SHOCKWAVE | IVL

DISRUPT PAD III A SUPERIOR STRATEGY FOR CALCIFIED PAD

IVL provides superior vessel prep and excellent long-term results in calcified vessels while preserving future treatment options

Disrupt PAD III provides the largest long-term Level 1 evidence in the treatment of heavily calcified femoropopliteal lesions

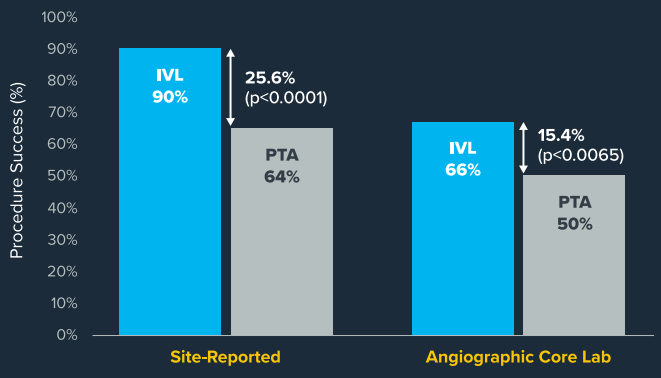
Prospective Multicenter Single-Blind RCT	45 Global Sites	306 SFA/Popliteal Lesions	83%* Severe Calcification†	129mm* Avg. Calcified Length

*IVL Arm †PARC Definition

SUPERIOR PREP

IVL's unique mechanism of action delivers significantly more luminal gain with lower dilation pressure and significantly lower dissections.

Superior Procedural Success



Procedural Success = Residual stenosis ≤30% without flow-limiting dissections prior to DCB +/- stenting

Atraumatic Treatment

↓44%

Lower Max Pressure
(6.3atm vs. 11.3atm) p<0.0001

↓77%

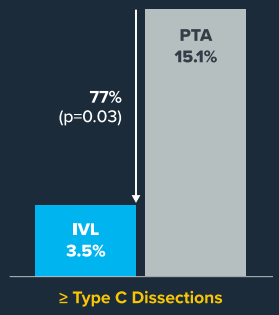
Reduction in Type ≥ C Dissections
(3.5% vs. 15.1%) p=0.03

PRESERVED OPTIONS

IVL maintains control of the procedure by minimizing complications such as dissections, embolization, and perforations. IVL significantly reduces the need for bailout stents, preserving future treatment options.

Reduced Dissections

77% Reduction in Type ≥ C Dissections



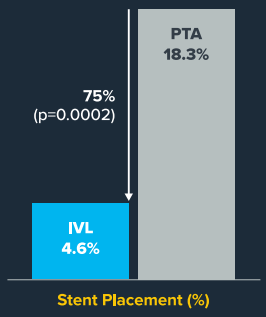
Low Complications

0%

Embolization
Perforation
Thrombus
No Flow

Reduced Bailout Stenting

75% Reduction in Bailout Stenting

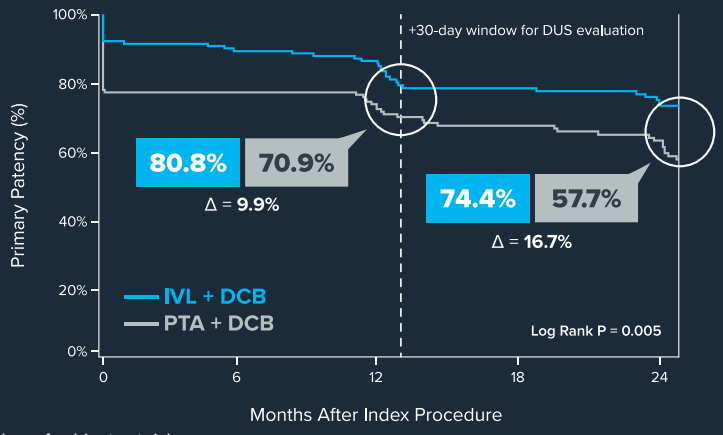


Embolic protection: Utilized in 1.3% of cases in IVL treatment arm.
Provisional stent: Utilized if residual stenosis ≥50% by visual estimate or unresolved ≥ type D dissection, and trans-lesional gradient > 10 mmHg

EXCELLENT LONG-TERM RESULTS

IVL has demonstrated excellent patency out to two years in a severely calcified patient population.

Primary Patency*



Number of subjects at risk

IVL	131	120	107	88	83
PTA	136	107	95	75	66

*Primary Patency defined as freedom from provisional stenting at index procedure, freedom from clinically-driven target lesion revascularization, and freedom from restenosis determined by duplex ultrasound

Tepe et al. *JSCAI, 2022.*

In the United States: Rx Only.

Indication for Use – The Shockwave Medical Intravascular Lithotripsy 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
Please contact your local Shockwave representative for specific country availability and refer to the Shockwave M^5, Shockwave M^{5+}, and Shockwave S^4 instructions for use containing important safety information.

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