

Intravascular Lithotripsy to Modify Calcified Coronary Artery Disease

How to use the Shockwave coronary Rx lithotripsy system.

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Up to a third of patients have moderate or severe calcification on coronary angiographic analysis.¹ The presence of coronary calcium is associated with difficult device delivery, suboptimal stent expansion, prolonged procedures with more complications, and poorer long-term clinical outcomes.

The Coronary Rx Lithotripsy System (Shockwave Medical Inc.) is a recent addition to the toolbox of devices

for calcium modification (Figure 1). This is achieved using an intravascular lithotripsy (IVL) balloon to emit pulsatile sonic pressure waves, creating microfractures in intimal and medial calcium in the vessel wall. Although it received CE Mark and has been available in Europe since 2017 (following the DISRUPT CAD I and II studies),^{2,3} FDA approval for the coronary device in the United States is awaited (with DISRUPT CAD III currently in follow-up).

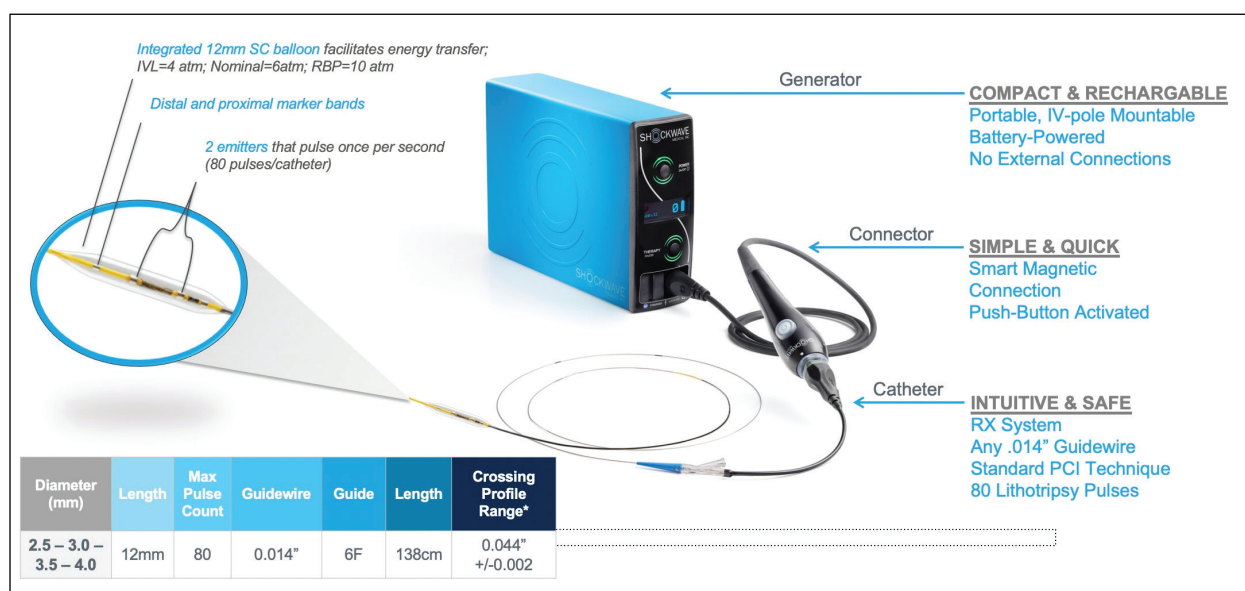


Figure 1. Shockwave coronary IVL system components. IV, intravenous; PCI, percutaneous coronary intervention; RBP, rated burst pressure; SC, semicompliant.

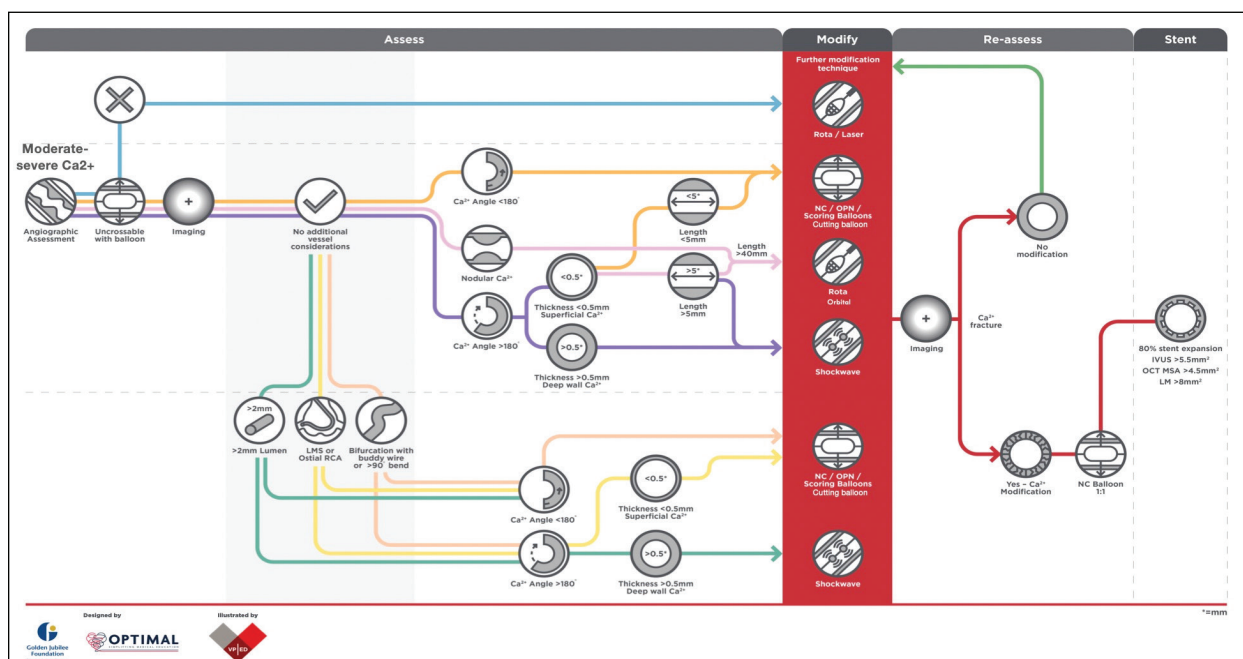


Figure 2. Calcium algorithm: a systematic approach to calcium modification. Illustration by McEntegart M, Spratt JC, and Vascular Perspectives Education.

With the armamentarium of tools now available for the treatment of calcified coronary artery disease (CAD), there should be a systematic approach to selecting the most appropriate device (Figure 2).

HOW I DO IT

With noncritical disease, after delivering a workhorse or support coronary guidewire, intravascular ultrasound (IVUS) or optical coherence tomography (OCT) should be performed to allow for a more detailed assessment of calcium morphology and severity. If the lesion is critical, predilatation with a small low-profile balloon can be performed before imaging. If IVUS or OCT are not available, some assessment of calcium severity and lesion distensibility can be obtained by inflating a noncompliant balloon (NCB) sized 1:1 with the estimated vessel diameter, looking for complete or incomplete expansion in contralateral views.

After establishing the requirement for IVL—either by angiographic appearance, intravascular imaging, or NCB underexpansion—an IVL balloon sized 1:1 with the estimated vessel diameter should be prepared, using a three-way stopcock to facilitate repeated deairing. To maintain

a lower crossing profile with tight lesions, preparing the balloon once it is across the stenosis should be considered.

The balloon is initially inflated to 4 atm to appose the plaque and a set of 10 pulses of therapy delivered, followed by an inflation to 6 atm to compress the fractured plaque. This is repeated in the same or an adjusted location until the lesion is adequately modified and the IVL balloon is seen to completely expand, with each balloon able to deliver a maximum of 80 pulses of therapy. It is also sometimes possible in severe lesions to engage and partially cross with the IVL balloon, then deliver some initial therapy to facilitate progressive balloon tracking.

Adequate calcium modification can be determined by confirming multiple fractures on imaging, or if not available, by reassessing expansion of a 1:1 NCB prior to stenting. Following stenting and postdilatation, repeat imaging can be used to ensure adequate stent expansion and apposition.

ANATOMY

An initial angiographic assessment of calcium location and severity should be performed. If there are only isolated spots of radiopacity, indicating mild calcification, the operator can usually proceed to predilatation with a 1:1 NCB and stenting.⁴ If at least moderate angiographic calcification is present (multiple radiopacities seen during the cardiac cycle), a more detailed assessment with intravascular imaging is recommended.

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the Shockwave coronary Rx lithotripsy system.

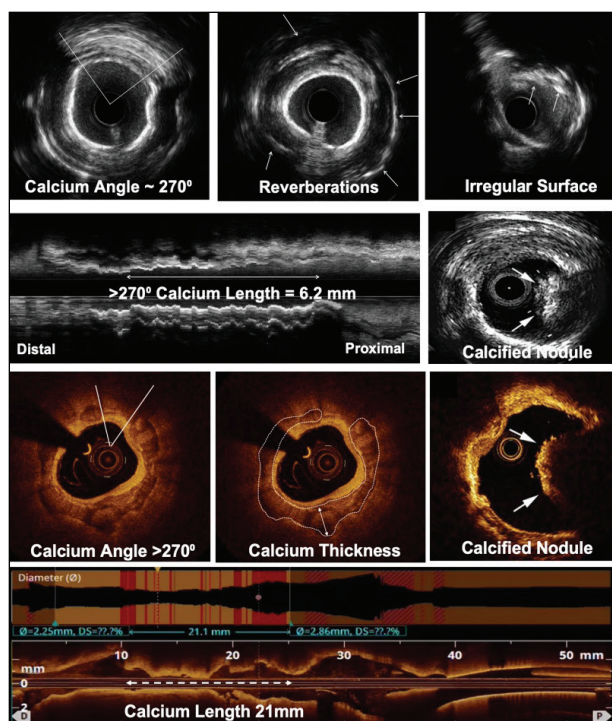


Figure 3. Calcium assessment using IVUS and OCT.

If the lesion is critical and uncrossable, rotational atherectomy (RA) or laser atherectomy should be considered (Figure 2). In critical left main (LM) bifurcation disease, when it is anticipated to be safer to maintain guidewires in multiple branches, predilatation with a low-profile balloon to facilitate IVL delivery can be attempted.

With noncritical disease, lesion location should first be considered. IVL potentially has specific advantages in the treatment of LM disease and other significant bifurcations, which include the ability to maintain multiple wires and access to all significant branches during treatment; reducing the number of times side-branch rewiring is required, thus improving safety and efficiency; and the ability to achieve plaque apposition and modification up to a lumen diameter of 4 mm. This is also relevant when treating large proximal vessels with a large plaque burden but a lumen diameter > 2 mm, where RA, even with favorable wire bias, may not achieve adequate plaque modification. With ostial LM or right coronary artery (RCA) disease, there is also an anticipated advantage of circumferential balloon apposition, allowing more effective delivery of therapy.

Next, the morphology and quantity of calcium should be assessed using imaging (Figure 3). If there is nodular calcium protruding into the lumen, RA or orbital atherectomy should be considered. Circumferential calcium should be quantified by assessing a number of characteristics: the size of the largest arc, length of the calcified seg-

ment, thickness when using OCT, or, alternatively, determining whether the surface is smooth with reverberations (suggestive of thin calcium) or irregular without reverberations (suggestive of thicker calcium) when using IVUS.^{5,6}

IVL is thought to be most effective with circumferential calcium with the recommendation that it be used with arcs > 180°. The high-frequency sonic waves reflect off calcium in the vessel wall and reverberate, amplifying the effect, and thus the more circumferential the calcium the more effective the therapy. It is also thought to be more effective in modifying thick calcium, creating both step-fractures and microfractures deep in the vessel wall (Figure 4). In addition, initial experience suggests it may also be effective in modifying nodular calcium.⁸

MATERIALS

When treating calcified CAD, it is important that the procedure is set up to facilitate all potential strategies. Therefore, although all the modifying devices are 6-F compatible, unless arterial access is prohibitive, 7-F sheaths and supportive guide catheters are recommended. Radial access should be used, if possible, to reduce the risk of femoral access complications in this higher-risk patient population who often have diffuse calcific vascular disease.

Although usually easily delivered, when treating severe stenoses you may initially need to predilate with a small NCB, and for lesions in the mid to distal vessel, as with any modifying balloon technology, you may require a guide extension to facilitate device delivery. This can be done by leading with the balloon with step-wise backup with the guide extension or more efficiently by inflating a smaller NCB across the lesion to anchor the guide catheter in position, tracking the guide extension across the lesion, delivering the IVL balloon, and then unsheathing it on withdrawal of the guide extension. This technique also avoids potential trauma to the balloon during delivery.

IVUS or OCT will allow the calcium to be quantified before treatment and can then confirm adequate modification post-IVL, with the strongest predictor of subsequent stent expansion being the presence of calcium fractures.⁹

The Shockwave C2 IVL balloons (Shockwave Medical Inc.) are available in 2.5 to 4 mm diameters and are all

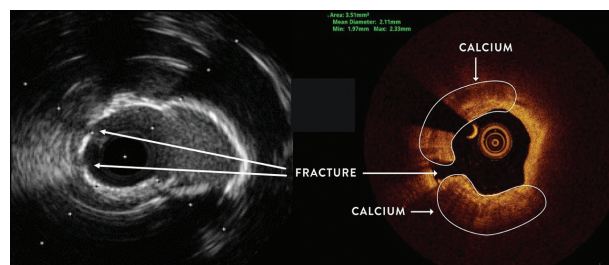


Figure 4. Calcium fractures detected using IVUS and OCT.

12 mm in length. They are 6-F compatible with a crossing profile of 0.044 inches, and each balloon delivers 80 pulses of therapy. Balloon preparation and compatible inflation devices are the same as for any coronary balloon catheter. After powering up the generator, the connector is plugged into the front, covered by a sterile ultrasound sleeve with an aperture, and connected to the back end of the balloon catheter by a magnetic connection (Figure 1). After balloon delivery across the lesion, the device is activated by pressing the orange therapy button on the generator, which turns green indicating the device is activated. After balloon inflation to 4 atm, therapy is delivered by pressing and holding the button on the top of the handle, as 10 pulses count down on the generator display. After 10 pulses, the therapy button will automatically deactivate (turning orange); the balloon is inflated to 6 atm before deflating and reactivating to green to allow delivery of the next round of shocks.

COMPLICATIONS

The safety of IVL was assessed in the Disrupt CAD II observational study (N = 120).³ There was one type B, one type C, and no type D-F dissections, with seven (5.8%) in-hospital non-Q-wave myocardial infarction (MI). At 30 days, there was one cardiac death (presumed stent thrombosis), one Q-wave MI, and one target vessel revascularization. The larger Disrupt CAD III FDA investigational device exemption study (N = 392) completed recruitment in March 2020.

Coronary IVL is associated with ventricular ectopy or “shocktopics” and asynchronous cardiac pacing, which is largely dependent on the patient’s resting heart rate.¹⁰ To date, with more than 24,000 devices used, there have

been some reports of atrial fibrillation and one episode of ventricular fibrillation during intervention. ■

1. Bourantas CV, Zhang YJ, Garg S, et al. Prognostic implications of coronary calcification in patients with obstructive coronary artery disease treated by percutaneous coronary intervention: a patient-level pooled analysis of 7 contemporary stent trials. *Heart*. 2014;100:1158-1164. doi: 10.1136/heartjnl-2013-305180
2. Brinton TJ, Ali ZA, Hill JM, et al. Feasibility of Shockwave coronary intravascular lithotripsy for the treatment of calcified coronary stenoses. *Circulation*. 2019;139:834-836. doi: 10.1161/CIRCULATIONAHA.118.036531
3. Ali ZA, Nef H, Escaned J, et al. Safety and effectiveness of coronary intravascular lithotripsy for treatment of severely calcified coronary stenoses: the Disrupt CAD II study. *Circ Cardiovasc Interv*. 2019;12:e008434. doi: 10.1161/CIRCINTERVENTIONS.119.008434
4. Mintz GS, Popma JJ, Pichard AD, et al. Patterns of calcification in coronary artery disease: a statistical analysis of intravascular ultrasound and coronary angiography in 1155 lesions. *Circulation*. 1995;91:1959-1965. doi: 10.1161/01.cir.91.7.1959
5. Fujino A, Mintz GS, Matsumura M, et al. A new optical coherence tomography-based calcium scoring system to predict stent underexpansion. *EuroIntervention*. 2018;13:e2182-e2189. doi: 10.4244/EIJ-D-17-00962
6. Wang X, Matsumura M, Mintz GS, et al. In vivo calcium detection by comparing optical coherence tomography, intravascular ultrasound, and angiography. *JACC Cardiovasc Imaging*. 2017;10:869-879. doi: 10.1016/j.jcmg.2017.05.014
7. Hoffmann R, Mintz GS, Popma JJ, et al. Treatment of calcified coronary lesions with Palmaz-Schatz stents. An intravascular ultrasound study. *Eur Heart J*. 1998;19:1224-1231. doi: 10.1053/ehj.1998.1028
8. Mattesini A, Nardi G, Martellini A, et al. Intravascular imaging to guide lithotripsy in concentric and eccentric calcific coronary lesions. *Cardiovasc Revasc Med*. 2020;16:S1553-8389(20)30220-7. doi: 10.1016/j.carrev.2020.04.016
9. Kubo T, Shimamura K, Ino Y, et al. Superficial calcium fracture after PCI as assessed by OCT. *JACC Cardiovasc Imaging*. 2015;8:1228-1234.
10. Wilson SJ, Spratt JC, Hill J, et al. Incidence of “shocktopics” and asynchronous cardiac pacing in patients undergoing coronary intravascular lithotripsy. *EuroIntervention*. 2020;15:1429-1435. doi: 10.4244/EIJ-D-19-00484

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