Indigo® System for Thromboembolic Disease

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Thromboembolic disease comprises a group of disorders that spans across multiple vascular beds. Although the underlying mechanism of thrombus formation may be similar, treatment options vary. This article focuses on thromboembolic disease involving the peripheral and visceral arterial circulation, vena cava, deep venous systems, and arteriovenous (AV) fistulas.

In order to discuss treatment options, we must define the underlying disorders. Arterial thrombosis is usually acute in nature and initiated with atherosclerotic plaque rupture, causing a cascade of events resulting in platelet activation/aggregation and, ultimately, thrombus formation. Venous thromboembolism (VTE) encompasses deep vein thrombosis (DVT) and pulmonary embolism (PE) and is the third most common vascular disorder after acute coronary syndrome and stroke. In VTE, Virchow's triad of endothelial damage, stasis, and hypercoagulability remains the cause behind the mixture of chronic and acute thrombus formation.

A plethora of endovascular thrombus removal techniques exist. Of these technologies, many have failed to treat the thromboembolic disease or have resulted in high complication rates. Complications have included vessel injury, incomplete revascularization, emboli to distal territory, or limited catheter trackability. The Indigo® System (Penumbra, Inc.) has been designed to address the limitations of the previous endovascular techniques. The Indigo System is an aspiration catheter that is available in a range of diameters and lengths, and when used in conjunction with Penumbra's Pump MAX™ and patented Separator™ technology, maintains continuous aspiration and limits clogging of the catheter's tip. The catheters (CAT3, CAT5, CAT6, CAT8, and CATD) vary in diameters from 3.4 to 8 F and lengths ranging from 50 to 150 cm. This allows smaller-diameter catheters to work coaxially through larger-diameter catheters to treat long lesions in tapering vessels. The varying catheter sizes enable the physician to track into vessels as small as those in the foot and as large as the vena cava.

The Indigo System offers operators a unique approach to quickly and efficiently remove clot from the body in a wide variety of thromboembolic disease states, reducing the need for systemic lytic therapy. The following cases highlight the rapid treatment of thromboembolic disease using Indigo in both arterial and venous occlusions.

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CASE REPORT: CLOT EXTRACTION USING CAT8 IN THE POPLITEAL ARTERY AND TIBIOPERONEAL TRUNK

A man in his late 60s presented 3 days after coronary artery bypass grafting (CABG) with no right leg pulses. An arterial duplex exam revealed no flow below the right knee. The patient was emergently brought to the angio suite. The patient was contraindicated for lytics due to CABG. A 4-F sheath was placed from the left common femoral artery. Pelvic angiography and right leg arteriography were performed. Fortunately, these vessels were widely patent, without pseudoaneurysm or extravasation. Angiography revealed complete occlusion of the right popliteal artery just above the knee joint and occlusion of the proximal tibioperoneal runoff (Figures 1 and 2). A meniscus sign was present in the mid-popliteal artery, suggesting fresh thrombus and the possibility of a favorable outcome with the Indigo System. The 4-F left common femoral artery sheath was then exchanged for an 8-F, 65-cm Destination® sheath (Terumo Interventional Systems), and 5,000 units of heparin were administered.

A Indigo CAT8 aspiration thrombectomy catheter was easily passed onto the top of the right popliteal artery occlusion. The CAT8 was connected to the Pump MAX for continuous aspiration, and the popliteal artery clot was removed. Follow-up imaging revealed dramatic recanalization with a widely patent popliteal artery and two-vessel runoff to the right foot, with no residual thrombus (Figures 3 and 4). The posterior tibial artery was chronically diseased but was distally reconstituted, with restored flow to the peroneal artery. The patient's pulses were Dopplerable on the table, and his right foot returned to normal without further issues. He was later discharged home once his anticoagulation reach a therapeutic level.

Figure 1. A baseline arteriogram revealing occlusion of the right popliteal artery and trifurcation vessels.

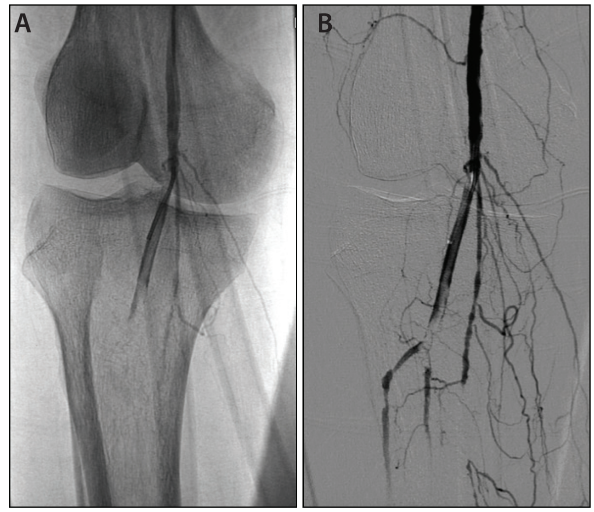

Figure 2. More selective imaging showing a large filling defect in the mid- (A) and lower popliteal artery (B) extending into the trifurcation.

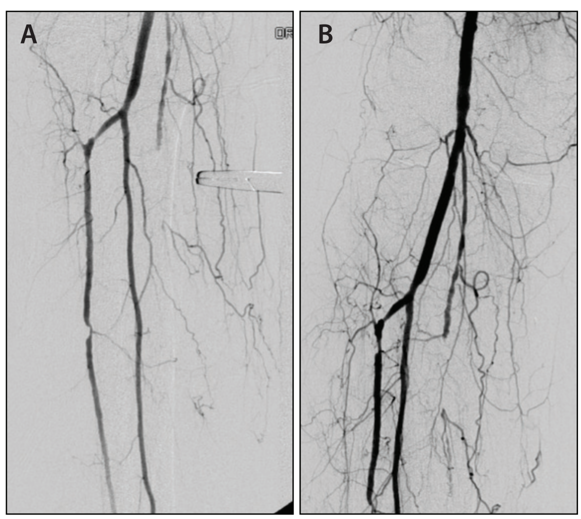

Figure 3. Dramatic and complete recanalization of the right popliteal artery (A) and mid-calf trifurcation vessels (B) after a single extraction with the CAT8 device.

Figure 4. An arteriogram of the distal runoff after restored flow to the proximal vessels.

DISCUSSION

The addition of the Indigo System has been an exciting and important addition to endovascular therapy. We have seen rapid and dramatic results in many patients, and these tools are especially important in the highest-risk patients who are not good candidates for lytic therapy or who are poor surgical candidates. We have used the Indigo System in our labs in a wide variety of applications, and we have been impressed with its rapidity, effectiveness, and ease of use.

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CASE REPORT: USE OF THE INDIGO SYSTEM TO ASPIRATE AORTIC AND RENOVISCERAL THROMBUS

A man in his late 50s who recently had a stroke developed sudden bilateral lower extremity weakness 3 days prior to referral to our facility (Arizona Heart Hospital in Phoenix, Arizona). At presentation, the patient showed evidence of severe bilateral lower extremity ischemia, with the right limb being much worse than the left, with mild abdominal pain. Motor and sensory deficits were apparent; the patient could barely move his ankles and toes, and sensory function was drastically decreased up to the patient's knees. In addition, he had absent femoral artery pulses. CTA confirmed an aortic occlusion, which was mostly acute in nature. Due to the patient's recent stroke, treatment options were limited.

The patient was brought emergently to the operative suite, was systemically heparinized, and bilateral open cut down was performed to the femoral vasculature. Open thrombectomy using a 5-F Fogarty® balloon (Edwards Lifesciences) was performed in an infrarenal fashion distally into the common and external iliac arteries to remove large volumes of thrombus. The superior mesenteric artery (SMA) and right renal artery were thrombosed, as shown on the angiogram and aortogram (Figures 1 and 2).

Access to the SMA was gained utilizing a 5-F diagnostic catheter and a 0.014-inch wire. The CAT6 and SEP6 catheters (Penumbra, Inc.), which are part of the Indigo System, were placed in the SMA (Figure 3), and the thrombus was aspirated in a proximal-to-distal manner. The right renal artery was then selected using the aforementioned 5-F diagnostic catheter and 0.014-inch wire. The CAT6 and SEP6 devices were then employed, and the thrombus in the right renal artery was successfully aspirated. The highly trackable Indigo catheters enabled us to selectively aspirate distally into the difficult-to-cannulate visceral arteries. Angiography of each vessel was performed, confirming restoration of blood flow into the SMA and right renal artery (Figures 4 and 5).

An infrarenal aortogram was obtained and revealed heavy sidewall thrombus along the aortic wall. The 8-F Indigo CAT8 catheter, which has a directional tip, enabled circumferential aspiration to remove the sidewall aortic thrombus. A final angiogram showed excellent flow into the visceral arteries but underlying disease along the aortic wall. It was decided that the best option to completely treat the diseased aorta was to place a 25- X 90-mm AFX® bifurcated stent graft (Endologix, Inc.). Completion aortography showed complete resolution of aortic disease (Figure 6). The patient was anticoagulated, and follow-up CTA showed excellent visceral artery and aortic flow.

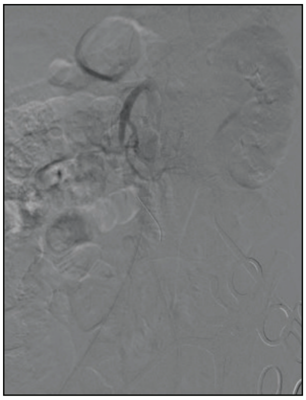

Figure 1. Selective angiography showing no distal perfusion into the SMA.

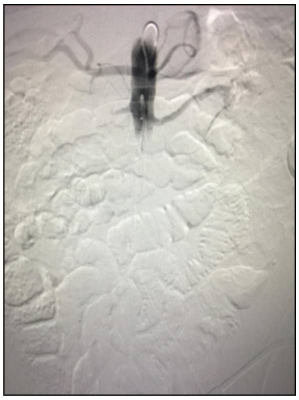

Figure 2. An aortogram showing no perfusion into the right renal artery.

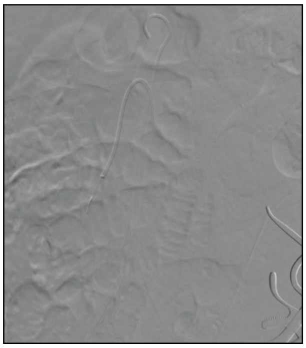

Figure 3. The CAT6 and SEP6 devices aspirating clot in the SMA.

Figure 4. Selective angiography of the patent SMA.

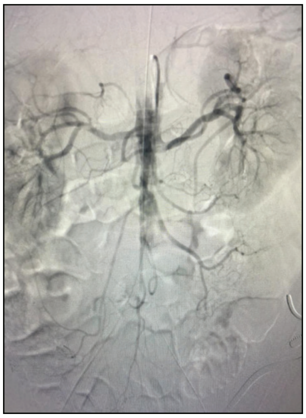

Figure 5. An aortogram showing restored blood flow to right renal artery.

Figure 6. A final aortogram showing resolution of aortic disease.

DISCUSSION

Prior to the Indigo System, the only reliable option for treating such a large bulk of visceral and aortic thrombus was open surgical embolectomy. Today, with the highly trackable Indigo System aspiration catheters, we have the ability to treat these patients with a rapid, minimally invasive endovascular approach.

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CASE REPORT: SUPERIOR VENA CAVA THROMBUS EXTRACTION

A woman in her late 60s who had a history of metastatic breast cancer and was on immunotherapy presented to the hospital with rapidly progressive bilateral upper extremity and facial edema. She had associated shortness of breath and hypoxemia.

Duplex ultrasound examination of the upper extremity veins demonstrated thrombosis of the brachial, basilic, axillary, subclavian, and brachiocephalic veins. Central venous waveforms were severely dampened. CT imaging of her chest, abdomen, and pelvis demonstrated diffuse osseous and mediastinal metastatic disease, with near-complete compression of the superior vena cava (SVC), azygos drainage of the upper extremities, and confluent mediastinal lymphadenopathy. New, small brain lesions were also identified by MRI. The patient was diagnosed with SVC syndrome. She underwent two emergency radiation sessions but had persistent clinical symptoms. Thrombolysis was relatively contraindicated by her hematologist-oncologist secondary to diffuse metastatic (including intracranial) disease.

She was brought to the angiography suite and was placed under general anesthesia. Ultrasound guidance was used for bilateral basilic vein access and right femoral vein access. A 10-F sheath access was obtained in her bilateral upper extremities, and an 8-F sheath access was achieved in the right common femoral vein. Bilateral upper extremity venography demonstrated SVC occlusion, with centrally expansile thrombus in the SVC, brachiocephalic, axillosubclavian, and bilateral basilic veins (Figure 1). Wire access was achieved from both arms into the inferior vena cava (IVC). From the groin access, a 16-mm balloon was inflated in the SVC below the occlusion/thrombus. The patient was systemically heparinized. The Indigo CAT8 XTORQ catheter (Penumbra, Inc.) was then used with multiple passes in the bilateral upper extremities to recanalize the occluded venous segments. Follow-up venography demonstrated near-complete stenosis of the SVC from extrinsic compression. Intravascular ultrasound was used to evaluate the treated segments for further acute versus chronic thrombus. Overlapping 14-mm self-expanding stents were then placed from both brachiocephalic veins into the SVC in a "kissing" fashion. There was complete resolution of thrombus and all collateral flow, with inline flow via both upper extremities to the right atrium (Figure 2). Upon checking the Indigo System vacuum canister, a mix of chronic and acute clot was removed with the CAT8 XTORQ (Figure 3).

DISCUSSION

SVC syndrome is an often-fatal complication of mediastinal malignancy but can also be seen with VTE disease, secondary but not limited to indwelling catheters and hypercoagulable states. Often, patients in this category are not good candidates for thrombolysis. However, the Indigo System provides effective immediate thrombus removal to re-establish central venous flow while also helping identify the underlying culprit lesions.

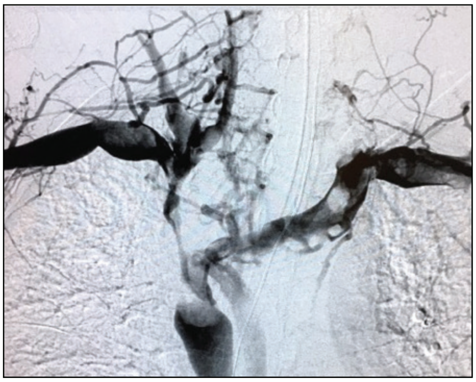

Figure 1. Venography from both upper extremities demonstrates thrombus in the subclavian veins, brachiocephalic veins, and the superior vena cava. Extensive collateralization is seen over the chest, and the azygos vein is dilated.

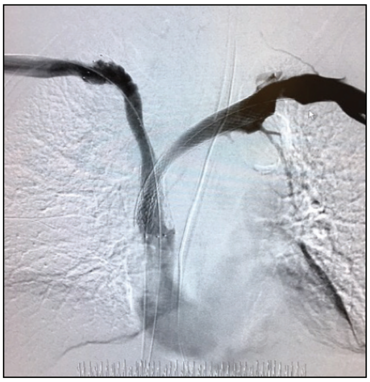

Figure 2. After thrombectomy and stenting, there is complete resolution of thrombus and collateral flow.

Figure 3. Chronic and acute clot was removed with CAT8 XTORQ.

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CASE REPORT: THROMBUS EXTRACTION AFTER LYTIC THERAPY IN A PATIENT WITH BILATERAL DVT

A woman in her late 50s presented to our facility with lower extremity pain and swelling. The patient had a past medical history of extensive bilateral DVT and PE and placement of a Greenfield™ filter (Boston Scientific Corporation) in 2005. She was diagnosed with factor V Leiden and was prescribed rivaroxaban. The use of CTA to detected a venous filling defect was limited due to the timing of contrast filling but did indicate that DVT was present in the common femoral vein, deep femoral vein, femoral vein, popliteal vein, posterior tibial vein, and external iliac vein. The patient's rivaroxaban was held, and she was heparinized.

On postpresentation day 2, the patient was brought to our angio suite and placed in the supine position on the operating table. Access was achieved via the internal jugular vein with a 5-F Pinnacle® sheath (Terumo Interventional Systems). Venography was performed and demonstrated thrombus from the proximal iliac veins up to the previously placed Greenfield filter (Figure 1). Due to the positioning and level of thrombus burden, we placed a Denali® filter (Bard Peripheral Vascular, Inc.) in the 26-mm suprarenal IVC. The patient was then placed in the prone position, and bilateral popliteal vein access was achieved using two 8-F Pinnacle sheaths. Using the bilateral access, we traversed the length of the thrombus occlusion through both IVC filters utilizing stiff, angled Glidewires® (Terumo Interventional Systems). After crossing the IVC filters, we placed two lytic catheters and delivered tissue plasminogen activator (tPA) for 24 hours.

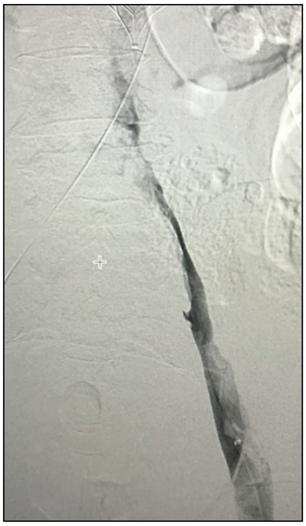

Figure 1. Postthrombolytic venogram demonstrating the thrombus burden present in the iliac veins into the IVC.

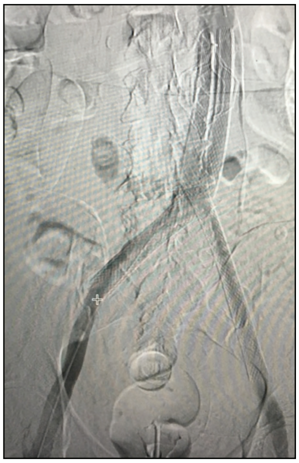

Figure 2. After aspiration thrombectomy with the Indigo System, a Wallstent was placed and venography showed restoration of blood flow from the iliac veins through the IVC.

After the 24-hour lytic drip, venography was performed, revealing thrombus (Figure 2). Due to the residual postlytic thrombus, we decided to use a CAT8 mechanical aspiration thrombectomy catheter. We aspirated the clot starting in the iliac veins, working the CAT8 XTORQ and SEP8 into the IVC. After CAT8 mechanical aspiration, two double-barrel 18- X 60-mm Wallstents™ (Boston Scientific Corporation) were placed in the IVC and postdilated with 12- X 40-mm Armada™ balloons (Abbott Vascular). The Indigo System's CAT8 was used again to aspirate thrombus out of the right external iliac vein. Postaspiration, a 16- X 90-mm Wallstent was placed in the patient's right common iliac vein and external iliac vein, and a 16- X 60-mm Wallstent was placed in the left common iliac vein. The final venogram showed restoration of blood flow from the iliac veins through the IVC filters (Figure 2).

The patient resumed using rivaroxaban and was discharged. At 2.5 months postintervention, the patient was brought back to the interventional suite to remove the Denali filter, and venography was performed demonstrating completely patent IVC and iliac veins.

DISCUSSION

Penumbra's Indigo System is essential for thrombus removal, both in de novo thrombectomy as well as adjunctive to failed thrombolytic therapy in the treatment of occluded IVCs and IVC filters. The CAT8 gives interventionists the ability to achieve prompt technical success in difficult situations, which might not be possible using traditional thrombectomy methods.

Introducing a New Size Configuration for the Indigo System: CATD and SEPD

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CASE REPORT: HeRO GRAFT RECANALIZATION USING CATD

A man in his early 70s with a clotted right arm HeRO® graft (Merit Medical Systems, Inc.) presented for a consult with interventional radiology for a declotting procedure to resume hemodialysis. After obtaining informed consent, the patient was brought to the angio suite, and his right arm was prepped and draped in a sterile fashion. The right upper arm HeRO graft was accessed with a Micropuncture® Introducer set (Cook Medical). An 8-F sheath (Flexor®, Cook Medical) was introduced over a 0.035-inch guidewire wire. A hydrophilic guidewire and angled 5-F catheter were then introduced and advanced into the venous outflow component of the graft to the level of the right atrium. Pullback venography was performed, which showed clot extending peripherally from the level of the HeRO connector component (Figure 1). A total of 5,000 units of heparin was administered intravenously. A 20-cm-long infusion catheter (Cragg-McNamara®, Medtronic) was inserted over a stiff guidewire, and 4 mg of tissue tPA diluted into 20 mL of contrast and heparinized saline was pulse injected across the clotted portion and set to dwell for 10 minutes (Figure 2).

Next, vacuum-assisted suction thrombectomy of the venous limb was performed using the Indigo System CATD aspiration catheter (Figure 3). The catheter was slowly advanced centrally until the entire length of thrombus was cleared. The angulated tip of the CATD allowed for circumferential aspiration within the HeRO graft. This was confirmed fluoroscopically by aspiration of thrombus laced with tPA

Figure 1. Initial venogram revealing clot extending peripherally from the HeRO connector component.

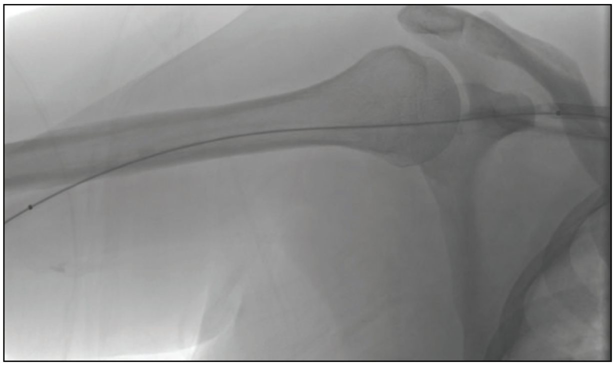

Figure 2. A 20-cm-long infusion catheter (Cragg-McNamara) positioned across thrombus.

and iodinated contrast (Figure 4). Only one central pass of the catheter was needed to clear the outflow (Figure 5). A total of 175 mL of blood was aspirated and recorded as blood loss.

After the venous limb of the graft was cleared by suction thrombectomy, a second access directed toward the arterial limb of the graft was obtained. The AV anastomosis was traversed with a hydrophilic guidewire and angled catheter. The catheter was exchanged over the guidewire for a 6-F vascular sheath. The angled catheter was positioned into the inflow artery. Contrast was injected and demonstrated patent arterial inflow, with clot extending from the arterial

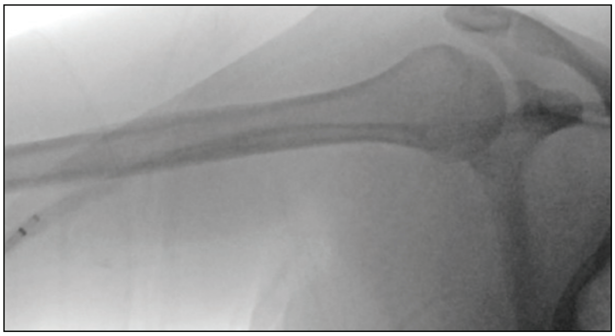

Figure 3. The CATD aspiration catheter was advanced into the HeRO graft, and the thrombus was injected with a tPA/contrast/saline mixture.

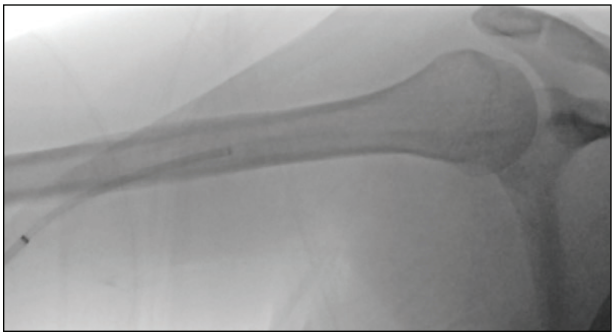

Figure 4. Fluoroscopic imaging immediately post-CATD aspiration showing that the contrast-laced thrombus was removed.

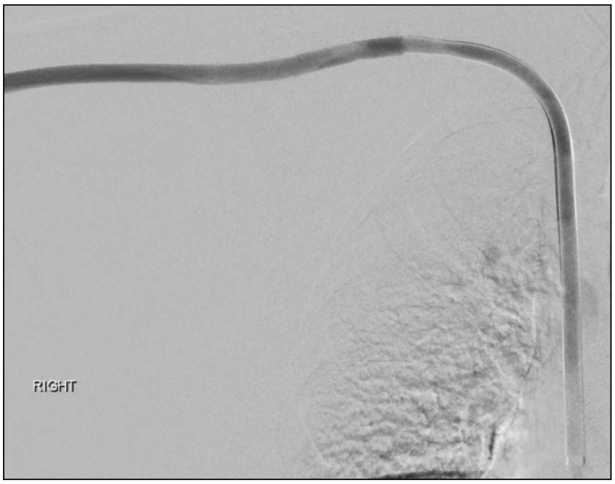

Figure 5. A fistulagram showing patent venous outflow.

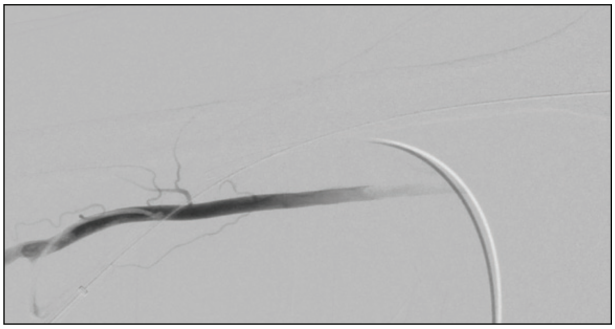

Figure 6. An arteriogram revealing patent arterial inflow and an arterial plug present at the arterial anastomosis.

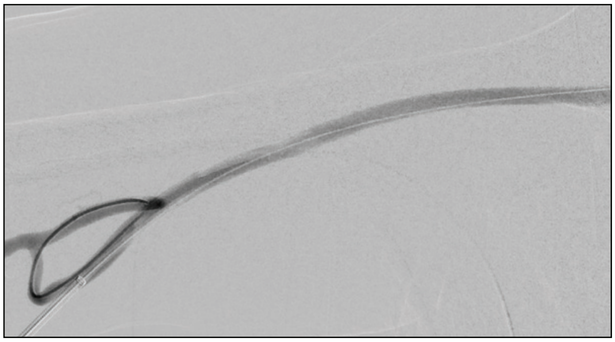

Figure 7. A fistulagram showing restored flow in the AV graft.

anastomosis (Figure 6). A Fogarty balloon was used to pull the arterial plug while the thrombus was simultaneously aspirated from the sheath. Repeat injection into the inflow artery demonstrated restored flow in the AV graft (Figure 7). An excellent thrill was palpable at the conclusion of the procedure.

The vascular sheaths and guidewire were removed, and hemostasis achieved with a purse-string suture at the antegrade 8-F access and manual compression alone over the retrograde 6-F access. The total procedure length was 47 minutes and required 12 minutes of fluoroscopy time.

DISCUSSION

HeRO grafts are a vital tool for patients who have exhausted all other dialysis sites in the upper arm. However, these grafts can frequently develop thrombus and need to be declotted. Traditional rheolytic thrombectomy disrupts hemodynamics, commonly causing bradycardia and pulmonary vasospasm. This risk is amplified in HeRO graft declotting procedures due to thrombi in close proximity to the heart. With Penumbra's CATD aspiration system, this risk is essentially eliminated because the CATD is a pure aspiration system that removes the thrombus without the risk of causing hemolysis, regardless of how close the thrombus is to the heart.

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CASE REPORT: CLOT EXTRACTION USING THE CATD FROM AN ARTERIOVENOUS GRAFT

A man in his early 60s presented with a clotted left brachiobasilic straight AV graft. The graft was implanted 8 months prior to patient presentation.

The venous outflow of the AV graft was accessed with a 4-cm, 8-F Prelude® sheath (Merit Medical Systems, Inc.). An initial fistulagram was obtained using a 40-cm Kumpe® diagnostic catheter (Cook Medical) and showed thrombus in the venous outflow of the AV graft (Figure 1). Four mg of tPA was administered across the thrombosed portion of the AV graft. Next, the Indigo System CATD device was used to aspirate thrombus centrally to distally, starting with the open flow channel then pulling back into the clot. The catheter was centrally advanced from the tip of the access sheath along the entire length of the thrombus. After thrombus aspiration, a graftogram was obtained, which confirmed removal of the thrombus but also revealed an underlying stenosis at the stent edge (Figure 2). The stenosis was treated with angioplasty and demonstrated a good angiographic result (Figure 3). A final graftogram was obtained, revealing restored flow in the AV graft (Figure 4). The patient had successful dialysis the same day.

DISCUSSION

Patients undergoing dialysis frequently have cardiopulmonary comorbidities, making them high-risk patients overall, thus techniques minimizing central thromboembolism offer a potential safety advantage in such patients with a clotted AV access. By removing the clot, the Indigo System CATD aspiration catheter can minimize the degree of emboli that may end up in the cardiopulmonary circuit. This is potentially a safer option for patients with this chronic condition. ■

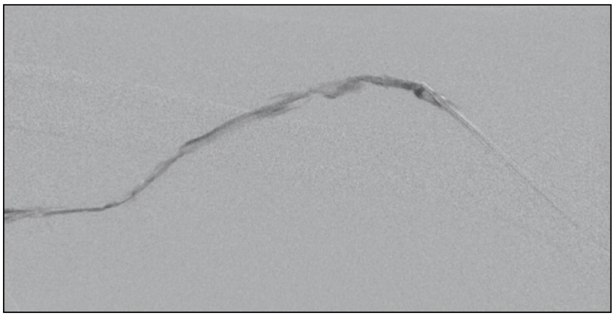

Figure 1. The initial fistulagram showing the thrombosed brachiobasilic graft.

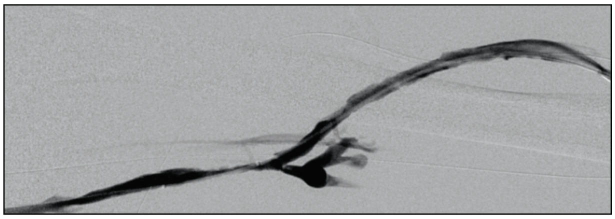

Figure 2. A fistulagram after CATD use, showing removal of thrombus and revealing an underlying venous stenosis.

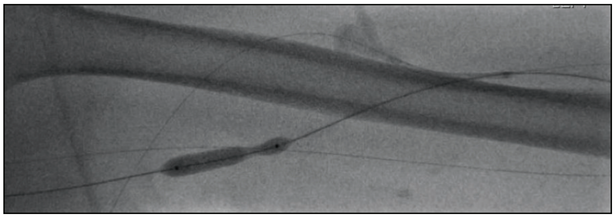

Figure 3. Intraprocedural angioplasty of the venous stenosis; however, despite PTA, residual stenosis > 50% persisted.

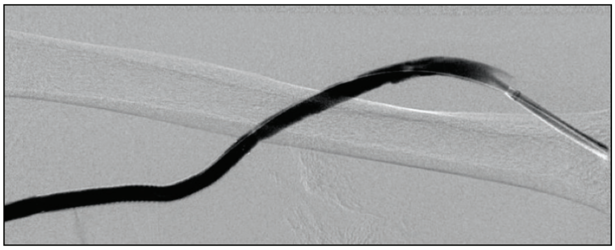

Figure 4. The final fistulagram showing patent AV graft.

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.