What Are the Best Tools to Prepare the Calcified Artery? Atherectomy, Serration Angioplasty, Scoring, Lithotripsy

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Disclosure

Speaker name:

I have the following potential conflicts of interest to report:

- [x] 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
Importance of Vessel Preparation for Calcified Lesions

• Calcified lesions remain a significant barrier to optimal vessel preparation.

• Difficulty in obtaining optimal luminal gain.

• More likely to cause severe dissection.

• Independent predictor of lesion failure, esp for DCBs
Orbital Atherectomy

• Offset crown that modifies calcific plaque.

• Provides some debulking, increases compliance of vessel.

Peripheral
Dealing with Calcification
Dealing with Calcification

2.0 mm Crown
Comparison of Orbital Atherectomy Plus Balloon Angioplasty vs. Balloon Angioplasty Alone in Patients With Critical Limb Ischemia: Results of the CALCIUM 360 Randomized Pilot Trial

- 50 patients with CLI
  - Randomized to POBA or orbital atherectomy + POBA

- All lesions with >25% angiographic calcium

- Mean lesion length 69 vs. 91 mm

Shammas et al, J Endovasc Ther 2012;19:480-488
• Procedural success 93% for OA, 82% for POBA

• Bailout stenting 7% vs. 14%

• One year freedom from TLR 93% vs. 89%.

Shammas et al, J Endovasc Ther 2012;19:480-488
### Serration Technology

Serration Technology provides **effective** and **stable** lumen gain

- **Effective**: achieving nominal lumen diameter
- **Stable**: resulting in minimal dissection

### Indication for Use:

The Serranator® PTA Serration Balloon Catheter is intended for dilatation of lesions in infrapopliteal arteries. Not for use in the coronary or neurovasculature.

### Table: Serration Balloon Catheter Specifications

<table>
<thead>
<tr>
<th>Balloon Diameter (mm)</th>
<th>Balloon Length (mm)</th>
<th>Guidewire Compatibility</th>
<th>Sheath Size (F)</th>
<th>Number of Strips</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5, 3.0, 3.5</td>
<td>40</td>
<td>0.014&quot;</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>80</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>120</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catheter Length: 150cm</td>
<td></td>
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</tr>
</tbody>
</table>
Mechanism of Action: Serration Angioplasty

- Serrating Elements use “Point Force”
  - Applies 1,000x the force compared to POBA
  - Enables low pressure inflation (6 ATM*)

- 3 Linear Serrated Strips (120° apart)
  - Symmetrical Stress Relief ensures equal pressure across treatment segment
  - Opens resistant lesions

*PRELUDE-BTK Study: 6ATM Average Maximum Pressure
**Objective**
Assess safety and efficacy of the Serranator® PTA Serration Balloon Catheter in subjects with atherosclerotic peripheral artery disease of the infrapopliteal arteries.

**Study Design**
Single Arm, Prospective Multi-center Study with atherosclerotic lesions in the infrapopliteal arteries and/or Critical Limb Ischemia (CLI).

**Core Lab Assessment**
Corelab assessments Angiogram OCT, IVUS

**Follow-up**
30 day & 6 month
100% data monitoring by local CRO

**Co-PIs**
Drs. Andrew Holden & Michael Lichtenberg

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rutherford 3, 4 or 5 (&lt; 20% of subjects enrolled with R3)</td>
<td>Rutherford 1, 2, or 6</td>
</tr>
<tr>
<td>RVD between 2.5 – 3.5</td>
<td>Previously implanted stent</td>
</tr>
<tr>
<td>Up to 2 lesions within infrapopliteal tibial arteries</td>
<td>CTO &gt; 12 cm</td>
</tr>
<tr>
<td>Stenosis &gt; 70%</td>
<td>Evidence of acute thrombus</td>
</tr>
<tr>
<td>Lesion(s) length &lt; 12 cm</td>
<td>Atherectomy</td>
</tr>
<tr>
<td>De-novo, or non-stented restenotic lesions</td>
<td>2 lesions in 1 vessel, only 1 qualifies</td>
</tr>
</tbody>
</table>
Case Example: Proximal & Distal Posterior Tibial

Pre-Procedure

Stenosis: 80%
Lesion Length: 119.96mm

Inflation #2

3.0 x 120 Serranator
Max ATM: 6

Post Final

Residual Stenosis: 22%
Lesion Length: 152.64mm
Dissection: No

PRELUDE-BTK Study: Case Example 07-001

Performed by Dr. Klaus Hertting
Scoring Balloon Angioplasty

• High performance balloon for precision, power, and safety
  • Minimal slippage
  • More dilatation force
  • Low dissection rate
• Optimized vessel prep
  • Score plaque
  • Score calcium
• PANTHER study
  • 101 patients
  • Overall patency 83.9% at 12 months
Angiosculpt Example
Intravascular Lithotripsy (IVL): Localized Lithotripsy to Treat Cardiovascular Calcium

Inspired by urological applications, but designed for cardiovascular system

**Lithotripsy**

- 30 years of safety data in kidney stone treatment
- *Sonic Pressure Waves* preferentially impact hard tissue, disrupt calcium, leave soft tissue undisturbed

**Cardiovascular Lithotripsy**

- Miniaturized and arrayed Lithotripsy Emitters for localized lithotripsy at the site of the vascular calcium

- Optimized for the Treatment of Cardiovascular Calcium

- Peripheral IVL Catheters
The Shockwave IVL System consists of an IV pole-mountable generator, a connector cable, and a catheter that houses an array of lithotripsy emitters enclosed in an integrated balloon.
### Peripheral IVL Catheter Specs

<table>
<thead>
<tr>
<th>DIAMETER (mm)</th>
<th>LENGTH (mm)</th>
<th>Max Pulse Count</th>
<th>GUIDEWIRE COMPATIBILITY (in)</th>
<th>SHEATH COMPATIBILITY</th>
<th>WORKING LENGTH (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5-6.0</td>
<td>60</td>
<td>300</td>
<td>0.014</td>
<td>6F</td>
<td>110</td>
</tr>
<tr>
<td>6.5-7.0</td>
<td>60</td>
<td>300</td>
<td>0.014</td>
<td>7F</td>
<td>110</td>
</tr>
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</thead>
<tbody>
<tr>
<td>2.5-4.0</td>
<td>40</td>
<td>160</td>
<td>0.014</td>
<td>5F</td>
<td>135</td>
</tr>
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Summary and Conclusions

• Calcium remains a barrier to optimal endovascular therapy

• Multiple options for vessel preparation in calcium
  • Atherectomy
  • Serration balloon angioplasty
  • Scoring balloon angioplasty
  • Intravascular lithotripsy

• Need data for combining these therapies with subsequent treatments