Rethinking Thrombus Removal With the Indigo System: Introducing Lightning Intelligent Aspiration

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The Indigo® System Lightning™ 12 (Penumbra, Inc.) is an intelligent aspiration system powered by the Penumbra ENGINE™ (Figure 1). Indigo, now with Lightning, utilizes a unique mechanism of action to help optimize thrombus removal procedures by differentiating between thrombus and blood. Lightning enables clot detection so the physician knows when the catheter is in thrombus and when it is in patent flow. Lightning has also demonstrated an 18:1 potential fluid loss savings during bench top testing when used versus the Dynamic Aspiration Tubing.

Lightning™ Intelligent Aspiration comes packaged with the Indigo CAT™ 8 or the newest CAT12, the next generation of the Indigo System catheters. CAT12 features a large 0.131-inch lumen and angled tip for additional circumferential sweep (Figure 2). Made of laser-cut hypotube technology, the CAT12 is Penumbra's most trackable and torqueable catheter to date. This combination of intelligent aspiration and large-lumen catheter engineering forms Lightning™ 12: the latest generation in clot removal technology.

Figure 1. Lightning Intelligent Aspiration.

Figure 2. Indigo System Catheter CAT12.

LOWER EXTREMITY VENOUS THROMBUS WITH LIGHTNING 12

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Disclosures: Owns public stock in Penumbra; consultant and course director for Penumbra, Inc.

PATIENT HISTORY

A 77-year-old woman presented to the emergency department with a history of esophageal varices and bleeding, contraindicating her for tissue plasminogen activator (tPA). Scans revealed a left lower extremity venous thrombus extending from the calf to the common iliac vein (CIV) (Figure 1).

INTERVENTION

- Access was gained using an 8-F sheath in the left popliteal vein, which was then upsized to a 12-F sheath.
- Lightning was hooked up to the Indigo System Catheter CAT12 and placed into the access sheath.
- Using the HTORQ angle on CAT12 to torque the catheter, several passes were made through the

INDIGO® SYSTEM WITH LIGHTNING™ INTELLIGENT ASPIRATION

Sponsored by Penumbra, Inc.

Figure 1. Scan showing preoperative left venous thrombus.

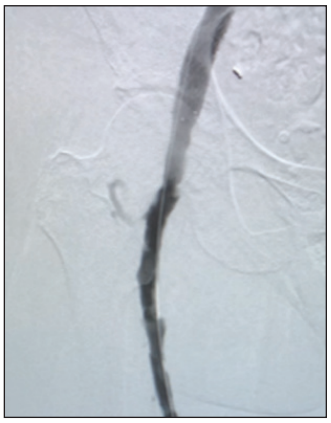

Figure 2. Postoperative angiogram showing 100% resolution of thrombus.

affected area, from the left popliteal to the external iliac vein (EIV) and internal iliac vein.

- The SEP12 was introduced to help clear the lumen of the catheter due to the heavy thrombus burden. Total aspiration time was 34 minutes.
- Intravascular ultrasound (IVUS) revealed May-Thurner syndrome, which was treated with stenting in the CIV and EIV; 100% of the clot was resolved (Figure 2).
- Figure 3 shows the total thrombus removed.

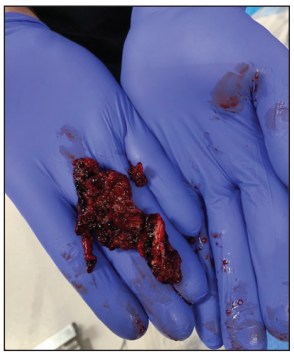

Figure 3. Image showing the total thrombus removed.

DISCUSSION

The Lightning 12 addition to the Indigo Aspiration System is a formative development in the thrombectomy space. Lightning Intelligent Aspiration allows physicians to optimize the thrombus removal needed to complete venous thrombus procedures that would otherwise be more complicated. The clot detection algorithm paired with the audiovisual cues lets the physician know when the catheter is in thrombus versus when it is in blood. The latest addition to the catheter line, the CAT12, is Penumbra's most torqueable and trackable catheter to date. The new HTORQ angle is complemented by the large lumen when accessing wall-adherent thrombus in the venous space.

LEFT AND COMMON FEMORAL VEIN THROMBOSIS WITH LIGHTNING 12

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Disclosures: None.

PATIENT HISTORY

A 67-year-old woman with a history of venous thrombus and iliac venous stenting presented with significant recurrent left lower extremity venous thrombus, and the patient's symptoms did not significantly improve with anticoagulation alone. Of note, the patient was not a good candidate for thrombolysis due to retroperitoneal hemorrhage from lymph node biopsy several days earlier. The decision was made to proceed with mechanical thrombectomy. A venogram was performed via left popliteal vein access, which demonstrated thrombosis of the left femoral vein (FV) and common femoral vein (CFV) (Figure 1) and the previously stented left common iliac vein (CIV) and external iliac vein (EIV) (Figure 2).

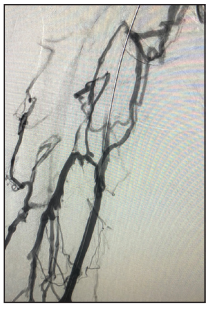


Figure 1. Venogram showing thrombosis of the left FV and CFV.

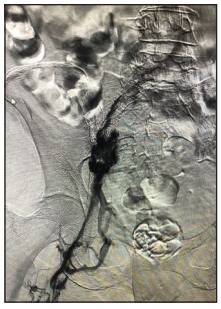


Figure 2. Venogram showing stents in the left CIV and EIV.

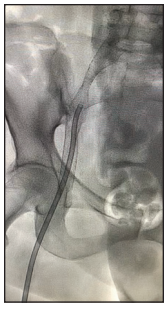


Figure 3. Venogram showing CAT12 in the CIV.

INTERVENTION

- The newly available Indigo CAT12 Aspiration Catheter (Penumbra, Inc.) was utilized to perform mechanical thrombectomy of the FV, CFV, and EIV and CIV without the use of thrombolytics (Figure 3).
- A postthrombectomy venogram (Figures 4 and 5)

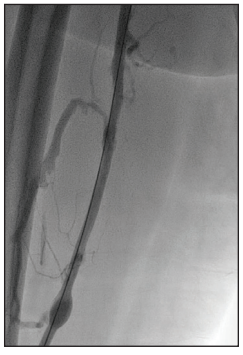


Figure 4. Postthrombectomy venogram.

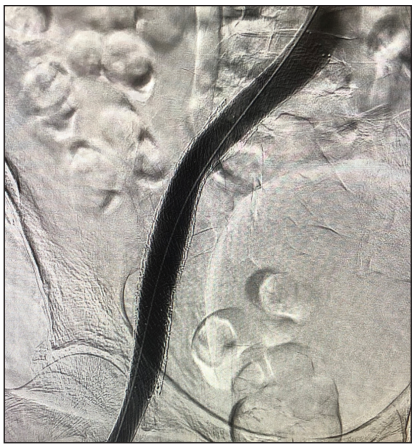


Figure 5. Postthrombectomy venogram.

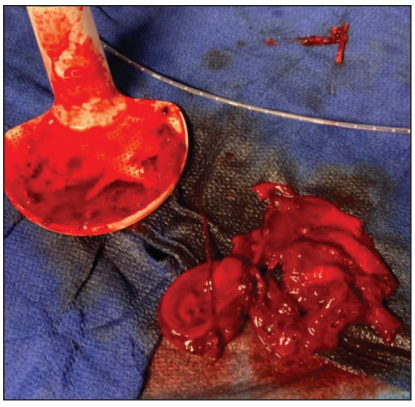


Figure 6. Image of thrombus aspirated using the Indigo CAT12 Aspiration Catheter.

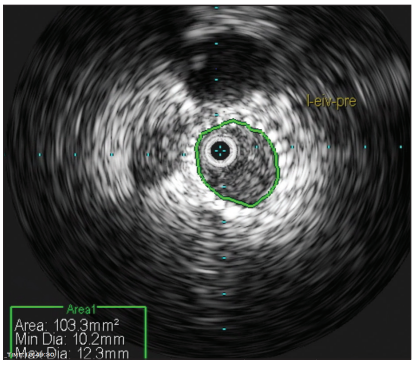


Figure 7. IVUS image showing May-Thurner narrowing of the left CIV and thrombus in the iliac vein.

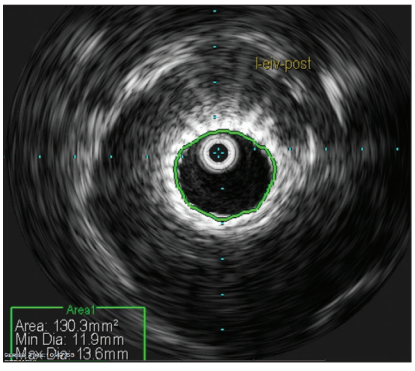


Figure 8. IVUS image showing a widely patent lumen after thrombectomy and stenting.

showed complete resolution of thrombus in all the deep veins of the left lower extremity.

- Significant thrombus was aspirated from the Indigo CAT12 Aspiration Catheter (Figure 6), with minimal blood loss given the utilization of the specially designed Lightning Intelligent Aspiration.
- May-Thurner narrowing of the left CIV was noted and treated with a Vici stent (Boston Scientific Corporation), with IVUS before treatment (Figure 7) showing thrombus in the iliac vein.
- IVUS after thrombectomy and stenting showed a widely patent lumen (Figure 8). The patient had significant improvement in her symptoms after the procedure.

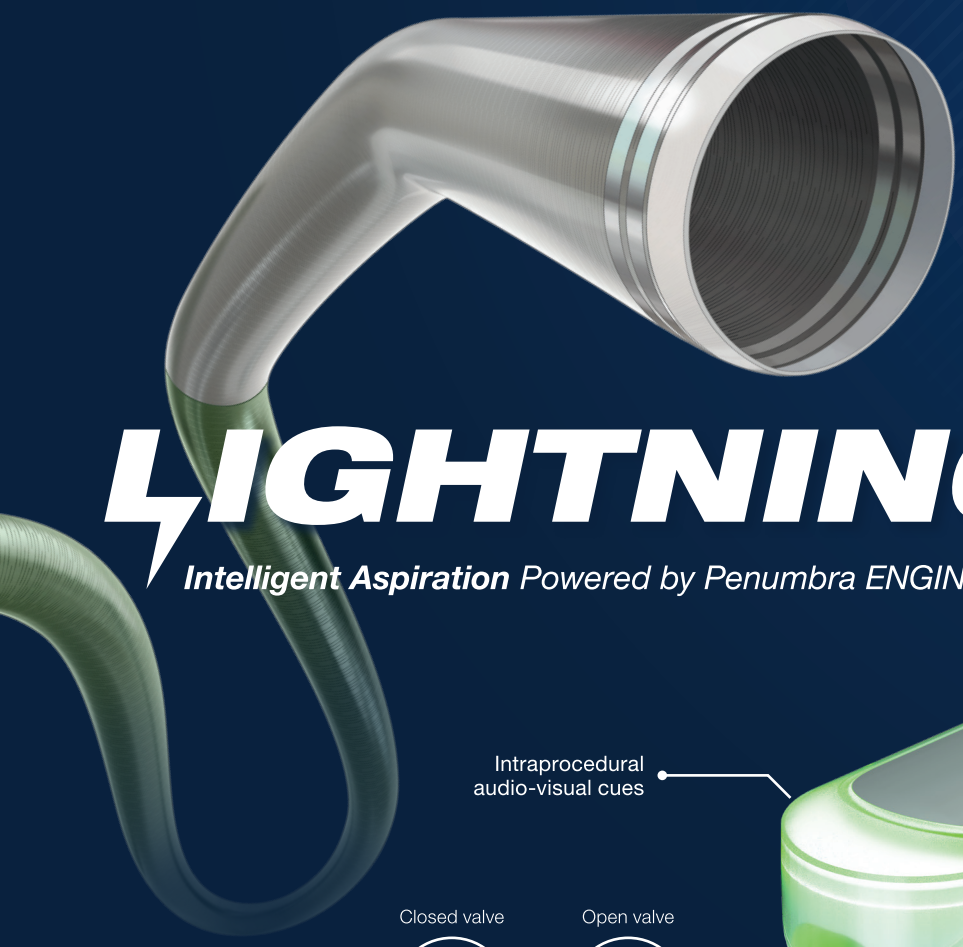
DISCUSSION

The Indigo CAT12 Aspiration Catheter is indicated for removal of fresh, soft emboli and thrombi from vessels of the peripheral venous systems. The Indigo CAT12 represents an advancement in mechanical thrombectomy given its ability to aspirate large-volume thrombus in a single-session setting, which is especially beneficial in larger-lumen vascular beds, such as large-caliber veins as demonstrated in this case. The catheter is robust and trackable, and the large lumen allows for thrombectomy either with a guidewire in place or without a guidewire. Aspiration may also be performed in conjunction with an Indigo System Separator™ (Penumbra, Inc.) to allow for constant clearing of thrombus from the lumen of the catheter. The 1:1 torqueability of the catheter was especially valuable for aspirating thrombus along the circumference of the larger-diameter iliac veins.

The new Indigo System is engineered to allow for thrombectomy while helping to prevent excessive blood loss during the procedure. When in free-flowing blood, this technology automatically stops aspirating blood and hence limits unnecessary loss of blood. An intuitive clicking sound is made by the device that signals that one is in free-flowing blood. When the catheter is engaged on thrombus or embolic material, the clicking sound ceases. This allows the operator to focus on the procedure and not on the canister.

In summary, Lightning 12 is an excellent addition to the peripheral thrombectomy armamentarium and may allow for successful treatment of complex patients.

Indigo® System | Mechanical Thrombectomy



CAT**12**
Maximized size and
circumferential sweep

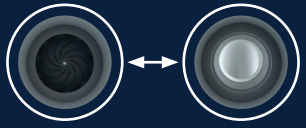
LIGHTNING™ 12

Intelligent Aspiration *Powered by Penumbra ENGINE™*

Intraprocedural
audio-visual cues

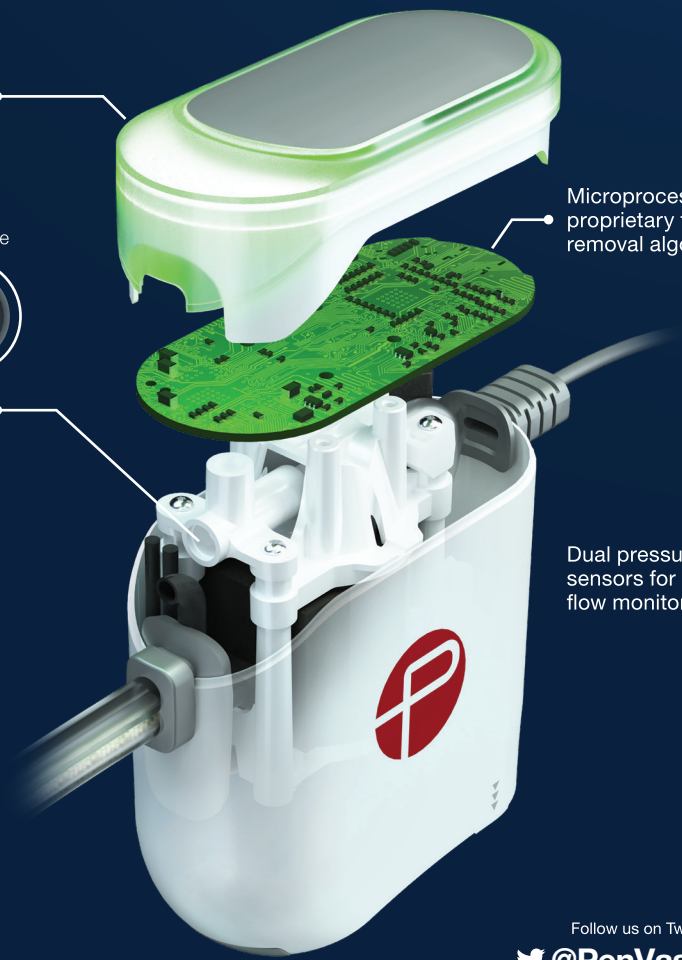
Closed valve

Open valve



Automatic valve control

Powered by Penumbra ENGINE



Microprocessor with
proprietary thrombus
removal algorithm

Dual pressure
sensors for real-time
flow monitoring

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EXTRACT-PE: INDIGO SYSTEM FOR THE TREATMENT OF PULMONARY EMBOLISM

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Disclosures: None.

The acute pulmonary embolism (PE) treatment paradigm is evolving to treat patients that have emergent symptoms and are unable to tolerate long thromboaspiration procedures. Now, the goal with thrombus removal in PE is to safely and effectively remove thrombus and potentially reduce treatment time. Thrombolysis is not a universal option for all patient groups, especially if the patient has an absolute or relative contraindication to a fibrinolytic agent. Large-bore embolectomy, when paired with a syringe, has led to variable results, with questions regarding the ideal technique to achieve a uniform state of vacuum aspiration.[1] The catheters used to aspirate should ideally be atraumatic and easily deliverable to be able to access and establish flow through the lobar branches of the pulmonary artery (PA), reducing right heart strain and PA pressure. Sustained aspiration from the Indigo System provides physicians with an alternative option for patients who are not ideal candidates for lytics or open embolectomy and provides a frontline therapy option that still preserves the use of any adjunctive therapy.

The Indigo Aspiration System provides a treatment option that is now cleared by the FDA to treat PE. The sustained aspiration from the Penumbra ENGINE provides constant uninterrupted full-vacuum aspiration throughout the procedure, addressing the constraints of syringe-based large-bore embolectomy, which include vacuum dropoff from the syringe filling with fluid. The CAT8's large lumen can allow for efficient clot removal, which can be enhanced when paired with mechanical separation from the SEP8. Engineered to be trackable, deliverable, and torqueable, the CAT8's atraumatic tip can navigate the lobar anatomy of the PA to help establish inflow and outflow, helping to restore patient vitals to normal.

The EXTRACT-PE study completed in 2019 evaluated the safety and efficacy of the Indigo Aspiration System in the management of submassive PE. The Indigo System Catheter CAT8 was used across 22 sites in the United States in patients with submassive PE who did not receive thrombolytics (98.3%), with a right ventricular/left ventricular (RV/LV) ratio reduction of 27.3% at 48 hours. The on-table PA pressures were statistically reduced, and the median device time was 37 minutes. This procedure time has been embraced by countless interventionalists concerned about prolonged case times with other thromboaspiration technologies. The major adverse event rate in EXTRACT-PE was 1.7%, and patients had a median intensive care unit stay of < 1 day. The EXTRACT-PE trial demonstrated that the Indigo System can provide immediate mechanical relief using sustained aspiration. As PE treatment options continue to grow, the EXTRACT-PE results with the Indigo System serve as a promising data set in helping move the PE landscape forward.

This new thromboaspiration technology allows for clot removal and potential reduction in right heart and PA pressure. It is low-profile and deliverable to all vascular territories in the pulmonary circulation. It is a welcome addition to our existing endovascular technologies for the treatment of acute PE.

1. Giri J, Sista A, Weinberg I, et al. Interventional therapies for acute pulmonary embolism: current status and principles for the development of novel evidence: a scientific statement from the American Heart Association. Circulation. 2019;140:e774-e801. doi: 10.1161/CIR.0000000000000707

INDIGO SYSTEM AS AN INITIAL TREATMENT FOR BILATERAL PE

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Disclosures: None.

PATIENT HISTORY

A 48-year-old man presented with a 3-day history of acute shortness of breath and chest pressure. The patient had a history of lower left extremity venous thrombus dating back to 2013, with chronic residual nonocclusive popliteal vein thrombus in 2018. The patient also had a history of bilateral PE dating back to October 2017, at which point rivaroxaban was prescribed. After considering the acute onset of symptoms and the history of thrombosis, we decided to proceed with the Indigo System to treat the bilateral PE in one session.

INTERVENTION

- CT revealed that the patient had a bilateral PE with an elevated RV/LV ratio of 2.26, an elevated troponin level of 0.151 µg/mL, and PA pressures at 35 mm Hg.

- We gained access through the right CFV using a 14-F sheath. To gain access into the lobar branches, a 5-F, 125-cm vertebral catheter over a 0.035-inch stiff, angled Glidewire® (Terumo Interventional Systems) was used. The Indigo CAT8 XTORQ was advanced over the select catheter and used in both the right and left PAs.
- Immediately postprocedure, a decrease in PA pressure from 35 to 27 mm Hg was observed. In addition, the RV/LV ratio decreased from 2.26 to 1.09, over a > 50% on-table decrease.
- At the 30-day follow-up, the patient no longer had residual shortness of breath or exertional dyspnea. The patient's echocardiogram showed normal RV size and function. Figures 1 and 2 show pre- and postprocedural angiograms, respectively, of the patient's left pulmonary anatomy.

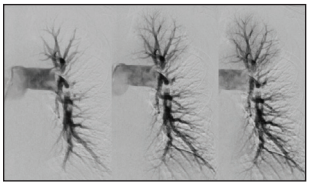

Figure 1. Preprocedural CT of the patient's left pulmonary anatomy.

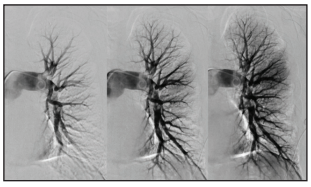

Figure 2. Postprocedural CT of the patient's left pulmonary anatomy.

DISCUSSION

Single-session management of PE using the Indigo System CAT8 allows physicians to treat emergent patients. In the current treatment of PE, standard treatments such as anticoagulation, thrombolysis, and open embolectomy have limitations. Continuous, sustained aspiration can effectively remove thrombus and potentially reduce the use of thrombolytics. The Indigo Aspiration System, along with the Penumbra ENGINE and Indigo CAT8, provide a frontline treatment option for PE patients that can lower on-table PA pressures and reduce RV/LV ratios by 27.3%, per their investigational device exemption trial, EXTRACT-PE.[1] The trial and our case experience at the University of Minnesota with CAT8 show that sustained aspiration with the Indigo System can provide safe mechanical relief in the treatment of PE.

1. Sista A. Evaluating the safety and efficacy of the Indigo® aspiration system in acute pulmonary embolism (EXTRACT-PE). Presented at Vascular InterVentional Advances (VIVA) 2019; November 6, 2019; Las Vegas, Nevada.

TREATMENT OF BILATERAL PE WITH INDIGO CAT8 AND LIGHTNING

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Disclosures: None.

PATIENT HISTORY

A 47-year-old woman with no previous history of thromboembolism presented with sudden-onset PE. CT showed a bilateral PE with right heart strain.

INTERVENTION

- Access was gained through the groin using an 8-F Destination® sheath (Terumo Interventional Systems). Mean PA pressure at the start of the case was 35 mm Hg.
- Low-dose tPA was dripped into the left and right lobes of the PA. Immediately after, Lightning with the Indigo System Catheter CAT8 was used to aspirate thrombus in the left PA (Figures 1 and 2).
- Due to increased amounts of thrombus in the right lobe, the SEP8 was introduced to clear the lumen of the catheter (Figures 3 and 4). The CAT8 with SEP8 were cycled through using several passes until thrombus burden was significantly reduced. Figure 5 shows the right PA after Lightning™ 8 treatment.
- Mean PA pressure postintervention was 21 mm Hg.

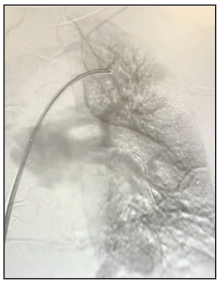

Figure 1. Left PA pre-Lightning 8.

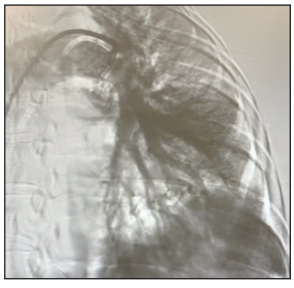

Figure 2. Left PA post-Lightning 8.

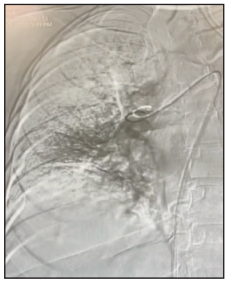

Figure 3. Right PA preintervention.

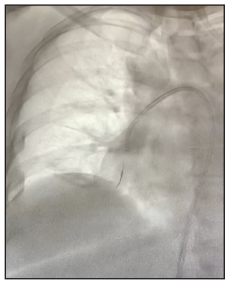

Figure 4. Right PA with the SEP8.

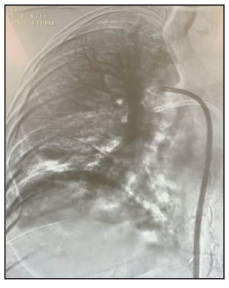

Figure 5. Right PA postintervention.

DISCUSSION

In PE cases, patients are often emergent and need interventions that provide immediate relief. In this case, the PE patient had an extremely high PA pressure of 35 mm Hg, which we were able to significantly reduce by 40%. With Lightning 8, we were able to clear the loft lobar branch and detect that we had established substantial inflow and outflow so we could move to the next affected lobe. The audiovisual cues from Lightning and the thrombus detection algorithm enabled us to navigate the lobar branches of the PA. Lightning's audio cues, in the form of clicking, help with clot detection to optimize thrombus removal and focus on the screen rather than monitor flow through the tubing and canister. From syringe aspiration to sustained aspiration and now to intelligent aspiration, the aspiration thrombectomy field has grown leaps and bounds, now finding itself at a place where the Indigo System with the Lightning Intelligent Aspiration optimizes the thrombus removal procedure by differentiating between thrombus and blood.

INDIGO SYSTEM FOR PERIPHERAL ARTERIAL CLOT MANAGEMENT

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Disclosures: None.

With contributions from Edoardo Pasqui, MD; Carlo Setacci, MD; and Giancarlo Palasciano, MD

Surgical management of lower extremity acute limb ischemia (ALI) has been considered the preferred treatment for years. However, it has also been associated with an unsatisfying revascularization rate due to the detection of residual thrombus in distal vessels. Intraoperative angiography can identify any arterial imperfection after surgical thromboembolectomy, which may be corrected simultaneously by endovascular techniques. However, these "hybrid procedures" include the invasiveness of open surgery and carry the risk of incomplete thrombus removal or vessel damage.[1]

Consequently, many new endovascular devices have been proposed to increase treatment success, decrease complications, and rapidly improve perfusion. Percutaneous manual thromboaspiration was the first technique proposed, followed by a series of percutaneous mechanical thrombectomy devices based on a different mechanism of action (mechanical fragmentation, aspiration, rheolytic thrombectomy, and their combinations). Many of the first-generation mechanical endovascular devices for thrombus removal have failed to be adequately successful or have been associated with unacceptable complication rates. The reasons have been mainly related to the limited trackability, the risk of vessel injury, and/or the incidence of incomplete revascularization, and the risk of bleeding and hemolysis.[2,3]

The Indigo System has been designed to address the limitations of traditional treatment options. The Indigo System aspiration catheter is available in a range of lengths and diameters that, when connected to the proprietary Penumbra Aspiration Pump, may help atraumatically remove the thrombus under continuous aspiration. By capturing the clot without maceration and under high aspiration power, the risk for distal emboli may be minimized.

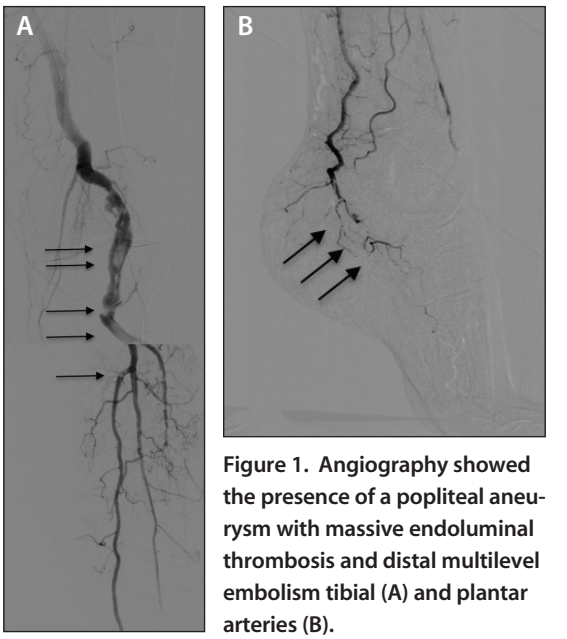

Figure 1. Angiography showed the presence of a popliteal aneurysm with massive endoluminal thrombosis and distal multilevel embolism tibial (A) and plantar arteries (B).

The catheters, which were initially designed for intracranial navigation for the treatment of acute stroke, are provided with an atraumatic tip. In particular, the Indigo catheters vary from 3 to 8 F—enabling the operator to remove thrombus from small vessels such as the pedal arch but also from large vessels such as the aorta or iliac arteries, due to the circumferential aspiration from the tip shapes offered in CAT8.

The Separator is specifically designed for mechanical clot engagement and is particularly helpful in acute-on-chronic thrombosis, in-stent/in-bypass fresh occlusion, and in below-the-knee (BTK) and all the way to the pedal arch thrombi localization (Figure 1).

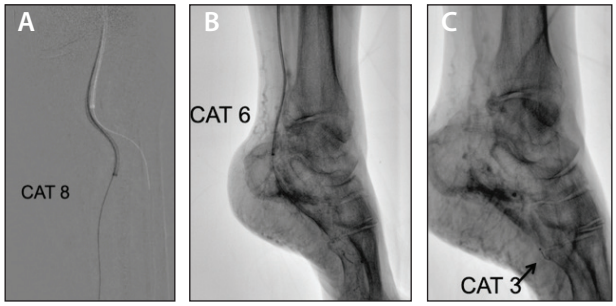

Figure 2. Advancement of the CAT8 and CAT6 through the popliteal and tibial arteries (A, B). CAT3 advanced through the pedal loop (C).

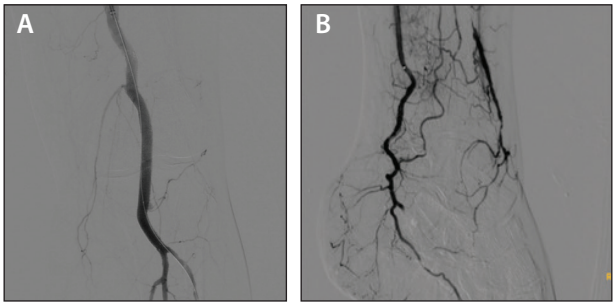

Figure 3. Angiography after Indigo power aspiration and popliteal aneurysm repair with a stent graft (Viabahn, Gore & Associates) revealed a patency of the tibial (A) and plantar (B) vessels.

THE INDIAN REGISTRY

The INDIAN registry is a prospective, multicenter registry designed to investigate, in a controlled setting, the safety and initial efficacy of the Indigo System in the treatment of acute peripheral arterial thromboembolism. Vessel patency is assessed using the thrombolysis in myocardial infarction (TIMI) score classifications, both before and after the use of the device.

The primary outcome is the rate of TIMI 2-3 revascularization after treatment using the Indigo System. A preliminary analysis of the first 143 patients showed a technical success (defined as complete or near-complete revascularization—TIMI 2-3 flow) after thromboaspiration procedure alone in 89.5%. After adjunctive endovascular (angioplasty, stenting, or lysis), TIMI 2-3 was reached in up to 95.3% of patients. At discharge, there have been no adverse device events, and clinical success at 1 month (defined as the absence of death and limb loss) is 98.6%.[4]

Localization of the thrombus was quite variable in our cohort of patients, although in the majority of cases (67%), patients presented with thrombus in the popliteal or BTK vessels. The thromboaspiration with the Indigo System was particularly useful in situations of multilevel vessel acute occlusion. Figure 1 shows a popliteal aneurysm with massive endoluminal thrombosis and distal multilevel embolism in the tibial and plantar arteries. In such a case, the use of multiple catheters (CAT8 for popliteal, CAT6 for tibials, and CAT3 for plantars) was particularly helpful (Figures 2 and 3).

Preliminary data from the INDIAN registry is promising regarding early safety and efficacy for the revascularization of acute peripheral arterial occlusions with thromboaspiration as primary therapy. Such results give more evidence for a shift of treatment recommendation toward endovascular options in the patients with ALI, as already suggested by the recent European Society of Cardiology/European Society for Vascular Surgery guidelines.[5]

1. de Donato G, Setacci F, Sirignano P, Galzerano G, Massaroni R, Setacci C. The combination of surgical embolectomy and endovascular techniques may improve outcomes of patients with acute lower limb ischemia. J Vasc Surg. 2014;59:729-36.
2. Deák Z, Strube H, Sadeghi-Azandaryani M, et al. Rotational thrombectomy of acute peripheral vascular occlusions using the ThromCat XT device: techniques, indications, and initial results. Diagn Interv Radiol. 2011;17:283-289. doi: 10.4261/1305-3825.DIR.3687-10.2
3. Carrera LA, Reddy R, Pamoukian VN, et al. Massive intravascular hemolysis with mechanical rheolytic thrombectomy of a hemodialysis arteriovenous fistula. Semin Dial. 2013;26: E5-7. doi: 10.1111/j.1525-139X.2012.01104.x
4. As presented on November 21, 2019, at VEITH 2019 by Dr. Gianmarco de Donato, University of Siena, Italy.
5. Björck M, Earnshaw JJ, Acosta S, et al. Editor's choice—European Society for Vascular Surgery (ESVS) 2020 clinical practice guidelines on the management of acute limb ischemia. Eur J Vasc Endovasc Surg. 2020;59:173-218. doi: 10.1016/j.ejvs.2019.09.006

REVASCULARIZATION OF A POPLITEAL ARTERY OCCLUSION WITH THE INDIGO SYSTEM

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Disclosures: None.

STRIDE is the newest study from Penumbra evaluating the removal of thrombus with the Indigo Aspiration System in patients with lower extremity ALI. The goal of this study is to create a prospective multicenter study that provides safety and performance data on the Indigo System as a frontline percutaneous aspiration thrombectomy approach for ALI patients for whom immediate treatment and revascularization can maintain limb viability. STRIDE is currently ongoing.

PATIENT HISTORY

A 57-year-old man presented with acute-onset left calf pain for the past 10 days and had recently taken a 4-hour flight. The patient, an active smoker, also had a history of pulmonary hypertension and hypercholesterolemia.

Upon arrival to the hospital, physical examination and a Doppler ultrasound examination revealed absent pulses in the left foot. Although motor function was still intact, there was decreased sensation and delayed capillary refill in the left foot and calf. CT revealed an occlusion in the popliteal artery (Figure 1).

INTERVENTION

- A 0.014-inch wire was used to track to the occlusion, and the Indigo System CAT6 was used to aspirate the clot (Figure 1). The XTRACT technique was used to cork the clot at the tip of the catheter and remove the catheter along with the clot from the body (Figures 2 and 3).
- With a device time of only 5 minutes and no use of tPA, the patient's symptoms were promptly relieved with no recurring episodes to date.

DISCUSSION

Traditionally, tPA or open embolectomy were the primary treatment options for acute-to-chronic lesions. More recently, a number of other endovascular mechanical thrombectomy devices have been introduced as treatment options; however, many physicians still rely on adjunctive tPA, either to "lace" the thrombus at time of procedure or postoperatively via an in-dwelling lytic catheter. The Indigo System has demonstrated high rates of revascularization with consistent success. The PRISM trial, a retrospective case analysis assessing the rate of TIMI 2-3 flow after the use of Indigo and specifically the XTRACT technique, showed an 87.2% rate of revascularization post-Indigo and subsequent treatment of underlying stenosis in the same setting.[1] The newly completed study studying the same primary outcome as PRISM, the INDIAN registry, showed an even higher rate of revascularization, 88.7%.[2] Sustained aspiration for ALI could potentially increase the revascularization rate by serving as an effective single-session frontline option.

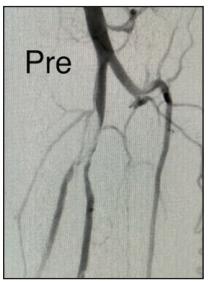

Figure 1. Preintervention.

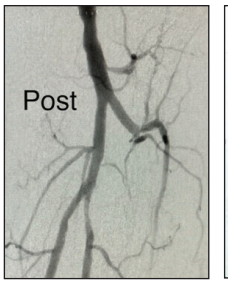

Figure 2. Postintervention.

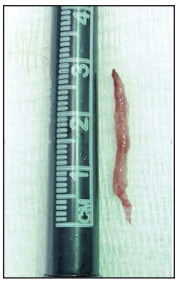

Figure 3. Image of clot removed.

1. 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. J Vasc Interv Radiol. 2018;29:92-100. doi: 10.1016/j.jvir.2017.08.019
2. As presented on November 21, 2019, at VEITH 2019 by Dr. Gianmarco de Donato, University of Siena, Italy.

INDIGO CAT8 FOR BILATERAL ACUTE LIMB ISCHEMIA

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PATIENT HISTORY

A 68-year-old man presented with a sudden coolness in both legs after stopping apixaban therapy for 3 days. The patient's right leg was completely cold, insensate, and immobile from the thigh down. The patient's left leg was cool to the touch with signs of paresthesia but with motor function still intact. CT revealed bilateral ALI (Figure 1).

INTERVENTION

- A wire test was conducted in the right leg to determine the composition of the clot. There was poor distal runoff after wire crossing, indicating acute thrombus (Figure 2).
- The Indigo System Catheter CAT8 was used in the superficial femoral artery (SFA) with several passes until flow was restored and the patient could move and feel his leg again (Figure 3).

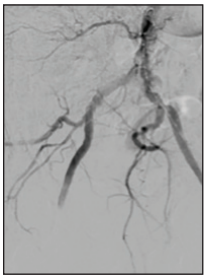

Figure 1. CT showing bilateral ALI.

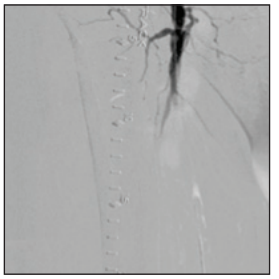

Figure 2. Poor distal runoff from acute thrombus.

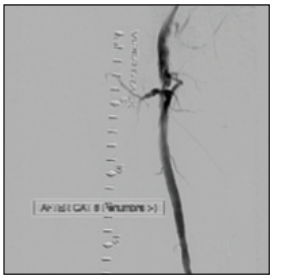

Figure 3. Post-CAT8 on the right leg.

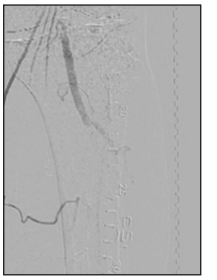

Figure 4. Poor flow through the left TPT.

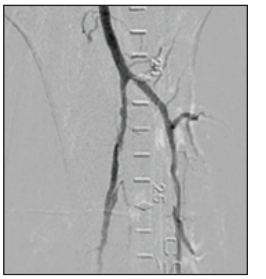

Figure 5. Restored distal flow to the left TPT.

- The wire test was done once again in the left leg, showing poor flow, a BTK clot, and evidence of chronicity. The wire was removed, and the CAT8 was used to remove thrombus from the popliteal artery.
- Fluoroscopy showed additional thrombus in the tibioperoneal trunk (TPT) (Figure 4). Due to it's smaller profile, the CAT RX was advanced coaxially through the CAT8 to resolve further thrombus in the TPT.
- Final fluoroscopy of the left leg showed restored distal runoff (Figure 5).

DISCUSSION

For bilateral occlusions where thrombus is laced throughout the SFA in both legs and with potential for acute-to-chronic occlusion distally, the Indigo System provides a frontline treatment option that potentially preserves limb viability. With the severity of this patient's symptoms, immediate relief was required to maintain limb viability and the different profiles of the Indigo catheters provided a complete portfolio for aspiration in the arterial vasculature, starting with the CAT8 in the SFA and BTK to using the CAT RX coaxially in the heavily diseased TPT. The Indigo System of catheters are trackable, deliverable, and can provide a nice treatment option for complex patients. ■

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 patient-specific attributes.

For LIT-18600.A

INDIGO® Aspiration System CAT™12 – Indication for Use
INDIGO Aspiration Catheters and Separators: As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. **INDIGO Aspiration Tubing:** As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump. **Penumbra Aspiration Pump:** The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems. **Contraindications** Not for use in the coronaries or the neurovasculature. **Warnings** • The safety and effectiveness of this device for use in the treatment of pulmonary embolism (PE) has not been established. Complications from the use of this device in this manner could lead to death, permanent impairment, and/or the need for emergency medical intervention. • The INDIGO Aspiration System should only be used by physicians who have received appropriate training in interventional techniques. • Do not advance, retract or use any component of the INDIGO System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter or SEPARATOR™ against resistance may result in damage to the device or vessel. • Do not use the INDIGO Aspiration System with a pump other than the Penumbra Aspiration Pump. **Precautions** • The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target vasculature location. • Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor. • Use prior to the "Use By" date. • Use the INDIGO Aspiration System in conjunction with fluoroscopic visualization. • Maintain a constant infusion of appropriate flush solution. • When performing aspiration, ensure that the INDIGO Aspiration Tubing valve is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the INDIGO Aspiration Tubing valve when aspiration is complete is not recommended. • The INDIGO SEPARATOR is not intended for use as a guidewire. If repositioning of the INDIGO Aspiration Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate guidewire using standard microcatheter and guidewire techniques. • Do not use automated high-pressure contrast injection equipment with the INDIGO Aspiration Catheter because it may damage the device. **Potential Adverse Events** Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; arteriovenous fistula; death; device malfunction; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at access site; inability to completely remove thrombus; infection; hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; intimal disruption; myocardial infarction; emergent surgery; fibrillation; hypotension; respiratory failure; peripheral thromboembolic events.

LIGHTNING™ Aspiration Tubing – Indication for Use
INDIGO Aspiration Tubing: As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump. **Contraindications** There are no known contraindications. **Warnings** • Do not use the INDIGO Aspiration System with a pump other than a Penumbra Aspiration Pump. • Use of LIGHTNING Aspiration Tubing adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, LIGHTNING Aspiration Tubing and the other equipment should be observed to verify that they are functioning properly. • Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of LIGHTNING Aspiration Tubing. Otherwise, this could result in degradation of the performance of this equipment. **Precautions** • The device is intended for single use only. Do not resterilize or reuse. • Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor. • Use prior to the "Use By" date. • When performing aspiration, ensure that the INDIGO Aspiration Tubing is open for only the minimum time needed to remove the thrombus. Excessive aspiration or failure to close the INDIGO Aspiration Tubing when aspiration is complete is not recommended. • Do not use in the presence of a flammable anesthetic mixture with air or nitrous oxide. • Do not use in oxygen rich environment. **Potential Adverse Events** Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; arrhythmia/fibrillation; arteriovenous fistula; death; device malfunction; distal embolization; emergent surgery; false aneurysm formation; hematoma, hemorrhage, or blood loss at access site; hematoma, hemorrhage, or blood loss; hypotension; inability to completely remove thrombus or control blood flow; infection; ischemia; kidney damage from contrast media; myocardial infarction; neurological deficits including stroke; respiratory failure; thromboembolic events; vascular complications (including vessel spasm, thrombosis, intimal disruption, dissection, or perforation).

PENUMBRA ENGINE™ – Indication for Use
The PENUMBRA ENGINE is indicated as a vacuum source for Penumbra Aspiration Systems. **Contraindications** There are no contraindications. **Warnings/Precautions** • The canister is intended for single use only. Do not reuse. Reuse may result in canister cracking or vacuum filter blockages, which may result in the inability to aspirate. • Do not block bottom air vents. Unit may overheat and shut off or fail to restart if run for extended periods of time without airflow. • To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth. • Do not position the PENUMBRA ENGINE so that it is difficult to remove the power cord. The means of mains disconnect is to remove the power cord. • Only use replacement fuse with correct rating (see Table 1 for fuse rating). • Remove and service the PENUMBRA ENGINE if liquids or solids have been drawn into the PENUMBRA ENGINE. • Do not use in the presence of a flammable anesthetic mixture with air or nitrous oxide. • Do not use in an oxygen rich environment. • To prevent fire or shock hazard, use a replacement power cord of equal rating. • Do not re-infuse blood or fluid from the canister back into the patient. • Do not use petroleum based compounds, acids, caustics, or chlorinated solvents to clean or lubricate any parts. It will reduce the service life of the PENUMBRA ENGINE. Use only water-based solvents for cleaning. • Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. • Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the PENUMBRA ENGINE. Otherwise, this could result in degradation of the performance of this equipment. • Common emitters (such as RFID emitters, security systems, diathermy equipment, and portable transmitters) should not be used in close proximity to the PENUMBRA ENGINE as they can interfere with and result in degradation of the performance of the equipment. • Equipment is not safe for MR use. • No modification of this equipment is allowed.

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