Orbital Atherectomy for Infrapopliteal Occlusions

A treatment option for critical limb ischemia.

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Vascular occlusions below the knee (BTK) are culpable for the majority of critical limb ischemia cases (CLI) presenting in today's aging population. Approximately 12 million people in the US alone are affected by peripheral arterial disease (PAD), and 20% to 30% of these individuals have diabetes.[1] Recent projections indicate that in the year 2030, the number of patients presenting with CLI will reach at least 16 million. Surgery, balloon angioplasty, stenting, and atherectomy are current revascularization treatment options available to reduce the overall morbidity and mortality associated with this disease process. Orbital atherectomy (OA) is an emerging form of atherectomy intended to treat BTK atherosclerotic PAD. Atraumatic ablation is a theoretical advantage of OA and may result in less restenosis.

A recent World Health Organization task force report identified diabetes as a rapidly emerging global healthcare problem expected to reach pandemic level by 2030, at which time there will be an estimated 366 million diabetic people worldwide (33.9 million diabetic patients in the US), a 72% increase from the 19.7 million reported in 2000.[2] Diabetic patients are particularly prone to BTK atherosclerosis, and as the incidence of diabetes increases, so too will the number of patients with moderate-to-severe outflow disease and CLI. With CLI comes the need for treatment therapies that range from physical therapy to amputation. Approximately 230,000 amputations occur every year in the US and Europe. Sixty percent of lower-limb amputations occur in diabetic patients, and 67% of amputations are performed as an initial treatment without any attempt at salvage by endovascular therapy.[3] A recent review of CLI indicated that perhaps as many as 85% of primary amputations are preventable. Healthcare costs for the diabetic population of the US were $132 billion in 2002 and are estimated to reach $192 billion in 2020.[4] By comparison, the current estimated annual healthcare cost of stroke in the US is $53 billion, and a recently reported perspective on coronary heart disease in the US indicated annual direct and indirect costs for coronary disease in the US were $142.5 billion.[5]

ATHERECTOMY IN PERSPECTIVE

Directional and rotational atherectomy devices were developed in the mid-to-late 1980s to mechanically remove fibrocalcific atherosclerotic plaque from bulky peripheral or coronary lesions that either resisted balloon dilatation or restenosed after plain old balloon angioplasty (POBA).[6,7] Directional atherectomy received FDA marketing clearance for a peripheral indication in 1987 and for a coronary indication in 1990. Rotational atherectomy and excimer laser atherectomy devices have also received marketing clearance for coronary and peripheral indications. The introduction of balloon-expandable stents in 1995 significantly reduced the use of atherectomy devices except for the treatment of proximal anterior descending and bifurcation coronary lesions or calcific and diffusely diseased coronary and ostial stenosis.[8-10] Application of atherectomy devices to the treatment of lower-extremity PAD, and particularly the restoration of blood flow in diffusely diseased arteries, has received favorable clinical acceptance in recent years.[11,12] As new and next-generation devices become available, their use as a viable endovascular treatment option for patients with CLI will become more common.

An ideal atherectomy device should be capable of treating a range of vessel diameters and lengths without requir-

Figure 1. The eccentric, diamond-coated crown (A) and handle control (B) of the Diamondback 360° Orbital Atherectomy System (Cardiovascular Systems, Inc., St. Paul, MN).

ing subsequent adjunctive stenting to maintain a viable vessel lumen. The tibial and peroneal arteries are small for stenting and prone to dissection after POBA, especially if atherosclerotic disease extends throughout the vessel wall. Effective plaque ablation is therefore a definite requirement of any atherectomy device combined with the absence of significant plaque material embolization. The device should also not cause thermal injury at the treatment site or otherwise disrupt the arterial media.

ORBITAL ATHERECTOMY

The OA system being developed by Cardiovascular Systems, Inc. uses a mechanical sanding process to remove plaque along the stenotic arterial segment. Final lumen diameter is dependent on the selected crown size and the rotational speed (80 K to 200 K rpm) during the atherectomy. A unique feature of OA is the mechanism of operation in which the crown diameter increases proportionally to crown rotational speed and crown weight. Current crown sizes of 1.2 mm, 1.7 mm, and 1.9 mm allow final lumen diameters ranging from 1.2 mm to 3.8 mm. The company intends to increase the number of crowns to five, allowing OA to potentially achieve final lumen diameters ranging from 1.25 mm to 6 mm.

Thirty-three separate *in vitro* experiments determined the average particulate size is 2.24 µm (99% confidence interval). Actual treatment times, depending on the lesion length, are typically <6 minutes. The OA catheter is advanced through the lesion or total occlusion on a preplaced guidewire; guidewires with .009-inch or .014-inch nominal diameters can be used. As with other atherectomy devices, a critical part of the atherectomy procedure is satisfactory guidewire placement through the index lesion/vessel, and this may require the use of other specialized crossing guidewires.

During the OASIS trial, which included the following two cases, a .009-inch X 325-cm RotaWire (Boston Scientific Corporation, Natick, MA) was used as the delivery guidewire. A next-generation controller, handle control, and family of guidewires, called the Diamondback 360° Orbital Atherectomy System (Figure 1), are undergoing reliability testing and will be available in the near term following marketing clearance of the system by the FDA.

The nominal crown diameter is achieved at low rpm during initial advancement over the guidewire. Orbit diameter is initially constrained by the fibrocalcific organization of the atheromatous lesion. As the orbit abrades and removes atheroma, the diameter of the elliptical orbit increases depending on the resistance of the vessel wall opposing the advancing crown and crown rotational speed (Figure 2).

Case Study 1

An 87-year-old man presented for consultation regarding a nonhealing ulcer, osteomyelitis of the right great toe, and rest pain affecting his right foot. Doppler examination demonstrated total occlusion of the right anterior and posterior tibial arteries and right peroneal artery with reconstitution of the right peroneal artery above the ankle. The ankle-brachial index was unobtainable. Severe cardiomyopathy, moderate renal insufficiency, history of inferior wall myocardial infarction, a subdural hematoma, and advanced Alzheimer's disease complicated the clinical presentation.

A 5-F arterial sheath was placed in the left common femoral artery, and an abdominal aortogram was obtained using a 5-F pigtail catheter placed in the descending aorta. The common iliac, external iliac, and common femoral arteries were widely patent bilaterally. Selective angiography of the right lower leg identified a 70% to 80% stenosis of the distal superficial femoral artery (SFA) and 90% stenosis of the popliteal artery. The anterior and posterior tibial arteries and tibioperoneal trunk were occluded with single-vessel runoff to the right lower extremity only through the right peroneal artery (Figure 3A). Collaterals from the peroneal

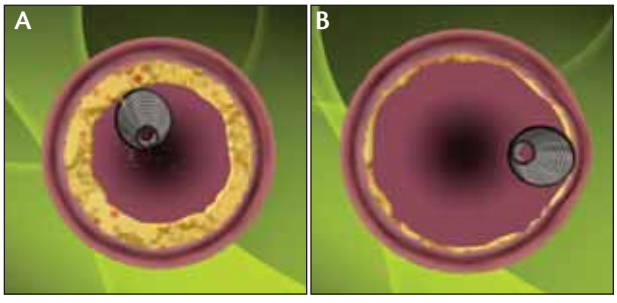

Figure 2. The orbiting crown debulking plaque (A). Tissue flexes away from orbiting crown (B).

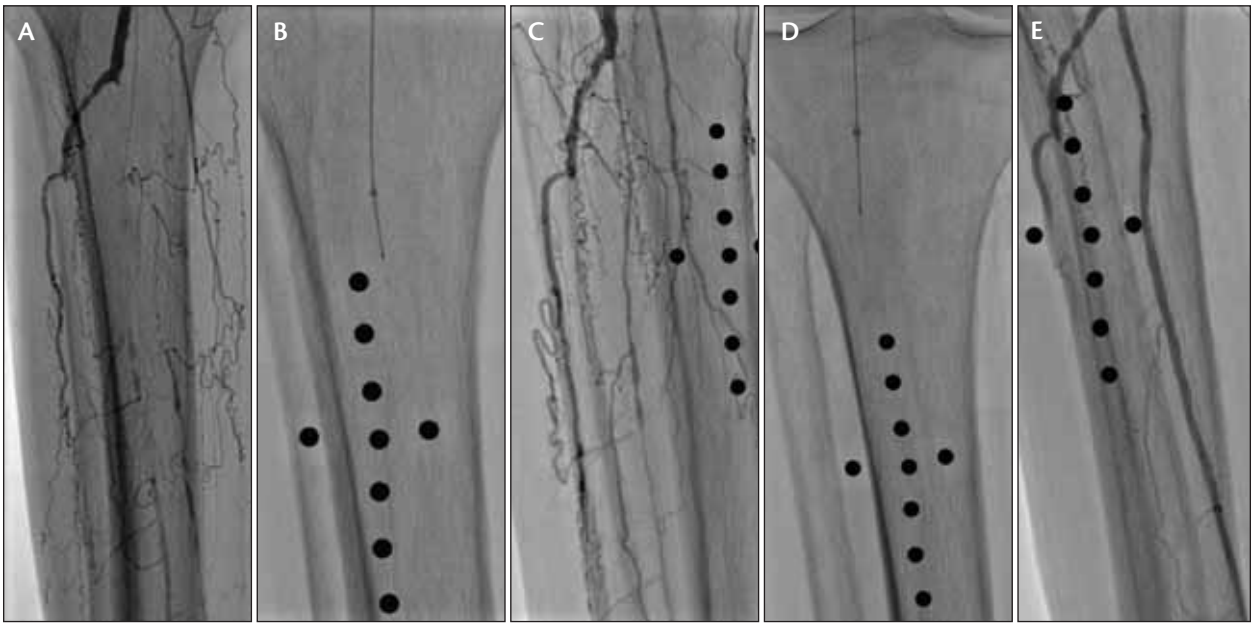

Figure 3. An occluded right peroneal artery at initial arteriography (A), the RotaWire is positioned with a 1.2-mm OA crown being advanced (B), an arteriogram of peroneal artery after three passes of the OA catheter (C), a 1.7-mm OA crown being advanced (D), and the final arteriogram following OA and balloon dilatation (E). Absence of dissection and pristine appearance of the luminal surface obviated the need for stent placement.

artery reconstituted flow distally to the right posterior tibial artery and the dorsalis pedis artery.

The patient was heparinized, and a 7-mm X 55-cm Raabe Sheath (Cook Medical, Bloomington, IN) was placed in the right SFA. A .035-inch X 300-cm SupraCore guidewire (Abbott Vascular, Santa Clara, CA) was advanced, and a 5-mm X 2-cm Powerflex Extreme balloon catheter (Cordis Endovascular, a Johnson & Johnson company, Miami, FL) was used twice to dilate the right popliteal artery. A .35-inch Quick-Cross catheter (Spectranetics Corporation, Colorado Springs, CO) was positioned at the ostium of the tibioperoneal trunk, and a .014-inch X 300-cm Miracle Bros 6 guidewire (Abbott Vascular) was advanced to cross the total occlusion of the tibioperoneal trunk. The .035-inch Quick-Cross catheter was removed and replaced with a .014-inch Quick-Cross catheter. The Miracle Bros guidewire was positioned distally after successfully crossing the total occlusion of the tibioperoneal trunk.

Intra-arterial nitroglycerin was administered, and a .009-inch X 325-cm RotaWire Floppy guidewire was placed in preparation for OA, which was performed sequentially with 1.2-mm and 1.7-mm crowns. The 1.2-mm crown (Figure 3B) was advanced four times at 80 K rpm followed by three passes at 140 K rpm, an eighth pass at 170 K rpm, and two final passes at 160 K rpm. All passes were performed over an interval of 30 seconds or less. Having re-established blood flow (Figure 3C), a 1.7-mm crown (Figure 3D) was placed and operated at 80 K rpm for one pass and then at 140 K rpm for three additional passes. A 30% residual stenosis was dilated after placement of a .014-inch X 300-cm Asahi Grand Slam guidewire (Abbott Vascular). The peroneal artery was post-dilated twice with a 2.5-mm X 120-mm Amphirion Deep balloon catheter (ev3, Inc., Plymouth, MN) at 10 atm for 3 minutes and 10 atm for 2 minutes. Based on the excellent angiographic appearance of the treated segment, 0% residual stenosis, and absence of dissection, no stenting was required (Figure 3E). The right popliteal artery and SFA were stented with overlapping 7-mm X 150-mm Protégé Everflex (ev3, Inc.) and 7-mm X 80-mm Xceed stents (Abbott Vascular), respectively, and postdilated to 5 mm with a 5-mm X 120-mm Submarine Plus balloon catheter (ev3, Inc.). The left femoral artery was closed using an Angio-Seal closure device (St. Jude Medical, Saint Paul, MN).

Doppler ultrasound 2.5 months after the procedure demonstrated patent stents within the right SFA and popliteal arteries and monophasic waveforms within the right peroneal artery.

Case Study 2

The patient was a 63-year-old man with an abdominal aortic aneurysm extending into the bilateral iliac arteries and severe bilateral lower-extremity claudication. CT angiography of the lower extremities demonstrated 80% stenosis of the right SFA and 100% occlusion of the left distal popliteal artery. There was also significant BTK disease including bilateral total occlusions of the anterior tibial

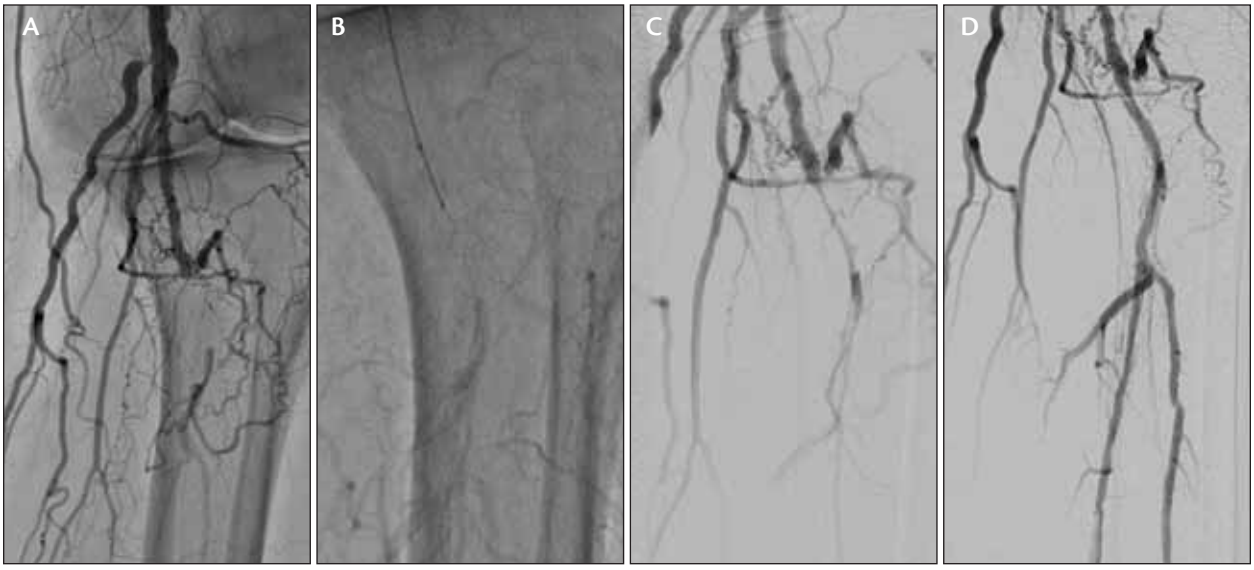

Figure 4. Occluded left tibioperoneal trunk at initial arteriography (A), the RotaWire is positioned with a 1.2-mm OA crown advancing (B), an arteriogram of the peroneal artery after three passes of the 1.2-mm OA catheter (C), and the final arteriogram following 1.9-mm OA and balloon dilatation (D). Arteriography demonstrated excellent three-vessel runoff without flow-limiting dissections.

arteries proximally and each tibioperoneal trunk. After discussing treatment options with the patient, we decided to proceed with endovascular treatment of both lower extremities. Initially, we treated the right lower extremity with laser atherectomy and realized substantial improvement. The patient returned for left lower-extremity intervention.

A 5-F arterial sheath was placed in the right common femoral artery, and arteriography confirmed left iliac artery aneurysmal dilation and severe tortuosity. Aided by fluoroscopy, a 6-F X 11-cm Brite Tip Sheath (Cordis Endovascular) was placed antegrade into the left SFA, and the patient was heparinized. A 70% stenosis of the mid SFA and 90% stenosis of the distal SFA were identified on arteriography. The left popliteal artery was patent; however, the left tibioperoneal trunk and anterior tibial artery were occluded, and the left posterior tibial artery had significant proximal disease (Figure 4). Before proceeding with the OA, balloon angioplasty of the SFA was performed, and an 8-mm X 40-mm EverFlex stent and 8-mm X 16-mm Smart stent (Cordis Endovascular) were deployed and postdilated. A .035-inch Quick-Cross catheter was positioned within the proximal left popliteal artery, and additional arteriography was performed. The total occlusion of the peroneal artery was crossed after multiple attempts with several different guidewires and Quick-Cross catheter exchanges. A .014-inch X 150-cm Miracle Bros 12 guidewire and .014-inch Quick-Cross catheter produced the desired wire placement across the occlusion. A .009-inch X 325-cm RotaWire Floppy was then placed in preparation for OA. Atherectomy was performed with 1.2-mm and 1.9-mm crown sizes in a stepwise fashion. Four passes with the 1.2-mm crown were performed initially at 84 K rpm and finally at 200 K rpm. The 1.9-mm crown was then introduced and passed through the artery four times at similar speeds. Postatherectomy balloon dilatations were performed in the proximal segment of the posterior tibial artery and tibioperoneal trunk using 3-mm, 3.5-mm, and 4-mm Savvy balloon catheters (Cordis Endovascular). Three-vessel runoff was established, and the angiographic outcome was excellent.

One month after the procedure, a noninvasive vascular study was performed on the patient. Ankle-brachial indices on the left and right were .95 and .88, respectively. Claudication symptoms had resolved, and the patient was able to walk much farther without any pain in his legs other than some arthritic-type pain in his knees and hips. He was thrilled with the results and denied any significant chest pain or shortness of breath, abdominal pain, syncope, near-syncope, or palpitations.

DISCUSSION

Patients presenting today for treatment of claudication, rest pain, ulceration, gangrenous lesions, or end-stage CLI may benefit from initial therapy by an endovascular approach, thereby obviating or at least delaying the more aggressive open surgical option. The majority of patients with PAD are elderly, with or without a history of diabetes, and have comorbid coronary, extracranial, and renal atherosclerosis. Many patients do not present until the atherosclerotic vascular disease has affected occlusion of the small arteries below the knee, adding to the challenge of an endovascular approach to remedial or palliative therapy. Vessel occlu-

sion and poor distal anatomy make amputation a reasonable treatment without consideration of the alternative endovascular therapy as a first-line approach to restoring blood flow. As more flexible and easier-to-use devices become available for accessing BTK vascular lesions, many patients will benefit from a first-line endovascular approach to revascularization.

With the advent of newer ablative atherectomy devices and the current armamentarium of specialized guidewires for crossing chronic total occlusions, noncompliant small-diameter balloon catheters, balloon-expandable and self-expanding covered and noncovered stents, cryotherapy, and localized drug delivery modalities, endovascular revascularization can restore an acceptable quality of life for the patient with moderate-to-severe CLI.

OA holds significant promise as a safe and effective treatment for restoring blood flow in the small arteries below the knee. Arteriography consistently demonstrates a remarkably smooth recanalized artery after OA, and a lumen that, even with conservative balloon dilatations, does not present significant dissection planes requiring stent placement. The stepwise progression in crown diameter, as illustrated in these case studies, has been shown through the OASIS trial to result in very favorable outcomes 6 months after the procedure. ■

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1. Marso SP, Hiatt WR. Peripheral arterial disease in patients with diabetes. J Am Coll Cardiol. 2006;47:921-929.
2. Wild S, Roglic G, Green A, et al. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. Diabetes Care. 2004;27:1047-1053.
3. Allie D, Hebert CJ, Lirtzman ML, et al. Critical limb ischemia, a global epidemic: a critical analysis of current treatment unmasks the clinical and economic costs of CLI. Euro Intervention. 2005;1:75-84.
4. Hogan P, Dall T, Nikolov P. Economic costs of diabetes in the US in 2002. ADA Diabetes Care. 2003;26:917-932.
5. Thom T, Haase N, Rosamond W, et al. Heart disease and stroke statistics—2006 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Circulation. 2006;113:e85-e151.
6. Simpson JB, Selmon MR, Robertson GC, et al. Transluminal atherectomy for occlusive peripheral atherosclerotic disease. Am J Cardiol. 1988;61:96G-101G.
7. Hansen DD, Auth DC, Hall M, et al. Rotational endarterectomy in normal canine coronary arteries: preliminary report. J Am Coll Cardiol. 1988;11:1073-1077.
8. Baim DS, Hinohara T, Holmes D, et al. Results of directional coronary atherectomy during multicenter preapproval testing: the US Directional Coronary Atherectomy Investigator Group. Am J Cardiol 1993;72:6E-11E.
9. Warth DC, Leon MB, O'Neill W, et al. Rotational atherectomy multicenter registry: acute results, complications, and 6-month angiographic follow-up in 709 patients. J Am Coll Cardiol. 1994;24:641-648.
10. Popma JJ, Brogan WC, Pichard AD, et al. Rotational coronary atherectomy of ostial stenoses. Am J Cardiol. 1993;71:436-438.
11. Zeller T, Rastan A, Sixt S, et al. Long-term results after directional atherectomy of femoropopliteal lesions. J Am Coll Cardiol. 2006;48:1573-1578.
12. Laird JR, Zeller T, Gray BH, et al. Limb salvage following laser-assisted angioplasty for critical limb ischemia: results of the LACI multicenter trial. J Endovasc Ther. 2006;13:1-11.