

# Orbital Atherectomy for Infrapopliteal Disease: Device Concept and Outcome Data for the Oasis Trial

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**Objective:** The purpose of this study was to assess the safety and short-term efficacy of orbital atherectomy for chronic infrapopliteal arterial occlusive disease. **Background:** Infrapopliteal occlusive disease is a common cause of critical limb ischemia and claudication. There are no American College of Cardiology/American Heart Association guidelines for infrapopliteal revascularization for chronic limb ischemia. **Methods:** One hundred twenty four patients (201 stenoses) were enrolled in a prospective non-randomized multicenter registry of orbital atherectomy for severe infrapopliteal disease. Data were collected as part of an investigational device exemption from the Food and Drug Administration. **Results:** The primary safety endpoint of major adverse events (MAE) at 30-days (death, myocardial infarction, amputation, or repeat revascularization) was observed in four patients (3.2%). The primary efficacy endpoint (final diameter stenosis) was  $17.8 \pm 13.5\%$ . The secondary endpoints of procedural success (final diameter stenosis  $\leq 30\%$ ) and 6 month MAE (death, amputation, or target vessel revascularization) were observed in 90.1 and 10.4% of patients, respectively. Stand-alone atherectomy was performed in 116 lesions (57.4%). At 6-months, no patients required surgical bypass or unplanned amputation, and improvement in Rutherford ordinal scale was observed in 78.2% of patients. **Conclusions:** Orbital atherectomy is a unique approach to infrapopliteal disease, and provides predictable and safe lumen enlargement. Short-term data demonstrate substantial symptomatic improvement and infrequent need for further revascularization or amputation. © 2009 Wiley-Liss, Inc.

**Key words:** atherectomy; peripheral arterial disease

## INTRODUCTION

Contemporary guidelines for revascularization of patients with acute and chronic limb ischemia focus on aortoiliac inflow and femoropopliteal outflow diseases, and barely mention management strategies for patients with chronic limb ischemia and severe infrapopliteal runoff disease [1,2]. The purpose of this study was to evaluate the safety and efficacy of a unique atherectomy system for revascularization of patients with clinical manifestations of chronic limb ischemia and severe infrapopliteal arterial occlusive disease.

## METHODS

### Study Design and Endpoints

The OASIS (Orbital Atherectomy System for the Treatment of Peripheral Vascular Stenosis) Trial is a multicenter prospective nonrandomized registry of patients with severe infrapopliteal arterial occlusive disease and chronic limb ischemia who were treated

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Conflict of interest: All investigators have received grant support to offset the costs of data collection. JPR, BW, VR, and RH have equity interests in CSI.

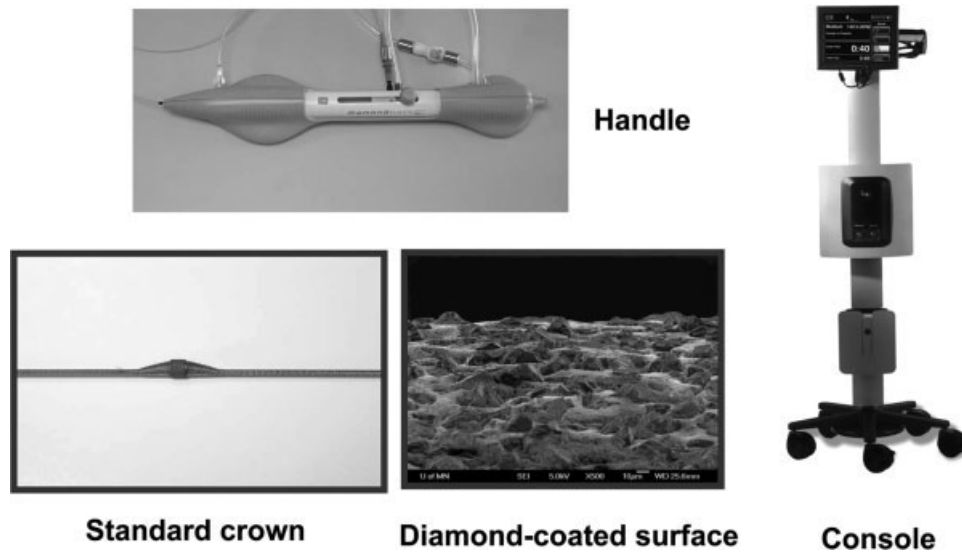
The names of all the investigators of this OASIS trial are listed in Appendix A.

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**Fig. 1.** Orbital atherectomy system consisting of the handle, the control console, and the plaque ablation catheter with a classic crown and its diamond-coated surface (scanning electron micrograph, magnification  $\times 500$ ).

with orbital atherectomy. The purpose of this study is to report the 30-day and 6-month outcomes of patients enrolled in this trial. The study was approved by the Institutional Review Board at each of the 20 participating institutions (Appendix A), and was in compliance with the Declaration of Helsinki. The primary endpoints included a safety endpoint (major adverse events [MAE] at 30 days, including death, myocardial infarction, amputation, or repeat revascularization) and an efficacy endpoint (final diameter stenosis at the completion of the procedure). Secondary endpoints included procedural success (defined as final diameter stenosis  $\leq 30\%$ ), MAE at 6 months (death, amputation, or repeat revascularization), and assessment of ankle-brachial index (ABI) and Rutherford classification (Appendix B) at 6 months.

### Patient Eligibility and Study Requirements

The major eligibility criteria included patients with chronic limb ischemia graded as Rutherford class 1–5, a target vessel reference diameter of 1.5–4.0 mm, and a target lesion with diameter stenosis  $\geq 50\%$  and length  $\leq 100$  mm. Patients were excluded from participation if they had gangrene in the target limb (Rutherford class 6) or if the lesion length exceeded 100 mm. Patients with chronic total occlusions were included in the study if collateral filling permitted accurate assessment of lesion length, and if the occlusion was successfully crossed with a guidewire. All patients underwent assessment of ABI before intervention and at 6 months, and were maintained on aspirin (81–325 mg

daily) before and after intervention. Other medications were prescribed at the discretion of the physician. During the interventional procedure, heparin was administered to achieve an activated clotting time  $> 300$  sec.

### Description of the Atherectomy System

The Diamondback 360<sup>TM</sup> Orbital Atherectomy System (OAS) (Cardiovascular Systems Inc. (CSI), St. Paul, MN) consists of three components: the plaque ablation catheter, the handle, and the control console (Fig. 1). The plaque ablation catheter consists of a flexible coil-wound drive shaft with an abrasive crown with a diamond-coated surface. The central lumen of the drive shaft is able to accommodate a 0.009-inch guidewire, although more contemporary versions of the device are used with a 0.014-inch guidewire. An infusion sheath around the drive shaft permits delivery of saline to cool the crown during rotation. In the study, crown sizes included diameters of 1.2, 1.7, and 1.9 mm, although contemporary sizes are now available from 1.25–2.25 mm. The handle is used for advancement and retraction of the crown. The console is used to monitor and control the rotational speed of the crown, and to maintain continuous flush of saline through the infusion sheath. The drive shaft is powered by a compressed gas turbine, which is operated by a foot pedal connected to the console. Rotational speed is controlled by a pressure valve located on the front panel of the console, and speed is monitored by a digital tachometer.

### Mechanism of Lumen Enlargement

The OAS has unique operational characteristics and mechanisms of lumen enlargement that have been established by extensive in-vitro and ex-vivo testing (data on file with CSI, Inc.). These studies demonstrate progressive and predictable lumen enlargement by plaque abrasion without barotrauma or thermal injury, by increasing the rotational speed of a given device size. The crown has an eccentric shape, shifting the center of mass away from the center of rotation. When rotated, the device generates an elliptical orbit in which the orbital diameter is determined by the crown diameter and the rotational speed. For example, a 2.0 mm crown will generate lumen diameters of 2.2, 2.9, and 3.4 mm when operated at rotational speeds of 80,000, 140,000, and 200,000 RPM, respectively. For a given crown, the efficiency of lumen enlargement may exceed 175% (i.e., a 2.0-mm crown can increase the lumen diameter to 3.4 mm), which is more efficient than other laser and atherectomy devices [3]. For all three crown sizes the mean particle size was 1.7–3.1 mm, and 99% of particles were less than 5 microns in diameter.

### Device Selection and Operation

Because this study was the first human experience, a conservative sizing strategy was recommended. In most patients, initial OA was performed with a 1.2-mm crown at 80,000 RPM, and higher rotational speeds were employed up to a maximum speed of 200,000 RPM, before using a larger crown. The maximum crown size that was recommended for initial treatment was equivalent to 50% of the reference vessel diameter (Appendix C), but final crown sizes were determined by the operator and were based on vessel size and the angiographic results. The interventional technique was similar to other devices: After initial angiography and assessment of baseline stenosis severity, lesion length, and reference vessel diameter, the target lesion was crossed with the guidewire using an interventional sheath  $\geq 6$  French. The choice of initial crossing guidewire was left to operator discretion, but OA required placement of a 0.009-inch guidewire. OA ultimately was performed using the selected crown size at 80,000 RPM, followed by increases in rotational speed up to 200,000 RPM, at operator discretion. In general, several passes were made antegrade and retrograde across the target lesion, and decisions about final crown size and rotational speed were determined by angiographic results. Judgments about using larger crowns or angioplasty balloons were left to operator discretion. Stents were strongly discouraged unless needed for severe dissection. Quantitative angi-

**TABLE I. Baseline Demographic and Clinical Characteristics (124 patients)**

Male: Female (%)	67:33
Age	70 $\pm$ 10 years
Risk Factors for PAD N (%)	
Diabetes	68 (55)
Current smoking	25 (20)
Hypertension	114 (92)
Hyperlipidemia	105 (85)
Cardiac/Vascular comorbidities N (%)	
Other peripheral arterial disease	115 (93)
Coronary artery disease	77 (62)
Prior myocardial infarction	31 (25)
Prior stroke	25 (20)
Chronic renal failure	14 (11)

ography was performed after administration of intra-arterial nitroglycerin (100–400 mcg), before and after revascularization. After completion of the procedure, decisions about manual compression or vascular closure devices were left to operator discretion.

### Statistical Methods

Data are reported as mean ( $\pm$ SD) for continuous variables and frequency for categorical variables. *P*-values  $\leq 0.05$  were considered statistically significant.

## RESULTS

### Patient Characteristics

Baseline demographic and clinical characteristics of the 124 patients are shown in Table I. Among the patients with chronic limb ischemia, 84 patients (68%) had claudication (Rutherford class 1–3), and 40 patients (32%) had critical limb ischemia with ischemic rest pain (Rutherford class 4) or nonhealing ulcers (Rutherford class 5). The baseline ABI was  $0.68 \pm 0.20$ , and was 0.6–0.9 in 81 patients (67%), 0.4–0.6 in 27 patients (22%), and  $< 0.4$  in 9 patients (7%).

### Interventional and Angiographic Results

The vascular approach to infrapopliteal intervention included retrograde femoral crossover in 104 patients (84%) and antegrade femoral approach in 20 patients (16%). Additional interventions in the iliac or femoral circulation were performed in 38 patients (30.4%). OA was performed in 201 lesions in 124 patients (Table II, Fig. 2), including OA of a single lesion in 68 patients (54.8%) and multiple lesions in 56 patients (45.2%). Angiographic results are shown in Table III, and target lesions included chronic total occlusion in 24 lesions (12%) and heavy calcification in 111 lesions (55%). Stand-alone OA was performed in 117 lesions (58.2%), adjunctive angioplasty was performed in 79 lesions (39.3%), and stenting was performed in five

lesions (2.5%), for moderate residual stenosis in four lesions and acute occlusion in one lesion (see below).

### Adverse Procedural Events

Adverse events during the interventional procedure were observed in five lesions (2.5%) in 5 patients (4.0%), including acute occlusion after adjunctive angioplasty in one patient (managed with successful stenting), angiographic slow flow (which was presumed

to be due to distal embolization) in one patient (no clinical sequelae), intraluminal filling defect consistent with non-flow limiting thrombus after angioplasty in one patient, and angioplasty-induced deep adventitial contrast stain without extravasation in two patients. (Table IV).

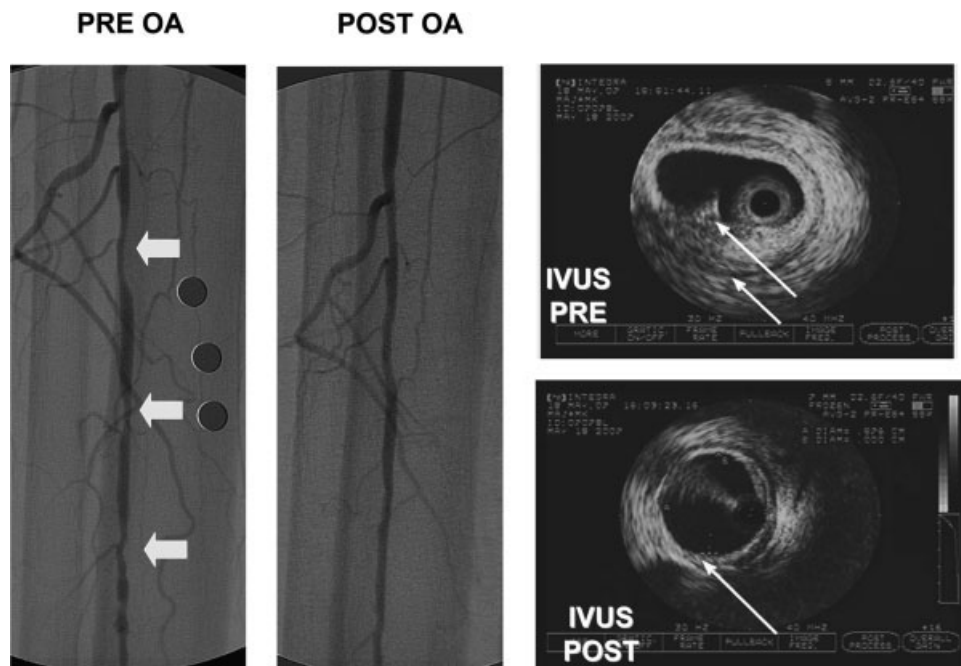
### Evaluation of Primary and Secondary Endpoints

The primary safety endpoint of MAE at 30-days was observed in four patients (3.2%), including death in two patients (1.6%), myocardial infarction in one patient (0.8%), and repeat revascularization in one patient (0.8%) (Table IV). The primary efficacy endpoint of final diameter stenosis was  $17.8 \pm 13.5\%$  ( $P < 0.001$  compared to baseline stenosis, Table III). Secondary endpoints included procedural success in 188 lesions (90.1%) (Table III), and cumulative MAE at 6 months in 13 patients (10.4%), including death in three patients (2.4%), planned minor amputation in three patients (2.4%) and target vessel revascularization in seven patients (5.6%) (Table IV). The ABI increased from  $0.68 \pm 0.2$  at baseline to  $0.82 \pm 0.10$  at 6 months ( $P < 0.001$ ). According to the Rutherford-Becker ordinal scale, there was improvement in signs and symptoms of chronic limb ischemia in 97 patients

**TABLE II. Vascular Approach and Target Vessels (124 patients, 201 lesions)**

Vascular Access N(%)	
Femoral antegrade	20 (16)
Femoral crossover	104 (84)
Vascular Intervention N(%)	
Non-target vessel	38 (30.4)
Target Vessel OA	201 lesions
Femoropopliteal artery	28 (14)
Runoff circulation	173 (86)
Anterior tibial artery	75 (37.3)
Tibioperoneal trunk	37 (18.4)
Posterior tibial artery	34 (16.9)
Peroneal artery	27 (13.4)
Single lesion OA	68 (55.2)
Multiple lesion OA	56 (44.8)

Abbreviations: OA, orbital atherectomy



**Fig. 2.** Angiographic and intravascular ultrasound result of stand-alone orbital atherectomy in a patient with critical limb ischemia (Rutherford class 4). Left panel, severe stenoses (arrowheads) in the peroneal artery. The radiographic spheres are used as references for quantitative angiography. Middle panel, final result after stand-alone orbital atherectomy with a 1.7-mm crown. Right panel (top), baseline image during intra-

vascular ultrasound shows eccentric fibrous plaque (arrows). Right panel (bottom), final intravascular ultrasound image shows a large lumen with trivial residual plaque (arrow) and no dissection. PRE, before, POST, after, OA, orbital atherectomy, IVUS, intravascular ultrasound (courtesy of Barry Weinstein, MD).

**TABLE III. Angiographic Results in 201 Lesions**

Baseline lesion morphology N (%)	
Stenosis	177 (88)
Occlusion	24 (12)
Heavy calcification	111 (55)
Quantitative angiography N (%)	
Reference vessel (mm)	3.15 ± 0.6
Lesion length (mm)	30 ± 26
Baseline diameter stenosis (%)	86.7 ± 11.8
Final diameter stenosis (%)	17.8 ± 13.5
Orbital atherectomy N (%)	
Stand-alone	117 (58.2)
Adjunctive intervention	84 (41.8)
Angioplasty	79 (39.3)
Stent	5 (2.5)
Procedural success (%)	
Per lesion	90.1

**TABLE IV. Adverse Events During the Procedure, at 30-days and at 6-months**

Procedural events (%)	
Acute occlusion	1 (0.8)
Distal embolization	1 (0.8)
Filling defect	1 (0.8)
Deep dye stain	2 (1.6)
Major adverse events (30-days)	
Death	2 (1.6)
Myocardial infarction	1 (0.8)
Vascularization	1 (0.8)
Amputation	0
Cumulative major adverse events (180-days) <sup>a</sup>	
Death	2 (2.4)
Minor amputation	3 (2.4)
Revascularization	7 (5.6)

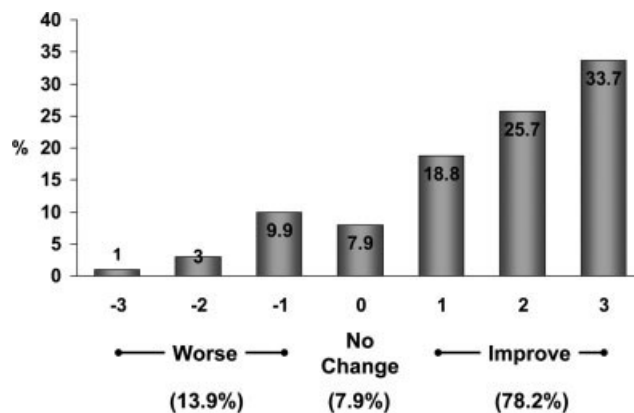
<sup>a</sup>Cumulative events include the events at 30-days.

(78.2%), no change in 10 patients (7.9%), and worsened claudication in 17 patients (13.9%) (Fig. 3).

## DISCUSSION

### Approach to the Patient With Infrapopliteal Disease

In most institutions, patients with claudication are managed with medical therapy and risk factor modification, and subsequent revascularization of the aortoiliac inflow and femoropopliteal outflow circulation is recommended in accordance with societal guidelines [1,2]. At the present time, currently available guidelines for management of lower extremity claudication do not include specific recommendations for patients with infrapopliteal disease. In contrast, patients with critical limb ischemia are managed more aggressively with revascularization to prevent amputation, which may occur in 30–90% of patients within 1 year, depending on Rutherford classification. Most physicians agree that the attainment of straight in-line flow



**Fig. 3.** Rutherford-Becker ordinal scale 6 months after orbital atherectomy. The scale indicates the change in symptomatic status (-1, -2, -3 are mild, moderate, and marked deterioration, respectively; 0 represents no change; and 1, 2, 3 are mild, moderate, and marked improvement, respectively).

to the foot is desirable within one or more of the tibial vessels, but there are no specific guidelines on which techniques to use.

### Endovascular Techniques for Infrapopliteal Revascularization

In the absence of large scale prospective randomized trials, balloon angioplasty has emerged as the “default” endovascular technique for infrapopliteal revascularization in patients with critical limb ischemia, often relying on the use of 0.014–0.018-inch guidewires and low profile balloon catheters. Several case series have reported procedural success rates > 85%, early resolution of ischemic symptoms, and limb salvage in 75–90% at 2–5 years [4–10]. However, known limitations of balloon angioplasty include vessel recoil, dissection, and inability to dilate rigid stenoses, which are commonly encountered in the infrapopliteal circulation. In efforts to address many of these limitations of balloon angioplasty, many other devices have been utilized, including laser [11–13] and excisional atherectomy [14–16] devices, cutting balloons [17] and scoring balloons to modify plaque compliance, cryotherapy [18], and stents [19–22]. Studies of all of the devices are somewhat limited by small numbers of patients, short-duration of follow-up, and differences in lesion length and morphology. Nevertheless, most of these devices are associated with procedural success rates > 90% and 1 year limb salvage in 70–90% of patients.

### Orbital Atherectomy for Infrapopliteal Disease

Data in this study indicate that OA should be included among the devices that may be safely applied for revascularization of infrapopliteal disease. Although

from an operational standpoint OA appears to have some similarities to mechanical rotational atherectomy (Rotablator), the Rotablator has greater limitations with respect to device size and lumen enlargement. Although the efficiency of lumen enlargement is 92% for Rotablator (a 2-mm burr will create a lumen diameter of 1.8 mm) [3], it is greater than 175% for OA. In this study, suboptimal results requiring stenting were observed in five lesions (2.5%) after OA, which is lower than 20% rate of bailout stenting were cryotherapy [17] and similar to the 3.8% rate of bailout stenting were excisional atherectomy [15]. Predilation with angioplasty was not required in this study, but was required in 29% of patients treated with excisional atherectomy [15], suggesting easier access to chronic total occlusions and calcified lesions with OA. The magnitude of improvement in symptoms and ABI, and the need for amputation are similar for OA, excisional atherectomy, and other devices [11–22].

### Limitations of Study

There are several limitations of this study. First, this study was intended as a first-in-man observational study of the safety and short-term efficacy of OA in infrapopliteal disease. It was not designed as a large-scale study of long-term efficacy, and it was not intended to be a definitive randomized clinical trial comparing OA to any other treatment strategy. Additional larger studies are needed to compare the outcomes of OA with angioplasty and other treatments. Second, the study included patients with claudication and critical limb ischemia, rather than critical limb ischemia alone. The inclusion criteria were designed with the hope of enhancing patient enrollment to include a broader patient population. Third, the study excluded patients with gangrene (Rutherford class 6). Patients with gangrene often have the most advanced vascular disease associated with much other comorbidity, who were considered less ideal candidates for a first-in-man study.

### CONCLUSIONS

Orbital atherectomy is a safe and unique approach to revascularization of the infrapopliteal arterial circulation in patients with chronic limb ischemia. Short term data demonstrate substantial symptomatic improvement and infrequent need for further revascularization or amputation.

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#### APPENDIX A. OASIS INVESTIGATORS

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#### APPENDIX B. RUTHERFORD CLASSIFICATION FOR CHRONIC LIMB ISCHEMIA

Class	Description
0	Asymptomatic
1 <sup>a</sup>	Exertional claudication, long distance
2 <sup>a</sup>	Exertional claudication, moderate distance
3 <sup>a</sup>	Exertional claudication, short distance
4 <sup>b</sup>	Ischemic rest pain
5 <sup>b</sup>	Non-healing ulcers
6 <sup>b</sup>	Gangrene

<sup>a</sup>Claudication, Rutherford class 1–3.

<sup>b</sup>Critical limb ischemia, Rutherford class 4–6.

#### APPENDIX C. GUIDELINES FOR THE LARGEST INITIAL CROWN DIAMETER

Reference vessel diameter (mm)	Crown diameter (mm)
4.0	2.0
3.5	1.75
3.0	1.25
2.5	1.25