Long-Term Inferior Vena Cava Filter Retrieval

A look at the feasibility of long-term retrieval and a case in which the Option filter was removed after 1,184 days.

BY JAMES F. McGUCKIN, MD

Venous thromboembolic disease is a major cause of mortality in the United States, with pulmonary embolism (PE) being the most severe complication of the disease. PE has been reported to result in as many as 240,000 deaths per year. The primary means of prevention and therapy for venous thromboembolism (VTE) is pharmacologic, including a regimen of anticoagulant agents. Although anticoagulants can be effective for treating VTE, in patients with deep vein thrombosis (DVT) or PE in which anticoagulants are contraindicated or there are complications, recurrent PE, or failure of anticoagulants, the use of an inferior vena cava (IVC) filter is recommended as an alternative treatment. In addition to these traditional indications for IVC filter placement, patients who are at high risk for developing PE may have a prophylactic indication for IVC filter placement.

RETRIEVABLE IVC FILTERS

There are a number of situations in which it may be desirable for a physician to remove an IVC filter once implanted. The risk of PE may be relatively short-term, thus the need for the filter is required for only a short period of time. The seminal Decousus article clearly showed that the advantage of continued IVC filtration decreased versus nonfiltration after the initial risk of PE had passed 2 years after implantation.[1] The removable filter era began in 2003, and there are now several such devices approved for use in the United States. Filters are approved for safe retrieval based on a range of days postimplantation within their Instructions for Use granted upon US Food and Drug Administration (FDA) approval.

The longest labeled explantation data are as follows: Günther Tulip (Cook Medical, Bloomington, IN), 20 days; OptEase (Cordis Corporation, Bridgewater, NJ), 23 days; G2 (Bard Peripheral Vascular, Tempe, AZ), 300 days; Celect (Cook Medical), 365 days. The longest explantation data recorded in the literature for these devices are: Günther Tulip, 494 days; OptEase, 59 days; G2, 1,463 days; Celect, 466 days; and ALN (ALN Implants Chirurgicaux, Ghisonaccia, France), 722 days.

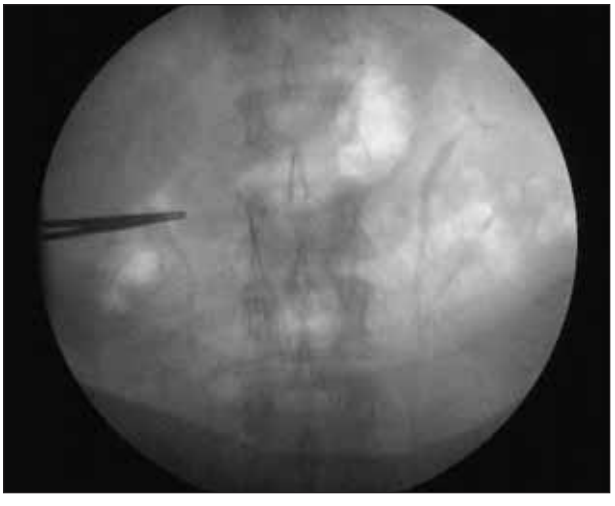

Figure 1. Postplacement fluoroscopic image.

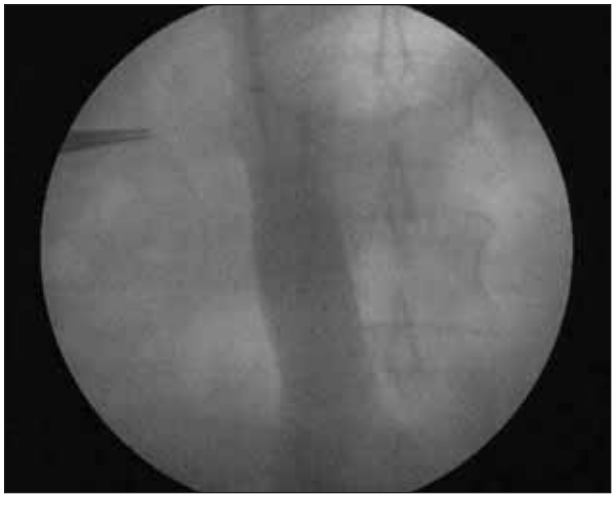

Figure 2. Postplacement IVC cavogram.

We believe that long-term retrieval reviews are of interest in the literature because they explore outcomes for potential clinical applications that were not directly studied during the FDA-approval process. This article discusses the successful removal of the Option IVC filter (Angiotech [designed by Rex Medical], Vancouver, BC, Canada) at 1,184 days after initial implantation.

Figure 3. Preretrieval IVC cavogram: 1,184 days after implantation.

Figure 4. Postretrieval IVC cavogram without evidence of mural injury or extravasation after successful Option filter retrieval.

The Option IVC Filter

The Option IVC Filter was simultaneously approved by the FDA for permanent and retrievable indications. The filter has a bell-shaped, three-dimensional configuration with parallel struts that are designed to add a centering capability. The Option's retention hooks are laser cut from the nitinol hypotube and have a talon-like configuration. When released from the delivery system, the hooks rotate out radially to engage the caval wall. This radial rotation of the retention hooks with a fixed, nonflexible "ankle" provide stability for the filter, and a nested retrieval hook at the apex allows for delivery through a 6.5-F delivery system. The curved delivery system is designed to allow the interventionist to keep the retrieval apex in the center of the lumen.

The Option first-in-human pilot study was performed in Paraguay from September 2006 to May 2007, and the United States multicenter Option Investigational Device Exemption (IDE) FDA trial was performed under the direction of Matthew Johnson, MD, at Indiana University. At the completion of the pilot study in Paraguay, there had been three filters removed after 1 year of placement, with the longest being at 367 days. In the 100-patient prospective IDE trial, the caval patency was 97% (97 of 100), the retrieval success rate was 92% (36 of 39), and the range of retrievals was from 1 to 175 days (mean, 67 d).

Prior to the case described in this article, the longest Option explantations to date were two retrievals at 366 days and at 367 days. There has been no evidence of extravasation, dissection, or caval trauma to any patients in the first-in-human or Option IDE trials throughout the entire explantation aspects of either phases of study.

Case Report

A 55-year-old woman with a history of morbid obesity, chronic obstructive pulmonary disease, DVT, and venous insufficiency presented with recent lower extremity fracture. She was also high risk for further DVT, and an Option filter was placed via the right internal jugular vein in a 20-mm cava with the apex at the level of the renal veins in the infrarenal IVC (Figures 1 and 2). The patient did well postprocedurally and was followed per study protocol. She had no clinical evidence of complications related to the filter and returned for annual radiographic follow-up visits, confirming no evidence of filter migration. At her 3-year follow-up visit, she requested that her filter be removed electively; she had no evidence of DVT on her lower extremity Doppler study, and she was ambulatory. After obtaining informed consent, we attempted the removal.

Via the right internal jugular approach, an 8-F, 90-cm braided Raabe sheath (Cook Medical) was placed, and a cavogram was obtained in anteroposterior and bilateral oblique projections using a measuring pigtail catheter. The Option filter was widely patent without evidence of migration or fracture, and the apex was confirmed to be centered within the lumen (Figure 3). After the retrieval hook was snared using an Ensnare (Merit Medical, South Jordan, UT), the braided sheath was advanced caudally via the jugular approach to encircle and gather the vertical filter struts. This "sheath-down" technique allows the radial hooks to rotate back into their original en face position. There is typically a 1- to 2-cm "incorporation zone" that represents the residual fibrous overgrowth over the retention hooks at the inferior aspect of the centering struts noted on fluoroscopy during retrieval.

The Option filter was then removed from the caval wall in the cephalad direction using a tug of approximately 5 ft/lb of force. The sheath-down maneuver was then completed with the retention hooks rotating back into their en face position, and the filter was brought completely within the retrieval sheath and removed

from the patient intact. The postretrieval cavogram showed no caval injury or spasm (Figure 4).

The procedure was performed using only local lidocaine at the neck. The patient admitted to feeling a tug on her abdomen and related a brief discomfort that resolved immediately. She rated the discomfort as a 3 out of 5 and had no pain after the filter was removed from the caval wall.

The filter was successfully removed after 1,184 days of implantation. The patient has had no postretrieval complications. This retrieval is the longest explantation of an Option filter to date.

DISCUSSION

The Option IVC filter has FDA clearance as both a retrievable and a permanent filter. However, the FDA recommends that physicians of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed.[2] The design of the Option filter permits extreme long-term retrievability on par with other multiyear explants in cases for which earlier retrieval was not possible for one reason or another. There was no difference in the force required to explant the Option filter between 367 days and 1,184 days. This 3.2-year retrieval of the Option filter suggests that long-term explantation success at this duration does not necessarily require sacrifice in filter design to prevent filter migration and maintain structural integrity, caval patency, and long-term retrievability. ■

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1. 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. Prévention du Risque d'Embolie Pulmonaire par Interruption Cave Study Group. N Engl J Med. 1998;338:409-415.
2. US Food and Drug Administration. Removing retrievable inferior vena cava filters: initial communication. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm221676.htm. Published August 09, 2010. Accessed September 8, 2010.