



Prevalence of Mixed Morphology Pathology within Peripheral Arterial Disease

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Disclosure

Speaker name: Miguel Montero-Baker, MD

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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

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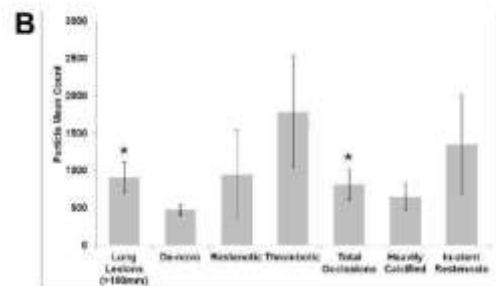
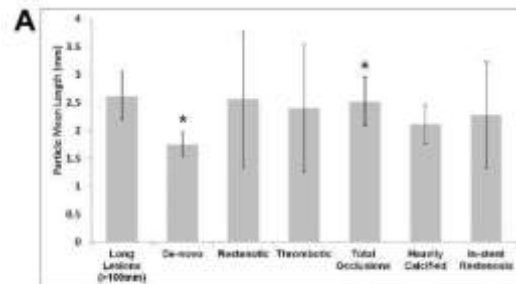
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◆ CLINICAL INVESTIGATION ◆

New Approach to Protected Percutaneous Transluminal Angioplasty in the Lower Limbs

Thomas Zeller, MD¹; Andrej Schmidt, MD²; Aljoscha Rastan, MD¹; Elias Noory, MD¹;
Klaus Brechtel, MD³; Sebastian Sixt, MD¹; Dierk Scheinert, MD²; and Gunnar Tepe, MD⁴

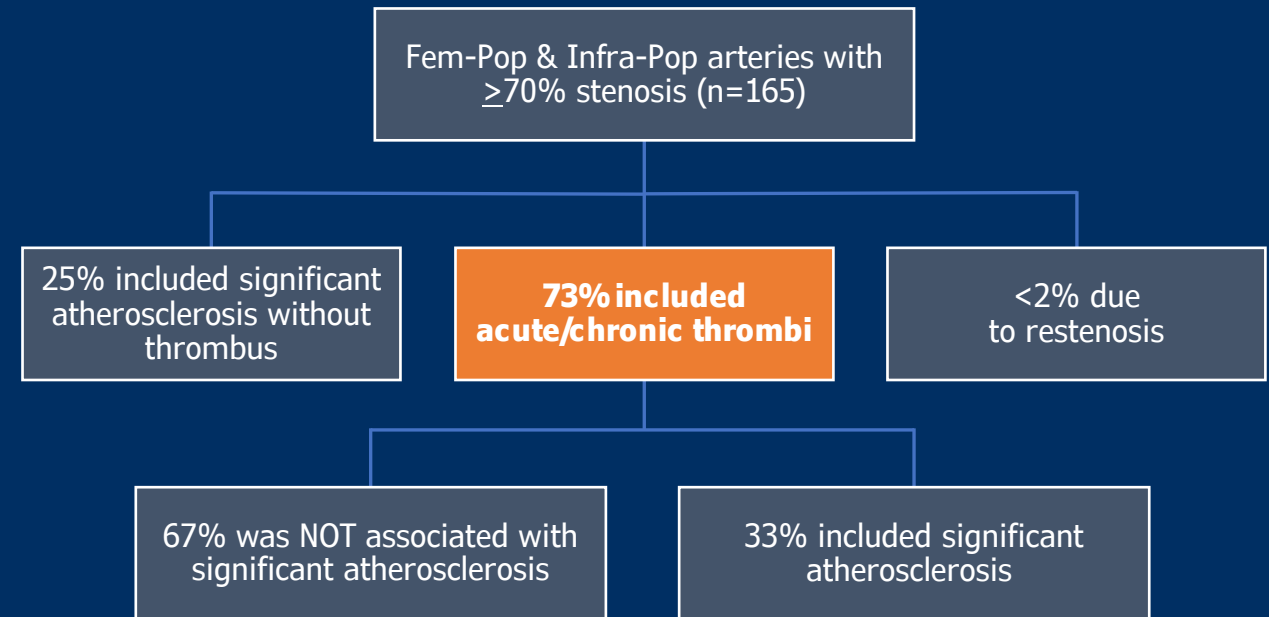
¹Department of Angiology, Universitaets-Herzzentrum Freiburg-Bad Krozingen, Bad Krozingen, Germany. ²Park-Krankenhaus, Leipzig, Germany. ³Department of Radiology, University Hospital Tübingen, Germany. ⁴Department of Radiology, Klinikum Rosenheim, Germany.



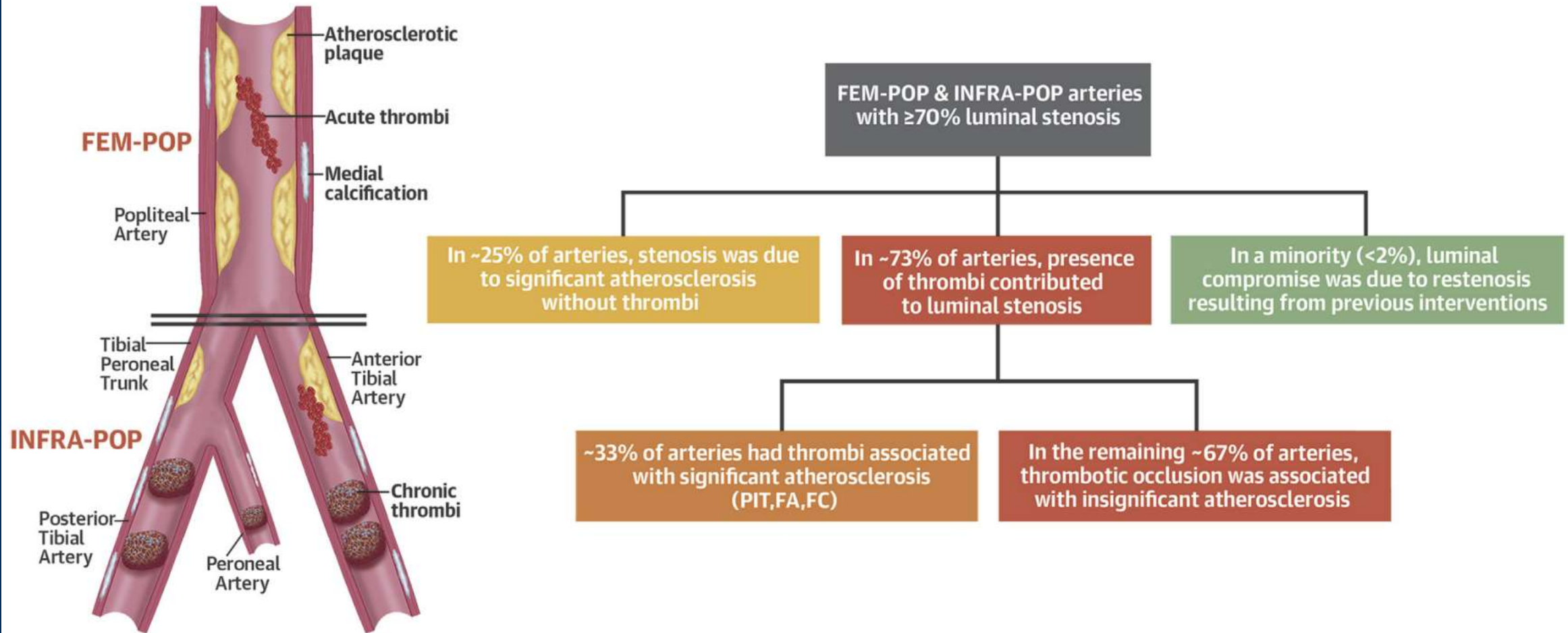
Pathology of CLI

- Narula et al evaluated 239 lower-extremity amputations to characterize the pathology of CLI
- Peripheral plaque morphology is typically heterogenous
- 73% of stenotic lesions included acute or chronic luminal thrombi
- 27% of stenotic lesions included pathological intimal thickening, fibroatheroma, fibrocalcific or restenosis

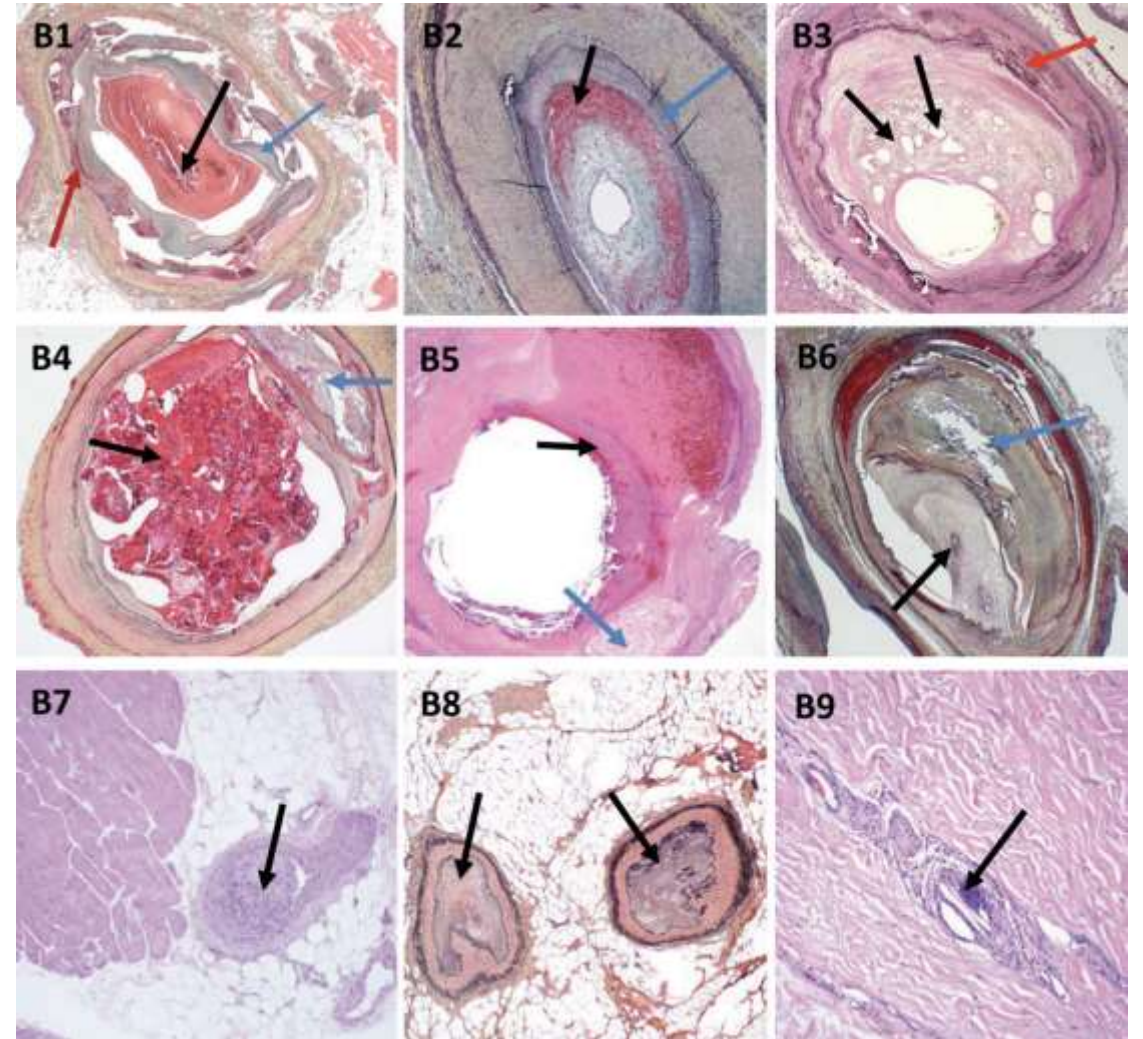
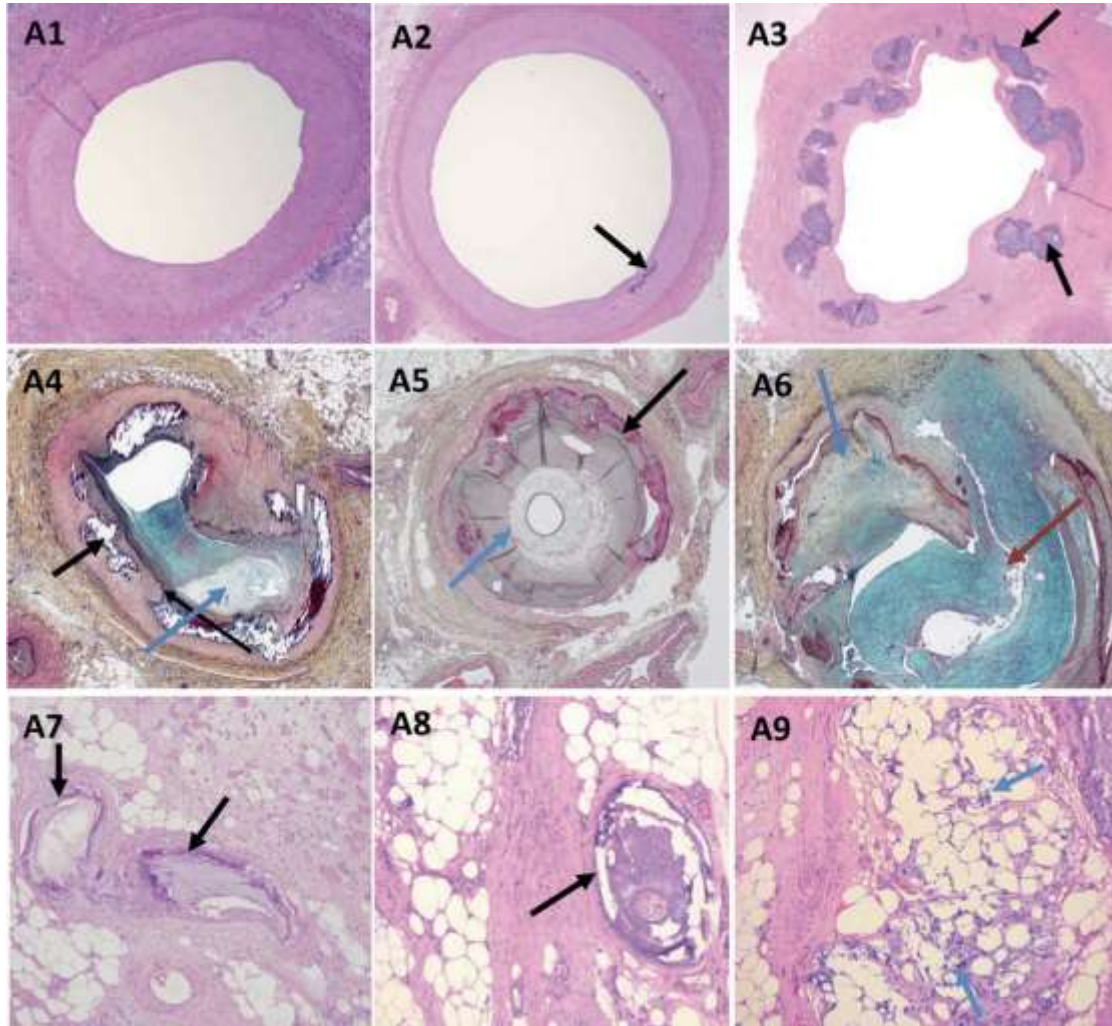
Pathological Characterization of Large Arteries in Amputations for CLI*



CENTRAL ILLUSTRATION Pathological Characterization of Large Arteries in Amputations for Critical Limb Ischemia



Narula, N. et al. J Am Coll Cardiol. 2018;72(18):2152-63.



Infrapopliteal calcification patterns in critical limb ischemia: diagnostic, pathologic, and therapeutic implications in the search for the endovascular holy grail

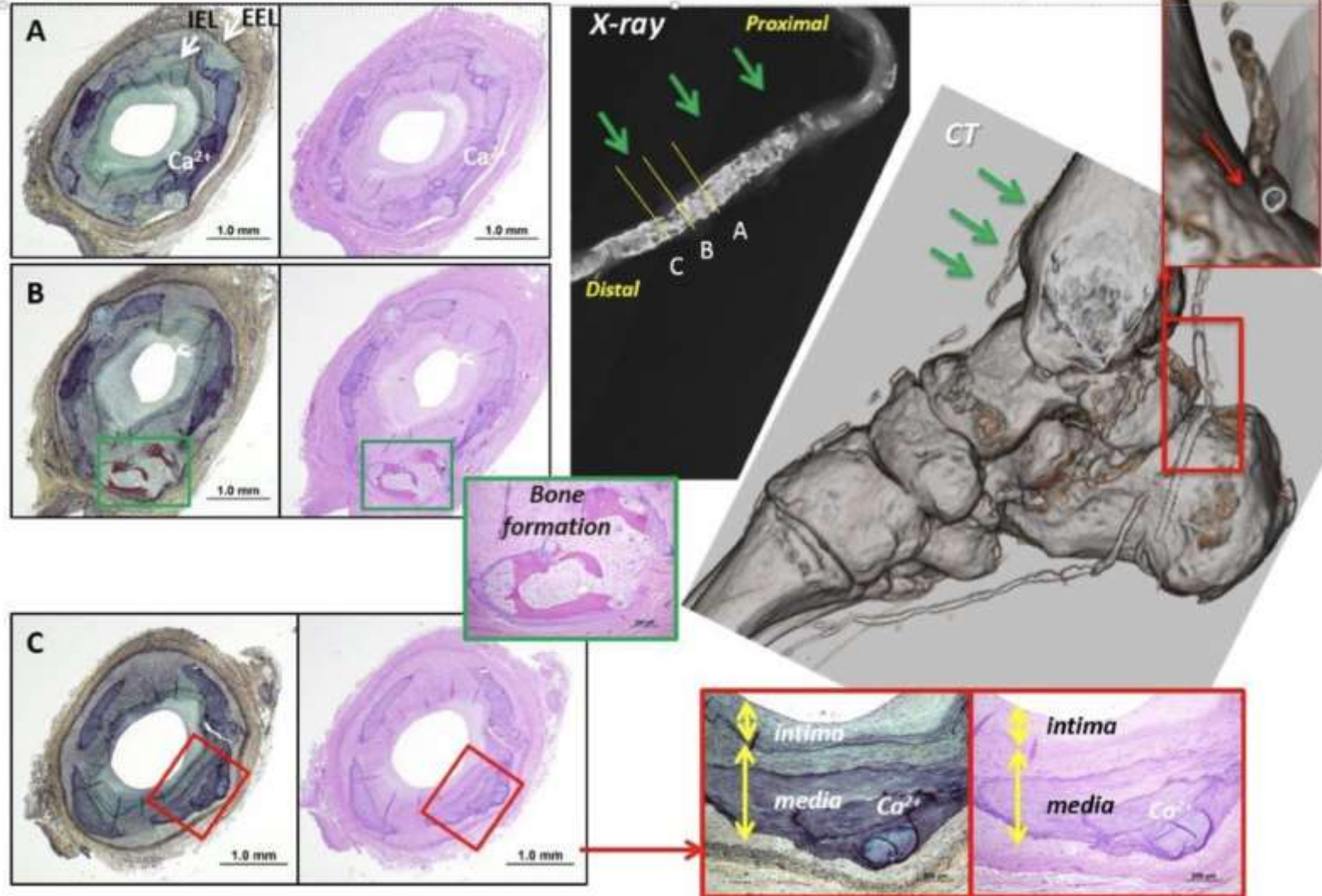
Jihad A MUSTAPHA, Larry DIAZ-SANDOVAL, Fadi SAAB

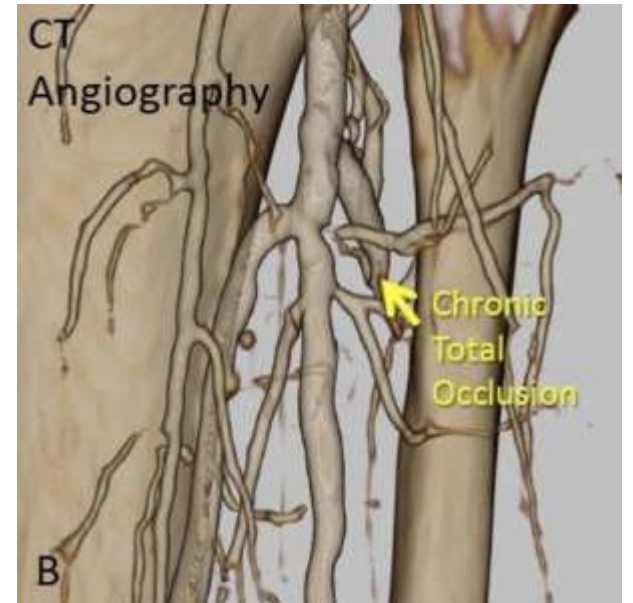
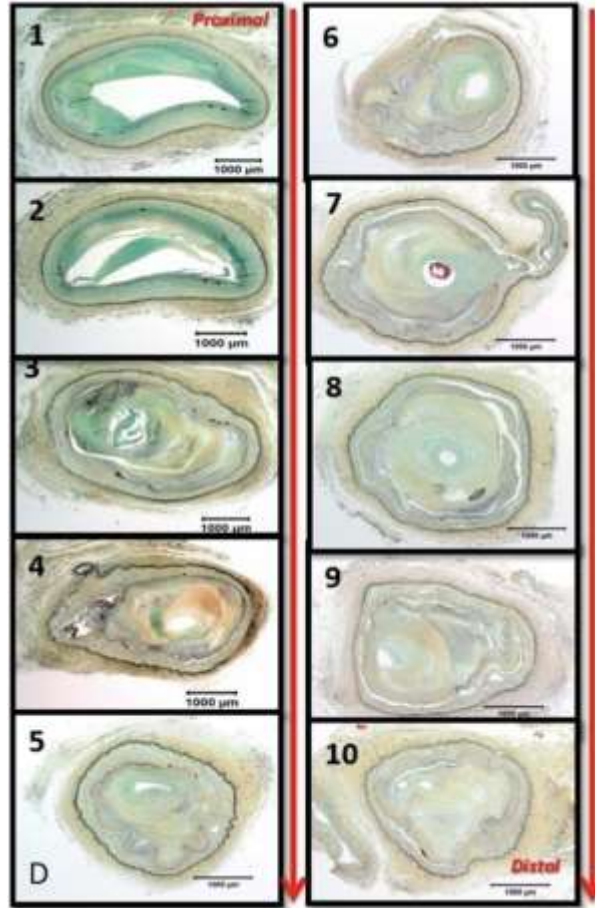
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Conclusions

- PAD dz has heterogenous morphology
- The development of tools needs to adapt to the variable plaque type
- Tools that can easily adapt to variable plaque morphology will champion our space
- Embolization during PAD endovascular interventions has consequences, any system that aims to address such complex lesions should have the ability to minimize this complication.



Thank You!

Rotarex™

Rotational Excisional Atherectomy System

The Straub Endovascular System is herein referred to as the BD Rotarex™ Rotational Excisional Atherectomy System

Indication For Use: When operated with a Rotarex™ single use catheter, the Straub Endovascular System is intended for use as an atherectomy device and to break up and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, pulmonary, iliac or renal vasculature.

Contraindications: Use of the Rotarex™ family of catheters is contraindicated in the following situations and locations: · In the cardiopulmonary, coronary, cerebral, iliac and renal vasculature · In the venous vasculature · In instances of persistent vasospasm · In patients not suitable for atherectomy/ thrombectomy · In patients with known or suspected allergies to any component of the Straub Endovascular System · In patients with haemodynamic instability, shock or severe coagulatory disorders · In patients where it is impossible to achieve sufficient anticoagulation and platelet aggregation inhibition · In areas of known or suspected infection, especially at the puncture site or target vessel segment · In vessels which are oversized or undersized for the particular Rotarex™ catheter used In stents, stent grafts or bypass grafts · Without the use of a Straub provided guidewire · When the Straub provided guidewire cannot completely cross the target lesion · Where the Straub provided guidewire is in a subintimal position of any length · Where the Straub provided guidewire has become threaded or entangled in the wire mesh of a stent, stent graft or the lining of a stent graft · Where the target lesion is located in a region of marked vessel tortuosity (has a radius of curvature ≤ 2 cm) or is heavily calcified · Where pre-existing damage is present in the vessel wall at or near the target lesion from prior surgery, aneurysms or other disease · During MRI procedures or where electrical current may be passed to an undesired location via the catheter, e.g., during electrocautery, electrosurgery or defibrillation. The Rotarex™ catheter and guidewire must be entirely removed before these therapies are administered, even in an emergency situation · Where the recommended separation distances from Radio Frequency and Electro- Magnetic Interference (EMI) sources cannot be maintained (Reference the manual for the Drive System) · Where any component of the Straub Rotarex™ Endovascular System has sustained damage, including any breach of the sterile barrier

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Potential Adverse Effects: Potential adverse effects include, but are not limited to: · Embolization, especially distal embolization · Pulmonary embolisms of all degrees of severity · Thrombosis, especially recurrent thrombosis · Re-occlusion · Vessel wall injury · Vessel dissection / perforation / rupture · Perforation as a result of mural calcium being torn out of the vessel wall · Arteriovenous fistula / pseudo-aneurysm · Hematoma, bleeding, hemorrhage · Organ perforation · Implants such as stents / stent grafts / bypass grafts getting damaged, caught or dislodged · Disruption of the catheter: debris remaining in the body · Allergic reactions · Infections or necrosis at the puncture site · Catheter-induced sepsis · Death