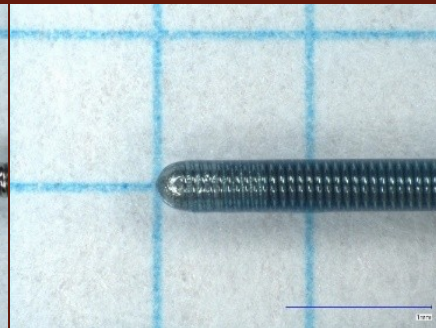
Pre-shape length: 1.4 mm
Pre-shape angle: 20°
Tapered length: 2 cm

Astato XS 40
(40 gf)



Tapered length: 2 cm
(Only straight type)

Victory® 14
(30 gf)



No tapered part
(Only straight type)

Approach® CTO
(25 gf)



*Tapered core length: 18 cm
(Only straight type)

VASSALLO® GT
Crossing
(40 gf)



Tapered length: 1.5 cm
(Only straight type)

Only ASAHI Offers Pre-shaped Tip

*Victory®14 data from Boston Scientific® web page.
*Vassallo®GT 14 G40 data from Cordis® web page.
*Approach® CTO data from COOK Medical web page.

SFA / Popliteal occlusion wiring



- Success with penetration wire
- Calcium landmarks, EVUS guidance

SFA / Popliteal Occlusion - Success



- Successful passage of 60 gm penetration wire

SFA / Popliteal Occlusion – EVUS



- Successful passage of 60 gm penetration wire (different procedure, illustrative)
- With good EVUS & Fluoro imaging and retrograde approach, near 100% success in crossing

Proximal SFA grossly patent



- Proximal SFA is grossly patent

IVUS guidance



- IVUS guidance to determine what areas to treat, and not to treat
- Vessel Sizing

IVUS guidance



- IVUS guidance - especially useful for iliac evaluation when using pedal approach

Serial Dilation



- NC balloon to high pressure – good expansion

Serial Dilation - DCB



- Serial dilation – DCB angioplasty

Serial Dilation - DCB



- From position – can see why pedal access is often the best approach
- Lower sedation requirement, significantly lower risk, greater patient comfort, greater in-line push through complex occlusions

Final Angiograms



- Prox SFA post

Final Angiograms



- SFA occlusion post treatment

Final Angiograms



- AT final

Final Angiograms



- Will it be enough?

Occluded Vessel Access – Pedal / Femoral

- 1. Liberal use of occluded vessel access points - occluded vessel access of the tibial vessels**
- 2. Occluded vessel access of SFA / pop - can be either very proximally (traditional “Schmidt” technique), or mid / distal access.**
- 3. Prox SFA access to pass luminally into the CFA, bareback balloon to create channel at the reentry point, and then complete the case**
- 4. Occluded vessel access of the mid / distal SFA to cross a long segment occlusion retrograde when the tibials are small, or can be used in conjunction with proximal SFA occluded access**
- 5. Crosslead Pro is extremely helpful with occluded vessel access technique**

Conclusions

- 1. With advancements in wire technology, (almost) everything is crossable - between multiple occluded vessel access points, adequate imaging guidance (EVUS + Fluoro), penetration wire, and low profile atherectomy and crossing balloons**
- 2. Looping a wire and shoving forward will usually not work in the really complex / calcified lesions because the path of least resistance is extravascular when the vessel is obliterated with calcium.**
- 3. 60 gm penetration wire will go where you ask it to - the key is precise identification of the target destination point**
- 4. Guidance by calcium landmarks (favored), EVUS (favored), or visualization from another access point (less favorable, IMHO due to second access point associated complexity**