
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
Directional Atherectomy for the Treatment of Critical Limb Ischemia – Evidence Review (and Image review submitted by Dr Motarjeme)

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
Disclosures

Speaker’s Bureau:
• None

Honorarium:
• Boston Scientific

Consultant:
• Boston Scientific

Stockholder:
• None

Grant/Research Support:
• Medtronic

Medical/Scientific Boards:
• None
Directional Atherectomy History

- AtheroCath
- SilverHawk
- RockHawk
- TurboHawk Super Cutter
- TurboHawk Smooth Cutter
- HawkOne 7F
- HawkOne 6F
- ev3 acquisition of FoxHollow
- TurboHawk Smooth / HE Devices
- TurboHawk 6F HE Devices
- MDT acquisition

Timeline:
- 1996
- 1997
- 2002
- 2003
- 2004
- 2005
- 2006
- 2007
- 2008
- 2009
- 2010
- 2011
- 2012
- 2013
- 2014
- 2015
- 2016
- 2017
HawkOne Directional Atherectomy System

Designed to treat all atherosclerotic plaque efficiently and effectively, including severe calcium

Improved crossing and cleaning capabilities compared to TurboHawk platform
HawkOne Device Technology

Three design enhancements enable operators to treat calcified lesions up to two times more effectively.  

1) Rotational Speed
   - 50% increase in rotational speed
     - HawkOne Cutter Driver: 12,000 RPM
     - TurboHawk Cutter Driver: 8,000 RPM

2) Robust Drive Shaft
   - 25% improvement in torsional performance
     - Increased outer diameter (OD) by 0.05mm

3) Blade Design
   - HawkOne Cutter
     - 4 contoured blades

---

1. Performance claims for HawkOne™ device are made in comparison to the TurboHawk™ platform.
HawkOne Device Technology

Cleaning

- Pre-loaded Distal Flush Tool (DFT) translates to fewer cleaning steps and a more intuitive process
- Cleaning time is up to 55% faster, as a result of a simplified process
- Larger distal flush mouth creates a larger exit for tissue

Device Length

- Effective length is maintained or extended
- Standardizing catheter length adds 3cm of effective length to the H1-LS

1. Performance claims for HawkOne device are made in comparison to the TurboHawk platform.
HawkOne Device Technology

Crossing and Deliverability

- Crosses more predictably in challenging lesions, due to a smaller crossing profile
- Provides 25% improvement in tracking and deliverability through an indicated 7F sheath

Tip Design

- Reduction overall tip diameter
- Long, tapered distal tip provides enhanced deliverability
- Enhanced visualization under angiography, as a result of radiopaque distal tip
- White coloration streamlines guidewire loading

1. Performance claims for HawkOne device are made in comparison to the TurboHawk platform.
## DEFINITIVE LE

### Overview

- **Design**
  - Prospective, multinational, single-arm study
  - Clinical events committee (CEC) adjudicated adverse events
  - Largest Core Lab* adjudicated atherectomy trial

- **Objective**
  - To evaluate the effectiveness of standalone SilverHawk / TurboHawk Peripheral Plaque Excision Systems for endovascular treatment of peripheral arterial disease in the femoropopliteal and tibioperoneal arteries

- **Subjects**
  - 800 Subjects
    - Prespecified comparison of subjects with and without diabetes

- **Sites**
  - 47 Sites
    - US and EU

---

DEFINITIVE LE

Inclusion and Exclusion Criteria

Inclusion Criteria
- RCC 1-6
- ≥50% stenosis
- Lesion Length ≤20 cm
- Reference Vessel ≥1.5 mm and ≤7.0 mm

Exclusion Criteria
- Severe calcification
- In-stent restenosis
- Aneurysmal target vessel

SilverHawk/TurboHawk Peripheral Plaque Excision Systems used in study

DEFINITIVE LE

Trial Details

<table>
<thead>
<tr>
<th>Subjects</th>
<th>CLAUDICATION</th>
<th>CRITICAL LIMB ISCHEMIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claudication</td>
<td>598 Patients(^2)</td>
<td>201 Patients</td>
</tr>
<tr>
<td>Primary Patency by Duplex Ultrasound at 12 months (PSVR ≤2.4 with no clinically-driven reintervention)</td>
<td></td>
<td>Freedom from Major Unplanned Amputation at 12 months</td>
</tr>
</tbody>
</table>

This presentation includes the 201 patients enrolled in the CLI arm.

2. One patient censored due to informed consent violation.
DEFINITIVE LE

*Freedom from Amputation Definition*¹

Primary Endpoint

- Freedom from **major unplanned amputation** of the target limb through 12 months.
- Major amputation defined as:
  - Amputation above the metatarsal region
  - Unanticipated before the index procedure

**Directional Atherectomy**

**DEFINITIVE LE CLI Cohort: Baseline Characteristics**

### Patient Characteristics

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient #</td>
<td>201 (RCC 4-6)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>72.1 ± 11.4</td>
</tr>
<tr>
<td>Men</td>
<td>49.8% (100)</td>
</tr>
<tr>
<td>DM</td>
<td>68.7% (138)</td>
</tr>
<tr>
<td>HT</td>
<td>92.0% (185)</td>
</tr>
<tr>
<td>HL</td>
<td>76.1% (153)</td>
</tr>
<tr>
<td>Smoking history</td>
<td>35.8% (72)</td>
</tr>
<tr>
<td>ABI</td>
<td>0.65 ± 0.16</td>
</tr>
</tbody>
</table>

### Lesion Characteristics

<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion #</td>
<td>279 (RCC 4-6)</td>
</tr>
<tr>
<td>Location</td>
<td></td>
</tr>
<tr>
<td>SFA</td>
<td>48.4% (135)</td>
</tr>
<tr>
<td>PA</td>
<td>17.2% (48)</td>
</tr>
<tr>
<td>Intrapop</td>
<td>34.4% (96)</td>
</tr>
<tr>
<td>RVD (mm)</td>
<td>3.7 ± 1.3</td>
</tr>
<tr>
<td>% Stenosis</td>
<td>75.9% ± 20.0</td>
</tr>
<tr>
<td>Length (cm)</td>
<td>7.2 ± 5.5</td>
</tr>
<tr>
<td>Occlusion</td>
<td>29.9% (83/278)</td>
</tr>
<tr>
<td>Ca²⁺</td>
<td>37.1% (103/278)</td>
</tr>
<tr>
<td>None-Mild</td>
<td></td>
</tr>
<tr>
<td>Mod-Severe</td>
<td></td>
</tr>
</tbody>
</table>

---

## Directional Atherectomy

### DEFINITIVE LE CLI Cohort: Outcomes

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient #</td>
<td>201 (RCC 4-6)</td>
</tr>
<tr>
<td>Lesion #</td>
<td>279</td>
</tr>
<tr>
<td>Bail-out Stent(^2)</td>
<td>3.2%</td>
</tr>
<tr>
<td>Procedural Success</td>
<td>83.0%</td>
</tr>
<tr>
<td>MAE (30d)</td>
<td>3.5%</td>
</tr>
<tr>
<td>1(^\circ) Patency (1y)</td>
<td>71.0%</td>
</tr>
<tr>
<td>1(^\circ) Patency Def</td>
<td>PSVR ≤ 2.4 by DUS</td>
</tr>
<tr>
<td>Limb Salvage (1y)</td>
<td>95%</td>
</tr>
</tbody>
</table>

2. Bail-out stent rate captured for entire study, including lesions associated with both claudicant and CLI cohorts.
Conclusions

• Directional atherectomy is safe and effective for the treatment of CLI
• DEFINITIVE LE demonstrated low AE and bail-out stent rate, as well as high limb salvage rate in CLI population
• HawkOne has evolved to be a more effective excisional catheter at a lower crossing profile than previous Hawk family devices
ALL images courtesy of Dr Amir Motarjeme
Directional Atherectomy to the AT Artery
Directional Atherectomy to the TP Trunk
Directional Atherectomy to the distal AT Artery
Thank you

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