REC Interv Cardiol. 2020;2(2):129-139

Review article

Current options for the management of calcified lesions

Héctor Cubero-Gallego,[a] Helena Tizón-Marcos,[b,c] and Beatriz Vaquerizo[b,c,*]

[a] *Unidad de Cardiología Intervencionista, Área del Corazón, Hospital Universitario Central de Asturias, Oviedo, Asturias, Spain*
[b] *Unidad de Cardiología Intervencionista, Servicio de Cardiología, Hospital del Mar, Universidad Autónoma de Barcelona, Barcelona, Spain*
[c] *Instituto Hospital del Mar de Investigaciones Médicas-IMIM, Barcelona, Spain*

ABSTRACT

Severe coronary calcium increases the complexity of percutaneous coronary interventions. It may affect the adequate preparation of the lesion, proper stent expansion and apposition and increase the risk of stent thrombosis and restenosis. The techniques available for the management of severe calcified lesions can be divided into 2 groups: non-balloon and balloon-based technologies. Rotational atherectomy has been the predominant technique to treat severe calcified lesions. As a matter of fact, there are new devices available that facilitate the modification of the plaque such as the new lithoplasty balloon that involves the use of high-energy mechanical pulses to crack coronary calcium. Coronary lithoplasty is an easy technique with a short learning curve that seems to be more effective on deep calcium by increasing luminal compliance. This may revolutionize the standard approach for the management of severe calcified coronary lesions. Also, the role of intravascular imaging is essential to select the most appropriate plaque-modification device and assess the optimal stent result. This review provides an overview of the techniques available and evidence on the currently approved devices to treat calcified lesions.

Keywords: Rotational atherectomy. Orbital atherectomy. Excimer laser. Coronary lithoplasty.

Opciones actuales para el tratamiento de las lesiones calcificadas

RESUMEN

El calcio coronario aumenta la complejidad del intervencionismo coronario percutáneo. La calcificación grave dificulta la preparación de la lesión, impide la adecuada expansión y la aposición del *stent*, y aumenta el riesgo de trombosis y de reestenosis. Las técnicas de modificación de placa se pueden dividir en 2 tipos según el tipo de dispositivo: sin balón y con balón. La aterectomía rotacional ha sido la técnica por excelencia para el tratamiento de lesiones gravemente calcificadas. Actualmente existen nuevos dispositivos que facilitan la preparación de la lesión, como el novedoso balón de litoplastia, que utiliza pulsos de alta energía mecánica para fragmentar el calcio coronario. La litoplastia coronaria es una técnica sencilla, con una curva de aprendizaje corta, que parece tener efecto sobre el calcio profundo y aumentar la distensibilidad luminal, lo que podría suponer un gran cambio en el enfoque del tratamiento de las lesiones calcificadas. Cabe destacar la relevancia de la imagen intravascular al seleccionar el dispositivo de modificación de placa más adecuado, así como para evaluar el resultado final del *stent*. Esta revisión proporciona una visión general sobre las técnicas disponibles y la evidencia de los dispositivos aprobados para el tratamiento de las lesiones calcificadas.

Palabras clave: Aterectomía rotacional. Aterectomía orbital. Láser de excímeros. Litoplastia coronaria.

Abbreviations

CL: coronary lithoplasty. **ELCA:** excimer laser coronary atherectomy. **IVUS:** intravascular ultrasound. **OA:** orbital atherectomy. **OCT:** optical coherence tomography. **PCI:** percutaneous coronary intervention. **RA:** rotational atherectomy. **SCCL:** severely calcified coronary lesion.

* **Corresponding author:** Hospital del Mar, Parc de Salut Mar, Passeig Marítim 25-29, 08003 Barcelona, Spain.
E-mail address: beavaquerizo@yahoo.es (B. Vaquerizo).

Online: 04-02-2020.
https://doi.org/10.24875/RECICE.M19000087

INTRODUCTION

Severely calcified coronary lesions (SCCL) pose a tremendous challenge to perform successful percutaneous coronary interventions (PCI).[1] Old age, diabetes mellitus, chronic kidney disease, and smoking are associated with increased coronary calcification.[2] Coronary calcium can be underestimated on the fluoroscopy and coronary angiography, and it is necessary to use intravascular imaging modalities such as the intravascular ultrasound (IVUS) and optical coherence tomography (OCT) for an accurate assessment of the severity and characterization of the plaque.[3]

Severe coronary calcification increases the complexity of the PCI.[4] It can affect the crossing of the lesion, the proper stent expansion and apposition, damage the drug-eluting polymer, increase the risk of stent thrombosis and restenosis, and have a negative impact on short and long-term results.[5] The optimal approach for the management of SCCL requires being knowledgable of a number of factors: the characteristics of the lesion, calcium distribution, intravascular imaging modalities, and the mechanism of action of every plaque-modification device.[6]

To this day, plaque-modification techniques can be divided into 2 groups based on the type of device used: with and without balloon.[6,7] Among the procedures with devices based on technologies without balloon we should mention rotational atherectomy ([RA], Rotablator and ROTAPro; Boston Scientific, United States), orbital atherectomy ([OA], Diamondback 360; Cardiovascular Systems, Inc., United States), and RA with excimer laser (CVX-300 Excimer Laser System, Philips, United States).[8,9] Among the procedures with devices based on technologies with balloon we find the cutting balloon (WOLVERINE, Boston Scientific, United States) and the scoring balloon. The most important ones are AngioSculpt (Biotronik, Germany), Scoreflex (OrbusNeich, China), and NSE Alpha (B. Braun, Germany); the ultra-high pressure non-compliant (NC) balloon, OPN (SIS Medical AG, Switzerland); and the coronary lithoplasty device ([CL], Shockwave Medical, Inc., United States).[8,9]

The widespread use of these techniques and devices has been limited due to the risk of complications, the degree of technical difficulty, the operator's experience, and the corresponding use of health resources. This review focuses on the techniques and evidence available today for the devices approved for the management of SCCLs.

ROTATIONAL ATHERECTOMY

Definition

RA is an endovascular procedure to modify atherosclerotic plaque by advancing a diamond-coated rotating metal olive-shaped burr.[10,11]

Operating principles

The RA device (Boston Scientific, United States) consists of an elliptical diamond crystal-coated olive-shaped burr rotating at high speed and performing differential cutting as it moves forward (figure 1 of the supplementary data). The RA pulverizes the plaque fibrocalcific components while preserving the adjacent elastic tissue by releasing microparticles into distal coronary circulation.[7,10]

The burr has different sizes (from 1.25 mm to 2.5 mm) and is mounted on a drive shaft connected to a console that supplies rotational energy. It has 3 connections (inside a single cable with 3 outputs connected to the console): a tachometer cable, a power connector, and a compressed air/nitrogen connection. From the console, the compressed air/nitrogen provides pressure for the rotation of the engine at selected revolutions. Similarly, there is a physiological saline solution connection to which heparin and vasodilators can be added to lubricate the sheath and cool the engine down (figure 1 of the supplementary data). A 0.5:0.6 ratio between the burr and the vessel is advisable. The olive-shaped burr is advanced on a 0.009 in specific guidewire (RotaWire, Boston Scientific, United States).[10,11] It should be mentioned that the RotaWire guidewire has different length diameters: the cable measures 0.009 inches and the radiopaque segment, 0.014 inches. The burr is compatible with the 0.009 in guidewire proximal segment. There are 2 different versions of RotaWire available (RotaWire Extra Support and RotaWire Floppy) used depending on the characteristics of the plaque and the support required.[10,11] (figure 1 of the supplementary data).

The rotational speed recommended is between 135 000 rpm and 180 000 rpm. Decelerations > 5000 rpm should be avoided. The burr should be advanced gradually with easy back-and-forth moves and rotablation time should be < 20 seconds with pauses in between each cycle. Once rotablation has been performed, the olive-shaped burr is removed and the Dynaglide mode is activated. Unless there is a technical issue, deceleration is usually indicative of a significant resistance to the advancement of the burr due to lesion severity and calcification and makes a distinctive sound. It is advisable to carefully listen while the RA is being performed because deceleration can be indicative of the risk of burr entrapment.[7,10,11] (table 1).

There is an update of this device, the ROTAPro, that facilitates manipulation by a single operator and provides an improved user interface with integrated controls in the advancement device. The pedal has been replaced by a button located on top of the burr advancement control. There is another button at the back of the device to activate the Dynaglide mode. The console is smaller, has a digital screen and requires less configuration time (figure 2 of the supplementary data).

Indications

The main indication for RA is for the treatment of SCCLs that are non-dilatable through conventional methods by modifying the plaque, which facilitates the proper stent expansion and apposition.[10,11] (figure 1).

The following factors significantly impact the outcomes of RA: calcium eccentricity, luminal area, and burr size. The optimal scenario to achieve proper luminal gain is a concentric lesion with a circumferential distribution of calcium and a minimal lumen area smaller than the burr size.[7] Another more controversial indication is for the management of stent restenosis due to stent underexpansion. Eccentric lesions with significant tortuosity are less eligible for RA treatment since there is a higher risk of complications.[9]

The RA can be used as the primary strategy for the modification of calcified lesions or as a bailout strategy after a failed balloon predilation attempt of the lesion.[9] It is a safe technique in both cases. However, the primary strategy is associated with shorter procedural and fluoroscopy times, fewer contrast volume, and less predilation balloons being used.[10] (table 1).

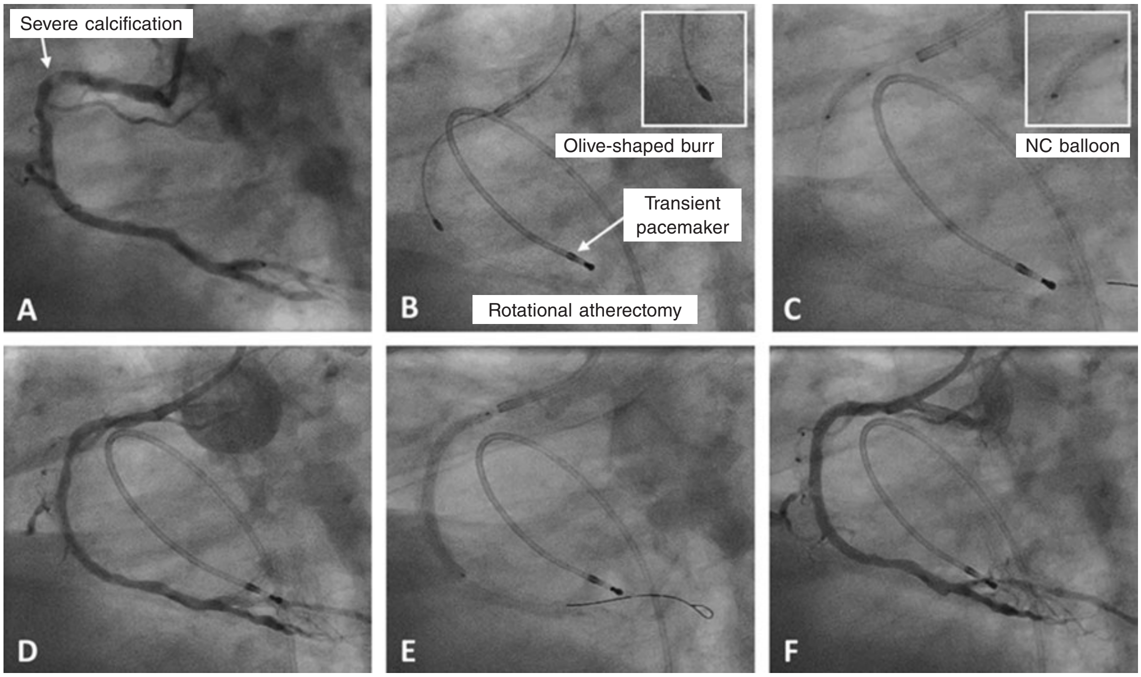

Figure 1. Case of rotational atherectomy on calcified lesion in right coronary artery. **A:** baseline angiography. **B:** rotablation of calcified lesion using a 1.5 mm olive-shaped burr. **C:** predilation with a 3 × 12 mm non-compliant balloon. **D:** angiographic result after rotablation. **E:** implantation of a 3 × 38 mm drug-eluting stent. **F:** final angiographic result after postdilation. NC, non-compliant balloon.

Clinical data

Currently the systematic use of RA is controversial because its clinical benefit has not been clearly demonstrated yet.[12-15] The ROTAXUS clinical trial[16] included 240 patients with moderate-severe calcification who were randomized to RA plus drug-eluting stent or balloon predilation plus drug-eluting stent. The RA had a higher success rate and initial luminal gain (1.56 ± 0.43 vs 1.44 ± 0.49 mm; *P* = .01), and there was a greater late stent luminal loss at the 9-month follow-up (0.44 ± 0.58 vs 0.31 ± 0.52 mm; *P* = .04). No significant differences were found regarding the rate of stent restenosis or thrombosis, need for new target lesion revascularization or rate of major adverse cardiovascular events (MACE) at the 9-month follow-up.[16]

The PREPARE-CALC clinical trial[17] included 200 patients with SCCLs randomized on a 1:1 ratio to receive treatment with cutting/scoring balloon or RA. No significant differences were seen regarding complications between the 2 groups. However, there was a higher procedural success rate with the RA and a lower percentage of residual stenosis (98% vs 81%; *P* = .0001). No significant differences were seen between the groups regarding the stent luminal loss or clinical outcomes at the 9-month follow-up.[17]

The ROTATE multicenter registry[18] included 1176 patients with SCCLs treated with RA plus drug-eluting stent. The rate of MACE at 1-year follow-up was 16%. The European multicenter RA registry included data from 963 patients. Clinical success rate was 92%, mortality rate was 12.5% and the rate of MACE at 1-year follow-up was 17% (results presented at the EuroPCR 2019 congress).[19]

Complications

The most dreaded complications of RA are burr entrapment, perforation, and coronary dissection (table 2).[10,20]

Two different types of burr entrapment can be distinguished: *a)* lesion entrapment (the burr cannot be moved forward or backwards) and *b)* distal entrapment (the burr cannot be removed but it can be moved forward). Several factors like significant lesions and very small burrs can predispose to this complication. In cases of burr entrapment, it is not advisable to activate rotablation or the Dynaglide mode.[10,11] To solve this complication, these maneuvers can be performed: *a)* controlled push and traction with catheter active intubation; *b)* cut the device catheter and advance the guide catheter extension as much as possible to pull with maximum strength; or *c)* place a second guide catheter through which a second guidewire and a balloon are advanced to release the burr.[11] This is a very serious complication that sometimes requires emergent surgery.[21]

Significant tortuosity and the lack of proper guide catheter coaxiality in the management of ostial lesion can lead to coronary dissections and increase the risk of perforation.[10,11]

The slow-flow/no-reflow phenomenon is a relatively common complication, although its incidence has dropped to 2.6% after improving the technique and with the operator's growing experience.[7,21] This phenomenon is more likely to happen in long and significant lesions where multiple ablations are performed and in the presence of a poor distal vessel. It is due to the embolization of residues towards microvasculature.[11] It can be prevented through short rotablation cycles by using small burrs at first, pausing between cycles, and controlling the flow angiographically.

Table 1. General characteristics of plaque-modification devices based on technologies without balloon

	Rotational atherectomy	Orbital atherectomy	Excimer laser coronary atherectomy
Operating principles			
Type of device	High-speed rotating olive-shaped burr	Crown at high-speed elliptical rotation	High energy light catheter
Mechanism of action	Antegrade differential cutting	Antegrade and retrograde differential sanding	Photoablation
Learning curve	Long	Long	Long
Device size	1.25-2.5 mm olive-shaped burr	1.25 mm crown	0.9-2 mm catheter
Compatible catheter	6-8-Fr	6-Fr	5-8-Fr
Type of guidewire	0.009/0.0014 in RotaWire	0.012/0.014 in ViperWire	0.014 in guidewire
Console	Small without pedal (ROTAPro)	Small without pedal	Large with pedal
Indications			
Main indication	Plaque-modification	Plaque-modification	Lesions hard to cross, like chronic total coronary occlusion
Optimal calcium location	Luminal	Luminal	Luminal
Stent restenosis	Yes	Yes	Yes
Complications			
Dissection	Moderate risk	Moderate risk	Moderate risk
Perforation	Moderate risk	Moderate risk	Moderate risk
Slow-flow/no-reflow	Moderate risk	Moderate risk	Moderate risk
Burr/crown entrapment	Moderate risk	Low risk	N/A
Practical advices			
Speed	135 000-180 000	80 000-120 000	N/A
Device-vessel ratio	0.5:0.6	N/A	0.5:0.6
Recommendations	Pecking motion Short cycles Pauses in between cycles Avoid significant tortuosity	Continuous and slow back-and-forth moves Short cycles Pauses in between cycles	Requires the continuous infusion of fluid

N/A, non-applicable.

Table 2. Complications of rotational atherectomy, strategy of prevention, and treatment

	Strategy of prevention	Treatment
Slow-flow/no-reflow	Use smaller burrs Avoid high rotation speeds Do short cycles with pauses in between	Intracoronary administration of nitrates, nitroprusside, adenosine Keep the right perfusion in the presence of hypotension
Dissection	Regarding lesions at segments with significant toruosity	In the presence of significant dissection, it is advisable to stop performing the atherectomy The standard management of dissection is advised
Perforation	Regarding the selection of large burrs, significant vessel tortuosity, and the selection of inadequate rotation speeds	Standard treatment advised (including the use of drug-eluting stents and urgent pericardiocentesis)
Burr entrapment	Rare complication; it can usually be avoided with an adequate selection of cases and performing the technique the right way	Perform controlled back-and-forth moves Position a second guidewire to advance a balloon to release the burr Increase support through active intubation or the use of a catheter extension to increase traction Cardiac surgery may be necessary

Once diagnosis has been established, it is treated with fluid therapy, local vasodilators at distal levels, vasoactive amines in the presence of hypotension, and atropine in the presence of bradycardia.[10,11]

ORBITAL ATHERECTOMY

Definition

OA is an endovascular procedure to modify atherosclerotic plaque by using a diamond-coated crown whose mechanism of action consists of the antegrade and retrograde modification of the plaque.[7]

Operating principles

The standard OA device is the Diamondback 360 (Cardiovascular Systems, Inc., United States). It consists of a one size only diamond-coated crown (1.25 mm) connected to a drive shaft and controller and powered by a pneumatic console (figure 3 of the supplementary data). The crown is advanced on a specific 0.012/0.014 in guidewire (ViperWire; Cardiovascular Systems, Inc., St. Paul, MN, United States). The centrifugal force generated during rotation compresses the crown against the plaque eventually cracking it and increasing distensibility.[22,23]

The OA mechanism of action is the elliptical rotation of the crown that gradually increases orbital diameter as rotation speed increases from 80 000 rpm to 120 000 rpm.[22] Increasing the orbit with higher rotation speeds allows the differential sanding of calcified lesions in vessels of up to 3.5 mm using the 1.25 mm crown.[7] For optimal results, the crown needs to be moved slowly and gradually through the lesion at a speed of 1-3 mm/s, which facilitates greater luminal gain and a lower rate of complications compared to higher moving speeds.[7,22]

The OA effect is time-dependent; 30 second-cycles are advisable with 30 second-pauses in between them.[22] The continuous infusion of a lubricant solution (ViperSlide) is required to minimize thermal lesions during OA; also, 18 mL/min of fluid are administered to cool the device down and eliminate residue, thus reducing ischemia and distal embolization.[22,24]

The Micro Crown system (Cardiovascular Systems, Inc., United States) is available for use. It is a technological advancement to improve the effectiveness of OA. It consists of a newly designed drive shaft to facilitate easier advances of the crown towards the lesion. It facilitates plaque modification at slower speeds (50 000 rpm-70 000 rpm)[9,22] (table 1).

Indications

The main indication of OA is for the management of calcified lesions non-dilatable using conventional methods to modify the plaque, increase vessel distensibility, and facilitate the proper stent expansion.[22,23] With the new OA Micro Crown system ostial and subocclusive lesions can be treated.[9] (table 1).

Clinical data

The ORBIT I clinical trial[25] included 50 patients and confirmed the safety and efficacy of OA for the management of calcified lesions. Procedural success was achieved in 94% of the patients and the rate of MACE was 8% at 6-month follow-up.

The ORBIT II clinical trial[26] included 443 patients. Procedural success was achieved in 98.6% of the patients, the rate of significant dissections was 2.3%, and the rate of MACE was 10.4% at the 30-day follow-up. The 3-year follow-up results showed a rate of MACE of 23.5%.[27]

The COAST clinical trial[28] that used the new Micro Crown system included 100 patients. Procedural success was achieved in 85% of the patients, and the rate of MACE was 22.2% at the 1-year follow-up. The ECLIPSE trial (NCT03108456) is being conducted now and will include 2000 patients with SCCLs randomized to OA plus drug-eluting stent or balloon predilation plus drug-eluting stent.

Complications

Complications are similar to those reported for RA. However, compared to RA, since the OA performs antegrade and retrograde sanding, it reduces the chances of crown entrapment in the lesion. The residues produced are smaller and they don't alter coronary flow during its application, thus reducing the risk of slow-flow/no-reflow phenomenon and thermal lesion of coronary endothelium.[7,24] Coronary perforation is one of the most serious complications of OA (between 0.7% and 2%).[26-28] OA is not advisavke when coronary anatomy shows significant tortuosity (> 90° angulations).

EXCIMER LASER CORONARY ATHERECTOMY

Definition

Excimer laser coronary atherectomy (ELCA) is an endovascular procedure for the management of significant and calcified lesions non-dilatable with the usual techniques. It uses a photochemical, photothermal, and photomechanical mechanism of action derived from applying high-energy light.[29,30]

Operating principles

The Philips CVX-300 ELCA system uses xenon chloride and emits pulses of ultraviolet (UV) light at a 308-nm wavelength. The UV pulses generated only penetrate 50 µm deep, which disintegrates the calcified plaque through a mechanism of ablation without damage to the middle or adventitia layers (figure 4 of the supplementary data).[31] There are 4 different sizes of ELCA monorail catheter available (0.9, 0.14, 1.7 and 2.0 mm) that can be advanced on a 0.014 in guidewire. The right size is selected on a 0.5:0.6[7] ratio between catheter and vessel.

Photomechanical effect occurs when the laser acts on a liquid environment (saline solution, contrast, or blood) with the corresponding release of expansion bubbles that act on the atherosclerotic plaque.[32] Slowly moving the device forward promotes an increased luminal gain at lesion level. The number of pulses, length and total time of ELCA treatment should be individualized depending on the characteristics of the lesion. The particles generated have a diameter < 10 µm so they are reabsorbed by the reticuloendothelial system, thus avoiding microvascular obstruction[31] (table 1).

Indications

The clinical use of ELCA es limited. Its main indication is for the management of lesions that are non-dilatable through conventional methods. It is rarely used as a first-line strategy for the management of SCCLs, but it is the only option when the lesion cannot be crossed with a microcatheter or with the RotaWire/ViperWire guidewires, as it occurs with chronic occlusions.[33,34]

Other more controversial indications are for the management of non-dilatable stent restenosis using the routine methods due to stent underexpansion,[35] ostial lesions, saphenous vein graft occlusions,[36] and lesions with thrombotic content.[37-39] This technique should be avoided in the presence of unprotected left main coronary artery disease, significant tortuosity, and in bifurcated lesions (table 1).

Clinical data

The data available on the medical literature come from randomized studies (balloon predilation vs ELCA) are old and did not show any significant differences regarding results.[29,30,40]

In acute myocardial infarction, the results of the multicenter CARMEL clinical trial[39] that included 151 patients with thrombotic lesions showed a device success rate in 95% of the cases. The multicenter CORAL registry[36] included 98 patients with significant stenosis of the saphenous vein graft and the rate of MACE was 18.4% at the 30-day follow-up.

A study that included 81 lesions of stent restenosis due to stent underexpansion confirmed the superiority of ELCA over predilation with high-pressure balloon; the OCT confirmed the ELCA-induced crack of calcium behind the struts.[35]

Complications

The potential complications of ELCA are similar to the ones reported for RA and OA. The main ones are coronary dissections and coronary perforations with incidence rates of 7% and 0.5%-8%, respectively.[29,30,33] However, improvements in its design, the use of a technique with continuous infusion of a saline solution, and the use of smaller caliber catheters has reduced the rate of complications.[33,34]

CORONARY LITHOPLASTY

Definition

CL is an innovative technique that uses high-energy mechanical pulses administered through a semi-compliant balloon that modiy the plaque by cracking coronary calcium.[41,42]

Operating principles

The device available is the Coronary Rx Lithoplasty System (Shockwave Medical, Inc., United States). The lithoplasty balloon (LB) is a single use 12 mm-long angioplasty balloon with diameters that go from 2.5 mm to 4 mm that is advanced on a 0.014 in guidewire.[42,43] It emits pulses of circumferential acoustic pressure to treat concentric calcified lesions (figure 5 of the supplementary data).

The LB is inflated at calcified lesion level at a pressure of 4 atm and 1 Hz shockwaves are administered.[43,44] Mechanical energy is transmitted to the lesion when the LB contacts the artery intima layer cracking the calcium in the superficial and deep layers of the vessel wall.[7] This facilitates the proper stent expansion and apposition.[7,42,43]

Once the LB is on the lesion, it is connected to an external unit that generates pulsatile mechanical waves (figure 5 of the supplementary data). It is advisable that the LB size and vessel keep a 1:1 ratio between them.[41,42] The LB is initially inflated at a pressure of 4 atm and 10 pulses are administered (around 10 seconds are required). Then, the LB is inflated at a 6 atm pressure and then it is deflated to restore the flow. New cycles are then applied; a total of 8 therapies (80 pulses) per balloon and lesion can be administered.[42,43] Due to its size, if the length of the lesion is > 12 mm, the LB can be repositioned to treat the lesion entirely. The use of the LB is easy, learning curve is short, and makes PCI easier[7,42] (table 3).

Indications

The main indication of CL is for the management of concentric, calcified lesions with a circumferential distribution of calcium.[41,42] It seems to be more effective on the deepest calcium compared to other plaque-modification techniques.[45-47] LC is effective in large caliber vessels since there are lithoplasty balloons of up to 4mm in diameter. This device can be used in bifurcated lesions since 2 guidewires can be released during the procedure for lateral branch protection. Similarly, the LB seems safe and effective in the presence of significant tortuosity, stent restenosis due to underexpansion,[48,49] and calcification involving the left main coronary artery with severe left ventricular dysfunction[50,51] (table 3). Another more controversial indication can be for the management of SCCLs in the context of an ST-segment elevation acute myocardial infarction[52] (figure 2).

Clinical data

The DISRUPT CAD I was a premarket clinical trial that confirmed the safety and efficacy of CL for the management of SCCLs before stent implantation; the rate of MACE at the 6-month follow-up was 8%.[45] The DISRUPT CAD II clinical trial that included 120 patients confirmed the safety profile of CL before stent implantation with a rate of MACE of 7.6% at the 30-day follow-up.[46] However, larger studies with longer follow-up periods are needed to confirm these results. The DISRUPT CAD III (NCT03595176) is a multicenter clinical trial with an estimate recruitment of 392 patients that will be analyzing the safety and efficacy of LB to obtain the Food and Drug Administration approval to use this device in the United States (table 4).

Complications

Perioperative complications (dissection and perforation) are uncertain. Although the device has proven successful in the short-term, there are few real-world data published on the use of LBs. It seems that the calcium crack caused by the LB remains *in situ* without causing distal embolization, which reduces the rate of the slow-flow/no-reflow phenomenon.[7,42,43]

Table 3. General characteristics of plaque-modification devices based on technologies with balloon

	Coronary lithoplasty	Cutting/scoring balloon	Ultra-high-pressure balloon
Operating principles			
Technology	Semi-compliant balloon that emits high-energy mechanical pulses	NC balloon with microblades/semi-compliant balloon with spiral struts	Double-layer NC balloon
Mechanism of action	Lithotripsy/Calcium cracking	Cutting of the plaque luminal surface	It allows inflation at 35-40 atm
Learning curve	Short	Short	Short
Device size	2.5-4 mm	2.75-3.5 mm/2.0-3.5 mm	1.5-4.5 mm
Compatible catheter	6-Fr	6-Fr	6-Fr
Indications			
Main indication	Preparation of calcified lesions	Stent restenosis	Stent optimization
Optimal calcium location	Luminal with circumferential distribution	Luminal	Luminal
Stent restenosis	Yes	Yes	Yes
Complications			
Difficulty crossing	Yes. Improved with the new generation LB	Yes/no	Yes
Dissection	Low risk	Moderate risk	Moderate risk
Perforation	Low risk	Low risk	Low risk
Slow-flow/no-reflow	Low risk	Low risk	Low risk
Practical advices			
Pulses administered	Up to 80 pulses (8 cycles)	N/A	N/A
Device-vessel ratio	1:1	0.8:1	1:1
Recommendations	Inflation at 4 atm, 10 pulses; then up to 6 atm and deflation Useful with tortuosity Useful in bifurcations	Slow and gradual inflation	Slow and gradual inflation It allows stent postdilation at high atm

LB, lithoplasty balloon; N/A, non-applicable; NC, non-compliant balloon.

OTHER TECHNIQUES AND DEVICES

Non-compliant balloon

The NC balloon sustains very few size changes event at high pressures. This facilitates focusing its power on a given point to dilate calcified lesions without causing excessive dilatation in other vessel segments. It is often used for stent postdilation and to guarantee proper stent expansion and apposition.[53] However, caution is required because the use of NC balloons for the management of SCCLs can cause coronary perforations and dissections of stent borders when used with postdilation purposes.[53]

Ultra-high-pressure balloon

The ultra-high-pressure balloon is a double-layer system that facilitates the balloon uniform expansion and reduces the risk of fracture and coronary perforation.[54] The OPN device (SIS Medical AG, Switzerland) provides pressures of up to 35-40 atm without tearing the balloon (table 3). These characteristics facilitate the management of stent underexpansion when other options have failed. The main limitation of this type of balloon is its crossing profile due to its greater rigidity and double-layer technology.[7,54]

Cutting balloon and scoring balloon

The WOLVERINE cutting balloon (Boston Scientific, Marlborough, MA, United States) consists of a NC balloon with 3 micro-blades longitudinally arranged on its surface. These blades create incisions inside the calcified lesion during balloon inflation; sequential inflation up to 6 atm is advisable.[55] The main limitations are its crossing profile and the risk of dissection and coronary perforation (table 3). The balloon crossing profile and navigability have improved with the new generation of devices: the AngioSculpt, Scoreflex, and NSE Alpha scoring balloons (table 3). It consists of a low-profile semi-compliant balloon surrounded by 3 nitinol spiral struts for better anchoring to the plaque, fewer chances of balloon gliding, and lower risk of dissection and perforation.[56]

COMBINING THE TECHNIQUES

The combination of RA plus cutting balloon for the management of SCCLs facilitates calcium cracking and better stent expansion and apposition.[57]

The RASER technique consists of combining ELCA plus RA or OA.[58] This combination can be used in lesions that don't allow the

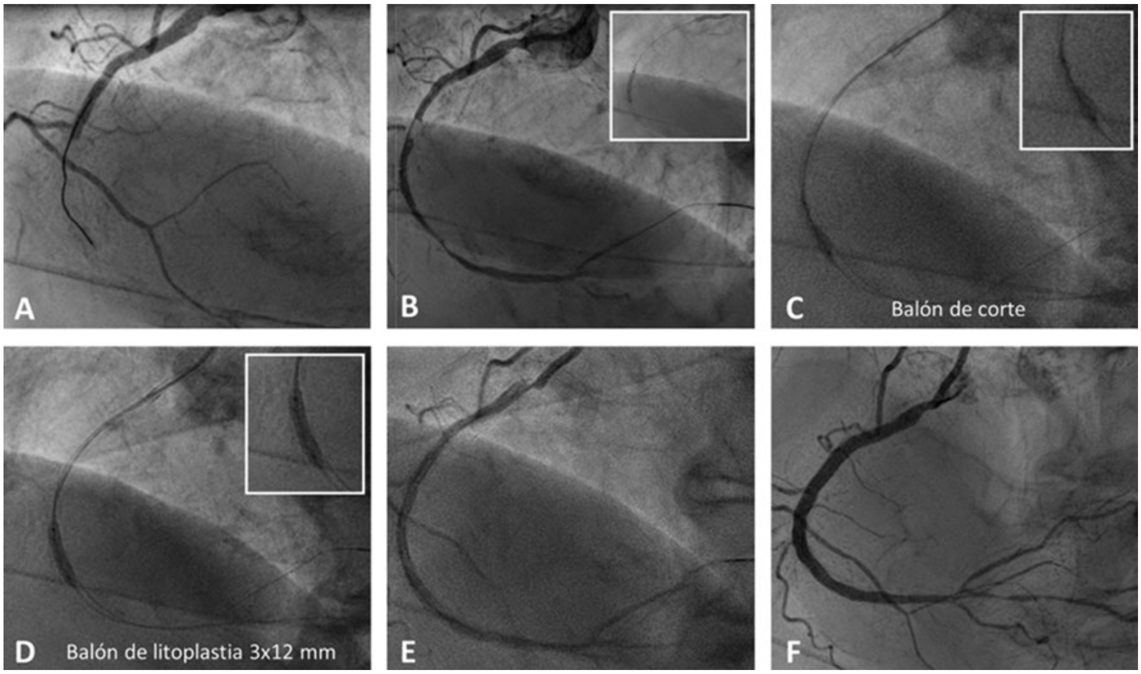

Figure 2. Case of coronary lithoplasty in a patient with inferior ST-segment elevation acute coronary syndrome. **A:** baseline angiography. **B:** result after predilation with a 2 × 15 mm semi-compliant balloon. **C:** failed predilation with a 2.5 × 8 mm non-compliant balloon and a 2.5 × 6 mm cutting balloon. **D:** coronary lithotripsy with a 3 × 12 mm lithoplasty balloon. **E:** angiographic result after coronary lithoplasty. **F:** final result after the implantation of 2 overlapping drug-eluting stents (2.75 × 33 mm and 3 × 38 mm) and postdilation with a 3 × 12 mm non-compliant balloon.

advancement of a microcatheter. The laser can do enough plaque modification to eventually advance the microcatheter and change it for a RotaWire/ViperWire guidewire to perform the RA or OA and achieve the proper stent expansion.[58]

The combination RA plus CL (RotaTripsy technique) has been described recently.[59] It can be useful in very serious and calcified lesions with circumferential distribution of calcium. In this type of lesions where the LB is hard to release on the target lesion, the RA can initially modify the plaque to advance the LB, thus increasing luminal distensibility for a proper stent expansion.[59]

INTRAVASCULAR IMAGING IN CALCIFIED LESIONS

Intravascular imaging modalities (IVUS and OCT) improve the identification of SCCLs and provide thorough assessments of the calcium load, distribution, and eccentricity.[7,42]

Thanks to the ultrasound deeper penetration, IVUS can detect calcified deposits at the deepest layers of the vessel wall. However, due to the acoustic shadowing, only the calcic arch can be seen and no information on its thickness.[60,61] The OCT has greater spatial resolution and higher definition. Calcium is seen as an attenuation region with a well-established luminal border. Compared to the IVUS it is a more precise technique to define calcium load because it provides information on the different degrees of calcic arch and the area, thickness, length, and volume of calcium distribution.[42,61-63]

Intravascular imaging is essential before selecting the plaque-modification device and to assess the stent final outcome. The OCT has greater sensitivity to detect stent underexpansion and malapposition and to assess the outcomes after postdilation.[7,61]

CONCLUSIONS

Coronary calcification is associated with complex lesions and patients with significant comorbidities, which is a predictor of poor prognosis in the short and long-term. More complex patients with more calcified lesions are being treated these days. This means plaque preparation is key in these cases to promote a proper stent expansion and apposition and avoid stent restenosis and thrombosis.

The ideal plaque-modification device is easy to use and implement,safe and effective during the procedure, and with good short and long-term results. With the appearance of CL and the upgrade of Rotablator and the cutting balloon, this field has a bright future ahead. There are many devices available today that can be classified into plaque-modification techniques with and without balloon.

We still lack much evidence from randomized studies and real-world registries to know what the exact role of each of these techniques is, and what benefit can be derived from combining them because they may be complementary, not exclusive. Regardless of the plaque-modification technique used, it is advisable to perform intravascular imaging to guarantee the proper stent expansion and apposition.

CONFLICTS OF INTEREST

None reported.

Table 4. Characteristics and results of the main studies on different plaque-modification techniques

Study and year	Number of patients and treatment groups	Characteristics of the lesion	Study results	
Rotational atherectomy				
ROTAXUS[16] (2014)	240 patients RA + stent vs standard PCI	Lesion with moderate-severe calcification	Luminal loss in the stent at the 9-month follow-up Rate of MACE at the 9-month follow-up	0.44 vs 0.31 mm; *P* = .04 24.2% vs 28.3%; *P* = .46
PREPARE-CALC[17] (2018)	200 patients Cutting/scoring balloon vs RA	Severely calcified lesion	Luminal loss at the 9-month follow-up Target lesion revascularization	0.16 ± 0.39 vs 0.22 ± 0.40 mm; *P* = .21 7% vs 2%; *P* = .17
ROTATE[18] (2016)	1176 patients RA + drug-eluting stent	Severely calcified lesion	Rate of MACE at the 1-year follow-up Rate of MACE at the 2-year follow-up	16% 24.9%
European RA Registry[19] (2019)	963 patients	Severely calcified lesion	Clinical success Rate of MACE at the 1-year follow-up	92% 17%
Orbital atherectomy				
ORBIT I[25] (2013)	50 patients	Calcified lesion	Procedural success Rate of MACE at the 6-month follow-up	94% 8%
ORBIT II[26,27] (2014)	443 patients	Severely calcified lesion	Procedural success Rate of MACE at the 1 and 3-year follow-up	98.6% 16.4% and 23.5%
COAST[28] (2017)	100 patients Micro Crown OA	Severely calcified lesion	Procedural success Rate of MACE at the 1-year follow-up	85% 22.2%
Coronary atherectomy with excimer laser				
AMRO[29] (1996)	308 patients (157/151) Standard PCI/laser	Severely calcified lesion/ stent restenosis	Luminal gain at the 6-month follow-up Rate of MACE at the 6-month follow-up	0.48 vs 0.44 mm; *P* = .34 29.9 vs 33.1%; *P* = .55
LAVA[30] (1997)	215 patients (98/117) Standard PCI/laser	Severely calcified lesion/ stent restenosis	Procedural success at the 1-year follow-up	96.9% vs 96.6%; *P* = .88 No significant differences
ERBAC[40] (1997)	222/232/231 patients Standard PCI vs ELCA vs RA	Lesion with moderate-severe calcification	Procedural success Target lesion revascularization	80% vs 77% vs 89%; *P* = .0019 32% vs 46% vs 42.4%; *P* = .013
Coronary lithoplasty				
DISRUPT CAD I[44] (2019)	60 patients	Severely calcified lesion	Angiographic success Rate of MACE at the 6-month follow-up	100% 8.3%
DISRUPT CAD II[45] (2019)	120 patients	Severely calcified lesion	Angiographic success Rate of MACE at the 30-day follow-up	100% 7.6%

AMRO, Amsterdam-Rotterdam trial; COAST; Coronary Orbital Atherectomy System Study; ELCA, excimer laser coronary atherectomy; ERBAC: Excimer Laser, Rotational Atherectomy, and Balloon Angioplasty Comparison; LAVA, Laser Angioplasty Versus Angioplasty; MACE, major cardiovascular adverse events; OA, orbital atherectomy; PCI, percutaneous coronary intervention; RA, rotational atherectomy; ROTAXUS, Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M19000087.

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