The versatility of directional atherectomy to address challenges of multi-level disease in CLTI

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Disclosure

Speaker name: K Stavroulakis

I have the following potential conflicts of interest to report:

- Consulting

- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
The CLTI pattern

Conte et al, JVS 2019
## The Hawk Devices

### H1-M (3-7 mm)

<table>
<thead>
<tr>
<th></th>
<th>H1-M</th>
<th>H1-S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheath Compatibility</td>
<td>6F</td>
<td>6F</td>
</tr>
<tr>
<td>Vessel Diameter (mm)</td>
<td>3.0-7.0</td>
<td>2.0-4.0</td>
</tr>
<tr>
<td>Crossing Profile (mm)</td>
<td>2.2</td>
<td>2.2</td>
</tr>
<tr>
<td>Working Length (cm)</td>
<td>135</td>
<td>151</td>
</tr>
<tr>
<td>Effective Length (cm)</td>
<td>129</td>
<td>145</td>
</tr>
<tr>
<td>Tip Length (cm)</td>
<td>5.9</td>
<td>5.9</td>
</tr>
<tr>
<td>Max Cut Length (mm)</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td>Packing Device</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### H1-S (2-4 mm)

### 6F Device*

<table>
<thead>
<tr>
<th></th>
<th>Cutter Height</th>
<th>Cut Depth</th>
</tr>
</thead>
<tbody>
<tr>
<td>HawkOne 6F</td>
<td>0.009” (0.23 mm)</td>
<td>0.36 mm (H1-M) 0.34 mm (H1-S)</td>
</tr>
<tr>
<td>TurboHawk SX-C</td>
<td>0.009” (0.23 mm)</td>
<td>0.37 mm</td>
</tr>
</tbody>
</table>

### 7F Device*

<table>
<thead>
<tr>
<th></th>
<th>Cutter Height</th>
<th>Cut Depth</th>
</tr>
</thead>
<tbody>
<tr>
<td>HawkOne 7F</td>
<td>0.011” (0.28 mm)</td>
<td>0.45 mm</td>
</tr>
<tr>
<td>TurboHawk 7F</td>
<td>0.012” (0.30 mm)</td>
<td>0.47 mm</td>
</tr>
</tbody>
</table>
DEFINITIVE LE trial: CLTI Cohort

Lower Extremity Revascularization Using Directional Atherectomy
12-Month Prospective Results of the DEFINITIVE LE Study

James F. McKinsey, MD; Thomas Zeller, MD; Krishna J. Rocha-Singh, MD; Michael R. Jaff, DO; Lawrence A. Garcia, MD; on behalf of the DEFINITIVE LE Investigators

ABSTRACT

OBJECTIVES: The aim of this study was to assess the safety and effectiveness of directional atherectomy (DA) for endovascular treatment of peripheral arterial disease (PAD) in infrainguinal arteries in patients with claudication or critical limb ischemia.

BACKGROUND: To date, no prospective, multicenter, independently adjudicated study has evaluated the effectiveness and durability of DA in the treatment of PAD. Previous DA studies have not been prospectively powered to evaluate any differences in outcomes in patients with and without diabetes.

METHODS: DEFINITIVE LE (Determination of Effectiveness of the SilverHawk® Peripheral Plaque Excision System [SilverHawk Device] for the Treatment of Infragenital Vessels/Lower Extremities) prospectively enrolled subjects at 47 multinational centers with an infrainguinal lesion length up to 2 cm. Primary endpoints were defined as primary patency at 12 months for claudicants and freedom from major unplanned amputation for critical limb ischemia (CLI) subjects. A pre-specified statistical hypothesis evaluation noninferiority of primary patency in diabetic versus nondiabetic claudicants. Independent angiographic and sonographic core laboratories assessed outcomes, and events were adjudicated by a clinical events committee.

RESULTS: A total of 800 subjects were enrolled. The 12-month primary patency was 78% (95% confidence interval: 74.0% to 80.6%) in claudicants, with a 77% rate in the diabetic subgroup versus 78% in the nondiabetic subgroup (noninferior, p < 0.001). The rate of freedom from major unplanned amputation of the target limb at 12 months in CLI subjects was 95% (95% confidence interval: 90.7% to 97.4%). Periprocedural adverse events included embolization (3.8%), perforation (5.3%), and abrupt closure (2.0%). The bail-out stent rate was 3.2%.

CONCLUSIONS: The DEFINITIVE LE study demonstrated that DA is a safe and effective treatment modality at 12 months for a diverse patient population with either claudication or CLI. Furthermore, DA was shown to be noninferior for treating PAD in patients with diabetes compared with those without diabetes. (Study of SilverHawk/TurboHawk in Lower Extremity Vessels [DEFINITIVE LE], NCT00883346). (J Am Coll Cardiol Intv 2014;7:923–33) © 2014 by the American College of Cardiology Foundation.

J Am Coll Cardiol Intv 2014;7:923–33
Directional atherectomy as stand alone therapy

Directional Atherectomy + Anti-Restenotic Therapy

The DAART Concept

DA: Vessel Preparation + Anti-restenotic treatment
Directional Atherectomy + DCB (DAART)

**Baseline Lesion Characteristics**

*Per Core Lab*

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>DAART (N=48)</th>
<th>DCB (N=54)</th>
<th>p-Value*</th>
<th>DAART Severe Ca++ Arm (N=19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Length (cm)</td>
<td>11.2</td>
<td>9.7</td>
<td>0.05</td>
<td>11.9</td>
</tr>
<tr>
<td>Diameter Stenosis</td>
<td>82%</td>
<td>85%</td>
<td>0.35</td>
<td>88%</td>
</tr>
<tr>
<td>Reference vessel diameter (mm)</td>
<td>4.9</td>
<td>4.9</td>
<td>0.48</td>
<td>5.1</td>
</tr>
<tr>
<td>Minimum lumen diameter (mm)</td>
<td>1.0</td>
<td>0.8</td>
<td>0.34</td>
<td>0.7</td>
</tr>
<tr>
<td>Calcification</td>
<td>70.8%</td>
<td>74.1%</td>
<td>0.82</td>
<td>94.7%</td>
</tr>
<tr>
<td>Severe calcification</td>
<td>25.0%</td>
<td>18.5%</td>
<td>0.48</td>
<td>89.5%</td>
</tr>
</tbody>
</table>

* p-value for DAART and DCB groups

**Key Study Outcome at 12 Months**

*DUS Patency - Potential Advantage Emerging in Long and Severely Calcified Lesions*

*Per Core Lab Assessment. “All Severe Ca++” group includes all patients treated with DAART therapy, including randomized and nonrandomized, patients with severe calcification.*

**Key Study Outcome at 12 Months**

*Angiographic Patency shows similar pattern*

Thomas Zeller, MD

CFA disease

Primary patency: 96% @ 7 years
CFA Stent therapy vs Surgery: Tecco trial

Global vascular guidelines on the management of chronic limb-threatening ischemia

Michael S. Conte, MD (Co-Editor), Andrew W. Bradbury, MD (Co-Editor), Philippe Kohl, MD (Co-Editor), John V. White, MD (Steering Committee), Florian Dick, MD (Steering Committee), Robert Fitridge, MBBS (Steering Committee), Joseph L. Mills, MD (Steering Committee), Jean-Baptiste Ricco, MD (Steering Committee), Kalkunete Suresh, MD (Steering Committee), M. Hassan Murad, MD, MPH, and the CVG Writing Group.

6.29 Consider endovascular treatment of significant CFA disease in selected patients who are deemed to be at high surgical risk or to have a hostile groin.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Level of evidence</th>
<th>Key references</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 (Weak)</td>
<td>C (Low)</td>
<td>Baumann, 2011; Bonvini, 2011; Gouëffic, 2017; Siracuse, 2017</td>
</tr>
</tbody>
</table>

6.30 Avoid stents in the CFA and do not place stents across the origin of a patent deep femoral artery.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Level of evidence</th>
<th>Key references</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

Keywords: Chronic limb-threatening ischemia, Critical limb ischemia, Peripheral artery disease, Diabetes, Foot ulcer, Endovascular intervention, Bypass surgery, Practice guideline, Evidence-based medicine.
DAART for CFA

68% vs 88%, (HR): 0.64; 95 CI: 0.22 to 2.81, P= .40

DAART for CFA Restenosis after Surgery
DAART for Bypass anastomosis stenosis
DAART long SFA lesion
### DAART long SFA lesion

<table>
<thead>
<tr>
<th>After Directional Atherectomy</th>
<th>DCB Angioplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image of arterial造影 after directional atherectomy" /></td>
<td><img src="image2.png" alt="Image of arterial造影 after DCB angioplasty" /></td>
</tr>
</tbody>
</table>

This image illustrates the outcomes of directional atherectomy followed by DCB angioplasty for a long SFA lesion in a patient.
DAART long SFA lesion
The pitfalls of stent therapy for popliteal disease

Figure 1.—The lower extremities vessels are subject to a variety of forces as a result of external mechanical demands.

Li et al, J Cardiovasc surg 2017;58:698-714
DAART for popliteal disease

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>DAART</th>
<th>P Wert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary patency</td>
<td>65%</td>
<td>82%</td>
<td>0.021</td>
</tr>
<tr>
<td>Freedom from TLR</td>
<td>82%</td>
<td>94%</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Stavroulakis et al JEV. 2017;24(2):181-188
DAART for BTK Disease: The ADCAT Trial

- 80 subjects
- 1:1 Randomization (DCB vs DAART)
- BTK long de- novo lesions (≥6cm)
- Repeat angiography at 3 months
- Primary endpoint: in-Segment Binary Restenosis
- Follow-up visits scheduled at 3, 6, 12 months

ClinicalTrials.gov Identifier: NCT01763476
Conclusions

- CLTI multivessel disease pattern
- DA can effectively remove calcium and minimize the risk for dissections and bailout stenting
- No clear long-term benefit
- DA valuable vessel prep tool for
  - CFA disease
  - Popliteal disease
  - Long/Calcified lesions
- Waiting for BTK data
Thank you!
The versatility of directional atherectomy to address challenges of multi-level disease in CLTI

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