Atherectomy: Where Do We Stand After 12 Years Since FDA Clearance

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

- **Affiliation/Financial Relationship**
  
  - Consulting Fees/Honoraria
    - Boston Scientific, Medtronic, Abbott, Covidien, Bard Peripheral Vascular, Volcano
  
  - Research Support
    - Atrium Medical, WL Gore
  
  - Scientific Advisory board/stock options
    - AngioScore, Angioplast, NexGen, Reflow, Endoluminal Sciences, Syntervention, PQ Bypass, Shockwave Medical

Board Member VIVA Physicians

Where Do We Stand?

- Continued evolution and improvement of devices
- Niche applications (Calcium, thrombus containing lesions, instent restenosis, “non-stent zones”)
- Limited data
- Excellent reimbursement in US (outpatient labs) driving usage
- Possibility of Atherectomy plus DCB

Device Evolution
Atherectomy Devices

<table>
<thead>
<tr>
<th>Jetstream™ 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><img src="image1" alt="Jetstream™ Atherectomy System" /></td>
<td><img src="image2" alt="Diamondback 360°, Stealth 360° Atherectomy System" /></td>
<td><img src="image3" alt="SilverHawk™ TurboHawk™ Plaque Excision System" /></td>
<td><img src="image4" alt="Turbo-Elite™ Laser Atherectomy Catheter" /></td>
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</table>

- Front-Cutting: ✔
- Differential Cutting: ✔ ✔
- Active Aspiration: ✔
- Concentric Lumens: ✔
- Lesion Morphology:
  - Calcium: ✔ (large vessel only) ✔
  - Soft/Fibrotic Plaque: ✔
  - Thrombus: ✔ (indicated for thrombectomy and atherectomy)


Excimer Laser

**Technical Improvements:**

- Evolution of Catheter Designs
  - Extreme
  - Optimally Spaced
  - Point 9
  - Turbo
  - Turbo Elite
  - Turbo Tandem

2.3 mm and 2.5 mm peripheral catheters FDA approved 2004

Excimer Laser

**Technical Improvements:**

<table>
<thead>
<tr>
<th>1.7mm TURBO elite laser catheter</th>
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<tbody>
<tr>
<td><strong>Attribute</strong></td>
</tr>
<tr>
<td>Model Number</td>
</tr>
<tr>
<td>Number of fibers</td>
</tr>
<tr>
<td>Active Area</td>
</tr>
<tr>
<td>Max. Output Energy</td>
</tr>
<tr>
<td>Sheath Compliance</td>
</tr>
<tr>
<td>Max. Guide Wire Compatibility</td>
</tr>
<tr>
<td>Working Length</td>
</tr>
</tbody>
</table>

Turbo Tandem

![Turbo Tandem](image5)
Pretreatment Angio
100% Lt SFA

Angio Post 2 mm Pilot channel
60 Fl/40 Hz

IVUS Post 2 mm Pilot channel

Angio Post 8 Fr TURBO-Booster with 2 mm catheter at 60 Fl/40 Hz
4 passes/11,114 pulses

IVUS Post PTA

Angio Post PTA using 5 mm x 8 cm and 6 mm x 2 cm balloons @ 2 atm
Clinical Evidence

- Peripheral Excimer Laser Angioplasty Trial (PELA)
  - Randomized trial of laser vs. PTA for long SFA occlusions
- Laser Angioplasty for Critical Limb Ischemia Trial (LACI)
  - Multicenter registry of laser plus adjunctive therapies for CLI
- CELLO Trial
  - Multicenter registry of Turbo Booster/Tandem device
- Excimer Laser Randomized Controlled Study for Treatment of Femoropopliteal In-Stent Restenosis (EXCITE ISR)
  - Randomized trial of laser vs. PTA for fem-pop ISR

Potential Applications

- Debulking long occlusions
- Instent restenosis
- Thrombus containing lesions
Limb Salvage Rate = 93%

EXCITE ISR Trial - Primary Patency

Product-Limit Survival Estimates
With number of subjects at risk

Days from Index Procedure

p < 0.005

Key words: critical limb ischemia, laser angioplasty, excimer laser, limb salvage
Occluded Viabahn Stent Graft

STEALTH 360º PAD SYSTEM
Clinical Evidence

- OASIS Trial
  - Prospective multicenter registry
- CONFIRM I and CONFIRM II
  - Post market registries
- CALCIUM 360°
  - Post market registry

Clinical Application

- Heavily calcified and non-dilatable lesions

Dealing with Calcification

Orbital Atherectomy
Post Atherectomy

HawkOne™ Directional Atherectomy System

- Treat All Morphologies
  - Treat all atherosclerotic plaque effectively, including severe calcium

HawkOne™ Directional Atherectomy System

- 50% increase in rotational speed (8,000 – 12,000 RPM)
- More robust drive shaft
- Modified blade design with 4 contoured blades
- Better crossing profile
- Simplified cleaning

Clinical Evidence

- TALON Registry
  - Post market registry
- DEFINITIVE LE
  - Large, prospective multicenter registry (claudication and CLI subgroups)
- DEFINITIVE Calcium
  - Prospective multicenter registry of excisional atherectomy for calcified lesions
- DEFINITIVE AR
  - Small randomized trial of DCB vs. Atherectomy plus DCB
Potential Applications

- Ostial lesions
- Common femoral lesions
- Eccentric, bulky plaque
- Calcified lesions
- Instent restenosis

Common Femoral Artery

TurboHawk Calcium Cutter

Diffuse SFA Disease in Diabetic Patient
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

Jetstream Calcium Study
- Multicenter study of patients with moderately to severely calcified peripheral artery disease (N=21)
- Results show 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

What's the quality of data supporting the use of atherectomy devices?

Poor!

- Many were approved by the FDA using 510K pathway based on predicate device and little data
- After all these years - Only 3 randomized trials
  - PELA Trial (Excimer Laser)
  - EXCITE ISR Trial (Excimer Laser)
  - DEFINITIVE AR (Directional atherecomy plus DCB vs. DCB)

Maehara et al. ISET 2013, Miami, FL
ClinicalTrials.gov NCT01436435
Combination Therapy: Atherectomy Plus DCB

Best of Both Worlds?

- Greater acute lumen gain of atherectomy without recoil/dissection of PTA
- DCB allows improved patency rates after atherectomy
- Reduced need for stents

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 DB treatment of the SFA and/or popliteal artery, particularly for longer or severely calcified lesions

Atherectomy and Drug-Coated Balloon Efficacy: Clinical Evidence

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Procedural Results

<table>
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<th>Lesion &gt;10 cm</th>
<th>All Severe Ca2+</th>
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<tr>
<td>Technical Success</td>
<td>DCB</td>
</tr>
<tr>
<td>Bail-out Stent</td>
<td>64.2%</td>
</tr>
<tr>
<td>Flow-limiting Dissection</td>
<td>3.7%</td>
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12-Month Results

- Lesions >10 cm
- All Severe Ca2+

Zeller, VIVA 2014.

DCB, drug-coated balloon; DUS, duplex ultrasound; SFA, superficial femoral artery.
Where Do We Stand?

- Better atherectomy devices available
- Device specific advantages for certain lesion subsets
- More options for heavily calcified lesions

But...

- These are expensive devices
- Limited good quality data
- Usage driven by favorable reimbursement

Go Giants!!