Pathway Jetstream® Atherectomy for Peripheral Artery Disease

A pair of case studies showing the safety and efficacy of this device in several types of lesions with varying degrees of calcification.

BY DINESH KUMAR, MD, AND WILLIAM A. GRAY, MD

There are challenges that face the interventionist when attempting percutaneous treatment of peripheral artery disease. Clinical outcomes with angioplasty alone have been unimpressive due to vessel recoil. Stents have had challenges in lower limb arteries because disease is often occlusive, diffuse, and heavily calcified. In addition, there are unique mechanical forces that impact stents; fractures, migration of stents, and "crushing" of the implant are other issues. Early experience with drug-eluting stents is uneven. Atherectomy devices are tedious to use (side-cutting blade, nose-cone, multiple passes, and the need to use multiple sizes). This is where the role of the Pathway atherectomy device (Pathway Medical Technologies, Inc., Kirkland, WA) comes in.

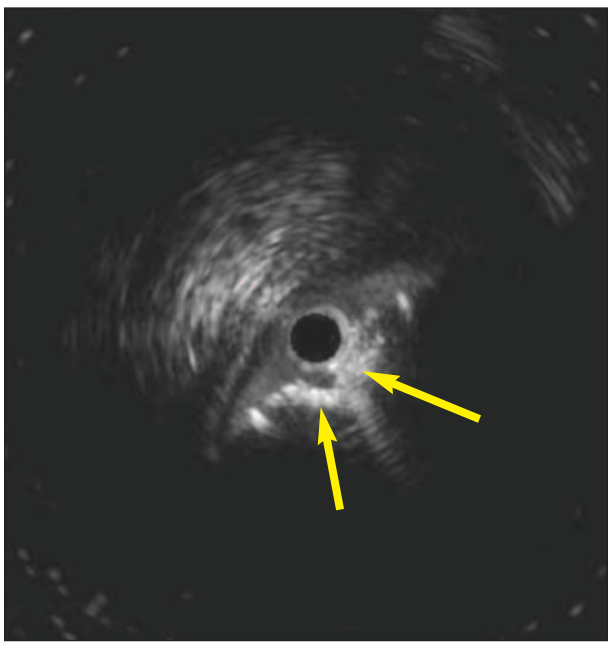

Figure 1. Case 1: Preintervention IVUS. Arrows indicate calcification.

The Pathway device offers a differential cutting tip that removes a variety of plaque types, including calcium; an aspiration port that collects plaque and thrombus; and a single, one-step size expansion from 2.1 to 3.1 mm.[1] The restenosis rate is low at 8%.[2]

CASE 1: SEVERE CALCIFICATION

The patient was a 74-year-old man with hypertension, dyslipidemia, and former tobacco use. He had coronary artery disease after a myocardial infarction (MI) with recent catheterization showing his right coronary artery to be 100% occluded and a normal ejection fraction. He also had a history of a transient ischemic attack with 100% stenosis of the left internal carotid artery, 50% stenosis of the right internal carotid artery, and stenting in 2003 of the right superficial femoral artery (SFA). The patient presented with claudication in his right calf after walking 50 feet. There was no recent history of rest pain or ulceration.

Left lower extremity angiography from the ipsilateral access site revealed only moderate left anterior tibial artery disease. Angiography of the affected limb demonstrated stenoses of 90% in the common femoral artery with very heavy calcification.

An 8-F, 45-cm sheath was advanced to the right external iliac artery; intravascular ultrasound (IVUS) was performed over an extra-support 0.014-inch wire. IVUS revealed a lumen cross-sectional area (CSA) of 6.14 mm^2 and extensive (> 270°) exophytic calcification throughout the common femoral artery stenosis (Figure 1).

Rotational atherectomy using the Jetstream® revascularization catheter was performed on the common femoral artery with the catheter in both the 2.1- and 3-mm profiles. Percutaneous transluminal angioplasty (PTA) with a 6- X 40-

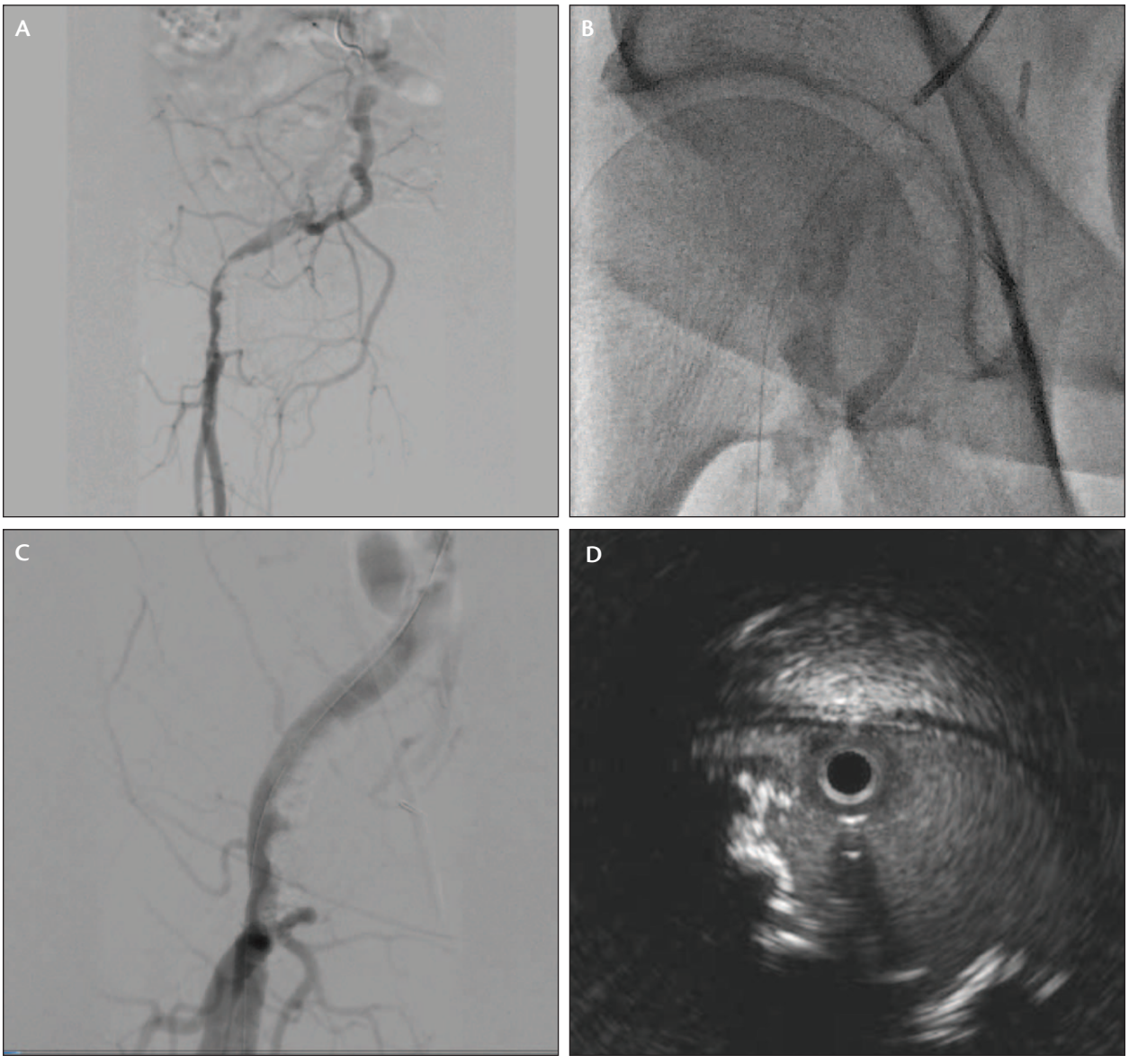

Figure 2. Case 1: Initial angiogram of severe common femoral artery stenosis (A). Jetstream® revascularization. Note heavy calcification (B). Final angiogram (C). Postprocedure IVUS (D).

mm balloon completed the intervention, with a markedly improved angiographic and IVUS result and a CSA of 32.24 mm^2 (Figure 2).

The patient's symptoms were resolved, and noninvasive flow studies improved. At 9 months, he remained symptom-free with a patent SFA.

CASE 2: DE NOVO LONG SFA CTO

A 69-year-old woman with hypertension, diabetes, dyslipidemia, coronary artery disease status post coronary artery bypass graft surgery, and previous percutaneous coronary intervention, presented with bilateral lower extremity claudication, which was greater in the right leg than in the left. Noninvasive flow studies revealed a right ABI of 0.64 and a left ABI of 0.59.

Angiography revealed a long chronic total occlusion (CTO) of the left SFA, as well as occlusion of the left anterior and posterior tibial vessels with single-vessel peroneal runoff to the foot to ankle. The right SFA and right posterior tibial artery also had long CTOs, and there was a 70% stenosis of the peroneal and anterior tibial arteries (Figure 3A).

Initial attempts to cross the CTO were performed carefully to maintain as central a passage as possible and to minimize subintimal travel using a Crosser (FlowCardia, Inc.,

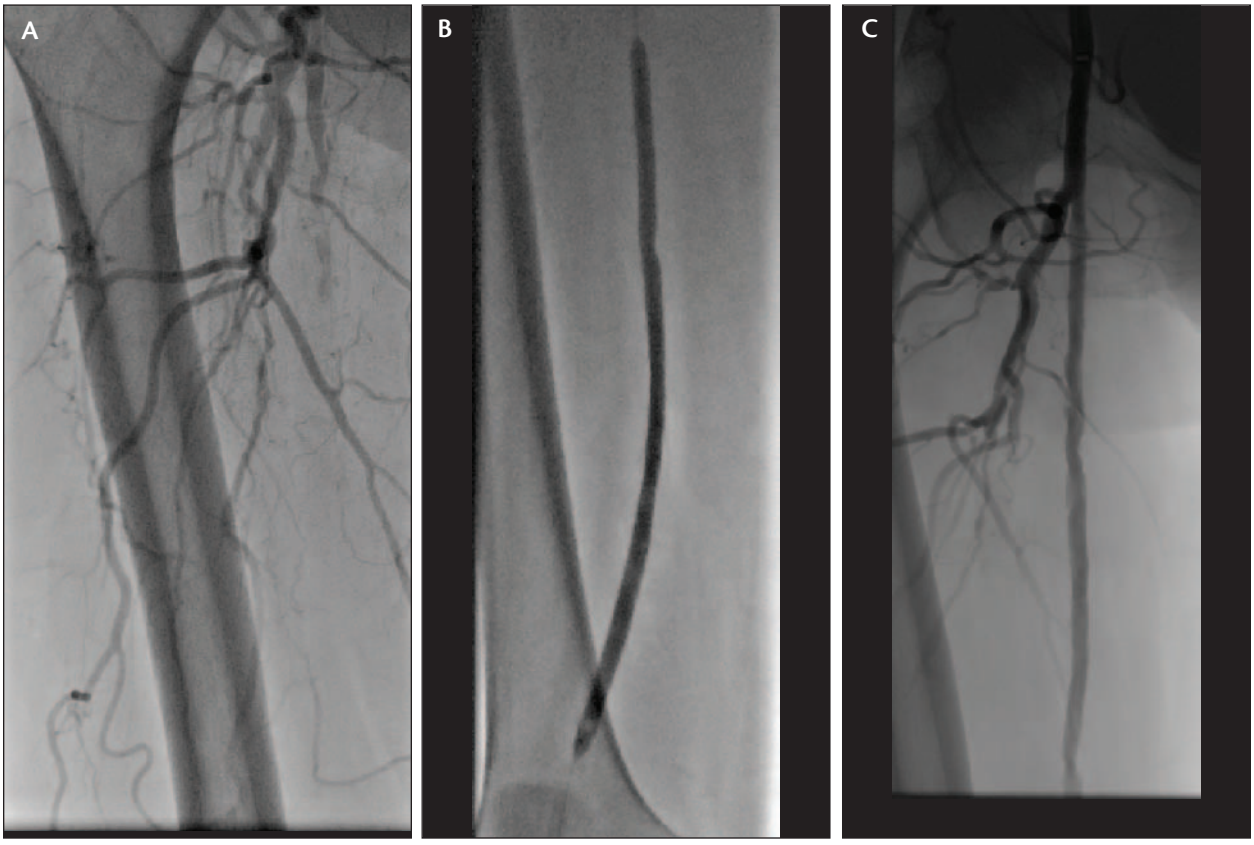

Figure 3. Case 2: Initial angiogram of index lesion (A). Right PTA after Jetstream® atherectomy (B). Final angiogram of right SFA (C).

Sunnyvale, CA). Once a hydrophilic wire successfully transited the CTO, the wire was exchanged for an extra-support 0.014-inch wire. IVUS was then performed and confirmed central lumen passage save for approximately 2- to 3-cm subintimal track. Atherectomy was performed with the Pathway Jetstream® device with both 2.1- and 3-mm sizes. Subsequently, PTA with a 6- X 120-cm balloon was performed with excellent final results (Figure 3B and C).

CONCLUSION

The variability of femoral and popliteal disease includes discrete lesions, some with various degrees of calcification and some long CTOs, each of which present their own challenges, especially with regard to permanent prosthesis implantation. As an example, severe calcification can significantly constrain the full expansion of nitinol stents and potentially reduce long-term patency.

The Jetstream® revascularization device enables the safe management of most types of lesions described in this series, as well as thrombotic lesions. In these two cases, there were no instances of distal embolization, and even when single-vessel runoff is present, the use of the Jetstream® does not appear to jeopardize distal circulation, due to its flushing and aspiration function.[1] Furthermore, it has demonstrated both safety (ie, lack of perforation) and efficacy with low restenosis[2] rates even in short segments of subintimal treatment. ■

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