The Phoenix Atherectomy System: How It Works And Why It Is Different And Possibly Better Than Older Atherectomy Systems: Indications And Initial Results

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Disclosures

• Atherectomy Catheter
• Wire Support Clip
• Battery-powered Handle
• Debris Collection Bag

The Phoenix Atherectomy System: The basics

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- Wire Support Clip
- Battery-powered Handle
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The Phoenix Atherectomy System: The Phoenix Hybrid Atherectomy System: Why It Is different and Possibly Better

Capture and clearance
Continuous capture and passive clearance of debulked material into the catheter resulted in a <1% rate of symptomatic distal emboli in the EASE trial.

Ease of use
Battery-powered and handle operated. No capital equipment or additional procedural accessories.

Deliverability
Low-profile, front-cutting, over-the-wire design allowing direct lesion access and good trackability and pushability.

The Phoenix Atherectomy System: Mechanism of Action: Cut, Capture, Clear

Over-the-wire device: rotating, front-cutting element at distal tip.

- Once positioned, an on-off switch (on device handle) activates rotation of the cutting element.
- The distal tip with the cutting blades rotates at 10,000 to 12,000 rpm.
- This design allows material to be directly shaved into the catheter and removed by an internal Archimedes screw.

The Phoenix Atherectomy System: Indications

A broad range of lesions

Benign plaque
Calcific plaque
Atherosclerotic plaque
Stable plaque
Unstable plaque
Vulnerable plaque

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The Phoenix Atherectomy System
Phoenix IDE trial: The EASE study

16 US and German centers

Intention-to-treat enrollment: 128 patients, 149 lesions
mean length: 34 mm, mean diameter stenosis: 89.5%
Lesion location in the ITT group: ATK (24.1%), popliteal (18.1%), and BTK (57.8%)
primary analysis per-protocol population: 105 patients with 123 lesions.

- Technical success was 95.1% (117/123)
- 30 day MACE rate = 5.7% (6/105)
- Improvement of ≥1 Rutherford class in 74.5% through 30 days and for 80% through 6 months.
- Six-month freedom from TLR and TVR was 88.0% and 86.1%, respectively.

Phoenix Hybrid Atherectomy System:
Initial results: Phoenix Registry

Enrolled patients 500
CLI 261

Prospective multi-center Non-randomized

Davis T and el, Savety and effectiveness of the Phoenix Atherectomy System in lower extremity arteries: Early and midterm outcomes from the prospective multicenter EASE study.


- Technical success was 95.1% (117/123).
- After post-atherectomy adjunctive therapy, residual stenosis ≤30% for 99.2% (122/123) of lesions (mean final diameter stenosis 10.5%).
- 30 day MAEs rate = 5.7% (6/105)
- Improvement of ≥1 Rutherford class in 74.5% through 30 days and for 80% through 6 months.
- Six-month freedom from TLR and TVR was 88.0% and 86.1%, respectively.

Phoenix Registry: Patient Baseline & Target Lesion Assessment

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Rutherford 2-3</th>
<th>CLI (4-6)</th>
<th>All-comers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>116</td>
<td>142</td>
<td>258*</td>
</tr>
<tr>
<td>Number of Lesions</td>
<td>120</td>
<td>150</td>
<td>270</td>
</tr>
<tr>
<td>Mean Length (mm)</td>
<td>86.2</td>
<td>114.2</td>
<td>102.2</td>
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<tr>
<td>Min Length (mm)</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Max Length (mm)</td>
<td>200</td>
<td>300</td>
<td>200</td>
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<tr>
<td>Baseline Stenosis (%)</td>
<td>88.6</td>
<td>60.6</td>
<td>89.6</td>
</tr>
<tr>
<td>Baseline Max (%)</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Anatomical Location</td>
<td></td>
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<tr>
<td>ATK (%)</td>
<td>45.7</td>
<td>25.8</td>
<td>30.2</td>
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<tr>
<td>BTK (%)</td>
<td>54.3</td>
<td>74.2</td>
<td>60.8</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>89.6</td>
<td>71.9</td>
<td>84.1</td>
</tr>
</tbody>
</table>

Phoenix Registry interim data presented by Dr Stilp at VIVA 2017

Summary & Outlook

- Phoenix Atherectomy System performance at this interim analysis of registry data is consistent with findings from the EASE study.
- Interim results reveal safety, sales and efficacy profile including in the CLI population.
- Interim data show durable improvements in CLI patients.
- Phoenix Atherectomy System is a viable solution in the treatment paradigm for all spectrums of PAD (Rutherford 2-6).
- The Phoenix atherectomy 1.8 mm tracking catheter is indicated for vessels 2.5 mm in diameter or above. The Phoenix atherectomy 2.2 mm tracking and 2.4 mm deflecting catheters are indicated for vessels 3.0 mm in diameter or above.
- While the 1.8 mm and 2.2 mm tracking catheters are indicated for femoral, popliteal, or distal arteries located below the knee, the Phoenix 2.4 mm deflecting catheter is indicated for femoral and popliteal only.
DC1  Do you have the excel for the graph on the right? I'd like to reformat them both if possible?
DeGregorio, Caitlin, 10/18/2018