Imaging and Treating the Complex Patient

Optimizing outcomes in complex PCI with orbital atherectomy.

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Whether from a randomized controlled trial, observational registry, or meta-analysis, data have consistently demonstrated the benefit of intravascular imaging on clinical outcomes.[1-3] The mechanism by which outcomes are improved is largely related to improved stent expansion when intravascular imaging is utilized.[1] Coronary artery calcification (CAC) is the predominant barrier to adequate stent expansion when stent sizing has been appropriate. Atherectomy has historically been indicated for undilatable and uncrossable lesions, but this indication falls short of the complete role of atherectomy in modern percutaneous coronary intervention (PCI).[4] In the presence of heavy calcification, lesion preparation should be used not just for successful stent delivery, but also importantly to facilitate adequate stent expansion via plaque modification.

INTRAVASCULAR IMAGING

Although intravascular ultrasound is an important intravascular imaging modality, in most cases where evaluation of coronary calcification is required, we prefer optical coherence tomography (OCT) due to its unique ability to readily assess important prognostic factors including calcium thickness and recognition of calcified nodules. Traditionally, CAC was classified based on its angiographic appearance, with calcium visualization on both sides of the lumen prior to contrast injection without motion considered to be severe calcification.[5] We now know that there are inherent limitations to angiographic assessment of coronary calcium. Angiographic recognition of calcification does not guide optimal treatment strategies and is simply a prompt for the need for further investigation with intravascular imaging to define the calcium morphology. An angiogram cannot distinguish between deep wall calcification, superficial calcification, and calcified nodules. Treatment of CAC should be determined based on this calcium morphology, which can only be characterized with intravascular imaging.

In the LightLab Study, OCT findings led to changes in angiographic-based decisions in 88% of lesions, with a change in need for vessel preparation observed in 28% of cases.[6] It is widely known that CAC is underrecognized with angiography.[5] Beyond recognition of calcium and understanding of its morphology, baseline intravascular imaging allows for precise selection of the optimal stent diameter and length.[7] After stent implantation, intravascular imaging can exclude significant edge dissection and severe malapposition while ensuring that adequate stent expansion has been attained.

CHARACTERIZATION OF CALCIUM

On baseline intravascular imaging, predominant calcium morphology should be characterized between concentric calcification, eccentric calcification, and calcified nodules.[8] The St. Francis Calcium-OCT Score, commonly known as the "rule of 5s," guides when orbital atherectomy should be considered (Figure 1). In the presence of CAC > 5 mm in length, an arc > 50% of a cross-section with a thickness > 0.5 mm indicates heavy calcification that is at increased risk for stent underexpansion without adequate lesion preparation.[9] Because conventional balloon-based technology is often inadequate to create calcium fracture when calcium thickness exceeds 0.5 mm, adjunctive therapies are

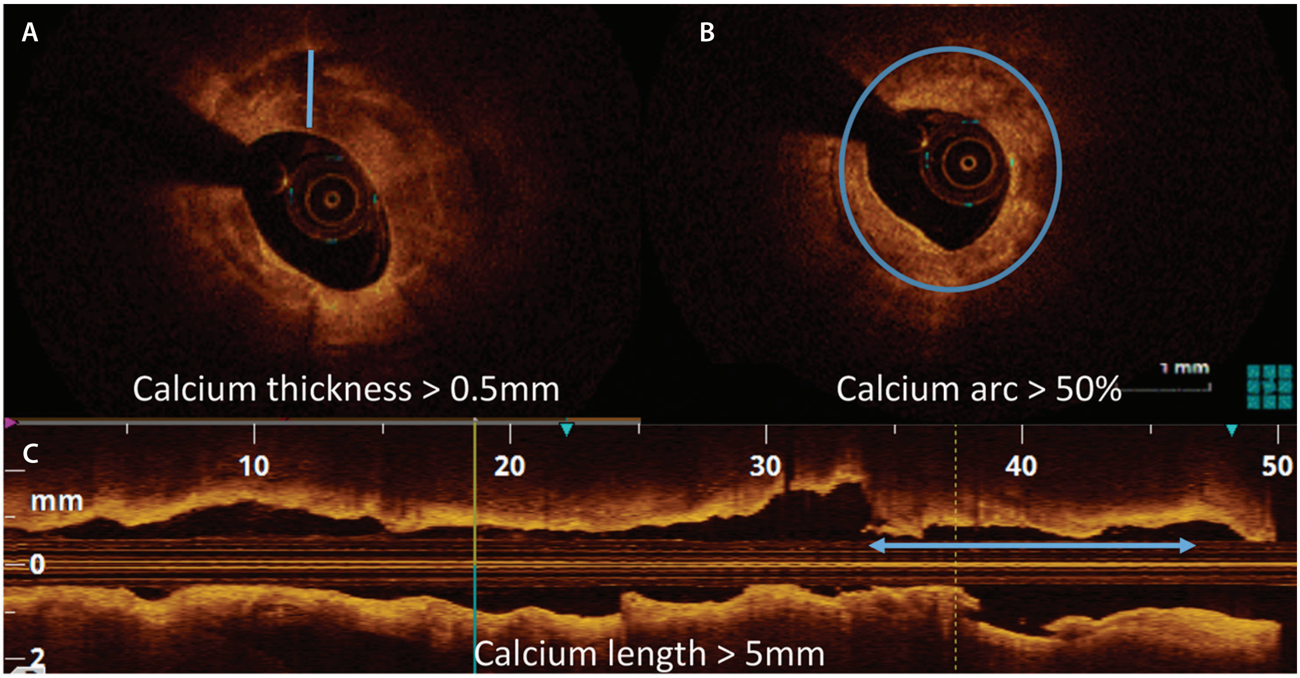

Figure 1. The St. Francis Calcium-OCT Score. Representative OCT demonstrating CAC with thickness > 0.5 mm (A), an arc of calcium > 50% of the cross-section (B), and length > 5 mm (C). In the presence of these three features, lesion preparation should be considered.

needed.[10] Plaque modification with calcium fracture can be achieved with lesion preparation with orbital atherectomy (Figure 2).

ORBITAL ATHERECTOMY

Orbital atherectomy (Diamondback 360® Coronary Orbital Atherectomy System, Cardiovascular Systems, Inc.) utilizes a 1.25-mm diamond-coated crown that orbits at either 80,000 rpm (low speed) or 120,000 rpm (high speed) in a bidirectional fashion to modify calcified plaque.[11] The unique dual mechanism of action utilizes differential sanding and pulsatile force that safely ablates superficial calcification while creating focused fractures in the calcified plaque, which enables expansion with stent implantation.[12,13] During superficial calcium sanding, the small crown size permits continuous flow during ablation, with creation of particles < 2 µm in size.[12] Yamamoto et al demonstrated that orbital atherectomy is associated with greater calcium modification in lesions with larger lumen area as compared with rotational atherectomy, with calcium fracture behind the stent attained in 82% of cases.[14] This is an important concept, as the universal orbital atherectomy crown size can be used to treat calcified plaque in a wide range of coronary vessel sizes, including the left main coronary artery.[15,16]

Calcified Nodules

A calcium nodule is defined as an eruptive accumulation of nodular calcification protruding into the lumen.[17] Calcium nodules are often underrecognized, as they cannot be appreciated by angiography. However, calcified nodules are not an uncommon entity, and are seen in as many as 6% of cases and over 48% of calcified lesions.[18,19] It is important to detect calcium nodules prior to stent implantation because they do not behave similarly to severe concentric CAC. Treatment of calcified nodules with other adjunctive lesion preparation modalities, including rotational atherectomy, intravascular lithotripsy, and specialty balloons is not ideal due to the eccentric protruding nature of these nodules. Orbital atherectomy uniquely allows for significant plaque modification of calcified nodules with debulking of the nodule with lumen enlargement (Figure 3).

CONCLUSION

Intravascular imaging not only guides when orbital atherectomy is needed but also demonstrates where orbital atherectomy should be applied in a vessel. Orbital atherectomy should be performed until the operator appreciates a change in tactile resistance and no longer hears audible pitch variation during treatment of the target region. After orbital atherectomy, intravascular imaging should be performed. By documenting fracture prior to

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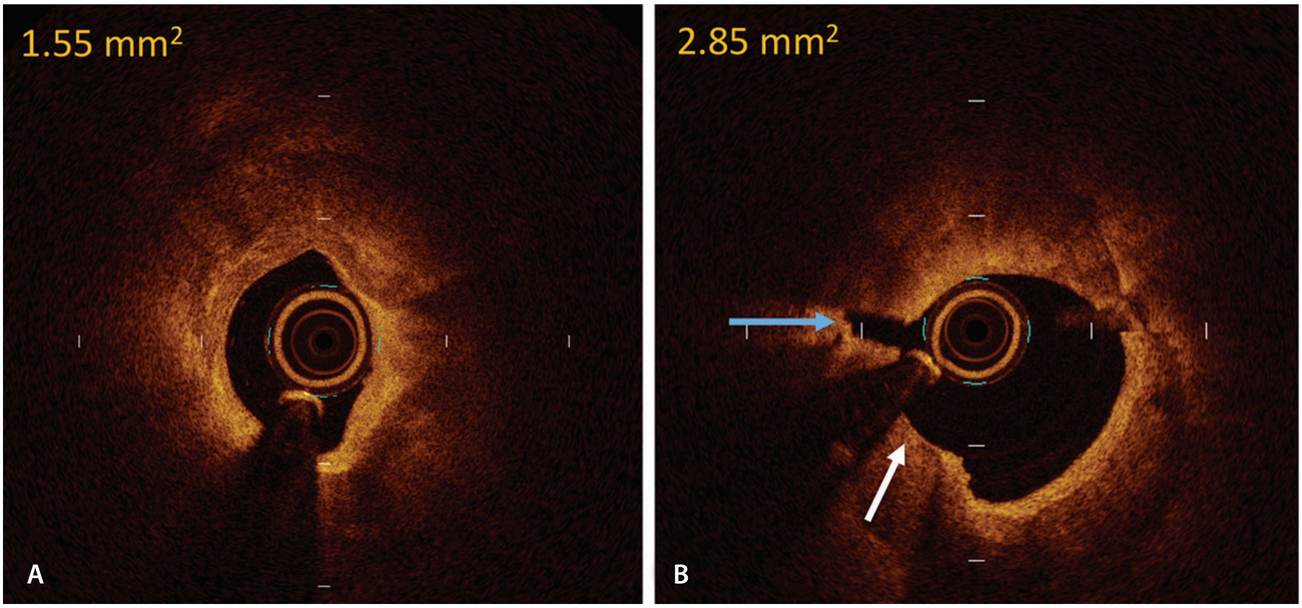

Figure 2. Baseline OCT with severe calcification and a lumen area of 1.55 mm^2 (A). OCT after lesion preparation with orbital atherectomy demonstrating the dual mechanism of action with both smooth concentric ablation (white arrow) and calcium fracture (blue arrow), with an enlarged lumen of 2.85 mm^2 (B).

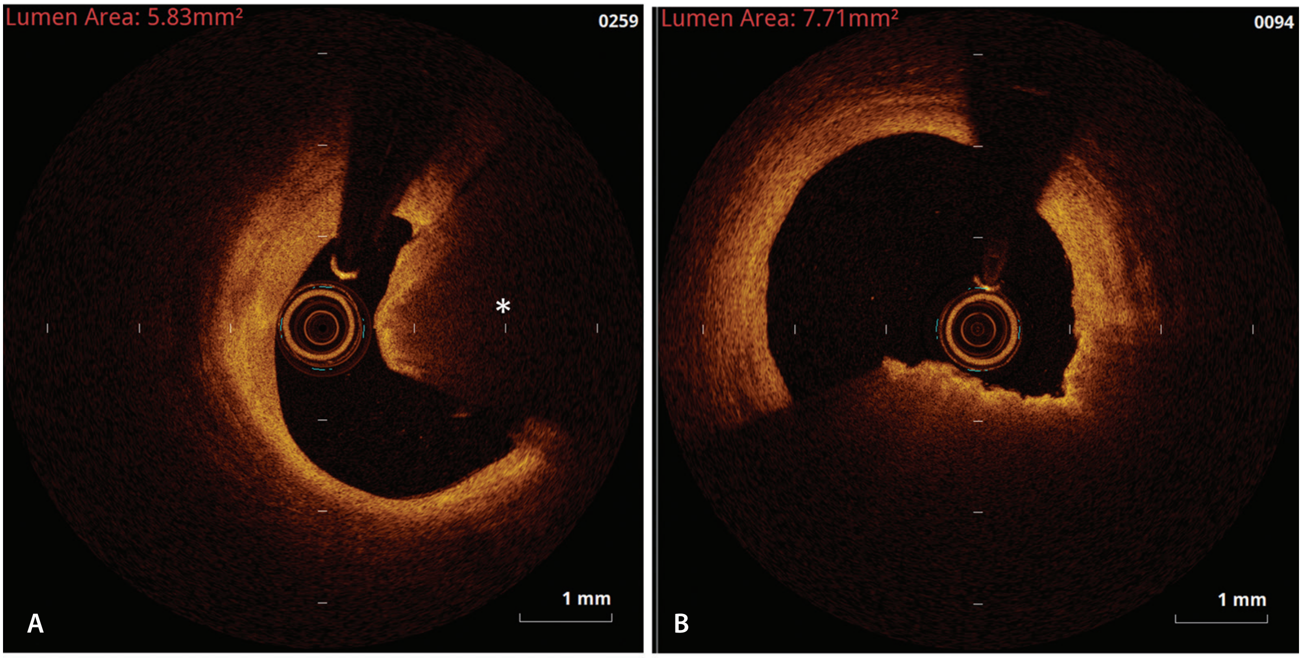

Figure 3. Baseline OCT demonstrating a protruding calcified nodule (*) (A). OCT after lesion preparation with orbital atherectomy demonstrates reduction in the nodule size with enlargement of the lumen area (B).

stent implantation with intravascular imaging, one can have a higher level of confidence they will achieve adequate stent expansion.

When treating calcium with PCI, adequate lesion preparation can enhance the likelihood of procedural success. Maximizing stent expansion with implantation can help to minimize future restenosis. Inadequate lesion preparation for de novo calcified lesions prior to stent implantation represents a lost opportunity, as any future treatment of in-stent restenosis is associated with outcomes worse than with de novo disease.[20] De novo calcification should be addressed with lesion preparation upfront when indicated and guided by intravascular imaging. Results from the large-scale, multicenter, randomized controlled ECLIPSE trial (NCT03108456) and its prespecified OCT substudy will provide substantial insights on the impact of orbital atherectomy and optimal techniques and lesion selection. ■

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