Atherectomy Device Review and Applications
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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 Company
• Grant/Research Support
  Abbott, Covidien/Medtronic
  Covidien/Medtronic, Boston Scientific, Abbott
  Arsenal, Primacea, TissueGen, CV Ingenuity, Spirox, Scion Cardiovascular, Syntervention, Essential Medical
• Consulting (non-compensated)
• Major Stock Shareholder/Equity
• Royalty Income
• Ownership/Founder
• Intellectual Property Rights
• Other Financial Benefit
• None
• Elite Vascular Ventures
  None
  None

Stenting?
• To date the meaningful stenting studies have evaluated 5-6 cm lesions and only 2 studies have tested long lesions closer to 20 cms that we consider “real world” cases
  – Do we honestly believe an 75-80% PP at 12 months is “good enough” to then deal with the permanent prosthesis?
• The gorilla in the room is restenosis
  – In-stent restenosis vs de-novo restenosis
  – Focal vs diffuse
  – Recurrent vs recurrent
• Alternative therapies have been shown to be just as durable and safe as DES/BMS and combination therapy appears very appealing

Shortcoming of SFA-Stents
Insufficient radial strength in calcified lesions

LASER
Laser – Spectronetics
• Ultraviolet 308 nm excimer laser
• The “step-by-step” technique can be used to cross chronic total occlusion
  – Lead with laser not wire
  – Probe lesion as you advance
• Perforation ~ 2%
• Embolization ~ 4%
• Excellent debulking thrombus, atheroma and emboli
• Questionable with heavy calcium
• Now on label ISRS

Current technology outlook
• ExCITE
  – Indication for ISRS
  – 6 month patency 48%
• PATENT
  – European ExCITE
    • 90 patients freedom from TLR at 6 months 76%
• Illuminate
  – Initial evaluation of laser with DCB
  – US IDE trial
    • Builds on PHOTOPAC European experience
**EXCITE**

- 250 patients in a 2:1 randomization protocol (initially slated 318 patients)
- Study stopped early for statistical superiority in both safety and efficacy
- Pivotal data release LBT published JACC Interv 2015
- LASER is now the only FDA approved device for treatment of in-stent restenosis

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**Directional atherectomy**

SilverHawk

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**DEF LE outcomes**

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Claudicants (n=743)</th>
<th>CLI (n=279)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patency (PSVR ≤ 2.4)</td>
<td>Lesion Length (cm)</td>
</tr>
<tr>
<td>All (n=1022)</td>
<td>76%</td>
<td>7.5</td>
</tr>
<tr>
<td>Lesion type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stenoses (n=506)</td>
<td>81%</td>
<td>6.3</td>
</tr>
<tr>
<td>Occlusions (n=211)</td>
<td>64%</td>
<td>11.1</td>
</tr>
<tr>
<td>Lesion Location</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF (n=671)</td>
<td>75%</td>
<td>8.1</td>
</tr>
<tr>
<td>Popliteal (n=182)</td>
<td>77%</td>
<td>6.0</td>
</tr>
<tr>
<td>Infrapopliteal (n=188)</td>
<td>90%</td>
<td>5.5</td>
</tr>
</tbody>
</table>

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**Effective in calcium**

12 Month Primary Patency Rates from DEFINITIVE LE

<table>
<thead>
<tr>
<th>Lesion Type</th>
<th>All Calcified Lesions</th>
<th>Femoral Lesions</th>
<th>Infrapopliteal Lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean lesion length (cm)</td>
<td>6.4</td>
<td>8.4</td>
<td>5.6</td>
</tr>
<tr>
<td>Num. of Lesions</td>
<td>272</td>
<td>262</td>
<td>12</td>
</tr>
</tbody>
</table>

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**Effective in non calcific ATK and BTK**

12 Month Primary Patency Rates from DEFINITIVE LE

- 75% SFA
- 77% Popliteal
- 90% Infrapopliteal

PSVR ≤ 2.4

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**DEFINITIVE AR Study Design**

Purpose: assess and estimate the effect of treating a vessel with directional atherectomy + DCB (DAART) compared to treatment with DCB alone

Registry arm for severely calcified lesions created to limit bail-out stenting (and therefore variables) in randomized arm.

- *Directional Atherectomy + Anti-Restenotic Therapy*
Baseline Lesion Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>DAART (N=48)</th>
<th>DCB (N=54)</th>
<th>p-Value*</th>
<th>DAART Severe Ca++ Arm (N=19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Length (cm)</td>
<td>11.2</td>
<td>9.7</td>
<td>0.05</td>
<td>11.9</td>
</tr>
<tr>
<td>Diameter Stenosis (%)</td>
<td>82%</td>
<td>85%</td>
<td>0.35</td>
<td>88%</td>
</tr>
<tr>
<td>Reference vessel diameter (mm)</td>
<td>4.9</td>
<td>4.9</td>
<td>0.48</td>
<td>5.1</td>
</tr>
<tr>
<td>Minimum lumen diameter (mm)</td>
<td>1.0</td>
<td>0.8</td>
<td>0.34</td>
<td>0.7</td>
</tr>
<tr>
<td>Calcification (%)</td>
<td>70.8%</td>
<td>74.1%</td>
<td>0.82</td>
<td>94.7%</td>
</tr>
<tr>
<td>Severe calcification (%)</td>
<td>25.0%</td>
<td>18.5%</td>
<td>0.48</td>
<td>89.5%</td>
</tr>
</tbody>
</table>

* p-value for DAART and DCB groups

12-Month Patency: DAART RCT Patients

Is it Important to Achieve ≤30% Residual Stenosis with Directional Atherectomy Post-Procedure?

- MLD = 6.27
- MLD = 7.84
- Rotational devices
  - Rotates, Aspirates, Adjunctive RX
  - Early data: 4.9 cm
  - JET registry discontinued

Current technology outlook

- Effective to over 4mm with larger Gen 3 device
- Standard sizing in Gen 2 device is to 3.1 mm with blades up
- Tibial device available for vessels under 1.6mm
- European/US JetStream 2012
  - Assess JetStream in denovo lesions at 12 months primary patency endpoint—DISCONTINUED
- No current study regarding JetStream and DCB

Key Study Outcome at 12 Months

Angiographic Patency shows similar pattern

- All Patients: DAART 82.4, DCB 88.9
- Lesions > 10 cm: DAART 71.6, DCB 77.8
- All Severe Ca++: DAART 58.3, DCB 42.9

Rotational devices

Pathway (rotational debulking)

- Rotates, Aspirates, Adjunctive RX
- Early data: 4.9 cm
- JET registry discontinued

CSI (sanding debulking)

- Centrifugal force
  - Sands atheroma
  - Debris relatively small
  - <1-7 µm
- Offset burr determines diameter
- Oasis trial used for approval- 3.1 cm
- CONFIRM registry 3000 patients device safety, efficacy study

Orbital Atherectomy for Infrapopliteal Disease: Device Concept and Outcome Data for the Oasis Trial

- 6 month data
- 124 patients for infrapopliteal revascularization (201 lesions)
- Claudicants 55%
- CLI 45%
- Treatment OA either stand alone or with adjunctive Rx
Orbital atherectomy

- CONIRM 3000 patient registry to be released
- Treatment 3000 patients 4700 lesions with no exclusion criteria, outcomes at 12 months self reported data
- COMPLIANCE 360 and Calcium 360 evaluated OA with PTA compared with PTA alone. OA had much lower balloon inflation pressure compared with PTA alone

Evidence based decisions

- Debubling strategies can be applied to the vast majority of patients we encounter for claudication and CLI
- Directional atherectomy is both safe and effective to 12 months in most lesions
  - DEFINITIVE/DEFINITIVE AR
- Calcific lesions need compliance change
  - Can be best treated with aggressive rotational or directional devices
  - OASIS/JETSTREAM/DEFINITIVE CA
- Costs therefore justified either in stand alone therapy or for adjunctive to stenting
- Combined therapy may afford the best primary patency
  - All combinations need scientific validation and cost benefit analysis