Use of atherectomy in CLI patients – current evidence

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Disclosure

Speaker name:
Erwin Blessing

I have the following potential conflicts of interest to report:

- [x] Consulting: Philips, Medtronic
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [x] Other(s): Honorarium: Philips, Medtronic

- [ ] I do not have any potential conflict of interest
Interventions below-the-knee

Clinical problem: high rate of restenosis and reocclusions

**Schmidt et al.**\(^1\)
POBA below the knee in CLI patients (77 lesions)
Angiographic follow up after 3 months:
- No restenosis: 31.2%
- Restenosis ≥ 50%: 31.2%
- Reocclusion: 37.6%

**Fernandez et al.**\(^2\)
POBA below the knee in CLI patients (123 lesions)
Follow up 12 months:
- Primary patency: 33%
- Secondary patency: 56%
- TLR: 50%

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Debulking

Rationale

Focused therapy on diseased segments

Recoil

Dissection

Restenosis

Barotrauma/Overstretching

Debulking removes plaque without causing vessel overstretch
Debulking Candidates
Directional atherectomy
Case example
Directional atherectomy

DEFINITIVE LE Infrapopliteal Subgroup

- 145 subjects
  - 75 with Claudication
  - 70 with CLI
- 189 lesions
  - 93 in claudicant cohort
  - 96 in CLI cohort
Primary Patency 12 months
Claudicant cohort

- SFA: 75% (Mean length: 8.1 cm, Number of Lesions: 536)
- Popliteal: 77% (Mean length: 6.0 cm, Number of Lesions: 114)
- Infrapopliteal: 90% (Mean length: 5.5 cm, Number of Lesions: 93)

Patency - PSVR ≤ 2.4
Primary Patency 12 months
Claudicant cohort, BTK Intervention

Mean length:
Short Lesions: 1.8 cm, 34 lesions
Medium Lesions: 6.2 cm, 42 lesions
Long Lesions: 13.4 cm, 12 lesions

Patency - PSVR < 2.4
Short Lesions: 90%
Medium Lesions: 89%
Long Lesions: 91%
Directional atherectomy

Primary Patency 12 months
CLI cohort, BTK intervention

- Short Lesions: 83%
- Medium Lesions: 73%
- Long Lesions: 73%

Mean length:
- Short Lesions: 1.8 cm
- Medium Lesions: 6.2 cm
- Long Lesions: 13.4 cm

Number of Lesions:
- Short Lesions: 31
- Medium Lesions: 34
- Long Lesions: 14

Patency - PSVR < 2.4
Orbital atherectomy
Mode of action

Centrifugal Force
360° crown contact designed to create a smooth, concentric lumen
Allows constant blood flow and particulate flushing during orbit

Differential sanding
- 30 µm diamond coating
- Average particulate size\(^1\) = 2 µm
- Bi-directional sanding of superficial calcium
- Healthy elastic tissue flexes away minimizing damage to the vessel

Pulsatile forces\(^1\)
- Dual frequency
- Orbital Frequency: low frequency of the crown orbiting against the vessel wall.
- Rotational Frequency: high frequency corresponding to the crown rotational speed.
- Observed in both crown motion and force.

Orbital atherectomy
Case example
Orbital atherectomy
Clinical data

CALCIUM 360°:
Study Design & Demographics

- Prospective, multi-center
- Randomized (1:1)
- Calcified BTK lesions

<table>
<thead>
<tr>
<th>Demographics</th>
<th>OAS + PTA N = 25</th>
<th>PTA ALONE N = 25</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age</td>
<td>70.7 ± 13.4</td>
<td>71.8 ± 10.9</td>
<td>0.75</td>
</tr>
<tr>
<td>Male / Female</td>
<td>68% / 32%</td>
<td>60% / 40%</td>
<td>0.77</td>
</tr>
<tr>
<td>Diabetic Type 1</td>
<td>4%</td>
<td>0%</td>
<td>1.00</td>
</tr>
<tr>
<td>Diabetic Type 2</td>
<td>68%</td>
<td>56%</td>
<td>0.56</td>
</tr>
<tr>
<td>Renal insufficiency (GFR &lt; 90)</td>
<td>25%</td>
<td>24%</td>
<td>1.00</td>
</tr>
<tr>
<td>Smoker (current or previous)</td>
<td>60%</td>
<td>60%</td>
<td>1.00</td>
</tr>
<tr>
<td>CAD</td>
<td>44%</td>
<td>56%</td>
<td>0.57</td>
</tr>
<tr>
<td>Hypertension</td>
<td>84%</td>
<td>84%</td>
<td>1.00</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>83%</td>
<td>72%</td>
<td>0.50</td>
</tr>
</tbody>
</table>

Orbital atherectomy
Clinical data

CALCIUM 360°: Results

Prospective, randomized, multi-center study that compared acute and long-term results of OAS+PTA and PTA alone in calcified BTK lesions

Results at 12 Months

<table>
<thead>
<tr>
<th></th>
<th>OAS + PTA n=15 patients</th>
<th>PTA ALONE n=15 patients</th>
<th>OAS + PTA n=15 patients</th>
<th>PTA ALONE n=19 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom From Revascularization</td>
<td>93.3% (p = 0.14)</td>
<td>80.0% (p = 0.006)</td>
<td>93.3% (p = 0.14)</td>
<td>57.9% (p = 0.006)</td>
</tr>
</tbody>
</table>

Orbital Atherectomy System changes compliance and provides durable results out to 12 months vs. PTA alone

**OPTIMIZE:**
RCT For OAS+DCB vs. DCB Alone In BTK Lesions

Study Details:
- Pilot study
- Prospective, 1:1 Randomization
- Below the knee lesions
- 2-year follow-up

Active Sites:
- Austria (Prof. Brodmann/Deutschmann & Dr. Werner)
- Germany (Prof. Zeller, Prof. Tepe, Prof. Andrassy, Prof. Blessing, Prof. Scheinert)
- Switzerland (Dr. Banyai)

Purpose: Demonstrate the ability of the OAS to prepare calcified, BTK lesions for optimal DCB deployment
**Versatility:** Phoenix effectively treats a broad range of tissue types, from soft plaque to calcified arteries, for lesions both above and below the knee.

**Center mass cutter:** Clears tissue in a way that may reduce potential trauma to the vessel. Phoenix cutter head allows debulked tissue be continuously captured, resulting in a <1% rate of distal embolization.

**Cut, capture and clear mechanism of action:** Front cutter clears tissue, blades continuously capture debulked material, which is removed by the Archimedes screw.
# Phoenix Registry Study Design

**Objective:** Evaluate the short and long-term clinical outcomes of patients treated with Phoenix Atherectomy System for peripheral artery disease (PAD)

<table>
<thead>
<tr>
<th><strong>N Patients</strong></th>
<th>500 (259 CLI patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Multicenter (N sites)</strong></td>
<td>17</td>
</tr>
<tr>
<td><strong>Enrollment</strong></td>
<td>September 14, 2015 - April 8, 2019</td>
</tr>
<tr>
<td><strong>Follow Up</strong></td>
<td>30 days (1 year for CLI patients)</td>
</tr>
<tr>
<td><strong>Randomization</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Phoenix Sizes</strong></td>
<td>1.8mm (5F), 2.2mm (6F), 2.4mm (7F)</td>
</tr>
<tr>
<td><strong>Primary Endpoints</strong></td>
<td>Technical Success, Procedural Success, Adverse device effects</td>
</tr>
<tr>
<td><strong>Secondary Endpoints</strong></td>
<td>WIIfI Classification, Target Vessel Revascularization (TVR), Target Lesion Revascularization (TLR), Major Amputation</td>
</tr>
</tbody>
</table>
## Key Efficacy Endpoints

Full cohort show high procedural **success rates**, >97% with CLI patients exhibiting greater technical and procedural success rates.

<table>
<thead>
<tr>
<th>Study</th>
<th>Definitions of Success</th>
<th>Success Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phoenix Registry</td>
<td><strong>Procedural</strong>: final target lesion(s) residual stenosis of ≤30% after treatment with Phoenix and any other adjunctive therapy</td>
<td><strong>Procedural Success</strong>&lt;br&gt; All Comers: 97% (485/500)&lt;br&gt; CLI: 97.7% (252/258)</td>
</tr>
<tr>
<td></td>
<td><strong>Technical</strong>: achieving a post-Phoenix (prior to any adjunctive therapy) residual diameter stenosis of ≤50%</td>
<td><strong>Technical Success</strong>&lt;br&gt; All Comers: 61.8% (309/500)&lt;br&gt; CLI: 68.6% (177/258)</td>
</tr>
</tbody>
</table>
## Secondary Endpoints at 30 days

### Full cohort: N=465

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLR</td>
<td>1.3%</td>
</tr>
<tr>
<td>Major Amputations</td>
<td>0%</td>
</tr>
</tbody>
</table>

### CLI cohort: N=237

<table>
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<tr>
<th>Endpoint</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLR</td>
<td>1.7%</td>
</tr>
<tr>
<td>Major Amputations</td>
<td>0%</td>
</tr>
</tbody>
</table>

- No Major Amputations at 30 Days
- Low rates of TLR at 30 Days
- CLI patients exhibit acute Rutherford score improvements, with greater than 60% of patients improving by at least 1 class @ 30 days

### Change in Rutherford Score

<table>
<thead>
<tr>
<th>Improvement</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved by 1</td>
<td>11.9%</td>
</tr>
<tr>
<td>Improved by &gt; 1</td>
<td>48.6%</td>
</tr>
</tbody>
</table>

**TLR:** Target lesion revascularization  
**Major Amputation:** Any amputation performed above the level of the ankle.
Phoenix atherectomy system

**PRESTIGE**

Phoenix Atherectomy and Stellarex DCB: clinical investigation in infrapopliteal interventions
ClinicalTrials.gov Identifier: NCT03744572, PI M. Lichtenberg

- Prospective, single-arm, multi-center
- N=75
- **Objective:** assess safety and efficacy of an IVUS-guided lesion preparation strategy with Phoenix atherectomy before DCB in CLI patients with BTK disease and moderate/severe calcium

- **Primary Endpoints:**
  - **Efficacy:** Patency at 6 months (freedom from TLR and TL occlusion by DUS)
  - **Safety:** freedom from MALE and/or 30-day perioperative death
- **Angio, IVUS, DUS Core-lab adjudication**

**RCC 4-5**
Clinical eligibility criteria met and IC signed

Angiographic eligibility criteria met (incl. moderate / severe Calcium)

### Atherectomy (Phoenix) + DCB (Stellarex)

<table>
<thead>
<tr>
<th></th>
<th>IVUS</th>
<th>Angio</th>
<th>DUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>post-Ather.</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>post-DCB</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>post-proc</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Follow-up**

- **FU 30-day:** Tel. Call
- **FU 6-months:** Clinical / DUS
- **FU 12-months:** Clinical / DUS
- **FU 24-months:** Clinical / DUS
Conclusions

Below-the-knee interventions are plagued by a high rate of target lesion failure

No convincing data so far for drug coated balloon angioplasty in below-the-knee arteries

Debulking is safe and effective also below-the-knee

Most convincing atherectomy data so far generated with directional atherectomy

Promising acute technical success also with orbital atherectomy and with the Phoenix system

Ongoing trials evaluating combination therapy (debulking plus drug coated balloons) below-the-knee in CLI patients
Use of atherectomy in CLI patients – current evidence

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