Mechanical Power Aspiration With the Indigo® System: Rethinking Clot Removal

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hromboembolic disease comprises a group of disorders that crosses into the arterial and venous vascular beds and a combination of both vascular beds in hemodialysis arteriovenous (AV) fistulas. Due to differing thrombus morphology, the traditional endovascular treatment options have been associated with high complication rates and intensive care unit stays. Complications have included bleeding, distal emboli, vessel damage, incomplete revascularization, and kidney damage.¹

The Indigo® System (Penumbra, Inc.) has been designed to address the limitations of the traditional treatment options. The goal of mechanical thrombus aspiration is two-fold: to deliver the highest power to aspirate the thrombus and design highly deliverable, atraumatic catheters to remove thrombus from hard-to-reach vessels.

With those two goals in mind, Penumbra has launched the proprietary Penumbra ENGINE™ pump (Figure 1). Penumbra ENGINE is capable of delivering and maintaining nearly pure vacuum (-29.2 inHg) with a very easy one-touch setup. It also has a clot catcher within the canister for live feedback during the procedure. Another recent upgrade includes dynamic aspiration tubing with a new sliding flow switch to enhance aspiration and flow dynamics. This new tubing is now packaged along with the Indigo System catheters, thereby enabling efficiency during the procedure (Figure 2).

The Indigo System aspiration catheters are available in a range of lengths and diameters that, when connected to the Penumbra ENGINE pump, can atraumatically remove the thrombus present in various peripheral vascular beds.

The catheters (CAT3, CAT RX*, CAT5, CAT6, CAT8, CATD) vary in diameters from 3.4 to 8 F and lengths of 50 to 150 cm to enable the operator to remove thrombus from small vessels, such as the pedal arch, to large vessels, such as the inferior vena cava.

The latest addition to the Indigo catheters is CAT RX, which is Penumbra's first rapid exchange catheter designed to remove fresh, soft emboli and thrombi from vessels of the coronary and peripheral vasculature. This continued innovation in mechanical power aspiration with the Indigo System has helped us move the field

*As part of the Indigo Aspiration System, the Indigo CAT RX Aspiration Catheters and Indigo Separator™ 4 are indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.



Figure 1. Proprietary Penumbra ENGINE pump.

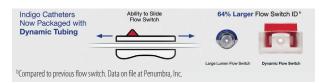


Figure 2. New dynamic aspiration tubing with a sliding flow switch.

forward toward single-session removal of thrombus. At our institutions, we first used the Penumbra System to remove arterial emboli in cases where patients had no other options to reperfuse the affected area and in which conventional treatment options would have fallen short. Since the initial launch of the Indigo System, the catheters and techniques have progressed, resulting in high rates of revascularization in various coronary and peripheral vascular beds with low complication rates. In our institutions, the Indigo System has now become the frontline tool for clot removal in the body.

We have also seen kidney injury and bleeding complications reduced by means of the Indigo System. Overall, this has resulted in the potential for better outcomes for patients. In the arterial vascular bed, the Indigo System and XTRACT technique have enabled operators to safely remove the entire clot intact and treat the culprit lesion, as shown in the PRISM trial.² In the venous vascular bed, in light of the ATTRACT trial advocating a reduction in the dose and duration of tissue plasminogen activator (tPA),³ the Indigo System with the coring technique (and tPA turbo infusion, when needed) has enabled operators to remove the clot in a single session

in a vast majority of cases. Finally, in the AV fistula and graft setting, the Indigo System has enabled operators to remove clot quickly. The following case reports highlight the Indigo System's progression in each vascular bed.

- Frank R. Arko III, MD, and James F. Benenati, MD

- 1. Escobar GA, Burks D, Abate MR, et al. Risk of Acute kidney injury after percutaneous pharmacomechanical thrombertomy using Angioiet in venous and arterial thrombosis. Ann Vasc Surg. 2017:42:238-245.
- Saxon RR, Benenati JF, Teigen C, et al. Utility of a power aspiration-based extraction technique as an initial and secondary approach in the treatment of peripheral arterial thromboembolism: results of the multicenter PRISM trial. I Vasc Interv Radiol. 2018:29:92-100.
- 3. Vedantham S, Goldhaber SZ, Julian JA, et al. Pharmacomechanical catheter-directed thrombolysis for deep-vein thrombosis. N Engl J Med. 2017;377:2240-2252.

THE POWER ASPIRATION-BASED XTRACT TECHNIQUE FOR ATRIAL FIBRILLATION CLOT REMOVAL



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The PRISM trial was a retrospective case analysis to assess the utility of the power aspiration—based XTRACT technique (Figure 1) as an initial and secondary approach in the treatment of peripheral arterial thromboembolism (Table 1). Before intervention with the Indigo System, patients had thrombolysis in myocardial infarction (TIMI) scores of 0 or 1.

After use of the Indigo System, TIMI 2-3 flow was achieved in 87.2% of patients, and after treating the underlying lesion, TIMI 2-3 flow was achieved in 96.2%.

We also performed a subset analysis of 12 patients with atrial fibrillation. TIMI 2–3 flow was achieved in 83.3% immediately after use of the Indigo System and in 100% of patients at the end of the entire procedure (Table 2). Additionally, no device-related adverse events occurred.

This trial showed that the XTRACT technique was a safe and effective intervention in all occlusions, even in atrial fibrillation, as the primary therapy or as a secondary therapy after other endovascular techniques had failed.



The contralateral sheath with RHV/Tuohy is positioned as close to the lesion as possible and the Indigo CAT8 is advanced through

PATIENT HISTORY

An 80-year-old woman presented with Rutherford 2A acute limb ischemia of the left lower extremity. The patient had an irregular heartbeat, mild dementia, and elevated international normalized ratio. The ankle-brachial index on the right was normal at 1.14, but was diminished on the left to 0.58.

- Contralateral access was gained using an 8-F
 Destination® sheath (Terumo Interventional Systems),
 tracked as far distally as possible, and then initial
 left lower extremity angiography was performed
 (Figure 2). It showed completely occluded distal
 popliteal and tibioperoneal trunk arteries.
- We chose the largest, nonocclusive catheter that would fit in the vessel for aspiration. In this case, the Indigo System with the CAT8 (115 cm, XTORQ tip) catheter was chosen for this distal popliteal artery.
- The Indigo CAT8 catheter was connected to the Penumbra ENGINE. Using the CAT8 and the XTRACT technique, we were able to completely remove all clot from the popliteal artery, but the tibioperoneal trunk was still occluded, so we telescoped using the CAT6 (135 cm) coaxially through the CAT8 catheter (Figures 3 and 4). After just two passes, there was complete restoration of flow to the vessel (Figure 5).



The Indigo CAT8 is placed just proximal to the face of the clot and wire is retracted



Aspiration is applied to Indigo CAT8 via Penumbra ENGINE until CAT8 becomes occluded (recommend waiting at least 90 seconds)



The Indigo CAT8 is removed under aspiration to ensure clot remains engaged in catheter tip and clot is extracted out of the body

Figure 1. The XTRACT technique, as described in the PRISM trial.

TABLE 1. PRISM TRIAL PROCEDURAL CHARACTERISTICS			
Treatment Modality	All Patients (N = 79)	Atrial Fibrillation (N = 12)	
XTRACT as frontline treatment	49.4%	58.3%	
XTRACT after thrombolytics	15.2%	16.7%	
XTRACT after other mechanical therapy	19%	8.3%	
XTRACT after both thrombolytics and mechanical thrombectomy	16.5%	16.7%	

TABLE 2. OUTCOMES OF THE PRISM TRIAL				
	All Patients	Subset of Patients With Atrial Fibrillation		
After Indigo System use	87.2% (74/78)	83.3% (10/12)		
At the end of the procedure	96.2% (76/79)	100% (5/5)		





graphy showing a completely

and tibioperoneal trunk.

occluded distal popliteal artery



Figure 3. Periprocedural imaging after use of the CAT8 catheter.



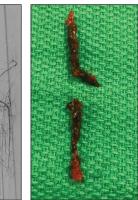


Figure 4. CAT6 telescoped through the CAT8 (A). Restoration of patent flow (B).

Figure 5. Extracted thrombus material.

· Final angiography was performed, confirming complete thrombus resolution and patent blood flow. Immediately after, the pulses were restored to normal, and by the next morning, the foot was warm, and all symptoms were resolved. Final noninvasive imaging showed that the left ankle-brachial index was 1.27, and all waveforms, including the digital waveforms, were normal as well.

DISCUSSION

tPA was an ineffective treatment for dissolving atrial fibrillation clots. Surgical embolectomy is much more

invasive and challenging due to difficulties in access and reaching the distal vessels.1

In the past, there was not a comprehensive option for removing arterial thrombus, especially for patients with atrial fibrillation. However, with the Indigo System, we are now able to achieve high rates of revascularization (83.3% TIMI 2-3 after Indigo System use in patients with atrial fibrillation), and it has demonstrated consistent success in removing arterial occlusions.

1. de Donato G, Setacci F, Sirignano P, et al. The combination of surgical embolectomy and endovascular techniques may improve outcomes of patients with acute lower limb ischemia. J Vasc Surg. 2014;59:729-736.

BENEFITS OF COMPLETE CLOT REMOVAL USING THE INDIGO SYSTEM IN LONG THROMBOTIC LESIONS



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PATIENT HISTORY

A 95-year-old man presented with a history of diastolic heart failure who had recently stopped rivaroxaban due to recurrent epistaxis. The patient presented to the clinic with a numb and cold right foot and some ankle/calf pain for about 24 hours. Upon Doppler examination of the popliteal artery, we noticed absent posterior tibial/dorsalis pedis signals and decided to intervene.

INTERVENTION

· Ultrasound-guided access was gained using a 6-F Destination sheath and initial angiography was

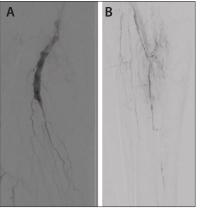
performed, revealing an occlusion at the popliteal artery (Figure 1).

- · We chose the largest nonocclusive catheter that would fit in the vessel for aspiration. In this case, the Indigo CAT6 catheter was chosen through angiographic measurements. The Indigo System with CAT6 catheter was connected to the Penumbra ENGINE pump system and was used to successfully aspirate the popliteal artery thrombus with just a few passes.
- · We then performed balloon angioplasty of the popliteal, anterior tibial, and peroneal arteries to get the final result (Figure 2).

DISCUSSION

Indigo System mechanical thrombectomy reduced the need for overnight lytics, and by aspirating the thrombus with CAT6 first, we were able to easily treat the underlying stenosis with balloon angioplasty. Further, a recent study by de Donato et al compared outcomes of balloon catheter embolectomy versus hybrid (surgical + endovascular) therapy in patients with acute lower limb ischemia.¹ The results showed that additional endovascular intervention postsurgery was needed in 86% of patients (210/242) (Table 1). Penumbra's mechanical thrombectomy catheters can potentially be utilized to aspirate residual thrombus in the superficial femoral arteries (SFAs) and popliteal arteries in the situations described in Table 1, as they are all highly trackable to below-the-knee vessels and are designed to be highly atraumatic due to the adaptation of the neurotracking technology.

In conclusion, an endovascular-first approach for acute limb ischemia could potentially reduce the morbidity previously associated with acute arterial occlusions. Intraoperative imaging is needed because of the high incidence of stenosis.



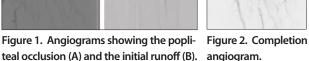




TABLE 1. FINDINGS POSTSURGERY NEEDING ADDITIONAL ENDOVASCULAR INTERVENTION			
Findings	No. of Patients		
Native arterial lesions (stenosis underlying thrombosis)	n = 90		
Residual thrombus in SFA and popliteal firmly adherent to the arterial wall	n = 54		
Residual thrombus in a BTK vessel (not appropriately reached by the balloon catheter thromboembolectomy)	n = 58		
Vessel injury after intraluminal balloon catheter manipulation	n = 8		
Total	210/242 (86%)		
Abbreviations: BTK, below the knee; SFA, superficial femoral artery.			

1. de Donato G, Setacci F, Sirignano P, et al. The combination of surgical embolectomy and endovascular techniques may improve outcomes of patients with acute lower limb ischemia. J Vasc Surg. 2014;59:729-736.

THE INDIGO SYSTEM FOR THROMBUS REMOVAL IN ISR



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Rates as high as 33% have recently been reported for restenosis of femoropopliteal and tibial vessels after percutaneous interventions. Therefore, we have initiated a prospective randomized trial of 30 patients with lower extremity in-stent restenosis (ISR) to determine whether using aspiration before traditional balloon angioplasty or stenting will result in improved blood flow and reduce distal embolization. Filters will be placed first in both the aspiration and control groups. In the aspiration group, mechanical

aspiration thrombectomy with the Penumbra System will be performed followed by balloon angioplasty or stenting if needed. In the control group, standard-of-care techniques such as balloon angioplasty or stenting to improve blood flow will be performed followed by aspiration thrombectomy if needed. Once blood flow is restored, the filters will be removed and examined to determine what material was removed.

PATIENT HISTORY

The patient presented to our emergency department with lower



Figure 1. Preprocedural angiogram showing an occluded stent.

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extremity rest pain and an ankle-brachial index of 0, but intact motor and sensory function to the foot. The patient was started on intravenous heparin and taken to the interventional suite. The patient had been treated 6 years and 6 months prior to this presentation with balloon angioplasty and primary stenting utilizing a 7- X 140-mm Zilver® PTX® stent (Cook Medical) and a 6-mm X 25-cm Gore® Viabahn® endoprosthesis (Gore & Associates). Preprocedurally, based on the patient's presentation, we believed that this represented an acute-on-chronic thrombus and that aspiration would be critical to the procedure.

INTERVENTION

- The initial angiogram demonstrated completely occluded superficial and popliteal artery stents
- The vessels reconstituted just proximal to the distal stents with two-vessel runoff to the foot.
- A distal filter was placed to protect the runoff if any interventions would be required following the initial aspiration.
- A Glidewire® hydrophilic guidewire (Terumo Interventional Systems) and Glidecath® hydrophiliccoated catheter (Terumo Interventional Systems) passed easily, indicating an acute-on-chronic thrombus.
- · An Indigo CAT8 XTORQ catheter was then used to remove the clot from the proximal occlusion to the distal popliteal over the filter wire.
- · Following aspiration, little to no disease was present in the underlying stents proximally. There was a single area of ISR at the distal overlap of the Viabahn and Zilver PTX stents, which was then treated with a single drug-coated balloon (Figure 2).

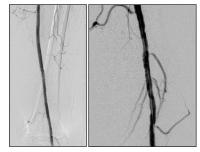


Figure 2. Final angiograms.



Figure 3. SpiderFX™ device (Medtronic) postprocedure.

- The entire procedure was guided with both arteriography and intravascular ultrasound.
- The filter was removed and closely inspected. There was no evidence of any distal emboli present at the end of the case (Figure 3).

DISCUSSION

For many years, aspiration or mechanical thrombectomy was used as a bailout option for embolism during the treatment of peripheral vascular disease. Recently, technology such as the Indigo System's CAT8 XTORQ has allowed us to rethink how we approach many of these morphologically complex lesions. Using the Indigo System in this patient population can potentially help us reduce the risk of distal emboli and determine the underlying culprit lesion that needs to be treated. This is a more recent application of this technology and shows promise.

1. Kibrik P, Victory J, Patel R, et al. A real-world experience of drug eluting and non-drug eluting stents in lower extremity peripheral arterial disease [published online May 12, 2019]. Vascular.

SINGLE-SESSION MECHANICAL THROMBECTOMY WITH THE INDIGO SYSTEM



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PATIENT HISTORY

A 56-year-old woman presented with left lower extremity redness, pain, and swelling for approximately 18 days. The patient had a previous deep vein thrombosis (DVT) in the same leg that was managed by compression stockings and anticoagulation.

Duplex ultrasound of the left lower extremity showed patency of the system below the knee. Above the knee, there was thrombus within the central femoral vein. Some collateral vessels were present. We decided to intervene with mechanical thrombectomy due to the concern for acute DVT with a possible underlying May-Thurner compression.

- · Popliteal access was gained using a 10-F sheath, and an initial angiogram (Figure 1) revealed a focal stenosis in the left proximal common iliac vein, consistent with May-Thurner compression. We proceeded with angioplasty and stenting of the iliac compression. Postangioplasty imaging showed resolution of stenosis but residual thrombus in the femoral segment.
- Due to the subacute nature of the thrombus burden (Figure 2), we decided to use the Turbo Pulse technique. A dwell time of 15 minutes was completed.

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Figure 1. Preprocedural angiogram.



Figure 2. Pre-CAT8 angiogram.



Figure 3. Imaging of the final result.

 Aspiration thrombectomy was performed with a CAT8 XTORQ catheter. After multiple passes, there was markedly improved flow in the veins (Figure 3).

DISCUSSION

Thrombolysis is associated with longer hospital stays; however, by using the Indigo System single-session mechanical thrombectomy technique, patients may be able to go home the same day and may not be put at risk for long thrombolysis infusions. The patient was followed up in the interventional radiology clinic, with patency of the femoral veins and stent on ultrasound and CT, and she had returned to normal daily activities.

SINGLE-SESSION MANAGEMENT OF AXILLOSUBCLAVIAN DVT USING THE TURBO PULSE TECHNIQUE AND INDIGO SYSTEM CAT8



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PATIENT HISTORY

A 25-year-old man who was previously an athlete presented to the emergency department with right arm pain and discoloration. After initial evaluation and confirmation of right axillosubclavian DVT, it was confirmed that the patient had venous thoracic outlet syndrome with acute upper extremity DVT. The two-stage treatment process was explained to the patient—first resolving the current clot and then surgical decompression of the underlying compression. After speaking with the patient and his family, we decided to proceed with endovascular treatment to remove the clot in one session rather than an overnight infusion.

- We chose the Indigo System with CAT8 catheter using the Turbo Pulse technique (Figure 1). The Indigo System allows for the effective removal of thrombus, potentially causing less distal emboli and reducing the amount of tPA to which the patient is exposed.
- Initial right upper extremity venography from basilic vein access was performed, confirming the presence of thrombus in the axillosubclavian vein (Figure 2).
- Due to the subacute nature of the thrombus burden, it was decided that tPA would be used to soften the clot

- before removing the thrombus burden with power aspiration via the Indigo System. The clot was infused with 8 mg of tPA using the Turbo Pulse technique.
- We selected the appropriate infusion catheter length, matching the length of the thrombus burden to the length of the infusion catheter. In this case, a 10-cm Unifuse™ infusion catheter (AngioDynamics) was selected.
- Next, 8 mg of tPA was mixed with 50 mL of saline.
 A three-way stopcock was placed at the back end of the infusion catheter, and the 50-mL syringe with tPA and 1-mL syringe were locked in. The tPA was trans-



Figure 1. Turbo Pulse technique setup.

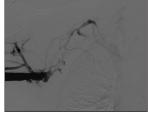


Figure 2. Right upper extremity venography showing thrombus in the axillosubclavian vein with collaterals.

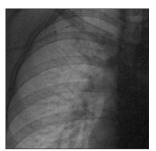


Figure 3. Complete thrombus resolution was achieved with the CAT8 XTORQ catheter in four passes.

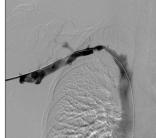


Figure 4. Completion venography showing persistent compression but a patent channel from the upper arm through the superior vena cava.

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ferred from the 50-mL syringe to the 1-mL syringe and then distributed throughout the clot burden. A dwell time of 15 minutes was completed.

- The Indigo System's CAT8 XTORQ catheter, SEP8 separator, and Penumbra ENGINE were used to remove the thrombus burden from the body. Using macromovements with the CAT8 XTORQ catheter, we were able to achieve near-complete thrombus resolution (Figure 3) with a total of four passes.
- · We then performed balloon venoplasty of the compression with a 10-mm Mustang™ balloon catheter (Boston Scientific Corporation).
- · Completion venography revealed persistent compression but a patent channel from the upper arm through the superior vena cava (Figure 4). Intravascular ultrasound confirmed near-complete resolution of thrombosis with persistent compression and adjacent chronic thrombus at the thoracic outlet.
- Total blood loss was 115 mL, with no need to place infusion catheters or large volumes of thrombus sent to his lungs.
- The patient was anticoagulated with enoxaparin postprocedurally and discharged the following day.

DISCUSSION

Single-session management of DVT clot using the Turbo Pulse technique and the Indigo System CAT8 allows us to treat properly selected patients without overnight lysis, drastically reducing the dose and duration of tPA. Patients treated by this method can avoid an overnight stay in the intensive care unit and the risks associated with tPA infusion. Data recently presented at VEITHsymposium showed a 100% technical success rate with venous patency until day of rib resection and no distal embolization or postoperative renal insufficiency.1

Our patient was effectively treated with thrombectomy and subsequent surgical decompression and is asymptomatic at 1 year. Many patients like him can be safely treated with thrombectomy using the Indigo System line of catheters and the Turbo Pulse technique as needed. If necessary, further thrombolysis can be performed but only as a bailout technique.

1. Maldonado TS. Endovascular thrombus removal in patients with Paget-Schroetter syndrome: use of the Indigo System. Presented at: VEITHsymposium 2018; November 16, 2018; New York, NY.

BELOW-THE-KNEE MECHANICAL THROMBECTOMY WITH CAT RX*



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PATIENT HISTORY

The patient presented with right lower extremity pain and decreased pulses in the foot. Doppler ultrasound showed no arterial blood flow in the distal SFA, a stented



Figure 1. Distal posterior tibial artery occlusion.



Figure 2. Imaging of Figure 3. Clot the final result in the aspirated with distal right posterior CAT RX. tibial artery.



popliteal artery, and tibioperoneal arteries consistent with occluded vessel and thrombosis.

- We decided to intervene by lysing with 2-mg/h tPA for 4 hours from the SFA to the anterior tibial artery with a 5-F, 40-cm Unifuse infusion catheter and then mechanical thrombectomy the same day.
- The 5-F sheath and infusion catheters were exchanged for a 6-F sheath.
- · A right lower extremity arteriogram was obtained and confirmed the Doppler ultrasound findings. After tPA, flow was restored to all vessels except the distal posterior tibial artery (Figure 1).
- We then advanced a 0.014-inch HT Whisper® wire (Abbott Vascular) to the distal right posterior tibial artery and performed mechanical aspiration using the CAT RX catheter at the level of the ankle.
- All thrombus was completely aspirated back to the canister within 10 seconds and CAT RX was able to restore in-line flow to the distal right posterior tibial artery (Figures 2 and 3).
- To achieve microvasculature revascularization, overnight tPA was administered at 1 mg/h. Post-tPA angiography revealed improved flow in the small branches of the distal posterior tibial artery. Angioplasty and stenting of the SFA and popliteal artery stenosis were then performed. Complete thrombus resolution to the distal right posterior tibial arteries was achieved.

^{*}As part of the Indigo Aspiration System, the Indigo CAT RX Aspiration Catheters and Indigo Separator™ 4 are indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

DISCUSSION

CAT RX has become my preferred catheter for mechanical aspiration thrombectomy below the knee because it allows me to maintain wire position due to the long rapid exchange lumen. It also has a maximized aspiration lumen while main-

taining a low 5.3-F profile, allowing me to comfortably advance as distal as possible with limited risk of dissection or traumatic vascular injury. The Indigo System technology has enabled us to push the envelope in terms of clot management and shift the paradigm toward single-session revascularization.

ENDOVASCULAR TREATMENT OF AN OCCLUDED DIALYSIS FISTULA



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PATIENT HISTORY

The patient presented with a history of a right upper extremity brachial-axillary AV graft. Physical examination revealed absence of a pulse and a thrill over the graft. Ultrasound examination prior to the procedure demonstrated thrombosis of the graft (Figure 1).

INTERVENTION

- Access was gained using an 8-F sheath. A 5-F Kumpe catheter (Cook Medical) was advanced over a Glidewire hydrophilic guidewire through the clotted AV graft centrally to the level of the left axillary vein. Contrast injection during catheter pullback demonstrated a patent axillary vein with occlusion starting near the venous anastomosis.
- Next, a CATD aspiration catheter was advanced into the graft. Vacuum-assisted aspiration thrombectomy was performed with repeated back-and-forth sweeps of the CATD device over the wire. Once slow, steady flow was reestablished in the vacuum canister, aspiration was stopped.
- Moderate-severe stenosis at the anastomosis of the graft was persistent following serial high-pressure balloon venoplasty up to 10 mm. Given the presence of persistent stenosis despite repeated venoplasty, the decision was made to deploy an 8-mm Flair® stent (BD Interventional) across the stenosis.
- A completion venogram demonstrated a patent AV graft with marked improvement in the caliber of the venous anastomosis following placement of a stent without residual stenosis. After the procedure, there was a strong pulse and a palpable thrill (Figure 2).

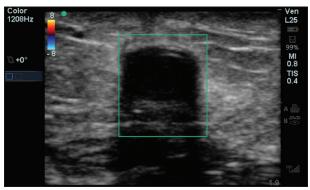


Figure 1. Ultrasound examination showing graft thrombosis.

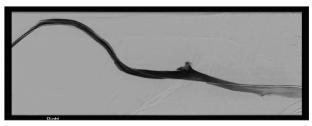


Figure 2. Postprocedural angiogram.

DISCUSSION

A recent case series reported the results of thrombus aspiration in 35 patients with acutely thrombosed dialysis fistulas.¹ All procedures were performed within 48 hours of the occurrence of thrombosis. Technical success of clot removal from an AV fistula and/or graft using the Indigo System was 97.1%, and clinical success, defined as a successful dialysis session after the procedure, was 91.4%. There were no technical or device-related complications. The average procedure time was 38.1 minutes, and the average blood loss during the procedure was 122.5 mL. The 6-month primary patency, primary assisted patency, and secondary patency rates were 71%, 80%, and 88.5%, respectively. Like in other vascular beds, even in cases of AV fistula/graft thrombosis, the Indigo System offers the advantage of removing thrombus instead of dissolving or macerating it within the body, with the goal of enhancing long-term patency. Marcelin et al showed a 6-month primary patency rate of 71% post-Indigo for this application.

The Indigo System is a useful adjunct for the treatment of acute dialysis fistula occlusion and offers a high technical success rate and low complication rate.

1. Marcelin C, D'Souza S, Le Bras Y, et al. Mechanical thrombectomy in acute thrombosis of dialysis arteriovenous fistulae and grafts using a vacuum-assisted thrombectomy catheter: a multicenter study. J Vasc Interv Radiol. 2018;29:993-997.

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.