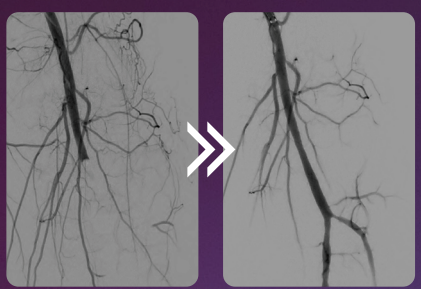
SUPPLEMENT TO

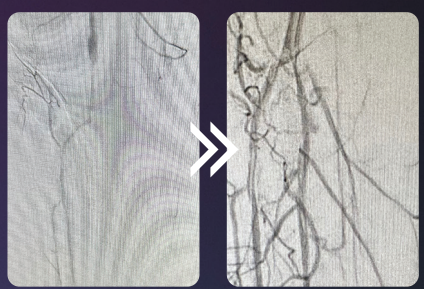
MAY 2024

Endovascular TODAY

RESTORING FLOW TO THE FOOT

TACKLING COMPLEX BTK CHALLENGES





CAPTURE

Tibial emboli or thrombi without aspiration or lysis

Peter Monteleone, MD

Christopher Leville, MD

Lucas Ferrer Cardona, MD

CROSS

Tight lesions & CTOs via radial, femoral, or pedal access

Craig Walker, MD

Amit Srivastava, MD

Pounce Thrombectomy

SURMODICS

Sublime Radial Access

Restoring Flow to the Foot

Tackling complex BTK challenges

Socks supplied by Flow Socks, visit flow-socks.com for more information.

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.

> "Tibial arteries have always been the Achilles' heel of ALI interventions…"

> "Embolization can convert a patient presenting with subacute thrombus with claudication into a patient with a truly acute, threatened limb—a real nightmare."

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.

"The Pounce™ System is a revolutionary device, and I don't say that lightly."

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

"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."

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. ■

1. Beckman JA, Schneider PA, Conte MS. Advances in revascularization for peripheral artery disease: revascularization in PAD. *Circ Res*. 2021;128:1885-1912. doi: 10.1161/CIRCRESAHA.121.318261
2. Results of a prospective randomized trial evaluation surgery versus thrombolysis for ischemia of the lower extremity. The STILE trial. *Ann Surg*. 1994;220:251-268. doi: 10.1097/00000658-199409000-00003
3. Gray BH, Wheibe E, Dicks AB, et al. Pounce thrombectomy system to treat acute and chronic peripheral arterial occlusions. *Ann Vasc Surg*. 2023;96:104-114. doi: 10.1016/j.avsg.2023.05.019
4. Maldonado TS, Powell A, Wendorff H, et al. Safety and efficacy of mechanical aspiration thrombectomy for patients with acute lower extremity ischemia. *J Vasc Surg*. 2024;79:584-592. doi: 10.1016/j.jvs.2023.10.062
5. Cooper CJ, El-Shiekh RA, Cohen DJ, et al. Effect of transradial access on quality of life and cost of cardiac catheterization: a randomized comparison. *Am Heart J*. 1999;138:430-436. doi: 10.1016/s0002-8703(99)70143-2
6. Mason PJ, Shah B, Tamis-Holland JE, et al. An update on radial artery access and best practices for transradial coronary angiography and intervention in acute coronary syndrome: a scientific statement from the American Heart Association. *Circ Cardiovasc Interv*. 2018;11:e000035. doi: 10.1161/HCV.0000000000000035

Peter Monteleone, MD, FACC, FSCAI
Interventional Cardiologist
Ascension Seton Medical Center
Austin, Texas
Disclosures: Advisory board member for Abbott, Boston Scientific, Medtronic, and RapidAI; consultant for Abbott, Boston Scientific, Medtronic, Penumbra, and Surmodics; receives speaker honoraria from Boston Scientific and Medtronic.

*See Surmodics Pounce™ Thrombectomy System Instructions for Use.

CASE REPORT:
Successful Removal of Organized TPT, PT, and AT Thrombus With Two Passes of the Pounce™ Thrombectomy System

By Peter Monteleone, MD, FACC, FSCAI

PATIENT PRESENTATION

A woman in her early 70s with a medical history of atrial fibrillation and incomplete compliance with her medication presented with sudden onset of a cold leg after 2 days of progressively worsening pain. Although she reported severe pain and tenderness at presentation, she observed no loss of sensation or motor function.

DIAGNOSTIC FINDINGS

An initial CT scan showed her left iliac artery, left common femoral artery (CFA), and left superficial femoral artery (SFA) were all open, but it also showed a complete occlusion of her left popliteal segment. She was immediately administered heparin and taken to the cath lab.

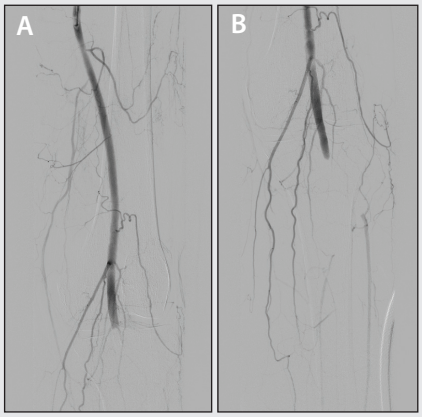


Figure 1. Patent SFA with P2 total occlusion (A) and faint reconstitution of PT and AT via geniculate collaterals (B).

TREATMENT

Access was achieved on the right CFA using micropuncture techniques and ultrasound guidance. An angiogram taken of the left leg showed a patent SFA but with an organized thrombus burden obstructing the popliteal artery, confirming the findings from the original CT scan (Figure 1). She had minor collateral flow, partially filling her posterior tibial (PT) and anterior tibial (AT) arteries, but runoff was poor. Due to her ongoing pain and symptoms, immediate endovascular intervention was deemed appropriate to remove occlusive material as promptly as possible. The patient's tibial and tibioperoneal trunk (TPT) vessels were estimated to be ≥ 3.5 mm, so the Pounce™ Thrombectomy System (Surmodics, Inc.) was chosen for thrombectomy.

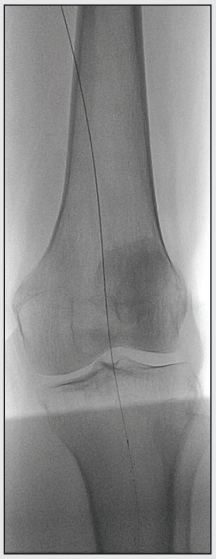


Figure 2. The Pounce™ System's basket wire deployed into the TPT, and the collection funnel deployed into the peroneal artery.

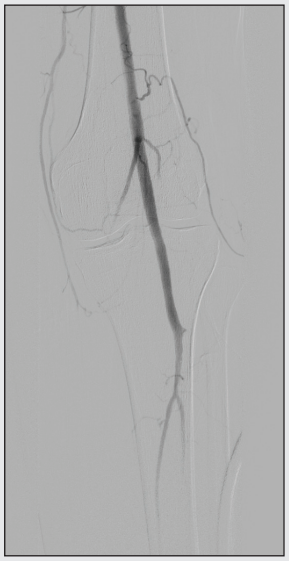


Figure 3. Patent popliteal, TPT, PT, and peroneal arteries after one pass of the Pounce™ Thrombectomy System.

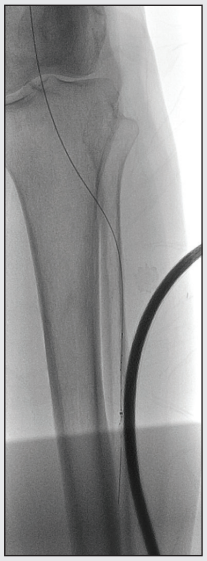


Figure 4. The basket wire deployed in the AT artery.

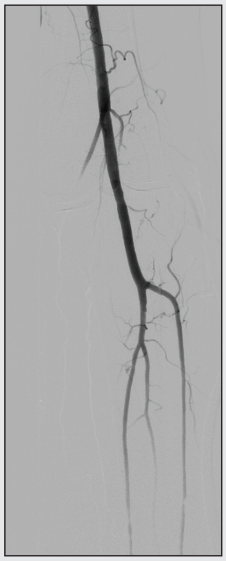


Figure 5. Complete thrombus removal in the popliteal, TPT, and AT arteries with two passes of the Pounce™ Thrombectomy System.

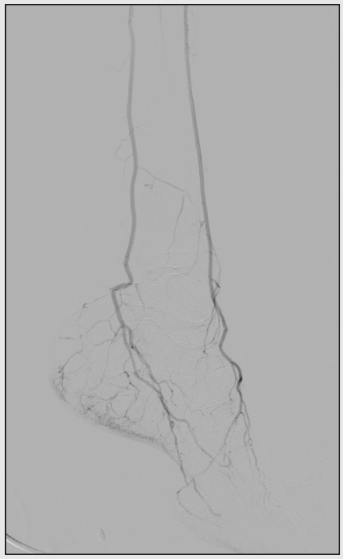


Figure 6. Normalized runoff with no distal embolization and full perfusion of the foot.

The initial 5 Fr procedural sheath was upsized over the already placed .035 Hi-Torque Versacore™ guidewire (Abbott) to a 7 Fr Destination® guiding sheath (Terumo Interventional Systems). The sheath and guidewire were then traversed through the left-side occlusion past the organized thrombus burden. The Pounce™ Thrombectomy System was prepared. The device's basket wire was deployed into the TPT via the delivery catheter and the funnel catheter was deployed over the basket wire into the popliteal artery (Figure 2). The basket wire was pulled back into the funnel catheter and the system was removed from the body. The first pass successfully removed organized material obstructing the popliteal artery. A follow-up angiogram showed reconstitution of the popliteal artery to the TPT (Figure 3), but there remained an obstructed AT artery.

A second pass of the Pounce™ Thrombectomy System was conducted in the AT artery. The basket wire was placed in the mid-AT artery (Figure 4), and the funnel catheter was placed in the popliteal artery. The basket wire was pulled back through the AT artery into the collection funnel located in the popliteal artery and removed from the body, removing additional thrombus burden. A follow-up angiogram showed complete resolution of flow to the AT artery, with continued strong flow in the popliteal and TPT (Figure 5) and no indications of embolization to the distal vasculature. The final angiogram also showed improved runoff to the foot (Figure 6).

POST-PROCEDURE OUTCOME

With complete thrombus removal and full resolution of flow to the foot, the patient was put on heparin after the access site was closed. Within 24 hours after the intervention, the patient's leg showed improvement. The following day the patient resumed apixaban treatment and was discharged home. The Pounce™ Thrombectomy System facilitated complete resolution of thrombus burden with just two passes and no need for adjunctive therapies, thrombolysis, or surgical intervention. ■

CASE REPORT: Successful Treatment of Infrapopliteal Arterial Thrombus With the Pounce™ Thrombectomy Platform

By Lucas Ferrer Cardona, MD

PATIENT PRESENTATION

A male patient presented to the emergency department with immediate onset of numbness and pain in his lower left leg and decreased motor and sensory function. The patient was immediately put on heparin and brought to the operating room.

DIAGNOSTIC FINDINGS

Right common femoral artery access was obtained. An initial CT scan revealed an occlusion in the patient's popliteal and tibial arteries that seemed to indicate a thrombotic event. An initial angiogram taken via a 7 Fr Destination® guiding sheath (Terumo Interventional Systems) showed complete thrombosis of the left popliteal, tibioperoneal trunk (TPT), and tibial arteries (Figure 1). The primary intervention strategy was to use the Pounce™ Thrombectomy System (Surmodics, Inc.) to remove the debris.

TREATMENT

The Pounce™ System was prepared and the basket wire was delivered to the TPT via the delivery catheter. The delivery catheter was removed, and the funnel catheter was delivered over the proximal portion of the basket wire and deployed at the popliteal artery. An initial pass of the Pounce™ System removed a moderate amount of organized thrombus. The Pounce™ System components were deployed again in the same locations, and another pass removed more of the organized material (Figure 2). Distal flow continued to be hampered by an occlusion in the proximal anterior tibial (AT) artery.

Because the AT artery was estimated to be < 3.5 mm in diameter (smaller than the indicated vessel range of the Pounce™ Thrombectomy System), the Pounce™ Low-Profile (LP) Thrombectomy System—indicated for 2 to 4 mm peripheral arteries—was prepared for use. The basket wire was placed in the mid AT artery and the funnel catheter was still placed in the popliteal artery. The basket wire was pulled back into the funnel catheter, collecting the remaining thrombus in the AT. After the pass with the

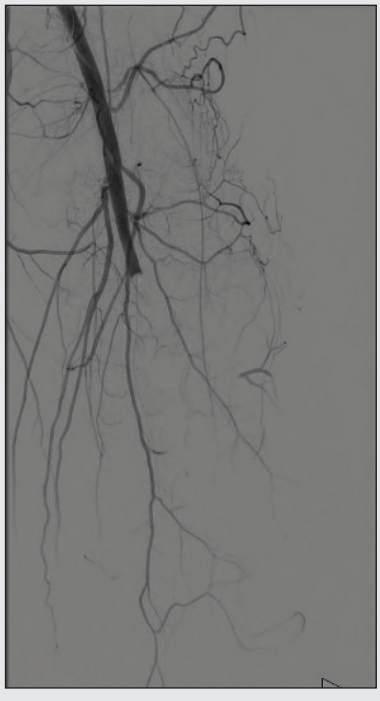


Figure 1. Initial angiogram showing occluded below-the-knee vessels.

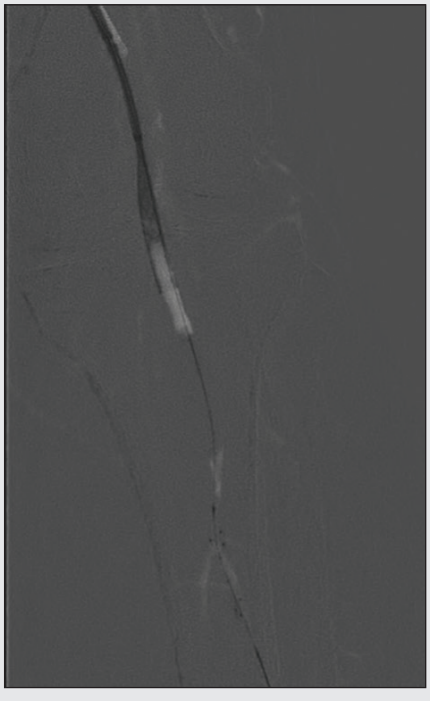


Figure 2. An angiogram after two passes of the Pounce™ Thrombectomy System in the popliteal and TPT arteries.

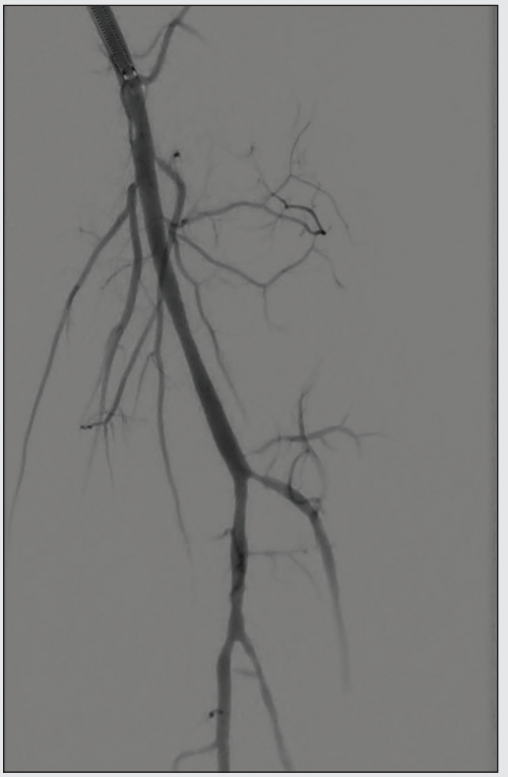


Figure 3. Final angiogram showing patent popliteal and TPT arteries, with three-vessel runoff to the foot.

Pounce™ LP device was completed, a follow-up angiogram showed complete removal and resolution of the thrombus burden with improved flow through the AT to the plantar arch (Figure 3).

POST-PROCEDURE OUTCOME

The patient was discharged 2 days after the intervention and restarted on apixaban medication. The combination of the Pounce™ and Pounce™ LP Thrombectomy Systems allowed for complete removal of organized thrombus from below-the-knee vessels, enabling improved flow to the distal vasculature without the need for thrombolytics or surgical intervention. ■

Lucas Ferrer Cardona, MD
Vascular Surgeon
Dell Seton Medical Center
The University of Texas Hospital
Austin, Texas
Disclosures: Consultant for Becton Dickinson, Penumbra, and Surmodics.

Sponsored by SURMODICS

Pounce™ Thrombectomy

Grab, Go, Restore Flow

Clearing arterial clots using traditional methods can be both time-consuming and ineffective against older thrombus.[1,2] The **Pounce™ Thrombectomy System** uses dual-basket technology to remove acute or chronic peripheral arterial clot on the spot—**now including below the knee.**

Pounce™ Thrombectomy LP

2mm–4mm vessel diameter

Suitable for removal of below-the-knee arterial thrombi and emboli

Pounce™ Thrombectomy

3.5mm–6mm vessel diameter

Suitable for removal of femoral-popliteal, upper extremity, mesenteric, and other peripheral arterial thrombi and emboli

The Pounce™ Thrombectomy System is designed to:

- Remove thrombi and emboli from the peripheral arterial vasculature
- Be fully mechanical, not requiring capital equipment to minimize setup time and shelf space
- Be used quickly in time-critical situations while helping to reduce fluoroscopy time
- Reduce thrombolysis usage during complex thrombectomy procedures
- Minimize blood loss
- Reduce risk of hemolysis
- Be atraumatic to avoid arterial wall injury

1. The STILE Investigators. Results of a prospective randomized trial evaluating surgery versus thrombolysis for ischemia of the lower extremity: the STILE trial. *Ann Surg.* 1994;220:251-268.
2. de Donato G, Pasqui E, Sponza M, et al. Safety and efficacy of vacuum assisted thrombo-aspiration in patients with acute lower extremity ischemia: the INDIAN trial. *Eur J Vasc Endovasc Surg.* 2021;61:820-828.

Restoring Flow to the Foot

Tackling complex BTK challenges

Dual nitinol self-expanding baskets mounted in series on a core wire for capturing thrombus

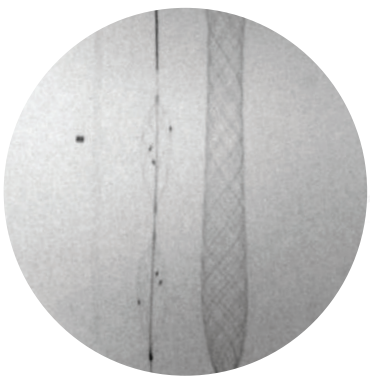
Nitinol funnel to capture baskets and entrain clot

Integrated handle with slider button for sheathing and unsheathing funnel. Wire lock maintains basket wire position in funnel during thrombus or embolus removal.

Basket wire's tapered tip includes a spring coil for atraumatic delivery

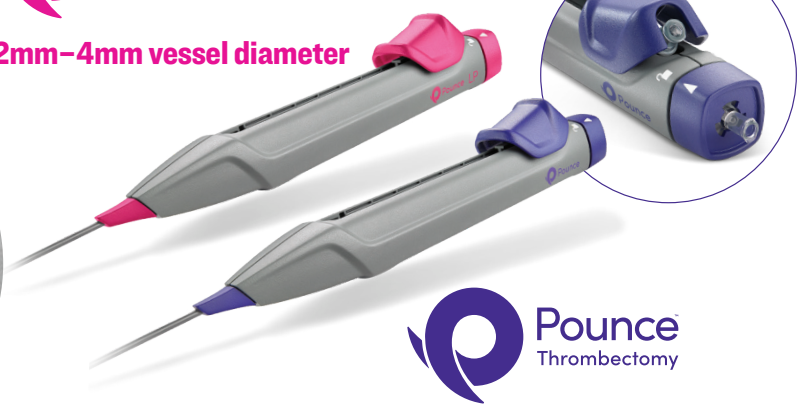
Pounce™ Thrombectomy LP

2mm–4mm vessel diameter



Pounce system components under fluoroscopy

Delivery catheter distal radiopaque marker (left), Basket wire (middle), Funnel (right)



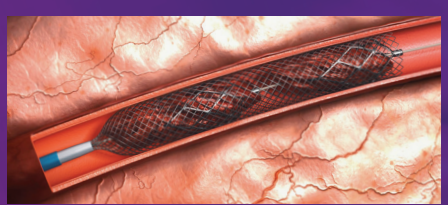
Pounce™ Thrombectomy

3.5mm–6mm vessel diameter

How it works

Scan to watch full animation.
qrco.de/pouncesystemanimation

The basket wire is delivered distal to the location of the thrombus, deploying two nitinol self-expanding baskets.



The baskets capture the clot and are retracted into a nitinol collection funnel.

With the clot entrained, the system is retracted into a minimum 7 Fr guide sheath through which the clot is withdrawn and removed from the body.

Cutting Down on Cutdowns With the Pounce™ LP Thrombectomy System

A conversation with Dr. Christopher Leville.

Vascular surgeon **Dr. Christopher Leville** is associated with the CentraCare-St. Cloud hospital, located an hour's drive northwest of Minneapolis, Minnesota. He serves a patient population of 800,000, spread out among several rural counties reaching as far west as South Dakota. At least half the patients he sees have lower extremity chronic or acute ischemia. Dr. Leville was an early adopter of the original Pounce™ Thrombectomy System (Surmodics, Inc.), intended for 3.5 to 6 mm arteries, and now also uses the Pounce™ Low-Profile (LP) device in 2 to 4 mm vessels, notably including the tibials. We spoke with Dr. Leville about the patients he treats and the role of the Pounce™ System in his practice.

What is the care pathway for acute limb ischemia patients at your facility?

When someone comes in with leg pain or swelling, our emergency room (ER) staff always perform a deep vein thrombosis (DVT) scan first because DVT is by far the most common issue. If the DVT scan is normal, patients typically receive a quick arterial duplex ultrasound scan. If that shows obstruction or thrombus, or there's a pulseless leg, they call us. Then, depending on the patient, we will look further with CT.

I usually see the patient first in the ER, and there I can usually determine whether an intervention needs to be done right away or if it can wait 24 hours. If they've been having symptoms for 2 weeks, they're much more likely to have chronic disease. If they've had symptoms for 3 hours and have paralysis of their foot, then it's obvious that intervention is needed right away.

How do you treat patients who do not require immediate intervention?

As a surgeon, I prefer whatever is least invasive and safest for the patient. In the case of a patient with neurologic function and pain, that often means thrombolysis if angiography indicates it is likely to be effective within 24 hours and the patient is a good candidate. That's the traditional role of tissue plasminogen activator (tPA), especially if the patient has had previous bypass surgery and there's scar tissue. If tPA fails after 24 hours, I may try another percutaneous approach, but if the patient has, say, long-segment thrombosis through a stent or bypass, I'm more likely to opt for open surgery.

> "What I like about the Pounce™ device is that it behaves more like a Fogarty balloon."

Having said that, I've found the Pounce™ System to be a good day 2 device after using tPA. There's almost always some residual clot after tPA, and that clot tends to be more chronic. By using the Pounce™ System in these situations, I've been able to avoid some surgery with cutdowns and Fogarty thrombectomies.

What's your approach to treating more acute patients?

For the patient who has loss of neurologic function, you can't wait 24 hours for thrombolysis to work. You have to either do a surgical thrombectomy or a percutaneous intervention, either with a mechanical or aspiration device. The Pounce™ System has been a good mechanical option for many of those acute cases. If you have chronic thrombus or embolic plaque that has embolized distally during a planned case, the Pounce™ System gives you the option to retrieve clot or debris without having to convert to open surgery. If there's no disease in the arteries and extensive clot, it can be fairly simple to use aspiration thrombectomy, but it can be really hard to use aspiration thrombectomy in diseased arteries. I'm much less likely to use aspiration in that situation because I'm worried about embolizing plaque.

Why is that?

When you're using aspiration, regardless of which device you use, you're typically treating from top-down: proximal to distal

through the thrombus. Usually you're keeping wire access and depending on the device not to embolize clot distally. But I find that it's harder to prevent embolization working proximal to distal if there's a stenosis or a severely diseased artery.

What I like about the Pounce™ System is that it behaves more like a Fogarty balloon. You start distal to the thrombus and withdraw back, just as you would with a Fogarty. In situations where you're concerned about distal embolization, it can make more sense to use a Pounce™ System. We do Fogarty procedures without wire access all the time—you just thread the catheter down the leg, inflate the balloon, and withdraw the clot. The Pounce™ System behaves very much like that. That's why I use it. The last thing I want to do is to have to convert a case from percutaneous to open surgical or overnight tPA in the intensive care unit if that's not what we had planned. The Pounce™ System gives me a third option.

How did you deal with embolized clots in the tibials before you had the Pounce™ LP System?

Embolizing plaque is terrible, and we really have had limited options to get that embolus out. We used to try to use Export™ catheters (Medtronic) or other devices, or even a SpiderFX™ filter (Medtronic) or other off-label uses, but everything was suboptimal. In these situations you can use the Pounce™ LP System on label very quickly, without major setup. You just open the package, get out the embolus, and a major problem is often resolved within minutes without surgical cutdown or another procedure with tPA.

Along the same lines, sometimes you get called in for a patient with atrial fibrillation who has a cold leg and they have a focal clot at a specific spot. That's an easy surgical case—you just do a little cutdown to get the clot out. But even in those cases, the patients are usually sick or hemodynamically unstable, so doing a cutdown with sedation can be hard on them. It's nice to have the Pounce™ System as an option because, in my experience, a one-stage percutaneous intervention is much better tolerated from an anesthesia and blood loss standpoint and reduces risk of complications. It's evident after you do a few procedures with the Pounce™ System successfully that it's better for the patient compared with having to do a cutdown. Sometimes we can remove a short clot with one pass of the device. Longer clots may require more passes.

"You just open the package, get out the embolus, and a major problem is often resolved within minutes without surgical cutdown or another procedure with tPA."

"Now, if there is remaining thrombus, I can go after it."

How has the availability of the Pounce™ LP System impacted your treatment of tibial vessels?

With the original Pounce™ System (indicated for 3.5 to 6 mm vessels), you were typically limited to going down to the popliteal or maybe the tibial peroneal trunk for some patients. The smaller Pounce™ LP System (indicated for 2 to 4 mm vessels) is much better suited for the tibials. Typically, it's long enough to allow you to reach down to the ankles from a contralateral approach.

If it's a chronic limb-threatening ischemia case, where we're not dealing with thrombus, we always start with angioplasty or atherectomy for tibial arteries, but those arteries can shut down and clot. In those situations, you can use the Pounce™ LP System to resolve the clot.

Has your use of the Pounce™ System at all changed or evolved since you began using it?

Yes, I'm now more inclined to work on cleaning more clot from targeted vessels. Even after restoring blood flow during an intervention, there are often these little hanging clots left behind. Before we had the Pounce™ System, we were more likely to say blood flow is okay, and even though there's still a little bit of clot, it'll clean up with anticoagulation. Unfortunately, these patients often come back with more problems if you don't clean everything out. I don't do that at all anymore. Now, if there is remaining thrombus, I can go after it. ■

Christopher Leville, MD
Vascular Surgeon
CentraCare Hospital
St. Cloud, Minnesota
Disclosures: Consultant for Boston Scientific, Shockwave, and Surmodics.

CASE REPORT:
Successful Removal of Brachial and Ulnar Artery Thrombus Using the Pounce™ LP Thrombectomy System

By Christopher Leville, MD

PATIENT PRESENTATION

A man in his late 60s presented to the emergency department with a cold left hand symptomatic for 24 hours. The patient had previously been seen at an outside hospital for open heart surgery, where his radial artery was harvested for the intervention. Beyond his prior open heart surgery, the patient's medical history included hypertension, hyperlipidemia, and chronic obstructive pulmonary disease. The patient was initially put on aspirin and statin medication and brought into the operating room for further diagnosis.

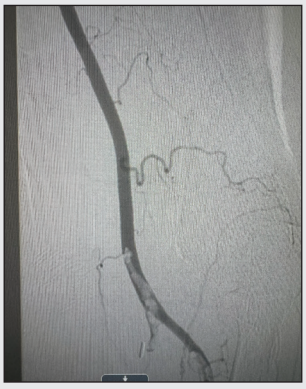


Figure 1. Initial angiogram of the left brachial artery.

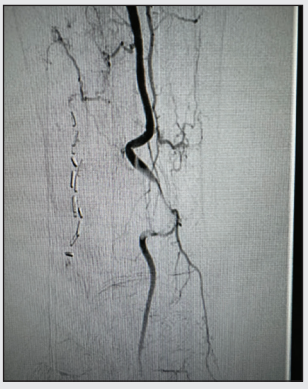


Figure 2. Initial angiogram of the ulnar artery.

DIAGNOSTIC FINDINGS

An initial ultrasound showed a complete occlusion of the patient's left brachial artery and partial occlusion of the left ulnar artery. A 6 Fr, 90 cm procedural guide sheath was inserted into the patient's femoral artery and was navigated to the left axillary artery. An initial angiogram confirmed the ultrasound findings (Figures 1 and 2). The patient was not a candidate for tissue plasminogen activator (tPA) due to his recent cardiac surgery, and open surgical thrombectomy was not deemed appropriate because the ulnar artery measured 2 mm. The interventional strategy was to conduct thrombectomy with the Pounce™ LP Thrombectomy System (Surmodics, Inc.).

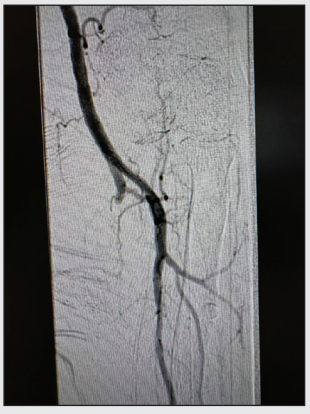


Figure 3. Angiogram of brachial artery after two passes with the Pounce™ LP Thrombectomy System.

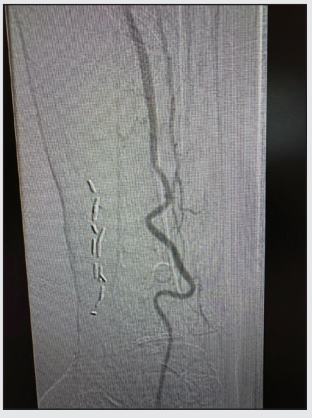


Figure 4. Angiogram of the left ulnar artery after one pass with the Pounce™ LP Thrombectomy System.

TREATMENT

The procedural guide sheath was upsized to a 7 Fr, 90cm version, and the tip of the sheath was placed in the left axillary artery. The .018 guidewire compatible Pounce™ LP Thrombectomy System was prepared, whereupon the basket wire was deployed in the distal brachial artery via the delivery catheter included with the system. The funnel catheter was deployed in the mid brachial artery. The baskets were pulled back into the collection funnel, retrieving partial thrombus, and removed from the body. A second pass was made in the brachial artery utilizing the same deployment steps and component positioning as the first pass. After the second pass in the brachial artery, the basket wire was deployed in the distal ulnar artery, and the funnel catheter was again deployed in the mid brachial artery. One pass was made to clear out the thrombus burden in the ulnar artery. Final angiograms showed a patent brachial artery (Figure 3) and complete resolution of the ulnar artery (Figure 4), with no embolization to the patient's hand.

POST-PROCEDURE OUTCOME

The patient was discharged the day after the intervention, with instructions to maintain his warfarin regimen for 3 months. At 1-month follow-up, the patient's brachial and ulnar arteries continued to show patency and good flow. Due to the Pounce™ LP Thrombectomy System's low profile, the thrombus burden was able to be removed in a percutaneous fashion without the need for surgical intervention and tPA. ■

Caution: *Federal (US) law restricts the Pounce™ Thrombectomy System and Pounce™ LP Thrombectomy System to sale by or on the order of a physician. Please refer to each product's Instructions for Use for indications, contraindications, warnings, and precautions. SURMODICS, POUNCE, and SURMODICS and POUNCE logos are trademarks of Surmodics, Inc. and/or its affiliates. Third-party trademarks are the property of their respective owners.*

The Utility of the Sublime™ Radial Access Platform for Peripheral Procedures

A conversation with Dr. Craig Walker.

Interventional cardiologist **Dr. Craig Walker** is the Founder and President of the Cardiovascular Institute of the South, which includes more than 20 clinics in Louisiana, Mississippi, and Illinois. He is also Founder of New Cardiovascular Horizons, a provider of multidisciplinary-accredited conferences to advance the field of cardiovascular care. Dr. Walker is known as a pioneer in interventional cardiology and peripheral vascular interventions and has trained more than 1,500 physicians in advanced peripheral interventional techniques. In this interview, Dr. Walker discusses the current state of the art for the radial-to-peripheral approach and his experience with the Sublime™ Radial Access Platform (Surmodics, Inc.).

You've helped to spearhead radial access for treatment of peripheral artery disease. What do you see as the major benefits of this approach?

The radial approach has been used in coronary interventions for years and now is considered an independent predictor of decreased complications, particularly bleeding complications. Bleeding complications can lead to other complications and increased mortality.[1] I've also found that bleeding complications can reduce patency over time, making it more likely arteries will occlude. But there's another component that many physicians don't speak of but is quite important: patient comfort. Patients find radial access far more comfortable than femoral access.[2]

Pedal access is also used as an alternative to the femoral approach for lower extremity procedures. How would you compare the radial and pedal approaches as alternative access sites?

There are certain anatomic reasons why we would not want to even try a pedal access. Whenever we are putting sheaths in small vessels, there's a chance that those vessels will occlude over time. When we're using radial, we're not using it because the arm is sick, but when we're doing a pedal approach, we're doing it because the leg is sick, and attrition of those vessels may be catastrophic in the long run. Radial is a low-bleeding access site.[1] Having said that, it has its own risks and challenges. But in patients who have been properly selected—those who have a radial artery of appropriate size and anatomy and have good palmar arch flow—radial access can be very safe with the proper technique. As a practical guide, I've written what I consider to be the 13 steps required to avoid radial artery complications in peripheral artery interventions.[3]

What are some of the other reasons for physicians to use radial access for peripheral procedures?

For treatment of peripheral disease, radial access can provide the ability to treat both legs in a single setting. That's very difficult to do from femoral access. Radial access allows us to treat and not have to compress an artery that we've just treated. When we compress an artery that we've just treated, we're diminishing the blood flow and thereby may be increasing the risk of thrombosis. In addition, we can use radial access even in patients who are completely anticoagulated with much less risk of subsequent bleed.[4] I've had many such patients—patients I was told could not come off their warfarin for even a second because if they did they would throw emboli from their aortic valves.

> "Even the longest Sublime™ balloon catheters aimed at infrapopliteal spaces, where I'm working at a great distance in highly obstructed lesions, I've found work very effectively."

There are many reasons to use radial access, but I think what's going to drive this in the long run is patient comfort. We don't speak about the fact that, for example, many men simply cannot urinate after we've given them contrast when they're lying on their backs. That's a really big deal. With radial access, a patient is sitting up in a lounge chair immediately after the procedure. They can watch and change the television channel. The patient feels in control at that moment, and so patients like this approach.

Of course, another driver of adoption for the radial-to-peripheral approach is creation of tools that are getting us to the lesions, allowing us to cross the lesions, and allowing us to treat these lesions. One of the first steps was development of low-profile, low-friction, slippery sheaths. Along with that has come longer wires, longer balloons, longer stent delivery systems, at least one atherectomy device that's longer, and a long drug-coated balloon. All these things have improved our ability to use the radial approach, albeit we still don't have a full armamentarium of tools. I suspect that will be coming.

What has been your experience with the Sublime™ portfolio of radial-to-peripheral products?

I have been impressed with the performance of the Sublime™ Guide Sheaths. They have the long lengths we can use. I think these sheaths are certainly on par with the best of the best—a very, very good sheath that's very easy to place. I like the feel of the sheath. From the outside, I think it works very well, and I've found it to go around bends very well. I've had a couple cases where a Sublime™ sheath passed when some competitive sheaths did not.

I've also been impressed with Sublime™ Radial Access Balloon Catheters. They're on a very long shaft, which gives me the ability to push further from the shaft. I've found these balloon catheters cross lesions very well. Even the longest Sublime™ balloon catheters aimed at infrapopliteal spaces, where I'm working at a great distance in highly obstructed lesions, I've found work very effectively.

You've recently had experience using Sublime™ Microcatheters for peripheral cases. Can you comment on their performance?

With radial access, when we're treating the lower extremities from a farther distance, we will have slightly less push, and we have to learn how to mitigate that. So, one of the things that I've been very impressed with are the Sublime™ Microcatheters that Surmodics has created.

"I've been impressed that by simply rotating these catheters in long total occlusions, I can easily cross lesions in very short order."

"The fact that these catheters have a braid, can telescope, and have a low coefficient of friction once wet really helps to negate some difficulty in crossing lesions."

These catheters help us cross lesions because, first, they're hydrophilic, they're very slippery. Second, one can rotate these catheters. Being able to rotate them, or torque them to use another term, allows the catheter to pass through a lesion much more easily. It's related to the physics of orthogonal displacement of friction, which occurs when we rotate things. So even when we're into a high frictional element, this device, which is very slippery, has a nice rigid body. In addition to that, the .014 and .018 catheters can fit inside of the .035, so we can create a telescoping system.

In some cases—even cases in which I'm not using these catheters from a radial approach—I've been impressed that by simply rotating these catheters in long total occlusions, I can easily cross lesions in very short order. I have a case that I've reported on this (page 18). This was a long chronic occlusion, not a patient who had just developed symptoms. The catheter easily crossed this entire lesion in about a minute with very little resistance. I never pushed the catheter, I simply rotated and kept rotating, and the catheter went through.

The fact that these catheters have a braid, can telescope, and have a low coefficient of friction once wet really helps to negate some difficulty in crossing lesions. I also like the concept of using Sublime™ catheters in a telescoping fashion, first placing the smaller catheter in very hard lesions followed by the bigger catheter because, in a sense, what that is doing is predilating the lesion. This may allow me to more easily deliver subsequent therapies that I'm planning to deliver.

In lectures I've given around the world, I've stressed that a wire always should work in concert with a crossing catheter, because a crossing catheter, if we bring it closer to the end of the wire, gives that wire far greater penetration. It gives us better ability to torque that wire at the end, because we are creating a shaft around the wire that stops the bend within the wire as you're going down, allowing us to direct the wire better. If we get hung up in a lesion, we can come down and give the wire a little more "umph" in crossing—a little greater push at that point. It also helps to protect the wire against damage.

Finally, using crossing catheters as I've described allows us to take a picture after crossing a lesion to better see what is going on beyond the lesion. Often, when there's a critical lesion or a total occlusion, we take pictures but may only see ghost-filling of vessels. We just don't see the vessel very well. Using crossing catheters allows us to obtain a very detailed image of what lies beyond, and that detailed image may really help us to better plan step two. When we're doing these cases, we're not playing checkers and thinking of just the first move. We have to think of subsequent moves, because our goal is checkmate and restored flow, not just taking one more piece off the board. ■

1. Lawton J, Tamis-Holland J, Bangalore S, et al. 2021 ACC/AHA/SCAI guideline for coronary artery revascularization: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2022;79:e21-e129. doi: 10.1016/j.jacc.2021.09.006
2. Cooper CJ, El-Shiekh RA, Cohen DJ, et al. Effect of transradial access on quality of life and cost of cardiac catheterization: a randomized comparison. *Am Heart J*. 1999;138:430-436. doi: 10.1016/s0002-8703(99)70143-2
3. Walker C. Thirteen steps to avoid radial artery access complications in peripheral arterial interventions. Vascular Disease Management. May 2022. Accessed April 15, 2024. https://www.hmpgloballearningnetwork.com/site/vdm/clinical-editors-corner/thirteen-steps-avoid-radial-artery-access-complications-peripheral
4. Ziakas AG, Koskinas KC, Gavrilidis S, et al. Radial versus femoral access for orally anticoagulated patients. *Catheter Cardiovasc Interv*. 2010;76:493-499. doi: 10.1002/ccd.22527

Craig Walker, MD
Interventional Cardiologist
Cardiovascular Institute of the South
Gray, Louisiana
Disclosures: Consultant for Abbott, Asashi Intecc, BD Interventional, Boston Scientific, Medtronic, and Philips; speaker's bureau for Abbott, Amgen, Asashi Intecc, BD Interventional, Boehringer-Ingelheim, Bristol-Myers Squibb/Sanofi, Esperion Therapeutics, Gore & Associates, Janssen Pharmaceuticals, and Philips; PVD training for Abbott, Asashi Intecc, BD Interventional, Boston Scientific, Cordis, and Philips; major stockholder in CardioFlow, Efemoral Medical, Micro Medical, Peytant Solutions, Inc.

CASE REPORT:
Revascularization of Femoropopliteal and Tibiopedal Total Occlusions Facilitated by Use of the Sublime™ Microcatheter

By Craig Walker, MD

PATIENT PRESENTATION

A man in his mid 70s with a history of peripheral artery disease (PAD), tobacco use (former), hypertension, chronic lung disease, and dyslipidemia presented to the clinic with severe PAD with true ischemic rest pain in the right lower extremity (Rutherford class 4) and prior femoropopliteal bypass surgery.

DIAGNOSTIC FINDINGS

A diagnostic angiogram of the right lower extremity revealed a subtotal occlusion of the peroneal artery and total occlusions of the superficial femoral artery (SFA), popliteal artery, anterior tibial (AT) artery, and the dorsalis pedis (DP) artery (Figure 1).

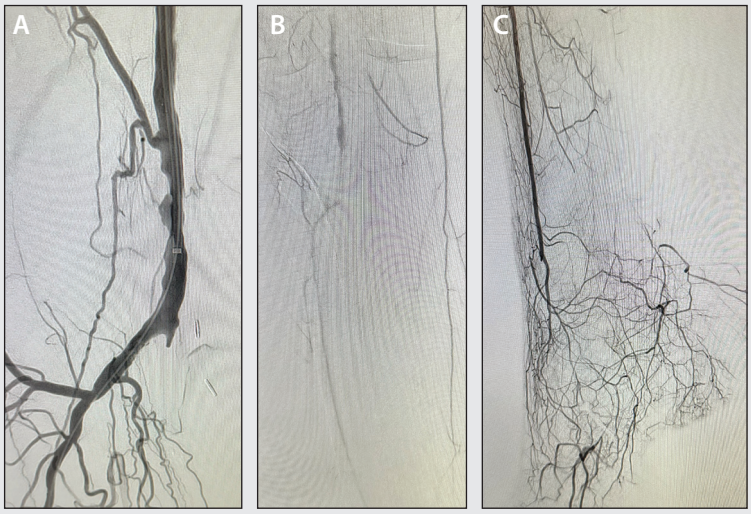


Figure 1. Diagnostic angiography revealed severe disease in the SFA (A), popliteal artery (B), and AT and DP arteries (C).

TREATMENT

Access was achieved under ultrasound guidance via the left femoral artery, and a 6 Fr, 45 cm sheath was advanced to the right iliac artery after the initial angiography. A .035 guidewire was inserted but was not able to advance through the vasculature, whereupon a .035 Sublime™ Microcatheter (Surmodics, Inc.) was advanced over the wire and—using rotation and gentle advancement with minimal force—the device crossed a 50 cm occlusion in the SFA and popliteal arteries. Intravascular ultrasound showed a true lumen crossing through the occlusion. Once the guidewire was across the occlusion, a 2.0 mm Turbo-Power™ laser atherectomy catheter (Philips) was advanced and passed twice in the SFA and popliteal artery.

A 5.0 X 220 mm balloon was then advanced and inflated in the SFA and popliteal artery, whereupon the .035, 135 cm Sublime™ Microcatheter was advanced to the DP via the AT. A 2.5 X 220 mm, .018 Sublime™ RX PTA Catheter was advanced to the distal portion of the AT, inflated, deflated, and removed. Because the guidewire would not advance through the DP, a .018, 170 cm Crosswalk® microcatheter (Asahi Intecc) was telescoped through the .035 Sublime™ Microcatheter to cross the DP (Figure 2). After the microcatheters were removed, a .014 guidewire was inserted and a .014" Sublime™ RX PTA Catheter was advanced and inflated in the DP, and pedal loop reconstruction was performed into the lateral plantar branch of

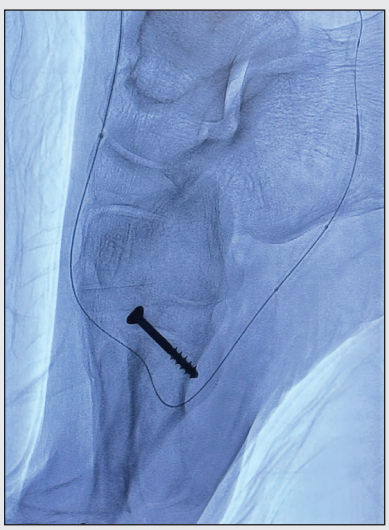


Figure 2. A .018, 170 cm Crosswalk® microcatheter was telescoped through the .035 Sublime™ Microcatheter to cross the DP artery.

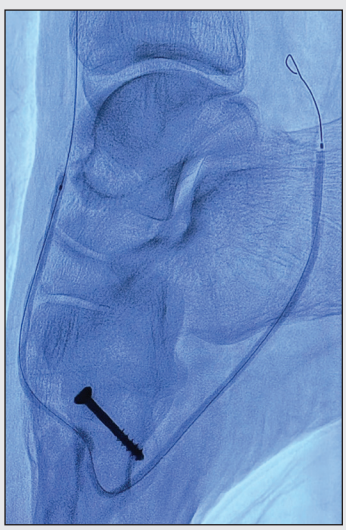


Figure 3. Balloon angioplasty of the DP artery using a .014 Sublime™ RX PTA Catheter.

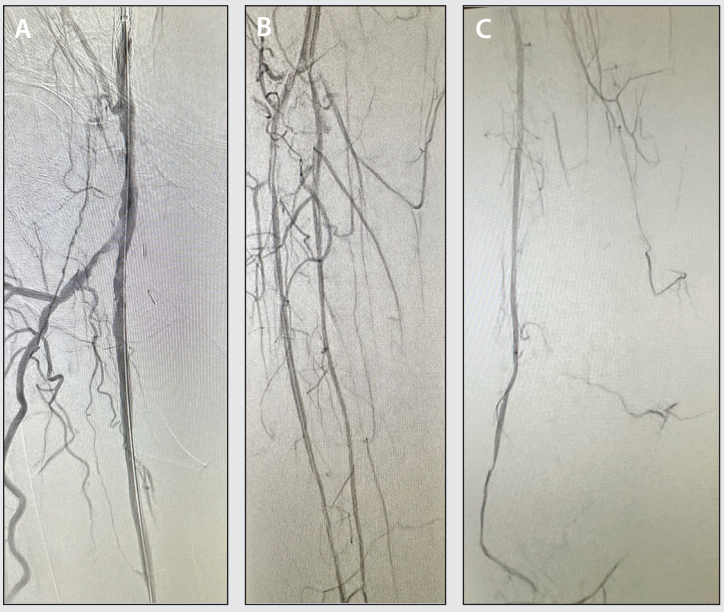


Figure 4. Arteriogram demonstrating successful revascularization of the SFA (A), peroneal and AT arteries (B), and AT and DP arteries (C).

the posterior tibial artery (Figure 3). Drug-coated balloons (DCBs) were then advanced and inflated in the SFA and popliteal artery.

POST-PROCEDURE OUTCOME

Laser, balloon angioplasty, and DCB application restored blood flow to the SFA, popliteal, peroneal, AT, and DP arteries (Figure 4). The Sublime™ Microcatheter played a pivotal role in securing access to treatment by crossing a 50 cm total SFA occlusion and assisting with crossing the occluded DP artery. ■

Powering Radial-Peripheral Procedures With Torqueable Microcatheters

A conversation with Dr. Amit Srivastava.

For the past several years, interventional cardiologist **Dr. Amit Srivastava** has helped drive the radial-to-peripheral movement as an early adopter, researcher, educator, and frequent presenter. Today, more than 80% of the interventions he performs at the Bay Area Heart Center in St. Petersburg, Florida, are peripheral—the vast majority conducted from the wrist. Recently, Dr. Srivastava participated in a prospective, multicenter registry study (N = 120) of radial-first lower extremity arterial interventions.[1] Since then, he has added the Sublime™ Microcatheters (Surmodics, Inc.) to his toolkit. We spoke with Dr. Srivastava about the radial-to-peripheral approach and his experience with Sublime™ Microcatheters, available in 65 to 200 cm lengths.

Radial-first for coronary interventions is now mainstream. Do you think the tide is turning for radial-to-peripheral?

I think we're seeing a growing fervor for it. The talks I've been giving on this topic at conferences have been standing room only. We're also seeing training programs turning out more and more operators who are very fast and adept at performing radial procedures.

I remember being at a Society for Cardiovascular Angiography & Interventions (SCAI) Fellows meeting 15 years ago when someone asked how many of us were taking a radial-first approach for coronary procedures. The answer was about 10%, with 90% going femoral. I asked the same question at a SCAI Fellows meeting last year and the answer was 90% radial.

Do you see more patients requesting radial access?

In our area, for sure. I think our practice has done a good job educating patients that radial access is the right thing to do for coronary interventions. We've also found that patients will do their own Google searches before they come in and will ask if radial access can be done for other procedures.

> "Radial-to-peripheral operators have really needed a long-length, hydrophilic, braided peripheral microcatheter…"

Many of our patients already have lumbar spinal disease and back issues. Bed rest for even just 2 hours after femoral access with use of a closure device can certainly be unpleasant for them. When they see the recovery in our surgical center, with patients sitting up and eating right after the procedure, that translates into a great patient experience and great word-of-mouth advertising for the practice.

The safety of femoral access has improved in recent years. What do you see as the most important clinical advantages of the radial approach today?

It's true that the use of micropuncture devices and ultrasound-guided access has improved patient safety for the femoral approach.[2,3] That's really good news. To me, radial access is not an anti-groin approach, it's a pro-patient approach. Before I perform a procedure from the wrist, I always tell a patient that we've prepped the groin in case we need it. If there's an iliac perforation, you're going to need to be able to quickly insert a 7 Fr sheath to place a covered stent. We'll also routinely prep pedal access. Having said that, radial access continues to be safer for patients compared with femoral access.[4]

There are other clinical advantages of the radial approach beyond safety. If you look at the angle of the superior mesenteric artery, renal arteries, and the celiac artery, it's always easier to access them from above than it is from below. This makes procedures easier to perform. The same thing goes with carotid stenting. I believe knowing how to go

"We've also had excellent results from the radial approach crossing calcified, highly stenotic lesions or chronic total occlusions…"

radial makes you a better operator because you can tackle more situations.

Let's talk about the radial-to-peripheral toolkit. Surmodics recently introduced a suite of torqueable peripheral microcatheters to its Sublime™ Radial Access portfolio. Can you describe your experience with Sublime™ Microcatheters?

Radial-to-peripheral operators have really needed a long-length, hydrophilic, braided peripheral microcatheter, so I was eager to try out the Sublime™ device. The first time I used it was actually from the pedal approach. We were up against a very tight, calcified chronic total occlusion that I hadn't been able to cross using other catheters. Using a 65 cm, angled, .018 Sublime™ Microcatheter, I was able to get through it easily. We've also had excellent results from the radial approach crossing calcified, highly stenotic lesions or chronic total occlusions with the angled microcatheters. The catheter length (≤ 200 cm) is perfect. I've been able to get in the popliteal artery with no problem, switch out my wire, and finish the cases much more easily.

What do you think differentiates this microcatheter?

I love the braiding and the fact that you can spin it clockwise or counterclockwise to get it to do what you need it to do. The hydrophilic coating is fantastic.[5] It's really a very lubricious and supportive catheter.

How would you describe the economics of radial versus femoral access for your practice?

The price of the sheaths and other tools certainly is higher for the radial-to-peripheral approach compared with the femoral approach. But in my experience, the price of a radial access sheath does not equal the price of a femoral sheath plus a closure device. So, radial access is still more cost-effective from that standpoint.

More importantly, aside from improving outcomes, radial-to-peripheral offers you the ability to minimize overhead costs and improve patient throughput. In our facility, one nurse can easily manage five radial-access patients in recovery. Bed rest is no longer than 2 hours after a procedure. Once a radial band is off, the patient is on their way. And what's literally changed the game from the endovascular standpoint is that patients no longer have to be routinely admitted overnight to manage and observe the femoral access site and make sure there are no complications. ■

1. Castro-Dominguez Y, Li J, Lodha A, et al. Prospective, multicenter registry to assess safety and efficacy of radial access for peripheral artery interventions. *J Soc Cardiovasc Angiogr Interv*. 2023;2:101107. https://doi.org/10.1016/j.jscai.2023.101107
2. Ben-Dor I, Sharma A, Rogers T, et al. Micropuncture technique for femoral access is associated with lower vascular complications compared to standard needle. *Catheter Cardiovasc Interv*. 2021;97:1379-1385. doi: 10.1002/ccd.29330
3. Seto AH, Abu-Fadel MS, Sparling JM, et al. Real-time ultrasound guidance facilitates femoral arterial access and reduces vascular complications: FAUST (Femoral Arterial Access With Ultrasound Trial). *JACC Cardiovasc Interv*. 2010;3:751-758. doi: 10.1016/j.jcin.2010.04.015
4. Bajraktari G, Rexhaj Z, Elezi S, et al. Radial access for coronary angiography carries fewer complications compared with femoral access: a meta-analysis of randomized controlled trials. *J Clin Med*. 2021;10:2163. doi: 10.3390/jcm10102163
5. Data on file at Surmodics, Inc.

Amit Srivastava, MD, FACC
Interventional Cardiologist
Bay Area Heart
Tampa, Florida
Disclosures: Consultant for Surmodics, Inc. and Terumo.

CASE REPORT:
Successful Revascularization of a 99% Left CFA Stenosis Via a Radial Approach Facilitated by the Sublime™ Microcatheter

By Amit Srivastava, MD, FACC

PATIENT PRESENTATION

A man in his early 70s with a prior medical history of a left femoral endarterectomy, peripheral artery disease, diabetes, hyperlipidemia, and hypertension presented with a recurrent wound in his left lateral malleolus from the original femoral endarterectomy. An arterial ultrasound demonstrated severe left femoral arterial stenosis with peak systolic velocity at 300 cm/second. Based on the patient's arterial ultrasound and prior history, the patient was immediately taken to the angiography suite.

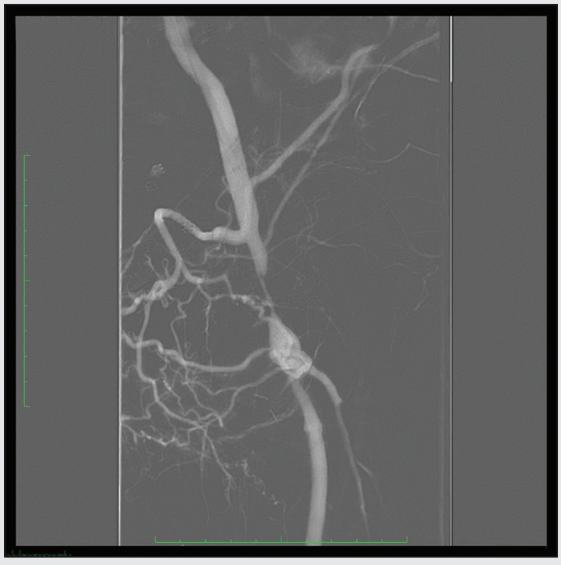


Figure 1. Initial angiogram of the CFA showing 99% stenosis.

DIAGNOSTIC FINDINGS

To avoid the femoral complication, a radial access approach was chosen; the right radial artery was accessed using ultrasound guidance. A 5/6 Fr Glidesheath Slender® hydrophilic coated introducer sheath (Terumo Interventional Systems) was introduced, and an internal mammary (IM) catheter was used to navigate through the aortic arch down into the lower extremity vasculature. The IM catheter was swapped out for a Glidecath™ PV multicurve catheter (Terumo Interventional Systems) and an angiogram was obtained. The initial angiogram showed a 99% left common femoral artery (CFA) stenosis, likely due to an injury from the original endarterectomy (Figure 1). The interventional strategy was to resolve the stenosis while avoiding the femoral complication area.

The Glidecath™ PV multicurve catheter was removed and the initial 5/6 Fr Glidesheath Slender® hydrophilic coated introducer sheath was exchanged for a 119 cm R2P™ Destination Slender™ guiding sheath (Terumo Interventional Systems). A stiff, angled Glidewire® guidewire (Terumo Interventional Systems) was introduced into the vasculature. Due to tough stenosis and tortuosity, a 200 cm length, .035 guidewire-compatible Sublime™ Microcatheter (Surmodics, Inc.) was introduced to aid in crossing the lesion. After a quick angulation of the catheter tip and in combination with the guidewire, the catheter was able to easily navigate through the stenosis and enable further execution of the intervention strategy. The Sublime™ Microcatheter was then used to exchange the initial stiff, angled guidewire for a ViperWire™ peripheral guidewire (Abbott).

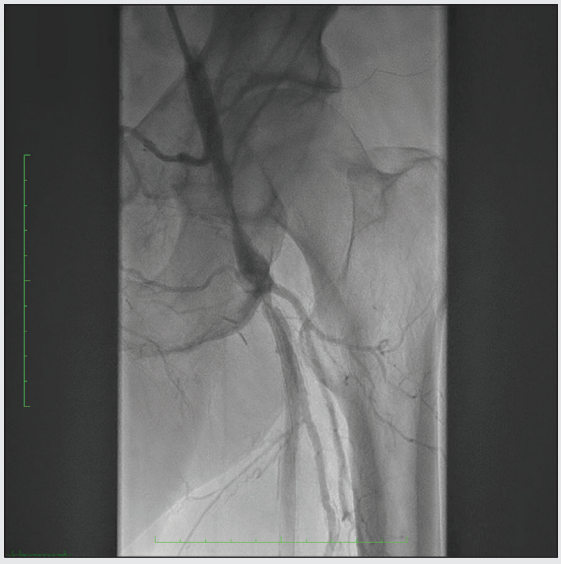


Figure 2. Angiogram of CFA postatherectomy.

Over the ViperWire™ peripheral guidewire, a 2 mm max crown Diamondback 360® orbital atherectomy system (Abbott) was introduced and two passes were made at 60,000 and 90,000 rpm to debulk the stenosis (Figure 2). After the two passes, a 6 X 100 mm Jade® PTA balloon catheter (Abbott, manufactured by OrbusNeich) was introduced to resolve residual stenosis in the CFA. After percutaneous transluminal angioplasty, a final angiogram was obtained, revealing full restoration of flow through the CFA with two-vessel runoff down to the foot with no embolization (Figure 3).

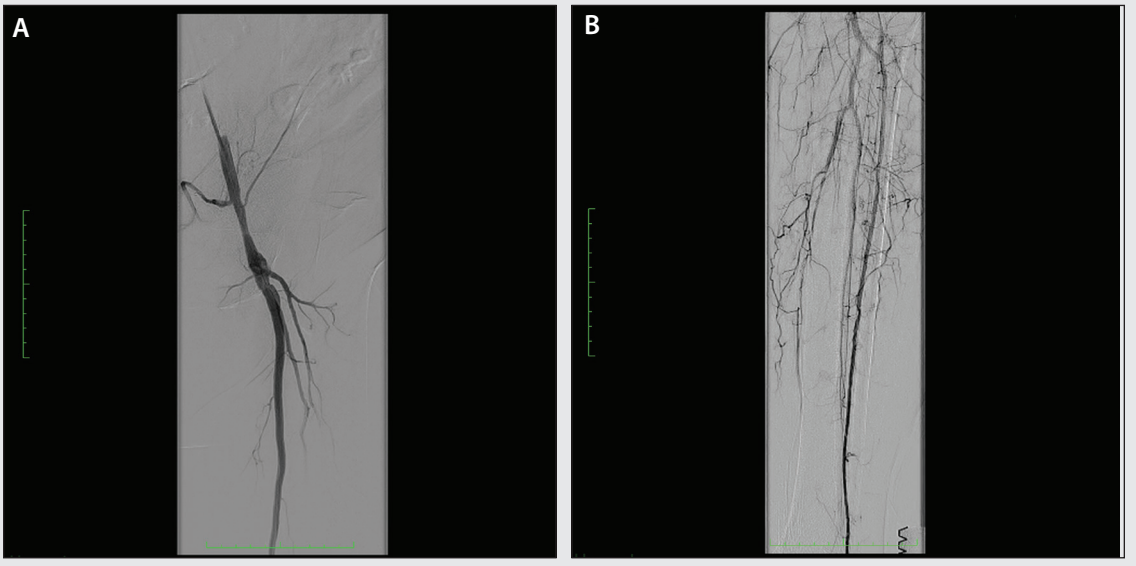


Figure 3. Final angiogram showing a patent CFA (A) and runoff to the distal vasculature with no embolization (B).

POST-PROCEDURE OUTCOME

The patient was discharged 90 minutes after the intervention. The patient's wound was healed at 2-week follow-up. The Sublime™ Microcatheter facilitated an effective true lumen crossing of the stenotic lesion, thereby allowing for further use of other interventional equipment to successfully complete the case. ■

Surmodics™ Pounce™ Thrombectomy System

INDICATION FOR USE/INTENDED USE
The Pounce™ Thrombectomy System is intended for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature. The Pounce™ Thrombectomy System is indicated for use in vessels ranging from 3.5 mm to 6 mm in diameter.

CONTRAINDICATIONS
- The device is not intended for venous applications.
- The device is not intended for peripheral vasculature dilatation.
- The device is not for coronary or neurovascular use.
- The device is contraindicated for use in patients who cannot receive recommended intravenous anticoagulant therapy.
- The safety and effectiveness of the device has not been established in pediatric patients (<18 years of age).
- The device is not intended to be deployed in vessels with previously implanted devices.

Surmodics™ Pounce™ LP Thrombectomy System

INDICATION FOR USE/INTENDED USE
The Pounce™ Thrombectomy System is intended for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature. The Pounce™ LP Thrombectomy System is indicated for use in vessels ranging from 2 mm to 4 mm in diameter.

CONTRAINDICATIONS
- The device is not intended for venous applications.
- The device is not intended for peripheral vasculature dilatation.
- The device is not for coronary or neurovascular use.
- The device is contraindicated for use in patients who cannot receive recommended intravenous anticoagulant therapy.
- The safety and effectiveness of the device has not been established in pediatric patients (<18 years of age).
- The device is not intended to be deployed in vessels with previously implanted devices.

The opinions, clinical and otherwise, presented here are informational only. The opinions are those of the presenter only and do not necessarily reflect the views of Surmodics. Results discussed from use of Surmodics or other products may not be predictive of all patients and may vary depending on differing patient characteristics.

Sublime™ Radial Access Guide Sheath

INDICATIONS FOR USE
The Guide Sheath is intended to introduce therapeutic or diagnostic devices into the vasculature, excluding the coronary and neurovasculature.

CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician. Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

Sublime™ Radial Access .014 and .018 RX PTA Dilatation Catheters

INDICATIONS FOR USE
The Sublime™ Radial Access .014 and .018 RX PTA Dilatation Catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) dilation of peripheral vasculature stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

CONTRAINDICATIONS
The Sublime™ Radial Access .014 and .018 RX PTA Dilatation Catheters are contraindicated for use in the coronary arteries and the neurovasculature.

CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician. Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

Sublime™ .014, .018, and .035 Microcatheters

INDICATIONS FOR USE
The Sublime™ Microcatheter is intended to access the peripheral vasculature in order to facilitate the placement and/or the exchange of guidewires. The Sublime™ Microcatheter is also intended to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

CAUTION: Federal (US) law restricts these devices to sale by or on the order of a physician. Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

The opinions, clinical and otherwise, presented here are informational only. The opinions are those of the presenter only and do not necessarily reflect the views of Surmodics. Results discussed from use of Surmodics or other products may not be predictive of all patients and may vary depending on differing patient characteristics.

POUNCE™
Venous
Thrombectomy

Chews wisely

The dual-action **Pounce™ Venous Thrombectomy System** collects, chews up, and removes clot in peripheral veins 6–16mm in diameter.

10 Fr
Pounce™ Venous Thrombectomy System

Captures wall-adherent clot while macerating and removing soft clot with an inner screw. The adaptable basket can be collapsed in untargeted segments.

12 Fr
Pounce™ Sheath

Compatible with the Pounce™ Venous Thrombectomy System

Indications for use: The Pounce™ Sheath is intended to introduce therapeutic or diagnostic devices into the vasculature.

Grab, Go, Restore Flow

Chews wisely at pouncevenous.com

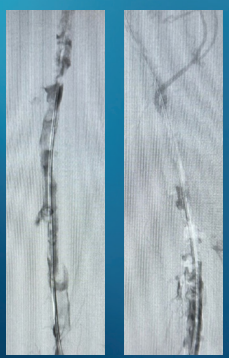
Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

CASE REPORT

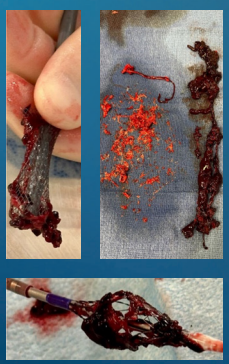
Removal of extensive mixed-morphology clot

65-year-old male with right leg swelling. Imaging revealed an extensive clot burden resulting from ~90% stenosis in the iliac vein. The Pounce™ Sheath (12 Fr) was used with the Pounce™ Venous Thrombectomy System to restore flow in ≈25 minutes.

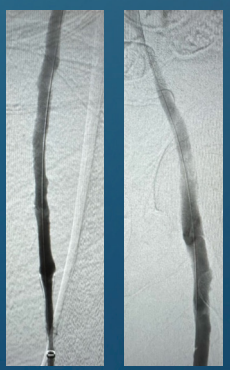
Mickey Graphia, MD*
Vascular Surgeon
Baton Rouge General
Baton Rouge, Louisiana



Initial Venogram revealed extensive clot from popliteal (above left) into external iliac vein (above right).



Clot Removal: mixed-morphology clot.

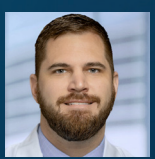


Final Venogram confirmed restoration of blood flow from popliteal (above left) through external iliac vein (above right).

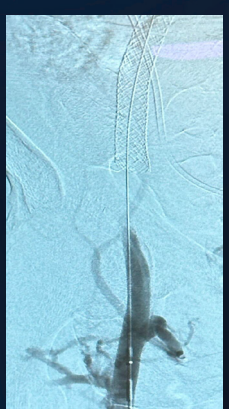
CASE REPORT

Removal of in-stent thrombus in iliac vein

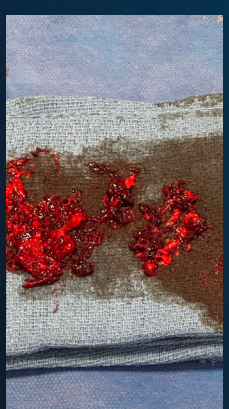
37-year-old female with right leg swelling. Imaging confirmed occluded stent in right iliac vein. Via popliteal access and 10 Fr introducer, Pounce™ Venous system removed mixed-morphology clot with 3 device passes in 20 minutes using collapsible basket and extraction screw.



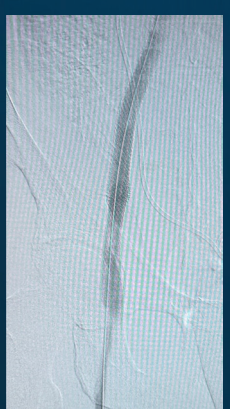
Garold Motes, MD*
Vascular Surgeon
Houston Methodist Hospital
Houston, Texas



Initial Venogram revealed occlusive clot within previously placed iliac venous stent.



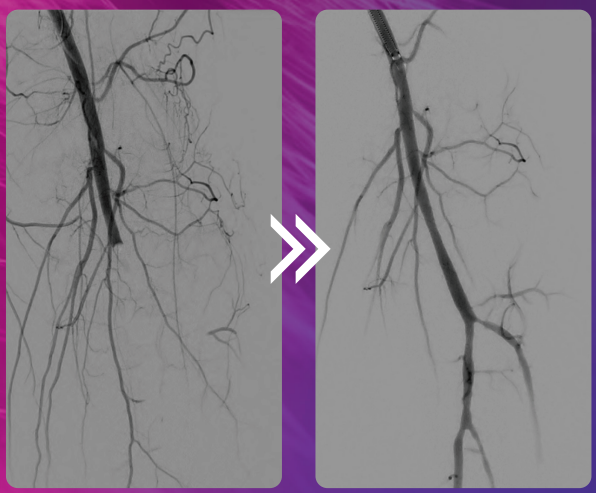
Clot Removal: mixed-morphology in-stent thrombus.



Final Venogram confirmed restoration of blood flow through stent without need for venoplasty.

*Not a consultant for Surmodics

Pounce™ Thrombectomy LP



Below-the-knee arteries before (left) and after (right) treatment with the **Pounce™ LP Thrombectomy System**

Capture tibial clot– *on the spot.*

NEW! The **Pounce™ LP Thrombectomy System** is designed to remove peripheral arterial clot in vessels 2–4mm in diameter.

JOIN THE HUNT
Schedule a product demonstration at pouncesystem.com/jointhehunt

Caution: Federal (US) law restricts this device to sale by or on the order of a physician. Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

@Surmodics **Surmodics, Inc.** **@Surmodics**

SURMODICS