Lithoplasty: A solution for calcified lesions?

Marianne Brodmann
Angiology, Medical University Graz, Austria
Disclosure

Speaker name:

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
Problem: Rigid fibrotic, calcified tissue

Today’s endovascular therapies fail

Current Cycle of Therapy
Introduction: Lithoplasty®

Lesion modification using localized lithotripsy in a balloon

Tissue-selective:
- Hard on hard tissue, Soft on soft tissue
- Lithotripsy waves travel outside balloon
- Designed to disrupt both superficial, deep calcium

- Designed to normalize vessel wall compliance prior to controlled, low pressure dilatation
- Effective lesion expansion with minimized impact to healthy tissue
- Familiar Balloon-based endovascular technique
- “Front-line” balloon strategy (.014”compatible)
Shockwave Medical Lithoplasty System

Generator

Connector Cable

Catheter
**Shockwave Medical Lithoplasty Balloon**

- **Lithotripsy delivery**: 4 atm
- **Nominal pressure**: 6 atm
- **Rated Burst Pressure**: 10 atm

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5 mm</td>
<td>60 mm</td>
</tr>
<tr>
<td>4.0 mm</td>
<td>60 mm</td>
</tr>
<tr>
<td>4.5 mm</td>
<td>60 mm</td>
</tr>
<tr>
<td>5.0 mm</td>
<td>60 mm</td>
</tr>
<tr>
<td>5.5 mm</td>
<td>60 mm</td>
</tr>
<tr>
<td>6.0 mm</td>
<td>60 mm</td>
</tr>
<tr>
<td>6.5 mm</td>
<td>60 mm</td>
</tr>
<tr>
<td>7.0 mm</td>
<td>60 mm</td>
</tr>
</tbody>
</table>

- **Guidewire Compatible**: 0.014”
- **Working Length**: 110 cm
- **Sheath compatibility**: 6F / 7F
Objective: To study the safety and effectiveness of the Shockwave Medical Lithoplasty® System in the treatment of calcified, stenotic infrainguinal peripheral arteries.

- Two-phase, prospective, non-randomized, multi-center study
- Monitoring with 100% source document verification
- Independent angiographic and duplex ultrasound core labs
- Independent clinical events committee

DISRUPT PAD I
35 subjects, 3 sites
Jan 2014 – Sep 2014

DISRUPT PAD II
60 subjects, 8 sites
Jun 2015 – Dec 2015
DISRUPT PAD Study Design

Key Eligibility Criteria
- Intermittent claudication: Rutherford Classification 2–4
- Ankle-brachial index ≤0.9
- SFA/Popliteal lesions ≥70% stenosis
- RVD 3.5–7.0 mm, ≤150 mm length
- Moderate and severe calcification by angiography

Study Device
- Shockwave Medical Peripheral Lithoplasty Catheter
- Diameters: 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 mm
- Length: 60 mm
DISRUPT PAD Acute Effectiveness

By angiographic core lab

% Stenosis

Pre-Proc  |  Post-Proc
---|---
% Residual Stenosis = 23.8%

Acute Gain

Acute Gain = 3.0 mm

Minimal Adjunctive Therapy

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>N=95</td>
<td></td>
</tr>
<tr>
<td>Pre-dilatation</td>
<td>11.6% (11)</td>
</tr>
<tr>
<td>Post-dilatation</td>
<td>7.4% (7)</td>
</tr>
<tr>
<td>Provisional stenting</td>
<td>1.1% (1)</td>
</tr>
</tbody>
</table>
### Case Study

<table>
<thead>
<tr>
<th>Pre-procedure</th>
<th>Calcification</th>
<th>Lithoplasty</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTO &amp; Subtotal Occlusion 21cm length</td>
<td>Severe Calcium</td>
<td>4.5mm &amp; 5.5mm Lithoplasty Balloons</td>
<td>&lt;30% Stenosis</td>
</tr>
</tbody>
</table>

(( Case courtesy of: Dr Marianne Brodmann ))
Case Study

Pre-procedure
95% Stenosis
57mm length

Calcification
Moderate Calcium

Lithoplasty Balloon
5.0mm Lithoplasty balloon

Final
24% stenosis
Acute gain 4.1 mm

(( Case courtesy of: Dr Marianne Brodmann ))
Case Study

Pre-procedure: 74% Stenosis, 90.7mm length
Calcification: Severe Calcium
Lithoplasty: 6.0mm Lithoplasty Balloon
Final: 22% Stenosis Acute gain 3.4 mm
18 Mo Follow Up: ABI - 0.9; 2.0 m/s DUS RC 0.
Conclusions

- DISRUPT PAD enrolled a patient population with moderate / severe calcification not frequently studied using other devices
- Limited use of adjunctive balloons with 1% provisional stent use
- Low rate of vascular complications, including no perforations, thrombosis or distal embolization events
- Consistent and repeatable effectiveness outcomes including low residual stenosis and high acute gain
- Sustained patency and TLR results through 6 months
- Familiar balloon-based technology that preserves future treatment options
Lithoplasty: A solution for calcified lesions?

Marianne Brodmann
Angiology, Medical University Graz, Austria