Indigo™ Percutaneous Mechanical Thrombectomy System

Experts discuss the effectiveness of this system in the rapid removal of emboli and thrombi from vessels of the peripheral vasculature.

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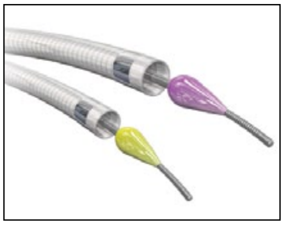
Existing endovascular options for lower extremity and visceral arterial thromboembolism face the challenges of limited trackability, vessel injury, and incomplete revascularization. At the forefront of advances in catheter materials and technology, Penumbra, Inc. recently introduced the Indigo™ System for mechanical thrombectomy in the periphery. The Indigo System is designed to address the limitations of conventional technology, bringing greater trackability and the power of large-bore catheters and the Indigo pump to the peripheral vasculature.

Lower extremity arterial thromboembolism or vessel thrombosis are major concerns, as they can block blood flow to the limbs.[1] This blockage can lead to acute and subacute limb ischemia.[2] Sudden loss or a decrease in limb perfusion that threatens limb sustainability carries a high threat of mortality (15%–20% 1-year mortality rate) and limb amputation (10%–15% in-hospital amputation rate) despite existing methods of treatment.[2]

With advances in endovascular techniques, including atherectomy and the greater use of stents and stent grafts in the peripheral arterial circulation, the chance of device occlusion/thrombosis or embolization during such procedures has greatly amplified. Atherectomy is associated with a substantial rate of distal embolization.[3] Rapid revascularization is critical to diminishing the patient's risk of long-term injury, amputation, or death when devices fail or runoff vessels are occluded during procedures. Although thrombolysis and surgical embolectomy are established therapies for these events, percutaneous devices are now available for the mechanical extraction of thrombus and distal emboli. These devices, such as the Penumbra Indigo System, are playing a larger role in the treatment of acute limb ischemia and in the rapid removal of atheroemboli when they occur during procedures.[1]

In January 2008, the Penumbra System® became available in the United States for the revascularization of occluded intracranial vessels in patients with acute ischemic stroke.



The Penumbra System used vacuum aspiration as its primary mechanism of action. A flexible, large-bore catheter was delivered to the site of occlusion, and aspiration was directly applied to the lesion itself. To maintain lumen patency of the large-bore catheter, a Penumbra Separator™ was used at the tip of the catheter to continually break up the clot once ingested under aspiration. The Separator allowed continuous thrombectomy under constant aspiration supplied by an external vacuum pump. Penumbra's latest innovation in stroke is the ACE™ device, which has demonstrated high rates of complete revascularization and has made Penumbra the market leader in stroke.

Recognizing the utility of this device, operators that were familiar with the Penumbra System for stroke care started using it in the peripheral vasculature for acute thrombotic and embolic events. This enabled physicians to treat lesions that were previously inaccessible with conventional technology. In 2014, Penumbra launched the Indigo System specifically for this application, redefining below-the-knee mechanical thrombectomy.

The Indigo System enables the removal of emboli and thrombi from vessels of the peripheral arterial system. Unlike thrombolysis, which often requires prolonged infusion times, Indigo is able to provide rapid restoration of flow to thrombosed vessels. It can also be used for revascularization when thrombolytic therapy and surgery are contraindicated. This is achieved by utilizing Penumbra's proprietary catheter-tracking technology and patented Separator technology for mechanical clot engagement. This 6 F–compatible percutaneous system is available in 6-F and 4-F catheter options with 132- to 150-cm catheter lengths. Indigo has the largest extraction lumen designed for vessels below the knee, with smaller and longer catheter options for hard-to-reach distal extremities. The following cases demonstrate rapid revascularization times (< 15 minutes) and acceptable safety profiles.

Case 1: Failed Thrombolysis for Embolic Occlusion of the Popliteal Artery

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When treating patients with acute or subacute arterial occlusions, there are times when thrombolytics are contraindicated or fail to lyse the thrombus. In such cases, the Indigo System has been a very effective tool, allowing us to reopen occluded vessels by successfully aspirating thromboemboli in a variety of difficult circumstances.

CASE REPORT

An 82-year-old woman with a history of atrial fibrillation developed class IIa acute limb ischemia. Initial angiography showed a popliteal artery occlusion and poor distal runoff, with thrombus in the proximal peroneal artery. It was elected to treat the patient with thrombolytic therapy, and a tissue plasminogen activator infusion was initiated through a multisidehole catheter placed across the occlusion.

Angiography was again performed after 24 hours of thrombolytic therapy. The popliteal artery was widely patent, but the distal vasculature was still poor, with diseased one-vessel peroneal runoff. It was elected to continue the lytics for an additional 12 to 24 hours in the hopes that the runoff would improve.

Unfortunately, after 40 hours of thrombolytics (Figure 1), the popliteal artery had rethrombosed for reasons that were unclear. Due to concerns about the risks associated with prolonged thrombolytics, we attempted a mechanical approach. Figure 2 shows the larger 6-F Indigo catheter and Separator in place as the system is slowly passed through the thrombus. After reopening the popliteal artery, the longer, 4-F Indigo catheter was used coaxially with the Separator to open the peroneal artery. After mechanical thrombectomy, percutaneous transluminal popliteal angioplasty was performed to treat a moderate residual stenosis. The final angiogram (Figure 3) showed that all of the thrombus was successfully removed, and diseased one-vessel runoff was preserved, with no distal embolization during the procedure.

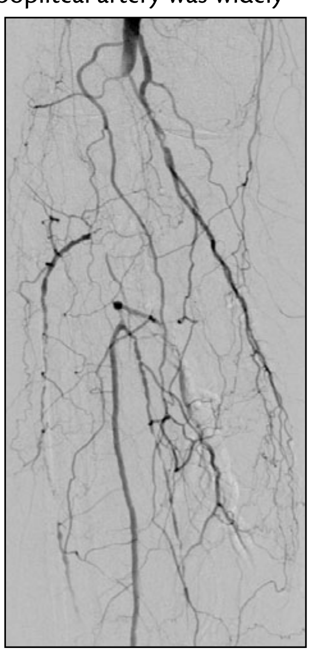

Figure 1. Thrombosed popliteal artery after 40 hours of lysis.

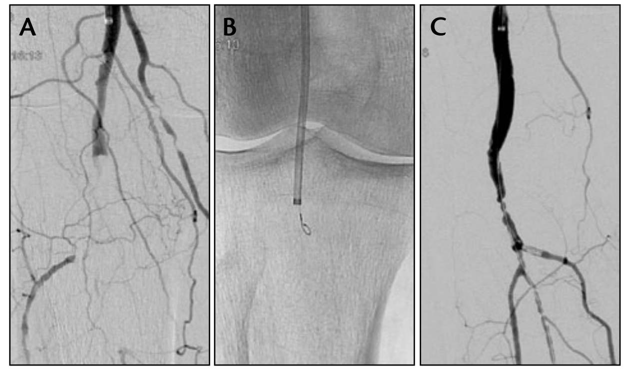

Figure 2. The 6-F Indigo catheter and Separator wire working in the popliteal artery.

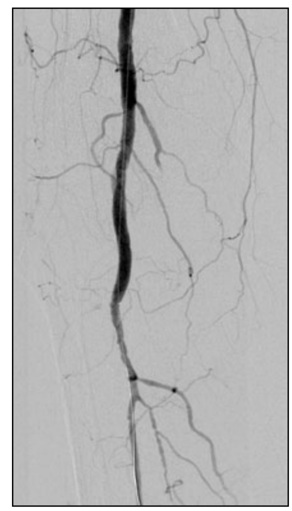

Figure 3. Final angiogram showing successful removal of thrombus.

Case 2: Distal Embolization During SFA CTO Recanalization

Today, there is an ever-growing array of endovascular techniques that can be used to treat occlusive disease causing claudication or critical limb ischemia. In order to perform more aggressive endovascular procedures safely, it is imperative to be completely equipped with the right set of tools to deal with any complications that may arise. In this case report, Indigo enabled the rapid removal of debris and restored flow following a reentry procedure.

CASE REPORT

A 70-year-old woman with chronic severe lower extremity claudication presented for endovascular treatment after being managed medically for many years. Initial angiography demonstrated a densely calcified superficial femoral artery (SFA) with a chronic total

Figure 1. The occluded SFA (A) with normal three-vessel run-off (B, C).

occlusion in its mid-portion (Figure 1). Note the normal three-vessel runoff with a widely patent distal posterior tibial artery (the dominant runoff vessel into the foot). The lesion proved difficult to cross, necessitating a subintimal approach using a reentry device.

After percutaneous transluminal angioplasty of the SFA, the severe residual stenosis was successfully treated by endograft placement (Figure 2A). However, runoff postintervention showed embolic occlusion of the distal posterior tibial artery at the ankle (Figure 2B). The 4-F Indigo catheter was used from a contralateral femoral approach (Figure 3A), and follow-up angiography after < 3 minutes of mechanical thrombectomy showed a widely patent posterior tibial artery (Figure 3B).

The Indigo device allowed for rapid removal of the distal debris in this case, restoring flow to this patient's dominant runoff vessel to the foot.

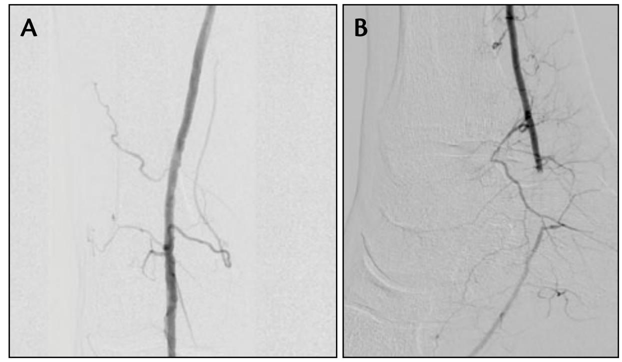

Figure 2. Successful treatment of the SFA (A). Distal runoff showing embolic occlusion of the distal posterior tibial artery (B).

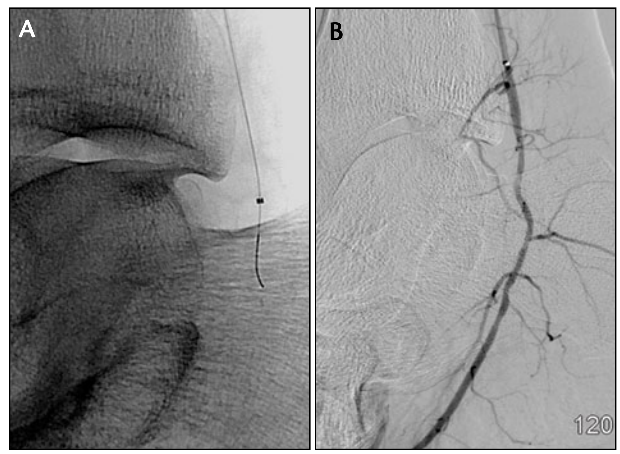

Figure 3. Indigo catheter and Separator used to treat embolic occlusion (A). The final angiogram showing a patent posterior tibial artery (B).

Case 3: Mechanical Thrombectomy of an Occluded Right Renal Artery

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With the rapidly changing landscape of peripheral arterial disease, it has now become possible to treat patients, who in years past would have required open surgery, with modern endovascular techniques such as mechanical thrombectomy with the Indigo System.

CASE REPORT

The patient had a juxtarenal abdominal aortic aneurysm and was not a candidate for open surgery. The snorkel technique was used to treat this patient. A stent graft was placed, along with two self-expanding covered stents in both renal arteries, to maintain blood flow. The postprocedure angiogram showed a faint blush in the abdominal aortic aneurysm sac. These usually tend to resolve, and therefore, no further intervention was performed.

The follow-up CT angiogram (CTA) at 1 month showed a persistent endoleak through the gutters bilaterally, with outflow through a patent lumbar artery on the right side. To treat the persistent endoleak, embolization with microcoils was performed from a

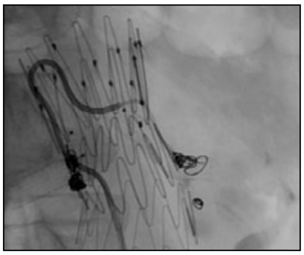

Figure 1. CTA shows occlusion of the right-side snorkel and renal artery.

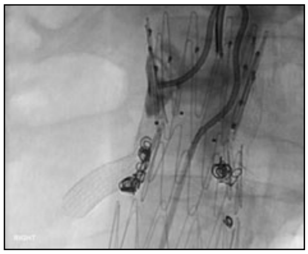

Figure 2. Selective angiogram showing occlusion of the right-side Viabahn snorkel.

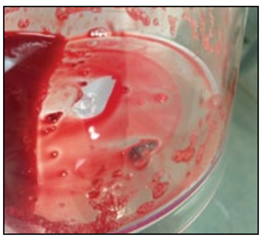

Figure 3. The Indigo System canister with clot removed from renal snorkel and artery.

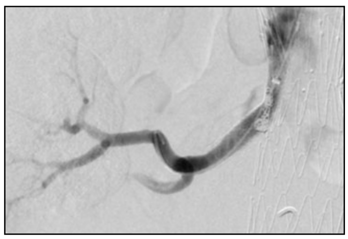

Figure 4. Selective right renal angiogram after thrombus aspiration with the Indigo System, showing antegrade flow in the renal artery.

femoral approach. A follow-up CTA showed resolution of the endoleak and reduction in the size of the aneurysm sac (Figure 1).

Four months later, the patient presented reporting 48 hours of anuria. The CTA showed bilateral renal snorkel occlusion with an already atrophic left kidney. Angiography confirmed that the right renal artery was also occluded and possibly causing the anuria (Figure 2). The 6-F Indigo catheter was delivered to the right renal artery through a 6-F sheath. The catheter was then connected to the Indigo pump and cleared the thrombus in minutes. The thrombus can be seen in the canister in Figure 3. This was then followed by the placement of a balloon-expandable stent to help ensure long-term patency of the right renal artery. The patient recovered renal function soon after the right renal artery was revascularized (Figure 4).

The treatment of occluded viscerals with conventional techniques is often time-consuming with limited success. Now, with the Indigo System, we have expanded the endovascular visceral thrombectomy options while decreasing procedure time. We are also now able to actually visualize the clot collected in the canister (Figure 3).

Case 4: Mechanical Thrombectomy Following Failed Angioplasty of a Restenosed SFA Stent

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Femoropopliteal in-stent restenosis (ISR) occurs in 18% to 40% of patients within the first year after femoropopliteal artery stenting.[4,5] Femoropopliteal ISR is even more common after stenting longer lesions (>15 cm) and may occur in association with femoropopliteal stent fracture.[6,7] The management of peripheral arterial disease continues to be a challenge for the interventional community. Angioplasty, stenting, and drug-eluting technologies are all continually being improved to provide adequate endovascular treatment options and prevent or prolong the duration before open surgery is required. Although drug-coated balloons and drug-eluting stents show promise, dealing with ISR in the current patient population warrants the need for good endovascular techniques. The Indigo System is proving to be a great option.

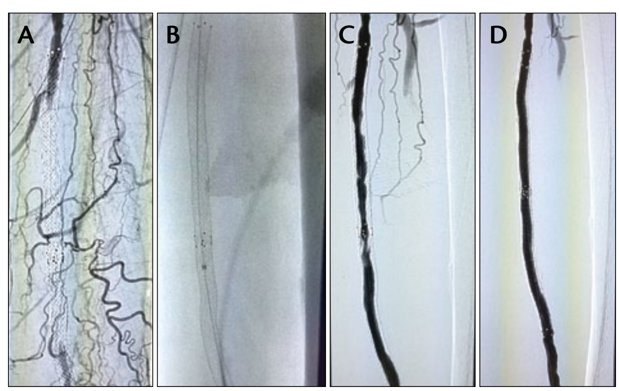

Figure 1. Occluded stent after cutting balloon (A). The Indigo CAT5 evacuating thrombus within the occluded stent (B). Location of culprit restenosis (C). Final angiogram following thrombectomy and stent placement (D).

CASE REPORT

The patient first presented in 2010 with bilateral claudication and was able to walk approximately 50 yards. Angiography revealed a total occlusion of the right common and external iliac arteries, as well as a chronically occluded left SFA. Percutaneous intervention was unsuccessful, and so a left common femoral-to-right common femoral bypass was performed to perfuse the right lower extremity. At approximately 3 months postprocedure, there was resolution of right lower extremity claudication.

However, the patient was now limited by left lower extremity claudication. The patient was therefore taken back to the catheterization lab, and antegrade access was achieved focusing on the left SFA occlusion. Upon successful crossing, angioplasty and stenting were performed with good success (100% to < 10% angiographic result).

In March 2014, this patient presented again with an occluded left SFA stent. Angioplasty was attempted with a cutting balloon throughout the stent but failed to reconstitute flow (Figure 1A). At this point, the larger Indigo catheter CAT5 (Penumbra, Inc.) was used to extract the thrombus that was causing the occlusion. The CAT5 was connected to the Indigo pump, which supplies continuous vacuum and allows for hands-free aspiration. Within minutes, the thrombus was completely evacuated from the stent (Figure 1B and C). It also showed the location of the culprit restenosis, which was then treated by placing two drug-eluting stents in an attempt to prevent future recurrence (Figure 1D).

Thrombus is a common component in lower extremity peripheral arterial disease, warranting the use of thrombectomy. In this case, the ability to connect the CAT5 device to the Indigo pump for continuous suction, without clogging the tip of the device, allowed for the safe and rapid removal of mural thrombus that had accumulated over the entire stent segment, without the need for wire exchanges.

Case 5: Mechanical Thrombectomy During Treatment of an Occluded Stent Graft

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Our vascular surgery practice is a referral institution for challenging aortic and peripheral disease cases. In treating these advanced stages of disease, the need for sophisticated interventional tools is heightened. Penumbra's Indigo technology has redefined mechanical thrombectomy at our institution.

CASE REPORT

The patient presented with acute thrombosis of a 6-mm covered stent in the above-the-knee popliteal artery that had been placed as a secondary intervention within an initially deployed bare stent. A diagnostic angiogram showed an occluded segment (Figure 1), with normal flow above and below the stent.

We decided to treat the occluded stent with a Jetstream® XC rotational atherectomy catheter (2.4/3.4 mm; Bayer) with FilterWire™ embolic protection (Boston Scientific Corporation), which created a patent channel through the stent but left residual thrombus in the distal aspect of the stent and in the native popliteal artery below. The larger 6-F Indigo catheter was used to successfully treat the residual thrombus.

The Indigo System has now become the standard thrombectomy tool in our peripheral practice and has significantly reduced the need for overnight lytics in the intensive care unit.

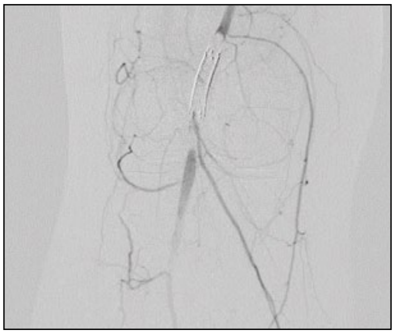

Figure 1. Preprocedural angiogram showing the occluded covered stent.

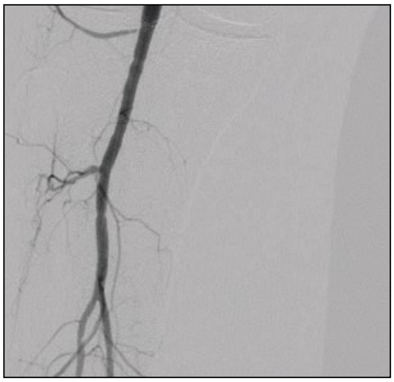

Figure 2. Postprocedural angiogram.

A 6- X 40-mm cutting balloon was then used to treat the stenosed segment; however, this resulted in new thrombus in the tibioperoneal trunk. An intra-arterial tissue plasminogen activator bolus was attempted, but failed to remove the thrombus. The same 6-F Indigo catheter was again used to clear the tibioperoneal trunk, with a very successful result (Figure 2).

The Indigo System has now become the standard thrombectomy tool in our peripheral practice and has significantly reduced the need for overnight lytics in the intensive care unit.

Case 6: Indigo Used to Treat Distal Embolization Caused During Power-Pulse Mechanical Thrombectomy for Acute Limb Ischemia

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Lower extremity arterial thromboembolism is a significant problem for the interventional community. With increasing use of endovascular techniques, the risk of embolization during procedures has also greatly increased. Current practice has evolved to utilizing distal protection devices during power-pulse mechanical thrombectomy to help capture debris and thrombus that may shower distally and thus avoid complications.

CASE REPORT

The patient had a power-pulse tissue plasminogen activator infusion/thrombectomy for ischemia from a previously placed covered stent in the SFA. After successful revascularization, the previously placed filter was removed, and the distal runoff looked poor (Figure 1). Distal debris was occluding the distal popliteal artery.

At this point, the decision was made to use the Indigo continuous thrombectomy system to treat the distal emboli. The Indigo catheter CAT5 easily tracked to the trifurcation and was connected to the Indigo pump (Figure 2). The Indigo Separator SEP5 was inserted through CAT5 to keep the catheter lumen patent during pump aspiration. Debris was rapidly cleared through the catheter into the canister after a single pass with the Indigo catheter. The final angiogram showed complete restoration of flow to the lower extremity (Figure 3). The clot that was removed is shown in Figure 3B.

Figure 1. Poor distal runoff.

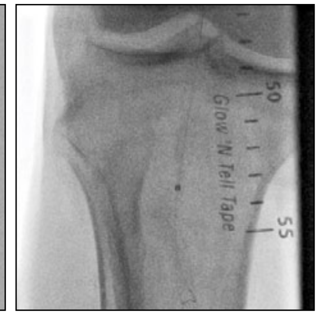

Figure 2. The Indigo catheter was tracked to the trifurcation.

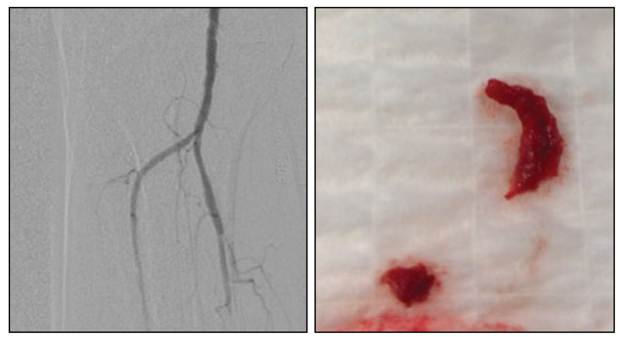

Figure 3. Complete restoration of flow (A). Visualization of clot in canister (B).

The Indigo System is an effective bailout tool during interventional procedures, as it can help in treating challenging complications that may arise while treating arterial disease.

CONCLUSION

Just as the Penumbra System was proven safe and effective in the neurovasculature, becoming a go-to device for stroke treatment, the new Indigo System will have a significant role to play in the peripheral vasculature. It allows rapid restoration of vascular flow caused by small to moderate thrombus burden in the arterial circulation.

As evidenced by the cases presented in this article, the Indigo System can be used for mechanical thrombectomy of native arterial occlusions, device occlusions, thromboemboli, and can reverse distal embolic complications at the time of peripheral arterial disease interventions. The device can be tracked all the way to the foot from a contralateral approach. As the interventional community continues to become more aggressive in its approach to PAD, we believe the Indigo System will be an essential part of the peripheral interventionalist's toolbox. ■

— Richard R. Saxon, MD, FSIR

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