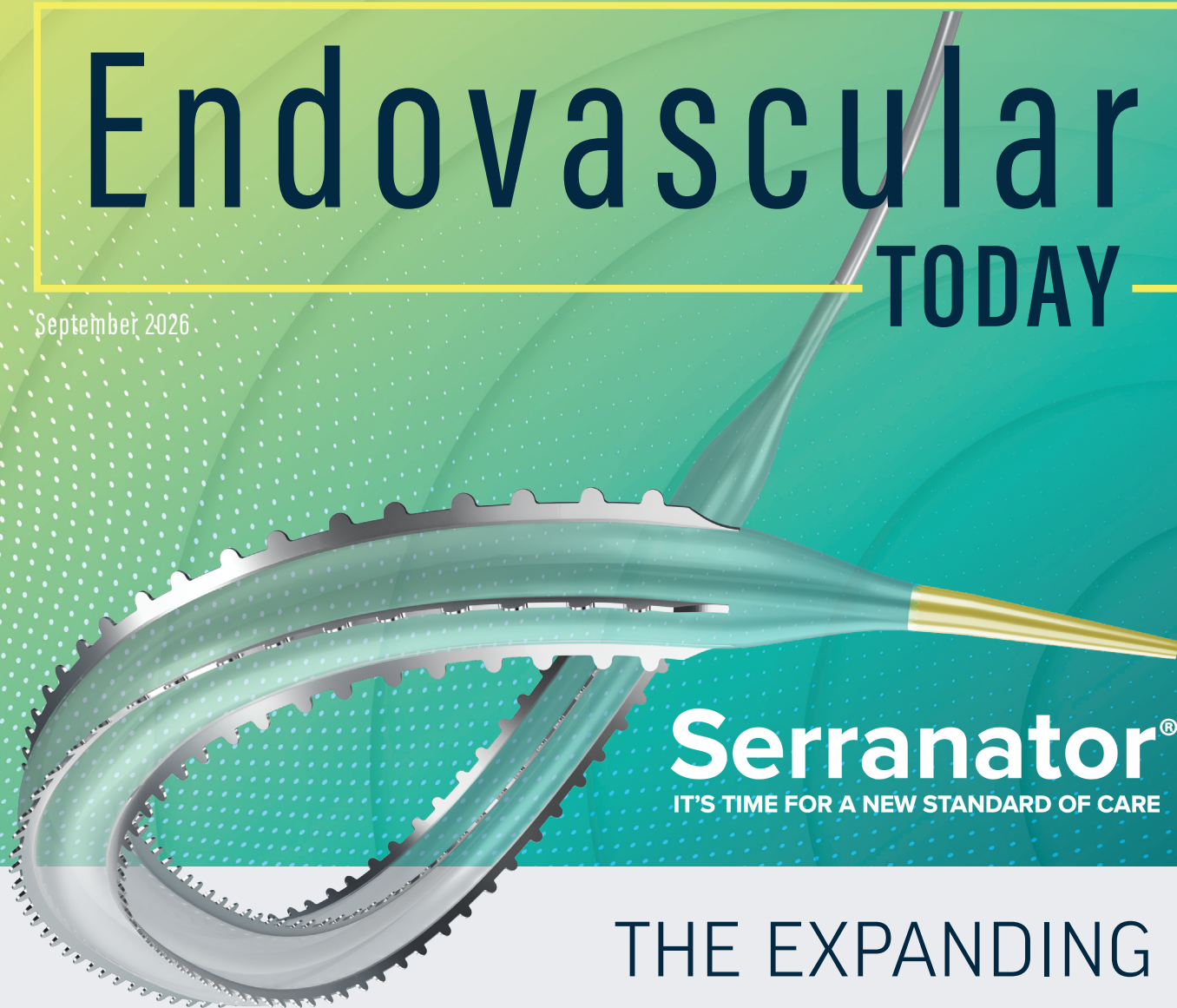


Supplement to

Sponsored by Cagent Vascular

Endovascular TODAY

September 2026



Serranator®
IT'S TIME FOR A NEW STANDARD OF CARE

THE EXPANDING ROLE OF **SERRATION** **REMODELING THERAPY:**

SRT
SERRATION
REMODELING
THERAPY

Clinical Evidence and Perspectives
From Leading Endovascular Physicians



Peter A.
Schneider, MD



Ajit
Rao, MD



Nelson L.
Bernardo, MD



Mazin
Foteh, MD



David
O'Connor, MD



Melissa
Keller, MD



Michael L.
Campbell, MD

Serranator[®]

PTA SERRATION BALLOON CATHETER



Optimize Lumen Gain

>97.7%

FF CD-TLR
@6MOS
(PRELUDE BTK)

Mitigate Recoil

6%

AVG. RECOIL VS.
55% FOR POBA
(RECOIL STUDY)

Minimize Dissection

1.9%

BAILOUT
STENT RATE
(PRELUDE BTK)

SRT[™]

SERRATION REMODELING THERAPY

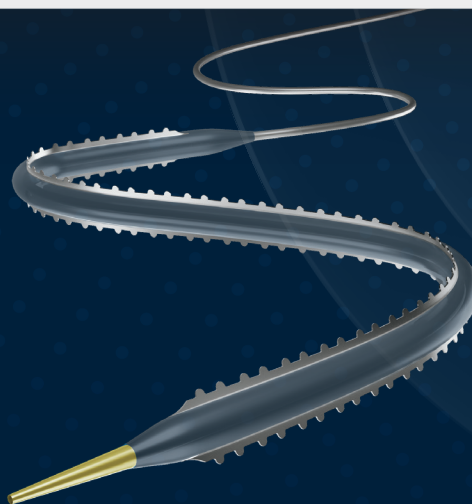
LEARN
MORE



- **SERRANATE WITH 1,000X MORE POINT FORCE THAN POBA**
- **PREDICTABLE LUMEN GAIN**
- **EFFECTIVE IN ALL LESION MORPHOLOGIES**

Serranator SL-PRO[™]

PTA SERRATION BALLOON CATHETER



PURPOSE-BUILT FOR **PEDAL**



CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Rx Only. Refer to the product labels and package inserts for complete warnings, precautions, and instructions for use.



SEE MORE



TABLE OF CONTENTS

4 Rethinking Balloon Angioplasty: Why Vessel Remodeling Matters

Incorporating Serration Remodeling Therapy to help achieve more predictable luminal gain and minimize vessel trauma to create the best possible foundation for durable outcomes.

By Peter A. Schneider, MD

6 My Algorithm for AV Fistula Treatment

Extending patency in dysfunctional dialysis access.

By Ajit Rao, MD

8 Serration, Not Dissection: A New Paradigm for Luminal Gain in BTK Endovascular Interventions

A distinct approach to vessel preparation or definitive therapy in BTK arterial occlusive disease.

By Nelson L. Bernardo, MD

SRT VERSATILITY CASE SERIES

10 SRT for EVAR: Achieving Large-Bore Delivery Access for EVAR in Severely Underexpanded Iliac Stents

By Mazin Foteh, MD, FACS, FSVS

11 SRT for PTAB: Predictable Lumen Expansion to Facilitate Percutaneous Transmural Arterial Bypass

By David O'Connor, MD

12 Pedal Disease: Can Vessel Remodeling Improve Distal Revascularization?

By Melissa Keller, MD, PhD

13 Achieving Durable Results Above the Knee

A consistent algorithm for complex femoropopliteal disease.

By Michael L. Campbell, MD

Rethinking Balloon Angioplasty: Why Vessel Remodeling Matters

Incorporating Serration Remodeling Therapy to help achieve more predictable luminal gain and minimize vessel trauma to create the best possible foundation for durable outcomes.

By **Peter A. Schneider, MD**

SEE MORE



Balloon angioplasty remains one of the most commonly performed procedures in vascular intervention. It is simple, familiar, and serves as the foundation for treating peripheral artery disease, dialysis access stenosis, and plays a role in most vascular reconstructions. Yet, despite decades of innovation surrounding adjunctive technologies, the balloon itself has changed very little.

Conventional angioplasty relies on force rather than precision. The vessel stretches until plaque fractures unpredictably or the artery dissects. Operators have come to expect elastic recoil, uncontrolled dissections, inconsistent luminal gain, and the possibility that additional devices—or permanent implants—will be needed simply to achieve an acceptable result. Negative outcomes have become routine and are viewed as an unavoidable consequence of angioplasty.

But they shouldn't be.

As our understanding of vascular biology has advanced, it has become increasingly clear that *how* we modify plaque is just as important as *how much* we expand the vessel. The goal should simply be a larger lumen and a controlled remodeling process that minimizes vessel injury while creating a durable foundation for long-term success.

Serration Remodeling Therapy (SRT) approaches angioplasty differently. Rather than relying solely on circumferential stretching, the serrated balloon creates controlled linear micro-fissures along the plaque surface, directing the energy in a manner that helps determine how the vessel expands during inflation (Figure 1). This allows plaque to yield more predictably, improving luminal expansion while reducing the uncontrolled vessel trauma.

The impact extends beyond the angiographic result. More predictable arterial expansion influences subsequent

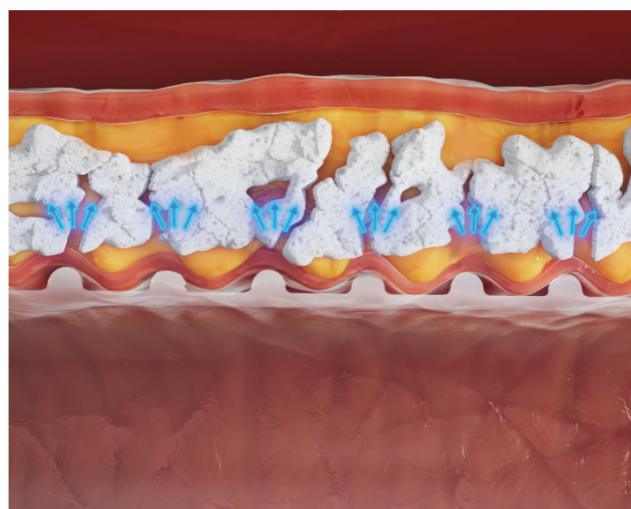


Figure 1. Serrator mechanism of action.

treatment decisions, whether the physician intends to use drug-coated balloons, avoid bailout stenting, preserve future treatment options, or simply achieve the best possible outcome with balloon angioplasty alone.

Importantly, the concept of SRT is supported by a growing body of core lab–adjudicated clinical evidence (Figure 2). In the PRELUDE-BTK study, treatment with the Serranator® PTA Serration Balloon (Cagent Vascular) demonstrated a 97.7% freedom from clinically driven target lesion revascularization at 6 months, with a low bailout stent rate of 1.9%. In a subset of lesions, intravascular imaging also demonstrated the intended mechanism of action, with serrations identified by optical coherence tomography or intravascular ultrasound in all target lesions evaluated.¹

Perhaps even more compelling is what we have learned when SRT has been directly compared with conventional

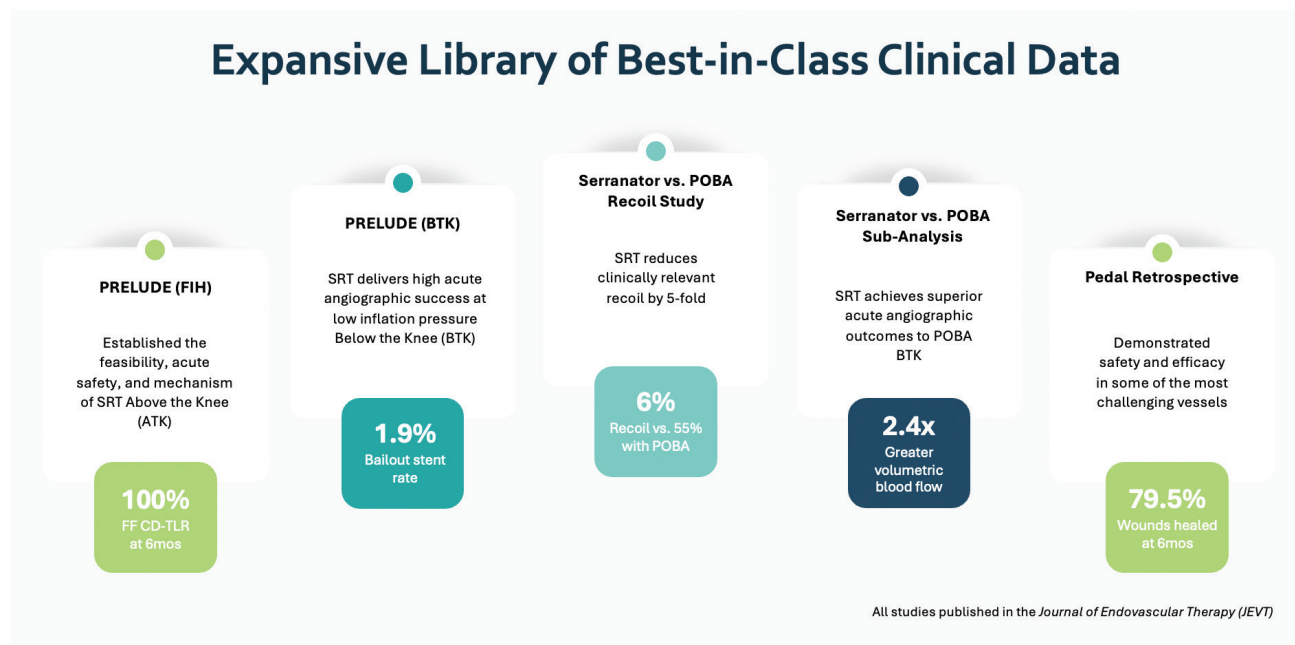


Figure 2. Growing body of clinical evidence supporting SRT.

balloon angioplasty. In a single-center analysis of PRELUDE-BTK, Serranator achieved significantly lower final residual stenosis than plain old balloon angioplasty (POBA), resulting in a 49% improvement in luminal gain and 2.4 times greater volumetric blood flow.² The RECOIL study further highlighted an important distinction between remodeling and conventional angioplasty, demonstrating mean recoil of just 6% following SRT compared with 55% following POBA, as assessed by angiography at 15 minutes after revascularization.³ More recently, the Pedal Study demonstrated the use of SRT in the challenging inframalleolar vasculature, with 79.5% of wounds healed or improving at follow-up and no vessel perforations or distal embolization reported in the study, further supporting the safety profile of controlled vessel remodeling observed with SRT in small, complex vessels.⁴ These findings begin to define what I believe differentiates vessel remodeling from conventional angioplasty: achieving lumen gain is important, but maintaining that gain while minimizing vessel injury and recoil may be equally important.

SRT is not limited to one lesion type or one vascular territory. As physicians have incorporated this technology into their practices, its role has expanded naturally—from femoropopliteal disease to below-the-knee interventions, dialysis access, pedal arteries, and large-bore access for structural and aortic procedures. The common thread is not anatomy. It is the need for controlled vessel remodeling wherever balloon angioplasty remains the cornerstone of treatment.

The cases presented throughout this supplement reflect that evolution and demonstrate how experienced physicians are integrating SRT into their treatment algorithms across diverse clinical scenarios. Although each anatomy presents unique challenges, the objective remains the same: achieve more predictable luminal gain, minimize vessel trauma, and create the best possible foundation for durable outcomes. ■

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
2. Guetti K, Muster V, Schweiger L, et al. 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.* 2024;31:615–621. doi: 10.1177/15266028221134891
3. Fereydooni A, Chandra V, Schneider PA, et al. Serration angioplasty is associated with less recoil in infrapopliteal arteries compared with plain balloon angioplasty. *J Endovasc Ther.* 2025;32:1600–1606. doi: 10.1177/15266028231215284
4. Gifford E, Siah M, Lichtenberg M, et al. Technical success and clinical outcomes of pedal serration angioplasty for chronic limb-threatening ischemia. *J Endovasc Ther.* Published online April 20, 2026. doi: 10.1177/15266028261440736



Peter A. Schneider, MD

Vascular Surgeon

Division of Vascular and Endovascular Surgery
University of California San Francisco
San Francisco, California

Disclosures: Consultant to Medtronic, Boston Scientific Corporation, Cagent Vascular, Acotec, Abbott, Endologix, Shockwave Medical, Healthcare Inroads, BD Interventional, Stryker, and Cordis.

My Algorithm for AV Fistula Treatment

Extending patency in dysfunctional dialysis access.

By Ajit Rao, MD

Arteriovenous (AV) fistula dysfunction remains one of the most common challenges in maintaining reliable hemodialysis access. Repetitive mechanical stress, turbulent flow, and neointimal hyperplasia contribute to stenosis and thrombosis if left untreated. Although conventional percutaneous transluminal angioplasty (PTA) remains the standard endovascular treatment, elastic recoil, flow-limiting dissections, and early restenosis frequently compromise procedural durability and often necessitate repeat interventions. Despite availability of drug-coated technology and stenting in dialysis interventions, long-term patency remains relatively low, necessitating consideration of alternate treatment options.

Serration Remodeling Therapy (SRT) with the Serranator® PTA Serration Balloon (Cagent Vascular) offers a fundamentally different approach to lesion modification. By creating controlled, longitudinal micro-fissures within the intima, SRT facilitates luminal expansion while minimizing uncontrolled vessel injury. This mechanism has been shown to reduce angiographic recoil and dissections compared with conventional PTA while preserving future treatment options and avoiding permanent implants whenever possible.

The following cases highlight the use of SRT in a dysfunctional AV fistula and demonstrate how effective lesion remodeling can translate into sustained patency and favorable long-term clinical outcomes in this challenging patient population.

TREATMENT ALGORITHM

In our practice, patients undergoing fistulograms have generally been treated with balloon angioplasty with stenting reserved for recoil after angioplasty. SRT offers an additional treatment option in these challenging lesions that are often prone to recoil necessitating early reinterventions. Specifically, we consider using SRT to help prevent lesion recoil, prep the vessel for drug-coated technology, and for cases of balloon-assisted maturation, particularly at cannulation sites.

CASE 1

Patient Presentation

The patient is a female in her early 60s with hypertension, type 2 diabetes mellitus, and end-stage renal disease (ESRD) on hemodialysis via a left arm brachial artery-to-axillary vein AV graft (AVG) placed several years ago. She was found to have an axillary vein stenosis, which required drug-coated

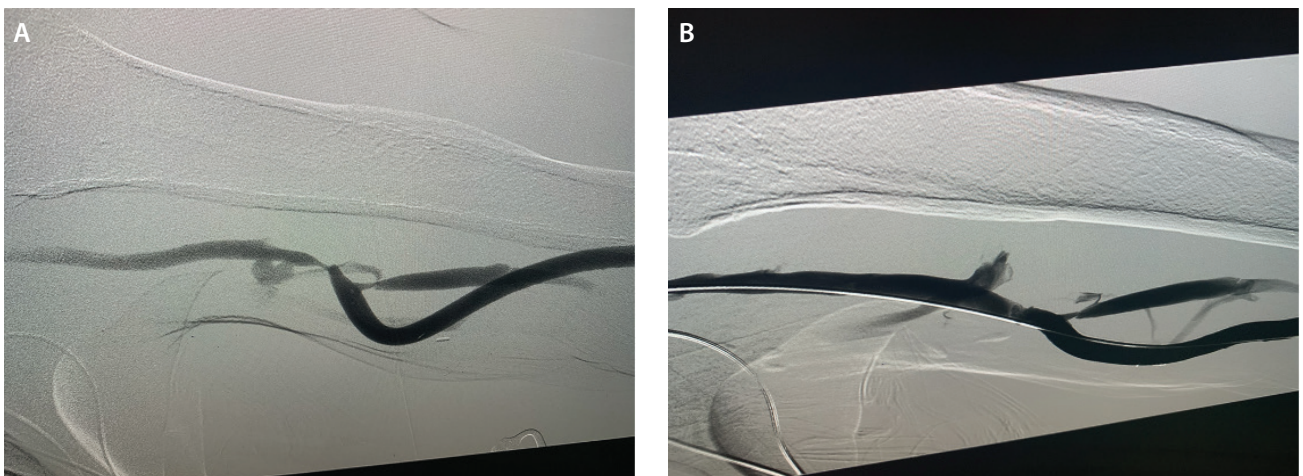


Figure 1. Diagnostic fistulogram (A). Completion fistulogram (B).

balloon angioplasty 6 months prior to presentation. She presented to the clinic for prolonged bleeding after hemodialysis.

Procedural Overview

An intraoperative fistulogram revealed a recurrent distal venous anastomotic stenosis at the axillary vein (Figure 1A). Through a 7-F short sheath, angioplasty of the axillary vein stenosis was performed using an 8-mm Serranator PTA Serration Balloon.

Postprocedure Results

A completion angiogram demonstrated complete resolution of the stenosis with brisk flow centrally (Figure 1B). The patient had an excellent thrill postoperatively and was discharged home. She was last seen in clinic at her 9-month follow-up with a patent AVG on an in-office duplex ultrasound and no evidence of restenosis.

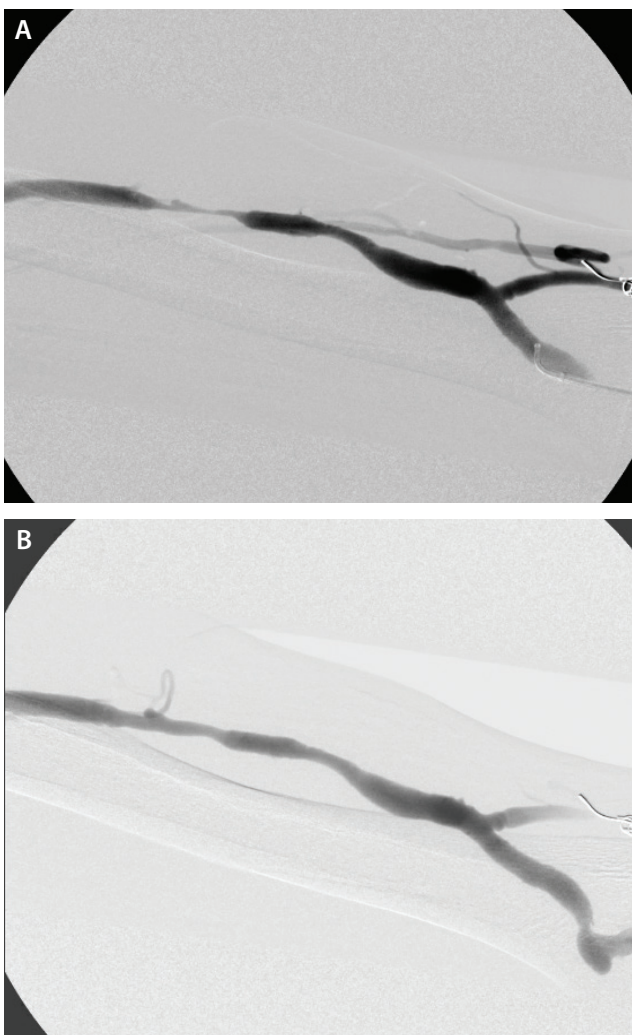


Figure 2. Diagnostic fistulogram (A). Completion fistulogram (B).

CLINICAL PERSPECTIVE

Unlike many physicians who first adopt Serranator for peripheral artery disease, Dr. Rao first incorporated SRT into his AV fistula practice. After observing favorable acute and long-term outcomes in dialysis access interventions, he expanded its use to below-the-knee and above-the-knee peripheral interventions, where SRT has become an integral part of his algorithm.



CASE 2

Patient Presentation

A male patient in his mid-70s with hypertension, type 2 diabetes mellitus, ESRD on hemodialysis via a left arm brachial artery-to-cephalic vein AV fistula placed several years ago presented with current episodes of inability to cannulate the fistula during dialysis.

Procedural Overview

An intraoperative fistulogram revealed a long-segment stenosis of the cephalic vein in the upper arm at the cannulation sites (Figure 2A). Through a 7-F short sheath, angioplasty of the cephalic vein long-segment stenosis was performed using a 7-mm Serranator PTA Serration Balloon.

Postprocedure Results

A completion angiogram demonstrated complete resolution of the stenosis with no significant recoil (Figure 2B). The patient had an excellent thrill postoperatively and was discharged home. He was last seen in clinic at his 6-month follow-up and remains symptom-free with a patent cephalic vein on duplex ultrasonography.

CONCLUSION

SRT offers a new approach to lesion modification in dialysis access cases. Early experience with SRT has shown promising results and may help improve outcomes following intervention in this challenging patient population. ■



Ajit Rao, MD

Vascular Surgeon
Mount Sinai Health System
New York, New York
Disclosures: None.

Serration, Not Dissection: A New Paradigm for Luminal Gain in BTK Endovascular Intervention

A distinct approach to vessel preparation or definitive therapy in BTK arterial occlusive disease.

By Nelson L. Bernardo, MD

Revascularization is essential in chronic limb-threatening ischemia (CLTI) to limit tissue loss and preserve a functional limb. Because these patients frequently have multilevel disease, the optimal strategy is direct revascularization that re-establishes straight in-line flow to the foot. When no such option exists, indirect revascularization that maximizes perfusion to the wound angiosome through collateral pathways is an acceptable alternative.¹ Revascularization options include percutaneous endovascular intervention, open surgical bypass or endarterectomy, or a hybrid approach that combines percutaneous endovascular intervention and surgery, performed either concomitantly or in a staged fashion. Ultimately, successful CLTI management depends on a collaborative, multispecialty approach aimed at complete wound healing, minimal tissue loss, and preservation of ambulatory status.

Serration Remodeling Therapy (SRT) using the Serranator® PTA Serration Balloon Catheter (Cagent Vascular) is a newer and mechanistically distinct therapy for CLTI that uses embedded metal serration strips to create linear rows of micro-fissures in the plaque. Serranator achieves optimal luminal gain at lower inflation pressure, reduction in elastic recoil, and mitigation of the complications associated with plain old balloon angioplasty (POBA).

CASE STUDY

Case Presentation

The patient is a man in his mid-70s with longstanding hypertension, type 2 diabetes mellitus with peripheral neuropathy (HbA1c, 6.7%), hyperlipidemia, paroxysmal atrial fibrillation on apixaban 5 mg twice daily, remote cerebrovascular accident without residual neurologic deficit, and lower extremity peripheral artery disease. He had no history of coronary artery disease and had never smoked. He was referred with ischemic rest pain of the right foot, occurring at night while supine (Rutherford category 4), after an unsuccessful attempt elsewhere to recanalize a totally occluded three-vessel right below-the-knee (BTK) arterial system. A month later, he underwent successful recanalization of the occluded right peroneal and anterior tibial (AT) arteries with peripheral excimer laser atherectomy (PELA) and balloon angioplasty and was discharged home improved on clopidogrel 75 mg

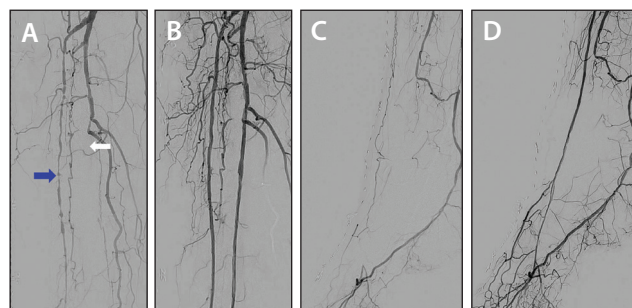


Figure 1. Baseline angiography of right BTK arteries (A) and of the distal pedal vessels (C) showing a totally occluded right AT artery (blue arrow, A) and totally occluded right peroneal artery (white arrow, A). Postintervention angiography showing re-establishment of two-vessel runoff to the periphery (B, D).

daily in addition to apixaban. Unfortunately, his nocturnal rest pain recurred approximately 3 to 4 months later, consistent with recurrent Rutherford category 4 ischemia.

Procedural Overview

Vascular access was obtained in the right common femoral artery using antegrade approach. Baseline angiography demonstrated a patent right superficial femoral artery (SFA) lined by nitinol self-expanding stents along its entire length, with a patent right deep femoral artery showing only mild disease. The right popliteal artery was patent with diffuse mild disease. The right AT artery was totally occluded, and the tibioperoneal trunk (TPT) was occluded proximally with resultant total occlusion of both the right posterior tibial (PT) and peroneal arteries. Bridging collaterals reconstituted the distal right peroneal artery, which continued as single-vessel runoff to the foot (Figure 1). The femoral access sheath was then exchanged for a 6-F, 45-cm Flexor® Ansel-0 sheath (Cook

"The Serranator mechanistically brings a distinct approach to vessel preparation or definitive therapy in BTK arterial occlusive disease."



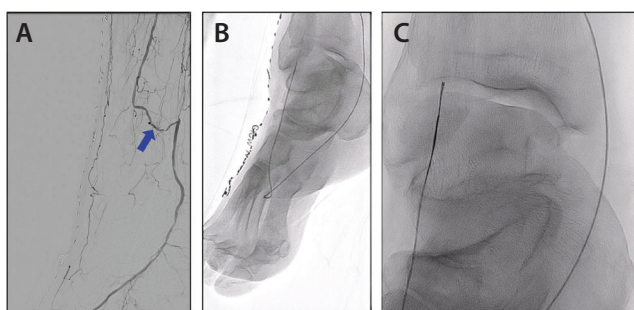


Figure 2. Communicating (calcaneal) branch of the right peroneal artery into the distal right PT artery (A). Guidewire advanced from the right peroneal artery and into the lateral plantar artery of the right PT artery and around the pedal-plantar loop (B). Guidewire advanced retrogradely up the right DPA into a 0.018-inch support catheter in the right AT artery (C).

Medical), which was advanced antegradely with its tip positioned in the mid-P2 segment of the right popliteal artery.

Intravenous anticoagulation was achieved with unfractionated heparin, with supplemental doses administered to maintain an activated clotting time above 250 seconds. The totally occluded right peroneal artery was crossed with a 0.014-inch Hi-Torque Command™ 14 guidewire (Abbott Vascular), which was then exchanged for a 0.014-inch Hi-Torque Spartacore® guidewire (Abbott Vascular). PELA was performed with a 1.4-mm Turbo-Elite® laser atherectomy catheter (Philips) initially at 45 mJ/mm² and 25 Hz and then at 60 mJ/mm² and 40 Hz, for a total of 15,375 pulses over a treatment time of 6 minutes and 58 seconds, successfully recanalizing the occluded vessel. The recanalized segment was predilated with a 1.5–2.0- X 210-mm NanoCross™ Elite PTA balloon catheter (Medtronic). SRT was then performed with a 2.5- X 120-mm Serranator PTA Serration Balloon with an excellent angiographic result.

With flow re-established through the recanalized right peroneal artery, a 0.014-inch Fielder® XT guidewire (Asahi Intecc) was advanced through the communicating (calcaneal) branch of the peroneal artery into the distal right PT artery and onward into the lateral plantar artery (Figure 2A). The wire was tracked distally around the pedal-plantar loop, where the lateral plantar artery joins the deep plantar branch of the dorsalis pedis artery (DPA; Figure 2B) and then retrogradely up the right DPA (Figure 2C). The Fielder XT was exchanged for a 0.014-inch Approach® CTO microwire (Cook Medical), which was advanced retrogradely through the totally occluded right AT artery and captured within a 0.018-inch support catheter positioned in the proximal vessel, completing the transpedal retrograde crossing. After exchanging for a 0.014-inch Spartacore guidewire, PELA of the AT artery was performed with a 1.4-mm Turbo-Elite laser atherectomy catheter, initially at 45 mJ/mm² and 25 Hz and then at 60 mJ/mm² and 40 Hz, for a total of 12,886 pulses over 6 minutes and 31 seconds. Definitive SRT was delivered with a 2.5- X 120-mm Serranator

Serration Balloon. Final angiography demonstrated pulsatile, straight, in-line flow from the patent right SFA and popliteal arteries through the TPT into two-vessel runoff (right AT and peroneal arteries) to the foot.

Postprocedure Results

Laboratory workup during the admission identified the patient as a clopidogrel nonresponder, with a platelet reactivity of 231 P2Y12 reaction units while on therapy. He was discharged home on ticagrelor 90 mg twice daily and apixaban 5 mg twice daily. There was complete resolution of his resting foot pain and there was no recurrence on his 9-month clinic visit.

DISCUSSION

Infrapopliteal disease in CLTI patients remains the most demanding territory in peripheral intervention. The vessels are small, the lesions are long and frequently occlusive, and calcification is the rule rather than the exception. Balloon angioplasty, the foundation of endovascular therapy since Dotter and Grüntzig, achieves luminal gain through uncontrolled vessel injury, and its limitations of elastic recoil, flow-limiting dissection, and restenosis are most consequential precisely where the margin for error is smallest. The evolution from POBA to plaque modification reflects a shift in philosophy: rather than overpowering the lesion with pressure, the aim is to alter its mechanical properties in a controlled, predictable fashion so that the vessel yields along predetermined lines.

In this instance, serration angioplasty delivered a smooth, well-expanded lumen with controlled dissection and without the need for bailout stenting, preserving future options in vessels that may require reintervention.

CONCLUSION

SRT with the Serranator PTA Serration Balloon mechanistically brings a distinct approach to vessel preparation or definitive therapy in BTK arterial occlusive disease. The embedded external serrated metal strips on the semicompliant balloon creates “controlled” longitudinal micro-fissures rather than dissection planes, which are very random and are associated with conventional balloon dilatation of the atheromatous plaque. ■

1. Gornik HL, Aronow HD, Goodney PP, et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral artery disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice. *Circulation*. 2024;149:e1313–e1410. doi: 10.1161/CIR.0000000000001251



Nelson L. Bernardo, MD

Director, Peripheral Vascular Laboratory
Medstar Heart and Vascular Institute at
Washington Hospital Center
Washington, DC
Disclosures: None.

SRT VERSATILITY CASE SERIES

**Mazin Foteh, MD,
FACS, FSVS**
Vascular Surgeon, Baylor
Scott & White The Heart
Hospital, Plano, Texas

SRT for EVAR: Achieving Large-Bore Delivery Access for EVAR in Severely Underexpanded Iliac Stents

SEE MORE

**CASE EXAMPLE****Case Presentation**

A woman in her early 80s with known aortoiliac occlusive disease presented for repair of an abdominal aortic aneurysm measuring 5.4 cm in maximum diameter. She had undergone prior bilateral iliac stenting. Imaging demonstrated severe in-stent restenosis bilaterally with chronic total occlusion of the left external iliac artery, and the existing stents were markedly underexpanded (Figure 1). The combination of dense neointimal hyperplasia and residual underexpansion produced an effective luminal diameter well below that required to advance the endograft delivery system. Given her age, iliac conduit creation or open repair carried substantial morbidity, and a totally endovascular solution was preferred.

Procedural Overview

Bilateral femoral access was obtained. Initial attempts to advance a large-caliber sheath failed on both sides, with the system arresting at the underexpanded stented segments. Sheath sizing was staged to what the vessels would accept: 16 F on the right and 14 F on the left.

The left external iliac occlusion was crossed intraluminally. Serration Remodeling Therapy (SRT) was performed bilaterally using 8.0- X 40-mm Serranator® PTA Serration Balloon Catheters (Cagent Vascular), one per iliac, with prolonged low-pressure inflations.

Both systems subsequently accepted the delivery sheaths, and a 36- X 80-mm Treo® Abdominal Stent-Graft System (Terumo Aortic) was deployed to exclude the aneurysm. On the postimplant CT scan, the iliac limbs demonstrated excellent expansion with no evidence of recurrent stenosis (Figure 2).

WHY SRT?

The prior iliac stents were both densely restenosed and significantly underexpanded, leaving a lumen that would not permit safe passage of a large-bore sheath. SRT was selected for its serration mechanism: the strips concentrate point force along the neointima, disrupting hyperplastic tissue at low inflation pressure rather than stretching it.

The disease state itself narrowed the options. Conventional angioplasty at the inflation pressures required to move a stent that had never fully expanded carries real risk of vessel injury or rupture, and dense neointima tends to recoil once the balloon comes down. Intravascular lithotripsy is designed to modify calcium and does little to hyperplastic tissue. Atherectomy within a stented segment introduces the risk of damage to the stent frame or device entrapment. SRT was the one modality that addressed both components of this lesion, the neointima and the stent geometry, in a single treatment at low inflation pressure, which made it the appropriate therapy for this anatomy.

That same point force allowed the underexpanded stents to be expanded further. Together, this created a durable delivery corridor and enabled a successful endovascular repair in a patient for whom iliac conduit or open conversion would have carried substantial morbidity. ■

Disclosures: Consultant to Cagent Vascular.

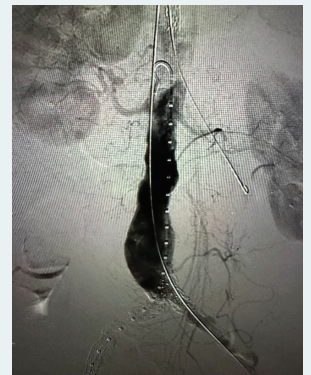


Figure 1. Preprocedure angiogram.



Figure 2. Postprocedure angiogram.

"SRT was selected for its serration mechanism: the strips concentrate point force along the neointima, disrupting hyperplastic tissue at low inflation pressure rather than stretching it."

SRT VERSATILITY CASE SERIES



David O'Connor, MD
Vascular Surgeon, Hackensack
University Medical Center,
Hackensack, New Jersey

SRT for PTAB: Predictable Lumen Expansion to Facilitate Percutaneous Transmural Arterial Bypass

SEE MORE



CASE EXAMPLE

Case Presentation

A man in his late 40s with a history of smoking, diabetes, and coronary artery disease presented with right lower extremity rest pain and a nonhealing second toe ulcer. The patient had undergone multiple prior femoropopliteal stenting procedures at outside institutions, which subsequently occluded. A previous attempt to recanalize the occluded stents restored patency for approximately 6 months before reocclusion. With multiple failed prior interventions and no suitable saphenous vein in either leg, treatment options were limited. The reconstituted P2 popliteal segment was also small in caliber at approximately 3.5 mm, making it a suboptimal distal target for surgical bypass.

Procedural Overview

Given the complexity of the anatomy and prior treatment failures, the decision was made to perform percutaneous transmural arterial bypass (PTAB) with the DETOUR™ System (Endologix). Right lower extremity treatment was performed using left femoral arterial access and retrograde right posterior tibial venous access.

The initial artery-to-venous connection was created in the proximal superficial femoral artery (SFA) within an occluded segment (Figure 1A-D). The segment was first recanalized and treated with Serration Remodeling Therapy (SRT) using a 4- X 40-mm Serranator® PTA Serration Balloon (Cagent Vascular) prior to creation of the arterial-to-venous connection. Serranator was then used across the initial septum, with complete resolution of balloon waist following inflation (Figure 2A and 2B).

The procedure continued through the venous channel in standard fashion. At reentry into the P2 popliteal segment, a 4- X 40-mm Serranator balloon was again used to treat the septum. Following Serranator inflation, there was no residual balloon waist or septal stenosis, facilitating creation of the distal anastomosis and subsequent balloon treatment of the distal popliteal artery (Figure 3A-C).

WHY SRT?

In this complex case, SRT provided targeted luminal expansion at critical points of the DETOUR procedure, including both initial septal creation and distal arterial reentry. ■

Disclosures: Consultant to Cagent Vascular.

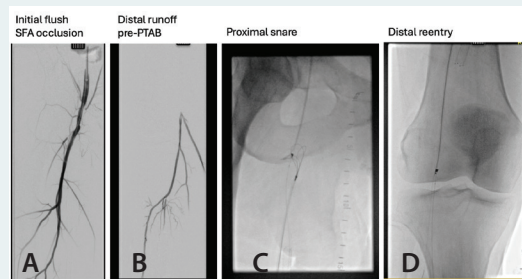


Figure 1.

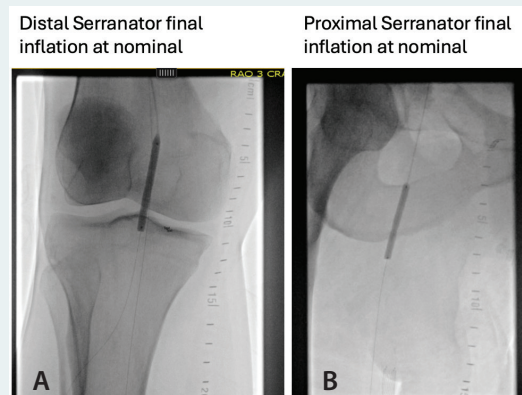


Figure 2.



Figure 3.

"In this complex case, SRT provided targeted luminal expansion at critical points of the DETOUR procedure, including both initial septal creation and distal arterial reentry."

SRT VERSATILITY CASE SERIES

Melissa Keller, MD, PhD
Vascular Surgeon, UC Davis
Health, Sacramento, California

Pedal Disease: Can Vessel Remodeling Improve Distal Revascularization?

SEE MORE

**CASE EXAMPLE****Case Presentation**

A male diabetic patient in his mid-60s with a history of prior lower extremity intervention presented with a new, nonhealing toe wound (Figure 1A). Although a previous toe wound and amputation had healed following revascularization, the posterior tibial (PT) artery had subsequently reoccluded. Angiography demonstrated significant tibial and inframalleolar disease with essentially single-vessel runoff through the anterior tibial (AT) artery (Figure 1B-1D). The goal was to re-establish PT and plantar flow to improve perfusion to the foot and address the stenosis in the AT artery.

Procedural Overview

Using a 6-F, 65-cm Destination® sheath and a 0.014-inch Glidewire® Advantage (both Terumo Interventional Systems), the PT was successfully recanalized into the lateral plantar artery. After initial plain old balloon angioplasty (POBA), Serration Remodeling Therapy (SRT) with a 2.5- X 120-mm Serranator® PTA Serration Balloon (Cagent Vascular) was utilized through the plantar and PT arteries, with additional SRT treatment using a 2.5- X 40-mm Serranator of a resistant focal segment to optimize expansion (Figure 1E-1H). No recoil or waist was observed. In the PT, drug-coated balloon (DCB) therapy using overlapping 4.0-mm Ranger™ DCB (Boston Scientific Corporation) was then used subnominal more distally (Figure 1I and 1J). The AT artery was then treated using a similar algorithm with a 3.0- X 40-mm Serranator as vessel prep, followed by a 4- X 40-mm Ranger DCB (Figure 1K and 1L).

Completion angiography demonstrated improved AT flow, restored PT flow, and improved filling into the foot (Figure 1M-1O). At follow-up toe-brachial index doubled at 2.5 (Figure 1P) and 5 months (Figure 1Q), the wound progressively healed and ultimately remains healed.

WHY SRT?

I use SRT across a range of peripheral interventions and have found it particularly valuable when treating tibial and pedal disease. These are some of the smallest and most challenging vessels we encounter, specifically those patients with chronic limb-threatening ischemia, often with a comorbidity of diabetes contributing with diffuse disease extending deep into the inframalleolar region. In this setting, improvement in blood flow is critical for wound healing and limb preservation, and there is very little margin for an unpredictable and ineffective angioplasty result.

What I appreciate about SRT in these vessels is using its controlled vessel remodeling to achieve meaningful luminal expansion without the usual recoil or residual waist. I routinely see a favorable angiographic result with improved flow while maintaining the integrity of the native vessel. That combination is important anywhere I use SRT, but it becomes especially valuable below the ankle, where every millimeter of lumen—and every additional small vessel branch of recruitment for perfusion—can matter. ■

Disclosures: Physician advisory board, Cagent Vascular.

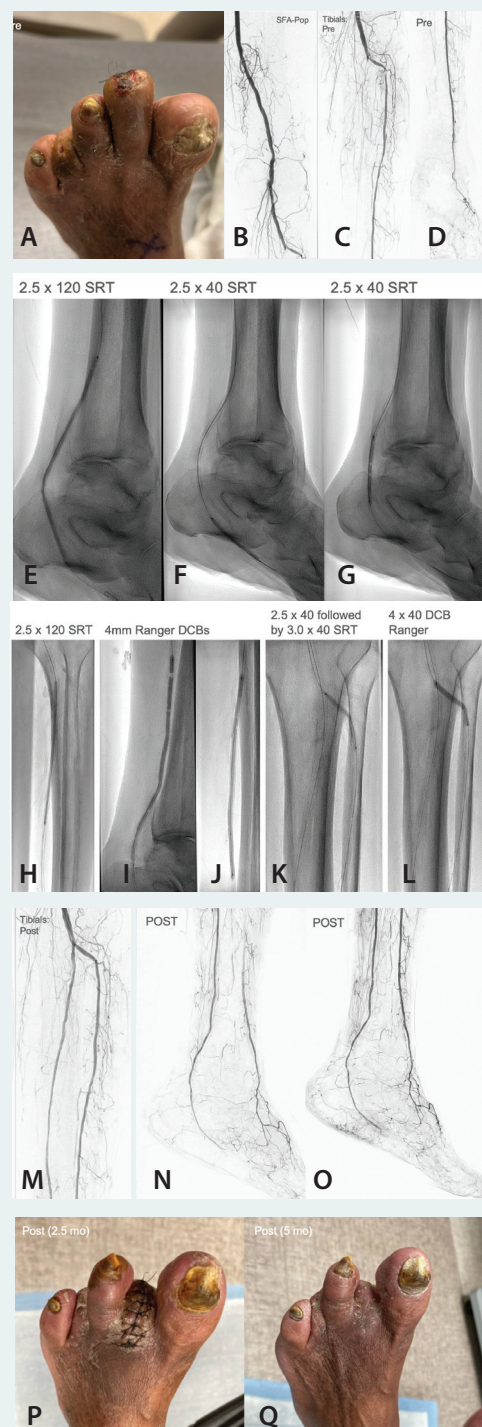


Figure 1.

Achieving Durable Results Above the Knee

A consistent algorithm for complex femoropopliteal disease.

By Michael L. Campbell, MD

The femoropopliteal segment is the longest arterial segment in the leg, subject to flexion, torsion, and compression, and it carries a high burden of calcification and long-segment disease. Restoring flow is rarely the whole objective. The harder question is how to restore it in a way that can be maintained and revised when it eventually fails.

Conventional balloon angioplasty applies undirected radial force to the entire vessel wall at once, so the operator has limited control over where and how the artery gives way. Serration Remodeling Therapy (SRT) with the Serranator® PTA Serration Balloon (Cagent Vascular) changes where that force is applied. Serration strips embedded along the balloon create longitudinal micro-fissures within the plaque at low pressure, so the artery opens along defined lines rather than wherever it happens to be weakest. The result is a smooth and uniformly enlarged lumen, and an artery remodeled for whatever treatment comes next.



Figure 1. Baseline angiography of the left SFA.



Figure 2. Final results after SRT with 4.0- X 120-mm Serranator and 4.0- X 200-mm Ranger DCB.

TREATMENT ALGORITHM

SRT is the constant in my above-the-knee (ATK) algorithm. What changes with lesion morphology is what happens before it, not whether it is used. In fibrotic and mixed disease, I go directly to SRT. In heavy calcification and chronic total occlusions, including previously stented segments, I debulk first with laser atherectomy and then perform SRT across the full treated length. Drug delivery follows in both.

Soft plaque, mixed plaque, and dense calcification all respond to the same controlled mechanism, and in each I finish with a smooth and uniformly expanded lumen at low pressure. Drug-coated balloon (DCB) therapy depends on contact with the vessel wall, and remodeling first gives it a consistent surface to work against.

CASE 1

Patient Presentation

A woman in her early 60s with type 1 diabetes, hypertension, coronary artery disease, and prior cerebrovascular accident was referred for a necrotic left lateral foot and heel wound of at least 5 months with associated cellulitis. Pedal pulses were nonpalpable, and she had never undergone a vascular workup. Duplex demonstrated monophasic flow throughout the left leg with no detectable flow in the dorsalis pedis artery (DPA).

Procedural Overview

Left lower extremity runoff angiography demonstrated diffuse long-segment disease of the superficial femoral artery (SFA) from the ostium throughout its course (Figure 1). The popliteal artery was patent, and the leg was supplied by single-vessel anterior tibial (AT) artery runoff.

SRT was performed across the diseased SFA segment using a 4.0- X 120-mm Serranator PTA Serration Balloon, followed by angioplasty with a 4.0- X 200-mm Ranger™ DCB (Boston Scientific Corporation) (Figure 2).

Postprocedural Results

Completion angiography demonstrated markedly improved luminal gain throughout the SFA without significant

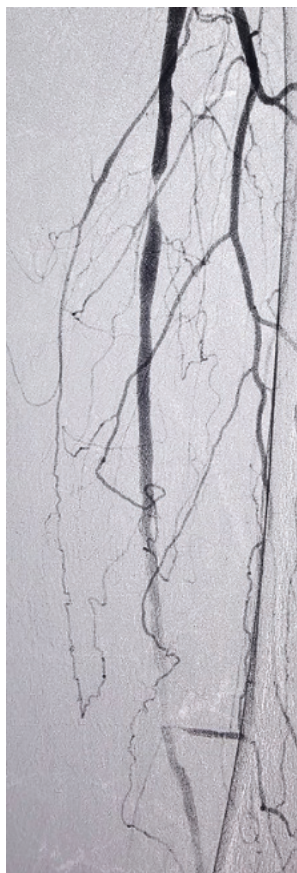


Figure 3. Baseline angiography of the left SFA with extensive collateral filling.

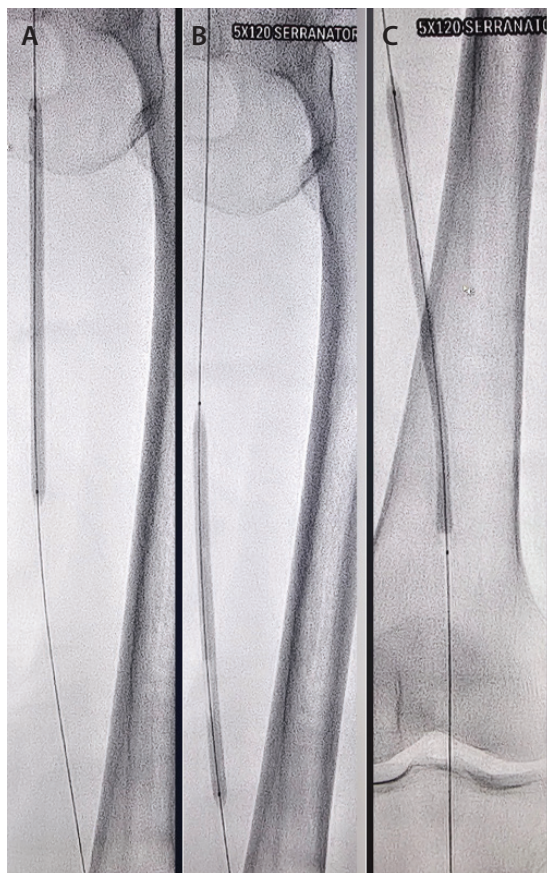


Figure 4. SRT through the proximal (A), mid (B), and distal (C) SFA with a single 5.0- X 120-mm Serranator.

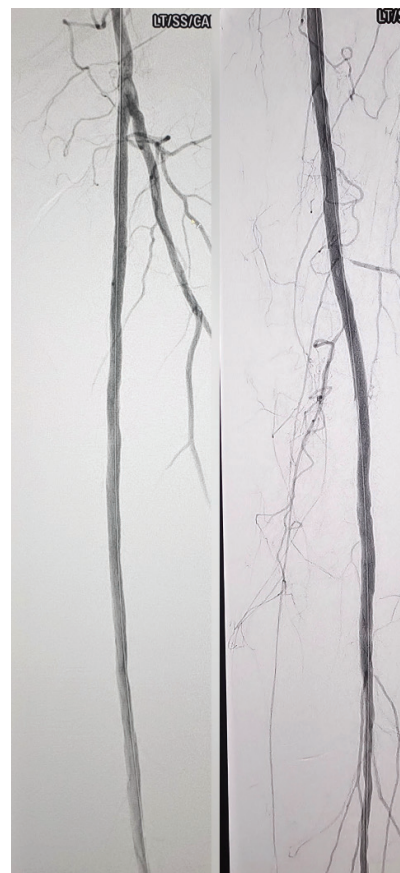


Figure 5. Completion angiography demonstrating a widely patent left SFA.

residual stenosis. No stent was required and no flow-limiting dissection was encountered. Single-vessel AT arterial flow was preserved with good flow through the pedal plantar loop.

A long, diffusely diseased femoral segment was opened gently and remodeled along its entire length,

"One Serranator opened the entire diseased SFA at low pressure, restoring uniform lumen without dissection and leaving nothing behind."



producing the uniform lumen I had aimed for before drug was delivered.

CASE 2

Patient Presentation

A woman in her late 70s weighing 38 kg was admitted with a nonhealing left lower extremity wound and progressive cellulitis. Her history included chronic obstructive pulmonary disease on home oxygen, chronic hypoxic respiratory failure, atrial fibrillation, heart failure with preserved ejection fraction, pulmonary hypertension, and treated lung cancer. Revascularization had been deferred during an earlier admission and remained pending when she returned with a worsening wound.

Procedural Overview

Angiography demonstrated moderate to severe stenosis of both common iliac arteries (CIAs) and multifocal stenotic lesions throughout the left SFA (Figure 3). The popliteal, posterior tibial, and peroneal arteries were patent, with no imaged flow in the DPA.

Inflow was addressed first and covered stenting of both CIAs. SRT was then performed throughout the entire course of the SFA using a single 5.0- X 120-mm Serranator, treated sequentially from proximal to distal (Figure 4).

Postprocedure Results

Completion angiography demonstrated a widely patent SFA without significant residual stenosis and no flow-limiting dissection (Figure 5). No implant was left in the femoropopliteal segment. The DPA, not imaged at baseline, was intact on completion. Total contrast was 40 mL with an air kerma dose of 117 mGy.

In a patient with minimal physiologic reserve, one Serranator opened the entire diseased SFA at low pressure, restoring a uniform lumen without dissection and leaving nothing behind in a vessel that flexes with every step.

CONCLUSION

Successful ATK intervention depends on opening the artery in a way it can tolerate and preparing it for the therapy that follows. SRT provides a controlled method of expanding and remodeling the vessel that behaves consistently across the full range of femoropopliteal morphology, achieving predictable expansion while preserving the artery and the options that come with it. ■



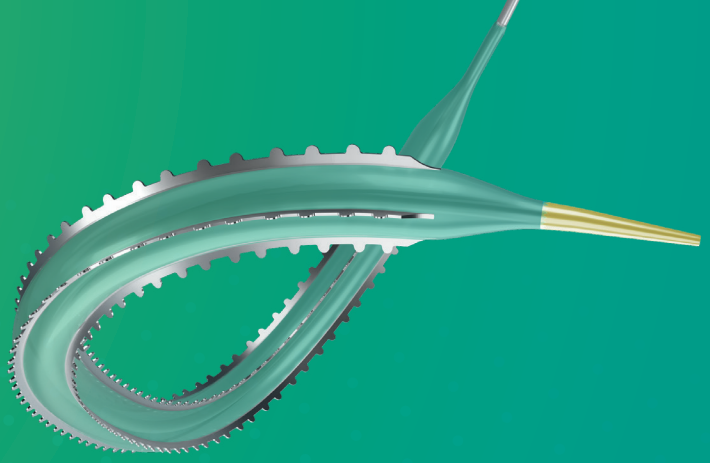
Michael L. Campbell, MD

Lakeland Regional Hospital
Lakeland, Florida

Disclosures: Consultant to Cagent Vascular.

SRT™

SERRATION
REMODELING
THERAPY



40,000+ PROCEDURES
5 CORE-LAB ADJUDICATED STUDIES
1 PLATFORM BUILT FOR REMODELING

EFFECTIVE IN ALL LESION MORPHOLOGIES

Optimize Lumen Gain

>97.7%

FF CD-TLR
@6MOS
(PRELUDE BTK)

Mitigate Recoil

6%

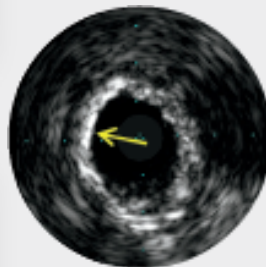
AVG. RECOIL VS.
55% FOR POBA
(RECOIL STUDY)

Minimize Dissection

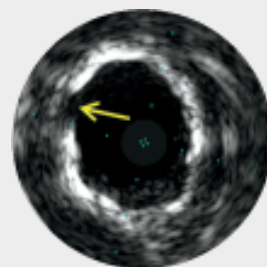
1.9%

BAILOUT
STENT RATE
(PRELUDE BTK)

Pre



Post



*IVUS imaging demonstrates SRT
in a calcified tibial vessel
showing cracking and significant
lumen gain without dissection
(PRELUDE BTK Study)*



Serranator®
IT'S TIME FOR A NEW STANDARD OF CARE

CAUTION: Federal law restricts this device to sale by or on the order of a physician.
Rx Only. Refer to the product labels and package inserts for complete warnings, precautions, and instructions for use.

Learn
More

