

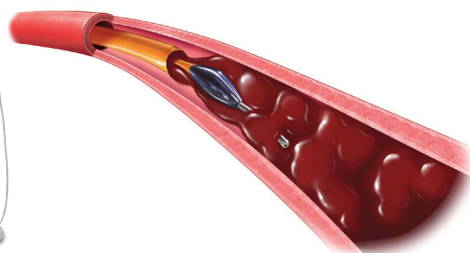
Indigo System for Peripheral Arterial Clot Management

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Acute limb ischemia resulting from a sudden decrease in limb perfusion is associated with high mortality and morbidity, leads to tissue loss, and threatens limb viability. Surgical arterial thromboembolectomy is a traditional treatment for acute arterial thromboemboli in lower limbs, especially if a single large artery is involved. Unfortunately, residual thrombus, propagation of thrombi, chronic atherosclerotic disease, and vessel injuries secondary to balloon catheter passage may limit the clinical success rate, particularly when below-the-knee (BTK) vessels are involved.¹ Intraoperative angiography can identify arterial imperfections after thromboembolectomy, which may be corrected simultaneously by endovascular techniques. However, these “hybrid procedures” include the invasiveness of open surgery and carry the risk of incomplete thrombus removal or vessel damage.¹

Consequently, in the last few years, we have seen a paradigm shift to total percutaneous endovascular interventions thanks to the availability of new endovascular tools dedicated to acute clot management, including mechanical fragmentation, rheolytic thrombectomy, and aspiration thrombectomy. However, these traditional endovascular mechanical fragmentation and rheolytic thrombectomy devices have been associated with high com-

plication rates and intensive care unit stays. Complications have included bleeding risk, distal emboli, vessel damage, incomplete revascularization, and damage to patients’ kidneys.²⁻⁴

The Indigo System (Penumbra, Inc.) was designed to address the limitations of traditional surgical and endovascular treatment options. The Indigo aspiration catheters are available in a range of lengths and diameters that, when connected to Penumbra’s proprietary Pump MAX, can remove the thrombus under continuous aspiration. By capturing the clot without maceration and under high aspiration power, the risk for distal emboli is reduced. The Indigo catheters vary from 3 to 8 F—including larger circumferential aspiration due to the tip shapes of CAT8—allowing the operator to remove thrombus from small vessels, such as the pedal arch, and large vessels, such as the aorta or iliacs.

The Indigo System’s Separator is intended for use with the system’s continuous aspiration mechanical thrombectomy catheter to aid in the removal of clot from the body. The Indigo Separator is advanced and retracted through the

	CAT 3	CAT 5	CAT 6	CAT 8	CAT D
Compatibility (Sheath/Guide)	5 F (1.65 mm) Compatibility	6 F (2.00 mm) Compatibility	6 F (2.00 mm) Compatibility	8 F (2.67 mm) Compatibility	8 F (2.67 mm) Compatibility
Working Length	150 cm	132 cm	135 cm	85 cm (Straight and TORQ Tips) & 115 cm (XTORQ Tip)	50 cm (TORQ Tip)
Wire Platform	.014–.025" (.36–.64 mm)	.014–.038" (.36–.97 mm)	.014–.038" (.36–.97 mm)	.014–.038" (.36–.97 mm)	.014–.038" (.36–.97 mm)
Compatible Penumbra Devices	Separator 3	Separator 5	Separator 6	Separator 8	Separator D

corresponding size Indigo catheter at the proximal margin of the primary occlusion to facilitate clearing of the thrombus from the catheter tip. These features are particularly helpful in case of acute-on-chronic thrombosis and in-stent/in-bypass fresh occlusion, as well as in thrombi localization below the knee and all the way to the pedal arch (Figure 1).

THE INDIAN REGISTRY

The INDIAN registry (NCT03386370) is a prospective, multicenter registry designed to investigate the safety and initial efficacy of the Indigo System in a controlled setting for treating acute peripheral arterial thromboembolism in a cohort of 150 patients.⁵ Assessment of vessel patency is indicated using the thrombolysis in myocardial infarction (TIMI) grade classifications both before and after use of the device. The primary outcome was the rate of TIMI 2–3 revascularization after Indigo System intervention and at the end of the procedure after any adjuvant procedure.

A preliminary analysis of the first 136 patients showed technical success (defined as complete or near-complete revascularization/TIMI 2–3 flow) in 89.6% of patients after the thromboaspiration procedure alone. After adjunctive endovascular treatment (angioplasty, stenting or lysis),

the rate of TIMI 2–3 flow was achieved in 95.4% of patients. At discharge, there have been no device-related adverse events, and clinical success at 1 month (defined as absence of death and limb loss) is 97.8%. Two patients died due to concomitant severe disease, and one below-the-ankle (BTA) amputation was performed in a patient with acute-on-chronic disease, with technical success of the aspiration but desert foot due to chronic occlusion of distal vessels led to the amputation. Procedural images in Figure 1 demonstrate the use of the Indigo System's CAT3 to revascularize a patient that presented with BTA occlusion.

Preliminary data show that thromboaspiration with the Indigo System is a safe and effective primary therapy for the revascularization of acute peripheral arterial occlusions with a very low procedure-related complication rate.⁶

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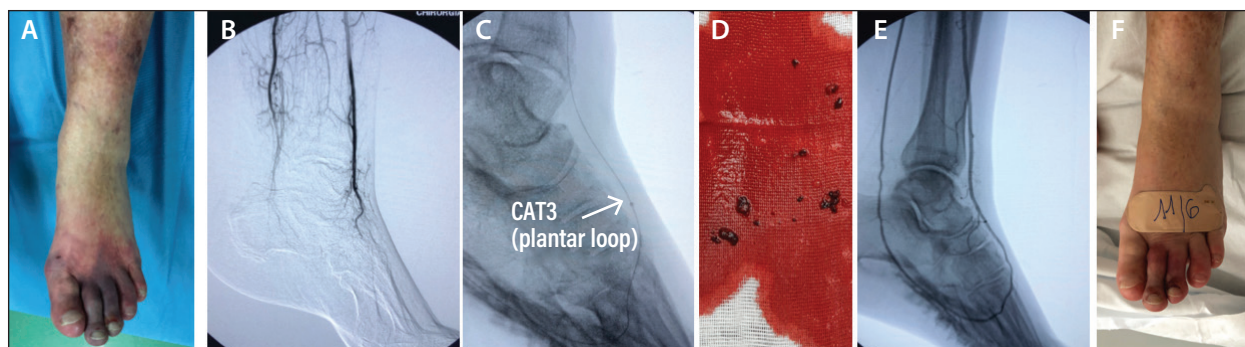


Figure 1. Clinical presentation of the acute forefoot occlusion (good pulsation of anterior and posterior tibial artery at the ankle) (A). Angiography shows acute BTA vessel occlusion (B). CAT3 advancing through the BTA vessels with the plantar loop technique (C). Macroscopic aspect of the thrombi aspirated (D). Angiography after Indigo power aspiration revealing nice patency of the plantar arch (E). Clinical appearance on postoperative day 1 (F).

INDIGO SYSTEM FOR ACUTE POPLITEAL ANEURYSM THROMBOSIS



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PATIENT PRESENTATION

A 67-year-old woman presented to our ambulatory center with a 48-hour history of acute pain of the left lower limb. The patient's medical history included arterial hypertension, moderate chronic obstructive pulmonary disease, and percutaneous transluminal coronary angioplasty with drug-eluting stent placement due to an acute myocardial infarction 3 months earlier. The clinical examination revealed no pulses at the left popliteal artery, sensory loss in the forefoot, and moderate muscle weakness. The patient had been prescribed dual antiplatelet therapy for 12 months. Ultrasound examination of the left leg showed

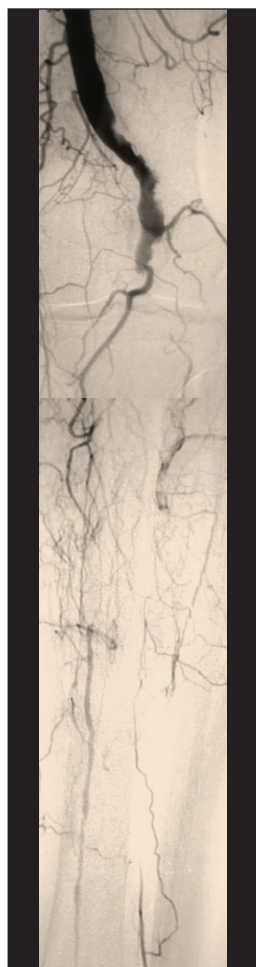


Figure 1. Intraoperative angiography showing the occlusion of the P2 and P3 segments.

an occlusion of a popliteal artery aneurysm (2.5 cm in diameter) with concomitant embolization of the proximal posterior tibial artery, total fibular artery, and proximal and medial anterior tibial artery (ATA) (Figure 1). This case was considered to be immediately threatened acute limb ischemia (Rutherford class 2B), and the patient was scheduled for immediate endovascular revascularization.

INTERVENTION

The treatment was performed under local anesthesia through a percutaneous antegrade approach. Before inserting a 10-F sheath, the sutures of the Perclose ProGlide® system (Abbott) were placed accordingly. The occluded aneurysm underwent intraluminal recanalization with a 0.018-inch support catheter (TrailBlazer™, Medtronic) and the V-18™ ControlWire™ guidewire (Boston Scientific Corporation). A pigtail

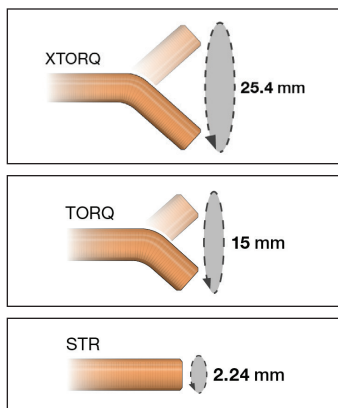


Figure 2. Circumferential aspiration with CAT8 angled tips.



Figure 3. First angiographic result after power aspiration of the left popliteal artery.

catheter was placed inside the occluded aneurysm and 2 mg of recombinant tissue plasminogen activator mixed with 2 mL of iodine contrast agent were injected using a 3-mL syringe to maximize distribution. We left the lytic agent acting for 15 minutes, and during that time, Indigo System and the dedicated pump were prepared.

The Indigo System's CAT8 XTORQ was inserted (Figure 2). After the clot was engaged using the Separator, successful partial revascularization of the aneurysm was achieved (Figure 3). It was determined that the tibiofibular trunk had residual thrombus, and therefore, the CAT6 was telescoped through the CAT8 XTORQ to remove the thrombus (Figure 4).

After successfully establishing two-vessel runoff (anterior and posterior tibial artery), we implanted two Viabahn® endoprotheses (Gore & Associates) to completely exclude the popliteal aneurysm (Figure 5). The patient continued antiplatelet medication because it was prescribed for the coronary drug-eluting stents, and the stent still remains patent at 1.5 years of surveillance.

DISCUSSION

To our best knowledge, this is the first case describing a thrombosed popliteal aneurysm that was treated percutaneously with the Indigo System. The effectiveness of this device has been confirmed already in the treatment of acute thromboembolism in different vascular territories.¹⁻³ In the current case, the main challenges were the coexistence of acute and old thrombi inside the aneurysm sac and the total or partial embolism of all three runoff vessels. The gold standard of treatment for

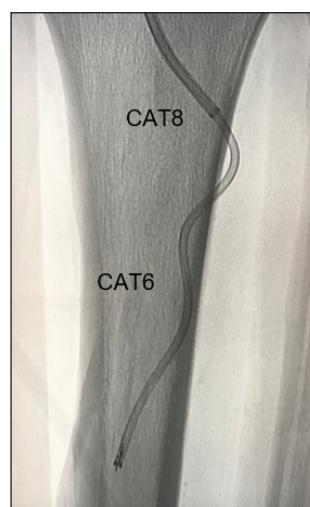


Figure 4. Telescope technique (insertion of CAT6 inside CAT8 XTORQ) for very distal power aspiration.



Figure 5. Final result after implanting the Viabahn endoprotheses.

this indication is surgical bypass, but in this specific case, dual antiplatelet therapy use and the absence of runoff vessels were the main criteria for an endovascular-first approach.

The continuous high aspiration power and the angled proximal tip of CAT8 XTORQ enabled direct circumferential aspiration of the older wall-adherent thrombi of the 2.5-cm aneurysm and facilitated direct advancement of the Separator into the different tibio-peroneal vessels. During advancement, the flexible proximal tips of both the catheter and the Separator allowed for efficient aspiration of the thrombus.

Moreover, Indigo catheters of different sizes can be introduced at the same time (telescope technique) to remove the clot up from the smaller vessel of the pedal arch. Finally, the transparent canister is of unique importance for the operator to check the amount of aspirated blood and assess the presence of thrombus into the Indigo catheter (no back flow).

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ACUTE LOWER LIMB ISCHEMIA TREATED WITH INDIGO SYSTEM



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PATIENT PRESENTATION

A 64-year-old woman with a history of lung cancer and atrial fibrillation presented with right-sided acute lower limb ischemia (ALLI; Rutherford class 2B) at arrival to the emergency department. Sensory loss extended to the right foot, and a mild toe motor deficit was observed. Doppler ultrasound was performed, identifying a proximal occlusion of the superficial femoral artery (SFA) extending down to the popliteal artery without distal runoff. The patient was referred to the interventional radiology department and was taken to the angiography suite for immediate intervention.

INTERVENTION

An angiogram through an antegrade 8-F common femoral artery approach confirmed the proximal occlusion of the SFA with a suspended popliteal artery and occlusion of all BTK vessels (Figure 1). Power aspiration using the

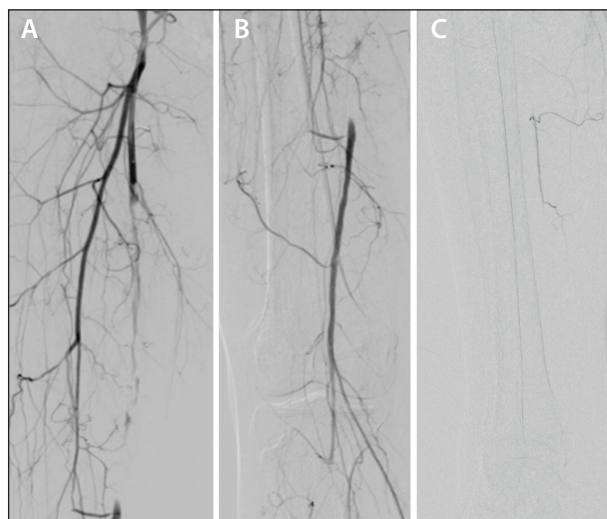


Figure 1. Angiograms showing the proximal SFA occlusion (A), suspended popliteal artery (B), and absence of distal BTK runoff (C).

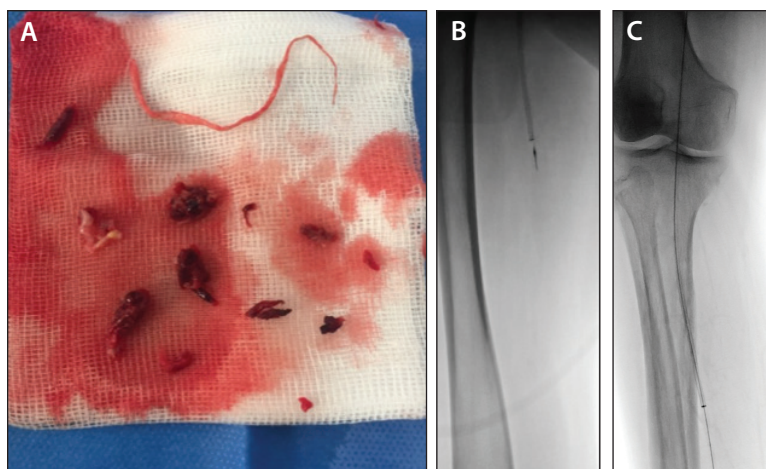


Figure 2. Power aspiration of red and white clots (A) in the SFA and proximal BTK vessels with CAT8 (B, C) followed by the use of CAT5 for the distal BTK.

CAT8 and SEP8 allowed recanalization of the SFA (Figure 2). Subsequently, to improve distal foot perfusion, thromboaspiration of the ATA was performed using CAT5 (the largest nonocclusive catheter possible) and SEP5. CAT5 allowed reperfusion of the pedal artery, dorsal arch, and plantar artery using the plantar loop technique. Antegrade thromboaspiration of the posterior tibial artery was then performed. The procedure was completed with angioplasty of the BTK vessels using a conical 2.5-mm balloon to treat associated chronic disease. Final angiography confirmed the recanalization of the treated vessel with immediate improvement in clinical symptoms (Figure 3).

DISCUSSION

Open embolectomy has been considered the gold standard of treatment.¹ Nevertheless, outcomes still remain unsatisfactory, particularly in patients with several comorbidities, associated chronic vascular disease, and BTK involvement.² Thrombolysis has been proposed as an alternative to open embolectomy, despite a hemorrhagic risk ranging from 6% to 12%.³

The Indigo System can allow complete treatment of ALLI. The powerful aspiration pump, generating -29 Hg of pressure, allows effective thrombectomy through different catheters, which present a smooth profile. The Indigo catheters come in a size range from 3 to 8 F, permitting power aspiration from the SFA to the pedal loop. The Indigo System can also allow reduced operative time and the amount of fibrinolytic agent. These character-

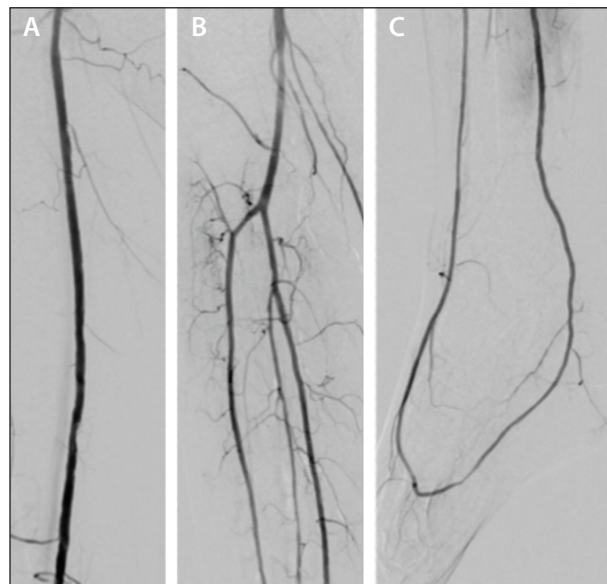


Figure 3. Final angiogram showing successful recanalization of the SFA (A), popliteal and tibial arteries (B), and the dorsal artery and plantar arch (C).

istics offer improved outcomes compared with open embolectomy.

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SINGLE-SESSION INTERVENTION WITH INDIGO SYSTEM FOR THROMBOEMBOLUS FROM POPLITEAL TRIFURCATION AND CONCOMITANT ILIAC ANGIOPLASTY



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PATIENT PRESENTATION

A 55-year-old man, who was usually fit and well, presented as an emergency admission with a 2-day history of an acutely ischemic right leg and calf with severe pain and paresthesia as well as right buttock claudication. Duplex examination demonstrated a 95% right external iliac artery (EIA) stenosis and a popliteal artery

that was occluded with recent well-organized thrombus, poorly attached in the proximal segment, and with total occlusion at the trifurcation. There was a strong suspicion that this represented thromboembolism. Intravenous heparin was commenced; a plan for urgent angiography was made with the aim of performing iliac angioplasty and mechanical thrombectomy in a single session.

INTERVENTION

Retrograde access from the left common femoral artery was achieved and diagnostic angiography was performed, confirming the proximal EIA stenosis. The popliteal artery was occluded distally with thrombus extending into the ATA and tibioperoneal trunk (TPT) and poor distal runoff (Figure 1). The EIA stenosis was angioplastied to 7 mm, with a good result (Figure 2).

A second left antegrade common femoral arterial puncture was made, and a straight, 6-F, 45-cm sheath (Destination®, Terumo Europe) was advanced into

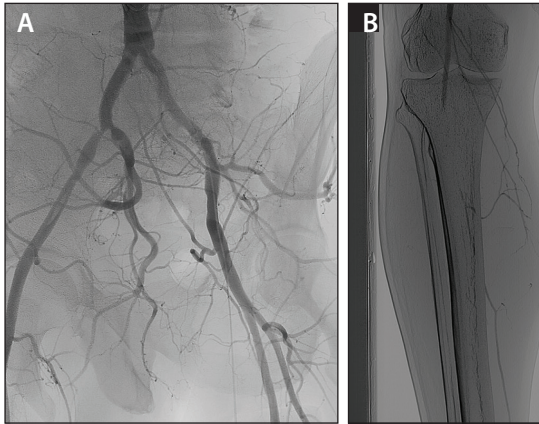


Figure 1. Angiogram confirming proximal EIA stenosis (A) and the popliteal artery occlusion extending into the ATA and TPT (B).

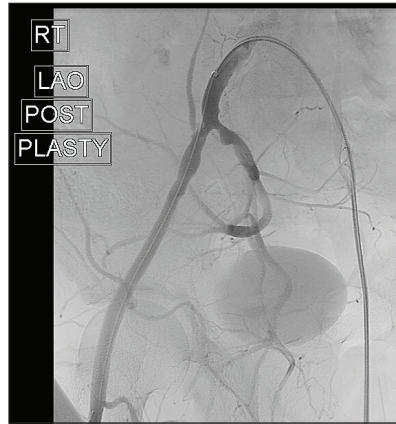


Figure 2. Angiogram postangioplasty of the EIA to 7 mm.

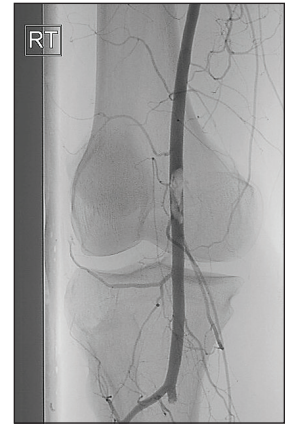


Figure 3. Dislodged thromboembolus in the above-the-knee popliteal artery.

the proximal popliteal artery. The Indigo System was set up, and the largest nonocclusive catheter possible, CAT6, was advanced over a 0.035-inch wire into the thromboembolus. Full vacuum in the Pump MAX was achieved, the flow switch was turned on, flow ceased into the system, the organized thrombus was aspirated, and the catheter was withdrawn proximally. However, the thromboembolus would not initially pass into the sheath, becoming dislodged, and was demonstrated in the above-the-knee popliteal artery (Figure 3) before re-embolizing to the trifurcation (Figure 4).

A clot extraction technique was therefore performed by withdrawing the CAT6 and Separator completely

with continuous aspiration, while also aspirating the 6-F sheath with a syringe to produce negative pressure. This resulted in en bloc aspiration of the organized thrombus (Figure 5).

Angiography demonstrated brisk flow through the popliteal artery and into the ATA to the foot, with some residual thrombus in the TPT (Figure 6). Further clot was aspirated from the TPT, and completion angiography



Figure 4. Second thromboembolus on the trifurcation.



Figure 5. Aspirated thromboembolus of the trifurcation.



Figure 6. Angiogram post-thrombectomy with flow through the distal popliteal artery and ATA. Some residual thrombus remains in the TPT.



Figure 7. Further clot was aspirated from the TPT, giving this final result of three-vessel runoff into the foot.

demonstrated three-vessel runoff into the foot (Figure 7).

No intra-arterial thrombolysis was given, and the procedure was finalized with bilateral closure devices. The patient made a good recovery, and intravenous heparin was stopped. He was discharged 48 hours after the single-session intervention on oral anti-coagulation. Follow-up duplex imaging at 14 days showed patent vessels with mild distal infrapopliteal stenoses. He was discharged to primary care with no further problems at 2-year follow-up.

DISCUSSION

In a young man with no previous medical history and presenting with an acutely ischemic leg, emergency intervention was performed including angioplasty of the primary underlying iliac stenosis and mechanical

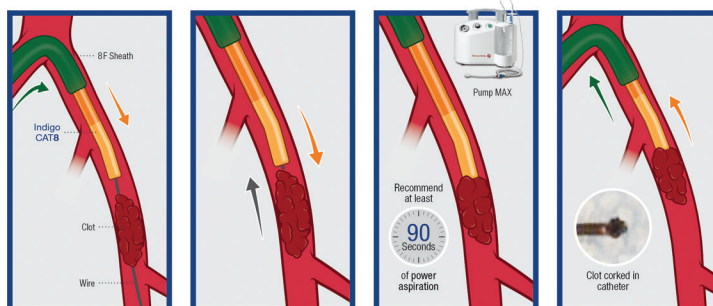


Figure 8. Illustration depicting the XTRACT technique.

aspiration of the popliteal embolus in a single-session intervention. Treatment using the Indigo System was quick, efficient, and safe with the XTRACT technique to withdraw organized thrombus en bloc (Figure 8). There was no requirement for thrombolytics, thus avoiding the need for intensive care. The patient was quickly discharged and returned to an active lifestyle.

IN-STENT THROMBOSIS TREATED WITH INDIGO SYSTEM



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PATIENT PRESENTATION

A female patient in her 70s with diabetes, previous stenting of the left SFA and popliteal artery, and a coronary bypass underwent total knee arthroplasty, which was reported to be uneventful. After waking up, the patient began to complain of acute rest pain in the left calf and foot. Physical examination showed a “cold leg” with no palpable peripheral pulses due to edema at the surgical site. Emergency CTA was performed to rule out damage to the femoropopliteal arterial segment (Figure 1).

With the perisurgical onset of ischemic thrombosis, fibrinolysis was contraindicated due to the high risk of bleeding from the surgical site. A surgical attempt to

perform a Fogarty embolectomy was also discounted because of the high risk of surgical reintervention.

INTERVENTION

Endovascular therapy to revascularize the leg was agreed on in a multidisciplinary setting. Contralateral femoral retrograde access was gained. Retrograde access was achieved by positioning a 6-F, 45-cm Destination introducer sheath. Continuous heparinized saline flush (1,000 IU) was preferred due to restriction of the perisurgical settings. Digital subtraction angiography confirmed the thrombotic filling defects of the entire site of stenting (Figures 2A and 2B) and infoldings of the proximal edge of the femoral stent—retrospectively, due to the ischemic band positioned during the surgical intervention. Crossing of the thrombosed segment was achieved with a 0.035-inch Glidewire Advantage® (Terumo Interventional Systems; Figures 2C and 2D).

Multiple passes of power aspiration were performed with a straight, 135-cm CAT6 (the largest nonocclusive catheter possible) and SEP6, starting from the distal part of the thrombosed segment. Complete thrombus removal was achieved without distal embolization (Figure 3). The procedure was completed by restenting the proximal edge of the infolded SFA stent with a 7- X 60-mm Tigris® stent (Gore & Associates), obtaining restoration of lumen diameter. Six-month CTA follow-up confirmed patency of the treated vessel site (Figure 4).

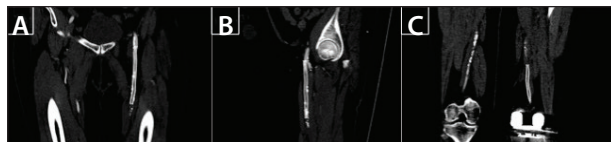


Figure 1. A multiplanar reconstruction better depicting the extension of thrombosis in the entire SFA length.

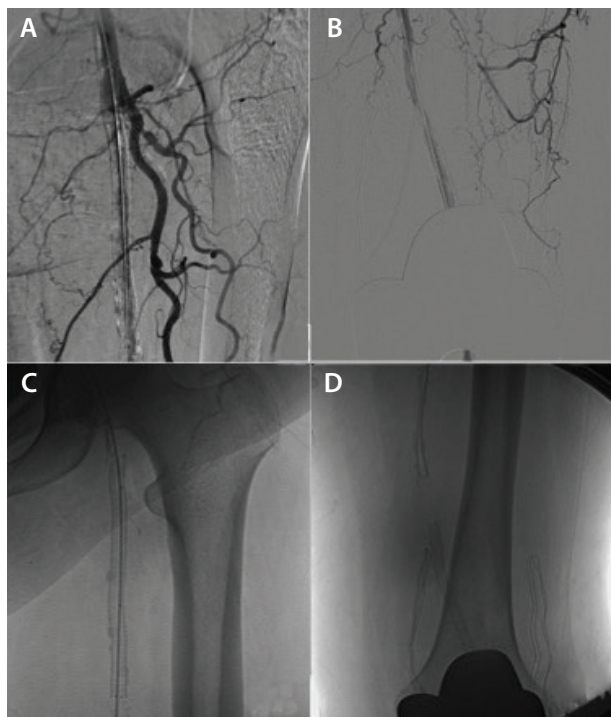


Figure 2. Angiogram confirming the thrombotic filling defects of the entire stent (A, B). Crossing the thrombosed segment (C, D).

DISCUSSION

Use of the Indigo System allows for a quick, efficient, and safe clot extraction procedure. The Indigo catheters

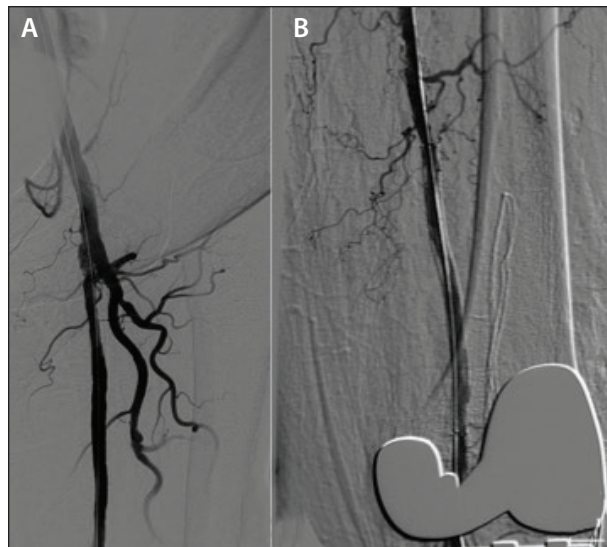


Figure 3. Angiogram showing complete thrombus removal.

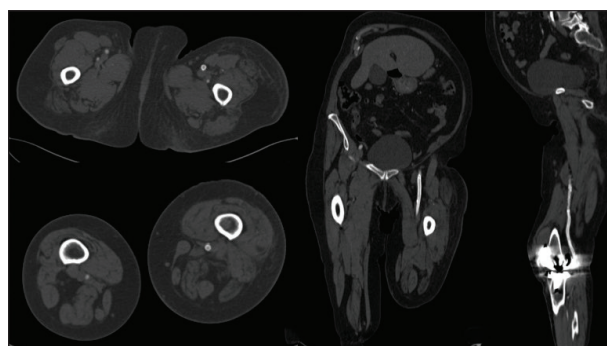


Figure 4. CTA at 6-month follow-up after aspirational thrombectomy and stenting.

of different sizes and atraumatic tips allow direct advancement into differently sized vessels, even in patients contraindicated to the use of thrombolytics.

INDIGO SYSTEM IN THE DISTAL POSTERIOR TIBIAL ARTERY



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PATIENT PRESENTATION

A man in his 40s was admitted with acute ischemia

of the right leg. Five days earlier, he had undergone arthroscopy at a different institution due to suspicion of a venous thrombosis. The leg showed marked swelling and sensory and motor deficits (Figure 1). CTA of the leg revealed a massive hematoma and compartment syndrome in the lower leg area with a rupture of the popliteal artery (Figure 2).

The patient underwent stenting of the popliteal aneurysm and a fasciotomy to relieve compartment syndrome (Figures 3 and 4). At 5 days poststenting, angiographic follow-up was performed. The ultrasound findings confirmed an occlusion of the posterior tibial artery.

INTERVENTION

Left femoral access was achieved with an 8-F, 40-cm Flexor® Check-Flo® introducer (Cook Medical). Selective angiography of the SFA was performed via an up-and-over technique. CAT6 was advanced over a 0.035-inch wire into the posterior tibial artery and angiography confirmed the ultrasound findings of an occlusion (Figure 5). Next, Pump MAX was turned on and the CAT6 was advanced in front of the clot. After 90 seconds and no flow into the cannister, the CAT6 was removed. Utilizing the XTRACT technique, the clot was captured on the CAT6 tip (see Figure 8 in Dr. Lewis's case). The clot then was removed through the sheath with continuous aspiration and negative pressure with a syringe on the sheath valve. Separator was not needed in this case.

Control angiography showed continuous posterior tibial artery flow after one pass with the Indigo System (Figures 6 and 7). The entire procedure lasted approximately 15 minutes.

DISCUSSION

A great advantage in emergency cases is the rapidity of the procedure achieved by constant power aspiration. The large lumen catheter and its atraumatic distal tip allow safe and efficient clot removal after intimal lesions. The Indigo System can help solve thrombotic complications intraoperatively within minutes and avoid further complications. ■

Drs. Theodosios Bisdas, Mario Corono, Gianmarco de Donato, Constantino Del Guidice, Katharine Lewis, and Martin Schröder were compensated in association with this article.

Disclaimer: The opinions and clinical experiences presented herein are for informational purposes only. The results may not be predictive of all patients. Individual results may vary depending on a variety of patient-specific attributes. Renderings are for illustrative purposes only.



Figure 1. Acute ischemia after arthroscopy 5 days earlier, with marked pallor and swelling of the lower right leg.



Figure 2. CTA showing a rupture of the popliteal artery with pronounced hematoma and compartment syndrome of the lower leg.

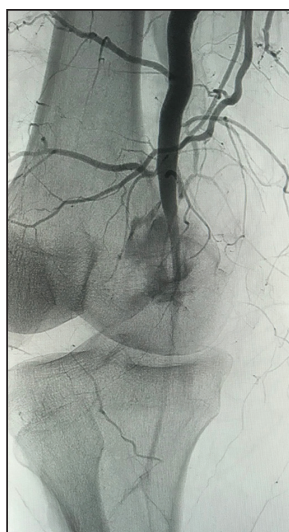


Figure 3. Intraoperative angiogram showing a rupture in the popliteal artery.

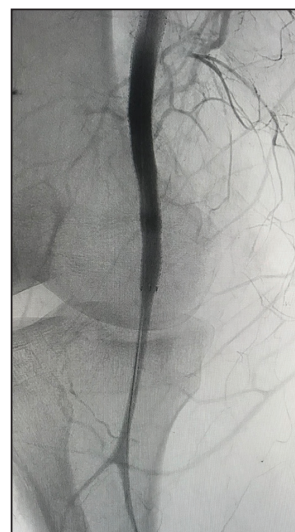


Figure 4. Coverage of the leak with a 7-mm Viabahn endoprosthesis.

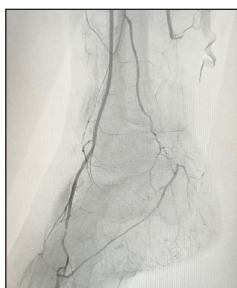


Figure 5. Occlusion of the posterior tibial artery.



Figure 6. Angiographic result after removal of the clot with the CAT6.

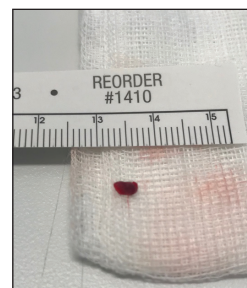


Figure 7. Aspirated thrombus from the posterior tibial artery.