Rotational Atherectomy and Thrombectomy in CLI: How is this Different

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Disclosures

Speaker’s Bureau:
• Abbott Vascular
• Medtronic

Honorarium:
• AstraZeneca

Consultant:
• CSI
• Terumo Medical
• Spectranetics
• Bard
• Avinger

Stockholder:
• Avinger
Lesion Characteristics Differ by Location

**Above the Knee**
- Calcium 35%
- CTOs 20%
- ISR 15%
- Fibrotic 10%
- Soft Plaque 10%
- Thrombus 10%

**Below the Knee**
- Calcium 75%
- CTOs 15%
- ISR 3%
- Soft Plaque 2%
- Thrombus 3%
- Fibrotic 3%

- Lesions more commonly calcified
- Dense calcium comprises a greater percentage of plaque (27% in tibial vs 12% in popliteal plaque)
- Small vessels (2-3.5 mm)
- Tortuous anatomy

• Multiple plaque types (mixed morphology)
• Large plaque burden
• Medium to large vessels (4-9 mm)

1. VIVA 2011 survey – 100 physicians surveyed.
Atherectomy Addresses Clinical Challenges

- Lesion characteristics
  - Calcium
  - In-stent restenosis
  - Chronic total occlusions (CTOs)
  - Soft plaque
  - Thrombus (thrombectomy)

- Procedural goals
  - Avoid stenting
  - Vessel preparation
    - Drug elution
    - Modify vessel compliance

Scenario:
Guidewire crosses lesion but device fails to follow
Why Remove Calcium?

- Calcium is heavily present in peripheral lesions\(^1\)
- Presence of calcium necessitates greater balloon pressures\(^2,3\)
- Calcium might influence drug-coated balloon efficacy\(^4\)
- Plaques associated with arterial dissections commonly have significant calcium deposits\(^5\)

**Calcium Increases Arterial Resistance to Balloon Dilation\(^2\)**

(Rabbit Model of Atherosclerosis)

<table>
<thead>
<tr>
<th>Artery Calcification</th>
<th>Calcium (mg/cm(^2) surface area)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistance to Balloon Dilation</td>
<td>(\Delta V_{\text{max}}) ((\mu\text{L}))</td>
</tr>
<tr>
<td>calcium/cholesterol</td>
<td>40</td>
</tr>
<tr>
<td>cholesterol</td>
<td>30</td>
</tr>
<tr>
<td>control</td>
<td>20</td>
</tr>
</tbody>
</table>

Consensus panel suggests that atherectomy should be considered as part of the SFA treatment algorithm for cases of severe calcification.
60 patients with SFA stenosis or occlusion treated with DCB

CTA, DSA, and IVUS used to quantify the calcium burden

At 1 year, greater calcification was associated with:
  
  • Lower patency
    • 50% for 270°-360° vs 100% for 0°-90°
  
  • Lower ankle-brachial index

  • Greater late lumen loss and TLR rate

Calcium Reduces Drug-coated Balloon Efficacy

• DEFINITIVE AR: directional atherectomy + DCB vs DCB alone
  • Third non-randomized arm for directional atherectomy + DCB for severely calcified lesions
• Results suggest that adjunctive atherectomy may improve procedural and clinical outcomes following DCB treatment of the SFA and/or popliteal artery, particularly for longer or severely calcified lesions

Procedural Results

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>Atherectomy + DCB</th>
<th>Atherectomy + DCB (Severe Ca²⁺)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success</td>
<td>64.2%</td>
<td>89.6%</td>
<td>84.2%</td>
</tr>
<tr>
<td>Bail-out Stent</td>
<td>3.7%</td>
<td>0%</td>
<td>5.3%</td>
</tr>
<tr>
<td>Flow-limiting Dissection</td>
<td>19%</td>
<td>2%</td>
<td>0%</td>
</tr>
</tbody>
</table>

12-Month Results

- **Lesions >10 cm**
  - DUS Patency: 97% vs 86%
  - % Stenosis: 31% vs 37%
- **All Severe Ca²⁺**
  - DUS Patency: 70% vs 63%
  - % Stenosis: 50% vs 47%

Zeller, VIVA 2014.
DCB, drug-coated balloon; DUS, duplex ultrasound; SFA, superficial femoral artery
Atherectomy and Embolization Risk

- Atherectomy device features intended to minimize the risk of embolization:
  - Remove plaque debris
    - Jetstream active aspiration
    - Directional atherectomy device debris capture
  - Generate particles small enough (i.e., <5 µm) to pass through the circulatory system
    - Peripheral Rotablator
    - Orbital atherectomy device¹

- Managing embolization
  - Embolic protection device
  - Salvage options include aspiration and mechanical thrombectomy

# Atherectomy Devices

<table>
<thead>
<tr>
<th>Source</th>
<th>Jetstream™ Atherectomy System (Boston Scientific)</th>
<th>Peripheral Rotablator™ Rotational Atherectomy System (Boston Scientific)</th>
<th>Diamondback 360™, Stealth 360™ Atherectomy System (Cardiovascular Systems, Inc)</th>
<th>SilverHawk™, TurboHawk™ Plaque Excision System (Covidien)</th>
<th>Turbo-Elite™ Laser Atherectomy Catheter (Spectranetics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front-Cutting</td>
<td>✓</td>
<td>✓</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Differential Cutting</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>N/A</td>
</tr>
<tr>
<td>Active Aspiration</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concentric Lumens</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion Morphology:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓ (large vessel only)</td>
<td>✓</td>
</tr>
<tr>
<td>Soft/Fibrotic Plaque</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Thrombus</td>
<td>✓ (indicated for thrombectomy and atherectomy)</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

Rotational Device Characteristics

- Front-cutting
  - Immediately engage the lesion
  - Facilitate guidewire placement across a CTO

- Differential cutting
  - Cut one material while sparing another based on differences in composition
  - Elastic tissue (vessel wall) deflects away from the atherectomy device while inelastic tissue (plaque) is selectively ablated
JETSTREAM™ Systems

- Rotational/differential cutting tips
- Aspiration ports collect plaque & thrombus
- .014GW / 7F sheath compatible

**JETSTREAM XC (eXpandable Cutter) System**
- 135 cm OTW
- Two sizing options in a single device

**JETSTREAM SC (Single Cutter) System**
- 145 cm OTW
- Single Cutter technology for tortuosity
Jetstream Clinical Studies

Pathway PVD study
• 172 patients at 9 European centers
  • 51% had lesions with moderate to high calcium, 31% total occlusions
• 74% TLR-free at 12 months
• Patients with diabetes had MAE rates and clinical improvement similar to those without diabetes

Jetstream Calcium Study
• Multicenter study of patients with moderately to severely calcified peripheral artery disease (N=21)
• Results show that the JetStream Atherectomy System removes and remodels superficial calcium in moderately and severely calcified lesions, resulting in significant luminal gain

JET Post-market Registry
• Ongoing registry to observe effects of Jetstream on various lesion types/morphologies

Maehara et al. ISET 2013, Miami, FL
ClinicalTrials.gov NCT01492699
One-Year Outcome of Percutaneous Rotational Atherectomy With Aspiration in Infrainguinal Peripheral Arterial Occlusive Disease: The Multicenter Pathway PVD Trial

Thomas Zeller, MD¹; Hans Krankenberg, MD²; Hermann Steinkamp, MD³; Aljoscha Rastan, MD¹; Sebastian Sixt, MD¹; Andrej Schmidt, MD⁴; Horst Sievert, MD⁵; Erich Minar, MD⁶; Marc Bosiers, MD⁷; Patrick Peeters, MD⁸; Jörn O. Balzer, MD⁹; William Gray, MD¹⁰; Thilo Tübler, MD²; Christian Wissgott, MD¹¹; Uwe Schwarzwälder, MD¹; and Dierk Scheinert, MD⁴

- **Objective:** assess performance/safety of the JETSTREAM™ Atherectomy System during percutaneous peripheral vascular interventions
- **Prospective, single arm, multi-center study**
- **172 patients at 9 European centers**
# PVD Study Results

- Jetstream™ device success was 99% (208/210 lesions were cleared)
- 85% of patients TLR-free at 6 months, 74% TLR-free at 12 months
- Stenting performed in 7% of lesions during the index procedure

## Major Adverse Events

<table>
<thead>
<tr>
<th>Event</th>
<th>30 Days (n=172)</th>
<th>6 Months (n=162)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAE</td>
<td>2 (1%)</td>
<td>31 (19%)</td>
</tr>
<tr>
<td>TVR</td>
<td>0 (0%)</td>
<td>4 (2%)</td>
</tr>
<tr>
<td>Death</td>
<td>0 (0%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Amputation</td>
<td>2 (1%)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2 (1%)</td>
</tr>
<tr>
<td>TLR</td>
<td>0 (0%)</td>
<td>25 (15%)</td>
</tr>
<tr>
<td>MI (non-Q-wave)</td>
<td>0 (0%)</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Preplanned amputations.

## Incidences of TLR or Restenosis by Lesion Location

<table>
<thead>
<tr>
<th>Lesion Location</th>
<th>6 Months</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>SFA (n=134)</td>
<td>23 (17.2%)</td>
<td>41 (30.6%)</td>
</tr>
<tr>
<td>ATA (n=2)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>TPT (n=13)</td>
<td>1 (7.7%)</td>
<td>2 (15.4%)</td>
</tr>
<tr>
<td>PTA (n=1)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Popliteal artery (n=58)</td>
<td>9 (15.5%)</td>
<td>14 (24.1%)</td>
</tr>
<tr>
<td>Peroneal artery (n=2)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Total (n=210)</td>
<td>33 (15.7%)</td>
<td>57 (27.1%)</td>
</tr>
</tbody>
</table>

ATA, anterior tibial artery; MAE, major adverse event; MI, myocardial infarction; PTA, posterior tibial artery; SFA, superficial femoral artery; TLR, target lesion revascularization; TPT, tibioperoneal trunk; TVR, target vessel revascularization.

Jetstream Calcium Study Results

Patient Demographics and Lesion Characteristics (N=21)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>72  [65, 79]</td>
</tr>
<tr>
<td>Male (%)</td>
<td>62%</td>
</tr>
<tr>
<td>Diabetic</td>
<td>52%</td>
</tr>
<tr>
<td>Insulin treated</td>
<td>28.6%</td>
</tr>
<tr>
<td>Lesion location</td>
<td></td>
</tr>
<tr>
<td>Superficial femoral artery</td>
<td>76%</td>
</tr>
<tr>
<td>Popliteal artery</td>
<td>33%</td>
</tr>
<tr>
<td>Common femoral artery</td>
<td>5%</td>
</tr>
<tr>
<td>Superficial and popliteal artery</td>
<td>10%</td>
</tr>
<tr>
<td>Common and superficial femoral artery</td>
<td>5%</td>
</tr>
<tr>
<td>De novo lesion</td>
<td>90.5%</td>
</tr>
</tbody>
</table>

Operator visual assessment

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium grading</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>33.3%</td>
</tr>
<tr>
<td>Severe</td>
<td>66.7%</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>55  [20, 120]</td>
</tr>
<tr>
<td>Lesion diameter (mm)</td>
<td>5.0  [4.3, 6.0]</td>
</tr>
<tr>
<td>Diameter stenosis</td>
<td></td>
</tr>
<tr>
<td>Pre-treatment (%)</td>
<td>82  [80, 90]</td>
</tr>
<tr>
<td>Post-atherectomy (%)</td>
<td>40  [30, 40]</td>
</tr>
</tbody>
</table>

Procedural Characteristics

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Device run time (min)</td>
<td>5.1  [3.3, 7.0]</td>
</tr>
<tr>
<td>Blades down time (min)</td>
<td>2.0  [1.6, 2.5]</td>
</tr>
<tr>
<td>Blades up time (min)</td>
<td>2.0  [1.0, 4.0]</td>
</tr>
<tr>
<td>Volume of aspiration (cc)</td>
<td>200 [113, 275]</td>
</tr>
<tr>
<td>Adjunctive treatment</td>
<td></td>
</tr>
<tr>
<td>PTA</td>
<td>71.4%</td>
</tr>
<tr>
<td>Stent</td>
<td>23.8%</td>
</tr>
<tr>
<td>Other</td>
<td>4.8%</td>
</tr>
<tr>
<td>None</td>
<td>0%</td>
</tr>
</tbody>
</table>

- Adjunctive therapy was used for most lesions:
  - 71% balloon angioplasty
  - 24% stent

- No MAEs (death, MI, TLR, unplanned amputation) reported within 30 days post-procedure

MAE, major adverse event; MI, myocardial infarction; TLR, target lesion revascularization
Maehara et al. ISET 2013, Miami, FL

NCVH 2015
In the lesion-level analysis, minimum lumen area increased from 4.3 to 7.4 mm$^2$
At the calcified plaque level, lumen area increased from 6.6 to 9.8 mm$^2$
Calcium reduction resulted in a 78% increase in lumen area.

Calcified Plaque Level Comparison (N=69)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-atherectomy</th>
<th>Post-atherectomy</th>
<th>p-value $^d$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumen area (mm$^2$)</td>
<td>6.6 [5.5, 7.7]</td>
<td>9.8 [8.7, 10.9]</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Minimum lumen diameter (mm)</td>
<td>2.2 [2.1, 2.4]</td>
<td>3.0 [2.8, 3.1]</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Lumen symmetry</td>
<td>0.68 [0.64, 0.71]</td>
<td>0.75 [0.71, 0.79]</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Decrease of calcium area (mm$^2$)</td>
<td>NA</td>
<td>2.2 [1.8, 2.7]</td>
<td>NA</td>
</tr>
<tr>
<td>Decrease of calcium/lumen gain (%)</td>
<td>NA</td>
<td>78 [70, 86]</td>
<td>NA</td>
</tr>
<tr>
<td>Maximum superficial calcium arc (°)</td>
<td>144 [121, 169]</td>
<td>137 [109, 164]</td>
<td>0.14</td>
</tr>
</tbody>
</table>

Surface shape of calcium

| Convex (%)                                    | 46/69 (67%)     | 18/69 (26%)      | 0.0004       |
| Concave (%)                                   | 23/69 (33%)     | 51/69 (74%)      |              |

Irregularity of surface of superficial calcium

| Irregular (%)                                  | 38/69 (55%)     | 22/69 (32%)      | 0.02         |
| Smooth (%)                                     | 31/69 (45%)     | 47/69 (68%)      |              |
| Reverberation (%)                              | 33/69 (48%)     | 33/69 (48%)      | 1.0          |
| Maximum arc of reverberation (°)               | 21 [13, 28]     | 69 [44, 94]      | 0.0006       |

$^d$P-value determined using non-parametric paired Wilcoxon test for continuous measures, McNemar’s test for categorical measures and generalized estimating equations (GEE) adjusted p-value to account for within patient clustering.
CLI Case

Thrombotic Popliteal artery occlusion

Jetstream XC 2.1/3.0 mm device
CLI Case

Post Jetstream Atherectomy/
Thrombectomy and Adjunctive PTA
SFA Lesion, 15 cm treated
*Moderately Calcified*

2 passes Blades Down
4 passes Blades Up

Adjunctive PTA
6 mm Armada Balloon

JETSTREAM Navitus™
Runtime: 4:12 mins
Dr. Zakir – Vascular Access Center
Piscataway, NJ  11-15-11

Pre Treatment
Lesion Location

Post
JETSTREAM G3® SF

Post Adjunctive
Treatment

JETSTREAM G3® SF
Runtime: 1:36 mins

Posterior Tibial CTO, 4 cm

2 Passes Blades Down
JetStream SF1.6 catheter

Adjunctive PTA
2.5mm Armada balloon

Console
Closing Remarks / Thank You
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