Orbital Atherectomy Prior to Drug-Coated Balloons Below-the-Knee: What Does the Future Hold?

Raymond Dattilo, MD, FACC

Flint Hills Heart, Vascular and Vein Clinic
Manhattan, KS
Disclosure

Speakers Bureau/Honoraria

• Abbott Vascular
• Cardiovascular Systems
Below-the-Knee

Characteristics

▪ Small vessel diameters

▪ Challenging anatomy

▪ Complex pattern of atherosclerosis - long, calcific stenosis/occlusions

More calcification BTK than ATK

- Age, DM, CKD

Complications

▪ 2-10% of the cases during or shortly after endovascular procedures
  - Vessel occlusion - Flow-limiting dissection related to high inflation pressure
  - Perforation
  - Access site complications

Outcomes

• BA of severely calcified lesions is limited by early elastic recoil and poor acute and long-term outcomes

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Solution

Atherectomy

Drug-coated balloons

BA = balloon angioplasty

Note: DCBs BTK are under investigation in the US.

DIAMONDBACK 360 PERIPHERAL ORBITAL ATERECTOMY SYSTEM

**Electric-Powered Handle**
- Simple device set-up
- Optimum torque transfer to the shaft and crown
- Short overall treatment times

**Crowns**
- Micro Crown
- Classic Crown
- Solid Crown

**Prime Control**
- Flush saline from device

**OAS Pump**
- Mounts directly to an I.V. pole
- Bathes shaft and crown to facilitate smooth device operation

Crows shown are the 1.25 mm Micro Crown, 1.50 mm Classic Crown, and 2.00 mm Solid Crown. Photographs are not to scale and for illustrative purposes only.
ORBITAL TECHNOLOGY
Mechanism of Action

**Centrifugal Force**
360° crown contact designed to create a smooth, concentric lumen
Allows constant blood flow and particulate flushing during orbit

**Differential sanding**
- 30 μm diamond coating
- Average particulate size\(^1\) = 2 μm
- Bi-directional sanding of superficial calcium
- Healthy elastic tissue flexes away minimizing damage to the vessel

**Pulsatile forces\(^1\)**
- Dual frequency
- Orbital Frequency: low frequency of the crown orbiting against the vessel wall.
- Rotational Frequency: high frequency corresponding to the crown rotational speed.
- Observed in both crown motion and force.

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Orbital Atherectomy – BTK Study
CALCIUM 360

Randomized, prospective, multi-center study comparing OAS + PTA to PTA alone in calcified BTK arteries

Mean Max Balloon Pressure (atm)  
OAS + PTA n=27 lesions  9.4  
PTA ALONE n=34 lesions  5.9  
p=0.001

Freedom From Revascularization at 12 Months  
OAS + PTA n=15 patients  93.3%  
PTA ALONE n=15 patients  80.0%  
p=0.14

Freedom from Major Adverse Events (MAE) at 12 Months  
OAS + PTA n=15 patients  93.3%  
PTA ALONE n=19 patients  57.9%  
p=0.006

Orbital atherectomy changed compliance and provided durable results out to 12 months vs. PTA alone

DCB – BTK Studies

Single-center studies – 1-year results

<table>
<thead>
<tr>
<th>Study</th>
<th>Restenosis</th>
<th>Occlusion</th>
<th>TLR</th>
</tr>
</thead>
</table>
| Leipzig 
1,2 | 74.0% | 55.0% | 43.0% |
| p<0.001 | p<0.001 | p=0.002 |
| DEBATE-BTK 
3 | 52.9% | 23.1% | 15.2% |
| p<0.05 | p<0.05 | |
| DeBelloM 
4 | Not reported | Not reported | |

RCTs – 1-year results

<table>
<thead>
<tr>
<th>Study</th>
<th>Restenosis</th>
<th>Occlusion</th>
<th>TLR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lutonix BTK</td>
<td>74.0%</td>
<td>55.0%</td>
<td>43.0%</td>
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<tr>
<td>13.1%</td>
<td>3.6%</td>
<td>9.2%</td>
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</tr>
<tr>
<td>Impact Deep5</td>
<td>9.2%</td>
<td>8.8%</td>
<td>10.1%</td>
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<td>No statistical differences</td>
<td></td>
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<tr>
<td>DEEP CD-TLR</td>
<td>26.9%</td>
<td>5.6%</td>
<td>6.0%</td>
</tr>
<tr>
<td>MAJOR AMP</td>
<td>31.3%</td>
<td>3.3%</td>
<td>9.4%</td>
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<tr>
<td>No statistical differences</td>
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</tr>
<tr>
<td>DEEP MAE</td>
<td>35.2%</td>
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Note: Studies completed OUS; DCBs BTK are under investigation in the US.

Calcium, Atherectomy, and DCB

Calcium is a Barrier for Drug Absorption

- Insufficient drug penetration and subsequent restenosis\(^1,2\)

As circumferential calcium increases, the effectiveness of drug-coated balloons decreases.\(^3\)

Vessel preparation with atherectomy for DCBs

- Calcium modification might be important in optimizing antiproliferative drug uptake and thereby enhancing the efficacy of DCB.

- Trend toward higher patency in long (>10 cm) and severely calcified lesions in patients treated with directional atherectomy and DCB.\(^4\)

- Patients who underwent IVUS-guided directional atherectomy followed by DCB had a 1 year TLR of 10%; bailout stenting was 6.5%.\(^1\)

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The purpose of the TRUTH study was to use VH-IVUS to determine the effect of OAS treatment on lesion modification.

Virtual histology IVUS (VH-IVUS) analysis revealed at the maximum calcium ablation site that calcium reduction was responsible for 86% of the lumen area increase.

The mean maximum balloon inflation pressure was 5.2+1.2 atm.

The minimum lumen area increased from 4.0 mm$^2$ to 9.1 mm$^2$ (<0.0001).
MINIMAL MEDIAL INJURY AFTER ORBITAL ATHERECTOMY – IVUS ANALYSIS

• In a post-hoc assessment of OAS-mediated vessel wall injury, IVUS images from the TRUTH study were analyzed before and after OAS for signs of medial injury

• 2 of the 23 post-OAS intervention images indicated medial injury (8.7%)

Orbital Atherectomy + DCB BTK Study

OPTIMIZE*

Study Details:
- Pilot study
- Prospective, 1:1 randomization
- Below the knee lesions
- 2-year follow-up
- 8 sites in Europe

Purpose:
Demonstrate the ability of the OAS to prepare calcified, BTK lesions for optimal DCB deployment

Device success, Technical success, Procedural success, Treatment success

- Late Lumen Loss of the Target Lesion at 6 months post-procedure
- Patency of the target lesion (by Duplex Ultrasound) at 6- and 12-months
- Rate of Major Adverse Events (MAEs)
- Freedom from unplanned Major Amputation
- Change in Rutherford Class
- Hemodynamic outcome (ABI and TBI)
- Change in quality of life (QoL) assessed by EuroQoL Quality of Life Questionnaire (EQ-5D)
- Change in walking capacity assessed by Walking Impairment Questionnaire (WIQ)
- Health economic outcomes

*Ongoing. clinicaltrials.gov. NCT02561299.

38 subjects enrolled as of May 2017
Conclusions

- Orbital atherectomy is an effective treatment for calcified BTK disease by removing calcium and improving lesion compliance while minimizing medial wall injury.
- DCB’s *may* be effective in reducing TLR rates in BTK lesions.
- Combining orbital atherectomy with DCB’s *may* improve the effect of drug-coated balloons in calcified BTK lesions and lead to further improvement in TLR and patency rates.
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