Calcium Removal and Plaque Modification in the Era of DEB and Contemporary Stenting for Femoro-Popliteal Disease

Thomas M. Shimshak, MD
Heart and Vascular Center
Florida Hospital Heartland Medical Center
Sebring, FL
Disclosures

Thomas M. Shimshak, MD

I have the following potential conflicts of interest to declare:

- Consulting and Speaker Program – Boston Scientific Corporation
- Research – Boston Scientific Corporation, Volcano Corporation
- Teaching Programs – Boston Scientific Corporation, Boston Scientific Corporation
Why is Plaque Modification Prior to DEB or Stenting Important?

• Plaque morphology in denovo lesions is complex
• Plaque burden is excessive and may limit stent expansion and effective drug delivery
• Debulking for ISR has been shown to be superior to angioplasty alone
Why Should We Remove Calcium?

- Calcium is present in peripheral lesions\(^1\)
- Presence of calcium necessitates greater balloon pressures\(^2,3\)
- Plaques with associated calcium have increased dissection rates after angioplasty\(^5\)
- Calcium may influence drug-coated balloon efficacy\(^4\) and stent expansion

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

(Rabbit Model of Atherosclerosis)

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Intravascular ultrasound evaluation of JETSTREAM atherectomy removal of superficial calcium in peripheral arteries

Akiko Maehara¹,², MD; Gary S. Mintz², MD; Thomas M. Shimshak³, MD; Joseph J. Ricotta 2nd⁴, MD, MS; Venkatesh Ramaiah⁵, MD; Malcolm T. Foster 3rd⁶, MD; Thomas P. Davis⁷, MD; William A. Gray¹*, MD

Objective

• Evaluate the treatment effects of Jetstream in moderately to severely calcified peripheral artery disease

Design

• Prospective, single arm, multicenter study
• Systematic use of IVUS analysis pre and post procedure
• Compare matched frames of IVUS images pre and post treatments with both quantitative and qualitative measurements

IVUS, intravascular ultrasound; MI, myocardial infarction
Inclusion Criteria

- Symptomatic lesions with superficial calcium $> 90^\circ$ and $> 5$ mm in length by IVUS

Primary Endpoint

- Calcium removal and luminal gain as measured by IVUS from pre to post-Jetstream treatment
Currently Available JETSTREAM™ Systems

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

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

**JETSTREAM SC (Single Cutter) System**
- 145cm OTW
- Single Cutter technology for tortuosity
## JETSTREAM Calcium Study
### Lesion Location and Characteristics

<table>
<thead>
<tr>
<th>Target lesion location</th>
<th>Percentage</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial femoral artery</td>
<td>62.5%</td>
<td>15/24</td>
</tr>
<tr>
<td>Popliteal artery</td>
<td>20.8%</td>
<td>5/24</td>
</tr>
<tr>
<td>SFA and Popliteal</td>
<td>12.5%</td>
<td>3/24</td>
</tr>
<tr>
<td>SFA and common femoral</td>
<td>4.2%</td>
<td>1/25</td>
</tr>
</tbody>
</table>
# JETSTREAM Calcium Study

## Lesion Characteristics

<table>
<thead>
<tr>
<th>De novo lesions</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiographic calcium grade</td>
<td>Moderate</td>
<td>36.4%</td>
<td>8/22</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>63.6%</td>
<td>14/22</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>45</td>
<td>[20, 103]</td>
<td></td>
</tr>
<tr>
<td>Reference vessel diameter (mm)</td>
<td>5.0</td>
<td>[4.5, 5.9]</td>
<td></td>
</tr>
<tr>
<td>Adjunctive treatment</td>
<td>Balloon angioplasty</td>
<td>61.5%</td>
<td>16/26</td>
</tr>
<tr>
<td></td>
<td>Stent</td>
<td>30.8%</td>
<td>8/26</td>
</tr>
<tr>
<td></td>
<td>Other atherectomy device</td>
<td>7.7%</td>
<td>2/26</td>
</tr>
</tbody>
</table>
## JETSTREAM Calcium Study
### Lesion Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Pre-treatment</th>
<th>Post atherectomy</th>
<th>Post adjunctive treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual diameter stenosis (%)</td>
<td>86 ± 9 (%)</td>
<td>37 ± 13 (%)</td>
<td>10 ± 6 (%)</td>
</tr>
<tr>
<td>Atherectomy treatment time (mins)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blades down</td>
<td>2.1 ± 1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blades up</td>
<td>2.5 ± 1.8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
JETSTREAM Calcium Removal Study
Procedural and 30-Day Adverse Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dissections</td>
<td>0</td>
</tr>
<tr>
<td>Perforation</td>
<td>0</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0</td>
</tr>
<tr>
<td>Major adverse events</td>
<td>0</td>
</tr>
</tbody>
</table>
Change in Lesion Dimensions

Decrease of calcium (2.2 mm²) accounted for 77% of luminal gain

**Increase in Lumen Area (mm²)**

- Pre Treatment: 6.4
- Post Atherectomy: 9.6

P <0.0001

**Maximum Arc of Reverberation °**

- Pre Treatment: 25
- Post Atherectomy: 70

p 0.001

Decrease of calcium (2.2 mm²) accounted for 77% of luminal gain.
Change in Lesion Dimensions Post Atherectomy at Minimum Lumen Area Site

The decrease in calcium area (2.8 mm$^2$) accounted for 86% of the lumen area increase.
Change in Lesion Dimensions at Maximum Calcium Ablation Site

**Increase in Lumen Area (mm²)**
- Pre Treatment: 6.6
- Post Atherectomy: 10.0
- p 0.001

**Decrease in Area Stenosis (%)**
- Pre Treatment: 53
- Post Atherectomy: 29
- p 0.0005
JETSTREAM Calcium Removal Study
Changes in MLA Post Atherectomy and Angioplasty

Minimum Lumen Area (mm²)

<table>
<thead>
<tr>
<th></th>
<th>Post Atherectomy</th>
<th>Post Angioplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td>p &lt; 0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.1</td>
<td>11.9</td>
<td></td>
</tr>
</tbody>
</table>

0 5 10 15
Post Atherectomy Post Angioplasty
IVUS Images From JETSTREAM Calcium Study Pre and Post JETSTREAM Atherectomy

- 3 mm$^2$ gain in lumen CSA with JETSTREAM
- Calcium reduction of 1.1 mm$^2$ (37% of lumen gain)

JETSTREAM Atherectomy
Angio and IVUS of Eccentric, Calcified CFA
JETSTREAM Atherectomy
Angio and IVUS of Eccentric, Calcified CFA
Complex Rt CFA and Bifurcation Lesion Debulked with JETSTREAM Atherectomy

Pre Treatment

Post Atherectomy and PTA
Left CFA Stenosis
Baseline Angio and IVUS

2.4 mm² Lumen CSA
Post Jetstream Atherectomy
Angio and IVUS

8.6 mm² Lumen CSA
Lessons from JETSTREAM Calcium Study

Evaluation of the rotational atherectomy with dynamic aspiration system in femoro-popliteal stenoses with moderate to severe superficial calcification showed;

• The ability to accurately identify and localize superficial calcium was limited by angiography (only 50% in the study).

• There was a significant increase in lumen cross-sectional area that was further augmented by adjunctive balloon angioplasty.

• The removal and modification of superficial calcium accounted for a significant amount of the luminal gain in cross sectional area.
What are the implications of these results in the era of plaque modification and DEB and stenting?

Pretreatment IVUS accurately characterizes plaque burden, morphology and detects the extent and location of superficial calcium.

Plaque modification and calcium removal pre POBA, DEB and/or stenting (bare, DES, covered, bio-absorbable) may improve early and long term results by

- reducing the incidence of balloon induced dissection
- optimizing drug delivery of DEB
- Improving stent expansion, luminal gain, and drug delivery of stent platforms
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