BTK Boot Camp: Rotational Atherectomy for Fibrocalcific Disease

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No Disclosures
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)
BTK Rotational Atherectomy
Tibial Arteries

- Tibial vessels may be the most difficult to treat
- Often are highly calcific, chronic total occlusions, distal or all 3
- Many of the treatment strategies used in the larger vessels are not applicable
- Often associated with poor runoff
- Even minor complications may have serious consequences
- Often not a candidate for bailout stenting
- Proper treatment of tibial disease is often the deciding factor in limb salvage

- **Craig Walker 101** “You must restore straight line flow to the foot or you haven’t completed the case”
BTK Rotational Atherectomy
Treatment Goals for Tibial Vessels

• Achieve adequate patency
• Avoid dissection
• Avoid stenting
• Avoid embolization
• Avoid restenosis
• PTA has long been the stand alone therapy for BTK lesions, however many BTK lesions are heavily calcified or involve chronic total occlusions
• PTA alone associated with a 20% immediate failure rate in the BASIL trial
• The strongest predictor for a poor outcome in a CLI case is the presence of a TASC D lesion
• Heavy calcification prevents proper balloon expansion
• Calcified lesions require higher inflations resulting in higher risk of dissection and more barotrauma increasing neointimal hyperplasia
• If stenting is required stand alone angioplasty may not allow proper stent deployment

BTK Rotational Atherectomy
Is it worth the time and added expense?
BTK Rotational Atherectomy
Is it worth the time and added expense?

• Atherectomy allows debulking of the lesion
• Better balloon expansion with less barotrauma
• Proper stent deployment if needed
• Fewer dissections with balloon inflation
• Potential for stand alone therapy
• More uniform delivery of drug coated balloons
# Atherectomy Devices

<table>
<thead>
<tr>
<th></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>
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<tr>
<td>Differential Cutting</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>NA</td>
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<tr>
<td>Active Aspiration</td>
<td>✓</td>
<td></td>
<td></td>
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<tr>
<td>Concentric Lumens</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Lesion Morphology:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<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>
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<tr>
<td>Thrombus</td>
<td>✓ ¹</td>
<td>contraindicated¹</td>
<td>contraindicated¹</td>
<td></td>
<td>✓ ¹</td>
</tr>
</tbody>
</table>

Peripheral Rotablator™ Rotational Atherectomy System

- 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 Rotablink® Plus (Advancer)

Peripheral Rotablink® 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*

*A 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.

A Rotablator System microparticle compared with a red blood cell and a 5 µm bead
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

BTK Rotablation

Porcine Model*

Angioplasty result with vessel injury

Rotational Atherectomy Intended Benefits
Designed to:
- 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 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

## Peripheral Rotablator™ Clinical Studies

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Population Characteristics</th>
<th>Procedural Characteristics</th>
<th>Acute Success</th>
<th>Complications</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Peripheral Rotablator IDE (1990)</strong></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>
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<td>88% mean stenosis</td>
<td></td>
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<tr>
<td><strong>Percutaneous Peripheral Atherectomy Using the Rotablator: A Single Center Experience</strong></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></td>
<td>93% calcified 63% bifurcation</td>
<td>Adjunctive PTA: 81% Fem 53% Pop 13% Distal</td>
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<tr>
<td></td>
<td>40 ± 2 mm lesion length</td>
<td>1.5-4.5 mm burrs</td>
<td></td>
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<tr>
<td><strong>Henry E, et al. J Endovasc Surg, 1995;2:51-66.</strong></td>
<td>18 patients</td>
<td>7 stand-alone rotational atherectomy</td>
<td>100% technical success</td>
<td>1 hemoglobinuria</td>
<td>89% 13-month limb salvage rate</td>
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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.
BTK Rotational Atherectomy Case Study

• Case by Dr. Sandra Noor, MD
• A 71-year-old African American woman with end stage renal disease, a previous cerebrovascular accident, coronary artery disease, and coronary artery bypass
• Critical Limb Ischemia
• 1.75 mm Rotablator burr
• 180,000 rpms with 4 minute total time run
• 2.5 x 220 balloon at nominal for 2 minute inflations
BTK Rotational Atherectomy
BTK Rotational Atherectomy Summary

• Select the proper tool for the job from the toolbox
• Rotational atherectomy offers several advantages in the heavily calcified BTK Lesion
• 20 years of safe effective use in the coronary bed
• Front cutting
• Does not require filter
• Ability for use in small vessel diameter
• Specifically designed to ablate calcium
• Rotational design allows vessel compliance modification with minimal trauma
Thank You For Your Attention
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