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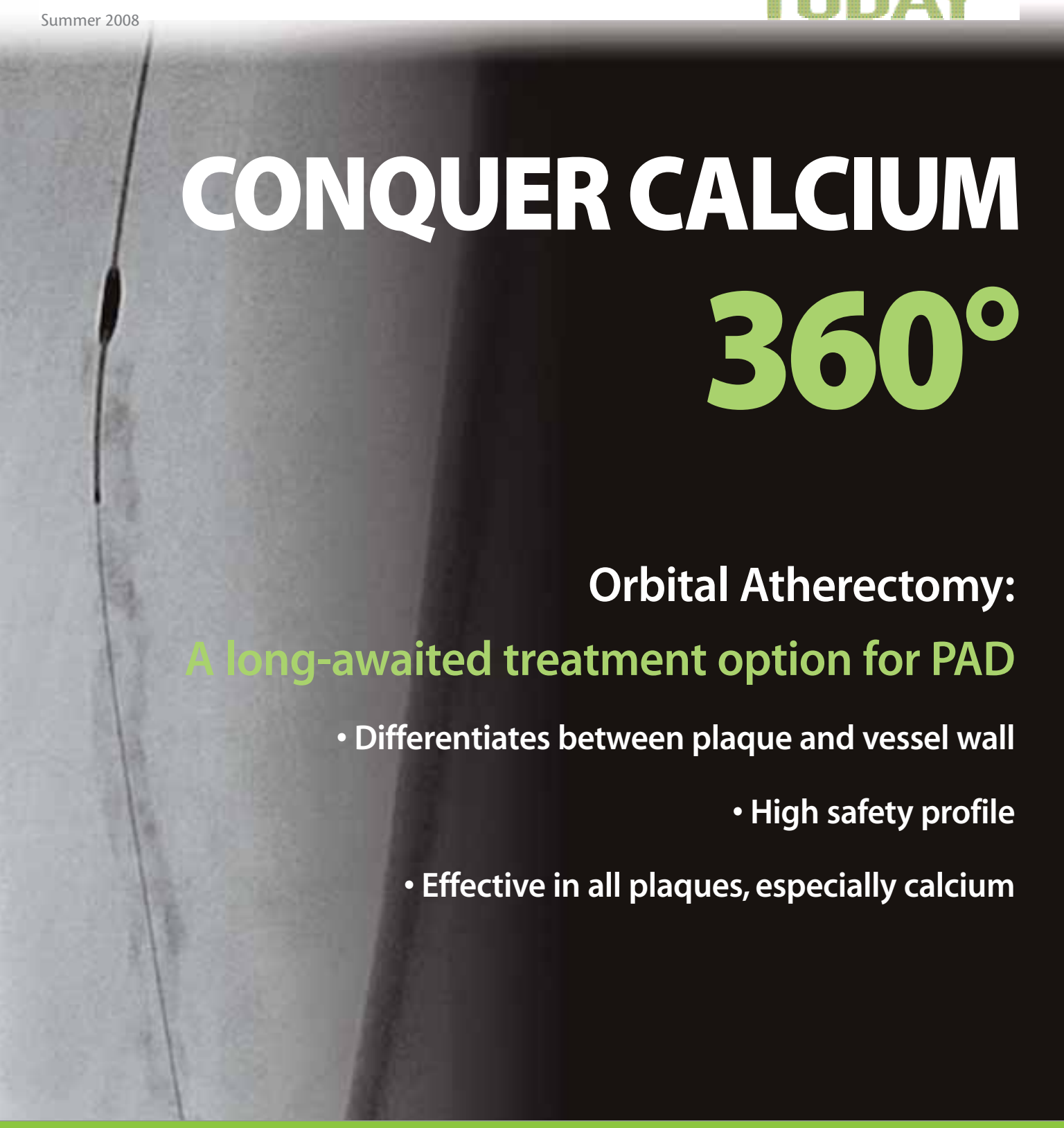


CONQUER CALCIUM 360°

Orbital Atherectomy:

A long-awaited treatment option for PAD

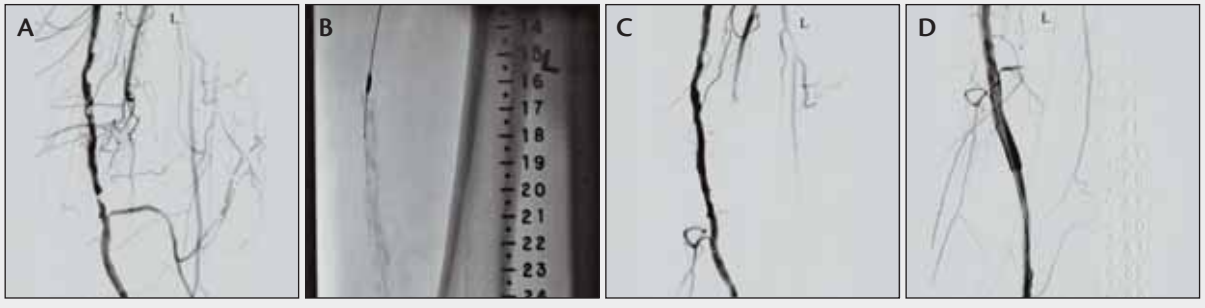
- Differentiates between plaque and vessel wall
- High safety profile
- Effective in all plaques, especially calcium

Contents

COVER STORY: HEAVILY CALCIFIED SFA LESIONS

A 69-year-old man had a history of peripheral arterial disease, coronary artery disease, scleroderma, lupus, congestive heart failure, and neuropathy. After atherectomy on the right side to advance healing of a foot wound, the patient re-presented with left-sided claudication. An abdominal aortogram showed heavily calcified lesions in the mid-to-distal superficial femoral artery (SFA) on the left side with 80% to 90% stenosis. The popliteal segment was free of significant disease, the tibial peroneal trunk was diffusely diseased with 20% to 30% stenosis, and there was two-vessel runoff via the peroneal and the anterior tibial arteries (A). The SFA was treated with a 2.25-mm Diamondback 360° Solid Crown (Cardiovascular Systems Inc., St. Paul, MN) (B). Brisk flow was re-established after 6 minutes of sanding time (C). Debulking and a resulting smooth lumen prepped the vessel for effective apposition and expansion of a stent (D). The total procedure time was <30 minutes.

Case study performed by James Park, MD, Presbyterian Hospital, Dallas, Texas



CONQUER CALCIUM 360°

Peripheral arterial disease (PAD) affects 12% to 20% of Americans ≥50 years of age. A national and global epidemic in obesity and a concomitant increase in diabetes are likely to cause an increase in PAD prevalence in the foreseeable future. Symptomatic PAD is characterized by ambulation-induced pain or claudication or, in the most severe form, critical limb ischemia (CLI) manifesting as pain at rest, nonhealing wounds, or gangrene with tissue loss. However, many patients with PAD are overlooked because they alter their lifestyles and become less active to reduce their symptoms. These "asymptomatic" patients are particularly at greater risk because they may not be treated with risk-factor modification for their ischemic limb.

Patients with PAD frequently have calcified diffuse atherosclerotic disease. In certain patients, this is encountered more frequently, especially in patients with diabetes mellitus, a history of tobacco use, renal insufficiency, and those who are older. Until recently, the endovascular approach for calcified plaques has been a formidable challenge with suboptimal results and greater complications. These patients may be ideal candidates for treatment with the Diamondback 360°™ Orbital Atherectomy System (Cardiovascular Systems Inc., St. Paul, MN) both in the small-diameter infrapopliteal arteries and in the infrainguinal arteries of the lower extremity where heavy calcium is often encountered.

The Diamondback 360° is a recent entry in the growing arsenal of endovascular technologies specifically developed for treating PAD. Orbital atherectomy safely and efficiently removes hard, calcific plaque to restore blood flow with a resulting smooth and concentric lumen, without a high risk of dissection, perforation, or ischemia due to distal embolization. Using the Diamondback 360° in the small-diameter vessels will improve circulation to the lower extremity and the pedal arch, advancing wound healing and obviating the need for surgical amputation. The device is a long-awaited treatment option that may help the 150,000 patients in the US that undergo amputation of a lower extremity each year due to advanced PAD.

Because the device can clear the majority of the below-the-knee stenoses with minimal risk to the vessel wall, adjunctive therapy may not be needed. In larger, above-the-knee stenoses, the device removes the calcium "cap" and changes vessel compliance to prepare the vessel for adjunctive therapy. After debulking with the Diamondback 360°, lower atmospheres of pressure may be needed with angioplasty, and stent apposition and expansion may be improved after the calcium cap has been removed.

Endovascular therapy is an accepted first-line treatment for patients with PAD; however, the option is not available to everyone. It is the intent of the authors to provide their insight into the disease process and its treatment, with the hope of educating others interested in providing this standard of care to the many critically ill patients facing the catastrophic possibility of limb amputation.

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Peripheral Arterial Disease

Are we doing enough to diagnose and treat patients with PAD?

BY DAVID COHEN, MD; ELIAS H. KASSAB, MD; GUY PUPP, DPM; DAVID K. ROBERTS, MD; AND MICHELLE SLOAN, RN, MSN, APN

Although healthcare providers are beginning to make great strides to advance the awareness, early diagnosis, and appropriate treatment of lower extremity peripheral arterial disease (PAD), it remains underdiagnosed and undertreated, with only 26% of the population having awareness of the symptoms and risk factors for the disease.[1,2] PAD affects an estimated 27 million adults older than 55 years of age living in Europe and North America, with an estimated 70% to 80% being asymptomatic. The prevalence of PAD in other parts of the world, including Asia, is not quantified but is presumed to be at least equivalent to Europe and North America, which further compounds the problem. The incidence of PAD increases with age to an on-average prevalence of up to 20% in persons 70 years of age or older.[3] Prospective population studies on the incidence of the more advanced stage of PAD, critical limb ischemia (CLI), project 500 to 1,000 new cases per year for every 1 million people in the population.[4]

The impact of PAD with respect to quality of life, functional capacity, amputation risk, and mortality is well established. Twenty-five to 30% of persons with CLI will be deceased within 1 year after clinical diagnosis; 30% will have undergone an amputation; and for the remaining 45%, the CLI will be resolved (25%) or persistent (20%).[5] A diabetic patient, after a first-time amputation, has 20% to 50% mortality within 3 years and a 5-year mortality rate as high as 70%.[6]

To raise public and health professional awareness about PAD and the associated sixfold higher risk of death from coronary artery disease, heart attack, or stroke, an alliance of leading health organizations, vascular health professional societies, and government agencies was organized several years ago. The PAD Coalition seeks to improve the prevention, early detection, treatment, and rehabilitation of people with, or at risk for, the disease. Coordinated by the Vascular Disease Foundation, the Coalition includes more than 70 members, representing more than 1 million dedicated health professionals.

Ongoing educational initiatives such as those provided by the Coalition are needed to promote early recognition of PAD, because screening is rarely included in an otherwise routine physical examination and only administered when PAD is suspected.

THE KEY TO SAVING LIMBS: EARLY DETECTION

Data from large-population or nationwide surveys indicate that 120 to 500 lower limb amputations for every 1 million people (or more than 150,000 in the US) are performed per year.[4] Of those, 50% of the patients have never had a vascular evaluation to determine if blood flow could be restored.[7] Interventionists and referral physicians alike can play an important role in screening patients for PAD and saving legs from the fate of amputation.

Many PAD patients are not properly diagnosed because their symptoms are often atypical or miscategorized (eg, arthritis, aging). These symptoms are not always simply described as leg pain or claudication; as identified through the PARTNERS study, the majority of PAD patients are asymptomatic or have atypical symptoms.

PAD screening questionnaires, such as the modified Rose Questionnaire and the Walking Impairment Questionnaire, which are administered by healthcare professionals, are useful in identifying the presence of PAD in individuals. Practice-based questionnaires such as the one developed by Michelle Sloan, RN, MSN, APN, from Eastlake

TABLE 1. PAD RISK FACTORS AND ASSOCIATIONS

Risk Factors
- Diabetes mellitus
- Cigarette smoking
- Dyslipidemia
- Hypertension
- Physical inactivity
- Overweight/obesity
- Buerger's disease
- Increased C-reactive protein

Demographic Associations
- Age >50 years with history of smoking or diabetes
- Family history of PAD, cardiovascular disease, or stroke
- Age ≥70 (17% of males, 20% of females)
- Male gender age >50 years, Female gender age >55 years
- Ethnicity: Hispanic, Latino, African, Asian ethnic descent
- Renal insufficiency
- Increased homocysteine with family history of PAD

THE SLOAN COMPREHENSIVE PAD FORM

Name:_____ **Date:**_____

SYMPTOM REVIEW			
	YES	NO	NOTES
1. Do you get any discomfort, aching, fatigue, or heaviness in your leg(s) when you walk that is relieved with rest?			Symptoms? Location? Distance?
2. Does the discomfort or fatigue disappear within 10 minutes if you stand still or rest?			
3. Does the discomfort ever begin when you are standing still or sitting?			
4. Do you ever need to stop and rest when you are walking or need assistance when walking?			Why?
5. Do you have difficulty keeping up with others?			Use of any assistance devices?
6. Are you bothered by burning in your feet or toes when lying in bed most nights?			Relief measures?
7. Do you have numbness in your feet?			
8. Do you have a history of ulcers or slow-healing wounds on your legs, feet, or toes?			

FUNCTIONAL STATUS			
	YES	NO	NOTES
1. How much walking or exercise do you do on a typical day?			
2. Would you have any difficulty walking one block, climbing a flight of stairs, or walking at an increased speed?			
3. Have you "slowed down" or feel less active than 1 year ago?			

RISK FACTOR ASSESSMENT

[ ] Tobacco use or smoking hx.
Duration/amt:_____ Date quit:_____
[ ] Diabetes
[ ] Coronary artery disease/MI
[ ] Dyslipidemia [ ] Metabolic syndrome
[ ] Hypertension
[ ] Previous stroke/TIA/CEA or carotid stenosis
[ ] Previous PVD hx:_____
[ ] ESRD
[ ] Age >50 _____
[ ] Obesity

Known hx. of potential differential dx:_____

PHYSICAL EXAM

	YES	NO
Skin cool to touch		
Absence of hair or uneven distribution		
Presence of dry atrophic skin		
Presence of skin discoloration		
Dystrophic brittle nails		
Muscle weakness or atrophy		
Wounds or ulcers present on lower ext.		
Rubor with dependency		
Pallor with 45° elevation for 30 seconds and sluggish capillary refill		
DP and/or PT pulses absent		
Bruits on exam		

Testing: [ ] ABI [ ] Arterial Doppler
[ ] Exercise ABI [ ] Duplex US
[ ] Segmental Pressures/PVR [ ] CT Angiogram/MRA
[ ] LE Angiogram [ ] Other
[ ] R: Pressures

Education: [ ] PAD Definition/Sx. [ ] Foot Care/Wear
[ ] Risk-Factor Modification [ ] Walking Program
[ ] Smoking Cessation [ ] Treatment Options
[ ] Other

Podiatrist:_____ **Signature:**_____
PCP:_____ **Notes:**_____

Figure 1. Administering a brief questionnaire such as this one can help identify patients at high risk for PAD.

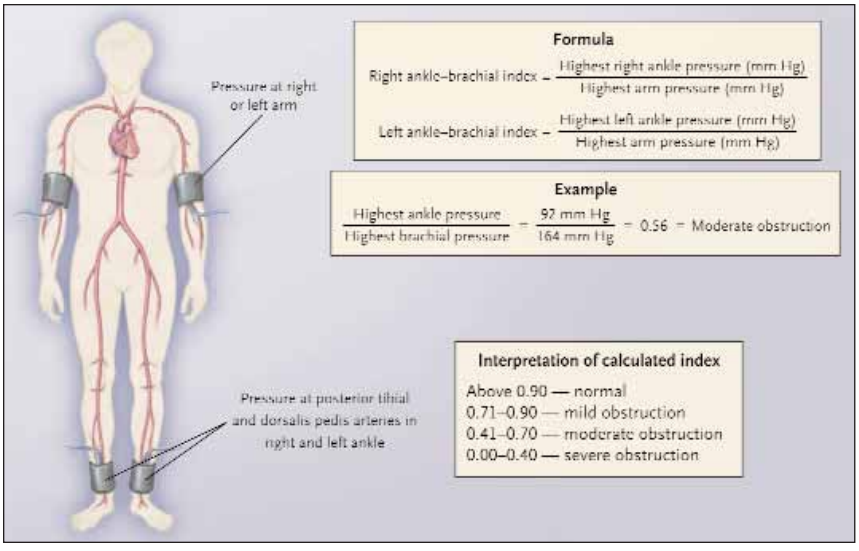

Figure 2. Pressure measurements and calculation of the ABI. (Reprinted with permission from White C. Intermittent claudication. N Engl J Med. 2007;356:1241-1250.[10])

Cardiovascular Associates in Detroit, assist in the early detection of PAD (Figure 1). The cardiologists in Sloan's practice believe that a comprehensive PAD surveillance process, including the administration of such questionnaires, also educates patients about the disease. These forms generally take only 5 to 10 minutes to complete, and by incorporating them into a center's clinical routine for high-risk patients, interventionists can potentially diagnose a patient at risk for myocardial infarction, stroke, and/or disease requiring amputation, which carries a 30% mortality rate at 5 years.

Common symptoms of PAD include:

- Muscle discomfort, cramping or pain in the hip, leg muscles, or feet when walking and relieved by rest (intermittent)
- Color changes in the skin of the legs or arms
- Numbness, weakness, or sensation of heaviness in the legs without pain when walking and relieved by rest (intermittent)
- Foot or toe sores that do not heal or are slow to heal
- Cold legs or feet
- Burning sensation or aching in the feet or toes while at rest
- Weak or absent pulse in the legs or feet
- Erectile dysfunction, especially with diabetes

The two risk factors most closely associated with the development of PAD are diabetes mellitus and a positive history of smoking (Table 1). Diabetic patients have a two-fold higher prevalence of PAD compared to nondiabetic patients. Insulin resistance, even in nondiabetics, increases the risk of developing PAD by 40% to 50%.[8] Smokers and former smokers show signs of PAD on average 10 years sooner than nonsmokers. Disease severity is directly proportional to the amount and duration of tobacco abuse, with heavy smokers having a fourfold higher risk of developing intermittent claudication.

A comprehensive PAD assessment includes diagnostic testing. Often, the first and easiest way to determine whether a patient has PAD is a noninvasive ankle-brachial systolic pressure index (ABI), such as that provided by the Unetixs Vascular Revo (Unetixs Vascular, Inc., North Kingstown, RI). "The ABI determines the hemodynamic extent of the disease when pedal pulses are diminished or absent," said Peter Moscovita, President of Unetixs Vascular, Inc. "ABIs can be done in approximately 5 minutes, and the Revo was designed to reduce operator variability. It also has a calibrated pulse volume recording with an accurate waveform that provides another measure of arterial health." An ABI of ≤0.9 is considered positive for PAD; if the ABI is between 0.95 and 0.91, the patient is considered to be borderline and requires further clinical testing (Figure 2). The lower the ABI, the greater the risk of cardiovascular events.

Recently published data obtained from a community-based population of patients older than 50 years in the PAD

TABLE 2. SURGICAL AND ENDOVASCULAR REVASCULARIZATION OPTIONS

Open Surgical

- Autogenous bypass grafts
- Synthetic bypass grafting
- Endarterectomy

Percutaneous Endovascular

Catheter-Based

- Balloon angioplasty
- Cutting balloons
- Balloon cryoplasty
- Balloon-expandable stents
- Self-expanding stents
- Stent grafts

Plaque Debulking

- Directional atherectomy
- Excimer laser atherectomy
- Orbital atherectomy

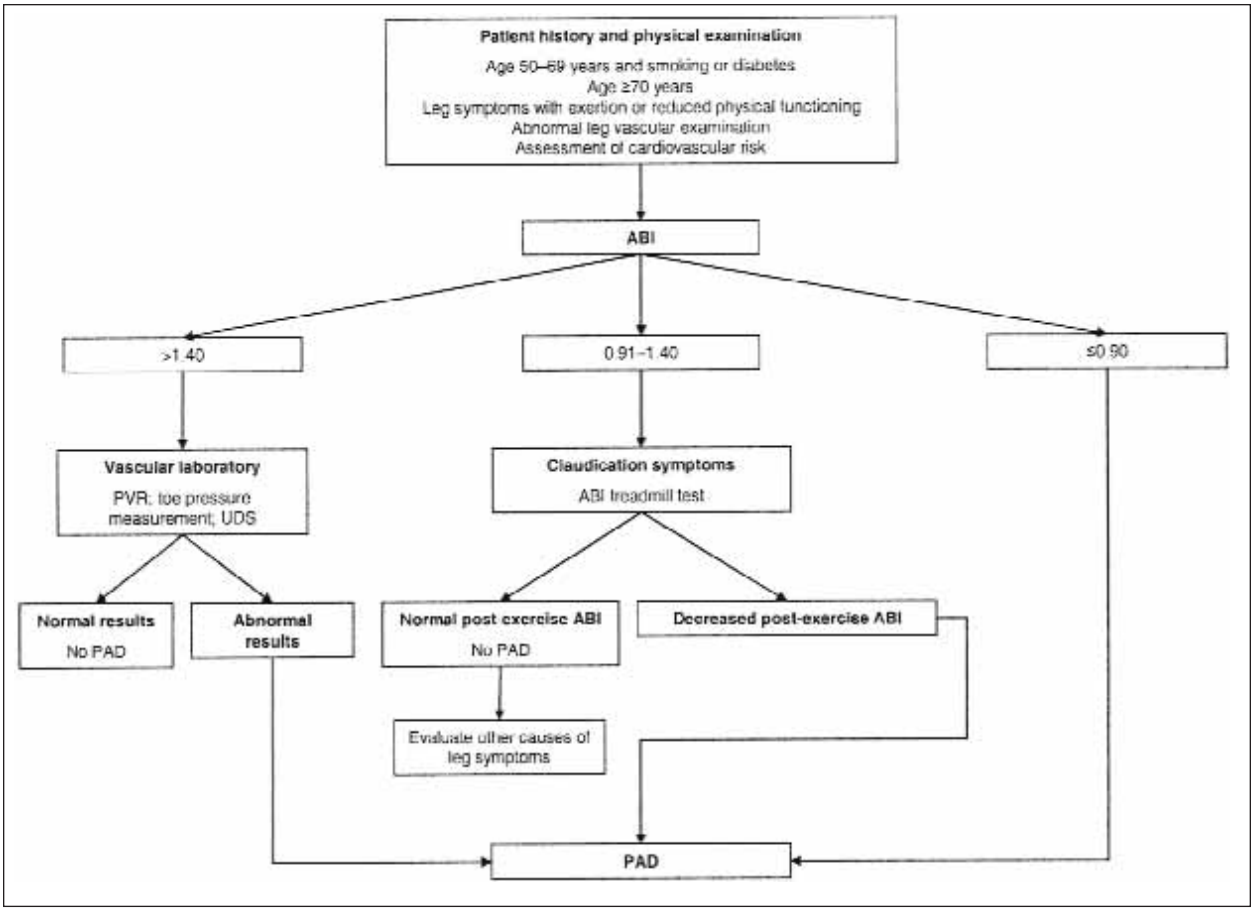

Figure 3. Protocol for the diagnosis of PAD in patients with diabetes. (Reprinted with permission from Hirsch et al. J Am Coll Cardiol. 2006;47:1239-1312.[5])

Awareness, Risk and Treatment: New Resources for Survival (PARTNERS) program identified an ABI value of 1.40 or higher in diabetic patients who typically have medial calcification of the peripheral arteries. The study implications were that high ABI values are not "normal" and are a marker for the development of foot ulcers or neuropathy and a reduced quality of life (especially in the diabetic population).[9]

If PAD is suspected in individuals with elevated ABIs, further vascular laboratory testing is indicated using a postexercise ABI, toe-brachial artery pressure index, arterial Doppler duplex ultrasound, velocity waveform analysis, and transcutaneous oxygen measurement (Figure 3).[6] Other diagnostic methods, with a significantly greater cost, include contrast-enhanced MRA and CTA. CTA or contrast-enhanced MRA imaging studies may be indicated to determine lesion characteristics and vascular access anatomy and to develop a best treatment strategy for endovascular therapy. They can also provide useful detail of lower extremity vascular anatomy, such as the presence and extent of distal runoff vessel disease.

ALLEVIATING SYMPTOMS AND RESTORING BLOOD FLOW

Once patients are diagnosed with PAD, they can benefit from any number of treatment options designed to alleviate symptoms and restore blood flow. Gone are the days of "watch and wait." Physicians and hospitals that offer progressive treatment options not only give patients new hope, but they also differentiate themselves in an ever-competitive healthcare environment.

First-line PAD therapy includes smoking cessation, a structured exercise program, weight loss, and pharmacotherapy with cilostazol.[5] Disease progression can also be decreased by the control of dyslipidemia with statin therapy, antiplatelet agents including aspirin and clopidogrel, controlled reduction in blood pressure, and dietary management.

When PAD worsens despite risk-factor modifications, endovascular or surgical treatment can restore distal pulsatile straight-line blood flow to heal or preserve lower extremity tissue and assist in maintaining walking ability.

The decision on whether to use an endovascular or surgi-

TABLE 3. TASC II CLASSIFICATIONS AND RECOMMENDED TREATMENT OF FEMORAL AND POPLITEAL LESIONS

Lesion Type	Lesion Characteristic/Intention to Treat	Recommended Treatment
A	Single stenosis ≤10 cm in length	Endovascular; angioplasty strongly preferred
	Single occlusion ≤5 cm in length	
B	Multiple stenoses or occlusions, each ≤5 cm in length	Endovascular;* angioplasty generally preferred
	Single stenosis or occlusion ≤15 cm in length and not involving the infrageniculate popliteal artery	
	Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass	
	Heavily calcified occlusion ≤5 cm in length	
	Single popliteal stenosis	
C	Multiple stenoses or occlusions totaling >15 cm in length with or without heavy calcification	Surgery for low-risk patients; endovascular for high-risk patients*
	Recurrent stenoses or occlusions that need treatment after two endovascular interventions	
D	Chronic total occlusions of common femoral artery or superficial femoral artery (>20 cm, involving the popliteal artery)	Surgery generally preferred
	Chronic total occlusion of popliteal artery or proximal tibioperoneal vessels	

**With consideration of comorbidities, patient preference, and physician endovascular expertise/success.*

cal bypass approach includes an assessment of comorbidities (such as diabetes, renal failure, and being overweight), anatomy (such as lesion length, location, and composition), as well as disease severity (Table 2).

Revised Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) guidelines recommend treatment options for PAD based on these considerations (Table 3).[8]

Stenoses or occlusions within the leg may be treated with a variety of percutaneous procedures including balloon angioplasty, atherectomy, and stenting with balloon-expandable, self-expanding, or covered stents. If thrombus is present, thrombolysis or thrombectomy may be useful before proceeding with the endovascular revascularization procedure.

Short, focal lesions are easily treated by simple balloon angioplasty. Below the inguinal ligament, self-expanding nitinol stents offer an advantage over balloon-expandable stents because of their crush resistance. However, nitinol stents do carry a risk of stent fracture, and most are not yet approved by the FDA for infrainguinal vascular implantation.

For more difficult cases, atherectomy is used to remove plaque, making subsequent balloon and stent therapy more effective. A recently available device—the Diamondback 360°™ Orbital Atherectomy System (Cardiovascular Systems Inc., St. Paul, MN)—offers a safe, new alternative for diabetics and other patients with below-the-knee calcific disease. Because the Diamondback 360° creates a smooth lumen without causing trauma to the vessel wall, adjunctive therapy frequently is not used.

As compared to the TASC I guidelines, TASC II recommends an expanded role for endovascular revascularization techniques, with morphologically intermediate type B and type C lesions now eligible for treatment by an endovascular approach.

Endovascular treatment of lesions beyond the popliteal artery should be limited to limb salvage in patients with CLI, given the absence of comparative trial data between surgical bypass and endovascular therapy. However, endovascular treatment can be used on short lesions in the anterior or posterior tibial arteries—when performed conjunctively with angioplasty of the popliteal or femoral arteries—due to the potential negative impact of outflow vessel disease.

HOPE FOR PATIENTS WITH PAD

Detecting PAD early and taking advantage of available treatment options can save lives and limbs. First steps include providing those at risk of PAD with a thorough diagnostic assessment, followed by risk factor modification including smoking cessation, a structured exercise program, weight loss, and pharmacotherapy.

When these first-line efforts fail to provide a sustained, acceptable functional capacity and quality of life, revascularization with percutaneous techniques—such as balloon angioplasty, stenting, and atherectomy—is appropriate. The Diamondback 360° is one of several recently introduced devices designed to facilitate and improve the procedural outcome and durability of percutaneous revascularization in patients with symptomatic lower extremity PAD.

Revascularization often results in visibly improved walking distance, enhanced quality of life, elimination of ischemic symptoms, and reduced amputation rates and therefore mortality. For patients who have exhausted other options, surgical intervention remains an alternative.

PAD pervasiveness will continue to increase as the population ages and the prevalence of diabetes and obesity increases. The medical community can work together and take bold steps now to reduce the overall morbidity and mortality associated with PAD. ■

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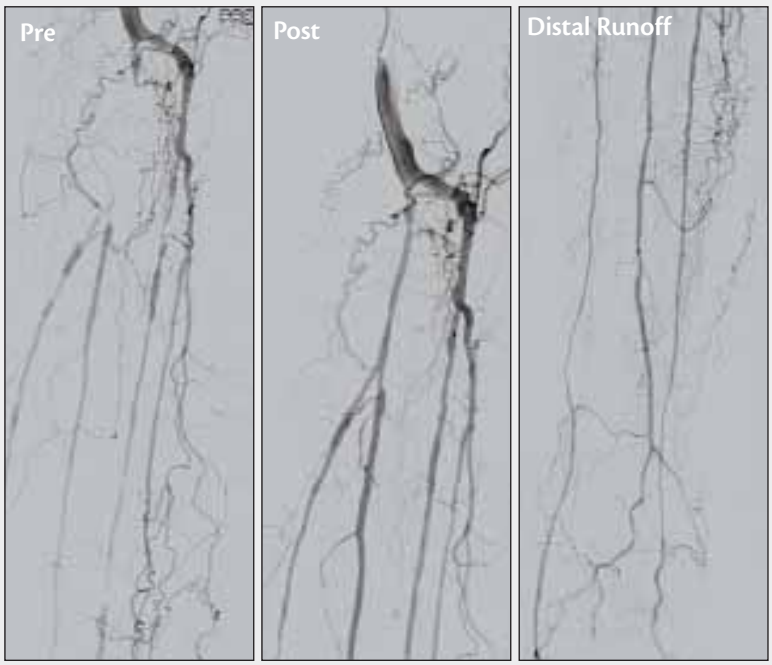
1. Selvin E, Erlinger TP. Prevalence of and risk factors for peripheral arterial disease in the United States: results from the National Health and Nutrition Examination Survey, 1999-2000. Circulation. 2004;110:738-743.
2. Ostchega Y, Paulose-Ram R, Dillon DF, et al. Prevalence of peripheral arterial disease and risk factors in persons aged 60 and older: data from the National Health and Nutrition Examination Survey, 1999-2004. J Am Geriatr Soc. 2007;55:583-589.
3. Hiatt WR, Hoag S, Hamman RF. Effect of diagnostic criteria on the prevalence of peripheral arterial disease. The San Luis Valley Diabetes Study. Circulation. 1995;91:1472-1479.
4. Norgren L, Hiatt WR, Dormandy MR, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). Eur J Vasc Endovasc Surg. 2007;33:S1-S70.
5. Hirsch AT, Haskal ZJ, Hertzer NR, Bakal WE, et al. ACC/AHA 2005 practice guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease). J Am Coll Cardiol. 2006;47:1239-1312.
6. Van Gils CC, Wheeler LA, Mellstrom M, et al. Amputation prevention by vascular surgery and podiatry collaboration in high-risk diabetic and nondiabetic patients. Diabetes Care. 1999;22:678-683.
7. Allie DE, Herbert CJ, Lirtzman MD, et al. Critical limb ischemia: a global epidemic. Eurointerventions. 2005;1:75-84.
8. Muntner P, Wildman RP, Reynolds K, et al. Relationship between HbA1c level and peripheral arterial disease. Diabetes Care. 2005;28:1981-1987.
9. Allison MA, Hiatt WR, Hirsch AT, et al. A high ankle-brachial index is associated with increased cardiovascular disease morbidity and lower quality of life. J Am Coll Cardiol. 2008;51:1292-1298.
10. White C. Intermittent claudication. N Engl J Med. 2007;356:1241-1250.

CASE STUDY: SINGLE-DEVICE TREATMENT OF MULTIVESSEL DISEASE

An 82-year-old man presented with multiple heavily calcified arteries of the left lower leg. The tibial peroneal trunk, anterior tibial artery, posterior tibial artery, and the peroneal were totally occluded and treated with 1.75-mm and 2-mm Diamondback 360° Classic Crowns. The total sanding time was less than 14 minutes. postprocedural residual stenosis was between 5% and 10%, and no adjunctive therapy was required.

Case study performed by Russell Lam, MD, Director of Endovascular Surgery at Presbyterian Hospital, Dallas, Texas



CASE STUDY: DEBULKING A COMPLETELY STENOSED POSTERIOR TIBIAL ARTERY

A 73-year-old woman was scheduled for a below-the-knee amputation in 2 days when the internist called for a final podiatric evaluation. The patient had a history of insulin-dependent diabetes mellitus, hypertension, end-stage renal disease, hyperlipidemia, renal transplant, neuropathy, glaucoma, and peripheral arterial disease (PAD). Current medical therapy included insulin glargine (rDNA origin) injection, hydromorphone, tacrolimus, estrogen, fluticasone propionate, prednisone, simvastatin, pregabalin, colase, alprazolam, amlodipine besylate, losartan, heparin, clopidogrel, pantoprazole, hydrazine, and fentanyl.

Previously, the patient underwent a series of attempts to address a nonhealing wound. An endovascular procedure was followed by amputation of the hallux. Because the foot continued to deteriorate, a second endovascular procedure was completed, followed by an amputation of the first metatarsal. Saphenous vein bypass graft implantation was subsequently performed. Continued deterioration of the gangrenous right foot led to the proposed below-the-knee amputation.

Vascular evaluation showed little flow to the foot, and atherectomy with the Diamondback 360° was proposed to debulk the heavily calcified, 100% stenosed posterior tibial artery. A successful endovascular procedure with the newly released atherectomy device followed by balloon therapy ultimately provided ample return of blood flow, which allowed additional leg-saving measures. A multidisciplinary approach involving an internal medicine physician, a cardiac interventionist, and a podiatrist was crucial to a successful patient outcome (Figures 1 through 4).

Case study performed by Guy Pupp, DPM, Providence Hospital, Southfield, Michigan, and Thomas P. Davis, MD, St. Johns Medical Center, Detroit, Michigan

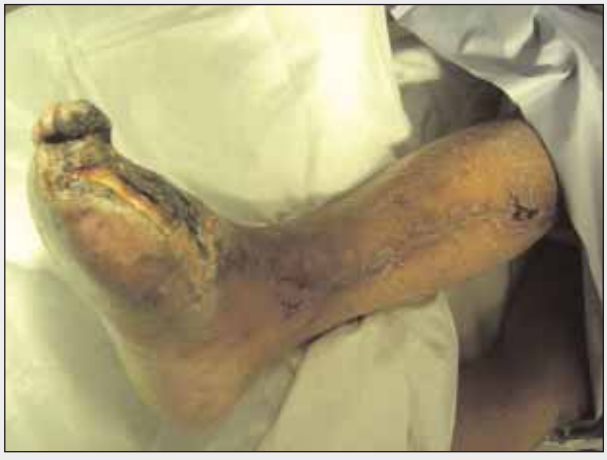


Figure 1. Deterioration of the gangrenous foot despite several attempts to restore flow through the popliteal artery.

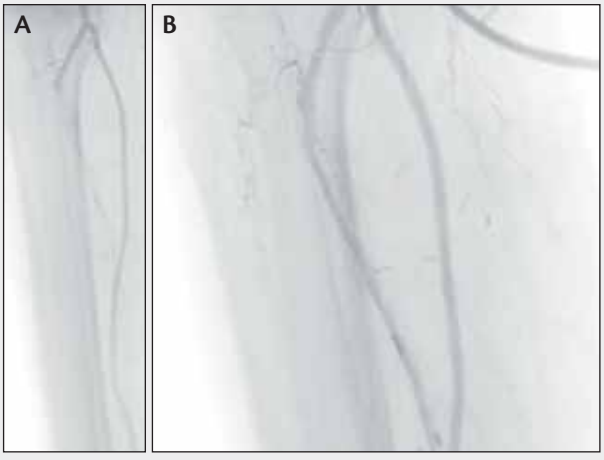


Figure 2. Pre- (A) and post- (B) revascularization of the posterior tibial artery.

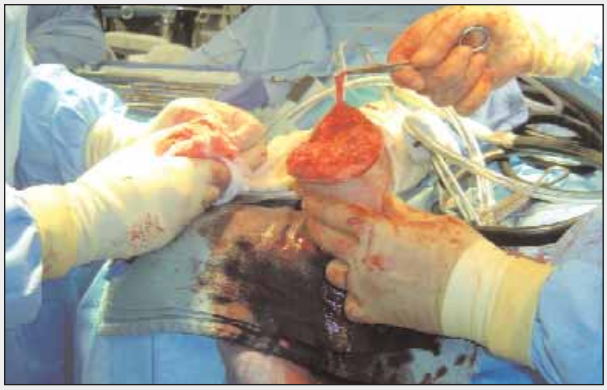


Figure 3. A chopart midfoot amputation, tendo-achilles lengthening (tenotomy), and an anterior tibial tendon transfer to the dorsal lateral foot were performed after revascularization.

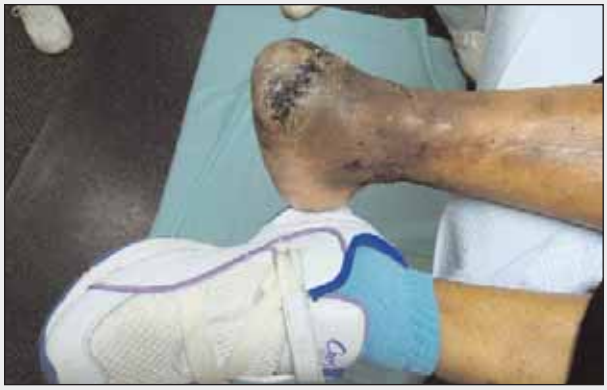


Figure 4. This patient's leg was saved from amputation due to arterial revascularization. A padded shoe is all that will be needed to restore this patient to full mobility.

A New Treatment Option for Patients With Peripheral Arterial Disease

The Diamondback 360°™ Orbital Atherectomy System.

BY ROBERT CUFF, MD; SEAN JANZER, MD; AND C. DAVID JOFFE, MD, FACC

The Diamondback 360°™ Orbital Atherectomy System (Cardiovascular Systems Inc., St. Paul, MN) gives physicians an effective new option for restoring blood flow to the lower extremities. A percutaneous endovascular device designed to remove calcific plaque in patients with stenotic or occluded peripheral arteries, the Diamondback 360° was cleared by the FDA for peripheral application in August 2007. FDA clearance was also received for treatment of stenoses in synthetic arteriovenous hemodialysis access grafts, and a European CE Mark was received for use in the treatment of peripheral arterial stenosis.

The Diamondback 360° gives patients with calcified peripheral arteries a treatment option like none before. Atheromatous disease is debulked using the sanding action of an orbiting diamond-coated crown (Figure 1), which is available in a variety of sizes and Classic and Solid Crown configurations (Figure 2). The crown is mounted on the end of a flexible drive shaft, and the entire catheter is placed over a .014-inch ViperWire™ guidewire, which allows for proper positioning of the crown and provides a center of rotation for the catheter. A control handle supports bidirectional sanding of arterial segments up to 7.5 cm in length (Figure 3). A touch-screen controller regulates rotational speed within a predetermined range, records operating time, and regulates saline flow.

The device's unique orbital mechanism of action, based on centrifugal force (crown mass X orbital speed^2 / orbit radius), causes the eccentrically mounted crown to "orbit" as it rotates while advancing through the lesion (Figure 4). As the rotational speed increases, the crown increases the luminal diameter up to 1.75 times the crown size, essentially upsizing within the vessel to achieve maximal luminal gain without exchanging catheters (Figure 5). The diamond-coated crown provides "differential sanding" for noncompliant, calcified tissue, while healthy, more elastic arterial tissue flexes away from the crown.

Orbital atherectomy with the Diamondback 360° is conceptually similar to rotational atherectomy (Rotablator, Boston Scientific Corporation, Natick, MA), which uses a diamond-coated burr. The major differences between the two devices are the shape of the crown/burr (eccentric vs concentric), the mechanism of action (Rotablator "rotates" like a power drill rather than "orbits"), and by the fact that the Diamondback 360° crown is not in continuous contact with the lumen, therefore allowing crown movement within the vessel lumen and reducing the potential for heat injury to the arterial wall.

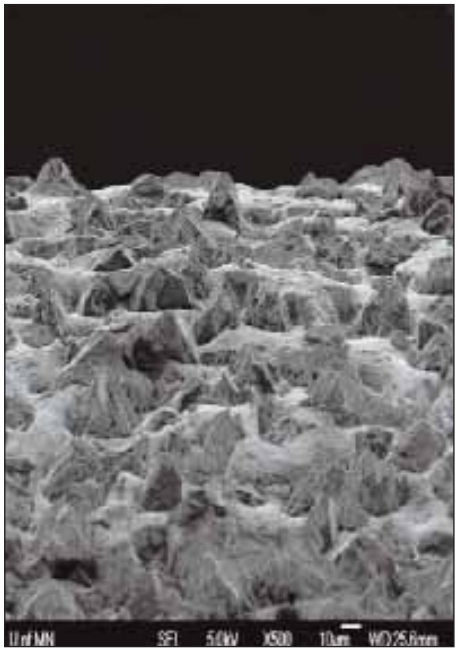


Figure 1. Scanning electron micrograph of the Diamondback 360° crown embedded with diamond chips.

THE DEVICE IN ACTION

The orbital atherectomy procedure first requires placement of the .014-inch core X 335-cm-long ViperWire™ guidewire across the lesion with the guidewire tip positioned in the distal true lumen. The ViperWire—available in flexible and firm support configura-

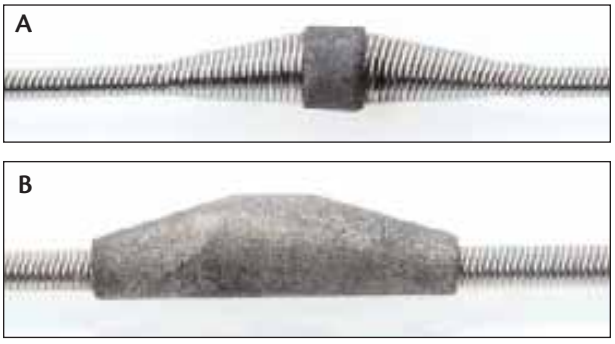


Figure 2. The Diamondback 360° Classic (A) and Solid Crowns (B).

tions—is the only guidewire that can be used with the Diamondback 360°. The ViperWire has a .017-inch-diameter spring coil tip to prevent inadvertent advancement of the atherectomy crown beyond the tip of the guidewire (Table 1). The flexible ViperWire is used with the Classic Crown, whereas the firm wire is used with the Solid Crown. Both wire configurations are compatible with .018-inch crossing devices as well as other endovascular devices.

The Classic and Solid Crowns range in size from 1.25 (Classic only) to 2.25 mm in 0.25-mm increments. The final orbit diameter ranges from 1.5 to 4.5 mm with a 1:1.75 device-to-lumen ratio, depending on the crown type and size, rotational speed, and plaque morphology.

Because the mass of the Classic Crown is smaller, it yields slightly smaller luminal gains, thus providing additional options for vessel-to-crown sizing. The Classic Crown is often used in more tortuous vessels and in the smaller vessels of the lower leg because it is slightly more flexible in the crown region. Only the middle of the elliptical portion on the Classic Crown is covered with extremely fine diamond grit, whereas the front and back tapered sections of the Solid Crown have diamond-coated surfaces that improve its ability to recanalize occluded arteries. Also, the entire elliptical portion of the Solid Crown is covered with a diamond coating and has more mass than the Classic Crown, giving it the ability to create slightly larger lumens (Figure 2). Both devices allow bidirectional sanding—proximal to distal and distal to proximal.

Crown type and size selection are determined following contrast angiography or intravascular ultrasound performed at the beginning of the procedure or from preprocedure noninvasive imaging by CTA or MRI. Proximal and distal vessel anatomy, including tortuosity and satisfactory distal runoff, contribute to device selection and the development of a treatment strategy. The Diamondback 360° sheath and catheter shaft are visible under fluoroscopy and are compatible with a 6- or 7-F sheath, depending on crown size (Table 1).

After the crown is positioned proximal to the lesion, a foot pedal actuator connected to the controller is depressed once to begin saline infusion into the catheter shaft. Pedal depression a second time, within 5 seconds of the first, opens the compressed gas line and starts the air-powered turbine to actuate shaft and crown rotation. The crown control knob is moved laterally to advance the crown antegrade through the lesion and then moved in the opposite direction to sand in the retrograde direction.

Because of a 1:1 ratio between the knob and crown movement that makes crown location predictable, and because potential injury to the arterial wall is minimal, the device can be run without live fluoroscopy. Combined with a brief procedure time (typically under 8 minutes total time with the Diamondback 360°), a reduction in radiation use is possible.

For any set position of the catheter sheath within the artery, crown forward movement is a maximum of 7.5 cm. To treat a longer or more distal lesion, the catheter is simply advanced further into the artery to perform atherectomy. Releasing the pedal closes the compressed gas line, stops crown rotation, and reduces the saline flow.

The rotating crown is most effectively advanced through a lesion in a gentle, slow, and continuous motion at approximately 1 cm per second, with brief resting intervals of 20 to 30 seconds between treatments. Crown rotational

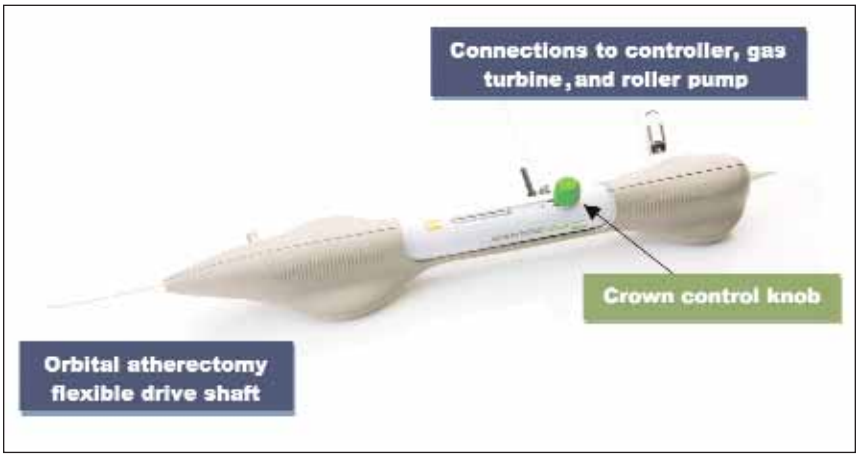
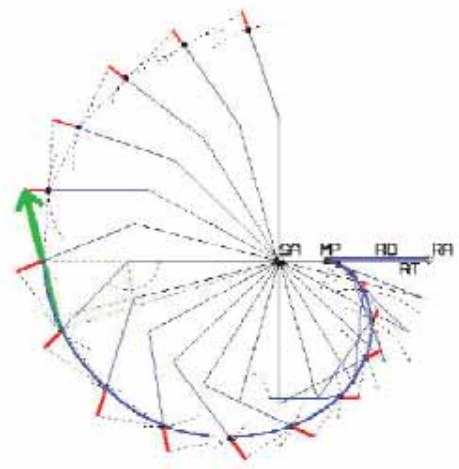


Figure 3. The Diamondback 360° ergonomic handle to which the orbital atherectomy drive shaft and controller are attached. The crown control knob is advanced to the left a maximum distance of 7.5 cm and then retracted to perform bidirectional atherectomy.



$$\text{Centrifugal Force} = \frac{\text{crown mass X orbital speed}^2}{\text{orbit radius}}$$

Figure 4. Centrifugal force decreases as the radius of the Diamondback 360° orbit increases. Maximal luminal gain is achieved with resulting lumens of up to 1.75 times the size of the crown.

TABLE 1. DIAMONDBACK 360° SPECIFICATIONS

Sheath Requirement		
Crown size: 1.25, 1.5, 1.75, 2 mm	6 F	
Crown size: 2.25 mm	7 F	
Crossing Profile	**Classic Crown**	**Solid Crown**
Crown size: 1.25, 1.5, 1.75 mm	.069 inch	.069 inch
Crown size: 2 mm	.076 inch	.079 inch
Crown size: 2.25 mm	.088 inch	.091 inch
Catheter Working Length	135 cm	
Guidewire Compatibility	ViperWire only; .014-inch core, 335 cm long	
Wire Configurations		
Firm and flexible	.017-inch tip	
Minimum Vessel Diameter	1.5 mm	

speeds are selected from a drop-down menu on the controller user interface with rotational speed options of low, medium, and high corresponding to orbital speeds ranging from 60,000 to 200,000 rpm, depending on the crown type and size. Other operational parameters and preset limits on device operation are automatically set by the software when the crown type and size are entered.

When the turbine is active, the user interface on the controller displays the selected speed, the real-time crown revolutions per minute, the individual run or event time, and total atherectomy treatment time. The total procedure time is the sum of all individual event times with one on/off cycle constituting an event. The physician can subjectively evaluate crown performance from parameters displayed on the user interface as well as from auditory and tactile feedback during the atherectomy procedure.

During resting periods, contrast injection through the introducer sheath allows angiographic assessment of the atherectomy results and guides subsequent steps in the procedure. If lumen patency is not satisfactory, the physician may continue to treat the lesion by moving the crown

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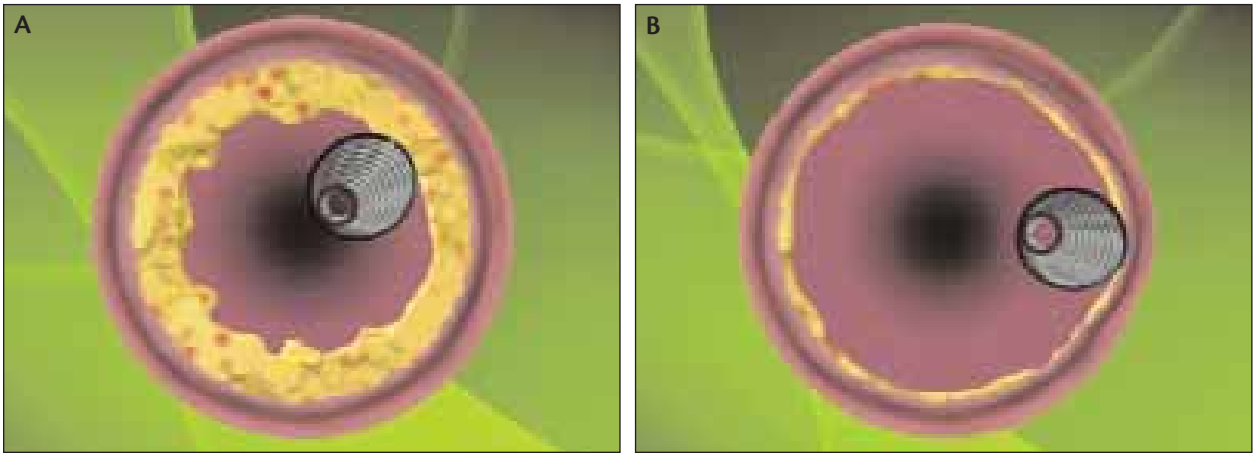

Figure 5. The Diamondback 360° diamond-coated crown differentially sands noncompliant, calcified tissue (A). The healthy, more elastic arterial tissue flexes away from the crown, helping to minimize damage to the vessel wall (B).

An Essential Complement to the Endovascular Toolbox

Orbital atherectomy fills an unmet need in safely treating PAD patients.

BY P.K. KHANNA, MD, FACC; AMIR Z. MALIK, MD, FACC, FSCAI; AND RAYMOND DATTILO, MD, FACC

Today, the endovascular physician has access to a number of medical devices to provide care to patients with peripheral arterial disease (PAD). Starting in the late 1980s, atherectomy devices were added to the toolbox to complement percutaneous balloon angioplasty (PTA) and stents. Each device performs a unique task and fills a unique need in treating patients. Orbital atherectomy with the Diamondback 360°™ Orbital Atherectomy System (Cardiovascular Systems Inc., St. Paul, MN)—a recent technological advancement—addresses the 70% of calcified infrageniculate and 30% of infrainguinal lesions[1] (Figure 1). An effective way to debulk challenging calcified lesions anywhere in the leg, as well as smaller below-the-knee vessels with any plaque morphology, the Diamondback 360° expands the interventionist's ability to safely treat more patients and quickly restore them to full mobility.

COMPARISON OF TOOLS

Although open surgical procedures have a high long-term durability rate, complication rates are also high, with major wound infections occurring in 10% to 30% of patients, myocardial infarction in 1.9% to 3.3% of patients, and a mortality rate of 1.3% to 6%.[2-6] As a result, bypass surgery has increasingly been replaced by minimally invasive endovascular therapy over the past decade as a first-line treatment for many patients with PAD. An evolving endovascular toolbox has accelerated this trend. Interventional treatments for infrapopliteal disease currently include angioplasty, stents, and atherectomy and endarterectomy devices that debulk or remove plaque from atheromatous lesions.

Balloon angioplasty and stents have been proven effective in managing coronary artery disease. However, when used in peripheral arteries, these devices have been less successful due to the nature of PAD that is often accompanied by calcified lesions, high rates of restenosis, diffuse disease, and heavy plaque burden.

Angioplasty

Disrupting the plaque from within the media and stretching the vessel wall to improve luminal diameter with angioplasty may affect intimal and medial hyperplasia leading to restenosis. Conversely, atherectomy physically removes the atheroma without causing barotrauma or resulting hyperplasia of the vessel wall. Debulking with the Diamondback 360°, in particular, creates a smooth, concentric lumen for optimal laminar flow.[1] Unlike atherectomy devices that shave or ablate plaque from the vessel wall, the Diamondback 360° uses the centrifugal force of an orbiting diamond-coated crown to sand noncompliant, heavily calcified plaque into 2- to 3-µm particles while preserving the integrity of healthy tissue.

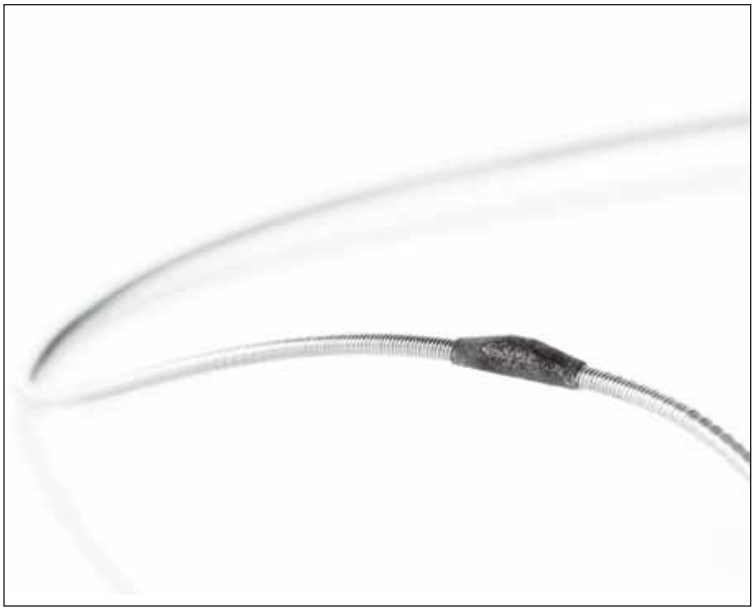

Figure 1. The Diamondback 360° is the most recently available treatment option in the endovascular toolbox.

Given the unique mechanism of action of the Diamondback 360°, the risk of dissection is smaller than with plain old balloon angioplasty (no major and 10.5% minor dissections in the OASIS Trial of 124 patients).[1] Balloon angioplasty's problems with dissection have been noted in heavily calcified coronary arteries,[7,8] at the junction of calcified and noncalcified plaque where the balloon inflation fractures the intima-medial border.

In a study of 41 patients with either peripheral or coronary lesions,[9] intravascular ultrasound after balloon angioplasty showed that localized calcium deposits have a direct role in promoting dissection, presumably by increasing shear stresses within the plaque. Seventy-six percent of patients in the study had significant dissection or plaque fracture after balloon dilation. Dissections were frequently located adjacent to the calcific portion of the vessel wall and were significantly larger in calcified vessels.

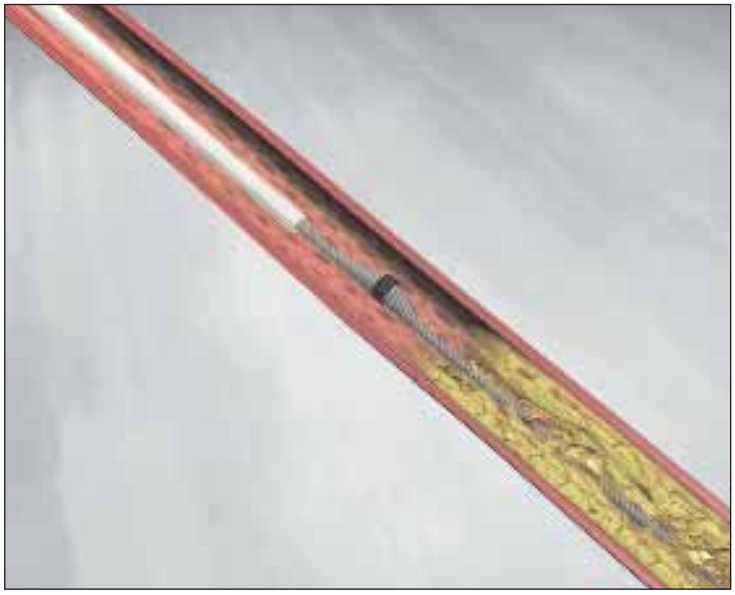

Figure 2. The Diamondback 360° differentiates between healthy, elastic tissue and essentially removes only the noncompliant calcified plaque.

Known for its effectiveness in calcium, the Diamondback 360° may achieve stand-alone results, especially below the knee. Debulking with the Diamondback 360° can also be used to improve arterial compliance, especially above the knee, making post-procedure vessels more elastic and preparing them for subsequent balloon therapy. Adjunctive balloon dilation after orbital atherectomy typically requires fewer atmospheres of pressure, which may spare the vessel from barotrauma and lessen the risk of dissection.

To overcome the failings of plain old balloon angioplasty, alternative balloon modalities, including cutting or scoring balloons and cryoplasty, have been developed. The cutting or scoring balloons have longitudinal microsurgical blades or scoring edges bonded to the balloon. The force of the balloon dilation causes the tips of the atherotomes to score the lesion, thereby allowing a more gradual and controlled vessel expansion. These devices can be effective in fibrotic or calcified lesions and have less risk of major dissection than plain old balloon angioplasty. AngioSculpt (AngioScore, Inc., Fremont, CA) dissections have occurred in 12.8% to 13.6% of lesions.[10,11] However, cutting and scoring balloons that are no longer than 2 cm make these devices impractical for treating diffuse disease or long occlusions.

Cryoplasty balloons expose intimal tissue to subzero temperatures, with the use of liquid nitrous oxide as the balloon inflation media. The cooling modifies the plaque and is thought to reduce proliferation rates essential to the restenotic process. Furthermore, a prospective multicenter registry of 102 patients receiving cryoplasty treatment showed a rate of major dissections of 7%.[12]

Although these advanced balloons have much lower dissection rates compared to plain-old balloon angioplasty, they still displace plaque rather than remove it, unlike atherectomy, which removes plaque.

Stents

Currently, the US FDA has cleared only one stent for use in the superficial femoral artery. The IntraCoil (ev3 Inc., Plymouth, MN) is constructed from a single strand of nitinol wire and wound into the shape of a simple coil, which allows extreme flexibility and resistance to fracture. However, the low ratio of metal surface to open area means that plaque is exposed and ridges are formed, which affects the flow dynamics and encourages restenosis. This issue is minimized with other nitinol stents with a tighter mesh design (frequently used "off label" in the femoropopliteal arteries). However, the potential for stent fracture and resulting higher restenosis rates remain. Stent fractures have been observed in up to 24.5% of cases in the femoropopliteal arteries.[13] The incidence of stent fracture is more likely to occur with longer stents, and patency rates decrease at 12 months for patients with stent fractures (41% vs 84%).[13]

Stent grafts, covered stents, and balloon-expandable

covered stents—developed to duplicate the gold standard of surgical bypass—have an advantage over stents in that they cover the vessel wall. They may be useful for treating dissections, perforations in smaller vessels, or aneurysmal disease.

Although stents and their derivatives allow increased laminar flow, device performance, both acutely and long-term, is limited by the potential for stent fractures, neointimal hyperplasia, incomplete stent expansion, malapposition, and impaired endothelialization with thrombosis. Removing obstructive atheromatous plaque with atherectomy before stent placement may resolve several of these issues.

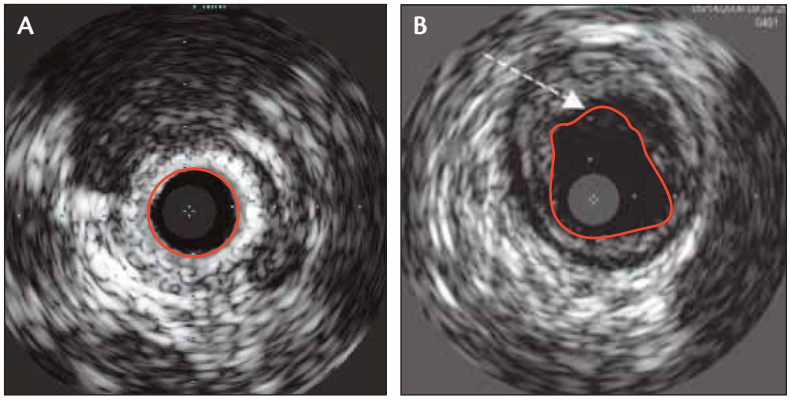

Figure 3. The Diamondback 360° leaves a smooth, concentric flow channel (A), whereas use of other devices may leave uneven linear flow channels from directional cutting (B).

The Diamondback 360° has an advantage in that it removes heavily calcified "rock piles" that stand in the way of successful stent apposition and expansion. The device's unique mechanism of action effectively primes the vessel for adjunctive therapy by differentiating between healthy, elastic tissue and essentially removing only the noncompliant calcified plaque (Figure 2). The subsequent smooth, concentric lumen mimics that of a native vessel and assists in making stent placement relatively trouble-free (Figure 3).

An excellent tool to debulk calcium anywhere in the leg, the Diamondback 360° is also effective in various plaque morphologies below the knee due to device sizes that achieve ample luminal gain. Stand-alone results are often possible in the smaller infrageniculate vessels, obviating the need for adjunct therapy.

Comparatively, the SilverHawk Plaque Excision System (ev3 Inc.) and Turbo Elite or Turbo-Booster Laser Catheters (Spectranetics Corporation, Colorado Springs, CO) perform well at excising thrombus and soft-to-fibrofatty plaque both above and below the knee.

The SilverHawk device uses a rotating carbide blade to shave plaque from the arterial wall. On activation, a nose cone is deflected to expose and place a carbide blade rotating at 8,000 rpm against the atheroma. Plaque removal is directional along the length of the artery and is performed during a series of passes, with 10° rotations of the blade orientation to remove plaque in all directions. Plaque excised from the SilverHawk device is shuttled into a reservoir within the tip of the catheter, and depending on the plaque volume, the catheter is removed from the artery to remove the plaque from the nose cone.

The SilverHawk catheters effectively cross chronic total occlusions containing fibrotic plaque and are most effective in short, fibrotic stenoses. Clinically significant macrodebris, necessitating the use of embolic protection, has been reported in patients treated with the SilverHawk.[14]

Unlike the Diamondback 360°, the SilverHawk and the Turbo Elite and Turbo-Booster laser catheters do not differentiate diseased from nondiseased tissue, increasing the risk of significant injury to the media and the creation of linear flow channels through thrombogenic substrata of the arterial wall (Figure 3).

The Turbo Elite and Turbo-Booster Laser Catheters use laser energy to ablate tissue. Ultraviolet laser light energy with a wavelength of 309 nm is delivered in pulses through a catheter tip to vaporize organic material by breaking molecular bonds and generating heat, which vaporizes water molecules that rupture cellular elements within or surrounding the tissue being treated. The Turbo-Booster Laser Guide Catheter differs from the Turbo Elite in that its laser-emitting component is placed to the side of the catheter shaft, allowing a quadrant-like excisional path along the diseased arterial wall. Both are powered by a laser unit that is large, cumbersome to store and maneuver, and requires a large capital investment. Saline is infused across the laser catheter to reduce the formation of microbubbles and minimize heat injury to the arterial wall.

The Turbo Elite catheters are most effective in soft plaque and thrombus-containing lesions. An advantage of these devices is that they can cross short- or long-segment occlusions without the use of a guidewire. Particle sizes after laser ablation are 10 µm or less in diameter, and complications from device use are infrequent: acute reocclusion (1%), perforation (2.2%), and distal embolization (3.9%). Table 1 includes a comparison of all of these devices.

TABLE 1. COMPARISON OF ATHERECTOMY DEVICES

	Cardiovascular Systems Inc.	Spectranetics Laser Guide Catheter	ev3/FoxHollow
Product	Diamondback 360°	Turbo-Booster	SilverHawk
Minimum sheath size (F)	6, 7	7, 8	6, 7, 8
Maximum guidewire size (inch)	.014	.014, .018	.014
Guidewire length (cm)	335 (OTW)	300 (OTW)	300 (OTW)
Working length (cm)	135	110	107, 110, 135
Available sizes (mm)	1.25, 1.5, 1.75, 2, 2.25	1.4, 1.7, 2	1.9, 2.7
Crossing profile (inch)	.069–.091	.06–.08	.08, 0.11
Maximum lumen gain (mm)	2–5.3	3.5–5	2–5.5

OTW, over the wire.

The endovascular toolbox continues to expand to safely and effectively restore straight-line blood flow to ischemic territories at risk of amputation. Each tool has its place in conquering PAD with fewer acute risks to the patient than open bypass surgery, which remains an option for patients with advanced disease. The Diamondback 360° is the most recently available percutaneous treatment option for patients with challenging peripheral lesions. A safe and effective treatment, the Diamondback 360° offers the unique advantage of debulking calcified peripheral vessels and is quickly being considered the "gold standard" for below-the-knee treatment of PAD. As new devices and design iterations continue to proliferate, so must the number of patients served by these advancements designed to save limbs and lives. ■

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1. CSI data on file.
2. Dalman RL, Taylor LM. Basic data related to infrainguinal revascularization procedures. Ann Vasc Surg. 1990;4:309-312.
3. Comerota AJ, Weaver FA, Hosking JD, et al. Results of a prospective randomized trial of surgery versus thrombolysis for occluded lower extremity bypass grafts. Am J Surg. 1996;172:105-112.
4. Ouriel K, Fiore WM, Geary JE. Limb-threatening ischemia in the medically compromised patient: amputation or revascularization? Surgery. 1988;104:667-672.
5. Taylor LM, Edwards JM, Porter JM. Present status of reversed vein bypass grafting: five year results of a modern series. J Vasc Surg 1990;11:193-206.
6. Taylor LM, Yeager RA, Moneta GL, et al. The incidence of perioperative myocardial infarction in general vascular surgery. J Vasc Surg. 1991;15:52-61.
7. Werner GS, Sold G, Buchwald A, et al. Intravascular ultrasound imaging of human coronary arteries after percutaneous transluminal angioplasty: morphologic and quantitative assessment. Am Heart J. 1991;122:212-220.
8. Potkin BN, Mintz GS, Keren G, et al. Ultrasound assessment of lesions composition predicts mechanisms of PTCA. Circulation. 1991;84:II-722.
9. Fitzgerald P, Ports T, Yock P. Contribution of localized calcium deposits to dissection after angioplasty. An observational study using intravascular ultrasound. Circulation. 1992;86:64-70.
10. Scheinert D, Graziani L, Peeters P, et al. Results from the multi-center registry of the novel AngioSculpt scoring balloon catheter for the treatment of infra-popliteal disease. Cardiovasc Revasc Med. 2007;8:113.
11. Mooney M, Teirstein P, Moses J, et al. Final results from the US multicenter trial of the AngioSculpt Scoring Balloon Catheter for the treatment of complex coronary artery lesions. Am J Cardiol. 2006;98(suppl):121M.
12. Laird J, Jaff MR, Biamino G, et al. Cryoplasty for the treatment of femoropopliteal arterial disease: results of a prospective, multicenter registry. J Vasc Interv Radiol. 2005;16:1067-1073.
13. Scheinert D, Scheinert S, Sax J, et al. Prevalence and clinical impact of stent fractures after femoropopliteal stenting. J Am Coll Cardiol. 2005;45:312-315.
14. Shammas N, Dippel E, Coiner D, et al. Preventing lower extremity distal embolization using embolic filter protection: results of the PROTECT registry. J Endovasc Ther. 2008;15:270-276.

CASE STUDY: LIMB SALVAGE PREVENTING ABOVE-THE-KNEE AMPUTATION

A 74-year-old man presented with gangrene on the right first and fourth toes and was advised to undergo an above-the-knee amputation (Figure 1). The patient has type 2 diabetes mellitus and a history of coronary artery disease, including a heart attack and coronary bypass. He has moderate mitral valve stenosis, left atrial and ventricular hypertrophy, and he has also undergone an aortic valve replacement.

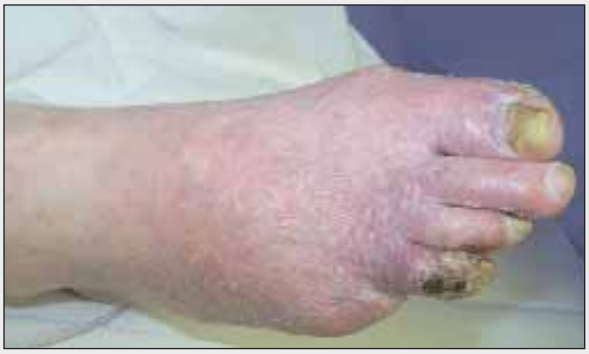


Figure 1. This patient was originally advised to undergo an above-the-knee amputation of his right foot, which prompted a second opinion and the resulting orbital atherectomy procedure. Ulcerative cellulitis and critical limb ischemia (gangrene) of the fourth toe were evident on examination.

Before undergoing an amputation, the patient sought a second opinion and subsequently received endovascular therapy with the Diamondback 360°. Baseline angiography determined that all three arteries below the knee were occluded with evidence of some collateralized flow (Figure 2A). A 1.75-mm Classic Crown restored blood flow to the lower limb, with atherectomy performed on two segments of the heavily calcified posterior tibial artery. Orbital atherectomy was performed at 80,000, 140,000, and 200,000 rpm with 1-minute treatments in each segment (Figure 2B). After debulking the posterior tibial artery, the peroneal artery opened spontaneously. At the conclusion of the procedure, a strong pulse was palpated in the posterior tibial artery. Improvements in the circulation to the lower leg were significant (Figures 2C and D), but one toe required surgical amputation. The patient otherwise regained full mobility without discomfort. This treatment resulted in successful limb salvage (Figure 3).

Case study performed by Joel Johnson, MD, Cardiovascular Surgeon, Bell Memorial Hospital, Ishpeming, Michigan

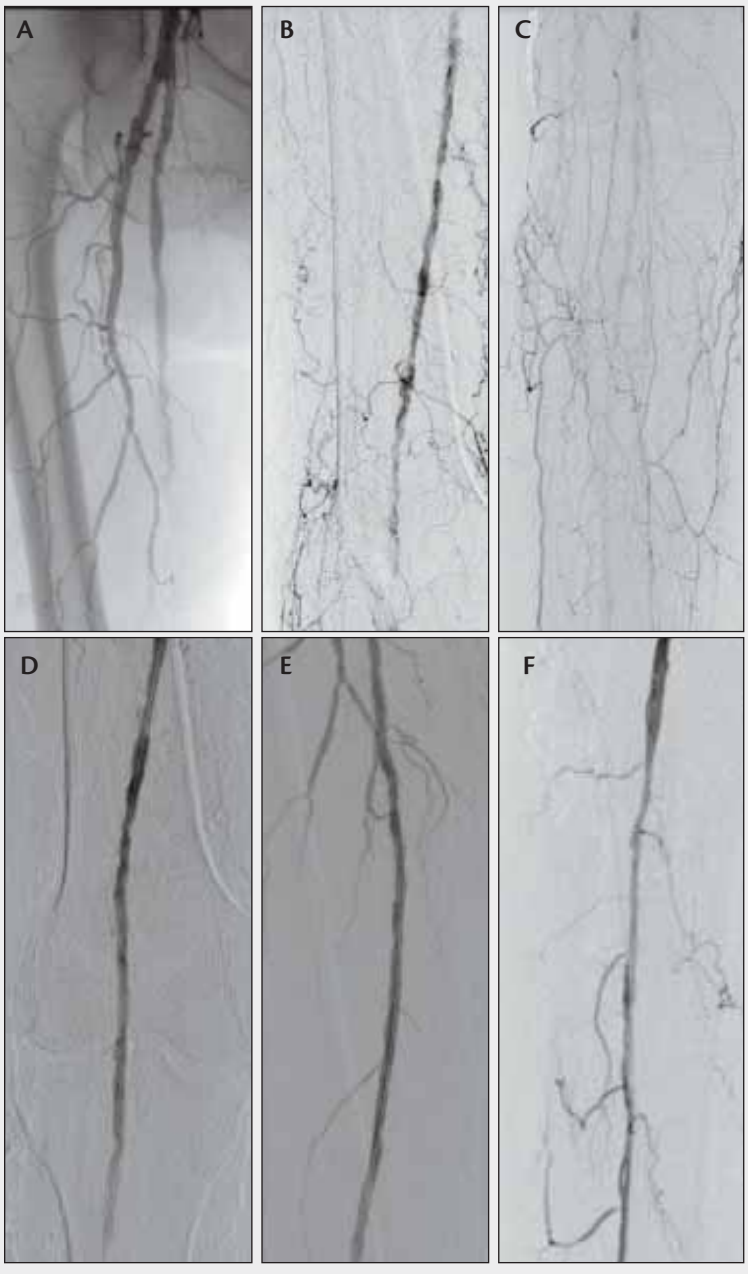
Figure 2. Occlusion of trifurcation vessels below the left knee with evidence of collateral flow distal to the posterior tibial artery (A). Two segments of the heavily calcified posterior tibial artery were treated with a 1.75-mm Classic Crown (B). The procedural outcome was remarkable and resulted in spontaneous opening of the peroneal artery. Brisk, straight-line flow was established at the posterior tibial trunk (C) and distally (D), and no adjunctive therapy was required.

Figure 3. Seven weeks after the index orbital atherectomy procedure, the patient reported significant improvement in the symptoms of claudication. Other than the loss of the gangrenous toe, the patient was walking without difficulty and extremely pleased to have been able to avoid the above-the-knee amputation. Limb salvage was accomplished.

CASE STUDY: SFA, POPLITEAL, AND PERONEAL ARTERY DISEASE TREATMENT

An 83-year-old diabetic woman with severe hypertension was admitted for an endovascular limb salvage procedure with the Diamondback 360° Orbital Atherectomy System. Physical examination identified critical limb ischemia (Rutherford Class 5) in the form of a nonhealing ulcer of the right great toe and fifth toe. The patient reported claudication and rest pain that significantly affected her ability to care for herself. Doppler ultrasound determined ankle brachial indices of 0.20 and 0.37 for the right and left posterior tibial arteries, respectively.

Total occlusion of the distal right superficial femoral artery (A) with modest collateralized flow into a calcified popliteal artery with subtotal occlusion (B) and subtotal occlusion of the tibioperoneal trunk below the knee (C) were observed in preprocedural CT evaluation.



The right posterior tibial and anterior tibial arteries were totally occluded with poor collateral reconstitution distally. A firm ViperWire™ guidewire (Cardiovascular Systems Inc.) was advanced into the distal right peroneal artery with the assistance of a Quick-Cross support microcatheter (Spectranetics Corporation, Colorado Springs, CO). Orbital atherectomy was then performed using a 1.75-mm Solid Crown with treatment extending from the distal occlusion of the right superficial femoral artery to the distal right peroneal artery with an excellent angiographic result distally. Debulking and the resulting smooth lumen allowed dilatation of a 2.5-mm balloon at low atmospheres, leaving a 10% to 20% residual stenosis. A 2.25-mm Diamondback 360° Solid Crown was then used to further treat the calcified superficial femoral artery as well as the popliteal artery, which effectively prepped the vessel for balloon angioplasty with a 4-mm-long balloon at low pressure. Excellent straight-line blood flow was restored within the SFA (D), popliteal artery, (E) and peroneal artery (F). Good perfusion to the right foot was demonstrated postprocedurally with the presence of a faint pulse and noticeable improvement in warmth. Treatment of the left lower extremity was deferred to another time.

Case study performed by Elias Kassab, MD, Interventional Cardiologist, Oakwood Hospital and Medical Center, Dearborn, Michigan

Orbital Atherectomy Safety Profile

Bench testing and clinical studies answer questions regarding the Diamondback 360° Orbital Atherectomy System.

BY STEVAN HIMMELSTEIN, MD; JAMES B. PARK, MD; AND CEZAR STANILOAE, MD

To evaluate the performance of the Diamondback 360°™ Orbital Atherectomy System, Cardiovascular Systems Inc. (St. Paul, MN) has obtained and analyzed bench test data, conducted clinical studies, and gathered data from more than 300 of its first US postmarket cases. The information collected, along with feedback from physician partners who have done more than 5,000 cases to date, has answered important clinical questions and provided relevant information about how to best use the device. After evaluating the effects of heat, particulate size, and procedural complications, it appears that the Diamondback 360° has a reliable safety record, making it an ideal tool for debulking even small or tortuous peripheral vessels—as well as heavily calcified vessels—in which other treatment options may not be sufficient.

DEVICE MECHANISM OF ACTION PRESERVES ARTERIAL INTEGRITY

Orbital atherectomy using the Diamondback 360° has been shown in animal studies to eliminate plaque with little to no damage to the internal elastic lamina (IEL), media, or external elastic lamina (EEL).[1] The device's unique orbital mechanism of action helps to maintain arterial integrity because the diamond-coated crown "differentially" sands noncompliant, calcified tissue, while the healthy, more elastic arterial tissue flexes away from the crown.

Evidence supporting the success of both the Diamondback 360° Classic and Solid Crowns in minimizing arterial damage was demonstrated in 434 histological sections collected during three different studies, including 55 arteries from 27 pigs treated with the device.[1]

On a scale of 0 to 5, with 0 indicating no damage and 5 indicating severe damage, a majority of vessels sustained "no" to "minimal" injury. Weighted average injury scores were <0.5 for the IEL, approximately 0.3 for the media, and close to 0 for the EEL (Figure 1).[1] This indicates that the vessel wall essentially remains intact in a Diamondback 360° procedure (Figure 2).

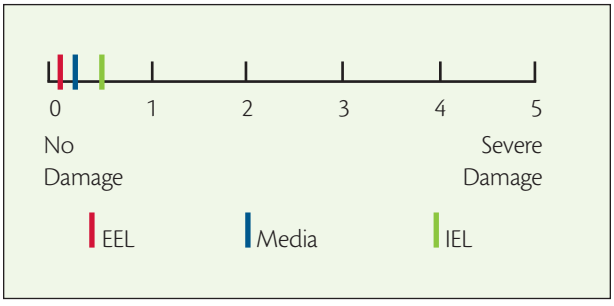


Figure 1. On a scale of 0 to 5, the majority of vessels in 434 histological sections from three porcine studies sustained no to minimal injury, indicating that the Diamondback 360° causes very little damage to the inner elastic lamina and virtually no damage to the media.[1]

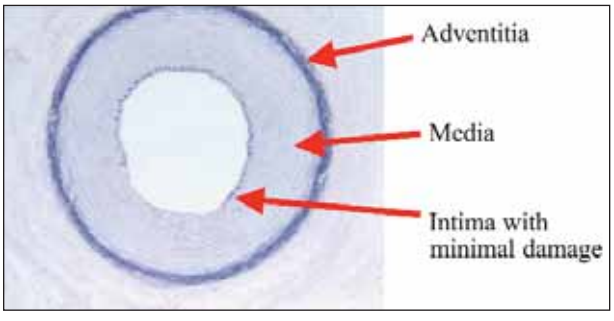


Figure 2. The lesion in this porcine coronary artery was created by balloon overexpansion. Orbital atherectomy was used to debulk the lesion, resulting in a smooth, concentric lumen that maximizes laminar flow. The IEL and subjacent superficial media are essentially intact after orbital atherectomy.

Additionally, the reduction of plaque volume and a resulting smooth lumen may improve vessel compliance, without causing barotrauma. Improved compliance may lead to minimized barotrauma from adjunctive therapy with balloons because they often require fewer atmospheres of pressure after a Diamondback 360° procedure. Stent apposition and expansion may also be improved after plaque removal.

THERMAL DAMAGE UNLIKELY

Previous studies have shown that rotational atherectomy is capable of generating significant heat, potentially resulting in thermal tissue damage.[2] Given this background, Cardiovascular Systems Inc., in conjunction with professors from the University of Minnesota and the University of St. Thomas in St. Paul, Minnesota,[3] conducted two experiments to determine the effects of heat associated with use of the Diamondback 360°.

First, orbital atherectomy was conducted at various speeds in a simulated graphite lesion, with thermocouples measuring the temperature of the graphite tube's wall in addition to fluid in the device sheath that confines the shaft. Second, thermocouples embedded in the outer surface of the posterior tibial arteries in three cadaver subjects measured the arterial temperature during device use. Finally, numerical calculations were conducted to simulate the possibility of thermal necrosis in living tissue.

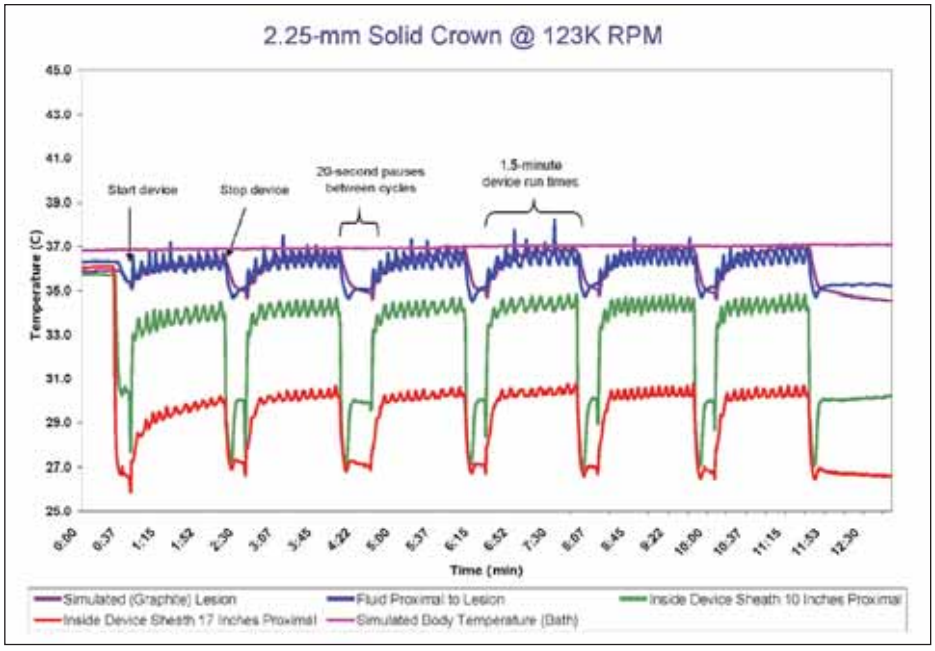


Figure 3. In vitro and cadaver-based experiments, coupled with numerical simulations of living tissue, reveal that thermal damage to the arterial wall is not a factor due to debulking with the Diamondback 360°. Shown here is a 2-mm Solid Crown being run in a surrogate graphite artery at 123,000 rpm for 90-second intervals, with 20-second rest periods. At its highest level, the temperature approximates body temperature (37°C).

The results of this experiment showed a minimal temperature rise 10 to 17 inches upstream of the tip of the device sheath due to friction between the catheter shaft, guidewire, and sheath. Negligible heat was generated at the sanding site, likely because the device (unlike rotational atherectomy) is not in constant contact with the vessel wall (Figure 3), and blood and saline continuously flow around the crown and through the vessel to dissipate heat in the Diamondback 360° procedure. The results of the mathematical simulation showed that thermal necrosis of the arterial wall is not a factor during debulking with the Diamondback 360°.[4] Heat generated during the orbital atherectomy procedure approximates body temperature of 37°C and has not been shown to cause thermal damage to arterial vessels.

PARTICULATE SMALLER THAN CAPILLARIES

In addition to dissipating heat, the continuous flow of saline and blood around the crown also flushes microparticulate distally. Thirty-five samples from eight studies, including cadavers, porcine, and carbon block models, were used to test the size of the particulate generated by sanding plaque with the Diamondback 360°. Ninety-nine percent of all particulate tested was small enough to fit through the capillaries. Average particulate size is approximately 2 µm,[1] far smaller than the average 9.5-µm diameter of a capillary (Figure 4).[5-8]

The small particles are metabolized via the reticuloendothelial system. The macrophages engulf and digest the debris, the majority of which will reach the liver within 10 to 20 minutes where they will be filtered, digested, and excreted.[9] The particulate burden in the body is small: .085% of total blood volume (based on the volume of particulate from a 6-mm-diameter, 15-cm-long chronic total occlusion lesion) and 0.82% of blood volume in the legs.[1]

TIPS AND TECHNIQUES FOR EFFECTIVE DEVICE USE

Since the US market release of the device in late August through the end of 2007, Cardiovascular Systems Inc. maintained a voluntary database of procedural information from 357 postmarket cases performed in the US.[1] All new and experienced Diamondback 360° users were invited to participate. Intraprocedure device information was collected to evaluate device performance, provide directional guidance

for research and development, and to instruct training initiatives. The data reinforced low rates of dissection, perforation, spasm, and embolism—consistent with outcomes from the OASIS Trial (Orbital Atherectomy System for the Treatment of Peripheral Vascular Stenosis), a study showing the safety and efficacy of 124 patients who underwent treatment with the Diamondback 360° (Table 1). The OASIS Trial was required by the FDA to receive clearance to market the device in the US. Full publication of the study is pending.

Complications such as these are well known and can occur in any endovascular procedure. The risk of these problems during an orbital atherectomy procedure can be minimized by proper device utilization and by following a number of tips and techniques.

Among the best practices for using the Diamondback 360° to prevent perforations and dissections are good wire and catheter techniques. The risk for perforation is predominantly affected by guidewire placement and in guidewire bias against the arterial wall in tortuous anatomy, such as the takeoff of the anterior tibial artery or the second bend in the anterior tibial artery. To reduce perforation risk in this type of anatomy, the flexible ViperWire (Cardiovascular Systems Inc.) should be used to minimize wire bias.

To provide maximum support and help orient the anterior tibial artery for crown advancement, a conservative crown size (50% of the size of the reference vessel diameter) should be selected and advanced over the guidewire, with the delivery sheath placed in the distal popliteal artery. Use of fluoroscopy during the atherectomy procedure allows tracking of crown movement through the lesion, as well as the ViperWire guidewire to ensure that the device is not used subintimally where a higher risk of damaging the vessel exists.

Slow to medium speeds are best for performing orbital atherectomy within a bifurcated lesion—for example, at the origin of either tibial artery—and the device should be advanced at 1 cm per second.

A crown size no larger than 75% of the reference vessel diameter is needed when treating a severe stenosis and 50% of the reference vessel diameter when approaching a chronic total occlusion. To open a channel and establish flow through a chronic total occlusion, start with a smaller device and use a "pecking" motion. If available, intravascular ultrasound can help when vessel sizing is difficult.

Speed setting progression, in most cases, should be low, medium, and high with high-speed selection dependent on the angiographic appearance of the treated segment. The speed of the device combined with the device mass (centrifugal force) causes the eccentrically mounted crown to "orbit," allowing maximum contact with the plaque for efficient sanding and creation of a progressively larger lumen.

If a dissection is noted before the procedure, therapy other than the Diamondback 360° should be used. If dissection is noted during the procedure, use of the device should be stopped, and the dissection should be treated per operator preference (ie, balloon dilation at low pressure or a self-expanding stent). These measures eliminate the potential for aggravation of the dissection.

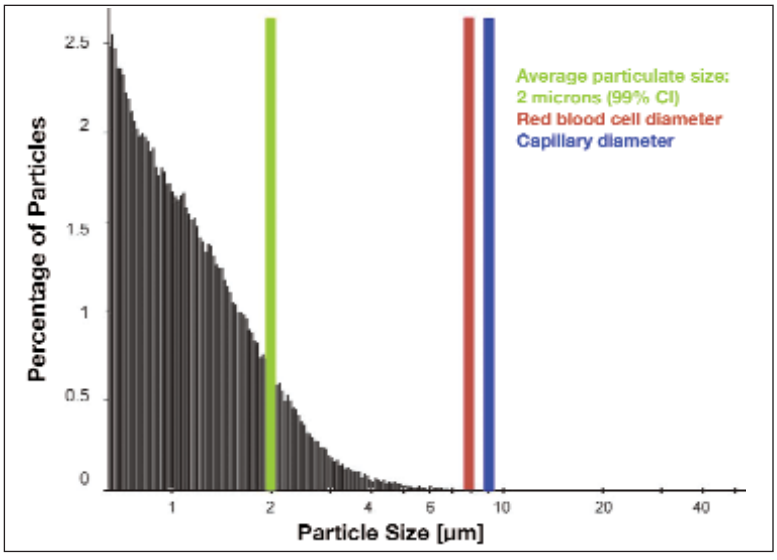


Figure 4. This graph shows the particulate size distribution after orbital atherectomy in eight studies using particulate samples from diseased cadaveric peripheral arteries, thermally injured porcine coronary arteries, and carbon block models. Ninety-nine percent of particulate caused by the Diamondback 360° is small enough to fit through the capillaries.

Embolization after percutaneous intervention is also a universal problem in the periphery.[10-12] The risk of distal embolization can result from guidewire crossing, balloon angioplasty, stent deployment, and atherectomy.[10,11] In the authors' early and subsequent experience, clinically significant embolization as a direct result of orbital atherectomy is uncommon. In fact, it was documented in only 2% of the Cardiovascular Systems Inc. postmarket cases and <2% in the OASIS Trial.

As noted previously, particulate associated with the orbital atherectomy device is ordinarily small enough to fit through the capillaries. If slow flow does occur, it may be attributed to any number of aspects of the procedure itself, not necessarily the Diamondback 360° mechanism of action. Slow flow may have a greater potential for occurring when treating the larger lesions above the knee because of a greater plaque

burden. To prevent slow flow, it may help to open up distal vessels by using the Diamondback 360° before treating the proximal vessels.

Spasm is another issue noted in the distal vessels regardless of treatment modality, and it is believed to be due to vessel irritation from whichever instrument is inserted. In the Diamondback 360° procedure, spasm may occur in response to high device speeds and can therefore be prevented by running the device at low and medium speed, increasing the speed only after a satisfactory lumen has been created. Individual run times within a segment should be limited to 30 to 60 seconds, with short rest intervals between runs. Flushing with antispasmodic medications between every one or two runs can also reduce the potential for vessel spasm. Ways to prevent spasm include giving boluses of 150 to 200 µg of nitroglycerin before running the device especially if the vessel caliber is small or if there is very poor outflow. Another best practice is to add 5 mg of verapamil and 5 mg of nitroglycerin (in addition to the recommended lubricant) in a 1-L saline bag.

The total procedure run time for any one lesion should be kept to less than 12 minutes (maximum run time per device is 8 minutes), and sanding in healthy vessel segments should be avoided to prevent unnecessary irritation. Spasm often subsides without any intervention. However, if it does not diminish naturally, antispasmodic medication can be delivered directly to the site, or a small balloon can be dilated at low pressure at the site.

As with other endovascular procedures, hemolysis is a potential complication of the orbital atherectomy procedure. A retrospective analysis by Cardiovascular Systems Inc. of the first 800 patients[1] showed that hemolysis was observed in <4% of cases and appears to be associated with more difficult cases in larger vessels that may require longer total procedural run times.

Defined as the breaking of red blood cells, hemolysis presents as discolored urine in patients after the procedure. This is typically not a cause for concern and clears within 24 to 48 hours after the procedure. No clinically significant short- or midterm adverse effects due to hemolysis after orbital atherectomy have been documented to date. Best practices for device utilization and reducing the potential for hemolysis include (1) engaging the Diamondback 360° in diseased vessels only and choosing an appropriate crown size to ensure the crown will be in contact with plaque when sanding, (2) shortening the length of each orbital run to 30 to 60 seconds and ensuring adequate saline flush is delivered through the sheath during the procedure, and (3) minimizing the use of the high orbital speeds and limiting total treatment time with orbital atherectomy to no more than 12 minutes (9 minutes per device).

Procedural complications with the Diamondback 360° appear to be rare, demonstrating the device's safety profile in patients with peripheral arterial disease. Further scientific and clinical research will be needed as the device and its clinical application continue to evolve. Cardiovascular Systems Inc. is committed to additional bench evaluation, as well as ongoing clinical observational studies, to ensure device effectiveness and optimal patient outcomes. ■

TABLE 1. CLINICAL ENDPOINT OCCURRENCE

Endpoint	OASIS Trial[1] 124 patients	Postmarket Cases[1] 357 patients
Dissection (minor)	8.1%	2%
Perforation	1.6%	2%
Embolism	0.8%	2%

Stevan Himmelstein, MD, trains physicians in the use of the Diamondback 360° device and procedure and has disclosed that he is a shareholder in Cardiovascular Systems Inc. Dr. Himmelstein may be reached at shimmelstein@gmail.com.

James B. Park, MD, is the Director of the Cardiac Catheterization Laboratory, Division of Cardiology and Heart and Vascular Department at the Presbyterian Hospital of Dallas, Texas. He is currently serving as Co-Director of the Endovascular Training Program for CIVA Vascular Group. He has disclosed that he is a paid consultant to Cardiovascular Systems Inc. Dr. Park may be reached at (214) 345-7688.

Cezar Staniloae, MD, is with the Division of Cardiology, Section of Peripheral and Vascular Interventions, St. Vincent's Hospital Manhattan in New York. He has disclosed that he is a paid consultant to Cardiovascular Systems Inc. Dr. Staniloae may be reached at cstaniloae@svcmcny.org.

1. CSI data on file.
2. Gehani A, Rees M. Can rotational atherectomy cause thermal tissue damage? Cardiovasc Intervent Radiol. 1998;21:481-486.
3. Abraham J, Sparrow E, Lovik R. Unsteady, three-dimensional fluid mechanic analysis of blood flow in plaque-narrowed and plaque-free arteries. Int J Heat Mass Transfer. In press.
   a. Sparrow E, Lovik R. Laboratory for Heat Transfer and Fluid Flow Practice, University of Minnesota, Minneapolis, MN.
   b. Abraham J. Laboratory for Heat Transfer and Fluid Flow Practice, University of St. Thomas, St. Paul, MN.
4. Lovik R, Abraham J, Sparrow E. Assessment of possible thermal damage of tissue due to debulking by the DiamondBack 360° Device. CSI data on file.
5. Mathura KR, Vollebregt KC, Boer K, et al. Comparison of OPS imaging and conventional capillary microscopy to study the human microcirculation. J Appl Physiol. 2001;91:74-78.
6. Biberthaler P, Wiedemann E, Nerlich A, et al. Microcirculation associated with degenerative rotator cuff lesions. In vivo assessment with orthogonal polarization spectral imaging during arthroscopy of the shoulder. J Bone Joint Surg Am. 2003;85:475-480.
7. Schwartz RW, Freedman AM, Richardson DR, et al. Capillary blood flow: videodensitometry in the atherosclerotic patient. J Vasc Surg. 1984;1:800-808.
8. Virgini-Magalhães CE, Porto CL, Fernandes FF, et al. Use of microcirculatory parameters to evaluate chronic venous insufficiency. J Vasc Surg. 2006;43:1037-1044.
9. Lin MS, Winchell HS. A "kit" method for the preparation of a technetium-tin(II) colloid and a study of its properties. J Nucl Med. 1972;13:58-65.
10. Shammas N. Embolization in lower extremity percutaneous interventions: recommendations and strategies for embolic filter protection use. Vasc Disease Mgmt. 2008;5:22-26.
11. Lam R, Shah S, Faries P, et al. Incidence and clinical significance of distal embolization during percutaneous interventions involving the superficial femoral artery. J Vasc Surg. 2007;46:1155-1159.
12. Allie D. Distal embolization in lower extremity interventions: it's time we "get our heads out of the sand." Vasc Disease Mgmt. 2008;5:27-29.

A New Solution for Patients With Below-the-Knee Calcium

Orbital atherectomy is an appropriate and effective endovascular treatment for infrapopliteal arterial disease.

BY RAJESH DAVE, MD; TONY DAS, MD; PATRICIO ILABACA, MD; GUY S. MAYEDA, MD; AND STEPHEN MURRAY, MD

Endovascular therapy can improve the quality of life and functional capacity of patients with symptomatic peripheral arterial disease (PAD).[1-3] Lower procedure cost, fewer complications, and lower morbidity rates, relative to surgical bypass, support the increased use of endovascular therapy as a first-line treatment for patients with PAD, especially the elderly or individuals considered at high surgical risk, vascularly compromised, or with multiple comorbidities. For most claudicants and patients with critical limb ischemia (CLI), lower extremity PAD extends from the large-diameter inflow arteries to the high-impedance outflow arteries below the knee (BTK). Patients with diabetes and/or chronic renal failure frequently present a particular challenge for revascularization due to calcification of the anterior and posterior tibial arteries and less frequently, the peroneal artery.[4] Straight-line blood flow to the foot through at least one of the three major BTK arteries is critical for wound healing in patients with CLI.[5] The Diamondback 360°™ Orbital Atherectomy System (Cardiovascular Systems Inc., St. Paul, MN) is an excellent endovascular therapy for treating BTK lesions in patients presenting with nonhealing wounds associated with calcified tibioperoneal occlusive arterial disease.

IMPORTANCE OF TIBIOPERONEAL ARTERIAL BLOOD FLOW

Tibioperoneal vessel patency may affect the long-term clinical success of any femoropopliteal revascularization procedure, including open surgical bypass. The STAR Registry and earlier clinical studies determined that poor tibial runoff was highly predictive of occlusion after femoropopliteal percutaneous transluminal angioplasty (PTA).[2,6,7,8] The STAR Registry enrolled 205 patients to identify variables that might predict long-term patency after femoropopliteal endovascular therapy consisting predominantly of PTA. Primary patency rates at 12, 24, and 36 months for all limbs treated were 87%±3%, 80%±3%, and 69%±5%, respectively. Poor tibial runoff was the single most predictive variable for reduced long-term patency. Satisfactory distal runoff is a major factor affecting the durability of femoropopliteal endovascular therapy, regardless of whether the vessel received PTA only or was adjunctively stented.

The Diamondback 360° is an ideal technology for restoring blood flow through diffusely diseased small-diameter arteries BTK. Although PTA alone can be used in these arteries, barotrauma associated with conventional PTA affects a high incidence of flow-limiting dissections, often due to cracking of the calcified intimal lesion. Sanding of the calcified lesion with orbital atherectomy restores lumen diameter with minimal risk of major dis-

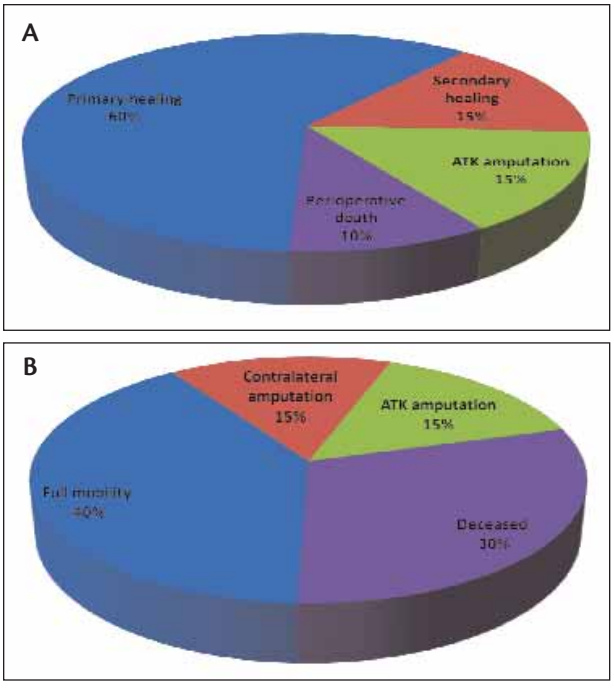


Figure 1. Fate of patients after BTK amputation at 1 year (A) and 2 years (B) postoperatively.[8]

section and may eliminate the need for balloon angioplasty. If the standard of care involves PTA, calcific plaque reduction will alter compliance and allow dilation at low pressure, resulting in less barotrauma to the vessel wall, which may thereby prevent significant hyperplasia.

One significant advantage of the Diamondback 360° is its ability to treat multisegment disease and BTK lesions with various plaque morphologies in a single insertion. The catheter can upsize in the vessel by increasing the device revolutions per minute, making it possible to treat vessels of varying sizes. Also, by simply redirecting the ViperWire™ guidewire (Cardiovascular Systems Inc.) into another BTK artery, additional debulking can be performed to increase the distal runoff capacity. Increasing the number of outflow vessels increases the probability for better outcomes, including long-term patency, in the femoropopliteal arteries.[9-11]

BTK REVASCULARIZATION

TASC II guidelines conservatively recommend endovascular therapy of infrapopliteal arteries for limb salvage in patients with CLI or short tibial artery stenoses adjunctive to femoral or popliteal PTA.[12] The guidelines support infrapopliteal endovascular therapy in CLI patients with rest pain, ischemic ulceration or gangrene, and medical comorbidity, provided the therapy has a good probability of restoring inline flow to the foot. One of the primary reasons for this paradigm shift in treatment recommendations from TASC I guidelines is that elderly patients with CLI are frequently considered high surgical risk due to comorbidities or poor-quality distal vessels for surgical bypass.

New CLI diagnoses in the US currently range between 150,000 to 300,000 annually with a 1-year mortality rate of 25% and an amputation rate of 30%.[8,12] Twenty-five percent of patients with CLI have lesions confined to the infrapopliteal arteries.[13] The prognosis for event-free survival after BTK amputation is poor, with 10% perioperative mortality and at 1 year, 60% of amputations healing by primary intervention, 15% healing after secondary procedures, and 15% converted to above-the-knee amputation (Figure 1A). At 2 years after BTK amputation, only 40% of the patients will have regained full mobility, and 30% of the patients will be deceased (Figure 1B).

A study of 417 patients with CLI who underwent infrainguinal amputation indicated that 67% of those patients had amputation as the primary treatment, and 50% of amputations were performed without previous angiography or ankle-brachial index (ABI) evaluations.[14] There is a large population of patients with advanced PAD that should benefit from the wider application of endovascular revascularization procedures, such as that provided by orbital atherectomy. These patients are predominantly diabetic with extensive calcific disease and less-compliant crural vessels. Improvements in guidewire technology, the availability of next-generation atherectomy devices, and an escalated level of technical expertise by physicians allow treatment of these small-diameter arteries with a high probability for procedural and clinical success in this growing population of elderly patients.

CLI patients or patients with lifestyle-limiting claudication should be provided the option of orbital atherectomy revascularization. Technical success for endovascular revascularization of BTK vessels approaches 90% with clinical success reported in approximately 70% of CLI patients.[5] Using endovascular therapy as a first approach in these patients does not preclude subsequent bypass and permits treatment of more than one diseased runoff vessel. The Diamondback 360° safely restores blood flow in these diseased small-diameter arteries, and if adjunct therapy is indicated, the risk of dissection, perforation, and barotrauma is greatly reduced by the physical removal of calcium from the arterial wall. Complications requiring surgical intervention after orbital atherectomy are extremely rare.

CASE STUDY 1

Case study performed by Rajesh Dave, MD

An 80-year-old woman with insulin-dependent diabetes mellitus presented for endovascular therapy of CLI consisting of a nonhealing ulcer on her left ankle. Left and right ABI values were 0.72 and 0.75, respectively. Baseline angiography identified occlusion of the proximal peroneal artery and occlusions of both tibial arteries. The peroneal artery reconstituted distally to fill the distal anterior and posterior tibial arteries and pedal arch; however, perfusion of the plantar and lateral aspects of the foot was deficient. The peroneal artery subtotal occlusion was crossed using a Quick Cross (Spectranetics Corporation, Colorado Springs, CO) support catheter and .014-inch Asahi Prowater Flex and .014-inch MiracleBros 3 guidewires (Abbott Vascular, Santa Clara, CA). The MiracleBros guidewire was exchanged for a .014-inch X 325-cm ViperWire Flex guidewire. Orbital atherectomy was performed with four passes of a 1.25-mm Classic Crown at low (x1), medium (x1), and high (x2) speeds. The diameter of the distal peroneal artery was measured at 2.62 mm using a Metricath Libra balloon (Angiometrx Inc., Richmond, BC Canada). A 1.75-mm Classic Crown was then passed at low (x1), medium (x2), and high (x3) speeds to achieve a satisfactory angiographic outcome. PTA of the distal peroneal artery was performed with a 2.5-mm X

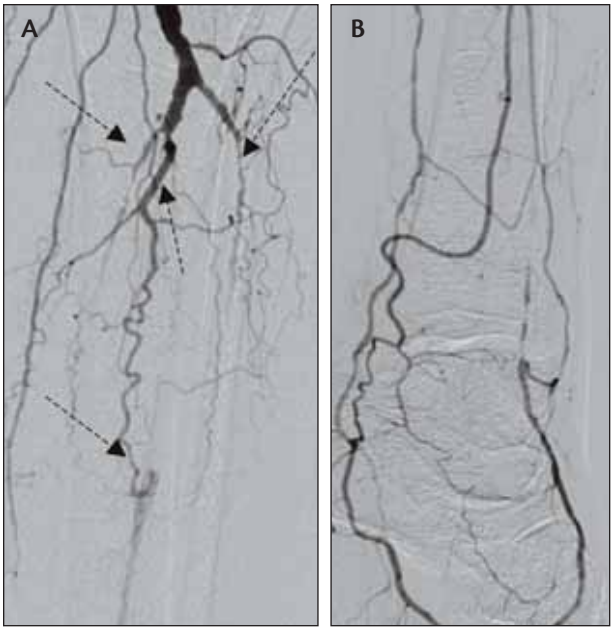


Figure 2. Occluded trifurcation arteries of the left leg (A) and reconstituted blood flow to the pedal arch (B).

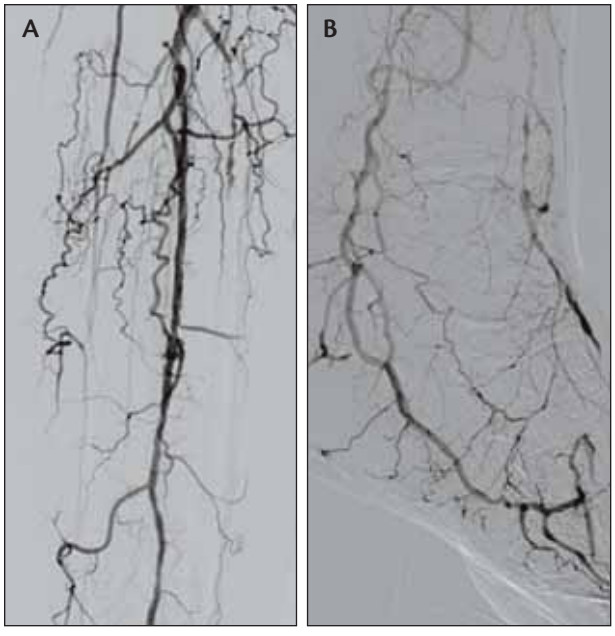


Figure 3. Straight-line blood flow within the peroneal artery (A) and improved microvascular perfusion of the left foot (B) after orbital atherectomy.

80-mm Vascutrak II balloon (YMed Inc., San Diego, CA) at 10 atm for 2 minutes. No other adjunct therapy was required, and excellent straight-line distal blood flow was observed with good perfusion of the foot (Figures 2 and 3).

CASE STUDY 2

Case study performed by Guy S. Mayeda, MD

A 65-year-old man with a history of hypertension presented for endovascular treatment to resolve nonhealing ulcers at the base of the left and right great toes. Angiography identified bilateral multilevel disease of the right posterior tibial artery. A staged intervention was undertaken with orbital atherectomy treatment of proximal 80% tandem stenoses, midvessel subtotal occlusion, and distal total occlusion at the level of the right ankle. The subtotal occlusion proximally was crossed with the assistance of a Flowcardia Crosser ultrasound device (Flowcardia, Inc., Sunnyvale, CA), and a .014-inch ViperWire guidewire was positioned within the full length of the posterior tibial artery. Orbital atherectomy was performed distally with multiple passes of a 1.5-mm Classic Crown, and the proximal lesions were treated with a 2-mm Classic Crown. Selective angiography identified brisk inline blood flow through the posterior tibial artery to the ankle with improved flow to the plantar surface of the right foot. No adjunct therapy was required (Figures 4 through 8).

Several weeks later, the patient underwent a second atherectomy procedure to restore blood flow to the left foot. The Diamondback 360º 1.75-mm Classic Crown was used to debulk a 90% heavily calcified stenosis in the peroneal artery as well as an 80% stenosis in the posterior tibial. The SilverHawk ES was used to clear remaining soft plaque in the proximal peroneal and posterior tibial vessels. Three-vessel runoff to the foot was established. Procedures in both legs resulted in wound healing progress (Figure 7 and Figure 8).

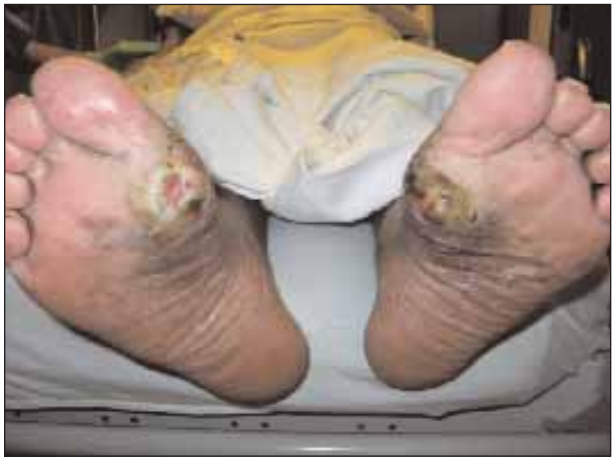


Figure 4. Nonhealing ulcers of the left and right foot that prompted endovascular therapy with the Diamondback 360°.

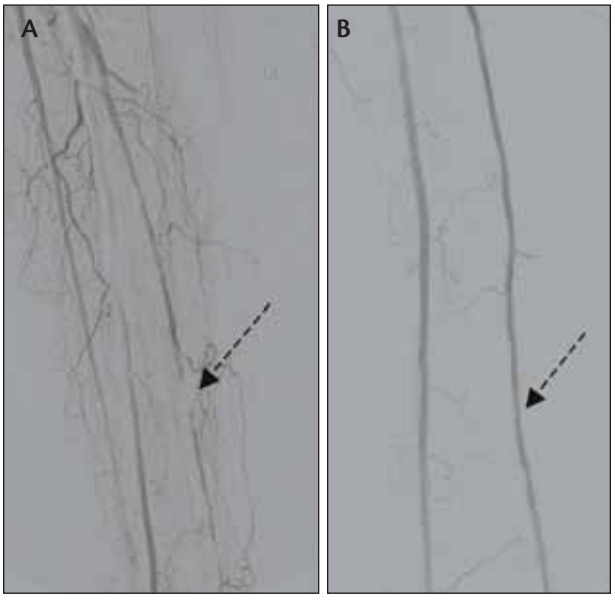


Figure 5. Diamondback 360° orbital atherectomy of the right posterior tibial artery using 1.5- and 2-mm Classic Crowns. Baseline (A) and final (B) angiograms.

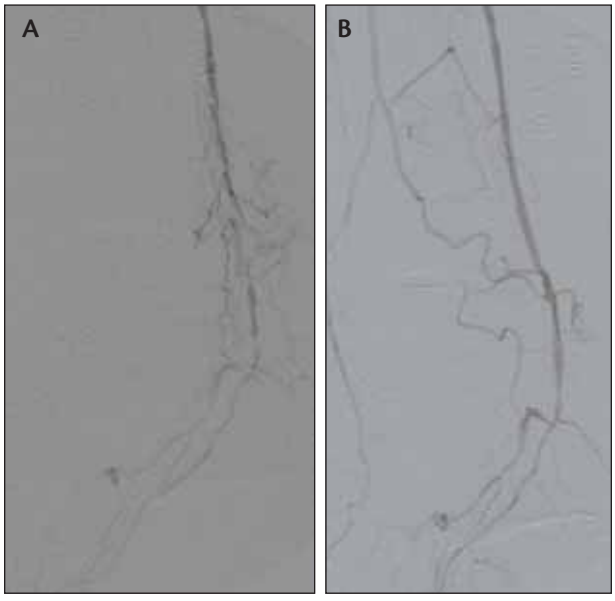


Figure 6. Distal runoff in the right leg at baseline (A) and improved runoff after orbital atherectomy (B).

Figure 7. Healing ulcer of the right foot 4 weeks after orbital atherectomy restored blood flow to the plantar surface of the foot.

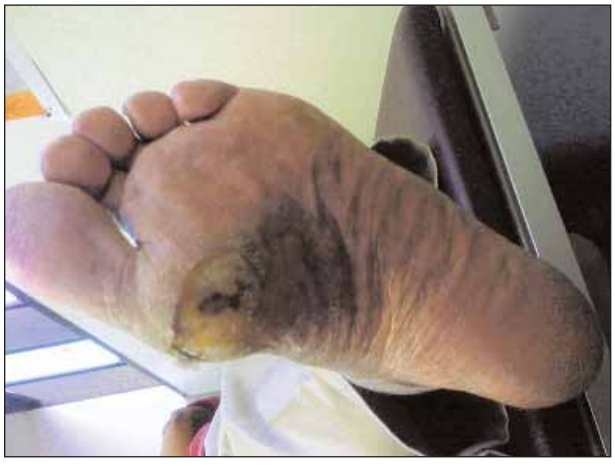


Figure 8. Wound-healing progress was also made on the left foot.

CONCLUSION

The main limiting factors for successful BTK revascularization have traditionally been heavy calcification, flow-limiting dissections, acute thrombosis, and early elastic recoil. Orbital atherectomy safely and effectively removes plaque of various morphologies from BTK arteries, often with stand-alone results. Increased lumen diameter and a reduction in arterial wall stiffness result in a decreased resistance to blood flow and improved pulsatile flow, and if adjunctive therapy is required, it allows for more effective stent placement and fewer atmospheres of pressure with balloons. Wound healing, functional capacity, and quality of life can all be improved after orbital atherectomy with the Diamondback 360°. The Diamondback 360° can recanalize calcified arteries above or BTK with minimal dissection risk and with a low incidence of thrombosis, perforation, or elastic recoil. With appreciation that more blood flow is required for wound healing than to maintain tissue integrity, the ability of the Diamondback 360° to restore straight-line blood flow without significant injury to the arterial wall may have a positive effect on healing lesions and preventing subsequent lesion recurrence. ■

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1. Adam DJ, Beard JD, Cleveland T, et al. Bypass versus angioplasty in severe ischemia of the leg (BASIL): multicentre, randomized, controlled trial. Lancet. 2005;366:1925-1934.
2. Clark TW, Groffsky JL, Soulen MC. Predictors of long-term patency after femoropopliteal angioplasty: results from the STAR Registry. J Vasc Interv Radiol. 2001;12:923-933.
3. Spronk S, Bosch JL, Veen HF, et al. Intermittent claudication: functional capacity and quality of life after exercise training or percutaneous transluminal angioplasty-systematic review. Radiology. 2005;235:833-842.
4. Guzman RJ, Brinkley M, Schumacher P. Tibial artery calcification as a marker of amputation risk in patients with peripheral arterial disease. J Am Coll Cardiol. 2008;51:1967-1974.
5. Tsetis D, Belli AM. The role of infrapopliteal angioplasty. Br J Radiology. 2004;77:1007-1015.
6. Krepel VM, van Andel GJ, van Erp WF, et al. Percutaneous transluminal angioplasty of the femoropopliteal artery: initial and long-term results. Radiology. 1985;156:325-328.
7. Johnston KW. Femoral and popliteal arteries: reanalysis of results of balloon angioplasty. Radiology. 1992;183:767-771.
8. Jamsen T, Manniene H, Tulla H, et al. The final outcome of primary infrainguinal percutaneous transluminal angioplasty in 100 consecutive patients with chronic critical limb ischemia. J Vasc Interv Radiol. 2002;13:455-463.
9. Johnston KW. Femoral and popliteal arteries: reanalysis of results of balloon angioplasty. Radiology. 1992;183:767-771.
10. Krepel V, van Andel G, van Erp, et al. Percutaneous transluminal angioplasty of the femoropopliteal artery: initial and long-term results. Radiology. 1985;156:325-328.
11. Matsi P, Manninen H, Vanninen R, et al. Femoropopliteal angioplasty in patients with claudication: primary and secondary patency in 140 limbs with 1-3 year follow-up. Radiology. 1994;191:727-733.
12. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). Eur J Vasc Endovasc Surg. 2007;33:S1-S70.
13. Fraser SC, Al-Kutoubi MA, Wolfe JH. Percutaneous transluminal angioplasty of the infrapopliteal vessels: the evidence. Radiology. 1996;200:33-43.
14. Allie DE, Hebert CJ, Lirtzman MD, et al. Critical limb ischemia: a global epidemic. A critical analysis of current treatment unmasks the clinical and economic costs of CLI. Eurointerventions. 2005;1:75-84.

(Continued from page 13)

across the lesion additional times at increased rotational speeds or by using a larger crown size. By increasing crown rotational speed, the device orbit increases, but the centrifugal force against the wall decreases. The decreased centrifugal force minimizes injury to the arterial tunica media while the differential sanding continues to remove the more rigid residual plaque. A resulting smooth lumen may restore nonturbulent laminar blood flow within the artery and improve distal perfusion. Often, residual stenosis of less than 20% can be achieved with the Diamondback 360° device alone. Depending on the angiographic appearance of the treated segment, adjunctive therapy may or may not be needed.

When subsequent adjunctive therapy is needed, it is often in above-the-knee procedures. The Diamondback 360° removes the calcium "cap" in these larger vessels, thereby improving vessel compliance and potentially making adjunct therapy more effective and less damaging to the artery.

Designed to safely address calcified plaque either above or below the knee, the Diamondback 360° expands the tool chest for endovascular physicians and offers a safe and effective way to remove or "debulk" atheromatous plaque. The fine crown texture of the Diamondback 360° presents minimal risk to the arterial wall while sanding plaque. A unique mechanism of action causes the crown to progressively increase its orbit, which increases the likelihood that one device can treat multiple vessels of various sizes. Furthermore, the device differentiates between diseased and healthy tissue, leaving a smooth, concentric lumen for optimal blood flow.

An easy device to operate, the Diamondback 360° makes the toughest cases doable. With the advent of this new tool, more patients with peripheral arterial disease now have an option for re-establishing the blood flow necessary to relieve their symptoms and restore their quality of life. ■

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CASE STUDY: ONE DEVICE USED IN MULTIPLE DISEASED VESSELS

An 86-year-old man presented with severe occlusive peripheral arterial disease with severe symptomatic claudication. The patient presented with a positive history of hypertension and hyperlipidemia, as well as chronic dialysis for end-stage renal disease. He previously had a right carotid endarterectomy.

Preprocedure diagnostic studies revealed 90% stenosis of the right common femoral artery, 80% to 90% stenosed, diffuse disease in the mid-superficial femoral artery (SFA) and popliteal artery, and two-vessel runoff. The popliteal was accessed in a retrograde fashion, and the lesions were treated distal to proximal. All lesions were treated with the same 2.25-mm Solid Crown at low, medium, and high speeds for a total sanding time of 10 minutes. Marked improvement in flow was seen in the common femoral artery, resulting in 40% residual stenosis, and the multiple SFA and popliteal lesions resulted in less than 30% residual stenosis. In order to spare the vessels from further distress, adjunctive therapy was not used (Figures 1 and 2).

Case study performed by David Joffe, MD, Dayton Heart & Vascular Hospital, Dayton, Ohio

Figure 1. Multiple lesions were treated with a single 2.5-mm Solid Crown in the right SFA and popliteal arteries.

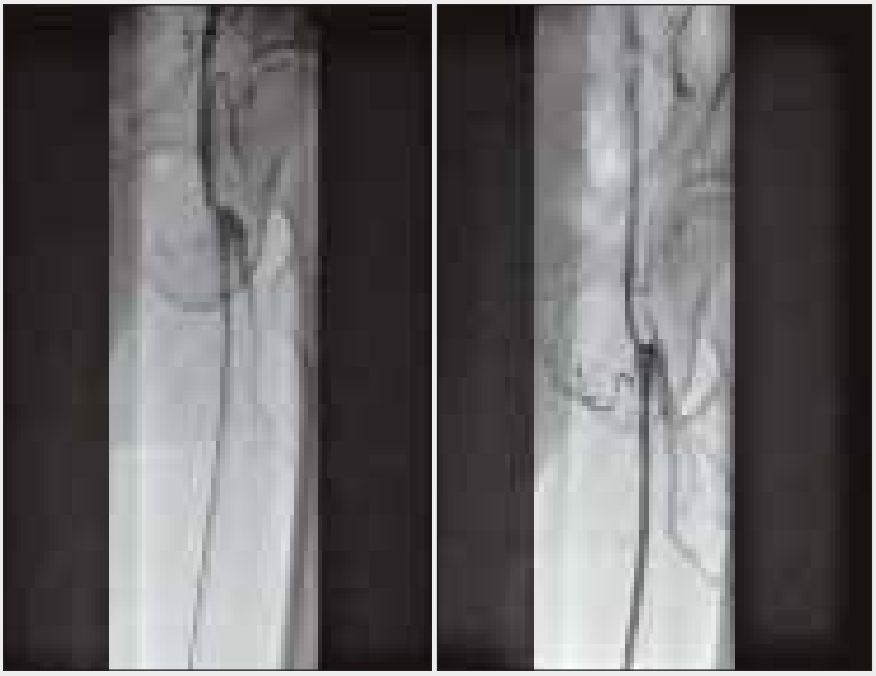

Figure 2. Pre- and postprocedural imaging of the common femoral artery. The same 2.5-mm Solid Crown was used to debulk the right common femoral artery.

The Value of a Smooth Postprocedure Arterial Lumen

Orbital atherectomy increases blood flow velocity and shear stress.

BY TOM DAVIS, MD, AND MICHAEL HAGLEY, MD

The objective of any revascularization procedure should be to restore a smooth lumen, free of thrombogenic catalysts, and of sufficient luminal diameter to maximize blood flow to the distal territory at risk of ischemic injury. Orbital atherectomy with the Diamondback 360°™ Orbital Atherectomy System (Cardiovascular Systems Inc., St. Paul, MN) improves volumetric blood flow by increasing vessel cross-sectional area. It also provides a unique advantage to patient outcomes because of a resulting smooth, concentric lumen that increases the blood flow velocity and shear stress (force of the flowing blood) within the vessel—thereby decreasing the potential for restenosis and reducing the risk of thrombus formation after the procedure.

Virchow hypothesized in 1856 that the three primary factors responsible for thrombus formation in a blood vessel are (1) blood flow, (2) surface physicochemical properties, and (3) blood chemistry.[1] The effect of any one of these parameters on thrombosis is complicated by the interdependence of the other two, hence the derivation of the phrase "Virchow's Triad" when attempting to explain factors affecting thrombosis. A disrupted atherosclerotic plaque at the luminal surface

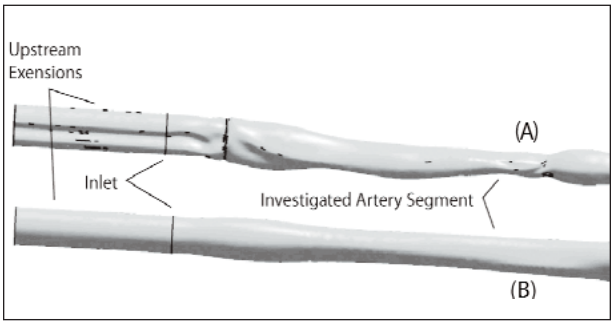

Figure 1. Reconstituted geometries of the bounding walls of the interior of the posterior tibial artery lumen before (A) and after (B) orbital atherectomy. The postprocedure result shows not only an increased vessel diameter but also a smooth, concentric lumen. (Reprinted with permission from Abraham J et al. International Journal of Heat and Mass Transfer. In press.[4])

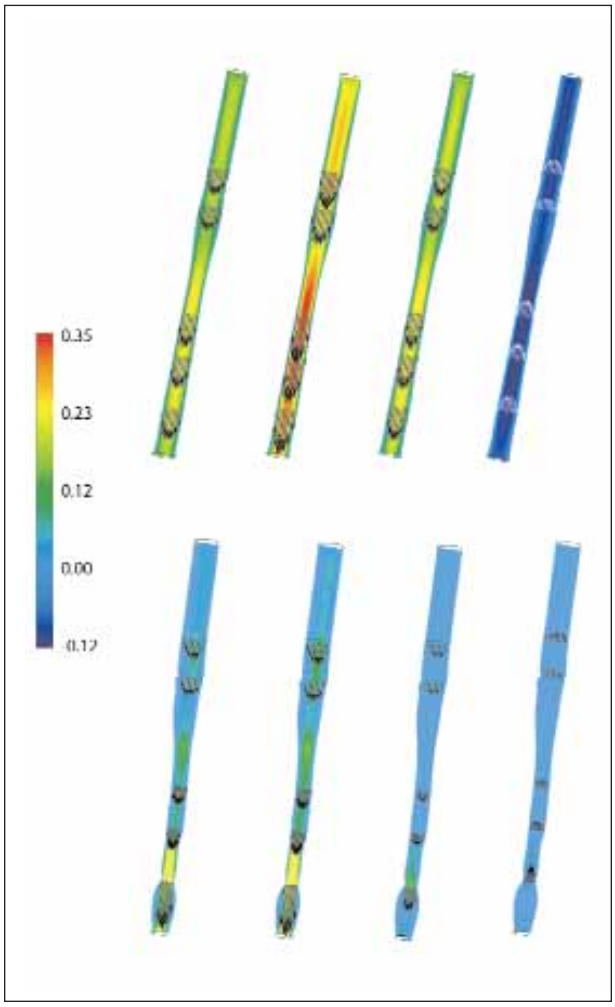

Figure 2. Velocity vector and contour diagrams for the vessel after treatment with the Diamondback 360° (upper tier) and preprocedure arterial segment (lower tier) during a cardiac cycle. The color is indicative of the magnitude of the axial velocity, and the lengths of the vectors correspond to the velocity magnitude. The diagrams demonstrate an expected increase in velocity after treatment. (Reprinted with permission from Abraham J et al. International Journal of Heat and Mass Transfer. In press.[4])

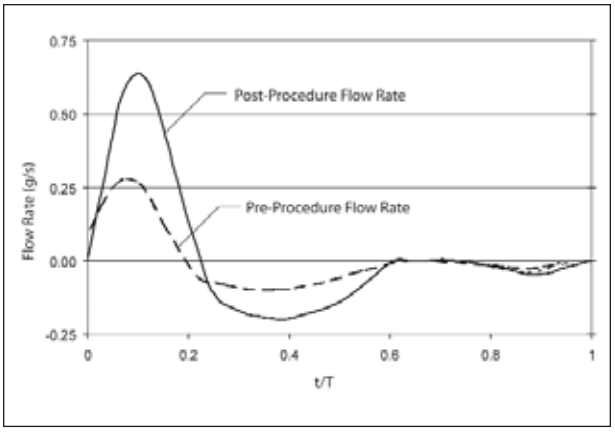

Figure 3. Mass flow rates within the posterior tibial artery before and after orbital atherectomy. The mass flow rate is increased 65% (or 2.5 times) after treatment with orbital atherectomy and attributed to a decreased resistance to flow by the increased lumen diameter.

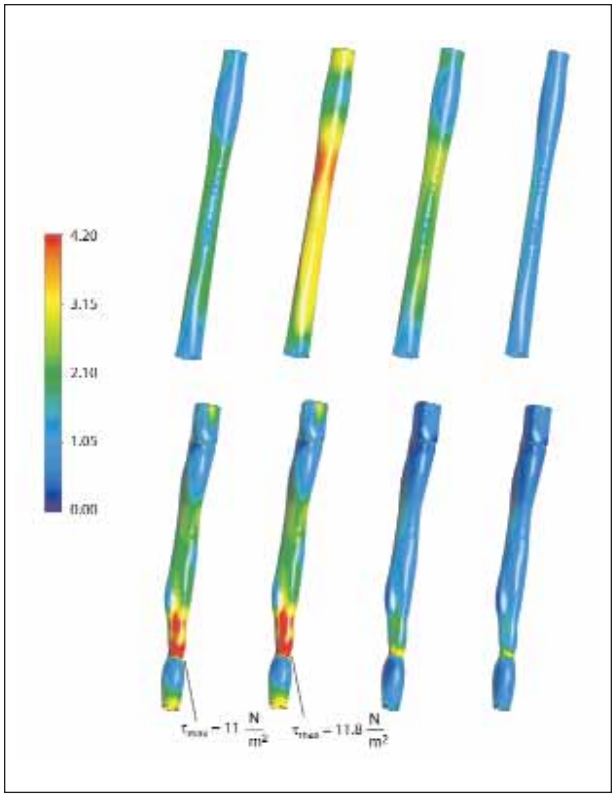

Figure 4. Wall shear stress patterns corresponding to the vessel after treatment with the Diamondback 360° (upper tier) and preprocedure arterial segment (lower tier) during a cardiac cycle. The magnitude of wall shear is color keyed to the legend on the left. In general, the shear stresses are more uniform and higher in the artery debulked with the Diamondback 360°, suggesting that the rate of plaque accumulation and arterial wall thickening will be diminished by the debulking. (Reprinted with permission from Abraham J et al. International Journal of Heat and Mass Transfer. In press.[4])

and resultant localized eddies affect blood, increase residence times, and contribute to the formation of surface-mediated atherothrombosis.[2,3]

The rate at which thrombus forms depends on fluid transport and shear force phenomena (blood flow), interfacial surface properties and morphologies (plaque deposits at bifurcations), and cellular and coagulation activation (blood chemistry). If the natural thrombolytic process cannot attenuate and interrupt the triad, thrombus formation leading to vessel occlusion or embolization is unavoidable.

Presentation of a smooth and concentric lumen to flowing blood is one of several means by which reocclusion can be prevented after revascularization. When hard, calcific plaque is treated with orbital atherectomy, a smooth, concentric, and enlarged lumen can be obtained and potentially present a more thromboresistant smooth interface.

THE SCIENCE OF THE SMOOTH LUMEN

Unlike excisional atherectomy devices, the Diamondback 360° with its orbital mechanism of action preferentially sands the calcific deposits to achieve a smooth, concentric lumen devoid of axial excisional tracks within the arterial media. Additionally, the use of centrifugal force to control the orbital path of the rotating crown preserves arterial integrity by effecting differential sanding. *Differential sanding* means that the crown preferentially removes hard calcific and fibrocalcific plaque without inducing significant injury to the arterial wall. As the plaque is removed, arterial wall compliance increases, allowing the plaque-reduced arterial wall to move away radially from the pressure imparted by the orbiting crown.

A numerical flow simulation was conducted to calculate changes in net flow and wall shear stress after orbital atherectomy in a human diseased cadaveric posterior tibial artery.[4] Using IVUS evaluation combined with computer modeling of the vessel lumen pre- and postprocedure (Figure 1), orbital atherectomy was shown to produce a 2.5-fold calculated increase in flow through the treated artery (Figures 2 and 3), as well as uniform and higher shear stresses than in the nondebulked artery (Figures 4 and 5).

Endothelial shear stress is defined as the tangential stress derived from the friction of the flowing blood on the endothelial surface of the arterial wall. It is equal to the product of blood viscosity and the spatial gradient

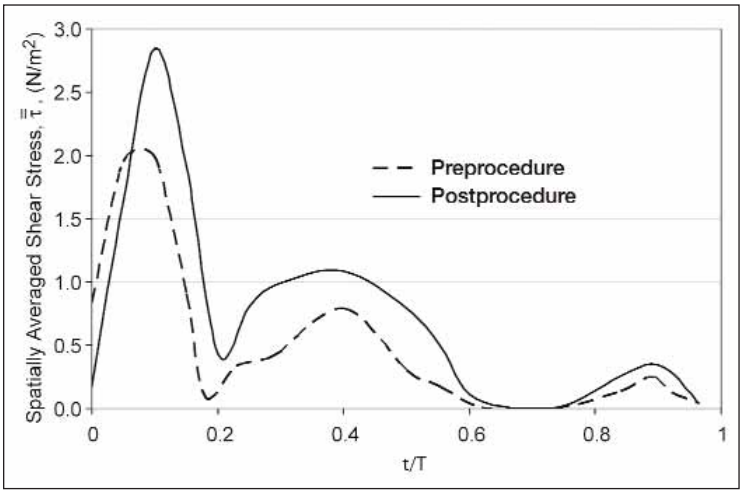

Figure 5. The results of the spatially averaged (circumferential and longitudinal) wall shear stress calculation showed a 70% increase in shear stress after treatment with the Diamondback 360°.

of blood velocity at the wall.[3] The increased shear stress after treatment with the Diamondback 360° may have multiple beneficial effects by reducing subsequent plaque accumulation, reducing arterial wall thickening, and reducing the potential for thrombus formation. Increased wall shear stress has been demonstrated to inhibit atheroma formation.[3,5]

Low shear stress, a confirmed stimulus for atherogenesis, can occur in geometrically irregular regions (such as curvatures, branches, and bifurcations); upstream or downstream of stenoses where smooth, streamlined (laminar) flow is disturbed; or in eddies where reversed flow occurs. Theoretically, low shear stress would occur in areas where an ablative device leaves behind linear flow channels. Although exci-

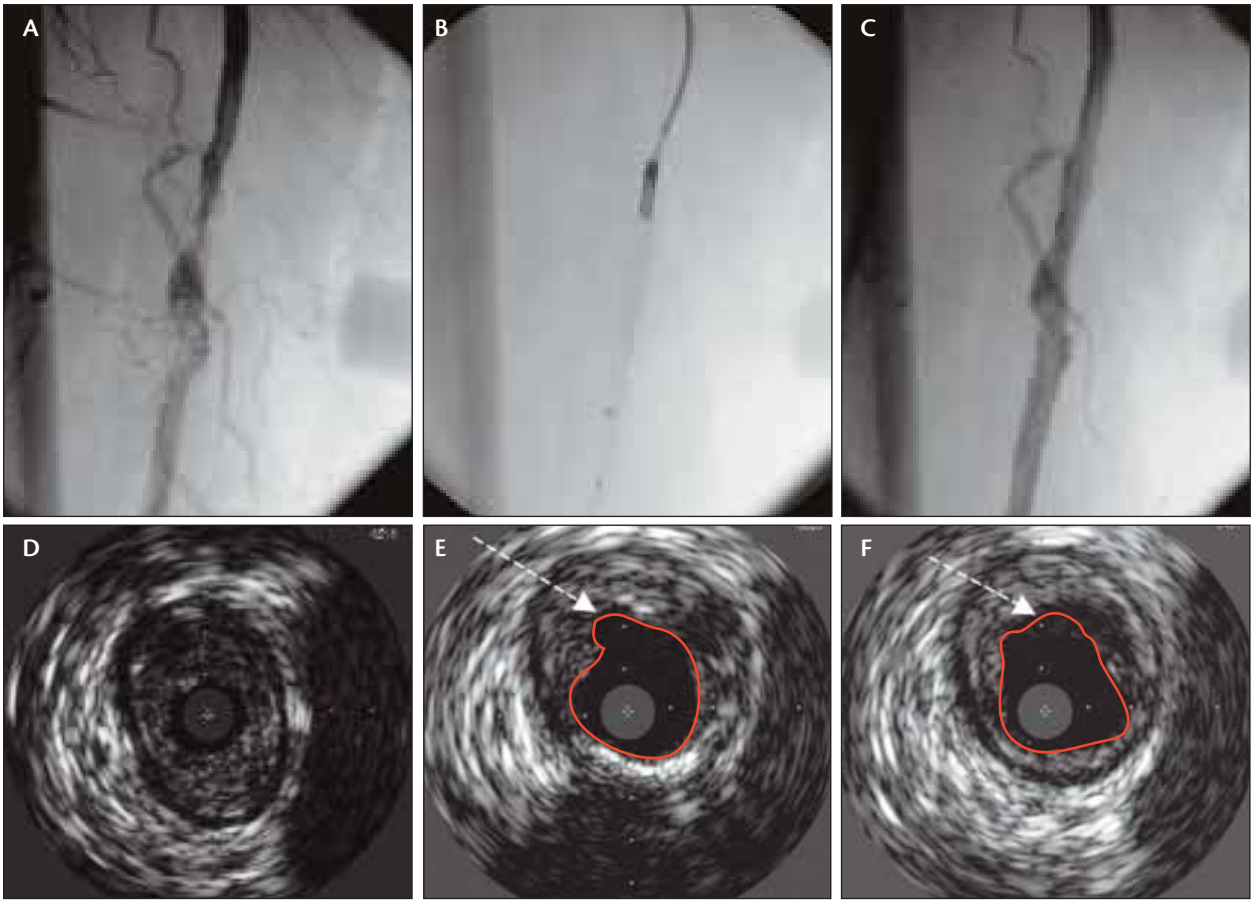

Figure 6. Angiograms from case 1 show the SFA before (A), during (B), and after (C) treatment with a SilverHawk LSM catheter. IVUS images of the atheroma (D-F). Arrows (E, F) indicate excisional track within the lumen and suboptimal removal of the atheroma from within the lumen.

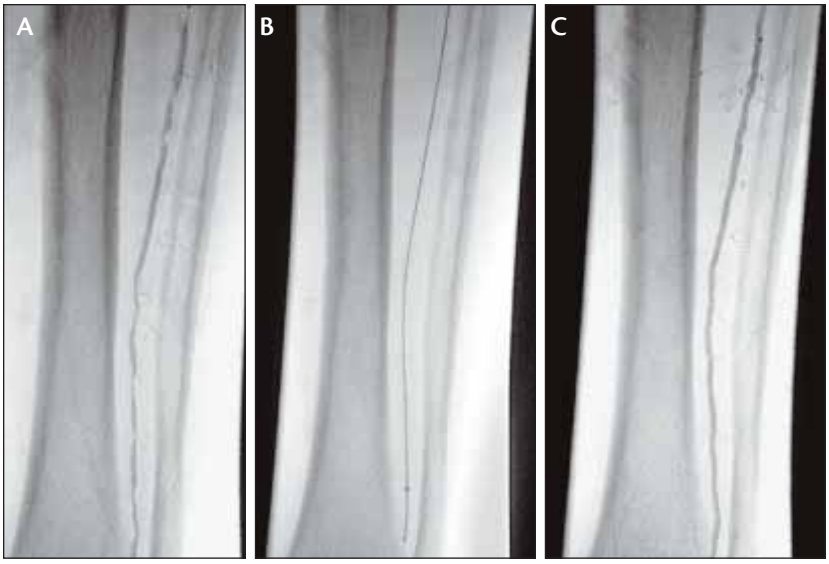

Figure 7. Angiographic images from case 2 before (A), during (B), and after (C) a stand-alone orbital atherectomy procedure.

sional atherectomy devices are instrumental in debulking plaque deposits to restore flow, they do not differentiate diseased from nondiseased tissue, increasing the risk of injury to the media and creating jagged edges on the vessel wall. If the jagged edges remain, they will create ideal areas for local lipid accumulation, inflammation, oxidative stress, matrix breakdown, and eventually further plaque progression and excessive expansive remodeling. These occurrences lead to the promotion of restenosis within the lumen.

CASE STUDIES USING EXCISIONAL AND ORBITAL ATHERECTOMY

Case studies performed by Michael Hagley, MD

Case 1: Excisional Atherectomy

The patient presented with a subtotal occlusion of the SFA (Figure 6A) and underwent excisional atherectomy treatment with a SilverHawk LSM catheter (ev3 Inc., Redwood City, CA) (Figure 6B). Figure 6C shows the final angiographic outcome after 20 passes of the device through the focal lesion. Although excisional atherectomy is effective in debulking plaque deposits from within the arteries of the lower extremity, it creates uneven flow channels through the thrombogenic substrata of the arterial wall.

Figures 6D through F show IVUS images of the atheroma within the SFA at baseline (Figure 6D), after 12 passes with the SilverHawk device (Figure 6E), and after an additional eight passes (Figure 6F). The arrows indicate the excisional track within the lumen and suboptimal removal of the atheroma from within the lumen despite what appears to be a satisfactory angiographic outcome (as shown in Figure 6C). An uneven vessel wall can decrease the shear rate within the lumen. A low shear stress has a confirmed role in the development and progression of atherosclerosis.

Case 2: Orbital Atherectomy

An 81-year-old woman with diabetes and severe claudication of her left leg that resulted after walking one-half block underwent an endovascular treatment to relieve the claudication (Figure 7). Diffuse multilevel stenoses in the left anterior tibial artery were detected on angiography (Figure 7A) and treated with a Diamondback 360° Classic Crown (Figure 7B) to achieve an excellent angiographic and procedural outcome (Figure 7C). No adjunct therapy was required, making this a stand-alone orbital atherectomy procedure.

The enlarged lumen was concentric and devoid of dissection planes, which frequently occur during excisional atherectomy, especially if the device is moved too quickly through tissue planes. The postprocedure lumen showed excellent concentricity, and there were no minor or major dissections in this calcified and diffusely diseased artery. A smooth, concentric lumen (Figure 8) after orbital atherectomy is relevant to increased shear stress that may assist in protecting the vessel wall from plaque buildup or thrombosis.

CONCLUSION

The Diamondback 360° safely and efficiently increases a vessel's cross-sectional area to allow maximal blood flow, and it does so while creating a smooth and concentric lumen. How much does a smooth arterial lumen after the procedure matter? It may have a unique advantage in that it is devoid of fissures, cracks, or exposed subendothelium where platelet- and white cell-enriched thrombus can form to embolize distally or occlude the artery. Furthermore, shear stress is increased after the procedure, suppressing the atherosclerotic process. If adjunctive therapy is not needed after debulking with orbital atherectomy, the arterial vessel is spared from further trauma and the potential resulting resurgence of the disease process. Intuitively, debulking with a device that creates a concentrically smooth lumen—similar to that of a nondiseased artery devoid of surface irregulari-

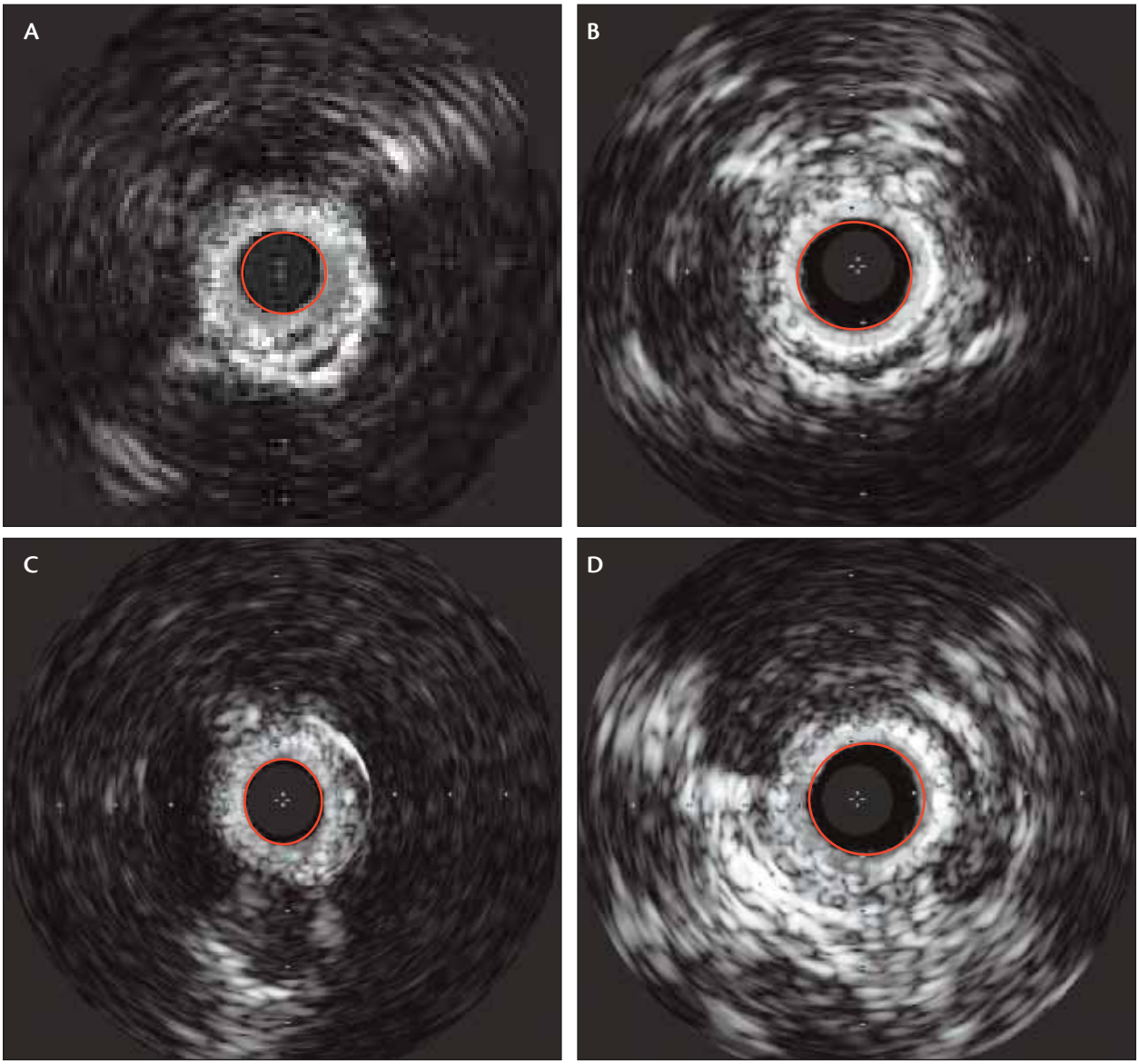

Figure 8. Location-matched IVUS images from case 2 of the calcified anterior tibial artery before (A) and after (B) orbital atherectomy. Additional location-matched IVUS images of the anterior tibial artery before (C) and after orbital atherectomy (D).

ties—should affect the optimal procedural and clinical objectives of restoring and maintaining adequate blood flow in the lower extremities. ■

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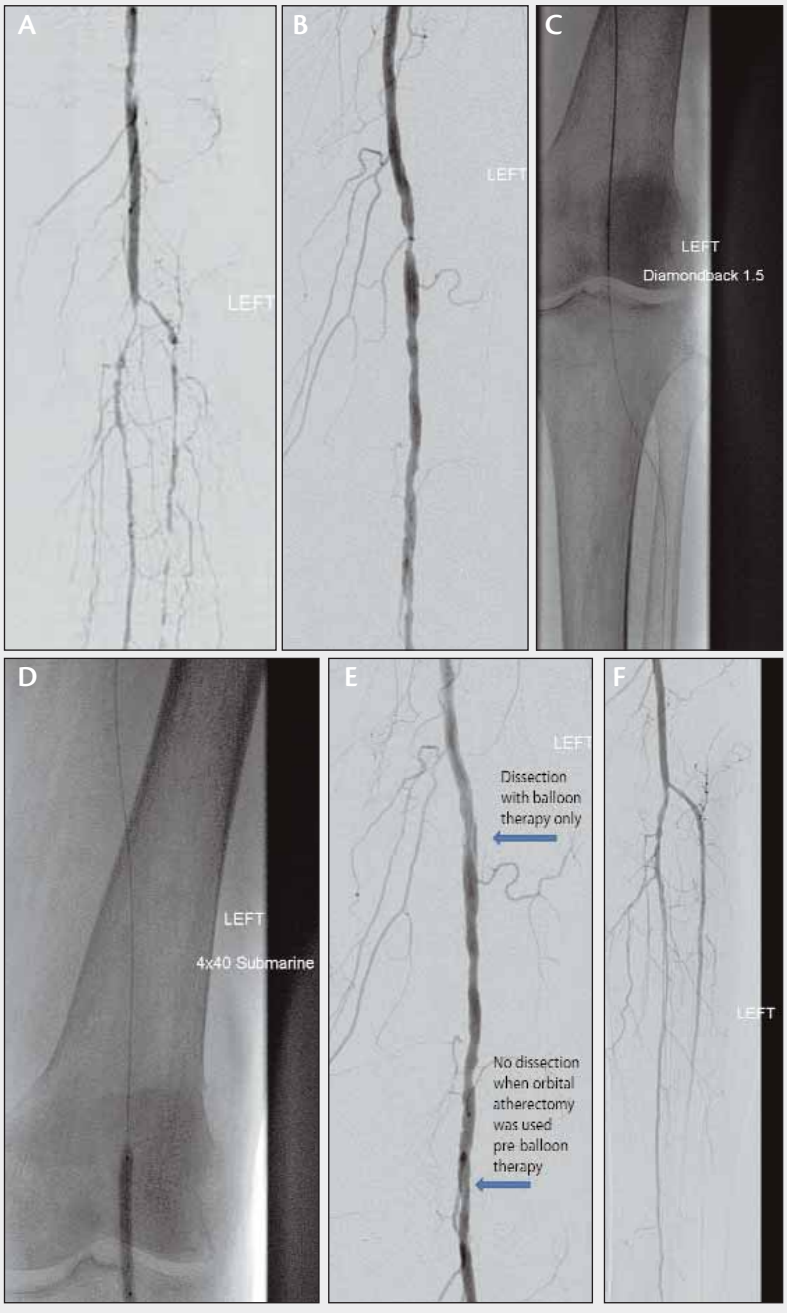
1. Virchow R. Gessammelte Abhandlungren zur Wissenschaftlichen Medzin. 1856. Meidinger, Frankfurt, Germany.
2. Ross R. Atherosclerosis— a problem of the biology of arterial wall cells and their interactions with blood components. Atherosclerosis. 1981;1:293-311.
3. Chatzizisis Y, Coskun AU, Jonas M, et al. Role of endothelial shear stress in the natural history of coronary atherosclerosis and vascular remodeling. J Am Coll Cardiol. 2007;49:2379-2393.
4. Abraham JP, Sparrow EM, Lovik RD. Unsteady, three dimensional fluid mechanic analysis of blood flow in plaque-narrowed and plaque-free arteries. International Journal of Heat and Mass Transfer. Special issue on bioheat and biofluid flow. In press.
5. Ku DN, Giddens DP. Pulsatile flow in a model carotid bifurcation. Arteriosclerosis. 1983;3:31-39.

CASE STUDY: CHANGING COMPLIANCE OF CALCIFIED VESSELS TO IMPROVE BALLOON THERAPY

This patient is a 78-year-old diabetic woman with nonhealing left foot ulcers. Angiography demonstrated two high-grade popliteal stenoses along with severe tibial vessel disease (Figures 1A and 1B). Orbital atherectomy was performed with the undersized 1.5-mm device on the more distal popliteal stenosis to improve flow into the tibial vessels (Figure 1C). The posterior tibial and peroneal arteries were treated with the 1.5-mm device plus low-pressure balloon dilatation.

The more distal popliteal stenosis, which had been treated with a single pass using the small 1.5-mm device, was then satisfactorily dilated with a 4-mm balloon inflated to 4 atm with complete balloon expansion (Figure 1D). The more proximal, nonpretreated, popliteal lesion required 8 atm of pressure for complete balloon expansion and resulted in the dissection shown (after a more prolonged inflation to "tack up" the dissection) (Figure 1E).



This case demonstrates that using the Diamondback 360° to favorably alter lesion compliance allows adjunctive low pressure balloon dilatation to be performed and often yields excellent acute results (Figure 1F). Primary balloon dilatation in a poorly yielding lesion often results in significant subintimal dissection, sometimes requiring bailout stenting if such was not the initial strategy. Deep vessel-wall injury and barotrauma associated with high-pressure balloon dilatation frequently required in less-compliant lesions are often cited as potential initiators of restenosis. The Diamondback 360° improves lesion compliance in larger vessels while allowing for a less traumatic, more predictable acute result with the potential for lower restenosis.

Case study performed by Raymond Dattilo, MD, FACC, Director Cardiac Catheterization Lab, St. Francis Health Center, Topeka, Kansas