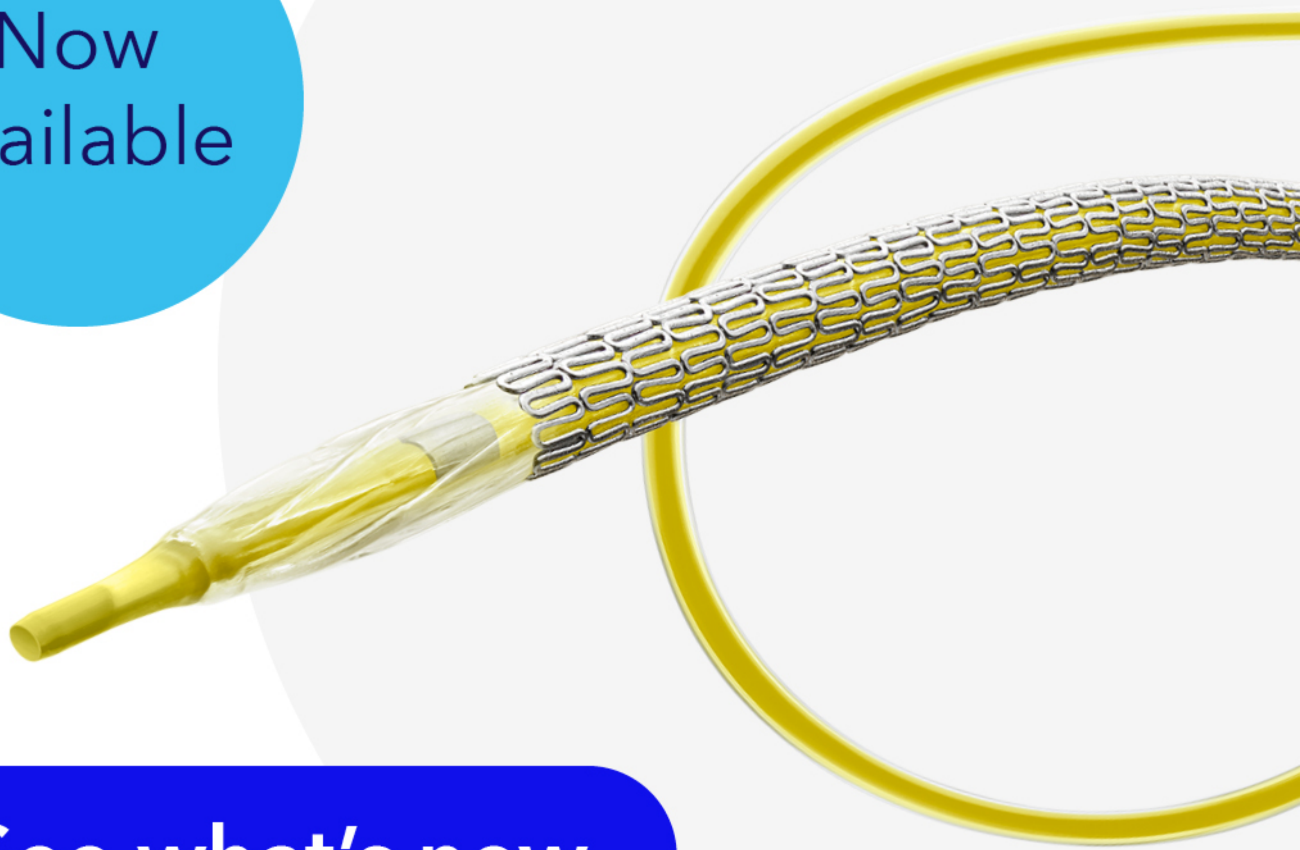

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REVIEW

WILEY

An algorithmic approach to balloon undilatable coronary lesions

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Abstract

Balloon undilatable lesions are lesions that have been successfully crossed by both a guidewire and a balloon but cannot be expanded despite multiple high-pressure balloon inflations. Balloon undilatable lesions can be de novo or in-stent. We describe a systematic, algorithmic approach to treat both de novo and in-stent balloon undilatable lesions using various techniques, such as high-pressure balloon inflation, plaque modification balloons, intravascular lithotripsy, very high-pressure balloon inflation, coronary atherectomy, laser coronary angioplasty, and extraplaque lesion crossing. Knowledge of the various techniques can increase the efficiency, success and safety of the procedure.

KEYWORDS

ATHR - atherectomy, BALC - balloon, complex PCI, cutting, LASR - laser, PCIC - percutaneous coronary intervention

1 | INTRODUCTION

Balloon undilatable lesions are lesions that have been successfully crossed by both a guidewire and a balloon but cannot be expanded despite multiple high-pressure balloon inflations.[1] These lesions are more commonly encountered in patients undergoing chronic total occlusions (CTO) percutaneous coronary intervention (PCI), but are also found in patients undergoing non-CTO PCI, such as PCI of heavily calcified or tortuous lesions.[1,2] Often, balloon undilatable lesions are also balloon uncrossable, i.e., the guidewire successfully crosses the lesion but the balloon does not follow.

In a large multicenter CTO PCI registry, the prevalence of balloon undilatable lesions was 8.5% and they were associated with a lower technical success rate and a higher occurrence of major adverse cardiovascular events (MACE).[3] Balloon undilatable CTOs are more likely to be longer, heavily calcified, and have a higher J-CTO score and Prospective Global Registry for the Study of Chronic Total Occlusion Intervention (PROGRESS-CTO) complications score compared with balloon dilatable CTOs.[1] Unless optimally treated, balloon undilatable lesions may lead to stent underexpansion that may predispose to in-stent restenosis and stent thrombosis.

Treatment of balloon undilatable lesions depends on whether the lesion is de novo or in-stent (implanted during the same or a previous procedure). In-stent lesions in newly implanted stents are a contraindication for orbital atherectomy (OA) and carry an increased risk of burr entrapment with rotational atherectomy (RA). In-stent undilatable lesions can benefit from the use of laser coronary angioplasty with simultaneous contrast injection (ESLAP: Extra-Stent Laser Assisted Plaque modification), which should be avoided in de novo lesions due to high risk of dissection and perforation.[4]

We provide a systematic, algorithmic approach for the management of balloon undilatable lesions. Figure 1 outlines an algorithm for approaching de novo balloon undilatable lesions and Figure 2 outlines an algorithm for approaching in-stent balloon undilatable lesions.

1.1 | Intravascular imaging

Intravascular imaging, with either intravascular ultrasound (IVUS) or optical coherence tomography (OCT), is of critical importance for detecting and treating balloon undilatable lesions, as coronary angiography may fail to identify calcification and lesion underexpansion. To ensure proper stent expansion, the lesion should be predilated with a balloon sized 1:1 with the target vessel. Intravascular imaging can be used to determine the appropriate predilatation balloon size and assess lesion characteristics that could lead to poor PCI result. Additionally, intravascular imaging can be used to ensure that an optimal result has been achieved after stenting.

1.2 | Likely to respond to balloon?

Heavily calcified lesions often fail to expand after balloon angioplasty. Two imaging scores have been developed for estimating the likelihood of stent underexpansion in calcified lesions, one for IVUS and one for OCT. The IVUS calcium score includes the following parameters: (1) superficial calcium angle >270° longer than 5 mm; (2) 360° of superficial calcium; (3) presence of a calcified nodule; and (4) vessel diameter <3.5 mm.[5] Each finding contributes one point to the score, and if the score is ≥2, plaque modification is recommended. The OCT calcium score has three components: (1) maximum calcium angle >180° (2 points); (2) maximum calcium thickness >0.5 mm (1 point); and (3) calcium length >5 mm (1 point).[6] Plaque modification is recommended for lesion with score of 4, which is associated with increased risk of stent underexpansion.

1.3 | High pressure balloon inflation

The first step in treating balloon undilatable lesions is usually high-pressure balloon inflation with a noncompliant (NC) balloon. Inflations can reach pressures up to 28 atm and can be prolonged (at least 30–60 s, sometimes more), while the balloon size should be 1:1 or slightly undersized (usually by 0.25–0.5 mm). Alternatively, two undersized balloons can be inflated side by side to create asymmetric pressure within the undilatable segment. Sometimes, a 1:1 sized balloon is inflated to high pressure and then undergoes multiple rapid reductions and increases in pressure to help expand the lesion.[2] One or more buddy wires can be advanced through the lesion before repeating high-pressure balloon inflation. Buddy wires can help modify the plaque and expand the lesion by altering the forces exerted on the vessel wall by the balloon ("focused force" technique).

High pressure balloon inflation can result in balloon rupture, which can lead to vessel perforation or dissection. Rapid loss of pressure during inflation suggests balloon rupture and should prompt immediate suction with the indeflator, followed by removal of the balloon, aspiration of the guide catheter to remove potential air, and coronary angiography to assess for potential injury of the target vessel. Conservative balloon sizing and good balloon preparation ensuring removal of all air before inflation can help minimize the adverse impact of balloon rupture. All ballooned segments should be subsequently covered by stents to reduce the risk of restenosis (geographic miss). Also, even when using NC balloons, there is a risk of overdilatation of the more compliant segments along the edges of the lesion ("dog-boning" effect), that could cause vessel injury. When balloons are inflated to high pressures, the overinflation of the hypotube can cause partial collapse of the rapid exchange port containing the guidewire. This can lead to the balloon becoming "sticky" and challenging to remove, sometimes leading to loss of wire position. The risk of losing wire position can be minimized by using fluoroscopy during balloon removal.

1.4 | Plaque modification balloons

Plaque modification balloons, such as the Angiosculpt (Philips), Chocolate (Teleflex), NSE Alpha (B Braun), Scoreflex (Orbus Neich), and the Wolverine cutting balloon (Boston Scientific Corporation) can facilitate modification of coronary lesions via microblades (also called microatherotomes) or wires wrapped around the balloon. Plaque modification balloons apply focused force to the lesion and cause controlled incisions of the fibrocalcific tissue. Additionally, they offer better balloon stability during inflation and prevent balloon slippage (watermelon seeding effect), which is more common in in-stent lesions.

The Wolverine cutting balloon (Boston Scientific Corporation) has three or four (depending on the balloons diameter) microblades that come in different lengths (6 mm, 10 mm, or 15 mm) and range in diameter from 2 to 4 mm.

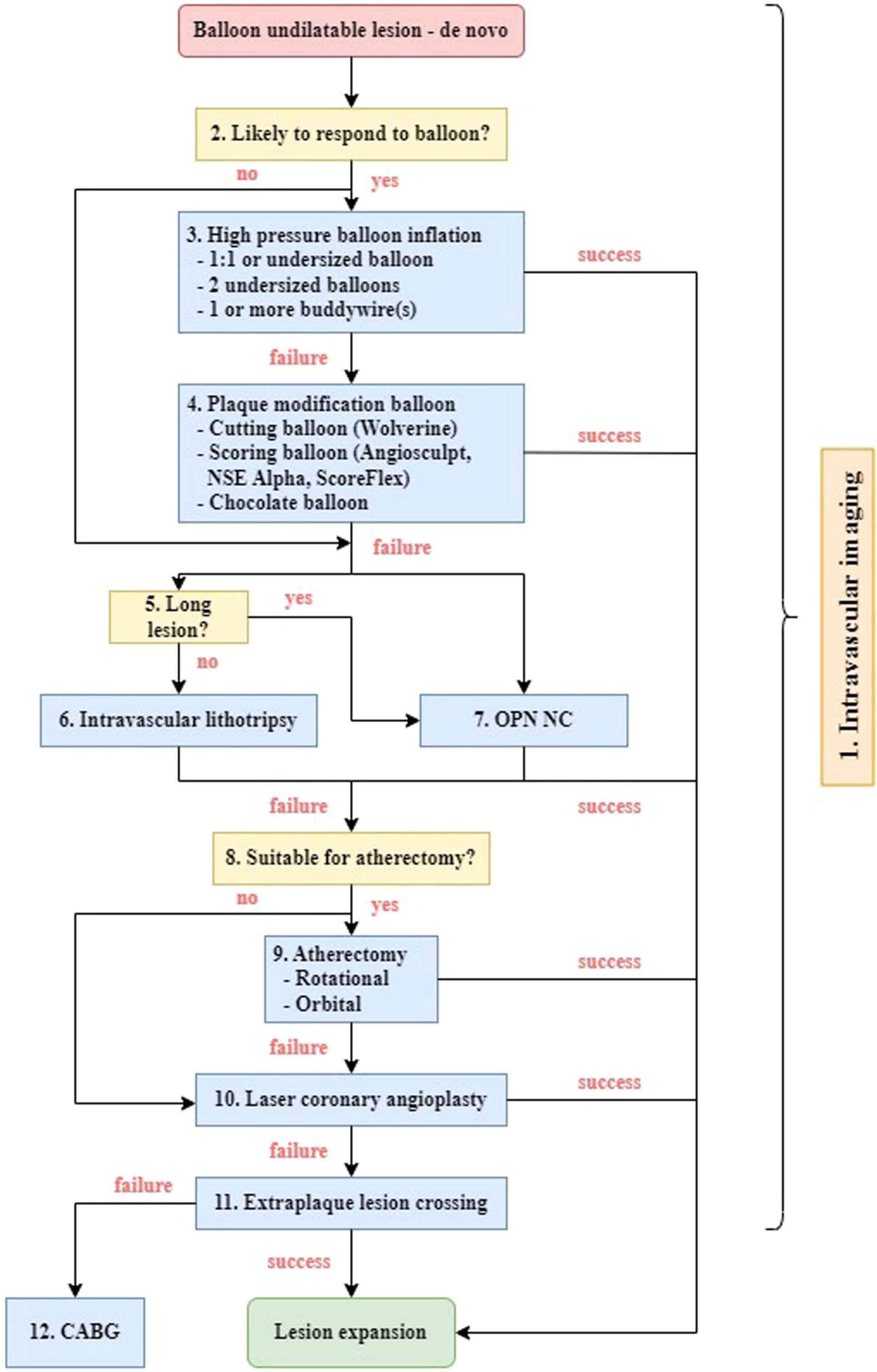

FIGURE 1 Algorithm for de novo balloon undilatable lesions. CABG, coronary artery bypass graft surgery; NC, noncompliant [Color figure can be viewed at wileyonlinelibrary.com]

Scoring balloons utilized a semi-compliant balloon and work in a similar way to cutting balloons, but instead of microblades, the balloon is surrounded by scoring elements. The AngioSculpt (Philips) and Scoreflex (Orbus Neich) balloons have nitinol wires, whereas the NSE Alpha (B Braun) baloon has nylon elements. An observational study of 299 patients, evaluating the use of the AngioSculpt scoring balloon showed larger postintervention minimal stent cross sectional area (CSA) ($6.8 \pm 1.5\ mm^2$) compared with direct stenting ($6.0 \pm 1.7\ mm^2$; $p = 0.02$)

and conventional balloons ($5.9 \pm 1.6\ mm^2$; $p = 0.02$).[7] Compared with the cutting balloon, scoring balloons have better flexibility and lower crossing profile. However, a 2019 study of 156 patients, comparing the cutting balloon with two different scoring balloons (NSE and Scoreflex) showed better acute gain with the cutting balloon (1.68 ± 0.46 [CB] vs. 1.14 ± 0.33 [NSE] vs. 1.18 ± 0.45 [Scoreflex]; $p < 0.0001$) in severely calcified coronary lesions.[8]

The Chocolate balloon (Teleflex) is a semi-complaint balloon that is encased in a nitinol-constraining structure (also called cage), which, when inflated, forms segmented pillows and grooves along the balloon surface. This helps achieve atraumatic dilatation of the lesion without the need for cutting or scoring.

Plaque modification balloons are costly, less deliverable and less flexible compared with standard balloons. In a large randomized trial in 1238 patients, cutting balloons were associated with higher long-term incidence of myocardial infarction (4.7% vs. 2.4% at 270 days after the procedure; $p = 0.03$) and death (1.3% vs. 0.3% at 270 days after the procedure; $p = 0.06$ compared with standard balloons, while coronary perforations occurred only in patients undergoing cutting balloon angioplasty (0.8% vs. 0%, $p = 0.03$).[9] In the same study, major dissection rates following angioplasty were similar between cutting balloon angioplasty and standard balloon angioplasty patients.[9] Another risk of cutting balloons is that the microblades are at risk of fracture and entrapment, especially with high pressure inflation.

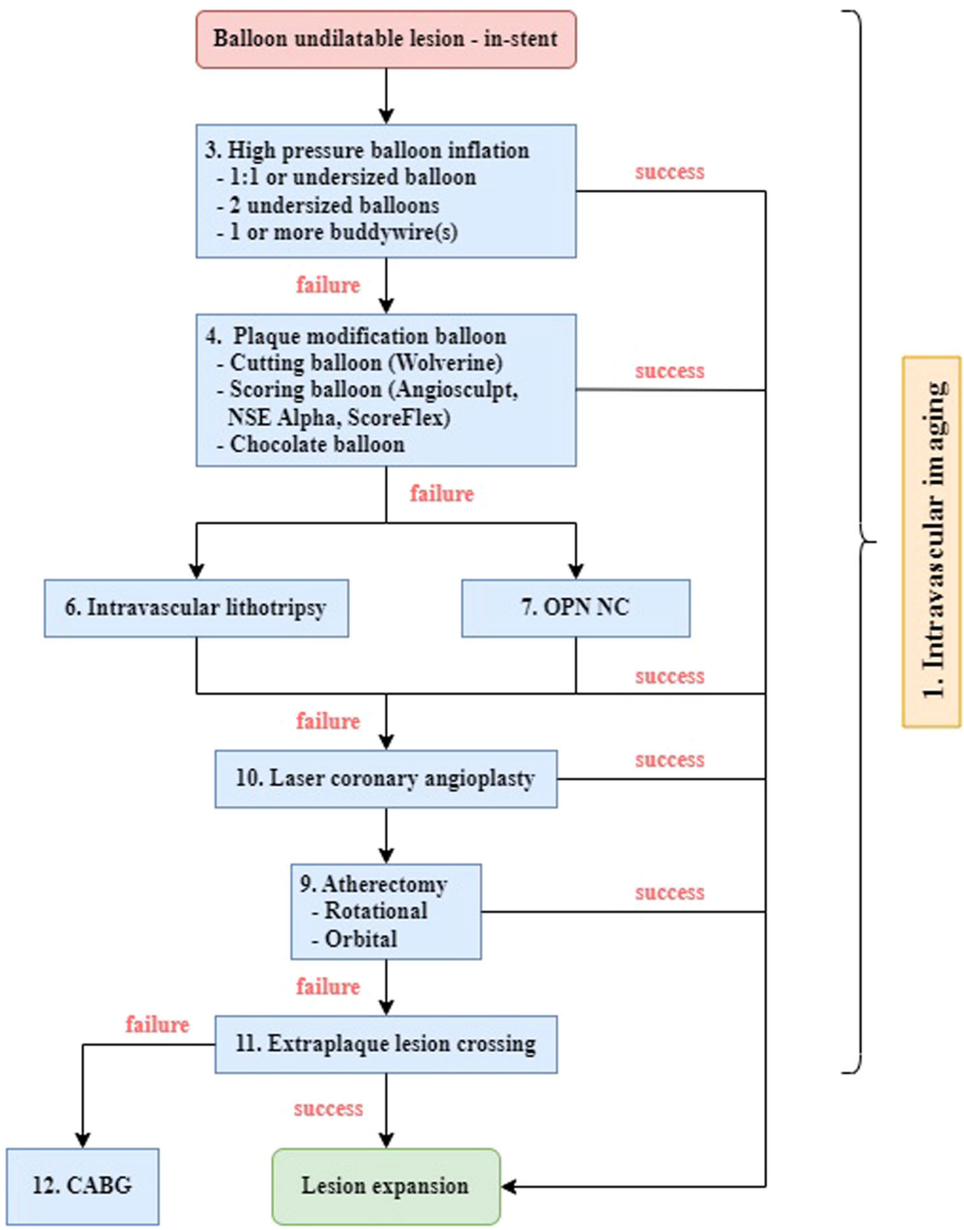

FIGURE 2 Algorithm for in-stent balloon undilatable lesions. CABG, coronary artery bypass graft surgery; NC, noncompliant [Color figure can be viewed at wileyonlinelibrary.com]

1.5 | Lesion too long for intravascular lithotripsy (IVL)

IVL is an important tool for treating short coronary lesions. However, the coronary lithotripsy balloon has a length of 12 mm, hence may be less suitable for longer lesions. The longer peripheral IVL catheters can be used off label in large coronary arteries, as described by Karacsonyi et al who treated a long (40 mm) undilatable lesion with 140 lithotripsy pulses using a 3.5 × 40-mm peripheral Shockwave balloon (Shockwave Medical Inc.).[10] This lithotripsy balloon has an array of five emitters, a crossing profile of 0.048″–0.050″, and can deliver up to 160 pulses (20 per cycle). Using a peripheral lithotripsy balloon for a coronary lesion can be challenging, as delivery is difficult and requires strong guide catheter support.

1.6 | Intravascular lithotripsy

The coronary IVL system (Shockwave Medical) utilizes a semi-compliant balloon catheter that contains two integrated lithotripsy emitters. The catheter is advanced across the lesion and the balloon is inflated to 4 atm. The emitters are then activated and vaporize the fluid within the balloon to create a rapidly expanding and collapsing bubble which generates sonic waves. An IVL cycle consists of 10 pulses, with one pulse generated per second, up to a maximum of 80 pulses per catheter. The sonic pressure waves travel through soft vascular tissue selectively cracking both superficial and deep calcium with an effective pressure of approximately 50 atm. After the first cycle, the balloon can be inflated to 6 atm to increase balloon compliance and maximize luminal gain. The coronary IVL balloons come at a standard 12 mm length and their diameter varies from 2.5 to 4.0 mm, while their crossing profile varies from 0.044 in to 0.047 in.

Four prospective, single-arm, multicenter studies have been conducted to assess the safety and effectiveness of IVL in patients with de novo heavily calcified coronary lesions with encouraging results (Table 1): Disrupt coronary artery disease (CAD) I,[11] Disrupt CAD II,[12] Disrupt CAD III,[13] and Disrupt CAD IV.[14] The Disrupt CAD IV study demonstrated good long-term (1 year) outcomes (MACE rate = 9.4%). However, these studies only included patients with de novo calcified lesions. However, off-label use of IVL in in-stent restenosis and stent underexpansion has shown promising results, with high success rate (87.1%) and acceptable 30-day postprocedure MACE rate (2.5%).[15] IVL has limitations, such as the balloon length of 12 mm which makes IVL less suitable for longer lesions, and difficult delivery. IVL is most effective in circumferential calcium, however a study demonstrated good outcomes in eccentric calcified lesions.[16]

1.7 | Very high-pressure balloon

The very high-pressure OPN balloon (SIS Medical) was recently approved for use in the United States. The OPN is a NC balloon that is available in diameters ranging from 1.5 to 4.5 mm and lengths of 10, 15, and 20 mm. It utilizes a twin-layer balloon technology which allows for very high-pressure inflations (rated burst pressure is 35 atm but >40 atm have been used) and also prevents "dog-boning" by ensuring uniform balloon expansion. Its crossing profile is high at 0.028″ but still better than plaque modification balloons (0.032″–0.047″). The OPN NC balloon can be difficult to use in patients with eccentric lesions, as it has a higher chance of dog-boning, and in patients with calcified nodules due to increased risk of perforation.

Two studies have assessed the very high-pressure balloon in patients with balloon undilatable lesions. The first one, published on 2016, included 91 consecutive lesions and reported a procedural success of 92.3% and no 30-day MACE.[17] The second one, published on 2019, included 326 consecutive lesions and reported a procedural success of 96.6% and 30-day MACE of 0.9%.[18] Further investigation is needed to assess the OPN NC balloon's safety, efficacy and long-term outcomes.

TABLE 1 Use of intravascular lithotripsy for de novo calcified lesions

Studies (*n* = number of patients)	Acute gain	Procedural success rate	Serious angiographic complications	30-day MACE	Follow-up MACE
Disrupt CAD I (26) (*n* = 60)	1.7 ± 0.4 mm	95% (*n* = 57)	0% (*n* = 0)	5% (*n* = 3) (no cardiac deaths)	6 months: 8% (*n* = 5)
Disrupt CAD II (27) (*n* = 120)	1.67 ± 0.49 mm	94.2% (*n* = 113)	0% (*n* = 0)	7.6% (*n* = 9) (1 cardiac death)	N/A
Disrupt CAD III (28) (*n* = 383)	1.68 ± 0.46 mm	92.2% (*n* = 354)	0.5% (*n* = 2) (type F dissection and perforation)	7.8% (*n* = 30) (2 cardiac deaths)	N/A
Disrupt CAD IV (29) (*n* = 64)	1.67 ± 0.37	93.8% (*n* = 60)	0% (*n* = 0)	6.3% (*n* = 4) (no cardiac deaths)	1 year: 9.4% (*n* = 6)

Note: Procedural success: achievement of <50% diameter stenosis without the presence of in-hospital MACE; serious angiographic complications include severe dissection (types D to F), perforation, abrupt closure, slow flow, and no flow.

Abbreviations: CAD, coronary artery disease; MACE, major adverse cardiac events (death, myocardial infarction, emergency coronary artery bypass grafting, repeat percutaneous coronary intervention).

1.8 | Suitable for atherectomy?

Atherectomy is usually avoided in saphenous vein graft lesions, in the setting of thrombus and vessel dissection, and in small and highly tortuous vessels.[19]

1.9 | Coronary atherectomy

Coronary atherectomy can successfully treat balloon undilatable lesions and its use has been increasing over the past years. There are two types of atherectomy, RA, and OA.

RA utilizes a diamond-encrusted elliptical burr, which usually rotates at 140,000–160,000 bpm and causes selective ablation of the calcified plaque, while sparing healthy arterial tissue.[20] In the 2021 American Heart Association/American College of Cardiology PCI guidelines, RA was given a Class IIA recommendation for patients with fibrotic and heavily calcified balloon uncrossable and balloon undilatable lesions, while other plaque modification techniques were given a Class IIB recommendation.[21] In a multicenter study of 966 patients RA was associated with good procedural (91.9% procedural success), in-hospital (4.7% in-hospital MACE), and long-term (13.2% 1-year MACE) outcomes.[22] Compared with plaque modification balloons, RA was more commonly successful (98% with RA vs. 81% with plaque modification balloons), while clinical outcomes were similar.[23] An analysis of 7740 patients undergoing RA, showed that higher operator RA PCI volume was associated with better outcomes.[24]

The Diamondback 360° Orbital Atherectomy System (Cardiovascular Systems) utilizes a 1.25 mm diamond-coated eccentrically mounted crown, which can be rotated bi-directionally, thus decreasing the risk of crown entrapment, at 80,000 bpm or at 120,000 bpm. The crown size is the same for all vessel sizes. Multiple studies have shown good outcomes of OA in de novo coronary lesions (Table 2).[25–27]

In a meta-analysis of 8 studies (4332 patients) comparing RA with OA,[28] OA was associated with lower long-term (1 year) MACE (odds ratio [OR]: 0.66; 95% confidence interval [CI]: 0.44, 0.99; $p = 0.04$), long-term target-vessel revascularization (OR: 0.40; 95% CI: 0.18, 0.89; $p = 0.03$), and short-term (in-hospital and 30-day) myocardial infarction (OR: 0.64; 95% CI: 0.44, 0.94; $p = 0.02$). On the other hand, OA was associated with more angiographic complications, including coronary artery dissections (OR: 2.61; 95% CI: 1.38, 4.92; $p = 0.003$) and device-related coronary perforations (OR: 2.79; 95% CI: 1.08, 7.19; $p = 0.03$). OA had a lower fluoroscopy time (mean difference: −3.96 min; 95% CI: −7.67, −0.25; $p = 0.04$).

Even though coronary atherectomy is a very useful technique for patients with balloon undilatable lesions, it should always be used with caution, because of the associated risks. In an analysis of 2,035,039 patients who underwent PCI, the 50,095 who underwent coronary atherectomy had significantly higher in-hospital mortality (adjusted odds ratio [aOR]: 1.39; 95% CI: 1.31, 1.46; $p < 0.001$) compared with nonatherectomy patients, which may be associated with higher rates of vascular complications, major bleeding, and acute kidney injury.[29] Slow-flow/no-reflow and burr entrapment are other complications associated with RA in particular, but their incidence has decreased over time.[20] Moreover, most studies conducted to date were for de novo uncrossable and undilatable lesions. Atherectomy has occasionally been used off-label for in-stent restenosis, with acceptable results as outlined in Table 3.[30–32] Orbital atherectomy is

TABLE 2 Studies of orbital Atherectomy for de novo calcified lesions

Studies (*n* = number of patients)	Perforation	Dissection	No reflow	30-day MACE	Follow-up MACE
ORBIT I Trial (45) (*n* = 50)	2% (*n* = 1)	12% (*n* = 6) (types A to C without clinical sequelae)	0% (*n* = 0)	6% (*n* = 3) (no cardiac deaths)	6 months: 8% (*n* = 4)
ORBIT II Trial (46) (*n* = 443)	2.2% (*n* = 4)	5.5% (*n* = 10)	0% (*n* = 0)	10.4% (*n* = 46) (1 cardiac death)	1 year: 16.9% (*n* = 74) 3 years: 23.5% (*n* = 101)
Lee et al.[26] (47) (*n* = 458)	0.7% (*n* = 3)	0.9% (*n* = 4)	0.7% (*n* = 3)	1.5% (*n* = 7) (6 deaths)	1 year: 11.3% (*n* = 51/453 with 1-year follow-up)

Abbreviation: MACE, major adverse cardiac events (death, myocardial infarction, emergency coronary artery bypass grafting, repeat percutaneous coronary intervention).

TABLE 3 Studies of atherectomy for in-stent lesions

Studies (*n* = number of patients) [Atherectomy type]	Perforation	Dissection	No reflow	Burr entrapment	30-day MACE
Sharma et al.[20] (50) (*n* = 100) [Rotational atherectomy]	0% (*n* = 0)	3% (*n* = 3) (types B and C)	1% (*n* = 1)	0% (*n* = 0)	3% (*n* = 3)
Ferri et al.[31] (51) (*n* = 16) [Rotational atherectomy]	0% (*n* = 0)	6.3% (*n* = 1)	0% (*n* = 0)	6.3% (*n* = 1)	6.3% (*n* = 1)
Neupane et al.[32] (52) (*n* = 41) [Orbital atherectomy]	5% (*n* = 2)	N/A	5% (*n* = 2)	N/A	In-hospital: 5% (*n* = 2)

Note: Procedural success: achievement of <50% diameter stenosis without the presence of in-hospital MACE.

Abbreviation: MACE, major adverse cardiac event (death, myocardial infarction, emergency coronary artery bypass grafting, repeat percutaneous coronary intervention).

contraindicated in in-stent lesions, although it has been successfully used in previously implanted stents.[32]

1.10 | Laser coronary angioplasty

The excimer laser coronary angioplasty (ELCA) (Philips) utilizes UV light pulses to ablate tissue by photochemical (fracture of molecular bonds), photothermal (molecular bond vibration and tissue vaporization), and photokinetic (rapid expansion and collapse of the vapor bubble—clearance of byproducts) mechanisms. An analysis of a multicenter CTO PCI registry indicated that ELCA use in balloon uncrossable and undilatable CTO PCIs was associated with high technical (91.5%) and procedural (88.9%) success with acceptable major complication rates (3.92% [ELCA used] vs. 3.51% [ELCA not used]; $p = 0.805$).[33] Another study, however, suggested that the complication risk was higher in patients undergoing ELCA (4.2% [ELCA used] vs 3.0% [ELCA not used]; $p < 0.001$), although the risk was lower in patients undergoing ELCA for in-stent restenosis (OR: 0.51; 95% CI: 0.42, 0.63; $p < 0.001$).[34]

Performance of ELCA with simultaneous contrast injection can help expand under-exapnded stents but should not be used in de novo lesions due to high risk of dissection and perforation.

1.11 | Extraplaque lesion crossing

One of the last resorts in treating balloon undilatable lesions is extraplaque (previously called "subintimal") lesion crossing. This is a complex technique, primarily used for balloon uncrossable lesions, but it can also be utilized for balloon undilatable lesions. In the extraplaque lesion crossing technique, the balloon undilatable segment of the lesion is crossed through the extraplaque space with a second guidewire. Subsequently, a balloon is advanced next to the lesion over the extraplaque guidewire and it is inflated to 8–10 atm externally "crushing" the plaque and facilitating lesion expansion. An IVL catheter has been used in a modification of this technique.[35] Extraplaque crossing can be challenging and requires expertise in CTO dissection and re-entry techniques. It is associated with an increased risk of vessel perforation and formation of extraplaque space hematoma that can compress the distal true lumen.

1.12 | Coronary artery bypass graft surgery

When all aforementioned techniques fail, coronary artery bypass graft surgery may provide a solution.

2 | CONCLUSIONS

Balloon undilatable lesions can be challenging to treat. A systematic, algorithmic approach can significantly facilitate successful treatment.

CONFLICTS OF INTEREST

Dr. Egred: consulting/speaker/proctoring honoraria from Abbott Vascular, Boston Scientific, Philips, Spectranetics, Volcano, Teleflex, Vascular Perspective, Merrill, Sveltte, EPS Medical, and AstraZeneca. Dr. Mashayeki: consulting/speaker/proctoring honoraria from Abbott Vascular, Abiomed, Ashai Intecc, AstraZeneca, Biotronik, Boston Scientific, Cardinal Health, Daiichi Sankyo, Medtronic, Shockwave Medical, Teleflex, and Terumo. Dr. Di Mario: recipient of institutional research grants from AMGEN, Abbott Vascular, Behring, Boston Scientific, Chiesi Pharmaceuticals, Daiichi Sankyo, Edwards Lifesciences, Medtronic, Shockwave Medical, and Philips Volcano. Dr. Burke: consulting and received speaker honoraria from Abbott Vascular and Boston Scientific. Dr. Brilakis: consulting/speaker honoraria from Abbott Vascular, American Heart Association (associate editor Circulation), Amgen, Asahi Intecc, Biotronik, Boston Scientific, Cardiovascular Innovations Foundation (Board of Directors), CSI, Elsevier, GE Healthcare, IMDS, Medicure, Medtronic, Siemens, and Teleflex; research support: Boston Scientific, GE Healthcare; owner, Hippocrates LLC; shareholder: MHI Ventures, Cleerly Health, Stallion Medical.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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REFERENCES

1. Tajti P, Karmpaliotis D, Alaswad K, et al. Prevalence, presentation and treatment of 'balloon undilatable' chronic total occlusions: insights from a multicenter US registry. *Catheter Cardiovasc Interv*. 2018;91:657-666.
2. McQuillan C, Jackson MWP, Brilakis ES, Egred M. Uncrossable and undilatable lesions-A practical approach to optimizing outcomes in PCI. *Catheter Cardiovasc Interv*. 2021;97:121-126.
3. Simsek B, Kostantinis S, Karacsonyi J, et al. Prevalence and outcomes of balloon undilatable chronic total occlusions: insights from the PROGRESS-CTO. *Int J Cardiol*. 2022;362:42-46.
4. Karacsonyi J, Armstrong EJ, Truong HTD, et al. Contemporary use of laser during percutaneous coronary interventions: insights from the laser veterans affairs (LAVA) multicenter registry. *J Invasive Cardiol*. 2018;30:195-201.
5. Zhang M, Matsumura M, Usui E, et al. Intravascular ultrasound-derived calcium score to predict stent expansion in severely calcified lesions. *Circ Cardiovasc Interv*. 2021;14:e010296.
6. Fujino A, Mintz GS, Matsumura M, et al. A new optical coherence tomography-based calcium scoring system to predict stent under-expansion. *EuroIntervention*. 2018;13:2182-2189.
7. de Ribamar Costa J, Mintz GS, Carlier SG, et al. Nonrandomized comparison of coronary stenting under intravascular ultrasound

guidance of direct stenting without predilation versus conventional predilation with a semi-compliant balloon versus predilation with a new scoring balloon. *Am J Cardiol*. 2007;100:812-817.
8. Matsukawa R, Kozai T, Tokutome M, et al. Plaque modification using a cutting balloon is more effective for stenting of heavily calcified lesion than other scoring balloons. *Cardiovasc Interv Ther*. 2019;34:325-334.
9. Mauri L, Bonan R, Weiner BH, et al. Cutting balloon angioplasty for the prevention of restenosis: results of the cutting balloon global randomized trial. *Am J Cardiol*. 2002;90:1079-1083.
10. Karacsonyi J, Nikolakopoulos I, Vemmou E, Rangan BV, Brilakis ES. Intracoronary lithotripsy. *JACC: Case Reports*. 2021;3:780-785.
11. Brinton TJ, Ali ZA, Hill JM, et al. Feasibility of shockwave coronary intravascular lithotripsy for the treatment of calcified coronary stenoses. *Circulation*. 2019;139:834-836.
12. Ali ZA, Nef H, Escaned J, et al. Safety and effectiveness of coronary intravascular lithotripsy for treatment of severely calcified coronary stenoses: the disrupt CAD II study. *Circ Cardiovasc Interv*. 2019;12:e008434.
13. Hill JM, Kereiakes DJ, Shlofmitz RA, et al. Intravascular lithotripsy for treatment of severely calcified coronary artery disease. *J Am Coll Cardiol*. 2020;76:2635-2646.
14. Saito S, Yamazaki S, Takahashi A, et al. Intravascular lithotripsy for vessel preparation in calcified coronary arteries prior to stent placement - Japanese disrupt CAD IV study 1-year results. *Circulation reports*. 2022;4:399-404.
15. Ielasi A, Moscarella E, Testa L, et al. IntravaScular lithotripsy for the management of UndILatable coronary StEnt: the SMILE registry. *Cardiovasc Revasc Med*. 2020;21:1555-1559.
16. Blachutzik F, Honton B, Escaned J, et al. Safety and effectiveness of coronary intravascular lithotripsy in eccentric calcified coronary lesions: a patient-level pooled analysis from the disrupt CAD I and CAD II studies. *Clin Res Cardiol*. 2021;110:228-236.
17. Secco GG, Ghione M, Mattesini A, et al. Very high-pressure dilatation for undilatable coronary lesions: indications and results with a new dedicated balloon. *EuroIntervention*. 2016;12:359-365.
18. Secco GG, Buettner A, Parisi R, et al. Clinical experience with very high-pressure dilatation for resistant coronary lesions. *Cardiovasc Revasc Med*. 2019;20:1083-1087.
19. Dobrzycki S, Reczuch K, Legutko J, et al. Rotational atherectomy in everyday clinical practice. Association of cardiovascular interventions of the Polish Society of Cardiology (Asocjacja Interwencji Sercowo-Naczyniowych Polskiego Towarzystwa Kardiologicznego - AISN PTK): expert opinion. *Kardiol Pol*. 2018;76:1576-1584.
20. Sharma SK, Tomey MI, Teirstein PS, et al. North American expert review of rotational atherectomy. *Circ Cardiovasc Interv*. 2019;12:e007448.
21. Lawton JS, Tamis-Holland JE, Bangalore S, et al. 2021 ACC/AHA/SCAI guideline for coronary artery revascularization: executive summary: a report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. *Circulation*. 2022;145:e4-e17.
22. Bouisset F, Barbato E, Reczuch K, et al. Clinical outcomes of PCI with rotational atherectomy: the European multicentre Euro4C registry. *EuroIntervention*. 2020;16:e305-e312.
23. Abdel-Wahab M, Toelg R, Byrne RA, et al. High-speed rotational atherectomy versus modified balloons prior to drug-eluting stent implantation in severely calcified coronary lesions. *Circ Cardiovasc Interv*. 2018;11:e007415.
24. Kinnaird T, Gallagher S, Sharp A, et al. Operator volumes and in-hospital outcomes. *JACC: Cardiovascular Interventions*. 2021;14:1423-1430.
25. Parikh K, Chandra P, Choksi N, Khanna P, Chambers J. Safety and feasibility of orbital atherectomy for the treatment of calcified coronary lesions: the ORBIT I trial. *Catheter Cardiovasc Interv*. 2013;81:1134-1139.
26. Lee M, Généreux P, Shlofmitz R, et al. Orbital atherectomy for treating de novo, severely calcified coronary lesions: 3-year results of the pivotal ORBIT II trial. *Cardiovasc Revasc Med*. 2017;18:261-264.
27. Lee MS, Shlofmitz E, Goldberg A, Shlofmitz R. Multicenter registry of real-world patients with severely calcified coronary lesions undergoing orbital atherectomy: 1-year outcomes. *J Invasive Cardiol*. 2018;30:121-124.
28. Khan AA, Murtaza G, Khalid MF, et al. Outcomes of rotational atherectomy versus orbital atherectomy for the treatment of heavily calcified coronary stenosis: a systematic review and meta-analysis. *Catheter Cardiovasc Interv*. 2021;98:884-892.
29. Darmoch F, Ullah W, Al-Khadra Y, et al. Characteristics and hospital outcomes of coronary atherectomy within the United States: a multivariate and propensity-score matched analysis. *Expert Rev Cardiovasc Ther*. 2021;19:865-870.
30. Sharma SK, Kini A, Mehran R, Lansky A, Kobayashi Y, Marmur JD. Randomized trial of rotational atherectomy versus balloon angioplasty for diffuse in-stent restenosis (ROSTER). *Am Heart J*. 2004;147:16-22.
31. Ferri LA, Jabbour RJ, Giannini F, et al. Safety and efficacy of rotational atherectomy for the treatment of undilatable underexpanded stents implanted in calcific lesions. *Catheter Cardiovasc Interv*. 2017;90:E19-E24.
32. Neupane S, Basir M, Tan C, et al. Feasibility and safety of orbital atherectomy for the treatment of in-stent restenosis secondary to stent under-expansion. *Catheter Cardiovasc Interv*. 2021;97:2-7.
33. Karacsonyi J, Alaswad K, Choi JW, et al. Laser for balloon uncrossable and undilatable chronic total occlusion interventions. *Int J Cardiol*. 2021;336:33-37.
34. Sintek M, Coverstone E, Bach R, et al. Excimer laser coronary angioplasty in coronary lesions: use and safety from the NCDR/CATH PCI registry. *Circulation: Cardiovascular Interventions*. 2021;14:e010061.
35. Yeoh J, Hill J, Spratt JC. Intravascular lithotripsy assisted chronic total occlusion revascularization with reverse controlled antegrade retrograde tracking. *Catheter Cardiovasc Interv*. 2019;93:1295-1297.

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