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Review Article

Coronary Artherectomy and Treatment of Calcified Coronaries

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Abstract

Since the introduction of first balloon angioplasty, the field of interventional cardiology has come a long way and witnessed the development of numerous tools and techniques. However, percutaneous coronary intervention (PCI) of heavily calcified coronary artery lesions has always remained as a challenging scenario as appropriate dilation of these lesions is difficult which may lead to inadequate stent deployment and ultimately reduce overall procedural success, increase angiographic complications and subsequent adverse cardiovascular events. Recently, plaque modification using dedicated cutting and scoring balloons and with various atherectomy devices has become progressively more important in the management of severely calcified coronary lesions. It alters the morphology of the lesion and improves the feasibility of PCI in severely calcified coronary lesions with an extremely high success rate and a favorable safety profile. All available atherectomy devices are characterized with diverse design, different mechanism of plaque modification, and indications. In this review, we will discuss various plaque modification strategies, with a particular focus on current atherectomy devices as they are commonly used for severely calcified coronary lesions.

Keywords: Percutaneous coronary intervention; calcification; coronary artery disease; plaque modification, rotational atherectomy; laser atherectomy; orbital atherectomy.

Introduction

The degree of atherosclerosis indicates the extent of coronary artery disease (CAD) and extent of coronary artery calcification (CAC) which ultimately determined the rate at which future cardiac events will occur [1-3]. Despite remarkable advances in the treatment of CAD and improvement in interventional devices and techniques since the first balloon angioplasty by Gruntzig [4] 42 years ago, the subset of heavily calcified coronary artery lesions (HCCL) present an impediment to percutaneous coronary intervention (PCI). HCCL may lead to coronary dissection [5], balloon ruptures [6], coronary perforation or rupture [7], malapposed and under expanded stents [8, 9], higher incidence of major adverse cardiac events (MACE) [10], higher incidence of restenosis and stent thrombosis [11, 12]. The real impact of HCCL is hard to fully appreciate as these patients are often excluded from randomized perspective trials. The various interventional techniques have been introduced and refined taking consideration into calcified lesions and adequate lesion preparation so that stent can be deployed successfully. The moderately calcified lesions can be treated with inflations up to high pressure with non-compliant balloons or also by using cutting and scoring balloons. However, HCCL requires an atherectomy device for plaque modification and optimal lesion preparation. In the following sections, we have discussed an overview of the pathophysiology of CAC and options for plaque modification in PCI when approaching these calcified lesions.

Pathophysiology of Coronary Artery Calcification

The moderate/severe CAC is prevalent in 32% of the PCI patient population of which 5.9% is considered severe [13]. The key risk factors for CAC are smoking, advanced age, hyperlipidemia, hypertension, diabetes and chronic kidney disease. The inflammatory response is escalated due to endothelial injury which activates leukocytes and smooth muscle cells and ultimately leads to the accumulation of calcium in media as well as intima of the coronary artery [14]. The rate of procedure success is very high even in severely calcified vessels and reaches up to 99% [15].

Revascularization Strategies – pci/cabg

Neither all calcified CAD warrants revascularization or all calcified CAD assigned to revascularization is appropriate for PCI however only obstructive lesions benefit from revascularization [16]. The rate of stenosis can lead to underestimation or overestimation of angiographic stenosis if CAC is present. Intravascular ultrasound (IVUS) and optical coherence tomography (OCT) are useful adjuncts in the case of angiographic ambiguity [17]. In addition to the anatomical significance of lesions on angiography, the physiological assessment with fractional flow reserve (FFR) can be performed to observe lesion significance. The presence of HCCL raises the SYNTAX (synergy between PCI with TAXUS and cardiac surgery) score which is an important angiographic tool for grading the lesion complexity and predicting the clinical outcomes after PCI or coronary artery bypass surgery (CABG) and in patients with multi-vessel and/or left main disease with a SYNTAX score of >22 are advised to undergo CABG, if this is an option [19, 20] [18].

Imaging Techniques

Coronary angiography (CAG) detects calcium with very low sensitivity and thus intracoronary imaging with IVUS and OCT should be used for effective detection of calcification. IVUS is considered gold standard for examination the calcification with 90% sensitivity and 100% specificity. Using IVUS, CAC can be classified into 4 classes which include Class-1: 0–99-degree, Class-2: 91-180-degree, Class-3: 180-270 degree, and Class-4, >270 degree calcified [21]. Furthermore, OCT identifies CAC as a signal-poor region with sharply delineated borders and also measures of calcium thickness, area, and volume [22].

Modification of Calcific Lesions

Many future events associated with PCI can be avoided if we modify the plaque before delivery of stent to achieve full expansion and apposition. A variety of plaque modification strategies have been developed to accomplish these goa**ls (Table 1).**

Balloon Angioplasty

The eccentric plaque in CAC may cause a higher rate of dissection or rupture when plain old balloon angioplasty (POBA) is used. A non-compliant balloon may be the first step to enhance the uniform expansion of the balloon [23]. However, even with this approach, the risk of eccentric balloon expansion is not fully mitigated due to the increased hoop stress contributed by severe calcification. The dense calcium which is present focally in the lesion causes non-uniform balloon expansion which results in “dog-boning”. The lesion may become resistant to high pressure dilatation when the arc of calcium extends to a large segment of the circumference of the vessel. To address these clinical needs, modified balloon catheters have been developed. Diaz et al [23] used non-compliant balloons up to high pressure of 40 atm in patients with calcified and non-dilatable lesions. This was a novel way of managing calcified lesions achieving a 75% success rate and there was no adverse effect. The OPN non-compliant super high-pressure balloon (SIS-Medical AG, Winterthur, Switzerland) utilizes a twin-layer balloon technology, which permits the use of very high-pressure inflations and ensures uniform expansion over a wide range of pressures, eliminating “dog-boning.” The balloon has a low-profile and is highly deliverable and non-compliant with a nominal pressure of 10 atm and rated burst pressure of 35 atm. The calcified lesion should be initially inflated with a small size balloon at 8 atm followed by a slow increment of pressure [23]. The OPN NC high pressure (SIS-Medical AG, Winterthur, Switzerland) can be used for this purpose as each balloon is tested to 40 atmospheres. These eliminate “dog-boning” and lead to uniform expansion. The mean minimal lumen diameter (MLD) and lumen gain are more with OPN NC balloons than plain NC balloons [24].

Atherectomy Devices

Other devices like cutting and scoring balloons cause small incisions in the plaque leading to more expansion of lesions and eliminates dissection which are uncontrolled [25]. They should be recommended in short and discrete lesions with mild to moderate CAC (Figure 1) [26]. However, for class 3-4 lesions according to IVUS, an option of cutting and scoring balloon procedure is not recommended.

Cutting balloon

Cutting balloon [(Flextome™) Cutting Balloon, Boston Scientific, Natick, MA, USA] was the first atherectomy device used in calcified lesions. It is delivered over-the-wire (OTW) and with a rapid exchange approach and it consists of a non-compliant balloon surrounded by 3-4 longitudinal blades (Figure 2). During dilatation, the device creates 3 or 4 endovascular radial incisions through calcific tissue allowing further expansion with conventional balloons. The balloons slippage is prevented due to the anchoring of blades into the intima of the vessels. Its rigidity and high profile can cause difficulty to cross the lesions. The cutting balloons should not be inflated more than 12 atm. This avoids the cutting blade’s penetration to the vessel wall [7, 27, 28]. The cutting balloons rupture at 16 atm and the ruptured balloon can cause difficulty in going back to the guiding catheter [29].

Scoring balloon

Together with the higher rate of perforation and difficulties associated with cutting balloon delivery (due to its high crossing profile: 0.041”–0.046”) lead to the development of alternative balloon-based atherectomy devices, such as scoring balloons.

FX miniRAIL balloon

The FX miniRAIL™ (Abbott Vascular, CA, USA) can score the plaque and it contains a platform of external stainless-steel wires [31].

Angio Sculpt

It is a semi-compliant nylon balloon that is enveloped by a helical scoring edge made of nitinol and has a dual lumen catheter (Figure 4). It has a fixed distal end and a semi-restricted proximal end and have three rectangular spiral struts. This specific design results in uniform expansion of the balloon and the nitinol cage prevent slippage while it scores the plaque it results in increasing the lumen expansion. The AngioSculpt is more flexible, and deliverable compared to cutting balloon.

However, it maintains the merits of cutting balloons such as decrease in balloon slippage, uniform expansion, no elastic recoil and the optimal lumen. No randomized controlled comparison exists between cutting and scoring balloons. The AngioSculpt enhanced stent expansion, compared with direct stenting and POBA with semi-compliant balloons in an observational study comprised of 299 patients who underwent IVUS-guided DES implantation [32]. In another study [33] which included 184 lesions treated with POBA vs. AngioSculpt before bioresorbable scaffold (BRS) implantation, the scoring balloon group demonstrated better procedural outcomes with IVUS about both BRS expansion and eccentricity. The one-year target lesion revascularization was similar between groups.

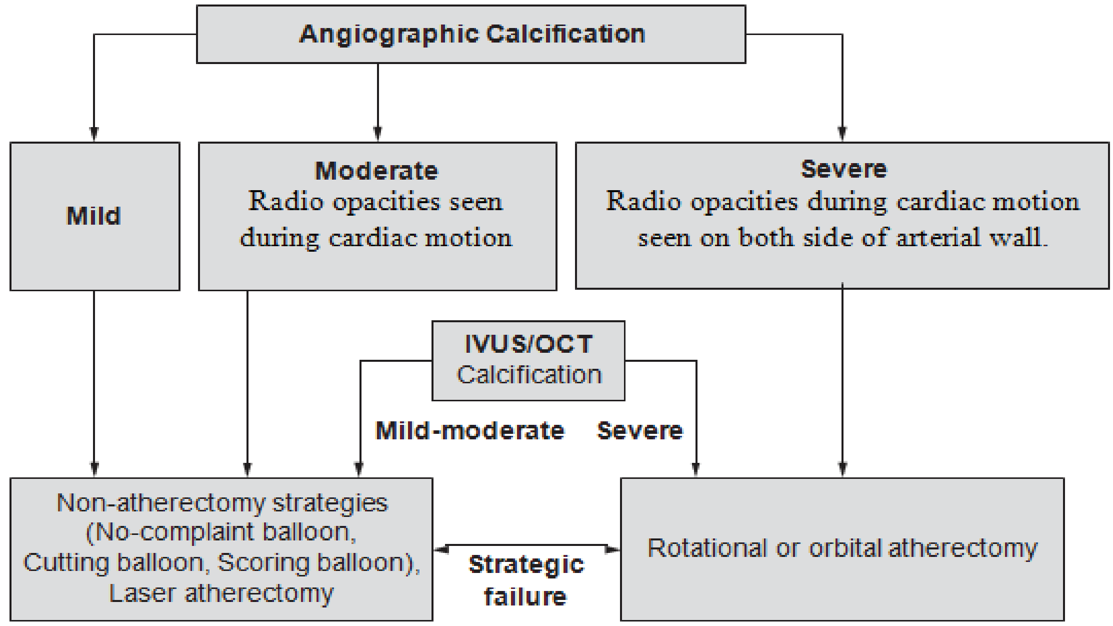

Figure 1: Case 1 - A) and B) Coronary Angiograms pre-and post-PCI; and C) and D) Intravascular ultrasound images pre- and post-PCI.

Chocolate balloon

The Chocolate balloon (TriReme Medical, Pleasanton, CA, USA) is OTW balloon catheter. It has a nitinol constraining structure which causes controlled inflation and rapid deflation. It results in dilatation which is atraumatic and does not require cutting as well as scoring. The nitinol constraining structure generates pillows that function to minimize local forces. (Figure 5). The grooves promote modification of the plaque these leads to less trauma to the vessels and less dissection [34].

Atherectomy

A strategy of debulking calcified lesions as a part of the bail-out technique to address balloon undeletable stenosis has evolved into a lesion preparation approach by plaque modification. Primary atherectomy leads to decrease the fluoroscopy time and contrast volume as compared to bail-out atherectomy [35]. The lesion preparation with atherectomy alters plaque morphology, inducing fractures in HCCL and changing lesion compliance, to increase the likelihood of maximal MLD and complete stent expansion. Atherectomy is currently archived with either rotational, orbital or laser atherectomy (Figure 6).

Directional atherectomy

Directional coronary atherectomy (DCA) has a small balloon with a cutter that rotates which has been pushed forward distally and pulled back proximally. While ablating the lesion it also aspirates the debris, hence, it can debulk lesions which have varied form of morphologies (Figure 6A). It is sometimes difficult to insert a DCA catheter into HCCL. Though ablation of HCCL may be difficult with DCA but possible if the housing can fit into the lesion.

Rotational Atherectomy

The Rotational atherectomy (RA) acts on the principle of "differential cutting" and "orthogonal displacement of friction" (Figure 6D and 6E). The commercially available Rot ablator (Boston Scientific, Natick, MA, USA) ablates plaque using high-speed (140,000–180,000 rpm) with elliptically shaped burr encrusted with 2000–3000 diamond microchips [35]. These microchips coated on the burr grind calcified plaque into microscopic particles (5–10 μm in diameter) smaller than red blood cells which are washed downstream across the coronary capillary bed and are removed from the circulation by the reticuloendothelial system. Selective ablation of fibrous and calcified plaque renders a polished smooth luminal surface compared to multiple intimal tears/dissection with balloon angioplasty, modifies plaque, reduce elastic recoil and barotrauma and thus helps in optimal stent delivery and adequate stent expansion [9].

Contemporary RA technique

Unlike conventional 0.014" guidewire, the Rot ablator wires are difficult to torque and navigate into tortuous vessels and across complex lesions, and the wire clip torque is trickier to use supplied. It is advisable to use a conventional guidewire and then exchange via a micro-catheter or "OTW balloon", to the Rot ablator guidewire. The hydrophilic guidewire helps in wire manipulation and delivery of the device, especially if HCCL is associated with angulation or tortuosity. If the device is still not delivered or the lesion fails to cross, useful adjunctive techniques such as deep intubation of guide, buddy wire or child-in-mother catheter should be used. The micro-catheters facilitate wire manipulation, lesion crossing and subsequent exchange for wires required for RA. It is prudent to go for primary wiring with 0.09" Rota Wire (Boston Scientific, Natick, MA), if the micro-catheter does not cross the lesion.

The guiding catheter should provide good back support and it should co-axial. The RA apparatus has a distal burr and helical drive shaft. The shaft is connected to the advancer which allows proximal and distal movement of the burr. It also has a console that controls the rotation of the burr. Administration of the flush solution which is made by normal saline IV heparin and vasodilators such as nitroglycerin and/or verapamil and nicorandil (Rota flush) along with glycoprotein IIb/IIIa inhibitors reduce the incidence of slow flow or no-reflow during the procedure [36].

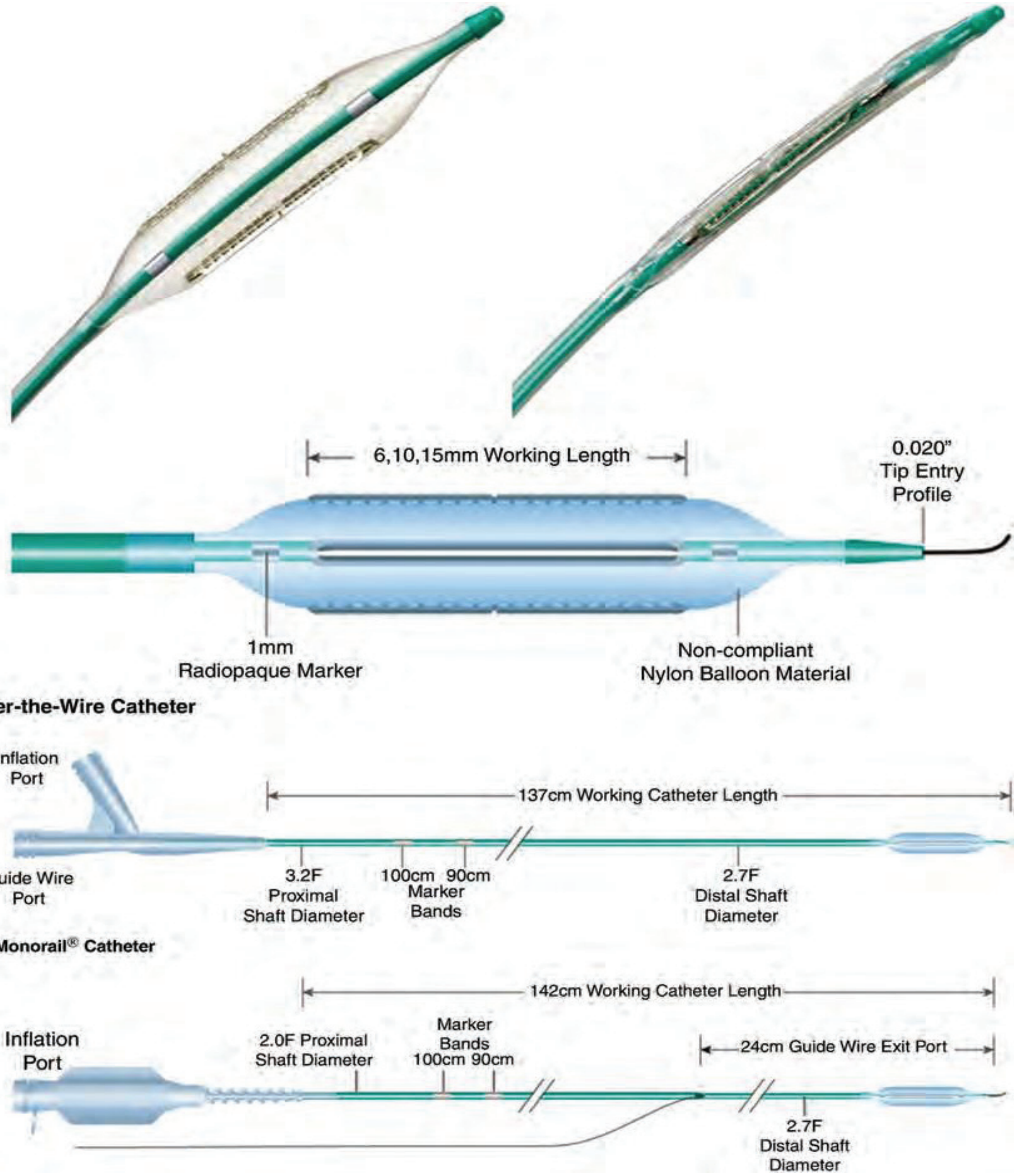

Figure 2: Flextome cutting balloon. Adapted from Stouffer et al. [30]..

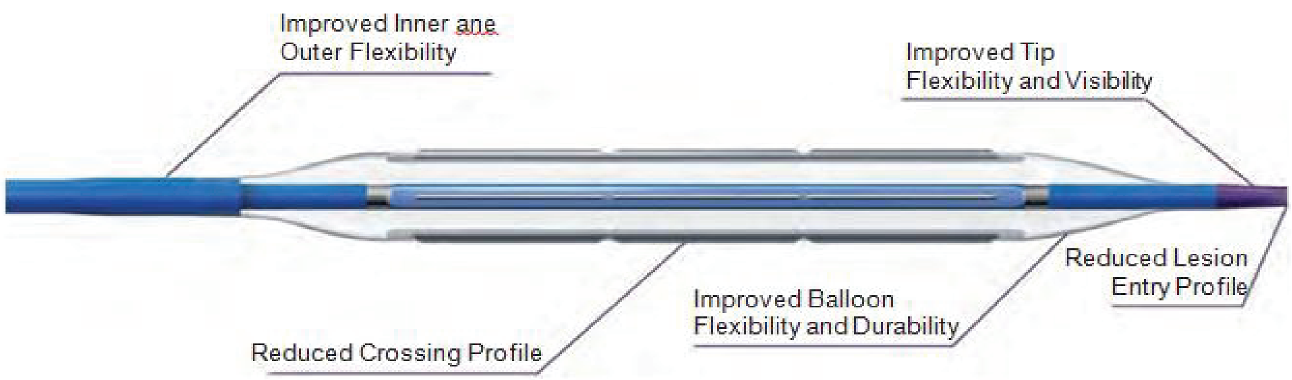

Figure 3: Wolverine cutting balloon device. Courtesy of Boston Scientific, Natick, MA, USA; Adapted from an online resource [73]. Image provided courtesy of Boston Scientific. 2020 Boston Scientific Corporation or its affiliates.

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Figure 4: AngioSculpt-X scoring balloon catheter. Adapted from an online resource [74].

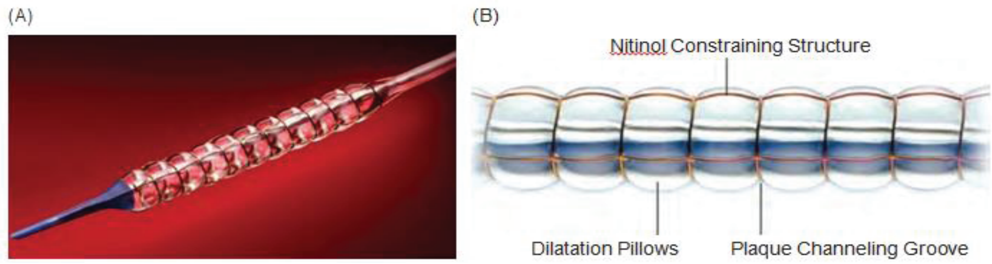

Figure 5: (A): Chocolate balloon catheter device. (B) "Pillows" and "grooves" of the chocolate balloon catheter. Adapted from an online resource [75, 76].

The proximal speed of atherectomy can be 140,000 rpm. Some interventionists use 160,000–180,000 rpm for small burrs (1.25–2.0 mm) and 140,000–160,000 rpm for large burrs (≥2.15 mm). Advancer knob is locked 2-3 cm forward before advancing the burr into a guide catheter. When the burr is proximal to the lesion, any forward tension on the drive shaft is relieved by unlocking the advancer knob and pulling it back. The rot ablation is commenced by loosening the advancer knob, depressing the foot pedal and gently moving the burr forward into the lesion. One must ensure that the initial burr speed is like that set outside the patient. The rotational speed significantly below that level would indicate the friction within the guide and will reduce burr performance. The interventionists must avoid over-tightening Y-adapter, tottering, stopping burr in and distal to the lesion, adjusting rpm during ablation, advancing rotating burr to point of contact with the guidewire spring tip and avoid burring in the guide catheter. The intermittent ablation within the lesion is preferred called the "pecking" technique where the burr moves in forward and backward direction within the lesion. There is no need to push the rot ablator in the lesion where the burr is moved forward and backwards the lesion, without pushing the rot ablation into the lesion (Figure 2). It is recommended to go for shorter ablation runs of 5–20 seconds, being careful enough not to advance the burr too fast or too forcibly [26]. Burr should be upsized, if necessary, in 0.25 cm increments. If we start with a smaller burr, it can reduce plaque debridement to the distal bed and patency of lumen is achieved more often in a very short time. Starting with a smaller burr reduces the plaque burden to the distal bed and a patent lumen is achieved in a shorter period. Many operators would choose two burrs in order to reduce the incidence of a no-reflow phenomenon. A smaller burr (1.25mm) is used first followed by a larger burr.

The burr size can be used aiming at burr to artery ratio less than (0.6-0.7). Using bigger burr results in more debulking but there is a higher risk of stuck burr, and it may damage more blood cells [37]. Burr run time should be kept short (≤30 seconds/run) [37], with immediate cessation if the revolutions drop by more than 50,000 rpm to limit the liberation of particulates and avoid hypotension and bradycardia. Special consideration should be given to rot ablation to a long area proximal to the subtotal occlusion. In this case, sudden liberation of ablated particulate material into the distal bed is prevented by pre-dilatation with a tiny balloon. After each ablation, the burr is brought back to the starting position and the patient's clinical status and electrocardiogram are checked. Once the burr has completely crossed the lesion, it can be advanced for longer times and over longer distances for final lesion 'polishing' (Table 2). After rot ablation, the burr is withdrawn using the Dyna Glide function which rotates the burr at a lower speed (60,000–90,000 rpm) reducing resistance within the guide/vessel. Moreover, RA is terminated in case of angina, coronary artery dissection, no-flow or abrupt vessel occlusion. Although thrombus or dissection in vessels and last remaining vessels is a contraindication to used RA.

The benefits of RA are attenuated if CAC is mild. Angiographically CAC is graded severe when radio-opacities involve both side arterial walls [figure 26.1] [9]. HCCL defined as superficial in nature with greater than 180° arc is seen in approximately 26% of cases in IVUS [38].

Prevention and potential remedies of complications due to RA-Contraindications

Over-Heating

The sufficient cooling must be ensured before the burr is activated. The amount of heat generated by plaque debridement depends on the technique used [39]. The risk of peri-procedural myocardial infarction and restenosis may increase as a result of thermal injury. It can be prevented by the initial use of a small burr in a pecking-like motion.

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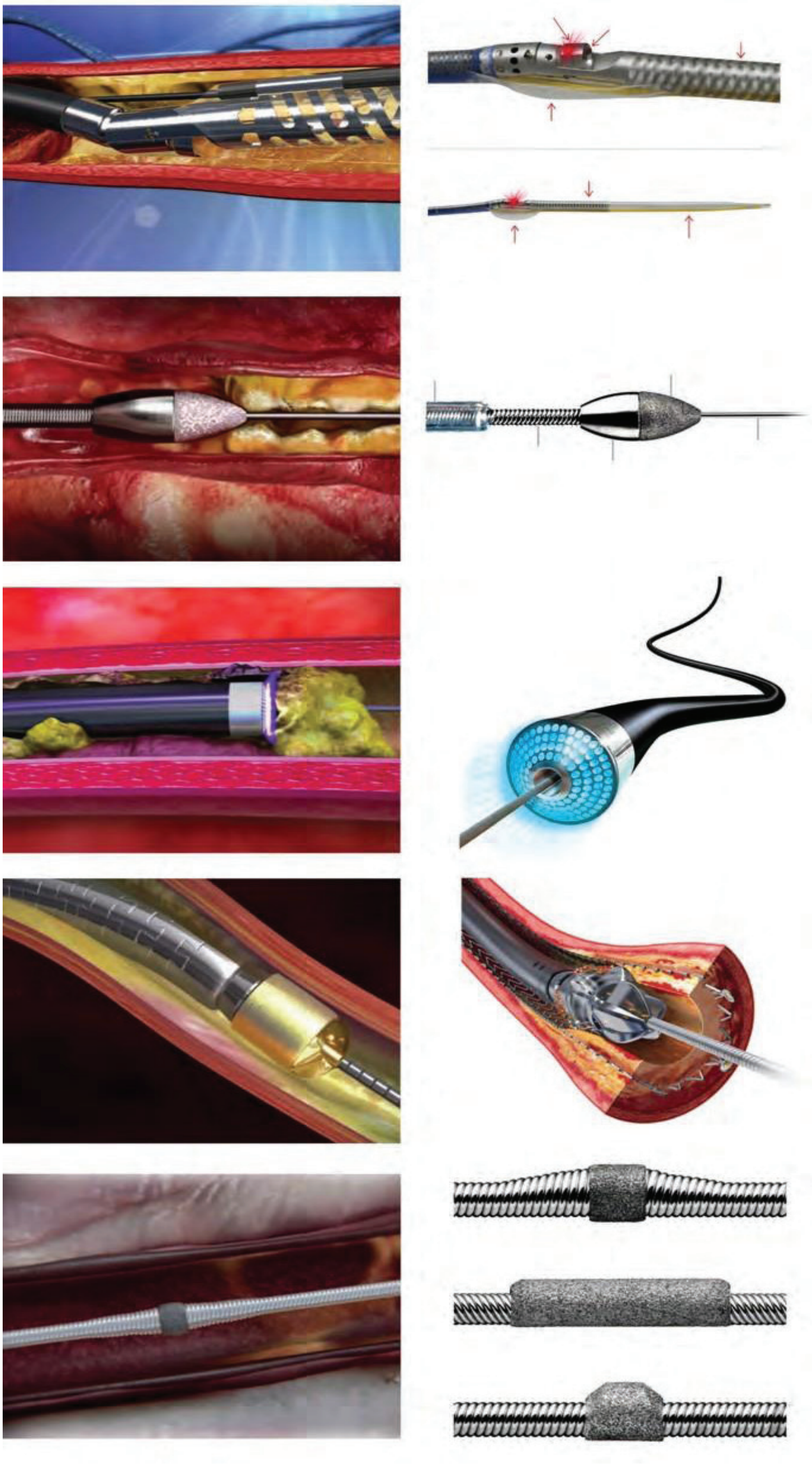

Figure 6: Atherectomy devices. (A) Directional atherectomy using the Pantheris catheter. Adapted from Fornell, https://www.dicardiology.com/ article/update-atherectomy-system-technology and Schwindt et al. [36]. (B) Rotational atherectomy. Adapted from an online resource [77]; Image pro-vided courtesy of Boston Scientific. © 2020 Boston Scientific Corporation or its affiliates. All rights reserved. (C) Excimer laser atherectomy. Adapted from [78,79]. (D) Transluminal extraction approach—Phoenix atherectomy system [left]. Adapted from an online resource [80]. (E) Jetstream atherectomy system [right]. Adapted from an online resource [81]; Image provided courtesy of Boston Scientific. © 2020 Boston Scientific Corporation or its affiliates. All rights reserved. (F) Coronary Orbital Diamondback 360 atherectomy system. (©2020 Cardiovascular Systems, Inc. CSI and Diamondback 360 are registered trademarks of Cardiovascular Systems, Inc.).

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No-Reflow

No-reflow is caused by excessive lesion debridement, microvascular embolization of atherosclerotic debris and associated thrombi which occurs in 7–8% of cases [40]. It can be prevented or reduced by maintaining an adequate blood pressure prior to burr advancement, optimal antiplatelet therapy including use of glycoprotein IIb/IIIa inhibitors, frequent use of vasodilators (i.e. adenosine, calcium antagonists, nitroglycerine, and nicorandil), and scrupulous technique (small burr sizing, intermittent ablation, avoidance of significant decelerations) [Table 3].

Burr Stalling

Burr stalling is defined as significant resistance to burr rotation. It may be due to kinking of the air hose, over-tightening of the "Y" connector, B: A ratio 1.0 or more, aggressive advancement in tight lesions, spasm in the platform zone and operation without saline infusion. Excessive reduction in burr speed of >5000 rpm is best managed by pulling the burr back from the lesion and advancing it more slowly or less forcefully in a pecking like motion. Sometimes, a higher burr speed or a smaller burr may be useful if all earlier measures fail.

Burr Entrapment

The burr has a diamond coating at its distal surface for antegrade ablation, but the proximal portion is smooth that prohibits retrograde ablation. If an excessive force is applied to advancing burr beyond a tight calcified lesion or embedded in a long, angulated HCCL, it can get stuck in the lesion or across the lesion but be unable to withdrawn. It can occur due to slippage of a burr across the lesion without the burring (coefficient of friction is less at the high speed than at the rest), ledge of the calcium behind the elliptical burr causing "Kokesi" effect. It may get entrapped in the tortuous segment of the lesion and occurs in around 0.5% cases [41]. It can be avoided using a smaller burr and a technique of gradual intermittent burr advancement. The burr should never be allowed to stop spinning within a lesion. The spinning of the burr should never be stopped within the lesion. One should keep visual assessment that is the advancement of burr smooth under fluoroscopy or should keep watch on pitch changes brought by the resistance of bulk or should feel the tactile sensation of the advancer knob or more vibration of the drive shaft.

The simplest method to retrieve the entrapped burr is manual retraction with on-Dyna glide or off-Dyna glide rotation. Disengaging the guide from the coronary ostium and navigating another guidewire deep into the aorta may avoid the deep seating of the guide and prevent ostial injury. Recrossing another guidewire beyond the entrapped burr followed by balloon dilatation of calcified lesion proximal to it may create a crack between the burr and vessel wall to retrieve it [39, 41]. In some cases, introducing another guidewire via another vascular access may be needed for the second guidewire and balloon [42, 43]. Alternatively, the guide may be exchanged for an 8 F one after cutting off the burr and sheath near the advancer [42]. The Rot ablator sheath can be removed to facilitate the insertion of additional guidewires and balloons after cutting off the shaft

Table 2: Tips and tricks for optimal coronary rotational atherectomy.

Guiding catheter with adequate backup and coaxial fitting.
Use of a temporary pacing wire in dominant RCA and/or LCX vessels.
Use of floppy Rota Wire unless burr won't engage and generally don't direct wire.
Preference for single smaller burr (usually 1.25 mm) with a burr-to-artery ratio of 0.5–0.6. Rotational speed of 140,000–150,000 rpm.
Gradual to-and-fro "pecking motion" of the burr. Shorter ablation runs of 15–20 seconds.
Lesion contact time of 1–3 seconds with longer 3–5 seconds of reperfusion to allow debris clearance. Strict avoidance of decelerations (>5000 rpm for >5 seconds).
Flushing of the system with diluted contrast during the ablation runs.
Maintenance of systolic blood pressure >100 mm Hg during the procedure. Keeping the guidewire always wet to avoid friction.
Continuous movement to keep the device from becoming warm especially in angled/tortuous vessels.
Spot rotablation of the segment proximal to long HCCL for easy stent passage.
Use of glycoprotein IIb/IIIa inhibitors in case if extensive ablation with bigger burrs.
Use of undersized burr with a tip of the guidewire just beyond the lesion in order to reduce sidewall tension in the tortuous vessel.
Source: Adopted from Diaz et al. [23].

Table 3: Prevention and remedies of complications attributed to rotational atherectomy.

Complications	Prevention and remedies
Bradycardia and AV block	• Limiting ablation times (<15–20 seconds) • Pretreatment with atropine • Deactivation of burr if heart rate decreases • Temporary pacemaker for RCA and LCX lesions
Slow flow/no-reflow	• Use of small burr • Intermittent ablation • Avoidance of significant decelerations • Limiting the ablation time to 15-30 seconds • Increasing the time between the ablations • Slower speed (140,000 rpm) associated with lower platelet aggregation • Prior use of GPIIb/IIIa
Over-heating	• Use of small burr in a pecking-like motion
Burr stalling	• Retraction of the burr from the lesion and moving it forward more slowly and less forcefully • Avoidance of kinking of the guide catheter • A higher burr speed and smaller burr size
Burr entrapment	• Manual pull back • Setting rotational speed up to 200,000 rpm and trying to negotiate the burr into the distal true lumen • Cutting off rotalink shaft distal to the advancer and removal of the outer sheath • Passing a 2nd guidewire (dual catheter technique) beyond entrapped burr inflation of balloon proximal to it. • Advancement of snare over the exposed drive shaft as close to the burr as possible and simultaneous retraction on the snare and guide • Negotiation of a child-in-mother catheter • Emergent surgery
Guidewire fracture	• Keeping the guidewire out of small branches • Repositioning the guidewire frequently during long ablations • Fastening the wire clip properly • Avoidance of guidewire tip prolapse • Retrieval with snares, baskets or forceps
Rota Wire entrapment	• Advancement of over-the-wire balloon or micro catheter on the Rotablator wire and tunneling outside the expanded stent to facilitate traction and wire removal

Source: Adapted from book 82.

near the advancer [44]. Extra guide support for increased traction can be gained by inserting a child-in-mother catheter over the exposed Rot ablator drive shaft, once the burr sheath has been removed [44]. A snare may be used to encircle the burr to provide extra traction [45]. Emergent bypass surgery is the last resort.

Guidewire Fracture

The thin 0.009" guidewire and its 0.14" radio-opaque tip can be damaged by the rotating burr. The guidewire fracture may be the result of excessive rotation of the burr in angulated and tortuous arteries, long ablation time. Angiographically, it is difficult to appreciate guidewire transactions as only the 15 mm tip of the Rot ablator wire is radio opaque. Guidewire fracture should be suspected when the advanced burr deviates off-line. IVUS or OCT are often required to confirm the fractured guidewire and locate the proximal end. This problem can be minimized by keeping the guidewire out of small branches, repositioning the guidewire frequently during long ablation, fastening the wire clip properly, avoiding prolapsing the guide- wire tip. A snare device should be attempted to remove the distal wire fragment, even if it is difficult. If it is unsuccessful, use of prolonged anticoagulant therapy should be considered to reduce wire-induced vessel thrombosis.

Contemporary Evidence

The restenosis was not reduced in various trails like DART (48) STARTAS (48) CARAT (49). The initial enthusiasm was followed by a marked decrease in the rate of RA. The conundrum of the post PCI restenosis has been largely eliminated by the advent of DES. HCCL remains the bugaboo of intervention. DES has a 6% failure rate to deliver and a twofold higher failure rate of successful deployment in calcified lesions compared to BMS [9]. Vigorous manipulations of DES in these lesions can crack the polymer leading to an increase in the vascular inflammatory response [50, 51]. Suboptimal deployment of DES could increase the risk of stent thrombosis [52]. DES implantation after RA has been reported to achieve a better prognosis [53].

The renaissance of RA in the DES era, particularly in very complex HCCL under-scores the importance of the plaque modifications before DES could be successfully delivered, precisely placed and deployed to exert the desirable effects. In fact, contemporary observational studies and registries [12, 54, 55] have demonstrated favorable results of DES deployment in HCCL after RA. The ROTAXUS trial was a clinical randomized trial that does not demonstrate the superiority of RA over conventional balloon dilatation [56]. The patients with HCCL cannot be treated without RA, and therefore cannot be randomized, as shown by the 8% higher crossover rate from POBA to RA observed in this trial [56]. The latest guidelines reflected the available data, granting a Class II a (level of evidence C) to RA, recommended for preparation for HCCL that remains balloon uncrossable or undeletable before planned stenting [57].

Orbital Atherectomy

Technology: The orbital atherectomy (OA, Diamondback 360, Cardiovascular System, Inc, St Paul, MN, USA) was approved (Figure 6) for use in the coronary arteries in 2013 [58]. It rotates at 80,000 rpm on low speed and 120,000 rpm on high speed and it has a diamond-coated eccentric crown that rotates over viper wire. It reduces the plaque but minimizes damage to the medium layer because of its differential sanding mechanism. The OA requires the continuous infusion of lubricant solution, and it disables itself by its own, if insufficient flush (Table 4). Its crown has diamond chips on both front and back and can ablate both anterogradely and retrogradely. The duration of treatment is <20 seconds/pass. The speed of the orbit and the burr advancement can be controlled due to unique mechanisms. The OA accomplishes this by enlarging the orbit of the crown at a faster speed. A crown is 1.25 mm which can be easily passed through 6F guide catheters can be effective for the vessel of 3.5 mm in size. The OA crown is advanced in gradual and continuous motion, and it can be entrapped in the region of interest which allows more time for ablation. The complication can be slow flow phenomena, perforation and dissection. In OA, there is less risk of heart block and no-reflow because there is a continuous flow and particulate size is small. As OA crown entrapment is rare, there is the bidirectional movement of the crown which is orbiting is smaller (Figure 6F).

Indication: Also, there is a fast flow of infusion which increases the flush of particulate from the microvasculature and secondary because it can ablate retrogradely as well [60]. In orbit-I trail, OA the success rate is 97% and procedure success was 93% in 50% of patient with calcified plaque [58, 61]. In orbit-II trail, OA is associated with a 97.7% rate of success and a low rate of MI 0.8% cardiac motility 0.2% and target vessels revascularization. Three-year follow-up showed 7.6% TLR in a patient treated with OA [62].

Contraindication: The comparison study by Kini et al., in a series of 20 patients, assesses the mechanistic differences of impact of RA and OA with OCT. The OA was associated with deeper dissections particularly in more lipidic and less calcific plaques. The OA treated patients had signaled toward increased stent expansion and significantly lower incidence of stent strut malposition as compared to RA [63]. Koifman et al. demonstrated similar safety and efficacy profiles of RA and OA in treating patients with calcified coronary lesions [64]. In view of the simplicity of usage and lesser complications (Table 4), OA might gain widespread use in future. However, it is unlikely to replace to RA as of today, because of the absence of studies directly comparing the safety and efficacy of the two modalities.

Excimer laser coronary angioplasty

Technology: Arthetomy vaporizes the plaque without causing damage to the surrounding tissue and uses energy and a monochromatic light beam to do these (Figure 6C). The light beam is delivered through fiber-optic catheters; but these techniques lost their favor because of a higher rate of complication however with its contemporary use the injury due to thermal current is not observed now. The ELCA use is safe due to shallow tissue penetration (49 μm) as the wavelength is shorter and it is used in conjunction of saline boluses [CVX-300^R (Spectranetics, Colorado Springs, CO, USA)]. It has the advantage that it can be delivered on standard 0.014'' guide wire [65]. It specially uses full if the lesion is not crossable or not dilatable as it modifies a plaque even if catheters do not cross. It can also be used in-stent restenosis in the calcified lesion. In some calcified lesions that cannot be fully debulked with ELCA alone, a 'pilot' hole' created by ELCA to permit a Rota wire for subsequent RA for procedural success. This combination of RA and ELCA is termed as 'RASER' [66].

Indication: There are different mechanisms by which ELCA ablates the plaque such as photochemical, photothermal and photomechanical. There is a dissipation of energy in between the pulses which dissolve the molecular bonds with very short pulse duration (130 nsec). These heat the intracellular water to vapors that leads to disruption of cells. This steam dissolves the tissue and clears the by-products away from the catheter

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tip which is termed a photomechanical process. The fragments released are <5 µm and are absorbed by reticulo- endothelial system avoiding microvascular obstruction [67].

ELCA catheters can be advanced over short monorail segments which is advantageous over alternative coronary atherectomy techniques where a specific guidewire is required. While using ELCA the guiding catheter should be co-axial, and it should provide decent backup support. The severity of the lesion and reference vessel diameter determined the size of the catheter. The 0.99 mm catheters can emit laser energy at a high power so it can be used in calcified lesions that is otherwise not crossable/ dilatable.

The photothermal process is potentiated by both blood and iodinated contrast media. So, the risk of thermal injury and dissection are increased. To decrease the risk of dissection and to control energy a saline infusion can be used. To clear the contrast from the system one-liter bag of normal saline solution is connected by a 3-way tap. Then 5 ml saline solution should be infused followed by 2 ml per second. The guide catheter should fully back up and should be co-axial, so the saline distribution does not happen. The activation automatically ceases after 5 sec with the 10 sec rest and the alarm sound indicates when to start the next cycle. The bigger catheters (0.9 mm × 80 mm) permit 10 seconds of activation 5 seconds' rest. The adequate absorption and ablation occur when the catheters can move slowly (0.5 mm/sec). The ablation will not be optimal if there is the fast advancement of catheters as tissue does not take time to absorb energy [68].

Contraindication: ELCA should not be used if the position of the guidewire is sub-intimal. In a retrospective, single-center study of ELCA followed by DES in severely calcified coronary lesions, procedural complications included no-reflow (8.0%) and perforation (4.0%). The angiographic success rate was 84% [69].

Other newer atherectomy devices

The Phonex (Philips, CA, USA) atherectomy system reduces the risk of distal emboli as it clears the debris during debulking with OTW design. With Rotarex S (Straub Medical AG, Switzerland) the occlusive material from the vessels can be removed. And lastly, it can be transported out of the patient's body. The Pantheris (Avinger) image-guided system avoids the disruption of normal arterial structure because it combines atherectomy with intravascular visualization and allows the plaque removal. All these devices have been used safely and effectively in the peripheral vasculature. However, their role in coronary vasculature needs to be proven.

Intravascular lithotripsy

Technology: Intravascular lithotripsy [IVL, (Shockwave Medical, Fremont, CA, USA)] is a normal device (Figure 7) [70] that delivers localized pulsatile sonic pressure waves and modify preferentially calcific plaque. It does not affect the tissue but modifies the plaque hence optimal stent delivery and expansion achieved. It generates high-speed sonic pressure waves by generating electrohydraulic wave it passes through soft tissue and breaks the calcium. In this technique, balloon at low pressure (4 atm) is inflated and 8 pulses of ultrasound energy of 10 sec each are delivered through the balloon. Then the balloon inflated up to 6 atm up to 15-20 sec.

Indication: It increases the balloon expansion and helps in the clearing of debris. The cycle is repeated and again, and it inflates till expansion had occurred at an optimal level. Maximum 8 cycles are repeated with the same catheter [71]. The Disrupt Coronary Artery Disease (Disrupt-CAD) study is a multi-centric prospective trial of 60 patients in which HCCL was treated with short wave IVL. This study shows that it is a safe procedure and can be performed without any complexity. This treatment is found to be effective in increasing the delivery of the stent and it also reduced restenosis. In this study, 100% of the patients have crossed the stents and the residual stenosis <50.

Contraindication: The major complication of the procedure was nil and success were seen in 95% of the patients. There was no cardiac mortality, MI, TVR for 30 days follow-up [72]. Recently (Disrupt-CAD) 2 and 3 show encouraging results for use of IVL.

Emerging concepts and innovations

In future, improvements in balloon catheter flexibility and crossing profile, as well the addition of hydrophilic coatings, will improve the negotiability (hence the utilization) of cutting and scoring balloons. The application of an ant proliferative drug-release system on these balloons would combine the benefit of balloon-based atherectomy and anti-proliferative properties of drug-eluting balloons. Further, refinements of the scoring/cutting balloon concepts have already taken place. The chocolate balloon causes atraumatic dilatation with minimal risk of dissection because of controlled inflation and rapid deflation. It is because it has mounted nitinol constraining structures ("pillows" and "grooves").

However, larger prospective studies are required to evaluate its efficacy and safety. The Lithiplasty system (Shockwave Medical, Fremont, CA, USA) is another novel innovation that uses acoustic pulse waves which preferentially impact hard tissue and disrupt calcium like lithotripsy for kidney stones. The atherectomy devices would further go for modifications mainly directed to simplifying their use. The new generation of the rot

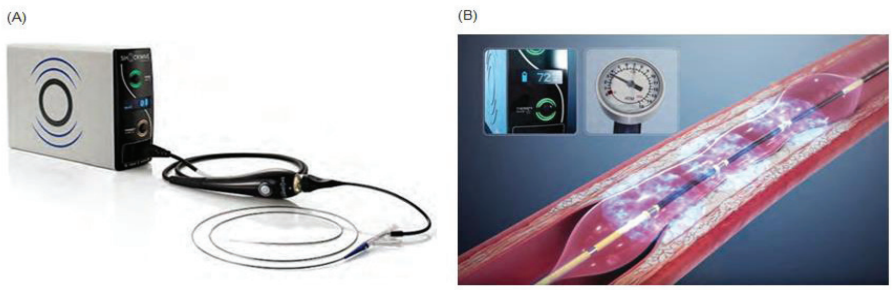

Figure 7: Lithoplasty system. (A) The Shockwave Medical system. Adapted from Sgueglia et al. [70], (B) Intravascular effects of the Shockwave system. Adapted from Shockwave Medical Company.

ablator system is being launched. The console is smaller, requiring less set-up time. The foot pedal is eliminated and replaced by a button positioned on the top of the burr control knob of the advancer. Another button is foreseen on the side of the advancer to replace the small knob of the pedal used to switch to Dynaglide mode. The integration of imaging modalities into the atherectomy devices identifies the location of healthy tissue. It allows determining the extent of the lesion hence allows precise ability to treat.

Conclusion

The landscape of PCI has dramatically changed during the past three decades. The HCCL patient is still difficult to treat despite of advancements the interventional devices and techniques. The PCI of HCCL results in under expansion and malposition of the stent which may result in more procedural complications. Technical challenges associated with the treatment of these lesions can result in worse long-term outcomes. The use of cutting and scoring balloons and other devices has resulted in better outcomes of the procedure. The current level of evidence for cutting, scoring and chocolate balloons consists only of small and mostly non-comparative studies making any consideration on the comparative performance of these devices is speculative. Despite the growing data for both RA and OA, the rigorous head-to-head comparison should be performed, and additional randomized trials are needed to further clarify the superiority of one atherectomy device over the other.

Author Contributions

The lead author of the review article is Dr Rohit Mody. Dr Debabrata Dash and Dr Bhavya Mody had equal and substantial contributions in the formation of this review article. They were involved in conceptualization, data duration, formal analysis, resources, software, validation, visualization, writing – original draft, Writing – review & editing.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Ethical approval was not required since it is from accepted work.

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