Optimizing DCB performance with Jetstream atherectomy

Dr. Gergana Taneva
Research Lead, Asklepios Clinic Langen, University of Frankfurt (Head: Prof. K. Donas), Germany;
Vascular Surgeon, Puerta de Hierro University Hospital, Madrid, Spain
Disclosure

I have the following potential conflicts of interest to report:
Consulting for Boston Scientific
Disclaimer

• 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.

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Why Remove Calcium?

• Calcium might influence drug-coated balloon efficacy\(^1\)
• Plaques associated with arterial dissections commonly have significant calcium deposits\(^2\)
• Presence of calcium necessitates greater balloon pressure\(^3,4\)

Lesion Calcification May Affect Drug-Coated Balloon Efficacy

• 60 patients with SFA stenosis or occlusion treated with DCB

• 50% primary patency rates in heavily calcified SFA lesions, regardless of lesion length

• Greater calcification was associated with poorer outcomes at 1 year:
  – Greater TLR rate
  – Lower ankle-brachial index
  – Greater late lumen loss

Calcium burden quantified with computed tomography angiography (CTA), digital subtraction angiography (DSA), and intravascular ultrasound (IVUS).

DCB, drug-coated balloon; SFA, superficial femoral artery; TLR, target lesion revascularization.
Advantages of Atherectomy

Atherectomy removes atherosclerotic / calcific tissue similar to surgical techniques, resulting in lumen gain without barotrauma.

Facilitating low pressure balloon angioplasty

Potentially simultaneously optimizing drug delivery to the vessel wall

Decreasing the chance for dissection, avoiding additional stent placement ‘leave nothing behind’
Jetstream Treatment Overview

Engineered to treat multiple types of morphologies: soft, fibrotic and calcified plaque & Thrombus

FRONT CUTTING: Engages tight or occluded lesions

CONCENTRIC LUMENS: Rotational, expandable blades maximize luminal gain through debulking

ACTIVE ASPIRATION: The ONLY atherectomy device with Active Aspiration
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 (Boston Scientific)

Differential Cutting
Elastic Tissue
Inelastic Tissue

Jetstream XC Catheters: SFA and Popliteal

2.1 / 3.0mm Catheter (OTW, 135cm shaft)
2.4 / 3.4mm Catheter (OTW, 120cm shaft)

2.1mm Blades-Down
3.0mm Blades-Up

2.4mm Blades-Down
3.4mm Blades-Up

Expandable-Blade Technology
Jetstream Clinical Studies in a “leave nothing behind” world

Jetstream Calcium Study

IVUS analysis of calcium removal and lumen gain

26 patients with moderately to severely calcified femoropopliteal artery lesions

Lumen area increased significantly after treatment with Jetstream;
The decrease in calcium area (2.8 mm$^2$) accounted for 86% of the lumen area increase

- Concentric “nutcracker” calcium case example
- Lumen area increased to 12.1 mm$^2$ post-balloon, without dissection

Jetstream + DCB vs Jetstream + PTA

Retrospective study of patients receiving Jetstream atherectomy to treat femoropopliteal obstructive disease

- N=75
- Treated Apr 2012 -Dec 2014 - **adjunctive PTA** (N=50)
- Treated Dec 2014–Jul 2016 -**adjunctive DCB** (N=25)
- Median treated length (p=0.053)
  - Adjunctive PTA: 15 cm
  - DCB: 10 cm

Investigator-sponsored studies are supported by grant funding from Boston Scientific. Boston Scientific is not responsible for the collection, analysis or reporting of these studies which remain the sole responsibility of the investigators.

https://doi.org/10.1016/j.carrev.2018.02.003
Jetstream Clinical Studies in a “bare” world

<table>
<thead>
<tr>
<th>Pathway PVD study</th>
<th>JET Registry</th>
</tr>
</thead>
<tbody>
<tr>
<td>172 patients at 9 European centers</td>
<td>Post-market registry of 241 patients at 37 US centers</td>
</tr>
<tr>
<td>51% had lesions with moderate to high calcium, 31% total occlusions</td>
<td>Mean lesion length 16 cm, 48% calcium grade 3 or 4, 36% total occlusions</td>
</tr>
<tr>
<td>99% device success (cleared vessel)</td>
<td>98.3% procedural success (≤30% residual stenosis)</td>
</tr>
<tr>
<td>Final residual stenosis 21.4% ± 10.5%</td>
<td>Final residual stenosis 9.8% ± 11.4%</td>
</tr>
<tr>
<td>7% bail out stent rate</td>
<td>35% adjunctive stenting</td>
</tr>
<tr>
<td>74% TLR-free at 12 months</td>
<td>81.7% TLR/TVR-free rate at 12 months</td>
</tr>
</tbody>
</table>

Garcia LA, et al. LINC 2017
### Patient characteristics

<table>
<thead>
<tr>
<th>All-comers (n=162)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>162 patients with femoropopliteal lesions</strong></td>
</tr>
<tr>
<td>Lesion length (cm)</td>
</tr>
<tr>
<td>Total occlusions (%)</td>
</tr>
<tr>
<td>Combined lesions* (%)</td>
</tr>
<tr>
<td>PACCS score (0) (%)</td>
</tr>
<tr>
<td>PACCS score (1) (%)</td>
</tr>
<tr>
<td>PACCS score (2) (%)</td>
</tr>
<tr>
<td>PACCS score (3) (%)</td>
</tr>
<tr>
<td>PACCS score (4) (%)</td>
</tr>
<tr>
<td>Mean Rutherford category</td>
</tr>
<tr>
<td>Rutherford category III</td>
</tr>
<tr>
<td>Rutherford category IV</td>
</tr>
<tr>
<td>Rutherford category V</td>
</tr>
</tbody>
</table>
Jetstream Long Lesion Registry: Results

Device success* = (88%)

Procedural success** = (99%)

Clinical success* = 149/162 (92%)

* Improvement of ≥2 Rutherford categories at follow-up
Jetstream Long Lesion Registry: Efficacy

<table>
<thead>
<tr>
<th></th>
<th>Overall Population (N=76)</th>
<th>Non-Stent (N=150)</th>
<th>Stent (N=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Binary Stenosis</strong>, % (n/N)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 Days</td>
<td>1.9% (3/162)</td>
<td>2% (3/150)</td>
<td>0.0% (0/12)</td>
</tr>
<tr>
<td>12 Months</td>
<td>13.6% (22/162)</td>
<td>12% (18/150)</td>
<td>8.3% (1/12)</td>
</tr>
</tbody>
</table>

* DUS-derived PSVR >2.5

- 12 patients (7.4%) received adjunctive stents
  - Stent placement performed at operator’s discretion
- Embolic protection used in 11.7% of cases

Overall restenosis rate at 12 months: 13.6%

Overall freedom from TVR/TLR: 87.4%

Target lesion revascularization (TLR)
**Morpheas Trial- P.I. Konstantinos Donas**

<table>
<thead>
<tr>
<th>Type</th>
<th>Prospective single-arm multicentric study (4 Vascular Surgery Departments in Germany), non-industry founded</th>
</tr>
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<tbody>
<tr>
<td>Subjects</td>
<td>114 patients with femoropopliteal OCCLUSIVE lesions  &lt;br&gt;Key inclusion criteria:  &lt;br&gt;• Rutherford category of 1-5  &lt;br&gt;• <em>de novo or restenotic complete occlusions, lesion length &gt; 10mm</em>  &lt;br&gt;• ≥1 patent runoff vessel</td>
</tr>
<tr>
<td>Endpoints?</td>
<td><strong>Primary:</strong> flow limiting dissection or recoil and need for stent placement  &lt;br&gt;<strong>Secondary:</strong> 30-day freedom from MAEs (amputation, death, TLR/TVR, MI, distal embolization that requires a separate intervention or hospitalization)</td>
</tr>
</tbody>
</table>
### Morpheas Trial

#### Fanelli Classification

<table>
<thead>
<tr>
<th>Classification</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25%</td>
<td>8</td>
<td>7.0%</td>
</tr>
<tr>
<td>25 – 50%</td>
<td>19</td>
<td>16.7%</td>
</tr>
<tr>
<td>50 – 75%</td>
<td>30</td>
<td>26.3%</td>
</tr>
<tr>
<td>75 – 100% calcification</td>
<td>57</td>
<td>50.0%</td>
</tr>
</tbody>
</table>

#### Length (median)

- 80.0 ± 107

#### Thrombotic component

- 29 (25.4%)

#### In stent occlusion

- 9 (7.9%)
In-stent restenosis and occlusion treated with JETSTREAM Atherectomy and thromboaspiration.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.
Popliteal CTO occlusion treated with JETSTREAM Atherectomy and thromboaspiration.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

After DCB adjunctive therapy.
## Morpheaes Trial: Results

### Operative data

| Stent          | 15 (13.2%) |

### Results

<table>
<thead>
<tr>
<th>Primary endpoint (flow limiting dissection or recoil needing stent placement)</th>
<th>18 cases (15.8%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary endpoint (Thromboembolism)</td>
<td>6 (5.3%)</td>
</tr>
<tr>
<td>Distal thromboembolism</td>
<td>4 (3.5%)</td>
</tr>
<tr>
<td>Thrombus in filter</td>
<td>2 (1.8%)</td>
</tr>
</tbody>
</table>

- Low incidence of stent placement despite CTOs treatment

- Low incidence of embolization underlines the **aspiration capacity**
## Morpheas Trial: Univariate Analysis

<table>
<thead>
<tr>
<th></th>
<th>Primary Endpoint n=18 – 15.8%</th>
<th>p</th>
<th>Secondary Endpoint n=6 – 5.3%</th>
<th>p</th>
<th>Composite n=23 – 20.2%</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length &gt;median &amp; Fanelli 3 &amp; 4</td>
<td>11 – 34.4</td>
<td>.001</td>
<td>2 – 6.3</td>
<td>.768</td>
<td>12 – 37.5</td>
<td>.004</td>
</tr>
<tr>
<td>Other patients, n=32</td>
<td>7 – 8.5</td>
<td></td>
<td>4 – 4.9</td>
<td></td>
<td>11 – 13.4</td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length &gt;median &amp; Fanelli 4</td>
<td>9 – 45.0</td>
<td>&lt;001</td>
<td>0 – 0.0</td>
<td>.246</td>
<td>9 – 45.0</td>
<td>.002</td>
</tr>
<tr>
<td>Other patients, n=20</td>
<td>9 – 9.6</td>
<td></td>
<td>6 – 6.4</td>
<td></td>
<td>14 – 14.9</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Length&gt;median and Hunter inv.</td>
<td>5 – 45.5</td>
<td>.005</td>
<td>0 – 0.0</td>
<td>.411</td>
<td>5 – 45.5</td>
<td>.028</td>
</tr>
<tr>
<td>Other patients, n=103</td>
<td>13 – 12.6</td>
<td></td>
<td>6 – 5.8</td>
<td></td>
<td>18 – 17.5</td>
<td></td>
</tr>
</tbody>
</table>

Analysis with Pearson’s chi square test, significant difference at p< .05 level appear bold-typed.

> 8cm occlusions in combination with Fanelli 3-4 associated significantly with flow-limiting dissections or recoil and need for stenting.
## Morpheas Trial: Logistic Regression

<table>
<thead>
<tr>
<th>Variables</th>
<th>p</th>
<th>Exp (B)</th>
<th>95% Confidence Interval Lower</th>
<th>95% Confidence Interval Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length above 80mm, n=68</td>
<td>.375</td>
<td>.452</td>
<td>.078</td>
<td>2.616</td>
</tr>
<tr>
<td>Fanelli Class 3 &amp; 4, n=87</td>
<td>.179</td>
<td></td>
<td>.045</td>
<td>1.788</td>
</tr>
<tr>
<td>Localization in Hunter Transition segment SFA/POPI Segment, n=14</td>
<td>.041</td>
<td>4.743</td>
<td>1.069</td>
<td>21.043</td>
</tr>
</tbody>
</table>

Hunter localization **associated** significantly with almost 5 times more risk for flow limiting dissections and need for stenting.
Conclusions

Vessel preparation with Jetstream Atherectomy beholds treatment advantages.

It increases lumen area while removing calcium and decreasing stent placement.

The presence of calcium may limit the effectiveness of DCB, while increasing dissection risk.

Plaque debulking with Jetstream atherectomy may enhance drug transfer to the arterial wall improving the results.

Jetstream Atherectomy System use for the treatment of femoropopliteal lesions can effectively modify arterial plaque and remove calcium leading to increased lumen area while lowering complication rates and potentially improving DCB effects.
Catheter INTENDED USE/INDICATIONS FOR USE
The JETSTREAM System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.

CONTRAINDICATIONS
None known.

Catheter WARNINGS
• Use room temperature infusate only. Use of heated infusate may lead to wrinkling, ballooning and/or bursting of the outer catheter sheath, which could lead to injury to the patient
• Operating the Catheter over a kinked guidewire may cause vessel damage or guidewire fracture.
• During treatment, do not allow the Catheter tip within 10.0 cm of spring tip portion of the guidewire. Interaction between the Catheter Tip and this portion of the guidewire may cause damage to or detachment of the guidewire tip or complicate guidewire management.
• The guidewire must be in place prior to operating the Catheter in the patient. Absence of the guidewire may lead to inability to steer the Catheter and cause potential vessel damage.
• If the guidewire is accidentally retracted into the device during placement or treatment, stop use, and remove the Catheter and the guidewire from the patient. Verify that the guidewire is not damaged before re-inserting the guidewire. If damage is noticed, replace the guidewire.
• Check the infusate bag frequently and replace when needed. Do not run the JETSTREAM System without infusate as this may cause device failure.

within the vessel, which could cause patient injury.
• Do not manipulate the Catheter against resistance unless the cause for that resistance has been determined.
• Prior to use of the JETSTREAM System, confirm the minimum vessel diameter proximal to the lesion per the following table:
  Model 1.6 1.85 2.1/3.0 2.4/3.4
  Minimum Vessel Diameter Proximal to Lesion 2.5 mm 2.75mm - -
  Minimum Vessel Diameter, Blades Down - 3.0 mm 3.5 mm
  Minimum Vessel Diameter, Blades Up - 4.0 mm 4.5 mm
• Catheter PRECAUTIONS
  • Do not bend or kink the Catheter during setup or during the procedure. This may damage the device and lead to device failure.
  • Do not inject contrast while the device is activated.
  • Only use listed compatible guidewires and introducers with the JETSTREAM System. The use of any supplies not listed as compatible may damage or compromise the performance of the JETSTREAM System.

Console WARNINGS AND PRECAUTIONS
• WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
• Do not open either pump door during operation of the System. Doing so could result in loss of aspiration and/or infusion and will halt device activation.
• Ensure the PVCN100 Console display is visible during the entire procedure.
• Follow normal safety practices associated with electrical/electronic medical equipment.
• Avoid excessive coiling or bending of the power cables during storage.
• Store the PVCN100 Console using appropriate care to prevent accidental damage.
• Do not place objects on the PVCN100 Console.
• Do not immerse the PVCN100 Console in liquids.

ADVERSE EVENTS
Potential adverse events associated with use of this device and other interventional catheters include, but are not limited to the following (alphabetical order):
Abrupt or sub-acute closure
Amputation
Bleeding complications, access site
Bleeding complications, non-access site
Death
Dissection
Distal emboli
Hypotension
Infection or fever
Minor burn
Perforation
Restenosis of the treated segment
Vascular complications which may require surgical repair
Thrombus
Varicosity