Shockwave Intravascular Lithotripsy in BTK Arteries:

Novel Technology Overview and Data Updates

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Presented on behalf of the DISRUPT PAD BTK II and FORWARD IDE/Feasibility Investigators.

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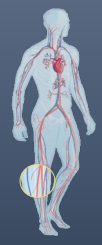
Disclosures

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship	Company
Medical Advisory Board Member	Medtronic, Gore, Philips, Boston Scientific
Clinical Investigator	Bard-BD, Boston Scientific, Cagent Medical, Cook Medical, Efemoral, Endologix, Endospan, Gore Medical, Intact Vascular, Medtronic, Nectero, Philips, Reflow Medical, Shape Memory, Shockwave Medical, Terumo

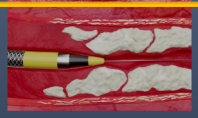
Treatment of Calcified BTK Lesions



- Increasing prevalence of CLTI and associated BTK disease[1]
- BTK disease can be challenging to treat with current technology
  - Small vessels
  - Long and diffuse lesions
  - Superficial and deep calcification[2,3]
- Intravascular Lithotripsy (IVL) modifies superficial and deep calcium and demonstrated favorable safety and efficacy in heavily-calcified infrapopliteal stenoses[4,5]

[1]Ferraresi, et al. J Cardiovasc Surg 2018 Oct;59(5):655-664. [2]Li et al. J Am Coll Cardiol Intv. 2024 Mar, 17 (5) 589–607. [3]Kim et al. Front Cardiovasc Med. 2023 Jan 26;10:1093355. [4]Adams et al. J Endovasc Ther 2022;29:76-83. [5]Brodmann et al. J Endovasc Ther. 2018 Aug;25(4):499-503.

New IVL Catheters for Patient Specific Treatment

	IVL Action (Animations NOT to Scale)	Treatment Steps
E8 (Balloon-based IVL)		1. Deliver catheter and inflate balloon to low pressure 2. Sonic pressure waves generated from IVL emitters in balloon modify calcium 3. Expand vessel
Javelin (Non-balloon- based IVL)		1. Deliver catheter 2. Sonic pressure waves generated at distally positioned IVL emitter 3. Modify calcium and advance across lesion 4. Post dilatation

E8 Catheter Design

80mm enhanced polymer balloon for improved durability, performance and longer treatment zone

Improved tip construction with lower durometer material and smoother entry profile

150cm catheter length for difficult-to-reach lesions

2Hz pulse rate for faster treatment times

Key Features:

- 150 cm / 5F & 6F sheath compatible
- 2.5-6.0mm balloon diameters
- 400 Pulses total (10 cycles at 40 pulses/cycle)
- 45cm Hydrophilic Coated length (compared to 15cm on S4 and no coating on M5+)
- Compatible with existing Shockwave generators

DISRUPT BTK II Study

Prospective, multi-center, single-arm study of the Shockwave Medical Peripheral IVL System (M5+ and S4) for the treatment of calcified BTK lesions

Key Baseline Characteristics (250 patients, 305 lesions)	
Age (Years)	71.6 ± 11.0
Sex (Male)	72.8% (182/250)
Wounds at Baseline	45.6% (114/250)
Hemodialysis dependent	15.2% (38/250)
Rutherford Category 4/5 (CLTI)	80.1% (201/251)
Severe Calcification (by PARC)	68.2% (206/302)
Chronic Total Occlusion	29.5% (89/302)

Key Site Reported Procedural Results (250 patients, 305 lesions)	
Pre-Dilatation	34.6% (109/315)
Successful delivery across target lesion	97.5% (307/315)
Post-Dilatation	34.8% (106/305)
Adjunctive Stent Use[1]	4.9% (15/306)

[1]Of the 15 Stent/Tack cases, 7 were placed according to protocol-driven criteria (Residual stenosis ≥ 50% by visual estimate, or unresolved flow-limiting (≥ Grade D) dissection, or if trans-lesional gradient >10mm Hg was observed) and 8 were placed due to physician preference.

DISRUPT BTK II Study

Primary Endpoints and Stenosis Reduction

Primary Effectiveness Endpoint	Final RS of ≤50% without serious angiographic complications	**97.9%** (232/237, 95% CI 95.1%-99.3%)
Primary Safety Endpoint	MALE or POD at 30 days	**0.8%** (2/242, 95% CI 0.1% - 3.0%)
Secondary Endpoint	Final RS of ≤30% without serious angiographic complications	**74.1%** (215/290, 95% CI 68.7%-79.1%)

MALE defined as a composite of all-cause death, above-ankle amputation of the index limb, and/or major reintervention to the index limb involving a BTK artery. Two amputations events were reported as not related to the study device or procedure and the decisions to amputate were made on clinical grounds by the treating physician.

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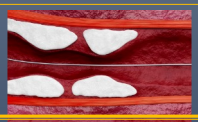
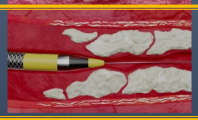
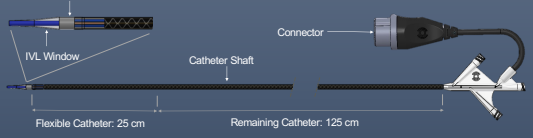
E8 (Balloon-based IVL)		1. Deliver catheter and inflate balloon to low pressure 2. Sonic pressure waves generated from IVL emitters in balloon modify calcium 3. Expand vessel
Javelin (Non-balloon- based IVL)		1. Deliver catheter 2. Sonic pressure waves generated at distally positioned IVL emitter 3. Modify calcium and advance across lesion 4. Post dilatation

Javelin Peripheral IVL Catheter

Single IVL emitter positioned distally



Key Features:

- 150 cm / 5F / 0.014" OTW System
- 1.5 mm Crossing Profile
- 50 cm Hydrophilic Coated
- 120 Pulses total (12 cycles at 10 pulses/cycle)
- Compatible with existing Shockwave generators
- Non-balloon-based catheter

FORWARD PAD IDE and Feasibility Studies

Pre-market, prospective, multi-center, single-arm studies of the Shockwave Medical Javelin Peripheral IVL catheter to treat heavily calcified, stenotic peripheral arteries

Key Baseline Characteristics (90 patients, 103 lesions)

Age (Years)	74.5 ± 9.3
Sex (Male)	74.4% (67/90)
BTK Lesion[1]	42.7% (44/103)
Renal Insufficiency	18.9% (17/90)
Rutherford Category 4/5 (CLTI)	53.3% (48/90)
Severe Calcification (by PARC)	82.5% (85/103)
Chronic Total Occlusion	38.0% (38/100)

Key Site Reported Procedural Results (90 patients, 103 lesions)

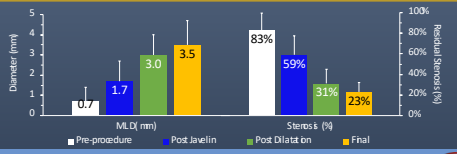
Pre-Dilatation	2.9% (3/105)
Device Success[2]	93.0% (107/115)
Post-Dilatation (mandated by protocol)	98.1% (102/104)
No balloon-based IVL after Javelin	74.3% (78/105)
Drug-Coated Balloon used	40.0% (42/105)
Adjunctive Stent Use	22.9% (24/105)

[1]BTK Lesion is derived from the proximal target lesion location which include Tibio-Peroneal Trunk, Anterior Tibial Artery, Peroneal Artery, Posterior Tibial Artery, Popliteal Artery (Below the Knee). [2]Defined as the ability to deliver, advance across the target lesion, pressurize, pulse, flush and retrieve the Javelin catheter

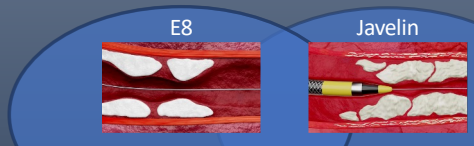
FORWARD PAD IDE and Feasibility Studies

Primary Effectiveness and Safety Endpoints Achieved

Primary Effectiveness Endpoint	Final RS of ≤50% without flow-limiting dissection	**99.0%** (PG 85%; 95%CI: 94.4%-100%, p<0.0001)
Primary Safety Endpoint	MAE at 30 days	**1.1%** (PG 11.2%; 95%CI: 0.0%-6.0%, p=0.0012)
Secondary Endpoint	Final RS of ≤30% without flow-limiting dissection	**78.6%** (95%CI: 69.1%-86.2%)

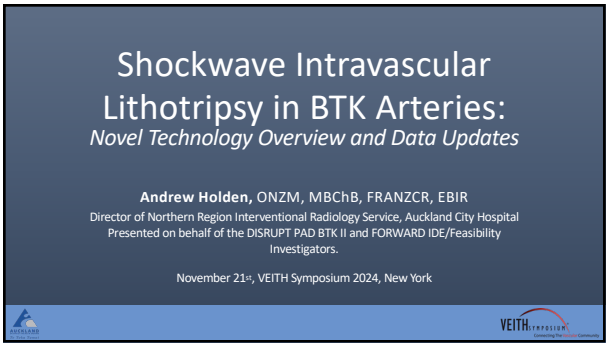


Which Device to Use in Calcified BTK Lesions?



Further experience with E8 and Javelin catheters will guide algorithm for IVL device selection in heavily calcified lesions

Animations not to scale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