Vascular Calcium: New Pre-Clinical Models and New Treatment Solutions

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Disclosure Statement of Financial Interest

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Calcium Correlates with Atherosclerosis Severity and Increases in the BTK Territory
Pathology Evaluation in CLI Patients Undergoing Amputation

Soor GS. Pathology 2008;40:385-391
### Types of Calcification in PVD

<table>
<thead>
<tr>
<th>Microcalcification</th>
<th>Fragmented calcification</th>
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<tr>
<th>Sheet calcification</th>
<th>Nodular calcification</th>
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Ca^{2+}

Renu Virmani, TCTMD 2107 (Modified)
Novel Porcine Model of Calcific SFA Stenosis for the Evaluation of Endovascular Therapies

Day 0

Day 21

DS: 42 ± 9%
LLL: 0.48mm

DS: 58 ± 18%

Inflammation
Endothelial Coverage
Neointima Coverage
Calcification
Media fibrosis

Courtesy of the CRF-Skirball Center for Innovation
Severe Vessel Calcification: Reduced Vessel Compliance and Stent Use

Reduced Vessel Compliance

Barrier to Optimal Dilatation

12-mo Primary Patency Rates
[and mean lesion lengths (cm); Core Lab-Adjudicated]

5. IN.PACT™ Admiral Instructions for Use, M052624T001_Rev1F_EN, Figure 10.
8. Lutonix™ 035 Instructions for Use, BAW 1387400r3 Section 10.5.
Severity of lesion calcification is associated with increased LLL after treatment with DCB.
Calcified Plaque Modification Alters Local Drug Delivery in the Treatment of Peripheral Atherosclerosis

OAS Treated SFA segments exhibited decreases in plaque thickness and circumferential arc.

26% deeper paclitaxel penetration and 70% larger effective diffusion coefficient.

Therapeutic Options to Vascular Calcification

NC balloons  Cutting balloon  Angiosculpt

Laser  Rotational atherectomy  Orbital atherectomy

Debulk or Disrupt or Debulk AND Disrupt?
Laser Mechanism of Action (Turbo Power)

With Each Pulse \( (Hertz = 40-80 \text{ pulses/second}) \)

1. Light is **Absorbed**, Breaking Molecular Bonds

2. Laser Induces **Acoustic Pressure Wave**
   - **DISRUPTS** Hard Plaque

3. **Hydraulic Vapor Bubble** Expands and Collapse
   - **DEBULKS** Mixed Morphologies
Bench Top Testing: Power of Acoustic Pressure Wave

Laser Mechanism of Action

Pre-Laser Pulse

Laser Pulse Crack Propagation

Bubble Formation

2.0 Turbo Elite Pulsed in Glass Tube
Laser Mechanism of Action in Humans

- Modify lesion from the tip with no moving parts
- Laser delivery is directional/rotational
- Rotation reduces “dead space” and may increase ablation capabilities
- More deliverable in calcific lesions

Images courtesy of Dr. George Adams
Conclusions

• Calcium is universally present in PVD; significant variability exist in regards to severity and location
• Calcium is a marker of disease severity and its presence correlates to worse peri-procedural and long term outcomes
• Circumferential superficial LAMINAR calcium may the biggest issue (as a barrier for drug delivery)
• Disrupting calcium (via different mechanisms) has been proposed to be beneficial to improve clinical outcomes
• Laser technology offers unique combination of calcium disruption and plaque debulking
• Clinical evidence warranted to support this hypothesis
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