Endovascular Treatment with the Phoenix Atherectomy System in Patients with Chronic Limb Ischemia.

A Series of 109 Consecutive Patients.

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Disclosure

Speaker name:
Grigorios Korosoglou

I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [x] Other(s)

- [ ] I do not have any potential conflict of interest
Atherectomy using the Phoenix device

The cutter is rotated at high speed (10,000 to 12,000 rpm).

**Table: Catheter Size (mm)**

<table>
<thead>
<tr>
<th>Catheter Size</th>
<th>Introducer Size (F)</th>
<th>Working Length (cm)</th>
<th>Guidewire Diameter (inches)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.8 tracking</td>
<td>5</td>
<td>130</td>
<td>0.014</td>
</tr>
<tr>
<td>2.2 tracking</td>
<td>6</td>
<td>130</td>
<td>0.014</td>
</tr>
<tr>
<td>2.4 deflecting tip</td>
<td>7</td>
<td>130</td>
<td>0.014</td>
</tr>
</tbody>
</table>

**Phoenix 2.4mm deflecting catheter**
- Minimum Introducer sheath 7fr
- 3.0 - 7.0 mm vessels
- OTW system – 127cm working length (straight)

**Figure 2.** The Phoenix Atherectomy System, shown with the catheter inserted into the handle drive unit. No external, ofatable components are required.

**Figure 3.** Magnified view of the front-cutting blade located on the distal tip of the Phoenix Atherectomy System.
Safety and effectiveness of the Phoenix Atherectomy System in lower extremity arteries: Early and midterm outcomes from the prospective multicenter EASE study

<table>
<thead>
<tr>
<th></th>
<th>128 patients (ITT population)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs.)</td>
<td>72±10</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>65 (51%)</td>
</tr>
<tr>
<td><strong>Procedural success (per patient)</strong></td>
<td>99%</td>
</tr>
<tr>
<td>Dissection</td>
<td>2%</td>
</tr>
<tr>
<td>Perforation</td>
<td>5%</td>
</tr>
<tr>
<td>Symptomatic embolization</td>
<td>1%</td>
</tr>
<tr>
<td>Abrupt occlusion</td>
<td>1%</td>
</tr>
<tr>
<td>Unplanned minor amputation</td>
<td>2%</td>
</tr>
</tbody>
</table>

Exclusion criteria:
- Active infection of target limb
- **Critical limb ischemia (CLI)** with Rutherford class 6
- In-stent restenosis within the target lesion
- Target lesion with severe circumferential calcification noted in two views
# Experience with the Phoenix atherectomy device

<table>
<thead>
<tr>
<th></th>
<th>All-comers (n=109)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs.)</td>
<td>76±11</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>51 (51%)</td>
</tr>
<tr>
<td>Ischemic rest pain or ulcerations (RF 4-6)</td>
<td>64 (59%)</td>
</tr>
<tr>
<td>TASC C/D</td>
<td>98 (90%)</td>
</tr>
<tr>
<td><strong>Bilateral calcifications (PACSS score ≥3)</strong></td>
<td>85 (78%)</td>
</tr>
<tr>
<td><strong>Procedural success rate</strong></td>
<td>108 (99%)</td>
</tr>
<tr>
<td><strong>Stent placement</strong></td>
<td>7 (6%)</td>
</tr>
</tbody>
</table>

*Procedural success: Residual stenosis <30% with Phoenix plus adjunctive therapy.*
### Safety data and complications

<table>
<thead>
<tr>
<th>Event</th>
<th>All-comers (n=109)</th>
<th>EASE Trial (n=128)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perforation or dissection</td>
<td>1 (1%)*</td>
<td>7%</td>
</tr>
<tr>
<td>Peripheral embolization**</td>
<td>5 (5%)**</td>
<td>1%</td>
</tr>
<tr>
<td>Vessel occlusion</td>
<td>0 (0%)</td>
<td>1%</td>
</tr>
<tr>
<td>Major amputations (within 1 month of follow-up)</td>
<td>0 (0%)</td>
<td>N/A</td>
</tr>
<tr>
<td>Minor amputations (all planed)</td>
<td>3 (3%)</td>
<td>2% not planed</td>
</tr>
<tr>
<td>Target vessels revascularisation</td>
<td>1 (1%)</td>
<td>1%</td>
</tr>
<tr>
<td>Deaths (within 1 month of follow-up)</td>
<td>1 (1%)***</td>
<td>0%</td>
</tr>
</tbody>
</table>

* Requiring implantation of a Viabahn

** In all 5 cases, minor embolizations (all remaining asymptomatic) were observed without peri-procedural vessel occlusion. Embolized tissue could be retrieved in all cases by catheter aspiration.

*** Cardiac arrhythmogenic death not related to the procedure
Clinical case I

♂, 74 yrs., RF 3
Clinical case I

♂, 74 yrs., RF 3

Baseline | After 7F Phoenix | DCB (4atm) | Final result
Clinical case II

♂, 56 yrs. RF 3

No deflection  Half deflection  Full deflection
Clinical case II

♂, 56 yrs. RF 3

Baseline | After 7F Phoenix | DCB (2atm) | Final result
Clinical case III

♂, 69 yrs., RF 3

~ 5cm
Clinical case III

♂, 69 yrs., RF 3

6F Phoenix
Angiosculp scoring balloon
Final result after Phoenix, Angiosculp & DCB
Limitations

- Prospective single center experience.
- Off-label use (ISR) in 10% of the cases.
- No follow-up data available yet.
- No randomized comparison for atherectomy versus atherectomy + DCB available.
Conclusions

- Phoenix atherectomy results in high procedural success rate (99%) with a low stent rate (6%) even in very calcified complex TASC C/D lesions and occlusions.

- Phoenix atherectomy is safe, resulting low rates of perforation/dissection (<1%).

- Peripheral embolization was more common than in the EASE trial but still low <5%, in light of the fact that 1. we focused on severely calcified lesion, which were excluded in the EASE trial by protocol and 2) no filter devices were used. All cases were successfully treated percutaneously and remained asymptomatic.

- Further studies, investigating long-term effects of Phoenix atherectomy are now warranted.
For Correspondence: Grigorios.Korosoglou@grn.de
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Evaluating patient characteristics and lesion anatomy, complexity and calcification

Less complex lesions with low or no calcification grade

Occlusive lesions that cannot be passed by an intraluminal approach.

Lesions, where stent placement is allowed or perforation may be difficult to handle (iliac arteries).

Younger patients. Convoy with the ‘leave nothing behind’ concept. Preserve bypass landing zones.

Complex TASC C/D, strongly calcified non-occlusive lesions (PACSS score ≥3). Long diffuse non-occlusive disease.

Occlusive lesions that can be passed by an intraluminal approach (antegrade or retrograde).

No-stent zones (common femoral and popliteal artery).

Consider atherectomy
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