From Evolution to Revolution: A Physician's Shockwave IVL Journey

A physician's perspective on their journey with Shockwave IVL technologies, from Shockwave M5 to Shockwave Javelin and beyond.

With Nicolas J. Mouawad, MD, MPH, MBA, DFSVS, FACS, FRCS, RPVI



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Since introducing Shockwave™ M5, Shockwave Medical, now Johnson & Johnson MedTech, has advanced calcium modification through innovative applications of intravascular lithotripsy (IVL). Throughout the product development process, the company has partnered with Dr. Nicolas J. Mouawad for clinical insights and expertise. Here, he shares how the evolution of IVL has transformed his practice.

CALCIUM CHALLENGES IN PAD

Why is it important to modify calcific peripheral artery disease (PAD) prior to definitive therapy? What risks or challenges can arise when treating these types of lesions?

When I see significant calcium in a peripheral lesion, I think about vessel preparation first and the definitive therapy second. The problem with heavy calcium is that the vessel simply does not behave normally. You can put a lot of pressure into the balloon and still not get adequate expansion because the calcium is acting almost like a rigid scaffold around the vessel. This creates several problems:

1. You may be left with substantial residual stenosis, inadequate luminal gain, flow-limiting dissection, or the need for bailout stenting.
2. The drug is only going to work well if you can get the vessel adequately expanded and create reasonable contact with the vessel wall.

So, for me, calcium modification is about creating a better vessel for whatever definitive therapy comes next, particularly when I am trying to avoid leaving a permanent implant.

What tradeoffs or limitations existed in calcium modification strategies prior to the introduction of Shockwave IVL?

Before IVL, we had several ways of dealing with calcium, but each came with a tradeoff (Figure 1). High-pressure balloon angioplasty was straightforward and readily available, but you were often exchanging pressure for vessel injury. With heavily calcified lesions, you could inflate to very high pressures and still not get adequate expansion, while increasing the risk of dissection or perforation.

Scoring and cutting balloons also have a role, but they are still fundamentally mechanical balloon technologies. There are situations where they simply cannot adequately address circumferential or deep medial calcium.

Atherectomy is another option, particularly when we need to debulk or modify very focal, resistant calcium. But, it introduces its own concerns such as distal embolization, wire bias, procedural cost, and the need to be very thoughtful about where and how aggressively you use it.

THE SHOCKWAVE IVL EVOLUTION

How does Shockwave IVL address the tradeoffs or limitations of other calcium modification strategies?

What attracted me to Shockwave IVL was that it approached the problem differently. Instead of trying to physically remove the calcium, you're using ultrasonic acoustic pressure waves at low balloon pressures to fracture the calcium within the vessel wall. That allows

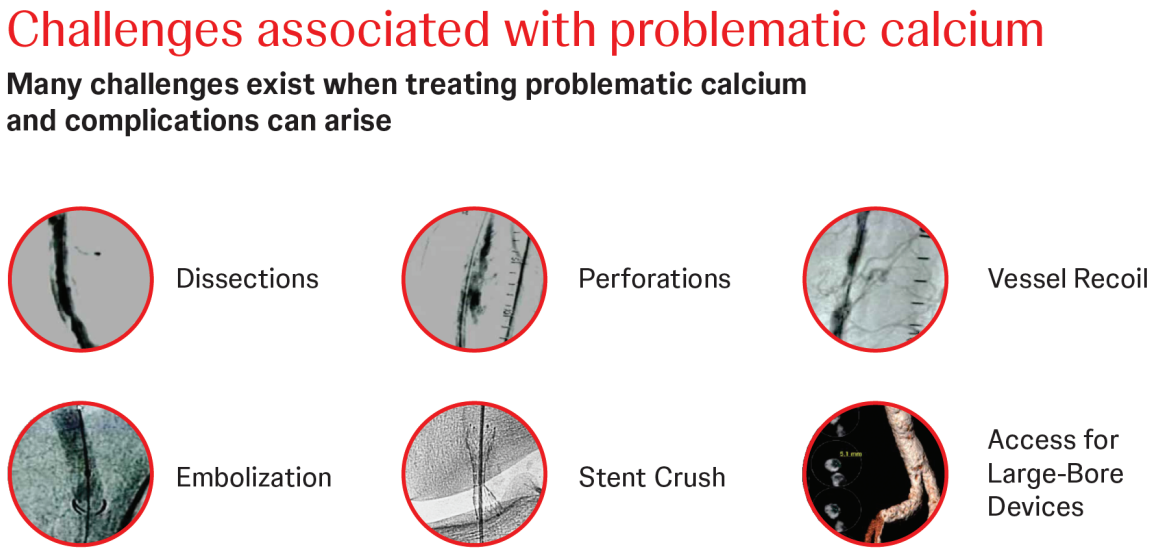


Figure 1. Shockwave IVL aims to minimize complications typically seen with legacy calcium modification strategies.

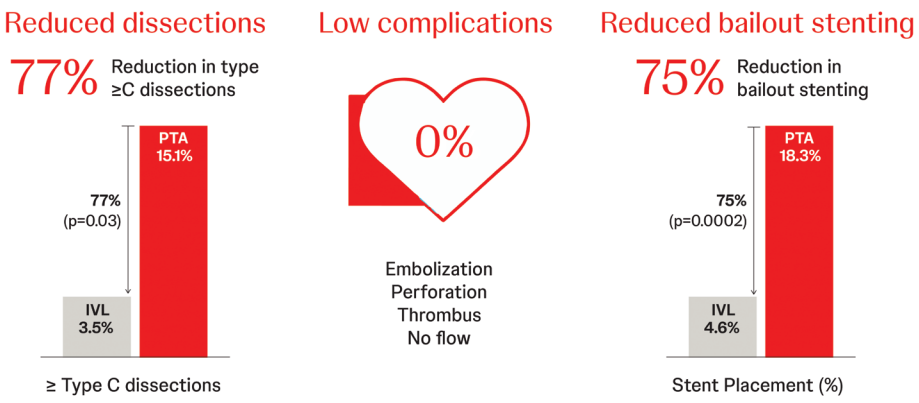
the vessel to become more compliant without having to generate the same degree of traumatic balloon force.

The clinical data support that concept. In the randomized DISRUPT PAD III study, IVL had higher procedural success and fewer flow-limiting dissections and provisional stents than conventional percutaneous transluminal angioplasty (PTA) (Figure 2).[1] At longer follow-up, the IVL group also had better primary patency.[2]

I don't look at Shockwave IVL as replacing every other calcium modification technology. I look at it as another tool that gives me a much more controlled way of dealing with calcium, and in many cases, it has become my preferred first-line calcium modification strategy.

What was your initial reaction to Shockwave IVL?

Initially, I was intrigued but appropriately skeptical, particularly about treating dense, circumferential calcium. As a vascular surgeon accustomed to removing these lesions through endarterectomy—and to balloons failing to expand adequately—I questioned whether acoustic pressure waves delivered through a balloon could meaningfully alter the lesion.



1. Tepe G, Brodmann M, Werner M, Bachinsky W, Holden A, Zeller T, et al. Intravascular Lithotripsy for Peripheral ArteryCalcification: 30-Day Outcomes From the Randomized Disrupt PAD III Trial. JACC Cardiovasc Interv. 2021 Jun28;14(12):1352–61. doi:10.1016/j.jcin.2021.04.010 PMID: 34167675.

Figure 2. DISRUPT PAD III randomized controlled trial demonstrated an improved safety profile compared to traditional balloon angioplasty—notably, a reduction in dissections and bailout stenting. Note: Provisional stent: Utilized if residual stenosis ≥ 50% by visual estimate or unresolved ≥ type D dissection and translesional gradient > 10 mm Hg.[1]

The other area where I was cautious was below the knee (BTK). Those vessels are small, often diffusely diseased, and frequently have very eccentric or circumferential calcium. I wasn't sure initially how much of a difference IVL would make in that environment.

What changed my thinking was seeing the vessel response after treatment. You could have a lesion that looked essentially rock-hard angiographically, deliver the Shockwave IVL, and then see the vessel

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become much more compliant with subsequent balloon inflation. That was really the "aha" moment for me.

I realized that the value of IVL wasn't necessarily that it was going to make every lesion disappear. It was that it could change the mechanical behavior of the vessel and make the rest of the procedure more predictable. Once I saw that repeatedly, in multiple vascular beds and particularly in heavily calcified disease, my skepticism decreased quickly and was replaced with enthusiasm.

How has your use of Shockwave IVL expanded since your initial adoption? Where does the strategy sit today in your treatment algorithm?

My use of IVL has expanded considerably—and into multiple vascular beds. Initially, I was using it selectively for the really obvious heavily calcified lesions. Over time, I started using it and challenging it in more complex lesions and cases.

The DISRUPT PAD III observational data were important in expanding use because they reflect the kind of patients we actually see in practice—long lesions, chronic total occlusions, multiple vessel beds, and substantial calcification—and still showed a very low rate of serious angiographic complications (Figure 3 and Table 1).[3]

Today, when I see moderate to severe calcification, particularly circumferential calcium, deep calcium, or a lesion that I know is going to be difficult to expand, IVL is very high on my list for vessel preparation. This rings true across different vascular beds, including femoropopliteal, common femoral, iliac, and BTK disease.

I no longer think of IVL as a rescue technology. For the right calcified lesion, I think of it as part of my initial vessel preparation strategy.

What advancement in Shockwave IVL's product portfolio has had the most significant impact in your practice?

The biggest impact for me has been the evolution of the catheters themselves in terms of deliverability, length, vessel size, and the ability to treat more anatomically challenging disease.

The original concept of Shockwave IVL was compelling, but as a practitioner, you still need to be able to get the device where you want it. The newer-generation devices, particularly the Shockwave E8, have made a meaningful difference because they are easier to deliver and give you more capability in longer and more distal lesions, including BTK disease. I also think the development of lesion-specific devices is important. The Shockwave L6, for example, gives you a purpose-built option for larger iliac vessels, while the Shockwave Peripheral Javelin addresses a different problem, the difficult-to-cross lesion.

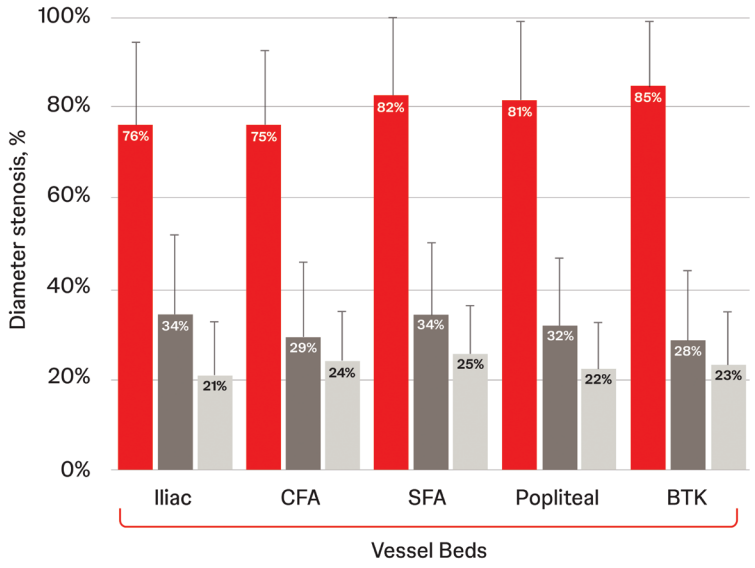


Figure 3. DISRUPT PAD III observational study demonstrated consistently high levels of procedural success across all peripheral vessel beds.[3] CFA, common femoral artery; SFA, superficial femoral artery.

What makes Shockwave IVL's current PAD product portfolio unique (Figure 4)?

It's not simply one catheter being stretched to fit every anatomy. The technology is becoming more tailored to the actual clinical problem we're trying to solve.

From a practical standpoint, that means I have more confidence that if I decide Shockwave IVL is the appropriate calcium modification strategy, I have a device that is better matched to the anatomy rather than having to force the anatomy to fit the device.

TABLE 1. DISRUPT PAD III OS REPORTED COMPARABLE SAFETY OUTCOMES IN REAL-WORLD PRACTICE, AS SEEN IN DISRUPT PAD III RCT[1,3]

	Disrupt PAD III RCT[1]	Disrupt PAD III OS[3]
N	153	1367
Vessels	SFA/Pop	Iliac, CFA, SFA/Pop, Infrapop
Dissection (Type D-F)	0%	0.7%
Perforation	0%	0.1%
Embolization	0%	0%
Slow flow/No reflow	0%	0%

Abbreviations: CFA, common femoral artery; OS, observational study; RCT, randomized controlled trial; SFA, superficial femoral artery.
Final angiographic complications (Core Lab).

THE SHOCKWAVE IVL REVOLUTION

How would you describe the pace and quality of innovation from Johnson & Johnson MedTech, and what upcoming Shockwave IVL technologies excite you the most?

I think one of the more impressive things about Shockwave has been that the company hasn't treated IVL as a single technology that was developed and then left alone. They've continued to address the limitations that physicians identified in the first-generation devices.

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We've seen improvements in deliverability, treatment length, vessel diameter, and the ability to address different vascular beds. That's important because innovation

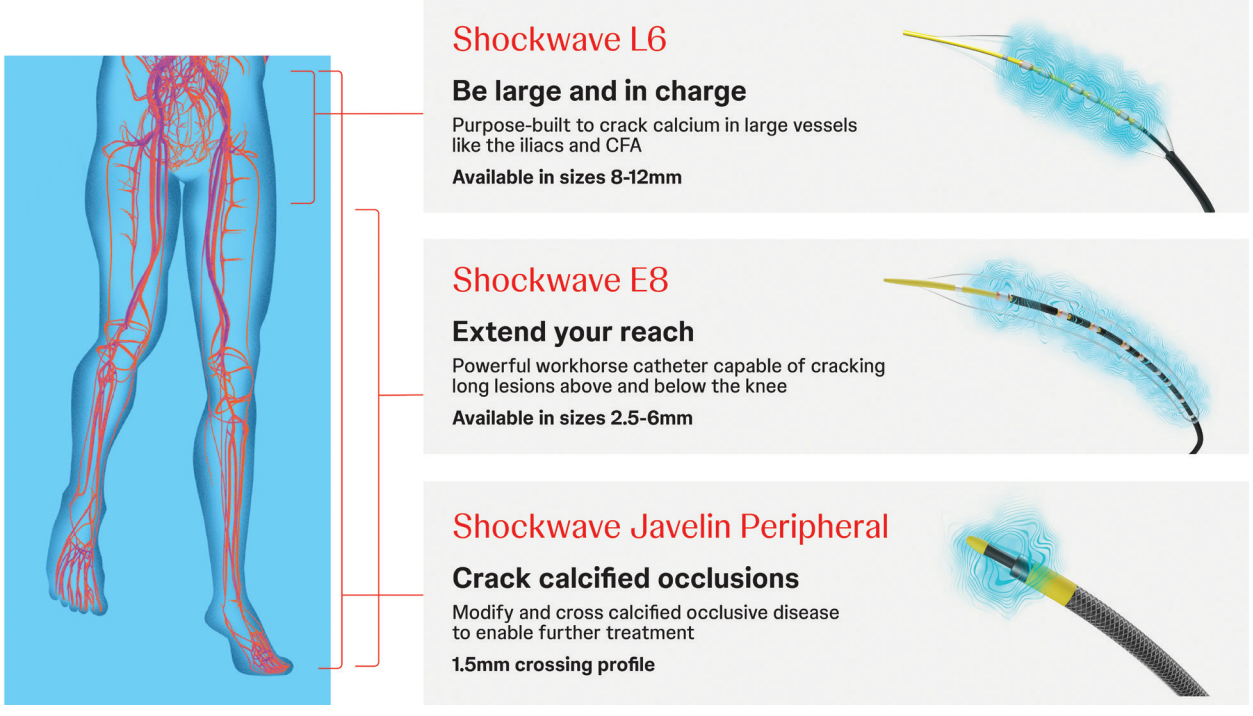


Figure 4. Shockwave IVL catheters are purpose-built to address real-world clinical problems, including long lesions, large vessels, and calcified occlusive disease.

> "Innovation in medical devices isn't just about making something technically more sophisticated. It's about solving the problems that come up when you're actually using the device in a real patient."

in medical devices isn't just about making something technically more sophisticated. It's about solving the problems that come up when you're actually using the device in a real patient.

I'm particularly interested in the continued expansion of Shockwave IVL into other vascular territories, particularly in the carotids. As the National Co-Principal Investigator of the SKYWARD trial transcarotid artery revascularization arm along with Dr. Peter Schneider, we are addressing this topic specifically.

Ultimately, what excites me most is the idea that calcium modification is becoming more predictable. If you can consistently modify the calcium while minimizing vessel trauma, you give yourself more options for the definitive treatment and potentially improve the durability of the overall procedure.

CONCLUSION

As conveyed by Dr. Mouawad, J&J MedTech has only scratched the surface on what Shockwave IVL is capable of. Stay tuned for continued updates on the Shockwave IVL revolution! ■

1. Tepe G, Brodmann M, Werner M, et al. Intravascular lithotripsy for peripheral artery calcification: 30-day outcomes from the randomized Disrupt PAD III trial. JACC Cardiovasc Interv. 2021;14:1352-1361. doi: 10.1016/j.jcin.2021.04.010 PMID: 34167675.
2. Tepe G, Brodmann M, Bachinsky W, et al. Intravascular lithotripsy for peripheral artery calcification: mid-term outcomes from the randomized Disrupt PAD III trial. J Soc Cardiovasc Angiogr Interv. 2022;1:100341. doi: 10.1016/j.jscai.2022.100341
3. Armstrong EJ, Adams G, Soukas PA, et al. Intravascular lithotripsy for peripheral artery calcification: 30-day outcomes from the Disrupt PAD III observational study. J Endovasc Ther. 2026;33:853-862. doi: 10.1177/15266028241283716

Disclosures: Dr. Mouawad is a paid consultant for Johnson & Johnson MedTech. The thoughts and views expressed are of their own opinions and do not necessarily represent Johnson & Johnson MedTech.

Shockwave M5, Shockwave M5+, Shockwave S4, Shockwave L6 and Shockwave E8 Safety Information

In the United States: Rx only.

Indications 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, and infra-popliteal arteries. Not for use in the coronary, carotid or cerebral vasculature. Peripheral IVL is also indicated for use in renal arteries in certain jurisdictions, including the United States. Please reference Instructions For Use for country specific information.

Contraindications—Do not use if unable to pass 0.014" (M5, M5+, S4, E8) or 0.018" (L6) 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 thinner–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/IFU

Shockwave Javelin Safety Information

In the United States: Rx only.

Indications for Use—The Shockwave Medical IVL System with the Javelin Peripheral IVL Catheter is intended for lithotripsy-enabled modification and crossing of calcified lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, and infra-popliteal arteries, prior to final treatment.
Not for use in the coronary, carotid, cerebral, or pulmonary vasculature.

Contraindications—Do not use if unable to pass 0.014" (0.36mm) guidewire across the treatment site-Not intended for treatment of in-stent restenosis or in coronary, carotid, cerebral or pulmonary 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—Avoid applying acoustic pressure pulses while IVL window is not filled with sterile saline—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 thinner–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.

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