Computer-assisted vacuum aspiration mechanical thrombectomy with Lightning Flash allows broader clinical application, enhanced procedural safety, and improved clinical outcomes for the treatment of acute and subacute iliofemoral and central deep venous thrombosis

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ABSTRACT

We describe our experience with the 16F Lightning Flash vacuum aspiration mechanical thrombectomy system in 25 patients. All patients were treated in a single session with a mean estimated blood loss of 60 mL. Alteplase was not used in any patient in this series. Resolution of at least 50% thrombus or more at the end of the procedure on intravascular ultrasound examination was performed for all patients. Eight-eight percent of patients maintained venous patency at their most recent follow-up range, 8-26 months). No perioperative pulmonary embolism or device-related complications were observed. (J Vasc Surg Cases Innov Tech 2025;11:101849.)

Keywords: IVUS; Intravascular ultrasound; Acute deep venous thrombosis; Subacute deep venous thrombosis; Aspiration mechanical thrombectomy; Lightning Flash; Venography

Percutaneous venous thrombectomy for symptomatic acute iliofemoral caval venous thrombosis can be achieved via several different modalities. Some well-known examples include catheter-directed thrombolysis, rheolytic thrombectomy, mechanical thrombectomy (MT), and vacuum aspiration MT (VAMT).[1] With the advent of newer thrombectomy devices in the past few years, we have witnessed a complete paradigm shift in the interventional management of iliofemoral caval deep venous thrombosis (DVT). In particular, there has been a shift away from the routine use of thrombolytic agents, intensive care unit (ICU) stay, and multisession thrombectomy.[2]

We have previously reported our novel experience with the Indigo Penumbra VAMT system (Penumbra, Alameda, CA). In particular, we described the outcomes of the CAT 8 (8F) and CAT 12 (12F) systems.[2] These were smaller caliber systems that demonstrated success in the clearance of iliofemoral caval venous thrombus, particularly with a unique modification that we have also previously described.[2] This novel modification included the use of a loop snare instead of a separator for the mechanical fragmentation of thrombus and removal of thrombus from the VAMT system and provided greater haptic feedback.

More recently, we have introduced the Penumbra Lightning Flash system into practice. This is a larger, 16F system. The aim of this report is to summarize our experience with the Lightning Flash computer-assisted vacuum thrombectomy system with longer-term follow-up.

METHODS

Type of research study. From January 2023 to September 2024, records of all patients with acute or subacute iliofemoral caval DVT who had VAMT performed using the Lightning Flash system were analyzed retrospectively. Informed consent was obtained from patients for the procedures performed. Institutional review board permission was not needed for this retrospective analysis of data.

Inclusion and exclusion criteria. Symptomatic patients with acute or subacute iliofemoral caval DVT, including iliofemoral caval venous stent thrombosis, who underwent single session AMT with Lightning Flash system were included. This included patients who were presenting up to 6 weeks from the onset of symptoms who had acute or subacute appearance of thrombus on ultrasound examination. Acute DVT under ultrasound examination demonstrates a dilated lumen with noncompressible thrombus that is hypoechoic. In contrast, chronic DVT shows a more contracted lumen that has a more echogenic appearance, partial compressibility, and associated development of recanalization or collaterals. Subacute DVT demonstrates features in the middle of the spectrum. Computed tomography venography was performed if the

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Fig 1. Coronal view of a computed tomography (CT) venogram showing left-sided iliac stent occlusion and patent inferior vena cava (IVC) filter and right iliac venous systems.

iliofemoral segments could not be adequately visualized with ultrasound examination (Fig 1). Patients who were treated with other thrombectomy modalities were excluded from this analysis. Anticoagulation was instituted in all patients at the time of detection of venous thrombosis. In-hospital anticoagulation was typically with enoxaparin, whereas the outpatient anticoagulation regimen consisted of direct oral anticoagulant agents such as apixaban or rivaroxaban. Knee-high compression stockings were recommended to all patients.

Inferior vena cava filters. Perioperatively, inferior vena cava (IVC) filters were not placed in any patient specifically for the purpose of the thrombectomy.

Technical success. In addition to venography, intravascular ultrasound (IVUS) was performed before and after the use of the Lightning Flash AMT system in all patients. IVUS is a better diagnostic tool than venography alone.[3] Technical success of the Lightning Flash system was defined as the resolution of the thrombus on IVUS after AMT by at least 50% (for both stents and native veins).[2]

AMT device. General components and catheters of the Penumbra AMT system have been described in detail previously.[2] The aspiration catheter connects to a vacuum pump (the Penumbra Engine), which generates suction through negative pressure (−29 in Hg or 98.2 kPa), as shown in Fig 2, *A*. The vacuum exerted on the thrombus is controlled by the aspiration tubing, which has a microprocessor running dual clot detection algorithms. The Lightning Flash CAT16 is a 16F laser-cut stainless steel tube with an atraumatic tip (Fig 2, *B*). Depending on the choice of venous access and venous segment in the body being treated, the 16F catheter associated with this system is available in the following different lengths: 80 cm, 100 cm, and 115 cm. Compared with earlier systems, the Lightning Flash has an advanced dual thrombectomy algorithm with the potential to quickly detect clots and restore flow in the venous vasculature. This, in turn, potentially translates into less procedural blood loss. Computer-assisted vacuum thrombectomy technology associated with the Lightning platform allows for a customized yet dynamic aspiration algorithm for each vessel and thrombus.

Statistical analysis. Statistical analysis was performed using a commercially available statistics program (Prism software, Irvine, CA). Mean and standard deviations were reported. Where appropriate, Fisher's exact test or *t* test was used. A *P* value of less than .05 was considered significant.

RESULTS

Demographics. Twenty-five patients underwent AMT with the Indigo Lightning Flash system as the primary thrombectomy modality in a single session. Eleven patients (44%) were male. The mean age was 60 ± 15 years (range, 18-86 years) and 15 (60%) patients were 65 years of age or older. Major comorbidities and other patient characteristics are shown in the Table.

Clinical and procedural parameters. Procedural technical success was noted in all patients (100%). Venous patency was restored in 100% of the treated patients immediately (Figs 3 and 4). The mean estimated blood loss with the device was 60 ± 20 mL. The mean number of passes for the device was 4. The mean dwell time inside the patient was 2 minutes. There was no statistically significant difference in between patients with preexisting thrombosed stents and native vein thrombosis in terms of estimated blood loss, device dwell time, number of device passes, residual thrombus, or other clinical outcomes.

There was no incidence of the following clinical parameters: renal failure, access site complications, pancreatitis, perioperative pulmonary embolism, or device-related complications. Alteplase was not used in any patient in this study. 100% of the patients were treated in a single session. No patient was sent to the ICU for postoperative monitoring.

Ninety-six percent of the patients were discharged within 12 to 24 hours of the procedure. Symptomatic improvement was noted in 96% of patients prior to discharge. On postoperative day 1, 24 of the 25 patients (96%) were patent with minimal residual thrombus on ultrasound examination. One patient, with venous occlusion on ultrasound, was found to have heparin-induced

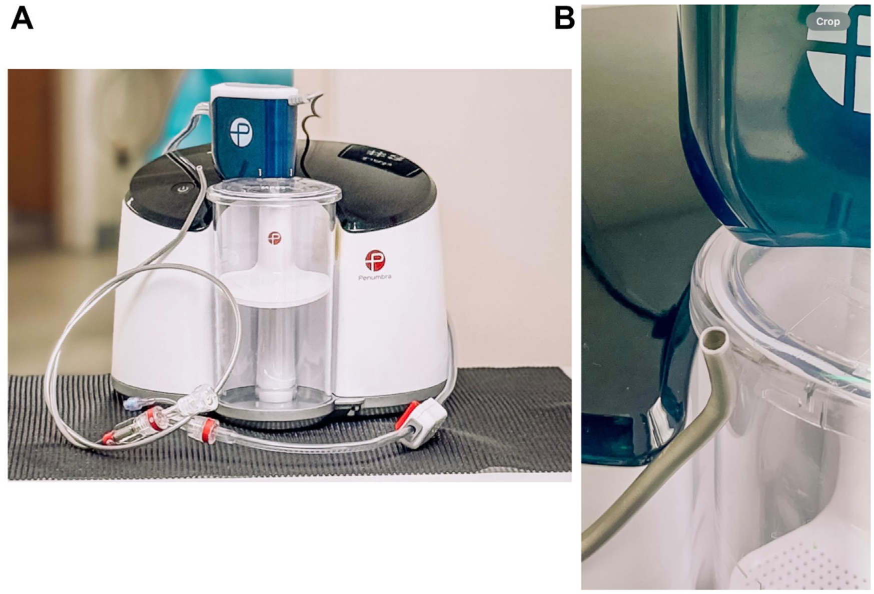

Fig 2. Components of the Lightning Flash aspiration mechanical thrombectomy (MT) system: **(A)** the catheter connects to the vacuum pump and the **(B)** atraumatic catheter tip.

Table. Demographic details of patients undergoing aspiration thrombectomy with Lightning Flash system

Variables	No. (%)
Demographics	
Male sex	11 (44)
Comorbidities	
Hypertension	12 (48)
Diabetes	10 (40)
History of cancer	8 (32)
Active malignancy	5 (20)
Renal insufficiency (creatinine ≥1.5 mg/dL)	10 (40)
History of major surgery within 4 weeks	7 (28)
Contraindication to thrombolytic agent use	12 (48)
Prior history of DVT or pulmonary embolism	5 (20)
Iliofemoral venous stent thrombosis	10 (40)
Associated IVC filter thrombosis	8 (32)
Type of DVT	
Iliofemoral type	15 (60)
Iliofemoral caval with inferior vena cava involvement	10 (40)

DVT, Deep venous thrombosis; *IVC,* inferior vena cava.

thrombocytopenia. Intravenous argatroban was initiated in this patient and his symptoms improved subsequently. Rethrombectomy was not attempted in this patient.

Follow-up. The mean follow-up was 1 year ±2 months (range, 8-26 months). The most recent follow-up was used for the purposes of the analysis. At the 6-week, 3-month, and 1-year follow-up ultrasound examinations, 22 of 25 patients (88%) demonstrated venous patency. At serial follow-ups, improvements in Venous Clinical Severity Score, edema grade, and pain persisted in most of the patients (96%). Iliofemoral caval venous stenting was done selectively; it was performed in two patients (8%) with severe May-Thurner syndrome noted on IVUS examination at the time of the thrombectomy. The purpose of stenting in these two particular patients was to decrease the risk of recurrent DVT.

The incidence of recurrent DVT after thrombectomy to the time of the most recent follow-up was 12%, inclusive of the patient with heparin-induced thrombocytopenia syndrome. No patients developed venous ulceration, hyperpigmentation, or lipodermatosclerosis at follow-up. In one of these patients with venous occlusion/recurrent DVT, recanalization of the occlusion and venous stenting was performed due to lifestyle symptoms that were not responsive to a trial of conservative therapy for 3 to 6 months (edema with pain, Clinical, Etiological, Anatomical, Physiological class C3). The remainder two patients with recurrent DVT did not have lifestyle-limiting symptoms; therefore, stenting was not offered to them. They were maintained on chronic anticoagulation without further instances of DVT recurrence.

DISCUSSION

This study showed that the Lightning Flash AMT system is a significant improvement in form and function upon its predecessors in the treatment of acute and subacute iliofemoral caval DVT. Minimal blood loss was observed with this system, in contrast with previous iterations (60 mL compared with approximately 250 mL noted previously). The clot extracted ranged from acute to

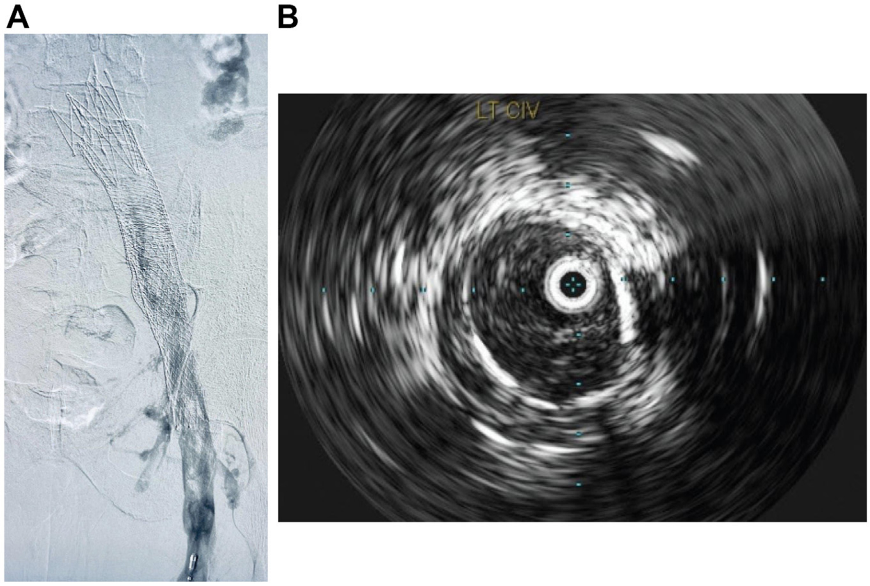

Fig 3. (A) Venography showing extensive thrombus burden in a left-sided iliofemoral stent column. **(B)** Intravascular ultrasound (IVUS) image showing occlusive thrombus in a iliac venous stent.

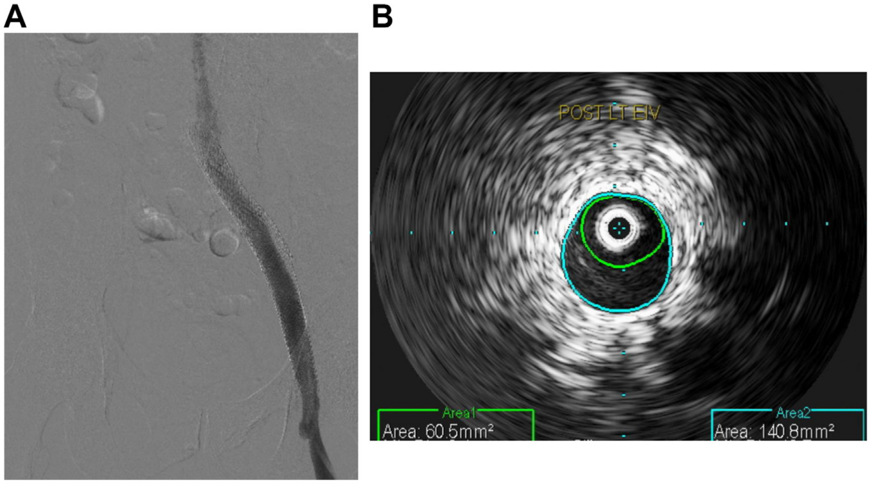

Fig 4. (A) Venography demonstrating inline flow channel post thrombectomy. **(B)** Intravascular ultrasound (IVUS) image demonstrating clearance of thrombus post thrombectomy from a left-sided iliofemoral venous stent column.

semiorganized in appearance (Fig 5). It was also interesting to note that some specimens resembled material typically extracted from patients with in-stent restenosis; this is typically considered to be a more chronic thrombus in nature. The use of the system did not constrain hospital resources in terms of frequent laboratory draws, ICU stay, or prolonged hospital stay. Risks associated with other thrombectomy modalities such as the Angiojet, have been described previously.[4,5] In this study, no patients experienced postoperative renal failure, pancreatitis, or bleeding complications. Alteplase was not administered to any patients. Lightning Flash was offered to patients who are traditionally considered higher risk for this type of procedure. This included patients with baseline renal insufficiency, active malignancy, a history of major surgery within a few weeks, and those with contraindications to thrombolytic therapy. There was no statistically significant difference in the clearance of acute or subacute thrombus with the Lightning Flash system. The use of IVUS, limited number of device passes needed, and low device dwell time practically translated into minimizing radiation exposure for the team and the patient as well as conservation of overall medical resources and time without any apparent adverse effect on clinical outcomes.

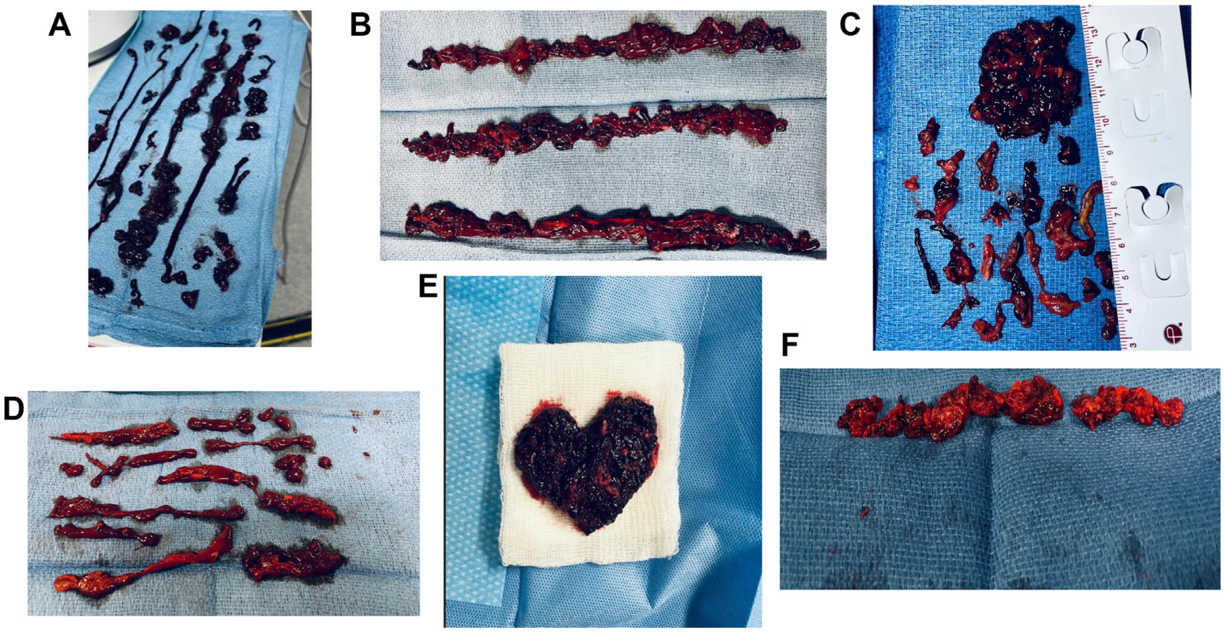

Fig 5. (A-F) Clot extracted ranged from acute to subacute. Some specimens from stented thrombosed patients also showed material typically seen in in-stent restenosis.

Few studies have examined the clearance of acute/subacute thrombus with the use of IVUS.[2,6] Technical success in this study was gauged by IVUS examination (100%) rather than venography alone. Venography was used to gauge the presence of an unobstructed in-line flow channel through the treated venous segments. In-line flow, in turn, translated into continuing autolysis of the thrombus using the body's natural thrombolytic systems.

The device navigated the iliac segment tortuosity very well without any instances of vessel perforation. The curve at the tip of the catheter helped to engage the vessel walls and provide the necessary apposition to the thrombus. Despite a 16F profile, there were no cases where the catheter could not be passed from the popliteal segment to the IVC. This profile is still lower compared with some of the other thrombectomy devices available. There were no instances where the catheter got entangled with the IVC filter tynes or the venous stent struts. No embolic protection device was placed in the IVC specifically for the purpose of the thrombectomy. Clinically, no perioperative pulmonary embolism was observed.

The question of how much residual thrombus can be left behind safely requires further investigation. We have previously shown that creation of a flow channel with in-line flow, despite residual thrombus, improves symptoms while not significantly affecting the long-term patency or outcomes in patients.[2,6,7] This study confirmed that finding as well. However, the longer-term impact of this on the development of post-thrombotic syndrome remains unclear.[8] Currently, the follow-up in most studies is certainly not adequate to confidently address this question.[9] It seems that very aggressive strategies such as multisession lytic therapy, repeated balloon maceration of thrombus, multiple device passes with prolonged radiation times, and universal stenting (with only moderate long-term patency rates) are not warranted in the majority of cases with acute or subacute DVT.

Most patients were deemed safe to be discharged after their single session thrombectomy procedure within 12 to 24 hours. This finding is consistent with a recent study that described an initial limited experience with the ambulatory management of acute iliofemoral DVT with May-Thurner syndrome with percutaneous MT in the recent times of staffing and supply chain shortages affecting the in-patient flow of care.[10]

The CLOUT registry analysis showed that the thrombus age does not always correlate with symptom duration and onset, especially when considering the presence of specific connective tissue elements such as collagen.[11] In almost 50% of patients, the thrombus was noted to be more chronic than would have been assumed based on symptom duration alone. In our study, patients with up to 6 weeks of symptoms with appropriate imaging supportive of that thrombus nature were included.

Study limitations. The main limitations of the study include its retrospective nature, single-center patient selection, and small sample size.

CONCLUSIONS

Lightning Flash is an improvement in form and function over previous iterations. It minimizes procedural blood loss while providing reasonable thrombus clearance in acute and subacute iliofemoral caval DVT.

AUTHOR CONTRIBUTIONS

Conception and design: TS
Analysis and interpretation: TS, SR
Data collection: TS
Writing the article: TS, SR
Critical revision of the article: TS, SR
Final approval of the article: TS, SR
Statistical analysis: TS
Obtained funding: Not applicable
Overall responsibility: TS

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DISCLOSURES

S.R. reports a US Patent, IVUS diagnostics.

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