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# Endovascular TODAY

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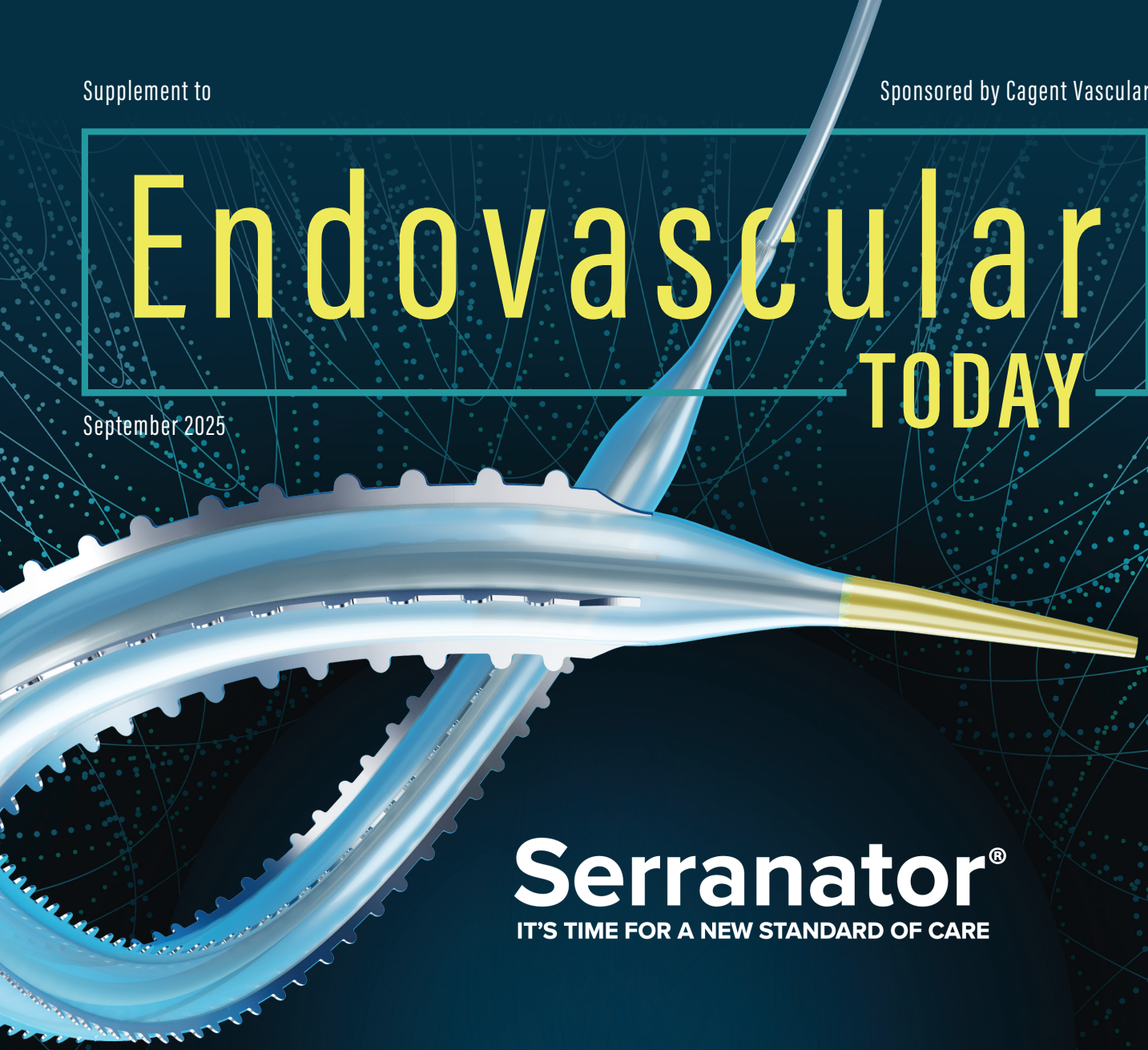



# ADVANCING YOUR ALGORITHM

## Real-world perspectives and cases in PAD and CLI treatment

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# Recoil, Dissection, and Restenosis in Below-the-Knee Arteries After Standard Balloon Angioplasty

Tools and techniques for addressing current challenges in the treatment of peripheral artery disease.

**By Michael Lichtenberg, MD**

The latest Global Burden of Disease Study report shows that the total number of people with peripheral artery disease (PAD) has increased globally from 1990 to 2019.[1] Chronic limb-threatening ischemia (CLTI) is the most severe manifestation of PAD, defined by critical hemodynamic status responsible for ischemic rest pain, nonhealing chronic ulceration (> 2 weeks of duration), or foot gangrene.[2] CLTI is commonly encountered in the tibiopedal vessels located below the knee (BTK), where surgical or endovascular treatments can be particularly challenging.

In BTK vessel recanalization, dissection is a severe problem after endovascular therapy, with an incidence varying from 5.9% to 30.7% (8 times more dissections detected on intravascular ultrasound vs angiography).[3-5]

One approach to treat post–balloon angioplasty dissection is to compress the separated intima using a slightly oversized balloon at low pressures with long inflation duration (≥ 3 minutes). Data show that severe dissections (type C or higher) in femoropopliteal (FP) lesions were observed less frequently after prolonged balloon dilation (> 3-minute inflation group: 22.7% vs 50.9%; $P < .001$),[6] and also immediate improvements in angioplasty in infrainguinal lesions were seen with 3-minute balloon inflation versus a short dilation strategy.[7] Furthermore, long versus short balloons may also affect the occurrence of dissections in the FP segment.[8] It has been shown that severe vessel dissection patterns (type C or higher) were fewer and shorter when using a long balloon after balloon angioplasty.[7]

## CUTTING, SCORING, AND MINIMAL TRAUMA BALLOONS

Given the challenges, dissections likely require additional treatment approaches, as they have been associated with reduced patient health outcomes. Long lesions with limited calcification and small diameter are more prone to dissection, and specialty balloons may limit the rates of dissection and bailout stenting.[8,9] There are three categories of specialty balloons that can be used: cutting balloons, scoring balloons, and minimal trauma balloons. Cutting balloons include very sharp metal blades at their surface for cutting the atherosclerotic plaque at a specific location. Scoring balloons have wires or polymer running over them, which significantly increase the pressure at specific points associated with precise rupture of the plaque—these have shown success in above-the-knee lesions, but further studies are needed to confirm the results obtained in small studies. Minimal trauma balloons can be encased in a nitinol cage, creating a series of grooves and pillows that limit the propagation of dissection into the vessel wall (eg, Chocolate PTA balloon, Medtronic). In this last case, the cage enables the balloon to dilate in a controlled manner, reducing overinflation and torsion that can promote dissection (Figure 1).[9]

## DISSECTION, RECOIL, AND RESIDUAL STENOSIS

Dissection and residual stenosis occur acutely after balloon angioplasty.[6] As such, vessel preparation can optimize endovascular therapy, particularly when planning to use a drug-coated balloon (DCB).[10] With that in mind, the goal of vessel preparation is to remove

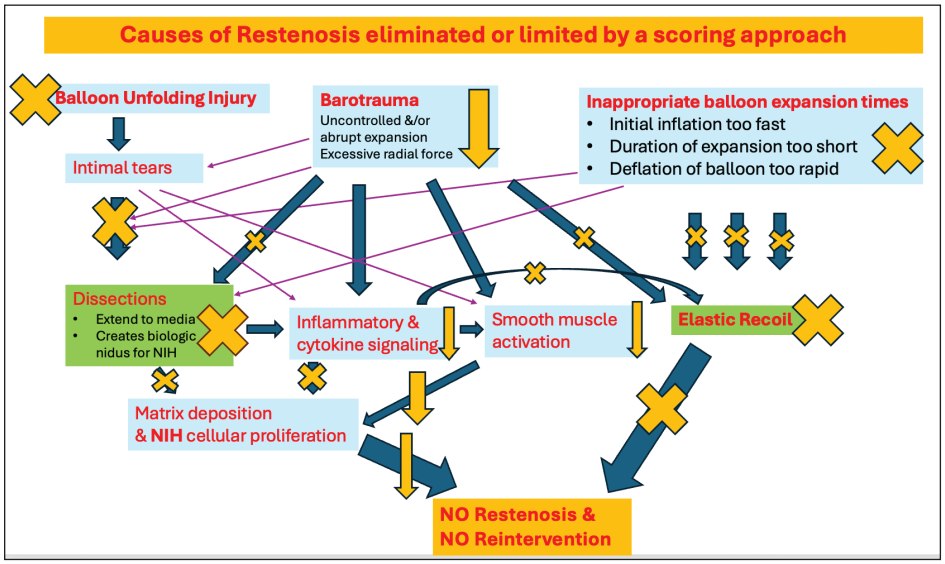


**Figure 1. Scoring approach prevents restenosis. NIH, neointimal hyperplasia.**

blocks for local drug delivery, avoiding drug loss on the way to the lesion, ensuring that a 1:1-sized DCB does not dissect the vessel, maximizing DCB expansion and vessel contact. Most operators use an aggressive lesion preparation strategy in an effort to "leave nothing behind" to create a functional lumen with the least amount of injury to the arterial wall. Currently, there's an arsenal of tools to address these needs, including an increasing array of guidewires and support catheters, atherectomy, and intravascular lithotripsy (IVL).[10] In simple lesions, atherectomy vessel preparation techniques are occasionally used as standalone definitive techniques, but they are usually followed by the use of more advanced therapies such as DCBs.[10] Each device has important applications in the treatment of complex lesions, and the decision to use a given device should be based on the perceived complexity of the lesion, the presence and extent of calcium, and the final goals of the therapy.

Of course, the choice of vessel preparation depends on the type of lesion.[9] As such, the presence of heavily eccentric calcification requires vessel lumen debulking using atherectomy or IVL devices.[9] For example, in a severely calcified BTK lesion, where even the crossing support catheter and a small-size balloon are unable to traverse the lesion, the atherectomy device can prove invaluable.[11,12] A recent single-center, non–industry-sponsored study showed that rotational atherectomy–assisted balloon angioplasty (BTK-RA) in CLTI BTK patients had significantly higher primary patency rates, target lesion revascularization, and lower in-hospital stay compared to the plain old balloon angioplasty (POBA) group.[13] Significant differences were found in minor amputation rates between the two groups ($P < .001$), while the respective limb salvage rates were similar in both groups.[13] This study showed that the use of BTK-RA for the treatment of BTK lesions in patients with CLTI adds clinical advantages compared to POBA alone. In relation to IVL devices, a subgroup analysis of the Disrupt PAD III trial demonstrated a 99% success rate for achieving residual stenosis of < 50%, with an average residual stenosis of 23.3% ± 12.5% and no flow-limiting dissections requiring adjunctive therapy in the IVL group compared to standard of care.[14] This subanalysis of the PAD III observational study represents the largest IVL treatment of heavily calcified BTK lesions in a "real-world" patient cohort, and current ongoing studies will soon better define the role of IVL in BTK PAD.[14]

## RECOIL MANAGEMENT

During balloon angioplasty, the elastic and muscle fibers undergo stretching. As such, if the force exerted by the balloon exceeds the vessel wall elasticity, plastic deformation occurs, and the artery will therefore not return to its former size.[15,16] Furthermore, infrapopliteal arteries are commonly severely calcified, with calcium being unequally distributed among the arterial wall layers, altering the elastic properties of the artery.[3,4,17,18] Also, because the tibial and pedal arteries are usually chronically occluded and underfilled, a challenge in the revascularization procedure is vessel size assessment and balloon undersizing, given that in different types of arteries, the degree of recoil was found to be directly related to the balloon-to-artery ratio.[18-20] It is now known that early recoil is highly prevalent in CLTI patients, with an incidence up to 97%, and that within 15 minutes after angioplasty alone, early elastic recoil can result in a mean lumen diameter decrease of 29%.[21]

Repeat angioplasty in cases of initial recoil should ideally be with a larger balloon for an extended duration of time.[7] In addition, the use of serration angioplasty in infrapopliteal PAD seems to produce substantially less arterial recoil versus POBA and an adequate lumen

gain.[22,23] The idea with a serration balloon is to dissipate the energy from the inflating balloon through the creation of channels that allow more predictability and control of the lumen expansion. A multicenter, sequential comparative study included patients with de novo or restenotic lesions of infrapopliteal arteries up to 22 cm in length and showed that arterial recoil (> 10%) occurred in fewer patients (25% of serration-treated lesions vs 64% in POBA-treated lesions; $P = .02$).[23] Moreover, after serration angioplasty, clinically relevant recoil (> 30%) was present in only 10% of the patients compared to 53% in POBA-treated group ($P = .01$).[22]

## FUTURE DIRECTIONS

There are also new concepts for reducing recoil, such as intra-arterial administration of iloprost, a prostacyclin mimetic, after balloon angioplasty of BTK vessels in CLTI, but more data are needed to corroborate this finding.[24] A novel retrievable scaffold therapy delivered via Spur peripheral retrievable scaffold system (Reflow Medical) showed that out of the 38 patients treated, recoil of tibial vessels was present in only 42.5% of the vessels, with 86.7% of vessels (26/30) patent at 6-month follow-up—although no significant difference in patency was found between lesions with recoil and lesions without recoil at 6 months (81.8% vs 89.5%).[25] This new retrievable scaffold therapy was also combined with sirolimus-coated balloon angioplasty to treat infrapopliteal artery lesions, showing negligible acute vessel recoil in 26% of the patients.[26] Both studies showed promise to reduce vessel recoil using a new interventional concept, such as using a temporary retrievable scaffold that can change vessel compliance and potentially allow the direct release of antiproliferative drugs to the lesion itself, which has proven challenging in the absence of a stent platform that facilitates vessel wall transfer. Just like with dissection and residual stenosis, research in vessel recoil after balloon angioplasty is urgently needed. We still don't understand the pathophysiology of phenotypic modulation of smooth muscle cells (SMCs) in CLTI patients, and identifying the genes associated with various SMC subphenotypes offers a potential for therapeutically targeting SMC phenotypic switching after angioplasty.

At this point, the need to integrate modern technologies into clinical routine seems mandatory to gain more favorable outcomes in these severely diseased patients and reduce the morbidity and mortality that ensues (Figure 1). ■

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CASE REPORT

# Multivessel Disease in a Diabetic, CLTI Patient

By Luai Tabaza, MD, FACC, FSCAI, FSVM, RPVI

## PATIENT PRESENTATION

A woman in her mid 60s with a history of diabetes, hypertension, and chronic myeloid leukemia presented with a nonhealing ulcer of her left foot, rest pain, and erythema in her toes (Figure 1). She had transitioned from intermittent claudication to symptoms consistent with chronic limb-threatening ischemia (CLTI). Ankle-brachial index (ABI) and peak velocity ratio (PVR) suggested multilevel disease in the left lower extremity. ABI measured 0.50 on the left side and 0.80 on the right (Figure 2A). Duplex ultrasound and angiography revealed multilevel peripheral artery disease (PAD), including a chronic total occlusion (CTO) of the left superficial femoral artery (SFA), disease in the distal popliteal artery, and single-vessel runoff via the anterior tibial artery (Figure 2B). The peroneal and posterior tibial arteries, along with the tibioperoneal trunk, were also diseased.

## PROCEDURE

Access was achieved via a bidirectional approach with a 7-F Roadster sheath (Merit Medical Systems, Inc.) through the right femoral artery and a 5-F Prelude sheath (Merit Medical Systems, Inc.) via pedal access under ultrasound guidance. The SFA CTO was crossed using a 0.014-inch Gladius Mongo ES wire (Asahi Intecc Co. Ltd.) supported by a Corsair Pro microcatheter (Asahi Intecc Co. Ltd.). The wire was externalized using a tip-in technique to achieve flossing.

The SFA CTO was then treated with optical coherence tomography–guided directional atherectomy using a 7-F Pantheris XL device (Avinger, Inc.). Angioplasty with a 5.0- X 100-mm Stellarex drug-coated balloon (DCB; Philips) was performed, an area of focal dissection was noted distally and a 5.5- X 80-mm Supera stent (Abbott) was deployed. For the below-the-knee (BTK) segment, including the tibioperoneal trunk and tibial vessels, multiple prolonged inflations were

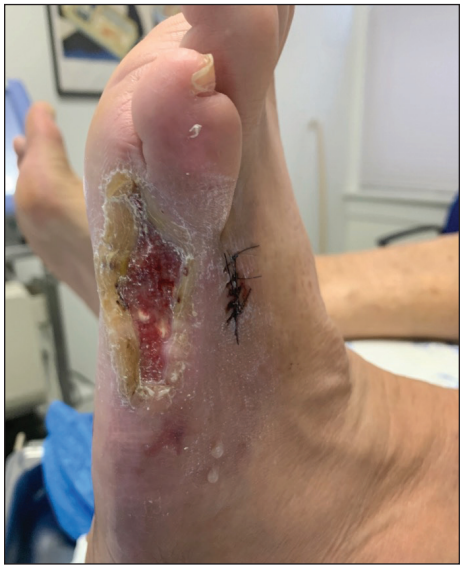

Figure 1. Left foot nonhealing ulcer.

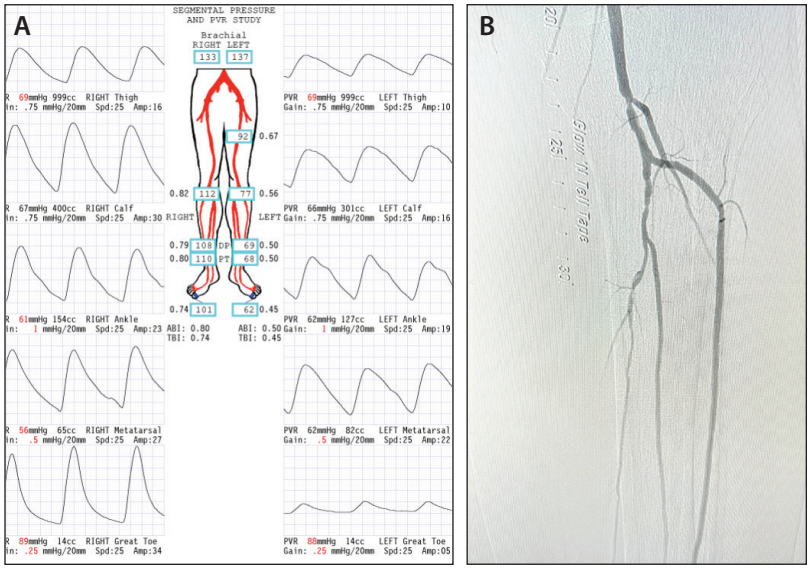


Figure 2. ABI and PVR at presentation (A). Initial angiogram (B).

## A Q&A WITH DR. TABAZA
## ON THE BENEFITS OF CHOOSING SERRANATOR

**Why was the Serranator chosen for this case?**

Serranator was selected to address immediate recoil commonly seen in BTK angioplasty. Prior to adopting Serranator, plain old balloon angioplasty frequently resulted in rapid recoil, necessitating stenting or reintervention. Serranator provided durable vessel prep with excellent luminal gain and low risk of dissection.

**What are the key benefits of using Serranator in BTK disease?**

Serranator allows for safer, more effective treatment of complex tibial lesions without creating flow-limiting dissections. In my experience, it has significantly reduced the need for bailout stenting, especially in CLTI patients with poor runoff and resistant disease. It has enabled better outcomes and contributed to long-term patency and wound healing.

**Are there other settings in which you use Serranator?**

Yes. Beyond BTK, Serranator has become a preferred tool in both pedal interventions and above-the-knee vessel preparation. In pedal cases, the new 2-mm platform enables treatment of distal disease within the foot, helping improve outflow in patients safely. In the SFA, Serranator is often used pre-DCB to reduce the risk of dissection and avoid stenting altogether. These applications have broadened its value across a range of CLTI and PAD anatomies.

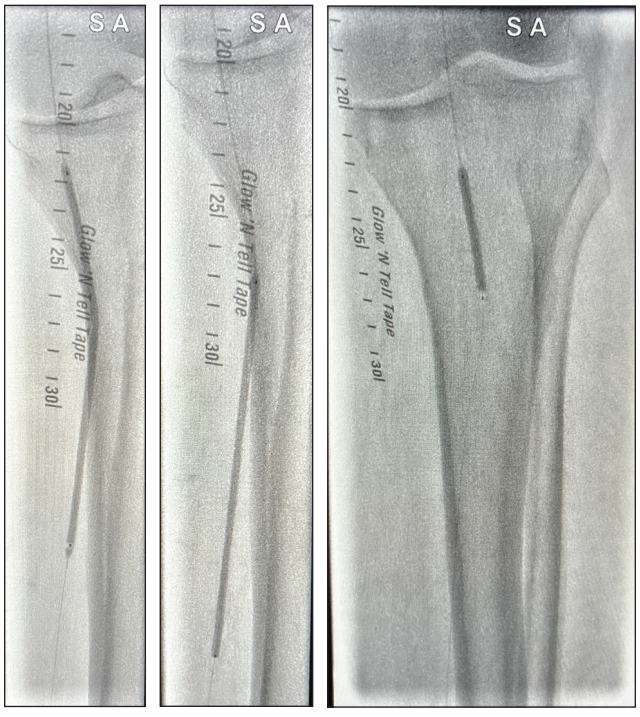


**Figure 3. Lesions in the posterior tibial and peroneal arteries treated with serration balloon angioplasty.**

performed using Serranator® PTA Serration Balloon Catheters (3 X 120 mm and 3.5 X 40 mm) (Cagent Vascular), with no need for additional therapy or bailout stenting (Figure 3).

### RESULTS

The patient was discharged the same day. After 3 months of continued wound care, the patient's ulcer healed completely (Figure 4). Her ABI improved from 0.55 to 0.91. Follow-up arterial ultrasound and angiography confirmed patency of the stented segment and robust three-vessel runoff (Figure 5).

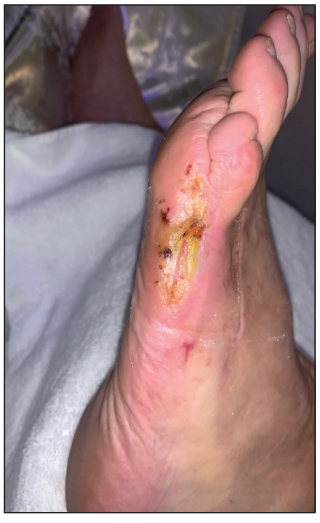

**Figure 4. Healed ulcer 3 months after revascularization.**

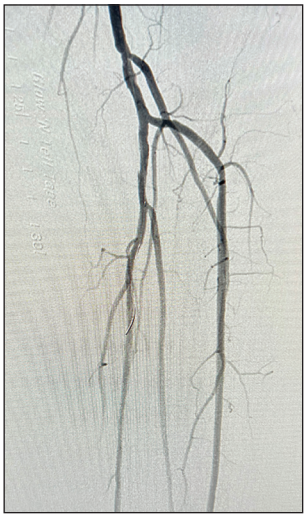

**Figure 5. Final angiogram of BTK runoff.**

She was transitioned to aspirin and low-dose rivaroxaban (2.5 mg), with no bleeding complications. At 2 years, she remains active, symptom-free, and ulcer-free, with no further interventions required on the treated limb. ■

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CASE REPORT

# Long-Segment SFA Stenosis With CTO Treated With Serranator® and DCB in a Patient With Forefoot Dry Gangrene

By Richard T. Rogers, MD, RPVI, and Shiv Patel, DO

## PATIENT PRESENTATION

A man in his late 50s with a history of smoking and diabetes presented with dry gangrene of the right toes and a history of rest pain. He was referred by his podiatrist after months of progressive ischemic symptoms in his right extremity. In-office duplex ultrasound revealed multilevel peripheral artery disease with long-segment, high-grade stenosis of the superficial femoral artery (SFA) (Figure 1). His ankle-brachial index (ABI) was 0.40, and vein mapping showed no suitable conduit for bypass.

Given the severity of ischemia and absence of bypass options, the patient was brought to the operating room for endovascular intervention.

## PROCEDURE

Left common femoral artery access was achieved, and angiography confirmed a severely diseased right SFA with segments of near occlusion, > 90% stenosis, and mid-to-distal short-segment occlusion (Figures 1-3). The popliteal artery was patent with codominant anterior tibial and posterior tibial runoff into the foot. A 7-F, 55-cm Destination sheath (Terumo Interventional Systems) was advanced, and the lesions were carefully crossed intraluminally using an 0.018-inch Hi-Torque Command wire (Abbott) and NaviCross catheter (Terumo Interventional Systems).

Serration angioplasty was performed along the entire SFA length—from proximal SFA to just

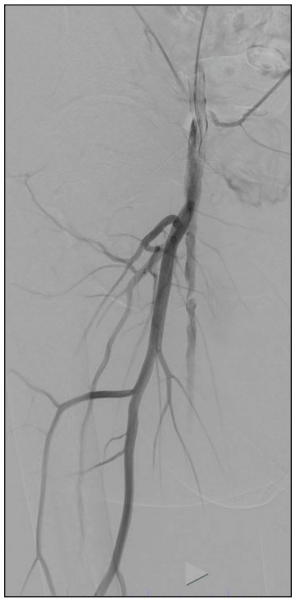

Figure 1. Preprocedure angiogram.

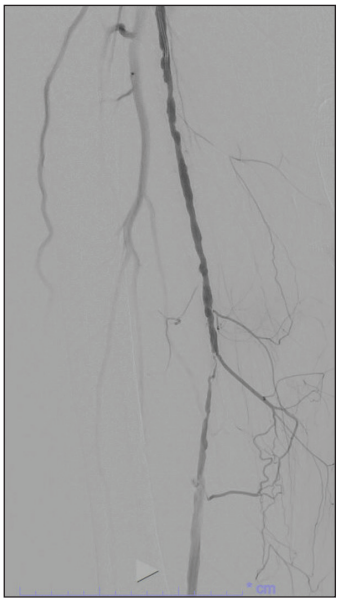

Figure 2. Preprocedure angiogram of the mid to distal SFA.

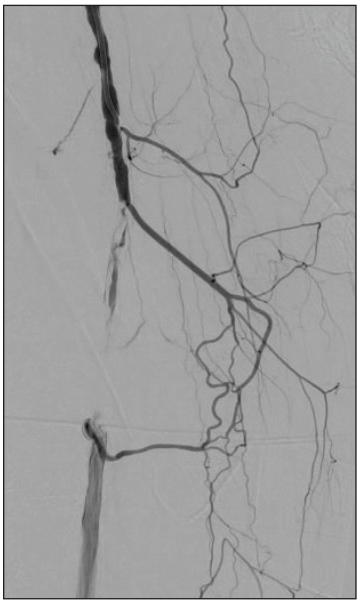

Figure 3. Distal SFA short-segment occlusion.

## A Q&A WITH DR. ROGERS ON SELECTING SERRANATOR

**Why was Serranator selected for this case?**

Serranator was chosen to maximize luminal gain while minimizing dissection risk, particularly important in this long-segment stenosis with chronic total occlusion (CTO) where no suitable vein was available for bypass. The device's serration technology allowed for controlled plaque modification and excellent vessel prep, enabling DCB delivery. I believe the microfracturing from the serrations helps facilitate deeper drug penetration, which may contribute to the durable outcomes we're seeing in these complex cases.

**How has Serranator performed across other vascular beds, including the iliacs?**

Beyond femoropopliteal and tibial use, I've used Serranator in pedal arteries and select iliac artery cases with good success. In the tibial and pedal arteries, it consistently delivers better luminal gain than plain old balloon angioplasty (POBA), often rescuing segments where plain balloons underperform. In the iliacs, I've used it for vessel prep—especially in cases with CTOs where plaque modification is essential. I'm highly anticipating the launch of larger Serranator sizes to broaden iliac treatment options.

**Do you have experience using Serranator in percutaneous transmural arterial bypass (PTAB) procedures?**

Yes, I've used Serranator during PTAB to dilate the proximal and distal arteriovenous (AV) "anastomosis." POBA often falls short due to significant recoil, making sheath or stent delivery very difficult. The serration technology provides excellent and durable expansion of the AV anastomosis, which helps maintain sheath access and eliminates the waist that can often be seen after stent deployment and postdilation. In my experience, it's a more effective option than standard balloons for ensuring tract patency in these complex cases.

beyond Hunter's canal—using a 6- X 120-mm Serranator® PTA Serration Balloon Catheter (Cagent Vascular) for multiple inflations. The procedure was completed with a 6- X 250-mm In.Pact Admiral drug-coated balloon (DCB) (Medtronic). There were no flow-limiting dissections, and stenting was not required. Figures 4 and 5 show completion angiograms. Palpable pedal pulses were noted postprocedure.

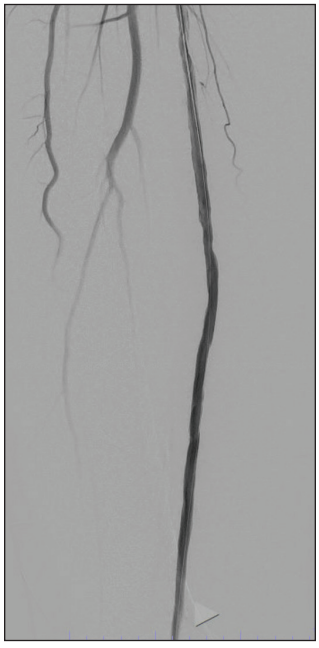

**Figure 4. Completion angiogram of the proximal and mid SFA.**

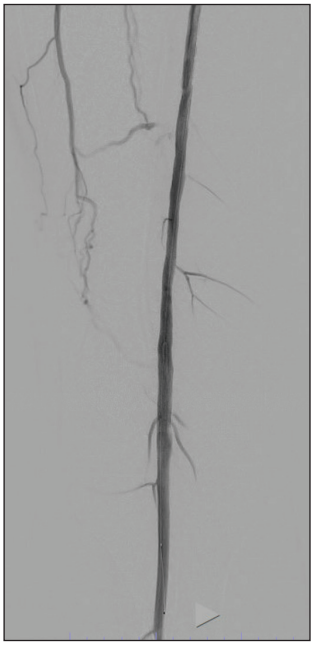

**Figure 5. Completion angiogram of the distal SFA.**

## RESULTS

The patient was discharged and subsequently underwent a transmetatarsal amputation, which healed completely. Follow-up ABI was 1.0, and over 1 year later, the patient remains well-perfused, walking independently, and free of recurrent stenosis or tissue loss. ■

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# Elevating Outcomes in AV Fistula Interventions With the Serranator® PTA Serration Balloon Catheter

Demonstrating the power of serration technology for improved durability, reducing restenosis, and navigating hostile anatomy, with a real-world case example.

**By Atish Chopra, MD, FSVS, FACS, RPVI**

Maintaining the patency of arteriovenous (AV) fistulas remains a significant challenge in patients requiring hemodialysis. Despite being the preferred form of vascular access, AV fistulas are prone to complications after intervention, particularly elastic recoil, inadequate luminal gain, and restenosis. These mechanical and biological challenges contribute to poor long-term outcomes and frequent reinterventions.

Elastic recoil is a major factor limiting the success of percutaneous transluminal angioplasty (PTA). After balloon deflation, vessel walls often elastically return to their preprocedural state, leading to significant residual stenosis and early failure. Recent studies have reported primary patency rates after angioplasty as low as 44% at 12 months, reflecting the persistent impact of recoil and neointimal hyperplasia (NIH).[1] Inadequate luminal gain compounds this problem. Lesions in AV fistulas are often highly fibrotic or calcified, making them resistant to full expansion, even with high-pressure, noncompliant balloons. Underexpanded lesions not only compromise immediate blood flow but also contribute to rapid restenosis.

Restenosis remains one of the most prevalent causes of AV access failure. Mechanical injury from PTA accelerates NIH. Longer lesion length, the presence of multiple stenoses, and high shear forces have all been associated with higher recurrence rates.[1] Despite high technical success rates immediately after intervention, durability remains poor, with freedom from reintervention often falling below 50% within the first year.

To address these challenges, stenting is sometimes used in AV fistula interventions. However, the role of stents is generally reserved for salvage cases. Although stents are beneficial in preventing early collapse or recoil, they do not address the underlying processes of restenosis and NIH. Stenting is not a universal solution, and in many cases, it may only delay the need for further interventions. It may also introduce long-term complications, including infection, thrombosis, difficulty in accessing the fistula for future procedures, and loss of opportunities for further proximal AV accesses.

These realities underscore the growing importance of vessel preparation and more effective primary therapies in AV fistula management. Traditional high-pressure and scoring balloons can help, but there remains a significant unmet need for technologies that both optimize luminal gain and minimize vessel trauma to reduce recoil and restenosis. Moreover, successful vessel preparation is crucial not only to create a larger, more sustainable lumen but also to establish a favorable vessel environment when pharmacologic therapies, such as drug-coated balloons (DCBs), are used. Recent randomized controlled trial data have demonstrated that DCB angioplasty can improve 12-month patency rates compared to plain old balloon angioplasty (POBA), but these benefits depend heavily on adequate vessel preparation.[2]

In this context, the Serranator® PTA Serration Balloon Catheter (Cagent Vascular) represents a novel approach to addressing the dual challenges of vessel preparation and primary therapy for AV fistula interventions.

The Serranator uses stainless-steel microserration technology, designed to create linear, interrupted scoring along the endoluminal surface. With 1,000 times more point force compared with POBA, serration occurs during slow-and-low balloon inflation and is designed to aid

vessel expansion, effectively optimizing luminal gain in all lesion morphologies with minimal recoil.

The Serranator offers a compelling solution for treating AV fistula stenoses—particularly in challenging lesions where traditional POBA may be insufficient. The Serranator has proven to be effective in treating peripheral artery disease and chronic limb-threatening ischemia, and its unique mechanism of action holds promise for addressing similar challenges in AV fistula management, providing a potential solution to improve outcomes and reduce the need for repeat interventions. Several case studies follow which illustrate the utility of Serranator angioplasty use for AV access–related complications.

## Case Report: Serranator Use for Recoil After Noncompliant Balloon PTA and In-Stent Restenosis for AV Fistula Treatment

### PATIENT PRESENTATION

A woman in her late 60s with a left brachiocephalic AV fistula created 5 years prior presented with prolonged bleeding and poor dialysis clearance. A duplex ultrasound demonstrated stenosis in the proximal segment and in-stent restenosis in the cephalic arch stent (Figure 1).

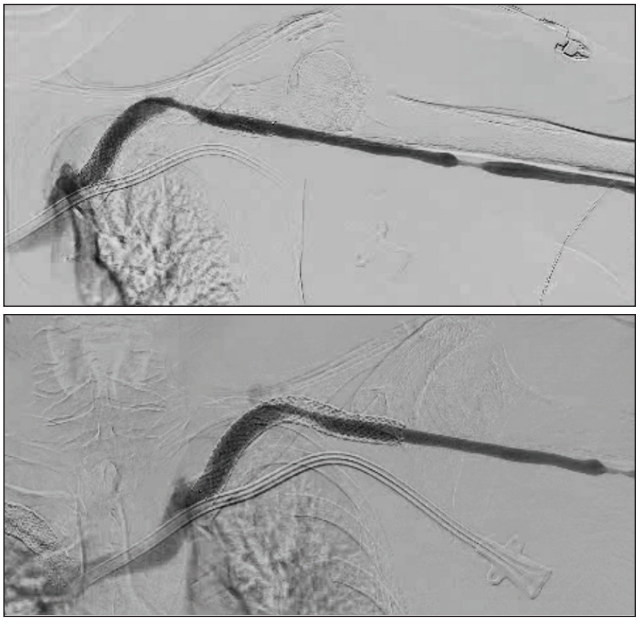

**Figure 1. High-grade stenoses present in the mid fistula and cephalic arch stent.**

**Figure 2. Waist seen with noncompliant PTA.**

### PROCEDURE

Antegrade access was achieved in the distal fistula and a 6-F sheath was inserted. Fistulagraphy was performed and demonstrated > 90% stenosis in the mid fistula as well as > 85% in-stent restenosis in the cephalic arch stent (Figure 1). PTA of both lesions was performed with a noncompliant 6- X 40-mm balloon, but significant recoil was encountered with > 50% residual stenosis (Figures 2 and 3). PTA was then performed with 6- X 40-mm Serranator Balloon followed by a 7- X 60-mm DCB angioplasty (Figure 4). Completion angiography demonstrated < 30% residual stenosis with a strong thrill present (Figure 5).

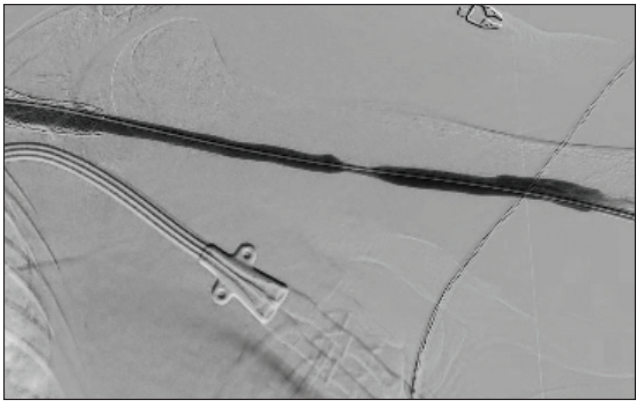

**Figure 3. Recoil after noncompliant PTA.**

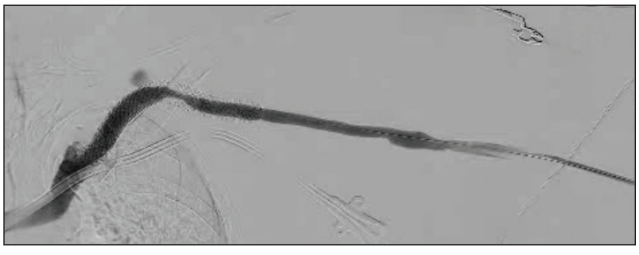

**Figure 4. Post–noncompliant PTA in the cephalic arch and Serranator in the mid fistula.**

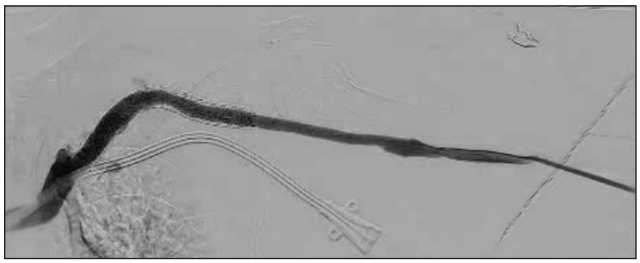

**Figure 5. Post-Serranator and DCB PTA.**

## RESULTS

The patient's symptoms resolved and the patient had > 1,000 mL/min volume flow on follow-up duplex ultrasound. She has not required repeat fistulagraphy at last follow-up 12 months postprocedure. ■

1. Zheng Q, Xie B, Xie X, et al. Predictors associated with early and late restenosis of arteriovenous fistulas and grafts after percutaneous transluminal angiography. Ann Transl Med. 2021;9:132. doi: 10.21037/atm-20-7690
2. Zhao Y, Wang P, Wang Y, et al. Drug-coated balloon angioplasty for dysfunctional arteriovenous hemodialysis fistulae: a randomized controlled trial. Clin J Am Soc Nephrol. 2024;19:336-344. doi: 10.2215/CJN.0000000000000359

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## A Q&A WITH DR. CHOPRA ON CHOOSING SERRANATOR

**Why did you choose to use the Serranator in this case?**

The lesion demonstrated significant recoil after noncompliant balloon angioplasty. The Serranator offered a way to modify the vessel more effectively with less trauma, allowing for better lumen gain and setting the stage for optimal DCB delivery.

**What made this a particularly challenging AV fistula case?**

This patient had in-stent restenosis and highly fibrotic segments—lesion types that often resist full balloon expansion. She had also undergone prior interventions, increasing the risk of limited durability. Recoil and restenosis were persistent issues.

**How does the Serranator fit into your approach to AV access interventions?**

The Serranator is a valuable tool for vessel prep in tough lesions where standard balloons fall short. It helped us reduce recoil and avoid stenting in this case. With larger sizes on the way, we'll be able to expand its use across a wider range of AV access and peripheral anatomies.

# Advancing Pedal Interventions With Serration Angioplasty

**With Mike Watts, MD, FSIR**

**Mike Watts, MD, FSIR**
Interventional Radiologist
Atlantic Medical Imaging
Vineland, New Jersey
*Disclosures: Advisory board member for Cagent Vascular.*

On the heels of new inframalleolar reimbursement codes and a recent study highlighting superior patient outcomes, Dr. Watts provides some insights from his experience treating pedal artery lesions.

## What prompted you to use the Serranator® PTA Serration Balloon Catheter (Cagent Vascular) in pedal interventions?

Pedal vessels are often heavily calcified and represent the last chance at limb salvage in many critical limb ischemia patients. I found that wherever angioplasty might work, serration angioplasty often works better. The Serranator allows us to tackle challenging lesions with more predictable lumen gain and fewer complications. It's become a go-to tool for us in this space, as the data we collected have shown excellent technical results and wound healing outcomes.

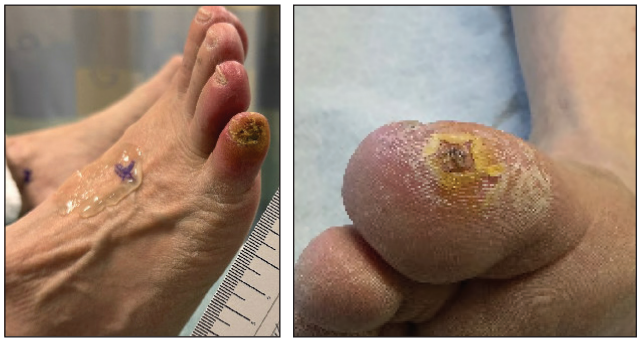

**Figure 1. A diabetic man in his late 60s with painful ulcerations of his right first and fifth toes.**

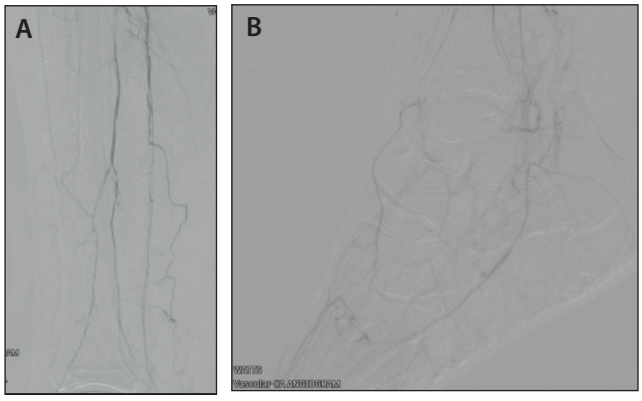


**Figure 2. Significant tibial artery occlusions were noted with only intact peroneal artery flow to the ankle (A). There was a patent lateral plantar artery on significantly delayed imaging (B).**

## How do you approach safety when working below the ankle?

I rely on a low and slow inflation—typically 4 atm for 60 seconds, then 6 atm for 60 seconds. That gentle approach, combined with the Serranator's point-force mechanism, creates controlled expansion without dissection or perforation. I use IVUS (intravascular ultrasound) routinely to confirm sizing and plaque morphology. With this strategy, we've seen consistently safe and effective results in pedal arteries.

## Can you share a recent success using the Serranator?

I used the 2.0- X 120-mm Serranator SL Pro to access and treat a long, occluded and calcified lateral plantar artery (Figures 1 and 2). The Serranator SL Pro was able to navigate tight spaces with control and safely open the artery without any recoil or dissection (Figures 3-5). The patient's rest pain resolved quickly, and within 4 weeks, the wound was almost completely healed (Figure 6). This was a clear demonstration of how restoring pedal flow changes outcomes.

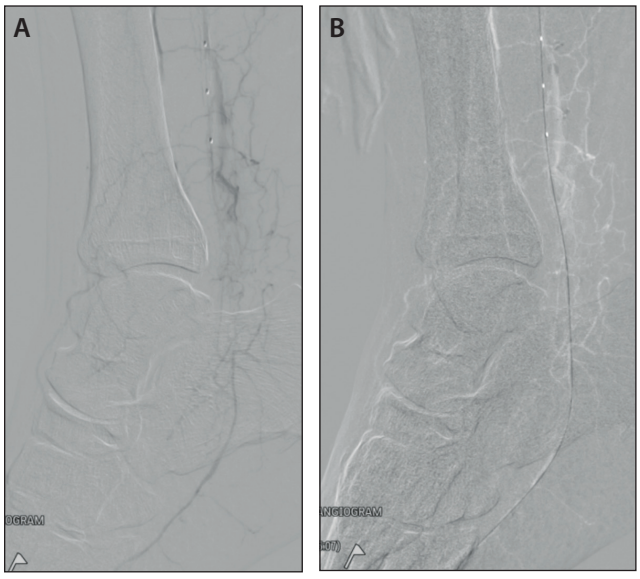


Figure 3. A wire was advanced across the distal posterior tibial and common plantar artery occlusions (A, B).

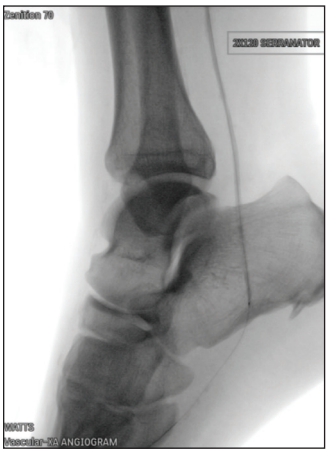

Figure 4. A 2.0- X 120-mm Serranator SL-Pro was advanced beyond the occlusion. Prolonged serration angioplasty was completed.

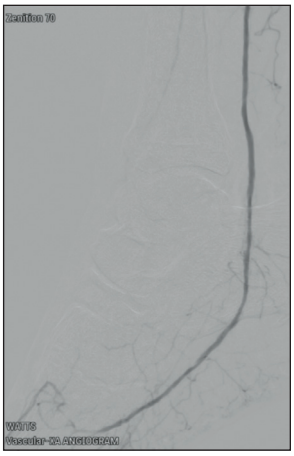

Figure 5. Serranator angioplasty resulted in brisk inline flow to the lateral plantar artery. Delayed images showed significantly improved filling of the inframalleolar arteries.

## What advice would you give to clinicians hesitant to treat pedal arteries?

I understand the hesitation—these are small, delicate vessels. However, the data support improved limb salvage and wound healing when pedal arteries are successfully revascularized. With a tool like the Serranator, we can treat these arteries with precision, minimal trauma, and real durability. If you can wire it, you can—and probably should—treat it.

## Please describe your initial experience with Serranator.

I was a very early adopter of Serranator. After I started using it, I was completely convinced of its superiority to existing technologies. It became known across the vascular interventional community that I was a frequent user of Serranator below the ankle, and I was recommending it constantly. At that point, it was an additional expense with little data to back it up except for my anecdotal experiences. I felt extremely vindicated when the pedal study was published. The data below the ankle were very similar to the previously published PRELUDE BTK data showing 93.3% freedom from clinically driven target lesion revascularization at 6 months, no perforations or embolization, and 89% wound healing at 5 months.[1] Hopefully, people now realize how good my advice was! ■

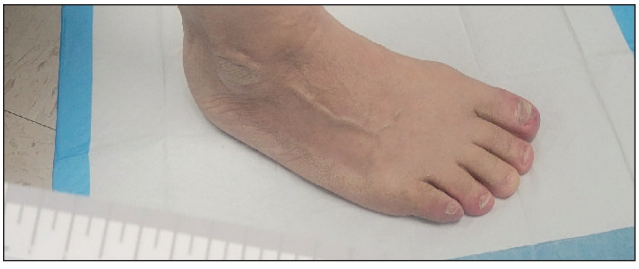

Figure 6. Within 6 weeks, the patient had complete resolution of his ulcerations, ischemic discoloration, and rest pain.

1. Holden A, Lichtenberg M, Nowakowski P, et al. Prospective study of serration angioplasty in the infrapopliteal arteries using the Serranator device: PRELUDE BTK study. J Endovasc Ther. 2022;29:586-593. doi: 10.1177/15266028211059917

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| FGS-0682-20020 | 852495008500 | 2.0 mm | 20 mm | 0.014" | 5F | 150 cm |
| FGS-0682-20040 | 852495008494 | 2.0 mm | 40 mm | 0.014" | 5F | 150 cm |
| FGS-0682-20120 | 852495008487 | 2.0 mm | 120 mm | 0.014" | 5F | 150 cm |
| FGS-0346-25040 | 852495008180 | 2.5 mm | 40 mm | 0.014" | 6F | 150 cm |
| FGS-0346-25080 | 852495008197 | 2.5 mm | 80 mm | 0.014" | 6F | 150 cm |
| FGS-0346-25120 | 852495008203 | 2.5 mm | 120 mm | 0.014" | 6F | 150 cm |
| FGS-0346-30040 | 852495008210 | 3.0 mm | 40 mm | 0.014" | 6F | 150 cm |
| FGS-0346-30080 | 852495008227 | 3.0 mm | 80 mm | 0.014" | 6F | 150 cm |
| FGS-0346-30120 | 852495008234 | 3.0 mm | 120 mm | 0.014" | 6F | 150 cm |
| FGS-0346-35040 | 852495008241 | 3.5 mm | 40 mm | 0.014" | 6F | 150 cm |
| FGS-0346-35080 | 852495008258 | 3.5 mm | 80 mm | 0.014" | 6F | 150 cm |
| FGS-0346-35120 | 852495008265 | 3.5 mm | 120 mm | 0.014" | 6F | 150 cm |
| FGS-0492-40040 | 852495008005 | 4.0 mm | 40 mm | 0.018" | 6F | 150 cm |
| FGS-0492-40120 | 852495008029 | 4.0 mm | 120 mm | 0.018" | 6F | 150 cm |
| FGS-0492-50040 | 852495008036 | 5.0 mm | 40 mm | 0.018" | 6F | 150 cm |
| FGS-0492-50120 | 852495008050 | 5.0 mm | 120 mm | 0.018" | 6F | 150 cm |
| FGS-0492-60040 | 852495008067 | 6.0 mm | 40 mm | 0.018" | 6F* | 150 cm |
| FGS-0492-60120 | 852495008081 | 6.0 mm | 120 mm | 0.018" | 6F* | 150 cm |
| FGS-0898-7040 | 852495008517 | 7.0 mm | 40 mm | 0.018" | 6F* | 110 cm |
| FGS-0898-8040 | 852495008524 | 8.0 mm | 40 mm | 0.018" | 7F | 110 cm |

6F* compatible with sheath IDs ≥ 0.087" (2.2 mm)

CAUTION: Federal law restricts this device to sale by or on the order of a physician.
IMPORTANT INFORMATION: Indications, warnings, and instructions for use can be found in the product labeling supplied with each device.
INDICATIONS FOR USE: The Serranator® PTA Serration Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, iliofemoral, popliteal, and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neurovasculature.
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