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

WITH FRANK R. ARKO III, MD; JAMES F. BENENATI, MD; VENITA CHANDRA, MD; PAUL ISENBARGER, MD; MINHAJ S. KHAJA, MD, MBA; MAUREEN P. KOHI, MD, FSIR; AND KUMAR MADASSERY, MD

Thromboembolic 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 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

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 thrombosis 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.

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.

INTERVENTION
• 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 and tibioperoneal trunk arteries.

• 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).

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**FEATURED TECHNOLOGY**

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**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.


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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.

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**INTERVENTION**

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

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**Table 1: PRISM Trial Procedural Characteristics**

<table>
<thead>
<tr>
<th>Treatment Modality</th>
<th>All Patients (N = 79)</th>
<th>Atrial Fibrillation (N = 12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>XTRACT as frontline treatment</td>
<td>49.4%</td>
<td>58.3%</td>
</tr>
<tr>
<td>XTRACT after thrombolytics</td>
<td>15.2%</td>
<td>16.7%</td>
</tr>
<tr>
<td>XTRACT after other mechanical therapy</td>
<td>19%</td>
<td>8.3%</td>
</tr>
<tr>
<td>XTRACT after both thrombolytics and mechanical thrombectomy</td>
<td>16.5%</td>
<td>16.7%</td>
</tr>
</tbody>
</table>

**Table 2: Outcomes of the PRISM Trial**

<table>
<thead>
<tr>
<th></th>
<th>All Patients</th>
<th>Subset of Patients With Atrial Fibrillation</th>
</tr>
</thead>
<tbody>
<tr>
<td>After Indigo System use</td>
<td>87.2% (74/78)</td>
<td>83.3% (10/12)</td>
</tr>
<tr>
<td>At the end of the procedure</td>
<td>96.2% (76/79)</td>
<td>100% (5/5)</td>
</tr>
</tbody>
</table>

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**Figure 2.** Preprocedure angiography showing a completely occluded distal popliteal artery and tibioperoneal trunk.

**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.
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. 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 highlyatraumatic 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.

**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
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 (Figure 1).
- 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® hydrophilic-coated 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).
- 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.


Figure 2. Final angiograms.
Figure 3. SpiderFX™ device (Medtronic) postprocedure.

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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.
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.

INTERVENTION
• 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-

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

INTERVENTION
• 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.

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.


**BELOW-THE-KNEE MECHANICAL THROMBECTOMY WITH CAT RX**

*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 maintaining 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).

**DISCUSSION**

A recent case series reported the results of thrombus aspiration in 35 patients with acutely thrombosed dialysis fistulas. 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.


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.