Rethink Atherectomy:
Expert Insights Into Clinical Application and Use of the JETSTREAM System
Optimizing Strategy in Peripheral Vascular Interventions: The Role of JETSTREAM® Atherectomy

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Over the past several years, major advancements have been made in the treatment of infrainguinal disease. The “tool box” has expanded with several manufacturers bringing to the market multiple balloons, wires, stents, atherectomy devices, CTO catheters, and so forth. Endovascular specialists are left to choose the right device for the right lesion based on their experience and understanding of how these devices operate and where they are most effective. In general, high-level evidence comparing effectiveness and safety of these devices is generally lacking with available data mostly derived from small, randomized trials or observational registries. Given the lack of clear recommendations about when certain devices are best applied for the most effective and safe results, a general guiding strategy to approach infrainguinal disease may be necessary. The “leave nothing strategy” appears to have gained momentum and reflects on our desire to keep the vessel free of stents. Despite randomized data indicating stenting can improve patency over balloon angioplasty, stents continue to have several problems in infrainguinal interventions with reduced patency on long-term follow-up, fractures, re-occlusion by a restenotic-thrombotic process, and possible interference with surgical options and emerging anti-restenotic technologies such as drug-coated balloons or drug-coated stents.

Changing vessel compliance to reduce dissections, bail out stenting and vessel barotrauma, protecting the outflow vessels, and reducing smooth muscle cell proliferation have been the main anchors of a guiding strategy in our laboratory when approaching infrainguinal disease. Recently published or presented randomized trials have shown that atherectomy can accomplish the task of reducing dissections and bail out stenting. Embolic filter protection and embolic capture balloon technology have added a level of protection to the outflow vessels, and now with drug-coated balloons, restenosis, and target lesion revascularization can be improved upon.

In this supplement to the Journal of Invasive Cardiology, I discuss the multiple challenges operators encounter when treating infrainguinal disease with a focus on the importance of atherectomy in addressing the issue of changing vessel compliance, reducing dissection, and stenting. The importance of protecting the outflow vessels during atherectomy is also presented. Dr. Ramaiah presents the JETSTREAM device and its distinguishing features from existing atherectomy devices on the market including active aspiration, front cutting rotational design, and expandable blade technology. Dr. Davis explores key tips and tricks with the use of the JETSTREAM device including introducers and wire selection, the importance of audible and tactile feel during the operation of the device, the technique of catheter advancement and pullback, the use of the blades-up and blades-down feature, and how to avoid distal embolization. Finally, Dr. Shimshak presents 2 case reports with the JETSTREAM system illustrating its strengths in treating severe calcified lesions. Intravascular ultrasound assessment of the lesion before and after treatment is also presented and shows the ability of the device to effectively remove calcium.

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Addressing Challenges in the Treatment of Infrainguinal Arterial Disease: an Endovascular Specialist’s Perspective

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ABSTRACT: Infrainguinal interventions remain challenging to endovascular specialists. Treatment of the femoropopliteal (FP) artery represents approximately 40% of all infrainguinal interventions. The FP artery is subject to multiple external forces. The use of self-expanding nitinol stents in this vessel modestly improves patency but is associated with several potential problems including stent fracture, in-stent restenotic-thrombotic re-occlusions and continued low patency rate on long-term follow-up. Also, infrapopliteal (IP) vessels are generally small in diameter and tend to be calcified with long segments of disease and occlusions. IP vessels are therefore likely to have a high rate of dissection with balloon angioplasty as a primary treatment. Stenting the IP vessels with current stent technology is a suboptimal strategy that should generally be avoided. Literature review supports a strategy based on a triad of improving vessel compliance and reducing barotrauma and dissection, minimizing distal embolization and applying anti-restenotic measures to improve patency and reduce target lesion revascularization. We review current literature and tools available to the endovascular specialist to achieve these goals.

Key words: femoropopliteal artery, restenosis, atherectomy, drug coated balloon, in-stent restenosis, distal embolization, tibial runoff, stent fracture, patency, target lesion revascularization, tibial artery, peroneal artery

Peripheral artery disease (PAD) is an endemic problem, predominantly apparent in elderly, diabetics, and smokers. Currently 12%-14% of people in the United States have PAD. The severity of PAD is a strong predictor of cardiovascular mortality. Therefore, treatment needs to focus on aggressive risk factor modification in addition to revascularization strategies to improve symptoms of claudication, reduce amputation, and improve survival.1

Endovascular treatment of infrainguinal disease (FP and IP) has remained a challenge particularly in advanced type C and D lesions as defined by The Trans-Atlantic Inter-Society Consensus Document on the Management of Peripheral Arterial Disease (TASC II).2 With the advent of multiple tools to treat these complex lesions, endovascular specialists are now approaching these lesions non-surgically. Despite a relatively high initial procedural success with catheter-based therapies, the long-term outcomes have been less than encouraging with an overall lower patency and high repeat target lesion revascularization (TLR).

We describe our approach in treating infrainguinal disease with a focus on improving compliance and minimizing dissection and bailout stenting, preserving distal runoff and applying anti-restenotic therapies for more durable long-term results.

Treatment of the Femoropopliteal Artery

De novo lesions

There is little debate that TASC II A and B lesions are best suited for endovascular therapies. Although the TASC II committee recommends surgical therapy for TASC C and D lesions, these are now increasingly being handled using an endovascular approach. There is no consensus to the best endovascular approach in treating de novo lesions in the FP artery. Both primary and provisional stenting of the FP segment are strategies practiced widely. Balloon angioplasty (PTA) alone leads to a higher rate of dissection and need for bailout stenting.3 In one study, predictors of bailout stenting included TASC D lesions, moderate (versus mild or none) calcification and primary use of PTA (versus initial debulking prior to adjunctive PTA).4

We have previously proposed a strategy based on the triad of improving vessel compliance and reducing bailout stenting (mechanical), preserving the outflow vessels (procedural), and reducing restenosis (biological) in approaching the treatment of FP segments.5

Several trials have evaluated the value of stenting in FP disease. Data suggest that stenting of the superficial femoral artery (SFA) reduces the rate of restenosis when compared to PTA. In 104 patients randomized to primary stenting versus PTA of the SFA (mean lesion length in the stent group 11.2 cm), Schillinger et al6 noted that the 6-month rate of restenosis on angiography was 24% in the stent group and 43% in the PTA group (P<0.05). At 2-year follow-up, restenosis rates were 45.7% vs 69.2%, respectively, by an intention-to-treat analysis (P=0.031) and 49.2% vs 74.3% (P=0.028), respectively, by actual treatment received.7 In a recent randomized trial, Laird et al8 reported freedom from TLR at 12 months to be 87.3% for the Lifestent (Bard Peripheral Vascular) compared with 45.1% for PTA as a primary therapy in treating short FP lesions (mean lesion length 7.1 cm in the stented group) (P<0.0001). Duplex ultrasound-derived primary patency at 12 months was better for the stent group (81.3% vs 36.7%; P<0.0001). At 3-year follow-up freedom from TLR was significantly better in the stent group (75.5% vs 41.8%, P<0.0001).9 In contrast, Krankenberg et al10 randomized 244 patients with SFA disease (mean lesion length 4.5 cm) to the Bard Luminexx 3 stent vs PTA. There was no difference in restenosis rates between the stent (31.7 %) and the PTA (38.6%) arms at 1 year. TLR rates at 1 year were 18.3% and 14.9% (non-significant), respectively. Differences in stent
design may have been one factor that accounted for the lack of improvement in patency and TLR in this study.

Irrespective of the stent used, there were continued significant high TLR rates at one and 2 years in patients who received stenting of the FP artery.\textsuperscript{6-11} Stenting reduces restenosis by preventing negative remodeling and recoil rather than reducing neointimal proliferation.\textsuperscript{12} Cryoplate was used to improve on stent results. Cryoplasty does reduce neointimal proliferation using cell apoptosis.\textsuperscript{13} Adjunctive cryoplasty after stenting of the FP segment did show a reduction in restenosis in diabetics. In the COBRA (cryoplasty therapy or conventional balloon post-dilation of nitinol stents for revascularization of peripheral arterial segments) randomized trial, FP binary restenosis after adjunctive cryoplasty was significantly reduced compared to PTA (29.3\% vs 55.8\%, \textit{p}=0.01).\textsuperscript{14} Recently the Zilver PTX,\textsuperscript{15} a paclitaxel-coated self-expanding stent, was approved in the US. In the Zilver PTX randomized trial, the ZilverPTX stent (Cook Medical) had a superior 12-month event-free survival (90.4\% vs 82.6\%; \textit{P}=0.004) and primary patency (83.1\% vs 32.8\%; \textit{P}=0.001) when compared with PTA.

Stents in the FP segment can fracture over time because they are subject to repetitive external forces, including flexion, torsion, and compression. Low grade stent fracture is less likely to cause restenosis but high grade fractures were associated with higher rate of restenosis.\textsuperscript{16,17} Furthermore, stent total re-occlusion is a restenotic-thrombotic process generally more difficult to treat and carries a higher rate of procedural complications, recurrent restenosis, and re-stenting.\textsuperscript{18,19} In addition, it is unclear how a stented FP segment interferes with the effectiveness of emerging anti-restenotic technologies such as drug-coated balloons or drug-coated stents. Finally, stents involving the popliteal or common femoral arteries may reduce future surgical options and are best avoided in these locations except in bailout situation.

Atherectomy has emerged as an alternative option to primary stenting of the FP artery. Using directional cutting of FP \textit{de novo} lesions, SilverHawk atherectomy (Covidien) improved vessel compliance and reduced dissection and bailout stenting compared to PTA alone.\textsuperscript{20} In the COMPLIANCE 360 trial,\textsuperscript{20} differential sanding using the Diamondback 360° of calcified FP lesions improved lesion compliance and resulted in reduction in bailout stenting. In addition to debulking with differential cutting or sanding, plaque modification with cutting balloon may improve compliance and reduce dissection. In short, in \textit{de novo} SFA lesions (<5 cm), CB had less restenosis than PTA (13\% vs 36\%; \textit{P}=0.049) at 12-month follow-up.\textsuperscript{21} However, this was not consistent across studies.

Amighi et al\textsuperscript{22} showed no reduction in restenosis post-CB treatment of short \textit{de novo} FP lesions compared to PTA (32\% PTA vs 62\% CB at 6 months, respectively; \textit{P}=0.048). The impact of ablative treatment using excimer laser (Spectranetics) or cutting with rotational atherectomy and aspiration with the JETSTREAM device (Bayer HealthCare) on vessel compliance and bailout stenting is unknown. In the CELLO trial (Clirpath Excimer Laser System to Enlarge Lumen Openings) patency of FP \textit{de novo} lesions were 59\% and 54\% at 6 and 12 months, respectively.\textsuperscript{23} Furthermore, in observational studies, bailout stenting of the FP segment after excimer laser was variable, ranging from 23\% to 50\% but these studies did not assess vessel compliance and had no comparative PTA arm.\textsuperscript{19,24} Zeller et al\textsuperscript{25} reported a 99\% device success rate in the multicenter Pathway Peripheral Vascular disease trial (using the JETSTREAM Atherectomy System, Bayer HealthCare) in infrainguinal disease (including non-\textit{stent} restenotic lesions). In this study, clinically driven TLR rates at 6 and 12 months were 15\% and 26\%, respectively and the 1-year restenosis rate was 38.2\% based on duplex imaging. Currently the ongoing JET multicenter prospective registry is evaluating the JETSTREAM rotational and aspiration catheter on TLR at 1 year, acute procedural results, distal embolization and bailout stenting in claudicans with \textit{de novo} or non-\textit{stent} restenotic FP lesions.\textsuperscript{26} At present, there are no randomized data comparing atherectomy with adjunctive drug-coated balloon (DCB) vs atherectomy alone or stenting alone or stenting with adjunctive DCB. A small non-randomized study from Italy suggested that atherectomy with DCB yielded better patency rates and improved TLR compared to atherectomy alone.\textsuperscript{27}

Paclitaxel-coated angioplasty balloons have reduced restenosis in the FP arteries. In the multicenter Thunder (local Taxan with short time exposure for reduction of restenosis in distal arteries) trial,\textsuperscript{28} TLR was 37\% at 6 months and 52\% at 24 months in the control group and 4\% and 15\% in the paclitaxel-coated balloon group (\textit{P}<0.001), respectively. In addition, Werk et al\textsuperscript{29} reported a TLR rate of 33\% in control and 6.7\% in the paclitaxel-coated balloon (\textit{P}<0.002) at 6 months. DCB are likely to be a game changing technology in the treatment of FP disease.

We have adopted the strategy of atherectomy with low pressure adjunctive PTA as the initial preferred therapy in our laboratory with a significant reduction in dissection rates and need for bailout stenting. The ongoing XL-PAD, a multicenter prospective registry, is currently collecting data on FP treatment to evaluate 6-month and 1-year outcomes using various treatment modalities and comparing them to stenting.\textsuperscript{30}

\textbf{In-stent restenotic lesions}

Treatment of in-stent restenosis (ISR) is challenging, particularly when re-occlusion has occurred. These re-occlusions are typically thrombotic-restenotic lesions with high distal embolic potential and may require additional stenting over existing stents.\textsuperscript{18,19} In patients with a previously placed stent, smooth muscle cell proliferation accounts for restenosis as recoil and negative remodeling are not likely. Re-stenting of the FP artery is generally not recommended. The short- and long-term outcomes of more than one layer of stent in the FP segment are unknown.

PTA has very high rate of restenosis and debunking has been attempted as a way to reduce or delay TLR. Zeller et al\textsuperscript{25} reported on 43 patients with FP ISR (mean lesion length of 131 mm) treated with SilverHawk atherectomy. Patency rate was 54\% at 1-year. Using excimer laser and the Viabahn (WL Gore and Associates) stent, Laird et al\textsuperscript{32} reported a primary patency at 12 months of 48\% in the SALVAGE trial. In the

The Journal of Invasive Cardiology\textsuperscript{8}
PATENT (Photo-Ablation Using the Turbo-Booster and Excimer Laser for In-Stent Restenosis Treatment) study, a prospective registry evaluating laser atherectomy for treating FP ISR, Zeller et al reported 82% and 52% freedom from TLR at 6 and 12 months, respectively. Similarly, Shammas et al reported a TLR of 48.7% at 1 year in 40 patients treated with the excimer laser for FP ISR with mean lesion length of 201.4 mm. Finally, Beschoner et al reported their data on 40 infrapopliteal ISR lesions treated with the Pathway PV atherectomy system. Primary patency was 33% after 12 months and 25% after 24 months. The ongoing JETSTREAM ISR registry is currently evaluating rotational atherectomy with aspiration in treating FP ISR lesions. In addition to its ability to remove de novo and restenotic tissue, the JETSTREAM is also a thrombectomy device, an added advantage in treating totally occluded FP ISR lesions. The ongoing EXCITE-ISR (Randomized Study of Laser and Balloon Angioplasty Versus Balloon Angioplasty to Treat Peripheral In-stent Restenosis) trial is a superiority study evaluating debulking with the excimer laser on ISR compared to PTA.

Debulking is emerging as an important tool in treating FP ISR. The value of debulking is mostly delaying TLR in the intermediate follow-up phase, which may reduce the need for early reintervention compared to PTA alone. Almost half the patients will return for reintervention at 1 year. Therefore debulking may need to be coupled with anti-restenotic measures to have a significant clinical impact on altering the course of FP ISR. Also it is unclear whether debulking in FP ISR would add a significant improvement in patency to DCB alone. Excimer laser followed by a paclitaxel-coated angioplasty balloon (PTX PTA) is currently being compared in Europe to PTX PTA alone in the treatment of FP ISR lesions.

Treatment of Infrapopliteal Artery

The treatment of IP lesions is mostly reserved for critical limb ischemia patients with the goal of limb salvage or in severe claudicants with only severe outflow obstructive disease. Stenting of IP vessels is currently not recommended except as a bailout strategy when other non-stent modalities have failed. Although some operators have used drug-eluting stents to treat tibial vessels, use for IP vessels is off-label in the United States. Improving vessel compliance, avoiding flow limiting dissection, and minimizing distal embolization are primary intraprocedural goals when treating the IP vessels.

A clear dichotomy exists between patency, need for TLR, and limb salvage in the treatment of IP lesions. Restenosis is typically high in treating IP vessels but limb salvage rates are in the upper 80% to low 90% at 1 year irrespective of what modality has been used to treat these vessels. TLR is also less likely to be needed after the wound has healed and despite loss of patency. This is likely attributable to the fact that a limb with an active wound requires significantly more blood flow for healing than a limb with no ulceration.

A large percentage of IP vessels have moderate to severe calcification. PTA is likely to result in significant dissection in IP vessels. Debubking prior to adjunctive low pressure PTA may improve compliance and reduce dissection rates. This hypothesis was validated in the Calcium 360 trial. In this multicenter randomized study of adjunctive balloon angioplasty following orbital atherectomy (CSI) of moderate to severely calcified IP vessels in patients with predominantly critical limb ischemia, debulking yielded an improvement in vessel compliance, less flow limiting dissection, and less bailout stenting when compared to PTA alone. Of interest in the Calcium 360 trial, the presence of a high residual narrowing post-PTA correlated with increased major adverse events on follow up, a finding that needs to be reproduced in larger clinical trials. Furthermore, Zeller et al reported their experience with directional atherectomy using the SilverHawk catheter (Covidien) in the treatment of IP disease. Only 4% of lesions required bailout stenting. In 98% of lesions treated, residual narrowing was <30%. Primary and secondary patency rates were 67% and 91% after 1 year and 60% and 80% after 24 months, respectively.

The main advantage of atherectomy over PTA in treatment of IP vessels is the reduction of dissection and bailout stenting. Although cryoplasty had favorable results in treating critical limb ischemia, two small, randomized trials suggested that cryoplasty using the PolarCath (Boston Scientific) does not significantly reduce dissection rate and need for stenting in the FP artery but randomized data in the IP vessels is lacking. Atherectomy with or without adjunctive balloon angioplasty will likely remain an important first line therapy of IP vessels.

Distal embolization

The treatment of FP or IP lesions carries the risk of distal embolization (DE), which requires treatment in 2%-3% of unselected infrapopliteal interventions. Predictors of DE include thrombotic occlusion, long lesions, TASC D lesions, heavy calcification, mechanical thrombectomy, and atherectomy. DE is associated with limb loss, longer procedure times, higher contrast use, and increased radiation exposure. Also, compromised distal runoff post-procedure may be a predictor for early restenosis/re-occlusion after FP PTA.

Embolic protection devices in treating the lower extremity vessels have recently been approved by the FDA: Spider Filter (Covidien) and Proteus balloon (Angioslide). Embolic protection adds significant cost to the procedure and is currently not reimbursed. The JETSTREAM System (Bayer HealthCare) is a rotational atherectomy device with simultaneous aspiration, a unique feature among all existing atherectomy devices and with a theoretical advantage of minimizing DE and possibly the need for routine embolic filter use. Both the JET and JETSTREAM ISR registries are evaluating occurrence of DE with the use of the JETSTREAM catheter in treating FP lesions.

Conclusion

A strategy of improving vessel compliance with debulking, minimizing flow limiting dissection, and bailout stenting coupled with adjunctive low pressure balloon inflation using a paclitaxel-coated balloon is likely to emerge as an effective strategy in treating infrapopliteal PAD. The use of embolic protection devices to protect the outflow vessels will be important.
SHAMMAS

particularly with excimer or SilverHawk atherectomy. Rotation-
al atherectomy with simultaneous aspiration (JETSTREAM) or orbital atherectomy may reduce clinically significant DE and the need for routine embolic protection devices.

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Peripheral arterial disease (PAD) is a major cause of morbidity in the United States, currently affecting 8 to 12 million Americans. During the last 10 years, there has been a paradigm shift away from open surgery toward endovascular therapy. In the United States, the rate of endovascular lower extremity interventions has quadrupled for critical limb ischemia and doubled for claudicants. This has been accompanied by a reduction in the rate of major amputations and length of hospital stay, despite an increase in the burden of patient comorbidities.

Endovascular therapy continues to have significant limitations. Balloon angioplasty of complex lesions and chronic total occlusions (CTOs) is associated with dissection, perforation, and distal embolization. Stents must be able to withstand significant biomechanical forces including compression, flexion, and stretching, which may lead to stent fractures, in-stent stenosis, and stent occlusion. Atherectomy may provide a viable alternative to the more established treatment strategies as we strive to employ a “leave nothing behind strategy.” Atherectomy offers the ability to debulk atherosclerotic plaque with minimal change in vessel diameter and reduce the need for subsequent stent placement.

JETSTREAM Technology

The JETSTREAM Atherectomy System (Bayer Healthcare) is a novel technology indicated for both atherectomy and thrombectomy. The JETSTREAM System’s unique rotational design allows it to debulk and evacuate the liberated debris through continuous aspiration. The JETSTREAM System consists of 2 primary components: the console that mounts to a standard IV pole and a sterile, single-use catheter and control pod unit.

Console

The electrically driven console consists of two peristaltic pumps for aspiration of debris and infusion of saline (Figure 1). The console also serves as a power source for the drive motors located in the catheter pod. The drive motor rotates the cutting tips to a maximum of 70,000-73,000 RPMs during system operation. The disposable catheters are easily attached to the console power source and pumps prior to a procedure. The console is maintained on an IV pole that holds a bag of normal saline for infusion and the collection bag for aspirated debris.

Catheters

The disposable sterile, single-use JETSTREAM atherectomy catheter set is available in 4 different sizes, providing a treatment solution for both above and below the knee disease. Each catheter set includes a control pod, cutting catheter, infusion and evacuation line, and collection bag. The system is 7 Fr compatible and is operated over a 300 cm 0.014” guidewire.

The recently released JETSTREAM SC/XC family of catheters demonstrates further innovation, providing a new user interface, improved ergonomics, and wire management. A new lighter and more ergonomically designed pod makes the device easier to use by single operators (Figure 2). Redundant control buttons have been removed and integrated into the removable “mouse” to facilitate dual or single operator technique. All JETSTREAM atherectomy catheters have a front cutting rotational tip. The front cutting five-fluted design has been optimized to deliver performance across a diverse mix of thrombus, plaque, and even complex calcium. The rotational design of this front cutting system makes it a good choice for treating diffuse disease and total occlusions.

The JETSTREAM XC catheters, intended to treat above and to the knee peripheral artery disease (PAD), offer two stage cutting with expandable blade technology. This allows physicians to treat both common femoral artery (CFA) and superficial femoral artery (SFA) disease with a single catheter.

The XC devices come in 2 sizes: 2.1/3.0 mm and 2.4/3.4 mm and are indicated for minimal reference vessels of 3.1 mm and 3.4 mm, respectively (Figure 2). As the device is operated in the blades down configuration, the distal cutter spins clockwise. This is typically used during the initial pass or passes of the catheter to create a channel roughly equivalent to the small tip size. If a larger flow channel is required, the tip direction is reversed via a button on the control pod at which time the
blades spin counterclockwise allowing the tip to expand to the maximum cutter size. Maximum luminal gain is achieved in the blades up position with the XC catheters.

The JETSTREAM SC catheters are primarily intended for below the knee application and are available in 1.6 mm and 1.85 mm cutter sizes (Figure 3). The 145 cm long SC devices have a single rotational cutting tip and are designed for vessels with a minimal diameter of 2.5 mm. With the exception of expandable blade technology, the SC catheters contain all features found in the XC line of catheters.

The versatility of this atherectomy system makes it a truly unique treatment option. JETSTREAM is the only FDA cleared atherectomy system with active aspiration. Continuous aspiration of ablated atheroma and thrombus is a feature offered across the device platform. Proximal to the cutting tip is an internal rotating cutter that breaks up particles entering the aspiration port (Figure 4). Liberated material and thrombus are continually aspirated from the treatment site to a collection bag, which is hung on the IV pole. Active aspiration is a safety feature that acts to minimize distal embolization and effectiveness in thrombus.

The true front cutting rotational design of the system provides options for treating multiple lesion morphologies, including calcium and thrombus. The front cutting feature of this device allows engagement of total occlusions when the lesion can be crossed with a wire. Additionally, the front cutting rotational design shortens procedural time when treating long segments of diffuse disease. Debulfing is accomplished by blades specifically designed to cut less resilient and less elastic plaque and thrombus while reducing the risk of affecting the more resilient healthy tissue.

Results from the early multicenter PVD trial are promising. There were 210 lesions treated with a 99% success rate. The average lesion length was 2.7 cm. Thirty-one percent were total occlusions; 51% had moderate to high calcium scores; and 15% had post-angioplasty restenosis.

The clinically driven target vessel revascularization rates were 15% at 6 months and 26% at 1 year. The restenosis rate was 38.2% at 1 year based on duplex ultrasound, as per core lab analysis. A post hoc analysis of this study showed that there were comparable results using the JETSTREAM atherectomy catheter in both diabetic and non-diabetic patients with similar major adverse event rates and clinically driven target lesion revascularization. The JETSTREAM System Endovascular Therapy post-market registry (JET) is currently enrolling patients globally. It will evaluate 6-month and 1-year patency with the JETSTREAM catheters in long, occluded, diffuse, thrombotic, or calcified lesions in PAD of the common femoral, superficial femoral, or popliteal arteries.

**Conclusion**

Recent technological advances have made it possible to increase the spectrum of treatable peripheral arterial lesions with high acute procedure success rates. However, the choice of the best endovascular strategy for the treatment of PAD still remains challenging because of the specific features of this vascular bed and the diffuse nature of the atherosclerotic process. Durability and long-term patency remain the major challenges to therapy in endovascular treatment of PAD. Despite significant advances and availability of new devices,
The principal failure continues to be recurrent restenosis. The role of atherectomy may be to overcome the limitation of balloon angioplasty and stent placement. A number of debulking modalities and devices are now available with good procedural results. Long-term outcomes need to be addressed by large, randomized trials.

The JETSTREAM System is an innovative peripheral revascularization platform designed to restore flow through many types of plaque morphologies encountered in PAD. Offering a range of sizes to treat vessels above and below the knee, this unique technology offers features that provide effective atherectomy in difficult arterial obstructions while preserving options for further treatment. The JETSTREAM System gives physicians a powerful tool to help fight PAD.

References
Tips for Success with JETSTREAM Atherectomy System

Thomas Davis, MD

PAD is a complex and challenging disease state. As tools continue to improve, we are able to treat increasingly complex disease. As interventionalists, our objectives are to restore flow, improve symptoms, and ultimately save limbs. My objective is to accomplish all of the above with hopes to preserve my future treatment options with my PAD patients. Therefore, we reserve stent use as a bailout strategy to keep all future treatment options open at my institution. We employ debulking PAD with atherectomy as a front line treatment strategy to accomplish this endpoint.

The JETSTREAM Atherectomy System (Bayer HealthCare) has rapidly evolved into a versatile tool in our treatment armamentarium for PAD. In 2008, the FDA cleared the first generation JETSTREAM device for atherectomy of peripheral vasculature and in 2009, an indication for thrombectomy of upper and lower extremity peripheral arteries was added. Since the initial product clearance, rapid evolution of the technology has resulted in seven new product introductions, the most recent being the JETSTREAM SC/XC family. The new catheters have a lighter control POD, simplified user interface, and a removable control mouse, which potentially reduces radiation exposure. Additionally, the new wire management GARD simplifies wire management during the case.

Clinical Sweet Spots

In our laboratory we use all commercially available atherectomy devices as we believe each have their own unique strengths and no single device is right for every case. The strengths of JETSTREAM technology are in its ability to manage mixed morphology lesions. The JETSTREAM System is our product of choice for total occlusions and diffuse disease from the common femoral artery through the popliteal because it allows front cutting and active aspiration. Total occlusions are typically composed of mixed morphology of disease (thrombus, calcium, and plaque) and the ability to both debulk and remove the liberated material is very important. Particulate matter (mobile plaque elements) within the target vessel have significant thromboembolic risk. Aspiration of these mobile elements has implicit value, and technique management should help mitigate the risks associated with JETSTREAM usage. The only prerequisite to using this device is being able to cross the lesion with a 0.014" wire. Typically I will cross with a crossing assist device to avoid sub-adventitial areas, which allows the device to make direct contact with the plaque rather than through a sub-adventitial space.

We also typically use JETSTREAM Atherectomy in long segments of diffuse disease. The rotational front cutting technology effectively prepares lesions for definitive therapy and minimizes fluoroscopy and procedural times. As demonstrated in the Calcium Study, JETSTREAM atherectomy remodels luminal irregularities and delivers a statistically significant improvement in luminal symmetry.1 The improved luminal symmetry better facilitates balloon angioplasty as balloon-to-vessel wall apposition is markedly improved when the luminal space is symmetric.

Wires

JETSTREAM is an over-the-wire system and requires a 300 cm 0.014" guidewire for delivery. Because the mechanism of action is high speed rotation (70,000-73,000 RPM), this device should only be used over approved wires. The JETSTREAM JETWIRE (Bayer HealthCare) was specifically manufactured for use with the JETSTREAM Atherectomy System and performs quite well. In addition to the JETWIRE, a list of compatible wires is included in the device instructions for use. A supportive wire is needed to allow lesion engagement with the front cutting technology. Never attempt to insert or operate the device over a bent or kinked wire because it causes poor tracking over the wire and can lead to loss of distal engagement.

Figure 1. Wire in GARD with tight loop.

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Disclosure: Dr. Davis reports that he owns stock in Avinger. He is also on the advisory board for Bayer HealthCare and Bard.

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wire placement when taking the device out after use. It is better to replace a compromised wire at the beginning of the procedure rather than struggling to re-cross after the initial passes.

**Wire Management**

Wire management during the case is an important and often overlooked operator responsibility. The device has a wire GARD that prevents the wire from rotating during operation. Once the lesion has been wired, the device is front loaded onto the wire. The wire exits the POD on the back end and should be inserted into the wire GARD forming a tight loop (Figure 1). As the device operates over the wire, the wire loop should grow if the guidewire is effectively anchored distally. If the loop fails to grow you can assume the wire is moving distally with the device. Distal wire movement is the result of inadequate wire parking. You should always strive to position your wire in the deepest possible distal position.

**JETSTREAM Procedure**

Procedural technique is the most important driver of success with the JETSTREAM atherectomy catheters. Maintaining discipline in the catheter advancement speed is imperative. The recommendation is 1 mm/second. Initially you may want to use radiopaque tape to help gauge your speed. We found that slow forward advancement followed by subtle pullback improves both the cutting and aspiration efficiency. Not to be confused with a pecking motion, the desired technique is analogous with one step forward—two steps back. Adhering to this technique allows the device to aspirate the liberated debris. This technique is equally important despite the lesion morphology (ie, thrombus, soft plaque, fibrous tissue, or calcium). It is common to advance the catheter too fast, but doing so may overwhelm the aspiration capability or stall the catheter.

In addition to the high-level guidance of 1 mm/second, the most important information you should use to guide catheter advancement is the auditory and tactile feedback from the device. The auditory feedback comes from the device motor and the objective is to maintain constant or near constant motor sounds. As the device engages lesion composed of calcium and hard plaque, you will typically hear the motor slow as it manages through the disease. This is less true with soft plaque and thrombus so in these morphology types the 1 mm/second advancement speed is imperative. Tactile feedback is transmitted through the catheter as it is advanced across the lesion. In more stubborn disease (hard plaque/calcium), the disease typically will not allow you to go too quickly. Table 1 provides a list of catheter advancement tips.

**Blades up or Blades down**

The JETSTREAM XC catheters have expandable blades allowing treatment of multilevel disease with one device. The initial passes across a lesion should be down in the “blades-down” or minimum tip configuration. Two blades down passes are recommended. Verbal and auditory feedback from the system will indicate when the lesion is prepped for blades up configuration. “Blades-up” should be performed from proximal to distal across the lesion. Generally, two passes will adequately debulk the lesion. Similar to the blades down configuration, the auditory and tactile feedback will indicate when debulking is complete.

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**Figure 2. Pre-JETSTREAM imaging of a tandem subtotal lesion in the popliteal artery with longitudinal IVUS pullback and VH volumetric analysis, which shows a bulky, concentric mixed morphology plaque and evidence of IEM calcification.**

**Figure 3. Post-JETSTREAM imaging of treatment site shows significant volume plaque reduction (17%) and lumen enlargement (26%), but an unchanged vessel volume (2%) signifying minimal “dottering” effect from the device. The lumen is smooth and concentric without evidence of dissection.**

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**Table 1. Catheter Advancement Technique**

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Engage lesion and advance catheter 1 mm/second.</td>
</tr>
<tr>
<td>2.</td>
<td>Advance catheter (1 mm) and pullback (2 mm) during treatment to maximize aspiration.</td>
</tr>
<tr>
<td>3.</td>
<td>Listen to the device. The motor sounds will provide feedback to guide advancement.</td>
</tr>
<tr>
<td>4.</td>
<td>Process the tactile feedback—slow down with resistance, never exceeding 1 mm/second.</td>
</tr>
<tr>
<td>5.</td>
<td>Resist the temptation to go fast through soft plaque and thrombus.</td>
</tr>
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</table>
Aspiration

The unique active aspiration feature on the JETSTREAM family of products makes this product a great choice in total occlusions and mixed morphology lesions. On rare occasion the device may lose aspiration, which is most typically the result of overwhelming the aspiration and quick advancement during active treatment. It is also important to note that aspiration works, albeit not at as high a flow, during REX mode too.

The following tips will optimize aspiration performance: Long segments of diffuse disease, total occlusions, and heavy thrombotic lesions may pose a challenge to the aspiration capability of the device, which may be mitigated by operator technique. Catheter advance technique is again paramount to the discussion. To allow the aspiration to remove the infused saline and debris, the operator must use 1 mm/second of forward movement with slight pullback following each step forward. Remember the auditory feedback will be limited in this setting as soft plaque and thrombus will have minimal impact on the device's motor speed. In this setting you must be disciplined and allow the device time to work.

Embolization

Embolization is a potential risk in all interventional procedures. The published literature and our personal experience do not suggest the risk is any higher with this device than other competitive technologies. As discussed in this manuscript optimal performance of this device is contingent upon proper user technique. Though not guaranteed, risk of distal embolization with this atherectomy device can be comparable to other interventional procedures if you are disciplined with regard to technique.

Summary

Atherectomy is evolving as an acceptable treatment option for peripheral arterial disease. While the newest entrant to the field, the JETSTREAM System has quickly evolved into a useful tool in the battle against this debilitating disease. The set of features on this product uniquely differentiates it from competitive devices and fills a clinical void. Though the device necessitates a specific technique, it is well worth developing. As technology and techniques continue to evolve so will the results we are able to deliver.
Peripheral arterial disease (PAD) is a major cause of morbidity and mortality in the United States, affecting 8 to 12 million people. The incidence of PAD is generally higher in older age groups and affects approximately 1 out of 5 people aged 55 and older. In addition to adversely impacting an individual’s quality of life and survival, PAD is associated with significant social and economic costs.1

Over the past decade, advances in percutaneous catheter-based therapies have resulted in improved early and late clinical results for symptomatic patients.2 Successful percutaneous revascularization leads to improved quality of life measures, functional capacity, avoidance of amputation, and improved survival in patients with intermittent claudication and critical limb ischemia. As a result of therapeutic advances, the number of percutaneous interventional procedures has increased fourfold for patients with critical limb ischemia and doubled for patients with intermittent claudication.2

Recently, several new atherectomy devices have been approved for use in the United States for the treatment of arterial occlusive disease, including the JETSTREAM rotational atherectomy system with dynamic aspiration (Bayer Healthcare). The introduction of the JETSTREAM device has expanded the endovascular treatment options for patients with symptomatic PAD. In addition, patients with complex disease who were not ideal candidates for percutaneous revascularization can now be treated. Two cases using this new and unique technology for the treatment of significant obstructive disease of the common femoral artery are presented.

Case Reports

Case Report 1. A 61-year-old man with known history of diffuse PAD and prior percutaneous revascularization was re-evaluated in April 2011 for progressive and lifestyle-limiting intermittent claudication affecting both legs, though his symptoms were worse in the right leg. He complained of exertional bilateral calf pain after walking <2 blocks with improvement of his symptoms within a few minutes of rest. He had a history of hypertension and cigarette smoking. His physical exam demonstrated a diminished right femoral pulse compared to the left side. Pedal pulses were diminished bilaterally. Resting ankle-brachial indices (ABI) performed 6 months earlier demonstrated an ABI of the right and left leg of 0.60 and 0.81, respectively. He underwent selective right iliac and femoral arteriography in April 2011. Arteriography demonstrated diffuse calcific disease of the right common femoral artery and mid superficial femoral artery with a 70%-75% stenoses (Figure 1). Intravascular ultrasound using the Volcano Eagle Eye® with Chromo® (Volcano) was also performed, demonstrating similar disease severity with eccentric fibro-calcific disease. A 7 Fr Pinnacle Destination contralateral sheath (TERUMO Medical Corp) was introduced and advanced to the right common femoral artery.

Case Report 2. A 66-year-old woman with known history of PAD and prior percutaneous revascularization was re-evaluated in April 2011 for progressive and lifestyle-limiting intermittent claudication affecting the left leg. She complained of exertional left calf pain after walking <2 blocks with no improvement of her symptoms within minutes of rest. She had a history of hypertension and hyperlipidemia. Her physical exam demonstrated a diminished left femoral pulse compared to the right side. Pedal pulses were diminished bilaterally. Resting ankle-brachial indices (ABI) performed 6 months earlier demonstrated an ABI of the right and left leg of 0.90 and 0.65, respectively. She underwent selective left iliac and femoral arteriography using contralateral access in April 2011. Arteriography demonstrated diffuse calcific disease of the left common femoral artery and mid superficial femoral artery with a 60%-65% stenoses (Figure 2). Intravascular ultrasound using the Volcano Eagle Eye® with Chromo® (Volcano) was also performed, demonstrating similar disease severity with eccentric fibro-calcific disease. A 7 Fr Pinnacle Destination contralateral sheath (TERUMO Medical Corp) was introduced and advanced to the right common femoral artery.
seconds, followed by manual compression. At the conclusion the femoral arterial sheath was removed when the ACT was <170 significant residual disease and/or intimal dissection. The left showed wide patency of the common femoral artery without 2-3 minutes at each site (Figure 2). Final angiography demon following atherectomy, adjunctive balloon angioplasty with a 5.0 blood and generated particulate material was obtained. Fol 70,000 RPMs during activation and continuous aspirate of external iliac artery over a .014" Hi-Torque Supra Core guide wire (Abbott Vascular). A 5,000 unit bolus of intravenous heparin was given and the ACT was maintained >250 seconds during the proce the lesion was crossed with a .014" JETSTREAM JETWIRE and advanced into the superficial femoral artery. We then performed rotational atherectomy with dynamic aspiration using the JETSTREAM device. Several slow passes were made with the cutter blades down (2.1 mm) and up (3.0 mm). The device was slowly advanced with each pass in a back and forth motion, maintaining roughly 70,000 RPMs. Atherectomy was followed by dilatation with a 5.0 mm balloon for 3 minutes at 6 atm. Repeat angiography demonstrated a mild (<30%) eccentric residual stenosis. Post-atherectomy and angioplasty IVUS demonstrated significant improvement in the lesion with the CSA of 12.5 mm² and significant reduction in the extent of calcium (Figure 4). He was dismissed on aspirin (325 mg) and clopidogrel (75 mg). The patient's post-procedure left leg ABI was .98 and he has remained asymptomatic at late follow-up.

Discussion

These two cases demonstrate the effectiveness of the JETSTREAM atherectomy device for the treatment of complex disease, including calcified common femoral arteries. Approved for clinical use in the United States in 2008, the JETSTREAM system has undergone multiple design iterations to improve its safety and performance. It is currently approved as both an atherectomy and thrombectomy device for the treatment of PAD. The JETSTREAM system consists of a sterile, single-use catheter and control pod, and a reusable power console. The catheter is a .014" over-the-wire (non-hydrophilic) system with a rotating 5-flute, front-end cutting tip. The cutter on all catheters rotates at 70,000-73,000 RPMs. Currently, catheters are available with 1.6 or 1.85 mm single cutters (SC), and 2.1/3.0 mm or 2.4/3.4 mm expandable cutters.
The distal end of the cutter of all currently available JETSTREAM devices is shown (A). The XC cutter demonstrates the aspiration port on the shaft of the catheter and the expandable blades. The blades are either up or down depending on the direction of torque of the drive shaft within the shaft of the catheter (B).

Vol. 25, Supplement B, 2013 15B

Figure 5. JETSTREAM cutter and XC catheter. Five-flute design on the distal end of the cutter of all currently available JETSTREAM devices is shown (A). The XC cutter demonstrates the aspiration port on the shaft of the catheter and the expandable blades. The blades are either up or down depending on the direction of torque of the drive shaft within the shaft of the catheter (B).

Figure 6. JETSTREAM atherectomy catheters. Current JETSTREAM catheters include the fixed, single cutter, small vessel devices (1.6 mm and 1.85 mm cutter), and the expandable XC devices (2.1 mm blades down; 3.0 mm blades up or 2.4 mm blades down; 3.4 mm blades up).

Pre-intervention to 12.5 mm$^2$ post-intervention. This final CSA is much larger than the predicted result from the cutter alone (7.07 mm$^2$) and represents the combined effect of the rotational cutter and plaque atherectomy, dynamic aspiration, and final balloon dilatation. IVUS demonstrated significant removal of calcium as well.

Similar results have recently been reported from the JETSTREAM Calcium Removal Study. In this prospective, single-arm, multicenter study, the JETSTREAM device was evaluated for its effectiveness in removing moderate and severe calcium in the peripheral arteries based on IVUS criteria. Lesion location was either the common or superficial femoral arteries in 81% of cases, of which 33% had moderate calcification and 67% had severe calcification by angiography. Based on IVUS evaluation, total lesion length was 44±35 mm; maximum arc of calcium was 149±82°. Area stenosis decreased from 61.8±19.7% to 38.5±19.6% (p<0.0002), minimum lumen area increased from 6.6±3.7 mm$^2$ to 10.0±3.6 mm$^2$ (p=0.0001). Calcium reduction resulted in a 78±27% increase in lumen area. Although the arc of superficial calcium did not change significantly in this small series, the arc of reverberation did increase significantly (21±20° to 69±71°, p=0.0006), indicating favorable device-related alteration in lesion calcium. These changes in lesion characteristics using the JETSTREAM device occurred without any adverse clinical events.

Although the JETSTREAM System has proven efficacy as an atherectomy and thrombectomy device in infra-inguinal PAD, its role as either stand alone or in combination with other therapies (including angioplasty, stenting, and/or drug-eluting balloons) remains to be determined. Future clinical trials in this country and outside of the US will help clarify how this technology will be integrated into the endovascular therapeutic armamentarium.

References
JETSTREAM® Atherectomy Systems

The JETSTREAM 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. It is not intended for use in coronary, carotid, iliac or renal vasculature. See product Information for Use for specific and complete prescribing information. Indications, operating specifications and availability may vary by country. Check with local product representation and country-specific Information For Use for your country.

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