

A New Twist on Below-the-Knee Treatment for CLI

Dual-action atherectomy and thrombectomy using the Jetstream G3 SF revascularization system for treating chronic limb ischemia below the knee.

BY GRAYSON H. WHEATLEY III, MD

Chronic limb ischemia (CLI) affects 1% to 2% of patients with peripheral arterial disease.¹ Although patients with CLI can have multivessel disease involving one or more of three distinct arterial segments contributing to CLI (aortoiliac, superficial femoral artery [SFA]/popliteal, and below-the-knee), most of the currently available endovascular therapies are designed primarily for intervention in the aortoiliac and SFA segments. A number of different endovascular therapies—such as angioplasty, stenting, cryoplasty, and atherectomy—have demonstrated effectiveness in patients with CLI involving the aortoiliac or SFA segments.² A host of new and improved endovascular devices for CLI resulting from above-the-knee disease are continuing to become available, and ongoing study of patient outcomes using these technologies is needed.

Building off of the successes of above-the-knee interventions, the next wave of treatment and innovation in endovascular therapies for CLI is targeted toward below-the-knee vessels. Evidence is beginning to emerge showing that CLI patients with below-the-knee disease can significantly benefit from endovascular revascularization as an additional treatment option alongside medical therapy or surgical bypass. However, unique aspects surrounding the anatomy and physiology of below-the-knee vessels, such as smaller vessel diameter, increased incidence of associated mural thrombus from sluggish arterial flow, and increased sensitivity to vasospasm, require a fundamental change in device design for endovascular revascularization.

Dual-action atherectomy and thrombectomy for treating CLI resulting from localized disease of the SFA has been

shown to be an effective emerging endovascular technology.³ The Jetstream G3 revascularization system (Pathway Medical Technologies Inc., Kirkland, WA) addresses a wide variety of plaque types and disease processes that can affect the SFA. This particular device offers a microcutter that spins at 70,000 rpm and features a 2.1-mm-diameter rotational cutter that can expand to 3 mm, along with a proximal active aspiration port. The size and construction of this device is compatible with both vessel diameter and the unique pathophysiology of above-the-knee vessels.

As more experience is gained with interventions for CLI resulting from below-the-knee disease, we are developing a deeper understanding of the unique challenges of endovascular revascularization for this anatomic location. Currently, few endovascular treatment options exist for below-the-knee CLI. It is becoming increasingly evident that due to smaller vessel size, along with other unique characteristics, below-the-knee endovascular intervention requires its own set of specialized techniques. Furthermore, differently designed devices are needed to safely and effectively address the wide array of below-the-knee arterial lesions that can be associated with CLI.

TECHNOLOGY

In June 2010, Pathway Medical Technologies Inc. received 510(k) clearance from the US Food and Drug Administration to market the Jetstream G3 SF revascularization system. This device features an over-the-wire, 1.85-mm, front-cutting, high-speed rotational catheter that is compatible with a 7-F sheath (Figure 1). The associated control pod generates a rotational speed of up to 73,000 rpm for the cutting tip, along with an active aspira-



Figure 1. The Jetstream G3 SF catheter with a 1.85-mm cutter (A) and the Jetstream G3 catheter with a 3-mm cutter (B) and associated proximal aspiration ports.

tion port that allows for continuous aspiration of debris (Figure 2). The G3 SF catheter offers equivalent aspiration and cutting efficiencies to the previous-generation G3 device. The 145-cm-long G3 SF catheter is compatible with a 0.014-inch wire, and its construction facilitates optimal performance in tortuous anatomy. It is compatible with the same console used for the Jetstream G3 catheter (Figure 3).

CASE REPORT

A 75-year-old woman with a history of peripheral vascular disease presented with chronic right foot pain and associated redness and swelling of the foot. A small 0.5- X 0.5-cm superficial ulcer was present on the distal aspect of her great toe. She had absent pulses to the dorsalis pedis and posterior tibial arteries, and the ankle-brachial index on the right leg was 0.4. A noninvasive duplex ultrasound of the right lower extremity determined that she had a chronic total occlusion (CTO) to the tibial peroneal trunk (TPT). As a result, she was taken to the catheterization laboratory, and angiography of the right lower extremity was performed using a contralateral left common femoral artery approach. The angiogram showed a CTO to the right distal popliteal artery, TPT, and proximal ATA, with collateral filling of a single-vessel runoff to the foot via the ATA (Figure 4).

A 7-F contralateral sheath was introduced through the contralateral left common femoral artery puncture site, and the lesion to the TPT was successfully crossed using a 0.018-inch hydrophilic wire. Significant care was taken to ensure that the wire stayed in the true lumen without traveling in the subintimal space. However, without the use of intravascular ultrasound, it can be difficult to confirm that the wire was entirely in the true lumen throughout the length of the CTO. There are a number of devices available for assistance with crossing below-the-knee CTOs, which can also aid in staying in the true lumen, but they were not needed in this particular case. As the wire crossed the CTO, using both careful tactile feedback and methodical visual assessment, we ensured that the wire stayed in the true lumen of the plaque. The wire did not spiral or deviate along its path—signs that the wire might be traversing the



Figure 2. The Jetstream G3 SF control pod.



Figure 3. This console is compatible with both the Jetstream G3 SF and Jetstream G3 revascularization systems.

subintimal space—and after crossing the calcified cap, the wire passed smoothly and without resistance, which also suggests that we were able to remain within the true lumen.

Then, a 0.018-inch Quick-Cross catheter (Spectranetics Corporation, Colorado Springs, CO) was advanced over the 0.018-inch hydrophilic wire into the distal ATA, and selective angiography of the runoff vessel confirmed that the catheter was in the true lumen and that there was a patent vessel distal to the foot. Furthermore, the diameter of the runoff vessel was confirmed to be 3 mm. A 0.014-inch, 300-cm-long wire was advanced into the distal right ATA through the Quick-Cross catheter, and the catheter was then removed.

A Jetstream G3 SF device was advanced over the wire to the target lesion via the 7-F contralateral sheath. Using a single-entry technique and beginning in the distal right popliteal artery, slow, steady advancement of the Jetstream G3 SF device was performed using a back-and-forth technique. The distal popliteal, TPT, and proximal ATA lesions were successfully crossed. Meticulous attention was directed to small interval advances and back-and-forth advancement of the device to ensure that ample time was provided to allow successful aspiration of plaque and thrombus debris. After the thrombectomy and atherectomy procedure was performed, the device was removed. A 3-mm X 10-cm Savvy long percutaneous transluminal angioplasty (PTA) peripheral catheter (Cordis Corporation, Bridgewater, NJ) was advanced over the 0.014-inch wire, and PTA was performed to the TPT and ATA. Low-pressure inflation (5 atm)

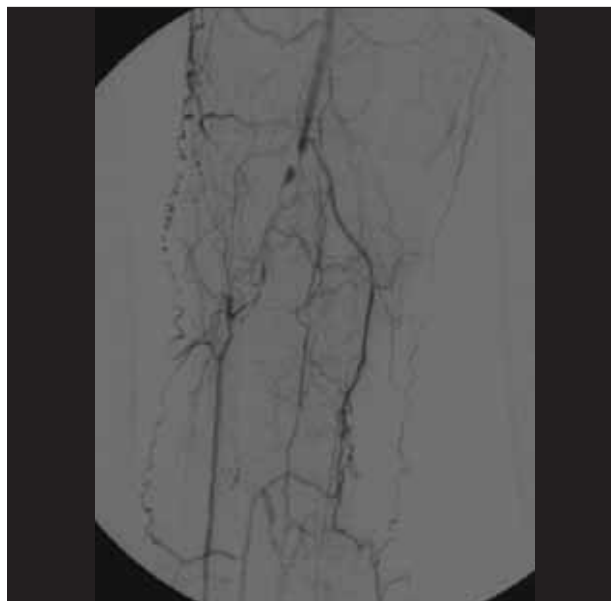


Figure 4. Angiogram of the right lower extremity below-the-knee vessels in a patient with CLI showing a CTO to the distal popliteal artery, TPT, and proximal anterior tibial artery (ATA), with a single-vessel runoff to the foot via the ATA.

and long duration (2 minutes) were used to minimize barotrauma to the treated vessels and to tack down any focal areas of dissection within the treated vessel. The catheter was removed, and a completion angiogram showed a widely patent distal right popliteal artery, TPT, and ATA, with excellent flow to the foot (Figure 5).

In addition, the posterior tibial artery was now patent and demonstrated a new, second-vessel runoff to the foot. The patient had an excellent Doppler signal to the dorsalis pedis and posterior tibial arteries at the ankle of the right foot. The patient awoke from the procedure and commented that her foot was much less painful. Four weeks after the procedure, the ulcer to the right great toe healed completely.

DISCUSSION

This case demonstrates a successful application of dual-action atherectomy and thrombectomy therapy for below-the-knee vessels. This is the only endovascular therapy for below-the-knee disease with active aspiration and may be a critically important feature in relation to the unique disease patterns of arterial disease located below the knee. It is becoming increasingly apparent that the pathophysiology of below-the-knee disease is fundamentally different from other vascular beds. Of primary distinction is the increased incidence of mural thrombus proximal and distal to the CTO and an associated calcified atheromatous cap (Figure 6).

It is believed that the smaller below-the-knee vessels have a more sluggish flow pattern, which increases the turbu-



Figure 5. Completion angiogram after dual-action atherectomy and thrombectomy using the Jetstream G3 SF revascularization system showing successful revascularization of the right distal popliteal artery, TPT, and proximal ATA.

lence of the blood proximal and distal to the occlusion. The unique flow characteristics, demonstrated as monophasic patterns on duplex ultrasound imaging, combined with smaller vessel diameter are more likely to predispose below-the-knee vessels to develop mural thrombus. As a result, any therapy that fails to address and remove the associated mural thrombus of below-the-knee disease could potentially predispose patients to the risk of distal embolization (Figure 7). This is particularly concerning in patients with below-the-knee CLI because these patients frequently have a single-vessel runoff. Loss of distal patency in these patients due to embolization of debris could be potentially catastrophic.

Continuous aspiration of debris associated with rotational atherectomy offers a very favorable solution to below-the-knee CLI. Managing particulate matter and minimizing embolic debris generated from atherectomy of below-the-knee disease is a critical differentiator between atherectomy devices. Personal experience with numerous atherectomy devices for below-the-knee disease has shown that without continuous aspiration, there is an increased incidence of distal embolization. There are limited data to confirm that continuous aspiration significantly decreases distal embolization as compared to other devices, and additional study and clinical experience is needed.

Figure 8 shows our most current understanding of successful stand-alone, dual-action atherectomy and thrombectomy therapy of a TPT CTO. Notice the removal of the

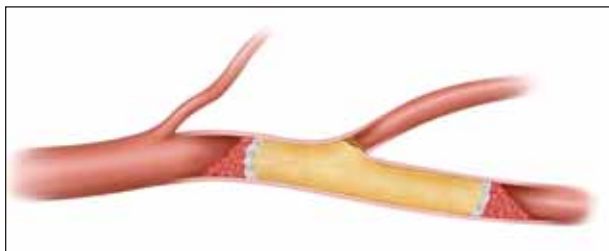


Figure 6. A typical below-the-knee CTO showing proximal and distal mural thrombus with a calcified proximal and distal atheromatous plaque.

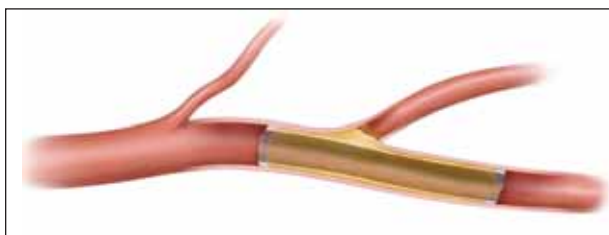


Figure 8. Successful removal of proximal and distal mural thrombi in association with atherectomy, which prevents distal embolization in below-the-knee CTOs.

proximal and distal thrombi and successful flow channel creation. Active aspiration of the complex plaque/thrombus construct of distal below-the-knee arterial disease may eliminate the need for concomitant use of distal embolic protection, which has the associated potential risk of intimal injury to the distal below-the-knee vessel at the site of deployment of the embolic protection device, and appears to be the most effective method for minimizing distal embolization.

There are several important technical considerations that can optimize the successful treatment of below-the-knee CLI using the Jetstream G3 SF revascularization system. First, the starting and finishing points of therapy are different from the radiographic beginning and ending of CTO or focal stenosis. Typically, it is best to initiate therapy several centimeters proximal to the CTO and continue treatment several centimeters beyond the lesion. Although this subjects portions of below-the-knee vessels to additional treatment, the benefit of extending the treatment zone beyond the radiographic lesion allows for optimal removal of any associated thrombus.

Second, slow back-and-forth advancement of the catheter is ideal. The slow speed at which the device is advanced can improve its performance. The back-and-forth type of advancement permits adequate time for the catheter to aspirate debris and minimizes the risk of distal embolization. Furthermore, it allows more time for the cutter to treat calcified lesions.

Third, it is important to adequately size the runoff vessel and ensure that the vessel is at least 2 mm in diameter.



Figure 7. The risk of distal embolization associated with the proximal and distal mural thrombi when thrombectomy is not performed with atherectomy for below-the-knee CTOs.

Because of the 1.85-mm tip size, vessels smaller than 2 mm could be injured due to device incompatibility with the runoff vessel. Finally, it can be helpful to keep the cutter on while retracting the catheter through the treatment zone to remove any remaining debris and provide additional cutting time.

CONCLUSION

In summary, new technologies continue to emerge to address the unique treatment considerations associated with below-the-knee CLI. Dual-action atherectomy and thrombectomy using the Jetstream G3 SF revascularization system can be an important endovascular treatment option for these patients. Its continuous aspiration port and 1.85-mm rotational-leading cutter facilitate successful treatment of complex lesion types including calcified plaque. Important technical considerations, such as an extended treatment zone, slow back-and-forth advancement, and appropriate runoff-vessel sizing, are critical to the safe and effective application of this technology. Additional study and clinical experience is needed with this technology to better understand its potential role in treatment of below-the-knee CLI. ■

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