# Meeting the Challenge of BTK Revascularization

A conversation with Dr. Peter Monteleone.

Interventional cardiologist **Dr. Peter Monteleone** directs the cardiac catheterization laboratories at Ascension Seton Medical Center in Austin, Texas, and serves as the Director of Cardiovascular Research for the Ascension Healthcare system nationally. Dr. Monteleone is also Program Director of the Interventional Cardiology Fellowship at the University of Texas at Austin Dell School of Medicine. He has authored many papers published in the clinical literature on clinical trial performance, outcomes, novel device development in peripheral vascular and cardiovascular medicine, and other topics. We spoke with Dr. Monteleone about the state of the art for endovascular below-the-knee (BTK) interventions and the role he sees for the Pounce™ Thrombectomy and Sublime™ Radial Access portfolios (Surmodics, Inc.) in addressing historical challenges in these procedures.

## What are the main challenges in treating acutely occluded BTK arteries?

There are several. The first is just getting to and across the treatment zone, the ability to deliver devices. If you're taking a contralateral approach, you may have to navigate through tortuous iliac anatomy all the way down through common femoral, superficial femoral, and popliteal artery segments that are likely to be stenotic or diseased. You need easily deliverable devices.

The second challenge, which historically has made things very difficult, is the small size of the BTK vessels themselves.[1] With aspiration thrombectomy, for instance, it's often been impossible to remove clot in these small vessels completely because the catheter can get "corked" on the vessel itself. Imagine a catheter that's the same size as the vessel lumen of the tibial artery. It can be hard to tell if you're actually trying to draw thrombus into the catheter or if you're just sucking against the vessel wall. That's one reason why distal perfusion and small tibial arteries have always been the Achilles' heel of acute limb ischemia (ALI) interventions.

Another challenge is when embolization occurs into the tibial arteries from upstream interventions. Embolization can convert a patient presenting with subacute thrombus with claudication into a patient with a truly acute, threatened limb—a real nightmare. A classic example would be a patient who has received a superficial femoral artery (SFA) stent initially placed because of a severe (but not complete) SFA occlusion leading to lifestyle-limiting claudication. Their claudication goes away initially after treatment, but 3 years later, it comes back worse than before when the stent occludes. The patient may not present emergently because their symptoms are ameliorated by collateral flow through profunda artery collaterals, and the acute thrombus has had time to organize and become chronic and fibrotic. In fact, the patient may wait months before seeing a physician. The concern is that when you're trying to remove this kind of organized material it may just get packed farther and farther down the arterial tree of the leg. If you fail to remove the material and continue packing it down, you can reach this somewhat terrible point in which that packed chronic material has the same lumen diameter as the actual tibial vessels and ends up occluding them completely. I can think of cases where we were trying to remove SFA thrombus and ended up pushing some of it down into the P3 segment and the tibial trifurcation. All of a sudden, the entire tibial trifurcation is occluded, and you're left with an emergent complication.

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## How did you deal with those kinds of situations in the past?

If our devices couldn't aspirate or suck out the clot—because it was bigger than the catheter tip—we might try to balloon macerate it or "stent jail" it, where you're putting a stent through it to rescue some lumen and allow flow. But then you're left with a stent in the distal tibial tree—a less-than-ideal outcome, especially when the stent is surrounded by thrombus. Sometimes we'd use nonindicated devices. On one occasion, we actually tried using a stentriever device indicated for neurointerventional applications, which unfortunately did not work. There were times when the best we could do was push the thrombus farther down, try to get it past the tibial trifurcation and into the peroneal. That way you at least establish some flow going into an anterior tibial or posterior tibial artery.

Then there were times we'd try infusing tissue plasminogen activator (tPA). Now, thrombolytic infusions can work very well, but of course, there are some patients that should not be treated with tPA, such as folks with intracranial or active bleeding issues. In other situations, the patient has ALI with an emergently threatened limb and acute severe pain. These patients cannot wait for an infusion and require immediate mechanical reestablishment of flow. In other situations, the thrombus you encounter is platelet-rich and very chronic, and tPA is not going to break that up.[2] But you have got to get that clot out, and historically we just didn't always have the tools to do it.

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## What has been your and your colleagues' experience with the original Pounce™ System and the Pounce™ LP device for BTK clot removal?

The Pounce™ System is a revolutionary device, and I don't say that lightly. You can categorize all ALI cases into those involving fresh thrombus, organized thrombus, or—for most of them—thrombus that is somewhere in between. There are a lot of devices that will work against fresh thrombus, but when the thrombus is very organized, in our experience nothing gets that out as well as Pounce™ Thrombectomy System devices do. It's a testament to the quality of the engineering behind these devices that the baskets really allow you to take hold of that organized material in a way that nothing else I have used can. We've used it to remove organized thrombus in a single pass that nothing else would remove. It's truly remarkable, especially because you can deliver the device down into tibial vessels. I also believe the nature of the device provides an inherent "backstop" reducing risk of further embolization.[3,4]

## What kinds of clinical problems does the Pounce™ System help to solve?

There are two nightmare scenarios, and the Pounce™ device works for both. One is distal embolization, as I mentioned previously. In my experience, nothing does as good a job as the Pounce™ System at taking out organized thrombus that either doesn't fit into an aspiration catheter or can't be broken up by one.

The second nightmare scenario is where that material is too big even for the 7 Fr sheath you typically use with the Pounce™ System or other thrombectomy systems. We had a patient with endocarditis who embolized a very organized, non–clot-based mass down into her leg, where it caused ALI. There was no way we were going to remove this large ball of organized material (likely fibrin and bacteria) with aspiration or break it up with lytics. We went down after it with a Pounce™ device, grabbed it, and pulled it back up into the funnel. Then, when we were trying to pull the device back into the 7 Fr sheath, it simply would not fit—the sheath was too small for this organized material. With other devices, this is a nightmare. If you have material stuck in an embolic protection device (EPD), for instance, and you cannot capture the device into the sheath, that can turn into a surgical disaster. Or at best you've got to start getting creative about getting buddy wires next to EPD wires and trying to exchange sheaths over multiple wires to rescue the procedure without releasing and embolizing the material in the EPD.

In this case, because we were working with a Pounce™ device, we were able to easily exchange the sheath to a 10 Fr sheath over the device's wire without doing anything else differently during the procedure.* The wire had enough body and support to allow that to happen. As soon as that 10 Fr sheath went down, we were able to replace the device's funnel, capture the material, and remove it through the 10 Fr sheath. I don't believe there's anything else that can allow that to be done. After that point, I told my colleagues locally and nationally that you might not use the Pounce™ device for every single case, but it's a device you should have on your shelf. Because you're going to bump into these situations where you're going to want it.

## Switching gears, let's talk about revascularization of tibial vessels from the radial approach. Until recently, BTK treatment via radial access has been limited by lack of equipment. What do you consider to have been the major gaps in the toolkit?

One of them has certainly been tools to help us overcome the difficulty of crossing complex chronic total occlusions (CTOs) to even reach the tibials. If you have an above-the-knee CTO, it can be difficult to transmit the force you need to cross from the wrist down the arch, through the iliac system, and through a CTO in the SFA or popliteal artery. Even if you're able to cross it, there have been limitations in your ability to actually deliver treatment. For a long time, we didn't even have angioplasty balloons that could reach from the radial access site to the femoropopliteal or tibial

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vessels. So, these equipment limitations have slowed adoption of radial-to-peripheral interventions, even at our own institution. I believe the availability of Sublime™ radial-to-peripheral products, particularly the long, crossing microcatheters and RX PTA balloons, will make people take a fresh look at BTK from the radial approach.

We are well aware from the abundance of coronary literature and from our own practices, not only that patients prefer radial access to femoral access,[5] but that radial access is a safe and effective way to get patients out of the hospital and back home soon after their procedures.[6] In my view, the case for radial access in peripheral cases is strengthened by the fact that the common femoral artery of patients with peripheral artery disease is often diseased, making their risk of access complications even higher.

The medical community has been in this intermediate zone where we could do some radial-to-peripheral interventions but may not have previously had the tools we needed to treat everything we may encounter during a procedure when we start from the wrist. I'm confident that technologies will continue to improve to the point where we'll be able to do whatever we need to do in terms of peripheral treatment from the radial approach. ■

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*See Surmodics Pounce™ Thrombectomy System Instructions for Use.