Lithoplasty for Treatment of Calcified Vascular Lesions

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Disclosure

Speaker name: Todd Brinton

I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [x] Stockholder of a healthcare company
- [x] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
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 Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

Company

- None
- Shockwave Medical, Inc., Kona Medical, Inc, Infogard Labs, Inc, Intersection Medical, inc. Qool Therapeutics
- Kona Medical, Inc, Infogard Labs, Qool Therapeutics, ELS
- None
- Shockwave Medical, Inc, BioParadox, Inc
- None
- None
Calcium
The enemy of the Interventionalist!
Problem: Rigid fibrotic, calcified tissue
Today’s endovascular therapies fail

Current Cycle of Therapy
Insight: Lithotripsy™

- Acoustic pulse waves preferentially impact hard tissue, disrupt calcium, leave soft tissue undisturbed

- Dose dependent result

- 25 years of safety data in kidney stone treatment

Dispersive Lithotripsy
Not focused Lithotripsy
Lithoplasty®

Lesion modification pre-dilation using lithotripsy in a balloon

- 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)

Tissue-selective: Hard on hard tissue, Soft on soft tissue

Lithotripsy waves travel outside balloon

Designed to disrupt both superficial, deep calcium

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Active Lithoplasty™
Shockwave Medical Case Study

Tandem Calcified Sub-total Popliteal Occlusions

Pre

Sub-Total Popliteal Occlusion

Calcification

4.5 x 60mm balloon

Lithoplasty Balloon

210 mm Lesion Length

Final

Patent artery post proximal/distal treatment

Case performed by:
Professor Marianne Brodmann
January 2016
LKH Klinikum Graz
Conclusions

• Lithoplasty™ is a novel technology for treatment of calcified vascular lesions.
• Early clinical experience demonstrates safety, tolerability, deliverability, and effectiveness for treatment of calcified SFA/popliteal lesions.
• A multi-center study DISRUPT PAD 1 was completed leading to a CE mark approval
  • Acute Results: Residual 23% w/o need for stents
  • 6-Month Patency: DUS 83% TLR 0%
• The DISRUPT PAD 2 multi-center study completed enrollment.
  • 6 & 12 Month Patency: In follow up
• Ongoing Registry Studies: Calcified Common Femoral and BTK Lesions
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