Evolving Techniques for a Complex Problem

Dual-action atherectomy and thrombectomy using the Jetstream G2™ revascularization system.

BY GRAYSON H. WHEATLEY, MD

Our understanding of the various types and complexities of atherosclerotic occlusive disease of the superficial femoral artery (SFA) is rapidly evolving. Enhanced imaging techniques—both preoperatively and intraoperatively—have revealed a significantly more complex process relating to atherosclerotic disease of the SFA than was previously appreciated. In the past, when our treatment options centered primarily on open surgical bypass, the physiology and nature of occlusive disease to the SFA were less significant and inconsequential to the successful completion of the bypass. Therefore, in the past, we viewed atherosclerotic disease of the SFA as a binary process—present or absent. However, as new technologies and techniques have been developed to better treat diseases of the SFA, we have gained a better appreciation of the subtleties relating to the disease processes of atherosclerotic occlusion of the SFA.[1] This appreciation has allowed us to better tailor our treatment to meet the anatomical and physiologic processes of the SFA and, as a result, deliver better treatments to our patients.

More specifically, the various treatment challenges of the SFA are broken down in Figure 1. Important variables to successful treatment of the SFA relate, of course, to the runoff and medical indications for the intervention (claudication vs limb salvage). However, from an anatomic and physiologic process, it is possible to break down our understanding of SFA disease and begin to approach it in an algorithmic fashion. Important concerns are the length of the lesion, degree of calcification, and presence or absence of thrombus. Each of these variables has an impact on the success of the chosen interventional technology. Because no technology has yet been developed that successfully treats all forms of SFA disease, it is important for interventional specialists to align the best device characteristics to meet the anatomic and physiologic challenges of the patient. In general, most interventional technologies are designed for a certain indication. For example, a balloon or stent treats occlusive disease but may not perform well in highly calcified lesions or in areas of fresh thrombus. Likewise, many atherectomy devices might work best for certain types of plaque but not fresh thrombus.[2] The future of interventional devices will be multipurpose, when a single device can perform multiple functions, thus treating a wider spectrum of complex SFA disease. Currently, the Jetstream G2™ revascularization system (Pathway Medical Technologies, Inc., Kirkland, WA) is designed and approved to treat both atherosclerotic occlusive disease and thrombus in the peripheral vasculature.

CASE REPORT

A 65-year-old man with an active lifestyle presented to

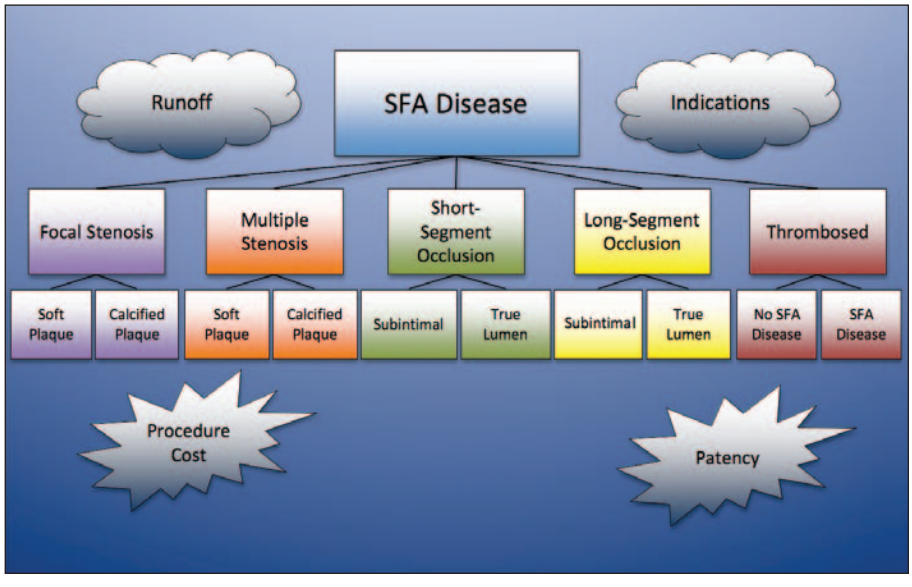

Figure 1. Algorithmic approach to atherosclerotic occlusive disease of the SFA.

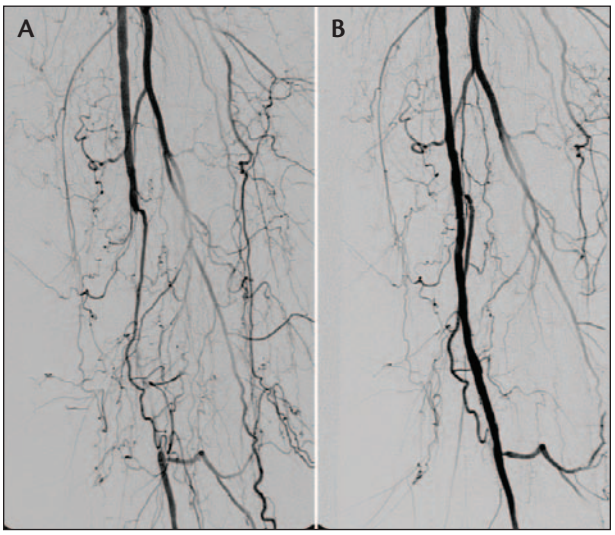

Figure 2. Before (A) and after (B) Jetstream G2™ revascularization system atherectomy and thrombectomy of SFA disease.

the outpatient clinic for evaluation of lifestyle-limiting claudication to his right leg. Diagnostic studies revealed a long-segment chronic total occlusion to the mid-right SFA (Figure 2). He had excellent runoff, and various treatment options were discussed with the patient; an interventional approach was agreed upon. In the endovascular suite, contralateral femoral access was obtained, and an 8-F contralateral sheath was placed. An angiogram of the right lower extremity reconfirmed the chronic total occlusion of the SFA. The lesion was crossed using a stiff guidewire, and the true lumen location of the wire was confirmed using an angiographic catheter advanced beyond the lesion. Using a 0.014-inch guidewire, the Jetstream G2™ revascularization system (Figure 3) was advanced through the lesion. The first pass of this device was with the cutting blades down, which aspirates any thrombus from the lesion. These lesions frequently have some degree of thrombus proximal and distal to the lesion, and even part of the lesion may have some chronic thrombus. By washing out the lesion before performing atherectomy, the risk of embolization is greatly diminished. Another advantage of this approach is that the entire treatment can be performed using a single entry into the sheath. There is no need for multiple insertions and removal.

After the first washout pass was performed, another pass of the device across the lesion was performed with the blades up. This creates a 4.2-mm channel and aspirates the debris into a separate external collection reservoir. After two passes in a proximal-to-distal fashion, the device was removed, and a completion angiography was performed. This demonstrated a successful recanalization of the lesion and excellent runoff without embolization. There were no focal dissections, and the SFA lumen caliber was excellent. The 8-F sheath was removed from the contralateral groin, and the access site was closed with a closure device. At his 30-day follow-up visit, the patient had palpable pulses in the right leg, and his claudication symptoms had completely resolved.

DISCUSSION

Most interventional devices for treating occlusive disease to the SFA have a sole mechanism of action. For example, balloon angioplasty opens a stenotic plaque but could cause distal embolization of associated mural thrombus around the treated lesion. A stent relieves a stenosis but likewise is not designed to address associated mural thrombus. Aspiration catheters can address thrombus but do not treat the underlying anatomic concern causing the thrombus. We are learning that SFA occlusive disease often is composed of a mixture of calcific plaque, soft plaque, and thrombus. An angiogram cannot distinguish among these problems, and therefore, most interventional treatments to the SFA risk under treatment or causing distal embolization.

As we learn more about how best to address complex SFA lesions, it is becoming apparent that significant improvements can be developed. Figure 1 details many of the complex lesions and problems of the SFA. No single device can address all of the different lesions, but emerging

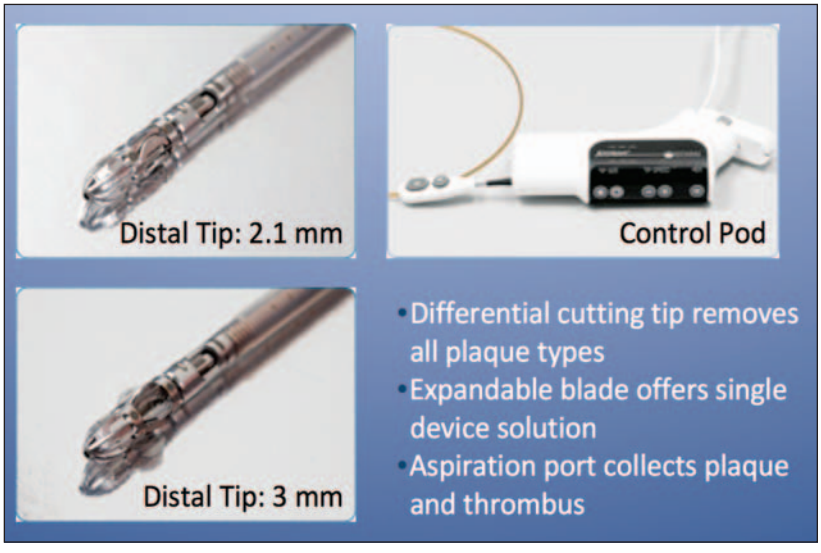

Figure 3. The Jetstream G2™ revascularization system.

evidence and experience are showing that it is critical to align a particular device's strength with the underlying pathology. With the release of the Jetstream G2™ revascularization system, we are one step closer to a single device that can address multiple anatomic problems of the SFA. Combination therapeutic devices are particularly effective for the treatment of occlusive disease of the SFA because they can address a broader array of lesions—either as a stand-alone treatment of a simple lesion or a combined therapy for a complex lesion.

The first Jetstream G2™ system is compatible with an 8-F sheath, although a redesigned system was recently released, which is compatible with a 7-F sheath over a 0.014-inch wire. The optimal rotational speed of the device is 70,000 rpm. There are two modes of use. The first is a blades-down 2.1-mm rotational tip that aspirates and creates a channel. The second mode of therapy is a 3-mm tip with the cutting blades up. Both modes are compatible with the aspiration function (thrombus and plaque) as well as atherectomy. These two modes can be activated through the external control handle and without removing the device. As a result, this device is a single-entry atherectomy and aspiration device that can treat a number of simple and complex SFA lesions.

There are a number of technical considerations regarding successful use and application of the Jetstream G2™ revascularization system. First, the system is more compatible with some 0.014-inch wires than others; it takes some trial and error with the system to appreciate which wires work best. Various agents have been added to the irrigation/aspiration solution to aid in improving the compatibility with 0.014-inch wires, but careful technique seems to be more important than irrigation solution. Some operators prefer to have the added protection of a distal embolic protection filter even though the device aspirates atherosclerotic and thrombotic debris. No data exist to support better outcomes or the need for an embolic protection device.[3-5] However, in a patient with compromised distal runoff, it is not unreasonable to consider use of distal embolic protection.

Finally, some experience is needed to determine the number of passes through the lesion in the blade-down and blade-up modes. This is also operator dependent. Most operators perform two passes of the system in an antegrade fashion with the blades down to wash out the lesion and remove any mural thrombus, and then they perform two antegrade passes with the blades up. There is some audible feedback available from the controller as to whether the device is meeting resistance. There will also be a corresponding drop in the rpms on the controller. If the rpms drop when crossing a lesion, then this may mean that the channel still has not opened up and additional passes may be necessary.

SUMMARY

Occlusive lesions to the SFA come in many varieties and forms. Successful revascularization depends on expertly aligning the strengths of a particular interventional device with the anatomic characteristics of the lesion. We have long passed the point when balloon angioplasty and/or stenting will treat all SFA lesions. As we learn more about the complexity of SFA lesions, we are discovering that occlusive lesions contain both plaque and thrombus. Ignoring the thrombus may put the patient at risk for distal embolization. Therefore, a new alternative exists to treat both the plaque and thrombus associated with an SFA lesion using the Jetstream G2™ revascularization system.

Although this system is already approved by the Food and Drug Administration for both atherectomy and aspiration thrombectomy, increasing clinical experience is being obtained with this device. Experienced operators are treating both long and short lesions of the SFA using a single-entry technique. Standard operating procedures suggest that the crossing wire should be in the true lumen if an atherectomy were to be performed. However, successful cases of treating a chronic total occlusion of the SFA in a subintimal approach followed by the Jetstream G2™ revascularization system have been reported. Extreme care must be performed to prevent injury to the vessel, but total recanalization of the SFA can be performed in this fashion.

In summary, the Jetstream G2™ revascularization system represents the latest generation of interventional devices for the SFA. This device comes at a time when we are learning more about the complex nature of occlusive disease of the SFA. As a result, we can better target complex lesions with a single device capable of treating a wide variety of pathologies. More experience is needed with this device to better understand its limitations, and certainly intermediate outcomes are needed regarding patency. ■

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