DISRUPT PAD III

WE TOOK A CRACK AT SUPERIORITY

The First Level 1 Evidence in Calcified PAD

PAD III By The Numbers

306
SFA/Popliteal lesions randomized to IVL or PTA

83%
Severe calcification by PARC by an independent core-lab*

129mm
Average calcified length by an independent core-lab*

*Data refer to IVL arm of randomized study

↓79%
Reduction in Grade D Dissection with IVL versus PTA

↓44%
Lower pressure to achieve better results with IVL versus PTA

↓75%
Reduction in provisional stent placement risk with IVL versus PTA

↓69%
Reduction in need for post-dilatation versus PTA

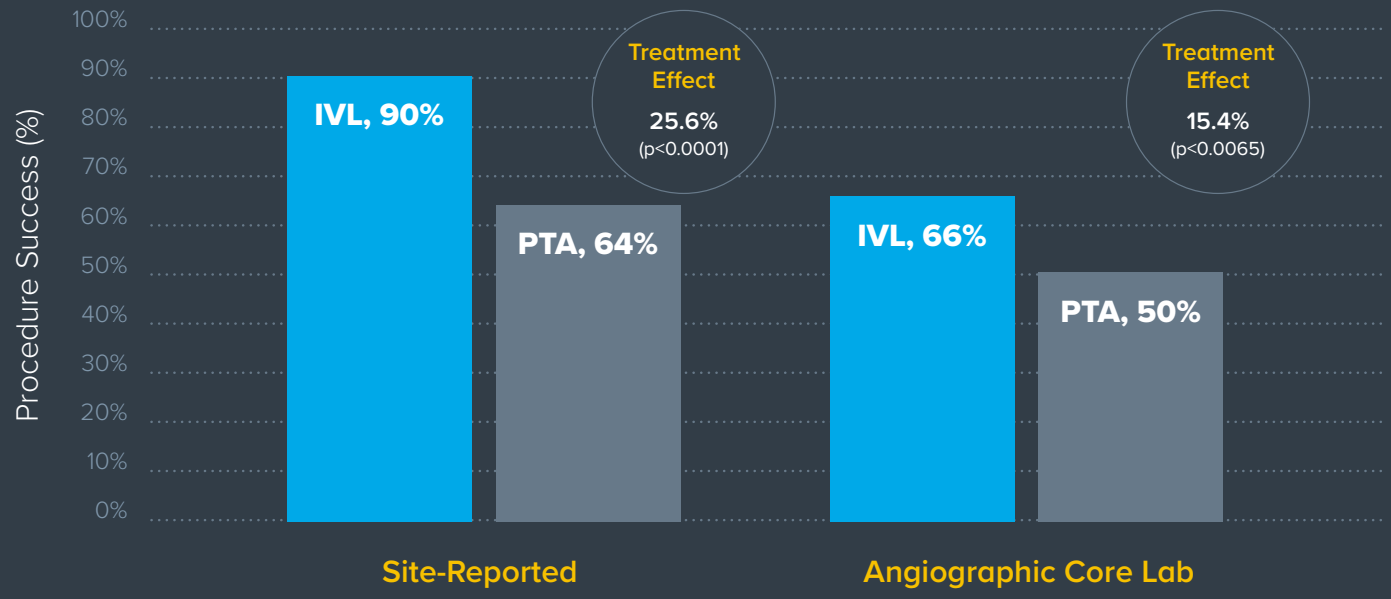
Key Findings

- In the largest-ever randomized clinical trial of severely calcified peripheral lesions, IVL demonstrates superiority over PTA
- IVL demonstrates a significant reduction in dissections and provisional stenting versus PTA
- IVL achieves superior vessel preparation with lower pressure, fewer stents, less need for post-dilatation and fewer dissections than PTA
- Disrupt PAD randomized data confirm the consistent safety and effectiveness of IVL from previous studies in multiple vessel beds

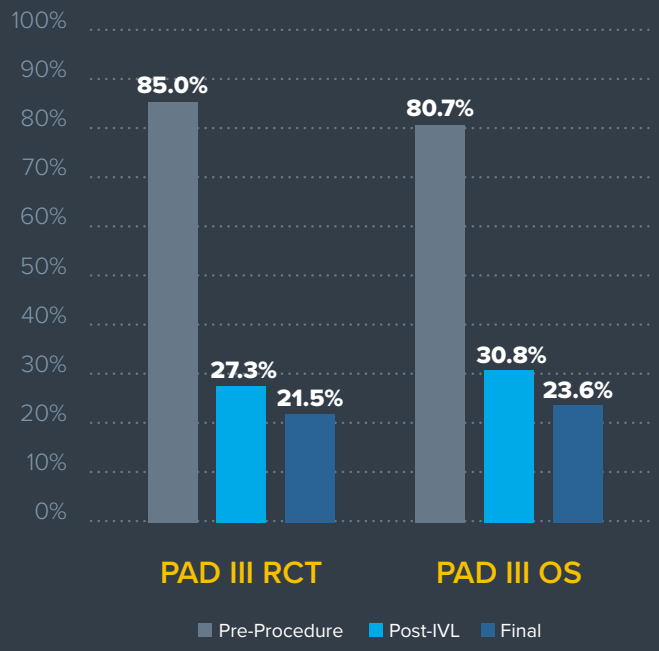
DISRUPT PAD III

Primary Endpoint: Procedure Success

Less than 30% residual stenosis without flow-limiting dissection prior to DCB or stenting by angiographic core lab



Diameter Stenosis



Final Angiographic Outcomes

	Disrupt PAD III	Disrupt PAD III OS
N	153	200
Vessels	SFA/Pop	Iliac, CFA, SFA/Pop, BTK
Moderate-Severe Ca^{++}	99%	97%
Angiographic core lab	Yes	Yes
Distal embolization	0.0%	0.0%
Dissection (Type D-F)	0.0%	1.1%
Perforation	0.0%	0.5%
Abrupt closure	0.0%	0.0%
Slow/No Flow	0.0%	0.0%

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Indication for Use – The Shockwave Medical Intravascular Lithotripsy (IVL) System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.

Contraindications – Do not use if unable to pass 0.014 guidewire across the lesion • Not intended for treatment of in-stent restenosis or in coronary, carotid, or cerebrovascular arteries.

Warnings – Only to be used by physicians who are familiar with interventional vascular procedures • Physicians must be trained prior to use of the device • Use the Generator in accordance with recommended settings as stated in the Operator's Manual

Precautions – Use only the recommended balloon inflation medium • Appropriate anticoagulant therapy should be administered by the physician • Decision regarding use of distal protection should be made based on physician assessment of treatment lesion morphology

Adverse Effects – Possible adverse effects consistent with standard angioplasty include: • Access site complications • Allergy to contrast or blood thinners • Arterial bypass surgery • Bleeding complications • Death • Fracture of guidewire or device • Hypertension/Hypotension • Infection/sepsis • Placement of a stent • Renal failure • Shock/pulmonary edema • Target vessel stenosis or occlusion • Vascular complications. Risks unique to the device and its use: • Allergy to catheter material(s) • Device malfunction or failure • Excess heat at target site

Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions, and adverse events. www.shockwavemedical.com