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Endovascular TODAY

DISRUPTING PERIPHERAL ARTERIAL THROMBECTOMY

The Impact of the **Pounce™ Thrombectomy System:** A Multispecialty Perspective

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Disrupting Traditional Approaches to ALI With the Pounce™ Thrombectomy System

A conversation with Dr. Dean Ferrera.

Dr. Dean Ferrera, an interventional cardiologist with Community Hospital in Munster, Indiana, works with a close-knit team of surgeons, interventionalists, podiatrists, and nurses to treat acute and critical limb ischemia (CLI) patients at their 500-bed facility. The team has adopted an endovascular-first approach to ischemia, with surgeons on consult as needed for complex cases. We spoke with Dr. Ferrera about his approach to tackling emergent arterial occlusions.

Can you describe the patient journey for limb ischemia patients at Community Hospital?

Our interventional cardiologists generally provide endovascular support for limb ischemia cases. Often it will begin with a call from the emergency department physician, who will assess the patient and make the initial diagnosis with imaging. If they call me with suspected ALI (acute limb ischemia), I will plan for either a CT scan or a duplex ultrasound study. If the patient has a high degree of renal insufficiency and we don't want to expose them to contrast, we can get a STAT (short turnaround time) arterial duplex ultrasound. If they don't, and there's high probability for arterial occlusion, a CT scan is usually the first step.

At that point, the patient's care typically is endorsed to interventional cardiology and whoever is on call for cardiovascular surgery. If it is a true ALI case with high risk of fasciotomies, we will want our surgeons involved right away. If we feel that it's reasonable to proceed with an endovascular intervention, we'll bring in our cath lab team and handle those patients emergently, either during daytime hours or at night.

What has been your approach to endovascular treatment?

The traditional method for us was to see if we could cross with wire and catheter techniques, find an area of vessel patency, and treat with thrombolysis catheters. We would use either a simple Cragg-McNamara™ micro therapeutics infusion catheter (Medtronic) or an Ekos™ endovascular system (Boston Scientific Corporation) and park the patient in the intensive care unit (ICU) overnight. We would then follow them and make a plan of care with the surgeons. Often, we would bring the patient back after they'd been treated with lytics, take a look, and decide what else needs to be done from an endovascular or surgical approach. We've also used aspiration and continue to use it for some niche cases.

> "The Pounce™ System has been disruptive. With this device in the product portfolio, I now have the ability to remove mixed-morphology clot rapidly in one session."

Has the Pounce™ Thrombectomy System (Surmodics, Inc.) changed your traditional approach?

The Pounce™ System has been disruptive. With this device in the product portfolio, I now have the ability to remove mixed-morphology clot rapidly in one session. I can get out a large thrombus burden with a relatively easy technique. One or two pulls goes a long way. Typically, I can obtain better perfusion before even leaving the cath lab.

As an interventionalist, that's very satisfying. You want to roll in, get it done, and walk out feeling that you've taken care of the problem. When you put thrombolysis catheters into play, you know there's going to be a time lag before seeing some improvement, and older thrombus doesn't always resolve with lytic therapy. You're also worried about the added risks of bleeding. For me, lytics have now become more or less the bailout option if nothing else is working. The Pounce™ System is becoming my default option for initial treatment.

"The Pounce™ System is becoming my default option for initial treatment."

What attributes do you see in the Pounce™ System?

I like its ability to treat different thrombus morphologies—pure thrombus and embolic debris—and I like its deliverability. I also think it's relatively atraumatic—I've rarely seen it cause any problems or even that much vasospasm, nothing too off-putting. And it can treat multiple vessel segments, which is great. It doesn't require a tiered approach, scaling down from a larger to a smaller device. As long as the vessel size is acceptable and you're on indication, you can use it. I also find I can get results fairly quickly. Once again, a couple of passes, or pulls, can go a long way.

Another thing that's really nice is that you're not using other therapies like lytics or straight aspiration that cause blood loss. Most endovascular procedures don't result in a high degree of blood loss, but bleeding is always a concern. In our experience, the Pounce™ System results in negligible blood loss. That's a value-added treatment.

Why have you scaled back your use of aspiration?

I think the aspiration devices can work fine, but again, some older thrombus structures don't always yield well to them. Most often, I will still need to put a lytic catheter down there to optimize results and hunt and peck with the aspiration catheter. Having something mechanical with the Pounce™ System, with the wall-apposing nitinol baskets, gives me the ability to get different shapes and volumes of thrombus extricated from the vessel with the immediacy of treatment I want. You can see a great angiogram and know that you've fixed the biggest part of the problem, or at least see the playing field clearly.

How do you select patients for the Pounce™ System?

As long as I feel comfortable with 7 Fr access for the patient I'm trying to treat—in other words, that the vessel size is appropriate

"Reducing the need to put in lytic catheters that are going to need to be watched by other teams has been a blessing."

"As long as the vessel size is acceptable and you're on indication, you can use it. I also find I can get results fairly quickly. Once again, a couple of passes, or pulls, can go a long way."

for the device—the Pounce™ System is going to be my first-pull device. In ALI cases, we've had success with the device when we've immediately identified a vessel with substantive occlusion that we can cross pretty easily. Then we go ahead and provide treatment on the spot. We'll reassess after that. If there's good flow, we'll manage the rest endovascularly or simply allow the patient to recover on heparin until we're ready to discharge them.

Beyond ALI, I've used the Pounce™ System in patients that have had recently closed SFAs (superficial femoral arteries). These patients may be battling CLI and they are not healing. We may do an interval assessment and realize that they've had reocclusion of a vessel. In those cases, I'm extricating thrombus, then I can see what I have left to treat. That has been a benefit.

Do you see value for the Pounce™ System from the hospital's perspective?

No question. Reducing the need to put in lytic catheters that are going to need to be watched by other teams has been a blessing. Having something like the Pounce™ System on the table, once you get a sense of the prep, allows the case to be more fluid and conclusive, which makes turnover to the next patient easier. You don't have to worry about that patient coming back to the lab for a repeat angiogram because they've been on lytics, which saves time and caseload in the cath lab. Saving a trip to the cath lab—as well as reducing blood loss, and saving a stay in the ICU—all of that is value added in procedural-based management. ■

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Disclosures: Consultant to AngioDynamics, Medtronic, Cardiovascular Systems, Inc., Shockwave Medical, and Surmodics.

CASE REPORT

Successful Treatment of Infrapopliteal Thromboembolic Arterial Occlusion With the Pounce™ Thrombectomy System

By Dean Ferrera, DO, FACC, FSCAI

Patient Presentation

A 75-year-old man presented to the hospital with pain and paresthesia of his right foot. Symptoms started 1 day prior to his arrival at the hospital. Evaluation in the emergency department led to the diagnosis of new-onset atrial fibrillation with evidence of thromboembolism to the right lower extremity by duplex ultrasonography. He was immediately started on metoprolol, aspirin, and heparin and was brought to the cath lab for angiography.

Diagnostic Findings

Micropuncture access was achieved at the right common femoral artery, and a 5 Fr diagnostic sheath and a V-18™ ControlWire™ guidewire (Boston Scientific Corporation) were placed ipsilateral down the right leg. The initial angiogram showed a 100% thrombotic occlusion of multiple below-the-knee vessels, including the right popliteal artery at the P1 segment, the right tibioperoneal trunk (TPT) with reconstitution via the proximal collaterals, the right proximal posterior tibial (PT) artery with visible reconstitution further down the vessel, the right peroneal artery, and the right anterior tibial (AT) artery (Figure 1). The plan was to remove visible thrombus and revascularize the below-the-knee vessels utilizing a thrombectomy and balloon angioplasty combination strategy.

Treatment

The 5 Fr diagnostic sheath was exchanged for a 7 Fr, 45 cm Pinnacle® Destination® guiding sheath (Terumo Interventional Systems). A .035 TrailBlazer™ support catheter (Medtronic) was advanced over the wire to the right peroneal artery under fluoroscopy. The Pounce™ Thrombectomy System was prepared. To start, the baskets were deployed mid AT, the funnel catheter was deployed over the basket wire, and the funnel was parked in the proximal AT.

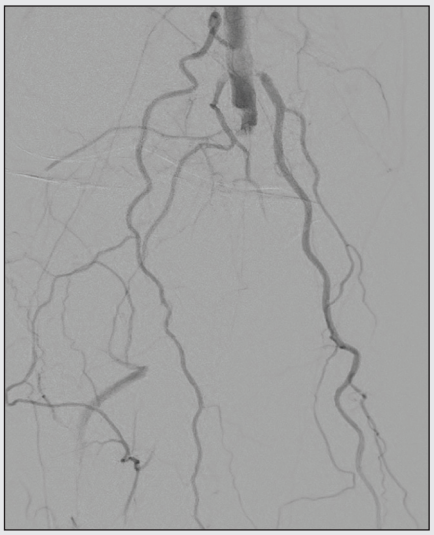

Figure 1. Preprocedure angiogram showing 100% thrombotic occlusion of popliteal, TPT, peroneal, PT, and AT arteries.

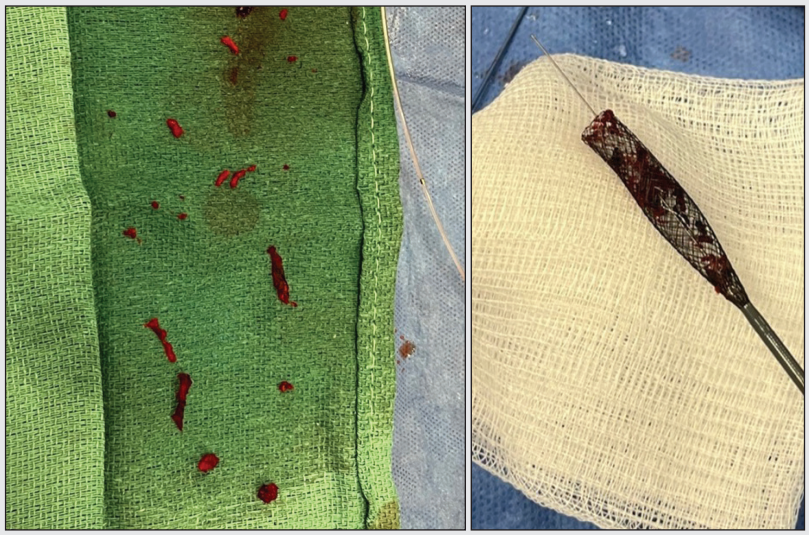

Figure 2. Thrombus removed after multiple passes with the Pounce™ Thrombectomy System.

After pullback of the basket wire into the funnel, the system was externalized through the 7 Fr sheath, cleaned, and then reinserted for a second pass. For the second pass, the basket wire was placed in the proximal PT, and the funnel was deployed in the proximal popliteal artery. After successful basket wire retraction through the PT and into the funnel, the system was removed through the 7 Fr sheath and cleaned once again. A 3.5 X 3.0 mm tapered PTA balloon was used in the PT to clean up some residual stenosis. After the PTA balloon was removed, the Pounce™ Thrombectomy System was deployed again for a third pass in the peroneal artery.

The basket wire was placed in the proximal peroneal artery, and the funnel was placed in the proximal popliteal artery. The baskets were successfully retracted back into the funnel, removing the thrombus. The Pounce™ System was externalized through the 7 Fr sheath. All three passes resulted in successful flow restoration and complete thrombus removal (Figure 2) from all three below-the-knee vessels (Figure 3).

Conclusion

The patient was monitored for 2 days post-procedure and discharged once the atrial fibrillation was controlled. The patient was put on Xarelto® (Janssen) for the atrial fibrillation diagnosis. Post-procedure ankle-brachial index was 1.1 on the right-side foot with normal Doppler velocities.

The Pounce™ System allows for rapid resolution of thrombotic debris. In this case example of a patient suffering from an acute thromboembolic event related to atrial fibrillation, restoration of inline flow of the infrapopliteal vessels was quickly achieved without the need for thrombolysis or open surgical intervention. In appropriately sized tibioperoneal vessels, the Pounce™ System can be used safely and efficiently for direct endovascular intervention. ■

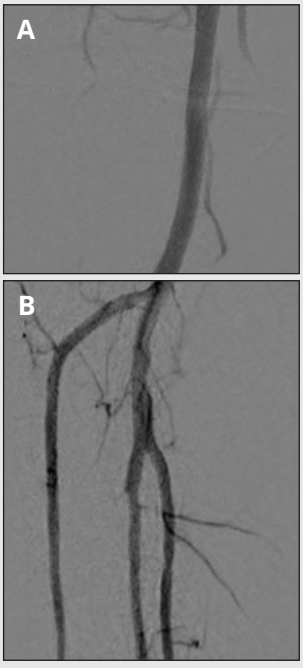

Figure 3. Patent popliteal (A), TPT, and tibial (B) arteries after Pounce™ Thrombectomy System passes.

Tackling Adherent Thrombus and Focal Emboli With the Pounce™ System

A conservation with Dr. Eric Scott.

Vascular surgeon Eric Scott, MD, works in a physician-owned, multispecialty group in Des Moines, Iowa, with a primary focus on treatment of arterial disease. An avid researcher, Dr. Scott has contributed to several papers on new endovascular therapies and is a frequent presenter at global conferences. He currently splits his arterial practice between an office-based lab setting and a tertiary hospital. We spoke with Dr. Scott about how he treats limb ischemia and his experience using the Pounce™ Thrombectomy System (Surmodics, Inc.).

Can you give us a snapshot of your acute limb ischemia (ALI) practice and the patient population you serve?

Our group covers multiple hospitals in Des Moines, including a tertiary care hospital that is also a level 1 trauma center, so we routinely encounter patients experiencing acute ischemic events. These patients present with all forms of ALI. Sometimes it's a 90-year-old with atrial fibrillation and a common femoral artery (CFA) or popliteal artery embolus. Sometimes it's a 60-year-old with a superficial femoral artery (SFA) stent thrombosis who presents with sudden symptoms of limb ischemia. And other nights, it's a surprise 30-year-old who has no sensory or motor function and arterial injury due to blunt or penetrating trauma to the leg. The presentations can be really diverse and require a full range of approaches.

What challenges does your health care system face in expediting care for these patients?

ALI is not a new phenomenon and most every emergency department in the region can recognize it, but most small-to-medium–size hospitals lack vascular call coverage or therapeutic amenities to rapidly treat it. Vascular emergencies like this are typically transferred from outlying communities to one of two hospitals in the city that are equipped to quickly and effectively provide therapy. Unfortunately, this can sometimes result in considerable delay in revascularization. One of the critical, lingering side effects of COVID is that emergency departments are often understaffed and overwhelmed. Just getting the right diagnosis of ALI sometimes takes too long. So, for many patients, time is running out when they finally arrive, and expedient therapies are badly needed.

> "The Pounce™ System is capable of removing more adherent, subacute thrombus from the vessel wall, which is something I've struggled to do with other devices."

How else did COVID impact care of ALI patients in your region and hospital?

Even before COVID hit in early 2020, we were beginning to realize that there were unmet needs when it came to dealing with thrombus in the periphery, particularly on the arterial side. Open surgical options are largely limited to Fogarty balloon thrombectomy, and this is not always effective, particularly when thrombus is subacute or small tibiopedal arteries are involved. In addition, there were fewer catheter-based options for dealing with thrombus in an endovascular fashion compared with now.

Then COVID hit. We saw patients coming in with limb- and even life-threatening thrombus in arterial beds not usually affected and in quantities typically unseen. Some of those cases made it clear to me that the thrombus burden exceeded all our capabilities—open or endovascular—to effectively deal with it. Thankfully, that period has passed, and we aren't seeing many patients present in that fashion anymore. But those challenges prompted many to seek out and learn the latest in percutaneous mechanical

thrombectomy (PMT) devices. There are now a host of PMT devices that can mechanically break up thrombus, aspirate it, or capture and extrude it. This has really opened the door to rapid, minimally invasive revascularization. My use of open thrombectomy, as well as catheter-directed thrombolysis (CDT), has dropped significantly.

How do you select patients for open surgery or catheter-directed treatments?

In my practice, open surgical methods are still utilized for most cases of aortoiliac or common femoral thromboembolization, simply due to the caliber of these vessels. Surgical exposure of the CFA can be accomplished quickly and under local anesthesia if needed and allows for rapid Fogarty balloon-based thrombectomy of the iliac arteries, the CFA, and even the femoropopliteal segment. Open surgical interventions are also often indicated for arterial trauma resulting in ALI. In particular, penetrating trauma often necessitates open surgical arterial repair or bypass, in addition to requiring that local thrombus formation be addressed.

Having said that, for most of my patients with thrombus below the inguinal ligament, endovascular therapies now provide sufficient thrombus-removing capability to avoid an open surgical approach. Patients presenting with class 1 ALI often have the greatest breadth of treatment options, as time is on their side. These patients can be effectively treated with CDT if there is diffuse thrombosis to treat, and I find this approach especially useful if there are multiple tibial arteries involved or if thrombus extends into the pedal arteries. Of course, not all these patients are ideal candidates for thrombolytic use.

However, I think patients presenting with class 2a and 2b ischemia benefit the most from PMT devices. These patients don't have the time to wait for CDT to work and need more urgent revascularization. As more and more different devices become available, each with a different mechanism of action, I think our success using percutaneous approaches will continue to expand.

What have you found separates the Pounce™ System from other arterial mechanical thrombectomy devices used for peripheral interventions?

Compared with other thrombectomy devices in the arterial peripheral space, the Pounce™ System has a different mechanism of action in that it has two nitinol baskets that can actively dislodge adherent thrombus from the vessel wall as the device is withdrawn across the thrombus. It's also large enough to effectively treat the entire circumference of vessel walls within its treatment range (3.5-6 mm) with a single pull-through, unlike angled aspiration catheters, which can require the correct angle of approach to engage focal, adherent thrombus.

In your experience, what are ideal applications for the Pounce™ System?

I think this device is particularly well-suited to treat emboli anywhere from the SFA and profunda femoris to the tibial arteries. (The Pounce™ System is intended for use in vessels 3.5-6 mm in diameter.) Our group has also had success using the device in cases of upper extremity thromboembolization and even acute emboli to the superior mesenteric artery. I find that the Pounce™ System is capable of removing more adherent, subacute thrombus from the vessel wall, which is something I've struggled to do with other devices.

How has use of the Pounce™ System affected your practice patterns?

Having the Pounce™ device on the shelf has made me more confident in tackling challenging infrainguinal ALI cases. For focal emboli, in my experience, I've often been successful removing material on a single pull-back, and the accompanying funnel does an excellent job preventing distal embolization. For cases of extensive femoropopliteal or tibioperoneal thrombosis, I may begin with CDT or an aspiration device that can clear an extensive quantity of thrombus, but I know the Pounce™ device is ready to clear adherent, residual thrombus and get into distal segments of the arterial tree to finish the job.

Where do you see the value of the Pounce™ System from a hospital's perspective?

One of the objectives of PMT is to reduce the risk of major bleeding resulting from the use of thrombolysis and to provide faster, more cost-effective care by avoiding use of the intensive care unit. Over the past 10 years, we've seen several different PMT devices come to market using aspiration as the central mechanism of action. But the Pounce™ System performs differently. The dual baskets for capturing material make this device an excellent tool for precise, targeted embolectomy under direct fluoroscopic visualization. The Pounce™ System is great for patients and saves hospital resources at the same time. ■

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Disclosures: Research for Abbott, Bard, Endologix, LimFlow; consultant to FastWave, Medtronic; speaker for Medtronic.

CASE REPORT

Successful Removal of an SMA Embolus With the Pounce™ Thrombectomy System

By Nate Mohr, MD, and Dennis Fry, MD

Patient Presentation

A 71-year-old man presented to the emergency department (ED) complaining of ongoing abdominal pain. Two days prior, he had visited the ED for a CT scan complaining of acute onset of abdominal pain in the morning. The CT scan was read as diverticulitis, and the patient was sent home on antibiotics. However, his symptoms continued to worsen, marked by increased bloating, abdominal distention, chills, and diarrhea, compelling him to seek urgent medical attention again.

Diagnostic Findings

A follow-up CT scan showed a focal occlusion/thrombosis of the mid-superior mesenteric artery (SMA) with distal reconstitution as well as some thick-walled loops of small bowel without pneumatosis or free air. Right common femoral artery (CFA) access was obtained, and an initial angiography was performed. The angiogram showed that the proximal main trunk of the SMA was open, while the distal main trunk of the SMA prior to branching showed embolic debris (Figure 1).

Treatment

The patient was taken to the angiography suite, placed in the supine position, prepped, and draped in the normal sterile fashion. The right CFA was accessed, and a 4 Fr sheath was placed. A right diagnostic catheter was placed into the aorta and was used to cannulate the SMA. Angiography confirmed occlusion in the distal SMA. A Rosen guidewire (Cook Medical) was advanced into the SMA. The 4 Fr sheath was swapped for an 8 Fr sheath. An additional 3,000 units of heparin were given to the patient. Once the 8 Fr sheath was in the SMA, a 7 Fr aspiration catheter was advanced into the SMA and aspiration thrombectomy was performed. Following a few passes of the aspiration catheter, follow-up angiography showed a channel into some branches of the SMA; however, the embolic debris was still occluding the SMA (Figure 2). The physician withdrew the aspiration catheter and advanced the Pounce™ Thrombectomy System into the SMA. The basket wire was deployed in the distal SMA, the funnel catheter was deployed in the proximal SMA, and an initial pass of the system was performed.

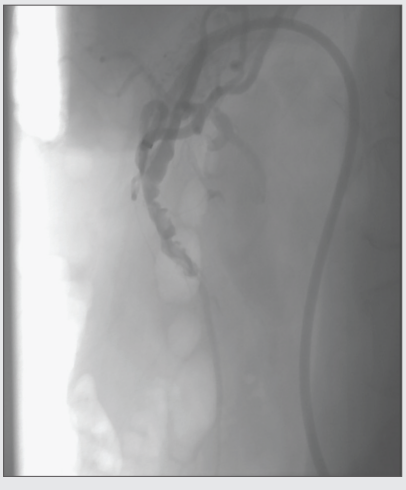

Figure 1. Initial angiography demonstrating an occlusion at the level of the mid-SMA.

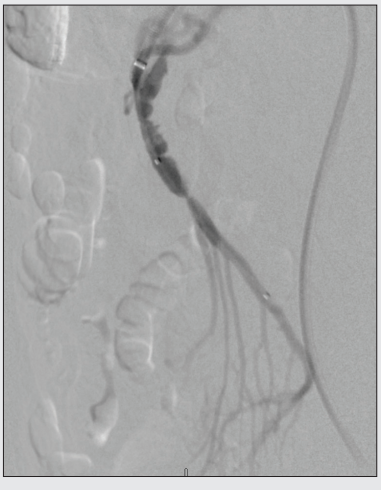

Figure 2. Angiography after aspiration catheter passes.

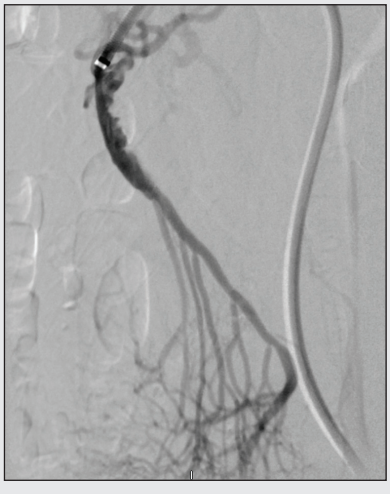

Figure 3. Angiography after Pounce™ System passes.

Repeat angiography showed flow into the mesenteric segments (Figure 3), with the patient immediately noticing relief of abdominal pain. Angiography showed flow into the mesenteric segments with minimal spasm. Additional SMA branches were accessed using suction thrombectomy to restore as much flow as possible in the small bowel mesentery. A further angiogram with nitroglycerin showed resolution of spasm as well as flow and perfusion throughout the SMA. At this point, with the patient's pain clinically resolved and the patient becoming hemodynamically stable, the case was concluded, and the access site was closed.

Post-Procedure Outcome

The patient was taken to the intensive care unit (ICU) and maintained on a heparin drip. The patient did well in the ICU and was transferred to the floor, with continued treatment for diverticulitis. The patient was able to be discharged after tolerating a diet and having regular bowel movements with no concerns for mesenteric ischemia.

The physician observed that the Pounce™ Thrombectomy System helped to remove the embolic debris in the mid-SMA immediately and without recourse to thrombolytics, helping to resolve the patient's pain. ■

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Disclosures: None.

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Disclosures: None.

CASE REPORT

Successful Removal of a Popliteal Embolus Using the Pounce™ Thrombectomy System Following Attempted Aspiration Thrombectomy

By Brett Voigt, DO

Patient Presentation

A 73-year-old male presented to the clinic with a 2-day history of left calf pain and numbness in his foot. His history included smoking and hypertension but no known peripheral artery disease and no medication.

Diagnostic Findings

Upon the initial exam, the patient had absent left popliteal and pedal pulses and cyanosis of his left digits. An initial venous duplex image was obtained but was negative for deep vein thrombosis. A subsequent angiogram was performed and showed an embolus in the popliteal artery (Figure 1). The patient was prepped for a thrombectomy intervention.

Treatment

The access sheath was upsized to an 8 Fr procedural sheath. An aspiration thrombectomy system was prepped and deployed to the area of the embolus within the popliteal artery. Unfortunately, after a few passes, the aspiration system failed to clear sufficient clot to improve flow to the patient's left foot. At that point, the Pounce™ Thrombectomy System was prepped and brought in to aid in removing the embolus. The physician's guidewire passed easily through the occlusion and landed in the anterior tibial (AT) artery. The Pounce™ System baskets were deployed in the mid-AT artery. The Pounce™ System funnel catheter was delivered over the Pounce™ System basket wire, and the funnel was deployed in the popliteal artery. The baskets were retrieved into the funnel, the whole system was locked, and the Pounce™ System was removed from the body, removing a moderate amount of clot (Figure 2). After further angiography, residual clot was also found in the posterior tibial (PT) artery. The physician then deployed the Pounce™ System again, with baskets in the mid-PT and the funnel in the popliteal artery. After a subsequent pass, the Pounce™ System was able to remove additional clot from the vasculature. A final angiogram revealed patent popliteal, AT, and PT segments (Figure 3).

Post-Procedure Outcome

The patient was discharged with an anticoagulation regimen with no immediate recurrences of thrombosis or

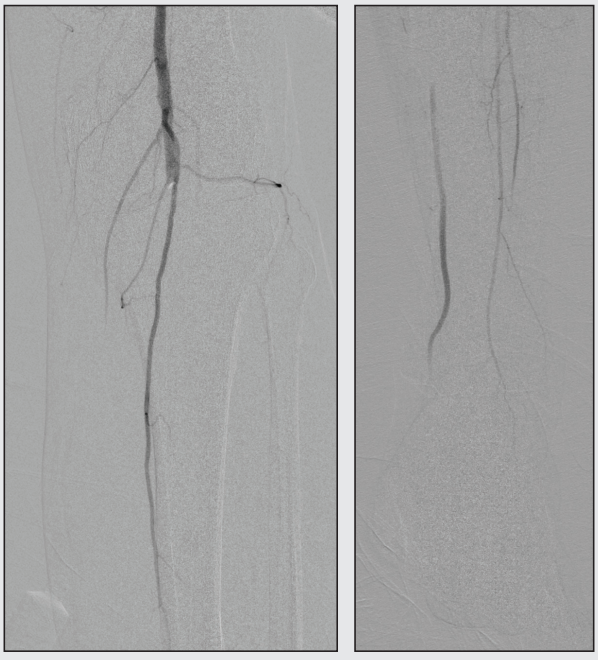

Figure 1. Initial angiogram demonstrating an occlusion of the popliteal artery (left) with distal reconstitution (right).

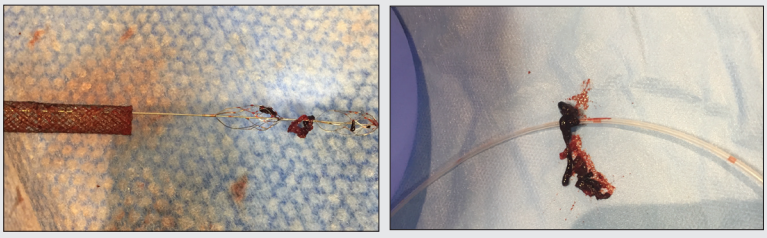

Figure 2. Clot removed during the Pounce™ Thrombectomy System passes. Used with permission from the author.

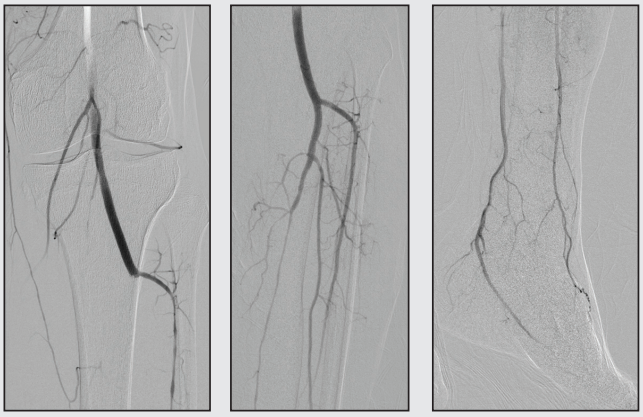

Figure 3. Final angiograms demonstrating patent popliteal, AT, and PT segments with reconstitution into the foot after Pounce™ Thrombectomy System passes.

need for secondary intervention. The 1-year duplex ultrasound continued to show a widely patent popliteal artery and tibioperoneal runoff. The Pounce™ Thrombectomy System was able to efficiently remove embolic debris where aspiration thrombectomy was unsuccessful. ■

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Disclosures: None.

Transitioning From Aspiration to the Pounce™ Thrombectomy System for ALI

A conversation with Dr. Vince Weaver.

Vascular surgeon Dr. Vince Weaver and his partners at the Vascular Specialty Center in Baton Rouge, Louisiana, collaborate with two tertiary hospitals and a community hospital to receive patients from throughout the state and parts of southern Mississippi. In addition to treating a large volume of patients with peripheral artery disease and acute limb ischemia (ALI), Dr. Weaver does a substantial amount of carotid, advanced aortic, endovascular aortic aneurysm, and venous work—as he says, "a little bit of everything." We spoke with Dr. Weaver about his approach to treating ALI and his use of the Pounce™ Thrombectomy System (Surmodics, Inc.) for rapid removal of acute and organized clots.

What is your general approach to treating ALI? Has it changed over time?

Yes, it definitely has changed. Years ago, when somebody came in with a cold leg, it may have seemed a little faster to bring the patient into the operating room and perform an open embolectomy or a bypass, depending on the severity of the ischemia or if the limb was truly threatened. Now, we've seen a change from open surgical revascularization to an endovascular-first approach.

Initially, the endo-first approach involved thrombolytics—you'd drop in an Ekos™ ultrasound-assisted thrombolytic catheter (Boston Scientific Corporation) or just a lytic catheter, drip them overnight with tPA (tissue plasminogen activator), bring them back the next day, and deal with what you had. Now, we're increasingly moving away from lytics and intensive care unit (ICU) stays and moving to mechanical devices.

Why did you transition from a lytic-first approach?

Even before the COVID pandemic, I saw advantages for mechanical thrombectomy in terms of ease of use and other benefits. But then COVID hit, and we saw an exponential rise in both arterial and venous clotting. Every day, someone was coming in with a massive DVT (deep vein thrombosis) or pulmonary embolism, and the number of ischemic limbs we treated went up tremendously. We just didn't have ICU or hospital beds, so we had to find a way to get patients revascularized without a hospital stay. In our practice, the volume of clotting cases still remains much higher than before the pandemic.

> "These days, it's very rare for me to use anything else besides the Pounce™ Thrombectomy System for mechanical thrombectomy."

In addition, the morphology of clots became more challenging with COVID. We tended to see a much more organized type of clot compared with before. The patient presentation would be acute, but it would almost seem as though the clot had been there for weeks. We continue to see very acute, fresh clot, but when we do these thrombectomies, we're encountering a lot of organized clots very early in the presentation.

The COVID pandemic had a severe impact on health care staffing nationwide. Did you witness that in your area?

Absolutely. You can't go to a hospital, surgery center, or even a doctor's office that hasn't been impacted by staffing availability. It's rampant. I'm on a lot of administrative boards in hospitals, and at every meeting we hear of nursing shortages and tech shortages. The question is, how do we get these

"In our practice, the volume of clotting cases still remains much higher than before the pandemic."

"Getting patients in and out without hospital stays has been key to keeping the whole system going."

employees and nurses back into the system? Getting patients in and out without hospital stays has been key to keeping the whole system going.

Can you summarize your ALI case mix today and how you select patients for various treatments?

These days, we use mechanical thrombectomy as our primary approach for well over half of our ALI cases, with primary lytics in about one-third of cases. We continue to use open surgical for a small subset of highly calcified cases, where I know that we're not going to be able to pass baskets and I don't think an Ekos™ catheter is going to do any good.

If ultrasound and CTA imaging indicate a significant amount of atherosclerotic disease—more of an acute-on-chronic situation—I may lean toward lytic therapy. In these cases, you may have a total thrombus occlusion within an atherosclerotic lesion. I will use lytics to recannulate the lesion. Then we may have to go back the next day and perform atherectomy, stent it, or do whatever it takes to keep it open and avoid bypass.

If I get in there and it all looks like soft thrombus, acute clot, then that's an easy mechanical thrombectomy. If we get into the angiogram and we're on the fence on which way we're going to go, I'll see how easily my wire can pass through the lesion. If the wire passes through easily, I'll definitely lean toward a mechanical approach. We have a very high success rate in these types of cases. If I have to really knuckle a wire and use support catheters to get through, I may just use lysis for those patients.

For mechanical thrombectomy, you've increasingly used the Pounce™ Thrombectomy System as your primary device. Can you explain how your use of mechanical thrombectomy has changed?

I've had access to just about all the arterial thrombectomy devices and have whittled them down. Our practice still has the AngioJet™ pharmacomechanical system (Boston Scientific Corporation), but I really don't use it anymore due to the use of tPA and the device's systemic effects (eg, renal impairment).[1] I used suction thrombectomy, the Indigo® aspiration system (Penumbra, Inc.) and QuickClear thrombectomy system (Philips), as my go-to devices up until about a year ago, when I started using the Pounce™ System.

Why did you make the switch?

The limitation I found with suction thrombectomy is that you could go in and take out a lot of fresh acute clot, but when you take your post-thrombectomy angiograms, you see that there's a lot of residual thrombus and organized stuff remaining. With the Pounce™ System, after one, maybe two passes, I've been able to remove, if not all, at least a significant amount of that more organized thrombus. I'm getting much more robust thrombectomy with the device, and my success rate has been much higher for the right patient. Beyond that, blood loss has been far lower for the Pounce™ System versus suction thrombectomy devices. These days, it's very rare for me to use anything else besides the Pounce™ Thrombectomy System for mechanical thrombectomy. ■

1. Acosta S, Karonen E, Eek F, Butt T. Short-term complications and outcomes in pharmaco-mechanical thrombolysis first and catheter-directed thrombolysis first in patients with acute lower limb ischemia. *Ann Vasc Surg*. 2023;94:253-262. doi: 10.1016/j.avsg.2023.02.018

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Disclosures: Consultant to Medtronic and Surmodics.

CASE REPORT

Successful Removal of Organized Thrombus With the Pounce™ Thrombectomy System After Attempted Pharmacomechanical Treatment

By Vince Weaver, MD

Patient Presentation

A 53-year-old man presented with 2-week onset of rest pain. Noninvasive studies suggested occlusive thrombus disease throughout the superficial femoral artery (SFA) and popliteal artery. The initial angiogram confirmed organized thrombus throughout the SFA and popliteal arteries (Figure 1).

Treatment

The initial procedural strategy was to drip tPA overnight. After 24-hour tPA treatment, the patient's foot appeared slightly improved and warmer to the touch; however, the follow-up angiogram did not indicate improvement of flow (Figure 2). It was decided that percutaneous mechanical thrombectomy with the Pounce™ Thrombectomy System should be attempted. For the first pass, the Pounce™ System baskets were deployed in the popliteal artery and the funnel catheter was deployed in the common femoral artery. The baskets were retrieved into the funnel and the Pounce™ System was withdrawn from the patient, successfully removing organized thrombotic material. Subsequent angiography showed thrombus at the tibioperoneal trunk (TPT) and an atherosclerotic lesion in the SFA (Figure 3). Another pass with the Pounce™ System was made at the TPT (Figure 4), followed by angioplasty at the TPT, resulting in tibial runoff to the foot (Figure 5). Attention was then directed to the lesion in the SFA, where atherectomy and angioplasty using a drug-coated balloon (DCB) were performed.

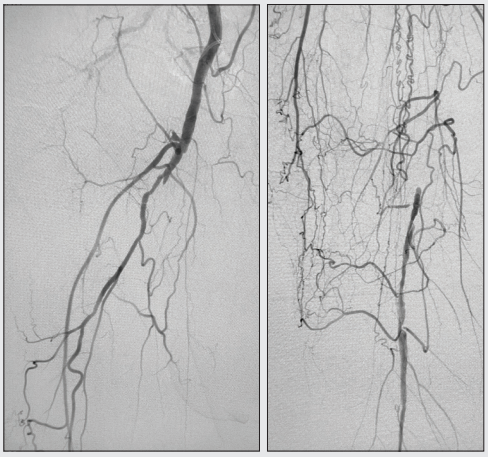


Figure 1. Initial angiogram.

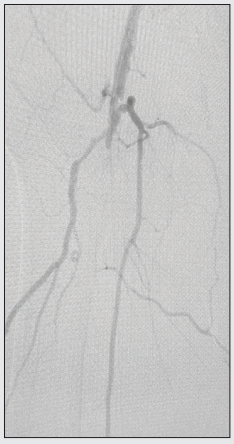


Figure 2. Angiogram after 24-hour pharmaco-mechanical treatment.

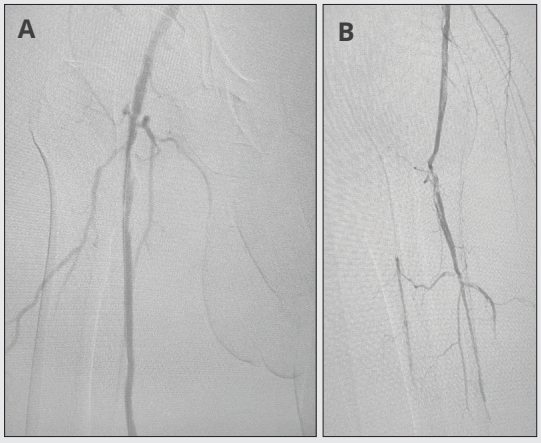


Figure 3. Angiography after single Pounce™ Thrombectomy System pass revealed residual atherosclerotic lesion at proximal SFA (A) and thrombus at the TPT (B).

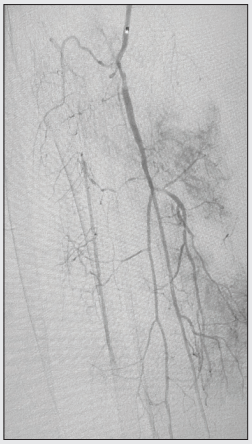


Figure 4. TPT after one pass with the Pounce™ Thrombectomy System.

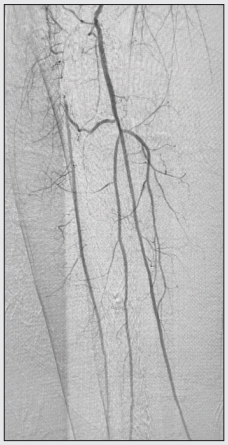


Figure 5. TPT after angioplasty.

Post-Procedure Outcome

The final angiogram (Figure 6) showed robust flow in the foot. The patient was discharged the same day as the Pounce™ Thrombectomy System procedure with a proper anticoagulation regimen. The physician noted that the Pounce™ System provided prompt clearance of organized thrombus to enable subsequent treatment of underlying atherosclerotic lesions. ■

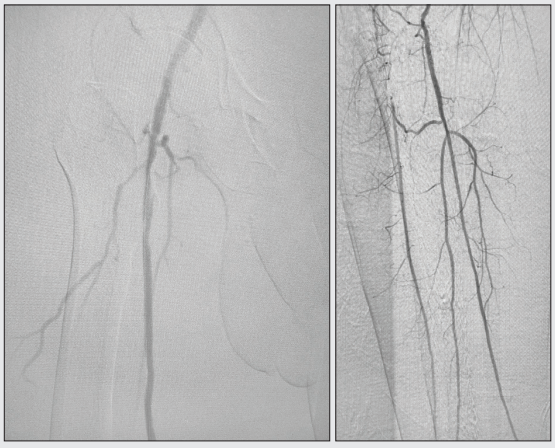
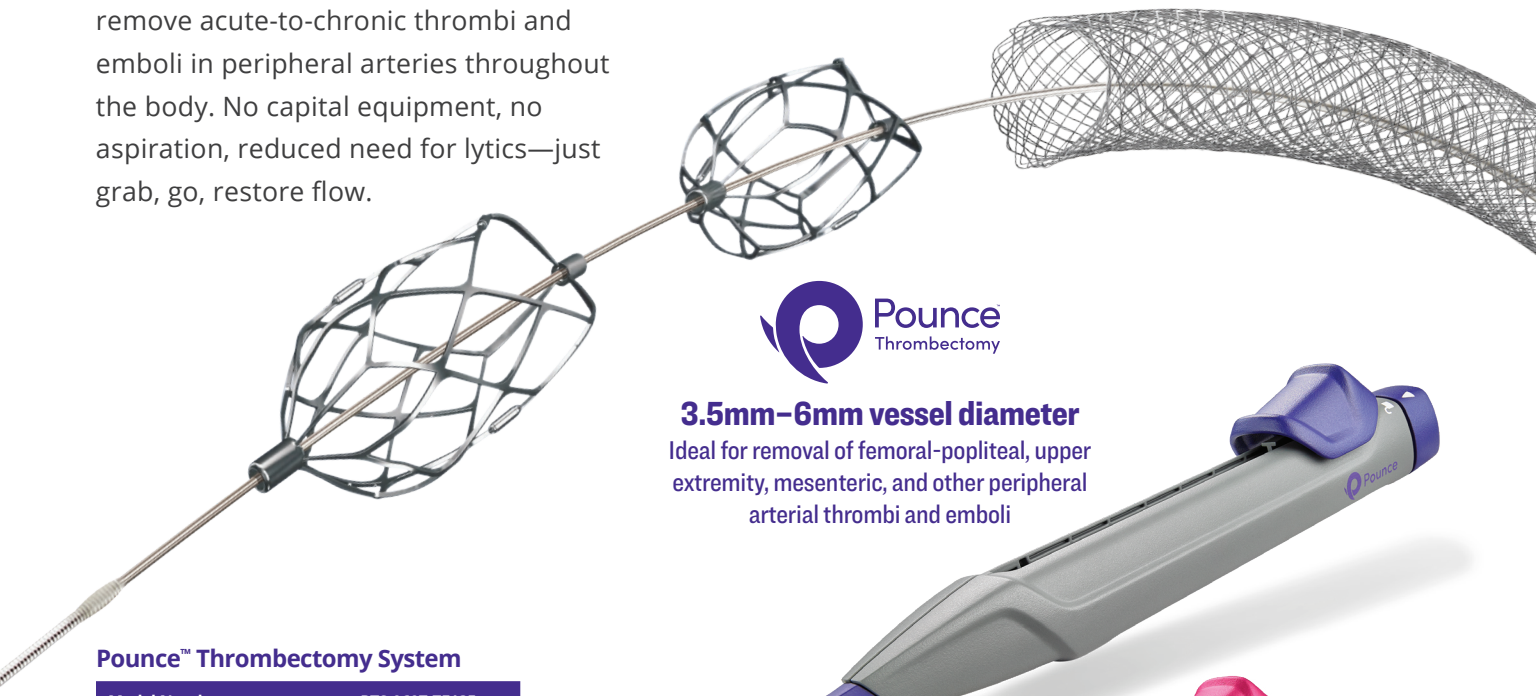


Figure 6. Final angiogram revealed robust flow to the foot.

Overview of the Pounce™ Thrombectomy System

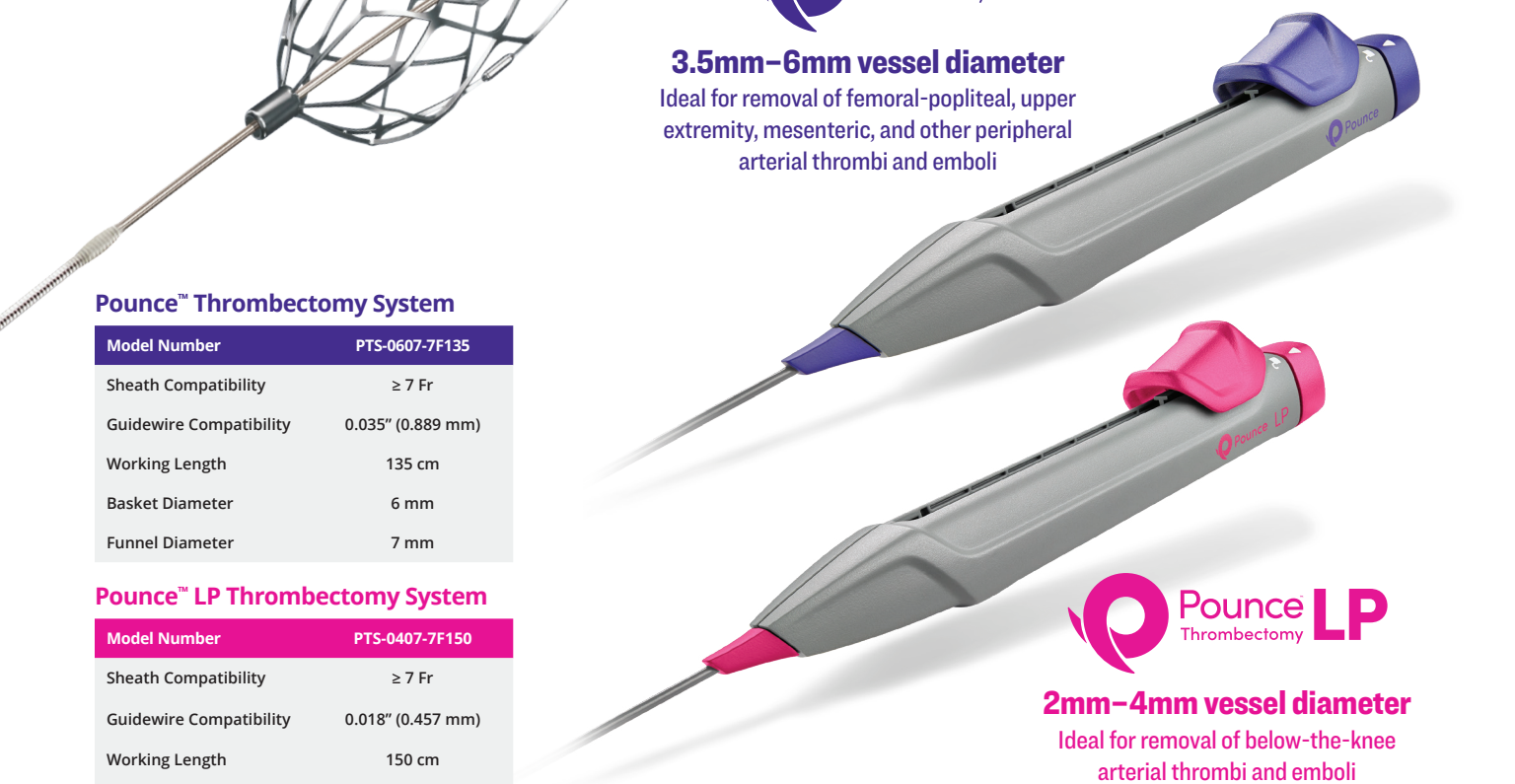
The Pounce™ System is designed to remove acute-to-chronic thrombi and emboli in peripheral arteries throughout the body. No capital equipment, no aspiration, reduced need for lytics—just grab, go, restore flow.



Pounce Thrombectomy

3.5mm–6mm vessel diameter

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



Pounce™ LP Thrombectomy

2mm–4mm vessel diameter

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

Pounce™ Thrombectomy System

Model Number	PTS-0607-7F135
Sheath Compatibility	≥ 7 Fr
Guidewire Compatibility	0.035" (0.889 mm)
Working Length	135 cm
Basket Diameter	6 mm
Funnel Diameter	7 mm

Pounce™ LP Thrombectomy System

Model Number	PTS-0407-7F150
Sheath Compatibility	≥ 7 Fr
Guidewire Compatibility	0.018" (0.457 mm)
Working Length	150 cm
Basket Diameter	4 mm
Funnel Diameter	7 mm

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.

Sponsored by SURMODICS

Expanding Single-Session ALI Thrombectomy at a High-Volume Center

A conversation with Dr. John Irish.

Interventional radiologist Dr. John Irish and his colleagues at Central Illinois Radiological Associates (CIRA) are the primary providers of acute limb salvage for the OSF St. Francis Medical Center in Peoria, Illinois. The tertiary care facility receives patients from a vast, largely rural catchment area whose radius reaches as far as Rockford, Illinois—135 miles north—and the Quad Cities of Illinois and Iowa, with occasional transfers from Missouri. Dr. Irish describes the severity and volume of limb ischemia cases at St. Francis Medical Center as "tremendous"—a situation exacerbated, he says, by the closing of rural hospitals in the region and a shortage of vascular surgeons in outlying areas. "There are quite a few folks that travel hours and hours" for care at the facility, he says. "Many of these patients just deal with their claudication until they throw a clot."

Over the past year, Dr. Irish has used the Pounce™ Thrombectomy System (Surmodics, Inc.) to help restore limb flow for a growing share of his acute limb ischemia (ALI) patients. We spoke with Dr. Irish about why and how he uses the Pounce™ System.

You've been using the Pounce™ Thrombectomy System for nearly 1 year. Where does it fit into your toolkit?

For me, the sweet spot for this device is a patient who comes in with pre-existing peripheral artery disease and has an acute-on-chronic thrombus in a relatively short segment. We see a lot of these patients. Their clots are typically not soft and fresh but have a chronic component. These are Rutherford class 2a or early 2b patients, often with atrial fibrillation (AFib) issues.

> "I've reduced my lysis volume significantly—I'd say by half or even more."

Using the Pounce™ System, we've had outstanding results removing emboli and getting improved flow down to the legs, often obviating the need for thrombolytic infusion and its associated risks and expense. If it's hyperacute thrombus, that's typically soft clot, and then we may change up the plan based on the total volume of thrombus. For a smaller volume of clot, we've had great results with the Pounce™ System, sometimes with aspiration for below-the-knee emboli. When the entire femoropopliteal segment is acutely occluded, these patients are often still getting overnight lysis.

Can you estimate how often you use the Pounce™ System in comparison with other approaches to ALI?

I would estimate we are using the Pounce™ System about 40% to 50% of the time as the first device off the shelf. At this point, surgical declotting has become fairly uncommon—maybe 5% to 10% of our cases. We are getting the first call for most of these cases. We have a great relationship with our vascular surgery partners. I was up most of the prior night for a ruptured abdominal aortic aneurysm that we repaired in combination. It's a great collaborative environment; we can work without the turf issues you see elsewhere.

Other than that, we still use lysis as the primary approach for around 40% to 50% of cases. The rest I'm trying to do in a

"If you can avoid using lysis and take care of the clot in a single session, that's a tremendous advantage."

single session, pulling a Pounce™ device with perhaps a little suction involved.

How were you dealing with peripheral arterial clots prior to your use of the Pounce™ System?

When I joined CIRA in the summer of 2022, lysis was our predominant approach, with suction thrombectomy used occasionally. With suction, we found we often couldn't clear out enough clot in those patients I described with AFib type material, something that's a little more chronic. The Pounce™ System has been very helpful in this respect. In my experience, it will often just drag out most of the clot in a single pass. At that point, the segment is more or less clear, although we may choose to do a little suction afterward to clean it up. Then, we balloon, stent, perform atherectomy, or do whatever else we need to do.

Has the availability of the Pounce™ System impacted your use of thrombolytics?

I've reduced my lysis volume significantly—I'd say by half or even more. We still use it occasionally, especially for long lines of fresh clot. But, if you can avoid using lysis and take care of the clot in a single session, that's a tremendous advantage. We have a huge volume of cases, so reducing the number of patients coming back to our rooms after lysis is important.

There are also a lot of advantages for patients in avoiding lysis. Not just the expense. It's safer for them, entails fewer procedures, and there's less chance of catheters getting dislodged, bleeding, infection, access site problems, things like that.[1]

The hospital is also dealing with a chronic shortage of beds—intensive care unit beds are precious. Eliminating the need to monitor people on lysis not only frees up a bed, it's easier on nursing resources. COVID contributed to a lot of burnout—people working long hours, sick patients, people dying. We're well-staffed here and have a great crew, but globally there are still staffing shortages. Some hospitals are still paying a lot of extra money to secure nurses. It's probably better than it was 2 years ago, but it's not where it needs to be. ■

1. Ebben HP, Jongkind V, Wisselink W, et al. Catheter directed thrombolysis protocols for peripheral arterial occlusions: a systematic review. *Eur Vasc Endovasc Surg*. 2019;57:667-675. doi: 10.1016/j.ejvs.2018.11.018

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Disclosures: None.

CASE REPORT

Successful Removal of Chronic Thromboembolic Debris Using the Pounce™ Thrombectomy System

By Sara McCann, MD

Patient Presentation

A 69-year-old patient with a history of metastatic lung cancer and mitral valve vegetations had presented previously to the hospital with acute left lower extremity ischemia. At that time, the patient was found to have a nearly complete left common iliac artery occlusion on a CTA, whereupon the physicians attempted pharmacomechanical thrombectomy. There was subsequent embolization, which was treated with aspiration thrombectomy and a short course of antiplatelet medication (Brilinta®, AstraZeneca). Unfortunately, 6 days after this first intervention, the distal popliteal artery reoccluded, and the patient presented back to the hospital.

Diagnostic Findings

The right common femoral artery was accessed using ultrasound access, and a 5 Fr X 11 cm vascular sheath was placed in the access site. A .035 Bentson guidewire was placed through the sheath and a 5 Fr Accu-Vu Omni™ Flush catheter (AngioDynamics, Inc.) was then placed and used to help navigate the Bentson wire to the left distal external iliac artery, where an initial angiogram was taken. The angiogram showed patent left common femoral, superficial femoral, and proximal left popliteal arteries with abrupt occlusion of the mid left popliteal artery at the knee joint (Figure 1) with distal reconstitution of flow at the origin of the posterior tibial and peroneal arteries.

Treatment

The Bentson wire was placed in the superficial femoral artery (SFA) and the 5 Fr vascular sheath was exchanged for a 7 Fr sheath, which was positioned at the origin of the SFA. The Bentson wire was swapped for a Glidewire Advantage® guidewire (Terumo Interventional Systems), the popliteal artery occlusion was crossed, and the guidewire was advanced to the mid peroneal artery. The Pounce™ Thrombectomy System was prepped, and the basket wire was delivered to the proximal peroneal artery. The funnel catheter was advanced over the proximal end of the basket wire to the proximal popliteal artery. Under direct fluoroscopy guidance, the baskets were retrieved back into the funnel, the basket

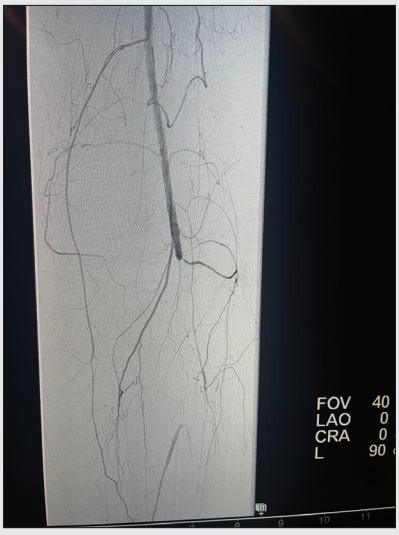

Figure 1. Initial angiogram demonstrating distal popliteal artery occlusion.

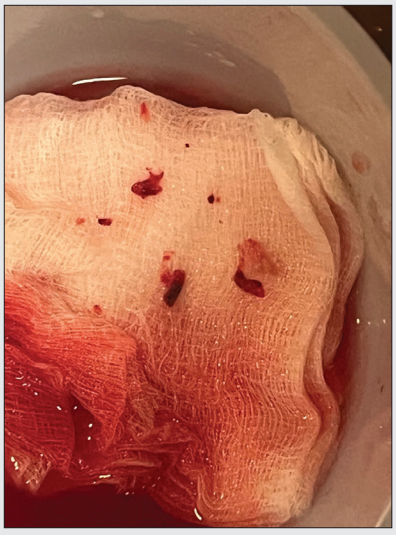

Figure 2. Clot removed during the Pounce™ System passes. Used with permission from the author.

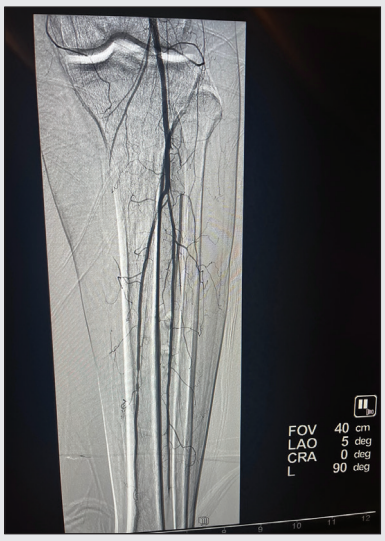

Figure 3. Angiogram after use of Pounce™ System showing patent popliteal and infrapopliteal vessels.

wire was locked to the funnel catheter, and the whole system was removed from the vasculature, successfully removing chronic thromboembolic debris (Figure 2). The 7 Fr sheath was aspirated, and a post-thrombectomy angiogram was taken, showing slightly improved flow with residual thrombus in the distal popliteal artery and tibioperoneal trunk (TPT). An additional two passes were made in the distal popliteal artery and TPT, respectively. After a third pass, a follow-up angiogram showed a patent left SFA, popliteal artery, and TPT, with two-vessel runoff to the foot via the posterior tibial and peroneal arteries (Figure 3).

Post-Procedure Outcome

The patient remained in the hospital after the procedure and was discharged with a medication plan, with follow-up scheduled 3 months post-intervention for reevaluation. The Pounce™ Thrombectomy System provided successful mechanical thrombectomy of the occluded segment with restoration of in-line flow without requiring further thrombolysis or surgical intervention. ■

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Disclosures: None.

Sponsored by SURMODICS

Optimizing Time Efficiency for Elective and Emergent Limb Ischemia Procedures

A conversation with Dr. Lucas Ferrer Cardona.

Dr. Lucas Ferrer Cardona is a vascular surgeon with the Dell Seton Medical Center at the University of Texas Hospital in Austin, Texas. At the hospital and at outlying clinics he visits in his outreach work, Dr. Ferrer focuses on limb salvage for a population that includes many lower-income patients with diabetes, end-stage renal disease, and critical limb ischemia (CLI), with acute limb ischemia (ALI) "ever-present." We spoke with Dr. Ferrer about his approach to treating limb ischemia and his experience with the Pounce™ Thrombectomy System (Surmodics, Inc.).

How has your approach to treating limb ischemia changed over time?

When I started training in 2017, the endovascular approach to thrombectomy was just starting to get a foothold, but there was still a strong predisposition for open surgical thrombectomy among the more conservative teaching staff. From an endovascular approach, we were using tPA (tissue plasminogen activator) catheters, the AngioJet™ pharmacomechanical thrombectomy system (Boston Scientific Corporation), and the Indigo® aspiration system (Penumbra, Inc.), but I would say we had inconsistent results in terms of thrombus removal.[1,2] It was also difficult for us to identify which patients would have a technical success with these approaches versus which patients we would need to convert to open surgery.

Since then, I've come to prefer an endovascular approach. I've become more comfortable with endovascular procedures and learned more about the strengths and weaknesses of devices.

How do you select patients for open surgery, tPA, or mechanical thrombectomy?

At this point in my practice, I don't go straight to open revascularization, and I don't go straight to tPA. It doesn't mean that I won't use these approaches, but for most patients, my approach will be endovascular mechanical thrombectomy. Open surgery is reserved for failure of the endovascular approach, while tPA is usually employed as a bridge between staged procedures.

> "The most significant benefit of the Pounce™ System over aspiration is that it's effective in treating both acute and chronic clot."

What is your approach to complex cases?

It depends on the extent of revascularization I need to do. I've had patients come in with complete occlusion and thrombosis of everything from the aorta down to the lower extremities. At that point, my approach is to get the patient through an expedited, simple procedure using mechanical thrombectomy. I'm not looking to get everything open down to the toes in the initial intervention but at least get inflow. I've given enough contrast and exposed the patient to enough radiation for the time being, and I think their clinical condition would benefit from us stopping the procedure and continuing the next day. At that point, I might use tPA as a bridge in between interventions, because the tPA might resolve part of the remaining distal thrombus. But this is unusual; most of the time I don't use tPA, and I no longer use it as frontline therapy.

Can you discuss your selection criteria for mechanical thrombectomy?

It's size dependent. In the iliac arteries and the aorta, I'll likely use the Indigo® aspiration system. In vessels < 7 mm, I use the Pounce™ Thrombectomy Catheter (the Pounce™ Thrombectomy System is indicated for vessels ranging from 3.5-6 mm). For vessels too small for the current Pounce™ System, we currently have the Indigo® CAT RX aspiration catheter (Penumbra, Inc.).

I'm looking forward to the introduction of the Pounce™ LP (Low Profile) System (Surmodics, Inc.; FDA cleared; intended for 2-4 mm vessels). We're already seeing a big benefit for the Pounce™ System in below-the-knee vessels within its range, and the ability to do more tibial vessels would address a big deficiency in our current treatment algorithm. Thrombus in tibial vessels still causes a visceral reaction

for any interventionalist—it's just technically more difficult to obtain a desirable outcome.

What do you see as the strengths and weaknesses of existing catheter-directed treatments?

Starting with tPA, the problem I've found is that sometimes the clot you're targeting can move down. Say you have clot in the femoropopliteal segment or the iliac segment. Depending on where you put the catheter, the clot can just move down as a column to your tibial vessels and then damage your outflow. So, it can turn from a very simple iliac femoral clot to very complex distal thrombus below the knee or the ankle, which is just more labor-intensive to clear. I think the attraction of tPA is that it just involves putting in a catheter and sending the patient to the intensive care unit (ICU). But aside from the technical problem that I mentioned, this obviously introduces the cost associated with an ICU stay and the potential complications related to tPA therapy.[3]

Regarding the AngioJet™ system, aside from my earlier comments, I believe it also introduces risk for embolization,[4] and I find it very time-consuming. You have to do the power pulse for tPA, wait 20 minutes, then come back and do multiple runs. Even with that, I find it difficult to get a perfect result.

Then you have aspiration-only catheters. For a long time, they were very inefficient.[2,5] Recently, there have been improvements to the technology that have improved their effectiveness, but you still have some limitations in terms of the size of the vessels you can treat with the new modifications and French sizes. Now I've started using the Pounce™ System and have found it very efficient and very flexible in its ability to treat different segments of the vasculature and chronicity of thrombi.

How does the Pounce™ System perform compared with aspiration?

I think the most significant benefit of the Pounce™ System over aspiration is that it's effective in treating both acute and chronic clot. Aspiration works great for fresh thrombus, but thrombus is usually not homogeneous. It's typically quite heterogeneous, especially in patients with previous interventions, bypasses, or other types of diseases.

Another significant benefit I've found with the Pounce™ System is the ability to get into smaller blood vessels and get a really good result. In the past, that's been a big deficiency in our treatment algorithm. Also, I've found the Pounce™ System to be time efficient, which is great. It takes me about 45 minutes to treat what I'm going to treat with the Pounce™ System. I find it efficient to be able to treat a range of heterogeneous clots with one device.

Could you expand on the benefit of time efficiency to your practice?

For us, time management is critical. Elective procedures are 60% to 80% of our practice. We schedule these weeks in advance. But, patients

> "I've found the Pounce™ System to be time efficient, which is great."

with ALI or ALI and CLI can't wait. They present at all times, and you have to treat them in a very time-sensitive manner because the outcomes are worse with delays. So, those two realities have to somehow coexist.

That requires time management and efficiency. Let's say I have an emergent patient come with rest pain. If, based on my experience, I feel confident I can get that patient in and out in a timely manner and bring in my other, scheduled patient—and my staff knows that and my cath lab manager knows that—then my flexibility to treat all patients and not have to put some things off and triage some patients increases significantly. Whatever makes that easier, more effective, and more predictable is going to benefit patients and the hospital. You're using less human capital, you're using less space, you're using less time that can be used for treating additional patients.

What's it been like for your staff to transition to the Pounce™ System?

It's been fairly seamless. The device is simple to use and has a limited number of components, so a limited number of staff need to be integrated into the process. For systems that require capital equipment, your scrub tech and the nurse in the room both have to be involved in setting up and operating the device. With the Pounce™ System, even if the tech isn't familiar with the device, I can easily show them, so the process just resolves. ■

1. Leung DA, Blitz LR, Nelson T, et al. Rheolytic pharmacomechanical thrombectomy for the management of acute limb ischemia: results from the PEARL registry. *J Endovasc Ther*. 2015;22:546-557. doi: 10.1177/1526602815592849
2. de Donato G, Pasqui E, Sponza M, et al. Safety and efficacy of vacuum assisted thrombo-aspiration in patients with acute lower limb ischaemia: the INDIAN trial. *Eur J Vasc Endovasc Surg*. 2021;61:820-828. doi: 10.1016/j.ejvs.2021.01.004
3. Ebben HP, Jongkind V, Wisselink W, et al. Catheter directed thrombolysis protocols for peripheral arterial occlusions: a systematic review. *Eur J Vasc Endovasc Surg*. 2019;57:667-675. doi: 10.1016/j.ejvs.2018.11.018
4. Acosta S, Karonen E, Eek F, Butt T. Short-term complications and outcomes in pharmaco-mechanical thrombolysis first and catheter-directed thrombolysis first in patients with acute lower limb ischemia. *Ann Vasc Surg*. 2023;94:253-262. doi: 10.1016/j.avsg.2023.02.018
5. Lopez R, Yamashita TS, Neisen M, et al. Single-center experience with Indigo aspiration thrombectomy for acute lower limb ischemia. *J Vasc Surg*. 2020;72:226-232. doi: 10.1016/j.jvs.2019.10.079

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Preliminary Clinical Evidence on Pounce™ Thrombectomy System Performance

A conversation with Dr. Bruce H. Gray.

We spoke with **Dr. Bruce H. Gray** about his recently published study[1] on the use of the Pounce™ Thrombectomy System (Surmodics, Inc.) for treatment of acute and chronic peripheral arterial occlusions. The study retrospectively examined 44 consecutive patients treated for lower extremity limb ischemia with suspected thrombus using the Pounce™ System at Prisma Health System, Greenville, South Carolina.

Recognizing that this was a preliminary study, what do you feel were the most notable findings?

Figure 1 summarizes what I consider to be key findings. We achieved 83% technical success in effectively removing thrombus from the peripheral arterial segments where the Pounce™ System was used.* This is particularly noteworthy because, unlike previous studies of arterial thrombectomy devices,[2-5] our study population included patients with subacute (15-30 days of symptoms) and chronic (> 30 days) limb ischemia in addition to acute limb ischemia (≤ 14 days). In just 2 of 44 cases, thrombolysis was used to resolve thrombus at a Pounce™ System treatment site. Most patients treated with thrombolysis had remote or distal clot not attempted with the Pounce™ System due to the system's indicated vessel range. Overall, most patients included in the study could be treated with a single-step procedure.

Clot removal was less complete in patients with longer-standing ischemia compared with those with shorter-standing ischemia. This is not surprising, as these patients will tend to have more chronic, wall-adherent thrombus. In my experience, this type of residua can be treated like plaque without concern for distal embolization. The central theme of treating these patients centers on treating thrombus like thrombus and plaque like plaque.

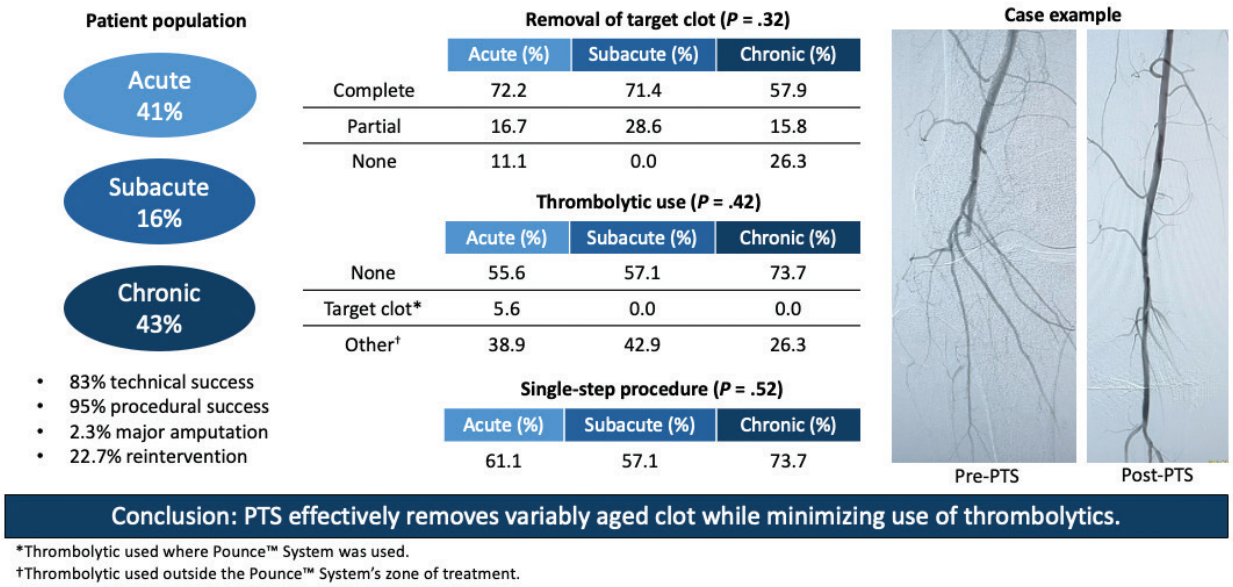

Figure 1. Pounce™ Thrombectomy System (PTS) for treatment of lower extremity ischemia in 44 patients.[1]

*In the study, technical success of the Pounce™ System was defined as the effective removal of thrombus from the treated arterial segment in which it was used.

"Unlike previous studies of arterial thrombectomy devices,[2-5] our study population included patients with subacute (15-30 days of symptoms) and chronic (> 30 days) limb ischemia."

Finally, although the device performed robustly in terms of thrombus removal and restoration of pulsatile flow, reintervention was not uncommon. Having a pristine angiographic result after a procedure is not enough—these patients need careful post-procedural management and aggressive anticoagulation.

Just to be clear, how do you define a "single-step" procedure?

A single-step procedure implies that at the time of a diagnostic arteriogram, the Pounce™ Thrombectomy System is used immediately, accompanied by any additional technique to treat underlying disease (ie, plain/drug-coated balloon angioplasty, plain/drug-eluting/covered stents), facilitating same-day discharge. The patient doesn't have to be admitted. This avoids catheter-directed thrombolysis (CDT), which entails bleeding risk, intensive care unit admission, repeat contrast injections, and the inconvenience of repeat angiographic radiation and sedation.

Can you describe your use of CDT for the patients in this study?

We used CDT predominantly in vessels not indicated for the Pounce™ System. CDT was a primary treatment in 15 patients whose clots were located outside the Pounce™ System's zone of treatment. As I mentioned, we performed CDT as a secondary treatment to improve initial results with the Pounce™ System in just 2 of 44 cases.

The study covered your first 44 uses of the Pounce™ System for lower extremity interventions. Did you see a change in your overall use of CDT during the study?

Prior to my use of the Pounce™ System, I would typically use thrombolytic therapy in about two-thirds to three-quarters of lower extremity ischemia cases. This rate dropped significantly when I began using the Pounce™ System and continued to drop as I accumulated experience with the device. The paper reports overall use of thrombolytic therapy in about one-third (36.4%) of cases but does not show the downward trajectory of my use of CDT during the study period.

What was your selection criteria for the Pounce™ device?

As I've said before, the "feel" of the clot tells you a lot about how easily it can be removed. Occlusions that are thrombus-dominant are easy to cross with a straight guidewire and can easily be treated with the Pounce™ System. In my experience, too many operators decide how to treat a patient's leg without assessing the occlusion itself. A patient's clinical history, important as it is, does not provide a definitive assessment of "age of thrombus," and treatment decisions made solely based on history may exclude many patients who might benefit from addressing the thrombotic component of occlusions.

What else influenced your patient selection for the Pounce™ System?

Patient comorbidity is a crucial consideration. Many patients have multiple heart, lung, or kidney comorbidities that make them less than ideal for surgery or multiple contrast-requiring procedures, not to mention an interruption of their antiplatelet or anticoagulation medications. I'm hesitant to use treatments that may induce hemolysis or volume loss in these patients, and I'd much prefer to resolve their ischemia in a one-step procedure without thrombolytics. Given its simple mechanism of action, the Pounce™ System was less intimidating to me to use for such patients.

What was your treatment approach for patients with lesions that were not able to be traversed by a guidewire?

Failure of the wire to traverse the lesion easily doesn't mean a patient cannot be treated with endovascular techniques; it just means thrombectomy may not be helpful. That goes for thrombolytics as well, since CDT works predominantly for fresh clot.[6] Therefore, lesions that are not easily traversable with a guidewire can be treated as "plaque only," or you may consider surgery in these cases. Likewise, if you can traverse the lesion but you do not retrieve any material via thrombectomy, in my experience this is predictive that surgical thrombectomy would be unsuccessful and that a bypass procedure may be necessary.

Keep in mind that most peripheral arterial occlusions are composed of thrombus and plaque. We have to think beyond coronary artery occlusion pathobiology, in which the fibrous cap of a plaque ruptures and the platelet plug forms, causing acute symptoms such as myocardial infarction. Leg symptoms can range from minimal to severe, with thrombus burden ranging from minimal to partial to predominate to complete. Balloon angioplasty alone can be helpful with minimal clot, as in a coronary artery, but is often ineffective in peripheral arterial occlusions. Therefore, my approach is to remove clot first, then treat the underlying plaque using tools designed to do that.

"Most patients included in the study could be treated with a single-step procedure."

Although the patient population in this study included a full range of clot chronicity (as defined by duration of symptoms), most patients had a relatively low level of ischemic severity (74% Rutherford class 2a). Do you see this as a limitation of the study?

No, I see this as a strength. In my experience, Rutherford class 2a is associated with subacute or chronic clot, whereas Rutherford class 2b, although a higher level of ischemic severity, is associated with acute clot. I have found that any thrombectomy device can remove acute clot—you can just suck it out. There are not a lot of devices that can remove subacute or chronic material. This is an important consideration, as the data sets we have for other thrombectomy devices tend only to include patients with < 15 days of ischemia.[2-5]

How did your use of the Pounce™ System change over time?

The question with a new device is always, "when do I default back to what I know will work?" Initially, I used the Pounce™ device only for easily guidewire-traversable occlusions in the superficial femoral artery/popliteal segment and used thrombolytic therapy to treat concomitant tibial artery clot (the Pounce™ System is indicated for treatment of vessels 3.5-6 mm in diameter). With experience, my comfort zone expanded to include more appropriate-size tibial arteries than I initially tried to tackle with the device, and I developed a better feel for how much is enough in terms of clot removal. In general, I became less likely to revert to CDT and I became slower to put in a balloon—if you're ballooning residual clot, sometimes that will embolize. So, my overall need for other modalities lessened as I accumulated experience with the Pounce™ System.

What was your typical approach to treating limb ischemia before using the Pounce™ System and to what degree, if any, did the availability of the Pounce™ device change this approach?

Prior to using the Pounce™ System, I would typically use mechanical thrombectomy to decrease the clot burden and then use thrombolytic therapy to clean up the residual thrombus. I had experience with most other mechanical devices on the market. The Pounce™ System quickly became my go-to device because it could minimize the need for thrombolytic therapy, thereby allowing many patients to be treated as outpatients. This helps to avoid hospitalization and subsequent next-day procedures.

The key to any treatment for ischemic limbs is reestablishing flow. The better the flow, the better the lysis and pain reduction for the patient. The Pounce™ System allowed me to reestablish robust flow earlier compared to other devices I've used. ■

"I had experience with most other mechanical devices on the market. The Pounce™ System quickly became my go-to device because it could minimize the need for thrombolytic therapy."

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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 information 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.

GRAB, GO, RESTORE FLOW

BELOW THE KNEE

2MM–4MM VESSEL SIZE

Pounce® Thrombectomy LP

2mm–4mm vessel diameter

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

Below-the-knee clot just became the prey!

The **Pounce™ LP (low-profile) Thrombectomy System** is designed to remove acute-to-chronic thrombi and emboli below the knee in peripheral arteries ranging from **2mm–4mm** in diameter. All without capital equipment. Reduced need for lytics and no aspiration for clot removal — just grab, go, restore flow.

pouncesystem.com

Pounce® Thrombectomy

3.5mm–6mm vessel diameter

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

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

SURMODICS