Retrospective Review of 120 Celect Inferior Vena Cava Filter Retrievals: Experience at a Single Institution

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CLINICAL STUDY

Retrospective Review of 120 Celect Inferior Vena Cava Filter Retrievals: Experience at a Single Institution

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ABSTRACT

Purpose: To evaluate retrospectively the safety and retrievability of the Celect IVC filter.

Materials and Methods: All patients undergoing Celect filter placement and retrieval during the period 2007–2012 were assessed for complications and retrievability.

Results: Of 620 patients who underwent Celect filter placement, 120 presented for removal. The indwelling time in these patients was 158.1 days ± 103.0 (range, 2–518 d). There were 106 filters (88.3%) removed; 14 filters were left in situ for the following reasons: filter embedment (n = 6), caval occlusion (n = 3), retained thrombus (n = 2), large floating thrombus in IVC (n = 2), or tilt >15° (n = 1). With filters in place, five patients developed new pulmonary embolism (PE), and two others presented with severe abdominal pain. The available 115 pairs of placement and removal cavagrams suggested limb penetration in 99 cases (86.1%), intracaval migration >2 cm in 5, secondary tilt >15° in 8, filter deformity in 10, retained thrombus within filters in 12, and IVC occlusion in 3. Among 38 available computed tomography (CT) scans, 9 scans (24%) showed asymptomatic limb penetration to the duodenum (n = 6), aortic wall (n = 2), or kidney (n = 1). No filter fracture was found.

Conclusions: This study showed a high penetration rate for Celect IVC filters, including penetrations that were symptomatic or involved adjacent structures. Penetration appears to correlate with indwelling time, suggesting that the filter should be removed as soon as PE protection is no longer indicated. Although most of the filters were removed, 5.8% of retrievals were unsuccessful because of technical failure.

ABBREVIATIONS

DVT = deep vein thrombosis, IVC = inferior vena cava, PE = pulmonary embolism

Retrievable inferior vena cava (IVC) filters have been developed to provide temporary or permanent protection from pulmonary embolism (PE). When a patient's indication for protection changes, the retrievable IVC filter can be removed to reduce the risk of potential long-term complications that may result from a permanent IVC filter (1–3). Over the past decade, several retrievable filters have been introduced to the U.S. market (4–8). As the use of these devices has become more widespread, various problems have arisen, such as limb penetration resulting in adjacent organ injury, severe tilt causing filter retrieval failure, and most importantly, filter fracture and distant migration of fracture fragments (9–14). After receiving many reports related to retrievable IVC filters, the U.S. Food and Drug Administration issued a general warning on August 9, 2010, concerning filter fracture, filter migration, filter embolization, and IVC perforation, in addition to the long-term risks of lower limb deep vein thrombosis (DVT) (15).

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The Celect IVC filter (Cook, Bloomington, Indiana) is a modification of the Günther-Tulip filter (Cook), which was first introduced for permanent use in April 2007 and for optional use in March 2008 (16). We performed a retrospective study to investigate the safety profile and to assess retrievability of the Celect filter at a single tertiary institution.

MATERIALS AND METHODS

Study Design

This retrospective study, which included all patients who underwent both placement and retrieval of the Celect IVC filter between September 2007 and January 2012, was approved by our institutional review board. Patient demographics and clinical data, including information about PE breakthrough and symptoms or complications possibly related to the filter placement, were retrieved from electronic medical records and outpatient clinic visit charts. Mortality data were obtained from the Social Security Death Index and hospital electronic medical records. Relevant images were collected from our imaging archiving system, including inferior vena cavagrams obtained at filter placement and retrieval, abdominal computed tomography (CT), chest CT, and CT pulmonary angiography studies that imaged the filter. Filter migration, tilt, fracture, deformity, and penetration were recorded according to the definitions of Zhu et al (6) and the guidelines of the Society of Interventional Radiology (SIR) (1). The presence and size of retained thrombus at the filter were estimated according to the visual scales of volume method described by Wang et al (17), with estimates based on the cavagram or a coronal reformatted CT image. Fluoroscopic time for the filter retrieval procedure (in min) was recorded, and the indwelling time was calculated. Factors that could have affected the success of an attempted retrieval, including retrieval techniques, were analyzed.

Placement and Retrieval Techniques

Celect filters, which consist of four long struts (primary legs) and eight short struts or arms (secondary legs), were placed via the right common femoral or right internal jugular vein according to the manufacturer's recommendations. Retrieval was prompted by referral from the primary service. Routine retrieval with a Günther-Tulip Filter Retrieval Set (Cook) was performed using a method described previously (18). When routine attempts failed, one or more advanced retrieval techniques were used, including curved catheter technique (18), loop-and-snare technique (19), balloon-assisted technique (20), or forceps technique (21), based on operator preference.

Image Analysis

All images were reviewed by two interventional radiologists. The images were retrieved in digital JPEG format and placed into Photoshop CS2 (Adobe Systems, San Jose, California). The image pairs for placement and retrieval were resized to match exactly and were fused together with proper transparency (6). Distance was calibrated using sizing catheters or the known filter length of 48 mm (when expanded).

Statistics

SPSS 13.0 for Windows (IBM SPSS, New York, New York) was used for data management and analysis. A two-sample *t*-test was applied to compare indwelling time between successful and unsuccessful retrievals and fluoroscopic time between secondary filter tilt $\leq 10^\circ$ and $> 10^\circ$. Pearson correlation coefficients were used to test the relationships between penetration distance and indwelling time, migration distance and penetration distance, and fluoroscopic time and secondary tilt or indwelling time. χ^2 testing was used to determine the relationships between retrievability and secondary tilt ($\leq 10^\circ$ vs $> 10^\circ$), migration distance (≤ 2 cm vs > 2 cm), or deformity. Logistic regression was used to test the relationship between retrievability and indwelling time. A P value $< .05$ indicated statistical significance.

RESULTS

Study Population and Indications

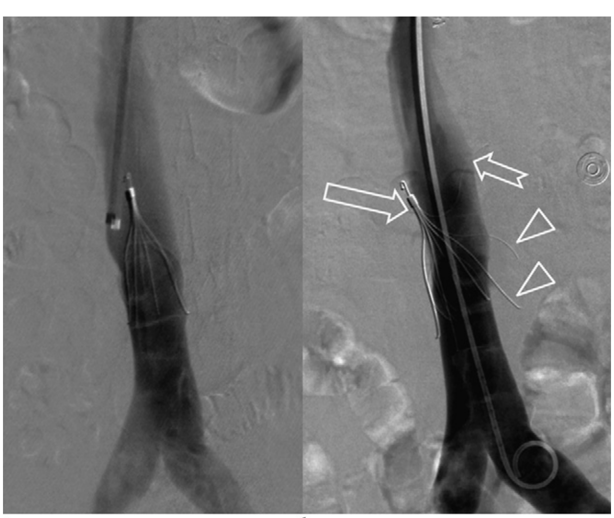
During the study period, 620 patients had Celect filters placed, and 120 of these patients presented for filter retrieval. Of the patients who presented for filter retrieval, 61 were women and 59 were men with an average age of 53.2 years (range, 13–79 y) at the time of filter placement. At retrieval, the average indwelling time of filters was 158.1 days ± 103.0 (range, 2–518 d). Indications for filter placement included PE or DVT with contraindications to anticoagulation (n = 99), recurrent PE despite adequate therapy (n = 8), bleeding during anticoagulation (n = 7), free-floating thrombus in IVC or iliac-femoral vein (n = 5), and severe cardiopulmonary disease with DVT (n = 1).

Although attempts were made to collect placement and retrieval images for all study patients, two placement images and three retrieval images were unavailable for review. Abdominal CT scans performed between filter placement and retrieval were available for 36 patients. Two CT scans of the chest with images of the IVC filter were also available. Five patients underwent CT pulmonary angiography because of newly developed clinical symptoms of PE while the filter was in situ.

Clinical Results

All 120 filters in this series were placed without incident, and 106 (88.3%) were successfully retrieved. The average indwelling time for the 106 retrieved filters was 158.7 days ± 104.6, and the average indwelling time for the 14 unsuccessful retrievals was 154.1 days ± 93.6 ($t = 0.156$; $P = .88$). Unsuccessful retrieval was the result of filter tip embedment in six cases (5.0%), chronic IVC occlusion in three cases (2.5%), retained thrombus with volume > 4 mL in two cases (1.7%), floating IVC thrombus below the filter in two cases (1.7%), and tilt > 15° in one case (0.8%). Retrieval failure prompted continued anticoagulation in all but one case, where hematuria secondary to bladder cancer did not allow for anticoagulation treatment.

After filter placement, five patients presented with symptoms highly suggestive of PE, including chest pain, dyspnea, and hypoxemia (occurring at 2, 9, 11, 27, and 86 d after filter insertion). CT pulmonary angiography was performed in these five symptomatic patients, and new PE was confirmed in three patients. At subsequent retrieval, cavagrams showed no thrombus in these five patients, but one filter had a severe tilt (17.4°) and could not be retrieved (**Fig 1a, b**). Two (1.7%) patients presented with severe pain that resolved immediately after filter retrieval. The first patient complained of intermittent mild abdominal pain lasting 1 week that became severe 514 days after filter placement. At retrieval, this filter was found to have considerable penetration, tilt (16.4°), and deformity (**Fig 2**). The second patient had PE breakthrough after an infrarenal G2 filter placement, with a cavagram showing a large thrombus trapped at the G2 filter. A Celect filter was placed at the suprarenal IVC. The patient presented with pain associated with breathing 25 days later. On CT scan, the suprarenal Celect filter showed penetration into the retroperitoneum and crux of the diaphragm. In this study cohort, seven patients ultimately died of underlying malignancy; two of these patients eventually died with the filter in situ after unsuccessful filter retrieval.



a. b.

Figure 1. CT pulmonary angiography in a 71-year-old woman who presented with severe shortness of breath 86 days after filter insertion. CT pulmonary angiography confirmed new emboli at the right lower lobar pulmonary artery. **(a)** The filter had good alignment on a cavagram taken immediately after IVC deployment, with the hook at the center of the IVC. **(b)** At retrieval, the filter was severely tilted (thick arrow), with the hook against the right lateral wall. In addition, the filter displayed both primary and secondary limb penetration (dovetail arrow) and deformity (arrowheads). This filter could not be removed.

Device-related Abnormalities

On 115 anteroposterior projection cavagrams, 99 filters (86.1%) displayed leg penetration, including 175 primary legs in 99 filters and 45 secondary legs in 28 filters (**Table 1**). All secondary leg penetrations coexisted with primary leg penetrations. The average penetration distance beyond the IVC lumen was 10.3 mm ± 4.8 for primary legs and 10.1 mm ± 4.0 for secondary legs. The primary leg penetration distance increased with increased indwelling time ($r = 0.293$; $P \leq .001$).

CT scans were available for 38 patients (indwelling time, 132.3 d ± 217.5); five of these studies were obtained after failed retrieval procedures. In these 38 patients, 25 (65.8%) of the filters had leg penetrations, including 71 primary legs in 25 filters and 6 secondary legs in 4 filters (**Table 1**). Among patients with available CT scans, nine filters had penetrated into adjacent organs (all were single primary leg): into the duodenum (n = 6), into the aortic wall (n = 2), and into the right kidney (n = 1) (**Fig 3**). All of these filter penetrations were incidental findings without clinical symptoms. From the nine proven cases of organ penetration, seven filters were successfully removed. Of the two that could not be removed, one penetrated the duodenum and could not be removed because of embedment of the filter tip; the other had a limb penetrating the aortic wall, and the filter could not be removed because of a significant clot trapped in the filter. The average filter tilt was as follows: primary tilt (occurred at the time of placement), 4.6° (range, –15.6° to 20.0°), with tilt > 15° in two cases; secondary tilt (occurred after placement), 7.3° (range, −17.4° to 40.0°), with tilt > 15° in eight cases.

In the 115 paired placement and retrieval cavagrams, 89 filters (77.4%) showed intracaval migration, with a maximal distance of 29.9 mm; 36 (40.4%; distance, 6.8 mm ± 6.7) had migrated cranially, and 53 (59.6%; distance, 7.6 mm ± 6.3) had migrated caudally (**Table 1**). Five filters (4.3%) had filter movement (defined by SIR guidelines as change in filter position >2 cm)—two cranially and three caudally. Caudal migration of the filter was positively correlated with penetration distance for both primary leg ($r = -0.396$; $P = .003$) and secondary leg ($r = -0.299$; $P = .030$). However, cranial migration was not significantly correlated with leg penetration (primary, $r = 0.245$; $P = .149$; secondary, $r = 0.304$; $P = .072$). There was no en bloc filter migration beyond the IVC and no evidence of fracture of filter components. In 115 retrieval cavagrams, 10 filters (8.7%) showed evidence of deformity, with four displaying leg asymmetry and six displaying mild bending or splaying of the legs (**Table 1**). Trapped thrombus was identified in 15 filters, 12 by cavagram (average volume, 2.6 mL; range, 1–4 mL) and 3 by CT scan (average volume, 2.3 mL; range, 1–4 mL) (**Table 1**). Thrombus identified on CT scan all had resolved at filter retrieval.

For 20 filters (16.7%), retrieval could not be accomplished with the routine technique, and advanced retrieval

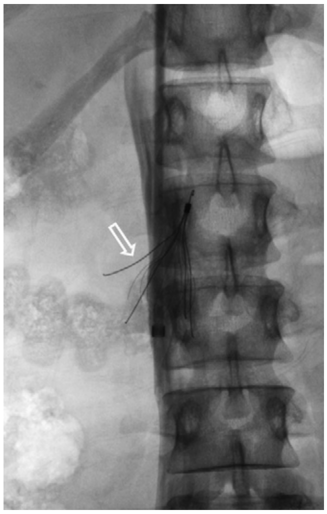


Figure 2. Cavagram in a 23-year-old woman who presented with severe abdominal pain 514 days after filter placement. Cavagram showed severe tilt, with the hook embedded in the left side of the caval wall. There were multiple legs penetrating beyond the caval wall (arrow). The patient's pain resolved immediately after the filter was removed.

techniques were required, including curved catheter technique in 3 cases, forceps technique in 8 cases, balloon-assisted technique in 5 cases, and loop-and-snare technique in 7 cases. Using these advanced retrieval techniques, 13 filters were removed, but 7 filters remained in situ; all of the in situ filters had a tilt greater than 8°, with the hook against the caval wall (probable embedment). Fluoroscopic time was positively correlated with the degree of secondary tilt ($r = 0.383$; $P < .001$) and indwelling time ($r = 0.258$; $P = .004$). Success of retrieval had no significant correlation to secondary tilt (> 10°; $\chi^2 = 3.021$, $P = .221$), filter movement (migration > 2 cm; $\chi^2 = 0.735$, $P = .692$), deformity ($\chi^2 = 0.826$; $P = 0.363$), or indwelling time ($P = .876$) (**Table 1**).

Table 1. Celect Filter Retrieval Characteristics

	Filters (n)	%
Penetration		
On cavagram (n = 115)		
Primary leg		
> 3 mm, ≤ 10 mm	56	48.7
> 10 mm	43	37.4
Secondary leg		
> 3 mm, ≤ 10 mm	15	13
> 10 mm	13	11.3
On CT (n = 38)	25	65.8
Secondary tilt (n = 115)		
≤ 10°	84	73.0
> 10°, ≤ 15°	23	20.0
> 15°	8	7.0
Migration (n = 115)		
Cranial		
> 0 mm, ≤ 10 mm	28	24.3
> 10 mm, ≤ 20 mm	6	5.2
> 20 mm	2	1.7
Caudal		
> 0 mm, ≤ 10 mm	40	34.8
> 10 mm, ≤ 20 mm	10	8.7
> 20 mm	3	2.6
Deformity (n = 115)	10	8.7
Retained thrombus		
On angiogram (n = 12)	12	10.4
On CT* (n = 25)	3	2.5
Caval occlusion (n = 120)	3	2.5
Fluoroscopic time (n = 120)		
≤ 10 min	89	74.2
> 10 min	31	25.8
PE breakthrough (n = 120)	5	4.2

PE = pulmonary embolism.
*Contrast enhancement.

DISCUSSION

In this study, the Celect filter was associated with a high penetration rate, and penetration appeared to correlate with indwelling time. Inferior vena cavagrams performed before removal of the filter showed evidence of at least one limb penetration in 86.1% of cases, a result significantly greater than results seen in previously published studies comprising 134 placements and retrievals (5,22,23) (**Table 2**) but slightly less than the 93% rate observed by Durack et al (24) in a prospective comparison study of Celect and Günther-Tulip filters. This high variation in reported penetration rates may be the result of varying observation methods or may be related to filter indwelling time. **Table 3** summarizes the incidence of penetration of Günther-Tulip filters in published studies (24–27).

There have been several previous reports of symptomatic penetration of the Celect IVC filter. In one report, abdominal pain appeared to be related to a primary strut lodging in the uncinate process of the pancreas 9 days after filter insertion (28). In a second report, acute lower abdominal and right leg pain was seen 17 days after filter insertion as a result of the four primary legs penetrating the IVC wall, producing a small retroperitoneal hemorrhage (29). Pseudoaneurysms of the infrarenal aorta and right renal artery 10 months after filter insertion have also been reported secondary to penetration (30). These pseudoaneurysms ultimately required autogenous aortic reconstruction, caval repair, and subsequent right nephrectomy. In this study, penetration resulted in severe abdominal pain in two cases, which required early filter retrieval.

Filter penetration is a well-recognized phenomenon that is most commonly associated with conical filters. Reported occurrence rates have ranged from 0%–93% (6,8,25,31). Sadaf et al (28) suggested that the stiff strut in the Celect filter may be the reason for frequent filter penetration beyond the caval wall. We believe that all conical filters rely on significant radial force in the long strut (primary leg) to secure the filter to the caval wall. The living IVC wall accommodates the radial force of the filter, and

Figure 3. Asymptomatic penetration was incidentally detected in a 61-year-old woman on CT scan 91 days after filter placement. Both axial (top) and coronal (bottom) images showed a primary limb of the Celect filter penetrating into the right kidney (arrow). The filter was successfully retrieved 411 days after placement.

penetration is likely to occur. Our study also showed that the degree of penetration (distance of the strut beyond the caval wall) correlates with filter indwelling time: The longer the filter was in place, the further the penetration beyond the caval wall ($P = .001$). These findings suggest that a Celect filter should be removed as soon as clinically indicated to reduce the risk of symptomatic penetration. Additionally, as with the G2 filter (Bard Peripheral Vascular, Inc, Tempe, Arizona) (6), caudal migration of the Celect filter was found to be positively associated with penetration in this study.

Fracture is another serious device failure that must be considered when retrievable IVC filters are used; such a failure can potentially lead to fatal complications. Although no fractures were seen in this study, the relatively short indwelling time does not allow us to draw the conclusion that Celect filters are not associated with a fracture risk. In a retrospective study of 363 Bard Recovery filters (Bard Peripheral Vascular, Inc), Tam et al (9) found that the earliest occurrence of fracture was at 4.1 months. A review of all published Celect filter studies involving more than 500 filters demonstrated evidence of just one fracture in a study by Sangwaiya et al (22), but no details regarding the fracture were provided. Distant en bloc migration of filters, another potentially fatal complication, has been reported in several case studies of the Günther Tulip filter (14,32,33). However, no such migrations occurred in this study or in previous studies of the Celect filter, indicating that the Celect filter probably has an improved anchoring mechanism compared with the Günther Tulip filter.

New PE after filter placement is another potential complication of these devices. In this cohort, five patients had symptoms thought to represent breakthrough PE. Three of these five patients had new PE confirmed by CT pulmonary angiography; the other two patients were treated for new PE based on typical symptoms. The incidence of PE breakthrough in this study (4.2%) was similar to that previously reported in studies of permanent and retrievable filters (6,8,34).

Successful retrieval in this study was achieved in 88.3% of patients who presented for removal of the filter. This rate was slightly lower than previously reported rates of 93.3%–96.6% (**Table 2**) but comparable to the rates associated with other retrievable filters: 90.2%–95.3% with the Günther Tulip (25,35,36), 84.9%–95% with the Bard Recovery G2 (37–39), 92.3% with the Option (Argon Medical Devices,

Table 2. Comparison of Retrievals of Celect Filter Studies

Study	Doody et al (5)	Sangwaiya et al (22)	Lyon et al (23)	Present Study
Retrievals (n)	61	15	58	120
Indwelling time (d)*	116.7 (14–267)	121 (5–381)	179 (5–466)	158.1 (2–518)
Retrieval rate (n)	57 (93.4%)	14 (93.3%)	56 (96.6%)	106 (88.3%)
Causes of failure (n)	Occluded IVC, 1; embedment, 3	Filter clot, 1	Tilt, 1; embedment, 1	tilt $> 15°$, 1; filter embedment, 6; retained thrombus, 2; floating IVC thrombus, 2; IVC occlusion, 3
PE breakthrough (n)	ND	3 (3/71, 4.1%†)	ND	5 (4.2%)
Filter-related pain (n)	ND	ND	ND	2 (1.7%)
Penetration (n)	2 (3.2%)	4 (22.2%)	21 (36.2%)	9/115 (86.1%)
Tilt $\geq 15°$ (n)	ND	ND	2 (3.4%)	7/115 (6.1%)
Local migration > 2 cm (n)	ND	0	ND	5 (4.3%)
Fracture (n)	ND	1/18 (CT, 5.6%)	0	0
Retained thrombus (n)	15 (24.6%)	1/18 (CT, 5.6%)	4 (7.0%)	12/115 (10.4%)
IVC occlusion (n)	1 (1.6%)	0	0	3 (2.5%)

IVC = inferior vena cava; ND = not determined; PE = pulmonary embolism.
* Mean value (range).
† Total placements.

Table 3. Incidence of Penetration of Günther-Tulip Filter in Published Studies

Study	Penetration Incidence	Interval (Mean)	Imaging
Marquess et al*(25)	92.6% (152/164)	63.0 d	Venogram
Ota et al (26)	56.1% (23/41)	11.7 mo	CT
Durack et al (24)	78% (18/23)	247 d	CT
Neuerburg et al (27)	2.7% (2/75)	136 d	Venogram

* Standard of protrusion was not defined.

Athens, Texas) (8), and 92.7%–99% with the ALN (ALN Implants Chirurgicaux, Ghisonaccia, France) (31,40).

In this study, 20 filters could not be removed using the retrieval kit provided by the manufacturer, and 7 filters could not be removed by any means. Unsuccessful retrievals can be the result of either technical (eg, filter tilting and incorporation of the retrieval hook into the IVC wall) or nontechnical (eg, retained thrombus at the filter, free-floating IVC thrombus, lack of central venous access, or IVC occlusion with the filter embedded entirely into the organized thrombus) causes (6). Excluding filters unsuitable for removal, there was a 5.8% failure rate for retrieval in this study.

Filter tilt, a common phenomenon for conical filters, is a prime factor complicating filter retrievals. Although the filter struts anchored at the caval wall form a relatively stable base, the tip floats freely without support. Over time, movement in the IVC or radial force in the filter allows the filter to reposition itself to its most stable position. In many cases, this places one side of the filter against the IVC wall. In this study, eight filters had tilt $>15^\circ$, but only one of these filters could not be removed. Alternatively, in the seven filters that could not be retrieved with advanced techniques, only one filter had tilt $>15^\circ$. However, even moderate tilt is sufficient to embed the hook of the filter in the caval wall, prohibiting filter capture. In a previous study, Van Ha et al (18) used multiple advanced retrieval techniques to successfully remove 37 of 38 filters that were considered difficult retrievals. These cases included filters with significant tilt and filters with the hook making contact with the IVC wall. With the excimer laser sheath technique, even deeply embedded filters were removed successfully in a study by Kou et al (41). Success of advanced filter retrievals appears to be associated with the operator's experience and aggressiveness and with the availability of advanced retrieval tools.

Study limitations should be mentioned. First, only 19.3% of patients presented for filter retrieval. In our practice, the Celect filter was placed for both permanent and short-term PE prophylaxis; most of the patients had permanent indications for filter placement. The relatively low retrieval rate was attributed to primary service–based referrals, patient mortality (in view of the large number of patients with cancer), and loss of follow-up because of the high percentage of out-of-state and international patients. To improve this retrieval rate, we have since initiated a filter follow-up program. Our institution now has a dedicated health care professional coordinating with the primary service to refer patients for filter retrieval (42,43). This program has greatly increased the number of retrievals. However, in the context of this study, this low rate of filter retrieval creates a selection bias, and the subset of retrieval cases may not accurately represent all Celect filter placements. Similarly, device-related complications were evaluated in retrieval patients only, and follow-up for this group of patients was relatively short. Long-term follow-up in patients not scheduled for filter retrieval may demonstrate a higher rate of complications, such as potential fractures. This study was also limited in that the penetration rate was likely underestimated by the catheter anteroposterior cavagram (24). Tilt was defined only as lateral deviation because tilt in the anteroposterior plane could not be determined. The actual incidence of PE breakthrough in this study is unknown because CT pulmonary angiography was performed only in patients who had typical PE symptoms in the clinic. Additionally, a few images were unavailable for review (5 of 240 cavagrams). Finally, the best method for assessing penetration and the only method to determine adjacent organ penetration is CT scan, but only a limited subset of patients underwent CT scans, possibly leading to a different selection bias.

In conclusion, the Celect IVC filter has a high rate of penetration; some of these penetrations are also associated with adjacent organ penetration, occasionally manifesting as significant abdominal pain. The degree of penetration appears to correlate with indwelling time. Close clinical follow-up after Celect filter insertion is recommended. Although most of the filters were removed, 5.8% of retrievals were unsuccessful because of technical failure.

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