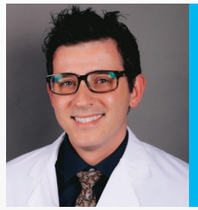
# Intravascular Lithotripsy for Critical Limb Ischemia



## Treatment of Challenging Below-The-Knee Calcium

Michael Meuse, MD
*Vascular and Interventional Specialists*
*Charlotte Radiology*

**Case Review:**
The patient is an 81-year-old female with history of hypertension, coronary artery disease, and congestive heart failure. She has a distant smoking history. She is not diabetic and renal function is normal.

She presented to our Interventional Radiology Clinic as a referral from wound care with an ischemic ulceration of the left great toe, non-healing over a four-week period initially felt to have started as a minor injury/scratch (Figure 1).

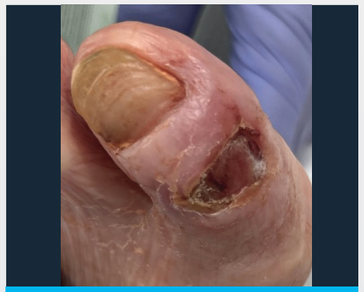


***Figure 1:*** *Left great toe ischemic ulceration on the day of revascularization*

On exam her left femoral and popliteal artery pulses are palpable, but pedal pulses non-palpable but audible by doppler. Her arterial duplex ultrasound showed multiphasic waveforms across the left femoropopliteal segment but monophasic blunted waveforms at the left ankle stations.

She was taken to angiography with left common femoral artery puncture for anterograde approach. Her diagnostic angiogram showed patency of the left superficial femoral and popliteal arteries. Her tibial station (Figure 2) showed severe tibial disease with no continuous patent runoff to the foot and multiple collaterals. The anterior tibial artery was occluded over a long segment with no distal reconstitution and non-opacification of the dorsalis pedis. The tibioperoneal trunk showed a critical greater than 90% stenosis. The peroneal artery was severely diseased and occluded proximally. The posterior tibial artery reconstituted proximally and was otherwise patent to the foot, providing best perfusion to the forefoot via the plantar arch.

**Figure 2.** Left tibial station angiogram (A. anteroposterior proximal calf and B. lateral foot) shows severe tibial disease with chronic occlusion of the anterior tibial artery and critical stenosis of the tibioperoneal trunk (arrow head).

The posterior tibial artery serves as sole runoff supplying forefoot perfusion.

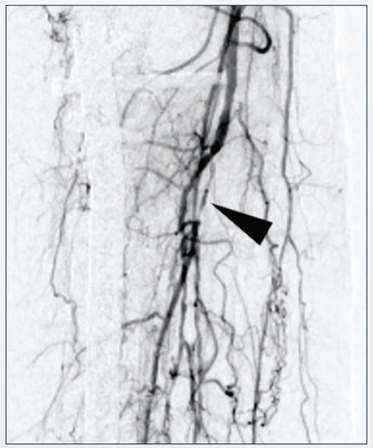


*Figure 2 A*

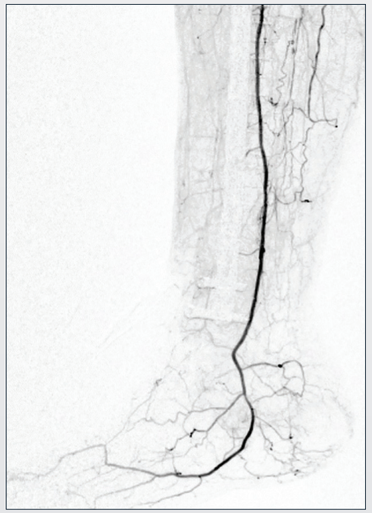


*Figure 2 B*

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A 6 French 25cm length sheath was placed at the access site and 5000 units intraarterial heparin administered. The TP trunk lesion was crossed using a 0.014" Glidewire Advantage with the support of an 0.014" CXI catheter. Underlying severe parallel wall and near napkin-ring calcification was present at the TP trunk lesion by fluoroscopy (Figure 3) and decision was made for treatment using intravascular lithotripsy balloon angioplasty. The Shockwave S⁴ 3 x 40mm balloon was inflated to 4 ATM with a total of three separate inflations and energy depositions across the TP trunk lesion, 60 pulses in total. No pre or post lithotripsy treatments were required.

**Figure 3.** A. The lesion was crossed using a 0.014" Glidewire Advantage. B. Heavy parallel wall calcification is present along the lesion by spot fluoroscopy. C. A 3 x 40mm Shockwave S4 balloon was inflated across the lesion for intravascular lithotripsy treatment with resultant D. restored wide patency at follow-up angiography.

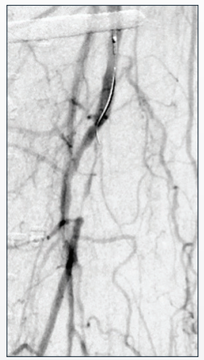

*Figure 3 A*

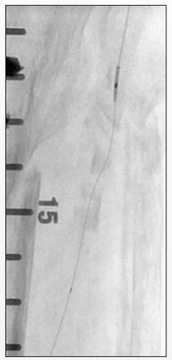


*Figure 3 B*

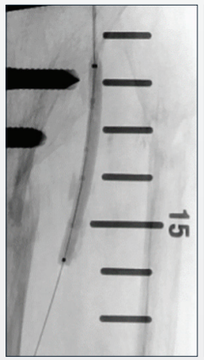


*Figure 3 C*

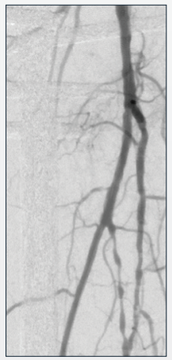

*Figure 3 D*

**Figure 4.** Left great toe ischemic ulceration healed at three-month clinical follow-up.

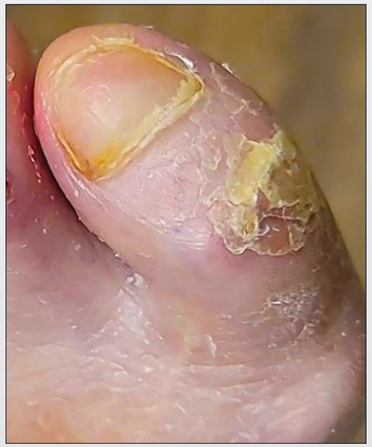

*Figure 4*

**Results:**
At follow up angiography there was excellent restored patency across the TP trunk with a restored palpable pulse at the left ankle. By two-dimensional iFlow perfusion imaging analysis there was improved peak perfusion transit time calculated at 6.3 seconds. Clopidogrel was added to the patients pre-existing aspirin regimen and continued until complete wound healing was achieved at about 3 months post intervention (Figure 4).

**Discussion:**
This case demonstrates the safety and effectiveness of the Shockwave balloon in providing limb preservation in a patient with CLTI as a standalone endovascular therapy. Often the most calcified tibial disease is accompanied by the most limited intrapedal outflow.

Shockwave offers a safe option in the treatment of severely calcified tibial arteries with patients with limited outflow as in the case above. The 0.014" platform should be familiar to any operator with experience with below-the-knee disease and ease of setup and use akin to balloon angioplasty adds little intra-procedural burden in often complex CTLI cases, or any case with severely calcified arterial disease.

SHOCKWAVE PERIPHERAL IVL

# Intravascular Lithotripsy for Critical Limb Ischemia

## Restoration of Flow in Popliteal CTO

Raj Pyne, MD, FSIR
*Division of Interventional Radiology*
*Program Director / Interventional Radiology Residency*
*Medical Director / Vein Treatment Center*
*Rochester Regional Health*
*Rochester, New York*

**Case Review:**
61 year old male with a history of PAD, smoking, DM, Bell's palsy, CKD, DVT, and prior CVA presents with Rutherford 5 PAD in the right lower extremity and severe worsening claudication at rest. Physical exam shows nonhealing wounds the size of dimes on the right heel and posterior ankle (Figure 1), sloughing skin, dry gangrene on the great toe, and cool right foot without palpable dorsalis pedis (DP) or posterior tibial (PT) pulses and only faintly noted pulses on Doppler.



***Figure 1:*** *Left great toe ischemic ulceration on the day of revascularization*

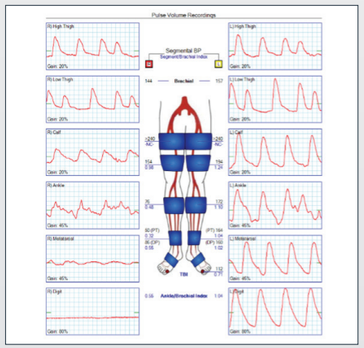

*Figure 2. ABI/PVR showing right femoropopliteal disease with ABI of 0.55.*

ABI of the right leg was 0.55 (Figure 2) and MRI demonstrated no evidence for osteomyelitis. CTA showed long segment chronic total occlusion (CTO) of the P1 and P2 segments of the right popliteal artery. Sagittal CTA 3-D vessel analysis reconstruction (Figure 3)

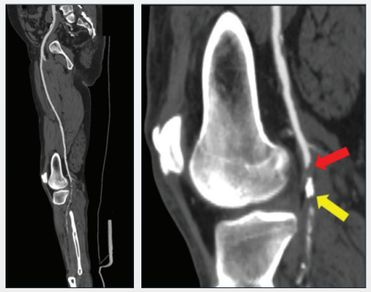

*Figure 3. Vessel analysis reconstruction shows CTO at P1 segment (red arrow) and eccentric plaque at the P2 segment (yellow arrow)*

demonstrated complete occlusion in the P1 segment (red arrow) secondary to a bulky eccentric atherosclerotic plaque in the P2 segment (yellow arrow). 3-D volumetric MIP reconstructions confirm the significant calcium plaque causing the occlusion.

Angiography confirmed complete occlusion at the right P1 segment of the popliteal artery secondary to a heavily calcified eccentric plaque just distal in the P2 segment with prominent geniculate collaterals providing poor flow below the knee (Figure 4).

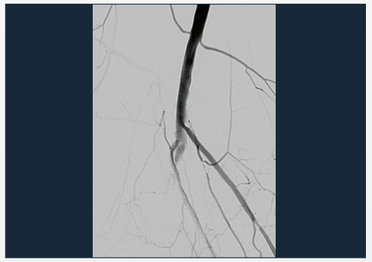

*Figure 4. Angiography showing CTO at P1, and heavy calcium at P2*

After crossing the CTO, initial treatment was attempted using plain old balloon angioplasty (POBA) with a 4mm high-pressure angioplasty balloon. However, the balloon could not be passed across the tight calcified lesion, and therefore a low-profile 2mm balloon was used to predilate. POBA was then performed with the 4mm high-pressure balloon with significant waist during inflation secondary to the heavily calcified plaque that could not be effaced despite inflating balloon past burst pressure. Follow-up angiography demonstrated minimal improvement of flow with a residual 95% stenosis (Figure 5).

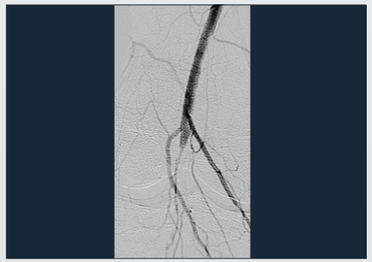

*Figure 5. Post-POBA angio showing 95% residual stenosis*

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The decision was made to use Shockwave intravascular lithotripsy using a 4.5x60mm Shockwave M$^{5+}$ balloon 300 pulses were given over multiple sites, mostly centered on the heavily calcified plaque in the P2 segment (Figure 6).

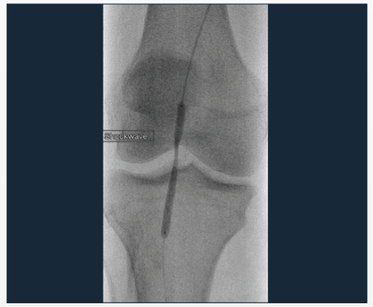

*Figure 6. 4.5x 60mm Shockwave M$^{5+}$ catheter used in P1 and P2 segments. 300 pulses given.*

**Results:**
Completion angiography demonstrated a 60% residual stenosis but with marked improvement allowing for restoration of in-line flow to a three-vessel runoff (Figure 7).

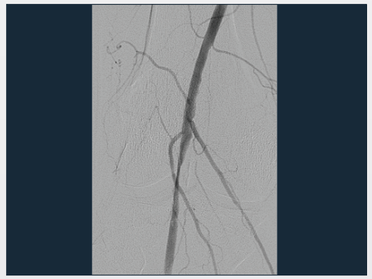

*Figure 7. Post-procedure angiogram showing restoration of in-line flow and no dissections, perforations, or distal embolization.*

Of note, the collaterals were markedly reduced due to the in-line flow. Moreover, there were no complications including no evidence for dissection, distal embolization, nor perforation. Most importantly, no bailout stent placement was required at this knee flexion point, mitigating the risk of future stent fracture or occlusion. Much of that residual stenosis was noted to improve after working on the infrapopliteal segments, consistent with vasospasm, and therefore nitroglycerin was injected intraarterially prior to removal of all catheters and wires.

The patient was noted to have restoration of strong palpable DP and PT pulses in the IR recovery area immediately following the procedure. He was noted to have resolution of his rest claudication by the next day. Follow-up clinic visits confirmed improvement and ultimately resolution of both the dry gangrene and the heel ulcers. (Figure 8) After one year, patient has had sustained clinical success including walking up to 2 miles without pain and no recurrence of any ulcers or wounds.

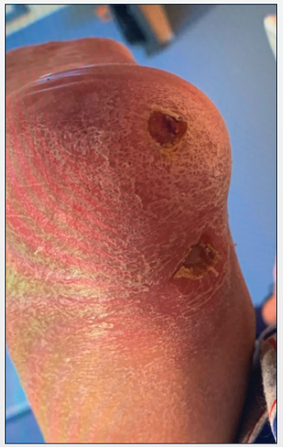

*Figure 8. One month*

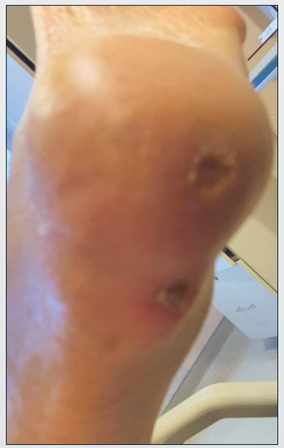

*Figure 8. Three months*

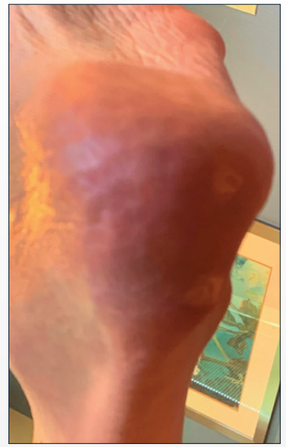

*Figure 8. Six months respectively*

**Discussion:**
In this case, Shockwave intravascular lithotripsy was utilized for a multitude of reasons. In this patient with few remaining treatment options, it was critical to be able to revascularize the lower leg as surgical bypass was not an option, leaving amputation as a real possibility if endovascular techniques failed. Additionally, for long-term success, it was strongly preferable to not place a stent in the popliteal artery due to risk of fracture or in-stent occlusion.

Treatment options on the table included a cutting balloon, which would address fracturing the superficial calcium but introduces a high risk for perforation and/or dissection, and therefore was not used. Drug-eluting balloons would have a low chance of success given the inability of the POBA balloon to fully efface the waist despite very high pressures, and therefore were not used. Finally, atherectomy devices were considered but would only address superficial calcium, thus likely only adding minimal intraluminal gain while adding a significant risk for complication, especially for distal plaque fragment embolization.

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**Conclusion:**

Shockwave IVL has become a mainstay of PAD and CLTI treatments in our practices. The learning curve is straightforward as anyone who has previously used angioplasty balloons will find it familiar. It has a low profile for crossing, is quick to deliver pulses with the new Shockwave M$^{5+}$, and has a great safety profile minimizing risk of iatrogenic dissection, perforation, and distal emboli while typically resulting in high technical success in regards to restoration of flow[1]. Bigger diameters and longer working lengths have resulted in more convenience and utility. Thus, for our practices, Shockwave IVL has become the front line treatment option for heavily calcified stenoses and occlusions in the iliacs, CFA, SFA, popliteal artery, and below the knee.

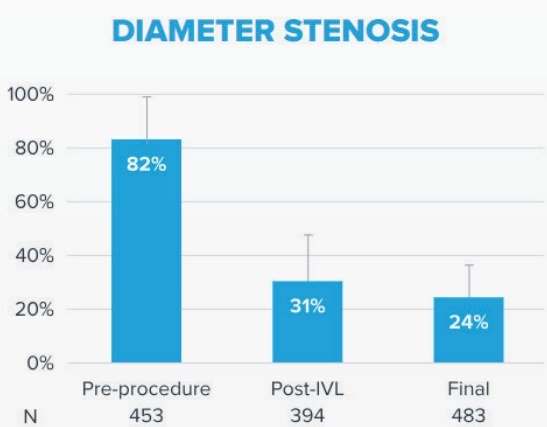
[1] *Tepe et al. JSCAI, 2022.*

## SHOCKWAVE IVL IS PROVEN SAFE AND EFFECTIVE IN CLI PATIENTS

### Angiographic Outcomes

Core Lab Adjudicated

| Complications | Post-IVL N=394 | Final N=482 |
|---|---|---|
| Dissections D-F | 1.8% | 0.8% |
| Perforation | 0% | 0.4% |
| Distal Emboli | 0.3% | 0% |
| Slow Flow/No Reflow | 0.3% | 0% |
| Abrupt Closure | 0% | 0% |




*P. Soukas, Late Breaking Trial AMP 2022*

Dr. Meuse and Dr. Pyne are consultants of Shockwave Medical.

**Important Safety Information**

**Peripheral IVL**

Shockwave M$^{5+}$, Shockwave M$^{5}$, Shockwave S$^{4}$ and Shockwave L$^{6}$ 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, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.

Contraindications—Do not use if unable to pass 0.014″ (M$^{5}$, M$^{5+}$, S$^{4}$) or 0.018″ (L$^{6}$) 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.
**https://discover.shockwavemedical.com/ifu**

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave S$^{4}$, Shockwave M$^{5}$ and Shockwave M$^{5+}$ instructions for use containing important safety information.



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