# The Role of Optional Filters

Are the perceived benefits and disadvantages real?

BY CHRISTOPH A. BINKERT, MD

The first permanent, percutaneous inferior vena cava (IVC) filters were introduced in 1973.[1] Since then, IVC filters have been widely used to prevent pulmonary embolism (PE). Despite the long history of IVC filters, there is only one randomized trial that has been published.[2] The study randomized 400 patients with deep vein thrombosis (DVT) to either filter and anticoagulation or anticoagulation alone. After 12 days, there were significantly more PEs in the group without a filter (Table 1); however, after 2 years, there were significantly more DVTs in the group with filters (Table 2). These findings promoted the idea of retrievable or optional filters that protect the patients in the acute phase, but can also be retrieved to avoid increased DVT long-term. The term *optional filter* is preferable over *retrievable filter* because it indicates that these filters are permanent filters with the option to be retrieved. Last year, the PREPIC study group published 8-year follow-up data of the Decousus study.[3] Because these two publications are the only randomized data available, it is worthwhile to take a closer look at them.

During enrollment, patients with contraindication to anticoagulation were excluded from the study. This exclusion criterion changes the study patient population compared to the patient population in the US who are treated with an IVC filter because contraindication to anticoagulation in the presence of DVT and/or PE is one of the absolute indications for filter placement, according to the latest guidelines.[4] The danger of anticoagulation is also evident in the Decousus study, with 3.75% (15 of 400) major bleeding, including two deaths at 12 days (Table 1) and 39 major bleedings within 2 years (Table 2). It can be argued that these bleeding complications could have been avoided or at least reduced without anticoagulation. In addition, six of 10 deaths at 12 days could potentially have been avoided by using standard indication for IVC filter placement and avoiding anticoagulation: two lethal bleedings during anticoagulation and four PEs in the group without a filter.

The PREPIC study group concluded that "At 8 years, vena cava filters reduced the risk of pulmonary embolism but increased that of deep-vein thrombosis."[3] The reduced risk of PEs with a filter in place is substantiated by three new symptomatic PE in the filter group compared to 12 in the no-filter group between 2-year and 8-year follow-up (Table 3). This finding of protection against PE in the filter group is even more interesting knowing that both patient groups were anticoagulated. On the other hand, there was no difference in new symptomatic recurrent DVT between the filter group (20 new DVTs) and the no-filter group (20 new DVTs) during 2 to 8 years of follow-up. Another interesting finding is that during the 8-year follow-up, 28 (26 of 200 [13%] in the filter group and two of 19 [11%] patients receiving a filter after initial randomization to the no-filter group) IVC thromboses were observed despite anticoagulation. Possible causes of IVC thrombosis will be discussed subsequently.

> "The real question should not be why to use optional filters, but much rather why not to use optional filters."

## AVAILABILITY

At present, there are two optional IVC filters that are FDA approved for placement and retrieval: the Günther Tulip (Cook Incorporated, Bloomington, IN) and the Optease (Cordis, a Johnson & Johnson company, Miami, FL). The third previously approved optional filter (the Recovery, Bard Peripheral Vascular, Tempe, AZ) has undergone design modifications. The modified Recovery G2 is only approved for permanent use in the US at this time, but will likely receive retrieval indication in the near future, once the clinical study for retrieval (EVEREST) is finished.

**TABLE 1. PRINCIPAL ENDPOINTS WITHIN THE FIRST 12 DAYS AFTER RANDOMIZATION TO THE FILTER OR NO-FILTER GROUP***

| Endpoint | Filter No. (%) | No Filter No. (%) | Odds Ratio (95% CI) | *P* Value |
|---|---|---|---|---|
| PE | | | | |
| Symptomatic | 2 | 5 | | |
| Asymptomatic | 0 | 4 | | |
| All | 2 (1.1) | 9 (4.8) | .22 (.05-.90) | .03 |
| Major bleeding | 9 (4.5) | 6 (3) | 1.49 (.53-4.20) | .44 |
| Death | 5 (2.5) | 5 (2.5) | .99 | .99 |
| Cause of death | 2 bleeding | 4 PE | | |

*Modified and reprinted with permission from Decousus et al.[2]

**TABLE 2. PRINCIPAL ENDPOINTS DURING THE 2-YEAR FOLLOW-UP PERIOD IN THE FILTER AND NO-FILTER GROUP***

| Event and Time of Occurrence | Filter No. (%) | No Filter No. (%) | Odds Ratio (95% CI) | *P* Value |
|---|---|---|---|---|
| Symptomatic PE | | | | |
| Enrollment | | | | |
| • 3 m | 2 | 6 | | |
| • >3 m-1 y | 0 | 4 | | |
| • >1-2 y | 4 | 2 | | |
| • All | 6 (3.4) | 12 (6.3) | .50 (.19-1.33) | .16 |
| Recurrent DVT | | | | |
| Enrollment | | | | |
| • 3 m | 9 | 6 | | |
| • >3 m-1 y | 8 | 7 | | |
| • >1-2 y | 20 | 8 | | |
| • All | 37 (20.8) | 21 (11.6) | 1.87 (1.10-3.20) | .02 |
| Major bleeding | | | | |
| Enrollment | | | | |
| • 3 m | 11 | 10 | | |
| • >3 m-1 y | 5 | 8 | | |
| • >1-2 y | 1 | 4 | | |
| • All | 17 (8.8) | 22 (11.8) | .77 (.41-1.45) | .41 |
| Death | | | | |
| Enrollment | | | | |
| • 3 m | 15 | 10 | | |
| • >3 m-1 y | 12 | 12 | | |
| • >1-2 y | 16 | 18 | | |
| • All | 43 (21.6) | 40 (20.1) | 1.10 (.72-1.70) | .65 |

*Modified and reprinted with permission from Decousus et al.[2]

There are likely several more optional filters coming to the US market in the near future. Some follow the concept of a cone-shaped filter with a hook at the tip (Celect, Cook [Figure 1]; Option, Rex Medical, Conshohocken, PA), whereas others introduce a different design for IVC filtration. The SafeFlo (Rafael Medical Technologies, Boston, MA) consists of a two nitinol wires that form two rings and a five-loop nitinol spiral (Figure 2). Because the fixation is achieved without hooks, the filter is supposedly retrievable, even after long dwell times. The "convertible" filter (B. Braun, Sheffield, UK) looks similar to the Vena Tech LP (B. Braun) in a closed configuration (Figure 3). However, if filtration is no longer needed, the cap that holds the central struts together can be removed, and the filter can be transformed into an IVC stent.

## MARKET WATCH

When introduced in 2002, optional filters caused a peak in the annual growth rate of the US filter market

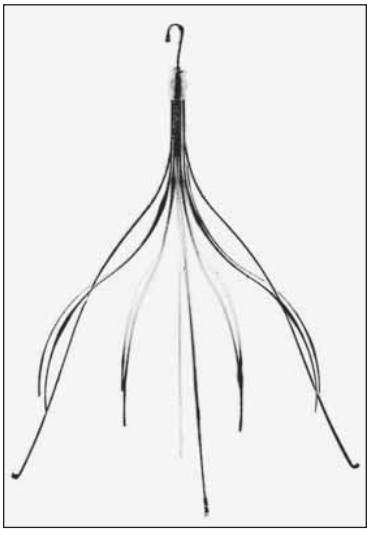

**Figure 1. The Celect filter is a modification of the existing Günther Tulip filter. The largest change is that there are no secondary struts around the legs, but there are independent arms centering the filter.**

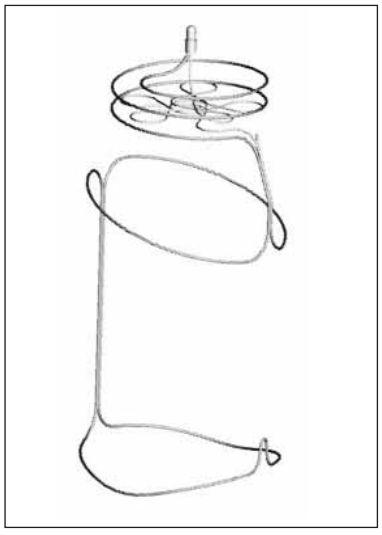

**Figure 2. The SafeFlo filter is a new design of an IVC filter. The fixation mechanism depends on two oversized nitinol rings. The rings hold a nitinol spiral in the center of the IVC for filtration.**

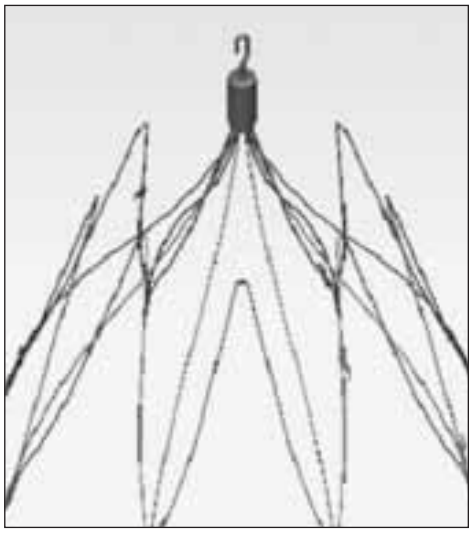

**Figure 3. The convertible filter appears similar to the standard Vena Tech filter. However, this filter can be converted into a stent by removing the central cap.**

(iData Research, 2006). According to the same source, the projected annual growth rate of the US filter market is slowing over the next 5 years. In addition, only a small increase of market share of optional filters, from 40% today to 55% in 2011, is expected.

This small projected increase in market share is unusual for a new medical device technology. What are the possible explanations? One cause could be the recently published guidelines for optional filters that did not identify new indications for optional filters.[4] Another reason is the relatively low percentage of retrievals of optional filters; for all approved optional filters reported, the percentage of attempted retrievals is between 58% and 78% (Günther Tulip, 53 attempts of 91 filters placed;[5] Recovery, 24 of 32 filters placed;[6] and Optease, 21 of 27 filters placed,[7] respectively). These early reports had at least more than half of the filters retrieved; a recent report describes retrieval attempts in a regular clinical setting to be as low as 13% (14 of 107) of implanted optional filters.[8]

## THE REAL QUESTION: WHY NOT OPTIONAL FILTERS?

We have learned that there are no new indications for optional filters,[4] that optional filters are only retrieved in a small percentage,[8] and that filters placed for between 2 and 8 years prevent PEs without additional DVTs.[3] Why bother to use optional filters? The real question should not be why to use optional filters, but much rather why not to use optional filters. It is important to remember that optional filters are permanent filters with the option to be retrieved, if indicated.

## PERCEIVED DISADVANTAGES

A common belief is that permanent IVC filters perform better as permanent filters than do optional filters.

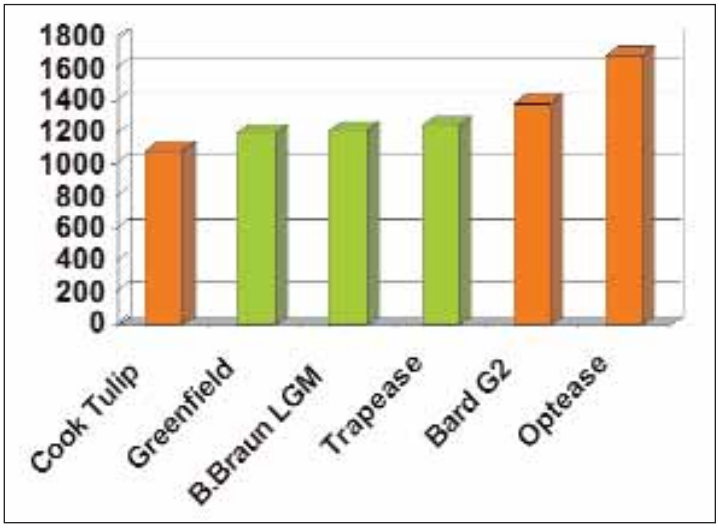


**Figure 4. List prices in US $ of commonly used IVC filters (January 2006).**

**TABLE 3. CUMULATIVE RATE OF THE CLINICAL OUTCOMES AT 8 YEARS***

| Characteristic | Filter (n=200) 8 y/[2 y] | No Filter (n=200) 8 y/[2 y] | Hazard Ratio (95% CI) | *P* Value |
|---|---|---|---|---|
| Symptomatic PE<br>Nonfatal<br>Fatal | 9 (6.2)†/[6]<br>7<br>2 | 24 (15.1)/[12]<br>19<br>5 | .37 (.17-.79) | .008 |
| Symptomatic recurrent DVT<br>DVT of the lower limb<br>Thrombosis of filter | 57 (35.7)/[37]<br>55<br>26 | 41 (27.5)/[21]<br>41<br>2‡ | 1.52 (1.02-2.27) | .042 |
| Symptomatic venous thromboembolism<br>PE only<br>DVT only<br>PE and DVT | 58 (36.4)<br>1<br>49<br>8 | 55 (35.4)<br>14<br>31<br>10 | 1.12 (.78-1.62) | .54 |
| Postthrombotic syndrome<br>Edema<br>Varicose veins<br>Trophic disorders<br>Ulcers | 109 (70.3)<br>92<br>48<br>32<br>5 | 107 (69.7)<br>80<br>52<br>39<br>15 | .87 (.66-1.13) | .30 |
| Death | 98 (48.1) | 103 (51) | .97 (.74-1.28) | .83 |
| Major bleeding | 26 (15.4) | 31 (18.5) | .84 (.50-1.42) | .52 |

* Data modified and reprinted with permission from PREPIC study.[3]
† Values are number of patients (cumulative rate in percent) or number of patients.
‡ Overall, 19 patients among 200 allocated to the no-filter group subsequently received a filter during the study period.

Therefore, "true" permanent filters would be preferred if permanent filtration is indicated. To my knowledge, there are no scientific data that support this assumption. Another point that is sometimes raised against optional filters for permanent filtration is the shorter track record. Although in general, optional filters are "newer" than some permanent filters, the following example illustrates that it is not true for commonly used filters. A commonly used permanent IVC filter in the US is the Trapease (Cordis), which was introduced in 2000 compared to the Günther Tulip, which was introduced in Europe in 1992 and in the US in 2000.

Another perceived disadvantage is that optional filters are more expensive than permanent filters. Looking at the list prices (January 2006) of six commonly used filters in the US (Figure 4), it is true that the listed optional filters have a tendency to be more expensive than permanent filters. This, however, seems to be related more to marketing and life cycle management of the product than to the type of filter itself. The least expensive listed filter is an optional filter (Günther Tulip).

## CLINICAL ASPECTS

According to the Society of Interventional Radiology guidelines, the best use of optional filters is in cases with a temporary contraindication for anticoagulation, such as trauma or perioperative situations.[4] Although filter placement in the presence of a DVT and/or PE is quite well accepted, there is no clear consensus about prophylactic filter placement. Only limited literature is available about prophylactic filter placement in patients at high risk for DVT/PE, such as trauma,[9] or in perioperative situations for spine[10,11] or bariatric surgery.[12] A frequent clinical problem is that duration and reversibility of the contraindication for anticoagulation is often difficult to assess at the time of filter placement. Therefore, to exclude anyone from the option to retrieve the filter, all patients with a possible reversible cause of filter indication should receive an optional filter.

The benefit of retrieval is likely highest in young patients with a long life expectancy to avoid small, but potentially substantial, risks of indwelling IVC filters. These risks include IVC obstruction (6% to 30%), filter migration (3% to 69%), IVC penetration (9% to 24%), filter fracture (1%), and guidewire entrapment (<1%).[13] Rare complications include penetration of adjacent organs, such as the aorta[14] and duodenum.[15]

Another clinical aspect that has not yet attracted much attention is the possible interaction between indwelling filters and the IVC wall. IVC occlusion with indwelling filters is a known complication. A large retrospective study described IVC occlusion in 3.2% of patients (55 of 1,731).[16] This retrospective study, however, did not investigate the IVC routinely, and therefore the true incidence is likely

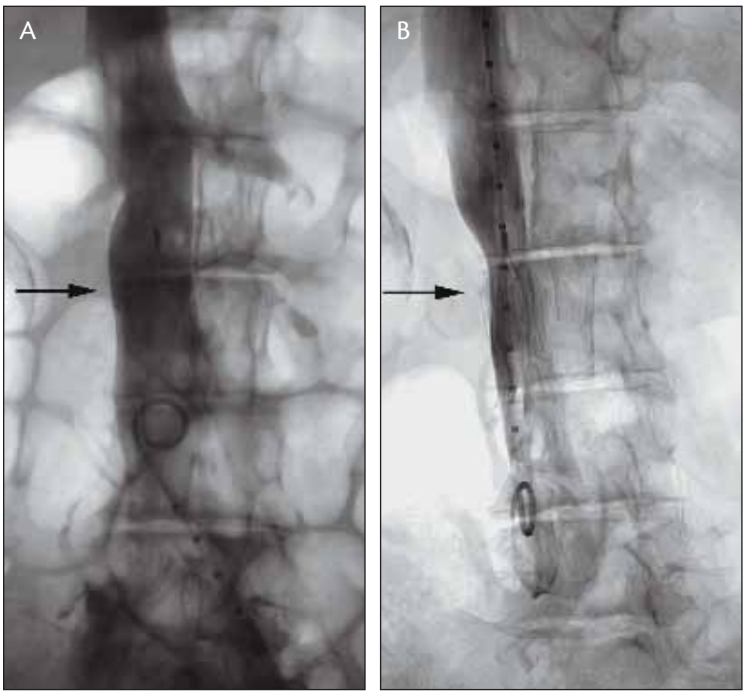


**Figure 5. IVC stenosis detected at time of retrieval. A 60-year-old woman had multiple pelvic fractures resulting from a motor vehicle accident (A). A Recovery G2 filter was placed prophylactically in a normal-appearing infrarenal IVC. At retrieval 135 days later, a 27% stenosis was seen at the level of the arms of the filter (arrow). While the arms are all displayed within the IVC in (A), there is mild stenosis of the IVC at the level of the arms (B).**

higher. The common belief is that IVC occlusion either occurs by trapped emboli or by thrombosis at the filter site.[3] The PREPIC 8-year follow-up study revealed IVC occlusion in 13% of patients (28 of 219).[3] These occlusions happened despite anticoagulation, which makes emboli or thrombosis rather unlikely. By reviewing our own experience of 66 retrievals, we found one IVC occlusion (1.5%) and four IVC stenoses (6%).[17] The patient with the IVC occlusion had moderate bilateral leg swelling, and all other patients were asymptomatic. IVC stenoses were found after relatively long dwell times (mean, 110 days; range, 21-262 days), which could explain why the phenomenon of stenosis at the filter site was not seen in most reports with shorter dwell times. The stenoses were typically seen at the level of the filter (Figure 5). Filter-induced IVC stenosis was previously described in an animal study using the Tempofilter (B. Braun).[18] The IVC narrowing seems to be reversible after the filter is removed.[19]

## CONCLUSION

Optional filters are permanent filters that can be retrieved, if indicated. Although there is no strong evidence yet about the advantages of optional filters, there is no scientific evidence of a disadvantage of optional filters compared to permanent filters. The question becomes: why should someone give up an option without any benefit? There is no good reason. Therefore, I believe that all IVC filters in the future will be optional filters. ■

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