

The Indigo System and CAT8

Experts discuss the use of the Indigo System and CAT8 for thrombectomy and fistula salvage.



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CASE REPORT

A woman in her 20s was referred to our institution with a deep vein thrombosis (DVT) of the right popliteal vein, extending into the right femoral and iliac veins, with, most likely, an acute occlusion on an already compromised venous system. A CT venogram showed thrombus extending from the left common iliac vein into the inferior vena cava. Furthermore, pulmonary emboli were present

in the right lung. Given the high probability of a long-standing problem, it was decided to proceed with a surgical thrombectomy and local thrombolysis. This procedure, performed while the patient is under general anaesthesia, consists of a local thrombolysis of the affected leg combined with a fluoroscopically guided venous thrombectomy of the iliac vein. To achieve local thrombolysis, a tourniquet is placed around the upper leg and 5,000 units of urokinase in 1,000 mL of saline are infused through a foot vein. This is followed by a venotomy of the common femoral vein and a thrombectomy, which occurs at the same time the thrombolytic agent is infused. After the venous thrombectomy, the tourniquet is released and the “flushing” of the leg is achieved.

Prior to the thrombectomy, an Optease® retrievable vena cava filter (Cordis, a Cardinal Health company®) was placed through a left common femoral vein access (10 F). Control phlebography after thrombectomy showed reconstitution of flow in the iliac segment and a filling defect in the caval filter (Figure 1). Subsequently, a thromboaspiration was performed using the Indigo CAT8 XTORQ catheter connected to the Indigo Pump MAX (Penumbra, Inc.; Figure 2). After one passage,

the filling defect was no longer visible (Figure 3) and examination of the contents of the canister revealed a long, organised, thrombotic mass (Figure 4) corresponding to the filling defect initially seen on the phlebogram. The patient did not have signs of additional pulmonary embolism (PE) after the procedure (that was completed with iliac stent placement, not shown here).

DISCUSSION

This case report demonstrates the feasibility of “cleaning out” a caval filter with an Indigo CAT8 XTORQ catheter, even when the thrombotic material is already organised. ■

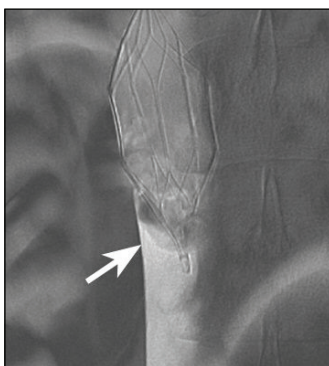


Figure 1. A roadmap image obtained during a thrombectomy procedure demonstrating a large filling defect (arrow) caused by an embolic thrombus fragment.

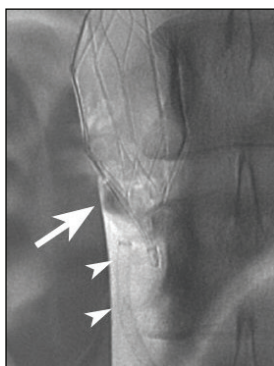


Figure 2. A roadmap image showing thrombus (arrow) and an Indigo CAT8 XTORQ catheter (arrowheads) during aspiration.

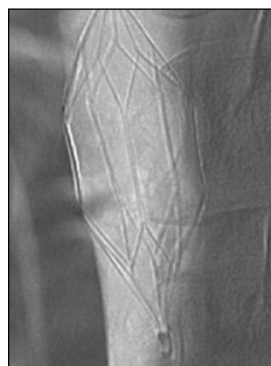


Figure 3. A roadmap image after aspiration of thrombus with an Indigo CAT8 XTORQ catheter.

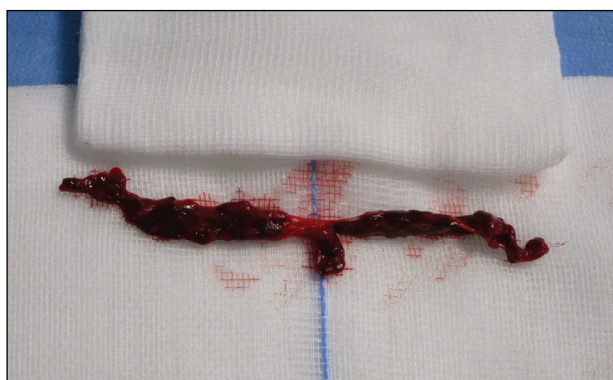
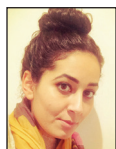


Figure 4. A thrombus fragment found in the canister.



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Due to an increasing number of patients with renal failure, it has become important to maximise efficient and effective management plans for renal dialysis patients.

Fistulas blocked by thrombus will not survive or function beyond 24 hours if the majority of the clot is not removed. Therefore, we encourage the use of mechanical thrombectomy devices, preferably those with soft tips and safe tracking ability to allow for the full removal of a clot in dynamic tortuous lumens, such as those found in fistulas.

CASE REPORT

A man in his 80s with a 5-year-old left radiocephalic fistula came to our center with a clotted fistula 3 days after failed dialysis. The patient had a history of myelodysplasia, type 2 diabetes with unstable angina, and a right-side pacemaker. His hemoglobin levels were 74 g/dL and both his skin and vessels were fragile.

The Indigo System (Penumbra, Inc.) was selected to salvage the blocked fistula after Doppler ultrasound and fistulagram confirmed total clot occlusion up to the central venous system. Access was gained by an



Figure 1. A left radiocephalic fistula, with clot extending from just above the dialysis puncture site. The wire is extending centrally into the superior vena cava.

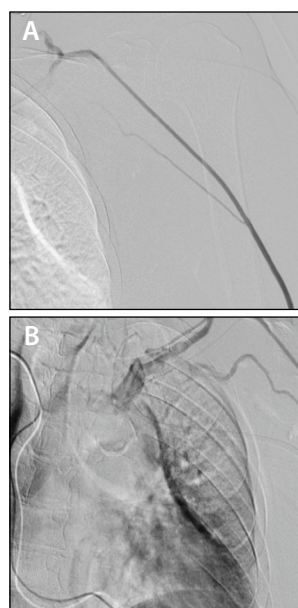


Figure 2. A central clot extension (A). A clot extension into the proximal subclavian vein (B).

8-F short sheath in the venous outflow direction. The first venogram confirmed almost complete thrombosis of the venous segment into the proximal subclavian vein (Figures 1 and 2). An 0.018-inch soft-tip wire was used to cannulate the fistula into the inferior vena cava. After connecting to the Pump MAX, the Indigo System CAT8 TORQ85 catheter (Penumbra, Inc.) and SEP8 separator (Penumbra, Inc.) were then introduced into the venous outflow. The Separator was used to facilitate clearing of the thrombus from the catheter tip (Figure 3). The proximal and distal venous segments were adequately declotted without the need for further intervention (Figure 4).

The total procedural time was 15 minutes; total aspiration time was approximately 5 minutes, with very minimal blood loss (< 50 mL). The final 8-mm balloon venoplasty treatment used a high-pressure balloon at 14 atm after aspiration. The patient was sent for dialysis, which was successful, and the fistula remained patent 6 months after the procedure.

CONCLUSION

With more fistula cases presenting, it is paramount to have an efficient and effective system in managing these patients to preserve fistula patency and function, while limiting repeated interventions and resources.

The age of the clot, the type of fistula, and the underlying cause of the acute thrombosis are important factors. These parameters should be matched

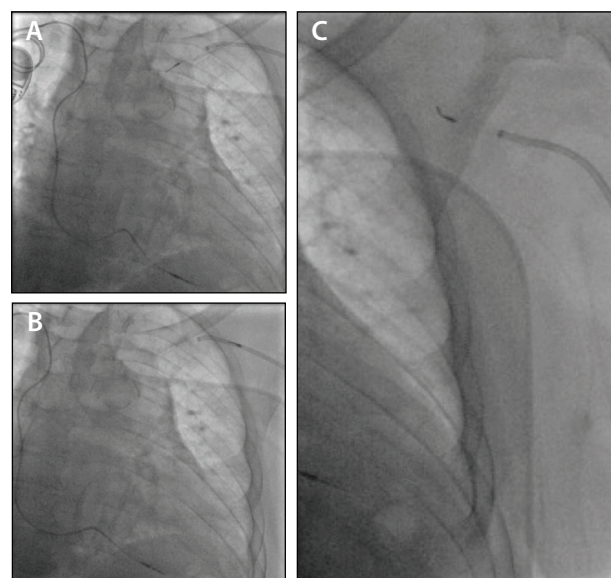


Figure 3. The Indigo System CAT8 catheter (A). The Indigo System CAT8 catheter with Separator (B) working through the clot (C).

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with the management plan. In our cases, acute thrombosed, complex (< 14 days), and aneurysmal fistulas are best managed with the Indigo System. We were able to clear the majority of the clot and navigate safely, within stents, anastomoses, and arterial segments. The underlying cause was stenosis, usually treated via balloon venoplasty.

The outcome has led to successful postprocedural dialysis and patency at 6-month follow-up. ■

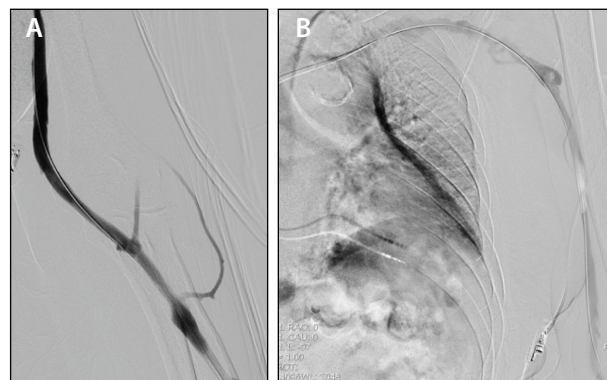


Figure 4. Complete clearance of the clot with a single pass of the Indigo System CAT8 catheter (A). An almost complete clearance of clot and recanalisation of the central venous system using a single pass of the Indigo System CAT8 catheter alone (B).



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CASE REPORT

A man in his 50s was referred to our hospital with a history of DVT of the left femoral vein, after a long period of immobilisation of his lower limbs. He exhibited sudden dyspnea, chest pain, and developed bradycardia. His condition progressed to hemodynamic instability and declining respiratory status. Subsequently, he was transferred to the intensive care unit, where vasopressors and intravenous fluid treatments were required to maintain adequate hemodynamic condition.

A CT scan evidenced several filling defects (thrombus) in relation to the right main pulmonary artery, right superior lobar artery, and bilateral inferior lobar arteries. Full therapeutic intravenous sodic heparin was initiated. An echocardiogram demonstrated moderate right ventricular dilatation and right heart hypokinesis, which was inconsistent with myocardial infarction.

The patient was transferred to the interventional suite. After being placed in the supine position, right femoral vein access was established under ultrasound guidance with placement of a 65-cm, 8-F Pinnacle®

sheath (Terumo Interventional Systems). The initial pulmonary angiogram using a straight pigtail catheter (Cordis, a Cardinal Health company®) demonstrated a large, obstructive PE in the right main pulmonary artery, right lobar arteries, and left inferior lobar artery.

A 115-cm Indigo CAT8 XTORQ catheter advanced through a Pinnacle® Destination® guiding sheath over a 260-cm hydrophilic stiff guidewire (Terumo Europe) was used to perform mechanical thrombectomy. Under aspiration using the Indigo System, multiple passes with the Indigo CAT8 XTORQ catheter were made until most of the thrombus was removed and flow was restored. The SEP8 separator was used to fragment the thrombus at the catheter tip. The thrombus was then suctioned through the catheter when aspiration thrombectomy was initiated. Final selective angiography was performed in each pulmonary artery (right and left) with a lower contrast injection flow (< 8 mL/s) to demonstrate good distal vascular flow. The total procedure time was 72 minutes.

After the completed thrombectomy procedure, the patient resumed therapeutic parenteral anticoagulation. The patient immediately displayed improvement in respiratory and hemodynamic status after the interventional procedure. Follow-up echocardiography revealed right ventricular strain improvement 24 hours later. No major procedure-related complications were reported. The patient was discharged from the critical care unit to the middle care unit after 6 days.

DISCUSSION

The fundamental objective of the technique using the Indigo System with CAT8 catheter to

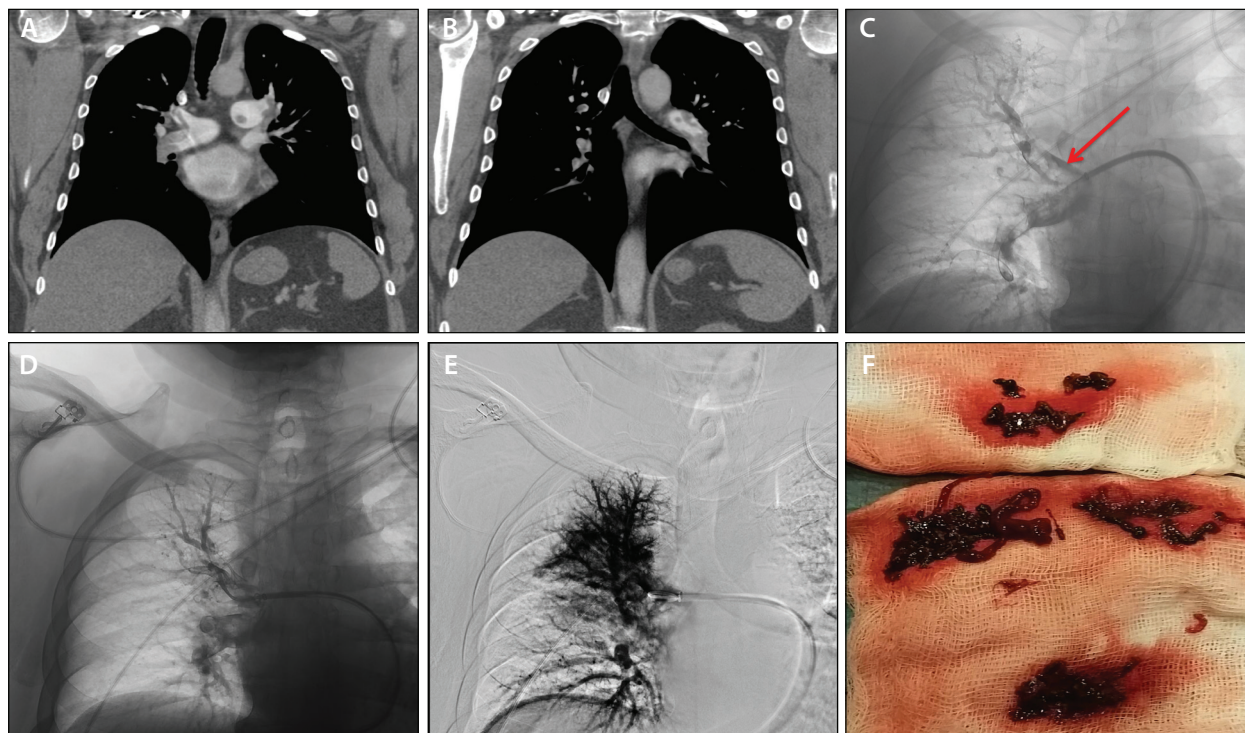


Figure 1. A man in his 50s with acute massive PE. CT images showed extensive filling defects within the right main pulmonary artery, right lobar arteries, and left inferior lobar artery (A, B). Selective pulmonary angiography shows large obstructive PE in the right main pulmonary artery and lobar arteries (red arrow). The Indigo System CAT8 aspiration catheter was placed into the thrombus and aspiration was started (C, D). Posttreatment angiography shows resolution of most of the clot burden and near normal perfusion of the right lung (E). Thrombotic material was obtained (F).

eliminate central pulmonary artery thrombus by a controlled process of fragmentation and suction, thus alleviating the main pulmonary obstruction. This allows for both improved perfusion and a reduction of right ventricular pressure overload. The Indigo System CAT8 catheter comes in three different tip designs—straight, 45°, 90°—which

allows a wide range of rotation. This device can be used in patients who are unstable or deemed to be at increased risk of hemodynamic compromise, or in patients with contraindications to systemic thrombolysis. We recommend this device to help patients improve clinical and echocardiographic outcomes. ■

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CASE REPORT

A man in his 70s, an active smoker with hypertension and a history of right superficial femoral artery (SFA) stenting, presented with closed claudication. A Doppler

ultrasound revealed an occlusion of the right SFA with patency of the popliteal artery and tibioperoneal vessels. The patient was then referred to our vascular interventional unit for lower extremity angiography and revascularisation.

Endovascular revascularisation in patients with intermittent claudication has been chosen as the first therapeutic approach because of high clinical success rates and lower complication rates compared to surgery.^{1,2} Even in the case of stenting or endoluminal bypass with a stent graft, the results of endovascular treatment are consistent with those obtained with above-the-knee femoropopliteal prosthetic bypass.^{3,4}

After informed consent was obtained from the patient, digital subtraction angiography of the right lower limb was performed through a 6-F, 45-cm sheath (Flexor® Check-Flo®, Cook Medical). The angiogram confirmed the occlusion of the SFA, with recanalisation at the Hunter's canal distally to the previously placed bare-metal stent. The popliteal and tibioperoneal arteries were patent, with a thin posterior tibial artery and opacification of the plantar arch through the dorsalis pedis and a hypertrophic collateral of the peroneal artery (Figure 1). After SFA angioplasty with a 5-mm balloon catheter (Pacific Plus OTW PTA Catheter, Medtronic), the control angiogram showed the presence of distal embolisation in the popliteal artery and poor opacification of the distal vessels (Figure 2).

The patient immediately reported acute right foot pain. To remove the obstruction from the popliteal artery, we decided to perform a mechanical thrombectomy through a long 8-F, 90-cm sheath (Flexor® Shuttle® Guiding Sheath, Cook Medical) with the Indigo System (Penumbra, Inc.)

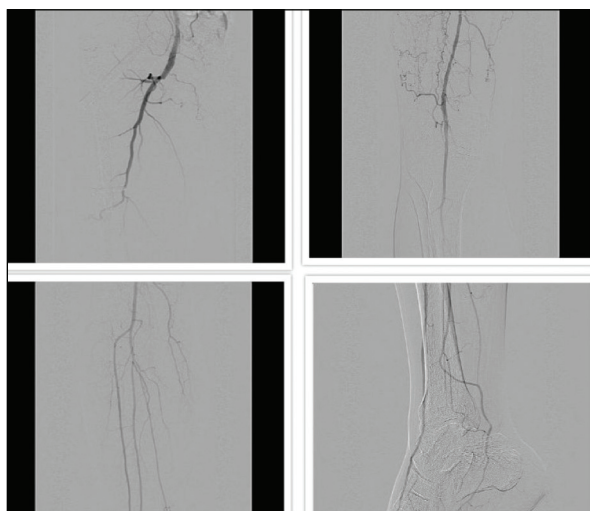


Figure 1. Preliminary angiography confirming SFA obstruction, recanalisation at Hunter's canal, and patency of tibio-peroneal vessels.

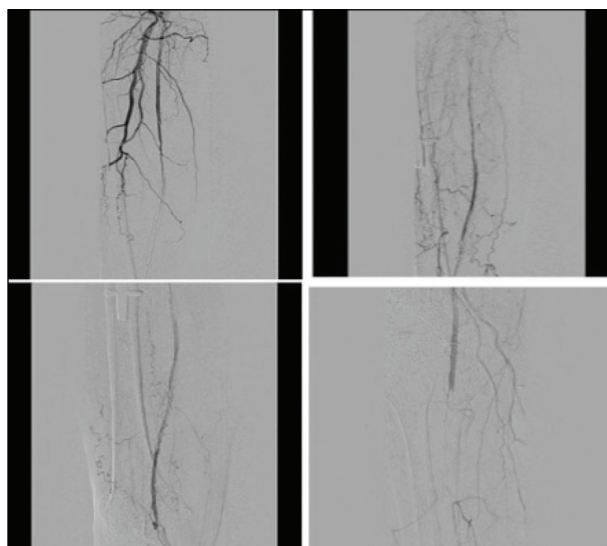


Figure 2. After PTA angiography. Distal embolisation in the popliteal artery with poor opacification of the distal vessels.

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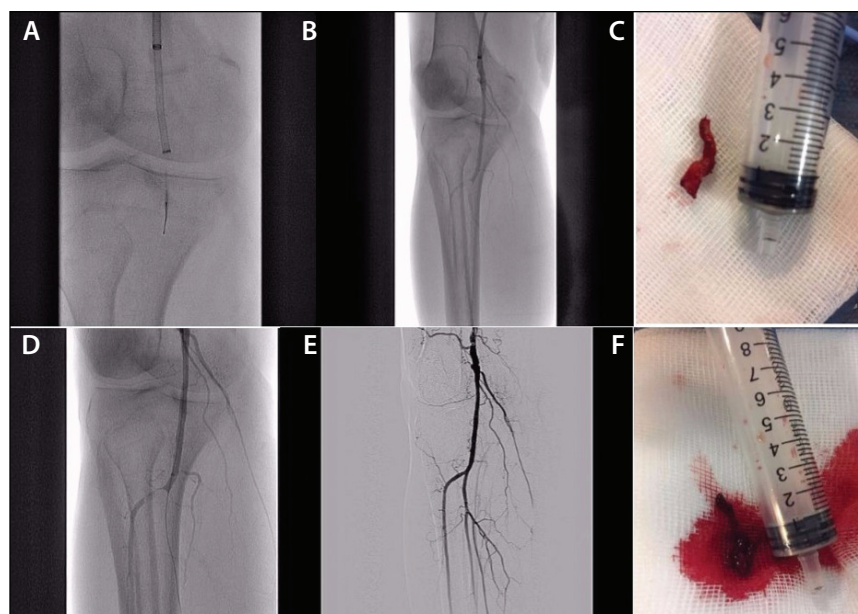


Figure 3. Indigo System CAT8 catheter and SEP8 Separator in the popliteal artery (A). Control angiography after thrombectomy utilizing the Indigo System CAT8 catheter demonstrates patency of the popliteal artery with residual thrombus above the tibioperoneal bifurcation (B). Thrombus removed from the popliteal artery (C). An Indigo System CAT5 catheter approaching the thrombus above the tibioperoneal bifurcation (D). Control angiography, restored patency of popliteal, and tibioperoneal vessels (E). Embolic material removed from tibioperoneal bifurcation (F).

using a CAT8 catheter and SEP8 separator to maximise the debris removal. Control angiography immediately after thrombectomy demonstrated restored patency of the popliteal artery (Figure 3A and B), but an endoluminal defect persisted above the anterior tibial artery and tibio-

peroneal trunk bifurcation (Figure 3C). We inserted a CAT5 catheter through the CAT8 catheter to perform aspiration of the distal thrombus, with restored vessel patency of tibioperoneal bifurcation. To fix any further source of embolic material along the SFA, we eventually deployed a 6- X 250-mm covered stent (Viabahn® Endoprosthesis, Gore & Associates) from its origin to the Hunter's canal. A control angiogram showed a positive result without any additional complication (Figure 4). The patient had no symptoms and was discharged on the second postoperative day.

DISCUSSION

Distal embolism of thrombi detached from an atheromatic plaque is a complication that may occur during percutaneous recanalisation of the femoropopliteal and below-the-knee arterial segments. Although it is a relatively rare complication of endovascular

therapy (approximately 1%–5%), it remains a concern due to the major adverse events that may follow. These complications can lead to additional procedures and an increase in limb amputation and mortality rates.⁵

The Indigo System catheters provide a highly trackable and atraumatic solution for clot extraction in the peripheral vessels. The setup is easy, and the use of adjunctive devices or thrombolytic agents is not required.⁶

However, in the event of a distal embolisation, it is necessary to be prepared and able to remove the embolised material in most cases. Aspiration catheters and thrombolytic drugs should be promptly available in the angiography suite. Sometimes an open surgical revision or bypass could be the only way to avoid major complications such as limb loss and death. ■

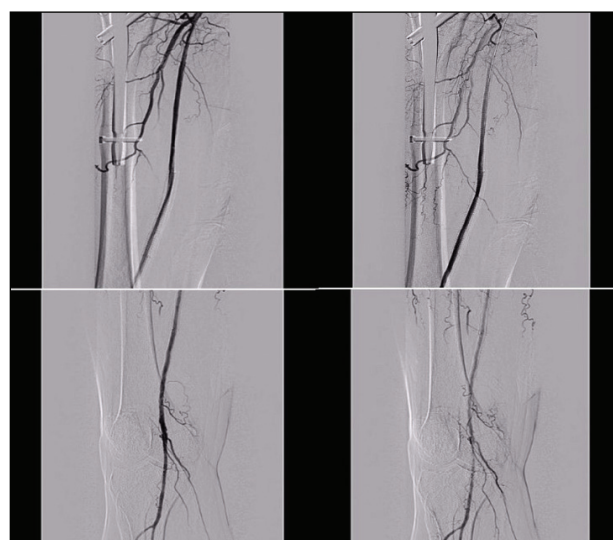


Figure 4. Final angiography after Viabahn stent deployment in the SFA.

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CASE REPORT

A woman in her 80s presented with an acute thrombosis of a right brachiocephalic arm graft dialysis. The graft, created 3 years earlier, had a history of two balloon angioplasties: a stent graft on venous anastomosis and a thrombosis treated 1 year earlier with Arrow-Trerotola™

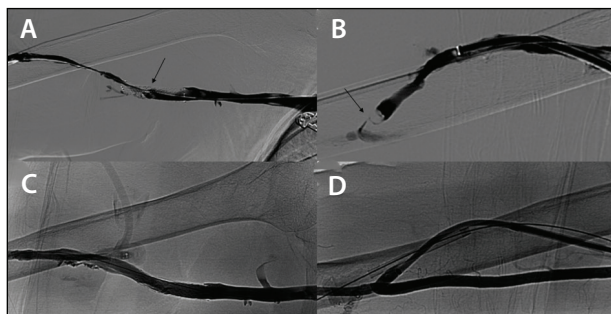


Figure 1. Thrombosis of a right brachiocephalic arm graft fistula. A contrast injection on anterograde puncture reveals clot (arrow) over the graft fistula on the stent (A). After aspiration with the Indigo System over the graft fistula, and after balloon angioplasty on the stenosis on the stent, an angiogram shows no residual clot (B). A contrast injection on retrograde puncture reveals clot (arrow) over the graft fistula (arrow) (C). After aspiration with the Indigo System over the graft fistula, an angiogram shows a completely patent graft, with no residual clot (D).

PTD® mechanical thrombectomy (Arrow International, a division of Teleflex).

The procedure was performed under conscious sedation and systemic heparinisation with 30 IU/kg of heparin initiated before the procedure. Both antegrade and retrograde vascular access to the venous segment of the arteriovenous fistula was performed under ultrasound guidance using an 8-F sheath. The injection of the contrast under fluoroscopy on the arterial pole confirmed the thrombosis and showed a probable intrastent stenosis (Figure 1). First, aspiration with the Indigo System catheter (CAT8 TORQ) was used on the antegrade sheath. Second, angioplasty of the stent stenosis was performed with an 8-mm balloon (Powerflex® Extreme, Cordis, a Cardinal Health company®). Last, aspiration on the retrograde sheath was performed until the anastomosis site. The total procedure time was 40 minutes, and 150 mL of blood was lost. The procedure was successful with a clinical thrill over the efferent vein, in addition to an angiogram showing no residual clot. The vascular sheaths were removed and hemostasis was achieved after a purse-string suture by manual compression.

DISCUSSION

The Indigo System appears safe and efficient for declotting dialysis grafts. Besides systemic thrombolysis, various systems for thrombectomy of vascular access sites exist, including Arrow-Trerotola PTD, AngioJet™ (Boston Scientific Corporation) and Fogarty® (Edwards Lifesciences). The main advantage of the Indigo device is the rapidity of the procedure and a decreasing need to thrombolysis. ■

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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.