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Long-term safety and performance of the orbital atherectomy system for treating calcified coronary artery lesions: 5-Year follow-up in the ORBIT I trial

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ABSTRACT

Background/Purpose: The ORBIT I trial, a first-in-man study, was conducted to evaluate the safety and performance of the orbital atherectomy system (OAS) in treating *de novo* calcified coronary lesions.
Methods/Materials: Fifty patients were enrolled between May and July 2008 based on several criteria, and were treated with the OAS followed by stent placement. The safety and performance of the OAS were evaluated by procedural success, device success, and overall major adverse cardiovascular event (MACE) rates, including cardiac death, myocardial infarction (MI) and need for target lesion revascularization (TLR). Our institution enrolled and treated 33 of the 50 patients and continued follow-up for 5 years.
Results: Average age was 54 years and 91% were males. Mean lesion length was 15.9 mm. Device success was 100%, and average number of orbital atherectomy devices (OAD) used per patient was 1.3. Stents were placed directly after OAS in 31/32 patients (96.9%). All stents (average stent per lesion 1.1) were successfully deployed with 0.3% residual stenosis. The overall cumulative MACE rate was 6.1% in-hospital, 9.1% at 30 days, 12.1% at 6 months, 15.2% at 2 years, 18.2% at 3 years and 21.2% at 5 years (4 total cardiac deaths). None of the patients had Q-wave MIs. Angiographic complications were observed in 5 patients. No flow/slow flow due to distal embolization was observed.
Conclusions: The ORBIT I trial suggests that OAS treatment continues to offer a safe and effective method to change compliance of calcified coronary lesions to facilitate optimal stent placement in these difficult-to-treat patients.

1. Introduction

Calcified coronary lesions are common, with 38% of all lesions showing calcification as detected by angiography and 73% of all lesions showing calcification as detected by intravascular ultrasound (IVUS) [1]. Calcific deposits are found more frequently and in greater amounts in elderly individuals and more advanced lesions [2].

Efforts to control coronary artery calcification (CAC) with medical therapy have not been successful. Despite advances in interventional equipment and techniques, the treatment of calcified coronary lesions continues to pose an ongoing challenge [3]. Calcified lesions respond poorly to balloon angioplasty, increase the likelihood of procedural failure, and are associated with a high frequency of restenosis and target lesion revascularization (TLR) [4]. Coronary calcification may impair stent delivery and expansion, and damage the polymer/drug coating, resulting in impaired drug delivery and predisposition to restenosis and stent thrombosis [5]. Attempts to remedy incomplete stent expansion with aggressive high pressure balloon dilatation may result in coronary artery rupture [6].

As a remedy to this problem, lesion preparation may be recommended to facilitate coronary stent implantation in these difficult lesions. Another goal of lesion preparation is to reduce plaque shift and allow optimal stent expansion [7]. Rotational atherectomy (RA) is one of the procedures used to modify calcified plaques and improve overall success of stent implantation, but distal embolization of debris from the procedure is a concern. The incidence of slow or no flow in these procedures has been reported to be 6% to 15% [8,9].

The Diamondback 360® Coronary Orbital Atherectomy System (OAS) (Cardiovascular Systems, Inc., St. Paul, MN), which has been used successfully to treat peripheral vascular stenosis, has also been evaluated for the treatment of calcified coronary lesions. The ORBIT I

Abbreviations: BMS, bare-metal stents; CAC, coronary artery calcification; CAD, coronary artery disease; DES, drug-eluting stents; IVUS, intravascular ultrasound; MACE, major adverse cardiovascular events; MI, myocardial infarction; OA, orbital atherectomy; OAD, orbital atherectomy device; OAS, orbital atherectomy system; PCI, percutaneous coronary intervention; RA, rotational atherectomy; SES, sirolimus-eluting stent; TLR, target lesion revascularization; ZES, zotarolimus-eluting stent.

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Table 1
Baseline characteristics of enrolled patients.

Baseline Characteristic	Observations n/N (%)
Average age (years; mean ± SD)	54.4 ± 9.1
Gender (males)	30/33 (90.9%)
Ethnicity (Asian Indian)	33/33 (100%)
Diabetes	10/33 (30.3%)
Hypertension	9/33 (27.3%)
Obesity	15/33 (45.5%)
Smoking	2/33 (6.1%)
Angina	32/33 (97.0%)
Stable angina	29/32 (90.6%)
Canadian Cardiovascular Society Angina class I	12/32 (37.5%)
Canadian Cardiovascular Society Angina class II	17/32 (53.1%)
Canadian Cardiovascular Society Angina class III	3/32 (9.4%)
Percutaneous coronary intervention history (>30 days prior to study)	5/33 (15.2%)
Coronary bypass graft surgery (prior to study)	1/33 (3.0%)

clinical trial was conducted to evaluate the safety and long-term results after OAS treatment of *de novo* calcified coronary lesions in adults. Initial, 6-month [10] and 3-year results [11] have been previously published. Here, we report on the 5-year follow-up of a subset of 33 patients enrolled at one of the participating centers.

2. Material and methods

The ORBIT I trial was a prospective, non-randomized, multi-center, feasibility study that evaluated the safety, performance and effectiveness of the OAS. A total of 50 patients were enrolled at 2 sites in India (New Delhi, n = 17; Ahmedabad, n = 33). One of the participating centers enrolled and followed 33 of these ORBIT I patients up to 5 years. Ethics committee approval was received and patients who gave written informed consent and met all inclusion and no exclusion criteria were enrolled. Inclusion and exclusion criteria have been previously described [10]. Briefly, patients with *de novo* coronary lesions with stenosis ≥50% and <100%, and at least 1 quadrant of calcification via IVUS were enrolled, and patients with prior percutaneous coronary intervention (PCI) or surgery or very recent myocardial infarction (MI) were excluded.

All procedures were performed electively and performed in the standard fashion. The procedure has been previously described [10]. Device success was defined as final achievement of ≤50% residual stenosis of the target lesion after OAS use only (before stent placement or any other adjunctive treatment), without a device malfunction. Procedural success was defined as ≤20% residual stenosis after stent placement. Change (lesion modification) was based on pre- and post-diameter stenosis of lesions treated with OAS. Patients were followed at 30 days, 3 months, 6 months, 2 years, 3 years and 5 years post-index treatment. The safety of the OAS was evaluated by procedural success, device success, and overall major adverse cardiovascular event (MACE) rates, including cardiac death, MI and need for TLR. Reporting of angiographic complications consisted of no flow or slow flow due to distal embolization, abrupt or threatened closure of the treated vessel, spasm requiring any surgical intervention (which could not be resolved via medications), dissection, perforation and other events seen angiographically.

Data collected on study specific case report forms were analyzed. Continuous variables including age, lesion characteristics, and OAS treatment parameters are presented as mean ± SD. The categorical data, including angina class, number of vessels, stents, and cumulative MACE rates are presented by frequency and percentage of patients. Adverse events were judged by the investigators as to their relatedness to the study device and treatment procedure to be "not related", "undetermined", or "related". Kaplan Meier survival probability estimates were determined. P-values were determined using GraphPad Prism Version 5.4; $p < 0.05$ was considered as statistically significant.

Table 2
Lesion characteristics.

Procedural Information	Observations n/N (%) (n = 33)
Target Vessel	
Left anterior descending	20/33 (60.6%)
Left circumflex artery	7/33 (21.2%)
Right coronary artery	6/33 (18.2%)
American College of Cardiology/American Heart Association (ACC/AHA) lesion class:	
Type A	2/33 (6.1%)
Type B1	11/33 (33.3%)
Type B2	20/33 (60.6%)
Balloon angioplasty predilation prior to IVUS	6/33 (18.2%)
Mean lesion length (mm), mean ± SD	15.9 ± 4.5
Reference vessel diameter (mm), mean ± SD	3.2 ± 0.4
Mean lumen diameter (mm), mean ± SD	1.3 ± 1.2

3. Results

A total of 33 patients, enrolled at a single center between May and July 2008, were followed for 5 years. Patient demographics have been previously reported [10] and are provided in Table 1. Lesions were classified according to the ACC/AHA system as Type A (6%), Type B1 (33%), and Type B2 (61%). Mean lesion length was 15.9 mm. Table 2 shows the lesion characteristics in details.

Procedural success (≤20% residual stenosis after stent placement) was achieved in 97% (32/33) of patients. In one subject, the IVUS catheter could not cross the lesion due to severe calcification and OAS treatment was not performed. Device success was 100% (32/32) (<50% residual stenosis after OAS use only with no device malfunction). Average number of orbital atherectomy devices (OAD) used per patient was 1.3. Stents were placed directly after OAS in 31/32 patients (96.9%). All stents (average stent per lesion 1.1) were successfully deployed with 0.3% residual stenosis. In only 1/32 patients (3.1%) was balloon angioplasty performed after OAS treatment and prior to stent placement. All post-atherectomy stents implanted were drug-eluting stents (DES) (sirolimus-eluting stent, 37.1%; zotarolimus-eluting stent, 62.9%). The pre- to post-atherectomy and post-stent placement difference in mean diameter stenosis was statistically significant ($p < 0.0001$). Table 3 presents the OAS treatment parameters and change in vessel diameter.

The observed MACE rates are as shown in Table 4. The overall cumulative MACE rate was 6.1% in-hospital (2 non-Q wave MIs), 9.1% at 30 days (1 additional non-Q-wave MI leading to TLR), 12.1% at 6 months (1 event of cardiac death), 15.2% at 2 years (1 additional event of cardiac death, 18.2% at 3 years (1 additional event of cardiac death) and 21.2% at 5 years (1 additional event of cardiac death [4 total cardiac deaths]). None of the patients had Q-wave MIs. Kaplan Meier survival probability estimates are placed in Table 4.

Angiographic complications were observed in 5 patients (2 minor dissections, 1 major dissection and 2 perforations). There was no occurrence of no flow/slow flow due to distal embolization.

Table 3
OAS treatment parameters and change in vessel diameter.

Procedural Information	Observations
Average number of OAD used per subject (n = 32), mean ± SD	1.3 ± 0.4
Average number of stents used per lesion (n = 32), mean ± SD	1.1 ± 0.3
Average stent diameter (mm) (n = 35), mean (range)	3.1 (2.5–4.0)
Average stent length (mm) (n = 35), mean (range)	22 (9–33)
Type of stent, n/N (%)	
Cypher (SES)	13/35 (37.1)
Endeavor (ZES)	22/35 (62.9)
% Diameter stenosis, mean ± SD	
Pre OAS (n = 33)	85.6 ± 7.8
Post OAS (n = 32)	39.4 ± 10.1
Post stent (n = 32)	0.3 ± 1.8
Change (lesion modification) (n = 32)	45.9 ± 11.8*

OAD: orbital atherectomy device; OAS: orbital atherectomy system; SES: sirolimus-eluting stent; ZES: zotarolimus-eluting stent.
* $p < 0.0001$.

Table 4
Cumulative MACE rates for 5 years.

	In-Hospital	30 day Follow-Up	6 month Follow-Up	2 year Follow-Up	3 year Follow-Up	5 year Follow-Up
Cardiac Death	0	0	3% (1/33)	6.1% (2/33)	9.1% (3/33)	12.1% (4/33)
Q-wave MI	0	0	0	0	0	0
Non Q-wave MI	6.1% (2/33)	6.1% (2/33)	6.1% (2/33)	6.1% (2/33)	6.1% (2/33)	6.1% (2/33)
TLR	0	3% (1/33)	3% (1/33)	3% (1/33)	3% (1/33)	3% (1/33)
MACE Rate	6.1% (2/33)	9.1% (3/33)	12.1% (4/33)	15.2% (5/33)	18.2% (6/33)	21.2% (7/33)
KM estimate	NA	1	0.99	0.98	0.97	0.96

MI: Myocardial Infarction; TLR: Target Lesion Revascularization; MACE: Major Adverse Cardiovascular Event; KM estimate: Kaplan Meier survival probability estimate.

4. Discussion

Severe coronary calcification should be considered as a marker of advanced atherosclerosis and an independent predictor of worse prognosis [12]. PCI of calcified lesions was independently predictive of adverse ischemic outcomes, including definite stent thrombosis and unplanned ischemia driven repeat revascularization within 1 year post-PCI, as compared with patients in whom all target lesions had no or only mild calcification [13].

CAC increases the likelihood of procedural failure and complications like dissection and acute vessel closure, MI, restenosis, and MACE after balloon angioplasty [14–16]. Although implantation of bare-metal stents (BMS) compared with balloon angioplasty improves acute and long term event-free survival in both calcified and noncalcified lesions, stent underexpansion, asymmetric expansion, and malapposition are frequently observed in heavily calcified lesions [3]. Several studies have shown that DES are more effective than BMS in calcified lesions [17–19]. However, data with regard to the absolute efficacy of DES in calcified lesions are conflicting [20,21].

Cutting and scoring balloons do not remove calcium. They improve vessel compliance by creating discrete incisions in the atherosclerotic plaque, enabling greater lesion expansion and reducing recoil while preventing uncontrolled dissections [22]. However, MI and vessel perforation were more common with cutting balloon atherotomy [23]. In contrast, high-speed RA ablates coronary calcium. BMS implantation after RA in calcified lesions facilitates greater acute lumen gains, although restenosis rates remained high [18,24]. DES use after RA has been associated with better long-term outcomes [25] although observational studies reported inconsistent results [26]. In the prospective, randomized ROTAXUS trial routine lesion preparation using RA did not reduce late lumen loss of DES at 9 months in complex calcified coronary lesions [27]. Rates of restenosis, TLR, definite stent thrombosis, and MACE were not significantly different between the groups. Thus, RA cannot routinely be recommended in calcified lesions if full balloon expansion is anticipated before DES. The latest PCI guidelines state that RA is a reasonable strategy in calcified lesions that are not crossable by a balloon catheter or adequately dilated before stent implantation (Class IIa, Level of Evidence: C) [6].

Orbital atherectomy (OA) produces a differential sanding effect on plaque surfaces, producing 2 μm particles in average [28]. This recently U.S. Food and Drug Administration-approved system consists of a diamond-coated crown, which rotates over the atherectomy guidewire as it orbits around the vessel, exerting a centrifugal force on the vessel wall. The device allows control of ablation depth, with increasing rotational speed (ranging from 60,000 to 120,000 rpm) translating to a larger orbit of rotation, besides allowing greater blood flow with less heat generation and thermal injury during the procedure. In contrast to RA, it is an abrasive burr that rotates concentrically on the guidewire.

Treatment of challenging calcified lesions often leads to increased MACE rates as the lesions are more complex and difficult to treat. In the ROTAXUS study, the MACE rate for calcified lesions treated with RA and DES was approximately 24% at 9 months [27]. In contrast, this subset of the ORBIT I trial demonstrated that patients with calcified coronary artery lesions treated with OAS and stent placement had lower MACE rates with up to 5 years of follow-up (9.1% at 30 days, 12.1% at 6 months, 15.2% at 2 years, 18.2% at 3 years and 21.2% at 5 years). The MACE rates for this study subset are also less than the MACE rates reported in the few DES trials that have included moderate and severely calcified lesion [29,30]. The ORBIT II prospective, multi-center clinical trial of 443 patients using OA was completed in the United States. In the ORBIT II the MACE rate was 10.4% at 30 days, [31] and 16.4% at 1 year [32]. Future long-term outcome studies need to be planned to evaluate the optimal technique for OA use and to determine whether routine use of OA before current-generation DES improves outcomes in high-risk patients with CAC.

5. Conclusions

In patients undergoing PCI of heavily calcified lesions, optimized methods of lesion preparation and calcium ablation are needed. The ORBIT I trial, a clinical pilot study, suggests that the OAS treatment may offer effective method to modify calcified coronary lesion compliance to facilitate optimal stent placement in these difficult-to-treat patients with acceptable levels of safety up to 5 years post-index procedure.

6. Study limitations

This trial has several limitations, which have been previously described [10,11]. The ORBIT I trial was designed as a feasibility study and, therefore, lacked a control group for comparison. Other key limitations are that this subset included a small number of patients treated with OAS at a single center and the lack of core lab adjudication in this pilot study. As with any new technology, a learning curve is present. Long-term follow-up has been conducted on subjects of a single site only. Additional experience may reduce the incidence of intra-procedural complications.

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References

[1] Mintz GS, Popma JJ, Pichard AD, Kent KM, Satler LF, Chuang YC, et al. Patterns of calcification in coronary artery disease. A statistical analysis of intravascular ultrasound and coronary angiography in 1155 lesions. Circulation 1995;91:1959–65.
[2] McClelland RL, Chung H, Detrano R, Post W, Kronmal RA. Distribution of coronary artery calcium by race, gender, and age: results from the Multi-Ethnic Study of Atherosclerosis (MESA). Circulation 2006;113:30–7.
[3] Madhavan MV, Tarigopula M, Mintz GS, Maehara A, Stone GW, Genereux P. Coronary artery calcification: pathogenesis and prognostic implications. J Am Coll Cardiol 2014;63:1703–14.
[4] Onuma Y, Tanimoto S, Ruygrok P, Neuzner J, Piek JJ, Seth A, et al. Efficacy of everolimus eluting stent implantation in patients with calcified coronary culprit lesions: two-year angiographic and three-year clinical results from the SPIRIT II study. Catheter Cardiovasc Interv 2010;76:634–42.
[5] Tsutsumi J, Ishikawa T, Nakano Y, Yoshimura M, Mutoh M. Long-term clinical and angiographic outcomes after sirolimus- and paclitaxel-eluting stent placement following rotablation for severely calcified lesions: a retrospective nonrandomized study. Cardiovasc Interv Ther 2015;30:29–37.
[6] Levine GN, Bates ER, Blankenship JC, Bailey SR, Bittl JA, Cercek B, et al. 2011 ACCF/AHA/SCAi guideline for percutaneous coronary intervention. 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. J Am Coll Cardiol 2011;58:e44-122.
[7] Moses JW, Carlier S, Moussa I. Lesion preparation prior to stenting. Rev Cardiovasc Med 2004;5(Suppl. 2):S16–21.
[8] Matsuo H, Watanabe S, Watanabe T, Warita S, Kojima T, Hirose T, et al. Prevention of no-reflow/slow-flow phenomenon during rotational atherectomy—a prospective randomized study comparing intracoronary continuous infusion of verapamil and nicorandil. Am Heart J 2007;154:994.e1–6.
[9] Kume T, Okura H, Kawamoto T, Akasaka T, Toyota E, Neishi Y, et al. Assessment of the histological characteristics of coronary arterial plaque with severe calcification. Circ J 2007;71:643–7.
[10] Parikh K, Chandra P, Choksi N, Khanna P, Chambers J. Safety and feasibility of orbital atherectomy for the treatment of calcified coronary lesions: the ORBIT I trial. Catheter Cardiovasc Interv 2013;81:1134–9.
[11] Bhatt P, Parikh P, Patel A, Chag M, Chandarana A, Parikh R, et al. Orbital atherectomy system in treating calcified coronary lesions: 3-year follow-up in first human use study (ORBIT I trial). Cardiovasc Revasc Med 2014;15:204–8.
[12] Bourantas CV, Zhang YJ, Garg S, Iqbal J, Valgimigli M, Windecker S, et al. Prognostic implications of coronary calcification in patients with obstructive coronary artery disease treated by percutaneous coronary intervention: a patient-level pooled analysis of 7 contemporary stent trials. Heart 2014;100:1158–64.
[13] Genereux P, Madhavan MV, Mintz GS, Maehara A, Palmerini T, Lasalle L, 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 ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) TRIALS. J Am Coll Cardiol 2014;63:1845–54.
[14] Savage MP, Goldberg S, Hirshfeld JW, Bass TA, MacDonald RG, Margolis JR, et al. Clinical and angiographic determinants of primary coronary angioplasty success. M-HEART Investigators. J Am Coll Cardiol 1991;17:22–8.
[15] Tan K, Sulke N, Taub N, Sowton E. Clinical and lesion morphologic determinants of coronary angioplasty success and complications: current experience. J Am Coll Cardiol 1995;25:855–65.
[16] Ambrosini V, Sorropago G, Laurenzano E, Golino L, Casafina A, Schiano V, et al. Early outcome of high energy Laser (Excimer) facilitated coronary angioplasty ON hARD and complex calcified and balloOn-resistant coronary lesions: LEONARDO Study. Cardiovasc Revasc Med 2015. http://dx.doi.org/10.1016/j.carrev.2015.02.002 [pii: S1553-8389(15)00036-6, Epub ahead of print].
[17] Seo A, Fujii T, Inoue T, Onoda S, Koga A, Tanaka Y, et al. Initial and long-term outcomes of sirolimus-eluting stents for calcified lesions compared with bare-metal stents. Int Heart J 2007;48:137–47.
[18] Khattab AA, Otto A, Hochadel M, Toelg R, Geist V, Richardt G. Drug-eluting stents versus bare metal stents following rotational atherectomy for heavily calcified coronary lesions: late angiographic and clinical follow-up results. J Interv Cardiol 2007;20:100–6.
[19] Zhang BC, Wang C, Li WH, Li DY. Clinical outcome of drug-eluting versus bare-metal stents in patients with calcified coronary lesions: a meta-analysis. Intern Med J 2015;45:203–11.
[20] Shimada Y, Kataoka T, Courtney BK, Morino Y, Bonneau HN, Yock PG, et al. Influence of plaque calcium on neointimal hyperplasia following bare metal and drug-eluting stent implantation. Catheter Cardiovasc Interv 2006;67:866–9.
[21] Kubota T, Ishikawa T, Nakano Y, Endoh A, Suzuki T, Sakamoto H, et al. Retrospective comparison of clinical and angiographic outcomes after sirolimus-eluting and bare-metal stent implantation in 312 consecutive, nonrandomized severely calcified lesions using a rotablator. Int Heart J 2011;52:65–71.
[22] Barath P, Fishbein MC, Vari S, Forrester JS. Cutting balloon: a novel approach to percutaneous angioplasty. Am J Cardiol 1991;68:1249–52.
[23] Bittl JA, Chew DP, Topol EJ, Kong DF, Califf RM. Meta-analysis of randomized trials of percutaneous transluminal coronary angioplasty versus atherectomy, cutting balloon atherotomy, or laser angioplasty. J Am Coll Cardiol 2004;43:936–42.
[24] Moussa I, Di Mario C, Moses J, Reimers B, Di Francesco L, Martini G, et al. Coronary stenting after rotational atherectomy in calcified and complex lesions. Angiographic and clinical follow-up results. Circulation 1997;96:128–36.
[25] Mezilis N, Dardas P, Ninios V, Tsikaderis D. Rotablation in the drug eluting era: immediate and long-term results from a single center experience. J Interv Cardiol 2010;23:249–53.
[26] Tomey MI, Kini AS, Sharma SK. Current status of rotational atherectomy. J Am Coll Cardiol Intv 2014;7:345–53.
[27] Abdel-Wahab M, Richardt G, Joachim Buttner H, Toelg R, Geist V, Meinertz T, 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. J Am Coll Cardiol Intv 2013;6:10–9.
[28] Adams GL, Khanna PK, Staniloae CS, Abraham JP, Sparrow EM. Optimal techniques with the Diamondback 360 degrees System achieve effective results for the treatment of peripheral arterial disease. J Cardiovasc Transl Res 2011;4:220–9.
[29] Mosseri M, Satler LF, Pichard AD, Waksman R. Impact of vessel calcification on outcomes after coronary stenting. Cardiovasc Revasc Med 2005;6:147–53.
[30] Clavijo LC, Steinberg DH, Torguson R, Kuchulakanti PK, Chu WW, Fournadjiev J, et al. Sirolimus-eluting stents and calcified coronary lesions: clinical outcomes of patients treated with and without rotational atherectomy. Catheter Cardiovasc Interv 2006;68:873–8.
[31] Chambers JW, Feldman RL, Himmelstein SI, Bhatheja R, Villa AE, Strickman NE, 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). J Am Coll Cardiol Intv 2014;7:510–8.
[32] Chambers JW, Genereux P, Young C, Mann M, Garrison L. Diamondback 360° coronary orbital atherectomy system for treating de novo, severely calcified lesions: ORBIT II 1-year results and cost comparison to a sample of Medicare hospital claims. Presented at SCAI; 2014.