From devices to mechanisms: Towards a structural approach to plaque preparation

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Abstract
Coronary artery calcification remains a major challenge in percutaneous coronary intervention, impairing device delivery, vessel expansion, and clinical outcomes. Despite the availability of multiple calcium-modifying technologies, optimal treatment strategies remain unclear, and the results according to device type are difficult to interpret, as they are influenced by numerous confounding variables.

This limitation reflects a predominantly device-centered approach, where plaque preparation is viewed as a preliminary step rather than a central determinant of procedural success. We propose a shift toward a structural and mechanistic understanding of lesion treatment, in which the objective is plaque transformation rather than simple lumen enlargement.

This review summarizes current calcium-modifying strategies and emphasizes the importance of procedural technique, iterative device use, and intravascular imaging for real-time assessment. We introduce an integrated framework in which plaque preparation is considered a dynamic and measurable process, guiding both device selection and therapeutic strategy.

By moving from a device-based to a mechanism-based approach, this paradigm aims to improve procedural coherence and better balance efficacy and safety in complex percutaneous coronary intervention.

Keywords
Coronary artery calcification, Plaque preparation, Intracoronary imaging, Calcium modification, Percutaneous coronary intervention

Introduction

Coronary artery calcification remains a major determinant of procedural complexity and adverse outcomes in percutaneous coronary intervention (PCI) [1,2]. The primary mechanism underlying these challenges is the intrinsic rigidity of calcified lesions. These lesions behave as a form of vascular “exoskeleton,” generating high mechanical resistance that limits vessel expansion and impairs optimal stent deployment. In addition, this structural rigidity can compromise device deliverability, further increasing procedural difficulty and the likelihood of major complications [3].

Coronary calcification, however, is not a homogeneous entity. Lesions may present with concentric circumferential calcium, eccentric bulky deposits, superficial or deep calcification, nodular protrusions, or diffuse calcific sheets, each generating distinct patterns of vessel rigidity and stress distribution. Consequently, lesion morphology, rather than calcium burden alone, is a major determinant of procedural complexity and should play a central role in determining the most appropriate plaque-modification strategy.

Although contemporary practice benefits from a wide range of calcium-modifying technologies and the increasing use of intravascular imaging, the treatment of calcified lesions remains challenging in routine clinical settings [4]. The multiplication of procedural steps may prolong intervention time and potentially impact procedural safety, while also increasing costs. Patient-specific clinical characteristics add an additional layer of complexity to the treatment decision-making process (Figure 1).

Over recent years, multiple clinical trials have aimed to evaluate and compare the safety and efficacy of different calcium-modifying devices. These studies have provided valuable insights but are characterized by heterogeneity in methodology, lesion selection, and study design. In parallel, expert consensus documents and treatment algorithms have been developed to help guide clinical decision-making. While these frameworks and algorithms are supported by an expanding body of data, their implementation in routine practice remains challenging.

Despite the various approaches, the end goal of lesion treatment is relatively well established. Most strategies aim to achieve what is commonly referred to as optimal plaque preparation, which ultimately corresponds to a state of mechanical liberation of the vessel. This state reflects effective circumferential constraint release and restoration of vessel compliance, enabling adequate stent expansion. Effective plaque transformation may broaden the spectrum of available treatment options, including the use of drug-coated balloons or hybrid strategies. Thus, plaque preparation should be considered a key determinant of both procedural success and therapeutic flexibility.

The present review first aims to provide a comprehensive overview of the available calcium-modifying technologies, with

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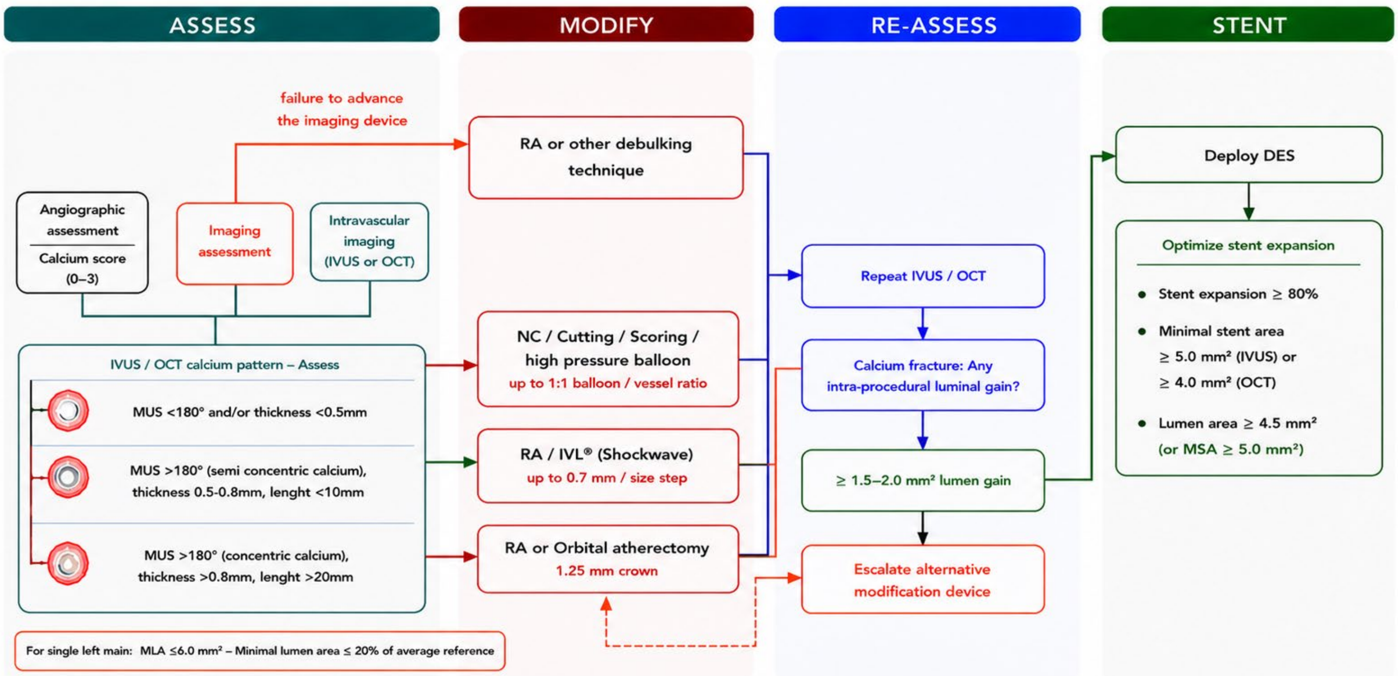

Figure 1 - Schematic, imaging-guided algorithm for coronary calcium modification.

special attention to their mechanisms of action and clinical evidence. Secondly, the review proposes a conceptual framework that redefines plaque preparation as the central driver of PCI strategy, emphasizing not only device selection but also the use and evaluation of these devices during the procedure. By integrating mechanistic insights, imaging guidance, and procedural strategy, this framework seeks to improve the coherence of decision-making and to achieve a better balance between efficacy and safety in the treatment of calcified coronary lesions.

Current State of the Art review: Devices, Imaging, and Treatment Algorithms

The contemporary treatment of calcified coronary lesions relies on a growing therapeutic armamentarium that can broadly be divided into balloon-based strategies, debulking-based strategies, and specific calcium-fracture technologies.

Balloon-Based Strategies

Dedicated balloon-based strategies occupy an important place in the treatment of balloon-crossable calcified lesions, through three main strategy types: scoring balloons, cutting balloons, and ultra-high-pressure balloons. The main advantage of these strategies lies in their wide availability, relative ease of use, and versatility in lesions where direct plaque modification can be achieved without upfront atherectomy.

Scoring balloons were the first dedicated balloons specifically developed to improve lesion preparation in calcified plaques. Their mechanism is based on the concentration of force through external nitinol elements, allowing focal stress delivery and controlled superficial scoring of the plaque [5]. These balloons are especially attractive in superficial, eccentric, or moderately resistant lesions, where stress concentration would be sufficient to achieve subsequent expansion. Clinical studies with devices such as AngioSculpt (Philips/Spectranetics, USA), NaviScore (Acotec Scientific, China), and Aperta Novel Scoring Elements (Nipro Corporation, Japan) have shown feasibility and good device success [6,7]. The devices' limitations become more evident in deep or nodular calcium, where superficial scoring may be insufficient to generate meaningful structural disruption.

Cutting balloons were developed to address more resistant fibrocalcific lesions by using microsurgical blades mounted on a noncompliant balloon. Compared with scoring balloons, they generate deeper and more defined incisions, allowing lesion expansion at lower nominal pressures and potentially more controlled plaque fracture [8]. Their role has been evaluated over time in de novo disease, in-stent restenosis, and, more recently, in calcified lesion preparation before stent implantation. The Cutting Balloon to Optimize Predilatation for Stent Implantation trial suggested improved stent expansion and lower underexpansion rates compared with non-modifying balloons [8]. The Short-CUT trial suggested noninferiority to intravascular lithotripsy (IVL) for final minimal stent area in selected settings, although interpretation remains nuanced because subgroup results and lesion characteristics may influence the apparent equivalence [9]. Similarly, a combined strategy using rotational atherectomy and

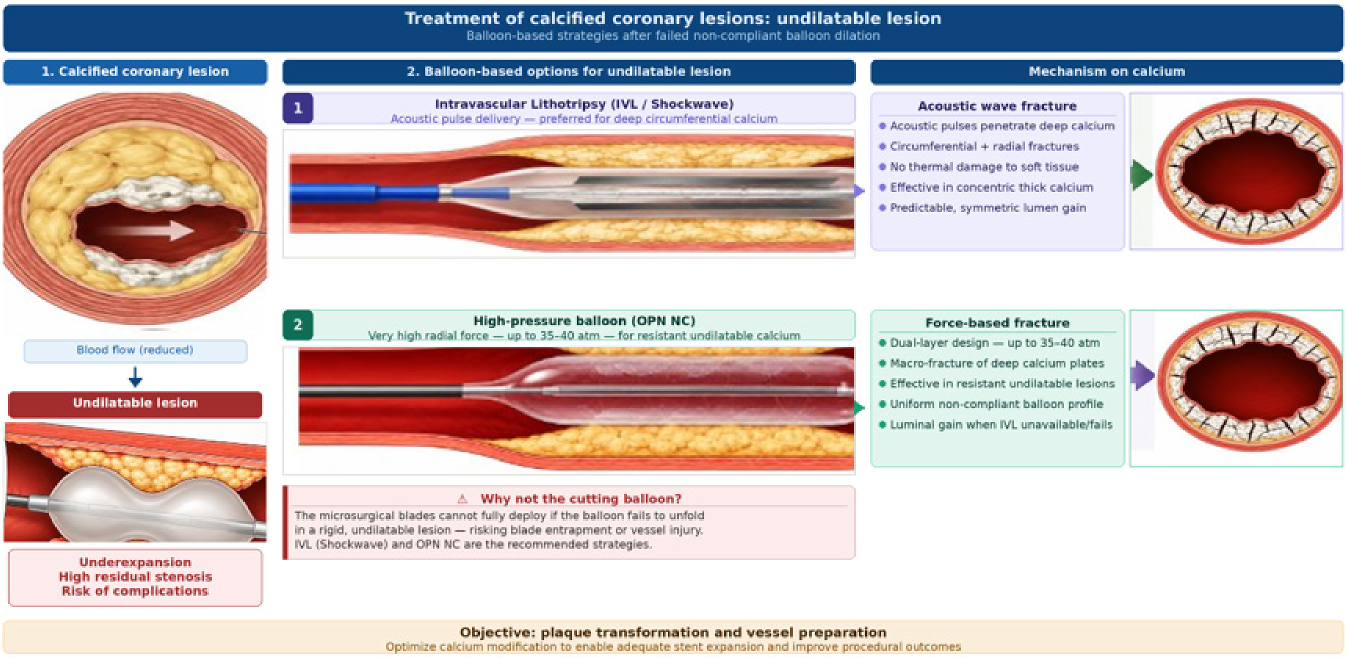

Figure 2 - Dedicated treatment options for undilatable calcified coronary lesions following failure of non-compliant balloon dilatation. IVL : intravascular lithotripsy; NC : non-compliant balloon; OPN : ultra-high-pressure balloon (OPN NC®).

a cutting balloon was initially appealing. This strategy, however, was later challenged by the randomized ROTA-CUT trial, which assessed the additional benefit of adding a cutting balloon, rather than a non-compliant balloon, after rotational atherectomy [10]. Nevertheless, a recent meta-analysis demonstrated a reduction in major adverse cardiovascular events (MACE) with the cutting balloon technique, although target vessel revascularization and target vessel failure rates remained similar [11].

A particularly relevant evolution within balloon-based treatment is the RODIN-CUT concept, in which repeated cutting balloon inflations are alternated with intravascular ultrasound reassessment [12]. This approach suggests that the lesion response may be cumulative and that repeated inflations may progressively increase plaque disruption and calcium fragmentation, rather than relying on a single inflation endpoint. In this sense, balloon performance may depend not only on device selection but also on the procedural logic through which the device is used. Overall, cutting balloons are particularly suited for lesions with superficial, relatively thin, and non-circumferential calcification. Although their efficacy is expected to decrease with increasing calcium thickness, repeated high-pressure inflations may progressively extend their effectiveness to more heavily calcified lesions.

Ultra-high-pressure balloons, especially the OPN non-compliant (NC), represent the most force-driven balloon-based strategy. The dual-layer design allows controlled inflation up to 40 atm and makes them particularly useful in balloon-crossable, but undilatable, lesions (Figure 2) [13]. OPN NC has shown favorable procedural success in resistant lesions; In the ISAR-CALC trial it achieved greater acute luminal gain and stent expansion than scoring balloons, with similar safety outcomes [14,15]. Optical coherence tomography (OCT)-based registry data have demonstrated visible calcium fracture, especially in concentric thick calcification [16]. More recently, the VICTORY trial compared the OPN NC balloon with IVL for lesion preparation in severely calcified lesions. The trial reported noninferiority for final stent expansion assessed by OCT standards, with similar procedural success, safety outcomes, and at a lower cost [17]. Still, the ultra-high-pressure balloon's role remains largely complementary rather than universal, especially because deliverability, wire interaction, and the risk of vessel trauma remain relevant procedural considerations.

Taken together, balloon-based strategies are no longer secondary tools used only in mild calcium; They now represent an important spectrum of plaque-modifying options. Their clinical impact, however, depends heavily on lesion morphology, inflation strategy, and imaging feedback. The algorithm of this review illustrates this stepwise logic very well, beginning with imaging-based characterization, then selecting the first-line balloon strategy according to calcium thickness and distribution, and finally escalating when plaque modification remains insufficient (Figure 1).

Debulking-Based Strategies

Debulking-based approaches include rotational atherectomy, orbital atherectomy, and, more selectively, laser atherectomy (Figure 3). Within the contemporary plaque-modification algorithm, these strategies' principal role is to reduce calcified plaque burden in uncrossable or undilatable lesions, or, in those lesions with extensive protrusive or nodular calcium, to restore compliance and enable subsequent balloon optimization and stent expansion [18].

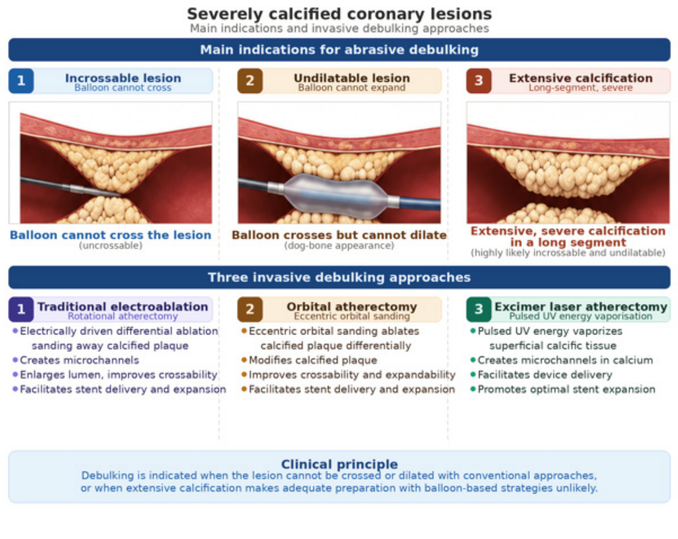

Figure 3 - Main indications and available devices for coronary debulking techniques.

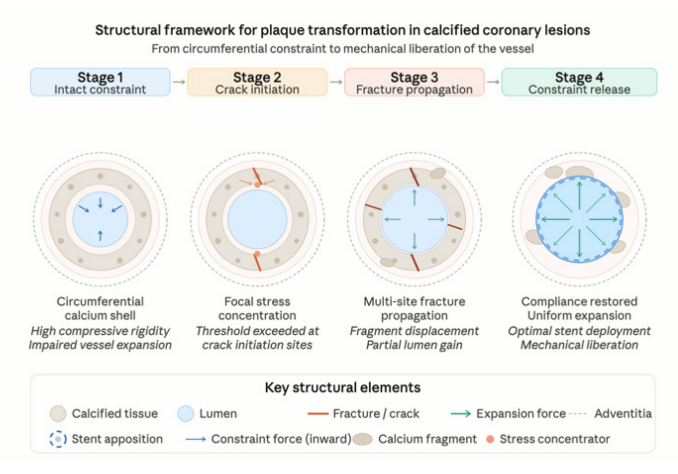

Figure 4 - Structural framework for plaque transformation in calcified coronary lesions.

Rotational atherectomy remains the most established debulking technique [19]. The PREPARE-CALC trial showed higher strategy success with rotational atherectomy compared with modified balloons, although acute lumen gain and nine-month clinical outcomes were similar for balloon-crossable lesions [20]. Long-term follow-up of PREPARE-CALC patients showed no major difference in target vessel failure at two years. At five years, however, a lower rate of target lesion revascularization was observed in the rotational atherectomy arm, suggesting that long-term differences may still emerge despite apparently similar early endpoints [21]. This illustrates one of the main interpretive difficulties in the field: acute mechanistic equivalence does not always predict identical late outcomes.

Orbital atherectomy has recently been evaluated in the large ECLIPSE clinical trial. In this study, orbital atherectomy prior to drug-eluting stent (DES) implantation was compared with a balloon angioplasty-based strategy in 2,005 patients with severely calcified lesions [22]. The primary imaging endpoint, post-PCI minimal stent area at the site of maximum calcification, was not significantly different between groups, and target vessel failure at one year was also similar. However, orbital atherectomy was associated with slower flow and a signal toward earlier mortality. Two-year follow-up again showed no difference in target lesion failure. Importantly, intravascular imaging use was high, and imaging guidance itself was associated with better outcomes. These results are highly informative because they do not invalidate orbital atherectomy as a tool, but rather suggest that a debulking strategy is not universally superior to a balloon-based strategy when both are applied within a modern DES-based framework. Overall, atherectomy techniques are primarily intended for lesions with superficial calcification and can be adapted to both concentric and eccentric calcium phenotypes. While rotational atherectomy is particularly well suited for balloon-uncrossable lesions and protruding calcified nodules, orbital atherectomy may offer specific advantages in tortuous vessels and in arteries with marked vessel size mismatch, owing to its orbiting mechanism and differential sanding effect.

Laser atherectomy remains a more selective option, usually reserved for niche situations such as fibrocalcific in-stent restenosis, uncrossable lesions with thrombotic or fibrotic components, or underexpanded stents. Laser atherectomy is less represented in randomized contemporary calcium trials, but it remains part of the debulking family in consensus algorithms and in multimodality practice [23,24].

Intravascular Lithotripsy as a Specific Calcium-Fracture Strategy

IVL deserves separate consideration because it is neither a classic balloon-based strategy nor a debulking technique. Its mechanism is based on acoustic pulse delivery that fractures calcium from within the vessel wall. This strategy is particularly useful in deep and short circumferential calcium lesions, where surface-modifying devices may be less effective [25]. However, its effectiveness may be limited in two circumstances: long calcified lesions, due to the finite number of treatment cycles available; and protruding calcified nodules, which are intrinsically more resistant to fragmentation.

Clinically, IVL has become a major comparator in recent trials because it provides a standardized and reproducible strategy for calcium fracture with relatively straightforward use (provided the lesion is crossable). Cost, lesion crossability, and device profile, however, remain relevant limitations.

Recent comparative studies have further complicated the interpretation of IVL techniques. The Short-CUT trial suggested that a cutting balloon treatment may be noninferior to IVL in terms of final minimum stent area in selected lesions [9]. The VICTORY trial suggested similar noninferiority of the OPN NC balloon versus IVL for OCT-based final stent expansion [17]. The ROLLING STONE registry then compared IVL with atherectomy in a prospective, real-world multicenter population [26]. This registry enrolled patients across 23 Italian centers and used procedural success and short-and mid-term MACEs as key endpoints. Such studies are clinically useful, but they also highlight a major issue: When different devices with different mechanisms are compared using procedural endpoints that may not discriminate between the quality of structural lesion transformation, the field may appear more homogeneous than it actually is.

Imaging in Calcified Coronary Disease

Imaging is now central to contemporary treatment for calcified lesions. Angiography alone underestimates calcium severity and distribution. Intravascular ultrasound (IVUS) and OCT provide direct information on arc, length, thickness, and depth of calcium, which have been associated with the risk of stent underexpansion [27].

The IVUS-based calcium score identifies lesions at high risk for underexpansion when superficial calcium arc exceeds 270°, calcium length exceeds five mm, and vessel diameter is below 3.5 mm [28]. The revised OCT-based calcium score integrates circumferential extent, thickness, and length, and highlights very high-risk patterns, such as 360° calcium or calcium thickness > 0.3 mm [29]. These scores do not replace procedural judgment, but they provide an increasingly objective framework for anticipating the need for plaque modification.

Imaging is also important because it may influence outcomes beyond device selection itself. In the ECLIPSE program, intravascular imaging guidance was associated with better one-year outcomes compared to angiographic guidance alone, regardless of whether orbital atherectomy or balloon angioplasty was used [22]. This supports the idea that the quality of lesion assessment and procedural optimization may be at least as important as the device family itself.

Another emerging direction is automation and artificial intelligence (AI)-supported analysis. AI-enhanced OCT software has been proposed to accelerate and standardize calcium detection and quantification, potentially facilitating image-based procedural planning [30].

Contemporary Algorithms and Consensus Documents

Several contemporary consensus documents have attempted to structure decision-making for calcified coronary lesion preparation. The most influential European framework is the European Association of Percutaneous Cardiovascular Interventions' clinical consensus statement developed in collaboration with the European Contemporary Care of patients with Calcified Complex lesions-Paris Course on Revascularization group. This document proposes a comprehensive approach to heavily calcified coronary stenoses, beginning with non-invasive and invasive imaging assessment and progressing toward selection of the most appropriate interventional tool. It reflects the current European shift toward morphology-guided calcium treatment rather than empirical device use [31].

In parallel, the Society for Cardiovascular Angiography and Interventions Expert Consensus Statement provides a North American framework for the identification and management of calcified coronary lesions requiring intervention. It emphasizes the use of intracoronary imaging to guide the selection of the strategy and the type of device to be used, including specialty balloons, atherectomy, and IVL [32].

More recently, the Japanese Association of Cardiovascular Intervention and Therapeutics group proposed an imaging-based device indication strategy for calcified coronary lesions [33]. This approach is particularly relevant because it provides a stepwise procedural logic: after guidewire crossing, IVUS or OCT/optical frequency domain imaging crossing is attempted; if imaging cannot cross, rotational or orbital atherectomy is considered; if imaging crosses, calcium severity is assessed using predefined imaging criteria; device selection is then guided by calcium score, lesion morphology, and residual calcification after initial plaque modification. The updated version also recognizes that IVL may be considered after atherectomy, when post-atherectomy imaging reveals persistent severe calcification and further atherectomy is unlikely to be effective or may be harmful.

Together, these consensus documents illustrate a clear evolution in the field: calcium lesion preparation is increasingly guided by imaging, morphology, and procedural context, rather than by angiography alone.

From Structure to Transformation: A Mechanistic Framework for Calcified Lesions

Calcified coronary lesions should not be regarded as a homogeneous entity; instead, they should be seen as a spectrum of structural phenotypes with distinct mechanical behaviors. Beyond the overall calcium burden, lesion morphology directly influences vessel compliance, plaque resistance, and, ultimately, the response to plaque-modification therapies. Within this conceptual framework, calcified lesions may be characterized according to three complementary dimensions that together provide a more comprehensive understanding of lesion behavior and guide procedural decision-making.

The first element of the framework is the visible morphological phenotype of the lesion. We describe in greater detail the calcium features directly relevant to operator strategy and procedural reasoning: the external shape of the deposit — nodular, eccentric and confined to a limited arc, or concentric and distributed along the full circumference — and the character of its surface, whether granular or smooth. These features shape device selection and deserve detailed consideration.

The second feature of the framework is the distinction between visible appearance versus true mechanical structure. This morphological description reflects the superficial or intimal appearance of the calcium rather than its true structure. The density and mechanical resistance of the deposit, its actual composition, the extent to which it is embedded within the vessel wall, and the depth and length of its wall contact largely determine how the lesion responds to plaque modification. Yet these variables remain difficult to appreciate even with intravascular imaging. Current classifications therefore capture what can be seen, not necessarily what mechanically matters, which reinforces the value of an iterative, response-based approach to lesion preparation.

Building on the two previous elements, the third factor of the proposed framework is a three-dimensional characterization of the lesion. A calcified lesion can be characterized along three complementary dimensions: morphological (shape and surface as visualized by imaging); technical (crossable versus uncrossable, dilatable versus undilatable); and the tendency of a lesion to grip or entrap the device — guidewire, balloon, or stent — arising not solely from a tight lumen but from a highly frictional, often spiculated surface. As this last property is not reliably captured by imaging, tactile operator feedback becomes an essential signal for recognizing it. Such lesions warrant a distinct strategy. Debulking approaches, such as rotational atherectomy, are better suited to reduce surface friction and restore deliverability, whereas balloon-based preparation must be approached with particular caution, given the higher risk of balloon rupture or vessel injury. We present this third dimension explicitly as a mechanistic hypothesis, offered as a conceptual extension to be refined and validated by future study.

Within this framework, the procedural objective extends beyond simple lumen enlargement, and instead should be understood as plaque transformation. Effective plaque modification involves sufficient structural alteration of the lesion to change its mechanical behavior through calcium fracture, disruption of circumferential integrity, fragmentation of calcified components, and redistribution of mechanical stress. Importantly, lumen enlargement alone does not necessarily reflect adequate transformation, as transient expansion may occur despite persistent structural rigidity, ultimately leading to suboptimal stent deployment.

The interaction between plaque-modification devices and calcified tissue should therefore be interpreted according to both lesion mechanics and device characteristics, not simply the latter. different calcium phenotypes exhibit distinct structural and mechanical properties, technologies relying on stress concentration, ultra-high-pressure expansion, abrasive debulking, or acoustic pressure waves are likely to perform differently depending on the underlying lesion architecture, rather than being universally applicable to all calcified lesions.

Intravascular imaging remains central to this paradigm. Beyond initial lesion characterization, serial imaging enables real-time assessment of calcium fracture, fissure formation, fragmentation, and changes in lesion geometry. In doing so, serial imaging provides direct insight into the progression of plaque transformation. This supports an iterative procedural strategy, in which each plaque-modification step is reassessed before further escalation, allowing treatment to be adapted according to the observed mechanical response of the lesion.

Emerging quantitative concepts further extend this framework. Metrics such as the Index of Device Efficiency relate the achieved luminal result to the nominal characteristics of the device, offering a potential means to assess the effectiveness of plaque modification [34]. Although still exploratory, such approaches highlight the possibility of defining objective procedural endpoints based on structural and mechanical lesion response.

Discussion

The present review highlights a central paradox in the contemporary management of calcified coronary artery disease. Over recent years, the field has evolved significantly, driven by the development of multiple device platforms, procedural strategies, imaging tools, and consensus-based algorithms (Figure 5). These advances have expanded therapeutic possibilities and improved the understanding of lesion morphology and device–lesion interaction [35].

Despite this progress, clinical application remains, in many aspects, debated and heterogeneous. One of the major challenges is the absence of a clear, objective, and reproducible definition of what constitutes an optimal plaque preparation process. While this concept is widely accepted as a key procedural objective, its practical definition remains largely implicit. In routine practice, operators often rely on a combination of angiographic impressions, imaging findings, and procedural experience to determine whether lesion preparation is sufficient, without a standardized framework to support this decision.

This limitation may partly explain why multiple randomized trials and observational studies have reported broadly comparable outcomes across plaque-modification devices with different mechanisms of action. Most comparative studies have been designed to assess angiographic or intravascular imaging endpoints, rather than clinical outcomes. Indeed, only a limited number of studies have been adequately structured to detect differences in MACEs, given the large sample sizes and prolonged follow-up required for such comparisons. Consequently, surrogate procedural endpoints have become the standard means of evaluating device performance.

Beyond endpoint selection, the interpretation of current trials is further limited by modest sample sizes and randomization procedures, that are rarely designed to stratify lesions according to calcium morphology and mechanical resistance. As a result, devices are often compared across mechanically heterogeneous lesions, which may dilute genuine differences and complicate the translation of trial results into everyday clinical practice.

Therefore, the apparent equivalence observed across plaque-modification devices should be interpreted cautiously. One possible explanation for this equivalence is that currently available techniques genuinely provide similar clinical and procedural effectiveness when used in appropriately selected lesions. Alternatively, conventional procedural endpoints may not fully capture the specific mechanical interaction between each device and the calcified plaque. Devices relying on fundamentally different mechanisms may induce distinct structural modifications that are incompletely reflected by conventional measures alone.

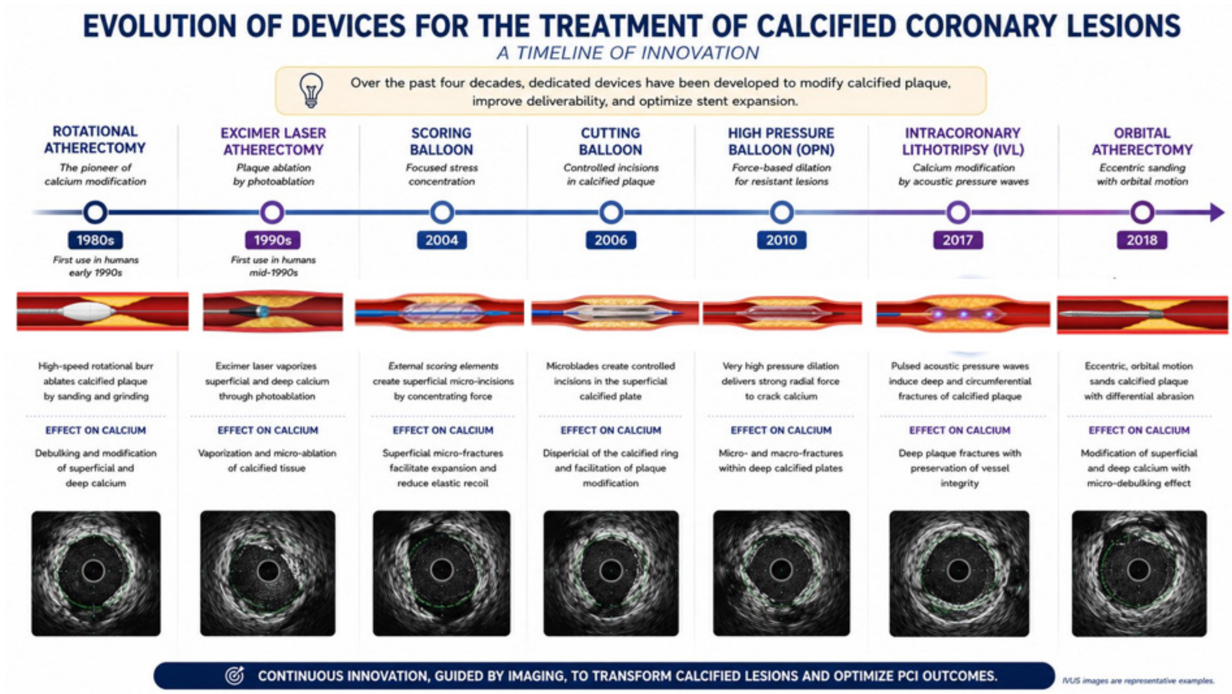

Figure 5 - Evolution of devices for the treatment of calcified coronary lesions over the years

In this context, and in the absence of a universally accepted definition, it may be necessary to consider plaque preparation as a composite process, in which multiple elements are integrated to guide procedural interpretation. Rather than relying on a single parameter, operators may benefit from combining several observable and measurable features that reflect the lesion's response to treatment.

These elements may include, first, the efficiency of the device, as reflected by quantitative indices such as the Index of Device Efficiency [34], which relates the achieved luminal result to the nominal characteristics of the device used. Second, the angiographic behavior of the lesion during balloon inflation, particularly the presence of a symmetric and cylindrical expansion pattern, may provide important information regarding the distribution of mechanical stress and the degree of residual constraint. Third, intravascular imaging findings, including evidence of structural deformation provide direct insight into the structural response of the plaque. These findings can be used iteratively during the procedure to assess the effect of each step, guide subsequent device selection, and refine procedural strategy. By using this multi-feature perspective, plaque preparation is no longer interpreted as a binary endpoint, but rather as a dynamic process that evolves throughout the procedure.

In addition, a more structured interpretation of lesion response may have implications for procedural safety. By better understanding the mechanical behavior of the lesion and the effect of applied forces, operators may be able to adjust device sizing, inflation strategies, and escalation steps more appropriately, potentially reducing the risk of complications.

The framework proposed in this review therefore aims to provide a more integrated and pragmatic approach to plaque preparation, based on a combination of mechanical, angiographic, and imaging-derived information. It does not replace existing algorithms, but instead complements them by offering a structured way to interpret procedural effects and guide decision-making.

Nevertheless, this approach must be interpreted within its current limitations. It is based on mechanistic reasoning and emerging clinical observations, including early data from imaging studies and device-specific analyses. This approach is not yet supported by large-scale prospective validation. Furthermore, variability in imaging interpretation and procedural technique may influence its reproducibility.

Future research should therefore pursue two complementary objectives. First, adequately powered comparative studies are needed to determine whether one plaque-modification strategy provides superior clinical outcomes in specific lesion subsets. Second, prospective studies should validate composite procedural criteria integrating mechanical, angiographic, and imaging-derived information, and determine whether these measures better predict both procedural success and long-term clinical outcomes than currently used surrogate endpoints.

To conclude, calcified coronary lesions remain a major challenge in contemporary percutaneous coronary intervention, as their intrinsic rigidity may impair device delivery, limit vessel expansion, promote stent underexpansion, and increase procedural complexity and risk. The expanding armamentarium of calcium-modifying technologies (including modified balloons, ultra-high-pressure balloons, debulking devices, and intravascular lithotripsy) provides operators with complementary tools that act through distinct mechanisms and should be selected according to lesion morphology and procedural context. In this setting, intracoronary imaging is essential for calcium characterization and device selection, and also for the iterative assessment of plaque modification and final procedural optimization. A shift from a device-centered to a mechanism-based, imaging-guided strategy may therefore improve procedural consistency and help achieve more predictable plaque transformation. In the future, more effective lesion preparation with even better-designed and optimized devices, and even higher-quality imaging may also broaden the use of "leave nothing behind" approaches in carefully selected patients.

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Conflict of interest

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Ethical Approval Statement

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