Jetstream® Aspirating Revascularization Technology

From calcium to thrombus: an overview of the evolution of this technology.

BY TED WULFMAN

Jetstream® aspirating revascularization technology (Pathway Medical Technologies, Inc., Kirkland WA) was initialized by a team of engineers who believed there was a definite need for a single device that could safely remove all types of atherosclerotic disease and thrombus. The founding engineering team had a history of developing atherectomy and other devices, specifically the Rotablator® coronary rotational atherectomy system (Boston Scientific Corporation, Natick, MA). However, no known device had been developed to remove all types of plaque, from heavily calcified plaque to thrombus, in the diffuse quantity that is seen in the peripheral vasculature. Pathway believes that combining high-speed rotational ablation with infusion and powerful aspiration addresses this need for an efficient, fully capable debulking device.

THE FIRST-GENERATION JETSTREAM®

The first-generation Jetstream® (Pathway Medical Technologies) was cleared by the Food and Drug Administration in 2008 for general atherectomy treatment in the peripheral vasculature, and in January 2009, it was also cleared for thrombectomy of upper and lower extremity peripheral arteries. The Jetstream® is an expandable, aspirating and infusing debulking catheter with a 2.1-mm tip that expands to 3 mm. The material removal is accomplished by stainless steel expandable blades that are designed to differentially scrape less-resilient, less-elastic plaque and thrombus from the more resilient and elastic vessel wall. The principle of differential cutting was originally discovered by the developers of the Rotablator®, and the Pathway engineers understood how to take advantage of this principle in the design of the blades. The decision to use blades for disease removal versus the diamond grit of the Rotablator® was made because of several design advantages. First, blades allowed a faster rate of disease removal at slower rotational speeds. This reduced potential heat generation as well as hemolysis. Hemolysis can be an issue as enzymes are released into the vasculature from the destroyed blood cells, which would cause significant physiologic effects. This was an issue early in the history of the Rotablator® until speeds were significantly reduced. Second, this technology allows for ablated particles to move between the blades toward aspiration ports. Third, the use of blades facilitates the use of an expandable tip. The patented expandable mechanism is accomplished by five specialized blades that pivot from a tangential position (blades down) when the tip is rotated clockwise to a radial position (blades up) when the tip is rotated counter-clockwise. Continuous, powerful aspiration of ablated particles and thrombus, and infusion to support the aspiration function, is accomplished by pumps located on a small console mounted on an IV pole. The combined expandable, rotational ablating tip, aspiration, and infusion are incorporated

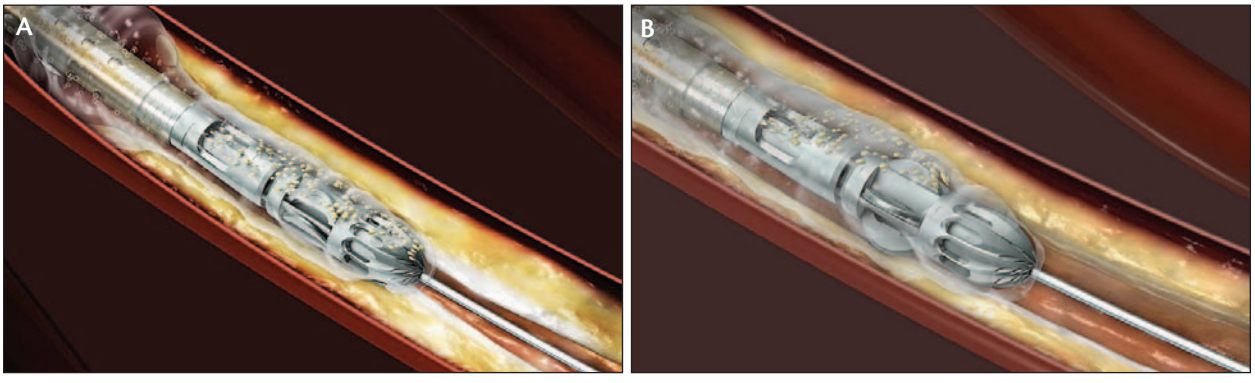

Figure 1. The Jetstream G2™ in the blades down (A) and blades up (B) positions.

into an over-the-wire 135-cm catheter, which in turn is joined to a control pod and activation handle that sit in the sterile field. The pod has controls for speed and for switching from minimum tip to maximum tip diameter, and also incorporates a guidewire clamp, called *Gard*, that prevents the wire from rotating when the device is activated.

This system is compatible with several 300-cm, 0.014-inch angioplasty guidewires on the market. A unique advancement in guidewire management is incorporated into the system. In a typical peripheral arterial disease case, such as treating the superficial femoral artery, the wire is placed across the lesion and advanced into a distal vessel, such as a tibial artery, so that 6 inches or more of wire is distal to the treatment zone. Some mild friction then exists between the wire and the distal vessel. The proximal wire that exits the back of the pod is placed in a 90º curve into the guidewire clamp. When the device is activated and advanced, reduced friction exists between the internal driveshaft that spins over the wire, and therefore the device can be advanced, and the wire will stay stationary. The curve of wire at the back of the pod will grow as the device translates down the wire and will become smaller as the device is retracted while activated. The advantage of this wire management system is that a long length of disease can be treated at one time, without having to reset the position of the catheter relative to the wire.

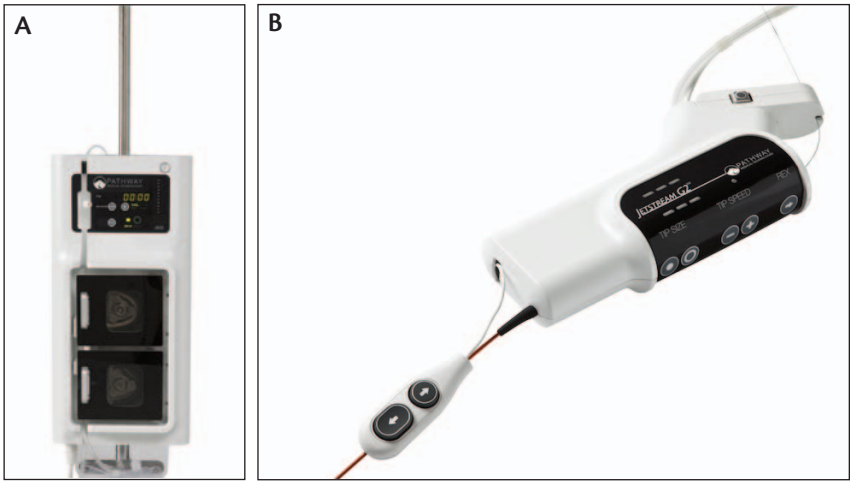

Figure 2. The Jetstream G2™ over-the-wire 135-cm high-speed rotational catheter control pod (A) with one-step expansion (B).

The Jetstream® technology was proven safe and effective in a multicenter European study of 172 patients with infrainguinal peripheral artery disease. The promise of fast debulking of all plaque modalities with a single-insertion catheter was established in this study, where the average activation time was < 4 minutes, and the average treatment time from insertion to removal of the study device was < 12 minutes.

THE JETSTREAM G2™

The engineers at Pathway discovered that by moving the aspiration ports from the distal tip of the catheter to just proximal to the blades, aspiration efficiency and lesion crossing times improved. The Jetstream G2™ (Figure 1) was launched in the spring of 2009 and incorporated this new proximal port aspiration. Also included in the G2™ is an internal rotating geometry, or "masticator," to break up particles entering the aspiration port. These improvements were met with enthusiasm by our customers. Further, customers have reported luminal gains often significantly greater than the actual maximum tip size of 3 mm depending on plaque morphology. The catheter has been used successfully in very calcific, diffuse, thrombosed, or totally occluded superficial femoral, popliteal, and tibial disease, as well as lesions in the common femoral artery.

THE JETSTREAM G2™ NXT

The recently launched Jetstream G2™ NXT is a completely new catheter that brings the capability of the Jetstream® technology to many more patients. Because it is 7-F compatible, it enables the catheter to be used in patients in whom placing an 8-F sheath is difficult or impossible. The catheter has a new construction that maintains pushability and trackability, while reducing the outer diameter. The engineers have accomplished a great feat in finding the combination of advanced material construction that allowed all functional parameters such as rotational speed, aspiration, and infusion to remain the same as the Jetstream G2™, in a smaller diameter with improved compatibility.

USING THE JETSTREAM G2™ NXT: OPTIMAL "PECK'NIQUE"

Like the predecessor Jetstream® technology, the use of the Jetstream G2™ NXT is in general a fairly simple procedure. A short, 40-second priming procedure is performed to fill the aspiration and infusion lumens with saline. Once a guidewire is placed across a lesion, the G2™ NXT is placed using an over-the-wire technique until the tip is approximately 1 cm from where the lesion begins. The proximal end of the guidewire is placed in a 90º curve through the Gard clamp.

The operator can then activate the device by pressing and holding the large button on the activation handle (Figure 2). A first pass is completed using the minimum-tip-size (blades

down) setting. The operator slowly moves the catheter through the treatment site, advancing at a rate of 1 mm per second. It is important to take short, 1-mm "bites" of the lesion, and the user can then back up slightly while still activating the device to allow the ablated particles to be aspirated through the catheter. The device is then advanced again, and the next 1 mm of plaque is removed, hence the "pecking" motion. Heavy calcium, acute and chronic thrombus, fibrotic plaque, and restenotic tissue are all optimally treated using this technique. Further, this gradual and deliberate pecking technique is intended to minimize the likelihood for potential adverse events, such as dissections and distal emboli.

Once the device debulks on the first pass using the blades down setting, a second pass using the maximum-tip-size setting (blades up) can then be performed using the same technique. This second pass at maximum size can debulk up to 100% or more plaque after the first minimum-size pass depending on plaque morphology. The blades up tip is twice as large by area as the blades down tip, and often removes more material than the actual diameter.

Calcium

How does the Jetstream® technology debulk extremely hard calcium? Actually, calcified lesions are a perfect match for the distal tip. The hardened stainless steel blades have a uniquely designed scraping geometry that prevents too much material from being removed by each blade. Calcium is inelastic, and this gives the Jetstream® technology the perfect opportunity to grind away difficult lesions, much like a bone saw cuts bone, while the elastic vessel wall can stretch around the blades, just like skin moves around a razor. The G2™ and G2™ NXT have shown excellent debulking of calcific lesions, and by using the pecking technique, the blades are allowed to grind the hardened plaque into small particles.

Thrombus

The Jetstream® family of technologies (including the Jetstream G2™ and the Jetstream G2™ NXT) is unique in that all of the devices are indicated for breaking apart and removing thrombus from upper and lower extremity peripheral arteries ≥ 3 mm, in addition to the more general indication for use in atherectomy of the peripheral vasculature. Several design features are key:

- The flutes and expandable blades break up tough thrombus with external mechanical action.
- The infusion and aspiration support the flow of the broken up thrombus into the catheter.
- The internal masticator breaks up even the toughest fibrin-laden thrombus.

Heavy acute and chronic thrombotic lesions are optimally treated with the Jetstream G2™ NXT by the slow-advance 1-mm technique as well. This controlled technique allows diffuse thrombus to be broken up and aspirated into the catheter in amounts that ensure optimal aspiration without pushing thrombus or overloading the catheter.

Other Disease Presentations and Treatments

Long total occlusions, restenotic lesions, and eccentric lesions can also be treated with the Jetstream G2™ NXT. Differential cutting debulks these lesions within the vasculature in the same manner described previously. Because the device is a single-insertion catheter that expands inside the vessel, treating even extremely long lesions is completed in a expedient manner. By debulking even large vessels such as the common femoral artery, the Jetstream G2™ NXT gives the opportunity to complete a low-force procedure, either stand alone or with the use of low-pressure balloon angioplasty to finish. This theoretically provides a better opportunity to avoid disruption of the plaque-media interface, which—if treated by high-pressure balloon angioplasty alone—may potentially result in dissections. For those lesions in which stenting is planned, debulking of diffuse and calcific disease may allow for more optimal stent expansion given the reduction in the amount of disease that must be displaced by the implanted stent.

FUTURE PRODUCTS AND INDICATIONS

In its early experience, Jetstream® technology has proven its ability to safely and effectively remove heavy calcified plaque and large thrombus burden. However, Pathway is dedicated to continuous improvement of the device. Learning from the market experience, evaluating reported adverse events or user feedback regarding challenging cases is important in striving to always improve a promising technology. Monitoring all experience to date with the Jetstream® and Jetstream G2™, and listening to our customers' feedback, has led to the consideration of several future products. The next-generation Jetstream® technology is intended to further optimize the current 2.1-mm/3-mm size device. Future products are planned that will expand the range of vessels that can be optimally treated with the Jetstream® technology. These catheters will target both larger- and smaller-vessel debulking. ■

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