# Long-term complications of inferior vena cava filters



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## ABSTRACT

Anticoagulation is the cornerstone for the treatment of deep venous thrombosis and pulmonary embolism. On occasion, this is not possible because of bleeding complications or, rarely, breakthrough pulmonary embolism associated with this treatment method. The development of vena cava interruption in the 1970s was a critical advance in the treatment of these patients. Placement of inferior vena cava (IVC) filters has been steadily increasing since their introduction. Nonetheless, the incidence of complications associated with placement of these devices is largely unknown. Most of the evidence regarding IVC filter complications relies on case reports, with scarce data coming from larger randomized controlled trials. We aimed to present a summary addressing long-term complications of IVC filters as published in recent articles addressing problems such as IVC thrombosis and IVC filter migration, perforation, fracture, embolization, and tilting. We performed a PubMed search and Google Scholar search using different combinations of "long term," "complications," "IVC filter," and "vena cava filter." We reviewed the available English publications and reported the findings in this summary. (J Vasc Surg: Venous and Lym Dis 2019;7:139-44.)


**Keywords:** Inferior vena cava; Filter; Complications

Venous thromboembolic disease is estimated to occur in as many as 1 or 2 patients per 1000 in the United States, with about 60,000 to 100,000 deaths annually attributed to deep venous thrombosis or pulmonary embolism (PE).[1,2] In hospitalized patients, PE is the third most common cause of death.[3] Since the development of retrievable inferior vena cava (IVC) filters, the use of IVC filters has grown rapidly. From 1985 to 2006, the National Hospital Discharge Survey indicated that there were 803,000 filters placed, of which 158,000 (19.6%) were placed in the absence of venous thromboembolism.[4] By 2012, an annual 259,000 filters were estimated to have been placed. As much as 25% of these filters were placed despite absence of lower extremity deep venous thromboses. Even though most filters placed are retrievable, the retrieval attempt rate in most studies is on average only 20% to 30%.[5,6] IVC filter placement aims to decrease the rate of fatal PE. Nonetheless, the placement of an IVC filter does not come without risks of potential complications. Hence, it is the firm belief of the authors as well as of many in the vascular interventionalist community that better effort falls on our shoulders once the immediate risk of PE has relapsed and the indication of IVC filter placement is no longer present.

The Food and Drug Administration (FDA) developed the Manufacturer and User Facility Device Experience (MAUDE) database to allow general device reporting, which includes reporting on IVC filters' complications. MAUDE has its shortcomings, but it is mandatory for facilities and device manufacturers. Manufacturers are required to have an established Medical Device Reporting to be certified by the FDA. On the other hand, the penalties for providers are weak and poorly enforced. In 2014, Andreoli et al[7] analyzed data from the MAUDE database and reported that the majority of IVC filter complications were associated with retrievable IVC filters (86.8%) compared with permanent IVC filters (13.2%). In that same report, the authors pointed out that whereas all filters are FDA approved, they are associated with various complications. The most common complications associated with these retrievable IVC filters are placement issues (45.1%), IVC penetration (29.9%), and IVC filter fracture (27.1%; Table I).

## IVC FILTER MIGRATION OR EMBOLIZATION

IVC filter migration is defined as movement of the filter's position from its deployment site by >2 cm in either the caudal or cephalad direction. IVC filter embolization refers to the movement of the filter or any of its parts to a distant anatomic location. The presence of a megacava with IVC diameter >28 mm is a well-known cause of migration and embolization of IVC filters. The instructions for use for each filter specify the maximum diameter of the IVC that is suitable for the filter's use to reduce the risk of this complication.

The use of nitinol has allowed the creation of more compact IVC filters deliverable through smaller French delivery systems. There is also reduction in the amount of positive fixation in the design of retrievable filters. These factors permit the option of retrieval as they are more easily compressed into a retrieval catheter and removed. As an undesirable consequence of this, however, these filters have less radial force and less ingrowth to the vena cava wall, thereby leading to their tendency to migrate or even to embolize to remote locations.

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**Table I.** Complications reported with permanent and potentially retrievable devices

| | Total, No. | pIVCFs, No. (% total) | rIVCFs, No. (% total) | *P* value |
|---|---|---|---|---|
| All complications | 1606 | 212 (13.2) | 1394 (86.8) | <.0001 |
| Fracture | 350 | 16 (4.6) | 334 (95.4) | <.0001 |
| Migration | 215 | 46 (21.4) | 169 (78.6) | <.0001 |
| Limb embolization | 154 | 4 (2.6) | 150 (97.4) | <.0001 |
| Tilt | 197 | 3 (1.5) | 194 (98.5) | <.0001 |
| IVC penetration | 228 | 14 (6.1) | 214 (93.9) | <.0001 |
| VTE/PE | 30 | 8 (26.7) | 22 (73.3) | <.007 |
| IVC thrombus | 41 | 8 (19.5) | 33 (80.5) | <.001 |
| Placement issue | 318 | 99 (31.1) | 219 (68.9) | <.0001 |
| Other | 73 | 14 (19.2) | 59 (80.8) | <.0001 |

*IVC*, Inferior vena cava; *PE*, pulmonary embolism; *pIVCF*, permanent IVC filter; *rIVCF*, retrievable IVC filter; *VTE*, venous thromboembolism.
From Andreoli JM, Lewandowski RJ, Vogelzang RL, Ryu RK. Comparison of complication rates associated with permanent and retrievable inferior vena cava filters: a review of the MAUDE database. Vasc Interv Radiol 2014;25:1181-5. Reprinted with permission of Elsevier.

In 2010, Nicholson et al[8] reported their findings in a retrospective review of the Bard IVC filters (first and second generations; Bard Peripheral Vascular, Tempe, Ariz). The authors reported a 16% incidence of strut fracture. Strut embolization occurred in 25% (7 of 28 patients) of the first-generation filters that had strut fracture; 71% of the embolized struts lodged in the heart, with three patients having severe symptoms and one patient suffering sudden death.

In fact, from 2005 to 2010, the FDA received reports of adverse events related to IVC filters on 921 occasions. Most commonly reported was device migration (328/921), followed by fractured parts embolization (146/921) and IVC perforation (70/921).[9]

Reports to the FDA concerning IVC filter migration using the MAUDE database involve retrievable filters more than three times as often as the permanent ones. In comparison to other retrievable filters, migration seems to have been reported more often with the OptEase filter (Cordis, Bridgewater, NJ) than with others[7] (Table II).

Laborda et al[10] and Chalhoub et al[11] reported on the dynamic nature of the IVC and how it can be a risk for IVC filter migration. Changes in the anatomy and hemodynamics of the IVC during ventilation and Valsalva maneuvers as well as during prone positioning and cardiopulmonary resuscitation have been reported as factors contributing to filter migration.

## IVC THROMBOTIC OCCLUSION

All filters have been implicated in IVC thrombosis. The highest rate of IVC thrombosis has been associated with the TrapEase (Cordis) and OptEase IVC filters.[12] In their prospective randomized study comparing Greenfield filters (Boston Scientific, Natick, Mass) with TrapEase filters, Usoh et al[12] found that during a mean 12-month follow-up, symptomatic IVC thrombosis developed in five patients (6.94%) in the TrapEase group and none in the Greenfield group ($P = .019$). These findings were noted as asymptomatic complications, as opposed to the seven IVC thromboses and 23 recurrent lower limb thromboses that were considered symptomatic complications.

IVC filter thrombosis has been reported to occur at a higher rate in retrievable IVC filters compared with permanent ones.[13] Although it is not as common a complication as migration, IVC filter thrombosis has been reported to occur more frequently with the Cordis OptEase filter. The Cook Celect filter (Cook Medical, Bloomington, Ind) and all of the Bard retrievable filters have been described to have associated thrombosis reported by users to the FDA.

Despite reports suggesting lower risk of complications with permanent vs retrievable filters, it is the opinion of the authors of this paper that a recommendation for placement of permanent filters in all patients is not the solution. Rather, the retrievable IVC filter must be used with the intent for which it is designed—as a temporary filter. It is imperative that the vascular interventionalist make every possible effort to retrieve the IVC filter once its indication is no longer the case. In cases in which retrieval is not an option, a consideration for permanent IVC filter placement should be assessed and discussed by the clinician with the patient.

## FILTER TILT

Filter tilt is usually defined as tilting of the IVC filter axis compared with the IVC axis by >15 degrees. The consequence of the filter's tilting is failure of protection from significant PE and difficulty in IVC filter retrieval.[14] In these cases, it is not uncommon for the filter retrieval hook to become embedded in the wall of the IVC, with tissue growth over it that would complicate its retrieval.

Studies have shown that IVC filters inserted through the left or right common femoral vein have a higher tendency to tilt as opposed to filters inserted from the right

**Table II.** Frequency of complications reported with potentially retrievable devices

| | Bard retrievable[a] | Cook Celect | OptEase | Gunther Tulip | Option | ALN |
|---|---|---|---|---|---|---|
| All complications | 1063 | 157 | 107 | 51 | 11 | 5 |
| Fracture | 288 (27.1) | 31 (19.7) | 9 (8.4) | 3 (5.9) | 2 (18.2) | 1 (20) |
| Migration | 120 (11.3) | 15 (9.6) | 26 (24.3) | 7 (13.7) | 0 (0) | 1 (20) |
| Limb embolization | 131 (12.3) | 16 (10.2) | 2 (1.9) | 0 (0) | 0 (0) | 1 (20) |
| Tilt | 165 (15.5) | 19 (12.1) | 6 (5.6) | 3 (5.9) | 1 (9.1) | 0 (0) |
| IVC penetration | 161 (15.1) | 47 (29.9) | 2 (1.9) | 3 (5.9) | 1 (9.1) | 0 (0) |
| VTE/PE | 15 (1.4) | 3 (1.9) | 1 (0.9) | 0 (0) | 2 (18.2) | 1 (20) |
| IVC thrombus | 21 (1.9) | 5 (3.2) | 7 (6.5) | 0 (0) | 0 (0) | 0 (0) |
| Placement issues | 144 (13.5) | 15 (9.6) | 33 (30.8) | 23 (45.1) | 3 (27.3) | 1 (20) |
| Other | 18 (1.7) | 6 (3.8) | 21 (19.6) | 12 (23.5) | 2 (18.2) | 0 (0) |

*IVC*, Inferior vena cava; *PE*, pulmonary embolism; *VTE*, venous thromboembolism.
Values are reported as number (%).
[a]Recovery, G2, G2X, G2 Express, Eclipse, and Meridian.
From Andreoli JM, Lewandowski RJ, Vogelzang RL, Ryu RK. Comparison of complication rates associated with permanent and retrievable inferior vena cava filters: a review of the MAUDE database. Vasc Interv Radiol 2014;25:1181-5. Reprinted with permission of Elsevier.

jugular approach.[15] Semaan et al[15] found that the degree of filter tilt at the time of retrieval proved statistically significant in determining success of removal. Other studies, however, have shown that filter tilting is associated with an increased need of using advanced techniques for IVC filter removal with improved retrieval success and an association with a higher risk of complications.[16,17]

Filter tilting has been reported to occur in nearly all retrievable IVC filters. This is a notable difference between permanent and retrievable filters (Table I). By comparison, filter tilting is similar between the Bard retrievable filters, Cook Celect, and Option (Argon Medical, Frisco, Tex), ranging from 9% to 15%. Reports from the MAUDE database[7] (Table II) seem to indicate that the OptEase and Gunther Tulip (Cook) tilt less, with no tilting reported for the ALN filter (ALN International, Inc, Miami, Fla).

## FILTER PERFORATION

Penetration of the vena cava intima and media is required for associated hooks to embed in the adventitia of the IVC wall. Movement of the IVC hooks or struts beyond this level is referred to as perforation. Perforation can be defined as a filter strut or anchor extending >3 mm outside the wall of the IVC. Some reports suggest that this perforation is more common than has previously been estimated. Nonetheless, most of these perforations are asymptomatic. Jia et al[18] reported that only 1 of 10 patients with filter penetration would present with symptoms. Their retrospective analysis identified penetration in 19% of patients (1699/9002); only 19% of these patients (332/1699) showed evidence of organ or structure involvement. In the population identified with filter penetration, only 8% were symptomatic. The most commonly reported symptom was pain (77%). Major complications were reported in 83 patients (5%).

Literature research showed reports of IVC filter perforation leading to symptomatic secondary pancreatitis, aortic pseudoaneurysm, symptomatic duodenal perforation, ureteral injury, retroperitoneal hematoma, and chronic pain syndrome. Perforation is more likely to occur in IVC filters made without hooks on the ends of all of their limbs. It has also been reported to occur in filter limbs used to center other filters and not anchor it to the IVC filter wall.

McLoney et al[19] reported a retrospective review of a single-institution experience of 470 filters. Review of computed tomography scans after filter placement was performed, with a mean follow-up of 10 months. Their study demonstrated that IVC perforation was observed in 126 of 255 patients with Celect filters (49%) with a mean follow-up of 277 days, 69 of 160 Tulip filters (43%) with a mean follow-up of 437 days, and one of 50 Greenfield filters (2%) with a mean follow-up of 286 days. They observed that women had a significantly higher IVC perforation rate (45.5%) compared with men (30.8%; $P = .002$). Patients with a history of malignant disease (43.7%) also had a higher perforation rate compared with patients with no history of malignant disease (29.9%; $P < .001$). Filter fracture was rare. It was observed in 2 of 255 Celect filters (0.8%), 1 of 160 Tulip filters (0.6%), and no Greenfield filters.

One of the contributing factors to IVC filter complications that is often overlooked is the dynamic nature of the vena cava. Laborda et al[10] demonstrated in their retrospective review that caval morphologic features as well as its hemodynamics were affected by respiratory changes and Valsalva maneuvers, leading to reduction of IVC cross-sectional area in association with higher risk of filter penetration.

Whereas complications related to the use of IVC filters are generally low, they continue to be reported at an

increasing rate.[20-22] Wood et al[23] analyzed the MAUDE database to look for an increase in complications associated with removable IVC filters over time. They reviewed the MAUDE database from January 2000 to June 2011 and reported on their findings of adverse events. These included occurrence of IVC perforation, type of filter, clinical presentation, and management of the perforation, including retrievability rates; 391 cases of IVC perforation were reported. The annual distribution of IVC perforation was 35 cases (9%), varying from 7 (2%) to 70 (18%). They noted a threefold increment in the number of adverse events related to IVC filters since 2004. Asymptomatic IVC wall perforation, as an incidental finding, was the most common presentation (n = 268 [69%]). The aorta was the most common structure in perforation involving surrounding organs, followed by small bowel. Twenty-five (25%) cases required an open procedure to remove the filter. No major bleeding requiring intervention or mortality was reported. The majority of filters involved in a perforation were retrievable.[24]

## FILTER FRACTURE

Filter fracture is defined as loss of structural integrity of the filter by a break or separation. The incidence of this complication has greatly increased with the newer generations of IVC filters. Since the advent of nitinol to make filters deliverable through smaller delivery systems, filters may not be as durable, especially when they are subjected to numerous cardiac cycles. Newer generations of nitinol filters have been developed through more robust metalloids. A review of the MAUDE database supports this in that 95% of all filter fractures reported have occurred in retrievable IVC filters. Of the potentially retrievable IVC filters reported, the highest rate of filter fractures has occurred in the Bard group (namely, Recovery, G2, G2X, G2Express, Eclipse, and Meridian IVC filters [27%]).[7]

In August 2010, the FDA published a warning concerning 146 cases of filter migration and 56 filter fractures. These events occurred among a variety of filter designs, including the Bard G2. The FDA communication expressed concern that these mechanical failures may be associated with the long-term placement of retrievable filters. The FDA concluded the communication with a recommendation that "implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed."[9] In 2013, Morales et al[25] published a decision analysis to weigh the risks and benefits of retrievable IVC filter use as a function of the filter's time in situ. In this study, they reviewed the medical literature on patients with IVC filters and a transient risk of PE. They assigned weights reflecting relative severity to each adverse event and then defined risk scores as weight × occurrence rate; they then combined the frequency and severity for each type of adverse event. In this analysis, the authors found that the net risk score reached its minimum between days 29 and 54 after implantation. This is consistent with an increasing net risk associated with continued use of retrievable IVC filters in patients with transient, reversible risk of PE. The investigators concluded that for patients with retrievable IVC filters in whom the transient risk of PE has passed, quantitative decision analysis suggests that the benefit-risk profile begins to favor filter removal between 29 and 54 days after implantation. The FDA continues to monitor the safety of these implantable devices. Most recently, the FDA sent a warning letter to manufacturers regarding deficiencies in manufacturing quality control.[26]

In their report on long-term complications of IVC filters, Wang et al[24] looked at IVC filters in place for at least 4 years. They found rate of fracture to be 14%, with perforation rates higher in retrievable filters (70%) compared with permanent filters (15%).

## FILTER RETRIEVAL

Theoretically, retrievable IVC filters provide the clinician and the patient with the advantage of caval filtration in the short term along with the ability to retrieve the filter once the indication has subsided to avoid long-term complications. The risk vs benefit profile tips in favor of device retrieval between 29 and 54 days after placement once the increased risk of PE subsides.

Nonetheless, as stated previously, most IVC filters are often not removed. The primary hurdle to retrieval of these devices is lack of follow-up of the patients. In 2007, Karmy-Jones et al[27] reported their findings of 446 patients (69% male, 92% blunt trauma) receiving retrievable IVC filters. Only 22% of retrievable IVC filters were retrieved. Loss to follow-up was the most common reason of nonretrieval, which was even higher when the specialist placing the IVC filter was not directly responsible for follow-up of the patient. In their retrospective report of 952 patients at a level I trauma center, Sarosiek et al[6] reported that the retrieval rate was 8.5% only. Many of the filters placed for trauma were actually placed after bleeding risk had subsided. In these cases, anticoagulation may have been appropriate. Many of the IVC filters were inserted for a perceived notion of anticoagulation contraindication despite that almost 25% of these patients were discharged on anticoagulation therapy.

Tan et al[28] reported 11 of 41 (26%) retrieval attempts with 8 successful retrievals. In their prospective study analysis of 220 patients, Mismetti et al[5] reported a 25% retrieval attempt rate. These reports represent real clinical practice data. Most reports indicate a retrieval attempt rate somewhere between 10% and 25%.

Multiple studies have reported an improved retrieval rate of IVC filters with the use of a dedicated IVC filter program at institutions. Kalina et al[29] reported an

improved retrieval rate from 15.5% to 31.5% with the use of a "filter registry." Another approach reported by Sutphin et al[30] to improve optional IVC filter retrieval rates was based on the Define, Measure, Analyze, Improve, Control (DMAIC) methodology of the Six Sigma process improvement paradigm. The program resulted in improving retrieval rate from 8% to 40%.

In their review of standard and advanced techniques of IVC filter retrieval, Kuyumcu and Walker[31] provided an extensive summary of different methods available to all of us in the vascular community to attempt filter retrieval. This includes the standard wire loop and snare, balloon displacement technique using a single-access approach. They also expanded on more novel and advanced techniques using a dual access approach, endobronchial forceps dissection, and laser thermal dissection. They concluded that with standard retrieval techniques, as many as 40% to 60% of retrievable-type filters cannot be removed because they either have become firmly attached to the cava or are tilted or malpositioned. Use of these advanced and more aggressive techniques would improve the retrieval rate, but they also carry an increased risk of complications.

In an Editor's Note, Redberg[32] presented the argument that IVC filter use has continued to rise after a U.S. FDA safety warning. The argument relies on the lack of evidence of the benefits of the IVC filters. The letter concluded with a call for a moratorium on IVC filter use until research shows that the benefit outweighs the risk of placing such filters. The authors' opinion remains that IVC filters have their role but should be used judiciously with the intent to remove the filter once the indication does not apply any more. Furthermore, in their evaluation of trends in IVC filter placement by indication in the United States, Saeed et al[33] reported that the rate of IVC filters had increased from 2005 to 2010 and has decreased steadily since 2010 to 2014. They also reported that the use of the IVC filter as a prophylactic tool had decreased from 28.9% of all IVC filters placed in 2005 to 22.6% in 2014.

A joint study of the Society for Vascular Surgery, the Society of Interventional Radiology, and the FDA has been developed. Predicting the Safety and Effectiveness of Inferior Vena Cava Filters (PRESEVE) is a physician-initiated investigational device exemption trial to better understand the current use of IVC filters and the adverse events associated with their use.[34] The PRESERVE study is a multicenter, prospective, open-label, nonrandomized investigation of commercially available IVC filters from seven manufacturers placed in patients for the prevention of PE. The primary objective of this clinical investigation is to evaluate the safety and effectiveness of the commercially available IVC filters (retrievable and permanent) in patients with a clinical need for mechanical prophylaxis of PE with an IVC filter.

## CONCLUSIONS

IVC filters are a valuable treatment in the effort to reduce the risk of PE and its associated mortality risk.[3,6,24,28] Reiterative process improvement has led to the evolution of these devices and an increase in their safety and efficacy. Nonetheless, they are not without risks, which extend beyond the procedural risk of filter placement. The "out of sight, out of mind" approach to IVC filter placement that is a trend in our practices needs to be revised and replaced with a more diligent approach to reducing IVC filter insertion in favor of anticoagulation and an increase in IVC filter retrieval attempts. Also, a closer look must be given to our current practices of filter placement when the anticoagulation contraindication period is much shorter than previously thought and practiced. This might allow us to place fewer unnecessary filters. This would ensure achieving the filter's maximum potential of helping patients who need it and avoid the possibility of long-term complications.

## AUTHOR CONTRIBUTIONS

Conception and design: DG
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Data collection: DG
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