

Surgical and Interventional Considerations in the Retrieval of the Celect™ Inferior Vena Cava Filters

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Abstract

Although inferior vena cava filters (IVCFs) are a known method for caval interruption and prevention of pulmonary embolism (PE), there is a lack of controlled trials conclusively proving that IVCF placement actually reduces the risk of PE or death. Additionally, their use has become a far more common practice since the development of retrievable IVCFs. The rationale for the use of retrievable IVCFs is that they provide the theoretical benefit of protection from PE, while allowing their removal when they are no longer needed, thus resulting in fewer long-term complications. Unfortunately, it is a fact that the majority of retrievable IVCFs are not removed and that they are associated with significant complications, most notably vena cava perforation and thrombosis. The Celect retrievable IVCF (Cook Medical, Bloomington, IN) is one of the systems available in the United States for caval interruption.

This manuscript describes three challenging cases of retrieval of Celect IVCFs. The first is the case of a young female who developed late complications related to a retrievable Celect IVCF that caused infrarenal caval occlusion and perforation into the surrounding retroperitoneal structures. She ultimately required open surgical filter retrieval. In addition, we also describe two patients in which alternative percutaneous methods for IVCF retrieval were used. We briefly review the literature concerning indications for IVCF placement and some of the pitfalls that can be encountered while attempting their retrieval. Further studies are necessary to investigate the efficacy and outcomes of retrievable IVCFs.

Keywords: Cava filter; Vena cava filters; Inferior vena cava filter

Abbreviations: IVDF: Inferior Vena Cava Filters; PE: Pulmonary Embolism; DVT: Deep Venous Thrombosis

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Introduction

Inferior vena cava filters (IVCFs) were originally developed for caval interruption in patients afflicted by venous thromboembolism (VTE) who had a contraindication to anticoagulation or in whom failure of anticoagulation was demonstrated. Since the inception of retrievable IVCFs, there appears to be an increase in their use, with the presumption that the filter will be removed, thus theoretically resulting in fewer long-term complications in comparison to permanent IVCFs [1]. Disappointingly, the literature demonstrates that the majority of retrievable IVCFs are not removed [2,3]. For instance, a study of trauma patients showed that over 75% of retrievable IVCFs are not removed, mainly because several patients are lost to follow-up [4].

Consequently, both early and delayed complications associated

with IVCFs still persist with retrievable device and range from local complications related to insertion site to IVC thrombosis and perforation [5-10].

One of these retrievable systems is the Celect™ IVCF (Cook Medical, Bloomington, IN). It consists of a 30 mm-diameter, 48 mm-long, non-magnetic filter preloaded on an introducer system with a stainless steel grasping hook, a 7.0 French coaxial introducer system, compatible with a 0.035 inch wire guide, and a hydrophilic-coated dilator. We herein present three case reports of patients in whom retrievable Celect™ IVCFs were placed and later retrieved. The first case is that of a young female with a retrievable IVCF-related infrarenal IVC occlusion and penetration of the filters struts into adjacent structures, almost two years post filter placement. The patient was managed surgically with vena caval cavotomy and filter removal.

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The last two cases are those of patients in which alternative percutaneous methods for IVCF retrieval were used. We briefly review the literature concerning indications for IVCF placement and some of the pitfalls that can be encountered while attempting their retrieval.

Case Report 1

A 26-year-old female with a known factor V Leiden deficiency and a history of recurrent deep vein thrombosis (DVT) in the left common iliac and left common femoral vein, as well as a history of PE while optimally anticoagulated, underwent Celect™ IVCF placement in June 2009.

Two years later, she presented with a four-week history of severe abdominal and back pain, melanotic stools and recurrent hematemesis. On exam, she was afebrile and with normal vital signs. She appeared in acute distress secondary to her abdominal pain. Her abdomen was soft but tender to palpation in the epigastric region. Laboratory studies showed a hemoglobin of 10.5 g/dl and an International Normalized Ratio (INR) of 1.3. A computerized tomography (CT) of the abdomen (**Figure 1**) demonstrated IVC occlusion. Four of the filter struts were protruding outside the IVC: the first entering the lumbar vertebral body, the second between the aorta and the superior mesenteric artery, the third entering the right psoas muscle, and the last one indenting the duodenum. Esophagogastroduodenoscopy showed no luminal intrusions by the IVC struts.

Consideration for percutaneous IVCF retrieval was given but aborted, given a significant IVC strut perforation, with ensuing concerns for IVC tear and catastrophic hemorrhage. Accordingly, a laparotomy through an upper abdominal midline incision revealed an IVC occlusion from its infrarenal segment up to the point where it joined the gonadal vein. Scarring around the perirenal IVC was noted. The gonadal vein was massively enlarged. Both renal veins were patent, and the IVC filter struts

could be palpated through the anterior portion of the gonadal vein and along the second portion of the duodenum. The adherent tissue along the IVC was taken down until control of the infra- and suprarenal IVC, the right and left renal veins, and the gonadal vein was achieved (**Figure 2**).

Under systemic heparinization, a longitudinal cavotomy was made at the level of the renal veins. The IVCF was identified and pulled out through the cavotomy. The IVCF was intact except for a single broken strut as it entered the vertebral body (**Figure 2**). The IVC cavotomy was oversewn with a double running suture of 4-0 Prolene. A postoperative abdominal radiograph confirmed a single strut left behind within the vertebral body. She was discharged home nine days after surgery in good condition.

Case Report 2

A 36-year-old obese and diabetic female was diagnosed with a right lower extremity DVT and bilateral PE. Ultrasound revealed a loosely adherent popliteal vein thrombus. An IVCF placement was decided as appropriate therapy. A Celect™ IVCF was placed via the right femoral vein. Two weeks later, once the clot was noted on ultrasound to be organized and attached to the vein wall, the patient was taken to a hybrid operating room suite for elective IVCF retrieval. A 7-French sheath was placed in the right internal jugular vein. Fluoroscopy demonstrated IVCF tilt with the retrieval hook lodged against the IVC wall. A 3-prong snare was advanced and positioned right above the filter. While trying to secure the hook, the snare became trapped by the filter struts below the hook. Untangling proved to be impossible. Fortunately, a gentle tug on the first snare allowed the hook to be moved away



Figure 1 Scout X-ray and three computed tomographic reconstruction of the first patient. Through these images it can clearly be seen the projection of the filter struts into the adjacent vertebral body.

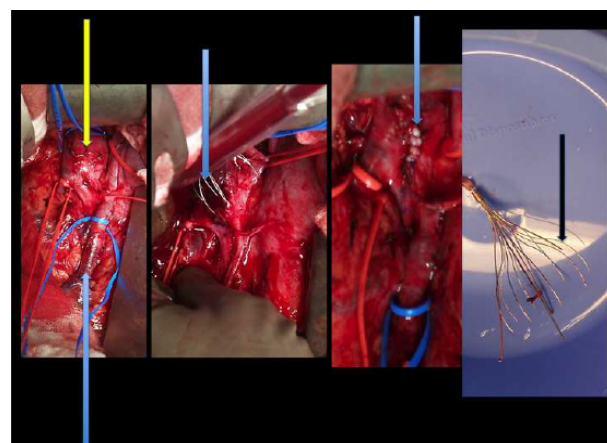


Figure 2 Four panels depicting the details of the case in which open surgical filter retrieval was required. On the first panel, from left to right, caval dissection can be seen. A very large gonadal vein can be seen (blue arrow), approximately one centimeter in diameter, and appeared to be a major collateral source around the IVC occlusion. The yellow arrow depicts the inferior vena cava. The second panel shows the IVC filter (arrow) being grasped with a hemostat and pulled out through the IVC cavotomy. The third panel shows the IVC cavotomy, which was oversewn with a double running simple suture of 4-0 Prolene (arrow). The last panel shows the specimen. Upon inspection of the IVC filter, it was found to be completely intact except for a single strut (black arrow), which appeared to be broken.

from the caval wall. A second buddy snare was advanced and now the hook was easily trapped. The filter was then collapsed under the 7-French sheath and successfully removed.

Case Report 3

An 83-year-old male with a history of severe coronary artery disease was incidentally found to have a popliteal DVT. This patient was electively admitted to our hospital to undergo coronary open revascularization. A bilateral lower extremity ultrasound vein mapping was ordered, which showed the DVT. In retrospect, patient admitted being afflicted by lower extremity swelling and discomfort for a few weeks prior to this finding. Placement of a retrievable IVCF was requested by the cardiac surgeon given his imminent intervention.

A Celect™ IVCF was chosen, placed through ultrasound-guided cannulation of the left common femoral vein. IVCF tilting was noted immediately after deployment. Cardiac surgery followed without any complications and the patient returned for IVCF retrieval one week postoperatively, once anticoagulation was restarted. A 7-French sheath was placed in the right internal jugular vein. A 3-prong snare was advanced and positioned right above the filter. Fluoroscopy demonstrated the filter to be severely tilted with its hook located well into the lumen of the right renal vein (**Figure 3**). The hook was impossible to snare due to its position. In the process of attempting IVCF retrieval, the snare was trapped by an IVCF prong. Several attempts to unhook it were unsuccessful. A second snare was advanced in order to snare the hook, which was also unsuccessful, despite gentle tugs on the first snare, trying to move the hook away from the caval wall. The right renal vein was cannulated with a guidewire and a

10 x 20-mm PowerFlex P3™ balloon (Cordis Endovascular Corp., Miami, FL) was used to attempt to straighten the IVCF hook, unsuccessfully. Next, the guidewire was advanced into the right renal vein and over this, the 3-prong snare was advanced well into that vessel. After several attempts, and once again adding gentle tugs to the first snare, the hook was finally caught and collapsed under the 7-French sheath. Vena cavagram revealed a widely patent cava with no obvious problems.

Discussion

IVC interruption for PE prevention has been practice since the late 19th century. The first percutaneous IVCF insertion for caval interruption was performed almost a century later. IVCFs are thought to be an effective method to prevent PE [11]. However, there are limited solid data on the precise indications for IVCF placement. Most of the available data are from case series or retrospective case reports. As an example, there is only one randomized, controlled trial in the matter, the Prevention du Risque d'Embolie Pulmonaire par Interruption Cave (PREPIC) study [4].

The use of IVCFs is generally accepted indicated for patients in who anticoagulation is not feasible or when anticoagulation has produced a complication; or in patients with recurrent VTE, despite adequate anticoagulation. No strong recommendations have been made in the literature for many of the other indications that are widely practiced [12]. To adhere to strict indications in our opinion is imperative since IVCFs are not exempt of complications, which at times could be catastrophic. IVCF migration, caval perforation or thrombosis, insertion site thrombosis and post-thrombotic syndrome have all been reported.

Several long-term risks have been recognized with permanent IVCFs. A landmark study by Decousus et al. [13]. 13 of 400 patients with proximal DVT treated with heparin randomized to filter insertion or no filter groups, showed that after 12 days there was a statistical significant protection against PE in the filter group. However, 2 years after, this benefit was not maintained. Furthermore, there was a statistically significant increase in DVT in the filter group. This study provided the impulse for the development of retrievable IVCFs for the short-term prevention of PE and the likelihood of reducing long-term complications on condition that the filter is removed. In this manner, delayed complications, such as IVC thrombosis and DVT associated with permanent IVCFs may be reduced [1].

Because of the ease with which retrievable IVCFs can be placed and retrieved, the number of retrievable IVCFs inserted annually is on the rise. A rapid evolution in technology has produced smaller devices and flexible delivery systems, allowing delivery from multiple venous access sites under fluoroscopic guidance, and in different hospital settings, such as the operating room, cardiac catheterization laboratory or even at bedside under ultrasound-guidance. These changes appear to have loosened the indications for IVCFs placement. Unfortunately, the literature demonstrates that the majority of retrievable IVCFs are not removed and identifies loss to follow-up, presence of large thrombi in the filter, and filter tilting and embedment as common reasons for poor filter retrieval [3-12].

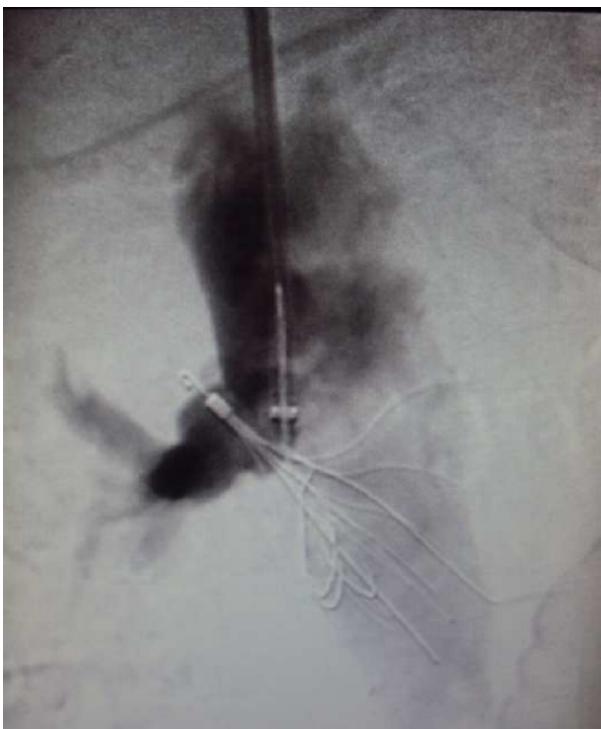


Figure 3 Fluoroscopic image showing severe filter tilting and projection of the filter hook into the right renal vein, making retrieval of this device highly challenging.

The design of the Celec™ IVCF is a modification of the Günther Tulip™ IVCF (Cook Medical, Bloomington, IN) for improved retrieval rates and longer dwell times. The theory was that the arrangement of the secondary wires in the Celec™ IVCF would allow effortless retrieval, regardless of whether the struts were incorporated into the wall of the IVC [14].

Furthermore, the instructions for the Celec™ IVCF set states that the retrieval of this device is “optional”. A recent study by Durack and colleagues, demonstrated that the IVC perforation rate was 93% in their group of patients that had a Celec™ IVCF placed, which is significantly higher than reported in other studies of this filter type [10,15]. These authors advocated filter retrieval as early as clinically indicated. Ultimately it is unknown which of the filters that have perforated the IVC will become symptomatic since there is a lack of long term studies of complications related to retrievable IVCFs. Likewise, a review by Rutherford suggests that temporary IVCFs cannot be left in for more than 2-6 weeks without encountering increasing problems that can ultimately compromise retrievability, and the author indicates that the instructions of many of the retrievable devices advise removal in 14 to 21 days [1]. In contrast, a review by Tschoe et al. [2] state that there is no set time limit for retrieving filters, and they reference success rates with dwell times as long as 357 days, which happened to be a Celec™ IVCF.

Our first case was that of 1 a young female with recurrent VTE that was managed with anticoagulation. However she developed hematemesis and consequently, anticoagulation was stopped and an IVCF was placed until anticoagulation could be recommenced. It is unknown whether the patient was lost to follow-up, because her anticoagulation therapy was restarted and her IVCF was not removed. Clinically symptomatic IVC perforation is rare. However, there are case reports in the literature with devastating consequences [16-20]. Additionally, the reports are mixed without clearly defined strategies regarding the diagnosis and management of IVC perforation.

Several studies concluded that caval penetration should be considered in a patient with abdominal symptoms after recent filter insertion [19] and that urgent diagnosis and surgical management may lead to the best outcome, preventing untoward consequences [18]. In contrast, 11 another case report suggests that IVCF related-hemorrhage is not an absolute indication for surgery, and emphasis should be placed on non-operative watchful waiting [16].

In consequence, management of IVC perforation remains a subject of continued controversy due to the lack of scientific evidence. Our patient was a young female that presented almost two years after IVCF placement with significant abdominal pain and gastrointestinal bleeding. The filter struts were penetrating adjacent structures. The extent of strut penetration was such that we were concerned that any attempt at endovascular IVCF retrieval would be of prohibitive risk. We felt that this filter had to be surgically removed to avoid a potential bleeding catastrophe. We believe that abdominal symptoms in the face of a history of IVCF placement necessitates expedited evaluation and diagnosis to further guide the management, whether it is operative or non-operative, to obtain best outcomes.

The latter two cases referred to challenges faced when the Celec™ IVCF is tilted. Removal of Celec™ IVCFs requires the capture of the filter hook located at its apex. This procedure is often straightforward and can be done with a high degree of success. However, not all retrievals are straightforward. Factors that increase the difficulty in removing any optional filter include IVCF tilting, increased dwell time, and thrombus caught in the filter. So far, maximum safe dwell times for retrievable devices have not been defined. In addition, the instructions for the Celec™ IVCF state that this filter has “self-centering properties, offering efficient clot-trapping and easier retrieval”.

Shelgikar et al. [21] compared the use of Celec™ with the standard Günther Tulip IVCF to determine if adoption of the former filter reduced tilting and delivered a discernible clinical benefit. They concluded that tilt angle at insertion did not differ between the IVCFs, although more Celec™ filters displayed self-centering. There was no difference between the groups in retrieval failure due to excess tilting. Despite its greater tendency to self-center, no measurable clinical advantages were noted. When an IVCF is severely tilted, the apex becomes in contact with the caval wall and an endothelial cap covers its surface, representing a major technical challenge for removal [22].

Lyon et al. [23] evaluated 95 cases in which Celec™ IVCFs were placed. They studied the retrievability of this filter over time and assessed the safety of the retrieval procedure in a prospective multicenter registry. Filter retrieval was attempted in 58 patients (mean indwell time of 179 days) with a successful retrieval rate of 96.6%. The unsuccessful retrieval attempts were attributed to filter tilt (n = 1) or excessive tissue growth with the hook embedded in the endothelium (n = 1).

Several techniques to deal with this problem have been reported, for instance the use of rigid endobronchial forceps or standard angioplasty balloons to free the apex from the caval wall [23,24] the use of a combined jugular-femoral vein access [25], using angulated catheters to advance wires toward the side of tilted filters, so that removal systems could be passed over-the-wire allowing hook engagement [26], using tip deflecting wires through the central lumen of a filter and then advancing the wire through the struts [27] By pulling back, traction is created, thereby straightening out the filter. Similar that the latter technique, the IVCFs in our two percutaneous retrieval cases were successfully removed largely due to the “misfortune” of accidentally engaging the first snare with the IVCF struts. This ultimately allowed us to apply a traction force on the IVCF, thus moving the hook away from the caval wall. It is conceivable that this “technique” could be used on purpose when dealing with tilted filters.

Further studies would be needed to assess the level of retrievability success and safety with this technique. After failure of standard methods, some authors have recently suggested the use of controlled photothermal ablation of filter-adherent tissue with a Spectranetics (The Spectranetics Corporation, Colorado Springs, CO), laser sheath and a CVX-300 laser system. This has been used in retrieving both permanent and retrievable IVCFs. This method allows circumferential ablation of dense fibrotic tissue between the filter and IVC, allowing separation without tearing [28].

Conclusion

IVC perforation could be a potential complication from using temporary IVCs permanently, which could lead to disastrous outcomes. We believe that abdominal symptoms in patients who have received IVCs necessitate a high level of suspicion and expedited evaluation and diagnosis. Further studies are necessary to investigate the efficacy and outcomes of retrievable IVCs, so as to establish adequate guidelines for their placement and for the management of complications related to these devices.

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Consent Statement

Informed consent has been obtained from the patients (or patients' guardian) for publication of the case report and accompanying images.

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