Supplement to

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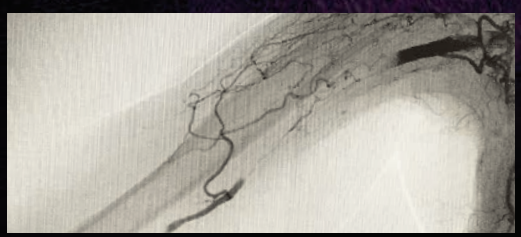
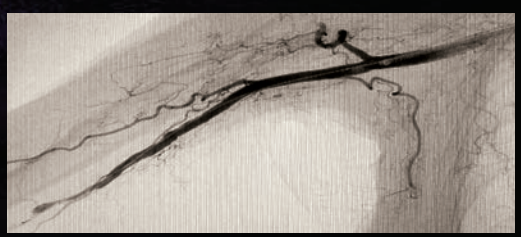
Endovascular TODAY

December 2022

GRAB, GO, RESTORE FLOW:

How the Pounce™ Thrombectomy System is redefining thrombus and embolus removal.





Full case on page 10

Gary Ansel, MD

J. Michael Bacharach, MD

Thekla Bacharach, MD

Joseph Campbell, MD

Bruce Gray, DO

Joseph Griffin, MD

John Phillips, MD

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Treating Thrombotic and Embolic Occlusions With the Pounce™ Thrombectomy System: Clinical Experience From 50 Patients

A conversation with Dr. Bruce H. Gray.

Bruce H. Gray, DO, MSVM, an endovascular surgery specialist in Greenville, South Carolina, has practiced medicine for more than 36 years and has co-authored 90 peer-reviewed articles. In 2017, the Society for Vascular Surgery awarded Dr. Gray the Jess R. Young award in recognition of his outstanding contribution to vascular medicine education.

"The Pounce™ Thrombectomy System can provide on-table results *without* the use of thrombolysis in most cases."

What is the most important way the treatment of acute limb ischemia (ALI) has changed since you began practicing?

Overall, it's been the reduction in the amount of time it takes to restore limb perfusion. In fact, no area of medicine has captivated my interest and fascination more than the search for the fastest route to normalization of flow in ALI.

How has this reduction been achieved?

Traditionally, surgical procedures such as Fogarty® catheter thrombectomy or bypass were thought to be the most efficacious treatments for the prompt restoration of flow. Now we know that catheter-based procedures can often restore flow quickly without closing doors to other treatment options. In this sense, the biggest change I've witnessed has been the evolution of catheter-based systems.

How would you describe the evolution of catheter-based treatments?

We've known for a long time that systemic anticoagulation improves limb viability and life expectancy but is ineffective at restoring arterial patency. So systemic administration (intravenous) of thrombolytic therapy—streptokinase, urokinase, and tissue plasminogen activator—was tried, but it was inefficient in reestablishing flow and carried significant bleeding risk to the patient.

In the late 1980s, physicians adopted direct delivery of a fibrinolytic agent into the occluded artery via catheter-directed thrombolysis (CDT). CDT improved efficacy but often required infusions beyond the initial day of treatment. The problem is, the longer you infuse, the higher the bleeding risk. By the 1990s, substantially reduced thrombolytic doses for CDT had decreased bleeding risk, but CDT still necessitated a prolonged infusion before restoration of flow. That's where mechanical thrombectomy changed the game. With first-generation mechanical thrombectomy devices, flow could be reestablished quickly. However, to normalize limb perfusion, mechanical thrombectomy was often combined with CDT to clean up the residual thrombus. These days, mechanical thrombectomy devices, such as the Pounce™ Thrombectomy System, can provide on-table results *without* the use of thrombolysis in most cases. This restoration of limb perfusion in a single session improves patient care, is cost-effective, and facilitates a return to the patient's regular activities.

You're now proficient at using the Pounce™ Thrombectomy System. How do you select patients for mechanical thrombectomy with the Pounce™ device?

Before considering any treatment, I need to know the patient's personal history and conduct a physical examination. Determining the lesion morphology is an essential consideration prior to treatment, so the history of a recent change in symptom status increases the likelihood of thrombus as a component of

"Occlusions that are thrombus dominant are easy to cross with a straight guidewire and can easily be treated with the Pounce™ Thrombectomy System."

the occlusion. For example, a patient who used to be able to walk 500 yards before the onset of leg pain and now can only walk 50 feet without pain is likely to have thrombus. After history and the physical exam, I assess if the guidewire can pass easily through the occlusion. If it can, the implication is that the clot can and should be removed.

The tactile feel of the lesion determines the ease of clot extraction. Occlusions that are thrombus dominant are easy to cross with a straight guidewire and can easily be treated with the Pounce™ Thrombectomy System. Once the clot is removed, if there is underlying atherosclerosis, the lesion can then be treated appropriately. Anecdotally, the markers on the baskets of the Pounce™ catheter will outline the contour of the arterial lumen when pulled back through stenoses. This helps identify areas of plaque in the artery. After that, ideally, you can treat clot like clot and plaque like plaque.

How do the Rutherford classifications systems for ALI and critical limb ischemia influence your patient selection?

Current Rutherford classification systems for acute and chronic ischemia are based on symptom duration (ie, about 2 weeks duration for acute and 4 weeks for chronic). But, you can't treat only on the basis of symptom duration because occlusions may act "younger" or "older." Treatment should be tailored to the underlying feel of the lesion as determined with wire traversal. That doesn't mean we need another classification system for clot morphology—we just need to be aware of what's occluding the artery.

You've now treated about 50 patients with the Pounce™ Thrombectomy System. What are your overall impressions of the device?

The Pounce™ Thrombectomy System is a game changer. It's simple to use, readily available on the shelf, and reestablishes flow promptly. More importantly, I believe it minimizes risk to the patient. We've only noted some minor groin hematomas in follow-up, given that these patients are treated with anticoagulation with few exceptions. Closure devices are routinely used to close the access site (7 Fr) without reversing anticoagulation.

With each pull of the device, the amount of extracted clot is immediately gratifying. The reassessment of arterial patency then helps determine the need for additional passes of the baskets. Frequent wire traversal of the arterial segment is not an issue because the access sheath is maintained, and replacement of the delivery catheter is easy. Each subsequent pass becomes easier than the previous pass. Without a doubt, the Pounce™ device has become my go-to catheter whenever a peripheral arterial occlusion is easily crossed and there is suspicion of thrombus present. The entire team, including the technologists, nurses, and residents, appreciate the ability to treat these complex patients quickly and decisively.

How has your use of the Pounce™ Thrombectomy System evolved since you first started using it?

As our clinical experience has grown, we've used the Pounce™ Thrombectomy System to achieve stand-alone thrombectomy without the need for subsequent thrombolytic therapy. This reduction is seen in our overall use of thrombolytic therapy, which is now less than 35%. This compares quite favorably to our experience with either the AngioJet™ or Indigo® System, where we've found that thrombolytic therapy is necessary in 90% of cases. We expect this rate to continue to drop despite taking on more complex thrombotic cases.

Initially, because the basket wire is fairly stiff, I had some concerns about pulling the device back through curves or tortuosity, such as the proximal anterior tibial artery. With experience, I've set these concerns aside, since the baskets are flexible, and their limited radial force is nontraumatic to the arterial wall. The catheter is designed to be used in peripheral arteries between 3.5 and 6 mm in diameter.

Have you been concerned with distal embolization when using the Pounce™ Thrombectomy System?

Not really, because the technique of removing proximal clot before removing distal clot limits embolization. You set up inflow

"The Pounce™ Thrombectomy System is a game changer. It's simple to use, readily available on the shelf, and reestablishes flow promptly."

"Most Pounce™ Thrombectomy System cases can be done within 60 to 90 minutes under local anesthesia and as an outpatient procedure."

first, then establish adequate outflow. If clot embolizes into another branch, it's easy to cross and remove with another pass of the baskets.

How do you feel about the utility of the Pounce™ Thrombectomy System in the outpatient setting?

Most Pounce™ Thrombectomy System cases can be done within 60 to 90 minutes under local anesthesia and as an outpatient procedure. This compares favorably to any other technique that is currently available. The avoidance of an intensive care unit stay (needed for thrombolytic therapy), admission to the hospital (extra cost), and repeat contrast requiring procedures (follow-up angiogram after thrombolytic therapy) make the Pounce™ System an indispensable device for any interventional suite.

"The learning curve for the Pounce™ Thrombectomy System is short; for experienced operators, three cases is enough."

What would be your advice to interventionalists who are just getting started with the Pounce™ Thrombectomy System?

The learning curve for the Pounce™ Thrombectomy System is short; for experienced operators, three cases is enough. A good place to start is with patients who have small clot burden in the superficial femoral or popliteal artery. With experience, it becomes simple to tackle greater clot burden or thrombectomy in atherosclerotic arteries.

Long occlusions can be debulked without initially crossing the entire lesion. Leaving the distal clot intact minimizes the risk of distal embolization by leaving a "cork" at the bottom of the occlusion. Then, it can be removed. It typically is not a problem to deploy the funnel in occluded segments because the baskets retrieve into the funnel easily. When in doubt, make another pass and use the angiographic appearance and pace of flow to figure out the thrombectomy endpoint. ■

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Disclosures: Consultant for InspireMD, Surmodics, and WL Gore.

CASE REPORT

Successful Removal of Bilateral Embolization Using the Pounce™ Thrombectomy System

By Bruce H. Gray, DO, MSVM

Patient Presentation

A 44-year-old woman who worked as a mail carrier presented with a 4-week history of claudication. She had no risk factors for atherosclerosis, was in normal sinus rhythm, and had no history of medical illness.

Diagnostic Findings

The patient was found to have bilateral embolization that caused an occlusion of the descending branch of the right profunda femoral artery, right popliteal artery occlusion, and left tibioperoneal trunk occlusion (Figure 1).

Treatment

Bilateral common femoral artery access enabled the Pounce™ Thrombectomy System to remove the emboli and reestablish normalized flow without thrombolysis or surgical intervention (Figures 2 and 3). With the Pounce™ Thrombectomy System, multiple vessels or branches of the arterial tree were able to be reopened during the same session.

Post Procedure Outcome

This embolization event was further evaluated with echocardiography (normal), but outpatient cardiac rhythm monitoring identified paroxysmal atrial fibrillation. She is still asymptomatic while on anticoagulation.

It is quite rewarding to normalize flow without an incision or exposing the patient to thrombolytic therapy. The Pounce™ Thrombectomy System enabled a successful outcome to this case. ■

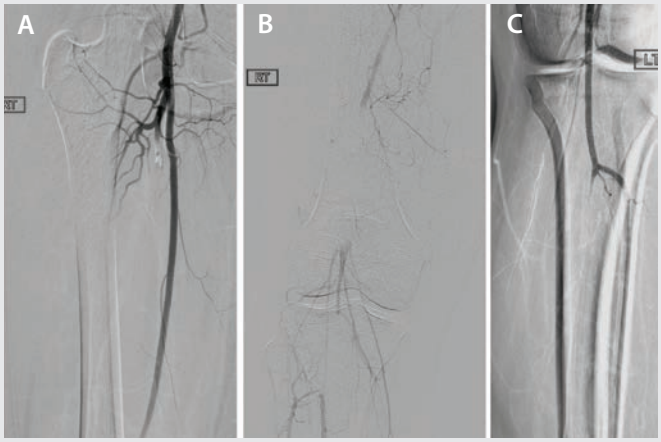

Figure 1. Baseline arteriogram of right profunda femoral artery (A), right popliteal artery (B), and left tibioperoneal trunk (C) occlusions.

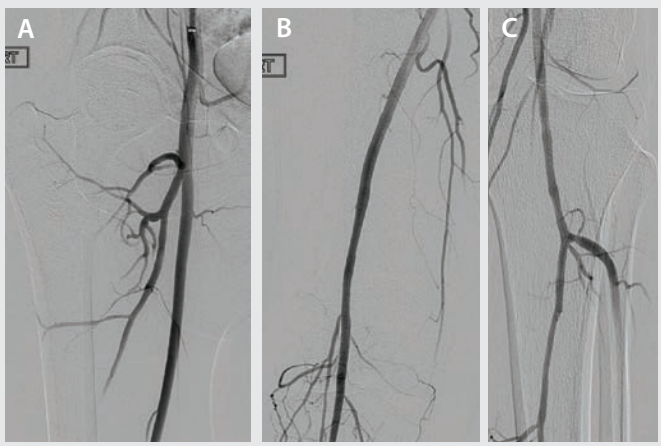

Figure 2. Arteriogram of right profunda femoral artery (A), right popliteal artery (B), and left tibioperoneal trunk (C) after Pounce™ passes.

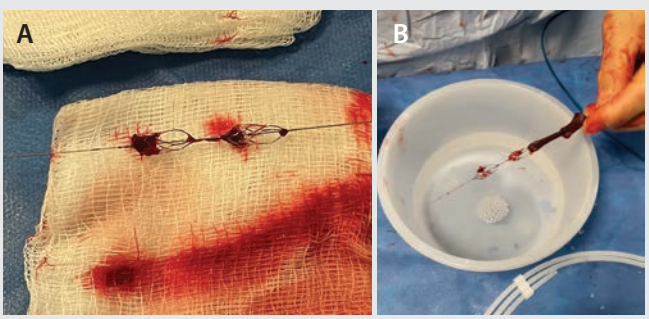

Figure 3. Clot removed from the right profunda artery (A) and left tibioperoneal trunk (B) after use of the Pounce™ Thrombectomy System. (Used with permission of the author.)

***Caution**: Federal (US) law restricts the Pounce™ Thrombectomy System to sale by or on the order of a physician. Please refer to the product Instructions for Use for indications, contraindications, warnings, and precautions.*

CASE REPORT

Successful Right Leg Revascularization Using the Pounce™ Thrombectomy System

By Bruce H. Gray, DO, MSVM

Patient Presentation

An 82-year-old woman presented with profound right leg ischemia with rest pain. Her symptoms began 6 months prior but had worsened within the past 2 months.

Diagnostic Findings

Arteriographically, the inflow (iliac, common femoral artery, profunda femoral artery) was patent. Her superficial femoral artery (SFA) was occluded with an isolated segment of patent popliteal artery with no identifiable tibial artery below the knee (Figure 1).

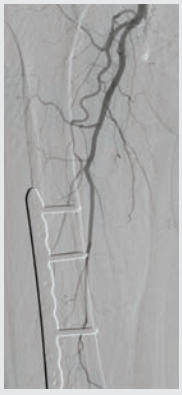

Figure 1. Arteriogram showing ostial right SFA/popliteal artery occlusion.

Treatment

The surgeon did not feel as if there was a target for surgical revascularization and was not in favor of multilevel/multivessel open thrombectomy. It was decided to proceed with use of the Pounce™ Thrombectomy System, which allowed reestablishment of flow through the SFA and popliteal artery (Figures 2-4). It also allowed us to place a catheter for thrombolysis focused on a tibial clot because the Pounce™ device is not indicated for the treatment of tibial arteries smaller than 3.5 mm.

Post Procedure Outcome

The key ingredient to treatment is flow, so improving flow to the tibial thrombus enhanced and shortened the duration of thrombolysis. Everything should focus on flow as an endpoint to limit symptoms and improve efficacy of thrombolysis. The patient did well, her symptoms resolved, and she was discharged to home on anticoagulation 1 day after initiation of therapy.

The Pounce™ Thrombectomy System was pivotal in reestablishing flow through the SFA and popliteal arteries by shortening the duration of thrombolytics and avoiding a surgical approach in an elderly patient. ■

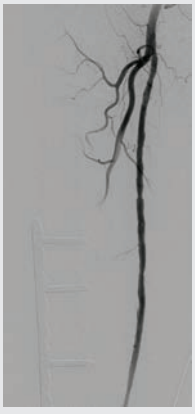

Figure 2. Arteriogram of the right SFA after use of the Pounce™ Thrombectomy System.

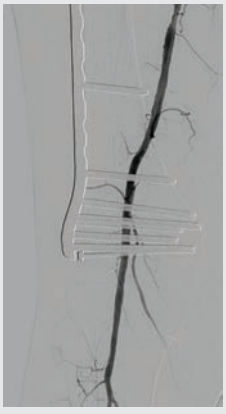

Figure 3. Arteriogram of the right popliteal artery after use of the Pounce™ Thrombectomy System.

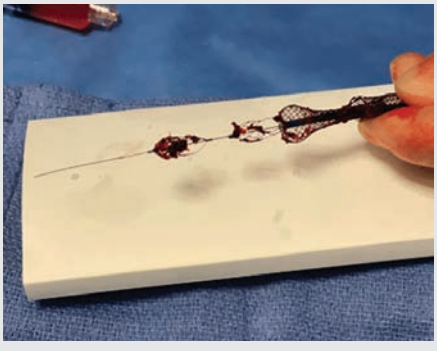

Figure 4. Clot removed after use of the Pounce™ Thrombectomy System. (Used with permission of the author.)

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Tackling Acute-to-Chronic Thrombus and Embolus

A conversation with Drs. J. Michael Bacharach and Thekla Bacharach.

J. Michael Bacharach, MD, FACC, FSCAI, MPH, specializes in vascular medicine and peripheral vascular invention at North Central Heart in Sioux Falls, South Dakota.
Thekla Bacharach, MD, specializes in vascular surgery at Sanford Vascular Associates in Sioux Falls, South Dakota.

You've now become familiar with the Pounce™ Thrombectomy System in clinical use. What do you think the device can do that other thrombectomy devices cannot?

Dr. Mike Bacharach: The Pounce™ System is excellent at removing organized thrombus, not just soft thrombus. In this respect, it outperforms any other thrombectomy device I've used. Importantly, it does this without aspiration. It's able to squeeze the liquid from the thrombus, so you're not removing a lot of normal blood along with the clot.

Dr. Thekla Bacharach: I would add that reducing the size of the clot this way allows the device to remove a large amount of organized material using only a 7 Fr sheath. That's fantastic, especially with elderly patients. Occasionally, you can get a good result with an aspiration device, but the occlusion has to be all acute material. In most cases, you can't have acute-on-chronic thrombus. If you use an aspiration device and intravascular ultrasound afterward, you see that there is still a lot of material outside the flow channel that aspiration didn't catch. I've seen no other device that removes organized thrombus the way that the Pounce™ Thrombectomy System does.

Aside from capturing organized material, what has been your experience removing large volumes of thrombus with the Pounce™ Thrombectomy System?

Dr. Mike Bacharach: Initially, we thought it would perform best for short embolic events or segments of thrombus. But early in my experience—I think it was the first or second case I did with the Pounce™ device—we were facing an occlusion of the entire superficial femoral artery (SFA) (see page 12). I was concerned about overwhelming the device with too much thrombus, but it worked fine. We placed the baskets quite far distally, close to the popliteal past the thrombus, and placed the collection funnel proximal to the thrombus. We made a few passes, identified the culprit lesion, and got the thrombus out. This exceeded all our expectations. The device is highly efficient at dehydrating clot.

I should mention that as we were dragging the clot back, we had an embolic event to the profunda femoris artery (PFA) because we were in the early learning phase. After we got the clot out of the SFA, we wired the PFA and pulled out the clot. The focal embolic event in the PFA was easily removed. We were very pleased with this case.

> "The Pounce™ System is excellent at removing organized thrombus, not just soft thrombus. In this respect, it outperforms any other thrombectomy device I've used."
> – J. Michael Bacharach, MD

You mentioned the limitations of aspiration thrombectomy in comparison to the Pounce™ Thrombectomy System. Can you describe them?

Dr. Thekla Bacharach: I'll give you an example. Before I had access to the Pounce™ Thrombectomy System, I had a case of a chronic occlusion in a gentleman who presented with a heart attack. The next day, I was asked to come in for a consult because he had a cold leg that was partially due to heart failure. I attempted to open the occluded vessel in the leg and was able to cross pretty easily, meaning it was probably acute or subacute. I used two different aspiration thrombectomy devices but couldn't really get anything out other than a flow channel. Once I had the flow channel, I was able to stent and reestablish flow. I was pleased with the result. However, a small amount of

"I've seen no other device that removes organized thrombus the way that the Pounce™ Thrombectomy System does."
– Thekla Bacharach, MD

chronic material ended up in the common femoral artery (CFA). I tried everything to suck it out because you can't stent that area, but that didn't work. At that point, I didn't have access to the Pounce™ Thrombectomy System, and I had to take this patient to the operating room. It was very frustrating. When they were putting the patient under anesthesia, he became unstable. Luckily, he did fine overall. If I had a device like the Pounce™ Thrombectomy System that could have pulled out that chronic organized thrombus, it would have been game-changing.

Dr. Mike Bacharach: This is a key point. Embolization is a major problem that occurs with all kinds of procedures. If you embolize chronic material into a vessel after you open a total occlusion, you've now taken a successful revascularization and managed to make it more complicated. Lytics are not a great option. In the past, this is when people turned to surgical rescue. Providing a percutaneous option to remove emboli makes the Pounce™ Thrombectomy System really valuable.

The Pounce™ Thrombectomy System is indicated for removal of emboli as well as thrombi. Have you used it for embolectomy unrelated to thrombus removal?

Dr. Mike Bacharach: One of our cases was an acute embolic occlusion to the arm from an atrial fibrillation in an elderly patient (see page 10). That's a case that normally would have gone to the operating room for a brachial arteriotomy and thrombectomy. We used the Pounce™ device with femoral access, came up from below, wired it, and identified the embolus. We made one pass with the Pounce™ Thrombectomy System and immediately restored circulation. We were done. We didn't have to balloon anything, didn't have to stent anything, and the patient was placed back on anticoagulation and went home the next day. No operation, no anesthesia, no incisions. Certainly, this was much more cost-effective and much easier for the patient. That's not a case that responds to aspiration thrombectomy or lytic therapy because atrial fibrillation–related occlusions are likely to be organized clot or plaque. We now have a catheter-based mechanism for these types of cases.

"Embolization is a major problem that occurs with all kinds of procedures…providing a percutaneous option to remove emboli makes the Pounce™ Thrombectomy System really valuable."
– J. Michael Bacharach, MD

Can you describe other cases you've done with the Pounce™ Thrombectomy System that would have been difficult or impossible with other percutaneous thrombectomy devices?

Dr. Mike Bacharach: One would be a superior mesenteric artery dissection that resulted in a thrombotic occlusion (see page 11). It sputtered along for a few days and the patient worsened. Normally, that's a case that would have gone to an emergent open laparotomy. Previously, there was no percutaneous device that could capture and remove that kind of thrombus. If you try to use lytic therapy and it embolizes distally, now you've made the patient worse. Without the Pounce™ Thrombectomy System, I wouldn't have taken that case on. Because I had the Pounce™ device, I was able to do it and had good results.

What has been your experience with the Pounce™ Thrombectomy System for chronic total occlusions (CTOs)?

Dr. Mike Bacharach: We've performed cases requiring recanalization of CTOs in the aortoiliac segment. This is generally uncomplicated; you can get through the occlusion above or below. These patients almost always require some form of stent. The problem is that some of these patients have been chronically occluded for a long time and the occlusions are very hard. Some patients have gone from having a CTO to a more heterogeneous mix of debris and material, some organized, some not. This is a minefield. You get through the occlusion, stent it, and if there's soft plaque, you just stent it up against the side wall. Occasionally, passing through that, you release some of the soft plaque, and where does it go? To the CFA, and now it obstructs everything. You went from being the hero to being the zero. With the Pounce™

"We were facing an occlusion of the entire SFA. I was concerned about overwhelming the device with too much thrombus, but it worked fine."
– J. Michael Bacharach, MD

Thrombectomy System, you can remove much more of this mixed, organized material before stenting, and if needed, you can remove any embolization further down without a surgical rescue. ■

***Caution**: Federal (US) law restricts the Pounce™ Thrombectomy System to sale by or on the order of a physician. Please refer to the product Instructions for Use for indications, contraindications, warnings, and precautions.*

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Disclosures: None.

CASE REPORT

Successful Removal of Brachial Embolus With the Pounce™ Thrombectomy System

By J. Michael Bacharach, MD, FACC, FSCAI, MPH, and Thekla Bacharach, MD

Patient Presentation

After discontinuation of anticoagulation for a dental procedure, an 84-year-old woman with a history of chronic atrial fibrillation developed sudden onset of a cold, painful right upper extremity. She was transferred from the neighboring community hospital and was immediately administered heparin.

Diagnostic Findings

The initial angiogram revealed a tortuous brachial artery with an embolus obstructing flow into the radial and ulnar arteries (Figure 1).

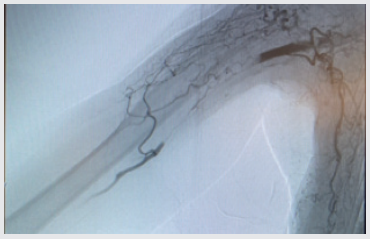

Figure 1. Right brachial embolus.

Treatment

Due to the patient's level of ischemia, intervention took place promptly after the diagnosis. The Pounce™ Thrombectomy System was prepared and one pass was made with the device. The Pounce™ Thrombectomy System successfully removed the embolus in the brachial artery (Figure 2) and reestablished flow into her radial and ulnar arteries (Figure 3). No further treatment (eg, drug-coated balloon or stent) was considered necessary.

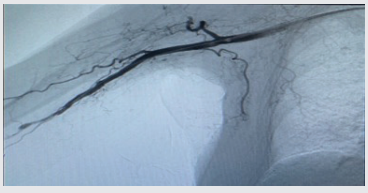

Figure 2. Embolus removed from the right brachial artery after one pass with the Pounce™ Thrombectomy System.

Post Procedure Outcome

The patient was discharged shortly after the procedure without a surgical intervention or any use of thrombolytics. ■

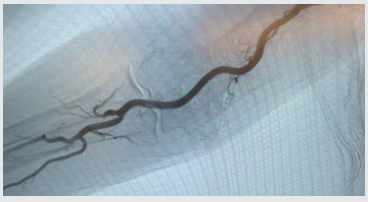

Figure 3. Flow reestablished into right radial and ulnar arteries after one pass with the Pounce™ Thrombectomy System.

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CASE REPORT

Successful Use of the Pounce™ Thrombectomy System to Remove a Superior Mesenteric Artery Thrombus

By J. Michael Bacharach, MD, FACC, FSCAI, MPH, and Thekla Bacharach, MD

Patient Presentation

A 49-year-old man presented with 3- to 4-day history of worsening abdominal pain that acutely worsened the night of presentation at the hospital. The patient was initially put on heparin and prepared for diagnostic imaging.

Diagnostic Findings

Left brachial access was obtained and an initial angiogram was taken that demonstrated an occlusion of the super mesenteric artery (SMA) (Figure 1). After the guidewire passed through the occlusion, indicating thrombus, the Pounce™ Thrombectomy System was prepared for use.

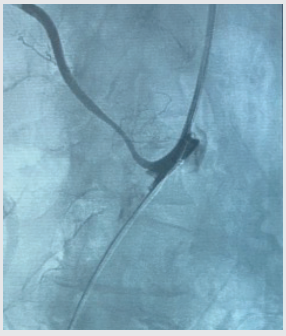

Figure 1. Left SMA obstruction.

Treatment

The clinical presentation was suggestive of an SMA dissection with subsequent thrombotic occlusion. The absence of an acute abdominal finding on examination and absence of air in the bowel wall or free air suggested that an endovascular approach could be attempted in hopes of saving the patient from an abdominal surgical procedure. Two successful passes were made with the Pounce™ Thrombectomy System, removing a moderate amount of thrombotic material (Figure 2). The vessel became patent but revealed an underlying lesion, which was stented with a 7.0 X 18 mm self-expanding stent. A final angiography was taken, revealing a widely patent SMA (Figure 3).

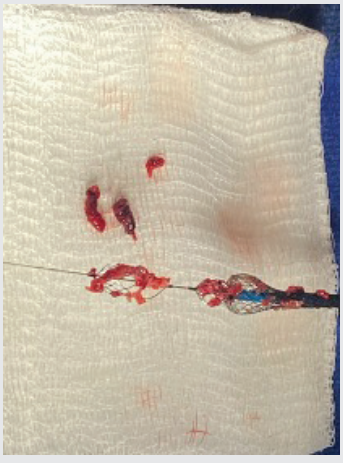

Figure 2. Thrombus removed after second pass with the Pounce™ Thrombectomy System. (Used with permission of the author.)

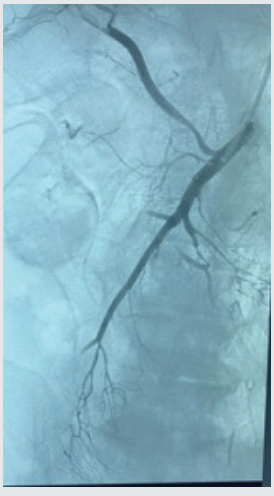

Figure 3. Widely patent SMA post procedure.

Post Procedure Outcome

The patient was discharged shortly after the intervention. The Pounce™ Thrombectomy System gave us the ability to quickly remove thrombus percutaneously and mechanically and promptly treat the underlying lesion, avoiding the need for an abdominal procedure. ■

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CASE REPORT

Successful Removal of 20 cm SFA Thrombus With the Pounce™ Thrombectomy System

By J. Michael Bacharach, MD, FACC, FSCAI, MPH, and Thekla Bacharach, MD

Patient Presentation

A 52-year-old woman presented to the emergency department with a cold and painful lower left leg. The pain started suddenly 6 days prior to presentation. Her past medical history included chronic lung disease. She was admitted to the hospital, started on intravenous heparin, and deemed to be a candidate for angiography.

Diagnostic Findings

An initial noninvasive study showed an ankle-brachial index (ABI) of 0.5 on the left side. The right common femoral artery (CFA) was accessed using ultrasound guidance, and a 6 Fr sheath was placed. An aortogram and left lower extremity angiogram were obtained, demonstrating patent infrarenal aorta and bilateral iliac arteries, CFA, and profunda femoral artery (PFA). However, the superficial femoral artery (SFA) was occluded with thrombus just beyond the origin, with reconstitution of the distal SFA via PFA collaterals (Figure 1). The lower leg was perfused with two-vessel runoff via the anterior tibial (AT) and peroneal arteries.

Treatment

A 7 Fr sheath was introduced into the right femoral access and advanced to the left CFA. From there, the SFA occlusion was crossed using a .018 Navicross® Support Catheter and an .018 Glidewire Advantage® Peripheral Guidewire. The Navicross® Support Catheter was removed from the vasculature, and the Pounce™ Thrombectomy System, which consists of a delivery catheter, a basket wire, and a funnel catheter, was prepared. The delivery catheter was advanced past the thrombus, and the basket wire was then advanced through the delivery catheter and deployed in the mid popliteal artery. The funnel catheter was advanced to the ostium of the SFA and deployed. The baskets were then pulled back along the length of the SFA (approximately 20 cm) into the funnel, and the funnel and baskets were removed through the 7 Fr sheath.

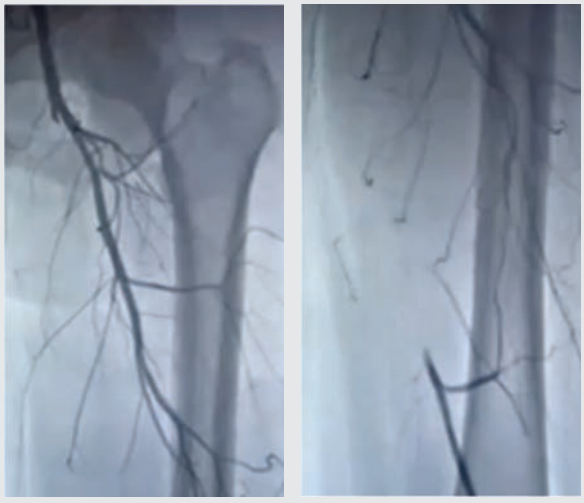

Figure 1. Occluded SFA with thrombus.

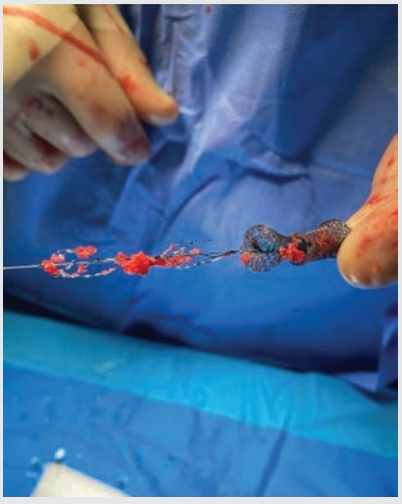

Figure 2. SFA thrombi and emboli removed after one pass. (Used with permission of the author.)

The first pass removed a significant amount of well-organized, firm thrombi and emboli (Figure 2). After this initial pass, an angiogram revealed a widely patent proximal SFA with a high-grade lesion in the mid portion of the SFA. A small section of the thrombus embolized into a large PFA branch due to the funnel being positioned proximal to the ostium of the PFA (Figure 3). The thrombus was easily crossed with an .018 Glidewire Advantage® Peripheral Guidewire, and the delivery catheter was placed into the mid PFA. The basket wire and funnel catheter were deployed in the mid PFA and ostial PFA, respectively.

The baskets were retracted into the funnel, the system was externalized through the sheath, and the clot was successively removed from the body. Angiography demonstrated normal PFA branches with no evidence of distal embolization (Figure 4). One final pass was performed using the Pounce™ Thrombectomy System to further clean out the SFA. Repeat angiography revealed complete thrombus removal in the SFA, with evidence

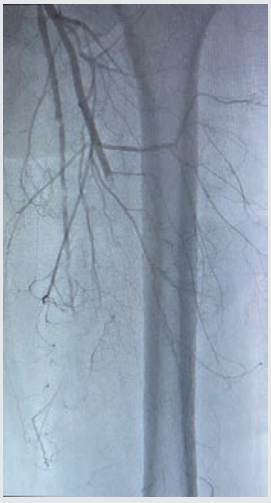

Figure 3. PFA embolus.

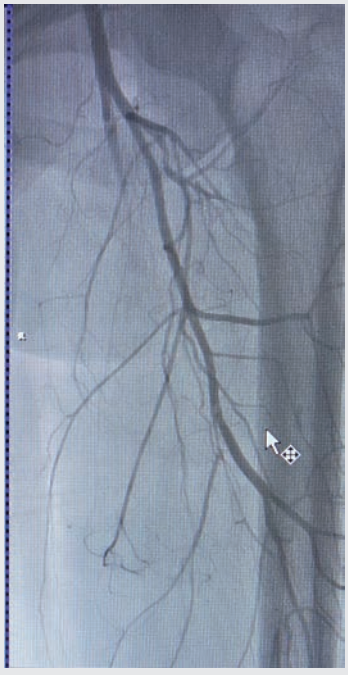

Figure 4. Patent PFA after one pass.

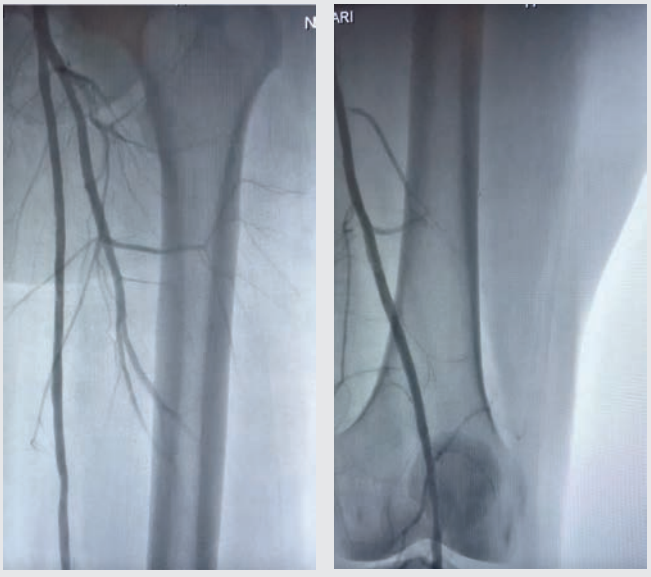

Figure 5. Final angiogram demonstrates a widely patent left CFA, SFA, and PFA.

of a mid SFA atherosclerotic lesion that appeared to have been the etiology of the arterial thrombosis. A 5 mm X 250 mm IN.PACT™ Admiral™ Drug-Coated Balloon was deployed and inflated at the site of the lesion. A final complete angiogram was conducted, demonstrating a widely patent left CFA, SFA, and PFA (Figure 5). The left popliteal artery was patent with two-vessel runoff to the foot via the AT and peroneal with no evidence of distal embolization.

Post Procedure Outcome

The patient was discharged home 12 hours after the procedure with dual antiplatelet therapy and encouraged to quit smoking. The follow-up arterial duplex ultrasound 1 month later demonstrated no evidence of stenosis with a normalization of the ABI to 1.0 on the left side.

The Pounce™ Thrombectomy System provided a first-line treatment for the long-length thrombotic occlusion in the diseased SFA. The quick restoration of flow both in the SFA and PFA avoided the need for thrombolytic therapy, further surgical revascularization, or any intensive care unit bed time. ■

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Have We Found the Holy Grail for Thromboembolectomy?

A conversation with Dr. Gary Ansel, inventor of the Pounce™ Thrombectomy System.

Throughout his 36 years as a physician, **Gary Ansel, MD**, has focused on overcoming challenges in endovascular medicine—not only as a renowned interventional cardiologist and clinical investigator but as a medical device inventor and entrepreneur. Among his medical device brainchildren are the Flexor® Ansel Guiding Sheath, one of the world's most-utilized interventional sheaths, and the Pounce™ Thrombectomy System, recently introduced by Surmodics, Inc. for removal of thrombi and emboli from the peripheral arterial vasculature. We spoke with Dr. Ansel about why he set out to design and develop what became the Pounce™ Thrombectomy System and why he believes it will have a profound impact on patient outcomes and clinical practice.

You've said that new medical devices must provide a really good answer to a big need. What big need does the Pounce™ Thrombectomy System address?

We need to make it easier for more physicians, across specialty lines, to remove arterial thrombi and emboli right on the angiographic table, without transferring patients to tertiary care centers. I saw this need very clearly when I was the Health System Medical Chief for the vascular program at OhioHealth (Columbus, Ohio). When we can't remove clot during the initial percutaneous procedure, the patient typically undergoes thrombolysis, permanent implantation of a stent, or referral for open surgery for thrombectomy or bypass. All these events add time and cost and lead to increased risk of complications and death.

In practical terms, we've long needed a stand-alone thrombectomy device that is easy to use and can provide safe, single-session removal of the full breadth of arterial thrombi and emboli interventionalists encounter in patients in real-world settings. By that, I mean mixed, organized thrombus, not just the soft stuff. That's what the Pounce™ Thrombectomy System does.

How does the Pounce™ Thrombectomy System work?

It's simple. Basically, I wanted a percutaneous device that could do what a Fogarty® catheter does but without the need for a surgical incision. With the Pounce™ System, you percutaneously place the basket wire distal to the clot, place the collection funnel proximal to the clot, pull back on the basket wire, collect the thrombus in the funnel, and pull out the clot (Figure 1). The Pounce™ Thrombectomy System is designed to macerate and dehydrate the clot, making it easy to remove large quantities of material through a small 7 Fr sheath.

> "We need to make it easier for more physicians, across specialty lines, to remove arterial thrombi and emboli right on the angiographic table, without transferring patients."

Where do you think other thrombectomy devices fall short?

In my experience, aspiration-based thrombectomy devices only work well on soft thrombus. Tougher clots are a real problem for them. That's why aspiration-based devices are rarely a stand-alone solution. The more aggressive devices, which also handle atheroma, are associated with increased risk of complications such as perforation.[1] Even today, most recommendations call for open surgery for an arterial embolus,[2] despite the minimal invasiveness and time savings of endovascular techniques. I believe this reflects the historical inadequacies of the percutaneous devices we've had available.

What clinical data have been published or presented on the Pounce™ Thrombectomy System to date?

Data on the first 20 consecutive patients were presented at the Charing Cross (CX Symposium International) 2022 meeting.[3] The patients included acute onset to chronic symptoms up to 8 months.

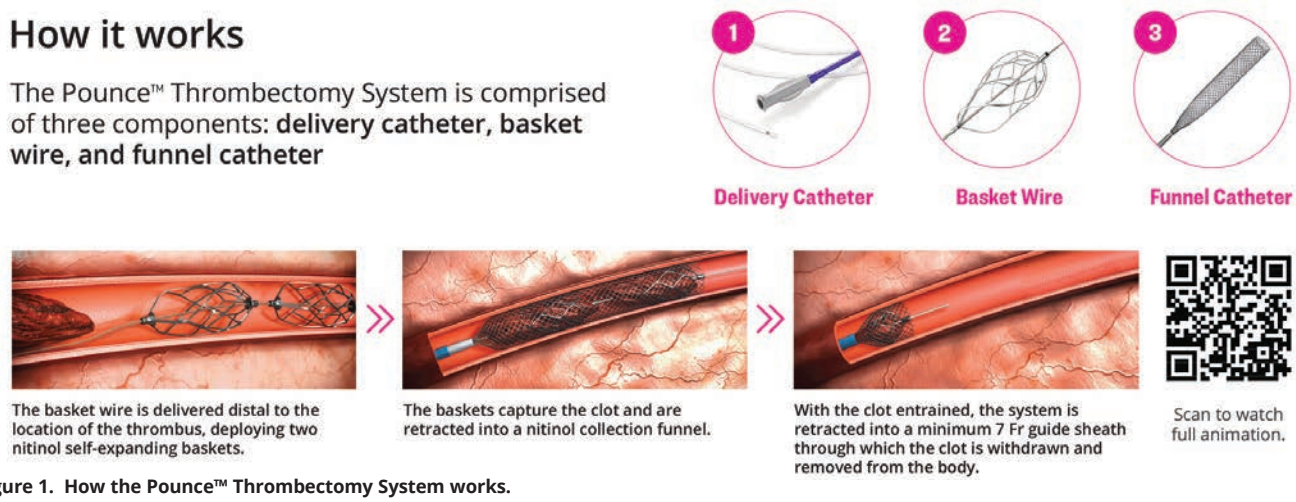

Figure 1. How the Pounce™ Thrombectomy System works.

"I wanted a percutaneous device that could do what a Fogarty® catheter does but without the need for a surgical incision."

The length of occlusion ranged from 5 to 300 mm. There was 100% on-table target lesion success, and the average procedure time was less than 90 minutes. No adjunctive thrombectomy treatments were required for thrombus treatment in the target vessels. Really very impressive results, especially when you consider that these initial, consecutive cases included any physician learning curve for the device.

What else have you learned from observing the Pounce™ Thrombectomy System in clinical use?

What's been really surprising is how effective we've seen Pounce™ work on thrombotic chronic total occlusions, the longest so far being 8 months. As a strategy, we've found that if a hydrophilic wire easily traverses an occlusion, which signifies a soft thrombotic core, physicians have been able to remove most of the angiographic occlusion made up of chronic thrombus, thereby shortening the treatment area due to the offending atherosclerotic lesion. The underlying atherosclerosis can then be simply treated with traditional means such as drug-coated balloons or stents with minimal concern for embolization. Honestly, the Pounce™ Thrombectomy System has exceeded my design expectations.

What were your original design specifications for the Pounce™ Thrombectomy System?

There were several areas that needed to be addressed. First, it had to be safe and simple to use by the breadth of interventional physicians and consistently provide on-table results without the need for additional devices, thrombolysis, or open surgical cutdowns. As an interventionalist myself, I felt that we should have a simple device that typically requires less than an 8 Fr sheath and does not aspirate or remove blood (Figure 2). I was also tired of the complex process of getting a capital purchase approved. I wanted something you could just grab and use without a console to be rolled into the room.

These were lofty goals, and we've been through a lot of blood, sweat, and tears to get to where we are now. The path from concept to market for this device began around 2009, and it wasn't for the faint of heart.

Why did you set a goal of less than 8 Fr size?

My experience is that there is not much difference between a 6 Fr and a 7 Fr sheath for crossing an aortic bifurcation or in terms of closure device outcomes. In my experience, once you go to 8 Fr, you reduce the success rate and increase the complication rate for your arterial procedures. As you increase French sizes, you also decrease the number of patients that can undergo a given procedure, because some patients can't tolerate a bigger sheath due to vessel diameter and aortic bifurcation angulation. That's why I thought 7 Fr was an important goal from the outset.

Explain why you were opposed to using aspiration.

Blood loss has been demonstrated to be associated with poorer patient outcomes. Often, the patients we treat also have anemia.

"In my experience, aspiration-based thrombectomy devices only work well on soft thrombus. Tougher clots are a real problem for them."

Model Number	Sheath Compatibility	Guidewire Compatibility
PTS-0607-7F135	≥ 7 Fr	0.035" (0.889 mm)

Working Length	Basket Diameter	Funnel Diameter
135 cm	6 mm	7 mm

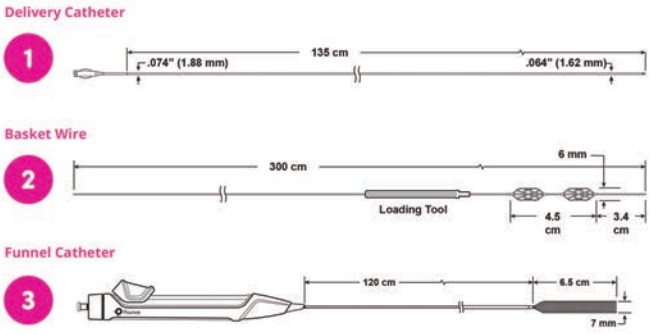

Figure 2. Pounce™ Thrombectomy System product specifications.

When removing significant amounts of blood during an aspiration thrombectomy, an operator must balance time of aspiration, and thus blood loss, with needed effect. Clearly, transfusions are undesirable because of their inherent risks, and they're a quality marker for a hospital. Significant anemia may take a month or more to resolve and patients feel terrible during that time—not desirable for patient experience surveys, which have become more and more important.

What was the biggest challenge you faced in meeting the goals you set for the Pounce™ Thrombectomy System?

Being true to the design criteria I developed, especially in striking the right balance between device size and thrombotic mass removal. When the team developed a funnel that could macerate and dehydrate the thrombus, the amount of clot needing removal decreased significantly. The funnel is the secret sauce.

Why two baskets on the basket wire and not one?

I wish I could tell you that two baskets was the first thought. Again, we were trying to mimic the approach of a Fogarty® catheter. Through trial and error, we found that efficiency dramatically improved with the second basket.

The Pounce™ Thrombectomy System is a fixed-wire system. What has been the early experience with crossing and re-crossing thrombotic occlusions?

I can understand why some physicians may be concerned about wire loss, but our experience has shown that after the first pass, subsequent wire passage becomes easier because you've developed a channel for the subsequent guidewire passage if needed. This is what Dr. Bruce Gray's team found in their first 50 cases using the Pounce™ Thrombectomy System (see Dr. Gray's article on page 3 of this supplement).

> "We've been through a lot of blood, sweat, and tears to get to where we are now."

What has been the early experience with embolization with the Pounce™ Thrombectomy System?

The dual baskets and double-wire funnel work together and were designed to have a low risk of embolization. Distal embolization has not been an issue to date.

COVID-19 has placed a lot of stress on health care systems. How does the Pounce™ Thrombectomy System fit into this picture?

Even before COVID, health care systems were facing a workforce problem, with projected shortages of physicians and staff. Then COVID came along, and we were faced with an acute shortage of technologists and nurses. This has led to disruption of traditional support teams and frequent use of contract personnel, which can really impact complex procedures such as acute limb ischemia. All these conditions make it incumbent for new medical devices to be simple and straightforward to use, with short learning curves. We've also seen that hospitals have become reluctant to invest in devices that require capital purchase and ongoing service agreements. The Pounce™ Thrombectomy System requires no capital purchase and was designed to be inherently simple to use and easily understood by the physician and the staff. ■

Please see page 23 for references.

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Disclosures: Consultant for Boston Scientific, Genesis Medtech, Medtronic, and Surmodics.

CASE REPORT

Treatment of Focal Arterial Embolus With Stand-Alone Mechanical Thrombectomy

By John A. Phillips, MD

Patient Presentation

An 82-year-old woman presented with symptoms of acute-onset pain and paresthesia. The patient's initial vascular exam was abnormal. The patient had a complex prior medical history, including chronic kidney disease, atrial fibrillation, heart failure with preserved ejection fraction, type 2 diabetes, hypertension, and dyslipidemia.

Diagnostic Findings

After the abnormal vascular exam, an angiogram revealed a focal embolic occlusion of the right common femoral artery (CFA) (Figure 1). A noninvasive exam showed an ankle-brachial index (ABI) of 0 on the right leg and 1.26 on the left leg. A 5 Fr, 10 cm Pinnacle® Destination® Sheath was placed, and an arteriogram was obtained, which confirmed an atrial fibrillation embolus in the right leg CFA.

Treatment

The patient was immediately started on heparin intravenously to prepare for an intervention. Left groin access was obtained by micropuncture, and a 7 Fr, 45 cm Flexor® Ansel Guiding Sheath was placed contralaterally into the right CFA.

The Pounce™ Thrombectomy System was prepared and a .035 Magic Torque™ Guidewire was used to cross the lesion. The Pounce™ delivery catheter was placed distal to the embolus, the Pounce™ basket wire was delivered through the delivery catheter into the mid superficial femoral artery (SFA), and the Pounce™ funnel catheter was advanced and deployed within the CFA with some draping into the bifurcation profunda SFA to clear the distal CFA.

The baskets were then pulled back into the funnel (Figure 2), capturing the embolus, and the device was removed through the guiding sheath. After cleaning the Pounce™ System, the baskets and funnel were deployed again in similar positions and another pass was made. Another angiogram was obtained (Figure 3), showing complete removal of the embolus in the two passes (Figure 4). No ancillary treatments (additional thrombectomy device, drug-coated balloon, or stent) were used.

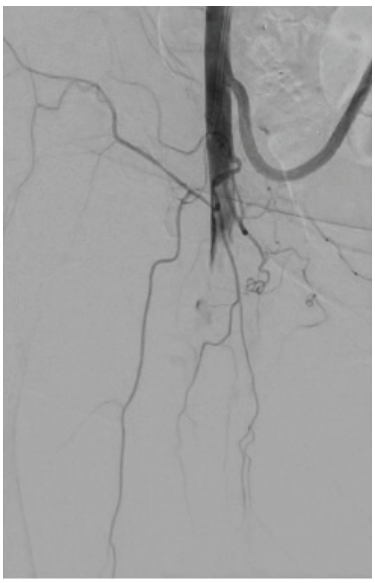

Figure 1. Pre-procedure angiogram of the right CFA.

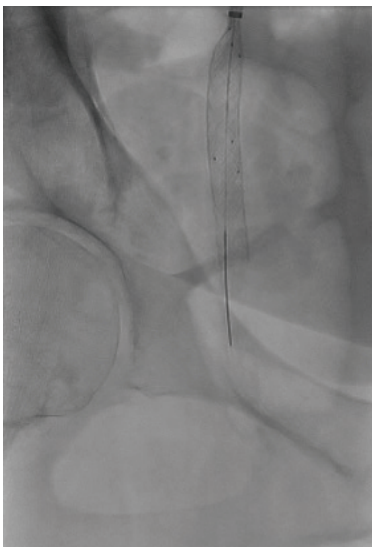

Figure 2. The Pounce™ Thrombectomy System basket retracted into funnel in the right CFA.

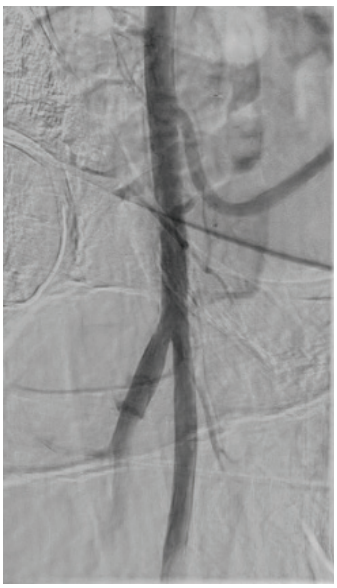

Figure 3. Post procedure angiogram of the right CFA.

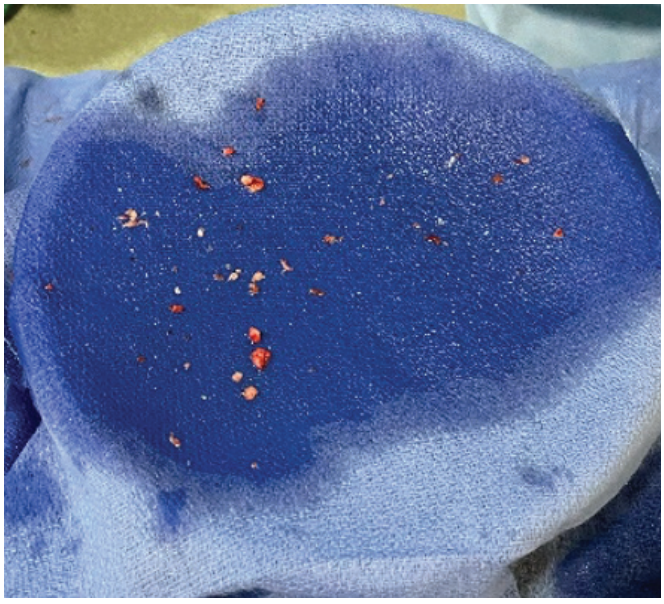

Figure 4. Embolus removed after two passes with the Pounce™ Thrombectomy System. (Used with permission of the author.)

Post Procedure Outcome

The patient was transferred back to the hospital floor symptom-free. Noninvasive studies performed after the procedure showed improvement of the ABI to 1.05 on the right leg and 1.36 on the left leg.

The Pounce™ Thrombectomy System provided prompt, on-table restoration of arterial flow for a patient with an embolic occlusion of the right CFA. No thrombolytics or other adjunctive therapies were used during the procedure.

I always worry about treating a thrombus in patients with underlying peripheral artery disease because their arteries may not be healthy. Having said that, I found the Pounce™ Thrombectomy System to be fairly atraumatic. With this device, I believe we now have an endovascular option for arterial thromboembolic phenomena that previously required surgical intervention. ■

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Disclosures: Bard, Boston Scientific, Cardiovascular Systems Inc., Cook, Medtronic, Philips, and Surmodics.

CASE REPORT

Efficient Removal of Lower Extremity Arterial Thrombus With the Pounce™ Thrombectomy System

By Joseph Griffin, MD, RVT, FACS

Patient Presentation

A 46-year-old woman with borderline hypertension and diabetes noticed her right leg suddenly became cold and numb and caused her to fall to the ground while walking. She immediately called an ambulance and was brought to the hospital.

Diagnostic Findings

Upon an initial consultation, the patient was deemed to have a bounding 4+ pulse of the right common femoral artery (CFA) with nonpalpable pulses of the right popliteal and pedal arteries along with a normal left-sided pulse examination. Her ankle-brachial index values were 0.34 on her right and 1.0 on her left, and the remaining clinical examination was otherwise normal. She was started on a heparin drip and brought into the cath lab.

Her left CFA was accessed using an ultrasound puncture technique. An angiogram was taken utilizing a 5 Fr sheath with 5 Fr Accu-Vu Omni™ Flush sizing catheter and a .035 stiff angled Glidewire™. Initial imaging showed an embolus at the distal CFA, occluding the profunda and superficial femoral artery (SFA). There was a large amount of embolic burden in the proximal and mid SFA with a secondary occlusive embolus at the location of the tibial trifurcation (Figure 1), with the distal SFA and popliteal artery remaining patent.

Treatment

The initial strategy was to use the 50 cm treatment zone EKOS™ Endovascular System and perform catheter-directed thrombolysis. The 5 Fr diagnostic sheath was exchanged for a 6 Fr, 45 cm length Pinnacle® Destination® Guiding Sheath. The distal tip of the EKOS™ catheter was placed in the mid posterior tibial artery and the proximal end within the CFA. Catheter-directed thrombolysis was then performed. The patient was admitted to the intensive care unit with a 1 mg/min tissue plasminogen activator (tPA) drip overnight. The patient was reexamined 24 hours later, and a repeat angiogram was obtained. There was minor improvement in the SFA and profunda artery. The popliteal artery also had minor

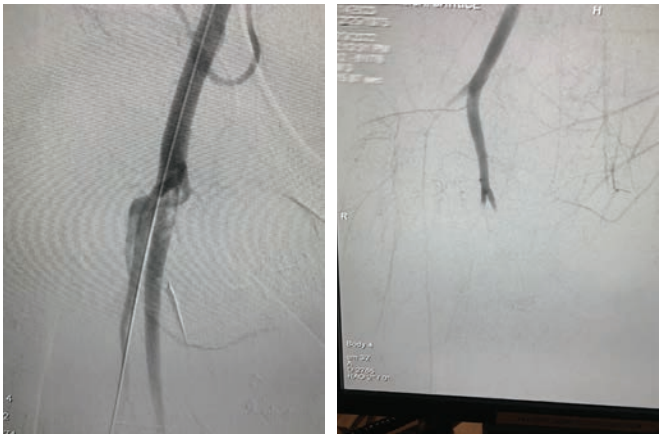

Figure 1. Baseline angiograms showing embolic burden in the SFA and secondary embolus in the tibial trifurcation.

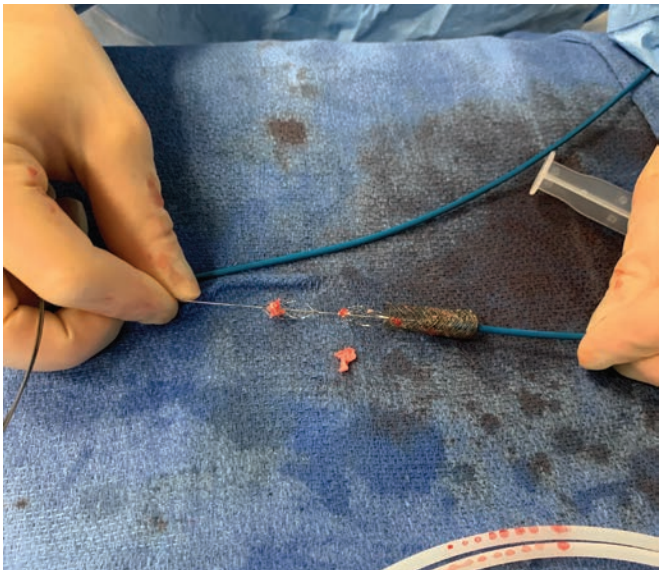

Figure 2. Embolus removed from the SFA. (Used with permission of the author.)

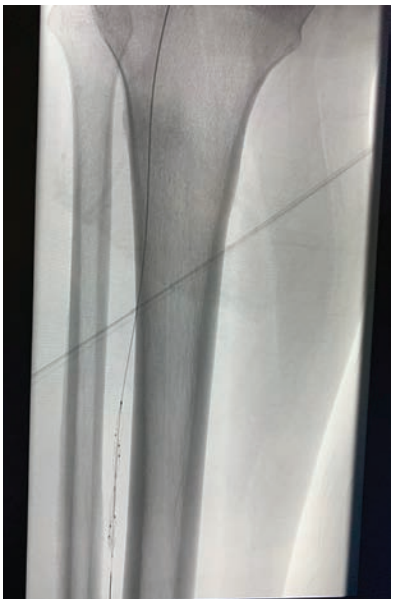

Figure 3. Pounce™ System baskets in distal posterior tibial artery.

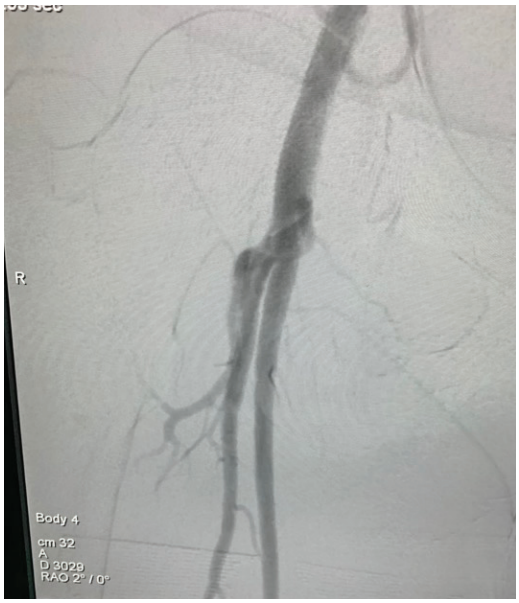

Figure 4. Patent SFA and profunda artery.

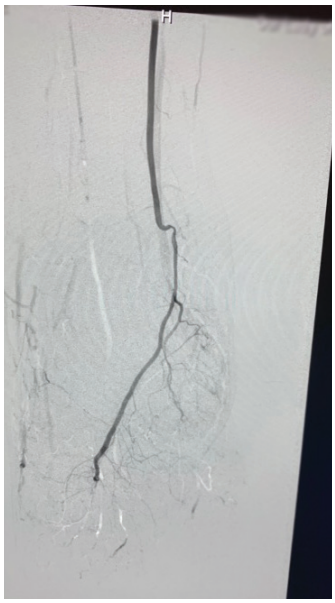

Figure 5. Patent peroneal and posterior tibial runoff into the foot.

improvement, while the three tibial vessels were still occluded at the trifurcation. Therefore, the patient was continued on tPA for another 24 hours at 1 mg/min across the various occluded vessel segments. At the 48-hour mark, repeat angiography showed no improvement.

A 6 Fr QuickClear™ Mechanical Thrombectomy System was passed into the profunda and was able to clear out the thrombus. The device was then passed three times through the SFA but was not able to remove the embolus. The physician was in-serviced on the Pounce™ Thrombectomy System for the first time.

The procedural sheath was upsized to a 7 Fr, 45 cm Pinnacle® Destination® Guiding Sheath. The basket wire was placed in the mid SFA via the delivery catheter, and the funnel catheter was placed in the distal CFA. The baskets were pulled back into the funnel, collecting the entire residual embolus in the SFA, and the device assembly was removed from the body through the procedural guide sheath (Figure 2). The peroneal artery was then wired, the basket wire was placed in the mid peroneal artery, and the funnel catheter was placed in the distal popliteal artery. After a single pull of the basket wire, the thrombus was successfully removed. Finally, the posterior tibial artery was cannulated, the basket wire was placed in the distal posterior tibial artery (Figure 3), and the funnel catheter was placed in the distal popliteal artery. After one pull, the thrombus in the posterior tibial artery was removed.

Post Procedure Outcome

A final angiogram was taken to show patency of the profunda, SFA (Figure 4), peroneal, and posterior tibial arteries with runoff into the foot (Figure 5).

After alternative technology and thrombolysis were unsuccessful, the simplicity of the Pounce™ Thrombectomy System allowed the physician to quickly learn the system and clear out three vessels on three separate passes. Because of the patient's morbid obesity, the physician wanted to avoid open embolectomy and subsequent surgical incisions breakdowns and infections. Without the Pounce™ Thrombectomy System, the patient would have been sent to the operating room, given that all other options had failed to remove the obstruction. The Pounce™ Thrombectomy System was able to efficiently and quickly remove the organized clot burden, helping to avoid additional tPA administration as well as providing a durable alternative to open embolectomy. ■

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CASE REPORT

Novel Use of the Pounce™ Thrombectomy System for Acute Left Axillary Artery Thrombosis

By Joseph Campbell, MD

Patient Presentation

A 71-year-old woman with a prior medical history of hypertension, hyperlipidemia, type 2 diabetes, and obstructive sleep apnea developed an abrupt onset of ischemic rest pain and numbness in her left hand and fingers. The emergency department obtained a CTA, which revealed a proximal axillary artery stenosis with a significant, moderate amount of proximal and large distal thrombus. She was started on intravenous heparin and prepped for a diagnostic intervention.

Diagnostic Findings

Right femoral access was obtained with a 5 Fr sheath and a .035 stiff angled Glidewire Advantage® Peripheral Guidewire. Arch angiography was performed with a pigtail catheter, which demonstrated a type 1 arch with no pathology. The pigtail catheter was then switched out for a 5 Fr JR4 catheter, which selectively engaged the left subclavian artery for diagnostic angiography. Diagnostic angiography revealed severe stenosis with presence of thrombus in the proximal left axillary artery (Figure 1). The procedural strategy was planned to initially remove the thrombus, look to dilate the target vessel using a drug-coated balloon (DCB), and then place a stent.

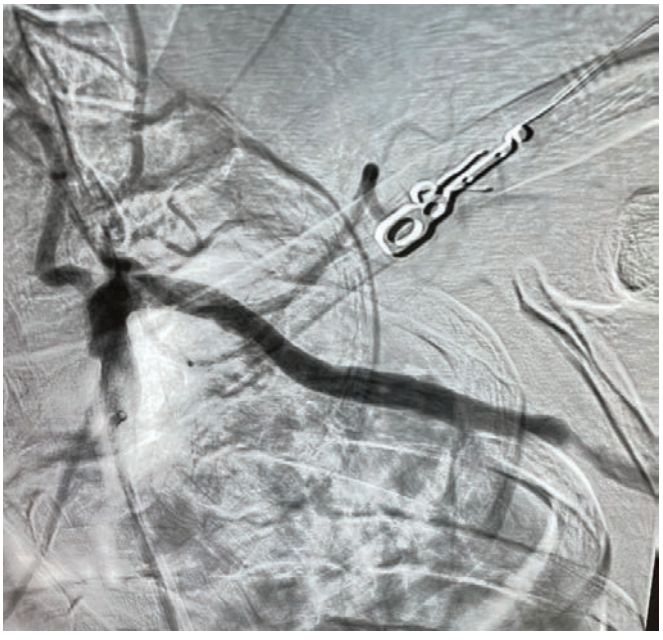

Figure 1. Diagnostic angiography from left subclavian artery.

Treatment

The 5 Fr JR4 catheter was replaced with a 7 Fr, 90 cm Flexor® Shuttle® Guiding Sheath. The thrombus was then crossed with a .035 stiff angled Glidewire Advantage® Peripheral Guidewire. The Pounce™ Thrombectomy System was prepped. The delivery catheter traversed the .035 stiff angled Glidewire Advantage® Peripheral Guidewire, the Glidewire was removed, and the basket wire was then delivered and positioned distal to the thrombus. The funnel catheter was inserted, and the funnel was positioned distal to the vertebral artery.

After one pull back of the basket wire into the funnel (Figure 2), significant debris was removed (Figure 3). A .014 wire was placed, and an intravascular ultrasound was completed that

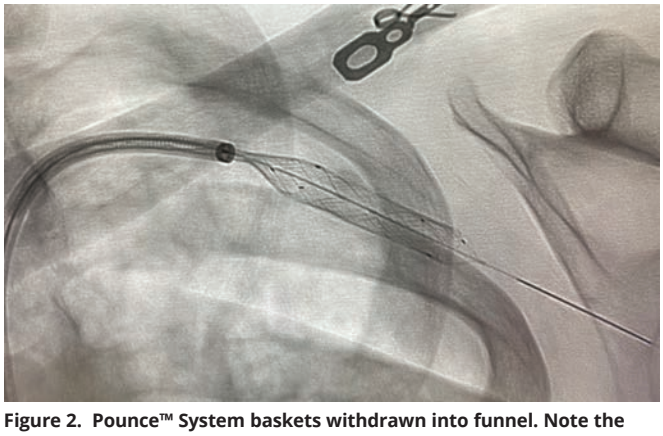

Figure 2. Pounce™ System baskets withdrawn into funnel. Note the distal basket markers located at the edge of the funnel.

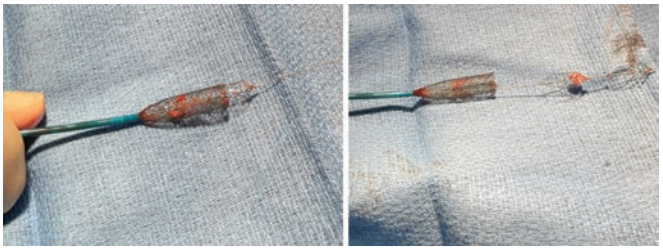

Figure 3. Clot removed after one Pounce™ System pass. (Used with permission of the author.)

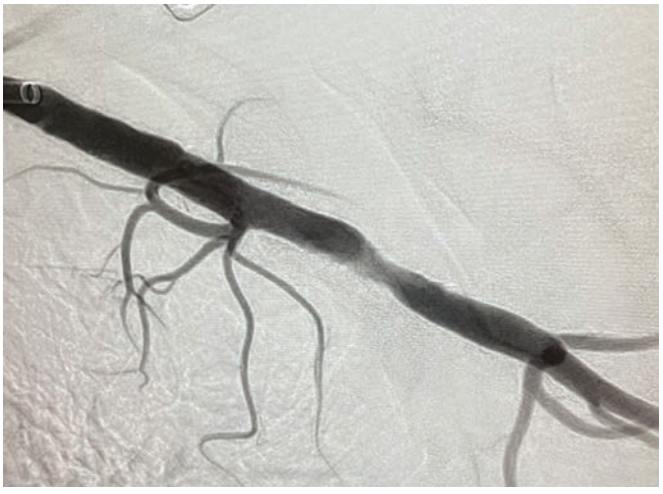

Figure 4. Post Pounce™ System pass.

demonstrated ruptured plaque and minimal wall-adherent thrombus remaining (Figure 4). The patient underwent a dilatation with a 6 mm X 40 mm IN.PACT™ Admiral™ Drug-Coated Balloon Catheter that was inflated to 7 atm. Final angiography was completed, showing minimal residual stenosis and normal runoff to the hand (Figure 5). The patient's symptoms reversed on the table, revealing normal palpable radial pulses. The total procedure time was 55 minutes from access to closure.

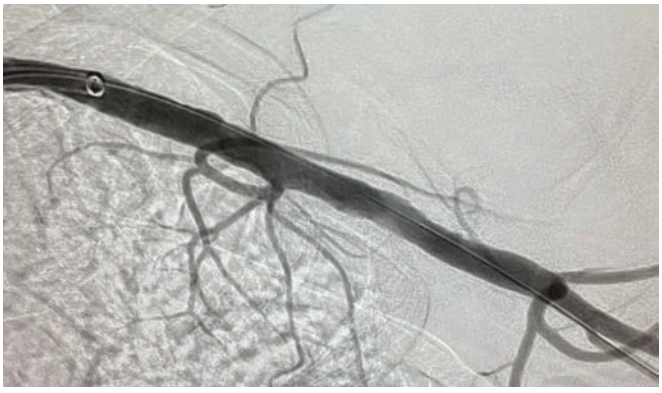

Figure 5. Post DCB final angiography.

Post Procedure Outcome

The patient was discharged the next morning on dual antiplatelet therapy after a normal motor and sensory examination.

The Pounce™ Thrombectomy System allowed for a complex clinical presentation to be treated simply and easily without the need for a brachial cutdown. There was no evidence of distal embolization. The patient returned to normal functional activity with no need for wound care or physical therapy. ■

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Disclosures: None.

Indications/Contraindications:

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 not intended for venous applications
- The device is not intended to be deployed in native vessels smaller than 3.5 mm or larger than 6 mm
- 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

References (from pages 14-16)

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Pounce™ Thrombectomy

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

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