HOW I USE DIRECTIONAL A THERECTOMY

TIPS FOR SUCCESSFUL VESSEL PREPARATION

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WEST DES MOINES, IOWA
DISCLOSURES

Abbott Medical: Research
Boston Scientific: Research
FastWave Medical: Consultant
LimFlow: Research
Medtronic: Consultant, Research, Speaker
Endologix: Research
DEFINITIVE LE: The Data Behind Directional Atherectomy

1-Year Primary Patency: 78%

Bail-out Stent Rate: 2.3%

Dissection Rate: 3.2%

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

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

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.

Methods This was a prospective, randomized, multinational, single-arm clinical trial. Patients were randomized to DA (SilverHawk or TurboHawk, Conformis, Inc., Stillwater, Minnesota) treatment for infrainguinal lesions. The primary end points were the per-procedure technical and clinical success rate at 1 month. The secondary end points included major adverse limb events at 12 months and a 12-month follow-up angiographic study.

Conclusions The DEFINITIVE LE study demonstrated that DA is a safe and effective treatment modality for infrainguinal lesions in patients with claudication or critical limb ischemia. The primary technical and clinical success rates at 1 month were 98% and 91%, respectively. The 12-month major adverse limb event rate was 3.2%.

CONCLUSIONS The DEFINITIVE LE study demonstrated that DA is a safe and effective treatment modality at 12 months in a diabetic patient population with either claudication or CLI, but it is own 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], NCT00883246). J Am Coll Cardiol Intv 2014;7(8):849-57 © 2014 by the American College of Cardiology Foundation.
1. **Choose 7Fr for Femoropopliteal Lesions**

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**HawkOne™ Directional Atherectomy**

<table>
<thead>
<tr>
<th>Model</th>
<th>Catalog number</th>
<th>Vessel diameter (mm)</th>
<th>Sheath compatibility (F)</th>
<th>Crossing profile (mm)</th>
<th>Working length† (cm)</th>
<th>Effective length**†† (cm)</th>
<th>Tip length (cm)</th>
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### TECHNICAL TIPS

#### HawkOne™ Directional Atherectomy

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1. Choose 7Fr for Femoropopliteal Lesions
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2. Maintain sheath – lesion distance of $\geq$ 10cm
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2. Maintain sheath – lesion distance of $\geq 10$cm

3. IVUS to Assess Lesions Morphology

Concentric Plaque Allows For Circumferential Cutting

Eccentric Lesions Require Directed Excision
1. Choose 7Fr for Femoropopliteal Lesions
2. Maintain sheath – lesion distance of ≥ 10cm
3. IVUS to Assess Lesions Morphology
4. Let The Device Cut (advance 2-4mm/sec)
Choose 7Fr for Femoropopliteal Lesions

Maintain sheath – lesion distance of ≥ 10cm

IVUS to Assess Lesions Morphology

Let The Device Cut (advance 2-4mm/sec)

Use Oblique Views to See More / Excise More
1. Bifurcation, Trifurcation Lesions
Femoral Bifurcation Lesion

Initial Lesion

Hawk One- LS

Final (DA + DCB)
Popliteal Bifurcation Lesion

Initial Lesion

Hawk One-M

Final (DA + PTA)
CASE SELECTION

1. Bifurcation, Trifurcation Lesions

2. Any Lesion I Don’t Want to Stent
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2. Any Lesion I Don’t Want to Stent
3. Shorter, Focal Lesions
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2. Any Lesion I Don’t Want to Stent
3. Shorter, Focal Lesions
4. Secondary Use Following Inadequate PTA
DA Following Inadequate PTA

40cm SFA Occlusion

6mm PTA

Following Proximal SFA DA
Eight Years Later....

Duplex Velocities

<table>
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<tr>
<th>Location</th>
<th>Velocity</th>
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<tr>
<td>Proximal SFA</td>
<td>92 cm/s</td>
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<tr>
<td>Mid SFA</td>
<td>72 cm/s</td>
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<tr>
<td>Distal SFA</td>
<td>73 cm/s</td>
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<tr>
<td>Popliteal</td>
<td>88 cm/s</td>
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ABI 1.23
CASE SELECTION

1. Bifurcation, Trifurcation Lesions
2. Any Lesion I Don’t Want to Stent
3. Shorter, Focal Lesions
4. Secondary Use Following Inadequate PTA
5. In-Stent Restenosis
DA For In-Stent Restenosis
Why Do I Choose DIRECTIONAL AHERECTOMY?

- JETSTREAM™
  Boston Scientific
- ROTABLATOR™
  Boston Scientific
- DIAMONDBACK™
  CSI
- PHOENIX™
  Phillips
- HAWKONE™
  Medtronic
- TURBOTANDEM™
  Phillips
Why Do I Choose DIRECTIONAL AThERECTOMY?

- SIMPLE SET UP
- EASE OF USE
- TITRATE USE TO LUMEN GAIN
- SAFELY USE AFTER PTA
- MINIMIZES BAIL-OUT STENTING

HAWKONE™ Medtronic
Lesion Length, 1-Year Patency and Stent Rate
CONCLUSIONS

Powerful plaque-excision tool for lumen gain

Essential tool for "no-stent" zones and "stent-free" femoropopliteal, tibial strategy

Versatility to treat from the CFA to the foot
HOW I USE DIRECTIONAL AHERECTOMY

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