Supplement to

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Endovascular TODAY

Sponsored by Shockwave Medical

A VERSATILE TOOL FOR CHALLENGING CALCIUM

Candid multidisciplinary perspectives and clinical considerations when integrating peripheral IVL into your treatment algorithm.


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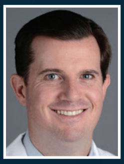
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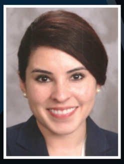
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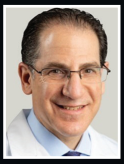
Ross Milner, MD

Cover image courtesy of istockphoto.com

Intravascular Lithotripsy: Cracking the Code in Peripheral Arterial Calcification

As physicians dealing with patients with peripheral artery disease are all too aware, the presence of significant vascular calcification can not only limit the chance of achieving an optimal result during revascularization procedures, but it is also linked with longer-term poor outcomes including need for major amputation. Despite utilization of a variety of plaque modification and atherectomy tools, physicians' ability to fully address medial calcification, the predominant histopathologic disease process in lower limb arterial calcification, has hitherto remained limited.

Intravascular lithotripsy (IVL), the delivery of high-energy acoustic pressure waves to fracture plates of arterial calcification and thereby favorably alter blood vessel compliance, has been demonstrated to be effective in modifying both superficial and medial calcification, providing a potential mechanistic advantage over conventional atherectomy techniques that can only impact the superficial calcium they can physically contact. IVL, delivered through a dedicated portfolio of balloon platforms containing emitters to generate acoustic pressure "shock" waves, combines ease of use with clinical trial–demonstrated safety and efficacy in the treatment of calcific peripheral artery disease.

The versatility of IVL in calcium modification across a range of vascular beds was outlined in the DISRUPT PAD III observational study and is confirmed by the cases reported and discussed in depth by expert endovascular interventionalists in this supplement. First, Carlos Guevara, MD; Leigh Ann O'Banion, MD; and Eric Secemsky, MD, present a series of calcific femoropopliteal interventions in chronic total occlusions, highlighting the ability of IVL technology to assist not only in the acute restoration of in-line flow to the foot in these highly complex clinical scenarios, but also to achieve and maintain the long-term patency necessary for wound healing. Next, Charles Briggs, MD, and JD Corl, MD, discuss the challenges of treating heavily calcified iliac arteries with currently available techniques and outline the unmet needs that have been addressed by the new Shockwave L⁶ peripheral (IVL) platform, specifically designed with a compact array of six emitters in a range of larger-diameter balloons. Finally, Angela Giese, MD; Trissa Babrowski, MD; and Ross Milner, MD, present the evolving paradigm of adjunctive IVL use to treat calcified access arteries in the setting of large-caliber EVAR and TEVAR procedures and demonstrate its utility in streamlining and simplifying such interventions.

Examples such as these case discussions highlight the range of clinical scenarios in which IVL can be the difference-maker, providing a simple but highly effective therapy to address the difficult problem of lower limb arterial calcification. Our ongoing trial work in the infrapopliteal space (DISRUPT BTK II), alongside novel developments designed to enhance and evolve our current technology, to provide new solutions for different lesion types, and in different vascular beds, emphasize our commitment to the endovascular space—and to providing physicians and their patients with safe, effective, and evidence-based solutions for cracking the code of calcific vascular disease. ■

Nick West, MD
Associate Chief Medical Officer
Shockwave Medical

Achieving Success in Calcified SFA and Popliteal Lesions

Multidisciplinary perspectives and optimal approaches to real-world scenarios.

With Carlos J. Guevara, MD, FSIR; Leigh Ann O'Banion, MD; and Eric A. Secemsky, MD, MSc, RPVI, FACC, FAHA, FSCAI, FSVM

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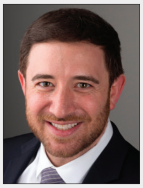

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When do you rely on angiographic images, and when do you progress to intravascular ultrasound (IVUS)?

Dr. O'Banion: With IVUS readily available and its ease of use, I routinely utilize the modality in nearly 100% of my endovascular interventions. It allows for improved vessel sizing and measurement of extent of disease as well as evaluation of response to therapy. IVUS should be considered adjunctive therapy to angiography if available to the interventionalist, as there is little downside and it can only improve outcomes and provide more information.

Dr. Secemsky: My algorithm is to have the IVUS console in the procedure room with an unopened IVUS catheter ready to go in all of my peripheral lower extremity procedures. For me, the decision to use IVUS is based on a few factors. First is how extensive the revascularization procedure is. If it's critical limb ischemia (CLI), multilevel, multisegment revascularization, I'm almost always going to use IVUS. I always find that there is a need at some point in the procedure where I can use IVUS to optimize my endovascular techniques. If it's a single-segment focal lesion in the superficial femoral artery (SFA) in a patient with claudication, it's a little bit more algorithmic for me. And unless a complication comes up, I'm going to usually just do an angiogram, my intervention, and a postangiogram.

Dr. Guevara: I routinely use IVUS for our procedures, probably at least 90% of the time. I do not use it if we have CTA images. If I do not use IVUS, I perform angiography in two projections in the area of concern.

If calcium is present, how do you choose which treatment modality to use first? What data impact your decision?

Dr. Secemsky: Often, it is challenging to determine the degree of calcium and how much it is going to inhibit my procedural plan. For instance, it's difficult to use a two-dimensional image to identify concentric calcium and even harder to know whether you're only going to apply drug to a cleft of calcium when using a drug-coated balloon (DCB). An IVUS is a 360° luminal representation of the vessel. You can see the entire perimeter of the vessel and understand exactly that characteristic and how much calcium is going to be an issue to gaining adequate luminal size in a safe manner.

If you prefer scaffolds and are trying to determine whether expansion is going to be successful, you can balloon aggressively and see if there's release of calcium, but this method can result in dissection. So, using IVUS allows identification of calcium severity and helps determine the success of balloon angioplasty or if another plaque-modifying technique is going to be needed.

And I'll go one step further. Now that we have intravascular lithotripsy (IVL) as an adjunctive method for plaque modification, where we typically were reliant on luminal atherectomy that really addresses luminal interval calcification, it's even more important to understand the burden and location of calcium. For instance, if there's medial calcification, that's unlikely to be affected by luminal atherectomy devices but will be more responsive to IVL, which is designed to address calcific disease deep into the vessel wall.

Dr. Guevara: For areas of complete occlusion or bulky stenosis, I will routinely combine atherectomy with IVL, especially if I'm trying to avoid stenting. For areas of moderate stenosis, I rely on IVL only, and depending on post-IVL IVUS, I will decide on DCB or stenting.

> "As we continue to see the results from the DISRUPT trials, the evidence is strong for the safety and efficacy of IVL across all vascular beds."
>
> **—Leigh Ann O'Banion, MD**

Dr. O'Banion: IVL has been a great tool to add to the armamentarium of devices utilized to treat patients with heavily calcified disease burden. Because over 99% of my treated patients have chronic limb-threatening ischemia (CLTI), often I am intervening on occlusive disease. With heavy calcification identified on CTA, plain film, or IVUS, I often incorporate Shockwave IVL (Shockwave Medical) for these cases to optimize luminal gain and avoid dissection and need for bailout stenting. This technology has been specifically useful in my practice when treating iliac occlusive disease and below-the-knee (BTK) disease.

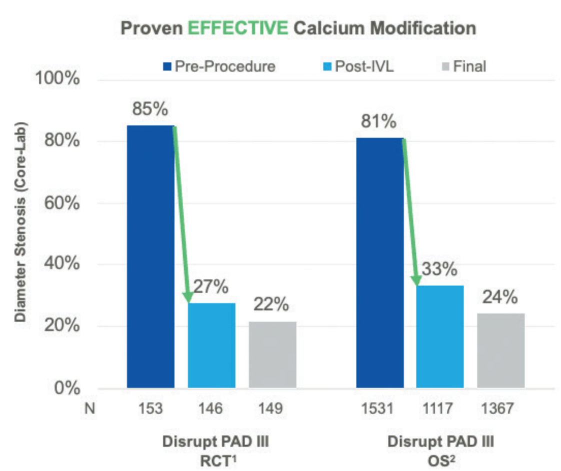
As we continue to see the results from the DISRUPT trials, the evidence is strong for the safety and efficacy of IVL across all vascular beds.[2] I think that we will continue to see the benefit in the BTK space, which is the one area we are severely lacking in high-quality technology to adequately treat complex disease patterns.

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
2. Armstrong E. Intravascular lithotripsy for the treatment of peripheral artery calcification: results from the Disrupt PAD III observational study. Presented at: Vascular InterVentional Advances (VIVA) 2022; November 1, 2022; Las Vegas, Nevada.

Exceptional SAFETY Profile

	DISRUPT PAD III RCT[1]	DISRUPT PAD III OS[2]
N	153	1367
Vessels	SFA/Pop	Iliac, CFA, SFA/Pop, Infrapop
Dissection (Type D-F)	0%	0.7%
Perforation	0%	0.2%
Embolization	0%	0%
Slow Flow/No Reflow	0%	0%
Abrupt Closure	0%	0%
Thrombus	0%	0%

Final Angiographic Complications (Core-Lab)



Use of IVL and Stenting to Treat a Severely Calcified and Occluded Popliteal Artery

By Eric A. Secemsky, MD, MSc, RPVI, FACC, FAHA, FSCAI, FSVM

CASE PRESENTATION

A man in his early 70s with a history of coronary artery disease, heart failure with reduced ejection fraction, hypertension, hyperlipidemia, and type 2 diabetes mellitus presented with left limb rest pain and a hallux ulcer (Figure 1). The severe claudication symptoms began 6 months prior, and the wound developed 6 weeks later in the setting of a nail trimming. The patient was referred to podiatry, where he endorsed the rest pain and newer ulcers, and the patient was referred for complex revascularization.

COURSE OF TREATMENT

Angiography of the left lower extremity showed occlusion at the level of the popliteal artery. Through use of external vascular ultrasound and delayed angiography, it was determined that the peroneal was the dominant runoff vessel. Our plan was to attempt antegrade wire escalation with or without reentry, with a secondary plan for retrograde peroneal access if we were unsuccessful; however, the goal was to avoid accessing the target runoff vessel if avoidable. Antegrade access was achieved with a 6-F, 55-cm Flexor Raabe sheath (Cook Medical) and 0.018-inch Quick-Cross catheter (Philips) with a 0.014-inch Fielder XT wire (Asahi Intecc USA, Inc.). The architected vessel was followed, and the distal cap was punctured with a 0.014-inch Astato XS wire (Asahi Intecc USA, Inc.). This appeared luminal, but the wire found the proximal portion of the known occluded anterior tibial artery (Figure 2). IVUS was used to confirm luminal cross-

Figure 1. Image of the left hallux ulcer.

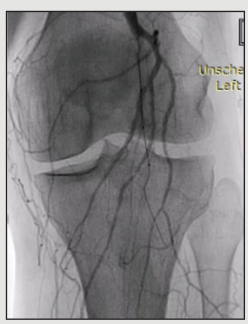


Figure 2. Angiogram demonstrating the popliteal artery occlusion with slow underfilled distal runoff provided by various collaterals.

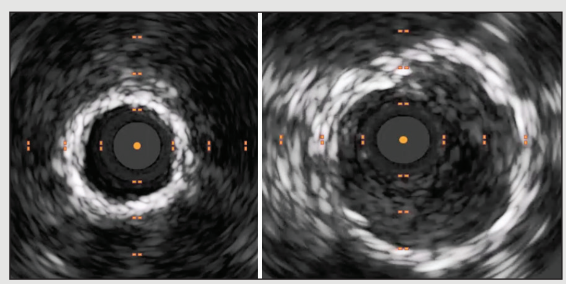


Figure 3. IVUS imaging, which confirmed severe concentric calcification throughout the vessel.

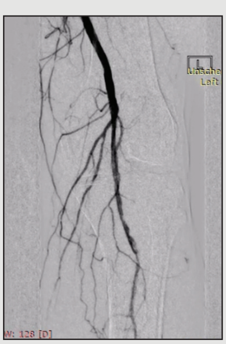


Figure 4. IVL was performed with a Shockwave S^4 to the TPT, followed by a Shockwave M^5 to the popliteal artery.

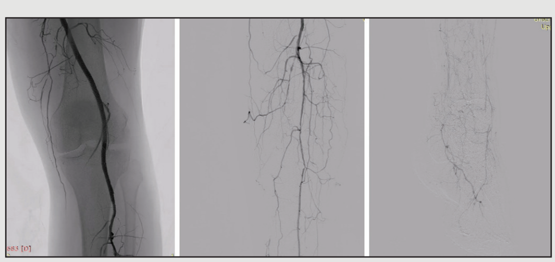


Figure 5. Final angiograms showing brisk flow through the popliteal artery stent into the peroneal artery with single-vessel runoff to the foot and newly restored pedal flow.

Figure 6. Photo showing the fully healed wound.

ing and demonstrated severe concentric calcification (Figure 3). In addition, the origin of the tibioperoneal trunk (TPT) was identified on IVUS.

We parallel-wired the TPT/peroneal artery with the Fielder XT wire and performed percutaneous transluminal angioplasty with a 4-mm balloon to restore flow through the popliteal artery. Our plan was to place a Supera stent (Abbott) across the popliteal artery, and vessel preparation was critical prior to deployment. IVL was performed with a 4- X 40-mm Shockwave S[4] peripheral IVL catheter (Shockwave Medical) to the TPT, followed by a 5- X 60-mm Shockwave M[5] to the popliteal artery to address the heavy calcific burden. Flow was significantly improved following IVL (Figure 4).

After IVL, a 5.5- X 120-mm Supera stent was placed across the popliteal artery into the TPT. At that point, there was poor outflow distal to the stent, and we prepared to snorkel a coronary stent into the peroneal artery. Final angiography after postdilation showed brisk flow through the popliteal artery with single-vessel runoff through the dominant peroneal artery and newly restored pedal flow (Figure 5).

At 1-month follow-up, the patient's wound had fully healed (Figure 6), the rest pain resolved, and he resumed exercise. At 8 months, the stents remained patent.

DISCUSSION

This case demonstrates the many complexities of managing chronic total occlusions (CTOs), particularly involving the popliteal space. First, successful crossing must be determined. IVUS was used to demonstrate luminal wire passage as well as to perform vessel sizing, identify the origin of the TPT artery, and grade severity of calcium. When popliteal artery stenting is performed, a dedicated vascular scaffold that can handle the external forces of this region is critical. Success of the scaffolds is dependent on adequate vessel preparation, and IVL is a safe and effective device to use in the popliteal artery space. Identifying upfront and addressing the heavy concentric calcium was key for successful stent deployment and expansion.

How do you decide which definitive therapy is needed for calcified SFA/popliteal lesions?

Dr. O'Banion: I really rely on both angiography and IVUS to dictate definitive therapy. If IVL and DCB result in adequate luminal gain with the absence of any flow-limiting dissection, the work is done. Often with heavily calcified CTOs, this can be difficult to achieve and thus stenting may be required. IVUS has really allowed the comprehensive evaluation of the therapy delivered to minimize unnecessary stenting.

Dr. Secemsky: I'm always considering the best way to modify plaque in the least aggressive way possible. My other considerations include: How am I going to get drug to deliver to the vessel wall and be effective if calcium is present? How am I going to avoid barotrauma or other trauma to the wall of the vessel to avoid a scaffold? Devices like IVL give us an opportunity to lower our balloon inflation pressure and allow for disruption of calcific or fibrocalcific disease to allow for luminal gain and drug delivery.

Dr. Guevara: After using IVL with or without atherectomy, I evaluate with IVUS, and if there is good luminal gain and no dissections, I then use a DCB. Otherwise, I use an interwoven nitinol stent.

When do you consider a surgery-first approach?

Dr. Guevara: Usually, I consider surgery for lesions such as common femoral artery (CFA) disease; however, with the recent data from the BEST-CLI study, the algorithm might change for some patients with CLTI, a good conduit, and who are good surgical candidates.

Dr. O'Banion: The BEST-CLI study has now given us the definitive answer to this question.[1] It really is all about patient risk, severity of limb threat, and anatomic complexity of disease. In patients with CLTI who have acceptable single-segment great saphenous vein (GSV) conduit and who are of appropriate surgical risk, I favor a bypass-first approach. It is our job to provide the patient with the safest and most durable form of revascularization, especially in the setting of CLTI.

Dr. Secemsky: I look at every patient holistically. The goal is to match the patient with the best treatment options available for that patient. As such, endovascular treatment will remain a primary revascularization strategy for peripheral artery disease. When we approach a vascular patient, more often they're referred for endovascular treatment as they are poor surgical candidates, usually due to the fact that they are older and have a number of comorbidities including diabetes, coronary artery disease, and chronic kidney disease.

There are patients who have venous conduits and are surgically eligible, and I think we're increasingly going to consider a surgical approach after the recent results of the BEST-CLI study. However, I think the reality is that the majority of our patients still remain poor surgical candidates or have preferences to avoid a surgery, even though we have provided all information that a surgical approach might be best.

1. Farber A, Menard MT, Conte MS, et al. Surgery or endovascular therapy for chronic limb-threatening ischemia. N Engl J Med. 2022;387:2305-2316. doi: 10.1056/NEJMoa2207899

Use of IVL and DCB Angioplasty in a Long-Segment, Heavily Calcified SFA CTO

By Leigh Ann O'Banion, MD

PATIENT PRESENTATION

A man in his early 70s presented with a new, chronic left great toe ulcer (Figure 1) after undergoing left iliofemoral endarterectomy, which was complicated by infection and requiring debridement and wound vac therapy. He also had a history of significant coronary artery disease and had previously undergone coronary artery bypass grafting with the left GSV and a right femoral-to-popliteal bypass with the right GSV. He was classified as Wound Ischemia foot Infection (WIfI) 221, which is clinical stage 4 (high risk for amputation).


Figure 1. Photo of the new, chronic left great toe ulcer.

COURSE OF TREATMENT

We proceeded with angiography and IVUS of the left lower extremity, which demonstrated an SFA occlusion and circumferential heavily calcified disease (Figure 2). Due to the patient's hostile groin and lack of autologous conduit, we elected to proceed with endovascular revascularization. The CTO was successfully crossed with a 0.014-inch Hi-Torque Command ES wire (Abbott) and CXI support catheter (Cook Medical), and true lumen position was confirmed angiographically and with IVUS. A 5- X 60-mm Shockwave M^{5+} balloon was selected, and IVL of the entire SFA was performed according to instructions for use, followed by DCB angioplasty with 5- and 6-mm balloons (Figure 3). The postintervention angiogram revealed < 30% residual stenosis in any one area with no evidence of dissection and unchanged dominant posterior tibial runoff into the foot (Figure 4). At 1-week follow-up, the patient's toe pressure improved to 102 from 36 mm Hg and his rest pain was resolved. He was scheduled for a great toe amputation by our podiatric colleagues.

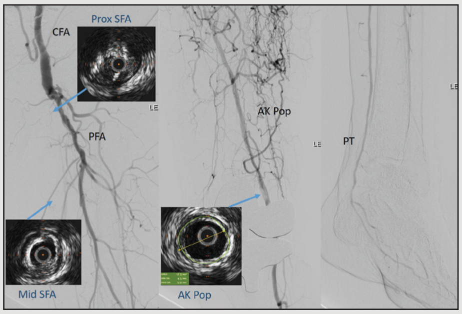


Figure 2. Pretreatment IVUS images.

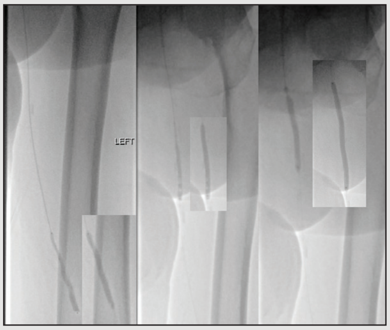


Figure 3. 5-mm Shockwave M^{5+} IVL and DCB treatment.

DISCUSSION

In any patient with CLTI, it is beneficial to employ a multidisciplinary comprehensive approach and tailor treatment algorithms based on the patient's risk profile, severity of limb threat, and anatomic complexity of disease. In this case, the patient was high surgical risk due to the hostility of his groin, had WIfI stage 4 with high-risk limb threat, and had a long-segment, heavily calcified SFA CTO in the absence of a suitable single-segment GSV. Due to the aforementioned reasons, we felt he was most suitable for an endovascular intervention. In choosing a treatment modality, both angiography and IVUS play a role.

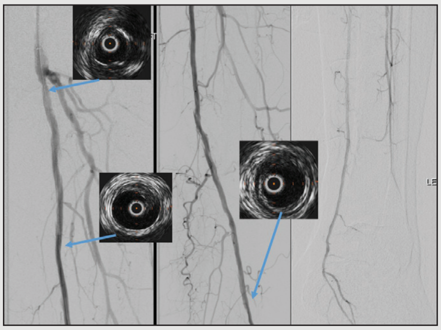


Figure 4. Posttreatment IVUS images showing > 30% residual stenosis.

> "IVL has become more of a workhorse for me for plaque modification over other atherectomy devices."
> —Eric A. Secemsky, MD

We confirmed intraluminal crossing, size of the vessel, and presence of circumferential calcium, making this an ideal case for IVL treatment followed by DCB angioplasty. IVL allowed maximal expansion of the DCB balloons and minimized recoil stenosis as evident on completion IVUS (Figure 4). In these heavily calcified CTOs, we find it prudent to treat the lesion from distal to proximal with overlap at each treating segment if predilatation is not utilized, as crossability of the device after inflation may prove challenging. The Shockwave M^{5+} catheter cuts cycle time in half with two times faster pulsing,* which is an added provider and patient benefit. This treatment algorithm has been demonstrated in the DISRUPT PAD III randomized controlled trial to have safe and excellent long-term results, even in complex lesions such as the one described here (> 15 cm, CTO, severe calcium, CLTI with tissue loss).[1] Although we have recent results from BEST-CLI reporting superiority of single-segment GSV bypass for patients with this anatomic pattern of disease, the reality is that not all patients are suitable for surgical bypass, and thus we must continue to push the endovascular limits and fill our toolboxes with the appropriate tools to optimize endovascular revascularization in these challenging patients.

In which situations would you use atherectomy over IVL, and vice versa?

Dr. O'Banion: We do not use atherectomy in our practice and thus I cannot comment on its utilization. I think that you should take each lesion individually, using all the imaging tools available to tailor the treatment approach.

Dr. Guevara: I believe IVL and atherectomy are complementary and using both can lead to the largest luminal gain and potentially avoid stenting. In areas that show complete occlusion or high-grade stenosis, atherectomy helps remove plaque from the lumen while IVL helps "crack" the remaining calcium to allow full vessel expansion with DCB or stent.

Dr. Secemsky: The SFA is the area where I think algorithms can change. We have seen improvements in IVL such as faster pulsing, resulting in quicker cycle time while treating the SFA. Sometimes, the algorithm includes a combination of devices with atherectomy and IVL, especially in very long, diseased segments.

The other situation where atherectomy might be preferred is balloon-uncrossable disease. If you can't cross a lesion with the balloon, it is usually impossible to deliver IVL.

For popliteal artery disease, this is another segment I much prefer to avoid a scaffold. As such, IVL plays a very large role in my algorithm for treating the popliteal segment. I find that IVL with a DCB can offer long-term patency without the need for a scaffold.

The BTK space is again where we continue to see some evolution. IVL is one of the few devices that have data for BTK and in CLI in particular. It's a great tool where we see high patterns of calcific disease. Outside of some atherectomy devices, we don't have a lot of technology other than balloon angioplasty for this region. The primary limitation to date is the length of the balloon and ability to deliver the balloon. As these aspects of the devices continue to improve, I see significant growth in use in the infrapopliteal space.

To what degree do you see calcium modification technologies competing and complementing each other?

Dr. Secemsky: I talk about this in every space that I practice in, whether it's pulmonary embolism, coronary intervention, venous disease, or lower extremity arterial disease. No single device does it all. We'd all love to have just one multipurpose solution; however, the reality is that you need several tools that you're familiar with and know how and when to use them, whether alone or in combination. I think IVL is exactly that. IVL has become more of a workhorse for me for plaque modification over other atherectomy devices. But again, there are certainly situations where other atherectomy devices are needed. I might decide to use atherectomy alone or in combination with IVL depending on the location of disease and how it's responding to my therapeutic modality. I encourage everyone to really think about the toolbox and not just a tool, because all of our strategic revascularization innovations have required more than one device that all can be used selectively or in combination to improve outcomes.

Dr. Guevara: In my practice, I use orbital atherectomy and IVL as complementary for CTOs or high-grade calcified stenosis, and for moderate stenosis or medial calcification, I rely on IVL to obtain the best response.

Dr. O'Banion: I think the long-term data will speak to itself. Currently, there is little high-quality data on

> "I find that IVL with a DCB can offer long-term patency without the need for a scaffold."
> —**Eric A. Secemsky, MD**

the superiority of atherectomy over other interventions in CLTI. The contemporary data suggest equivocal results to DCB alone across multiple studies, which shows we need better tools to treat this difficult patient population. I consider IVL an adjunctive treatment to definitive therapy, which aids in luminal gain and plaque modification, and the data are promising in the CLTI patient population.

**Compared to Shockwave M5.*

1. 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 Angiog Interv. 2022;1:100341. doi: 10.1016/j.jscai.2022.100341

Use of Atherectomy, IVL, and Angioplasty for Bulky, Occluded, Calcified Plaque

By Carlos J. Guevara, MD, FSIR

CASE PRESENTATION

A patient in their mid-70s with a past medical history of smoking, diabetes mellitus, and obesity presented with ischemic rest pain. An outside hospital attempted to revascularize the patient, which led to a CFA pseudoaneurysm that was treated with stent graft. Arterial duplex ultrasonography showed occluded diffuse monophasic waveforms from the SFA to the popliteal artery. Runoff CTA showed the right CFA stent graft and an occluded SFA with dense, calcified plaque extending to the popliteal artery.

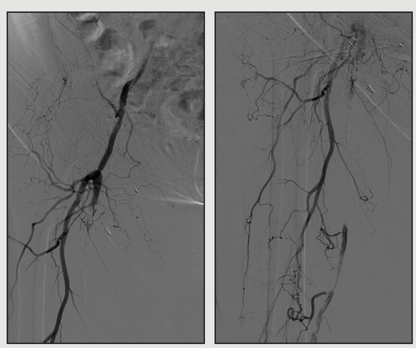


Figure 1. Preintervention images of the SFA.

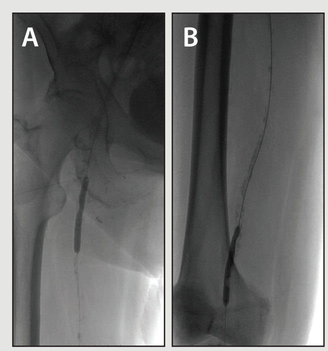


Figure 3. Shockwave IVL of the SFA (A) and the popliteal artery (B).

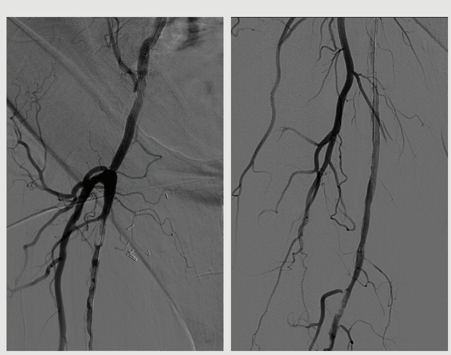


Figure 2. Post–orbital atherectomy.

Figure 4. Final angiograms of the SFA after Shockwave IVL and DCB.

COURSE OF TREATMENT

The initial angiogram confirmed dense, calcified plaque with complete occlusion of the SFA (Figure 1). Using contralateral CFA access, the occlusions were crossed, and orbital atherectomy was first used to debulk the calcified plaque with hopes of avoiding stenting (Figure 2). This was followed by IVL from the popliteal artery to the proximal SFA (Figure 3A and 3B) and, finally, DCB angioplasty of the entire SFA and above-the-knee popliteal artery. The final angiogram showed brisk flow through the treated areas (Figure 4), and IVUS confirmed no residual stenosis in the SFA and popliteal artery. Postrevascularization, the patient's rest pain resolved, and he was able to fulfill all of his activities without any cramps.

DISCUSSION

Treating patients with calcified plaque and critical limb ischemia is challenging because the goal is not only to restore physiologic flow but also to achieve long-term patency. In this case, we were able to obtain good luminal gain without any stents and preserve the three-vessel runoff. ■

Disclosures
Dr. Guevara: Consultant to Shockwave Medical, Cardiovascular Systems, Inc., and AngioDynamics.
Dr. O'Banion: Principal Investigator, Shockwave BTK study.
Dr. Secemsky: Funding from NIH/NHLBI K23Hl150290, US Food and Drug Administration, University of California San Francisco; grants to institution from BD, Boston Scientific Corporation, Cook Medical, Cardiovascular Systems, Inc., Laminate Medical, Medtronic, Philips; speaking/consulting for Abbott, BD, Bayer, Boston Scientific Corporation, Cook Medical, Cardiovascular Systems, Inc., Inari Medical, Janssen, Medtronic, Philips, Shockwave Medical, VentureMed.

Drs. Guevara, Secemsky, and O'Banion are paid consultants of Shockwave Medical. Views expressed are those of the authors and not necessarily those of Shockwave Medical.

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, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.

Contraindications—Do not use if unable to pass 0.014" (M5, M5+, S4) 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.

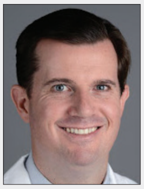
Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events.

www.shockwavemedical.com/IFU

The New Shockwave L6 Peripheral Intravascular Lithotripsy (IVL) Catheter

Larger sizes now available for large calcified vessels.

With Charles Briggs, MD, and JD Corl, MD, FACC, FSCAI



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What are the specific challenges in treating heavily calcified iliac arteries?

Dr. Briggs: I am a big proponent of optimizing lower extremity arterial inflow by treating the aortoiliac and common femoral segment. Some of the happiest patients I see back in clinic after an intervention are typically those in whom I have restored flow through this segment. That said, up until a few months ago, there was a subset of these patients in whom I would alter my treatment paradigm. These were patients with severe calcification of the common iliac arteries (CIAs), regardless of TransAtlantic Inter-Society Consensus (TASC) II classification. Severe calcification presents several challenges to endovascular intervention. For one, severe calcification is largely unresponsive to balloon angioplasty.

Dr. Corl: We know that heavily calcified plaque negatively impacts procedural success and long-term durability. Large vessels such as the iliac arteries can be especially challenging. Calcified iliac arteries are at a higher risk of embolization, dissection, and perforation. These complications can be very unforgiving when they occur in the iliac arteries. Treatment options can be limited and often less effective in larger vessels due to equipment specifications such as actual sizes available as well as sheath and guidewire compatibility. Standard balloon angioplasty often requires high-pressure inflations to sufficiently dilate these calcified vessels. Higher-pressure inflations increase the risk of complications. Fibroelastic recoil is common after standard balloon angioplasty in calcified vessels. Atherectomy is typically not a useful or effective treatment option in larger vessels, and stent options are somewhat limited in larger vessels as well. Larger stents, such as covered stents and balloon-expandable stents, often require larger sheaths and are often only available with shorter shaft lengths. Due to these logistics, common femoral artery (CFA) access is typically required to deliver these stents.

> "Large vessels such as the iliac arteries can be especially challenging. Calcified iliac arteries are at a higher risk of embolization, dissection, and perforation." –JD Corl, MD

How do you usually approach treating calcium in the iliac arteries?

Dr. Briggs: Efforts to have the calcification respond to balloon angioplasty may include inflating a semicompliant balloon to extremely high pressures. Unfortunately, the balloon typically overinflates in the more compliant areas of the artery that are not severely calcified, which, in some circumstances, can lead to vessel dissection and rupture. In a high-flow vessel, like the CIA, this can be a life-threatening situation. As this area is also adjacent to the aortic bifurcation, management of unilateral iliac dissection or rupture may require aortic and contralateral iliac intervention with balloon occlusion, stent grafting, or even open conversion.

Dr. Corl: My algorithm starts with imaging with angiography from a radial access approach, followed by intravascular ultrasound (IVUS). IVUS provides an accurate reference vessel diameter and detailed plaque mor-

> "Does one advance and deploy a stent that may poorly expand due to severe calcification or predilate and risk vessel dissection and rupture?" –Charles Briggs, MD

phology. Before the Shockwave L[6] balloon (Shockwave Medical) was available, I primarily used standard balloon angioplasty, often high pressure, followed by stent placement. Occasionally intravascular lithotripsy (IVL) with the Shockwave M[5+] balloon (Shockwave Medical) was an option in patients with smaller than average iliac arteries.

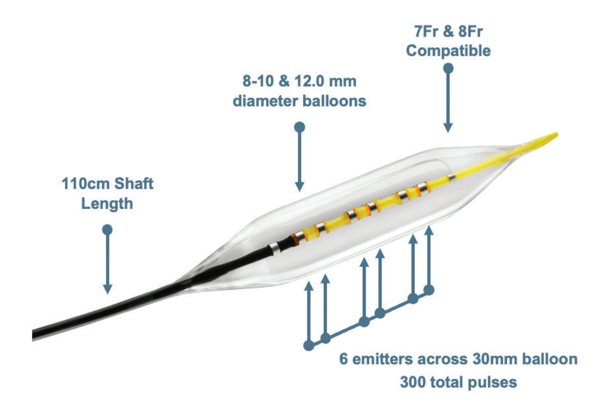
Do you stent in the iliacs? If so, when and why?

Dr. Briggs: Primary stenting of the CIA, particularly with balloon-expandable covered stents, has been shown to be superior to bare-metal stents in complex iliac anatomy since the COBEST trial.[1] In heavily calcified arteries, however, there is a risk of poor stent expansion of any stent. Further, as there is a balloon angioplasty component "baked into" the deployment of these stents, there remains a risk of vessel injury, dissection, and rupture. This risk is heightened by severe calcification. A conundrum is then created—does one advance and deploy a stent that may poorly expand due to severe calcification or predilate and risk vessel dissection and rupture?

Dr. Corl: I routinely use stents when treating the iliac arteries. I prefer balloon-expandable covered stents in the CIAs and self-expanding stents in the external iliac arteries (EIAs). Stents deployed in the CIA and EIA have excellent long-term patency when the stents are sized with IVUS guidance and full stent expansion is achieved. Moderate-to-severe vascular calcium can lead to stent underexpansion and malapposition. Effective plaque modification with IVL allows for full stent expansion without relying on high-pressure predilatation.

How is Shockwave L[6] uniquely positioned to treat calcium in the iliac arteries?

Dr. Briggs: IVL—and the Shockwave L[6] device specifically—has completely changed my management of heavily calcified CIAs. The Shockwave L[6] catheter has uniformed sonic energy output across the entire length of the 30-mm balloon. This length is perfect, as the CIA is not much longer than 30 mm and its lesions are usually focal. The balloons also are at a larger diameter than the Shockwave M[5+], from 8 to 12 mm. This is helpful for lesions in larger-diameter iliac vessels, as in men or in predilating focal iliac lesions for large-bore access for endovascular aneurysm repair, thoracic endovascular aortic repair, or transfemoral aortic valve repair.



Dr. Corl: The Shockwave L[6] balloon has been a welcome addition to my iliac artery treatment algorithm. The balloon diameter range of 8 to 12 mm expands IVL to these large vessels. The 30-mm balloon length is ideal for the iliac arteries. This compact balloon length provides a focused, high-energy profile across the entire length of the balloon. This energy profile modifies both superficial and deep calcium, which improves transmural vessel compliance and decreases fibroelastic recoil. Stent expansion is optimized following effective IVL.

What do you find to be the most important feature(s) of Shockwave L[6] and how would you describe it/their benefit(s)?

Dr. Briggs: As with most devices intended for CIA treatment, the Shockwave L[6] utilizes a 7- or 8-F sheath. It has a 110-cm working length. The balloon catheter is on a 0.018-inch system, which provides moderate support for post-IVL stent deployment. The IVL therapy pressure is as low as 2 atm with a balloon burst pressure of 6 atm. These low pressures, combined with the uniform sonic energy output, provide impactful remodeling of tricky CIA calcified plaque with low risk of vessel injury.

Dr. Corl: The Shockwave L[6] balloon diameter sizes are perfect for the iliac arteries. The larger balloon diameters attain appropriate vessel wall apposition to facilitate effective transmission of sonic energy. The compact emitter profile with six emitters positioned across the 30-mm balloon length creates a high sonic energy output across the length of the lithotripsy balloon. This energy profile reaches and fractures the deep calcium found in these large iliac

> "IVL—and the Shockwave L[6] device specifically—has completely changed my management of heavily calcified CIAs." –Charles Briggs, MD

arteries. The combination of excellent wall apposition with the larger balloons and the deep penetrating energy profile with the compact emitter design allows effective lesion preparation with an ultra-low-pressure inflation. With effective IVL, we can safely achieve full balloon expansion at 2 to 4 atm. The Shockwave L^6 IVL catheters are 0.018-inch guidewire compatible, which provides adequate wire support for iliac artery interventions. The Shockwave L^6 IVL balloon, like the other Shockwave balloons, is straightforward to use on an intuitively simple platform.

How do you generally size in the iliac arteries? What imaging modality do you use for sizing? Does the ultra-low pressure of Shockwave L^6 impact your sizing strategy?

Dr. Briggs: I routinely obtain CTA in any patient with symptomatic aortoiliac artery inflow disease. CTA is helpful to size and strategize for any intervention and to allow for discussion of treatment plans with patients. My approach to treating severely calcified iliac vessels before IVL was either medical management alone, surgical bypass grafting, or performing a relatively risky endovascular intervention. I would primarily stent with a covered balloon-expandable stent and then postdilate, sometimes with high pressures, until there was < 30% residual stenosis and/or a lack of significant pressure gradient across the lesion. Although I have never ruptured a CIA myself, I would be prepared for this complication by utilizing the hybrid operating room with anesthesia as well as having available an aortic balloon occluder and an open instrument tray.

Currently, I cross my lesion with an 0.035-inch wire, upsize to a 7- or 8-F sheath, and exchange to a 0.018-inch wire. I then utilize 0.018-inch IVUS to confirm vessel sizing (from preintervention CTA) and location of landmarks such as the CIA ostia and bifurcation. I predilate a calcified CIA lesion with the Shockwave L^6 IVL catheter at 2 atm and sometimes 4 atm until the balloon fully expands. IVL balloon sizing is at a 1.1 to 1 (balloon-to-artery) diameter ratio. Because of the low inflation pressures, I do not worry about dissection or rupture. I then deploy an appropriately sized balloon-expandable covered stent over the 0.018-inch wire to the CIA ostia or extend into the aorta by 1 to 2 mm. After intervention, I check my work with IVUS and antegrade digital subtraction angiography.[2,3]

> **"Effective plaque modification with IVL allows for full stent expansion without relying on high-pressure predilatation." –JD Corl, MD**

Dr. Corl: I routinely perform IVUS for my peripheral interventions. IVUS provides accurate reference vessel measurements, which is key for sizing balloons and stents. Vessel diameter is often underestimated with angiography, which can lead to undersized balloons and stents. Undersized balloons and stents translate to poor long-term outcomes. IVL balloon sizing is very important. In the iliac arteries, I size the IVL balloon 1:1 (or greater) to vessel diameter based on IVUS measurements. The ability to modify calcified plaque with a low-pressure inflation permits safe IVL therapy with 1:1 (or greater) balloon sizing. Alternatively, high-pressure inflation with a standard balloon sized 1:1 in these densely calcified arteries carries a significant dissection and perforation risk.

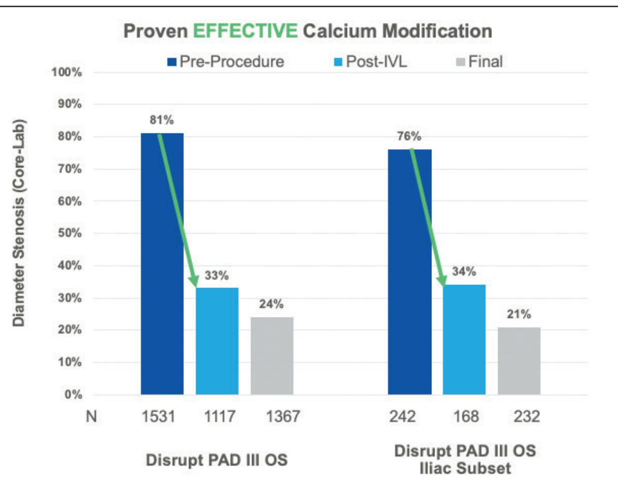
Do you think the use of Shockwave L^6 could impact your decision to stent?

Dr. Briggs: IVL using the Shockwave L^6 balloon catheter has completely changed my treatment paradigm for severe CIA calcification. I have been able to treat

Exceptional SAFETY Profile

	DISRUPT PAD III OS	DISRUPT PAD III OS Iliac Subset
N (Lesions)	1,531	242
Vessels	Iliac, CFA, SFA/Pop, Infrapop	Iliac
Dissection (Type D-F)	0.7%	0%
Perforation	0.2%	0%
Embolization	0%	0%

Final Angiographic Complications (Core-Lab)



Armstrong E, VIVA Late Breaking Clinical and Shockwave-Sponsored Symposium, VIVA 2022

> **"In the iliac arteries, I size the IVL balloon 1:1 (or greater) to vessel diameter based on IVUS measurements. The ability to modify calcified plaque with a low-pressure inflation permits safe IVL therapy with 1:1 (or greater) balloon sizing."**
> **–JD Corl, MD**

more patients with lower morbidity endovascular intervention. The low-pressure, high-sonic energy output of the Shockwave L^{6} balloon remodels calcification in this anatomy in up to 12-mm-diameter vessels, which can then be stented or traversed with large-bore devices. This mechanism allows the provider to worry less about the catastrophic complications of stent compression, vessel dissection, or rupture. Finally, patients will be able to return to clinic happy that their lifestyle-limiting symptoms are relieved after an easily tolerated endovascular intervention.

Dr. Corl: I think I will continue to utilize stents in the CIA and EIA following IVL with the Shockwave L^{6} balloon. Vessel prep with IVL allows for optimal stent deployment in these heavily calcified vessels.

When do you see using Shockwave L^{6} versus Shockwave M^{5+} in the iliac arteries?

Dr. Briggs: The Shockwave M^{5+} balloon can also be useful in the iliacs. I find it to be better in long, calcified lesions where there is not much vessel caliber change like the EIA or femoropopliteal segment. The shorter length of Shockwave L^{6} is perfect for the CIA, as it is not much longer than 30 mm and lesions are usually focal. I also don't need to worry about the shoulders of a longer balloon extending into a smaller-caliber EIA if the balloon is sized to the CIA, as vessel sizes can differ significantly.

Dr. Corl: Vessel diameter is the main consideration. The Shockwave L^{6} balloon is appropriate for iliac arteries > 8 mm in diameter, whereas the Shockwave M^{5+} is suited for vessels < 8 mm in diameter. The Shockwave L^{6} and Shockwave M^{5+} overlap at the 8-mm diameter, and either balloon can be used in an 8-mm-diameter iliac artery. In general, the Shockwave M^{5+} balloon may be better suited for more diffuse iliac disease, where the Shockwave L^{6} is more apt for a focal iliac stenosis. In most iliac arteries, I would typically select the Shockwave L^{6} IVL balloon to take advantage of the deep penetrating energy profile created by the compact layout of the six emitters. Another consideration is that the Shockwave M^{5+} IVL catheter has a 135-cm shaft compared to the 110-cm shaft on the Shockwave L^{6} catheter. The longer shaft on the Shockwave M^{5+} catheter can reach the iliac arteries from a radial access approach, which grants a radial-to-peripheral option for select patients.

There's been significant improvement in Medicare hospital reimbursement for peripheral IVL. Does this impact your access to IVL at your institution?

Dr. Briggs: IVL is now reimbursed at the level of other plaque-modifying devices, like atherectomy, but it is the only plaque-modifying device intended for use in the iliac arteries. At my institution, I had access to IVL for use in the iliac arteries before the new reimbursement paradigm. My partners and I used it for large-bore access to avoid iliac conduit and to increase calcified iliac arterial compliance

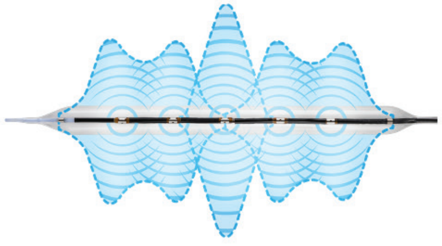
SHOCKWAVE | M^{5+}

Shockwave M^{5+} Specifications

Balloon Diameter (mm)	Balloon Length (mm)	Guidewire Compatibility (in)	Sheath Compatibility	Catheter Working Length (cm)	Max Pulse Count
3.5-6.0	60	0.014	6F	135	300
6.5-7.0	60	0.014	6F*	135	300
8.0	60	0.014	7F	135	300

*6 F Compatible with Terumo Pinnacle® Destination® Guiding Sheath and Cook Flexor® Ansel Guiding Sheath.

Energy Profile[1]

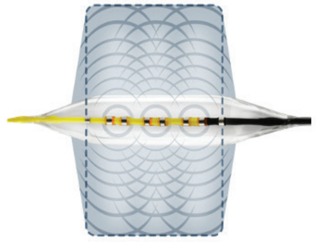


SHOCKWAVE | L^{6}

Shockwave L^{6} Specifications

Balloon Diameter (mm)	Balloon Length (mm)	Guidewire Compatibility (in)	Sheath Compatibility	Catheter Working Length (cm)	Max Pulse Count
8.0 & 9.0	30	0.018	7F	110	300
10.0 & 12.0	30	0.018	8F	110	300

Energy Profile[2]



[1]Kereiakes et. al. Principles of intravascular lithotripsy for calcific plaque modification. J Am Coll Cardiol Intv 2021 | [2]Data on file at Shockwave Medical

before stent deployment. IVL has worked well for us for many years. Before IVL, when treating heavy iliac calcification, there seemed to be a much higher risk of vessel dissection, avulsion, rupture, and/or stent nonexpansion. These have a profound effect on cost, not to mention patient morbidity and mortality. Management of iliac complications, including intensive care unit care, hospital care, and reinterventions, are all quite expensive. So, while it is fantastic that IVL has seen significant improvement in hospital reimbursement, I would use it regardless. The data from DISRUPT PAD support its use. At the end of the day, my job is to do what is best and safest for patients. I would use IVL in stenotic, calcified iliac arteries whether it was reimbursed or not.

Dr. Corl: Fortunately, at The Christ Hospital, access to IVL and other beneficial treatment technologies has always been based on patient need as opposed to relying on financial considerations. That being said, it is a huge plus that IVL reimbursement has improved to take some of the stress off the finances involved in these complex procedures.

1. Mwipatayi BP, Thomas S, Wong J, et al. A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease. J Vasc Surg. 2011;54:1561-1570. doi: 10.1016/j.jvs.2011.06.097
2. Tetteroo E, van der Graaf Y, Bosch JL, et al. Randomised comparison of primary stent placement versus primary angioplasty followed by selective stent placement in patients with iliac-artery occlusive disease. Dutch Iliac Stent Trial Study Group. Lancet. 1998;351:1153-1159. doi: 10.1016/s0140-6736(97)09508-1
3. 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

Severe Aortic and CIA Calcifications; CIA Treated With Shockwave L6 IVL

By Charles Briggs, MD

CASE PRESENTATION

A woman in her early 60s was referred for right lower extremity lifestyle-limiting claudication and ischemic rest pain. She described lifestyle-limiting claudication of the right buttock, hip, thigh, and calf, as well as right foot numbness while in bed at night, which was relieved by getting up and "shaking it off." Her comorbidities included coronary artery disease, heart failure with preserved ejection fraction, chronic obstructive pulmonary disease, atrial fibrillation, hypertension, hyperlipidemia, and type 2 diabetes mellitus. She was an active smoker. She was considered high risk for open surgery. Preoperative workup included an ankle-brachial index (ABI) of 0.42 on the right and 0.81 on the left. CTA of the abdomen and pelvis had been performed in 2019, which revealed severe calcification of the aortic bifurcation and CIAs with associated stenosis (Figure 1).

PROCEDURAL OVERVIEW

The patient was brought to the hybrid operating room, where she was anesthetized generally. Both groins were prepped, bilateral CFA access was achieved, and 5-F sheaths were placed bilaterally. From the left groin, a flush catheter was advanced into the abdominal aorta for aortography (Figure 2), given that there were no prior contrasted imaging results since 2019. From the right groin, I crossed the subtotally occluded CIA in a retrograde fashion with a 0.035-inch stiff straight Glidewire and Glidecath (Terumo Interventional Systems). The sheath was upsized bilaterally to 8 F. The wires were exchanged for 0.018-inch wires over which the IVUS catheter was advanced, which is helpful to confirm true luminal crossing, identify landmarks such as the CIA ostia, and obtain length and diameter measurements. The right CIA was predilated with a

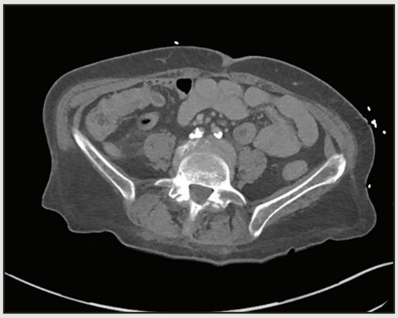


Figure 1. CTA of the abdomen and pelvis showing severe calcification and stenosis of the aortic bifurcation and CIAs.

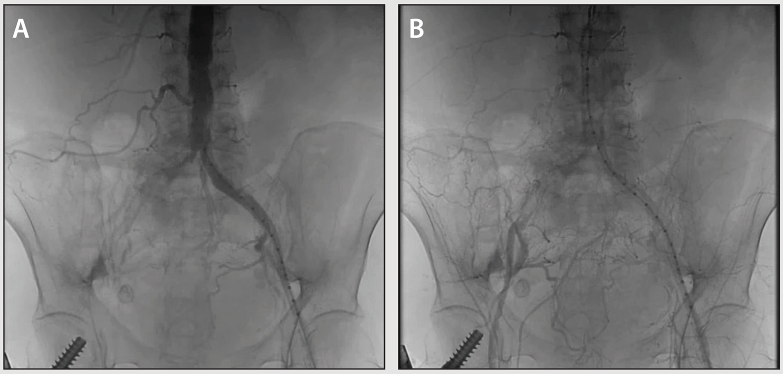


Figure 2. Aortograms demonstrating a nearly occluded right CIA with delayed antegrade filling of the right CIA bifurcation (A, B).

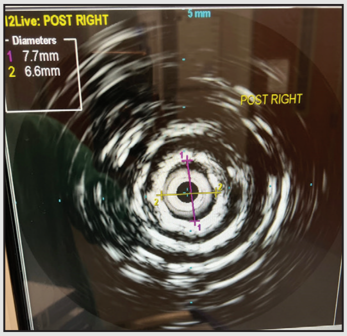


Figure 3. IVUS after treatment with the Shockwave L^6 IVL catheter.

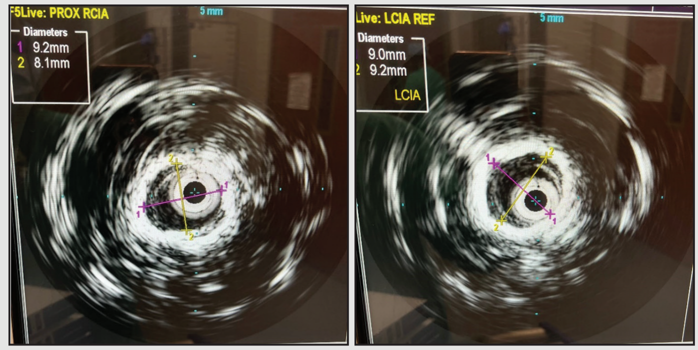


Figure 4. IVUS showing an optimal result of the right CIA stent.

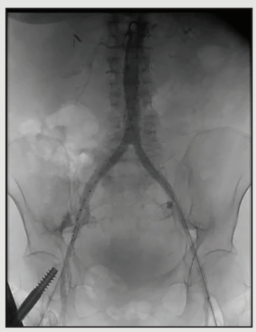


Figure 5. Posttreatment completion aortogram.

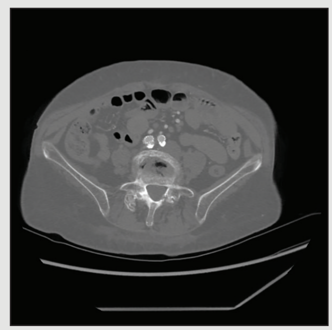


Figure 6. Postintervention CTA demonstrating patent aortic and bilateral CIA stents.

4- X 40-mm balloon, as the IVUS catheter would not initially pass. After predilation, IVUS revealed a > 75% right CIA stenosis. CIA length was also shown to be 46 mm. IVUS also highlighted severe distal aortic stenosis and moderate left CIA stenosis. I elected to proceed with complete endovascular reconstruction of the aortic bifurcation.

Over the 0.018-inch wires bilaterally, I advanced 8.0-mm Shockwave L^6 IVL balloons to the proximal CIA, as maximal iliac diameter was 7.4 mm. IVL was done at 2 and then 4 atm for a total of two inflations. The lesions yielded quickly with the first low (2 atm) pressure inflation, but I elected to reinflate to 4 atm to be extra confident in my upcoming stent deployment. The Shockwave L^6 design was helpful here, as I would otherwise have needed several wire exchanges between 0.035- and 0.014-inch to do IVL and stenting if I had used the Shockwave M^{5+} balloon. I also appreciated the 30-mm Shockwave L^6 design in this case to avoid the shoulders of my balloon potentially causing a dissection in the relatively narrow, chronically underperfused EIAs. With its uniform sonic energy output, the Shockwave L^6 IVL catheter also appeared more powerful, even at much lower pressures. I deployed an 8- X 59-mm Gore Viabahn VBX balloon-expandable covered stent (Gore & Associates) in the distal aorta over the 0.018-inch wire and postdilated it proximally with a 14- X 20-mm Atlas balloon (BD Interventional). The stent had been advanced and deployed through the left groin with the wire pulled back slightly from the right. The wire from the right was now advanced through the true lumen of the stent and confirmed with IVUS, which also showed the result of the right IVL treatment (Figure 3). Bilaterally, I then advanced and deployed 8- X 79-mm Viabahn VBX stents into the distal aortic stent, which also postdilated the distal aortic stent. IVUS was readvanced bilaterally, demonstrating an optimal result of the right CIA stent (Figure 4). Antegrade completion aortogram showed a satisfactory result (Figure 5). After sheath removal, the patient had palpable pedal pulses in both feet. Dual antiplatelet and maximal-dose statin therapy was prescribed.

At follow-up, the patient was asymptomatic from a peripheral artery disease standpoint, with normal ABIs bilaterally. A postintervention CTA demonstrated widely patent aortic and bilateral CIA stents (Figure 6).

Use of Shockwave L^6 IVL in Severely Calcified Iliac Arteries

By JD Corl, MD, FACC, FSCAI

CASE PRESENTATION

A woman in her early 70s was initially referred for evaluation and treatment of severe lifestyle-limiting claudication involving the bilateral lower extremities. Her claudication symptoms had worsened over the past 3 to 4 months. Her past medical history included coronary artery disease, diabetes, hypertension, hyperlipidemia, tobacco abuse, obesity, and a history of a transient ischemic attack. A recent lower extremity duplex ultrasound study revealed monophasic waveforms in bilateral CFAs consistent with significant inflow disease.

PROCEDURAL OVERVIEW

An abdominal aortogram from right radial access revealed a subtotal occlusion of the right CIA and a severe stenosis involving the left CIA (Figure 1). The pigtail catheter was removed, the radial sheath was exchanged for a 119-cm R2P sheath (Terumo Interventional Systems), and 8-F sheaths were placed in the bilateral CFAs using ultrasound-guided access. An invasive arterial blood pressure test obtained in the right EIA showed a severely dampened pressure waveform (Figure 2B). Both CIAs were successfully crossed with 0.018-inch guidewires via the CFA sheaths. IVUS

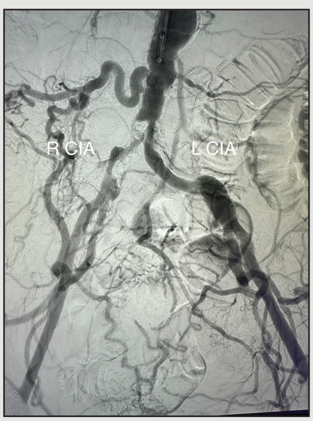


Figure 1. Preprocedural abdominal aortogram.

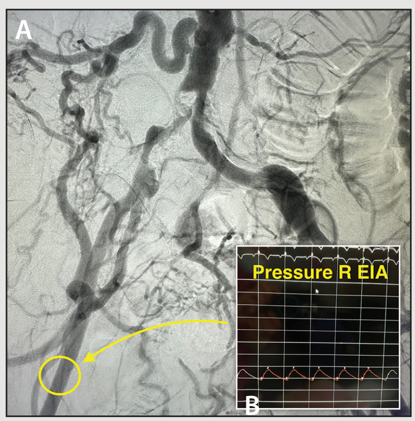


Figure 2. Heavily calcified right CIA (A). Invasive arterial blood pressure test of the right EIA (B).

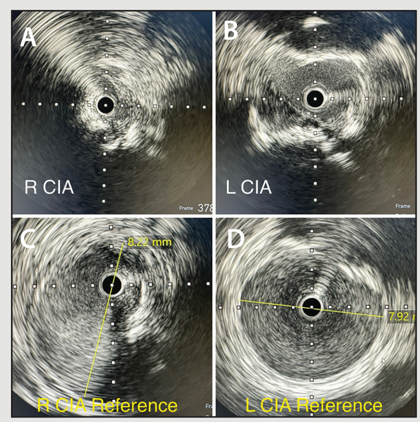


Figure 3. IVUS showing severe calcification and luminal narrowing in the right (A) and left (B) CIA. Reference IVUS images (C, D).

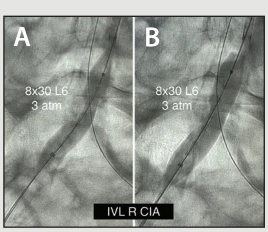


Figure 4. 8.0-mm Shockwave L^6 catheter at 3 atm.

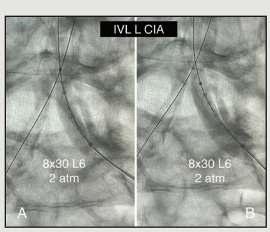


Figure 5. 8.0-mm Shockwave L^6 catheter at 2 atm.

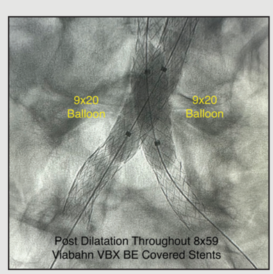


Figure 6. Postdilation of the covered stents.

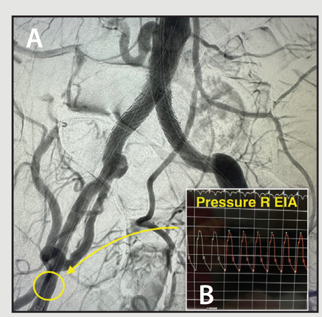


Figure 7. Postintervention angiogram showing an excellent result (A). Improved postintervention invasive blood pressure testing (B).

showed severe calcification and heavy plaque burden with severe luminal narrowing in the right and left CIA (Figure 3A and 3B). The reference vessel diameters were 8.22 and 7.92 mm for the right and left CIA, respectively (Figure 3C and 3D).

IVL was performed on the bilateral CIAs using an 8- X 30-mm Shockwave L^6 catheter, delivering 180 pulses in the right CIA with six low-pressure inflations (Figure 4) and 120 pulses in the left CIA with four low-pressure inflations (Figure 5). All Shockwave L^6 inflations ranged from 2 to 4 atm. A pair of 8- X 59-mm Viabahn VBX balloon-expandable covered stents were introduced and deployed simultaneously in bilateral CIAs extending up into the distal aorta using a kissing technique. Postdilatation was performed throughout both covered stents using two 9- X 20-mm balloons (Figure 6). The postintervention angiogram showed an excellent angiographic result (Figure 7A), with significant improvement and normalization of invasive blood pressure in the right EIA postintervention (Figure 7B).

DISCUSSION

Severely diseased, heavily calcified bilateral CIAs were safely treated with the ultra-low-pressure Shockwave L^6 IVL catheter and Viabahn VBX balloon-expandable covered stents. Alternatively, these calcified stenoses could have been treated with high-pressure standard balloon angioplasty instead of IVL for vessel preparation. However, high-pressure balloon angioplasty in these vessels would carry significant risk of embolization, dissection, or perforation. IVL can effectively modify calcified plaque with low-pressure inflations (2-4 atm), minimizing the risk of complications related to barotrauma secondary to higher-pressure balloon inflations. IVL with the Shockwave L^6 catheter is simple and intuitive. In this case, heavily calcified, severely stenosed CIAs (Figure 1) were successfully modified and prepped with an appropriately sized Shockwave L^6 balloon. After the vessel was safely and effectively prepped with IVL, a pair of Viabahn VBX balloon-expandable covered stents were deployed with full expansion to achieve an excellent angiographic result (Figure 7A). This case further supports that severely calcified iliac arteries can be safely and effectively modified using the Shockwave L^6 IVL catheter to facilitate optimal stent deployment. ■

> **"This case further supports that severely calcified iliac arteries can be safely and effectively modified using the Shockwave L^6 IVL catheter to facilitate optimal stent deployment." –JD Corl, MD**

Disclosures
Dr. Briggs: Paid consultant to Shockwave Medical.
Dr. Corl: Paid consultant to Shockwave Medical.

Views expressed are those of the authors and not necessarily those of Shockwave Medical.

Integrating Shockwave Peripheral IVL Into Our EVAR/TEVAR Practice

Larger sizes now available for large, calcified vessels.

With Angela Giese, MD; Trissa Babrowski, MD; and Ross Milner, MD, FACS

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Tell us a little bit about your abdominal aortic aneurysm (AAA) program at UChicago.

The University of Chicago Center for Aortic Diseases specializes in managing the full range of aortic disease with a recognized track record of success. We often treat complex cases in high-risk patients who were denied care at other institutions. Treatment of patients with AAAs is a large component of our practice. We employ a wide array of techniques from endovascular to traditional open surgical repair as well as hybrid solutions to provide our patients with personalized care. Our groundbreaking research and ongoing clinical trials give us a unique opportunity to work with the latest industry devices and cutting-edge technology to offer comprehensive modern vascular surgery care.

What are the risk factors for AAA?

AAA disease is often referred to as the "silent killer." AAAs are typically asymptomatic until they rupture, which requires emergent surgical intervention, and is often fatal. Given the high proportion of individuals who have an AAA and are asymptomatic, it is important to understand the risk factors for developing an AAA. Patient education and screening for the disease are salient strategies to reduce aneurysm-related mortality. Those at higher risk are patients aged > 65 years with a history of smoking, a positive family history of AAA, and patients with genetic syndromes (ie, collagen vascular disorders). Although more frequently identified in men, women also can develop AAAs. Modifiable lifestyle risk factors that predispose for AAA include uncontrolled high blood pressure, high cholesterol, and tobacco abuse.

What is your algorithm for determining your AAA repair approach (open surgical vs endovascular repair)?

Younger patients who are in good health are frequently reasonable candidates for traditional open surgical treatment, as this method provides the most durable, long-term solution. Older patients and those with significant comorbidities who have the appropriate anatomy for an endovascular approach may be better candidates for an endovascular aneurysm repair (EVAR). We always consider overall patient fitness and anatomy when evaluating each person for an elective aneurysm repair.

How do you go about case planning for EVAR?

First, we consider the patient's age, comorbidities, and anatomic constraints. History of previous surgery, femoral access size and quality, burden of atherosclerotic disease, iliac tortuosity, aortic neck size and length, neck angulation, and thrombus in the neck are important factors when considering a patient for any treatment modality. Based on these factors, we discuss the options with the

> "Iliac rupture, especially when close to the aortic bifurcation, is one of the toughest complications to manage and thus is often fatal."

patient and list the various risks/benefits and long-term expectations for each treatment option. Female patients tend to have smaller arteries than their male counterparts, which may increase the complexity of an endovascular repair in this patient population.

What is your philosophy on access for both EVAR as well as thoracic endovascular aortic repair (TEVAR)?

We typically require an access vessel 6 mm in diameter bilaterally for EVAR delivery, especially on the main body side, and 7 mm on at least one side for TEVAR. For patients who are not candidates for an open operation but have small access, we employ various adjuncts to assist—creation of open and endoconduits, plain old balloon angioplasty (POBA), Shockwave Intravascular Lithotripsy (IVL; Shockwave Medical), or even the use of inferior vena cava for TEVAR deployment.

What factors determine your access approach?

The size and atherosclerotic disease burden of the access vessels dictate our approach. With other factors being equal, we use the larger access vessel to introduce the largest sheath. The presence of atherosclerosis and calcified arteries not only at the point of access but also throughout the iliac arteries can be problematic. Depending on the location, diseased arteries are either treated with open endarterectomy in the common femoral arteries or Shockwave IVL for calcific disease within the iliacs. Adjunctive stenting is also sometimes necessary to facilitate device delivery. If there is minimal calcific disease, we typically predilate the lesion with a standard angioplasty balloon to accommodate the appropriate delivery sheath or device.

What challenges does calcium specifically pose in access?

Calcified plaque is often recalcitrant to traditional POBA, which carries inherent risk. Balloon angioplasty requires high inflation pressures to treat challenging lesions. This results in a high risk of rupture, dissection, and stent fracture within highly calcified arteries. Atherectomy is not indicated in the aortoiliac/femoral segments, and thus this disease pattern is traditionally treated with angioplasty and balloon-expandable stents in an attempt to "crack and pave" the lesions and create an endoconduit. This method is less desirable when EVAR is already planned. Iliac rupture, especially when close to the aortic bifurcation, is one of the toughest complications to manage and thus is often fatal.

When did you start incorporating Shockwave IVL into access? What got you onboard with using IVL for access?

We have been using Shockwave IVL more routinely in our EVAR/TEVAR cases over the last 2 years. We have found that this pretreatment not only facilitates safe navigation of larger sheaths in patients with calcified stenotic iliac arteries but also creates what we think is a more effective seal zone in an otherwise diseased iliac artery. We feel the action of IVL, producing cracks in calcified arteries, improves arterial compliance thus allowing our planned stent to expand more fully as intended. In addition to their ability to crack calcium, we prefer the use of the Shockwave IVL balloons given their low inflation pressures (2 and 4 atm) compared with traditional angioplasty balloons that require higher balloon inflations. This reduces risk of iliac rupture. An additional benefit, in our experience, has been a reduction in limb occlusion. Anecdotally, we have found that disrupting these calcified stenoses with Shockwave IVL reduces the likelihood of recoil within these segments and helps prolong primary patency.

Given your comments on more effective seal zones, are there instances where you use IVL to change compliance of the vessel for better graft deployment versus simply access?

In patients with significant aortoiliac disease and effectively minimal to no "healthy" seal zone, we believe that improving the compliance in the iliacs with IVL facilitates complete stent graft expansion. Anecdotally, we have found that this reduces limb occlusions in this population.

> "We have found that this pretreatment not only facilitates safe navigation of larger sheaths in patients with calcified stenotic iliac arteries but also creates what we think is a more effective seal zone in an otherwise diseased iliac artery."

How have the larger-diameter offerings (8-12–mm diameter balloons) of the Shockwave L⁶ device (Shockwave Medical) impacted your practice?

Larger diameters work great for vessel preparation of calcified iliac arteries prior to EVAR. A length of 30 mm provides the requisite coverage for a standard common iliac artery (CIA) without the unnecessary angioplasty of more distal vessels. With the shorter balloon length of Shockwave L^6, we don't have to worry about inflating in the external iliac artery where the balloon may be oversized for that caliber vessel and put the patient at undue risk. Moreover, the transition to an 0.018-inch platform on the L^6 device has the advantage of improved wire support in tortuous vessels.

Has the availability of IVL minimized your need for complicated access pre-EVAR/TEVAR? What are the benefits?

Yes, 100%. Since integrating IVL into our practice, we rarely have the need to create endoconduits to facilitate EVAR deployment in diseased iliac vessels. This means we can perform the procedure without placing those additional stents, reducing cost. Additionally, avoiding the creation of an open surgical conduit has obvious benefits.

"Since integrating IVL into our practice, we rarely have the need to create endoconduits to facilitate EVAR deployment in diseased iliac vessels."

As device profiles improve, do you still see a role for IVL pre-EVAR/TEVAR?

As long as there is calcified iliac disease, there will be a role for IVL to optimize vessel preparation. If device profiles become significantly smaller and there is no iliac disease, then we don't see a need for IVL in those individuals.

What unmet needs are there still for AAA patients? What new technology do you see as impactful in the space?

Type II endoleaks are the Achilles' heel of EVAR. They are often difficult to treat and draw considerable resources to manage. New technology within this space would be very useful. Decreasing device profile is an obvious benefit to prevent prolonged limb ischemia and iliac complications in patients with smaller access.

CASE 1: USE OF SHOCKWAVE IVL IN A TORTUOUS AND CALCIFIED LEFT EIA DURING COMPLEX EVAR

By Trissa Babrowski, MD

CASE PRESENTATION

A woman in her late 60s presented for evaluation of an asymptomatic pararenal AAA and bilateral CIA aneurysms. Her past medical history was pertinent for dementia, hypertension, and hyperlipidemia. Her surgical history included an abdominal hysterectomy. She was a former smoker. Recent CTA showed an interval increase in her pararenal AAA to 5.5 cm (from 5.0 cm) and bilateral CIA aneurysms, with the left measuring 3.6 mm (from 2.7 mm) and the right 3.1 mm (from 3.1 mm). Given the rate of expansion over 8 months, particularly of her left CIA aneurysm, we recommended proceeding with repair. We discussed the options including an endovascular approach, open surgery, and observation. The patient's family member elected to proceed with an endovascular approach.

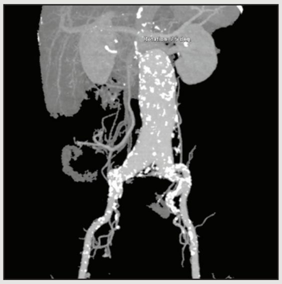

Figure 1. Pararenal AAA with bilateral CIAs and bilateral iliac calcification.

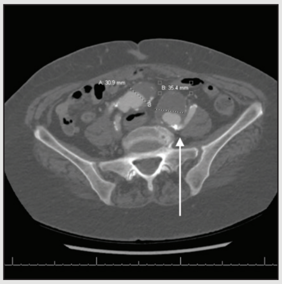

Figure 2. Bilateral CIA aneurysms. The arrow depicts the origin of left EIA making a hairpin turn with a severe calcified preocclusive stenosis.

PROCEDURAL OVERVIEW

Endovascular repair presented several challenges given her anatomic constraints and calcified arteries (Figure 1). The suprarenal neck anatomy was not ideal given some dilation at this level. Unfortunately, the

Figure 3. Angiogram after Shockwave IVL of the left EIA origin.

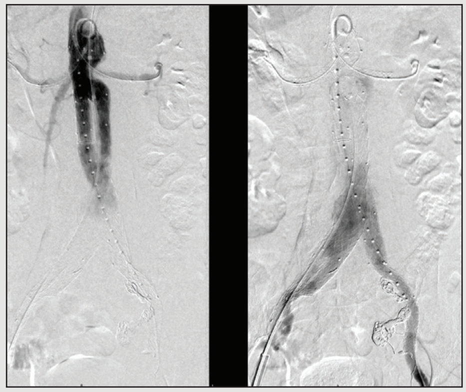

Figure 4. Completion angiogram. Left side shows top of graft and right side shows filling of right IBE and left EIA stent graft. Also note small gutter leak evident on the right image.

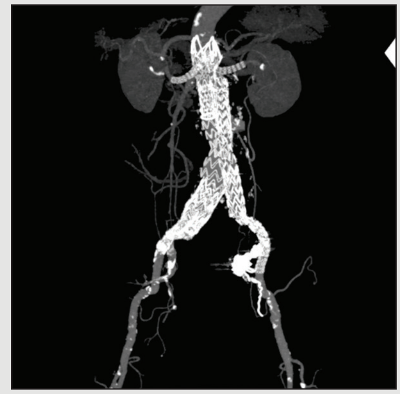

Figure 5. One-month postoperative CTA.

patient was not a candidate for a fenestrated repair due to neck angulation. The risks and benefits of a two-vessel versus four-vessel parallel grafting endovascular aortic repair (chimney EVAR) were discussed. Her bilateral CIA aneurysms also met size criteria for repair. She was a candidate for unilateral iliac branch endoprosthesis (IBE) on the right but would require coil and coverage of the left hypogastric artery. We also planned to use Shockwave IVL at the origin of the left external iliac artery (EIA) given the hairpin tortuosity and calcified stenosis at this location (Figure 2). In light of her comorbidities, the family wished to proceed with the lowest-risk procedure. Thus, the tentative plan was to treat with an aortic device to the level of the superior mesenteric artery (SMA) with placement of two chimney renal stents, a right IBE, left EIA IVL, and left hypogastric coil and coverage.

Intraoperatively, initial attempts to advance catheters and wires via a left iliac approach were unsuccessful due to significant stenosis within the distal left CIA and proximal EIAs. Eventually, a 0.014-inch wire was advanced up the left side and an 8-mm Shockwave M^{5+} IVL catheter (Shockwave Medical) was positioned across the stenosis. After performing IVL, our ability to track the larger sheath improved (Figure 3). Subsequently, we were able to perform left hypogastric coiling, right IBE placement, placement of two renal snorkel stents, and EVAR. A small gutter leak was identified on completion angiogram (Figure 4), which later resolved. Her postoperative course was uncomplicated, and the patient was discharged on postoperative day 2. She represented for follow-up at 1- and 6-month intervals with evidence of a small type II endoleak but reducing AAA sac sizes at 4.32 cm (from 5.5 cm) (Figure 5). Iliac stent seal was excellent, with no evidence of kinking or fracture within the left EIA hairpin turn (Figure 6). Her type II endoleak is being observed.

Figure 6. Bilateral CIA aneurysms with patent stent graft flow. No evidence of kinking.

CASE 2: CALCIFIED CIAs TREATED WITH SHOCKWAVE IVL AS VESSEL PREPARATION PRIOR TO EVAR

By Ross Milner, MD, FACS

CASE PRESENTATION

A man in his early 80s presented with an expanding 5.7-cm AAA and calcified iliac arteries. He had a medical history significant for hypertension, hypercholesterolemia, and was a former smoker. CTA showed an infrarenal AAA with extensive circumferential mural thrombus. There was significant atherosclerotic calcification of the abdominal aorta and its branches (Figure 1). There was also little visualized flow within the bilateral internal iliac arteries, but these were not thought to be occluded (Figure 2). The risks and benefits of EVAR were explained to the patient. Given his exceptionally calcified CIAs, we planned to use Shockwave IVL in order to safely place the aortic device.

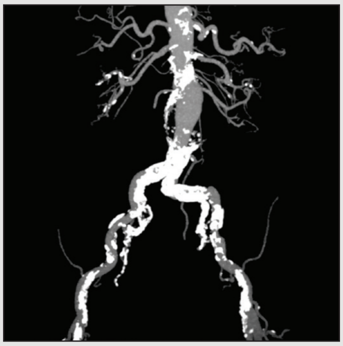

Figure 1. AAA and severe bilateral calcified iliac disease.

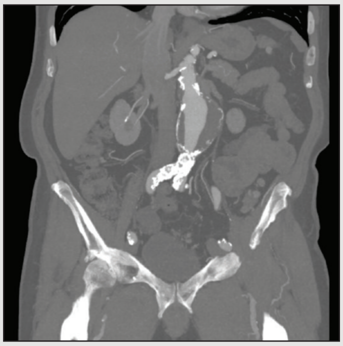

Figure 2. AAA and severe bilateral calcified iliac disease with patent flow throughout the iliac segment.

PROCEDURAL OVERVIEW

Intraoperatively, after the appropriate access was obtained, an exchange was then made for a 0.014-inch Hi-Torque Spartacore (Abbott) wire bilaterally. We then placed bilateral 8-mm Shockwave M^{5+} catheters. These were initially deployed into the CIAs. They were inflated to 4 atm, and four separate cycles of IVL treatments were performed. The IVL catheter was then retracted into the distal CIAs and proximal EIAs, and four additional cycles of IVL treatment were performed. Following IVL treatment, the iliac arteries were now appropriately large enough to accommodate larger sheaths and the aortic device (Figure 3). The EVAR was then completed without difficulty. Completion angiography showed patent renal arteries and flow throughout the graft without evidence of endoleak (Figure 4).

The patient recovered uneventfully and was discharged on postoperative day 1. The patient presented 2 months postoperatively with a decreasing AAA sac size measuring 5.5 cm and a patent EVAR stent with no evidence of endoleak (Figure 5).

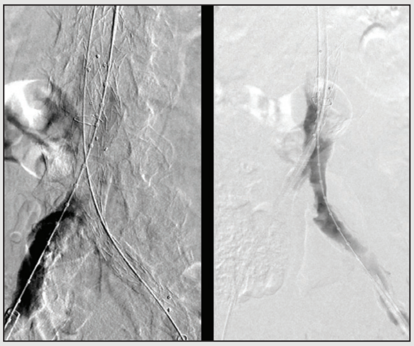

Figure 3. Angiogram after Shockwave IVL of the bilateral CIAs and deployment of the aortic device. Right CIA and left CIA depicted on the left- and right-hand fluoroscopic images, respectively.

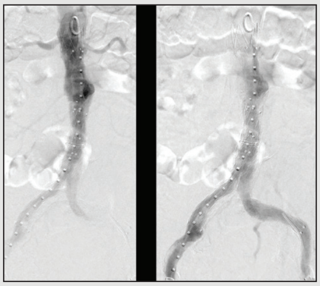

Figure 4. Completion angiogram with patent renal arteries (left) and flow throughout the graft without evidence of endoleak (right).

Figure 5. Postoperative CTA with patent EVAR and no evidence of endoleak. Patent right limb (left side) and patent left limb (right side).

CASE 3: AN ENLARGING AAA WITH SEVERE BILATERAL ILIAC ARTERY CALCIFICATION PRETREATED WITH SHOCKWAVE IVL

By Ross Milner, MD, FACS

CASE PRESENTATION

A man in his early 70s presented with a known slowly enlarging juxtarenal AAA. The patient remained asymptomatic but now meets criteria for repair at 5.6 cm. His past medical history included chronic obstructive pulmonary disease, hypertension, and present tobacco abuse. Of note, the patient just completed a course of pulmonary rehabilitation. Imaging showed a partially thrombosed infrarenal AAA measuring up to 5.6 cm (Figure 1). The focal outpouching consistent with penetrating aortic ulcer in the proximal portion of the aneurysm was new from prior imaging. Severe atherosclerotic disease of the vasculature was present and most severe in the proximal right CIA (Figure 2). In the setting of his age and comorbidities, we discussed the risks and benefits of EVAR. Given his aortoiliac disease, we discussed the possibility of femoral-femoral bypass and uni-iliac device if we were unable to insert a bifurcated device. In addition to EVAR, our operative plan included the use of IVL for his calcified occlusive disease and more flexible Viabahn VBX balloon-expandable stents (Gore & Associates) as the limbs of the endograft.

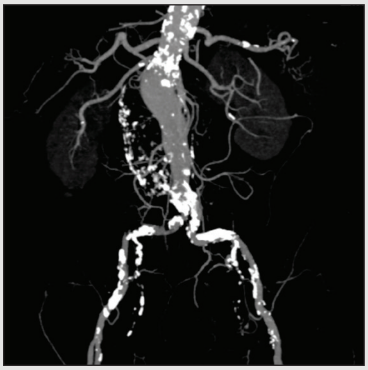

Figure 1. AAA and calcified atherosclerotic disease throughout the aorta and its branches.

Figure 2. Preoperative CTA showing severe calcification of bilateral iliac arteries.

Figure 3. Intraoperative bilateral retrograde angiograms before Shockwave IVL. Note the diseased bilateral CIAs.

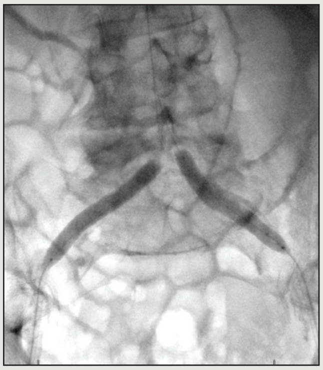

Figure 4. Shockwave IVL angioplasty of bilateral CIAs.

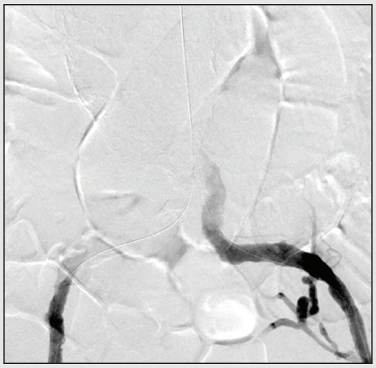

Figure 5. Post-Shockwave retrograde iliac angiogram showing improvement in vessel caliber in the left CIA.

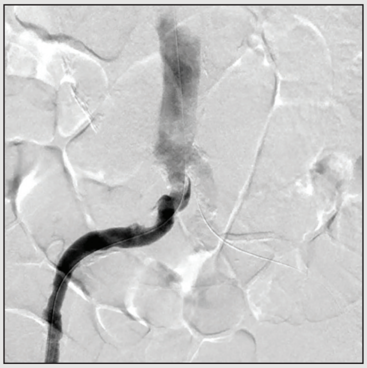

Figure 6. Post-Shockwave retrograde iliac angiogram showing improvement in vessel caliber in the right CIA.

Figure 7. Completion angiogram revealed a type Ia endoleak.

Figure 8. Angiogram after EndoAnchor placement showing a diminished type Ia endoleak.

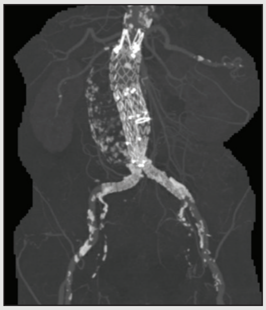

Figure 9. Postoperative CTA at 1 month showing a patent EVAR and no evidence of endoleak.

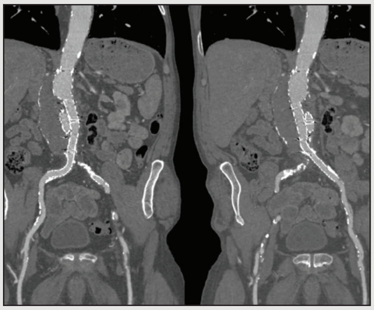

Figure 10. Postoperative CTA at 1 month with excellent seal of bilateral iliac limbs and no evidence of compression or endoleak.

PROCEDURAL OVERVIEW

Intraoperatively, after the appropriate access was achieved, we performed retrograde angiograms of the right and left iliac arteries to assess the degree of disease (Figure 3). It was obvious that pretreatment of the iliac stenoses would be required prior to advancement of the graft. We advanced a 0.014-inch wire bilaterally and then inserted bilateral 8-mm Shockwave M^{5+} catheters. These were used in the CIAs on both sides (Figure 4). After performing IVL for the maximum amount that the balloons could be utilized on both sides (300 pulses total), significant improvement was seen such that endograft placement was possible (Figures 5 and 6).

On the left side, a serial dilation was performed with 12-, 14-, and 16-F sheaths. On the right side, a 12-F sheath was inserted into the abdominal aorta. The 16-F sheath was then removed from the left common femoral artery, and the main body device was advanced without difficulty. The contralateral gate was cannulated and then extended with a 10- X 82-mm limb. This was specifically deployed above the aortic bifurcation. We then advanced an 8- X 79-mm balloon-expandable Viabahn VBX. This was left undeployed to allow for enough space at the aortic bifurcation to complete the delivery of the device on the other side. The main body device and ipsilateral limb were then completely deployed and removed without difficulty. A 16-F sheath was then inserted. We were able to extend with a 10- X 82-mm limb on this side as well. This came down to just above the aortic bifurcation and matched nicely with the other limb. We selected a 9- X 79-mm balloon-expandable Viabahn VBX for the left side. Both balloon-expandable VBX stents were then deployed simultaneously. The proximal neck and all overlap sites were then ballooned. Angioplasty of the VBX stents was performed in a kissing balloon fashion from the bifurcation of the device all the way to the end of the iliac limbs. The iliac stents opened up very nicely. On completion angiography, the patients had evidence of a type Ia endoleak (Figure 7). Nine EndoAnchors (Medtronic) were placed with significant improvement of endoleak (Figure 8).

The patient had an uneventful recovery and was discharged on postoperative day 3. Postoperative CTA at 1 month showed a patent EVAR with decreasing AAA sac measuring 5.3 cm and no evidence of endoleak (Figures 9 and 10). ■

Disclosures
Dr. Giese: Paid consultant to Shockwave Medical.
Dr. Babrowski: Paid consultant to Shockwave Medical.
Dr. Milner: Paid consultant to Shockwave Medical.

Views expressed are those of the authors and not necessarily those of Shockwave Medical.

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