Vena Cava Filter Performance Based on Hemodynamics and Reported Thrombosis and Pulmonary Embolism Patterns

Aneal Harlal, MASc, Matadial Ojha, PhD, and K. Wayne Johnston, MD

PURPOSE: Three inferior vena cava (IVC) filters of different designs were studied to identify the potential links between published clinical results for thrombosis and recurrent pulmonary embolism (PE) rates and in vitro hemodynamics patterns in the region of the filters.

MATERIALS AND METHODS: The filters studied were the Greenfield over-the-wire filter (Medi-tech/Boston Scientific, Watertown, Mass), TrapEase filter (Cordis Europa, Roden, the Netherlands), and Mobin-Uddin umbrella filter (Edwards Laboratories, Santa Ana, Calif). To assess hemodynamics, velocity contour maps were generated for each filter by using the in vitro photochromic flow visualization technique. Results were obtained for both the unoccluded and partially occluded states. Steady flow (R_e = 600) was used to model physiologic conditions. To estimate the rates of IVC occlusion and recurrent PE, the authors analyzed published clinical studies spanning more than 30 years and a U.S. Food and Drug Administration database.

RESULTS: For both the unoccluded and partially occluded Mobin-Uddin and TrapEase filters, regions of flow stagnation and/or recirculation and turbulence developed downstream of the filter. The Greenfield filter did not produce any prothrombotic flow patterns for either the unoccluded or partially occluded states. Results of published clinical studies supported the hemodynamic findings, with the TrapEase and Mobin-Uddin filters having high rates of IVC occlusion and recurrent PE compared with those of the Greenfield filter.

CONCLUSIONS: Flow stagnation or recirculation and turbulence have been linked to thrombosis and thrombus and/or PE formation. Thus, the hemodynamic results from this study may help explain the relatively higher rates of filter thrombosis and PE for the Mobin-Uddin and TrapEase filters versus the Greenfield filter.

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Abbreviations: FDA = Food and Drug Administration, IVC = inferior vena cava, MAUDE = Manufacture and Facilities Device Experience, PE = pulmonary embolism

INFERIOR vena cava (IVC) filters have been clinically used for more than 30 years with the intent of preventing recurrent pulmonary emboli (PE) in high-risk patients or those in whom anticoagulation therapy is ineffective or contraindicated. Successful prevention of PE with the use of IVC filters requires the filter to be nonthrombogenic, be nonmigratory, demonstrate high clot-catching efficiency, and not impede normal venous return (1). The three filters evaluated in this study are shown in **Figure 1** and described below.

The Mobin-Uddin umbrella filter (Edwards Laboratories, Santa Ana, Calif) was the first true IVC device used to prevent the migration of emboli. It was originally developed in 1967 and eventually released for general use in 1973. The original version of the filter had an umbrella-shaped silicone membrane with six radiating stainless steel alloy spokes. The outside diameter of the opened filter was designed to be 23 mm—the maximum diameter of the patient's IVC. The apex of the filter was pointed caudally (inferiorly) and the silicone membrane had 18 fenestrations (perforations), each measuring 3.0 mm in diameter (three fenestrations between spokes). The silicone membrane would ripple between the spokes if placed in a patient whose IVC diameter was smaller than 23 mm. In the mid 1970s, the filter diameter was increased to 28 mm due to the number of reports of filter migration. The Mobin-Uddin filter was no longer available after 1986 because

From the Department of Chemical Engineering and Applied Chemistry (A.H., M.O.), Institute of Biomaterials and Biomedical Engineering (M.O., K.W.J.), and Department of Surgery (K.W.J.), University of Toronto, Toronto, Ontario, Canada. Received May 3, 2006; revision requested October 14, 2006; final revision received and accepted October 16, 2006. **Address correspondence to** M.O., The University Health Network, 90 Gerrard St W, NR 2-232, Toronto, Ontario, Canada M5G 1J6; E-mail: dyal.ojha@utoronto.ca

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of poor clinical performance on the basis of caval occlusion rates of 0%–86% (2–11).

The Greenfield over-the-wire stainless steel filter (Medi-tech/Boston Scientific, Watertown, Mass) was introduced in 1994 and approved by the U.S. Food and Drug Administration (FDA) in 1995. It has a conical configuration made up of six struts or legs that can be compressed into a 12-F carrier and can be deployed by using a centering guide wire, which addresses the tilting and asymmetry issues seen with the previous generation of the titanium Greenfield filter. This filter can be used in IVCs with diameters no larger than 28 mm. Four of the six leg hooks point superiorly, whereas the two opposite leg hooks point inferiorly to prevent filter migration (12,13).

The TrapEase filter (Cordis Europa, Roden, the Netherlands) was approved in 2000. The filter is manufactured by using a laser to shape it from a single tube of nitinol, making welding unnecessary. It has a symmetric double-basket design (pointing in opposite directions), which provides two levels of clot trapping and/or filtration. The two baskets are connected through six side rails, each with proximal and distal hooks to provide filter anchoring. The filter is designed to be used in patients with IVC diameters smaller than 30 mm.

In this study, these filters were chosen because they represent the major groups of the most commonly used filter designs: the inverted umbrella, the cone, and a combination of the two.

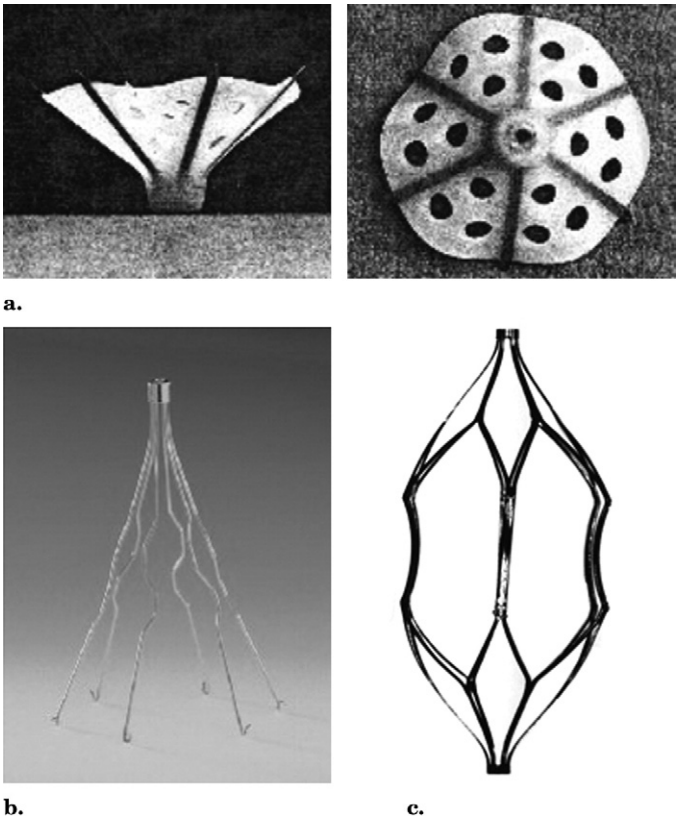

Figure 1. **(a)** Mobin-Uddin filter, **(b)** Greenfield over-the-wire stainless steel filter, and **(c)** TrapEase filter.

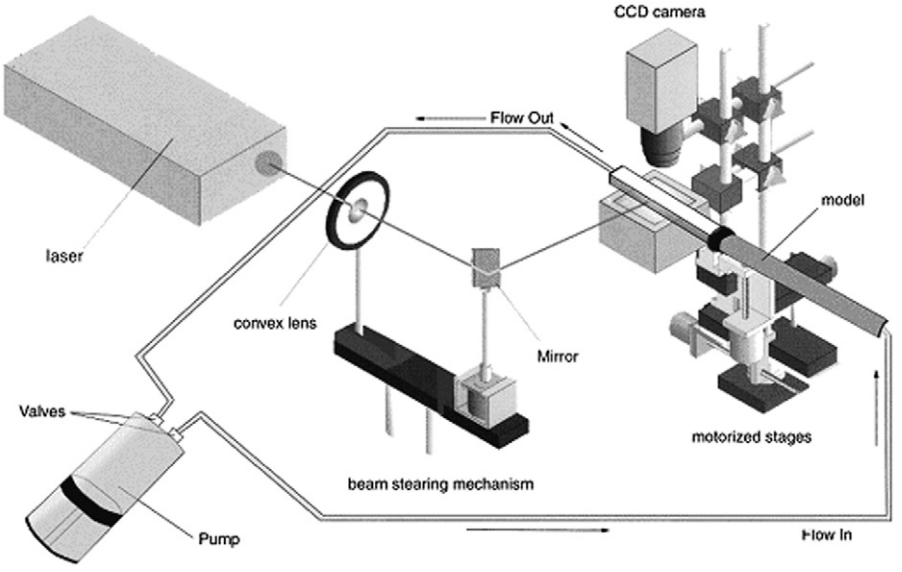

Figure 2. Diagram shows the experimental set-up for the photochromic dye tracer technique. An ultraviolet laser is used to excite the dye in the test fluid. The trace displacement at a given position is recorded with a Charge-Coupled Device (CCD) camera that is interfaced with a computer.

MATERIALS AND METHODS

The primary objective of this study was to identify the hemodynamics associated with each of these filter types and thus gain insights that would account for the differences in performance as observed from published clinical data and the U.S. FDA database.

Hemodynamic Data Acquisition Methods

There are four major components in this experimental procedure: (*a*) the vena cava test model, (*b*) the filter and/or idealized filter, (*c*) the idealized clot, and (*d*) the flow visualization apparatus. Each component will be described in further detail below. **Figure 2** shows the main components of the experimental set-up.