Supplement to

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Cardiac Interventions TODAY

Optimizing Outcomes in Complex PCI With Orbital Atherectomy

Insights into the contemporary practice and use of the Diamondback® System.

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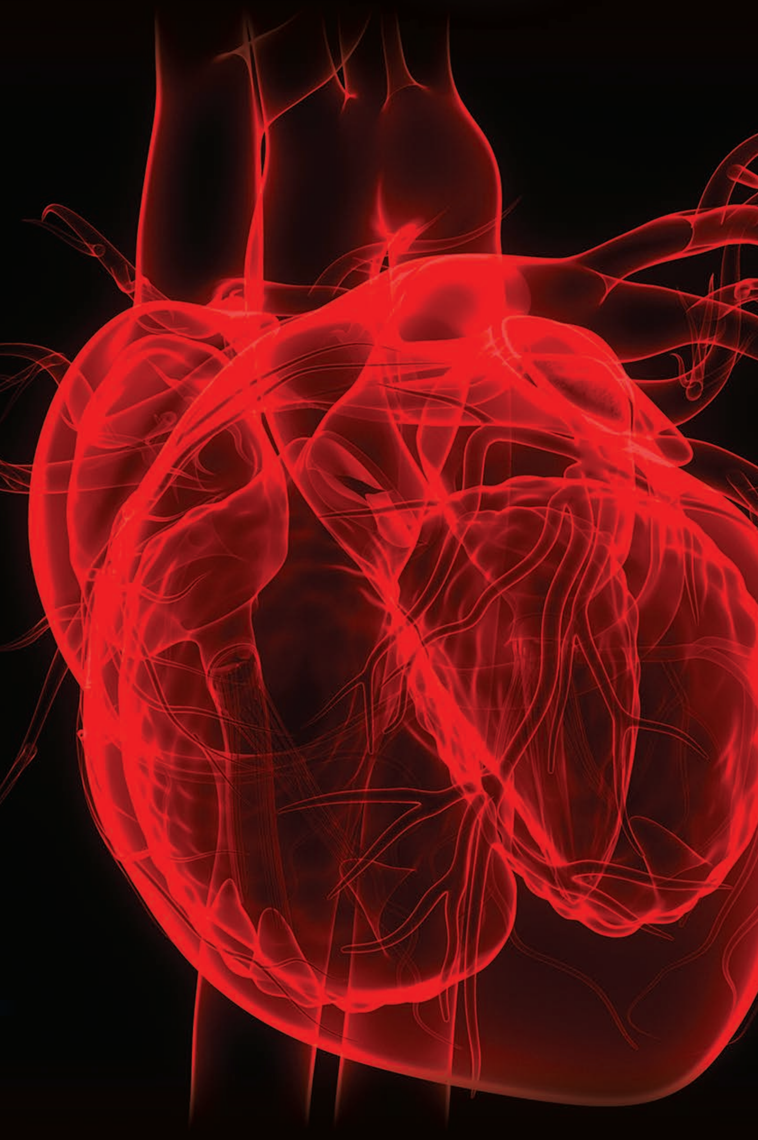
Optimizing Outcomes in Complex PCI With Orbital Atherectomy

Contents



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Introduction

By Jeffrey W. Chambers, MD

Calcified coronary arteries remain one of the most difficult types of lesions to treat. The disease states that are predictive of coronary artery calcification, including advanced age, diabetes, smoking, chronic kidney disease, hypertension, hyperlipidemia, gender, ethnicity, and body mass index, are on the rise.[1,2] Currently, calcification is found in an estimated 40% to 70% of imaged lesions[3] and severe calcification is present in 6% to 20% of coronary artery disease (CAD) patients.[4,5] These rates are expected to increase over the next 10 years.

It is challenging to achieve optimal results in severely calcified lesions with percutaneous coronary intervention (PCI), and it is difficult to completely dilate calcified plaques because the process may lead to underexpansion or malaposition.[2,6,7] Calcified occlusions are prone to dissection during balloon angioplasty or predilitation.[8] Delivering a stent to the desired location and calcium may result in stent distortion and insufficient drug penetration.[2,9,10] Patients are often referred to bypass surgery due to the potential for adverse outcomes (both short and long term) related to treating severe coronary calcification.[5,11-13] Fortunately, the availability and optimization of coronary atherectomy has allowed many patients to be treated successfully.

In 2013, the Diamondback 360® Orbital Atherectomy System (OAS) (Cardiovascular Systems, Inc.) was approved by the United States Food and Drug Administration for the treatment of de novo, severely calcified coronary artery lesions. In nearly a decade of clinical use, refinements in technique, including integration of imaging strategies along with a growing body of evidence and continuous innovation of the device platform, have enhanced outcomes with orbital atherectomy.[14]

The OAS uses a unique dual mechanism of action that combines differential sanding and pulsatile forces to sand intimal lesions and fracture medial calcium, thereby allowing optimal stent expansion.[11,14] A single Diamondback® device treats vessels from 2.5 to 4.0 mm in diameter. Differential sanding protects soft tissue, while continuous flow of blood and saline during treatment reduces the risk of slow flow and no reflow events. Because of this, a single Diamondback device can safely treat a broad range of lesions with concentric, eccentric, and nodular calcium.

Diamondback utilization and therapy has evolved from early experience and clinical trials. The ORBIT I and ORBIT II clinical trials, as well as 11 major studies, including real-world multicenter studies enrolling approximately 1,000 patients,[15,16] have constantly demonstrated the long-term safety and efficacy of coronary OAS

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for the treatment of severely calcified coronary lesions prior to stent delivery, with low procedural complication rates and low rates of revascularization through 3 years.[11,14,15,17,18]

The evidence supporting orbital atherectomy continues to expand. The prospective, randomized, multicenter ECLIPSE trial (NCT03108456) is currently enrolling. ECLIPSE will evaluate vessel preparation with Diamondback compared to conventional balloon angioplasty technique prior to drug-eluting stent implantation in severely calcified coronary artery lesions. Approximately 2,000 patients with severely calcified coronary lesions will be enrolled at approximately 150 sites in the United States.

This series of articles provides insight into the contemporary practice and use of the Diamondback® system. ■

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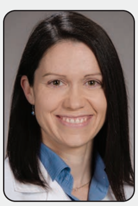
Orbital Atherectomy in PCI for Calcific Disease: What Have We Learned and Where Are We Headed?

A data review on the role of orbital atherectomy in PCI for calcific coronary disease.

By Kathleen E. Kearney, MD



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Advances in stent technology and cardiology training have led to broader adoption of percutaneous coronary intervention (PCI) in increasingly complex patients,[1] yet calcific disease continues to hamper outcomes.[2] Atherectomy is now widely available regionally, but practice heterogeneity and variability in the access to and utilization of technology dedicated toward vessel preparation in calcified coronary arterial disease (CAD) persist. This article reviews the available data to guide our learning curve on orbital atherectomy (OA) as it applies to this space, identifies gaps in current knowledge, and suggests future studies that may impact practice patterns.

IMPLICATIONS OF CALCIFIC DISEASE IN OUTCOMES OF PCI

Advances in stent design and operator experience have reduced in-stent complications, with definite or probable stent thrombosis in less than 1% of the non–acute coronary syndrome population at 2 years[3] and in approximately 1% of all cases in the Medicare population,[4] yet 10% of PCI in the National Cardiovascular Data Registry was performed for in-stent restenosis (ISR).[5] ISR can be challenging to manage and is associated with a major adverse cardiac event (MACE) rate of approximately 30% in less than 1 year.[6] This is why adequate vessel preparation is so critical. In a pooled analysis from randomized trials using contemporary drug-eluting stents (DESs), moderate-to-severe calcium was a major predictor of target lesion failure between 30 days to 1 year, observed at a rate of 2.1%.[7] Although the rate of probable or definite stent thrombosis at 1 year was fortunately only 0.6% in the same pooled analysis, other studies have implicated severe calcification as a significant risk factor,[8] likely linked to stent underexpansion. Limitations in practice for calcium management are numerous; among them are operator training and experience with atherectomy and concerns about time and cost. Lack of definitive data is also cited in the face of these other concerns for those who have not adopted atherectomy in their practice.

ATHERECTOMY: DATA, TRIALS, AND TRIBULATIONS

The constant conundrum facing the interventional cardiologist regarding device selection is a balance of risks and benefits of applying a technology. Of course, device utilization is impacted by operator training in best practices, but case selection, complication management, and practice environment all color that risk-benefit assessment. Additionally, our practice patterns emphasize the short-term outcomes for the patient, and a lack of disease-based registries or consistent definitions in disease characteristics such as calcium burden make the application of data more complicated than the surface layer of results. In the case of atherectomy, successful stent implantation may be possible without additional calcium modification, but the question remains: do we improve long-term patient outcomes in cases of

TABLE 1. DATA OVERVIEW OF STUDIES EVALUATING CORONARY ATHERECTOMY						
Study	**Year**	**N**	**Dissection (%)**	**Perforation (%)**	**Slow Flow/ No Reflow (%)**	**30-Day TVR (%)**
ORBIT II[9]	2014	443	3.4*	1.8	0.9	1.4
Lee et al[10]	2016	458	0.9	0.7	0.7	0.0
COAP-PCI[11]	2018	273 OAS	1.3*	0.4	–	–
Koifman et al[12]	2018	67	7.5	–	–	–
Chambers et al[13]	2018	78	–	–	1.3	1.3
Desai et al[14]	2018	40	0.0	2.5	2.5	0.0
Whitbeck et al[15]	2018	70	0.0†	1.4	1.4	Only acute (up to discharge) MACE rates were reported
Okamoto et al[16]	2019	184	1.6	1.6	2.2	–
COAST[17]	2020	100	2.0*	2.0	2.0	1.0

*Type C-F significant or severe dissections.
†There was no severe dissection, but 4.3% type A dissections.
Abbreviation: TVR, target vessel revascularization.

calcific disease with atherectomy? Unfortunately, these questions may never be fully answered in randomized trials as those who stand to gain the most from device therapies are often not enrolled when the operator does not see equipoise, and crossover to the intervention arm clouds results. Despite these limitations, several trials have identified the relative efficacy and safety profile of atherectomy use, and this article focuses on the recent data exhibiting clinical outcomes after OA (Table 1).[9-17]

Rotational atherectomy (RA) was early to the market and used in the first studies evaluating atherectomy as an adjunct to PCI in calcific CAD. The ROTAXUS trial randomized patients to DES implantation with or without the aid of RA but failed to show a clinical benefit with regard to early restenosis or clinical outcomes at 2 years.[18,19] A more recent follow-up trial that randomized 200 patients to RA versus cutting/scoring balloon as vessel preparation demonstrated improved procedural success with RA, but again clinical events were not significantly different nor were they powered for detection in this analysis.[20] Notably, there was 16% crossover, and while patients with severe calcification were included, the core laboratory found that 25% of cases fit criteria for moderate calcification. These early trials are important in emphasizing key characteristics for interventional trials—challenges with anatomic definitions, crossover to the interventional strategy, and power to detect clinical events in stable ischemic heart disease patients and the current DES platforms.

OA is the more recent addition to the market (Diamondback 360® Coronary Orbital System, Cardiovascular Systems, Inc.), and is thus building on a different mechanism of action, using centrifugal forces and orbital motion of the burr to fracture calcium and perform differential sanding.[21-23] ORBIT I was the introductory study and first evaluated 50 elective PCI patients in 2008 across nine operators and two sites, in lesions ≤ 25 mm in length with mild-to-severe calcium to establish baseline safety and efficacy data.[24] Procedural success, defined as ≤ 20% residual stenosis after stent placement, was 97%, with 2 minor and 1 major dissections noted without clinical consequence and one perforation after stent placement. Of note, only 6 patients underwent angioplasty after OA prior to stent placement, while some did have angioplasty and intravascular ultrasound (IVUS) performed prior to OA. Still, in-hospital MACE was low, including only 6% (2 patients) and 12% at 6 months. This led the way for ORBIT II, evaluating 443 consecutive patients with severely calcified coronary lesions across 49 sites.[9] Of note, 11% of patients in ORBIT II received bare-metal stents. Severe calcification was defined as fluoroscopic visualization without cardiac motion on both sites of the vessel, length > 15 mm, or ≥ 270° arc on IVUS

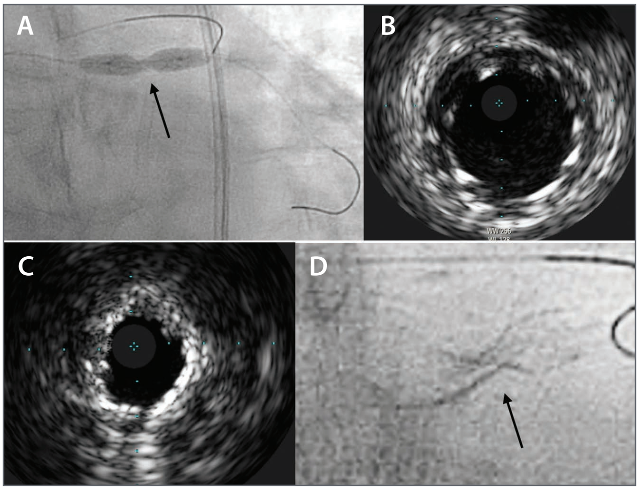

Figure 1. A 70-year-old man with IVUS-guided sizing for a 5.0-mm stent based on the proximal vessel. There was poor expansion (arrow) despite high-pressure inflation with a 5.0-mm noncompliant balloon catheter (A). IVUS of the proximal stent showed adequate apposition and expansion (B). IVUS corresponding to the waist demonstrated a diameter of 2.4 mm (C). Cineography of the stent demonstrated a severely underexpanded section (arrow) (D).

cross-sectional imaging. The efficacy endpoint of stent implantation with < 50% residual stenosis after stent implantation and freedom from in-hospital MACE was met in 88.9% of participants, with successful stent delivery and < 50% stenosis in 97.7% of cases and low rates of in-hospital Q-wave myocardial infarction (MI) (0.7%), cardiac death (0.2%), and target vessel revascularization (TVR) (0.7%). Follow-up at 3 years was completed in 360 (81.3%) patients, demonstrating a cumulative event rate of MACE of 23.5%, cardiac death of 6.7%, MI of 11.2%, and TVR of 10.2%. Target lesion revascularization at 3 years was 7.8%, as compared with 13.8% and 16.7% in the ROTAXUS trial in the RA and control treatment arms, respectively.[9,18,19,25] In contrast with current practice for many operators, the minority of lesions were treated with angioplasty after OA prior to stent placement (still only up to 42% in ORBIT II), whereas 52% had postdilatation after stent placement.[9] In total, these data indicate OA may improve management of severely calcific disease with an acceptable safety profile in a patient population that has been poorly represented in trials but are yet limited by lack of a control arm. Recognizing that multiple facets of PCI have changed over time and other patient selection factors differ across studies, these data are encouraging in that calcific CAD can and should be treated in patients with an indication for PCI.

APPLYING DATA TO THE REAL WORLD: DOES IT WORK WHERE IT REALLY COUNTS?

Given the confines of the trial setting and the often lower overall risk profile of patients, subsequent registries shed insight into understanding outcome data in the broader population with real-world use. Lee et al published a study of 458 consecutive patients with severely calcified CAD who underwent OA-assisted PCI.[10] This retrospective review of 458 consecutive patients showed low rates of 30-day MACE (1.7%), with 0.9% stent thrombosis, 1.1% MI, 0% TVR, and 1.3% all-cause mortality, indicating significant overlap in these presenting events. Perforation, dissection, and no reflow were all < 1% each, indicating an acceptable safety profile in real practice, although generalizable in the context where operators are likely highly trained in device utilization and managing complications in complex PCI.

Meraj et al performed a prospective registry to evaluate outcomes related to PCI using OA versus RA in 907 patients across five tertiary care hospitals.[11] OA was associated with lower rates of the primary endpoint of in-hospital MI (primary endpoint of 6.7% vs 13.8% in RA) and similar procedural safety outcomes in the 546 cases compared after propensity score matching. A recent meta-analysis of seven retrospective studies comparing rates of MI and vascular complications also noted a stronger association of periprocedural MI after RA versus OA but a lower risk of dissection or perforation.[26] Although these data are subject to selection bias based on angiographic features and operator preferences despite propensity matching, they do support future study regarding the best use for OA in treating calcified CAD.

Imaging Versus Angiographic Classification of Calcification

The definition of significant calcification by angiography and variable definitions used in studies to date are significant limitations of the current data. In ORBIT II, calcification burden was defined by IVUS in only 8% of cases, with the remaining patients included on the basis of angiographic criteria. A substudy evaluating IVUS in ORBIT II found that there was a reduction in the number of stents used in those with IVUS; 3-year MACE rates were not statistically different but were higher in the no-IVUS cohort (24.2% vs 14.3% in the IVUS group; $P = .26$).[27] As this substudy was limited to 35 patients who underwent IVUS prior to OA, this may favor lesions that were more amenable to imaging prior to OA. However, taken in the context of contemporary data supporting IVUS as a tool to improve PCI outcomes,[28] it is likely that coupling intracoronary imaging with atherectomy would further improve PCI outcomes in treating calcified lesions.

LOOKING AHEAD: WHAT QUESTIONS REMAIN?

The current data have established a platform for OA in treating calcified CAD but are limited in terms of patient selection and how that applies to the operator making a rapid decision that has real consequences to the patient: should atherectomy be used in this patient? Frequently, this is not realized until a poor stent result is recognized and is much more challenging to recover (Figure 1). The evaluation of treatment strategies for severe calcific coronary arteries (OA vs angioplasty technique) prior to implantation of DES in the ECLIPSE trial will aid in answering these questions. Currently enrolling with a target of 2,000 patients, this randomized trial is comparing vessel preparation with OA and balloon pre-dilatation to that with conventional and/or specialty balloon preparation, with a primary outcome of target vessel failure at 1 year (composite of cardiac death, target vessel–related MI, or ischemia-driven revascularization). An imaging cohort using optical coherence tomography in 500 patients will also assess minimal stent area as another primary endpoint, as well as secondary outcomes of procedural and strategy success. Importantly, the study population is expanded to include ACS patients provided they are stabilized > 48 hours after ST-segment elevation MI and excludes patients with severe heart failure symptoms or left ventricular ejection fraction < 25%.

The ECLIPSE trial is well positioned to inform whether the practice of using OA or "vessel preparation with balloon angioplasty only" provides the best outcomes. This study far outpaces the aforementioned studies evaluating RA and OA in terms of size; the inclusion of an imaging cohort, evaluating crossover to the alternative strategy, and use of current-generation DESs will lend further insight as to how the vessel preparation strategy affects clinical and procedural outcomes.

CONCLUSION

Early data evaluating the safety and efficacy of OA are promising. Although patient selection and best practices for technique remain paramount for improving clinical outcomes, many cases should not be undertaken without additional calcium modification and vessel preparation, and training in these tools is imperative for the modern interventional cardiologist. Studies using better-defined classification schemes based on intracoronary imaging to define calcific burden and assess procedural outcomes will better showcase the risks and benefits of OA and further guide use of the full complement of tools aimed at treating calcific CAD. ■

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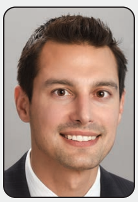
Imaging and Treating the Complex Patient

Optimizing outcomes in complex PCI with orbital atherectomy.

By Evan Shlofmitz, DO, and Richard Shlofmitz, MD



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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

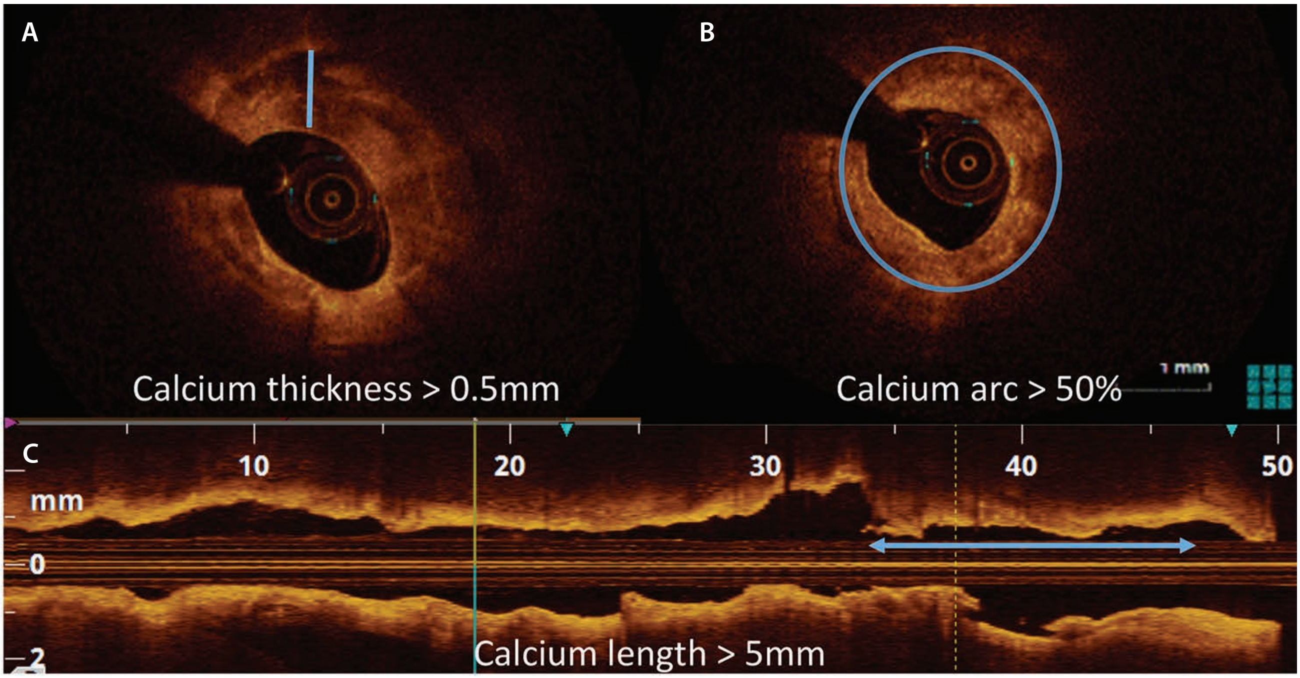

Figure 1. The St. Francis Calcium-OCT Score. Representative OCT demonstrating CAC with thickness > 0.5 mm (A), an arc of calcium > 50% of the cross-section (B), and length > 5 mm (C). In the presence of these three features, lesion preparation should be considered.

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

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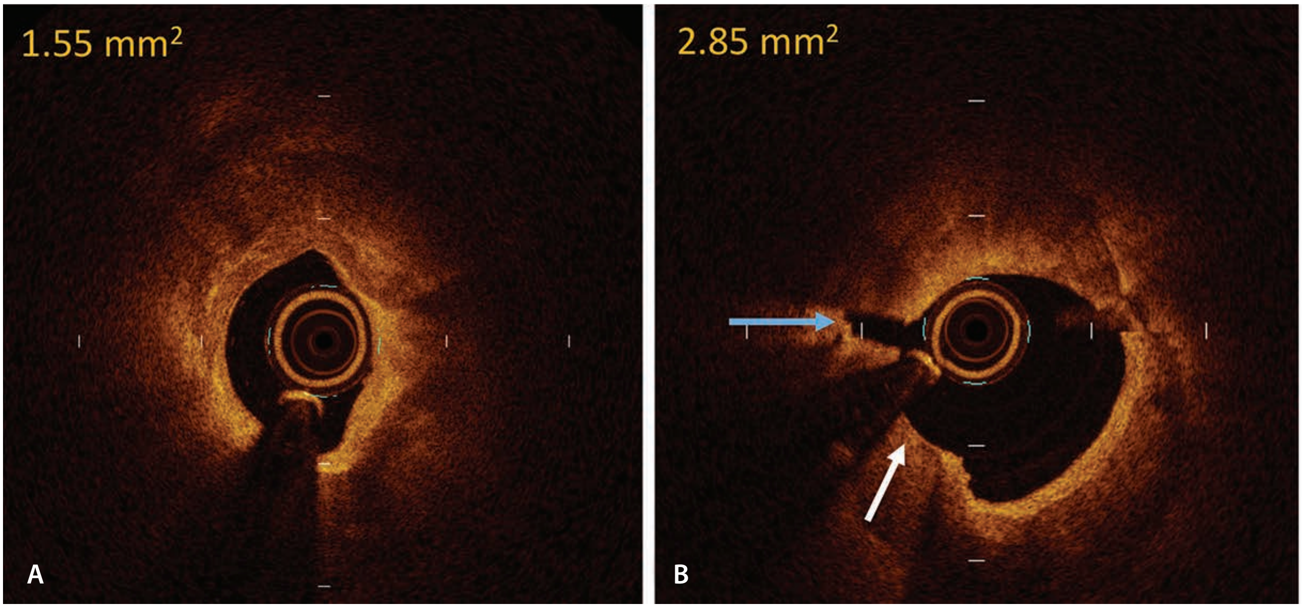

Figure 2. Baseline OCT with severe calcification and a lumen area of 1.55 mm² (A). OCT after lesion preparation with orbital atherectomy demonstrating the dual mechanism of action with both smooth concentric ablation (white arrow) and calcium fracture (blue arrow), with an enlarged lumen of 2.85 mm² (B).

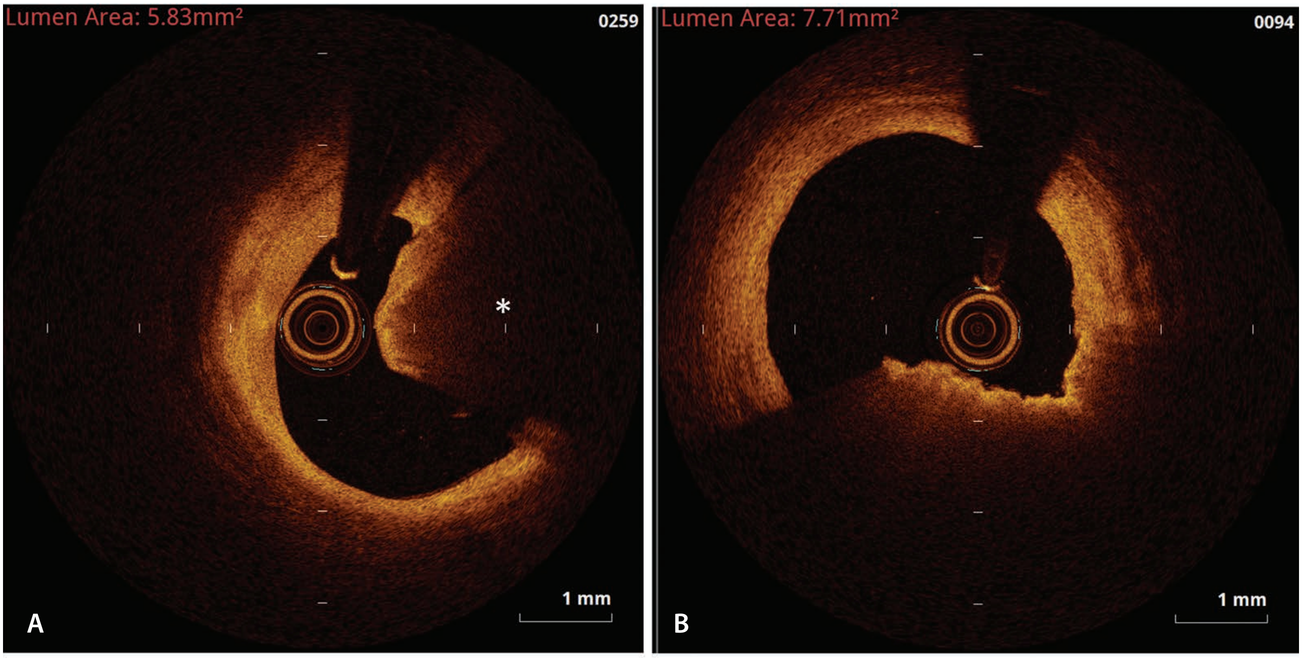

Figure 3. Baseline OCT demonstrating a protruding calcified nodule (*) (A). OCT after lesion preparation with orbital atherectomy demonstrates reduction in the nodule size with enlargement of the lumen area (B).

imaging should be performed. By documenting fracture prior to 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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Streamlining Care With Orbital Atherectomy in Complex PCI

Facilitating evidence-based adjunctive therapy for PCI procedures in calcified lesions

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In the current health care environment, providers and patients are looking for opportunities to improve efficiency and minimize time in the hospital while improving safety. Radial approaches, intravascular imaging, appropriate device selection, and same-day discharge after outpatient percutaneous coronary intervention (PCI) procedures can help achieve these goals.

Calcification can impede stent delivery and deployment and increase procedural risk.[1,2] Atherectomy has improved clinicians' ability to treat calcified lesions. In 2015, the Centers for Medicare & Medicaid Services assigned unique codes with incremental reimbursement for PCI with atherectomy. This enabled physicians to incorporate imaging and hemodynamic assessment alongside atherectomy to optimize procedural outcomes with less financial concern.

With technical, pharmacologic, and PCI-related advancements, many atherectomy patients are suitable for same-day discharge, enabling patients to recover at home and avoid hospital-related infections; hospitals can also maintain capacity while reducing costs of routine observation. In 2018, the Society for Cardiovascular Angiography and Interventions updated its length of stay guidelines.[3] Focus shifted from proscriptive criteria to a more patient-focused approach, including consideration of same-day discharge for stable patients undergoing successful procedures as part of a structured program. We were able to successfully incorporate Diamondback 360® Coronary Orbital Atherectomy System (OAS) (Cardiovascular Systems Inc.) into this program.

The Diamondback 360® is a useful tool to adjunctively treat severely calcified coronary artery stenoses. It offers several clinical advantages to streamline complex PCI:

- A single Diamondback® device can treat lesions from 2.5 mm to 4.0 mm in diameter, as well as long, diffuse lesions and multivessel disease
- Diamondback is 6-F guide catheter compatible for lesions as large as 4.0 mm, making it ideal for radial access procedures
- Diamondback allows continuous blood flow during treatment, minimizing the risk of slow flow and no reflow that can increase periprocedural complications and prevent same-day discharge
- The need for temporary pacemaker placement is extremely low with Diamondback, eliminating the need for additional access sites

Due to the unique mechanism of action of the Diamondback 360 system, there are other potential advantages that can improve efficiency:

- The ViperWire Advance® Coronary Guide Wire with Flex Tip (Cardiovascular Systems Inc.) has excellent deliverability and can be used to directly wire lesions prior to treatment with Diamondback to avoid wire exchange
- Given its one-size-fits-all design, inventory management may be simplified
- Diamondback's electric-powered drive train requires less setup

Our institution has successfully incorporated Diamondback atherectomy into our outpatient same-day discharge PCI program.

We share two patient cases using Diamondback with the new, nitinol ViperWire® with Flex Tip Guide Wire to treat heavily calcified lesions via a radial approach, safely discharging them on the same day of their procedure.

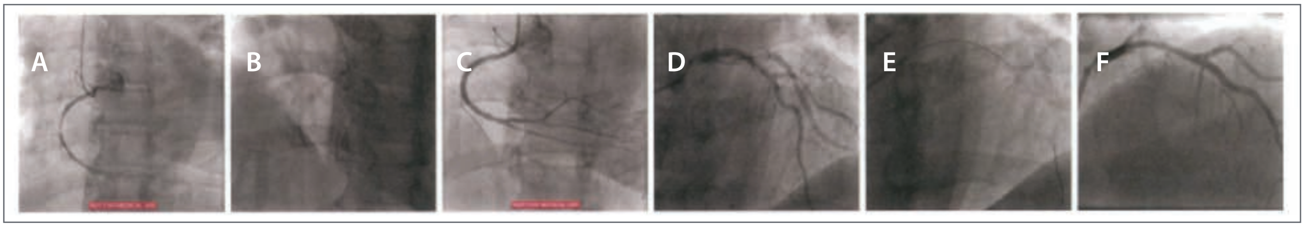

Figure 1. Focal, calcified mid right coronary artery lesion (A). Predilatation with a 1.5-mm balloon (B). Final result after OA and a 3.5- X 23-mm DES deployment (C). Diffuse, calcified left anterior descending artery lesion (D). OA performed at 80K rpm (E). Final result after deployment of a 2.5- X 23-mm and a 3- X 12-mm DES (F).

CASE PATIENT 1

A 68-year-old woman presented for diagnostic coronary angiography after experiencing chest heaviness during yard work for several weeks. She was diabetic and had hyperlipidemia. Despite the focality of the extremely tight mid-right coronary artery lesion (Figure 1A), due to the extent of calcification we used an orbital-first approach to streamline treatment. Initial attempts to deliver the Diamondback® System were unsuccessful, so a 1.5-mm compliant balloon was used to facilitate access (Figure 1B). We performed atherectomy at 80 kRPM for two passes, administering an aminophylline infusion (250 mg intravenously over 5 minutes) just prior to beginning orbital atherectomy (OA). No bradycardia or heart block was observed during atherectomy. We performed wire exchanges with a 2.5-mm over-the-wire balloon, which we then used for predilation. Finally, we deployed a 3.5- X 23-mm drug-eluting stent (DES) at 18 atm, noting uniform stent expansion with an optimal angiographic result (Figure 1C). The sheath was removed, and a hemostasis band provided site compression. The patient was observed for 6 hours and was discharged to home at 5 PM. We contacted her the next morning and she had an uneventful night.

CASE PATIENT 2

A 72-year-old man was referred for coronary angiography after anterior wall motion abnormality was observed on stress echocardiography. He had hypertension and hyperlipidemia treated with medications. We confirmed the significance of the left anterior descending artery lesion with fractional flow reserve of 0.72 (at baseline prior to hyperemia). An angiogram identified a long, diffuse, severe calcification (Figure 1D). After crossing the lesion with a workhorse wire, we exchanged that for a ViperWire with Flex Tip and performed three passes of OA at 80 kRPM (Figure 1E). During treatment, the patient became transiently hypotensive but responded to a bolus injection of Neosynephrine®. (Interestingly, the patient admitted to using an erectile dysfunction medication on the morning of the procedure.) We predilated the lesion with a 2.5-mm balloon, then deployed a 2.5- X 23-mm DES distally and a 3.0- X 12-mm DES proximally in this long, tapered lesion, and we postdilated to 3.25 mm. Final results showed optimal stent expansion with normal flow into the distal vessel and side branch (Figure 1F). The radial band was removed and hemostasis was confirmed. Recovery was uneventful and the patient was discharged after 6 hours of observation. He was contacted the following morning and reported no adverse events overnight.

CONCLUSION

OA with the Diamondback System can facilitate evidence-based[4] adjunctive therapy for PCI procedures in calcified lesions. Carefully selected patients may be suitable for a shortened length of stay as part of a structured program. With current outpatient reimbursement programs, clinicians can utilize appropriate therapies to achieve optimal clinical results with fiscal responsibility. ■

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Indication: The Diamondback 360® Coronary Orbital Atherectomy System (OAS) is a percutaneous orbital atherectomy system indicated to facilitate stent delivery in patients with coronary artery disease (CAD) who are acceptable candidates for PTCA or stenting due to de novo, severely calcified coronary artery lesions. Contraindications: The OAS is contraindicated when the ViperWire Advance® Coronary guide wire cannot pass across the coronary lesion or the target lesion is within a bypass graft or stent. The OAS is contraindicated when the patient is not an appropriate candidate for bypass surgery, angioplasty, or atherectomy therapy, or has angiographic evidence of thrombus, or has only one open vessel, or has angiographic evidence of significant dissection at the treatment site and for women who are pregnant or children. Warnings/Precautions: Performing treatment in excessively tortuous vessels or bifurcations may result in vessel damage; The OAS was only evaluated in severely calcified lesions, a temporary pacing lead may be necessary when treating lesions in the right coronary and circumflex arteries; On-site surgical back-up should be included as a clinical consideration; Use in patients with an ejection fraction (EF) of less than 25% has not been evaluated. See the instructions for use before performing Diamondback 360 coronary orbital atherectomy procedures for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential adverse events. Caution: Federal law (USA) restricts this device to sale by, or on the order of, a physician.