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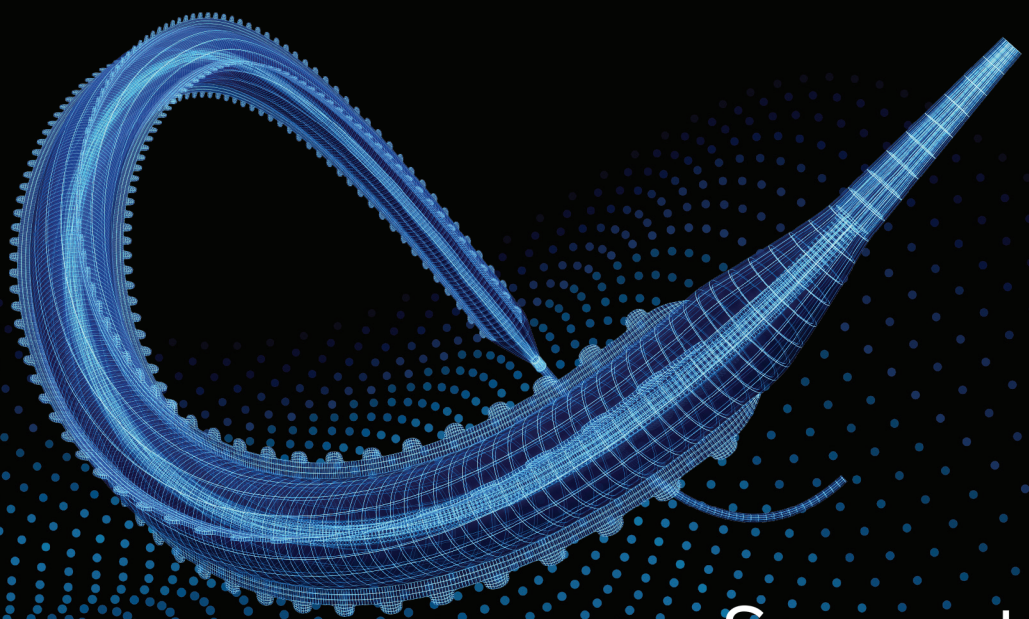

Serranator®
PTA Serration Balloon Catheter

ADDRESSING THE UNMET NEED

ELEVATING PAD TREATMENT WITH SERRATION ANGIOPLASTY

Serranator®
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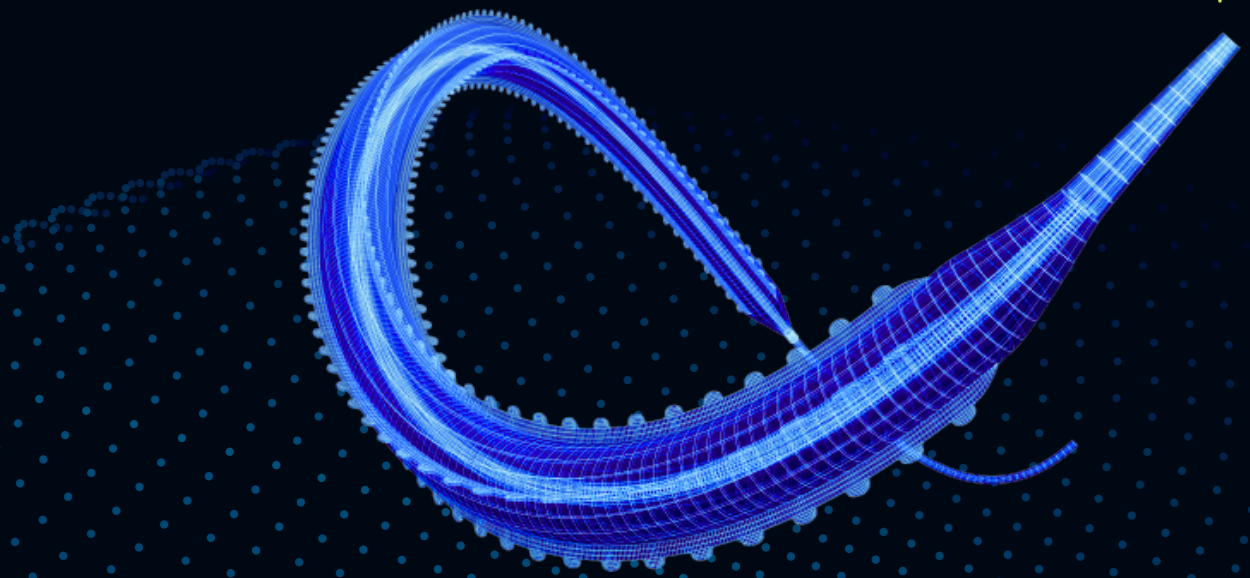
SERRATE & INFLATE™



LUMEN GAIN SIMPLIFIED

With 1,000x more Point Force than POBA
Effective in all lesion morphologies

Improve
Lumen Gain

49%
LESS RESIDUAL STENOSIS THAN POBA

Increase
Blood Flow

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GREATER BLOOD FLOW THAN POBA

Reduce
Recoil

89%
LESS AVERAGE RECOIL THAN POBA

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1) Guetl K, Muster V, Schweiger L, Tang WC, Patel K, Brodmann M. Standard Balloon Angioplasty Versus Serranator Serration Balloon Angioplasty for the Treatment of Below-the-Knee Artery Occlusive Disease: A Single-Center Subanalysis From the PRELUDE-BTK Prospective Study. *J Endovasc Ther*. 2022 Nov.
2) Lichtenberg, M. Recoil Study: Serranator versus POBA. Presented at LINC 2023.

The Serranator® PTA Serration Balloon Catheter: Addressing the Unmet Need in Complex PAD Patients

By S. Jay Mathews, MD, MS, FACC, FSCAI

Peripheral artery disease (PAD) is a global pandemic. In 2010, an estimate of 100 million people were diagnosed with PAD, and it is forecasted to rise from 30% to 50% by 2045, both driven by an aging population in higher income countries and the global rise of diabetes.[1] Within this population, chronic limb-threatening ischemia (CLTI) patients are among the most technically challenging to treat and manage. Despite our advanced medical system, over 20% of CLTI patients still undergo primary amputation, with marked variation based on race and socioeconomic status.[2] Despite access to advanced technologies, over 40% of CLTI patients need reintervention at 1 year.[3] And despite our best efforts, over 40% of those undergoing major amputation will die at 1 year.[2] Complex infrainguinal lesions perhaps require better solutions to achieve better outcomes.

SERRATION BALLOON ANGIOPLASTY

With the increasing complexity of disease in CLTI patients, there exists a need for optimizing endovascular therapies. The Serranator® PTA Serration Balloon Catheter (Cagent Vascular) is a disruptive technology over plain old balloon angioplasty (POBA) (Figure 1).

Unlike other focal force balloons that utilize helical or longitudinal wires, the Serranator utilizes metallic elements that have surface serrations to concentrate pressure on multiple points of contact. This results in a point force 1,000 times greater than POBA and significant improvement over other focal force balloons where pressure is dissipated along the length of the wire elements (Figure 2).[4]

Serration balloon angioplasty may also reduce dissection and uncontrolled fractures seen with POBA by directing energy along "serration" planes. Current iterations of the device come in a broad size matrix from 2.5 to 6.0 mm and from 40 to 120 mm in length, all 6-F compatible (see Specifications of Serranator Sidebar).

The value proposition of such a tool comes from its deliverability and ease of use. It could be utilized for both vessel preparation prior to drug or stent delivery or utilized as a standalone tool while limiting recoil and dissections. It can be used in all lesion morphologies, including both fibrotic and calcific tissues. Compared to tools such as intravascular lithotripsy, there is a more favorable crossing profile with longer lengths, simpler setup, no loss of energy in noncalcified tissue, and no finite number of treatments with a single device. Moreover, in contrast to some atherectomy devices, risk of distal embolization is low, with the ability to both prepare and treat the vessel with a single solution.

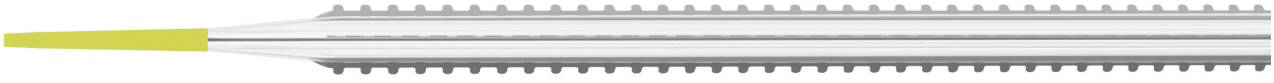

Figure 1. The Serranator has a nylon semicompliant balloon with three embedded external serrated metal strips. The elements are serrated, designed to create linear, interrupted scoring along the endoluminal surface.

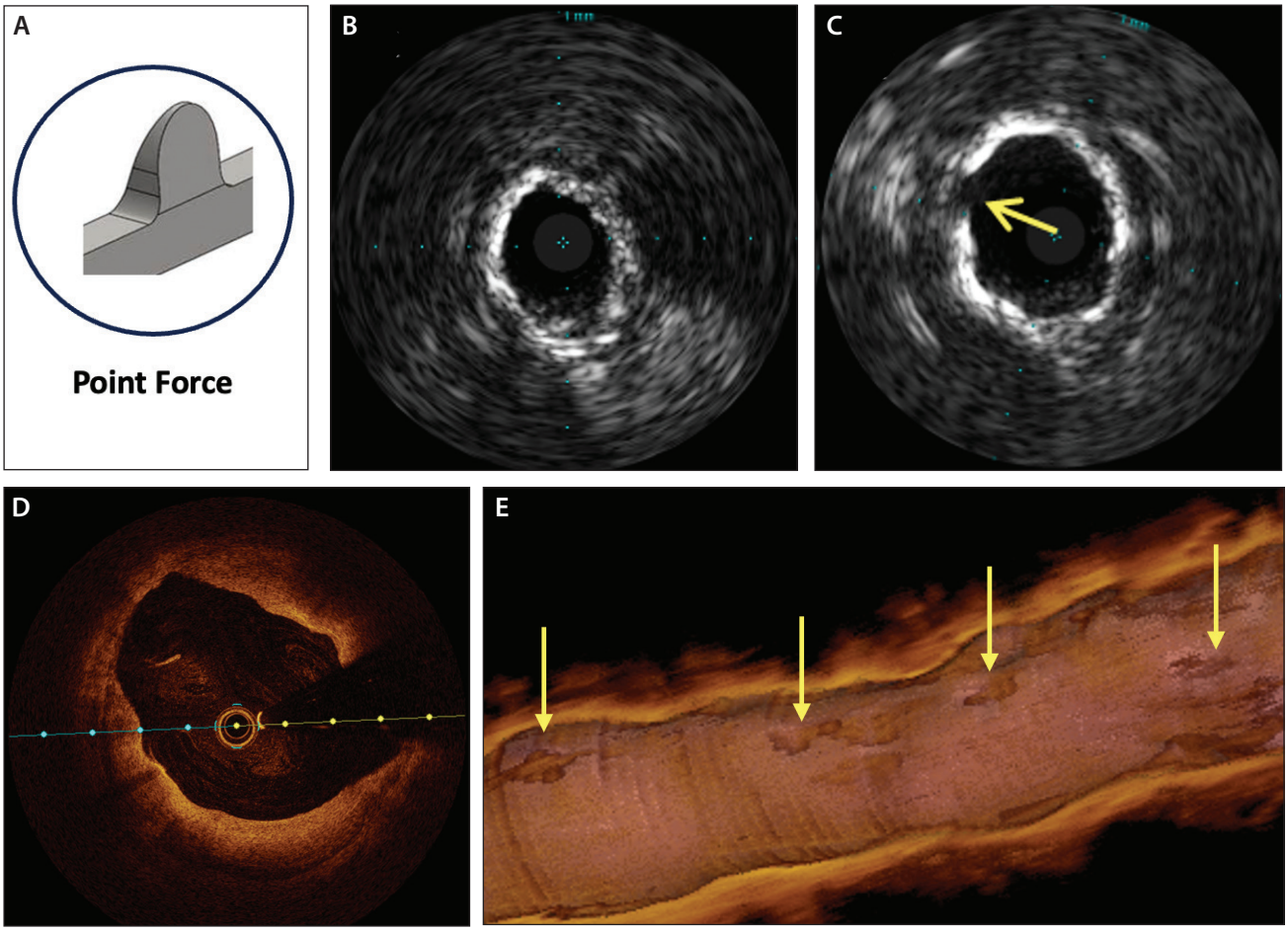

Figure 2. Serranator applies 1,000 times the force compared to POBA (A). Pre- (B) and post-Serranator (C) intravenous ultrasound images of the tibial artery demonstrate the effectiveness in calcification. Post-Serranator optical coherence tomography (OCT) shows the serration technology mechanism of action in the superficial femoral artery (D). Post-Serranator OCT shows serration effect within tibial artery (arrows, E).

ADDRESSING ATK DISEASE

There are multiple options for treatment of above-the-knee (ATK) disease. Fundamental to the nature of angioplasty is dissection. Despite the advent of drug-coated balloon (DCB) technologies, dissections may impact outcomes postintervention. The THUNDER study suggested higher target lesion revascularization (TLR) with significant dissection, but DCB angioplasty might mitigate restenosis as long as the lesions are not flow limiting.[5] Serration angioplasty allows for controlled expansion of lesions, creates uniform fracture planes, and limits uncontrolled dissection.

Scaffolds (including drug-eluting stents [DESs]) have been shown to be effective in this space, especially when there are flow-limiting residual lesions after POBA.[6] However, this could be at the expense of limiting normal vasomotor function of the superficial femoral and popliteal arteries. The chronic outward radial force and higher metal-to-tissue ratio may be associated with an intimal hyperplastic response, potentially with decreased patency and increased TLR, even when using biomimetic scaffolds.

As such, DCB devices remain attractive, as they may improve patency without leaving a durable implant. However, DCB efficacy can be impacted by calcium, which can limit

SPECIFICATIONS OF THE SERRANATOR

- 0.018- and 0.014-inch guidewire compatible
- 6-F sheath compatible
- 150 cm catheter length
- 2.5 to 6.0 mm balloon diameters
- 40, 80, 120 mm balloon lengths
- Serration elements protrude 0.2 mm

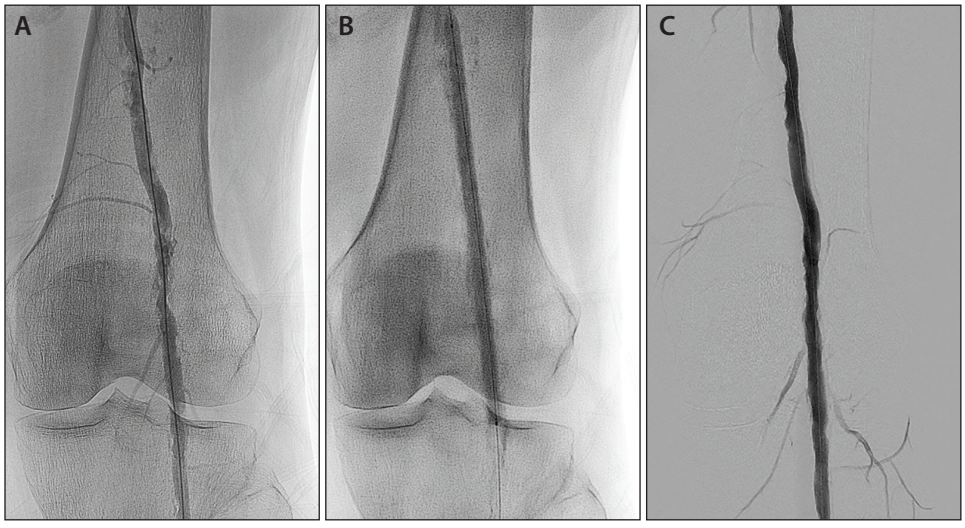

Figure 3. A fibrocalcific femoropopliteal lesion in a RC 3 claudicant patient is seen at baseline (A), Serranator-inflated (B), and post-DCB (C), showing excellent expansion and restoration of normal flow, without significant dissection.

drug uptake. Serration balloon angioplasty results in small fractures within treated lesions. In a porcine model, the microfissures created by the Serranator resulted in three times greater drug uptake versus POBA when used as preparation for DCB angioplasty.[7] This may potentially address one of the greatest limitations of drug delivery in the PAD space, actually getting drug into the medial/adventitial layers where it could be most effective in slowing progression of disease; however, these findings need to be demonstrated clinically in humans.

DCB devices also do not address recoil, which historically has been addressed with vessel preparation tools and ultimately a high-radial-force scaffold. Atherectomy has also been leveraged to help improve angiographic results without clear improvement in outcomes.[8] Serration angioplasty mitigates recoil with its high point force, allowing for other treatments, including both DCB or placing a scaffold when necessary.

Data supporting use of the Serranator in ATK lesions come from the PRELUDE study.[9] This was a prospective, core lab–adjudicated study (N = 25) in native femoropopliteal lesions that showed low 22.7% residual stenosis and low bailout stent rate of 4.0% (one patient).[9] Moreover, lesion expansion was achieved at low mean inflation pressures of only 8 atm regardless of the degree of calcification.[9] Freedom from clinically driven TLR (CD-TLR) and target vessel revascularization was 100% at 6 months even without use of adjunctive DCB therapy.[9]

In this clinical example, a fibrocalcific femoropopliteal lesion in a Rutherford class (RC) 3 claudicant patient is seen at baseline (Figure 3A), Serranator-inflated (Figure 3B), and post-DCB (Figure 3C), showing excellent expansion and restoration of normal flow, without significant dissection.

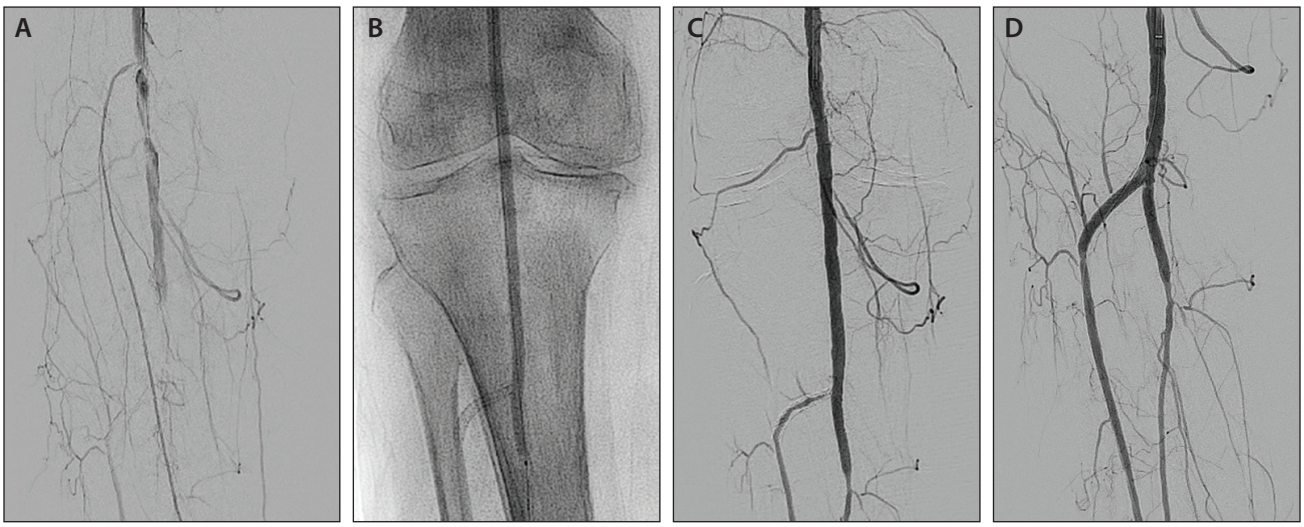

Figure 4. A severely diseased popliteal artery into the TPT with AT in-stent restenosis in a CLTI patient with a hallux wound (RC 5) (A). Serranator and DCB were initially used in the popliteal artery and TPT, showing both excellent luminal gain without recoil or dissection (B, C). Additional serration angioplasty of the AT was performed with resolution of occlusion (D).

ADDRESSING BTK DISEASE

Below-the-knee (BTK) lesions present even greater challenges with regard to effective and durable outcomes in managing CLTI patients. A fundamental issue with addressing infrapopliteal disease is recoil seen in over 50% of patients post-POBA and may suggest why many trials have failed.[10] But the answer is not simply to place a scaffold, as this strategy is limited by the lack of approved devices. Coronary DESs (off-label) may work well in the proximal third of the calf but face excessive crush forces beyond this zone.[11] Tack scaffolds (Philips) are only used for dissection and cannot address recoil forces.[12] Drug-eluting scaffolds such as Saval (Boston Scientific Corporation) were met with disappointing results.[13] Results from bioresorbable drug-eluting technologies such as Esprit BTK (Abbott) are forthcoming, but also likely require aggressive vessel preparation to achieve optimal expansion.[14]

Data supporting use of serration angioplasty in BTK lesions come from the PRELUDE BTK study.[15] This was a prospective, core lab–adjudicated study (N = 46; 53 lesions) of infrapopliteal lesions (47.8 ± 37.4 mm).[15] Technical success was 91.7% with luminal expansion at low mean inflation pressures (6 atm).[15] There was a low 21.8% residual stenosis with a low bailout stent rate of 1.9% (one patient).[15] Freedom from major adverse limb events and postoperative death at 30 days was 95.7% and the 6-month freedom from CD-TLR was 97.7%.[15]

In a separate core lab–adjudicated infrapopliteal artery recoil study, serration angioplasty was associated with significantly less mean recoil than with POBA 15 minutes posttreatment (6% vs 55%; $P = .009$).[10] This finding may help explain the successful 6-month outcomes seen in PRELUDE BTK. Recoil is perhaps even more prominent in lesions below the ankle, which have been excluded from most BTK trials. In an ongoing retrospective study, Serranator use in pedal arteries was examined (N = 41), including the pedal arch, which found 97% amputation-free survival and 89% wound healing at 5 months.[16] Both the technical and clinical success of this technology in these zones may offer hope for even the most complex CLTI patients.

In this clinical example, we see a severely diseased popliteal into the tibioperoneal trunk (TPT) with anterior tibial (AT) in-stent restenosis in a CLTI patient with a hallux wound (RC 5) (Figure 4A). Serranator and DCB were initially used in the popliteal artery and TPT, showing both excellent luminal gain without recoil or dissection (Figure 4B and 4C). Additional serration angioplasty of the AT was performed with resolution of occlusion (Figure 4D).

CONCLUSION AND FUTURE DIRECTIONS

Serration balloon angioplasty offers a novel mechanism of action to facilitate vessel modification and preparation, either as a standalone option or adjunctive to other therapies. However, the technology could also conceivably be adapted to many other disease states where there exists a need for focal force balloon angioplasty. Obvious applications include larger balloons to facilitate large-bore access (ie, structural heart devices and endovascular aortic repair). Existing solutions also work for arterial inflow lesions and intragraft or fistulae stenoses in dialysis access cases. But, the technology could also be easily adapted to address larger venous outflow lesions and central vein stenoses, where recoil is a common phenomenon due to their fibrotic and elastic nature. Serration balloon angioplasty could also break fibrous bands seen in postthrombotic vein lesions. The applications of this mechanism of action to other disease states are potentially very attractive. Increased experience with this technology among clinicians will help drive adoption and identify unmet needs that could be addressed with basic modifications of the technology.

With the inherent limitations of existing plaque modification strategies, there exists a need for simple yet effective tools to achieve optimal results in both a cost-effective and efficient manner. Serration balloon angioplasty may offer such a paradigm, advancing the CLTI toolbox. ■

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Disclosures: None.

SFA CTO Treated With Serranator and Drug-Eluting Therapy

With Raman Sharma, MD

Raman Sharma, MD
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Assistant Professor of Medicine, Division of Cardiology
Mount Sinai Hospital
New York, New York
Disclosures: None.

PATIENT PRESENTATION

A female patient in her upper 60s with typical past medical history of peripheral artery disease (PAD) including hypertension, hyperlipidemia, type 2 diabetes mellitus, history of tobacco use, as well as a penetrating ulcer of the ascending aorta and post-thoracic endovascular aortic repair and previous left common/external iliac Dacron graft placement, presented for the treatment of PAD. She presented with Rutherford class 2/3 claudication and was symptomatic, walking less than two blocks on optimal medical therapy.

DIAGNOSTIC ASSESSMENT

Prior to intervention, the patient underwent arterial duplex ultrasound, which demonstrated bilateral superficial femoral artery (SFA) chronic total occlusions (CTOs) (Figure 1). Her ankle-brachial indices were 0.62 and 0.63 on the right and left, respectively.

INTERVENTION

The target treatment vessel for this case was the left SFA, with the right SFA CTO to be treated at another time. Contralateral access through the Dacron graft was performed, but due to a blunt ostium with no taper, accessing the SFA was challenging. Multiple attempts were made to wire down the SFA, including using an angled catheter with a stiff wire, but these proved unsuccessful. A second access was attempted via direct access to the SFA. Using a Spartacore wire (Abbott), the SFA was crossed in a retrograde fashion. After snaring and externalizing the wire, successful antegrade access was achieved; the retrograde wire was removed and the antegrade wire passed distally into the poster tibial artery. An Emboshield Nav6 filter (Abbott) was placed in the popliteal artery, and directional atherectomy (HawkOne, Medtronic) was performed in the proximal and distal segments of the SFA, with 4- X 120-mm plain balloon angioplasty (POBA) treatment through the course of the SFA. After POBA, a 5- X 120-mm Serranator® PTA Serration Balloon Catheter (Cagent Vascular) was used to achieve optimal lumen gain (Figures 2 and 3). Drug-coated balloon therapy was utilized in the mid segment, and stents were placed at the proximal and distal segment of the SFA. The filter was removed, and on gross inspection was empty. Final angiography showed widely patent SFA, with no residual stenosis (Figure 4).

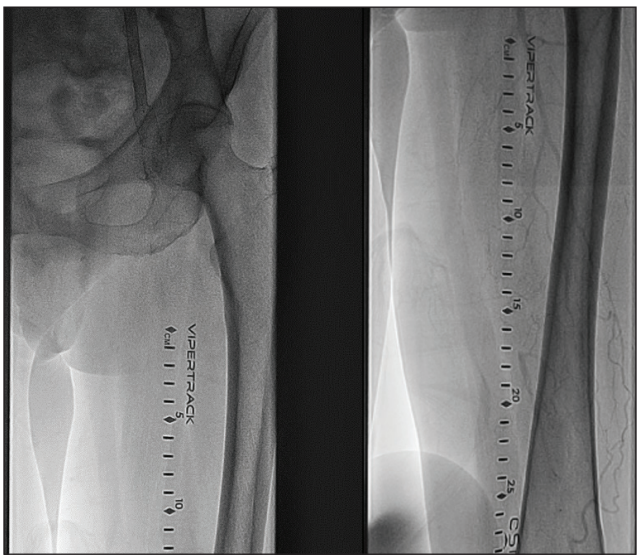

Figure 1. Baseline angiography demonstrating the SFA CTO.

Looking back, what led to your decision to use the Serranator balloon?

Dr. Sharma: I knew I needed more than POBA and I wanted to leave as little metal as possible. The above-the-

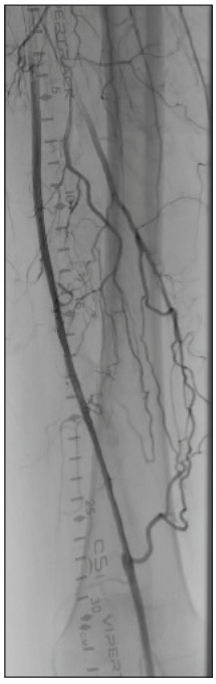

Figure 2. Angiography after directional atherectomy of the proximal and distal cap.

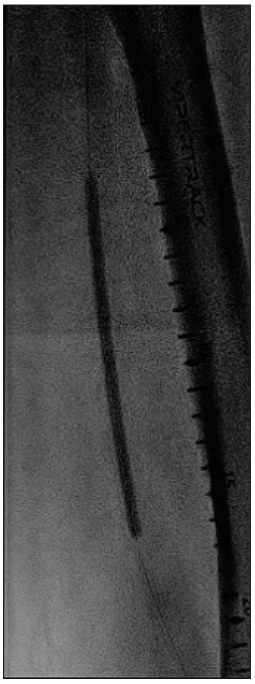

Figure 3. A 5- X 120-cm Serranator balloon inflated in the mid SFA (located from approximately 2-16 on ruler).

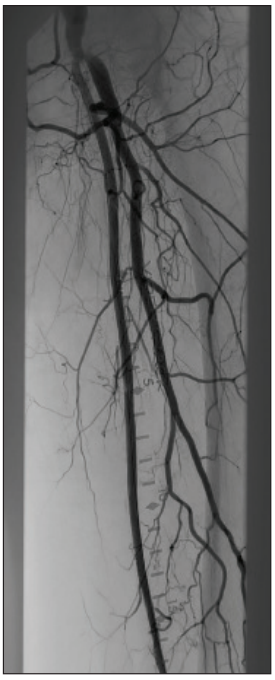

Figure 4. Angiography post-Serranator.

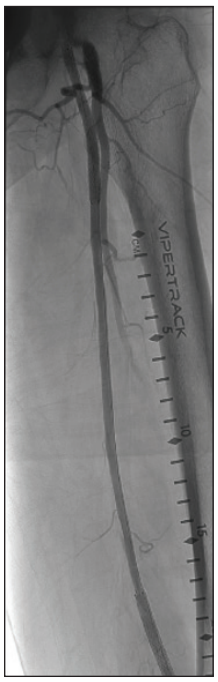

Figure 5. Final angiogram after DCB in mid-segment and proximal and distal stent placement.

knee Serranator had recently been released, and given my positive experiences using it below the knee, I was confident it would help achieve large lumen gain with minimal risk of dissection. I also knew I was planning on using drug-elution therapy to conclude the case, and there is potentially greater drug uptake following Serranator compared to POBA.

We have learned from Prof. Brodmann's paper that there is more blood flow following Serranator use versus POBA.[1] Do you see that in your practice as well?

Dr. Sharma: I would agree, the luminal gain is better than POBA, and it's obvious on angiography.

This was a patient with claudication. Have you also used the Serranator in patients with critical limb ischemia? If so, when and why might you use it?

Dr. Sharma: I believe it really helps with wound healing. Good antegrade blood flow is needed for wounds to heal, and when we use the Serranator, we get good blush, not sluggish flow. And most importantly, all without the need for stents.

You used the Serranator with atherectomy in this case. How do you think they work together in your practice?

Dr. Sharma: There are no randomized data, but as an interventional cardiologist at a high-volume center, I believe in debulking. Atherectomy, when used appropriately for the right vessel and right level, can debulk and allow the Serranator to then open the lumen. In this case, we debulked at the distal and ostial cap of the CTO and used the Serranator to expand the SFA and prepare for drug elution. I believe this combination use is great, if chosen appropriately.

Do you see recoil following use of the Serranator?

Dr. Sharma: There is less recoil after Serranator use for sure. I try hard to avoid the need for bailout stenting. The goal is to achieve robust flow to the foot with minimal risk of dissection and recoil and no need for a stent. The mechanism of action of the Serranator makes that more likely than POBA. ■

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Use of Serranator as Standalone Treatment in a SFA Occlusion

With Vincent M. DiGiovanni, DO

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Disclosures: None.

PATIENT PRESENTATION

A man in his early 70s presented with bilateral lower extremity claudication at approximately 50 yards. The patient is a former smoker, with a 50 pack-year history of tobacco use. Noninvasive arterial testing demonstrated a right resting and post-exercise ankle-brachial index (ABI) of 1.23 and 0.82, respectively, and a left resting and post-exercise ABI of 0.82 and 0.52, respectively. The decision to intervene on this patient was made based on his failure of conservative therapy and his recurrent symptoms, particularly on the left side, which were severe.

PROCEDURAL OVERVIEW

After the patient was prepped in the interventional lab, access was obtained on the contralateral (right) femoral access, and a 6-F Destination sheath (Terumo Interventional Systems) was advanced over the aortic bifurcation. The lesion in the distal left superficial femoral artery (SFA) was unable to be crossed successfully due to numerous collaterals (Figure 1). Pedal access was then obtained into the dorsalis pedis artery, which immediately collateralized through an occluded peroneal artery. The proximal anterior tibial artery was patent; however, the distal anterior tibial artery was chronically occluded. Nevertheless, the wire advanced through the peroneal artery and was able to cross the occlusion in the SFA successfully. The wire was then exteriorized through the 6-F sheath using a microsnare. Serration angioplasty was completed using a 5- X 120-mm Serranator® PTA Serration Balloon Catheter (Cagent Vascular) for the SFA occlusion (Figure 2) and a 2.5- X 80-mm Serranator balloon for the peroneal artery. Subsequent angiography demonstrated excellent luminal gain without dissection in both previously occluded segments (Figure 3). After removal of the microsheath from the pedal artery, there were strong, palpable pulses in both the dorsal pedis and posterior tibial arteries. Postintervention studies at 6 weeks demonstrated normal ABIs in the bilateral lower extremities at rest with normal arterial Doppler results throughout the left leg.

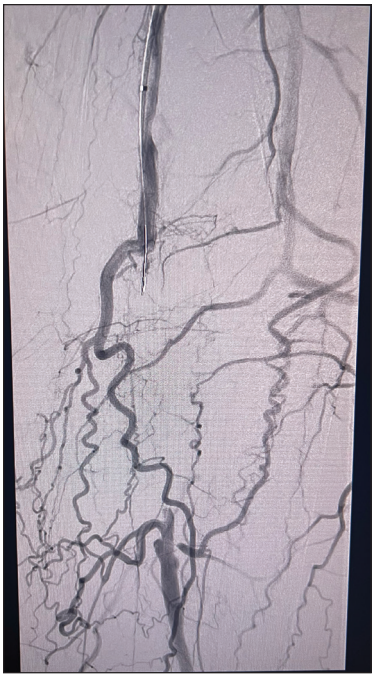

Figure 1. Pre-procedure angiogram.

CONCLUSION

In this patient, there was excellent reestablishment of arterial blood flow to the lower left extremity without requiring internal scaffolding, which was a result of mitigating vessel trauma due to the novel balloon design provided by the Serranator device.

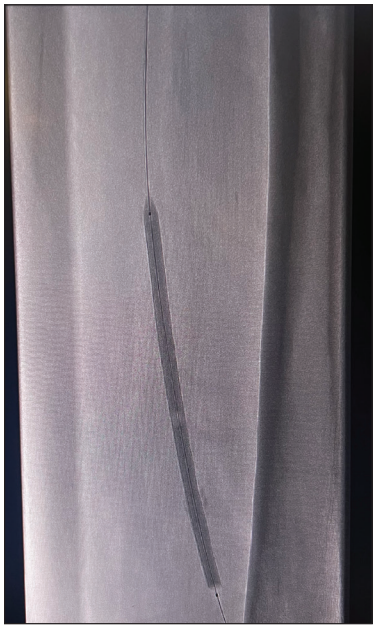

Figure 2. Serration angioplasty of the SFA occlusion with the Serranator balloon.

Figure 3. Completion angiogram showing an excellent result with no dissection.

What is your typical treatment algorithm and when do you choose Serranator?

Dr. DiGiovanni: Serranator has become a workhorse for us, not just below the knee, but also in the SFA/popliteal segments where balloon-associated vessel trauma typically drives the decision for stent placement. The ability to have a low-pressure balloon capable of providing a durable arterial lumen without significant concerns for dissection has proven invaluable to our high-volume practice.

How important is excellent lumen gain prior to using drug-coated therapy? Do you feel like Serranator consistently provides this in the SFA?

Dr. DiGiovanni: Anecdotally, luminal gain appears to be one of the most important aspects of maintaining patency of intervened segments prior to using drug therapy throughout, but most importantly, in the SFA/popliteal segment of the lower extremity. Serranator has consistently offered our patients excellent luminal gain without significant untoward issues, such as dissections, often seen in high-pressure balloon inflations or in heavily calcified vessels.

Is there something about the Serranator's mechanism of action that you believe makes it different than other specialty balloons?

Dr. DiGiovanni: It's ability to establish excellent lumen gain at low pressures, while minimizing vessel trauma, is truly unique in my experience with other specialty balloon technologies. I didn't quite appreciate the mechanism of serration until I began working with the technology; it's remarkably controlled and produces very consistent results regardless of morphology. ■

Distal SFA CTO Treated With Serranator for Significant Luminal Gain Prior to DCB Angioplasty

With Henry D. Hirsch, MD

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Disclosures: None.

PATIENT PRESENTATION

A man in his early 60s with history of tobacco abuse and coronary artery disease with prior coronary stenting was evaluated at an outside institution for severe short-distance claudication and was found to have an ankle-brachial index of 0.6 on the right and 0.4 on the left. CTA revealed bilateral superficial femoral artery (SFA) occlusions, and he underwent left leg interventions with stent placement. He was maintained on dual antiplatelet therapy and a statin. He subsequently presented for evaluation of short-distance claudication of the right leg.

DIAGNOSTIC ASSESSMENT

Noninvasive vascular testing was repeated, which found a right distal SFA occlusion, and the patient was brought to the catheterization laboratory for revascularization. Left common femoral artery access was established for aortography and right leg angiography. There was heavy calcification of the right SFA with chronic total occlusion (CTO) of a 6-cm segment in the distal SFA and popliteal reconstitution with three-vessel runoff (Figure 1).

INTERVENTION

A 7-F Destination sheath (Terumo Interventional Systems) was inserted, and the CTO lesion was crossed using a Glidewire Advantage and NaviCross catheter (both Terumo Interventional Systems). Popliteal re-entry was confirmed with angiography. The wire was exchanged to a 0.014-inch Grand Slam guidewire (Asahi Intecc), and predilation was performed with a 4- X 150-mm plain angioplasty balloon. A 0.014-inch intravascular ultrasound (IVUS) was then inserted, and the SFA was examined. The wire course was found to be luminal, without evidence of subintimal dissection. The lesion was heavily calcified, and significant stenosis was identified proximal to the area of CTO. The wire was exchanged to a 7-mm SpiderFX embolic protection device (Medtronic) and a 2.4-mm Jetstream XC atherectomy catheter (Boston Scientific Corporation) was inserted. Atherectomy was performed throughout the occluded segment and proximal stenotic areas. Five total passes were performed, but the fifth pass was truncated due to patient tolerance.

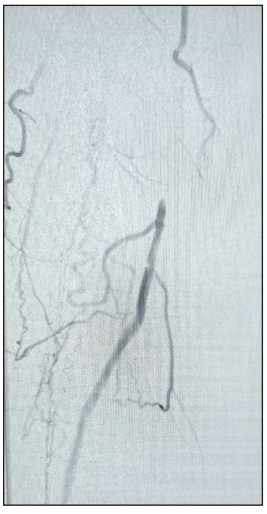

Figure 1. Pre-procedure angiogram.

Although significant lumen gain was achieved with atherectomy, there remained areas of significant stenosis (Figure 2). The filter wire was captured and exchanged to a 0.014-inch Grand Slam. Balloon angioplasty with the 5- X 120-mm Serranator® PTA Serration Balloon Catheter (Cagent Vascular) was performed using two overlapping inflations of 120 seconds each at 8 atm (Figure 3). There was significant luminal improvement after serration balloon angioplasty (Figure 4). Therapy was completed with drug-coated balloon (DCB) angioplasty of the entire treated area using a 6- X 200-mm Ranger balloon (Boston Scientific Corporation; Figure 5). The result was excellent, with revascularization of the distal SFA and three-vessel runoff. The sheath was withdrawn and manual pressure held for hemostasis. The patient was maintained on dual antiplatelet therapy and a statin.

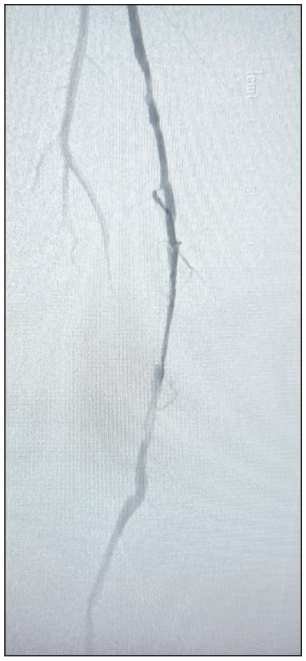

Figure 2. Post-atherectomy with remaining significant stenosis.

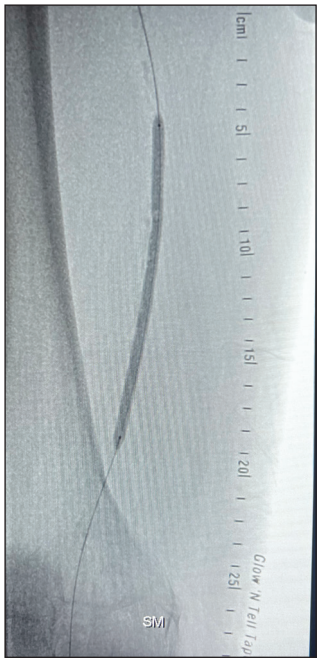

Figure 3. Inflation of the Serranator.

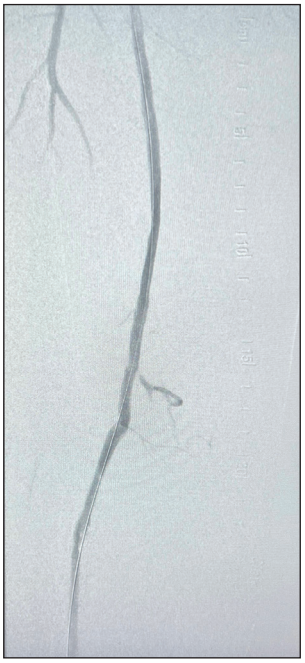

Figure 4. Improvement after serration balloon angioplasty.

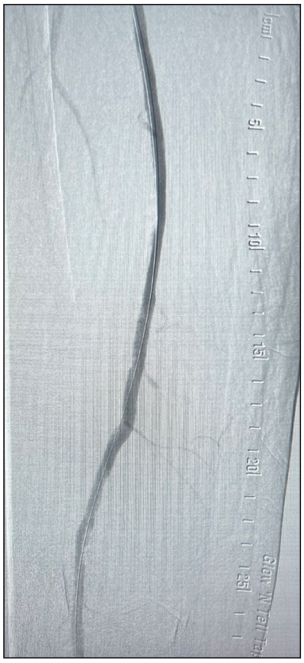

Figure 5. Completion angiogram after DCB angioplasty.

CONCLUSION

This case exemplifies the use of IVUS in decision-making for treatment of complex SFA lesions. Atherectomy and serration balloon angioplasty served as important adjuncts in lesion preparation for DCB angioplasty and the use of stents was avoided, with excellent outcome.

What is your typical treatment algorithm and when do you choose Serranator?

Dr. Hirsch: Treatment algorithm varies by lesion location and characteristics. When possible, I avoid the use of stents, favoring balloon angioplasty, atherectomy, and DCB angioplasty. Serranator has been particularly valuable in complex lesions with heavy calcium or residual stenosis following other plaque-modifying therapies.

How important is excellent lumen gain prior to using drug-coated therapy? Do you believe Serranator consistently provides this in the SFA?

Dr. Hirsch: Lesion preparation with good lumen gain prior to DCB angioplasty has proven to be the best strategy in our practice. I seldom rely on DCB alone for lumen gain. Serranator has become a reliable choice for plaque modification in resistant SFA lesions, particularly in cases with bad circumferential disease.

Is there something about the Serranator's mechanism of action that you believe makes it different than other specialty balloons?

Dr. Hirsch: The serrated strip is significantly different from previous types of cutting balloons. The Serranator strips seem more aggressive than previous "controlled plaque fracture" balloons, achieving more predictable results with fewer dissections.

Do you utilize Serranator below the knee, and what types of results are you seeing?

Dr. Hirsch: The majority of Serranator cases have been below-knee applications, where I universally avoid stent placement. Results of tibial angioplasty with Serranator have been excellent with high limb salvage rates and exceptional patency for tibial level intervention. ■

How Much Lumen Are You Willing to Lose?

Serranator® PTA Serration Balloon Catheter versus plain old balloon angioplasty.

With Michael Lichtenberg, MD, FESC

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Disclosures: Consultant for Cagent Vascular.

Despite recoil being understood as a phenomenon in below-the-knee (BTK) intervention, there are limited studies and literature that investigate this unique challenge. What is your experience with recoil in your clinical practice?

Dr. Lichtenberg: We are very aware of recoil in our practice. Baumann et al illustrated recoil in 29/30 (97%) of patients at 15 minutes after balloon angioplasty,[1] and in my estimation as an angiologist, this is something that is really affecting the patency outcome. It's a real clinical challenge with a real clinical impact.

What is recoil and why does it happen?

Dr. Lichtenberg: Recoil is loss of acute lumen after angioplasty in diseased vessels, and it is especially seen in the BTK vessels. When we perform standard plain old balloon angioplasty (POBA) in a BTK diseased vessel, which typically presents as highly calcified, we find that after only 15 minutes, the result is much the same as before we started. Recoil severely effects the outcome of these critical limb ischemia patients (Figure 1).

How does a vessel that experiences recoil impact flow? Is there an impact on the clinical outcome?

Dr. Lichtenberg: When the vessel recoils, you are essentially losing lumen you created within minutes of the procedure and consequently losing flow to the foot, which will certainly impact the clinical outcome. Our goal is to create the largest, most stable lumen possible. This means we must reduce or eliminate recoil to achieve the necessary outcome.

LESIONS TREATED WITH SERRANATOR HAVE 89% LESS RECOIL THAN POBA

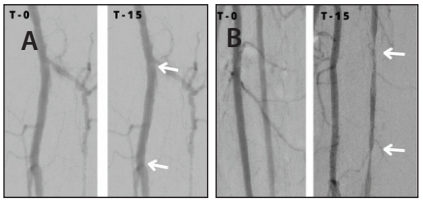

Figure 1. The Serranator had 6% mean recoil across all lesions at 15 minutes post-inflation (A). POBA had 55% mean recoil across all lesions at 15 minutes (B).

Tell us about the RECOIL study that compared Serranator® PTA Serration Balloon Catheter (Cagent Vascular) to POBA.[2]

Dr. Lichtenberg: We found a very impressive and highly significant difference between POBA and Serranator at 15 minutes post-inflation. This core lab–adjudicated study showed that Serranator has an 89% improvement in recoil over POBA in these tibial vessels. The mean recoil percent in the Serranator group was 6% versus 55% in the POBA group (Figure 1). My personal belief is that serration angioplasty increases the compliance of the vessel, and in doing so, lowers the risk of barotrauma, dissection, restenosis, and recoil. ■

1. Baumann F, Fust J, Engelberger RP, et al. Early recoil after balloon angioplasty of tibial artery obstructions in patients with critical limb ischemia. J Endovasc Ther. 2014;21:44-51. doi:10.1583/13-4486MR.1
2. Serranator Recoil study. Clinicaltrials.gov website. Accessed September 5, 2023. https://www.clinicaltrials.gov/study/NCT05161039

Pedal Intervention Using Serranator

An interview with Edward D. Gifford, MD, FSVS, FACS, RPVI

Edward D. Gifford, MD, FSVS, FACS, RPVI
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Co-Director, East Region Limb Preservation Program
Hartford HealthCare Heart & Vascular Institute at Hartford Hospital
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Disclosures: Receives research funding from Cagent Vascular.

Treatment in the pedal arteries is often cited as important, but it isn't commonplace in many practices. You recently led and presented results from a retrospective study looking at the impact of treating pedal lesions with Serranator® serration angioplasty (Cagent Vascular). What caused you to want to investigate this?

Dr. Gifford: We noticed that in patients we treat, disease often doesn't stop at the ankle joint. There is often significant disease within the pedal vasculature, limiting flow where it is needed most. Unfortunately, we have very limited options for treatment of these patients, and it's an area in which we don't want to cause vessel injury. To that end, we noticed that serration angioplasty was achieving great on-table results that were also very durable. We got together with investigators from the United States and Germany and looked retrospectively at results using serration angioplasty below the ankle joint.

What are some of the challenges operators encounter in the pedal anatomy?

Dr. Gifford: There are two real problems in pedal intervention. The first is, can you successfully deliver your therapy to that anatomic bed? You're going through calcified, tortuous vessels to deliver below the ankle joint. The second consideration is, can you treat small pedal vessels safely? A vessel injury on the table can be catastrophic and result in major amputation. Some of the Serranator's unique features lend themselves very well to pedal artery intervention. For instance, the individual point tips along the serrated strips can collectively apply up to 1,000 times greater force than plain old balloon angioplasty (POBA) at very low inflation pressures—allowing us to achieve a lot of directed therapy without barotrauma.

What is your goal when treating in the pedals?

Dr. Gifford: As I mentioned, we have to give chronic limb-threatening ischemia patients not only an efficacious result at the time of treatment but also a durable result for wound healing. We saw > 90% freedom from pedal reintervention in this study and 97% freedom from major amputation at our most recent follow-up, which is pretty remarkable in a very high-risk patient population.

Does the mechanism of action give you some leeway on your choice of diameter and balloon-to-artery ratio? How do you decide which size to use?

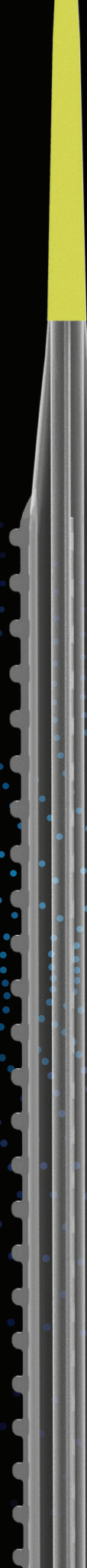
Dr. Gifford: I think that is one of the barriers we've really had with POBA prior to this. If our first goal is to do no harm, we don't want to use something that is too aggressive that is going to injure the vessel. A 1.5- or 2-mm balloon probably isn't doing much below ankle joint. Here, we are able to go closer to the true vessel size whether using intrvascular ultrasound or angiography to size that; we're starting off with a 2.5-mm Serranator balloon and going up from there. In our series, we actually had 10 patients who tolerated 3- and 3.5-mm balloons below the ankle, which is pretty remarkable.

How do the results of this study inform your real-world algorithm?

Dr. Gifford: As a vascular surgeon, I like to use all the tools in my toolbox. We recognize that patients with intrinsic pedal disease have very limited options available to them to improve blood flow in that anatomic distribution. For me, it's such a benefit to have a particular tool that we've shown in this study to be safe and very effective in this difficult-to-treat patient population. ■

Serranator®

PTA Serration Balloon Catheter



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