OCT Guided Atherectomy: Avinger’s Pantheris Device and the VISION Trial Outcomes Correlated With Plaque Histology

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Disclosures
• Avinger - Consultant, Stock Holder

Pantheris Catheter [Avinger, Inc.]
• 8Fr/7Fr
• 130/110 cm working length
• .014 guidewire compatible
• Cutter rotation = 1000rpm
• OCT - frequency

Cutting & Reviewing Troughs

Real Time OCT Video
Plaque = 94.43% Medial Tissue = 5.7% Adventitial Tissue = 0%

**Atherectomy Tissue Gross + Histology**

**Baseline Demographics & Co-morbidities**

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Per Protocol Cohort (n=130 Subjects)</th>
<th>Co-morbidities</th>
<th>Per Protocol Cohort (n=130 Subjects)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>Mean ± 1 std (nc)</td>
<td>Smoking</td>
<td>45.8% (76/169)</td>
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<td></td>
<td>54.4 ± 10.6std (130)</td>
<td>Diabetes</td>
<td>46.7% (67/130)</td>
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<td>Hypertension requiring medication</td>
<td>81.1% (107/130)</td>
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<td></td>
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<td>Coronary artery disease</td>
<td>66.9% (86/130)</td>
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<td></td>
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<td>Other vascular disease</td>
<td>86.6% (113/130)</td>
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1. Site reported data

**OCT-Guided Treatment Length Longer than Fluoroscopic-Guided Lesion Length (per protocol cohort)**

**Pantheria +/- Adjunctive Therapy**

**Major Adverse Events (MAE) Through 6 Months**

<table>
<thead>
<tr>
<th>Event</th>
<th>Per-Protocol Cohort (n=125 patients)</th>
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<tbody>
<tr>
<td>Overall MAE</td>
<td>17.4% (22/129)</td>
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<tr>
<td>Coronary artery related death</td>
<td>3.3% (4/121)</td>
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<td>Unplanned, major, non-target angioplasty</td>
<td>0% (0/121)</td>
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<tr>
<td>Target lesion revascularization (TLR)</td>
<td>4.9% (11/123)</td>
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<td>Myocardial infarction</td>
<td>2.4% (3/125)</td>
</tr>
<tr>
<td>Device related events</td>
<td>6.4% (8/125)</td>
</tr>
</tbody>
</table>

Notes: MAE = major adverse events; TLR = target lesion revascularization; Symptomatic = ischemia or angina; Symptomatic + TLR = ischemia or angina and target lesion revascularization; ST = ST elevation myocardial infarction; NSTEMI = non-ST elevation myocardial infarction.
Don’t Do Blind Endarterectomies

So Why Blind Atherectomy?

1. **Primary Safety = Efficacy Endpoints Successfully Met**
   - 92% Freedom from TLR at 6 months
2. Zero dissections, zero perforations, and zero late aneurysms
3. 1% adventitia (n=144 lesions) confirms precision of OCT guidance
4. OCT guided treatment lengths longer than fluoroscopic measured lesion length (p=0.002)
5. Low rate of bail-out stenting in high grade stenosis (4%) and CTOs (3%)
6. 5-10 case learning curve:
   - Longer lesions treated
   - Reduced adventitial injury
   - Improved freedom from TLR

**Vision**

**Histologic Analysis: 6 Month TLR by Lesion Length & Type (Per Protocol)**

**Histologic Analysis: Non-TLR vs. TLR (Per Protocol Cohort)**

**Pantheris Learning Curve**

**Conclusions**

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