Advanced Endovascular Techniques, Retrograde Pedal Access, Drug Eluting Stents, and Drug Eluting Balloons.

Osama A. Ibrahim, MD, FACC
Director of Peripheral Endovascular Therapies.
Director of Limb salvage and Amputation Prevention Program.
Director of Quality, Cardiac Catheterization Laboratories.
North Memorial Heart and Vascular Institute.
North Memorial Healthcare.
Minneapolis, MN

Founder, Twin Cities Vascular Forum (TCVF)
Chairman, NCVH Regional Minneapolis Chapter
## Disclosures

**Speaker’s Bureau:**
- None

**Honorarium:**
- Boston Scientific

**Consultant:**
- Boston Scientific

**Stockholder:**
- None

**Grant/Research Support:**
- Medtronic

**Medical/Scientific Boards:**
- None
Background

• PAD is a common disorder affection over 200 million people worldwide, including approximately 17 million Americans\(^1\)-\(^2\)
• The femoropopliteal artery (FPA) is a common site of obstructive atherosclerotic disease
• While the endovascular approach has emerged as a first-line therapy for FPA disease, no single device modality has emerged as a “gold standard”\(^3\)-\(^4\)
• While comparing across studies has limitations, what can be learned from the growing body of evidence that can shape FPA treatment practice?

History

- Over the past 15 years tremendous advancements have occurred on our understanding of management of PAD.
- Advancements in the medical device industry has substantially affected our ability to treat this deadly disease.
- More available viable options for the affected patients.
- Limb salvage has consistently improved over the past 10 years with more and more CLI operators joining the cause.
Limitations

- High acute vessel recoil with POBA >>>>> Stents
- High ISR rates with BMS >>>>> ? Drug Elution/Covered Stents
- Calcium >>>>> Atherectomy
- Mechanical forces >>>>> Stent design
- Compliance/Surveillance >>>>> Follow up
Advancements

• Technical:
  • Physician training.
  • Physician awareness.
  • Newer techniques.
  • Better devices (CTO wires, CTO crossing catheters, DCB, DES…etc).
  • Alternative access (Pedal access).

• Operational:
  • Creation of Multidisciplinary teams.
Core Lab-Adjudicated 12-mo 1° Patency

Mean lesion length (cm) and bail-out stent rate % also shown.
Definitions, statistical methods, etc. vary across studies.
Balloon Therapy Overview

POBA
DCB
POBA Data

• 12-mo restenosis rates ranging from 40-60%
• Employed as historical comparator for stent studies since the VIVA Performance Goal paper was published\(^1\)
• Traditionally reserved for short, non-complex lesions

DCB Data

- DCBs demonstrate clinical safety and effectiveness treating FPA disease in randomized controlled trials
- Follow-up beyond two years is more variable
- DCB use in real-world registries enrolling more complex disease is associated with increased provisional stenting
- Both FDA-approved DCB also have ISR indications

# DCB Device Overview

<table>
<thead>
<tr>
<th></th>
<th><strong>Lutonix 035</strong> (Bard)</th>
<th><strong>IN.PACT Admiral</strong> (MDT)</th>
<th><strong>Stellarex</strong> (Spectranetics)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Configurations</strong></td>
<td>4-7mm diameter 40-150mm length</td>
<td>4-7mm diameter 40-150mm length</td>
<td>4-6mm diameter 40-120mm length</td>
</tr>
<tr>
<td><strong>Platform</strong></td>
<td>Lutonix PTA</td>
<td>Admiral PTA</td>
<td>Stellarex PTA</td>
</tr>
<tr>
<td><strong>Drug and Dosage</strong></td>
<td>Paclitaxel 2.0µg/mm²</td>
<td>Paclitaxel 3.5µg/mm²</td>
<td>Paclitaxel 2.0µg/mm²</td>
</tr>
<tr>
<td><strong>Excipient / Coating</strong></td>
<td>Sorbitol / Polysorbate</td>
<td>Urea</td>
<td>Polyethylene Glycol</td>
</tr>
<tr>
<td><strong>Commercial Availability</strong></td>
<td>Worldwide</td>
<td>Worldwide</td>
<td>Outside US</td>
</tr>
<tr>
<td><strong>US Indication</strong></td>
<td>SFA &amp; PA + ISR ≤300mm lesions</td>
<td>SFA &amp; PA + ISR ≤180mm lesions</td>
<td>Not FDA approved</td>
</tr>
</tbody>
</table>
**DCB Multicenter RCTs - Patency**

**Primary Patency Definitions**
- **LEVANT II**: PSVR ≤ 2.5 and freedom from TLR$^{1-2}$
- **IN.PACT SFA**: PSVR ≤ 2.4 and freedom from CD-TLR$^{3-5}$
- **ILLUMENATE EU and US RCTs**: PSVR ≤ 2.5 and freedom from CD-TLR$^{6-7}$

**Table of Primary Patency Rates**

<table>
<thead>
<tr>
<th>Trial Type</th>
<th>Time</th>
<th>Lutonix 035</th>
<th>Δ (%)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LEVANT II</strong></td>
<td>1-yr</td>
<td>73.5%</td>
<td>Δ 16.7%</td>
<td>P &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PTA 56.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2-yr</td>
<td>58.6%</td>
<td>Δ 5.6%</td>
<td>P &lt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PTA 53.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3-yr</td>
<td>62.5%</td>
<td>Δ 24.4%</td>
<td>P &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PTA 45.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>IN.PACT SFA</strong></td>
<td>1-yr</td>
<td>87.5%</td>
<td>Δ 31.7%</td>
<td>P &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PTA 55.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2-yr</td>
<td>78.9%</td>
<td>Δ 28.8%</td>
<td>P &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PTA 50.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3-yr</td>
<td>69.5%</td>
<td>Δ 24.3%</td>
<td>P &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PTA 45.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ILLUMENATE EU</strong></td>
<td>1-yr</td>
<td>89.0%</td>
<td>Δ 24.0%</td>
<td>P &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PTA 65.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pivotal</strong></td>
<td>1-yr</td>
<td>82.3%</td>
<td>Δ 11.4%</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PTA 70.9%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Only long-term Level 1 evidence demonstrating highly statistical benefit of DCB compared to PTA.

Primary patency rates derived from respective trials’ Kaplan Meier estimates. Statistical significance of DCB over PTA in ILLUMENATE US RCT not reported (NR).

---

# DCB Multicenter RCTs - Revascularization

**TLR**
- **LEVANT II**: All TLR<sup>1-2</sup>
- **IN.PACT SFA**: Reintervention at target lesion due to symptoms or drop of ABI of ≥20% or >0.15 compared to baseline<sup>3-5</sup>
- **ILLUMENATE EU and US RCTs**: Reintervention at target lesion due to an increase in RCC >1 category or deterioration in the ABI by >0.15 compared to baseline<sup>6-7</sup>

## Definitions

### LEVANT II Trial<sup>1-2</sup>

<table>
<thead>
<tr>
<th></th>
<th>Lutonix 035</th>
<th>PTA</th>
<th>Difference</th>
<th>Stat. Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-yr</td>
<td>89.7%</td>
<td>84.8%</td>
<td>Δ4.9% NSS</td>
<td></td>
</tr>
<tr>
<td>2-yr</td>
<td>82.0%</td>
<td>79.0%</td>
<td>Δ3.0% NR</td>
<td></td>
</tr>
</tbody>
</table>

### IN.PACT SFA Trial<sup>3-5</sup>

<table>
<thead>
<tr>
<th></th>
<th>IN.PACT Admiral</th>
<th>PTA</th>
<th>Difference</th>
<th>Stat. Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-yr</td>
<td>97.6%</td>
<td>79.4%</td>
<td>Δ18.2% P&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>2-yr</td>
<td>91.0%</td>
<td>72.2%</td>
<td>Δ18.8% P&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

### ILLUMENATE EU RCT<sup>6</sup>

<table>
<thead>
<tr>
<th></th>
<th>Stellarex</th>
<th>PTA</th>
<th>Difference</th>
<th>Stat. Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-yr</td>
<td>94.8%</td>
<td>85.3%</td>
<td>Δ9.5% P=0.01</td>
<td></td>
</tr>
<tr>
<td>2-yr</td>
<td></td>
<td></td>
<td>Δ6.3% NR</td>
<td></td>
</tr>
</tbody>
</table>

### ILLUMENATE Pivotal<sup>7</sup>

<table>
<thead>
<tr>
<th></th>
<th>Stellarex</th>
<th>PTA</th>
<th>Difference</th>
<th>Stat. Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-yr</td>
<td>93.6%</td>
<td>87.3%</td>
<td>Δ6.3% NR</td>
<td></td>
</tr>
</tbody>
</table>

Revascularization rates derived from respective trials' Kaplan Meier estimates. Statistical significance of DCB over PTA at 1 year and at 2 years for ILLUMENATE US RCT and LEVANT II, respectively, not reported (NR). Difference in revascularization rate between DCB and PTA at 1 year in LEVANT II not statistically significant (NSS).

Only long-term Level 1 evidence demonstrating highly statistical benefit of DCB compared to PTA.

---

Clinical Evidence – Long Lesion Cohorts

Follow-up and Outcomes

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>LEVANT Long Lesion&lt;sup&gt;1&lt;/sup&gt;</th>
<th>IN.PACT Long Lesion&lt;sup&gt;2&lt;/sup&gt;</th>
<th>IN.PACT CTO&lt;sup&gt;3&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>107 &amp; 102 subjects for primary safety and effectiveness endpoints, respectively; Core lab-adjudicated</td>
<td>157 subjects; Core lab-adjudicated</td>
<td>126 subjects; Core lab-adjudicated</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12-mo Outcomes</th>
<th>LEVANT</th>
<th>IN.PACT Long Lesion&lt;sup&gt;2&lt;/sup&gt;</th>
<th>IN.PACT CTO&lt;sup&gt;3&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt; Patency (%)</td>
<td>68.9%</td>
<td>91.1%</td>
<td>85.3%</td>
</tr>
<tr>
<td>FF TLR/CD-TLR (%)</td>
<td>87.8%</td>
<td>94.0%</td>
<td>89.1%</td>
</tr>
<tr>
<td>Bail-out Stent (%)</td>
<td>39.8%</td>
<td>40.4%</td>
<td>46.8%</td>
</tr>
<tr>
<td>Amputations (%)</td>
<td>NR</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

• Varying patency
• High FF Reintervention
• High bail-out stent rate

Primary patency definitions (KM estimates shown):
LEVANT PSVR ≤ 2.5 & FF TLR at day 365;
IN.PACT PSVR ≤ 2.4 & FF CD-TLR at day 360.

---

1. Bard Lutonix Instructions for Use BAW1387400r3, Section 10.5. Moderate to severe calcification reported; amputations not reported (NR).
Clinical Evidence – ISR Cohorts

Follow-up and Outcomes

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>LEVANT ISR&lt;sup&gt;1&lt;/sup&gt; Lutonix 035</th>
<th>IN.PACT ISR&lt;sup&gt;2&lt;/sup&gt; IN.PACT Admiral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim report of 53 DCB subjects (see note 1); Core lab-adjudicated</td>
<td>131 subjects Complete follow-up; Core lab-adjudicated</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12-mo Outcomes</th>
<th>LEVANT</th>
<th>IN.PACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1&lt;sup&gt;°&lt;/sup&gt; Patency (%)</td>
<td>66.2%</td>
<td>88.7%</td>
</tr>
<tr>
<td>FF CD-TLR (%)</td>
<td>78.4%</td>
<td>92.9%</td>
</tr>
<tr>
<td>Bail-out Stent (%)</td>
<td>0.0%</td>
<td>14.5%</td>
</tr>
<tr>
<td>Amputations (%)</td>
<td>NR</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

Primary patency definitions (KM estimates shown):
LEVANT  PSVR ≤ 2.5 & FF CD-TLR at day 365;
IN.PACT PSVR ≤ 2.4 & FF CD-TLR at day 360.

- Varying patency and FF reintervention
- Varying bail-out stent rate

1. Bard Lutonix Instructions for Use BAW1387400r3, Section 10.6. Moderate to severe calcification reported; amputations not reported (NR). Initially designed as an RCT to randomize 240 subjects to either Lutonix 035 or PTA, the trial was amended to a single-arm study after enrolling 82 subjects after which enrollment was halted; interim results of the 53 DCB subjects presented.
DCB and Calcium

1. Calcium deserves special consideration in the use of DCB, as demonstrated by Fanelli, et al.¹

2. Differences in calcium reporting obscure perception of individual DCB performance in calcium

3. Role for Atherectomy and need for vessel preparation.

---

### Vessel Prep with DCB

**Optimal PTA: Effect of Short vs Long Balloon Inflation Times on the Morphologic Results**

<table>
<thead>
<tr>
<th></th>
<th>Inflation Time (sec)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30</td>
<td>180</td>
</tr>
<tr>
<td>Major dissection (grades 3 or 4)</td>
<td>16</td>
<td>5</td>
</tr>
<tr>
<td>Minor or no dissection (grades 1 and 2)</td>
<td>21</td>
<td>32</td>
</tr>
<tr>
<td>Further interventions (Stent, repeat dilatation, dilation with larger diameter)</td>
<td>20</td>
<td>9</td>
</tr>
<tr>
<td>Residual stenosis (&gt;30%)</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Complication (embolization, thrombosis)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Mean ankle-brachial index (before, after intervention)</td>
<td>0.66, 0.87</td>
<td>0.65, 0.84</td>
</tr>
</tbody>
</table>

- Inflation times of 180 seconds improve immediate Infrainguinal PTA results vs. a short dilation strategy.
- Significantly fewer major dissections and a modest reduction of residual stenoses are observed.
- Significantly fewer continued interventions.

**Atherectomy**

Atherectomy may be used in conjunction with or in lieu of predilation as part of appropriate vessel preparation before DCB use.

---

Stent Therapy Overview

BMS
DES
Covered Stents
BMS Data

- 12-mo restenosis rates typically between 20-40%
- Proven superior to PTA, but may exhibit length-dependent performance
- While some stent designs may be more fracture-resistant than others, ISR is a concern as a class

2. Complete SE Instructions for Use (Medtronic).
7. Innova Instructions for Use (Boston Scientific).
DES Data

- Historically, -limus-based DES did not exhibit compelling results, though some 12-mo data looked promising (SIROCCO)
- Zilver PTX demonstrates sustained improvement over PTA and BMS (Zilver) through 5 years
- New entrant Eluvia still cultivating data

The Two Drug-Eluting Stents

<table>
<thead>
<tr>
<th></th>
<th>Zilver PTX (Cook)</th>
<th>Eluvia (Boston Scientific)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Configurations</td>
<td>6, 7, 8mm diameter 40-120mm length</td>
<td>6, 7mm diameter 40-150mm length</td>
</tr>
<tr>
<td>Platform</td>
<td>Zilver Stent</td>
<td>Innova Stent</td>
</tr>
<tr>
<td>Drug and Dosage</td>
<td>Paclitaxel 3µg/mm²</td>
<td>Paclitaxel 0.167µg/mm²</td>
</tr>
<tr>
<td>Polymer / coating</td>
<td>None</td>
<td>Polymer</td>
</tr>
<tr>
<td>Drug Transfer Time</td>
<td>&lt; 72 hours&lt;sup&gt;1&lt;/sup&gt;</td>
<td>&gt; 12 months&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>Commercial Availability</td>
<td>Worldwide</td>
<td>Outside US</td>
</tr>
<tr>
<td>US Indication</td>
<td>SFA &amp; PPA</td>
<td>Not FDA approved</td>
</tr>
</tbody>
</table>

Stent-Graft Data

• Length-independent performance
• More care needed in considering collateral coverage, sizing, DAPT, follow-up
• May be reserved for last resort prior to bypass in select patients
• Viabahn (Gore) has ISR approval

Atherectomy Therapy Overview
Atherectomy Data

- Inconsistent reporting metrics with few Core Lab-adjudicated studies
- No device manufacturer-sponsored data beyond 12mo
- Still, dissection rates and bail-out stent rates low with some modalities
- Laser atherectomy (Spectranetics) has ISR indication

Available Devices

Directional Atherectomy
- Hawk portfolio: Silver Hawk, TurboHawk, & HawkOne (Medtronic)
- Pantheris (Avinger)

Orbital Atherectomy
- Diamondback 360 (CSI)

Rotational Atherectomy
- JetStream (Boston Scientific)
- Phoenix (Volcano)

Photoablation Atherectomy
- Turbo-Elite & Turbo-Tandem (Spectranetics)
## Available Solo Atherectomy Data

<table>
<thead>
<tr>
<th>Study (* Core Lab)</th>
<th>Type</th>
<th>Patients</th>
<th>Lesions</th>
<th>Dissection (≥Grade D)</th>
<th>BO Stent</th>
<th>30-day MAE</th>
<th>Primary Patency</th>
<th>1-year</th>
<th>&gt;1-year</th>
</tr>
</thead>
<tbody>
<tr>
<td>* DEFINITIVE LE³</td>
<td>DA</td>
<td>598</td>
<td>743</td>
<td>2.2% (13/598) 2.5% (5/201)</td>
<td>3.2% (33/1022)</td>
<td>1.0% (6/598) 3.5% (7/201)</td>
<td>78% 71%</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>* DEFINITIVE CA²</td>
<td>DA</td>
<td>133</td>
<td>168</td>
<td>0.8% (1/131)</td>
<td>4.1% (7/169)</td>
<td>6.9% (9/131)</td>
<td>NR  ?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VISION-IDE³</td>
<td>DA</td>
<td>158</td>
<td>198</td>
<td>NR</td>
<td>5.1% (10/198)</td>
<td>16.6% (6-mo)</td>
<td>NR  ?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OASIS⁴</td>
<td>OA</td>
<td>124</td>
<td>201</td>
<td>NR</td>
<td>2.5% (5/201)</td>
<td>3.2% (4/124)</td>
<td>NR  ?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COMPLIANCE 360⁵</td>
<td>OA</td>
<td>25</td>
<td>38</td>
<td>NR</td>
<td>5.3% (2/38)</td>
<td>NR</td>
<td>81.2%</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>CALCIUM 360⁶</td>
<td>OA</td>
<td>25</td>
<td>29</td>
<td>3.5% (1/29)</td>
<td>6.9% (2/29)</td>
<td>0%</td>
<td>NR  ?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* PATHWAY PVD⁷</td>
<td>RA</td>
<td>172</td>
<td>210</td>
<td>9% (15/172)</td>
<td>7% (14/210)</td>
<td>1.0% (2/172)</td>
<td>61.8%</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>* CELLO⁸</td>
<td>Las</td>
<td>65</td>
<td>65</td>
<td>NR</td>
<td>23.2% (15/65)</td>
<td>0%</td>
<td>54.3%</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>* EXCITE-ISR⁹</td>
<td>Las</td>
<td>169</td>
<td>169</td>
<td>2.4% (≥Grade C)</td>
<td>4.1% (7/169)</td>
<td>5.8% (9/155)</td>
<td>71.1% (6-mo)</td>
<td>?</td>
<td></td>
</tr>
</tbody>
</table>

### Anatomical Location

<table>
<thead>
<tr>
<th>DA</th>
<th>RA</th>
<th>OA</th>
<th>Laser</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Above-knee</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>Below-knee</td>
</tr>
</tbody>
</table>

### Lesion Morphology

<table>
<thead>
<tr>
<th>Morphology</th>
<th>DA</th>
<th>RA</th>
<th>OA</th>
<th>Laser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focal</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>CTO</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Eccentric</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Concentric</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

### Plaque Composition

<table>
<thead>
<tr>
<th>DA</th>
<th>RA</th>
<th>OA</th>
<th>Laser</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>Ca$^{2+}$</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Soft</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>Thrombus</td>
</tr>
</tbody>
</table>

### In-Stent Restenosis

<table>
<thead>
<tr>
<th>ISR</th>
<th>DA</th>
<th>RA</th>
<th>OA</th>
<th>Laser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Individual operator experience and preference are likely the primary influencers in device selection.*
DEFINITIVE AR

Pilot study to detect trends in treatment differences between groups and designed to assess the effect of treating lesions with DA followed by DCB (DAART)

**DAART: Directional Atherectomy + Anti-Restenotic Therapy**

**Inclusion Criteria**
- RCC 2-4
- ≥ 70% stenosis of SFA and/or popliteal artery
- Lesion Length 7-15cm
- Reference Vessel ≥ 4mm and ≤ 7mm

**Exclusion Criteria**
- In-stent restenosis
- Aneurysmal target vessel
- Multiple lesions in target limb that require treatment

**General and Angiographic Criteria Assessment**

- Lesion severely calcified?*
  - NO
  - YES

**Randomization**

- DAART (n=48)
- DCB (n=54)
- DAART Severe Ca+ (n=19)

DEFINITIVE AR: 12-mo Patency via DUS

Potential Advantage Emerging in Long and Severely Calcified Lesions

Per Core Lab Assessment. “All Severe Ca++” group includes all patients treated with DA+DCB therapy including randomized and non-randomized patients with severe calcium.

DEFINITIVE AR:  12-mo Patency via Angio

Same trend:
Potential Advantage Emerging in Long and Severely Calcified Lesions

Results for all patients who returned for angiographic follow-up.

Future Combination Therapy

OPTIMIZE BTK

- Multicenter, randomized (atherectomy+DCB vs DCB)
- Target N = 50 at up to 10 EU sites
- RCC 3-5, BTK lesions
- Diamondback (CSI) + 0.014” DCB
- Estimated target completion date: June 2018

REALITY

- Multicenter, single-arm study
- Target N ≤ 250, ≤ 15 sites in US and Germany
- RCC 2-4, FPA lesions
- HawkOne / TurboHawk + IN.PACT Admiral
- Currently enrolling; target completion estimate 2018

Summary

• POBA exhibits a relatively high level of restenosis and may be most suitable to short, focal lesions in patients where DCB or implants are contraindicated

• DCB demonstrates promising results, though long-term follow-up variable, and complex lesions may still require stenting

• Atherectomy data variable in quality, though 12-mo results demonstrate fewer dissections and lower bail-out stent rate

• BMS data are often regarded as the benchmark, but ISR is a known obstacle that must be treated (or avoided by using other modalities)

• DES, i.e. Zilver PTX, offers compelling 5-yr results in comparison to conventional therapies (POBA and BMS)

• Stent-grafts, i.e. Viabahn, may be indicated in patients with long, complex lesions that would otherwise be surgical candidates.
Conclusions

Unfortunately – WE STILL HAVE A LOT OF WORK TO DO !!!
Thank You
Advanced Endovascular Techniques, Retrograde Pedal Access, Drug Eluting Stents, and Drug Eluting Balloons.

Osama A. Ibrahim, MD, FACC
Director of Peripheral Endovascular Therapies.
Director of Limb salvage and Amputation Prevention Program.
Director of Quality, Cardiac Catheterization Laboratories.
North Memorial Heart and Vascular Institute.
North Memorial Healthcare.
Minneapolis, MN

Founder, Twin Cities Vascular Forum (TCVF)
Chairman, NCVH Regional Minneapolis Chapter

18th Annual Conference
May 31 - June 02
THE PERIPHERAL EVENT OF THE YEAR