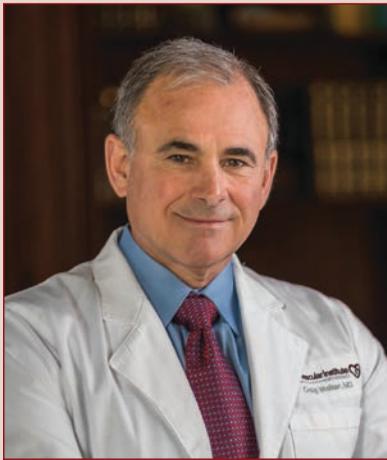


## Caught Between a Rock and a Hard Place



**Craig Walker, MD, FACC, FACP**  
**Clinical Editor**  
**Interventional Cardiologist**  
**Founder, President, and**  
**Medical Director**  
 Cardiovascular Institute of the South;  
 Clinical Professor of Medicine  
 Tulane University School of Medicine  
 Louisiana State University School  
 of Medicine

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up to 50 atmospheres of approximately 5 microseconds in duration. These waves travel through a mixture of saline and contrast in the balloon. Once the connections are made, the device is advanced over a 0.014" guidewire across the lesion and the balloon, filled with saline and iodinated contrast, is inflated to approximately 4 atmospheres to create vascular contact. The emitters are then activated for a prespecified cycle time (10 seconds in coronary arteries and 20 seconds in peripheral vessels). If inadequate expansion occurs, the balloon is inflated to higher pressures and the sequence repeated. This process continues until successful dilation occurs or, in rare cases, if it fails to expand at maximum-rated inflation pressures or a maximum number of impulses. The catheters are limited to a total of 80

Hello and welcome to the March 2022 edition of *Vascular Disease Management*. I have decided to comment on Dr. Qais Radaideh and colleagues' case report, "Shockwave Lithoplasty as the Last Option to Restore Flow in a Nonagenarian With an Acute Coronary Syndrome."

I have titled this "Caught Between a Rock and a Hard Place" because extensive dystrophic vascular calcification within atherosclerotic segments is reported in approximately one-third of coronary artery lesions and one-half of peripheral arterial obstructions. Calcification, particularly when it is dense and circumferential, is associated with negative prognostic significance in coronary and vascular arterial interventions. It is associated with greater risk of dissection and inadequate expansion of stenotic or obstructive lesions with balloon angioplasty and stenting. Calcified segments treated with intervention are more likely to develop restenosis and, ultimately, occlusion. Vascular perforation with potentially catastrophic results is more common than it is in noncalcified vessels. Historically, atherectomy has been utilized in calcified segments to remove tissue and improve compliance of the diseased arterial segment. Although atherectomy can dramatically improve the initial result in calcified lesions, it adds cost and complexity, and significantly increases the risk of arterial perforation.

In this report, an older patient with acute coronary syndrome presented with a calcified lesion in the left anterior descending coronary that did not yield to high-pressure balloon dilation. The vessel subsequently occluded post standard balloon angioplasty with a large dissection precluding atherectomy. Attempts at crossing the lesion with focal force balloons were unsuccessful. The authors were able to successfully cross and dilate the coronary artery obstruction utilizing a Shockwave lithoplasty balloon. This allowed subsequent stent delivery and expansion, resulting in a favorable clinical outcome in this very high-risk patient.

I have chosen to comment on this case report as the Shockwave lithoplasty balloon is a novel FDA-approved device designed to effectively dilate calcified arterial lesions. The Shockwave system consists of 3 parts: an intravascular lithotripsy (IVL) generator, a connector cable, and the IVL catheter with an array of integrated lithoplasty emitters mounted on the catheter's distal segment within a balloon. When electrical energy from the IVL generator is delivered to the catheter, acoustic waves are sequentially created from the impregnated linear sequenced emitters in the catheter. The resultant acoustic shock waves can create pulses of atmospheric pressures of

total pulses in coronary arteries or 180 pulses in peripheral arterial segments. Coronary catheters have 3 emitters, and the peripheral lithoplasty catheters have 5 emitters. The catheters come in a wide array of balloon diameters, but the longest balloon length is 6 cm, which is somewhat suboptimal in peripheral vascular intervention when one is treating long-segment disease.

In the Disrupt CAD and Disrupt PAD trials, the Shockwave IVL system demonstrated improved initial angioplasty results with less risk of dissection and perforation than conventional balloon angioplasty when treating calcified arterial obstructive lesions. These devices are being used successfully to dilate lesions with a better initial angioplasty result and very low risk of vessel perforation. As compared with atherectomy, the lithoplasty balloon is easier to use and has less risk of perforation. When treating coronary lesions, occasionally predilation with a standard small lower profile balloon is required to subsequently deliver the device.

Although the initial results have been promising, we have more to learn about when and how to ideally utilize the IVL device. We must better define and document whether calcium is localized or circumferential, as well as if it is luminal, medial, or both, if we are to definitively discern the most appropriate indications. We will need to determine if lithoplasty is a definitive therapy or if it is predominately a better preparation device for subsequent potential definitive therapy such as drug-coated balloons or stents. We must determine whether the tissue removal associated with the use of atherectomy devices has any evidence of better long-term patency than lithoplasty secondary to enhanced drug uptake or less late-term vascular remodeling. We must determine if the 50 atmospheres of pressure created by the acoustic impulses will have associated deep arterial injury that may ultimately be manifested as restenosis weeks or months following treatment. Hopefully, ongoing studies will provide greater evidence of how to best utilize these devices.

Controlled trials of various atherectomy devices vs lithoplasty as well as trials where atherectomy or lithoplasty, if followed by drug-eluting stents, are needed to ultimately determine best practices. We need to determine if IVL therapy is simply a better vessel preparation tool, which of course is still vital, or definitive therapy. We will need to determine whether there is greater benefit than is associated with successful high-pressure noncompliant balloon angioplasty preparation.

Lithoplasty has many desirable traits: It is easy to use, it seems to be associated with a low incidence of complications, and it often yields impressive initial angiographic results. Drawbacks include difficult delivery in some cases, inadequate balloon lengths in very long obstructive lesions, and occasionally not enough available shock wave impulses in long-segment peripheral arterial disease.

As with all new promising technologies, we need more data. The initial results with IVL have been incredibly encouraging. If these outcomes are maintained on a long-term basis, this will be transformative in coronary and peripheral arterial vascular interventions. ■