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THE ISR TREATMENT PARADIGM

Defining the best way to approach femoropopliteal in-stent restenosis.

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Defining a Paradigm for Femoropopliteal In-Stent Restenosis

BY CRAIG WALKER, MD, AND ERIC J. DIPPEL, MD, FACC

Advancements in stent technology have revolutionized treatment of femoropopliteal disease. However, in-stent restenosis (ISR) remains a challenging clinical problem affecting more than 115,000 patients in the United States each year. More than 200,000 stents are implanted annually in the superficial femoral (SFA) and popliteal arteries, and the volume of stents in the population of patients with peripheral artery disease continues to grow at 6% to 7% annually.[1] Additionally, 30% to 40% of these patients will present with initial ISR within 2 years of implantation, and 65% will return with recurrent ISR posttreatment.[2] Until recently, there were no therapies approved by the US Food and Drug Administration (FDA) for the treatment of this growing clinical problem. Fortunately, two devices now have approved indications to treat ISR, the excimer laser and Viabahn endoprosthesis (Gore & Associates), and new options such as drug-coated balloons (DCBs) and drug-eluting stents are being actively evaluated. Despite these recent developments, many questions remain when weighing treatment options.

LESION MORPHOLOGY AND DEVELOPMENT OF ISR

When considering treatment options for ISR, it is important to first understand the unique lesion morphology and underlying pathophysiology. The development of ISR has multiple components, including vessel recoil, negative remodeling, and the formation of neointimal hyperplasia (NH) (Figure 1). In terms of morphology, the NH is primarily composed of a highly aqueous collagen matrix (60%–80% of the restenotic volume), which is important given that the conventional treatment of ISR has been utilization of percutaneous transluminal angioplasty (PTA). Unfortunately, data suggest that up to 65% of patients with "simple lesions" treated with PTA will present with recurrent ISR within 2 years, and the rate of reoccurrence can be much higher in total occlusions and longer lesions.[2] The drawback of PTA is that while the balloon temporarily compresses the lesion, releasing the water, the majority of the NH remains located in the stent, and over time, the tissue rehydrates. Additionally, stenting limits positive vessel remodeling. Thus, removing as much of the NH as possible during initial treatment may be an important step toward improving patency and reducing risk for recurrent ISR.

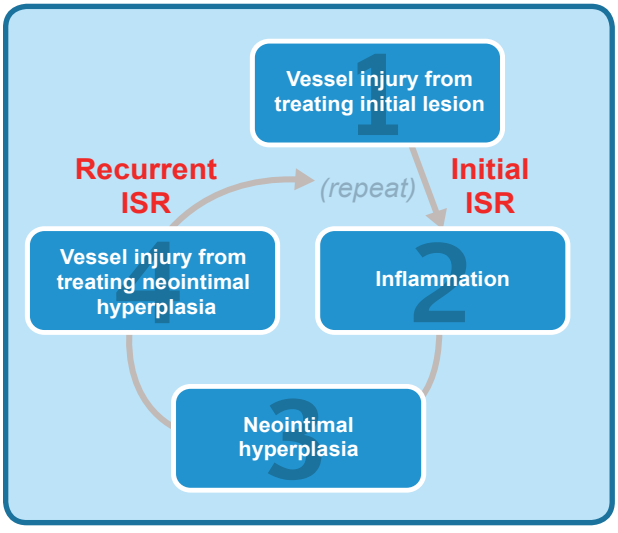

Figure 1. Injury process for development of ISR.

INTERVENTIONS FOR ISR AND SUPPORTING RANDOMIZED TRIALS

Supporting data for any one treatment for ISR have been limited, as most results were derived from single-center observational studies with limited follow-up. Recently, results of a few key randomized multicenter trials (EXCITE, RELINE, and FAIR trials)[3-5] have been presented; two of these trials evaluated the two devices approved in the United States for use in ISR—the excimer laser, the only atherectomy device currently FDA indicated for use in ISR, and the Viabahn endoprosthesis (Table 1).

The EXCITE ISR trial was the first large, prospective, randomized study to demonstrate the superiority of excimer laser atherectomy (ELA) plus PTA for treating femoropopliteal ISR versus PTA alone.[3] Compared to patients treated with PTA alone, patients treated with ELA plus PTA had superior procedural success (93.5% vs 81.7%), significantly fewer procedural complications (including no stent fractures in the laser group), greater freedom from target lesion revascularization (TLR) at 6 months (73.5% vs 51.8%), a 52% reduction in TLR, and a lower rate of major adverse events (5.8% vs 20.5%). At 12 months, ELA plus PTA was associated with a 43% reduction in TLR. Additionally, subanalysis of a subset of complex lesions (TASC C/D) revealed improved freedom from TLR at 12 months after treatment with ELA plus PTA as compared with PTA alone (47% vs 24.5%; $P < .002$) (Figure 2 and Table 2).[3] These data demonstrate that ELA plus PTA is safer and more efficacious than PTA alone and highlights the ability of the excimer laser to improve outcomes in long, complex lesions.

The RELINE study, a small randomized controlled trial conducted in Europe, reported improved clinical outcomes after treatment with the Viabahn endoprosthesis compared to PTA alone; however, safety was nonsuperior to PTA.[4] Similar to the EXCITE trial, the RELINE trial included longer lesions (mean lesion length, 17.3 cm).

The FAIR trial, designed to assess the efficacy of paclitaxel-coated balloons (DCBs) versus PTA in SFA ISR, recently reported a significant improvement in primary patency after use of DCB in shorter ISR lesions compared to PTA alone.[5] However, the use of DCBs for ISR is not yet approved in the United States.

SELECTING A TREATMENT OPTION FOR ISR

There are many factors to consider when selecting a treatment option for ISR, including stenosis versus occlusion, vessel runoff, acute versus chronic symptoms (suggesting acute thrombus), stent fractures, type of stent, length of lesion, stent compression, and location of stent. A primary goal of any ISR intervention should be to achieve maximum luminal gain (see *Physician Perspective* sidebar). Removal of the NH is critical in the regression of the lesion and may potentially reduce the chance of recurrent ISR. The laser's ability to ablate and remove NH and thrombus is ideally suited for creation of a clean channel, which can accommodate subsequent complementary treatment (eg, PTA) as needed.

TABLE 1. AVAILABLE DEVICES AND INDICATION FOR ISR

Device	ISR Indication
TurboPower (excimer laser atherectomy; Spectranetics Corporation)	Yes
Viabahn stent graft (Gore & Associates)	Yes
SilverHawk (directional atherectomy; Medtronic, Inc.)	Contraindicated
Diamondback (orbital atherectomy; Cardiovascular Systems, Inc.)	Contraindicated
Jetstream (rotational atherectomy; Boston Scientific Corporation)	Not indicated

The Viabahn endoprosthesis is another indicated option for ISR in the SFA particularly as an alternative to bypass surgery for persistent recurrent disease that is unresponsive to treatment. It is important to note that use of the endoprosthesis is restricted to patients with patent vessel runoff to the ankle, as a covered stent may entrap collaterals and requires administration and maintenance of dual antiplatelet therapy. Given that treatment with a covered stent requires full expansion of a balloon, and given what we understand about the tendency for NH to rehydrate and rebound to its original condition, removing NH tissue using laser atherectomy followed by PTA seems to be a reasonable strategy for preparing the lesion prior to additional treatment. The SALVAGE trial was an attempt to define the role of combination therapy using ELA and the Viabahn stent graft for the treatment of SFA ISR. Unfortunately, this study was terminated prematurely for nonclinical reasons before adequate enrollment

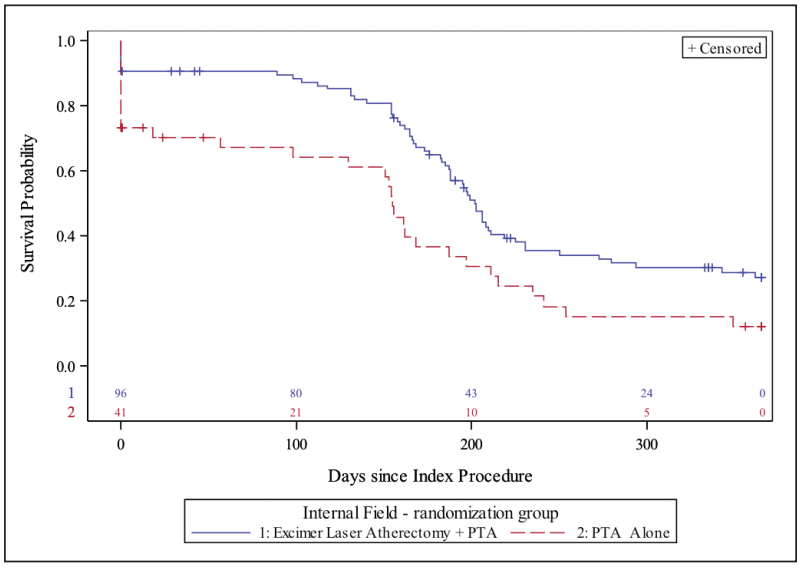

Figure 2. Freedom from TLR through 1 year.

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TABLE 2. EXCITE 12-MONTH SUBANALYSIS: TASC C/D LESIONS

	ELA + PTA (N = 96)	PTA alone (N = 41)	*P* value
Male	58.3%	61.0%	.85
Age (y)	68.5 ± 10.1	68.8 ± 12.1	.89
Critical limb ischemia	24.0%	7.3%	.03
Average lesion length (cm)	27.1 ± 9.0	26.7 ± 9.6	.80
> 30 cm	35.1%	34.2%	1.00
Calcification			
None/mild	70.8%	97.6%	.001
Moderate	26.0%	2.4%	.001
# of below-the-knee runoff vessels			.08
0 or 1	40.6%	24.4%	
2 or 3	59.4%	75.6%	
Outcomes			
Posttreatment % diameter stenosis (core lab reported)	24.6 ± 8.6	30.9 ± 9.2	.001
Posttreatment residual stenosis > 30% (core lab reported)	21.3%	43.2%	.02
Any dissection	1.1%	9.8%	.03
Freedom from TLR at 1 year	47%	25%	.002
Freedom from TLR at 1 year (without bailout stenting)	52.5%	36%	< .05

was achieved. Based on the few patients enrolled in the study, the results suggested that the strategy of ELA and PTA prior to implantation of a stent graft was safe and associated with high procedural success.

ON THE HORIZON

In the United States, paclitaxel DCBs are not yet approved for use in ISR. In Europe, they have shown utility in preventing restenosis in short ISR lesions of the femoropopliteal artery compared with PTA alone.[5] The approval of DCBs in ISR in the United States is eagerly anticipated; however, larger randomized trials are needed to evaluate the potential clinical benefits of these novel combination therapies. Many of these modalities may be complementary, and combination treatment strategies will need to be evaluated through clinical investigation. ■

PHYSICIAN PERSPECTIVE: GOALS IN TREATING ISR

1. **Reduce the likelihood of future treatments:** Recurrent ISR is common even when initial angiographic results are ideal.
2. **Remove as much stenosis as possible:** The stent limits positive remodeling and high-grade stent fractures, and compressed stents greatly increase the risk of repeat restenosis. In theory, removal of NH and thrombus may result in better patency.
3. **Leave nothing behind:** Layering stents can limit future treatment and increase the likelihood of recurrent ISR.

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Craig Walker, MD
Founder, President, and Medical Director
Cardiovascular Institute of the South
Houma, Louisiana
Clinical Professor of Medicine
LSU School of Medicine and Tulane University School of Medicine
New Orleans, Louisiana
drcrwalker@gmail.com
Disclosures: Consultant for Spectranetics Corporation.

Eric J. Dippel, MD, FACC
Interventional Cardiologist
Cardiovascular Medicine PD
The Genesis Heart Institute
Davenport, Iowa
dippel@cvmedpc.com
Disclosures: Advisory board and is a shareholder for Spectranetics Corporation and is on the advisory board for Gore & Associates.

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Diverse Applications for Turbo-Power Excimer Laser Atherectomy

Leading experts in the field present case reports and discuss the utility of excimer laser atherectomy in the SFA and popliteal arteries.

Peripheral vascular disease is a common affliction that affects millions of patients worldwide. Endovascular therapy is becoming an attractive initial strategy adopted by clinicians throughout the spectrum of specialties (vascular surgery, interventional radiology, and interventional cardiology). There are various modalities to treat stenotic or occlusive atherosclerotic disease in the superficial femoral artery. Percutaneous transluminal angioplasty was previously a standard of care; however, results are suboptimal in longer lesions. Atherectomy in peripheral artery disease has gained interest due to its perceived benefits over simple percutaneous transluminal angioplasty without creating barotrauma and overstretching the vessels, and it should yield higher patency rates. The atheroablative laser technology that is currently available is the CVX-300 excimer laser (Spectranetics Corporation). Excimer laser uses flexible fiber-optic catheters that produce photoablation of atherosclerotic disease by using an ultraviolet light at 308 nm to penetrate atheroma, dissolve the molecules (producing thermal energy), and create kinetic energy that breaks chemical bonds at the molecular level and vaporizes intracellular water without damaging the surrounding tissue, thus minimizing restenosis.

The Turbo-Power ELA catheter was introduced by Spectranetics in November 2015 under FDA 510(k) clearance for use in in-stent restenosis. Turbo-Power is a laser atherectomy catheter designed for the treatment of de novo or restenotic lesions in native infrainguinal arteries. This new laser catheter carries rotational capabilities allowing the photomechanical effect created by the laser to impact a larger cross-sectional area within the vessel, which offers more precise directional control. Turbo-Power is compatible with a 7-F delivery system and up to 0.018-inch wires and has fluence (power) between 30 and 60 mJ/mm^2 and frequency (repetition) rate between 25 and 80 Hz.

First-in-Man Application of Turbo-Power Excimer Laser Atherectomy for Treatment of Complex Femoropopliteal ISR

By Amjad AlMahameed, MD, MPH; Pradeep K. Nair, MD, FACC, FSCAI; and Craig Walker, MD

A 62-year-old woman with known advanced atherosclerotic vascular disease presented with true ischemic rest pain (Rutherford class 4). She had undergone stenting of the entire left superficial femoral artery (SFA) and proximal popliteal (femoropopliteal) arteries. She noted disabling recurrent claudication 2 months before her initial outpatient visit. Her exam showed absent pulses in the left leg. Noninvasive evaluation confirmed a marked reduction in resting ankle-brachial index (0.4), and arterial duplex ultrasonography revealed total occlusion of the femoropopliteal arteries and monophasic, low-velocity waveforms in the tibial vessels.

Her past medical history included stable coronary artery disease, coronary artery bypass grafting and stenting, compensated ischemic cardiomyopathy (left ventricular ejection fraction, 35%), moderate bilateral carotid and left subclavian artery stenosis, dyslipidemia, hypertension, and prior cigarette smoking. Medications included atorvastatin, cilostazol, prasugrel, aspirin, and nebivolol.

Selective arteriography of the left lower extremity revealed total occlusion (in-stent restenosis [ISR]) of the entire left SFA and the proximal popliteal artery (Figures 1 and 2), as well as minimal flow into the tibial arteries via antegrade collaterals without discrete runoff to the foot. It was decided that intervention should be performed to revascularize the leg and relieve the symptoms. Because the occlusion was ISR, planned intervention included laser atherectomy, followed by balloon angioplasty.

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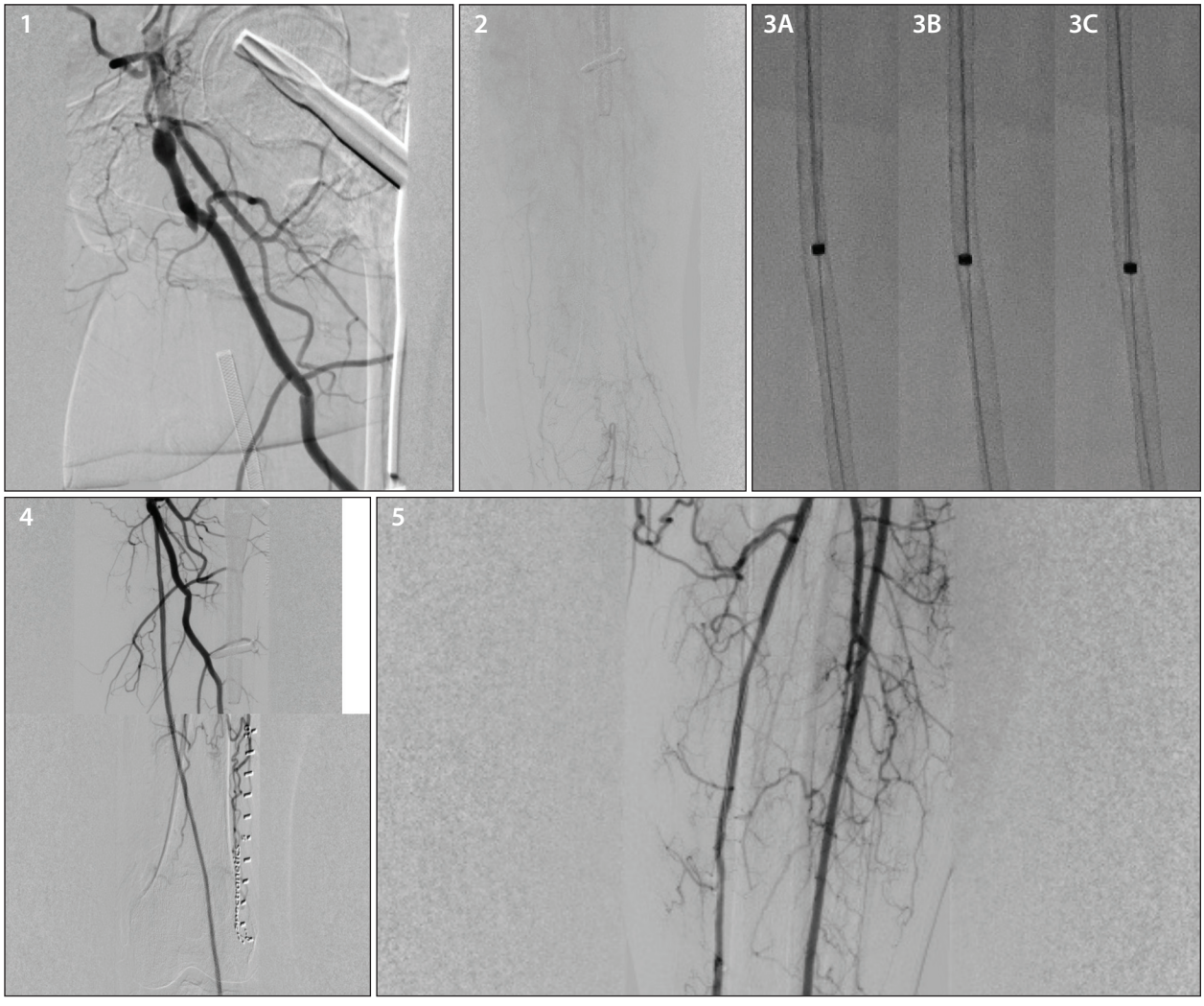

PROCEDURAL DESCRIPTION

Retrograde percutaneous access was achieved via the right common femoral artery. A 7-F Pinnacle Destination sheath (Terumo Interventional Systems) was placed into the distal contralateral external iliac artery. Weight-based intravenous unfractionated heparin was administered and titrated to maintain therapeutic activated clotting time. The patient received aspirin and prasugrel before the procedure. Selective left leg arteriography was performed and illustrated occlusion of the entire SFA and reconstitution at the P2 segment (Figures 1 and 2).

The totally occluded left femoropopliteal segment (Figure 1) was crossed with a combination of a Glidewire (Terumo Interventional Systems) and a 4-F straight Glidecath (Terumo Interventional Systems), which was then exchanged for a 300-cm, 0.018-inch V-18 guidewire (Boston Scientific Corporation). Subsequently, the 2.3-mm OTW Turbo-Power excimer laser atherectomy (ELA) catheter (Spectranetics Corporation) was advanced (Figure 3), and two passes were performed. The first pass used a fluence of 40 mJ/mm^2 and frequency of 40 Hz, and the second pass used a fluence of 60 mJ/mm^2 and frequency of 60 Hz. The Turbo-Power excimer catheter easily traversed this long occlusion. Notably, the catheter tip navigates away from stent struts and realigns to the central lumen. For example, Figure 3A shows the catheter tip in proximity to the lateral aspect of the stent wall, almost in contact with the struts. As the catheter tip was rotated to traverse the lesion at varying angles, the tip rotated medially (as seen in Figure 3B) and allowed for subsequent directional control toward the central lumen (Figure 3C). These still frame images were isolated from a 4-second continuous loop recording.

This was followed by balloon dilatation with a 4- X 200-mm ultra-noncompliant Dorado catheter (Bard Peripheral Vascular, Inc.) at 20 atm. Subsequent angiography showed patency of the treated segment, and diffuse severe disease, and poor flow in the anterior tibial artery. Because there was true ischemic rest pain, the anterior tibial artery was then crossed and dilated with a 2.5- X 300-mm VascuTrak balloon (Bard Peripheral Vascular, Inc.) at 8 atm.

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RESULTS

Final angiography showed an excellent angiographic result with patency of the femoropopliteal segment (Figure 4). The tibial (Figure 5) and pedal vessels were widely patent with two-vessel runoff to the foot.

DISCUSSION

This case represents the first-in-man application of the Turbo-Power ELA catheter for the treatment of ISR and illustrates the technical and anatomical challenges associated with ISR lesions and the complex patient substrate affected by this process. The high-risk characteristics of this lesion include total chronic occlusion of the stents, which involved a very long segment (the entire SFA and part of the popliteal artery), as well as the small-diameter femoropopliteal vessels and the diffusely and severely diseased outflow (tibial) vessels that required recanalization to establish adequate flow to the foot.

Although ISR material can be hardened, effective debulking was achieved utilizing Turbo-Power ELA followed by balloon angioplasty and yielded excellent results and relief of symptoms. Since the system became available, we have routinely applied Turbo-Power directly to totally occluded stents, allowing the device to vaporize at the tip and create its own pilot channel. Employing additional passes and boosting the power can achieve further debulking to maximize luminal gain as needed.

Personalizing PAD Intervention With Laser Atherectomy

By Vinayak Subramanian, BS, and George L. Adams, MD, MHS

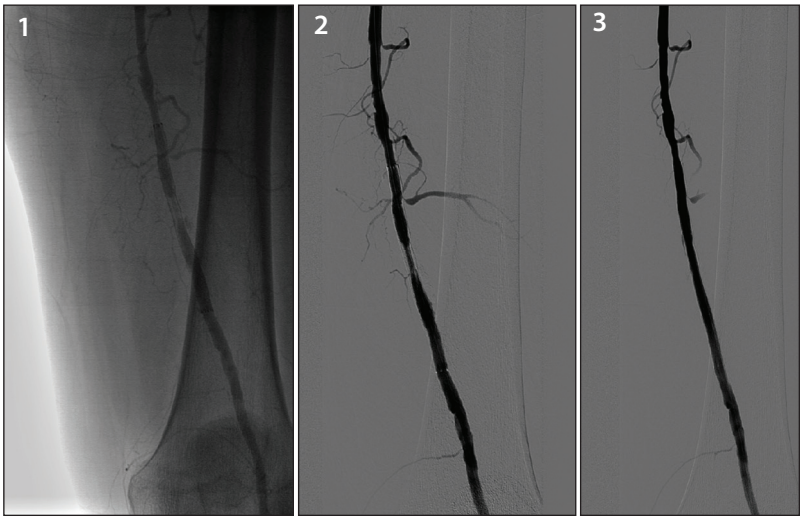
Atherectomy has emerged as a valuable modality for interventionists to treat the complex lesions often involved in peripheral artery disease (PAD). The use of atherectomy to prep the vessels followed by adjunctive therapy with percutaneous transluminal angioplasty or stenting may improve the patency of the vessels and procedural success rates. Laser atherectomy is particularly useful in the treatment of homogenous and thrombotic plaque morphologies, which are common in restenotic lesions often encountered in the PAD population. Laser atherectomy is unlike other atherectomy modalities, which use mechanical interaction between the device and lesion to modify plaque, in that it utilizes a photoablative mechanism instead. This allows it to be used in in-stent restenosis (ISR) lesions. The following case illustrates the utility of laser atherectomy to personalize care for patients in order to optimize procedural success.

PROCEDURAL DESCRIPTION

A 65-year-old man with a past medical history of coronary artery disease, hypertension, and dyslipidemia underwent stenting of his left superficial femoral artery 3 years ago before presenting to our institution. He presented to the clinic with claudication of his left leg after walking < 200 yards. His ankle-brachial index was 0.72, and duplex ultrasound of the left leg showed a > 70% ISR lesion in the distal SFA. Diagnostic angiography confirmed this finding (Figure 1). After successfully crossing the lesion and recognizing that ISR lesions may have a thrombotic component, a 2.3-mm Turbo-Power laser atherectomy device (Spectranetics Corporation) was used to photochemically ablate the lesion. After atherectomy, the stenosis was effectively modified and reduced to approximately 50% (Figure 2). Adjunctive antirestenotic therapy resulted in < 20% residual stenosis (Figure 3).

CONCLUSION

Laser atherectomy is an important tool in the interventionist's tool box for treating PAD. This case illustrates the utility of laser atherectomy in restenotic lesions composed of homogenous/thrombotic plaque. Laser atherectomy allows the operator to personalize therapy, reducing embolic complications and prepping the lesion prior to treatment with angioplasty and/or stenting. To this end, laser atherectomy is a valuable tool to optimize technical success.



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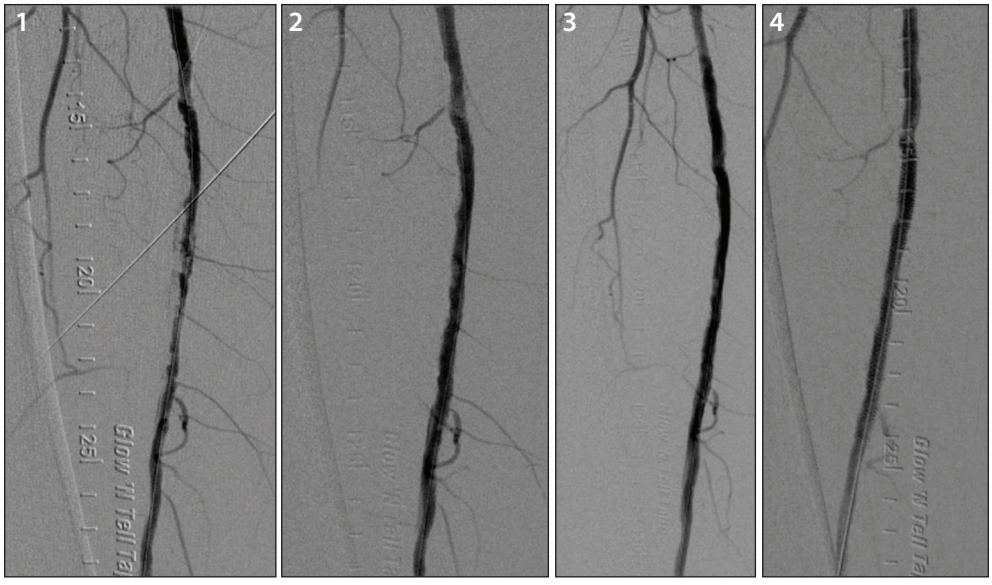
Turbo-Power Excimer Laser Atherectomy for Treatment of a De Novo Lesion in the SFA

By Sachin Kumar Amruthlal Jain, MD, and Prakash Krishnan, MD, FACC, FSCAI



A 70-year-old woman was initially evaluated for bilateral claudication (Rutherford class 2, category 3, Fontaine IIB). The patient complained of worse pain in the right calf. Her Doppler exam revealed a resting ankle-brachial index of 0.70 in her right leg. Her medical history was notable for insulin-dependent diabetes mellitus, hypertension, hyperlipidemia, and prior cigarette smoking. Medications included metformin, metoprolol, losartan, atorvastatin, and insulin. Angiography revealed peripheral artery disease with critical stenosis of the midsegment of the right superficial femoral artery (SFA), as well as moderate stenosis of the tibioperoneal trunk and the anterior tibial artery.

PROCEDURAL DESCRIPTION

The patient underwent endovascular intervention using the left common femoral artery (CFA) access with a micropuncture technique, and a 5-F sheath was placed. A Tempo Flush catheter (Cordis/Cardinal Health) was placed in the distal abdominal aorta, and abdominal angiography was done. A 0.035-inch Wholey guidewire (Medtronic) was used to cross over and placed in the right CFA. Selective right extremity angiography was performed. The 5-F sheath was exchanged for a 7-F Pinnacle Destination sheath (Terumo Interventional Systems) and advanced to the level of the right CFA. A 300-mg oral loading dose and 5,000 units of heparin was given; activated clotting time was checked and found to be therapeutic.

The lesion (Figure 1) in the right SFA was crossed with a 0.014-inch SpartaCore guidewire (Abbott Vascular). A 2.3-mm Turbo-Power excimer laser catheter (Spectranetics Corporation) was used, and two passes were made across the lesion. The first pass was made at a fluence of 45 mJ/mm^2 and a repetition rate of 25 Hz. The catheter was then pulled back and rotated 180°, and a second pass was made at 45 mJ/mm^2 and 45 Hz (Figure 2). The dilation with balloon angioplasty (6- X 20-mm Armada PTA catheter [Abbott Vascular]) was performed subsequent to excimer laser atherectomy (Figure 3). Due to a residual stenosis, a 6- X 80-mm Zilver PTX drug-eluting stent (Cook Medical) was placed at the site of the right SFA (Figure 4). Postdilatation was performed with a 6- X 20-mm Dorado balloon (Bard Peripheral Vascular, Inc.).

RESULTS

There were no complications during the procedure, and final angiography revealed a widely patent right SFA with brisk flow and no residual stenosis. There was excellent distal flow and no evidence of embolization.

DISCUSSION

The use of the Turbo-Power excimer laser device provides an excellent treatment option for de novo lesions in the SFA. In this case, use of laser atherectomy provided an optimal interventional result with no change in distal postintervention runoff.

Laser is very useful in crossing chronic total occlusions or long stenotic lesions. The Turbo-Power catheter is designed to treat at the tip with vaporizing technology for maximal luminal gain. The device debulks the lesion in a single step and offers remote automatic rotation for precise directional control.

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Laser Atherectomy for Chronic Total Occlusion

By Fadi Saab, MD, and J.A. Mustapha, MD

Peripheral vascular disease is a common disease that impacts millions of patients worldwide. Endovascular therapy is becoming an attractive initial strategy adopted by clinicians throughout the spectrum of specialties (vascular surgery, interventional radiology, and interventional cardiology). Laser atherectomy is a time-honored tool that has been utilized effectively in multiple infrainguinal vascular beds. The unique mechanism of action in laser atherectomy allows the operator to achieve multiple short- and long-term goals. The goals include plaque debulking in relatively large vascular conduits (superficial femoral artery [SFA] and popliteal artery) and extend to plaque modification in relatively smaller vascular beds in the tibial plantar circulation. The following case study demonstrates the application of this new device in a patient with a chronic total occlusion (CTO).

A 57-year-old man presented with complaints of life-limiting claudication that affected his ability to work (Rutherford class 3). The patient was unable to ambulate more than 25 feet secondary to significant discomfort in his left calf. He was an active smoker with more than a 30 pack-year history of smoking. His medical history included multiple risk factors, including hypertension, type 2 diabetes, and hyperlipidemia.

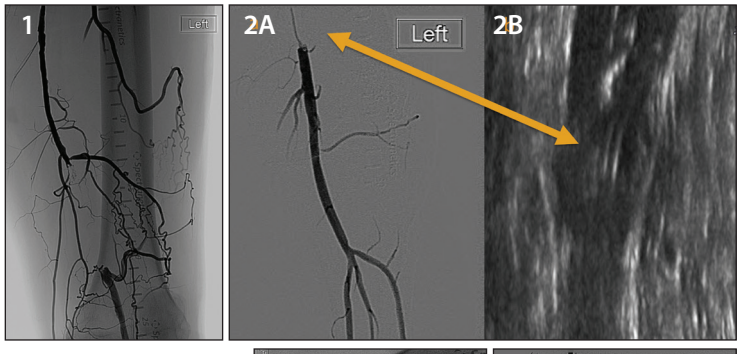
Cardiovascular exam had relatively normal results. Pulses were intact in the upper extremities. Groin pulses were palpable bilaterally with presence of a loud right groin bruit. Pedal and popliteal pulses were not palpable. Doppler examination revealed bilateral monophasic pedal pulses. Ankle-brachial index (ABI) revealed a severely diminished left ABI at 0.5. The pulse volume recording suggested a diminished waveform in the calf region. These findings supported the possibility of severe infrainguinal femoropopliteal disease.

The patient agreed to stop smoking with the aid of pharmacologic therapy. He was already on appropriate medical therapy with aspirin and statin and had historically not tolerated additional therapy with cilostazol. A diagnostic angiogram was performed, which identified disease involving the left SFA (Figure 1).

PROCEDURAL DESCRIPTION

The decision to treat with an endovascular approach was pursued. After obtaining ultrasound-guided access in an antegrade fashion of the left common femoral artery (CFA), angiography was performed. The distal SFA was occluded with reconstitution in the popliteal artery. CTO crossing and treatment of the lesion was approached in the following stepwise fashion:

1. Extravascular ultrasound (EVUS) assisted crossing of the 100% occluded left SFA/popliteal artery. This technique relies on visual feedback from the equipment within the vessel using an ultrasound probe. The EVUS technique guided the 0.035-inch support catheter to navigate the CTO. Once crossed into the reconstitution, intravascular position of the catheter tip was confirmed via angiography (Figure 2A). The hypo-echogenic appearance was suggestive of an atherothrombotic plaque under ultrasound (Figure 2B).
2. After crossing the CTO, an Emboshield Nav6 embolic protection device (EPD) (Abbott Vascular) was deployed.
3. Ultrasound-guided atherectomy was performed using 2.3 Turbo-Power laser atherectomy (Spectranetics Corporation), utilizing the rotating function of the catheter while advancing the device. Slow advancement is essential to capitalize on the effect of laser atherectomy.



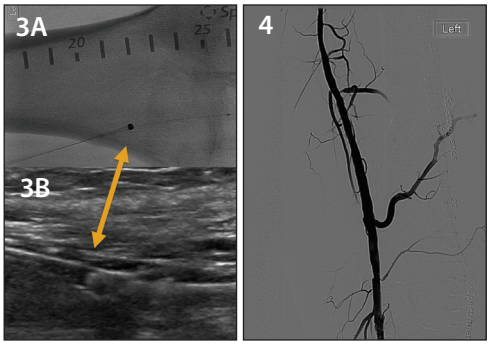


Figure 1. Angiogram of occluded distal left SFA extending into the popliteal artery.
Figure 2. Angiogram after crossing the CTO (A). EVUS image of crossing catheter within the lumen of the vessel (B). The CTO is identified by the arrow in each image.
Figure 3. Turbo-Power laser atherectomy performed under fluoroscopy (A) and EVUS (B).
Figure 4. Final angiogram after Turbo-Power laser atherectomy and angioplasty with a drug-coated balloon.

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The eccentric beam created can affect a larger area than its traditional coaxial predecessor. In addition, the rotational capabilities allow the catheter to travel the length of the vessel in an easier fashion. Figure 3 shows the catheter activated under ultrasound and fluoroscopic guidance.

4. After debulking and plaque modification, an angiogram showed a brisk flow with no immediate complication. The EPD was retrieved, and the case proceeded to final therapy.

5. Using a 6-mm AngioSculpt balloon (Spectranetics Corporation), the vessel was treated with low atmospheric balloon angioplasty (5 atm) followed with a 7-mm In.Pact Admiral (Medtronic) drug-coated balloon inflated for 3 minutes. Final angiogram showed brisk flow with no immediate complications (Figure 4).

RESULTS

The patient was discharged home the next day. On 30-day follow-up, he reported complete resolution of his claudication symptoms (Rutherford class 0). His left ABI normalized at 0.97, with arterial duplex evaluation showing vessel patency. The patient was maintained on dual antiplatelet therapy and aggressive lipid-lowering therapy.

The current body of evidence suggests that laser atherectomy in patients with de novo lesions or in-stent restenosis may have better outcomes in contrast to balloon angioplasty alone. Ongoing trials and registries, such as the Peripheral Registry of Endovascular Clinical Outcomes (PRIME registry), continue to explore treatment algorithms in peripheral vascular disease and critical limb ischemia. ■

Amjad AlMahameed, MD, MPH
Interventional Cardiologist
Cardiovascular Institute of the South
Houma, Louisiana
drmjhameed@gmail.com
Disclosures: None.

Pradeep K. Nair, MD, FACC, FSCAI
Interventional Cardiologist
Cardiovascular Institute of the South
Houma, Louisiana
Disclosures: None.

Craig Walker, MD
Interventional Cardiologist
Founder, President, and Medical Director
Cardiovascular Institute of the South
Houma, Louisiana
Clinical Professor of Medicine, LSU School of Medicine and Tulane University School of Medicine
New Orleans, Louisiana
drcrwalker@gmail.com
Disclosures: Consultant/medical/scientific boards for Abbott Vascular, Boston Scientific Corporation, Cardiva, Cook Medical, Bard Peripheral Vascular, Lake Regional Medical, Medtronic, Spectranetics Corporation; PVD training for Abbott Vascular, Bard Peripheral Vascular, Boston Scientific Corporation, Spectranetics Corporation, TriReme Medical; stockholder in CardioProlific, Cardiva, Spectranetics Corporation, Vasamed; and on the speakers' bureau for Abbott Vascular, Bard Peripheral Vascular, Boehringer Ingelheim, Bristol-Myers-Squibb/Sanofi, Cardiva, Cook Medical, Cordis Corporation, DSI/Lilly, Gore & Associates, ACHL/Merck, and Spectranetics Corporation.

Vinayak Subramanian, BS
Department of Biomedical Engineering
North Carolina State University
Raleigh, North Carolina
Disclosures: None.

George L. Adams, MD, MHS
Rex Hospital
University of North Carolina Health System
Raleigh, North Carolina
george.adams@unchealth.unc.edu
Disclosures: Consultant for Spectranetics Corporation.

Sachin Kumar Amruthlal Jain, MD
Endovascular Interventional Cardiology Fellow
Mount Sinai Heart
New York, New York
doctorsachin@gmail.com
Disclosures: None.

Prakash Krishnan, MD, FACC, FSCAI
Assistant Professor of Medicine–Cardiology and Radiology
Icahn School of Medicine
Director of Endovascular Interventions
Mount Sinai Hospital
New York, New York
prakash.krishnan@mountsinai.org
Disclosures: Speaker and teacher for Abbott Vascular, Bard Peripheral Vascular, Inc., and Medtronic.

Fadi Saab, MD
Interventional Cardiologist
Metro Health Hospital
Wyoming, Michigan
Clinical Assistant Professor of Medicine
Michigan State University CHM and COM
East Lansing, Michigan
Disclosures: Consultant for Spectranetics Corporation, Abbott Vascular, and Medtronic, Inc.

J.A. Mustapha, MD
Director, Cardiovascular Catheterization Laboratories
Metro Health Hospital
Wyoming, Michigan
Clinical Assistant Professor of Medicine
Michigan State University CHM and COM
East Lansing, Michigan
jihad.mustapha@metrogr.org
Disclosures: Consultant for Spectranetics Corporation, Abbott Vascular, and Medtronic, Inc.

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What Does Histology Say About Vessel Preparation in Femoropopliteal ISR?

Initial pilot study results on laser revascularization with adjunctive DCB use.

BY RENU VIRMANI, MD, FACC, AND FRANK D. KOLODGIE, PHD

Peripheral artery disease (PAD) represents an advanced stage of atherosclerotic disease with an increasing prevalence, particularly in an aging population.[1] In regard to femoropopliteal disease, the most common location for occlusion is the superficial femoral artery (SFA), as it's uniquely one of the longest and most dynamically active vessels in the body, undergoing torsion, compression, flexion, and extension from hip and knee motion. Moreover, it has been reported that blood flow patterns associated with complex vascular geometry of the femoral artery is conducive to the development of atherosclerosis. Historically, the treatment of PAD was managed by medical therapy and open surgical bypass procedures.[2] Over the past decade, endovascular therapies including percutaneous transluminal angioplasty (PTA), stenting, and atherectomy, have evolved and become more widespread. However, endovascular procedures such as stenting invariably cause mechanical overstretch, resulting in endothelial denudation, plaque dissection, lesion protrusion into the lumen, rupture of the internal elastic lamina, and medial tears. Consequently, primary patency and clinical outcomes are dependent on the extent of vessel recoil with repair mechanisms that contribute to neointimal hyperplasia. The influence of these processes over time with continuous stress eventually lead to the formation of a complex in-stent restenotic (ISR) lesion with an underlying morphology that is distinct from de novo lesions.[3]

ISR lesions are heterogeneous and consist primarily of collagen types I and III along with varying amounts of proteoglycans and smooth muscle cells (60%–80% of the restenotic volume is aqueous), resulting in a high restenosis burden. A variety of factors contribute to the development of SFA ISR (Figure 1). Angiographic characteristics of femoropopliteal ISR lesions are also an important predictor of subsequent outcomes. Tosaka et al[4] described angiographic patterns of ISR specific to the femoropopliteal segment: short, focal lesions (class I: ≤ 50 mm) and diffuse lesions (class II: > 50 mm) are associated with reasonable patency after treatment; however, total in-stent occlusions (class III) often predict recurrent ISR

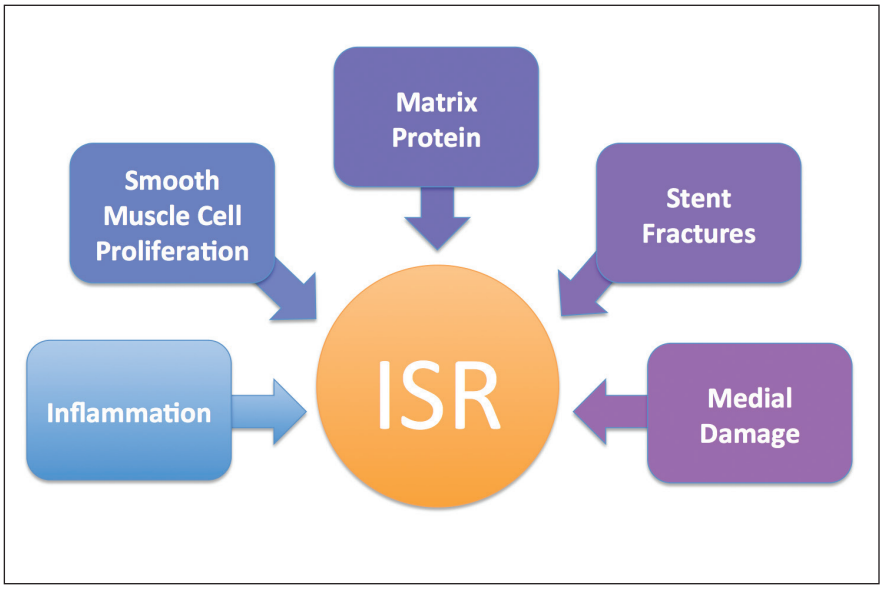

Figure 1. Factors contributing to ISR.

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TABLE 1. HISTOMORPHOMETRY 28 DAYS AFTER TREATMENT (120D IN FIGURE 2)

	Sections	Lumen Area (mm^2)	Neointimal Area (mm^2)	Stenosis (%)	Neointimal Thickness (mm)
PTA + DCB	6	2.91 ± 0.58	2.82 ± 0.3	49.59 ± 6.74	0.35 ± 0.05
Laser + DCB	12	3.60 ± 0.94	2.36 ± 0.54	40.27 ± 11.50	0.21 ± 0.12
P value	–	.060	.036*	.044*	.012*

Abbreviations: DCB, drug-coated balloon; PTA, percutaneous transluminal angioplasty.
*Significant based on one-tailed t-test ($P < .05$).

when treated with PTA (85% recurrence at 2 years).[4] Approximately one-third of ISR lesions are class III total occlusions,[4,5] confirming the inadequacy of simple balloon dilation (angioplasty) and the need for more advanced endovascular techniques in this complex subset of lesions.

ESTABLISHING A TRANSLATIONAL MODEL TO ASSESS ISR-CTO TREATMENTS

Currently, there is no reliable translational ISR-chronic total occlusion (CTO) model to assess endovascular devices and treatments. An ISR model in the carotid artery of hypercholesterolemic rabbits was established after stent overstretch and bovine thrombin injections to create CTOs (Figure 2), thereby mimicking class III-type lesions in humans. The composition of the matured thrombus within the stent mass is mainly derived from dense to loosely packed smooth muscle cells within a proteoglycan matrix, scattered nonfoamy macrophages, and varying degrees of angiogenesis, similar to what has been observed in human ISR lesions/total occlusions. The creation of this animal model of ISR-CTO allows for pilot studies to explore the potential benefits of new technologies, such as drug-coated balloons (DCBs), that are currently not approved for use in human ISR in the United States. The objective of our pilot study was to assess the early outcomes of laser debulking with adjunctive DCB (n = 4) compared with standard PTA and DCB (n = 3) in a rabbit model of ISR CTO.

Figure 2

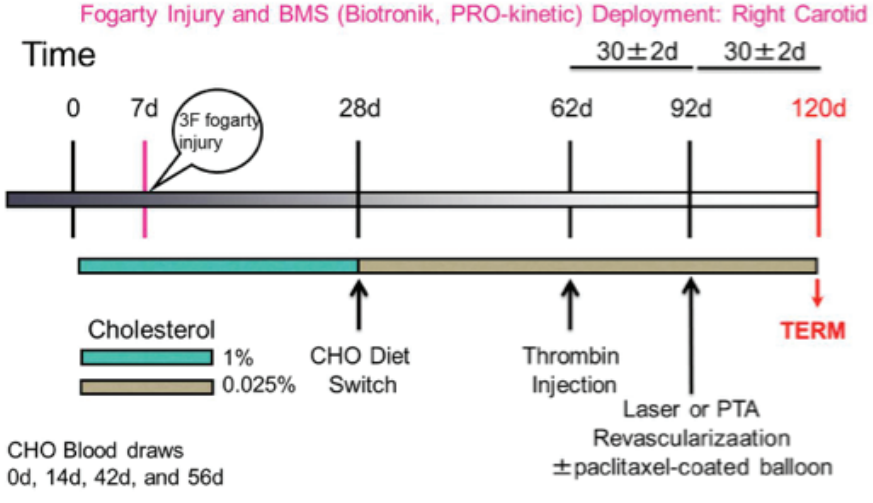

Figure 2. Experimental design, animal model of ISR-CTO. The study lasted for a total of 120 days. Animals were fed a 1% high-cholesterol diet (0–28d; CHO) with subsequent 3-F Fogarty-induced vascular injury and bare-metal stent implantation after 7 days (7d). The atherogenic high-cholesterol diet was continued until day 28 (28d), at which time the diet was switched to 0.025% cholesterol for the remainder of the study. An intraluminal bovine thrombin injection was performed at 62 days (62d) after initiation of the CHO diet to create the total occlusion. Thirty days after thrombin injection, animals underwent endovascular treatment (92d). Final follow-up results were obtained 28 days after treatment (120d).

Persistent in-stent total occlusion at the time of the endovascular intervention (Figure 2, 92d) was noted in seven of eight arteries. Of the vessels that were occluded at treatment, 75% of laser and DCB vessels (3 of 4) versus 0% (0 of 2) PTA and DCB–treated vessels remained patent at 28-day postintervention follow-up (Figure 2; 120d). The PTA and DCB group exhibited an

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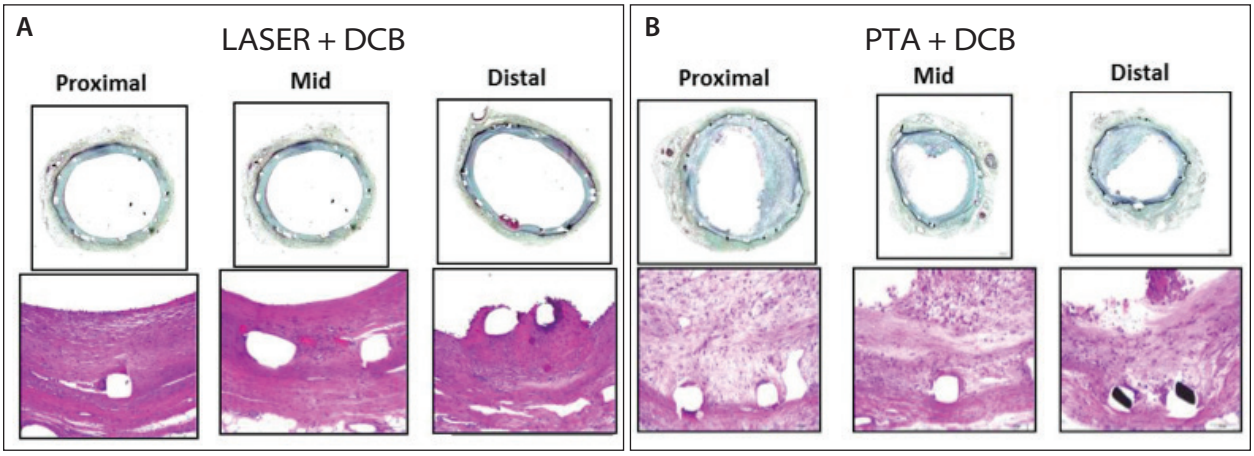

Figure 3. Selected in-stent histomorphology 28 days after treatment (120d in Figure 2). Laser and DCB, the stent remains widely patent 28 days after treatment (A). PTA and DCB, the stent remains occluded 28 days after treatment (B).

unhealed luminal surface with exposed plaque material consisting mainly of macrophage-derived foam cells and focal platelets/fibrin with incomplete endothelium while the laser and DCB treatment showed focal fibrin deposition and/or inflammatory cell aggregates admixed with fibrin, whereby stent struts were covered by a thin neointimal layer. Laser debulking with adjunct paclitaxel DCB in established CTOs in the animal model produced overall better lumen quality, reduced stenosis, and lessened intimal thickness at 28 days after treatment compared to PTA and DCB (Table 1; Figure 3).

CONCLUSIONS

The management of ISR can be very challenging and may require repeated interventions. This pilot study confirms the feasibility and successful outcome of laser revascularization with DCB adjunctive in a rabbit carotid artery in-stent total occlusion model. ■

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Renu Virmani, MD, FACC
President
CVPath Institute, Inc.
Gaithersburg, Maryland
rvirmani@cvpath.org
Disclosures: Research support from Abbott Vascular, BioSensors International, Biotronik, Boston Scientific Corporation, Medtronic, MicroPort Medical, OrbusNeich Medical, SINO Medical Technology, and Terumo Interventional Systems; speaker for Merck; honoraria from Abbott Vascular, Boston Scientific Corporation, Bard Peripheral Vascular, Medtronic, and Terumo Interventional Systems; consultant for 480 Biomedical, Abbott Vascular, Medtronic, and Gore & Associates.

Frank D. Kolodgie, PhD
Associate Director
CVPath Institute, Inc.
Gaithersburg, Maryland
Disclosures: None.

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Treatment of Complex Femoropopliteal Lesions Using the Turbo-Power Excimer Laser

Targeting ISR, chronic total occlusions, and heavy thrombus burden with laser atherectomy.

BY EHRIN J. ARMSTRONG, MD, MSc

Excimer laser atherectomy has a number of diverse applications for treatment of complex femoropopliteal lesions. By acting through a unique combination of photochemical, photomechanical, and photothermal mechanisms, excimer laser atherectomy can effectively ablate both mixed morphology and thrombotic lesions in the superficial femoral artery (SFA), popliteal, and infrapopliteal vessels.

The Turbo-Power excimer laser (Spectranetics Corporation) was approved by the US Food and Drug Administration (FDA) in November 2015 for the treatment of infrainguinal de novo and in-stent restenosis (ISR). The device features a 2.3-mm excimer laser fiber pack that is eccentrically offset from a 0.018-inch wire lumen port. Rotation of the device (up to six rotations in each direction) allows the laser to create a larger lumen cross-section area than a standard 2.3-mm laser, and therefore maximize plaque debulking and lesion modification. Another advantage of the Turbo-Power laser is the combined ability to create a pilot channel (using the 2.3-mm laser without rotation), followed by more extensive debulking using the rotational function of the device. The current iteration of the Turbo-Power is 7-F compatible and can be used at a fluence of up to 60 mJ/mm^2 and frequencies up to 80 Hz. Potential clinical applications of the Turbo-Power system include maximal debulking for treatment of femoropopliteal in-stent restenosis (FP-ISR), modification of complex femoropopliteal lesions, and treatment of large thrombus burden among patients with acute limb ischemia.

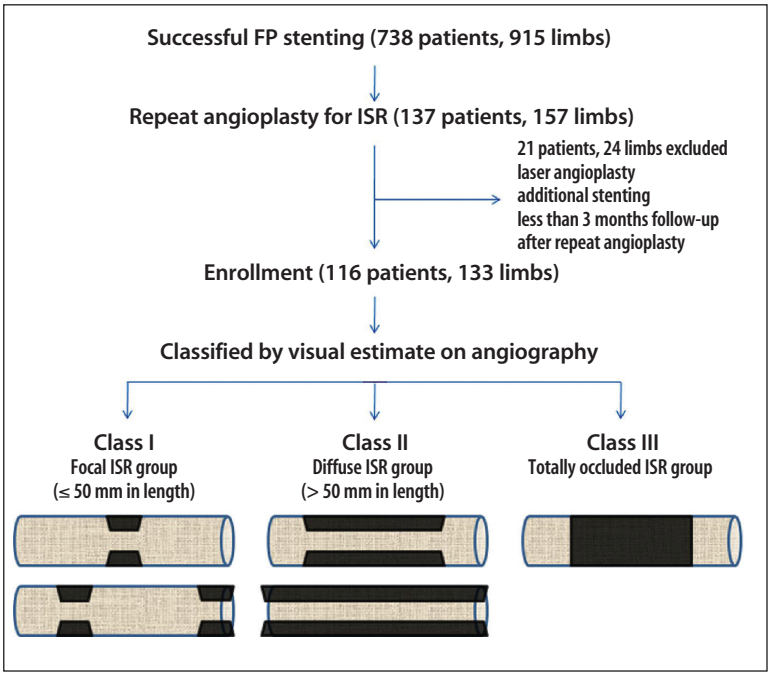

Figure 1. Visual estimate of lesion classification on angiography. Reprinted from J Am Coll Cardiol, Vol 59, Tosaka A, Soga Y, Iida O, et al, Classification and clinical impact of restenosis after femoropopliteal stenting, pg 16-23, Copyright 2012, with permission from Elsevier.[1]

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FEMOROPOPLITEAL IN-STENT RESTENOSIS

FP-ISR is a common problem associated with high rates of restenosis after balloon angioplasty and/or adjunctive stenting. The Tosaka classification provides a stratification of outcomes for FP-ISR after balloon angioplasty (Figure 1).[1] Tosaka class I FP-ISR, defined as focal stenosis of ≤ 50 mm in length, is associated with relatively high rates of patency after balloon angioplasty, whereas Tosaka class II (diffuse restenosis > 50 mm) and Tosaka class III FP-ISR (in-stent occlusion) are associated with high rates of restenosis after treatment with balloon angioplasty. Additional adjunctive therapies are therefore necessary to optimize the long-term outcomes of patients with FP-ISR.[2]

Laser atherectomy is an effective and FDA-approved treatment for FP-ISR. The recently published EXCITE-ISR trial was a randomized study of laser atherectomy with adjunctive balloon angioplasty versus balloon angioplasty alone for the treatment of FP-ISR.[3] The primary efficacy endpoint of the study was target lesion revascularization at 6 months. The trial demonstrated procedural safety of laser atherectomy, as well as higher rates of acute procedural success. At 6 months, freedom from target lesion revascularization was 73.5% for patients treated with laser atherectomy versus 51.8% for patients treated with balloon angioplasty. Real-world observational data have also confirmed the benefit of laser atherectomy, with the greatest benefit seen among patients with long-segment FP-ISR (Tosaka class II) or in-stent occlusion (Tosaka class III).[4] Application of the Turbo-Power laser to the treatment of FP-ISR may provide additional benefit to previous excimer laser catheters, as the increased luminal gain with rotational laser atherectomy may more effectively ablate neointima prior to balloon angioplasty or other adjunctive therapies.

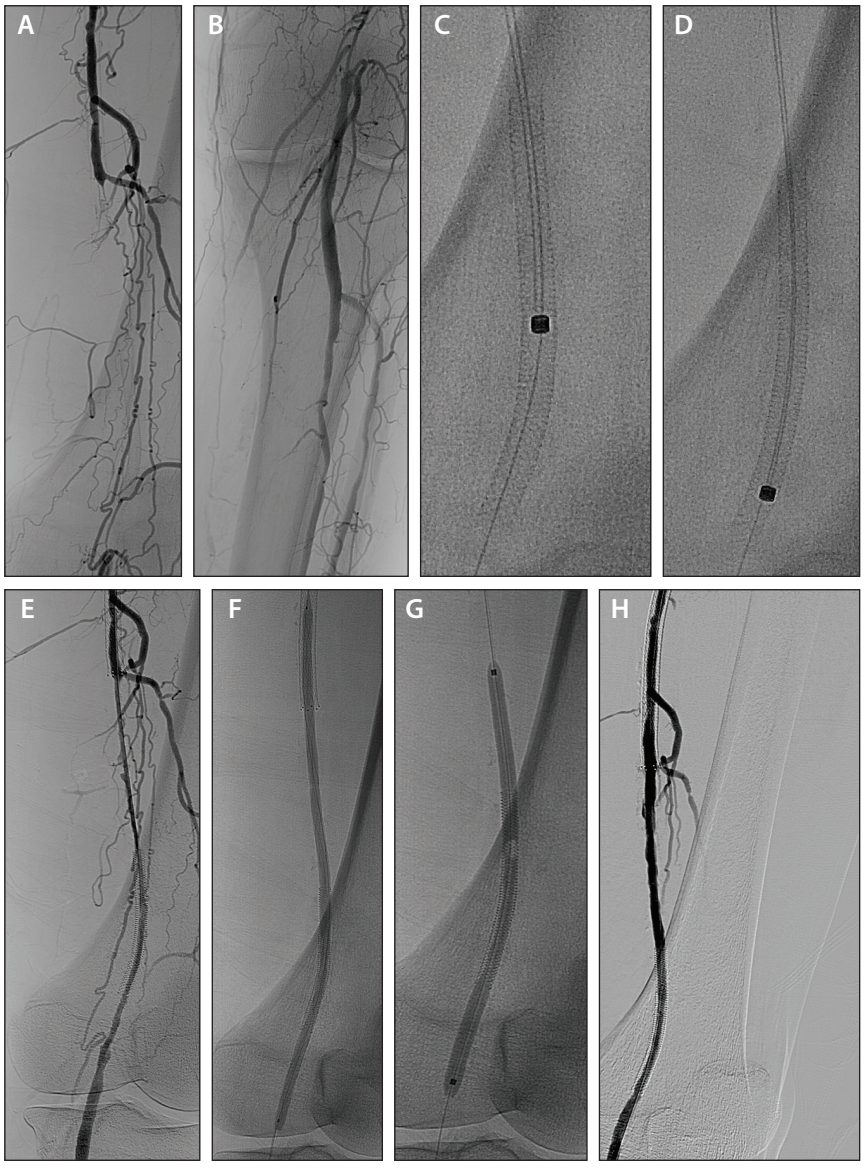

Figure 2. Treatment of femoropoliteal in-stent restenosis with Turbo-Power excimer laser.

Figure 2 illustrates a case of a patient with long-segment FP-ISR due to occlusion of nitinol stents that had been placed 2 years prior in the distal SFA and proximal popliteal artery (Figure 2A and 2B). The FP-ISR segment was successfully crossed with a Treasure 12 0.018-inch wire (Asahi Intecc USA, Inc.). Four quadrant passes were then performed with the Turbo-Power laser at a fluency of 60 mJ/mm^2 and rate of 60 Hz. Figures 2C and 2D demonstrate the eccentric wire position of the Turbo-Power with rotation; the relative location of the fiber pack to the wire can be used to orient the laser for differential cutting. Subsequent angiography confirmed excellent luminal gain with laser atherectomy (Figure 2E).

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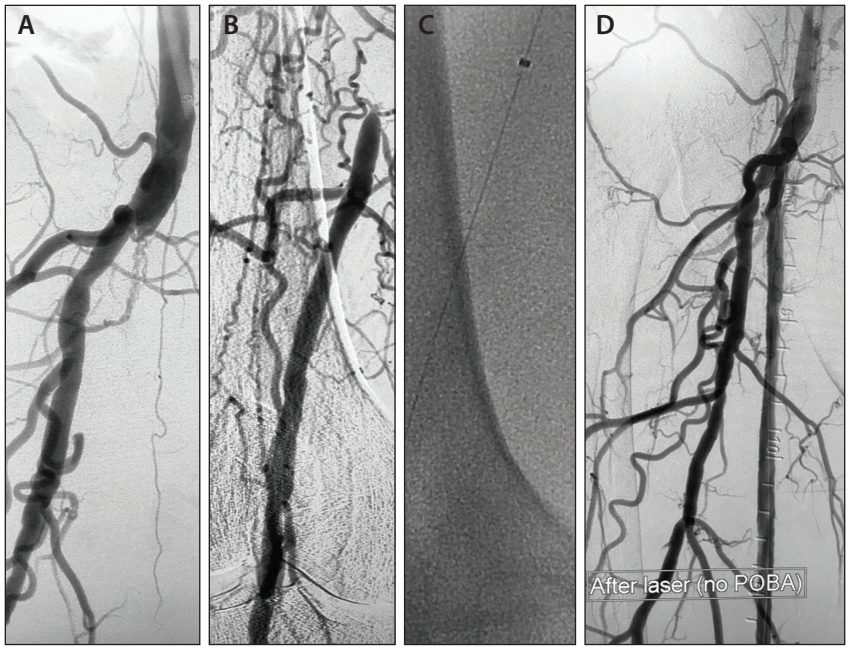

Figure 3. Treatment of a long SFA occlusion with the Turbo-Power excimer laser.

A 5- X 200-mm AngioSculpt balloon (Spectranetics Corporation) was then deployed to maximize stent expansion (Figure 2F), followed by angioplasty with two overlapping 5- X 120-mm In.Pact paclitaxel-coated balloons (Medtronic) (Figure 2G). Final angiography revealed excellent angiographic results with minimal recoil.

The patient remains asymptomatic at 6 months with a patent stent by duplex ultrasound. This case demonstrates the effective role of the Turbo-Power for neointimal ablation.

COMPLEX FEMOROPOPLITEAL OCCLUSIONS

Laser atherectomy has been extensively studied for the treatment of femoropopliteal chronic total occlusions. In many cases, femoropopliteal occlusions have an organized cap at the proximal edge, but softer plaque and semiorganized thrombus in the mid- to distal segment of the occlusion. The application of laser atherectomy to ablate thrombus and mixed morphology may therefore simplify the overall treatment of an otherwise long-segment occlusion. Multiple studies have demonstrated that laser atherectomy is safe and effective for treatment of long-segment femoropopliteal occlusions, with lower rates of bailout stenting compared to balloon angioplasty alone.[5-7]

Figure 3 demonstrates a case of a 74-year-old man with a history of Rutherford class III claudication despite optimal medical therapy and completion of a walking program. The patient had a proximal occlusion of the SFA (Figure 3A) with reconstitution in the distal vessel just proximal to Hunter's canal (Figure 3B). The lesion was crossed through the true lumen using a Treasure 12 0.018-inch wire. Laser atherectomy was then performed with four passes of the Turbo-Power laser; each pass was made in a different quadrant (Figure 3C). Subsequent angiography demonstrated dramatic ablation of the lesion with antegrade flow and minimal dissection throughout the entire course of the SFA (Figure 3D). The patient was then treated with overlapping paclitaxel drug-coated balloons (DCBs). Final angiography revealed preserved three-vessel runoff without any distal embolization. The patient has done well for the past 6 months, without any symptoms of claudication and no evidence of restenosis by duplex ultrasound.

BYPASS GRAFT OCCLUSION

Excimer laser atherectomy is especially effective at ablating thrombus, based on the observation that the maximal absorption spectrum of thrombus closely overlaps the 308-nm ultraviolet light spectrum of the excimer laser. For this reason, the Turbo-Power laser may be particularly effective for treatment of lesions with large thrombus burden. Possible applications include the use of the Turbo-Power in cases of acute limb ischemia due to stent thrombosis or surgical graft thrombosis. In such cases, use of excimer laser atherectomy may offer advantages over the use of intra-arterial tPA by avoiding the need for lytics and the attendant risk of bleeding.

Figure 4 demonstrates a case of Turbo-Power laser atherectomy for the treatment of bypass graft thrombosis. A 67-year-old man with a past medical history of severe claudication and prior right lower extremity femoropopliteal bypass complicated by graft stenosis 2 years prior presented with acute onset of right lower extremity pain and sensory loss. The patient was taken urgently to the catheterization laboratory, where angiography revealed acute thrombosis of the bypass graft and chronic occlusion of the patient's native SFA, with reconstitution via collaterals in the below-knee popliteal artery (Figures 4A and 4B). A Turbo-Power laser was used at a fluence of 60 mJ/mm^2 and rate of 60 Hz throughout the approximately 400-mm length of the

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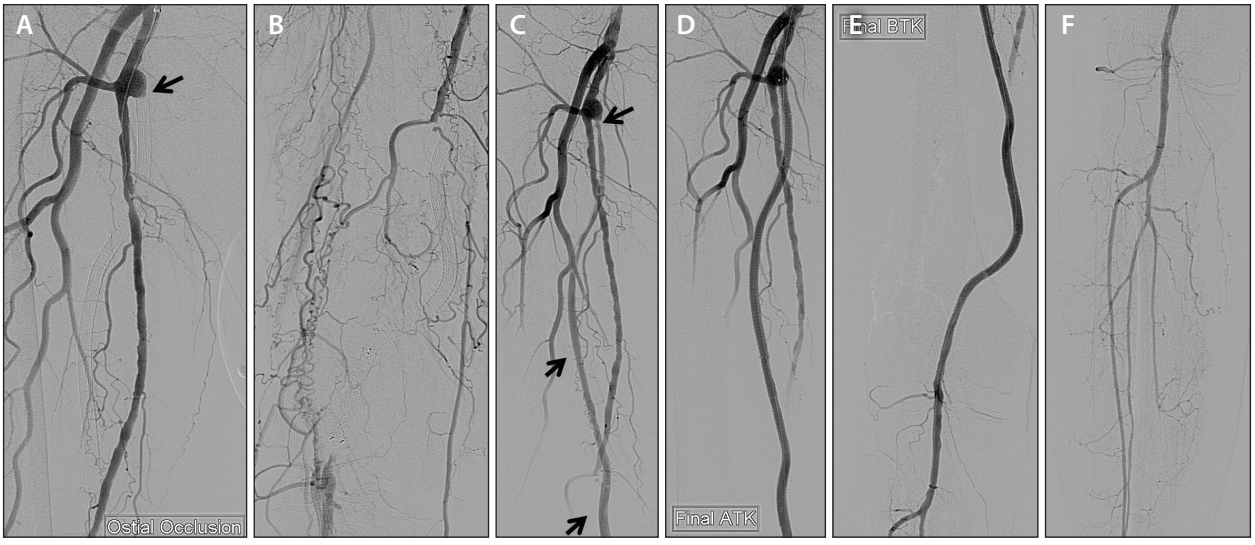

Figure 4. Treatment of a thrombosed bypass graft with the Turbo-Power excimer laser.

graft, with a total of four directional passes. Subsequent angiography revealed significant ablation of thrombus with antegrade flow (Figure 4C). Further balloon angioplasty achieved an excellent angiographic result, with brisk antegrade flow, three-vessel distal runoff, and no evidence of distal embolization (Figures 4D–4F). This case demonstrates the efficacy of laser atherectomy for treatment of acute thrombosis, even in long-segment graft thrombosis. Close attention to slow advancement of the laser at 1 mm/sec helps maximize thrombus ablation and minimize the risk of distal embolization.

FUTURE DIRECTIONS

Eccentric debulking using the Turbo-Power laser is an effective tool for treatment of many complex femoropopliteal pathologies, including in-stent restenosis, long-segment femoropopliteal occlusions, and graft thrombosis. Future studies will provide real-world data on clinical outcomes with this and other atherectomy devices. Of special interest is the possible combined application of laser atherectomy with DCB technology. Although not currently approved for this indication in the United States, DCBs have demonstrated improved outcomes for treatment of FP-ISR compared to historical outcomes with balloon angioplasty in a few studies.[8,9] The Turbo-Power laser provides better acute luminal gain in FP-ISR, which may make it a good preparation for DCBs. Although a small study has shown a possible benefit of combined laser atherectomy with DCB angioplasty for the treatment of FP-ISR,[10] additional studies are necessary to determine the benefits of this combined treatment approach for FP-ISR and other de novo femoropopliteal disease. ■

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Ehrin J. Armstrong, MD, MSc
Division of Cardiology
University of Colorado School of Medicine
ehrin.armstrong@gmail.com
Disclosures: Consultant for Abbott Vascular, Boston Scientific Corporation, Cardiovascular Systems, Inc., Cook Medical, Medtronic, and Spectranetics Corporation.

TRUTH #14

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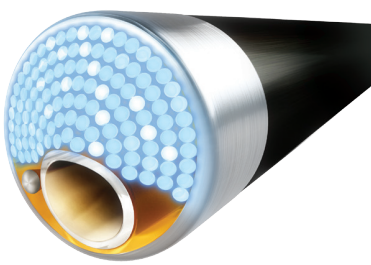

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