Shockwave Intravascular Lithotripsy System treatment of calcified lesions: Intravascular OCT analysis

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Disclosure

Speaker name: **Andrew Holden**.

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 – **Clinical Investigator**
- I do not have any potential conflict of interest
Intravascular Lithotripsy

- Tissue selective – hard on hard tissues, soft on soft tissues
- Designed to disrupt both intimal and medial calcium
- Aim to normalize vessel wall compliance to facilitate controlled, low pressure dilatation

- Uses a familiar catheter-based technique
- 0.014” guidewire platform
Peripheral IVL System:

Clinical Programs

**DISRUPT PAD I**
- Pre Market
- Single Arm
- N = 35

**DISRUPT PAD II**
- Post Market
- Single Arm
- N = 60

**DISRUPT BTK**
- Post Market
- Single Arm
- N = 20

**DISRUPT PAD III**
- Post Market
- Randomized
- N = 334

Study Completed

Enrolling
DISRUPT PAD Results

% Residual Stenosis = 23.8%
Acute Gain = 3.0 mm

By angiographic core lab

Procedural Safety

<table>
<thead>
<tr>
<th>Dissection</th>
<th>Post-Procedure N=95</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>86.3% (82)</td>
</tr>
<tr>
<td>A</td>
<td>0.0%</td>
</tr>
<tr>
<td>B</td>
<td>7.4% (7)</td>
</tr>
<tr>
<td>C</td>
<td>6.3% (6)</td>
</tr>
<tr>
<td>D</td>
<td>1.1%*</td>
</tr>
</tbody>
</table>

*One Grade D resolved following stent implant
Intravascular Imaging: OCT vs IVUS

**Table 1** Physical characteristics of optical coherence tomography vs. IVUS

<table>
<thead>
<tr>
<th></th>
<th>OCT</th>
<th>IVUSb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy source</td>
<td>Near-infrared light</td>
<td>Ultrasound (20–45 MHz)</td>
</tr>
<tr>
<td>Wave-length, μm</td>
<td>1.3</td>
<td>35–80</td>
</tr>
<tr>
<td>Resolution, μm</td>
<td>15–20 (axial); 20–40 (lateral)</td>
<td>100–200 (axial); 200–300 (lateral)</td>
</tr>
<tr>
<td>Frame rate, frames/s</td>
<td>15–20</td>
<td>30</td>
</tr>
<tr>
<td>Pull-back rate, mm/s</td>
<td>1–3</td>
<td>0.5–1</td>
</tr>
<tr>
<td>Max. scan diameter, mm</td>
<td>7</td>
<td>15</td>
</tr>
<tr>
<td>Tissue penetration, mm</td>
<td>1–2.5</td>
<td>10</td>
</tr>
</tbody>
</table>

Intravascular Imaging by OCT

**Fibrotic plaque:** characterized by high signal (reflectivity) and low attenuation (deep penetration)

**Calcified plaque:** sharp borders, low signal (reflectivity) and low attenuation (deep penetration)

**Lipid rich plaque:** characterized by diffuse border, high signal (reflectivity) and high attenuation (poor penetration)

OCT Protocol & Analysis

OCT Protocol
• OCT imaging pre treatment and post treatment
• St Jude Medical LightLab C7-XR with Optis Mobile Co-registration
• Angiographic co-registration to identify treated segment
• Pull back speed: 20 mm / sec
• Length/pull back 70mm
• Scan frame rate: 15 frames / sec

Analysis Protocol
• Entire treatment segment analyzed
• Analysis frame thickness : 2mm
• Lumen area, calcium angle and calcium thickness analysis
• Mean calcium angle normalized to treatment length
### DISRUPT PAD: OCT Sub-Study

<table>
<thead>
<tr>
<th>Calcification Findings by OCT&lt;sup&gt;†&lt;/sup&gt;</th>
<th>5 subjects, 10 lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium length (mm)</td>
<td>Mean: 77.5, SD: 23.5</td>
</tr>
<tr>
<td>Calcium length (mm): Ca &gt;1.0mm</td>
<td>Mean: 55.5, SD: 15</td>
</tr>
<tr>
<td>Pre-procedure maximum calcium angle (°)</td>
<td>Mean: 204.2, SD: 71.1</td>
</tr>
<tr>
<td>Pre-procedure lumen area (mm²)</td>
<td>Mean: 13.6, SD: 4.1</td>
</tr>
</tbody>
</table>

Calcium seen at 3 depth levels - < 0.5mm, 0.5-1.0mm and > 1.0mm suggesting both intimal and medial calcification were modified

<sup>†</sup>Core Lab Adjudicated (Cardiovascular Research Foundation)
OCT Sub-study Results†

High acute gain across all levels of calcium thickness

**Min. Lumen Area**
- Pre = 3.9 mm$^2$
- Post = 12.8 mm$^2$

**Acute Gain**
- Acute Gain = 8.7 mm$^2$

†Core Lab Adjudicated
Shockwave Peripheral Intravascular Lithoplasty: Specific Changes Seen on OCT

1. Both intimal and medial calcification was seen

Calcium intimal thickness <0.5 mm  
Medial Calcium
Shockwave Peripheral Intravascular Lithoplasty: Specific Changes Seen on OCT

1. Both intimal and medial calcification was seen
2. Micro-fractures were visible—characterized by being shallow and non-angulated
3. Micro-fractures were most commonly seen in areas where calcium was >1.0 mm thick
1. Both intimal and medial calcification was seen
2. Micro-fractures were visible—characterized by being shallow and non-angulated
3. Micro-fractures were most commonly seen in areas where calcium was >1.0 mm thick
4. Micro-dissections – minimal length and flap angle, with no compromise in lumen

**Shockwave Peripheral Intravascular Lithoplasty: Specific Changes Seen on OCT**

**Results**

<table>
<thead>
<tr>
<th></th>
<th>Final (5 subjects, 10 lesions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micro-dissections (OCT)</td>
<td>8</td>
</tr>
<tr>
<td>Max angle of flap</td>
<td>56±33°</td>
</tr>
<tr>
<td>Length (mm)</td>
<td>10.0±8.2</td>
</tr>
</tbody>
</table>
Micro-dissections after Lithoplasty had no impact on the IEL as is often seen with conventional angioplasty.
5. As well as micro-fractures and micro-dissections, changes in the signal (reflectivity) and attenuation were seen post-lithoplasty.

Supports the concept of changing vessel compliance along the treated segment.
Shockwave Peripheral Intravascular Lithoplasty: Specific Changes Seen on OCT

Subject AUC-001 – Intimal calcification case
Shockwave Peripheral Intravascular Lithoplasty: Specific Changes Seen on OCT

Subject AUC-002 – Medial calcification case
Case Example

Pre-procedure:
- 69% Stenosis
- 91mm length

Calcification:
- Severe calcium

IVL Balloon:
- 6.0mm IVL balloon

Final:
- 28% Stenosis
- Acute gain 2.5mm
Case Example

Pre-procedure

Pre-procedural OCT
Case Example

Final Post-procedural OCT
OCT Analysis: Peripheral & Coronary IVL

<table>
<thead>
<tr>
<th></th>
<th>Coronary</th>
<th>Peripheral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium present in both intimal and medial Layers</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Micro-fractures present, regardless of thickness</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Change in reflection signal &amp; attenuation post-IVL</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

OCT demonstrated calcium disruption leading to acute luminal gain and alteration in vessel compliance in both SFA and coronary arteries.

Conclusions

• Excellent luminal gain with IVL, including > 1 mm calcium thickness
• Luminal gain primarily by controlled micro-fractures and micro-dissections
• Uncontrolled dissections and disruption of IEL and EEL was not seen
• Controlled disruption of calcium unlike angioplasty, where spiral dissections may require bail out stenting
• Signal and attenuation changes suggest a diffuse change to vessel compliance
• May allow for better drug uptake in conjunction with DCB treatment
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