Shockwave Intravascular Lithotripsy in Calcified Tibial Artery Lesions: How Well Does It Work?

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Relevant Disclosures

• Dr Holden is a Clinical Investigator and Medical Advisory Board Member for Shockwave Medical
• No other relevant disclosures

Calcified Tibial Arteries – Some FACTS

• Arterial calcification is very common in tibial arteries and associated with advanced age, diabetes, chronic renal insufficiency and critical limb ischemia (CLI)\textsuperscript{1}
• The severity of tibial calcification is predictive of ischemia severity, wound healing rate\textsuperscript{2}, amputation risk\textsuperscript{3} and mortality

Calcified Tibial Arteries – Some FACTS

• Arterial calcification may occur in the intima or media
• Medial calcification is particularly common in tibial arteries\textsuperscript{1}
• Medial calcification increases arterial stiffness and drives poor outcomes\textsuperscript{2,3,4}
• Most vessel preparation devices (eg atherectomy, scoring balloons) do not modify medial calcification

Calcified Tibial Arteries – Some FACTS

• Most tibial arteries undergo considerable elastic recoil after angioplasty\textsuperscript{1}
• Medial calcification is associated with more severe elastic recoil and restenosis\textsuperscript{2,3,4}

Calcified Tibial Arteries – Some FACTS

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Intravascular Lithotripsy (IVL): Localized Lithotripsy to Treat Cardiovascular Calcium

Inspired by urological applications, but designed for cardiovascular system
Cardiovascular Lithotripsy

Peripheral IVL Catheters

Sonic Pressure Waves
preferentially impact hard tissue,
disrupt calcium, leave soft tissue undisturbed

Localized Lithotripsy: 30 years of safety data
in kidney stone treatment

Optimized for the Treatment of Cardiovascular Calcium

Peripheral IVL Catheters
Shockwave IVL System Components

**IVL Generator**
- COMPACT & RECHARGABLE
- PORTABLE, IV-Pole Mountable
- BATTERY-POWERED
- NO EXTERNAL CONNECTIONS

**IVL Connector**
- CABLE
- SIMPLE & QUICK
- SMART MAGNETIC CONNECTION
- PUSH-BUTTON ACTIVATED

**IVL Catheter**
- INTUITIVE & SAFE
- OTW SYSTEM
- ANY .014" GUIDEWIRE
- STANDARD PTA TECHNIQUE
- 180 LITHOTRIPSY PULSES
- INTEGRATED PTA BALLOON
- LITHOTRIPSY EMISSORS
- SONIC PRESSURE WAVES CRACK CALCIUM INSIDE ARTERY WALL

After inflating the integrated balloon to 4 atm, the generator produces 1 energy pulse each second, that travels through the connecting cable and catheter to the emitters. A small spark at the emitters vaporizes the saline-contrast solution and creates a bubble which rapidly expands and collapses within the balloon, creating a short burst of sonic pressure waves.

The catheter can then be used to dilate the lesion to maximize lumen gain.

**Case Example**

**OCT Analysis**
- Confirms microfractures and micro-dissection to achieve luminal gain
- Also see changes in signal (reflectivity) indicating compliance change in the vessel wall

**Peripheral IVL System: Clinical Programs**

### DISRUPT PAD I
- Post Market
- Single Arm
- N = 35
- 2014

### DISRUPT PAD II
- Post Market
- Single Arm
- N = 60
- 2015

### DISRUPT BTK
- Post Market
- Single Arm
- N = 20
- 2017

### DISRUPT PAD III
- Observational Registry
- Single Arm
- N = 500
- 2017

Study Completed
- Enrolling
DISRUPT BTK Study: Infrapopliteal Disease

**Objective:** To study the safety and performance of the Shockwave Medical Peripheral Intravascular Lithotomy System in the treatment of calcified, stenotic infrapopliteal peripheral arteries

**Design**

- **Key eligibility criteria**
  - Rutherford category 1-5 infrapopliteal disease
  - Infrapopliteal lesions ≥50% stenosis
  - RVD 2.5–3.5 mm, ≤150 mm length
  - Moderate and severe calcification by angiography

- **Endpoints**
  - **Procedural**
    - **Primary Effectiveness:** Acute reduction in % diameter stenosis
    - **Follow up:** 30 days
  - **Major adverse events (Death, MI, TLR, amputation)**

**Objective:** To study the safety and performance of the Shockwave Medical Peripheral Intravascular Lithotomy System in the treatment of calcified, stenotic infrapopliteal peripheral arteries

DISRUPT BTK Study: Patient Demographics and Angiographic Findings

**Baseline Characteristics N = 20**

- **Age, years, mean ± SD** 79±9.6
- **Male Gender, % (n)** 70.0% (14)
- **Diabetes, % (n)** 40.0% (8)
- **Hypertension, % (n)** 95.0% (19)
- **Hyperlipidemia, % (n)** 75.0% (15)
- **Renal Insufficiency, % (n)** 40.0% (8)
- **Coronary Artery Disease, % (n)** 40.0% (8)
- **Current or Former Smoker, % (n)** 25.0% (5)
- **Rutherford Class, % (n)**
  - RC 3 20.0% (4)
  - RC 4 5.0% (1)
  - RC 5 75.0% (15)

**Pre-procedure N=21 lesions, 19 subjects**

- **Tibio-peroneal trunk** 9.5% (2)
- **Anterior tibial** 38.1% (8)
- **Posterior tibial** 38.1% (8)
- **Peroneal** 9.5% (2)
- **Popliteal artery below knee** 4.8% (1)

- **Reference vessel diameter, mm, mean ± SD (range)** 3.2 ± 0.6 (2.4-4.8)
- **Lesion length, mm, mean ± SD (range)** 52.2 ± 35.8 (13.8-144.0)
- **Calcified length, mm, mean ± SD (range)** 72.1 ± 37.6 (12.4-172.6)
- **Calcification, % (n)**
  - Moderate 52.4% (11)
  - Severe 47.6% (9)

**Mean luminal diameter, mm, mean ± SD (range)**

- 0.9 ± 0.6 (0.0-1.9)

**Diameter stenosis, % 72.6%**

**Follow-Up 30 Days**

- **100% freedom from TLR**
- **No MAE (death, amputation, MI)**

DISRUPT BTK Study: Safety and Effectiveness

- **Dissections 0 Grade D or greater**
- **Embolization No embolic events**
- **Perforations, thrombosis, abrupt closure No complications**

- **Residual stenosis 26.2%**
- **Acute gain 1.5%**

**Safety and Effectiveness Study Completed**

DISRUPT BTK Study: Case Example

**Peripheral IVL System: Clinical Programs**

**DISRUPT PAD I**
- Pre Market
- N = 35
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**DISRUPT PAD II**
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- Single Arm
- N = 60
- 2015

**DISRUPT BTK**
- Post Market
- Single Arm
- N = 20
- 2017

**DISRUPT PAD III**
- Post Market
- Randomized
- N = 400
- 2017

**Observational Registry**
- Post Market
- Single Arm
- N = 500
- 2017

**Study Completed**

**Enrolling**

**Registry BTK Case – Left Heel Ulcer (Rutherford 5)**

**Case Courtesy of Prof. Andrew Holden**
**Shockwave IVL in Tibial Arteries: Summary**

- IVL is designed to treat both intimal and medial calcium allowing vessel expansion with minimal angiographic complications
- Acute results in the DISRUPT BTK Study show low residual stenosis with minimal vascular complications including no perforations, distal embolization, no reflow or abrupt closure
- 30 day safety results report no MAE including revascularization or amputation.
- Dedicated S4 BTK catheter available
- Ongoing experience is being gained in a real world registry