Pedal Intervention Using Serranator

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

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

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

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

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

What is your goal when treating in the pedals?

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

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

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

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

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