Treatment of Stenotic Lesions Below-the-Knee with an OCT-guided Atherectomy Catheter

Michael Lichtenberg, MD, FESC
Vascular Center
Klinikum Hochsauerland
Arnsberg, Germany
Disclosure

Speaker name: Michael Lichtenberg

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
Revascularisation of BTK Lesions

• Initial treatment strategy for patients with claudication or critical limb ischemia was angioplasty, first with plain balloons and then with (optional) drug-coated balloons.

• Results are mixed between non-coated and drug-coated balloons when used alone, with restenosis of treated BTK lesions ranging from 15% to 70% just one year post-procedure.

• Atherectomy used in conjunction with angioplasty has demonstrated significantly lower revascularization rates with reduced complications, such as vessel dissection.

Clinical Benefits of Atherectomy in BTK Lesions

- Atherectomy debulks the lesion rather than merely pressing it into the vessel wall.
- Removal of tissue permits better balloon expansion with less barotrauma and more uniform delivery of antineoplastic medication from DCBs.
- Initial findings suggest promising safety and efficacy outcomes, such as higher immediate luminal gain, less need for stenting, and lower incidence of vessel wall recoil.

 Pantheris SV (6 Fr) Atherectomy Device

Technical Specifications:
• 2.2 mm Crossing Profile
• 144 cm Working Length
• 6 Fr Sheath Compatible
• 0.014” Guidewire Compatible

Key Benefits:
• OCT image guidance at point of treatment
• OCT-powered diameter measurement for accurate sizing of adjunctive therapy tools (e.g., stents, balloons)
• Precision targeting of plaque excision to avoid injury to healthy vessel wall
Advantages of OCT-guided Atherectomy

• OCT imaging enables better visualization than IVUS of internal vessel architecture to evaluate level of stenosis, occurrence of dissection, and plaque morphology to assist in planning treatment strategy.

• Real-time OCT imaging allows the physician to directly address diseased tissue while minimizing contact with and injury to healthy wall tissue.

• Intravascular OCT facilitates measurement of the lumen for more accurate sizing of adjunctive treatment by balloon or stent.

Real-time OCT imaging Identifies Eccentric Disease Below the Knee

Cutter initially facing healthy media and adventitia @ 10 o’clock

Cutter rotated to eccentric fibrous disease @ 3 o’clock

Following 3cm distal advancement, disease debulked, exposing media
Prospective, global, single-arm, nonrandomized, multi-center post-market study of OCT-guided directional atherectomy in lesions below the knee (BTK)

Up to 60 subjects at 4 sites (2 USA and 2 EU)

Safety Endpoints
- Primary—freedom from MAEs through 30-day follow-up

Effectiveness endpoints
- Primary—proportion of target vessels with a residual diameter stenosis ≤ 50% post atherectomy only
- Secondary
  - Proportion of vessels with residual stenosis ≤30% post adjunctive therapy
  - Freedom from TVR at 6 & 12 months post procedure
  - Primary patency measured by duplex ultrasound at 6 & 12 months post procedure
  - Improvement in ABI at all follow-up visits

Images Core Lab adjudicated; AEs assessed by a CEC
Data Collected as of 1 May 2023

- No. of subjects enrolled: 41
- No. of lesions treated: 46
- No. of subjects completing index procedure: 41
- No. of subjects completing 6-month visit: 31
- No. of subjects completing 1-year visit: 24
Subjects’ Baseline Characteristics (N=41)

- Sex: 68% M / 32% F
- Mean Age: 71 ± 12 years
- Mean Weight: 90.2 ± 27.1 kg
- Mean Height: 169 ± 16 cm
- Race: Caucasian (72%), Black (28%),
- Hx Smoking (65%),
  - Hypertension (88%),
  - Diabetes (48%)
  - CAD (57%)

Rutherford Classes:
- Class 0: 0
- Class 1: 0
- Class 2: 0
- Class 3: 23%
- Class 4: 26%
- Class 5: 52%
- Class 6: 0

Mean ABI: 0.77 ± 0.32
Baseline Target Lesion Characteristics (N=41)

- **Location:**
  - Distal Popliteal Artery – 1%
  - Anterior Tibial Artery – 42%
  - Posterior Tibial Artery – 30%
  - Tibioperoneal Trunk Tibial – 19%
  - Peroneal Artery – 5%
  - Dorsalis Pedis Artery – 2%

- **Mean reference vessel diameter:** $3.1 \pm 1.3$ mm
- **Mean length of lesion:** $12.9 \pm 5.4$ cm (range 1 to 80)
- **Type:** *de novo* 79%. Restenosis 21%
- **Mean percent vessel diameter stenosis pre-procedure:** $94\% \pm 8.9\%$
- **Severity of Calcification:**
  - None 17%
  - Mild 52%
  - Moderate 21%
  - Severe 10%
Elapsed Times of Procedural Elements

• Mean time from start to finish of the procedure: 71 ± 2 minutes

• Mean time of the Atherectomy treatment: 8 ± 0.5 minutes

• Mean time from finish to discharge: 95 ± 12 minutes

• Mean time from start to discharge: 153 ± 32 minutes
Anterior Tibial Lesion: 150 mm in the AT; severe calcification (medial)
Primary Safety Endpoint: Freedom from MAEs at 30 Days Post-procedure (N=38)

- Major Adverse Events:
  - Clinically-driven TLR: 0
  - Major, unplanned amputation of the treated limb: 0
  - All-cause mortality 30 days following the procedure: 0

FF MAE – 100%
Effectiveness Endpoints

**Primary:**

98% of the BTK occlusions had a residual diameter of stenosis ≤ 50% after excision of tissue by the Pantheris catheter alone (N=41)

**Secondary:**

100% of the BTK occlusions had a residual diameter of stenosis ≤ 30% at the end of the index procedure (N=41)

Freedom from target vessel restenosis:

- 6 mo post-procedure (N=31): 96%
- 1 yr post-procedure (N=24): 96%

Patency with DUS assessment by independent core lab (using PSVR <2.4 as patency):

- Mean % patent limbs at 6 months (N=26): 96%
- Mean % patent limbs at 1 year (N=19): 93%
Reduction in Stenosis

- Pre-Procedure: 94%
- Post-Atherectomy: 25%
- Post-Adjunctive Tx: 9%

73% Reduction
90% Reduction
Changes in Rutherford Class Over Time

- Pre-Procedural:
  - RC 0: 51%
  - RC 1: 26%
  - RC 2: 23%
  - RC 3: 49%
  - RC 4: 11%
  - RC 5: 11%
  - RC 6: 6%

- 30 Days Post:
  - RC 0: 26%
  - RC 1: 49%
  - RC 2: 17%
  - RC 3: 14%
  - RC 4: 4%
  - RC 5: 11%
  - RC 6: 10%

- 6 Months Post:
  - RC 0: 23%
  - RC 1: 46%
  - RC 2: 14%
  - RC 3: 46%
  - RC 4: 10%
  - RC 5: 10%
  - RC 6: 17%

- 1 Year Post:
  - RC 0: 23%
  - RC 1: 61%
  - RC 2: 10%
  - RC 3: 61%
  - RC 4: 10%
  - RC 5: 19%
  - RC 6: 14%

Legend:
- RC 0: Green
- RC 1: Orange
- RC 2: Blue
- RC 3: Brown
- RC 4: Yellow
- RC 5: Red

Graph shows percentage changes in various Rutherford classes over time.
Intravascular Image-guided Atherectomy Helps the Surgeon Avoid Arterial Wall Injury: Analysis of Excised Tissue from BTK lesions (N=36)

Mean tissue weight: 21.05 mg (range 1.8 to 30.3)
Mean percent area of SMC-rich plaque: 31.4% (range 3.3 to 46.6)
Mean percent area of lipids/inflammation: 1% (range 0 to 9.5)
Mean percent area of thrombus: 2.5% (range 0 to 11.1)
Mean percent area of media: 19.5% (range 0.1 to 41.7)
Mean percent area of adventitia: 0.68% (range 0 to 1.9)

Representative tissue: no Adventitia– trace volume of Media (yellow outlines)

Data on file at Avinger, Inc.
Conclusions from Experience to Date

• The IMAGE BTK study demonstrates that directional atherectomy with real-time intravascular imaging revascularizes occluded lower extremity vessels with minimal adverse events or complications.

• Intravascular imaging supporting atherectomy improves safety and efficacy in treating BTK lesions with minimal excision of adventitial tissue (<1% of the total excised tissue in this study to date).

• Adjunctive treatment improves reduction of residual stenosis.