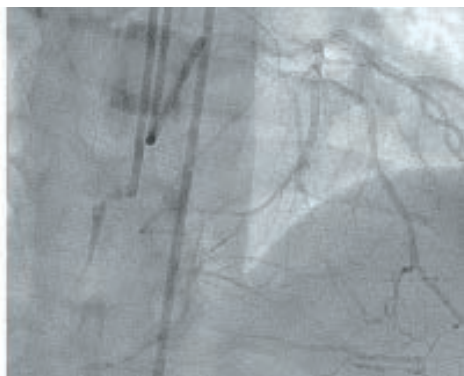


Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



CASE REPORT

Retrograde CTO PCI in a Difficult-to-Cross Lesion

Diljon S. Chahal, MD

Chronic total occlusion (CTO) percutaneous coronary intervention (PCI) can be a challenging intervention. However, having the right equipment and tips/tricks for troubleshooting can simplify these interventions. We describe suggested equipment and ideas for troubleshooting in the case below.

Case Report

A 43-year-old male with hypertension, hyperlipidemia, gastroesophageal reflux disease (GERD), and obesity presented with complaints of progressive angina. A nuclear stress test demonstrated evidence of extensive inferior ischemia with normal left ventricular systolic function.

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SINGLE-CENTER STUDY

Use of Cangrelor in a Contemporary Practice of STEMI Interventions

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Abstract

Objectives: To evaluate the safety and efficacy of using cangrelor in a real-world, contemporary practice of ST-segment elevation myocardial infarction (STEMI) interventions with short door-to-balloon (D2B) times. **Background:** Short D2B times reduce mortality in STEMI interventions. There is a disparity between the race to treat STEMI and the delayed action of oral P2Y₁₂ inhibitors. As a result, in the majority of patients that are P2Y₁₂ inhibitor-naïve, oral agents leave a freshly implanted stent vulnerable to thrombosis. Cangrelor, a parenteral, ultrashort-acting, direct, and reversible-binding P2Y₁₂ inhibitor, has ideal pharmacokinetic attributes for STEMI. Although studied in clinical trials, the use of cangrelor in short D2B time interventions has not been reported. **Methods:** We conducted a prospective, single-center registry of 50 consecutive short D2B time percutaneous coronary interventions (PCI). Cangrelor was added to the intraprocedural regimen, which included bivalirudin. In-hospital major adverse cardiac events (MACE), stent thrombosis, and bleeding events were monitored.

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CALCIUM CORNER

When to Use IVL: An Exploration of Treatment Algorithms



CLD talks with Evan Shlofmitz, DO, Director of Intravascular Imaging, St. Francis Hospital - The Heart Center, Roslyn, New York.

How has the use of intravascular imaging helped create treatment algorithms at St. Francis Hospital?

One of the unique features of St. Francis Hospital is that intravascular imaging is standard of care, something that isn't truly the case across much of the United States. Rather than looking at arteries from the outside in, with intravascular imaging, we are looking from the inside out. The value goes beyond simply identifying the type of predominant plaque in the arteries at the time of treatment.

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When to Use IVL: An Exploration of Treatment Algorithms

CLD talks with Evan Shlofmitz, DO, Director of Intravascular Imaging, St. Francis Hospital - The Heart Center, Roslyn, New York.

Intravascular imaging provides much more detailed information than would ever be available on an angiogram, allowing us to make precise measurements and accurately select the best stent size. Rather than just guessing, we are taking precise measurements and using information from intravascular imaging in order to offer our patients the best possible outcomes. St. Francis Hospital has become the largest intravascular imaging center in the country. We have over 20 interventional cardiologists and intravascular imaging is a standard of care for all of the interventional cardiologists in our lab. We believe that intravascular imaging changes the way that we practice.

Information from the past five years of intravascular imaging at St. Francis Hospital, thousands of cases, has allowed us to develop algorithms or workflows for approaching stent implantation, which

has been particularly helpful when approaching calcified lesions (Figure 1).¹ An angiogram will tell you if there is calcium present, but it doesn't tell you the type of calcium, how thick it is, and the arc of the calcium. All these things matter, because this information allows us to determine the best device to modify that calcium, particularly now that there are so many more devices on the market. Ten years ago when the only real lesion preparation device was rotational atherectomy, it may have been acceptable to know only whether severe calcium was present, but now we have orbital atherectomy, specialty balloons, and intravascular lithotripsy (IVL; Shockwave Medical). It is critical to know what type of calcium exists when plaque modification is needed and which device is the best plaque modification tool for that specific lesion.

The insights from intravascular imaging are unlike anything we can gather from an angiogram alone. Intravascular imaging allows us to identify the presence of each specific type of calcium. For example, there is superficial calcium, deep calcium, and calcified nodules. Calcified nodules are an entity that almost was unrecognized by angiography alone, but we have discovered it is actually fairly common for patients with calcified coronary disease to have calcified nodules that protrude into the lumen and inhibit adequate stent expansion. By detecting calcium features with intravascular imaging before we implant any stents, we can assess the predominant type of calcium when there is severe calcification, and then we can determine the next best step, whether it is simply pre dilatation with a balloon, or using an adjunctive device. At St. Francis, in partnership with the Cardiovascular Research Foundation (CRF), we developed an optical coherence tomography (OCT) imaging-based calcium score, the St. Francis calcium score, nicknamed the 'Rule of Fives'.² We look for three features that predict that a stent won't expand appropriately without lesion preparation: 5 millimeters (mm) of calcium length, a thickness of calcium of 0.5 mm, or an arc of calcium greater than 50%. When all three of those features are present, we know that if lesion preparation is not used, these features will most likely be associated

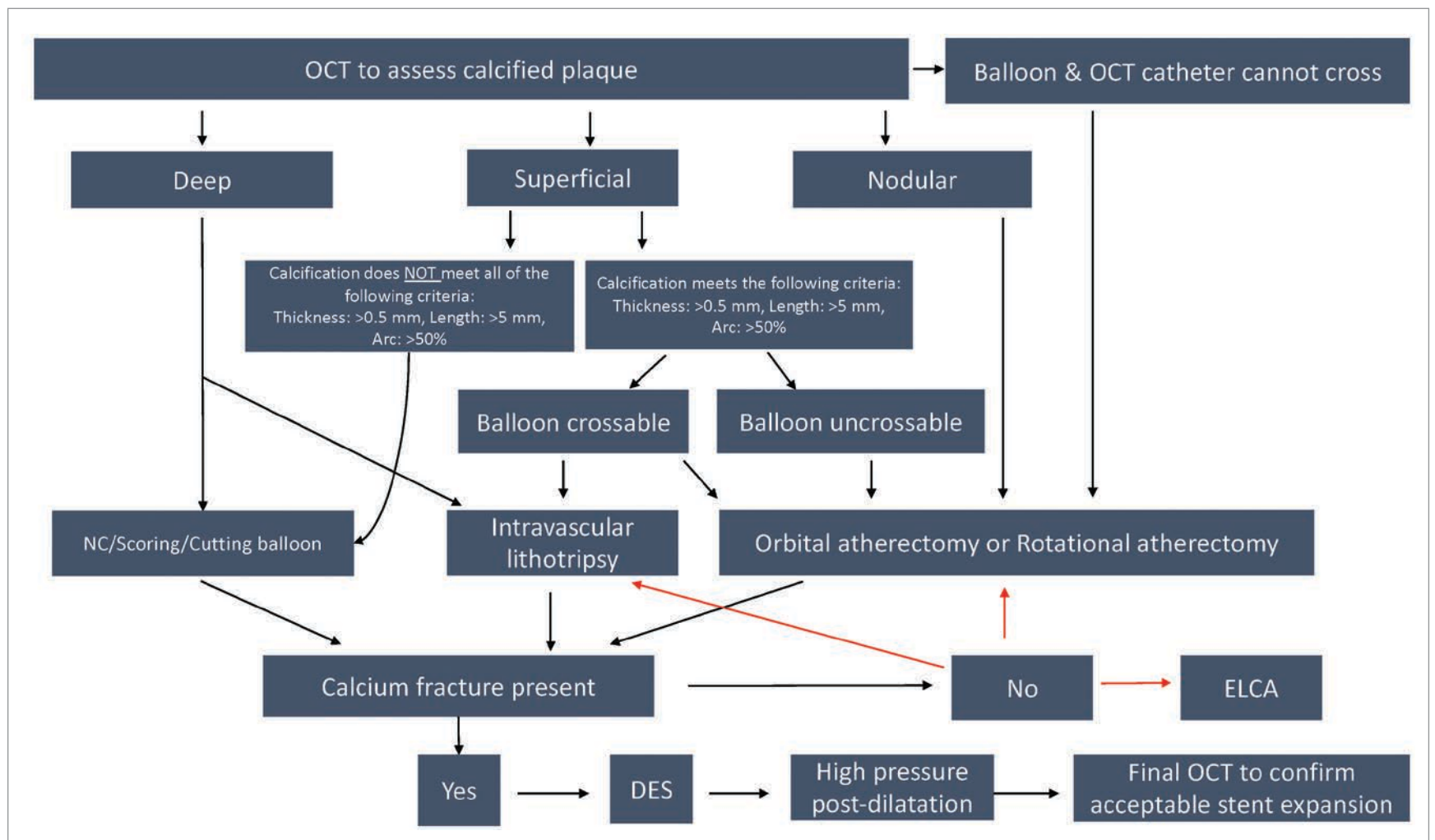


Figure 1. Algorithmic approach for optical coherence tomography (OCT)-guided treatment of calcified lesions. DES, drug-eluting stent; ELCA, excimer laser coronary atherectomy; OCT, optical coherence tomography.

with stent under-expansion. Concentric, superficial calcium is one of the predominant scenarios where intravascular lithotripsy plays a critical role. The number-one predictor of whether or not you will have adequate stent expansion is calcium fracture. Fracturing and modifying the calcium facilitates adequate stent expansion. The biggest predictor of calcium fracture is calcium thickness. The only modality that measures in vivo calcium thickness is optical coherence tomography, and this type of assessment of calcified disease is really one of the strengths of OCT. We can precisely measure calcium thickness in order to gauge whether or not we need atherectomy or lithotripsy. It is not uncommon that angiographically, a lesion can look like it has severe calcium, but then intravascular imaging reveals that is not the case, and thus we don't need these adjunctive techniques, meaning balloon angioplasty alone will be adequate to modify the plaque. From a cost standpoint, it is cost efficacious to use intravascular imaging. It guides the optimal therapy, but it also helps us to ensure that we can provide the best outcomes possible.

When calcium modification is required, how do you decide which device is appropriate?

Our typical test is delivering an intravascular imaging catheter. If you can cross with an OCT catheter, it is likely you will be able to cross the lesion and deliver the Shockwave lithotripsy balloon. If you have difficulty crossing with an OCT catheter and it is a severely calcified lesion, we then typically treat with orbital or rotational atherectomy at the operator's discretion. A protruding calcified nodule tends to be very eccentric, and for that we usually prefer orbital atherectomy, because of its ability to modify that calcium, as well as to debulk it. If it is a crossable lesion with concentric calcium, there are some major advantages with intravascular lithotripsy, including its ease of use and excellent safety profile. The Shockwave balloon is only inflated to four atmospheres. It delivers 10 pulses with each cycle, but the energy delivered is equivalent to greater than tenfold of that pressure. Even though the balloon is only inflated to four atmospheres, the energy is enough to fracture that hard calcium. If you were using a traditional noncompliant balloon at 28 atmospheres, you would find that you are still unable to fracture that thick calcium. With the use of intravascular lithotripsy in concentric calcium that is greater than a millimeter thick, our OCT studies show significant calcium fracture and displacement. It is that displacement and fracture of the calcium that allows for stent expansion.

Can you share some of your background with intravascular lithotripsy use in the coronary arteries?

Coronary intravascular lithotripsy (IVL; Shockwave Medical) was recently approved in the United States, but I first became involved with IVL use as part of Disrupt CAD III (ClinicalTrials.gov Identifier:

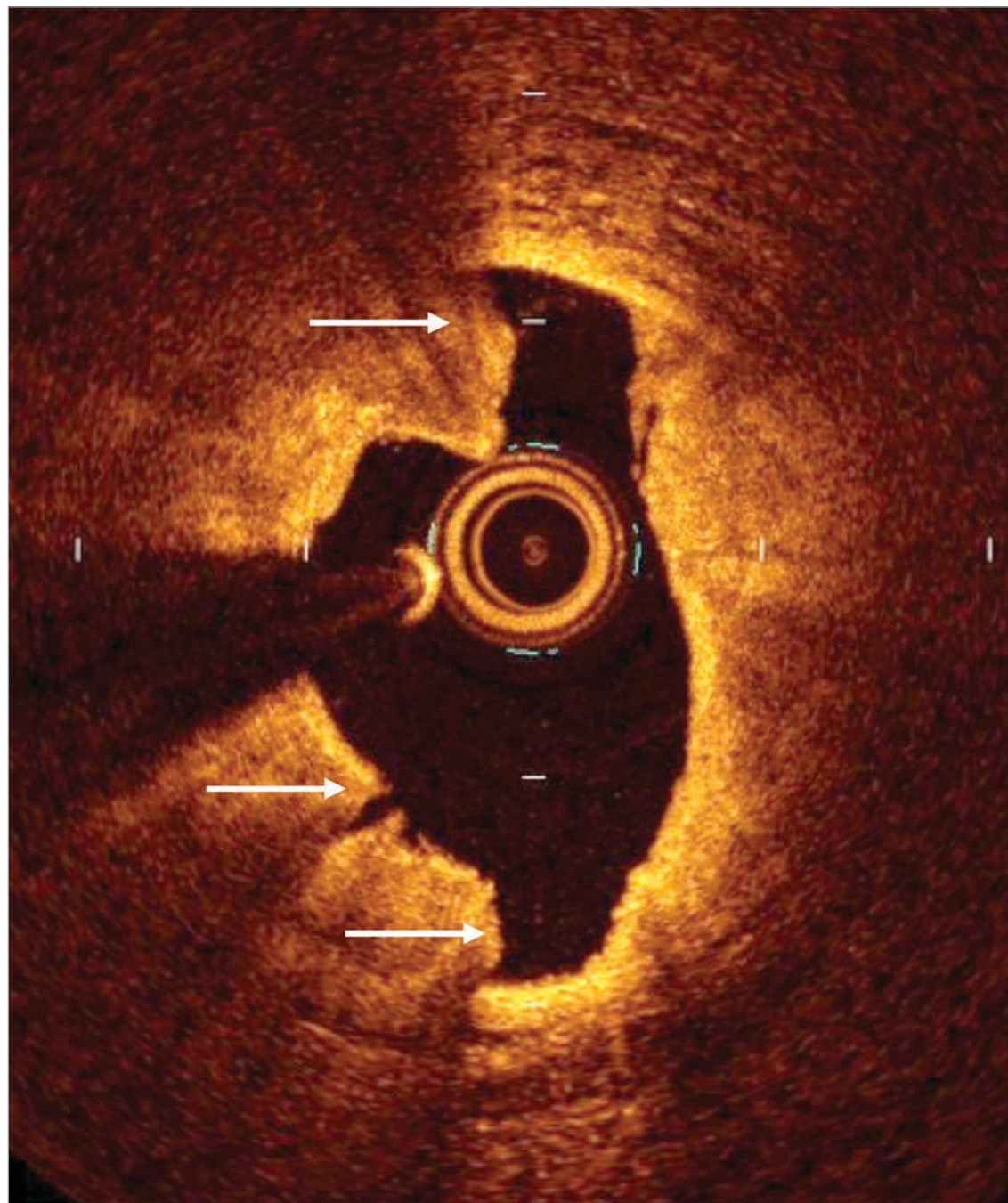


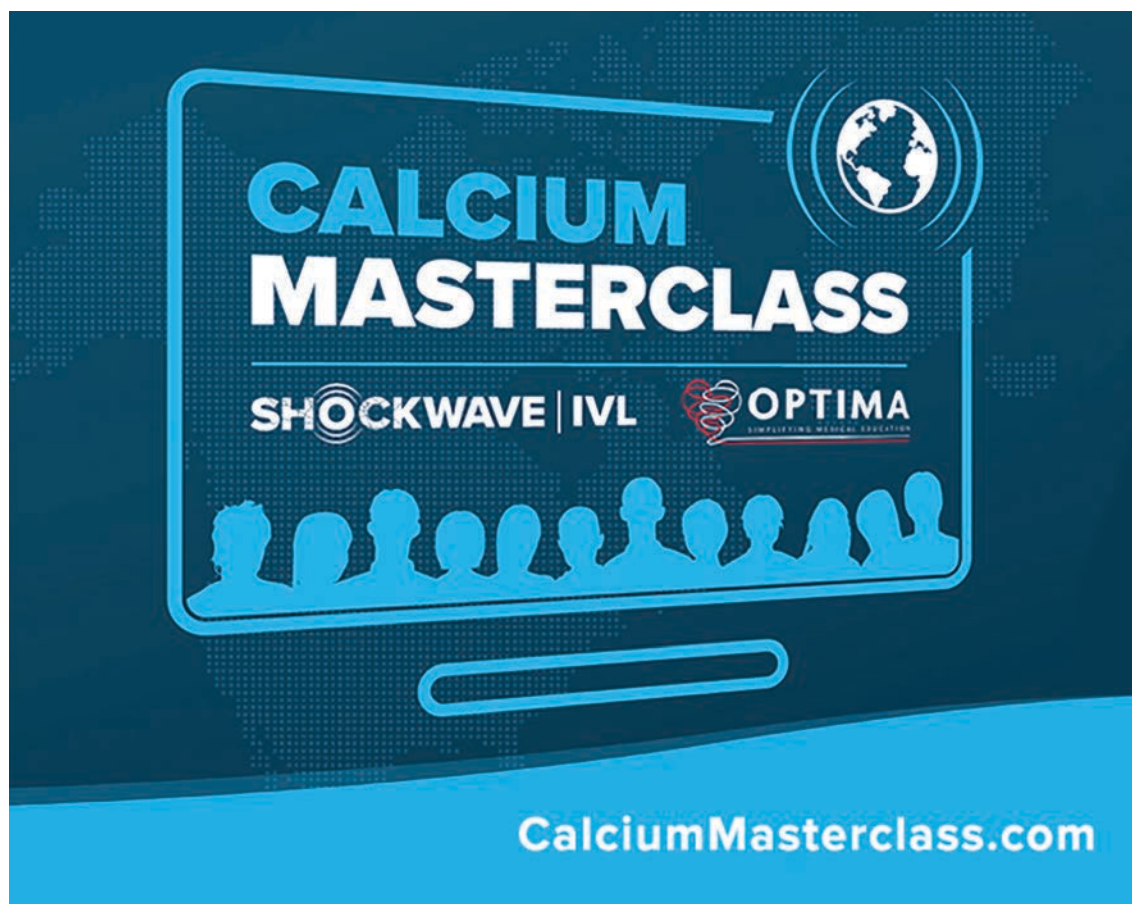
Figure 2. Optical coherence tomography cross section demonstrating contralateral calcium fractures of a calcified coronary lesion following treatment with intravascular lithotripsy.

NCT03595176), the trial that led to IVL approval in the United States. The most striking thing about IVL, the first time you use it, is how easy it is. Its use is nearly the same as any other balloon that we use in interventional cardiology and it is simple compared with the other lesion preparation devices, which require more set up and experience in order to understand their nuances of use.

What do you mean by IVL's 'fracture and displacement' of calcium?

If you think of a shifting tectonic plate, intravascular lithotripsy is similarly shifting the calcium and creating that fracture, and allowing for expansion of the stent. This is all within the media. Intravascular lithotripsy is not embolizing; it allows calcium to be safely cracked so that the stent can adequately expand. The number-one predictor of future stent-related events comes down to the stent expansion. The

larger we can make the stent, the less likely it is that the patient will return with restenosis related to that stent. We need to expand the calcium to ensure the stent is enlarged, and doing so in a safe, user-friendly way is important. One of the main advantages of intravascular lithotripsy is its ease of use. Every interventional cardiologist is comfortable with and knows how to use balloon angioplasty. Aside from some basic steps in learning the setup of how to prepare the device, once you deliver intravascular lithotripsy, it is essentially the same as any balloon angioplasty. I think intravascular lithotripsy is going to transform the way interventional cardiologists approach calcified lesions, because, unfortunately, up until now, there hasn't been as much lesion preparation as there is severe calcium. We know, based on the latest data, two-thirds of centers in United States do zero atherectomy, yet calcium is ubiquitous and is present in patients that we treat



on a daily basis.³ I think the complexity that is associated with atherectomy has limited a number of operators from using adequate lesion preparation. The ease of use and safety profile with intravascular lithotripsy will allow much greater utilization of lesion preparation for stenting.

What do we know about the safety of intravascular lithotripsy?

The safety data in Disrupt CAD III were excellent.⁴ There are complications associated with treating calcified lesions, which I think is an important distinction to make: it is not necessarily the device, whether atherectomy, lithotripsy, or even just balloon angioplasty. Calcified lesions are associated with greater complications compared to non-calcified lesions. When you assess the data, you can see that there will always be an increased risk of complications treating calcified lesions. Having said that, the safety profile seen in Disrupt CAD I, II, and III has been excellent, considering the complexity of the lesions.⁵

Compared with some of the alternative devices, another major advantage of lithotripsy is its use in bifurcation lesions. Calcium often occurs at bifurcations and one of the trouble spots comes if you choose to wire both branches when treating a bifurcation lesion. There is some concern about having a wire in a side branch with atherectomy devices. A number of operators have reported their success using microcatheters to protect the wire, but still the conventional practice is to avoid using atherectomy with a wire in the side branch. When treating severely calcified bifurcations, one of the major advantages of intravascular lithotripsy is that

you can have the protection of a wire in the side branch and still use lithotripsy. You are not worried about an atherectomy burr basically shaving the additional guidewire.

Our colleagues in Europe have some experience in a potential combination use of lithotripsy and atherectomy, so we are also working to fine-tune the best role for a combination of atherectomy and lithotripsy use. If there are uncrossable lesions, we will typically go with atherectomy, and after imaging, if there is inadequate calcium fracture, you can consider going to lithotripsy, and vice versa. If you have done intravascular lithotripsy and for whatever reason, either you haven't achieved calcium fracture, or perhaps you have used up all your pulses in that balloon and there is still an extensive lesion, you may opt to use another lithotripsy balloon or an alternative device as well.

Is OCT the dominant intravascular imaging modality for calcified lesions at St. Francis Hospital?

In the majority of lesions, either intravascular ultrasound (IVUS) or OCT can be used, based on the operator's preference. While there are drawbacks and advantages to each device, with OCT, there are two areas where it has its major advantages over IVUS: calcium and in-stent restenosis. This is based on the high definition and resolution of OCT, as well as its specific ability to measure the thickness of calcium, something you can't see on intravascular ultrasound alone. Intravascular imaging allows you to appropriately select and predict which lesions are going to best respond to intravascular lithotripsy, and we have shown that concentric, thick

calcium is best suited for intravascular lithotripsy use. There is no way to ascertain the concentricity from an angiogram alone (which is just a lumino-gram and has its limitations). From a cost-efficacy standpoint, if we are going to use intravascular lithotripsy, we want to make sure that we will be successful. Selecting appropriate patients for use helps ensure excellent results, which is exactly what we saw in Disrupt CAD III's OCT substudy, which assessed 100 patients with serial OCT imaging (baseline OCT, post intravascular lithotripsy, and final OCT). Of note, the use of this series of three intravascular imaging pullbacks did not add any significant procedural time. One myth is that intravascular imaging adds time to the procedure and that misunderstanding is why many people say they don't use intravascular imaging. However, in Disrupt CAD III, in a clinical trial of severely calcified lesions, using a minimum of three OCT pullbacks did not add any significant time to the procedure. There was no statistical difference in the cases that had intravascular imaging and those cases that had no intravascular imaging. While not statistically significant, numerically, procedural time was lower in the OCT arm compared to the no-OCT arm. Intravascular imaging guides you and allows you to predict what is needed for the procedure. It not only helps you achieve the best outcomes, but it is an efficient use of your time as well as resources.

Every case at St. Francis with use of intravascular lithotripsy also involves serial intravascular imaging, including before lithotripsy, after lithotripsy use, and then final imaging. These data are all being analyzed at the Cardiovascular Research Foundation to improve our knowledge and to allow us to help better treat these patients. As we gain new insights from these data over the next few months to a year, hopefully it will allow us to continue to improve and modify our algorithms so that the interventional community at large can offer our patients the best possible treatment.

Can you share more about what you see with OCT around the use of intravascular lithotripsy?

Our goal is to modify the calcium and OCT shows whether we were successful in doing so. It has become our practice, even before we stent, to use OCT after intravascular lithotripsy. We are specifically looking for calcium fracture, which is readily recognizable on OCT (Figure 2). If we see calcium fracture, we know at that point there is a high probability of adequate stent expansion. As a result, we have developed what we call a pulse management strategy. Each intravascular lithotripsy balloon has up to 80 pulses to deliver, and for cost reasons, minimizing the number of intravascular lithotripsy balloons that are needed has its advantages. We will use the baseline intravascular imaging to guide where we focus the IVL pulses, and we typically reserve the last cycle of 10 pulses. If intravascular imaging after lithotripsy use shows some severely calcified areas of the lesion that aren't fractured, we still have those saved 10 pulses. Using OCT and angiographic

co-registration, we apply those extra pulses only in the areas where it is needed. Once we have achieved the additional calcium fracture, we implant the stent, based on the OCT sizing. Then we do a final intravascular imaging pullback to make sure we have actually achieved adequate stent expansion, and ascertain whether there are any areas that are needed for further optimization.

Any final thoughts?

Intravascular imaging allows for real-time assessment. We check our work in real time and assess, before the patient leaves the cath lab, whether there is anything we can do to offer them better results. Especially with novel devices, we, as an individual community, are still learning. This is the beginning of intravascular lithotripsy use in the real world and in the U.S. market, and there are insights that we can gain. Utilizing the advantages of intravascular imaging allows us to enhance our ability to use lithotripsy, including case selection for use and ensuring that we are achieving adequate outcomes. ■

This article is sponsored by Shockwave Medical. Dr. Shlofmitz is a paid consultant for Shockwave Medical. See Important Safety information below.

Rx only

Indications for Use— The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C2 Coronary IVL Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting.

Contraindications— The Shockwave C2 Coronary IVL System is contraindicated for the following: This device is not intended for stent delivery. This device is not intended for use in carotid or cerebrovascular arteries.

Warnings— Use the IVL Generator in accordance with recommended settings as stated in the Operator's Manual. The risk of a dissection or perforation is increased in severely calcified lesions undergoing percutaneous treatment, including IVL. Appropriate provisional interventions should be readily available. Balloon loss of pressure was associated with a numerical increase in dissection which was not statistically significant and was not associated with MACE. Analysis indicates calcium length is a predictor of dissection and balloon loss of pressure. IVL generates mechanical pulses which may cause atrial or ventricular capture in bradycardic patients. In patients with implantable pacemakers and defibrillators, the asynchronous capture may interact with the sensing capabilities. Monitoring of the electrocardiographic rhythm and continuous arterial pressure during IVL treatment is required. In the event of clinically significant hemodynamic effects, temporarily cease delivery of IVL therapy.

Precautions— Only to be used by physicians trained in angiography and intravascular coronary procedures. Use only the recommended balloon inflation medium. Hydrophilic coating to be wet only with normal saline or water and care must be taken with sharp objects to avoid damage to the hydrophilic coating. Appropriate anticoagulant therapy should be administered by the physician. Precaution should be taken when treating patients with previous stenting within 5mm of target lesion.

Learn more about coronary intravascular lithotripsy use by visiting Cath Lab Digest's Calcium Corner. Click on the QR Code at right or start at cathlabdigest.com. CLD home page -> Topics -> Calcium Corner

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Use this QR code to access the Calcium Corner directly.



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Potential adverse effects consistent with standard based cardiac interventions include— Abrupt vessel closure - Allergic reaction to contrast medium, anticoagulant and/or antithrombotic therapy-Aneurysm-Arhythmia-Arteriovenous fistula-Bleeding complications-Cardiac tamponade or pericardial effusion-Cardiopulmonary arrest-Cerebrovascular accident (CVA)-Coronary artery/vessel occlusion, perforation, rupture or dissection-Coronary artery spasm-Death-Emboli (air, tissue, thrombus or atherosclerotic emboli)-Emergency or non-emergency coronary artery bypass surgery-Emergency or non-emergency percutaneous coronary intervention-Entry site complications-Fracture of the guide wire or failure/malfunction of any component of the device that may or may not lead to device embolism, dissection, serious injury or surgical intervention-Hematoma at the vascular access site(s)-Hemorrhage-Hypertension/Hypotension-Infection/sepsis/fever-Myocardial Infarction-Myocardial Ischemia or unstable angina-Pain-Peripheral Ischemia-Pseudoaneurysm-Renal failure/insufficiency-Restenosis of the treated coronary artery leading to revascularization-Shock/pulmonary edema-Slow flow, no reflow, or abrupt closure of coronary artery-Stroke-Thrombus-Vessel closure, abrupt-Vessel injury requiring surgical repair-Vessel dissection, perforation, rupture, or spasm.

Risks identified as related to the device and its use: Allergic/immunologic reaction to the catheter material(s) or coating-Device malfunction, failure, or balloon loss of pressure leading to device embolism, dissection, serious injury or surgical intervention-Atrial or ventricular extrasystole-Atrial or ventricular capture.

Prior to use, please reference the Instructions for Use for more information on warnings, precautions and adverse events. www.shockwavemedical.com/IFU

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave C2 Coronary IVL system instructions for use containing important safety information.

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