

Utilizing Pioneer Plus & IVUS supporting improved outcomes

Frank R. Arko III, MD

Sanger Heart and Vascular Institute

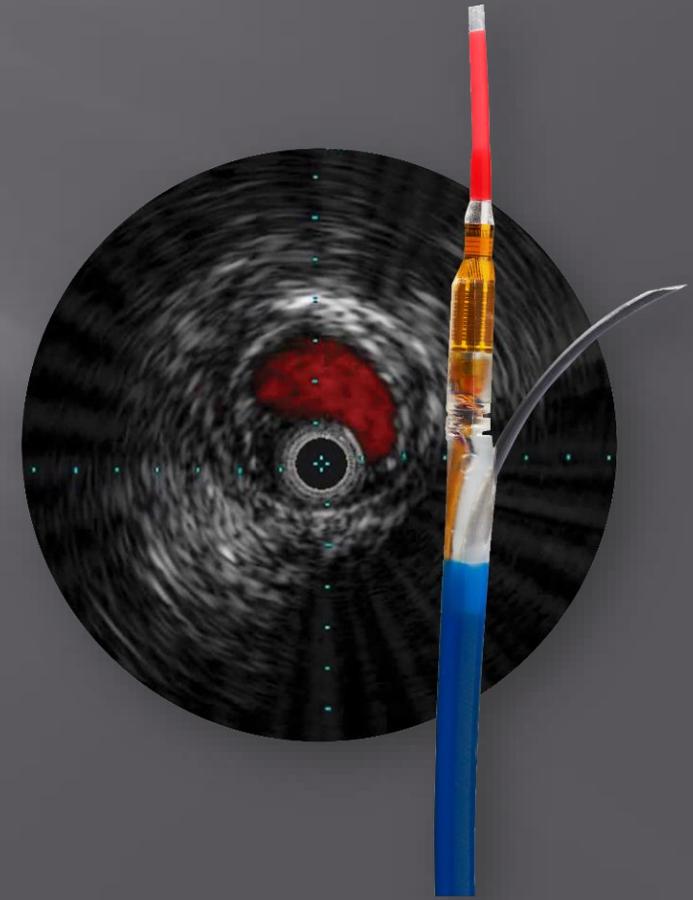
Carolinas Medical Center

Charlotte, NC

Division of Vascular and Endovascular Surgery

Department of Cardiovascular and Thoracic Surgery

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Pioneer Plus: True Lumen Return Goals

Controlled Re-entry

- Increase angioplasty success rates
- Reduce side branch occlusion
- Reduce overall treated length
- Reduce chance of sending patient to surgery
- Reduce procedure-related variables such as time, fluoro, ancillary devices, etc.

Pioneer Plus: IVUS-guided clarity to true lumen re-entry

The
only
re-entry device
with IVUS and
ChromaFlo



Procedural time
for effective re-entry
ranging from
6-10
minutes¹



Subintimal angioplasty
procedural success rate
from
95 to 100%²



Pioneer Plus is the only IVUS-guided re-entry catheter delivering quick, confident and controlled true lumen re-entry.³

1. Saket R., Razavi, M., Padidar A., et al. Novel Intravascular Ultrasound-Guided Methods to Create Transintimal Arterial Communications: Initial Experience in Peripheral Occlusive Disease and Aortic Dissection. J Endovasc Ther. 2004; 11: 274-280.

2. Al-Ameri, H et al. Peripheral Chronic Total Occlusions Treated with Subintimal Angioplasty and a True Lumen Re-Entry Device. Journal of Invasive Cardiology. 2009; 21(9): 468-472.

3. Saket et al., Novel Intravascular Ultrasound-Guided Method to Create Transintimal Arterial Communications, J Endovascular Therapy, 11:274-280, 2004. Krishnamurthy et al., Intravascular ultrasound-guided true lumen reentry device for recanalization of unilateral chronic total occlusion of iliac arteries: technique and follow-up. Ann Vasc Surg. 24:487-97, 2010.

Pioneer Plus: Tips and Tricks

Steep Aortic Bifurcation

- If device will not pass over bifurcation, consider 7F sheath
- Consider ipsilateral approach

Device will not track calcified re-entry site

- Heavily calcified vessel wall may require small diameter 2.0 mm balloon dilation prior to using the device.
- Do not overdilate, which can compress true lumen target and subintimal space too wide for needle to re-enter.

Re-entry Site

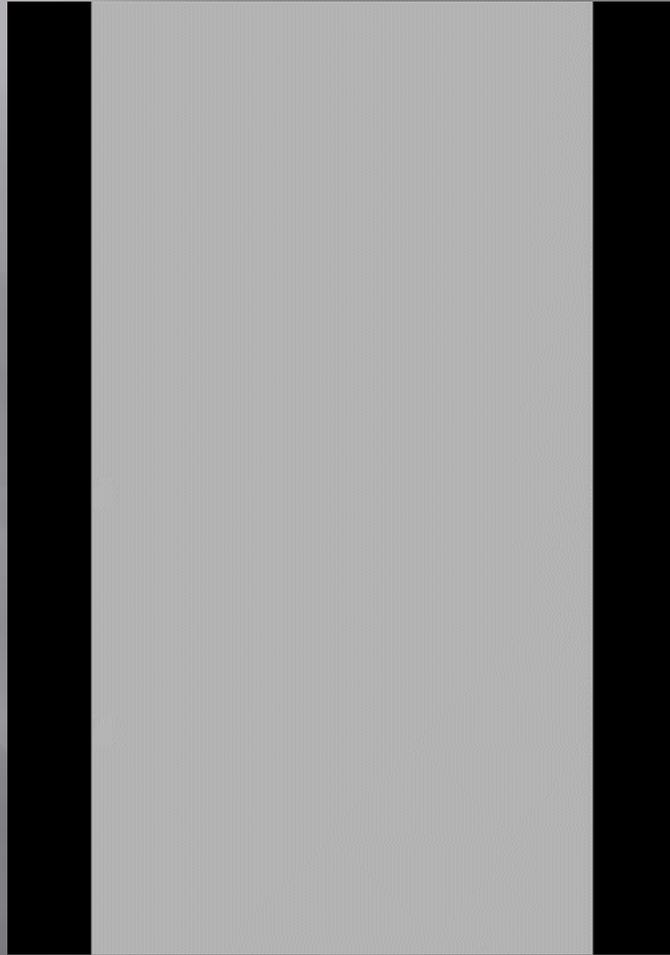
- Avoid calcified site, if possible
- Choose healthy artery as proximal as possible to avoid losing collaterals

Pioneer Plus Case Review

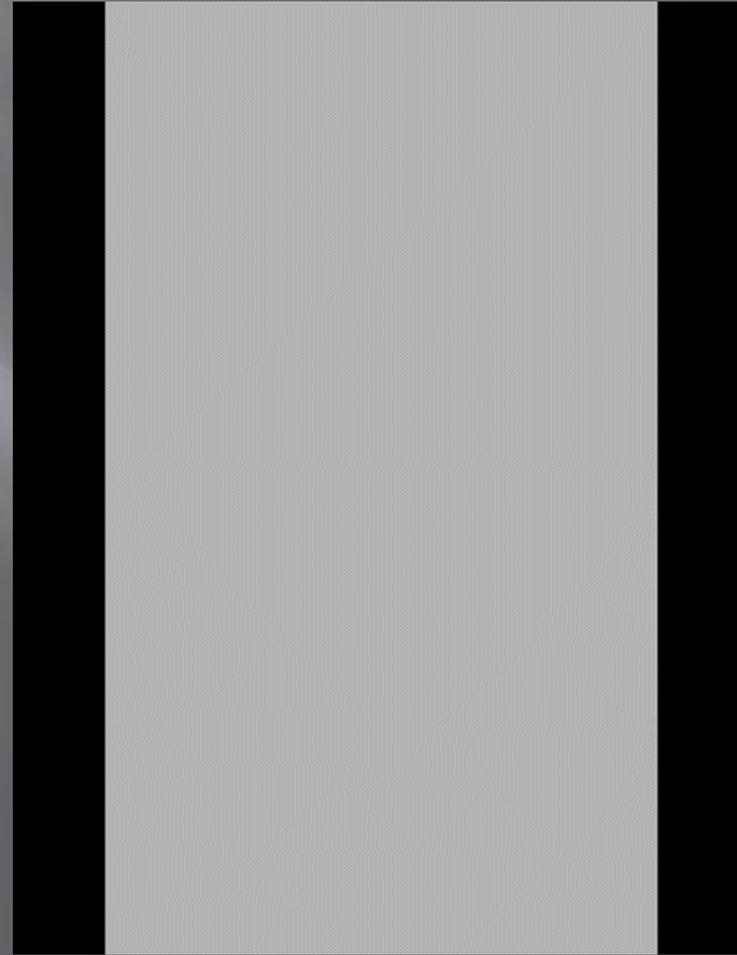
Patient Presentation

- 82 year-old female
- History of lifestyle limiting right leg claudication
- RSFA occlusion
- ABI .4, toe pressures 10

Pre Treatment

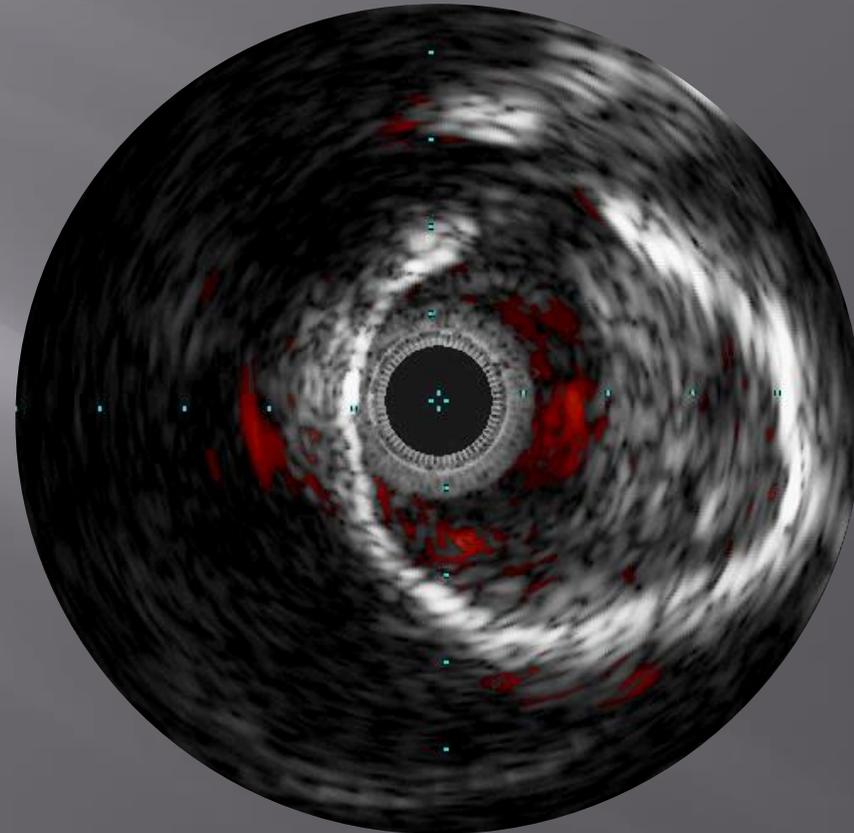


RSFA takeoff



RSFA reconstitution

Pre Treatment

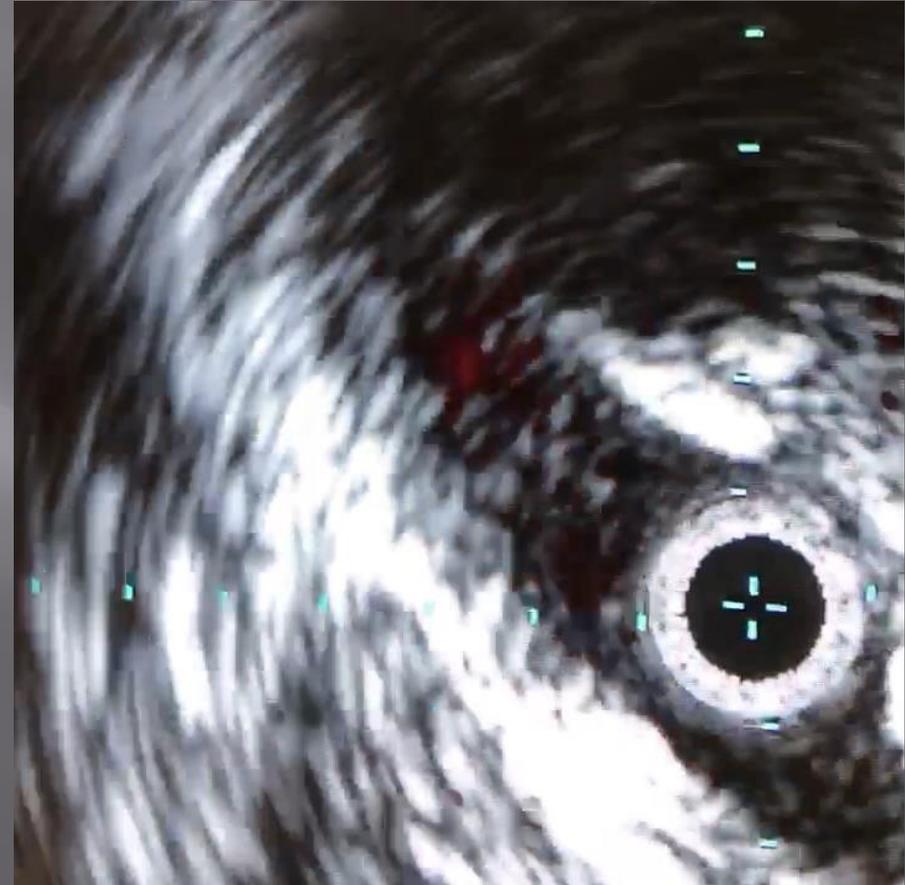


- Subintimal track too tight to pass Pioneer Plus
- Dilate track with 3 x 150 mm Sterling balloon, 2.5 x 60 mm Coyote balloon

Treatment with Pioneer Plus

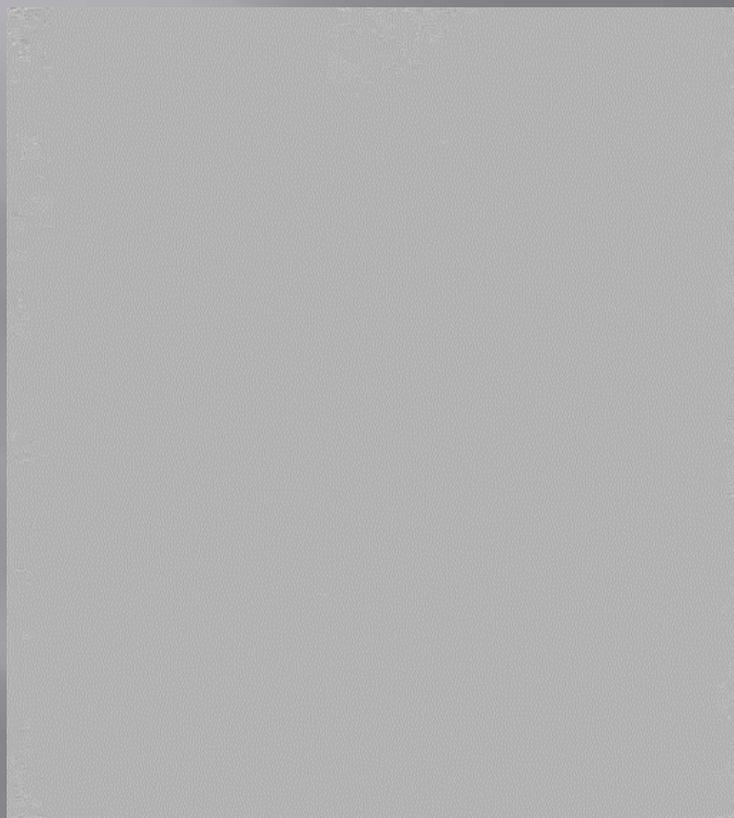


Pioneer Plus Angiogram



Pioneer Plus IVUS with ChromaFlo

Treatment

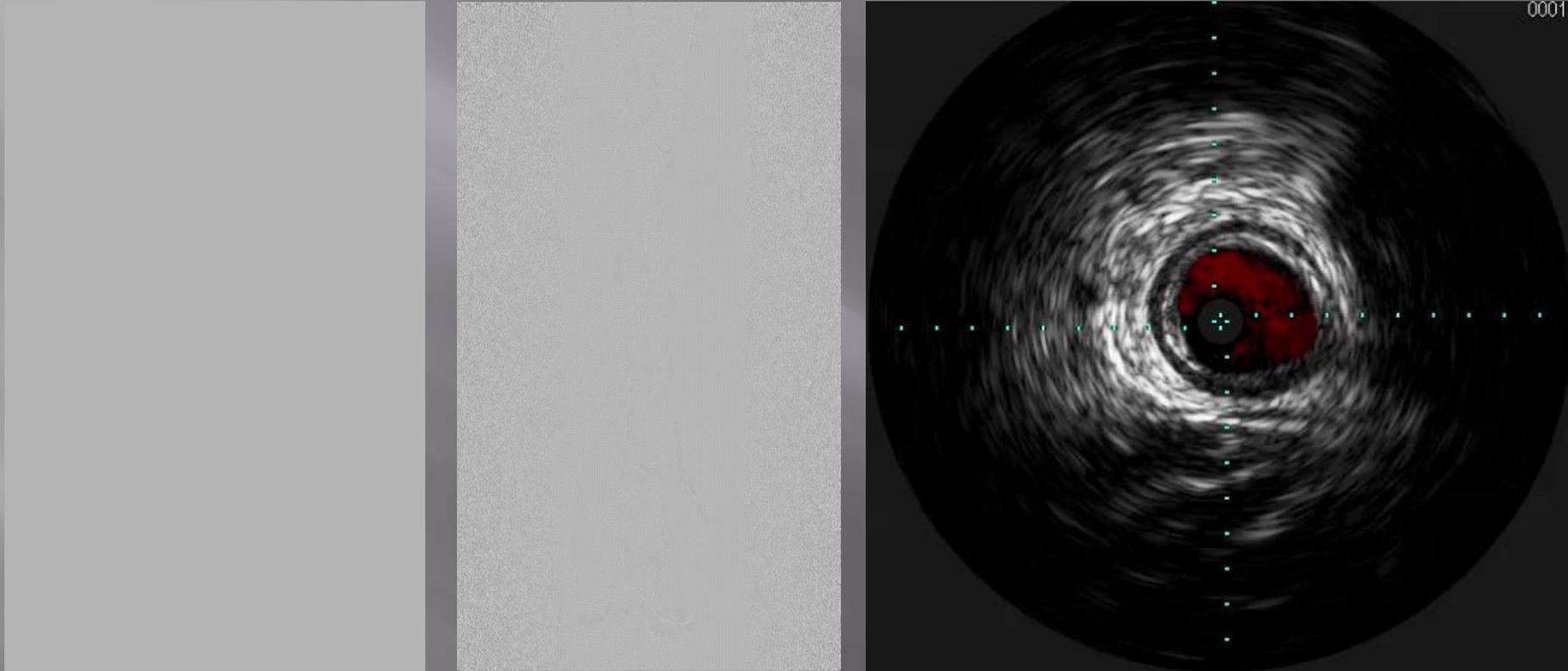


Confirm true lumen



Occluded segment post
6 x 200 mm Mustang balloon

Final Result



- Deployed 4/ea 6 x 120 mm Zilver PTX drug-eluting stent
- Post Dilate 7 x 200 Mustang balloon

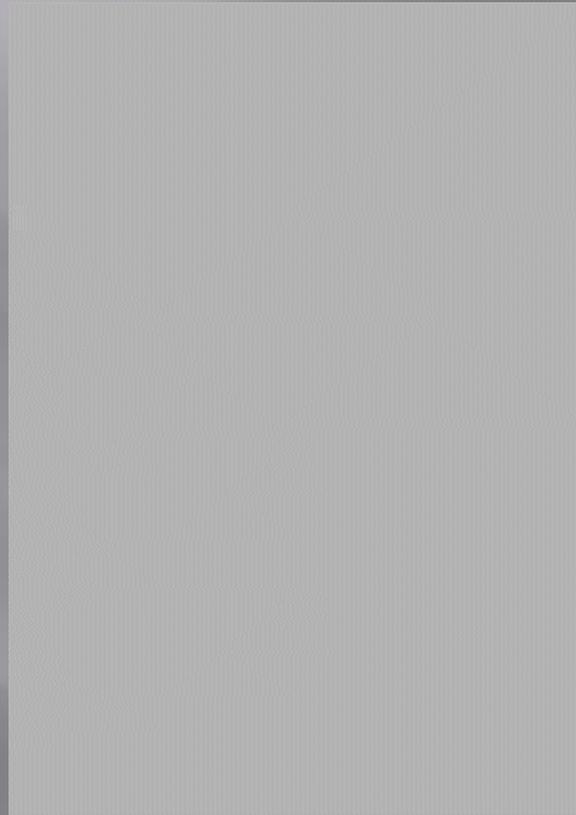
PV .014 IVUS Case Review

Patient Presentation

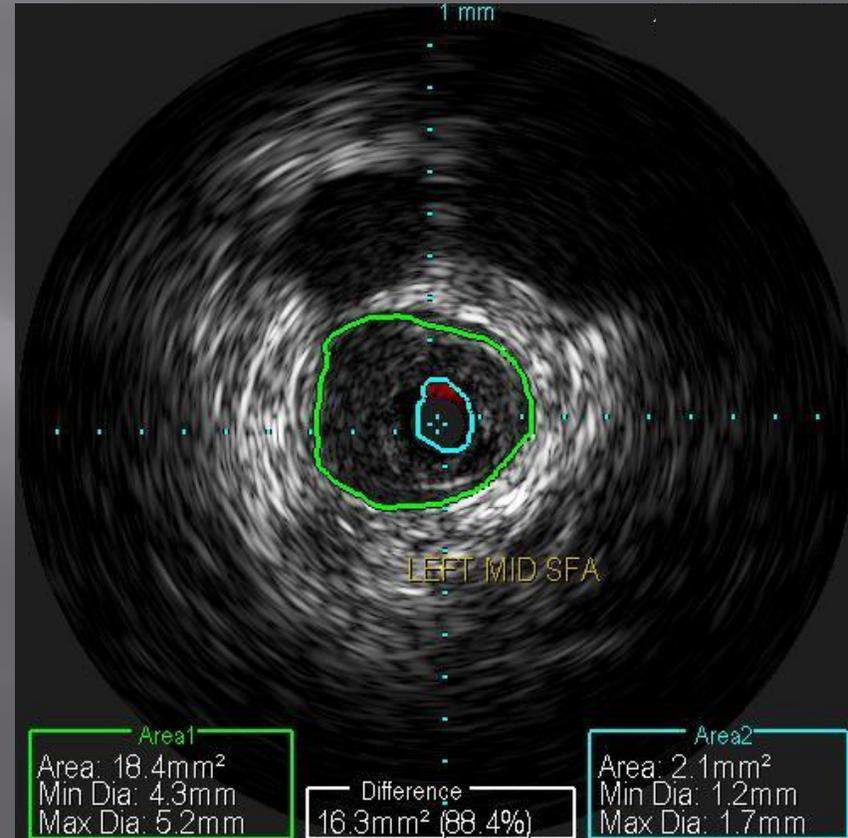
- 72 year old female
- History of lifestyle limiting L leg claudication
- Prior treatment via optimal medical therapy



Pre Treatment

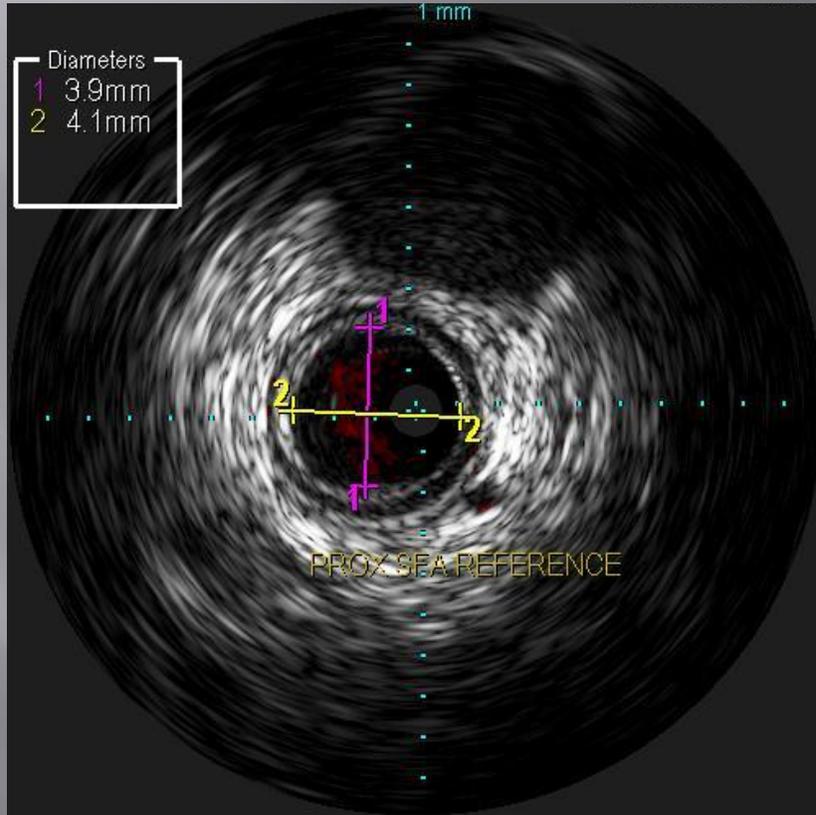


Left SFA Angio

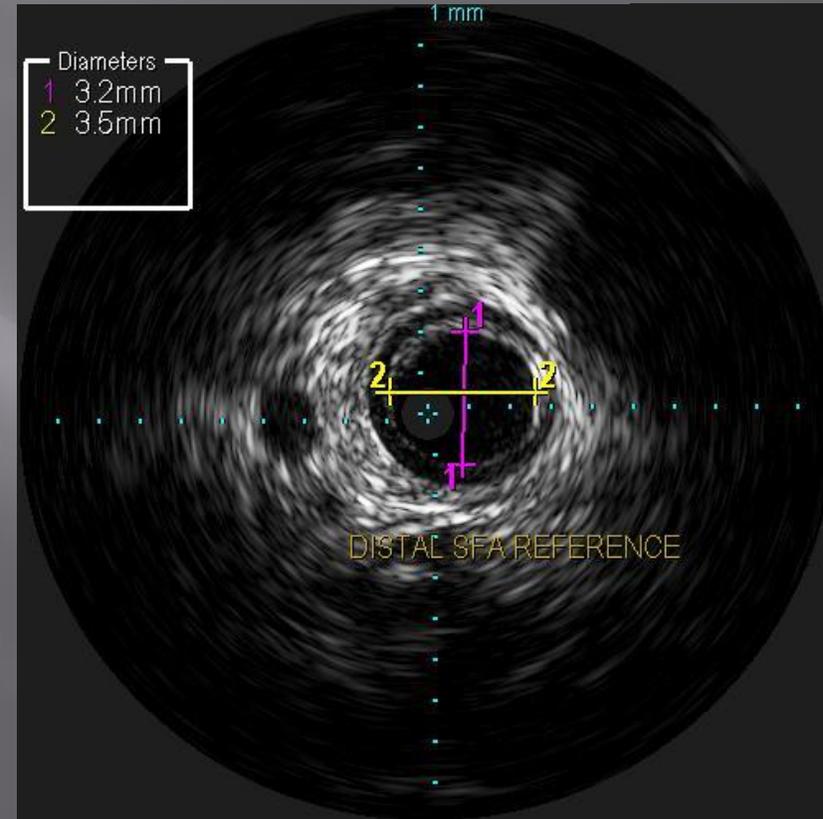


IVUS Measurements

IVUS Reference Measurements



Proximal Reference

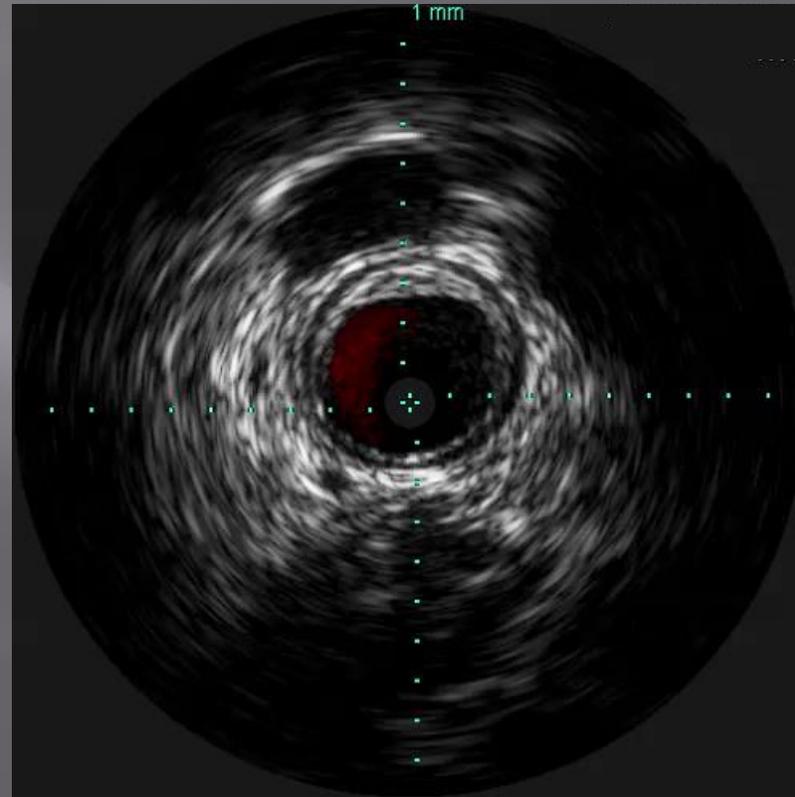


Distal Reference

Post 4x40 In.Pact Admiral DCB

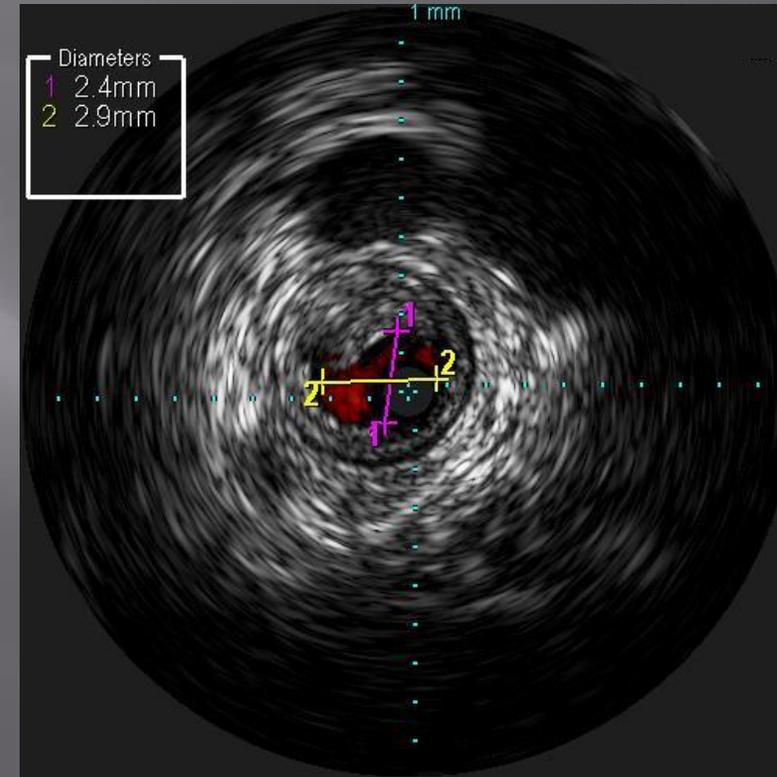
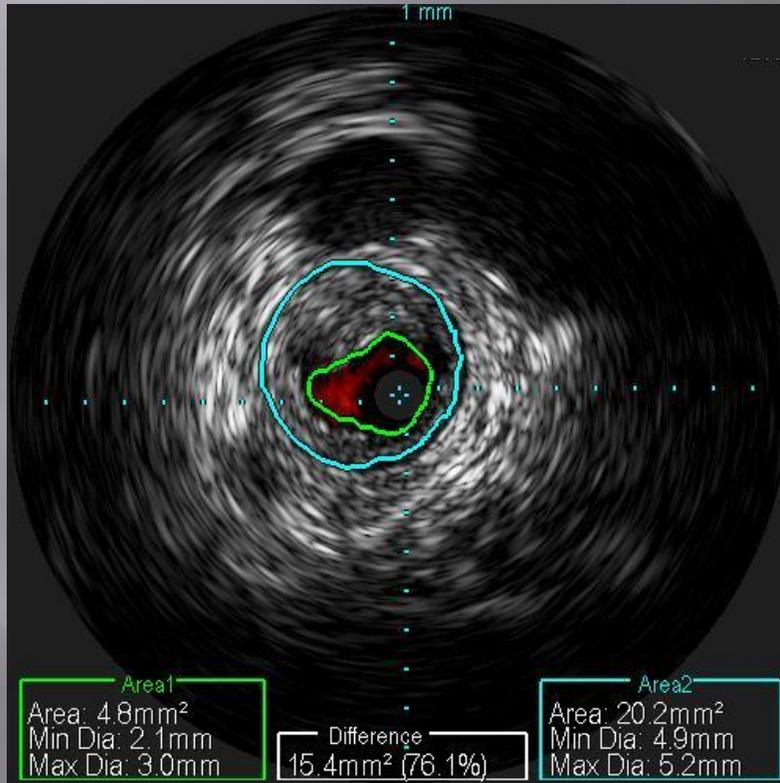


Post DCB Angio

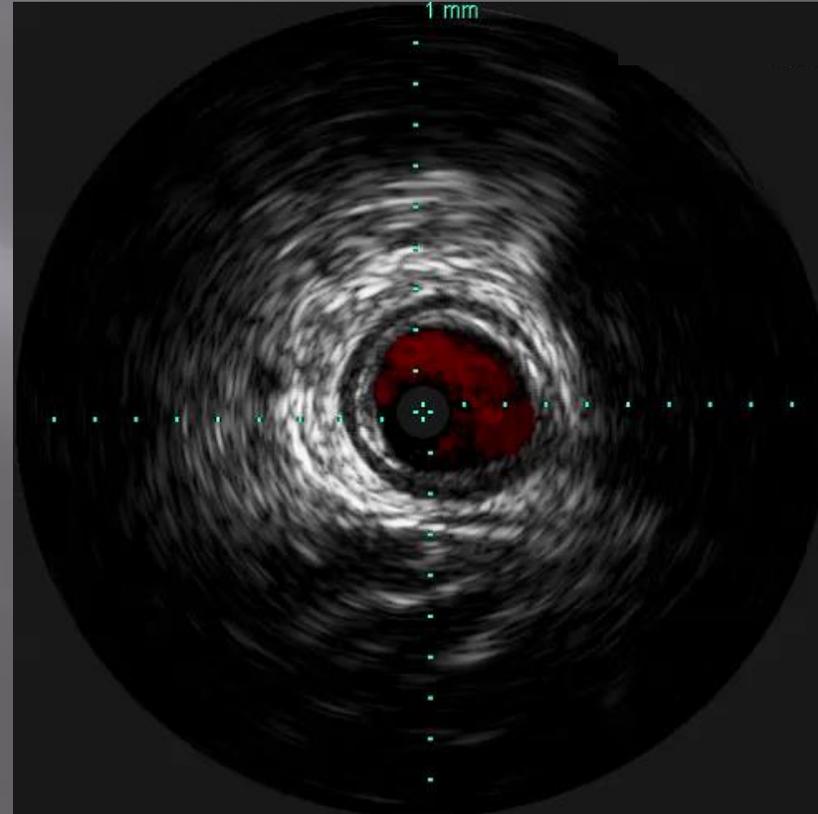


Post DCB IVUS

Residual Stenosis



Post 5x60 Gore Tigris Stent & 5x60 BSC Sterling



Key Takeaways

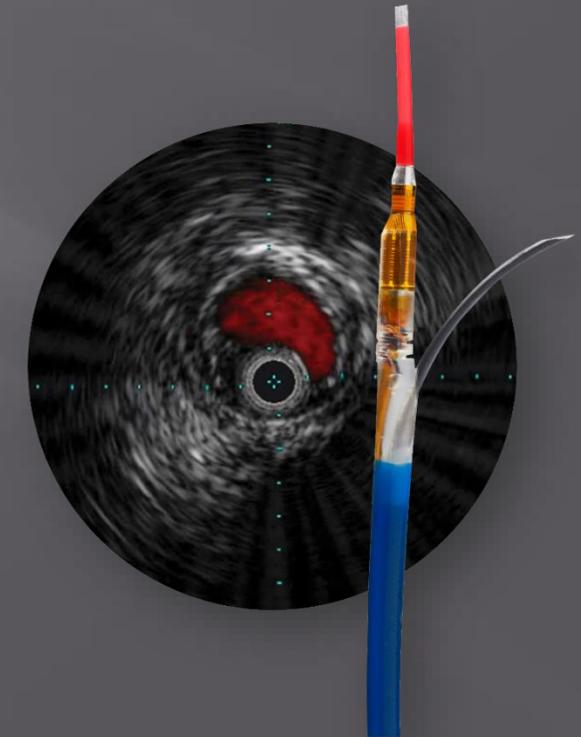
IVUS

Assists in determining the:

- Diameter of treatment area¹
- Plaque morphology¹
- Length of stenosis¹

Pioneer Plus

- Real time IVUS-guidance (no guesswork) ²
- Quick procedure with lowered complications ^{2,3}
- Easy to track over steep aortic bifurcation ⁴
- Potentially less contrast given with IVUS ⁵
- Adjustable needle depth (3, 5, 7 mm) ⁶
- Dual-wire system (0.014") ⁶



1. Kashyap et al. Angiography Underestimates Peripheral Atherosclerosis: Lumenography Revisited. J Endovasc Ther 2008; 15:117-125.

2. Al-Ameri, H et al. Peripheral Chronic Total Occlusions Treated with Subintimal Angioplasty and a True Lumen Re-Entry Device. Journal of Invasive Cardiology. 2009; 21(9): 468-472.

3. Saket et al., Novel Intravascular Ultrasound-Guided Method to Create Transintimal Arterial Communications, J Endovascular Therapy, 11:274-280, 2004. Krishnamurthy et al., Intravascular ultrasound-guided true lumen reentry device for recanalization of unilateral chronic total occlusion of iliac arteries: technique and follow-up. Ann Vasc Surg. 24:487-97, 2010.

4. Data on file at Volcano

5. Llipsitz EC, et al. Does the endovascular repair of aortoiliac aneurysms pose a radiation safety hazard to vascular surgeon? J Vasc Surg 2000; 35:1123-112.6

6. Reference Pioneer Plus IFU