**Tibial Interventions**

Atherectomy is a necessity?!

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**Disclosure Statement of Financial Interest**

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

### Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

**Company**

- iDev, Covidien, TriReme
- Covidien, Boston Scientific, Angiosculpt, Pathway(MedRad)
- Arsenal, Primera, TransGen, CV Ingenuity, Spero, Sorensen Cardiovascular
- None
- None
- None
- None
- None

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**Clinical Limitations & Unmet Needs**

**Calcium as a Barrier**

- Longer lesion length is an independent predictor of decreased patency

**Calcium May Limit Drug Effect**

- Calcium is a marker for amputation and poor wound healing

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**Tibial calcification**

- Association with PAD and abnormal ABI independent of serum calcium, other biochemical levels (CRP etc)
- Association with renal failure and independent to age, gender, diabetes and tobacco

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**Arterial compliance**

- Several studies (registries, non-CL adjudicated) have suggested a debulk first strategy assists with arterial compliance and lower balloon pressures for dilation (Compliance 360, Calcium 360)
LIBERTY Device Usage by Lesion

LIBERTY Freedom from Major Adverse Events (MAEs)

Atherectomy devices

- Pantheris (Avinger) above knee trial
- Phoenix (Volcano) above and BTK data registry
- Anecdotal BTK data

DISRUPT BTK Study: Infrapopliteal Disease

Objective: To study the safety and performance of the Shockwave Medical Intravascular Lithotripsy System in the treatment of infrapopliteal stenotic and occluded infrapopliteal peripheral arteries.

Endpoints

- Procedural
  - Primary Effectiveness: Acute reduction in % diameter stenosis

Follow-up: 30 days

Major adverse events (Death, MI, TLR, amputation)

DISRUPT BTK: Patient Demographics and Angiographic Findings†

DISRUPT BTK: Safety & Effectiveness†

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Device Usage</th>
<th>No Device Usage</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedural</td>
<td>95.7% (178)</td>
<td>93.2% (162)</td>
<td>0.54 (NS)</td>
</tr>
<tr>
<td>Major adverse events</td>
<td>7.6% (15)</td>
<td>11.4% (19)</td>
<td>0.45 (NS)</td>
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</tbody>
</table>

† Core lab adjudicated

LIBERTY data based on European studies.
Conclusions

• Arterial compliance is an issue for many if not all endovascular procedures
• Many devices available to alter vessel compliance
• Arterial outcomes appear (registry data) improved (primary patency, MALE) with upfront atherectomy for tibial circulation
• No data to date to suggest atherectomy improves amputation free survival
• Other devices on the horizon may afford similar outcomes
  – Costs remain a question
• More data clearly needed on these cost consuming strategies
• DCB data mixed and moderately positive at 6 months