Effective Debulking With the JETSTREAM™ Atherectomy System

Strategies for effective treatment of PAD in the era of drug-coated balloons and contemporary stenting.

BY THOMAS M. SHIMSHAK, MD, FACC, FSCAI

Peripheral artery disease (PAD) is a major cause of morbidity and mortality in the United States, affecting 8 to 12 million people. The incidence of PAD increases in the presence of well-defined atherosclerotic risk factors, including cigarette smoking, diabetes mellitus, hypertension, hyperlipidemia, and advanced age, and is estimated to affect > 20% of adults aged 55 years and older. When symptomatic, PAD may adversely have an impact on functional capacity, ability to work, and quality of life. Furthermore, PAD is associated with significant social and economic costs[1] and increases the risk of future cardiovascular events.

Advances in percutaneous catheter-based therapies have led to improved early and late clinical results in symptomatic patients.[2] Successful percutaneous revascularization improves quality-of-life measures, functional capacity, amputation rates, and survival in patients with intermittent claudication and critical limb ischemia. Use of adjunct devices and improved procedural outcomes have resulted in an increase in the number of PAD patients treated with endovascular therapy. The number of endovascular procedures has doubled for patients with intermittent claudication, and it has increased fourfold in patients with critical limb ischemia.[2]

Endovascular therapy of the superficial femoropopliteal arterial segment has historically been challenging. Although overall procedural results have been favorable, late results have been limited by unacceptable high restenosis rates and recurrent symptoms. The atherosclerotic disease process in the femoropopliteal arterial segment is often diffuse with complex histologic morphologies, including soft or fibrous tissue, thrombus, and superficial and deep calcium. In addition, chronic total occlusions (CTOs) are common (Table 1).[3] These factors have limited the utility of balloon angioplasty alone for sustainable favorable results and have led to the use of alternative therapies, including stenting (bare-metal, drug-eluting, and covered nitinol stents), atherectomy, and more recently, drug-coated balloons (DCBs).

TABLE 1. LESION LOCATION AND CHARACTERISTICS*

Variable	No. (%) or Mean ± SD
Stenosis	1,334 (62.4)
Chronic total occlusion	615 (28.8)
In-stent restenosis	188 (8.8)
Mean length, mm	100.8 ± 9.4
Location	
Femoral	660 (30.9)
Popliteal	266 (12.4)
Tibial	513 (24.0)
Bypass graft	59 (2.7)
Multilevel	389 (18.3)
TASC classification	
A	297 (13.9)
B	632 (29.5)
C	592 (27.7)
D	616 (28.8)

**Based on data from Shrikhande GV, Khan SZ, Hussain HG, et al. Lesion types and device characteristics that protect distal embolization during percutaneous lower extremity interventions. J Vasc Surg. 2011:53:347-352.*[3]

The JETSTREAM Atherectomy System (Boston Scientific Corporation) is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus. It consists of a sterile, single-use catheter and control pod and a reusable power console. The catheter is compatible with an 0.014-inch wire (including the Thruway™ Guidewire [Boston Scientific

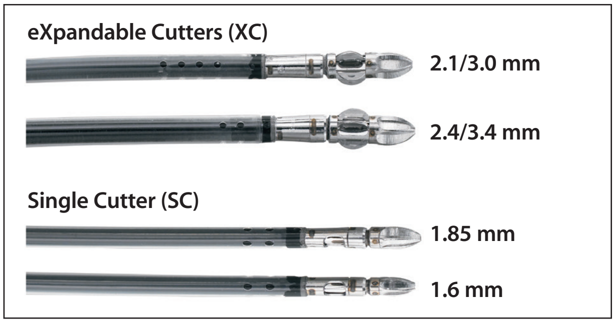

Figure 1. The JETSTREAM Atherectomy System cutters. Two different expandable cutter (XC) catheters are available in sizes 2.1/3.0 mm and 2.4/3.4 mm. The single cutter (SC) catheters have fixed, nonexpandable cutters and are available in two sizes, 1.6 mm and 1.85 mm. All catheters are 7-F sheath and 0.014-inch guidewire compatible (including the Boston Scientific Thruway Guidewire. It is also approved for use with Atherectomy Lubricants, such as Rotaglide™ Lubricant).

Corporation]) and 7-F sheath. It consists of a five-flute, front-end cutting tip that rotates at 70,000 to 73,000 RPM. Catheters are available in a variety of sizes, including two with nonexpandable cutters (1.6 mm or 1.85 mm), and two catheters with expandable cutters (2.1/3.0 mm, and 2.4/3.4 mm) (Figure 1). The JETSTREAM Atherectomy System is designed to treat a variety of lesion morphologies including soft, fibrotic, calcified, and/or thrombus. By virtue of its property of differential cutting, it preferentially cuts atheromatous disease, while sparing normal tissue. It also incorporates dynamic and continuous aspiration of particulate debris and thrombus, a feature that reduces distal emboli and improves device and procedural safety. Although other atherectomy systems have demonstrated effectiveness in removing calcium, the JETSTREAM Atherectomy System is unique in terms of combining differential cutting with dynamic aspiration (Table 2).

CASE PRESENTATIONS*

Case 1: Diffuse Distal SFA and Popliteal CTO

A 78-year-old woman presented with severe, limiting, intermittent claudication of her right leg. She had undergone complex endovascular therapy of her left leg several months earlier, after presenting with an ischemic great toe ulcer. The ulcer had healed, but she had limiting exertional right calf pain, which had been present for more than 6 months. Previous CT angiography had demonstrated wide patency of the right common and external iliac arteries, common femoral artery (CFA) and profunda, and proximal right superficial femoral artery (SFA). The distal right SFA was diffusely diseased, and the popliteal artery was chronically occluded.

The interventional procedure was completed using antegrade access with a 7-F sheath, demonstrating a diffusely diseased, calcified distal right SFA with multiple subtotal stenoses. The proximal portion of the popliteal artery was chronically occluded with reconstitution of the midportion of the popliteal artery via collaterals (Figure 2). The distal popliteal artery had a dis-

TABLE 2. COMPARISON OF PROPERTIES OF DIFFERENT ATHERECTOMY DEVICES

	JETSTREAM™ Atherectomy System (Boston Scientific Corporation)	Peripheral Rotablator™ Rotational Atherectomy System (Boston Scientific Corporation)	Diamondback 360™, Stealth 360™ Atherectomy System (Cardiovascular Systems, Inc.)	SilverHawk™, TurboHawk™ Plaque Excision System (Medtronic)	Turbo-Elite Laser™ Atherectomy Catheter (Spectranetics Corporation)
Front cutting	✔	✔			N/A
Differential cutting	✔	✔	✔		N/A
Active aspiration	✔				
Concentric lumens	✔	✔			
Lesion morphology:					
Calcium	✔	✔	✔	✔ (large vessel only)	✔
Thrombus	✔				✔

Sources: Endovascular Today Buyer's Guide 2014. JETSTREAM System Brochure, Boston Scientific Website, 2014. Peripheral Rotablator product website, Boston Scientific, 2014. Diamondback 360 product website, CSI, 2014. Covidien website, Directional Atherectomy products, 2014. Turbo-Elite Laser Atherectomy Catheter Instructions for Use, May 2014.

**Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.*

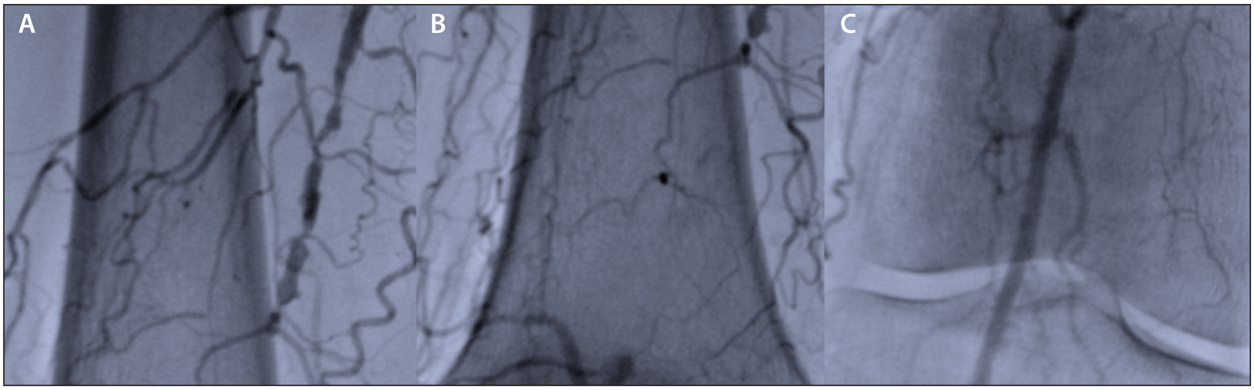

Figure 2. Distal right SFA (A). CTO of the proximal popliteal artery (B). Reconstituted midpopliteal artery (C).

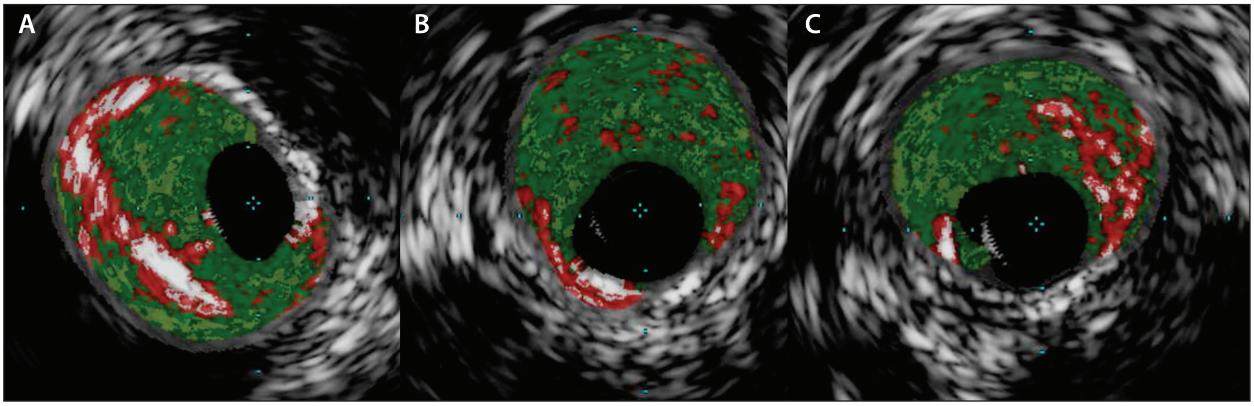

Figure 3. IVUS using virtual histology of the popliteal artery following recanalization and predilatation. Eccentric dense fibrocalcific plaque with scattered thrombus and an extensive arc of superficial calcium encompassing > 270° (A). Eccentric fibrocalcific plaque and scattered associated thrombus (B). Predominantly fibrous plaque and localized thrombus and superficial calcium (C).

crete subtotal stenosis. There was diffuse infrapopliteal disease, characterized by an occluded distal peroneal artery and proximal occlusion of the posterior tibial artery. The anterior tibial artery was widely patent.

After administering 2,500 units of intravenous (IV) heparin, a 0.018-inch, 300-cm-long, 30-g Victory™ Guidewire (Boston Scientific Corporation) was used to recanalize the CTO using a 4-F angled Glidecath® (Terumo Interventional Systems). The wire tip was directed freely into the anterior tibial artery with fluoroscopic guidance. After recanalizing the occluded popliteal artery, an additional 5,000 units of IV heparin were administered to achieve a therapeutic activated clotting time. After exchanging for a 0.014-inch guidewire, the popliteal artery and distal SFA were then dilated with a 2- X 150-mm balloon catheter, performing multiple overlapping inflations encompassing the mid and proximal popliteal artery and distal SFA. The 0.018-inch guidewire was exchanged for a 0.014-inch, 315-cm-long BareWire (Abbott Vascular) delivery wire. Intravascular ultrasound (IVUS) was then performed using the 2.5-mm Eagle Eye® Platinum IVUS catheter (Volcano Corporation). Virtual histology and Chromaflo (Volcano Corporation) were used to assess the disease severity, extent of calcium, lesion morphology, and vessel dimensions and found severe fibrocalcific disease with mixed thrombus and extensive superficial calcium encompassing a > 270° arc of calcium (Figure 3).

The JETSTREAM Atherectomy System was used to debulk the lesion and remove calcium. Prior to introducing the 1.6-mm cutter, a 4- to 7-mm Emboshield NAV6® (Abbott Vascular) was deployed in the distal popliteal artery. The 1.6-mm cutter was advanced manually just proximal to the disease. The device was then activated, and two passes were made, encompassing the entire length of the diseased segment. This was followed by additional passes with the 2.1- to 3-mm cutter. Adjunctive angioplasty of the distal SFA and proximal popliteal arteries was performed with a 4-mm Chocolate® balloon (Cordis Corporation). A 4.5-mm braided self-expanding stent was deployed in the distal SFA with minimal elongation. Final angiogram and IVUS demonstrated wide patency and full stent apposition (Figures 4 and 5). The distal popliteal lesion was also

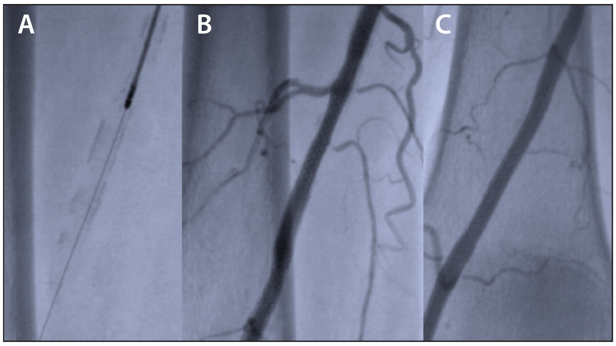

Figure 4. The JETSTREAM Atherectomy System was used on the right distal SFA, which had associated calcium (A). Final arteriogram of distal SFA after using the JETSTREAM Atherectomy System, angioplasty, and stenting (B). Final arteriogram of the popliteal artery after using the JETSTREAM Atherectomy System and balloon angioplasty (C).

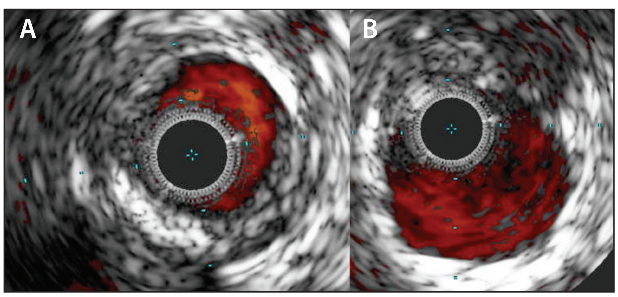

Figure 5. IVUS images of the popliteal artery after JETSTREAM Atherectomy, adjunctive balloon angioplasty (A), and stenting (B). Posttreatment IVUS showed significant calcium and plaque removal and an increase in luminal cross-sectional area compared to pretreatment.

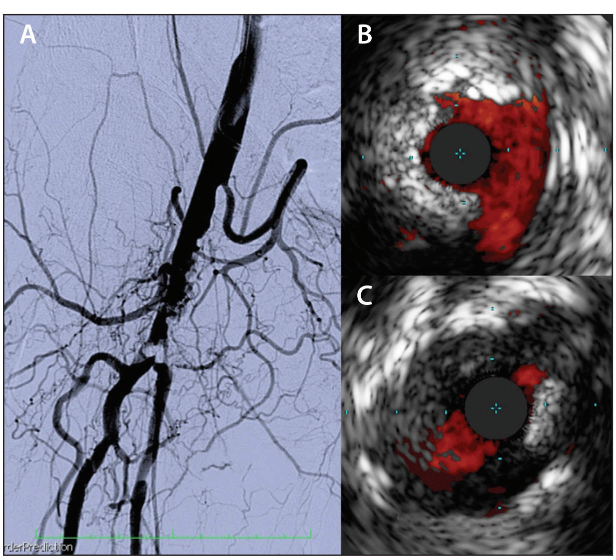

Figure 6. Angiogram of the right CFA, SFA, and profunda artery (A). IVUS images of the CFA (B) and SFA origin (C).

treated with the 2.1-mm JETSTREAM Atherectomy System. The patient's postprocedure course was uneventful. She was discharged the following day and remained stable and symptom free at 6-month follow-up.

Case 2: Complex Calcific Disease in the CFA, Profunda, and SFA

An 84-year-old man presented with severe, bilateral exertional calf discomfort after walking < 1 block. Noninvasive evaluation included a resting ankle-brachial index in the right leg of 0.68. He underwent CT angiography, which demonstrated discrete, high-grade disease of the right CFA and of the proximal and distal right SFA. He had two-vessel runoff below the knee, consisting of the anterior tibial and peroneal arteries. He was referred for selective right iliofemoral arteriography and runoff and possible endovascular therapy. Contralateral access from the left femoral artery using a 6-F Flexor® Ansel sheath (Cook Medical) was used. Selective right iliac arteriography demonstrated highly calcified, complex disease and critical obstructive disease of the right SFA with an eccentric subtotal (95%) stenosis. There was also high-grade disease at the origin of the profunda artery, with an eccentric 85% to 90% stenosis. The CFA was extensively calcified and had significant distal disease just proximal to the bifurcation (Figure 6). The patient was given 5,000 units of IV heparin, and the right SFA was crossed with a 0.014-inch 30-g Victory™ Guidewire. A second 0.014-inch, ChoICE™ PT Guidewire (Boston Scientific Corporation) was directed into the profunda artery using a two-wire technique. A series of sequential balloon inflations were then performed with 2.5-mm and 3-mm X 20-mm balloons, dilating the CFA-SFA origin, followed by the CFA-profunda arteries. The balloons were inflated to 10 to 12 atm, and full balloon expansion was achieved.

At this point, the CFA, SFA, and profunda artery were evaluated with the 2.5-mm Eagle Eye® Platinum IVUS catheter. IVUS demonstrated a dense, extensive arc of superficial calcium of the SFA, encompassing > 270° of the luminal circumference (Figure 6). Based on the arteriographic findings and the IVUS data, the JETSTREAM Atherectomy System was used. A 4-F Glidecath® was advanced over the 0.014-inch-long guidewire into the mid-SFA. The 0.014-inch guidewire was exchanged for a 0.035-inch, 300-cm Supra Core® (Abbott Vascular) guidewire. The 6-F sheath was then exchanged for a 7-F Flexor Ansel® contralateral sheath, which was advanced to the distal right external iliac artery. An additional 2,500 units of IV heparin were administered to achieve a therapeutic activated clotting time. The Glidecath® was reintroduced over the Supra Core® wire to the

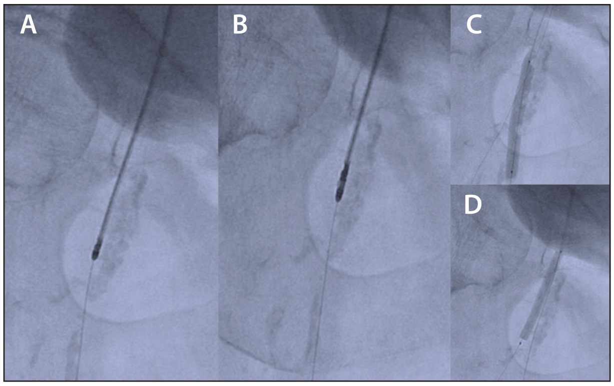

Figure 7. The 1.85-mm SC JETSTREAM cutter (A) and 2.1- to 3-mm XC JETSTREAM cutter (B). Balloon angioplasty of the proximal CFA-SFA after JETSTREAM Atherectomy (C). Balloon angioplasty of the CFA-profunda artery after JETSTREAM Atherectomy (D).

mid-SFA. The 0.035-inch wire was then exchanged for a 0.014-inch, 315-cm BareWire, which was advanced to the distal SFA, and a 4- to 7-mm Emboshield NAV6® was then deployed. The guidewire in the profunda artery was removed. The CFA and origin of the SFA were then treated with the 1.85-mm SC JETSTREAM catheter, followed by the 2.1- to 3-mm XC JETSTREAM catheter (Figure 7).

After withdrawing the JETSTREAM catheter over the wire, repeat arteriography demonstrated significant improvement in the SFA, with < 50% residual disease. There was persistent high-grade disease at the origin of the profunda artery. The SFA was then dilated with a series of prolonged, low-pressure inflations using the 5-mm balloon (Figure 7C) and 6-mm Chocolate® balloon catheter. The CFA was ultimately dilated with a 7-mm balloon catheter (Figure 7D). A 0.014-inch ChoICE PT wire was then directed into the profunda artery, and the origin was then dilated with a 5-mm balloon catheter. Finally, kissing-balloon inflations were performed in both the profunda and SFAs. The final arteriogram demonstrated wide patency of the CFA and SFA and moderate eccentric disease of the proximal profunda artery (Figure 8A). Repeat IVUS of the SFA and CFA demonstrated a significant reduction in plaque burden, calcium, and an increase in cross-sectional area (Figure 8B and 8C).

DISCUSSION

Both cases demonstrate the effectiveness of the JETSTREAM Atherectomy System in treating complex, calcified PAD. Preatherectomy IVUS characterized the location and extent of the lesion-specific calcium and the complex morphology of the disease. These cases also demonstrate that lesion morphology and complexity may not be fully appreciated by angiography alone. IVUS characterizes vessel size, extent and severity of disease, and morphologic features, including the presence and location of calcium. The JETSTREAM Atherectomy System is effective in removing plaque and calcium, resulting in significant luminal cross-sectional area. It was particularly effective for highly calcified disease of the CFA and SFA. Despite the severity and complexity of the disease in this challenging location, a favorable procedural result was achieved with combined atherectomy and balloon angioplasty.

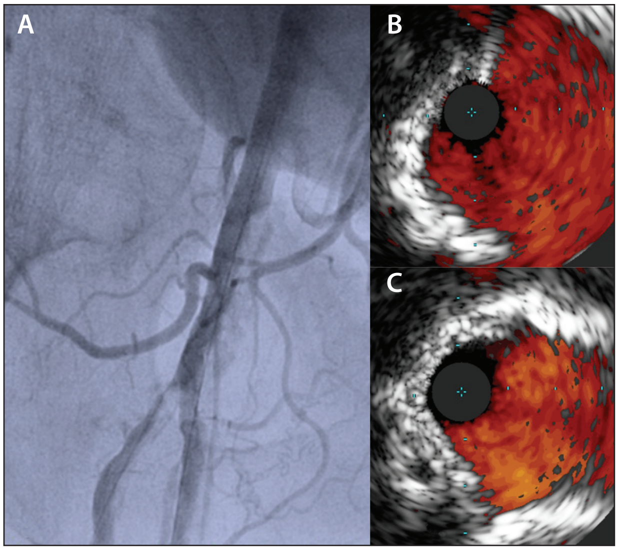

Figure 8. Final angiogram of the right CFA, SFA, and profunda artery (A). Final IVUS image of the right CFA (B). Final IVUS image of the right SFA origin (C).

Why Is Calcium Removal Important?

Calcium is common in patients with PAD, and its presence adversely affects procedural results and long-term outcomes. The presence of calcium necessitates greater balloon inflation pressures, resulting in an increased rate of dissections after balloon angioplasty. Despite using high balloon inflation pressures, the presence of calcium and excessive plaque burden may limit stent expansion.[4-7] The presence of severe calcium limits the long-term effectiveness of DCBs by interfering with effective drug absorption. In a recent analysis, 12-month patency of femoropopliteal arterial segments following treatment with a DCB was 50% for lesions with calcium encompassing 270° to 360°, versus 100% for lesions with calcium from 0° to 90°. Compared to lesions with less severe calcium, excessive calcium was associated with lower ankle-brachial indices, greater late-lumen loss, and high target lesion revascularization.[8]

Benefits of the JETSTREAM Atherectomy System

The JETSTREAM Atherectomy System is effective in removing calcium in femoropopliteal disease. The safety and effectiveness of this device in removing moderate to severe superficial calcium in de novo femoral and popliteal arterial occlusive disease was evaluated in the JETSTREAM Calcium Study.[9] This prospective, multicenter registry used IVUS before and after atherectomy to characterize the efficacy of the JETSTREAM Atherectomy System in removing calcium. The study demonstrated a significant reduction in stenosis diameter (86%, preatherectomy; 37%, postatherectomy; and 10%, postadjunct therapy) and an increase in luminal area (pre: 6.6 ± 3.7 mm^2; post: 10.0 ± 3.6 mm^2; $P = .001$). In addition, calcium removal was responsible for 86% ± 23% of the increase in luminal area following treatment. The ability of the JETSTREAM Atherectomy System to remove plaque (including superficial calcium) improves luminal diameter and cross-sectional area. These luminal gains are further enhanced by adjunct balloon angioplasty (plain-old balloon angioplasty or caged balloons). By virtue of plaque modification and calcium removal, the JETSTREAM Atherectomy System may lead to improved stent results using conventional self-expanding nitinol stents.

Finally, the ability to remove calcium may also improve late results following use of adjunctive DCBs. The DEFINITIVE AR study,[10] a prospective, multicenter, randomized pilot study, evaluated the use of SilverHawk™ and TurboHawk™ (Medtronic) directional atherectomy systems and Bayer HealthCare's peripheral paclitaxel-coated angioplasty catheter with Paccocath® technology. It was designed to assess the clinical benefits of plaque removal using this device, followed by treatment with a DCB with an endpoint of 12-month angiographic patency. DEFINITIVE AR demonstrated higher technical success and a lower incidence of flow-limiting dissections following this treatment strategy compared to using a DCB alone. Additionally, directional atherectomy combined with a DCB improved patency in long and severely calcified lesions. Primary patency rates for the long (> 10 cm) lesion subset at 12 months as evaluated by duplex ultrasound were 96.8% in patients treated with directional atherectomy and antirestenosis therapy (DAART) compared to 85.9% in patients treated with a DCB alone. Primary patency rates at 12 months in severely calcified lesions, per core lab assessment, were 70.4% in DAART patients, compared to 62.5% in patients treated with DCB alone. DAART resulted in 94.1% primary angiographic patency when more plaque was removed with directional atherectomy (< 30% residual stenosis was achieved), compared to 68.8% patency when less plaque was removed (> 30% residual stenosis) before treatment with the DCB.

CONCLUSION

PAD is complex and diffuse, and it is often associated with calcium deposition. The presence of calcium may limit the effectiveness of balloon angioplasty, stenting, and DCBs. Calcium has also been associated with increased rates of dissection following balloon angioplasty. The JETSTREAM Atherectomy System is effective in removing calcium and leads to improved luminal dimensions and cross-sectional area. Plaque modification using the JETSTREAM Atherectomy System may lower complication rates (dissection) and improve early and late results using adjunctive balloon angioplasty, stenting, and/or DCBs. ■

Thomas M. Shimshak, MD, FACC, FSCAI, is an interventional cardiologist for the Heart and Vascular Center, Florida Hospital Heartland Medical Center, in Sebring, Florida. He has disclosed that he is a consultant and speaker for Bayer, Volcano Corporation, and Boston Scientific Corporation; performs training programs for Bayer and Volcano Corporation; and receives research funding from Bayer. He receives honoraria from Bayer, Volcano Corporation, and Boston Scientific Corporation. Dr. Shimshak may be reached at tshimshak@gmail.com.

1. Fowkes FG, Murray GD, Butcher I, et al. Ankle brachial index combined with Framingham risk score to predict cardiovascular events and mortality: a meta-analysis. JAMA. 2008;300:197-208.
2. Egorova NN, Guillerme S, Gelijns A, et al. An analysis of the outcomes of a decade of experience with lower extremity revascularization including limb salvage, lengths of stay, and safety. J Vasc Surg. 2010;51:878-885.
3. Shrikhande GV, Khan SZ, Hussain HG, et al. Lesion types and device characteristics that protect distal embolization during percutaneous lower extremity interventions. J Vasc Surg. 2011:53:347-352.
4. Bishop PD, Feiten LE, Ouriel K, et al. Arterial calcification increases in distal arteries in patients with peripheral arterial disease. Ann Vasc Surg. 2008;22:799-805.
5. Demer LL. Effect of calcium on in vivo mechanical response of rabbit arteries to balloon dilation. Circulation. 1991;83:2083-2093.
6. Makam P. Use of orbital atherectomy treatment in a high-volume clinical practice modifies non-compliant plaque to deliver durable long-term results. J Invasive Cardiol. 2013;25:85-88.
7. Fitzgerald PJ, Ports TA, Yock PG. Contribution of localized calcium deposits to dissection after angioplasty: an observational study using intravascular ultrasound. Circulation. 1992;86:64-70.
8. Fanelli F, Canavale A, Gazzetti M, et al. Calcium burden assessment and impact on drug-eluting balloons in peripheral arterial disease. Cardiovasc Intervent Radiol. 2014;37:898-907.
9. Akiko M, Mintz GS, Shimshak TM, et al. Intravascular ultrasound evaluation of JETSTREAM atherectomy for removal of superficial calcium in peripheral arteries. EuroIntervention. 2015;11:96-103.
10. Zeller T. Definitive AR. Presented at: Vascular InterVentional Advances (VIVA); November 4–7, 2014; Las Vegas, Nevada.