Retrievable Filter Update: The Denali Vena Cava Filter

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Abstract

Keywords

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- filter tilt
- strut perforation

Over the past decade, there has been a gradual evolution of the retrievable inferior vena cava (IVC) filter, as the indications for caval filtration have expanded since the first such filters came into use. However, the particular design of retrievable or optional filters has introduced a subset of both symptomatic and asymptomatic device failures that have prompted a reassessment in the approach to patient selection as well as a new lexicon of technical considerations when considering retrieval. The Denali Vena Cava Filter (Bard Peripheral Vascular, Inc., Tempe, AZ) represents one of the latest filters to come to market that specifically addresses the various issues of its predecessors. While the body of published experience with this filter is still relatively sparse, the incidence of filter tilt, strut perforation, strut fracture, and filter migration appears acceptably low and the filters remain relatively easy to retrieve even after long dwell times.

Objectives: Upon completion of this article, the reader will be able to (1) discuss the potential complications of retrievable IVC filters; (2) describe the Bard Denali IVC filter; and (3) define the technical challenges when attempting to retrieve IVC filters that have tilted or penetrated the caval wall.

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The advent of the retrievable inferior vena cava (IVC) filter was born out of the necessity to provide temporary caval filtration in patients who had significant risk for pulmonary embolism (PE) but were simultaneously at risk for the long-term complications of having a filter. The first such commercially

available filter in the United States was the Gunther Tulip filter (Cook, Bloomington, IN). It was first used in Europe as early as 1992 but did not become commercially available in the United States until its launch in 2003. It had a retrieval window of 14 days as recommended by the manufacturer. The filter was followed by the launch of the OptEase filter (Cordis, Miami Lakes, FL), which had a slightly longer recommended retrieval window of 23 days. Since then, the retrieval windows have significantly expanded as have the number of retrievable or optional filters approved for use by the U.S. Food and Drug Administration (FDA). As of 2015, there are currently nine optional filters available for use. This article will focus on the Denali Vena Cava Filter (Bard Peripheral Vascular, Inc., Tempe, AZ), which was approved by the FDA and launched for use in 2013.

Denali Filter

The Denali filter represents a redesign of the Eclipse filter (Bard Peripheral Vascular, Inc.), which received FDA clearance in June 2010. The new filter design incorporates electropolished cranial and caudal anchors as well as penetration limiters. The Denali is a conical filter composed of 12 shape-memory struts laser cut from a single piece of nitinol

(nickel-titanium alloy) (►Fig. 1). The 12 struts are divided into 6 upper and lower filter arms to provide two levels of embolic filtration. The cranial and caudal anchors are located at the base of the six lower filter arms and are designed to resist superior and inferior migration as well as provide points for incorporation into the caval wall should the filter be left in permanently. The filter length is 50 mm, similar to other optional filters on the market, and has an indicated maximal filter diameter of 28 mm, per the manufacturer's indications for use.¹ The retrieval hook is located at the filter apex, and also cut from the same piece of nitinol as the filter; this is in contrast to hooks that are welded to the filter, as seen in other apical hook designs (►Fig. 1).

The delivery system is packaged in jugular and femoral access kits. Both the jugular and femoral systems have an 8.4F inner diameter, are 55 cm long, and intended for use with a 0.035-inch guidewire. The kits also contain 8 and 10F dilators, an introducer sheath, a pusher, and the filter contained within a clear plastic storage tube.

Filter Performance Testing and the Denali Trial

Prior to commercial release, in vivo testing consisted of two good laboratory practice compliant animal studies to assess both the filter itself and the delivery system. The studies were

Fig. 1 The Bard Denali vena cava filter. Cranial and caudal anchors are at the base of the six lower filter arms to resist migration. The six upper filter arms are double curved inward to keep the filter centered as well as resist caval perforation. (Images used with permission from C. R. Bard, Inc., Bard and Denali trademarks, and/or registered trademarks of C. R. Bard, Inc.).

conducted by C. R. Bard using ovine animal models, testing 12 filter retrievals following implantation periods of 4 and 12 weeks. The primary objectives were to evaluate ease of retrieval as assessed by a clinical evaluator, and for caval wall damage as assessed by venography, gross evaluation, and histopathology.²

Clinical testing was performed through the DENALI Trial (ID code NCT01305564, clinicaltrials.gov), an industry-sponsored, prospective, multicenter, nonrandomized, single-arm study conducted at 21 centers in the United States. The primary objectives of this safety and efficacy trial were to evaluate technical and clinical success of filter placement and retrieval. A total of 200 patients were enrolled in the study, of whom 114 patients underwent screening for filter removal. Three of these patients had removal deferred due to the presence of thrombus in the filter on venography, resulting in 111 retrieval attempts. There were 108 successful retrievals, representing a technical retrieval success rate of 97.3%. The mean dwell time of the 108 successfully retrieved filters was 165 days, with a range of 5 to 632 days. The findings were published by Stavropoulos et al.³

Filter Deployment

The dilator in the introducer sheath contains multiple side holes and can be attached to a power injector for injection up to 800 psi, allowing it to be used as the flush catheter for the initial cavagram after sheath placement.¹ In addition, there are two radiopaque marker bands located at the end of the dilator, spaced at an outer-to-outer distance of 28 mm that can be used for caval diameter measurements. The pusher is used to advance the filter through the introducer sheath to a predeployment marker on the pusher itself. At this point, the filter is located at the edge of the introducer sheath. Deployment is a "pin-pull" maneuver similar to other filter deployment designs in which the pusher and filter are stabilized or pinned, while pulling back the sheath, uncovering, and releasing the filter (►Fig. 2a,b). The six upper filter arms are shaped in an angulated fashion inward and away from the caval wall. This not only centers the filter in angulated or tortuous caval segments but also points the ends of the struts toward the vessel lumen to resist penetration.

Retrieval

When there is no longer an indication for caval filtration, the filter may be removed from the apical approach by snaring the hook (like other filter designs). The Bard Snare Retrieval Kit (Bard Peripheral Vascular, Inc.) is recommended by the manufacturer and consists of a 20-mm loop snare placed through a dual sheath system, consisting of an 11F access sheath and a 9F retrieval sheath. After performing the initial cavagram to assess for clot and filter integrity, the hook is snared and the 9F sheath is advanced to partially collapse the filter, allowing the 11F sheath to fully enclose the filter arms in telescoping fashion allowing the filter and 9F sheath to be removed. This retrieval can be done with either the Bard retrieval kit or any combination of other dual sheath and snare systems of similar or larger size.

Fig. 2 (a) The Denali delivery system. The inner dilator can be used with a power injector and contains distal radiopaque markers for caval measurement. The filter is preloaded on the pusher. (Images used with permission from C.R. Bard, Inc., Bard and Denali trademarks, and/or registered trademarks of C. R. Bard, Inc.). (b) Position of the Denali filter after deployment. The strut design helps keep the apical hook (arrow) centered in the IVC, even in a tortuous cava as noted in the image.

Technical Considerations

Numerous articles have been published in the literature that highlight some of the unique technical challenges when removing optional filters. These include the use of various sheath sizes, snares, angioplasty balloons, catheter-directed techniques that use a wire to bypass the apical hook, lasers, and endobronchial forceps to dissect and grasp filters embedded in the caval wall.^{4–15} It is often the case that for a complex filter retrieval, the operator must have knowledge and experience with various endovascular techniques to tailor an approach for the particular scenario. At the author's institution, a technique has been adopted that allows for variations of the previously described techniques performed through the one time placement of a working sheath. In such cases, we typically start by placing a 16F, 35- or 45-cm sheath with a radiopaque distal marker (Cook, Bloomington, IN) from the jugular approach. Through this, we place an additional sheath and snare system is placed either from existing inventory in the endovascular suite or from one of the prepackaged retrieval kits from various manufacturers. For the Denali, the inner sheath system

should be at least 9F in diameter and longer than the 16F sheath to allow the filter to be collapsed in telescoping fashion. A 16F sheath is large enough to allow the filter apex to be engaged through any of the above-described techniques, including being large enough for placement of both endobronchial forceps and a large compliant balloon, such as those used in aortic stent grafting, that would have a diameter adequate to tamponade the IVC in the event of caval tear or laceration. In addition, the 16F sheath is rigid enough to provide the mechanical advantage necessary to collapse embedded filters.

Unlike permanent filters, retrievable or optional filters require significant design modifications that allow it to be collapsed and removed, while at the same time be durable and reliable enough to function as a permanent filter should it be left in place. There have been numerous published reports on the difficulty of achieving such a balance, and thus with the emergence of retrievable filters there has been simultaneous development of a new vocabulary that describes the imaging findings associated with mechanical failure of the filter.^{16–19} Of these findings, filter tilt is one of the most important when considering removal

of a filter. Successfully engaging the apex of the filter is the hallmark of filter retrieval; filter tilt can make this maneuver significantly more challenging if the tilt results in either incorporation of the apex and hook into the caval wall, or penetration of the apex through the cava (►Fig. 3a–e).

The DENALI Trial reported no instances of filter fracture, migration, or filter tilt greater than 15 degrees.³ At the author's institution, over 180 Denali filters have been placed at the time of this publication and the experience has been similar to that reported in the pivotal trial. In addition, the Denali filter appears to resist strut perforation of the caval wall, a potentially problematic occurrence well documented with earlier retrievable designs.^{16,20–23}

It is clear that experience with retrievable or optional filters is an ever-evolving science from both clinical and manufacturing perspectives. Numerous studies have already established that a query of the FDAs Manufacturer and User Facility Device Experience (MAUDE)

database shows a higher complication rate with retrievable versus permanent filters.^{16,24} Therefore, it follows that it takes some time to develop a body of user experience large enough to understand a new filter's strengths, weaknesses, and retrieval pitfalls. In this regard, patient selection and the decision to place a retrievable versus permanent filter still remains the most important step in filter placement.

Conclusion

The Denali Vena Cava Filter is one of the newest generations of retrievable filters available for use in the United States. The multicenter randomized controlled DENALI Trial, as well as the author's experience, suggests that the construction of the filter represents a promising balance of retrievability and freedom from the relatively high complication rates that have plagued past retrievable filter designs.

Fig. 3 (a) Digital subtraction vena cavagram in a young trauma patient presenting for elective G-2 filter retrieval. The filter apex is embedded in the caval wall (black arrow) and at least two filter struts have perforated the wall of the IVC (white arrows). (b) The filter apex was engaged with standard loop snare technique. (c) The 16F outer sheath was used to gently dissect the apex from the caval wall while maintaining firm upward traction with the snared filter. However, the filter strut that had perforated the cava fractured from the main body on retrieval (arrow). (d) Spot film demonstrating removal of the fractured strut using a loop snare. (e) Completion cavagram shows an intact cava and no remaining filter fragments.

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