Prevalence of Mixed Morphology Pathology within Peripheral Arterial Disease

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Disclosure

Speaker name: Miguel Montero-Baker, MD

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New Approach to Protected Percutaneous Transluminal Angioplasty in the Lower Limbs

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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*

- Fem-Pop & Infra-Pop arteries with \( \geq 70\% \) stenosis (n=165)
  - 73% included acute/chronic thrombi
  - 25% included significant atherosclerosis without thrombus
  - 67% was NOT associated with significant atherosclerosis
  - 33% included significant atherosclerosis
  - <2% due to restenosis

Pathological Characterization of Large Arteries in Amputations for Critical Limb Ischemia

- Atherosclerotic plaque
- Acute thrombi
- Medial calcification

- FEM-POP & INFRA-POP arteries with ≥70% luminal stenosis

  - In ~25% of arteries, stenosis was due to significant atherosclerosis without thrombi
  - In ~73% of arteries, presence of thrombi contributed to luminal stenosis
  - In a minority (<2%), luminal compromise was due to restenosis resulting from previous interventions

  - ~33% of arteries had thrombi associated with significant atherosclerosis (PIT, FA, FC)
  - In the remaining ~67% of arteries, thrombotic occlusion was associated with insignificant atherosclerosis

Infraopliteal 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 coagulopathic 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 electrosurgery, 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

**Warnings:** Rotarex™ catheters and the Drive System are intended for use only by suitably qualified medical personnel experienced in the diagnosis and treatment of peripheral vascular disease by percutaneous methods - The Rotarex™ family of catheters may only be used in conjunction with the Drive System - The Rotarex™ family of catheters may only be used with the Straub provided guidewire with which they are packaged - Rotarex™ catheters are supplied sterile for single-use only. Do not reprocess or resterilize. Resterilization or reconditioning may severely impair the function of the product - Do not use Rotarex™ catheters whose packaging is damaged or whose sterilization expiration date has passed - Position the flexible tip of the guidewire as far distally as possible from the vessel occlusion being treated to avoid the tip being aspirated into the rotating helix. Recommended distance is >10 cm (4 in). Operators should take care that manipulations of the catheter do not alter the desired position of the guidewire - Risk of distal embolization is greatly increased if the operator attempts to advance the catheter faster than the recommendations in these instructions, especially near the distal end of the occlusion - Failure to ensure sufficient blood flow to the catheter head could result in a slow embolization - Monitor the blood flow to the collecting bag continuously throughout the procedure - Do not operate the Rotarex™ catheter near fractured areas of broken stents or stent grafts. If a protruding stent strut penetrates into the side window of the catheter head, the stent, stent graft or vessel may become severely damaged, destroyed and/or dislodged, or the catheter head may become entrapped in the stent or stent graft in such a manner that the catheter and the stent or stent graft must be surgically recovered - Rotarex™ catheters should only be used under adequate visual monitoring with suitable radiographic techniques

**Cautions:** Rotarex™ catheters do not contain any parts that can be maintained or serviced by the end-user. Do not repair or change the configuration of the product - Use of the Rotarex™ catheter through a kinked or damaged introducer or where the catheter itself has become kinked or bent, may cause erratic function and or device failure - Rotarex™ catheters must not be allowed to operate "dry" and must be primed and flushed using heparinized saline before and during use per the instructions in this FDU. Throughout catheter use, always ensure there is a sufficient blood flow to the catheter head. Allowing the catheter to operate without heparinized saline solution priming and flushing or without adequate amounts of aspirated blood will cause the device to operate erratically and or cease functioning - Failure to manipulate the catheter slowly in a back and forth motion as described in the instructions may result in fracture of the helix and/or guidewire - Insufficient blood flow through the catheter may result in intra-catheter clotting, slow or absent therapeutic function, fracture of the helix and/or guidewire, and/or overheating of the catheter - The guidewire adapter must be in the working position (pulled back) when the motor is active - When active, the handle of the Rotarex™ Catheter and the portion of the catheter outside the patient’s body must be kept at the same height as the introducer sheath and straight at all times with the outlet tube to the collecting bag hanging vertically below the motor in a straight line. Failure to position the catheter and outlet tube in this manner may result in catheter blockage, helix fracture and/or guidewire fracture

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