# Vena Caval Filters in the Treatment of Acute DVT

IVC filter placement provides protection against PE caused in part by thrombus fragmentation during the thrombectomy or thrombolytic procedure.

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he incidence of deep vein thrombosis (DVT) is estimated to affect 48 per 100,000 persons annually, as determined by large epidemiological studies, with an in-hospital case-fatality rate due to complications of thromboembolism of 12%. Thus, 300,000 hospitalizations per year in the US can be directly attributed to venous thrombotic disease, with studies reporting as many as 90% of patients traditionally admitted to the hospital.<sup>2,3</sup> It is also estimated that DVT affects 20% to 30% of all major surgical patients and, as a result of pulmonary embolism (PE), is responsible for more than 60,000 deaths annually in the US.<sup>1,3</sup> Venous thromboembolic disease, both DVT and PE, is an underdiagnosed medical problem that frequently results in high rates of severe morbidity and mortality. Most studies cite inadequate venous thromboprophylaxis in surgical and medical patients as a causative factor in DVT and PE. Regardless of the occurrence of PE, DVT alone can negatively impact patient outcomes and increase health care costs. Patients with multiple venous segment involvement, particularly in the iliofemoral veins, or with extension of a calf vein DVT, are among those most frequently hospitalized for

Endovascular interventions of acute DVT using various therapeutic modalities, such as thrombolysis, mechanical thrombectomy, and inferior vena cava (IVC) filter placement, have received increased attention from health care providers in the past decade, a phenomenon that is possibly fueled by several factors. A significant advance has taken place in the current medical management of DVT

as the pharmaceutical industry has developed many effective and convenient outpatient medications using low-molecular-weight heparin in the treatment of acute DVT. This has generally resulted in improved patient compliance and reduced hospitalization compared to conventional intravenous heparin anticoagulation. The improvement in medical therapy has also heightened the awareness of primary care physicians and the general public regarding the clinical sequelae of DVT. As a result, patients

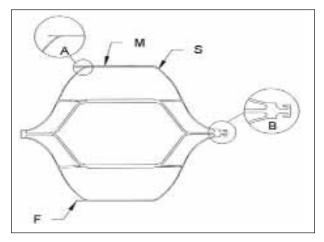


Figure 1. Schematic depiction of the OptEase filter. The T-shaped retrieval hook is located on the caudal apex of the filter. The fixation barbs are extensions of the cephalic end of the filter side struts. (Inset: Enlargement of fixation barb [A]; T-shaped retrieval hook [B]. M = the midstrut section of the filter side strut; S = filter shoulder; F = fixation barb.)

with symptomatic venous thromboembolism are more likely to be referred to physicians for therapeutic interventions. In addition, the rapid evolution of catheter-based interventions has increased the available armamentarium for interventionists to remove thrombus and maintain venous patency in acute DVT. Many researchers have demonstrated the effectiveness of thrombolytic therapy or mechanical thrombectomy in acute iliofemoral DVT, with excellent long-term outcomes. Lastly, recent advances in IVC filter technology, particularly with retrievable IVC filters, have provided greater treatment options in the management of DVT and the prevention of PE.

The indications of venous thrombolysis in acute DVT, as well as the ideal thrombolytic agent of choice, have been a subject of debate. Although anticoagulation is effective in preventing PE, many patients go on to experience post-thrombotic syndrome, which is a chronic sequelae of DVT, with resultant valvular insufficiency of the lower extremity. It is well documented that lytic therapy leads to a more rapid and complete dissolution of clot compared with heparin treatment alone.<sup>5-8</sup> Complete clot dissolution was observed in 35% of those undergoing lysis versus 4% of those treated with heparin alone. The concept of early venous thrombolysis has been promoted by the iliofemoral venous thrombosis registry, which is a multicenter registry designed to determine the role of catheter-directed thrombolysis in the treatment of DVT as compared to systemic heparin anticoagulation. The study found no differences in mortality or in the incidence of PE between the two groups, although bleeding complications were seen in 17% of the lytic group and in 4% of the heparin-treated group. Patients having successful catheter-directed thrombolysis (complete and partial lytic success) derived significant benefit in terms of improvement of quality of life versus those treated with anticoagulation alone.

Despite these studies demonstrating improved treatment efficacy of thrombolysis compared to systemic anticoagulation, the ideal treatment strategy for symptomatic DVT remains to be defined. Although the occlusive effects of DVT can quickly and effectively be treated with thrombolytic therapy, bleeding complications are significantly increased. The crucial question that remains to be answered is whether lytic therapy lessens the destructive effects of DVT on valve function and leads to significantly improved clinical outcome.

Endovascular management utilizing percutaneous mechanical thrombectomy alone, or in combination with pharmacological thrombolytic agents, has recently received much attention in the literature as a safe and effective means for the treatment of acute DVT.<sup>4,10</sup> Along with possible preservation of venous valve function, this

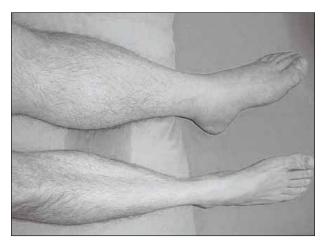


Figure 2. Significant left lower swelling caused by an acute iliofemoral DVT.

treatment strategy also permits simultaneous correction of inciting anatomic lesions, such as iliac vein stenosis. IVC filter placement is beneficial during the mechanical thrombectomy procedure, partly because of device-related fragmentation of iliofemoral thrombus, which could potentially result in PE. This article will discuss endovascular treatment strategies for acute DVT—specifically, the utility of mechanical thrombectomy along with various retrievable IVC filters in the setting of DVT are examined. An illustrative case of acute DVT, which was treated with endovascular intervention with IVC filter placement, is presented.

# ENDOVASCULAR TREATMENT MODALITIES OF ACUTE DVT

Endovascular treatment of acute DVT should be considered in patients who present with symptomatic acute iliofemoral DVT or persistent swelling despite appropriate medical therapy, including systemic anticoagulation and bed rest with leg elevation. A thorough venous duplex ultrasound is imperative to document the severity or progression of iliofemoral DVT. Although the efficacy of thrombolytic therapy in acute iliofemoral DVT has been described previously, this article will focus on an endovascular treatment modality utilizing mechanical thrombectomy and retrievable IVC filter protection.

### **Percutaneous Mechanical Thrombectomy**

Although there are a variety of percutaneous mechanical thrombectomy (PMT) devices that can be used to remove thrombus burden in acute DVT, the discussion of this article will focus on the Angiolet PMT system (Possis Medical Inc., Minneapolis, MN). The treatment of symptomatic acute iliofemoral DVT in our clinical practice largely relies

on the Angiolet thrombectomy system.<sup>10</sup> Concomitantly, we routinely place a temporary IVC filter to reduce procedure-related PE during Angiolet mechanical thrombectomy.<sup>11</sup> The IVC filter is electively removed after the completing the therapy or resolution of the DVT symptoms.

Relief of clot burden by directly extracting thrombus, either mechanically or pharmacologically, at least theoretically decreases the risk of PE and also that of post-thrombotic syndrome, resulting in manifestations of chronic venous insufficiency. Primarily because of the bleeding risks of catheter-directed thrombolysis, PMT has emerged as an advantageous option for treating acute DVT. The principle of the Angiolet rheolytic thrombectomy system is based on the Venturi effect, which creates rapidly flowing saline jets that are directed backward from the tip of the device to outflow channels in a coaxial fashion, which generates a vacuum force that draws the thrombus into the catheter. One major advantage of this percutaneous treatment modality is that the thrombectomy catheter can be delivered through a small-bore introducer sheath,

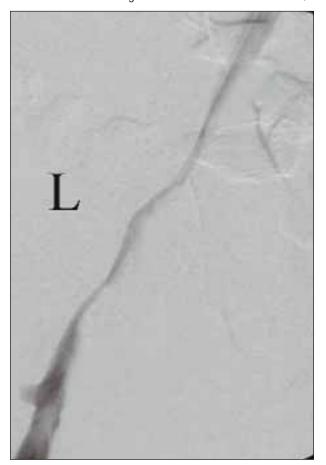


Figure 3. An initial venogram, which was obtained via the left popliteal vein in the prone position, revealed an extensive DVT in the left iliofemoral venous system.

which reduces access site trauma and avoids operative arterial exposure required with the conventional Fogarty thromboembolectomy.

The Angiolet thrombectomy system consists of three components: a single-use catheter, a single-use pump set, and a pump drive unit. The 6-F Xpeedior catheter has a working length of 60 cm, 100 cm, or 120 cm, and is introduced via a percutaneous approach (6-F sheath) and operates over a .035-inch guidewire. The drive unit/pump generates high-pressure (~10,000 psi) pulsatile saline flow that exits the catheter tip through multiple, retrogradely directed jets. These high-velocity jets create a localized low-pressure zone, in accordance to the Bernoulli principle, for thrombus aspiration and maceration. The jets also provide the driving force for evacuation of thrombus particulate debris through the catheter. The AngioJet system works in an isovolumetric manner: the saline infusion flow rate (60 mL/min) is in balance with the evacuation rate of thrombus particulate debris.

A clinical study that evaluated the efficacy of the Angiolet system has demonstrated that such a mechanical thrombectomy system is effective in thrombus removal, venous patency restoration and maintenance, and symptom relief.4 The Angiojet rheolytic thrombectomy system uses multiple columns of high-velocity saline jets within the catheter tip, which creates an area of low pressure in the vicinity of the catheter tip for thrombus removal. Via this mechanism, thrombus surrounding the catheter tip is macerated and rapidly evacuated via an effluent lumen into a collection chamber. In this study, only four (23.5%) patients achieved >90% thrombus clearance with PMT alone. One advantage of the AngioJet catheter is that it permits concomitant infusion of thrombolytic agent, which can further enhance the capacity for thrombus removal by means of a combined mechanical and pharmacological thrombolytic effect. In this study, a thrombolytic catheter is left in place for continual thrombolysis if suboptimal thrombectomy results are noted, and the average duration of thrombolytic therapy was 20.2 hours. Clinical symptomatic improvement was seen in 82% over a follow-up time frame of 11 months.

# Retrievable IVC Filter Placement in Acute DVT Management

Due in part to concerns regarding the long-term safety of permanent IVC filters in young patients, as well as clinical interest in patients who require short-term PE prophylaxis, there has been a surge in the clinical interest of using retrievable IVC filters to provide temporary protection against PE. There are two varieties of nonpermanent filters—temporary and retrievable. A temporary IVC filter generally describes devices that remain attached to an

accessible wire or transcutaneous catheter so that removal of the filter is feasible and required. Potential disadvantages of these temporary filters are the necessity of device removal after a certain time period and risk of infection. In contrast, retrievable IVC filters are designed similarly to conventional permanent filters but with modifications to the caval attachment sites that allow retrieval using a snare or specially designed filter grasper. The potential advantage is that the filter can be retrieved at a later stage, or left in place permanently. Undoubtedly, the ability to safely remove these devices depends on accurate evaluation of the thromboembolic risks for the patient before filter retrieval is performed.

Several types of retrievable IVC filters recently received approval from the FDA for clinical application. As a result, clinical interest has risen among physicians to perform retrievable IVC filter placement for PE prevention during endovascular DVT interventions. 12-14 One major advantage of such a treatment strategy is that the filter may be removed once the DVT intervention is completed and the patient no longer requires filter protection. Table 1 lists the categorical indications for IVC filter placement as published by the Vena Caval Filter Consensus Conference in 2003.<sup>15</sup> The commonly accepted indications for the use of IVC filters are documented venous thromboembolism (in particular), proximal occlusion with active bleeding, or contraindications to anticoagulation therapy. Additional indications include patients with recurrent PE despite anticoagulant therapy or patients with long-term predisposition to PE (as an alternative to life-long therapy). It is noteworthy that filter insertion as an adjunctive measure for PE prevention during thrombectomy or thrombolytic therapy is regarded as a clinical indication.

The efficacy of IVC filter placement during acute DVT management by means of either catheter-directed thrombolysis or thrombectomy has been reported in several clinical reports. 16 Terry et al reported their experience with implantation of temporary vena cava filters in 132 patients with lower-extremity DVT who received thrombolytic therapy. The investigators reported presence of thrombus in the IVC filter after thrombolytic therapy in 41 (31%) of the 132 patients. Specifically, such observation was made in 21 of 63 cases with partially occlusive iliofemoral DVT, and in 20 of 69 with occlusive DVT. No PE occurred among the 132 patients. This study showed the IVC filter was efficacious in preventing PE during thrombolytic treatment in at least 41 of these patients, if not all 132 patients. 16 In our clinical experience of patients who underwent retrievable IVC filter placement during a mechanical thrombectomy procedure, radiographic visible thrombus within the IVC filter was observed in 40% of the patients immediately after the thrombectomy proce-

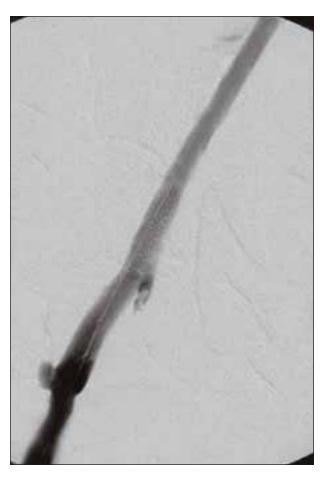


Figure 4. Completion venogram after PMT demonstrated a focal iliac venous stenosis that was successfully treated with a self-expanding stent placement, resulting in an excellent radiographic result.

dure.<sup>11</sup> IVC filters were retrieved only when no visible thrombus was noted within the filter, either at the completion of the thrombectomy procedure or by subsequent venography.

Retrievable IVC filters may be left in place indefinitely, serving as a permanent caval filter. Alternatively, they may be retrieved, depending on the indication. If temporary filter retrieval is indicated, it should be performed within several weeks after the implantation via either the internal jugular or femoral approach. The ideal timing of filter removal remains elusive, depending on the filter designs and clinical indication of filter placement. The process of caval filter retrieval is accomplished by utilizing a snare or grasper to anchor the end of the retrieval filter, which is then pulled within a guiding sheath for retrieval. The main concern with delayed caval filter removal is the development of endothelialization in the vena cava, which can incorporate the filter into the caval wall endothelium, thus

making retrieval impossible without injuring the native vessel or possibly even causing dissection or perforation. Burbridge et al recently demonstrated that endothelialization can develop as soon as 2 weeks after IVC filter placement.<sup>17</sup>

# CURRENTLY AVAILABLE RETRIEVABLE IVC FILTERS

Currently, there are several IVC filters that can be used either permanently or temporarily with subsequent retrieval for PE prevention. If these filters are left in place, they function as a permanent IVC filter. Alternatively, these filters may be retrieved once the duration of PE prophylaxis has been achieved. Examples of these retrievable filters include the Günther Tulip (Cook Incorporated, Bloomington, IN), OptEase (Cordis Corporation, a Johnson & Johnson company, Miami, FL), and Recovery nitinol filters (Bard Peripheral Vascular, Tempe, AZ).

## The Günther Tulip Filter

The Günther Tulip filter is a retrievable filter that is constructed of nonmagnetic metal. The Günther Tulip filter can be inserted via either femoral or jugular venous access. The filter has the shape of a half basket, with four centering wires extending outside the basket and a curvature designed to follow the IVC wall. A retrieval hook is located at the apex of the filter, which allows percutaneous retrieval. To retrieve this filter, a retrieval snare in an 11-F sheath is used from the right jugular site. The manufacturer recommends that the filter be removed within 10 days of implantation. In a multicenter registry, Millward et al reported a total of 90 patients who underwent implantation with 91 Günther Tulip filters. Retrieval of 53 filters had been attempted between 2 and 25 days, and 52 filters were successfully retrieved from 51 patients. The incidence of filter occlusion was 5% and no other complications occurred.18

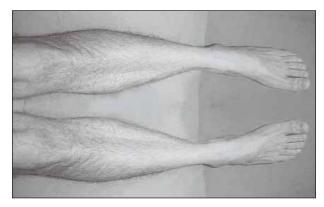


Figure 5. At the time of discharge, the patient's left leg had returned to normal without pain or swelling.

# TABLE 1. INDICATIONS FOR IVC FILTER PLACEMENT

- Contraindication to anticoagulation
- Complication of anticoagulation
   Failure: objectively documented extension of existing DVT or new DVT or PE while therapeutically anticoagulated Hemorrhage: major or minor Thrombocytopenia

Chin na arasia

Skin necrosis

Drug reaction evidence/probability of poor compliance

- Prophylaxis: no thromboembolic disease
- Prophylaxis with thromboembolism in addition to anticoagulation
- Failure of previous device to prevent PE; central extension of thrombus through an existing filter or recurrent PE
- In association with another procedure: thrombectomy, embolectomy, or thrombolytic therapy.

Note: These indications were reported by the participants in the Vena Caval Filter Consensus Conference in 2003.

### The OptEase Filter

The OptEase filter is a retrievable filter based on the design of an earlier permanent version of the TrapEase Filter (Cordis), and has a unique self-centering design that provides dual-level filtration. Similar to the TrapEase permanent IVC filter, the OptEase retrievable filter is made from a single nitinol metal tube and has a double-basket design with six straight struts connecting the proximal and distal baskets. In contrast to the symmetric TrapEase filter, the OptEase filter has a set of six fixation barbs to prevent cranial migration at the cranial end of the filter instead of at the caudal end (Figure 1). Furthermore, a hook is located at the caudal end of the OptEase filter to allow retrieval with an endovascular snare. The OptEase can be deployed from the femoral, brachial, or jugular venous approach through a 6-F delivery system. It is the only retrievable filter that can be recovered from a femoral approach. In contrast to the Recovery nitinol filter or the Günther Tulip filter, retrieval of the OptEase filter only requires a 10-F guiding catheter. One benefit of using the femoral approach over the jugular approach during retrieval is the avoidance of inadvertent passage of the retrieval sheath through the heart, which would lessen the potential for myocardial injury or arrhythmia. Another advantage of the femoral retrieval approach is that the filter can be removed through the same femoral or popliteal venous access site after the completion of iliofemoral thrombectomy or thrombolysis for DVT intervention.

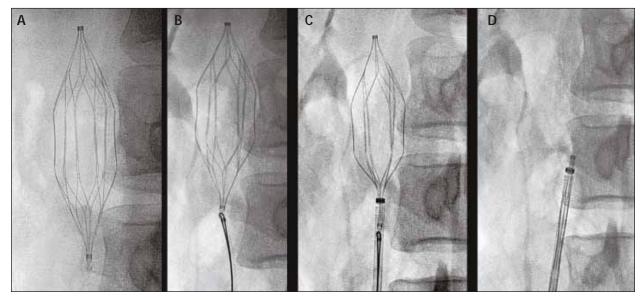


Figure 6. Retrieval process of the OptEase filter. The OptEase filter in the IVC (A). A snare is used to anchor the caudal hook of the OptEase filter (B). With gentle vertical traction, a guiding sheath is advanced forward over the snare, which captures the OptEase filter (C). The OptEase filter is fully captured by the guiding sheath and successfully retrieved (D).

### The Recovery Nitinol Filter

The Recovery nitinol filter is a retrievable filter made of nitinol. It is composed of twelve, .13-inch nitinol wires that extend from a nitinol sleeve. The resting diameter of each of the arms is 30.5 mm, and 32 mm for each of the legs. The filter measures 40 mm in height. At the apex of each filter is a docking device that allows for retrieval. Retrieval is achieved using a specially designed urethane-covered retrieval cone via the jugular approach. Animal studies have demonstrated that the Recovery filter can be safely retrieved up to 12 weeks after insertion. <sup>19</sup>

### **ILLUSTRATIVE CASE STUDY**

The following case study illustrates the endovascular management of an acute iliofemoral DVT utilizing mechanical thrombectomy and a retrievable IVC filter. A 53-year-old man presented to the emergency room with a 2-day history of left lower leg swelling. He had been on an 8-hour transatlantic flight 4 days earlier. He reported significant swelling of the left calf and thigh, which was warm to the touch. He also described severe lower leg pain that worsened with ambulation. He had no significant medical history and was not on any medication. He also denied any trauma to his lower extremity. Physical examination revealed marked swelling of the left lower extremity involving the calf and the thigh, which were tender to the touch (Figure 2). Although the calf was soft to the touch, it became painful with both passive and active dorsiflexion of the foot. The right lower leg was unremarkable in its appearance and examination.

### **Diagnostic Evaluation**

Venous duplex ultrasound of the lower extremities demonstrated a large noncompressible echolucent density in the left common femoral vein, which was consistent with acute DVT. There was a complete venous occlusion with venous thrombus extending proximally to the external and common iliac veins, as well as distally to the superficial femoral and popliteal veins. Doppler signals showed an absence of normal phasic flow, which was consistent with venous occlusion. The diagnosis of acute left iliofemoral DVT was made based on the venous duplex ultrasound.

### **Treatment Approach**

Because of the marked leg swelling and constant pain, treatment to remove the DVT and restore the iliofemoral venous flow was indicated. The treatment approach included an initial placement of an OptEase IVC filter from the right femoral vein approach, which was performed with the patient in the supine position. Placement was accomplished by percutaneously accessing the right femoral vein in which the OptEase filter was inserted through the 6-F delivery system in the infrarenal IVC. The OptEase filter was chosen because it would provide protection against PE during mechanical iliofemoral thrombectomy. In addition, the OptEase filter would allow retrieval from either the femoral or popliteal venous approach, if necessary, at the completion of a mechanical thrombectomy procedure. After insertion of the OptEase filter, the patient was placed in

the prone position. The left popliteal fossa was then prepared and draped in a sterile manner. Under ultrasound guidance, the left popliteal vein was percutaneously cannulated using a Micropuncture needle (Boston Scientific Corporation, Natick, MA). A 6-F introducer sheath (Boston Scientific) was placed over a guidewire into the popliteal vein. An initial venogram showed a complete thrombosis of the superficial femoral vein and extensive DVT in the iliofemoral venous system (Figure 3). After the placement of a guidewire through the iliofemoral DVT, an AngioJet thrombectomy catheter was delivered over the guidewire into the venous thrombus. Serial thrombectomy was performed, which percutaneously removed the thrombus from the superficial femoral vein and the iliofemoral venous system. Repeated venogram demonstrated an underlying venous stenosis in the left common iliac vein, which was successfully treated with a Smart stent (Cordis) via the popliteal vein approach. Completion venography demonstrated a patent iliofemoral venous system without evidence of thrombus or stenosis (Figure 4).

The patient was given systemic heparin (100 u/kg) and oral warfarin anticoagulation 3 days later. Repeat venous duplex ultrasound was performed the next day, which demonstrated a complete resolution of the femoral and iliac vein without evidence of DVT. At the time of discharge 4 days later, the patient's left leg swelling had completely subsided and there was no pain (Figure 5). The OptEase filter was removed electively 2 weeks after insertion via the right femoral vein approach (Figure 6). The patient remained free of symptoms and had no recurrence of DVT at 1-year follow-up.

### CONCLUSIONS

Current management of acute symptomatic iliofemoral DVT requires timely diagnosis and prompt intervention. Efforts to remove thrombus burden by means of mechanical thrombectomy or thrombolytic therapy are effective in alleviating clinical symptoms, restoring venous patency, and reducing the future risk of post-thrombotic syndrome. IVC filter placement provides protection against PE caused in part by thrombus fragmentation during the thrombectomy or thrombolytic procedure. The availability of various retrievable IVC filters allows subsequent filter retrieval when the symptoms of iliofemoral venous thrombosis are fully resolved and the risk of venous thromboembolism is significantly reduced. Advances in retrievable IVC filters have resulted in expanded and exciting indications of PE prophylaxis in the endovascular treatment of venous thromboembolism.

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