Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Novel Micro Crown Orbital Atherectomy for Severe Lesion Calcification

Coronary Orbital Atherectomy System Study (COAST)

Björn Redfors, MD, PhD; Samin K. Sharma, MD; Shigeru Saito, MD; Annapoorna S. Kini, MD; Arthur C. Lee, MD; Jeffrey W. Moses, MD; Ziad A. Ali, MD, DPhil; Robert L. Feldman, MD; Rohit Bhatheja, MD; Gregg W. Stone, MD

BACKGROUND: Percutaneous coronary intervention of severely calcified lesions carries a high risk of adverse events despite the use of contemporary devices. The Classic Crown Orbital Atherectomy System (OAS) was safe and effective for severely calcified lesion preparation in the ORBIT II study (Evaluate the Safety and Efficacy of OAS in Treating Severely Calcified Coronary Lesions) but was not optimized for tight lesions. COAST (Coronary Orbital Atherectomy System Study) evaluated the safety and efficacy of calcified lesion preparation before stent implantation with the Diamondback 360 Micro Crown Coronary OAS, designed for use in tighter lesions.

METHODS: COAST was a prospective, multicenter, single-arm study that enrolled 100 patients with severely calcified de novo coronary lesions at 17 sites in the United States and Japan. The primary effectiveness end point was procedural success, defined as stent delivery with residual stenosis <50% without in-hospital major adverse cardiac events (MACE), and the primary safety end point was freedom from MACE (composite of cardiac death, myocardial infarction, or target vessel revascularization) at 30 days.

RESULTS: The OAS Micro Crown was inserted in all patients. A stent was delivered with a residual stenosis <50% in all except one patient (99.0%). Procedural success was achieved in 85 (85.0%) subjects versus 391 (88.9%) in ORBIT II (P=0.30), and freedom from MACE at 30 days was achieved in 85.0% versus 89.6% in ORBIT II (P=0.21). Freedom from MACE was 77.8% at 1 year.

CONCLUSIONS: Prestent preparation of severely calcified lesions using the novel Micro Crown OAS resulted in similar rates of procedural success and freedom from MACE compared with the Classic Crown OAS.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.

REGISTRATION: URL: https://www.clinicaltrials.gov. Unique identifier: NCT02132611.

Key Words: atherectomy ■ percutaneous coronary intervention ■ safety ■ stents

Percutaneous coronary intervention (PCI) of calcified lesions is increasingly common and is associated with high rates of adverse ischemic events despite the use of contemporary techniques and devices.[1–7] Stent implantation in calcified lesions may result in failure to deliver the stent[1] and is often suboptimal due to inadequate or asymmetrical stent expansion[8] or procedural complications such as vessel dissection.[9] Furthermore, extensive calcium can damage the polymer coating of drug-eluting stents, thereby reducing their

Correspondence to: Gregg W. Stone, MD, Mount Sinai Healthcare System, Cardiovascular Research Foundation, 1700 Broadway, 9th Floor, New York, NY 10019. Email gregg.stone@mountsinai.org

The Data Supplement is available at https://www.ahajournals.org/doi/suppl/10.1161/CIRCINTERVENTIONS.120.008993.

For Sources of Funding and Disclosures, see page 8.

WHAT IS KNOWN

- Percutaneous coronary intervention of severely calcified lesions carries a high risk of adverse events despite the use of contemporary devices.
- The Classic Crown orbital atherectomy system (OAS) was safe and effective for severely calcified lesion preparation in the ORBIT II study (Evaluate the Safety and Efficacy of OAS in Treating Severely Calcified Coronary Lesions) but was not optimized for tight lesions.

WHAT THE STUDY ADDS

- Prestent preparation of severely calcified lesions using the novel Micro Crown OAS resulted in similar rates of procedural success and freedom from major adverse cardiac events compared with the Classic Crown OAS.
- With the completion of COAST (Coronary Orbital Atherectomy System Study), prospectively collected and centrally adjudicated clinical outcomes data are now available for OAS use in severely calcified lesions in ≈550 patients from 2 multicenter studies. Despite the lack of randomization, the results with OAS compare favorably to those observed with alternative treatment strategies.

Nonstandard Abbreviations and Acronyms

COAST	Coronary Orbital Atherectomy System Study
IVUS	intravascular ultrasound
MACE	major adverse cardiac events
OAS	Orbital Atherectomy System
OCT	optical coherence tomography
ORBIT II	Evaluate the Safety and Efficacy of OAS in Treating Severely Calcified Coronary Lesions
PCI	percutaneous coronary intervention

effectiveness.[10] Previous dedicated devices for prestent preparation of calcified lesions, such as rotational atherectomy, have not been shown in randomized trials to reduce the risk of adverse events or improve long-term outcomes after PCI of calcified lesions.[1,2]

The orbital atherectomy system (OAS; Cardiovascular Systems, Inc, St Paul, MN) uses a diamond-coated eccentric crown that rotates in an expanding lateral direction with increasing centrifugal force resulting in a differential sanding of coronary calcification. The ORBIT II trial (Evaluate the Safety and Efficacy of OAS in Treating Severely Calcified Coronary Lesions) was a single-arm, multicenter study that demonstrated high procedural success rates and relatively low rates of 30-day and 2-year adverse events among 443 patients with severely calcified lesions who had prestent lesion preparation using the Classic Crown OAS.[11,12] However, the relatively high profile of the advancing edge of the Classic Crown may make passage through tight lesions challenging. The novel Diamondback 360 Coronary OAS Micro Crown, which can access tight (0.5 mm) lesions and produce similar output (outward force) at a lower rotational speed (thereby minimizing thermal injury), was developed to address this limitation. COAST (Coronary Orbital Atherectomy System Study) was designed to assess the safety and effectiveness of the Micro Crown OAS in patients with severely calcified coronary lesions before stent implantation and served as the United States and Japan preapproval study for this device.

METHODS

Device Description

The Diamondback 360 Coronary OAS Micro Crown is a catheter-based system that is designed for facilitating stent delivery in patients with calcified coronary artery lesions. Like the original Classic Crown, the OAS Micro Crown uses an orbiting, diamond-coated crown to reduce luminal plaque burden (Figure 1).[11,13,14] The same design principles and mechanism of action of the OAS Classic Crown apply to the OAS Micro Crown.[11,13] The 2 primary design objectives for the OAS Micro Crown design were (1) to enhance its ability to traverse tighter lesions and (2) to produce an orbit similar to that of the Classic Crown device but at lower speeds (low and high speeds of 50/80 versus 80/120 krpm), thereby reducing the potential for thermal injury. The Table in the Data Supplement summarizes the design characteristics that were incorporated to meet these objectives.

Study Design

COAST was a prospective, single-arm, multicenter study designed to provide data on the safety and effectiveness of the OAS Micro Crown. COAST was conducted in the United States and Japan under the United States–Japan Medical Device Harmonization by Doing program.[15] The study was approved by the institutional review board at each participating hospital. An independent angiographic core laboratory (Cleveland Clinic, Cleveland, OH) adjudicated postprocedure minimal lumen diameter and postprocedure diameter stenosis for all patients. All other angiographic variables are presented as reported by the investigators. The study was sponsored by Cardiovascular Systems, Inc. The sponsor participated in site selection and management and in data analysis. The first and senior author had unrestricted access to the data, wrote the article, and vouch for the accuracy and completeness of the data and analyses. The data, analytic methods, and study materials are proprietary to the sponsor and at this time are not available to nonstudy participants.

The enrollment criteria were designed to be similar to the ORBIT II study.[11] Men and women at least 18 years of age who had a clinical indication for PCI of a single de novo, severely calcified coronary lesion were enrolled in the study if they met study eligibility criteria and provided written informed consent.

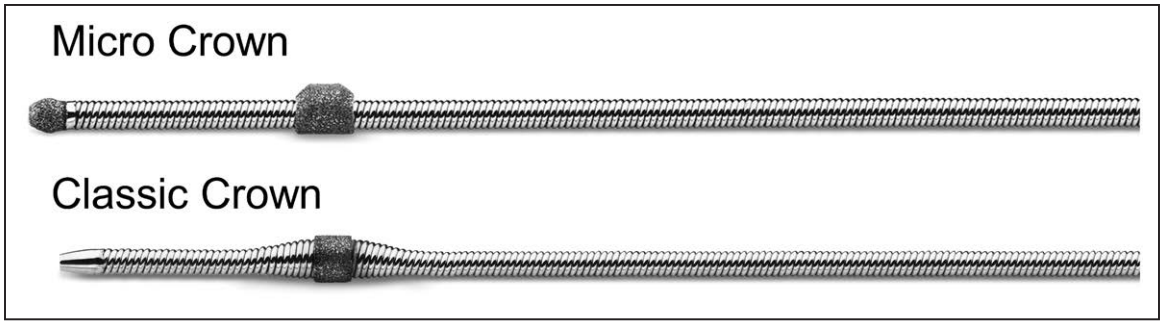

Figure 1. The Diamondback 360 Micro Crown and Classic Crown Orbital Atherectomy Systems.
The size of the diamond-coated crown is 1.25 mm for both devices, but the diamond-coated distal tip allows the second generation Micro Crown Orbital Atherectomy System (**top**) to more easily traverse a 0.5 mm diameter channel, representing a 60% reduction in the minimum lesion size the device is able to treat compared with the previous Classic Crown device (**bottom**). Other design characteristics incorporated into the Micro Crown are described in the Table in the Data Supplement.

Key inclusion criteria included: (1) target vessel reference diameter ≥2.5 and ≤4.0 mm with lesion length ≤40 mm and a stenosis ≥70% and <100%, or ≥50% and <70% with evidence of ischemia, defined as a positive stress test, fractional flow reserve ≤0.8, or intravascular ultrasound (IVUS) or optical coherence tomography (OCT) minimum lumen area ≤4.0 mm^2; (2) Thrombolysis in Myocardial Infarction flow grade 3 at baseline; and (3) fluoroscopic, IVUS, or OCT evidence of severe target lesion calcification. Severe fluoroscopic calcium was defined as the presence of radiopacities noted without cardiac motion before contrast injection, involving both sides of the arterial wall in at least one location, with a total length of ≥15 mm and partially extending into the target lesion. IVUS or OCT evidence of severe calcification was defined as the presence of ≥270° of calcium in at least one cross-section. Key exclusion criteria were (1) previous implantation of a stent in the target vessel unless the stent was implanted in a different branch than the target lesion and was implanted >30 days before with ≤30% in-stent restenosis; (2) recent myocardial infarction (within 30 days); (3) chronic renal failure unless on hemodialysis; and (4) left ventricular ejection fraction ≤25%.

Following treatment with the Micro Crown, PCI and stent implantation were completed per standard of care. The use of thrombectomy, embolic protection devices, brachytherapy, or cutting balloons was not allowed. There were no study-specific mandated medications. Clinical follow-up was performed at 30 days and 1 year. The trial was registered on the National Institutes of Health website.

End Points and Definitions

The end points were identical to those from the ORBIT II study. The primary effectiveness end point was procedural success, defined as stent delivery with a residual stenosis of <50% without the occurrence of an in-hospital major adverse cardiac event (MACE, defined as the composite of cardiac death, myocardial infarction, or target vessel revascularization). The primary safety end point was freedom from MACE at 30 days. Myocardial infarction was defined as a creatine kinase-myocardial band level >3× the upper limit of normal. Target vessel revascularization was defined as any repeat revascularization of the target vessel (including the target lesion). Angiographic success was defined as success in facilitating stent delivery with a residual stenosis <50% and without severe angiographic complications, including severe dissection (types C through F), perforation, persistent slow flow or no reflow, or abrupt closure.

Statistical Analysis

Continuous variables are presented as mean ± SD and were compared using 2-sample Wilcoxon test; categorical variables are reported as percentage and were compared using the Fisher exact test. Cumulative event rates were assessed using Kaplan-Meier methodology. The Kaplan-Meier product-limit method was used for analysis of the primary safety end point. The proportion of subjects who met the primary effectiveness end point was assessed as a simple proportion, with the 95% CI calculated as Clopper-Pearson Exact confidence intervals.

For the present study, the assumed procedural success rate was 84%, the same procedural success rate assumed for the primary effectiveness event in the ORBIT II study. The assumed 30-day MACE rate was 12%, the same event rate assumed for the primary safety end point in the ORBIT II study. The proportion of subjects who met the primary efficacy and safety end points were compared between COAST and ORBIT II using the Fisher exact test and Cox proportional hazards regression. However, the present study was not powered for statistical hypothesis testing. Statistical analyses were performed using SAS software (SAS Institute Inc, Cary, NC) and R (R Cove Team 2012, R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Patient and Lesion Characteristics

The COAST study enrolled 100 patients; 74 were recruited from the United States at 12 different sites and 26 were recruited from Japan at 5 different sites. The study population was high risk, with modest differences from ORBIT II (Table 1). Angiographic characteristics are presented in Table 2. Compared with patients enrolled in ORBIT II, COAST patients were more likely to have lesions of American College of Cardiology/American Heart Association class B2 or C (84.0% versus 74.1%, P=0.04) but had slightly larger vessels. Compared with patients in ORBIT II, patients in COAST more commonly qualified with severe calcification by

Table 1. Baseline Clinical Characteristics

	COAST (N=100)	ORBIT II (N=443)	*P* Value
Age, y	70.7±10.1	71.4±9.9	0.54
Female	29 (29.0%)	157 (35.4%)	0.24
Body mass index, kg/m^2	27.2±6.1	29.4±6.0	0.001
Diabetes mellitus	38 (38.0%)	160 (36.1%)	0.73
Smoking			
Current	12 (12.0%)	75 (16.9%)	0.29
Former	61 (61.0%)	218 (49.2%)	0.04
Estimated GFR,* mL/min/1.73 m^2	70.9±35.1	75.8±26.2	0.33
Hyperlipidemia	84 (84.0%)	407/442 (92.1%)	0.02
Hypertension	95 (95.0%)	406 (91.6%)	0.31
Prior transient ischemic attack or stroke	10 (10.0%)	39/442 (8.8%)	0.70
Prior myocardial infarction	22 (22.0%)	99/438 (22.6%)	0.99
Prior PCI	38 (38.0%)	205/439 (46.7%)	0.12
Prior coronary artery bypass grafting	11 (11.0%)	65 (14.7%)	0.43
Prior angina pectoris	89 (89.0%)	348 (78.6%)	0.02
Stable angina	50/89 (56.2%)	223/348 (64.1%)	0.18
Unstable angina	39/89 (43.8%)	125/348 (35.9%)	0.18
Left ventricular ejection fraction, %	58.1±10.3	56.6±9.6	0.25

Values are n/N (%) or mean ± SD. COAST indicates Coronary Orbital Atherectomy System Study; GFR, glomerular filtration rate; ORBIT II, Evaluate the Safety and Efficacy of OAS in Treating Severely Calcified Coronary Lesions; and PCI, percutaneous coronary intervention.

*GFR, calculated with the Modification of Diet in Renal Disease Study Group (MDRD) study equation (National Kidney Foundation) formula.

intravascular imaging, predominantly due to more frequent use of IVUS at Japanese versus US sites (17/26 [65.4%] Japanese patients in COAST versus 4/74 [5.4%] US subjects in COAST and 35/440 [8.0%] patients in ORBIT II [all United States]). In addition, OCT was used in 14 (14%) of COAST patients versus 0% in ORBIT II.

Procedural Results and Outcomes

Procedural results and parameters are presented in Table 3. Low speed runs were more common with the Micro Crown in COAST than with the Classic Crown in ORBIT II and fewer devices were used per patient, although the total device time was somewhat greater. However, total procedure time and contrast volume were lower in COAST compared with ORBIT II. Ninety-nine of the 100 enrolled subjects (99.0%) had successful stent delivery and a residual stenosis <50%. Core laboratory-determined postprocedure minimal lumen diameter and postprocedure residual stenosis were 2.78±0.53 mm and 4.2±13.1% in COAST versus 2.87±0.53 mm and 4.7±14.2% in ORBIT II (*P*=0.17 and *P*=0.79, respectively).

The primary effectiveness end point of procedural success was 85.0% in COAST and 88.9% in ORBIT II (*P*=0.30; Table 4). Angiographic success was achieved in 92.0% of patients, with 7.0% having one or more severe angiographic complication, including 2 patients with perforations. Covered stents were used in 3 patients. In-hospital MACE occurred in 14 subjects (14.0%).

The observed rate of the primary safety end point (freedom from MACE at 30) days was 85.0% in COAST versus 89.6% in ORBIT II (hazard ratio 1.45 [95% CI, 0.81–2.59], *P*=0.21; Table 5 and Figure 2). The rate of freedom from MACE at 1 year was 77.8% (95% CI, 69.6%–86.1%) also not significantly different from that observed in ORBIT II (83.1% [95% CI, 79.6%–86.7%], *P*=0.22). The 1-year rate of myocardial infarction was 13.0% in COAST and 9.3% in ORBIT II (*P*=0.27).

Outcomes in the United States and Japan

The primary effectiveness end point was met is a similar proportion of patients enrolled at US and Japanese sites (83.8% versus 88.5%, *P*=0.75). The proportion of subjects who met the primary safety end point was also similar for the 2 countries (85.1% versus 84.6% respectively, *P*=0.93).

DISCUSSION

In the United States and Japan preapproval COAST study, the novel Diamondback 360 Coronary Micro Crown OAS had similar procedural results and clinical outcomes compared with the original Classic Crown OAS when used for prestent plaque modification of severely calcified lesions.

Table 2. Angiographic Characteristics

	COAST (N=100)	ORBIT II (N=440)	*P* Value
Target vessel			0.13
Left anterior descending coronary artery	62 (62.0%)	227 (51.6%)	
Left circumflex coronary artery	6 (6.0%)	64 (14.5%)	
Left main coronary artery	1 (1.0%)	10 (2.3%)	
Right coronary artery	30 (30.0%)	132 (30.0%)	
Ramus intermedius	1 (1.0%)	7 (1.6%)	
ACC/AHA lesion classification			0.02
A	2 (2.0%)	0 (0.0%)	
B1	14 (14.0%)	114 (25.9%)	
B2	48 (48.0%)	197 (44.8%)	
C	36 (36.0%)	129 (29.3%)	
Target lesion length, mm	21.4±8.6	18.9±8.9	0.005
Target lesion reference vessel diameter, mm	3.18±0.37	3.09±0.41	0.01
Target lesion minimal lumen diameter, mm	0.49±0.28	0.49±0.29	0.72
Target lesion percent stenosis, %	84.7±8.8	84.4±9.0	0.82
Calcification determined by angiography only	65 (65.0%)	405 (92.0%)	<0.001
Total length of CAC, mm	24.0±9.3	28.6±15.5	0.064
CAC visible on both sides of the vessel	65/65 (100.0%)	405/405 (100.0%)	…
Subjects with CAC determined by IVUS	21 (21.0%)	35 (8.0%)	<0.001
IVUS maximum arc of CAC, °	318.6±41.9	295.0±36.3	0.04
Subjects with CAC determined by OCT	14 (14.0%)	…	…
OCT maximum degree of CAC, °	304.6±38.8	…	…

As reported by the participating sites. Values are n/N (%) or mean ± SD. ACC indicates American College of Cardiology; AHA, American Heart Association; CAC, coronary arterial calcification; COAST, Coronary Orbital Atherectomy System Study; IVUS, intravascular ultrasound; OCT, optical coherence tomography; and ORBIT II, Evaluate the Safety and Efficacy of OAS in Treating Severely Calcified Coronary Lesions.

Compared with the Classic Crown OAS, the Micro Crown OAS retains the same mechanism of action but was designed to facilitate crossing of tighter lesions while using lower rotational speeds. A single sized crown may thus be used in a greater proportion of severely calcified lesions, and the hypothetical risk of thermal injury is minimized. In the present study fewer crowns were required with the Micro Crown compared with the Classic Crown for treatment of similar lesions and rotational speeds were substantially lower, perhaps contributing to reduced contrast volume and procedural times despite the need for longer device run times. The 30-day MACE rate was 15.0% in COAST compared with 10.4% in ORBIT II. While this difference was not significant (P=0.21), the present study was not powered to detect small differences between the 2 OAS. In addition, improvements in procedural success with the Micro Crown may principally be evidenced in very tight heavily calcified lesions, and a large randomized trial would be required to determine whether the lower rotational speeds of the Micro Crown compared with the Classic Crown result in greater freedom from stent thrombosis or clinical restenosis in certain lesion subtypes.

The present trial was also not designed to afford direct comparisons of OAS with high-speed rotational atherectomy, although such comparisons are inevitable. In this regard, the incidence of slow/no reflow and type C to F dissections were lower than what has been observed after preparation of severely calcified lesion using rotational atherectomy.[16–19] In contrast to rotational atherectomy, which uses a concentric burr that does not allow blood and particulate debris to pass during atheroablation, the elliptical orbit of the OAS allows passage of micro particles during crown activation, thus cooling the crown and theoretically reducing the risk of injury to the vessel wall.[11,13] Rotational speed of OAS is also lower than rotablation, potentially reducing platelet activation and thermal injury.[20,21] The ablated particles produced by OAS are also smaller in size and may be more efficiently cleared by the reticuloendothelial system, thus reducing slow and no reflow and periprocedural myocardial infarction.[11,13,22,23] However, large-scale randomized trials of OAS and rotational atherectomy are required to determine whether these differences result in meaningful clinical improvements.

With the completion of COAST, prospectively collected and centrally adjudicated contemporary clinical outcomes data are now available for OAS use in severely calcified lesions in ≈550 patients from 2 multicenter studies. Despite the lack of randomization, the results with OAS compare favorably to those observed with alternative treatment strategies. In prior studies PCI of

Table 3. Procedural Characteristics

	COAST (N=100)	ORBIT II (N=440)	*P* Value
Pre-OAS balloon dilatation	2 (2.0%)	8 (1.8%)	0.99
Subjects treated with OAS	99 (99.0%)	432 (98.2%)	0.70
OAS devices used per patient	1.0±0.0	1.1±0.2	0.01
Device speed used			<0.001
Low only*	47/99 (47.5%)	93/432 (21.5%)	
Low* and high†	52/99 (52.5%)	317/432 (73.4%)	
High only†	0/99 (0.0%)	22/432 (5.1%)	
Total device run time, s	82±56	67±46	0.003
Post-OAS/prestent balloon dilatation	76 (76.0%)	181 (41.1%)	<0.001
Maximum inflation pressure, atm	13.1±3.9	12.1±3.9	0.056
Stent implanted	99 (99.0%)	432 (98.2%)	0.99
Number of stents per patient	1.24±0.50	1.26±0.56	0.89
Bare metal	10/123 (8.1%)	62/543 (11.4%)	0.34
Covered	3/123 (2.4%)	2/543 (0.4%)	0.045
Drug-eluting	110/123 (89.4%)	479/543 (88.2%)	0.88
Maximum deployment pressure, atm	13.6±2.8	13.8±3.2	0.47
Poststent balloon dilatation	57 (57.0%)	227 (51.6%)	0.38
Postprocedure minimal lumen diameter,‡ mm	2.78±0.53	2.87±0.53	0.17
Postprocedure residual stenosis,‡ %	4.2±13.1	4.7±14.2	0.79
Total procedure time, min	45.0±27.4	52.5±29.6	0.008
Fluoroscopy time, min	17.5±10.5	18.2±12.3	0.76
Total contrast volume, mL	145.4±72.5	173.9±86.4	0.001

Values are n/N (%) or mean ± SD. COAST indicates Coronary Orbital Atherectomy System Study; OAS, orbital atherectomy system; and ORBIT II, Evaluate the Safety and Efficacy of OAS in Treating Severely Calcified Coronary Lesions.

*50 krpm for the Micro Crown and 80 krpm for the Classic Crown.

†80 krpm for the Micro Crown and 120 krpm for the Classic Crown.

‡Core laboratory determination.

severely calcified lesions after lesion preparation with balloon angioplasty alone was associated with considerably higher rates of ischemic events than observed in COAST and ORBIT II.[3–7] Ischemic event rates were also higher in both the rotational atherectomy and balloon only arms of the ROTAXUS trial (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease), despite the fact that in this

Table 4. Primary Effectiveness and Angiographic Outcomes

	COAST (N=100)	ORBIT II (N=440*)	*P* Value
Procedural success†	85 (85.0%)	391 (88.9%)	0.30
Residual stenosis ≥50%	1 (1.0%)	6 (1.4%)	0.12
Severe angiographic complication, any	7 (7.0%)	32 (7.2%)	0.99
Severe dissection‡	2 (2.0%)	15 (3.4%)	0.75
Perforation	2 (2.0%)	8 (1.8%)	0.99
Persistent slow flow/no reflow	2 (2.0%)	4 (0.9%)	0.31
Abrupt closure	3 (3.0%)	8 (1.8%)	0.43
In-hospital major adverse cardiac event	14 (14.0%)	43 (9.8%)	0.21
Cardiac death	1 (1.0%)	1 (0.2%)	0.34
Myocardial infarction	13 (13.0%)	41 (9.3%)	0.27
Target vessel revascularization	0 (0.0%)	3 (0.7%)	0.99

Values are n/N (%). COAST indicates Coronary Orbital Atherectomy System Study; and ORBIT II, Evaluate the Safety and Efficacy of OAS in Treating Severely Calcified Coronary Lesions.

*Three patients had the guidewire cross the lesion, but the orbital atherectomy device was never inserted. These 3 patients were included in the primary safety end point analysis (Table 5) but not for the primary effectiveness end point (Table 4).

†Stent delivery with a residual stenosis of <50% without the occurrence of in-hospital major adverse cardiac events (cardiac death, myocardial infarction, or target vessel revascularization).

‡Type C, D, E, or F dissection.

Table 5. Major Adverse Cardiac Event Rates at 30 Days and 1 Year

	COAST (N=100)	ORBIT II (N=443)	*P* Value
30 days			
Major adverse cardiac events	15.0% (15)	10.4% (46)	0.21
Cardiac death	1.0% (1)	0.2% (1)	0.29
Myocardial infarction	14.0% (14)	9.7% (43)	0.24
Q-wave	2.0% (2)	0.9% (4)	0.12
Target vessel revascularization	1.0% (1)	1.4% (6)	0.78
Target lesion revascularization	1.0% (1)	0.7% (3)	0.74
Definite or probable stent thrombosis	0% (0)	0.2% (1)	…
1 year			
Major adverse cardiac events	22.2% (22)	16.9% (74)	0.22
Cardiac death	1.0% (1)	3.2% (14)	0.27
Myocardial infarction	14.0% (14)	10.6% (47)	0.36
Q-wave	2.0% (2)	0.9% (4)	0.12
Target vessel revascularization	9.4% (9)	5.8% (25)	0.21
Target lesion revascularization	6.3% (6)	4.7% (20)	0.53
Definite or probable stent thrombosis	0% (0)	0.2% (1)	…

Values are Kaplan-Meier failure % (events). COAST indicates Coronary Orbital Atherectomy System Study; and ORBIT II, Evaluate the Safety and Efficacy of OAS in Treating Severely Calcified Coronary Lesions.

trial only ≈50% of the lesions were severely calcified.[1,2] However, the extent to which these differences are due to the atherectomy platform versus varying stent types and other patient- and technique-related differences is unknown, particularly in light of comparative data from 2 large registries that found no significant difference in procedural[24] or short-term clinical outcomes[25] after OAS versus rotational atherectomy. Comparative randomized trials are warranted to elucidate differences in procedural safety, effectiveness, and long-term outcomes between these devices.

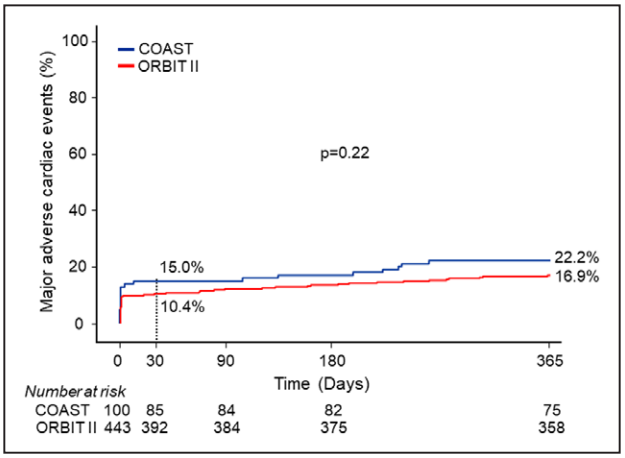

Figure 2. One-year Kaplan-Meier failure rate for the primary safety end point.
Major adverse cardiac events, defined as the composite of cardiac death, myocardial infarction, or target vessel revascularization, occurred in 15.0% of patients at 30 d and in 22.2% of patients at 1 y in patients with heavily calcified lesions treated with the Micro Crown orbital atherectomy system followed by percutaneous coronary intervention (PCI) in the COAST study (Coronary Orbital Atherectomy System Study) or with the Classic Crown orbital atherectomy system followed by PCI in the ORBIT II study (Evaluate the Safety and Efficacy of OAS in Treating Severely Calcified Coronary Lesions).

Limitations

The most important limitations of the COAST study are the lack of a control arm and enrollment of a modest number of patients; however, the inclusion criteria and study populations in COAST and ORBIT II were similar, and both studies used the same primary safety and efficacy end points. Therefore, an indirect comparison of the results from COAST and the larger ORBIT II study is valid but should be considered hypothesis generating. Second, intraprocedural medications were not recorded. Third, preprocedure angiographic variables were not assessed by an independent angiographic core lab, and the use of IVUS and OCT were different in COAST and ORBIT II. The extent to which the observed differences in number of OAS devices used, total device run time, procedural time, and contrast volume relate to these factors rather than device performance is unknown. Finally, neither COAST nor ORBIT II incorporated routine angiographic or intravascular imaging follow-up, the results of which may have provided insights into the mechanisms of OAS action and vascular responses from arterial injury.

Conclusions

Among subjects undergoing PCI of severely calcified lesions, prestent lesion preparation using the novel Diamondback 360 Coronary Micro Crown OAS demonstrated similar procedural success and clinical outcomes

as were observed with the original Classic Crown OAS. Currently, atheroablation at many centers is reserved for treatment of very heavily calcified lesions in which balloon preparation techniques are unlikely to improve lesion compliance sufficiently to afford stent delivery and expansion. A 2000 patient randomized trial (Evaluation of Treatment Strategies for Severe Calcific Coronary Arteries: Orbital Atherectomy Versus Conventional Angioplasty Technique Prior to Implantation of Drug-Eluting Stents: The ECLIPSE Trial; URL: https://clinicaltrials.gov. Unique identifier: NCT03108456) is ongoing to determine whether the routine use of OAS to debulk severely calcified coronary lesions identified by angiography or intravascular imaging before drug-eluting stent implantation improves long-term clinical outcomes.

ARTICLE INFORMATION

Received January 15, 2020; accepted June 3, 2020.

Affiliations

Clinical Trials Center, Cardiovascular Research Foundation, New York, NY (B.R., J.W.M., Z.A.A., G.W.S.). NewYork-Presbyterian Hospital/Columbia University Irving Medical Center, NY (B.R., J.W.M., Z.A.A.). Department of Cardiology, Sahlgrenska University Hospital, Gothenburg, Sweden (B.R.). The Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, NY (S.K.S., A.S.K., G.W.S.). Shonan Kamakura General Hospital, Kamakura, Japan (S.S.). The Cardiac and Vascular Institute, Gainesville, FL (A.C.L.). St Francis Hospital, Roslyn, NY (J.W.M., Z.A.A.). MediQuest Research Group at Advent-Health Ocala, FL (R.L.F.). AdventHealth, Orlando, FL (R.B.).

Sources of Funding

The COAST (Coronary Orbital Atherectomy System Study) was sponsored by Cardiovascular Systems Inc (St Paul, MN).

Disclosures

Dr Lee reports consultant to CSI. Dr Ali reports institutional research grants to Columbia University: Abbott, Cardiovascular Systems Inc; consultant: Abbott, Medtronic, Boston Scientific, Opsens, and AstraZeneca. Dr Feldman reports Stockholder: Boston Scientific Corporation. Consultant and medical advisory board: Boston Scientific Corporation. Rohit Bhatheja: speaker/consultant for CSI, Abbott, Phillips. Dr Stone reports consultant to Shockwave. The other authors reports no conflicts.

REFERENCES

1. Abdel-Wahab M, Richardt G, Joachim Büttner H, Toelg R, Geist V, Meinertz T, Schofer J, King L, Neumann FJ, Khattab AA. 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. doi: 10.1016/j.jcin.2012.07.017
2. de Waha S, Allali A, Büttner HJ, Toelg R, Geist V, Neumann FJ, Khattab AA, Richardt G, Abdel-Wahab M. Rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions: two-year clinical outcome of the randomized ROTAXUS trial. *Catheter Cardiovasc Interv.* 2016;87:691–700. doi: 10.1002/ccd.26290
3. Mosseri M, Satler LF, Pichard AD, Waksman R. Impact of vessel calcification on outcomes after coronary stenting. *Cardiovasc Revasc Med.* 2005;6:147–153. doi: 10.1016/j.carrev.2005.08.008
4. Généreux P, Madhavan MV, Mintz GS, Maehara A, Palmerini T, Lasalle L, Xu K, McAndrew T, Kirtane A, Lansky AJ, 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;63:1845–1854. doi: 10.1016/j.jacc.2014.01.034
5. Bourantas CV, Zhang YJ, Garg S, Iqbal J, Valgimigli M, Windecker S, Mohr FW, Silber S, Vries Td, Onuma Y, 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;100:1158–1164. doi: 10.1136/heartjnl-2013-305180
6. Clavijo LC, Steinberg DH, Torguson R, Kuchulakanti PK, Chu WW, Fournadjiev J, Satler LF, Kent KM, Suddath WO, Waksman R, et al. Sirolimus-eluting stents and calcified coronary lesions: clinical outcomes of patients treated with and without rotational atherectomy. *Catheter Cardiovasc Interv.* 2006;68:873–878. doi: 10.1002/ccd.20615
7. Généreux P, Redfors B, Witzenbichler B, Arsenault MP, Weisz G, Stuckey TD, Rinaldi MJ, Neumann FJ, Christopher Metzger D, Henry TD, et al. Two-year outcomes after percutaneous coronary intervention of calcified lesions with drug-eluting stents. *Int J Cardiol.* 2017;231:61–67. doi: 10.1016/j.ijcard.2016.12.150
8. Moussa I, Di Mario C, Moses J, Reimers B, Di Francesco L, Martini G, Tobis J, Colombo A. Coronary stenting after rotational atherectomy in calcified and complex lesions. Angiographic and clinical follow-up results. *Circulation.* 1997;96:128–136. doi: 10.1161/01.cir.96.1.128
9. 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. doi: 10.1161/01.cir.86.1.64
10. Pinto DS, Stone GW, Ellis SG, Cox DA, Hermiller J, O'Shaughnessy C, Mann JT, Mehran R, Na Y, Turco M, et al; TAXUS-IV Investigators. Impact of routine angiographic follow-up on the clinical benefits of paclitaxel-eluting stents: results from the TAXUS-IV trial. *J Am Coll Cardiol.* 2006;48:32–36. doi: 10.1016/j.jacc.2006.02.060
11. Chambers JW, Feldman RL, Himmelstein SI, Bhatheja R, Villa AE, Strickman NE, Shlofmitz RA, Dulas DD, Arab D, Khanna PK, 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. doi: 10.1016/j.jcin.2014.01.158
12. Généreux P, Bettinger N, Redfors B, Lee AC, Kim CY, Lee MS, Shlofmitz RA, Moses JW, Stone GW, Chambers JW. Two-year outcomes after treatment of severely calcified coronary lesions with the orbital atherectomy system and the impact of stent types: Insight from the ORBIT II trial. *Catheter Cardiovasc Interv.* 2016;88:369–377. doi: 10.1002/ccd.26554
13. 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;81:1134–1139. doi: 10.1002/ccd.24700
14. Sotomi Y, Cavalcante R, Shlofmitz RA, Suwannasom P, Tateishi H, Tenekecioglu E, Zheng Y, Abdelghani M, de Winter RJ, Wykrzykowska JJ, et al. Quantification by optical coherence tomography imaging of the ablation volume obtained with the Orbital Atherectomy System in calcified coronary lesions. *EuroIntervention.* 2016;12:1126–1134. doi: 10.4244/EIJV12I9A184
15. Uchida T, Ikeno F, Ikeda K, Suzuki Y, Todaka K, Yokoi H, Thompson G, Krucoff M, Saito S; Harmonization by Doing Program Working Group. Global cardiovascular device innovation: Japan-USA synergies: Harmonization by Doing (HBD) program, a consortium of regulatory agencies, medical device industry, and academic institutions. *Circ J.* 2013;77:1714–1718. doi: 10.1253/circj.cj-12-1431
16. Sakakura K, Ako J, Wada H, Naito R, Funayama H, Arao K, Kubo N, Momomura S. Comparison of frequency of complications with on-label versus off-label use of rotational atherectomy. *Am J Cardiol.* 2012;110:498–501. doi: 10.1016/j.amjcard.2012.04.021
17. Tsuchikane E, Suzuki T, Asakura Y, Oda H, Ueda K, Tanaka T, Matsubara T, Hsu YS, Tamai H, Katoh O; DOCTORS Investigators. Debulking of chronic coronary total occlusions with rotational or directional atherectomy before stenting: final results of DOCTORS study. *Int J Cardiol.* 2008;125:397–403. doi: 10.1016/j.ijcard.2007.07.117
18. Brown DL, George CJ, Steenkiste AR, Cowley MJ, Leon MB, Cleman MW, Moses JW, King SB, III, Carrozza JP, Holmes DR, et al. High-speed rotational atherectomy of human coronary stenoses: acute and one-year outcomes from the New Approaches to Coronary Intervention (NACI) registry. *Am J Cardiol.* 1997;80(10A):60K–67K. doi: 10.1016/s0002-9149(97)00765-0
19. Rathore S, Matsuo H, Terashima M, Kinoshita Y, Kimura M, Tsuchikane E, Nasu K, Ehara M, Asakura Y, Katoh O, 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. doi: 10.1002/ccd.22437
20. Reisman M, Shuman BJ, Dillard D, Fei R, Misser KH, Gordon LS, Harms V. Analysis of low-speed rotational atherectomy for the

reduction of platelet aggregation. *Cathet Cardiovasc Diagn.* 1998; 45:208–214. doi: 10.1002/(sici)1097-0304(199810)45:2<208::aid-ccd21>3.0.co;2-f

21. Reisman M, Shuman BJ, Harms V. Analysis of heat generation during rotational atherectomy using different operational techniques. *Cathet Cardiovasc Diagn.* 1998;44:453–455. doi: 10.1002/(sici)1097-0304(199808)44:4<453::aid-ccd21>3.0.co;2-i
22. Kini A, Marmur JD, Duvvuri S, Dangas G, Choudhary S, Sharma SK. Rotational atherectomy: improved procedural outcome with evolution of technique and equipment. Single-center results of first 1,000 patients. *Catheter Cardiovasc Interv.* 1999;46:305–311. doi: 10.1002/(SICI)1522-726X(199903)46:3<305::AID-CCD9>3.0.CO;2-U
23. Adams GL, Khanna PK, Staniloae CS, Abraham JP, Sparrow EM. Optimal techniques with the Diamondback 360° System achieve effective results for the treatment of peripheral arterial disease. *J Cardiovasc Transl Res.* 2011;4:220–229. doi: 10.1007/s12265-010-9255-x
24. Aggarwal D, Seth M, Perdoncin E, Schreiber T, Kaki A, Alaswad K, Menees D, Sukul D, Gurm HS. Trends in utilization, and comparative safety and effectiveness of orbital and rotational atherectomy. *JACC Cardiovasc Interv.* 2020;13:146–148. doi: 10.1016/j.jcin.2019.09.027
25. Goel S, Pasam RT, Chava S, Gotesman J, Sharma A, Malik BA, Frankel R, Shani J, Gidwani U, Latib A. Orbital atherectomy versus rotational atherectomy: a systematic review and meta-analysis. *Int J Cardiol.* 2020;303:16–21. doi: 10.1016/j.ijcard.2019.12.037