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PTA Serration Balloon Catheter

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IT'S TIME FOR A NEW STANDARD OF CARE

Addressing the Challenge of PAD Treatment With Serration Technology

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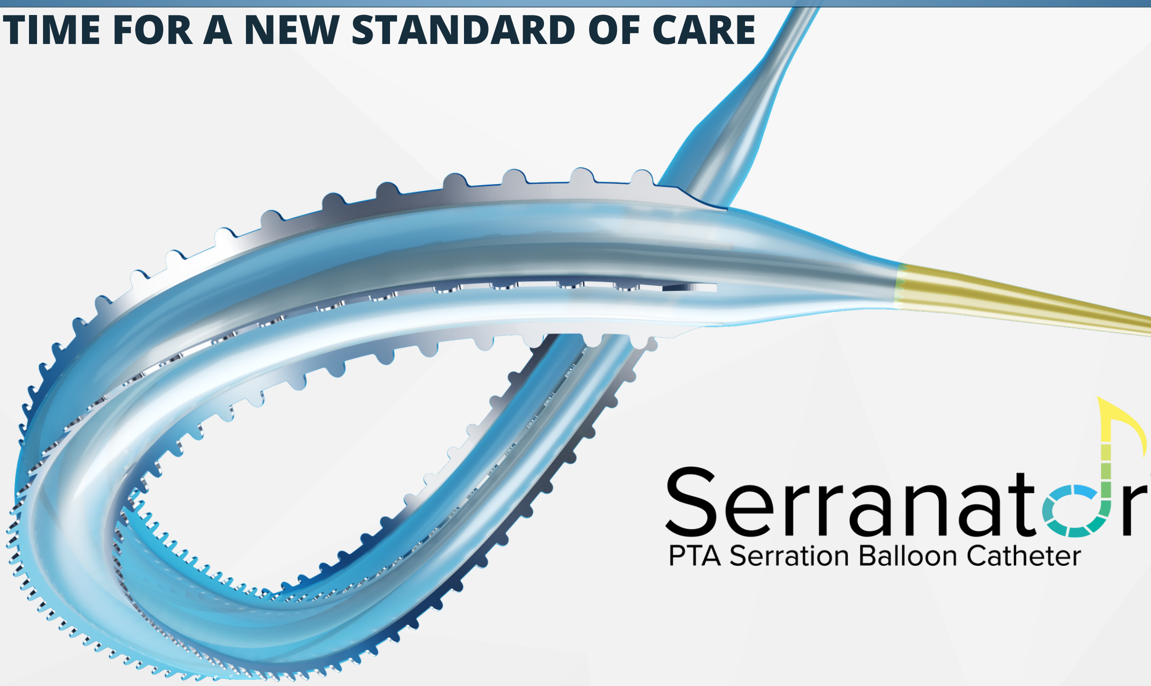


Serranator®

PTA Serration Balloon Catheter

Serranate with 1,000x more Point Force than POBA

• Predictable lumen gain • Effective in all lesion morphologies •

Optimize Lumen Gain	Mitigate Recoil	Minimize Dissection
>97.7% FREEDOM FROM CD-TLR @6MOS	89% LESS AVERAGE RECOIL THAN POBA	1.9% BAILOUT STENT RATE PRELUDE-BTK

The Serranator® PTA Serration Balloon Catheter: It's Time for a New Standard of Care

By Peter A. Soukas, MD

Peripheral artery disease (PAD) and critical limb ischemia (CLI) are major and growing health concerns with profound implications for both patients and health care systems. PAD affects approximately 200 million people globally, and its prevalence is increasing due to rising rates of obesity and diabetes.[1] CLI, a severe form of PAD, involves critical reductions in blood flow to the limbs, leading to severe complications such as nonhealing ulcers and gangrene. The severity of CLI is reflected in its high rates of limb amputation and mortality, with a 45% mortality rate at 12 months for patients who undergo a major amputation.[2] The mortality rate for CLI exceeds that of many cancers, with some experts describing it as "vascular cancer" due to its severe and often fatal nature.[3]

Moreover, CLI imposes a substantial economic burden. The cost of CLI-related major amputations is significant, with an estimated direct medical cost of $13.4 billion. However, this amount doesn't include the costs related to long-term care and loss of productivity; the annual cost for follow-up care exceeds $160,000 per patient, with lifetime costs adding an additional $11.1 billion, for a total of $24.5 billion.[4] Alarmingly, over 50% of CLI patients receive major amputations without undergoing adequate revascularization, emphasizing the need for improved screening and intervention strategies to reduce both the human and economic toll of this condition.[5] Addressing these challenges requires concerted efforts to enhance treatment approaches and preventive measures to better manage this debilitating disease.

SERRATION BALLOON ANGIOPLASTY

The Serranator® PTA Serration Balloon Catheter (Cagent Vascular) represents a significant advancement over plain old balloon angioplasty (POBA). Unlike other focal force therapies that use helical or longitudinal wires, the Serranator has stainless steel serrated elements along the surface of the balloon so that pressure can be concentrated longitudinally along many points of contact (Figure 1). This design generates a point force over 1,000 times greater than POBA. This technology may reduce the risk of dissection and uncontrolled fractures often associated with POBA by directing energy along the serrated line. Serranator can be utilized for vessel preparation prior to drug or stent delivery or as a standalone tool while minimizing recoil and dissections. It is effective across all lesion morphologies, including both fibrotic and calcific tissues, providing optimal lumen gain. The PRELUDE and PRELUDE BTK studies demonstrated a > 97.7% freedom from target lesion revascularization rate at 6 months[6,7] and only a 1.9% bailout stent rate in the PRELUDE BTK study.[7]

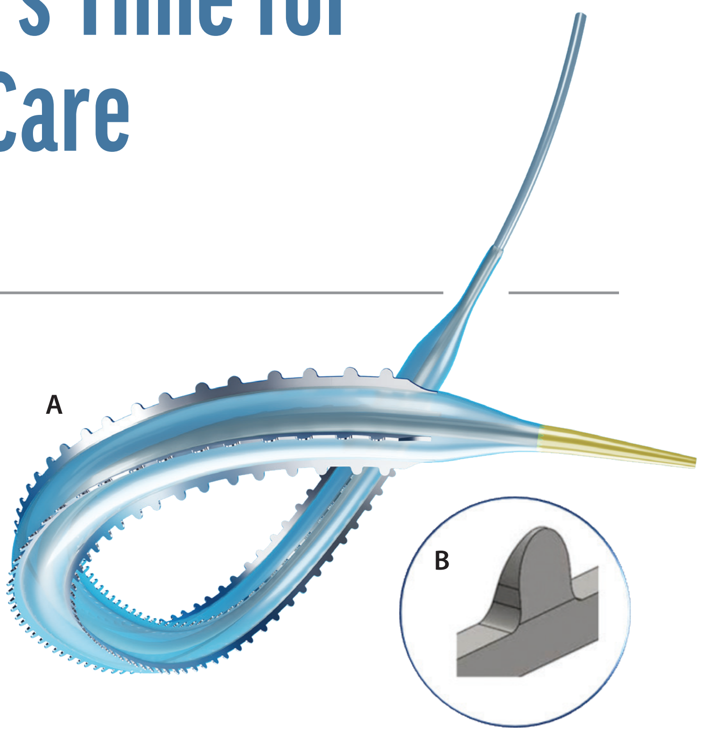


Figure 1. The Serranator has stainless steel serrated elements along the surface of the balloon to create linear, interrupted scoring along the endoluminal surface (A). Serranator applies 1,000 times the force compared to POBA (B).

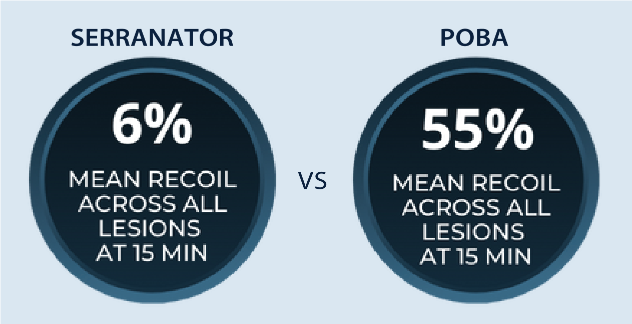
ATK LANDSCAPE

Above-the-knee (ATK) interventions generally involve larger vessels, where endovascular techniques, drug-coated or drug-eluting therapies, and stenting are more straightforward. The primary challenge in the ATK space is achieving durable outcomes without concerns about intensive anticoagulation. Although stenting is more commonly used ATK, where the risk of thrombosis and bleeding complications is comparatively lower than below the knee (BTK), drug-coated balloon (DCB) angioplasty may help mitigate restenosis and offer a more durable result. Proper lesion preparation was emphasized in the THUNDER study as critical before DCB use, particularly in minimizing the occurrence of flow-limiting dissections that could compromise the effectiveness of the DCB.[8] Serration angioplasty enables controlled lesion expansion and luminal gain and reduces the risk of uncontrolled dissection and therefore can be an effective tool prior to the use of DCB.

BTK LANDSCAPE

BTK interventions present unique challenges that differentiate them from ATK treatments. BTK disease tends to be more diffuse, with longer and more heavily calcified lesions. Although scaffolding has proven to be effective in ATK disease, it is not typically a strategy in BTK due to the lack of available devices, particularly for distal tibial locations where stent crush is possible.

Recoil is also a significant issue in vascular interventions, as highlighted in the study by Baumann and colleagues, which demonstrated a 29% recoil rate just 15 minutes after treatment.[9] This study has been widely recognized for its impact on how we understand and approach vascular recoil. Additionally, the more recent RECOIL study, led by Michael Lichtenberg, MD, further emphasized the challenges of recoil. This study compared Serranator and POBA, resulting in only 6% mean recoil following the use of Serranator as compared with 55% mean recoil following POBA.[10] These findings underscore the importance of addressing recoil to improve the success of vascular procedures. Providing durable lumen gain in these tibial vessels is important for preventing restenosis and improving flow to the foot to promote wound healing and prevent amputation.



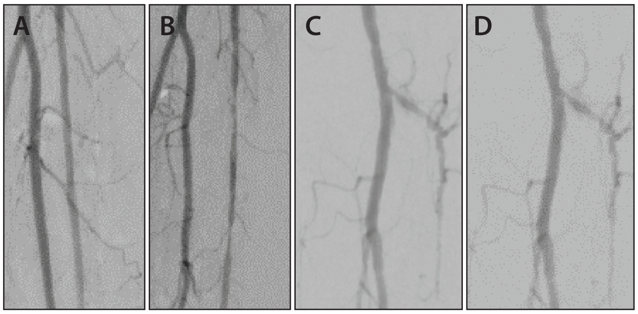


Figure 2. Results post-POBA at 0 (A) and 15 minutes (B) and post-Serranator angiography at 0 (C) and 15 minutes (D).

IMPORTANCE OF VESSEL PREPARATION AND OPTIMAL LUMEN GAIN

Multiple studies have demonstrated the importance of quality vessel preparation prior to the use of definitive therapy in both the ATK and BTK space. Although stenting has not historically been included in the treatment algorithm for BTK disease, the LIFE-BTK study represented a significant advancement for drug-eluting stent (DES) technology in the BTK space. This study focused on the use of a novel DES, Esprit BTK (Abbott), which is specifically designed for BTK arteries. The study showed a primary patency rate of 76.9% at 6 months, with a low major adverse limb event rate of 6.7%.[11] However, this DES is limited for use in the proximal third of the BTK vessels.

Coronary DESs have been used BTK, mostly as a bailout option, and they are available only in very short lengths. Given that most BTK disease is diffuse, calcified, and occlusive, it's not practical or economically tenable to use 10 or 12 coronary stents in a single patient. Therefore, it is even more important in these long tibial vessels to open the lesion without causing a flow-limiting dissection.

Another study of note is the REAL trial, which compared DCB to DES in BTK disease, and found that DESs outperformed DCBs, demonstrating better patency rates and clinical outcomes.[12] However, many patients in the study received "full metal jackets," with long stent lengths used to cover extensive disease. Although this approach improved outcomes compared to DCBs, it also raises concerns about antithrombotic management and the risks associated with leaving a permanent prosthesis in these small, distal vessels.

One of the reasons for the limited success of DCB trials in BTK disease has been inadequate vessel preparation and device undersizing. For example, Fujihara et al confirmed

SERRANATOR IN MY PRACTICE

Serration technology finds a role in both my ATK and BTK procedures. The 120-mm-length device is particularly useful in the diffusely diseased, tibial vessels and allows me to treat long lesions quickly and economically while providing a predictable result. Serranator has also proven useful in the common femoral, superficial femoral, and profunda arteries, utilized prior to a DCB. With Serranator, it's impressive to see what looks like a "stent-like" result but without the stent (Figure 2). I've also had a very positive experience with the device for treating in-stent restenosis and for preparing proximal and distal anastomosis sites in patients undergoing Detour (Endologix LLC) percutaneous bypass procedures.

that BTK interventions guided by intravascular ultrasound (IVUS) resulted in a significantly higher wound healing rate compared with angiographically guided interventions, with similar freedom from target lesion revascularization and limb salvage rates. Mean balloon size was 2.45 ± 0.4 mm versus 2.23 ± 0.4 mm (*P* < .001) in the IVUS-guided group with greater skin perfusion pressures but similar technical success and complication rates.[13] Techniques such as atherectomy, intravascular lithotripsy, and advanced vessel preparation devices like the Serranator can improve outcomes by optimizing vessel conditions before using drug-eluting therapies.

SOLUTION

If DCBs for BTK become available and are combined with effective vessel preparation with the Serranator, I anticipate that this approach will likely become a standard treatment method for BTK interventions. The Serranator allows for more controlled and predictable vessel dilation along the linear serrated line at comparatively lower inflation pressures. We all recognize the critical importance of vessel preparation, and in my view, the only way to make significant progress in treating CLI is to combine thorough vessel preparation with advanced drug delivery technologies. ■

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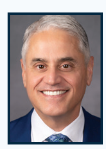

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Tibial Occlusive Disease Treated With Serranator® PTA Serration Balloon Catheter

With Michael Lieb, DO

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PATIENT PRESENTATION

A woman in her late 50s, a nonsmoker with a history of diabetes mellitus, coronary artery disease, congestive heart failure, and ischemic cardiomyopathy, presented to the hospital with osteomyelitis of the right great toe and plantar foot abscess (Figure 1A). She has had no previous arterial interventions in her lower extremities. She underwent emergent incision and drainage by the podiatry service, with tarsometatarsal amputation of the great toe and extensive soft tissue debridement of the foot for source control (Figure 1B and 1C). Vascular surgery was consulted postoperatively for the lack of palpable pulses and concerns for wound healing potential.

She underwent noninvasive vascular testing with ankle-brachial index (ABI)/pulse volume recording showing a right ABI of 0.56 and a right toe-brachial index of 0.24. CTA with runoff showed multifocal stenosis with a high-grade lesion in the distal superficial femoral artery (SFA) as well as tibial occlusive disease. She was offered angiography with

Figure 1. Initial presentation (A). After incision and drainage and amputation (B). At follow-up in wound care with a granulating wound after revascularization (C).

Figure 2. AT and DP artery outflow showing no pedal arch (A). PT artery outflow showing filling of plantar vessels but no pedal arch (B).

intervention to restore inline flow to the foot and facilitate wound healing.

PROCEDURAL OVERVIEW

Angiography of the right leg was performed via ultrasound-guided left femoral artery access, and right leg runoff imaging was obtained. There was evidence of calcified vessels but no hemodynamically significant stenosis from the aortic bifurcation to the mid SFA. There were two hemodynamically significant stenoses in the distal SFA leading into Hunter's canal. The popliteal artery was patent without significant disease. The dominant outflow in the calf was via the anterior tibial (AT) artery, filling the dorsalis pedis (DP) artery (Figure 2A). The tibioperoneal trunk (TPT) and proximal posterior tibial (PT) artery were occluded. There was reconstitution of the mid and distal PT artery, which was then continuous into the foot, filling the plantar branches. The peroneal artery was occluded. There was no continuous pedal arch, with both the DP and plantar arteries filling into terminal branches (Figure 2B).

No intervention was necessary on the anterior circulation to the foot other than maximizing blood flow; however, the posterior circulation to the foot required inline flow.

After administering heparin, a 6-F, 60-cm sheath was advanced, and we crossed the SFA lesions and focused first on the tibial disease. We manipulated a 0.014-inch Hi-Torque Command wire (Abbott) into the TPT and ultimately into the PT artery with the assistance of an 0.014-inch TrailBlazer catheter (Medtronic). After angiography confirmed we were within the true lumen, serial balloon angioplasty of the lesion was performed, first utilizing a 1.5- X 80-mm Ultraverse balloon (BD Interventional) inflated up to 12 atm, followed by a 3- X 120-mm Serranator® PTA Balloon Catheter (Cagent Vascular) inflated up to 6 atm for 2 minutes (Figure 3A and 3B). Repeat imaging showed continuous flow throughout the PT artery into the pedal vessel without evidence of recoil (Figure 3C). The SFA lesion was then treated with a 5- X 40-mm Ultraverse balloon inflated to 12 atm for 2 minutes (Figure 4A). Repeat imaging showed good flow through the treated areas without any significant recoil (Figure 4B) and no further treatment was deemed necessary. At case completion, the patient had inline flow to the foot via both AT and PT arteries.

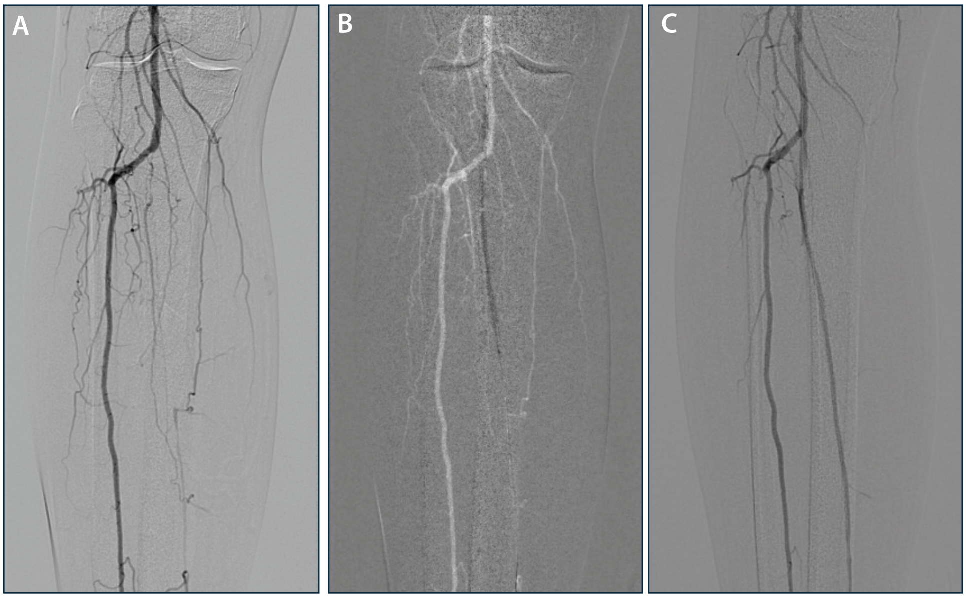

Figure 3. Initial angiogram (A). Use of a 3- X 120-mm Serranator (B). Completion angiogram (C).

POSTTREATMENT COURSE

The patient subsequently underwent serial debridements and ultimately Integra graft placement (Integra LifeSciences) with the podiatry team to facilitate wound healing. The patient underwent repeat angiography 4 months later at an outside institution. She underwent stenting of the SFA at that time; however, the previously treated tibial vessels were still patent and did not require further intervention (Figure 4C).

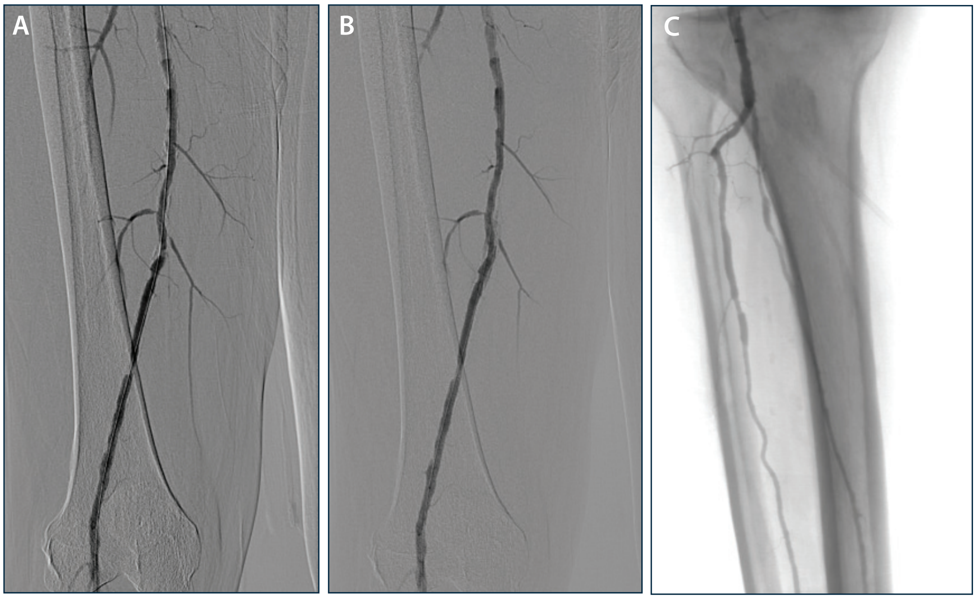

Figure 4. Initial angiogram (A). Completion angiogram (B). This POBA-treated SFA required revascularization 4 months later and was treated at an outside institution. At that time, the Serranator-treated PT artery was still patent (C).

What is your typical treatment algorithm for peripheral artery disease (or critical limb ischemia [CLI] if a below the knee [BTK]) cases, and when do you choose Serranator?

Dr. Lieb: BTK disease is historically difficult to treat given the heavily calcified vessels. Traditional angioplasty relies on high-pressure balloon inflations to fracture plaque, which can lead to dissection flaps. The Serranator technology allows for increased luminal gain at lower inflation pressures due to the multiple contact points along the balloon provided by the serration strips. This results in multiple fracturing points throughout the plaque achieved at lower pressures than standard balloon angioplasty. The end result is improved luminal gain with lower chance of complications.

How important is excellent lumen gain prior to using drug-coated balloon (DCB) therapy? Do you feel like Serranator consistently provides this?

Dr. Lieb: DCB offers significant benefit to prevent long-term restenosis in the appropriate patients. As the DCB delivery balloon is not intended for the initial treatment of the lesion, it is important to have the most optimal luminal gain achievable prior to using the DCB. In my practice, Serranator has consistently provided reliable luminal gain in cases where traditional angioplasty has resulted in lesion recoil.

How concerned are you with recoil in these smaller BTK arteries?

Dr. Lieb: Target lesion recoil can be a significant issue in the heavily calcified tibial vessels. This is likely secondary to the linear fracture pattern and incomplete plaque remodeling, which is achieved with plain old balloon angioplasty (POBA). The Serranator technology results in more fracture points along the treated plaque, resulting in better remodeling of the plaque around the balloon. This is also achieved at lower pressures than standard balloon angioplasty, lowering the chance for dissection in these heavily diseased vessels.

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

Dr. Lieb: The multiple contact points on the serration strips provides focused pinpoint pressure delivered directly to the calcified arterial wall. This results in multiple, controlled fracture points along the treated lesion at lower pressures than those needed to form the linear fractures achieved with standard balloon angioplasty. The increased fracture points allow for better lesion remodeling around the angioplasty balloon, which reduces the risk of lesion recoil. Additionally, treatment at lower pressures reduces the risk of vessel damage and dissections. ■

Vessel Preparation With the Serranator® PTA Serration Balloon Catheter in Two Patients With Severely Calcified SFA Occlusions

With Deepika Kalisetti, MD

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Disclosures: Consultant to Cagent Vascular.

CASE STUDY 1

Patient Presentation

A man in his late 60s, a smoker with a history of coronary artery disease, diabetes, hypertension, chronic kidney disease, and lifestyle-inhibiting claudication, presented with right leg pain. The right superficial femoral artery (SFA) had mild to diffuse disease with a severely calcific, subtotally occluded distal segment into the popliteal artery (Figure 1A). The posterior tibial (PT) artery was occluded and filled distally by the communicating branch from the peroneal artery, while the anterior tibial (AT) artery was patent. Based on the results of angiography, the decision was made to perform an intervention and to treat the lesion in the distal SFA and popliteal artery.

Procedural Overview

Contralateral femoral access was obtained, and a 6-F, 45-cm Destination sheath (Terumo Interventional Systems) was advanced to the common femoral artery. A 0.035-inch Glidewire Advantage (Terumo Interventional Systems) with a 0.035-inch, 135-cm Quick-Cross microcatheter (Philips) were advanced to the distal SFA lesion where it could not be crossed. The wire was exchanged for an 0.035-inch straight, stiff Glidewire and advanced through the lesion and into the peroneal artery. The 0.035-inch Quick-Cross was advanced into the peroneal artery, where the straight, stiff Glidewire was removed and exchanged for 0.014-inch Viperwire (Abbott). Following placement of the Viperwire, the Quick-Cross was removed and a 2.0-mm Diamondback 360 (Abbott) was advanced to the lesion. Orbital atherectomy was performed for multiple passes utilizing low, medium, and high speeds. A 6- X 40-mm Serranator® PTA Balloon (Cagent Vascular) was then advanced and inflated for 2 minutes at 6 atm and provided excellent luminal gain without dissection (Figure 1B and 1C). Lastly, a 6- X 60-mm Ranger drug-coated balloon (DCB; Boston Scientific Corporation) was used to treat the same SFA segment.

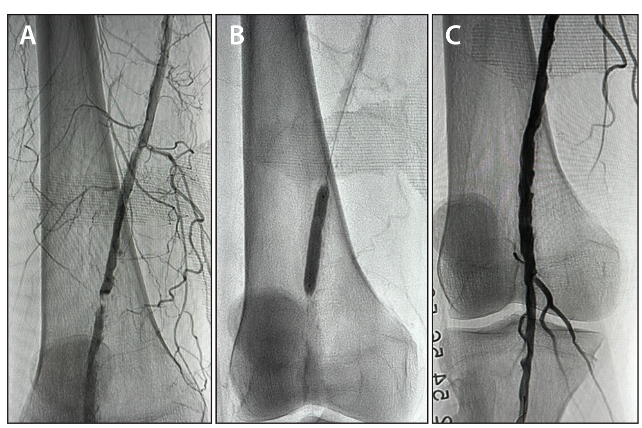


Figure 1. Preprocedure angiogram (A). A 6- X 40-mm Serranator balloon inflated to 6 atm for 2 minutes (B). Post-Serranator angiogram demonstrating lumen gain and no dissection (post-DCB image not shown) (C).

Final angiography showed excellent results with brisk flow to the popliteal segment and brisk filling of the tibial vessels.

CASE STUDY 2

Patient Presentation

A woman in her early 70s, a smoker with hypertension and high cholesterol, presented with lifestyle-inhibiting claudication and resting pain in her left foot. Initial imaging demonstrated a highly calcified chronic total occlusion (CTO) of the left common iliac artery to the external iliac artery as well as a CTO of the left SFA (Figure 2A and 2B). A decision was made to stage the intervention and first treat the iliac lesion. She was treated with serration balloon angioplasty using a 5- X 40-mm Serranator balloon to provide optimal vessel preparation for placement of a 7- X 59-mm Omnilink stent (Abbott).

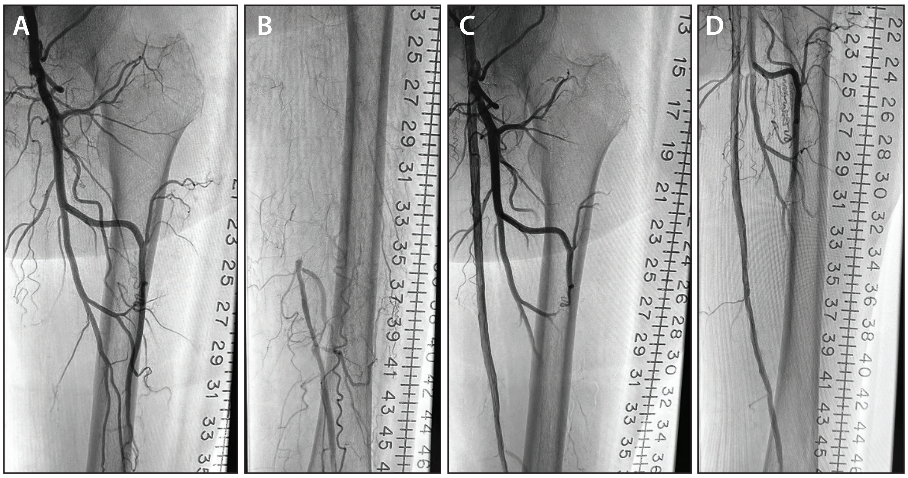


Figure 2. Preprocedure angiograms of the proximal (A) and distal (B) SFA CTO. Postprocedure angiograms showing a patent proximal (C) and distal (D) SFA.

Procedural Overview

A few months later, the patient returned for the treatment left SFA CTO, and initial angiography showed that the previously placed stent in the left common iliac artery was patent. Due to the complexities of the CTO, contralateral and retrograde popliteal access were necessary to cross the CTO. The CTO was crossed using a 0.035-inch Glidewire Advantage with a 0.035-inch, 90-cm Quick-Cross microcatheter from the retrograde approach. Following successful crossing, a 0.018-inch Visions PV intravascular ultrasound (IVUS) catheter (Philips) was advanced and pullback imaging was performed, showing diffuse, multiple segments of fibrotic disease with minimal calcification throughout. The vessel measured at 5.1 to 5.3 mm. A 5- X 120-mm Serranator balloon was utilized to treat the entire SFA with prolonged inflations. After serration angioplasty, angiography showed excellent results. The IVUS catheter was advanced again, showing effective luminal gain without dissection; therefore, a 5- X 150-mm Ranger DCB was used.

Final angiography showed excellent results with brisk flow through the SFA (Figure 2C and 2D).

What has been your overall experience with Serranator?

Dr. Kalisetti: I've had an overall good experience utilizing the Serranator. It is consistent at reducing recoil in the tibial vessels as well as minimizing flow-limiting dissection above the knee.

Has the Serranator replaced any devices on your shelf? If yes, what and why?

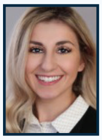
Dr. Kalisetti: Following multiple uses of the Serranator, we chose to replace both Chocolate balloon (Medtronic) and AngioSculpt scoring balloon (Philips) with the Serranator balloon. The results I've seen have been dramatically improved, both postangiography as well as normal ankle-brachial indices during clinical follow-up.

What types of cases do you typically treat with Serranator?

Dr. Kalisetti: I utilize the Serranator above the knee, below the knee, the iliacs, subclavian artery, renal arteries, the superior mesenteric artery, and inferior mesenteric artery. The Serranator is also great for vessel preparation for pre-DCB due to the potential for increased drug absorption. As a user of intravascular lithotripsy, I've found that the mechanism of action of the Serranator can potentially increase the effectiveness of IVL therapy. ■

Serranator® PTA Serration Balloon Catheter as Vessel Prep Prior to Bioresorbable Scaffold Use for Below-the-Knee Disease

With Jessica Katsiroubas, MD, and Rajesh K. Malik, MD, FACS, RPVI



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CASE STUDY 1

Patient Presentation

A woman in her mid-50s with multiple comorbidities presented with bilateral leg cramping and significant rest pain. Ankle-brachial indices (ABIs) were obtained, showing an ABI of 0.70 on the right and 0.65 on the left. Left lower extremity angiography was performed, which demonstrated a stenosed popliteal and an occluded posterior tibial (PT) artery (Figure 1A and 1B).

Procedural Overview

After unsuccessful attempts at crossing antegrade, it was deemed necessary to obtain access distally via the PT artery. Working from below, using a 6-F sheath and crossing wire (0.014-inch Hi-Torque Command [Abbott] and 0.46-mm [0.58-mm outer diameter], 150-mm TrailBlazer [Medtronic]), we were able to cross the popliteal artery and snare the wire to externalize

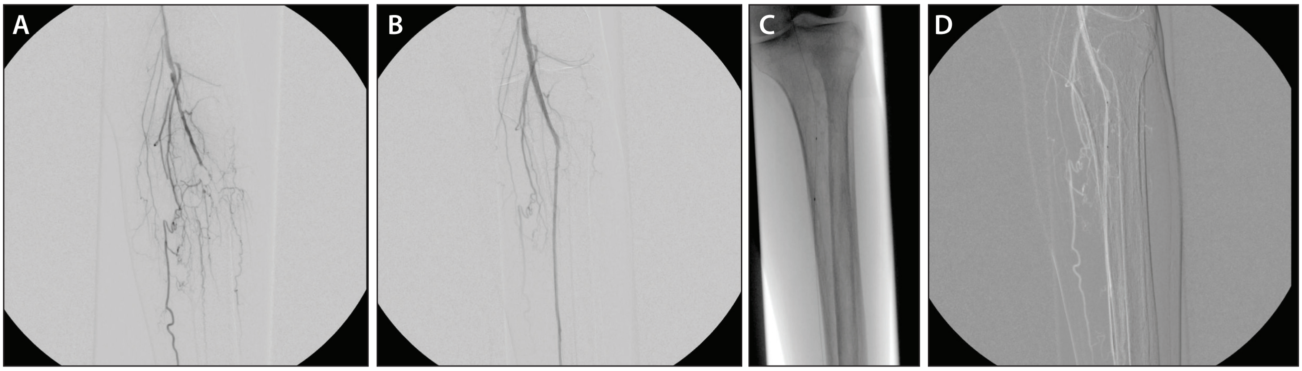


Figure 1. Initial angiograms (A, B). A 2.5- X 80-mm Serranator PTA Serration Balloon for vessel preparation of the occluded PT artery prior to use of a bioresorbable scaffold (BRS) (C). Completion angiogram (D).

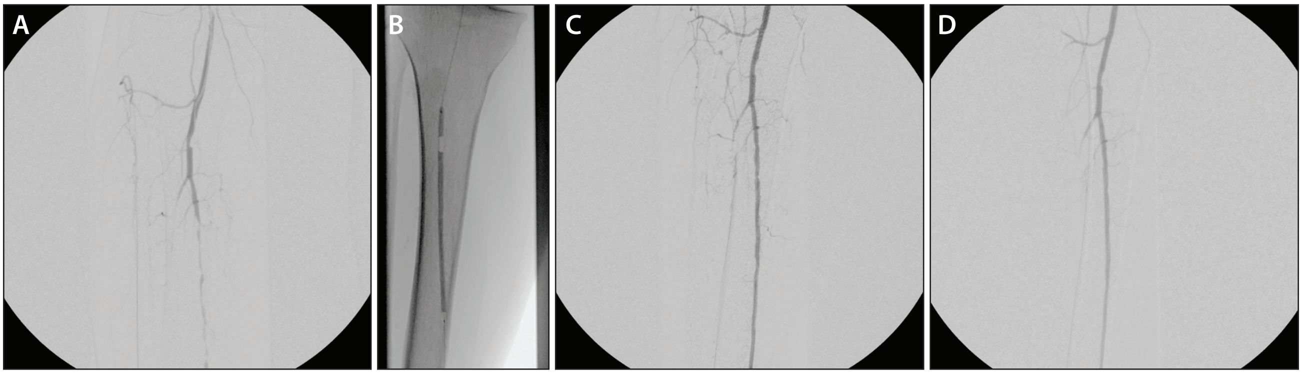


Figure 2. Initial angiogram (A). Vessel prep with a 2.5- X 120-mm Serranator PTA Serration Balloon prior to use of a BRS (B). Final angiograms showing inline flow throughout the PT artery and no dissection (C, D).

the wire. The TurboHawk directional atherectomy device (Medtronic) was utilized throughout the popliteal artery, extending into the PT artery and then followed by a 5- X 150-mm (80- and 130-cm catheter effective length) In.Pact Admiral drug-coated balloon (DCB) in the popliteal artery. We then turned our attention to the occluded PT artery and utilized a 2.5- X 80-mm Serranator® PTA Serration Balloon (Cagent Vascular) (Figure 1C). The Serranator provided the vessel preparation needed to follow with an Esprit BTK everolimus-eluting resorbable scaffold (Abbott).

Conclusion

A completion angiogram showed good inline flow through the popliteal and PT arteries (Figure 1D). There was likely an arteriovenous fistula in the distal portion of the popliteal artery, but it slowed down by the end of the case and we were satisfied with the result.

CASE STUDY 2

Patient Presentation

A man in his mid-70s with a past medical history of chronic kidney disease, coronary artery disease treated with coronary artery bypass grafting, hypertension, hyperlipidemia, peripheral vascular disease, and diabetes mellitus presented with rest pain and a nonhealing right foot wound. His arterial duplex ultrasound showed multilevel bilateral disease; therefore, angiography was performed. This patient was lining up to be a perfect candidate for use of a BRS.

Procedural Overview

Angiography revealed severe disease proximally in the popliteal artery, single-vessel runoff via the PT artery, and a high-grade stenosis going into the foot (Figure 2A). Antegrade access and crossing using a 6-F Destination sheath (Terumo Interventional Systems) and 0.014-inch Hi-Torque Command wire was successful. Atherectomy using the TurboHawk device was performed, followed by a 5- X 80-mm In.Pact DCB in the popliteal artery. After revascularization of the popliteal artery, we began treatment of the PT artery with a 2.5- X 120-mm Serranator PTA Serration Balloon to effectively prep the vessel prior to delivery of the BRS (Figure 2B). Three Esprit BTK everolimus-eluting resorbable scaffolds (one 3 X 38 mm and two 3.5 X 38 mm) were utilized throughout the PT artery. We did not have a 3.0-mm Serranator at the time, but the serration technology still provided the stable lumen gain for the slightly larger BRS.

Conclusion

Final angiography demonstrated wonderful inline flow throughout the PT artery and excellent blood flow without any dissection (Figure 2C and 2D).

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

Drs. Katsiroubas and Malik: We are seeing patients with complex calcified tibial disease in Brooklyn, so we would like to maximize the outcomes of our index procedures. We are using Serranator and Esprit in our primary treatment algorithm when treating below-the-knee (BTK) tibial disease.

How important is excellent lumen gain prior to using drug therapy?

Drs. Katsiroubas and Malik: Good vessel preparation for drug therapy is critical for successful drug uptake, as is proven in many other endovascular modalities. Achieving maximum lumen gain, eliminating recoil, and avoiding dissection are key aspects in vessel preparation. We are maximizing lumen gain and effectively preparing the vessel with Serranator compared to standard angioplasty.

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

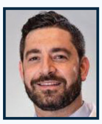
Drs. Katsiroubas and Malik: The Serranator's mechanism is unique because the serration points give the balloon some rigidity, and the semicompliant properties help in these difficult BTK lesions. The three serration strips allow the balloon to open at an equalized force without needing to increase the pressure and aid in minimizing recoil.

Do you utilize Serranator without drug therapy and what are your typical results?

Drs. Katsiroubas and Malik: Yes, we also utilize the Serranator without drug therapy and have appreciated its properties and ability to gain lumen size in challenging lesions. In distal lesions, we have seen remarkable angiographic results as compared to plain old balloon angioplasty. As we continue to utilize the device more, we hope this translates into longer patency, better wound healing rates, and freedom from reintervention. ■

The Serranator® PTA Serration Balloon Catheter in Practice

Dr. Bitton-Faiwiszewski shares his experience treating ATK and BTK disease in an underserved patient population, plus provides results of POBA versus Serranator in a case example.



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Napa, California
Disclosures: Consultant to Cagent Vascular.

Describe your current practice (typical patients, disease state, below the knee [BTK] vs above the knee [ATK]).

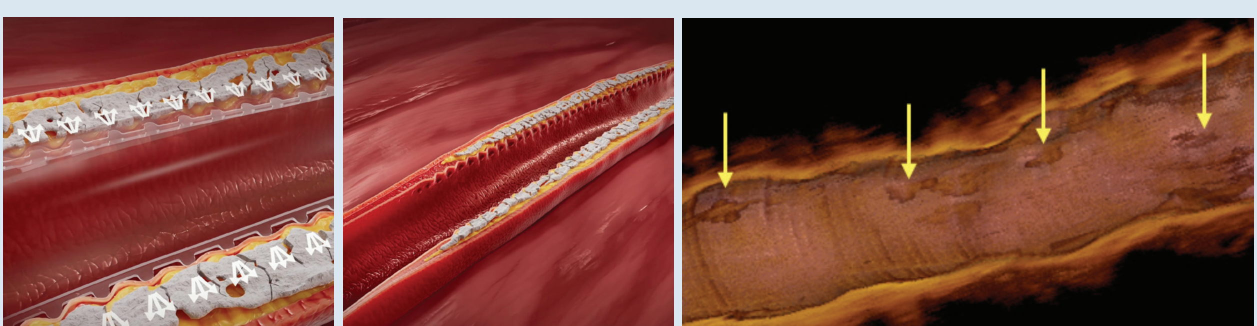
In my practice as an interventional cardiologist at a community hospital, I primarily serve a rural, underserved patient population with advanced disease. About 80% of my work focuses on peripheral vascular disease, including both ATK and BTK conditions, as well as venous thromboembolic disease. A significant portion of my patients present with critical limb ischemia, often due to nonhealing wounds, amputations, or diabetic ulcers. I manage approximately three to five critically ill inpatients per week, providing specialized care to those who might otherwise lack access.

What are your typical algorithms and decision points for ATK treatment?

When treating ATK lesions, my primary decision point is whether the artery is totally occluded. Most of my patients present with total occlusions, and my priority is to cross luminally, avoiding dissection at reentry if possible. After crossing, I implement plaque modification, usually with atherectomy, to ensure the vessel can expand properly. The Serranator® PTA Serration Balloon Catheter (Cagent Vascular) often helps with lesion preparation, minimizing the risk of spiral dissections and allowing for effective drug-coated balloon (DCB) treatment. This strategy frequently results in excellent angiographic outcomes without the need for a permanent scaffold, even in challenging long chronic total occlusions.

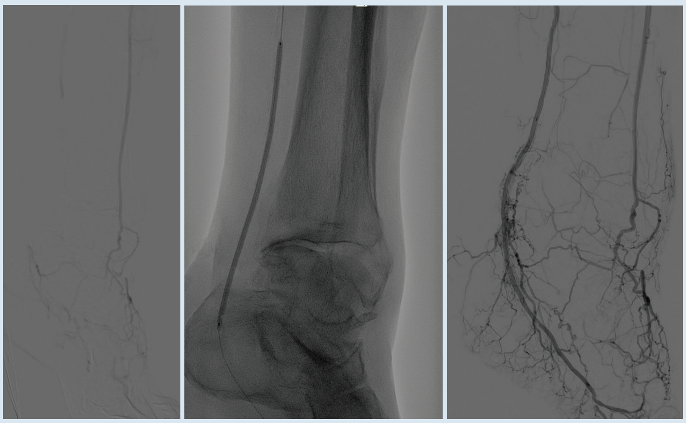
MECHANISM OF ACTION OF SERRANATOR

The Serranator's mechanism of action is distinct because, unlike traditional angioplasty that often creates multiple, unpredictable dissection planes, serration technology provides a controlled line of microdissection or microfissuring within the lesion that releases the internal elastic lamina. This approach allows the vessel to expand in a predictable and safe manner along the serrated line, similar to tearing a sheet of paper out of a notebook. This controlled expansion is preferable over conventional balloon angioplasty, where the outcomes can be less predictable.

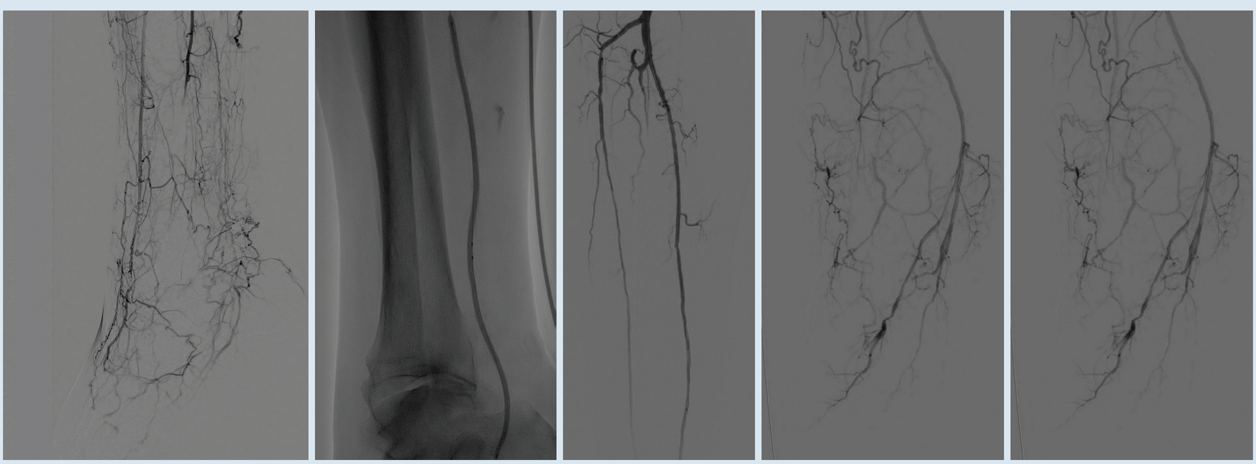


CASE EXAMPLE: CLTI PATIENT WITH BILATERAL DISEASE

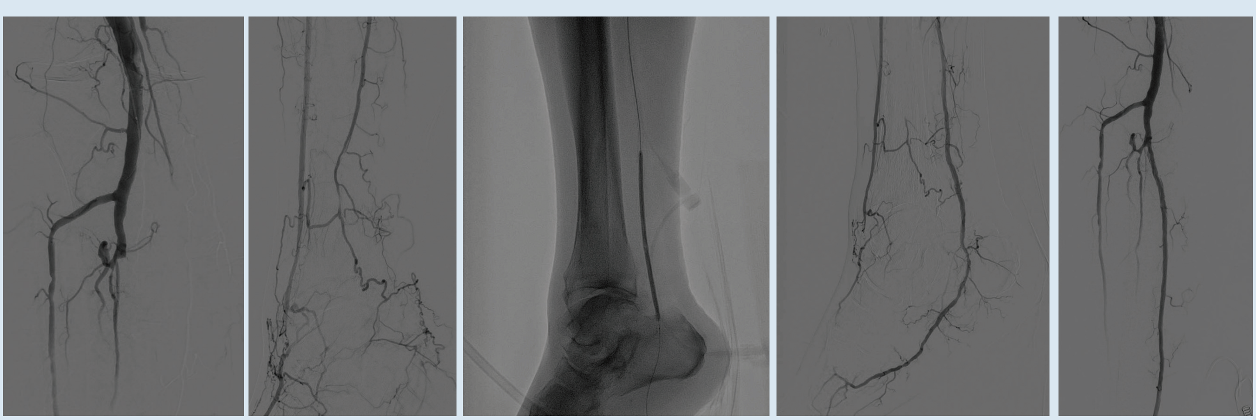
LEFT LEG TREATMENT: SERRANATOR



RIGHT LEG TREATMENT: POBA ONLY



RIGHT LEG TREATMENT 2 MONTHS LATER: PATIENT RE-PRESENTED WITH OCCLUDED PT ARTERY IN THE POBA-TREATED LESION AND SERRANATOR WAS USED TO REVASCULARIZE



If the artery isn't occluded, my approach is to treat the lesion without leaving a scaffold. Typically, I begin with either laser or directional atherectomy and then utilize the Serranator to achieve optimal lumen gain prior to finishing with a DCB. For soft, focal lesions, I will go straight to Serranator.

What about for in-stent restenosis (ISR)?

If the occlusion involves an existing stent, I find the Serranator to be highly effective for treating ISR. The Serranator creates serrations in the fibroelastic tissue, often associated with neointimal hyperplasia inside the stent. This technique results in significant lumen gain and restoration of flow through the occluded stent. In most cases, I can avoid placing an additional stent and follow on with a DCB, achieving excellent angiographic results without introducing more metal.

Is there something unique about the mechanism that makes it different than other specialty balloons, especially when utilizing drug-eluting therapies?

The Serranator plays a critical role in vessel preparation before drug-eluting therapies by achieving two key objectives. First, it ensures the vessel is adequately expanded without significant dissection or recoil, which is crucial for a successful procedure. The Serranator excels in this area by creating controlled microfissures that promote effective vessel expansion.

Second, it's important for drug delivery that the drug comes into contact with the vessel tissue. In my opinion, the Serranator's ability to create controlled microfissures allows the drug to navigate around calcified lesions, which supports the goal of improving tissue contact during drug-eluting therapy. This unique mechanism sets the Serranator apart from other specialty balloons, making it a valuable tool in vessel preparation.

In a recent publication, Serranator demonstrated 89% less recoil when compared to plain old balloon angioplasty (POBA). Is recoil a phenomenon you observe in your BTK clinical practice, and how does Serranator fit into your BTK treatment algorithm?

Recoil is a significant issue, especially in the tibial space, where treatment options are limited, and many practitioners still rely on POBA with or without atherectomy.

In my practice, I view the Serranator as a more definitive therapy for tibial interventions, and it has yielded excellent results for my patients. Although I haven't conducted formal recoil measurements, in cases where there's been a delay between angiograms, I've noticed a marked difference with the Serranator compared to standard balloon angioplasty. Although this is anecdotal, it suggests that the Serranator may offer advantages in managing recoil in BTK interventions.

For instance, I treated a patient with acute limb ischemia in both legs, who had thrombosed femoropopliteal segments and severe BTK disease. I used the Serranator on one leg and POBA on the other, with both legs receiving identical treatment ATK. Two months later, the leg treated with POBA showed restenosis, while the leg treated with the Serranator remained patent and in good condition, indicating a possible recoil-mediated advantage of the Serranator (see Case Example Sidebar).

In what ways do you feel like Serranator has aided in procedure outcomes?

I feel that the Serranator has significantly improved procedure outcomes in several ways. In cases where I achieve a good angiographic result with the Serranator, particularly in the BTK space, I have greater confidence in achieving a longer duration of freedom from target lesion revascularization. This improved outcome likely stems from the Serranator's effectiveness in managing recoil and enhancing vessel preparation. Additionally, in the above-knee space, the Serranator has been instrumental in reducing the need for bailout stenting, which contributes to more successful and durable results.

What other applications would you see for Serration technology in the future?

In the future, serration technology could be highly valuable in the coronary space. With growing interest in DCBs as an alternative to stenting, serration technology may enhance vessel preparation by ensuring effective lumen expansion and minimizing dissection. Additionally, it could address ISR, where fibroelastic tissue often resists treatment with standard or scoring balloons. Serration balloons might provide the focused force needed to manage these challenging lesions, potentially transforming approaches to coronary interventions.

Serration technology could also be beneficial in the iliac arteries, especially for cases involving transfemoral approaches for transcatheter aortic valve replacement (TAVR). Currently, institutions often use intravascular lithotripsy (IVL) for dense calcific lesions in the iliac arteries. However, incorporating the Serranator in addition to IVL might help avoid stenting and reduce the risk of significant dissection. This could enable a smoother transfemoral procedure and eliminate the need for leaving a scaffold behind. This is an intriguing possibility and something I plan to explore further, as it could improve outcomes in iliac artery interventions and enhance the feasibility of TAVR. ■

Serranator®
PTA Serration Balloon Catheter

LET'S GET TO THE POINT

IT'S TIME FOR A NEW STANDARD OF CARE

RECOIL STUDY

HOW MUCH LUMEN ARE YOU WILLING TO LOSE?

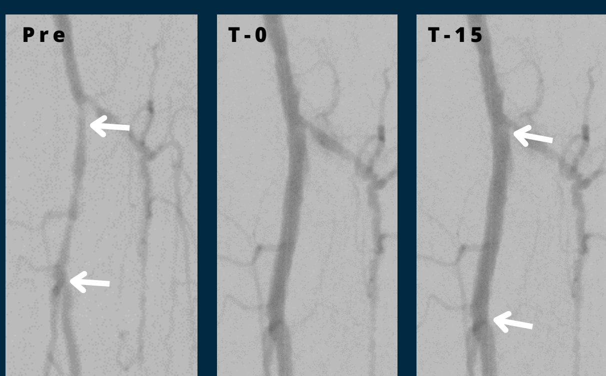
LESIONS TREATED WITH SERRANATOR HAVE 89% LESS RECOIL THAN POBA

Serranator®
PTA Serration Balloon Catheter

6% Recoil

6% (+/- 26) MEAN RECOIL ACROSS ALL LESIONS AT 15 MIN

(n=20)

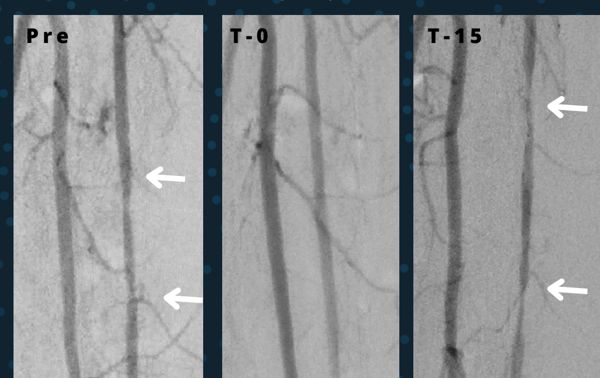


POBA

55% Recoil

55% (+/- 69) MEAN RECOIL ACROSS ALL LESIONS AT 15 MIN

(n=19)



p value = 0.009

Study Design:

- Multi-center feasibility study assessed 39 atherosclerotic lesions in the infrapopliteal arteries.
- Angiographic imaging collected on all lesions (pre, during, post, and post 15 mins)
- Core Lab-adjudicated comparison of serration angioplasty vs POBA

Conclusions:

- Serranator provides 49% reduced recoil compared to POBA, which is statistically significant
- The unique mechanism of action of the Serranator reduces recoil

Fereydooni A, Chandra V, Schneider PA, Giasolli R, Lichtenberg M, Stahlhoff S. Serration Angioplasty Is Associated With Less Recoil in Infrapopliteal Arteries Compared With Plain Balloon Angioplasty. J Endovasc Ther. 2023 Dec 7:15266028231215284. doi: 10.1177/15266028231215284.

Serranator®
PTA Serration Balloon Catheter

Serranate with 1,000x more Point Force than POBA
•Predictable lumen gain • Effective in all lesion morphologies •