Flash Presentation:
Concepts for atherectomy in femoropopliteal arteries:
When to use which system?

William A. Gray MD
System Chief of Cardiovascular Services, Main Line Health
President, Lankenau Heart Institute
Wynnewood, PA
USA
Why atherectomy?

• Calcification is the norm not the exception
  – Most trials do not include heavy calcification

• There is no presumptive requirement for an endoprosthesis

• Side-branches are generally not threatened

• Repeat or other interventions are possible

• Opportunity for dedicated combination therapy
Role of atherectomy/debulking

• Stent avoidance
  – No stent zones
  – Long diffuse non-occlusive disease

• Stent promotion/expansion
  – Marked calcification

• Preparation for biologic restenosis solutions
  – Securing vessel patency without prosthesis

• Debulking ISR

• Thrombectomy
Atherectomy Device Overview

Many Choices

Figure 1A. The TurboHawk plaque excision system (Covidien). Image courtesy of Covidien.

Figure 1B. Jetstream atherectomy catheters (Bayer Healthcare) feature expandable blades down/blades up technology, enabling treatment of multiple vessel sizes with a single device. Reproduced with permission of Bayer HealthCare LLC. Jetstream is a registered trademark of Bayer.

Figure 1D. The Diamondback 360 (CSI). Image courtesy of Cardiovascular Solutions Inc. (CSI).

Figure 1C. The Turbo Elite laser (Spectranetics). Image courtesy of The Spectranetics Corporation.
Medtronic HawkOne
Directional Atherectomy: Key Trial

DEFINITIVE LE

• Study Design and Oversight
  o Prospective, non-randomized, global study
  o 800 patients, 47 centers
  o CEC + Steering Committee oversight/CEC adjudication
  o Angio + Duplex Core lab

Key Inclusion
• RCC 1-6
• ≥ 50% stenosis
• LL up to 20cm
• RVD ≥1.5mm to ≤7.0mm

Key Exclusion
• Severe Ca++
• ISR
• Aneurysmal target vessel

Directional Atherectomy: Key Trial

DEFINITIVE LE: Primary Patency in Subgroups

- Lesion lengths comparable IC vs CLI ~ 7cm
- Lesion lengths occlusions ~ 10 cm

Directional Atherectomy: Key Trial

DEFINITIVE LE Conclusions

• Largest independently adjudicated study of peripheral atherectomy to date

• Directional atherectomy is safe and effective at 12 months
  o Effective for short, medium, and long lesions in claudicants and CLI patients

• Diabetic subgroup analysis showed directional atherectomy performs equally as well diabetics vs. non-diabetics (PP 77% vs. 78%)

Laser

Laser: Spectranetics

- Ultraviolet 308 nm excimer laser
- Excellent debulking thrombus, atheroma and emboli
- Questionable with heavy calcium
- In-stent restenosis indication pending
- The “step-by-step” technique can be used to cross chronic total occlusion
  - Lead with laser not wire
    - Probe lesion while advancing
  - Perforation ~ 2%
  - Embolization ~ 4%
Laser Atherectomy: Key Trial

EXCITE ISR

- Study Design and Oversight
  - Prospective, RCT, US study
  - 250 patients, 40 centers
  - Angio + Duplex Core lab

Key Inclusion
- RCC 1-4
- ISR lesion ≥ 4 cm, no lesion limit
- ≥ 1 patent tibial artery
- RVD ≥ 5.0mm to ≤ 7.0mm

Key Exclusion
- Target lesion extends >3cm beyond stent margin
- Untreated inflow lesion
- Grade 4 or 5 stent fx
Laser Atherectomy: Key Trial

EXCITE ISR

Primary Efficacy Endpoint

Freedom from TLR thru 6 months

<table>
<thead>
<tr>
<th>Group</th>
<th>0%</th>
<th>20%</th>
<th>40%</th>
<th>60%</th>
<th>80%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITT</td>
<td>73.5%</td>
<td>51.8%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ITT w/o Bailout Stenting as TLR</td>
<td></td>
<td>61.7%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per protocol</td>
<td>78.8%</td>
<td></td>
<td>46.7%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

P<0.005

P<0.05

P<0.001
Laser Atherectomy: Key Trial

EXCITE ISR Conclusions

• ELA with adjunctive PTA superior to PTA alone for ISR in early f/u
  o Complicated lesions with average length 19cm
  o Higher procedural success, better safety
  o Lower TLR through 6 months

• 1st FDA approved IDE RCT to demonstrate benefits of atherectomy in lower extremities
BSC Jetstream™
Revascularization System

**Distal Tip**
- Differential cutting tip removes all plaque types
- Expandable blades offer single device solution
- Aspiration port collects plaque and thrombus

**Control Pod**

2.1 mm

3.0 mm
Overview: Pathway PVD Study

• Purpose: A prospective, single arm, multi-center study to assess performance of the Pathway PV™ Atherectomy System during percutaneous peripheral vascular interventions

  – Drs. Scheinert and Zeller - co-PIs
  – 172 patients at 9 European centers
  – 100% data monitoring
  – Angiographic core lab and CEC adjudicated
Pathway: Procedural Outcomes

- 99% device success
- Mean device activation time = 3:37 minutes
- 33% of procedures were stand-alone
- 57% used adjunctive balloon
- Only 7% require adjunctive stent
Orbital Atherectomy System (OAS)

• Offset crown

• Diamond grit coated

• Creates lumen 1.75x greater than crossing profile
Mechanism of Action: Differential Sanding

Speed = Lumen Size

- Increased speed and/or increased mass increase the centrifugal force
- Greater centrifugal force creates bigger lumens

\[ CF \approx \text{Mass} \times \text{Rotational speed}^2 \]

radius of the orbit

1.9mm crown at 80k RPMs

1.9mm crown at 200k RPMs
Pivotal trial: OASIS

- 121 patients (201 stenoses)
  - Mixed population of critical limb (32%) and claudicants (68%)

- Primary efficacy endpoint: residual diameter stenosis

## Atherectomy device: lesion type most advantageous

<table>
<thead>
<tr>
<th>Atherectomy Type</th>
<th>Directional</th>
<th>Rotational</th>
<th>Photoablative</th>
<th>Orbital</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lesion Type</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eccentric/Mild to Severe Ca++</td>
<td>SilverHawk/TurboHawk</td>
<td>Jetstream</td>
<td>Laser</td>
<td>Diamondback 360</td>
</tr>
<tr>
<td>Lesion w/Thrombus</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>BTK Lesion</td>
<td>X-</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Highly Ca++, Focal</td>
<td>X-</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>ISR w/thrombus</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Above and BTK popliteal</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>CTO</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>
Rationale for Atherectomy + DCB

*Theoretical benefit for DCB therapy*

- Plaque removal could facilitate local drug delivery
  - May optimize drug transfer into vessel wall
- Vessel prep in more challenging TASC C-D lesions may improve technical/clinical success by
  - ↓ residual stenosis
  - ↓ flow limiting dissections
  - ↓ bailout stent rate
Rationale for Atherectomy + DCB

Theoretical benefit for Atherectomy

• DCB may inhibit the inflammatory response caused by mechanical trauma of plaque excision.

• DCB’s may improve patency in longer lesions, occlusions, and more calcified vessels post atherectomy where more exaggerated vessel trauma induced.
Atherectomy: evidence-based decisions

- Several available devices
- Directional atherectomy is safe and effective to 12 months in most atherosclerotic lesions
- Calcific lesions can be best treated with aggressive rotational or directional devices
  - OASIS/Jetstream/TurboHawk
- Combined therapy may afford the best primary patency
  - All combinations need scientific validation and cost benefit analysis (DEFINITIVE AR: 2014)
- Cost-effectiveness of atherectomy/combination RX will be a consideration
Flash Presentation: Concepts for atherectomy in femoropopliteal arteries:

When to use which system?

William A. Gray MD
System Chief of Cardiovascular Services, Main Line Health
President, Lankenau Heart Institute
Wynnewood, PA
USA