## Orbital Atherectomy for Heavily Calcified Peripheral Arterial Disease

### Rajesh Gupta, M.D. Assistant Professor of Medicine University of Toledo





## Calcification: Enemy of Endovascular Success

- Vascular Calcification is highly prevalent in patients with symptomatic PAD
- Lesion calcification:
  - reduces acute procedural success
  - increases risk of flow-limiting dissection and bail-out stenting after angioplasty
  - Increases long-term adverse risk
- Lesion Calcification must be recognized and addressed to improve treatment success





## Peripheral Orbital Atherectomy System



# **Orbital Atherectomy**

- 360° crown contact designed to create a smooth, concentric lumen
- Allows constant blood flow and particulate flushing during orbit



- Average particulate size<sup>1</sup> = 2 μm
- Bi-directional sanding of <u>superficial</u> calcium
- Healthy elastic tissue flexes away from the crown, minimizing damage to the vessel
  - \* In a phantom non-diseased popliteal artery
  - \*\* Results vary based upon plaque morphology, calcification, and anatomy
  - 1. Based on cadaver atherosclerotic lesions, porcine coronary lesions, and graphite blocks
  - 2. Test models: Zheng et al., 2016. Med Eng Phys. 2016 Jul;38(7):639-47

#### • Low frequency (18-40 Hz) represents crown <u>orbit</u> inside vessel\*

- High frequency (1000-1900 Hz) represents rotation of eccentric crown over the wire, producing pulsatile mechanical forces\*
- These pulsatile forces may affect <u>deeper</u> plaque and contribute to compliance change\*\*







• 70 year old male

- Past medical history:
  - CHF
  - Former smoker
  - CAD
  - PAD

- Presents with worsening claudication

- Rutherford grade III claudication
- ABI 0.60 on right leg







### Mid to distal SFA calcified lesion









### Mid to distal SFA calcified lesion









Single Vessel peroneal artery runoff





Single vessel runoff – peroneal collaterals to distal AT





# 



**Orbital Atherectomy: 2.0 mm burr** 







**Orbital Atherectomy: 2.0 mm burr** 









### **Post-Atherectomy**







### IN.PACT 6.0 x 150 mm DCB





### **Final Result**













# Case Summary



Post

DCB

Atherectomy

TCTAP 2019

Pre

Cove

**Final** 

# LIBERTY 360° Study

- LIBERTY 360 is a prospective, observational, multi-center study of endovascular interventions in patients with symptomatic lower extremity PAD
- The LIBERTY study included any FDA-approved technology to treat claudication and CLI
- 4 core laboratories were utilized for independent analysis
- **1204 subjects** were enrolled at 51 sites and will be followed up to 5 years
- 60% were <u>calcified</u> lesions and atherectomy used in 60% of cases, with majority being <u>orbital atherectomy</u>

Adams et al. The LIBERTY Study Design. American Heart Journal. 2016;174:14-21. Mustapha et al. One-Year Results of the LIBERTY 360 Study: Evaluation of Acute and Midterm Clinical Outcomes of Peripheral Endovascular Device Interventions. J Endovascular Therapy. 2019, Vol. 26(2) 143–154. LIBERTY 360 is sponsored by Cardiovascular Systems, Inc. ClinicalTrials.gov NCT01855412





Comparison between Rutherford categories significant (p<0.05)





Mustapha et al. One-Year Results of the LIBERTY 360 Study: Evaluation of Acute and Midterm Clinical Outcomes of Peripheral Endovascular Device Interventions. J Endovascular Therapy. 2019, Vol. 26(2) 143–154.



## Severe Angiographic Complications



Core Lab reported lesions.
P-Values from Fisher's Exact Test. All p-values >0.05.

30-Oct-2017 Data





# Advantages of Orbital Atherectomy

- Quick and easy to use atherectomy system
- Small Sheath required:
  - 4 6 French compatible depending on burr size
- Can usually skip distal embolic filter protection which reduces procedural complexity, time, and cost compared with alternative atherectomy devices
- Change compliance of lesion, enabling effective endovascular treatment with a low rate of flow-limiting dissections



