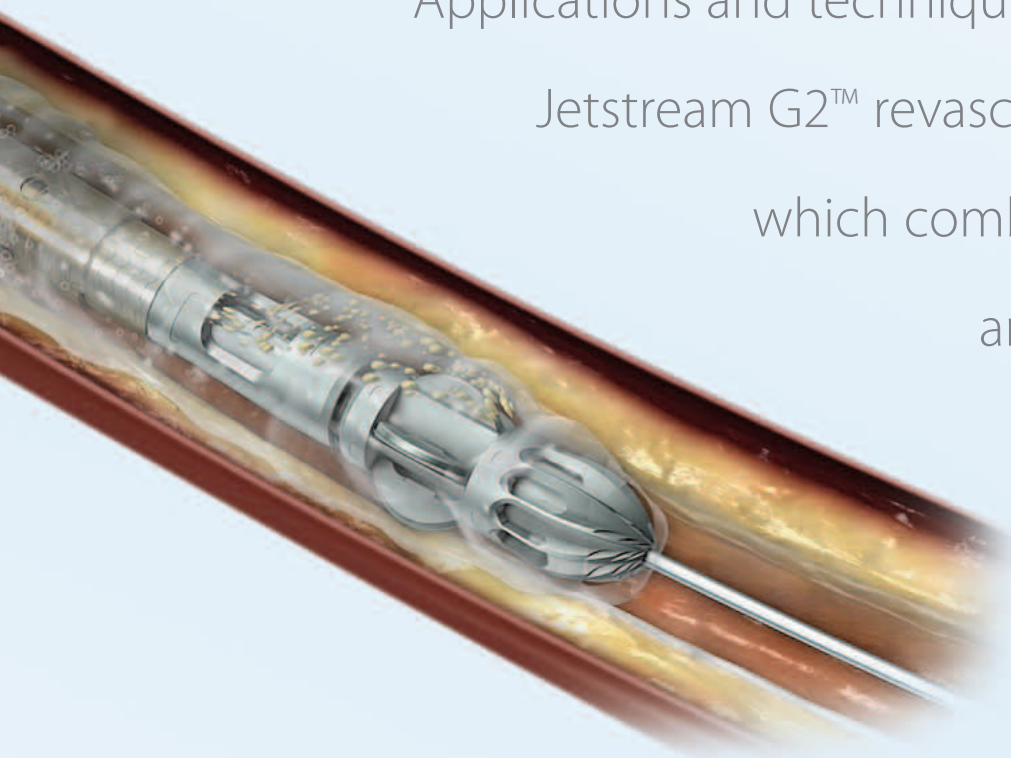


Endovascular **TODAY**

September 2009

Atherectomy Evolves

Applications and techniques using Pathway's
Jetstream G2™ revascularization system,
which combines atherectomy
and thrombectomy.



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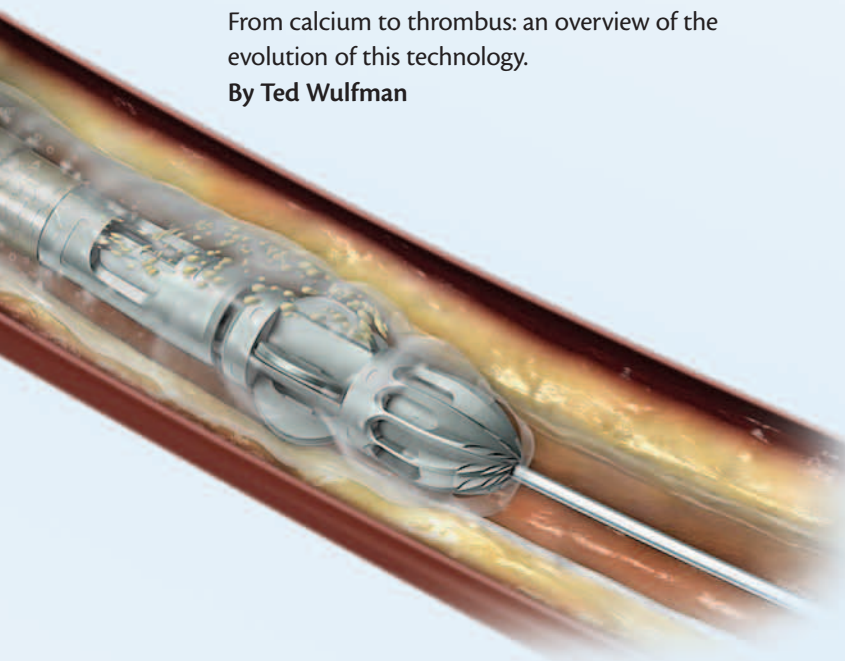
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Disclaimer

Indications for use: The Jetstream G2™ System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries ≥ 3.0 mm in diameter. It is not intended for use in coronary, carotid, iliac or renal vasculature.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

The Role of Atherectomy in the Femoropopliteal Artery

With the growing number of tools for femoropopliteal artery intervention, what is the role of atherectomy in the endovascular treatment of femoropopliteal artery disease?

BY IVAN P. CASSERLY, MB, BCH

The femoropopliteal (FP) artery refers to the composite of the superficial femoral artery (SFA) and popliteal artery and measures approximately 50-cm long in adults. Atherosclerosis of this vessel is characterized by diffuse involvement, a propensity for superimposed calcification, a high incidence of progression to occlusion, and a large plaque burden (Figure 1).^{1,2} These factors present a significant challenge for endovascular interventions in this artery.

Despite these challenges, there has been a dramatic increase in percutaneous revascularization procedures in the FP artery, rising from 69 to 184 per 100,000 Medicare beneficiaries in the period from 1996 to 2006 (Figure 2).³ This represents approximately 55% of all lower extremity endovascular procedures, highlighting the frequency of involvement of this arterial segment in patients with peripheral artery disease. Interestingly, the rise in the overall number of FP endovascular procedures is paralleled by the increased use of atherectomy (ie, a term used to describe a group of technologies that allow either ablation or removal of plaque) (Figure 3). In 2006, atherectomy was used in 42% of all FP endovascular procedures,³ and with the recent availability of additional atherectomy technologies, this number is likely to be significantly higher today.

The rapid adoption of atherectomy as a therapeutic strategy in FP intervention has been criticized by some. It is true that there are no comparative studies of atherectomy versus conventional therapy with balloon angioplasty and/or stenting with nitinol stents, and there are no data showing a decrease in long-term restenosis rates with atherectomy. However, in the clinical practice of endovascular specialists, what is indisputable is that atherectomy has allowed the successful treatment of an increasing spectrum of FP disease and has provided the means to revascularize an increasing proportion of patients with FP disease without placing stents, which have significant limitations in this location. This is clearly one of those areas in medicine where

the science lags behind the art of clinical practice.

This paper summarizes the potential beneficial aspects of atherectomy and provides a perspective of the challenges that remain in applying this technology in the FP artery.

EXPANDING THE SPECTRUM OF TREATABLE DISEASE

Ostial Disease

Involvement of the ostium of the SFA by atherosclerosis increases the likelihood of plaque shift into the profunda femoral artery (PFA) using conventional balloon and stent therapies (Figure 4). This risk is increased in patients with an acute angulation between the origins of the PFA and the SFA. Because the PFA serves as the sole arterial supply to the lower extremity via collaterals to the distal SFA and popliteal arteries in the presence of an occlusion of the SFA, significant plaque shift is a serious complication. The ability to debulk the SFA ostium certainly reduces the risk of plaque shift and allows interventionists to approach the treatment of ostial SFA disease with greater confidence.

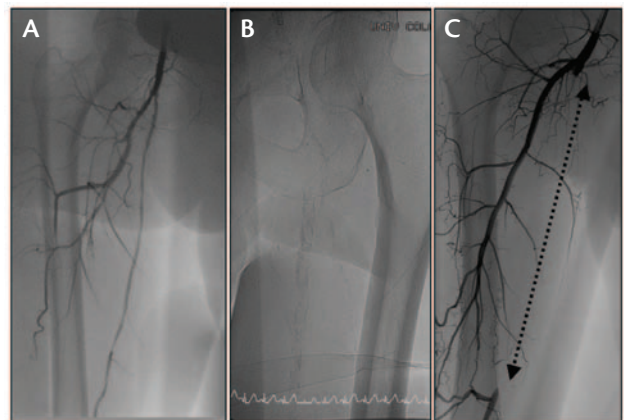


Figure 1. Typical pattern of atherosclerosis in the FP artery characterized by diffuse involvement (A), heavy calcification (B), and progression to complete occlusion (C).

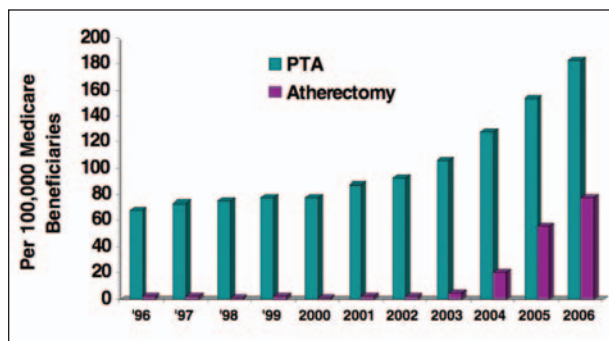


Figure 2. Frequency of endovascular procedures in the FP artery between 1996 and 2006 per 100,000 Medicare beneficiaries. Adapted from Goodney et al. *J Vasc Surg* (2009;50:54-60).³

Popliteal Disease

The popliteal artery crosses the knee joint and therefore is regarded as a site where stenting should be avoided if possible. Before the availability of atherectomy technologies, the unpredictability of a balloon-angioplasty-alone outcome resulted in some reluctance to approach such disease using endovascular techniques.

Calcified Plaque

Densely calcified plaque in the FP artery was previously a major limitation for the endovascular approach to revascularization. Balloon angioplasty of such plaque was often ineffective due to failure to achieve adequate balloon expansion. The use of higher balloon pressures in an attempt to achieve expansion often resulted in an

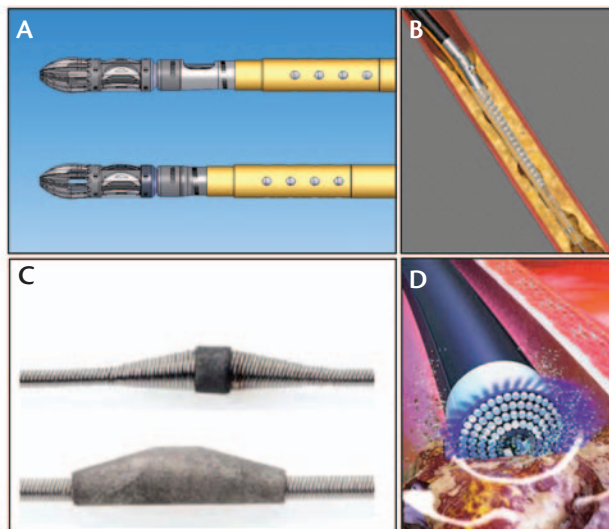


Figure 3. Tools currently available to perform atherectomy or plaque ablation: Jetstream® catheter (A), SilverHawk (B), Diamondback 360° (C), and Turbo Elite laser catheter (D).

increased risk of flow-limiting dissections due to trauma to the compliant noncalcified portion of the media. Significant deformity and incomplete expansion of stents at the sites of dense calcification was also a problem.

New atherectomy tools allow the treatment of calcified plaque with a high degree of success (Figure 5). The Diamondback 360° device (Cardiovascular Systems Inc., St. Paul, MN) was specifically designed to treat calcified disease and has proven very effective in clinical practice. The Jetstream® catheter (Pathway Medical Technologies,

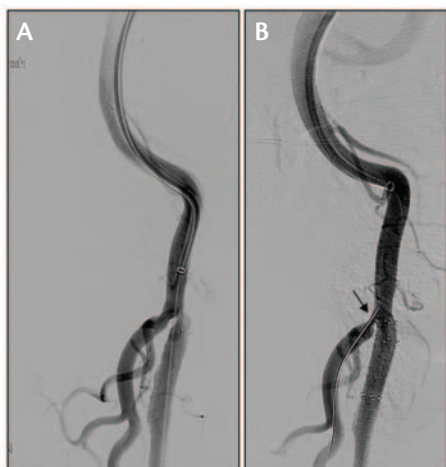


Figure 4. Plaque shift into the profunda femoral artery after placement of a stent at the ostium of the superficial femoral artery.

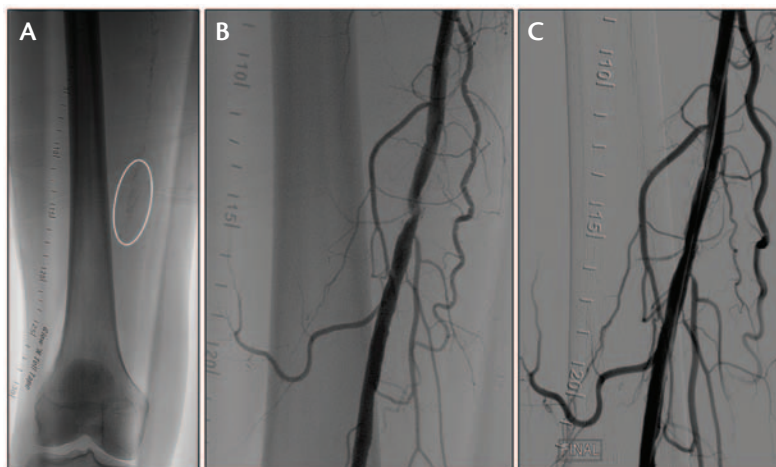


Figure 5. Treatment of calcified plaque. Fluoroscopic image showing severe calcification at the site of stenosis (circle) (A). Baseline angiogram (B). Angiogram after treatment with 1.5- and 2.25-mm Diamondback 360° catheters and low-pressure angioplasty showing stent-like result (C).

Inc., Kirkland, WA) has also demonstrated success in case reports of heavily calcified disease. The SilverHawk LS-C (RockHawk) (ev3 Inc., Plymouth, MN) has specific design changes in the geometry and the material of the cutting blade to aid the treatment of calcified lesions. The Turbo Elite laser ablation catheter (Spectranetics Corporation, Colorado Springs, CO) is also effective in the treatment of calcified disease. In summary, the availability of these tools has transformed the confidence with which heavily calcified disease can be approached with the expectation of a successful result.

Diffuse Disease

Using conventional balloon and stent therapy, diffuse involvement of the FP artery is problematic for a number of reasons. With balloon angioplasty, the risk of flow-limiting dissections increases with the length of disease. Stenting of diffuse disease often requires the placement of multiple overlapping stents with extension into the popliteal artery, which all increase the risk of stent fractures and in-stent restenosis.

Atherectomy tools typically produce a more stable vascular lumen, reducing the risk of flow-limiting dissections even when adjunctive PTA is applied, and decrease the need for the placement of stents (Figure 6). In practice, treatment of diffuse disease with the SilverHawk device is made more difficult by the need to empty the nosecone intermittently, necessitating repeated removal and re-introduction of the catheter, although recent modifications of the packing system of the nosecone has attenuated this problem. Because

there is no mechanism for removal or aspiration of plaque, the use of the Diamondback 360° device as a stand-alone treatment for long diffuse disease raises some concern because of the potential burden of embolized microparticles to the distal circulation, particularly in patients with critical limb ischemia. The Pathway Jetstream® and Turbo Elite ablation catheter systems may have an advantage for the treatment of diffuse disease, but both require patient advancement of the respective catheters along the length of disease to achieve an optimal result.

LIMITATIONS OF STENTING IN THE FP ARTERY

The availability of self-expanding nitinol stents represented a major advancement in the endovascular treatment of FP disease. They allowed endovascular specialists to achieve a highly predictable acute angiographic result, are easy to use, and require relatively little time to deploy. To date, they are the only technology proven to reduce the rate of restenosis compared to angioplasty in the treatment of long disease in the SFA.⁴

However, there are significant limitations to stenting of the FP artery. There is clear evidence in the form of stent fractures that stents in the FP artery are subject to biomechanical forces that disrupt the integrity of the stent architecture to varying degrees.⁵ The frequency of stent fracture has been related to the stent length, the use of overlapping stents, patient activity, and stent type.^{6,7} Although still debated, there does appear to be a relationship between the presence of stent fractures and the rate of in-stent restenosis.⁷ Further, there have been rare reports of more serious consequences of stent fracture such as acute thrombotic occlusion⁸ and vessel perforation.⁹

Using three-dimensional models of the FP artery generated in patients undergoing routine angiography in the catheterization lab, we recently reported a quantitative analysis of the conformational change in the FP artery between the straight leg and crossed leg positions.^{10,11} The SFA and popliteal arteries shortened by a mean of 18.2 ± 13 mm and 32.2 ± 12.9 mm, respectively. This represents 6% and 15.8% of their entire lengths, respectively. There was an increase in the mean curvature along the length of the SFA and popliteal arteries of 0.04 ± 0.04 cm⁻¹ and 0.2 ± 0.09 cm⁻¹, respectively. The mean twist angle for the SFA and popliteal arteries per centimeter length of vessel was

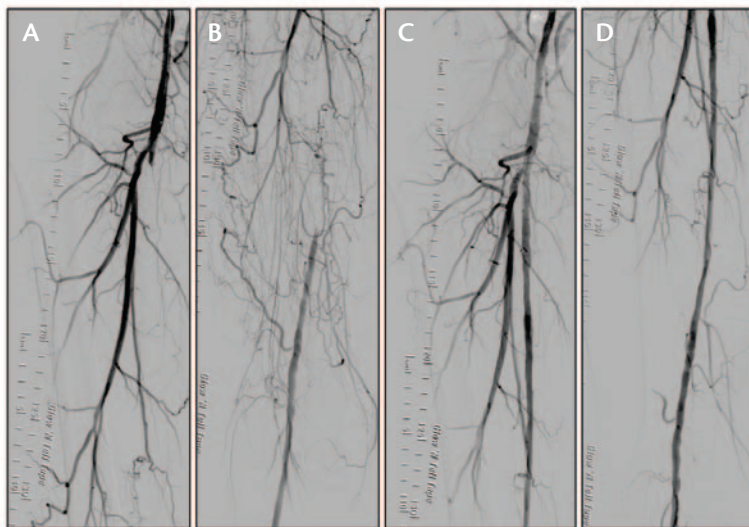


Figure 6. Treatment of a long occlusion of the superficial femoral artery. Baseline angiography (A, B). Angiographic appearance after treatment with the Jetstream® catheter and low-pressure angioplasty (C, D).

$1.69^{\circ}/\text{cm} \pm 1.01^{\circ}/\text{cm}$ and $3.46^{\circ}/\text{cm} \pm 1.90^{\circ}/\text{cm}$, respectively. Finally, a mean of 2.4 new flexion angles $> 15^{\circ}$ were generated in the popliteal artery (Figure 7). These findings reinforce the conclusion that significant axial compression, twisting, and bending forces are exerted upon the FP artery during leg movement.

In addition, a recent study by Nikanorov et al that subjected a variety of stents in a cadaver model to what were believed to be clinically relevant axial compression and bending forces showed high rates of stent fracture for all except one of the stents studied.¹² Taken together, it is clear that future stent designs require some modification such that they can withstand the forces exerted upon them and prevent the development of stent fractures. The challenge of designing new-generation stents with sufficient radial force to withstand the large and often calcified plaque burden in the FP artery and sufficient conformability to withstand the physical forces exerted on the vessel is significant. The new, wire-interwoven, nitinol Supera stent (IDev Technologies Inc., Houston, TX) purports to meet this challenge, but long-term clinical data are clearly required before making a final judgment.

In addition to stent fracture, the other major limitation of stenting in the FP artery is the high rate of restenosis and the lack of an effective therapy for the treatment of in-stent restenosis. For younger patients who are being treated for claudication, this is a significant limitation because recurrent intervention every 6 to 12 months is not an effective or realistic option.

FUTURE CHALLENGES

Significant challenges remain in the application of atherectomy in the endovascular treatment of FP disease. The safety and efficacy of this technology is heavily dependent on remaining within the true lumen of the FP artery during the recanalization portion of the procedure. Subintimal recanalization of long occlusions, which is a common event in contemporary practice even with the recent availability of crossing tools,¹³ is problematic for atherectomy technologies for two reasons. First, the risk of perforation and the creation of arteriovenous fistulae with the deep femoral vein are likely increased (Figure 8). Although tools that perform directional atherectomy (ie, SilverHawk) as opposed to concentric atherectomy (ie, Pathway Jetstream®, Diamondback 360°) might have a theoretic advantage in this regard, the inability to currently guide directional atherectomy in three-dimensional space with image guidance likely nullifies this potential advantage. Second, the ability to achieve effective atherectomy of the plaque burden is decreased because a variable area

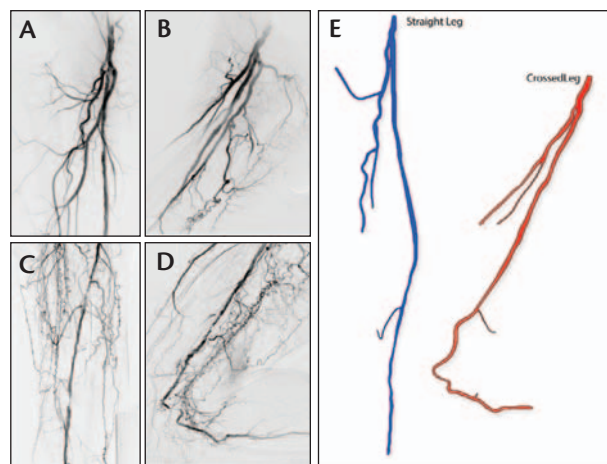


Figure 7. Orthogonal angiographic images of the FP artery in the straight leg and cross-leg position (A through D) in a patient with peripheral artery disease, with corresponding three-dimensional models of the FP artery (E). Reprinted with permission from Klein AJ et al. *Cathet Cardiovasc Interv* (May 7, 2009).¹¹

of the media forms a portion of the newly formed vascular channel. It remains unclear whether the inability to achieve effective debulking will have an impact on the long-term patency rates achieved with atherectomy.

Even when recanalization occurs entirely within the true lumen of the FP artery, it is common for the channel in which the wire lies to have an eccentric location within the arterial lumen. Balancing the risk of perforation and/or arteriovenous fistula formation versus effective plaque debulking at the sites of maximum eccentricity remains an important consideration.

In addition to the short-term safety issues of arteriovenous fistula formation and perforation, the long-term issue of the risk of pseudoaneurysm formation due to trauma to the media with atherectomy tools needs to be assessed carefully. Individual cases of pseudoaneurysm formation with the SilverHawk device have been reported.¹⁴ Although atherectomy catheters that remove plaque in a concentric manner may be less prone to this problem, long-term studies that specifically assess this issue are required.

Distal embolization is a particular problem in the application of atherectomy technologies that needs to be addressed. Atherectomy produces a significant disruption of a large plaque burden within the FP artery that may have superimposed thrombus. Although the Pathway Jetstream® device has the theoretic advantage of combining aspiration with atherectomy and the SilverHawk catheter removes plaque deposited in the nosecone, clinical studies are required to demonstrate

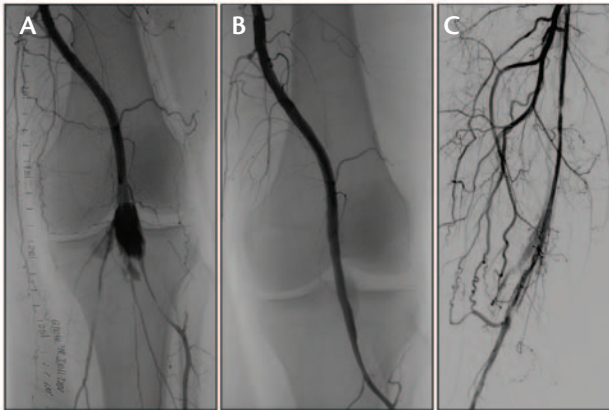


Figure 8. Potential complications of atherectomy in the FP artery. Perforation of the popliteal artery after treatment of occlusion with SilverHawk catheter (A) requiring treatment with a Viabahn covered stent (W.L. Gore & Associates, Flagstaff, AZ) (B). Arteriovenous fistula of the FP artery after atherectomy of the FP artery (C).

the clinical efficacy of this approach over other atherectomy technologies. The utilization of distal embolic protection filters during atherectomy procedures adds expense and has certain technical challenges that are unique to peripheral intervention such as the inability to visualize the filter during all interventional maneuvers along the length of the FP artery. Compatibility issues between the atherectomy catheters and the various filters also need to be resolved. Despite these issues, the author recommends the use of embolic protection devices in high-risk anatomic and clinical situations when atherectomy is used, such as single vessel tibial runoff in patients with critical limb ischemia.

The four currently available atherectomy/plaque ablation technologies (SilverHawk, Diamondback 360°, Turbo Elite, Pathway Jetstream®) have very distinct mechanisms of action, and their ability to treat atherosclerotic disease with different morphologies (eg, fibrotic, calcific) is unlikely to be uniform. While the individual companies clearly have a vested interest in promoting their technology for the broadest range of FP disease morphology, clinicians must learn to tailor the application of each of these technologies to the characteristics of the plaque in the individual patient. The further refinement of atherectomy technologies to allow a consistent and predictable result in the broadest range of plaque morphologies by interventionists with varying experience will simplify this task.

Finally, but not least, it must be highlighted that no atherectomy tool has been shown to reduce the long-term rate of restenosis in the FP artery. Comparative clinical studies need to be performed to address this

issue, and should they prove negative, the search for adjunctive biological therapies to complement the acute mechanical revascularization achieved with atherectomy will be needed.

CONCLUSION

Endovascular intervention of the FP artery remains a significant challenge. Atherectomy technologies have expanded the spectrum of FP disease in which a successful acute procedural result can be achieved, and has decreased the proportion of cases in which a stent is required to achieve this result. Significant challenges remain in improving the safety and effectiveness of atherectomy and in addressing the vexing issue of poor long-term patency of endovascular interventions in the FP artery. ■

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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 differ-

entially 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

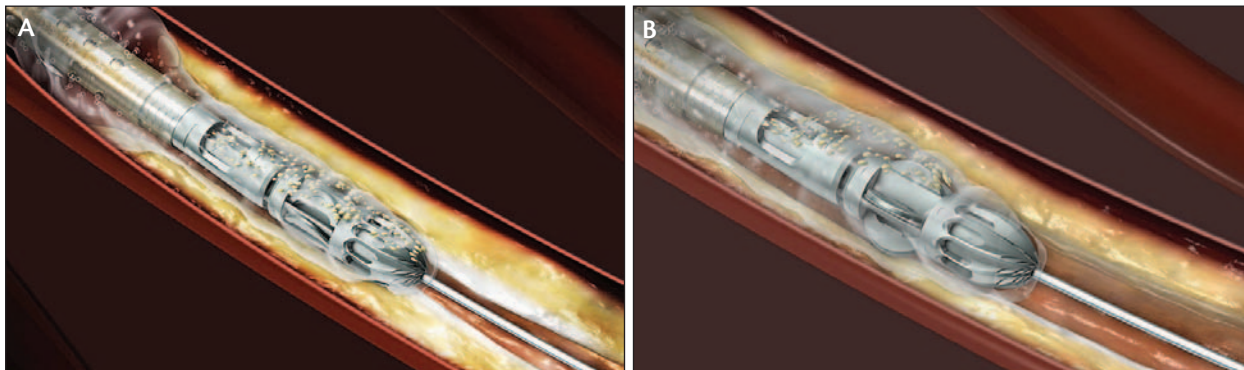


Figure 1. The Jetstream G2™ in the blades down (A) and blades up (B) positions.

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 90° 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.

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

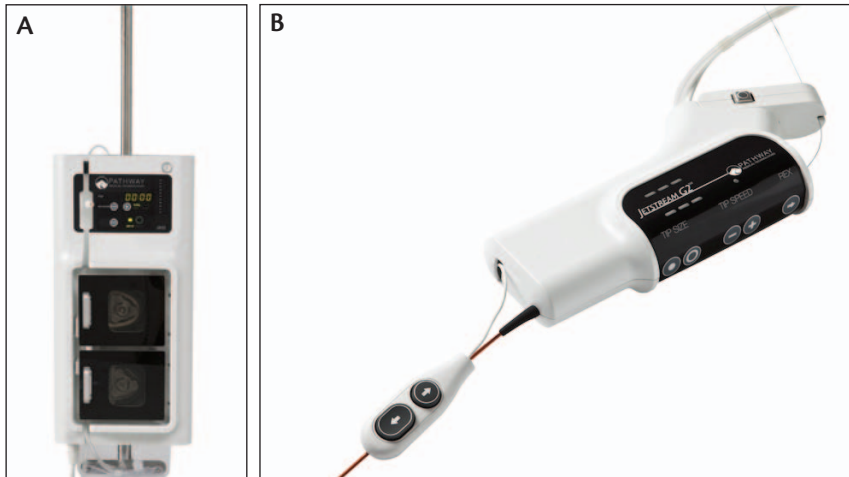


Figure 2. The Jetstream G2™ over-the-wire 135-cm high-speed rotational catheter control pod (A) with one-step expansion (B).

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 90° 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.

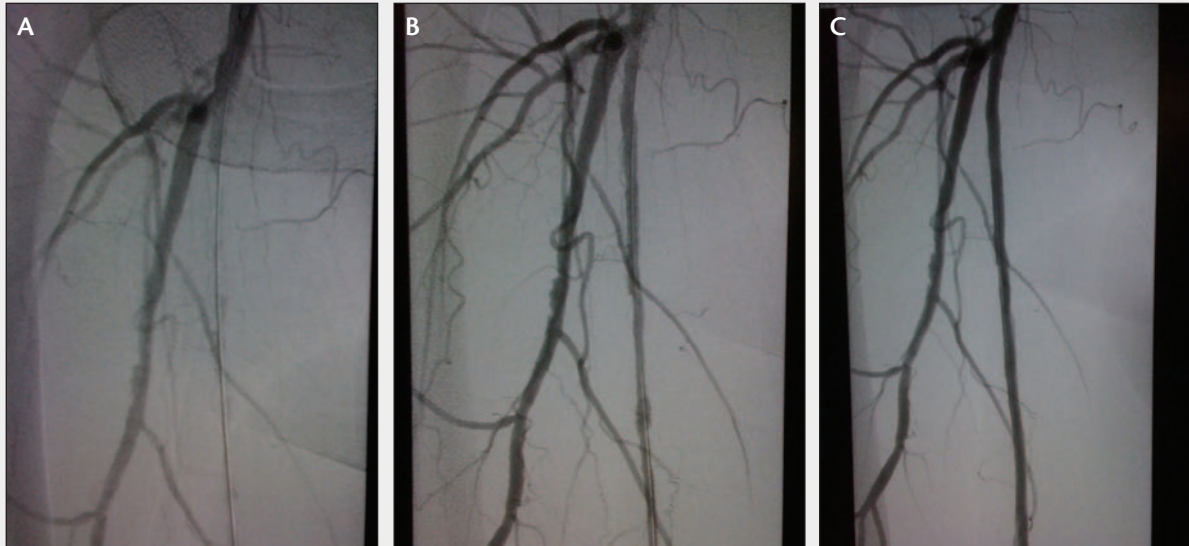
FUTURE PRODUCTS AND INDICATIONS

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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Case 1: SFA Chronic Total Occlusion

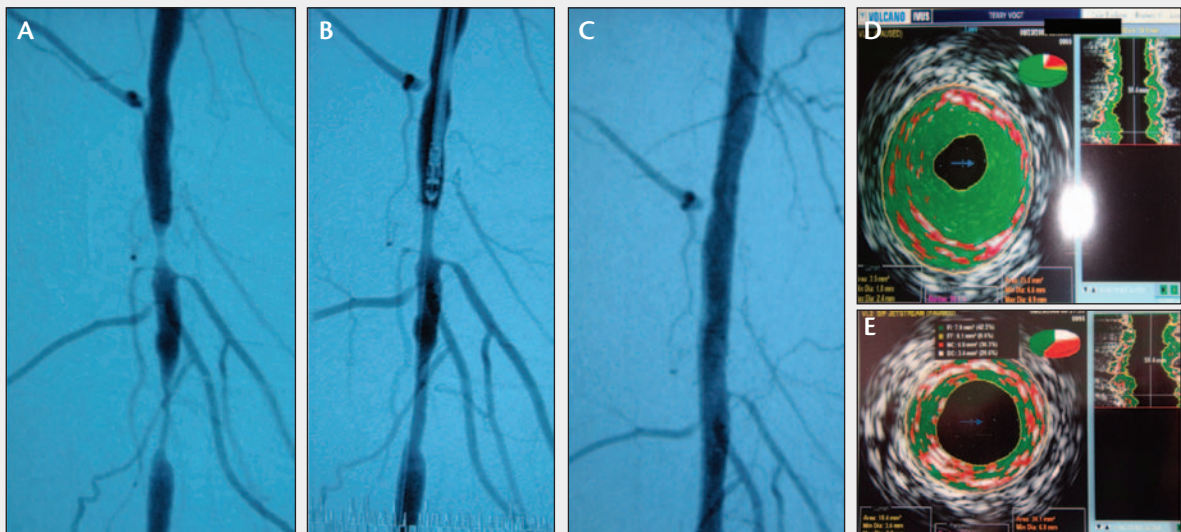
BY NORMAN KUMINS, MD, CENTRAL DuPAGE HOSPITAL (WINFIELD, IL), MAY 12, 2009



Pretreatment angiogram of 15-cm right superficial femoral artery (SFA) chronic total occlusion (CTO) (A). After two passes with the Jetstream G2™ with the blades up (B). After 5- X 150-mm percutaneous transluminal angioplasty (PTA) (C), 3 minutes at 5 ATM. Total Jetstream G2™ run time: 9:42.

Case 2: Popliteal Lesion

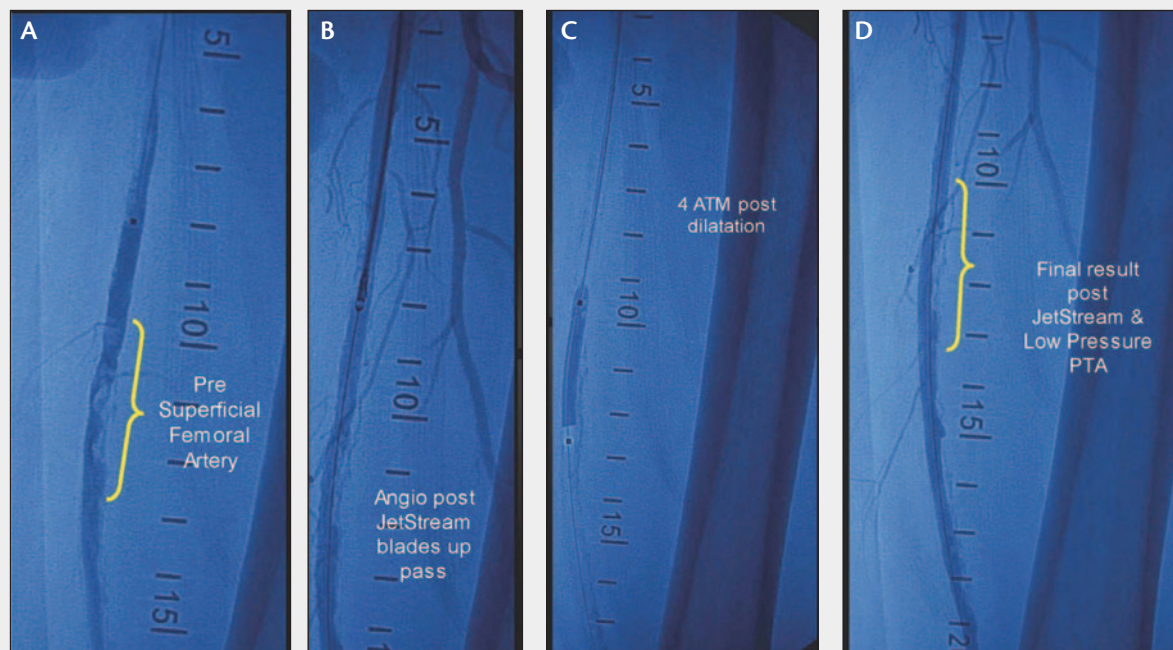
BY TOM DAVIS, MD, ST. JOHN HOSPITAL, (DETROIT, MI), OCTOBER 2008



Baseline (A) showing 99% popliteal tandem lesion. Jetstream® revascularization (run time, blades down: 1:00 min (B); run time, blades up: 3:40 min; total Jetstream® run time: 4:40 min). Stand-alone result after Jetstream® (C). Before (D) and after (E) IVUS images show significant luminal gain with a resulting concentric lumen.

Case 3: SFA Claudication

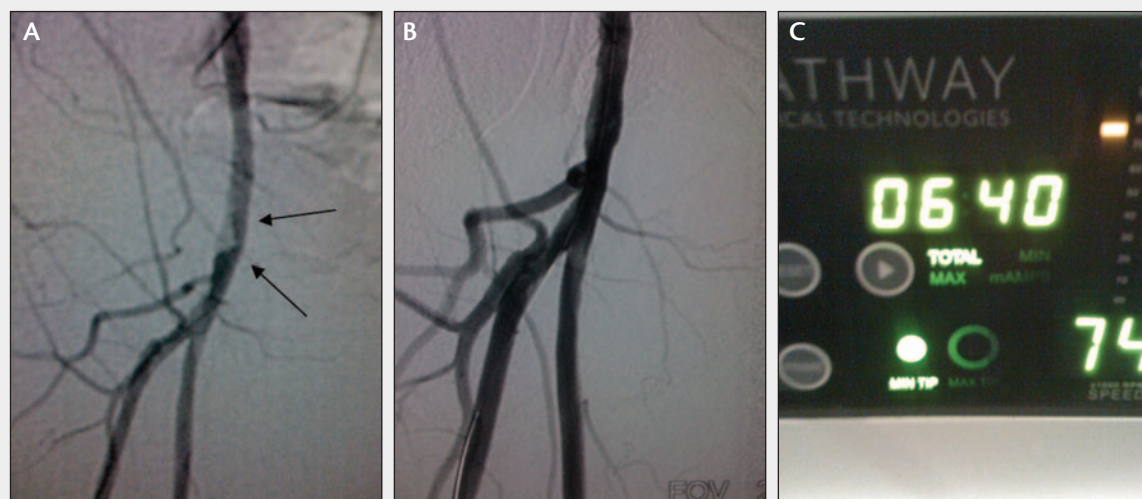
BY STEVEN OWEIDA, MD, WELLSTAR COBB HOSPITAL (ATLANTA, GA), SEPTEMBER 17, 2008



Baseline angiogram (A) showing claudicant with calcified SFA stenosis. Angiogram after Jetstream®, blades up pass (B). Four ATM after dilatation (C). Final result with low-pressure PTA (D).

Case 4: Calcified CFA

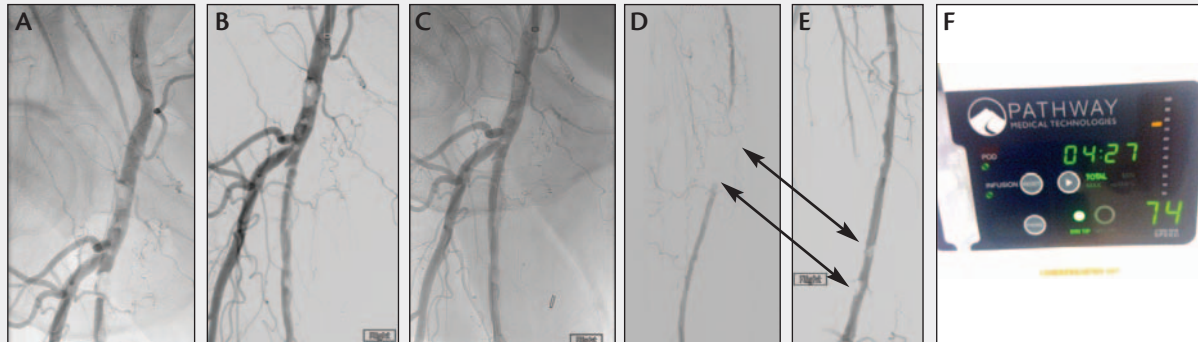
BY TERRY BRADY, MD, OSF ST. FRANCIS (PEORIA, IL), JUNE 15, 2009



Eccentric calcified lesion in the common femoral artery (CFA) (A). After Jetstream G2™ revascularization (one pass blades down with wire in the SFA; two passes blades up with wire in the SFA; two passes blades up with wire in femoral profunda artery) (B). Jetstream G2™ total run time: 6:40 min (C).

Case 5: Calcified Multilevel Disease

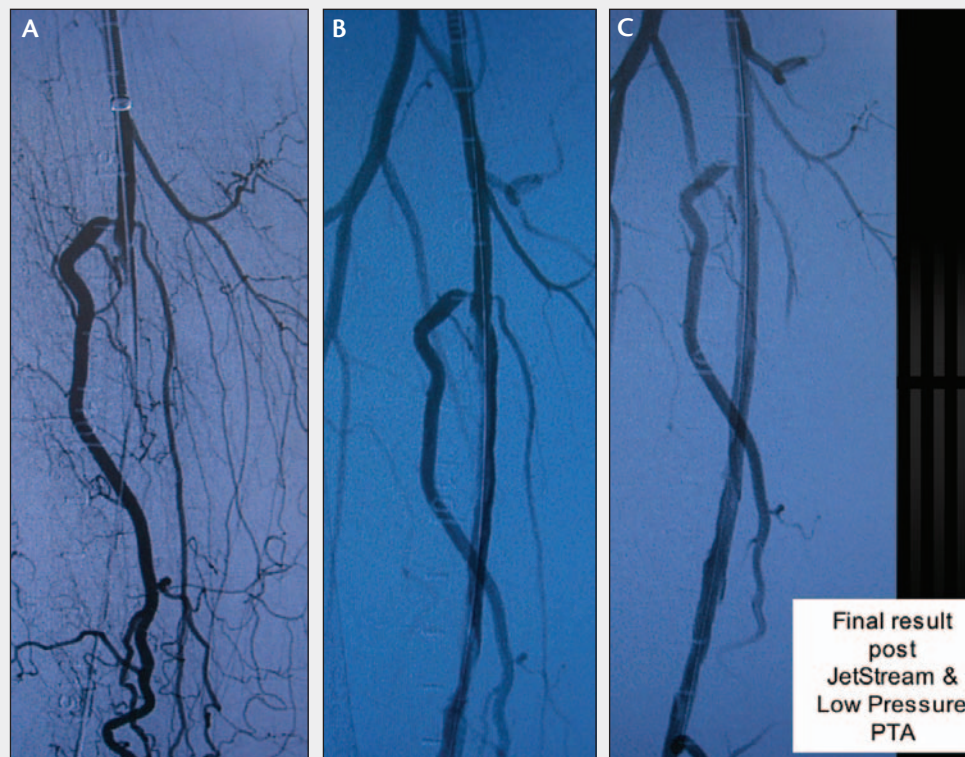
BY LAWRENCE GARCIA, MD, ST. ELIZABETH'S MEDICAL CENTER (BOSTON, MA), FEBRUARY 18, 2009



Before Jetstream G2™ (A). Highly calcified CFA lesion and 99% proximal SFA occlusion. After Jetstream G2™ (B). One pass blades down for the CFA; one pass blades down for the SFA; one pass blades up for the SFA. After PTA (C). After 7-mm PTA of the CFA and 6-mm AngioSculpt scoring balloon angioplasty (AngioScore, Inc., Fremont, CA) of the SFA at 6 ATM. Pre-Jetstream G2™ (D). Ninety-nine percent calcified eccentric occlusion. After Jetstream G2™ (E). Stand-alone result: one pass blades up, one pass blades down. Total activation time: 4:27 (F).

Case 6: SFA Total Occlusion

BY HECTOR DOURRON, MD, WELLSTAR COBB HOSPITAL (ATLANTA, GA), JANUARY 2, 2009



Baseline angiogram (A). After Jetstream® (B). Final result after low-pressure PTA (C).

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

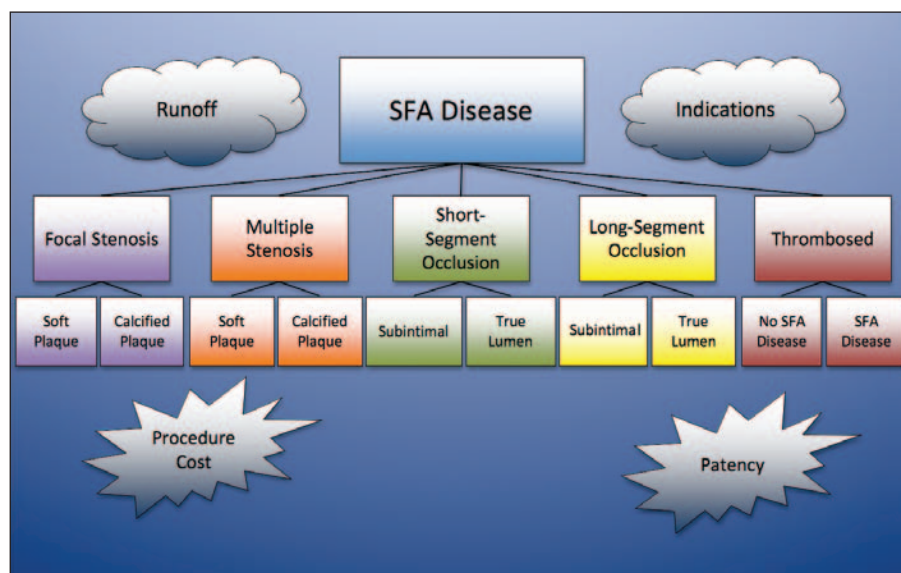


Figure 1. Algorithmic approach to atherosclerotic occlusive disease of the SFA.

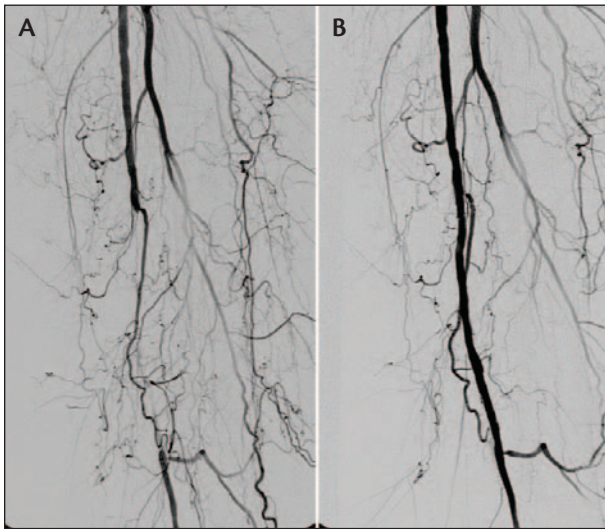


Figure 2. Before (A) and after (B) Jetstream G2™ revascularization system atherectomy and thrombectomy of SFA disease.

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

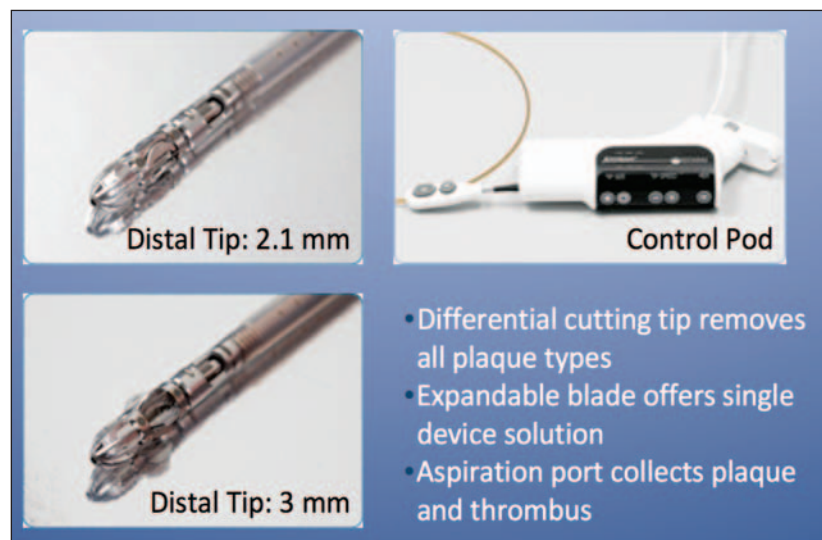


Figure 3. The Jetstream G2™ revascularization system.

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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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.

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 mm² 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-

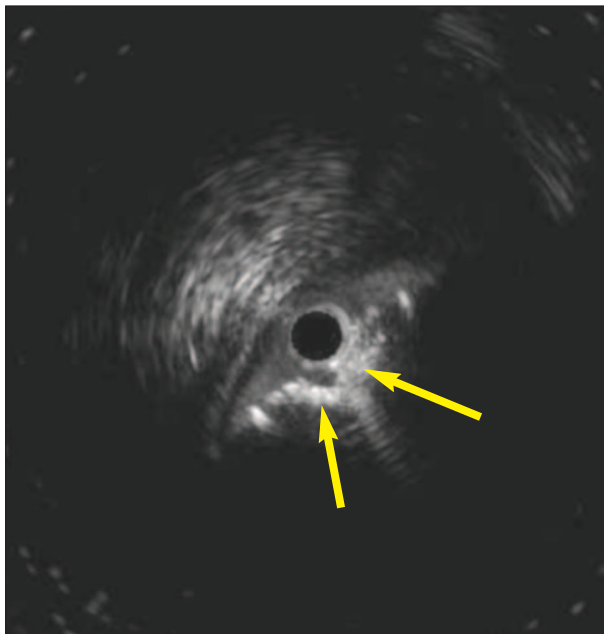


Figure 1. Case 1: Preintervention IVUS. Arrows indicate calcification.

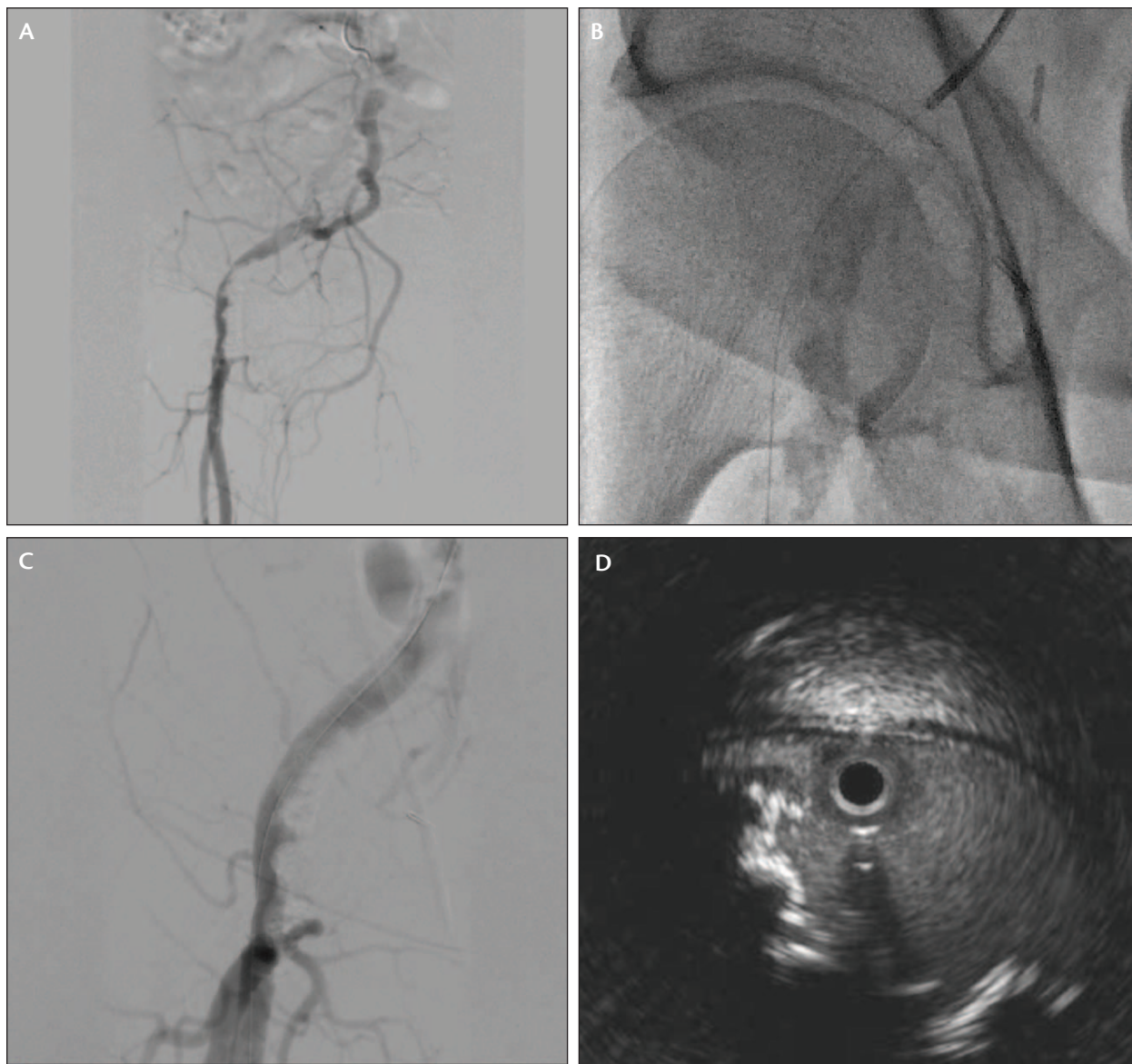


Figure 2. Case 1: Initial angiogram of severe common femoral artery stenosis (A). Jetstream® revascularization. Note heavy calcification (B). Final angiogram (C). Postprocedure IVUS (D).

mm balloon completed the intervention, with a markedly improved angiographic and IVUS result and a CSA of 32.24 mm² (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.,

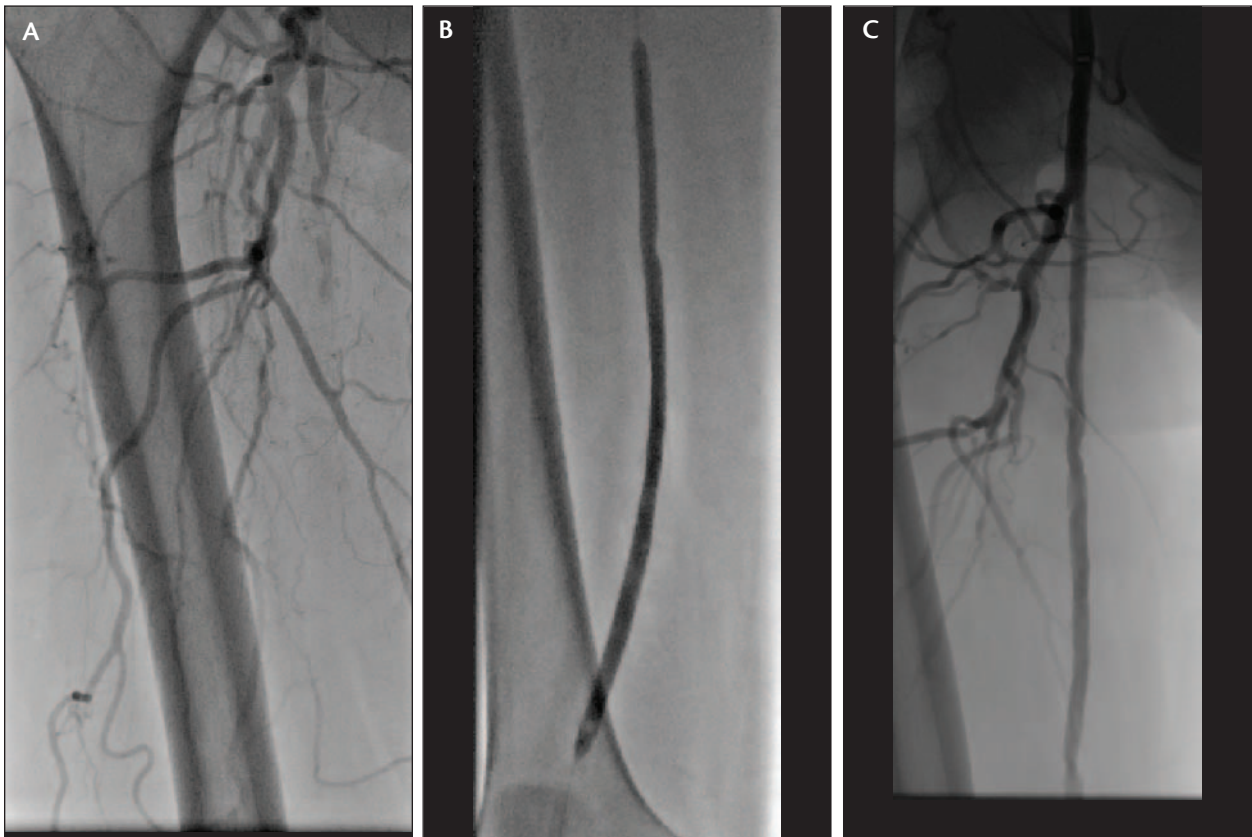


Figure 3. Case 2: Initial angiogram of index lesion (A). Right PTA after Jetstream® atherectomy (B). Final angiogram of right SFA (C).

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 restenosis² rates even in short segments of subintimal treatment. ■

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