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Contemporary tools and devices for coronary calcium modification

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Abstract

With the aging population, up to a third of patients referred for percutaneous coronary intervention (PCI) have moderate or severe calcified lesions assessed by coronary angiography. The presence of coronary calcium is associated with difficult device delivery, sub-optimal stent deployment, and prolonged procedures, with more complications. Furthermore, it is known that sub-optimal stent expansion is associated with poor clinical outcomes. In this manuscript we describe how to quantify the severity of coronary calcium, review the armamentarium of contemporary devices available for calcium modification, and provide a systematic approach to device selection, assessment of successful calcium modification, and stent optimization.

Keywords

Coronary artery disease, calcium modification, intravascular imaging, calcium modifying adjuncts

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Introduction

Coronary artery calcification (CAC) increases with age, is more prevalent in men, in those presenting with stable angina and is associated with type 2 diabetes mellitus.[1] CAC is an independent marker for advanced coronary artery disease (CAD), and the extent of calcification strongly correlates with the incidence of future cardiac events.[2] With the aging population, an increasing number of elderly patients with multiple co-morbidities, considered inoperable or high-risk for coronary artery bypass surgery (CABG), are being referred for percutaneous coronary intervention (PCI) with complex coronary anatomy.[3,4] The presence of moderate or severe CAC is reported in up to 30% of cases by coronary angiography (CAG),[5] and is associated with difficult device delivery, sub-optimal stent deployment, and prolonged procedures, with more complications. Furthermore, it is known that sub-optimal stent expansion is associated with poor clinical outcomes.[5]

There is now an armamentarium of contemporary tools available to modify CAC (Table 1). While there is observational data on the efficacy and safety of each of these devices, there is very limited randomized data comparing the different approaches. In this review we describe how to identify and quantify CAC, the available devices, how to confirm adequate lesion modification prior to stenting, and provide a systematic algorithm as a pragmatic guide to the treatment of CAC during complex PCI.

Identification and quantification of coronary artery calcification

Coronary angiography

CAC can be identified as radiopacities within the wall or lumen of the coronary artery and can be graded as mild, moderate (only noted during the cardiac cycle before contrast injection), or severe (seen without cardiac motion, usually affecting both sides of lumen).[6] However, the overall sensitivity of CAG to detect CAC, confirmed on intravascular ultrasound (IVUS) or optical coherence tomography (OCT), is approximately 50% but with specificity as high as 95%.[7] However, when extensive calcification is present, the sensitivity of CAG is higher (60% for three-quadrant and 85% for four-quadrant CAC by IVUS).[6]

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Table 1. Calcium modification devices.

Device	Mechanism	Specification
High-pressure balloons (OPN)	Non-compliant, twin-layered balloon High pressure inflation with uniform expansion	• 5F compatible • Available diameters 1.5 to 4.5 mm and lengths 10, 15 and 20mm • Crossing profile: 0.028” • Nominal to burst pressures: 10 to 35 atm
Scoring balloons (SB)	Focal concentrated along scoring elements Produce 4-fold increase in stress to fibro-calcific plaques compared to semi-compliant balloon	AngioSculpt • 6F compatible • Available diameters 2.0 to 3.5 mm and lengths 10, 15 and 20mm • Crossing profile: 0.036” • Nominal to burst pressures: 8 to 16 atm Scoreflex • 5F compatible • Available diameters 2.0 to 4.0 mm and lengths 10, 15 and 20mm • Crossing profile: 0.032” • Nominal to burst pressures: 6 to 16 atmospheres NSE Alpha • 5F compatible • Available diameters 2.0 to 4.0 mm and length 13mm • Crossing profile: 0.050” • Nominal to burst pressures: 6 to 14 atmospheres
Cutting balloon (CB)	Balloon mounted microblades create radial incisions in fibro-calcific plaques	Wolverine • 6F compatible • Available diameters 2.0 to 4.0 mm and lengths 6, 10 and 15mm • Crossing profile: 0.041 to 0.046” • Nominal to burst pressures: 6 to 12 atmospheres
Rotational Atherectomy (RA)	Uni-directional burr differentially cuts and ablates inelastic fibro-calcific plaque while deflecting away from adjacent elastic tissues	• 6F (1.25–1.5 mm); 7F (1.75 mm); 8F (2.00–2.15 mm); 9F (2.25–2.38 mm); 10F (2.5 mm) • Burr located at the device tip • Requires propriety wire (RotaWire) • Ablation speed: 135,000 to 180,000 rpm
Orbital Atherectomy (OA)	Bi-directional orbiting crown using centrifugal force to differentially sand inelastic fibro-calcific plaque while deflecting away from adjacent elastic tissue	• 6F compatible • Diamond-coated eccentrically mounted 1.25 mm crown proximal to the tip • Requires propriety wire (ViperWire) • Ablation speed: 80,000 to 120,000 rpm
Intravascular lithotripsy (IVL)	Balloon emitting pulsatile sonic pressure waves creating calcium microfractures	• 5F compatible • Available diameters 2.5 to 4.0 mm and length 12mm • Crossing profile: 0.042 to 0.046” • Nominal to burst pressures: 6 to 10 atmospheres
Excimer laser coronary atherectomy (ECLA)	Catheter delivered photoablation for molecular breakdown of tissue Efficient in fibrous tissue but less so with severe calcium	• 6F (0.9 mm and 1.4 mm); 7F (1.7 mm); 8F (2.0 mm) • 0.014” guidewire compatible • Uses xenon chloride to produce ultraviolet light B with a penetration depth of 30–50 μm

Intravascular ultrasound

IVUS is highly sensitive for CAC detection because calcium is a good reflector of ultrasound (Figure 1). As a result, minimal ultrasound penetrates its surface and CAC appears as bright echo-dense plaque with acoustic shadows on the adventitial side. Although fibrous plaque can also appear as echo-dense and may cast an acoustic shadow, the presence of ‘reverberations’ is specific to CAC, manifesting as multiple reflections of concentric arcs at reproducible distances resulting from oscillation of the ultrasound beam between the calcium and the probe. CAC can be quantified by IVUS using the size of the arc of calcium around the circumference of the vessel and the

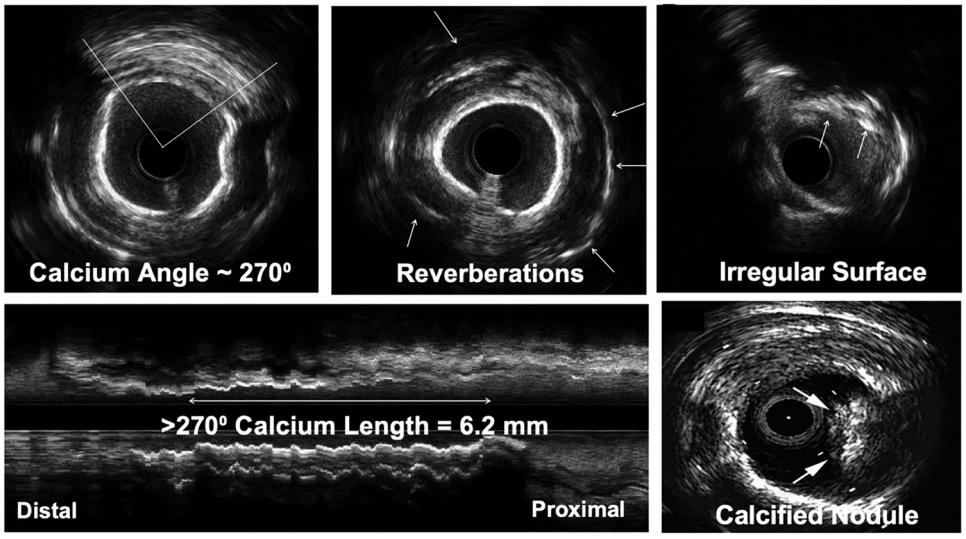

Figure 1. Intravascular ultrasound assessment of calcium.

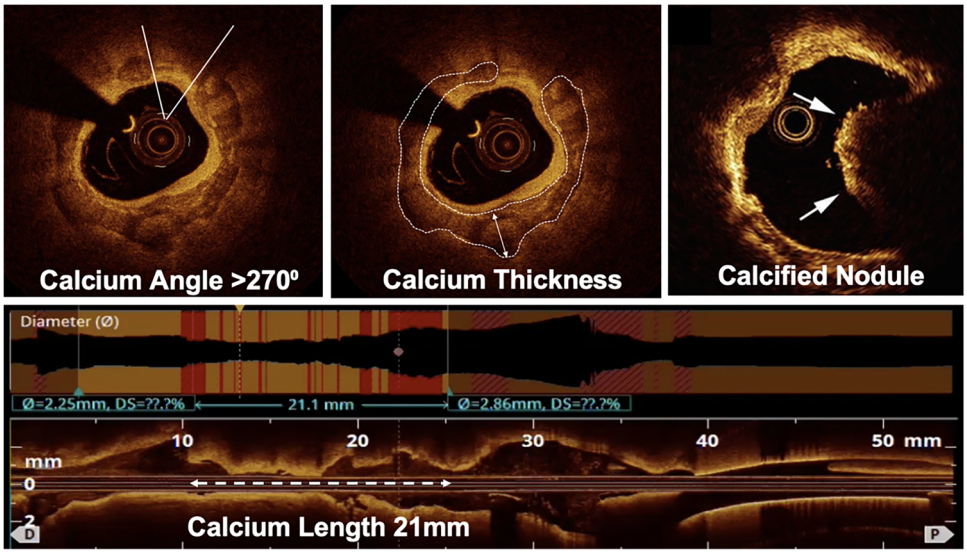

Figure 2. Optical coherence tomography assessment of calcium.

length of calcified segment measured on the longitudinal pullback. Due to the acoustic shadows behind calcified plaques, it is not possible to measure calcium thickness, although some assessment of superficiality and depth can usually be made. In addition, the presence of a smooth echo-dense surface with reverberations on IVUS has been shown to indirectly indicate thin calcium measured by OCT, while an irregular surface without reverberations indicates thicker calcium.[7] CAC can also manifest as calcified nodules, seen as echo-dense plaque protruding into the lumen with a bright leading edge.

Optical coherence tomography

While the axial resolution of OCT is 10 times better than IVUS, providing precise evaluation of superficial calcium, the rapid attenuation of signal limits its ability to assess deeper CAC (Figure 2).[8] While calcium can be confused with dense fibrous plaque on IVUS, it is most often confused with lipid-rich plaque or necrotic core on OCT, as both manifest as areas of low signal intensity. However, while CAC has a sharply delineated border, lipid or necrotic core has a poorly defined border. In addition to the arc and length, OCT can also measure the thickness of calcium. An OCT-based

calcium scoring system has been proposed to identify plaques that require modification prior to stent implantation,[9] with a calcium arc >180°, thickness >0.5 mm, and length >5 mm found to be predictors of stent under-expansion.[9]

Tools and devices for coronary calcium modification

High-pressure balloon

Conventional non-compliant balloons (NCB) have a rated burst pressure of 18 to 20 atm, although are used off-label up to 30 atm (Table 1). The super high-pressure OPN (OPN NC®; SIS Medical AG, Winterthur, Switzerland) is a twin-layered NCB that allows 30 to 45 atm. The OPN balloon has been reported to be safe and effective in a retrospective registry of 326 patient with only 3 (0.9%) coronary perforations.[10] However, there is no prospective randomized data on its performance compared to other devices. It has the advantage, unlike atherectomy, of not requiring additional skills. It can be useful specifically in the treatment of under-expanded stents, but caution should be used in the presence of a calcified nodule where super high-pressure dilatation can result in vessel rupture.

Scoring balloons (Sb)

The AngioSculpt (AngioScore Inc., Fremont, CA, USA) is a balloon with a spiral nitinol element wrapped around it. On inflation the lesion is 'scored', with the radial force of the balloon concentrated along the surface of the nitinol wires, resulting in plaque modification. With lower inflation pressures required to produce the same radial force the risk of coronary dissection or perforation is theoretically lower. An observational study comparing AngioSculpt (n = 37) to semi-compliant balloon (SCB) pre-dilatation or direct stenting, reported better stent expansion.[11] A further retrospective study comparing Angiosculpt (n = 29) to SCB (n = 155) lesions preparation prior to bioresorbable scaffold implantation, reported better scaffold expansion and eccentricity on IVUS, despite the AngioSculpt lesions being more calcified.[12]

The Scoreflex (OrbusNeich, Hong Kong, China) is a balloon with a straight nitinol wire on the outside, serving as one of the scoring elements, with the guidewire exiting just proximal to the tip and acting as the second scoring element. As a result of this design, it has the lowest crossing profile of the scoring and cutting balloons. The dual wire system creates focal stress lines resulting in controlled plaque modification at lower inflation pressures. Prolonged inflations (3 cycles of 3 min) have been shown to result in dilation of severely calcified lesions resistant to other techniques. This postulated "creep phenomenon" is thought to be due to longitudinal forces that occur in the vessel wall under a prolonged sustained load.[13]

The Non Slip Elements (NSE) alpha (B Braun, Melsungen, Germany) (previously known as Lacrosse NSE), is a balloon with three nylon scoring elements with a triangular cross section that are embedded in the balloon folds to create a smaller crossing profile. The balloon can be delivered using the "leopard-crawl" technique, creating a wedge into the calcified plaque with a low pressure inflation, then creeping forward during balloon deflation, allowing delivery across severe lesions.[14]

Cutting balloons (Cb)

The Flextome (Boston Scientific, Marlborough, MA, USA) is a balloon with three or four radially directed microblades on its surface, effective in modifying both fibrous and calcific plaques by creating endovascular incisions. In the Cutting Balloon Angioplasty versus Plain Old Balloon Angioplasty Study (CAPAS) trial, CB resulted in more acute luminal gain at lower pressures in calcified lesions and was associated with reduced restenosis rates at 3 months.[15] In the Cutting Balloon Global Randomized Trial of 1238 lesions, routine use of CBs was associated with a higher incidence of perforation and with no reduction in angiographic restenosis at 6 months.[16] The Wolverine (Boston Scientific, Marlborough, MA, USA) is the recent iteration of the CB with a shorter T-slot height upon which the blades are mounted resulting in an improved crossing profile and deliverability. In addition to de novo fibro-calcific lesions, CBs can specifically be useful in the treatment of fibro-calcific in-stent stenosis.

Rotational atherectomy (Ra)

RA is performed using the Rotablator® system (Boston Scientific, Marlborough, MA, USA), composed of a diamond-coated burr, advancer, and console. The most recent iteration is the RotaPro® system, redesigned for easier set-up and user training. During RA the burr differentially cuts and ablates inelastic fibro-calcific plaques while deflecting away from adjacent elastic tissues. Its efficacy relies of 3 important parameters, the luminal area, burr size, and degree of guidewire bias in order to successfully modify a calcified lesion.[17] For example, with a 360° arc of calcium and burr size larger than the minimal luminal area (MLA), RA will effectively modify and fracture the calcium, whereas when the burr size is smaller than the MLA, guidewire bias will usually steer the burr towards the less calcified contralateral wall and modification will be sub-optimal. Intravascular imaging can be useful to guide burr size after taking into consideration guidewire bias and calcium location.

Aiming to optimize the use of RA, both European and United States (US) consensus documents have been published in 2015 and 2019 with the main recommendations being: a burr-to-artery ratio of 0.4 to 0.6; rotational speeds of 140,000 to 150,000 rpm; burr advancement

with a pecking motion with each run 15 to 20 s; avoid decelerations of >5000 rpm; and complete the procedure with a final polish run.[3,4]

A key specific advantage of RA, due to the burr being located at the tip of the device, is that it can be used to modify balloon uncrossable lesions.

The Rotational Atherectomy Before Paclitaxel-Eluting Stent Implantation in Complex Calcified Coronary Lesions (ROTAXUS) randomized controlled trial, comparing routine RA to balloon pre-dilatation in angiographically assessed calcified lesions in 240 patients, found no benefit for the primary outcome of late lumen loss but higher procedural success rates with RA.[18] This was confirmed by the more recent PREPARE-CALC randomized controlled trial of 200 patients again with angiographically assessed calcified lesions comparing RA to pre-dilatation with SC or CB.[19]

Orbital atherectomy (Oa)

OA is performed using the Diamondback 360° Coronary Orbital Atherectomy System (Cardiovascular Systems Inc., St Paul, MN, USA), currently only approved for use in the US and Japan. It's composed of an eccentrically mounted 1.25 mm diamond-coated crown on a ViperWire™ guidewire with an advancer to control the crown movements at low (80,000 rpm) or high speeds (120,000 rpm). The orbiting crown uses centrifugal force to perform differential sanding of hard, inelastic fibro-calcific plaques while flexing away from elastic tissue, in a similar fashion to RA. Clinical outcome data is currently limited to single-arm (ORBIT I and ORBIT II) studies.[20,21] and registries reporting the safety and efficacy of OA out to 3 years.[22]

The proposed technical advantages of OA over RA are: It is easier to set-up and comes in one crown size; the bi-directional nature of the ablation makes crown entrapment less likely; micro-particle debris is smaller in size (<2 μm compared to <5 μm in bench testing) and is less likely to result in complications due to distal embolization; continuous blood flow is maintained during ablation; and thermal injury is less likely.

There is no randomized comparison between the two atherectomy devices. One small retrospective observational study of 30 patients treated with OA and 30 patients treated with RA for severely calcified (>270° arc of calcium) lesions with OCT guidance found that with both devices, more calcium modification occurred when there was a smaller lumen and larger arc of calcium, and was influenced by guidewire bias, and that both devices resulted in similar stent expansion.[23] OA has now received CE mark approval and is available for use in Europe.

Excimer laser coronary atherectomy (ELCA)

ELCA uses photochemical, photothermal, and photomechanical mechanisms to ablate tissue at the molecular level. While this is very efficient in fibrous tissue and thrombus, it is less effective with severe calcium. The catheter can be advanced on a standard guidewire and while technically easier than the other atherectomy techniques it is available in limited centres and used infrequently, usually as a bailout technique when other devices have failed. There is very limited observational data and reports of it being effective in balloon uncrossable lesions and under-expanded stents.[24] Of note, the use of laser with contrast instead with normal saline flush in resistant lesions or under-expanded stents[25,26] has been shown to be more effective, but should remain restricted to experienced laser users. A recent analysis from the British Society of Cardiovascular Intervention registry of 1471 ELCA cases showed that ELCA use was associated with higher risk baseline and procedural characteristics,[27] reflecting the fact that it is usually reserved as a last resort in high-risk cases, when other calcium-modifying adjuncts have failed.

Intravascular lithotripsy (IVL)

The Shockwave Medical Coronary Rx Lithotripsy System (Shockwave Medical Inc., Fremont, CA, USA) is the latest addition to the toolbox of devices for calcium modification. The IVL balloon emits pulsatile sonic pressure waves creating micro-fractures in calcium in the vessel wall. The waves reflect off calcium reverberating and amplifying the effect, and thus the more circumferential the calcium the more effective the therapy. The balloon is initially inflated to 4 atm for apposition to the plaque, a set of 10 pulses is delivered, and then inflated to 6 atm to compress the fractured plaque, with each balloon able to deliver a maximum of 8 sets of therapy.

The DISRUPT CAD I (n = 60) and II (n = 120) prospective, European multicentre, single-arm studies found that IVL could be safely performed in angiographically assessed severely calcified lesions with high procedural success and minimal complications.[28,29] DISRUPT CAD III (n = 431), a prospective, UK and US multicentre, single-arm study with a primary endpoint of 30-day major adverse cardiac event (MACE), recently confirmed that IVL was safe and achieved calcium fracture in 67% of cases, as demonstrated by OCT.[30] With a CE mark since 2017, FDA has eventually approved its use in at the beginning of 2021.

The key advantages of IVL are: Its ease of use compared to atherectomy devices; the ability to maintain multiple guidewires during use; a theoretical ability to create fractures deep in thick calcium; efficacy in larger lumens with 1:1 balloon-to-vessel sizing and no guidewire bias;[31] a potentially lower risk of trauma to the vessel wall and embolization of debris. The main limitations are the anticipation that it is less effective in less circumferential (<270°) and nodular calcium and due to its bulkier nature, it would require a guide extention catheter or extra support guidewires for it to be delivered down tortuous and calcified vessels.

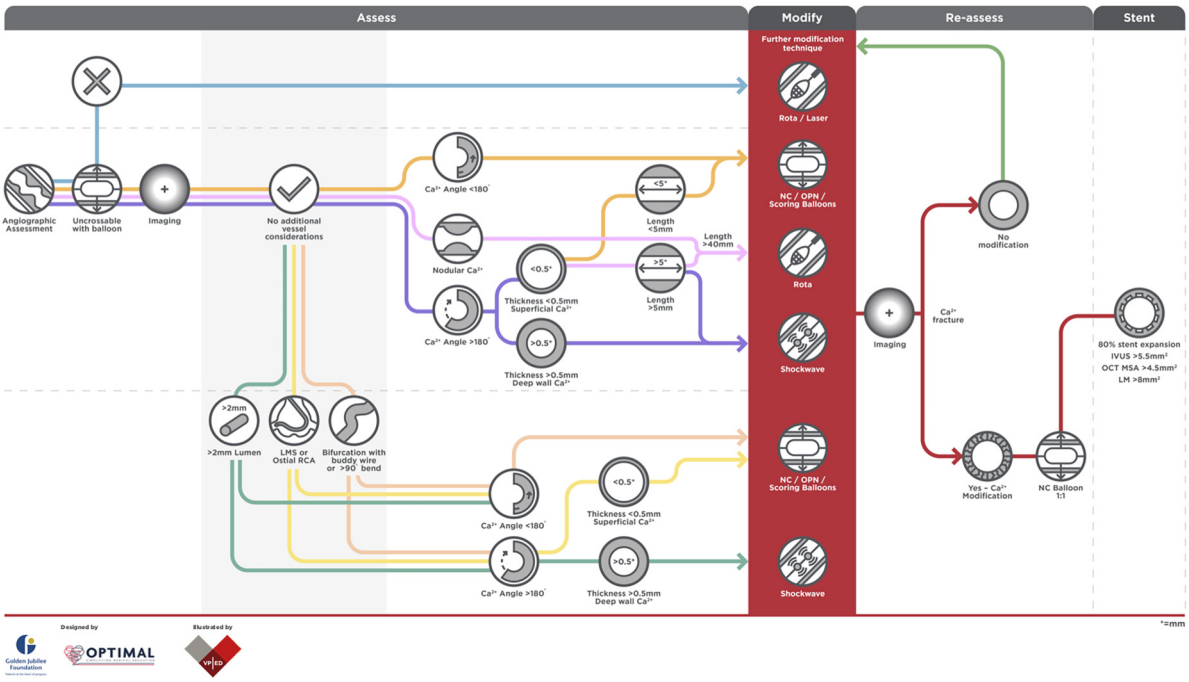

Figure 3. Calcium algorithm: A systematic approach to coronary calcium modification [LMS, left main stem; RCA, right coronary artery; Ca^{2+}, calcium; rota, rotational atherectomy; NC, non-compliant balloon; OPN, high pressure balloon; shockwave, intravascular lithotripsy; IVUS, intravascular ultrasound; OCT, optical coherence tomography; MSA, minimal stent area].

Confirming adequate calcium modification

As suboptimal stent expansion is known to be associated with poor clinical outcomes,[5] irrespective of the tool used, it is essential to confirm that CAC has been adequately modified prior to stent deployment. The presence of calcium fractures is a strong independent predictor of stent expansion,[32,33] and therefore it is recommend that this be confirmed by IVUS or OCT prior to stenting. The absence of visible fractures or significant luminal gain should prompt a re-evaluation of the CAC modification strategy.

A systematic approach to calcium modification

Based on the available data and expert consensus a systematic algorithm was devised to guide calcium assessment and appropriate device selection (Figure 3). If a lesion is uncrossable RA or laser is the necessary initial strategy. Otherwise IVUS or OCT should be performed to assess the calcium morphology. If nodular, RA or OA is likely to be most effective. If concentric, the arc, thickness and length of calcified segment should be assessed and used to guide initial device selection. Lesion location and morphology (eg. Left main stem, ostial right coronary artery, large vessel lumen, bifurcation) should also be considered. Following the initial strategy intravascular imaging should be repeated to confirm calcium fractures or significant luminal gain, and the modification confirmed with pre-dilatation with a 1:1 NCB prior to stenting. If modification is inadequate, use of an alternative device should be considered. Stent expansion should be assessed with optimized with further post-dilatation as required.

Conclusion

With the increasing burden of CAC in the aging population, calcium modification is frequently required during PCI. With the wide range of tools available we describe a systematic approach, using intravascular imaging guidance, for appropriate device selection and stent optimization.

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