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Indigo Percutaneous Mechanical Thrombectomy System

Experts discuss a potential paradigm shift in acute clot management in venous and arterial occlusions.

WITH MICHAEL LICHTENBERG, MD, FESC; THEODOSIOS BISDAS, MD; JOS C. VAN DEN BERG, MD, PHD; YANN LE BRAS, MD; FRANCOIS PETITPIERRE, MD; AND FLORIAN WOLF, MD, MBA, EBIR, EBCR

Michael Lichtenberg, MD, FESC
Vascular Center Clinic
Arnsberg, Germany
m.lichtenberg@klinikum-arnsberg.de
Disclosures: Speaker for Penumbra.

Deep vein thrombosis (DVT) is a major health care problem, with an incidence of 300,000 to 600,000 new patient cases per year in the United States[1] and approximately 50,000 annual hospitalizations in Germany. Globally, DVT is the third most common cause of cardiovascular mortality after myocardial infarction and cerebrovascular disease. In addition to the acute condition of pulmonary embolism, DVT of the pelvic veins and the proximal femoral vein (iliofemoral DVT) constitutes a high risk for a subsequent postthrombotic syndrome (PTS). In Germany, the prevalence of PTS is reportedly about 5% after DVT.[2] This represents a significant economic public health burden, as patients tend to retire earlier and work fewer weeks per year.

In addition to local catheter-directed thrombolysis (CDT) for treatment of DVT, mechanical thrombectomy techniques have generated significant interest. However, determining which endovascular treatment to use for DVT is challenging due to a lack of data. Existing endovascular options for venous and arterial thromboembolism face the challenges of limited trackability, limited effectiveness, vessel injury, and incomplete revascularization. With the addition of larger 6- and 8-F systems and a venous indication, Penumbra Inc.'s Indigo System is designed to address the limitations of conventional technology. The Indigo System brings greater trackability and more powerful, larger-bore aspiration catheters to the peripheral vasculature to evacuate thromboemboli from small and large vessels.

Unlike CDT, which often requires prolonged infusion times, the Indigo System can provide rapid restoration of flow to thrombosed vessels. It is indicated for use on its own when thrombolytic therapy and surgery are contraindicated, as well as in conjunction with lysis to shorten lengthy infusions and costly intensive care unit stays. Such benefits are driven by the Indigo System's Pump Max and proprietary Separator, which maximize aspiration power and efficiency. These two technologies ensure

continuous aspiration throughout the system without clogging the catheter's tip. This percutaneous system is available in four diameter options (CAT3, CAT5, CAT6, and CAT8) ranging from 3.4 to 8 F and lengths ranging from 85 to 150 cm. This range of sizes allows for smaller-diameter catheters to work coaxially through larger-diameter catheters to treat long lesions in tapering vessels. The following cases highlight rapid revascularization with the Indigo System in both arterial and venous systems.

CASE REPORT: ENDOVASCULAR MECHANICAL THROMBECTOMY FOR ILIOFEMORAL DVT

First Experiences With the Penumbra Indigo Thrombectomy System

A 35-year-old woman was admitted to our emergency department with a 1-day history of severe painful swelling of her left leg (Figure 1). Other than treatment for hypertension, her past medical history was not significant. Family history of DVT was also negative. Duplex ultrasound was immediately performed, which showed a descending iliofemoral DVT from the common iliac vein to the femoral deep vein. The distal superficial femoral vein and popliteal vein did not show any thrombus. The deep profunda vein inflow was affected by thrombus; however, the great saphenous vein did not show any thrombus burden. Due to the short 1-day history and the ongoing painful swelling, the patient was scheduled for immediate endovascular venous mechanical thrombectomy.

Before starting the procedure, 5,000 U of heparin were administered. The patient was placed in the supine position and given sedation and local anesthesia. The patient's left distal superficial femoral vein was punctured under ultrasound guidance and an 8-F sheath was placed. Initial venography showed a thrombotic and organized occlusion of the common and external iliac vein, which confirmed the initial hypothesis of a descending iliofemoral DVT caused by May-Thurner syndrome (Figure 2). Many ascending venous collaterals were visible in this area, which proved the concept of chronic compression. The CAT8 was inserted through the 8-F sheath and tracked to the thrombus. Vacuum thrombectomy was then initiated. The CAT8 was then slowly moved upward to the common iliac vein as the system extracted acute clot. Significant resistance was met at the level of the May-Thurner compression point, indicating a likely chronic process in this location. Two additional passes were performed with the Indigo CAT8 System. Repeat angiography revealed a sufficient inflow and thrombus removal, but there was a high-grade stenosis of the proximal iliac vein (Figure 3). Therefore, angioplasty with a 14- X 60-mm Atlas balloon (Bard Peripheral Vascular, Inc.) was performed, followed by a venous stent implantation (Vici 16 X 90 mm; Veniti, Inc.). Final angiography showed a complete resolution of the left iliac vein system with normal inflow and outflow (Figures 4A and 4B). By this time, inflow was documented from the deep profunda femoral vein and also from the superficial femoral vein. The sheath was removed and manual compression was held. The left leg was wrapped with an elastic bandage from foot to thigh. Oral anticoagulation was started immediately. Painful swelling disappeared hours after the procedure, and the patient was discharged 2 days later.

DISCUSSION

Acute and chronic iliofemoral DVT cause painful swelling in the affected extremity due to obstruction to blood flow. Traditionally, endovascular techniques

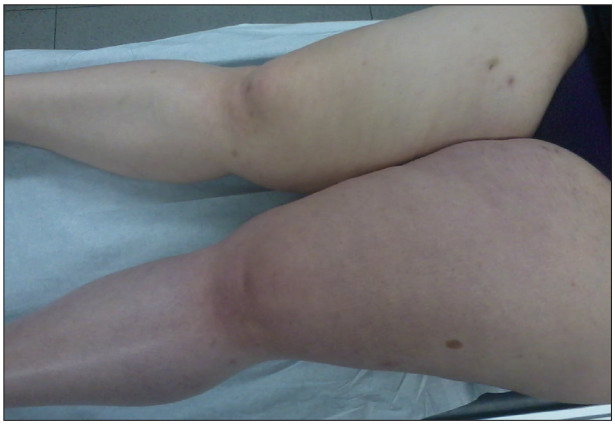

Figure 1. The case patient with severe painful swelling of the left leg.

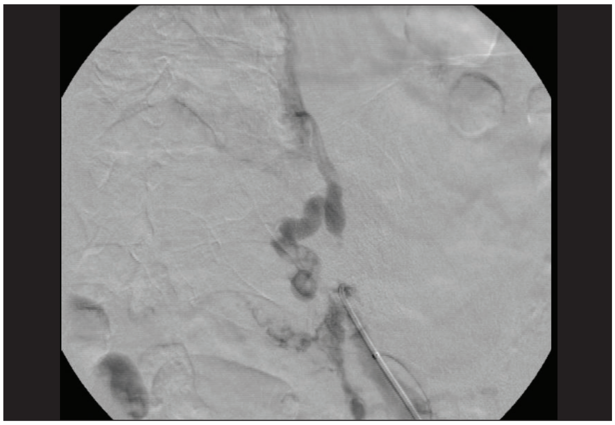

Figure 2. Initial venogram showing a thrombotic and organized occlusion of the common and external iliac vein.

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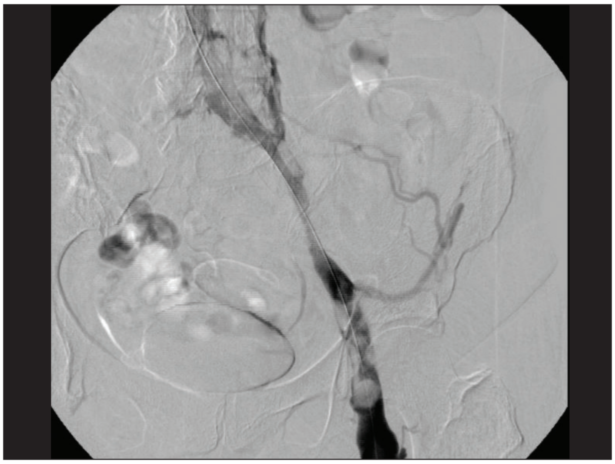

Figure 3. Angiogram showing a sufficient inflow with thrombus removal and a high-grade stenosis of the proximal iliac vein.

have struggled to completely remove thrombus. This outcome is especially detrimental to young and active patients who are likely to develop PTS after 2 years and are most at risk for decreased quality of life.[2] These patients should be regarded as ideal candidates for endovascular treatment, as they usually experience the greatest improvement in quality of life from rapid evacuation of thrombus. Patients who suffer from progressive thrombosis even on effective anticoagulation are also likely to benefit from endovascular treatment options to prevent further DVT-associated complications.

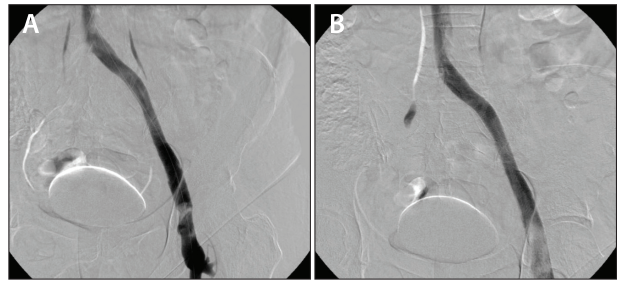

Figure 4. Final angiograms showing complete resolution of the left iliac vein system with a normal inflow (A) and outflow (B).

The Indigo System is a new option for a pure mechanical thrombectomy treatment for patients with iliofemoral DVT who are contraindicated to lytic therapy. Mechanical thrombectomy with the Indigo System for this indication increases safety because it can significantly lower bleeding complications. The ability to control the directional working channel with the curved tip of the catheter, combined with the immense suction power of pure vacuum, increases efficacy of thrombus extraction. ■

1. Beckman MG, Hooper WC, Critchley SE, Ortel TL. Venous thromboembolism: a public health concern. Am J Prev Med. 2010;38(4 suppl):S495-S501.
2. Rabe E, Pannier-Fischer F, Bromen K, et al. Bonn Vein Study by the German Society of Phlebology Epidemiological study to investigate the prevalence and severity of chronic venous disorders in the urban and rural residential populations. Phlebologie. 2003;32:1-14.

Theodosios Bisdas, MD
Department of Vascular Surgery
St. Franziskus Hospital
University Clinical of Münster
Münster, Germany
theodosios.bisdas@sfh-muenster.de
Disclosures: None.

Chimney endovascular aortic repair (chEVAR) is an alternative option for the total endovascular treatment of juxtarenal aortic aneurysms. The technique consists of placing parallel endografts into the aorta: one main aortic endograft for the exclusion of the aneurysm and one or more bridging endografts (chimneys/snorkels) for the perfusion of the covered target vessels. However, the bridging stent grafts (similar to fenestrated devices) carry the risk of early or late occlusion. In such a challenging scenario, the Indigo System has been a very effective tool, allowing us to reopen the occluded bridging chimneys by direct thromboaspiration of the embolus.

CASE REPORT: OCCLUSION OF THE RENAL ARTERY AFTER CHIMNEY ENDOGRAFTING

Three months prior to presentation, a 63-year-old man underwent total endovascular repair of a juxtarenal aortic aneurysm by means of chEVAR. His comorbidities included arterial hypertension, current tobacco use, and previous laparotomy due to bladder cancer. The postoperative course was uneventful.

The patient presented in our ambulatory unit with acute flank pain on the left side. Laboratory testing revealed elevated serum lactate dehydrogenase (584 U/L) and serum creatinine (3.03 mg/dL) levels. The duplex ultrasound showed a high suspicion of acute occlusion of the left renal artery. CT angiography of the abdominal aorta confirmed the initial diagnosis.

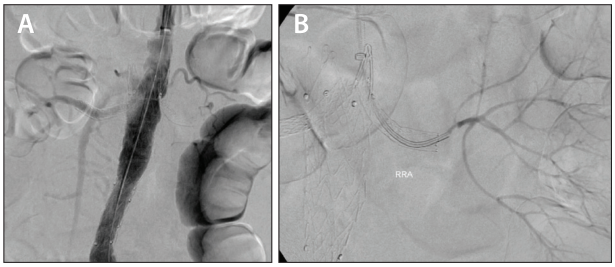

Figure 1. Diagnostic angiography confirming the occlusion of the chimney endograft within the left renal artery (A). Controlled positioning after crossing the occluded chimney endograft (B).

We performed diagnostic angiography through the left brachial artery. The transbrachial access was the only access option due to the cephalad orientation of the chimney endografts (Figure 1A). An 8-F, 90-cm Shuttle sheath (Cook Medical) was used to stabilize the support catheter and the wire. With the help of a vertebral catheter and a 0.018-inch wire (V18, Boston Scientific Corporation), we were able to get the wire into the bridging stent graft and cross the occlusion. After advancing the vertebral catheter through the thrombus, we angiographically controlled its position (Figure 1B). We changed the 0.018-inch wire with a 0.014-inch Hi-Torque Spartacore guidewire (Abbott Vascular) in order to place its atraumatic tip as distal as possible into the small renal branches to avoid any dislocation of the devices (Figure 2A).

The CAT8 Indigo catheter was delivered through the sheath into the thrombus. Once delivered to the thrombus, aspiration was turned on, allowing for the gentle removal of the thrombotic material from the occluded renal artery (Figure 2A). In contrast to other vascular beds, we did not use the Separator. Instead, the 0.014-inch guidewire was used to keep the sheath stable and to advance the CAT8 safely through the bridging stent graft. Next, a 6-mm Viabahn endograft (Gore & Associates) was placed to smooth the transition between the occluded stent and the uncovered part of the renal artery (Figure 2B). The patient recovered renal function after the third postoperative day and was discharged on postoperative day 6 (Figure 3).

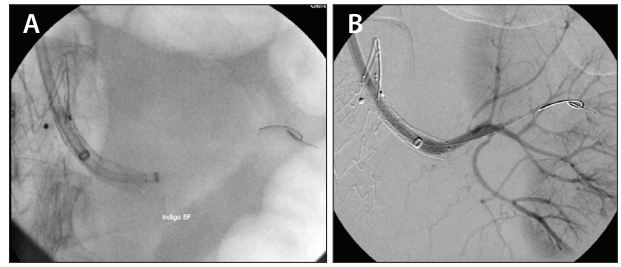

Figure 2. Fluoroscopic image of the CAT8 (A). Control angiogram after successful thrombus removal (B).

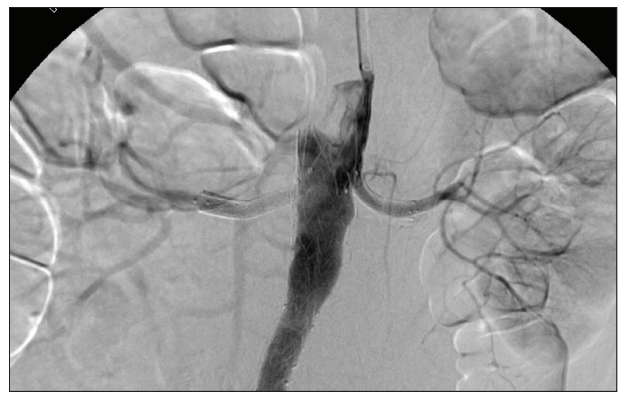

Figure 3. Final angiographic result after relining the chimney endograft with a Viabahn stent graft.

DISCUSSION

The treatment of occluded bridging stent grafts after fenestrated or chimney endografting is very challenging, and little is known about the best therapeutic approach. The Indigo System offers a safe and effective option for such challenging cases. Penumbra's technology has redefined mechanical thrombectomy of acute arterial occlusions in different vascular beds encountered in my daily practice. ■

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Jos C. van den Berg, MD, PhD
Head of Service of Interventional Radiology
Ospedale Regionale di Lugano
Lugano, Switzerland
jos.vandenberg@eoc.ch
Disclosures: None.

CASE REPORT

A 60-year-old man was referred to our hospital with a 2-day history of deep vein thrombosis (DVT) of the left femoral vein, extending into the external iliac vein as shown by duplex ultrasound. Medical history included a previous episode of left-sided calf thrombosis (femoropopliteal) 4 years prior and type 2 diabetes mellitus. Magnetic resonance phlebography confirmed the presence of left-sided iliofemoral thrombosis and raised suspicions of May-Thurner syndrome.

With the patient in a prone position, the left popliteal vein was punctured using ultrasound guidance, and a 4-F introducer sheath was placed. Phlebography confirmed the presence of thrombosis of the proximal femoral vein, extending to the

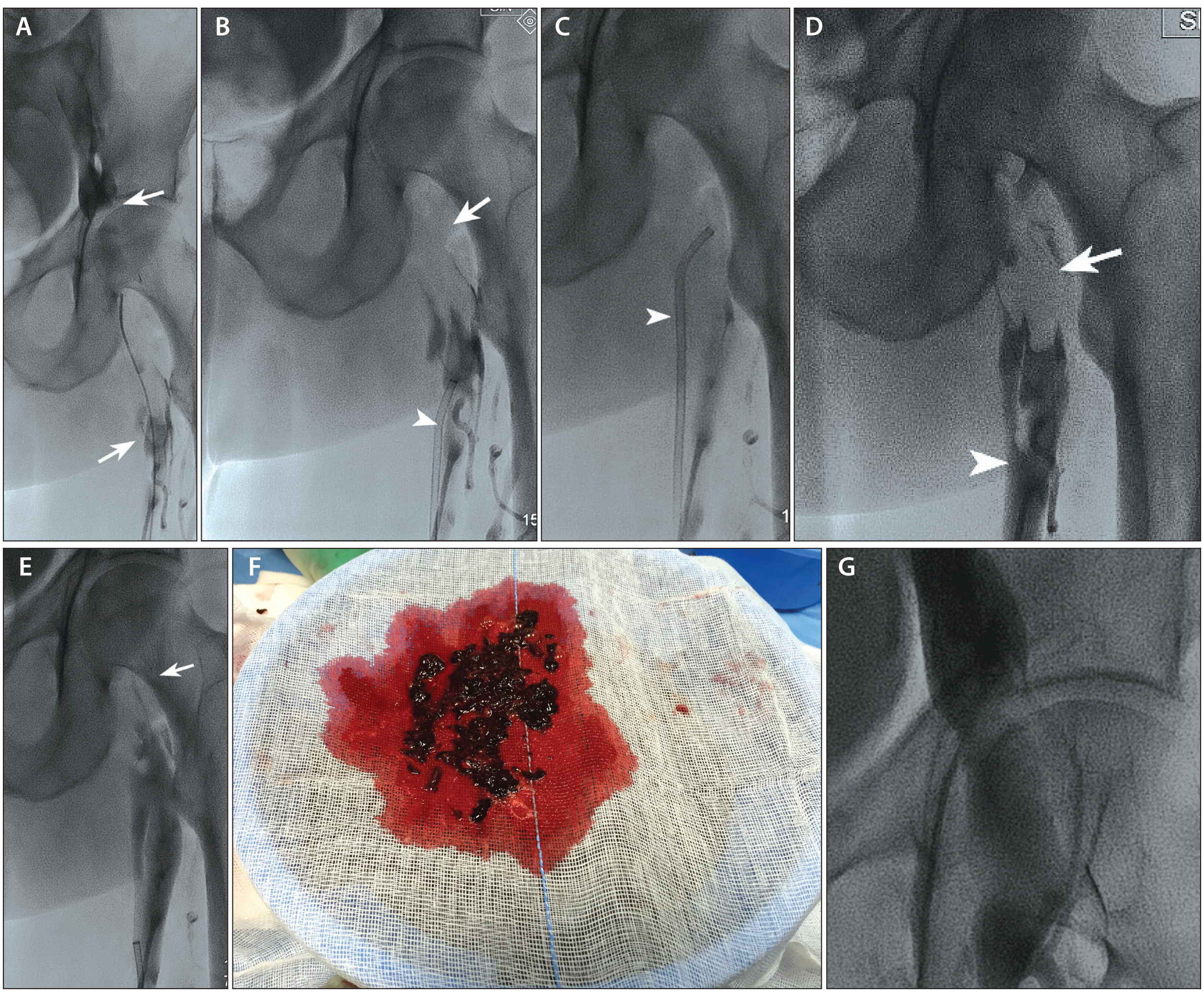


Figure 1. Fluoroscopic image demonstrating extensive iliofemoral thrombosis (arrows) (A). Enlarged fluoroscopic image after exchange for Indigo CAT8 catheter (arrowhead), clearly demonstrating thrombus in femoral vein (arrow) (B). Fluoroscopic image showing the Indigo CAT8 catheter (arrowhead) (C). Fluoroscopic image after first passage of Indigo CAT8 catheter showing patency of inferior segment of femoral vein (arrowhead), while thrombus is still present proximally (D). Fluoroscopic image after additional passages showing further resolution of thrombus burden (arrow) (E). Photograph of thrombotic material obtained (F). Enlarged fluoroscopic image demonstrating almost complete removal of thrombus in common and superficial femoral vein (G).

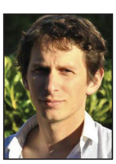
common femoral vein and external iliac vein. At the level of the common iliac vein, a typical image of May-Thurner syndrome was seen with a double-barrel appearance of the left common iliac vein. After crossing the occluded vessel segment with a Glidewire (Terumo Interventional Systems) and a 4-F multipurpose diagnostic catheter, the 4-F introducer was exchanged for a 10-F sheath.

Subsequently, multiple passages with the Indigo System CAT8 XTORQ were made until all thrombus was completely removed and flow was restored (Figure 1). The residual stenosis of the left common iliac vein was subsequently treated with a sinus-Obliquus stent (Optimed; not shown), obtaining an excellent acute result.

DISCUSSION

Traditionally, acute DVT has been treated by catheter-directed thrombolysis. Although relatively safe, it still carries a risk of bleeding complications and requires a stay in the intensive care or medium care unit, which incurs additional costs. Furthermore, repeat control phlebograms need to be performed at set intervals to check proper progression of the thrombolytic process. The Indigo System allows for completion of the procedure in one therapeutic session, without requiring an intensive care unit stay. The XTORQ catheter removes mural thrombus, even in large-diameter vessels, as demonstrated in this case. The rapid restoration of flow is especially helpful in patients with acute DVT and phlegmasia cerulea dolens that threatens the limb and requires urgent treatment and flow restoration. ■

Yann Le Bras, MD
Imagerie Diagnostique et Interventionnelle de l'Adulte
Groupe Hospitalier Pellegrin
Place Amélie Raba Leon
Bordeaux-Cedex, France
Yann.lebras@chu-bordeaux.fr
Disclosures: Consultant for Penumbra.



Francois Petitpierre, MD
Imagerie Diagnostique et Interventionnelle de l'Adulte
Groupe Hospitalier Pellegrin
Place Amélie Raba Leon
Bordeaux-Cedex, France
Disclosures: Consultant for Penumbra.

Recanalization of thrombosed hemodialysis access grafts remains challenging for the interventional community. Multiple techniques have been available since the early 1980s, including manual catheter-directed aspiration with or without urokinase infusion or declotting with either the Fogarty embolectomy catheter (Edwards Lifesciences) or Arrow-Trerotola percutaneous thrombolytic device (Arrow International, a division of Teleflex). Although surgical and endovascular treatments show promise, managing thrombosed hemodialysis grafts in the current patient population warrants improved endovascular techniques. The Indigo System utilizes proprietary Separator technology and an external vacuum pump to more efficiently extract thrombus without the need for lytics.

CASE REPORT

A 56-year-old man presented with acute thrombosis of a hemodialysis prosthetic graft created 2 years prior. The graft occlusion was 2 days old. The patient was treated under deep sedation and continuous monitoring. The arterial pole was punctured with an 8-F short introducer sheath using an antegrade

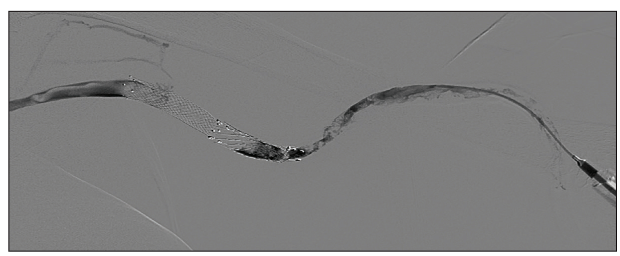


Figure 1. Initial angiogram showing an occluded prosthetic graft with no flow through the stent.

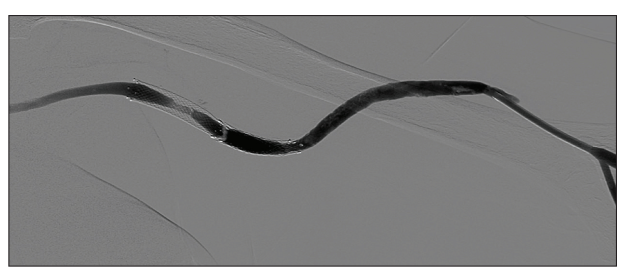


Figure 2. Angiogram after one aspiration with the Indigo CAT8.

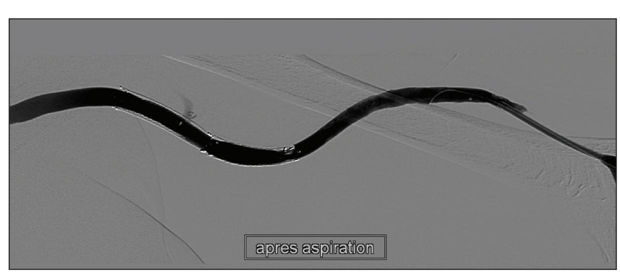
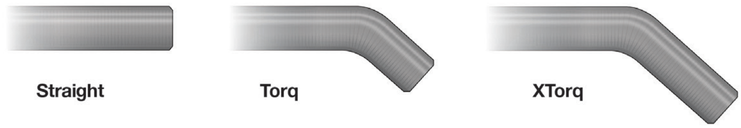


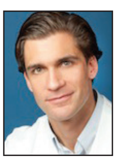
Figure 3. Final angiogram after thrombectomy and angioplasty.



approach. The first angiogram, performed through the introducer, showed thrombosis of the hemodialysis access and a probable intrastent stenosis (Figure 1). First, we attempted to recanalize the shunt with the Indigo CAT8 device (Figure 2). The device was used with the Separator to facilitate the clot fragmentation within the catheter tip and limit the blood aspiration. After a single pass (aspirating from the introducer to the stent and then back to the introducer), the shunt was almost completely recanalized. Total aspiration time was approximately 3 minutes, and blood loss was 150 mL. The treatment was completed by dilatation of the intrastent stenosis using an 8-mm high-pressure balloon inflated at 15 atm (Figure 3). The total procedure time was 58 minutes.

DISCUSSION

The Indigo System appears to safely and efficiently declot hemodialysis shunts. Its main advantages include the rapidity of the procedure achieved by constant power aspiration through a large lumen catheter, as well as the absence of urokinase infusion. Other benefits include the catheter's atraumatic distal tip, which is important in preventing restenosis or secondary thrombosis after intima lesions. Angled tip shapes allow for circumferential aspiration in larger vessels, such as large prosthetic grafts or aneurysms. The internal structure of the catheter prevents catheter collapse or ovalization while under aspiration. Lastly, the Separator device helps to break up extensive thrombus burdens within the catheter tip and can help to decrease blood loss. ■



Florian Wolf, MD, MBA, EBIR, EBCR
Associate Professor of Radiology
Vice Director
Division of Cardiovascular and Interventional Radiology
Department of Biomedical Imaging and Image-Guided Therapy
Medical University of Vienna
Vienna, Austria
florian.wolf@meduniwien.ac.at
Disclosures: Consultant for Penumbra.

Distal embolization during recanalization and percutaneous transluminal angioplasty (PTA) of the superficial femoral and popliteal arteries is a common complication. Although this is especially true for treating complex, calcified, and long lesions, the use of atherectomy devices can trigger similar results. In most cases, embolizing particles are extremely small and are often not clinically relevant; however, some can be limb threatening. The rate of embolization can be up to 100%,[1,2] as was shown in different studies using distal embolization protection devices. Therefore, patients who undergo endovascular therapies must be protected from complications. In the event complications do arise, an immediate solution is required.

CASE REPORT

A 66-year-old man presented with pain in the right lower leg while walking. He complained of a 6-week history of worsening pain and an inability to walk more than 50 meters without stopping. During the clinical examination, no popliteal or foot pulses were detected. Duplex ultrasound examination showed a short occlusion of the proximal right popliteal artery, which needed to be recanalized.

Under local anesthesia, the right common femoral artery was punctured antegrade, and a 6-F sheath was inserted. Diagnostic angiography showed a short

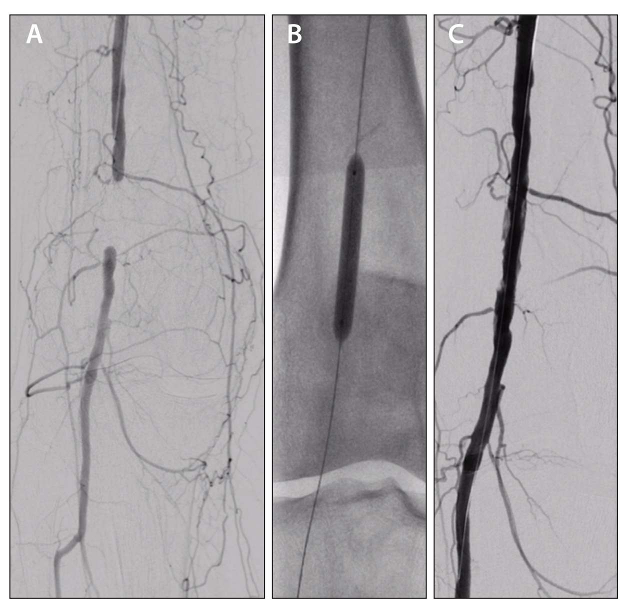


Figure 1. Short occlusion of the proximal right popliteal artery (A). After conventional PTA and PTA with a drug-coated balloon (B), control angiography showed a satisfactory result with no relevant residual stenosis (C).

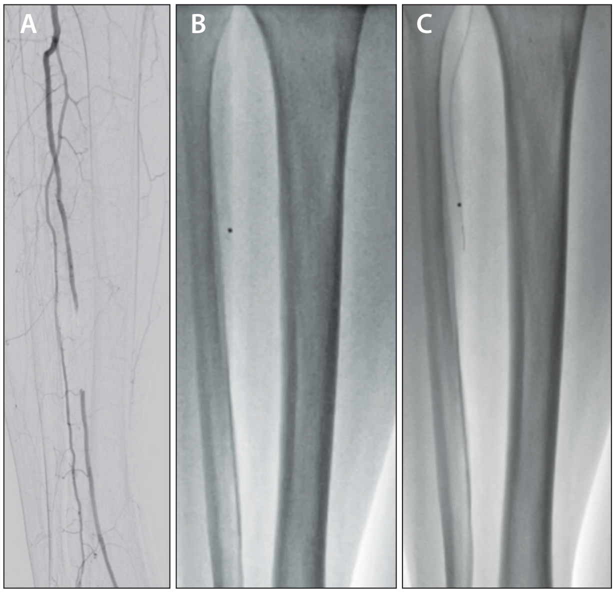


Figure 2. Short embolic occlusion of the mid-anterior tibial artery caused intraprocedurally (A). Thrombectomy was performed using a CAT3 without (B) and with a Separator 3 (C).

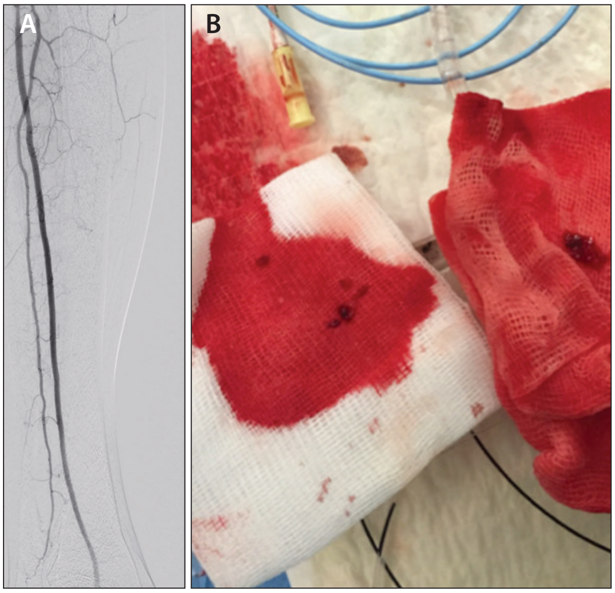


Figure 3. Completely patent and regular anterior tibial artery (A) and the thrombus material (B) removed with the Indigo System.

occlusion of the proximal popliteal artery with a regular reconstitution of the mid and distal popliteal artery and the lower leg vessels (Figure 1A). Intraluminal recanalization of the popliteal artery was achieved using an angled, stiff hydrophilic 0.035-inch guidewire, and PTA was performed using a 4-cm X 40-mm PTA balloon. In order to avoid placing a stent in this region, another PTA was performed using a 5-cm X 40-mm drug-coated balloon (Figure 1B). The final result was excellent, with no residual stenosis and only a tiny, non–flow-limiting dissection (Figure 1C). Final angiogram of the lower leg vessels showed an iatrogenic embolic short occlusion of the mid-anterior tibial artery with very slow filling of the anterior tibial artery distal to the occlusion (Figure 2A). Such an acute complication, in which the anterior tibial artery is the leading vessel in this patient with a two-vessel runoff, required an immediate solution.

The Indigo CAT3 system was quickly introduced and tracked easily into the anterior tibial artery. A Separator 3 was subsequently introduced to facilitate clot extraction by minimizing catheter tip clogging. By cycling the Separator under aspiration, the thrombus was removed quickly back and forth (Figures 2B and 2C). After three passes, the anterior tibial artery was completely patent again (Figures 3A and 3B). The puncture site was occluded using a closure system, and the patient left the hospital the next day in excellent condition.

DISCUSSION

The setup of the Indigo System is extremely easy, requiring just a couple of minutes. Moreover, the Indigo catheters are highly flexible and extremely atraumatic. They can be safely advanced to very small vessels in the distal peripheral vasculature, especially in patients with larger thrombus formations. The Separator has helped evacuate clot more effectively by limiting catheter clogging. The Indigo System should be part of every well-equipped angiography suite. It can help solve thrombotic complications after vessel recanalization and PTA/stent implantation within minutes and avoid overnight thrombolysis. ■

1. Shammas NW, Coiner D, Shammas GA, et al. Percutaneous lower-extremity arterial interventions with primary balloon angioplasty versus Silverhawk atherectomy and adjunctive balloon angioplasty: randomized trial. J Vasc Interv Radiol. 2011;22:1223-1228.
2. Zeller T, Schmidt A, Rastan A, et al. New approach to protected percutaneous transluminal angioplasty in the lower limbs. J Endovasc Ther. 2013;20:409-419.