New Evidence Review for OCT Guided Atherectomy: Long Term Patency, In-Stent Restenosis, and Zero Contrast/Fluoroscopy in CKD Patients

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Disclosure

Speaker name:
Dr. Tom Davis

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
New Evidence Review

- OCT Guided Atherectomy 12 month patency outcomes
- Interim VISION 24 month outcomes data
- ISR Therapy
- Radiation and Contrast Sparing
- OCT Guided Learnings
OCT Guided Directional Atherectomy Case Series (n=30 patients; 35 lesions)

Graz, Austria
Case Series Breakdown

TOTAL COHORT
- Patients treated n=30 (35 lesions)
- Treated dates July – December 2015
- Average lesion length 103 mm (20-300mm)

CTO COHORT
- Patients/lesions treated n=19/21 (63% total patient cohort)
- OCT guided CTO crossing (Ocelot) standalone success (n=20/21 true lumen): 95.2%
- Average CTO lesion length 110mm (40-300mm)
6 vs. 12 Month Outcomes
Duplex PSVR, ABI, TLR

Freedom from TLR
- 6 month (n=35 lesions): 94.3%
- 12 month (n=33 lesions): 88%

Primary Patency (PSVR<2.4)
- 6 month (n=35 lesions): 89%
- 12 month (n=33 lesions): 86%
Non-CTO vs. CTO @ 12 Months
TLR, Duplex PSVR

Freedom from TLR

<table>
<thead>
<tr>
<th></th>
<th>Non-CTO (n=14 lesions)</th>
<th>CTO (n=21 lesions)</th>
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<tbody>
<tr>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25%</td>
<td></td>
<td></td>
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<tr>
<td>50%</td>
<td></td>
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<tr>
<td>75%</td>
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<tr>
<td>100%</td>
<td>93%</td>
<td>86%</td>
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Primary Patency (PSVR<2.4)

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<tr>
<td>75%</td>
<td></td>
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</tr>
<tr>
<td>100%</td>
<td>93%</td>
<td>81%</td>
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</table>

Average Non-CTO lesion length = 72mm
Average CTO lesions length = 110mm
24 Month Outcomes
Interim Analysis (n=55 patients)
24 Month Outcomes
Freedom from Target Lesion Revascularization (TLR)

Survival Probability (%)

TLR rate low + relatively flat from 12 --> 24 months

At Risk Population
- n=193
- n=120
- n=56
- n=51
- n=44

Time (months)
24 Month Outcomes
Freedom from TLR + Amputation by Subject

0% Amputation Rate through 24 months
24 Month Outcomes
Rutherford Classification

Baseline

<table>
<thead>
<tr>
<th>Rutherford Classification</th>
<th>Baseline</th>
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<tbody>
<tr>
<td>0</td>
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</tr>
<tr>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>2</td>
<td>29.1%</td>
</tr>
<tr>
<td>3</td>
<td>54.4%</td>
</tr>
<tr>
<td>4</td>
<td>13.9%</td>
</tr>
<tr>
<td>5</td>
<td>2.5%</td>
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24 Months

<table>
<thead>
<tr>
<th>Rutherford Classification</th>
<th>24 Months</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>1</td>
<td>18.8%</td>
</tr>
<tr>
<td>2</td>
<td>10.4%</td>
</tr>
<tr>
<td>3</td>
<td>8.3%</td>
</tr>
<tr>
<td>4</td>
<td>8.3%</td>
</tr>
<tr>
<td>5</td>
<td>0%</td>
</tr>
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P=0.001
### Learning Curve

**Outcomes by Physician Case Experience**

#### %Adventitia by Area (Atherectomy specimen)

<table>
<thead>
<tr>
<th>Category</th>
<th>Value (%)</th>
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<tbody>
<tr>
<td>≤ 2 (N=62)</td>
<td>1.4%</td>
</tr>
<tr>
<td>&lt; 5 (N=125)</td>
<td>1.1%</td>
</tr>
<tr>
<td>&gt; 5 (N=62)</td>
<td>0.6%</td>
</tr>
<tr>
<td>&gt; 10 (N=17)</td>
<td>0.09%</td>
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</tbody>
</table>

- p = 0.2397

#### TLR rate @ 6 Months (%(m/N))

<table>
<thead>
<tr>
<th>Category</th>
<th>Value (%)</th>
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<tbody>
<tr>
<td>≤ 2 (N=4/58)</td>
<td>6.9%</td>
</tr>
<tr>
<td>&lt; 5 (N=10/120)</td>
<td>8.3%</td>
</tr>
<tr>
<td>&gt; 5 (N=2/68)</td>
<td>2.9%</td>
</tr>
<tr>
<td>&gt; 10 (N=0/17)</td>
<td>0%</td>
</tr>
</tbody>
</table>

- p = 0.2164

#### TLR rate @ 24 Months (%(m/N))

<table>
<thead>
<tr>
<th>Category</th>
<th>Value (%)</th>
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</thead>
<tbody>
<tr>
<td>≤ 2 (N=3/23)</td>
<td>13.0%</td>
</tr>
<tr>
<td>&lt; 5 (N=4/47)</td>
<td>8.5%</td>
</tr>
<tr>
<td>&gt; 5 (N=1/12)</td>
<td>8.3%</td>
</tr>
<tr>
<td>&gt; 10 (N=0/2)</td>
<td>0%</td>
</tr>
</tbody>
</table>

- p = 1.0000

**Physician Cases**

- Small learning curve leads to improved patient outcomes
1) Interim Analysis of VISION Cohort at 24 months

2) TLR rate relatively flat and stable between 12 and 24 months

3) Zero (0%) amputations through 24 months

4) Statistically significant improvements in ABI and Rutherford at 30 days maintained through 24 months

5) >50% standalone atherectomy rate (n=104/198)
   • Low stent rate: 5.1% (n=10/198)
   • Low adjunctive Drug Coated Balloon (DCB) rate: 9.6% (n=19/198)

6) 5 case learning curve leads to reduction in TLR through 24 months
In-Stent Restenosis (ISR)

**Design:** Retrospective case series

**Investigators:** 6 institutions US and Europe

**Patients:** n=21 patients (21 lesions)

**Average Lesion Length:** 171 mm (20 - 450) (n=18)

**Average Stent Length:** 148 mm (70 - 200) (n=14)

**Acute Primary Efficacy:** Post-Pantheris Stenosis < 30% = **100%**

**Acute Primary Safety (Emboli, Dissection, Perforation, Device Related events):** 0%

1: 3 lesion lengths not measured
2: 7 stent lengths not measured
Lesion Characteristics

Lesion Location (N=21)

- SFA: 67%
- Popliteal: 14%
- SFA & Popliteal: 14%
- SFA & Iliac: 5%
Procedural Characteristics

AVERAGE PRE-PANTHERIS / POST PANTHERIS / FINAL STENOSIS (N=21)

Average Percent:
- Pre-Procedure Stenosis: 87%
- Post-Pantheris Stenosis: 13%
- Final Stenosis: 3%
Pantheris In-Stent Restenosis (ISR) Global IDE

Catheter
- 9cm nosecone (3cm longer)
- Extended scaffold
- Shaft length markings
- 360 degree nosecone viewing window
- Reinforced proximal catheter and driveshaft

Trial Design
- US + OUS
- 100 patients
- 30 day, 6 month, 12 month ABI, Rutherford, Duplex

Timeline
- Enroll Q2 2017 OUS + US
Radiation & Contrast Sparing
Ocelot Radiation Reduction

>150mm SFA CTO Peer Reviewed Data

1. Davis, T. Lumivascular approach to crossing chronic total occlusions. JACC. 64:11 Supplement B, pg B157-158
IVUS creates larger radiation burden secondary to independent catheter placement pre/post therapy.
**Summary**

- Between March 2016 and June 2016, 38 lesions using OCT-guidance directional atherectomy were treated with the Pantheris Catheter.
- Results demonstrated a significant 63% reduction in median fluoroscopic exposure across all procedures completed using OCT guidance (p<0.05).

**OCT-guided atherectomy:**

- **71%** reduction in DAP vs. Fluoroscopy
- **41%** reduction in contrast vs. Fluoroscopy

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**Fluoroscopic Exposure (mSv)**

- Median Fluoroscopic Dosage w/ Pantheris: 463.1 mSv
- Median Fluoroscopic Dosage w/ Generic*: 1260 mSv

**DAP (Gy-cm²) and Contrast**

- OCT GUIDED: DAP 211.2 Gy-cm², Contrast 112 mL
- FLUOROSCOPY GUIDED: DAP 187 Gy-cm², Contrast 61.3 mL
OCT Learnings
OCT Guided Treatment Length
Longer than Fluoroscopic-Guided Lesion Length (Per Protocol Cohort)

- All lesions (n=164)
  - OCT Guided: 73.3
  - Fluoroscopy Guided: 53.6

- Stenotic lesions (n=129)*
  - OCT Guided: 64.8
  - Fluoroscopy Guided: 46.3

- CTOs (n=33)*
  - OCT Guided: 107.1

* Baseline percent stenosis unknown in 2 lesion

[Graph showing lesion length comparisons]
Conclusion

1) 12 and 24 month outcomes data demonstrate favorable patency and sustained low TLR rates out to 2 years
2) Acute ISR data demonstrates superior efficacy profile – global IDE pending
3) OCT may be used to eliminate or greatly diminish contrast and radiation across all LE revascularizations
4) OCT guided therapy learning curve approx. 5 cases for improved outcomes
5) OCT highlights longer disease burden vs. angiographic interpretation
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