The Utility of Atherectomy and the Jetstream™ Atherectomy System

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• IMPORTANT INFORMATION: These materials are intended to describe common clinical considerations and procedural steps for the on-label use of referenced technologies as well as current standards of care for certain conditions. Of course, patients and their medical circumstances vary, so the clinical considerations and procedural steps described may not be appropriate for every patient or case. As always, decisions surrounding patient care depend on the physician’s professional judgment in light of all available information for the case at hand.

• Boston Scientific (BSC) does not promote or encourage the use of its devices outside their approved labeling.

• The presenter’s experience with BSC products may not be interpreted or relied upon to support clinical claims about BSC devices or product comparison claims regarding BSC and competitive devices. The experiences of other users may vary.
PAD is Diverse

- Data from a lower extremity revascularization registry
  - 2137 lesions treated in 1029 patients
- Indication for treatment:
  - Claudication 44%
  - Rest pain 13.7%
  - Tissue loss 42.3%
- Mean length: 100.8 ± 9.4 mm
- Overall:
  - 62.4% stenotic
  - 28.8% CTO
  - 8.8% in-stent restenosis

Table II. Lesion location and characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. (%) or Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stenosis</td>
<td>1334 (62.4)</td>
</tr>
<tr>
<td>Chronic total occlusion</td>
<td>615 (28.8)</td>
</tr>
<tr>
<td>In-stent restenosis</td>
<td>188 (8.8)</td>
</tr>
<tr>
<td>Mean length, mm</td>
<td>100.8 ± 9.4</td>
</tr>
<tr>
<td>Location</td>
<td></td>
</tr>
<tr>
<td>Femoral</td>
<td>660 (30.9)</td>
</tr>
<tr>
<td>Popliteal</td>
<td>266 (12.4)</td>
</tr>
<tr>
<td>Tibial</td>
<td>513 (24.0)</td>
</tr>
<tr>
<td>Iliac</td>
<td>250 (11.7)</td>
</tr>
<tr>
<td>Bypass graft</td>
<td>59 (2.7)</td>
</tr>
<tr>
<td>Multilevel</td>
<td>389 (18.3)</td>
</tr>
<tr>
<td>Mean runoff</td>
<td></td>
</tr>
<tr>
<td>Preop</td>
<td>1.5 ± .9</td>
</tr>
<tr>
<td>Postop</td>
<td>1.7 ± .8</td>
</tr>
<tr>
<td>TASC classification</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>297 (13.9)</td>
</tr>
<tr>
<td>B</td>
<td>632 (29.5)</td>
</tr>
<tr>
<td>C</td>
<td>592 (27.7)</td>
</tr>
<tr>
<td>D</td>
<td>616 (28.8)</td>
</tr>
</tbody>
</table>

SD, Standard deviation; TASC, Transatlantic Inter-Society Consensus.
Lesion Characteristics Differ by Location

Above the Knee\(^1\)
- Calcium: 35%
- CTOs: 20%
- Fibrotic: 10%
- ISR: 15%
- Soft Plaque: 10%
- Thrombus: 10%

Below the Knee\(^1\)
- Calcium: 75%
- CTOs: 15%
- Fibrotic: 3%
- ISR: 2%
- Soft Plaque: 2%
- Thrombus: 3%

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

- Multiple plaque types (mixed morphology)
- Large plaque burden\(^2\)
- 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
  - Calcium reduction as a therapeutic endpoint
  - Vessel preparation for other therapy
    - Drug elution
    - Modify vessel compliance (prevent incomplete stent expansion)
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)

- **Calcium (mg/cm\(^2\) surface area)**
- **\(\Delta V_{\text{max}} (\mu L)\)**
  - calcium/cholesterol
  - cholesterol
  - control

Artery Calcification

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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

CTA, computed tomography angiography; DCB, drug-coated balloon; DSA, digital subtraction angiography; IVUS, intravascular ultrasound; SFA, superficial femoral artery; TLR, target lesion revascularization.

Atherectomy and Drug-Coated Balloon Efficacy: Clinical Evidence

- 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% (Atherectomy + DCB), 86% (DCB)
- Stenosis: 31% (Atherectomy + DCB), 37% (DCB)

All Severe Ca²⁺
- DUS Patency: 70% (Atherectomy + DCB), 63% (DCB)
- Stenosis: 50% (Atherectomy + DCB), 47% (DCB)

Zeller, VIVA 2014.
DCB, drug-coated balloon; DUS, duplex ultrasound; SFA, superficial femoral artery
# Atherectomy Devices

<table>
<thead>
<tr>
<th>Atherectomy Devices</th>
<th>Jetstream™ Atherectomy System (Boston Scientific)</th>
<th>Diamondback 360™, Stealth 360™ (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>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Differential Cutting</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>
</tr>
<tr>
<td>Concentric Lumens</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion Morphology:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium</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>
</tr>
<tr>
<td>Thrombus</td>
<td>✓ (indicated for thrombectomy and atherectomy)</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™ Atherectomy System

SYSTEM EVOLUTION
Continuous innovation to support your success

**JETSTREAM**
- First commercially available Pathway Medical product
- Expandable blades
- Aspiration port integrated into distal cutter
- 8 F introducer sheath

**JETSTREAM G2**
- Aspiration port moved proximal of cutting blades
- Macerator added
- 10% increase in aspiration efficiency¹
- Approved for thrombectomy

**JETSTREAM G2 NXT**
- Pebax outer shaft and stainless steel hypotube (reduced OD, compared to earlier generation designs)
- 7 F compatibility
- Improved trackability (compared to earlier generation designs)

**JETSTREAM G3**
- 5-flute distal cutter design
- Increased torque (power)
- 54% Increase in differential cutting efficiency²
- 11% increase in aspiration efficiency²

**JETSTREAM G3 GTI**
- Increased ease of use/ reliability (compared to JETSTREAM G3)
- New liner over driveline
- Improved distal bushing
- Enhanced GW management
- Improved User Interface

**JETSTREAM Navitus™**
- Robust Bushing and Distal Liner (same as GTI)
- Elimination of bushing tail related wire sticking
- Protection against thrombus stick
- Durable liner with improved aspiration
- Guidewire management enhancements for smoother operation over the wire

**JETSTREAM Navitus™ L**
- Largest JETSTREAM Catheter
  - 2.4 mm / 3.4 mm
  - 30% larger lumens²
- Shortened Coupler
- Improved performance in tortuous anatomy
- Navitus technology integrated
  - Identical liner and bushing technology
  - Guidewire management enhancements

**JETSTREAM™ XC/SC**
- Entire portfolio redesign
- New ergonomic POD design
- 32% smaller than previous
- Redesigned user interface
- Improved wire GARD simplifies wire management
- New package and POD design reduces environmental footprint

1. Compared to JETSTREAM G2 NXT in blades down during bench testing
2. Compared to JETSTREAM G2 NXT in bench testing
3. Data on file report: EU09194

JETSTREAM™ Atherectomy System is manufactured and distributed in EU by Bayer Interventionsal
All cited trademarks are the property of their respective owners. CAUTION: The user must ensure these devices to be used by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.
JETSTREAM™ Atherectomy Systems

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

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

**JETSTREAM™ SC (Single Cutter)**
- 145cm 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 showed 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 NCT01436435
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
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

### PVD Study Results

#### Major Adverse Events

<table>
<thead>
<tr>
<th></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>ATA (n=2)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>MAE (n=134)</td>
<td>23 (17.2%)</td>
<td>41 (30.6%)</td>
</tr>
<tr>
<td>TVR (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>TPT (n=13)</td>
<td>1 (7.7%)</td>
<td>2 (15.4%)</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.

PVD Study Results: Diabetes

• The 12-month MAE rate was 25% among diabetic patients (N=80) and 31.5% among non-diabetic patients (N=92)
• Rutherford category improvement and hemodynamic success rates at 12 months did not differ significantly between diabetic and non-diabetic patients


<table>
<thead>
<tr>
<th>12-Month Major Adverse Events</th>
<th>Non-Diabetic</th>
<th>Diabetic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1,1%</td>
<td>1,3%</td>
</tr>
<tr>
<td>MI</td>
<td>1,1%</td>
<td>1,3%</td>
</tr>
<tr>
<td>TLR</td>
<td>28,3%</td>
<td>20,0%</td>
</tr>
<tr>
<td>TVR</td>
<td>5,4%</td>
<td>3,8%</td>
</tr>
<tr>
<td>Amputation</td>
<td>0,0%</td>
<td>2,5%</td>
</tr>
</tbody>
</table>
Atherectomy of Calcified CTO

Highly Calcified 3cm long CTO

Very slow flow around CTO

1 Pass Blades Down, 2 Passes Blades Up

4x100 14 ATM

Results from case studies are not predictive of results in other cases. Results in other cases may vary.
Jetstream Calcium Study
Maehara et al. EuroIntervention, in press.

Design
• Prospective, single arm, multicenter study of the treatment effects of Jetstream in moderately to severely calcified peripheral artery disease

Primary Endpoint
• Calcium removal and luminal gain as measured by IVUS from pre to post-treatment
  – 2-3 matched slices from pre and post-atherectomy segment sites with maximum calcium reduction were analyzed
  – Minimum lumen area and proximal and distal reference sites (defined as least diseased sites) were also analyzed

Secondary Endpoints
• MAE (target lesion or vessel revascularization, death, unplanned amputation or MI) and use of adjunctive balloons or stents

Maehara et al. ISET 2013, Miami, FL.
ClinicalTrials.gov NCT01273623
Jetstream Calcium Study Results

Patient Demographics and Lesion Characteristics (N=21)

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>72 [65, 79]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (%)</td>
<td>62 %</td>
</tr>
<tr>
<td>Diabetes (%)</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 |            |
| Calcium grading           |            |
| Moderate                  | 33.3%      |
| Severe                    | 66.7%      |
| Lesion length (mm)        | 55 [20, 120] |
| Lesion diameter (mm)      | 5.0 [4.3, 6.0] |
| Diameter stenosis         |            |
| Pre-treatment (%)         | 82 [80, 90] |
| Post-atherectomy (%)      | 40 [30, 40] |

Procedural Characteristics

| Device run time (min)   | 5.1 [3.3, 7.0] |
| Blades down time (min)  | 2.0 [1.6, 2.5] |
| Blades up time (min)    | 2.0 [1.0, 4.0] |
| Volume of aspiration (cc)| 200 [113, 275] |

| Adjunctive treatment   |            |
| PTA                    | 71.4 %     |
| Stent                  | 23.8 %     |
| Other                  | 4.8 %      |
| None                   | 0 %        |

- 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.
Calcium Study IVUS Analysis

- 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
Maehara et al. ISET 2013, Miami, FL.

Pre-Intervention
Lumen Area=5.2 mm²

Post-Jetstream
Reverberation arc
Lumen Area=6.9 mm²

Post-balloon, Final
Lumen Area=15.2 mm²
Conclusions

• PAD encompasses diverse patient and lesion characteristics

• Atherectomy may improve outcomes of endovascular therapy for PAD by:
  – Reducing lesion severity and removing calcium (primary therapy or vessel preparation)
  – Avoiding incomplete stent expansion
  – Promoting drug-coated therapy efficacy
The Utility of Atherectomy and the Jetstream™ Atherectomy System

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