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Phoenix with IVUS case reviews Performed by Dr. Tom Davis Detroit, MI

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innovation you

Case 1

Patient presentation

70-year-old male referred due to life-style limiting claudication with a history of:

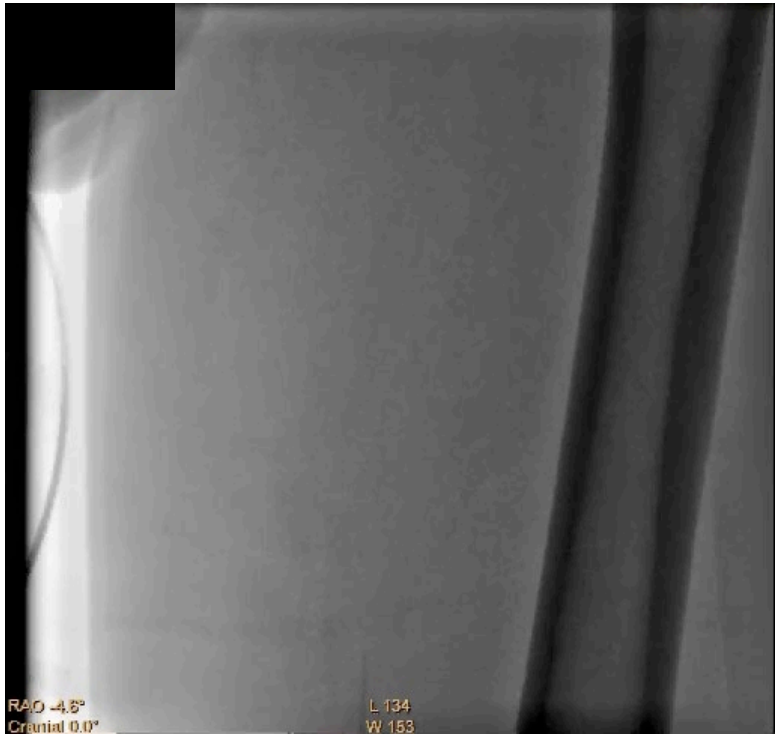
- Tobacco dependency
- Controlled diabetes
- Hypertension

Underwent non-invasive peripheral arterial studies prior to our assessment which demonstrated:

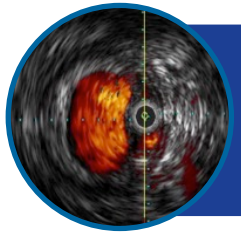
- An ABI of 0.50 in the area of the left superficial femoral artery
- A duplex ultrasound showed a left superficial femoral artery critical stenosis

With a diagnosis of critical lower extremity ischemia (Rutherford class 4), angiography was offered with possible endovascular revascularization

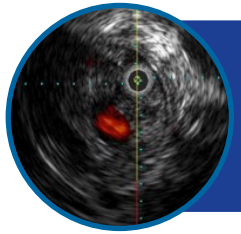
Initial angiogram



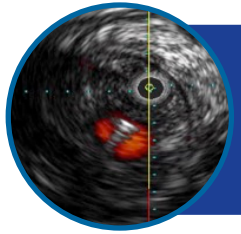
IVUS assessment



IVUS demonstrated that wire was sub-intimal



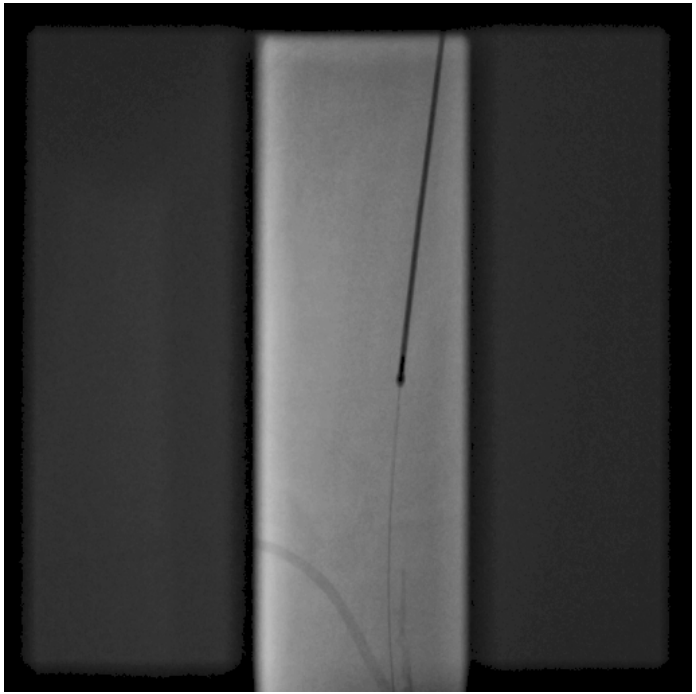
IVUS was then pulled back to determine where the wire went sub-intimal



IVUS was left in the sub-intimal space to facilitate true lumen crossing of a second wire

Phoenix atherectomy system

- Atherectomy performed by Phoenix 2.2 mm x 149 cm device
- PTA performed post atherectomy

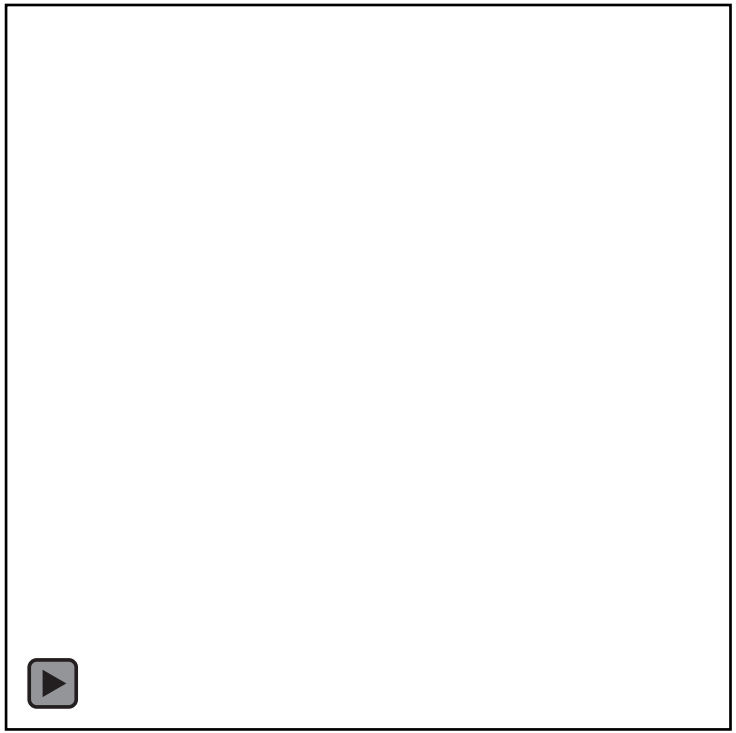


The Phoenix device was used in the true lumen of the vessel being treated

IVUS after the Phoenix atherectomy system

IVUS and adjunctive angiogram after Phoenix atherectomy demonstrated:

- Adequacy of atherectomy
- Smooth laminar flow achieved without adventitial cuts or major dissections



Final angiogram

Conclusion

Phoenix aided the case by:

- Providing an atherectomy tool that continuously cuts, captures and passively clears debulked material into the catheter which resulted in a 1% rate of symptomatic distal emboli in the EASE trial[1]
- Front cutter clears tissue in a way that may help reduce potential trauma to the vessel[1]

IVUS aided the case by determining:

- Facilitating true lumen crossing of the wire which left options for therapy to be utilized
- Lesion was suitable for the Phoenix atherectomy system
- Size and length of balloon to use post atherectomy
- Demonstrating no adventitial cuts or major dissections were present post Phoenix
- Demonstrating smooth laminar flow was achieved with the Phoenix atherectomy system

1. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD

Case 2

Patient presentation

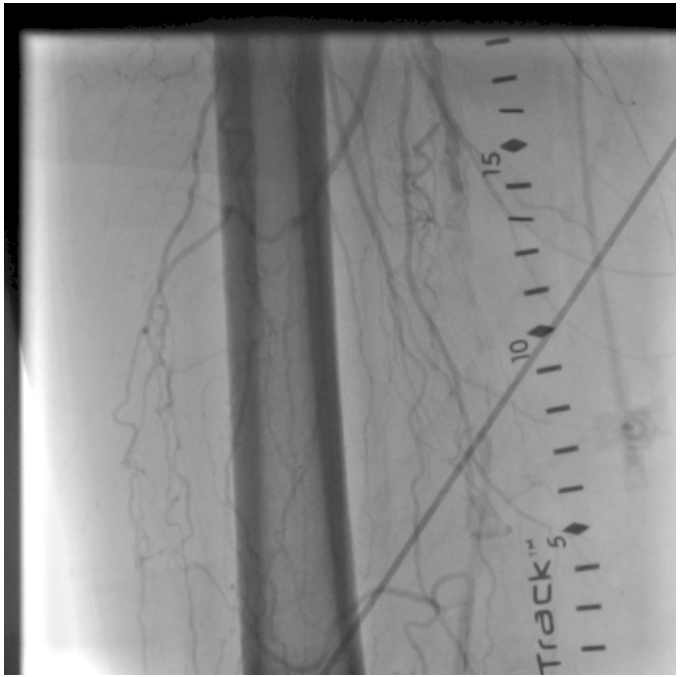
61-year-old male

- History of tobacco dependency
- History of uncontrolled diabetes
- Hypertension

- Referred due to life-style limiting claudication which affected right lower extremity
- Could walk for very short distances and had resting pain
- Underwent non-invasive peripheral arterial studies prior to our assessment which demonstrated a right superficial femoral artery critical stenosis or occlusion

Initial angiogram

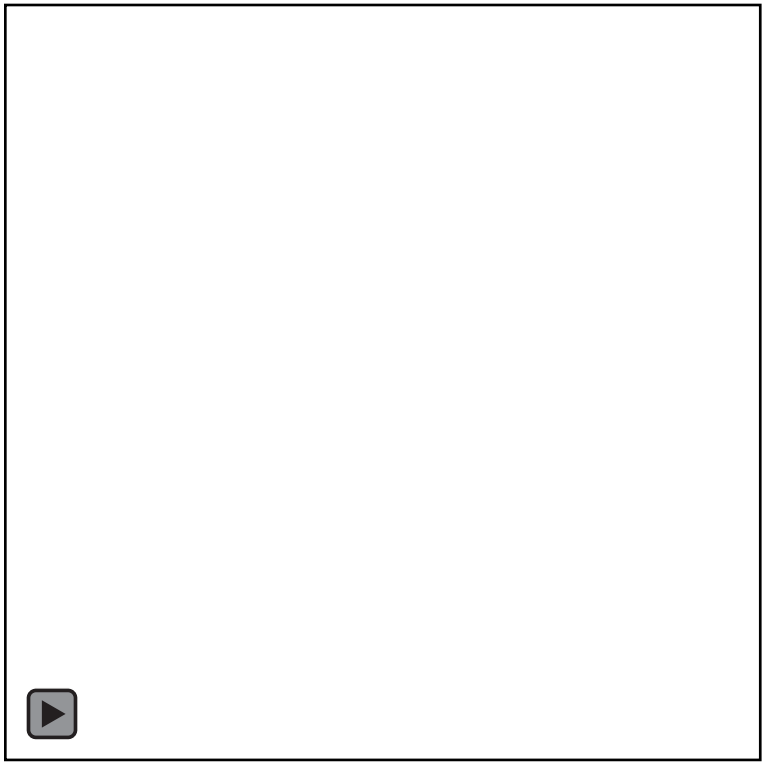
Flush occlusion of the proximal SFA to the distal SFA just above the knee



IVUS assessment

IVUS was used to determine:

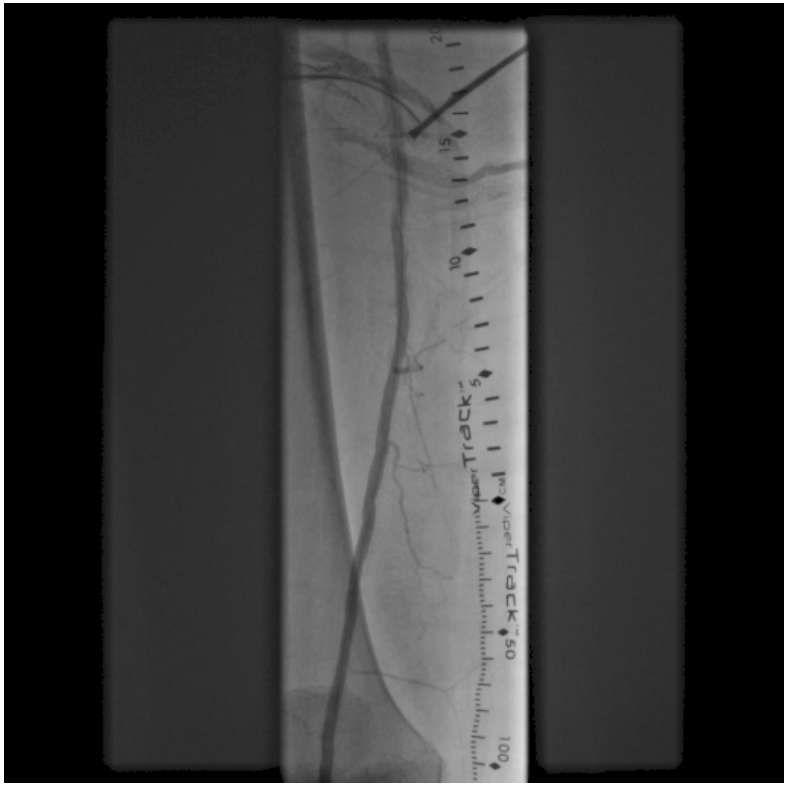
- If wire is in the true lumen
- Extent of disease
- Presence of dissections or hematomas
- Vessel diameter proximal and distal to the lesion
- Suitable therapy for the lesion



Phoenix atherectomy system

- Atherectomy performed using Phoenix 2.2 mm x 150 cm device
- PTA performed post atherectomy

Final angiogram



Conclusion

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- Providing an atherectomy tool that continuously cuts, captures and passively clears debulked material into the catheter which resulted in a 1% rate of symptomatic distal emboli in the EASE trial[1]
- Front cutter clears tissue in a way that may help reduce potential trauma to the vessel[1]

IVUS aided the case by determining:

- The wire was in the true lumen
- Lesion was suitable for the Phoenix atherectomy system
- Size and length of balloon to use for post dilatation
- Filter wire was not necessary for the procedure

1. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD