The use of orbital atherectomy and lithoplasty in fem-pop disease – What is the concept, and how to best select the cases?

The “Sand Blasting” technique for vessel preparation

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Disclosures

• None pertaining to this talk
The Problem...
Severe Calcification

- Disruptor for therapeutic delivery
- Vessel wall resists balloon remodeling
  - Impede drug delivery
  - Increase dissection/complications
  - Inadequate stent expansion
- No gold standard for vessel preparation
Severe Calcium Acts as a Barrier to DCB

12 month Results

Primary Patency

LLL

Calcium distribution evaluation by CTA (circumferential) and DSA (longitudinal)

# Severe Calcification in DE Trials

<table>
<thead>
<tr>
<th></th>
<th>Zilver PTX RCT</th>
<th>IN.PACT SFA II</th>
<th>LEVANT 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Calcification</td>
<td>37.7%</td>
<td>8.1%</td>
<td>10.4%</td>
</tr>
</tbody>
</table>

Imperial (Eluvia): >60% patients with moderate to severe calcification
Classification

**PACSS:**

Proposed Fluoroscopy/DSA based Peripheral Arterial Calcification Scoring Systems (PACSS): Intimal and medial vessel wall calcification at the target lesion site as assessed by high intensity fluoroscopy and digital subtraction angiography (DSA) assessed in the AP projection.

**Grade 0:** No visible calcium at the target lesion site

**Grade 1:** unilateral calcification < 5cm; a) intimal calcification; b) medical calcification; c) mixed type

**Grade 2:** unilateral calcification ≥ 5cm; a) intimal calcification; b) medical calcification; c) mixed type

**Grade 3:** bilateral calcification < 5cm; a) intimal calcification; b) medical calcification; c) mixed type

**Grade 4:** bilateral calcification ≥ 5cm; a) intimal calcification; b) medical calcification; c) mixed type

**PARC:**

<table>
<thead>
<tr>
<th>Degree of lesion calcification (34,26)</th>
<th>Focal</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
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<tr>
<td></td>
<td>&lt;180° (1 side of vessel) and less than one-half of the total lesion length</td>
<td>&lt;180° and greater than one-half of the total lesion length</td>
<td>≥180° (both sides of vessel at same location) and less than one-half of the total lesion length</td>
<td>&gt;180° (both sides of the vessel at the same location) and greater than one-half of the total lesion length</td>
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</table>
Disease State Prevalence

PAD patients with calcium => large and growing problem in the U.S.

Incidence of Arterial Calcium:
- CAD: 6-20% severe calcium\(^8,\,9\)
- PAD: up to 80% moderate & severe calcium\(^10\)
- Key predictors include Diabetes & kidney disease


Current methods of treatment

- Scoring/cutting balloon
- Atherectomy
  - Front-cutting
  - Excisional
  - Orbital
- Lithoplasty
“Sand Blasting” Vessel Prep

• **DIAMONDBACK 360° Peripheral Orbital Atherectomy System**
  – Solid crown (1.5 or 2.0)
    • 5-6 passes total
    • 30 sec between each
    • +/- Embolic protection

• **Shockwave balloon**

• **Deliver therapy**
DIAMONDBACK 360° Peripheral Orbital Atherectomy System

Sleek Electric-Powered Handle
- Simple device set-up
- Optimum torque transfer to the shaft and crown
- Short overall treatment times

Prime Control
- Flush saline from device

Simple Speed Settings

Instant Response On/Off Switch

Brake

Saline Pump
- Mounts directly to an I.V. pole
- Bathes shaft and crown to facilitate smooth device operation

Crowns
- Micro Crown
- Classic Crown
- Solid Crown

Photographs are not to scale and for illustrative purposes only.
Micro-fissures after OAS

Sotomi, Y et al. JACC Interv 2015
Intravascular Lithoplasty (IVL)

- DISRUPT CALCIUM
- RESTORE FLOW
- EXPAND POSSIBILITIES

Reshape interventional therapy with the power of Lithoplasty® Technology.

Dilate to reference vessel diameter ≤ 6 ATM

Lithoplasty®

Our System
IVL: Early Clinical Data

• **Disrupt PAD II**
  - 60 pts
  - 85% severe Ca++
  - 98 mm length
  - 12 mo primary patency: **54.5% (62.9%)**
  - 12 mo C-TLR: **20.7% (8.6%)**  Brodmann, M et. al. Cath Cardiovasc Interv. 2018

• **Disrupt PAD III**
  - IVL + DCB vs. DCB alone – currently enrolling
76 yo F, DM, CKD, RC V

BLASTING, no SAND
Why both? Disrupt the ‘cast’ around the vessel

- **OAS**
  - Micro-fissures
  - Superficial disruption

- **IVL**
  - Micro and Macro-fissures
  - Deeper disruption

*Change vessel compliance, increase lumen gain*
*Reduce recoil*
*Reduce spiral dissection*
Patient Selection

- **Severe, dense calcification**
  - Must maintain true lumen
  - Eccentric
  - Regions less desirable for scaffold
    - CFA
    - Across knee joint
  - In Fem-pop region*, acceptable runoff

*Smaller diameter lithoplasty balloons for tibials now available*
Patient #1: 63 yo M, DM, tobacco abuse

- RC II claudication, life-style limiting
- Abnormal resting ABI on Right (0.69), Left normal
- Abnormal pulse exam on R, normal L
Post procedure & 6 mo follow up

- 2+ palpable pulses end of procedure, no distal embolization

- 6 mo ABI: R: 1.01  L:0.96
- 6 mo Arterial Duplex: <50% stenosis R SFA
12 Mo Follow up

- Procedure date: 10/2017
- Last visit: 10/2018
  - RC O, doing well.
  - ABI 10/2018: R: 1.57      L: 1.57, normal bilateral PVRs
  - Arterial duplex 10/2018: <50% R SFA by arterial duplex
55 yo M, HTN, DM, RC III
Popliteal After CSI
After IVL
Popliteal after DCB
SFA- after CSI and Lithoplasty, DES
Limitations

- Atherectomy device
- Lithoplasty
- Orbital atherectomy + lithoplasty ≠ standalone treatment
- Need for DCB, DES

Small sample size: 5 patients
- 100% technical success, 0% complications
- 2 pts followed 18 months, TLR 0%, Duplex <50% stenosis, normal ABI
Moving Forward

- Registry of patients with severe calcifications
  - OAR + lithoplasty vs. lithoplasty alone using IVUS
  - End points
    - Patency, TLR

- Cost analysis
  - Initial, longitudinal
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