SUPPLEMENT TO

DECEMBER 2024

Endovascular TODAY

PERIPHERAL ARTERIAL CLOT?

#POUNCEIT

When minutes matter – remove acute or chronic thrombi or emboli without aspiration, thrombolytics, or capital equipment.


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Reducing the Need for Overnight Thrombolysis in ALI With the Pounce™ Thrombectomy Platform

A conversation with Dr. David J. O'Connor.

Dr. David J. O'Connor is a vascular surgeon with 11 years of experience in both open surgical and endovascular interventions, having completed his training at Mount Sinai Medical Center in New York. He practices primarily at Hackensack University Medical Center in New Jersey, where he serves as Director of Vascular Research. His practice and research have spanned a broad range of vascular conditions, including aortic aneurysms, carotid disease, chronic peripheral artery disease (PAD), and venous and arterial thrombosis.

For the past 2.5 years, Dr. O'Connor has used the Pounce™ Thrombectomy System (suitable for 3.5-6 mm peripheral arteries) (Surmodics, Inc.) for clot removal in the management of acute limb ischemia (ALI). More recently, he added the Pounce™ LP (Low Profile) Thrombectomy System (suitable for 2-4 mm peripheral arteries) (Surmodics, Inc.) to his toolkit. We spoke with Dr. O'Connor about his approach to treating ALI and his use of the Pounce™ Platform.

How would you describe your PAD and ALI patient population?

Most of the patients we receive for interventions have critical limb ischemia. These are people with chronic ischemic rest pain and nonhealing wounds. They sometimes present with gangrene. They're our more critical patients in need of urgent revascularization. We do treat a smaller subset of patients with claudication.

We also handle various emergencies. We often see patients with atheroembolism from a cardiac source, such as atrial fibrillation (AFib), that embolizes to the lower extremities. We also have patients with acute-on-chronic disease, often older patients with preexisting disease who have a critical stenosis that becomes thrombogenic, leading to ALI.

How do you select between surgical and endovascular approaches to ALI?

I'll nearly always take a surgical approach for patients who present with what we call "hard signs" of ischemia, such as decreased motor function, decreased sensation, or severe mottling of the leg. These are Rutherford class IIb cases, where the leg is in immediate jeopardy, especially if the patient has had those symptoms for more than 6 hours. It's almost like a heart attack—we need to get blood to that leg as quickly and successfully as possible because they may have already developed permanent motor or sensory dysfunction that could lead to amputation. We often perform a prophylactic fasciotomy for these patients at the time of revascularization to reduce risk of compartment syndrome.

> "The number of overnight thrombolysis cases I'm doing has gone down significantly over the past few years because of the Pounce™ Platform—I'd say at least by 70% to 75%."

For more stable patients, such as those with class I or IIa ischemia where motor sensation is intact, there's some form of Doppler signal in the leg, and baseline viability of the extremity is present, we have more options. In these cases, we usually consider endovascular therapy as first-line treatment. This is because we have more time—although the leg does need revascularization, typically within 24 hours, we don't need as rapid a restoration of flow if motor sensation is intact. This allows us to try less invasive approaches.

How do you select between endovascular treatments?

The decision between thrombolysis or mechanical thrombectomy really depends on the distribution and severity of disease we see on angiography. In patients with severe outflow disease—meaning there is complete thrombosis below the knee, with no reconstitution of a tibial vessel—we've found that patients tend to do better with thrombolysis. The thrombolytic tissue plasminogen activator (tPA) can get into the capillary microcirculation to dissolve, at least initially, a lot of clot. That

"Now, using the Pounce™ Thrombectomy Platform, we can get rid of that more organized thrombus we just can't remove with aspiration."

may not be the only procedure the patient receives, but when we're facing a thrombotic state that extensive, we really want to do some form of thrombolytic therapy to get into that microvascular circulation.

In these situations, you can sometimes try doing mechanical thrombectomy first, especially if the patient is in a significant amount of pain and we don't want to wait 6 to 12 hours for the tPA to start doing its work. But in general, those patients are going to need some form of thrombolytic therapy.

For cases where there is reconstitution, I'll typically try to use mechanical thrombectomy in a single-session procedure. I may take this approach for anything from a focal thrombus to entirely occluded superficial femoral artery (SFA) or proximal tibial vessels. I'll sometimes start with some initial aspiration if I think there's a component of fresh thrombus—for example, if there appears to be no calcification in the wall of the vessel and a wire passes through the clot easily. Aspiration can help get rid of a lot of the easily removed material before we re-image. But in the vast majority of cases, there's going to be clot left over.

In the past, this is the time when we would often turn to overnight thrombolysis, with the potential for subsequent surgery. Now, using the Pounce™ Thrombectomy Platform, we can get rid of that more organized thrombus we just can't remove with aspiration.

How does the Pounce™ Platform help in this respect?

The problem with aspiration has always been removing that thicker, more fibrotic clot. I've found that there is usually a component of organized thrombus with ALI patients. There are very few cases that will allow me to use an aspiration catheter to clear out all the clot I encounter.

With the Pounce™ Platform, the baskets open and grab that more fibrous or rubbery clot as you pull up the device. That's enabled us to get over the edge with a lot of patients who would otherwise have needed follow-up procedures. The number of overnight thrombolysis cases I'm doing has gone down significantly over the past few years because of the Pounce™ Platform—I'd say at least by 70% to 75%.

"I'd say 70% to 80% of the time I'll choose the Pounce™ Platform for mechanical thrombectomy."

I've also found the Pounce™ Platform useful for follow-up procedures after an initial thrombolytic intervention. For example, I may be covering for one of my partners who has used an EKOS™ Endovascular System (Philips) for an ALI patient. I'm on call and I bring the patient back for the second procedure. Sometimes it looks great. The patient may have had an AFib embolus but has no underlying calcification or atherosclerotic disease. They came in early after experiencing symptoms and the tPA got rid of everything. We see a good number of these.

But there are also many cases where we find clot with underlying disease—let's say, a stenosis in the SFA. Do we really want to go in and just balloon and stent that stenosis? This could introduce the risk of "toothpasting" any existing clot and embolizing it downstream. In these cases, I will nearly always go in with the Pounce™ System to try to differentiate between chronic and subacute disease.

When you choose mechanical thrombectomy for ALI patients, how often are you using the Pounce™ Platform compared with other percutaneous devices?

I'd say 70% to 80% of the time I'll choose the Pounce™ Platform for mechanical thrombectomy.

Have you found other useful applications for the Pounce™ Platform?

I've found the Pounce™ Platform to be helpful in some iatrogenic cases. For example, if someone's doing a transcatheter aortic valve replacement procedure or other endovascular procedure and they didn't give enough heparin or they dissect a vessel, this can lead to thrombosis that travels downstream. You often can't give tPA to these patients because of preexisting conditions like stroke, and they may not be stable enough to go to the operating room. So, you need to find some way to restore flow to their legs without thrombolytics or a major operation. The Pounce™ Platform can really help to get rid of that thrombus that has acutely closed the vessel.

Atherosclerotic debris or calcium can also get dislodged during these procedures and go downstream into, say, the popliteal artery. That material may be too big to fit into a small-caliber aspiration catheter, and aspiration isn't going to break it up. Thrombolysis won't dissolve it. The Pounce™ Platform can often grab it in one piece and pull it out.

What has been your experience using the Pounce™ LP Thrombectomy System?

I use that device for disease that goes to the trifurcation. So, if there's clot in the below-knee popliteal, anterior tibial, or popliteal to tibioperoneal trunk (TPT), especially if it's an embolus that's traveled to that last distal bifurcation point, I've found the Pounce™ LP System to be helpful.

But clot may not be isolated to that area. Often, I'm dealing with additional thrombus higher up in that column of the leg. In that case, I may use both the larger Pounce™ System and smaller Pounce™ LP System. Other times a patient will have large enough tibial vessels to allow me to use just the larger Pounce™ System—for example, if the patient has a TPT that is 4.5 mm. It really depends on the case. ■

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CASE REPORT

Removal of Mid-SFA Thrombus Using the Pounce™ Thrombectomy System

By David J. O'Connor, MD, FACS, RPVI

Patient Presentation

A woman in her mid 70s undergoing treatment for stage IV rectal cancer presented with simultaneous acute pulmonary embolism (PE) with right heart strain and an acute ischemic left lower extremity. Symptoms included shortness of breath, chest pain, and coldness of the left leg.

Diagnostic Findings

CTA of the lower extremity showed thrombosis of the left mid-superficial femoral artery (SFA) within an apparent calcified stenosis. Thrombolytic therapy was ruled out for PE and limb ischemia treatment due to unacceptable bleeding risk.

Treatment

The patient was first treated for PE. To address the patient's limb ischemia, right femoral artery access was obtained, and a 7 Fr sheath was advanced up and over to the left lower extremity artery. Initial angiography confirmed the CTA findings of an occlusion in the mid-SFA artery (Figure 1A). After crossing the occlusion with a Glidewire Advantage® Peripheral Guidewire (Terumo Interventional Systems) and NaviCross® Support Catheter (Terumo Interventional Systems), the Pounce™ Thrombectomy System (Surmodics, Inc.) was prepared. The Pounce™ System baskets were deployed distal to the SFA occlusion, and the funnel was deployed proximal to the occlusion in the common femoral artery/SFA junction. Two passes were performed and a moderate amount of thrombus was removed. Repeat angiography showed a reduced occlusion (Figure 1B). Plain balloon angioplasty followed by drug-coated balloon angioplasty were then performed. Repeat angiography demonstrated no residual thrombus and restoration of SFA flow with no flow-limiting dissections (Figure 2).

Postprocedure Outcome

The patient remained hospitalized for 2 days after the procedure for monitoring and transition to oral anticoagulation. The Pounce™ Thrombectomy System allowed for rapid removal of the thrombotic portion of a calcified stenosis in a patient contraindicated for thrombolysis. ■

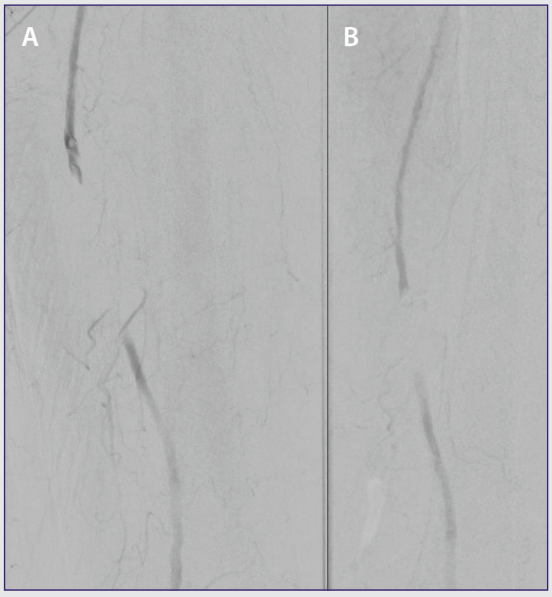

Figure 1. Calcified stenosis with thrombotic occlusion in the left mid-SFA artery before (A) and after (B) two passes with the Pounce™ Thrombectomy System.

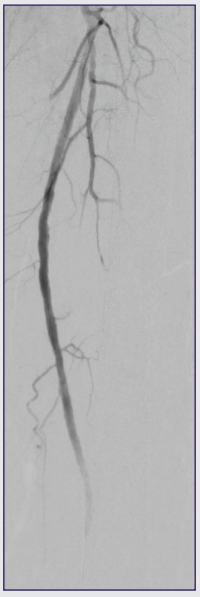

Figure 2. Postprocedure restored flow in the SFA.

Optimizing Endovascular Thrombectomy for Acute Limb Ischemia: A Surgeon's Journey

A conversation with Dr. Joseph V. Blas.

Vascular surgeon **Dr. Joseph Vincent Blas** started the endovascular aortic aneurysm program at Prisma Health Greenville Memorial Hospital in Greenville, South Carolina, a region he describes as a "hotbed of peripheral artery disease (PAD) and diabetes." In addition to his focus on complex aortic disease and PAD, he has extensive experience treating cerebrovascular, carotid artery, and peripheral venous disorders.

Today, Dr. Blas uses the endovascular Pounce™ Thrombectomy Platform (Surmodics, Inc.) for rapid removal of chronic or acute peripheral arterial clot. He is a principal investigator of the PROWL study, an open-label, retrospective, multicenter, United States registry of the Pounce™ Thrombectomy Platform for nonsurgical removal of emboli and thrombi in the peripheral arterial vasculature. We spoke with Dr. Blas about his approach to treating acute limb ischemia (ALI) and his growing use of the fully mechanical Pounce™ Platform.

What is your treatment algorithm for ALI?

Based on a detailed history and physical exam, I'll try to determine what type of lesion I'm addressing. If it's a short, focal, distal lesion in a patient with a high atherosclerotic burden, with a high likelihood of diseased arteries above or below, I'm going to try to do something percutaneous, because I have more options available to me—the Pounce™ Platform, aspiration, and thrombolysis are still on the table. You lose those options, especially thrombolysis, when you surgically open the patient's groin.

If someone has an acute limb with a cardiogenic embolus right at the popliteal artery and the patient is young and healthy, I think it's dealer's choice. I can make a small incision in the superficial femoral artery (SFA) and pull out the embolus with a Fogarty catheter. That's a 30-minute case and the patient goes home the next day. Or, I can handle that percutaneously, which is my current preference. I can go down there with the Pounce™ System and, potentially, the patient goes home the same day.

If I see a large thrombotic burden in a patient that I know has established atherosclerosis and is very large in stature, I'm going to try to treat that percutaneously—just chomp at the clot a little bit at a time and not lose the options I've mentioned. If there is embolization into the foot or tibials, I can go after that with either the Pounce™ Platform within its indicated range or thrombolysis, because I think those are better options than an over-the-wire (OTW) Fogarty device.

> "…I've found that the Pounce™ Platform typically obtains the kinds of results I'd expect from a Fogarty catheter."

Why would you prefer not to use the OTW Fogarty catheter in that situation?

OTW Fogarty catheters add time and complexity to the case. Furthermore, if you introduce the catheter with a groin incision and don't get an adequate result, then what? You can't lyse the patient because of the incision. You can use balloons, stents, and tools like that, but you may not achieve the result you were hoping for. In any case, I've found that the Pounce™ Platform typically obtains the kinds of results I'd expect from a Fogarty catheter.

Can you estimate how often you now use the Pounce™ Platform in ALI cases?

I would say it is around 40% to 50% Pounce™ Platform thrombectomy, about 25% surgery, and the rest is a blend of other approaches. At this point, I consider aspiration an adjunct therapy.

What do you see as the limitations of aspiration thrombectomy?

With the Pounce™ Platform, I can treat the softer lesions I could with an Indigo® Aspiration Thrombectomy System (Penumbra, Inc.) and also remove the harder, more fibrotic type of clot that tends to resist aspiration. Or I can go into the distal tibial arteries and remove clot with the Pounce™ LP (Low Profile) Thrombectomy System (suitable for 2-4 mm peripheral arteries) (Surmodics, Inc.), including bulky, high-volume clot. You can't necessarily do that with the smaller-caliber aspiration devices in the tibials.

With aspiration, I find that the longer the catheter, the less suction power there is at the end. With the Pounce™ Platform, I can come all the way across the bifurcation and not lose any power in terms of clot removal.

What was your approach to ALI before your adoption of percutaneous thrombectomy devices?

As vascular surgeons, we were taught that if someone comes in with an acute leg, their history will often determine the proper treatment. When patients have a history of chronic claudication, you're probably looking at somebody with an in-situ thrombosis of highly diseased arteries. For those cases, I preferred not to use a Fogarty catheter because of the risk of balloon rupture and subsequent vessel damage from using the device in atherosclerotic stenoses. For those types of cases, if I could see any distal flow, I'd consider using lysis. If I didn't see any flow, I knew I needed to find a distal target and then, in all likelihood, perform a bypass.

Patients who didn't have a history of chronic claudication often went straight to the operating room. For example, a patient may have experienced a cardiogenic embolus that went directly down to the lower extremity. You would put them to sleep, make a little cut down on the common femoral, loop it all out, send down a Fogarty catheter, and close the incision. You had it done within about 45 to 60 minutes.

Most of the time, you'd achieve an adequate result with pulse in the foot. If not, you'd need to seek more information, for example with an on-table angiogram. This would increase the complexity of the case tremendously, especially if the patient were being treated on a regular operating room table instead of an angiography table because of a lapse in planning. Once you found your target, you'd typically go after it with an OTW Fogarty catheter. If the results were still inadequate—well, you couldn't lyse the patient because of the groin incision.

When did you begin using percutaneous thrombectomy devices?

Around 2016, we began using pharmacomechanical devices, most often the AngioJet™ System (Boston Scientific Corporation), which seemed faster than the others and could get down into the tibials with the lower-profile catheters. Often, using the AngioJet™ System involved a 2- to 3-day process to open a flow channel, and then we would use thrombolytic, which works best when you have flow in an artery. But, there were several downsides with this approach, including the requirement for intensive care unit admission and complication risks.[1] But it was a very useful technique in its time.

Then we moved on to suction thrombectomy, at first done manually and later with the Indigo® Aspiration System. We found that we were getting some good results, not great results, with that system—certainly not the type of results we could achieve with a Fogarty catheter. I still believe the Fogarty catheter set the standard for ALI in a patient who has nonatherosclerotic lesions—it's rapid and reliable. With aspiration, we found that arteries could collapse on themselves, and it became difficult to move the catheter forward or backward. You could lose access to some of these arteries, requiring you to put the device down a wire, but when you removed the wire, you had access issues again. Beyond that, as I mentioned, the kind of clot you could remove through a 6, 7, or 8 Fr bore, 135 cm from the console, was limited. You couldn't remove the big, bulky stuff. So we really didn't adopt that very widely in the practice.

> "...I can go into the distal tibial arteries and remove clot with the Pounce™ LP (Low Profile) Thrombectomy System, including bulky, high-volume clot."

When and why did you begin using Pounce™ Thrombectomy System?

Dr. Bruce Gray introduced us to the Pounce™ Thrombectomy System (suitable for 3.5-6 mm peripheral arteries) about 4 years ago. We were still staunch believers in surgery, with a little mechanical suction thrombectomy used when we didn't think patients could tolerate surgery. Gradually, we began using the Pounce™ System instead of suction in those cases. Then we began to realize that we could use it in place of an open Fogarty approach for patients who could tolerate surgery, and we began to adopt it for more patients. We found that it achieved much the same result we would want a Fogarty to achieve. ■

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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CASE REPORT

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Infrapopliteal Revascularization With the Pounce™ Thrombectomy System

By Joseph V. Blas, MD, FACS

Patient Presentation

A female patient in her mid 60s presented to the emergency department with a 5-day history of acute-onset, left lower extremity pain, with left foot pain at rest. Patient history included chronic obstructive pulmonary disease, diabetes mellitus, COVID, end-stage renal disease on peritoneal dialysis, hypercholesterolemia, hypertension, and recent discharge from an inpatient stay for sepsis. A thrombectomy had been performed on the patient 8 weeks earlier to treat a contralateral right popliteal artery occlusion.

Diagnostic Findings

A physical examination showed Rutherford class IIa ischemia and left first toe gangrene (Figure 1), right pedal Doppler signals, and absent left pedal Doppler signals with a bedside left ankle brachial index of 0. An initial angiogram revealed left proximal tibial artery occlusion (Figure 2).

Treatment

Right femoral access was achieved, and a 7 Fr sheath was advanced up and over to the left lower extremity. The occlusion was crossed with a .035 Glidewire Advantage® Peripheral Guidewire and a Glidecath® Hydrophilic Coated Catheter (both Terumo Interventional Systems). The Pounce™ Thrombectomy System (Surmodics, Inc.) was advanced through the sheath, with basket deployment distal to the occlusion in the tibioperoneal trunk (TPT) and funnel deployment proximal to the occlusion in the popliteal artery. Two passes with the Pounce™ System were performed, and highly organized, mixed-morphology thrombus was retrieved. A follow-up angiogram revealed a residual occlusion affecting the anterior tibial (AT) artery (Figure 3). The AT artery was cannulated, whereupon the Pounce™ System baskets were deployed distal to the occlusion in the AT artery, and the funnel catheter was deployed proximal to the occlusion in the popliteal artery.* One pass with the Pounce™ System was performed in the AT artery, resulting in complete recanalization. At the conclusion of the procedure, pulse was detected in the left dorsalis pedis artery, signifying restored flow (Figure 4). The total case time was 40 minutes.

Postprocedure Outcome

The patient was started on apixaban following the procedure. The Pounce™ Thrombectomy System enabled prompt removal of highly organized, mixed-morphology clot and restoration of flow to the foot. ■

*The indicated vessel range for the Pounce™ Thrombectomy System is 3.5-6 mm.

Courtesy of Dr. Joseph V. Blas.

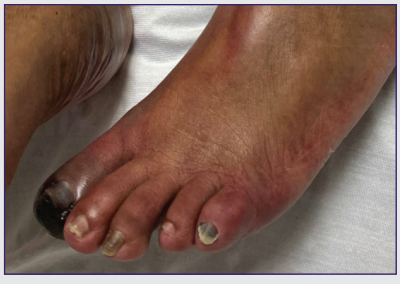

Figure 1. Gangrenous left first toe.

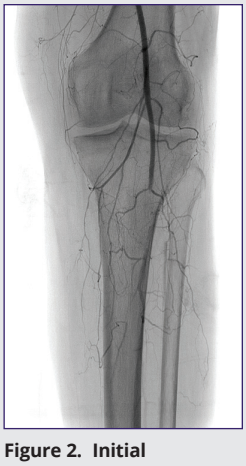

Figure 2. Initial angiogram showing left proximal tibial artery occlusion.

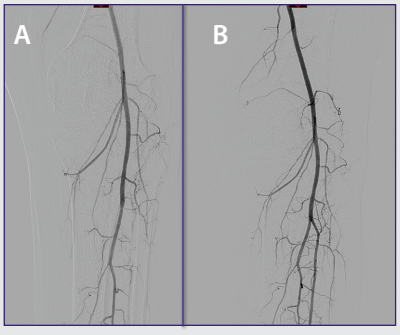

Figure 3. Residual occlusion in AT artery (A) and repeated angiogram (B) after one pass with the Pounce™ Thrombectomy System.

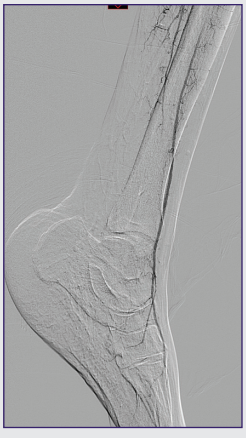

Figure 4. Restored flow in the left foot with detected pulse in the left dorsalis pedis artery.

CASE REPORT

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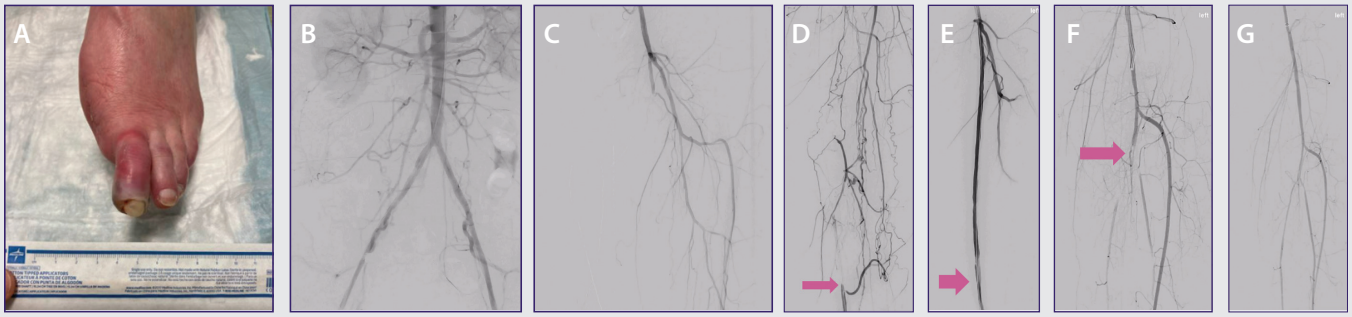
Removal of Distal Embolus Using the Pounce™ Thrombectomy System

By Joseph V. Blas, MD, FACS



Courtesy of Dr. Joseph V. Blas.

Figure 1. Left second toe ulcer in patient with previous bilateral toe amputations (A). Angiography revealing patent aortoiliac segment containing previously placed stents (B) and long-segment left SFA occlusion with distal three-vessel runoff (C). Organized distal cap of the long-segment SFA occlusion (D). A small dissection at the distal cap (E) and distal embolization in the TPT (F). Final angiography showing normalized inline flow to the foot after two passes with the Pounce™ Thrombectomy System in the TPT (G).

Patient History

A female patient in her early 50s with a history of bilateral toe amputations was seen by a wound care specialist for a left second toe ulcer (Figure 1A). The patient had experienced no recent acute-onset leg or foot pain. Patient history included chronic kidney disease, diabetes mellitus, hyperlipidemia, hypertension, a history of right leg deep vein thrombosis, smoking, and placement of two stents in the aortoiliac segment. Upon 2-week follow-up with wound care, further deterioration of the wound was noted, with no pulses in the affected toe. The patient was referred to vascular surgery.

Diagnostic Findings

Upon examination by the vascular team, the patient had a left ankle brachial index (ABI) of 0.60 and toe brachial index of 0.22. An arteriogram and toe amputation were planned. Angiography revealed that the previously stented aortoiliac segment was patent (Figure 1B). However, a long-segment left superficial femoral artery (SFA) occlusion with distal three-vessel runoff was noted (Figure 1C).

Treatment

Contralateral femoral access was obtained, and a standard crossing technique was done with a Glidewire Advantage® Peripheral Guidewire and Glidecath® Hydrophilic Coated Catheter (both Terumo Interventional Systems) to cross the occlusion, which had organized proximal and distal caps (Figure 1D). Balloon angioplasty was conducted in the SFA, resulting in good luminal gain and flow. A small dissection at the distal cap and distal embolization to the tibioperoneal trunk (TPT) were noted (Figure 1E and 1F). The Pounce™ Thrombectomy System (Surmodics, Inc.) was prepared and two passes were performed through the TPT. Final angiography showed normalized inline flow to the foot (Figure 1G), and a postprocedure left ABI of 0.87 was noted (Figure 2). Toe amputation was performed at the same time, with the site left partially open due to cellulitis.

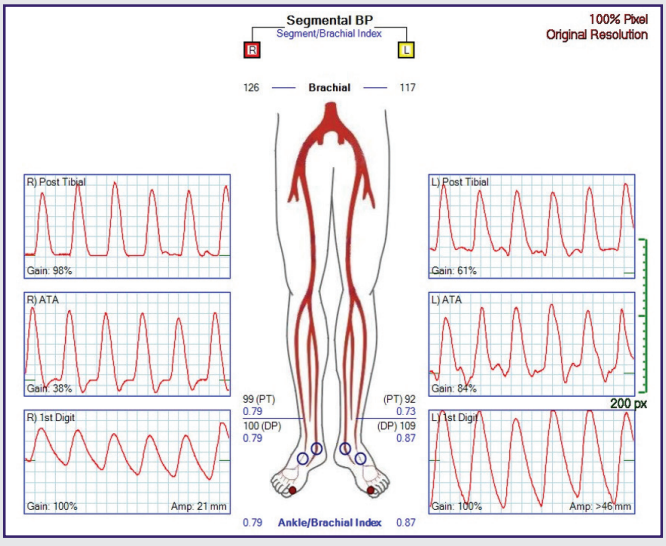


Figure 2. Postprocedure ABI.

Postprocedure Outcome

The patient was discharged on the same day with instructions to take prescribed oral anticoagulation and aspirin. The Pounce™ Thrombectomy System removed a distal embolus after recanalization and restored inline flow to the foot. ■

Caution: *Federal (US) law restricts the Pounce™ Thrombectomy System to sale by or on the order of a physician. Please refer to the 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.*

CASE REPORT

Removal of Multifocal Organized Thrombi Using the Pounce™ and Pounce™ LP Thrombectomy Systems

By Michael Nagib, MD

Patient Presentation

A female patient in her mid 70s presented with a 1-day history of left lower extremity pain. The patient reported pain in her left calf and foot that worsened with activity. Patient history included gastric cancer and atrial fibrillation, with cessation of anticoagulation due to upcoming gastrointestinal endoscopy. On physical exam, palpable pulses were found in the right foot and diminished pulses were found in the left foot, the latter intermittently detected via Doppler ultrasound. Motor function and sensation were intact bilaterally, but a temperature difference was observed between the left and the right foot.

Diagnostic Findings

Upon admission, CTA showed multifocal mild-to-moderate atherosclerotic disease in the left superficial femoral artery (SFA) with focal popliteal artery occlusion. Of note, the patient had variant anatomy with a high takeoff of the left anterior tibial (AT) artery. Findings were confirmed on catheter-directed angiography via right common femoral access with occlusion of the popliteal artery and subocclusive clot extension into the high takeoff of the AT artery. Prior to the intervention, the patient had single-vessel runoff via the AT artery and distal reconstitution of the left posterior tibial (PT) artery.

Treatment

Using right common femoral access, a 7 Fr, 65 cm Pinnacle® Destination® Guiding Sheath (Terumo Interventional Systems) was introduced up and over the aortic bifurcation into the left lower extremity. With the assistance of a Seeker™ Crossing Support Catheter (BD), a .014 guidewire successfully crossed the lesion and was advanced into the left AT artery. The Pounce™ Thrombectomy System* (Surmodics, Inc.) was then introduced with basket deployment in the proximal AT artery and funnel deployment in the proximal popliteal artery. One pass with the Pounce™ System removed organized thrombus, restoring patency in the popliteal artery (Figure 1). Balloon angioplasty of the peroneal and PT arteries was performed; however, angiography showed persistent occlusion of the PT artery with clot extension toward the peroneal artery origin. The Pounce™ LP Thrombectomy System† (Surmodics, Inc.) was then deployed with the baskets in the PT artery and the funnel in the popliteal artery. One pass with Pounce™ LP System was performed, removing organized thrombus, restoring patency of the PT artery, and clearing thrombus that was extending toward the peroneal artery origin (Figure 2). Final angiography showed three-vessel runoff to the left ankle and dominant flow into the foot via the AT and PT arteries.

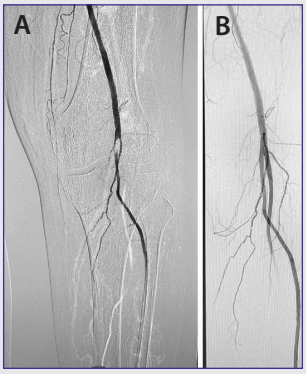


Figure 1. Angiogram of popliteal artery before intervention (A) and restored flow after one pass of the Pounce™ Thrombectomy System (B).

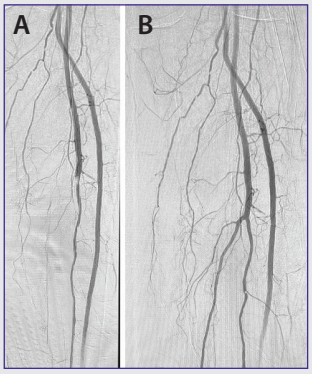


Figure 2. Pre- (A) and postintervention (B) angiograms demonstrate restored patency of the PT artery and cleared thrombus that was extending toward the peroneal artery origin after one pass of the Pounce™ LP Thrombectomy System.

Postprocedure Outcome

The patient tolerated the procedure well and was discharged 5 days later to allow for continued monitoring due to the history of atrial fibrillation. The patient was transitioned from heparin to apixaban prior to discharge, and outpatient follow-up was scheduled in 2 to 3 weeks. The Pounce™ Thrombectomy Platform extracted multifocal organized thrombi in a patient with variant anatomy and restored robust flow to the foot without the need for thrombolysis or aspiration thrombectomy. ■

*The indicated vessel range for the Pounce™ Thrombectomy System is 3.5-6 mm.
†The indicated vessel range for the Pounce™ LP Thrombectomy System is 2-4 mm.

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Removing Recalcitrant Arterial Emboli and Thrombi With the Pounce™ Thrombectomy Platform

A conversation with Dr. Venkatesh Ramaiah.

Vascular surgeon **Dr. Venkatesh Ramaiah** is Chief of Vascular and Endovascular Surgery at Osborn Hospital in Scottsdale, Arizona, and Director of Research and Innovation in the HonorHealth Network. He is also a cofounder of Pulse Cardiovascular Institute, an office-based lab and ambulatory surgical center in Scottsdale, and Chairman of the TED (Transformative Endovascular Decisions) conference. His comprehensive clinical expertise encompasses a range of vascular conditions, including peripheral artery disease and limb salvage procedures, deep vein thrombosis, complex thoracic and abdominal aortic surgeries, and advanced transcarotid artery revascularization techniques.

Since 2021, Dr. Ramaiah has included the Pounce™ Thrombectomy System (Surmodics, Inc.) in his limb ischemia toolkit. We spoke with Dr. Ramaiah about his approach to treating acute limb ischemia (ALI) and his experience with the Pounce™ System.

Has your treatment of ALI changed since you begin practicing?

It has. I began treating limb ischemia in 1997 during my fellowship. Back then, we primarily treated it with open surgery. Now, our approach is more endovascular. If the patient's leg is in immediate jeopardy, we are still likely to go right to open surgery as the fastest route to revascularization. However, if the patient's leg is viable and not completely insensate, we evaluate the endovascular option, or sometimes a combination of endovascular and open repair. If the endovascular approach doesn't work, we can always proceed with an open operation.

How do you approach percutaneous thrombectomy in ALI?

Starting with the basics, we'll usually go up and over from the contralateral leg. So, if the left leg is ischemic, we'll access the right groin and perform angiography in the right leg for comparison, then advance across the aortic bifurcation and obtain a diagnostic angiogram. Once we get a wire across the occlusion and confirm true lumen, it's time to decide which thrombectomy device to use. That decision depends on the patient and the acuity of the clot.

If the clot is fresh—say, less than a week old—an aspiration device may be able to suction it all out. For older clot or that sticky, fibrotic material you see in emboli associated with atrial fibrillation, I've found the Pounce™ Thrombectomy System works very well.[1] Of course, the Pounce™ Platform also works well in removing acute thrombus. Nonetheless, some operators may choose to use aspiration to clear acute thrombus from a lesion before using the Pounce™ Platform because they'd prefer not to lose wire access. If so, clearing acute clot first opens a channel that facilitates returning a wire if needed.

> "For older clot or that sticky, fibrotic material you see in emboli associated with atrial fibrillation, I've found the Pounce™ Thrombectomy System works very well."

Why did you first begin using the Pounce™ Thrombectomy Platform?

One of the first applications was in occluded prosthetic bypass grafts. Now, if a patient's graft has occluded on the day of the procedure or the day before, suction thrombectomy may be all you need to remove that fresh clot. But in these types of occlusions, there is often fibrotic clot distal to the acute clot, at the anastomosis, where the wider graft meets the narrower artery. There may also be narrowing in that artery from intimal hyperplasia, with sticky, organized material stuck in the narrowing and perhaps in downstream vessels as well.

In the past, when we used the Indigo® Thrombectomy System (Penumbra, Inc.), we'd often find it would leave that sticky, more organized material sitting right at the anastomosis. We'd put in balloons, do other things, but it would never come out, just move to the side. In this situation, we found that a Pounce™ Thrombectomy device could be phenomenal, because the two baskets, which are very good, could often drag out that irritating piece of sticky clot

"The Pounce™ Platform can also be very good when other approaches fail and you don't want to convert the patient to an open operation or do thrombolysis."

rather easily. Eventually, we started using the Pounce™ System alone rather than using it in combination with suction.

Are there some circumstances when you would choose not to use mechanical thrombectomy for an occluded bypass?

I would hesitate to use any mechanical thrombectomy device, including the Pounce™ System, as primary treatment in a native bypass graft because I believe these grafts are susceptible to damage from mechanical thrombectomy. In these cases, I'm more likely to try rapid thrombolysis first, meaning I'll cross the occlusion and put in an EKOS™ thrombolytic catheter (Boston Scientific Corporation) for 2 to 4 hours in the recovery room, then bring the patient back for a second look. This kind of rapid thrombolysis will often clear out 80% or 90% of the thrombus, and I can generally remove the rest with aspiration or mechanical thrombectomy. This approach helps the patient avoid an overnight stay in the intensive care unit for thrombolysis while using a much lower thrombolytic dose than standard catheter-directed thrombolysis.

Summing up, where does the Pounce™ Platform fit into your current ALI toolkit?

To me, the strength of these devices is removing clot from native vessels, particularly for emboli. Again, this is not acute clot, but fibrotic material that does not lend itself to suction thrombectomy. The Pounce™ Platform can also be very good when other approaches fail and you don't want to convert the patient to an open operation or do thrombolysis. ■

1. 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-

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Disclosures: None.

CASE REPORT

Removal of a Common Femoral Arterial Thrombus With the Pounce™ Thrombectomy System

By Venkatesh Ramaiah, MD, FACS

Patient Presentation

A female patient in her late 80s presented to the hospital with complaints of progressive claudication and rest pain in the left lower extremity. She reported worsening symptoms over the past week, with increased pain during ambulation and decreased ability to perform daily activities. Patient history included diabetes mellitus, atrial fibrillation, hypertension, and known peripheral vascular disease. Physical examination revealed diminished pulses in the left lower extremity, with the left foot observably cooler than the right. No active ischemic changes such as ulcers or gangrene were noted. Patient underwent a duplex ultrasound that confirmed near-total occlusion of the common femoral artery (CFA). Given her worsening symptoms and history, further vascular investigation was warranted.

Diagnostic Findings

A left lower extremity angiogram was performed to assess underlying arterial pathology. The angiogram revealed an acute subtotal occlusion of the CFA, with significant thrombus burden visualized at the site of the occlusion (Figure 1). Given the presence of the thrombotic occlusion, the decision was made to attempt an endovascular intervention for revascularization. An open-surgical approach was also considered.

Treatment

A 7 Fr, 45 cm sheath was placed and the Pounce™ Thrombectomy System* (Surmodics, Inc.) was prepared. The Pounce™ System baskets were deployed in the superficial femoral artery (SFA) with the funnel proximal to the occlusion. A first pass was made, removing thrombus and establishing a degree of flow. The Pounce™ Thrombectomy System baskets were then placed in the profunda femoris artery (PFA), with the funnel again placed proximal to the occlusion, and a second pass was made. More thrombus was removed, further improving blood flow.

After the thrombus was removed, a postprocedural angiogram revealed underlying stenosis in the proximal femoral artery. This was treated with a 7 X 40 mm Evercross™ PTA Catheter (Medtronic), which was inflated to dilate the stenotic segment and restore adequate arterial flow.

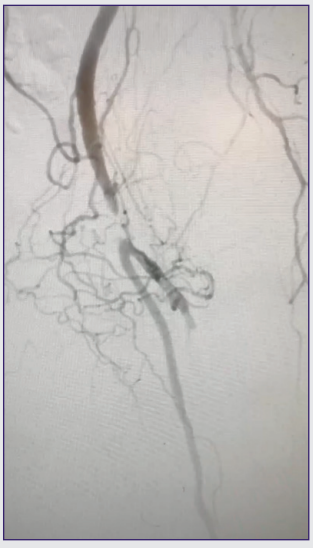

Figure 1. Angiogram revealing acute subtotal CFA occlusion with significant thrombus burden.

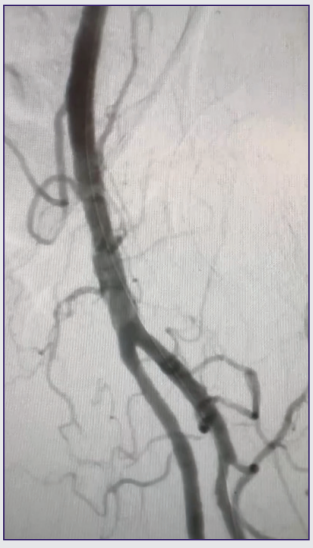

Figure 2. Final angiogram showing brisk CFA and PFA flow with no residual stenosis or thrombus.

A final angiogram showed improved flow through both the CFA and PFA, with no residual stenosis or thrombus and restoration of brisk flow to the lower extremity (Figure 2).

Postprocedure Outcome

The patient was discharged the next day after the intervention with prescribed medication. Endovascular thrombectomy with the Pounce™ Thrombectomy System combined with balloon angioplasty was effective in restoring blood flow to the affected limb, with a favorable postprocedure outcome. ■

*The indicated vessel range for the Pounce™ Thrombectomy System is 3.5-6 mm.

CASE REPORT

Removal of Mixed-Morphology, Multivessel Lower Extremity Clot With 3 Passes of the Pounce™ Thrombectomy System

By Jay Mohan, DO, FACC, FSCAI, FASE, RPVI

Patient Presentation

A woman in her early 80s presented with approximately 2 weeks of right lower extremity pain with numbness and tingling. Patient history included severe peripheral artery disease, a history of left femoral stent placement, and atrial fibrillation. The patient had been taken off apixaban due to hemorrhoidal bleeding.

Diagnostic Findings

Preoperative assessment with duplex ultrasound showed subacute limb ischemia of the right lower extremity with suspected embolus in the popliteal artery. An initial angiogram showed a total occlusion of the popliteal artery that further suggested organized embolic material (Figure 1).

Treatment

Left femoral access was achieved and a 7 Fr, 45 cm Destination™ Peripheral Guiding Sheath (Terumo Interventional Systems) was placed up and over into the right superficial femoral artery (SFA). A .035 Glidewire Advantage® Peripheral Guidewire (Terumo Interventional Systems) and Quick-Cross™ Support catheter (Philips) were then used to cross the total occlusion in the right popliteal artery. The Pounce™ Thrombectomy System (Surmodics, Inc.) was introduced with the baskets deployed in the popliteal artery and the funnel in the distal SFA (Figure 2). Two passes were performed in the popliteal artery and a significant amount of thrombus was removed. Angiography showed improved popliteal flow while revealing an occlusion within the mid-anterior tibial (AT) artery (Figure 3). An additional pass with the Pounce™ System removed a significant amount of chronic material. Repeat angiography showed TIMI (thrombolysis in myocardial infarction) grade 3 flow into the foot (Figure 4). Intravascular ultrasound confirmed no evidence of dissection or residual thrombus.

Postprocedure Outcome

The patient tolerated the procedure well with no complications and was discharged the next day with instructions to take prescribed aspirin and clopidogrel. Three passes of the Pounce™ Thrombectomy System aided in removal of multivessel, mixed-morphology clot, with subsequent restoration of robust blood flow to the foot. ■

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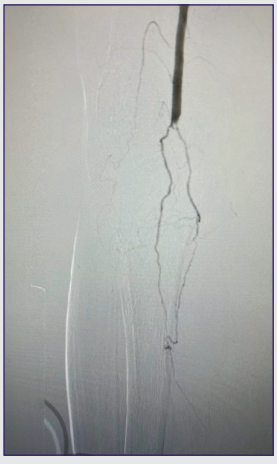


Figure 1. Total occlusion of the right popliteal artery.

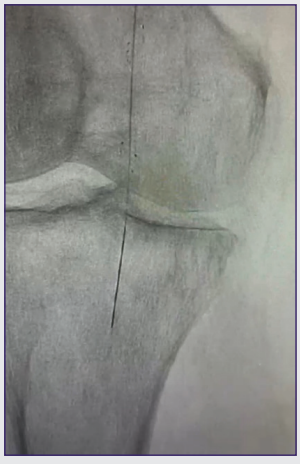


Figure 2. Deployment of the Pounce™ Thrombectomy System in the right popliteal artery.

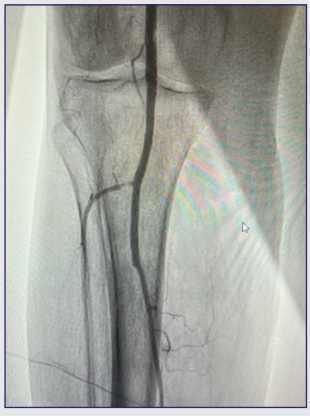


Figure 3. Restored flow in the right popliteal artery following two passes of the Pounce™ Thrombectomy System. Angiogram revealed occlusion in the mid-AT artery.

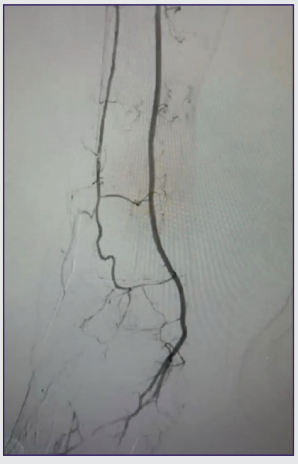


Figure 4. Final angiogram showing restored flow in the AT, posterior tibial, and dorsalis pedis arteries.

Sponsored by SURMODICS

Pounce™ Thrombectomy

Grab, Go, Restore Flow

Pounce™ Thrombectomy Platform is a percutaneous mechanical thrombectomy solution that uses dual-basket technology to remove peripheral arterial clot on the spot, without aspiration, thrombolytics, or capital equipment.

Pounce Thrombectomy XL **NEW**

5.5–10mm vessel diameter

Suitable for removal of thrombi and emboli from peripheral arteries--including iliac and femoral—within its indicated range.

Pounce Thrombectomy

3.5–6mm vessel diameter

Suitable for removal of thrombi and emboli from peripheral arteries--including the femoropopliteal and brachial--within its indicated range.

Pounce Thrombectomy LP

2–4mm vessel diameter

Suitable for removal of thrombi and emboli from peripheral arteries—including tibial, radial, and ulnar—within its indicated range.

- Removes thrombi and emboli from the peripheral arterial vasculature
- Rapid, efficient removal of acute or chronic clot
- No aspiration used for clot removal—minimizes blood loss
- No thrombolytics required—optimizes single-session treatment
- Fully mechanical, no capital equipment required
- Atraumatic to avoid arterial wall injury

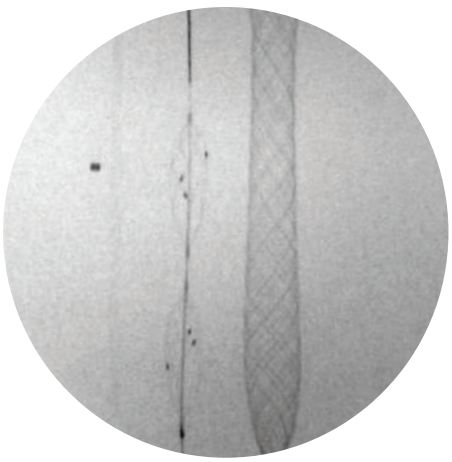
Peripheral Arterial Clot?
#POUNCEIT

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

Nitinol funnel to capture baskets and entrain clot

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

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

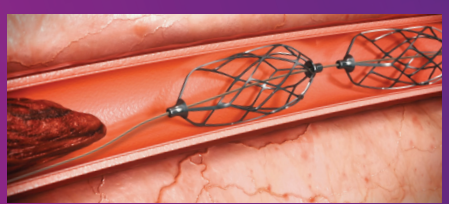


Pounce™ Platform components under fluoroscopy

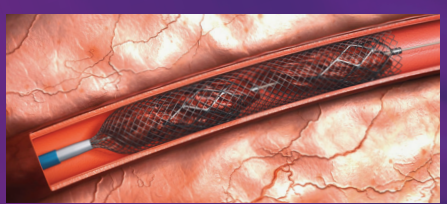
Delivery catheter distal radiopaque marker (left), Basket wire (middle), Funnel (right)

How it works

Scan to watch full animation



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.

CASE REPORT

Successful First Case With the Pounce™ Thrombectomy System to Remove Popliteal and Proximal Tibial Thrombi

By Charles DeCarlo, MD

Patient Presentation

A man in his late 50s presented to the emergency department with 4 weeks of acute-onset, severely limiting short distance claudication in his right lower extremity.

Diagnostic Findings

A CTA showed a popliteal artery occlusion, confirmed by a follow-up angiogram that showed minimal distal reconstitution (Figure 1A).

Treatment

Left femoral access was obtained and a 7 Fr Destination™ Peripheral Guiding Sheath (Terumo Interventional Systems) was delivered up and over into the right femoral artery. A .035 guidewire crossed the lesion easily, indicating thrombus present. The Pounce™ Thrombectomy System* (Surmodics, Inc.) was introduced with the baskets initially deployed distal to the occlusion in the proximal posterior tibial (PT) artery and the funnel deployed proximal to the occlusion in the superficial femoral artery (SFA)/popliteal junction. Four passes were performed: two in the PT artery (Figure 1B), one in the anterior tibial (AT) artery (Figure 1C), and one in the peroneal artery (Figure 1D). A final angiogram demonstrated restored flow to all tibial vessels with no signs of residual clots or embolization (Figure 1D).

Postprocedure Outcome

The patient was hospitalized for 2 days after the intervention for medical monitoring of a mechanical atrioventricular valve. The Pounce™ Thrombectomy System enabled removal of infrapopliteal and tibial thrombus and flow restoration below the knee with no signs of residual thrombus or embolization. ■

*The indicated vessel range for the Pounce™ Thrombectomy System is 3.5-6 mm.

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Disclosures: Consultant to Surmodics.

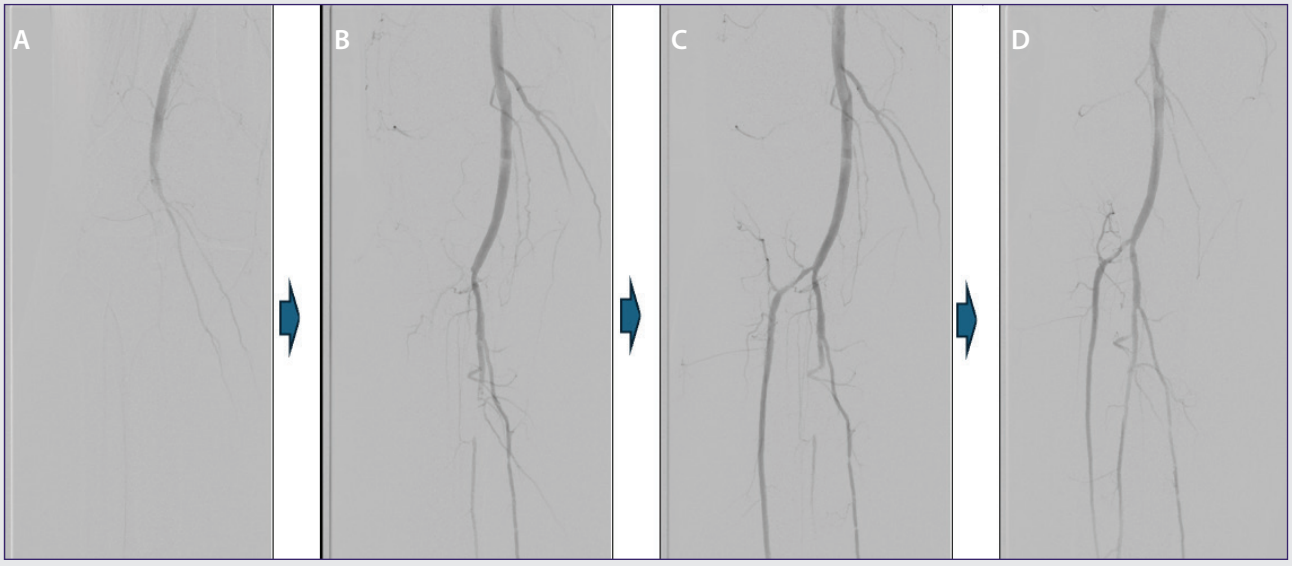

Figure 1. Preprocedure angiogram (A) and follow-up angiograms after four separate passes with the Pounce™ Thrombectomy System: two passes in the PT artery (B), one pass in the AT artery (C), and one pass in the peroneal artery (D).

CASE REPORT

Removal of Below-the-Knee Thrombus With the Pounce™ LP Thrombectomy System

By Charles DeCarlo, MD

Patient Presentation

A man in his mid 60s presented to the emergency department with severe pain in his right foot. Patient history included an above-knee femoropopliteal bypass on the same side 2 years earlier.

Diagnostic Findings

Duplex ultrasound revealed a patent bypass graft despite an ankle-brachial index close to zero. A follow-up angiogram confirmed a patent bypass graft but the popliteal artery below the graft was found to be totally occluded, with minimal reconstitution of tibial arteries and no flow below the ankle (Figure 1).

Treatment

Left femoral access was obtained and a thrombolysis catheter was introduced up and over into the distal anterior tibial (AT) artery. An amputation was planned if thrombolytic treatment did not improve flow to the foot.

After 24-hour thrombolysis treatment, a follow-up angiogram demonstrated a recanalized popliteal artery (Figure 2) but still no flow detected in the foot (Figure 3A). A 7 Fr Destination® Peripheral Guiding Sheath and a .018 Glidewire Advantage® Peripheral Guidewire (both Terumo Interventional Systems) were advanced up and over into the AT artery. The Pounce™ LP Thrombectomy System (Surmodics, Inc.) was then introduced, with the baskets deployed distal to the occlusion in the AT artery and the funnel deployed in the popliteal artery. Three passes with the Pounce™ LP System were performed, and a follow-up angiogram showed a fully recanalized AT and restored flow into the dorsalis pedis artery (Figure 3B).

Postprocedure Outcome

The patient was hospitalized for 2 days after the procedure to allow for monitoring of a minor hematoma caused by the thrombolysis treatment. The Pounce™ LP Thrombectomy System provided efficient removal of a distal AT occlusion that was not resolved with 24-hour thrombolytic treatment, thereby helping to prevent a foot amputation. ■

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Disclosures: Consultant to Surmodics.

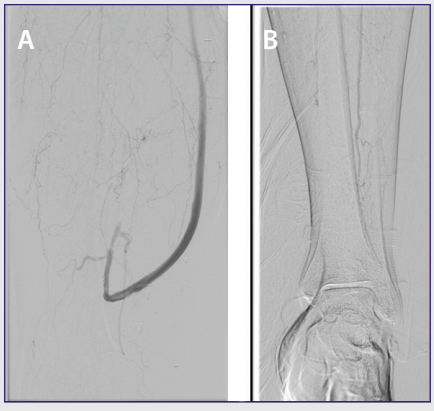

Figure 1. Initial angiogram showing a patent bypass graft with a distal popliteal artery occlusion (A), minimal reconstitution of tibial arteries, and no flow below the ankle (B).

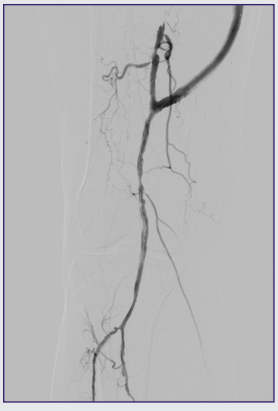

Figure 2. Recanalized popliteal artery after 24-hour thrombolytic treatment.

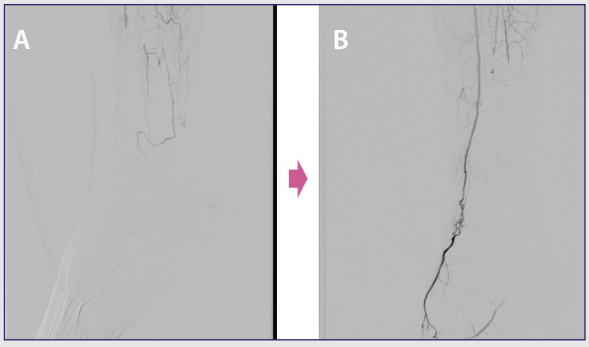

Figure 3. Distal tibial angiogram following 24-hour thrombolytic treatment (A) and repeated angiogram after one pass with the Pounce™ LP Thrombectomy System (B).

CASE REPORT

Removal of Thrombus in Brachial and Ulnar Arteries Via Combined Radial and Femoral Access

By Wail E. Asfour, MD, FACC, FSCAI

Patient Presentation

A male in his early 70s with a history of diabetes mellitus, hypertension, hyperlipidemia, and COVID-19 underwent orthopedic lower back surgery and developed postoperative pain and numbness of the left forearm. The patient was contraindicated for tissue plasminogen activator. On exam, the patient's forearm was cold and without peripheral pulses.

Diagnostic Findings

Access was initially achieved through the right common femoral artery (CFA). An angiogram of the left axillary artery showed a clotted left brachial artery (Figure 1). No on-hand aspiration thrombectomy catheter was capable of reaching the left brachial artery from the right CFA; therefore, access from the left radial artery was achieved and aspiration thrombectomy was attempted from the radial approach.

Treatment

Despite multiple passes, aspiration thrombectomy was unsuccessful, whereupon the interventional team elected to attempt thrombectomy with the Pounce™ Thrombectomy System (Surmodics, Inc.). (Notably, the patient's left radial and distal brachial arteries were 4 mm and 6 mm in diameter, respectively.) The Pounce™ System was passed through the left radial artery into the left brachial artery, and the baskets were deployed in the distal brachial artery with the funnel in the mid-radial artery. The clot was removed from the brachial artery with one pass of the Pounce™ System; however, a repeat angiogram showed residual clot occluding the left ulnar artery.

Due to tortuosity from the radial artery to the location of the occlusion in the ulnar artery, the interventional team elected to use the Pounce™ System through the right CFA. With a 7 Fr sheath in the CFA, the Pounce™ System was able to reach the left ulnar artery. (Notably, the patient's left ulnar artery diameter was 4 mm.) The Pounce™ System's baskets were deployed in the mid-ulnar and the funnel in the brachial artery, and a large clot was removed after one pass. The final angiogram showed robust flow to the left brachial, radial, and ulnar arteries (Figure 2).

Postprocedure Outcome

Due to his continued recovery from spinal surgery, the patient was discharged the day after the intervention, with instructions to take prescribed apixaban and aspirin. The Pounce™ Thrombectomy System was able to efficiently remove a large volume of thromboembolic material (Figure 3) following failure of aspiration thrombectomy. ■

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Munster, Indiana
Disclosures: None.

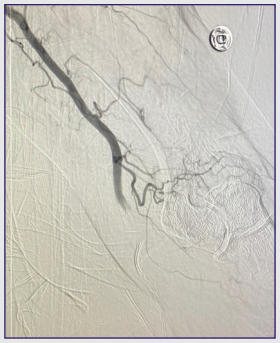

Figure 1. Diagnostic angiogram revealed clotted left brachial artery.

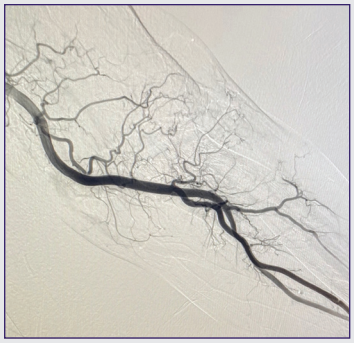

Figure 2. Final angiogram revealed robust flow to the left brachial, radial, and ulnar arteries.

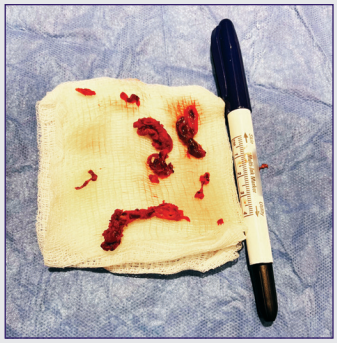

Figure 3. Clot removed from left brachial and ulnar arteries with the Pounce™ Thrombectomy System.

Peripheral Arterial Clot?
#POUNCEIT

Surmodics™ Pounce™ Thrombectomy Platform

INTENDED USE
The Pounce™ Thrombectomy System is intended for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature.

CONTRAINDICATIONS
The device is contraindicated for use in patients who cannot receive recommended intravenous anticoagulant therapy.

Model Information

Model Number	Model Description	Indicated Vessel Range
PTS-0407-7F150	Pounce™ LP Thrombectomy System	2 mm to 4 mm in diameter
PTS-0607-7F135	Pounce™ Thrombectomy System	3.5 mm to 6 mm in diameter
PTS-1011-7F135	Pounce™ XL Thrombectomy System	5.5 mm to 10 mm in diameter

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

Check out the **power and control** of the Pounce™ Venous Thrombectomy System for peripheral venous clots (6–16mm vessel diameter).

Exceptional performance in removing fresh or organized clot from both lower and upper extremity veins within the indicated range.

Grab, Go, Restore Flow

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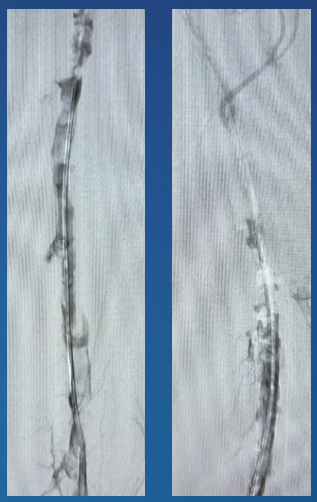
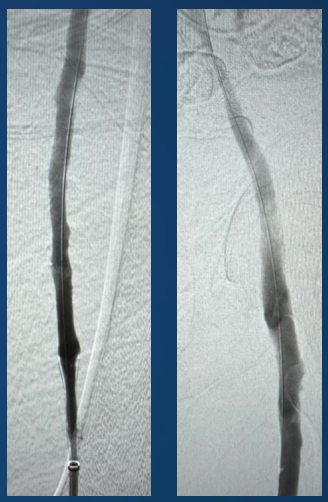
CASE REPORT

Removal of extensive mixed-morphology clot



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

Clot Removal: mixed-morphology clot.



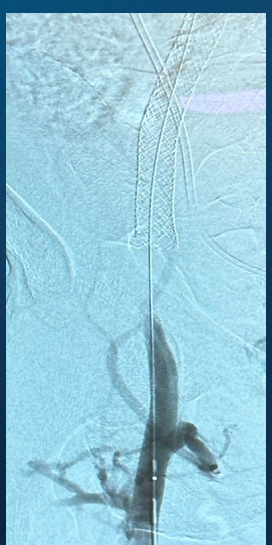
Final Venogram confirmed restoration of blood flow from popliteal (above left) through external iliac vein (above right).

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

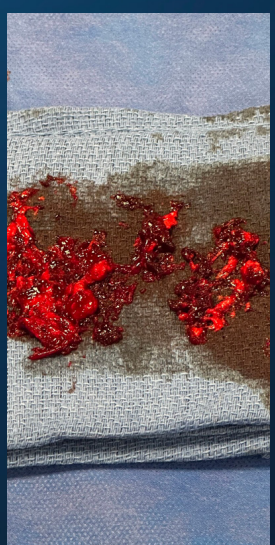
Scan to read the case report

CASE REPORT

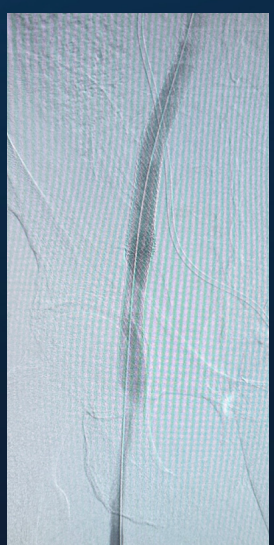
Removal of in-stent thrombus in iliac vein



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.

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

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Drs. Graphia and Motes are not consultants for Surmodics

SURMODICS

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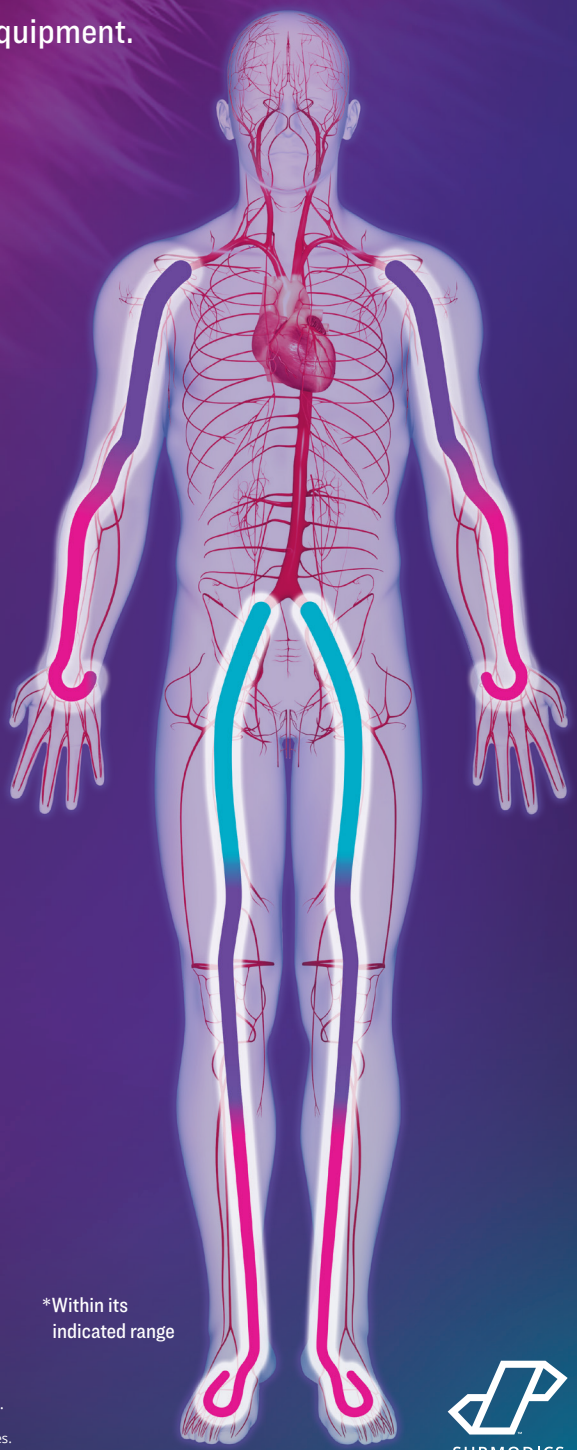
2–4mm vessel diameter



*Within its indicated range

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