Severe Calcific Tibial Disease Treatment with Rotablator Atherectomy

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THE PERIPHERAL EVENT OF THE YEAR
Disclosures

Speaker’s Bureau:
- Abbott Vascular
- Medtronic

Honorarium:
- Avinger

Consultant:
- CSI
- Spectranetics
- St. Judes
- Bard Vascular
- AstraZeneca

Stockholder:
- Avinger
Above-the-Knee Disease

- Mixed morphology (multiple plaque types & thrombus)
- Medium to large vessels (4-9mm)

Below-the-Knee Disease

- Lesions more commonly calcified
- Tortuous, challenging anatomy
- Small vessels (1.5 – 3.5 mm)

1. VIVA 2011 survey – 100 physicians surveyed.
BTK Challenges

• Long, complex, often calcified nature of lesions¹
• Often associated with multilevel disease, thus success inflow- and outflow-dependent²
• High restenosis rate³
• Limb salvage poorly correlated to primary patency
• Literature landscape dominated by small series and case studies, with limited Level I evidence

Up to 50% post-PTA TLR rate in real world CLI pts
Figure 2. Longitudinal stress elongates the vessel wall when a plain balloon unfolds during inflation.
Calcific Tibial Disease

- Why Remove Calcium
  - PTA alone had a 20% immediate failure rate in the basil trial
  - Calcium might influence drug-coated balloon efficacy
  - Plaques associated with arterial dissections commonly have significant calcium deposits
  - Presence of calcium necessitates greater balloon pressures
  - May limit stent expansion

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).
Late Lumen Loss Increases with Calcium Severity

Dr. Tepe’s Peripheral DCB Study (Retrospective, 91 patients, 6 month follow-up)
Core lab adjudicated study to assess the association of lesion calcification with late lumen loss

Six Month Mean Late Lumen Loss

Conclusion¹:

- Prevalence of calcium is increasing and may decrease drug penetration
- Severity of lesion calcification remains a single independent predictor of LLL outcome after DCB treatment
- Pretreatment of severely calcified lesions with atherectomy might be mandatory to maximize the therapeutic effect of DCB treatment

As calcium severity increases, late lumen loss at 6 months increases.¹

Combination Therapy

OPTIMIZE BTK

- Multicenter, randomized (atherectomy+DCB v DCB)
- Target N = 50 at up to 10 EU sites
- RCC 3-5, BTK lesions
- Diamondback (CSI) + 0.014” DCB
- Primary Endpoints:
  - Technical success
    - (< 50% residual stenosis without significant angiographic complications)
  - Procedural success
    - (achievement of technical success for all target lesions treated during the index procedure)
  - Device success
    - (successful delivery and deployment of the DCB to the target lesion as described IFU)
  - Treatment success
    - (percentage of target lesions meeting technical success with <30% residual stenosis post DCB angioplasty without the use post-adjunctive treatments)
- Estimated target completion date: June 2018

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 to pass through the circulatory system

- Peripheral Rotablator 5 µm diamond-coated burr
- Orbital atherectomy device

Jetstream aspirates plaque debris

Peripheral Rotablator microparticles are <5 µm in size

Boston Scientific data on file. Preclinical results may not necessarily be indicative of clinical performance.
# Atherectomy Devices

<table>
<thead>
<tr>
<th>Atherectomy Devices</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></td>
<td></td>
<td>NA</td>
</tr>
<tr>
<td>Differential Cutting</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>NA</td>
</tr>
<tr>
<td>Active Aspiration</td>
<td>✓</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Concentric Lumens</td>
<td>✓</td>
<td></td>
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<tr>
<td><strong>Lesion Morphology:</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Calcium</td>
<td>✓ 2,3</td>
<td>✓ 4,5</td>
<td>✓ 6</td>
<td>✓ (large vessel only)¹</td>
<td>✓ ¹</td>
</tr>
<tr>
<td>Soft/Fibrotic Plaque</td>
<td>✓ ²</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombus</td>
<td>✓ ¹</td>
<td>contraindicated¹</td>
<td>contraindicated¹</td>
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</tr>
</tbody>
</table>

Peripheral Rotablator Rotational Atherectomy System

Peripheral RotaLink Plus (Advancer)

- Rotablator has been used for more than 20+ years to treat challenging calcific coronary artery disease

- Diamond-coated burr is designed to preferentially engage calcium and modify lesion compliance

Peripheral RotaLink Plus (Burr Catheter)
Rotablator System Treatment Overview

• The Rotablator System:
  • is designed to ablate hard plaque and calcium into microparticles
  • does not require an embolic protection device*

*Based on design specifications of the Filterwire, embolic protection devices are designed to capture particles >100 µm. Preclinical results may not necessarily be indicative of clinical performance.
Rotablator System Treatment Overview

• Rotablator’s diamond-coated burr spins concentrically on the wire
• Designed to:
  • Provide a predictable lumen size
  • Efficiently ablate calcium
  • Create predictable microparticle release

• Rotablator’s burr is engineered to immediately engage the lesion with its front-cutting surface
• Designed to:
  • Enable user-controlled ablation
  • Provide a direct and efficient tactile response from the burr back to the user
  • Facilitate treatment of tight or occluded lesions
**Porcine Model**

Angioplasty result with vessel injury

Rotational Atherectomy Intended Benefits

- Minimize vessel wall stretch and elastic recoil
- Eliminate vessel barotrauma
- Produce a smooth lumen/channel
- Facilitate passage of adjunct devices

Rotablator System result with minimal vessel injury
Peripheral RotaLink Plus Burr Catheter

- 135 cm catheter length
- 4.3 F (0.058”) protective sheath
- 3.5” (8.9 cm) throw length
- Nickel-coated brass burr
- 5-micron exposed diamond crystal cutting surface

<table>
<thead>
<tr>
<th>Burr Size</th>
<th>Guide Sheath or Introducer Sheath Size French*</th>
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<tbody>
<tr>
<td>1.25 mm</td>
<td>4/5F</td>
</tr>
<tr>
<td>1.50 mm</td>
<td>5F</td>
</tr>
<tr>
<td>1.75 mm</td>
<td>6F</td>
</tr>
<tr>
<td>2.00 mm</td>
<td>6F/7F</td>
</tr>
<tr>
<td>2.25 mm</td>
<td>7F</td>
</tr>
<tr>
<td>2.50 mm</td>
<td>7F/8F</td>
</tr>
</tbody>
</table>

* For a given French size guide sheath or introducer sheath, the internal lumen and hemostasis valve will vary from manufacturer to manufacturer. When using an introducer for the first time, it should be tested with the largest Peripheral RotaLink Plus burr intended to be used with it.
<table>
<thead>
<tr>
<th>Study Description</th>
<th>Population Characteristics</th>
<th>Procedural Characteristics</th>
<th>Acute Success</th>
<th>Complications</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral Rotablator IDE (1990)</td>
<td>157 patients 258 lesions</td>
<td>Stand-alone rotational atherectomy</td>
<td>90.7% success rate</td>
<td>0.4% perforation 0.8% dissection/flap 0.8% occlusion 1.0% emboli 1.9% spasm</td>
<td>51% 6-mo patency</td>
</tr>
<tr>
<td>Calcifications</td>
<td>88% mean stenosis</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Percutaneous Peripheral Atherectomy Using the Rotablator: A Single Center Experience</td>
<td>150 patients 212 lesions</td>
<td>if &lt;20% residual stenosis, stop procedure; if 20-50%, adjunctive PTA; if &gt;50%, larger burr</td>
<td>97% technical success (per lesion)</td>
<td>11% spasm 8% thrombosis 2% dissection 0.6% perforation 1.3% distal emboli 1.3% no reflow</td>
<td>24% restenosis (among lesions evaluated at ≥4 months follow-up; mean observation time 14 months)</td>
</tr>
<tr>
<td>Calcifications</td>
<td>93% calcified 63% bifurcation</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>40 ± 2 mm lesion length</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Rotablator: A Forgotten Tool in Limb Ischemia?</td>
<td>18 patients 89% CLI</td>
<td>7 stand-alone rotational atherectomy 11 adjunctive PTA</td>
<td>100% technical success</td>
<td>1 hemoglobinuria</td>
<td>89% 13-month limb salvage rate</td>
</tr>
<tr>
<td>Dormal, et al. Acta Chir Belg, 2005; 105;231-234.</td>
<td>89% single vessel runoff 14 calcified 72% diabetic 22% on dialysis</td>
<td></td>
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</tbody>
</table>

This is a selection of studies that depict various Peripheral Rotablator methodologies across different points in time, and does not serve as a comprehensive review of all Peripheral Rotablator studies.
Percutaneous Peripheral Atherectomy Using the Rotablator: A Single-Center Experience

Michel Henry, MD, Max Amor, MD, Gérard Ethevenot, MD, Isabelle Henry, MD, and Mohamed Allaoui, MD

- Single center case series (150 patients, 212 lesions)
  - 93% calcified
  - 44% had atherectomy + PTA
- 76% free of restenosis

Procedural Complications (N=150 patients)

<table>
<thead>
<tr>
<th>Complication</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spasm</td>
<td>11%</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>8%</td>
</tr>
<tr>
<td>Dissection</td>
<td>2%</td>
</tr>
<tr>
<td>Perforation</td>
<td>0.6%</td>
</tr>
<tr>
<td>Distal Emboli</td>
<td>1.3%</td>
</tr>
<tr>
<td>No Reflow</td>
<td>1.3%</td>
</tr>
</tbody>
</table>

Restenosis Rate

<table>
<thead>
<tr>
<th>Lesion</th>
<th>% Restenosis (≥50% luminal narrowing)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>24%</td>
</tr>
<tr>
<td>Femoral</td>
<td>36%</td>
</tr>
<tr>
<td>Popliteal</td>
<td>7%</td>
</tr>
<tr>
<td>Distal</td>
<td>21%</td>
</tr>
<tr>
<td>Length &gt;7 cm</td>
<td>60%</td>
</tr>
</tbody>
</table>

aAmong 163 lesions evaluated at ≥4 months follow-up

Peripheral Rotablator Ablation Technique

Recommendations:
- Limit RPM drop to under 5,000 RPM
- Limit ablation runs to 15-30 seconds
- Target a final burr to artery ratio of 70-85%
- Add RotaGlide Lubricant and optional adjunctive pharmaceuticals (per hospital protocol) to 1 liter bag of sterile saline

Goals:
- Reduce heat accumulation
- Facilitate downstream dispersion of particulates
- Prevent spasm and in situ thrombosis

CLI patient. Non-healing left toe.

1.5 mm Rotalink burr

Post 3.0 tapered balloon

Joseph Cardenas, MD, AZ Heart & Vascular, Yuma, AZ
Conclusions

• Rotational atherectomy has 20 years of safe and effective use in the coronary bed
• Given its front cutting feature, does not require a filter, is a promising device to modify compliance and safely treat severely calcified tibial disease
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