Sponsored by Cook Medical

The Celect Platinum Inferior Vena Cava Filter

A single-center experience and first reported evaluation of filter placement outcomes.

BY ATUL GUPTA, MD, AND TYLER WARNECKE, PA-C

The concept of surgical caval interruption was suggested as early as 1868 by Trousseau, who proposed creating a barrier in the inferior vena cava (IVC) to prevent venous emboli from the legs from reaching the lungs.[1] In 1967, nearly 100 years later, the first endovenous filter was implanted.[2]

Although the basic concept of caval filtration has largely remained the same over the past century, advancements in metallurgy, filter design, retrievability, and imaging have greatly expanded the use of IVC filters. In the United States, there are currently at least 14 types of IVC filters available to physicians, and of these, at least six filters are retrievable.

Since 2010, there has been increased scrutiny on filters by the US Food and Drug Administration (FDA) regarding device migrations, fractures, caval thrombosis, caval penetration, and filter tilt.[3] Thus, since 2011, after a decade-long progressive increase in filter placement volume, annual filter placement volumes began declining.

The breadth of clinical literature generally supports the safety and efficacy of IVC filters, although the designs of filters and their delivery systems continue to evolve to tackle the admittedly rare, yet potentially catastrophic, complications. Furthermore, evolutionary changes to IVC filter designs and filter delivery systems have been ongoing. These changes have been incorporated to improve filter placement by reducing tilt, penetration, and migration, with the overall goal of easing subsequent filter retrieval. This article describes our early experience with the newest-generation Celect Platinum IVC filter (Cook Medical).

CELECT PLATINUM IVC FILTER

The Celect Platinum IVC filter is a conical-shaped filter constructed from a cobalt chromium alloy with a platinum radiopaque marker on each primary filter leg to enhance filter visibility during procedural imaging (Figure 1A and 1B). These markers also allow the physician to assess for potential anteroposterior (AP) tilt during retrieval.

The filter comes preloaded on a 65-cm coaxial 7-F introducer sheath equipped with a 10-F dilator that contains two radiopaque markers. The filter can be delivered either via a femoral or jugular vein approach; the femoral introducer has a flexible tip ("Flex Tip"), which was designed to enhance tracking through the venous anatomy.

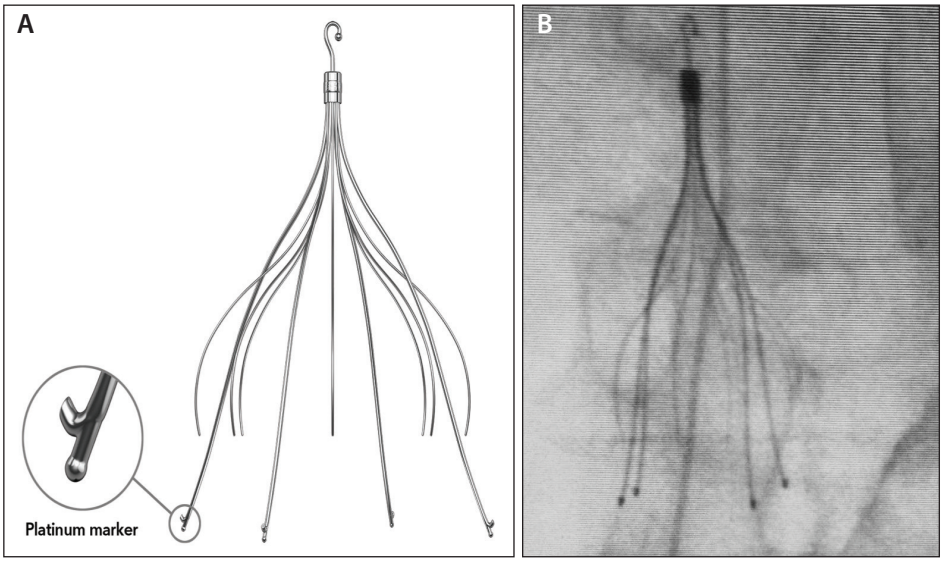

Figure 1. Celect Platinum filter with inset showing platinum markers on the primary struts (A). Fluoroscopy image of the Celect Platinum filter with radiopaque markers (B).

Sponsored by Cook Medical

Consistent with the indications for use for all IVC filters marketed in the United States, the Celect Platinum IVC filter is intended for the prevention of recurrent pulmonary embolism (PE) in the following situations: pulmonary thromboembolism when anticoagulant therapy is contraindicated; failure of anticoagulant therapy in thromboembolic diseases; emergency treatment following massive PE in which anticipated benefits of conventional therapy are reduced; and chronic, recurrent PE in which anticoagulant therapy has failed or is contraindicated.

A SINGLE-CENTER EXPERIENCE WITH THE CELECT PLATINUM IVC FILTER

We prospectively evaluated product performance data related to early experience with the Celect Platinum IVC filter from physician evaluation forms completed during filter placement procedures at a single center between December 2013 and August 2014. During the study period, 99 patients received a Celect Platinum IVC filter. Patient demographics, clinical diagnosis, and device performance evaluations were recorded at the time of placement. Patients with missing procedure information or filter tilt data (ie, procedure time, fluoroscopy time, access site, or postplacement tilt) were excluded from the analysis. Seventy-seven patients were included in the analysis: 36 (47%) male patients and 41 (53%) female patients (mean age, 74 ± 16 years; range, 28–98 years).

The most common reason for filter placement was deep vein thrombosis (DVT) with contraindication to anticoagulation (45/77; 58%). The remaining 32 patients had a current PE (32/77; 42%). Active bleeding was reported in 23 patients (23/77; 29%), and history of malignancy was reported in 11 patients (11/77; 14%). Filters were placed almost equally as permanent devices (45/77; 58%) and with a goal of eventual retrieval (32/77; 42%).

Filter Placement

All implant procedures were performed according to the manufacturer's instructions for use. The mean time required for the total filter placement procedure was 6.57 ± 2.78 minutes, with a mean total fluoroscopy time of 1.02 ± 0.53 minutes. During imaging, traditional contrast venography (mean contrast volume, 17.67 ±10.4 mL) was utilized for most patients (60/77; 78%), while carbon dioxide was utilized as the contrast agent in 17 patients (22%). Venous access and filter placement were primarily achieved using the right common femoral vein (57/77; 74%); filters were also placed via the left common femoral vein (15/77; 19%) and the right internal jugular vein (5/77; 7%).

Procedure success and insertion problems were assessed using the definitions from the Society of Interventional Radiology (SIR) Standards of Practice Committee consensus statement guidelines for IVC filter placement. Specifically, filter tilt is defined as the apex of the filter tilting > 15° from the IVC axis, and caval penetration is defined as filter struts extending > 3 mm from the external wall of the IVC.[4]

The platinum markers were clearly visible after filter placement in all 77 cases (100%), assisting in an assessment of filter position in the IVC, AP tilt in particular. Following filter placement, filter tilt was assessed relative to the AP image of the IVC on venacavagram. The degree of filter tilt was categorized as: 0° (n = 44), 1° to 5° (n = 24), 6° to 10° (n = 8), 11° to 15° (n = 1), 16° to 20° (n = 0), and > 20° (n = 0). Thus, 68 filters (68/77; 88%) had a tilt of ≤ 5° at the time of filter placement. Notably, no filter was tilted > 15° on postdeployment imaging, and only one filter (1/77; 1.2%) was tilted > 10°. Among the 15 filters placed via the left femoral vein, a more tortuous route to the IVC, no filter was tilted > 10° on postdeployment imaging (0/15; 0%).

Filter placement procedure success was 100% (77/77); all filters were deployed in a location that was determined suitable for mechanical protection against PE. There were no filter insertion problems; specifically, there were no instances of malfunction of the filter or deployment system, no incomplete opening of the filter, no tilt > 15°, no misplacement of the filter outside of the infrarenal IVC, nor any acute prolapse of any filter component.

Device Evaluation

The acute performance of Celect Platinum was compared to other filters commonly used in our practice. Overall satisfaction and perceived change in procedure time, fluoroscopy time, or filter tilt were evaluated and rated on a scale of 1 to 7 (1 being "very dissatisfied" and 7 being "very satisfied"). Overall satisfaction was rated as very satisfied on all available evaluations (72/72; 100%). Importantly, there was a strong perception that the degree of tilt associated with the Celect Platinum filter at time of placement was decreased (53/73; 73%) or stayed the same (20/73; 27%) as compared to routinely implanted filters based on available evaluations. No perceived changes in procedural or fluoroscopy times were reported.

CASE STUDY

A 46-year-old woman presented to our department with a history of failed anticoagulation therapy with extensive right lower extremity DVT, PE, and new gastrointestinal (GI) bleeding. Filter placement was indicated due to her contraindication to anticoagulation in the presence of PE and DVT. A Celect Platinum IVC filter was placed with the intent to evaluate for possible filter retrieval in 3 to 6 months if she remained asymptomatic and was either effectively anticoagulated or if there was no residual clot burden. The filter was placed via a

Sponsored by Cook Medical

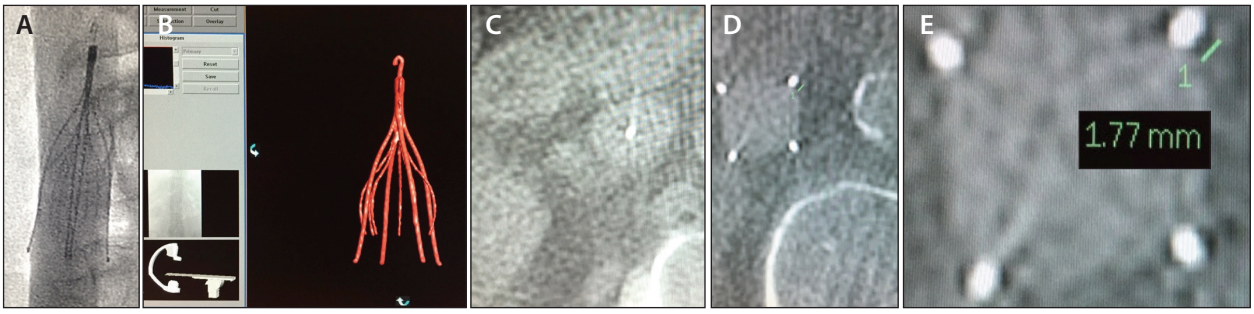

Figure 2. Celect Platinum filter immediately postimplantation demonstrating no significant tilt (A). At retrieval, 3D reconstructed image of the Celect Platinum filter, which is used to assess tilt and select optimal C-arm retrieval angle (B). Cone beam XperCT demonstrates the filter hook to be centered in the IVC without tilt (C). Cone beam XperCT shows no significant penetration (ie, > 3 mm) of primary struts at 224 days (D, E).

right femoral approach, and filter tilt was only 0° to 5° immediately after placement (Figure 2A), which was not considered significant as per SIR guidelines. The total procedure time was 8 minutes, total fluoroscopy time was 0.9 minutes, and 20 mL of contrast was used. No procedural complications occurred.

After filter placement, the patient did well and was placed in our filter registry for close follow-up by our physician assistant, who manages all our patients with retrievable filters. In our experience, implementing a filter registry is critically important to ensure that patients with filters are not lost to follow-up and to maximize the filter retrieval rate (if retrieval is indicated), as per the FDA safety communication.

Three months following filter placement, the patient returned for a preretrieval office consultation, which included a bilateral lower extremity venous Doppler ultrasound examination. Preretrieval imaging confirmed that the patient was negative for any residual DVT. The patient was considered asymptomatic with no residual PE or GI bleeding and was effectively anticoagulated. Upon consultation with the patient's hematologist, filter retrieval was scheduled.

The patient elected to schedule retrieval at 224 days postimplantation, and she was placed on the angiography table in the supine position with the right neck draped and prepped per standard protocol. As part of our retrieval program, all patients undergo a 4-second, low-dose cone beam CT scan (XperCT, Philips Healthcare) at the time of retrieval, which also allows the physician to perform instant three-dimensional (3D) reconstruction to visualize potential filter tilt and assess potential caval penetration. Degree of tilt and possible penetration were assessed as defined by the SIR consensus statement (ie, apex of the filter tilting > 15° from the IVC axis and filter struts extending > 3 mm from the external wall of the IVC.).[4]

The 3D images and cone beam CT revealed no significant filter tilt (0°–5°) (Figure 2B) or evidence of any caval penetration (Figure 2C to 2E). The Celect Platinum IVC filter was easily retrieved without complication utilizing the standard Cook filter retrieval set, including a snare and sheath (Figure 3). The patient was discharged 2 hours later in good condition.

DISCUSSION

In this prospective, early evaluation of the performance of the Celect Platinum IVC filter in 77 patients, the filter was associated with a 100% procedural success rate and no insertion problems. Moreover, physician feedback data suggested high performance satisfaction. Specifically, after review of the technical aspects of filter placement, the Celect Platinum IVC filter was perceived to be at least similar to other currently utilized filters, with no perceived change in procedure or fluoroscopy

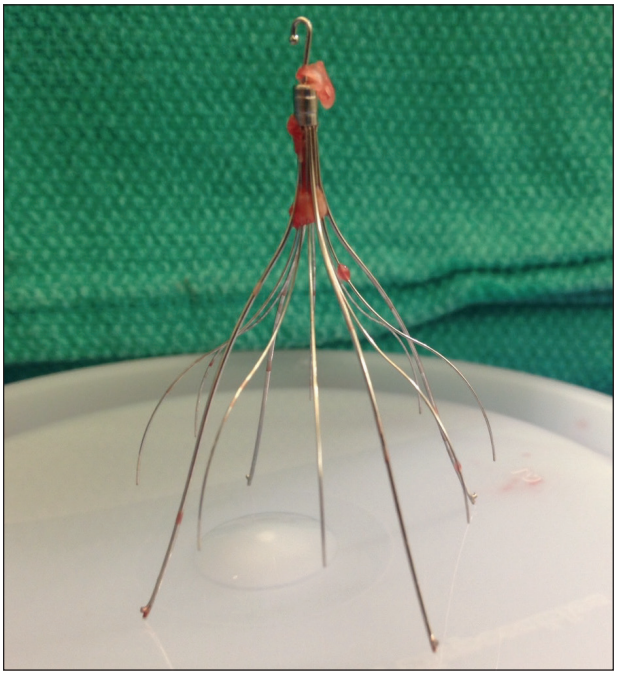

Figure 3. Celect Platinum IVC filter following retrieval.

Sponsored by Cook Medical

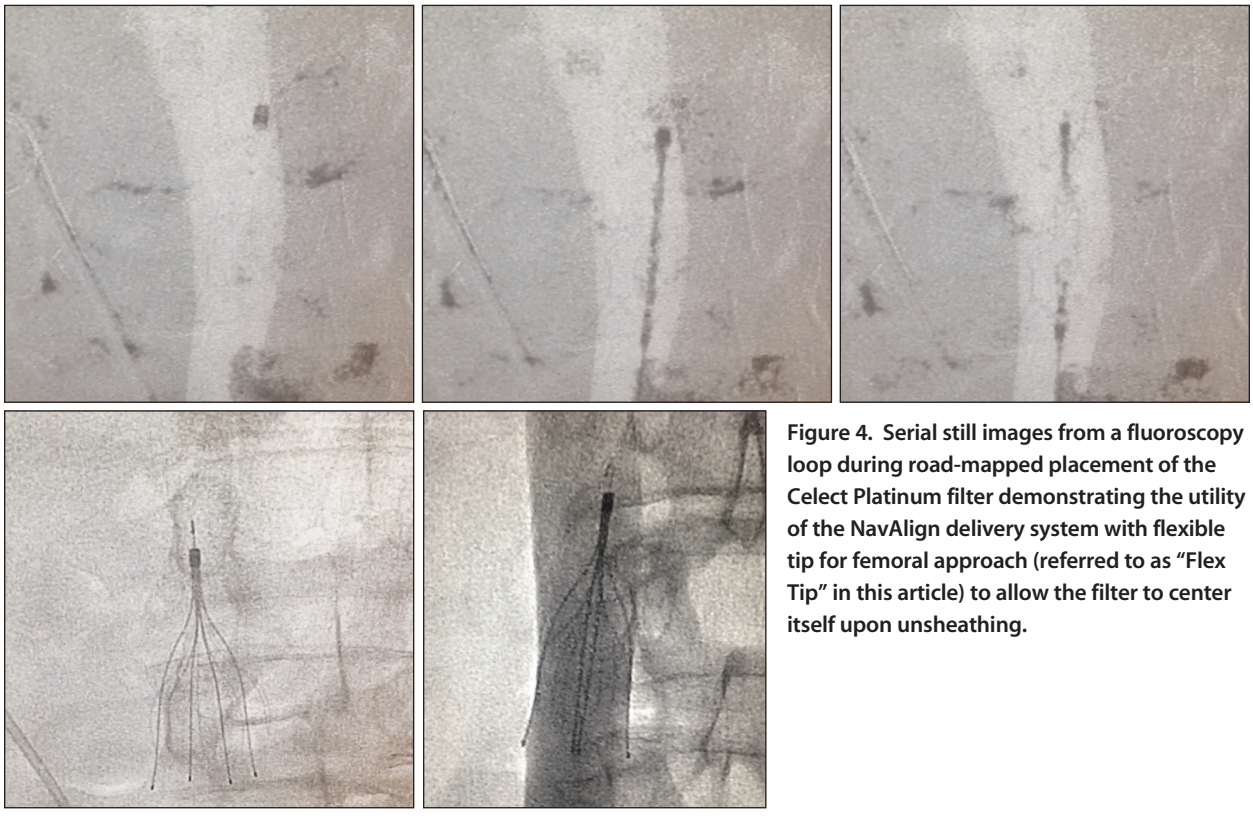

Figure 4. Serial still images from a fluoroscopy loop during road-mapped placement of the Celect Platinum filter demonstrating the utility of the NavAlign delivery system with flexible tip for femoral approach (referred to as "Flex Tip" in this article) to allow the filter to center itself upon unsheathing.

time versus the other filters, despite the presence of a new Flex Tip femoral delivery system.

Most intriguing was physician feedback demonstrating a strong perception (73%) that the Celect Platinum filter tilt at the time of placement was decreased as compared to routinely implanted filters. This may be related to the unique Flex Tip delivery system, which appears to allow for easy tracking through a tortuous femoral venous anatomy and has the added potential benefit of allowing the filter to center itself upon unsheathing. Specifically, our experience suggests that the Celect Platinum filter apex does not significantly tilt toward the IVC wall unlike other conical IVC filters that are deployed via stiff, "rod-like" delivery systems (Figure 4).

Our quantification of degree of filter tilt at the time of placement supports this physician feedback as well, as there were no cases (0%) in which the Celect Platinum had problematic tilt (ie, > 15° as defined by SIR). In fact, 88% of our implants demonstrated minimal tilt (0°–5°). In contrast, the reported filter tilt rate of previous-generation Celect IVC filter (which does not utilize the Flex Tip delivery system) at the time of retrieval was 8.9% (5/58) and 10.4% (20/193).[5,6] As there has been no change in the general configuration of the primary and secondary struts between the old- and new-generation Celect filters, other than the addition of the platinum markers to facilitate visualization, it appears that the lack of tilt with the Celect Platinum IVC filter may be attributed to this new delivery system.

Understanding the degree of filter tilt at the time of placement is important, as filter tilt has a high degree of influence on eventual retrievability. Filter removal may be difficult or impossible if endothelialization of the filter apex to the caval wall occurs. Therefore, off-label techniques have been described to facilitate optimal filter placement; these techniques force centering and prevent tilt of conical filters at the time of placement.[7] In addition, techniques have been described to remove filters that have been identified as already tilted and embedded, including snaring of looped guidewires, balloon centering, double-sheath or laser dissection, and use of endovascular forceps; however, these techniques are more aggressive maneuvers that are outside the device manufacturer's instructions for use. These aggressive retrieval techniques could result in increased complications, including caval injury or filter fracture.[8] Clearly, elimination of the underlying problem of filter tilt is most preferable.

One strategy to aid in retrieval is the use of advanced 3D imaging and cone beam CT during retrieval. Recent studies have suggested preretrieval CT scans may be warranted for identification of filter tilt, penetration, and fracture to tailor retrieval approach.[9]

To aid in our retrieval planning, we routinely perform a 4-second, low-dose, noncontrast cone beam CT (XperCT) with associated 3D rotational scan at the time of retrieval, even before vascular access is achieved.

Sponsored by Cook Medical

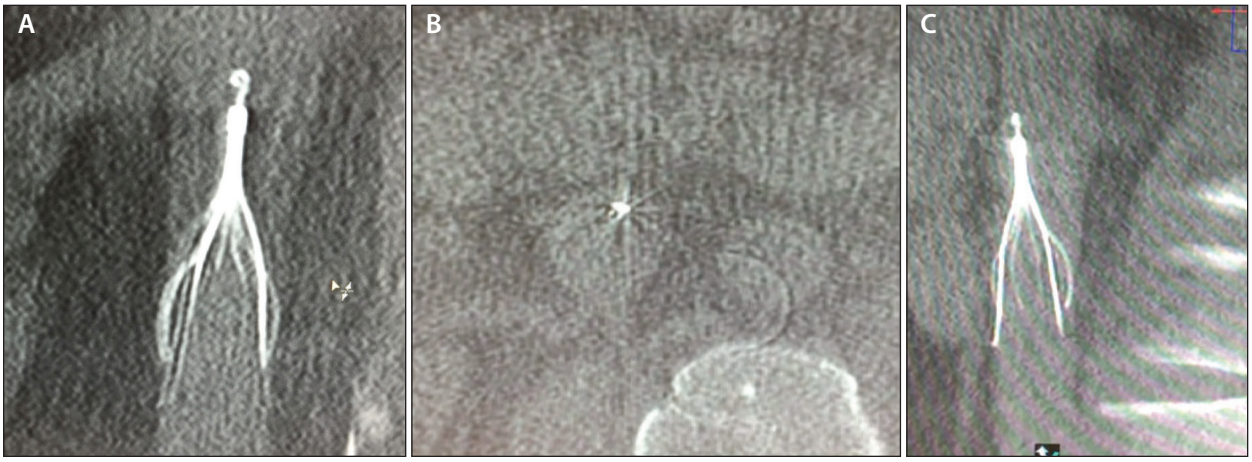

Figure 5. Example of the utility of preretrieval XperCT to assess for "hidden" filter tilt. Coronal XperCT image of old-generation Cook Celect suggesting a well-centered, nontilted IVC filter. Relying solely on an AP fluoroscopy image could result in misjudgment of tilt and prolonged retrieval times (A). Axial XperCT image of the same patient showing the hook of IVC filter tilted anteriorly (B). Near-sagittal XperCT image confirms the anterior tilt of the IVC filter in the IVC and gives the optimal C-arm retrieval angle (in this case 82° lateral) (C).

Preretrieval imaging allows for the evaluation of filter tilt that might not be appreciated from a two-dimensional (2D) image. Filters and vessels are 3D structures, and visualization of the filter in a single plane with conventional 2D imaging often results in misjudgment of filter tilt, potentially resulting in lengthened retrieval times and increased exposure of radiation to patient and staff. Even before gaining vascular access, the use of 3D planning allows for exact C-arm angulation to be identified and the optimal sheath and snare shape to be selected. Thus, by adding the single 4-second procedure to the beginning of filter retrieval, the "trial and error" process is eliminated, which often occurs with multiple randomly selected x-ray angles and sheaths. In addition, the associated cone beam CT soft tissue data give detailed information regarding any possible penetration of the filter struts (Figures 5A to 5C).

Additional multicenter studies are now underway, including the PRESERVE study and the Cook IVC (CIVC) Filter study. Although our study was not a retrievability study, we hypothesize that the new platinum markers on the Celect Platinum may offer advantages beyond visibility and potentially could offer some benefit in minimizing penetration (Figure 2E). These larger multicenter studies will further assess the safety and performance of various filters, including tilt, retrieval, and penetration, and we look forward to their results.

In conclusion, our early experience with the latest-generation Cook Celect Platinum IVC filter suggests that it has a high technical success rate (100%), no insertion complications, and strong performance satisfaction. Most notably, we had no cases of significant tilt with this filter at placement, which may be related to its novel Flex Tip delivery system. ■

The authors thank Jennifer McCann-Brown, PhD, and Sara Sherman, MS, of Cook Research Incorporated for assistance with manuscript preparation.

Atul Gupta, MD, is an interventional radiologist and Director, Interventional Vascular Consultants in Philadelphia, Pennsylvania. He has disclosed that he is a clinical research consultant for Cook Medical and is the Chief Medical Officer for Philips IGT (Image-Guided Therapy). Dr. Gupta may be reached at guptarad@live.com.

Tyler Warnecke, PA-C, is an interventional radiology physician assistant. He has stated that he has no financial interests related to this article.

1. Trousseau A. Phlegmatia alba dolens. In: Clinique édicale de l'Hôtel-Dieu de Paris. 3rd ed. J.B. Baillière: Paris; 1868:652–695.
2. Dupont PA. The Mobin-Uddin umbrella filter in the management of proven and threatened pulmonary embolism. Ann R Coll Surg Engl. 1976;58:318-321.
3. US Food and Drug Administration. Removing retrievable inferior vena cava filters: initial communication. Updated May 11, 2015. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm221676.htm. Accessed November 18, 2015.
4. Caplin DM, Nikolic B, Kalva SP, et al. Quality improvement guidelines for the performance of inferior vena cava filter placement for the prevention of pulmonary embolism. J Vasc Interv Radiol. 2011;22:1499-1506.
5. Ryu RK, Desai K, Karp J, et al. A comparison of retrievability: Celect versus option filter. J Vasc Interv Radiol. 2015;26:865-869.
6. Bos A, Van Ha T, van Beek D, et al. Strut penetration: local complications, breakthrough pulmonary embolism and retrieval failure in patients with Celect vena cava filters. J Vasc Interv Radiol. 2015;26:101-106.
7. Knott EM, Beachman B, Fry WR. New technique to prevent tilt during inferior vena cava filter placement. J Vasc Surg. 2012;55:869-871.
8. DeRubertis BG. Advanced IVC filter retrieval techniques: options when risk of permanents device implantation outweigh the potential complications of retrieval. Endovasc Today. 2012;11:69-73.
9. Dinglasan LA, Oh JC, Schmitt JE, et al. Complicated inferior vena cava filter retrievals: associated factors identified at preretrieval CT. Radiology. 2013;266:347-354.