The Safety and Effectiveness of the Retrievable Option Inferior Vena Cava Filter: A United States Prospective Multicenter Clinical Study

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PURPOSE: To evaluate the safety and effectiveness of the retrievable Option inferior vena cava (IVC) filter in patients at risk for pulmonary embolism (PE).

MATERIALS AND METHODS: This was a prospective, multicenter, single-arm clinical trial. Subjects (N = 100) underwent implantation of the IVC filter and were followed for 180 days; subjects whose filters were later removed were followed for 30 days thereafter. The primary objective was to determine whether the one-sided lower limit of the 95% CI for the observed clinical success rate was at least 80%. Clinical success was defined as technical success (deployment of the filter such that it was judged suitable for mechanical protection from PE) without subsequent PE, significant filter migration or embolization, symptomatic caval thrombosis, or other complications.

RESULTS: Technical success was achieved in 100% of subjects. There were eight cases of recurrent PE, two cases of filter migration (23 mm), and three cases of symptomatic caval occlusion/thrombosis (one in a subject who also experienced filter migration). No filter embolization or fracture occurred. Clinical success was achieved in 88% of subjects; the one-sided lower limit of the 95% CI was 81%. Retrieval was successful at a mean of 67.1 days after implantation (range, 1–175 d) for 36 of 39 subjects (92.3%). All deaths (n = 17) and deep vein thromboses (n = 18) were judged to have resulted from preexisting or intercurrent illnesses or interventions and unrelated to the filter device; all deaths were judged to be unrelated to PE.

CONCLUSIONS: Placement and retrieval of the Option IVC filter were performed safely and with high rates of clinical success.

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

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SINCE the late 1960s, inferior vena cava (IVC) filters have been implanted in patients at high risk for pulmonary embolism (PE) (1). They are recommended for use in patients with acute deep vein thrombosis (DVT) and in those with acute PE when first-line anticoagulant therapy is contraindicated or ineffective (2,3). The sole purpose of these filters is to prevent clinically significant PE by trapping venous emboli that have formed in the lower extremities before they reach the lungs (2). Although IVC filters have been proven effective in reducing PE, chronic use has been associated with an increased risk of DVT (4,5). Other less common complications include venous access site thrombosis, penetration of the vessel wall, and filter migration, tilting, obstruction, and/or fracture (1). Mortality rates appear to be unaffected by IVC filter use (4–6).

Percutaneous retrieval of existing permanent filters was first cleared in the United States by the Food and Drug Administration in 2003 (2). With the advent of "retrievable" IVC filters, physicians had the option of leaving the filter permanently in place or removing it at a time of their choosing, after the risk of bleeding had resolved or the immediate risk of PE had diminished. In this way, it was hoped that many of the longer-term complications associated with permanent devices could be avoided. At this time, the benefits of retrievable filters are largely inferred rather than proven, as there have been no prospective randomized controlled trials directly comparing permanent and retrievable devices (7,8).

The Option IVC Filter (Rex Medical, Conshohocken, Pennsylvania) is among the second generation of filters specifically developed as a retrievable device. The current study was undertaken to assess the safety and effectiveness of this filter as both a permanent and retrievable device.

MATERIALS AND METHODS

Study Design and Conduct

This was a single-arm, prospective, multicenter, nonrandomized clinical trial conducted in patients who were at permanent or temporary increased risk of PE and in whom IVC interruption was judged to be clinically indicated (clinicaltrials.gov identifier, NCT00488865). Subjects who met the selection criteria underwent implantation of the Option IVC filter. In the original protocol, filters were to be considered permanent if they were not removed within 90 days of placement. The protocol was amended midway through the study to extend the postimplantation filter retrieval window from 90 days to 175 days because it was recognized that a longer period of implantation was often clinically necessary. Therefore, subjects who did not have the filter removed within 175 d ± 3 after implantation were considered permanent filter subjects (hereafter "permanent subjects"); Permanent subjects were followed to 180 days after implantation. Subjects who had the filter removed within 175 d ± 3 after implantation were considered retrieved filter subjects (hereafter "retrieved subjects"); Retrieved subjects were followed for 30 days after retrieval.

Ten investigational sites in the United States screened subjects for this study; nine of these sites enrolled subjects between March 2007 and November 2008. At eight sites, interventional radiologists implanted and retrieved filters in interventional radiology suites; at the ninth site (Mill–Peninsula Medical Center, Burlingame, California), filter placement and retrieval was performed by a vascular surgeon. Each site obtained institutional review board approval before commencing the study at their facility. Study subjects provided written informed consent before their enrollment into this study. In addition, subjects who were candidates for filter retrieval provided written informed consent before the retrieval procedure. All aspects of the study were governed by the applicable sections of Food and Drug Administration Regulation 21 Code of Federal Regulations, and by the standard operating procedures of all reviewing ethics committees, the study sponsor, and the contract research organization that monitored the study and handled all aspects of data management. An independent physician served as the medical monitor for this investigation. In this capacity, the monitor was responsible for the review and validation of all reported adverse events that were considered serious and/or device- and/or procedure-related. Where evidence of a relationship to the device was incomplete, inconclusive, or otherwise ambiguous, a conservative approach was used and the event was adjudicated to be possibly filter-related.

Inclusion/Exclusion Criteria

Subjects, aged 18 years and older, were eligible for enrollment in this study if caval filtration was judged to be clinically indicated for one or more of the following four conditions: pulmonary thromboembolism when anticoagulant therapy was contraindicated; failure of anticoagulant therapy in thromboembolic disease; complication as a result of anticoagulant therapy in thromboembolic disease; or indication for temporary caval filtration (eg, trauma or planned operation such as bariatric or pelvic surgery). Subjects were required to have an IVC transverse diameter of no more than 32 mm and adequate venous anatomy to allow for insertion of the filter into the IVC, either from femoral or jugular access sites. At the time of the index procedure, subjects also had to have a patent internal, external, or anterior jugular vein to allow potential retrieval of the filter. Female subjects of childbearing potential had to have had a negative pregnancy result test within 48 hours of the implantation procedure. Subjects were excluded from enrollment if they already had a filter in place or had undergone filter retrieval within the previous 60 days. They were also excluded if they had confirmed bacteremia, a duplication of the IVC, a life expectancy of less than 6 months, a known sensitivity to radiographic contrast medium that could not be adequately premedicated prophylactically, a known hypersensitivity to nickel or titanium alloys, or any comorbid condition that the investigator deemed might compromise the study.

Study Device

The Option IVC filter is laser-cut from a single piece of shape-memory, nickel-titanium alloy (nitinol) tubing. Six expandable and collapsible struts flare out symmetrically from a central apex (**Fig 1**). A single large hook is located at the apex. During deployment through a venous sheath (6.5 F

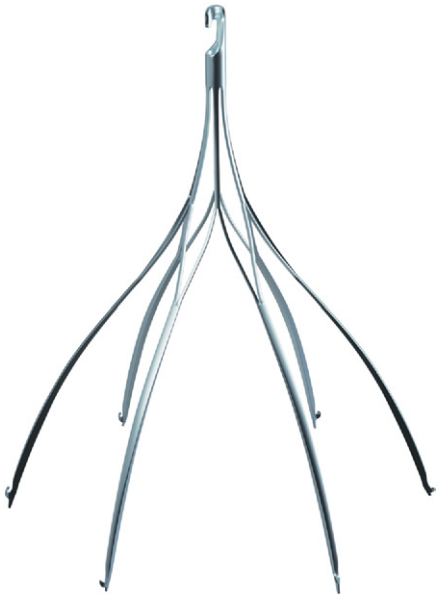

Figure 1. The Option IVC filter. (Available in color online at www.jvir.org.)

outer diameter, 5 F internal diameter, 70 cm length), the struts are released and expand to fit the internal diameter of the IVC. The filter has been cleared by the Food and Drug Administration for use in caval diameters as large as 30 mm. Before deployment, the filter measures 2 mm in diameter by 57.5 mm in height; following deployment in an IVC of 30 mm, the filter height measures approximately 54.5 mm. Retention anchors at the end of each strut are designed to secure the device to the vessel wall. If desired, an 8-F or 10-F retrieval sheath can be used at a later date to collapse the struts. A snare device, inserted through the retrieval sheath, can be used to engage the hook at the central apex of the filter and draw the filter into the sheath, at which time the sheath and its contents can be removed.

Study Procedures and Filter Implantation and Retrieval Technique

Femoral or jugular venous access was obtained for all enrolled subjects, and a measuring flush catheter was advanced into the caudal IVC. Frontal cavography was performed after administration of contrast medium through the catheter to assess for caval variant anatomy or thrombus, determine the location of the renal veins, and establish that the IVC transverse diameter was less than or equal to 32 mm. The catheter was replaced, over a guide wire, with the filter introducer sheath, which was advanced to the desired filter delivery site in the infrarenal IVC. The sheath dilator and guide wire were removed and the filter was inserted into the delivery sheath and pushed through the sheath to the target site. Filter delivery was performed by retracting the delivery sheath and uncovering the filter. Cavography was performed after filter placement to verify that the filter was positioned properly. On-table posteroanterior and lateral radiographs were obtained for later assessment of tilting and filter migration. The start and end times for filter placement were recorded at insertion of the first hemostasis sheath and at final withdrawal of the diagnostic catheter, respectively. Within 96 hours of the implantation procedure, and before patient discharge, a record was made of the subject's anticoagulation/antiplatelet regimen, relevant medical history, and physical examination as they pertained to venous thromboembolic disease, and the occurrence, treatment, and outcome of any adverse events.

At the investigator's discretion, filter retrieval could be attempted within 175 days ± 3 of implantation in subjects who met all selection criteria for this procedure. These subjects were required to provide written informed consent and had to undergo a preretrieval evaluation. Candidates for retrieval had to have evidence of a patent internal, external, or anterior jugular vein from which the IVC filter could be retrieved. Female subjects of childbearing potential had to have had a negative pregnancy test result within 48 hours of retrieval. In the investigator's opinion, the risks of subsequent clinically significant PE and of the retrieval procedure had to be low. Filter retrieval was not to be attempted if the investigator was unable to pass a catheter to the caudal IVC to obtain a cavogram. In addition, based on venography and the investigator's visual estimate, retrieval was not to be attempted if more than 1 mL of thrombus was present in the filter or persistent thrombus/embolus was present within the caudal vena cava. At the time of the retrieval visit, a record was made of the procedural parameters, the anticoagulation/antiplatelet regimen, relevant medical history, physical examination, and any adverse events. Preprocedural vena cavography was performed to ensure selection criteria were met. Posteroanterior and lateral radiographs were obtained to assess filter migration and tilting. If clinically indicated, a preprocedural ultrasound examination of the bilateral lower extremity veins was performed to assess for DVT. Filter retrieval was performed in accordance with the instructions for use. The recommended retrieval catheter was an 8-F or 10-F Flexor Check-Flo device (Cook, Bloomington, Indiana); recommended endovascular snares included the Amplatz Goose Neck snare (ev3, Plymouth, Minnesota) and the En-Snare device (Angiotech, Gainesville, Florida). The start and end times for filter retrieval were recorded at insertion of the retrieval system and at removal of the retrieval catheter, respectively. During and after retrieval, radiography was used to characterize the device position and IVC.

Follow-up

Retrieved subjects were followed at 30 days ± 7 after retrieval. Permanent filter subjects were followed for 180 days after implantation. Follow-up visits were scheduled at 90 d ± 30 and at 180 d ± 30 after implantation. At each of these visits, a record was made of the subject's anticoagulation/antiplatelet regimen, relevant medical history, physical examination, and any adverse events. In addition, a radiograph was obtained at the 180-day visit to assess filter migration and tilting.

Study Cohort

One hundred subjects underwent filter placement between March 20, 2007, and June 10, 2008. Of these, 36 subjects (retrieved subjects) had their filter successfully retrieved and completed the full 30 days of postretrieval follow-up. No retrieved subjects died, were withdrawn, or were lost to follow-up. Of the 64 subjects who did not undergo retrieval, 17 died of preexisting or intercurrent illness before any attempted retrieval. The remaining 47 subjects (permanent subjects) com-

Table 1
Baseline Characteristics and Medication Use

Characteristic	Retrieved Filter (n = 36)	All Pts. (n = 100)
Sex (M/F)	18/18 (50/50)	52/48 (52/48)
Age (y)	49.5 ± 16.6	59.1 ± 16.7
Weight (lbs)	239.6 ± 92.0	210.3 ± 77.1
Body mass index	37.0 ± 13.3	32.4 ± 10.9
Race		
White	28 (77.8)	83
Black	7 (19.4)	15
Asian	1 (2.8)	2
Medication use ≤ 7 d		
Unfractionated heparin	—	24
Low molecular weight heparin	—	40
Warfarin	—	26
Aspirin	—	18
Thrombolytic	—	3
Clopidogrel	—	1
Ticlopidine	—	0
Other	—	94

Note.—Values in parentheses are percentages. Values are presented as means ± SD where applicable.

pleted the 180 days of follow-up with the filter still in place: 44 completed without a retrieval attempt and three underwent failed attempts at filter retrieval with the result that the filter remained in place. No permanent subjects were lost to follow-up. All 100 subjects (36 retrieved and 64 nonretrieved) formed the safety population for the reporting of demographics, baseline characteristics, and adverse event outcomes. Similarly, these subjects formed the effectiveness population for the reporting of the primary outcome of clinical success. The 39 subjects in whom retrieval was attempted formed the intent-to-treat population for the reporting of the primary outcome of retrieval clinical success. The demographic and baseline characteristics of the study cohort are presented in **Tables 1–3**; indications for filter placement are presented in **Table 4**.

Table 2
Relevant Medical History for the Entire Cohort (n = 100)

Condition	No. of Pts.
Previous lower extremity DVT	39
Previous PE	26
Varicose veins	22
Other venous disease	9
Congestive heart failure	12
Diabetes	30
Renal insufficiency (creatinine ≥ 2 mg/dL)	12
Chronic obstructive pulmonary disease	10
Smoking history	39
Within the past 30 d	11
Gastrointestinal/genitourinary bleeding	16
Prolonged immobilization*	46
Bed rest of ≥ 3 d	42

* Including bed rest of ≥ 3 d, extended travel, paralysis, and limb cast.

Table 3
Current Thromboembolic Disease and Comorbid Conditions for the Entire Cohort (n = 100)

Condition	No. of Pts.
Thromboembolic disease	65
Lower extremity DVT	57
Common femoral vein	30
Femoral vein	24
Popliteal vein	36
Calf vein	28
Iliac vein	9
IVC	2
Other	7
Upper extremity DVT	2*
PE	27
Unilateral and segmental	9
Bilateral and segmental	13
Other	5
Stroke	8
Morbid obesity	20
Hypercoagulability	12
Cancer	32
Trauma	14
Surgery	64
Orthopedic	21
Bariatric	11
Gastrointestinal	8
Spine	5
Intracranial neurosurgery	5
Other	17

* Two subjects presented with upper extremity DVT involving the subclavian (1.0%), axillary (1.0%), cephalic (1.0%), basilic (2.0%), or brachial (2.0%) veins.

Study Endpoints

The Option vena cava filter was evaluated in accordance with the Society of Interventional Radiology (SIR) reporting standards (9,10). The two predefined primary endpoints for this study were clinical success and retrieval clinical success; the latter endpoint is applicable only to retrieved subjects. By definition (**Table 5**), these primary endpoints combined safety and effectiveness outcomes of key interest to the placement of IVC filters. The two effectiveness endpoints were technical success and retrieval technical success. Predefined safety endpoints included the incidence of DVT, filter migration (> 2 cm), filter embolization, symptomatic caval thrombosis, and recurrent PE. The incidence and severity of all other adverse events, including procedural complications (eg, insertion site thrombosis, site infection) that occurred at the times of filter placement and retrieval, were also reported. Adverse events were classified as serious, device-related, procedure-related, medication-related, preexisting condition–related, and/or anticipated. An adverse event was considered serious if that event resulted in death, was life-threatening, required or prolonged hospitalization, resulted in persistent or significant disability/incapacity, or was an important medical event that jeopardized the subject and required medical or surgical intervention. Note that a serious adverse event, as defined earlier, is similar in nature to that of a "major complication" as defined under the SIR clinical practice guidelines classification system (11). An adverse event was considered to be device-related when, in the

Table 4
Indications for Filter Placement

Indication	Attempted Retrieval Cohort (n = 39)	Total Cohort (n = 100)
Thromboembolic disease	10 (25.6)	50 (50.0)
With contraindications to anticoagulant therapy	7 (17.9)	34 (34.0)
Active bleeding	1 (2.6)	5 (5.0)
High risk of bleeding	0	9 (9.0)
Surgery	4 (10.3)	12 (12.0)
Trauma	2 (5.1)	3 (3.0)
Other*	0	5 (5.0)
With complication of anticoagulant therapy (bleeding)	2 (5.1)	9 (9.0)
With failure of anticoagulant therapy	1 (2.6)	7 (7.0)
Thromboembolic disease†	9 (23.1)	15 (15.0)
Also receiving anticoagulant therapy	7 (17.9)	13 (13.0)
Also receiving thrombolytic agent	1 (2.6)	1 (1.0)
Also receiving both	1 (2.6)	1 (1.0)
No thromboembolic disease (prophylactic)	20 (51.3)	35 (35.0)
Surgery	18 (46.2)	28 (28.0)
Trauma	1 (2.6)	2 (2.0)
Other risk factors‡	1 (2.6)	5 (5.0)

Note.—Values in parentheses are percentages.
* One subject had a history of glioblastoma, one had evidence of a floating clot, two presented with an abscess, one had increased creatinine levels.
† Requiring, in the investigator's opinion, additional protection beyond the anticoagulant/thrombolytic therapy they were already receiving.
‡ One subject presented with a fall risk, one had a history of hypercoagulability, one required extra protection while warfarin was discontinued, and two had a background history of thromboembolic disease and received a filter in view of recent bleeding. All had multiple risk factors for the development of thromboembolism including advanced age, cancer, obesity, and a history of DVT or PE.

judgment of the investigator (and further validated by the medical monitor), the clinical event had a reasonable time sequence associated with use of the investigational device, was unlikely to be attributed to concurrent disease or other procedures or medications, and was reasonably caused by the device. In addition to effectiveness and safety outcomes, the following procedural data were collected: mean filter placement time, mean filter retrieval time, and mean fluoroscopy times during both procedures.

Statistical Analysis

Statistical analyses were performed using SAS/STAT software (version 8.2 or higher; SAS, Cary, North Carolina) for Windows (Microsoft, Redmond, Washington). Exact statistical tests were performed and CIs generated with use of StatXact (version 4.0.1; Cytel, Cambridge, Massachusetts). The hypothesis tested in this study was that the one-sided lower limit of the 95% CI for the observed clinical success rate was greater than or equal to 80%. This rate was selected based on a combined total of 20% for the complication thresholds suggested by SIR in 2003 for the five elements that contribute to clinical failure: 3% for technical failure, 5% for subsequent PE, less than 1% for significant filter migration, 10% for IVC occlusion, and 2% for other complications requiring removal or invasive intervention (12). A sample size of 100 subjects was deemed sufficient to test this hypothesis, ie, it was estimated that this sample size would produce a lower limit of greater than 0.80 when the observed proportion of subjects with clinical success was 0.87 or greater (which was the conservative estimate of the expected clinical success rate for this trial).

All statistical summaries and analyses for effectiveness and safety endpoints were performed on the intent-to-treat population as the primary population. The intent-to-treat population was defined as all subjects who met all study selection criteria and had an Option IVC filter inserted into the vasculature. Descriptive statistics were used to summarize all baseline, demographic, and procedural data. Categoric data were summarized as counts and percentages with 95% CIs reported where appropriate. Continuous data were summarized as means and SDs. The primary endpoints of this study, clinical success and retrieval clinical success, were reported as proportions of patients with success; 95% one-sided lower confidence limits for these outcomes were generated by the Clopper–Pearson exact method (13). As part of a post-hoc analysis, clinical success was also reported for the population without definite PE, and for the population with filter-related PE. Effectiveness endpoints (ie, placement technical success and retrieval technical success) were similarly reported as proportions of patients with success; 95% two-sided confidence limits were generated for all secondary endpoints. All retrieval outcomes were reported as the proportion of patients and as relative frequencies. Safety endpoints were reported as the proportion of subjects with at least one report of the adverse event. Device-specific adverse events were summarized with descriptive statistics.

RESULTS

Filter Placement

One hundred filters were implanted—one filter per subject—with a mean filter placement procedure time of 23.6 minutes ± 11.8 (range, 5.0–99.0 minutes) and a mean fluoroscopy time of 3.7 minutes ± 2.6 (range, 0.6–15.1 minutes). The mean IVC diameter was 21.4 mm ± 3.5 (range, 15.3–31.0 mm). Most subjects (n = 97; 97%) had a normal caval anatomy. The three cases of abnormal caval anatomy were not considered exclusion criteria; these included a vena cava described as "tortuous," a vena cava with a slight tilt to the right, and one case of suprarenal caval compression syndrome. During filter placement, the most common sites for vascular access were the right internal jugular vein (n = 63; 63%) and the right common femoral vein (n = 27; 27%); other access sites included

Table 5
Study Endpoint Definitions

Endpoint	Definition
Primary	
Clinical success	Technical success without subsequent PE, significant filter migration or embolization, symptomatic caval thrombosis, or other complication requiring filter removal or invasive intervention
Retrieval clinical success	Retrieval technical success without associated injury or damage to the vena cava requiring intervention or other retrieval-related complication requiring intervention
Effectiveness	
Technical success	Successful deployment of the filter at the intended placement level such that the filter was judged suitable by the investigator for mechanical protection from PE*
Retrieval technical success	Intact filter retrieved via percutaneous techniques from the vasculature
Safety	
Significant filter migration	Change of > 2 cm in filter position within IVC versus immediate postdeployment position, as documented by radiographic or CT imaging
Filter embolization	Postdeployment movement of the filter or a piece of the filter to a nonintended anatomic structure outside the IVC
Symptomatic caval thrombosis	Clinical signs or symptoms of vena caval thrombosis (eg, lower extremity swelling, pain attributed to impeded venous return) are present, and thrombus associated with the filter device is observed on venography or CT imaging or is visually confirmed on surgery or autopsy, occurring after placement of the filter device
DVT	Thrombosis of a deep vein as confirmed by imaging or direct visualization, and characterized as new or progressive
Recurrent PE	Definite PE recurring after filter placement and confirmed by pulmonary angiogram, CT, MR imaging, or pathologic examination of thrombus or probable PE recurring after filter placement and results of a perfusion or ventilation/perfusion lung scan were interpreted a showing a high probability and site of recurrent PE was previously uninvolved or had documentation of resolution

* No significant migration (> 2 cm), no embolization of the filter, no extravascular penetration of the guide or filter device, complete opening of the filter, adequate distribution of the filter mechanism with no additional filters placed, and the filter aligned with the longitudinal axis of the vena cava (within 15° visual estimate by the investigator). Note that a technical failure was considered to have occurred if the filter could not be placed as intended and a second attempt with a different filter was required.

the left common femoral vein (n = 7; 7%) and left internal jugular vein (n = 3; 3%). The filter was deployed and postprocedural imaging was completed in all 100 subjects.

Filter Retrieval

In total, 42 retrieval procedures were attempted in 39 subjects; 36 of these procedures were successful. The mean filter implantation period for the 36 subjects in whom filters were successfully retrieved was 67.1 days ± 50.4 (range, 1–175 d), with 11.1% of filters retrieved between 151 and 175 d after implantation (**Fig 2**). The mean procedure time for successful filter retrievals was 50.1 minutes ± 36.6 (range, 7.0–190.0 minutes), with a mean fluoroscopy time of 15.1 minutes ± 15.0 (range, 1.1–85.1 minutes). The right jugular vein was used in 100% of all retrieval procedures. Retrieval was attempted in 19 of the 65 subjects (29.2%) with evidence of thromboembolic disease; more commonly, it was attempted in subjects who had no evidence of thromboembolic disease with a filter placed for prophylaxis (20 of 35 [57.1%]; **Table 4**). Some subjects had more than one indication for filter retrieval. The two most common indications for attempted filter retrieval were that the subject was no longer thought to be at risk for venous thromboembolism (30 of 39; 76.9%) and/or that the subject was deemed to be in a fully anticoagulated state (21 of 39;

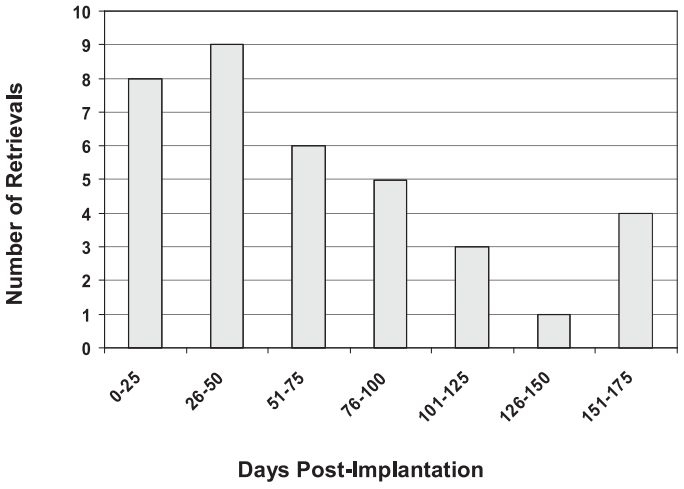

Figure 2. Distribution of subjects by time to retrieval after implantation (n = 36).

53.8%). Three of 39 subjects (7.7%) underwent filter retrieval for reasons classified as "other." One subject with a history of left leg DVT underwent prophylactic filter placement before surgery for replacement of an infected left total knee replacement. Filter retrieval was performed after surgery at the request of the hematologist; the specific indication was not recorded. One subject received a filter before undergoing thrombolysis; the filter was retrieved the next day after completion of the thrombolysis procedure. One young subject who had sustained extensive trauma received a filter for extensive thromboembolic disease with a contraindication to anticoagulation. This subject underwent filter retrieval to minimize the risk of postthrombotic syndrome, after an assessment that the DVT had resolved and the subject was eligible to undergo full anticoagulation.

Thirty-six subjects underwent a single retrieval procedure; two were unsuccessful. In one case, retrieval was attempted at 163 days after implantation. The investigator was unable to dislodge the filter legs from the caval wall, and a decision was made to leave the filter in place. In the other case, at 20 days after implantation, the subject was no longer thought to be at risk for thromboembolism. At that time, multiple attempts at filter retrieval were undertaken with use of different sizes of retrieval snares and approaches. During these various filter manipulations, the filter was pulled caudally 6 cm and three of the right lateral legs were unintentionally inverted. This created a 13° tilt, such that the filter could not be grasped. The filter was left in place without clinical sequelae. No complications were evident at the 180-day follow-up; further follow-up was not performed. Three subjects each underwent two retrieval procedures. In two cases, the filters were successfully retrieved on the second attempts (at days 163 and 175 after implantation). One subject underwent two unsuccessful retrieval attempts (one at 23 d and one at 193 d after implantation), resulting in the decision for the filter to remain in place permanently. In this case, the apex of the filter had become incorporated into the caval wall and could not be separated or snared for retrieval.

Follow-up

Based on the venographic imaging performed before any attempted filter retrieval procedure, none of the 36 subjects who underwent successful retrieval had evidence of filter fracture or filter embolization. At the time of retrieval, no subject demonstrated any evidence of trapped thrombus exceeding 1 mL within the filter on available imaging. For the one subject who had a larger amount of thrombus before attempted retrieval at 14 days after implantation, the intended procedure was discontinued and anticoagulant therapy was initiated; the filter was later removed at 41 days after implantation. Six subjects (16.7%) had venographic evidence of an abnormal vena cava after filter retrieval: three (8.3%) had mild caval stenosis at the implant site in the range of 9%–20% of the total vessel diameter. These events were not considered flow-limiting. One subject (2.8%) exhibited a small residual clot in the IVC at the point that the apex had been in contact with the vena cava, one had a mild irregularity of the left IVC wall, and one had caval stenosis remote from the site of filter placement that was deemed unrelated to the device and either procedure.

All 36 subjects who underwent successful retrieval completed the 30-day (±7 d) postretrieval assessment. The mean follow-up duration was 31.8 days ± 7.9 (range, 15–50 d). During the 30-d postretrieval follow-up period, five subjects (13.9%) presented with a total of eight adverse events. These events included one episode each of constipation, gastritis, urinary tract infection, DVT, contusion, vitamin B12 decrease, peripheral edema, and confusional state. The first four events were judged to be serious; none were judged by the medical monitor to be related to the filter or its placement or retrieval. The case of DVT occurred in the lower extremity contralateral to that used for filter placement and thus was judged to be the result of an intercurrent illness.

Of the 64 nonretrieved subjects (61 without a retrieval attempt, three retrieval failures), 47 completed the 180-day (± 30 d) follow-up and were considered permanent subjects. Permanent subjects were followed up for a mean of 183.8 days ± 22.2 (range, 148–246 d). Seventeen subjects died before completion of the follow-up period.

Technical Success and Clinical Success

Technical success was achieved in 100% of subjects (**Table 6**). The primary endpoint of clinical success was achieved in 88.0% of all subjects with a lower limit of the 95% CI equal to 81%. There were 13 instances of clinical failure in 12 subjects (**Table 7**). These included two reports of minor filter migration (both 23 mm), eight reports of an episode of PE after filter placement, and three reports of symptomatic caval occlusion/thrombosis (one of these occurred in a subject for whom minor filter migration was also reported; see *Overall Safety and Predefined Safety Outcomes* for further details). Of the cases of PE, six were judged to be definite cases and two were deemed to be probable (see footnote in **Table 7** for definitions). Four episodes of definite PE were judged to be related to the filter (4%). When only the definite cases of PE were included in the assessment of clinical failure, the clinical success rate was calculated to be 90.0%; when only definite cases of PE that were determined to be filter-related were included in the assessment of clinical failure, the clinical success rate reached 92.0%.

Retrieval Technical Success and Retrieval Clinical Success

A total of 39 subjects underwent 42 attempted retrieval procedures. Retrieval technical success was achieved in 36 of the 42 procedures (85.7%), and in 36 of 39 subjects (92.3%) in whom retrieval was attempted, with a lower limit of 81% (**Table 6**). Six separate retrieval attempts in five subjects were unsuccessful; filter retrieval was ultimately unsuccessful in only three subjects (see *Filter Retrieval* for a brief review of each case). Retrieval clinical success was achieved in the same number of procedures and in the same number of subjects as retrieval technical success. All six attempts that were classified as retrieval clinical failure were the result of retrieval technical failure. No retrieval attempts resulted in caval injury or complications requiring medical intervention.

Table 6
Effectiveness Endpoints: Placement and Retrieval Success

Endpoint	Retrieved (n = 36)		Not Retrieved (n = 64)		All (n = 100)	
	n (%)	95% CI‡	n (%)	95% CI‡	n (%)	95% CI‡
Placement						
Technical success	36 (100.0)	90–100	64 (100.0)	94–100	100 (100)	96–100
Clinical success*	33 (91.7)	80	55 (85.9)	77	88 (88)	81
Clinical success without definite PE	33 (91.7)	80	57 (89.1)	80	90 (90)	84
Clinical success without definite filter-related PE	33 (91.7)	80	59 (92.2)	84	92 (92)	86
Retrieval†						
Technical success by procedure	36/42 (85.7)	71–95	—	—	—	—
Technical success by patient	36/39 (92.3)	79–98	—	—	—	—
Clinical success by procedure	36/42 (85.7)	74	—	—	—	—
Clinical success by patient*	36/39 (92.3)	81	—	—	—	—

* Primary study endpoint.
† For all retrieval attempts and all subjects in whom retrieval was attempted.
‡ One-sided lower limit of the 95% CI, calculated by the Clopper–Pearson exact method, are reported for the primary endpoints of clinical success and retrieval clinical success, and two-sided 95% CIs are reported for all secondary endpoints.

Table 7
Predefined Safety Endpoints (n = 100)

Endpoint	Cases (95% CI)	Device-related
Death	17	0
Filter migration*	2 (0–7)	2
Filter embolization*	0 (0–4)	0
All caval occlusion/thrombosis	9	5
Symptomatic caval occlusion*	3 (1–9)	2
Asymptomatic caval occlusion	1	1
Symptomatic caval thrombus†	0	0
Asymptomatic caval thrombus†	5	2
DVT	18 (11–27)	0
Recurrent PE*‡	8 (4–15)	6
Complication requiring filter removal or invasive intervention*	0 (0–4)	0

* Events impacting the primary endpoint, clinical success, in which one case of filter migration occurred in a subject who also experienced symptomatic caval occlusion.
† Without complete occlusion.
‡ Four cases of recurrent PE were judged to be definitely related to the study device; two were judged to be probably related. Definite recurrent PE was defined as occurring after filter placement and confirmed via pulmonary angiogram with constant intraluminal filing defect in pulmonary artery, positive CT or MR imaging in a high-quality image study, or pathologic examination of thrombus removed at surgery or autopsy; and site or recurrent PE was previously uninvolved or had document of resolution. "Probable" recurrent PE was used in situations in which testing for definite level of recurrence was not performed or results were indeterminate, results of a perfusion or ventilation/perfusion lung scan were interpreted as showing a high probability, and the site of PE was previously uninvolved or had documentation of resolution.

Overall Safety and Predefined Safety Outcomes

Throughout the course of this study, 76 subjects (76%) experienced a total of 360 adverse events; 65 (65%) presented with 233 events determined to be serious. Most subjects (n = 73; 73%) presented with events that were determined to be unrelated to the filter device or its placement or retrieval. Most commonly, subjects presented with events that were associated with preexisting (42%) and/or intercurrent conditions (60%). No adverse events occurred that were determined to be unanticipated device effects. Seventeen deaths occurred (Table 7); none were judged to be related to the filter or its placement or retrieval. Fifteen deaths were determined to be related to a preexisting condition: 13 were related to a preexisting history of cancer, one was from systemic lupus erythematosus, and one was from pneumonia with chronic obstructive pulmonary disease, coronary artery disease, and diverticulitis listed as conditions that may have contributed to death. Two deaths were determined to be related to an intercurrent condition. Of these, one subject with several comorbidities (chronic PE, aspiration pneumonia, congestive heart failure, diabetes mellitus, previous myocardial infarction, hypertension, and azotemia) was originally hospitalized with a primary diagnosis of pulseless electrical activity that was attributed to aspiration pneumonia. The death was ultimately adjudicated by the medical monitor to be a result of pulseless electrical activity. The second death occurred in a subject who had a history of recent hemiparesis caused by hemorrhagic stroke; the subject died 65 days after filter implantation from a cerebrovascular accident.

Of the other predefined safety outcomes (Table 7), there were no incidents of filter embolization (0%). Filter migration was observed in two sub-

jects (2%); in both cases, the degree of migration was 23 mm. In one case, the entire infrarenal cava was observed to be occluded at the 180-day follow-up visit. In this subject, extensive caval thrombus was present before filter placement. The investigator noted that caval occlusion had produced a decrease in caval diameter, with subsequent caval contraction, resulting in caudad filter movement. The second case was one of cephalad filter migration that occurred in a morbidly obese subject with a body mass index of 66.3 who received a filter before bariatric surgery. The subject, who had achieved a significant weight loss between the time of filter placement and attempted retrieval, did not exhibit any clinical sequelae and the investigator determined the event to be an incidental finding. Three subjects (3%) experienced symptomatic caval occlusion, which were considered primary endpoint events. Symptoms included leg pain and swelling. All had a history of thromboembolic disease with caval thrombus reflecting a progression of DVT from the lower extremities. Eight subjects (8.0%) presented with eight episodes of recurrent PE after filter placement. None of these episodes were associated with caval penetration or filter migration, fracture, or tilt in excess of 15°. No PE events resulted in death. Of the eight cases, six were adjudicated by the medical monitor to be episodes of definite recurrent PE: four were determined to be definitely related to the device, one was attributed to an intercurrent condition (a sequence of progressive venous thromboembolic events associated with a hypercoagulable state), and one was attributed to the placement procedure (during placement, access had occurred through the right common femoral vein adjacent to existing thrombus such that placement may have disrupted chronic thrombus, resulting in caval thrombosis and subsequent PE). In all four cases adjudicated to be device-related, the source of the embolism was determined to occur at or below the level of the filter such that a relationship to the filter could not be ruled out. The two remaining cases were judged to be probable recurrent PE, possibly related to the filter. In one case, the subject was diagnosed with possible PE based on a 3-day episode of hypertension and sinus tachycardia, presenting with a systolic blood pressure between 120 and 160 mm Hg and sinus tachycardia in the range of 90–120 bpm in the absence of hypoxia. In this case, the managing physician decided that objective imaging of PE was unnecessary as it would not have influenced the patient's current therapeutic regimen. In the other case, the subject presented with hypoattenuation on chest computed tomography (CT) scan in one upper lobe branch of the pulmonary artery; the interpreting radiologist reported that this hypoattenuation could possibly represent a PE. In both cases, there was a lack of diagnostic evidence to support a definitive diagnosis. Therefore, the rate of new unequivocal PE judged to be related to the filter was 4%. Seventeen subjects presented with 18 episodes of DVT after filter placement. One subject underwent catheter-directed lytic therapy for DVT in the left and right lower extremity, which was reported as two separate episodes of DVT. All 17 subjects had a history of thromboembolic disease; 11 presented with active disease at the time of enrollment. Eight of the 17 subjects had DVT judged to be related to a preexisting condition, eight were judged to be caused by an intercurrent condition, and one was judged to be a result of an intercurrent intervention. None were judged to be related to the filter or its placement or retrieval.

Device- or Procedure-related and Serious Adverse Events

Sixteen subjects (16%) presented with a total of 19 events that were determined to be related to the filter or its placement or retrieval. Within this cohort, 13 subjects (13%) presented with 16 events classified as serious. Of the 16 subjects, 11 presented with 13 events that were judged to be related to the device (all were classified as serious), three presented with four events related to the placement procedure, one presented with one event related to the retrieval procedure, and one presented with an adverse event related to an ancillary device. There were no retrieval device–related events. Of the 13 filter-related events (**Table 7**), there were two cases of filter migration (described earlier). Five subjects presented with caval thrombosis or occlusion determined to be related to the filter: two cases of asymptomatic caval thrombosis without complete occlusion and three cases of caval occlusion (one asymptomatic and two symptomatic, one of these in a patient who also experienced device-related filter migration). In four of these five cases, caval occlusion/thrombosis was thought to be the result of thrombus progression from the lower extremity to the site of filter placement. In all four cases, the filter was left in place as a permanent device and no invasive intervention was performed. However, because of the location of the thrombus, a causal relationship to the filter could not be completely excluded and, as a result, the medical monitor subsequently adjudicated these cases to be device-related. In the fifth case, the subject had no baseline history of thromboembolic disease and received a filter as a prophylactic measure. Seventy-six days after placement, the subject had had no evidence of any new or progressive PE or DVT, was thought to no longer be at risk for thromboembolism, and underwent filter retrieval. At that time, the subject presented with a 1.9-mm penetration of a filter leg outside the caval wall and a minimal filling defect at the apex of the filter as detected on venography and judged by the investigator to be compatible with a small thrombus. At the 30-day postretrieval assessment, all events had resolved, there was no evidence of new or progressive DVT or PE, and the subject was receiving any prophylactic regimen for DVT. Six subjects presented with PE determined to be definitely or possibly related to the filter; one of these also had asymptomatic caval occlusion. In all cases, the source of the embolism was determined to be at or below the level of the filter such that a causal relationship to the filter could not be ruled out.

The three subjects who experienced placement procedure–related events included one case of small intramuscular bleeding at the placement access site occurring the day after the procedure. No action was required. Two subjects presented with three placement procedure–related events classified as serious. One subject exhibited bilateral PE and thrombus within the filter at imaging 4 days after implantation, regarding which the medical monitor determined that the place-

ment procedure may have disrupted chronic thrombus resulting in caval thrombosis and PE. One subject with a history of metastatic cancer and hypercoagulopathy manifested extensive thrombus progression from the lower extremity to the superior vena cava. This case was judged to be possibly related to the placement procedure. The one subject who experienced a retrieval procedure–related event had had the right carotid artery inadvertently accessed during the retrieval procedure. In this case, manual pressure was applied and the event resolved without further incident. The event did not meet the definition of serious.

Other Safety Outcomes: Device Retrieval Observations

A number of device retrieval observations were reported that did not directly affect the primary endpoint of retrieval clinical success or the effectiveness endpoint of retrieval technical success. Difficulty snaring the filter hook was reported for 12 of the 39 subjects in whom it was attempted (30.8%); filter retrieval was ultimately unsuccessful in only three subjects. Difficulty disengaging struts from the caval wall was reported for five subjects (12.8%); none of these subjects experienced clinical sequelae and filters were successfully retrieved in four of the five cases. Difficulty sheathing the filter struts was reported for five subjects (12.8%); retrieval success was ultimately achieved in all cases. Crossed filter struts after implantation were reported for one subject (2.6%); there was no evidence of crossed struts at the time that the filter was successfully retrieved. At the time of retrieval, filter tilt of 15° or greater was reported for three of 39 subjects (7.7%); the filter was successfully retrieved in all cases. In one subject, the filter was tilted to the left and posterior direction. The second subject presented with filter tilt toward the left lateral wall of the IVC. The filter apex was cannulated with a guide wire and the filter was subsequently snared and retrieved. In the third subject, the filter was tilted toward the left lateral wall, with the hook adjacent to the wall. Two snares were used to retrieve the filter: one to straighten the device by applying pressure to one of the filter legs, and the second to hook the device. In addition, in one subject who had previously undergone an unsuccessful filter retrieval attempt, there was apparent caval penetration of greater than 3 mm demonstrated by venography at the time of the second (successful) retrieval procedure, with extension of two filter struts beyond the apparent lumen of the IVC. Caval penetration, which was thought to be a result of filter manipulation during the first retrieval attempt, was not confirmed by cross-sectional imaging.

DISCUSSION

The data from this study met the primary objective to test the hypothesis that the one-sided lower limit of the 95% CI for the observed clinical success with the filter was greater than or equal to 80%. In this study, clinical success was achieved in 88% of subjects, with a one-sided lower limit of the 95% CI exactly equal to 81%. The definition of clinical success that was used in this study—technical success without subsequent PE, significant filter migration or embolization, symptomatic caval thrombosis, or other complication requiring filter removal or invasive intervention—conformed to the reporting standard recommended by the participants in the Vena Cava Filter Consensus Conference (10). Despite the recommendation made in 2003, this composite endpoint does not appear to have been widely adopted. More commonly, the individual elements of the definition are reported, ie, technical success or failure rates and incidence of specific complications. Results of our study compare favorably when interpreted within the framework of published literature for these endpoints, summarized in various comprehensive reviews (1,9,14–16) (**Table 8**) (9,16). It should be noted that there is a lack of level I evidence for IVC filters and that most publications in this field report retrospectively collected data of filter use, often from a single investigational site (10).

The first element of clinical success, technical success, was achieved in 100% of subjects in our study, a result that meets the 97% threshold suggested by the SIR Standards of Practice Committee (9). In contrast, placement failure rates as high as 4.6% have been reported for some filters (16).

In our study, only four cases (4%) of definite recurrent PE were judged by the medical monitor to be related to the filter, a rate within the 5% threshold suggested by the SIR Committee (9) and within the range of 0%–6.0% commonly reported in the literature for various other filter designs, including retrievable filters (1,9,14–17). Although the suggested threshold was set at 5%, it is well recognized that the actual rate of PE may be higher than those generally reported because many studies report only rates of symptomatic definite PE confirmed on imaging, with "probable" incidents left unreported. In our study, two additional patients who experienced symptoms of recurrent PE lacked sufficient imaging to support a diagnosis of definite PE. These were the only two cases in our study categorized as "probable"; they were also judged to be filter-related, leading to a rate of 6% for all filter-related PE. It should be noted that this study was designed to look for clinically significant PE events. Neither CT angiography nor pulmonary arteriography was routinely performed after filter deployment; rather, these procedures were performed only when there was a clinical indication to do so. As a result, subclinical PE could have been missed in the present study. It is noteworthy that the clinical success rate of 88% in the present study was achieved in a population of subjects with numerous comorbidities: 32% of subjects had a history of malignancy and 46% were obese, both of which have been documented as significant risk factors for the development of various comorbidities including PE (14,18,19).

Other complications of interest to the primary endpoint in our study included two minor reports of filter migration of 23 mm (2%), no reports of filter embolization (0%), three reports of symptomatic caval occlusion (3%), and no incidents of complications requiring filter removal or invasive intervention (0%; **Table 8**). All were within the suggested threshold and/or within the upper limits reported in the literature (9,16). Although there is no established threshold for filter migration and the incidence of clinically significant migration is thought to be low, reports for other IVC devices have

Table 8
Elements of Clinical Success and Other Outcomes of Interest: Comparative Data (9,16)

Outcome	Option IVC Filter Study (%)	Suggested Threshold (%)*	Reports in the Literature	
			Incidence (%)	Study†
Elements of clinical success				
Technical placement success	100	97	1.1−4.6	Chung and Owen, 2008 (16)
Placement failure	0			
Recurrent PE	4 Definite and device-related	5	0.5−6	Grassi et al, 2003 (9)
			0−6.2 (Permanent), 0−1.9 (Retrievable)	Chung and Owen, 2008 (16)
Filter migration	2	NS	0−18	Grassi et al, 2003 (9)
			1−3	Chung and Owen, 2008 (16)
Filter embolization	0	2	2−5	Grassi et al, 2003 (9)
IVC thrombus	5 (All asymptomatic)	NS	3.1−11.4 (Filter thrombus)	Chung and Owen, 2008 (16)
IVC occlusion	3 Symptomatic, 1 asymptomatic	10	2−30	Grassi et al, 2003 (9)
			0.6−6.7	Chung and Owen, 2008 (16)
Other outcomes of interest				
Death, device-related	0	0.12	< 1	Grassi et al, 2003 (9)
DVT	18 (none device-related)	NS	3.1−44	Chung and Owen, 2008 (16)
Access site thrombosis	0	1 (Major)	0−6 (Major only)	Grassi et al, 2003 (9)
			3.8−4.2	Chung and Owen, 2008 (16)
Filter fracture	0	NS	2−10	Grassi et al, 2003 (9)
			0	Chung and Owen, 2008 (16)
IVC wall penetration	2.9‡	NS	0−41	Grassi et al, 2003 (9)
			0	Chung and Owen, 2008 (16)

Note.—NS = not specified.
* As recommended by Grassi et al (9) to the SIR Standards of Practice Committee.
† The 2003 review by Grassi et al (9) primarily summarizes data reported from studies published before 2000; the 2008 review by Chung and Owen (16) summarizes data reported from 17 studies (six of permanent filters, 11 of retrievable filters) published between 2000 and 2006.
‡ One suspected case among 39 attempted retrievals.

ranged from 0% to 18% (9). The reported incidence of filter migration (1%–3%) has been much lower among studies published since 2000 (16). In the case of filter embolization, the suggested threshold was set at 2%, with reports in the literature ranging from 2% to 5% (12). Regarding symptomatic caval occlusion, the suggested threshold was set at 10%, with reports in the literature ranging as high as 30% (9,16). In addition, each of the three cases of caval occlusion in the present study was believed to represent a progression of DVT to the level of the filter, and did not reflect a new event. It should be noted that, although two of these cases were adjudicated by the medical monitor to be device-related, this was a conservative assessment reflective of the fact that a causal relationship to the filter could not be completely excluded. Based on these results and placed in the context of the published data, the retrievable Option IVC filter exhibited an excellent safety profile for these complications. In addition, there were no filter fractures, no device- or procedure-related deaths or DVT diagnoses, and no access site thromboses. And even though there was one case of suspected IVC wall penetration (of approximately 3 mm) in the present study, this too was at the low end of the range reported with other devices (9).

Retrieval clinical success was achieved in 92.3% of subjects in whom it was attempted. The mean filter implant period was 67 days and successful retrieval was achieved as long as 175 days after placement. Although some difficulties were reported in attempting to retrieve the filter—most commonly, difficulty snaring the hook—various manipulations were used successfully in all but three cases to retrieve the filter. Of note, filters were successfully retrieved in all three subjects in our study for whom a filter tilt of greater than 15° was reported. Because of the nature of clinical trials, filter retrieval in the present study was attempted in all subjects for whom it was indicated. However, outside of this setting, many patients who may be eligible for filter retrieval never return to have their filter removed. In this way, any benefit is lost that may have been achieved through temporary placement and the avoidance of long-term complications. It is incumbent on the interventional radiologist to arrange for follow-up of these cases.

Finally, this study was conducted at multiple sites and was prospectively designed. Nonetheless, interpretation of these results is limited by the lack of a randomized, controlled, blinded design that would have provided more rigorous level I clinical evidence of the safety, effectiveness, and retrievability of the IVC filter under investigation.

In summary, in this population of 100 subjects at risk for PE, placement and retrieval (at a maximum of 175 days) of the Option IVC filter was performed with clinical success, within

the effectiveness and safety thresholds suggested by SIR, and with complication rates well within the limits of safety profiles reported for similarly marketed devices.

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References

1. Kinney TB. Update on inferior vena cava filters. J Vasc Interv Radiol 2003; 14:425–440.
2. Kaufman JA, Kinney TB, Streiff MB, et al. Guidelines for the use of retrievable and convertible vena cava filters: report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. J Vasc Interv Radiol 2006; 17:449–459.
3. Kearon C, Kahn SR, Agnelli G, Goldhaber S, Raskob GE, Comerota AJ. Antithrombotic therapy for venous thromboembolic disease. American College of Chest Physicians evidence-based clinical practice guidelines (8th edition). Chest 2008; 133(suppl):454S–545S.
4. Decousus H, Leizorovicz A, Parent F, et al. A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients with proximal deep-vein thrombosis. N Engl J Med 1998; 338:409–415.
5. PREPIC Study Group. Eight-year follow-up of patients with permanent vena cava filters in the prevention of pulmonary embolism: the PREPIC (Prévention du Risque d'Embolie Pulmonaire par Interruption Cave) randomized study. Circulation 2005; 112; 416–422.
6. Segal JB, Streiff MB, Hofmann LV, Thornton K, Bass EB. Management of venous thromboembolism: a systematic review for a practice guideline. Ann Intern Med 2007; 146:211–222.
7. Kaufman JA. Optional vena cava filters: what, why, and when. Vascular 2007; 15:304–313.
8. Kaufman JA, Rundback JH, Kee ST, et al. Development of a research agenda for inferior vena cava filters: proceedings from a multidisciplinary research consensus panel. J Vasc Interv Radiol 2009; 20:697–707.
9. Participants in the Vena Caval Filter Consensus Conference. Recommended reporting standards for vena caval filter placement and patient follow-up. J Vasc Interv Radiol 2003; 14(Suppl):S427–S432.
10. Millward SF, Grassi CJ, Kinney TB, et al., for the Technology Assessment Committee of the Society of Interventional Radiology. Reporting standards for inferior vena caval filter placement and patient follow-up: supplement for temporary and retrievable/optional filters. J Vasc Interv Radiol 2005; 16: 441–443.
11. Sacks D, McClenny TE, Cardella JF, Lewis CA. Society of Interventional Radiology Clinical Practice Guidelines. Introduction. J Vasc Interv Radiol 2003; 14(Suppl):S199–S202.
12. Grassi CJ, Swan TL, Cardella JF, et al., for the Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for percutaneous permanent inferior vena cava filter placement for the prevention of pulmonary embolism. J Vasc Interv Radiol 2003; 14(Suppl):S271–S275.
13. Clopper CJ, Pearson ES. The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika 1934; 26:404–413.
14. Streiff MB. Vena caval filters: a review for intensive care specialists. J Intens Care Med 2003; 18:59–79.
15. Patel SH, Patel R. Inferior vena cava filters for recurrent thrombosis: current evidence. Tex Heart Inst J 2007; 34:187–194.
16. Chung J, Owen RJT. Using inferior vena cava filters to prevent pulmonary embolism. Can Fam Physician 2008; 54: 49–55.
17. Kim HS, Young MJ, Narayan AK, Hong K, Liddell RP, Streiff MB. A comparison of clinical outcomes with retrievable and permanent inferior vena cava filters. J Vasc Interv Radiol 2008; 19:393–399.
18. Memtsoudis SG, Besculides MC, Gaber L, et al. Risk factors for pulmonary embolism after hip and knee arthroplasty: a population-based study. Int Orthop 2008; 33:1739–1745.
19. Cushman M. Epidemiology and risk factors for venous thrombosis. Semin Hematol 2007; 44:62–69.