# OCT-Guided Treatment of Calcified Coronary Artery Disease: Breaking the Barrier to Stent Expansion

Evan Shlofmitz[1] · Fernando A. Sosa[2] · Ziad A. Ali[3,4,5] · Ron Waksman[1] · Allen Jeremias[3,4] · Richard Shlofmitz[3]

## Abstract

**Purpose of Review** Our objective is to review the current status of OCT-guided treatment of calcified coronary artery disease.
**Recent Findings** New treatment modalities provide multiple options for approaching interventions involving calcified lesions.
**Summary** Coronary artery calcification is associated with stent underexpansion and worse procedural outcomes. Optimizing stent expansion is essential to reduce restenosis and the need for revascularization. Optical coherence tomography (OCT) allows for accurate diagnosis and detailed characterization of calcified lesions. The features of coronary artery calcification are determinant of the optimal lesion preparation and treatment strategy. We recommend an OCT-guided treatment approach for calcified coronary lesions.

**Keywords** Calcified lesion · Percutaneous coronary intervention · Optical coherence tomography · Intravascular lithotripsy · Orbital atherectomy · Rotational atherectomy

## Introduction

Severely calcified coronary artery disease represents a challenging lesion subset that is often encountered in patients treated with percutaneous coronary intervention (PCI). The presence of calcification is often underappreciated by angiography alone [1•]. Accurate recognition and classification of coronary artery calcification permits appropriate decision-making to determine the optimal treatment approach. We herein review the role of optical coherence tomography (OCT) in guiding the treatment of calcified lesions with PCI.

✉ Evan Shlofmitz
Evan.Shlofmitz@MedStar.net

1    MedStar Washington Hospital Center, 110 Irving Street NW, Suite 4B1, Washington, DC 20010, USA

2    Abbott Vascular, Santa Clara, CA, USA

3    St. Francis Hospital - The Heart Center, Roslyn, NY, USA

4    Cardiovascular Research Foundation, New York, NY, USA

5    Columbia University Medical Center, New York, NY, USA

## Impact of Calcification

Coronary artery calcification is associated with decreased procedural success and worse clinical outcomes [2–4]. Specifically, underexpansion which is one of the strongest predictors of future stent thrombosis and in-stent restenosis is closely related to the degree of lesion calcification [5]. Atherectomy, the term coined by John Simpson in the 1980s, refers to device-based plaque modification [6]. The value of intravascular imaging with the use of atherectomy has been recognized since the initial reports of atherectomy use [7]. Historically, atherectomy devices were reserved for uncrossable or undilatable lesions. In recent years, there has been a paradigm shift to an upfront *lesion preparation* approach to modify calcified plaque to maximize stent expansion. This comes with an important distinction; with lesion preparation, the goal is not simply to facilitate stent delivery, but rather to optimize stent expansion.

## Role of OCT

Intravascular imaging assessment is essential to accurately assess the burden of calcified plaque [8–10]. Two independent studies conducted decades apart both corroborated the significant inaccuracies of angiography

alone for the detection and diagnosis of coronary artery calcifications [11, 12]. Mintz et al. initially reported that angiography detected calcium in just 38% lesions, whereas intravascular ultrasound (IVUS) detected lesion calcium in 73% of lesions [13]. The more contemporary study, which compared OCT in addition to IVUS and angiography, found similar conclusions [12].

Intravascular imaging should be performed on all lesions with suspected calcification undergoing PCI to guide selection of appropriate therapies and ensure adequate stent expansion is achieved. Occasionally, angiographically severe calcification can be found to be only mild-moderate in severity following intravascular imaging assessment and does not require lesion preparation beyond balloon-based therapies. Conversely, and more commonly, severe calcification is significantly underappreciated by angiography alone. This is associated with greater morbidity [14]. Unrecognized severe calcification in patients undergoing PCI increases the likelihood for stent underexpansion.

Intravascular imaging allows for more than mere quantification and diagnosis of coronary artery calcification. Beyond assessing mild, moderate, or severe calcification, there are important morphologic characteristics that influence the optimal treatment strategy. An algorithmic approach to integrate OCT into PCI is recommended to ensure comprehensive assessment and procedure planning [15•]. OCT can safely and quickly provide information influencing treatment decisions in real time [16, 17].

## Coronary Calcification Classification

Angiographic calcification is classified as mild, moderate, or severe. The use of intravascular imaging allows for more specific characterization and quantification of calcification. Beyond determining severity of calcification, it is important to determine if the calcification is superficial or deep (Fig. 1) and eccentric or concentric (Fig. 2). These factors are often determinant of the optimal treatment technique.

It is important to recognize the presence of calcified nodule, which is often underappreciated by angiography alone. OCT studies have demonstrated calcified nodules are present in greater than 6% of patients with angiographically nonobstructive lesions and in roughly one third of severely calcified culprit lesions in patients with ACS [18•, 19].
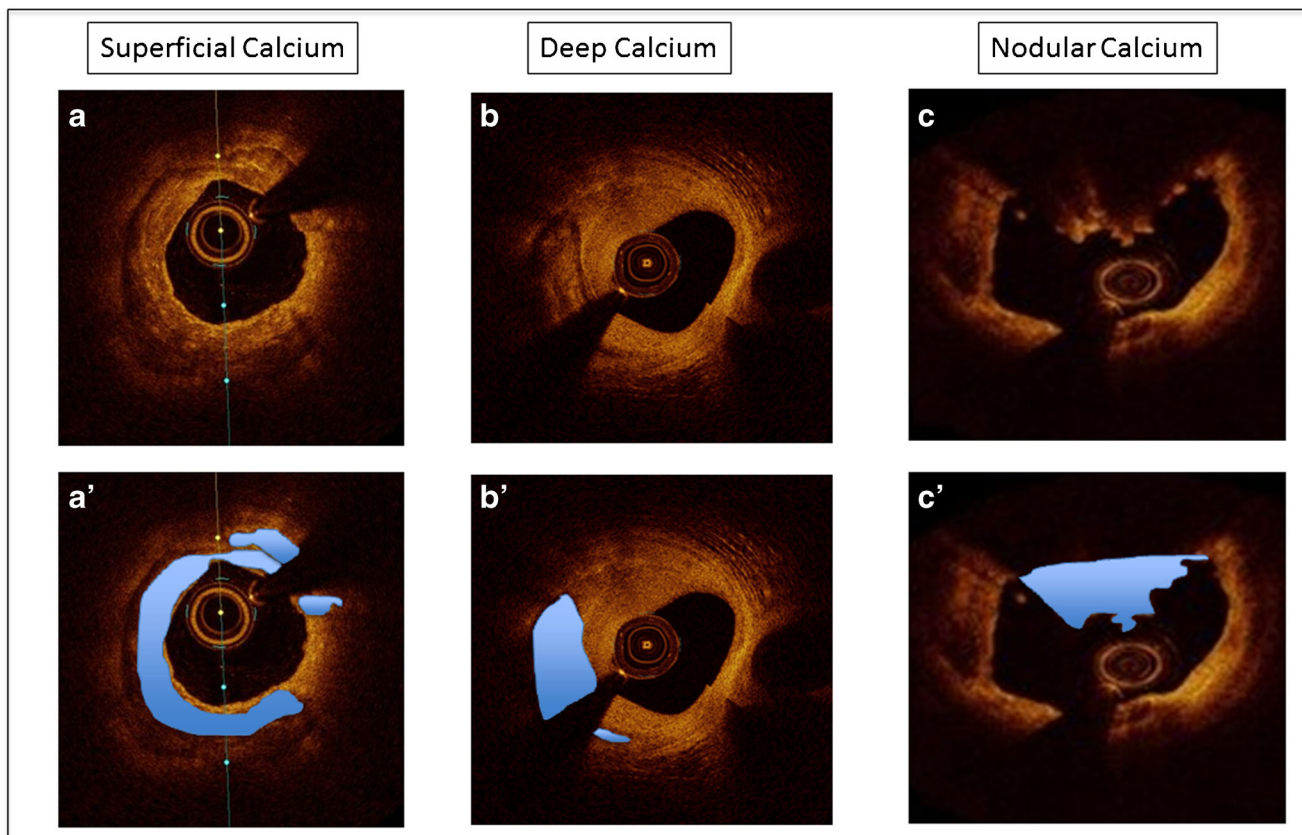


Fig. 1 Classification of calcification. OCT cross-section demonstrating superficial calcification (A), deep calcification (B), and nodular calcification (C). Blue overlay highlights the calcification in the respective OCT cross-sections (A′, B′, C′)

**Fig. 2** Calcified plaque classification. OCT cross-section demonstrating eccentric calcified plaque (A) and concentric calcified plaque (B). Blue overlay highlights the calcification in the respective OCT cross-sections (A′, B′)
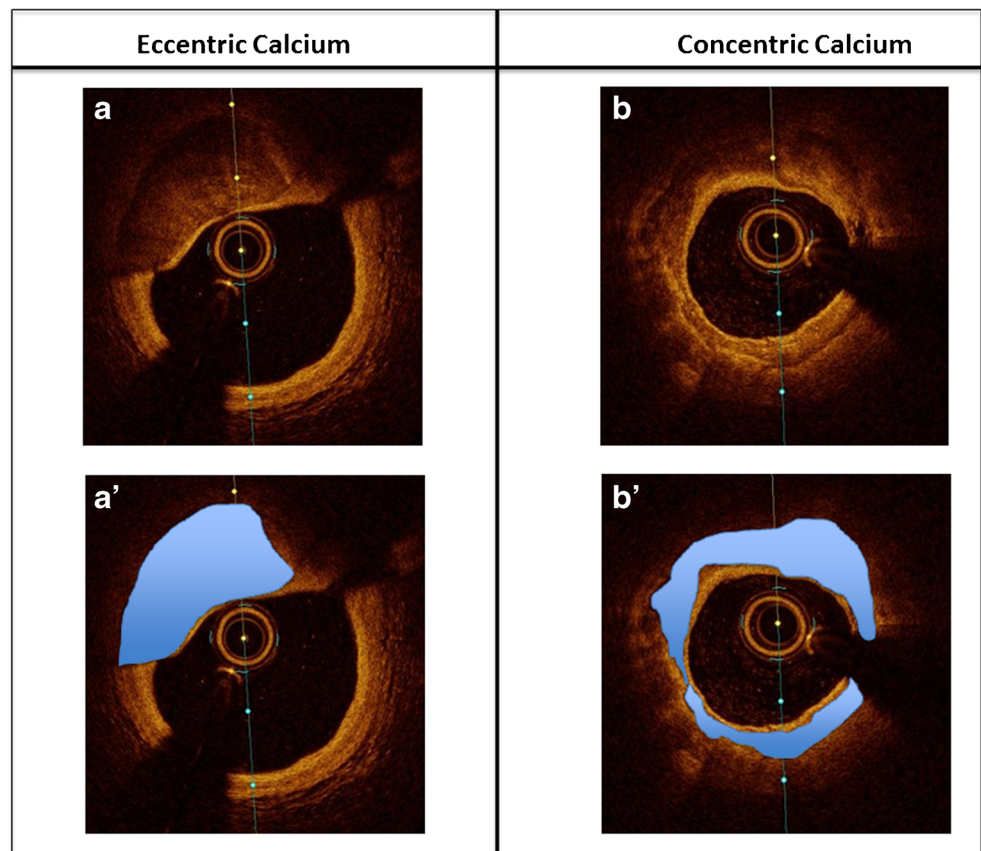


## OCT-Based Calcium Scoring System

OCT allows unique in vivo characterization of coronary artery calcification. Recognition of the features of calcified plaque that can predict stent underexpansion is important for selecting appropriate lesion preparation strategies. An OCT-based calcium scoring system can be used to quickly calculate the risk of a calcified lesion for stent underexpansion [20••]. If pre-stent OCT demonstrates maximum calcium angle > 180°, continuous length > 5 mm, and calcium thickness > 0.5 mm, the lesion is at risk for stent underexpansion with PCI (Fig. 3). Consequently, these lesions should be treated with an upfront lesion preparation strategy to facilitate plaque modification and calcium fracture prior to stent implantation. This can be achieved with lesion preparation with either intravascular lithotripsy, orbital atherectomy, or rotational atherectomy.

## Rotational Atherectomy

Rotational atherectomy was first introduced by David Auth and colleagues in the 1980s and has been the predominant atherectomy modality in use for calcified coronary artery disease [21, 22]. Rotational atherectomy uses a diamond-coated elliptical burr to rotate concentrically while advancing in a forward direction. The Rotablator system (Boston Scientific

**Fig. 3** OCT-based calcium scoring system. The presence of an arc of calcium > 180°, length > 5 mm, and calcium thickness > 0.5 mm predisposes to stent underexpansion
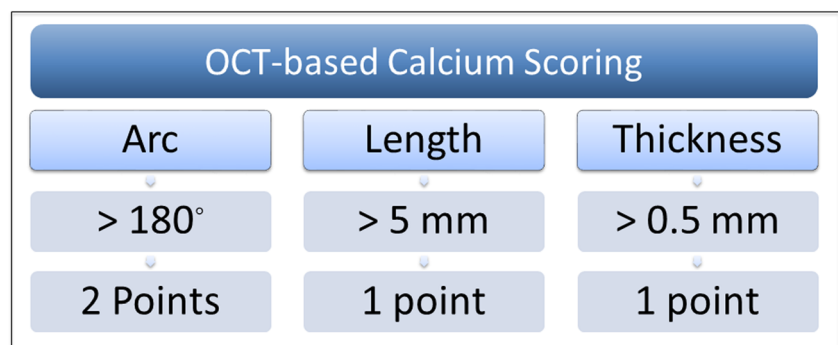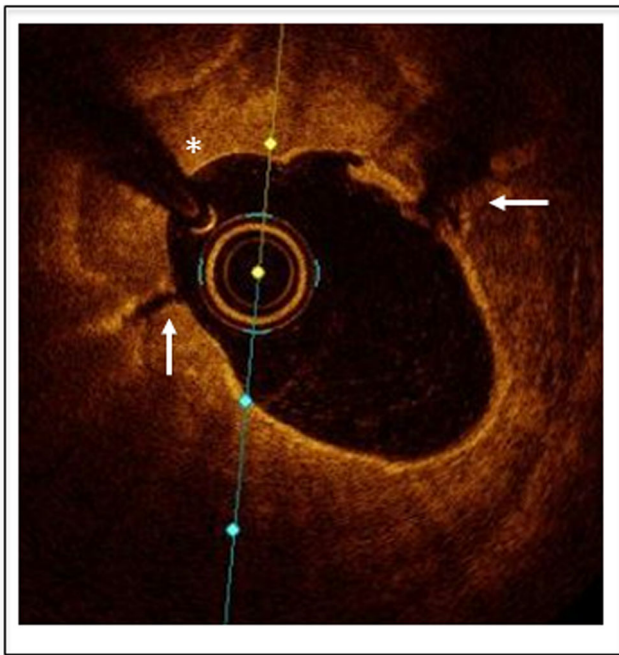
**Fig. 4** Calcium fracture with lesion preparation. OCT cross-section following lesion preparation with orbital atherectomy demonstrating characteristic smooth, concave polishing at the surface (asterisk) with deep fracture of calcium (white arrows)

Corporation, Marlborough, MA) historically was controlled using a console, with activation by a foot pedal; however,

more recent iterations include the RotaPro rotational atherectomy system (Boston Scientific Corporation, Marlborough, MA) which integrates the controls into the console. Rotational atherectomy burr sizes vary from 1.25 to 2.5 mm.

Initial trials comparing rotational atherectomy with conventional approaches failed to demonstrate a major difference in outcomes [23–25]. The PREPARE-CALC trial randomized patients with severely calcified lesions undergoing treatment with PCI to rotational atherectomy vs. lesion preparation with scoring or cutting balloons. The investigators found that with contemporary PCI, rotational atherectomy was associated with greater strategy success (98% vs. 81%, $p < 0.001$) [26]. Overall revascularization at 9-month follow-up was lower in those treated with rotational atherectomy (8% vs. 21%, $p = 0.01$), with no significant difference in other clinical outcomes at 9 months in the 200 randomized patients [26]. OCT intravascular imaging studies suggest that use of a cutting balloon following lesion preparation with rotational atherectomy is associated with calcium fracture and greater stent expansion compared with conventional balloon following rotational atherectomy [27].

## Orbital Atherectomy

Orbital atherectomy was approved for the treatment of severely calcified coronary lesions prior to stent implantation in
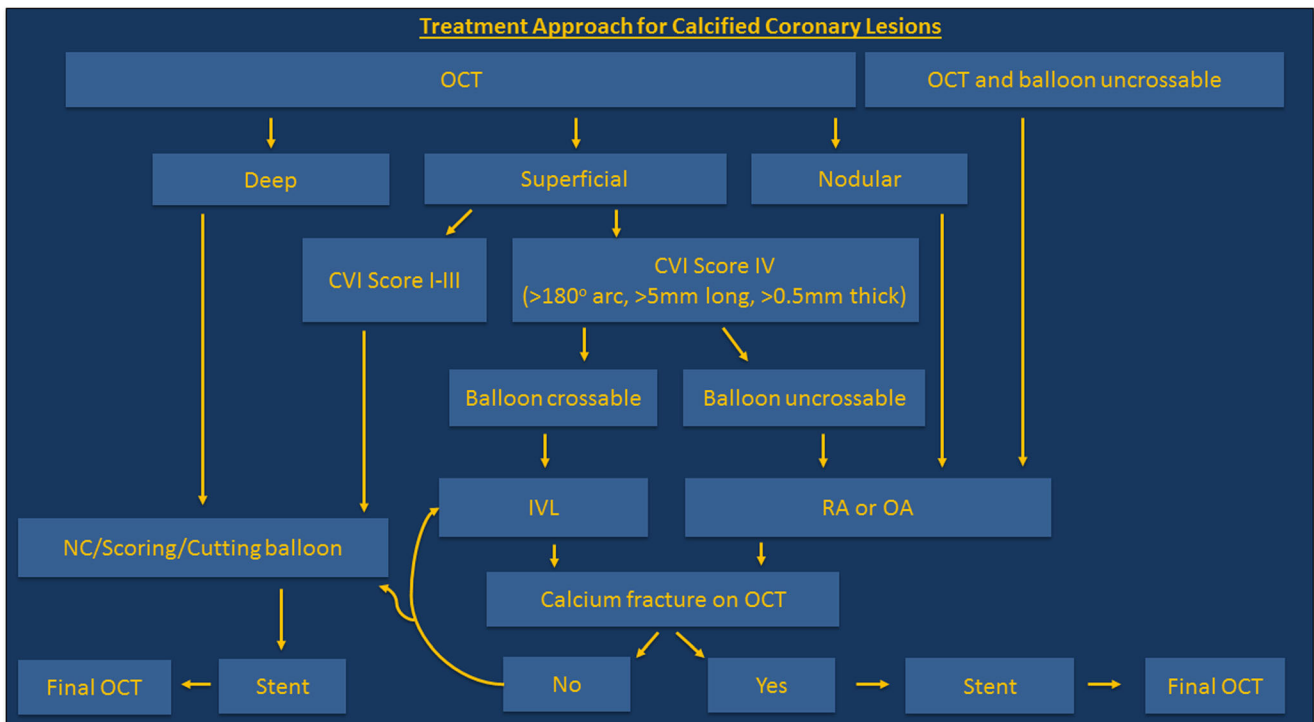


**Fig. 5** OCT-guided approach to calcified lesions. An algorithmic, OCT-based approach should be incorporated to optimize treatment of calcified lesions undergoing PCI to ensure adequate lesion preparation and optimal stent expansion. IVL intravascular lithotripsy, NC non-compliant, OCT optical coherence tomography, OA orbital atherectomy, RA rotational atherectomy

**Table 1**  Ongoing pivotal OCT studies

| Study | Estimated $n=$ | Population | Design | Primary endpoint(s) |
|---|---|---|---|---|
| ILUMIEN IV (NCT03507777) | 3656 subjects at 125 global sites | High-risk patients or complex lesions | Randomized, OCT vs. angiography-guided PCI | ➢ Post-PCI MSA<br>➢ Target vessel failure (TVF) at a minimum of 1 year and up to 2 years |
| ECLIPSE (NCT03108456) | 2000* | Severely calcified de novo lesions | Randomized, orbital atherectomy vs. conventional balloon angioplasty prior to stent implantation | ➢ Acute minimum stent area (MSA) in the OCT cohort<br>➢ Target vessel failure (TVF) at 1 year |
| DISRUPT CAD III (NCT03595176) | 392* | Severely calcified de novo lesions | Prospective, multicenter, single-arm, global study assessing the safety and efficacy of intravascular lithotripsy | ➢ 30-day MACE<br>➢ Rate of procedural success without in-hospital MACE |
| COCOA [45] | 550 subjects in Japan | All-comer, de novo lesions | Randomized trial, OCT-guided PCI vs. angiography-guided PCI | ➢ Minimum stent area post-PCI |
| RENOVATE-COMPLEX-PCI (NCT03381872) | 1620 subjects in Korea | Complex lesions | Randomized trial, IVUS or OCT vs. angiography-guided PCI | ➢ Target vessel failure at 1 year |

*$n=$ represents total estimated study enrollment. OCT sub-study includes a smaller population, not specified

2013. The Diamondback 360 coronary orbital atherectomy system (Cardiovascular Systems, Inc., St. Paul, MN) uses a diamond-coated, eccentrically mounted 1.25-mm burr that orbits bi-directionally at 80,000 rpm on low speed and 120,000 rpm on high speed [28]. The ORBIT II trial demonstrated the safety and efficacy of orbital atherectomy in patients with severe calcified coronary artery disease [29]. At 3-year follow-up, patients treated with orbital atherectomy had a 10.2% rate of target vessel revascularization [30]. In a real-world, multicenter registry that included high-risk patients excluded in the ORBIT II trial, orbital atherectomy was associated with low complication rates, including a perforation rate of 0.7%, and favorable results at 1-year follow-up [31, 32].

The mechanism of action of orbital atherectomy includes polishing of the surface of calcified plaque, with a characteristic smooth, concave ablation and calcium fracture as a result of pulsatile force, which can be appreciated on OCT assessment following treatment (Fig. 4) [33]. Calcium fracture as a result of plaque modification contributes to greater stent expansion [34]. OCT-based imaging studies have found that compared with rotational atherectomy, orbital atherectomy is associated with greater calcium modification in lesions with larger lumen area, whereas the effect in lesions with smaller lumen area is similar between devices [35••].

## Intravascular Lithotripsy

Intravascular lithotripsy (IVL) is a novel catheter-based device that allows for disruption of calcified plaque with fracturing of calcium due to sonic pressure waves that are released from emitters during balloon inflation at 4 atm [36, 37]. IVL for the treatment of calcified coronary artery disease is commercially available in Europe; however, it is currently limited to clinical investigation in the USA. Due to its ease of use, IVL represents promising technology for both de novo coronary calcification and in-stent restenosis with underexpanded stents due to severe calcification [38–40]. Data from the DISRUPT CAD III study will inform the long-term results following lesion preparation with IVL.

## OCT-Guided Treatment of Calcified Lesions

The goal of lesion preparation with severely calcified lesions is calcium fracture to facilitate stent expansion [41]. We recommend an algorithmic approach to treating calcified lesions (Fig. 5). Our approach is grounded in OCT and its ability to efficiently characterize the degree of calcification and systematically inform optimal device selection as well as assess treatment efficacy. OCT is essential prior to stent implantation in calcified lesions to ensure appropriate stent sizing and adequate lesion preparation. When the OCT imaging catheter cannot cross the lesion due to severe stenosis, pre-dilatation with small, non-compliant balloons can facilitate pre-stent intravascular imaging. The treatment approach for lesion preparation should be guided by the OCT calcium score (Fig. 3). Lesions with a calcium score of 4 should be approached with adjunctive therapies to include intravascular lithotripsy, orbital atherectomy, or rotational atherectomy. OCT following lesion preparation allows for recognition

of calcium fracture and determination if additional lesion modification is necessary prior to stent implantation.

Following stent implantation, OCT should be performed to ensure adequate endpoints have been reached, with further stent optimization employed as needed. Liberal use of balloon pre- and post-dilatation are employed as needed before and after each step to ensure optimal results.

## Future Outlooks

While comparisons have been reported between orbital and rotational atherectomy, these have been based on observational registries and there are no randomized trial comparing these modalities [42–44]. While there are advantages for each device in certain lesion subtypes and clinical scenarios, either may be used in most cases of severe calcification. The key is to ensure adequate lesion preparation is achieved, and for an operator to use the device with which they are most proficient.

There are several ongoing pivotal clinical trials that will provide important insight into the role of OCT and lesion preparation strategies in PCI. The ILUMIEN IV trial (NCT03507777) is a randomized, multicenter global clinical trial that will be the largest intravascular imaging trial to date and is comparing OCT-guided PCI with angiographic-guided PCI. The ECLIPSE randomized trial (NCT03108456) is also ongoing and will be the largest randomized PCI trial of patients with severely calcified coronary artery disease. The ECLIPSE trial (NCT03108456) is comparing a lesion preparation strategy with orbital atherectomy prior to stent implantation vs. conventional balloon angioplasty prior to stent implantation. The DISRUPT CAD III (NCT03595176) study is assessing the safety and efficacy of the novel intravascular lithotripsy device. Both the ECLIPSE trial and DISRUPT CAD III studies have pre-specified OCT sub-studies that will also provide additional important insight into the treatment of calcified coronary artery disease. Table 1 summarizes the ongoing pivotal OCT studies.

## Conclusions

Successful PCI and reduction in future revascularization is closely tied to final stent expansion. Coronary artery calcification is often underappreciated by angiography alone. OCT permits recognition of calcified plaque with accurate anatomic and morphologic characterization. Lesion preparation based on the presence, severity, and morphology of coronary calcium can facilitate optimal stent expansion. We recommend an OCT-based algorithmic approach to the diagnosis and treatment of calcified plaque in all patients treated with PCI.

## Compliance with Ethical Standards

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