Challenges With Severe Coronary Artery Calcification in Percutaneous Coronary Intervention: A Narrative Review of Therapeutic Options.

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Word Count: 6716 including title page, abstract, text, references and tables

Short Title: Coronary Atherectomy

Article Type: Full Review Article

Funding Sources: None

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UNSTRUCTURED ABSTRACT:

Coronary calcification often complicates atherosclerosis. With an aging population, coinciding with lower thresholds for coronary angiography and percutaneous coronary intervention (PCI), severe calcific coronary stenoses remain a challenge for interventional cardiologists. While advances in coronary guidewires, percutaneous balloons and adjunctive procedural devices have improved success of PCI, recalcitrant calcified lesions no amenable to conventional technique frequently occur. Coronary atherectomy with plaque modification provides a therapeutic alternative. As such, various modalities such as rotational, orbital or laser atherectomy, and more recently shockwave lithoplasty, have become therapeutic options for PCI. We provide a summary of the principles, technique and contemporary evidence for these currently approved devices designed to treat severe coronary calcific lesions.
ONLINE ABSTRACT:

Given the increasing complexity of percutaneous coronary intervention (PCI), adjunctive treatment devices such as rotational, orbital, laser and more recently, shock-wave lithotripsy, have become increasingly important in the management of calcified coronary lesions. The objective of this article are to summarize the principals, technique and contemporary evidence for the use of these devices in the management of severe coronary artery calcification.
Introduction

Since the advent of percutaneous transluminal coronary angioplasty (PTCA) and its application to manage complex coronary anatomy, the optimal treatment of severe calcific coronary stenosis continues to remain a challenge for interventional cardiology. High-pressure balloon inflations have led to perforations, along with extensive intimal and medial luminal dissections. The concept of ‘plaque modification’ with an atherectomy device was appealing, as it led to significant alterations to plaque geometry with minimal injury to the arterial media (1, 2). Subsequent to animal model trials, rotational atherectomy (RA) was evaluated in humans in the late 1980s (3-5), albeit initially as a replacement to balloon angioplasty.

However, with any new technology, the initial enthusiasm has waned over time due to technical challenges with preparation/application and microembolization questioning the clinical utility of RA. Moreover, advances in balloon and stent technology helped facilitate complex PCI (6).

Still, the current interventional practice has seen a shift in its percutaneous revascularization referral pattern – with a patient population having multiple comorbidities and complex calcified coronary disease (7, 8). In this context, conventional PCI of calcified lesions has greater risk of stent under-expansion and mal-apposition, both of which are associated with adverse clinical outcome (8). In order to facilitate optimal angioplasty, resurgence in the utilization of atherectomy devices – rotational, orbital, laser and shockwave lithoplasty – has occurred (9). The objectives of this article are to summarize the principals, technique and contemporary evidence for these currently approved devices.
**Rotational Atherectomy**

*Principles and Indications*

Presently, the primary indication for RA (Rotablator™, Boston Scientific, Natick, MA) is plaque modification to facilitate delivery and adequate expansion of balloon and stent devices. RA operates on two tenets: 1) differential cutting, whereby the diamond-tipped burr pulverizes inelastic tissue while maintaining integrity of the relatively normal elastic arterial segments and, 2) orthogonal displacement of friction characterized by almost complete elimination of contact between the burr and the arterial wall at rotational speeds >60,000rpm, allowing the negotiation of tortuous segments. The particulates generated are usually smaller than the size of a red blood cell, and these are scavenged by circulating macrophages as they traverse the coronary microcirculation. The use of RA is contraindicated in soft, thrombus containing lesions (i.e. acute coronary syndromes), saphenous vein grafts and within coronary lesions with extensive dissection planes.

Severe calcific stenosis remains the primary indication for RA (10). Severe coronary calcification is usually noted on fluoroscopy as radio-opacities before contrast injection on both sides of the arterial wall; though angiographic detection of coronary artery calcification is highly specific, its true severity may be underestimated especially within short or tortuous segments; this insensitivity only becomes apparent with intravascular imaging (11) or when unanticipated difficulties are encountered during coronary intervention. Therefore, debulking these lesions became an attractive target for RA. However, several randomized comparisons between RA and balloon angioplasty for de novo coronary and in-stent restenosis have not provided definitive outcomes supporting RA. As highlighted in Table 1, despite immediate lumen gain and acute
procedural success with atherectomy, short-term restenosis rates were exceedingly high with no net between-group angiographic differences during follow-up. Moreover, a lack of improved angiographic outcomes were noted with “aggressive” (burr-to-artery ratio >0.7) compared with a “routine” (burr-to-artery ratio ≤0.7) RA strategy. In fact, in the 9,222 patients enrolled within 16 sixteen trials conducted between 1993-2002, the Bittl et al. meta-analysis suggested no difference in angiographic outcomes and found a higher incident rate of peri-procedural MI with ablation compared with balloon angioplasty (OR 1.83 [95% confidence interval 1.43 to 2.34]) and an increase in major adverse cardiac events (OR 1.54 [95% confidence interval 1.25 to 1.89]) (12). To some extent, the results of these earlier RA clinical trials were limited by the absence of stent availability to treat procedure-related dissections. However, even in a more recent Cochrane review (3474 patients, 12 trials from 2002-2012), routine atherectomy compared with balloon angioplasty was associated with greater procedural complications, and did not offer longer term benefits (13). The latter meta-analysis included the more contemporary ROTAXUS trial, in which RA had higher procedural success rate and short-term lumen gain, but significantly higher late lumen loss at 9-month follow up (14). However, it is noteworthy to point out ROTAXUS only evaluated first generation DES with one in five patients lost to angiographic follow-up. As well, ROTAXUS was not powered to adequately detect differences in clinical outcome at follow-up.

Despite the unclear evidence, there appears to be a continued role for RA in contemporary clinical practice where discrete plaque modification in resistant calcific lesions with RA helps facilitate optimal stent expansion and apposition (a lack of RCT data in these specific patients). In these select instances, operators need to have a
practical understanding on the preparation, technique and potential procedural risks for RA.

Preparation, technique and complications

In light of gaining popularity with radial arterial access, successful RA utilizing small burr sizes (< 1.75mm) has been performed with standard 6Fr guiding catheters, and only in exceptional circumstances, a larger (≥ 1.75mm) burr size is required necessitating the use of ≥ 7Fr guide catheters. The Rotablator system uses a dedicated 330cm 0.009-inch stainless steel guidewire (with the distal spring tip at 0.014-in to prevent burr advancement beyond the wire tip), and is available as floppy or extra-support. Both versions of the RotaWire are limited by their poor lesion crossability. As such, operators frequently utilize standard workhorse 0.014-inch PCI guidewires to cross lesions, followed by exchange to a RotaWire using either an over-the-wire (OTW) balloon or a microcathether. Infrequently, the delivery of a microcatheter to facilitate RotaWire exchange is not possible, and operators may resort to ‘bare wiring’ lesions with the Rotawire in order to proceed with atherectomy.

While majority of RA can be performed with the floppy wire, particular scenarios, like aorto-ostial stenosis, may require the extra-support version. The extra-support wire however has a tendency to straighten the vessel, and predispose to dissections, as the burr is forced against the outer curvature of the stretched artery. On the other hand, the floppy wire may not provide adequate support as the burr moves around tight bends, and may lead to undesirable ablation along the lesser artery curvature.
Connected to one end of the Advancer tool is a helical driveshaft containing the 
elliptical front-loaded, diamond-tipped burr. On the other end is pressure tubing 
containing a flush solution (combination of nitroglycerin, verapamil and heparin in 
saline, or RotaGlide solution) to ensure smooth shaft rotation and avoid damage to the 
advancer unit. The knob on the advancer controls the fine to-and-fro longitudinal burr 
motion, while the foot pedal-console allows switching between RA and Dynaglide 
modes.

Following the results of the STRATAS (15) and CARAT (16) trials (Table 1), smaller burr sizes are now preferred with most interventionists opting for a single burr 
and balloon facilitated PCI over a stepwise sequential increase in burr size. The 1.5mm 
burr generally achieves a good compromise between negotiating tortuosity and achieving 
an optimal burr-to-artery ratio. However, in lesions not crossable with a 1.5mm burr or in 
very long tortuous segments, a 1.25mm burr with stepwise escalation may be necessary.

In complex scenarios, such as in true bifurcations lesions where RA is considered 
primarily for the main branch, thoughtful pre-procedural planning is critical. While we 
acknowledge these decisions will often be dynamic as the procedure progresses, it is 
important to make note that guidewires not be left in side-branches during main-vessel 
RA (even when >6Fr guide catheters are being used), as they can be sheared by the RA 
burr. Additionally, in the rare event of a burr stall, the side branch wire could become 
potentially trapped behind the burr. Therefore, to achieve optimal and safe patient 
outcomes, judicious peri-procedural planning is the most fundamental tenet. A summary 
of the operational principles with the use of ablative devices is highlighted in Table 1 and 
Figure 1.
With any niche technology, arise unique complications associated with their use. In 13,335 rotablation procedures performed within the J-PCI Registry, the observed rate for in-hospital death, cardiac tamponade or need for emergency surgery was 1.31% (17). In this analysis, institutional volume appeared to be inversely related to the occurrence of adverse procedural outcomes. It is therefore not only important for these higher risk procedures to be performed at higher volume centers, but additionally, operators need to be cognizant that complications can largely be prevented with meticulous technique and good ‘rota hygiene’.

No reflow / slow flow

This phenomenon is thought to result from the interaction of athero-embolic debris, platelet activation, microvasculature spasm and reflex bradycardia that culminates into deterioration of epicardial and microvasculature blood flow with delayed angiographic clearance of contrast dye. The risk of this potentially ominous complication (frequently associated with peri-procedural myocardial infarcts) can largely be reduced with use of appropriate burr speeds, short burr runs (ideally <20 seconds), adequate coronary perfusion pressures, and using vasodilators such as nitrates, calcium channel blockers and nicorandil (currently unavailable in Canada) (18). Additionally, the risk of peri-procedural MIs has been shown to be significantly lower with upfront abciximab use (19). However, caution is recommended with this strategy especially with higher risk anatomy for coronary perforation. Ensuring adequate hemodynamic support during the time of no/slow re-flow is fundamental, and as long as other etiologies that mimic no
flow, such as dissections, are excluded, this phenomenon is generally transient and flow is gradually re-established with time and intra coronary vasodilators. In contemporary practice, rates of no flow / slow re-flow remain under 5% (9, 14, 20), a significant decline from ~15% reported over a decade ago (21).

**Burr entrapment**

The lack of diamond bits on the posterior aspect of the RA burr prevents retrograde ablation. Analogous with the relationship of the head and neck of the Japanese Kokeshi doll, the RA burr has the potential to slip past the coronary lesion without forward ablation. Since the burr is larger than the lesion lumen, the burr can become trapped and may be difficult to withdraw. Prevention of burr entrapment is therefore of utmost importance. Operational principles of relieving tension in the system prior to burr activation prevents it from jumping across a non ablated segment, and returning the burr back to the ‘landing zone’. Also, ensuring the burr maintains rotation (i.e. always spinning) within the lesion avoids entrapment - a fundamental tenet to avoiding burr stall. In addition, maintaining burr speeds of 135,000 – 180,000 rpm, avoiding decelerations >5000 rpm, gradual pecking burr motion, and above all, utmost attention to the auditory, tactile and visual response of the burr within the coronary segment are important strategies to also prevent burr entrapment (6, 22). Also noteworthy is meticulous detail to wire position, ensuring the radio-opaque wire segment is placed in the distal epicardial coronary segment rather than into a small and distal side branch to prevent wire fracture.
In the event of a burr entrapment, several percutaneous rescue strategies have been described (23): 1) cautious deep guide intubation with controlled back and forth traction on the helical shaft, 2) second arterial access and balloon facilitated burr dislodgement, 3) partial disassembly of the Rotablation set-up to allow advancement of Guide catheters or ‘mother and child’ catheters, and if unsuccessful, 4) cardiovascular surgery.

Coronary Perforation

Choosing an appropriate burr size, appreciation of acute angulation, recognizing severe dissections, and appropriate distal wire tip position are important in avoiding coronary perforation. Both wire and athero-ablation related perforations are managed similarly to those during standard PCI, and dictated by hemodynamic compromise and degree of perforation. Treatment options include intracoronary balloon inflations at the site of perforation, covered stents, coils or embolization particles, pericardial drainage and infrequently emergent cardiac surgery.

High-grade atrioventricular block

Transient high-grade atrioventricular block has been recognized as a complication with ablation of dominant right or circumflex coronary arteries. However, with improved techniques, the incident rate of this risk has substantially declined. Some operators still routinely use temporary pacing wires prophylactically, while others have venous access ready if temporary pacing is required. Overall, the prophylactic use of temporary pacing during RA has significantly decreased. In our practice, the decision on whether or not to
prophylactically use temporary pacing is often based on the presence of pre-existing conduction system disease. Peri-procedural use of pharmacological agents such as aminophylline or atropine have additionally helped mitigate the need for prophylactic pacing in RA.

**Orbital Atherectomy**

Similar in operational concept to RA, the design of orbital atherectomy (OA) (Diamondback 360®, Cardiovascular Systems, Inc., St. Paul, MN) overcomes some of the limitations of rotational atherectomy. OA uses an eccentrically mounted 1.25mm diamond studded crown located at the end of a triple wire coil helix for its mechanistic sanding action. The diamond studs are located on both the front and back ends of the crown permitting athero-ablation while the crown orbits in both antegrade and retrograde directions. The crown design also facilitates blood to flow continuously around the crown during rest and active ablation; this not only mitigates the risk of no/slow flow, but additionally reduces heat injury to the adjacent coronary endothelium. Only one sized crown, 1.25mm, is used to complete orbital atherectomy. Deeper ablation arcs are created by increasing contact time between the crown and the plaque, increasing the number of passes and using the faster speed option. Therefore, to achieve optimal ablation results, it is imperative that the crown moves across the lesion slowly and gradually (typically at 1-3mm/sec). Faster crown advancement not only increases the potential for a sub optimal result, but additionally poses a higher risk of dissection or perforation. Two rotational velocities are available: low 80,000rpm and high 120,000rpm; the lower speed is always used as the default to start, and should often be used as the only option for tortuous,
angulated segments and in arteries <3mm. Since the amount of athero-ablation is time-dependent, continued plaque modification continues to occur with subsequent runs even after the crown successfully goes through the lesion the first time. However, for each run, the recommended maximal treatment time is 30 seconds; an in-built device notification is set to occur at 25 seconds. An equal amount of pause, as each run time, is recommended prior to a subsequent run. It is critical to highlight that longer lesions may require multiple runs, but never longer individual run times. Total treatment time should not exceed 5 minutes. Common principles relating to good ablation practices discussed under RA, such as choice of guide catheter, distal wire positioning, relationship between distal end of atherectomy device and the proximal end of the radio-opaque part of the wire, are critically important in mitigating iatrogenic procedural complications. The individual incident risk for each of the major complications (perforation, cardiac tamponade, dissection or no-reflow) is reported at <1% (24).

Select trial characteristics evaluating OA are summarized in Table 3. The ORBIT I first in human trial evaluated the safety, feasibility and effectiveness of OA for treating calcific coronary stenosis in 50 patients within 2 centers in India. Procedural success was achieved in 94%; angiographic complications occurred in seven patients (six dissections and one perforation), with low overall 6-month MACE rates of 8% (25). In the much larger ORBIT II study, the safety of preparing de novo calcific coronary stenosis with OA was established in 443 patients within 49 centers in the United States. In this nonrandomized, single-arm trial design, the primary efficacy end-point, successful stent delivery and <50% residual stenosis, occurred in 97.7% and 98.6%, respectively. The primary safety endpoint, 30-day MACE, occurred in 10.4%, largely driven by non-Q
wave MIs (26). Outcomes of patients enrolled within ORBIT-II at 3-year follow-up similarly demonstrated a low rate of adverse ischemic events (27). While the ORBIT II was certainly a large sized study for the tested intervention, the implications inherent with its single-arm, non-randomized design need to be considered in the context of generalizability of its results to individual patients. In order to provide a broader perspective of the ORBIT trial results in day-to-day clinical practice, Lee et al demonstrate in 458 high-risk OA treated patients in 3 U.S centers, a 30-day and 1-year major adverse cardiac and cerebrovascular composite of rate of 1.7% and 12.6%, respectively (24, 28).

The Micro Crown OA system represents the next technological advance aimed at improving the efficiency of orbital athero-ablation. This OA iteration has its driveshaft re-designed to aid in crown delivery, the available sanding area increased and importantly modified to operate at lower rotational speeds (low: 50,000rpm and high: 70,000rpm). Using this technology in the Coronary Orbital Atherectomy System Study (COAST), 30-day freedom from major adverse cardiac events (MACE) of 85% (78, 92) was reported. Evolution of this technology is likely to expand the options available to safely implement coronary atherectomy in the increasingly complex patient and angiographic profiles being presented for percutaneous treatment in contemporary clinical care. The results of the ongoing, randomized 2000 patient Evaluation of Treatment Strategies for Severe CaLcIfic Coronary Arteries: Orbital Atherectomy vs. Conventional Angioplasty Technique Prior to Implantation of Drug-Eluting StEnts: The ECLIPSE Trial (ECLIPSE, ClinicalTrials.gov Identifier: NCT03108456) will be instrumental in elucidating whether or not routine lesion preparation with OA will result in improved acute luminal gain and
one-year target vessel failure in comparison with balloon angioplasty alone. Further, integrated applications of this technology with intravascular imaging are also being evaluated and will likely expand on our understanding on how to optimize lesion modification prior to stenting (ORBID-OA study, ClinicalTrials.gov Identifier: NCT03058510).

Not surprisingly, with the increased adoption of OA in clinical practice, are several observational comparisons between RA and OA for both surrogate and hard clinical patient outcomes (29). While suggestions of lower major complication risk have been reported with OA compared with RA, significant bias associated with selection and confounding exist with non-randomized comparisons. The choice of which atherectomy device to select should therefore consider patient and angiographic characteristics jointly with local availability, operator and institutional expertise.

**Excimer Laser Coronary Atherectomy (ELCA)**

In principle, this technology uses a combination of a reactive and noble gas to generate short wavelength laser beams to ablate and modify recalcitrant lesions. The CVX-300® system (Spectranetics, Colorado Springs, CO) uses xenon chloride and through a series of inter-related processes emits pulses of ultraviolet light at 308nm wavelengths; the generated ultraviolet pulses only penetrate tissue depths of 50 micrometers, and therefore leads to relatively pure plaque disintegration without injuring the deeper medial or adventitial layers. Four monorail-based ELCA catheter sizes, used over a workhorse 0.014” guidewire, are available for coronary intervention (0.9mm, 0.14mm, 1.7mm and 2.0mm; the 0.9mm X-80 is recommended for initial use and is compatible with 6Fr guide catheters). In order to minimize the risk of inadvertent
dissections or perforations induced by microbubbles generated from particles within the blood, a continuous normal saline infusion (usually at 1-2ml/second) during laser is recommended; exceptions to use of contrast instead of/in addition to saline is in the treatment of under-expanded stents. However, caution is required in the use of this high-energy ELCA strategy (pressure pulses as high as 100 atmospheres) as this significantly increases the risk of coronary perforation. The number of pulses, their length and total ELCA treatment time should be individualized for lesion characteristics.

While ELCA has been approved for coronary intervention over 20 years ago, its use has been largely limited following its initial failure to improve clinical outcomes over stand-alone balloon angioplasty or RA (Select ELCA trials described in Table 4) In fact, a greater risk for major and minor procedural complications have been noted with laser compared with conventional balloon angioplasty. However, with improved iterations of this device, niche indications for ELCA have become apparent in current clinical practice (30, 31). In acute coronary syndromes, results of the single-center LaserAMI (32) and the multicenter CARAMEL study (33) demonstrate both safety and efficacy of ELCA as a PCI-adjunct in high thrombus containing lesions. Similarly, the CORAL trial demonstrated safe use of ELCA in saphenous vein graft PCI prior to stenting (34). However, given that other thrombus modulating strategies such as aspiration thrombectomy have been unsuccessful when universally applied during primary PCI, an improved understanding is required for selecting ELCA in managing heavy thrombus burden.
The more widely adopted application of laser has been for the treatment of in-stent restenosis (especially for under-expanded stents) since its mechanism of action allows for more effective ablation of fibrotic tissue behind stent struts. In instances where calcific nodules exist within fibrotic restenosis, in balloon undilatable/uncrossable lesions or during PCI of chronic total occlusions, optimal lesion preparation with combination use of laser and RA (denoted as “razer”) has been described. ELCA is unlikely to have broad applications in day-to-day PCI but it is imperative that interventional cardiologists be aware of its niche applications and referral to PCI centers adept in performing ELCA. To our knowledge, only the Mazankowski Alberta Heart Institute (Edmonton), Montreal Heart Institute (Montreal) and the Royal Jubilee Hospital (Victoria) perform these procedures in Canada. Figure 2 provides a recent case of ELCA performed successfully for balloon uncrossable in-stent restenosis.

Shockwave Lithoplasty

Adapting the use of sonic technology designed to treat kidney stones, the use of lithotripsy waves for the treatment of coronary calcification has recently been evaluated in the DISRUPT CAD trial. In this 60-patient trial, a specially designed balloon was delivered across the lesion over a 0.014” guide wire, and inflated at 4atms to deliver the generated tissue-selective lithotripsy waves followed by balloon angioplasty at 6atms. No angiographic complications were evident on core-lab review and 30-day MACE (cardiac death, MI, target vessel revascularization) rates of only 5.0% were reported (ClinicalTrials.gov Identifier: NCT02650128). Further safety and efficacy data should
become available with the results of the larger DISRUPT CAD II trial (ClinicalTrials.gov Identifier: NCT03328949).

**Other Procedural Techniques**

*Cutting and Scoring balloons*

The treatment of restenotic lesions has been a particular interventional challenge. Creating controlled intimal and medial dissections rather than the more traumatic dissections associated with aggressive conventional balloon angioplasty was considered to be more favorable in the reduction of subsequent restenosis. Therefore, 3-4 atherotomes or scoring helices were incorporated onto a non-compliant balloon to facilitate lesion engagement and reduce the risk of slippage during balloon inflation, and additionally allow the application of greater and more predictable outward balloon expansion. However, the comparison of routine cutting to conventional balloon angioplasty for denovo stenosis (Global trial)(35) and in-stent restenosis (RESCUT and REDUCE II trials)(36) have consistently failed to demonstrate improved clinical outcomes. As such, the routine use has been largely abandoned. On a case-by-case basis cutting or scoring balloons may be used to treat severe ISR not amenable to optimal conventional balloon angioplasty, or for aorto-ostial and bifurcation stenosis.

*Ultra-high pressure balloons*

The OPN NC (1.5mm – 4.5mm diameter) is a twin layer balloon designed to provide the highest rated burst pressure (35 atms) and virtually mitigate the ‘dog-bone effect’ encountered with standard non-compliant balloons. Its profile is further enhanced with the use of a long tapered tip to enhance lesion cross ability, a challenge with the
available cutting or scoring balloons. However, there are concerns with vessel perforation given the high pressure inflation with the OPN NC – hence caution is required.

**Recommendations and Conclusions**

In current practice, complex fibro-calcific coronary lesions commonly require adjunctive techniques to facilitate successful percutaneous coronary intervention. With over two decades of use with RA, and more recent experience with OA, laser and shockwave lithoplasty, these procedures have demonstrated high procedural success rate with relatively low risk. Clinicians need to be aware of these niche applications in order to support complex coronary intervention. Equally important is the need to develop and integrate data collection processes to effectively track outcomes associated with the redefined indication for the use of these and other adjunctive devices especially given the significant parallel improvements in stent platforms, antiplatelet therapies and mechanical support systems. Finally, several randomized trials evaluating the use of these technologies are underway and their outcomes in the management of calcific coronary stenosis are eagerly awaited.

**Disclosures**

The authors have no relevant conflicts of interest to disclose
**Figure 1:** Integrated principles for coronary atherectomy in complex percutaneous coronary intervention

**Figure 2:** A recent case of excimer laser coronary atherectomy (ELCA) used for balloon uncroassable in-stent restenosis at the Mazankowski Alberta Heart Institute. (A): Chronic total occlusion (CTO) attempt (dual injection) of an occluded right coronary artery due to type IV in-stent restenosis of an old bare-metal stent. (B): Unable to wire lesion retrogradely. Able to wire lesion antegradely but unable to advance a 1.25 sprinter legend balloon across the lesion. Able to advance a 0.9mm Turbo Elite Laser Atherectomy catheter to perform ECLA (arrow). (C): Percutaneous coronary intervention (PCI) performed of the right coronary artery with everolimus-eluting stents (EES).
Table 1: Operational fundamentals for plaque-modification techniques

<table>
<thead>
<tr>
<th></th>
<th>Rotational</th>
<th>Orbital</th>
<th>Laser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device</td>
<td>Rotablator</td>
<td>Diamondback 360</td>
<td>CVX-300</td>
</tr>
<tr>
<td>Available sizes</td>
<td>1.25, 1.5, 1.75, 2.0, 2.25, 2.38 and 2.5mm</td>
<td>1.25mm</td>
<td>0.9, 1.4, 1.7, 2.0mm</td>
</tr>
<tr>
<td>Guide catheter compatibility</td>
<td>&lt;1.75mm burrs: 6Fr guide</td>
<td>6Fr guide</td>
<td>0.9 and 1.4mm: 6Fr guide 1.7mm: 7Fr 2.0mm: 8Fr</td>
</tr>
<tr>
<td>Guidewire</td>
<td>0.009” floppy or extra-support Rotawire</td>
<td>0.012”/0.014” VIPERWIRE advanced coronary guidewire</td>
<td>0.014” workhorse guidewire</td>
</tr>
<tr>
<td>Flush solution</td>
<td>Rotaglide, variable infusion rate, usually under a pressure bag Alternative: heparin, nitroglycerin and verapamil in normal saline</td>
<td>ViperSlide, standard infusion rate</td>
<td>Normal saline flush and infusion, 1-2ml per second Contrast may be carefully considered for under-expanded stents</td>
</tr>
<tr>
<td>Operational principles</td>
<td>Burr speeds 135000-180000, avoid decelerations &gt;5000rpm Gradual pecking motions with short ablative runs (≤ 30seconds each)</td>
<td>80000rpm and 120000rpm speed options. Larger ablative arc with higher speed</td>
<td>Auto-deactivation after 5 seconds with 10-second pause before next laser pulse Slow advancement through lesion (0.5mm/second)</td>
</tr>
<tr>
<td>Contraindications</td>
<td>PCI in bypass grafts, thrombus containing lesions, stents, presence of significant dissections</td>
<td>PCI in bypass grafts, thrombus containing lesions, stents, presence of significant dissections</td>
<td>Deep, long sub-intimal guidewire position Unprotected left main PCI (relative contraindication)</td>
</tr>
<tr>
<td>CTO PCI</td>
<td>Acceptable over Rotawire</td>
<td>N/A</td>
<td>Acceptable over workhorse wires</td>
</tr>
</tbody>
</table>

*Caution with contrast: Excessive heat generation and greater risk of perforation

CTO, chronic total occlusion; N/A, not applicable; PCI, percutaneous coronary intervention
Table 2: Select rotational atherectomy trial characteristics and outcomes

<table>
<thead>
<tr>
<th>Study name/First author/Year</th>
<th>Treatment arms (Number of patients in each arm)</th>
<th>Lesion characteristics</th>
<th>Study outcome(s)</th>
<th>Result(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guerin (37) 1996</td>
<td>PTCA vs. RA (32 each arm)</td>
<td>Denovo stenosis</td>
<td>Composite of lesion stenosis reduction &lt;20%, residual stenosis &lt;50% in the absence of death, Q wave MI, or CABG</td>
<td>PTCA vs. ECLA vs. RA 87.5% vs. 93.7%, p=NS</td>
</tr>
<tr>
<td>ERBAC (38) 1997</td>
<td>PTCA vs. ELCA vs. RA (222 and 232 and 231)</td>
<td>Denovo stenosis</td>
<td>Composite of diameter stenosis &lt;50%, absence of death, Q wave MI, or CABG TLR at 6-months</td>
<td>PTCA vs. RA 89% vs. 77% vs. 80%, p=0.0019 42.4% vs. 46% vs 31.9%, p=0.013</td>
</tr>
<tr>
<td>Eltchaninoff (39) 1997</td>
<td>PTCA vs. RA (26 and 24)</td>
<td>Denovo stenosis&gt;50%</td>
<td>Angioscopic evaluation for 1.Flaps 2.Thrombi 3.Sub-intimal hemorrhage 4.Longitudinal dissections</td>
<td>PTCA vs. RA 1.54% vs. 33%, p=0.08 2.31% vs. 16.7%, p=0.16 3.15% vs. 29%, p=0.15 4.23% vs. 4%, p=0.05</td>
</tr>
<tr>
<td>COBRA (40) 2000</td>
<td>PTCA vs RA (250 and 252 patients) Bail-out stenting</td>
<td>Denovo stenosis&gt;70%</td>
<td>Composite of lesion stenosis reduction &lt;20%, residual stenosis &lt;50% in the absence of death, MI, or CABG TVR at 6 months</td>
<td>PTCA vs. RA 73% vs. 84%, p=0.006 23% vs. 21%</td>
</tr>
<tr>
<td>Mehran (41) 2000</td>
<td>ELCA vs. RA (119 and 130) Both followed by PTCA</td>
<td>Instent restenosis</td>
<td>Post intervention luminal dimensions 1-year TLR</td>
<td>No between group differences 26% vs. 28%, p=NS</td>
</tr>
<tr>
<td>CARAT (16) 2001</td>
<td>“Aggressive RA” (burr:artery&gt;0.7) vs. “Routine RA” (burr:artery ≤0.7) (104 and 118)</td>
<td>Denovo stenosis</td>
<td>MLD at end of procedure Composite of death, MI, TLR at 6 months</td>
<td>Aggressive vs. Routine 1.8mm vs. 2.0mm, p=NS 36.3% vs. 32.7%, p=NS</td>
</tr>
<tr>
<td>STRATAS (15) 2001</td>
<td>“Aggressive RA” (burr:artery&gt;0.7) vs. “Routine RA” (burr:artery ≤0.7) (248 and 249)</td>
<td>Denovo and restenosis</td>
<td>MLD at end of procedure Composite of death, MI, CABG within 30-days</td>
<td>Aggressive vs. Routine 1.97mm vs. 1.95mm 2.0% vs. 4.0%, p=0.20</td>
</tr>
<tr>
<td>ARTIST (42) 2002</td>
<td>PTCA vs RA (146 and 152)</td>
<td>Instent restenosis ≥70%</td>
<td>Residual stenosis&lt;30% Net mean luminal gain at 6</td>
<td>PTCA vs. RA 89% vs. 88%, p=NS 0.67mm vs. 0.45 mm,</td>
</tr>
<tr>
<td>Study</td>
<td>Treatment 1</td>
<td>Treatment 2</td>
<td>Comparison</td>
<td>Endpoints</td>
</tr>
<tr>
<td>---------------</td>
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<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Kwon (43) 2003</td>
<td>PTCA vs RA</td>
<td>PTCA vs RA</td>
<td>PTCA vs. RA</td>
<td>Freedom from tamponade, MI, TVR or death at 6 months, p=0.0019</td>
</tr>
<tr>
<td></td>
<td>(20 and 21)</td>
<td>(20 and 21)</td>
<td>31.3% vs. 33.3%, p=0.80</td>
<td>91.3% vs. 79.6%, p=0.0052</td>
</tr>
<tr>
<td>ROSTER (44) 2004</td>
<td>PTCA vs. RA</td>
<td>PTCA vs. RA</td>
<td>PTCA vs. RA</td>
<td>Freedom from tamponade, MI, TVR or death at 6 months, p=0.0019</td>
</tr>
<tr>
<td></td>
<td>(100 each arm)</td>
<td>(100 each arm)</td>
<td>45% vs. 32%, p=0.042</td>
<td>52% vs. 38%, p=0.04</td>
</tr>
<tr>
<td>Lee (45) 2005</td>
<td>Cutting balloon angioplasty vs. RA</td>
<td>PTCA vs. RA</td>
<td>PTCA vs. RA</td>
<td>Freedom from tamponade, MI, TVR or death at 6 months, p=0.0019</td>
</tr>
<tr>
<td></td>
<td>(55 and 58)</td>
<td>(100 each arm)</td>
<td>14.0% vs. 14.9%, p=0.89</td>
<td>3.6% vs. 3.2%, p=0.94</td>
</tr>
<tr>
<td>ROTAXUS (14) 2014</td>
<td>RA followed by stent</td>
<td>PTCA vs. RA</td>
<td>PTCA vs. RA</td>
<td>Freedom from tamponade, MI, TVR or death at 6 months, p=0.0019</td>
</tr>
<tr>
<td></td>
<td>Standard stenting</td>
<td>(100 each arm)</td>
<td>24.2% vs. 28.3%, p=0.46</td>
<td>24.2% vs. 28.3%, p=0.46</td>
</tr>
<tr>
<td></td>
<td>(120 in each arm, both groups received Taxus Liberte stent)</td>
<td>(120 in each arm, both groups received Taxus Liberte stent)</td>
<td>24.2% vs. 28.3%, p=0.46</td>
<td>24.2% vs. 28.3%, p=0.46</td>
</tr>
</tbody>
</table>

CABG, coronary artery bypass graft surgery; CBA, cutting balloon angioplasty; MI, myocardial infarction; OA, MLD, minimum lumen diameter; orbital atherectomy; PTCA, percutaneous transluminal coronary angioplasty; RA, rotational atherectomy; TLR, target lesion revascularization; TVR, target vessel revascularization
<table>
<thead>
<tr>
<th>Study name/Year</th>
<th>Treatment arms (number of patients in each arm)</th>
<th>Lesion characteristics</th>
<th>Study outcome(s)</th>
<th>Result(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORBIT I (25) (2013)</td>
<td>Single arm design OA, 50 patients</td>
<td>Denovo stenosis</td>
<td>Composite of cardiac death, MI or TVR: In-hospital, 2.30-days, 3.6 months</td>
<td>4%, 6%, 8%</td>
</tr>
<tr>
<td>ORBIT II (26) (2014)</td>
<td>Single arm design OA, 443 patients</td>
<td>Denovo stenosis</td>
<td>Composite of cardiac death, MI or TVR at 30 days</td>
<td>10.4%</td>
</tr>
<tr>
<td>COAST (46)</td>
<td>Single arm design MicroCrown OA, 100 patients</td>
<td>Denovo stenosis</td>
<td>Freedom from composite of cardiac death, MI or TVR at 30 days</td>
<td>85% (95% CI 78%, 92%)</td>
</tr>
</tbody>
</table>

MI, myocardial infarction; OA, orbital atherectomy; TVR, target vessel revascularization
Table 4: Select laser atherectomy trial characteristics and outcomes

<table>
<thead>
<tr>
<th>Study name/ Year</th>
<th>Treatment arms (number of patients in each arm)</th>
<th>Lesion characteristics</th>
<th>Study outcome (s)</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMRO (47) 1996</td>
<td>PTCA vs. Laser (157 and 151)</td>
<td>Denovo stenosis and restenotic lesions</td>
<td>Composite of death, MI, CABG, or PTCA at 6 months Net lumen gain at 6 months</td>
<td>PTCA vs. Laser 29.9% vs. 33.1%, p=0.55 0.48mm vs. 0.44mm (p=0.34)</td>
</tr>
<tr>
<td>ERBAC (38) 1997</td>
<td>PTCA vs. ELCA vs. RA (222 and 232 and 231)</td>
<td>Denovo stenosis</td>
<td>Composite of diameter stenosis&lt;50%, absence of death, Q wave MI, or CABG TLR at 6-months</td>
<td>PTCA vs. RA 89% vs. 77% vs. 80%, p=0.0019 42.4% vs. 46% vs 31.9%, p=0.013</td>
</tr>
<tr>
<td>LAVA (48) 1997</td>
<td>PTCA vs. Laser (98 and 117)</td>
<td>Denovo stenosis or restenotic lesions</td>
<td>Composite of diameter stenosis&lt;50%, absence of death, Q wave MI, PTCA or CABG</td>
<td>PTCA vs. Laser 96.9% vs. 96.6%, p=0.88</td>
</tr>
</tbody>
</table>
References


Coronary Atherectomy

Indications
- Calcified Lesions (selected devices)
- In-stent Restenosis (selected devices)

Operational Principles
- Centers of Excellence
- Tools and Technique

Patient Profile
- Patient Profile
- Lesion Profile

Complications
- Flow Related
- Mechanical Related