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

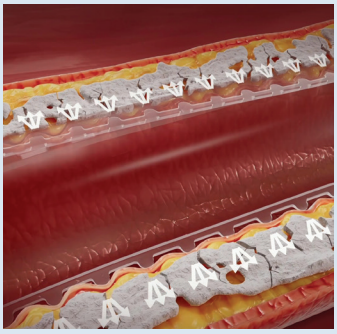
In my practice as an interventional cardiologist at a community hospital, I primarily serve a rural, underserved patient population with advanced disease. About 80% of my work focuses on peripheral vascular disease, including both ATK and BTK conditions, as well as venous thromboembolic disease. A significant 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.

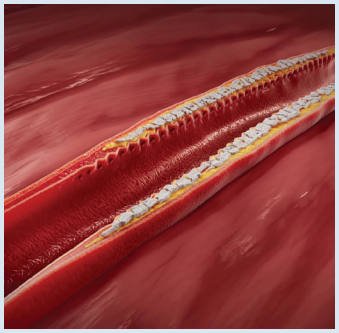
What are your typical algorithms and decision points for ATK treatment?

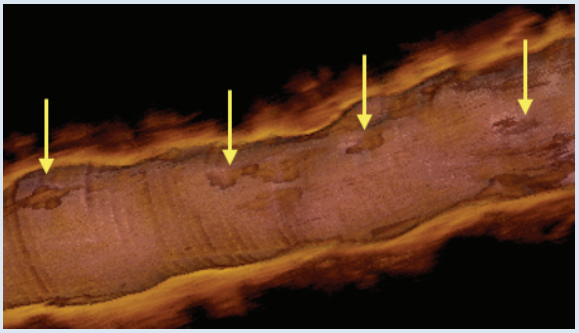
When treating ATK lesions, my primary decision point is whether the artery is totally occluded. Most of my patients present with total occlusions, and my priority is to cross luminally, avoiding dissection at reentry if possible. After crossing, I implement plaque modification, usually with atherectomy, 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.

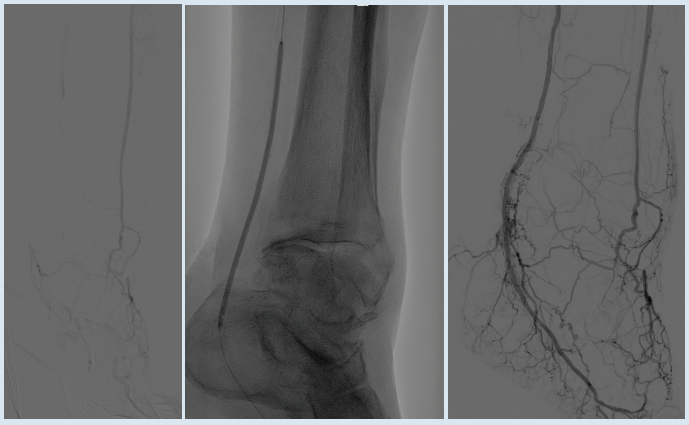




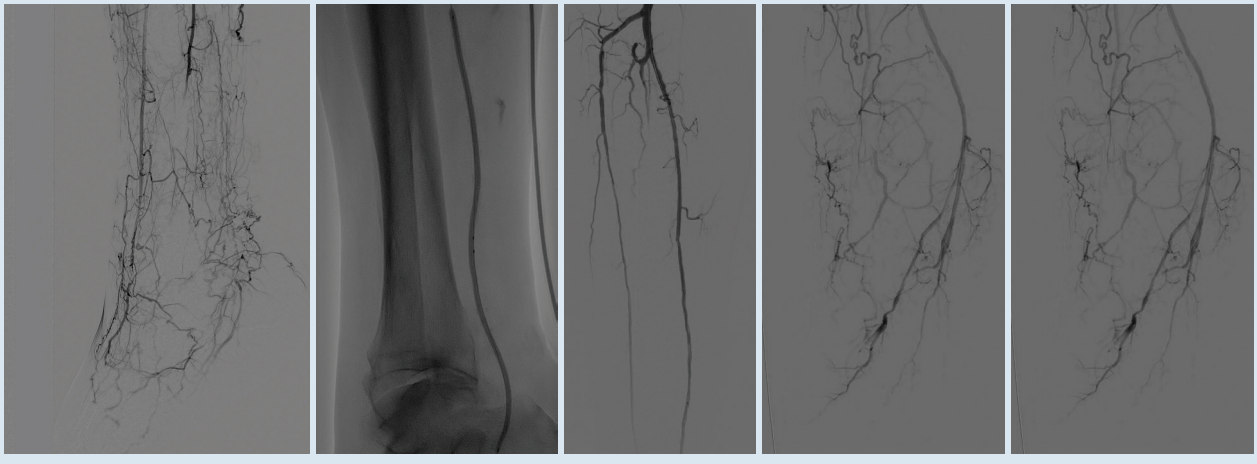


CASE EXAMPLE: CLTI PATIENT WITH BILATERAL DISEASE

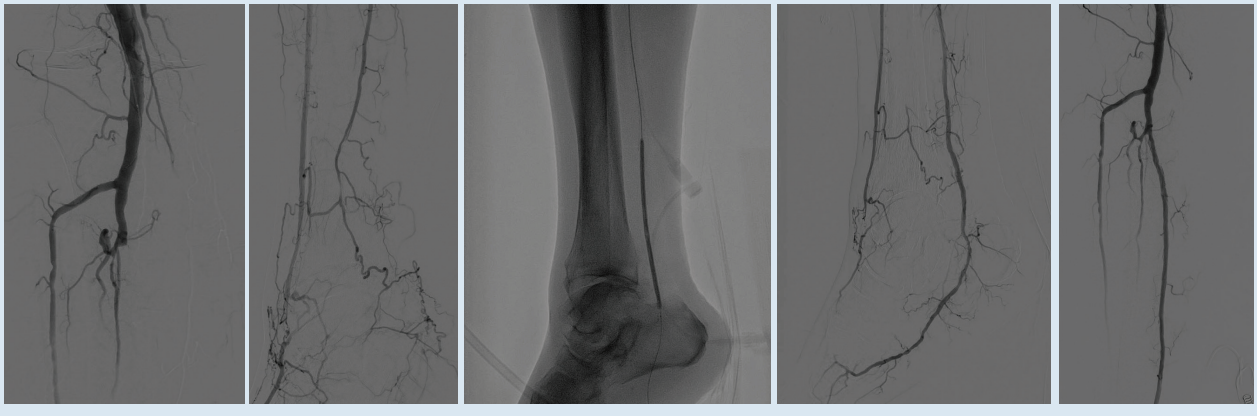
LEFT LEG TREATMENT: SERRANATOR



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. ■