

Coronary Atherectomy: A Current Assessment

A contemporary review of atherectomy devices for treating calcified coronary artery lesions.

BY EVAN SHLOFMITZ, DO

In one of the initial articles on interventional cardiology, Gruntzig et al noted, “At present, the technic [sic] is limited by anatomic factors, such as vessel tortuosity... and calcified stenosis.”¹ Despite the many advances in the field, these words proved to be prophetic, as coronary artery calcification continues to pose many challenges to successful percutaneous coronary intervention (PCI).

Coronary artery calcification increases the complexity of PCI, with less favorable results than in noncalcified lesions. Severely calcified lesions increase the risk of dissection, inhibit stent delivery and adequate stent expansion, and are prone to stent malapposition with insufficient drug penetration.²⁻⁶ These factors may contribute to increased restenosis and stent thrombosis.^{4,6} Failure to pretreat calcified lesions may lead to increased major adverse cardiac events (MACE).⁷ The true impact of calcified lesions is hard to fully appreciate because patients with severely calcified coronary artery disease are often excluded from randomized prospective trials. Pooled analysis from the HORIZONS-AMI and ACUITY data demonstrated a relationship between the severity of target lesion calcification and adverse outcomes, including MACE, death, and target lesion revascularization.⁸

Risk factors associated with coronary artery calcification, including advanced age, diabetes, kidney disease, and smoking, have been increasing in prevalence. Coronary calcium is often underestimated and undertreated. In an intravascular ultrasound (IVUS) analysis, Mintz et al showed that target lesion calcification was only seen in 38% of lesions via angiography but was detected in 73% of lesions when utilizing IVUS.⁹

Lesion preparation prior to PCI has become increasingly important when calcified coronary disease is present. Restenosis is frequently due to inadequate vessel preparation because balloon angioplasty alone is often inadequate to optimally treat severely calcified lesions. Lesion preparation alters the morphology of the lesion, changing the lesion compliance. Modification of lesion

compliance may allow for complete stent expansion and lead to improved procedural success. Mild to moderately calcified lesions can often be managed with noncompliant balloons with high-pressure inflations, as well as with cutting, scoring, and sculpting balloons. However, moderate to severely calcified lesions often require an atherectomy strategy for optimal lesion preparation. Following atherectomy, stent delivery should utilize the latest-generation drug-eluting stent, whenever possible, to minimize restenosis.

The atherectomy devices that are currently commercially available differ by design and mechanism of action. The unique mechanisms of action help to determine which device is best suited for different types of lesions. The following sections provide an overview of these atherectomy modalities, with a particular focus on rotational and orbital atherectomy, as they are the two modalities in current use for severely calcified coronary lesions to facilitate stent delivery.

LASER ATHERECTOMY

Laser atherectomy has been used in the clinical setting since 1983.¹⁰ The ELCA coronary laser atherectomy catheter (Spectranetics Corporation) delivers a high-energy light beam via a specialized catheter with short pulses, vaporizing thrombi, and debulking plaque. The ELCA device is approved for the treatment of lesions that previously failed PCI, total occlusions traversable by a guidewire, occluded saphenous vein grafts, in-stent restenosis prior to brachytherapy, ostial lesions, long lesions (> 20 mm), and moderately calcified lesions.¹¹

The CARMEL multicenter study enrolled 151 acute myocardial infarction patients with a large thrombus burden and showed that excimer laser angioplasty was successful in 91% of patients treated, with an 8.6% rate of MACE.¹¹ Use for in-stent restenosis was demonstrated to be safe in the LARS multicenter registry, in which laser angioplasty decreased 30-day target vessel revascularization.

At 1 year, however, there was no significant reduction.¹² The CORAL study demonstrated the feasibility of the ELCA device in diseased vein grafts in 98 patients, with comparable 30-day MACE (18.4%) to the control group (19.4%) in the comparative SAFER trial.¹³

DIRECTIONAL ATHERECTOMY

Directional coronary atherectomy (DCA) was approved for use by the US Food and Drug Administration (FDA) in 1990.¹⁴ A DCA catheter is equipped with a rotating cutter that ablates plaque through a small window with the assistance of an inflated balloon. The rotating cutter is advanced distally, ablating the lesion and aspirating the debris. DCA is capable of debulking lesions with mixed morphologies. However, in the United States, it is no longer commercially available for use in the coronary arteries and can only be used for treatment of the peripheral vasculature.

TRANSLUMINAL EXTRACTION CATHETER

Transluminal extraction catheter (TEC) atherectomy simultaneously excises and extracts plaque and thrombi¹⁵ and received FDA approval in 1993. TEC was used to treat lesions of heterogeneous morphology and in bypass grafts prior to angioplasty. TEC is no longer commercially available.

ROTATIONAL ATHERECTOMY

Rotational atherectomy was first used in 1988 and uses high-speed (140,000–180,000 rpm) rotation to ablate

inelastic plaque, resulting in debris with an average size of < 5 µm.¹⁶ Rotational atherectomy has been the most commonly used atherectomy modality to date. It is commercially available as the Rotablator atherectomy system (Boston Scientific Corporation) and incorporates a diamond-tipped elliptical burr, which spins concentrically as it advances in a forward direction. A cocktail consisting of RotaGlide lubricant (Boston Scientific Corporation), verapamil, nitroglycerin, and heparin can be infused during ablation to reduce vasospasm. The Rotablator system is controlled using a console, with activation by a foot pedal. Available crown sizes vary from 1.25 to 2.5 mm. Rotational atherectomy increases lumen diameter by ablating calcium and achieving plaque modification.

The ERBAC study included 685 patients from a single center who were randomized to one of three revascularization strategies. No significant differences were observed for in-hospital adverse events and at 6-month follow-up, despite the enhanced procedural success with rotational atherectomy.¹⁷ The results of the COBRA study were not significantly different.¹⁸ A meta-analysis of randomized atherectomy trials published in 2004 suggested that the combined experience indicated that ablative devices failed to achieve predefined clinical and angiographic outcomes.¹⁹ In the contemporary ROTAXUS trial, routine lesion preparation using rotational atherectomy did not reduce late lumen loss of drug-eluting stents at 9 months in patients with moderate to severe coronary calcium. However, the use of rotational atherectomy did result in a significantly higher procedural success rate compared

TABLE 1. SUMMARY OF KEY ROTATIONAL ATHERECTOMY CLINICAL DATA

First Author/ Trial Name	Year Published	Study Design	No. of Patients	Conclusion
ERBAC study ¹⁷	1997	Single-center, randomized study	685	No major difference was observed with in-hospital complications and 6-month follow-up in RA vs laser atherectomy vs balloon angioplasty
COBRA study ¹⁸	2000	Multicenter, prospective study	502	Long-term clinical and angiographic outcomes are comparable between RA and balloon angioplasty
Bittl et al ¹⁹	2004	Meta-analysis of randomized trials	9,222	Combined data did not support the hypothesis that routine ablation is beneficial during PCI
Rathore et al ²¹	2010	Retrospective series	516	RA can be performed with high success rates and low complications, and RA followed by DES significantly reduced restenosis rates as compared to RA + BMS
ROTAXUS trial ²⁰	2013	Multicenter, prospective, randomized controlled trial	240	Routine lesion preparation using RA did not reduce late lumen loss of DES at 9 months in patients with moderate to severe coronary calcium

Abbreviations: BMS, bare-metal stent; DES, drug-eluting stent; RA, rotational atherectomy.

to standard PCI.²⁰ A summary of key clinical data on rotational atherectomy is presented in Table 1.¹⁷⁻²¹

Procedural complications that occur with rotational atherectomy include dissection, perforation, slow flow/no reflow phenomenon, burr entrapment, vasospasm, and transient heart block. Procedural complications may be reduced by adhering to proper technique (ie, slower speeds, short runs [< 20 sec] and limited deceleration [$< 5,000$ rpm]). Although it has been recommended to insert a temporary transvenous pacemaker prior to treatment with rotational atherectomy in right coronary artery or dominant left circumflex artery lesions due to possible heart block, many experienced operators seldom use temporary pacemakers, as the incidence and clinical consequences are minimal and can simply be treated with mechanical maneuvers (eg, coughing, vigorous rhythmic closure of fist) and/or pharmacologic measures (eg, atropine).²²

Rotational atherectomy has shown a lack of benefit in reducing long-term restenosis in clinical trials. Consequently, its use is often limited to a bailout strategy when a lesion is not dilatable or a stent is not deliverable. Contemporary guidelines on management of calcified lesions indicate that rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation (class IIa, level of evidence C).²³ Guidelines caution that rotational atherectomy should not be routinely performed for de novo lesions or in-stent restenosis (class III, level of evidence A).²³

ORBITAL ATHERECTOMY

Orbital atherectomy was approved for use in coronary arteries in 2013. The Diamondback 360 coronary orbital atherectomy system (Cardiovascular Systems, Inc.) uses a diamond-coated, eccentrically mounted burr that rotates over a ViperWire guidewire (Cardiovascular Systems, Inc.) at 80,000 rpm on low speed and 120,000 rpm on high

speed. The standard crown size is 1.25 mm. ViperSlide lubricant (Cardiovascular Systems, Inc.) is infused during ablation.

The orbiting mechanism utilizes centrifugal forces to increase the lumen diameter by differentially ablating calcium. The recommended duration of treatment is 20 seconds or less per pass. The unique mechanism of action of orbital atherectomy allows continuous flow of blood and saline during orbit, decreasing heat generation. Microparticulate debris averages $< 2 \mu\text{m}$ in size. The Diamondback 360 orbital atherectomy system has a quick setup and allows the operator to control the speed of orbit and advancement of the burr.

The ORBIT II trial established that orbital atherectomy helped facilitate stent delivery and improved both acute and 30-day clinical outcomes compared with the outcomes of historic control subjects in patients with severely calcified coronary disease.²⁴ Three-year follow-up from the ORBIT II trial demonstrated the durability of these results, with a 7.8% target lesion revascularization rate in patients treated with orbital atherectomy.²⁵ In a retrospective multicenter registry, Lee et al showed that 30-day MACE with orbital atherectomy was 1.7%, with low angiographic complications in a complex, real-world patient population.²⁵ A summary of key clinical data on orbital atherectomy is presented in Table 2.^{23,25,26}

Procedural complications that occur with orbital atherectomy include dissection, perforation, and slow flow/no reflow phenomenon. The small particulate size and continuous flow during orbit may contribute to the low rates of transient heart block and no reflow that has been seen with orbital atherectomy, as compared to rotational atherectomy. As the orbital atherectomy system ablates bidirectionally, burr entrapment has not been an issue. Procedural complications may be reduced by avoiding high-speed ablation in vessels < 3 mm in diameter and in tortuous vessels.

Orbital atherectomy offers unique advantages in that it is used for both complex lesions that cannot be treated with

TABLE 2. SUMMARY OF KEY ORBITAL ATHERECTOMY CLINICAL DATA

First Author/ Trial Name	Year	Study Design	No. of Patients	Conclusion
ORBIT I ²⁶	2013	Prospective nonrandomized study	50	OA treatment may change calcified lesion compliance to facilitate stent placement
ORBIT II ²⁴	2014	Prospective, multicenter, nonblinded clinical trial	443	Preparation of severely calcified plaque with OA helped facilitate stent delivery in 97.7% of cases, with 89.6% freedom from 30-day MACE
Lee et al ²⁵	2016	Multicenter, retrospective registry	458	30-day MACE with OA was 1.7% with low angiographic complications in a complex, real-world patient population

Abbreviations: MACE, major adverse cardiac events; OA, orbital atherectomy.

conventional PCI, as well as for optimal vessel preparation. The ease of setup, low procedural complication rates, and low rates of restenosis out to 3 years have led to increased utilization of orbital atherectomy. Because it is new technology, recommendations for the use of orbital atherectomy have not yet been included in the latest guidelines.

FUTURE DIRECTIONS

The first intravascular image-guided atherectomy system approved for use is the Pantheris atherectomy device (Avinger, Inc.), which integrates optical coherence tomography imaging into the device. However, this device is currently only approved for the treatment of peripheral artery disease. To date, there are no atherectomy devices that integrate intravascular imaging that are approved for coronary disease, but we believe that an intravascular imaging-guided atherectomy device would enhance coronary atherectomy as well. Intravascular imaging allows for optimization of treatment, allowing precise treatment with the ability to diagnose the extent of the lesion while identifying the location of healthy tissue. The ability to gain this information while the atherectomy device is at the lesion has the potential to improve treatment results. Postprocedural imaging can detect dissections and confirm adequate lesion preparation with high sensitivity.

Other future directions include atherectomy devices with lower profiles and increased flexibility. An orbital atherectomy device with an additional microcrown tip is currently under clinical investigation. With the addition of bioresorbable vascular scaffolds to the interventional toolbox, lesion preparation will be essential to ensure optimal results in many of these patients.

Despite the growing data for both rotational and orbital atherectomy, to date there have been no studies directly comparing the safety and efficacy of the two modalities. Atherectomy has historically been used for debulking calcified lesions and as a bailout strategy. As routine intravascular imaging utilization increases, recognition of coronary artery calcification will incrementally rise, as will detection of the mechanism of in-stent restenosis, with a large percentage due to inadequate pretreatment. To achieve optimal results, vessel preparation is essential as an initial revascularization strategy to ensure complete vessel expansion with PCI. With improvements in technology, atherectomy has evolved into an essential tool for lesion preparation to optimize PCI results. ■

1. Grüntzig AR, Senning A, Siegenthaler WE. Nonoperative dilatation of coronary-artery stenosis: percutaneous transluminal coronary angioplasty. *N Engl J Med*. 1979;30:61-68.
2. Fitzgerald PJ, Ports TA, Yock PG. Contribution of localized calcium deposits to dissection after angioplasty. An observational study using intravascular ultrasound. *Circulation*. 1992;86:64-70.
3. Gilutz H, Weinstein JM, Iliia R. Repeated balloon rupture during coronary stenting due to a calcified lesion: an intravascular ultrasound study. *Catheter Cardiovasc Interv*. 2000;50:212-214.
4. Moussa I, Di Mario C, Moses J, et al. Coronary stenting after rotational atherectomy in calcified and complex lesions. Angiographic and clinical follow-up results. *Circulation*. 1997;96:128-136.
5. Mosseri M, Satler LF, Pichard AD, Waksman R. Impact of vessel calcification on outcomes after coronary stenting. *Cardiovasc Revasc Med*. 2005;6:147-153.
6. Ichihashi S, Kichikawa K. Role of the latest endovascular technology in the treatment of intermittent claudication. *Ther Clin Risk Manag*. 2014;10:467-474.
7. Tanigawa J, Barlis P, Mario CD. Heavily calcified coronary lesions preclude strut apposition despite high pressure balloon dilatation and rotational atherectomy in-vivo demonstration with optical coherence tomography. *Circ J*. 2008;72:157-160.
8. Généreux P, Madhavan MV, Mintz GS, et al. Ischemic outcomes after coronary intervention of calcified vessels in acute coronary syndromes. Pooled analysis from the HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) and ACUTITY (Acute Catheterization and Urgent Intervention Triage Strategy) trials. *J Am Coll Cardiol*. 2014;63:1845-1854.
9. Mintz GS, Popma JJ, Pichard AD, et al. Patterns of calcification in coronary artery disease. A statistical analysis of intravascular ultrasound and coronary angiography in 1155 lesions. *Circulation*. 1995;91:1959-1965.
10. Akkus NI, Abdulbaki A, Jimenez E, Tandon N. Atherectomy devices: technology update. *Med Devices (Auckl)*. 2015;8:1-10.
11. ELCA: Instructions for Use. Spectranetics web site. March 2016. <http://www.spectranetics.com/resources/ifu-library>. Accessed November 2, 2016.
12. Giri S, Ito S, Lansky AJ, et al. Clinical and angiographic outcome in the laser angioplasty for restenotic stents (LARS) multicenter registry. *Catheter Cardiovasc Interv*. 2001;52:24-34.
13. Giugliano GR, Falcone MW, Mego D, et al. A prospective multicenter registry of laser therapy for degenerated saphenous vein graft stenosis: the Coronary Graft Results Following Atherectomy With Laser (CORAL) trial. *Cardiovasc Revasc Med*. 2012;13:84-89.
14. Simonton CA, Leon MB, Baim DS, et al. 'Optimal' directional coronary atherectomy: final results of the Optimal Atherectomy Restenosis Study (OARS). *Circulation*. 1998;97:332-339.
15. Popma JJ, Leon MB, Mintz GS, et al. Results of coronary angioplasty using the transluminal extraction catheter. *Am J Cardiol*. 1992;70:1526-1532.
16. Tomey ML, Kini AS, Sharma SK. Current status of rotational atherectomy. *JACC Cardiovasc Interv*. 2014;7:345-353.
17. Reifart N, Vandormael M, Krajcar M, et al. Randomized comparison of angioplasty of complex coronary lesions at a single center. Excimer Laser, Rotational Atherectomy, and Balloon Angioplasty Comparison (ERBAC) study. *Circulation*. 1997;96:91-98.
18. Dill T, Dietz U, Hamm CW, et al. A randomized comparison of balloon angioplasty versus rotational atherectomy in complex coronary lesions (COBRA study). *Eur Heart J*. 2000;21:1759-1766.
19. Bittl JA, Chew DP, Topol EJ, et al. Meta-analysis of randomized trials of percutaneous transluminal coronary angioplasty versus atherectomy, cutting balloon atherectomy, or laser angioplasty. *J Am Coll Cardiol*. 2004;43:936-942.
20. Abdel-Wahab M, Richardt G, Büttner HJ, et al. High-speed rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions: the randomized ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) trial. *JACC Cardiovasc Interv*. 2013;6:10-19.
21. Rathore S, Matsuo H, Terashima M, et al. Rotational atherectomy for fibro-calcific coronary artery disease in drug eluting stent era: procedural outcomes and angiographic follow-up results. *Catheter Cardiovasc Interv*. 2010;75:919-927.
22. Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *Catheter Cardiovasc Interv*. 2012;79:453-495.
23. Chambers JW, Feldman RL, Himmelstein SJ, et al. Pivotal trial to evaluate the safety and efficacy of the orbital atherectomy system in treating de novo, severely calcified coronary lesions (ORBIT II). *JACC Cardiovasc Interv*. 2014;7:510-518.
24. Chambers JW. Three-year ORBIT II results. Presented at Society for Cardiovascular Angiography and Interventions 2016 Scientific Sessions; May 4-7, 2016; Orlando, FL.
25. Lee MS, Shlofmitz E, Kaplan B, et al. Real-world multicenter registry of patients with severe coronary artery calcification undergoing orbital atherectomy. *J Interv Cardiol*. 2016;29:357-362.
26. Parikh K, Chandra P, Choksi N, et al. Safety and feasibility of orbital atherectomy for the treatment of calcified coronary lesions. *Catheter Cardiovasc Interv*. 2013;81:1134-1139.

Evan Shlofmitz, DO

Department of Cardiology
Northwell Health
Manhasset, New York
eshlofmi@northwell.edu

Disclosures: Received honorarium from Cardiovascular Systems, Inc.

1. Grüntzig AR, Senning A, Siegenthaler WE. Nonoperative dilatation of coronary-artery stenosis: percutaneous transluminal coronary angioplasty. *N Engl J Med*. 1979;30:61-68.
2. Fitzgerald PJ, Ports TA, Yock PG. Contribution of localized calcium deposits to dissection after angioplasty. An observational study using intravascular ultrasound. *Circulation*. 1992;86:64-70.
3. Gilutz H, Weinstein JM, Iliia R. Repeated balloon rupture during coronary stenting due to a calcified lesion: an intravascular ultrasound study. *Catheter Cardiovasc Interv*. 2000;50:212-214.